AMPLYA

ACUTE MULTITHERAPEUTIC SYSTEM

USER MANUAL

IB5328062ENG REV.00 Ed. 01/16
SW 4.1

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CONTENTS

EXPRESSIONS USED IN THE MANUAL

WARNING

Refers to operating procedures and conditions which, if not applied, may have adverse effects on the patient or the machine.

CAUTION

Warns the operator not to take any particular action or carry out a procedure that may cause potential risks which, if ignored, may produce serious injury to the patient and/or the user.

NOTE

Refers to important operating procedures and conditions.

This manual constitutes an integral and essential part of the machine.

The manufacturer reserves the right to make any changes to this manual and the machine without prior notice. Should typographic or other kinds of error be noticed, the corrections will be included in the later versions/editions of the manual.

DEFINITION OF TERMS AND ABBREVIATIONS

The specific terms used in this manual are explained below:

CPFA	Coupled Plasma Filtration Adsorption treatment.
RRT	Renal Replacement Therapy.
CVVHDF	Continuous Veno-Venous Haemodiafiltration RRT treatment.
CVVHD	Continuous Veno-Venous Haemodialysis RRT treatment.
CVVH	Continuous Veno-Venous Haemofiltration treatment.
SCUF	Slow ContinuousUltrafiltration treatment.
IHDF	Intermittent Haemodiafiltration treatment.
IHD-SLED	Intermittent Haemodialysis - Slow Extended Dialysis treatment.
IHF-HVHF	Intermittent Haemofiltration - High Volume Haemofiltration treatment.
ABYLCAP	Carbon dioxide removal treatments.
PEX	Plasma exchange treatment.
HP	Haemoperfusion treatment
Mediasorb	Cartridge containing styrene resin in saline solution for plasma clearance.
Replacement fluid	Haemodiafiltration solution infused in the patient to compensate for ultrafiltrate removal.
Access pressure	Pressure measured in the extracorporeal circuit between the patient and the blood pump.
Return pressure	Pressure measured in the extracorporeal circuit between the dialyser outlet and the return line to the patient.
Transmembrane pressure (TMP)	Hydrostatic pressure difference in the dialyser across the membrane from the blood side to the dialysate side.
Priming/rinsing	Physical process that uses fluid from the infusion bags to remove air and any deposits from the extracorporeal circuit.
Ultrafiltration	Process of plasma water removal from the patient’s blood by means of a filtering membrane.

Venous/lower cassette	Lower cassette that receives the cleared blood and supplies it to the patient through the return line.
Plasma/infusion fluid/upper cassette	In CPFA, this cassette fills with plasma treated by Mediasorb. It returns the plasma to the blood through the hemofilter inlet. In RRT, this cassette fills with replacement fluid. It supplies the replacement fluid to the dialysate compartment of the hemofilter through the inlet and/or the outlet of the hemofilter (pre/post infusion).
Disposable	Single-use device.
Mediasorb holder	Clip to fasten to the hemofilter and which supports Mediasorb.
Adsorbent column holder	Device to support the adsorbent column used in haemoperfusion.
Single-use set	Single-use device containing the extracorporeal circuit (lines, filters and two cassettes)
Exchange pumps	All the pumps except the blood pump and the syringe pump.
Infusion bags	Bags containing replacement fluid.
Collection bags	Ultrafiltrate collection bags.
Weight loss	Patient weight loss/gain.
Double electroclamp	Device on the front blood pump cover of the machine consisting of two housings for two branches of the extracorporeal circuit. Its purpose is to occlude one of the two branches, leaving the other one free.
Upper and lower level pumps	Pumps used to adjust the levels in the plasma/infusion fluid/upper and venous/lower cassettes.
Oxygenator	Filter with polymethylpentene fibres consisting of a gas exchange module to which an integrated heat exchanger is connected. Device used for carbon dioxide removal.
Oxygenator holder	Device to support the oxygenator and the fluid circulating inside it to allow proper heating of its blood compartment.
ECMO	Cardiopulmonary support technique for patients suffering from acute heart and/or respiratory failure (ExtraCorporeal Membrane Oxygenation)

1 INTRODUCTION

1.1 NAME

Unless otherwise specified, the name AMPLYA will be used throughout this manual.

AMPLYA
ACUTE MULTITHERAPEUTIC SYSTEM

1.2 INTENDED USE

The device is intended for hospital use for treatments involving haemofiltration, haemodiafiltration, haemodialysis, ultrafiltration, plasma adsorption (CPFA), CO_2 removal (ABYLCAP), plasmapheresis with reinfusion of new plasma (PEX) and haemoperfusion (HP) for the purpose of blood clearance in acute patients and also in clinical conditions of possible acute or chronic renal failure and water overload.

The treatments that can be performed with the device are:

1. **CPFA (Coupled Plasma Filtration Adsorption)**
2. **RRT (Renal Replacement Therapy)**
3. **ABYLCAP CO_2 Removal**
4. **PEX (Plasma Exchange)**
5. **HP (Haemoperfusion)**

In addition, the machine allows performing CPFA, RRT or HP treatments while simultaneously performing ECMO (ExtraCorporeal Membrane Oxygenation).

WARNING
The ABYLCAP, PEX and HP treatments may be performed only if enabled by a specialised technician.

WARNING
The CPFA, RRT and HP treatments with ECMO may be performed only if enabled by a specialised technician.

WARNING
1. For all treatments, the operator shall define the settings according to the patient's condition, the corresponding state of the art and published scientific literature.
2. For treatments using the MEDIASORB adsorbent cartridge, the specifications and rules defined by the cartridge manufacturer must be followed for priming, rinsing and use. The operator must therefore also refer to the information provided by the manufacturer on the therapeutic use of the cartridge.
3. In an HP treatment, the adsorbent column is chosen under the responsibility of the physician. In addition, the operator is responsible for setting priming and treatment parameters according to the instructions for use of the adsorbent column.

1.3 LIMITATIONS OF USE

The AMPLYA device is not designed, marketed or intended for use different from that specified. It may not be used outside the specifications and operating values indicated by the manufacturer.
AMPLYA may 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.

1.4 PRINCIPLES OF EXTRACORPOREAL CLEARANCE

The flow control principle of AMPLYA is based on blood circulation and the automatic evaluation of the masses exchanged by means of the weights indicated on the scales.

Extracorporeal blood circulation is achieved by means of a peristaltic pump. During treatment, the blood access and return pressures are continuously monitored, including for the presence of air bubbles.

The **waste** fluid is removed by the hemofilter by means of a pump. It contains the filtrate (ultrafiltrate) removed from the blood by convection and, in HD/HDF treatments, the dialysate used. In PEX treatments, it is the plasma removed from the patient. A scale measures the total weight.

The **replacement fluid** is pumped from the infusion bags. The proportion, or ratio, of fluid supplied in pre- and/or post-infusion and the dialysate flow are set by the operator.

The patient weight variation is maintained on the value defined by the operator by adjusting the waste fluid flow in HD and the replacement fluid flow in HDF, HF and CPFA.

The machine is equipped with a hematocrit sensor that helps the operator control the actual patient volemia variations.

WARNING: During treatment, the operators must monitor the patient fluid balance in order to prevent hypotension due to fluid removal as well as oedema due to fluid build-up.

The function of the **fluid heater** is to heat the replacement fluid. This is particularly important when the fluid is cold, the flow is high (e.g. high-volume haemofiltration) or when the clinical situation requires it.

Based on a defined medical protocol, two syringe pumps are available to be used for infusion.

1.5 TREATMENTS

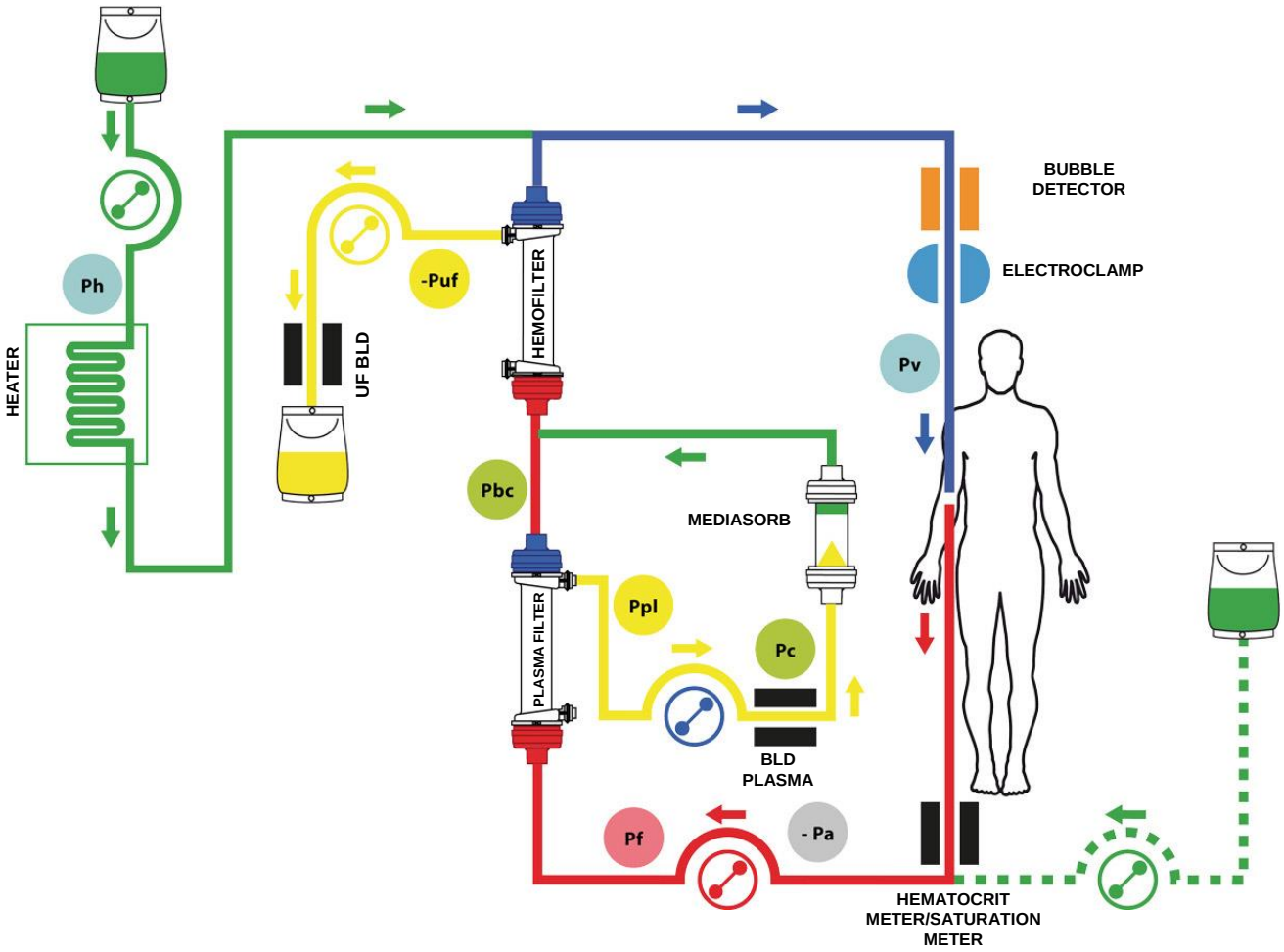
The treatments are differentiated both in pump and in sensor control and in the single-use devices employed.
A specific set of lines is used for each type of treatment.
The main differences between the various treatments are described in the following paragraphs.

1.5.1 CPFA treatment

CPFA is a continuous treatment that couples plasma adsorption and haemofiltration.
Bellco provides one single circuit for CPFA with a 1.4 m^2 hemofilter.
The **replacement fluids** that can be used are medications produced and validated for haemofiltration treatments.
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.
The cartridge must be positioned in the correct flow direction (the required flow direction is indicated by an arrow on MEDIASORB) in order to prevent sorbent loss in the patient.

WARNING
Take particular care to ensure that the cartridge inlet and outlet are connected to the correct connectors in order to prevent injecting sorbent molecules into the patient.



The functional diagram above shows:

- The blood pump and the blood flow on the access side in red
- The blood flow on the return side in blue
- The infusion pump, the bags and the infusion flow in green on the left
- The pre-dilution pump, the bags and the pre-dilution flow in green on the right
- The ultrafiltration or UF pump, the bags and the UF (plasma water) flow in yellow on the left
- In the centre, the plasma flow into the Mediasorb cartridge in yellow, the plasma flow out of the Mediasorb cartridge in green, and the plasma pump in blue
- The hemofilter, the plasma filter and the Mediasorb cartridge
- The heater, the sensors (saturation meter/hematocrit meter, UF BLD and plasma BLD, venous air bubble detector) and the venous electroclamp
- The pressures measured directly or indirectly: access (-Pa), return (Pv), plasma filter inlet (Pf), hemofilter inlet or plasma filter outlet or Mediasorb outlet (Pbc), infusion pump outlet (Ph), UF pump inlet (-Puf), Mediasorb inlet (Pc), plasma pump inlet (Ppl).

Below are the treatment specifications (for more details see paragraphs 5.1.6 and 6.1.6).
- 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
- Manually set plasma flow: 5-20% of the blood flow
- Automatically set plasma flow: 13-20% of the blood flow in the first two hours, then always 20%
- Target plasma volume: 200 ml of plasma per kg of patient weight

1.5.2 RRT treatments

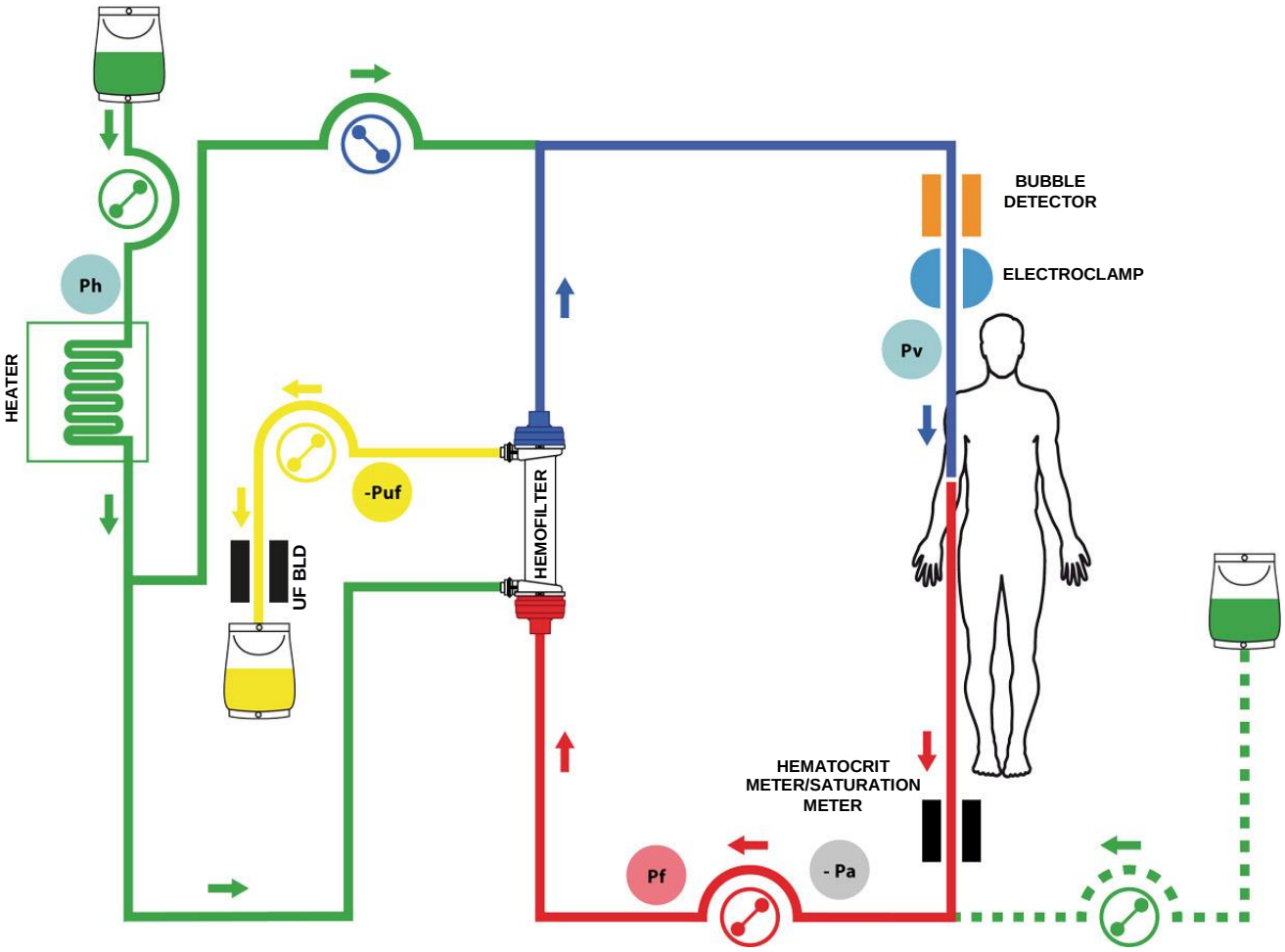
The RRT treatments are defined as continuous when the treatment time is not established, and as intermittent when the treatment time is not more than 24 hours.
The single-use extracorporeal circuit includes only one filter (hemofilter/hemodialyser) for plasma water removal. The maximum treatment time is 72 hours.

The types of RRT treatment are:
- Continuous and intermittent haemodiafiltration
- Continuous and intermittent haemodialysis
- Continuous and intermittent haemofiltration
- Continuous ultrafiltration.

The RRT treatments share the same priming/rinsing procedure.

HAEMODIAFILTRATION

Haemodiafiltration is an RRT treatment and may 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 **replacement fluids** that can be used are medications produced for haemofiltration treatments.
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).



The functional diagram above shows:

- The blood pump and the blood flow on the access side in red
- The blood flow on the return side in blue
- On the left, the infusion pump in green, the post-infusion pump in blue, and the bags and infusion flow for the dialysate compartment of the filter and for post-infusion in green
- The pre-dilution pump, the bags and the pre-dilution flow in green on the right
- The ultrafiltration or UF pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow
- The hemofilter
- The heater, the sensors (saturation meter/hematocrit meter, UF BLD, venous air bubble detector) and the venous electroclamp
- The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), infusion pump outlet (Ph), UF pump inlet (-Puf).

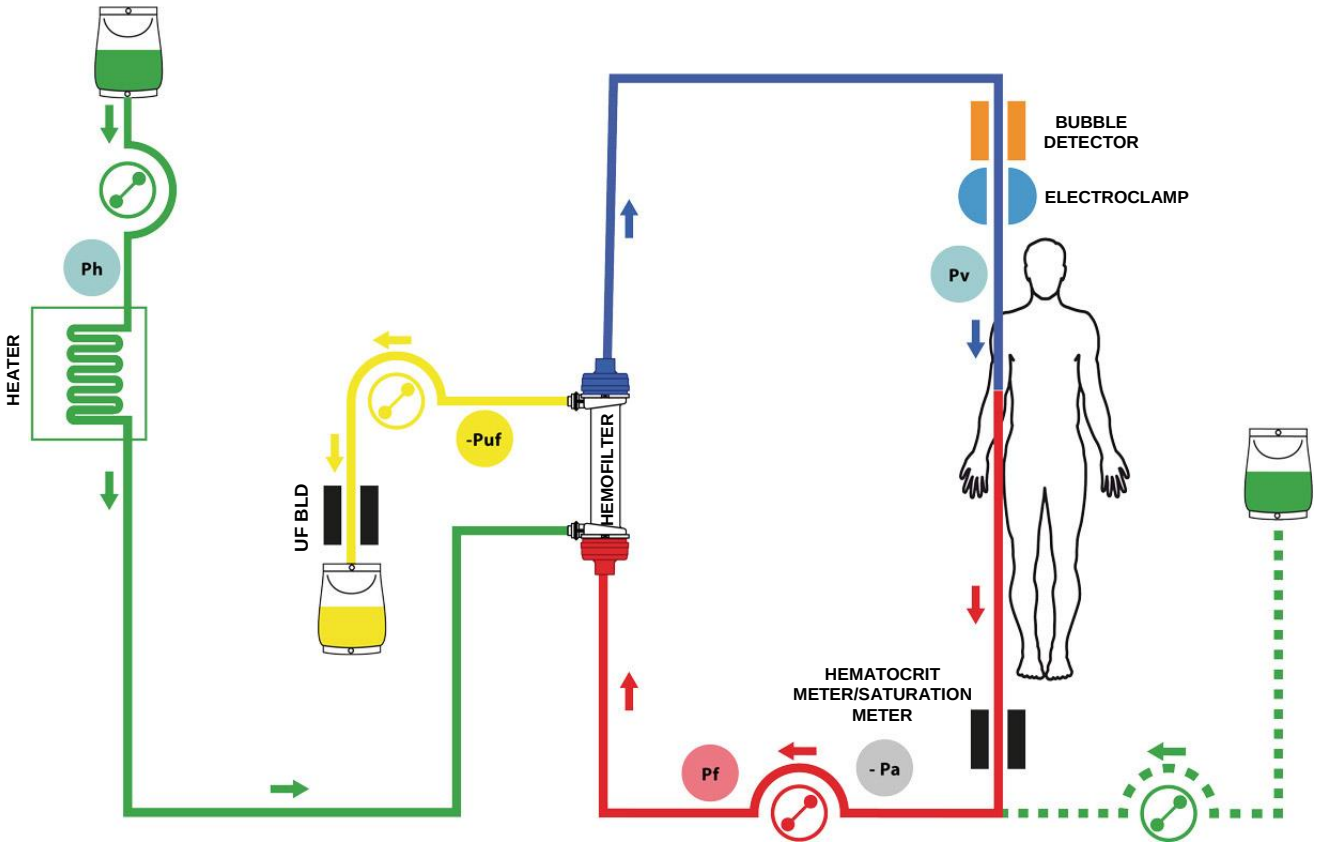
Below are the treatment specifications (for more details see paragraphs 5.1.6 and 6.1.6).

- 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 – UF flow) l/h
- UF flow: 0 or 0.1 - (12 – dialysate flow) l/h
- Maximum UF pump flow rate: 16 l/h
- Maximum intermittent treatment time: 24 hours

NOTE: the haemodiafiltration treatment with null dialysate flow is described in detail in paragraphs 5.1.6 and 6.1.6 in the NOTES on the HAEMODIAFILTRATION parameter tables.

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 **replacement fluids** that can be used are medications produced for haemofiltration treatments.
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).

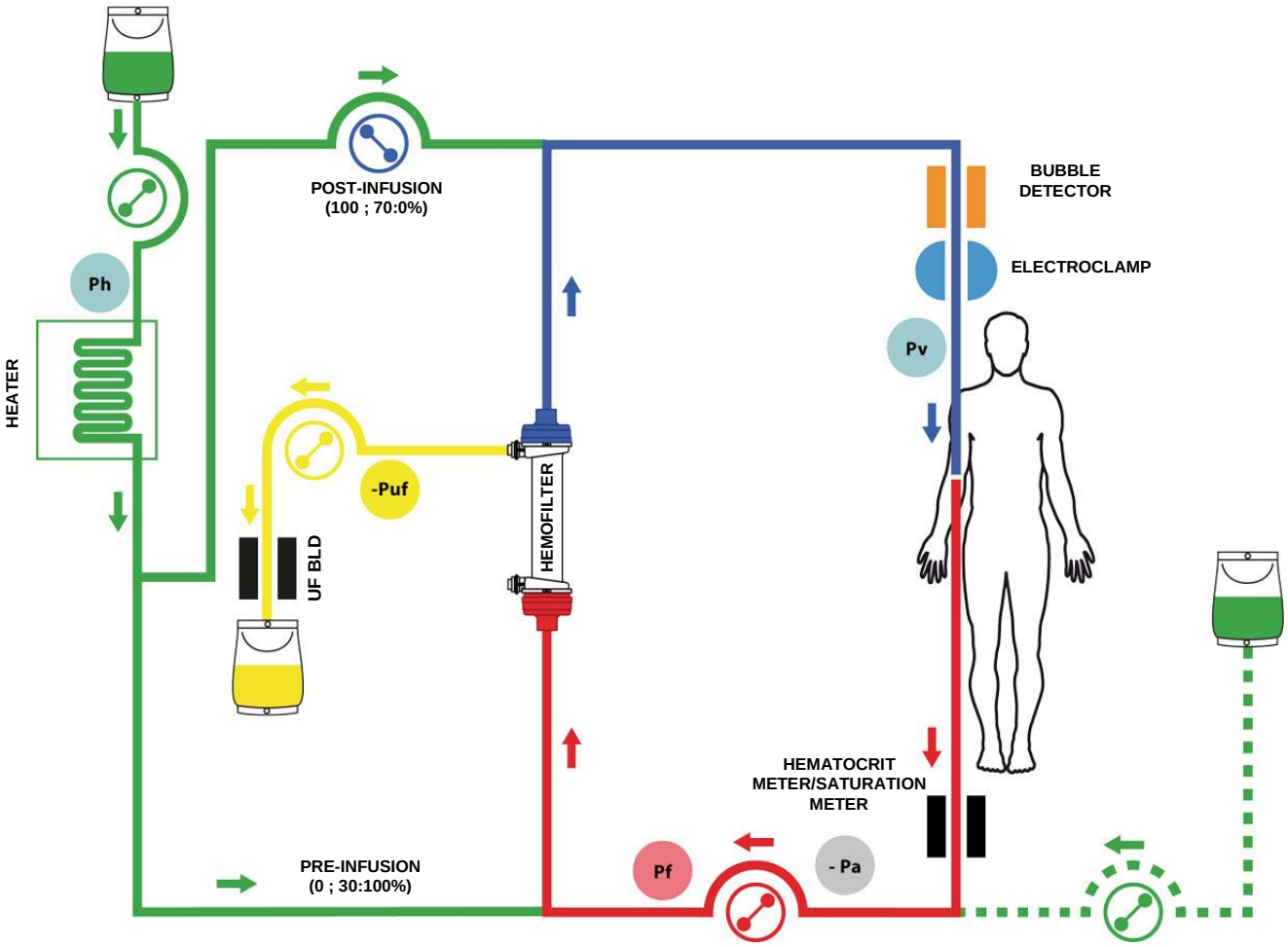


The functional diagram of the circuit above shows:
- The blood pump and the blood flow on the access side in red
- The blood flow on the return side in blue
- The infusion pump, the bags and the infusion flow for the dialysate compartment of the filter in green on the left
- The pre-dilution pump, the bags and the pre-dilution flow in green on the right
- The ultrafiltration or UF pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow
- The hemofilter
- The heater, the sensors (saturation meter/hematocrit meter, UF BLD, venous air bubble detector) and the venous electroclamp
- The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), infusion pump outlet (Ph), UF pump inlet (-Puf).

Below are the treatment specifications (for more details see paragraphs 5.1.6 and 6.1.6).
- 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 hours

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 **replacement fluids** that can be used are medications produced for haemofiltration treatments.
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).



The functional diagram of the circuit above shows:

- The blood pump and the blood flow on the access side in red
- The blood flow on the return side in blue
- On the left, the infusion pump in green, the post-infusion pump in blue, and the infusion bags and the pre- and post-infusion flow in green
- The pre-dilution pump, the bags and the pre-dilution flow in green on the right
- The ultrafiltration or UF pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow
- The hemofilter, the heater, the sensors (saturation meter/hematocrit meter, UF BLD, venous air bubble detector) and the venous electroclamp
- The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), infusion pump outlet (Ph), UF pump inlet (-Puf).

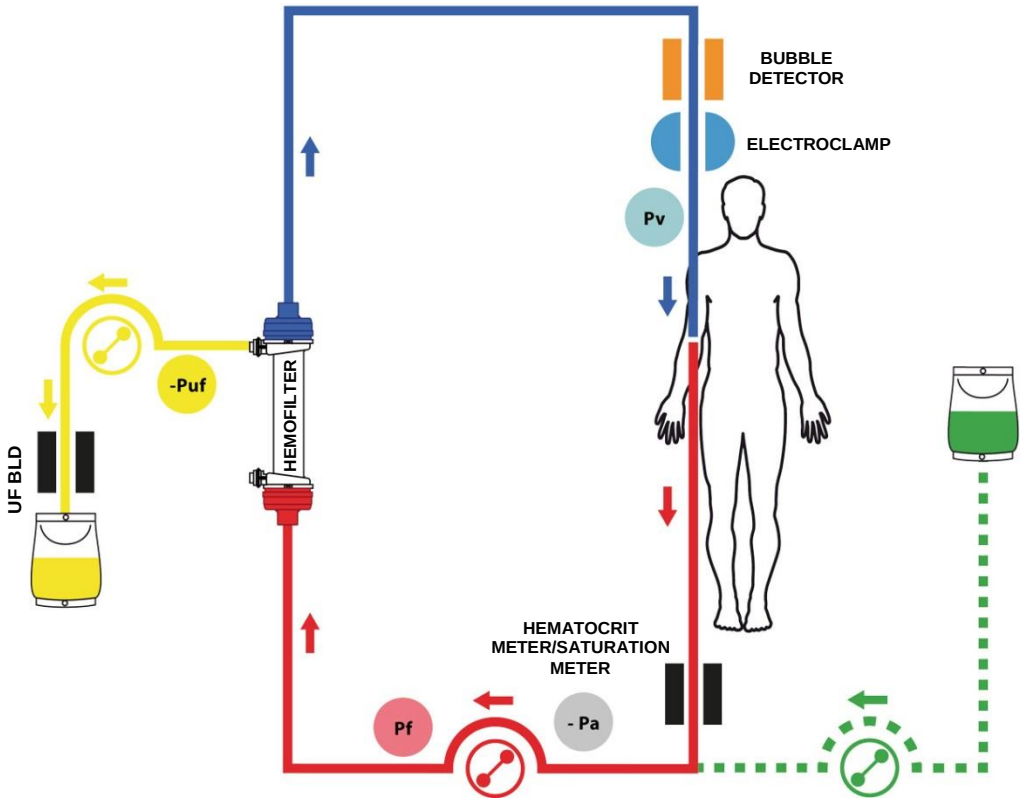
Below are the treatment specifications (for more details see paragraphs 5.1.6 and 6.1.6).

- 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
- UF flow: 0.5 - 12 l/h
- Maximum UF pump flow rate: 16 l/h
- Pre-infusion flow (determined by the difference in the flows supplied by the total infusion and post-infusion pumps): 0 or 30% - 100% of the infusion flow
- Maximum intermittent treatment time: 24 hours

NOTE: the haemofiltration treatment with null pre-infusion flow is described in detail in paragraphs 5.1.6 and 6.1.6 in the NOTES on the HAEMOFILTRATION parameter tables.

ULTRAFILTRATION

Ultrafiltration or SCUF is a continuous RRT treatment.
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).



The functional diagram of the circuit above shows:

- The blood pump and the blood flow on the access side in red
- The blood flow on the return side in blue
- The pre-dilution pump, the bags and the pre-dilution flow in green
- The ultrafiltration or UF pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow

- The hemofilter
- The sensors (saturation meter/hematocrit meter, UF BLD, venous air bubble detector) and the venous electroclamp
- The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), UF pump inlet (-Puf).

Below are the treatment specifications (for more details see paragraphs 5.1.6 and 6.1.6).
- Blood flow (Q_b): 0; 30 - 450 ml/min
- Patient weight loss: 0 - 2 l/h
- Pre-dilution pump flow (5^{th} pump): 0 - 4 l/h
- Maximum UF pump flow rate: 6 l/h

1.5.3 ABYLCAP treatment

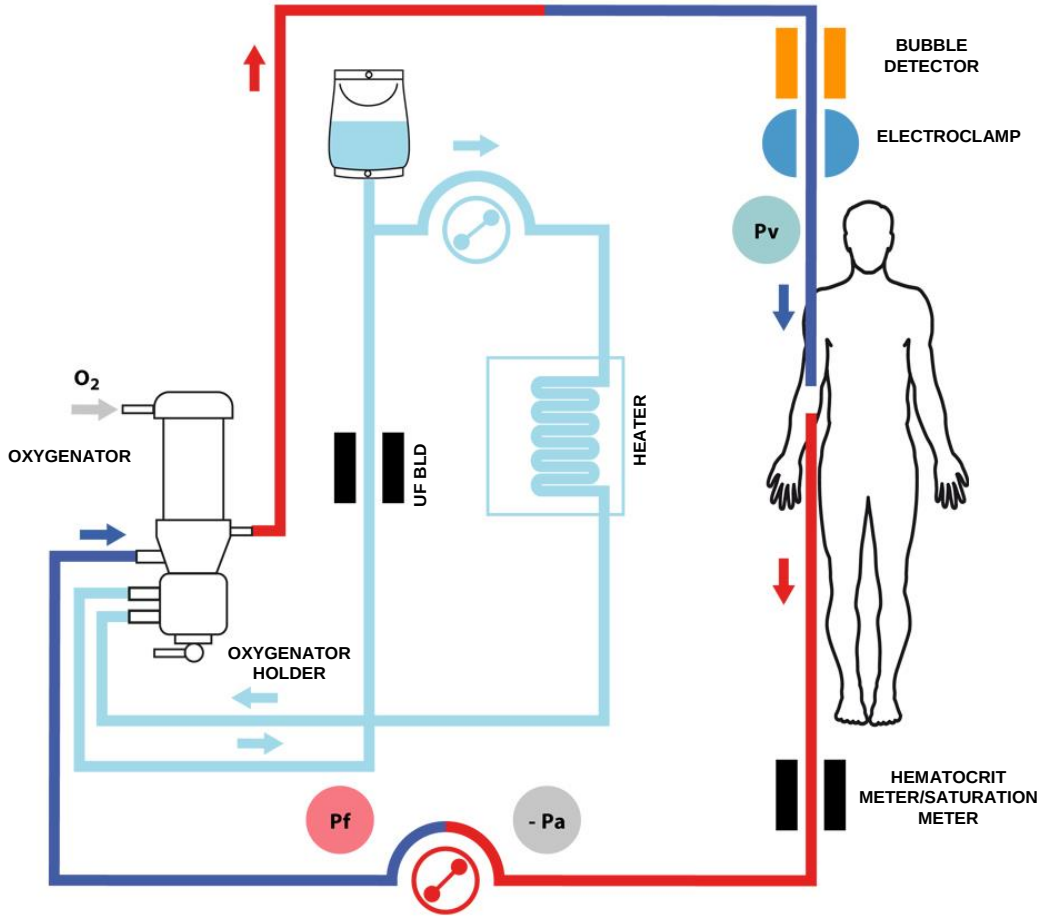
The flow control principle on AMPLYA is based on blood circulation and CO_2 removal. The amount of CO_2 removed is related to the CO_2 pressure gradient.
The CO_2 is removed through the gas outlet which MUST stay open throughout the treatment.

WARNING
Given that the gas exchange occurs in compartments not isolated from the working environment:
- **Consider all the warnings and precautions relating to the presence and handling of oxygen in the working environment.**
- **Do not administer anaesthetic gases to the patient during the treatment.**

WARNING:
1. The oxygenator characteristics have been tested for passage of oxygen (O_2) only.
2. The CO_2 variation may modify the patient's acid-base balance. Consequently, the patient's blood pH value needs to be monitored regularly throughout the treatment.
3. The patient's temperature has to be monitored continuously. A high O_2 flow may induce blood cooling; if necessary, reduce the O_2 flow in order to maintain the blood temperature constant.

WARNING
In order to prevent excessive carbon dioxide removal from the patient during the treatment:
- **Periodically monitor the patient**
- **Periodically perform a blood gas analysis**
- **Use the device under specialist medical supervision**

The single-use extracorporeal circuit is made up of two units: the extracorporeal circulation circuit and the heating circuit.
The blood is drawn from the patient and, going through the **extracorporeal circulation circuit**, is circulated in the oxygenator before being returned to the patient.
The water for injectable preparations, going through the **heating circuit**, is heated by the Amplya plate heater and then recirculated in the dedicated oxygenator holder.

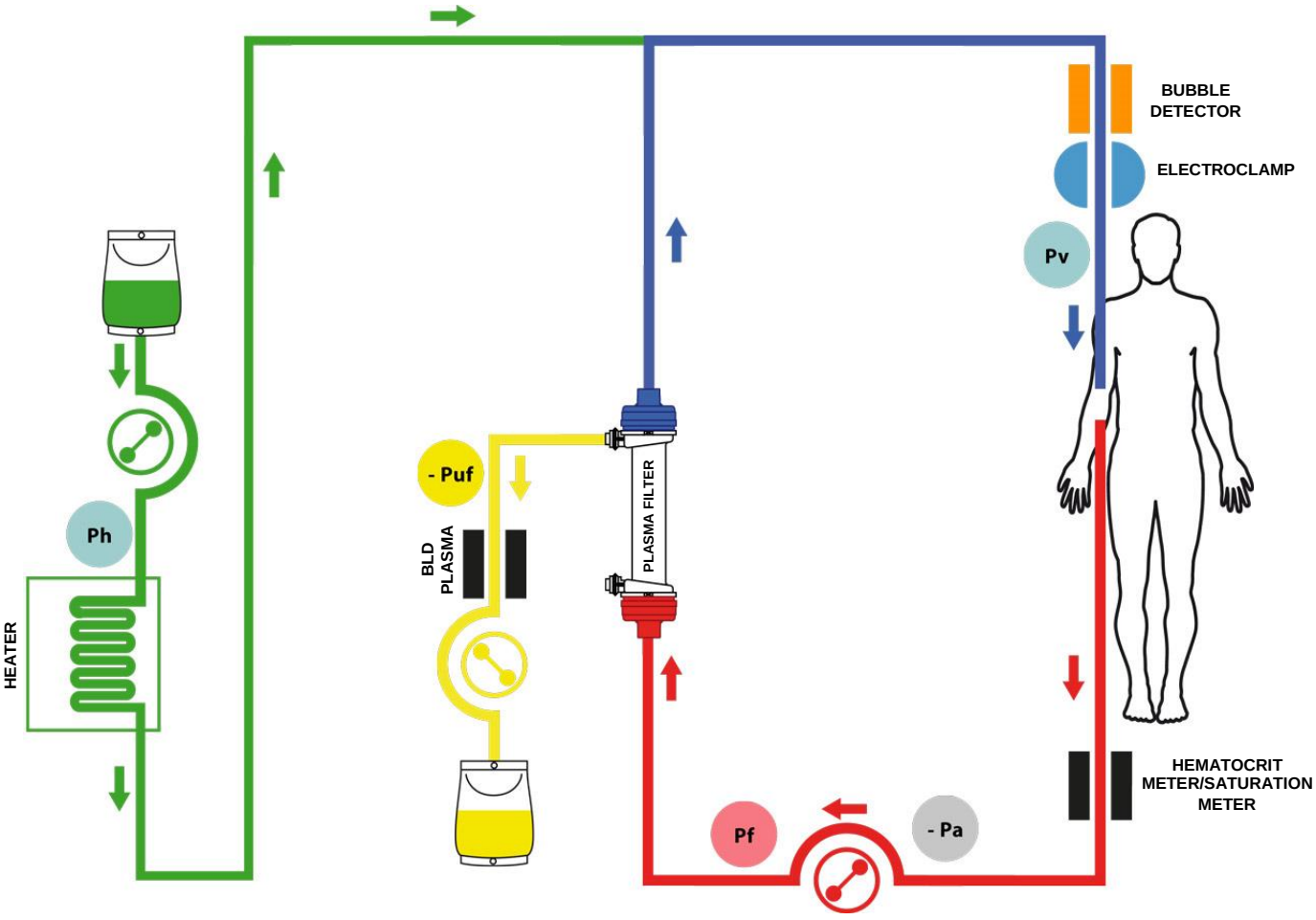


The functional diagram above shows:
- The blood pump, the blood flow on the access side and out of the oxygenator in red
- The blood flow on the return side and into the oxygenator in blue
- The infusion pump used in Abylcap for recirculation of the water for injectable preparations, the bag and the recirculation flow in sky-blue
- The heater, the sensors (saturation meter/hematocrit meter, UF BLD, venous air bubble detector) and the venous electroclamp
- The pressures measured: access (-Pa), return (Pv), oxygenator inlet (Pf).

Below are the treatment specifications (for more details see paragraph 7.1.5).
- Blood flow (Q_b): 30 - 550 ml/min
- Infusion pump flow (for heating liquid recirculation): 200 ml/min

1.5.4 PEX treatment

Therapeutic treatment aimed at separating from the whole blood and subsequently removing part of the plasma fraction through a plasma filter, compensating for this plasma fraction volume with fluids specifically produced for this purpose or plasma from a donor.
Plasma exchange (PEX) is a treatment whereby plasma is separated and removed from the blood through a plasma filter and the removed plasma replaced with a replacement fluid. The replacement fluids are **colloidal type pharmaceutical solutions** (e.g. HES, albumin solution) or frozen fresh plasma (from a donor).
Bellco provides a circuit comprising a plasma filter with a 0.5 m^2 membrane.
The single-use circuit includes a line for plasma infusion at the plasma filter outlet (post-infusion) and a line for plasma extraction from the patient's blood.
The treatment is always performed in post-infusion only.



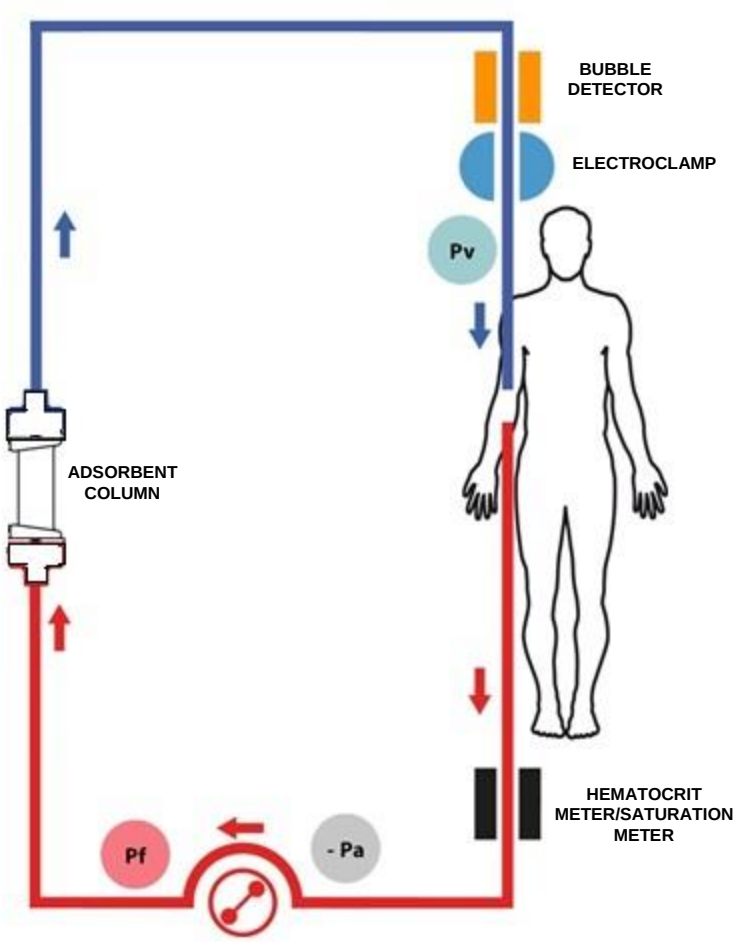
The functional diagram above shows:
- The blood pump and the blood flow on the access side in red
- The blood flow on the return side in blue
- The infusion pump and the plasma bag in green on the left
- The ultrafiltration or UF pump, the collection bag and the flow of plasma removed from the blood in yellow in the centre

- The plasma filter, the heater, the sensors (saturation meter/hematocrit meter, plasma BLD, venous air bubble detector) and the venous electroclamp
- The pressures measured directly or indirectly: access (-Pa), return (Pv), plasma filter inlet (Pf), infusion pump outlet (Ph), UF pump inlet (-Puf).

Below are the treatment specifications (for more details see paragraph 8.1.6).
- Blood flow (Q_b): 30 - 250 ml/min
- Plasma infusion/removal flow: 5-20% of the blood flow
- Target plasma volume: 0 - 30 l/h

1.5.5 HP treatment

Therapeutic treatment aimed at blood clearance by means of adsorption of toxic substances during extracorporeal circulation when the patient's blood is passed through an adsorbent column.



The functional diagram above shows:
- The blood pump and the blood flow on the access side in red
- The blood flow on the return side in blue
- The pressures measured directly or indirectly: access (-Pa), return (Pv) and adsorbent column inlet (Pf).

Below are the treatment specifications (for more details see paragraph 9.1.5).
- Blood flow (Q_b): 30 - 450 ml/min

1.5.6 CPFA/RRT/HP treatments with ECMO

ECMO (ExtraCorporeal Membrane Oxygenation) is a cardiopulmonary support technique for patients suffering from severe acute heart and/or respiratory failure, potentially reversible but immune to conventional maximal medical and pharmacological treatment. ECMO is hence not a therapeutic intervention but a support which keeps the heart and/or the lungs at rest thus allowing their functional recovery. AMPLYA allows performing ECMO only in CPFA, RRT or HP treatments.

1.6 ANTICOAGULATION

In the treatments described above factors such as:
- contact of blood with artificial surfaces
- air/blood contact areas (e.g. in the pressure transducers or cassettes)
- vortexes
- blood flow stagnation following treatment interruptions
- blood concentration in the filters

are among the causes of frequent thrombus formation in the extracorporeal circuit. These thrombi reduce the effectiveness of the clearance treatments and may result in high blood loss if failing to return blood to the patient.
It is therefore essential to treat the patient's blood ensuring efficient anticoagulation of the extracorporeal circuit.
AMPLYA allows:
- In all the treatments, systemic anticoagulation through the administration of heparin.
- Only in CPFA, HD, HF, HDF and SCUF, local-regional anticoagulation through the administration of citrate and calcium chloride or citrate and calcium gluconate.

Local-regional anticoagulation can be performed in two modes:
- ASSISTED, where the system automatically calculates the value of some flows based on the blood flow, patient weight and weight loss/gain (not available for SCUF treatments).
- UNASSISTED, where all the parameters are to be set by the operator.

For more details, see chapter 6.

WARNING
In case of local-regional anticoagulation in UNASSISTED mode, AMPLYA allows administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate.
AMPLYA allows administration of these solutions under the full responsibility of the physician.
In particular, the physician is responsible for:

- **The choice of anticoagulation model in relation to the type of patient and the treatment set.**
- **The choice of anticoagulant solution (type, composition, concentration).**
- **Setting the flows on AMPLYA.**
- **The choice of the calcium infusion site, the relative line and its proper control in order to prevent risks such as infusing air into the patient.**

WARNING
In case of local-regional anticoagulation in UNASSISTED mode, a citrate-based anticoagulant substance can be infused upstream of the blood pump using the pre-dilution pump. Calcium chloride or calcium gluconate can be administered at the end of the blood circuit using the syringe pump positioned above the heater.
AMPLYA does not control the amount of citrate or calcium infused nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

1.7 MAIN CHARACTERISTICS

The AMPLYA device is manufactured in the model with five pumps and is equipped with advanced sensors (hematocrit meter, level sensors, sensors to detect blood in the filtrates, pressure sensors) whose function is to monitor the patient and prevent complications from arising.
AMPLYA allows performing various treatments each of which is associated with an extracorporeal circuit.
Various single-use line kits are available for each of which you can select one of the treatments available (see paragraph 2.6.3).

AMPLYA has an electronic multiprocessor architecture composed of a control and a protection microprocessor which control functioning of 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 allows use of a high-level software so that the operator can flexibly and easily dialogue with AMPLYA. Guide messages shown on the display make all the operating functions easy for the operator to understand. The relevant data for conducting the dialysis session are shown on the operator interface.
AMPLYA's vertical structure allows easy cleaning of external surfaces, and thanks to the openable rear panel, the internal components are easily accessible for maintenance/repair operations.

SAFETY PHILOSOPHY

AMPLYA has a multiprocessor architecture and guarantees patient safety even in single failure condition.
The self-diagnostic tests run automatically at power on, during priming/rinsing and before starting a treatment allow checking proper functioning of the components; if any malfunction is found during the tests, the treatment cannot be started.
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.
AMPLYA immediately visually, optically and acoustically signals any alarm condition to the operator:

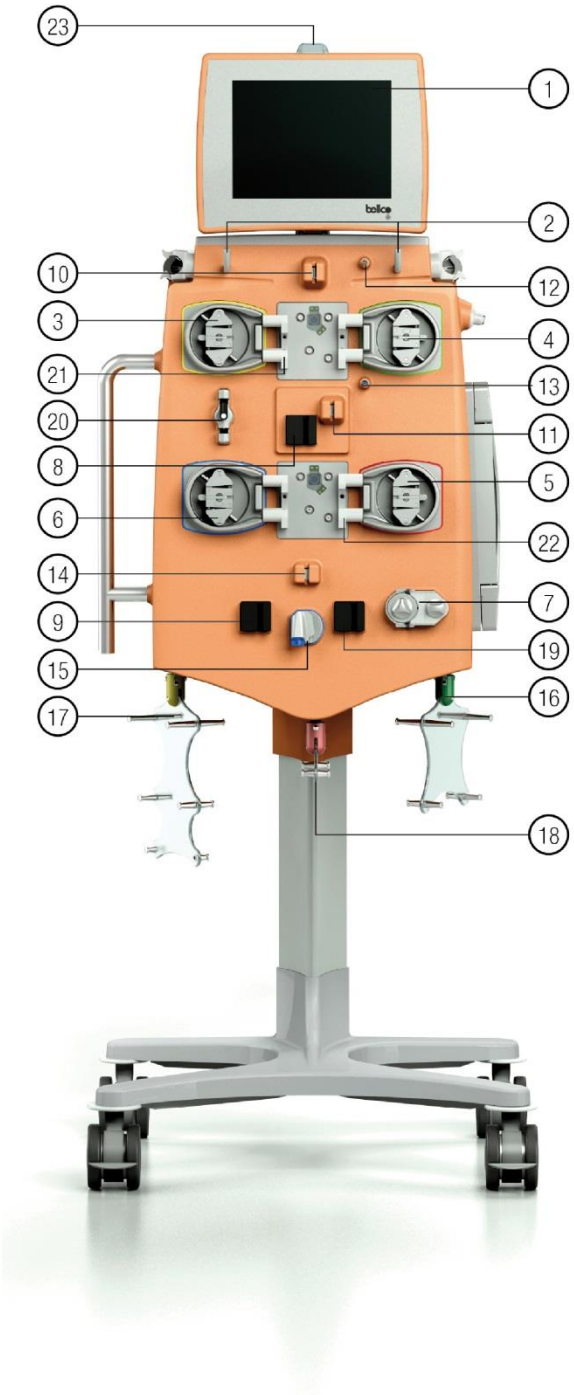
- Visually: messages and/or windows on the display
- Optically: flashing light positioned at the top of the screen
- Acoustically: buzzer with different intensity according to a scale of priorities.

AMPLYA is equipped with non-invasive measurement transducers devoid of stasis points and not subject to contamination. The transducers are equipped with self-diagnostic systems that check functioning before each treatment and do not require any particular calibration except during maintenance.

2 MACHINE PRESENTATION

FRONT VIEW

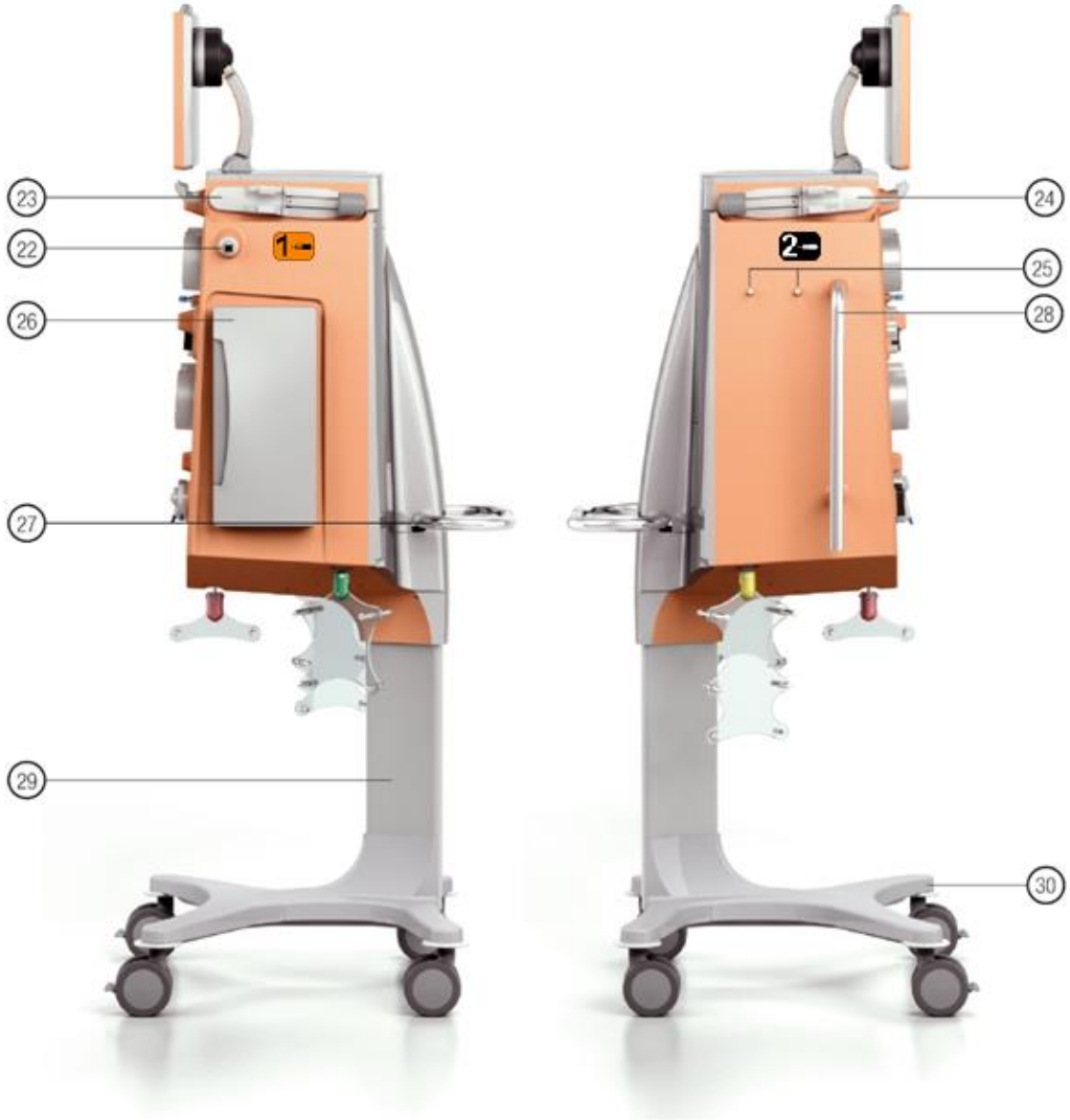
The image below shows the devices positioned on the front panel of the machine.



1. Touch screen
2. Front hooks
3. UF/ultrafiltration pump (yellow)
4. Infusion/replacement pump (green)
5. Blood pump (red)
6. Post-infusion/plasma pump (blue)
7. Fifth pump/pre-dilution pump (grey)
8. Blood leakage detector (BLD) – plasma
9. Blood leakage detector (BLD) – ultrafiltrate
10. Plasma or infusion fluid/upper level sensor
11. Venous/lower level sensor
12. Plasma or infusion fluid pressure transducer
13. Venous pressure transducer
14. Air detector
15. Venous electroclamp
16. Infusion/replacement scale (green)
17. UF/waste/ultrafiltrate scale (yellow)
18. Central scale (red)
19. Hematocrit meter/saturation meter
20. Double electroclamp
21. Plasma/infusion fluid/upper cassette seats
22. Venous/lower cassette seats
23. Visual alarm indicator

SIDE VIEWS

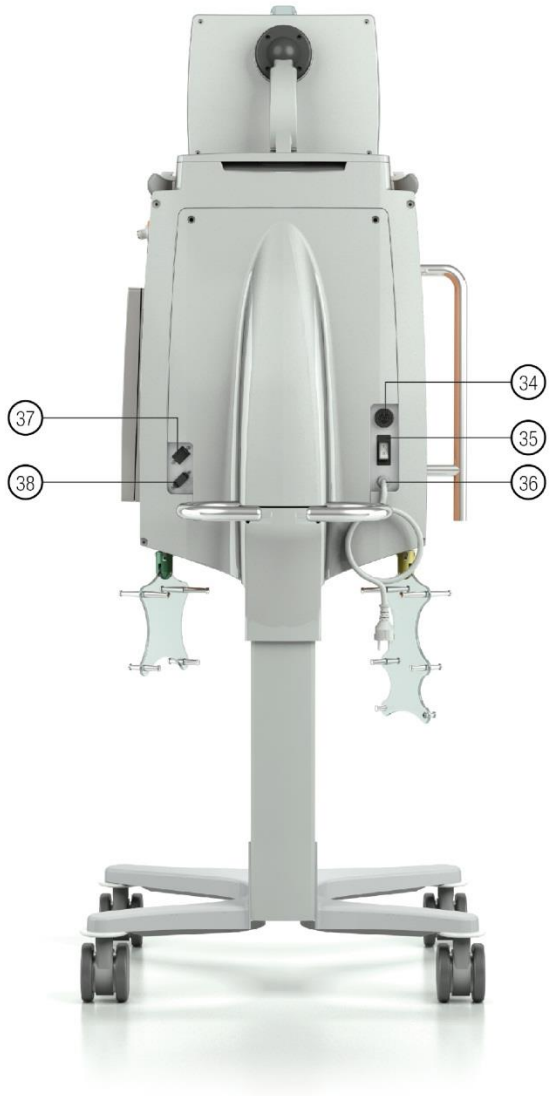
The image below shows the devices positioned on either side of the machine.



22. Syringe pressure transducer port (for future applications)
23. Syringe pump 1
24. Syringe pump 2
25. Side pins
26. Heater
27. Rear movement handles
28. Side movement handle
29. Support base
30. Base and wheels

REAR VIEW

The image below shows the devices positioned on the rear of the machine.



34. Acoustic alarm
35. ON/OFF switch
36. Power cable
37. ETHERNET communication port
38. USB communication port

2.1 FLUID HEATER

The fluid heater allows heating the replacement fluid that circulates in the bag in contact with the heating element (for its position, see the side views at the beginning of this chapter).

CAUTION
The heater is not intended for directly heating the blood. Therefore, do not let the blood circulate in the heater bag.

During priming and rinsing of the extracorporeal circuit, the heater is on at a temperature of around 34°C.
During treatment, the heater temperature can be set to six levels in a range between 30 and 41°C.
The outgoing replacement fluid temperature depends on the flow and temperature of the incoming replacement fluid and the temperature level selected.

The image below shows the heater with the door open.

The system is capable of detecting during both priming and treatment:

- Any fluid leakage from the bag in contact with the heating element (by means of an optical sensor)
- Door opening (by means of a Hall sensor)
- Presence of the bag in the heater when the door is closed (by means of a microswitch).

2.2 FIFTH PUMP AND CENTRAL SCALE

The fifth pump draws pre-dilution fluid from a bag hung on the central scale (for the position of the pump and the central scale, see the front view at the beginning of this chapter).

During treatment, the fifth pump is activated coupled to the blood pump (the flow is set in relation to the blood) in order to:

- pre-dilute the blood, infusing pre-dilution fluid before the blood pump in case of systemic anticoagulation
- anticoagulate the blood, infusing citrate before the blood pump in case of local-regional anticoagulation.

During treatment, the fifth pump operates only when the ultrafiltration pump operates.

The image below shows the fifth pump.

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

2.3 SYRINGE PUMPS

AMPLYA is equipped with a syringe pump for anticoagulation (syringe pump 1) and a pump for ancillary infusion (syringe pump 2).
Syringe pump 1 is used for the administration of a bolus or continuous infusion of heparin in case of systemic anticoagulation and for continuous infusion of calcium chloride or calcium gluconate in case of local-regional anticoagulation.
Syringe pump 2 can be used for an ancillary infusion (e.g. infusion of heparin during a treatment performed with local-regional anticoagulation).
The syringe pumps are identified by numbered labels applied on the sides of the machine (see the side views at the beginning of this chapter). Syringe pump 1 is positioned on the right-hand side and identified by the following label:

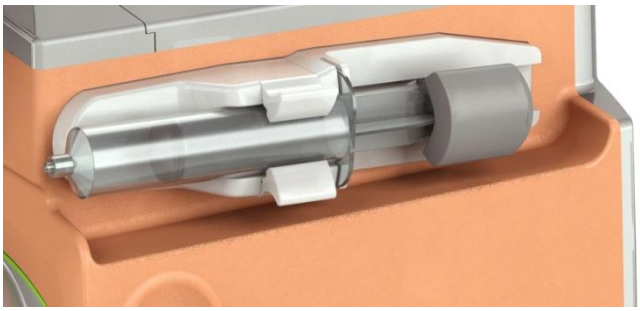
Syringe pump 2 is positioned on the left-hand side and identified by the following label:

CAUTION
For safety reasons, the syringe pumps may not be used for infusions different from those described in the intended use (see par. 3.1).

For the specifications of the usable syringes, see par. 11.16.

During treatment, the syringe pump flow is stopped only if the blood flow is stopped in the event of syringe pump malfunctioning or, more in general, in the event of some types of alarm that require reducing the blood flow.

The image below shows syringe pump 1 with a syringe inserted.



The system is capable of detecting (by means of an optical sensor), during both priming and treatment, when the syringe pump pusher has reached the end of stroke. This allows the system to, for example, inform the operator when one of the syringes is empty.

2.4 HEMATOCRIT AND OXYGEN SATURATION MEASURING SYSTEM

The sensor interfaces with the single-use cuvette inserted in the blood access line and is capable of continuously providing the absolute hematocrit and oxygen saturation values (for the position of the sensor see the *front view* at the beginning of this chapter).
This is made possible by a reader that makes optical absorbance measurements at different wavelengths with initial autocalibration.
The qualities of the system are its non-invasive measurement, absolute sterility and the ease of use for the operator. In addition, the hematocrit and oxygen saturation measurements do not affect machine performance.
The operator interface allows viewing the data in graphic form during the treatment.
The measurements made by the device help understand the haemodynamic state of the patient, the refilling capacity and the need to modify the treatment fluid parameters, which, together with filtration modulation, can improve the haemodynamic state of the patient.

2.5 COMMUNICATION PORTS

AMPLYA is equipped with a USB communication port so that data can be downloaded to a flash drive (see points 16 and 17 in paragraph 3.1).

AMPLYA is also equipped with an Ethernet communication port to which you can connect via a dedicated interface to acquire data from the system. The connection is made via a dedicated protocol configurable by specialised technicians (see paragraph 4.5.3).
Enabling the connection does not in any way alter AMPLYA operation and the user is given no indication of the connection, not even during data transmission. For details on the connection, refer to the manual REMOTE LOG TCP PROTOCOL MANUAL (provided on request to the user).

CAUTION
AMPLYA may only be connected to protectively earthed equipment in compliance with CEI EN 60950 or EN 60601-1. The connection must be made in compliance with the requirements of EN 60601-1-1.
The connection must be made with cables that conform to Ethernet connection standards.
The use of non-compliant cables and connections to incompatible equipment may damage the interface.

For the position of the two ports, see the *rear view* at the beginning of this chapter.

2.6 SINGLE-USE DEVICES

In order to perform treatments with AMPLYA, the single-use devices described below are required.

2.6.1 Set of tubes, filters, sorbents

CAUTION
Using a circuit, bags, lines, filters or cartridges on AMPLYA different from those provided by Bellco may be a source of injury to the patient. In this case, the operator acts on his own responsibility.

Based on the type of treatment, various pre-assembled circuits are available (each listed with its own code in paragraph 2.6.3).
The circuits must be selected based on the medical protocol to be applied to the clinical situation of the patient.

Depending on the treatment, the circuits use different filters.
The **CPFA circuit** includes a pre-assembled plasma filter MPS05 (with 0.5 m^2 membrane) and a hemofilter HFT14 (with 1.4 m^2 membrane).
The CPFA kit also includes the **Mediasorb** cartridge for plasma adsorption.
Mediasorb is a medical device dedicated to **removal of toxic metabolites in the treatment of sepsis and multiple organ failure** (e.g. hepatic, pulmonary, cerebral, renal and cardiac dysfunction).
For Mediasorb connection, the circuit has:

- Outlets with dedicated connectors to prevent the risks of disconnection and leaks
- A label indicating the cartridge name (Mediasorb) and a colour code that helps identify the lines to be connected to the inlet and outlet of Mediasorb.

The **RRT circuit** contains a pre-assembled hemofilter whose characteristics vary from circuit to circuit, allowing you to set different flows depending on the type of patient to be treated and the type of RRT treatment you want to perform.
The hemofilters provided by Bellco in the RRT circuits are HFT03, HFT05, HFT08, HFT14, HFT17, HFT22 (with 0.3, 0.5, 0.8, 1.4, 1.7, 2.2 m^2 membranes, respectively).

WARNING
The pre-assembled RRT circuit must be replaced within 72 hours of use. Use after this period of time might cause failure with serious harm to the patient.

The **ABYLCAP and HP circuits** do not have any filters but only the tubes necessary to perform the treatment.

The **PEX circuit** includes a pre-assembled plasma filter MPS05 (with 0.5 m^2 membrane).

2.6.2 Concentrates and bags

CPFA and RRT
From 1 to 4 infusion bags can be connected to the infusion line.
If performing a treatment that requires pre-infusion of replacement fluid or citrate from the 5th pump line, up to a maximum of 2 bags can be connected to this line. The **waste fluid** is collected in 5-litre bags with female Luer-lock connectors.
From 1 to 5 collection bags can be connected to the extracorporeal circuit (see chapter 4.7.3).

ABYLCAP
For priming, only one infusion bag can be connected to the constricted tube (marked with a yellow label) of the infusion line, and two 5-litre collection bags fitted with constricted connectors (contained in the Abylcap kit) can be connected to the collection lines. In addition, you need to connect a bag of water for injectable preparations to the heating circuit inlet line to be hung on the side hooks of the machine (see chapter 4.8.3).

PEX
Saline bags can be connected to the infusion line during priming while plasma bags can be connected during treatment. In addition, 5-litre collection bags with female Luer-lock connectors can be connected to the extracorporeal circuit (see chapter 4.9.3).
The **waste plasma** is collected in the collection bags.

HP
For priming, only one priming fluid bag can be connected to the constricted tube (marked with a yellow label) of the access line and only one 5-litre collection bag to the return line (see chapter 4.10.3).

2.6.3 Kits available for all the treatments

Listed below are the single-use kits for the treatments that AMPLYA performs.

Product	Medical devices	Accessories
CPFA kit	1. CPFA preassembled device	9. Collection set 10. Mediasorb set
RRT HFT 03 kit	2. RRT preassembled device with HFT 03	9. Collection set
RRT HFT 05 kit	3. RRT preassembled device with HFT 05	9. Collection set
RRT HFT 08 kit	4. RRT preassembled device with HFT 08	9. Collection set
RRT HFT 14 kit	5. RRT preassembled device with HFT 14	9. Collection set
RRT HFT 17 kit	6. RRT preassembled device with HFT 17	9. Collection set
RRT HFT 22 kit	7. RRT preassembled device with HFT 22	9. Collection set
Pre-infusion set		8. Infusion line set
ABYLCAP kit	11. ABYLCAP A preassembled device 12. ABYLCAP B preassembled device	13. Oxygenator 14. Oxygenator holder 15. Abylcap collection set 16. Heating circuit priming set
PEX kit	17. PEX preassembled device	9. Collection set
HP kit	18. HP preassembled device	9. Collection set

1. CPFA preassembled device: medical device sterilized by gamma radiation. Extracorporeal circuit for CPFA, including a plasma filter MPS05, a hemofilter HFT14, a 4-way line for connection of the infusion bags, and a 6-way line for connection of the collection bags.
2. RRT preassembled device with HFT03: medical device sterilized by gamma radiation. Extracorporeal circuit for RRT, including a hemofilter HFT03, a 4-way line for connection of the infusion bags, and a 6-way line for connection of the collection bags.
3. RRT preassembled device with HFT05: medical device sterilized by gamma radiation. Extracorporeal circuit for RRT, including a hemofilter HFT05, a 4-way line for connection of the infusion bags, and a 6-way line for connection of the collection bags.
4. RRT preassembled device with HFT08: medical device sterilized by gamma radiation. Extracorporeal circuit for RRT, including a hemofilter HFT08, a 4-way line for connection of the infusion bags, and a 6-way line for connection of the collection bags.
5. RRT preassembled device with HFT14: medical device sterilized by gamma radiation. Extracorporeal circuit for RRT, including a hemofilter HFT14, a 4-way line for connection of the infusion bags, and a 6-way line for connection of the collection bags.
6. RRT preassembled device with HFT17: medical device sterilized by gamma radiation. Extracorporeal circuit for RRT, including a hemofilter HFT17, a 4-way line for connection of the infusion bags, and a 6-way line for connection of the collection bags.
7. RRT preassembled device with HFT22: medical device sterilized by gamma radiation. Extracorporeal circuit for RRT, including a hemofilter HFT22, a 4-way line for connection of the infusion bags, and a 6-way line for connection of the collection bags.
8. Infusion line set: accessory sterilized by EtO. This is the line for the fifth pump.
9. Collection set: accessory sterilized by EtO. It includes 5 collection bags
10. Mediasorb set: includes a Mediasorb cartridge (medical device sterilized by steam).
11. ABYLCAP A preassembled device: medical device sterilized by gamma radiation.
12. ABYLCAP B preassembled device: medical device sterilized by gamma radiation.
13. Oxygenator: medical device
14. Oxygenator holder
15. Abylcap collection set: accessory sterilized by EtO. Includes 2 collection bags.
16. Heating circuit priming set: accessory sterilized by EtO. Includes 2 Y-lines for heating circuit priming.
17. PEX preassembled device: medical device sterilized by gamma radiation. Extracorporeal circuit for PEX, including a plasma filter MPS05.
18. HP preassembled device: medical device sterilized by gamma radiation.

The above listed extracorporeal circuits for the treatments that AMPLYA performs (CPFA, RRT, ABYLCAP, PEX and HP) are contained in a blister pack and include up to two cassettes.
The venous cassette (lower) is intended for collection of the blood to be returned to the patient though the return line (blue). It is fitted with a filter that prevents any clots from passing through the return line to the patient.

The plasma/infusion fluid cassette (upper) is intended for collection of the replacement fluid (in RRT) or the plasma (in CPFA), which respectively dilute the blood before and after the hemofilter.
In ABYLCAP, the plasma/infusion fluid cassette (upper) is intended for collection of the water for injectable preparations.
The upper cassette is not used in PEX.
The upper cassette is not used in HP.

WARNING
The oxygenator is intended for use in an ABYLCAP treatment for a maximum time of 120 hours.

WARNING
In ABYLCAP, the oxygen flow through the GAS INLET port of the oxygenator may not exceed 6-8 l/min.

3 BEFORE USING THE MACHINE

3.1 WARNINGS

1. Carefully read the instructions contained in this manual and inserted in the packages of the single-use devices before starting the machine for the first time. Improper use, application of procedures different from those indicated, or the use of accessory devices not provided for may pose a hazard to the patient and/or the machine. The manufacturer declines all responsibility if the machine is not used in compliance with the instructions in this document.

2. AMPLYA must always be installed by technicians authorised by the manufacturer Failing this, the manufacturer declines all responsibility for safety and reliability of the machine. The authorised technicians are also solely responsible for periodic service and maintenance if the operator deems necessary in order to guarantee machine safety.

3. The place where the machine is used must be dry, free of water infiltration and in compliance with the operating conditions specified in Chapter 11.

4. The machine must be positioned at least one metre away from the patient and in a place protected against direct sunlight.

5. Do not lift the machine using the rear handles and the side handle.

6. Do not move the machine by pulling on the filters and/or the lines.

7. The electric system of the haemodialysis rooms or the intensive care unit where the machine is installed must be in compliance with the relative regulations. To prevent the risk of electric shock, the machine must be connected to an earthed electrical distribution network. It is important that the machine be connected only to mains sockets equipped with an earth connection in order to meet the requirements for Class I medical electrical devices.

8. AMPLYA may only and exclusively be used for blood clearance. Amplya may only be used by persons who have acquired adequate knowledge of the extracorporeal blood clearance process and who have been suitably trained on proper use of the machine and the hazards related to such use. Contact the manufacturer for information on the personnel training procedures regarding the use of Amplya.

9. The hospital must inform the manufacturer of any machine defect, and in the event of a defect that determines or may determine very serious harm (e.g. death), immediately notify the manufacturer.

10. In case of reverse ultrafiltration, the use of replacement fluids that conform to the prescription does not pose a risk to safety.

11. In case of high-flux treatments (> 6 l/h) lasting more than 12 hours, check for blood leaks as there is a higher probability of risk to the patient.

12. When an alarm occurs, follow the instructions given in the alarm message.

13. Monitor the machine and the patient for the entire time alarm override mode is active.

14. The probability of a safety risk increases if the machine is hit by an electromagnetic field with power and frequency values not in compliance with the EN 60601-1-2 requirements. Use of mobile telephones or other devices that emit electromagnetic waves in proximity of AMPLYA may cause machine malfunctioning.

15. Syringe pump 1 must exclusively be used for anticoagulation. Syringe pump 2 can be used for an ancillary infusion during the treatment (e.g. infusion of heparin during a treatment performed with local-regional anticoagulation).

16. During treatment, never connect to the USB communication ports.

17. It is not possible to connect active components (e.g. PC, electrically powered memory devices) to the USB communication port.

18. AMPLYA may only be connected via the Ethernet communication port to protectively earthed equipment in compliance with CEI EN 60950 or EN 60601-1. The connection must be made in compliance with the requirements of EN 60601-1-1.

19. Some alarms can temporarily be deactivated by pressing the dedicated button to allow the operator to resolve the conditions that generated them. The operator must pay the utmost attention and is in any case responsible for monitoring the deactivated alarms. Repeated deactivation of alarms of which the cause has not been identified may be hazardous for the patient.

3.2 RULES FOR USE

The staff that uses the machine must strictly follow the rules below:

1. Do not shake the machine during treatment and do not load the scales with weights different from the bags intended for the treatment.

2. Make sure that the device is installed in compliance with the specifications given in this document.

3. During treatment, lock the 4 wheels using the brakes.

4. Check that only single-use devices approved by the manufacturer are used and follow the instructions contained in the packages. The medical centre is responsible for any damage caused by devices not indicated by Bellco.

5. Ensure that the replacement fluid conforms to the treatment prescription for the specific patient and that it meets the applicable standards.

6. Keep all the data shown on the display under control, checking that the values are as expected.

7. Interrupt the treatment and disconnect the patient if its continuation may pose a risk to the health of the patient.

8. Wait for the end of the treatment before attempting to remove the single-use set and, in the case of CPFA, do not invert the connection of the MEDIASORB cartridge after rinsing.

9. With the aim of preventing cross-infections, replace all the single-use devices for each new patient to be subjected to treatment with the machine. Also replace the single-use devices each time the machine requests and at each treatment.

10. Check that the sterile devices and the bags are not damaged in any way before opening the respective packages.

11. Check that the single-use device packaging, which ensures sterility, is not damaged and that the sterilization validity date has not expired.

12. Check that the single-use devices are properly and aseptically installed.

13. Never touch the patient and the machine at the same time.

14. Should the machine no longer be able to make the pressure measurements in one of the cassettes because of the presence of blood or biological fluid in the line that connects the circuit to the pressure transducers, interrupt the treatment, clamp the measuring line and check that the fluid has not seeped through the water-repellent membrane (membrane side facing the machine) of the filter (blood catcher).

15. If fluid has passed through the membrane towards the pressure port, stop the treatment and return the blood to the patient. Once the treatment has ended, a qualified technician must check that the fluid has not also gone beyond the membrane of the second filter (placed in series to the first towards the sensor), and if so, also the inside of the machine must be checked to establish whether disinfection is necessary before restarting the machine.

16. Never set a transmembrane pressure that exceeds the maximum permitted value specified by the manufacturer of the filter used.

As a general rule, the operator must monitor the clinical conditions of the patient throughout the therapeutic session so as to ensure proper and safe performance of the treatment.

3.3 CLEANING AND MAINTENANCE

CAUTION
The operator/user may not carry out any periodic cleaning or maintenance operation different from those listed. The rear panel that allows access to the electronic components may only be opened by technicians authorised by the manufacturer.

WARNING
Before any periodic maintenance operation, cut the power to the machine by pulling out the plug or turning it off at the main switch. Do not touch the switch or live parts with wet hands.

LOAD-BEARING BODY
The dust that deposits on the external panels and on the screen can be removed with a cloth or a soft brush. Any deposits of salt, blood, etc. can be removed with a cloth moistened in a neutral detergent. Never spray detergents directly onto the machine bodywork or onto the components to be cleaned.
A certain number of detergents/disinfectants commonly used in dialysis centres have been tested and did not cause any alteration or damage to the machine panels. These products are therefore recommended:

- ANTISAPRIL (Amuchina)
- CITROSIL (Manetti - Roberts)
- Ethyl ALCOHOL
- QUATHOEX (B. Braun)
- MELSEPT SPRAY (B. Braun)
- HYGIEN SPRAY (B. Braun)

If using different products, please contact the manufacturer to check compatibility.

WARNING
Any liquid spilled on the machine must immediately be removed to prevent it from penetrating the machine and damaging the components. Do not use chemical products containing benzene, acetone, toluene, xylene, iodine or similar solvents. These solutions damage the polyurethane panels.

FRONT PUMPS
To clean each pump on the front panel of the machine body:
1. Pull the drive handle outwards.
2. Turn the rotor until finding the point of release.
3. Remove the rotor from the shaft.
4. Clean the cover, the pump cradle and the rotor rollers with a cloth moistened in disinfectant (see paragraph above).

DISINFECTION
Disinfection is normally not required as the blood only comes into contact with single-use devices. If, for a particular reason, there is a medical need to disinfect the machine, contact your local representative.

BATTERIES
The UPS lead batteries to operate the machine in the event of a power failure and the Ni-MH batteries to retain the data in memory and power the clock do not require any maintenance by the operator. Nonetheless, if the machine is not used for 3 months, it is recommended to turn on the machine for 10 hours in order to fully recharge the batteries.

PERIODIC MAINTENANCE (BY AN AUTHORISED TECHNICIAN)
Periodic maintenance must be carried out every 3000 hours of operation or every 12 months by qualified and authorised technicians or authorised persons.
If you find or suspect a defect, the machine must be checked by an authorised technician.

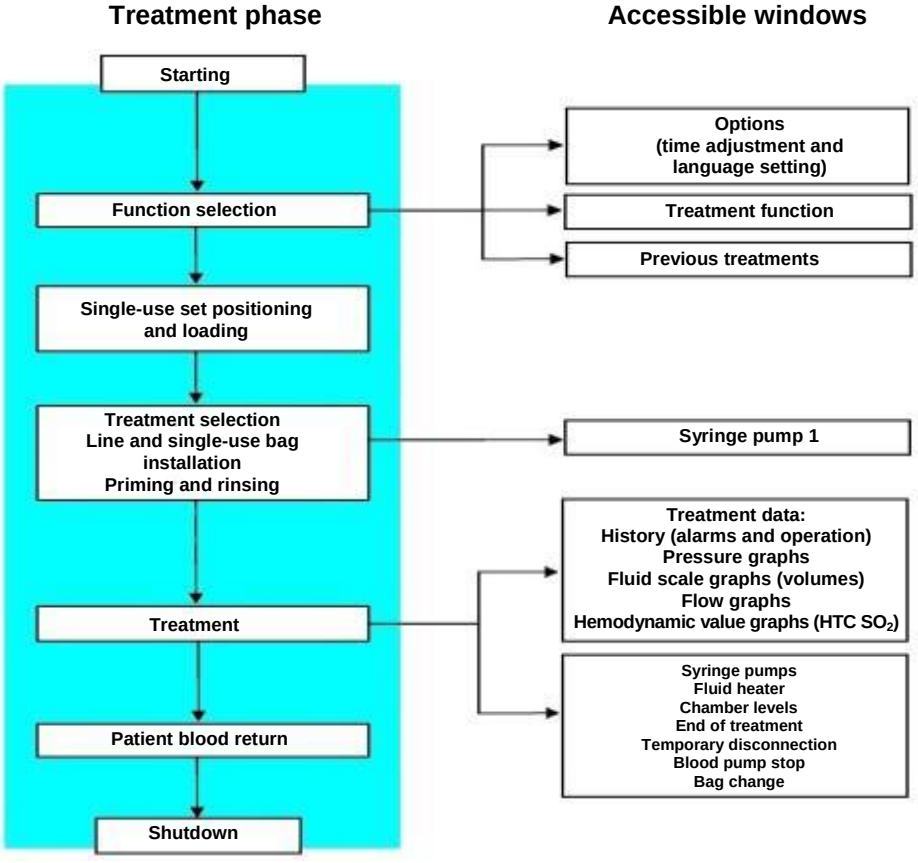
4 STARTING THE MACHINE AND RINSING THE LINES

Turn on the machine using the main switch on the rear of the machine.
After a few seconds, the screen comes on and the machine runs the self-diagnostic tests (electrical tests and component check). Subsequently, the screen shows a loading bar and when loading is complete the home page is displayed (see par. 4.4): at this point, the system is ready for programming.

WARNING
To check proper functioning of the alarm signals, check that when AMPLYA is turned on, the light turns into RED and YELLOW in sequence and that an acoustic signal is sounded.

4.1 PROCESS FLOW DIAGRAM

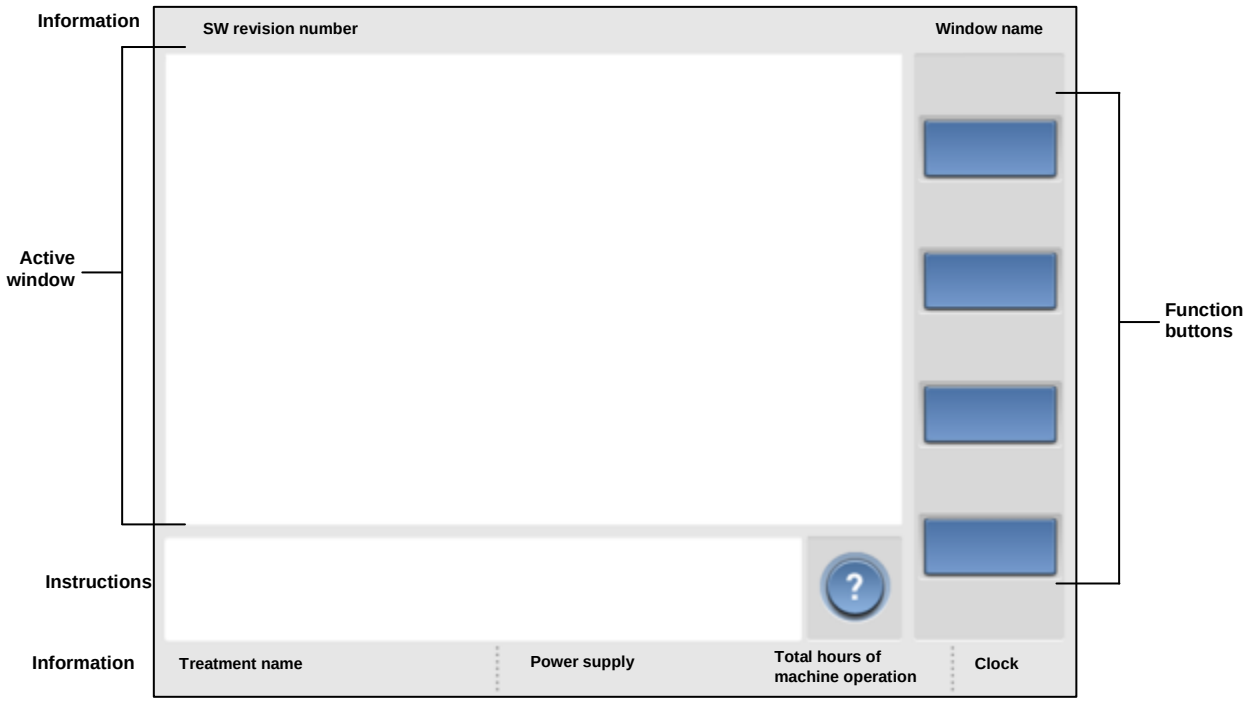
Machine operation follows the process flow diagram shown below where each phase is characterised by a different page on the screen. Sequential access to the main pages (light blue column) depends on the positive outcome of the previous phase. To access the other pages from the main pages, operate as described below.



4.2 SCREEN LAYOUT

The interface between the operator and the machine is a touchscreen that displays the data and allows the operator to modify the treatment parameters. The screen is divided into 5 areas in which information messages may be shown.

Information: this area is divided into a top section containing the software revision number and the title of the active window and a bottom section that shows the treatment name, the power supply (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 contains the buttons that allow activating 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 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.

4.3 DATA INPUT

The operator can define the treatment parameters by entering data into the system. To set/modify one or more treatment parameters, operate as follows:

1. Press with a fingertip on the white field of the parameter. A numerical keypad (see par. 4.3.1) or an alphanumerical keypad (see par. 4.3.2) appears.
2. Enter the value by pressing the keypad buttons.
3. Press the CONFIRM button to confirm the selection or the CANCEL button to cancel the operation. If you confirm, you access the confirmation page.
4. Repeat steps 1 to 3 if you want to change the value just set or set/modify other parameters.
5. On the confirmation page press the CONFIRM button to activate the modification or the CANCEL button to go back to the values prior to the modification.

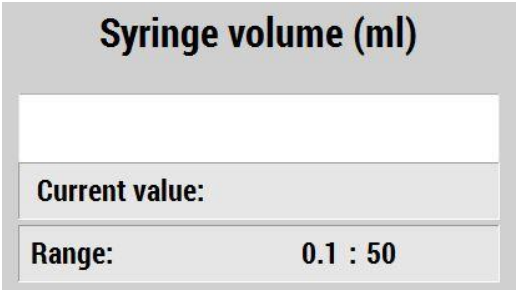
4.3.1 NUMERICAL KEYPAD

This keypad allows setting numbers. It comprises the numbers from 0 to 9, a dot for decimal numbers and a button to cancel the numbers entered (red arrow).

For some parameters you can also set the + or - sign. For example, the access pressure requires setting a negative value.
The button shown below performs this function:

At the top of the keypad the following are shown from top to bottom:

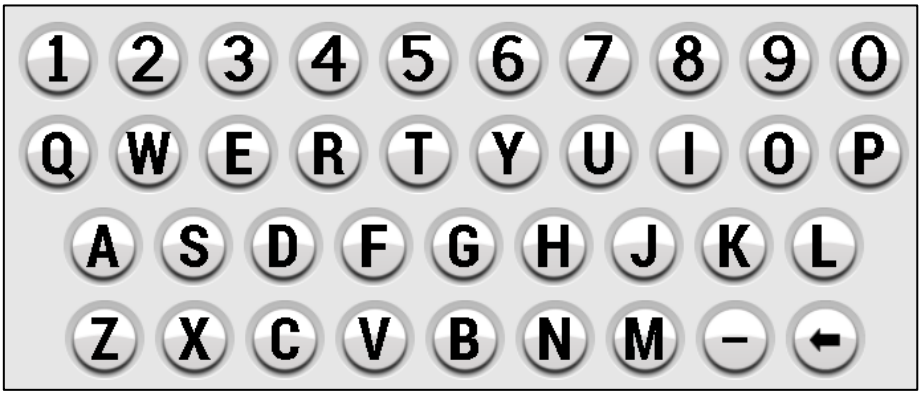
- The name of the parameter you want to set/modify followed by the unit of measure.
- A white field in which to enter the value.
- The current value and the permitted range of values for this parameter.



The values entered are checked before you confirm and the system immediately signals any inconsistency to prevent further difficulties (e.g. value entered out of range).

4.3.2 ALPHANUMERICAL KEYPAD

This keypad comprises the numbers from 0 to 9, the letters of the alphabet, an underscore sign ("_") and a button to cancel the letters and/or numbers entered (red arrow).



At the top of the keypad the name of the parameter you want to set/modify and next to it a white field to enter the desired alphanumerical value are shown.
The keypad may have an additional button, for example, to select the filter and the treatment type (continuous or intermittent) if you want to store a specific treatment in memory (see paragraph 4.6.2).
The values entered are checked and the system immediately signals any inconsistency to prevent further difficulties (e.g. name already stored in memory).

4.3.3 CONFIRMATION AND CANCELLATION

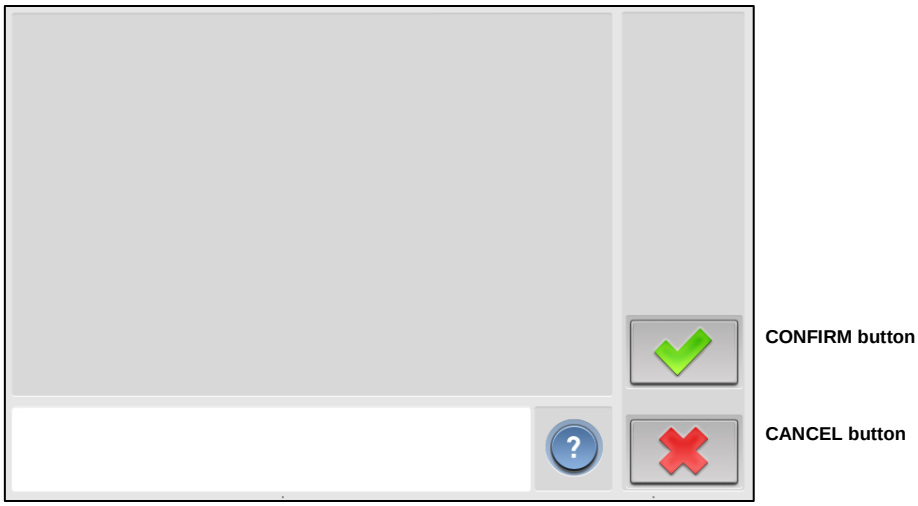
Both the numerical and the alphanumerical keypad have a CANCEL button which when pressed makes the keypad disappear and cancels any entry made. When you enter a value in the white field of a numerical or alphanumerical keypad, a CONFIRM button appears in addition to the CANCEL button.

Confirm: pressing this button, confirms the actions or the values entered/modified.

Cancel: pressing this button, cancels the actions or the values entered/modified.

4.3.4 CONFIRMATION PAGE

When you set or change the value of one or more parameters, the system displays a page asking you to confirm or cancel the value or values entered.
The image below shows the buttons that characterise the generic confirmation page, located at the bottom right in the Function Button area.



4.4 HOME PAGE

This is the first page that appears when the machine is turned on.
You need to wait for the bar in the Information area on the right to fill before you can act on the screen.
The Bellco logo appears in the centre of the page and the following buttons in the Function Button area on the right:

1. Options (par. 4.5)
2. Previous Treatments (par. 4.8)
3. Treatment Function (par. 4.6)
4. Position Set (par. 4.7, 4.8, 4.9, 4.10).

The functions of each button are described below.

4.5 OPTIONS

Pressing the OPTIONS button displayed on the home page, you access a page where you can modify the general parameters valid for all the treatments (language, date and time), the hospital NETWORK connection settings and, if enabled from the technical page, AMPLYA configuration for ECMO.

The page comprises three panels: GENERAL, TREATMENT and NETWORK, accessible by pressing on the relative tab.

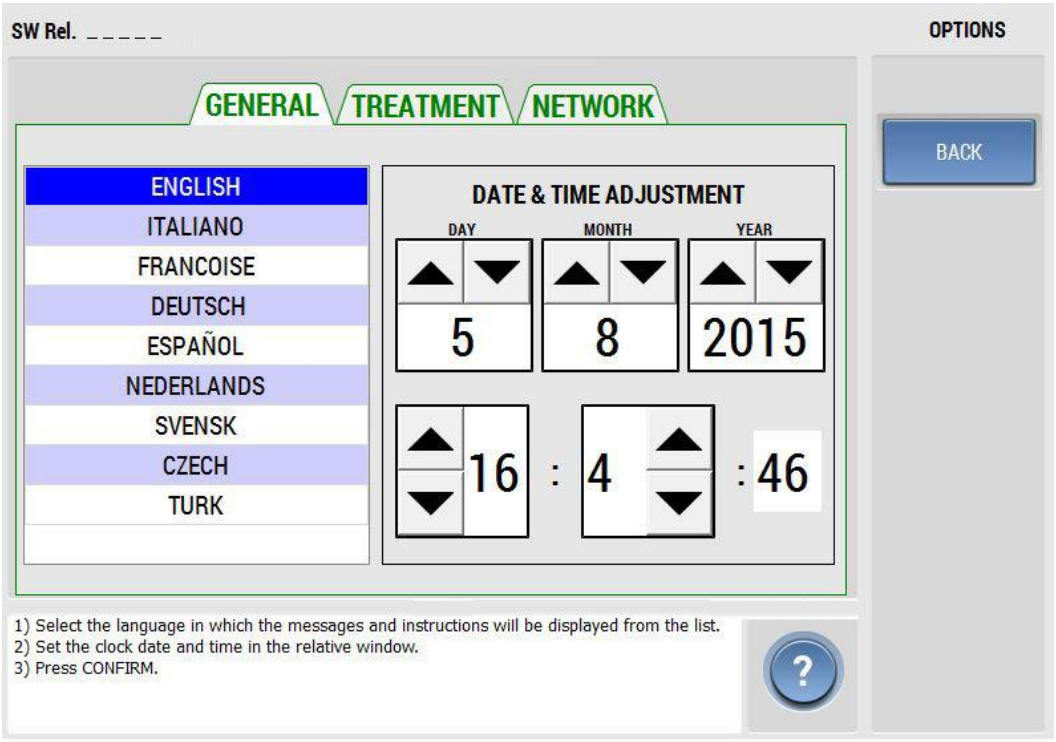
4.5.1 GENERAL panel

In the GENERAL panel you can select the language and change the date and time.

Language: list of the languages available. This parameter should be set to the official language of the place where the machine is used, or if this language is not available, to a language most of the nursing staff can understand.

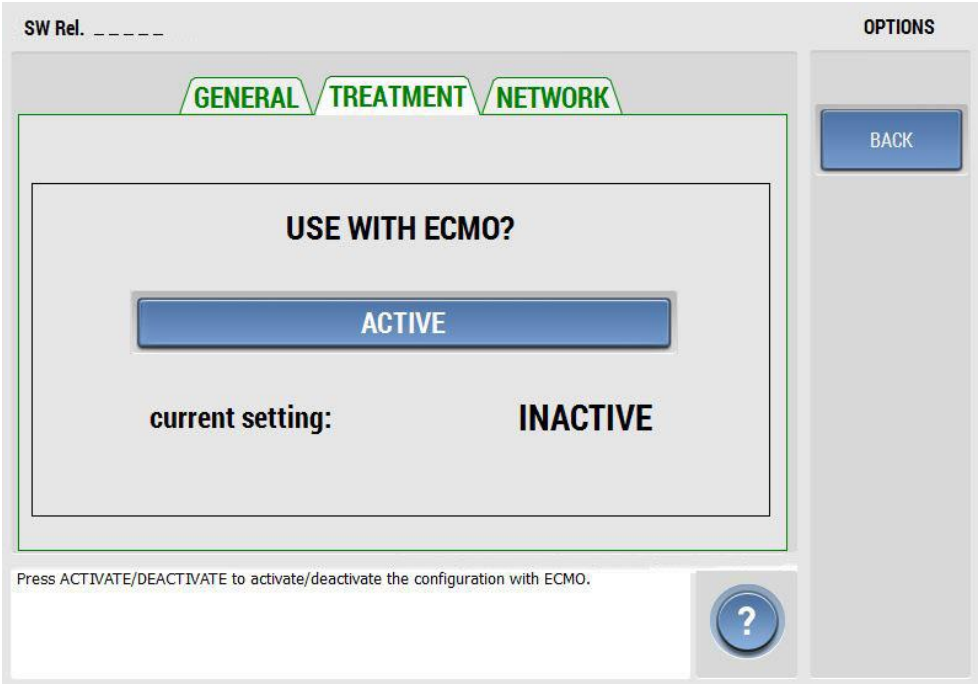
Date and time: allows changing the system date and time. This information is used only in the log files (see par. 4.11, 5.2.2., 6.2.2, 7.2.2, 8.2.2 and 9.2.2) and is displayed in the bottom Information area (see par. 4.2).

You are asked to turn the machine off and on again to make the changes effective.



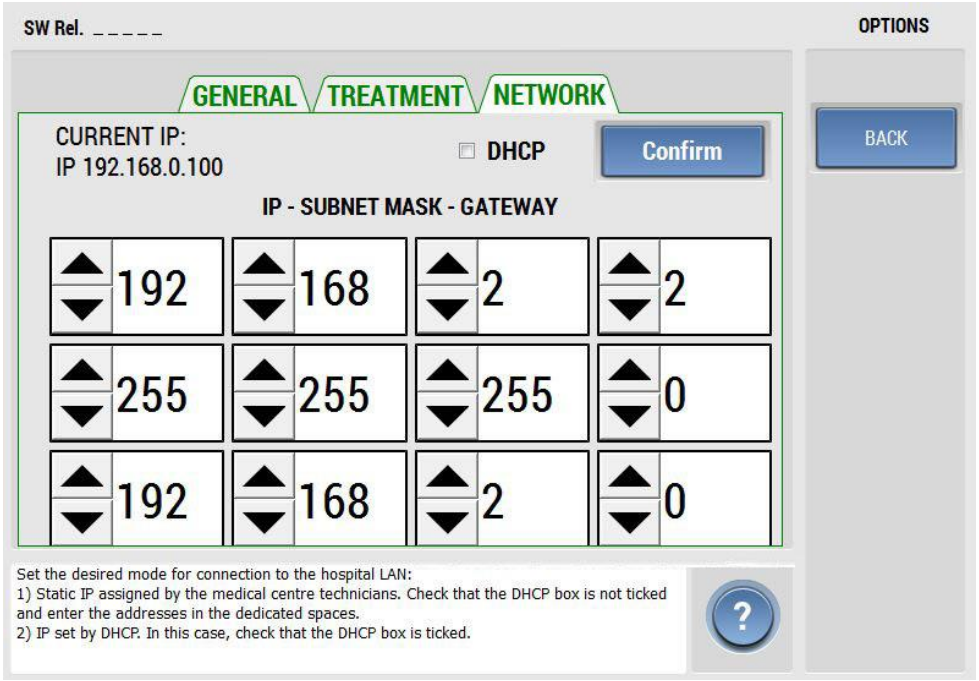
4.5.2 TREATMENT panel

In the TREATMENT panel you can enable/disable AMPLYA configuration for ECMO. Enabling this type of configuration, you can perform CPFA, RRT and HP treatments and simultaneously perform ECMO with external devices.



4.5.3 NETWORK panel

In the NETWORK panel you can set the parameters for connection to the hospital LAN.



The LAN can be configured in two ways:

1. Static IP assigned by the medical centre technicians. In this case, check that the DHCP box is not ticked and enter the addresses in the dedicated spaces:
    a. The first is the machine IP address;
    b. The second is the LAN SUBNET MASK address;
    c. The third is the LAN GATEWAY address.
2. IP set by DHCP. In this case, check that the DHCP box is ticked.

For details on the Ethernet connection configuration settings, refer to the manual REMOTE LOG TCP PROTOCOL MANUAL (provided on request of the user).

4.6 TREATMENT FUNCTION

Pressing the TREATMENT FUNCTION button displayed on the home page, you access a section where you can:

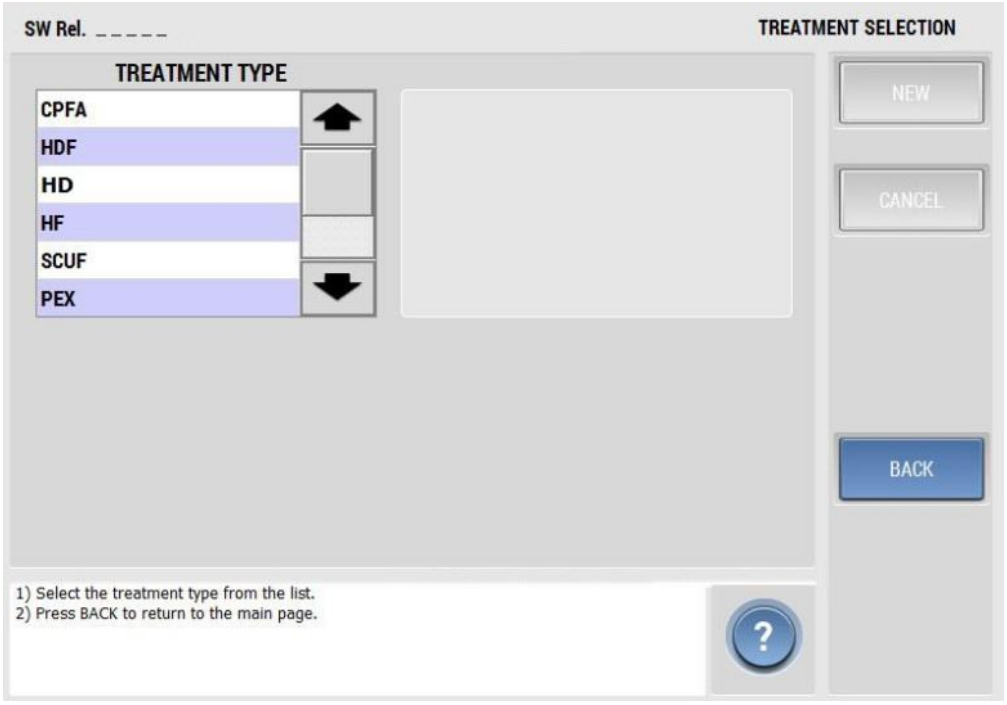
1. View the treatments stored in memory and modify the relative parameters if necessary
2. Remove the treatments stored in memory
3. Create new treatments.

The system is supplied with one treatment already in memory for each of the treatment types AMPLYA can perform: CPFA, HDF, HD, HF, SCUF, ABYLCAP, PEX and HP. These treatments, identified with the name DEFAULT,

- can be selected from the list of treatments in memory and used as standard protocol
- cannot be modified or removed
- have reference values for each of the parameters that characterise them and are automatically suggested when setting a new treatment.

In addition to the DEFAULT treatments, the system allows storing custom treatments according to the treatment required for a specific patient.

Pressing the TREATMENT FUNCTION button, you access a page containing the list of all the treatment types the machine can perform: HDF, HD, HF, SCUF, CPFA, ABYLCAP, PEX and HP.



4.6.1 Selecting, modifying and removing a treatment

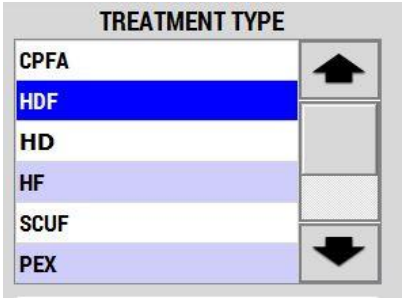
The operations to perform to view, modify or remove a treatment previously stored in memory are:

1. Select the treatment characteristics:
    - Select the treatment type: HDF, HD, HF, SCUF, CPFA, ABYLCAP, PEX and HP
    - When enabled, select continuous mode (time not defined) or intermittent mode (time defined)
    - When required, select the hemofilter type (small, medium or large) required for that treatment.
2. Select the treatment name
3. Modify or remove the treatment.

The first two steps allow viewing all the parameters and the characteristic values for the treatment type selected.

To **view/modify an RRT treatment** in memory, operate as follows:

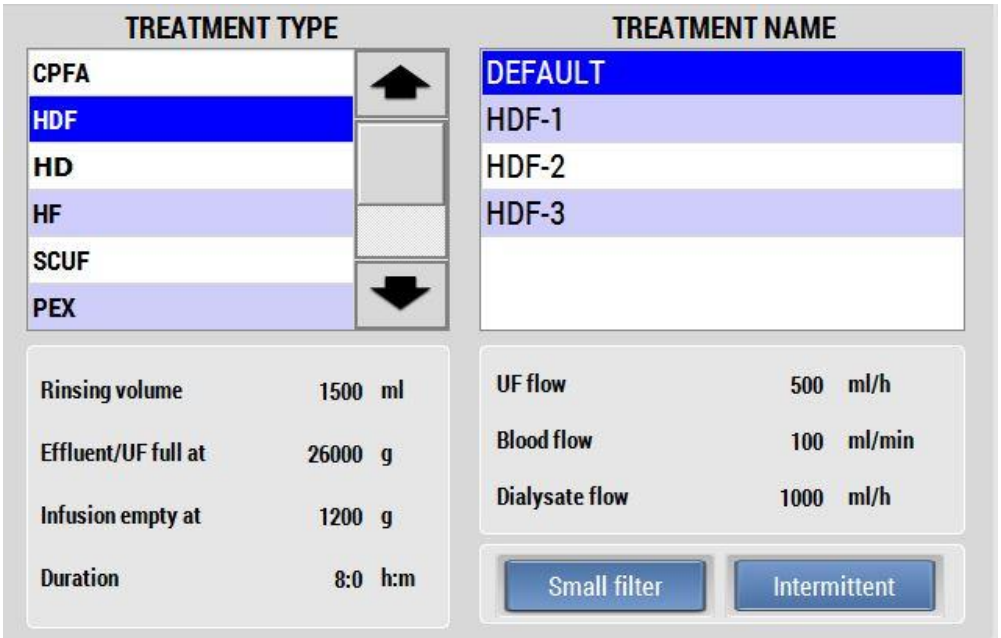
1. Select an RRT treatment type from the list of types.



2. If enabled, press the CONTINUOUS/INTERMITTENT button to view (in the panel at the top right) only the continuous RRT treatments (default) or the intermittent RRT treatments (pressing once).

3. Press the FILTER button to view (in the panel on the right) only the RRT treatments with small filter (default), medium filter (pressing once) or large filter (pressing twice).

4. Select the name of the RRT treatment you want (from the panel at the top right) and view the parameters and relative values for that particular treatment (in the panel at the bottom right).

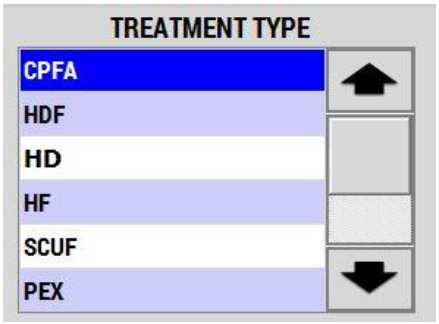


5. Press BACK (Function Button area) if you do not want to modify any parameter, otherwise, for each parameter you want to modify, press on the corresponding white field (in the panel at the bottom right) and set the desired value using the *numerical keypad* (see par. 4.3).
6. If you have modified the parameters, confirm or cancel them by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

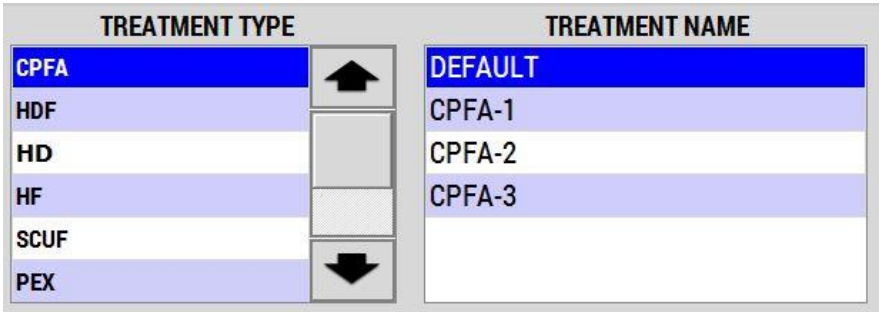
To **cancel an RRT treatment** in memory, select the treatment you want to cancel following steps 1 to 4 and press the CANCEL button (Function Button area).

To **view/modify a CPFA treatment** in memory, operate as follows:

1. Select the CPFA treatment type from the list of types.



2. Select the name of the CPFA treatment you want and view the parameters and relative values for that particular treatment.

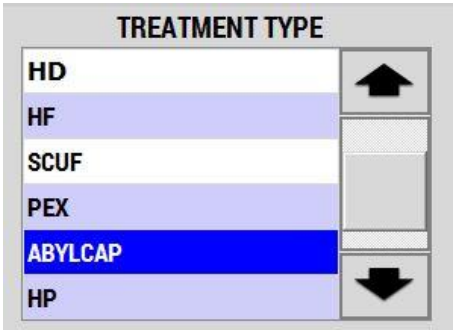


3. Press BACK (Function Button area) if you do not want to modify any parameter, otherwise, for each parameter you want to modify, press on the corresponding white field and set the desired value using the *numerical keypad* (see par. 4.3).
4. If you have modified the parameters, confirm or cancel them by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

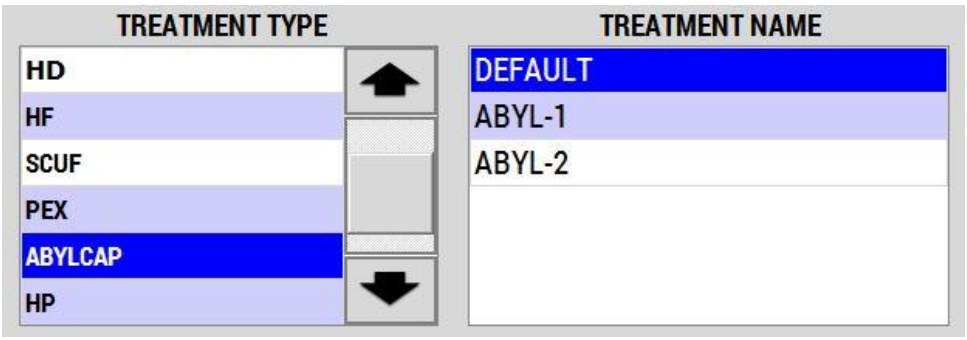
To **cancel a CPFA treatment** in memory, select the treatment you want to cancel following steps 1 to 4 and press the CANCEL button (Function Button area).

To **view/modify an ABYLCAP treatment** in memory, operate as follows:

1. Select the ABYLCAP treatment type from the list of types.



2. Select the name of the ABYLCAP treatment you want and view the parameters and relative values for that particular treatment.

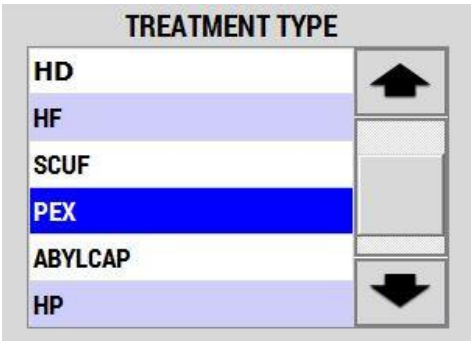


3. Press BACK (Function Button area) if you do not want to modify any parameter, otherwise, for each parameter you want to modify, press on the corresponding white field and set the desired value using the *numerical keypad* (see par. 4.3).
4. If you have modified the parameters, confirm or cancel them by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

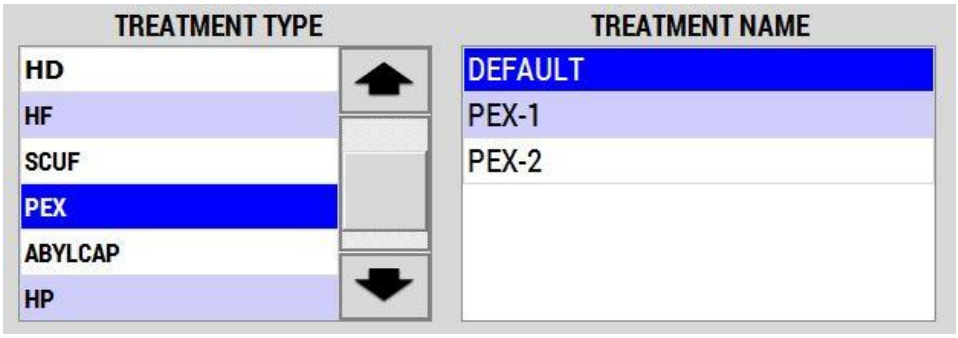
To **cancel an ABYLCAP treatment** in memory, select the treatment you want to cancel following steps 1 to 4 and press the CANCEL button (Function Button area).

To **view/modify a PEX treatment** in memory, operate as follows:

1. Select the PEX treatment type from the list of types.



2. Select the name of the PEX treatment you want and view the parameters and relative values for that particular treatment.

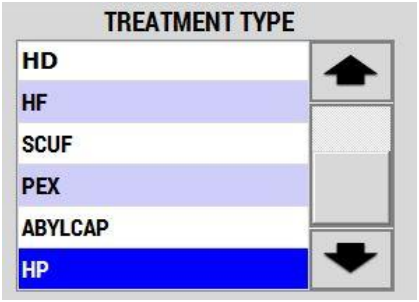


3. Press BACK (Function Button area) if you do not want to modify any parameter, otherwise, for each parameter you want to modify, press on the corresponding white field and set the desired value using the *numerical keypad* (see par. 4.3).
4. If you have modified the parameters, confirm or cancel them by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

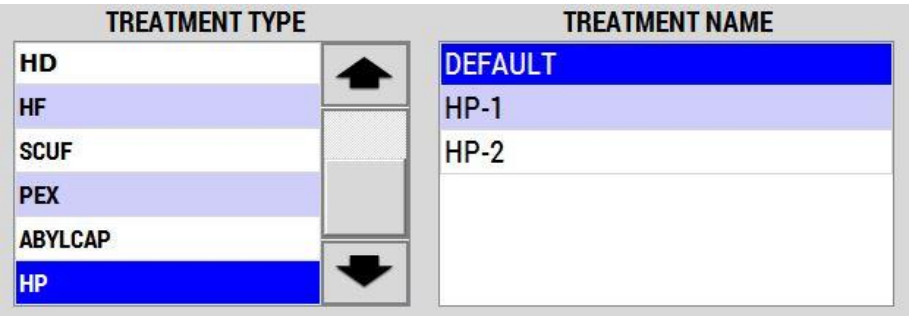
To **cancel a PEX treatment** in memory, select the treatment you want to cancel following steps 1 to 4 and press the CANCEL button (Function Button area).

To **view/modify an HP treatment** in memory, operate as follows:

1. Select the HP treatment type from the list of types.



2. Select the name of the HP treatment you want and view the parameters and relative values for that particular treatment.



3. Press BACK (Function Button area) if you do not want to modify any parameter, otherwise, for each parameter you want to modify, press on the corresponding white field and set the desired value using the *numerical keypad* (see par. 4.3).
4. If you have modified the parameters, confirm or cancel them by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

To **cancel an HP treatment** in memory, select the treatment you want to cancel following steps 1 to 4 and press the CANCEL button (Function Button area).

4.6.2 New treatment

To **create a new treatment,** operate as follows:
1. Select the treatment type from the list of types.
2. Press the NEW button (Function Button area).
3. Enter the treatment name using the *alphanumerical keypad* (see par. 4.3)
4. When present on the keypad, press the CONTINUOUS/INTERMITTENT button to select continuous or intermittent mode.

5. When present on the keypad, press the FILTER button to associate the treatment with a certain filter type (small, medium, large or unique) and confirm the operations carried out in steps 3, 4 and 5 by pressing the CONFIRM button on the keypad.

6. For each *reference parameter* you want to modify, press on the corresponding white field and set the desired value using the *numerical keypad* (see par. 4.3).
7. Confirm or cancel the previous operations by pressing the corresponding button on the *confirmation page* (see par. 4.3).

Steps 1 to 5 allow viewing all the parameters and the relative default values for the type of treatment selected at the bottom of the active window. These parameters are modifiable as explained in step 6.

You can create a new treatment by pressing the NEW button also during selection of an existing treatment (selecting the type, mode and any filter). The treatment will be the same type as the treatment selected.

4.6.3 Treatment parameters

The treatment time and the list of parameters that can be viewed and/or set in TREATMENT FUNCTION are indicated below for each treatment family.

CPFA

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	3000	3000	6000
UF flow (ml/h)	1500	0	minimum between 4500 and 0.3*blood flow
Blood flow (ml/min)	150	30	250

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Effluent/UF full at (g)	26000
Infusion empty at (g)	1200

CONTINUOUS HAEMODIAFILTRATION (CVVHDF)

Small filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	4000
UF flow (ml/h)	500	0; 100	minimum between 4000, (2.32*dialysate flow) and (0.3*blood flow)
Dialysate flow (ml/min)	1000	Maximum value between 500 and 0.43*UF flow	2000
Blood flow (ml/min)	100	30 (or 50 only if dialysate flow = 0)	250 (or 200 only if dialysate flow = 0)

Medium filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	4000
UF flow (ml/h)	1000	0; 100	minimum value between (12000-dialysate flow), (2.32*dialysate flow) and 0.3*blood flow
Dialysate flow (ml/min)	3000	Maximum value between 500 and 0.43*UF flow	12000-UF flow
Blood flow (ml/min)	150	30 (or 50 only if dialysate flow = 0)	450 (or 200 only if dialysate flow = 0)

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Effluent/UF full at (g)	26000
Infusion empty at (g)	1200

INTERMITTENT HAEMODIAFILTRATION (IHDF)

The parameter values in intermittent haemodiafiltration are the same as indicated in the continuous haemodiafiltration tables.
Unlike continuous haemodiafiltration, intermittent haemodiafiltration has a settable and finite time.

	Default value	Minimum value settable	Maximum value settable
Time (h)	8	1	24

CONTINUOUS HAEMODIALYSIS (CVVHD)

Small filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	2500
Dialysate flow (ml/min)	1000	0; 100	4000
Blood flow (ml/min)	100	30	250

Medium filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	2500
Dialysate flow (ml/min)	2000	0; 500	12000
Blood flow (ml/min)	150	30	450

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Effluent/UF full at (g)	26000
Infusion empty at (g)	1200

INTERMITTENT HAEMODIALYSIS (IHD-SLED)

The parameter values in intermittent haemodialysis are the same as indicated in the continuous haemodialysis tables.
Unlike continuous haemodialysis, intermittent haemodialysis has a settable and finite time.

	Default value	Minimum value settable	Maximum value settable
Time (h)	8	1	24

CONTINUOUS HAEMOFILTRATION (CVVH)

Small filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	2500
UF flow (ml/h)	1000	100	minimum value between 4000 and (0.3*blood flow/post-infusion ratio/100) *with post-infusion ratio=100-pre-infusion ratio*
Pre-infusion ratio (%)	50	0; 30	100
Blood flow (ml/min)	100	30 (or 50 only if pre-infusion flow = 0)	250 (or 200 only if pre-infusion flow = 0)

Medium filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	2500
UF flow (ml/h)	1000	500	minimum value between 12000 and (0.3*blood flow/post-infusion ratio/100) *with post-infusion ratio=100-pre-infusion ratio*
Pre-infusion ratio (%)	50	0; 30	100
Blood flow (ml/min)	150	30 (or 50 only if pre-infusion flow = 0)	450 (or 200 only if pre-infusion flow = 0)

Large filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	2500
UF flow (ml/h)	3000	500	minimum value between 12000 and (0.3*blood flow/post-infusion ratio/100) *with post-infusion ratio=100-pre-infusion ratio*
Pre-infusion ratio (%)	50	0; 30	100
Blood flow (ml/min) (*)	150	30 (or 50 only if pre-infusion flow = 0)	450 (or 200 only if pre-infusion flow = 0)

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Effluent/UF full at (g)	26000
Infusion empty at (g)	1200

INTERMITTENT HAEMOFILTRATION (IHF-HVHF)

The parameter values in intermittent haemofiltration are the same as indicated in the continuous haemofiltration tables.
Unlike continuous haemofiltration, intermittent haemofiltration has a settable and finite time.

	Default value	Minimum value settable	Maximum value settable
Time (h)	8	1	24

SCUF

Small filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	2500
Blood flow (ml/min)	100	30	250

Medium filter

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1500	1500	2500
Blood flow (ml/min)	150	30	450

For treatments that require infusion of replacement fluid, the parameter "Infusion empty at" (settable in TREATMENT FUNCTION) is modifiable during treatment when the infusion bags reach the minimum weight value entered for the parameter in question. The system signals when the minimum weight has been reached and suggests reducing the value if you want (see alarm 345 in par. 10.11).

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Effluent/UF full at (g)	26000

ABYLCAP

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	with set A: 1200 with set B: 700	with set A: 1200	with set A: 2000
Blood flow (ml/min)	300	30	550

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Effluent full at (g)	5000
Time (h:m)	60:0

PEX

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	1200	1200	1500
Plasma/blood (%)	15	5	20
Plasma volume (g)	5000	100	30000
Blood flow (ml/min)	100	30	250

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Effluent/UF full at (g)	5000
Infusion empty at (g)	300

HP

	Default value	Minimum value settable	Maximum value settable
Rinsing volume (ml)	2000	1000	5000
Blood flow (ml/min)	150	30	450

Together with the above parameters also the following non-settable parameters are displayed:

	Value
Time (h:m)	60:0

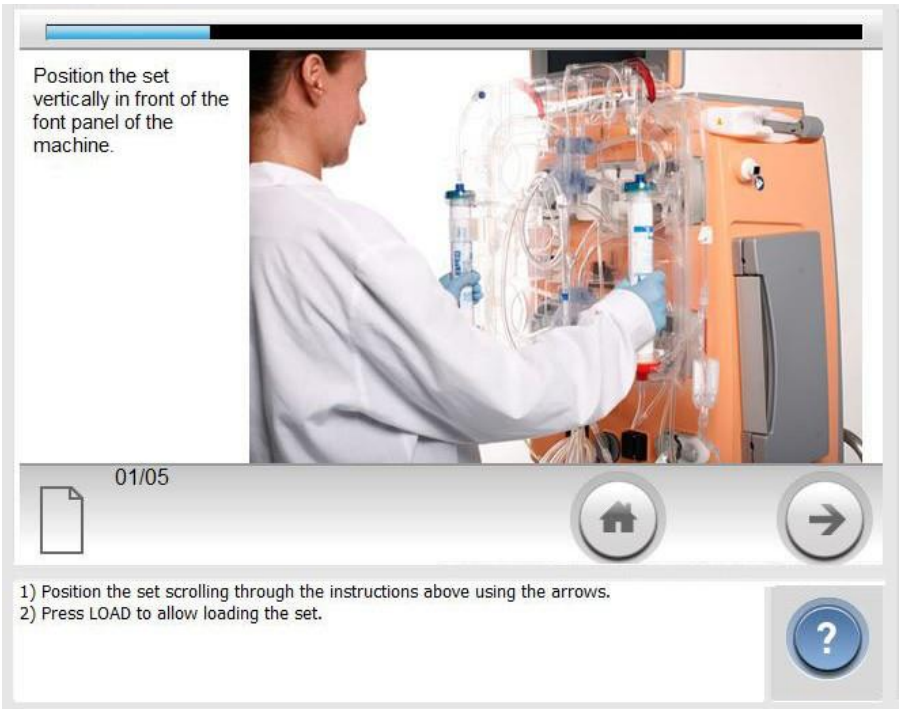
4.7 CPFA and RRT: SINGLE-USE SET, TREATMENT SELECTION AND PRIMING

There are six phases prior to the treatment phase:

1. Loading the single-use set
2. Selecting the specific treatment
3. Installing the lines of the single-use kit
4. Installing syringe 1 when heparin or calcium infusion is required
5. Priming or rinsing the circuit
6. End of rinsing.

4.7.1 Loading the single-use set

Pressing the POSITION SET button on the home page (Function Button area), you access a page asking you to load the single-use set suited to the treatment you want to perform.

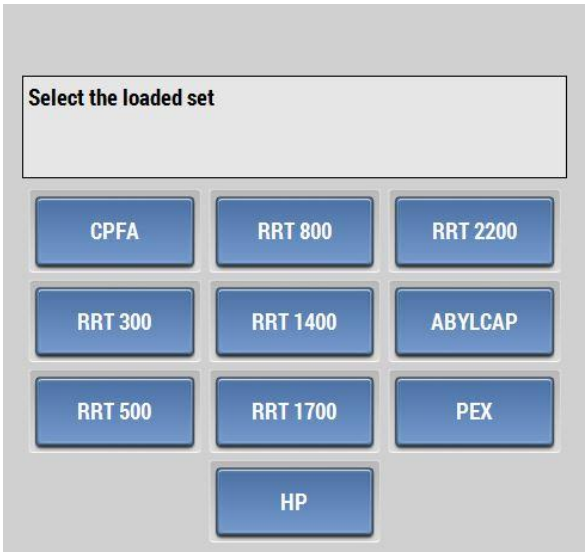


You can go back to the home page by pressing BACK. If you want to continue, the page shows a sequence of illustrated instructions (see the Active Window area in the image above) for positioning the set on the front panel of the machine.
When you have completed the set positioning procedure, press the LOAD button to allow the machine to load the set.

When you press the button, a loading request confirmation window appears.
After confirming the request, wait until loading of the single-use set is complete.
If the system fails to load the single-use set, you are informed through a warning window. Pressing the CONFIRM button in the window, you access a page where you can select whether you want to repeat loading or remove the single-use set.

4.7.1.1 Set identification via barcode

When the loading phase is complete, the system reads the barcode on the back of the set identifying the type of set loaded (in the specific case, CPFA or RRT300 or RRT500 or RRT800 or RRT1400 or RRT1700 or RRT2200) and asks you to confirm that the type of set identified is actually the one loaded.
You can confirm or manually select the type of set by pressing SET SELECTION.
Pressing the CONFIRM button, the system displays a page with the list of the types of treatment that can be performed with the single-use set loaded and from which you can select the treatment you want to perform.
Pressing the SET SELECTION button, a special keypad appears, which allows selecting the type of set loaded by pressing the corresponding button.



Each button has a name of a set that identifies:
- The treatment family (CPFA, RRT, ABYLCAP, PEX and HP)
- The type of hemofilter installed (0.3, 0.5, 0.8, 1.4, 1.7 and 2.2 m^2) only in the case of RRT treatment.

Pressing the button corresponding to the set loaded, you are asked to confirm the selection.
When you confirm, the system displays a page with the list of the types of treatment that can be performed with the single-use set selected and from which you can select the treatment you want to perform.

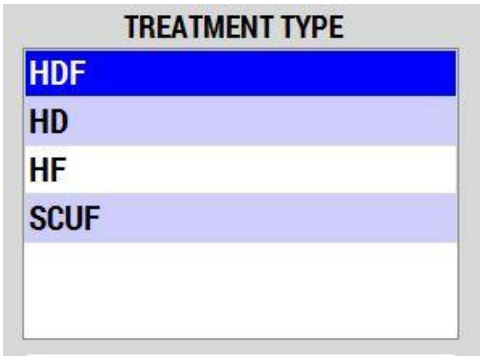
WARNING
Make sure that you select a treatment consistent with the set loaded

4.7.2 Selecting the treatment and installing the lines

You are asked to select the treatment you want to perform from those stored in memory and consistent with the specific single-use set loaded. Alternatively, you can remove the set by pressing the relative button (Function Button area) if you do not want to continue.

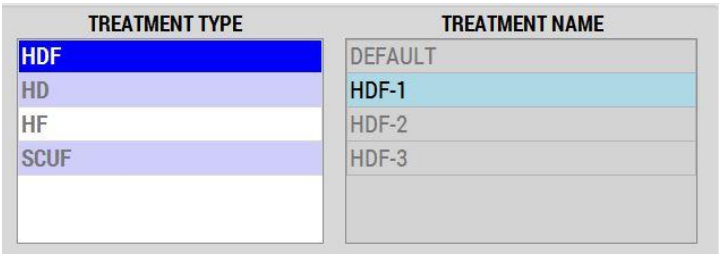
If you have loaded a single-use set for RRT treatments, continue as follows:

1. Select the RRT treatment type



2. If enabled, press the CONTINUOUS/INTERMITTENT button to view only the continuous or intermittent RRT treatments.

3. Select the name of the desired **RRT treatment** from the list resulting from the selections you have made in steps 1 and 2.

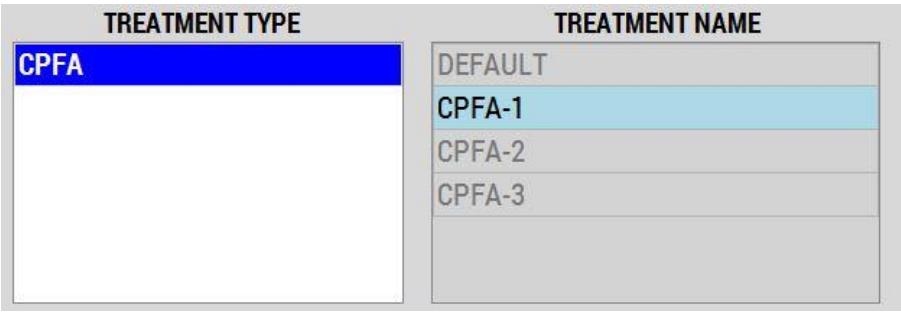


4. Select the anticoagulation type, local-regional in ASSISTED mode (HD, HF and HDF only) or systemic with heparin.

5. Confirm or cancel the selection by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

If you have loaded a single-use set for **CPFA treatment**, continue as follows:

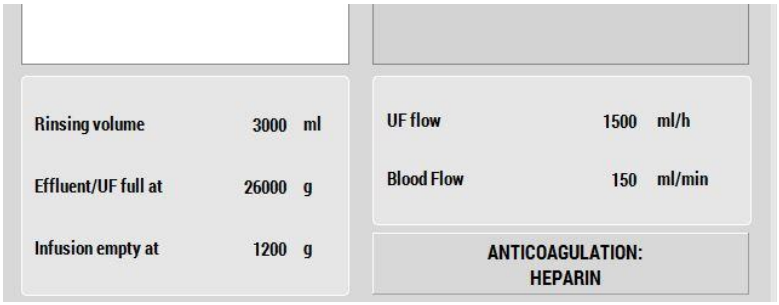
1. Select the name of the desired CPFA treatment.



2. Select the anticoagulation type, local-regional in ASSISTED mode or systemic with heparin.

3. Confirm or cancel the selection by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Selecting an RRT or CPFA treatment from those in memory, the relative characteristic parameters are displayed (see par. 4.6.3).



This allows you to check that the values stored for that treatment are correct.
In each step of the selection, you can remove the single-use set by pressing the relative button (Function Button area) if you do not want to continue.

WARNING
Assisted local-regional anticoagulation requires the use of a solution of 10 mmol/l trisodium citrate and 2 mmol/l citric acid on the central scale. In CPFA and HF use replacement fluid bags with 1.5 mmol/l calcium on the right-hand scale. In HD and HDF use calcium-free replacement fluid bags on the right-hand scale.

WARNING
Make sure that you select a treatment consistent with the set loaded

4.7.3 Installing the lines

When you confirm the treatment selected, you access a page containing a sequence of illustrated instructions for installation of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.

From this page you can:

- Program syringe pump 1 by pressing the SYRINGE PUMPS button if you want to infuse heparin (systemic anticoagulation) or calcium (local-regional anticoagulation) into the circuit during priming/rinsing and during treatment (see par. 4.7.4).
- Start the priming/rinsing procedure by pressing the START PRIMING button (see par. 4.7.5).
- Repeat selection of the desired treatment from those in memory and consistent with the single-use set loaded by pressing the BACK button.

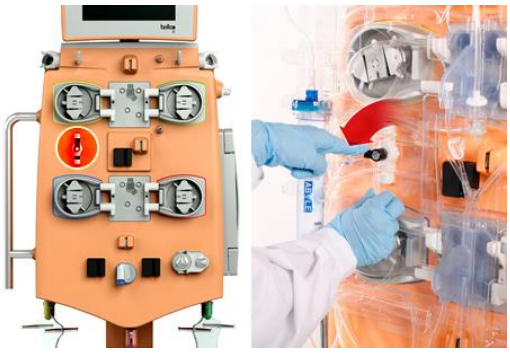
Described below are the operations to be carried out to install the lines of the single-use set.

WARNING
Check that you have selected a treatment consistent with the set loaded.

WARNING
Circuit assembly must be carried out in aseptic conditions according to the validated techniques for extracorporeal blood circulation.

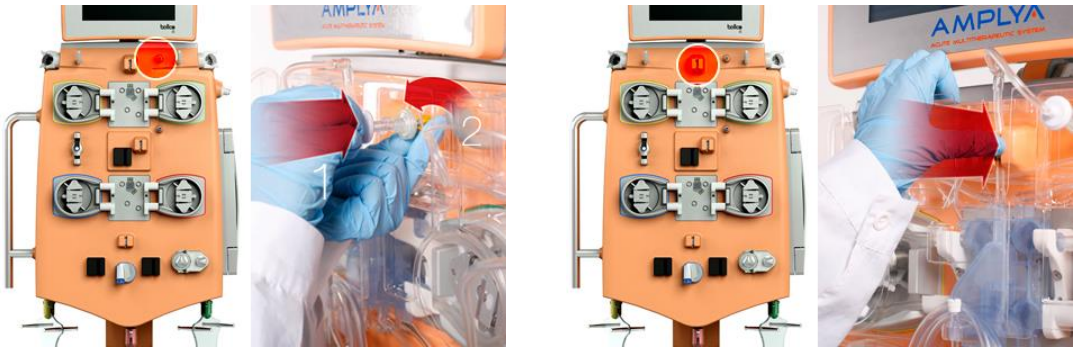
Double electroclamp key

Push the section of the single-use set that surrounds the double electroclamp towards the front of the machine and turn the key of the double electroclamp so that the two lines slip into their housings.



Level lines

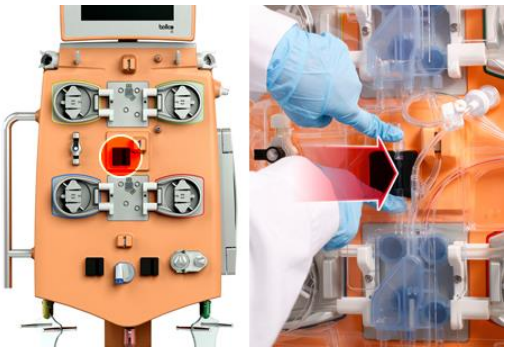
1. Remove the cap from the yellow terminal of the upper level line.
2. Fit the terminal into its yellow port and turn the fastening ring nut anticlockwise until the torque is significantly increased.
3. Fit the line into the relative level sensor pushing the tube fully into the seat to allow proper fluid detection.



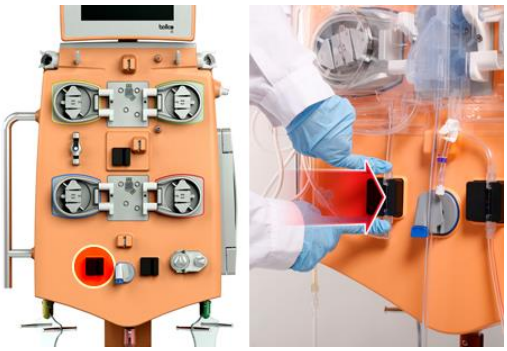
4. Repeat steps 1, 2 and 3 for the lower level line; in this case the terminal and the port with fastening ring nut are blue.

Blood leak lines

1. If you have loaded a CPFA single-use set, fit the *cuvette* (rigid tube) of the plasma line (positioned above the venous cassette) into the relative BLD.

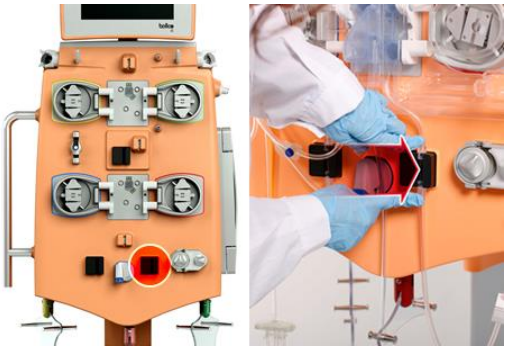


2. Fit the *cuvette* (rigid tube) of the UF line (yellow) into the relative BLD.



Access line

Fit the *cuvette* (rigid tube) of the access line (red) into the hematocrit meter.



Return line

Fit the return line (blue) into the *air detector*, pushing the tube fully inside to prevent incorrect air detection, and into the *venous electroclamp*, pushing the tube into the side seat of the electroclamp.



Mediasorb cartridge

The operations to be carried out for proper connection of Mediasorb are:

1. Hold the cartridge in vertical position with the outlet connector (OUT) facing up, remove the protective cap from the outlet connector and connect the cartridge to the relative line (green).
2. Turn the cartridge so that the inlet connector (IN) sits higher than the outlet connector, remove the protective cap from the inlet connector and connect the cartridge to the relative line (yellow).
3. Position Mediasorb on its holder fastened to the hemofilter.





WARNING:

- **Pay particular attention to the directional arrows (IN at the top and OUT at the bottom) on the cartridge label and to the colours of the Mediasorb inlet and outlet lines indicated on the label, which identify them in the blister pack (see the images of Mediasorb installation above), in order to ensure that you connect the cartridge inlet and outlet to the correct connectors and hence prevent injection of sorbent molecules into the patient.**
- **When connecting the cartridge to the circuit, be particularly careful when removing the protective caps from the cartridge inlet and outlet connectors in order to prevent emptying.**

UF and infusion lines and bags

Other than the single-use set and Mediasorb, the kit also contains 5 ultrafiltrate collection bags.

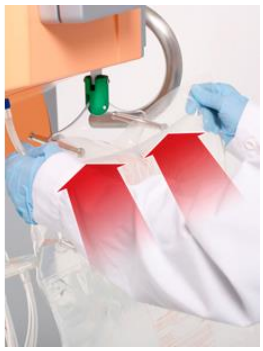
1. Connect the multi-way line to 5 UF bags.
2. Load the 5 empty bags on the UF scale (yellow).



The single-use set is supplied with the access line (red) connected to the multi-way line on the infusion side (green) and the return line (blue) connected to the multi-way line on the UF side. This line configuration in the set is required only to properly carry out the priming/rinsing phase.

NOTE: When connecting the patient, you will be asked to disconnect the access line from the multi-way line on the infusion side and the return line from the multi-way line on the UF side (see par. 5.2.4).

3. Load maximum 4 infusion bags on the relative scale (green).
4. Connect each bag to a branch of the infusion line (green) leading from the single-use set.


Heater bag

The bag to be positioned in the fluid heater is supplied already connected to the single-use set. As it is asymmetrical and tied to the set, it can only be inserted in the heater in one position.

To position the bag:
1. Open the heater door
2. Fasten the bag to the internal pins of the heater through its 3 top and 2 bottom holes
3. Close the door.

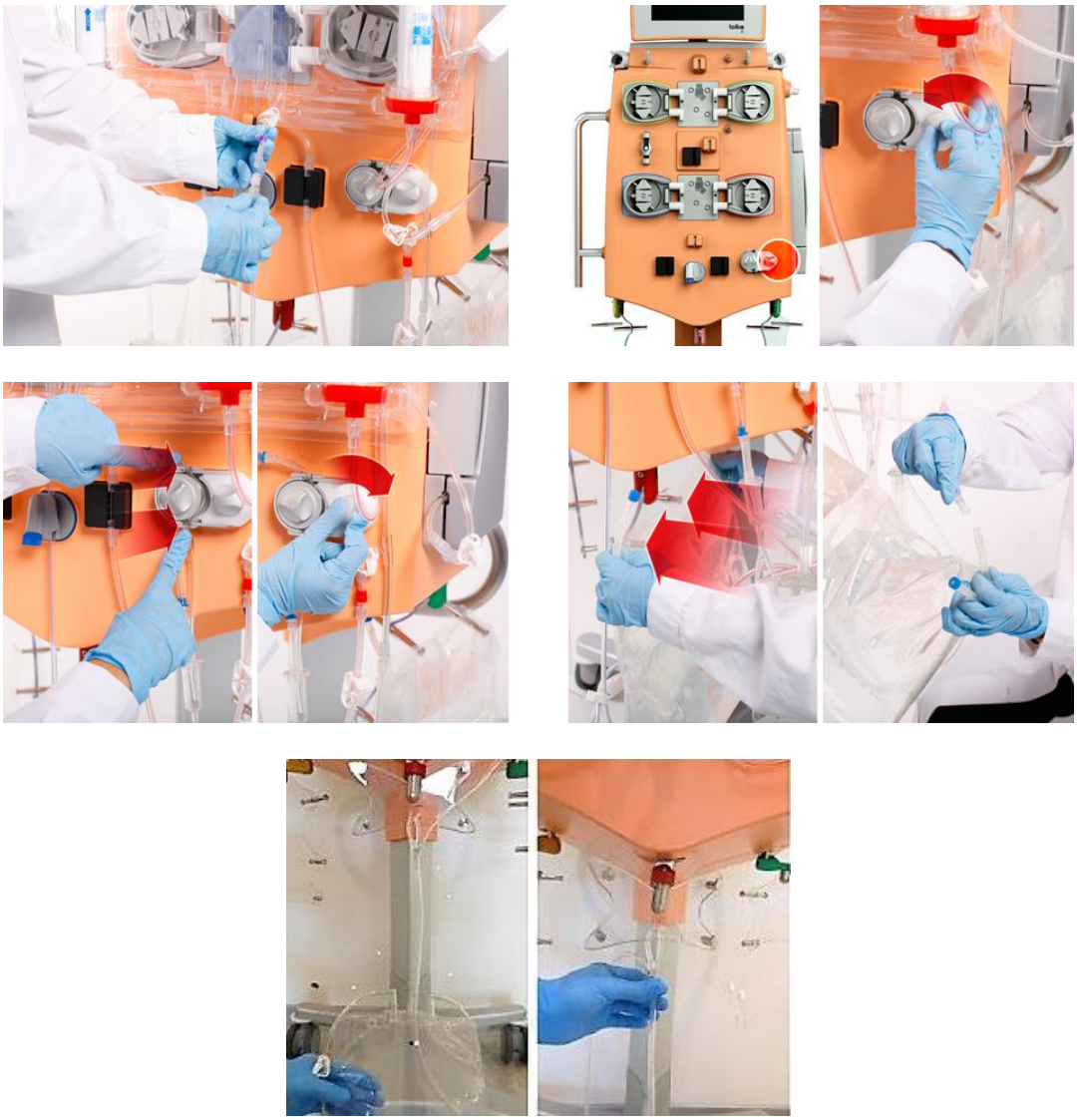


WARNING
Make sure that the heater door is properly closed (you should hear a "click" indicating proper closure) and it must stay closed until the treatment has ended.
While closing the door, it is important to check that the bag has no folds in order to prevent blocking replacement fluid flow.

Pre-dilution

In the case of a treatment that requires pre-dilution of the replacement fluid:

1. Connect the pre-dilution line supplied separately to the dedicated line leading from the single-use set (violet);
2. Open the fifth pump cover by turning the knob anticlockwise;
3. Fit the pre-dilution line into the pump and close the cover by turning the knob clockwise;
4. Load maximum 2 bags of replacement fluid, or in the case of local-regional anticoagulation, of citrate on the central scale (red);
5. Connect each bag loaded to one of the 2 branches of the pre-dilution line or, if you intend to change the bags with the pumps on, connect the central line of the additional bag to the central scale and the two side lines to the pre-dilution fluid bags.



WARNING
If you have selected systemic anticoagulation and you intend to pre-infuse replacement fluid using the fifth pump, you need to load the bags on the central scale before circuit rinsing starts (i.e. during treatment selection or line installation), otherwise the machine assumes that you are not using the central scale.

WARNING
The bags must be connected to the dedicated lines paying attention to the line colours. The bags must also be hung on their dedicated scales paying attention to the scale colours.

WARNING
After installing the single-use kit, check that there are no folds or kinks in the lines, as these constrictions of the extracorporeal circuit are not detectable by the machine and might cause haemolysis for the patient.

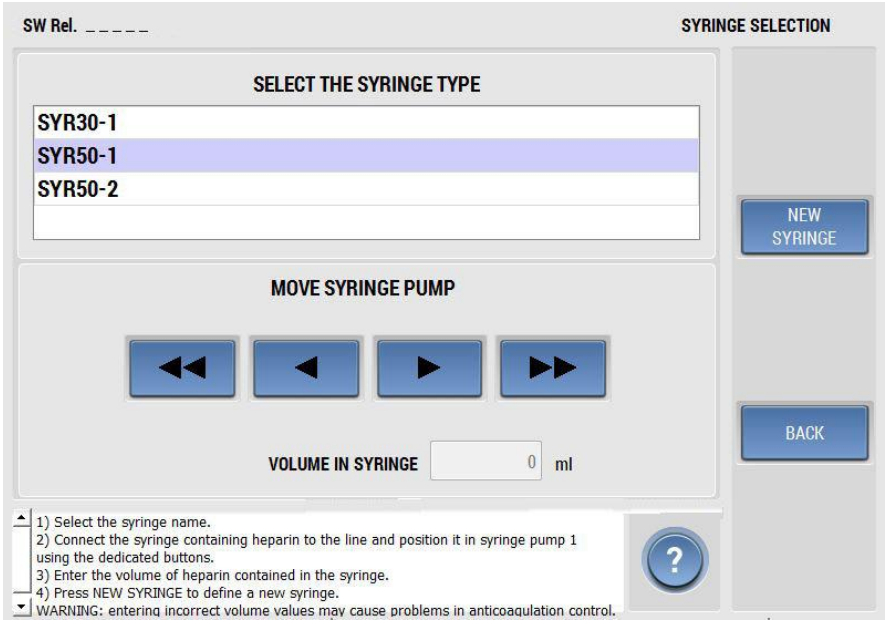
Line / device	Colour
Line / UF scale	Yellow
Line / infusion scale	Green
Access line	Red
Return line	Blue
Pre-dilution line (in the set)/central scale	Violet/red
Upper level line terminal / plasma/infusion fluid pressure transducer	Yellow
Venous level line terminal / venous pressure transducer	Blue
Indication of the Mediasorb inlet on the Mediasorb label and indication of the Mediasorb inlet line on the Mediasorb line label	Yellow
Indication of the Mediasorb outlet on the Mediasorb label and indication of the Mediasorb outlet line on the Mediasorb line label	Green

4.7.4 Defining and installing a syringe

Any type of syringe can be used provided that it meets the specifications given in paragraph 2.3. Nevertheless, each syringe must be stored in the machine memory before use in one of the two syringe pumps. After being defined, the syringes remain in the machine memory until they are removed by the operator.

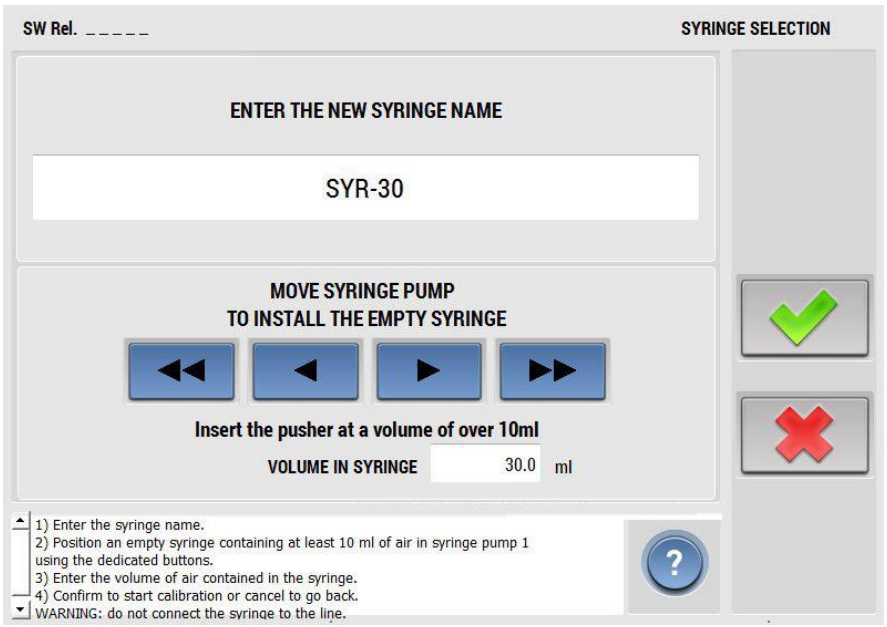
Pressing the SYRINGE PUMPS button (Function Button area) on the line installation page (see par. 4.7.3), you access a section where you can define a syringe for infusion of heparin or calcium during priming and/or treatment and install a syringe in syringe pump 1.

NOTE: Syringe pump 2 can be programmed and activated only during treatment by selecting one of the syringes stored in the machine memory.



To **define a new syringe,** operate as follows:

1. Press the NEW SYRINGE button (Function Button area)
2. Enter the name with which you want to identify the syringe using the *alphanumerical keypad* (see par. 4.3) after pressing on the corresponding white field
3. Press on the arrows on the screen to move the syringe pump 1 pusher and position the previously named syringe containing at least 10ml of air in its holder in such a way that the pusher comes into contact with the syringe plunger
4. Enter the volume of air contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3)



5. Confirm to start calibration or cancel to go back.

At the end of calibration, you are asked to check that the test was successful. If the calibration was successful, the syringe is ready to be programmed (see below how to install a previously stored syringe), otherwise the test must be repeated.

WARNING
The name given to the syringe must allow correct identification among all the syringes available at the dialysis centre.
Therefore, the name "30 ml" is not sufficient if there are 2 types of 30 ml syringes. In this case, you should use "brand_name 30 ml" to indicate that it is a 30 ml syringe of that particular brand.

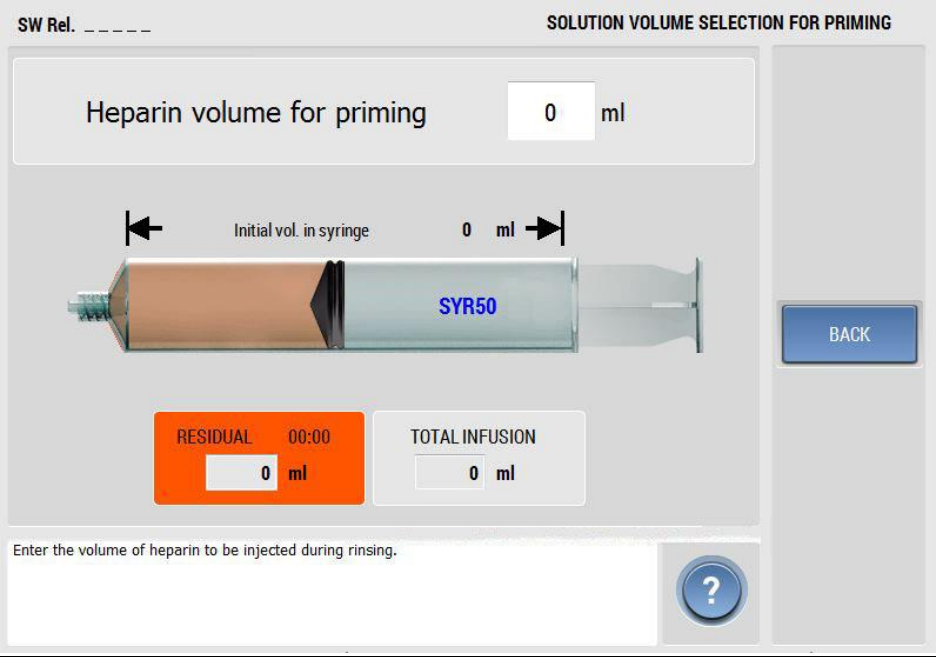
To **remove** a syringe previously stored in memory, select it from the list of syringes and press REMOVE SYRINGE.

To **install the syringe in syringe pump 1** and program the syringe pump, operate as follows:

1. Select the name of the syringe you want to use from the list of syringes previously stored in memory (pressing BACK you go back to the installation instruction page)
2. Connect the syringe to the relative line:
   - Line leading from the single-use set at the top right for syringes containing heparin.
   - Line chosen by the physician for syringes containing calcium.

WARNING
In case of local-regional anticoagulation in ASSISTED and UNASSISTED mode, the physician is responsible for the choice of the calcium infusion site, the relative line and its proper control in order to prevent risks such as infusing air into the patient.

3. Press on the arrows on the screen to move the syringe pump 1 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger
4. Enter the value of the heparin or calcium volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3)
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3)
6. If you confirm, if necessary enter the volume of heparin or calcium you want to infuse during rinsing pressing the corresponding white field and setting the value using the *numerical keypad* (pressing BACK you go back to the installation instruction page).



7. Confirm the volume just entered or cancel to repeat entry.

Once you have programmed syringe pump 1, you can no longer change the heparin or calcium volume the syringe contains for the entire duration of priming and neither the heparin or calcium volume to be infused during priming. During treatment you can reset the volume only when the syringe needs to be replaced and syringe pump 1 reprogrammed.

CAUTION
Using a syringe that does not correspond to that defined may cause injection-related hazards.

4.7.5 Priming/Rinsing

The priming/rinsing procedure is essential for patient safety, as it prepares the machine and the single-use devices, checking that they are able to perform the treatment.

WARNING
All the single-use devices (line set, bags, auxiliary lines, syringes) must be installed before priming.

The volume of fluid that flows in the circuit during priming/rinsing is determined by the treatment selected after loading the set (for the reference values see the tables in par. 4.6.3).

CAUTION
During this procedure the patient must not be connected to the machine.

In order to prevent needless alarms, before starting priming check that:

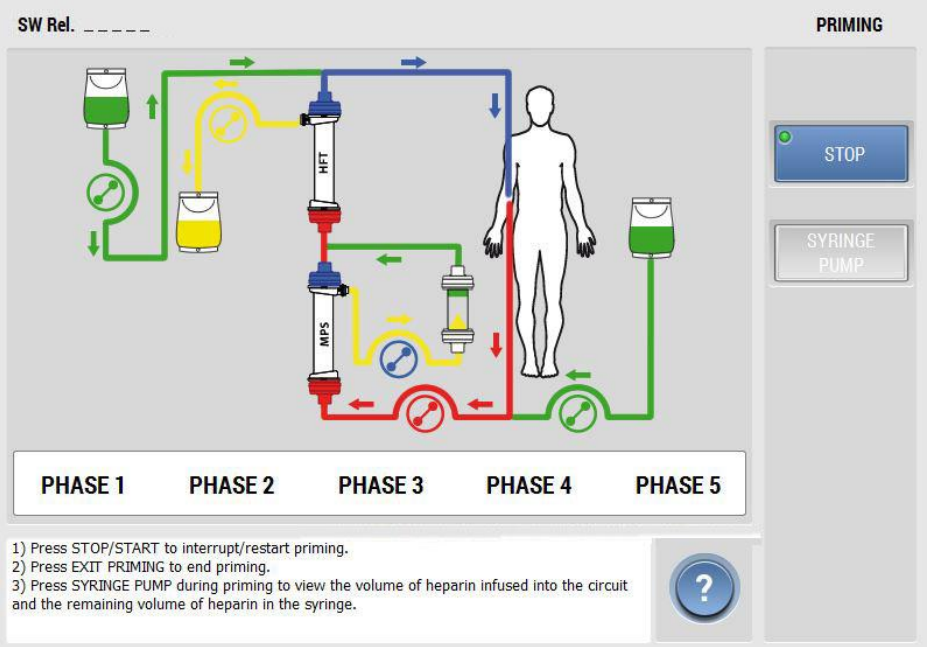
1. The two Luer-lock connectors of the pressure transducers that control the level and the pressure in the two cassettes are securely tightened
2. All the electroclamps on the circuit lines are open
3. All the fracture cones on the infusion bags are properly broken open
4. All the parts are fully inserted in their holders (blood leak cuvette in the BLD, tubes in the double electroclamp, return line in the electroclamp and in the air detector, syringe 1 and Mediasorb in their respective holders, level lines in the level sensors)
5. Check that all the bags are on the relative scales and that they do not touch other parts of the machine or bags on other scales
6. Check that you have selected a treatment consistent with the set loaded.

After the above checks, start the priming/rinsing procedure by pressing the START PRIMING button (Function Button area).

Priming consists of an initial stage in which a solution coming from the infusion bags (green scale) is run through the circuit in order to fill it followed by a rinsing stage during which a volume of fluid, defined for the treatment type selected, is circulated in the circuit in order to eliminate any production process residues.
The fluid injected into the circuit is then collected in collection bags (yellow scale).

During the priming/rinsing phase, some tests are automatically run (pressures, line integrity, scale and sensor functioning, proper set functioning/loading) and the relative page shows:

- A progress bar that indicates which priming phase the system is executing
- A synoptic diagram of the treatment type selected.

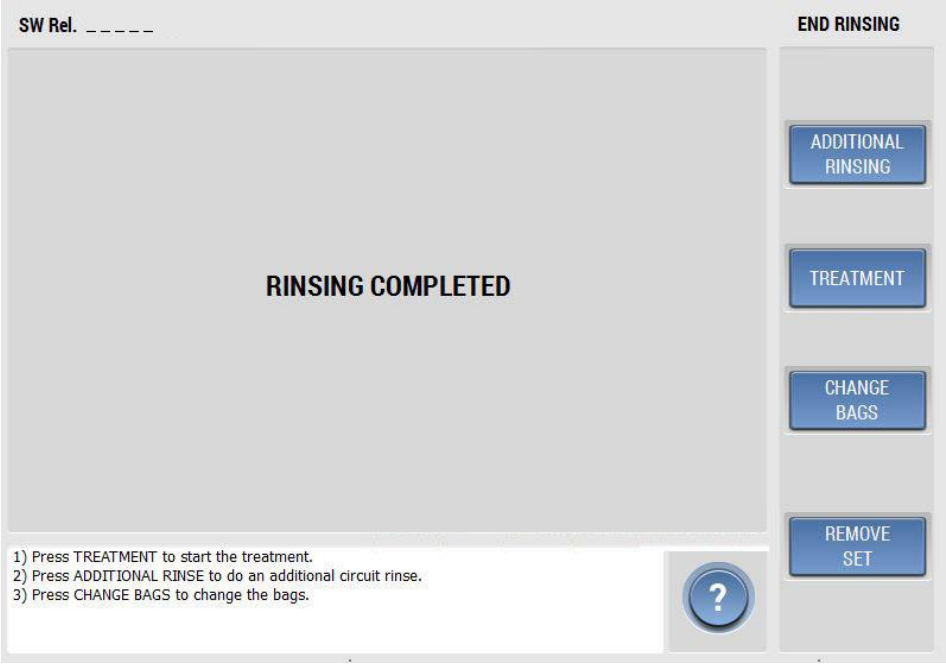


If during the first three priming/rinsing phases, the system has consumed a volume of fluid such as not to allow the proper executing of the fourth phase, the system informs you of the incorrect consumption of fluid via an alarm window (see alarm 2400 in par. 8.11). When you press the CONFIRM button in the alarm window, priming/rinsing restarts from the beginning.

You can press the STOP button (Function Button area) at any time to pause operation.
You can resume the priming/rinsing procedure by pressing the START button (Function Button area) or finally exit the procedure by pressing EXIT PRIMING (Function Button area). Pressing EXIT PRIMING, you go back to the treatment selection page (see par. 4.7.2)
Pressing SYRINGE PUMPS (Function Button area), you can monitor heparin or calcium consumption during priming/rinsing.
The heparin in case of systemic anticoagulation or the calcium in case of local-regional anticoagulation is infused for the entire duration of priming at a rate calculated based on the value set for the heparin volume to be infused during priming and the value set for the rinsing volume.

4.7.6 End of rinsing

At the end of rinsing, you automatically access the End Rinse page from where you can:
1. Change the bags by pressing the CHANGE BAGS button
2. Perform additional rinsing by pressing the ADDITIONAL RINSE button
3. Start the treatment by pressing the TREATMENT button
4. Remove the set by pressing REMOVE SET.



From the End Rinse page you can turn off the machine with the main switch in order to move it to the patient's bedside.

Bag change

The bags may need to be changed in cases where:

- The replacement fluid or, in case of local-regional anticoagulation, the citrate to be infused has run out and one or more infusion bags therefore need to be replaced.
- The collection bags are full and they therefore need to be replaced.

WARNING
Check that all the bags loaded are on the relative scales and that they do not touch other parts of the machine or bags on other scales.

Additional rinsing

You can start rinsing by pressing START on the relative page. The page shows the volume of fluid that is circulated in the circuit.
You can press the STOP button at any time to pause operation and if necessary change the bags.
You can resume rinsing by pressing START or exit rinsing only after the machine has circulated at least 300 ml of fluid by pressing END RINSE (Function Button area).
During additional rinsing you can activate or deactivate syringe pump 1 to infuse heparin or calcium according to the type of anticoagulant set.

Turning off the machine to move it to the patient's bedside
When the machine is turned on again, you automatically access the End Rinse page. The treatment mode and the treatment parameters remain as selected before the priming/rinsing phase.
If 4 hours have passed since turning off the machine, it requests additional rinsing of least 300 ml before allowing you to start the treatment.
If more than 16 hours have passed, the machine requests a bag change and subsequently additional rinsing of at least 300 ml before allowing you to start the treatment.

4.8 ABYLCAP: SINGLE-USE SET, TREATMENT SELECTION AND PRIMING

The ABYLCAP treatment time is maximum 120 hours. The single-use set can be used for a guaranteed maximum time of 60 hours, therefore, provision has been made to allow you to replace the set if you want to continue the treatment for another 60 hours. The ABYLCAP kit hence includes two sets: one (hereinafter referred to as set A) for the first 60 hours and the other (hereinafter referred to as set B) for another 60 hours if necessary.

There are six phases prior to treatment with the first set A:
1. Loading the single-use set
2. Selecting the specific treatment
3. Installing the lines of the single-use kit
4. Installing syringe 1 when anticoagulant infusion is required
5. Priming or rinsing the circuit
6. End of rinsing.

If you choose to replace the set before the 60 hours of treatment have elapsed or to continue the treatment after the 60 hours of treatment, once you have returned the blood to the patient and turned the machine off and on again (as the system suggests), there are 5 phases prior to treatment with the new set B:
1. Loading the single-use set
2. Installing the lines of the single-use kit
3. Installing syringe 1 when anticoagulant infusion is required
4. Priming or rinsing the circuit
5. End of rinsing.

4.8.1 Loading the single-use set

WARNING

If you want to perform an ABYLCAP treatment, do not use the devices contained in the ABYLCAP kit if:

- **The ABYLCAP kit package is not intact**
- **The oxygenator and/or extracorporeal circulation lines (set and accessory lines) have expired or have not properly been stored.**

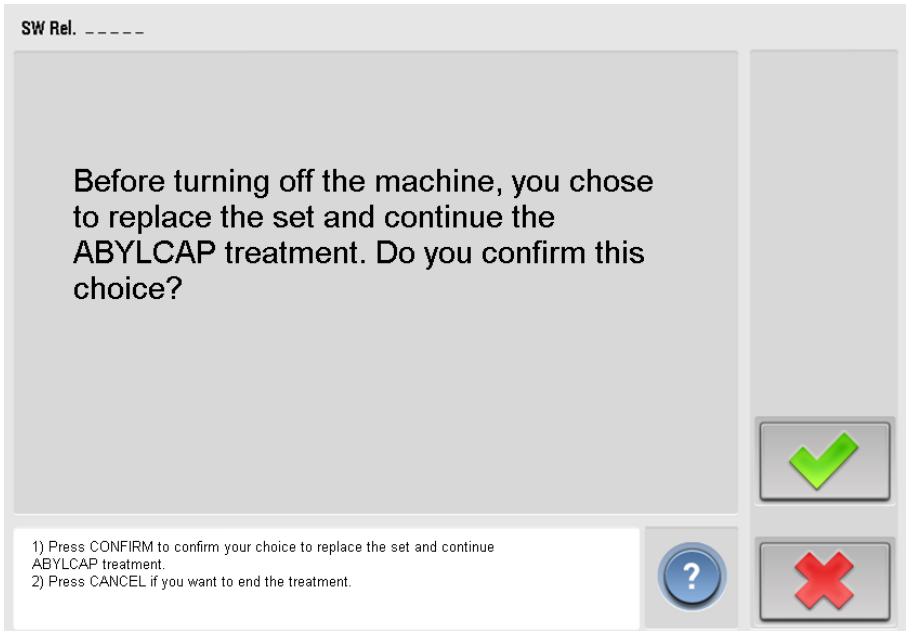
4.8.1.1 Positioning set A

Pressing the POSITION SET button on the home page (Function Button area), you access a page asking you to load the single-use set suited to the treatment you want to perform.

You can go back to the home page by pressing BACK. If you want to continue, the page shows a sequence of illustrated instructions (see the Active Window area in the image above) for positioning the set on the front panel of the machine.
When you have completed the set positioning procedure, press the LOAD button to allow the machine to load the set.

4.8.1.2 Positioning set B

When the machine is turned on again after you have removed set A, you are asked to confirm your choice to continue the treatment.



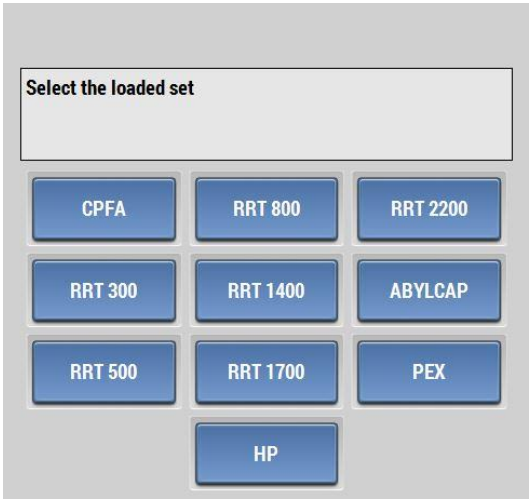
If you do not confirm, a page will be displayed asking you to turn off the machine. If you confirm, you access a page asking you to load the single-use set suited to the treatment you want to perform.

The page shows a sequence of illustrated instructions (see the Active Window area in the image above) for positioning the set on the front panel of the machine.
When you have completed the set positioning procedure, press the LOAD button to allow the machine to load the set.

4.8.1.3 Loading and identifying set A via barcode

When you press the LOAD button, a loading request confirmation window appears.
After confirming the request, wait until loading of the single-use set is complete.
If the system fails to load the single-use set, you are informed through a warning window. Pressing the CONFIRM button in the window, you access a page where you can select whether you want to repeat loading or remove the single-use set.

When the loading phase is complete, the system reads the barcode on the back of the set identifying the type of set loaded (in the specific case, ABYLCAP) and asks you to confirm that the type of set identified is actually the one loaded.
You can confirm or manually select the type of set by pressing SET SELECTION.
Pressing the CONFIRM button, the system displays a page with the list of the types of treatment that can be performed with the single-use set loaded and from which you can select the treatment you want to perform.
Pressing the SET SELECTION button, a special keypad appears, which allows selecting the type of set loaded by pressing the corresponding button.



Each button has a name of a set that identifies:
- The treatment family (CPFA, RRT, ABYLCAP, PEX and HP)
- The type of hemofilter installed (0.3, 0.5, 0.8, 1.4, 1.7 and 2.2 m^2) only in the case of RRT treatment.

Pressing the button corresponding to the set loaded, you are asked to confirm the selection.
When you confirm, the system displays a page with the list of the types of treatment that can be performed with the single-use set selected and from which you can select the treatment you want to perform.

WARNING
Make sure that you select a treatment consistent with the set loaded

4.8.1.4 Loading set B

When you press the LOAD button, a loading request confirmation window appears.
After confirming the request, wait until loading of the single-use set is complete.
If the system fails to load the single-use set, you are informed through a warning window. Pressing the CONFIRM button in the window, you access a page where you can select whether you want to repeat loading or remove the single-use set.

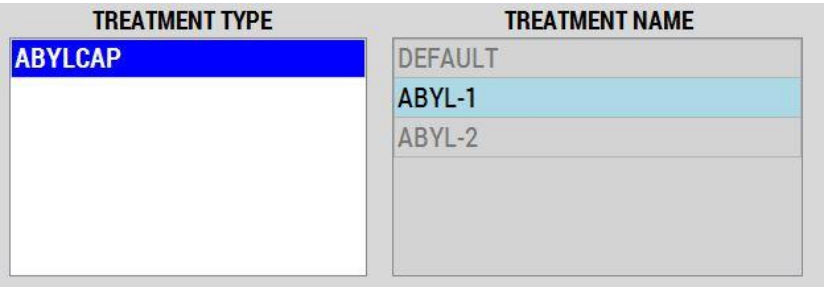
When the loading phase is complete, you access a page containing a sequence of illustrated instructions for installation of the lines of the single-use set (see par. 4.8.3, SET B).

WARNING
Make sure that you have loaded an ABYLCAP set.

4.8.2 Selecting/confirming the treatment

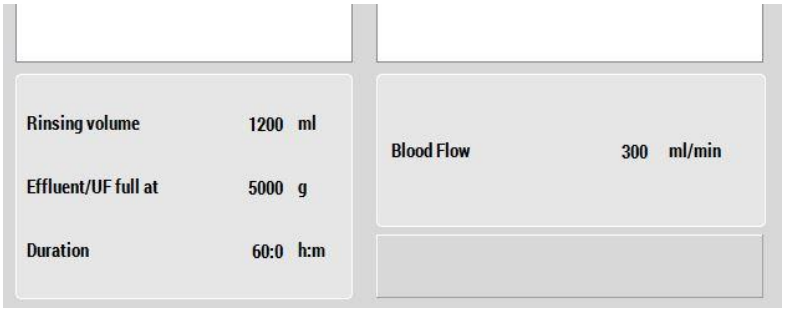
Selecting treatment with set A
You are asked to select the treatment you want to perform from those stored in memory and consistent with the specific single-use set loaded. Alternatively, you can remove the set by pressing the relative button (Function Button area) if you do not want to continue.

If you have loaded a single-use set for **ABYLCAP treatment**, continue as follows:
1. Select the name of the desired ABYLCAP treatment



2. Confirm or cancel the selection by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Selecting an ABYLCAP treatment from those in memory, the relative characteristic parameters are displayed (see par. 4.6.3).

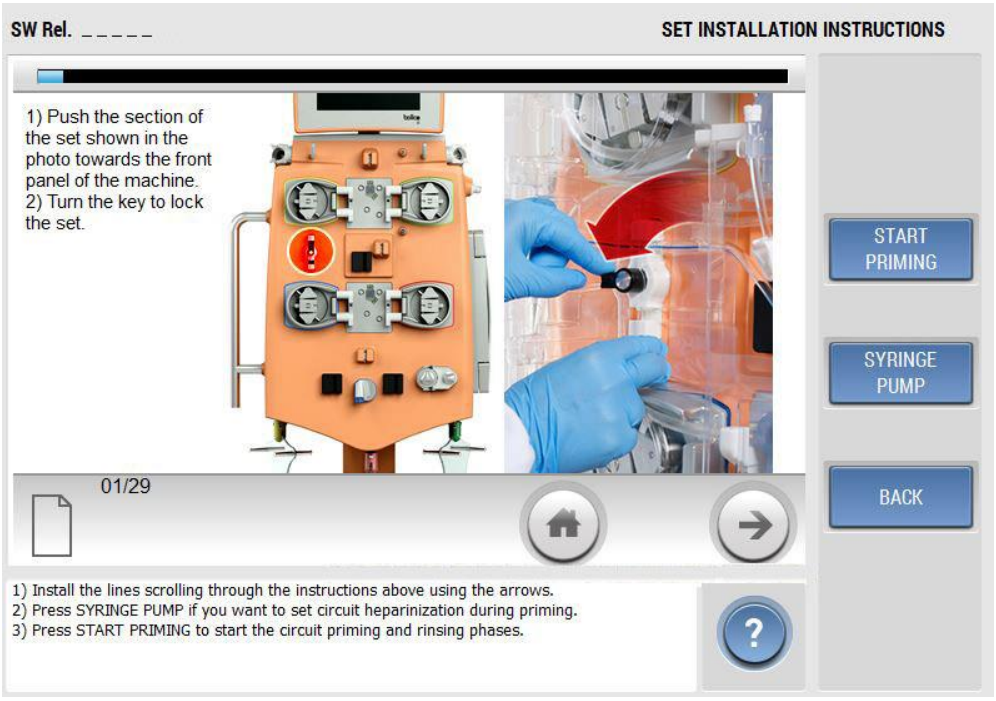


This allows you to check that the values stored for that treatment are correct.
In each step of the selection, you can remove the single-use set by pressing the relative button (Function Button area) if you do not want to continue.

Selecting treatment with set B
The treatment has already been selected with set A.

4.8.3 Installing the lines

SET A
When you confirm selection of the treatment with **set A**, you access a page containing a sequence of illustrated instructions for installation of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.



From this page you can:

- Program syringe pump 1 by pressing the SYRINGE PUMPS button if you want to infuse heparin into the circuit during priming/rinsing and during treatment (see par. 4.8.4)
- Start the priming/rinsing procedure by pressing the START PRIMING button (see par. 4.8.5).
- Repeat selection of the desired treatment from those in memory and consistent with the single-use set loaded by pressing the BACK button.

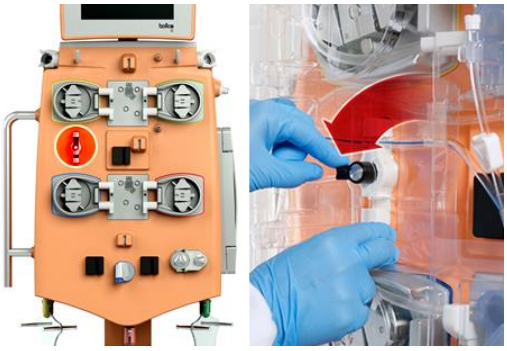
WARNING
Check that you have selected a treatment consistent with the set loaded.

Described below are the operations to be carried out to install the lines of the single-use **set A**.

WARNING
Circuit assembly must be carried out in aseptic conditions according to the validated techniques for extracorporeal blood circulation.

Double electroclamp key

Push the section of the single-use set that surrounds the double electroclamp towards the front of the machine and turn the key of the double electroclamp so that the two lines slip into their housings.



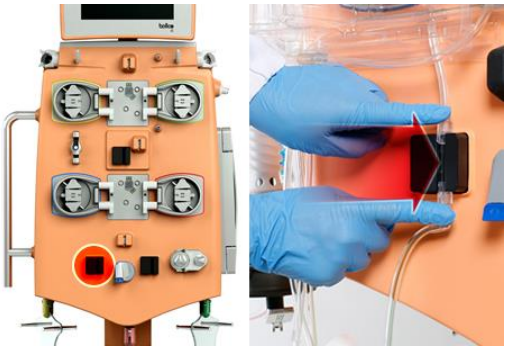
Level lines

1. Remove the cap from the yellow terminal of the upper level line.
2. Fit the terminal into its yellow port and turn the fastening ring nut anticlockwise until the torque is significantly increased.
3. Fit the line into the relative level sensor pushing the tube fully into the seat to allow proper fluid detection.

4. Repeat steps 1, 2 and 3 for the lower level line; in this case the terminal and the port with fastening ring nut are blue.

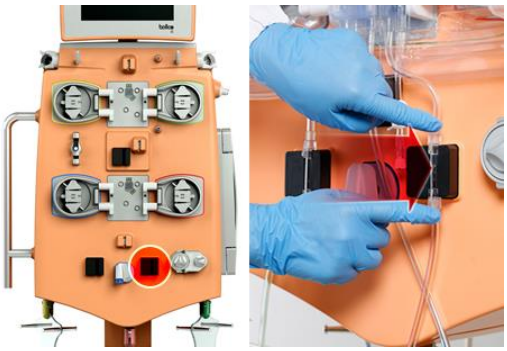
Blood leak lines

Fit the *cuvette* (rigid tube) of the oxygenator holder outlet line (green) on the set side into the UF BLD.



Access line

Fit the *cuvette* (rigid tube) of the access line (red) into the hematocrit meter.



Return line

Fit the return line (blue) into the *air detector*, pushing the tube fully inside to prevent incorrect air detection, and into the *venous electroclamp*, pushing the tube into the side seat of the electroclamp.

Heater bag

The bag to be positioned in the fluid heater is supplied already connected to the single-use set. As it is asymmetrical and tied to the set, it can only be inserted in the heater in one position.

To position the bag:

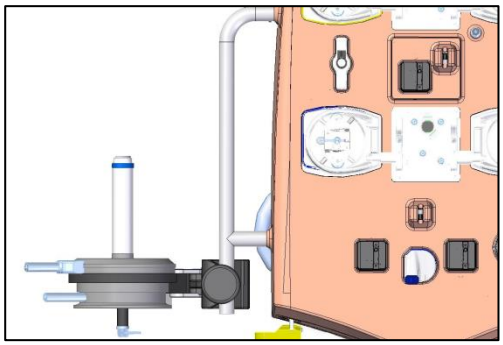
1. Open the heater door
2. Fasten the bag to the internal pins of the heater through its 3 top and 2 bottom holes
3. Close the door.

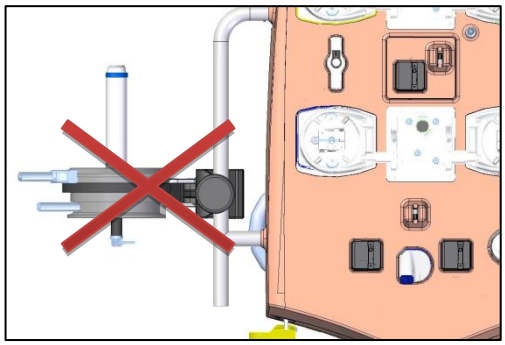
WARNING
Make sure that the heater door is properly closed (you should hear a "click" indicating proper closure) and it must stay closed until the treatment has ended.
While closing the door, it is important to check that the bag has no folds in order to prevent blocking replacement fluid flow.

Oxygenator

To connect the oxygenator:

1. Unscrew the tightening screw of the oxygenator holder;
2. Secure the oxygenator holder on the lower part of the side movement handle as shown below;
3. Tighten the tightening screw of the oxygenator holder.





WARNINGS
Positioning the oxygenator in a different position may result in its improper functioning during priming.

Oxygenator and liquid drainage/drawing lines/bags

Each single-use set (A and B) comprises:

- A yellow line for drainage of air and water for injectable preparations, which circulate in the part of the circuit where heat exchange with the blood occurs
- The oxygenator inlet line (blue) on the blood side connected via a bypass line to the oxygenator outlet line (red) on the blood side. This line configuration in the set is required only to properly carry out the first three priming/rinsing phases. Between the third and the fourth priming phase, you are asked to remove the bypass line and connect the two lines to the respective ports on the oxygenator (see par. 4.8.5 and alarm 2343 in par. 10.11)
- A line (green) for drawing water for injectable preparations
- An inlet line (colourless) and an outlet line (green) on the water for injectable preparation side, both leading from the left-hand side of the set, to be connected to the oxygenator holder.

WARNING

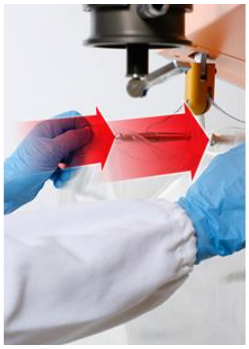
When connecting the patient, you will be asked to:

1. **Disconnect the access line from the saline bag making sure that you remove the line with constricted tube marked with a yellow label.**
2. **Disconnect the return line from the relative collection bag (see par. 7.2.4).**

Other than the two single-use sets (A and B), the kit also contains 4 collection bags (2 per set) fitted with constricted connectors.

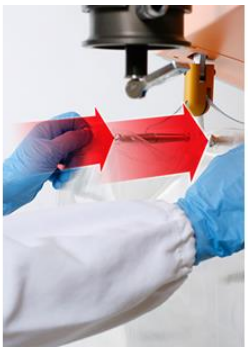
The collection bags are intended for separate collection of water for injectable preparations and saline solution.

1. Connect the return line (blue) to one of the two collection bags contained in the kit and load the bag on the UF scale (yellow).



2. Connect the UF line (yellow) to the second collection bag contained in the kit and load the bag on the UF scale (yellow).





3. Load a bag of at least 2 litres of saline on the relative scale (green)
4. Connect the access line (red) to the saline bag by means of the constricted tube



5. Remove the red cap from the ARTERIAL OUTLET port of the oxygenator (checking that no liquid leaks out, which could mean poor hydraulic sealing of the oxygenator holder) and using a clamp connect the relative red accessory line with red cap (contained in the ABYLCAP kit) to the port.



6. Remove the blue cap from the BLOOD INLET port of the oxygenator (checking that no liquid leaks out, which could mean poor hydraulic sealing of the oxygenator holder) and using a clamp connect the relative blue accessory line with blue cap (contained in the ABYLCAP kit) to the port.

7. Fit the oxygenator in its holder (positioned on the side movement handle)
8. Turn the lever underneath the holder to the CLOSE position

9. Connect the inlet line (colourless) and the outlet line (green with cuvette) on the water for injectable preparation side, respectively, to the WATER IN and WATER OUT ports of the oxygenator holder.

10. Hang a bag of at least 1 litre of water for injectable preparations on the pins on the left-hand side of the machine.
    NOTE: If you do not have a 1-litre bag available, you can also use two smaller bags using the Y-connector to be connected to the bags and the drawing line (as indicated below).
11. Connect the bag to the water for injectable preparation drawing line (green) leading from the left-hand side of the set and allow the oxygenator heating circuit to fill by gravity making sure that all the clamps are open.

WARNING
Make sure that you connect the blue and red accessory lines contained in the ABYLCAP kit to the relative BLOOD INLET and ARTERIAL OUTLET ports of the oxygenator securing the lines with clamps.

WARNING
Make sure that you properly connect the inlet line (colourless) and the outlet line (green) on the water for injectable preparation side, both leading from the left-hand side of the set: the inlet line is to be connected to the WATER IN port of the oxygenator holder and the outlet line (green) to the WATER OUT port of the oxygenator holder.

WARNING
Once the oxygenator has been positioned on its holder, check that you have turned the lever underneath the holder to the CLOSE position.

WARNING
Be careful not to invert the water for injectable preparation bag with the saline bag. The water for injectable preparation bag is to be connected to the access line (green) leading from the left-hand side of the set and hung on the side hooks of the machine. The saline bag is to be connected to the terminal constricted tube of the access line (red) and hung on the pins of the infusion scale (green).

WARNING
The bags must be connected to their dedicated lines paying attention to the line colours. The bags must be also be hung on their dedicated scales paying attention to the scale colours.

SET B
When the loading phase of **set B** is complete (see par. 4.8.1 - Positioning set B), you access a page containing a sequence of illustrated instructions for installation of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.

From this page you can:

- Program syringe pump 1 by pressing the SYRINGE PUMPS button if you want to infuse heparin into the circuit during priming/rinsing and during treatment (see par. 4.8.4)
- Start the priming/rinsing procedure by pressing the START PRIMING button (see par. 4.8.5)
- Remove the set by pressing REMOVE SET.

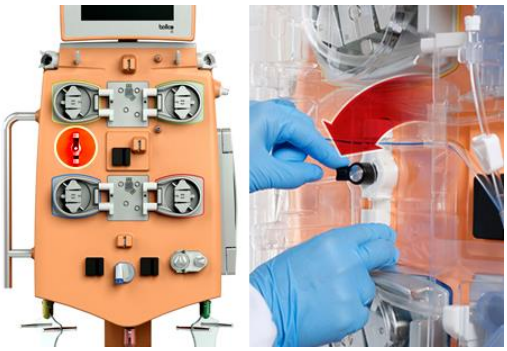
WARNING
Make sure that you have loaded an ABYLCAP set.

Described below are the operations to be carried out to install the lines of the single-use **set B**.

WARNING
Circuit assembly must be carried out in aseptic conditions according to the validated techniques for extracorporeal blood circulation.

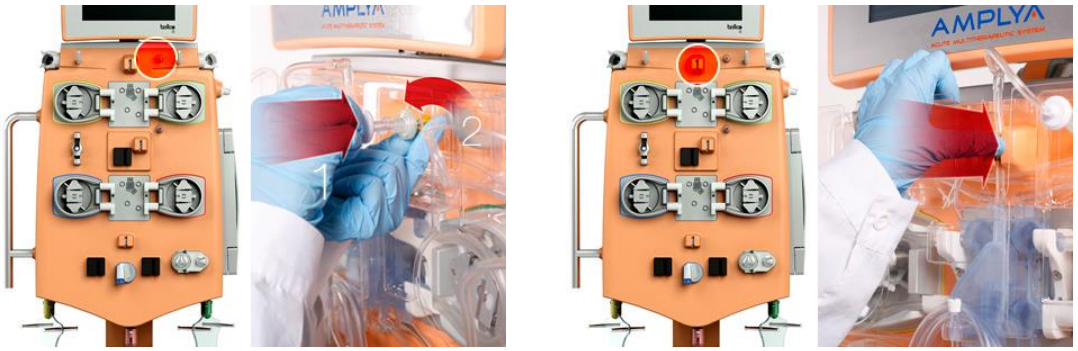
Double electroclamp key

Push the section of the single-use set that surrounds the double electroclamp towards the front of the machine and turn the key of the double electroclamp so that the two lines slip into their housings.



Level lines

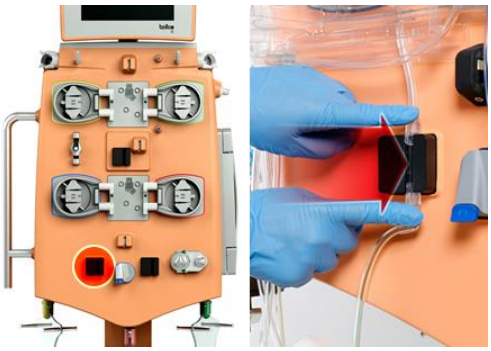
1. Remove the cap from the yellow terminal of the upper level line.
2. Fit the terminal into its yellow port and turn the fastening ring nut anticlockwise until the torque is significantly increased.
3. Fit the line into the relative level sensor pushing the tube fully into the seat to allow proper fluid detection.



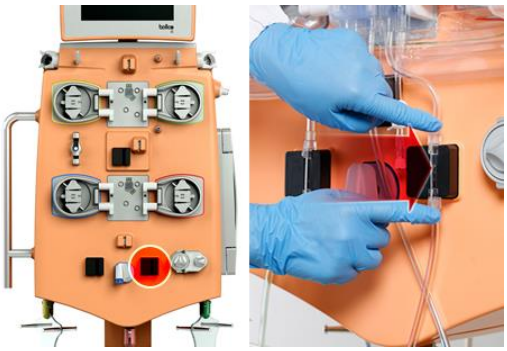
4. Repeat steps 1, 2 and 3 for the lower level line; in this case the terminal and the port with fastening ring nut are blue.

Blood leak lines

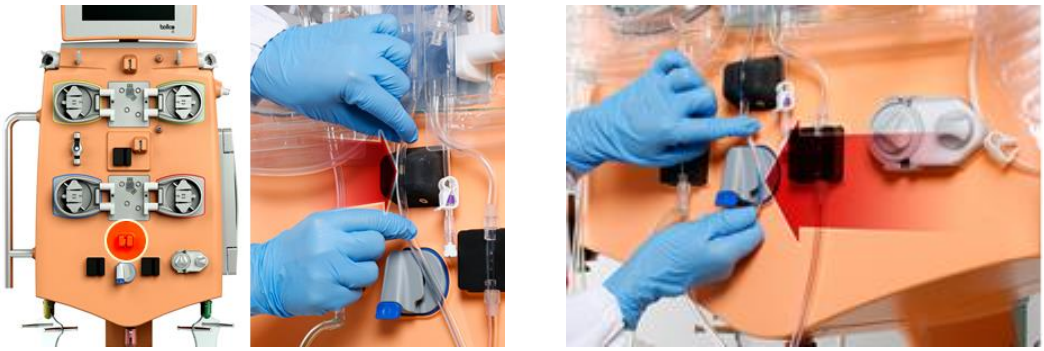
Fit the *cuvette* (rigid tube) of the oxygenator holder outlet line (green) into the UF BLD.



Access line
Fit the *cuvette* (rigid tube) of the access line (red) into the hematocrit meter.



Return line
Fit the return line (blue) into the *air detector*, pushing the tube fully inside to prevent incorrect air detection, and into the *venous electroclamp*, pushing the tube into the side seat of the electroclamp.



Heater bag
The bag to be positioned in the fluid heater is supplied already connected to the single-use set. As it is asymmetrical and tied to the set, it can only be inserted in the heater in one position.



To position the bag:

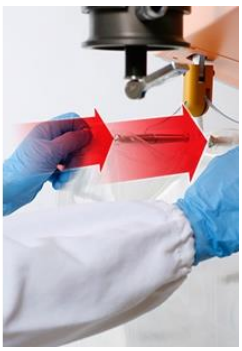
1. Open the heater door
2. Fasten the bag to the internal pins of the heater through its 3 top and 2 bottom holes
3. Close the door.

WARNING
Make sure that the heater door is properly closed (you should hear a "click" indicating proper closure) and it must stay closed until the treatment has ended.
While closing the door, it is important to check that the bag has no folds in order to prevent blocking the flow of water for injectable preparations.

Oxygenator and liquid drainage/drawing lines/bags

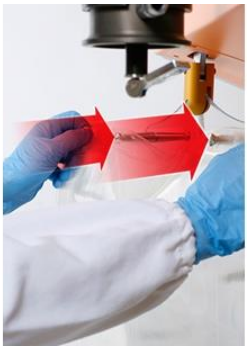
1. Connect the return line (blue) to one of the two collection bags contained in the kit and load the bag on the UF scale (yellow).





2. Connect the UF line (yellow) to the second collection bag contained in the kit and load the bag on the UF scale (yellow).





3. Load a bag of at least 2 litres of saline on the relative scale (green).
4. Connect the access line (red) to the saline bag by means of the constricted tube.



5. Connect the inlet line (colourless) and the outlet line (green with cuvette) on the water for injectable preparation side respectively to the WATER IN and WATER OUT ports of the oxygenator holder.


6. Hang a bag of at least 1 litre of water for injectable preparations on the pins on the left-hand side of the machine.

   NOTE: If you do not have a 1-litre bag available, you can also use two smaller bags using the Y-connector to be connected to the bags and the drawing line (as indicated below).

7. Connect the bag to the water for injectable preparation drawing line (green) leading from the left-hand side of the set and allow the oxygenator heating circuit to fill by gravity making sure that all the clamps are open.

WARNING
Make sure that you properly connect the inlet line (colourless) and the outlet line (green) on the water for injectable preparation side, both leading from the left-hand side of the set: the inlet line (colourless) is to be connected to the WATER IN port of the oxygenator holder and the outlet line (green) to the WATER OUT port of the oxygenator holder.

WARNING
Be careful not to invert the water for injectable preparation bag with the saline bag. The water for injectable preparation bag is to be connected to the access line (green) leading from the left-hand side of the set and hung on the side hooks of the machine. The saline bag is to be connected to the terminal constricted tube of the access line (red) and hung on the pins of the infusion scale (green).

WARNING
The bags must be connected to their dedicated lines paying attention to the line colours. The bags must be also be hung on their dedicated scales paying attention to the scale colours.

Line/device	Colour
Line / UF scale	Yellow
Line / infusion scale	Green
Access line	Red
Return line	Blue
Upper level line terminal / plasma/infusion fluid pressure transducer	Yellow
Venous level line terminal / venous pressure transducer	Blue
Oxygenator inlet line/oxygenator inlet port on the blood side	Blue
Oxygenator outlet line/oxygenator outlet port on the blood side	Red

WARNING
After installing the single-use kit, check that there are no folds or kinks in the lines, as these constrictions of the extracorporeal circuit are not detectable by the machine and might cause haemolysis for the patient.

4.8.4 Defining and installing a syringe

See the instructions in paragraph 4.7.4 if using heparin anticoagulant.

4.8.5 Priming/Rinsing

The priming/rinsing procedure is essential for patient safety, as it prepares the machine and the single-use devices, checking that they are able to perform the treatment.

WARNING
All the single-use devices (line set, bags, auxiliary lines, syringes) must be installed before priming.

The volume of fluid that flows in the circuit during priming/rinsing is determined by the treatment selected after loading the set (for the reference values see the tables in par. 4.6.3).

CAUTION
During this procedure the patient must not be connected to the machine.

In order to prevent needless alarms, before starting priming check that:

1. The two Luer-lock connectors of the pressure transducers that control the level and the pressure in the two cassettes are securely tightened
2. All the electroclamps on the circuit lines are open
3. All the fracture cones on the infusion bags are properly broken open
4. All the parts are fully inserted in their holders (blood leak cuvette in the BLD, tubes in the double electroclamp, return line in the electroclamp and in the air detector, syringe 1 and oxygenator in their respective holders, level lines in the level sensors)
5. Check that all the bags are on the relative scales and that they do not touch other parts of the machine or bags on other scales
6. Check that the bag of water for injectable preparations is hung on the side hooks of the machine
7. Check that you have selected a treatment consistent with the set loaded or, if you have already performed an ABYLCAP treatment with set A and have already loaded a new set B to continue the treatment, that you have loaded an ABYLCAP set.

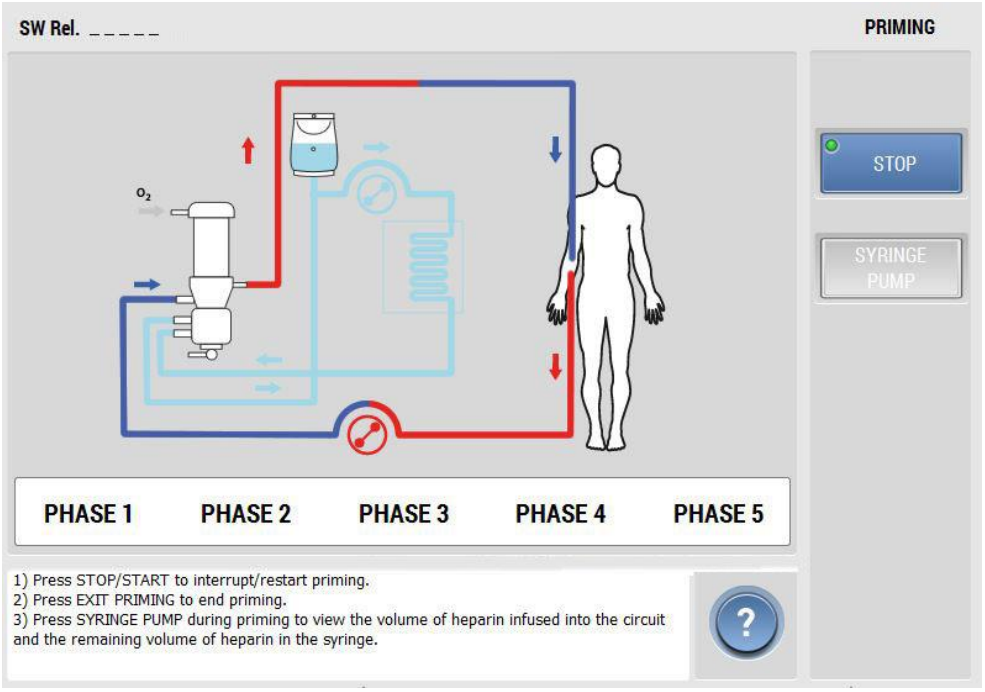
WARNING
Do not connect the oxygen system to the GAS INLET port on the oxygenator before pressing the START PRIMING button or during priming.

After the above checks, start the priming/rinsing procedure by pressing the START PRIMING button (Function Button area).

ABYLCAP priming consists of an initial stage in which saline solution coming from the relative bag (green scale) is run through the extracorporeal circulation circuit and water for injectable solutions coming from the relative bag through the heating circuit with the purpose of filling the two circuits. In the subsequent rinsing stage, a volume of fluid, defined for the treatment type selected (in the specific case, ABYLCAP treatment), is circulated in the two circuits in order to eliminate any production process residues.
The fluid injected into the two circuits is then collected in collection bags (yellow scale).

During the priming/rinsing phase, some tests are automatically run (pressures, line integrity, scale and sensor functioning) and the relative page shows:

- A progress bar that indicates the priming phase the system is executing
- A synoptic diagram of the treatment type selected.



If during the first three priming/rinsing phases, the system has consumed a volume of fluid such as not to allow properly executing the fourth phase, the system informs you of the incorrect consumption of fluid via an alarm window (see alarm 2400 in par. 8.11). When you press the CONFIRM button in the alarm window, priming/rinsing restarts from the beginning.

You can press the STOP button (Function Button area) at any time to pause operation.
You can resume the priming/rinsing procedure by pressing the START button (Function Button area) or finally exit the procedure by pressing EXIT PRIMING (Function Button area). Pressing EXIT PRIMING, you go back to the treatment selection page (see par. 4.8.2).
Pressing SYRINGE PUMPS (Function Button area), you can monitor heparin consumption during priming/rinsing.

The heparin is infused for the entire duration of priming at a rate calculated based on the value set for the heparin volume to be infused during priming and the value set for the rinsing volume.

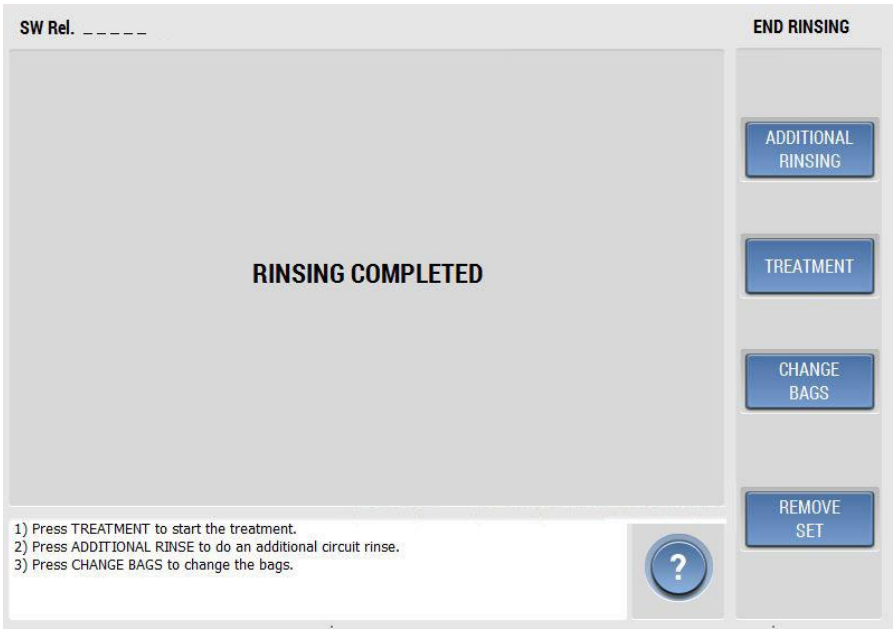
Between the third and the fourth priming phase, you are asked to remove the bypass line that connects the oxygenator inlet line (blue) and outlet line (red) to each other, and to connect:

- The oxygenator inlet line (blue) on the set side to the blue line on the oxygenator side (connected to the BLOOD INLET port on the oxygenator).
- The oxygenator outlet line (red) on the set side to the red line on the oxygenator side (connected to the ARTERIAL OUTLET port on the oxygenator) (see alarm 2343 in par. 10.11).

4.8.6 End of rinsing

At the end of rinsing, you automatically access the End Rinse page from where you can:

1. Change the bags by pressing the CHANGE BAGS button
2. Perform additional rinsing by pressing the ADDITIONAL RINSE button
3. Start the treatment by pressing the TREATMENT button
4. Remove the set by pressing REMOVE SET.



From the “End Rinse” page you can turn off the machine with the main switch in order to move it to the patient's bedside.

Bag change
The bags may need to be changed:
- Before treatment if the water for injectable preparations (in the bag hung on the pins on the left-hand side of the machine) has run out.
- If you intend to perform additional rinsing and the water for injectable preparations (in the bag hung on the pins on the left-hand side of the machine) or the saline solution (in the bag hung on the infusion scale) has run out.

WARNING
Check that all the bags loaded are on the relative scales and that they do not touch other parts of the machine or bags on other scales.
Check that the bag of water for injectable preparations is hung on the side hooks of the machine.

Additional rinsing
You can start rinsing by pressing START on the relative page. The page shows the volume of fluid that is circulated in the circuit.
You can press the STOP button at any time to pause operation and if necessary change the bags.
You can resume rinsing by pressing START or exit rinsing only after the machine has circulated at least 300 ml of fluid by pressing END RINSE (Function Button area).
During additional rinsing you can activate or deactivate syringe pump 1 to infuse heparin.

Turning off the machine to move it to the patient's bedside
When the machine is turned on again, you automatically access the End Rinse page. The treatment mode and the treatment parameters remain as selected before the priming/rinsing phase. If 4 hours have passed since turning off the machine, it requests additional rinsing of least 300 ml before allowing you to start the treatment. If more than 16 hours have passed, the machine requests a bag change and subsequently additional rinsing of at least 300 ml before allowing you to start the treatment.

4.9 PEX: SINGLE-USE SET, TREATMENT SELECTION AND PRIMING

There are six phases prior to the treatment phase:
1. Loading the single-use set
2. Selecting the specific treatment
3. Installing the lines of the single-use kit
4. Installing syringe 1 when anticoagulant infusion is required
5. Priming or rinsing the circuit
6. End of rinsing.

4.9.1 Loading the single-use set

Pressing the POSITION SET button on the home page (Function Button area), you access a page asking you to load the single-use set suited to the treatment you want to perform.

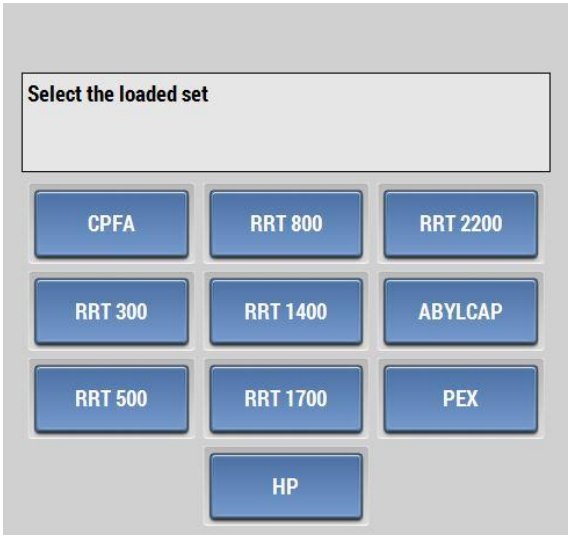
You can go back to the home page by pressing BACK. If you want to continue, the page shows a sequence of illustrated instructions (see the Active Window area in the image above) for positioning the set on the front panel of the machine.
When you have completed the set positioning procedure, press the LOAD button to allow the machine to load the set.

When you press the button, a loading request confirmation window appears.
After confirming the request, wait until loading of the single-use set is complete.
If the system fails to load the single-use set, you are informed through a warning window. Pressing the CONFIRM button in the window, you access a page where you can select whether you want to repeat loading or remove the single-use set.

4.9.1.1 Set identification via barcode

When the loading phase is complete, the system reads the barcode on the back of the set identifying the type of set loaded (in the specific case, PEX) and asks you to confirm that the type of set identified is actually the one loaded.
You can confirm or manually select the type of set by pressing SET SELECTION.

Pressing the CONFIRM button, the system displays a page with the list of the types of treatment that can be performed with the single-use set loaded and from which you can select the treatment you want to perform.
Pressing the SET SELECTION button, a special keypad appears, which allows selecting the type of set loaded by pressing the corresponding button.



Each button has a name of a set that identifies:
- The treatment family (CPFA, RRT, ABYLCAP and PEX)
- The type of hemofilter installed (0.3, 0.5, 0.8, 1.4, 1.7 and 2.2 m^2) only in the case of RRT treatment.

Pressing the button corresponding to the set loaded, you are asked to confirm the selection.
When you confirm, the system displays a page with the list of the types of treatment that can be performed with the single-use set selected and from which you can select the treatment you want to perform.

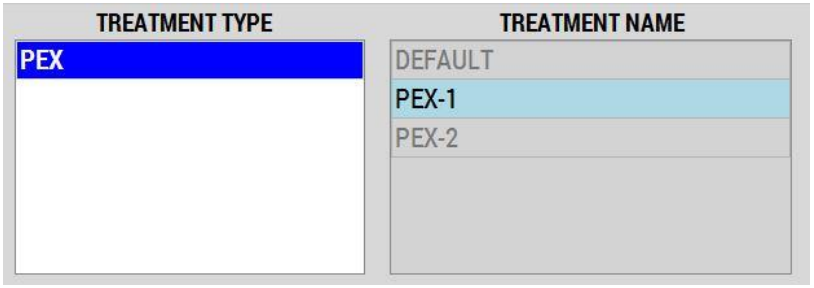
WARNING
Make sure that you select a treatment consistent with the set loaded.

4.9.2 Selecting the treatment and installing the lines

You are asked to select the treatment you want to perform from those stored in memory and consistent with the specific single-use set loaded. Alternatively, you can remove the set by pressing the relative button (Function Button area) if you do not want to continue.

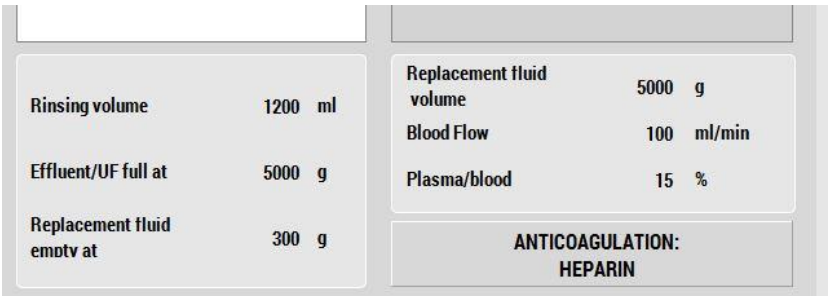
If you have loaded a single-use set for **PEX treatment**, continue as follows:

1. Select the name of the desired PEX treatment.



2. Confirm or cancel the selection by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Selecting a PEX treatment from those in memory, the relative characteristic parameters are displayed (see par. 4.6.3).



This allows you to check that the values stored for that treatment are correct.
In each step of the selection, you can remove the single-use set by pressing the relative button (Function Button area) if you do not want to continue.

WARNING
Make sure that you select a treatment consistent with the set loaded.

4.9.3 Installing the lines

When you confirm the treatment selected, you access a page containing a sequence of illustrated instructions for installation of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.

From this page you can:

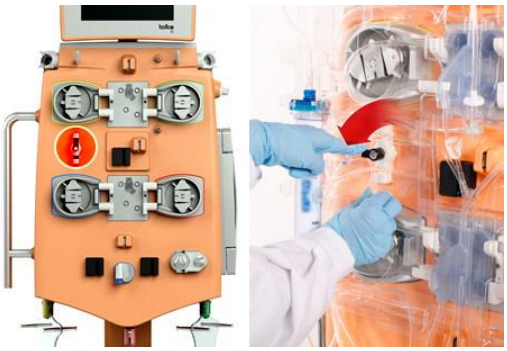
- Program syringe pump 1 by pressing the SYRINGE PUMPS button if you want to infuse heparin into the circuit during priming/rinsing and during treatment (see par. 4.9.4)
- Start the priming/rinsing procedure by pressing the START PRIMING button (see par. 4.9.5)
- Repeat selection of the desired treatment from those in memory and consistent with the single-use set loaded by pressing the BACK button.

Described below are the operations to be carried out to install the lines of the single-use set.

WARNING
Check that you have selected a treatment consistent with the set loaded.

WARNING
Circuit assembly must be carried out in aseptic conditions according to the validated techniques for extracorporeal blood circulation.

Double electroclamp key
Push the section of the single-use set that surrounds the double electroclamp towards the front of the machine and turn the key of the double electroclamp so that the two lines slip into their housings.

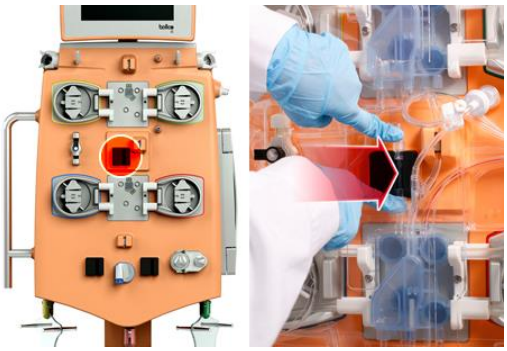


Level lines

1. Remove the cap from the blue terminal of the lower level line
2. Fit the terminal into its blue port and turn the fastening ring nut anticlockwise until the torque is significantly increased
3. Fit the line into the relative level sensor pushing the tube fully into the seat to allow proper fluid detection.

Blood leak lines

Fit the *cuvette* (rigid tube) of the line through which the plasma circulates (after being extracted from the blood through the plasma filter by the UF pump) into the Plasma BLD.



Access line

Fit the *cuvette* (rigid tube) of the access line (red) into the hematocrit meter.


Return line

Fit the return line (blue) into the *air detector*, pushing the tube fully inside to prevent incorrect air detection, and into the *venous electroclamp*, pushing the tube into the side seat of the electroclamp.




UF and infusion lines and bags

Other than the single-use set, the PEX kit also contains ultrafiltrate (patient's plasma) collection bags.

1. Connect one collection bag to the UF line (yellow) and one to the return line (blue).
2. Load the collection bags on the UF scale (yellow).




The single-use set is supplied with the access line (red) connected to a branch of the infusion line (green) by means of a constricted tube. In addition, a connector that connects all the branches of the infusion line is provided in the single-use set. This line configuration in the set is required only to properly carry out the priming/rinsing phase.

NOTE: When connecting the patient, you will be asked to disconnect the access line from the constricted tube that connects it to a branch of the infusion line (see par. 8.2.4).

3. Load a bag of at least 2 litres of saline on the relative scale (green).
4. Connect the bag to a branch of the infusion line (green) leading from the single-use set.



Heater bag

The bag to be positioned in the fluid heater is supplied already connected to the single-use set. As it is asymmetrical and tied to the set, it can only be inserted in the heater in one position.

To position the bag:

1. Open the heater door
2. Fasten the bag to the internal pins of the heater through its 3 top and 2 bottom holes
3. Close the door.



WARNING
Make sure that the heater door is properly closed (you should hear a "click" indicating proper closure) and it must stay closed until the treatment has ended.
While closing the door, it is important to check that the bag has no folds in order to prevent blocking replacement fluid flow.

WARNING
The bags must be connected to the dedicated lines paying attention to the line colours. The bags must be also be hung on the dedicated scales paying attention to the scale colours.

WARNING
After installing the single-use kit, check that there are no folds or kinks in the lines, as these constrictions of the extracorporeal circuit are not detectable by the machine and might cause haemolysis for the patient.

Line/device	Colour
Line / UF scale	Yellow
Line / infusion scale	Green
Access line	Red
Return line	Blue
Venous level line terminal / venous pressure transducer	Blue

4.9.4 Defining and installing a syringe

See the instructions in paragraph 4.7.4 if using heparin anticoagulant.

4.9.5 Priming/Rinsing

The priming/rinsing procedure is essential for patient safety, as it prepares the machine and the single-use devices, checking that they are able to perform the treatment.

WARNING
All the single-use devices (line set, bags, auxiliary lines, syringes) must be installed before priming.

The volume of fluid that flows in the circuit during priming/rinsing is determined by the treatment selected after loading the set (for the reference values see the tables in par. 4.6.3).

CAUTION
During this procedure the patient must not be connected to the machine.

In order to prevent needless alarms, before starting priming check that:

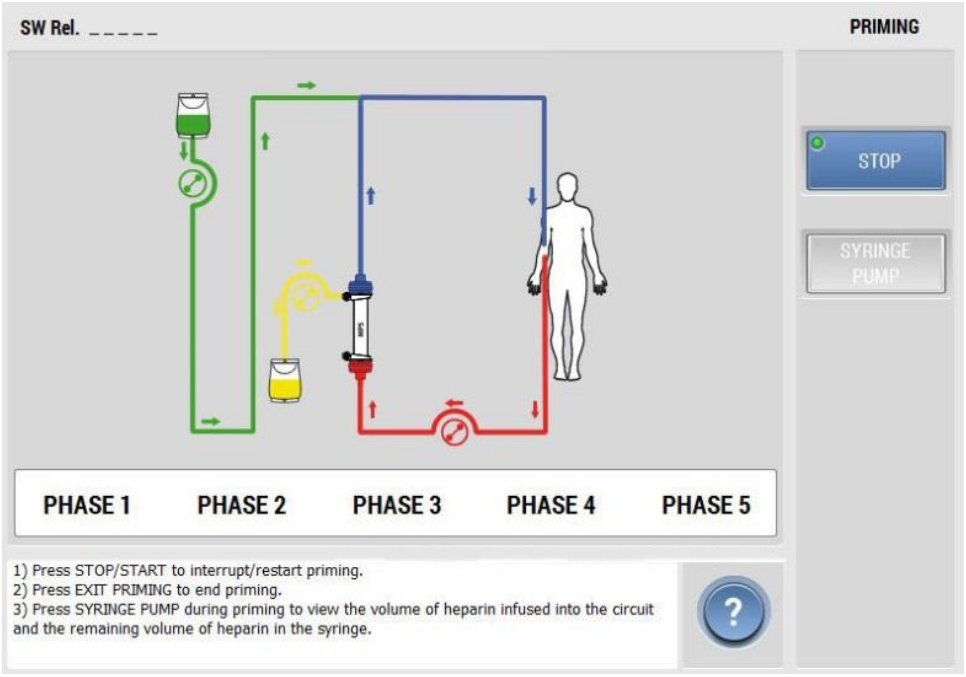
1. The Luer-lock connector of the pressure transducer that controls the level and the pressure in the venous cassette is securely tightened.
2. All the electroclamps on the circuit lines are open.
3. All the fracture cones on the infusion bags are properly broken open.
4. All the parts are fully inserted in their holders (blood leak *cuvette* in the BLD, return line in the electroclamp and in the air detector, syringe 1 in its holder, venous level line in the relative level sensor).
5. Check that all the bags are on the relative scales and that they do not touch other parts of the machine or bags on other scales.
6. Check that you have selected a treatment consistent with the set loaded.

After the above checks, start the priming/rinsing procedure by pressing the START PRIMING button (Function Button area).

Priming consists of an initial stage in which the replacement fluid coming from the infusion bag (green scale) is run through the circuit in order to fill it followed by a rinsing stage during which a volume of fluid, defined for the treatment type selected (in the specific case, PEX treatment), is circulated in the circuit in order to eliminate any production process residues.
The fluid injected into the circuit is then collected in collection bags (yellow scale).

During the priming/rinsing phase, some tests are automatically run (pressures, line integrity, scale and sensor functioning) and the relative page shows:

- A progress bar that indicates which priming phase the system is executing
- A synoptic diagram of the treatment type selected.



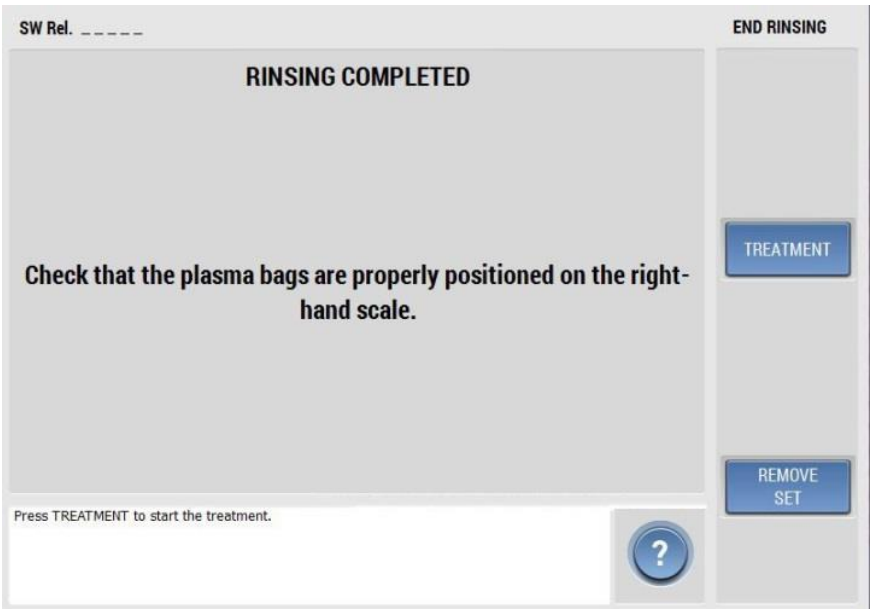
If during the first three priming/rinsing phases, the system has consumed a volume of fluid such as not to allow the proper executing of the fourth phase, the system informs you of the incorrect consumption of fluid via an alarm window (see alarm 2400 in par. 8.11). When you press the CONFIRM button in the alarm window, priming/rinsing restarts from the beginning.

At the beginning of the fifth priming phase, a message is shown on the screen telling you to replace the saline bag on the infusion scale (green) with a plasma bag (see alarm 2500 in par. 8.11).
When you press the CONFIRM button, the system starts priming the plasma infusion line. Priming of the plasma infusion line in the last priming phase is timed (it ends with the end of priming) and allows, once the treatment has started, drawing the plasma from the patient and at the same time infusing new plasma.

You can press the STOP button (Function Button area) at any time to pause operation.
You can resume the priming/rinsing procedure by pressing the START button (Function Button area) or finally exit the procedure by pressing EXIT PRIMING (Function Button area). Pressing EXIT PRIMING, you go back to the treatment selection page (see par. 4.9.2).
Pressing SYRINGE PUMPS (Function Button area), you can monitor heparin consumption during priming/rinsing.
The heparin is infused for the entire duration of priming at a rate calculated based on the value set for the heparin volume to be infused during priming and the value set for the rinsing volume.

4.9.6 End of rinsing

At the end of rinsing, you automatically access the “End Rinse” page from where you can:
1. Start the treatment by pressing the TREATMENT button
2. Remove the set by pressing REMOVE SET.



From the “End Rinse” page you can turn off the machine with the main switch in order to move it to the patient's bedside.

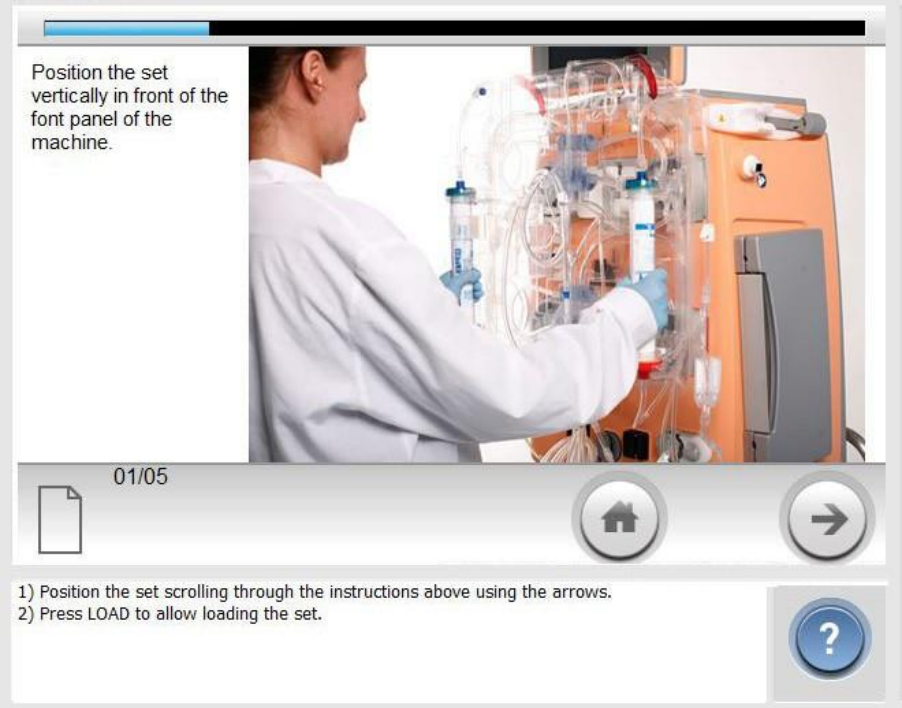
Turning off the machine to move it to the patient's bedside
When the machine is turned on again, you automatically access the End Rinse page. The treatment mode and the treatment parameters remain as selected before the priming/rinsing phase.

4.10 HP: SINGLE-USE SET, TREATMENT SELECTION AND PRIMING

There are six phases prior to the treatment phase:
1. Loading the single-use set
2. Selecting the specific treatment and connecting the adsorbent column if indicated in the instructions for use of the adsorbent column
3. Installing the lines of the single-use kit
4. Installing syringe 1 when anticoagulant infusion is required
5. Priming or rinsing the circuit
6. End of rinsing.

4.10.1 Loading the single-use set

Pressing the POSITION SET button on the home page (Function Button area), you access a page asking you to load the single-use set suited to the treatment you want to perform.



You can go back to the home page by pressing BACK. If you want to continue, the page shows a sequence of illustrated instructions (see the Active Window area in the image above) for positioning the set on the front panel of the machine.
When you have completed the set positioning procedure, press the LOAD button to allow the machine to load the set.

When you press the button, a loading request confirmation window appears.
After confirming the request, wait until loading of the single-use set is complete.
If the system fails to load the single-use set, you are informed through a warning window. Pressing the CONFIRM button in the window, you access a page where you can select whether you want to repeat loading or remove the single-use set.

4.10.1.1 Set identification via barcode

When the loading phase is complete, the system reads the barcode on the back of the set identifying the type of set loaded (in the specific case, HP) and asks you to confirm that the type of set identified is actually the one loaded.
You can confirm or manually select the type of set by pressing SET SELECTION.
Pressing the CONFIRM button, the system displays a page with the list of the types of treatment that can be performed with the single-use set loaded and from which you can select the treatment you want to perform.
Pressing the SET SELECTION button, a special keypad appears, which allows selecting the type of set loaded by pressing the corresponding button.

Each button has a name of a set that identifies:

- The treatment family (CPFA, RRT, ABYLCAP, PEX and HP)
- The type of hemofilter installed (0.3, 0.5, 0.8, 1.4, 1.7 and 2.2 m^2) only in the case of RRT treatment.

Pressing the button corresponding to the set loaded, you are asked to confirm the selection.
When you confirm, the system displays a page with the list of the types of treatment that can be performed with the single-use set selected and from which you can select the treatment you want to perform.

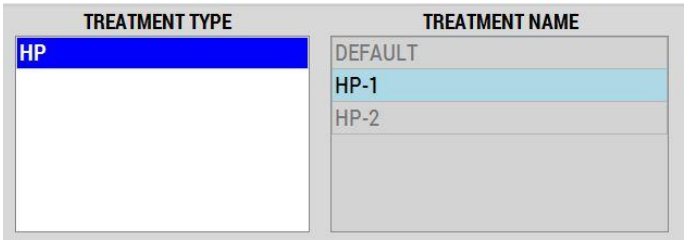
WARNING
Make sure that you select a treatment consistent with the set loaded.

4.10.2 Selecting the treatment and installing the lines

You are asked to select the treatment you want to perform from those stored in memory and consistent with the specific single-use set loaded. Alternatively, you can remove the set by pressing the relative button (Function Button area) if you do not want to continue.

If you have loaded a single-use set for **HP treatment**, continue as follows:

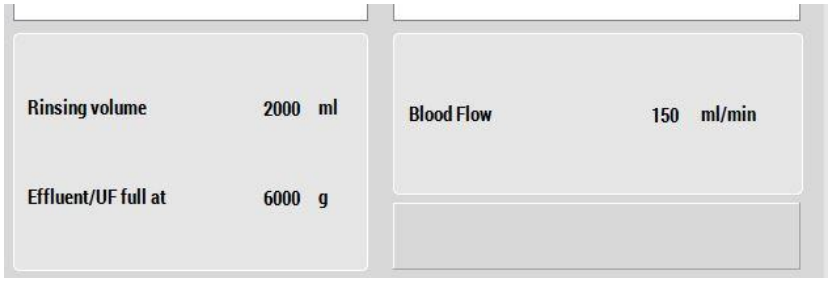
1. Select the name of the desired HP treatment.



2. Select whether you want to connect the adsorbent column before starting priming or during priming taking into account the characteristics of the adsorbent column you intend to use (see the instructions for use of the adsorbent column).

3. Confirm or cancel the selection by pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Selecting an HP treatment from those in memory, the relative characteristic parameters are displayed (see par. 4.6.3).

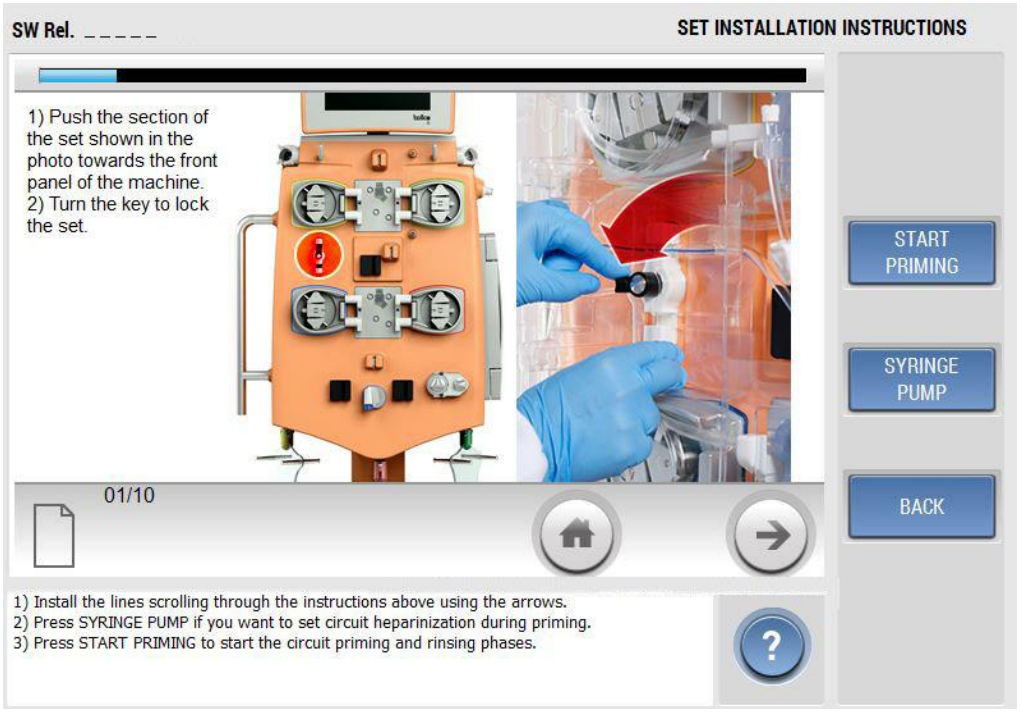


This allows you to check that the values stored for that treatment are correct.
In each step of the selection, you can remove the single-use set by pressing the relative button (Function Button area) if you do not want to continue.

WARNING
Make sure that you select a treatment consistent with the set loaded.

4.10.3 Installing the lines

When you confirm the treatment selected, you access a page containing a sequence of illustrated instructions for installation of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.



From this page you can:

- Program syringe pump 1 by pressing the SYRINGE PUMPS button if you want to infuse heparin into the circuit during priming/rinsing and during treatment (see par. 4.10.4)
- Start the priming/rinsing procedure by pressing the START PRIMING button (see par. 4.10.5).
- Repeat selection of the desired treatment from those in memory and consistent with the single-use set loaded by pressing the BACK button.

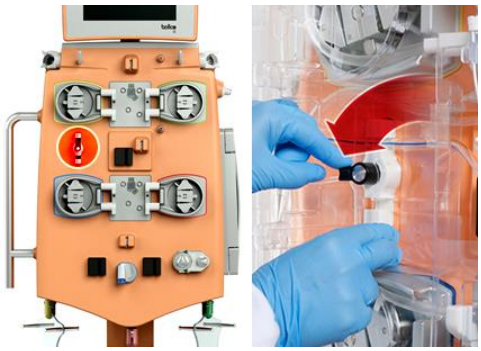
Described below are the operations to be carried out to install the lines of the single-use set.

WARNING
Check that you have selected a treatment consistent with the set loaded.

WARNING
Circuit assembly must be carried out in aseptic conditions according to the validated techniques for extracorporeal blood circulation.

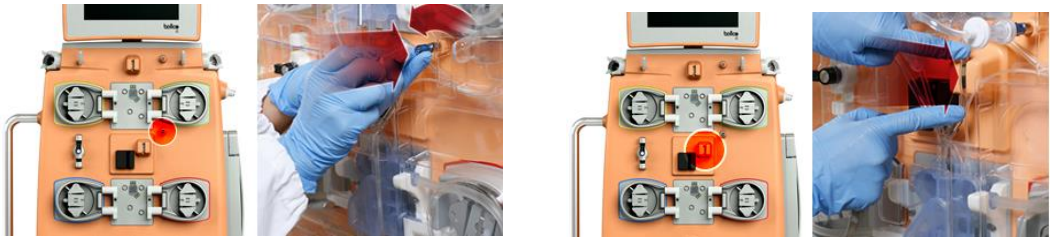
Double electroclamp key

Push the section of the single-use set that surrounds the double electroclamp towards the front of the machine and turn the key of the double electroclamp so that the two lines slip into their housings.



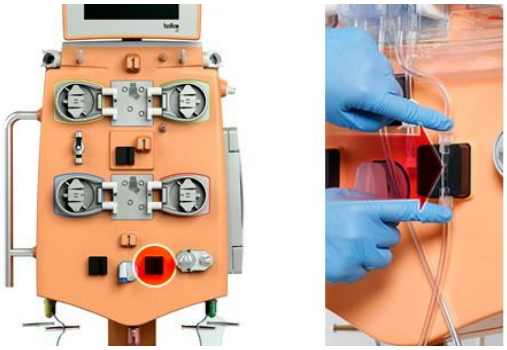
Level lines

1. Remove the cap from the blue terminal of the lower level line
2. Fit the terminal into its blue port and turn the fastening ring nut anticlockwise until the torque is significantly increased
3. Fit the line into the relative level sensor pushing the tube fully into the seat to allow proper fluid detection



Access line

Fit the *cuvette* (rigid tube) of the access line (red) into the hematocrit meter.



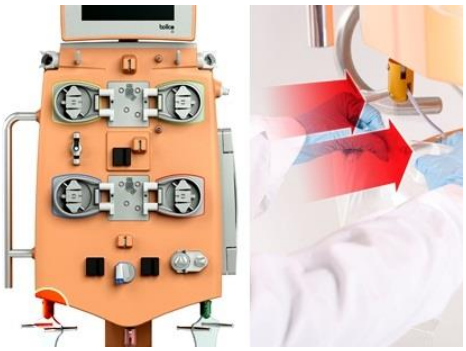
Return line

Fit the return line (blue) into the *air detector*, pushing the tube fully inside to prevent incorrect air detection, and into the *venous electroclamp*, pushing the tube into the side seat of the electroclamp.

Priming fluid collection bags and priming fluid bags

The HP device is supplied with a priming fluid collection bag preconnected to the return line (blue).

1. Load the collection bag connected to the return line (blue) on the UF scale (yellow).



2. Load a bag of at least two litres of rinsing solution on the relative scale (green).
3. Connect the access line (red) to the saline bag by means of the constricted tube marked with a yellow label.



NOTE: When connecting the patient, you will be asked to disconnect the access line from the constricted tube marked with a yellow label (see par. 9.2.3).

WARNING
The bags must be connected to their dedicated lines paying attention to the line colours. The bags must be also be hung on their dedicated scales paying attention to the scale colours.

WARNING
After installing the single-use kit, check that there are no folds or kinks in the lines, as these constrictions of the extracorporeal circuit are not detectable by the machine and might cause haemolysis for the patient.

Adsorbent column
If you have chosen to connect the adsorbent column before starting priming (see par. 4.10.2), position the column on a dedicated holder, remove the bypass line that connects the inlet (red) and outlet (blue) lines of the adsorbent column to each other and connect the two lines of the circuit to the respective connectors of the adsorbent column.

Line/device	Colour
UF scale	Yellow
Infusion scale	Green
Access line	Red
Return line	Blue
Venous level line terminal / venous pressure transducer	Blue
Adsorbent column inlet line on the circuit side	Red
Adsorbent column outlet line on the circuit side	Blue

4.10.4 Defining and installing a syringe

See the instructions in paragraph 4.7.4 if using heparin anticoagulant.

4.10.5 Priming/Rinsing

The priming/rinsing procedure is essential for patient safety, as it prepares the machine and the single-use devices, checking that they are able to perform the treatment.

WARNING
All the single-use devices (line set, bags, auxiliary lines, syringes) must be installed before priming.

The volume of fluid that flows in the circuit during priming/rinsing is determined by the treatment selected after loading the set (for the reference values see the tables in par. 4.6.3).

CAUTION
During this procedure the patient must not be connected to the machine.

In order to prevent needless alarms, before starting priming check that:

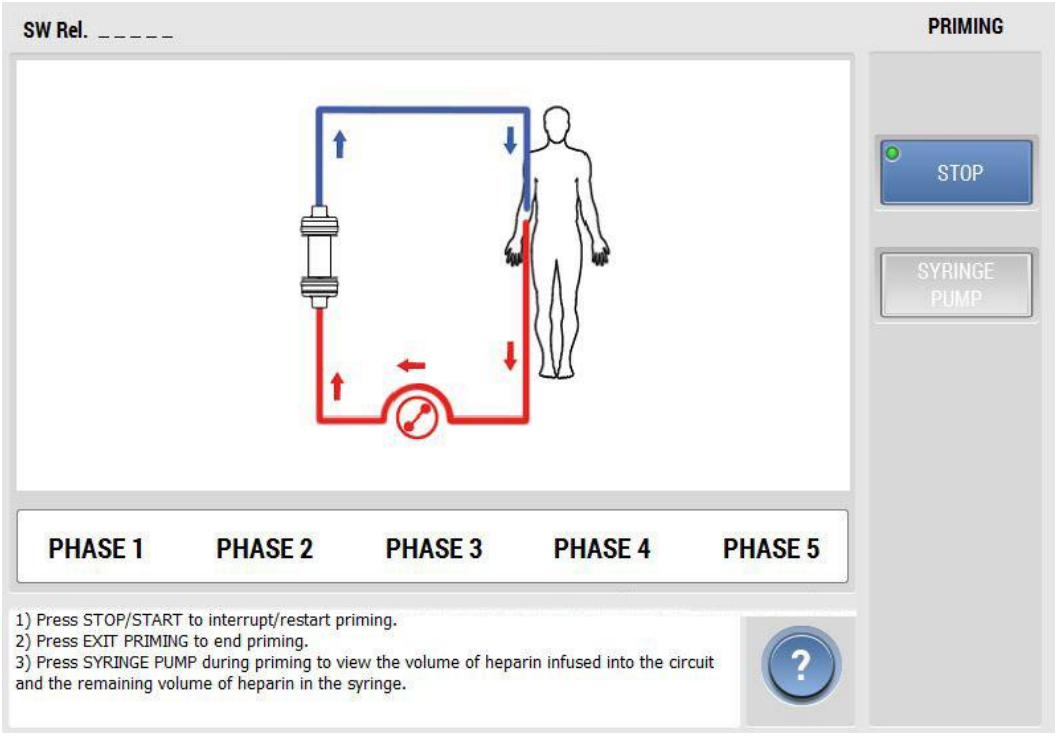
1. The Luer-lock connector of the pressure transducer that controls the level and the pressure in the venous cassette is securely tightened.
2. All the electroclamps on the circuit lines are open.
3. All the fracture cones on the priming fluid bags are properly broken open.
4. All the parts are fully inserted in their holders (return line in the electroclamp and in the air detector, syringe 1 in its holder, venous level line in the relative level sensor).
5. Check that all the bags are on the relative scales and that they do not touch other parts of the machine or bags on other scales.
6. Check that you have selected a treatment consistent with the set loaded.

After the above checks, start the priming/rinsing procedure by pressing the START PRIMING button (Function Button area).

Priming consists of an initial stage in which the replacement fluid coming from the priming fluid bag (green scale) is run through the circuit in order to fill it followed by a rinsing stage during which a volume of fluid, defined for the treatment type selected (in the specific case, HP treatment), is circulated in the circuit in order to eliminate any production process residues.
The fluid injected into the circuit is then collected in collection bags (yellow scale).

During the priming/rinsing phase, some tests are automatically run (pressures, line integrity, scale and sensor functioning) and the relative page shows:

- A progress bar that indicates which priming phase the system is executing
- A synoptic diagram of the treatment type selected.



If during the first three priming/rinsing phases, the system has consumed a volume of fluid such as not to allow the proper executing of the fourth phase, the system informs you of the incorrect consumption of fluid via an alarm window (see alarm 2400 in par. 10.11). When you press the CONFIRM button in the alarm window, priming/rinsing restarts from the beginning.

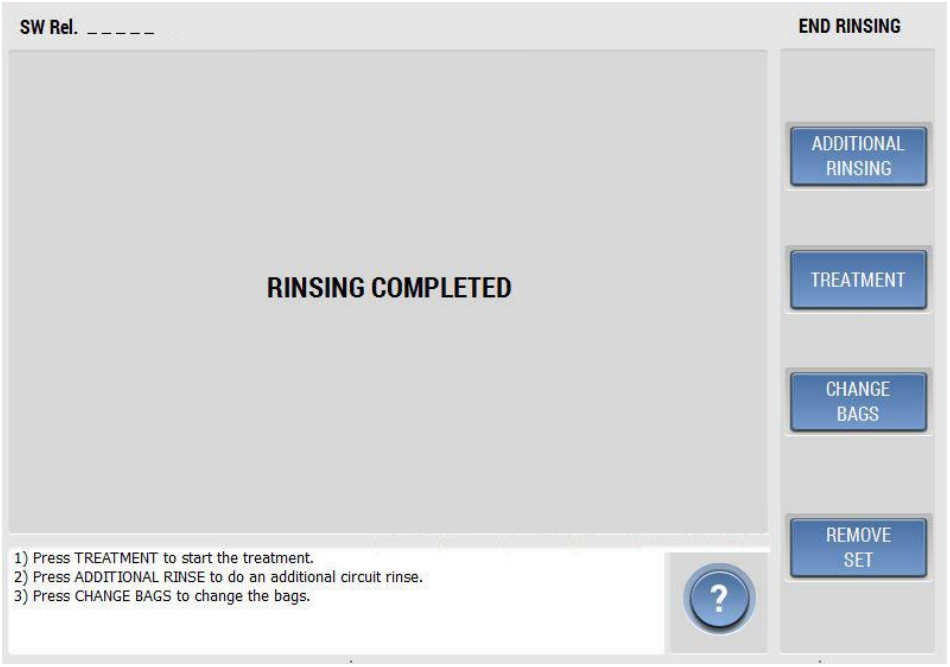
You can press the STOP button (Function Button area) at any time to pause operation.
You can resume the priming/rinsing procedure by pressing the START button (Function Button area) or finally exit the procedure by pressing EXIT PRIMING (Function Button area). Pressing EXIT PRIMING, you go back to the treatment selection page (see par. 4.10.2).
Pressing SYRINGE PUMPS (Function Button area), you can monitor heparin consumption during priming/rinsing.

The heparin is infused for the entire duration of priming at a rate calculated based on the value set for the heparin volume to be infused during priming and the value set for the rinsing volume.

If you have chosen to connect the adsorbent column once priming has started (see par. 4.10.2), during the second priming phase, you are asked to remove the bypass line that connects the inlet (red) and outlet (blue) lines to each other and to connect them to the respective connectors of the adsorbent column positioned on a dedicated holder.

4.10.6 End of rinsing

At the end of rinsing, you automatically access the End Rinse page from where you can:
1. Start the treatment by pressing the TREATMENT button
2. Perform additional rinsing by pressing the ADDITIONAL RINSE button
3. Remove the set by pressing REMOVE SET.



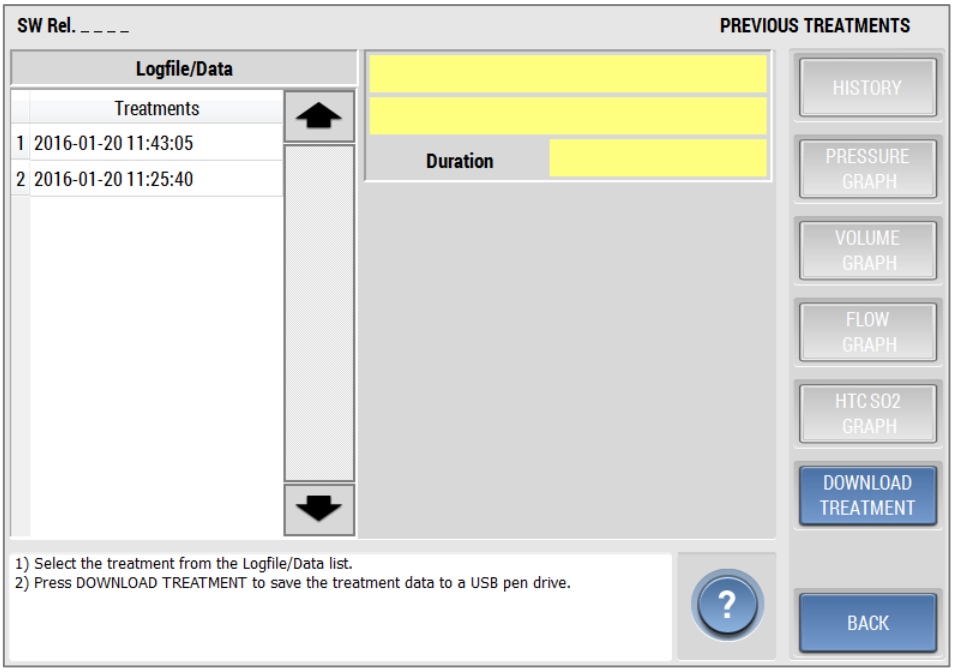
From the End Rinse page you can turn off the machine with the main switch in order to move it to the patient's bedside.

Turning off the machine to move it to the patient's bedside
When the machine is turned on again, you automatically access the End Rinse page. The treatment mode and the treatment parameters remain as selected before the priming/rinsing phase.

Additional rinsing
You can start rinsing by pressing START on the relative page. The page shows the volume of fluid that is circulated in the circuit.
You can press the STOP button at any time to pause operation and if necessary change the bags.
You can resume rinsing by pressing START or exit rinsing only after the machine has circulated at least 300 ml of fluid by pressing END RINSE (Function Button area).
During additional rinsing you can activate or deactivate syringe pump 1 to infuse heparin.

4.11 PREVIOUS TREATMENTS

Pressing the PREVIOUS TREATMENTS button on the home page, you access a page listing all the treatments and priming performed up to that moment identified by the date and time of execution.
Pressing the DOWNLOAD TREATMENT button, you can download all the data for internal analyses within Bellco.

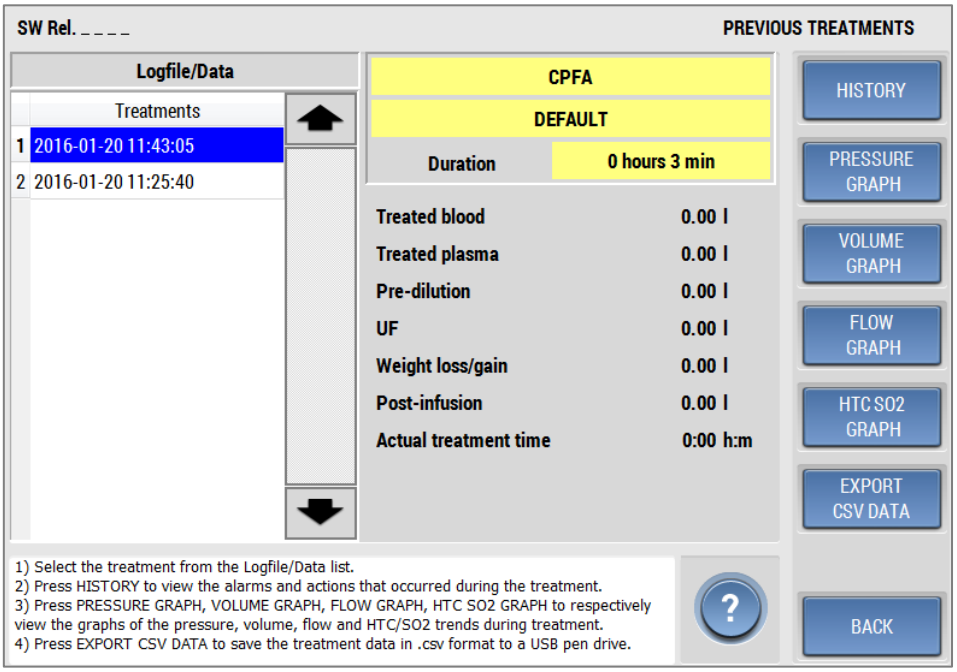


Selecting a treatment/priming from the list you can view:
- Treatment/priming type and name
- Treatment time
- Volumes of fluids treated during treatment
- Actual treatment time

Selecting a treatment, you can access the graphs and the history of the events relating to the treatment selected.

You can analyse the data of a treatment a posteriori by downloading them in .csv format to a USB pen drive. To this end, insert the USB pen drive in the dedicated communication port, select the

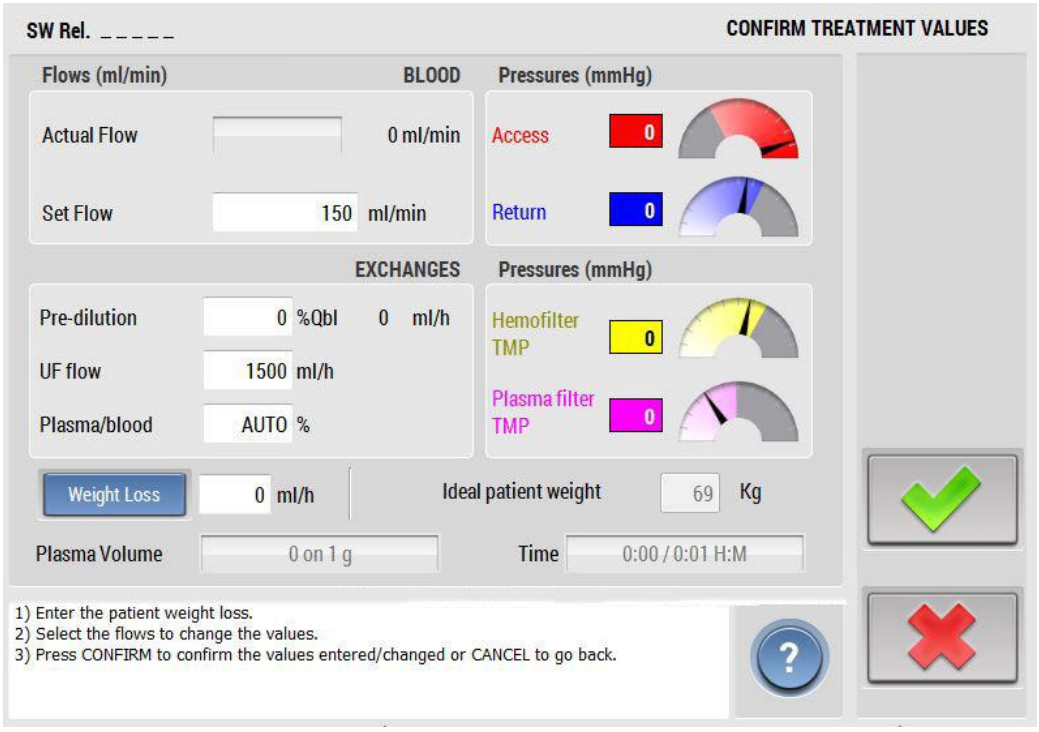
treatment of which you want to download the data and press the EXPORT CSV DATA button. A file in .csv format is saved, which can be imported by any spreadsheet program.



5 PERFORMING A CPFA/RRT TREATMENT WITH SYSTEMIC ANTICOAGULATION

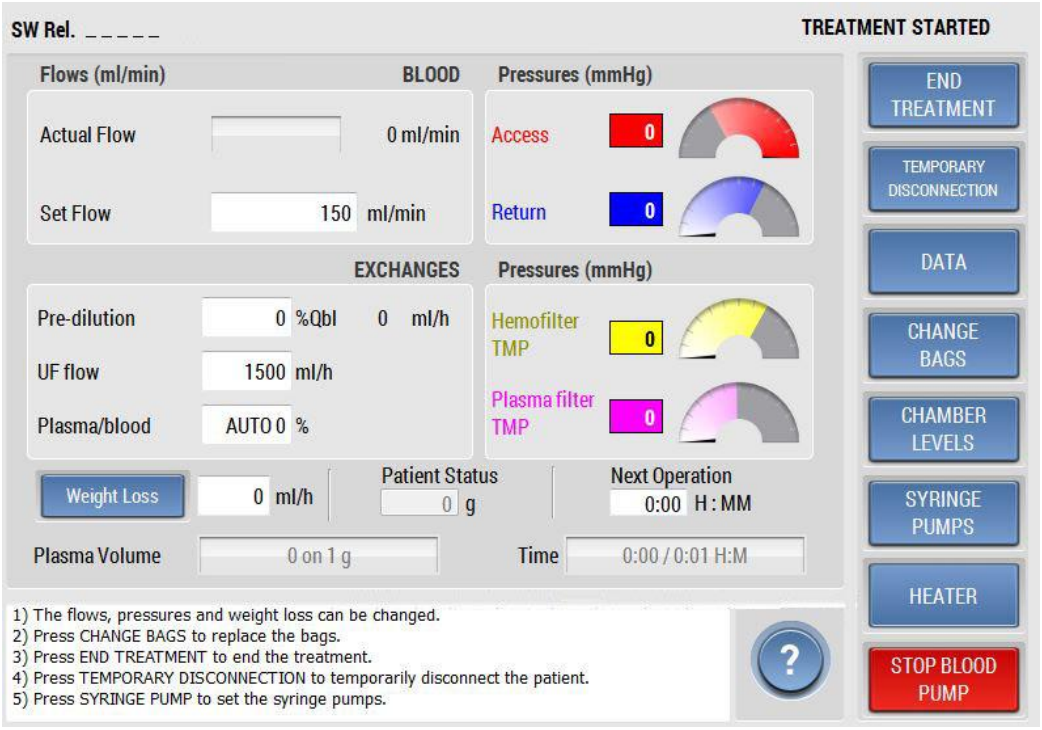
If you have selected a CPFA treatment with systemic anticoagulation (see par. 4.7.2), pressing the TREATMENT button from the End Rinse page, you access a page where you need to set the sex, height and age of the patient in order to allow the system to calculate the "ideal weight". The system requires the ideal weight for calculation of the target plasma volume (200 ml of plasma per kg of ideal weight).
Confirming the calculated Ideal Weight value, you access a page where to confirm the values for the treatment parameters.

If the treatment selected is CPFA, the page appears as shown in the image below.

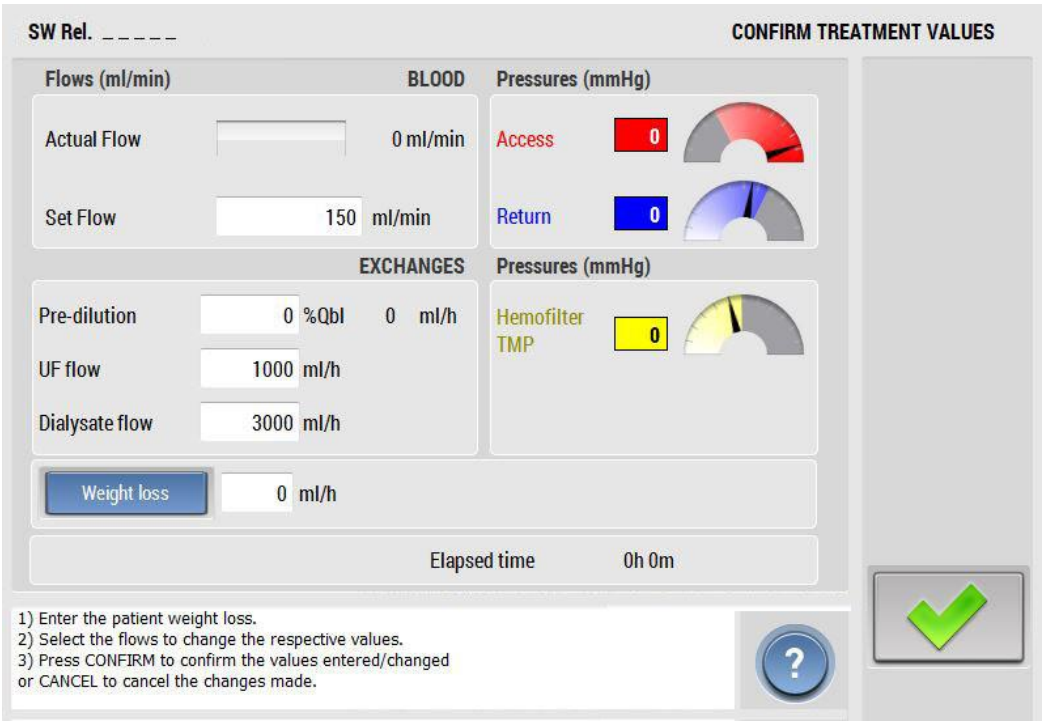


From the "treatment values confirmation" page, having made and confirmed all the required settings for the specific treatment (see par. 4.3.4), you can start the treatment by pressing the START button (Function Button area) on the "start treatment" page and so access the "treatment started" page.

WARNING
Check that the filter connectors are properly screwed on.

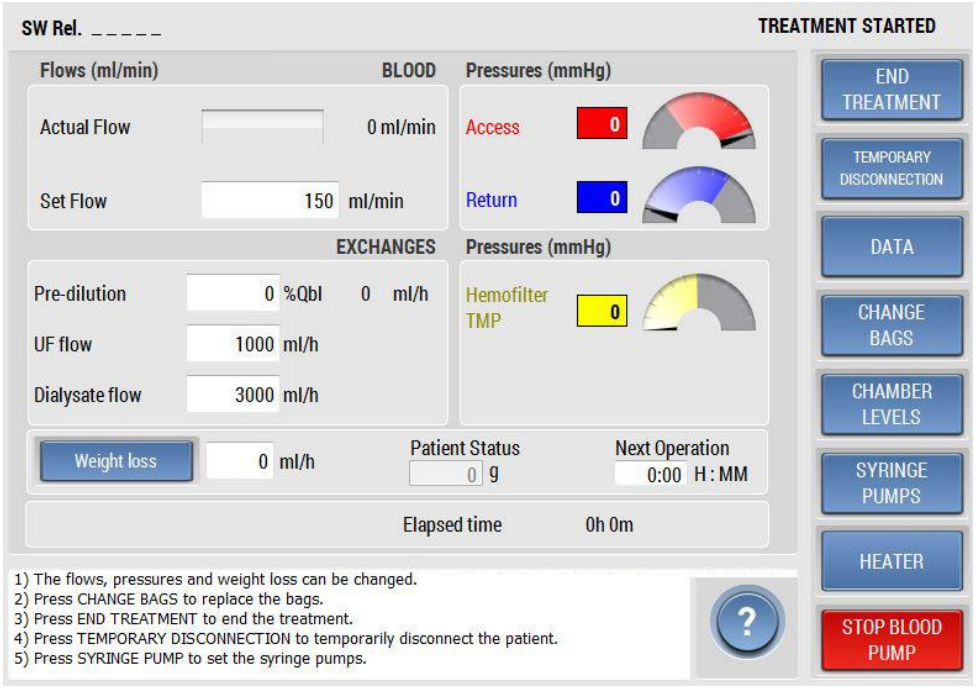


If you have selected an RRT treatment with systemic anticoagulation, pressing the TREATMENT button from the End Rinse page, you access the “treatment values confirmation” page.
If the treatment selected is HDF, the page appears as shown in the image below.



The page structure is the same for all the RRT treatments. Only some of the parameters displayed change.

From the "treatment values confirmation" page, having made and confirmed all the required settings for the specific treatment (see par. 4.3.4), you can start the treatment by pressing the START button (Function Button area) and so access the "treatment started" page.



The page structure is the same for all the RRT treatments. Only some of the parameters displayed change.

The "start treatment" and "treatment started" pages are structured as follows:

- An *active* area divided into four control blocks (blood, exchange, fluid balance and time) where the characteristic parameters of the selected treatment and the respective values are shown.
- A *function button* area to the right of the four blocks with buttons that offer access to some useful treatment functions.
- An *information* area at the bottom where the treatment name and power supply (mains or battery) are shown.

The flow and pressure parameters are shown in the various control blocks.
Some of the parameters displayed allow you to monitor treatment progress (therefore, before starting the treatment, their value is zero).
Other parameters are settable/modifiable by the operator using the *numerical keypad* (see par. 4.3) after pressing on the corresponding white field.

5.1 TREATMENT PARAMETERS

5.1.1 Blood

The blood control parameters are shown under BLOOD at the top of the active area of the "start treatment" and "treatment started" pages.
The actual flow and the set flow expressed in ml/min form part of the "Flows" panel.

The **actual flow** indicates the actual blood pump flow supplied by rotation of the pump during the treatment (therefore it is 0 before treatment start when the pumps are all off). During treatment, the value of this parameter allows you to monitor the blood flow instant by instant.
The actual flow depends on the access pressure, the blood pump speed and deterioration of the relative line.

The **set flow** indicates the blood flow operating value desired for the specific treatment. The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment. The blood flow numerical keypad also indicates the minimum and maximum values within which it is recommended to set the blood flow.

The access pressure and the return pressure expressed in mmHg form part of the "Pressures" panel.
The **access pressure** is the pressure, monitored during treatment, before the blood pump at the blood inlet to the extracorporeal circuit.
The **return pressure** is the pressure, monitored during treatment, in the venous cassette before the blood is returned to the patient through the return line (blue tube section).

When the treatment is started, only the blood pump and syringe pump 1 (if set) start. The blood pump gradually accelerates until reaching the operating flow set in relation to the blood pressure variations. After reaching the operating blood flow, the exchange pumps start:

- Infusion pump, UF pump, syringe pump 2 (if set) and fifth pump after 1 minute if infusion bags are loaded on the central scale and the pre-dilution flow is set, otherwise after 4 minutes.
- Post-infusion pump (only in RRT treatments) after 1 minute if the pre-dilution flow set is different from 0, after 4 minutes if the pre-dilution flow is null.
- Plasma pump (only in CPFA treatments) after 8 minutes.

5.1.2 Exchanges

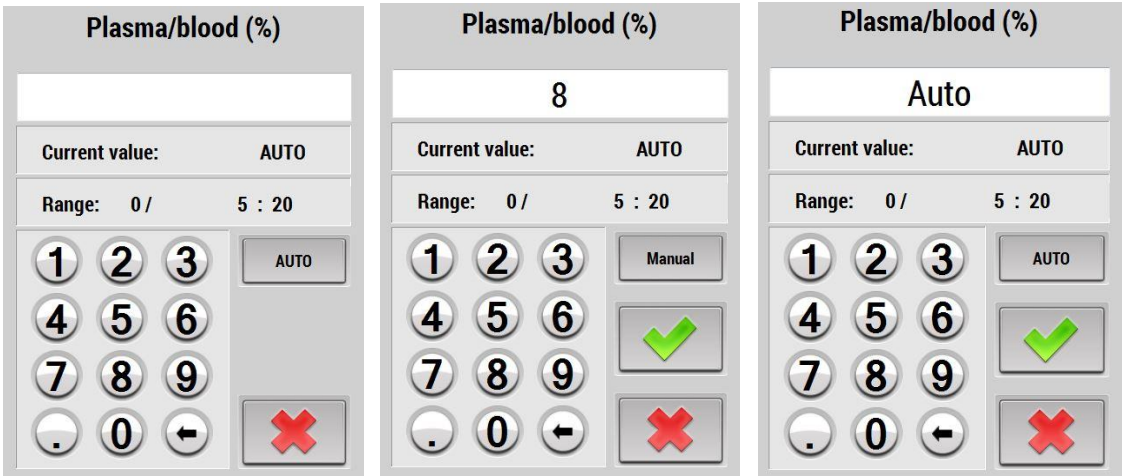
The **exchange** defines the clearance to be achieved by convection, diffusion or adsorption. The exchange mechanism control parameters will hence change in relation to the treatments.
In all cases you can define the clearance by means of a flow in ml/h or as a percentage of the blood flow. In addition, the transmembrane pressure/s are shown.

The exchange control parameters are shown under EXCHANGES in the centre of the active area of the "start treatment" and "treatment started" pages.

In the exchange flows panel:

- in CPFA, HDF and HF, the **UF flow** is shown expressed in ml/h. This flow indicates the desired operating value of the ultrafiltrate flow extracted by convection for the specific treatment. The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment.

- In CPFA, the **plasma flow** *(plasma/blood*) is shown expressed as a percentage of the flow generated by the blood pump and supplied by rotation of the plasma pump. The plasma flow is by default automatically controlled by the system. Automatic plasma flow control consists of a linear increase of the flow for first two hours of treatment (from 13% to 20% of the flow generated by the blood pump) after which the percentage of plasma extracted from the blood is maintained constant (20% of the flow generated by the blood pump). When the word AUTO appears in the white field, it means that automatic plasma flow control is active.
  The percentage plasma flow of the flow generated by the blood pump can also manually be controlled by the operator both during programming and treatment. The keypad used to program the plasma flow has a dedicated button in addition to those described earlier (par. 4.3), which allows changing from automatic to manual flow control and vice versa.
  When plasma flow control is automatic (see keypad image on the left) and you enter a value in the dedicated field of the keypad, the button changes from AUTO to MANUAL (see keypad image in the middle) and confirming the value entered, plasma flow control becomes manual. To go back to automatic control, press the MANUAL button on the keypad and confirm (see keypad image on the right).



- In HDF and HD, the dialysate flow is shown expressed in ml/h. This flow indicates the operating value of the replacement fluid flow destined for the dialysate compartment of the hemofilter (where the exchange between the blood and the fluid takes place by diffusion). The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment.
- In HF, the pre-infusion ratio is shown expressed as a percentage value of the total infusion flow. This flow is obtained as the difference between the total infusion flow supplied by the top right pump and the post-infusion flow supplied by the bottom left pump and indicates the replacement fluid flow operating value with which the blood is diluted at the hemofilter inlet. The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment.
- If before starting the priming/rinsing phase one or two infusion bags were loaded on the central scale with the purpose of performing a pre-dilution, the additional information on the **pre-dilution flow** is shown in both CPFA and RRT. This flow, expressed both as a percentage of the blood flow and in ml/h, is supplied by rotation of the fifth pump and indicates the desired operating value of the replacement fluid flow at the extracorporeal circuit inlet for the specific treatment. Pre-dilution consists of diluting the patient's blood at the extracorporeal circuit inlet through infusion of replacement fluid before the blood pump. The pre-dilution flow can only be set as a percentage of the blood flow (see par. 5.1.6).

The transmembrane pressure or TMP of the hemofilter is shown in the Pressures panel. Only in CPFA the TMP of the plasma filter is also shown. The TMP is expressed in mmHg.

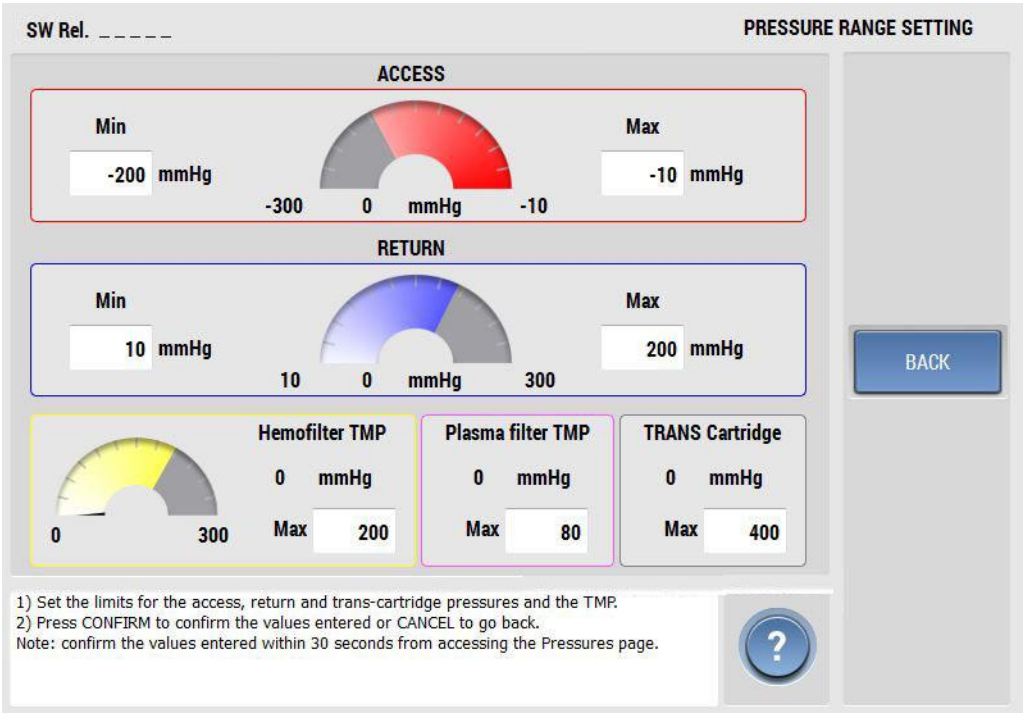
The **TMP of the hemofilter** is calculated as the difference between the mean blood pressure in the filter and the pressure of the ultrafiltrate (waste fluid) coming out of the filter.
The **TMP of the plasma filter** is calculated as the difference between the mean blood pressure in the filter and the pressure of the plasma coming out of the filter.

NOTE:
- Both in CPFA and in RRT, the ultrafiltrate pressure is the pressure monitored during treatment before the UF pump.
- In CPFA, the plasma pressure is the pressure monitored during treatment before the plasma pump.
- Both in CPFA and RRT, the mean blood pressure in the filter is calculated between the pressure values at the inlet and outlet of each filter.
- In CPFA, the pressures at the inlet and outlet of the plasma filter are the pressures monitored during treatment after the blood pump and in the upper cassette, respectively.
- In CPFA, the pressure at the hemofilter inlet is the pressure measured in the upper cassette and the pressure at the hemofilter outlet is the pressure measured in the venous cassette.
- In RRT, the pressure at the hemofilter inlet is the pressure measured after the blood pump and the pressure at the hemofilter outlet is the pressure measured in the venous cassette.

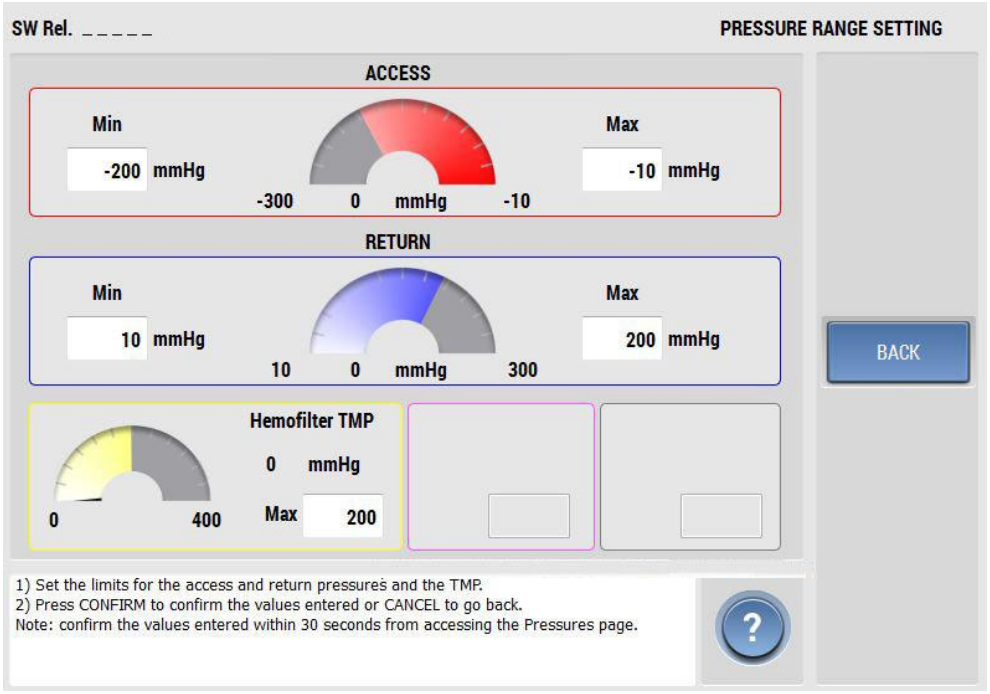
5.1.3 Pressure

Both during programming and treatment, pressing on the "Pressures" panels relating to blood and exchange control, you access the pressure range page.

In CPFA, the page appears as shown in the image below.



In RRT, the page appears as shown in the image below.



On this page you can view and set:

- The minimum and maximum permitted access and return pressures
- The maximum permitted transmembrane pressures
- Only in CPFA, the mean pressure of the plasma in Mediasorb indicated as trans-cartridge pressure (calculated as the difference between the pressures at the inlet and outlet of the cartridge).

NOTE: In CPFA, the pressures at the inlet and outlet of the cartridge are the pressures monitored during treatment after the plasma pump and in the upper cassette, respectively.

To set the minimum and maximum values, see par. 5.3.3.

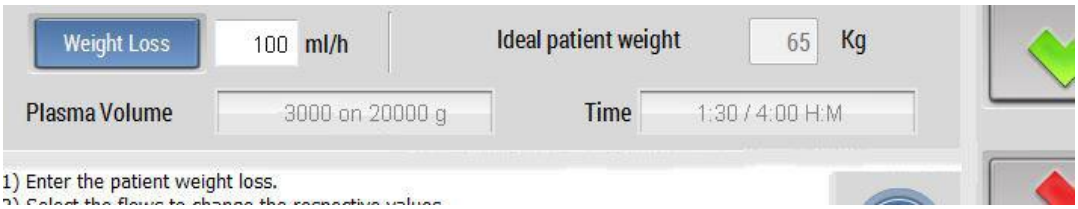
5.1.4 Weight and fluid balance

On the "start treatment" and "treatment started" pages, under exchange control, are shown the weight loss/gain parameter and, during treatment, the patient status parameter.
The fluid balance value you want to obtain performing the treatment, **weight loss/gain**, is set to zero by default so as to correspond to a balanced fluid balance.
Both during programming and treatment, to set the value of this parameter, press the button that shows the desired balance (weight loss or gain) and enter the correlated value in the white field.
Pressing the WEIGHT LOSS button, it changes to WEIGHT GAIN after confirmation.
Pressing the WEIGHT GAIN button, it changes to WEIGHT LOSS after confirmation.

When the fluid balance set is positive, the button (in this case, WEIGHT GAIN) is red, as this rare event might be the result of a setting error.
The **patient status** value allows moment by moment monitoring of the patient weight variation.
Only in CPFA, during treatment programming the settable **ideal weight** parameter is shown.
The system requires setting the sex, height and age of the patient for calculation of the ideal weight.
Pressing on the white field relating to the ideal weight, you access the page where you can enter the patient's height and age.
The system requires the ideal weight for calculation of the target plasma volume (200 ml of plasma per kg of ideal weight). The start of a CPFA treatment depends on programming of this parameter; failing to program this parameter, the system signals that the treatment cannot be started if the ideal weight has not been set.

5.1.5 Time

The parameters that allow monitoring the treatment time are shown at the bottom of the *active* area of the page.
In CPFA, the information on the treatment time is provided by the **volume of plasma treated out of the minimum volume of plasma to be treated (target)** (on the left) and by the **treatment time elapsed out of the total time necessary to treat the target volume of plasma** (on the right).



To calculate the volume of plasma treated, the machine takes into account the solution flow rate in pre-dilution and assumes a hematocrit value of 35%.
When the volume of plasma treated reaches the target volume:

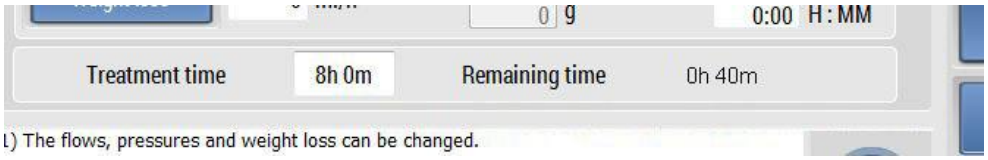
- a message on the screen informs you that the target plasma volume has been reached;
- the information on the target volume disappears, while the volume of plasma treated and the elapsed time continue to be displayed.

During a continuous RRT treatment, the information on the **elapsed time** is provided (on the right).

During an intermittent RRT treatment, the time information provided is:

- **Remaining time**, i.e. the remaining time to the end of the treatment (on the right)
- **Treatment time** (on the left)

on both the "start treatment" and the "treatment started" page.



The time default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment, provided it is not set to below the time elapsed from the beginning of the treatment.
Both during a CPFA and an RRT treatment, the next operation is indicated next to the patient status, i.e. the time remaining to the next bag replacement or the next syringe replacement.

Pressing on the Next Operation field a menu appears indicating:

- The time remaining to the next UF bag change
- The time remaining to the next infusion bag change
- The time remaining to the next bag change on the central scale
- The time remaining to the next syringe 1 change
- The time remaining to the next syringe 2 change

Half an hour before each of these times runs out, a message on the screen informs you what needs to be changed (see alarms 1071, 1072, 1073, 1074, 1076 in par. 8.11).
Subsequently, this message appears every 5 minutes until you make the change.

5.1.6 Treatment specifications

The tables below give definitions of parameters settable and/or modifiable by the operator for each CPFA/RRT treatment family. In each table reference is made to the NOTES below the table, giving further definitions of parameters and relative values settable by the user.

CPFA

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 5 and 7)	150	30	250
UF flow (ml/h) (see Notes 2 and 4)	1500	1) When not setting a weight loss/gain: 0 2) When setting a weight loss: weight loss+50 3) When setting a weight gain: 0	minimum between 4500 and (0.3*blood flow) (see Note 3)
Weight loss/gain (ml/h)	0	0	1) When setting a weight loss: minimum between 2000 and UF flow 2) When setting a weight gain: 2000
Plasma/blood (%)	AUTO	0; 5	20
Pre-dilution flow (%)	0	0; 5	30 (see Note 1)
Min. access pressure (mmHg)	-200	-300	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	+10 (or +50 based on the machine configuration; with ECMO -50)	+10 or -50 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	200	0	300
Max. plasma filter TMP (mmHg)	50	0	80
Max. trans-cartridge pressure (mmHg)	400	X	600

NOTES:

1. The pre-dilution flow is settable as a percentage of the blood flow either at 0% or in the range 5-30%, provided it is below 4000 ml/h. Modifying the blood flow, the fifth pump flow rate varies maintaining constant the percentage with respect to the blood flow unless exceeding the maximum permitted value; in this case, the treatment is suspended (blood pump at minimum speed) and you are asked to set compatible values for the pre-dilution and blood flows (see alarm 403 in par. 10.11).

2. UF flow = infusion flow + weight loss
   UF flow = infusion flow - weight gain
   The infusion flow is calculated by the system, starting from the UF flow and weight loss/gain values set.

3. **The maximum UF flow settable is always 30% lower than the blood flow set.** If as a result of modification of the blood flow value, the UF flow value exceeds the maximum UF flow, the system signals the inconsistency and asks you to program compatible values for the weight loss, UF flow and blood flow (see alarm 401 in par. 10.11).

4. **The actual UF flow supplied by the UF pump takes into account the UF flow set as well as any pre-dilution flow set.**

5. **The actual blood flow supplied by the blood pump takes into account the blood flow set as well as any pre-dilution flow set.**

6. **If after setting or modifying the value of one or more parameters, a limit to a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.**

7. The recommended minimum blood flow value indicated on the relative numerical keypad is calculated as ((10/3)*UF flow) ml/min; the recommended maximum blood flow value indicated on the relative numerical keypad is calculated as (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

CONTINUOUS AND INTERMITTENT HAEMODIAFILTRATION (CVVHDF/IHDF)

Small filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 6 and 9)	100	30 (see Note 1b)	250 (see Note 1b)
UF flow (ml/h) (see Notes 3 and 5)	500	1) When the maximum UF value is smaller than 100 and a weight loss has been set: weight loss+50 2) When the maximum UF value is smaller than 100 and a weight gain has been set: 0 3) When the maximum UF value is greater than 100 and a weight loss has been set: maximum between (0; 100) and weight loss +50 4) When the maximum UF value is greater than 100 and a weight gain has been set: 0 (see Note 1a)	1) When setting a weight loss: minimum between 4000, (2.32*dialysate flow + weight loss) and 0.3*blood flow 2) When setting a weight gain: minimum between 4000, (2.32*dialysate flow - weight gain) and 0.3*blood flow (see Notes 1a and 4)
Weight loss/gain (ml/h)	0	0 (see Note 1a)	1) When setting a weight loss: minimum between 1000, UF flow-50 and 0.2*blood flow 2) When setting a weight gain: minimum between 1000 and (2.32*dialysate flow-UF flow) (see Note 1a)
Dialysate flow (ml/h)	1000	1) When setting a weight loss: maximum between 500 and 0.43*(UF flow-weight loss) 2) When setting a weight gain: maximum between 500 and 0.43*(UF flow+weight gain) (see Note 1)	2000
Pre-dilution flow (%)	0	0; 5	30 (see Note 2)

	Default value	Minimum value settable	Maximum value settable
Min. access pressure (mmHg)	-200	-300 (see Note 1c)	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	150	0	300

Medium filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 6 and 9)	150	30 (see Note 1b)	450 (see Note 1b)
UF flow (ml/h) (see Notes 3 and 5)	1000	1) When the maximum UF value is smaller than 100 and a weight loss has been set: maximum between 0 and weight loss +50 2) When the maximum UF value is smaller than 100 and a weight gain has been set: 0 3) When the maximum UF value is greater than 100 and a weight loss has been set: maximum between (0; 100) and weight loss +50 4) When the maximum UF value is greater than 100 and a weight gain has been set: 0; 100 (see Note 1a)	1) When setting a weight loss: minimum between (12000-dialysate flow), (2.32*dialysate flow+weight loss) and (0.3*blood flow) 2) When setting a weight gain: minimum between (12000-dialysate flow-weight gain), (2.32*dialysate flow-weight gain) and (0.3*blood flow) (see Notes 1a and 4)
Weight loss/gain (ml/h)	0	0 (see Note 1a)	1) When setting a weight loss: minimum between 2000, UF flow-50 and 0.3*blood flow 2) When setting a weight gain: minimum between 2000, (2.32*dialysate flow-UF flow) and (12000-UF flow-dialysate flow) (see Note 1a)
Dialysate flow (ml/h)	3000	1) When setting a weight loss: 0 ; maximum between 500 and 0.43*(UF flow-weight loss) 2) When setting a weight gain: 0; maximum between 500 and 0.43*(UF flow+weight gain) (see Note 1)	1) When setting a weight loss: (12000-UF flow) 2) When setting a weight gain: (12000-UF flow+weight gain)
Pre-dilution flow (%)	0	0; 5	30 (see Note 2)

	Default value	Minimum value settable	Maximum value settable
Min. access pressure (mmHg)	-200	-300 (see Note 1c)	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	200	0	400

NOTES:

1. If the dialysate flow is set to null:
   a) - The minimum UF flow value when setting a weight loss is the maximum value between 500 ml/h and weight loss +50;
   - The minimum UF flow value when setting a weight gain is 0 ml/h;
   - The maximum UF flow value when setting a weight loss is the minimum value between 2400 ml/min and (20% of the blood flow + weight loss) provided it is not below 600 ml/h;
   - The maximum UF flow value when setting a weight gain is the minimum value between 2400 ml/min and (20% of the blood flow - weight gain) provided it is not below 600 ml/h;
   - The maximum weight loss value in the case of the small filter is the minimum value between 1000, 20% of the blood flow and UF flow-50;
   - The maximum weight loss value in the case of the medium filter is the minimum value between 2000, 20% of the blood flow and UF flow-50;
   - The maximum weight gain in the case of the small filter is the minimum value between 1000 and 20% of the blood flow;
   - The maximum weight gain in the case of the medium filter is the minimum value between 2000 and 20% of the blood flow;
   b) The permitted blood flow values are between 50 and 200 ml/min. Entering a blood flow value not within the 50-200 ml/min range will open a panel where you are asked to set a blood flow value between 50 and 200 ml/min.
   c) The minimum access pressure is automatically set to -200 mmHg; if the maximum access pressure had a value below -200 before setting the dialysate flow to null, it is automatically set to -190 mmHg.
   d) The double electroclamp changes position occluding the dialysate line and leaving the pre-infusion line free.

WARNING
In this configuration, the maximum permitted value for the infusion flow in pre-infusion is +10% of the total infusion flow.

2. The pre-dilution flow is settable as a percentage of the blood flow either at 0% or in the range 5-30%, provided it is below 4000 ml/h. Modifying the blood flow, the fifth pump flow rate varies maintaining constant the percentage with respect to the blood flow unless exceeding the maximum permitted value; in this case, the treatment is suspended (blood pump at minimum speed) and you are asked to set compatible values for the pre-dilution and blood flows (see alarm 403 in par. 10.11).

3. UF flow = post-infusion flow + weight loss
   UF flow = post-infusion flow - weight gain
   Total infusion flow = dialysate flow + post-infusion flow.

   The post-infusion flow is calculated by the system, starting from the UF flow and weight loss values set, and is the flow supplied by the post-infusion pump. The total infusion flow is calculated by the system, starting from the calculated post-infusion flow and the dialysate flow value set, and is the flow supplied by the infusion pump.

4. **The maximum UF flow settable is always 30% lower than the blood flow set.** If as a result of modification of the blood flow value, the UF flow value exceeds the maximum UF flow, the system signals the inconsistency and asks you to program compatible values for the weight loss, UF flow and blood flow (see alarm 401 in par. 10.11).

5. **The actual UF flow supplied by the UF pump takes into account the UF flow set as well as the dialysate flow and any pre-dilution flow set.**

6. **The actual blood flow supplied by the blood pump takes into account the blood flow set as well as any pre-dilution flow set.**

7. **If after setting or modifying the value of one or more parameters, a limit to a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.**

8. The recommended minimum blood flow value indicated on the relative numerical keypad is calculated as ((10/3)*UF flow) ml/min; the recommended maximum blood flow value indicated on the relative numerical keypad is calculated as (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

CONTINUOUS AND INTERMITTENT HAEMODIALYSIS (CVVHD/IHD-SLED)

Small filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 4 and 6)	100	30	250
Weight loss/gain (ml/h) (see Note 3)	0	Maximum between -1000 and –dialysate flow+50	Minimum between 1000 and 0.3*blood flow
Dialysate flow (ml/h) (see Notes 2 and 3)	1000	Maximum between 0 and 50-weight loss	4000
Pre-dilution flow (%) (see Note 3)	0	0; 5	30 (see Note 1)
Min. access pressure (mmHg)	-200	-300 (see Note 1c)	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	150	0	300

Medium filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 4 and 6)	150	30	450
Weight loss/gain (ml/h) (see Note 3)	0	0	1) When setting a weight loss: minimum between 2000 and 12000-dialysate flow 2) When setting a weight gain: minimum between 2000 and dialysate flow
Dialysate flow (ml/h) (see Notes 2 and 3)	2000	Maximum between 0 and 50-weight loss	1) When setting a weight loss: 12000-weight loss 2) When setting a weight gain: 12000
Pre-dilution flow (%) (see Note 3)	0	0; 5	30 (see Note 1)
Min. access pressure (mmHg)	-200	-300	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	200	0	400

NOTES:

1. The pre-dilution flow is settable as a percentage of the blood flow either at 0% or in the range 5-30%, provided it is below 4000 ml/h. Modifying the blood flow, the fifth pump flow rate varies maintaining constant the percentage with respect to the blood flow unless exceeding the maximum permitted value; in this case, the treatment is suspended (blood pump at minimum speed) and you are asked to set compatible values for the pre-dilution and blood flows (see alarm 403 in par. 10.11).

2. The dialysate flow is the flow supplied by the infusion pump.

3. **The flow supplied by the UF pump takes into account the weight loss, dialysate flow and any pre-dilution flow set.**

4. **The actual blood flow supplied by the blood pump takes into account the blood flow set as well as any pre-dilution flow set.**

5. **If after setting or modifying the value of one or more parameters, a limit to a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.**

6. The recommended minimum blood flow value indicated on the relative numerical keypad is calculated as ((10/3)*UF flow) ml/min; the recommended maximum blood flow value indicated on the relative numerical keypad is calculated as (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

CONTINUOUS AND INTERMITTENT HAEMOFILTRATION (CVVH/IHF-HVHF)

Small filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 6 and 8)	100	30 (see Note 1b)	250 (see Note 1b)
UF flow (ml/h) (see Notes 3 and 5)	1000	1) When setting a weight loss: maximum between 100 and weight loss +50 2) When setting a weight gain: 100	1) When setting a weight loss: a) minimum between 4000 and [(0.3*blood flow/post-infusion ratio)- (weight loss/post-infusion ratio)+weight loss)] *with post-infusion ratio=100-pre-infusion ratio* b) UF flow is 0 when (0.3*blood flow-weight loss) is < 0 2) When setting a weight gain: a) minimum between 4000 and [(0.3*blood flow/post-infusion ratio)+ (weight gain/post-infusion ratio)-weight gain] *with post-infusion ratio=100-pre-infusion ratio* b) maximum UF flow is 0 when (0.3*blood flow+weight gain) is < 0 (see Notes 1a and 5)
Weight loss/gain (ml/h)	0	Maximum between -1000 and UF flow-12000	Minimum between 1000, UF flow-50 and 0.3*blood flow
Pre-infusion ratio (%)	50	0 or 30 (see Note 1)	100
Pre-dilution flow (%)	0	0; 5	30 (see Note 2)

	Default value	Minimum value settable	Maximum value settable
Min. access pressure (mmHg)	-200	-300 (see Note 1c)	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	150	0	300

Medium filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 6 and 8)	150	30 (see Note 1b)	450 (see Note 1b)
UF flow (ml/h) (see Notes 3 and 5)	1000	1) When setting a weight loss: maximum between 500 and weight loss +50 2) When setting a weight gain: 500 (see Notes 1a and 2a)	1) When setting a weight loss: a) minimum between 12000 and [(0.3*blood flow/post-infusion ratio)- (weight loss/post-infusion ratio)+weight loss)] *with post-infusion ratio=100-pre-infusion ratio* b) 0 when (0.3*blood flow-weight loss) is < 0 2) When setting a weight gain: minimum between 12000-weight gain) and [(0.3*blood flow/post-infusion ratio)+ (weight gain/post-infusion ratio)-weight gain)] *with post-infusion ratio=100-pre-infusion ratio* (see Notes 1a and 5)
Weight loss/gain (ml/h)	0	Maximum between -2000 and UF flow-12000	1) When setting a weight loss: minimum between 2000, UF flow-50 and 0.3*blood flow 2) When setting a weight gain: minimum between 2000, UF flow-50 and 0.2*blood flow
Pre-infusion ratio (%)	50	0 or 30 (see Note 1)	100
Pre-dilution flow (%)	0	0; 5	30 (see Note 2)

	Default value	Minimum value settable	Maximum value settable
Min. access pressure (mmHg)	-200	-300 (see Note 1c)	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	200	0	400

Large filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 6 and 8)	150	30 (see Note 1b)	450 (see Note 1b)
UF flow (ml/h) (see Notes 3 and 5)	3000	1) When setting a weight loss: maximum between 500 and weight loss +50 2) When setting a weight gain: 500 (see Notes 1a and 2a)	1) When setting a weight loss: a) minimum between 12000 and [(0.3*blood flow/post-infusion ratio)- (weight loss/post-infusion ratio)+weight loss)] *with post-infusion ratio=100-pre-infusion ratio* b) maximum UF flow is 0 when (0.3*blood flow-weight loss) is < 0 2) When setting a weight gain: minimum between 12000-weight gain) and [(0.3*blood flow/post-infusion ratio)+ (weight gain/post-infusion ratio)-weight gain)] *with post-infusion ratio=100-pre-infusion ratio* (see Notes 1a and 5)
Weight loss/gain (ml/h)	0	Maximum between -2000 and UF flow-12000	Minimum between 2000, UF flow-50 and 0.3*blood flow
Pre-infusion ratio (%)	50	0 or 30 (see Note 1)	100
Pre-dilution flow (%)	0	0; 5	30 (see Note 2)

	Default value	Minimum value settable	Maximum value settable
Min. access pressure (mmHg)	-200	-300 (see Note 1c)	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	200	0	400

NOTES:

1. If the pre-infusion flow is set to null:
   a) - The minimum UF flow value when setting a weight loss is the maximum value between 0 ml/h and weight loss+50
   - The minimum UF flow value when setting a weight gain is 0 ml/h
   - The maximum UF flow value when setting a weight loss is the minimum value between 2400 ml/min and (20% of the blood flow + weight loss) provided it is not below 600 ml/h
   - The maximum UF flow value when setting a weight gain is the minimum value between 2400 ml/min and (20% of the blood flow - weight gain) provided it is not below 600 ml/h
   - The maximum weight loss value in the case of the small filter is the minimum value between 1000, UF flow-50, 20% of the blood flow
   - The maximum weight loss value in the case of the medium and large filters is the minimum value between 2000 and 20% of the blood flow
   - The maximum weight gain in the case of the small filter is the minimum value between 1000 and 20% of the blood flow, in the case of the medium and large filters 2000.
   b) The permitted blood flow values are between 50 and 200 ml/min. Entering a blood flow value not within the 50-200 ml/min range will open a panel where you are asked to set a blood flow value between 50 and 200 ml/min.
   c) The minimum access pressure is automatically set to -200 mmHg; if the maximum access pressure had a value below -200 before setting the dialysate flow to null, it is automatically set to -190 mmHg.

WARNING
In this configuration, the maximum permitted value for the infusion flow in pre-infusion is +10% of the total infusion flow.

2. If the post-infusion flow is set to null:
   a) - The minimum UF flow value when setting a weight loss is the maximum value between 0 ml/h and weight loss
      - The minimum UF flow value when setting a weight gain is 0 ml/h
   b) The permitted blood flow values are between 50 and 200 ml/min. Entering a blood flow value not within the 50-200 ml/min range will open a panel where you are asked to set a blood flow value between 50 and 200 ml/min.
   c) The minimum access pressure is automatically set to -200 mmHg; if the maximum access pressure had a value below -200 before setting the dialysate flow to null, it is automatically set to -190 mmHg

3. The pre-dilution flow is settable as a percentage of the blood flow either at 0% or in the range 5-30%, provided it is below 4000 ml/h. Modifying the blood flow, the fifth pump flow rate varies maintaining constant the percentage with respect to the blood flow unless exceeding the maximum permitted value; in this case, the treatment is suspended (blood pump at minimum speed) and you are asked to set compatible values for the pre-dilution and blood flows (see alarm 403 in par. 10.11).

4. UF flow = infusion flow + weight loss
   UF flow = infusion flow - weight gain
   Pre-infusion flow = infusion flow - post-infusion flow
   The infusion flow is calculated by the system, starting from the UF flow and weight loss values set, and is the flow supplied by the infusion pump. The post-infusion flow is calculated by the system, starting from the calculated infusion flow and the percentage pre-infusion flow value set, and is the flow supplied by the post-infusion pump.

5. If as a result of modification of the blood flow value or the pre-infusion ratio, the UF flow value exceeds the maximum UF flow, the system signals the inconsistency and asks you to program compatible values for the weight loss, UF flow and blood flow (see alarm 401 in par. 10.11).

6. **The actual UF flow supplied by the UF pump takes into account the UF flow set as well as any pre-dilution flow set.**

7. **The actual blood flow supplied by the blood pump takes into account the blood flow set as well as any pre-dilution flow set.**

8. **If after setting or modifying the value of one or more parameters, a limit to a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.**

9. The recommended minimum blood flow value indicated on the relative numerical keypad is calculated as ((10/3)*UF flow) ml/min; the recommended maximum blood flow value indicated on the relative numerical keypad is calculated as (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

SCUF

Small filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 3 and 5)	100	30	250
Weight loss (ml/h) (see Note 2)	0	50	Minimum between 1000 and 0.3*blood flow
Pre-dilution flow (%)	0	0; 5	30 (see Note 1)
Min. access pressure (mmHg)	-200	-300	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	150	0	300

Medium filter

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 3 and 5)	150	30	450
Weight loss (ml/h) (see Note 2)	0	50	Minimum between 2000 and 0.3*blood flow
Pre-dilution flow (%) (see Note 2)	0	0; 5	30 (see Note 1)
Min. access pressure (mmHg)	-200	-300	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. hemofilter TMP (mmHg)	200	0	400

NOTES:

1. The pre-dilution flow is settable as a percentage of the blood flow either at 0% or in the range 5-30%, provided it is below 4000 ml/h. Modifying the blood flow, the fifth pump flow rate varies maintaining constant the percentage with respect to the blood flow unless exceeding the maximum permitted value; in this case, the treatment is suspended (blood pump at minimum speed) and you are asked to set compatible values for the pre-dilution and blood flows (see alarm 403 in par. 10.11).

2. **The flow supplied by the UF pump takes into account the weight loss and any pre-dilution flow set.**

3. **The actual blood flow supplied by the blood pump takes into account the blood flow set as well as any pre-dilution flow set.**

4. **If after setting or modifying the value of one or more parameters, a limit to a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.**

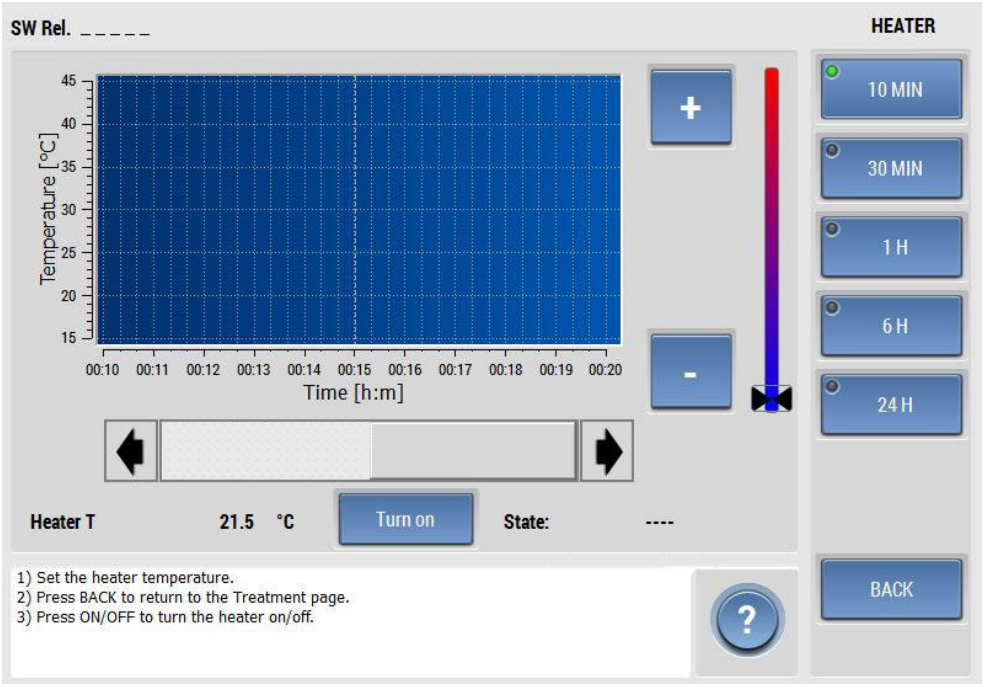
5. The recommended minimum blood flow value indicated on the relative numerical keypad is calculated as ((10/3)*UF flow) ml/min; the recommended maximum blood flow value indicated on the relative numerical keypad is calculated as (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

5.2 FUNCTION BUTTONS

The function buttons on the right of the “start treatment” and “treatment started” pages allow access to other pages and functions.

5.2.1 Heater

The button is available on both the “start treatment” and the “treatment started” page.
Pressing this button, you access a page from where you can turn the heater on and off. This page also displays a graph showing the temperature over time.



You can select six temperature levels that cover a range between 30 and 41°C.
The outgoing fluid temperature measured is shown at the bottom of the page.
The fluid heater is on at minimum level by default.
To turn on the heater:

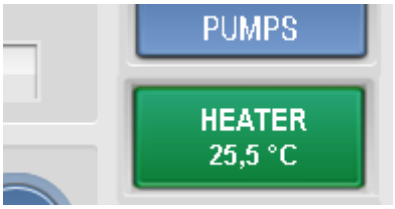
- Press the ON/OFF button (at the bottom of the page) and confirm.
- Select the desired temperature (by pressing the + and – buttons to the right of the graph) and confirm.

To turn off the heater, press the ON/OFF button again and confirm.
The heater status is indicated next to the ON/OFF button:

- ON indicates that the heater is on
- OFF indicates that the heater is off
- DEACTIVATED indicates that the heater is inactive as it has not passed the test during priming.

The temperature graph in the centre of the page allows viewing the actual **outgoing fluid temperature.**

During treatment, the HEATER button is green if the heater is on. It also shows the actual outgoing fluid temperature.



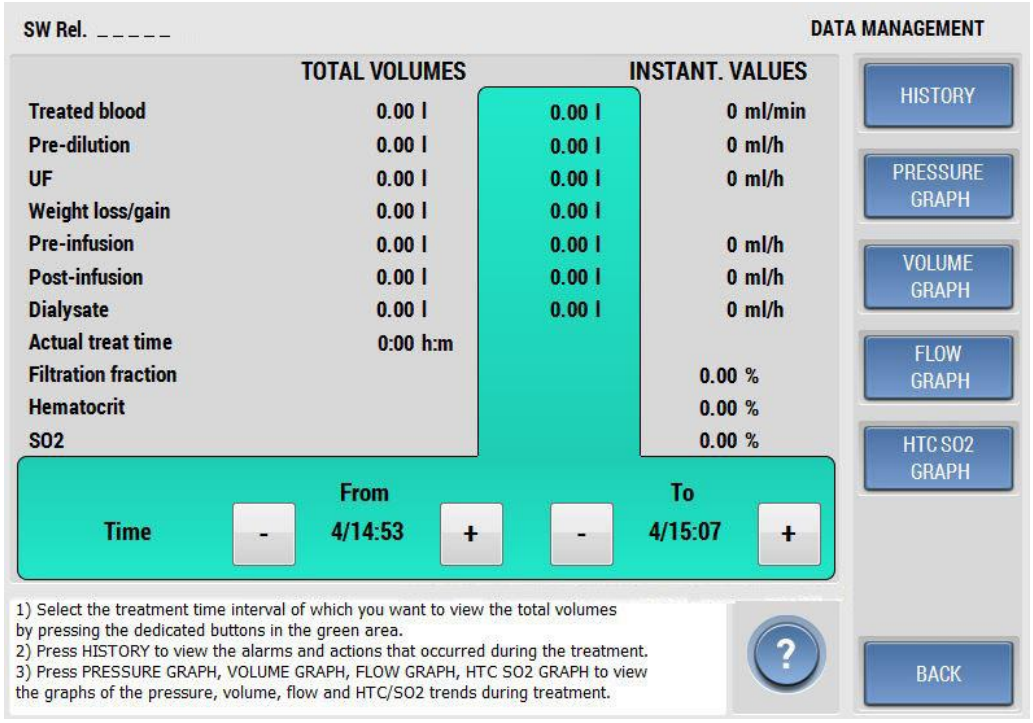
WARNING
When the infusion fluid temperature falls below 33.5°C, the system informs you by turning the word HEATER on the button into yellow and showing the button with a yellow border.

WARNING
If the pressure in the upper cassette is less than 10 mmHg, the heating capacity of the heater could be reduced and hence the temperature of the outgoing replacement fluid might differ from the temperature displayed by one or more degrees. The system informs you of this difference by changing the HEATER button to yellow.

5.2.2 Data

The button is available on both the “start treatment” and the “treatment started” page.
Pressing this button, you access the relative page where the following are shown:

- The total volume of the fluids (left column)
- The volume of the fluids of a certain period (central green section of the page)
- The instantaneous flow values (right column).



Pressing the corresponding buttons (Function Button area) on this page, you can access the pages containing, respectively:

- The pressure graphs
- The volume graphs
- The flow graphs
- The hematocrit and oxygen saturation graphs
- The treatment history, which lists:
    1. All the actions performed (e.g. buttons pressed) up to that moment
    2. All the parameter modifications made up to that moment
    3. All the alarm events that occurred up to that moment.

These data remain in memory also after the end of the treatment.

The pages containing the graphs allow selecting the time interval within which to display the relative graph.

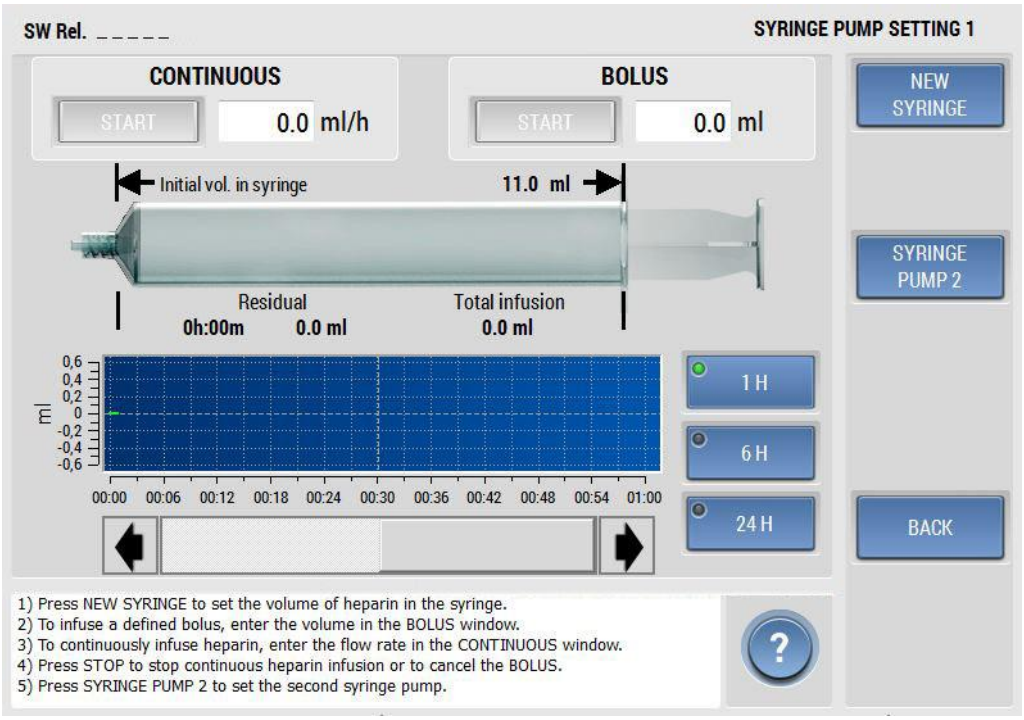
WARNING
Having selected systemic anticoagulation, in case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate,AMPLYA does not control the amount of citrate or calcium necessary nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

5.2.3 Syringe pumps

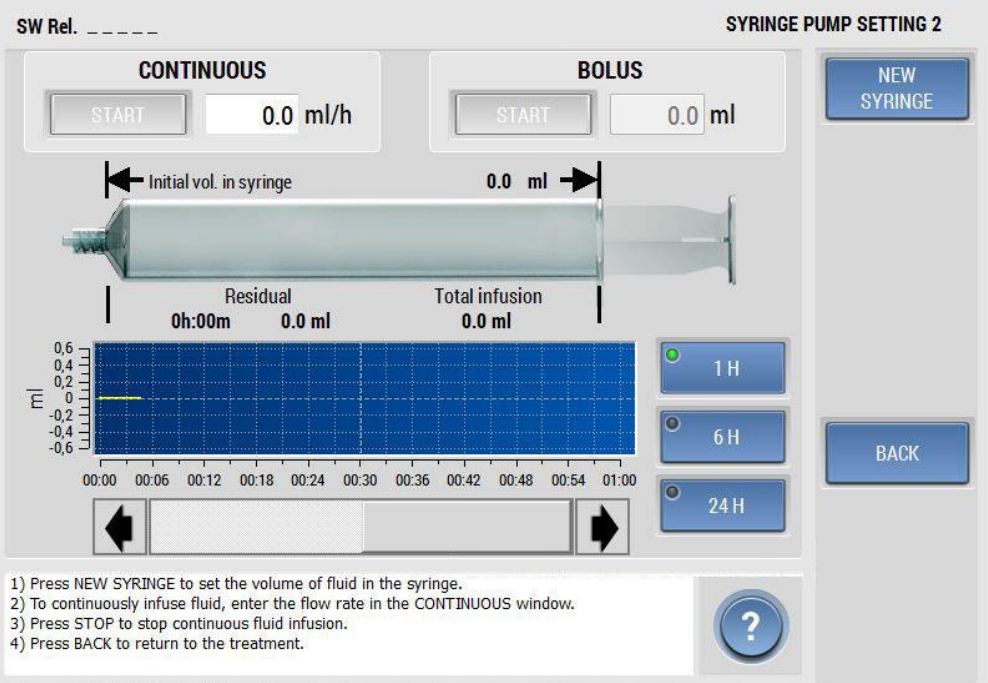
The SYRINGE PUMPS button is available on both the "start treatment" and the "treatment started" page.
Pressing this button, you access a page from where you can:

- Control the syringe pumps by setting continuous infusion and/or bolus infusion.
- Install a new syringe.
- Replace a syringe.
- Set the volume contained in the syringes installed in the pumps.

When at least one of the two pumps is active, the SYRINGE PUMPS button is green. If only one of the two pumps is active, the infusion flow of that pump is shown on it.
Pressing the SYRINGE PUMPS button, you directly access the page where you can set heparin infusion by means of syringe pump 1. This page displays a graph showing heparin infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 1 setting" page, you can replace and/or install a new syringe in syringe pump 1.



Pressing the SYRINGE PUMP 2 button, you access the page where you can set ancillary infusion by means of syringe pump 2. This page displays a graph showing infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 2 setting" page, you can replace and/or install a new syringe in syringe pump 2.



WARNING
Having selected systemic anticoagulation, in case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate,AMPLYA does not control the amount of citrate or calcium necessary nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

Programming heparin infusion (syringe pump 1)
If a syringe has not yet been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows installing a heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:

1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 1 programming page during treatment).
2. Connect the syringe containing heparin to the relative line (leading from the single-use set at the top right).
3. Press on the arrows on the screen to move the syringe pump 1 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger
4. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 1 programming page.
If a syringe has already been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows replacing the heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:

1. If necessary, replace the syringe with another one of the same type containing heparin and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the right-hand syringe pump pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

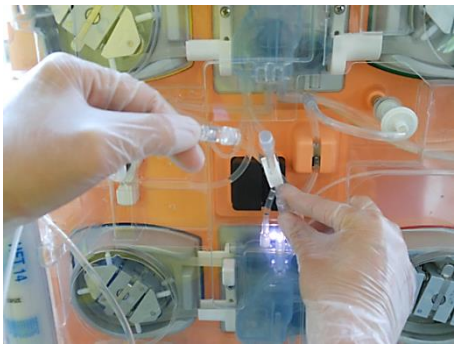
Confirming the settings, you go back to the syringe pump 1 programming page.

Programming ancillary infusion (syringe pump 2)

If a syringe has not yet been installed in syringe pump 2, pressing the SYRINGE PUMP 2 button and then the NEW SYRINGE button, you access a page that allows installing a syringe in the relative pump for ancillary infusion during the treatment.

To install a syringe, operate as follows:

1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 2 programming page during treatment).
2. Connect the syringe for ancillary infusion to the service line of the venous cassette (the connection line can be supplied to the user on request).



3. Press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
4. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

If a syringe has already been installed in syringe pump 2, pressing the NEW SYRINGE button, you access a page that allows replacing the syringe for ancillary infusion during the treatment.

To install a syringe, operate as follows:

1. If necessary, replace the syringe with another one of the same type and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

Replacing one of the syringes
One of the syringes may need to be replaced:
- When the residual syringe content has all been infused.
- If an excessive value has been set for the initial volume of fluid in the syringe, which results in display of an incorrect residual value (different from zero) when the volume available in the syringe has run out.
- If there is an obstruction along the infusion line.

Bolus and continuous infusion
From the "syringe pump 1 setting" page, you can use the numerical keypad to set bolus and/or continuous infusion to the patient during the treatment by means of syringe pump 1.
From the "syringe pump 2 setting" page, you can use the numerical keypad to set continuous infusion to the patient during the treatment by means of syringe pump 2.

NOTE: You cannot set infusion boli by means of syringe pump 2.

The white fields of the *bolus and continuous* areas for syringe pump 1 and *continuous* for syringe pump 2 are active only if a syringe has previously been installed and the residual content in the syringe is not null.
When you program syringe pump 1 to simultaneously perform a bolus and a continuous infusion, the bolus will always be administered first upon treatment start.
During the treatment, you can cancel the bolus set by pressing the STOP button in the corresponding panel (on the right) and/or stop the continuous infusion set by pressing the STOP button in the corresponding panel (on the left). Subsequently, you can reset the bolus so that the system administers it automatically and/or press the START button to resume continuous infusion.

5.2.4 Treatment start

WARNING
Make sure that you have loaded a set consistent with the treatment to be performed (indicated at the bottom left of the screen).

To start the treatment, press the START button on the "start treatment" page.
When you press the button, you are asked to check the connections of the access and return lines to the patient (see *patient connection* below) and to confirm that they are properly connected. Once confirmed, the system starts the treatment. In the initial transition phase:

1. Syringe pump 1 starts at the same time as the blood pump, which gradually increases its speed.
2. After reaching the blood flow set for the treatment, the exchange pumps and syringe pump 2 (if set) start (in the order described in par. 5.1.1).

NOTE: In CPFA, the ideal weight must be set in order for the treatment to start when pressing the START button (see par. 5.1.4).

Patient connection
The patient is to be connected during treatment programming ("treatment started" window).
To connect the patient:

1. Close the electroclamp of the access line, the electroclamp of the multi-way line on the infusion side to which the access line is connected, the electroclamp of the return line and the electroclamp of the multi-way line on the UF side to which the return line is connected.
2. Disconnect the access line from the multi-way line on the infusion side and the return line from the multi-way line on the UF side.
3. Connect the access and return lines to the patient's catheter and open the respective electroclamps.

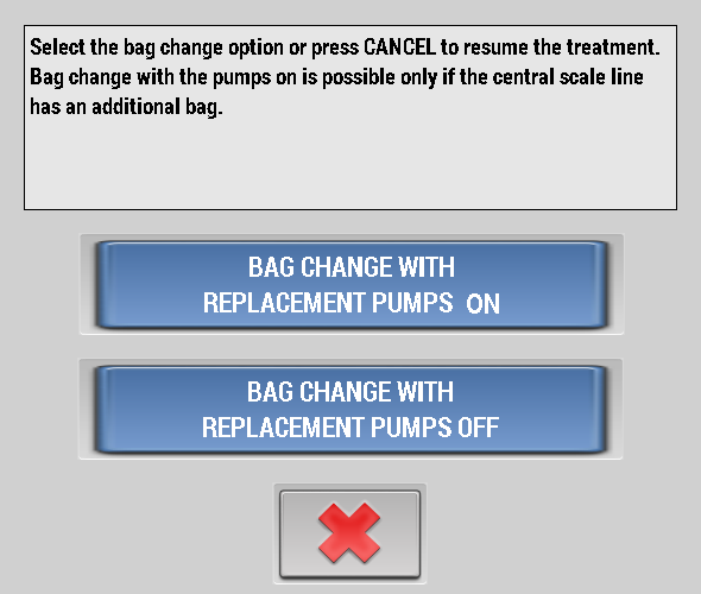
CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

5.2.5 Bag change

Press CHANGE BAGS on the "treatment started" page to replace the bags. The bags may need to be changed if they are full (collection bags) or almost empty (infusion bags).

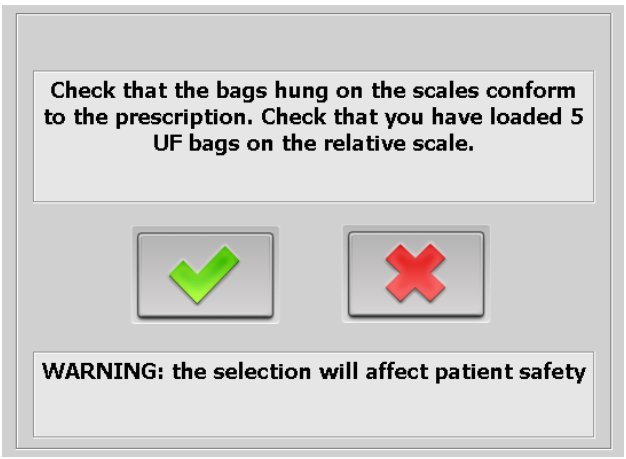
Pressing the button, a panel is displayed where you can select the bag change mode: **bag change with pumps off** and **bag change with pumps on**.



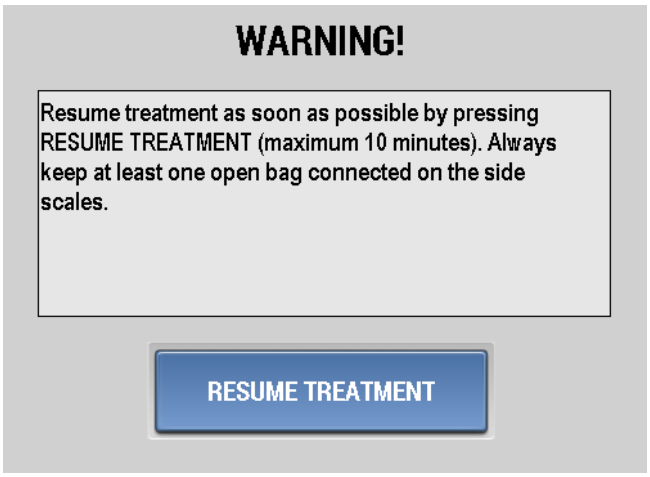
- Pressing the BAG CHANGE WITH REPLACEMENT PUMPS OFF button activates an acoustic signal and stops the exchange pumps except:
    - The blood pump, which continues running at the set speed in CPFA and at reduced speed in RRT.
    - Only in CPFA, the plasma pump, which continues running at the speed calculated from the percentage blood flow value.

  In this way, the machine goes into PAUSE mode during which a message is shown on the screen warning you to resume treatment as soon as possible.

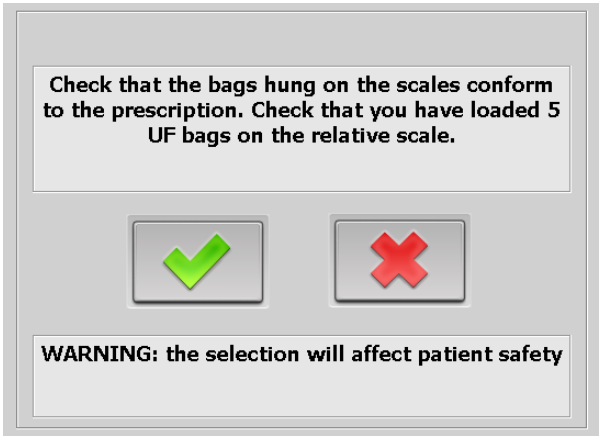
When you have pressed the RESUME TREATMENT button, the system reminds you to check that the bags connected to the circuit conform to the prescription.



- Pressing the BAG CHANGE WITH REPLACEMENT PUMPS ON button, the machine sets the pump speed so as to maintain the average flows prior to pressing the button and does not take into account the weight variations detected on the scales.
  NOTE: Bag change mode with the pumps on is only available if the central scale is active.
  A message is shown on the screen warning you to complete the bag change as soon as possible and to check that there is at least one open bag on the side scales. The treatment continues in this mode for maximum 10 minutes after which the bag change mode with the pumps off is automatically activated. Alarm 1079, activated after 8 minutes, warns you that you are about to go into bag change mode with the pumps off.



When you have pressed the RESUME TREATMENT button, the system reminds you to check that the bags connected to the circuit conform to the prescription.



NOTE: The BAG CHANGE WITH REPLACEMENT PUMPS ON button is active only when all the safety conditions have been checked. In particular:

- Constant pump speed
- More than 10 minutes bag autonomy
- Absence of alarms in the 4 minutes prior to pressing the button
- Less than 4 bag changes with the pumps on in the last 7 hours.

Should the button temporarily not be active, it is advisable to wait for it to reactivate.

WARNING
Check that all the bags have been loaded on the relative scales and that they do not touch other parts of the machine or bags on other scales.

5.2.6 Blood pump stop

To stop the blood pump at any time, press the STOP BLOOD PUMP button on the "treatment started" page.

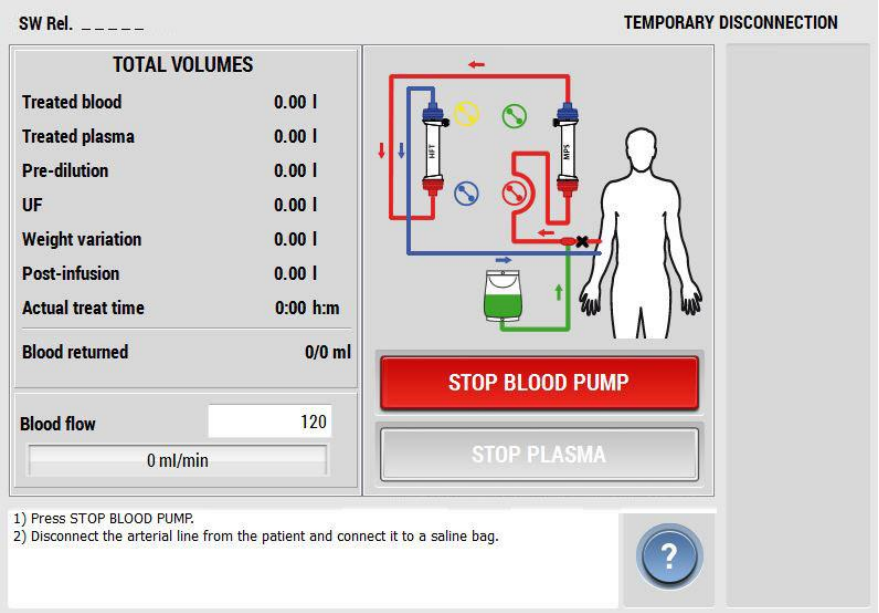
Use this button only when an unexpected event occurs and not to replace the bags (see par. 5.2.5, CHANGE BAGS button).
When you press this button, the system stops the pumps and warns you of the risk of the blood coagulating because of an extended blood pump stop by means of an acoustic signal, a yellow warning light and a message on the screen.

5.2.7 Temporary disconnection

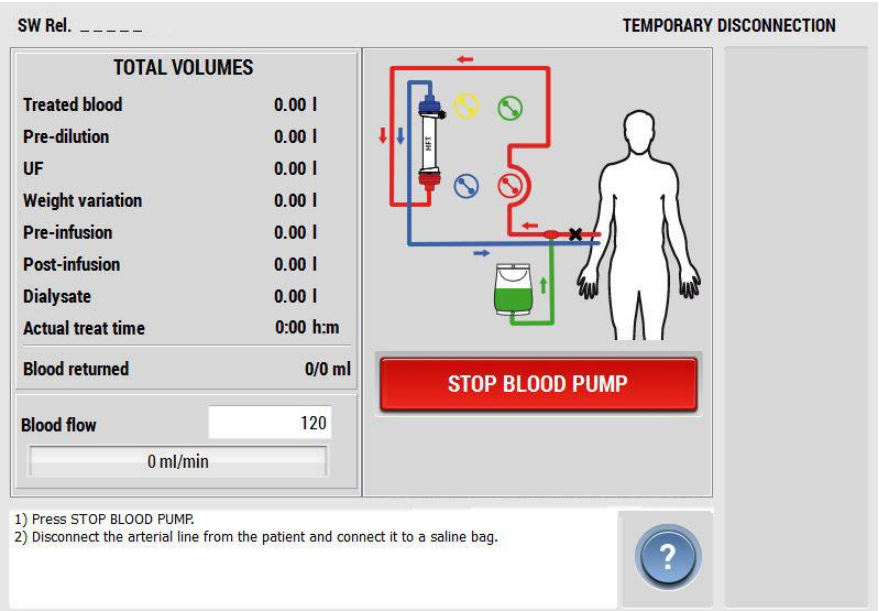
To disconnect the patient at any time, press the TEMPORARY DISCONNECTION button on the "treatment started" page. The function of this button is to allow you to return the blood to the patient following an unexpected event that requires patient disconnection.

Pressing this button, you access a page that allows you to return the blood to the patient.

In CPFA, the page appears as shown in the image below.



In RRT, the page appears as shown in the image below.



When you access the blood return page, the exchange pumps stop.

From the blood return page, if you have decided to disconnect the patient, operate as follows:
1. Press the STOP BLOOD PUMP button to stop the blood pump.
2. Disconnect the access line (red) and connect it to a saline bag.
3. Press BLOOD RETURN (RRT) or START RETURN (CPFA).

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

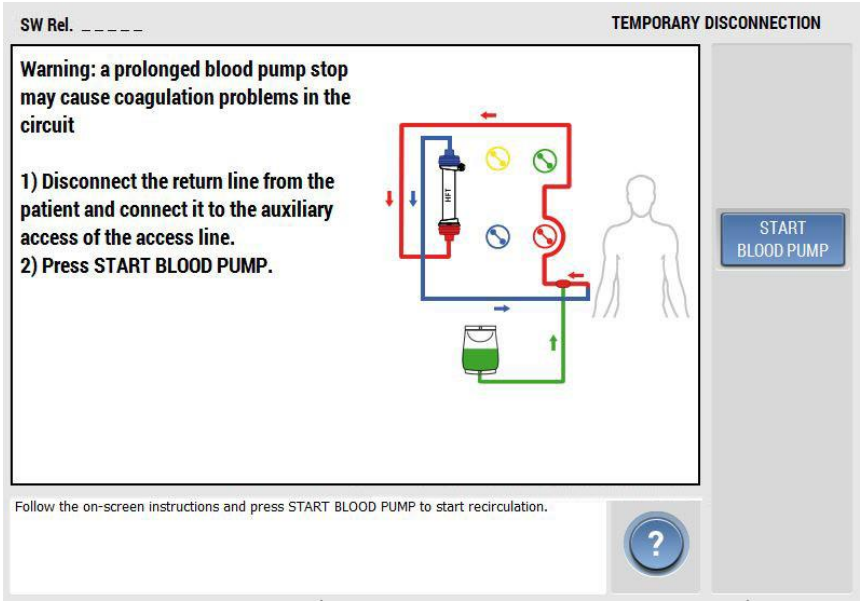
NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

WARNING
The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.

In CPFA, when blood return has started, you can stop plasma return by pressing the button that stops the plasma pump.

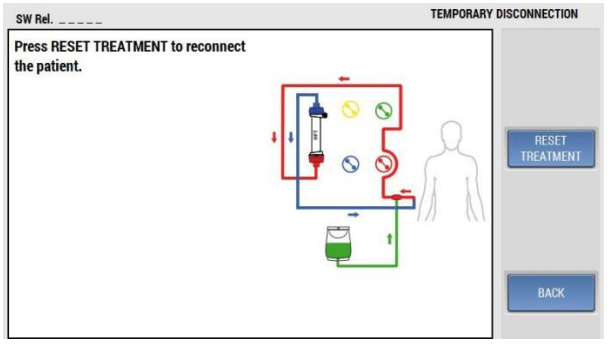
At any time during blood return you can:
- In RRT, stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood return (BLOOD RETURN button).
- In CPFA, stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood and plasma return (START RETURN button) or only blood return (BLOOD RETURN ONLY button).
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

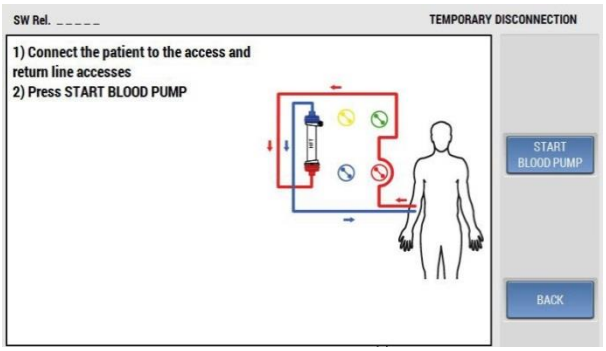
When blood return has been completed:
1. Disconnect the patient from the return line.
2. Connect the return line to the branch on the arterial line.
3. Press the START BLOOD PUMP button to restart the blood pump and allow recirculation of any blood that has remained in the circuit so that it cannot coagulate while waiting for patient reconnection.



When the patient is ready to be reconnected to the circuit, operate as follows:

- Press RESUME TREATMENT
- Connect the catheter accesses to the access and return lines
- Press START BLOOD PUMP to restart all the pumps and resume the treatment.





CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

1. **Use aseptic techniques that prevent cross-infections between patients**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

5.2.8 End of treatment

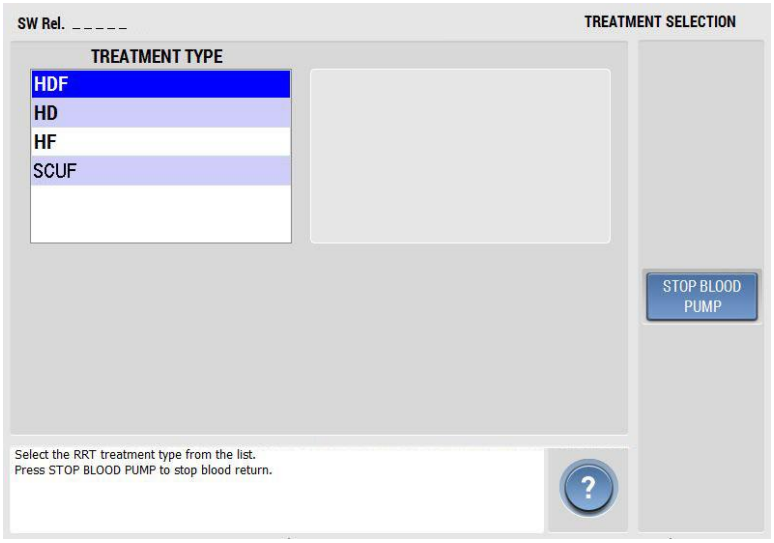
To end the treatment at any time, press the END TREATMENT button on the "treatment started" page.

During an RRT treatment, pressing this button allows you to select whether to:
- Change the treatment (see "Changing the treatment" below).
- End the treatment (see "Ending the treatment" below).

NOTE: The treatment can be changed only in case of systemic anticoagulation.

During a CPFA treatment, pressing this button allows you to:
- Confirm the selection to end the treatment (see "Ending the treatment" below)
- Cancel the selection to resume the treatment.

Changing the treatment
Confirming the selection to change the treatment, the machine stops the dialysis pumps and reduces the blood flow to 80 ml/min. You access the "treatment selection" page as shown below.



NOTE: You can only select a treatment of the same type (continuous or intermittent) as the treatment just ended. In other words, you can select the CVVHDF, CVVHD, CVVH and SCUF treatments only if the previous treatment was continuous, and the IHDF, IHD-SLED and IHF-HVHF treatments only if the previous treatment was intermittent.

For a detailed description of the operations to be performed to select the treatment, see paragraph 4.7.2.

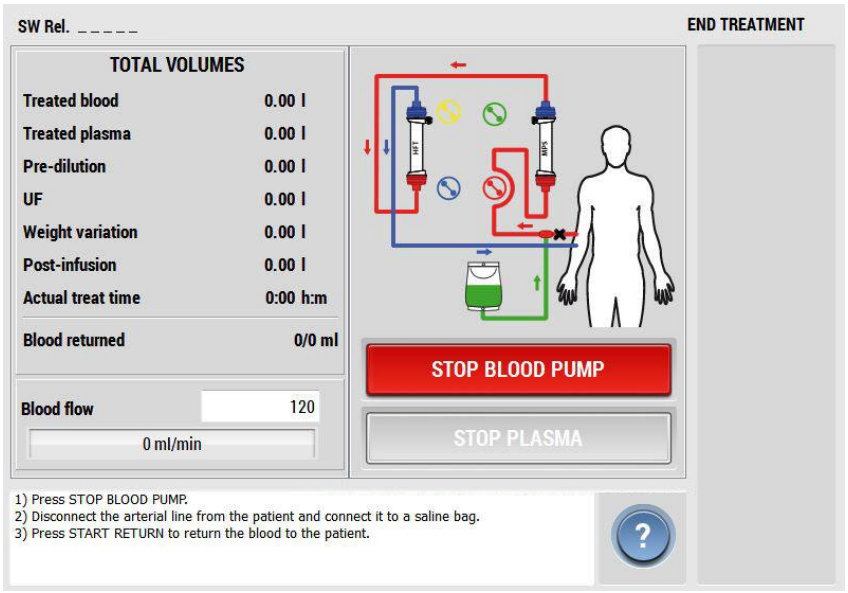
NOTE: The STOP BLOOD PUMP button is active throughout the treatment change procedure so that you can press it in case of an emergency.

Once you have selected the new treatment, you access the “treatment” page where the scale weights are re-acquired and you restart, as after a bag change, with the pumps off. The weight loss/gain parameters, treatment time, pre-dilution flow, heparin infusion, scale and pressure alarm settings remain unchanged with respect to the previous treatment. On the contrary, the machine suggests new dialysate flow, blood flow and UF flow values.

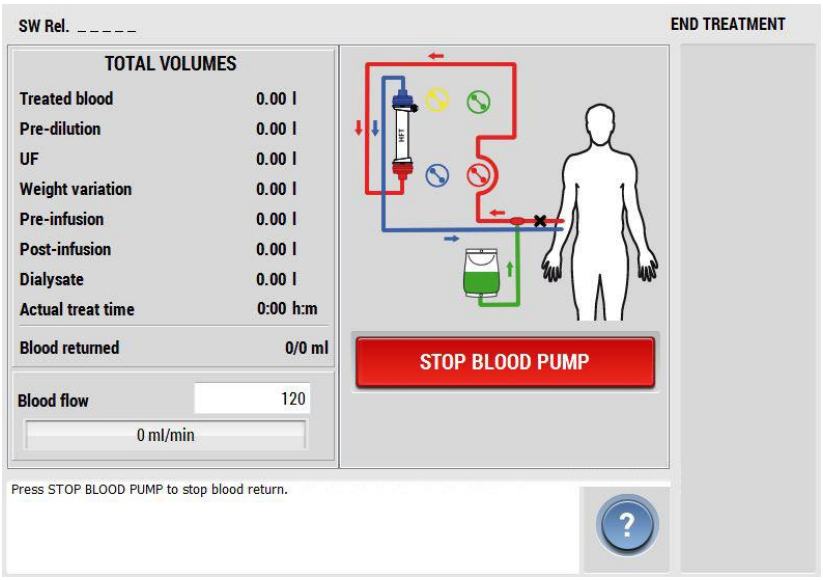
Ending the treatment

Confirming the selection to end the treatment, you access a page that allows you to return the blood to the patient.

In CPFA, the page appears as shown in the image below.



In RRT, the page appears as shown in the image below.



When you access the blood return page, the exchange pumps stop. From this page you can:
1. Press the STOP BLOOD PUMP button to stop the blood pump
2. Disconnect the access line (red) and connect it to a saline bag
3. Press START RETURN.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

WARNING:
1. **The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.**
2. **It is of fundamental importance that the blood return procedure be correctly carried out before disconnecting the power in order to prevent needless patient blood leakage.**

In CPFA, when blood return has started, you can stop plasma return by pressing the button that stops the plasma pump.

At any time during blood return you can:
- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood and plasma return (START RETURN button) or only blood return (BLOOD RETURN ONLY button).
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

NOTE: in CPFA, pressing the STOP BLOOD PUMP button, the blood pump will stop as well as the plasma pump if it is running.

During this pause phase, only the following alarms are active:
- Access and return pressure alarms
- Air alarm.

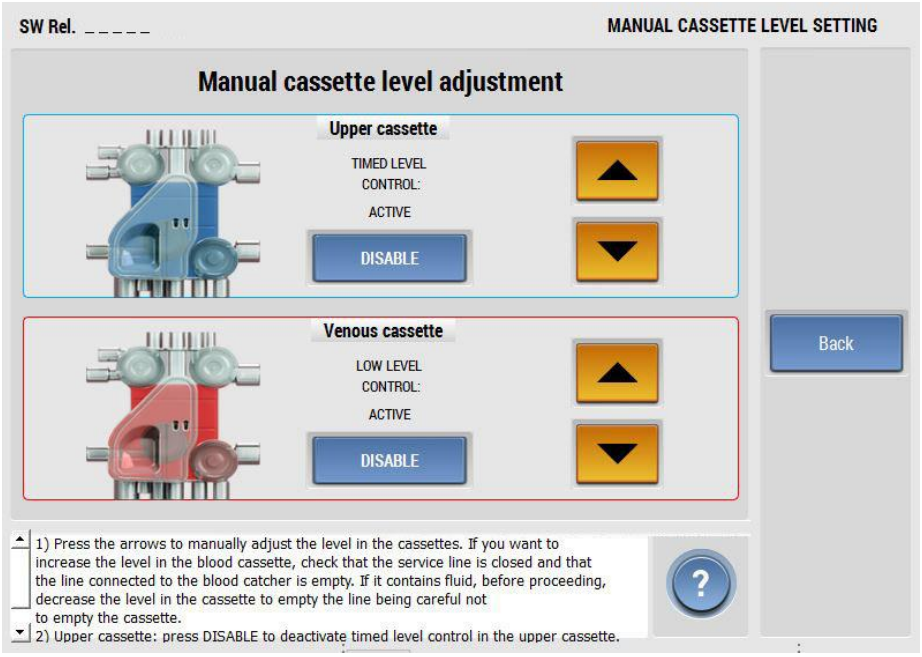
CAUTION
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

When blood return is complete, you access a page containing a sequence of illustrated instructions for removal of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.
From this page you can remove the set, once you have disconnected the lines as illustrated in the instructions, by pressing REMOVE SET. When you press this button, you access a page informing you that the treatment has ended and that you can turn off the machine using the switch on the rear (see REAR VIEW in Chapter 2 Machine Presentation).

5.2.9 Chamber levels

Pressing the CHAMBER LEVELS button, you access a page where you can manually adjust the levels in the venous cassette and the level in the upper cassette using the relative buttons to raise and lower the level. From this page you can also disable level control of each cassette by pressing the dedicated button.



5.3 ROUTINE OPERATIONS DURING TREATMENT

During the treatment, some routine operations must be performed to safeguard the patient.

5.3.1 Patient temperature check

Throughout the treatment the patient's temperature must be checked whenever the situation requires.
The machine is equipped with a heater which must be used to prevent the patient from getting cold when this is undesirable for clinical reasons.
Use of the heater is described in paragraphs 2.1 and 5.2.1 in this manual.

5.3.2 Patient fluid balance check

Throughout the treatment it must be checked that the patient's fluid balance is between values that cannot cause harm to the patient. If you have any doubts about the fluid balance, the treatment MUST immediately be interrupted.
In particular, in the event that alarms occur indicating that the patient weight cannot properly be controlled, the actual clinical conditions of the patient MUST be checked.
You also need to check that the weight variation specified in the treatment is always adequate for the clinical conditions of the patient.

5.3.3 Pressure check

Right from the beginning of the treatment, the pressure values must be checked to verify that they fall within an acceptable range.

It is recommended to:
- **Operate the machine within the minimum and maximum default values for the access, return, TMP and trans-cartridge pressures (see par. 5.1.6).**
- **Pay particular attention to haemolysis phenomena if the TMP values of the plasma filter exceed 50 mmHg.**

To adjust the alarm limits both before the treatment starts and during the treatment, operate as described below:
1. Press on the Pressures panel on the treatment page to access the page where to set the pressure limits (see par. 5.1.3)
2. Set the new limits with respect to the return and access pressures measured
3. Confirm the modified values and go back to the treatment page.

WARNING
In some cases, the access pressure can be relatively high and the return pressure relatively low. In this condition, if the maximum access pressure limit is > -10 mmHg and/or the maximum return pressure limit is < +10 mmHg, an alarm message informs you that the system may be unable to signal patient disconnection. If the data is confirmed, the Pressures panel on the treatment page turns red to indicate that the alarm limits are potentially hazardous.

WARNING
In the case of a CPFA/RRT treatment with ECMO, the access pressure may also reach values higher than the maximum absolute limit (defined by the system and hence not settable), therefore the maximum access pressure parameter cannot be set by the operator. The Pressures panel on the Treatment page is red to indicate that this configuration is potentially hazardous: in fact, the maximum access pressure alarms are not active (see alarms 202 and 302 in par. 8.11).

CAUTION
Inadequate setting of the access and return pressure limits may reduce the system's ability to detect any disconnected blood lines.

CAUTION
Access and return pressure monitoring is not always able to detect disconnection of the access or return line from the relative patient access. Disconnection results in blood leakage into the surrounding environment.
Disconnection of a line from the relative patient access may cause a decrease (return) or an increase (access) in the relative pressure although it remains within the permitted alarm range. In this case, therefore, the machine is unable to detect disconnection despite the alarm thresholds being set correctly.
In order to reduce the risk of the access and return lines disconnecting from the relative access:

- Check that the access and return lines are properly connected to the relative access on the patient side by means of their fastening ring nut;
- Check that the patient access and return accesses are visible at all times during the dialysis treatment;
- Frequently check the patient access and return accesses;
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limits for both pressures as close as possible to the actual value of the relative pressure of the patient in order to avoid the alarm from continuously intervening.

When you set a return pressure threshold below 10 mmHg or an access pressure threshold above -10 mmHg, the system warns you that the machine may not detect any disconnection on the patient side. With these pressure limit values, the operator is hence responsible for constantly monitoring the access and return pressures.

In order to reduce the risk of access and return line disconnection:
- Check that the patient accesses and relative lines are properly connected as prescribed by the protocol of your clinic.
- Check that the patient accesses are visible at all times during the dialysis treatment.
- Frequently check the patient accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limit for the return pressure and the maximum alarm limit for the access pressure as close as possible to the actual value of the respective pressures on the patient.

5.3.4 Replacing the fluid bags

The bags containing the replacement fluid and/or waste fluid can be replaced at any time. The machine generates an alarm when the replacement fluid bags are empty and the waste bags are full.
To change the bags at any time, operate as follows:
1. Press the CHANGE BAGS button and select the bag change mode (see par. 5.2.5)
2. Replace the bags and make sure that the new bags conform to the prescription (as requested by the system via a warning window)
3. Press the RESUME TREATMENT button in the window that appeared when you pressed the CHANGE BAGS button (see par. 5.2.5).

WARNING
Check that all the bags loaded are on the relative scales and that they do not touch other parts of the machine or bags on other scales.

5.4 END OF TREATMENT

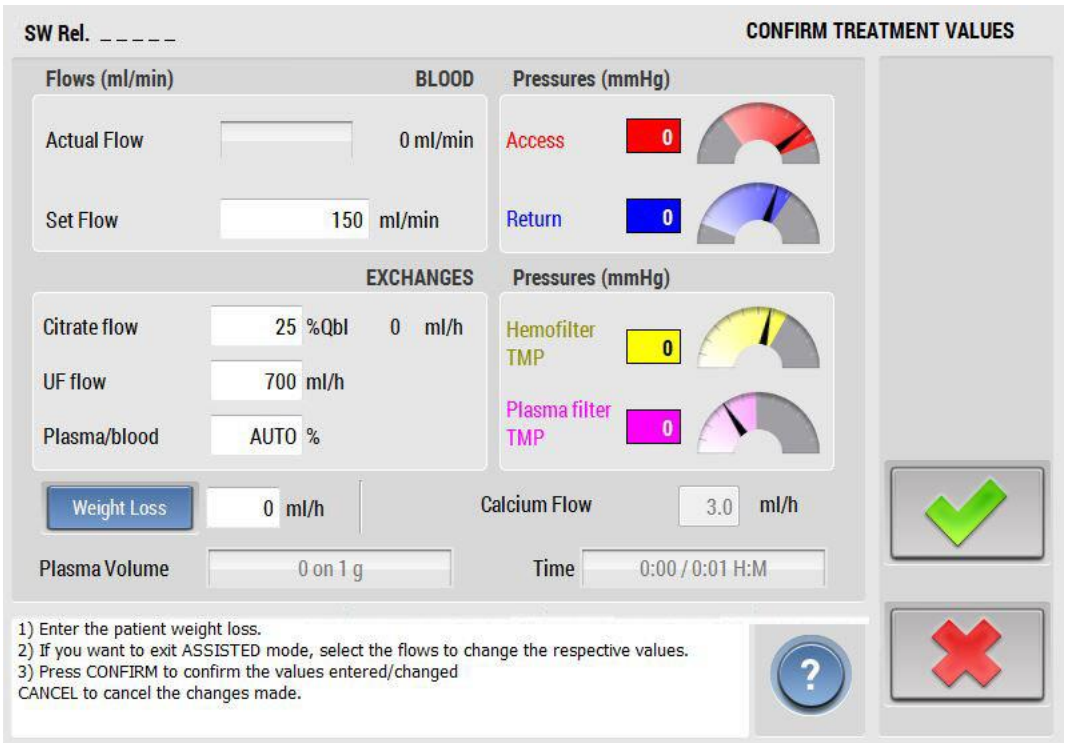
In CPFA, the system informs you when you reach 24 hours of treatment. Subsequently, you are informed every half an hour of the time elapsed after the 24 hours.

In intermittent RRT treatment, the treatment automatically ends when the **Remaining time** parameter reaches 0:
- All the pumps stop except the blood pump that runs at minimum speed.
- A yellow warning light on the monitor informs you of the end of the treatment.
- You can reset the time if the treatment lasted less than 24 hours (maximum time settable for an intermittent treatment) or press the END TREATMENT button to confirm the end of the treatment (see par. 5.2.8).

6 PERFORMING A CPFA/RRT TREATMENT WITH LOCAL-REGIONAL ANTICOAGULATION

If you have selected a CPFA treatment with local-regional anticoagulation, pressing the TREATMENT button from the End Rinse page, you access a page where you need to set the sex, height and age of the patient in order to allow the system to calculate the "ideal weight". The system requires the ideal weight for calculation of the target plasma volume (200 ml of plasma per kg of ideal weight) and, specifically for ASSISTED mode, calculation of other treatment flows (see par. 6.1.6).
Confirming the calculated Ideal Weight value, you access a page where to select the type of calcium to be injected during the treatment: you can choose between **calcium chloride** and **calcium gluconate**.
Confirming the type of calcium selected, you access a page where to confirm the values for the treatment parameters.

If the treatment selected is CPFA, the page appears as shown in the image below.

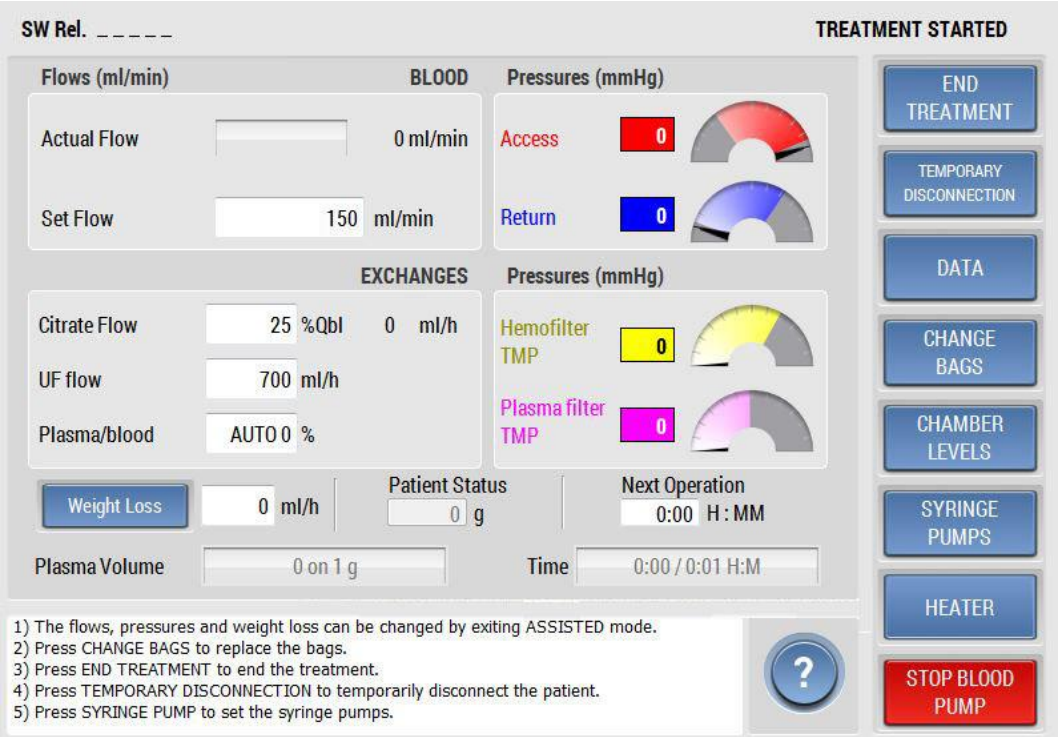


From the "treatment values confirmation" page you can:

- Start the CPFA/RRT treatment in **ASSISTED** mode after confirming the values the system suggests for the exchange flows.
- Start the CPFA/RRT treatment in **UNASSISTED** mode after modifying and confirming the values the system suggests for the exchange flows.

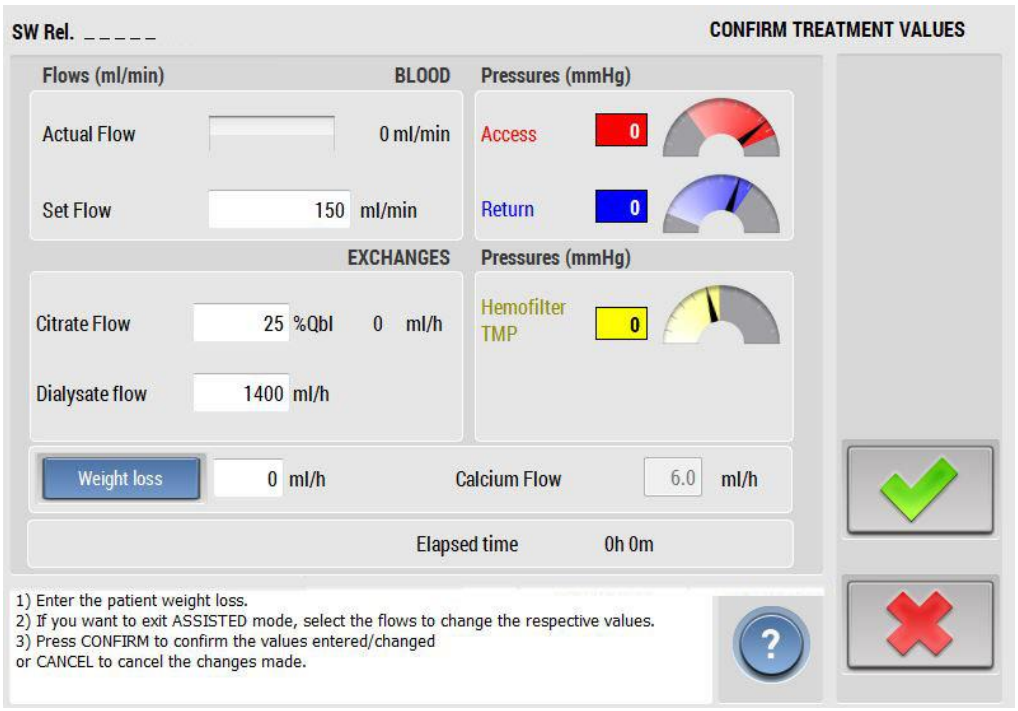
Pressing the CONFIRM button on the "treatment values confirmation" page, you access the "start treatment" page from where you can start the treatment by pressing the START button (Function Button area) and so access the "treatment started" page.

WARNING
Check that the filter connectors are properly screwed on.



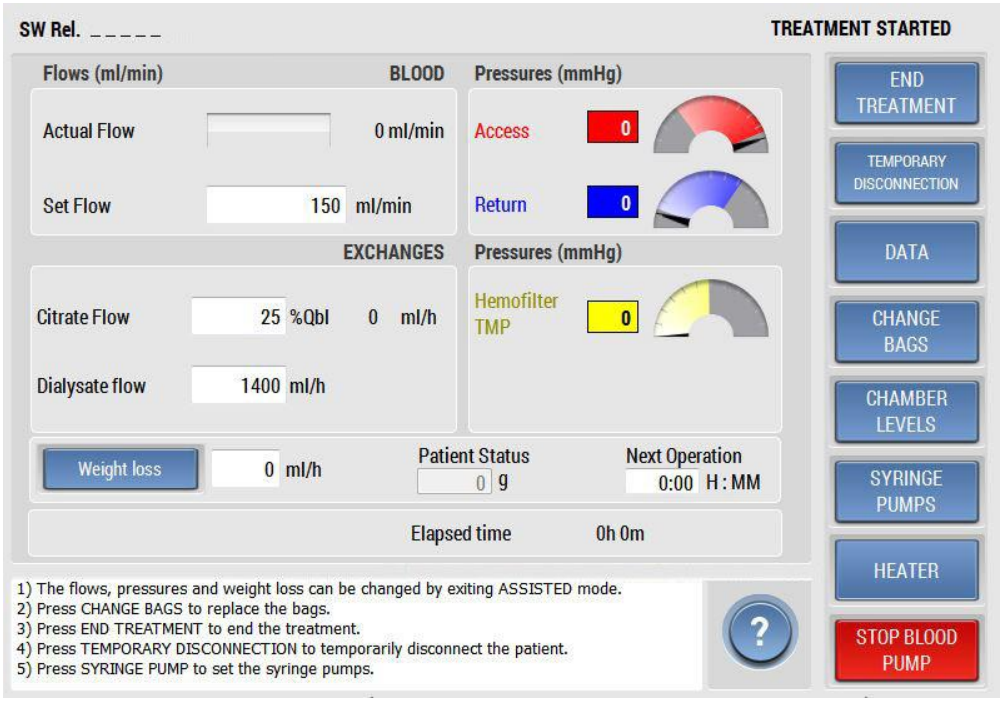
If you have selected an HD, HDF or HF treatment with local-regional anticoagulation in ASSISTED mode (see paragraph 4.7.2), pressing the TREATMENT button from the End Rinse page, you access a page where you need to set the sex, height and age of the patient in order to allow the system to calculate the "ideal Weight". Specifically for ASSISTED mode, the system requires the ideal weight for calculation of the treatment flows (see par. 6.1.6).
Confirming the calculated Ideal Weight value, you access a page where to select the type of calcium to be injected during the treatment: you can choose between **calcium chloride** and **calcium gluconate**.
Confirming the type of calcium selected, you access a page where to confirm the values for the treatment parameters.

If the treatment selected is HD, the "treatment values confirmation" page appears as shown in the image below.



The page structure is the same for HF and HDF treatment. Only some of the parameters displayed change.

Pressing the CONFIRM button on the "treatment values confirmation" page, you access the "start treatment" page from where you can start the treatment by pressing the START button (Function Button area) and so access the "treatment started" page.



The page structure is the same for HF and HDF treatment. Only some of the parameters displayed change.

The "start treatment" and "treatment started" pages are structured as follows:
- An *active* area divided into four control blocks (blood, exchange, fluid balance and time) where the characteristic parameters of the selected treatment and the respective values are shown.
- A *function button* area to the right of the four blocks with buttons that offer access to some useful treatment functions.
- An *information* area at the bottom where the treatment name and power supply (mains or battery) are shown.

The flow and pressure parameters are shown in the various control blocks.
Some of the parameters displayed allow you to monitor treatment progress (therefore, before starting the treatment, their value is zero).
Other parameters are settable/modifiable by the operator using the *numerical keypad* (see par. 4.3) after pressing on the corresponding white field.

6.1 TREATMENT PARAMETERS

6.1.1 Blood

The blood control parameters are shown under BLOOD at the top of the active area of the "start treatment" and "treatment started" pages.
The actual flow and the set flow expressed in ml/min form part of the "Flows" panel.
The **actual flow** indicates the actual blood pump flow supplied by rotation of the pump during the treatment (therefore it is 0 before treatment start when the pumps are all off). During treatment, the value of this parameter allows you to monitor the blood flow instant by instant.
The actual flow depends on the access pressure, the blood pump speed and deterioration of the relative line.

The **set flow** indicates the blood flow operating value desired for the specific treatment. The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment. The blood flow numerical keypad also indicates the minimum and maximum values within which it is recommended to set the blood flow.

The access pressure and the return pressure expressed in mmHg form part of the "Pressures" panel.
The **access pressure** is the pressure, monitored during treatment, before the blood pump at the blood inlet to the extracorporeal circuit.
The **return pressure** is the pressure, monitored during treatment, in the venous cassette before the blood is returned to the patient through the return line (blue tube section).

When the treatment is started, only the blood pump and syringe pump 1 containing calcium chloride or calcium gluconate (depending on what you selected - see the beginning of this chapter) start. The blood pump gradually accelerates until reaching the operating flow set in relation to the blood pressure variations. After reaching the operating blood flow, the exchange pumps start:

- Infusion pump, UF pump, post-infusion pump (only in RRT treatments), syringe pump 2 (if set) and the fifth pump once the operating blood flow has been reached.
- Plasma pump (only in CPFA treatments) after 8 minutes from reaching the operating blood flow.

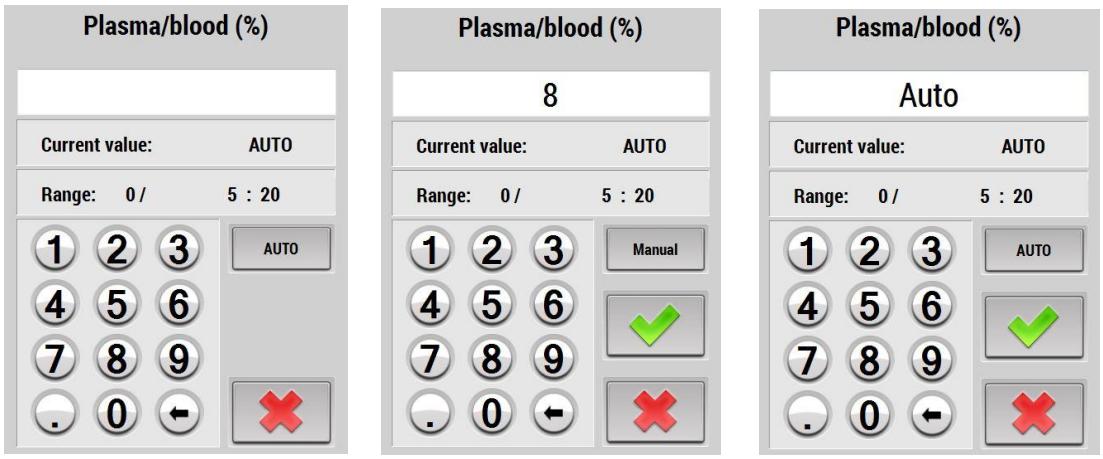
6.1.2 Exchanges

The **exchange** defines the clearance to be achieved by convection, diffusion or adsorption. The exchange mechanism control parameters will hence change in relation to the treatments.
In all cases you can define the clearance by means of a flow in ml/h or as percentage part of the blood flow. In addition, the transmembrane pressure/s are shown.

The exchange control parameters are shown under EXCHANGES in the centre of the active area of the "start treatment" and "treatment started" pages.

In the exchange flows panel:

- In CPFA HF and HDF, the **UF flow** is shown expressed in ml/h. This flow indicates the desired operating value of the ultrafiltrate flow extracted by convection for the specific treatment. The default value is that calculated by the system starting from the ideal weight and weight loss/gain values set and can be modified both during programming and treatment resulting in going from treatment in ASSISTED mode to treatment in UNASSISTED mode (see par. 6.1.6).
- In CPFA, the **plasma flow** *(plasma/blood*) is shown expressed as a percentage of the flow generated by the blood pump and supplied by rotation of the plasma pump. The plasma flow is by default automatically controlled by the system. Automatic plasma flow control consists of a linear increase of the flow for first two hours of treatment (from 13% to 20% of the flow generated by the blood pump) after which the percentage of plasma extracted from the blood is maintained constant (20% of the flow generated by the blood pump). When the word AUTO appears in the white field, it means that automatic plasma flow control is active.
  The percentage plasma flow of the flow generated by the blood pump can also manually be controlled by the operator both during programming and treatment. The keypad used to program the plasma flow has a dedicated button in addition to those described earlier (par. 4.3), which allows changing from automatic to manual flow control and vice versa.
  When plasma flow control is automatic (see keypad image on the left) and you enter a value in the dedicated field of the keypad, the button changes from AUTO to MANUAL (see keypad image in the middle) and confirming the value entered, plasma flow control becomes manual. To go back to automatic control, press the MANUAL button on the keypad and confirm (see keypad image on the right).



- In HD and HDF, the **dialysate flow** is shown expressed in ml/h. This flow indicates the operating value of the replacement fluid flow destined for the dialysate compartment of the hemofilter (where the exchange between the blood and the fluid takes place by diffusion). The default value is that calculated by the system starting from the blood flow and ideal weight values set and can be modified both during programming and treatment resulting in going from treatment in ASSISTED mode to treatment in UNASSISTED mode (see par. 6.1.6).
- In HF, the **pre-infusion ratio** is shown expressed as percentage value of the total infusion flow. This flow is obtained as the difference between the total infusion flow supplied by the top right pump and the post-infusion flow supplied by the bottom left pump and indicates the replacement fluid flow operating value with which the blood is diluted at the hemofilter inlet. The default value is 0 and can be modified both during programming and treatment resulting in going from treatment in ASSISTED mode to treatment in UNASSISTED mode (see par. 6.1.6).
- Both in CPFA and RRT, additional information on the **citrate flow** is shown. This flow, expressed both in percentage of the blood flow and in ml/h, is supplied by rotation of the fifth pump and indicates the desired operating value of the citrate flow at the extracorporeal circuit inlet (before the blood pump) for the specific treatment. The citrate flow can only be set as percentage of the blood flow. The default value is that calculated by the system starting from the blood flow value set and can be modified both during programming and treatment resulting in going from treatment in ASSISTED mode to treatment in UNASSISTED mode (see par. 6.1.6).

The transmembrane pressure or TMP of the hemofilter is shown in the “Pressures” panel. Only in CPFA the TMP of the plasma filter is also shown. The TMP is expressed in mmHg.

The **TMP of the hemofilter** is calculated as the difference between the mean blood pressure in the filter and the pressure of the ultrafiltrate (waste fluid) coming out of the filter.
The **TMP of the plasma filter** is calculated as the difference between the mean blood pressure in the filter and the pressure of the plasma coming out of the filter.

NOTE:
- Both in CPFA and in RRT, the ultrafiltrate pressure is the pressure monitored during the treatment before the UF pump.
- In CPFA, the plasma pressure is the pressure monitored during the treatment before the plasma pump.

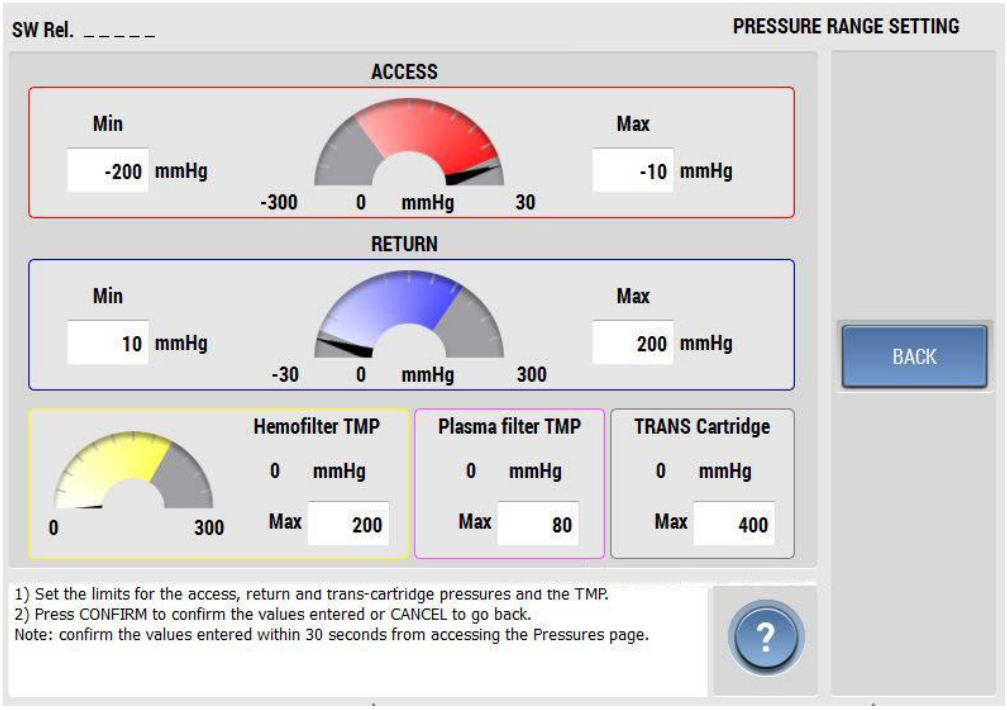
- Both in CPFA and RRT, the mean blood pressure in the filter is calculated between the pressure values at the inlet and outlet of each filter.
- In CPFA, the pressures at the inlet and outlet of the plasma filter are the pressures monitored during the treatment, respectively after the blood pump and in the upper cassette.
- In CPFA, the pressure at the hemofilter inlet is the pressure measured in the upper cassette and the pressure at the hemofilter outlet is the pressure measured in the venous cassette.
- In RRT, the pressure at the hemofilter inlet is the pressure measured after the blood pump and the pressure at the hemofilter outlet is the pressure measured in the venous cassette.

WARNING
In UNASSISTED mode, in case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate, AMPLYA does not control the amount of citrate or calcium necessary nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

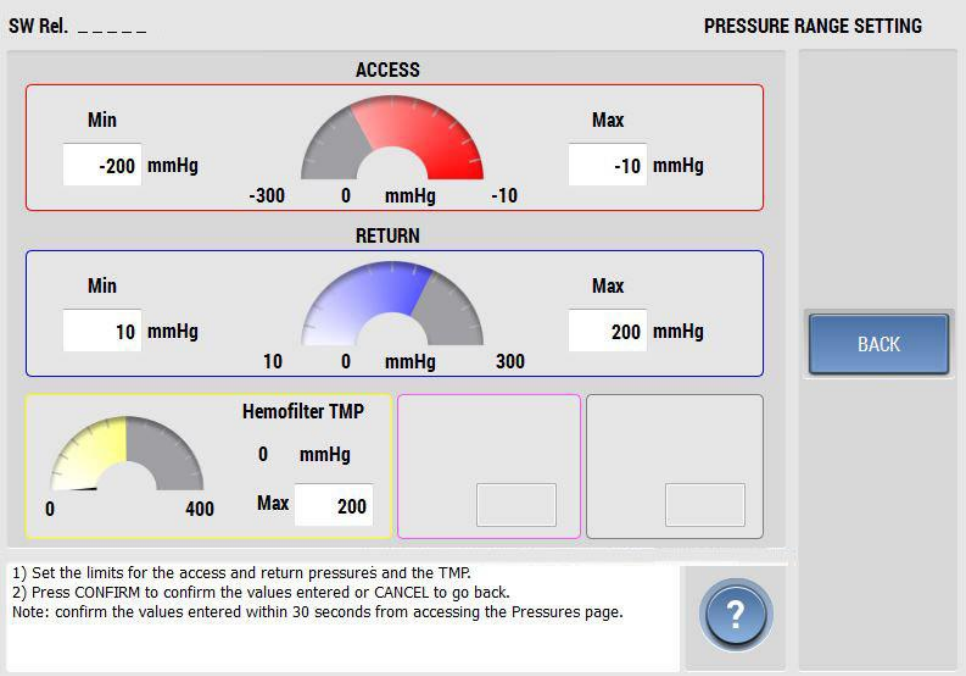
6.1.3 Pressure

Both during programming and treatment, pressing on the Pressures panels relating to blood and exchange control, you access the pressure range page.

In CPFA, the page appears as shown in the image below.



In RRT, the page appears as shown in the image below.



On this page you can view and set:

- The minimum and maximum permitted access and return pressures
- The maximum permitted transmembrane pressures
- Only in CPFA, the mean pressure of the plasma in Mediasorb indicated as trans-cartridge pressure (calculated as difference between the pressures at the inlet and outlet of the cartridge).

NOTE: In CPFA, the pressures at the inlet and outlet of the cartridge are the pressures monitored during the treatment after the plasma pump and in the upper cassette, respectively.

To set the minimum and maximum values, see par. 6.3.3.

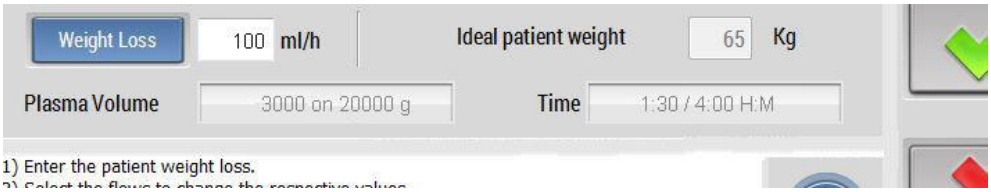
6.1.4 Weight and fluid balance

On the “start treatment” and “treatment started” pages, under exchange control, the weight loss/gain parameter is shown and during treatment the patient status parameter.
The fluid balance value you want to obtain performing the treatment, **weight loss/gain**, is set to zero by default so as to correspond to a balanced fluid balance.
Both during programming and treatment, to set the value of this parameter, press the button that shows the desired balance (weight loss or gain) and enter the correlated value in the white field. Setting a weight loss or gain, the system automatically modifies the UF flow (see par. 6.1.6).
Pressing the WEIGHT LOSS button, it changes to WEIGHT GAIN after confirmation.
Pressing the WEIGHT GAIN button, it changes to WEIGHT LOSS after confirmation.

When the fluid balance set is positive, the button (in this case, WEIGHT GAIN) is red, as this rare event might be the result of a setting error.
The **patient status** value allows instant by instant monitoring the patient weight variation.

6.1.5 Time

The parameters that allow monitoring the treatment time are shown at the bottom of the *active* area of the page.
In CPFA, the information on the treatment time is provided by the **volume of plasma treated out of the minimum volume of plasma to be treated (target)** (on the left) and by the **treatment time elapsed out of the total time necessary to treat the target volume of plasma** (on the right).



To calculate the volume of plasma treated, the machine takes into account the solution flow rate in pre-dilution and assumes a hematocrit value of 35%.
When the volume of plasma treated reaches the target volume:

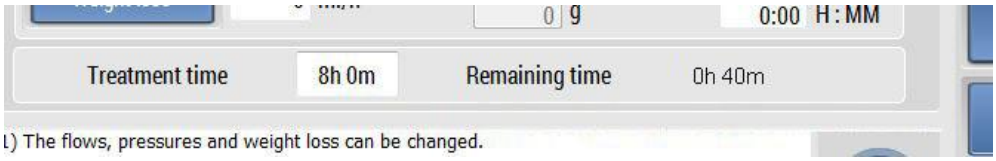
- a message on the screen informs you that the target plasma volume has been reached;
- the information on the target volume disappears, while the volume of plasma treated and the elapsed time continue to be displayed.

During a continuous RRT treatment, the information on the **elapsed time** is provided (on the right).

During an intermittent RRT treatment, the time information provided is:

- **Remaining time**, i.e. the remaining time to the end of the treatment (on the right)
- **Treatment time** (on the left)

on both the “start treatment” and the “treatment started” page.



The time default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment, provided it is not set to below the time elapsed from the beginning of the treatment.
During a CPFA, HD, HF and HDF treatment, the next operation is indicated next to the patient status, i.e. the time remaining to the next bag replacement or the next syringe replacement.

Pressing on the Next Operation field a menu appears indicating:
- The time remaining to the next UF bag change
- The time remaining to the next infusion bag change
- The time remaining to the next bag change on the central scale
- The time remaining to the next syringe 1 change
- The time remaining to the next syringe 2 change
- The time remaining to the next systemic ionised calcium measurement.

Half an hour before each of these times runs out, a message on the screen informs you what needs to be changed (see alarms 1071, 1072, 1073, 1074, 1076 in par. 8.11).
Subsequently, this message appears every 5 minutes until you make the change.

6.1.6 Treatment specifications

The tables below indicate the parameter values for each CPFA/RRT treatment family, which in ASSISTED mode are automatically set by the system in relation to the ideal patient weight and whose modification results in going from ASSISTED to UNASSISTED mode.

WARNING
In UNASSISTED mode, in case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate, AMPLYA does not control the amount of citrate or calcium necessary nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

CPFA

Parameters automatically set by the system (ASSISTED mode)	Default value
Blood flow (ml/min)	150
UF flow (ml/h)	Ideal weight*10 ± weight loss/gain
Citrate flow (%)	25
Calcium chloride flow (ml/h)	4 if Ideal Weight is 15-60 kg 3 if Ideal Weight is 60-85 kg 2 if Ideal Weight is 85-200 kg
Calcium gluconate flow (ml/h)	At parity of ideal weight (3* calcium chloride flow value)

Parameters settable by the operator (resulting in going to UNASSISTED mode)	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 1 and 3)	See the table above	See par. 5.1.6	See par. 5.1.6
UF flow (ml/h) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Weight loss/gain (ml/h)	0	- Ideal weight*10	1) When setting a weight loss: minimum between 2000 and (0.3*blood flow - Ideal weight*10) 2) When setting a weight gain: Ideal weight*10
Plasma/blood (%)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Citrate flow (%) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Min/max access pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Min/max return pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Max. hemofilter TMP (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Max. plasma filter TMP (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Max. trans-cartridge pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6

NOTES:

1. When the blood flow set in relation to the treatments (see par. 4.6) is greater than 150 ml/min, it is forced to 150 ml/min on the "Treatment values confirmation" page.
2. If the value of this flow is modified, the system goes from ASSISTED to UNASSISTED mode.
3. **If after setting or modifying the value of one or more parameters, a limit of a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.** If the UF flow, weight loss/gain or pre-dilution flow panel is red, the only way to continue the treatment in ASSISTED mode is to reset the blood flow so that it is between the recommended minimum and maximum values shown on the blood flow keypad, respectively ((10/3)*UF flow) and (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

CONTINUOUS AND INTERMITTENT HAEMODIALYSIS (CVVHD/IHD-SLED)

Medium filter

Parameters automatically set by the system (ASSISTED mode)	Default value
Blood flow (ml/min)	150
Dialysate flow (ml/h)	Maximum between 500 and Ideal weight*20
Citrate flow (%)	25
Calcium flow (ml/h)	5 if Ideal Weight is 15-60 kg 6 if Ideal Weight is 60-85 kg 7 if Ideal Weight is 85-200 kg
Calcium gluconate flow (ml/h)	At parity of ideal weight (3* calcium chloride flow value)

Parameters settable by the operator (resulting in going to UNASSISTED mode)	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 1 and 3)	See the table above	See par. 5.1.6	See par. 5.1.6
Weight loss/gain (ml/h)	0	Maximum between -2000 and –dialysate flow	Minimum between +2000, 12000-dialysate flow and 0.3*blood flow
Dialysate flow (ml/h) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Citrate flow (%) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Min/max access pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Min/max return pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Max. hemofilter TMP (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6

NOTES:

1. When the blood flow set in relation to the treatments (see par. 4.6) is greater than 150 ml/min, it is forced to 150 ml/min on the "treatment values confirmation" page.
2. If the value of this flow is modified, the system goes from ASSISTED to UNASSISTED mode.
3. **If after setting or modifying the value of one or more parameters, a limit of a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.** If the UF flow, weight loss/gain or pre-dilution flow panel is red, the only way to continue the treatment in ASSISTED mode is to reset the blood flow so that it is between the recommended minimum and maximum values shown on the blood flow keypad, respectively ((10/3)*UF flow) and (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

CONTINUOUS AND INTERMITTENT HAEMOFILTRATION (CVVH/IHF-HVHF)

Medium filter

Parameters automatically set by the system (ASSISTED mode)	Default value
Blood flow (ml/min)	150
UF flow (ml/h)	Maximum between 500 and (Ideal weight*10 ± weight loss/gain)
Pre-infusion flow (%)	0
Citrate flow (%)	25
Calcium flow (ml/h)	4 if Ideal Weight is 15-60 kg 3 if Ideal Weight is 60-85 kg 2 if Ideal Weight is 85-200 kg
Calcium gluconate flow (ml/h)	At parity of ideal weight (3* calcium chloride flow value)

Parameters settable by the operator (resulting in going to UNASSISTED mode)	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Note 1)	See the table above	See par. 5.1.6	See par. 5.1.6
UF flow (ml/h) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Weight loss/gain (ml/h)	0	Maximum between -2000, -0.2*blood flow and –Ideal weight*10	Minimum between 2000 and 0.2*blood flow-Ideal weight*10
Pre-infusion flow (%) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Citrate flow (%) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Min/max access pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Min/max return pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Max. hemofilter TMP (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6

NOTES:

1. When the blood flow set in relation to the treatments (see par. 4.6) is greater than 150 ml/min, it is forced to 150 ml/min on the "Treatment values confirmation" page.
2. If the value of this flow is modified, the system goes from ASSISTED to UNASSISTED mode.
3. **If after setting or modifying the value of one or more parameters, a limit of a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.** If the UF flow, weight loss/gain or pre-dilution flow panel is red, the only way to continue the treatment in ASSISTED mode is to reset the blood flow so that it is between the recommended minimum and maximum values shown on the blood flow keypad, respectively ((10/3)*UF flow) and (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

CONTINUOUS AND INTERMITTENT HAEMODIAFILTRATION (CVVHDF/IHDF)

Medium filter

Parameters automatically set by the system (ASSISTED mode)	Default value
Blood flow (ml/min)	150
UF flow (ml/h)	Weight loss
Dialysate flow (ml/h)	Maximum between 500 and Ideal weight*20
Citrate flow (%)	25
Calcium flow (ml/h)	5 if Ideal Weight is 15-60 kg 6 if Ideal Weight is 60-85 kg 7 if Ideal Weight is 85-200 kg
Calcium gluconate flow (ml/h)	At parity of ideal weight (3* calcium chloride flow value)

Parameters settable by the operator (resulting in going to UNASSISTED mode)	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Notes 1 and 3)	See the table above	See par. 5.1.6	See par. 5.1.6
Weight loss/gain (ml/h)	0	0	Minimum between +2000 and 0.3*blood flow
UF flow (ml/h) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Dialysate flow (ml/h) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Citrate flow (%) (see Note 2)	See the table of parameters automatically set by the system	See par. 5.1.6	See par. 5.1.6
Min/max access pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Min/max return pressure (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6
Max. hemofilter TMP (mmHg)	See par. 5.1.6	See par. 5.1.6	See par. 5.1.6

NOTES:

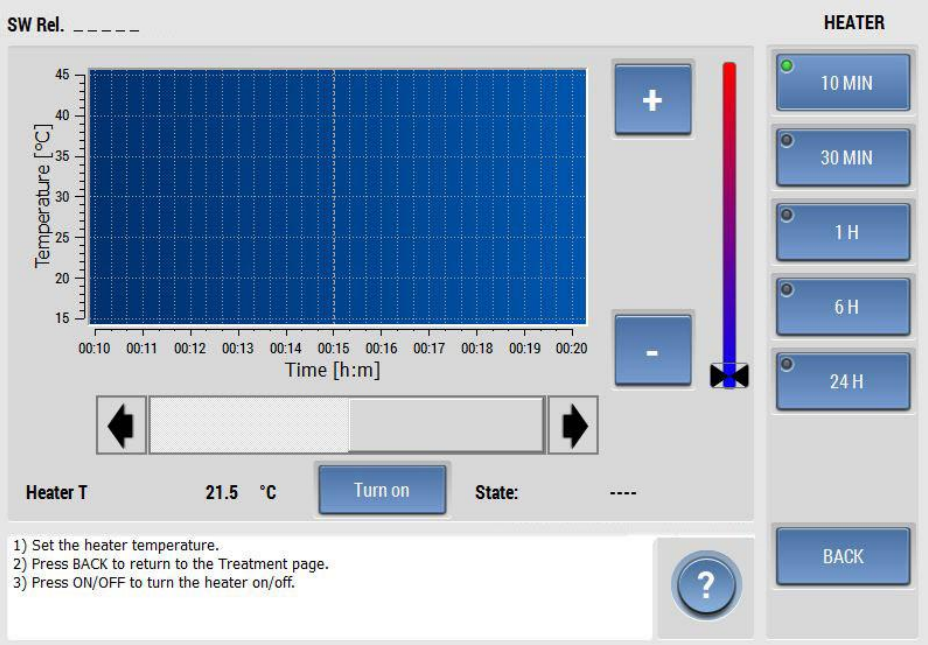
1. When the blood flow set in relation to the treatments (see par. 4.6) is greater than 150 ml/min, it is forced to 150 ml/min on the "Treatment values confirmation" page.
2. If the value of this flow is modified, the system goes from ASSISTED to UNASSISTED mode.
3. **If after setting or modifying the value of one or more parameters, a limit of a parameter among those listed in the table is exceeded, the box of the parameter in question turns red.** If the UF flow, weight loss/gain or pre-dilution flow panel is red, the only way to continue the treatment in ASSISTED mode is to reset the blood flow so that it is between the recommended minimum and maximum values shown on the blood flow keypad, respectively ((10/3)*UF flow) and (4/Pre-dilution flow/60) ml/min with pre-dilution flow expressed in % and < 0.25.

6.2 FUNCTION BUTTONS

The function buttons on the right of the “start treatment” and “treatment started” pages allow access to other pages and functions.

6.2.1 Heater

The button is available on both the “start treatment” and the “treatment started” page.
Pressing this button, you access a page from where you can turn the heater on and off. This page also displays a graph showing the temperature over time.



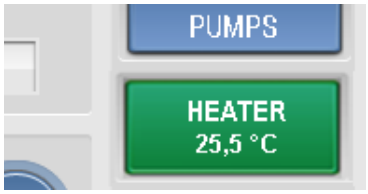
You can select six temperature levels that cover a range between 30 and 41°C.
The outgoing fluid temperature measured is shown at the bottom of the page.
The fluid heater is on at minimum level by default.
To turn on the heater:

- Press the ON/OFF button (at the bottom of the page) and confirm.
- Select the desired temperature (by pressing the + and – buttons to the right of the graph) and confirm.

To turn off the heater, press the ON/OFF button again and confirm.
The heater status is indicated next to the ON/OFF button:

- ON indicates that the heater is on
- OFF indicates that the heater is off
- DEACTIVATED indicates that the heater is inactive as it has not passed the test during priming.

The temperature graph in the centre of the page allows viewing the actual **outgoing fluid temperature.**
During treatment, the HEATER button is green if the heater is on. It also shows the actual outgoing fluid temperature.



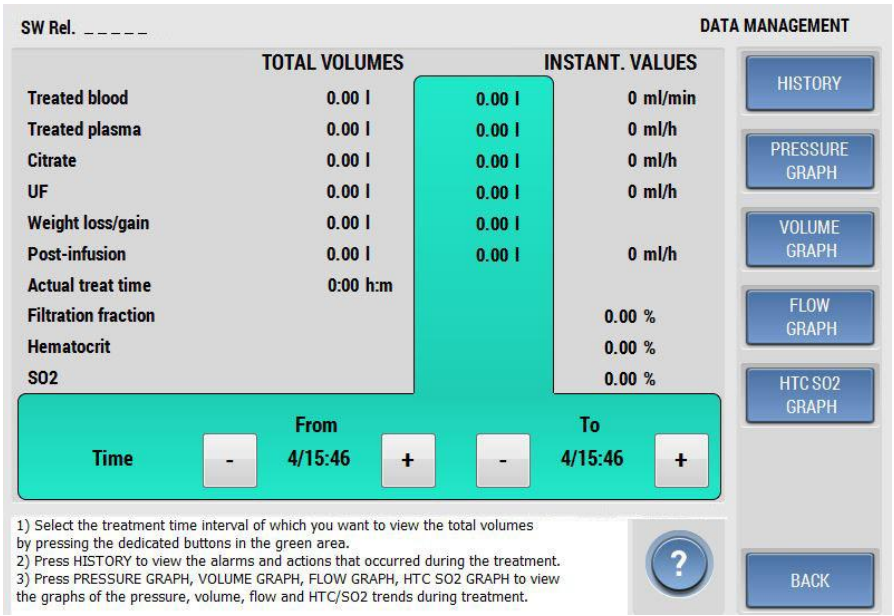
WARNING
When the infusion fluid temperature drops to below 33.5°C, the system informs you by turning the word HEATER on the button into yellow and showing the button with a yellow border.

WARNING
If the pressure in the upper cassette is less than 10 mmHg, the heating capacity of the heater could be reduced and hence the temperature of the outgoing replacement fluid might differ from the temperature displayed by one or more degrees. The system informs you of this difference by changing the HEATER button to yellow.

6.2.2 Data

The button is available on both the "start treatment" and the "treatment started" page.
Pressing this button, you access the relative page where the following are shown:

- The total volume of the fluids (left column)
- The volume of the fluids of a certain period (central green section of the page)
- The instantaneous flow values (right column)



Pressing the corresponding buttons (Function Button area) on this page, you can access the pages containing, respectively:

- The pressure graphs
- The volume graphs
- The flow graphs
- The hematocrit and oxygen saturation graphs
- The treatment history, which lists:
    1. All the actions performed (e.g. buttons pressed) up to that moment
    2. All the parameter modifications made up to that moment
    3. All the alarm events that occurred up to that moment.

These data remain in memory also after the end of the treatment.

The pages containing the graphs allow selecting the time interval within which to display the relative graph.

WARNING
In UNASSISTED mode, in case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate, AMPLYA does not control the amount of citrate or calcium necessary nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

6.2.3 Syringe pumps

The SYRINGE PUMPS button is available on the “treatment values confirmation”, “start treatment” and “treatment started” pages.
Pressing this button, you access the “syringe pump 1 setting” page from where you can:

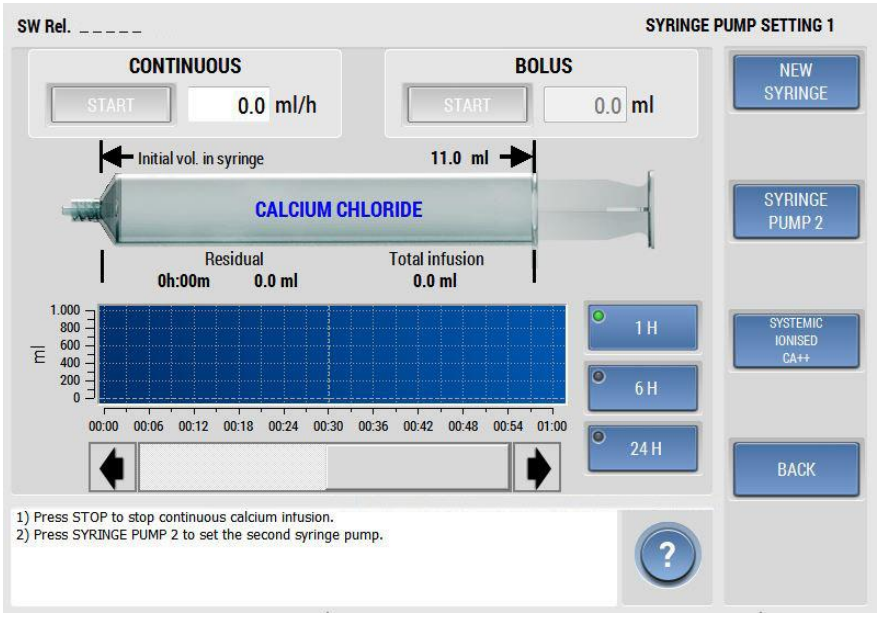
- Modify the amount of calcium (chloride or gluconate, depending on what you selected previously; see the beginning of this chapter) - automatically calculated by the system based on the ideal patient weight - to infuse during the treatment.
- Enter the systemic ionised calcium measurement.
- Replace a syringe.
- Install a syringe.
- Control the syringe pumps by setting continuous infusion and/or bolus infusion.
- Set the volume contained in the syringes installed in the pumps.

When at least one of the two pumps is active, the SYRINGE PUMPS button is green. If only one of the two pumps is active, the infusion flow of that pump is shown on it.

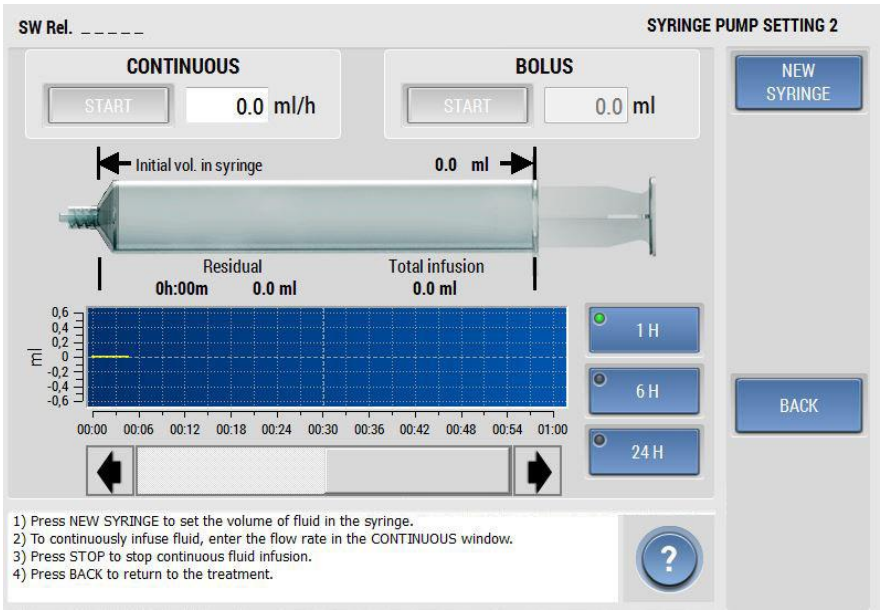
Modifying the calcium flow calculated by the system results in going from ASSISTED to UNASSISTED mode.

Pressing the SYRINGE PUMPS button, you directly access the page where you can set calcium infusion by means of syringe pump 1. This page displays a graph showing calcium infusion over time. The type of calcium selected at the beginning of the treatment is shown in the image of syringe 1 (calcium chloride in the image below).

Pressing the NEW SYRINGE button from the "syringe pump 1 setting" page, you can replace and/or install a new syringe in syringe pump 1.



Pressing the SYRINGE PUMP 2 button, you access the page where you can set ancillary infusion by means of syringe pump 2. This page displays a graph showing infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 2 setting" page, you can replace and/or install a new syringe in syringe pump 2.



Programming calcium infusion (syringe pump 1)
Pressing the STOP button, which stops the calcium flow, you can choose to confirm the STOP command resulting in going from ASSISTED to UNASSISTED mode or continue with syringe replacement directly accessing the "syringe selection" page.
From this page, you can replace the calcium syringe if necessary and set the volume of calcium contained in the syringe.

If you want to install a new syringe in the relative pump and/or set the volume of calcium contained in the syringe, operate as follows:

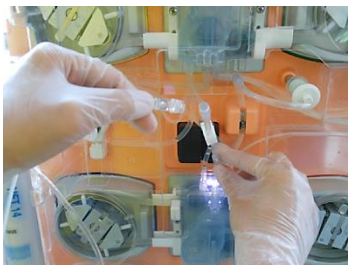
1. If necessary, replace the syringe with another one of the same type containing calcium and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the syringe pump 1 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume of calcium contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the previous operations by pressing the corresponding button on the *confirmation page* (see par. 4.3). If you choose to cancel the operations by pressing the corresponding button on the *confirmation page* (see par. 4.3), a message is shown on the screen to remind you to continue with setting (see alarm 780 in par. 10.11). The same message appears at 5-minute intervals from pressing CONFIRM in the message if the calcium pump is not set.

Confirming the settings, you go back to the syringe pump 1 programming page and the pump resumes infusion of a calcium flow equal to what it was before pressing STOP.
If you do not replace the syringe and/or set the calcium volume from the "syringe 1 selection" page, a message is shown on the screen after one minute to remind you to continue with setting (see alarm 780 in par. 10.11). The same message appears at 5-minute intervals from pressing CONFIRM in the message if the calcium pump is not set.

Programming ancillary infusion (syringe pump 2)
If a syringe has not yet been installed in syringe pump 2, pressing the SYRINGE PUMP 2 button and then the NEW SYRINGE button, you access a page that allows installing a syringe in the relative pump for ancillary infusion during the treatment.

To install a syringe, operate as follows:

1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 2 programming page)
2. Connect the syringe for ancillary infusion to the service line of the venous cassette (the connection line can be supplied to the user on request).



3. Press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
4. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

If a syringe has already been installed in syringe pump 2, pressing the NEW SYRINGE button, you access a page that allows replacing the syringe for ancillary infusion during the treatment.

To install a syringe, operate as follows:

1. If necessary, replace the syringe with another one of the same type and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

Replacing one of the syringes

One of the syringes may need to be replaced:

- When the residual syringe content has all been infused.
- If an excessive value has been set for the initial volume of fluid in the syringe, which results in display of an incorrect residual value (different from zero) when the volume available in the syringe has run out.
- If there is an obstruction along the infusion line.

Continuous infusion

From the “syringe pump 1 setting” and “syringe pump 2 setting” page, you can use the numerical keypad to set continuous calcium infusion and/or ancillary infusion to the patient during the treatment by means of pump 1 and pump 2, respectively.
Setting continuous calcium infusion results in going from ASSISTED to UNASSISTED mode.
The white field of the *continuous* area is active only if the residual content in the syringe is not null.

NOTE: You cannot set calcium boli and therefore the white field of the *bolus* area is not active.

NOTE: You cannot set infusion boli by means of syringe pump 2 and therefore the white field of the *bolus* area is not active.

WARNING
In UNASSISTED mode, in case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate, AMPLYA does not control the amount of citrate or calcium necessary nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

WARNING
In case of local-regional anticoagulation in ASSISTED and UNASSISTED mode, the physician is responsible for the choice of the calcium infusion site, the relative line and its proper control in order to prevent risks such as infusing air into the patient.

6.2.3.1 Systemic ionised calcium

The system requires that the systemic ionised calcium of the patient be measured and the value entered on the relative page at regular intervals (see alarm 480 in par. 10.11). Depending on the systemic ionised calcium value entered, the system maintains constant or modifies the flow supplied by the calcium pump (see the table below). The duration of the time interval that elapses between one systemic ionised calcium measurement and the next depends on the last systemic ionised calcium value entered. The time remaining to the next systemic ionised calcium measurement is shown on the Treatment page in the "Next Operation" panel.

You can also enter the systemic ionised calcium value without waiting for the system to prompt you to do so by pressing the SYSTEMIC IONISED CA++ button on the "syringe pump 1 setting" page. The SYSTEMIC IONISED CA++ button is active only if 20 minutes have elapsed from entering the last systemic ionised calcium value.

Systemic ionised calcium measurement (mmol/l)	*Calcium chloride flow correction (ml/h)*	*Calcium gluconate flow correction*
< 0.8	+2	+6
between 0.8 and 0.99	+1	+3
between 1 and 1.2	no correction	no correction
between 1.2 and 1.33	-1	-3
> 1.34	-2	-6

You can accept or reject the calcium flow values the system suggests. If you reject them, the system goes from ASSISTED to UNASSISTED mode.

WARNING
In UNASSISTED mode, in case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate, AMPLYA does not control the amount of citrate or calcium necessary nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

WARNING
In case of local-regional anticoagulation in ASSISTED and UNASSISTED mode, the physician is responsible for the choice of the calcium infusion site, the relative line and its proper control in order to prevent risks such as infusing air into the patient.

6.2.4 Treatment start

WARNING
Make sure that you have loaded a set consistent with the treatment to be performed (indicated at the bottom left of the screen).

To start the treatment, press the START button on the "start treatment" page.
When you press the button, you are asked to check the connections of the access and return lines to the patient (see *patient connection* below) and to confirm that they are properly connected. Once confirmed, the system starts the treatment. In the initial transition phase:

1. Syringe pump 1 starts at the same time as the blood pump, which gradually increases its speed;
2. After reaching the blood flow set for the treatment, the exchange pumps start (in the order described in par. 6.1.1).

Patient connection
The patient is to be connected during treatment programming ("treatment started" window).
To connect the patient:

1. Close the electroclamp of the access line, the electroclamp of the multi-way line on the infusion side to which the access line is connected, the electroclamp of the return line and the electroclamp of the multi-way line on the UF side to which the return line is connected;
2. Disconnect the access line from the multi-way line on the infusion side and the return line from the multi-way line on the UF side;
3. Connect the access and return lines to the patient's catheter and open the respective electroclamps.

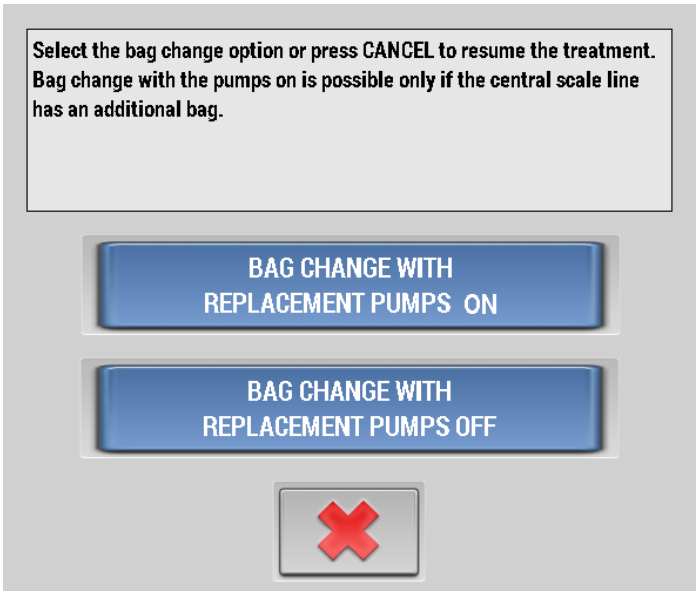
CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

1. **Use aseptic techniques that prevent cross-infections between patients**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

6.2.5 Bag change

Press CHANGE BAGS on the "treatment started" page to replace the bags. The bags may need to be changed if they are full (collection bags) or almost empty (infusion bags).

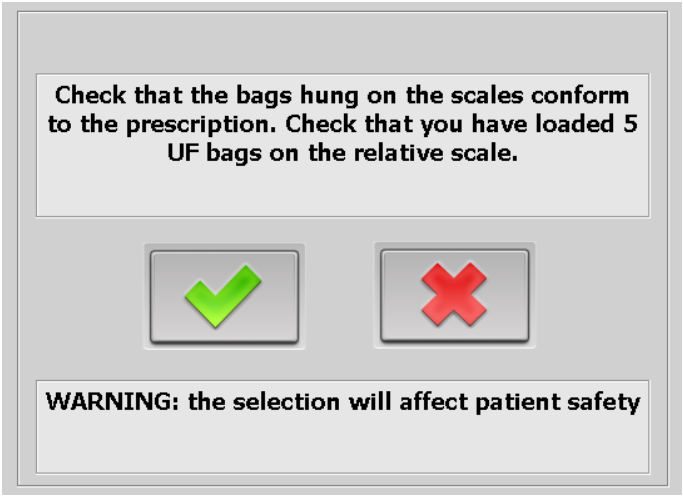
Pressing the button, a panel is displayed where you can select the bag change mode: **bag change with pumps off** and **bag change with pumps on**.



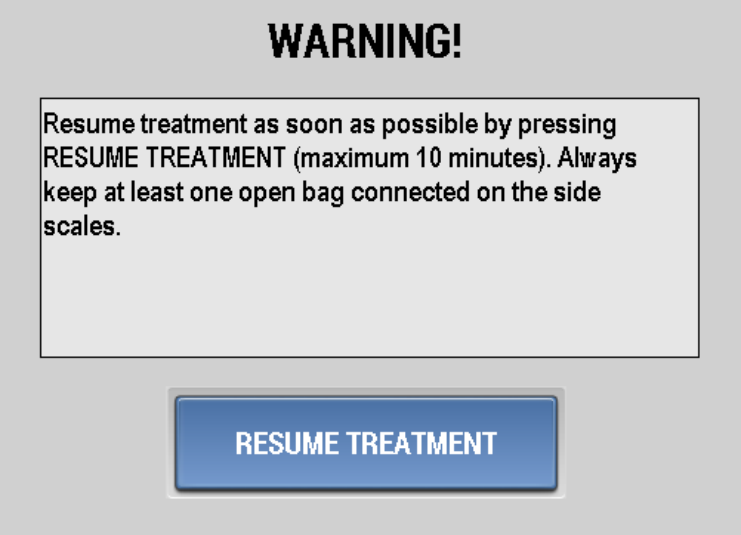
- Pressing the BAG CHANGE WITH REPLACEMENT PUMPS OFF button activates an acoustic signal and stops the exchange pumps except:
    - The blood pump that continues running at the set speed in CPFA and at reduced speed in RRT.
    - Only in CPFA, the plasma pump that continues running at the speed calculated on the percentage blood flow value.

  In this way, the machine goes into PAUSE mode during which a message is shown on the screen warning you to resume treatment as soon as possible.

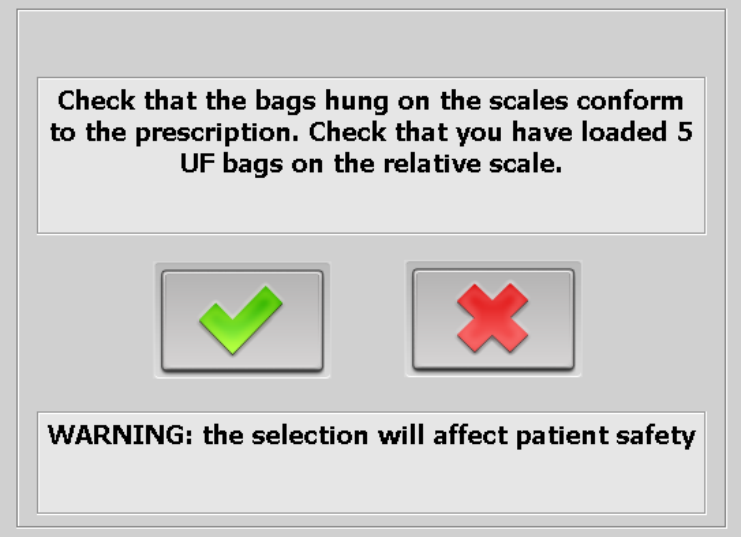
When you have pressed the RESUME TREATMENT button, the system reminds you to check that the bags connected to the circuit conform to the prescription.



- Pressing the BAG CHANGE WITH REPLACEMENT PUMPS ON button, the machine sets the pump speed so as to maintain the average flows prior to pressing the button and does not take into account the weight variations detected on the scales.
  NOTE: Bag change mode with the pumps on is only available if the central scale is active.
  A message is shown on the screen warning you to complete the bag change as soon as possible and to check that there is at least one open bag on the side scales. The treatment continues in this mode for maximum 10 minutes after which the bag change mode with the pumps off is automatically activated. Alarm 1079, activated after 8 minutes, warns you that you are about to go into bag change mode with the pumps off.



When you have pressed the RESUME TREATMENT button, the system reminds you to check that the bags connected to the circuit conform to the prescription.



NOTE: The BAG CHANGE WITH REPLACEMENT PUMPS ON button is active only when all the safety conditions have been checked. In particular:

- Constant pump speed
- More than 10 minutes bag autonomy
- Absence of alarms in the 4 minutes prior to pressing the button
- Less than 4 bag changes with the pumps on in the last 7 hours.

Should the button temporarily not be active, it is advisable to wait for it to reactivate.

WARNING
Check that all the bags have been loaded on the relative scales and that they do not touch other parts of the machine or bags on other scales.

6.2.6 Blood pump stop

To stop the blood pump at any time, press the STOP BLOOD PUMP button on the "treatment started" page.

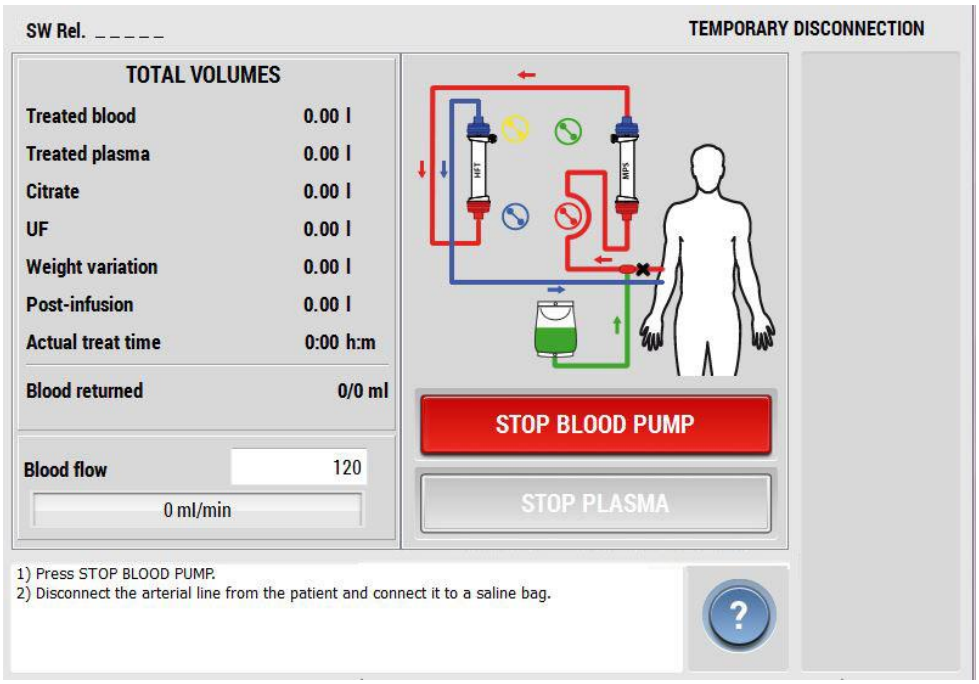
Use this button only when an unexpected event occurs and not to replace the bags (see par. 6.2.5, CHANGE BAGS button).
When you press this button, the system stops the pumps and warns you of the risk of the blood coagulating because of an extended blood pump stop by means of an acoustic signal, a yellow warning light and a message on the screen.

6.2.7 Temporary disconnection

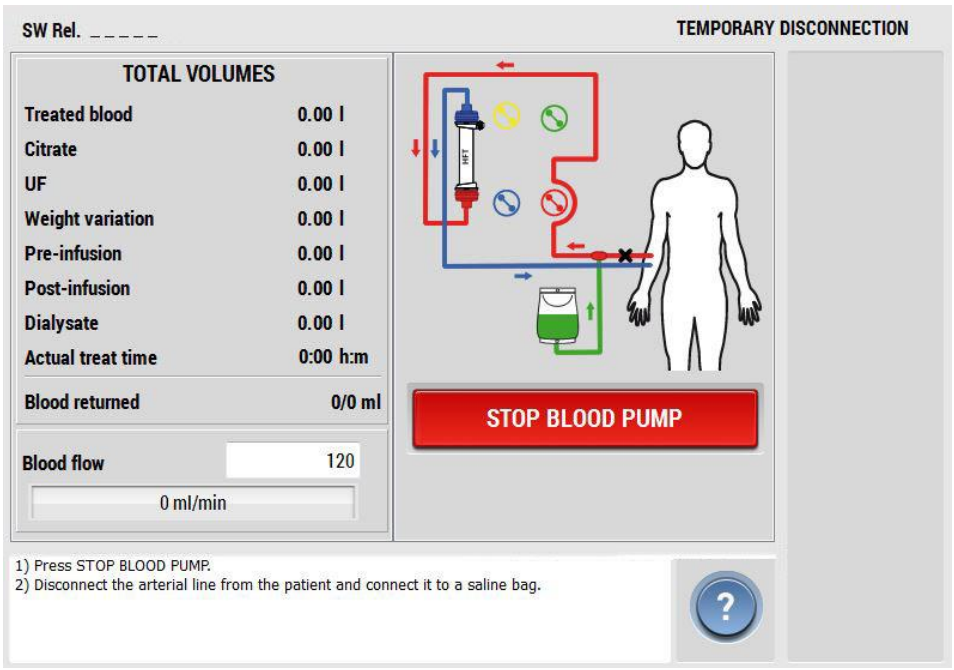
To disconnect the patient at any time, press the TEMPORARY DISCONNECTION button on the "treatment started" page. The function of this button is to allow you to return the blood to the patient following an unexpected event that requires patient disconnection.

Pressing this button, you access a page that allows you to return the blood to the patient.

In CPFA, the page appears as shown in the image below.



In RRT, the page appears as shown in the image below.



When you access the blood return page, the exchange pumps stop.

From the blood return page, if you have decided to disconnect the patient, operate as follows:
1. Press the STOP BLOOD PUMP button to stop the blood pump
2. Disconnect the access line (red) and connect it to a saline bag
3. Press BLOOD RETURN (RRT) or START RETURN (CPFA).

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

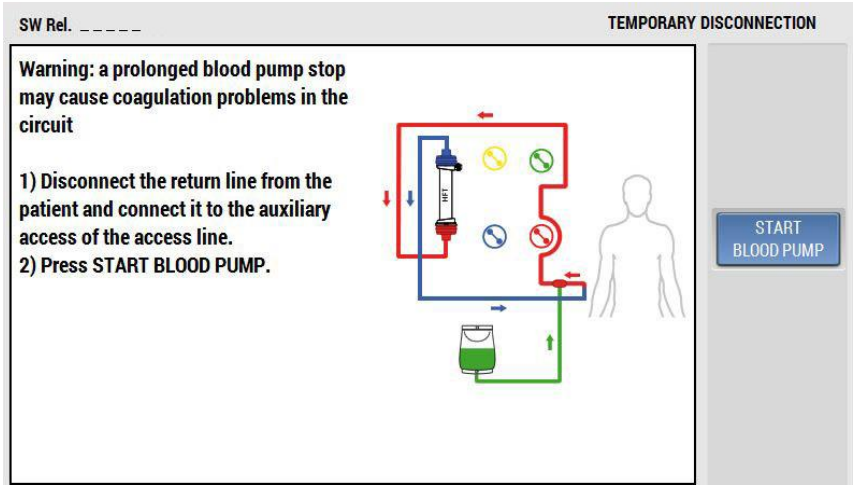
WARNING
The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.

In CPFA, when blood return has started, you can stop plasma return by pressing the button that stops the plasma pump.

The button can be selected only if the plasma pump has not been off for over two hours. If the plasma pump has been off for more than two hours, blood return is automatically stopped by the pump in question.

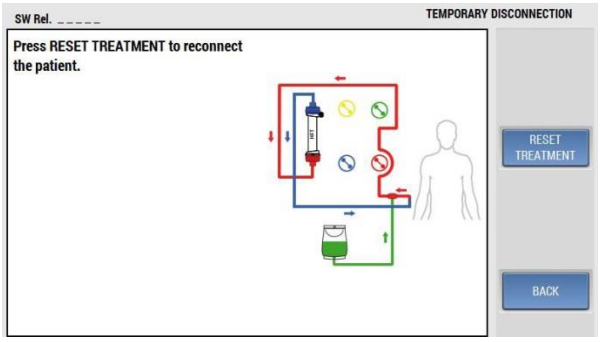
At any time during blood return you can:
- In RRT, stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood return (BLOOD RETURN button)
- In CPFA, stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood and plasma return (START RETURN button) or only blood return (BLOOD RETURN ONLY button)
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

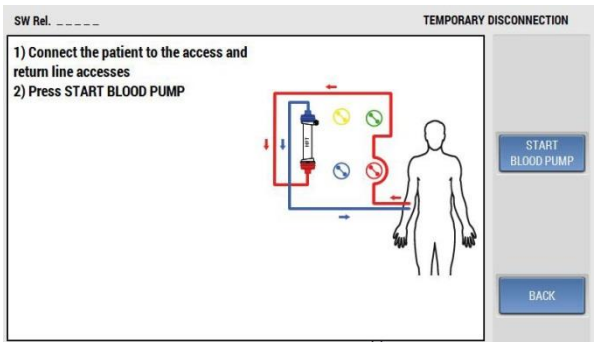
When blood return has been completed:
1. Disconnect the patient from the return line
2. Connect the return line to the branch on the arterial line
3. Press the START BLOOD PUMP button to restart the blood pump and allow recirculation of any blood that has remained in the circuit so that it cannot coagulate while waiting for patient reconnection.



When the patient is ready to be reconnected to the circuit, operate as follows:

- Press RESUME TREATMENT
- Connect the catheter accesses to the access and return lines
- Press START BLOOD PUMP to restart all the pumps and resume the treatment.





CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

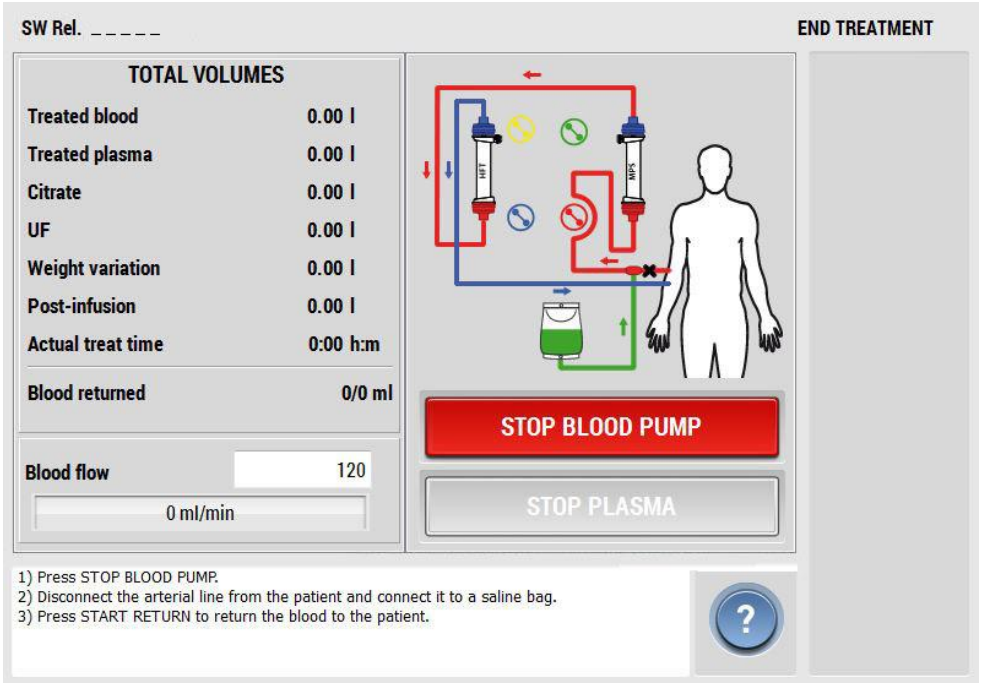
6.2.8 End of treatment

To end the treatment at any time, press the END TREATMENT button on the "treatment started" page.

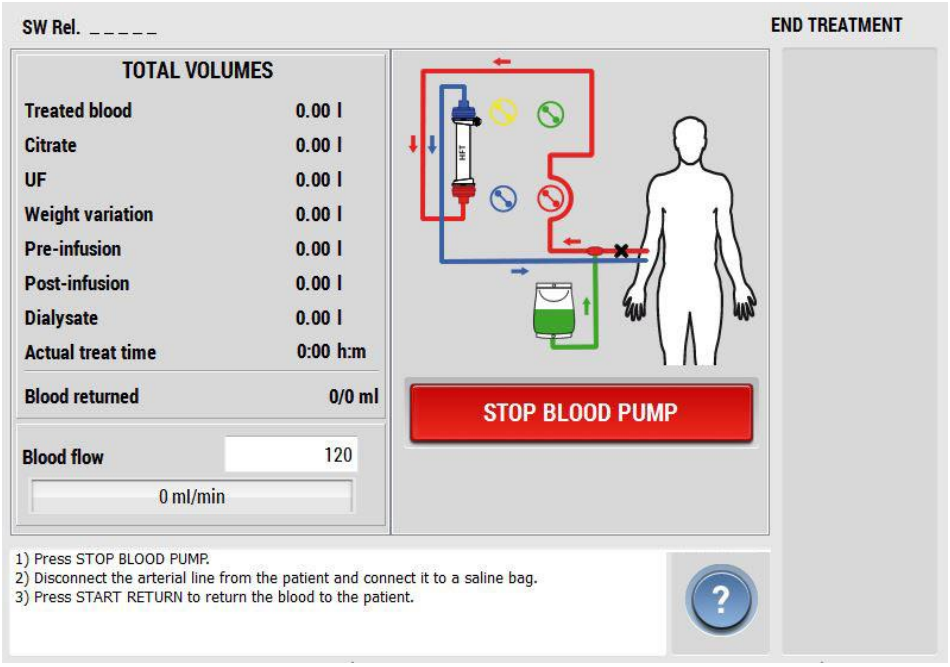
During a CPFA or RRT treatment, pressing this button allows you to:
- Confirm the selection and end the treatment
- Cancel the selection to resume the treatment

Confirming the selection to end the treatment, you access a page that allows you to return the blood to the patient.

In CPFA, the page appears as shown in the image below.



In RRT, the page appears as shown in the image below.



When you access the blood return page, the exchange pumps stop. From this page you can:

1. Press the STOP BLOOD PUMP button to stop the pump
2. Disconnect the access line (red) and connect it to a saline bag
3. Press the BLOOD RETURN button.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

WARNING:

1. **The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.**
2. **It is of fundamental importance that the blood return procedure be correctly carried out before disconnecting the power in order to prevent needless patient blood leakage.**

In CPFA, when blood return has started, you can stop plasma return by pressing the button that stops the plasma pump.

The button can be selected only if the plasma pump has not been off for over two hours. If the plasma pump has been off for more than two hours, blood return is automatically stopped by the pump in question.

At any time during blood return you can:
- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood return (RESUME BLOOD RETURN button);
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

NOTE: in CPFA, pressing the STOP BLOOD PUMP button, the blood pump will stop as well as the plasma pump if it is running.

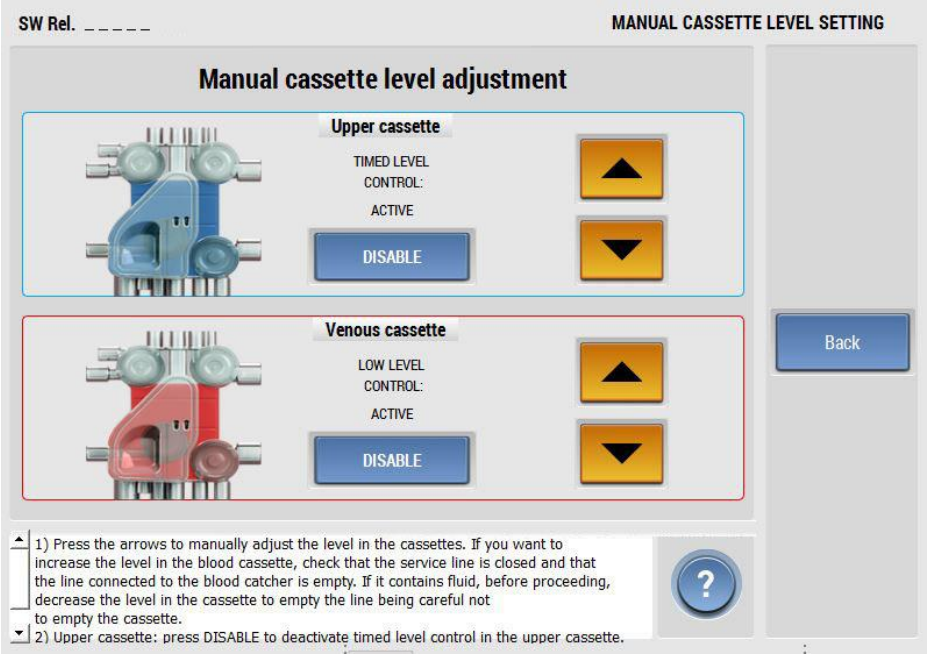
During this pause phase, only the following alarms are active:
- Access and return pressure alarms
- Air alarm.

CAUTION
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:
1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

When blood return is complete, you access a page containing a sequence of illustrated instructions for removal of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.
From this page you can remove the set, once you have disconnected the lines as illustrated in the instructions, by pressing REMOVE SET. When you press this button, you access a page informing you that the treatment has ended and that you can turn off the machine using the switch on the rear (see REAR VIEW in Chapter 2 Machine Presentation).

6.2.9 Chamber levels

Pressing the CHAMBER LEVELS button, you access a page where you can manually adjust the levels in the venous cassette and the level in the upper cassette using the relative buttons to raise and lower the level. From this page you can also disable level control of each cassette by pressing the dedicated button.



6.3 ROUTINE OPERATIONS DURING TREATMENT

During the treatment, some routine operations must be performed to safeguard the patient.

6.3.1 Patient temperature check

Throughout the treatment the patient's temperature must be checked whenever the situation requires.
The machine is equipped with a heater that must be used to prevent the patient from getting cold when this is undesirable for clinical reasons.
Use of the heater is described in paragraphs 2.1 and 6.2.1 in this manual.

6.3.2 Patient fluid balance check

Throughout the treatment it must be checked that the patient's fluid balance is between values that cannot cause harm to the patient. If you have any doubts about the fluid balance, the treatment MUST immediately be interrupted.
In particular, in the event that alarms occur indicating that the patient weight cannot properly be controlled, the actual clinical conditions of the patient MUST be checked.

You also need to check that the weight variation specified in the treatment is always adequate for the clinical conditions of the patient.

6.3.3 Pressure check

Right from the beginning of the treatment, the pressure values must be checked to verify that they fall within an acceptable range.

It is recommended to:

- **Operate the machine within the minimum and maximum default values for the access, return, TMP and trans-cartridge pressures (see par. 6.1.6);**
- **Pay particular attention to haemolysis phenomena if the TMP values of the plasma filter exceed 50 mmHg.**

To adjust the alarm limits both before the treatment starts and during the treatment, operate as described below:

1. Press on the Pressures panel on the treatment page to access the page where to set the pressure limits (see par. 6.1.3)
2. Set the new limits with respect to the return and access pressures measured
3. Confirm the modified values and go back to the treatment page.

WARNING
In some cases, the access pressure can be relatively high and the return pressure relatively low. In this condition, if the maximum access pressure limit is > -10 mmHg and/or the maximum return pressure limit is < +10 mmHg, an alarm message informs you that the system may be unable to signal patient disconnection. If the data is confirmed, the Pressures panel on the treatment page turns red to indicate that the alarm limits are potentially hazardous.

CAUTION
Inadequate setting of the access and return pressure limits may reduce the system's ability to detect any disconnected blood lines.

CAUTION

Access and return pressure monitoring is not always able to detect disconnection of the access or return line from the relative patient access. Disconnection results in blood leakage into the surrounding environment.

Disconnection of a line from the relative patient access may cause a decrease (return) or an increase (access) in the relative pressure although it remains within the permitted alarm range. In this case, therefore, the machine is unable to detect disconnection despite the alarm thresholds being set correctly.

In order to reduce the risk of the access and return lines disconnecting from the relative access:

- Check that the access and return lines are properly connected to the relative access on the patient side by means of their fastening ring nut;
- Check that the patient access and return accesses are visible at all times during the dialysis treatment;
- Frequently check the patient access and return accesses;
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limits for both pressures as close as possible to the actual value of the relative pressure of the patient in order to avoid the alarm from continuously intervening.

When you set a return pressure limit below 10 mmHg or an access pressure limit above -10 mmHg, the system warns you that the machine may not detect any disconnection on the patient side. With these pressure limit values, the operator is hence responsible for constantly monitoring the access and return pressures.

In order to reduce the risk of access and return line disconnection:

- Check that the patient accesses and relative lines are properly connected as prescribed by the protocol of your clinic;
- Check that the patient accesses are visible at all times during the dialysis treatment;
- Frequently check the patient accesses;
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limit for the return pressure and the maximum alarm limit for the access pressure as close as possible to the actual value of the respective pressures on the patient.

6.3.4 Replacing the fluid bags

The bags containing the replacement fluid and/or waste fluid can be replaced at any time. The machine generates an alarm when the replacement fluid bags are empty and the waste bags are full.
To change the bags at any time, operate as follows:

1. Press the CHANGE BAGS button and select the bag change mode (see par. 6.2.5)
2. Replace the bags and make sure that the new bags conform to the prescription (as requested by the system via a warning window)
3. Press the RESUME TREATMENT button in the window that appeared when you pressed the CHANGE BAGS button (see par. 6.2.5).

WARNING
Check that all the bags loaded are on the relative scales and that they do not touch other parts of the machine or bags on other scales.

6.4 END OF TREATMENT

In CPFA, the system informs you when you reach 24 hours of treatment. Subsequently, you are informed every half an hour of the time elapsed after the 24 hours.

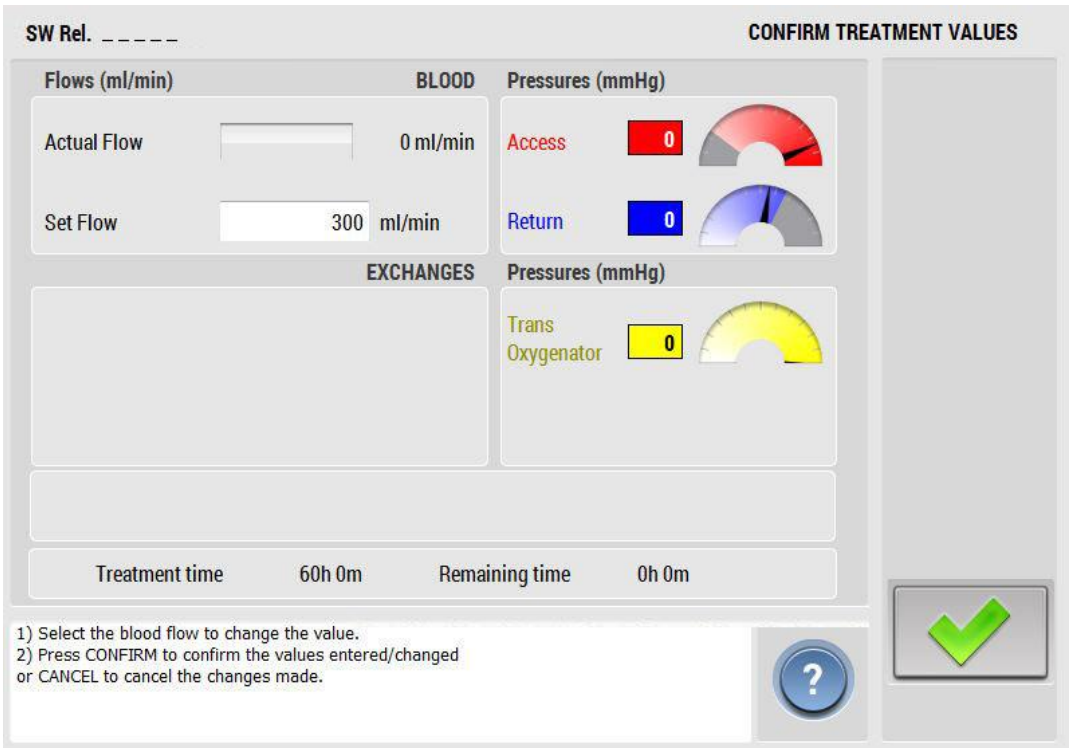
In intermittent RRT treatment, the treatment automatically ends when the **Remaining time** parameter reaches 0:

- All the pumps stop except the blood pump that runs at minimum speed.
- A yellow warning light on the monitor informs you of the end of the treatment.
- You can reset the time if the treatment lasted less than 24 hours (maximum time settable for an intermittent treatment) or press the END TREATMENT button to confirm the end of the treatment (see par. 6.2.8).

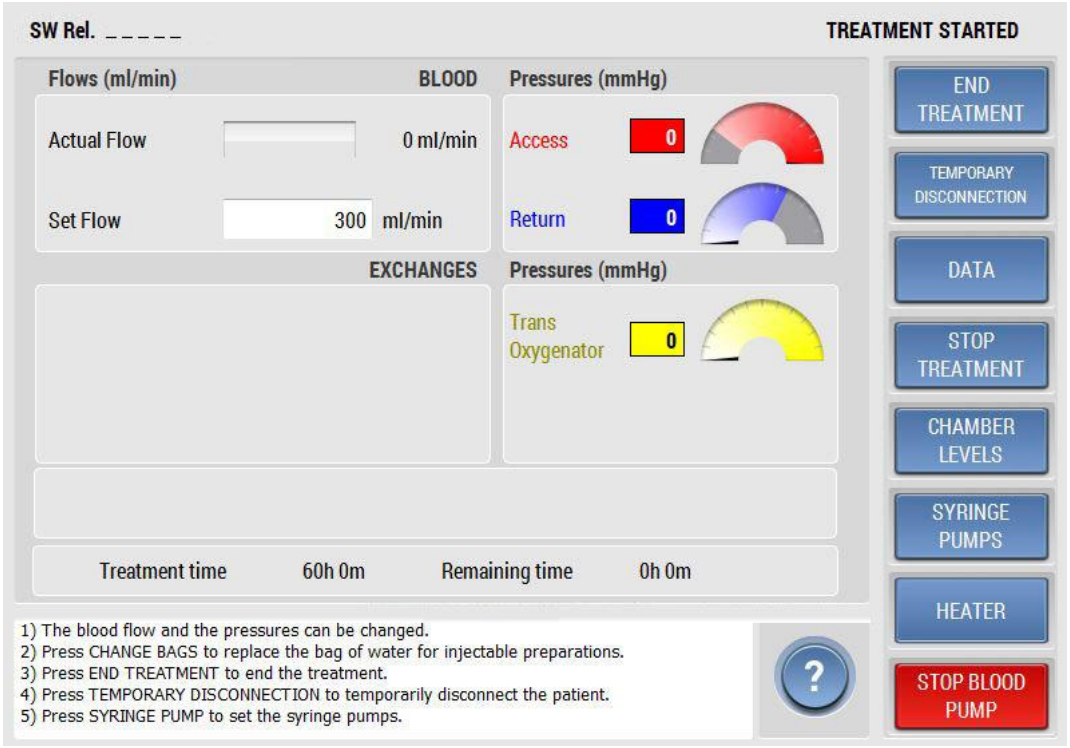
7 PERFORMING AN ABYLCAP TREATMENT

Pressing the TREATMENT button from the “End Rinse” page, you access a page where you can program and start the ABYLCAP treatment selected.

If the treatment selected is ABYLCAP, the page appears as shown in the image below.



From the “start treatment” page, having made and confirmed all the required settings for the specific treatment (see par. 4.3.4), you can start the treatment by pressing the START button (Function Button area) and so access the “treatment started” page.



The "start treatment" and "treatment started" pages are structured as follows:

- An *active* area divided into three control blocks (blood, exchange and time) where the characteristic parameters of the selected treatment and the respective values are shown;
- A *function button* area to the right of the three blocks with buttons that offer access to some useful treatment functions;
- An *information* area at the bottom where the treatment name and power supply (mains or battery) are shown.

The flow and pressure parameters are shown in the various control blocks.

Some of the parameters displayed allow you to monitor treatment progress (therefore, before starting the treatment, their value is zero).

Other parameters are settable/modifiable by the operator using the *numerical keypad* (see par. 4.3) after pressing on the corresponding white field.

7.1 TREATMENT PARAMETERS

7.1.1 Blood

The blood control parameters are shown under BLOOD at the top of the active area of the “start treatment” and “treatment started” pages.
The actual flow and the set flow expressed in ml/min form part of the Flows panel.

The **actual flow** indicates the actual blood pump flow supplied by rotation of the pump during the treatment (therefore it is 0 before treatment start when the pumps are all off). During treatment, the value of this parameter allows you to monitor the blood flow instant by instant.
The actual flow depends on the access pressure, the blood pump speed and deterioration of the relative line.

The **set flow** indicates the blood flow operating value desired for the specific treatment. The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment.

The access pressure and the return pressure expressed in mmHg form part of the “Pressures” panel.

The **access pressure** is the pressure, monitored during treatment, before the blood pump at the blood inlet to the extracorporeal circuit.

The **return pressure** is the pressure, monitored during treatment, in the venous cassette before the blood is returned to the patient through the return line (blue tube section).

When the treatment is started, the blood pump and syringe pump 1 (if set) start at the same time. The infusion pump (which pumps the water for injectable preparations) and syringe pump 2 (if set) start once the operating blood flow has been reached. The blood pump gradually accelerates until reaching the operating flow set in relation to the blood pressure variations.

7.1.2 Exchanges

The **trans-oxygenator pressure,** expressed in mmHg, which corresponds to the pressure drop between the oxygenator inlet and outlet on the blood side, is shown in the "Pressures" panel on the "start treatment" and "treatment started" pages. The maximum permissible value is fixed and not modifiable.

7.1.3 Pressure

Both during programming and treatment, pressing on the "Pressures" panels relating to blood and exchange control, you access the pressure range page.

In ABYLCAP, the page appears as shown in the image below.

On this page you can view and set the minimum and maximum permitted access and return pressures.

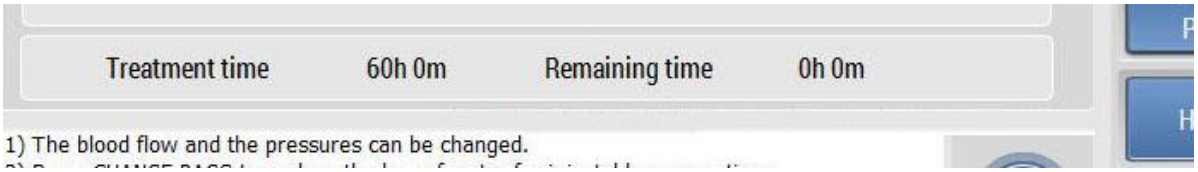
To set the minimum and maximum values, see paragraph 7.3.3.

7.1.4 Time

The parameters that allow monitoring the treatment time are shown at the bottom of the *active* area of the page.

During an ABYLCAP treatment, the time information provided is:
- **Remaining time**, i.e. the remaining time to the end of the treatment (on the right)
- **Treatment time**, i.e. the maximum time of an ABYLCAP treatment using only one set (on the left, not settable)

on both the "start treatment" and the "treatment started" page.



7.1.5 Treatment specifications

The tables below give definitions of parameters settable and/or modifiable by the operator.

ABYLCAP

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min)	30	30	550
Min. access pressure (mmHg)	-200	-250	Max. access pressure
Max. access pressure (mmHg)	-10	Min. access pressure	-10
Min. return pressure (mmHg)	10	+10	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300

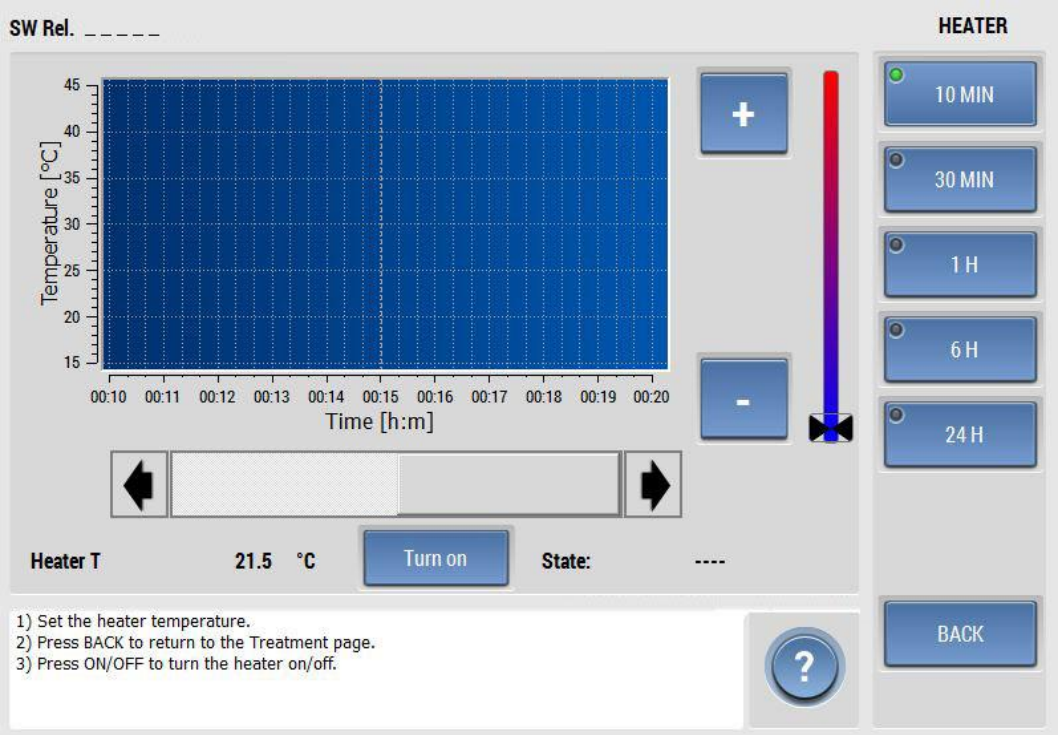
NOTE: the flow of the water for injectable preparations (through the circuit for heat exchange with the blood) is 12000 ml/h and is fixed and not modifiable.

7.2 FUNCTION BUTTONS

The function buttons on the right of the “start treatment” and “treatment started” pages allow access to other pages and functions.

7.2.1 Heater

The button is available on both the “start treatment” and the “treatment started” page.
Pressing this button, you access a page from where you can turn the heater on and off. This page also displays a graph showing the temperature over time.



You can select six temperature levels that cover a range between 30 and 41°C.
The outgoing fluid temperature measured is shown at the bottom of the page.
The fluid heater is on at minimum level by default.
To turn on the heater:

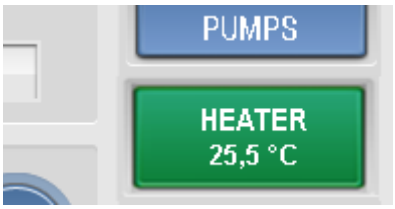
- Press the ON/OFF button (at the bottom of the page) and confirm;
- Select the desired temperature (by pressing the + and – buttons to the right of the graph) and confirm.

To turn off the heater, press the ON/OFF button again and confirm. If the heater is turned off, the infusion pump stops.
The heater status is indicated next to the ON/OFF button:

- ON indicates that the heater is on
- OFF indicates that the heater is off
- DEACTIVATED indicates that the heater is inactive as it has not passed the test during priming.

The temperature graph in the centre of the page allows viewing the actual **outgoing fluid temperature.**

During treatment, the HEATER button is green if the heater is on. It also shows the actual outgoing fluid temperature.

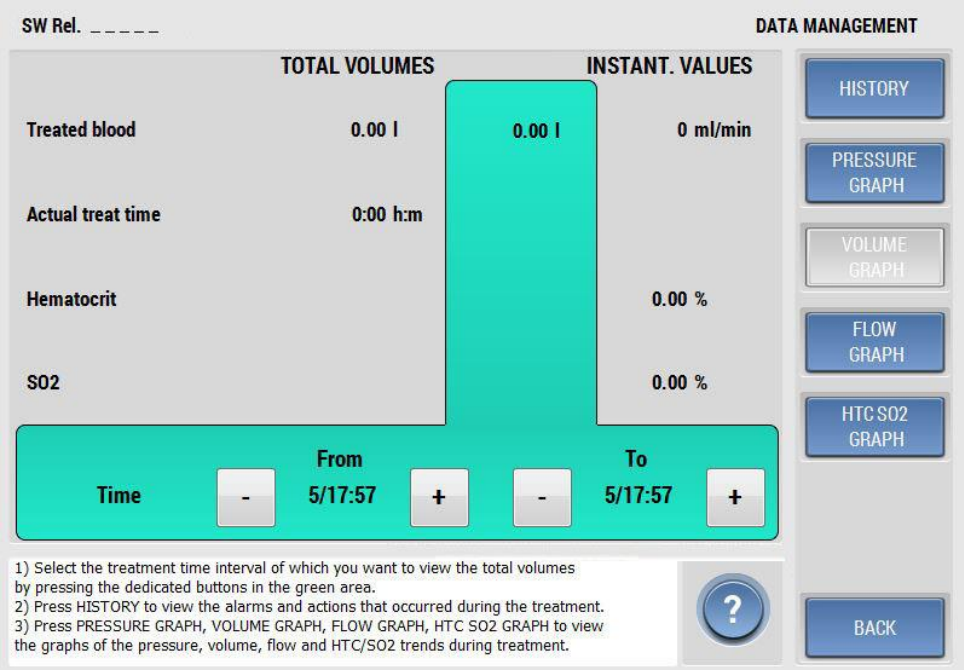


WARNING
When the infusion fluid temperature drops to below 33.5°C, the system informs you by turning the word HEATER on the button into yellow and showing the button with a yellow border.

7.2.2 Data

The button is available on both the "start treatment" and the "treatment started" page.
Pressing this button, you access the relative page where the following are shown:

- The total blood volume (left column)
- The blood volume of a certain period (central green section of the page)
- The instantaneous flow values (right column).



Pressing the corresponding buttons (Function Button area) on this page, you can access the pages containing, respectively:

- The pressure graphs
- The flow graphs
- The hematocrit and oxygen saturation graphs
- The treatment history, which lists:
    1. All the actions performed (e.g. buttons pressed) up to that moment
    2. All the parameter modifications made up to that moment
    3. All the alarm events that occurred up to that moment.

These data remain in memory also after the end of the treatment.

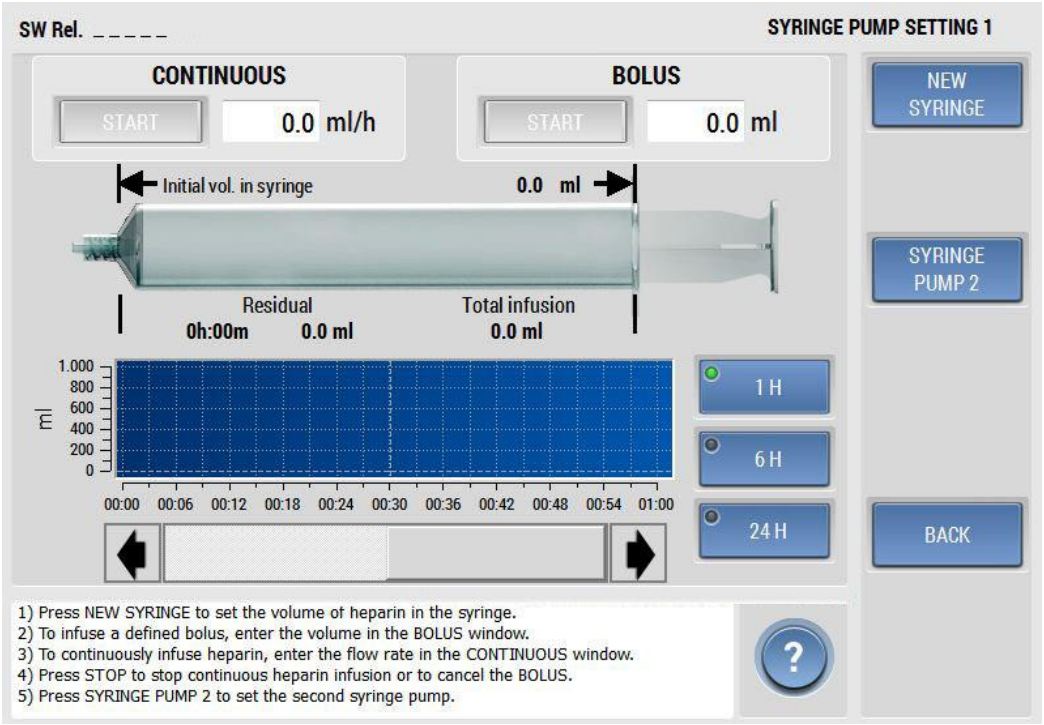
The pages containing the graphs allow selecting the time interval within which to display the relative graph.

7.2.3 Syringe pumps

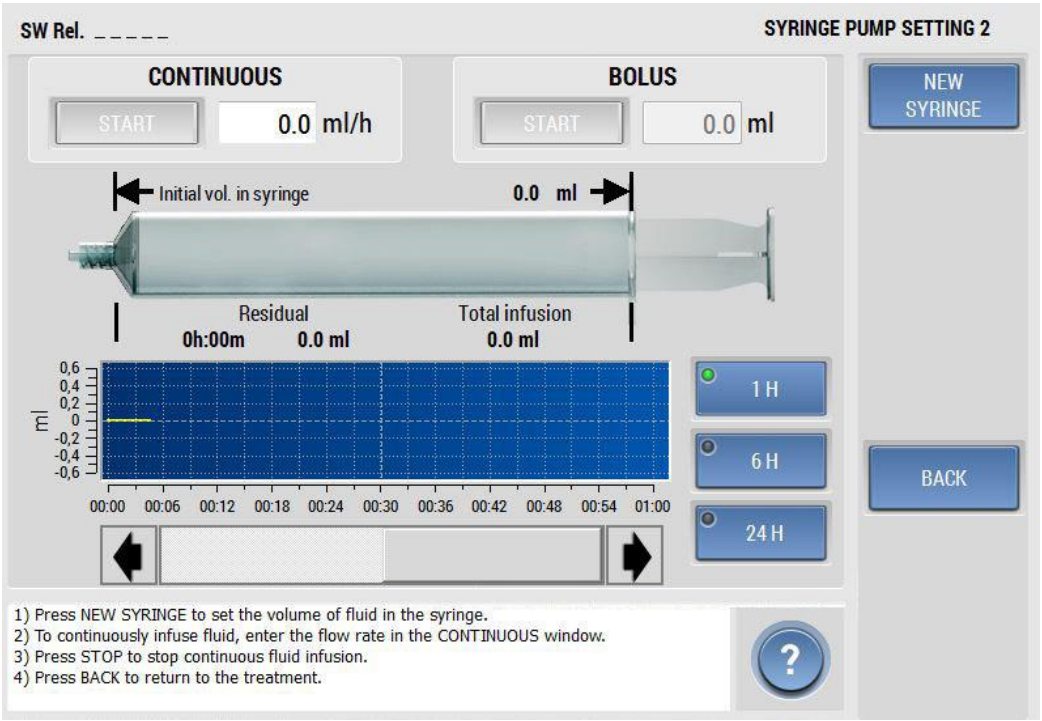
The SYRINGE PUMPS button is available on both the "start treatment" and the "treatment started" page.
Pressing this button, you access the relative page from where you can:

- Control the syringe pumps by setting continuous infusion or bolus infusion
- Install a new syringe
- Replace a syringe
- Set the volume contained in the syringes installed in the pumps.

When at least one of the two pumps is active, the SYRINGE PUMPS button is green. If only one of the two pumps is active, the infusion flow of that pump is shown on it.
Pressing the SYRINGE PUMPS button, you directly access the page where you can set heparin infusion by means of syringe pump 1. This page displays a graph showing heparin infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 1 setting" page, you can replace and/or install a new syringe in syringe pump 1.



Pressing the SYRINGE PUMP 2 button, you access the page where you can set ancillary infusion by means of syringe pump 2. This page displays a graph showing infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 2 setting" page, you can replace and/or install a new syringe in syringe pump 2.



Programming heparin infusion (syringe pump 1)
If a syringe has not yet been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows installing a heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:
1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 1 programming page).
2. Connect the syringe containing heparin to the relative line (leading from the single-use set at the top right).
3. Press on the arrows on the screen to move the syringe pump 1 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger
4. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

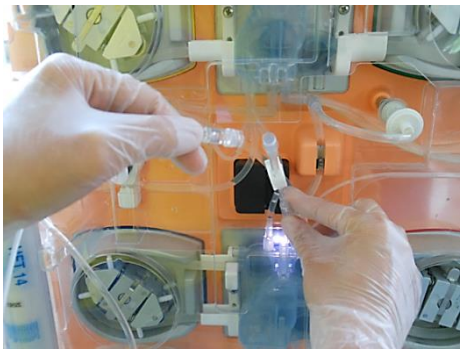
Confirming the settings, you go back to the syringe pump 1 programming page.
If a syringe has already been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows replacing the heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:
1. If necessary, replace the syringe with another one of the same type containing heparin and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the right-hand syringe pump pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 1 programming page.

Programming ancillary infusion (syringe pump 2)
If a syringe has not yet been installed in syringe pump 2, pressing the SYRINGE PUMP 2 button and then the NEW SYRINGE button, you access a page that allows installing a syringe in the relative pump for ancillary infusion during the treatment.

To install a syringe, operate as follows:
1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 2 programming page).
2. Connect the syringe for ancillary infusion to the service line of the venous cassette (the connection line can be supplied to the user on request).



3. Press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
4. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

If a syringe has already been installed in syringe pump 2, pressing the NEW SYRINGE button, you access a page that allows replacing the syringe for ancillary infusion during the treatment.

To install a syringe, operate as follows:

1. If necessary, replace the syringe with another one of the same type and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

Replacing one of the syringes

One of the syringes may need to be replaced:

- When the residual syringe content has all been infused;
- If an excessive value has been set for the initial volume of fluid in the syringe, which results in display of an incorrect residual value (different from zero) when the volume available in the syringe has run out;
- If there is an obstruction along the infusion line.

Bolus and continuous infusion

From the “syringe pump 1 setting” page, you can use the numerical keypad to set bolus and/or continuous infusion to the patient during the treatment by means of pump 1.

From the "syringe pump 2 setting" page, you can use the numerical keypad to set continuous infusion to the patient during the treatment by means of pump 2.

NOTE: You cannot set infusion boli by means of syringe pump 2.

The white fields of the *bolus and continuous* areas for syringe pump 1 and *continuous* for syringe pump 2 are active only if a syringe has previously been installed and the residual content in the syringe is not null.
When you program syringe pump 1 to simultaneously perform a bolus and a continuous infusion, the bolus will always be administered first upon treatment start.
During the treatment, you can cancel the bolus set by pressing the STOP button in the corresponding panel (on the right) and/or stop the continuous infusion set by pressing the STOP button in the corresponding panel (on the left). Subsequently, you can reset the bolus so that the system administers it automatically and/or press the START button to resume continuous infusion.

7.2.4 Treatment start

WARNING
Make sure that you have loaded a set consistent with the treatment to be performed (indicated at the bottom left of the screen).

To start the treatment, press the START button on the "start treatment" page.
When you press the button, you are asked to check the connections of the access and return lines to the patient and the connection of the gas line to the oxygenator and to confirm that they are all properly connected (see *patient connection* below). Once confirmed, the system starts the treatment.
In the initial transition phase:

1. Syringe pump 1 starts at the same time as the blood pump, which gradually increases its speed.
2. After reaching the blood flow set for the treatment, also the infusion pump (which allows circulating water for injectable preparations) and syringe pump 2 (if set) start.

WARNING
Given that the gas exchange occurs in compartments not isolated from the working environment:

- **Consider all the warnings and precautions relating to the presence and handling of oxygen in the working environment;**
- **Do not administer anaesthetic gases to the patient during the treatment.**

Patient connection
The patient is to be connected during treatment programming ("treatment started" window).

To connect the patient:
1. Close the electroclamp of the access line (connected to the bag containing saline hung on the infusion scale) and the electroclamp of the return line (connected to the collection bag hung on the UF scale);
2. Disconnect the access line from the bag containing saline hung on the infusion scale (see the WARNING below) and the return line from the collection bag hung on the UF scale;
3. Connect the access and return lines to the patient's catheter and open the respective electroclamps;
4. Connect the oxygen system line to the dedicated oxygenator connector (GAS INLET) and keep the delivery valve closed (to be opened when prompted by the machine).

NOTE: when you have loaded a set B, the gas line is already connected to the oxygenator, therefore, when you press START, you only need to check that it is properly connected.

A few minutes after pressing the START button, a window appears on the screen asking you to start the oxygen flow (see alarm 1070 in par. 8.11).

WARNING
When connecting the patient, make sure that you remove the connector (marked with a yellow label saying "Remove after priming") that connects the access line to the saline bag from the access line terminal.

WARNING
Do not connect the oxygen system line to the BLOOD INLET and ARTERIAL OUTLET ports of the oxygenator (see par. 4.8.3).

WARNING
The oxygen flow through the GAS INLET port of the oxygenator must not exceed 6-8 l/min. When the alarm message 1070 appears (see par. 8.11), this flow will be supplied.

WARNING
The GAS INLET port of the oxygenator must only be connected to the line of the hospital oxygen system compliant to the reference standard.

CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:
1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

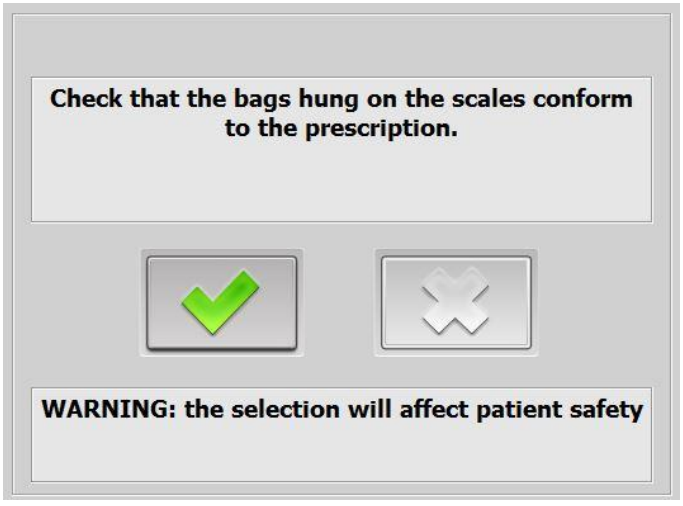
7.2.5 Treatment stop

To temporarily stop the treatment at any time, press the STOP TREATMENT button on the "treatment started" page. The function of this button is to allow the operator to change the bag containing water for injectable preparations hung on the left-hand side of the machine. The bag may need to be changed when it is almost empty.

Pressing the button activates an acoustic signal and stops the infusion pump while the blood pump continues running at reduced speed. In this way, the machine goes into PAUSE mode during which:

- A message is shown on the screen warning you to resume treatment as soon as possible (given the risk of the blood coagulating in the circuit because of blood pump deceleration) and to replace the bag of water for injectable preparations if you think necessary.
- A message is shown on the screen asking you to stop the oxygen flow (see alarm 1069 in par. 8.11).

When pressing the RESUME TREATMENT button, a message is shown on the screen reminding you to check that the bag connected to the circuit conforms to the prescription.



WARNING
Check that the bag has been loaded on the hooks on the left-hand side of the machine and not on one of the three scales.

Pressing the confirmation button of the last message shown on the screen, you go back to the "treatment started" page. When treatment is resumed, a message is shown on the screen asking you to start the oxygen flow (see alarm 1070 in par. 8.11).

WARNING
The oxygen flow through the GAS INLET port of the oxygenator must not exceed 6-8 l/min. Pressing the confirmation button when the alarm message 1070 appears (see par. 8.11), this flow will be supplied.

7.2.6 Blood pump stop

To stop the blood pump at any time, press the STOP BLOOD PUMP button on the "treatment started" page.
Use this button only when an unexpected event occurs and not to replace the bags (see par. 7.2.4, STOP TREATMENT button).

When you press this button, the system:
- Stops all the pumps;
- Warns you of the risk of the blood coagulating because of an extended blood pump stop by means of an acoustic signal, a yellow warning light and a message on the screen;
- Shows a message on the screen asking you to stop the oxygen flow (see alarm 1069 in par. 8.11).

Pressing the START BLOOD PUMP button, you go back to the "treatment started" page. When treatment is resumed, a message is shown on the screen asking you to start the oxygen flow (see alarm 1070 in par. 8.11).

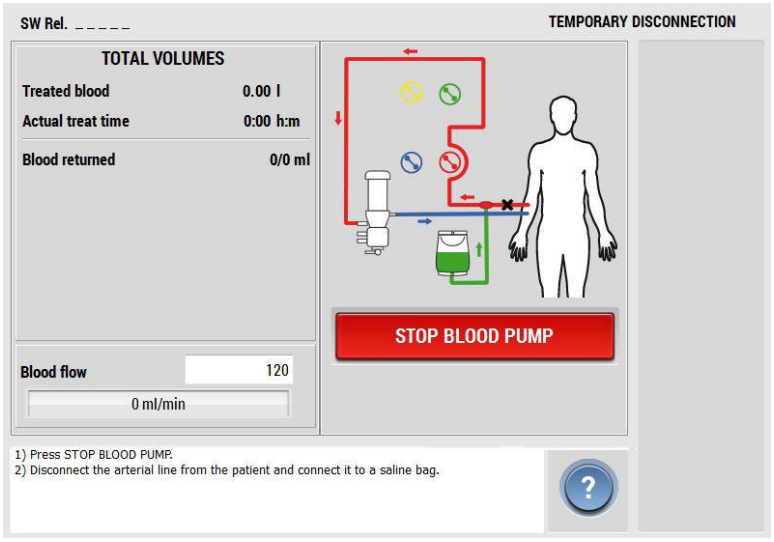
WARNING
The oxygen flow through the GAS INLET port of the oxygenator must not exceed 6-8 l/min. Pressing the START BLOOD PUMP button when the alarm message 1070 appears (see par. 8.11), this flow will be supplied.

7.2.7 Temporary disconnection

To disconnect the patient at any time, press the TEMPORARY DISCONNECTION button on the "treatment started" page. The function of this button is to allow you to return the blood to the patient following an unexpected event that requires patient disconnection.

Pressing the TEMPORARY DISCONNECTION button:
- You access a page that allows you to return the blood to the patient.
- The system shows a message on the screen asking you to stop the oxygen flow (see alarm 1069 in par. 8.11).

The page from which you can start blood return appears as shown in the image below.



When you access the blood return page, the infusion pump stops.

From the blood return page, if you have decided to disconnect the patient, operate as follows:
1. Press the STOP BLOOD PUMP button to stop the blood pump
2. Disconnect the access line (red) and connect it to a saline bag
3. Press the BLOOD RETURN button.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

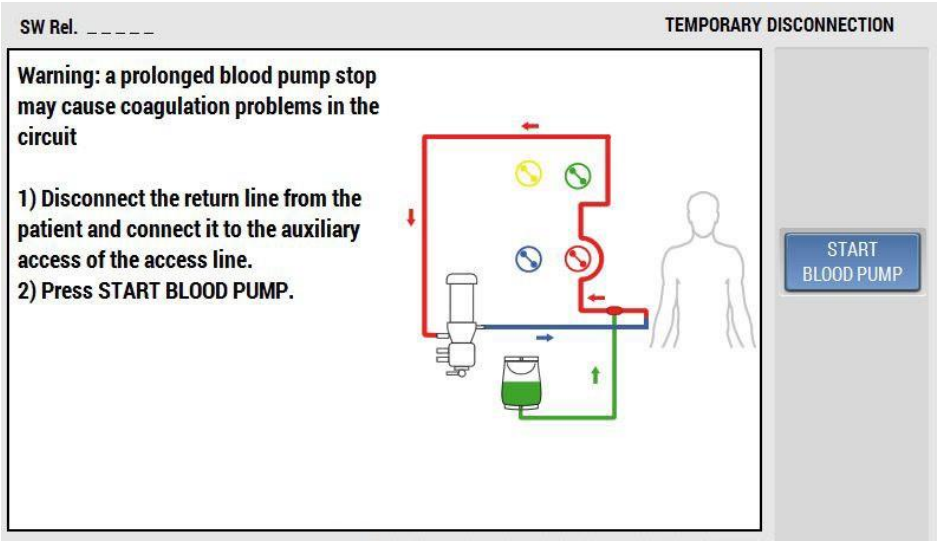
WARNING
The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.

At any time during blood return you can:

- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood return (RESUME BLOOD RETURN button)
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button)

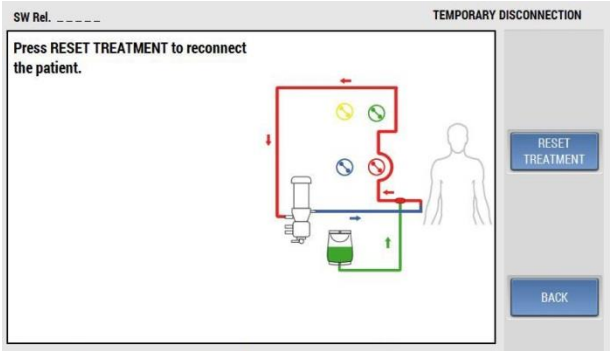
When blood return has been completed:

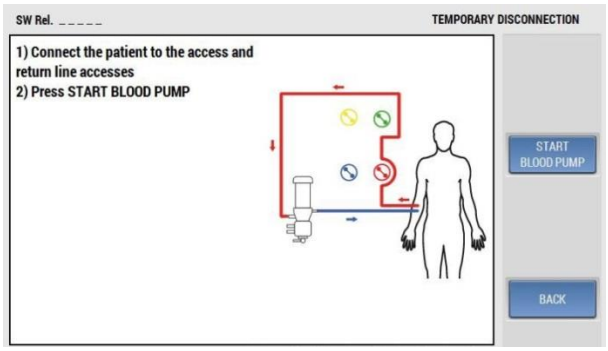
1. Disconnect the patient from the return line
2. Connect the return line to the branch on the arterial line
3. Press the START BLOOD PUMP button to restart the blood pump and allow recirculation of any blood that has remained in the circuit so that it cannot coagulate while waiting for patient reconnection.



When the patient is ready to be reconnected to the circuit, operate as follows:

- Press RESUME TREATMENT
- Connect the catheter accesses to the access and return lines
- Press START BLOOD PUMP to restart all the pumps and resume the treatment.





Pressing the START BLOOD PUMP button, you go back to the "treatment started" page. When treatment is resumed, a message is shown on the screen asking you to start the oxygen flow (see alarm 1070 in par. 8.11).

WARNING
The oxygen flow through the GAS INLET port of the oxygenator must not exceed 6-8 l/min. Pressing the START BLOOD PUMP button when the alarm message 1070 appears (see par. 8.11), this flow will be supplied.

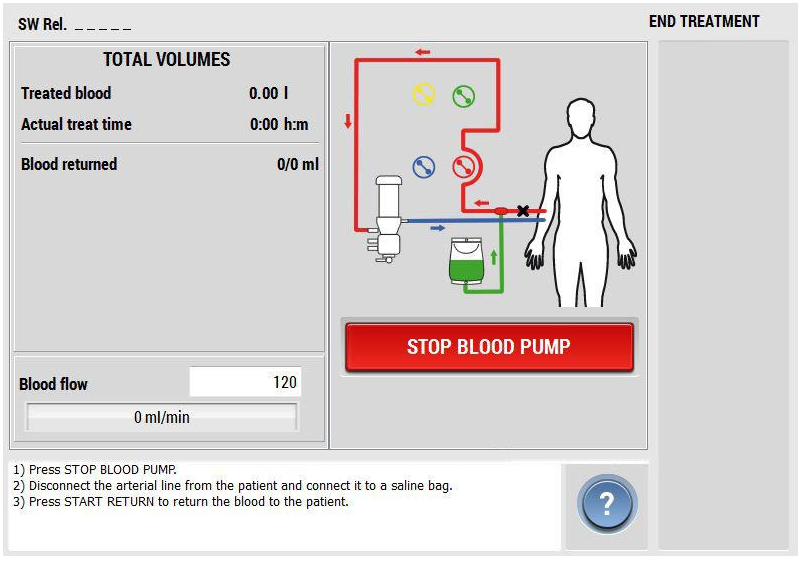
CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:
1. **Use aseptic techniques that prevent cross-infections between patients;**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection;**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

7.2.8 End of treatment

To end the treatment at any time, press the END TREATMENT button on the "treatment started" page.

When you press this button, you are asked to select whether you want to:
- Finally end the treatment;
- Continue the treatment replacing the set (see par. 7.4).

When you have made your choice, you access a page that allows you to return the blood to the patient and a message is shown on the screen asking you to stop the oxygen flow (see alarm 1069 in par. 8.11).
The page appears as shown in the image below.



When you access the blood return page, the exchange pumps stop. From this page you can:
1. Press the STOP BLOOD PUMP button to stop the pump;
2. Disconnect the access line (red) and connect it to a saline bag;
3. Press the BLOOD RETURN button.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

WARNING:
1. **The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.**
2. **It is of fundamental importance that the blood return procedure be correctly carried out before disconnecting the power in order to prevent needless patient blood leakage.**

At any time during blood return you can:
- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood return (RESUME BLOOD RETURN button);
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

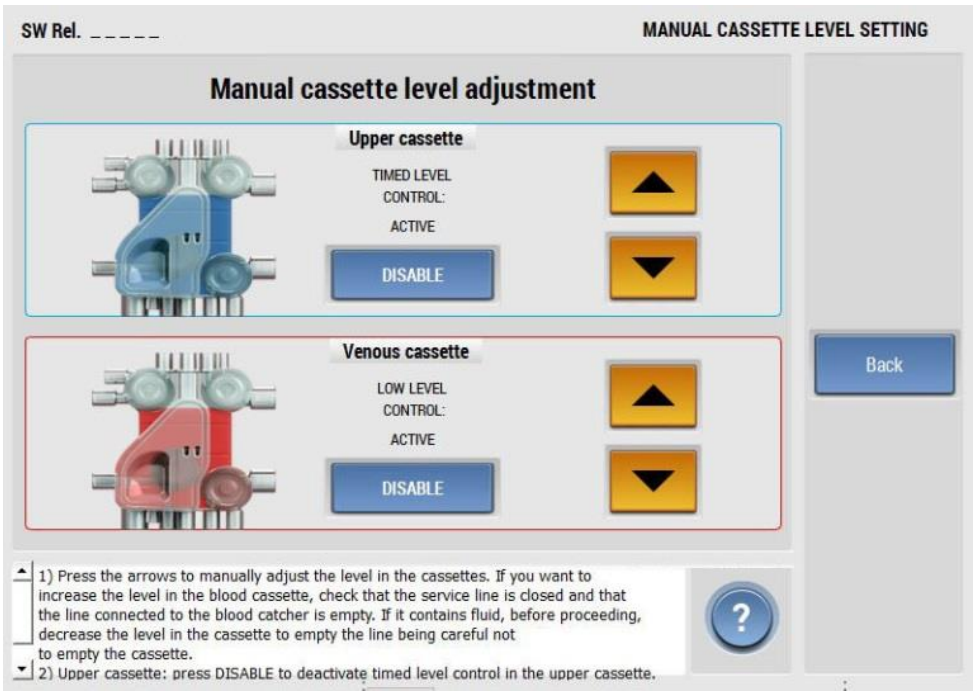
During this pause phase, only the following alarms are active:
- Access and return pressure alarms
- Air alarm.

CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:
1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

When blood return is complete, you access a page containing a sequence of illustrated instructions for removal of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.
From this page you can remove the set, once you have disconnected the lines as illustrated in the instructions, by pressing REMOVE SET. When you press this button, you access a page informing you that the treatment has ended and that you can turn off the machine using the switch on the rear (see REAR VIEW in Chapter 2 Machine Presentation).

7.2.9 Chamber levels

Pressing the CHAMBER LEVELS button, you access a page where you can manually adjust the levels in the venous cassette and the level in the upper cassette using the relative buttons to raise and lower the level. From this page you can also disable level control of each cassette by pressing the dedicated button.



7.3 ROUTINE OPERATIONS DURING TREATMENT

During the treatment, some routine operations must be performed to safeguard the patient.

WARNING
In order to prevent excessive carbon dioxide removal from the patient during the treatment:
- **Periodically monitor the patient**
- **Periodically perform a blood gas analysis**
- **Use the device under specialist medical supervision**

7.3.1 Patient temperature check

Throughout the treatment the patient's temperature must be checked whenever the situation requires.
The machine is equipped with a heater which must be used to prevent the patient from getting cold when this is undesirable for clinical reasons.
Use of the heater is described in paragraphs 2.1 and 7.2.1 in this manual.

7.3.2 Pressure check

Right from the beginning of the treatment, the pressure values must be checked to verify that they fall within an acceptable range.

It is recommended to:
- **Operate the machine within the minimum and maximum default values for the access and return pressures (see par. 7.1.6).**
- **Pay particular attention to haemolysis phenomena if the trans-oxygenator values exceed 50 mmHg.**

To adjust the alarm limits both before the treatment starts and during the treatment, operate as described below:
1. Press on the Pressures panel on the treatment page to access the page where to set the pressure limits (see par. 7.1.3);
2. Set the new limits with respect to the return and access pressures measured;
3. Confirm the modified values and go back to the treatment page.

CAUTION: Inadequate setting of the access and return pressure limits may reduce the system's ability to detect any disconnected blood lines.

CAUTION
Access and return pressure monitoring is not always able to detect disconnection of the access or return line from the relative patient access. Disconnection results in blood leakage into the surrounding environment.
Disconnection of a line from the relative patient access may cause a decrease (return) or an increase (access) in the relative pressure although it remains within the permitted alarm range. In this case, therefore, the machine is unable to detect disconnection despite the alarm thresholds being set correctly.
In order to reduce the risk of the access and return lines disconnecting from the relative access:
- Check that the access and return lines are properly connected to the relative access on the patient side by means of their fastening ring nut.
- Check that the patient access and return accesses are visible at all times during the dialysis treatment.
- Frequently check the patient access and return accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limits for both pressures as close as possible to the actual value of the relative pressure of the patient in order to avoid the alarm from continuously intervening.

In order to reduce the risk of access and return line disconnection:
- Check that the patient accesses and relative lines are properly connected as prescribed by the protocol of your clinic.
- Check that the patient accesses are visible at all times during the dialysis treatment.
- Frequently check the patient accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limit for the return pressure and the maximum alarm limit for the access pressure as close as possible to the actual value of the respective pressures on the patient.

7.3.3 Replacing the fluid bags

You can replace the bag containing water for injectable preparations at any time.
To change the bag at any time, operate as follows:
1. Press the STOP TREATMENT button (see par. 7.2.4).
2. Replace the bag and make sure that the new bag conforms to the prescription (i.e. contains water for injectable preparations, as requested by the system via a warning window).
3. Press the RESUME TREATMENT button in the window that appeared when you pressed the STOP TREATMENT button (see par. 7.2.4).

7.4 END OF TREATMENT

Treatment with set A
When reaching 60 hours of treatment (when **Remaining time** reaches 0):
- The only buttons active are END TREATMENT and DATA (Function Button area).
- A message is shown on the screen informing you that 60 hours have elapsed and asking you to press END TREATMENT.

When you press END TREATMENT, you are asked whether you want to finally end the treatment after returning the blood to the patient (see par. 7.2.8) or return the blood to the patient, replace the set and continue with the treatment (see par. 4.8).
When you have made your choice, you access a page that allows you to return the blood to the patient and a message is shown on the screen asking you to stop the oxygen flow (see alarm 1069 in par. 8.11).
When blood return is complete, follow the instructions shown in the active area of the page:
1. Disconnect the oxygenator from the relative lines of the set and leave it positioned on the heat exchanger if you have chosen to continue with the treatment
2. Remove the other lines of the set
3. Unload the set
4. Turn off the machine
5. Turn the machine on again if you have chosen to continue with the treatment.

If during the treatment you decide to replace the set before the 60 hours of treatment have elapsed (see par. 4.8), on pressing END TREATMENT you are asked whether you want to continue the treatment (with set A), end the treatment definitively after returning the blood to the patient (see par. 7.2.8), or return the blood to the patient, replace the set and continue with the treatment (see par. 4.8).
When blood return is complete, follow the instructions shown in the active area of the page:

1. Disconnect the oxygenator from the relative lines of the set and leave it positioned on the heat exchanger if you have chosen to continue with the treatment
2. Remove the other lines of the set
3. Unload the set
4. Turn off the machine
5. Turn the machine on again if you have chosen to continue with the treatment.

WARNING
When you disconnect the inlet line (blue) and the outlet line (red) on the set side from the relative blue line (BLOOD INLET) and red line (ARTERIAL OUTLET) on the oxygenator side, make sure that you:

1. **Close the electroclamps of the above mentioned lines on both the oxygenator and the set side;**
2. **Fit the blue and red sterile accessory caps provided in the ABYLCAP kit respectively on the blue and red line on the oxygenator side.**

Treatment with set B
If you have chosen to continue with the treatment by turning the machine off and on again and replacing set A with set B and have started the treatment after priming the new set, the treatment automatically ends when the **Remaining time** parameter reaches 0:

- The only buttons active are END TREATMENT and DATA (Function Button area)
- A message is shown on the screen informing you that 60 hours have elapsed and asking you to press END TREATMENT.

Pressing END TREATMENT, you access a page from where you can start blood return to the patient and a message is shown on the screen asking you to stop the oxygen flow (see alarm 1069 in par. 8.11).

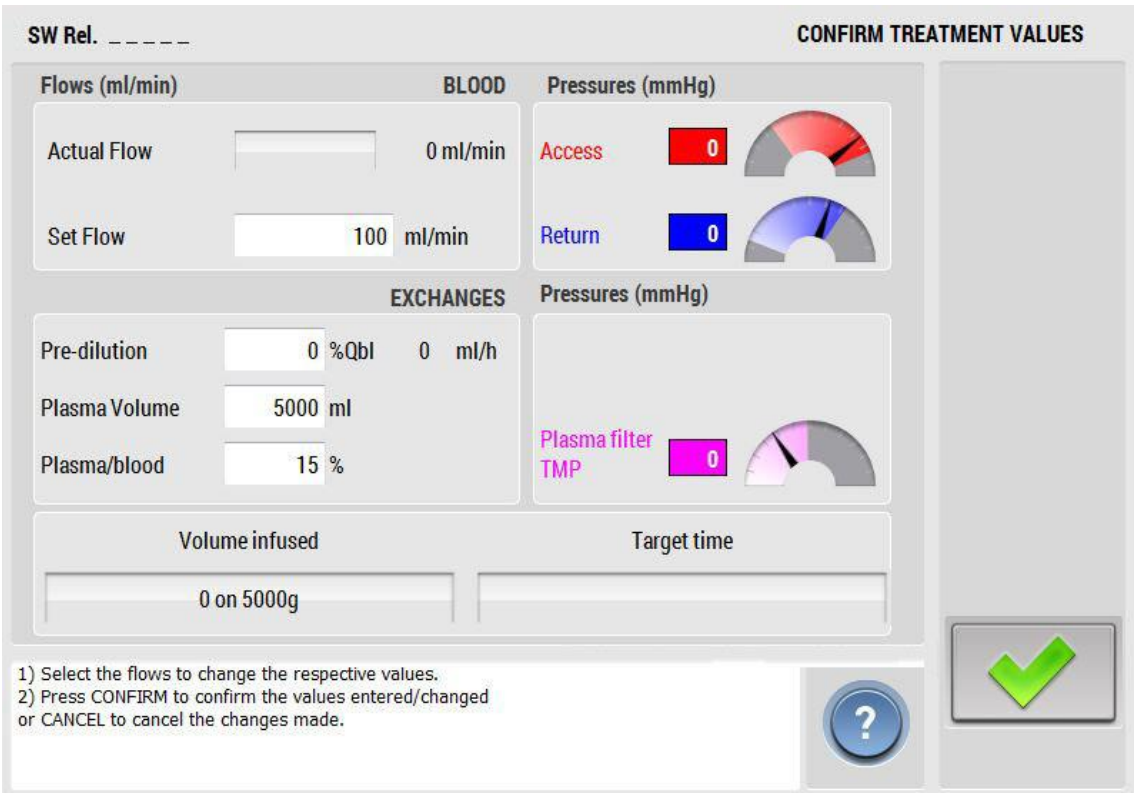
When blood return is complete, follow the instructions shown in the active area of the page:

1. Disconnect the oxygenator from the relative lines of the set
2. Remove the other lines of the set
3. Unload the set
4. Turn off the machine.

8 PERFORMING A PEX TREATMENT

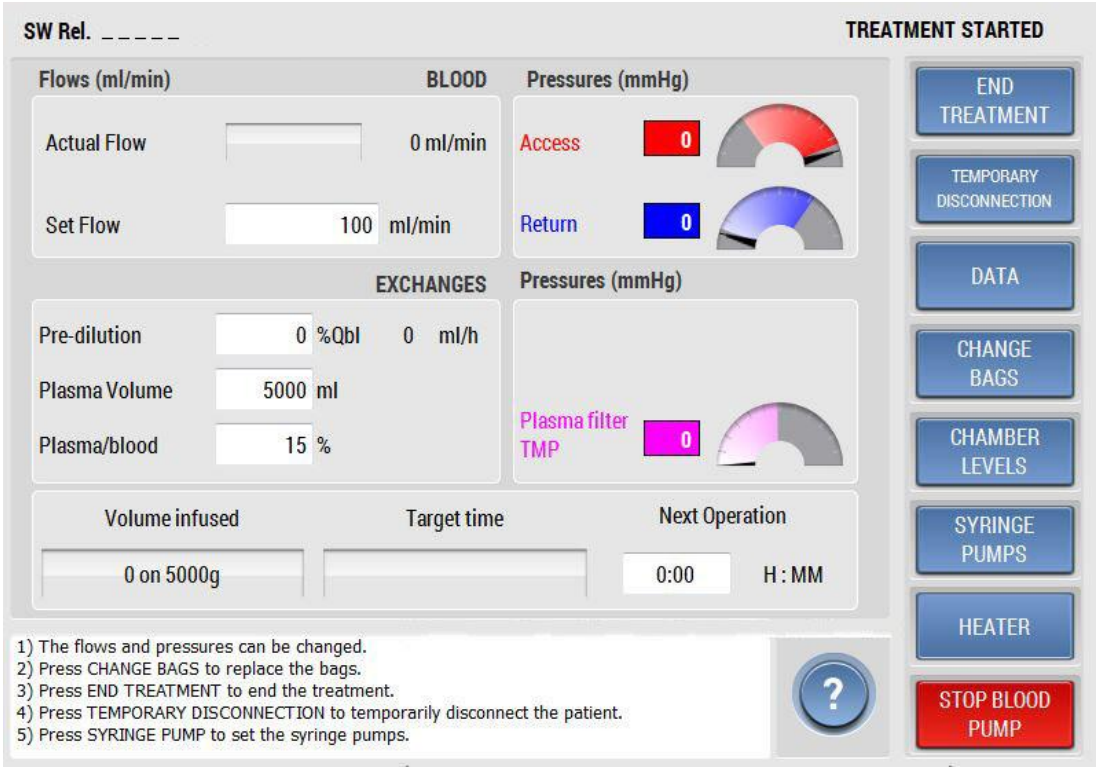
Pressing the TREATMENT button from the "End Rinse" page, you access a page where you can program and start the PEX treatment selected.

If the treatment selected is PEX, the page appears as shown in the image below.



From the "start treatment" page, having made and confirmed all the required settings for the specific treatment (see par. 4.3.4), you can start the treatment by pressing the START button (Function Button area) and so access the "treatment started" page.

WARNING
Check that the filter connectors are properly screwed on.



The "start treatment" and "treatment started" pages are structured as follows:

- An *active* area divided into three control blocks (blood, exchange and time [Volume infused and Target time]) where the characteristic parameters of the selected treatment and the respective values are shown.
- A *function button* area to the right of the three blocks with buttons that offer access to some useful treatment functions.
- An *information* area at the bottom where the treatment name and power supply (mains or battery) are shown.

The flow and pressure parameters are shown in the various control blocks.

Some of the parameters displayed allow you to monitor treatment progress (therefore, before starting the treatment, their value is zero).

Other parameters are settable/modifiable by the operator using the *numerical keypad* (see par. 4.3) after pressing on the corresponding white field.

8.1 TREATMENT PARAMETERS

8.1.1 Blood

The blood control parameters are shown under BLOOD at the top of the active area of the “start treatment” and “treatment started” pages.
The actual flow and the set flow expressed in ml/min form part of the “Flows” panel.

The **actual flow** indicates the actual blood pump flow supplied by rotation of the pump during the treatment (therefore it is 0 before treatment start when the pumps are all off). During treatment, the value of this parameter allows you to monitor the blood flow instant by instant.
The actual flow depends on the access pressure, the blood pump speed and deterioration of the relative line.

The **set flow** indicates the blood flow operating value desired for the specific treatment. The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment.

The access pressure and the return pressure expressed in mmHg form part of the “Pressures” panel.
The **access pressure** is the pressure, monitored during treatment, before the blood pump at the blood inlet to the extracorporeal circuit.
The **return pressure** is the pressure, monitored during treatment, in the venous cassette before the blood is returned to the patient through the return line (blue tube section).

When the treatment is started, only the blood pump and syringe pump 1 (if set) start. Syringe pump 2 (if set) starts once the operating blood flow has been reached. The blood pump gradually accelerates until reaching the operating flow set in relation to the blood pressure variations. Four minutes after reaching the operating blood flow, the exchange pumps (infusion, UF) start:

8.1.2 Exchanges

The **exchange** defines the clearance to be achieved by convection, diffusion or adsorption. The exchange mechanism control parameters will hence change in relation to the treatments.
In all cases you can define the clearance by means of a flow in ml/h or as percentage part of the blood flow. In addition, the transmembrane pressure/s are shown.

The exchange control parameters are shown under EXCHANGES in the centre of the active area of the "start treatment" and "treatment started" pages.

In the exchange flows panel:

- The **plasma flow** *(plasma/blood*) is shown expressed as a percentage of the flow generated by the blood pump and supplied by rotation of the infusion pump.
  The percentage plasma flow of the flow generated by the blood pump can be set by the operator both during programming and treatment.

- The **plasma volume** is shown (target volume of plasma to be treated) This volume can be set by the operator both during programming and treatment.

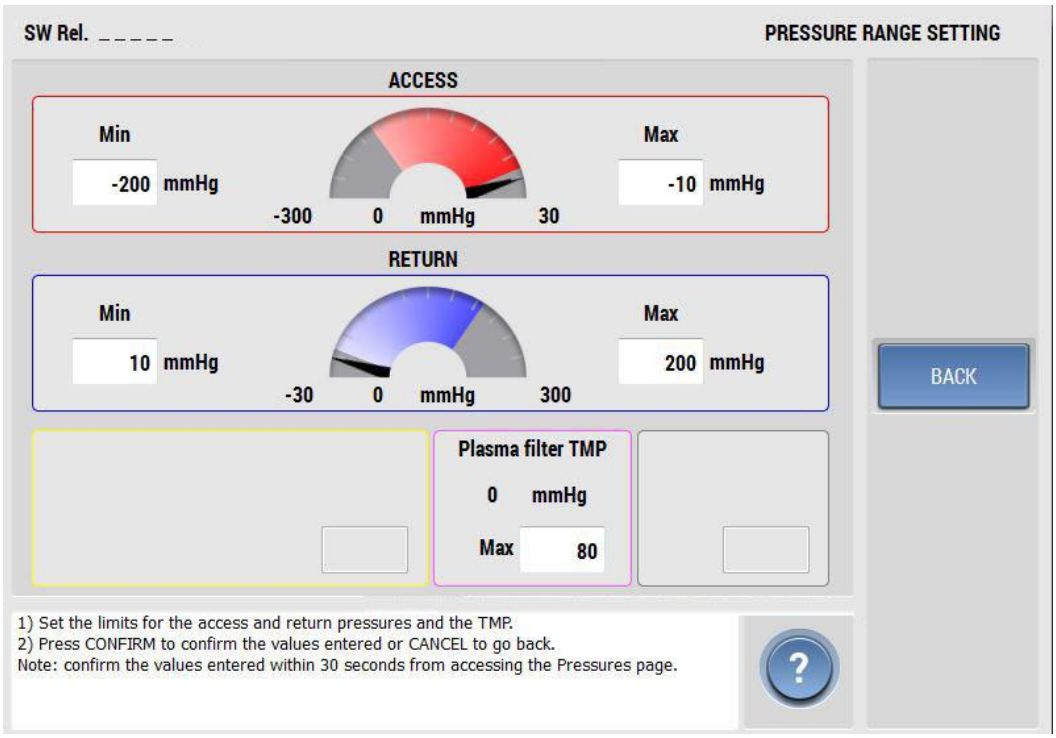
The transmembrane pressure or TMP of the plasma filter is shown in the "Pressures" panel. The TMP is expressed in mmHg.
The **TMP of the plasma filter** is calculated as the difference between the mean blood pressure in the filter and the pressure of the plasma coming out of the plasma filter (i.e. the plasma drawn from the patient's blood).

NOTE:
- The pressure of the plasma coming out of the plasma filter is the pressure monitored during the treatment before the UF pump.
- The mean blood pressure in the plasma filter is calculated between the pressure values at the inlet and outlet of the plasma filter.
- The pressures at the inlet and outlet of the plasma filter are the pressures monitored during the treatment, respectively after the blood pump and in the venous cassette.

8.1.3 Pressures

Both during programming and treatment, pressing on the Pressures panels relating to blood and exchange control, you access the pressure range page.

The page appears as shown in the image below.



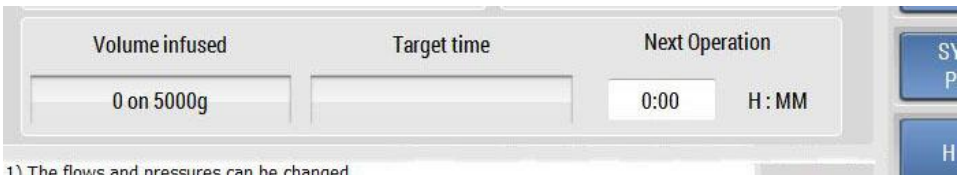
On this page you can view and set:

- The minimum and maximum permitted access and return pressures
- The maximum permitted plasma filter transmembrane pressures.

To set the minimum and maximum values, see paragraph 8.3.3.

8.1.4 Time

The parameters that allow monitoring the treatment time are shown at the bottom of the *active* area of the page.
The information on the treatment time is provided by the **volume of plasma infused** (on the left), the **time necessary to treat the target volume of plasma** (in the centre) and the **next operation time**.



When the volume of plasma treated reaches a target volume of less than 30 litres, you are asked whether you want to continue the treatment resetting the volume of plasma to be infused/treated or end the treatment returning the blood to the patient.
When the volume of plasma treated reaches 30 litres:

- The system does not allow continuing the treatment
- The only buttons active are DATA (see par. 8.2.2) and END TREATMENT (see par. 8.2.8).

The system advises you to end the treatment after 24 hours (see par. 8.4.).

During a PEX treatment, the next operation time is indicated next to the target time, i.e. the time remaining to the next bag replacement or the next syringe replacement.
Pressing on the Next Operation field a menu appears indicating:

- The time remaining to the next UF bag change
- The time remaining to the next infusion bag change
- The time remaining to the next syringe 1 change
- The time remaining to the next syringe 2 change

Five minutes before each of these times runs out, a message on the screen informs you what needs to be changed (see alarms 1071, 1072, 1074, 1076 in par. 8.11).
Subsequently, this message appears every 5 minutes until you make the change.

8.1.5 Treatment specifications

The tables below give definitions of parameters settable and/or modifiable by the operator. In each table reference is made to the NOTES below the table, giving further definitions of parameters and relative values settable by the user.

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min) (see Note 5)	150	30	250
Plasma/blood (%)	15	0; 5	20
Min. access pressure (mmHg)	-200	-300	Max. access pressure
Max. access pressure (mmHg)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 (or -30 based on the machine configuration)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. plasma filter TMP (mmHg)	50	0	80

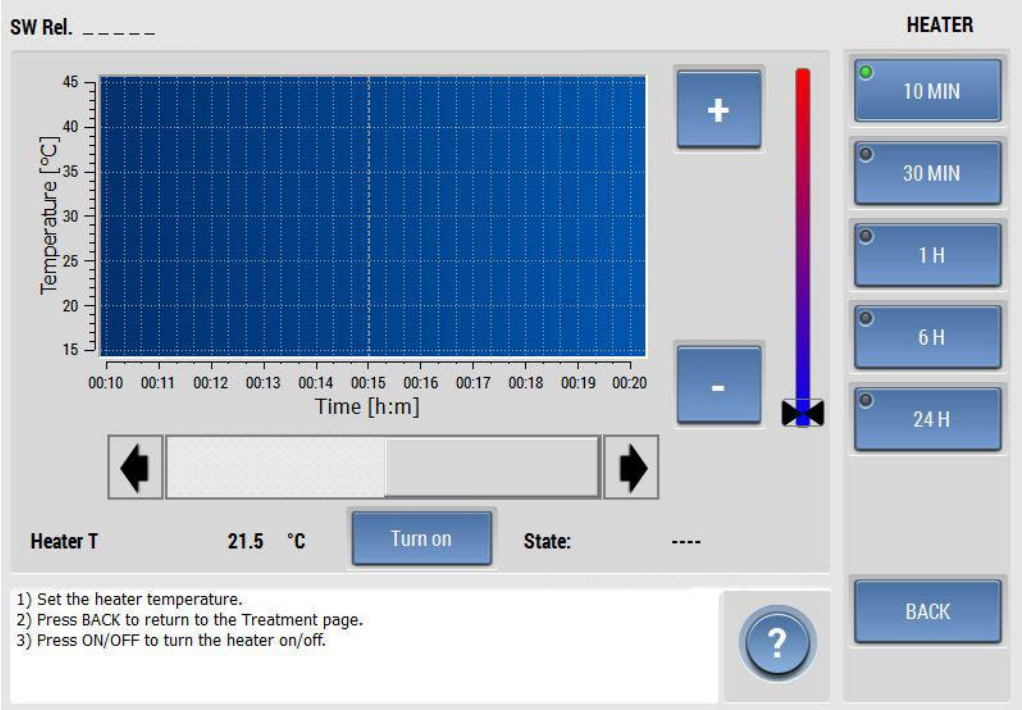
NOTES:
The system sets the UF flow (plasma removed from the blood) equal to the infusion flow (plasma infused).

8.2 FUNCTION BUTTONS

The function buttons on the right of the “start treatment” and “treatment started” pages allow access to other pages and functions.

8.2.1 Heater

The button is available on both the “start treatment” and the “treatment started” page.
Pressing this button, you access a page from where you can turn the heater on and off. This page also displays a graph showing the temperature over time.



You can select six temperature levels that cover a range between 30 and 41°C.
The outgoing fluid temperature measured is shown at the bottom of the page.
The fluid heater is on at minimum level by default.
To turn on the heater:

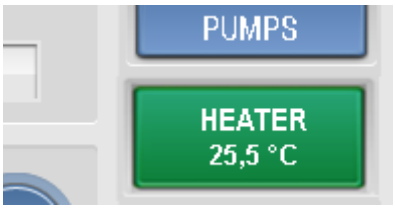
- Press the ON/OFF button (at the bottom of the page) and confirm;
- Select the desired temperature (by pressing the + and – buttons to the right of the graph) and confirm.

To turn off the heater, press the ON/OFF button again and confirm.
The heater status is indicated next to the ON/OFF button:

- ON indicates that the heater is on
- OFF indicates that the heater is off
- DEACTIVATED indicates that the heater is inactive as it has not passed the test during priming.

The temperature graph in the centre of the page allows viewing the actual **outgoing fluid temperature.**

During treatment, the HEATER button is green if the heater is on. It also shows the actual outgoing fluid temperature.

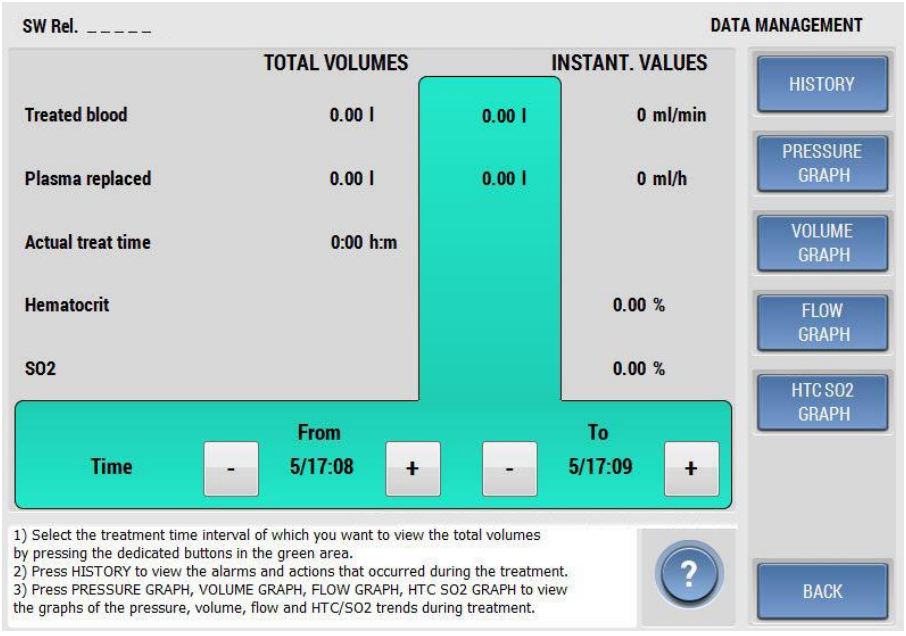


WARNING
When the infusion fluid temperature drops to below 33.5°C, the system informs you by turning the word HEATER on the button into yellow and showing the button with a yellow border.

8.2.2 Data

The button is available on both the "start treatment" and the "treatment started" page.
Pressing this button, you access the relative page where the following are shown:

- The total volume of the fluids (left column)
- The volume of the fluids of a certain period (central green section of the page)
- The instantaneous flow values (right column).



Pressing the corresponding buttons (Function Button area) on this page, you can access the pages containing, respectively:

- The pressure graphs
- The volume graphs
- The flow graphs
- The hematocrit and oxygen saturation graphs
- The treatment history, which lists:
  1. All the actions performed (e.g. buttons pressed) up to that moment
  2. All the parameter modifications made up to that moment
  3. All the alarm events that occurred up to that moment.

These data remain in memory also after the end of the treatment.

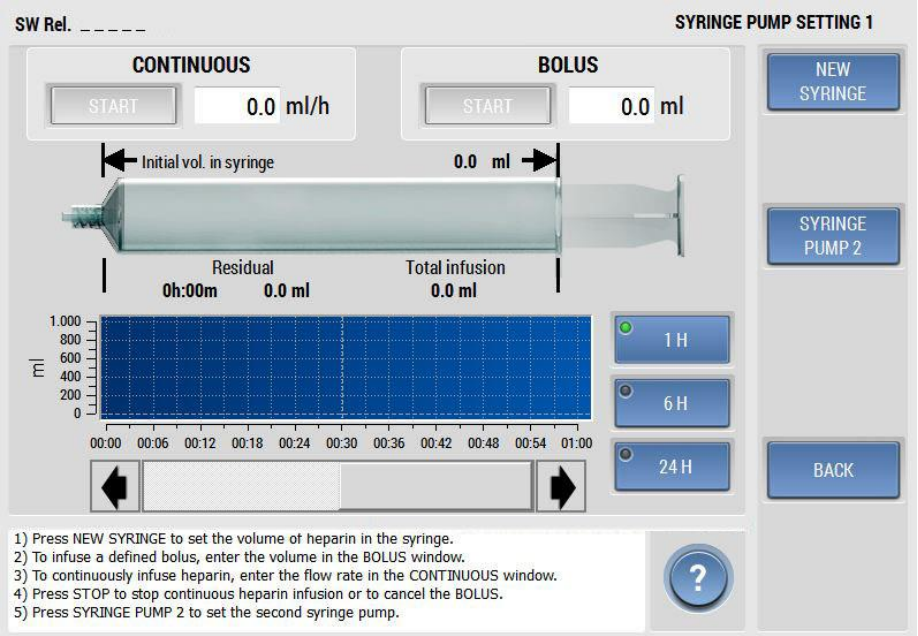
The pages containing the graphs allow selecting the time interval within which to display the relative graph.

8.2.3 Syringe pumps

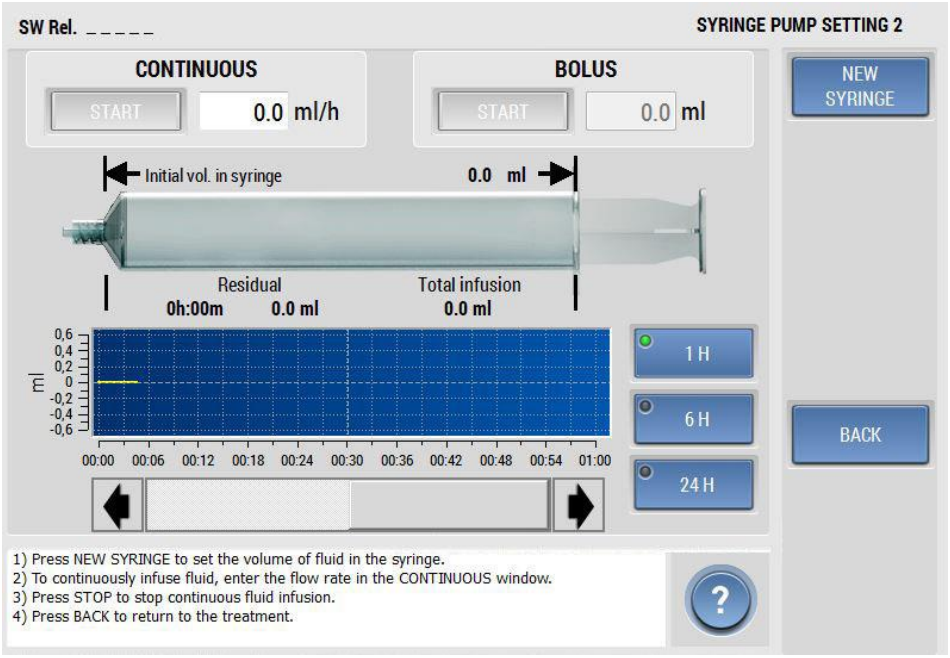
The SYRINGE PUMPS button is available on both the "start treatment" and the "treatment started" page. Pressing this button, you access a page from where you can:

- Control the syringe pumps by setting continuous infusion or bolus infusion
- Install a new syringe
- Replace a syringe
- Set the volume contained in the syringes installed in the pumps.

When at least one of the two pumps is active, the SYRINGE PUMPS button is green. If only one of the two pumps is active, the infusion flow of that pump is shown on it.
Pressing the SYRINGE PUMPS button, you directly access the page where you can set heparin infusion by means of syringe pump 1. This page displays a graph showing heparin infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 1 setting" page, you can replace and/or install a new syringe in syringe pump 1.



Pressing the SYRINGE PUMP 2 button, you access the page where you can set ancillary infusion by means of syringe pump 2. This page displays a graph showing infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 2 setting" page, you can replace and/or install a new syringe in syringe pump 2.



Programming heparin infusion (syringe pump 1)
If a syringe has not yet been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows installing a heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:
1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 1 programming page).
2. Connect the syringe containing heparin to the relative line (leading from the single-use set at the top right).
3. Press on the arrows on the screen to move the syringe pump 1 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger
4. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

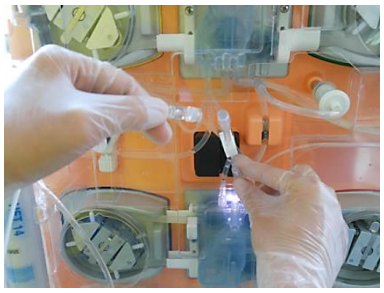
Confirming the settings, you go back to the syringe pump 1 programming page.
If a syringe has already been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows replacing the heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:
1. If necessary, replace the syringe with another one of the same type containing heparin and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the right-hand syringe pump pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 1 programming page.

Programming ancillary infusion (syringe pump 2)
If a syringe has not yet been installed in syringe pump 2, pressing the SYRINGE PUMP 2 button and then the NEW SYRINGE button, you access a page that allows installing a syringe in the relative pump for ancillary infusion during the treatment.

To install a syringe, operate as follows:
1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 2 programming page)
2. Connect the syringe for ancillary infusion to the service line of the venous cassette (the connection line can be supplied to the user on request)



3. Press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
4. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.
If a syringe has already been installed in syringe pump 2, pressing the NEW SYRINGE button, you access a page that allows replacing the syringe for ancillary infusion during the treatment.

To install a syringe, operate as follows:
1. If necessary, replace the syringe with another one of the same type and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

Replacing one of the syringes
One of the syringes may need to be replaced:
- When the residual syringe content has all been infused.
- If an excessive value has been set for the initial volume of fluid in the syringe, which results in display of an incorrect residual value (different from zero) when the volume available in the syringe has run out.
- If there is an obstruction along the infusion line.

Bolus and continuous infusion
From the “syringe pump 1 setting” page, you can use the numerical keypad to set bolus and/or continuous infusion to the patient during the treatment by means of pump 1.
From the “syringe pump 2 setting” page, you can use the numerical keypad to set continuous infusion to the patient during the treatment by means of pump 2.

NOTE: You cannot set infusion boli by means of syringe pump 2.

The white fields of the *bolus and continuous* areas for syringe pump 1 and *continuous* for syringe pump 2 are active only if a syringe has previously been installed and the residual content in the syringe is not null.
When you program syringe pump 1 to simultaneously perform a bolus and a continuous infusion, the bolus will always be administered first upon treatment start.
During the treatment, you can cancel the bolus set by pressing the STOP button in the corresponding panel (on the right) and/or stop the continuous infusion set by pressing the STOP button in the corresponding panel (on the left). Subsequently, you can reset the bolus so that the system administers it automatically and/or press the START button to resume continuous infusion.

8.2.4 Treatment start

WARNING
Make sure that you have loaded a set consistent with the treatment to be performed (indicated at the bottom left of the screen).

To start the treatment, press the START button on the "start treatment" page.
When you press the button, you are asked to check the connections of the access and return lines to the patient (see *patient connection* below) and to confirm that they are properly connected. Once confirmed, the system starts the treatment. In the initial transition phase:

1. The blood pump speed gradually increases and a few seconds after the blood pump has started, syringe pump 1 starts.
2. A few minutes after the blood flow set for the treatment has been reached, the exchange pumps start (as described in par. 8.1.1).

Patient connection
The patient is to be connected during treatment programming ("treatment started" window).
To connect the patient:

1. Close the electroclamp of the access line (connected to a branch of the infusion line by means of a constricted tube) and the electroclamp of the return line.
2. Disconnect the access line from the constricted tube that connects it to the branch of the infusion line and the return line from the relative collection bag.
3. Connect the access and return lines to the patient's catheter and open the respective electroclamps.

CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

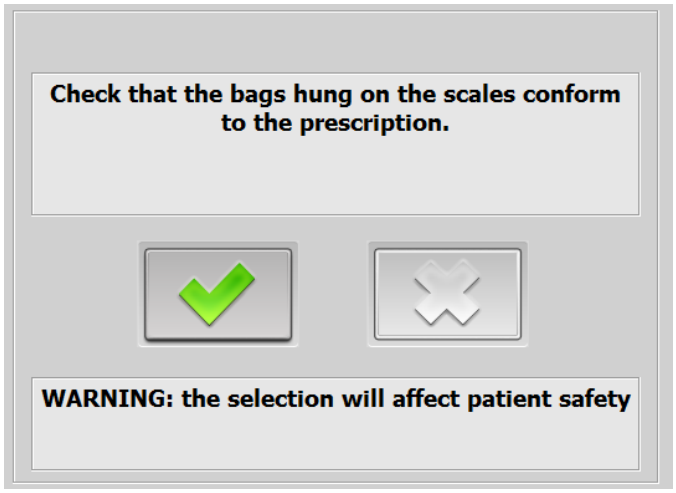
1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

8.2.5 Bag change

To temporarily stop the treatment at any time, press the CHANGE BAGS button on the "treatment started" page. The function of this button is to allow the operator to change the bags. The bags may need to be changed if they are full (collection bags) or almost empty (plasma bags).

Pressing the button activates an acoustic signal and stops the exchange pumps except the blood pump that continues running at reduced speed. In this way, the machine goes into PAUSE mode during which a message is shown on the screen warning you to resume treatment as soon as possible (given the risk of the blood coagulating in the circuit because of blood pump deceleration) and to replace the bags if necessary.

When you have pressed the RESUME TREATMENT button, the system reminds you to check that the bags connected to the circuit conform to the prescription.



WARNING
Check that all the bags have been loaded on the relative scales and that they do not touch other parts of the machine or bags on other scales.

8.2.6 Blood pump stop

To stop the blood pump at any time, press the STOP BLOOD PUMP button on the "treatment started" page.

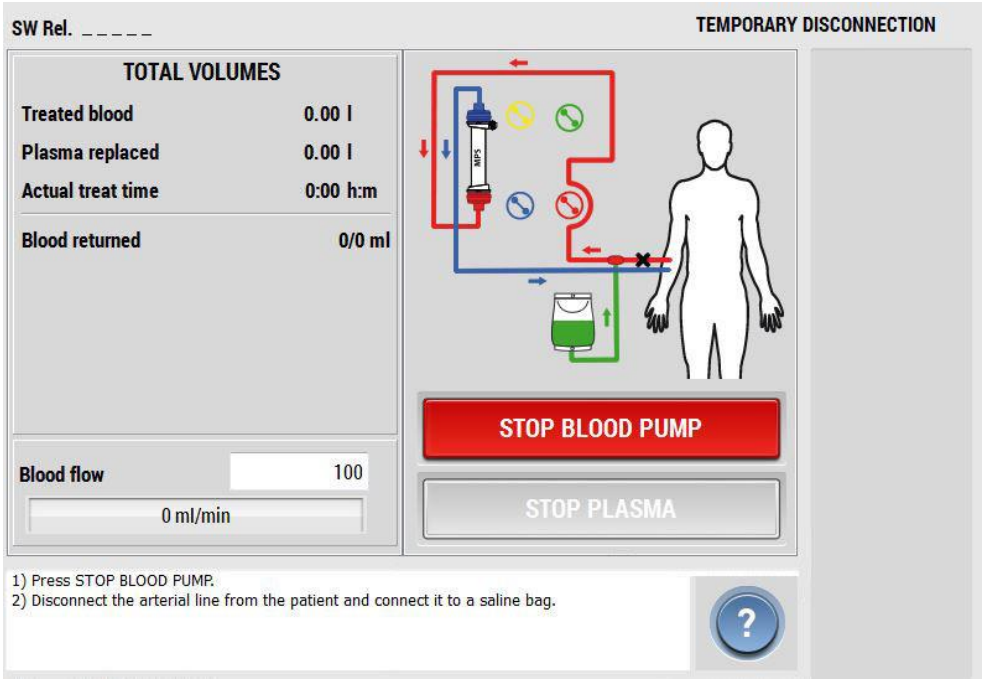
Use this button only when an unexpected event occurs and not to replace the bags (see par. 8.2.4, CHANGE BAGS button).
When you press this button, the system stops the pumps and warns you of the risk of the blood coagulating because of an extended blood pump stop by means of an acoustic signal, a yellow warning light and a message on the screen.

8.2.7 Temporary disconnection

To disconnect the patient at any time, press the TEMPORARY DISCONNECTION button on the "treatment started" page. The function of this button is to allow you to return the blood to the patient following an unexpected event that requires patient disconnection.

Pressing this button, you access a page that allows you to return the blood to the patient.

The page appears as shown in the image below.



When you access the blood return page, the exchange pumps stop.
From the blood return page, if you have decided to disconnect the patient, operate as follows:

1. Press the STOP BLOOD PUMP button to stop the blood pump.
2. Disconnect the access line (red) and connect it to a saline bag.
3. Should the infusion fluid/plasma have run out, disconnect at least one plasma infusion line and connect it to a saline bag. Position the bag on the infusion scale.
4. Press START RETURN.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

WARNING
The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.

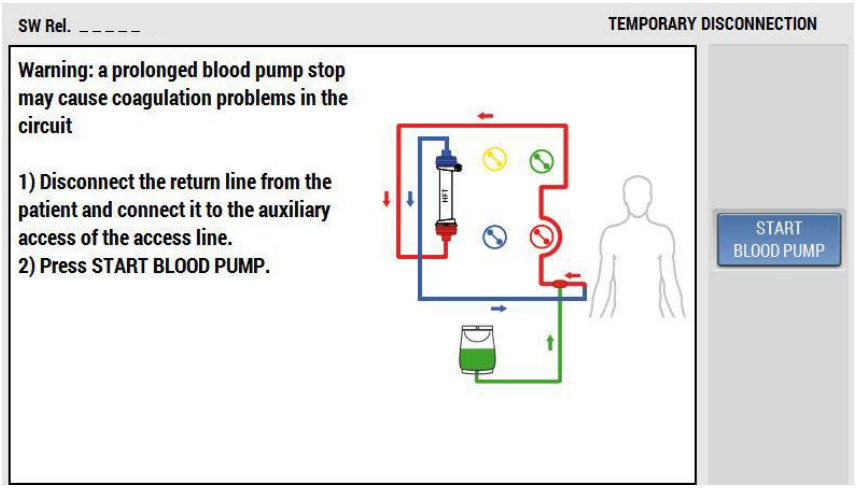
When blood return has started, you can stop plasma return by pressing the button that stops the plasma infusion pump.

At any time during blood return you can:

- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood and plasma return (START RETURN button) or only blood return (BLOOD RETURN ONLY button).
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

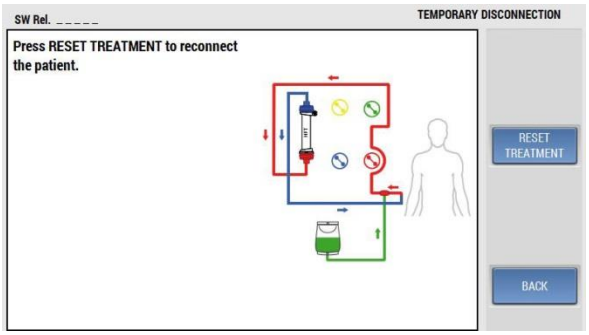
When blood return has been completed:

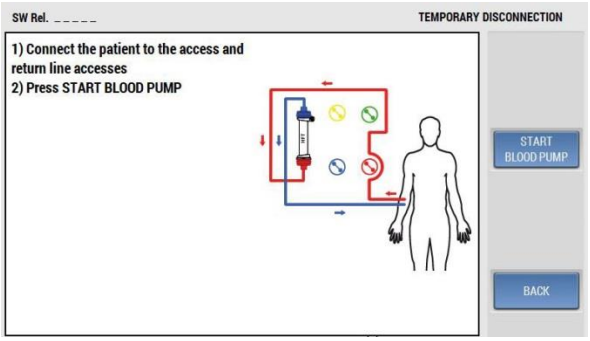
1. Disconnect the patient from the return line.
2. Connect the return line to the branch on the arterial line.
3. Press the START BLOOD PUMP button to restart the blood pump and allow recirculation of any blood that has remained in the circuit so that it cannot coagulate while waiting for patient reconnection.



When the patient is ready to be reconnected to the circuit, operate as follows:

- Press RESUME TREATMENT
- Connect the catheter accesses to the access and return lines
- Press START BLOOD PUMP to restart all the pumps and resume the treatment.





CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

8.2.8 End of treatment

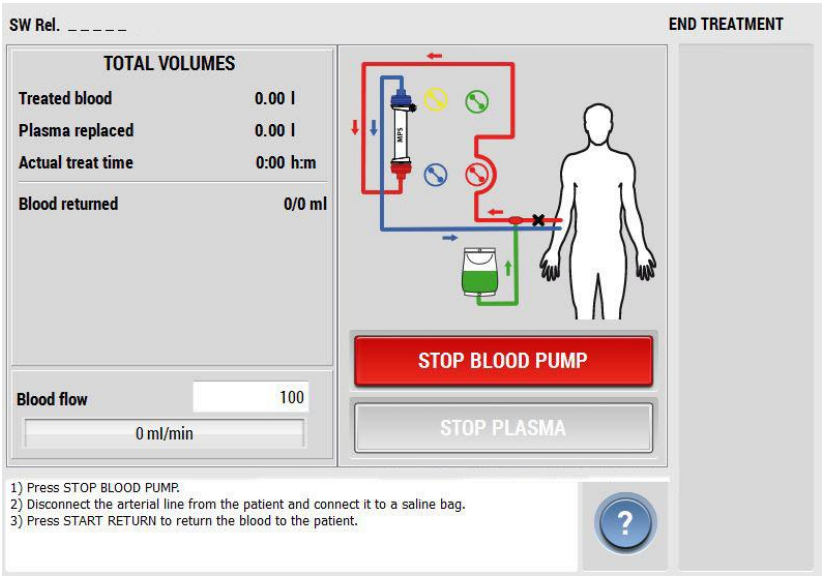
To end the treatment at any time, press the END TREATMENT button on the "treatment started" page.

Pressing this button before the maximum 24 hours of treatment have elapsed, allows you to:

- Confirm the selection and end the treatment.
- Cancel the selection to resume the treatment.

Confirming the selection to end the treatment, you access a page that allows you to return the blood to the patient.

The page appears as shown in the image below.



When you access the blood return page, the exchange pumps stop. From this page you can:
1. Press the STOP BLOOD PUMP button to stop the blood pump
2. Disconnect the access line (red) and connect it to a saline bag
3. Should the infusion fluid/plasma have run out, disconnect at least one plasma infusion line and connect it to a saline bag. Position the bag on the infusion scale
4. Press START RETURN.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

WARNING:
1. **The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.**
2. **It is of fundamental importance that the blood return procedure be correctly carried out before disconnecting the power in order to prevent needless patient blood leakage.**

When blood return has started, you can stop plasma return by pressing the button that stops the plasma infusion pump.

At any time during blood return you can:
- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood and plasma return (START RETURN button) or only blood return (BLOOD RETURN ONLY button).
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

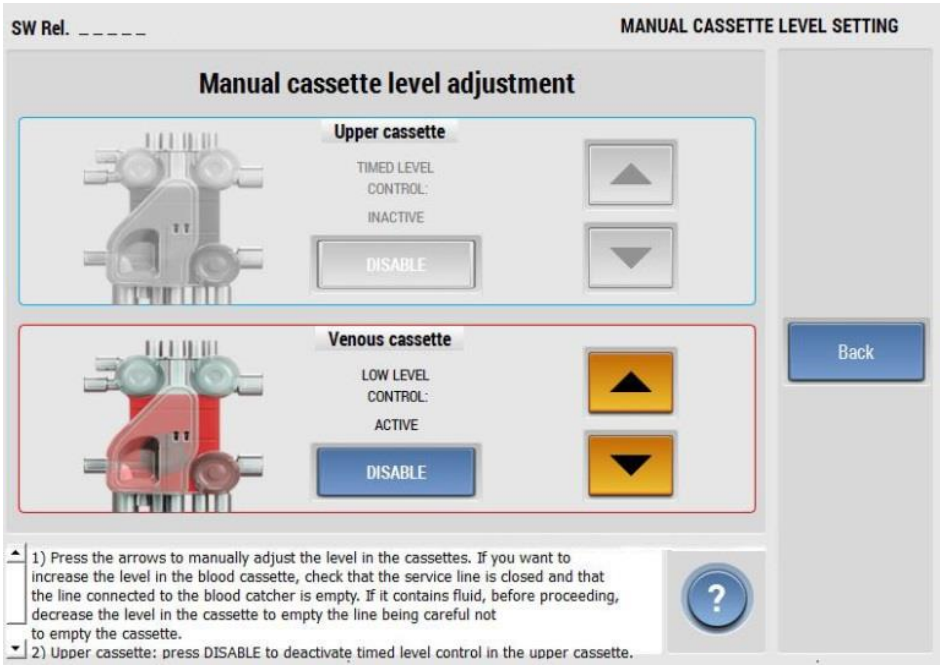
During this pause phase, only the following alarms are active:
- Access and return pressure alarms
- Air alarm.

CAUTION
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:
1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

When blood return is complete, you access a page containing a sequence of illustrated instructions for removal of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.
From this page you can remove the set, once you have disconnected the lines as illustrated in the instructions, by pressing REMOVE SET. When you press this button, you access a page informing you that the treatment has ended and that you can turn off the machine using the switch on the rear (see REAR VIEW in Chapter 2 Machine Presentation).

8.2.9 Chamber levels

Pressing the CHAMBER LEVELS button, you access a page where you can manually adjust the level in the venous cassette using the relative buttons to raise and lower the level. From this page you can also disable level control of the venous cassette by pressing the dedicated button (remember that the upper cassette is not used in PEX and the level control is therefore disabled).



8.3 ROUTINE OPERATIONS DURING TREATMENT

During the treatment, some routine operations must be performed to safeguard the patient.

8.3.1 Patient temperature check

Throughout the treatment the patient's temperature must be checked whenever the situation requires.
The machine is equipped with a heater that must be used to prevent the patient from getting cold when this is undesirable for clinical reasons.
Use of the heater is described in paragraphs 2.1 and 8.2.1 in this manual.

8.3.2 Pressure check

Right from the beginning of the treatment, the pressure values must be checked to verify that they fall within an acceptable range.
It is recommended to:

- **Operate the machine within the minimum and maximum default values for the access and return pressures and the plasma filter TMP (see par. 8.1.6).**
- **Pay particular attention to haemolysis phenomena if the TMP values of the plasma filter exceed 50 mmHg.**

To adjust the alarm limits both before the treatment starts and during the treatment, operate as described below:

1. Press on the Pressures panel on the treatment page to access the page where to set the pressure limits (see par. 8.1.3).
2. Set the new limits with respect to the return and access pressures measured.
3. Confirm the modified values and go back to the treatment page.

In some cases, the access pressure can be relatively high and the return pressure relatively low. In this condition, if the maximum access pressure limit is > -10 mmHg and/or the maximum return pressure limit is < +10 mmHg, an alarm message informs you that the system may be unable to signal patient disconnection. If the data is confirmed, the Pressures panel on the treatment page turns red to indicate that the alarm limits are potentially hazardous.

CAUTION
Inadequate setting of the access and return pressure limits may reduce the system's ability to detect any disconnected blood lines.

CAUTION
Access and return pressure monitoring is not always able to detect disconnection of the access or return line from the relative patient access. Disconnection results in blood leakage into the surrounding environment.
Disconnection of a line from the relative patient access may cause a decrease (return) or an increase (access) in the relative pressure although it remains within the permitted alarm range. In this case, therefore, the machine is unable to detect disconnection despite the alarm thresholds

being set correctly.
In order to reduce the risk of the access and return lines disconnecting from the relative access:

- Check that the access and return lines are properly connected to the relative access on the patient side by means of their fastening ring nut.
- Check that the patient access and return accesses are visible at all times during the dialysis treatment.
- Frequently check the patient access and return accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limits for both pressures as close as possible to the actual value of the relative pressure of the patient in order to avoid the alarm from continuously intervening.

When you set a return pressure threshold below 10 mmHg or an access pressure threshold above -10 mmHg, the system warns you that the machine may not detect any disconnection on the patient side. With these pressure limit values, the operator is hence responsible for constantly monitoring the access and return pressures.

In order to reduce the risk of access and return line disconnection:

- Check that the patient accesses and relative lines are properly connected as prescribed by the protocol of your clinic.
- Check that the patient accesses are visible at all times during the dialysis treatment.
- Frequently check the patient accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limit for the return pressure and the maximum alarm limit for the access pressure as close as possible to the actual value of the respective pressures on the patient.

8.3.3 Replacing the fluid bags

The bags containing the plasma and/or waste fluid can be replaced at any time. The machine generates an alarm when the plasma bags are empty and the waste bags are full.
To change the bags at any time, operate as follows:

1. Press the CHANGE BAGS button (see par. 8.2.4);
2. Replace the bags and make sure that the new bags conform to the prescription (as requested by the system via a warning window);
3. Press the RESUME TREATMENT button in the window that appeared when you pressed the CHANGE BAGS button (see par. 8.2.4).

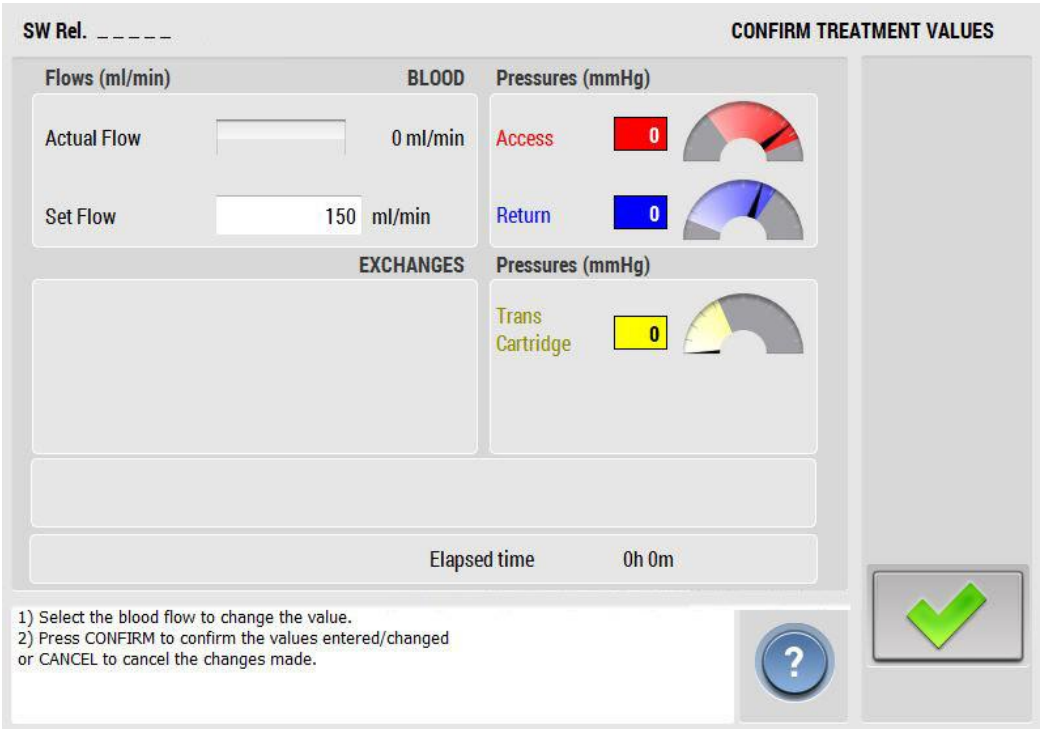
WARNING
Check that all the bags loaded are on the relative scales and that they do not touch other parts of the machine or bags on other scales.

8.4 END OF TREATMENT

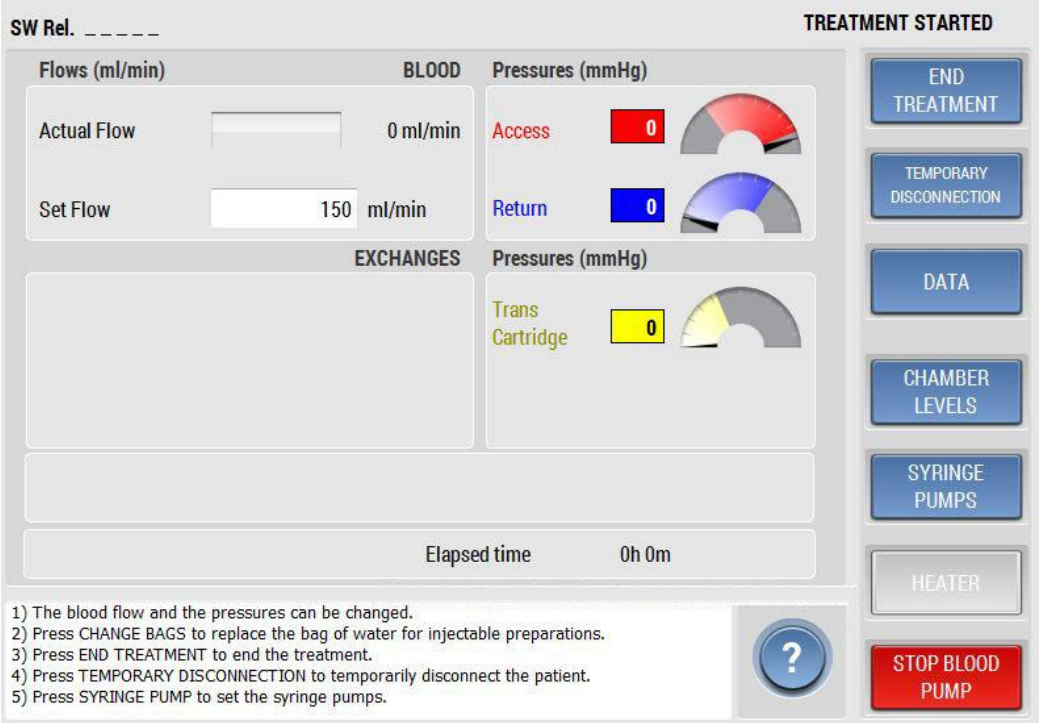
When the treatment time reaches 24 hours, it does not end automatically, but a message is shown on the screen informing you that the 24 hours have elapsed and asking you to end the treatment (END TREATMENT button) and to return the blood to the patient.

9 PERFORMING AN HP TREATMENT

Pressing the TREATMENT button from the “End Rinse” page, you access a page where you can program and start the HP treatment selected.



From the “start treatment” page, having made and confirmed all the required settings for the specific treatment (see par. 4.3.4), you can start the treatment by pressing the START button (Function Button area) on the “treatment values confirmation” page and so access the “treatment started” page.



The "start treatment" and "treatment started" pages are structured as follows:

- In three of the four control blocks (blood, exchange and time) into which the *active* area is divided the characteristic parameters of the selected treatment and the respective values are shown.
- A *function button* area to the right of the four blocks with buttons that offer access to some useful treatment functions.
- An *information* area at the bottom where the treatment name and power supply (mains or battery) are shown.

The flow and pressure parameters are shown in the various control blocks.

Some of the parameters displayed allow you to monitor treatment progress (therefore, before starting the treatment, their value is zero).

Other parameters are settable/modifiable by the operator using the *numerical keypad* (see par. 4.3) after pressing on the corresponding white field.

9.1 TREATMENT PARAMETERS

9.1.1 Blood

The blood control parameters are shown under BLOOD at the top of the active area of the "start treatment" and "treatment started" pages.
The actual flow and the set flow expressed in ml/min form part of the Flows panel.
The **actual flow** indicates the actual blood pump flow supplied by rotation of the pump during the treatment (therefore it is 0 before treatment start when the pumps are all off). During treatment, the value of this parameter allows you to monitor the blood flow instant by instant.
The actual flow depends on the access pressure, the blood pump speed and deterioration of the relative line.

The **set flow** indicates the blood flow operating value desired for the specific treatment. The default value is that set when the selected treatment was stored in memory (see par. 4.6, Treatment Function) and can be modified both during programming and treatment.

The access pressure and the return pressure expressed in mmHg form part of the Pressures panel.
The **access pressure** is the pressure, monitored during treatment, before the blood pump at the blood inlet to the extracorporeal circuit.
The **return pressure** is the pressure, monitored during treatment, in the venous cassette before the blood is returned to the patient through the return line (blue tube section).

When the treatment is started, only the blood pump and syringe pump 1 (if set) start. Syringe pump 2 (if set) starts once the operating blood flow has been reached. The blood pump gradually accelerates until reaching the operating flow set in relation to the blood pressure variations.

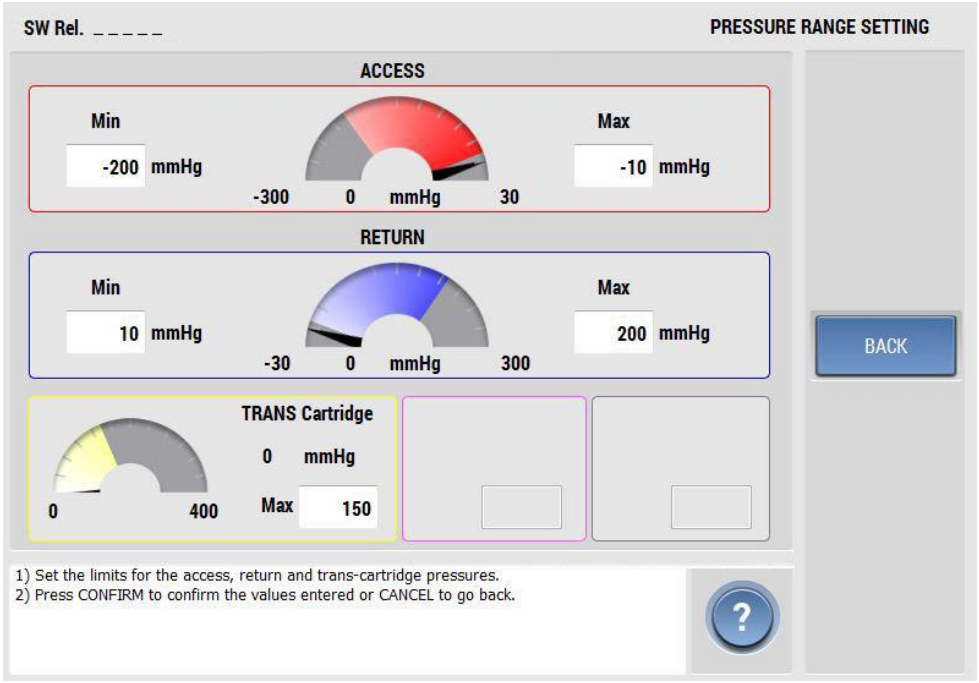
9.1.2 Exchanges

The **trans-cartridge pressure,** expressed in mmHg, which corresponds to the pressure drop between the adsorbent column inlet and outlet, is shown in the "Pressures" panel in the centre of the active area of the "start treatment" and "treatment started" pages.

9.1.3 Pressure

Both during programming and treatment, pressing on the "Pressures" panels relating to blood and exchange control, you access the pressure range page.

The page appears as shown in the image below.



On this page you can view and set:

- The minimum and maximum permitted access and return pressures;
- The trans-cartridge pressure value (calculated as difference between the pressures at the inlet and outlet of the adsorbent column).

NOTE: The pressures at the inlet and outlet of the cartridge are the pressures monitored during the treatment after the blood pump and in the lower cassette, respectively.

To set the minimum and maximum values, see paragraph. 9.3.1.

9.1.4 Time

The parameters that allow monitoring the treatment time are shown at the bottom of the *active* area of the page.

During treatment, the time information provided is:

- **Elapsed time**, i.e. the elapsed time from the beginning of the treatment (on the right)

on both the “start treatment” and the “treatment started” page.

9.1.5 Treatment specifications

The tables below give definitions of parameters settable and/or modifiable by the operator.

HP

	Default value	Minimum value settable	Maximum value settable
Blood flow (ml/min)	150	30	450
Min. access pressure (mmHg)	-200	-300	Max. access pressure (with ECMO +10 or -30 based on the machine configuration)
Max. access pressure (mmHg) (not settable with ECMO)	-10	Min. access pressure	-10 (or +30 based on the machine configuration)
Min. return pressure (mmHg)	10	+10 or -30 based on the machine configuration (-50 with ECMO)	Max. return pressure
Max. return pressure (mmHg)	200	Min. return pressure	300
Max. trans-cartridge pressure (mmHg)	150	X	400

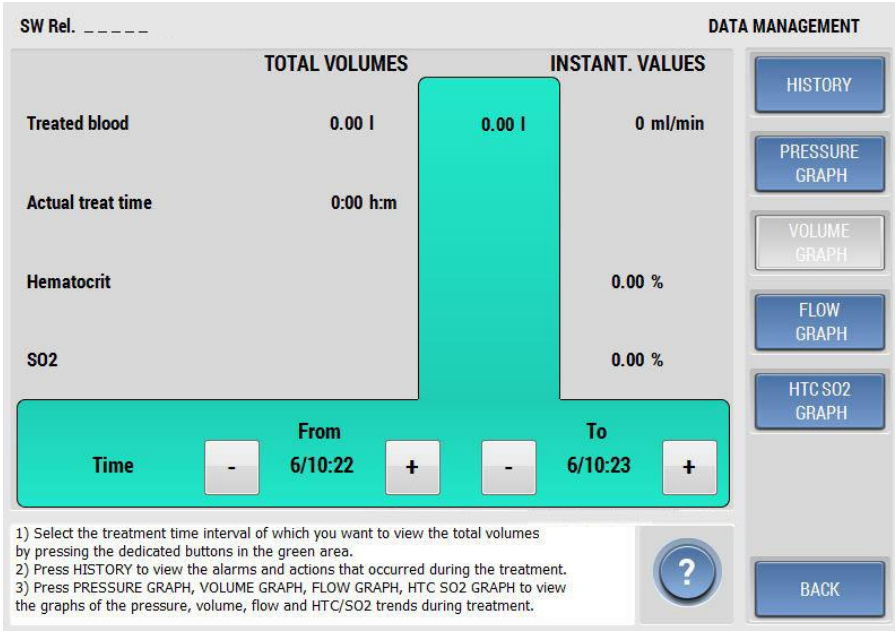
9.2 FUNCTION BUTTONS

The function buttons on the right of the “start treatment” and “treatment started” pages allow access to other pages and functions.

9.2.1 Data

The button is available on both the “start treatment” and the “treatment started” page.
Pressing this button, you access the relative page where the following are shown:

- The total volume of the fluids (left column)
- The volume of the fluids of a certain period (central green section of the page)
- The instantaneous flow values (right column).



Pressing the corresponding buttons (Function Button area) on this page, you can access the pages containing, respectively:

- The pressure graphs
- The flow graphs
- The hematocrit and oxygen saturation graphs
- The treatment history, which lists:
    1. All the actions performed (e.g. buttons pressed) up to that moment
    2. All the parameter modifications made up to that moment
    3. All the alarm events that occurred up to that moment.

These data remain in memory also after the end of the treatment.

The pages containing the graphs allow selecting the time interval within which to display the relative graph.

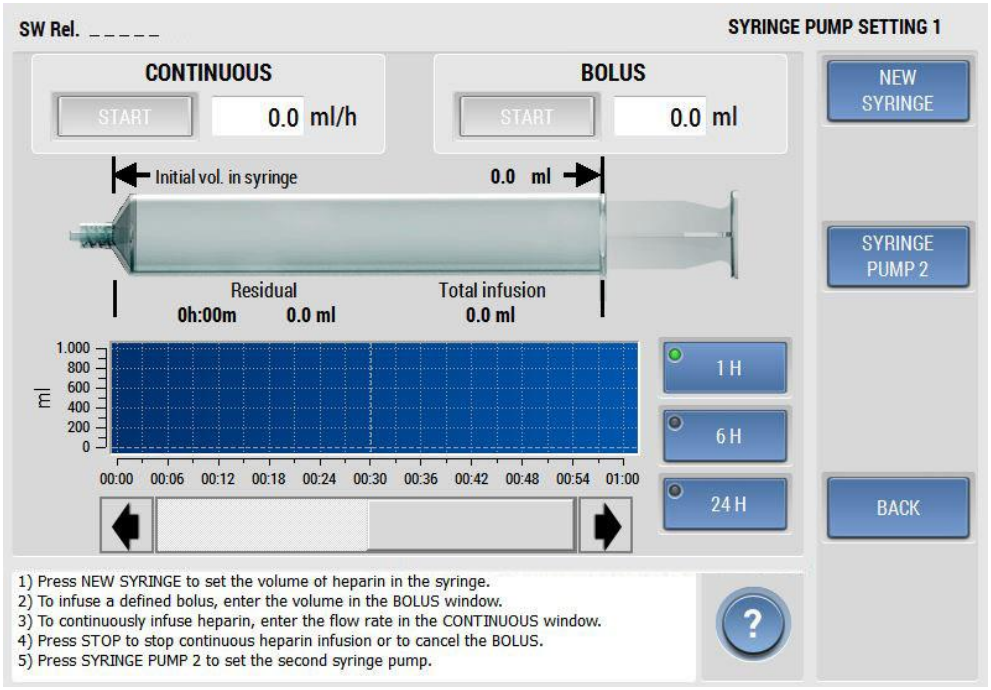
9.2.2 Syringe pumps

The SYRINGE PUMPS button is available on both the “start treatment” and the “treatment started” page.
Pressing this button, you access a page from where you can:

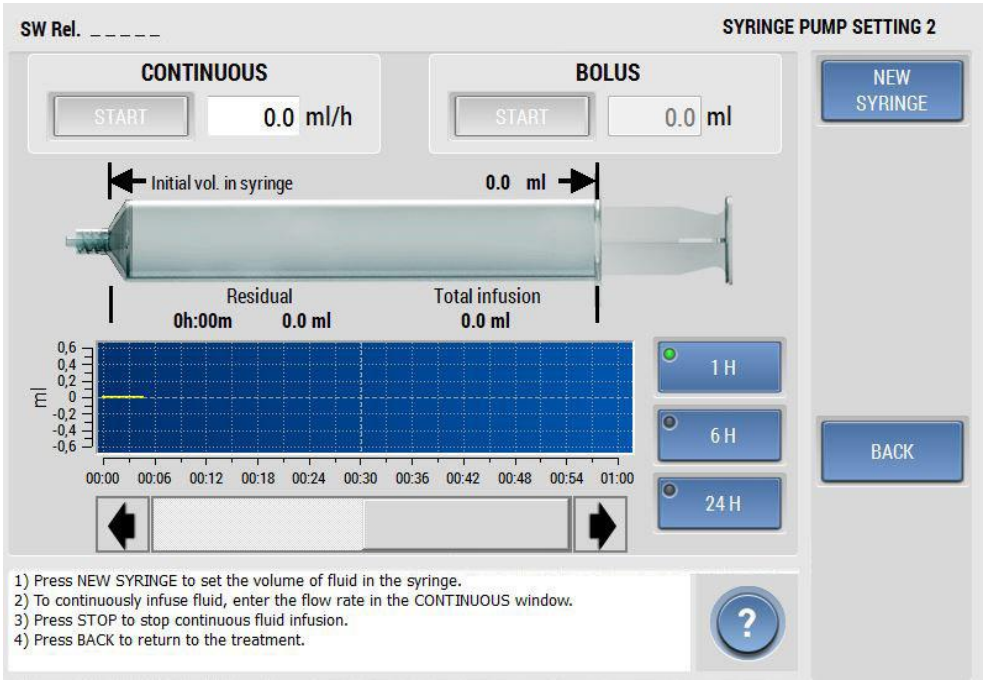
- Control the syringe pumps by setting continuous infusion or bolus infusion
- Install a new syringe
- Replace a syringe
- Set the volume contained in the syringes installed in the pumps.

When at least one of the two pumps is active, the SYRINGE PUMPS button is green. If only one of the two pumps is active, the infusion flow of that pump is shown on it.
Pressing the SYRINGE PUMPS button, you directly access the page where you can set heparin infusion by means of syringe pump 1. This page displays a graph showing heparin infusion over time.

Pressing the NEW SYRINGE button from the "syringe pump 1 setting" page, you can replace and/or install a new syringe in syringe pump 1.



Pressing the SYRINGE PUMP 2 button, you access the page where you can set ancillary infusion by means of syringe pump 2. This page displays a graph showing infusion over time.
Pressing the NEW SYRINGE button from the "syringe pump 2 setting" page, you can replace and/or install a new syringe in syringe pump 2.



Programming heparin infusion (syringe pump 1)
If a syringe has not yet been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows installing a heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:
1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 1 programming page).
2. Connect the syringe containing heparin to the relative line (leading from the single-use set at the top right)
3. Press on the arrows on the screen to move the syringe pump 1 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger
4. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 1 programming page.

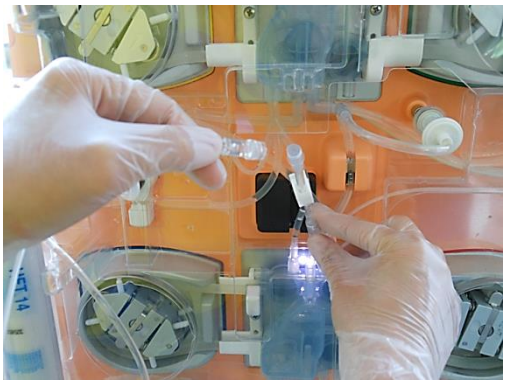
If a syringe has already been installed in syringe pump 1, pressing the NEW SYRINGE button, you access a page that allows replacing the heparin syringe for infusion of anticoagulant during the treatment.

To install a syringe, operate as follows:
1. If necessary, replace the syringe with another one of the same type containing heparin and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the right-hand syringe pump pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger
3. Enter the volume of heparin contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 1 programming page.

Programming ancillary infusion (syringe pump 2)
If a syringe has not yet been installed in syringe pump 2, pressing the SYRINGE PUMP 2 button and then the NEW SYRINGE button, you access a page that allows installing a syringe in the relative pump for ancillary infusion during the treatment.

To install a syringe, operate as follows:
1. Select the name of the syringe you want to use from the list of syringes in memory (pressing BACK you go back to the syringe pump 2 programming page).
2. Connect the syringe for ancillary infusion to the service line of the venous cassette (the connection line can be supplied to the user on request).



3. Press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
4. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
5. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

If a syringe has already been installed in syringe pump 2, pressing the NEW SYRINGE button, you access a page that allows replacing the syringe for ancillary infusion during the treatment.

To install a syringe, operate as follows:

1. If necessary, replace the syringe with another one of the same type and connect the new syringe to the relative line.
2. If you have connected a new syringe, press on the arrows on the screen to move the syringe pump 2 pusher and position the syringe in its holder in such a way that the pusher comes into contact with the syringe plunger.
3. Enter the volume contained in the syringe pressing on the corresponding white field and setting the value using the *numerical keypad* (see par. 4.3).
4. Confirm the above operations or, if you want to repeat the procedure, cancel them pressing the corresponding buttons on the *confirmation page* (see par. 4.3).

Confirming the settings, you go back to the syringe pump 2 programming page.

Replacing one of the syringes
One of the syringes may need to be replaced:
- When the residual syringe content has all been infused.
- If an excessive value has been set for the initial volume of fluid in the syringe, which results in display of an incorrect residual value (different from zero) when the volume available in the syringe has run out.
- If there is an obstruction along the infusion line.

Bolus and continuous infusion
From the "syringe pump 1 setting" page, you can use the numerical keypad to set bolus and/or continuous infusion to the patient during the treatment by means of pump 1.
From the "syringe pump 2 setting" page, you can use the numerical keypad to set continuous infusion to the patient during the treatment by means of pump 2.

NOTE: You cannot set infusion boli by means of syringe pump 2.

The white fields of the *bolus and continuous* areas for syringe pump 1 and *continuous* for syringe pump 2 are active only if a syringe has previously been installed and the residual content in the syringe is not null.
When you program syringe pump 1 to simultaneously perform a bolus and a continuous infusion, the bolus will always be administered first upon treatment start.
During the treatment, you can cancel the bolus set by pressing the STOP button in the corresponding panel (on the right) and/or stop the continuous infusion set by pressing the STOP button in the corresponding panel (on the left). Subsequently, you can reset the bolus so that the system administers it automatically and/or press the START button to resume continuous infusion.

9.2.3 Treatment start

WARNING
Make sure that you have loaded a set consistent with the treatment to be performed (indicated at the bottom left of the screen).

To start the treatment, press the START button on the "start treatment" page.
When you press the button, you are asked to check the connections of the access and return lines to the patient (see *patient connection* below) and to confirm that they are properly connected. Once confirmed, the system starts the treatment. In the initial transition phase, the blood pump speed gradually increases and a few seconds after the blood pump has started, syringe pump 1 starts. Syringe pump 2 (if set) starts once the operating blood flow has been reached.

Patient connection
The patient is to be connected during treatment programming ("treatment started" window).
To connect the patient:

1. Close the electroclamp of the access line and the electroclamp of the return line.
2. Disconnect the access line from the priming fluid bag (see the WARNING below) and the return line from the priming fluid collection bag.
3. Connect the access and return lines to the patient's catheter and open the respective electroclamps.

WARNING
When connecting the patient, make sure that you remove the connector (marked with a yellow label saying "Remove after priming") that connects the access line to the priming fluid bag from the access line terminal.

CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:

1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

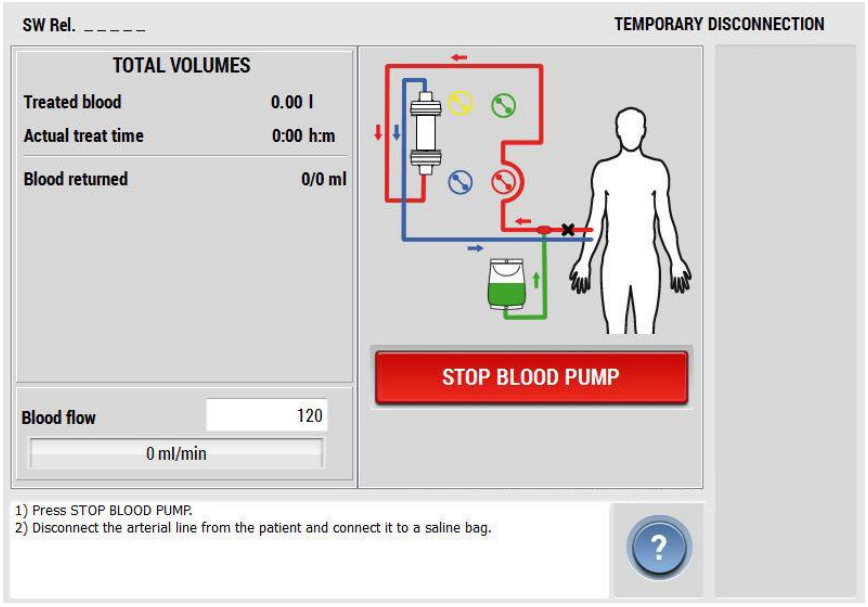
9.2.4 Blood pump stop

To stop the blood pump at any time, press the STOP BLOOD PUMP button on the "treatment started" page.
Use this button only when an unexpected event occurs.
When you press this button, the system stops the blood pump and warns you of the risk of the blood coagulating because of an extended blood pump stop by means of an acoustic signal, a yellow warning light and a message on the screen.

9.2.5 Temporary disconnection

To disconnect the patient at any time, press the TEMPORARY DISCONNECTION button on the "treatment started" page. The function of this button is to allow you to return the blood to the patient following an unexpected event that requires patient disconnection.

Pressing this button, you access a page that allows you to return the blood to the patient.



From the blood return page, if you have decided to disconnect the patient, operate as follows:

1. Press the STOP BLOOD PUMP button to stop the blood pump
2. Disconnect the access line (red) and connect it to a saline bag
3. Press the BLOOD RETURN button.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

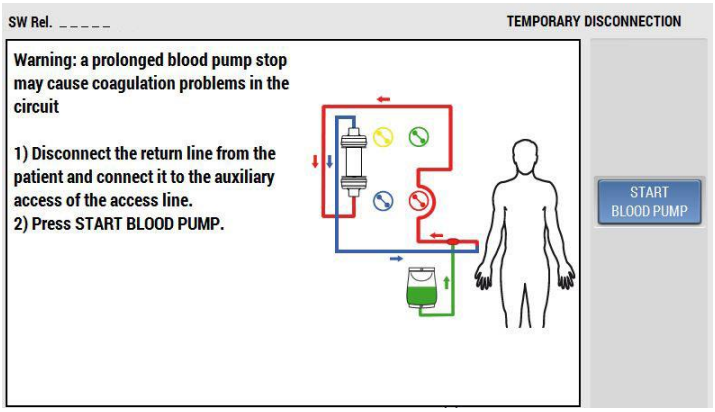
WARNING
The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.

At any time during blood return you can:

- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood return (BLOOD RETURN button).
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

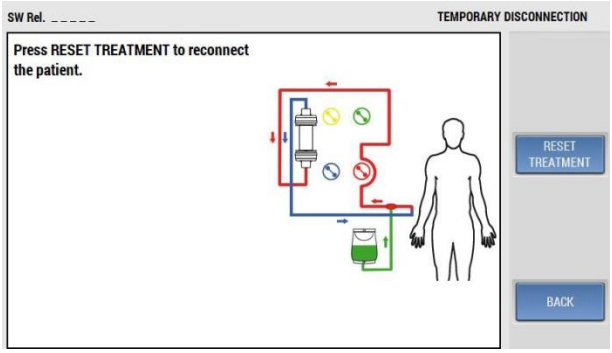
When blood return has been completed:

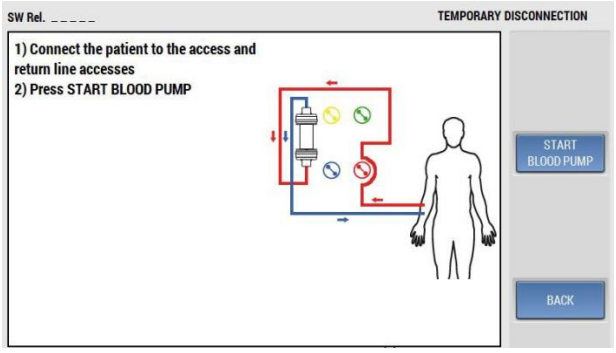
1. Disconnect the patient from the return line
2. Connect the return line to the branch on the arterial line
3. Press the START BLOOD PUMP button to restart the blood pump and allow recirculation of any blood that has remained in the circuit so that it cannot coagulate while waiting for patient reconnection.



When the patient is ready to be reconnected to the circuit, operate as follows:

- Press RESUME TREATMENT
- Connect the catheter accesses to the access and return lines
- Press START BLOOD PUMP to restart all the pumps and resume the treatment.





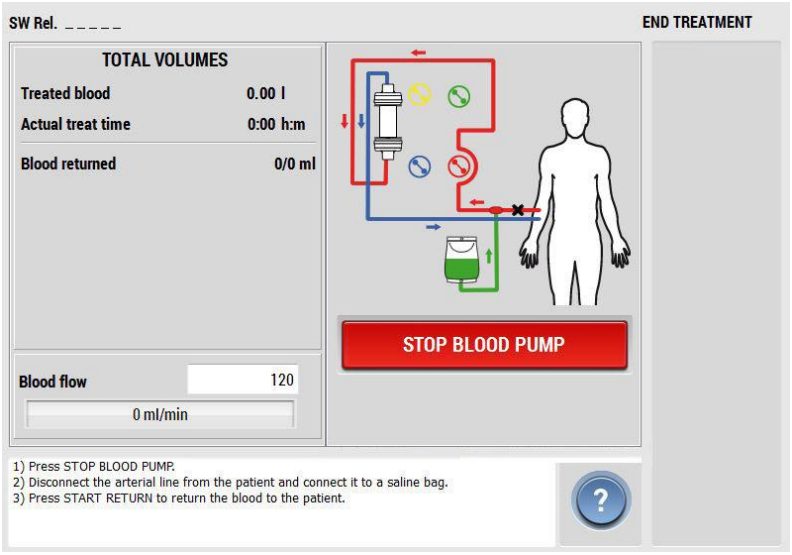
CAUTION:
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:
1. **Use aseptic techniques that prevent cross-infections between patients.**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection.**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

9.2.6 End of treatment

To end the treatment at any time, press the END TREATMENT button on the "treatment started" page.

During an HP treatment, pressing this button allows you to:
- Confirm the selection and end the treatment.
- Cancel the selection to resume the treatment.

Confirming the selection to end the treatment, you access a page that allows you to return the blood to the patient.



When you access the blood return page, the exchange pumps stop. From this page you can:
1. Press the STOP BLOOD PUMP button to stop the pump
2. Disconnect the access line (red) and connect it to a saline bag
3. Press the BLOOD RETURN button.

NOTE: The volume of blood returned to the patient is shown on the blood return page in real-time to facilitate the return operation. Once a volume equal to the volume of blood contained in the circuit has been returned, you are warned with an acoustic signal (see alarm 1077). In this case, if deemed appropriate, you can continue with return by pressing the CONFIRM button.

NOTE: The pins positioned at the top left-hand side of the machine can be used to support the saline bag required for blood return.

WARNING:
1. **The patient access line must be connected to a saline bag whenever blood needs to be returned to the patient.**
2. **It is of fundamental importance that the blood return procedure be correctly carried out before disconnecting the power in order to prevent needless patient blood leakage.**

At any time during blood return you can:
- Stop the blood pump (STOP BLOOD PUMP button) and subsequently resume blood return (RESUME BLOOD RETURN button)
- Stop the blood pump (STOP BLOOD PUMP button) and end blood return (END BLOOD RETURN button).

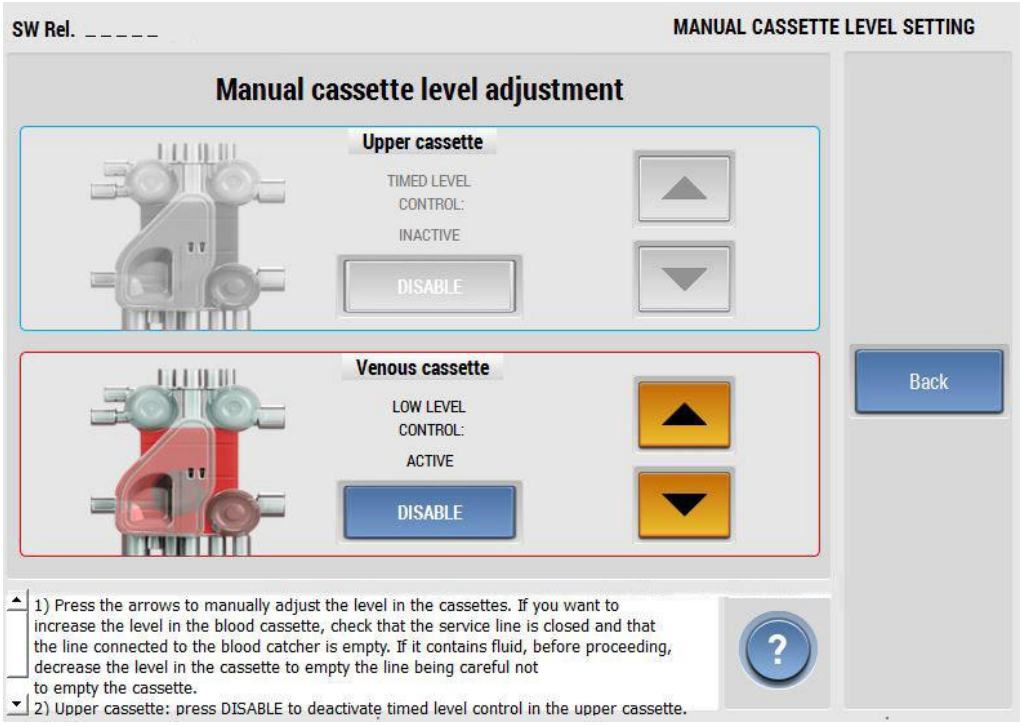
During this pause phase, only the following alarms are active:
- Access and return pressure alarms
- Air alarm.

CAUTION
The patient must be connected and disconnected in compliance with validated medical procedures, more specifically:
1. **Use aseptic techniques that prevent cross-infections between patients;**
2. **Securely tighten the patient connections to the blood lines to prevent disconnection;**
3. **Properly connect the access and return lines to the relative patient accesses to prevent blood recirculation with consequent reduced blood clearance.**

When blood return is complete, you access a page containing a sequence of illustrated instructions for removal of the lines of the single-use set. You are asked to follow the instructions scrolling them with the arrows at the bottom right of the active window.
From this page you can remove the set, once you have disconnected the lines as illustrated in the instructions, by pressing REMOVE SET. When you press this button, you access a page informing you that the treatment has ended and that you can turn off the machine using the switch on the rear (see REAR VIEW in Chapter 2 Machine Presentation).

9.2.7 Chamber levels

Pressing the CHAMBER LEVELS button, you access a page where you can manually adjust the level in the venous cassette using a button to raise and lower the level. From this page you can also disable level control of the cassette by pressing the dedicated button.



9.3 ROUTINE OPERATIONS DURING TREATMENT

During the treatment, some routine operations must be performed to safeguard the patient.

9.3.1 Pressure check

Right from the beginning of the treatment, the pressure values must be checked to verify that they fall within an acceptable range.

Operate the machine within the minimum and maximum default values for the access, return, TMP and trans-cartridge pressures (see par. 9.1.5).

To adjust the alarm limits both before the treatment starts and during the treatment, operate as described below:

1. Press on the Pressures panel on the treatment page to access the page where to set the pressure limits (see par. 9.1.3)
2. Set the new limits with respect to the return and access pressures measured
3. Confirm the modified values and go back to the treatment page.

WARNING
In some cases, the access pressure can be relatively high and the return pressure relatively low. In this condition, if the maximum access pressure limit is > -10 mmHg and/or the maximum return pressure limit is < +10 mmHg, an alarm message informs you that the system may be unable to signal patient disconnection. If the data is confirmed, the Pressures panel on the treatment page turns red to indicate that the alarm limits are potentially hazardous.

WARNING
In the case of an HP treatment with ECMO, the access pressure may also reach values higher than the maximum absolute limit (defined by the system and hence not settable), therefore the maximum access pressure parameter cannot be set by the operator. The Pressures panel on the Treatment page is red to indicate that this configuration is potentially hazardous: in fact, the maximum access pressure alarms are not active (see alarms 202 and 302 in par. 10.11).

CAUTION
Inadequate setting of the access and return pressure limits may reduce the system's ability to detect any disconnected blood lines.

CAUTION
Access and return pressure monitoring is not always able to detect disconnection of the access or return line from the relative patient access. Disconnection results in blood leakage into the surrounding environment.
Disconnection of a line from the relative patient access may cause a decrease (return) or an increase (access) in the relative pressure although it remains within the permitted alarm range. In this case, therefore, the machine is unable to detect disconnection despite the alarm thresholds being set correctly.
In order to reduce the risk of the access and return lines disconnecting from the relative access:

- Check that the access and return lines are properly connected to the relative access on the patient side by means of their fastening ring nut.
- Check that the patient access and return accesses are visible at all times during the dialysis treatment.
- Frequently check the patient access and return accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limits for both pressures as close as possible to the actual value of the relative pressure of the patient in order to avoid the alarm from continuously intervening.

When you set a return pressure threshold below 10 mmHg or an access pressure threshold above -10 mmHg, the system warns you that the machine may not detect any disconnection on the patient side. With these pressure limit values, the operator is hence responsible for constantly monitoring the access and return pressures.

In order to reduce the risk of access and return line disconnection:
- Check that the patient accesses and relative lines are properly connected as prescribed by the protocol of your clinic.
- Check that the patient accesses are visible at all times during the dialysis treatment.
- Frequently check the patient accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the minimum alarm limit for the return pressure and the maximum alarm limit for the access pressure as close as possible to the actual value of the respective pressures on the patient.

9.4 END OF TREATMENT

The HP treatment automatically ends after 60 hours.
When 60 hours of treatment have elapsed:
- The syringe pumps stop while the blood pump continues running at minimum speed;
- A warning light (see alarm 1075) informs you of the end of the treatment;
- The only buttons active are DATA (see par. 9.2.1) and END TREATMENT (see par. 9.2.7).

10 SAFETY RISKS AND PROTECTION SYSTEMS

AMPLYA is equipped with an ALARM SYSTEM by means of which the machine detects and controls malfunctions and faults, establishing the presence of potential or actual risks.

CAUTION
Setting the alarm limits to extreme values might make the alarm system unusable.

CAUTION
Using different alarm configurations and settings for machines of the same model in use in the same centre may pose a potential hazard to the patient.

An alarm condition in the machine is indicated by:
- Generating a visual signal consisting of a warning light at the top of the screen coming on;
- Generating a further visual signal consisting of an alarm window appearing on the screen giving a description of the alarm condition;
- Generating an acoustic signal consisting of a sequence of sound pulses.

These alarm signals can correctly be detected by an operator standing normally in front of the machine at a distance of one metre.

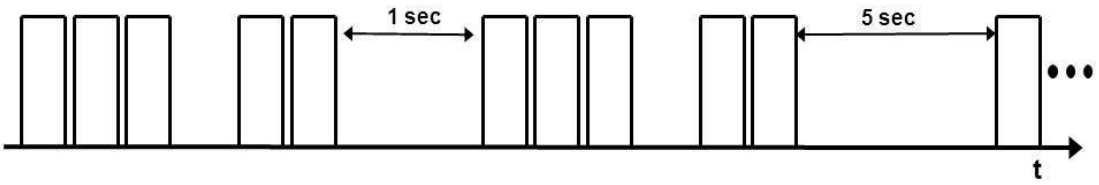
When turning on the machine, check proper functioning of the alarm signal generation devices as described below:
- The buzzer (acoustic signal) must emit a sound pulse;
- The warning light (visual signal) must come on in the following sequence of colours: RED-OFF-YELLOW.

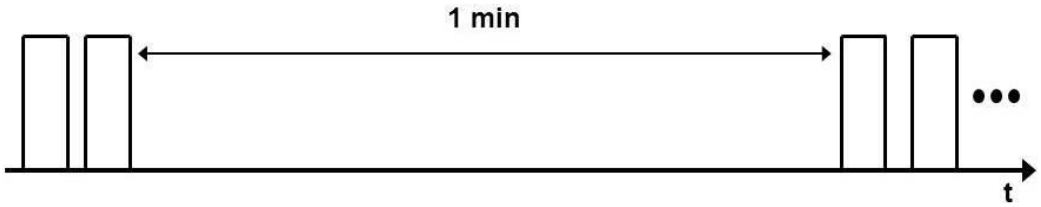
10.1 INFORMATION ON THE ALARMS

The alarms are divided into the following groups:
- PHYSIOLOGICAL ALARMS: generated by particular physiological conditions of the fluids in the extracorporeal circuit (see par. 10.2 - 10.7);
- TECHNICAL ALARMS: generated by particular faults regarding the machine (see par. 10.8 and 10.9).

The alarm PRIORITY levels are classified based on the importance of the alarm and the urgency with which it needs to be resolved. In particular, they are distinguished in:
- HIGH PRIORITY alarm
- LOW PRIORITY alarm

Indicated below are the characteristics of the visual and acoustic signals generated in correspondence to a HIGH and LOW priority alarm:

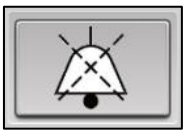
HIGH PRIORITY
Acoustic signal:    Sound pressure level: 74.2 dB(A)
Visual signal: RED warning light flashing at a frequency of 2 Hz and a RED alarm window appearing on the screen giving a description of the alarm condition.
The alarm causes stopping or deceleration of the blood pump and the alarm window background and the warning light are 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.

LOW PRIORITY
Acoustic signal:    Sound pressure level: 73.7 dB(A)
Visual signal: YELLOW warning light permanently on and a YELLOW alarm window appearing on the screen giving a description of the alarm condition.
The low priority alarms have only a warning function and the alarm window background and the warning light are yellow to indicate that the blood is continuing to circulate and the treatment continues despite the alarm.

When an alarm occurs:

- **Carefully follow the instructions shown in the window to exit the alarm condition and then press the CONFIRM (tick mark) button.**

- **You can silence the acoustic alarm for 2 minutes by pressing the SILENCE button.**



When the SILENCE button is pressed, it turns orange for the entire silence time.

WARNING
If the alarm persists and you need to notify the manufacturer, make sure that you note down the alarm number.

NOTE: AMPLYA does not directly make physiological measurements on the patient that generate alarms.

10.1.1 Two protection levels

The alarm system provides two levels of protection.
In case of **failed or inconsistent intervention of the first protection level**, the second protection level generates alarms characterised by higher limit values and greater intervention times.
The second protection level alarms are identifiable by a violet alarm window and a white warning light. The occurrence of an alarm generated by the second protection level results in all the pumps being stopped, the electroclamp being closed and the heater being turned off.

In this case, you can choose to:
1. Continue with manual blood return to the patient (see par. 10.10) and contact After-sales Service.
2. Reset the treatment by turning the machine off and on again.

When the machine is turned on again, a page appears informing you that the machine has been reset after a serious error. From this page you can:
1. Resume the interrupted treatment by pressing TREATMENT. In this case, you need to:
    - Confirm or if necessary modify and confirm the treatment parameters.
    - Check that the double electroclamp position is consistent with the treatment selected:

Treatment	*Double electroclamp position*
CPFA, HF	Upper housing open, lower housing closed
HDF, HD	Upper housing closed, lower housing open
SCUF	Upper housing closed, lower housing open
HDF with null dialysate flow	Upper housing open, lower housing closed
ABYLCAP, PEX and HP	Upper and lower housings open

- Press START to resume treatment or END TREATMENT to finally end the treatment.

2. Remove the single-use set by pressing REMOVE SET (after manually returning the blood to the patient as described in paragraph 10.10).

10.2 AIR DETECTION IN THE BLOOD RETURN LINE

An air bubble detection system is fitted on the blood return line to the patient whose purpose is to prevent the risk of infusing air into the patient. As soon as the sensor detects a volume of air exceeding 40 µl, the system generates an alarm that closes the venous electroclamp, stops all the pumps and turns off the heater.
Unlike all the other alarms (see alarm 1 and 1.1 in par. 10.11), the air alarm is accompanied by three windows appearing in sequence:

1. The first two windows illustrate the procedure to be performed to remove the air. Operate as follows:
   - Lower the level in the venous cassette by pressing the DOWN arrow that appears to the right of the message.
   - Clamp the blood line between the hemofilter (CPFA and RRT), the oxygenator (ABYLCAP), the plasma filter (PEX) or the adsorbent column (HP) and the venous cassette.
   - Set the return pressure shown in the alarm window to -20 mmHg and press the UP arrow.
   - Check that the air bubbles have been removed from the return line, and if not, press the UP arrow that appears to the right of the message until all the air has been removed.
   - Remove the clamp and press CONFIRM.

2. The third window asks you to confirm that you have correctly performed the guided procedure and that you have actually removed the air bubble from the return line.

10.3 PRESSURES

The system is equipped with various pressure sensors able to monitor the pressures and generate alarms if excessive pressure values may cause failure of the single-use device with the resulting blood leakage into the environment.
The system generates an alarm in the following cases:

- When a pressure value exceeds the absolute maximum and minimum values, i.e. defined by the system and not settable;
- When a pressure value exceeds the relative maximum and minimum values, i.e. settable by the operator and always lower than the absolute values.

Access pressure

In order to protect the vascular access of the patient and detect any disconnection or occlusion of the blood line, the system continuously checks that the access pressure value measured by the pressure sensor located upstream of the blood pump remains within the limits set and within the range of values between:

- -300 and -10 mmHg (or +30 mmHg based on the limit configured by the hospital facility for the specific machine) in CPFA, RRT, PEX and HP treatments (see CAUTION: access and return pressure below).
- -250 and -10 mmHg in ABYLCAP treatments.

When the pressure value measured exceeds the absolute limits set or the minimum or maximum value settable, the protection system generates an alarm (see alarms 201, 202, 301, 302, 9301, 9302 in par. 10.11).

WARNING

In the case of a CPFA, RRT and HP treatment with ECMO, the access pressure may also reach values higher than the maximum absolute limit (defined by the system and hence not settable), therefore the maximum access pressure parameter cannot be set by the operator. The Pressures panel on the Treatment page is red to indicate that this configuration is potentially hazardous: in fact, the maximum access pressure alarms are not active (see alarms 202 and 302 in par. 10.11).

Return pressure

In order to prevent patient blood leaks due to disconnection of the return line or rupture of the return line if it is occluded, the system continuously checks that the return pressure value measured by the pressure sensor in the venous cassette remains within the limits set and within the range of values between:

- +10 mmHg (or -30 mmHg based on the limit configured by the hospital facility for the specific machine) and +300 mmHg in CPFA, RRT and PEX treatments.
- +10 and +300 mmHg in ABYLCAP treatments.

When the pressure value measured exceeds the absolute limits set or the minimum or maximum value settable, the protection system generates an alarm (see alarms 203, 204, 303, 304, 9302, 9304 in par. 10.11) (see CAUTION: access and return pressure below).

CAUTION: access and return pressure

Access and return pressure monitoring is not always able to detect disconnection of the access or return line from the relative patient access. Disconnection results in blood leakage into the surrounding environment.

Disconnection of a line from the relative patient access may cause a decrease (return) or an increase (access) in the relative pressure although it remains within the permitted alarm range. In this case, therefore, the machine is unable to detect disconnection despite the alarm thresholds being set correctly.

In order to reduce the risk of the access and return lines disconnecting from the relative access:

- Check that the access and return lines are properly connected to the relative access on the patient side by means of their fastening ring nut.
- Check that the patient access and return accesses are visible at all times during the dialysis treatment.
- Frequently check the patient access and return accesses.
- Set adequate access and return pressure alarm limits; in particular, it is advisable to set the

minimum alarm limits for both pressures as close as possible to the actual value of the relative pressure of the patient.

In CPFA, RRT, PEX and HP, when you set a return pressure threshold below 10 mmHg or an access pressure threshold above -10 mmHg, the system warns you that the machine may not detect any disconnection on the patient side. With these pressure limit values, the operator is hence responsible for constantly monitoring the access and return pressures.

Blood pre-pump pressure

In order to prevent blood leaks from the circuit due to disconnection of the line downstream of the blood pump before the filter or rupture of the line if it is occluded, the system continuously checks that the pressure value measured by the pressure sensor located downstream of the blood pump remains within a range of values between:

- +30 and +600 mmHg in CPFA, RRT and PEX treatments.
- +30 and +400 mmHg in HP treatments.
- +30 and +300 mmHg in ABYLCAP treatments.

When the pressure value measured exceeds the absolute limits, the protection system generates an alarm (see alarms 205 and 206 in par. 10.11).

Mediasorb inlet and outlet pressure in CPFA

In order to prevent blood leaks from the circuit due to rupture of the line downstream of the plasma pump before Mediasorb if it is occluded, the system continuously checks that the pressure value measured by the pressure sensor located downstream of the plasma pump does not exceed +500 mmHg.

In order to prevent blood leaks from the circuit due to rupture of the line at the Mediasorb outlet if it is occluded, the system continuously checks that the pressure value measured by the pressure sensor located downstream of Mediasorb (and which measures the pressure in the upper cassette and at the plasma filter outlet) does not exceed +600 mmHg.

When the pressure values measured exceed the absolute limits, the protection system generates an alarm (see alarms 207 and 319 in par. 10.11).

Transmembrane pressure

An increase in the transmembrane pressure exceeding the absolute limit (400 mmHg in the case of the hemofilter, 80 mmHg in the case of the plasma filter) or the maximum value settable, triggers an alarm to prevent rupture of the filter membranes (see alarms 252, 253, 305, 307 in par. 10.11).

Trans-filter pressure

The trans-filter pressure is continuously checked and generates an alarm that indicates possible clot formation when, in stable conditions, the pressure gradient between the filter inlet and outlet increases exceeding the absolute limit values of 650 mmHg in the case of the hemofilter and 250 mmHg in the case of the plasma filter (see alarms 209 and 210 in par. 10.11).

Trans-cartridge pressure in CPFA

The trans-cartridge pressure is continuously checked and generates an alarm that indicates possible clot formation at Mediasorb level with possible rupture of Mediasorb when, in stable conditions, the pressure gradient between the filter inlet and outlet increases, exceeding the absolute limit value of 600 mmHg or the maximum value settable (see alarms 251 and 309 in par. 10.11).

Trans-oxygenator pressure in ABYLCAP
The trans-oxygenator pressure is continuously checked and generates an alarm that indicates possible clot formation at oxygenator level with possible rupture of the oxygenator when, in stable conditions, the pressure gradient between the filter inlet and outlet increases exceeding the absolute limit value of 200 mmHg (see alarm 211 in par. 10.11).

Trans-cartridge pressure in HP
The trans-cartridge pressure is continuously checked and generates an alarm that indicates possible clot formation at adsorbent column level with possible rupture of the column when, in stable conditions, the pressure gradient between the column inlet and outlet increases exceeding the absolute limit value of 400 mmHg (see alarm 212 in par. 10.11).

10.3.1 RRT: Pressure autotest

During RRT treatments, at the fourth hour, the twenty-fourth hour and after 24 hours every two hours, a 60-second autotest is run to check proper functioning of the pressure measurement system. The autotest status is shown on the screen in a yellow box with the message AUTOTEST (next to the battery charge status symbol in the Information area - see the image below); it entails appropriately setting the infusion and post-infusion pumps and the double electroclamp for the entire duration of the test. At the end of the test, the machine reverts back to the configuration prior to the test.

Should the machine detect a malfunction in the measuring system, a message is shown on the screen informing you that the test will be repeated after 10 minutes and advising you that if the test repeatedly fails, you should return the blood to the patient and, if necessary, perform a new treatment with a new set (see alarms 422 and 423 in par. 10.11).

10.4 BLOOD LEAKAGE THROUGH THE MEMBRANE

Blood in the filtrate may indicate rupture of the filter membrane.
In CPFA, blood leakage is detected by two sensors, one on the ultrafiltrate line downstream of the UF pump (UF BLD) and one on the plasma line downstream of the plasma pump (plasma BLD).
In RRT and ABYLCAP, blood leakage is detected only by the sensor on the ultrafiltrate line (downstream of the UF pump).
In PEX, blood leakage is detected only by the sensor on the plasma line (upstream of the UF pump).
Both the blood leakage detectors generate an alarm (see alarms 321, 324, 9321 in par. 10.11) the moment the blood concentration is greater than permitted (see par. 10.11) and if the relative line is absent (see alarms 323, 326, 9323 in par. 10.11).
The blood leakage detectors are tested when the machine is turned on. If a blood leakage detector fails the test, the system informs the operator via the alarm window that the test has failed (see alarms 322, 325, 9322 in par. 10.11). The test is repeated after pressing the CONFIRM button in the alarm window.

Plasma BLD

The sensor generates alarm 324 for blood detection in the plasma (see par. 10.11) the moment the blood concentration is greater than permitted (see par. 10.11). Pressing the CONFIRM button in the alarm window, the system overrides the alarm for one minute and then reactivates it.
During treatment and, only in CPFA, if the condition that generates alarm 324 reoccurs three consecutive times in 10 minutes, alarm 324.1 is generated (see par. 10.11).
The 324.1 alarm window allows continuing in the following alternative ways:

1. Override the alarm for blood detection in the plasma by pressing the button shown below

2. Continue by pressing the CONFIRM button, in which case the system overrides the alarm for one minute and then reactivates it.

If you choose to override the alarm for blood detection in the plasma, the symbol below is shown on the screen (next to the battery charge status symbol in the Information area).

When the blood concentration values are lower than the maximum limit permitted for 10 consecutive minutes, the system automatically reactivates the alarm for blood detection in the plasma and the override symbol disappears.

CAUTION
If the alarm for blood detection in the plasma is overridden, the operator assumes responsibility for checking that the entity of blood leakage is compatible with the patient's conditions.

10.5 FLUID BALANCE ERROR

In CPFA and RRT, the fluid balance protection system is based on three pump/scale systems: infusion/dialysate, pre-dilution, UF.
In PEX, the fluid balance protection system is based on two pump/scale systems: infusion and UF.

The systems checks that during the treatment the weight variations, calculated with respect to an initial time (treatment start or bag change), of the bags on the UF, infusion and pre-dilution scales are consistent with the expected values calculated based on the values set by the operator and, if not, generates the alarms 332, 333 and 334, respectively (see par. 10.11).

Fluid balance errors, if validated beyond a certain number of times per treatment, may accumulate and pose a risk to the safety of the patient. The system therefore asks you to suspend the treatment the third time the same scale alarm is triggered (see alarms 332, 332.1, 333, 333.1, 334 and 334.1 in par. 10.11).

10.6 COAGULATION RISK

With the aim of preventing coagulation risks, the system generates alarms if the heparin in the syringe runs out (see alarms 350, 351, 9350, 9351 in par. 10.11) and if the syringe pump malfunctions (see alarms 352, 9352 in par. 10.11).

In CPFA and RRT treatments, in order to prevent blood concentrations in the hemofilter and the consequent coagulation risks, the system does not allow setting **a UF flow incompatible with the blood flow**. In the event of excessive UF flow, the system generates the alarms 401 (systemic anticoagulation and local-regional anticoagulation in UNASSISTED mode) and 406 (local-regional anticoagulation in ASSISTED mode). For the maximum UF flow values and compatible with the blood flow, see par. 5.1.6 (systemic anticoagulation) and 6.1.6 (local-regional coagulation).

In CPFA, in order to prevent blood concentrations in the extracorporeal circuit and the consequent coagulation risks, the system continuously checks that the **plasma pump speed** is consistent with the value the operator has set for the relative flow, and, if not, generates the alarm 376 (see par. 10.11).

In PEX, in order to prevent blood concentrations in the extracorporeal circuit and the consequent coagulation risks, the system continuously checks that the **UF pump speed** is consistent with the value the operator has set for the plasma flow, and, if not, generates the alarm 371 (see par. 10.11).
In CPFA, RRT, ABYLCAP, PEX and HP, in order to prevent blood concentrations in the extracorporeal circuit and the consequent coagulation risks, the system continuously checks that the **blood pump speed** is consistent with the value the operator has set for the relative flow, and, if not, generates the alarm 373 (see par. 10.11).

10.7 HEATER ALARMS

The temperature is controlled by comparing the temperature the system has to reach, based on what the operator has selected, with the actual temperature measured on the ceramic plate by means of a sensor. The actual outgoing fluid temperature is shown on the heater page and on the HEATER button on the main treatment page.
System safety is assured by the fluid and plate overheating alarms and by the test on the temperature sensors (see alarms 360, 361, 365, 366, 368, 9360, 9361, 9365, 9366 in par. 10.11).
The system signals when the heater door is open, when there is no bag in the heater and when there is fluid leakage from the bag via the alarms 362, 363, 364, 9362, 9363, 9364 (see par. 10.11).
Alarm 368 is generated when the infusion fluid temperature drops to below 33°C. The alarm window allows continuing in the following alternative ways:

- Continue by pressing the CONFIRM button, in which case the system overrides the alarm for five minutes and then reactivates it.
- Definitively deactivate this alarm by pressing the ALARM DEACTIVATION button. If you choose to override the alarm for minimum infusion fluid temperature, the symbol below is shown on the screen (next to the battery charge status symbol in the Information area).

CAUTION
If the alarm for minimum infusion fluid temperature (368 in par. 10.11) is overridden, the operator assumes responsibility for checking that the infusion fluid temperature is compatible with the patient's conditions.

10.8 POWER FAILURE

In the event of a power failure during execution of a treatment, the machine activates use of an auxiliary battery warning you of this event by means of alarm 8000 and automatically disables the heater.

In this mode, you have 20 minutes to return the blood to the patient; if the power is not restored, the remaining time for battery-powered operation is indicated in the icon at the bottom of the screen (Information area) by means of notches.
If the power is restored, the treatment is resumed and the heater reactivated.

After 20 minutes of battery-powered operation (with the battery fully charged) the machine goes into shutdown, warning you beforehand with a visual and acoustic signal of one minute. You can manually return the blood to the patient (see par. 10.10) or wait for the power to be restored and resume the treatment if necessary.
If a power failure has occurred, the next time the machine is turned on, the battery is considered not fully charged (alarm 8002 appears) and should another power failure occur, you will have less than 20 minutes to return the blood to the patient depending on the battery charge.
When the battery is completely flat, an X is shown on the battery icon.
The battery is fully recharged in 6 hours when the machine is on.

CAUTION
Pressing the main switch of the machine during treatment is not interpreted as a power failure. If you have interrupted the treatment by pressing the main switch, you can resume treatment simply by turning on the machine.

In each of the following situations during execution of a treatment:
- machine shut down with the main switch;
- machine shut down because the battery is flat following a power failure;
- machine shut down because the battery is unusable and there is a power failure;

all the treatment parameters and all the alarm thresholds used before machine shutdown are saved to memory. These values will be retrieved and used when you decide to resume the treatment regardless of how long the machine has been off.
Once the treatment has ended and the set is unloaded, you are forced to shut down the machine. When you turn the machine back on to perform a new treatment, the default parameters and alarm thresholds for the treatment you want to perform will be used.

10.9 SYSTEM ALARMS

The system
- continuously runs data consistency tests between the processors and the PC;
- continuously tests proper functioning of the machine devices (i.e. motors, scales and sensors).

If the above tests fail, a system alarm is activated characterised by a white warning light and a violet alarm window or a red warning light and a red alarm window.
The alarms generated by the second protection level also form part of these alarms (see par. 10.1.1).

In the event of a system alarm, you can choose to:
1. Continue with manual blood return to the patient (see par. 10.10) and contact After-sales Service.
2. Reset the treatment by turning the machine off and on again.

When the machine is turned on again, a page appears informing you that the machine has been reset after a serious error. From this page you can:
1. Resume the interrupted treatment by pressing TREATMENT.
2. Remove the single-use set by pressing REMOVE SET.

If you select to resume the treatment, you must:
1. Confirm or if necessary modify and confirm the parameters you set at the beginning of the treatment.
2. Check that the double electroclamp position is consistent with the treatment selected (see the table at the end of this paragraph).
3. Press START to resume treatment or END TREATMENT to finally end the treatment.

Treatment	*Double electroclamp position*
CPFA, HF	Upper housing open, lower housing closed
HDF, HD	Upper housing closed, lower housing open
SCUF	Upper housing closed, lower housing open
HDF with null dialysate flow	Upper housing open, lower housing closed
ABYLCAP, PEX and HP	Upper and lower housings open

10.10 BLOOD RETURN PROCEDURE IN CASE OF AN EMERGENCY

In all cases where you are asked to proceed with manual return of blood to the patient or if you suspect that the machine is in an uncontrolled condition (i.e. the pump operating speed is unusually high, the screen does not respond or remains black, etc.) the recommended procedure for blood return to the patient is as follows:

1. Turn off the machine
2. Hang a bag of saline on one of the pins located on the left-hand side of the machine
3. Disconnect the access line from the patient and connect it to the above mentioned bag
4. Remove the return line from the venous electroclamp
5. Break the seal of the single-use blister pack along the broken line in correspondence to the blood pump, remove it and manually turn the blood pump anticlockwise using the dedicated handle
6. If necessary, disconnect the patient
7. Contact After-sales Service

CAUTION
During this procedure, after the machine has been turned off, all the protections are deactivated. Therefore, be extremely careful in order to prevent hazardous situations for the patient, in particular air injection and blood leaks.

CAUTION
When breaking the seal and manually operating the blood pump, wear gloves to protect your hands.

CAUTION
If manually returning the blood, do not reinfuse the plasma through the plasma pump.

10.11 LIST OF ALARMS

Described below are the alarms and warnings signalled by AMPLYA.
The following are indicated for each alarm:

- Name: the name that identifies the alarm and which appears at the top of the alarm window;
- Code: the number that identifies the alarm and which appears at the top of the alarm window;
- Description: a brief description of the alarm;
- Operator action: the information the alarm window provides to the operator (the causes of the alarm and the actions to take to resolve the alarm and continue);
- Effects: the behaviour of the machine when an event occurs (visual and acoustic signal and actuators as described in par. 10.1);
- Intervention time: intervention time of the protection system;
- Priority: HIGH or LOW as described in par. 10.1;
- Active: phases in which the alarm is active.

Unless otherwise specified, the alarms are present in all the treatments: CPFA, RRT (HDF, HD, HDF, SCUF), ABYLCAP, PEX and HP.

Name: **AIR DETECTED**	
Code: 1	**Description:** Air detected.
Operator action	**CPFA and RRT:** 1) Press the DOWN arrow to decrease the blood level in the lower cassette as shown in the figure. 2) Clamp the blood line between the hemofilter and the cassette. 3) Press the UP arrow until reaching a return pressure of -20mmHg. **ABYLCAP:** 1) Press the DOWN arrow to decrease the blood level in the lower cassette as shown in the figure. 2) Clamp the blood line between the oxygenator and the cassette. 3) Press the UP arrow until reaching a return pressure of -20mmHg. **PEX:** 1) Press the DOWN arrow to decrease the blood level in the lower cassette as shown in the figure. 2) Clamp the blood line between the plasma filter and the cassette. 3) Press the UP arrow until reaching a return pressure of -20mmHg. **HP:** 1) Press the DOWN arrow to decrease the blood level in the lower cassette as shown in the figure. 2) Clamp the blood line between the adsorbent column and the cassette. 3) Press the UP arrow until reaching a return pressure of -20mmHg. **(pressing CONFIRM in the alarm window, alarm 1.1 appears)**
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **AIR DETECTED**	
Code: 1.1	**Description:** Air detected.
Operator action	**First page** The pressure in the cassette has dropped to below -50 mmHg. 1) Check that the air in the return line has been removed. 2) If not, continue pressing the top arrow to the right of the message. 3) Remove the clamp and press CONFIRM. **(pressing CONFIRM in the alarm window, the second page appears)** 1) Check that you have removed the air and the clamp. 2) Press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp opening, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **AIR DETECTED**	
Code: 2	**Description:** Air detected.
Operator action	**See alarm 1** **(pressing CONFIRM in the alarm window, alarm 2.1 appears)**
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **AIR DETECTED**	
Code: 2.1	**Description:** Air detected.
Operator action	**See alarm 1.1**
Effects	Red warning light, acoustic warning, venous clamp opening, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **VENOUS ELECTROCLAMP**	
Code: 3	**Description:** Venous electroclamp.
Operator action	Release the venous clamp button and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	1 second
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **VENOUS ELECTROCLAMP**	
Code: 4	**Description:** Inconsistent position of venous electroclamp.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **DOUBLE ELECTROCLAMP**	
Code: 5	**Description:** Inconsistent position of double electroclamp.
Code: 8	**Description:** Double electroclamp sensor error.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **AIR SENSOR**	
Code: 6	**Description:** Air sensor test signal error.
Code: 9	**Description:** The control has not run the air bubble test.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	White warning light, violet alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **AIR SENSOR LINE**	
Code: 7	**Description:** Air sensor line.
Operator action	Insert the return line in the air sensor before starting the treatment and press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	1 second
Priority	LOW
Active	Between priming end and treatment start (pressing START).

Name: **SYSTEM ERROR**	
Code: 10-115	**Description:** System error.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **UPPER CASSETTE MAXIMUM PRESSURE**	
Code: 120	**Description:** The internal upper level adjustment pump is not off and pushes in the upper cassette.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient.
Effects	Red warning light, acoustic warning.
Intervention time	100 ms
Priority	HIGH
Active	During temporary disconnection, bag change, blood pump stop and treatment end.

Name: **LOWER CASSETTE MAXIMUM PRESSURE**	
Code: 121	**Description:** The internal lower level adjustment pump is not off and pushes in the lower cassette.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient.
Effects	Red warning light, acoustic warning.
Intervention time	100 ms
Priority	HIGH
Active	During temporary disconnection, bag change, blood pump stop and treatment end.

Name: **SYRINGE PUMP 1**	
Code: 150	**Description:** Syringe pump 1 is not off.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **SYRINGE PUMP 2**	
Code: 151	**Description:** Syringe pump 2 is not off.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **INFUSION PUMP**	
Code: 170	**Description:** The infusion pump is not off.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **UF PUMP**	
Code: 171	**Description:** The UF pump is not off.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **PLASMA PUMP**	
Code: 172	**Description:** The plasma pump is not off.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **BLOOD PUMP**	
Code: 173	**Description:** The blood pump is not off.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **FIFTH PUMP**	
Code: 174	**Description:** The fifth pump is not off.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **PLASMA FLOW**	
Code: 182	**Description:** The plasma flow exceeds 50 ml/min.
Treatments	CPFA
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **BLOOD FLOW**	
Code: 183	**Description:** The blood flow exceeds 80 ml/min.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **MINIMUM ACCESS PRESSURE**	
Code: 201	**Description:** **CPFA, RRT, PEX, HP:** The access pressure is lower than -300 mmHg. **END OF INTERMITTENT RRT TREATMENT:** The access pressure is lower than -300 mmHg. **ABYLCAP:** The access pressure is lower than -250 mmHg.
Operator action	**CPFA, RRT, PEX, HP:** 1) Check that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow and/or modify the exchange flow value. 3) Confirm the flow values. **END OF INTERMITTENT RRT TREATMENT:** Check that the lines are not obstructed and press CONFIRM. **ABYLCAP:** Check that the lines are not obstructed and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **FAILED CONFIRMATION**	
Code: 201.1, 204.1, 205.1	**Description:** The blood pump has been off for more than 2 minutes.
Operator action	Restart the pump as soon as possible to prevent the risk of blood coagulation.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	**Code 201.1:** 2 minutes from pressing CONFIRM in the 201 alarm window **Code 204.1:** 2 minutes from pressing CONFIRM in the 204 alarm window **Code 205.1:** 2 minutes from pressing CONFIRM in the 205 alarm window
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **MAXIMUM ACCESS PRESSURE**	
Code: 202	**Description:** **CPFA, RRT, PEX, HP:** The access pressure is higher than -10/+30 mmHg. The access line could be disconnected. **END OF INTERMITTENT RRT TREATMENT:** The access pressure is higher than -10/+30 mmHg. The access line could be disconnected. **ABYLCAP:** The access pressure is higher than -10 mmHg. The access line could be disconnected.
Operator action	**CPFA, RRT, PEX, HP:** Check that there are no leakages in the circuit and press CONFIRM. The alarm will be disabled for 30 seconds from reaching the operating blood flow. **END OF INTERMITTENT RRT TREATMENT:** Check that there are no leakages in the circuit and press CONFIRM. **ABYLCAP:** Check that there are no leakages in the circuit and press CONFIRM. The alarm will be disabled for 30 seconds from reaching the operating blood flow.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end, and in CPFA/RRT with ECMO.

Name: **MINIMUM RETURN PRESSURE**	
Code: 203	**Description:** **CPFA, RRT, PEX, HP:** The return pressure is lower than +10/-30 mmHg. The return line could be disconnected or the blood catcher could be wet. **CPFA, RRT and HP with ECMO:** The return pressure is lower than -50 mmHg. The return line could be disconnected or the blood catcher could be wet. **END OF INTERMITTENT RRT TREATMENT:** The return pressure is lower than +10/-30 mmHg. The return line could be disconnected or the blood catcher could be wet. **ABYLCAP:** The return pressure is lower than +10 mmHg. The return line could be disconnected or the blood catcher could be wet.
Operator action	**CPFA, RRT, PEX, HP:** Check that there are no leakages in the circuit and press CONFIRM. The alarm will be disabled for 30 seconds from reaching the operating blood flow. **CPFA, RRT and HP with ECMO:** Check that there are no leakages in the circuit and press CONFIRM. The alarm will be disabled for 30 seconds from reaching the operating blood flow. **END OF INTERMITTENT RRT TREATMENT:** Check that there are no leakages in the circuit and press CONFIRM. **ABYLCAP:** Check that there are no leakages in the circuit and press CONFIRM. The alarm will be disabled for 30 seconds from reaching the operating blood flow.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM RETURN PRESSURE**	
Code: 204	**Description:** **CPFA, RRT, PEX, HP, ABYLCAP, END OF INTERMITTENT RRT TREATMENT:** The return pressure is higher than 300 mmHg.
Operator action	**CPFA, RRT, PEX, HP, ABYLCAP:** 1) Check that the lines are not obstructed, that the blood catcher is not wet and that the relative line is properly inserted in the sensor. 2) Press CONFIRM and if necessary reduce the blood flow and/or modify the exchange flow value. 3) Confirm the flow values. **END OF INTERMITTENT RRT TREATMENT:** 1) Check that the lines are not obstructed, that the blood catcher is not wet and that the relative line is properly inserted in the sensor. 2) Press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming and always after treatment start (pressing START).

Name: **MAXIMUM BLOOD POST-PUMP PRESSURE**	
Code: 205	**Description:** **CPFA, PEX:** The pressure at the plasma filter inlet is higher than 600 mmHg. **RRT, END OF INTERMITTENT RRT TREATMENT** The pressure at the hemofilter inlet is higher than 600 mmHg. **ABYLCAP:** The pressure at the oxygenator inlet is higher than 300 mmHg. **HP:** The pressure at the adsorbent column inlet is higher than 400 mmHg.
Operator action	**CPFA, RRT, PEX, HP:** 1) Check that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow. 3) Confirm the new value. **ABYLCAP, END OF INTERMITTENT RRT TREATMENT:** Check that the lines are not obstructed and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **MINIMUM BLOOD POST-PUMP PRESSURE**	
Code: 206	**Description:** **CPFA, PEX:** The pressure at the plasma filter inlet is lower than 30 mmHg. **RRT, END OF INTERMITTENT RRT TREATMENT** The pressure at the hemofilter inlet is lower than 30 mmHg. **ABYLCAP:** The pressure at the oxygenator inlet is lower than 30 mmHg. **HP:** The pressure at the adsorbent column inlet is lower than 30 mmHg.
Operator action	**CPFA, RRT, PEX, ABYLCAP, HP:** Check that there are no leakages in the circuit and press CONFIRM. The alarm will be disabled for 30 seconds from reaching the set blood flow. **END OF INTERMITTENT RRT TREATMENT:** Check that there are no leakages in the circuit and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **UPPER CASSETTE MAXIMUM PRESSURE**	
Treatments	CPFA, RRT, ABYLCAP
Code: 207	**Description:** **CPFA:** The pressure in the upper cassette (or at the plasma filter or cartridge outlet) is higher than 600 mmHg. **RRT, END OF INTERMITTENT RRT TREATMENT** The pressure in the upper cassette (or at the post-infusion pump inlet) is higher than 600 mmHg. **ABYLCAP:** The pressure in the upper cassette (or at the heat exchanger inlet) is higher than 400 mmHg.
Operator action	**CPFA, RRT:** 1) Check that there are no obstructions on the lines downstream of the cartridge and/or the plasma filter or that the blood catcher is not wet. 2) Press CONFIRM and if necessary modify the blood flow and/or the exchange flow value. 3) Confirm the flow values. **ABYLCAP, END OF INTERMITTENT RRT TREATMENT:** 1) Check that there are no obstructions on the line downstream of the upper cassette or that the blood catcher is not wet. 2) Press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **FAILED CONFIRMATION**	
Treatments	CPFA, RRT
Code: 207.1, 209.1	**Description:** The blood pump has been off for more than 2 minutes.
Operator action	Restart the pump as soon as possible to prevent the risk of blood coagulation.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	**Code 207.1:** 2 minutes from pressing CONFIRM in the 207 alarm window **Code 209.1:** 2 minutes from pressing CONFIRM in the 209 alarm window
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **MAXIMUM TRANS-HEMOFILTER PRESSURE**	
Treatments	CPFA, RRT
Code: 209	**Description:** The trans-hemofilter pressure is higher than 650 mmHg.
Operator action	**CPFA, RRT:** 1) Check that the filter is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow and/or modify the exchange flow value. 3) Confirm the flow values. **END OF INTERMITTENT RRT TREATMENT:** Check that the filter is not clogged and that the lines are not obstructed and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **MAXIMUM TRANS-HEMOFILTER PRESSURE**	
Treatments	CPFA, PEX
Code: 210	**Description:** The trans-plasma filter pressure is higher than 250 mmHg.
Operator action	1) Check that the filter is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow and/or modify the exchange flow value. 3) Confirm the flow values.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **FAILED CONFIRMATION**	
Treatments	CPFA, PEX, ABYLCAP, HP
Code: 210.1, 211.1, 212.1	**Description:** The blood pump has been off for more than 2 minutes.
Operator action	Restart the pump as soon as possible to prevent the risk of blood coagulation.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	**Code 210.1:** 2 minutes from pressing CONFIRM in the 210 alarm window **Code 211.1:** 2 minutes from pressing CONFIRM in the 211 alarm window **Code 212.1:** 2 minutes from pressing CONFIRM in the 212 alarm window
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **MAXIMUM TRANS-OXYGENATOR PRESSURE**	
Treatments	ABYLCAP
Code: 211	**Description:** The trans-oxygenator pressure is higher than 200 mmHg.
Operator action	1) Check that the filter is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow. 3) Confirm the blood flow value.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **MAXIMUM TRANS-CARTRIDGE PRESSURE**	
Treatments	HP
Code: 212	**Description:** The trans-cartridge pressure is higher than 400 mmHg.
Operator action	1) Check that the adsorbent column is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow. 3) Confirm the flow values.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **MINIMUM ACCESS PRESSURE**	
Treatments	RRT (HF and HDF)
Code: 221	**Description:** The access pressure is lower than -200 mmHg.
Operator action	**RRT:** 1) Check that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow and/or modify the exchange flow value. 3) Confirm the flow values. **END OF INTERMITTENT RRT TREATMENT:** Check that the lines are not obstructed and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START) and when setting null dialysate flow (HDF) or null pre-infusion flow (HF).

Name: **FAILED CONFIRMATION**	
Treatments	RRT (HF and HDF)
Code: 221.1	**Description:** The blood pump has been off for more than 2 minutes.
Operator action	Restart the pump as soon as possible to prevent the risk of blood coagulation.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	2 minutes from pressing CONFIRM in the 221 alarm window
Priority	HIGH
Active	Always after treatment start (pressing START) and when setting null dialysate flow (HDF) or null pre-infusion flow (HF).

Name: **MAXIMUM TRANS-CARTRIDGE PRESSURE**	
Treatments	CPFA
Code: 251	**Description:** The trans-cartridge pressure is higher than 600 mmHg.
Operator action	1) Check that the cartridge is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the plasma flow and/or modify the value of the other flows. 3) Confirm the flow values if they have been modified.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **MAXIMUM TMP**	
Treatments	CPFA, RRT
Code: 252	**Description:** The hemofilter TMP is higher than 400 mmHg.
Operator action	1) Check that the filter is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary reduce the blood flow and/or modify the exchange flow value. 3) Confirm the flow values.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM TMP**	
Treatments	CPFA, PEX
Code: 253	**Description:** The plasma filter TMP is higher than 80 mmHg.
Operator action	1) Check that the filter is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary (when permitted) reduce the plasma flow and/or modify the value of the other flows. 3) Confirm the flow values if they have been modified.
Effects	Red warning light, acoustic warning, blood pump at minimum speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **MINIMUM ACCESS PRESSURE**	
Code: 301	**Description:** The access pressure is lower than the defined minimum limit.
Operator action	1) Check that there are no obstructions between the vascular access and the pump and press CONFIRM. 2) If necessary, reduce the minimum alarm limit and confirm. 3) If necessary, reduce the blood flow.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM ACCESS PRESSURE**	
Code: 302	**Description:** The access pressure is higher than the defined maximum limit.
Operator action	1) Check that the lines are not disconnected and press CONFIRM. 2) If necessary, increase the maximum alarm limit and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end, and in CPFA/RRT with ECMO.

Name: **MINIMUM RETURN PRESSURE**	
Code: 303	**Description:** The return pressure is lower than the defined minimum limit.
Operator action	1) Check that the lines are not disconnected and that the blood catcher is not wet, then press CONFIRM. 2) If necessary, reduce the minimum alarm limit and confirm.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM RETURN PRESSURE**	
Code: 304	**Description:** The return pressure is higher than the defined maximum limit.
Operator action	1) Check that the lines are not obstructed and that the blood catcher is not wet, then press CONFIRM. 2) If necessary, increase the maximum alarm limit and confirm. 3) If necessary, reduce the blood flow.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM TMP**	
Treatments	CPFA, RRT, PEX
Code: 305	**Description:** The hemofilter TMP is higher than the maximum operating range.
Code: 307	**Description:** The plasma filter TMP is higher than the maximum operating range.
Operator action	1) Check that the filter is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary, increase the maximum alarm limit and confirm.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	100 ms
Alarm deactivation time from pressing CONFIRM in the relative window	20 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM TRANS-CARTRIDGE PRESSURE**	
Treatments	CPFA, HP
Code: 309, 313	**Description:** The trans-cartridge pressure is higher than the maximum operating range.
Operator action	**CPFA:** 1) Check that the cartridge is not clogged and that the lines are not obstructed. 2) If necessary (when permitted) increase the maximum alarm limit and confirm. **HP:** 1) Check that the adsorbent column is not clogged and that the lines are not obstructed. 2) If necessary (when permitted) increase the maximum alarm limit and confirm.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **PLASMA PUMP OUTLET PRESSURE ERROR**	
Treatments	CPFA
Code: 310	**Description:** Likely leakage of the transducer at the plasma pump outlet.
Operator action	Press CONFIRM. If the error persists, stop the treatment by pressing END TREATMENT and return the blood to the patient.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	12 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM INFUSION POST-PUMP PRESSURE**	
Treatments	CPFA, RRT, PEX
Code: 311	**Description:** The pressure at the infusion pump outlet is higher than 800 mmHg.
Operator action	1) Check that there are no obstructions on the line between the pump and the heater bag. 2) Press CONFIRM and if necessary reduce the infusion flow and/or modify the value of the other flows. 3) Confirm the flow values.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **BLOOD PUMP OUTLET PRESSURE ERROR**	
Treatments	CPFA, RRT, PEX
Code: 312, 314	**Description:** Likely leakage of the transducer at the blood pump outlet.
Operator action	Press CONFIRM. If the error persists, stop the treatment by pressing END TREATMENT and return the blood to the patient.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	12 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM UF POST-PUMP PRESSURE**	
Treatments	CPFA, RRT, PEX
Code: 315	**Description:** The pressure at the UF pump outlet is higher than 150 mmHg.
Operator action	Check that there are no obstructions on the UF line and that the collection bag clamps are open, then press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MINIMUM INFUSION PRE-PUMP PRESSURE**	
Treatments	CPFA, RRT, PEX
Code: 318	**Description:** The pressure at the infusion pump inlet is lower than -150mmHg.
Operator action	Check that there are no obstructions on the infusion fluid access line on the relative bags and that the clamps are open, then press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM PRE-CARTRIDGE PRESSURE**	
Treatments	CPFA
Code: 319	**Description:** The pressure at the cartridge inlet is higher than 500 mmHg.
Operator action	1) Check that the cartridge is not clogged and that the lines are not obstructed. 2) Press CONFIRM and if necessary (when permitted) reduce the plasma flow and/or modify the value of the other flows. 3) Confirm the flow values if they have been modified.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **MAXIMUM UF PRE-PUMP PRESSURE**	
Treatments	PEX
Code: 320	**Description:** The pressure at the UF pump inlet is lower than -110 mmHg.
Operator action	1) Check that the filter is not clogged and that there are no obstructions on the line for drawing the plasma from the patient's blood. 2) Press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **BLOOD IN UF LINE**	
Treatments	CPFA, RRT
Code: 321	**Description:** Blood in UF line
Operator action	Check that there is no blood in the UF line. If blood is present, 1) Press CONFIRM: the alarm will be disabled for 1 minute from pressing CONFIRM. 2) If necessary, stop the treatment and manually return the blood to the patient. If blood is not present, press CONFIRM and resume treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	30 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF BLD TEST**	
Treatments	CPFA, RRT
Code: 322	**Description:** UF BLD test failed
Operator action	The test will be repeated 1 minute after pressing the CONFIRM button.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	30 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	30 seconds
Priority	HIGH
Active	During priming and after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF CUVETTE**	
Treatments	CPFA, RRT
Code: 323	**Description:** UF cuvette
Operator action	Insert the rigid tube of the UF line into the relative BLD and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	11 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **BLOOD IN PLASMA LINE**	
Treatments	CPFA, PEX
Code: 324	**Description:** Blood in plasma line
Operator action	Check that there is no blood in the plasma line. If blood is present, 1) Press CONFIRM: the alarm will be disabled for 1 minute from pressing CONFIRM. 2) If necessary, stop the treatment and return the blood to the patient. If blood is not present, press CONFIRM and resume treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **BLOOD IN PLASMA LINE**	
Treatments	CPFA, PEX
Code: 324.1	**Description:** Blood in plasma line
Operator action	The alarm for blood detection in the plasma line has been triggered several times in the last 10 minutes. Press the plasma BLD override button to override the alarm for blood detection in the plasma. In this case, the operator must check that the blood in the plasma line is compatible with the patient's conditions. Press CONFIRM if you want to keep the alarm for blood detection in the plasma active. In this case, the alarm will be disabled for 1 minute. **(pressing CONFIRM in the alarm window, the second page appears)** You have chosen to override the plasma BLD alarm. Press CONFIRM to confirm or CANCEL to go back.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.
NOTE:	**Appears instead of alarm 324 after alarm 324 has appeared twice in 10 minutes.**

Name: **PLASMA BLD TEST**	
Treatments	CPFA, PEX
Code: 325	**Description:** Plasma BLD test failed.
Operator action	The test will be repeated 1 minute after pressing the CONFIRM button.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	30 seconds
Priority	HIGH
Active	During priming and after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **PLASMA CUVETTE**	
Treatments	CPFA, PEX
Code: 326	**Description:** Plasma cuvette.
Operator action	Insert the rigid tube of the plasma line into the relative BLD and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	11 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **UF CUVETTE TEST**	
Treatments	CPFA, RRT, ABYLCAP
Code: 327	**Description:** UF cuvette test.
Operator action	After loading the set, insert the cuvette in the UF blood leakage detector. The machine is unable to detect failed cuvette insertion. You can perform the treatment, but call Technical Service as soon as possible to have automatic detection of cuvette insertion restored.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Immediately after power on.

Name: **UF CUVETTE TEST**	
Treatments	CPFA, RRT, ABYLCAP
Code: 327.1	**Description:** UF cuvette test.
Operator action	Check that the cuvette is properly inserted in the UF blood leakage detector.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Between priming end and treatment start (pressing START).

Name: **PLASMA CUVETTE TEST**	
Treatments	CPFA, PEX
Code: 328	**Description:** Plasma cuvette test.
Operator action	After loading the set, insert the cuvette in the plasma blood leakage detector. The machine is unable to detect failed cuvette insertion. You can perform the treatment, but call Technical Service as soon as possible to have automatic detection of cuvette insertion restored.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Immediately after power on.

Name: **PLASMA CUVETTE TEST**	
Treatments	CPFA, PEX
Code: 328.1	**Description:** Plasma cuvette test.
Operator action	Check that the cuvette is properly inserted in the plasma blood leakage detector.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Between priming end and treatment start (pressing START).

Name: **UF AND PLASMA CUVETTE TEST**	
Treatments	CPFA
Code: 329	**Description:** UF and plasma cuvette test.
Operator action	After loading the set, insert the cuvette in the blood leakage detectors. The machine is unable to detect failed cuvette insertion. You can perform the treatment, but call Technical Service as soon as possible to have automatic detection of cuvette insertion restored.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Immediately after power on.

Name: **UF AND PLASMA CUVETTE TEST**	
Treatments	CPFA
Code: 329.1	**Description:** UF and plasma cuvette test.
Operator action	Check that the cuvette is properly inserted in the UF and plasma blood leakage detectors.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Between priming end and treatment start (pressing START).

Name: **UF SCALE**	
Code: 332	**Description:** The weight read by the UF scale is inconsistent with the flow values set.
Treatments	CPFA, RRT, PEX.
Operator action	Check that the line is properly connected and not obstructed, then press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF SCALE**	
Code: 332.1	**Description:** The weight read by the UF scale is inconsistent with the flow values set.
Treatments	CPFA, RRT, PEX.
Operator action	1) Press CONFIRM. 2) Stop the treatment by pressing END TREATMENT and return the blood to the patient.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.
NOTE	**Appears instead of alarm 332 after alarm 332 has appeared twice.**

Name: **INFUSION SCALE**	
Treatments	CPFA, RRT, PEX.
Code: 333	**Description:** The weight read by the infusion scale is inconsistent with the flow values set.
Operator action	Check that the infusion line is properly connected and not obstructed. Check that all the fracture cones of the bags are properly broken open and that all the clamps are open and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION SCALE**	
Treatments	CPFA, RRT, PEX.
Code: 333.1	**Description:** The weight read by the infusion scale is inconsistent with the flow values set.
Operator action	1) Press CONFIRM. 2) Stop the treatment by pressing END TREATMENT and return the blood to the patient.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.
NOTE	**Appears instead of alarm 333 after alarm 333 has appeared twice.**

Name: **CENTRAL SCALE**	
Treatments	CPFA, RRT.
Code: 334	**Description:** The weight read by the central scale is inconsistent with the flow values set.
Operator action	Check that the pre-dilution line is properly connected and not obstructed. Check that all the fracture cones of the bags are properly broken open and that all the clamps are open and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **CENTRAL SCALE**	
Treatments	CPFA, RRT.
Code: 334.1	**Description:** The weight read by the central scale is inconsistent with the flow values set.
Operator action	1) Press CONFIRM. 2) Stop the treatment by pressing END TREATMENT and return the blood to the patient.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.
NOTE	**Appears instead of alarm 334 after alarm 334 has appeared twice.**

Name: **CENTRAL SCALE**	
Treatments	CPFA, RRT.
Code: 334.2	**Description:**
Operator action	No weight variation has been detected on the central scale. Check that all the fracture cones of the bags are properly broken open and that all the clamps are open and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **COLLECTION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 338	**Description:** The collection bags are full.
Operator action	**CPFA, RRT:** 1) Press CONFIRM. 2) Press CHANGE BAGS to replace the bags and load a minimum of 5 collection bags. **PEX:** 1) Press CONFIRM. 2) Press CHANGE BAGS to replace the bags.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 339	**Description:** The weight read by the infusion scale is greater than the maximum permitted.
Operator action	1) Press CONFIRM. 2) Press CHANGE BAGS to remove some bags so as to stay within the permitted weight.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PRE-DILUTION BAGS**	
Treatments	CPFA, RRT.
Code: 340	**Description:** The weight read by the central scale is greater than the maximum permitted.
Operator action	1) Press CONFIRM. 2) Press CHANGE BAGS to remove some bags so as to stay within the permitted weight.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **COLLECTION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 341	**Description:** An abnormal weight variation has been detected on the UF scale.
Operator action	**CPFA, RRT:** Check the condition of the UF bags and press CONFIRM. **PEX:** Check the condition of the collection bags and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 342	**Description:** An abnormal weight variation has been detected on the infusion scale.
Operator action	**CPFA, RRT:** Check the condition of the infusion bags and press CONFIRM. **PEX:** Check the condition of the plasma bags and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **CENTRAL BAGS**	
Treatments	CPFA, RRT
Code: 343	**Description:** An abnormal weight variation has been detected on the central scale.
Operator action	Check the condition of the bags on the scale and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **COLLECTION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 344	**Description:** The weight read by the UF scale is lower than the minimum permitted (200 g).
Operator action	**CPFA, RRT:** 1) Press CONFIRM. 2) Press CHANGE BAGS and load 5 collection bags. **PEX:** 1) Press CONFIRM. 2) Press CHANGE BAGS to replace the bags.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 345	**Description:** The bags on the infusion scale are empty.
Operator action	1) Press CONFIRM and then CHANGE BAGS to replace the bags. 2) Press CHANGE LIMIT to reduce the minimum weight set according to the number of bags used.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PRE-DILUTION BAGS**	
Treatments	CPFA, RRT
Code: 346	**Description:** The bags on the central scale are empty.
Operator action	1) Press CONFIRM. 2) Press CHANGE BAGS to replace the bags.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **COLLECTION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 347	**Description:** The weight on the UF scale changed by 50g while the UF pump was off.
Operator action	Likely leakage on the UF scale. Check the condition of the UF bags and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 348	**Description:** The weight on the infusion scale changed by 50g while the infusion pump was off.
Operator action	Likely leakage on the infusion scale. Check the condition of the infusion bags and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PRE-DILUTION BAGS**	
Treatments	CPFA, RRT
Code: 349	**Description:** The weight on the central scale changed by 50g while the fifth pump was off.
Operator action	Likely leakage on the central scale. Check the condition of the bags on the scale and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE 1 END-OF-STROKE**	
Code: 350	**Description:** Syringe pump 1 has reached the end of stroke.
Operator action	Replace the syringe.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE PUMP 1**	
Code: 351	**Description:** Syringe pump 1 is off.
Operator action	1) Check that the syringe is properly connected, press CONFIRM and reactivate it. 2) Replace the syringe if necessary.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE PUMP 1**	
Code: 352	**Description:** Syringe pump 1 is not infusing correctly.
Operator action	Press CONFIRM to disable the pump.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	25 minutes
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **TEMPERATURE**	
Treatments	CPFA, RRT, PEX
Code: 360	**Description:** The incoming fluid temperature exceeds 41°C.
Code: 361	**Description:** The outgoing fluid temperature exceeds 41°C.
Code: 366	**Description:** The heating plate temperature is too high.
Operator action	Wait until the temperature goes down.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	**Code 360:** 4 seconds **Code 361:** 3 seconds **Code 366:** 1 second
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **TEMPERATURE**	
Treatments	CPFA, RRT, PEX
Code: 360.1, 361.1, 366.1	**Description:** The temperatures of the heating plate and the incoming and outgoing fluid are correct.
Operator action	Press CONFIRM to restart the pumps.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	1 second
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER**	
Treatments	CPFA, RRT, PEX
Code: 362	**Description:** The heater door is open.
Operator action	Close the door and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always, except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER BAG**	
Treatments	CPFA, RRT, PEX
Code: 363	**Description:** A fluid leak has been detected in the heater.
Operator action	Press CONFIRM to restart the pumps.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always, except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER BAG**	
Treatments	CPFA, RRT, PEX
Code: 364	**Description:** There is no bag in the heater.
Operator action	Insert a bag and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always, except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER TEST**	
Treatments	CPFA, RRT, PEX
Code: 365	**Description:** The test of the heating plate transducers has failed.
Operator action	Press CONFIRM to restart the pumps; the heater will be deactivated.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **TEMPERATURE**	
Code: 367	**Description:** The heating plate temperature is higher than 60°C.
Operator action	Turn off the machine, turn it back on and resume treatment if possible. If necessary, remove the return line from the venous clamp and manually return the blood to the patient.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **TEMPERATURE**	
Code: 368	**Description:** The infusion fluid temperature is lower than 33°C.
Operator action	Before continuing the treatment, check that this temperature is compatible with the patient's conditions. You can definitively deactivate this alarm by pressing the ALARM DEACTIVATION button.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 minutes from START and 5 minutes from alarms
Priority	HIGH
Active	Treatment

Name: **TEMPERATURE**	
Code: 368.1	**Description:** The infusion fluid temperature is lower than 33°C.
Operator action	You have chosen to override the minimum temperature alarm. Press CONFIRM to confirm or CANCEL to go back. If you confirm, you are responsible for ensuring that the patient's conditions are compatible with the low temperatures of the infused fluids.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 minutes from START and 5 minutes from alarms
Priority	HIGH
Active	Treatment

Name: **HEATER OUTLET TEMPERATURE TRANSDUCER TEST**	
Code: 369	**Description:** The outgoing fluid temperature transducer is unable to correctly read the temperature. Contact Technical Service to restore the machine.
Operator action	Contact Technical Service.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	2 seconds
Priority	HIGH
Active	At power on.

Name: **INFUSION PUMP**	
Treatments	CPFA, RRT, PEX
Code: 370	**Description:** The infusion pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF PUMP**	
Treatments	CPFA, RRT
Code: 371	**Description:** The UF pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **POST-INFUSION PUMP**	
Treatments	RRT (HDF and HF)
Code: 372	**Description:** The post-infusion pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Priority	HIGH
Active	Always during bag change with replacement pumps on and after treatment start (pressing START), except during temporary disconnection, bag change with replacement pumps off, blood pump stop, treatment end.

Name: **BLOOD PUMP**	
Code: 373	**Description:** The blood pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **PLASMA PUMP**	
Treatments	CPFA
Code: 376	**Description:** The plasma pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, blood pump stop, treatment end.

Name: **FIFTH PUMP**	
Treatments	CPFA, RRT
Code: 385	**Description:** The cover of the fifth pump is open.
Operator action	Close the cover.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always, except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION PUMP**	
Treatments	CPFA, RRT
Code: 390	**Description:** The infusion pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	90 seconds
Priority	HIGH
Active	Only during bag change with pumps on.

Name: **UF PUMP**	
Treatments	CPFA, RRT
Code: 391	**Description:** The UF pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	30 seconds
Priority	HIGH
Active	Only during bag change with pumps on.

Name: **FIFTH PUMP**	
Treatments	CPFA, RRT
Code: 394	**Description:** The fifth pump speed is different from that expected.
Operator action	Press CONFIRM. If the problem persists, end the treatment.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	90 seconds
Priority	HIGH
Active	Only during bag change with pumps on.

Name: **UF FLOW**	
Treatments	CPFA, RRT (HDF and HF)
Code: 401	**Description:** The UF flow set is greater than the maximum permitted value.
Operator action	Press CONFIRM and adjust the UF flow and/or weight loss to the blood flow value.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF FLOW**	
Treatments	CPFA, RRT (HDF and HF)
Code: 402	**Description:** The UF flow selected is lower than the weight loss set.
Operator action	Press CONFIRM and set new UF flow and weight loss values.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PRE-DILUTION FLOW**	
Treatments	CPFA, RRT
Code: 403	**Description:** The pre-dilution flow is higher than the maximum settable value.
Operator action	Press CONFIRM and set the pre-dilution flow to a value consistent with the blood flow.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF FLOW**	
Treatments	RRT (HDF and HF)
Code: 404	**Description:** The UF flow set is greater than the maximum permitted value.
Operator action	Press CONFIRM and adjust the UF flow and/or weight loss to the blood flow value.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START) when dialysate flow = 0 (HDF) or pre-infusion flow = 0 (HF), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **WEIGHT LOSS**	
Treatments	CPFA, RRT
Code: 405	**Description:** The weight loss set is greater than the maximum permitted value.
Operator action	Press CONFIRM and reduce the weight loss and/or increase the blood flow.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF FLOW**	
Treatments	CPFA and RRT with local-regional anticoagulation in ASSISTED mode
Code: 406	**Description:** The UF flow is incompatible with ASSISTED mode.
Operator action	Press CONFIRM and modify the blood flow in order to stay in ASSISTED mode.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF FLOW/WEIGHT LOSS**	
Treatments	CPFA and RRT with local-regional anticoagulation in ASSISTED mode
Code: 407	**Description:** The weight loss and blood flow set are incompatible with ASSISTED mode.
Operator action	Press CONFIRM and reduce the weight loss and/or increase the blood flow in order to stay in ASSISTED mode.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF FLOW/WEIGHT LOSS**	
Treatments	CPFA, HDF, HF and SCUF
Code: 408	**Description:** The UF flow is incompatible with the weight loss selected. Press CONFIRM and adjust the UF flow.
Operator action	Press CONFIRM and adjust the UF flow
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **DIALYSATE FLOW**	
Treatments	HD
Code: 408	**Description:** The dialysate flow is incompatible with the weight loss selected. Press CONFIRM and adjust the dialysate flow.
Operator action	Press CONFIRM and adjust the Dialysate flow
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF FLOW**	
Treatments	HF
Code: 409	**Description:** The UF flow is incompatible with the percentage pre-infusion selected. Press CONFIRM and adjust the UF flow.
Operator action	Press CONFIRM and adjust the UF flow
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PRESSURE SENSOR TEST**	
Treatments	RRT (HDF, HF, HD)
Code: 422, 423	**Description:** Pressure sensor autotest failed: problem on set detected.
Operator action	The test will be repeated 10 minutes after pressing the CONFIRM button. If the test repeatedly fails, it is advisable to return the blood to the patient and remove the set.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	**Code 422:** instantaneous **Code 423:** 4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.
NOTES	**Code 422: appears when the test fails after 24 hours of treatment.** **Code 423: appears when the test fails after 4 hours of treatment.**

Name: **SYRINGE 2 END-OF-STROKE**	
Code: 450	**Description:** Syringe pump 2 has reached the end of stroke.
Operator action	Replace the syringe.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE PUMP 2**	
Code: 451	**Description:** Syringe pump 2 is off.
Operator action	1) Check that the syringe is properly connected, press CONFIRM and reactivate it. 2) Replace the syringe if necessary.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE PUMP 2**	
Code: 452	**Description:** Syringe pump 2 is not infusing correctly.
Operator action	Press CONFIRM to disable the pump.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	25 minutes
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **IONISED CALCIUM**	
Treatments	CPFA and RRT with local-regional anticoagulation
Code: 480	**Description:** ionised calcium
Operator action	1) Measure the systemic ionised calcium of the patient. 2) Press CONFIRM and enter the value measured.
Effects	Yellow warning light, acoustic warning.
Intervention time	Instantaneous
Priority	LOW
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION PUMP**	
Treatments	CPFA, RRT, PEX
Code: 570	**Description:** The infusion pump is malfunctioning.
Operator action	Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	100 ms (after 3 consecutive errors)
Priority	LOW
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF PUMP**	
Treatments	CPFA, RRT, PEX
Code: 571	**Description:** The UF pump is malfunctioning.
Operator action	Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	100 ms (after 3 consecutive errors)
Priority	LOW
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **POST-INFUSION PUMP**	
Treatments	RRT
Code: 572	**Description:** The post-infusion pump is malfunctioning.
Operator action	Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms (after 3 consecutive errors)
Priority	LOW
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **BLOOD PUMP**	
Code: 573	**Description:** The blood pump is malfunctioning.
Operator action	Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms (after 3 consecutive errors)
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **FIFTH PUMP**	
Treatments	CPFA, RRT
Code: 574, 577, 578, 579, 580	**Description:** The fifth pump is malfunctioning.
Operator action	Check that the fifth pump line is properly connected and that the line is not obstructed, then press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **BLOOD PUMP**	
Treatments	CPFA, RRT
Code: 575	**Description:** The fifth pump is locked.
Operator action	Check that the fifth pump line is not obstructed and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PRESSURE SENSOR TEST**	
Treatments	RRT (HDF, HF, HD)
Code: 721	**Description:** It was not possible to perform the pressure sensor autotest.
Operator action	The test will be repeated 10 minutes after pressing the CONFIRM button.
Effects	Yellow warning light, acoustic warning.
Intervention time	Instantaneous
Priority	LOW
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PUMP INCONSISTENCY**	
Treatments	CPFA, RRT
Code: 780	**Description:** The fifth pump is running while syringe pump 1 is off.
Operator action	Press CONFIRM and turn off the fifth pump or activate the syringe pump.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	Always after treatment start (pressing START).

Name: **PUMP INCONSISTENCY**	
Treatments	CPFA, RRT
Code: 781	**Description:** Syringe pump 1 is running while the fifth pump is off.
Operator action	Press CONFIRM and turn off the syringe pump or activate the fifth pump.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	Always after treatment start (pressing START).

Name: **COMMUNICATION ERROR**	
Code: 1000, 1001, 1003-1008, 1010-1015, 1039, 1043, 1044	**Description:** Communication error.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **SYSTEM ERROR**	
Code: 1002	**Description:** System error.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	White warning light, violet alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **BLOOD PUMP INLET PRESSURE TOO LOW**	
Code: 1016	**Description:** The pressure read by the transducer at the blood pump inlet is lower than -430mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **BLOOD PUMP INLET PRESSURE TOO HIGH**	
Code: 1017	**Description:** The pressure read by the transducer at the blood pump inlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **BLOOD PUMP OUTLET PRESSURE TOO LOW**	
Code: 1018	**Description:** The pressure read by the transducer at the blood pump outlet is lower than -400mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **BLOOD PUMP OUTLET PRESSURE TOO HIGH**	
Code: 1019	**Description:** The pressure read by the transducer at the blood pump outlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **BOTTOM LEFT PUMP OUTLET PRESSURE TOO LOW**	
Code: 1020	**Description:** The pressure read by the transducer at the bottom left pump outlet is lower than -400mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **BOTTOM LEFT PUMP OUTLET PRESSURE TOO HIGH**	
Code: 1021	**Description:** The pressure read by the transducer at the bottom left pump outlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **BOTTOM LEFT PUMP INLET PRESSURE TOO LOW**	
Code: 1022	**Description:** The pressure read by the transducer at the bottom left pump inlet is lower than -400mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **BOTTOM LEFT PUMP INLET PRESSURE TOO HIGH**	
Code: 1023	**Description:** The pressure read by the transducer at the bottom left pump inlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **VENOUS CASSETTE PRESSURE TOO LOW**	
Code: 1024	**Description:** The pressure in the venous cassette is lower than -400 mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **VENOUS CASSETTE PRESSURE TOO HIGH**	
Code: 1025	**Description:** The pressure in the venous cassette is higher than 600 mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **INFUSION PUMP INLET PRESSURE TOO LOW**	
Code: 1026	**Description:** The pressure read by the transducer at the infusion pump inlet is lower than -400mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that All the fracture cones on the infusion bags are properly broken open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **INFUSION PUMP INLET PRESSURE TOO HIGH**	
Code: 1027	**Description:** The pressure read by the transducer at the infusion pump inlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **INFUSION PUMP OUTLET PRESSURE TOO LOW**	
Code: 1028	**Description:** The pressure read by the transducer at the infusion pump outlet is lower than -400mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **INFUSION PUMP OUTLET PRESSURE TOO HIGH**	
Code: 1029	**Description:** The pressure read by the transducer at the infusion pump outlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **UF PUMP OUTLET PRESSURE TOO LOW**	
Code: 1030	**Description:** The pressure read by the transducer at the UF pump outlet is lower than -400mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **UF PUMP OUTLET PRESSURE TOO HIGH**	
Code: 1031	**Description:** The pressure read by the transducer at the UF pump outlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **UF PUMP INLET PRESSURE TOO LOW**	
Code: 1032	**Description:** The pressure read by the transducer at the UF pump inlet is lower than -400mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **UF PUMP INLET PRESSURE TOO HIGH**	
Code: 1033	**Description:** The pressure read by the transducer at the UF pump inlet is higher than 600mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **UPPER CASSETTE PRESSURE TOO LOW**	
Code: 1034	**Description:** The pressure in the upper cassette is lower than -400 mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open. Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **UPPER CASSETTE PRESSURE TOO HIGH**	
Code: 1035	**Description:** The pressure in the upper cassette is higher than 600 mmHg.
Operator action	Check that all the electroclamps on the circuit lines are open.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **MAXIMUM UF WEIGHT**	
Code: 1036	**Description:** Maximum weight read on the UF scale.
Operator action	Check the condition of the UF bags and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **MAXIMUM INFUSION WEIGHT**	
Code: 1037	**Description:** Maximum weight read on the infusion scale.
Operator action	Check the condition of the infusion bags and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **MAXIMUM PRE-DILUTION WEIGHT**	
Code: 1038	**Description:** Maximum pre-dilution weight.
Operator action	Check the condition of the bags on the scale and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	During priming.

Name: **NO UF CUVETTE**	
Treatments	CPFA, RRT
Code: 1040	**Description:** No UF cuvette.
Operator action	Insert the rigid tube of the UF line into the relative BLD and press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	Before treatment start (pressing START).

Name: **NO PLASMA CUVETTE**	
Treatments	CPFA, PEX
Code: 1041	**Description:** No plasma cuvette.
Operator action	Insert the rigid tube of the plasma line into the relative BLD and press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	Before treatment start (pressing START).

Name: **TREATMENT END**	
Treatments	Intermittent RRT
Code: 1045	**Description:** The intermittent treatment has ended. If you have set a treatment time of 24 hours, the time is no longer modifiable for the same treatment.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	Before treatment start (pressing START).

Name: **UNSTABLE WEIGHT ON SCALES**	
Treatments	CPFA, RRT, PEX
Code: 1046	**Description:** The weight on the scales is unstable.
Operator action	Wait a few seconds for the weight to stabilise and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **TREATMENT TIME**	
Treatments	CPFA, PEX
Code: 1047	**Description:** The treatment time elapsed so far has exceeded 24 hours.
Code: 1047.1	**Description:** The treatment time elapsed so far has exceeded 24 hours since *num_hrs : num_min.*
Operator action	**PEX:** Press END TREATMENT, return the blood to the patient, remove the set and turn off the machine.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	After treatment start (pressing START).

Name: **PLASMA TARGET REACHED**	
Treatments	CPFA, PEX
Code: 1048	**Description:** The target volume of plasma to be treated has been reached.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	After treatment start (pressing START).

Name: **TREATMENT TIME**	
Treatments	ABYLCAP
Code: 1049	**Description:** 60 hours have elapsed since the start of the ABYLCAP treatment.
Operator action	If you want to continue the treatment: 1) Press CONFIRM. 2) Proceed with automatic blood return (END TREATMENT button). 3) Remove the used set and turn off the machine. 4) Turn on the machine, load a new ABYLCAP set and start priming the new set. 5) Resume the treatment.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	After treatment start (pressing START).

Name: **SYSTEM ALARM**	
Code: 1050	**Description:** Firmware test failed.
Code: 1051	**Description:** Power supply test failed.
Code: 1052	**Description:** EEPROM memory test failed.
Code: 1053	**Description:** Protection voltage test failed.
Code: 1054	**Description:** Fifth pump test failed.
Code: 1055	**Description:** Infusion pump test failed.
Code: 1056	**Description:** Blood pump test failed.
Code: 1057	**Description:** UF pump test failed.
Code: 1058	**Description:** Plasma/post-infusion pump test failed.
Code: 1059	**Description:** UF scale test failed.
Code: 1060	**Description:** Infusion scale test failed.
Code: 1061	**Description:** Central scale test failed.
Code: 1062	**Description:** Upper cassette level control system test failed.
Code: 1063	**Description:** Venous cassette level control system test failed.
Code: 1064	**Description:** Communication error with UF BLD.
Code: 1065	**Description:** Communication error with plasma BLD.
Code: 1066	**Description:** Communication error with hematocrit meter/saturation meter.
Code: 1067	**Description:** Air bubble threshold test failed.
Code: 1068	**Description:** EEPROM reading test failed.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	Red warning light, red alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **OXYGEN**	
Treatments	ABYLCAP
Code: 1069	**Description:** oxygen.
Code: 1070	**Description:** oxygen.
Operator action	**Code 1069:** Stop the oxygen flow. **Code 1070:** Start the oxygen flow.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	After treatment start (pressing START).

Name: **COLLECTION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 1071	**Description:** The collection bags on the UF scale are almost full.
Operator action	Replace them with new collection bags as soon as possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **COLLECTION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 1071.1	**Description:** The bags on the UF scale are almost full.
Operator action	Less than 5 minutes remain to select bag change with the pumps on after which it will no longer be possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **INFUSION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 1072	**Description:** The bags on the infusion scale are almost empty.
Operator action	Replace them with new infusion bags as soon as possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **INFUSION BAGS**	
Treatments	CPFA, RRT, PEX
Code: 1072.1	**Description:** The bags on the infusion scale are almost empty.
Operator action	Less than 5 minutes remain to select bag change with the pumps on after which it will no longer be possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **PRE-DILUTION BAGS**	
Treatments	CPFA, RRT
Code: 1073	**Description:** The bags on the central scale are almost empty.
Operator action	Replace them with new bags as soon as possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **PRE-DILUTION BAGS**	
Treatments	CPFA, RRT
Code: 1073.1	**Description:** The bags on the central scale are almost empty.
Operator action	Less than 5 minutes remain to select bag change with the pumps on after which it will no longer be possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **SYRINGE 1**	
Code: 1074	**Description:** Syringe 1 is almost empty.
Operator action	Replace it with a new syringe as soon as possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **TREATMENT END**	
Treatments	HP
Code: 1075	**Description:** The HP treatment has ended.
Operator action	1) Press CONFIRM and after pressing the END TREATMENT button, proceed with automatic blood return. 2) Remove the set and turn off the machine.
Effects	Yellow warning light, acoustic warning.
Intervention time	5 seconds
Priority	LOW
Active	After treatment start (pressing START).

Name: **SYRINGE 2**	
Code: 1076	**Description:** Syringe 2 is almost empty.
Operator action	Replace it with a new syringe as soon as possible.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	After treatment start (pressing START).

Name: **VOLUME REINFUSED**	
Code: 1077	**Description:** A blood volume of 250 ml has been reinfused.
Operator action	**RRT, ABYLCAP, HP:** To continue with return, press the BLOOD RETURN button. **CPFA, PEX:** To continue with return, press the START RETURN button.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Return/temporary disconnection.

Name: **TREATMENT TIME**	
Treatments	RRT
Code: 1078	**Description:** The treatment time elapsed so far has exceeded 72 hours.
Code: 1078.1	**Description:** The treatment time elapsed so far has exceeded 72 hours since *num_hrs : num_min.*
Operator action	**RRT, ABYLCAP, HP:** To continue with return, press the BLOOD RETURN button. **CPFA, PEX:** To continue with return, press the START RETURN button.
Effects	Yellow warning light, acoustic warning.
Intervention time	72 hours of RRT treatment
Priority	LOW
Active	After treatment start (pressing START).

Name: **BAG CHANGE WITH PUMPS ON**	
Treatments	CPFA, RRT
Code: 1079	**Description:** Less than 2 minutes remain to complete the bag change with the pumps on. Beyond this time, the replacement pumps stop waiting for the bag change to be completed.
Operator action	Speed up bag change.
Effects	Yellow warning light, acoustic warning.
Intervention time	8 minutes
Priority	LOW
Active	Bag change with pumps on.

Name: **SYSTEM ALARM**	
Code: 2000, 2002	**Description:** Communication error with barcode reading sensor.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During single-use set loading.

Name: **PRIMING ALARM (PHASE 1)**	
Code: 2100	**Description:** **CPFA, RRT:** PRIMING PHASE I: The replacement fluid in the bags hung on the infusion scale is less than the rinsing volume set. **ABYLCAP, PEX. HP:** PRIMING PHASE I: The priming fluid in the bag hung on the infusion scale is less than the rinsing volume set.
Operator action	**CPFA, RRT:** 1) Load a maximum of 4 bags on the infusion scale and sufficient to allow the system to consume the rinsing volume set. 2) Press CONFIRM. **ABYLCAP, PEX. HP:** 1) Load an amount of fluid on the infusion scale sufficient to allow the system to consume the rinsing volume set. 2) Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 1)**	
Treatments	CPFA, RRT
Code: 2101	**Description:** PRIMING PHASE I: The replacement fluid in the bags hung on the infusion scale is less than the rinsing volume set. In addition, the replacement fluid in the bags hung on the central scale is less than the minimum value set.
Operator action	1) Load a number of bags on the infusion scale sufficient to allow the system to consume the rinsing volume set. 2) Load a number of bags on the central scale equal to a fluid volume of at least 500 ml. 3) Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 1)**	
Treatments	CPFA, RRT
Code: 2102	**Description:** PRIMING PHASE I: The replacement fluid in the bags hung on the central scale is less than the minimum value of 500 ml required for priming the fifth pump and the pre-dilution line during treatment.
Operator action	1) Load a maximum of 2 bags on the central scale and equal to a fluid volume of at least 500 ml. 2) Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 1)**	
Treatments	CPFA, RRT
Code: 2103	**Description:** PRIMING PHASE I - FIFTH PUMP LINE PRIMING: A variation of at least 5ml has not been detected on the central scale.
Operator action	Check that: 1) The fifth pump line is properly connected to its access. 2) The line segment has been properly inserted in its seat. 3) The line is intact and that there are no obstructions. 4) The replacement fluid bag or bags have been properly loaded on the central scale and are properly connected to the line. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 1)**	
Treatments	CPFA, RRT
Code: 2104	**Description:** PRIMING PHASE I - FIFTH PUMP LINE PRIMING: The 50ml replacement fluid required for priming the fifth pump line has not been consumed.
Operator action	Check that: 1) The line is properly connected to its access. 2) The segment has been properly inserted in its seat. 3) The line is intact and that there are no obstructions. 4) The bag or bags have been properly loaded on the central scale and are properly connected to the line. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING START ALARM**	
Code: 2137	**Description:** PRIMING START: 10 seconds have elapsed since pressing the START button to start the rinsing procedure and the double electroclamp is not correctly positioned.
Operator action	Press CONFIRM to allow the system to retry bringing the double electroclamp into the correct position or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **DOUBLE ELECTROCLAMP RESET FAILED**	
Code: 2138	**Description:** The double electroclamp was unable to position correctly.
Operator action	Press CONFIRM to continue.
Effects	Yellow warning light, acoustic warning.
Intervention time	10 s
Priority	LOW
Active	During priming.

Name: **PRIMING START ALARM**	
Code: 2143	**Description:** PRIMING START: The initial value of the pressures is higher than the maximum permitted.
Operator action	Connect the lines only after loading the single-use set. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Before loading start.

Name: **PRIMING ALARM (PHASE 2)**	
Code: 2200	**Description:** **CPFA, RRT:** PRIMING PHASE II - PRIMING: 2 minutes have elapsed since the start of the second priming phase and the infusion pump has not drawn the required 250ml of replacement fluid from the relative bags. **ABYLCAP:** More than 1 minute has elapsed since the start of the second priming phase and the blood pump has not drawn the required 100ml of fluid from the saline bag hung on the infusion scale. **PEX:** PRIMING PHASE II - PRIMING: 2 minutes have elapsed since the start of the second priming phase and the infusion pump has not drawn the required 250ml of saline from the relative bag. **HP:** PRIMING PHASE II - PRIMING: 2 minutes have elapsed since the start of the second priming phase and the infusion pump has not drawn the required 170ml of priming fluid from the relative bag.
Operator action	**CPFA, RRT:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The replacement fluid bag or bags have been properly loaded on the infusion scale and are properly connected to the branches of the infusion line. Press CONFIRM. **ABYLCAP:** Check that: 1) The access line is intact and that there are no obstructions. 2) The saline bag has been properly loaded on the infusion scale and is properly connected to the access line. Press CONFIRM. **PEX:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The saline bag has been properly loaded on the infusion scale and is properly connected to the infusion line. Press CONFIRM. **HP:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The priming fluid bag has been properly loaded on the infusion scale and is properly connected to the infusion line. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 2)**	
Code: 2201	**Description:** PRIMING PHASE II - FIRST RINSING: Two minutes have elapsed since the end of the circuit priming phase and the required 20g variation has not been detected on the UF scale.
Operator action	Check that: 1) The UF line is intact and that there are no obstructions. 2) The collection bag or bags have been properly loaded on the UF scale and are properly connected to the branches of the UF line. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Before loading start.

Name: **PRIMING ALARM (PHASE 2)**	
Code: 2202	**Description:** **CPFA:** 4 minutes have elapsed since the end of the circuit priming phase and the infusion pump has not drawn the required 300ml of replacement fluid from the relative bags or one of the two cassettes has not been rinsed properly. **RRT:** 4 minutes have elapsed since the end of the circuit priming phase and the infusion pump has not drawn the required 225ml of replacement fluid from the relative bags or one of the two cassettes has not been rinsed properly. **ABYLCAP:** More than 2 minutes have elapsed since the end of the circuit priming phase and the blood pump has not drawn the required 150ml of fluid from the saline bag hung on the infusion scale or one of the two cassettes has not been rinsed properly. **PEX:** 4 minutes have elapsed since the end of the circuit priming phase and the infusion pump has not drawn the required 225ml of saline from the relative bag or the venous cassette has not been rinsed properly. **HP:** More than 2 minutes have elapsed since the end of the circuit priming phase and the blood pump has not drawn the required 150ml of fluid from the priming fluid bag hung on the infusion scale or the venous cassette has not been rinsed properly.
Operator action	**CPFA:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The replacement fluid bag or bags have been properly loaded on the infusion scale and are properly connected to the branches of the infusion line. 3) The pressure transducers have been properly inserted in the respective ports and the level lines in the respective sensors. Press CONFIRM. **RRT:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The replacement fluid bag or bags have been properly loaded on the infusion scale and are properly connected to the branches of the infusion line. 3) The pressure transducers have been properly inserted in the respective ports and the level lines in the respective sensors. Press CONFIRM. **ABYLCAP:** Check that: 1) The access line is intact and that there are no obstructions. 2) The saline bag has been properly loaded on the infusion scale and is properly connected to the access line. 3) The pressure transducers have been properly inserted in the respective ports and the level lines in the respective sensors. Press CONFIRM. **PEX:**

	Check that: 1) The infusion line is intact and that there are no obstructions. 2) The saline bag has been properly loaded on the infusion scale and is properly connected to the infusion line. 3) The venous pressure transducer has been properly inserted in the relative port and the venous level line in the relative sensor. Press CONFIRM. **HP:** Check that: 1) The access line is intact and that there are no obstructions. 2) The priming fluid bag has been properly loaded on the infusion scale and is properly connected to the access line. 3) The venous pressure transducer has been properly inserted in the relative port and the venous level line in the relative sensor. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 2)**	
Treatments	CPFA, RRT
Code: 2203	**Description:** PRIMING PHASE II - DOUBLE ELECTROCLAMP ROTATION: 5 minutes have elapsed since the pump stop and the double electroclamp position has not changed.
Operator action	Press CONFIRM to allow the system to repeat the double electroclamp rotation procedure or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Before loading start.

Name: **PRIMING ALARM (PHASE 2)**	
Treatments	CPFA, RRT, ABYLCAP, PEX
Code: 2204	**Description:** PRIMING PHASE II - SECOND RINSING: The heater test has failed. The heater will be deactivated for the entire remaining rinsing time and cannot be activated during treatment.
Operator action	Press CONFIRM to continue rinsing.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Before loading start.

Name: **PRIMING ALARM (PHASE 2)**	
Code: 2205	**Description:** **CPFA:** 3 minutes have elapsed since the end of the first circuit rinsing phase and the infusion pump has not drawn the required 300ml of replacement fluid from the relative bags. **RRT:** 3 minutes have elapsed since the end of the first circuit rinsing phase and the infusion pump has not drawn the required 125ml of replacement fluid from the relative bags. **ABYLCAP:** More than 2 minutes have elapsed since the end of the first circuit rinsing phase and the blood pump has not drawn the required 250ml of fluid from the saline bag hung on the infusion scale. **PEX:** 3 minutes have elapsed since the end of the first circuit rinsing phase and the infusion pump has not drawn the required 125ml of saline from the relative bag. **HP:** More than 2 minutes have elapsed since the end of the first circuit rinsing phase and the blood pump has not drawn the required 250ml of fluid from the priming fluid bag hung on the infusion scale.
Operator action	**CPFA:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The replacement fluid bag or bags have been properly loaded on the infusion scale and are properly connected to the branches of the infusion line. Press CONFIRM. **RRT:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The replacement fluid bag or bags have been properly loaded on the infusion scale and are properly connected to the branches of the infusion line. Press CONFIRM. **ABYLCAP:** Check that: 1) The access line is intact and that there are no obstructions. 2) The saline bag has been properly loaded on the infusion scale and is properly connected to the access line. Press CONFIRM. **PEX:** Check that: 1) The infusion line is intact and that there are no obstructions. 2) The saline bag has been properly loaded on the infusion scale and is properly connected to the infusion line. Press CONFIRM. **HP:** Check that: 1) The access line is intact and that there are no obstructions. 2) The priming fluid bag has been properly loaded on the infusion scale and is properly connected to the access line. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **ADSORBENT COLUMN CONNECTION**	
Treatments	HP
Code: 2206	**Description:** Adsorbent column connection.
Operator action	Disconnect the bypass line from the adsorbent column inlet (red) and outlet (blue) lines leading from the set. Connect the adsorbent column inlet (red) and outlet (blue) lines to the relative ports on the column.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **DOUBLE ELECTROCLAMP RESET FAILED**	
Code: 2207	**Description:** The double electroclamp was unable to position correctly.
Operator action	Press CONFIRM to continue.
Effects	Yellow warning light, acoustic warning.
Intervention time	10 seconds
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2300	**Description:** **CPFA, RRT, PEX:** PRIMING PHASE III - START: 40 seconds have elapsed since the end of the second rinsing phase and the infusion pump was unable to bring the circuit to a pressure of at least 100 mmHg in order to run the positive pressure test. **ABYLCAP, HP:** PRIMING PHASE III - START: 40 seconds have elapsed since the end of the second rinsing phase and the blood pump was unable to bring the circuit to a pressure of at least 100 mmHg in order to run the positive pressure test.
Operator action	**CPFA, RRT:** Check that: 1) The circuit lines are intact. 2) There are no open free branches on the infusion and UF lines. Press CONFIRM. **ABYLCAP, PEX:** Check that: 1) The circuit lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. Press CONFIRM. **HP:** Check that: 1) The circuit lines are intact. 2) The access and return lines are properly connected to the relative bags. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2301	**Description:** **CPFA, RRT, PEX:** PRIMING PHASE III - START: 80 seconds have elapsed since the end of the second rinsing phase and the infusion pump was unable to bring the circuit to a pressure of at least 320 mmHg in order to run the positive pressure test. **ABYLCAP, HP:** PRIMING PHASE III - START: 80 seconds have elapsed since the end of the second rinsing phase and the blood pump was unable to bring the circuit to a pressure of at least 320 mmHg in order to run the positive pressure test.
Operator action	**CPFA, RRT:** Check that: 1) The circuit lines are intact. 2) There are no open free branches on the infusion and UF lines. Press CONFIRM. **ABYLCAP, PEX:** Check that: 1) The circuit lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. Press CONFIRM. **HP:** Check that: 1) The circuit lines are intact. 2) The access and return lines are properly connected to the relative bags. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2302	**Description:** **CPFA, RRT, PEX:** PRIMING PHASE III - POSITIVE PRESSURE READING TEST: The infusion pump was unable to bring the circuit to a pressure of at least 250 mmHg in order to repeat the positive pressure reading test. **ABYLCAP, HP:** PRIMING PHASE III - POSITIVE PRESSURE READING TEST: The blood pump was unable to bring the circuit to a pressure of at least 250 mmHg in order to repeat the positive pressure reading test.
Operator action	**CPFA, RRT:** Check that: 1) The circuit lines are intact. 2) There are no open free branches on the infusion and UF lines. Press CONFIRM. **ABYLCAP, PEX:** Check that: 1) The circuit lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. Press CONFIRM. **HP:** Check that: 1) The circuit lines are intact. 2) The access and return lines are properly connected to the relative bags. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2303	**Description:** **CPFA, RRT, PEX:** PRIMING PHASE III - POSITIVE PRESSURE STABILITY TEST: The infusion pump was unable to bring the circuit to a pressure of at least 250 mmHg in order to repeat the positive pressure stability test. **ABYLCAP, HP:** PRIMING PHASE III - POSITIVE PRESSURE STABILITY TEST: The blood pump was unable to bring the circuit to a pressure of at least 250 mmHg in order to repeat the positive pressure stability test.
Operator action	**CPFA, RRT:** Check that: 1) The circuit lines are intact. 2) There are no open free branches on the infusion and UF lines. Press CONFIRM. **ABYLCAP, PEX:** Check that: 1) The circuit lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. Press CONFIRM. **HP:** Check that: 1) The circuit lines are intact. 2) The access and return lines are properly connected to the relative bags. Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2310	**Description:** the transducers that read the pressures in the venous and upper cassette, respectively, have not passed the reading test.
Code: 2311	**Description:** the transducer that reads the pressure in the upper cassette has not passed the reading test.
Code: 2312	**Description:** the transducer that reads the pressure at the infusion pump outlet has not passed the reading test.
Code: 2313	**Description:** the transducer that reads the pressure in the venous cassette has not passed the reading test.
Code: 2314	**Description:** **CPFA:** The transducer that reads the pressure at the plasma pump outlet has not passed the reading test. **RRT:** The transducer that reads the pressure at the post-infusion pump outlet has not passed the reading test.
Code: 2315	**Description:** the transducer that reads the pressure at the blood pump outlet has not passed the reading test.
Code: 2316	**Description:** **CPFA, RRT:** The transducer that reads the pressure at the bottom left pump inlet has not passed the reading test. **PEX:** The transducer that reads the pressure at the UF pump inlet has not passed the reading test.
Code: 2317	**Description:** at least two transducers that read the pressures in the circuit have not passed the reading test.
Code: 2318	**Description:** all the transducers that read the pressures in the circuit have not passed the reading test.
Operator action	**Code 2310, 2311, 2312 (PEX), 2313 (CPFA, RRT), 2314, 2315 (CPFA, RRT), 2316, 2317 (CPFA, RRT), 2318 (CPFA, RRT):** Check that: 1) The circuit lines are intact. 2) There are no open free branches on the infusion and UF lines. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service. **Code 2313 (ABYLCAP, PEX, HP), 2315 (ABYLCAP, PEX, HP), 2317 (ABYLCAP, PEX, HP), 2318 (ABYLCAP, PEX, HP):** Check that: 1) The circuit lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2320	**Description:** the transducers that read the pressures in the venous and upper cassette, respectively, have not passed the stability test.
Code: 2321	**Description:** the transducer that reads the pressure in the upper cassette has not passed the stability test.
Code: 2322	**Description:** the transducer that reads the pressure at the infusion pump outlet has not passed the stability test.
Code: 2323	**Description:** the transducer that reads the pressure in the venous cassette has not passed the stability test.
Code: 2324	**Description:** **CPFA:** The transducer that reads the pressure at the plasma pump outlet has not passed the stability test. **RRT:** The transducer that reads the pressure at the post-infusion pump outlet has not passed the stability test.
Code: 2325	**Description:** the transducer that reads the pressure at the blood pump outlet has not passed the stability test.
Code: 2326	**Description:** **CPFA, RRT:** The transducer that reads the pressure at the bottom left pump inlet has not passed the stability test. **PEX:** The transducer that reads the pressure at the UF pump inlet has not passed the stability test.
Code: 2327	**Description:** at least two transducers that read the pressures in the circuit have not passed the stability test.
Code: 2328	**Description:** all the transducers that read the pressures in the circuit have not passed the stability test.
Operator action	**Code 2320, 2321, 2322 (CPFA, RRT), 2323 (CPFA, RRT), 2324, 2325 (CPFA, RRT), 2326, 2327 (CPFA, RRT), 2328 (CPFA, RRT):** Check that: 1) The circuit lines are intact. 2) There are no open free branches on the infusion and UF lines. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service. **Code 2322 (ABYLCAP, PEX, HP), 2323 (ABYLCAP, PEX, HP), 2325 (ABYLCAP, PEX, HP), 2327 (ABYLCAP, PEX, HP), 2328 (ABYLCAP, PEX, HP)** Check that: 1) The circuit lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Treatments	CPFA, RRT, PEX, HP
Code: 2330	**Description:** 5 seconds have elapsed since the end of the positive pressure tests and the venous clamp has not opened to allow decreasing the pressure in the circuit as required in this phase.
Code: 2331	**Description:** 20 seconds have elapsed since venous clamp opening and the pressure in the circuit has not gone down to below 20 mmHg as required in this phase.
Operator action	**Code 2330:** Press CONFIRM to allow the system to repeat the venous clamp opening procedure or, if necessary, contact Technical Service. **Code 2331:** 1) Check that there are no obstructions in the circuit lines. 2) Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Treatments	CPFA, RRT
Code: 2332	**Description:** The pressure in the venous cassette has not gone down to below -150 mmHg in less than 2 minutes from the start of the test.
Code: 2333	**Description:** the pressure at the UF pump inlet has not gone down to below -100 mmHg, therefore, the transducer that reads the pressure at the UF pump inlet has not passed the test.
Operator action	**Code 2332:** 1) Check that the circuit lines are intact and that there are no obstructions. 2) Press CONFIRM. **Code 2333:** 1) Check that the circuit lines are intact. 2) Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Treatments	ABYLCAP
Code: 2334	**Description:** The pressure in the UF cassette is lower than -100 mmHg.
Code: 2335	**Description:** The pressure in the UF cassette has not increased by at least 100 mmHg in 20 seconds.
Operator action	**Code 2334:** Check that the bag of water for injectable preparations has been hung on the hooks on the left-hand side of the machine and is properly connected and that the clamp on the relative line has been opened. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service. **Code 2335:** Check that: 1) The bag of water for injectable preparations has been hung on the hooks on the left-hand side of the machine and is properly connected and that the clamp on the relative line has been opened. 2) The circuit lines are intact. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2340	**Description:** The pressure in the venous cassette is higher than 400 mmHg and the venous clamp has not opened as required.
Code: 2341	**Description:** The pressure at the blood pump inlet in static conditions (pumps off) is lower than -100 mmHg, therefore, the transducer that reads the blood pump inlet pressure could not be tested.
Operator action	**Code 2340:** Press CONFIRM to allow the system to repeat the venous clamp opening procedure or, if necessary, contact Technical Service. **Code 2341:** 1) Check that there are no obstructions in the circuit lines. 2) Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Code: 2342	**Description:** The pressure variation between before and after blood pump activation is lower than 100 mmHg, therefore, the transducer that reads the blood pump inlet pressure has not passed the test.
Operator action	**CPFA, RRT:** Check that: 1) The access and infusion lines are intact. 2) There are no open free branches on the infusion line. 2) Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service. **ABYLCAP, PEX, HP:** Check that: 1) The access and infusion lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. 2) Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 3)**	
Treatment	ABYLCAP
Code: 2343	**Description:** Blood inlet negative pressure test.
Operator action	Disconnect the bypass line from the oxygenator inlet (blue) and outlet (red) lines leading from the set. Connect the oxygenator inlet (blue) and outlet (red) lines to the relative ports on the oxygenator.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 1, 2, 3, 4)**	
Code: 2400	**Description:** An amount of liquid more than required in this phase has been consumed.
Operator action	Check the integrity of the lines. Press CONFIRM to restart priming from the beginning. At priming restart, replace the set and repeat priming if necessary.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 4)**	
Treatments	CPFA, RRT, PEX
Code: 2401	**Description:** the weight variations on the infusion and UF scale, respectively, differ by more than 50g.
Operator action	**CPFA, RRT:** Check that: 1) The circuit lines are intact. 2) There are no open free branches on the infusion and UF lines. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service. **PEX:** Check that: 1) The circuit lines are intact. 2) The infusion and UF lines are properly connected to the relative bags. Press CONFIRM to allow the system to repeat the test or, if necessary, contact Technical Service.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **DOUBLE ELECTROCLAMP OCCLUSION TEST FAILED**	
Treatments	CPFA
Code: 2402	**Description:** Lines not correctly inserted in the double clamp.
Treatments	CPFA
Operator action	Press CONFIRM and insert the lines in the double clamp.
Effects	Yellow warning light, acoustic warning.
Intervention time	15 seconds
Priority	LOW
Active	During priming.

Name: **LINE REPOSITIONING**	
Treatments	CPFA
Code: 2403	**Description:**
Operator action	Check that the lines are properly inserted in the double clamp. Press CONFIRM to continue.
Effects	Yellow warning light, acoustic warning.
Intervention time	10 seconds
Priority	LOW
Active	During priming.

Name: **PRIMING ALARM (PHASE 5)**	
Treatments	PEX
Code: 2500	**Description:** bag change.
Operator action	1) Replace the saline bags with the plasma bags on the infusion scale. 2) Close all the infusion lines not connected to the plasma bags. 3) Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **ADDITIONAL RINSE ALARM**	
Treatments	CPFA, RRT, ABYLCAP, HP
Code: 2501	**Description:** **CPFA, RRT:** The volume of replacement fluid on the infusion scale is less than 800 ml and insufficient. **ABYLCAP, HP:** The volume of saline on the infusion scale is less than 800 ml and insufficient.
Operator action	**CPFA, RRT:** 1) Load a number of bags on the infusion scale equal to a fluid volume of more than 800 ml. 2) Press CONFIRM. **ABYLCAP, HP:** 1) Load a fluid volume of more than 800 ml on the infusion scale. 2) Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **ADDITIONAL RINSE ALARM**	
Treatments	CPFA, RRT, ABYLCAP, HP
Code: 2502	**Description:** **CPFA, RRT:** New bags have been loaded on the infusion scale. **ABYLCAP, HP:** A new bag has been loaded on the infusion scale.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **EXTRACORPOREAL CIRCUIT UNLOADING ERROR**	
Code: 3001	**Description:** Error in peristaltic pump movement to zero.
Code: 3002	**Description:** Error in peristaltic pump positioning.
Code: 3003	**Description:** Cassette unloading timeout.
Code: 3004	**Description:** Cassette seat movement timeout/error.
Code: 3009	**Description:** Double electroclamp positioning error.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During single-use set unloading.

Name: **EXTRACORPOREAL CIRCUIT LOADING ERROR**	
Code: 3005	**Description:** Error in peristaltic pump movement to zero.
Code: 3006	**Description:** Error in peristaltic pump positioning.
Code: 3007	**Description:** Cassette pressurization error.
Code: 3008	**Description:** Cassette seat movement error. Check that the lines do not interfere with the plasma BLD.
Code: 3010	**Description:** Cassette pressure connection error.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During single-use set loading.

Name: **UPPER LEVEL COMMUNICATION ERROR**	
Code: 4000, 4000.1	**Description:** Communication error with the upper level control system.
Operator action	**Code 4000:** If you are in treatment, it is advisable to press CHAMBER LEVELS and deactivate automatic level control. **Code 4000.1:** Press CONFIRM to disable automatic upper level control.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **UPPER LEVEL BLOCKED**	
Treatments	CPFA, RRT, ABYLCAP
Code: 4001	**Description:** The level in the upper cassette has stopped moving despite intervention by the relative level pump.
Operator action	Press CONFIRM to allow the system to repeat the cleaning procedure of the upper level line.
Effects	Yellow warning light, acoustic warning.
Intervention time	60 seconds
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **UPPER LEVEL IRRECOVERABLE**	
Treatments	CPFA, RRT, ABYLCAP
Code: 4003	**Description:** The level in the upper cassette has stopped moving despite intervention by the relative level pump.
Operator action	Press CONFIRM to allow the system to repeat the cleaning procedure of the upper level line.
Effects	Yellow warning light, acoustic warning.
Intervention time	2 minutes
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **UPPER LEVEL BLOCKED**	
Treatments	CPFA, RRT, ABYLCAP
Code: 4004	**Description:** The level in the upper cassette has stopped moving during cleaning of the relative level line up to the corresponding sensor.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **UPPER CASSETTE LEVEL**	
Treatments	CPFA, RRT, ABYLCAP
Code: 4102, 4202	**Description:** The level in the upper cassette is too high.
Operator action	If necessary, manually adjust the level by pressing the relative arrows (to the right of the message). Press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **VENOUS LEVEL COMMUNICATION ERROR**	
Code: 5000, 5000.1	**Description:** Communication error with the lower level control system.
Operator action	**Code 5000:** If you are in treatment, it is advisable to press CHAMBER LEVELS and deactivate automatic level control. **Code 5000.1:** Press CONFIRM to disable automatic lower level control.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **VENOUS LEVEL BLOCKED**	
Code: 5001	**Description:** The level in the venous cassette has stopped moving despite intervention by the relative level pump.
Operator action	Press CONFIRM to allow the system to repeat the cleaning procedure of the venous level line.
Effects	Yellow warning light, acoustic warning.
Intervention time	60 seconds
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **VENOUS LEVEL IRRECOVERABLE**	
Code: 5003	**Description:** The level in the venous cassette has not gone down despite intervention by the relative level pump.
Operator action	Press CONFIRM to allow the system to repeat the cleaning procedure of the venous level line.
Effects	Yellow warning light, acoustic warning.
Intervention time	2 minutes
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **VENOUS LEVEL BLOCKED**	
Code: 5004	**Description:** The level in the venous cassette has stopped moving during cleaning of the relative level line up to the corresponding sensor.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming and after treatment start (pressing START).

Name: **VENOUS CASSETTE LEVEL**	
Code: 5101, 5201	**Description:** The level in the venous cassette is too low.
Operator action	**CPFA, RRT, ABYLCAP, PEX, HP:** If necessary, manually adjust the level by pressing the relative arrows (to the right of the message) and press CONFIRM. If the level in the cassette is correct, press CONFIRM; venous cassette level control will automatically be disabled. **END OF INTERMITTENT RRT TREATMENT:** If necessary, manually adjust the level by pressing the relative arrows (to the right of the message). Press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	5 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **VENOUS CASSETTE LEVEL**	
Code: 5102	**Description:** The level in the venous cassette is too high.
Operator action	If necessary, manually adjust the level by pressing the relative arrows (to the right of the message) and press CONFIRM.
Effects	Red warning light, acoustic warning, venous clamp closure, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START).

Name: **SYRINGE VOLUME RUN OUT**	
Code: 6000	**Description:** The volume of fluid in syringe 1 has run out.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **SYRINGE PUMP ERROR IN PRIMING**	
Code: 6001	**Description:** Syringe pump 1 error.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	During priming.

Name: **SYRINGE PUMP 1 ERROR**	
Code: 6002, 6003, 6007	**Description:** Syringe pump 1 movement error during calibration.
Operator action	Press CONFIRM and repeat calibration.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Before priming.

Name: **SYRINGE PUMP 1 ERROR**	
Code: 6004, 6005, 6006	**Description:** Syringe pump 1 movement error.
Operator action	**Code 6004:** Press CONFIRM and repeat the slow movement command. **Code 6005:** Press CONFIRM and repeat the fast movement command. **Code 6006:** Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **SYRINGE PUMP 1 ERROR**	
Code: 6008 - 6038	**Description:** Syringe 1 setting error.
Operator action	Press CONFIRM and repeat setting.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **SYRINGE PUMP 2 ERROR**	
Code: 7002, 7003, 7006, 7007	**Description:** Syringe pump 2 movement error.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Treatment

Name: **SYRINGE PUMP 2 ERROR**	
Code: 7004, 7005	**Description:** Syringe pump 2 movement error.
Operator action	**Code 7004:** Press CONFIRM and repeat the slow movement command. **Code 7005:** Press CONFIRM and repeat the fast movement command.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Treatment

Name: **SYRINGE PUMP 2 ERROR**	
Code: 7008 - 7038	**Description:** Syringe 2 setting error.
Operator action	Press CONFIRM and repeat setting.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Treatment

Name: **BATTERY**	
Code: 8000	**Description:** No power supply. The battery is almost flat.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **BATTERY FLAT**	
Code: 8001	**Description:** The machine has been turned off with the battery flat. Wait for the battery to recharge before starting the treatment.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Immediately after power on.

Name: **BATTERY NOT FULLY CHARGED**	
Code: 8002	**Description:** The battery is not fully charged. It is inadvisable to start the treatment.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Between priming end and treatment start (pressing START).

Name: **BATTERY**	
Code: 8003	**Description:** NI-MH battery not detected. It is advisable NOT to start the treatment or if it has already been started to interrupt it, because when the power is restored after a power failure, malfunctioning may occur which the machine is unable to manage and safety is therefore not guaranteed.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **MINIMUM ACCESS PRESSURE**	
Treatments	ABYLCAP
Code: 9301	**Description:** The access pressure is lower than the defined minimum limit.
Operator action	1) Check that there are no obstructions between the vascular access and the pump and press CONFIRM. 2) If necessary, reduce the minimum alarm limit and confirm. 3) If necessary, reduce the blood flow.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, syringe pump stop, heater on, infusion pump on.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM ACCESS PRESSURE**	
Treatments	ABYLCAP
Code: 9302	**Description:** The access pressure is higher than the defined maximum limit.
Operator action	1) Check that the lines are not disconnected and press CONFIRM. 2) If necessary, increase the maximum alarm limit and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, syringe pump stop, heater on, infusion pump on.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MINIMUM RETURN PRESSURE**	
Treatments	ABYLCAP
Code: 9303	**Description:** The return pressure is lower than the defined minimum limit.
Operator action	1) Check that the lines are not disconnected and press CONFIRM. 2) If necessary, reduce the minimum alarm limit and confirm.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, syringe pump stop, heater on, infusion pump on.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM RETURN PRESSURE**	
Treatments	ABYLCAP
Code: 9304	**Description:** The return pressure is higher than the defined maximum limit.
Operator action	1) Check that the lines are not obstructed and press CONFIRM. 2) If necessary, increase the maximum alarm limit and confirm. 3) If necessary, reduce the blood flow.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, syringe pump stop, heater on, infusion pump on.
Intervention time	8 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MAXIMUM INFUSION POST-PUMP PRESSURE**	
Treatments	ABYLCAP
Code: 9311	**Description:** The pressure at the infusion pump outlet is higher than 800 mmHg.
Operator action	1) Check that there are no obstructions on the line between the pump and the heater bag. 2) Press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **PRESSURE READING ERROR**	
Treatments	ABYLCAP
Code: 9316	**Description:** Pressure reading error at the blood pump outlet. Likely leakage of the transducer at the blood pump outlet.
Operator action	Press CONFIRM. If the error persists, 1) Stop the treatment by pressing END TREATMENT and return the blood to the patient. 2) Turn off the machine and, if necessary, start a new treatment with a new set.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, syringe pump stop, heater on, infusion pump on.
Intervention time	12 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **MINIMUM INFUSION PRE-PUMP PRESSURE**	
Treatments	ABYLCAP
Code: 9318	**Description:** The pressure at the infusion pump inlet is lower than -150mmHg.
Operator action	Check that there are no obstructions on the line between the heat exchanger outlet and the infusion pump inlet and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **BLOOD IN HEATER LINE**	
Treatments	ABYLCAP
Code: 9321	**Description:** blood in heater line.
Operator action	Check that there is no blood in the water line for heat exchange. If blood is present, 1) Press CONFIRM: the alarm will be disabled for 1 minute from pressing CONFIRM. 2) If necessary, stop the treatment and manually return the blood to the patient. If blood is not present, press CONFIRM and resume treatment.
Effects	Red warning light, acoustic warning, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	1 minute
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF BLD TEST**	
Treatments	ABYLCAP
Code: 9322	**Description:** UF BLD test failed
Operator action	The test will be repeated 1 minute after pressing the CONFIRM button.
Effects	Red warning light, acoustic warning, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Alarm deactivation time from pressing CONFIRM in the relative window	30 seconds
Priority	HIGH
Active	During priming and after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **UF BLD CUVETTE**	
Treatments	ABYLCAP
Code: 9323	**Description:** UF BLD cuvette.
Operator action	Insert the rigid tube of the water line for heat exchange into the UF BLD and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	11 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE 1 END-OF-STROKE**	
Treatments	ABYLCAP
Code: 9350	**Description:** Syringe pump 1 has reached the end of stroke.
Operator action	Replace the syringe.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE PUMP 1**	
Treatments	ABYLCAP
Code: 9351	**Description:** Syringe pump 1 is off.
Operator action	1) Check that the syringe is properly connected, press CONFIRM and reactivate it. 2) Replace the syringe if necessary.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop (in CPFA, the plasma pump continues running), syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYRINGE PUMP 1**	
Treatments	ABYLCAP
Code: 9352	**Description:** Syringe pump 1 is not infusing correctly.
Operator action	Press CONFIRM to disable the pump.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, syringe pump stop, heater on, infusion pump on.
Intervention time	25 minutes
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **TEMPERATURE**	
Treatments	ABYLCAP
Code: 9360	**Description:** The incoming fluid temperature exceeds 40°C.
Code: 9361	**Description:** The outgoing fluid temperature exceeds 41°C.
Code: 9366	**Description:** The heating plate temperature is too high.
Operator action	Wait until the temperature goes down.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	**Code 9360:** 4 seconds **Code 9361:** 3 seconds **Code 9366:** 1 second
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **TEMPERATURE**	
Treatments	CPFA, RRT, PEX
Code: 9360.1, 9361.1, 9366.1	**Description:** The temperatures of the heating plate and the incoming and outgoing fluid are correct.
Operator action	Press CONFIRM to restart the pumps.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	1 second
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER**	
Treatments	ABYLCAP
Code: 9362	**Description:** The heater door is open.
Operator action	Close the door and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always, except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER**	
Treatments	ABYLCAP
Code: 9363	**Description:** A fluid leak has been detected in the heater.
Operator action	Press CONFIRM to restart the pumps.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always, except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER BAG**	
Treatments	ABYLCAP
Code: 9364	**Description:** There is no bag in the heater.
Operator action	Insert a bag and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always, except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **HEATER TEST**	
Treatments	ABYLCAP
Code: 9365	**Description:** The test of the heating plate transducers has failed.
Operator action	Press CONFIRM to restart the pumps.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	4 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION PUMP**	
Treatments	ABYLCAP
Code: 9370	**Description:** The infusion pump speed is different from that expected.
Operator action	1) Check the integrity of the lines and that they are not obstructed. 2) Press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	30 seconds
Priority	HIGH
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **INFUSION PUMP**	
Treatments	ABYLCAP
Code: 9570	**Description:** The infusion pump is malfunctioning.
Operator action	Check that the lines are properly connected and press CONFIRM.
Effects	Red warning light, acoustic warning, blood pump at reduced speed, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms (after 3 consecutive errors)
Priority	LOW
Active	Always after treatment start (pressing START), except during temporary disconnection, bag change, blood pump stop, treatment end.

Name: **SYSTEM ALARM**	
Code: 10000	**Description:** No communication between the PC and the control microprocessor
Code: 10001	**Description:** No communication between the PC and the protection microprocessor
Code: 10002	**Description:** Machine status inconsistent. Likely forcing by dip-switch.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	White warning light, violet alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH

Name: **SYSTEM ERROR**	
Code: 10003	**Description:** Incorrect uC SW version.
Code: 10004	**Description:** Incorrect uP SW version.
Code: 10005	**Description:** Inconsistent hardware version.
Operator action	Contact Technical Service.
Effects	White warning light, violet alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	At power on.

Name: **TREATMENT INCONSISTENCY**	
Code: 10006	**Description:** The data of the treatment in execution are inconsistent with those stored. The treatment cannot be continued. Manually return the blood to the patient and remove the set. Contact Technical Service to restore the machine.
Operator action	Continue with manual blood return to the patient and remove the single-use set. Contact Technical Service.
Effects	White warning light, violet alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	10 seconds
Priority	HIGH
Active	Always

Name: **SYSTEM ERROR**	
Code: 50000 - 50015	**Description:** System error caused by an untested precondition.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	White warning light, violet alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always

Name: **SYSTEM ERROR**	
Code: 50016	**Description:** Status not recognised in air bubble.
Operator action	Turn off the machine. If possible, turn on the machine and resume treatment. Otherwise, remove the return line from the venous clamp and manually return the blood to the patient, turn on the machine and remove the single-use set.
Effects	White warning light, violet alarm window, acoustic warning, venous clamp closure, blood pump stop, exchange pump stop, syringe pump stop, heater off.
Intervention time	100 ms
Priority	HIGH
Active	Always

Name: **LOW LEVEL**	
Code: 60000 - 60014	**Description:** Low level warning.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **CLOCK**	
Code: 60015	**Description:** The PC clock is inconsistent (it has gone back in time).
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **SCALE TIMEOUT**	
Code: 60016	**Description:** Timeout in waiting for end-of-scale-synchronization signal.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **WARNING**	
Code: 60017 - 60021	**Description:** Treatment started with an error.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

Name: **WARNING**	
Code: 60022	**Description:** Syringe pump 1 is out of control failing commands from the operator.
Operator action	Press CONFIRM.
Effects	Yellow warning light, acoustic warning.
Intervention time	100 ms
Priority	LOW
Active	Always

10.12 ALARM CONDITION RECORDING

The machine has a data recording system for the following information:

- Alarm conditions that occur during the treatment.
- Modification of the parameters and alarm thresholds by the operator.
- Operator actions during the treatment.

The list of this information can be consulted at any time during the treatment by pressing the DATA button on the main page and then the HISTORY button.
In particular, the alarm-related information stored is listed below.

- Date and time
- Alarm identification code
- Description of the alarm condition
- Any alarm silencing
- Any modification of the alarm threshold by the operator.

In the event of a power failure during a treatment, these records are kept in memory and are available to the operator when resuming the treatment.
At the end of the treatment, this information is stored and can be consulted later by accessing the PREVIOUS TREATMENTS section.
The storage capacity is limited to 300 hours of treatment. When this limit is exceeded, the oldest previous treatments stored in memory are deleted.

11 TECHNICAL SPECIFICATIONS

11.1 PRODUCT CODE

The product code is made up of 9 alphanumerical characters.

In the example:

I	B	A	X	X	X	7	0	0

- The first two characters are the same for all the machines and identify the Bellco product (IB)
- The third character (alphabetical) identifies the machine (A corresponds to *Amplya*)
- The fourth and fifth characters (alphanumerical) identify the model
- The sixth character (alphanumerical) specifies the version
- The seventh character identifies the power supply voltage (7 corresponds to *230 V*)
- The eighth and ninth characters (numerical) are numbers between 00 and 99 and identify the options installable on the machine (00 corresponds to *no options*).

11.2 SERIAL NUMBER (S/N)

The serial number is made up of 8 alphanumerical characters:

In the example:

A	X	0	0	0	1	1	2

- The first and second characters (alphanumerical) identify the machine (A corresponds to *Amplya*).
- The third, fourth, fifth and sixth characters (numerical) identify machine registration in sequence irrespective of the model (*0001* and *9999* respectively indicate the first and last machine manufactured during the year).
- The seventh and eighth characters (numerical) identify the year of machine manufacture (*12* indicates 2012).

11.3 DIMENSIONS AND WEIGHT

Height, depth, width

- with monitor not extended: 147x60x70 cm
- with monitor fully extended: 176x60x70 cm

Weight: 87 kg

11.4 MAXIMUM APPLICABLE WEIGHT

Central scale	12 kg
Infusion/replacement scale (right-hand)	23 kg
UF/ultrafiltration/waste scale (left-hand)	27 kg
Side pins (two)	3 kg on each pin
Object tray:	500 g

11.5 AMBIENT AND STORAGE CONDITIONS

Operation

Temperature	+20 to +30°C
Relative humidity	30-75% without condensate
Pressure	700-1060 hPa

Storage and transport

Temperature	-19 to +70°C
Relative humidity	10-95% without condensate
Pressure	700-1060 hPa

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

11.6 MOVING THE MACHINE

To move AMPLYA, operate as follows:
1. Lift the monitor.
2. Remove any weights on the upper tray and any connected bags.
3. Disengage the brakes if engaged.
4. Stand behind AMPLYA and push/pull the machine.

To move the machine, disengage the four wheel brakes and use the rear handles to move it forward and sideways and the side handle to move it sideways. Once positioned, engage the four wheel brakes.

11.7 ELECTRICAL DATA

Nominal power supply voltage	220V~ ± 10% 230V~ ± 10% 240V~ ± 10%
Nominal power supply frequency	50/60 Hz (220, 230, 240V~)
Maximum absorption	2.5 A (220, 230, 240V~)
Average power absorbed during treatment	400 W
Power failure	An alarm (acoustic and visual) intervenes informing the operator that the machine is battery powered and the system allows continuing the treatment for a time that depends on the battery charge (20 minutes if at least 6 hours have elapsed from the last power failure) after which the machine turns off. When turning the machine back on, the system allows resumption of treatment, showing the parameter values (flows, minimum and maximum pressures permitted, etc.) set by the operator before the shutdown.
Battery operation	Two 12V 3.4Ah lead batteries One 7.2V 1.3A NiMH battery
Electromagnetic compatibility	In compliance with EN 60601-1-2

11.8 MACHINE CLASSIFICATION IN ACCORDANCE WITH EN 60601-1

Type of protection against electrical hazards:	Class I device
Degree of protection against direct and indirect contacts	Applied part type CF (extracorporeal circuit)
Degree of safety of use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	The device is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.
Conditions of use	The device is intended for continuous operation
Degree of protection against penetration of solids and liquids	IPX1

11.9 MACHINE CLASSIFICATION IN ACCORDANCE WITH DIRECTIVE 93/42/EEC AND SUBSEQUENT AMENDMENTS REGARDING MEDICAL DEVICES

Classification rule: All devices intended to administer and/or remove medicines, body liquids or other substances to or from the body in a potentially hazardous manner, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application are in Class IIb.
Classification rationale: AMPLYA is a medical device intended to administer and/or remove medicines and body liquids to or from the body for blood clearance in acute patients. AMPLYA does this in a manner that is potentially hazardous and is hence in Class IIb.

11.10 BLOOD FLOW

CPFA, PEX and in RRT treatments with small filter (0.3 and 0.5 m^2)	30 - 250 ml/min
In RRT treatments with medium and large filter (0.8; 1.4; 1.7; 2.2 m^2) and HP	30 - 450 ml/min
ABYLCAP	30 - 550 ml/min
Accuracy (measured 30 minutes from treatment start)	±15% for input pressures higher than -150 mmHg and any output pressures in the operating range; ±30% for input pressures between -300 mmHg and -150 mmHg and any output pressures in the operating range.
Long-term accuracy	Refer to the parameter "Actual blood flow displayed".

In all cases where the blood pump is stopped (pressing the STOP BLOOD PUMP button, alarms that stop the blood pump), the system draws the operator's attention with an acoustic warning and a message on the risk of the blood coagulating in the circuit if the pump is stopped for an extended period of time.

Actual blood flow displayed

$Actual\ Qb = Qb \cdot [0.75 + (0.0008 \cdot PAsp) - (0.00009 \cdot t)]/0.71$	t < 700 minutes
$Actual\ Qb = Qb \cdot [0.68 + (0.0008 \cdot PAsp) - (0.00002 \cdot t) + 0.0168]/0.71$	t ≥ 700 minutes
Resolution Actual blood flow accuracy displayed (blood flow displayed with respect to that actually drawn from the patient):	1 ml/min ±20%

where:
Actual Qb is the actual blood flow (in ml/minute), *t* is the time elapsed from pressing the START button on the START TREATMENT page (see the introduction to Chapter 5) up to the current instant (in minutes), *Qb* is the blood flow set by the user (in ml/minute), *Pasp* is the access pressure (in mmHg).

11.11 UF FLOW, WEIGHT LOSS AND INFUSION

CPFA and RRT
The system requires setting the UF flow and/or the weight loss (weight loss/gain) and automatically calculates the infusion flow value. The value to be reached is represented by the hourly weight loss, which is the difference between the amount infused (hourly infusion flow) and the amount filtered (hourly ultrafiltration flow). The method the system uses to reach the weight loss set consists of servo-controlling the infusion flow and the ultrafiltration flow, respectively by means of a scale (right-hand) that weighs the infusion bags and a scale (left-hand) that weighs the collection bags (for the scale measurement range see the first row of the table in par. 11.14).
If the treatment requires pre-dilution, the pre-dilution flow servo-controlled by the pre-dilution scale (central) is added to the infusion flow servo-controlled by the infusion scale (right-hand).

Flows and relative accuracies
In all the treatments
Weight loss/gain
Range: 0 : 2 l/h
Resolution: 1 ml/h
Accuracy: 150 g in 24 hours (with maximum thermal drift of ±3°C in 24 hours).

UF pump flow (infusion pump flow ± weight loss/gain)
Range: 0 : 16 l/h
Accuracy: ±25 ml/h

Pre-dilution flow
Range: 0 : 4 l/h
Accuracy: ±15 ml/h

In CPFA
UF flow (infusion flow ± weight loss/gain)
Range: 0 : 4.5 l/h
Accuracy: ±25 ml/h

In CVVHDF, CVVH, CVVHD
Infusion flow (UF flow ± weight loss/gain)
Range: 0; 0.5 : 12 l/h (in HD it corresponds to the dialysate flow)
Accuracy: ±25 ml/h

In CVVHDF
Dialysate flow
Range: 0; 0.5 : 12 l/h
Accuracy: ± (10% of the post-infusion flow + 25 ml/h).

Post-infusion flow (infusion flow – dialysate flow)
Accuracy: ±10% of the expected value

In CVVH
Pre-infusion flow
Range: 0; 30-100% of the infusion flow
Accuracy: ± (10% of the post-infusion flow + 25 ml/h).

Post-infusion flow (infusion flow – pre-infusion flow)
Accuracy: ±10% of the expected value

WARNING
In case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate,AMPLYA does not control the amount of citrate or calcium infused nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

ABYLCAP and HP
The system does not require setting infusion and ultrafiltration flows and weight loss.

PEX
The system requires setting the flow of the plasma to be infused as percentage of the blood flow. The value to be reached is represented by the set volume of plasma to be treated. The method the system uses to reach the volume set consists of servo-controlling the infusion flow of the replacement fluid and the ultrafiltration flow of the patient's plasma by measuring, respectively, the weight variation on the infusion scale (right-hand) and on the UF scale (left-hand) - for the scale measurement range, see the first row in the table in par. 11.14 - so that the volume of plasma removed corresponds to the volume of fluid infused so as not to have a patient weight variation.

Flows and relative accuracies
Plasma flow
Range: 0; 5-20 % of the blood flow
Accuracy: ±25 ml/h

11.12 PRESSURES MEASURED DURING TREATMENT

The pressure measurement range varies from transducer to transducer and between the various treatments.

Blood return pressure	Type: Operating range: Resolution: Accuracy: Alarm (min/max):	Pressure transducer (part of the protection system) -100 to +600 mmHg 1 mmHg ±10 ± 3% mmHg of the current value In ABYLCAP +10/+300 mmHg; in the other treatments +10 (or -30 based on the machine configuration) / +300 mmHg
Blood access pressure	Type: Operating range: Resolution: Accuracy: Alarm (min/max):	Pressure transducer (part of the protection system) -400 to 100 mmHg 1 mmHg ±10 ± 3% mmHg of the current value In ABYLCAP -250/-10 mmHg; in HF with pre-infusion flow = 0 and in HDF with dialysate flow = 0 -200/-10 mmHg (or +30 based on the machine configuration); in the other treatments -300/-10 mmHg (or +30 based on the machine configuration).
Hemofilter inlet pressure or blood post-pump pressure (RRT)	Type: Operating range: Resolution: Accuracy: Alarm (min/max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +30/+600 mmHg
Plasma filter inlet pressure or blood post-pump pressure (CPFA, PEX)	Type: Operating range: Resolution: Accuracy: Alarm (min/max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +30/+600 mmHg
Oxygenator inlet pressure (ABYLCAP)	Type: Operating range: Resolution: Accuracy: Alarm (min/max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +30/+300 mmHg
Ultrafiltrate pressure	Type: Operating range: Resolution: Accuracy: Alarm (max):	Pressure transducer (part of the protection system) 0 to +200 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +150 mmHg
UF pre-pump pressure	Type: Operating range: Resolution: Accuracy:	Pressure transducer (part of the protection system) -400 to +100 mmHg 1 mmHg ±10 ± 3% mmHg of the current value

Mediasorb cartridge inlet pressure (CPFA)	Type: Operating range: Resolution: Accuracy: Alarm (max):	Pressure transducer (part of the protection system) 0 to +600 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +500 mmHg
Mediasorb cartridge outlet pressure or pressure in the upper cassette or plasma filter outlet pressure or hemofilter inlet pressure (CPFA)	Type: Operating range: Resolution: Accuracy: Alarm (max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +600 mmHg
Pressure in the upper cassette or post-infusion pre-pump pressure (RRT)	Type: Operating range: Resolution: Accuracy: Alarm (max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +600 mmHg
Pressure in the upper cassette (ABYLCAP)	Type: Operating range: Resolution: Accuracy: Alarm (max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +400 mmHg
Plasma pre-pump pressure (CPFA)	Type: Operating range: Resolution: Accuracy:	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value
Replacement fluid access pressure or infusion pre-pump pressure	Type: Operating range: Resolution: Accuracy: Alarm (min):	Pressure transducer (part of the protection system) -200 to 0 mmHg 1 mmHg ±10 ± 3% mmHg of the current value -150 mmHg

Heater bag inlet pressure or infusion post-pump pressure	Type: Treatment range: Resolution: Accuracy: Alarm (max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value 800 mmHg
Blood post-pump pressure or adsorbent column inlet pressure (HP)	Type: Operating range: Resolution: Accuracy: Alarm (min/max):	Pressure transducer (part of the protection system) 0 to +800 mmHg 1 mmHg ±10 ± 3% mmHg of the current value +30 to +400 mmHg

NOTE: The *maximum access pressure* and *minimum return pressure* alarm limits can be configured on a page accessible only to technical staff.

11.13 PRESSURES CALCULATED DURING TREATMENT

Trans-hemofilter pressure (CPFA, RRT)	Range: Resolution: Alarm (max):	0 to +700 mmHg 1 mmHg 650 mmHg
Trans-plasma filter pressure (CPFA, PEX)	Range: Resolution: Alarm (max):	0 to +300 mmHg 1 mmHg 250 mmHg
Hemofilter TMP (CPFA, RRT)	Range: Resolution: Alarm (max):	0 to +500 mmHg 1 mmHg 400 mmHg
Plasma filter TMP (CPFA, PEX)	Range: Resolution: Alarm (max):	0 - 200 mmHg 1 mmHg 80 mmHg
Trans-cartridge pressure (CPFA)	Range: Resolution: Alarm (max):	0 to +700 mmHg 1 mmHg 600 mmHg
Trans-oxygenator pressure (ABYLCAP)	Range: Resolution: Alarm (max):	0 - 200 mmHg 1 mmHg 200 mmHg
Trans-cartridge pressure (HP)	Range: Resolution: Alarm (max):	0 - 400 mmHg 1 mmHg 400 mmHg

Trans-filter pressure = filter inlet pressure – filter outlet pressure
Trans-oxygenator pressure = oxygenator inlet pressure – oxygenator outlet pressure (blood side)
Trans-cartridge pressure = inlet pressure - cartridge/adsorbent column outlet pressure
Transmembrane pressure (TMP) = (filter outlet pressure + filter inlet pressure) / 2 – filtrate pressure.
The accuracy depends on the accuracy of the transducers that measure the pressures in the various ports of each filter.

11.14 SENSORS

<table>
<tr><td rowspan="3">SCALES

Type: load cells

Measuring errors:
0.035% F.S. (linearity, hysteresis, repetitiveness)
0.050% F.S. (stability error)
0.014% F.S./°C (thermal drift)</td><td>Infusion/replacement scale (green)

Measuring range: 0 - 23 kg</td></tr>
<tr><td>UF/ultrafiltrate/waste scale (yellow)

Measuring range: 0 - 27 kg</td></tr>
<tr><td>Central scale (red)

Measuring range: 0 - 12 kg</td></tr>
<tr><td>AIR SENSOR</td><td>Type: ultrasound
Sensitivity: bubbles ≥ 40 µl
The sensitivity was obtained following “AIR BUBBLE INFUSION” tests.

WARNINGS:
1) The air detection sensor reading may be compromised by the presence of clots or the use of gel for ultrasound devices.
2) Air might enter the extracorporeal circuit at connection points downstream of the air detection sensor when negative pressures occur.</td></tr>
<tr><td>BLOOD LEAKAGE DETECTOR IN PLASMA (Plasma BLD)</td><td>Type: optical
Accuracy: 0.35 ml/min of blood (Hct 0.32) at a maximum plasma flow of 64 ml/min</td></tr>
</table>

BLOOD LEAKAGE DETECTOR IN PLASMA WATER (UF BLD)	Type: Accuracy:	optical 0.35 ml/min of blood (Hct 0.32) at a maximum plasma water flow of 16 l/h
HEMATOCRIT METER/ SATURATION METER	Operating principle	Optical absorbance
	Hematocrit meter	Reading: 25-50% Resolution: 0.1% Accuracy: 1.5% (25-33%) 2% (33-50%)
	Oxygen saturation	Reading: 40-100% Resolution: 0.1% Accuracy: 3%
	Interface with single-use device	The reader interfaces with the single-use cuvette inserted in the blood access line.
	Patient safety	The device is not an applied part. The hematocrit and oxygen saturation measurements do not affect machine performance.
PERISTALTIC PUMP ENCODER	Type: optical (part of the protection system) Range: 0 - 1.7 Hz Accuracy: 1%	

11.15 REPLACEMENT FLUID HEATER

Type	Plate
Setting	Qualitative with scroll bar (6 levels with increasing values)
Outgoing fluid temperature range displayed	from 30 to 40°C in relation to the infusion flow

The thermoregulation system is equipped with 4 temperature sensors (part of the protection system):

- 2 PT1000s measure the plate temperature and have:
  Resolution: 0.1°C
  Accuracy: ± 1.1°C
- 1 PT1000 in contact with the bag inlet line measures the temperature of the fluid coming into the heater and has:
  Resolution: 0.1°C
  Accuracy: ±2.5°C
- 1 PT1000 in contact with the bag outlet line measures the temperature of the fluid going out of the heater and has:
  Resolution: 0.1°C
  Accuracy: ± 1.1°C

The heating device also has the following sensors:

Hall magnetic sensor	Detects door closure when the distance between the door and body of the device is ≤ 5 mm
Optical sensor	Detects fluid leaks ≥ 10 ml
Microswitch	Detects the presence of the bag in contact with the heating element when the door is closed

11.16 SYRINGE PUMPS

Syringe capacity	30, 50 cc
Syringe shape	classic
Syringe connector	Luer-lock
Syringe seals	rubber
Syringe outside diameter (see image 3)	• 23-31.5 mm if the syringe pump model shown in Figure 1 is installed. • 23-30 mm if the syringe pump model shown in Figure 2 is installed.
Maximum syringe flange thickness (see image 4)	3 mm
Syringe stroke (see image 3)	17-107.5 mm
Continuous infusion flow	0.1-30 ml/h (increments of 0.1 ml/h)
Bolus (syringe pump 1 only)	0.1-20 ml at maximum speed (3585.7 mm/h)
Accuracy	±0.2 ml/h ±2% (if calibration is properly performed)
Maximum operating pressure	600 mmHg (syringe pump 1), 300 mmHg (syringe pump 2)

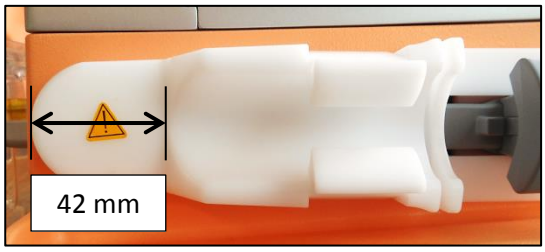


Image 1

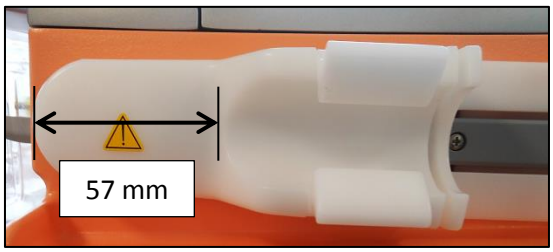


Image 2

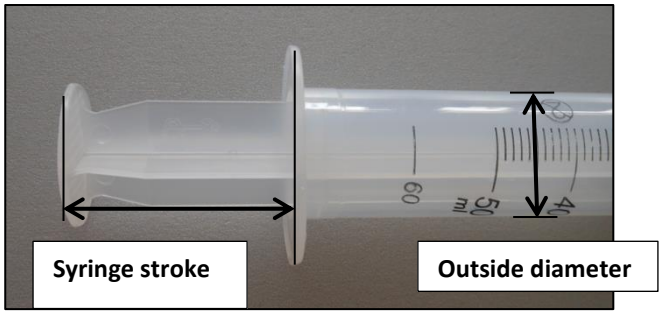


Image 3

Image 4

WARNING
Using syringes that don't conform to the specifications may cause leakage from the syringe and prevent proper anticoagulant infusion. In this case, the operator assumes responsibility for infusion.

WARNING
In case of administration of local-regional anticoagulant solutions, such as diluted citrate and calcium chloride or calcium gluconate,AMPLYA does not control the amount of citrate or calcium infused nor their ratio; clinical studies point out that external instruments (e.g. blood gas analyser) can be used to control the level of administration of these substances.

11.17 OPERATOR INTERFACE

Acoustic warning device	Buzzer. Sound level > 65 dB at 1 meter. Acoustic alarm silencing time: 2 minutes
Display	12.1" TFT colour touch screen
Keyboard	Touch screen

11.18 MATERIALS

BODY
BAYDUR 110
Aluminium UNI 5076 GA/Si_{11} $MgCu_2$ (Fe)
Fe 430 - UNI 7070
Al - anticorodal EN AW – 6060 T6
POM - NATURAL DELRIN
Silicone LSR – 40 ShA – RAL1018
Arnite
Stainless steel tube – AISI 304 D25x1
Al UNI 46100
Al - anticorodal 6082 UNI P006/4

MATERIALS IN CONTACT WITH BLOOD AND DIALYSIS FLUID
Soft PVC
Rigid PVC
ABS
PE
Copolyester
IR (latex-free rubber)
PP, Polycarbonate
Polyethersulfone
Polyurethane
Elastomer
EPDM
PET

11.19 IEC 60601-1-2:2007 REQUIREMENTS

IEC 60601-1-2:2007 REQUIREMENTS		
AMPLYA is intended for use in the electromagnetic environment specified below. The customer or the user of AMPLYA should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	AMPLYA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 2	AMPLYA must emit electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	AMPLYA is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	AMPLYA is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions EN 61000-3-3	Compliant	AMPLYA is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

IEC 60601-1-2:2007 REQUIREMENTS			
AMPLYA is intended for use in the electromagnetic environment specified below. The customer or the user of AMPLYA should ensure that it is used in such an environment.			
Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	6 kV contact 8 kV air	EN 60601-1-2 test level	Residential/Hospital
Electrical fast transient/burst EN 61000-4-4	2 kV for power supply lines 1 kV for input/output lines >3m	EN 60601-1-2 test level	Residential/Hospital
Surge EN 61000-4-5	1 kV differential mode 2 kV common mode	EN 60601-1-2 test level	Residential/Hospital
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% U_T for 0.5 cycle 40% U_T for 5 cycles 70% U_T for 25 cycles 0% U_T for 5 sec.	EN 60601-1-2 test level	Residential/Hospital
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	EN 60601-1-2 test level	Residential/Hospital

IEC 60601-1-2:2007 REQUIREMENTS			
AMPLYA is intended for use in the electromagnetic environment specified below. The customer or the user of AMPLYA should ensure that it is used in such an environment.			
Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.4 GHz		Residential/Hospital
Conducted RF EN 61000-4-6	3 V/m 150 MHz to 80 GHz		Residential/Hospital

Recommended separation distances for equipment and systems that are not life-supporting.

AMPLYA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of AMPLYA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and AMPLYA as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz - 80 MHz $\mathbf{d = 1.2\ \sqrt{P}}$	**80 kHz - 800 MHz** $\mathbf{d = 1.2\ \sqrt{P}}$	**80 kHz - 2.5 MHz** $\mathbf{d = 2.3\ \sqrt{P}}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

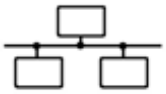
For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 MISCELLANEOUS

12.1 SYMBOLS ON THE MACHINE

The following symbols are found on the machine or on the identification plate:

	Applied part TYPE CF (ref. CEI EN 60601-1)
IPX1	Drip proof
	Date of manufacture
	Machine powered by alternating current
	Off (not powered)
	On (powered)
	WARNING. Consult the manual.
	Protection ground
	Equipotential socket
	Dangerous voltage
	Conformity with Directive 93/42/EEC relating to Medical Devices. Notified body: TÜV Product Service - Munich (Germany)
	Indicates the obligation of separate collection of electrical and electronic equipment. See the paragraph on disposal (par. 12.3).

	Indicates that the instructions for use need to be followed.
	Indicates the presence of an Ethernet port.
	Indicates a RISK of the machine overturning when pushing it, putting it down, leaning against it, etc.
	Machine weight
	Syringe pump 1
	Syringe pump 2

12.2 MANUFACTURER'S RESPONSIBILITY

The manufacturer is responsible for the safety, reliability and proper functioning of AMPLYA only if the electric system of the intensive care unit is in compliance with the regulations in force, the machine is used in accordance with the instructions in the user manual and any maintenance operation is carried out by authorised technical staff.
Proper functioning of AMPLYA is guaranteed only if the machine is used and maintained in accordance with the instructions provided by the manufacturer. The manufacturer declines all responsibility following incorrect or improper use of the machine, as well as in the event of errors on the part of the Haemodialysis Centre staff.
All the maintenance and repair operations and the periodic checks must be carried out exclusively by After-sales Technical Service staff or by staff appropriately trained and authorised by the manufacturer in accordance with the specifications in the technical manual.

Bellco undertakes to provide on request the wiring diagrams, lists of component parts, calibration instructions or other information the appropriately qualified staff of the user may need for repair of the parts of the device the manufacturer deems repairable.

Bellco is a certified company according to EN ISO 13485:2003.
AMPLYA has been designed and constructed in compliance with the 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 carries the CE marking in compliance with the European Directive 93/42/EEC of 14 June 1993 relating to medical devices.
Notifying Body: TÜV SÜD Product Service - Munich (Germany), number 0123.
The CE marking printed in this manual is valid only if the accompanying machine also carries the same marking.

Should you need any further information, please contact the manufacturer directly (or your nearest distributor).

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Tel : +39 0535 29271 (Italy)
Tel: +39 0535 29402 (international)
Fax: +39 0535 29400
e-mail: service@bellco.net

12.3 DISPOSAL

NOTE
The following is applicable only to member states of the European Union that have adhered to Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment (WEEE) and is applied in observance of the limits laid down in the European Directive and the implementation decrees of the individual member states.
The estimated lifetime of the device is 10 years.
In order to safeguard, protect and improve the quality of the environment and to protect human health, at the end of its useful lifetime the machine must be disposed of as special waste and be collected separately in observance of the national regulations in force.
Illegal disposal of WEEE (Waste Electrical and Electronic Equipment) is punishable by a fine.

The manufacturer is responsible for collection and disposal of the machine and undertakes to treat it according to the reuse, recycling and scrapping procedures and other forms of WEEE recovery as laid down by the law.

Only authorised Bellco technicians may remove, replace, transport and dispose of the batteries contained in the machine according to the Bellco internal procedure.
The machine is equipped with two 12V 3.4Ah lead batteries and one 7.2V 1300mA NiMH battery.
Please contact your local distributor who will act according to this agreement with the manufacturer.

The customer may request that the manufacturer collect and dispose of historical WEEE (placed on the market before 13 August 2005) if purchasing a new machine equivalent to the old one (according to the equivalence criteria indicated in Directive 2002/96/EC).

In compliance with Directive 2002/96/EC, the machine to be disposed of must be returned to the manufacturer appropriately disinfected and accompanied by a declaration stating that the machine is NOT infected. The disinfection must be performed and the declaration written by the hospital and signed by a person officially appointed by the hospital.
The manufacturer will not collect machines that have not been disinfected and are not accompanied by the duly signed declaration.

12.3.1 Packaging disposal

The materials of which the AMPLYA packaging is made up are:
- Wood with phytosanitary treatment (pallet)
- Cardboard KSTSK 96369 BC
- PESP50
- PESP48

12.3.2 Single-use device and fluid disposal

The medical devices and single-use accessories (single-use circuits and lines) are designed as single-use products. After each treatment they must be disposed of in accordance with the provisions of the medical centre for this type of potentially contaminated waste (soft and rigid PVC, ABS, PE, Copolyester, Latex-free rubber, PP, Polycarbonate, Polyethersulfone, Polyurethane, Elastomer, EPDM, PET).

The fluids used must be disposed of in compliance with the current regulations on polluting solutions.