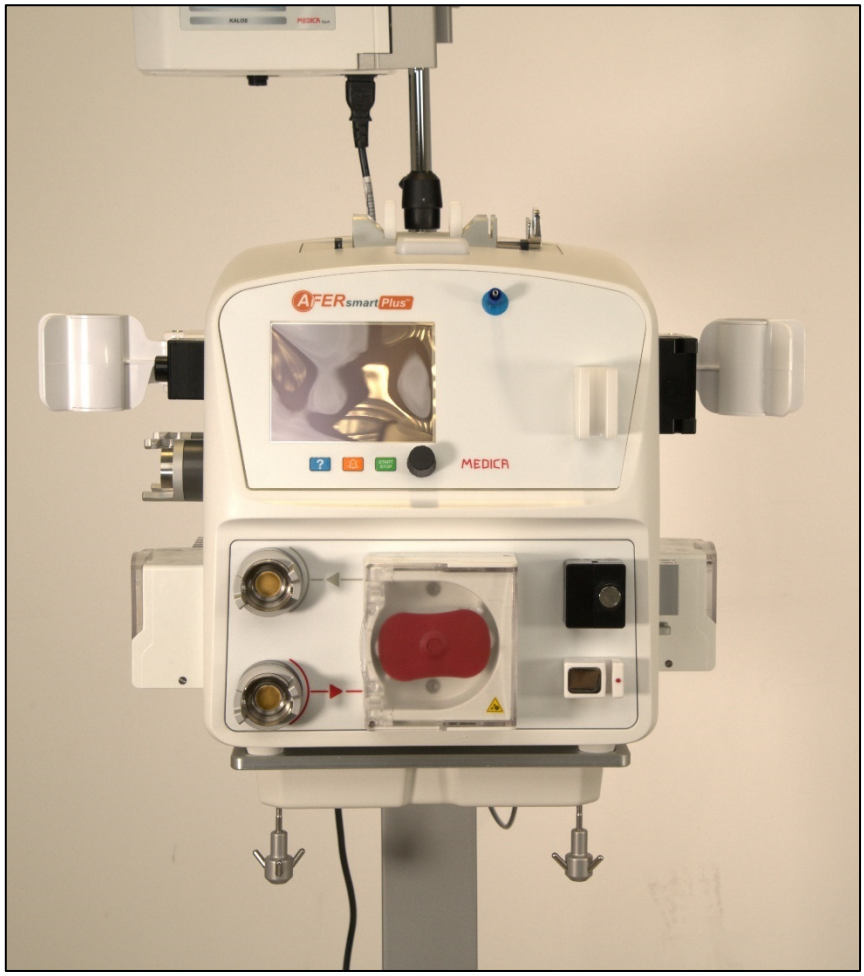
AFERsmart PLUS
USER MANUAL



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Manufactured by:

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Summary

1. INTRODUCTION

This manual is intended for qualified operators and all those who, for reasons of role, competence or appointment, find themselves conducting and managing treatments using AFERSMART PLUS.

AFERSMART PLUS must be used in a healthcare-clinical-hospital environment, by healthcare personnel. Home use of the devices is not permitted.
The choice of methods of use, as well as the areas of application, is the exclusive responsibility of doctors with experience in the treatment of the pathologies involved.
The device operation, as well as by the doctor, can be managed by nursing staff under the supervision of a responsible doctor.

This manual contains all the information necessary for the proper and correct installation and use of AFERSMART PLUS; avoid working with AFERSMART PLUS before you have carefully read and understood the meaning of these instructions, in order to act correctly and safely.

Avoid working according to procedures that are not foreseen and contemplated in this manual. If you have any doubts or need clarification, do not hesitate to contact the After-Sales Service at:

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Do not attempt to carry out repairs or work of any technical nature on the AFERSMART PLUS without the necessary competence or preparation and without specific authorisation from MEDICA or its authorised dealers.

MEDICA will not be held responsible in any way or under any circumstances in the event of any damage or accidents to the patient or user deriving from incorrect compliance with the instructions contained in this manual.

The lifetime of the device is 10 years (understood as the minimum period of availability of spare parts for the DMA); during this period Medica guarantees in/out warranty service.

Indications for place of use:

- AFERSMART PLUS is a medical device only intended to be used in hospitals.
- AFERSMART PLUS is not intended to be used in a residential environment. It does not provide adequate protection from electromagnetic interference in such an environment.
- The device MUST NOT be used in an ENVIRONMENT with HIGH LEVELS OF OXYGEN or in the presence of FLAMMABLE ANESTHETICS, FLAMMABLE OR EXPLOSIVE AGENTS OR GASES.
- The device complies with Electromagnetic Compatibility standards. However, it is a good precaution not to use the device in the immediate vicinity of high-powered equipment or equipment which, by its nature, emits strong electromagnetic fields. (SEE ELECTROMAGNETIC COMPATIBILITY WARNINGS CHAPTER).

NOTE

Any serious incident that has occurred in relation to the device should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

1.1. SIGNIFICANCE OF THE WARNING

Warning

Advises the operator that failure to observe this information can result in personal or patient injury.

1.2. SIGNIFICANCE OF THE NOTE

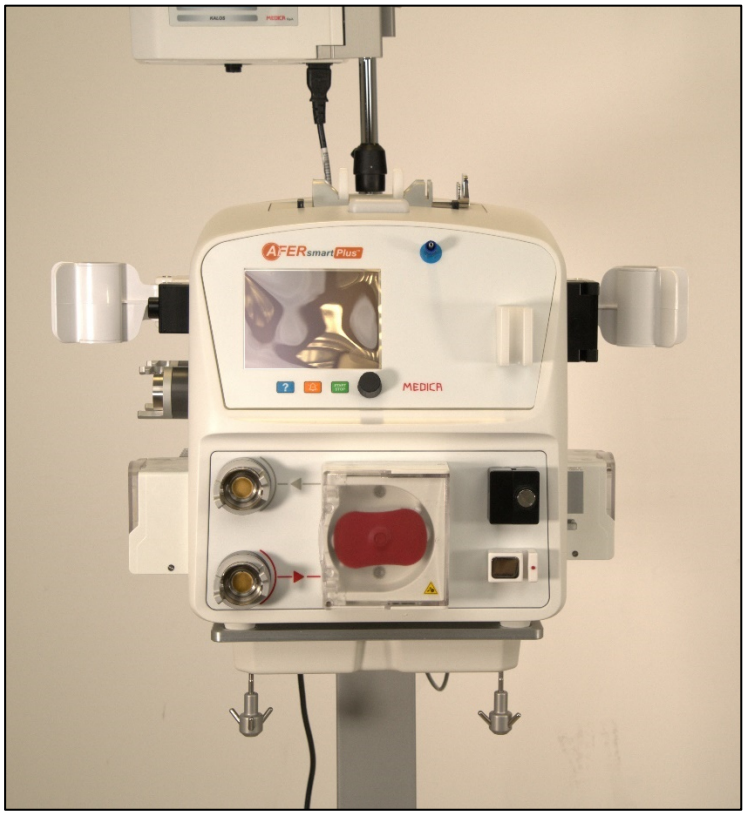
Note

Advises the operator that failure to observe this information can resultin the following:

- damage to the device
- required functions will not be executed at all or not executedcorrectly

Warnings and Notes are to be intended as “Residual Risks” to be communicated to the User

2. SYSTEM DESCRIPTION



The intended use of the active medical device (AMD) is to support and manage the treatments described below.

Treatment	**Display**
HEMOPERFUSION	HP
PLASMA EXCHANGE	PEX
DOUBLE FILTRATION RHEOPHERESIS	DF
DOUBLE FILTRATION RHEOPHERESIS ADSORBTION	DFA
RHEOPHERESIS SELECTIVE APHERESIS	SA

The devices are controlled in accordance with the control procedures defined within the Medica SpA certified Quality System. (ISO 9001 and ISO 13485).
The system has been developed in accordance with the following standards:

Device reference standards:	**IEC 60601-1** **IEC 60601-1-2** **IEC 60601-2-16**
Product classification according to Medical Device Regulation 2017/745:	**II b Rule 12**
Product classification (IEC 60601-1):	**Class I Type BF**
IP classification according to IEC 60529	**IP X1**

The AFERSMART PLUS active medical device (AMD) is NOT manufactured:

- With materials of direct or indirect human and/or animal origin;
- With blood (human or animal) or parts derived from it;
- With latex.

The AFERSMART PLUS active medical device is equipped with software capable of managing the execution of treatments, potential risk situations and related alarm statuses.

The device consists of a casing (monitor) made of painted self-extinguishing plastic material on which are located:

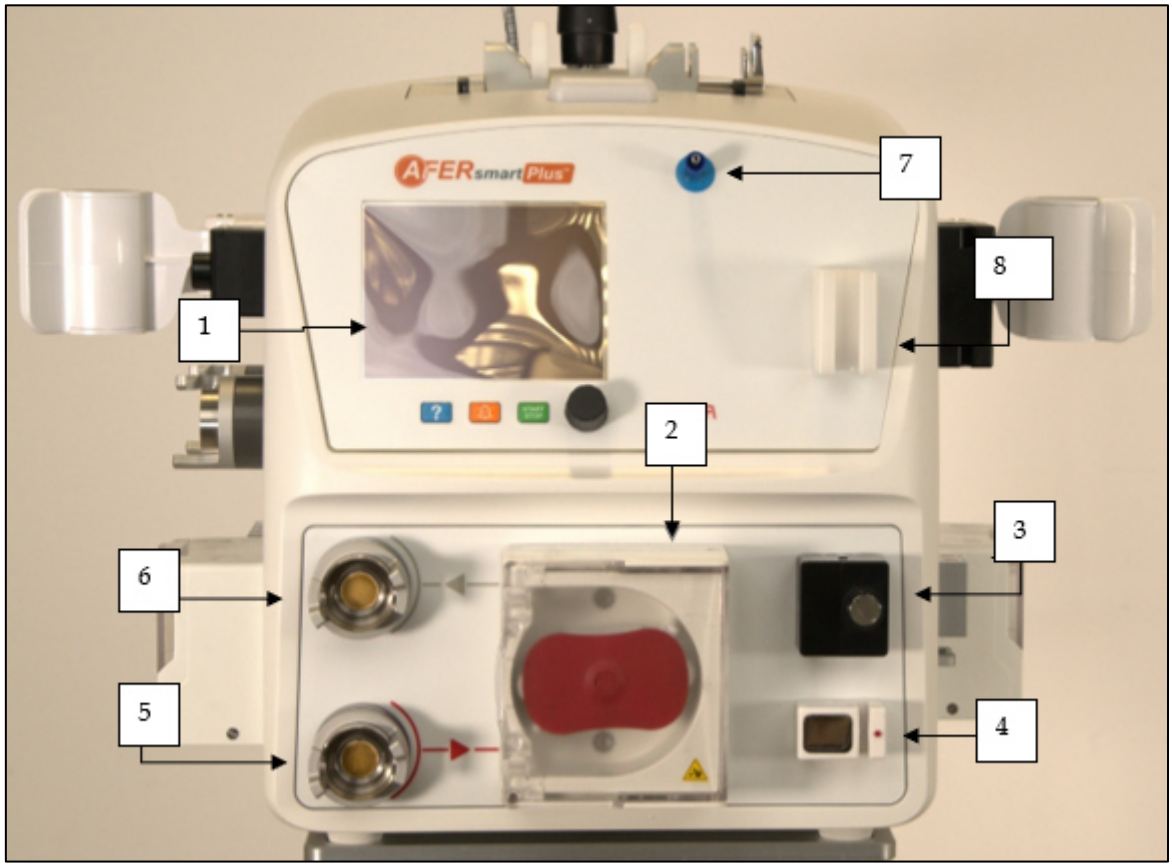
- An aluminium panel on which are fixed:
  - The blood pump (peristaltic type with 2 occluding rollers),
  - two Dome type transducers for arterial and pre-filter pressure detection,
  - an air detector for bubble detection and an optical detector for blood presence detection on the blood venous line to the patient,
  - an electric Venous clamp to stop the return of blood to the patient, in case of detection of air bubbles or any other critical alarms.
- An aluminium panel on which the heparin pump is fixed.
- A multi-coloured LED indicator light showing the status of the machine.
- A panel of insulating material onto which are fixed:
  - A luer lock connector for venous pressure detection,
  - Control and display keys,
  - Bubble catcher support with automatic level adjustment system.
- An aluminium panel on which are fixed:
  - The plasma pump (peristaltic type with 2 occluding rollers),
  - two Dome type transducers for Plasma pressure and Filtrate pressure detection,
  - four line selection clamps,
  - a blood leak and hemolysis detection sensor (BLD),
  - a filter holder.
- An aluminium panel on which are fixed:
  - two line selection clamps,
  - a filter holder,
  - a drip sensor,
  - the citrate pump (peristaltic type with 2 occluding rollers).
- A user interface consisting of a backlit display, with buttons and a knob for navigation.

The monitor is supported by a special support trolley, equipped with:

- two scales with a maximum capacity of 6 kg each, on which the solution container bags will be hooked on one side and the drain container on the other side,
- four swivelling and braking wheels, which allow AFERSMART PLUS to be moved easily and to position it close to the patient's bed.

The device is supplied with its own power supply cable, equipped with a "V-LOCK" type mechanism to prevent unintentional disconnection.
To perform the treatments, AFERSMART PLUS also requires special sterile and apyrogenic SETs, including disposable cartridges, to be purchased separately.

2.1. OPERATING MODEL FRONT VIEW



1	Command and control panel
2	Blood pump
3	Air detector and optical detector
4	Electroclamp
5	DOME arterial pressure transducer
6	DOME pre-filter pressure transducer
7	Venous pressure connector (venous)
8	Bubble catcher support

2.1.1. FRONT PANEL DESCRIPTION

1: Command and control panel: with a 5.7-inch backlit LCD graphic colour display. Allows programming and real-time management of all functions and operating parameters in graphic and numerical form.

2: Blood pump: consists of an outer casing (cradle) made of PVC, which houses the rotating part (rotor) with two rollers at the ends. The cradle is closed by a transparent plastic cover. The pump rotates anti-clockwise and is of the peristaltic type; meaning that it creates a flow by deforming a piece of tubing (between the rollers and the internal surface of the cradle) which has an internal diameter of 6.36 mm and an external diameter of 9.54 mm . The flow rate shown on the display is calculated on this type of tube; the pieces mentioned are included in the Disposable Kits for AFERSMART PLUS.
The blood pump is also equipped with a magnetic blood pump cover opening alarm sensor, which monitors the correct closing of the cover:
- If the cover is open, the pump does not start;
- If the pump is running, opening the door causes it to stop.
- If the pump door is open, the rotor does not occlude the pump tubing

3: Air detector and optical detector: placed on the venous line, it detects the presence of air bubbles in the section of the blood circuit returning to the patient and triggers the clamp. It is also equipped with an optical sensor that detects the presence of blood in the line.

4: Electroclamp: normally closed (LED on). The clamping position of the tube is indicated by a lit red light on the fixed part of the clamp.
The snap clamp intervenes by blocking the return of blood to the patient in case of passage of air bubbles and whenever the blood pump is stopped.

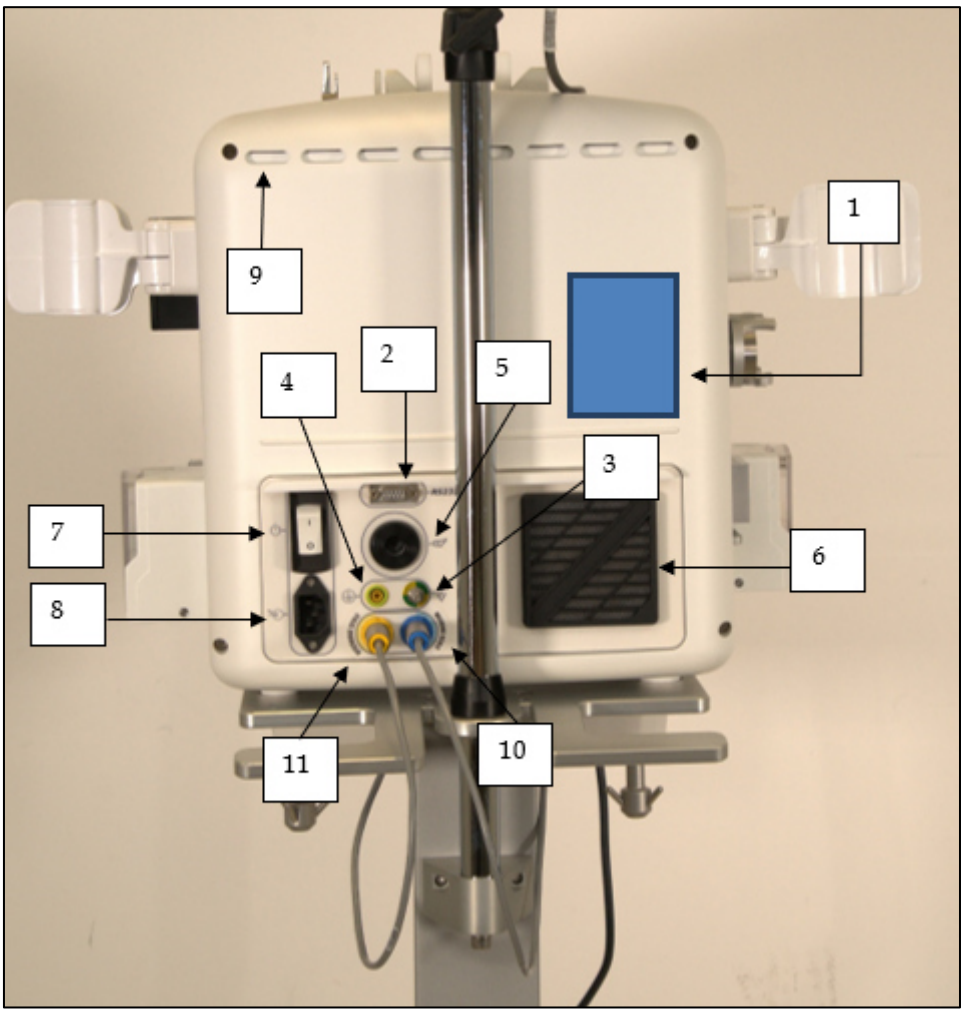
5: DOME arterial pressure transducer: It allows the aspiration pressure of the blood from the patient to be measured. This is shown directly on the display during treatment. The stand is a DOME type and has a rotating ring to facilitate assembly and to lock the line; the line with the membrane from the disposable kit for AFERSMART PLUS must be connected to it.

6: DOME transducer for pre-filter pressure: allows the pressure at the filter inlet to be measured. The support is of the DOME type and has a rotating ring to facilitate assembly and to lock the line; the line with the membrane from the disposable kit for AFERSMART PLUS must be connected to it.

7: Venous pressure connector: it allows you to measure the blood venous pressure to the patient. This is shown directly on the display during treatment. The male luer lock fitting has a rotating ring to facilitate assembly; the tube protected by the relative blood catcher, which comes from the disposable kit for AFERSMART PLUS, must be connected to it.

8: Bubble catcher support: The bubble catcher support allows the bubble catcher of the disposable kit to be housed in it.

2.2. OPERATING MODULE REAR VIEW



1	Plate Label	7	Main switch
2	Serial connector	8	Power supply cable socket
3	Ground connection screw	9	Air intakes
4	Equipotential socket	10	Washing scale socket
5	Buzzer	11	Drain scale socket
6	Air recirculation fan		

2.2.1. Rear panel description

1: Plate Label: contains power supply, manufacturer, model, serial number and year of construction Date.

2: Serial connector: can be used by the manufacturer MEDICA for control and programming operations of the equipment. It also serves the data exchange with the external console

3: Ground connection screw: allows the trolley to be connected to the ground.

4: Equipotential socket: enables equipotential bonding with other equipment within the department

5: Buzzer: It signals the presence of alarms with an intermittent repeated sound, which can be temporarily deactivated with the <Mute> button.
The sound can be:

- continuous: in the event of a power failure; to deactivate press the power button
- intermittent (three beeps) at low sound intensity: to signal situations that are not dangerous for the patient but still require the operator's attention
- intermittent loud sound: for alarm signals

6: Air recirculation fan: allows air to circulate inside the machine, preventing the electronics from reaching too high temperatures.

NOTE
Periodically check that the filtering grille is clean and never obstruct the nozzle, thus preventing the passage of air.

7: Main switch: On ('I') / Off ('O')

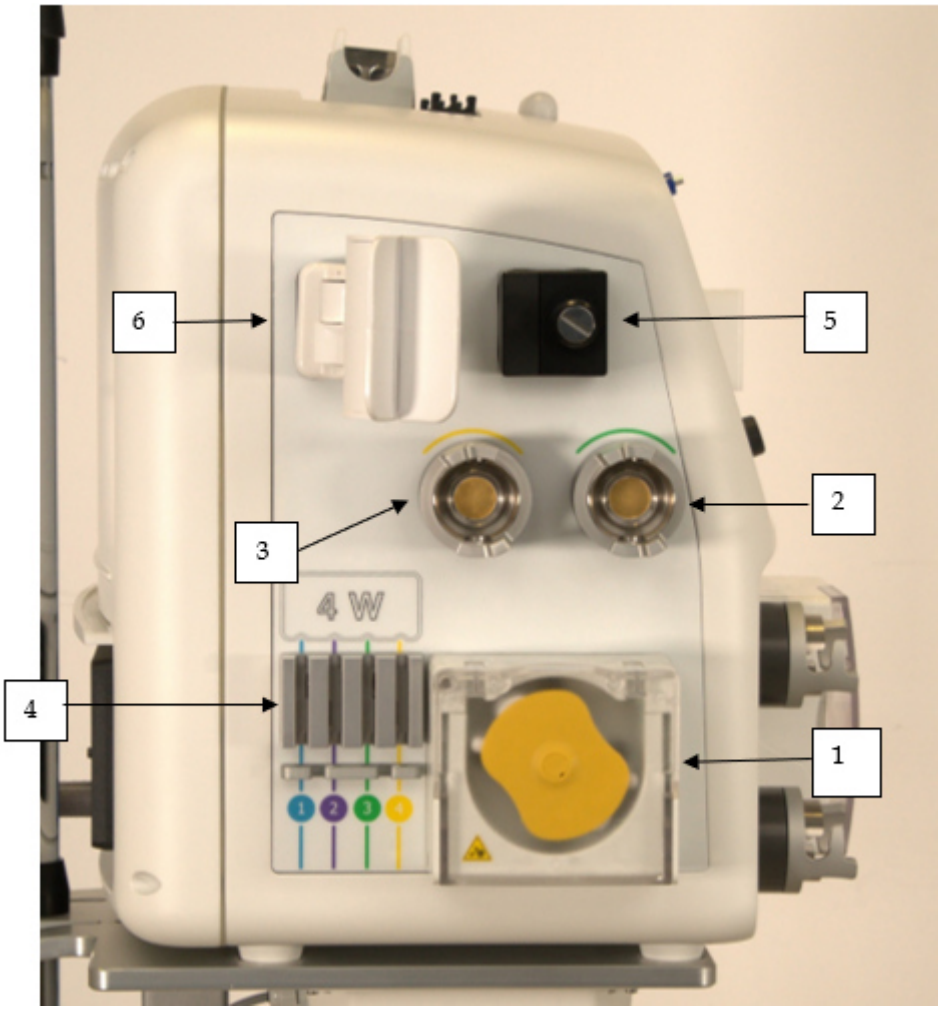
8: Power supply cable socket

9: Air intakes: On the top of the rear panel of the machine, there are air intakes to allow air to circulate inside the enclosure.

10: Washing scale (Scale 1) socket: allows connection to the scale where the cartridge flushing solution container or the waste plasma bag will be connected

11: Drain scale socket: allows connection to the scale where the cartridge Waste bag or the Replacement Fluid bags will be connected

2.3. DEVICE BODY: LEFT SIDE VIEW



1	Plasma pump
2	DOME transducer for Plasma pressure
3	DOME transducer for Filtrate pressure
4	Lines selection 4-ways clamps
5	Blood Leak and Haemolysis Detector (BLD)
6	Plasma filter holder

2.3.1. Left panel description

1: Plasma pump: consists of an outer casing (cradle) made of PVC, which houses the rotating part (rotor) with two rollers at the ends. The cradle is closed by a transparent plastic cover. The pump rotates anti-clockwise and is peristaltic, meaning that it creates a flow by deforming a piece of tubing (between the rollers and the internal surface of the cradle) which has an internal diameter of 4.77 mm and an external diameter of 7.95 mm. The flow rate shown on the display is calculated on this type of tube.
This tubing is included in the disposable kit for AFERSMART PLUS.
The plasma pump is also equipped with a magnetic sensor for the plasma pump cover opening alarm, which monitors the correct closing of the cover:
- If the cover is open, the pump will not start.
- If the pump is running, opening the cover causes it to stop.
- If the pump door is open, the rotor does not occlude the pump tubing

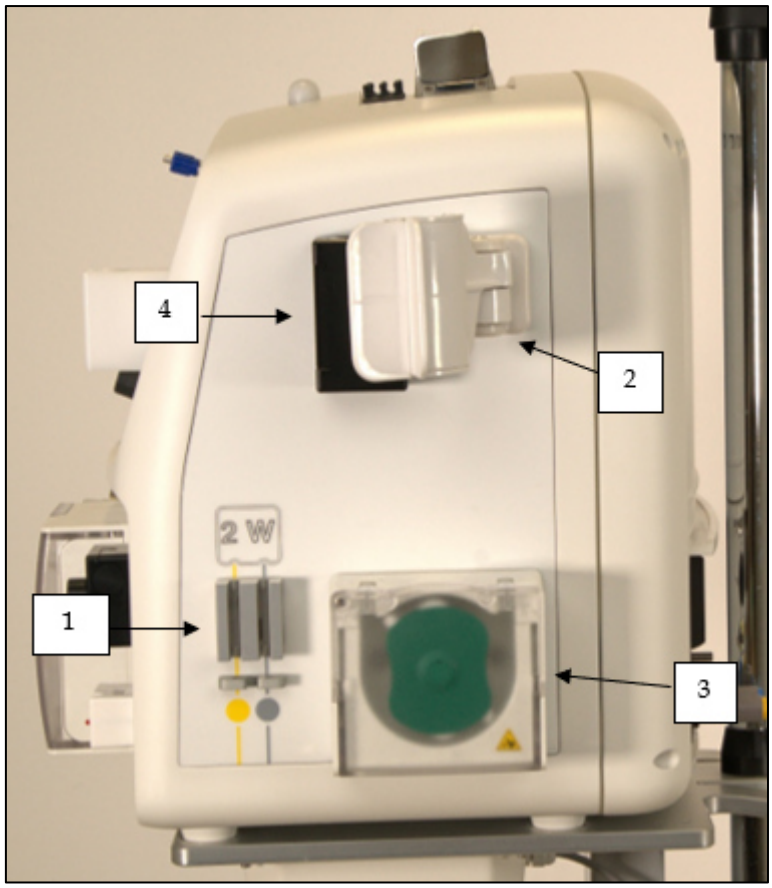
2: DOME transducer for plasma pressure: allows the plasma supply / discharge pressure to be measured. This is shown directly on the display during treatment. The support is of the DOME type and has a rotating ring to facilitate assembly operations and to lock the line; the line with the membrane from the disposable kit for AFERSMART PLUS must be connected to it.
3: DOME transducer for Filtrate pressure: the plasma suction pressure.
This is shown directly on the display during treatment. The support is of the DOME type and has a rotating ring to facilitate assembly operations and to lock the line; the line with the membrane from the disposable kit for AFERSMART PLUS must be connected to it.

4: Lines selection 4-ways clamps: the assembly consists of four clamps, which, depending on the phase in which the DMA is located, automatically open or close the fluid passage lines coming from the scales depending on the treatment chosen.

5: Blood Leak and Haemolysis Detector: This sensor detects any break in the capillary membranes during treatment, directly on the tube of the plasma line of the AFERSMART PLUS kit. The sensor inside the tube holder detects changes in the colour of the plasma.
The alarm conditions detected by the sensor are therefore two:
- any break in the capillary membranes during treatment
- hemolysis caused by clotting or inappropriate filtration conditions
- absence of the tube from the sensor

6: Holder for Plasma Filter: allows to hold the plasmafilter (or haemofilter in HP) during the treatment

2.4. DEVICE BODY: RIGHT SIDE VIEW



2.4.1. Right side panel description

1	**2-way clamp for plasma/waste selection**
2	**Plasma Fractionator Filter support**
3	**Citrate pump**
4	**Citrate drip sensor**

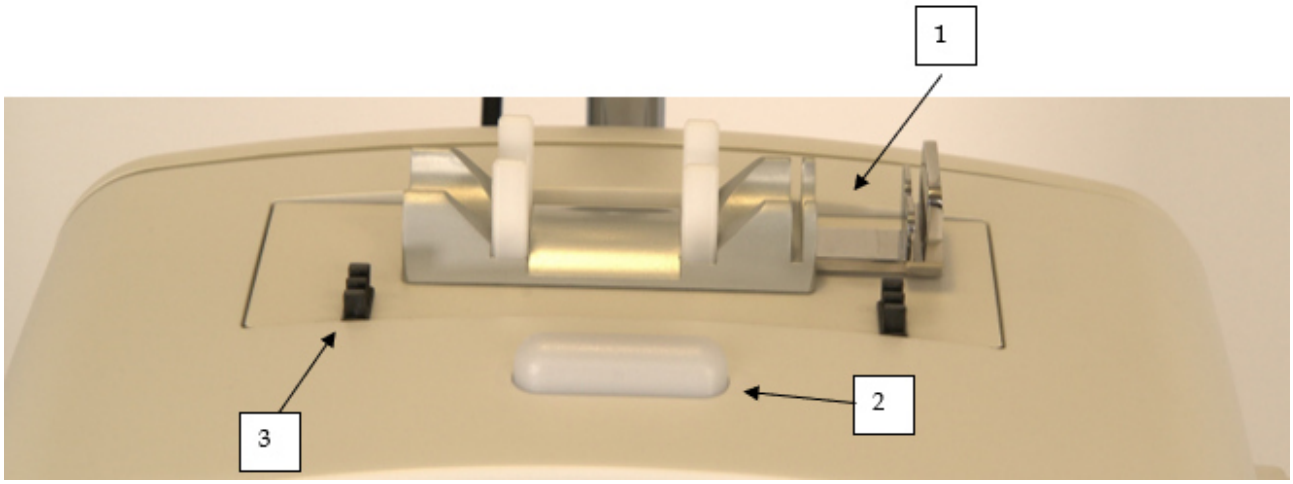
1: 2-way clamp for plasma/waste selection: The assembly consists of two terminals which, depending on the phase in which the DMA is located, automatically open or close the fluid passage lines that flow into:
- Fractionator waste line
- Plasma return line to the venous line

2: Plasma Fractionator Filter support allows to hold the plasma fractionator filter during the double filtration treatments (DF and DFA)

3: Citrate pump: consists of an outer casing (cradle) made of PVC, which houses the rotating part (rotor) with two rollers at the ends. The cradle is closed by a transparent plastic door. The pump rotates anti-clockwise and is peristaltic, i.e. it creates a flow by deforming a piece of tubing (between the rollers and the internal surface of the cradle) which has an internal diameter of 2 mm and an external diameter of 5.5 mm. The flow rate shown on the display is calculated on this type of tube.
This tube is included in the disposable kit for AFERSMART PLUS.
The citrate pump is also equipped with a magnetic sensor for the citrate pump door opening alarm, which ensures that the door is closed correctly:
- If the door is open, the pump will not start.
- If the pump is running, opening the door will stop it.
- If the pump door is open, the rotor does not occlude the pump tubing

4: Citrate drip sensor: sensor capable of detecting and counting citrate drops.

2.5. UPPER PANEL VIEW



1	Heparin pump
2	LED light beacon
3	Dual line guides

2.5.1. Upper panel description

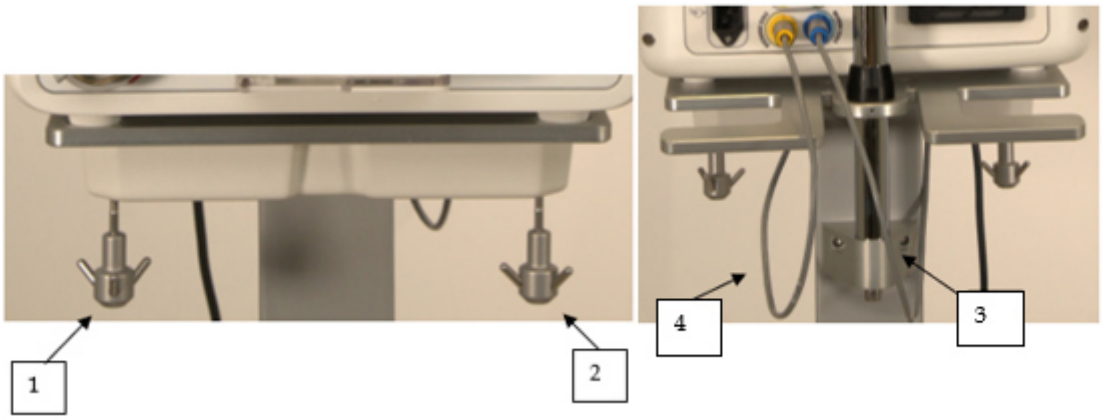
1: Heparin pump: administers anticoagulant solution in continuous or bolus mode. This model specifically requires the use of the syringe included in the AFERSMART PLUS kit.

2: LED light beacon: indicates the status of the machine:
- Green light on means that the machine is operating correctly and that there are no alarms.
- Flashing yellow light means a warning status or override alarm.
- Flashing red light identifies an alarm

The second line of the screen, the one for Alarm Presence, turns the same colour as the status of the machine.

3: Dual line guides: are used to fix two lines along their designated positions

2.6. BOTTOM SECTION VIEW



1	Washing scale hook
2	Drain scale hook
3	Washing scale connector
4	Drain scale connector

2.6.1. Bottom section description

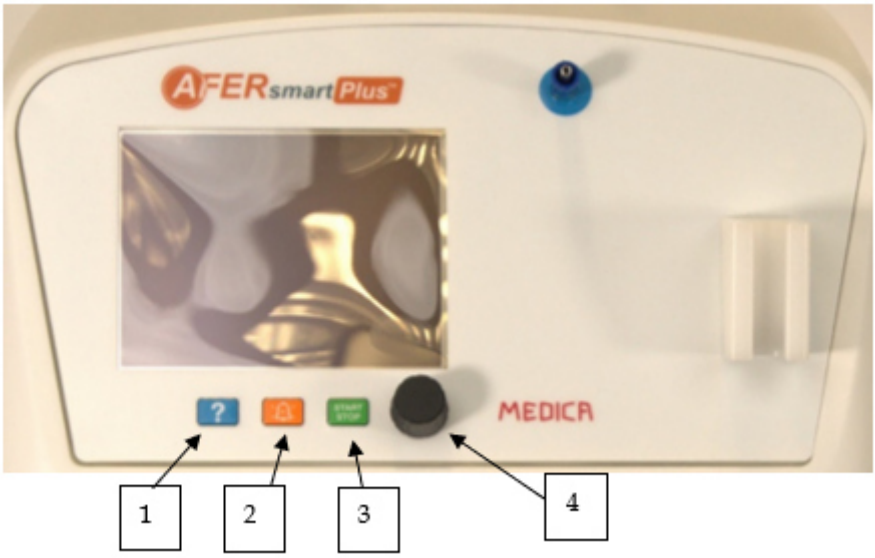
1: Washing scale hook: allows the positioning of Venous Line Waste and Retentate Waste / Replacement Fluid bags during priming and treatment

2: Drain scale hook: allows the Flushing solution container / Waste Plasma to be positioned during priming and treatment phases

3: Washing scale connector (blue): allows the connection with the device

4: Drain scale connector (yellow): allows the connection with the device

2.7. COMMAND AND CONTROL PANEL



1	Help button <?>	3	<Start / Stop> button
2	Buzzer mute and alarm cancellation button <Mute>	4	Selection knob

2.7.1. Command and control panel description

The panel allows the operator interface to be programmed and managed.
In all operating modes, the AFERSMART PLUS operator interface displays the progress of the session and the relevant treatment parameters both in written form and with the aid of graphic ideograms. It also displays any alarm conditions that can be easily dealt with and resolved with the help of the online help, which helps the operator with dedicated messages according to the situation that arises.
The interface philosophy is conversational and allows the operator to navigate through the various levels available, using the multifunction knob.
On-line help is enabled in all operating conditions and can be activated by the operator by pressing the dedicated button.

1 : Help button < ?> : if pressed in any screen enables the HELP ONLINE function, which allows alarm information to be read.

2 : Buzzer mute and alarm cancellation button <Mute>: During signalling of all the alarms, the button silences the audible alarm for 2 minutes; this function is only enabled if there are alarms present. The button also allows resetting the alarms that appear in the appropriate line during machine operation.

3 : <Start / Stop> button: When pressed, activates or deactivates the blood pump.

4 : Selection knob : Turn the knob to select functions, change values and press to confirm.

2.8. BATTERY

The battery is only used for the audible alarm in the event of a power failure alarm. It is permanently recharged if the main switch remains on "I". It should be noted that this battery does not refer to the UPS option (optional, see Chapter 25).
It is necessary to check the battery status before each treatment, as follows:
"After turning AFERSMART PLUS on with the ON key, disconnect, just for testing, the power cable from the connector; the green POWER light will go out and the audible alarm should be triggered."
If this does not happen, let the battery recharge for at least 8 hours by connecting the power cable and pressing the switch in position "I".
However, AFERSMART PLUS is equipped with an alarm that warns the operator if the battery is low and stops the machine every 10 minutes, so an operator must be present to restart it and finish the treatment.

NOTE

The audible alarm will not be activated if the power cable is disconnected when AFERSMART PLUS is switched off in the condition that the main switch is in position "0".

2.9. DESCRIPTION OF THE EXTERNAL CONSOLE (OPTIONAL)

USB Ethernet I/O

The external console has 3 signal ports:

- USB is a USB type A 2.0 port intended for the connection of a storage unit for data download, to be used exclusively for post-treatment data analysis by operator.

WARNING

Use the USB port only to download log files.

- Ethernet is an RJ45 type port for connecting the device to the hospital ethernet network: the functionality is not implemented.

WARNING

Do not to use the ethernet port.

- I/O is the port for connecting the console to the AMD, where the unidirectional data exchange over the RS232 protocol takes place, using an exclusive cable supplied by the manufacturer. The same connection allows to power on the console.

WARNING

Do not disconnect the cables during treatment.

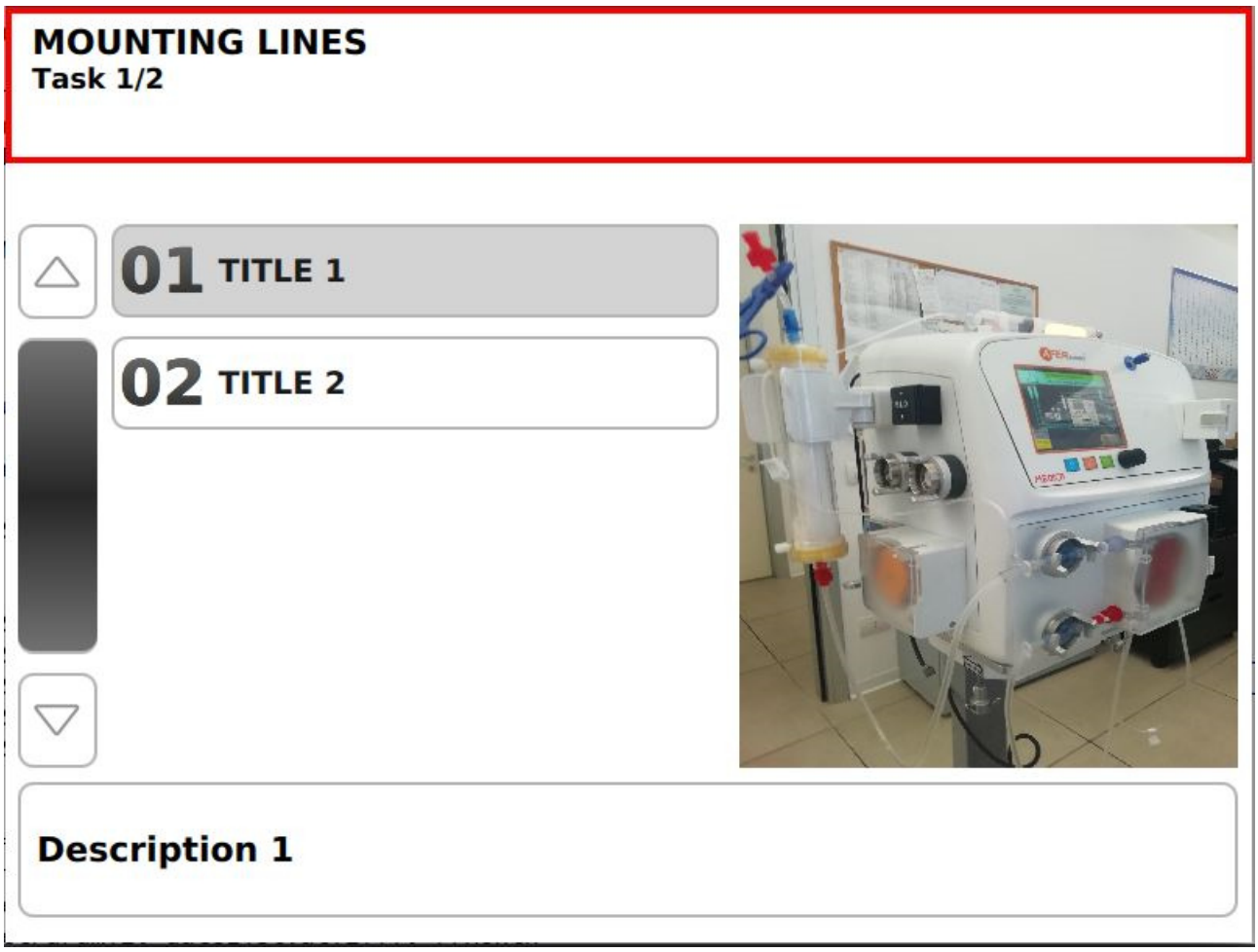
Do not use for other purposes.

The "AFERSMART PLUS CONSOLE" is an optional support device of the AFERSMART PLUS device useful to display relevant information and detailed instructions to simplify use of the device. Information is displayed for machine management, in particular for preparation of the single-use kit, through videos, making machine management easier even for new users; it tracks pressure values to make the trend clear and to prevent possible clots and to reproduce other relevant information, such as alarms, so that they can be visible from further away.
The console application is a sequence of screens, the automatic update as well as the device screen updates follow the various phases of the use of the device.

The initial screen shows whether the AFERSMART PLUS console is connected to the main device or not. If connected, the screen is updated every second. After 3 seconds if the signal not received, "Not Connected" is shown.

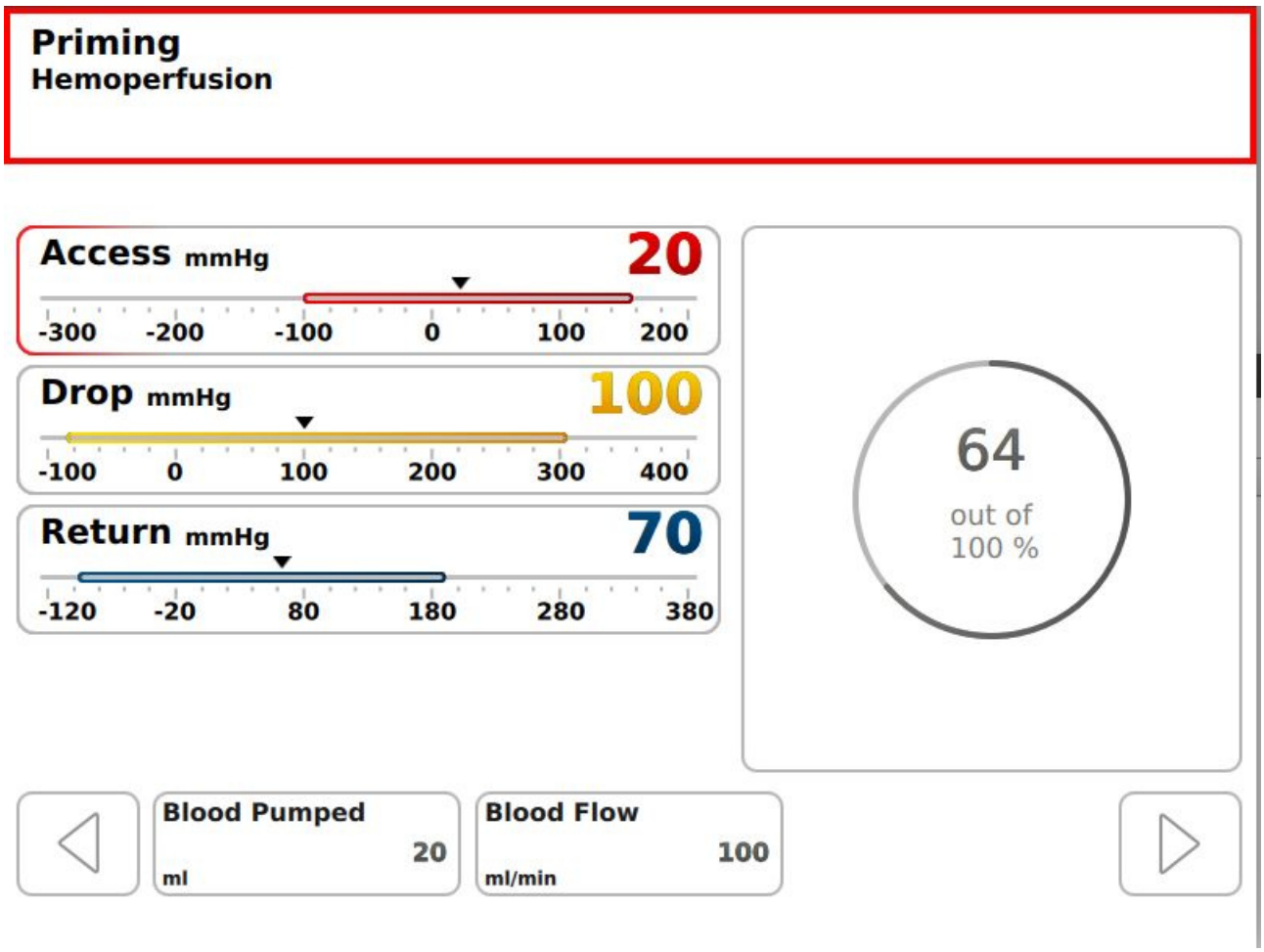
By clicking the key "Service" at the top, it is possible to enter in a special page protected by password used by the technician to set or update the device.

2.9.1.Line installation screen



Once the treatment has been selected from the main device HOME PAGE, a list of operation is displayed with a description and a photo or a video associated, that help the user to install the disposable

2.9.2. Preparation screens



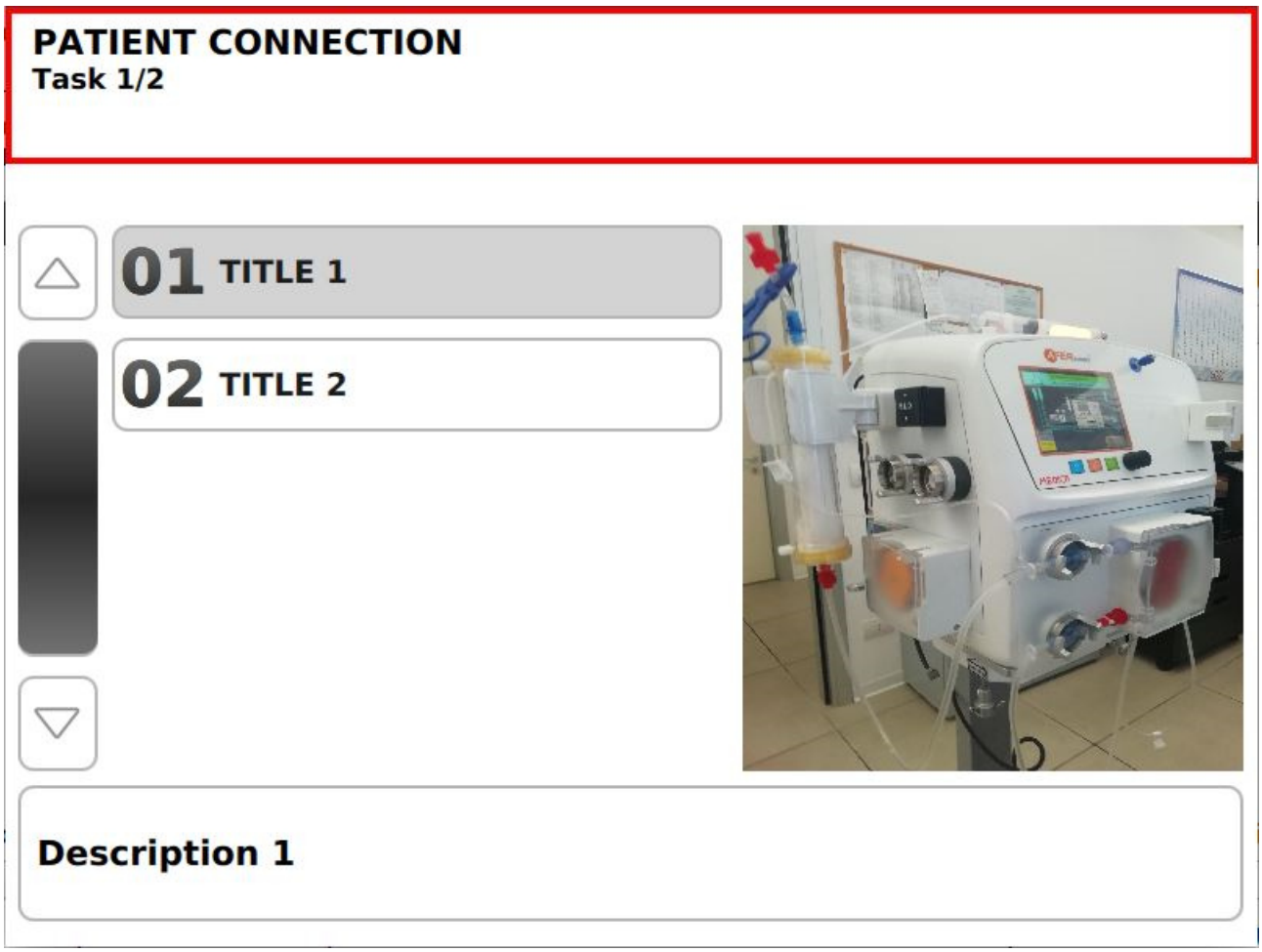
Once the operator proceeds with the Preparation, the priming phase start and the "Priming" screen is shown.
On this page the user can check several treatment parameters as:

- Selected treatment
- Priming progress circle bar
- Blood circuit pressures
- Flows of the pumps
- Treated volumes

If there are active alarms they are displayed on the upper part of the screen: high priority alarms are in red, medium priority alarms are in yellow, attention messages are in cyan and phases information are in green.

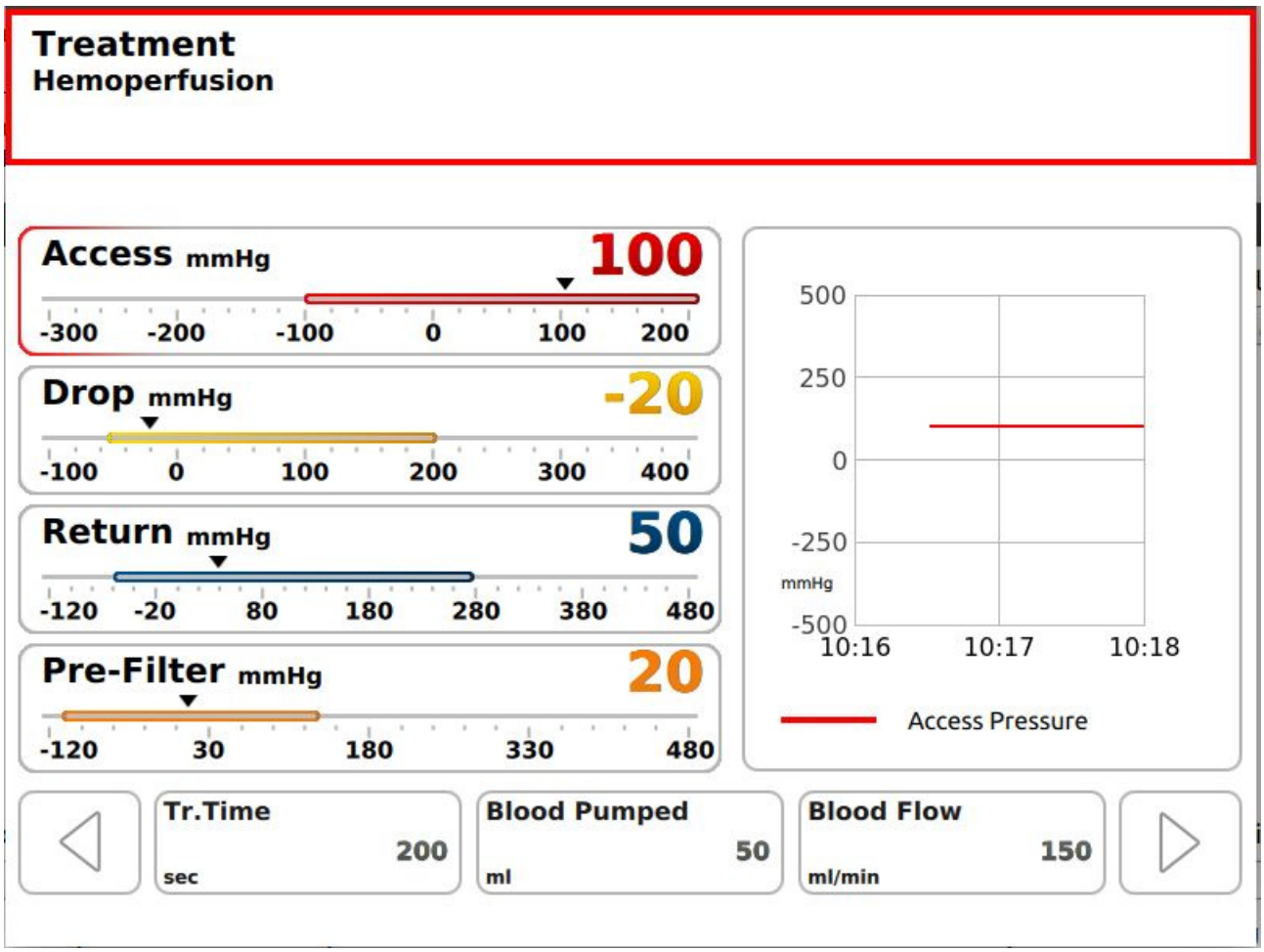
The end of this phase is notified by the priming progress circle bar (completely grey colored).

2.9.3. Patient connection screen



Once the priming has been successfully terminated the console show a list of operation with a description and a photo or a video associated, that help the user to connect the patient.

2.9.4. Treatment screen

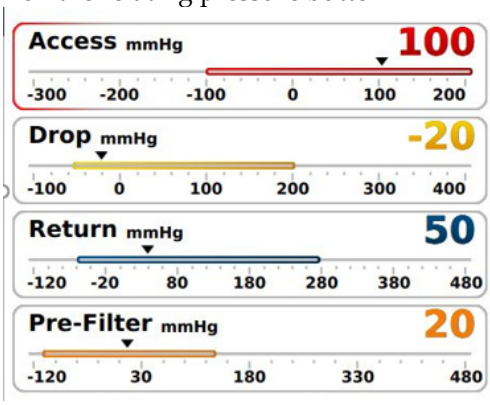


Once the treatment has been started, the **Treatment** screen is displayed.
On this page the user can check several treatment parameters as:

- Running treatment
- Time of the treatment
- Blood circuit pressures with a related graph
- Flows of the pumps
- Treated volumes
- Set points of the treatment (previously set)

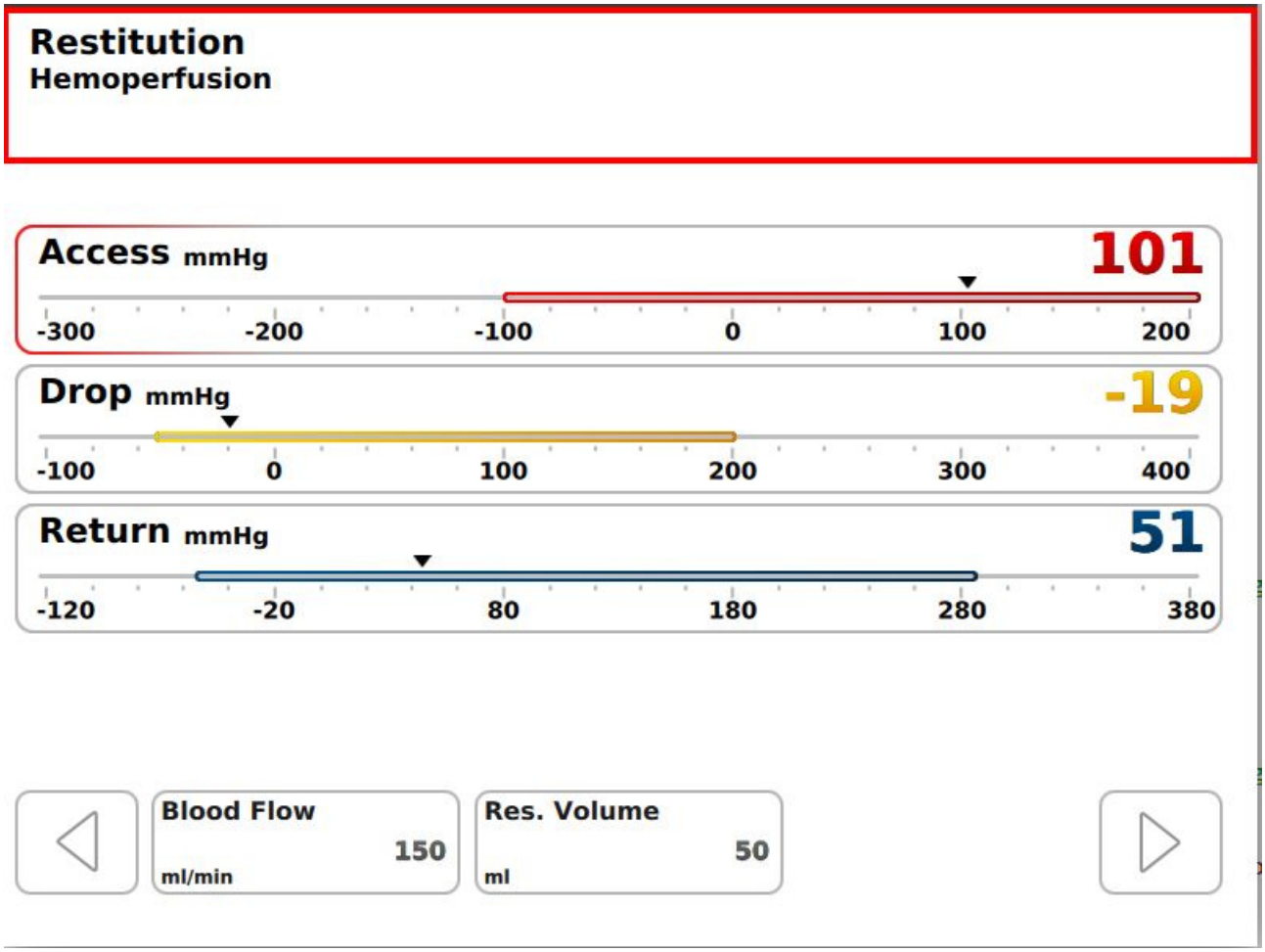
If there are active alarms they are displayed on the upper part of the screen: high priority alarms are in red , medium priority alarms are in yellow, attention messages are in cyan and phases information are in green.

The graph can be changed by push on the relating pressure button



The graph shows the trend of the pressure selected in the last 2 minutes of treatment.

2.9.5. Restitution screen



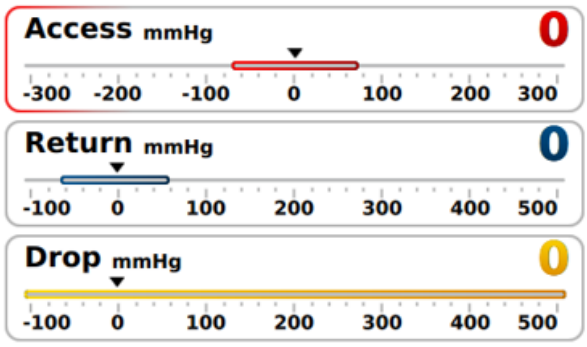
Once the treatment is finished, the user can reinfuse blood still in the disposable, to the patient.
The Restitution screen is displayed.

On this page the user can check several reinfusion parameters as:

- Running treatment
- Blood circuit pressures with a related bargraph
- Flows of the pumps
- Treated volumes

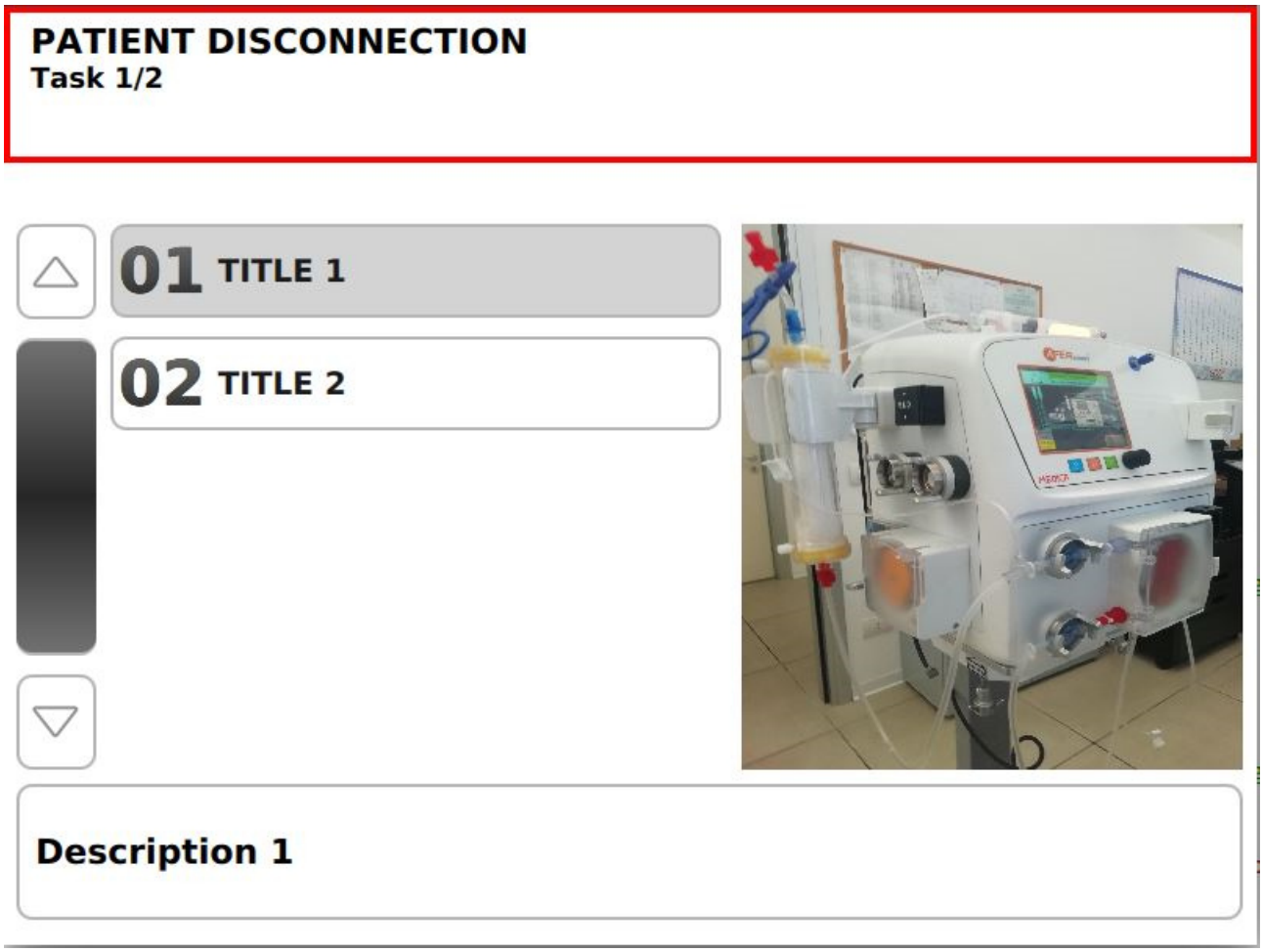
If there are active alarms they are displayed on the upper part of the screen: high priority alarms are in red , medium priority alarms are in yellow, attention messages are in cyan and phases information are in green.

The graph can be changed by push on the relating pressure button



The graph shows the trend of the pressure selected in the last 15 minute of treatment.

2.9.6. Patient connection screen



Once the restitution is finished the console show a list of operation with a description and a photo or a video associated, that help the user to disconnect the patient.

2.10. PRESENCE OF AIR IN THE RETURN TO PATIENT LINE

If the sensor, placed on the patient venous line, detects one or more air bubbles, the DMA implements all the necessary measures to put the patient in safety. This consists of a video alarm, a light signal, an acoustic signal, blood pump stops, electro-gripper closure and treatment time interrupted.
The suggested procedure in this case is as follows:

- Identify the source of the air bubbles.
- If air bubbles are detected in the venous line, eliminate them as follows:
  - Occlude the line coming from the filter just before entering the venous chamber with a klemmer
  - Occlude with a klemmer the line outgoing from the electric gripper
  - Insert a syringe into the access point of the venous chamber, open the relevant klemmer and release the pressure in the chamber.
  - Remove the klemmer from the tube coming out of the electric gripper
  - Aspirate with the syringe creating a negative of 40 mmHg and manually open the electro-gripper. The negative pressure in the dripper will suck the air until it is completely eliminated.
  - Remove the klemmer from the line coming from the filter just before entering the venous chamber
  - Close the klemmer on the venous chamber and remove the syringe.
- Press the  button to restart.

WARNING:

RISK OF GASEOUS EMBOLISM DUE TO AIR IN THE LINES

Blood clots (clotting) in the tubing system or contamination / moisture on the air bubble detector can interrupt the proper functioning of the air detector.

- **The air bubble detector must be clean and dry.**
- **Do not use objects or supports that conduct ultrasound.**

2.11. MANUAL RESTITUTION OF BLOOD TO THE PATIENT

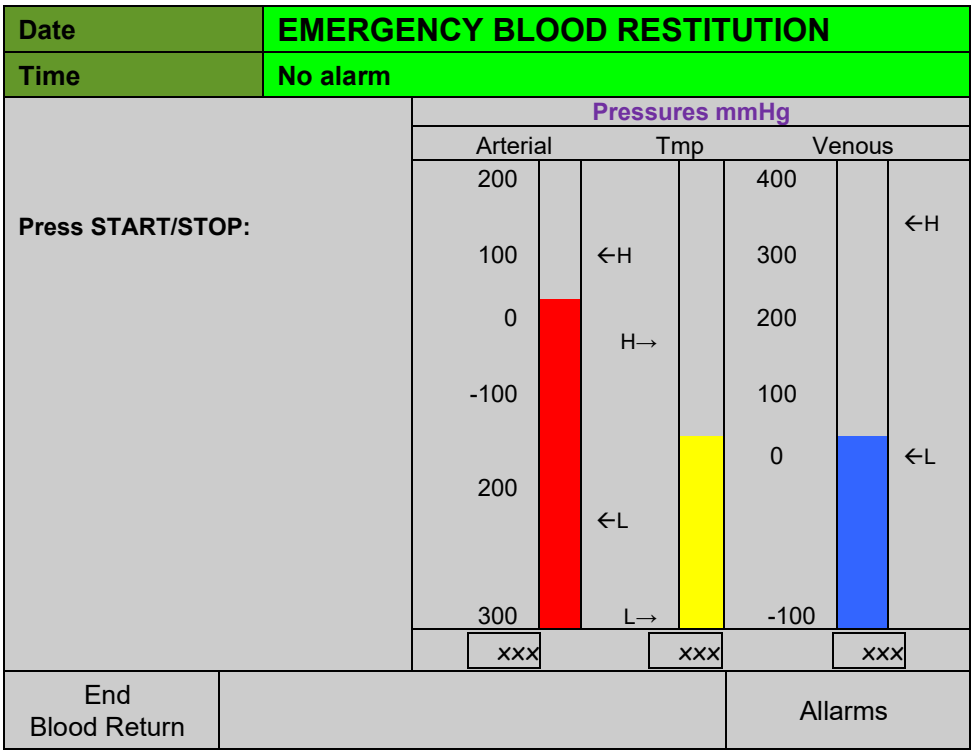
If it is not possible to proceed with the extracorporeal circulation of the blood in case of absence of mains voltage and waiting for his patient, or with the return of blood to the patient, it is necessary to proceed with a manual return.
The suggested procedure in this case is as follows:

- Occlude the patient access line with a klemmer
- Disconnect the arterial line from the patient and connect it to a bag of system fluid.
- Place the bag on a 1.5m or at high stand at a height greater than the patient as it must be returned by gravity.
- Open the blood pump door, remove the klemmer on the arterial line and make sure that the line is free from any obstructions.
- Press the electric clamp and that there is enough fallen to return the blood to the patient.
- Once the restitution is finished, occlude the venous line with a klemmer and proceed to detach the patient.

2.12. EMERGENCY RESTITUTION OF BLOOD TO THE PATIENT

If it is not possible to finish the treatment in progress in case of breakage of a critical component (e.g. air sensor) and it is therefore necessary to return the blood to the patient, the suggested procedure is the following:

- Press and hold the  and  buttons simultaneously for 20 seconds to enter the EMERGENCY BLOOD RESTITUTION page
- Press and hold  button to proceed with the return of blood.



WARNING:

Pay particular attention to the venous line as air bubbles may not be detected which could be dangerous for the patient.

3. INTENDED USE

The dev ice is intended for adult patients requiring the following therapeutic treatments:

3.1. PATHOLOGIES TREATED WITH THE AFERSMART PLUS SYSTEM

AFERSMART PLUS is an active medical device, manufactured by Medica S.p.A., intended for carrying out the following treatments:

1 HEMOPERFUSION
2 THERAPEUTIC PLASMA EXCHANGE (TPE)
3 DOUBLE FILTRATION RHEOPHERESIS
4 RHEOPHERESIS SELECTIVE APHERESIS
5 DOUBLE FILTRATION RHEOPHERESIS ADSORPTION

Patient populations:

Hemoperfusion
This treatment can be adopted for patients > 10 kg, with various pathological conditions, including:

- Sepsis / Severe Sepsis / Septic Shock / Multiple Organ Failure Syndrome (MOF)
- Familial hypercholesterolemia
- Dialysis Related Amyloidosis (DRA)
- Lp(a) hyperlipoproteinemia.

TPE
The treatment is indicated for patients > 10 kg, suffering multiple diseases including:

- Vasculitis (Goodpasture and Wegener Syndrome)
- Thrombotic thrombocytopenic purpura (PTT)
- Cryoglobulinemia
- Micromolecular and macromolecular myeloma
- Lupus Erythematosus
- Hemolytic uremic syndrome
- Guillain-Barré syndrome.

Double filtration Rheopheresis
The treatment is indicated for patients > 10 kg, suffering different diseases, including:

- Anti-GBM nephritis (autoimmune disease characterized by rapidly progressive glomerulonephritis and the presence of circulating antibodies directed against the basement membrane of the glomerulus)
- Goodpasture syndrome
- Myasthenia gravis
- Chronic inflammatory neuropathy
- Guillain-Barré syndrome
- Vasculitis associated with anti-neutrophil cytoplasmic autoantibodies (ANCA = Anti-Neutrophilic Cytoplasmic Autoantibody)
- Acute antibody mediated rejection (in post solid organ transplantation), both for AB0 incompatible transplants and in patients with anti-HLA antibodies
- Alterations of the physiological rheology of the blood
- High HCV (Hepatitis C Virus) charge

Rheopheresis Selective Apheresis
The treatment is indicated for patients > 10 kg, suffering of multiple pathologies, including:

- Familial hypercholesterolemia
- Peripheral artery occlusive syndrome
- Focal segmental glomerular sclerosis
- Systemic Lupus Erythematosus
- Goodpasture syndrome

- Cryoglobulinemia
- Thrombotic thrombocytopenic purpura (PTT)
- Devic's Neuromyelitis Optic

Double Filtration Reopheresis Adsorption
This technique allows the treatment of patients > 10 kg, with septic shock in which it is necessary to remove pro-inflammatory cytokines, which are secreted in large quantities in the case of sepsis.

Device users:
AFERSMART PLUS must be used in a healthcare-clinical-hospital environment, by healthcare personnel. Home use of the devices is not permitted.
The choice of methods of use, as well as the areas of application, is the exclusive responsibility of doctors with experience in the treatment of the pathologies involved.
The device operation, as well as by the doctor, can be managed by nursing staff under the supervision of a responsible doctor.

3.1.1. Diseases treated with the treatment of Hemoperfusion

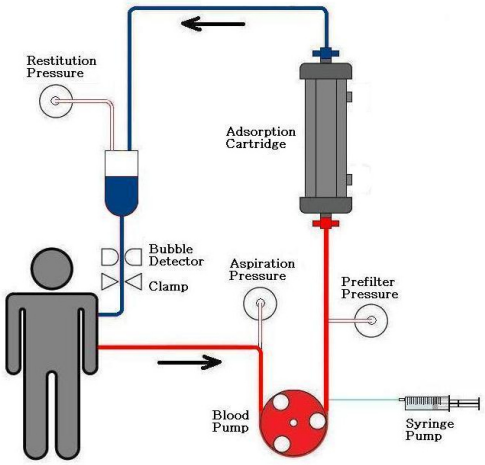
HEMOPERFUSION: this treatment requires the use of an adsorption cartridge able to retain specific molecules responsible for development of particular diseases directly from the blood.
Current technology allows identifying the molecules responsible for some diseases and realising specific sorbents able to retain them.

The hemoperfusion treatments have proved their effectiveness in all those cases in which there is the need to remove selectively known molecules directly from blood, such as:

- Pro- and anti-inflammatory mediators;
- Lipoprotein [es: LDL, Lp(a)];
- B-2 Microglobulin.

Consequently, this treatment can be adopted to various pathological conditions caused / mediated by these molecules, including:

- Sepsis / Severe Sepsis / Septic Shock / Multiple Organ Failure (MOF);
- Familial Hypercholesterolemia;
- Dialysis related amyloidosis (DRA, Dialysis Related Amyloidosis).



3.1.2. Diseases treated with the treatment of Plasmaexchange

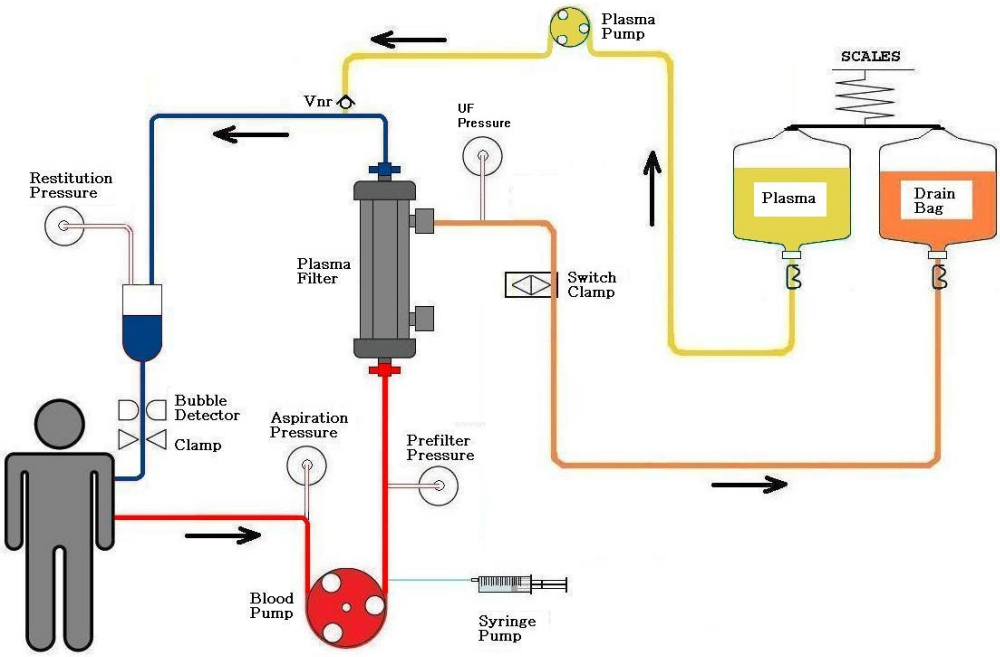
PLASMAEXCHANGE (PEX - PLASMAPHERESIS): This clearance technique requires drawing whole blood from the patient through a vascular access. The plasma is separated by centrifugation or filtration. In the filtration processes, the plasma is separated from the corpuscular elements in a plasma filter by applying pressure (TMP) on the membrane. The plasma with all the substances it contains is removed.
The plasma from a donor or a replacement solution is reinfused into the circuit after the plasma filter and the thus regenerated blood is reinfused to the patient.

Given the characteristics of the treatment, plasmapheresis can be used for the removal of the following molecules:

- Antibodies to glomerular basement membrane;
- Antibodies to ADAMTS;
- Macroglobulins IgM;
- Antibodies to ADAMS 13;
- Immunoglobulins G (IgG);
- Immunoglobulins A (IgA).

Accordingly, plasmapheresis can be indicated in the treatment of multiple mediated / certain diseases from those molecules, including:

- Vasculitis (Goodpasture's syndrome and Wegener);
- Thrombotic thrombocytopenic purpura (PTT);
- Cryoglobulinemia;
- Myeloma small molecular and macromolecular;
- Lupus Erythematosus;
- Hemolytic uremic syndrome;
- Guillain-Barré syndrome.



3.1.3. **Diseases** treated with the treatment of Double Filtration Rheopheresis

RHEOPHERESIS: the rheopheresis treatment requires returning the plasma to the patient after its clearance by either filtration or adsorption. The plasma is separated from the blood through a plasma filter or with a centrifuge system. The following RHEOPHERESIS treatments can be performed:

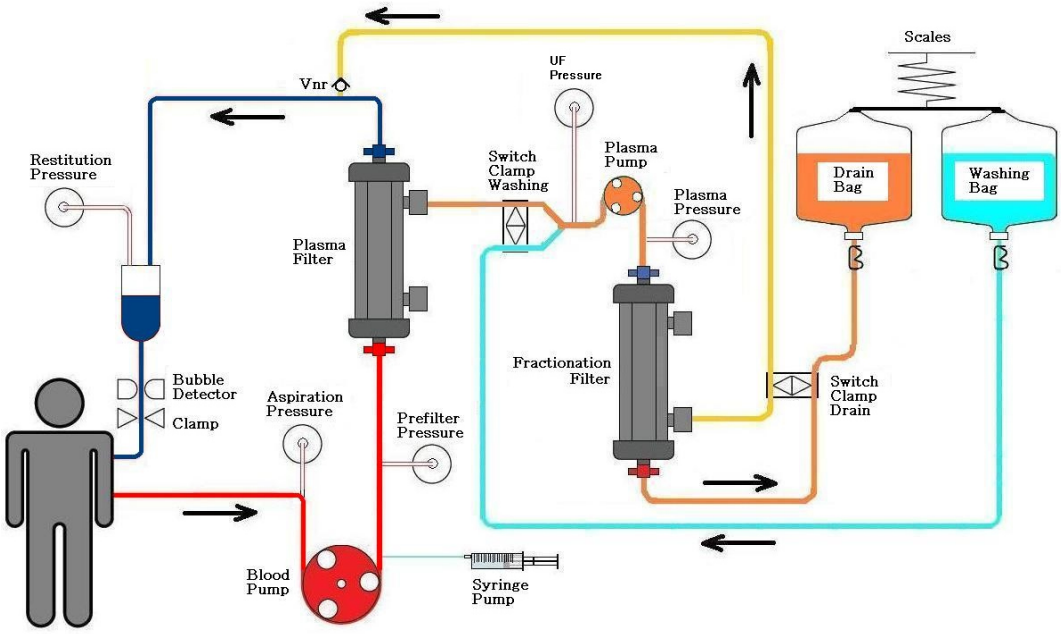
DOUBLE FILTRATION RHEOPHERESIS: the Double Filtration treatment requires clearance of the plasma obtained by filtration or centrifugation by means of a second filter known as fractionation filter. The plasma is channelled into the hollow fibres of the fractionation filter placed in cascade, determining sequestration inside it of all the molecules over the molecular weight corresponding to the filter cut-off. Filters with different cut-off are available to obtain different separation profiles. The noble part of the plasma rich in substances like albumin is rerouted to the patient. Each time the fractionation filter fills with high molecular weight molecules, the system fully automatically performs tangential PRIMING of the filter consequently regenerating it.

The therapy can be used for removing multiple molecules, which can be classified as follows

- Antibodies
- Pathogenic substances
- Metabolic factors (es: LDL)
- Inflammation mediators

Consequently, the DFR therapy is indicated in many areas of use, including

- Goodpasture's syndrome;
- Kidney transplantation: prevention and management of acute antibody-mediated rejection, post solid organ transplantation, both AB0 incompatible transplants in patients with anti-HLA antibodies;
- Alterations of physiological blood rheology;
- Detoxifying treatments and antiviral: reduction of the charge HCV.



3.1.4. Diseases treated with the treatment of Rheopheresis Selective Apheresis

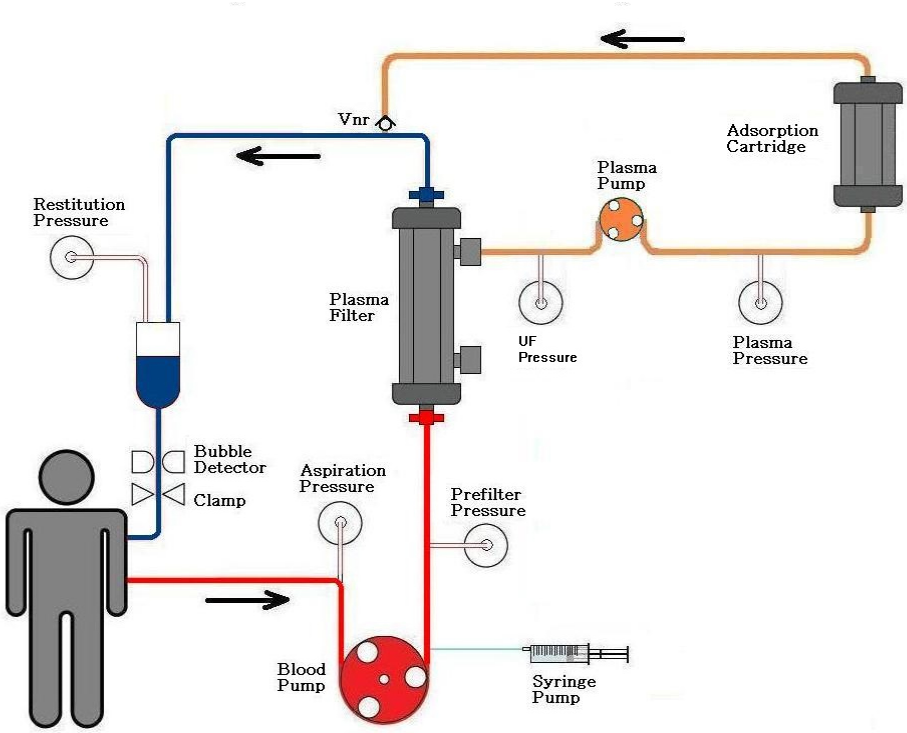
RHEOPHERESIS SELECTIVE APHERESIS: the Selective Apheresis treatment requires clearance of the plasma coming from a filter or centrifuge. The plasma passes through a sorbent cartridge able to retain specific molecules related to the diseases to be treated. Current technology allows identifying the molecules responsible for some diseases and realising specific sorbents able to retain them.

Due to the characteristics, this technique can be used for the removal of many types of molecules:

- Lipoproteins containing apo-B [es: LDL, Lp(a)];
- Inflammation mediators;
- Antibodies to DNA;
- Anti-cardiolipin:
- Immunocomplexes;

Consequently, the selective apheresis allows the treatment of various diseases caused / mediated by these molecules:

- Familial Hypercholesterolemia;
- Peripheral artery occlusive syndrome;
- focal segmental glomerular sclerosis;
- Systemic Lupus Erythematosus;
- Goodpasture Syndrome;
- Crioglobulinemia;
- Thrombotic thrombocytopenic purpura (PTT);
- Devic's neuromyelitis optica
- Sepsis / Severe Sepsis / Septic Shock / Multiple Organ Failure Syndrome (MOF);



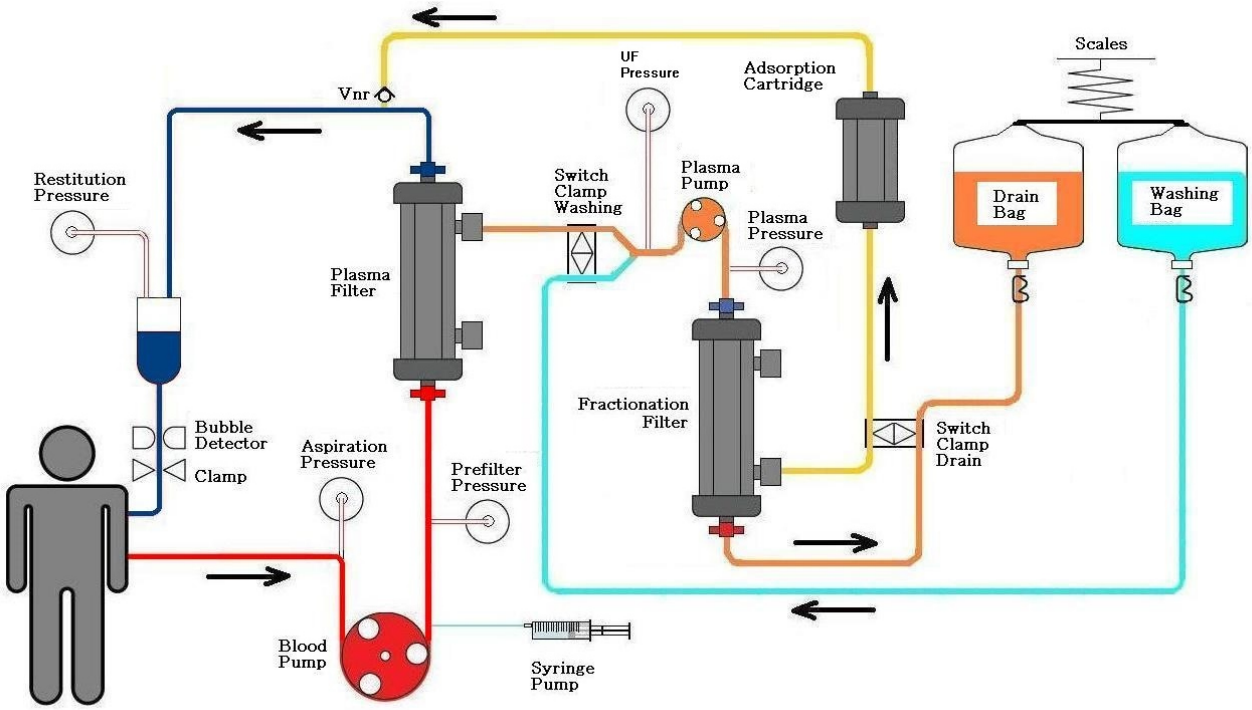
3.1.5. Diseases treated with the treatment of Double Filtration Adsorption Rheopheresis

DOUBLE FILTRATION RHEOPHERESIS ADSORPTION: the Double Filtration Adsorption treatment is a combined treatment of the plasma coming from a plasma filter or centrifuge using a fractionation filter and a sorbent cartridge.
After being cleared of high to medium molecular weight molecules by means of a filtration process, the noble part of the plasma rich in substances like albumin is rerouted to the patient, and during its course, an adsorption cartridge removes the specific low molecular weight molecules, for example, cytokines. This treatment allows combining the benefits of blood viscosity reduction with consequent improvement of microcirculation with those of clearance by adsorption of molecules such as cytokines related to the inflammatory process. Like the other Rheopheresis methods, this treatment does not require infusion of replacement substances and is therefore biocompatible and well tolerated by the patient.

The clinical example of using the reopheresis double filtration and adsorption derived from the treatment of septic shock in which you need to remove the pro-inflammatory cytokines that are secreted in large quantities in the case of sepsis. Such molecules are generally of medium-small size, therefore, are able to cross both plasma filter and the fractionator without being removed. Only a specific adsorbent column allows their removal from the circulation prior to reinfusion of the patient and the treated blood plasma.

Consequently, the treatment of Reopheresis Double Filtration Adsorption allows the treatment of the following pathologies:

- Septic shock treatment (removal of pro-inflammatory cytokines)



4. CONNECTIONS TO OTHER MEDICAL DEVICES

Performing treatment with AFERSMART PLUS should be handled with a single tube set that handles the passage of extracorporeal blood in a compact, integrated format.
Performing treatment with AFERSMART PLUS requires the use of a single-use A/V set.

The plastic materials used are medical grade; the lines are supplied in a single, sterile, non-pyrogenic package. The kit is disposable, do not use it if the packaging is damaged or if the protective capsules are out of place.

The set is to be used aseptically immediately after removing the protective capsules. Check the correct connection and safety of connections to other medical devices before starting treatment.

Some of the components of the lines are coloured blue to make it easier to recognise the venous line from the arterial line of the blood circuit, which is coloured red.

For the characteristics of the adsorbers / filters used in the AFERSMART PLUS, please refer to the instruction booklet contained in the kit.

WARNING

These medical devices must be used under supervision of a doctor. The correct functioning and performance of the AFERSMART PLUS is only guaranteed if MEDICA (or MEDICA approved) products are used.

5. USE OF THE POTENTIAL EQUALISATION CONDUCTOR

The device is equipped with a terminal for the connection of the potential equalisation cable, with the following characteristics:
The terminal is accessible to the operator under all NORMAL USE conditions.
The terminal allows the conductor to be independent without the use of a TOOL.
The terminal is indicated by the following symbol:

The terminal should not be used for grounding connections.

Use and functions of the Terminal Equalisation Conductor
If more than one medical device is used on the same patient, the operator must connect all the Equalisation Conductor terminals of the active medical device together.

6. TREATMENT KIT

The main codes for disposable medical devices (hereafter referred to as "KIT"), which are accessories needed to use AFERSMART PLUS, are summarised below.

Kit description	Treatment	Code
Disposable Haemoperfusion device	HP	M90426
Disposable Rheopheresis/double filtration device	DF	M90420
Disposable Rheopheresis/plasma-adsorption device	SA	M90422
Disposable Rheopheresis/double filtration-adsorbing device	DFA	M90424
Disposable Plasmaexchange device	PEX	M90428

WARNING

The above kit must be used under supervision of a doctor:

- **The disposable kit is only compatible with active, manufacturer-approved medical devices.**

WARNING

The sterile, disposable tubing set for AFERSMART PLUS MUST be used under supervision of a doctor:

- **The sterile, single-use tubing set may only be used if the packaging is undamaged and the expiry date has not been exceeded.**
- **DO NOT sterilise or reuse the sterile, single-use tubing set.**
- **The Sterile Tubing Set is a single-use device, which means it should only be used once.**

Reuse, reprocessing, or re-sterilization could compromise the structural integrity of the Tube Set and/or cause the Tube Set to fail which in turn could result in patient injury, damage, or death.

7. CONTRAINDICATIONS

AFERSMART PLUS has not been designed and cannot be sold for uses other than its intended use and as specified in this User Manual.
Do not use the AFERSMART PLUS if the treatment of the patient requires performance outside its operating range, accuracy and safety limits specified in this User Manual.
This medical device must not be used in environments where flammable anaesthetic gas mixtures may form.

8. SAFETY PHILOSOPHY

AFERSMART PLUS has been developed in accordance with the safety requirements defined by the IEC 513 standard in the event of a single fault (first failure proof).
AFERSMART PLUS's electronic architecture is based on the use of two microprocessors, one of which manages and controls the operator interface and acts as a control-regulation body, while the other acts as a system protection device.
Specifically, the control microprocessor controls all the AFERSMART PLUS actuators (pumps, electric power unit, line selection terminals) and monitors the sensors (pressure transducers, pump door opening sensors, electric power unit closing sensors, load cells, air sensor, BLD), while the protection microprocessor monitors the activities of the control microprocessor.
Thanks to this type of structure, if there is a fault in the electronics, AFERSMART PLUS puts itself in a safe condition that prevents it from being used by the operator.

9. MANUFACTURER'S LIABILITY

MEDICA S.p.A. shall be responsible for the safety, reliability and technical assistance of the equipment, if and only if it is used according to the indications contained in this User's Manual and with electrical connections conforming to the standards in force.

MEDICA has been certified and operates in compliance with and in accordance with the standards imposed by ISO 9001, ISO 13485.

10. STORAGE

After use, AFERSMART PLUS should be stored in a suitable place away from adverse weather conditions.
When cleaning the device, use a soft cloth and detergents that do not contain alcohol or harsh chemicals.
Do not use sprays or liquids directly on the device because AFERSMART PLUS is not watertight.
It is recommended that you cover AFERSMART PLUS to protect it from dust or dirt and put it in a place where it will not be affected by shocks.

11. MAINTENANCE

WARNING

- **To clean the machine, wear suitable disposable gloves and any other PPE required to minimise any possible contamination.**
- **All cleaning operations must be carried out with the machine switched off and the power cable disconnected.**
- **Pay attention to dripping during cleaning, as AFERSMART PLUS is not completely waterproof.**

11.1. CLEANING

The AFERSMART PLUS does not require sterilisation.
The AFERSMART PLUS uses a sterile, single-use tubing circuit.

To clean the AFERSMART PLUS use a soft cloth, Quaternary Ammonium Salts detergent (maximum concentration 0.5%) or alcoholic solution (maximum concentration 50% in water) without corrosive chemicals..
Be aware that AFERSMART PLUS is not waterproof so please do not spray liquids directly onto the machine.

The machine must be cleaned as often as necessary for the operating conditions. The parts generally affected by cleaning are:

- the external surface of the machine and the rear cover;
- the stainless steel connection with the venous pressure reading line;
- the display;
- the rotor and cradle of the blood pump
- the rotor and cradle of the plasma pump
- the rotor and cradle of the citrate pump
- the air bubble detector;
- the electro-clamp;

At the end of each treatment, any biological residues (blood, etc.) must be removed by using with a Sodium Hypochlorite based solution (0.05% Sodium Hypochlorite in water).
This Sodium Hypochlorite based solution (0.05%) should also be used for the stainless-steel connection to the venous pressure reading line, which should be done before each treatment.

WARNING

Prevent solution from entering the stainless-steel fitting of the venous pressure trasducer.

After cleaning, any particles or dust that may have settled on AFERSMART PLUS can be removed with a soft cloth dampened with water. If the dirt deposited is particularly stubborn, we recommend using Quaternary Ammonium Salts detergent (maximum concentration 0.5%) or alcoholic solution (maximum concentration 50% in water). Do not use sprays or liquids directly as AFERSMART PLUS is not completely watertight.

WARNING

Any cleaning procedure other than that provided for in this manual is the responsibility of the physician or organization responsible for testing its safety and effectiveness.
Other cleaning procedures may damage the machine.
Medica S.p.A. assumes no responsibility if another cleaning procedure is used.

11.2. PERIODIC INSPECTION

We recommend periodic inspection of the state of preservation of all the command, detection and control components of AFERSMART PLUS. In case of problems, we recommend that you contact technical support.

11.3. CLEANING THE ROTOR AND CRADLE OF BLOOD AND PLASMA PUMPS

If it is necessary to dismantle the blood pump rotor for cleaning, proceed as follows:

- Open the cover
- Unscrew the central Allen screw and remove the rotor.
- Use a soft cloth dampened with water to clean the rotor.
- Use Quaternary Ammonium Salts detergent (maximum concentration 0.5%) or alcoholic solution (maximum concentration 50% in water) if the rotor is heavily soiled; if the rotor is contaminated with biological fluids, use Sodium Hypochlorite based solution (0.05% Sodium Hypochlorite in water);
- Dry the rotor thoroughly;
- Proceed as described above for cleaning the cradle;
- Place the rotor on the motor shaft and gently slide it towards the inside of the cradle until it stops;
- Insert the Allen screw and screw it in as far as it will go;
- Close the cover.

11.4. CLEANING THE AIR BUBBLE DETECTOR

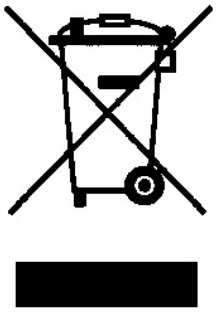
It is recommended to clean the inside of the bubble detector periodically and especially after long periods of non-use, as dust, dirt or various liquids can cover the internal sensors that determine the relevant alarm conditions.

12. DISPOSAL OF THE DEVICE

WARNING

Due to the risk of environmental pollution and contamination when disposing of the device and accessories, please follow the instructions in this manual carefully.

The medical device must be disposed of in accordance with the regulations in force in each country.
For countries belonging to the European Community, it must be disposed of in accordance with Directive 2012/19/EU and the relevant national transpositions.
It is therefore mandatory not to dispose of this Medical Device as urban waste and to collect it separately as Waste Electrical and Electronic Equipment (WEEE).
The device complies with the provisions of Directive 2012/19/EU, as implemented in the individual states.
The packaging material must be disposed of in accordance with the regulations in force in the individual countries of sale.
The following symbol indicates the separate collection of electrical and electronic equipment as required by European Directive 2012/19/EU.



AFERSMART PLUS uses a lithium battery and a rechargeable nickel-MH battery for the auxiliary power supply to the electronic circuits of the display and the audible alarm; follow the regulations in force when replacing or disposing of these batteries.

WARNING

For proper disposal of the device, also take into account applicable laws and hospital procedures regarding contaminated devices.

12.1. DISPOSAL OF PACKAGING MATERIAL

The packaging material of the medical device must be disposed of in accordance with the regulations in force in the individual countries of sale.

13. WARRANTY

The warranty period is valid for 24 months from the date on which AFERSMART PLUS is delivered to the client.
During this period, the proper functioning of the appliance is guaranteed, both in terms of the quality of the materials used and the care taken in its manufacture, provided that the user complies with the instructions in the following manual, particularly as regards maintenance operations, which must be carried out by technical personnel authorised by Medica.
Any unauthorized intervention during the warranty period will immediately cancel the warranty.
MEDICA cannot control maintenance operations carried out on the AFERSMART PLUS by unauthorised personnel and therefore declines all responsibility for the effects that such operations may have on people and/or things when using the AFERSMART PLUS.
The warranty does not cover parts and components which are defective due to negligence or carelessness in use, incorrect installation or maintenance, transport and handling performed without due care, or circumstances which cannot be directly attributed to manufacturing defects.

If the equipment has manufacturing defects, the warranty covers the resolution of such defects; however, compensation for direct or indirect damage of any kind caused to persons or property due to the period of possible inefficiency of the machine is excluded.
The costs of shipping the machine to the service centre shall be borne by the purchaser.

MEDICA, moreover, declines all responsibility for any damage which may be caused, directly or indirectly, to persons or things as a result of failure to observe the instructions given in the instructions, especially those concerning warnings on the installation, use and maintenance of AFERSMART PLUS.
Parts replaced under warranty remain the property of MEDICA.

For any disputes that may arise, Medica designates the Court of Modena as the only competent court, unless otherwise specified by law.
The purchase of the machine together with the delivery of this instruction manual constitutes full acceptance of the above warranty conditions; moreover, it cancels any other implicit or explicit warranty previously formulated.
For further information or clarifications concerning use, maintenance and technical assistance please contact Medica SpA or Medica personnel at the following addresses:

MEDICA S.p.A. Via Degli Artigiani, 7 41036 MEDOLLA MODENA - ITALY	Tel. +39 (0)535 51159 Fax +39 (0)535 52605 e-mail: info@medica-spa.com home page: www.medica-spa.com

Marketing office	sales@medica-spa.com
Quality/Regulatory office	quality@medica-spa.com
Service office	service-dma@medica-spa.com

14. SAFETY WARNINGS AND PRECAUTIONS

Warnings according to IEC 60601-2-16

14.1. GENERAL WARNINGS FOR RISK PREVENTION

- This manual must be read and understood before starting to work with AFERSMART PLUS. MEDICA will not be held responsible in any case where accidents to persons or property occur as a result of failure to follow or incorrect application of the instructions contained in this manual.
- This manual must always be kept near the machine, in a place where it is easily accessible and within the operators' reach and must be stored in such a way as to guarantee its durability and integrity. If this manual is lost, request a copy from the manufacturer or authorised distributors.
- For the safety of the patient, the choice of methods of use, as well as the areas of application, is the exclusive responsibility of doctors with experience in the treatment of the pathologies involved. The operation of AFERSMART PLUS, as well as by the doctor, can be managed by nursing staff under the supervision of a responsible doctor.

14.2. WARNINGS FOR THE PREVENTION OF RISKS RELATED TO THE POWER SUPPLY SYSTEM

- To connect the device to the mains, use only the specific mains cable supplied with the device.
- The power cable may only be replaced with an equivalent cable of the same length and cross-section. Contact the MEDICA spa service department or the authorized distributor for replacement.
- Avoid using extension cables or adapters for the power cable.
- Do not cut or remove the ground contact from the power socket.
- Make sure that the nominal value of the power supply is compatible with the technical characteristics of the device and that the electrical system complies with the applicable electrical standards.
- If the AFERSMART PLUS is working at the same time as other equipment, it is possible to make the equipotential connection using the special terminal located on the rear panel of the machine and marked with the following symbol:

14.3. WARNINGS FOR THE PREVENTION OF RISKS DUE TO THE CHOICE OF TREATMENT LIQUIDS

• The improper use of bags of concentrated liquids can cause damage to the patient
• Since the machines do not monitor the composition of the dialysate based on conductivity, the use of improper concentrates with a certain machine can cause injury to the patient.
• The use of infusion fluids suitable for the chosen treatment is recommended
• Use only replacement solutions in compliance with the regulations and standards in force. Also check, before use, that there is no precipitate in the solutions.

14.4. WARNINGS FOR CROSS-CONTAMINATION PREVENTION BETWEEN PATIENTS

- In order to prevent cross-contamination between patients it is necessary:
- Clean the stainless steel connection for venous pressure reading before each use and after use.
- Use AFERSMART PLUS only with the disposable devices foreseen; the use of medical devices different from those foreseen releases Medica from any liability related to damages to patients, users and/or things.
- The disposable kit is supplied sterile and non-pyrogenic; check the integrity of the protective wrapping and avoid using it if there are tears, damage to the wrapping or if the expiry date has passed.
- The kit is a single-use device, which means that it should only be used once.
- Reuse or re-sterilisation of sterile, single-use kits may compromise the structural integrity and/or lead to damage of the tubing set, which may in turn lead to patient illness, injury or death.
- The risk of exchange of infection between patients caused by contamination of the pressure transducer connection is prevented by the presence of 0.22 µm hydrophobic luer-lock filters on the single-use line that are immovably attached. The operator must not use lines without these filters.
- Handle the DISPOSABLE kit with the utmost care; the disassembly of the circuits after the treatment is finished must be carried out using disposable gloves for the operator's safety and taking all necessary precautions to reduce the risk of exposure or transmission of potentially contaminating infectious agents such as HIV or hepatitis viruses.
- For the protection and safety of the patient, the choice of methods of use, as well as the areas of application, is the exclusive responsibility of doctors with experience in the treatment of the pathologies involved. The operation of AFERSMART PLUS, as well as by the doctor, can be managed by nursing staff under the supervision of a responsible doctor.

14.5. WARNINGS TO PREVENT RISKS ASSOCIATED WITH CONNECTING AND DISCONNECTING THE PATIENT TO THE MEDICAL DEVICE

In order to correctly connect and disconnect the patient, it is necessary to:

- ensure such operations are performed by healthcare personnel, taking care that the luer-lock attachments, once the protective cap has been removed, do not come into contact with different materials or surfaces and are immediately inserted into the appropriate catheter or fistula needle attachments.
- securely anchor arterial and venous accesses to the patient using appropriate patches.
- take note that any disconnection of the return to the patient is signalled by measuring the venous pressure with a subsequent alarm at a value below +5mmHg.

14.6. WARNINGS FOR THE PREVENTION OF RISKS RELATED TO THE INSTALLATION AND USE OF THE MEDICAL DEVICE DISPOSABLE KIT

In order to reduce the risks arising from incorrect connection of the disposable device (extracorporeal circuit) it is necessary that:

- the operator carefully read and follow the instructions in the chapters on line assembly for individual treatments.
- the operator follows the instructions displayed in the form of images on the monitor of the device which help in the correct assembly of the single-use lines.
- the disposable set is used immediately after opening and should not be delayed.
- any contact between the disposable tubing set and chemicals or solvents that could be hazardous to its integrity is avoided. If in doubt, do not use the Disposable Tube Set.

Refer to the manufacturer's information on the disposable kit for the use of the disposable accessory device.
Only the 30cc syringes supplied in the disposable set should be used.

14.7. WARNINGS TO PREVENT THE RISK OF BLOOD LOSS FROM THE DISPOSABLE KIT

In order to reduce the risk of blood loss from the extracorporeal circuit:

- MEDICA recommends changing the circuits within the maximum duration time, since the pumping parts of the disposable AFERSMART PLUS kit are subjected to mechanical stress due to the blood pump rollers. In particular, following the mechanical stress tests performed by MEDICA under operating conditions of maximum flow, 250 ml/min, a maximum duration time of 24 hours has been ascertained, so MEDICA recommends replacing the kit after these durations, if there are no situations that require it to be replaced beforehand.
- Any disconnection/loss on return to the patient is signalled by measuring the venous pressure with consequent alarm at a value lower than +5mmHg.
- Avoid pulling the kit tubes with blood connected to the patient.
- Before the priming phase preceding the treatment, check that all the connections of the disposable kit are screwed on.

14.8. WARNINGS TO PREVENT THE RISK OF HARM TO THE PATIENT

In order to reduce the risk of harm to the patient:

- The operator should not make repeated alarm silences without resolving the cause and understanding the nature of the problem and the resulting hazard.
- The alarm system cannot completely prevent the possibility of blood leakage into the environment, especially if the pipe sets are not properly installed.
- When there is the activation of any alarm, refer to this User Manual or the On-line Guide contained in the second line from above in the user interface and follow the instructions.
- During the temporary disconnection of the protection systems concerning the minimum venous pressure threshold (for a time of 10 seconds) and BLD (for a time of 30 seconds), the operator is responsible for monitoring the parameters.

To understand the nature of the problem, the operator may refer to the chapter on alarms and the HELP ONLINE function.

14.9. WARNINGS TO PREVENT THE RISK OF CAUSING HAEMOLYSIS

In order to reduce the risk of haemolysis:

- the operator should avoid reducing the tube cross section of extracorporeal lines.

14.10. WARNINGS TO PREVENT THE RISK OF LOSS OF FUNCTION OF THE AIR DETECTION SYSTEM IN THE VENOUS CIRCUIT

The air detection sensor may malfunction if clots form in the line. This risk is made unlikely by the presence of a specially designed conical filter inside the venous bubble catcher.

Excessive application of cleaning solutions on ultrasonic sensor of the bubble detector housing may cause loss of sensitivity of the bubble detector.

The operator must be careful that in the event of negative pressures there may be an entry of air into the extracorporeal circuit at the connection points downstream of the air sensor; this may occur in the case of applications of high blood flows, using vascular accesses that are not adequate to properly support these flows.

14.11. WARNINGS FOR THE PREVENTION OF RISKS DURING NORMAL USE

- Medical and paramedical staff must be present throughout the treatment.
- The sterile tubing sets used as accessories of the AFERSMART PLUS active medical device must be used under the supervision of a doctor
- Sterile tubing sets should only be used if the pouch is undamaged and the expiration date has not passed.
- Open the packaging carefully and use aseptic techniques to preserve the sterility of the sterile tubing set.
- Use only disposable kits compatible with the AFERSMART PLUS active medical device and approved by the manufacturer.
- The device is not intended to be sterilized. The device uses STERILE and DISPOSABLE tubing sets as accessories to carry out the required treatments.
- Do not suspend other objects from the hooks of the scales as this alters the measurement of the fluid balance made by the device.
- The medical device must not operate if exposed to direct sunlight, especially if concentrated on the BLD sensor.
- The hooks available on the device are intended for the bags for the solutions necessary for the treatment. Do not suspend other objects from the hooks of the scales as this alters the measurement of the fluid balance made by the device.
- Press only one key at a time on the control panel, as the device will only accept the last key pressed.
- If the display becomes black or unreadable during treatment, the treatment must be stopped and the Technical Assistance Service must be informed.
- The manufacturer assumes no liability of any kind in the event of accidents or damage to patients or users resulting from the incorrect use of the instructions contained in the User Manual.
- Before working on the AFERSMART PLUS, make sure that all the operations required for a complete and safe installation have been carried out, also make sure that the stability of the system is adequate and that the control unit has been fastened correctly to the trolley.
- When moving AFERSMART PLUS, it must be pushed from the rear using the handles provided.
- It is forbidden to lift the equipment fixed to the trolley. To lift the appliance use the lower part of the trolley.
- The equipment complies with Electromagnetic Compatibility standards. However, it is a good precaution not to use the appliance in the immediate vicinity of high-powered equipment or equipment which by its nature emits strong electromagnetic fields. (SEE ELECTROMAGNETIC COMPATIBILITY WARNINGS CHAPTER).
- AFERSMART PLUS is not intended for use in a residential environment. It does not provide adequate protection from electromagnetic interference in such an environment.
- Put brakes on the wheels of the AMD trolley to limit its movement during use.
- It is recommended to use infusion fluids appropriate for the chosen treatment.
- If alarms occur, act according to the instructions in this manual, in the chapter on alarms or activate the HELP ONLINE function of the AMD and follow its instructions.
- The operator is recommended to set the treatment parameters before starting the treatment, following the instructions in the treatment description chapters.
- The equipment enables healthcare professionals to carry out the various treatments according to the parameters and therapeutic uses listed in the bibliography to date.
- The choice of the operating parameters of the equipment and the evaluation of the contraindications for each treatment are the responsibility of the user doctor.
- For each treatment, the choice of filter (see ACCESSORIES chapter) is the responsibility of the user, depending on the type of therapy carried out.
- AFERSMART PLUS does not handle concentrated dialysis fluids.
- AFERSMART PLUS does not perform on line HDF and on line HF treatments.
- If the suction (arterial) pressure is very negative, less than -300 mmHg, the flow value of the blood pump is reduced and the accuracy of its regulation is reduced. Consequently, the effectiveness of the treatment will also be reduced.
- It is recommended that the operator and responsible organisation do not use electro-medical equipment with leakage currents at the patient's applied parts exceeding the maximum currents for the product

classification given in the SYSTEM DESCRIPTION chapter in the patient's environment in combination with central venous catheters with atrial location.

- OPERATOR'S POSITION during treatment:
  - If the operator is working on the device or the patient, the operator is at a distance of approximately 50 cm from the device.
  - When the operator is away from the device, the operator must be within a safe distance to hear auditory alarms and/or see visual alarms.
- The device MUST NOT BE USED in an environment RICH IN OXYGEN or in the presence of FLAMMABLE ANESTHETICS, FLAMMABLE OR EXPLOSIVE AGENTS OR GASES.

WARNING

Leakage of liquid from the batteries could damage the device, so it is necessary to remove the batteries if the device is not to be used for an extended period of time. Service operators should check the batteries at least once a year during preventive maintenance of the device (see service manual). If the battery check is negative, the service technician must replace the batteries (see service manual).

- The maximum load that can be applied to the anchorage system of the stand is 10 kg, as the worst case involves the use of 1 of 5-litre bag per hook. The weight can be divided between the various hooks but must never exceed the maximum load indicated (5 Kg maximum per hook).
- Any obstruction in the passage of fluids in the EXTRACORPOREAL CIRCUIT (such as a tight kink in the blood line or a cannula of too small a diameter) may cause haemolysis and this DANGER SITUATION for the patient may not be detected by the device's PROTECTION SYSTEM.
- The alarm system cannot completely prevent the possibility of blood loss into the environment, especially if the tubing sets are not properly installed.
- Avoid pulling the tubing set with blood connected to the patient.
- Avoid using a mobile phone near the device.
- Ensure that the control panel and graphical display function properly and that the information contained therein is as expected. Do not use the device if there is a discrepancy between the parameters on the display and the parameters expected by the operator. In this case, it is necessary to inform the Technical Assistance Service.
- When any alarm is triggered, refer to this User's Manual or the HELP ONLINE function by pressing the appropriate key.
- The device tells the operator when the fluid bags used during priming need to be replaced. Refer to the fluid bag replacement instructions.
- Before the priming step prior to treatment, check that all disposable kit connections are screwed in place.

14.12. WARNINGS FOR THE PREVENTION OF RISKS IN THE PHASE OF ORDINARY OR EXTRAORDINARY MAINTENANCE

- Refer to this User's Manual (see next chapter) and the Service Manual for the preventive maintenance period.
- Do not carry out repairs or service without training or authorisation from the manufacturer or its authorised distributors. The device contains no parts that can be repaired by the operator. Perform regular maintenance on the device as prescribed by the manufacturer, referring to this User's Manual and the Service Manual.
- Do not modify the device without the manufacturer's permission.
- Before carrying out any cleaning or maintenance work on the device, disconnect it from the power socket.
- Before connecting the machine to the mains, check that the power supply corresponds to that indicated on the label on the back of the machine.
- Make sure that the power outlet to which the machine is connected has electrical protection and a ground connection.
- Connect the machine to the power socket without using adapters between the plug and the socket.

- Before opening and inspecting the machine, make sure that the main switch is in the OFF (O) position and that the power cord is disconnected from the power socket.
- Do not connect or disconnect the power plug with wet or damp hands.
- If liquid has accidentally entered the machine during use, switch off the machine immediately and pull out the power plug, then have the interior inspected by personnel authorised by the manufacturer.
- Disconnect the power plug by grasping it with your hand and never by pulling the cord.
- Do not damage or remove labels and identification symbols from panels or the structure of the device. If symbols or labels are illegible or missing, they must be restored or replaced by a service technician.
- Do not use detergents or chemicals that can damage the exterior surface of the device.
- Do not use any type of lubricants on the internal or external components of the device as they may adversely affect the operation of the device.
- The accuracy of the device in the control and balancing of the patient's fluids depends largely on a correct calibration of the weight measurement system applied to the bag hook. Check the calibration of the load cells and other sensors of the device at the times indicated in the service manual.
- Remove bags from the device stand as it moves.

15. SAFETY WARNING FOR SERVICE OPERATORS

WARNING

Do not modify this device without the manufacturer's authorisation.

Do not carry out repairs or servicing without the necessary training or authorisation from the manufacturer or its authorised distributors.

- Switch off the device and disconnect the power cord from the mains before opening the device casing for servicing.
- The manufacturer accepts no liability whatsoever for accidents or damage to patients or users resulting from incorrect use of the instructions in the Service Manual.
- Service technicians must perform preventive maintenance once a year (see Service Manual).
- Service technicians must check the batteries during preventive maintenance once a year (see Service Manual). If the battery check is negative, the service operator must replace the batteries (see Service Manual).

WARNING

Leakage of liquid from the batteries may damage the device, so remove the batteries if you do not plan to use the device for an extended period of time.

16. INSTALLATION INSTRUCTIONS

The following instructions relate to the installation of the device.

WARNING:
READ THIS MANUAL CAREFULLY BEFORE USING THE EQUIPMENT.

AFERSMART PLUS is supplied unassembled, in a special cardboard box.
The contents of each cardboard box are listed below:

1. DMA body (contained in additional packaging)
2. Trolley with scales
3. IV Pole
4. Power cord
5. N ° 4 screws for fixing the machine on the trolley
6. N°1 screw for fixing the IV Pole on the trolley
7. User manual

The parts are fitted into slots in the protective material inside the enclosure.

NOTE

Do not lift the machine body from the carton by gripping the plastic supports

Remove the device from the packaging.

Connect the device to the power supply.

- Check that the voltage and frequency of the supplied Power System are the same as those listed on the label located on the rear panel.
- Verify the presence of power and ground connections to the Power System or there may be potential hazards to the user and patient.

WARNING

To ensure that the appliance meets the specifications of the assigned insulation class, it is important that the protective grounding in the electrical installation complies with the applicable standards.

- Avoid using extension cords or adapters to the power cord.
- Avoid cutting or removing the grounding contact from the power plug.
- The device must not be placed and used in a room with unfavourable conditions, such as rooms with excessively high temperatures, excessive humidity, high artificial light or too much sunshine, a high amount of dust, or in rooms with aggressive, flammable substances or anaesthetic gases in the air.
- The working position of the DMA must be stable and without any tilting, vibration or impact with other objects.
- Keep the plug of the power cable easily accessible for disconnection from the mains in case of need.

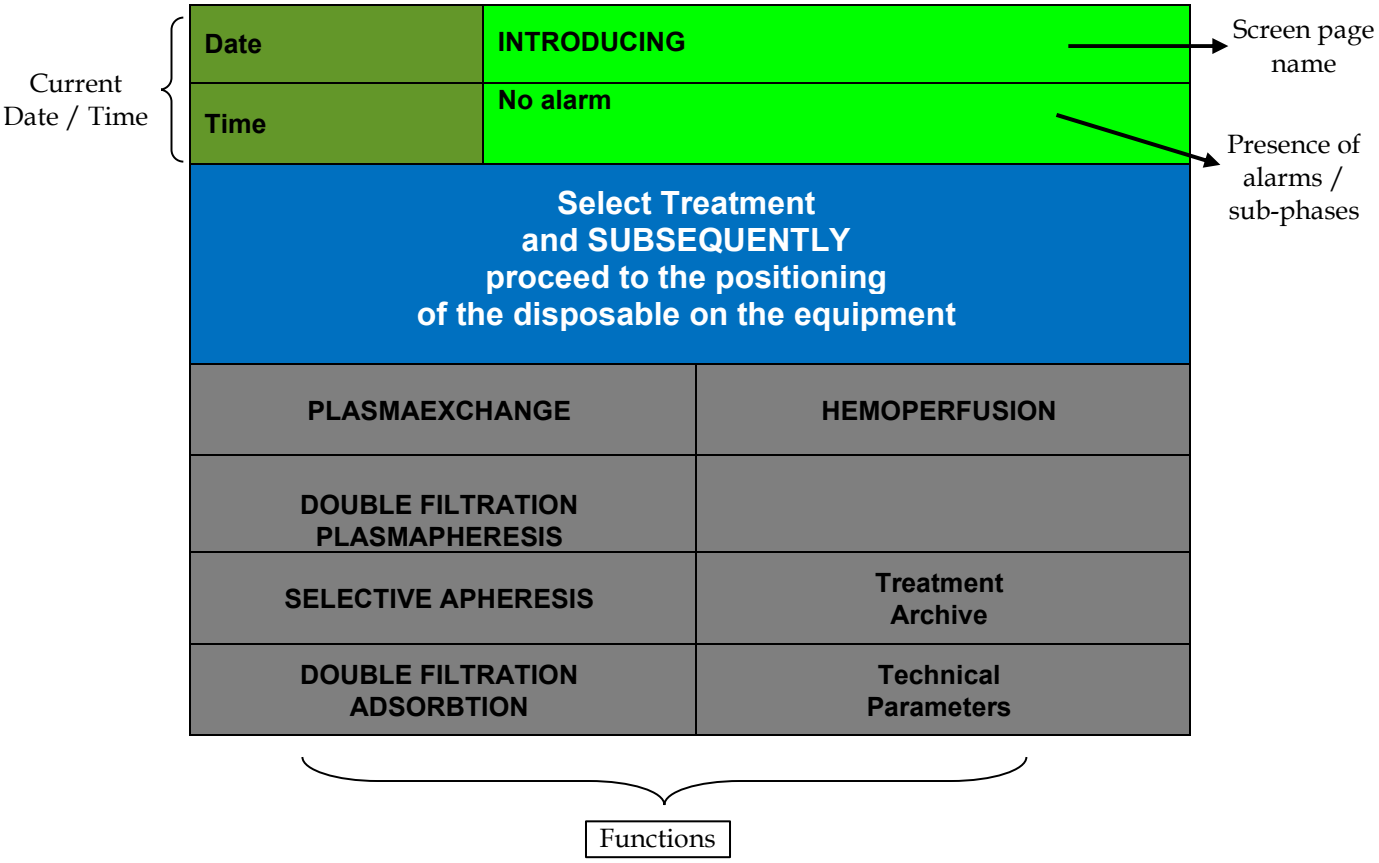
17. SYSTEM ACTIVATION

WARNING

The device is CLASS I, it is important that the protective grounding in the electrical installation complies with the applicable standards.

Switch on the AMD by setting the main switch to the "I" position.

After an appropriate sound signal has been emitted for a few seconds, the display will show the presentation image for a few seconds and then the "PRESENTATION" screen will appear.



NOTE

If the screen darkens or becomes unreadable during this phase, terminate the phase and notify the technical assistance service.

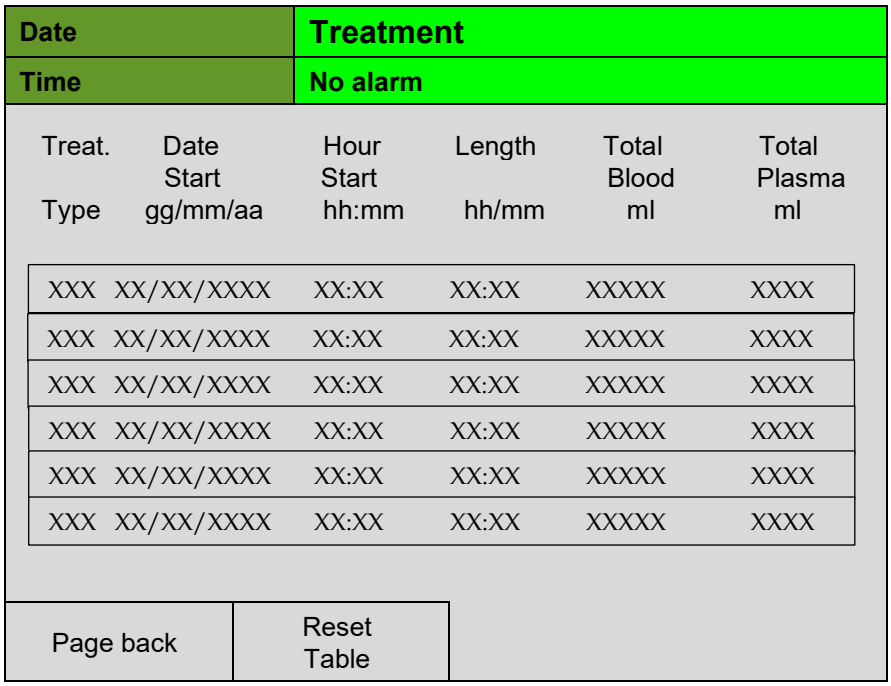
At this point, the machine will display the following functions in addition to the summary description of the AFERSMART PLUS characteristic:

PLASMAEXCHANGE	**HEMOPERFUSION**
DOUBLE FILTRATION PLASMAPHERESIS	
SELECTIVE APHERESIS	**Treatment Archive**
DOUBLE FILTRATION ADSORBTION	**Technical Parameters**

Use the knob on the display panel to select one of the functions listed above; the box containing the selected function will appear with a yellow background.

In the following screens, the term PLASMAPHERESIS appears instead of RHEOPHERESIS, with reference to the definition of "Intended Use" as per Chapter 3, it should be noted that, for the purposes of the user, the terms PLASMAPHERESIS and RHEOPHERESIS, from a point of view of functionality and clinical use of AFERSMART PLUS, are to be considered synonymous and have the same meaning.

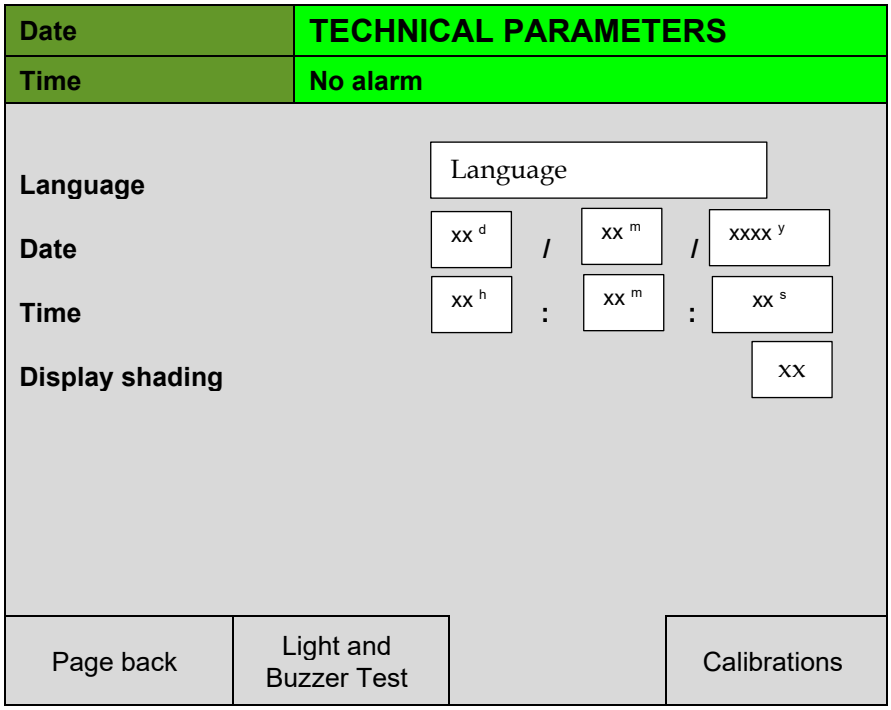
17.1. TREATMENT ARCHIVE



- **Treatment:** It indicates the type of treatment.
- **Date Start:** It indicates the date when starts the treatment.
- **Hour Start:** It indicates the time when starts the treatment.
- **Length:** It indicates the duration of treatment.
- **Total Blood:** It indicates the processed blood in ml during the treatment.
- **Total Plasma:** It indicates the processed plasma in ml during the treatment.

Use the rotary knob below the display to select one of the functions listed above; the field with the selected function has a yellow background; press the rotary knob to confirm the selection.

17.2. TECHNICAL PARAMETERS



WARNING

Editable values are those within white boxes, while those in grey boxes are informative values that cannot be changed.

The <Technical Parameters> function allows you to control the settings for

- **Language**: it enables the activation of display messages in the selected language
- **Date**: it adjusts the current date
- **Time**: it adjusts the current time
- **Display shading**: it adjusts the intensity of the display brightness in a range between 0 and 100

To change any value, select it using the rotary control (making sure it is highlighted in yellow).
Press the knob to enter edit mode (the box will turn blue); change the value by turning the knob, press it again to save the change.

NOTE

If the "Language" or "Date" or "Time" fields are modified it is necessary restart AFERsmart Plus to make the changes effective.

Pressing < Light and Buzzer Test > it allows to perform the alarm system test.

Pressing <Calibrations> it allows to enter the calibration page.

To exit the screen, select the <Page back> button and confirm by pressing the knob.

17.2.1. Calibration page

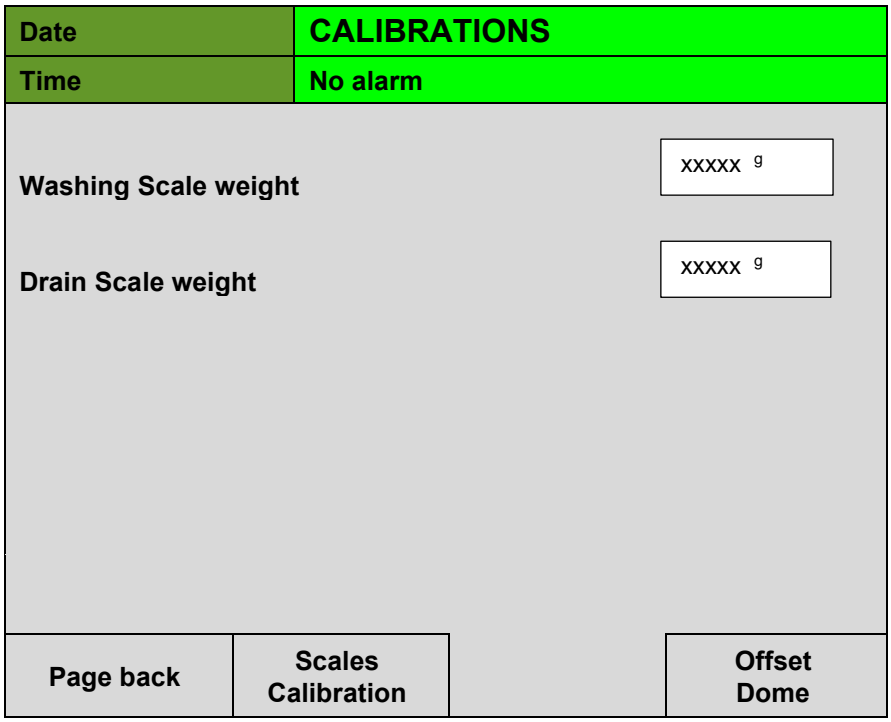
The <Calibrations> function allows you to calibrate and check:

- Scales
- Offset of the DOME transducers

WARNING

The editable values are those inside the white boxes, while those in the grey boxes are information values that cannot be changed.

In the event that the AMD provides alarms that indicate failures of parts of the same, contact technical assistance.

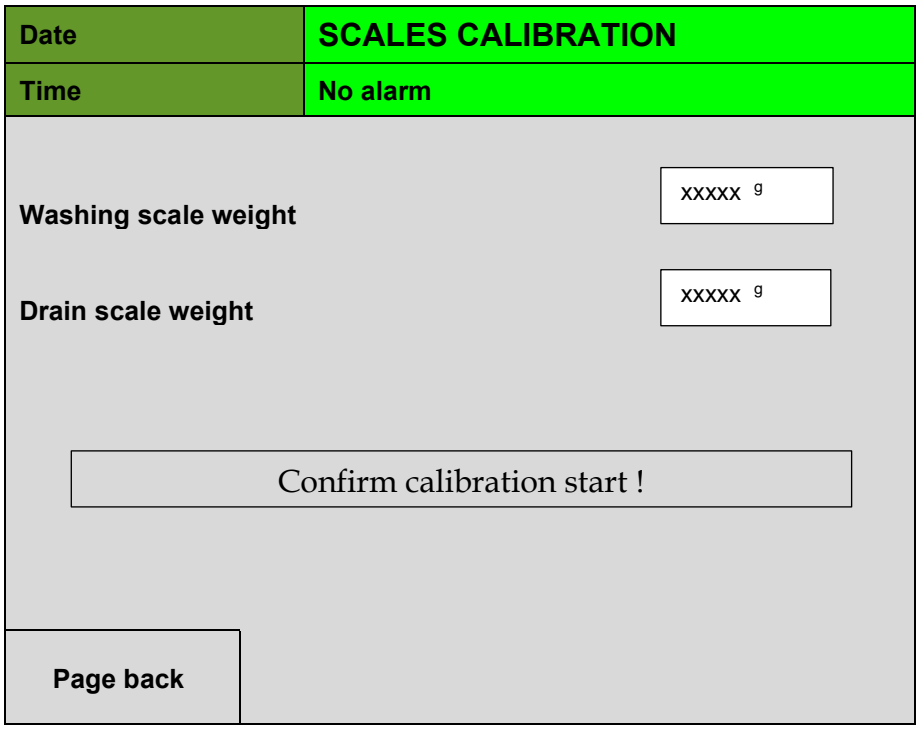


Press the <Page back> key to return to the "INTRODUCING" page

17.2.1.1. Scales Calibration

It is possible to calibrate the 0 value of the scales if the value read on the CALIBRATION page is not optimal.

To be able to carry out the calibration, press the <Calibration Scale> key.



Then remove any weight in the scales and press the < Confirm calibration start !> and <Remove all weight and confirm!> keys in sequence and wait for the end of calibration phase.

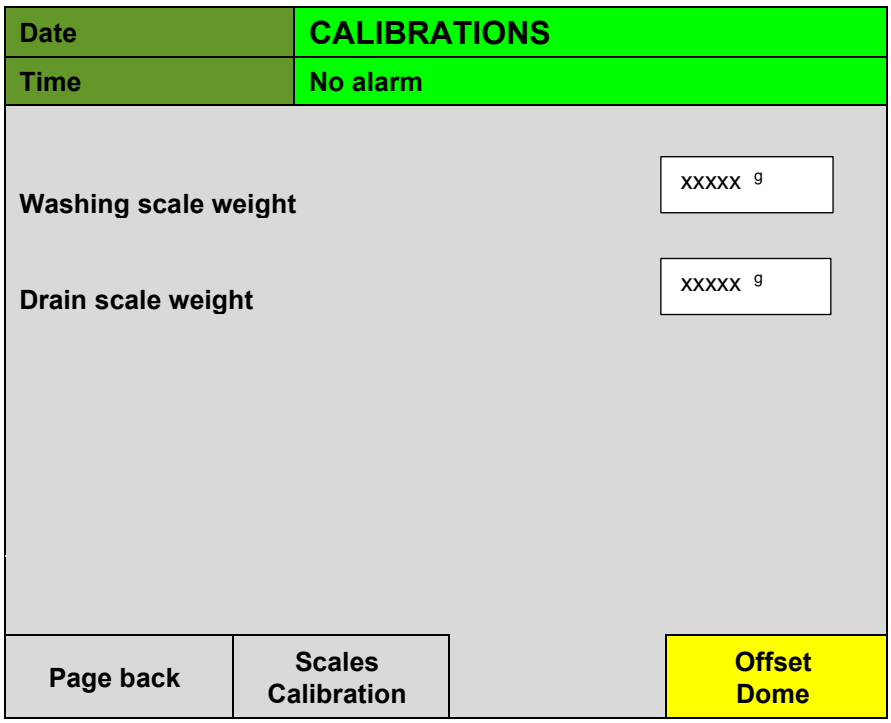
If the calibration is successful, the <End Calibration!> key will appear.

Press the <End Calibration> and <Page back> keys in sequence to return to the CALIBRATION page

17.2.1.2. Pressures offset calibration

It is possible to calibrate the 0 value of the blood pressure, prefilter, plasma and FILTRATE sensors if the value read on the page during the treatment is not optimal.

To proceed with the calibration, press the <Offset Dome> key.



Press the <Page back> key to return to the "INTRODUCING" page

18. BATTERY FUNCTIONALITY

AFERSMART PLUS is equipped with a 9V Ni-MH rechargeable battery with a capacity of 160mAh (Please note that this battery does not refer to the UPS option).
Its purpose is to keep the warning buzzer on in the event of an unwanted power failure.
This battery will activate its function if:

- The main button is on "I", the battery is always charging;
- During an interruption of the main power supply, the system shuts down, interrupting any treatment in progress. If the power switch remains in the "I" position, the buzzer sounds to indicate the alarm status and the battery is not being charged. When mains power is restored, the alarm signal goes off and the battery returns to its charged state.

If the battery state of charge is not optimal, the System activates a warning level alarm with the message: Battery voltage. The alarm is resettable and does not affect the execution of the treatment in progress.

WARNING

It is recommended to replace the battery at least every 2 years.

19. OPERATIONS OF USE

NOTE

To allow the machine electronics to reach operating temperature, it is advisable to leave the machine on with the main page displayed for about 20 minutes

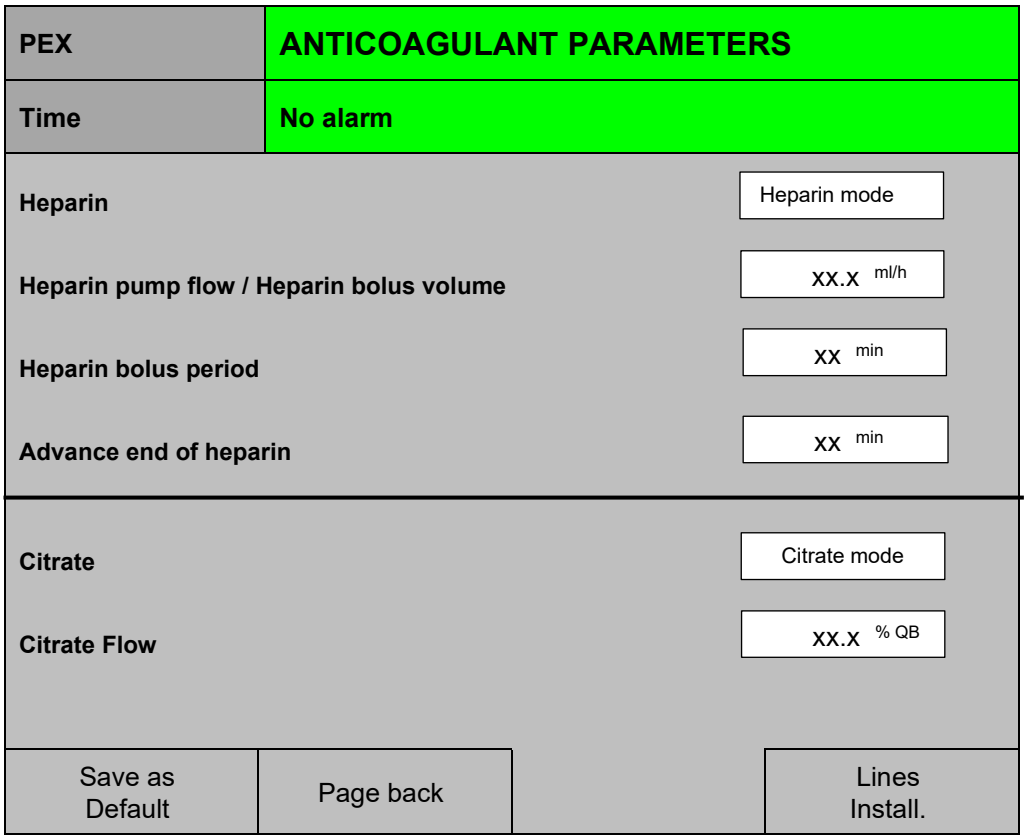
19.1. PLASMAEXCHANGE

19.1.1. PREPARATION

19.1.1.1. ANTICOAGULANT PARAMETERS

It is possible to set / modify the parameters related to the anticoagulant before entering in the priming procedure. These parameters can be modified even during the treatment phase, by pressing < Parameters> key.

- Heparin: Disabled/ Continue/ Bolus
- Heparin pump flow (available only in "Continue" mode): [0.1 – 20.0] [ml/h]
- Heparin bolus volume (available only in "Bolus" mode): [0.1 – 5.0] [ml/h]
- Heparin bolus period (available only in "Bolus" mode): [5 – 60] [min]
- Advance end of heparin: [0 – 30] [min]
- Citrate: Disabled/ Enabled
- Citrate Flow (available only in "Enabled" mode) : [0.5 – 10.0] [% QB]



NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

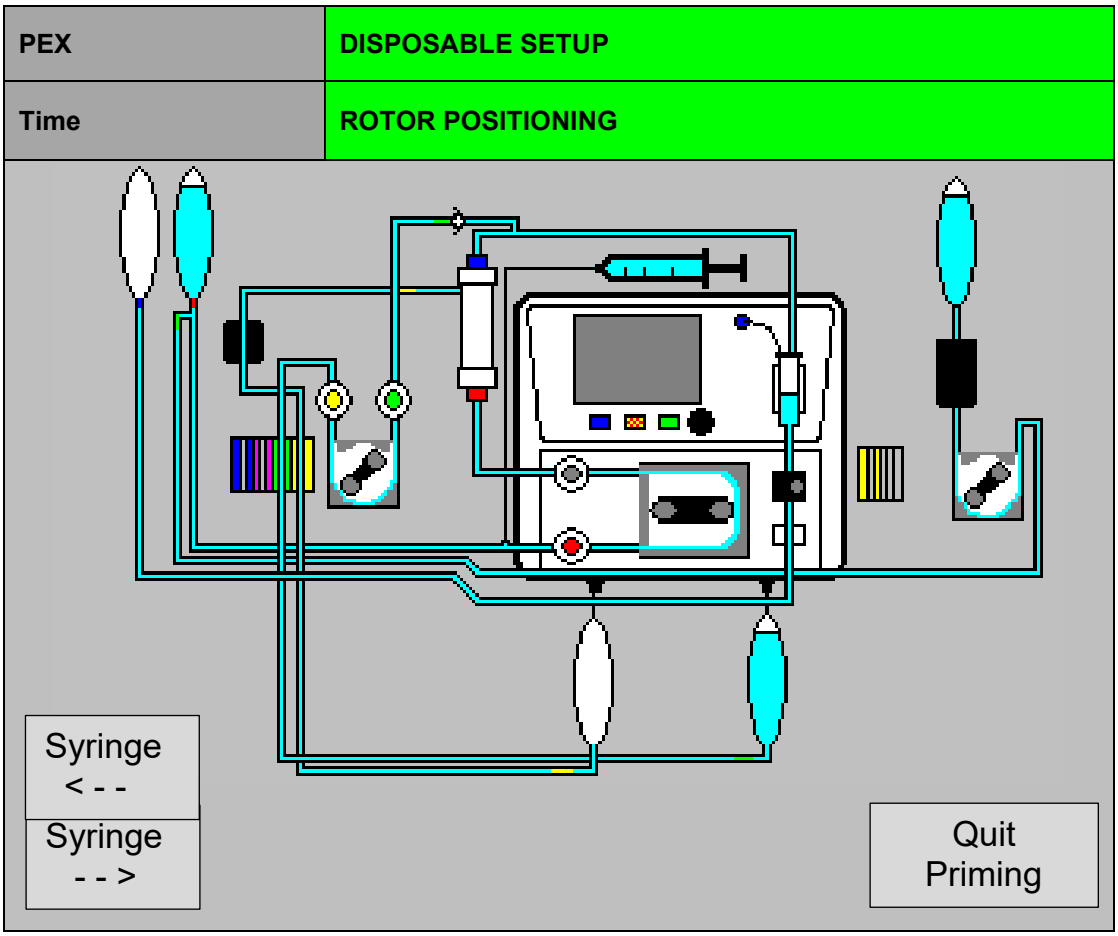
Press "Save as Default" to save set parameters and make them available for the next treatments

Press the <Page back> key to return to the "INTRODUCING" page

Press the <Lines Install.> key to proceed to the "DISPOSABLE SETUP" page

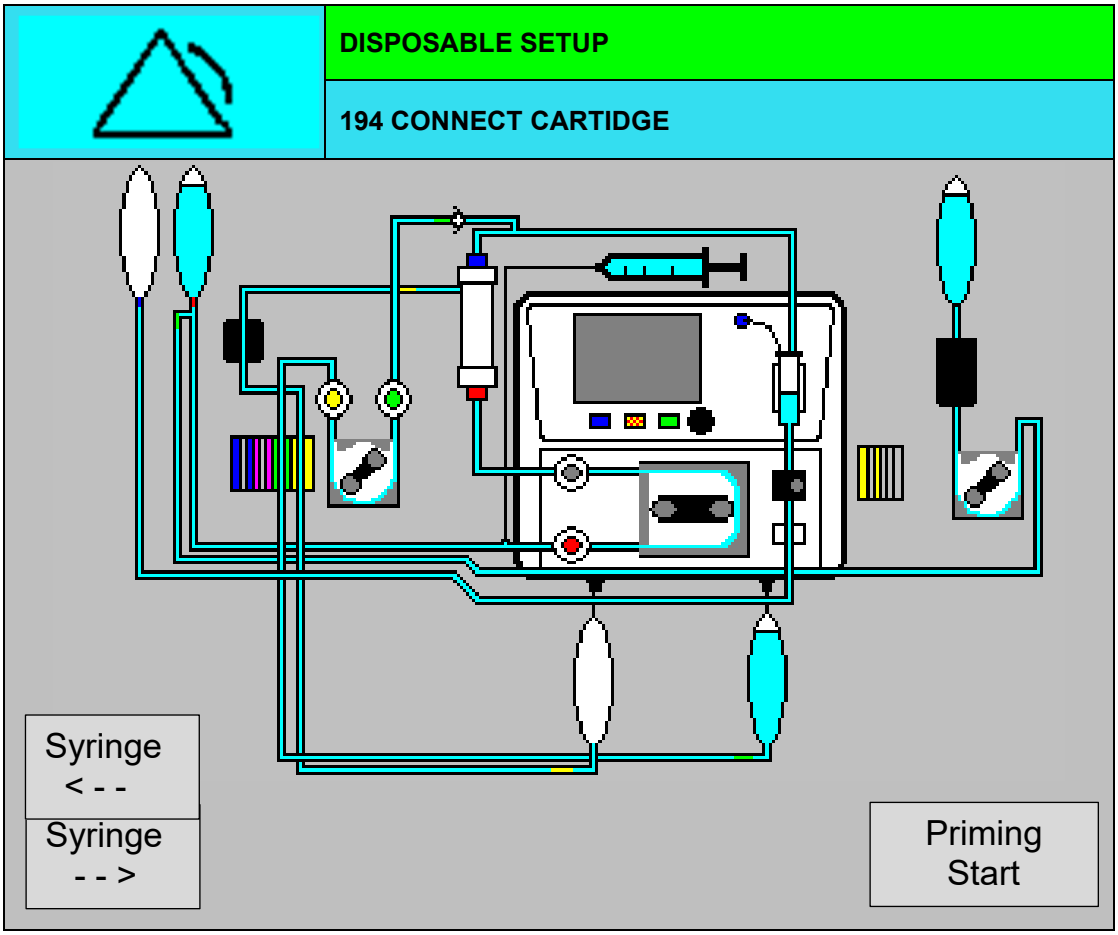
19.1.1.2. DISPOSABLE SETUP

On this page it is possible to install the disposable, the Plasmafilter and the bags needed to perform the PEX treatment and its priming



Once entering this page AFERsmart PLUS will execute the automatic pump rotors positioning (Blood, Plasma and Citrate) needed to ease the installation of Blood/Citrate and Plasma tubing set.

After the "ROTORS POSITIONING" phase the "194 CONNECT CARTRIDGE" message will appear, the venous electroclamp will open and the red light over the clamp will switch off and it will be possible to install the disposable kit, the Plasmafilter and the bags as shown on the screen



At this phase make sure that the hooks of the scale are completely free.

The AFERSMART PLUS Kit is enclosed in a paper-film envelope, inside are:

Semi-finished arterial and Citrate line (identified with red- and green-coloured components)
Semi-finished venous line (identified with blue-coloured components)
Semi-finished plasma line (identified with yellow components) including separated waste line

- Hang the Priming Solutions and the citrate solution (if Citrate anticoagulation was set) on the stand pole.
- Hang to the washing scale the Plasma waste container
- Hang to the drain scale the Plasma fresh container
- Remove the plasma line from the bag
- Open the plasma pump cover (ref. 1 Chapter 2.3)
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  Close the plasma pump lid
- Open the UF pressure transducer and connect the relevant UF DOME (ref. 3 Chapter 2.3)

- Open the plasma pressure transducer and connect the corresponding plasma DOME (ref. 2 Chapter 2.3)
- Place the plasma filter in its support (ref. 6 Chapter 2.3)
- Insert the separated waste line cuvette into the BLD with the nose pointing outward (ref. 5 Chapter 2.3)
- Connect the yellow Hansen connection of the separated waste line to the upper lateral plasma compartment port of the plasma filter
- Insert the inlet part of the separated waste line into clamp n °1 and connect it to the waste plasma container on the washing scale
- Insert the UF line (inlet part of plasma line) into clamp n°3 and connect it to the fresh plasma container on the drain scale

WARNING

Take great care when inserting each line inside each selection clamp. Make sure that all the lines are firmly in place and that the color on the line corresponds to the color on the clamp.

- If Citrate anticoagulation was set:
  - Place the ACD chamber in the appropriate support (ref. 4 Chapter 2.4), inserting it from top to bottom
  - Open the ACD pump cover (ref. 3 Chapter 2.4),
  - Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  - Close the lid of the ACD pump
  - Connect the ACD input with the white clamp to a citrate bag positioned on the stand pole
- Open the blood pump cover (ref. 2 Chapter 2.1),
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth.
  Close blood pump cover.
- Open the arterial pressure transducer and connect the relative arterial DOME (ref. 5 Chapter 2.1),
- Open the prefilter pressure transducer and connect the relative prefilter DOME (ref. 6 Chapter 2.1),
- Connect the red adapter at the outlet of the arterial line to the inlet (lower part) of the plasmafilter.
- If heparin anticoagulation was set:
  - Connect the heparin tube fitting to the 30-cc syringe previously filled with heparinized solution

  Insert the syringe in its seat, using the arrows < ← > and < → > to position the cursor

WARNING

After inserting the syringe, do not move the piston of the anticoagulant pump manually

- Connect the arterial line to the priming solution bag positioned on the stand pole
- Take the venous line from the envelope
- Place the venous bubble catcher in the appropriate support (ref. 8 Chapter 2.1), by inserting it from top to bottom
- Connect the hydrophobic Venous Pressure Transducer Protector Luer Lock to the Venous Pressure Transducer (ref. 7 Chapter 2.1),

WARNING

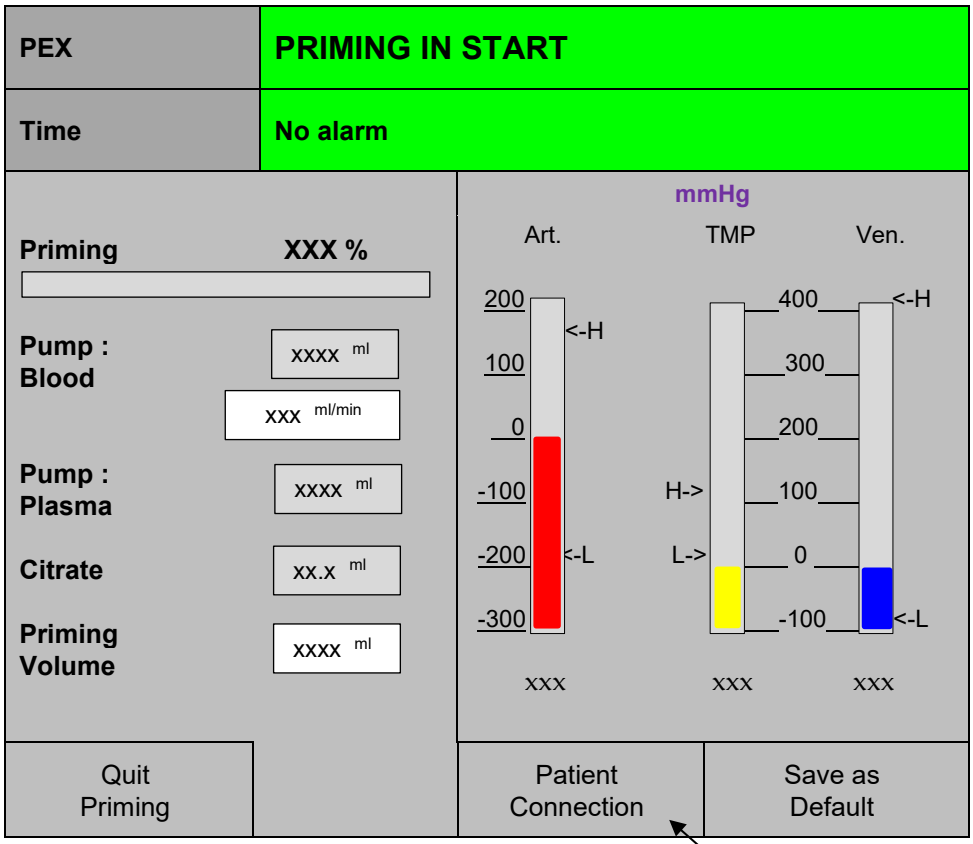
To correctly mount the blood catcher to the conical attachment of the restitution pressure transducer you need to:

- **Insert the blood catcher fully making it rotate slightly until it locks.**
- **Turn the colored ring anti-clockwise to prevent disconnection.**

- Connect the blue adapter at the inlet of the venous line to the outlet (Upper part) of the Plasmafilter.
- Insert the tube coming out of the venous bubble catcher into the air / blood sensor (ref. 3 Chapter 2.1) and then into the electroclamp (ref. 4 Chapter 2.1)
- Place the venous waste bag already connected to the venous line on the stand pole (ref. 2 Chapter 2.6)
- Connect the outlet of Plasma line to the connector near the Plasmafilter outlet of the venous line

19.1.1.3. Priming

Make sure you have connected the circuit as described above.
Select and confirm the <Priming Start> function; this takes you to the "PRIMING IN START" screen.



If no anomalies have occurred, this button appears at the end of the Priming.

The page displays:

- Pump: Blood (volume) [ml];
- Pump: Blood (speed) [ml/min]: adjustable from 5 to 250;
- Pump: Plasma (volume) [ml];
- Citrate (pump volume) [ml];
- Priming volume (total) [ml]: adjustable from 1000 to 4000;
- The current value of the Arterial (RED), TMP (YELLOW) and Venous (BLUE) pressures and the related alarm thresholds.

AFERSMART PLUS then begins the automatic priming procedure.

NOTE

To temporarily stop priming, simply press the <START / STOP> button once. Press this button again to restart priming.

Press "Save as Default" to save set parameters and make them available for the next treatments

During Priming it is advisable to adjust the level in the restitution drip chamber. To do this, operate as follows:

- Close the clamp on the restitution line to the patient.
- Open the service line on the restitution drip chamber.
- When the desired level has been reached, normally 2/3 the volume of the drip chamber, close the service line and reopen the clamp on the restitution line to the patient.

If you want to end PRIMING before it has been completed, select and confirm "Quit priming". You will be asked for confirmation that you want to quit PRIMING:

Quit Priming	Confirm

After selecting and confirming "Quit Priming" return to the "INTRODUCING" page.

Once the Priming of the disposables has been successfully completed, the Priming status bar is at 100% and the "Patient Connection" key will appear.

Quit Priming		Patient Connection	Save as Default

A further flushing phase can be performed by pressing the "START STOP" physical button located below the display.

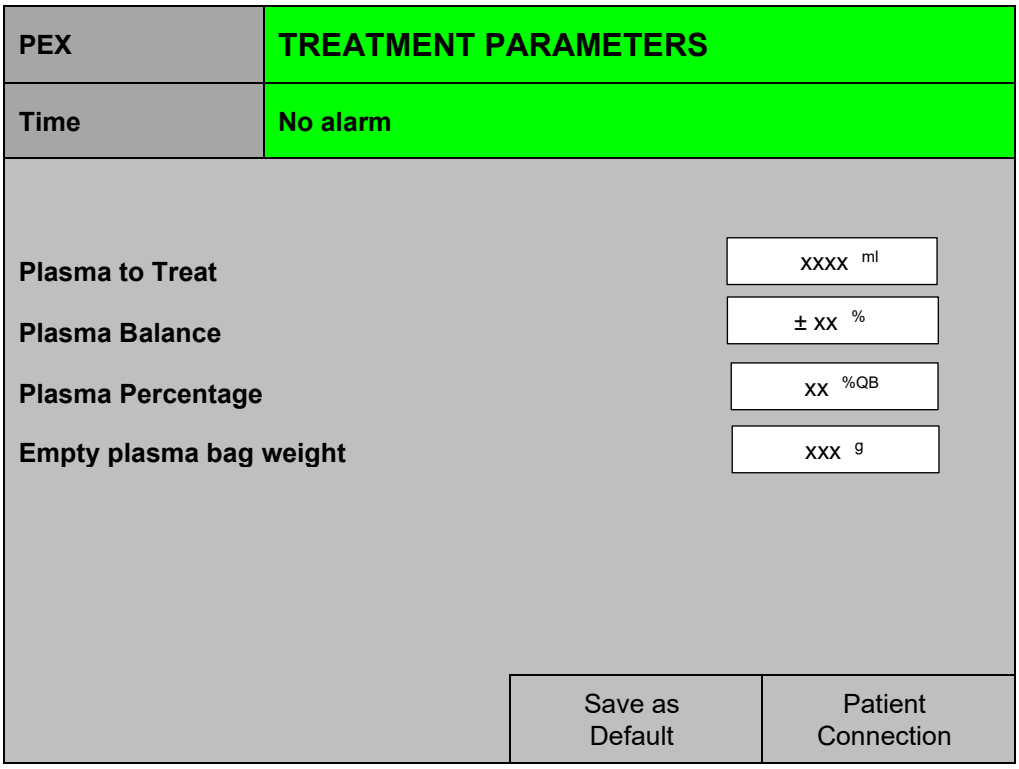
In this phase a total of one litre of priming solution will be processed by the Blood pump.
This operation can be repeated several times.

Press "Patient Connection" key to proceed to the clinical parameters settings before the treatment.

19.1.2. TREATMENT

19.1.2.1. TREATMENT PARAMETERS

The TREATMENT PARAMETERS screen allows you to set the parameters relating to the treatment.
Check and, if necessary, modify the parameters relating to the treatment, then press <Patient Connection>.



Available setting parameters:

- **Plasma to Treat [ml]:** Total plasma volume to treat.
  - Range: [100 - 6000] ml
  - Default: 1000ml
  - Step: 50 ml

- **Plasma balance [%]**:Percentage between plasma treated and plasma returned to the patient.
  - Range: [-20 – +20] %
  - Default: 0 %
  - Step: 1 %

  If it is 0% an equal exchange occurs and the plasma removed is replaced with the same amount of fresh plasma; if the percentage is negative, the plasma removed is less than that returned and vice versa.

- **Plasma Percentage [% QB]:** Plasma pump speed.
  - Range: [5 – 30] %QB
  - Default: 10 %QB
  - Step: 1 %QB

- **Empty plasma bag weight [g]:** Net weight of empty bag/ fresh plasma end-of-bag alarm threshold.
  - Range: [0 – 200] g
  - Default: 100 g
  - Step: 10 g

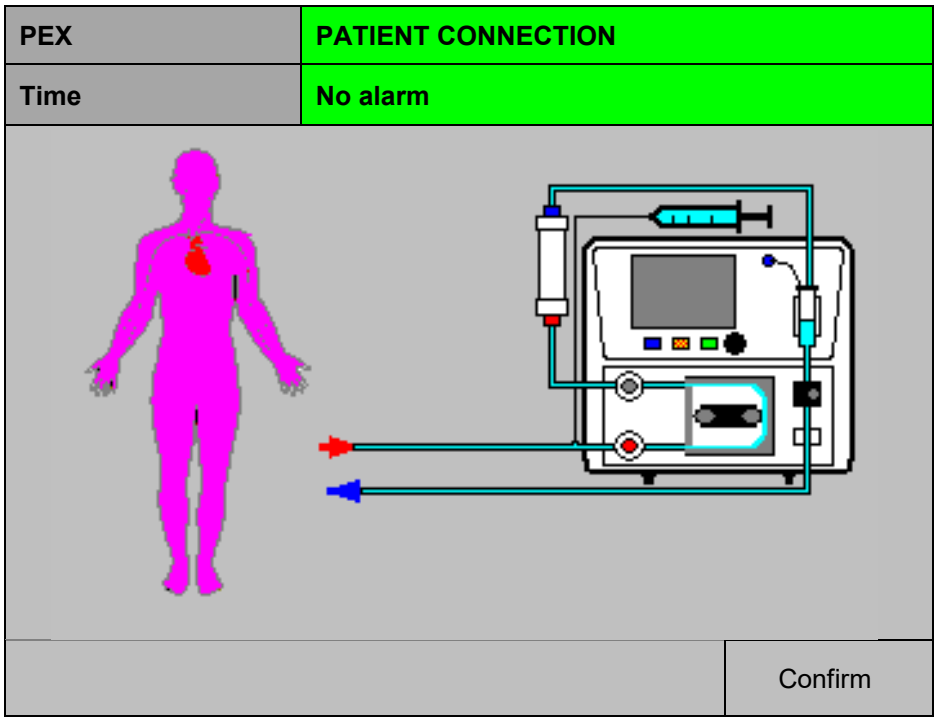
Press "Save as Default" to save set parameters and make them available for the next treatments

19.1.2.2. PATIENT CONNECTION

After setting the treatment parameters, select <Patient Connection>.

Disconnect the priming lines from the arterial line, remove the priming bags from the stand and connect the arterial and the venous line to the patient.

When done, press <Confirm>.



WARNING

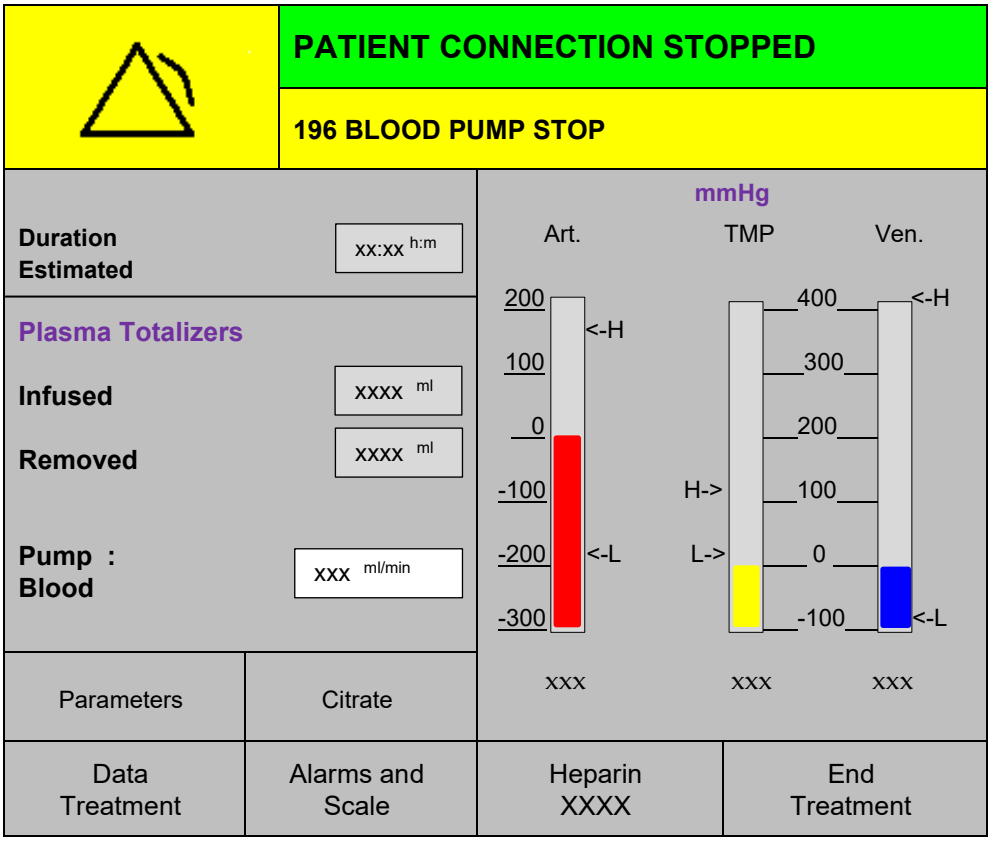
- **Risk of embolism due to air in the lines**
- **Risk of haemolysis due to kinking or crushing of lines**
- **Risk of blood loss due to not hermetically sealed connection points**

Before starting a treatment, check the following:

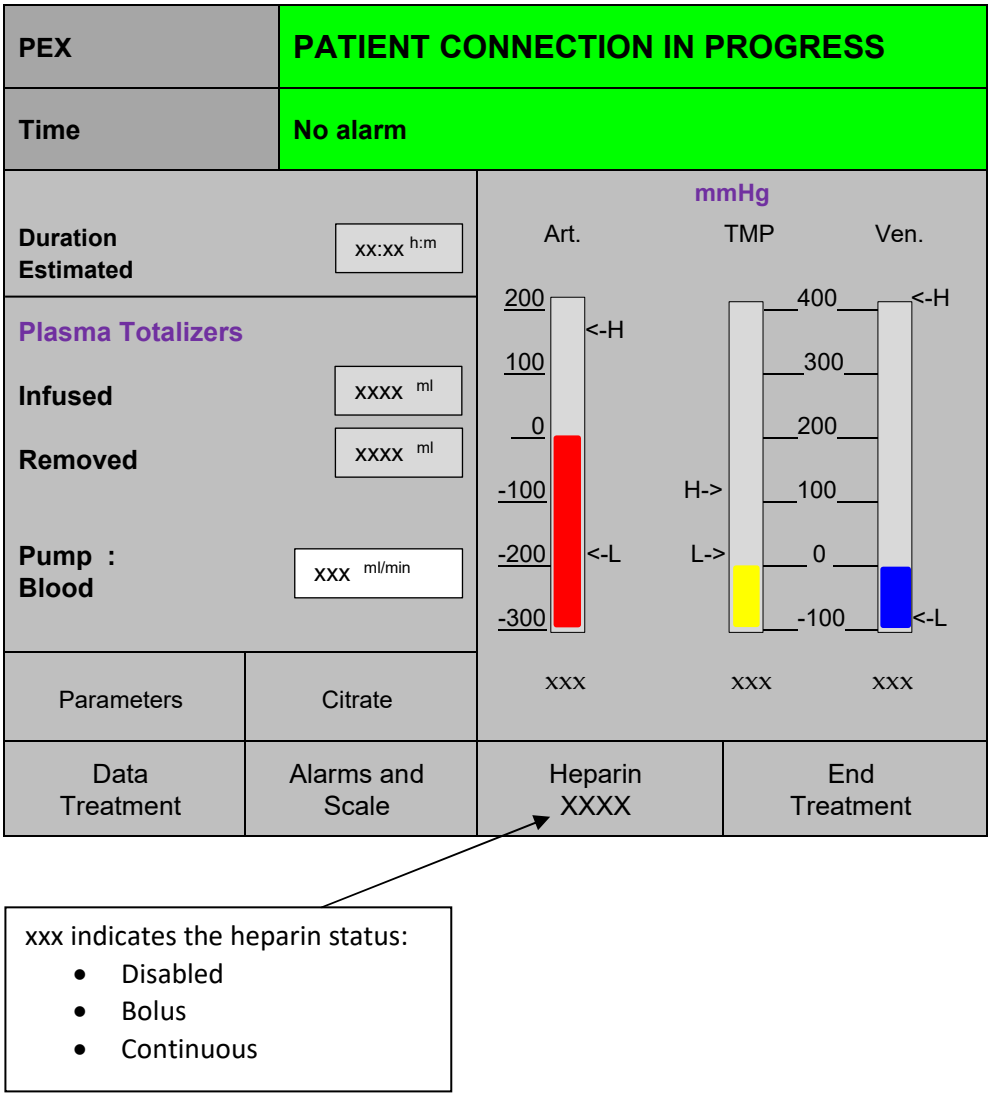
- All line joints are firmly connected
- There are no noticeable leaks in the lines, neither during nor after filling
- If leaks are found, tighten the relevant connections as needed.
- If necessary, replace the entire disposable.
- Lines are airless, inserted cleanly with no kinks, line tension or twisting and
- all fluid levels are correct.

19.1.2.3. TREATMENT

When start the treatment is show the "PATIENT CONNECTION STOPPED" screen, like reported in the following picture.



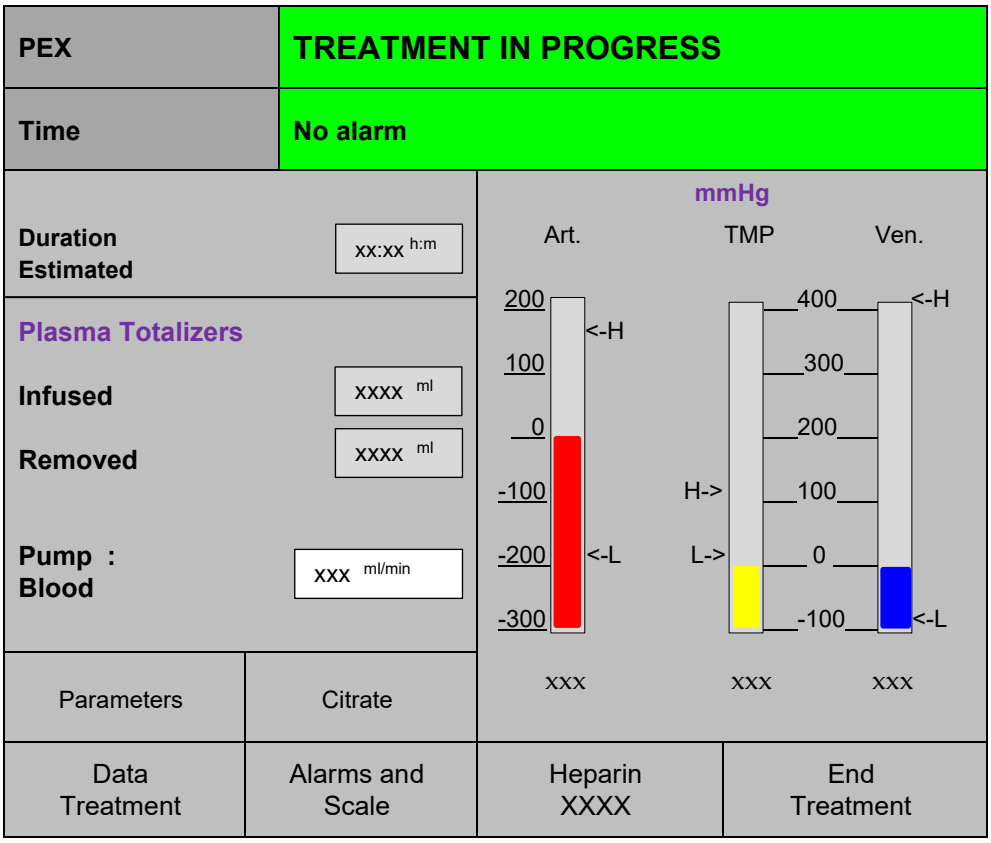
Push the START/STOP button (rif.16) to switch on the blood pump and enter the patient connection phase.



For the first 100 ml of processed liquid by the blood pump, the machine considers the treatment as being in the connection phase and hence does not activate the infusion pump.

At the end of the patient connection phase AFERsmart PLUS automatically enters the treatment phase.

From the main screen it is possible to monitor the status of the treatment, by setting and / or monitoring the main treatment parameters.



Available setting parameters:

- **Pump: Blood** [ml / min].
  - Range: [5 - 250] ml / min
  - Default: 50ml / min
  - Step: 5ml / min

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Duration Estimated [h:m]**: It indicates the treatment time estimated.
- **Infused [ml]:** It indicates the total plasma infused.
- **Removed [ml]:** It indicates the total plasma removed.
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The TMP pressure is the pressure that work over the filter fibers.
  The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

NOTE

If Citrate was previously selected in the anticoagulant to be used, the range of the blood pump speed will be set in relation to the citrate percentage set and vice versa. AFERsmart PLUS automatically reject any incorrect value of Blood pump speed or citrate percentage that will be set.
The maximum value the citrate pump can reach is 5 ml/min.

Example of work situation:

- **If Blood Pump is set at 250 ml/min the citrate percentage must be 2% or less**
- **If Citrate percentage set is 5% the blood pump speed must be 100 ml/min or less**

From the main screen it is possible to access various functions through the menu located at the bottom:

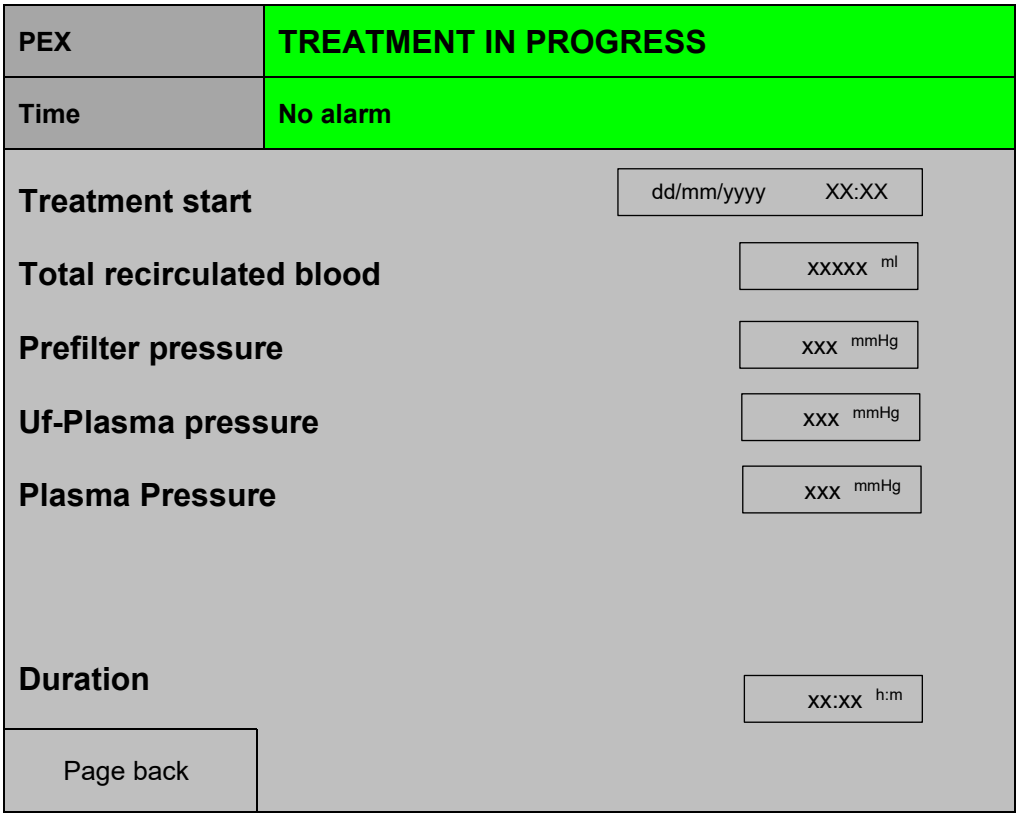
Parameters

See the Treatment parameters chapter 19.1.2.1

With the "Page back" button is possible to come back in the "TREATMENT IN PROGRESS" page.

Data Treatment

The DATA TREATMENT screen shows the data relating to the treatment:



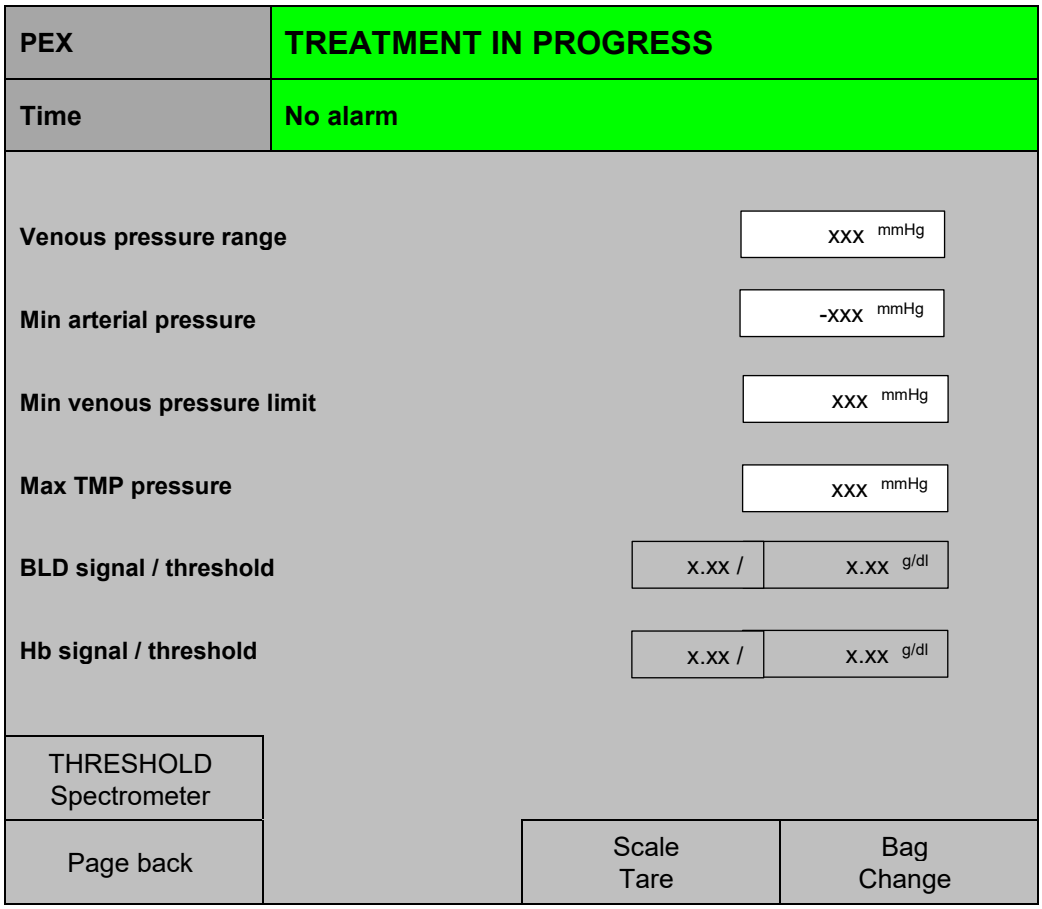
Allows accessing to the page where the following data are shown:

- Treatment start: Date and time of the treatment;
- Total recirculated blood [ml];
- Prefilter pressure [mmHg];
- Uf-Plasma pressure [mmHg];
- Plasma Pressure [mmHg] ;
- Duration [h:m]

With the "Page back" button is possible to come back in the "TREATMENT IN PROGRESS" page.

Alarms and Scale:

The ALARMS AND SCALE screen allows you to set / view the alarm thresholds:



On this page, you can view and change the following values:

- **Venous pressure range**: It indicates the range of values within which the restitution pressure must be maintained during the treatment; if the value read is not within this range
  - Range: [40 - 200] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min arterial pressure**: It indicates the aspiration pressure alarm threshold value.
  - Range: [-250 - 0] mmHg
  - Default: -200 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min venous pressure limit**: It indicates the minimum value alarm of venous/restitution pressure
  - Range: [-30 - 5] mmHg
  - Default: 5 mmHg
  - Step: 1 mmHg

  The relative alarm will be displayed.

- **Max TMP pressure** : It sets the maximum transmembrane pressure on the plasma filter
  - Range: [0 - 300] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

  When this value is reached, the plasma pump automatically starts decelerating until reaching the minimum value available

- **BLD signal / threshold:** It indicates the value of blood in the plasma read by the spectrometer and the related alarm threshold

- **Hb signal / threshold:** It indicates the value of haemolyzed plasma read by the spectrometer and the related alarm threshold

From this screen it is possible to access various functions through the menu located at the bottom:

Scale Tare: if one of the bags hanged to the scales is accidentally moved and it is necessary to continue the treatment it is possible to tare the scales.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Confirm
Scale Tare

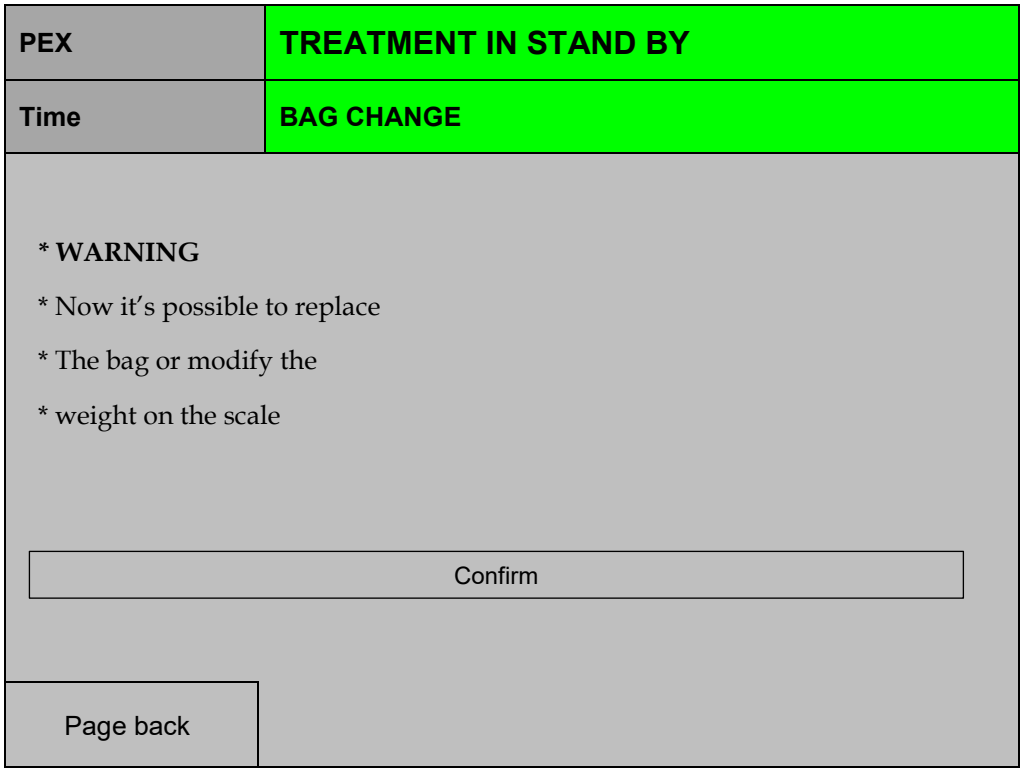
Bag Change: if it is necessary to replace one or more bags located on one or both scales, it is possible to activate the associated replacement procedure.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Confirm
Bag Change

After correctly performing the Functions described above, it is necessary to follow the instructions that appear on the display.

NOTE

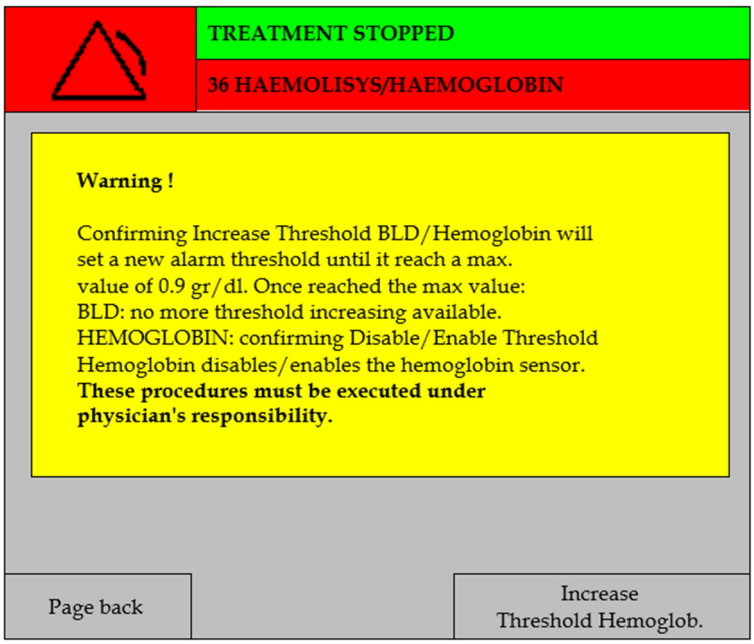
During the Change bag procedure, the Treatment phase change automatically to "TREATMENT IN ST-BY" (Stand By phase)



Press "Confirm" when connect at the scale the new bag.
With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

THRESHOLD Spectrometer: if the value of blood in plasma or plasma hemolyzed, read by the spectrometer, exceeds the value of the related threshold, this function key appears.
By selecting and confirming the function key the following pages will be shown.
In particular, if the alarm raised up is:

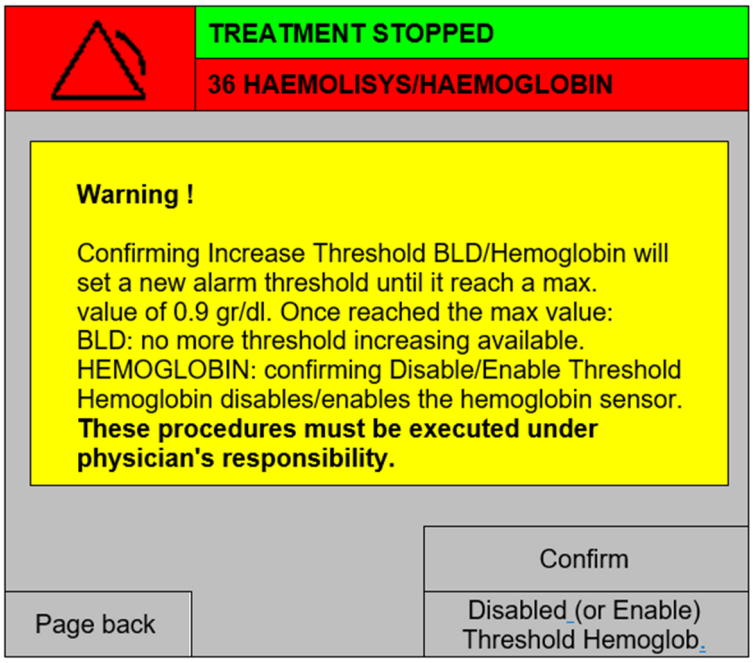
- **36 HAEMOLISYS/HAEMOGLOBIN**



press "Increase Threshold Hemoglob." to increase of 0.2 g/dl the value of the threshold of the alarm and come back into the "TREATMENT STOPPED" page.

With the "Page back" key it's possible to come back into the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl and the alarm rises up or the reading of haemolyzed plasma by the spectrometer is disabled following page will be shown by pressing on "THRESHOLD Spectrometer" function key.



Press "Disabled Threshold Hemoglob." and "Confirm" to disable the reading of haemolyzed plasma by the spectrometer and come back into the "TREATMENT STOPPED" page.

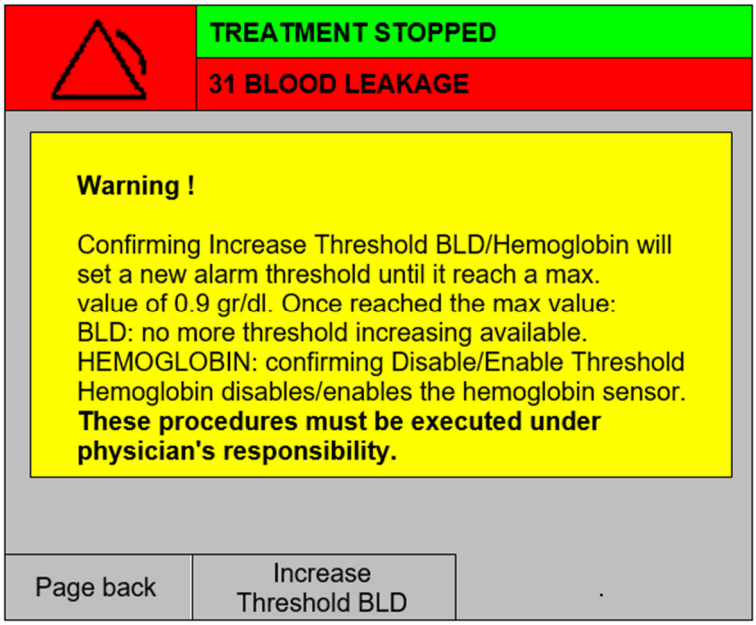
Press "Enable Threshold Hemoglob." and "Confirm" to enable the reading of haemolyzed plasma by the spectrometer and come back into the "TREATMENT STOPPED" page.

WARNING

Raising the alarm threshold and deactivating the spectrometer's reading of haemolysed plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

- **31 BLOOD LEAKAGE**



Press "Increase Threshold BLD" to increase of 0.2 g/dl the value of the threshold of the alarm and come back in the "TREATMENT STOPPED" page.

With the "Page back" button it's possible to come back in the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl the "THRESHOLD Spectrometer" function key will not appear

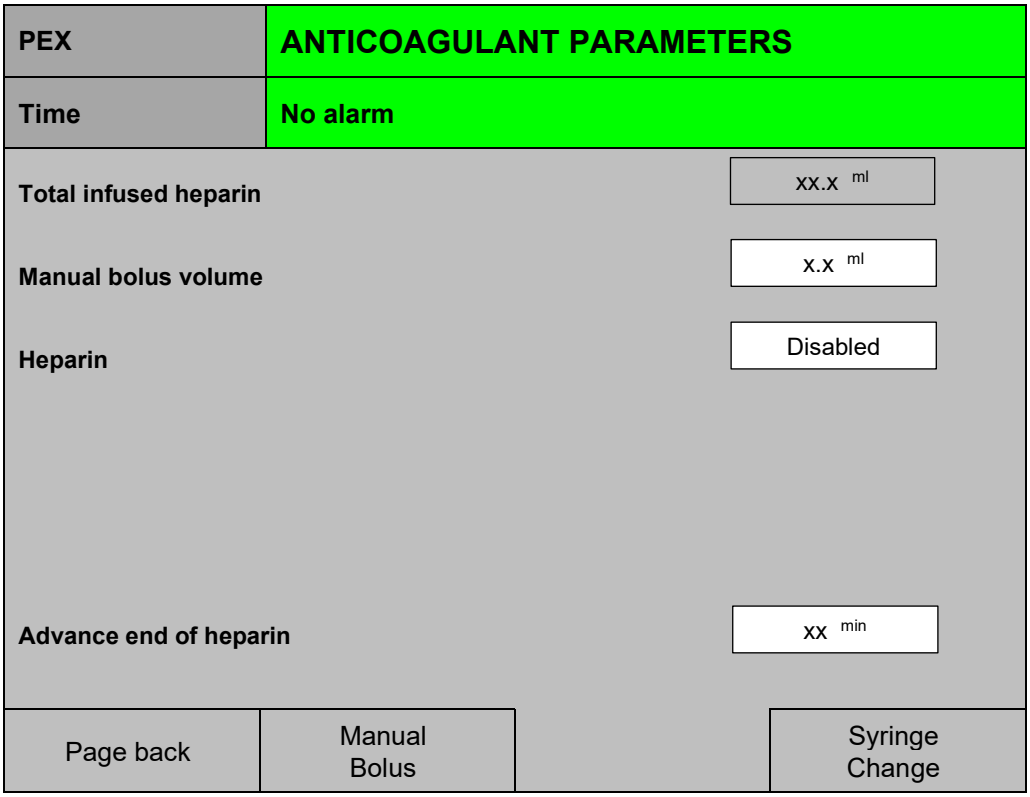
WARNING

Raising the alarm threshold of blood in plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

Heparin XXXX:

On this page it is possible to check and change the operating status/mode of the heparin pump:



The screen above shows the "Disabled" heparin mode.

- **Total Infused Heparin:** Volume in ml of heparin injected into the extracorporeal circuit (not modifiable)
- **Manual Bolus Volume**: It indicated the heparin bolus volume that the user can manually injected into the extracorporeal circuit
  - Range: [0.1 – 5.0] ml
  - Default: 1.0 ml
  - Step: 0.1 ml/min

  Press the "Manual Bolus" key to inject this bolus.
- **Heparin:** This parameter indicates the operating status/mode of the heparin syringe; the pump operating mode can be changed during treatment.
- **Advance end of heparin:** It indicates the time in minutes when the heparin infusion should be stopped before the end of the treatment.

NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

From this screen it is possible to access various functions through the menu located at the bottom:

Manual Bolus: trough this function it is possible to administering an additional heparin bolus of 1 ml respect the normal heparin operating mode.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Manual Bolus	Confirm

Syringe Change: trough this function it is possible to replace the anticoagulant syringe .
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Confirm	Syringe Change

Confirmed the "Change Syringe" appear the following screen with reported the instructions to replace the syringe.

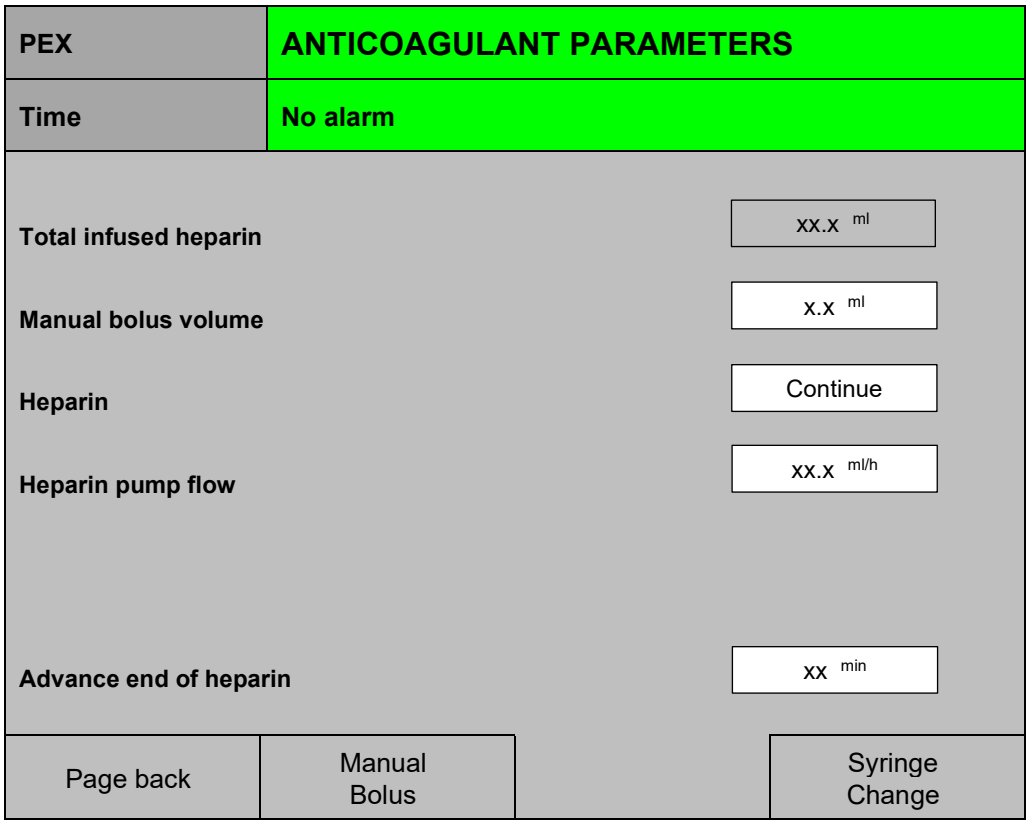
PEX	**TREATMENT IN PROGRESS**		
Time	**CHANGE SYRINGE**		
*** Close the syringe line clamp** *** Remove the empty syringe** *** Set syringe cursor** *** Introduce new syringe** *** Open syringe line clamp** *** Confirm syringe change**			
Page back	Syringe < - -	Syringe - - >	Change Syringe

Follow the on-screen instructions and confirm "Change Syringe" key.

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Other Heparin Modes available:

- **Heparin Continue:**

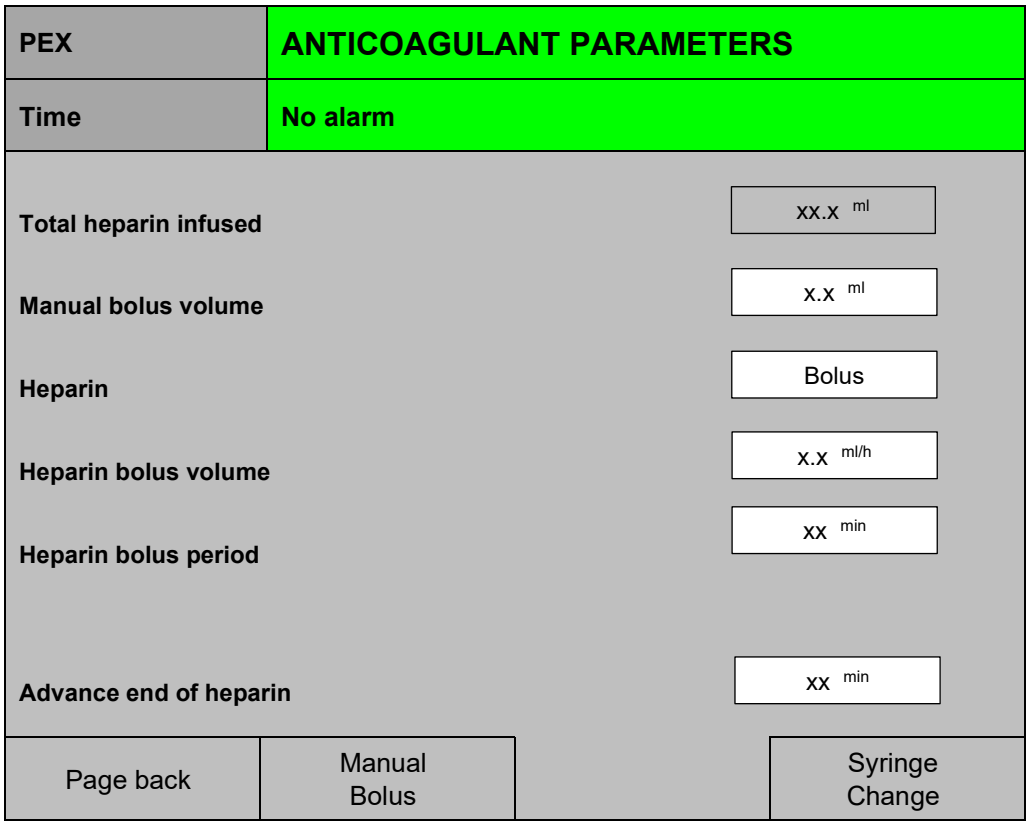


Compared with the heparin disable screen the only add parameter is:

Heparin pump flow: It indicated the anticoagulant flow in ml/min .

- Range: [0.1 – 20.0] ml
- Default: 0.4 ml
- Step: 0.1 ml

- **Heparin Bolus:**



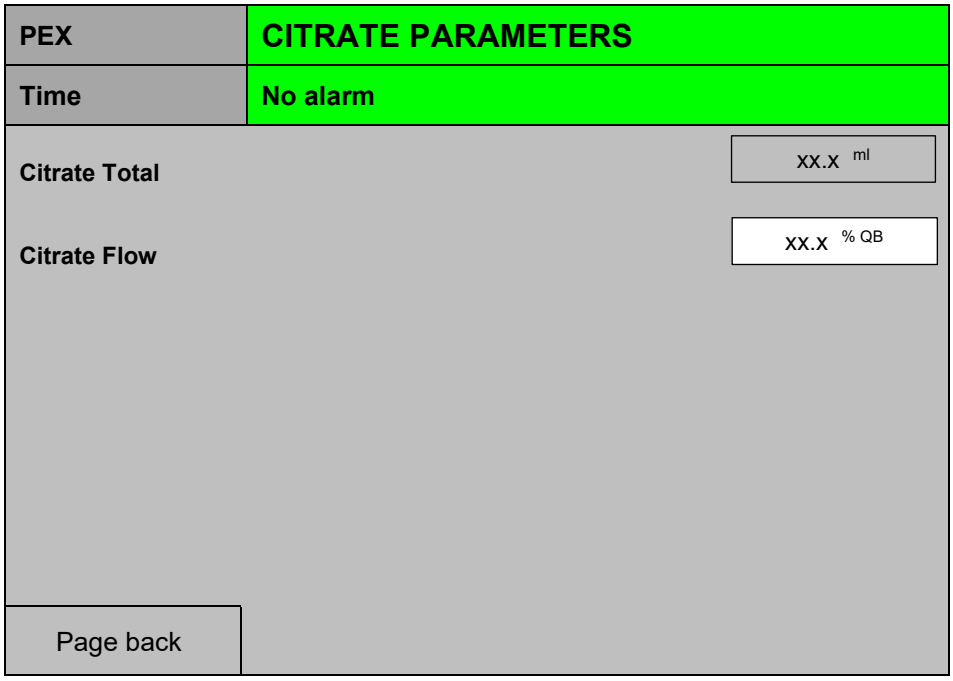
Compared with the heparin disable screen the only add parameter is:

Heparin bolus volume: It indicated the anticoagulant bolus volume regularly injected.
- Range: [0.1 – 5.0] ml
- Default: 0.1 ml
- Step: 0.1 ml

Heparin bolus period: It indicated the time between two consecutive bolus anticoagulant injection.
- Range: [5 – 60] min
- Default: 20 min
- Step: 1 min

Citrate (if enabled before Priming):

On this page it is possible to check and change the operating status/mode of the citrate pump:



- **Citrate Total:** Volume in ml of citrate infused into the extracorporeal circuit (not modifiable)
- **Citrate Flow**: Indicated the citrate pump speed respect the blood pump flow rate
  - Range: [0.0 – 10.0] % QB
  - Default: 3.0 % QB
  - Step: 0.1 % QB

End Treatment

See End Treatment chapter 19.1.2.4.

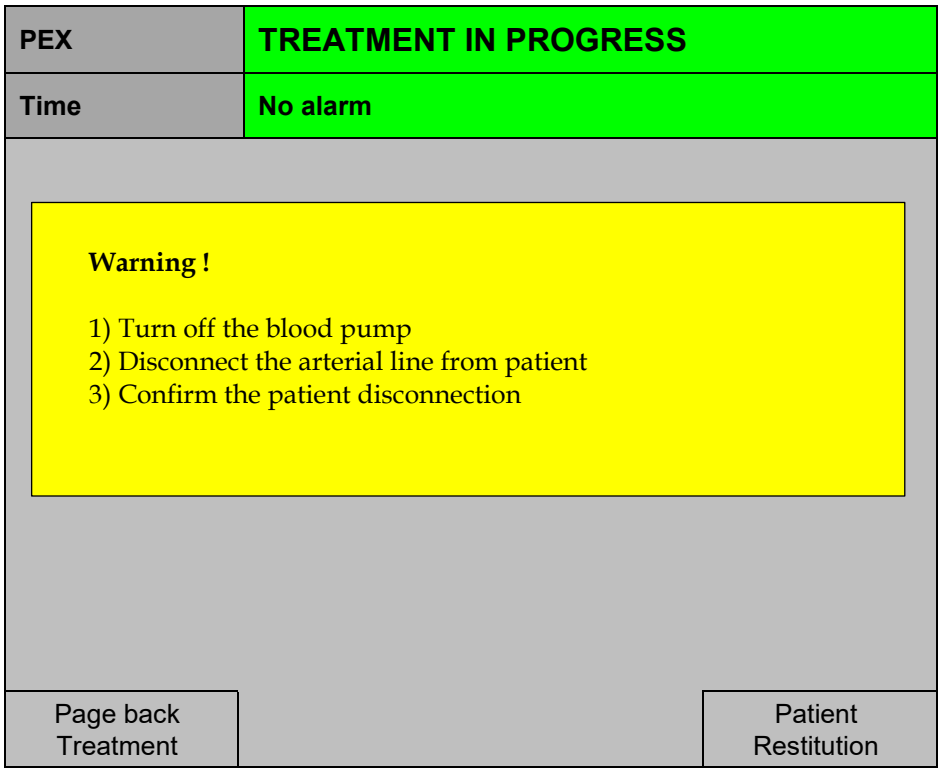
19.1.2.4. End Treatment

When AFERSMART PLUS has reached the target of treated blood volume, the message "501 END TREATMENT" appears on the screen.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the treatment at any time by pressing "End Treatment" key also if the treatment is not completed.

Select "End Treatment" and perform the operations that appear on the display to proceed.

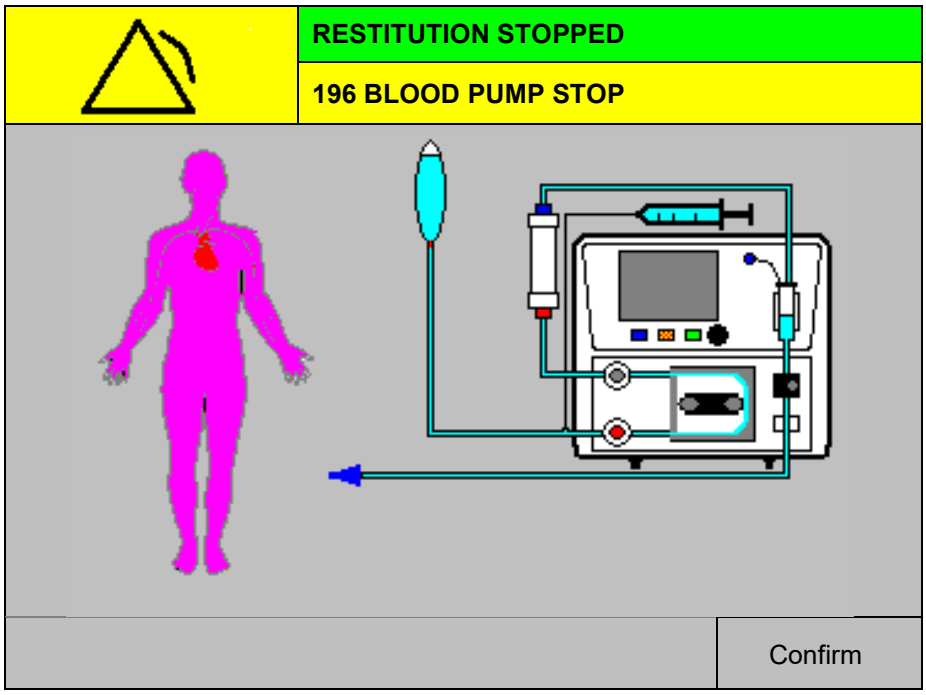


Press "Patient Restitution" key to start the blood restitution phase.
Press "Page back Treatment" key to return the treatment phase.

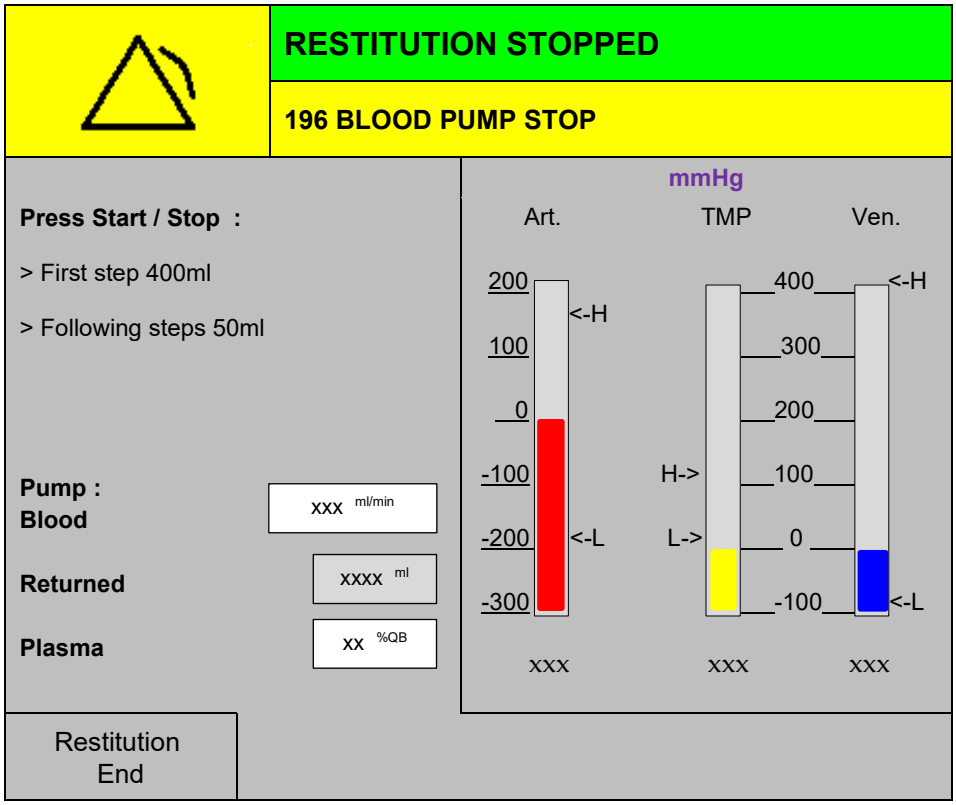
19.1.3. BLOOD RESTITUTION

19.1.3.1. Restitution

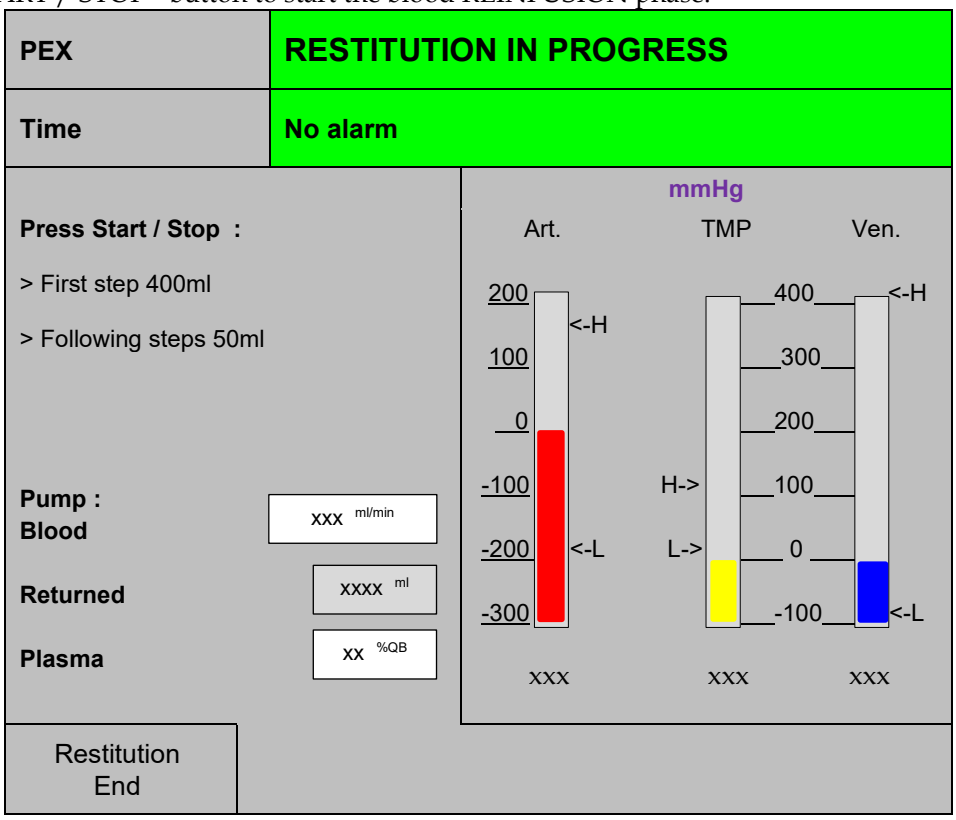
The restitution phase allows the patient to re-infuse most of the blood remaining in circulation in the lines. Disconnect the arterial line from the patient and connect it to the NaCl solution (1000 ml container).



When entering the page above, the blood pump stops to allow to connect the aspiration line to saline solution bag.
Press "Confirm" key to enter the main page of restitution phase.



Press the <START / STOP> button to start the blood REINFUSION phase.



The first time the START/STOP button is pressed and 400 ml of blood are returned.
The next times the button is pressed 50ml at a time are returned.
During standard or additional reinfusion, it is always possible to stop the blood pump by pressing <START / STOP>

Available setting parameters:

- **Pump: Blood** (flow) [ml / min].
  - Range: [0 - 100] ml / min
  - Default: 30ml / min
  - Step: 5ml / min

- **Plasma** (flow) [%QB].
  - Range: [0 - 50] %QB
  - Default: 30 %QB
  - Step: 1 %QB

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Returned [ml]:** It indicates the total blood returned.
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]

The TMP pressure is the pressure that work over the filter fibers. The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

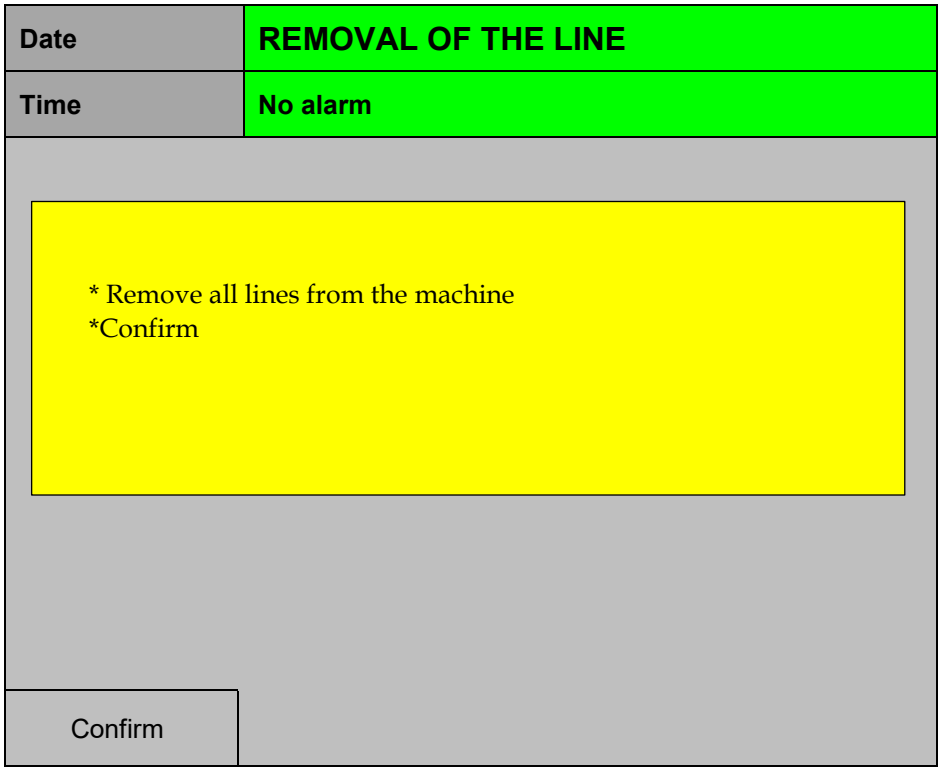
In this phase, only the air bubble detector and the pressure and safety alarms (covers, etc.) are active.
Once the restitution has been completed, select "Restitution End" to disconnect the circuit from the machine.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the restitution at any time by pressing "Restitution End" key also if the blood restitution is not completed.
If you do not confirm the "Restitution End" before turning off the machine. The next time you turn it on, it will restart from this page and not from the INTRODUCING page. In this case, confirm the "Restitution End" after turning on

19.1.3.2. Removal of the line

The patient can be disconnected from the venous line.
It is possible to remove the lines and the plasma filter and proceed with disposal them.



After the uninstallation of the lines, push "Confirm" to go to the "INTRODUCING" page.

The AFERsmart PLUS can now be turned off.

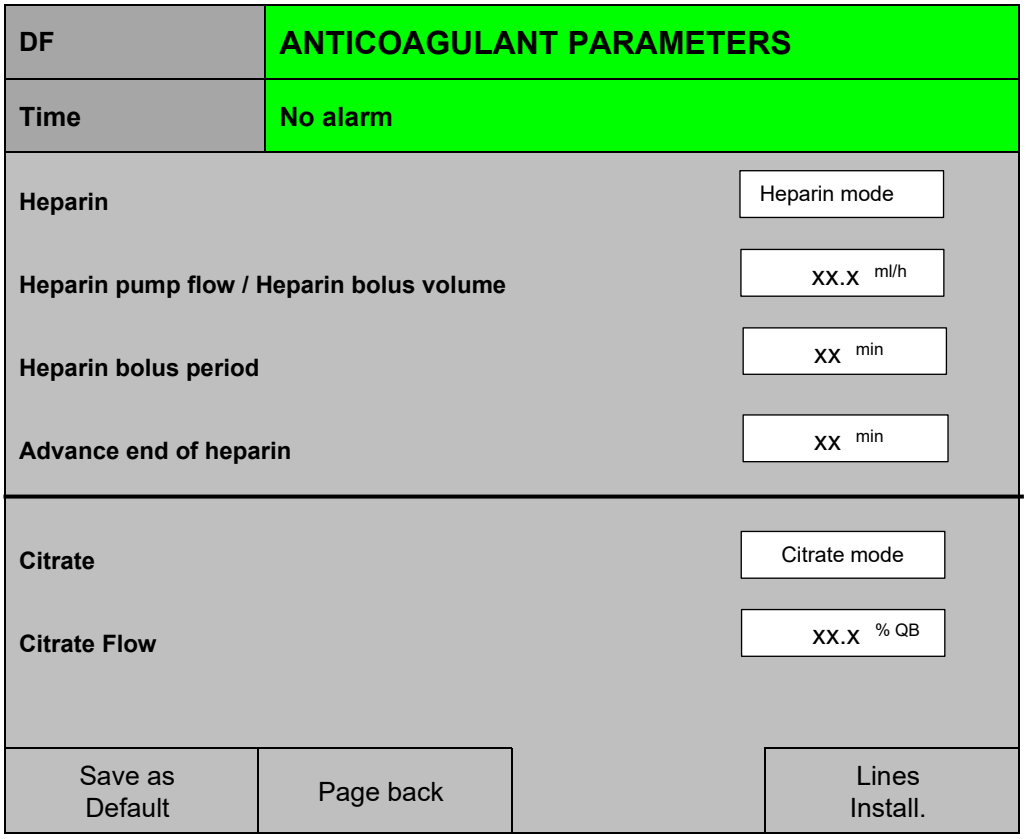
19.2. DOUBLE FILTRATION PLASMAPHERESIS

19.2.1. PREPARATION

19.2.1.1. ANTICOAGULANT PARAMETERS

It is possible to set / modify the parameters related to the anticoagulant before entering in the priming procedure. These parameters can be modified even during the treatment phase, by pressing < Parameters> key.

- Heparin: Disabled/ Continue/ Bolus
- Heparin pump flow (available only in "Continue" mode): [0.1 – 20.0] [ml/h]
- Heparin bolus volume (available only in "Bolus" mode): [0.1 – 5.0] [ml/h]
- Heparin bolus period (available only in "Bolus" mode): [5 – 60] [min]
- Advance end of heparin: [0 – 30] [min]
- Citrate: Disabled/ Enabled
- Citrate Flow (available only in "Enabled" mode) : [0.5 – 10.0] [% QB]



NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

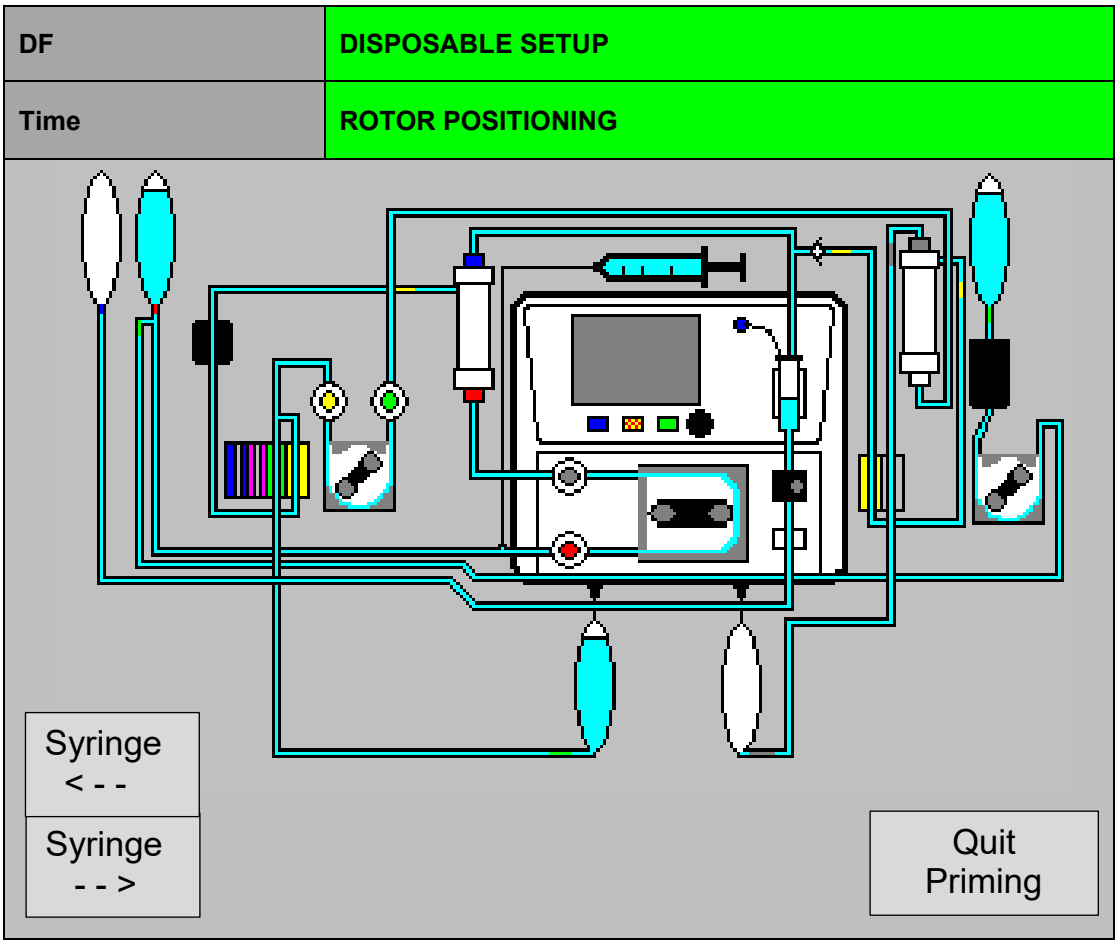
Press ”Save as Default” to save set parameters and make them available for the next treatments

Press the <Page back> key to return to the “INTRODUCING” page

Press the <Lines Install.> key to proceed to the “DISPOSABLE SETUP” page

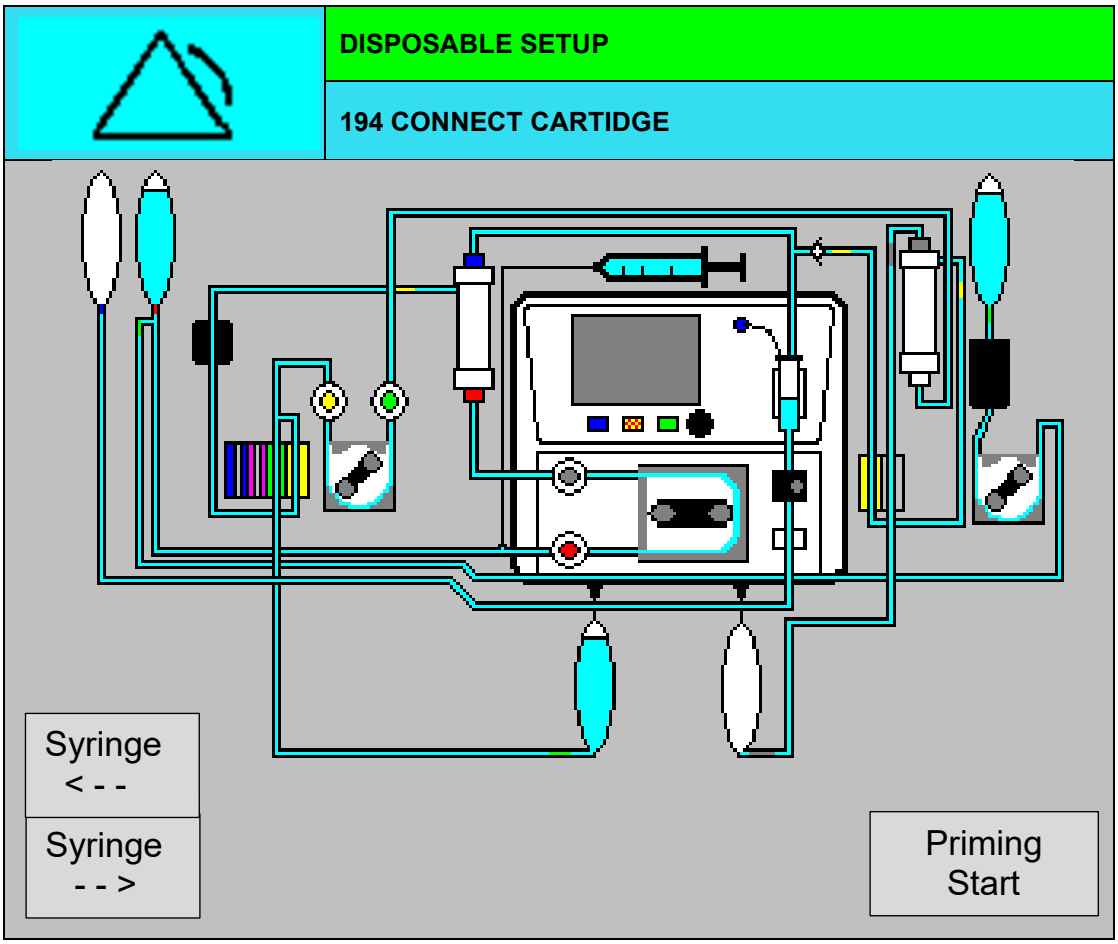
19.2.1.2. DISPOSABLE SETUP

On this page it is possible to install the disposable, the Plasmafilter and the bags needed to perform the DF treatment and its priming



Once entering in this page AFERsmart PLUS will execute the automatic pump rotors positioning (both Blood and Plasma) needed to ease the installation of Blood and Plasma tubing set.

After the "Rotors positioning" phase the "194 CONNECT CARTRIDGE" message will appear, the venous electroclamp will open and the red light over the clamp will switch off.
and it will be possible to install the disposable kit, the Plasmafilter and the bags as shown on the screen



At this phase make sure that the hooks of the scale are completely free.

The AFERSMART PLUS Kit is enclosed in a paper-film envelope, inside are:

Semi-finished arterial line and ACD (identified with red- and green-coloured components)
Semi-finished venous line (identified with blue-coloured components)
Semi-finished plasma line (identified with yellow components)
Semi-finished drainage line (identified with grey components)

- Hang the Priming Solutions and the citrate solution (if Citrate anticoagulation was set) on the stand pole.
- Hang to the washing scale the washing solution container
- Hang to the drain scale the waste container
- Place the plasma filter in its support (ref. 6 Chapter 2.3)
- Place the plasma fractionator in its support (ref. 2 Chapter 2.4)
- Remove the plasma line from the bag

- Open the plasma pump cover (ref. 1 Chapter 2.3)
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  Close the plasma pump cover

- Open the UF pressure transducer and connect the relevant UF DOME (ref. 3 Chapter 2.3)

- Open the plasma pressure transducer and connect the corresponding plasma DOME (ref. 2 Chapter 2.3)

- Insert the washing section of the plasma line into the clamp n°3 (ref. 4 Chapter 2.3) and connect it to the washing solution container on the washing scale (ref. 1 Chapter 2.6)

- Insert the plasma section of the plasma line into the clamp n°4 and successively insert the cuvette into the BLD with the nose pointing outward (ref. 5 Chapter 2.3)

- Connect the yellow Hansen connection of the plasma section of the plasma line to the upper lateral plasma compartment port of the plasma filter

- Connect the fractionator section of the plasma line (outgoing from plasma DOME) to the inlet (lower part) of the fractionator filter

WARNING
Take great care when inserting each line inside each selection clamp. Make sure that all the lines are firmly in place and that the color on the line corresponds to the color on the clamp.

- If Citrate anticoagulation was set:
  - Place the ACD chamber in the appropriate support (ref. 4 Chapter 2.4), inserting it from top to bottom
  - Open the ACD pump cover (ref. 3 Chapter 2.4),
  - Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  - Close the cover of the ACD pump
  - Connect the ACD inlet, with the white clamp to the citrate bag positioned on the stand pole

- Open the blood pump cover (ref. 2 Chapter 2.1),
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth.
  Close blood pump cover.

- Open the arterial pressure transducer and connect the relative arterial DOME (ref. 5 Chapter 2.1),

- Open the prefilter pressure transducer and connect the relative prefilter DOME (ref. 6 Chapter 2.1),

- Connect the red adapter outgoing from the prefilter DOME to the inlet (lower part) of the plasma-filter.

- If heparin anticoagulation was set:
  - Connect the heparin tube fitting to the 30-cc syringe previously filled with heparinized solution Insert the syringe in its seat, using the arrows < ← > and < → > to position the cursor
- Connect the inlet connector of the arterial line to the priming solution bag positioned on the stand pole
- Take the venous line from the envelope
- Place the venous chamber in the appropriate support (ref. 8 Chapter 2.1), by inserting it from top to bottom
- Connect the hydrophobic Venous Pressure Transducer Protector Luer Lock to the Venous Pressure Transducer (ref. 7 Chapter 2.1),
- Connect the blue adapter, at the inlet of the venous line, to the outlet (Upper part) of the plasma-filter.
- Insert the tube outgoing from the venous chamber into the air / blood sensor (ref. 3 Chapter 2.1) and, successively, into the venous electroclamp (ref. 4 Chapter 2.1)
- Place the venous waste bag already connected to the venous line on the stand pole (ref. 2 Chapter 2.6)
- Take the drainage line from the envelope
- Connect the blue adapter of the waste section of the drainage line to the outlet (upper part) of the fractionator filter, insert it in the clamp n°6 and successively connect it to the waste bag positioned on the drain scale
- Connect the white Hansen connector of the plasma section of the drainage line to the upper lateral plasma compartment port of the fractionator filter, insert it in the clamp n°5 and successively connect it to the luer connector of the venous line positioned at the inlet of the tray.

WARNING

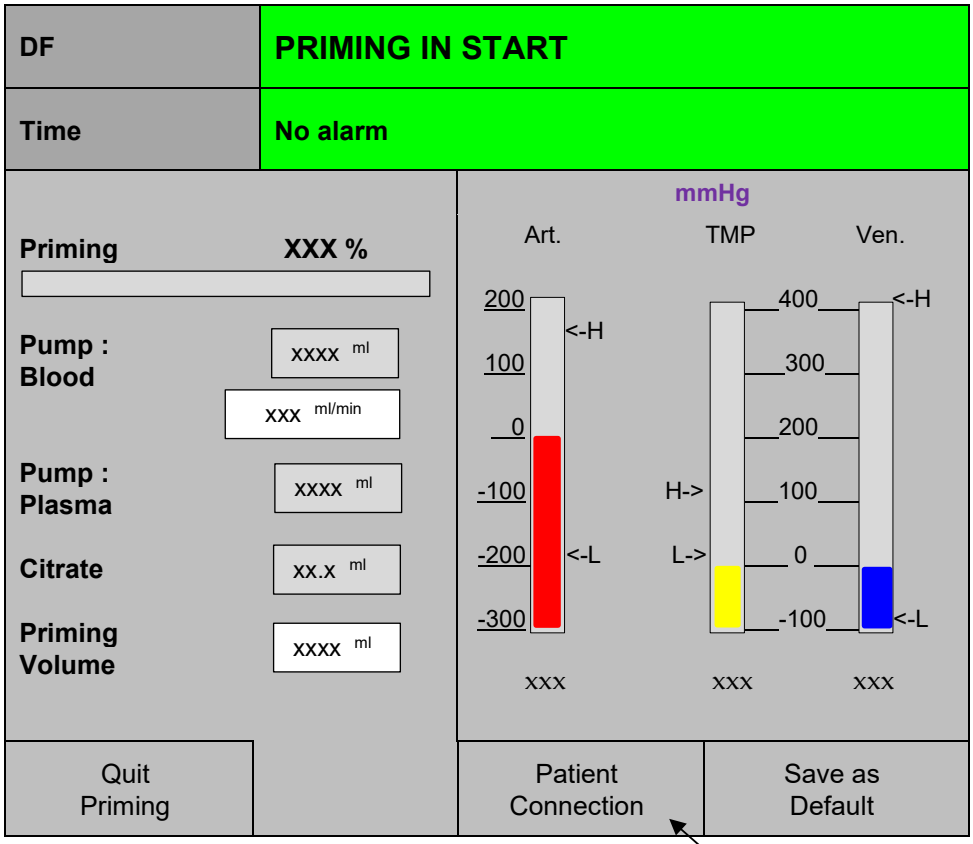
To correctly mount the venous pressure transducer protector to the conical connections of the pressure transducers, it is necessary to:

- **Fully insert the venous pressure transducer protector by making it make a slight rotational movement until it locks.**
- **Turn the ring anticlockwise to prevent it from disconnecting.**

19.2.1.3. Priming

Make sure you have connected the circuit as described above.

Select and confirm the <Priming Start> function; this takes you to the "PRIMING IN START" screen.



If no anomalies have occurred, this button appears at the end of the Priming.

The page displays:

- Pump: Blood (volume) [ml];
- Pump: Blood (speed) [ml/min]: adjustable from 5 to 250;
- Pump: Plasma (volume) [ml];
- Citrate (pump volume) [ml];
- Priming volume (total) [ml]: adjustable from 1000 to 4000;
  The current value of the Arterial (RED), TMP (YELLOW) and Venous (BLUE) pressures and the related alarm thresholds.

AFERSMART PLUS then begins the automatic priming procedure.

NOTE

To temporarily stop priming, simply press the <START / STOP> button once. Press this button again to restart priming.

Press ”Save as Default” to save set parameters and make them available for the next treatments

During Priming it is advisable to adjust the level in the restitution drip chamber. To do this, operate as follows:
- Close the clamp on the restitution line to the patient.
- Open the service line on the restitution drip chamber.
- When the desired level has been reached, normally 2/3 the volume of the drip chamber, close the service line and reopen the clamp on the restitution line to the patient.

If you want to end PRIMING before it has been completed, select and confirm “Quit priming”. You will be asked for confirmation that you want to quit PRIMING:

Quit Priming	Confirm

After selecting and confirming “Quit Priming” return to the “INTRODUCING” page.

Once the Priming of the disposables has been successfully completed, the Priming status bar is at 100% and the “Patient Connection” key will appear and the warning “500 END PREPARATION” rise up.

Quit Priming		Patient Connection	Save as Default

A further flushing phase can be performed by pressing the "START STOP" physical button located below the display.

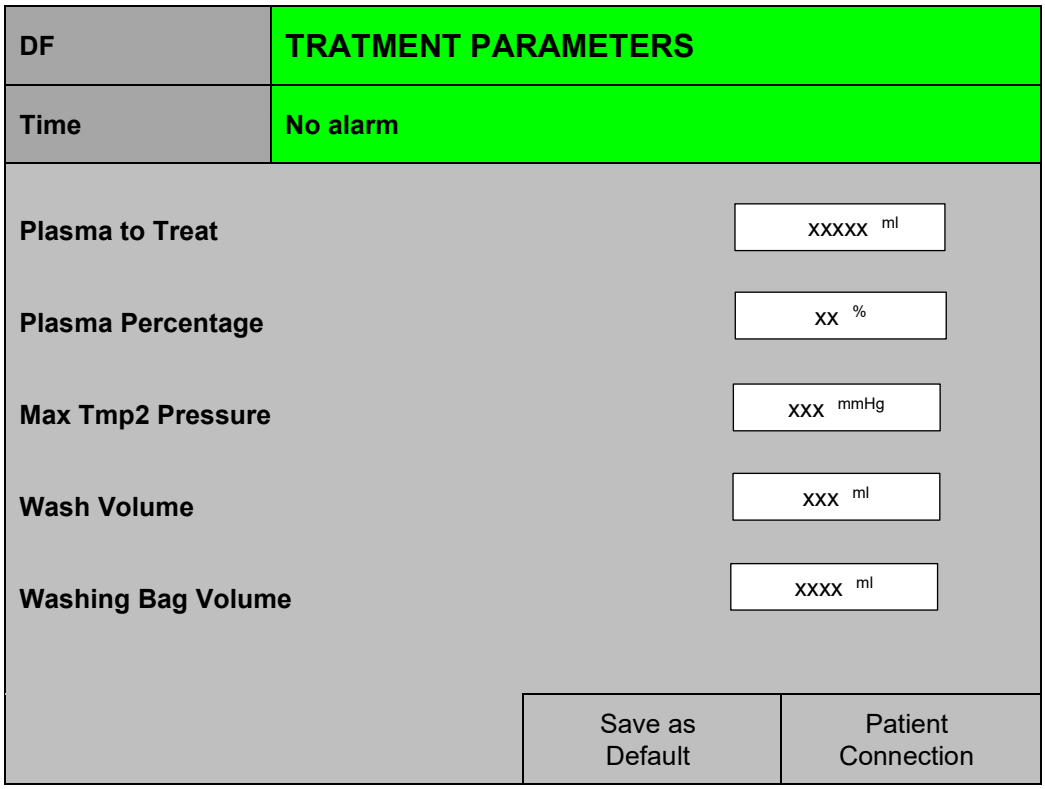
In this phase a total of one litre of priming solution will be processed by the Blood pump.
This operation can be repeated several times.

Press “Patient Connection” key to proceed to the clinical parameters settings before the treatment.

19.2.2. TREATMENT

19.2.2.1. TREATMENT PARAMETERS

The TREATMENT PARAMETERS screen allows you to set the parameters relating to the treatment.
Check and, if necessary, modify the parameters relating to the treatment, then press <Patient Connection>.



Available setting parameters:

- **Plasma to Treat [ml]:** Total plasma volume to treat.
  - Range: [500 - 20000] ml
  - Default: 500 ml
  - Step: 50 ml
- **Plasma Percentage [%]:** Plasma pump speed.
  - Range: [1 – 30] %QB
  - Default: 10 %QB
  - Step: 1 %QB
- **Max Tmp2 Pressure [mmHg]:** it indicates the pressure threshold at which the machine starts the washing cycle of the fractionation filter.
  - Range: [50 – 350] mmHg
  - Default: 200 mmHg
  - Step: 10 mmHg
- **Wash volume [ml]:** it indicates the quantity of washing solution per cycle.
  - Range: [10 – 500] ml
  - Default: 100 ml
  - Step: 10 ml
- **Washing bag volume [ml]:** it indicates the volume of the washing solution bag.
  - Range: [500 – 5000] ml
  - Default: 1000 ml
  - Step: 500 ml

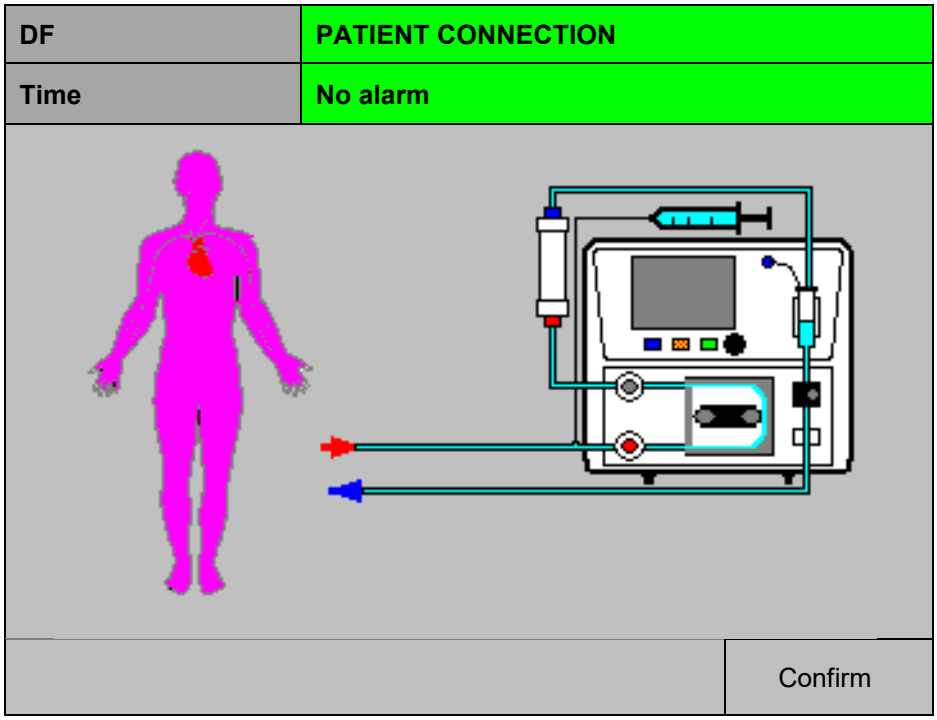
Press "Save as Default" to save set parameters and make them available for the next treatments.

19.2.2.2. PATIENT CONNECTION

After setting the treatment parameters, select <Patient Connection>.

Disconnect the priming lines from the arterial line, remove the priming bags from the stand and connect the arterial and the venous line to the patient.

When done, press <Confirm>.



WARNING

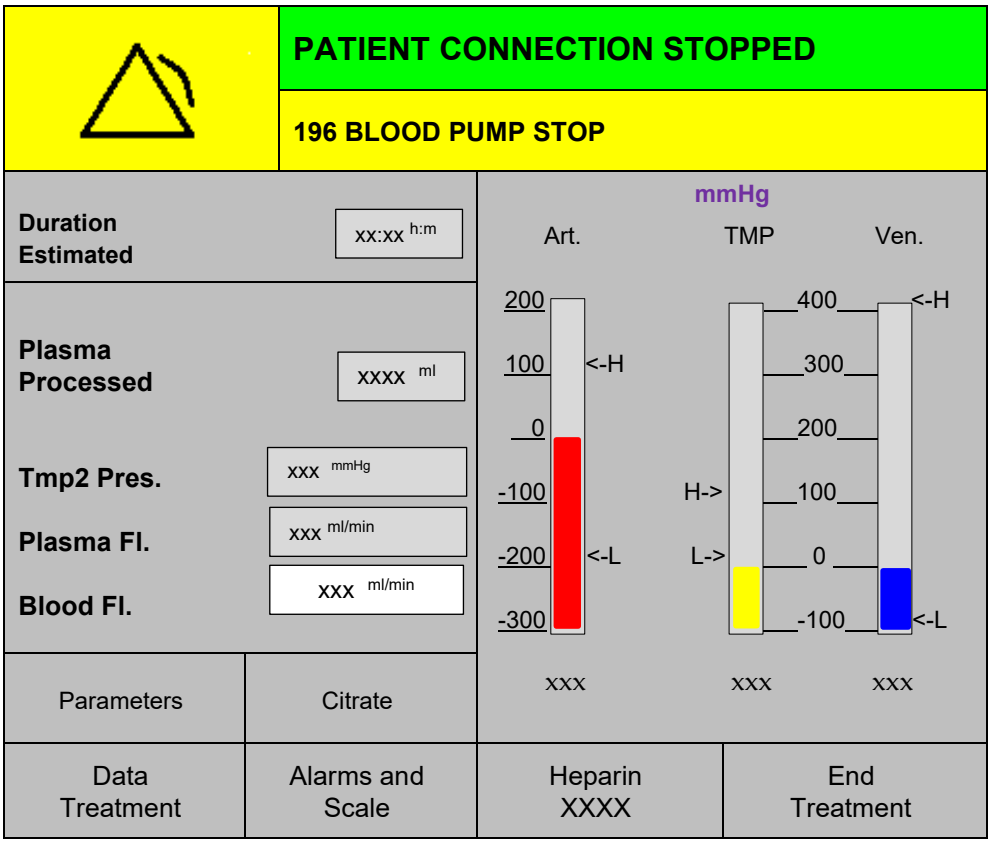
- **Risk of embolism due to air in the lines**
- **Risk of haemolysis due to kinking or crushing of lines**
- **Risk of blood loss due to not hermetically sealed connection points**

Before starting a treatment, check the following:

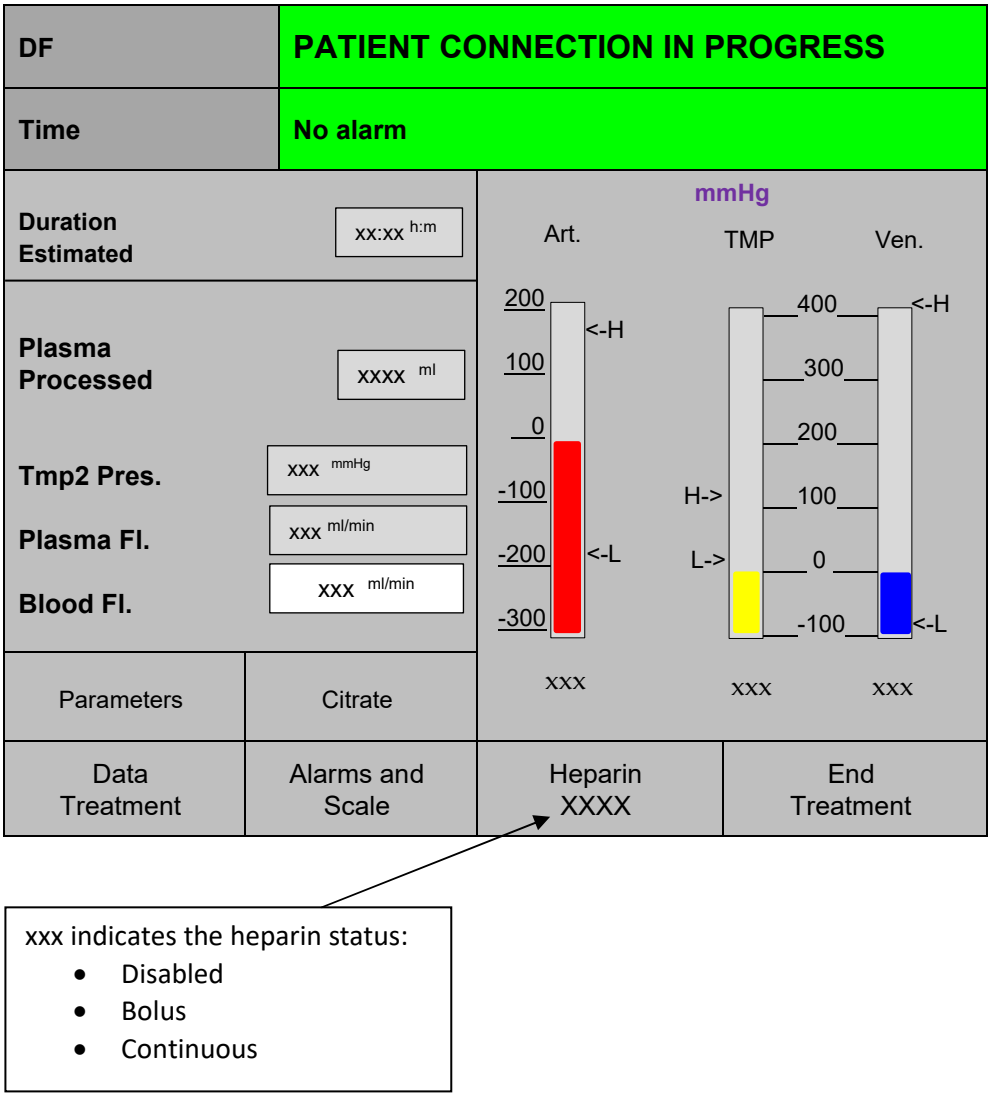
- All line joints are firmly connected
- There are no noticeable leaks in the lines, neither during nor after filling
- If leaks are found, tighten the relevant connections as needed.
- If necessary, replace the entire disposable.
- Lines are airless, inserted cleanly with no kinks, line tension or twisting and
- all fluid levels are correct.

19.2.2.3. TREATMENT

When start the treatment is show the "PATIENT CONNECTION STOPPED" screen, like reported in the following picture.



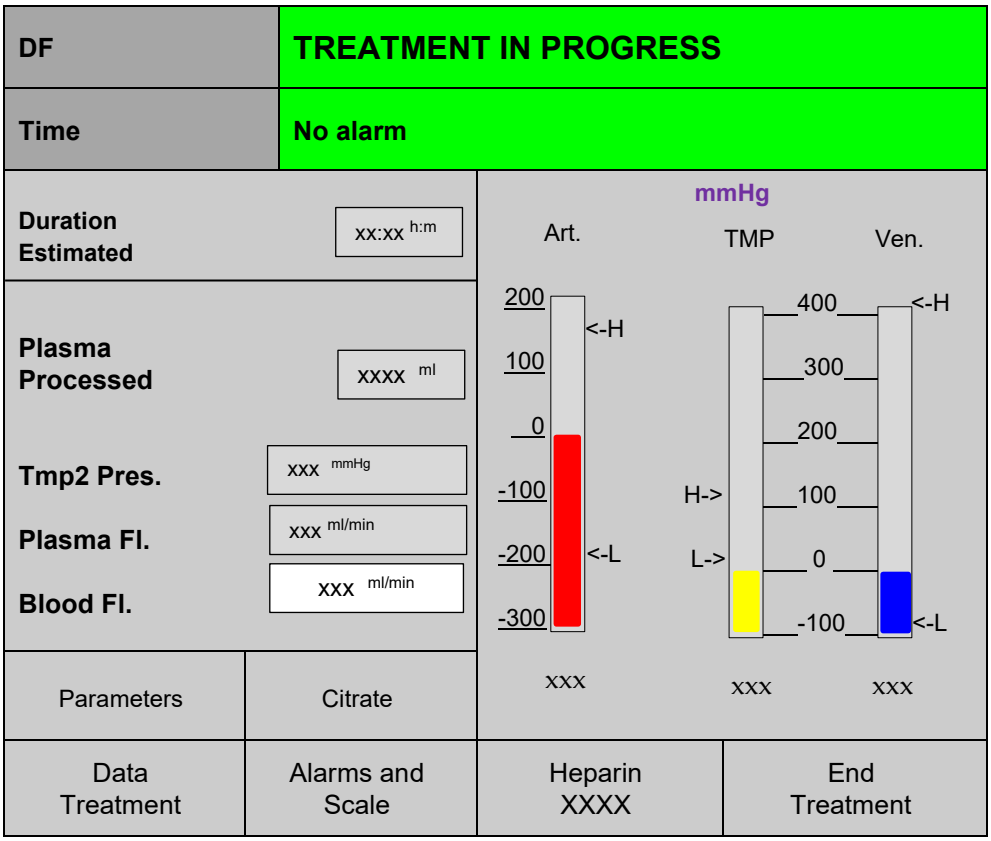
Push the START/STOP button (rif.16) to switch on the blood pump and enter in the patient connection phase.



For the first 100 ml of processed liquid by the blood pump, the machine considers the treatment as being in the connection phase and hence does not activate the infusion pump.

At the end of the patient connection phase AFERsmart PLUS automatically enters the treatment phase.

From the main screen it is possible to monitor the status of the treatment, by setting and / or monitoring the main treatment parameters.



Available setting parameters:

- Blood Fl. (flow) [ml / min].
  - Range: [5 - 250] ml / min
  - Default: 50ml / min
  - Step: 5ml / min

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Duration Estimated [h:m]**: It indicates the treatment time estimated.
- **Plasma processed [ml]:** It indicates the volume of plasma treated.
- **Tmp2 pressure [mmHg]**: It indicates the pressure of in the adsorber filter.
- **Plasma Fl.**: It indicates the actual plasma pump flow rate
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The TMP pressure is the pressure that work over the filter fibers.
  The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

NOTE

If Citrate was previously selected in the anticoagulant to be used, the range of the blood pump speed will be set in relation to the citrate percentage set and vice versa. AFERsmart PLUS automatically reject any incorrect value of Blood pump speed or citrate percentage that will be set.
The maximum value the citrate pump can reach is 5 ml/min.

Example of work situation:

- **If Blood Pump is set at 250 ml/min the citrate percentage must be 2% or less**
- **If Citrate percentage set is 5% the blood pump speed must be 100 ml/min or less**

From the main screen it is possible to access various functions through the menu located at the bottom:

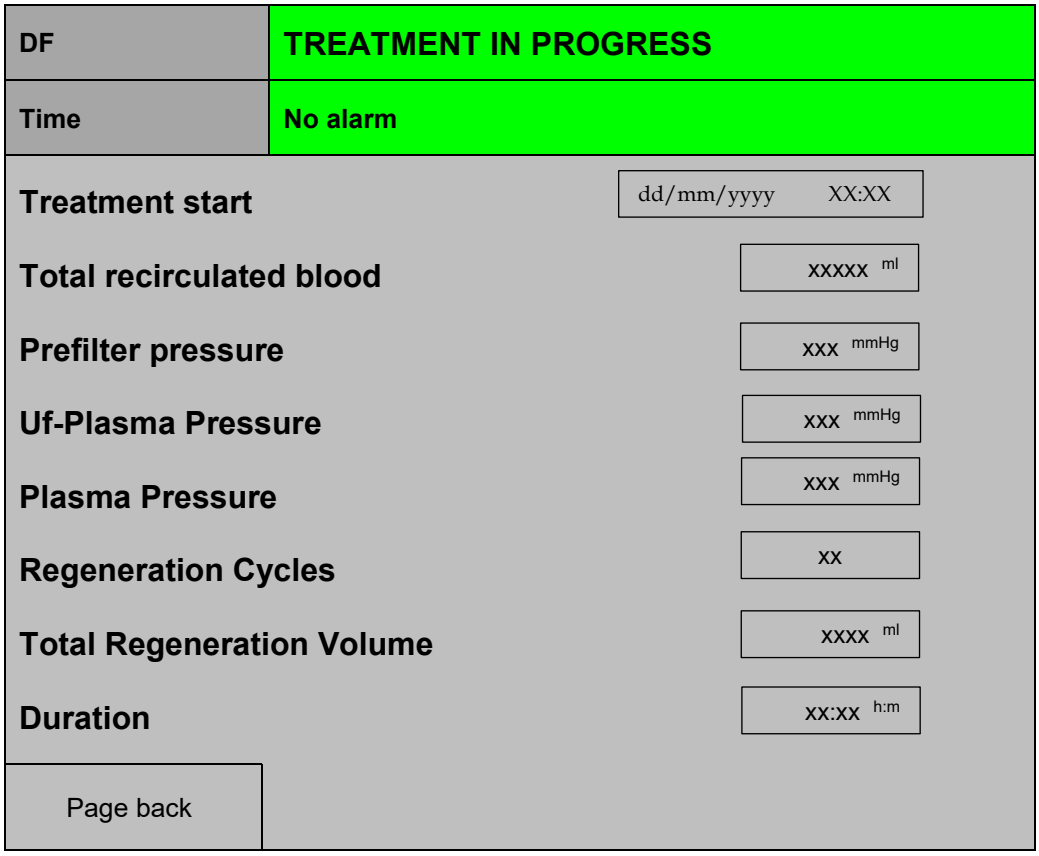
Parameters

See the Treatment parameters chapter 19.2.2.1

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Data Treatment

The DATA TREATMENT screen shows the data relating to the treatment:



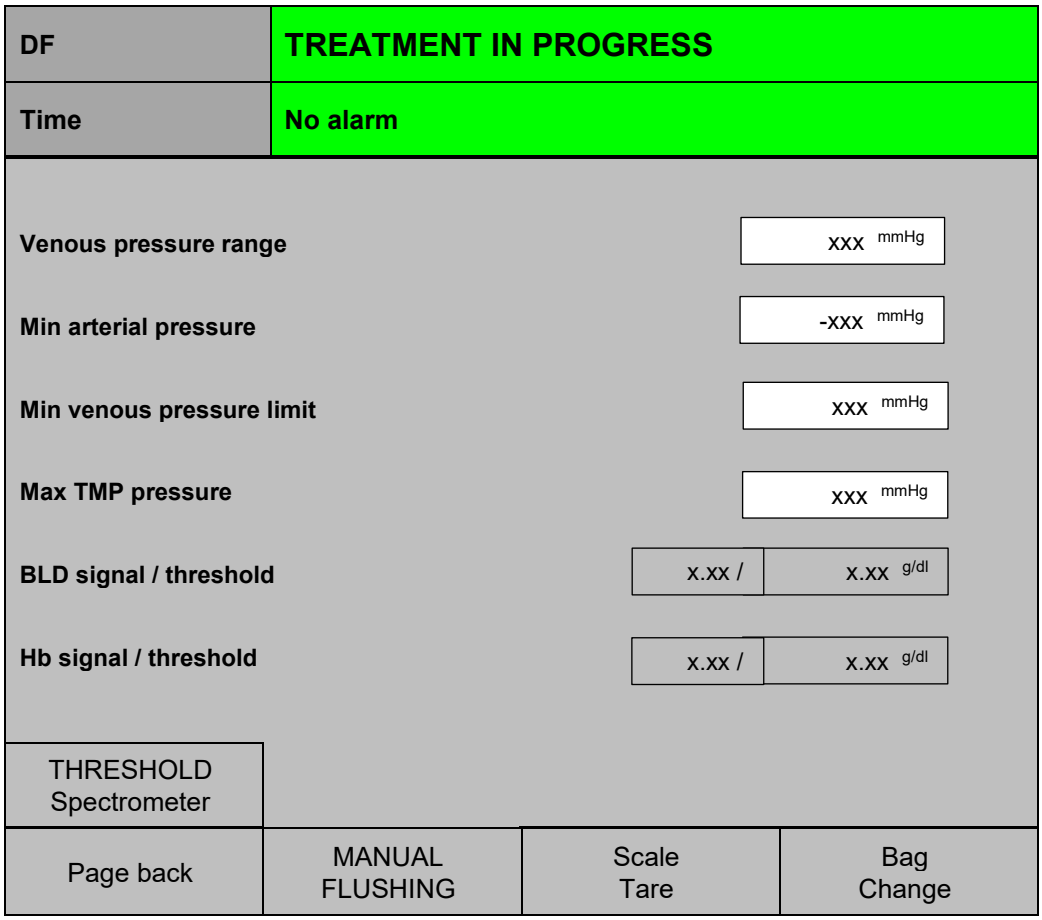
Allows accessing to the page where the following data are shown:

- Treatment start: Date and time of the treatment;
- Total recirculated blood[ml];
- Prefilter pressure [mmHg];
- Uf-Plasma Pressure [mmHg];
- Plasma Pressure [mmHg];
- Regeneration Cycles;
- Total Regeneration Volume [ml] ;
- Duration [h:m]

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Alarms and Scale:

The "ALARMS AND SCALE" screen allows you to set / view the alarm thresholds:



On this page, you can view and change the following values:

- **Venous pressure range**: It indicates the range of values within which the restitution pressure must be maintained during the treatment; if the value read is not within this range
  - Range: [40 - 200] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min arterial pressure**: It indicates the aspiration pressure alarm threshold value.
  - Range: [-250 - 0] mmHg
  - Default: -200 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min venous pressure limit**:Indicates the minimum value alarm of venous/restitution pressure
  - Range: [-30 - 5] mmHg
  - Default: 5 mmHg
  - Step: 1 mmHg

  The relative alarm will be displayed.

- **Max TMP pressure**: Sets the maximum transmembrane pressure on the plasma filter
  - Range: [0 - 300] mmHg
  - Default: 100 mmHg

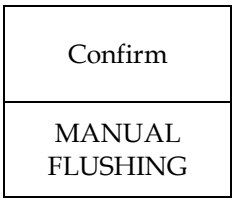
- Step: 10 mmHg

When this value is reached, the plasma pump automatically starts decelerating until reaching the minimum value available

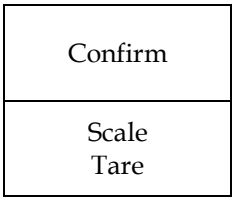
- **BLD signal / threshold:** It indicates the value of blood in the plasma read by the spectrometer and the related alarm threshold
- **Hb signal / threshold:** It indicates the value of haemolyzed plasma read by the spectrometer and the related alarm threshold

From this screen it is possible to access various functions through the menu located at the bottom:

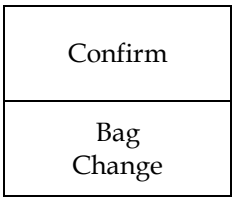
MANUAL FLUSHING: if the TMP2 is growing up or it is necessary to clean the plasma fractionator it is possible to start a plasma fractionator flushing phase.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:



Scale Tare: if one of the bags hanged to the scales is accidentally moved and it is necessary to continue the treatment it is possible to tare the scales.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:



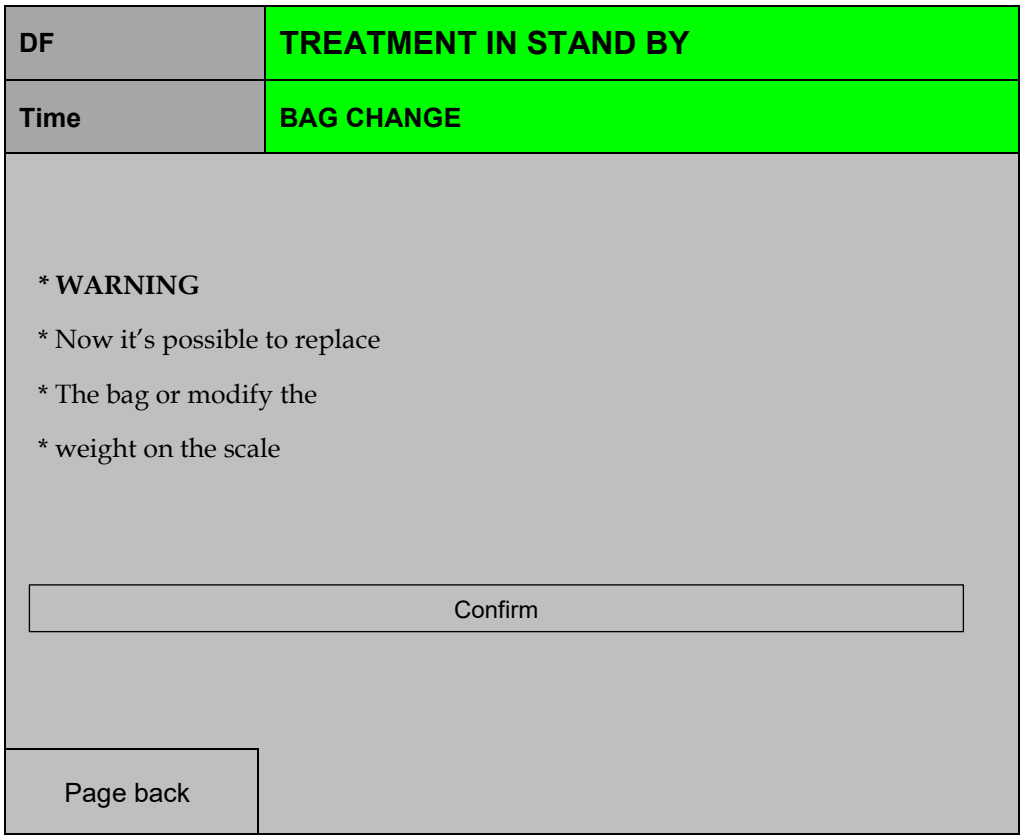
Bag Change: if it is necessary to replace one or more bags located on one or both scales, it is possible to activate the associated replacement procedure.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:



After correctly performing the Functions described above, it is necessary to follow the instructions that appear on the display.

NOTE

During the Change bag procedure, the Treatment phase change automatically to "TREATMENT IN ST-BY" (Stand By phase)



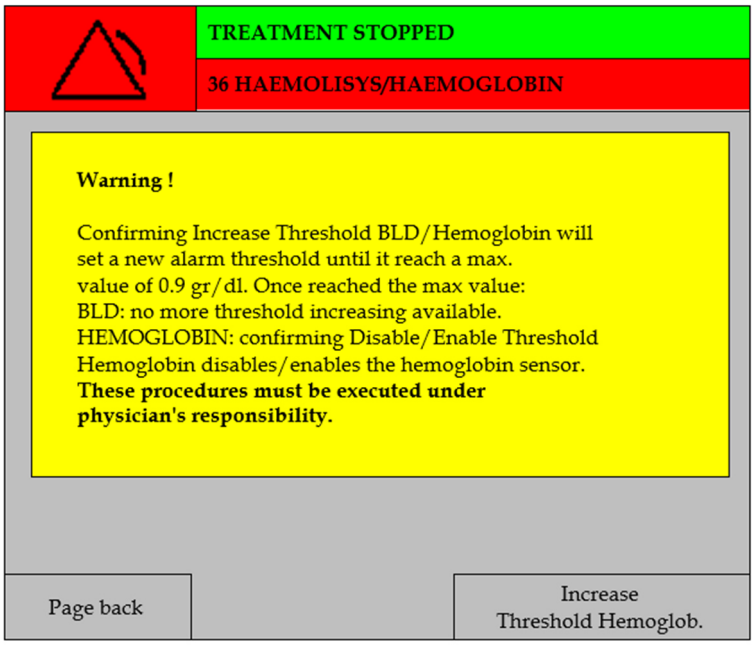
Press "Confirm" when connect at the scale the new bag.
With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

THRESHOLD Spectrometer: if the value read by the spectrometer of blood in plasma or plasma haemolyzed exceeds the value of the related threshold this function key appears.

By selecting and confirming the function key the following pages will be shown.

In particular, if the alarm raised up is:

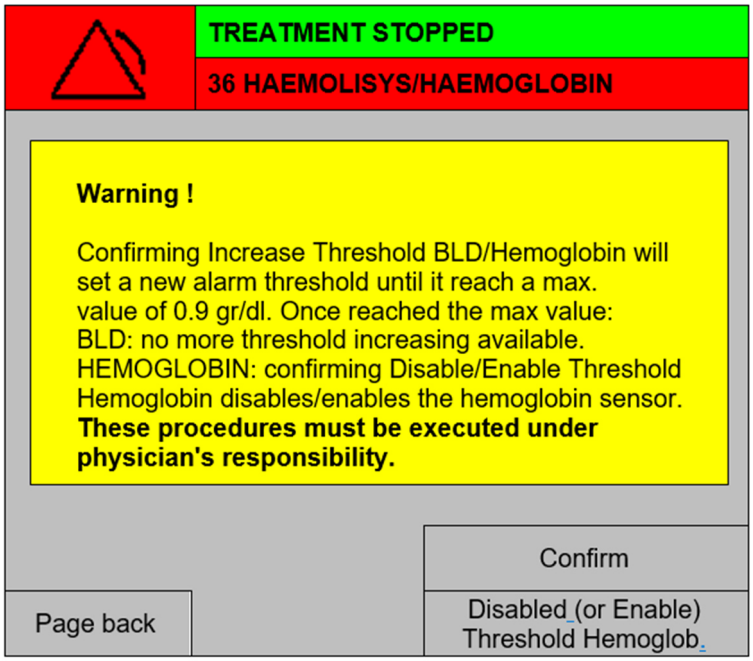
- **36 HAEMOLISYS/HAEMOGLOBIN**



Press "Increase Threshold Hemoglob." to increase of 0.2 g/dl the value of the threshold of the alarm and come back in the "TREATMENT STOPPED" page.

With the "Page back" button it's possible to come back in the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl and the alarm rise up or the reading of haemolyzed plasma by the spectrometer is disabled following page will be shown by pressing on "THRESHOLD Spectrometer" function key.



Press "Disabled Threshold Hemoglob." and "Confirm" to disable the reading of haemolyzed plasma by the spectrometer and come back in the "TREATMENT STOPPED" page.

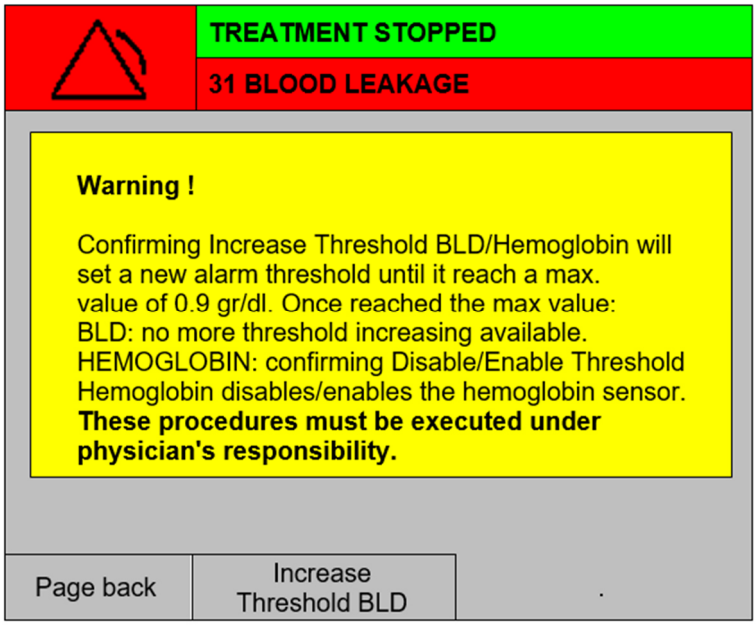
Press “Enable Threshold Hemoglob.” and “Confirm” to enable the reading of haemolyzed plasma by the spectrometer and come back in the “TREATMENT STOPPED” page.

WARNING

Raising the alarm threshold and deactivating the spectrometer's reading of haemolysed plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

- **31 BLOOD LEAKAGE**



Press "Increase Threshold BLD" to increase of 0.2 g/dl the value of the threshold of the alarm and come back in the "TREATMENT STOPPED" page.

With the "Page back" button it's possible to come back in the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl the "THRESHOLD Spectrometer" function key will not appear

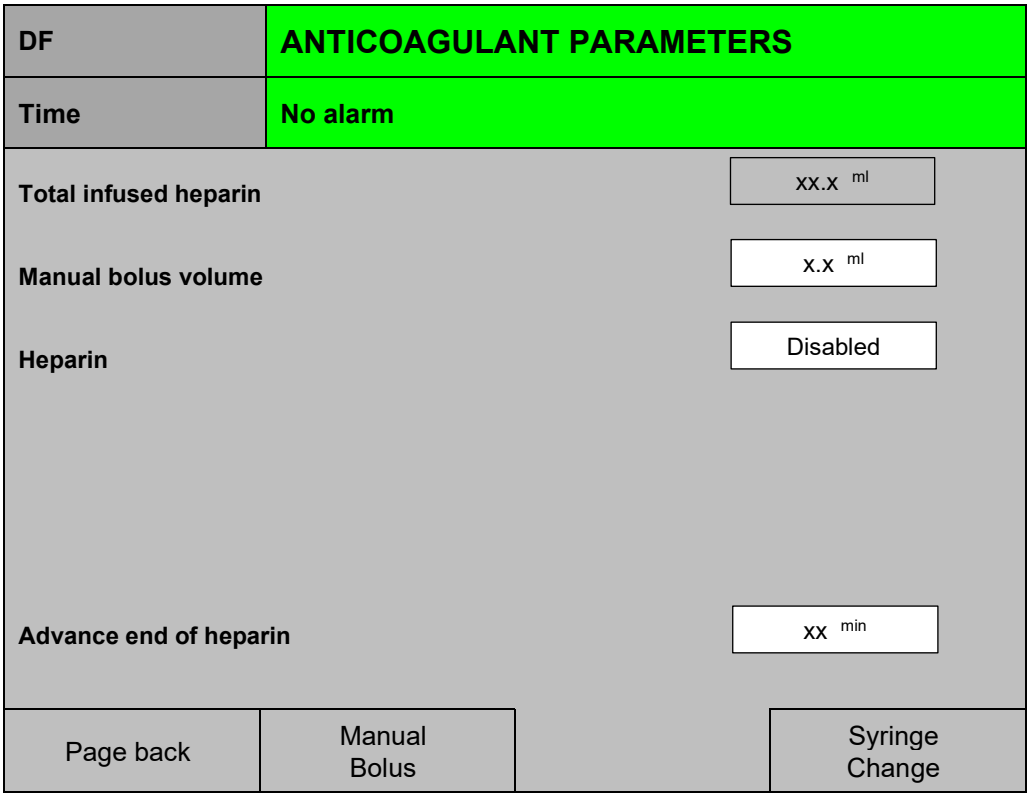
WARNING

Raising the alarm threshold of blood in plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

Heparin XXXX:

On this page it is possible to check and change the operating status/mode of the heparin pump:



The screen above shows the "Disabled" heparin mode.

- **Total Infused Heparin:** Volume in ml of heparin injected into the extracorporeal circuit (not modifiable)
- **Manual Bolus Volume**: It indicated the heparin bolus volume that the user can manually injected into the extracorporeal circuit
  - Range: [0.1 – 5.0] ml
  - Default: 1.0 ml
  - Step: 0.1 ml/min

  Press the "Manual Bolus" key to inject this bolus.
- **Heparin:** This parameter indicates the operating status/mode of the heparin syringe; the pump operating mode can be changed during treatment.
- **Advance end of heparin:** It indicates the time in minutes when the heparin infusion should be stopped before the end of the treatment.

NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

From this screen it is possible to access various functions through the menu located at the bottom:

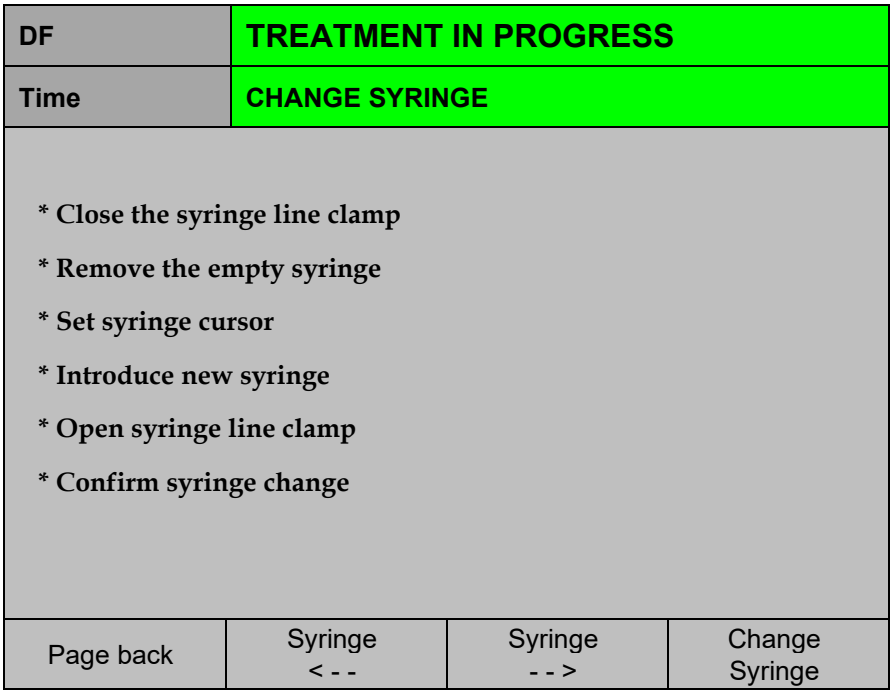
Manual Bolus: trough this function it is possible to administering an additional heparin bolus of 1 ml respect the normal heparin operating mode.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Manual Bolus	Confirm

Syringe Change: trough this function it is possible to replace the anticoagulant syringe .
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Confirm	Syringe Change

Confirmed the "Change Syringe" appear the following screen with reported the instructions to replace the syringe.

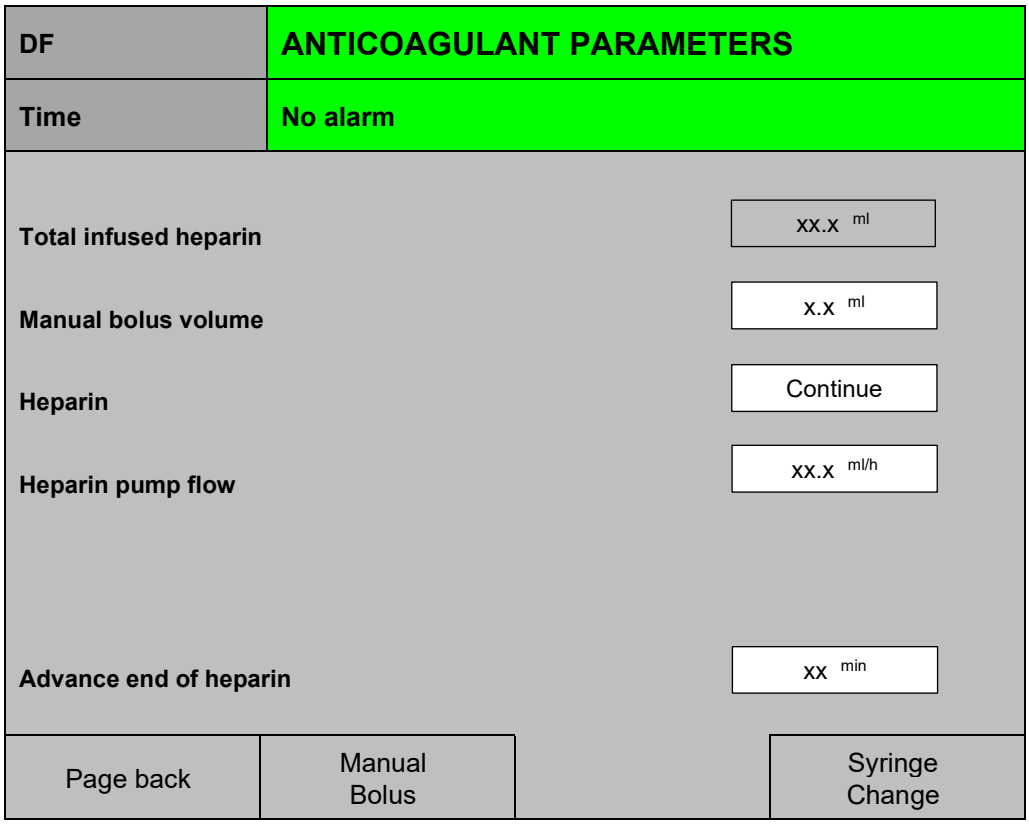


Follow the on-screen instructions and confirm "Change Syringe" key.

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Other Heparin Modes available:

- **Heparin Continue:**

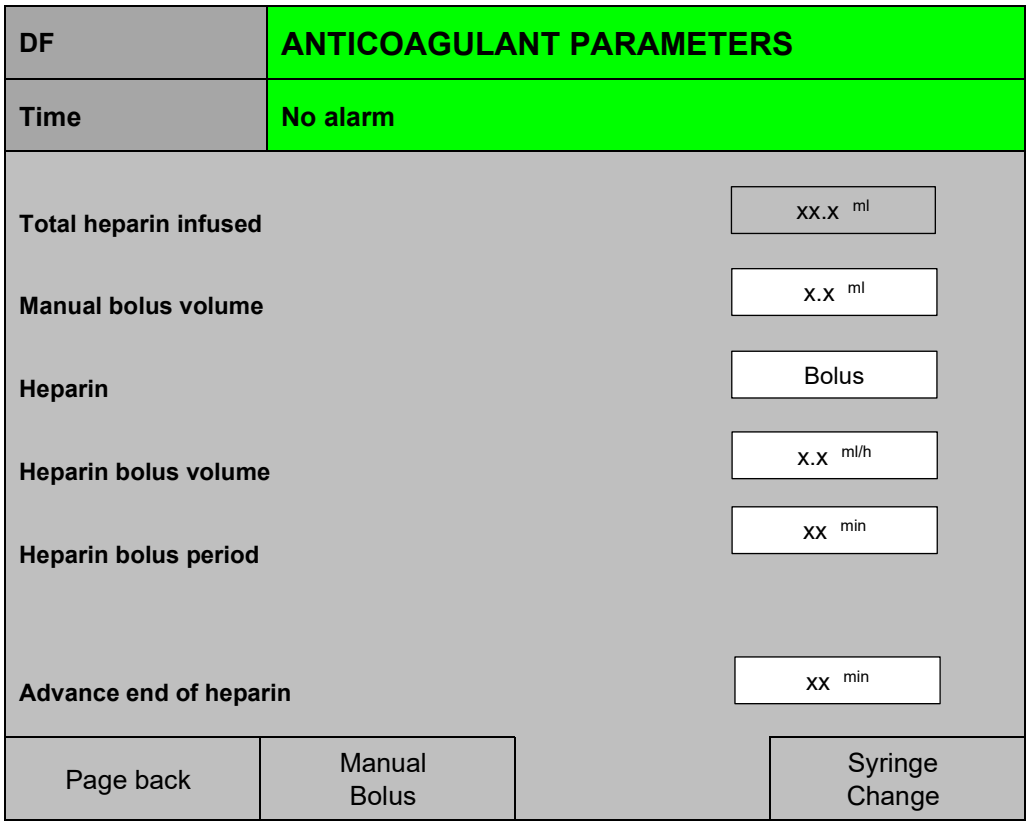


Compared with the heparin disable screen the only add parameter is:

Heparin pump flow: It indicated the anticoagulant flow in ml/min .

- Range: [0.1 – 20.0] ml
- Default: 0.4 ml
- Step: 0.1 ml

- **Heparin Bolus:**



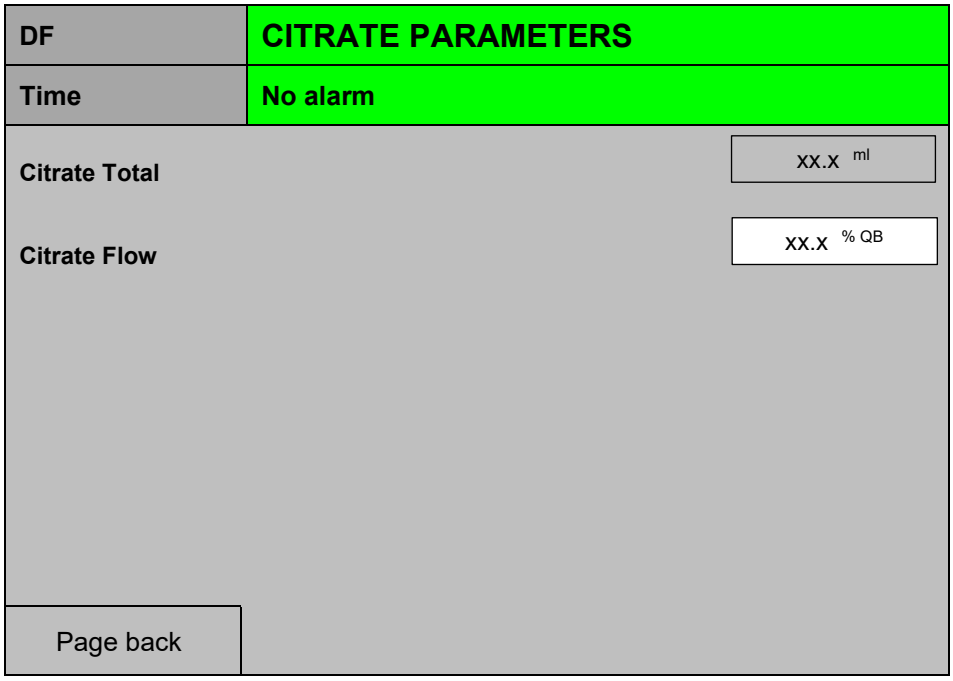
Compared with the heparin disable screen the only add parameter is:

Heparin bolus volume: It indicated the anticoagulant bolus volume regularly injected.
- Range: [0.1 – 5.0] ml
- Default: 0.1 ml
- Step: 0.1 ml

Heparin bolus period: It indicated the time between two consecutive bolus anticoagulant injection.
- Range: [5 – 60] min
- Default: 20 min
- Step: 1 min

Citrate (if selected before Priming):

On this page it is possible to check and change the operating status/mode of the citrate pump:



- **Citrate Total:** Volume in ml of citrate infused into the extracorporeal circuit (not modifiable)
- **Citrate Flow**: It indicated the citrate pump speed respect the blood pump flow rate
  - Range: [0.0 – 10.0] % QB
  - Default: 3.0 % QB
  - Step: 0.1 % QB

End Treatment

See End Treatment chapter 19.2.2.4.

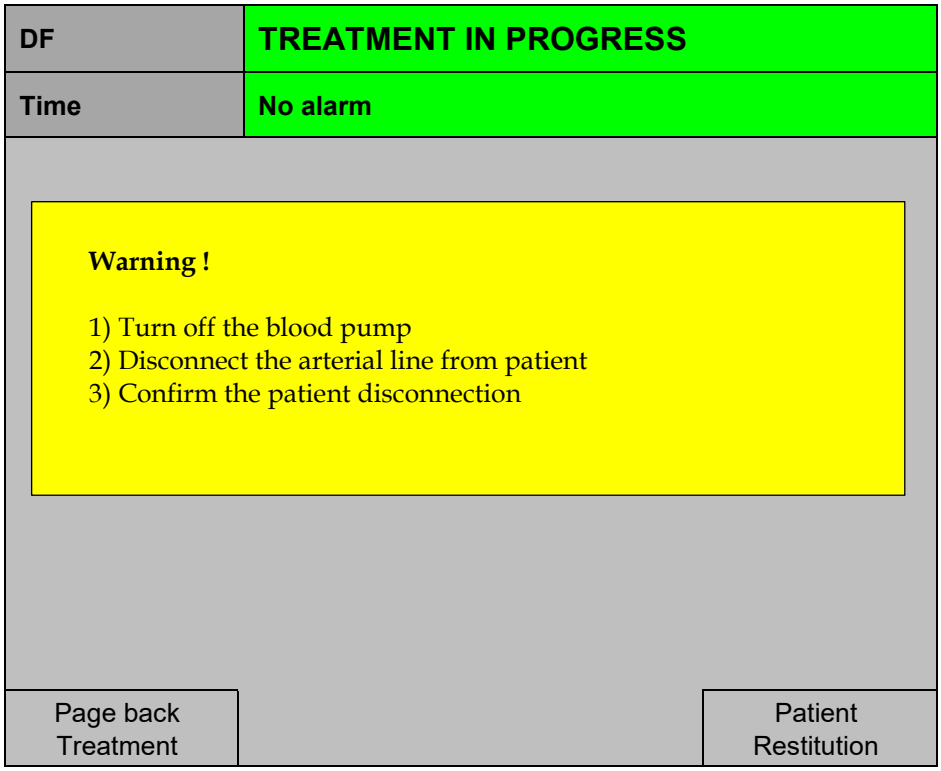
19.2.2.4. End Treatment

When AFERSMART PLUS has reached the target of treated blood volume, the message "501 END TREATMENT" appears on the screen.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the treatment at any time by pressing "End Treatment" key also if the treatment is not completed.

Select "End Treatment" and perform the operations that appear on the display to proceed.

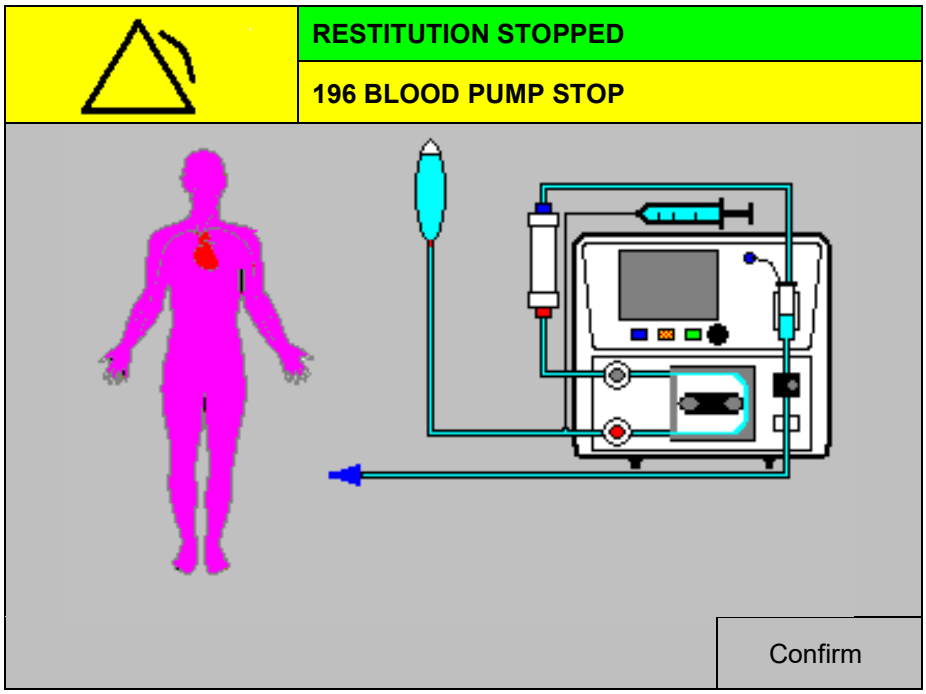


Press "Patient Restitution" key to start the blood restitution phase.
Press "Page back Treatment" key to return the treatment phase.

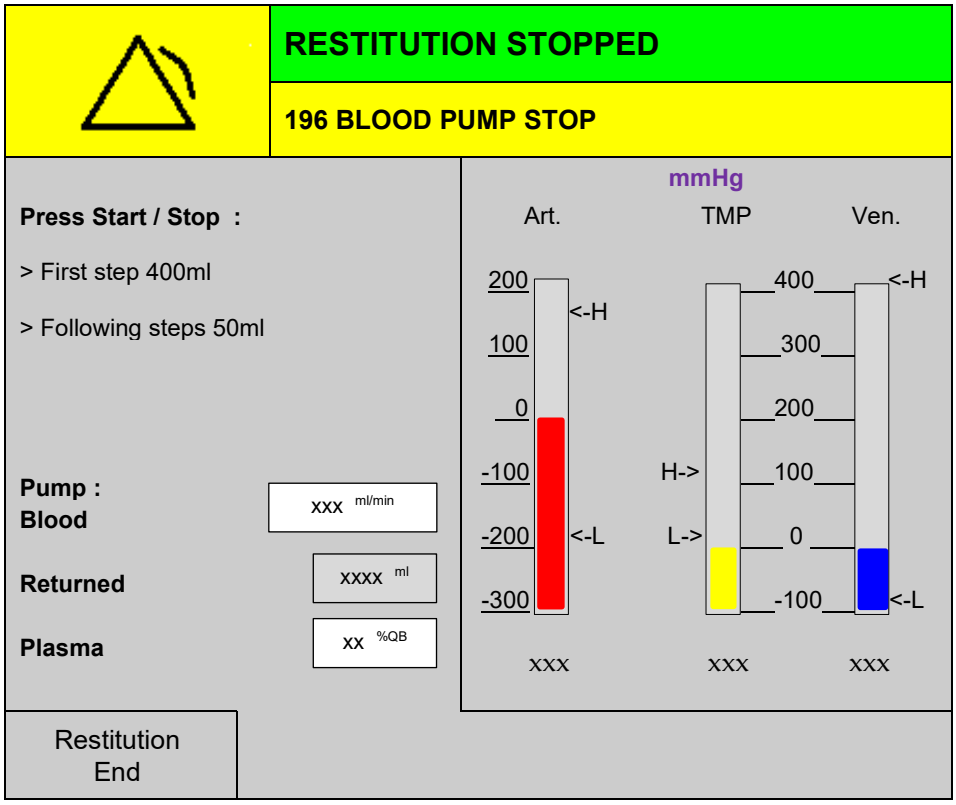
19.2.3. BLOOD RESTITUTION

19.2.3.1. Restitution

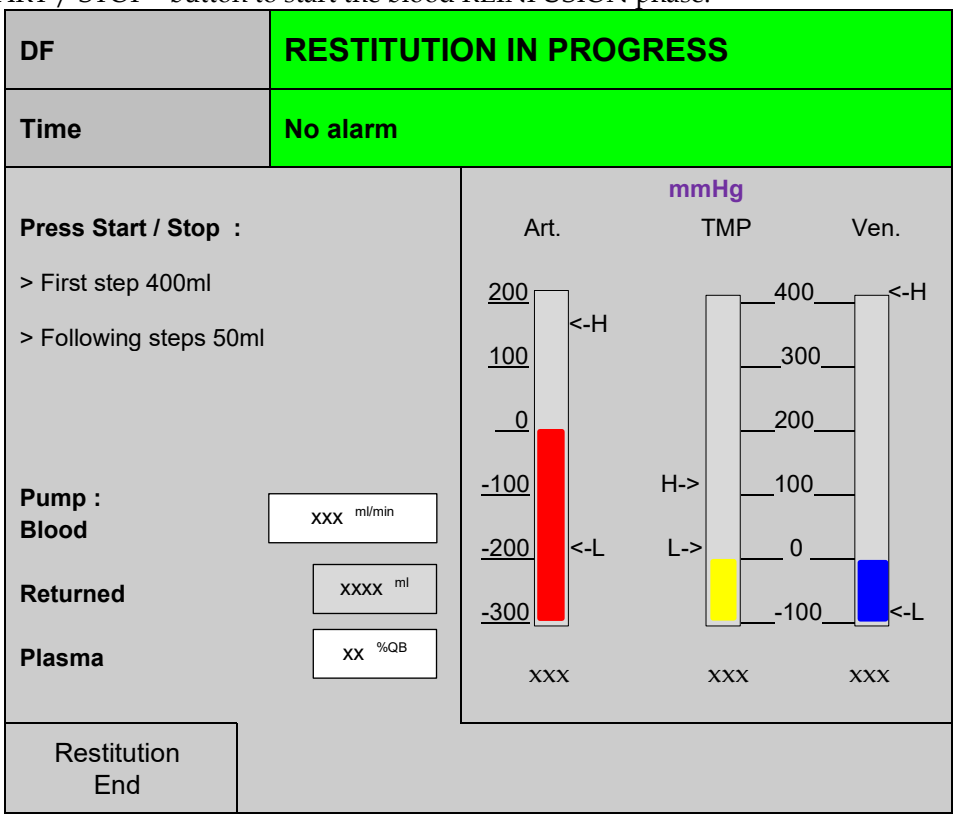
The restitution phase allows the patient to re-infuse most of the blood remaining in circulation in the lines.
Disconnect the arterial line from the patient and connect it to the NaCl solution (1000 ml container).



When entering the page above, the blood pump stops to allow to connect the aspiration line to saline solution bag.
Press "Confirm" key to enter the main page of restitution phase.



Press the <START / STOP> button to start the blood REINFUSION phase.



The first time the START/STOP button is pressed and 400 ml of blood are returned.
The next times the button is pressed 50 ml at a time are returned.
During standard or additional reinfusion, it is always possible to stop the blood pump by pressing <START / STOP>

Available setting parameters:

- Pump: Blood (flow)[ml / min].
  - Range: [0 - 100] ml / min
  - Default: 30ml / min
  - Step: 5ml / min

- **Plasma** (flow) [%QB].
  - Range: [0 - 50] %QB
  - Default: 30 %QB
  - Step: 1 %QB

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Returned [ml]:** It indicates the total blood returned.
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The TMP pressure is the pressure that work over the filter fibers. The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

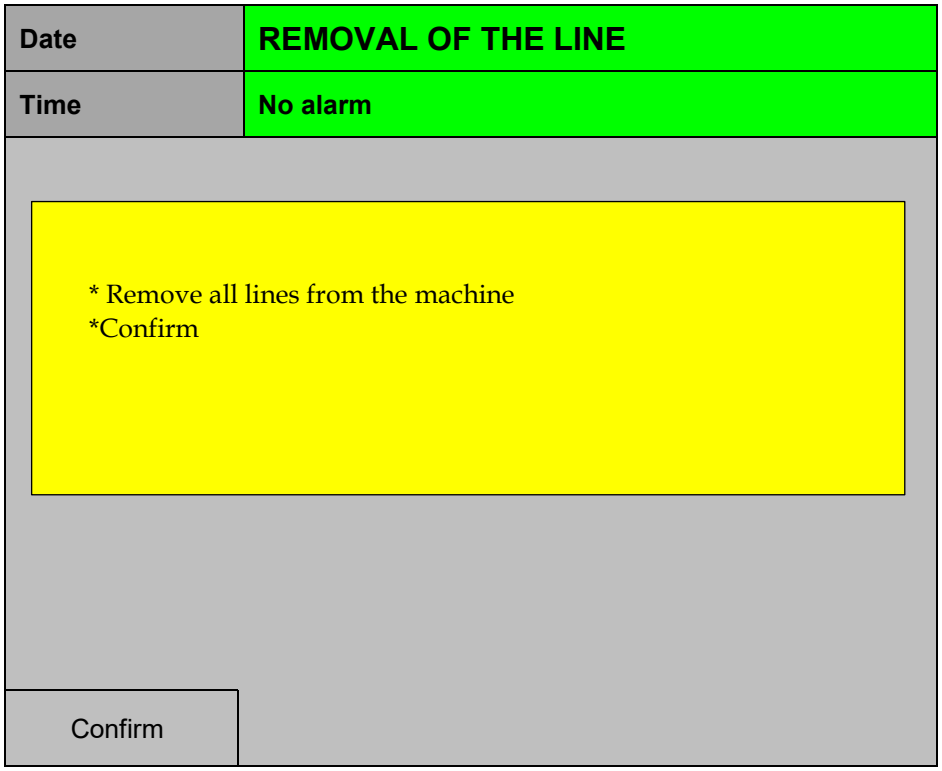
In this phase, only the air bubble detector and the pressure and safety alarms (covers, etc.) are active.
Once the restitution has been completed, select "Restitution End" to disconnect the circuit from the machine.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the restitution at any time by pressing "Restitution End" key also if the blood restitution is not completed.
If you do not confirm the "Restitution End" before turning off the machine. The next time you turn it on, it will restart from this page and not from the INTRODUCING page. In this case, confirm the "Restitution End" after turning on

19.2.3.2. Removal of the lines

The patient can be disconnected from the venous line.
It is possible to remove the lines and the plasma filter and proceed with disposal them.



After the uninstallation of the lines, push "Confirm" to go to the "INTRODUCING" page.

The AFERsmart PLUS can now be turned off.

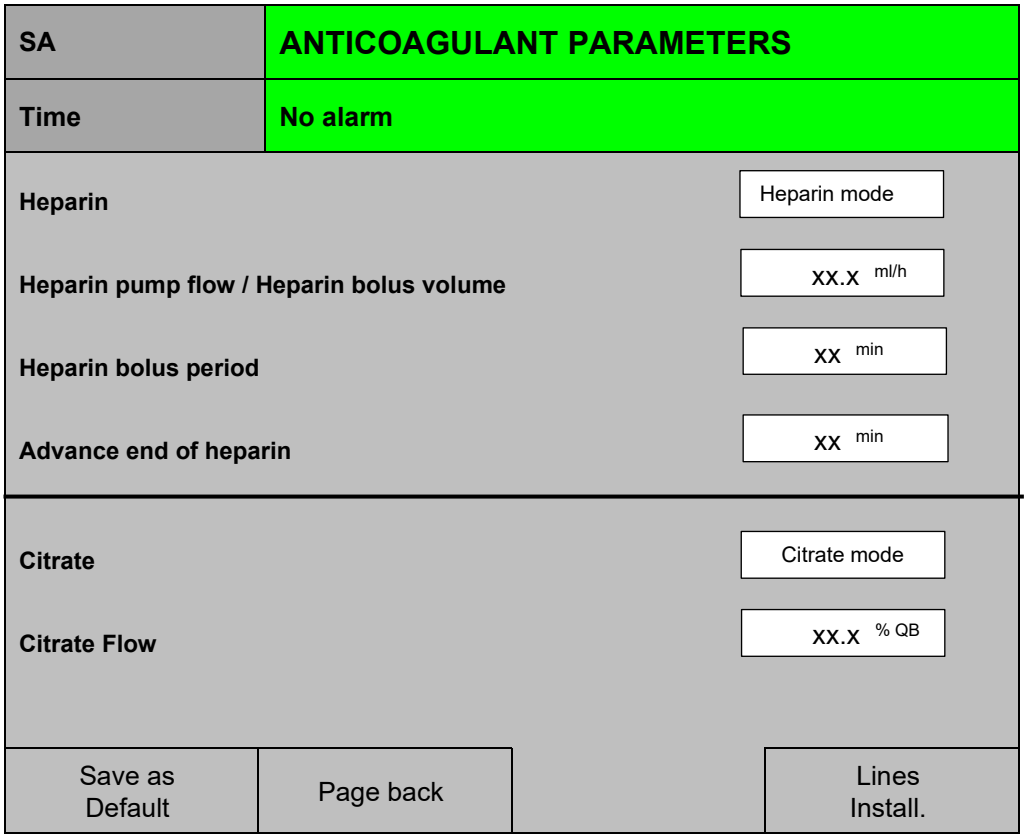
19.3. SELECTIVE APHERESIS

19.3.1. PREPARATION

19.3.1.1. Anticoagulant Parameters

It is possible to set / modify the parameters related to the anticoagulant before entering in the priming procedure. These parameters can be modified even during the treatment phase, by pressing < Parameters> key.

- Heparin: Disabled/ Continue/ Bolus
- Heparin pump flow (available only in "Continue" mode): [0.1 – 20.0] [ml/h]
- Heparin bolus volume (available only in "Bolus" mode): [0.1 – 5.0] [ml/h]
- Heparin bolus period (available only in "Bolus" mode): [5 – 60] [min]
- Advance end of heparin: [0 – 30] [min]
- Citrate: Disabled/ Enabled
- Citrate Flow (available only in "Enabled" mode) : [0.5 – 10.0] [% QB]



NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

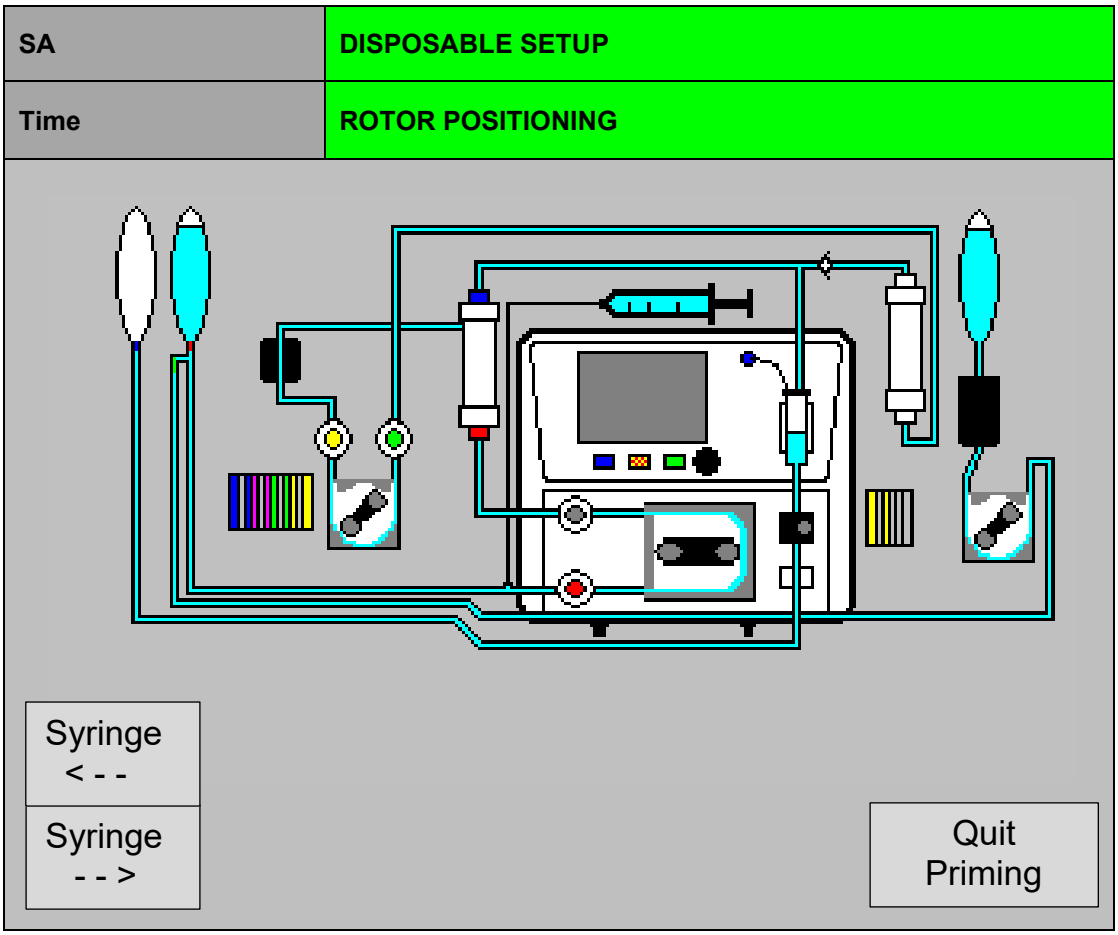
Press ”Save as Default” to save set parameters and make them available for the next treatments

Press the <Page back> key to return to the “INTRODUCING” page

Press the <Lines Install.> key to proceed to the “DISPOSABLE SETUP” page

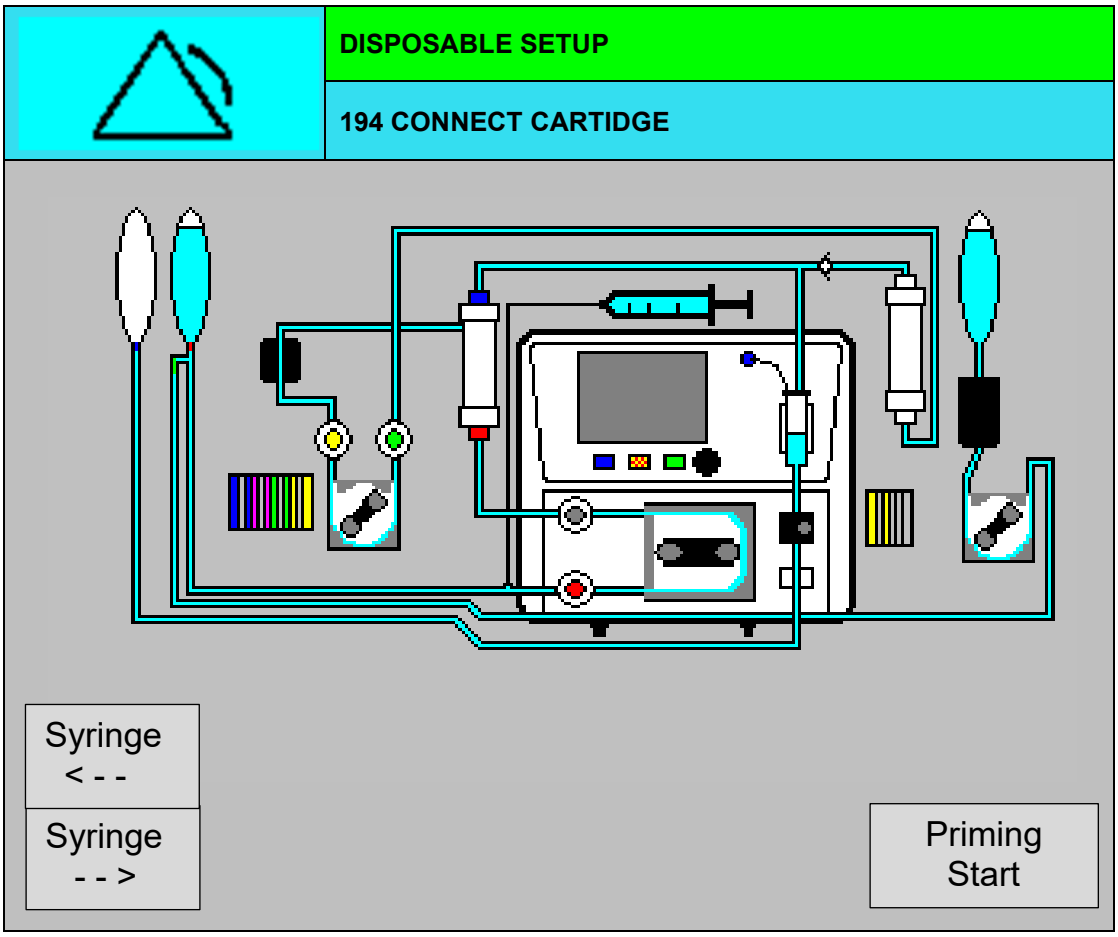
19.3.1.2. DISPOSABLE SETUP

On this page it is possible to install the disposable, the Plasmafilter and the bags needed to perform the SA treatment and its priming



Once entering in this page AFERsmart PLUS will execute the automatic pump rotors positioning (both Blood and Plasma) needed to ease the installation of Blood and Plasma tubing set.

After the "Rotors positioning" phase the "194 CONNECT CARTRIDGE" message will appear, the venous electroclamp will open and the red light over the clamp will switch off.
and it will be possible to install the disposable kit, the Plasmafilter and the bags as shown on the screen



At this phase make sure that the hooks of the scale are completely free.

The AFERSMART PLUS Kit is enclosed in a paper-film envelope, inside are:

Semi-finished arterial line and ACD (identified with red- and green-coloured components)
Semi-finished venous line (identified with blue-coloured components)
Semi-finished plasma line (identified with yellow components)

- Hang the Priming Solutions and the citrate solution (if Citrate anticoagulation was set) on the stand pole.
- Place the plasma filter in its support (ref. 6 Chapter 2.3)
- Place the plasma fractionator in its support (ref. 2 Chapter 2.4)
- Remove the plasma line from the bag
- Open the plasma pump cover (ref. 1 Chapter 2.3)
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  Close the plasma pump cover

- Open the UF pressure transducer and connect the relative UF DOME (ref. 3 Chapter 2.3)
- Open the plasma pressure transducer and connect the corresponding plasma DOME (ref. 2 Chapter 2.3)
- Insert the cuvette of the plasma section of the plasma line (outgoing from UF DOME) into the BLD with the nose pointing outward (ref. 5 Chapter 2.3)
- Connect the yellow Hansen connection of the plasma section of the plasma line to the upper lateral plasma compartment port of the plasma filter
- Connect the fractionator section of the plasma line (outgoing from plasma DOME) to the inlet (lower part) of the fractionator filter

WARNING

Take great care when inserting each line inside each selection clamp. Make sure that all the lines are firmly in place and that the color on the line corresponds to the color on the clamp.

- If Citrate anticoagulation was set:
  - Place the ACD chamber in the appropriate support (ref. 4 Chapter 2.4), inserting it from top to bottom
  - Open the ACD pump cover (ref. 3 Chapter 2.4),
  - Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  - Close the cover of the ACD pump
  - Connect the ACD inlet, with the white clamp to the citrate bag positioned on the stand pole
- Open the blood pump cover (ref. 2 Chapter 2.1),
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth.
  Close blood pump cover.
- Open the arterial pressure transducer and connect the relative arterial DOME (ref. 5 Chapter 2.1),
- Open the prefilter pressure transducer and connect the relative prefilter DOME (ref. 6 Chapter 2.1),
- Connect the red adapter (outgoing from the prefilter DOME) to the inlet (lower part) of the plasma-filter.
- If heparin anticoagulation was set:
  - Connect the heparin tube fitting to the 30-cc syringe previously filled with heparinized solution
  Insert the syringe in its seat, using the arrows < ← > and < → > to position the cursor
- Connect the inlet connector of the arterial line to the priming solution bag positioned on the stand pole
- Take the venous line from the envelope

- Place the venous chamber in the appropriate support (ref. 8 Chapter 2.1), by inserting it from top to bottom
- Connect the hydrophobic Venous Pressure Transducer Protector Luer Lock to the Venous Pressure Transducer (ref. 7 Chapter 2.1),
- Connect the blue adapter, at the inlet of the venous line, to the outlet (Upper part) of the plasma-filter.
- Insert the tube outgoing from the venous chamber into the air / blood sensor (ref. 3 Chapter 2.1) and, successively, into the venous clamp (ref. 4 Chapter 2.1)
- Place the venous waste bag already connected to the venous line on the stand pole (ref. 2 Chapter 2.6)
- Connect the white adapter of the fractionator section of the venous line to the outlet (upper part) of the fractionator filter

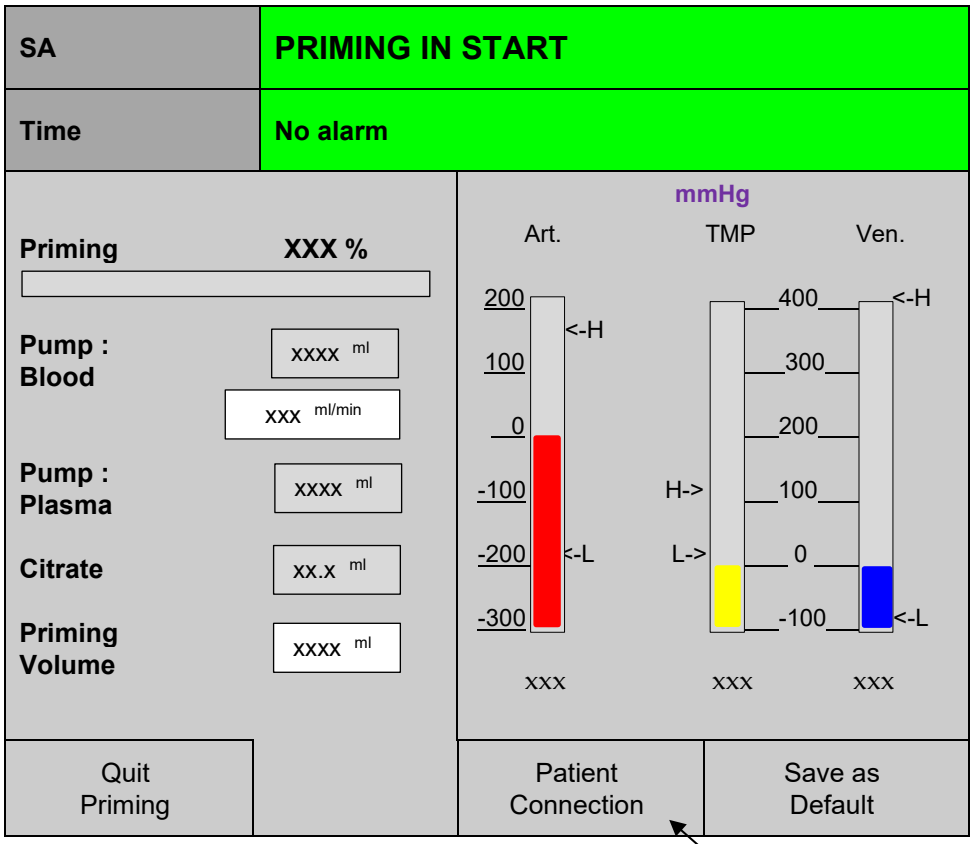
WARNING

To correctly mount the venous pressure transducer protector to the conical connections of the pressure transducers, it is necessary to:

- **Fully insert the venous pressure transducer protector by making it make a slight rotational movement until it locks.**
- **Turn the ring anticlockwise to prevent it from disconnecting.**

19.3.1.3. Priming

Make sure you have connected the circuit as described above.
Select and confirm the <Priming Start> function; this takes you to the "PRIMING IN START" screen.



If no anomalies have occurred, this button appears at the end of the Priming.

The page displays:

- Pump: Blood (volume)[ml];
- Pump: Blood (flow)[ml/min]: adjustable from 5 to 250;
- Pump: Plasma (volume)[ml];
- Citrate (volume)[ml];
- Priming Volume (total)[ml]: adjustable from 1000 to 4000;
- The current value of the Arterial (RED), TMP (YELLOW) and Venous (BLUE) pressures and the related alarm thresholds.

AFERSMART PLUS then begins the automatic priming procedure.

NOTE

To temporarily stop priming, simply press the <START / STOP> button once. Press this button again to restart priming.

Press "Save as Default" to save set parameters and make them available for the next treatments

During Priming it is advisable to adjust the level in the restitution drip chamber. To do this, operate as follows:

- Close the clamp on the restitution line to the patient.
- Open the service line on the restitution drip chamber.
- When the desired level has been reached, normally 2/3 the volume of the drip chamber, close the service line and reopen the clamp on the restitution line to the patient.

If you want to end PRIMING before it has been completed, select and confirm "Quit priming". You will be asked for confirmation that you want to quit PRIMING:

Quit Priming	Confirm

After selecting and confirming "Quit Priming" return to the "INTRODUCING" page.

Once the Priming of the disposables has been successfully completed, the Priming status bar is at 100% and the "Patient Connection" key will appear and the warning "500 END PREPARATION" rise up.

Quit Priming		Patient Connection	Save as Default

A further flushing phase can be performed by pressing the "START STOP" physical button located below the display.

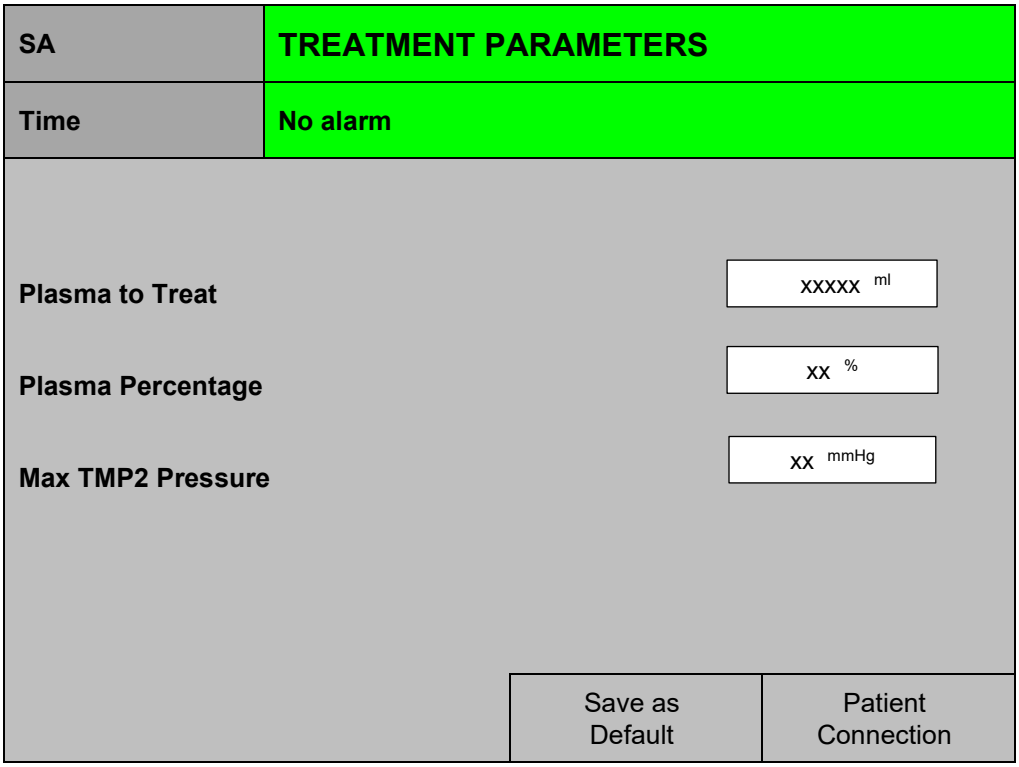
In this phase a total of one litre of priming solution will be processed by the Blood pump.
This operation can be repeated several times.

Press "Patient Connection" key to proceed to the clinical parameters settings before the treatment.

19.3.2. TREATMENT

19.3.2.1. TREATMENT PARAMETERS

The TREATMENT PARAMETERS screen allows you to set the parameters relating to the treatment.
Check and, if necessary, modify the parameters relating to the treatment, then press <Patient Connection>.



Available setting parameters:

- **Plasma to Treat [ml]:** Total plasma volume to treat.
  - Range: [500 - 20000] ml
  - Default: 500 ml
  - Step: 50 ml
- **Plasma Percentage [%]:** Plasma pump speed.
  - Range: [1 – 30] %QB
  - Default: 10 %QB
  - Step: 1 %QB
- **Max TMP2 Pressure [mmHg]:** indicates the pressure threshold at which the machine triggers the alarms for reaching of the maximum TMP2 pressure allowed
  - Range: [50 - 350] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

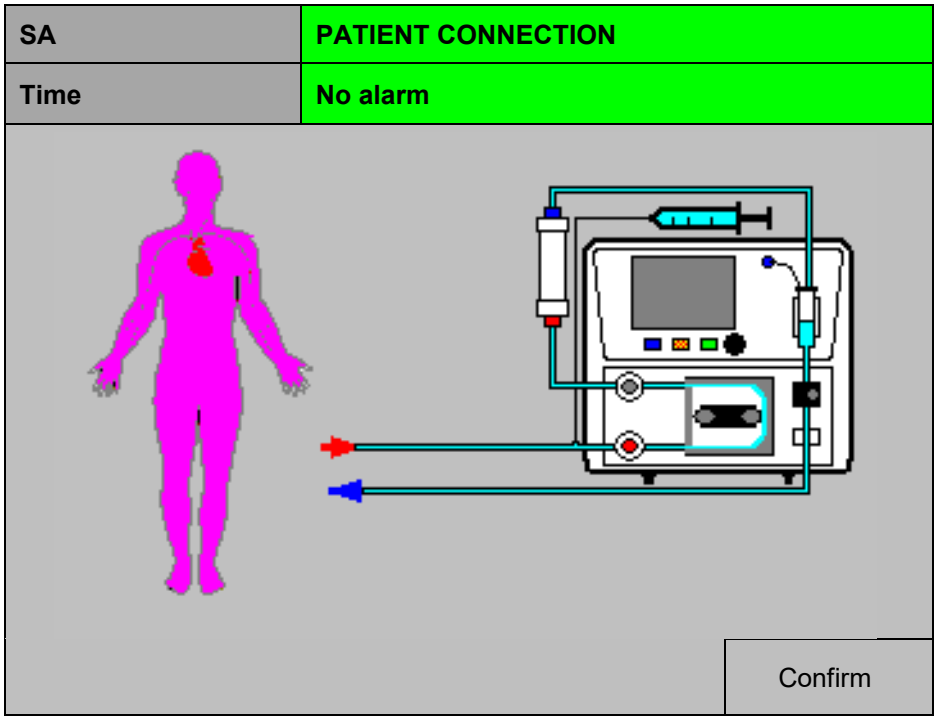
Press "Save as Default" to save set parameters and make them available for the next treatments

19.3.2.2. PATIENT CONNECTION

After setting the treatment parameters, select <Patient Connection>.

Disconnect the priming lines from the arterial line, remove the priming bags from the stand and connect the arterial and the venous line to the patient.

When done, press <Confirm>.



WARNING

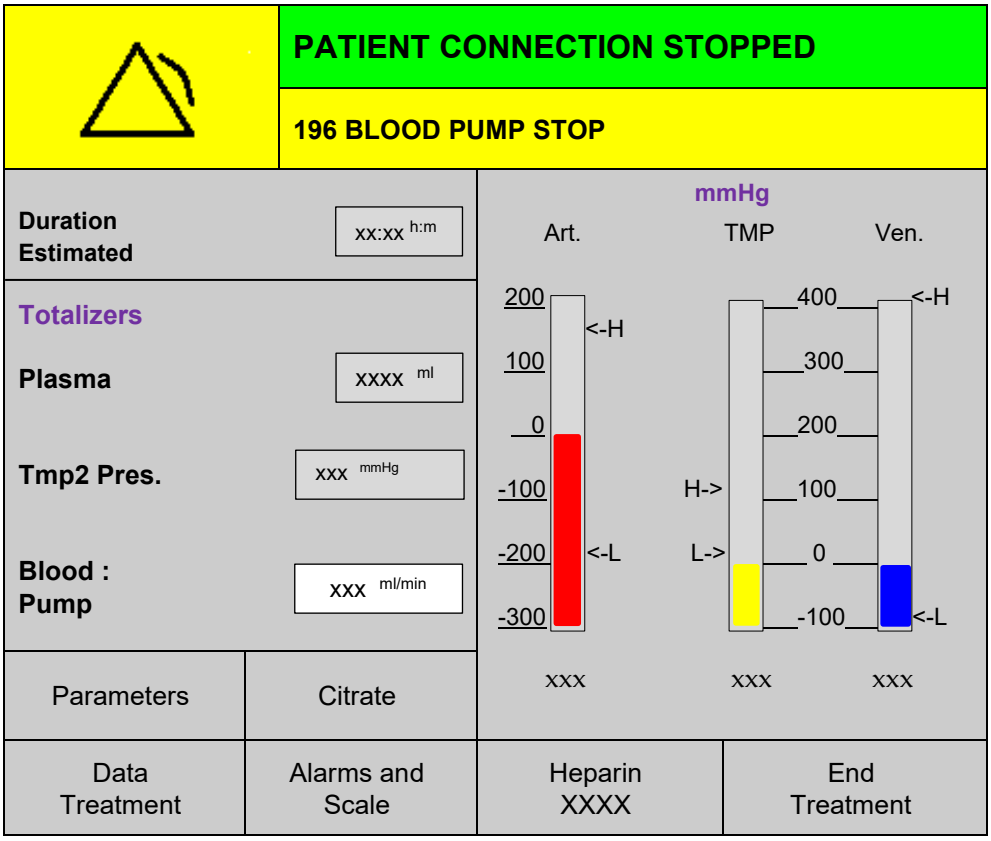
- **Risk of embolism due to air in the lines**
- **Risk of haemolysis due to kinking or crushing of lines**
- **Risk of blood loss due to not hermetically sealed connection points**

Before starting a treatment, check the following:

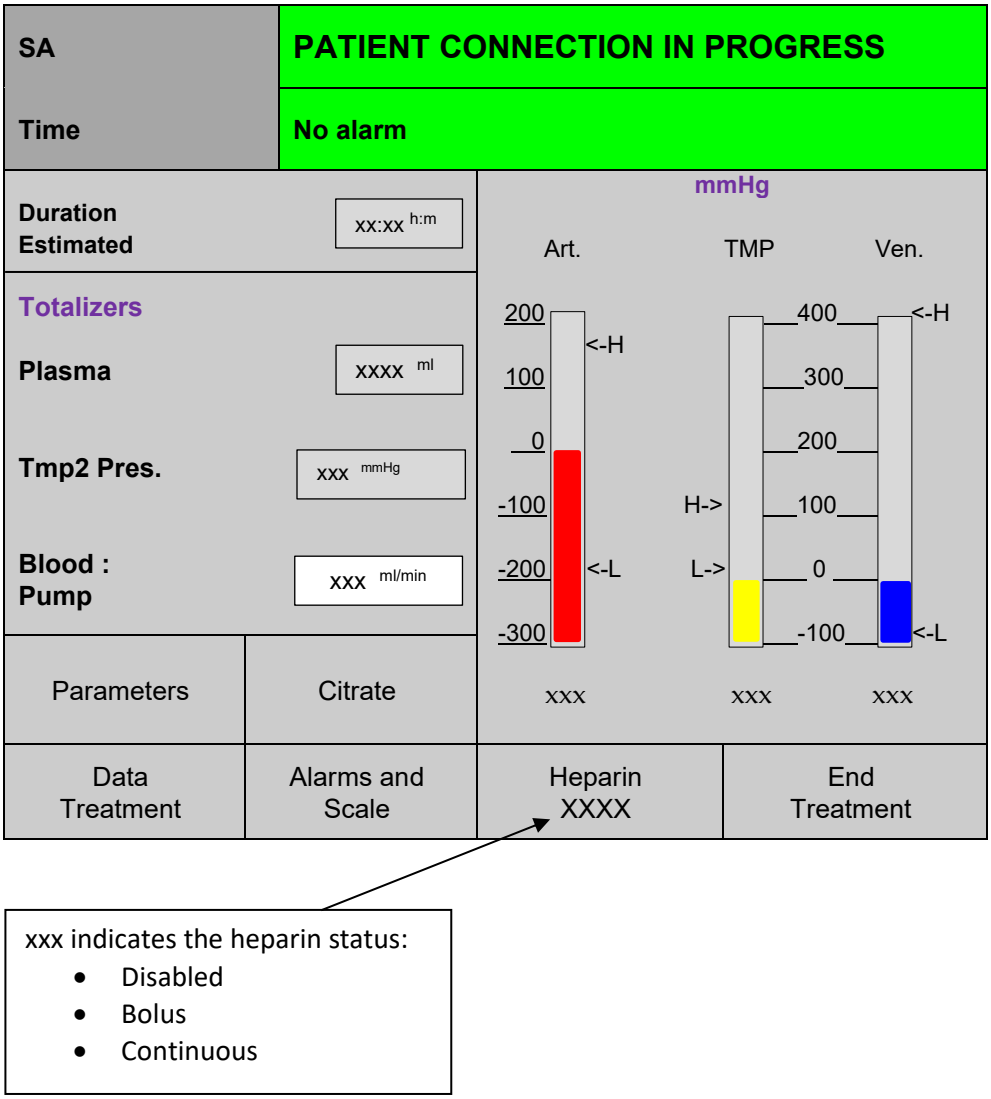
- All line joints are firmly connected
- There are no noticeable leaks in the lines, neither during nor after filling
- If leaks are found, tighten the relevant connections as needed.
- If necessary, replace the entire disposable.
- Lines are airless, inserted cleanly with no kinks, line tension or twisting and
- all fluid levels are correct.

19.3.2.3. TREATMENT

When start the treatment is show the "PATIENT CONNECTION STOPPED" screen, like reported in the following picture.



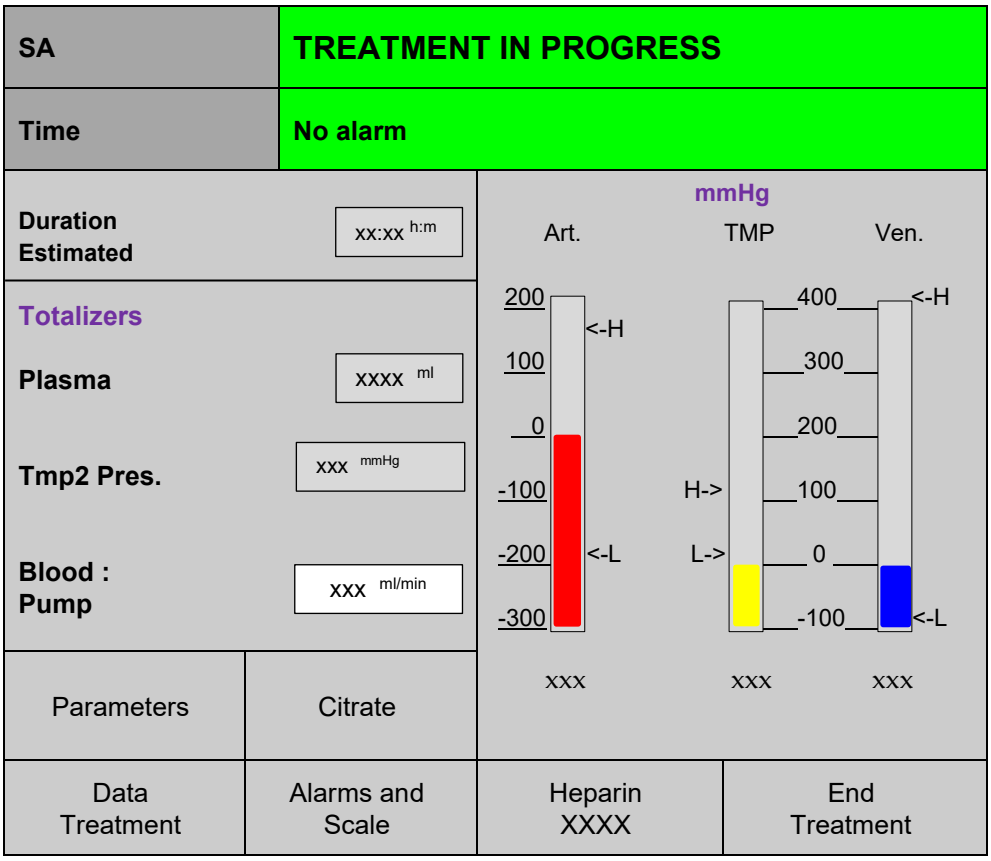
Push the START/STOP button (rif.16) to switch on the blood pump and enter in the patient connection phase.



For the first 100 ml of processed liquid by the blood pump, the machine considers the treatment as being in the connection phase and hence does not activate the infusion pump.

At the end of the patient connection phase AFERsmart PLUS automatically enters the treatment phase.

From the main screen it is possible to monitor the status of the treatment, by setting and / or monitoring the main treatment parameters.



Available setting parameters:

- Pump: Blood (flow)[ml / min].
  - Range: [5 - 250] ml / min
  - Default: 50ml / min
  - Step: 5ml / min

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Duration Estimated [h:m]**: It indicates the treatment time estimated.
- **Plasma [ml]:** It indicates the volume of plasma treated.
- **Tmp2 pres. [mmHg]**: It indicates the pressure inside the adsorber.

- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The TMP pressure is the pressure that work over the filter fibers.
  The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

NOTE

If Citrate was previously selected in the anticoagulant to be used, the range of the blood pump speed will be set in relation to the citrate percentage set and vice versa. AFERsmart PLUS automatically reject any incorrect value of Blood pump speed or citrate percentage that will be set.
The maximum value the citrate pump can reach is 5 ml/min.

Example of work situation:

- **If Blood Pump is set at 250 ml/min the citrate percentage must be 2% or less**
- **If Citrate percentage set is 5% the blood pump speed must be 100 ml/min or less**

From the main screen it is possible to access various functions through the menu located at the bottom:

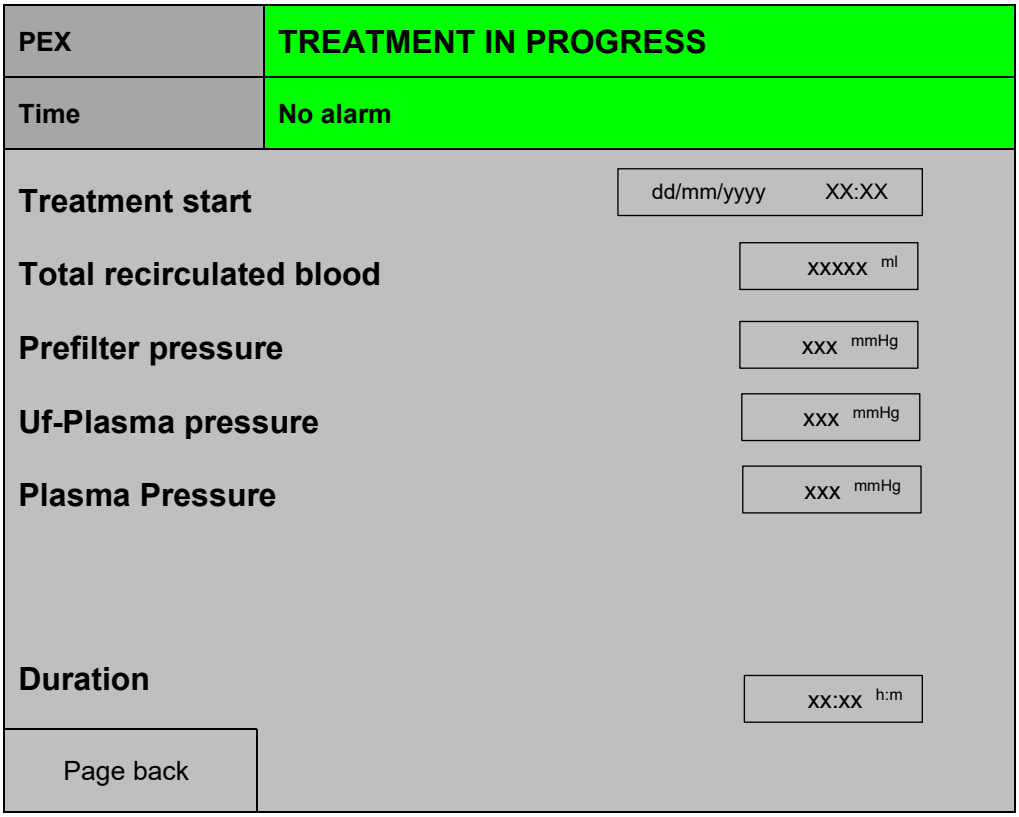
Parameters

See the TREATMENT PARAMETERS chapter 19.3.2.1

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Data Treatment

The DATA TREATMENT screen shows the data relating to the treatment:



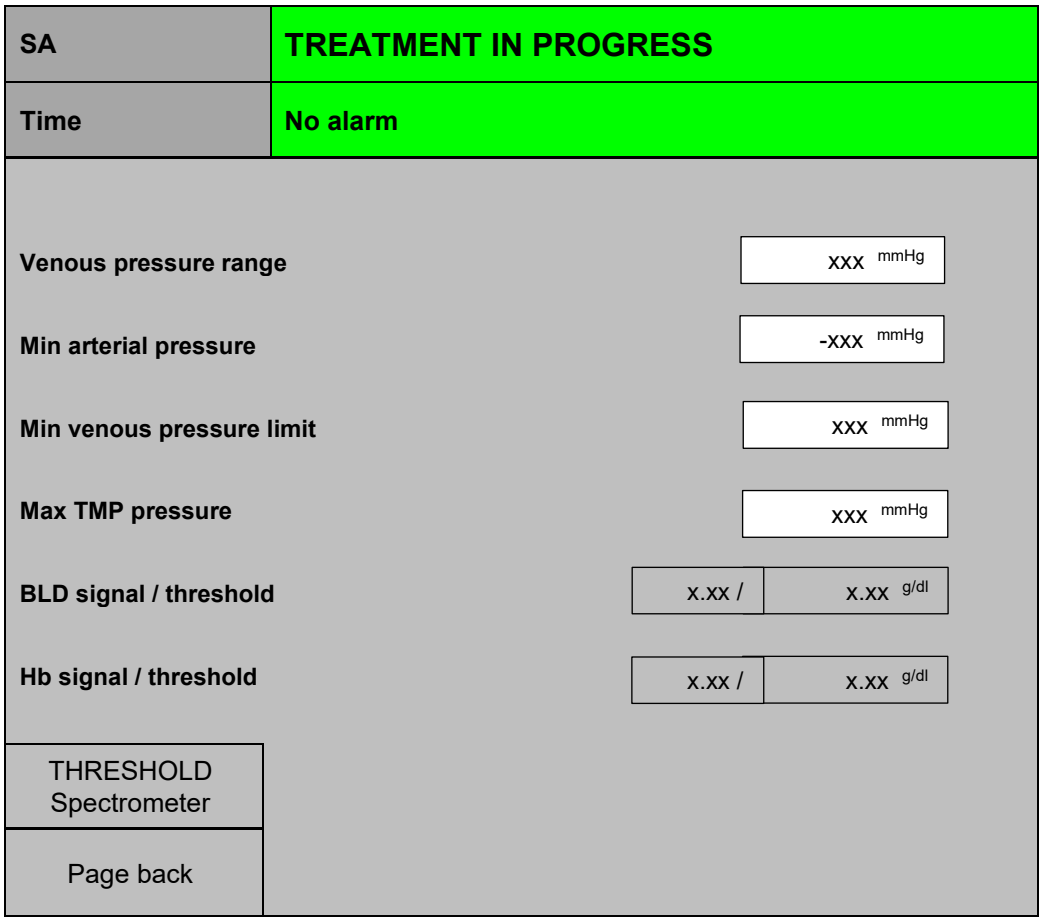
Allows accessing to the page where the following data are shown:

- Treatment start: Date and time of the treatment;
- Total recirculated blood [ml];
- Prefilter pressure [mmHg];
- Uf-Plasma pressure [mmHg];
- Plasma Pressure [mmHg] ;
- Duration [h:m]

With the "Page back" button is possible to come back in the "TREATMENT IN PROGRESS" page.

Alarms and Scale:

The "ALARMS AND SCALE" screen allows you to set / view the alarm thresholds:



On this page, you can view and change the following values:

- **Venous pressure range**: It indicates the range of values within which the restitution pressure must be maintained during the treatment; if the value read is not within this range
  - Range: [40 - 200] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min arterial pressure**: It indicates the aspiration pressure alarm threshold value.
  - Range: [-250 - 0] mmHg
  - Default: -200 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min venous pressure limit**:Indicates the minimum value alarm of venous/restitution pressure
  - Range: [-30 - 5] mmHg
  - Default: 5 mmHg
  - Step: 1 mmHg

  The relative alarm will be displayed.

- **Max TMP pressure**: Sets the maximum transmembrane pressure on the plasma filter
  - Range: [0 - 300] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

When this value is reached, the plasma pump automatically starts decelerating until reaching the minimum value available

- **BLD signal / threshold:** It indicates the value of blood in the plasma read by the spectrometer and the related alarm threshold

- **Hb signal / threshold:** It indicates the value of haemolyzed plasma read by the spectrometer and the related alarm threshold

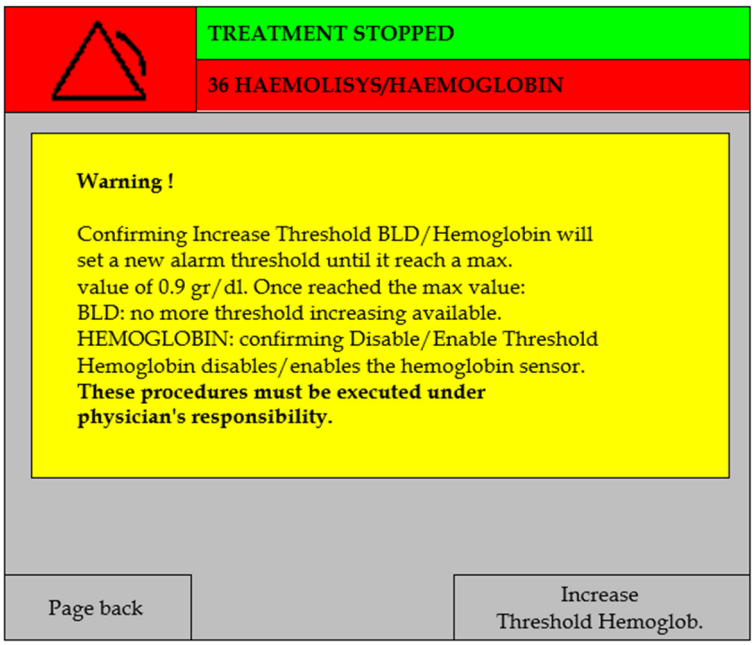
With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

THRESHOLD Spectrometer: if the value read by the spectrometer of blood in plasma or plasma haemolyzed exceeds the value of the related threshold this function key appears.

By selecting and confirming the function key the following pages will be shown.

In particular, if the alarm raised up is:

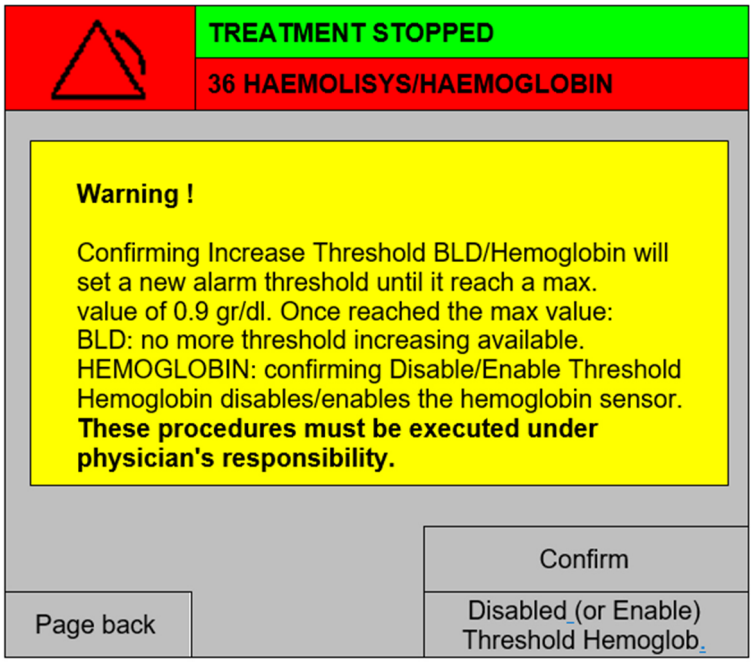
- **36 HAEMOLISYS/HAEMOGLOBIN**



Press "Increase Threshold Hemoglob." to increase of 0.2 g/dl the value of the threshold of the alarm and come back in the "TREATMENT STOPPED" page.

With the "Page back" button it's possible to come back in the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl and the alarm rise up or the reading of haemolyzed plasma by the spectrometer is disabled following page will be shown by pressing on "THRESHOLD Spectrometer" function key.



Press "Disabled Threshold Hemoglob." and "Confirm" to disable the reading of haemolyzed plasma by the spectrometer and come back in the "TREATMENT STOPPED" page.

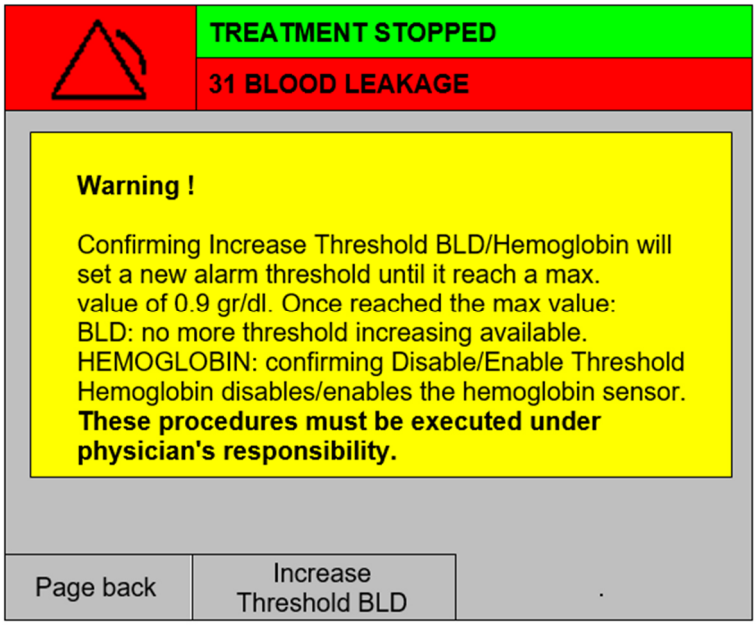
Press "Enable Threshold Hemoglob." and "Confirm" to enable the reading of haemolyzed plasma by the spectrometer and come back in the "TREATMENT STOPPED" page.

WARNING

Raising the alarm threshold and deactivating the spectrometer's reading of haemolysed plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

- **31 BLOOD LEAKAGE**



Press "Increase Threshold BLD" to increase of 0.2 g/dl the value of the threshold of the alarm and come back in the "TREATMENT STOPPED" page.

With the "Page back" button it's possible to come back in the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl the "THRESHOLD Spectrometer" function key will not appear

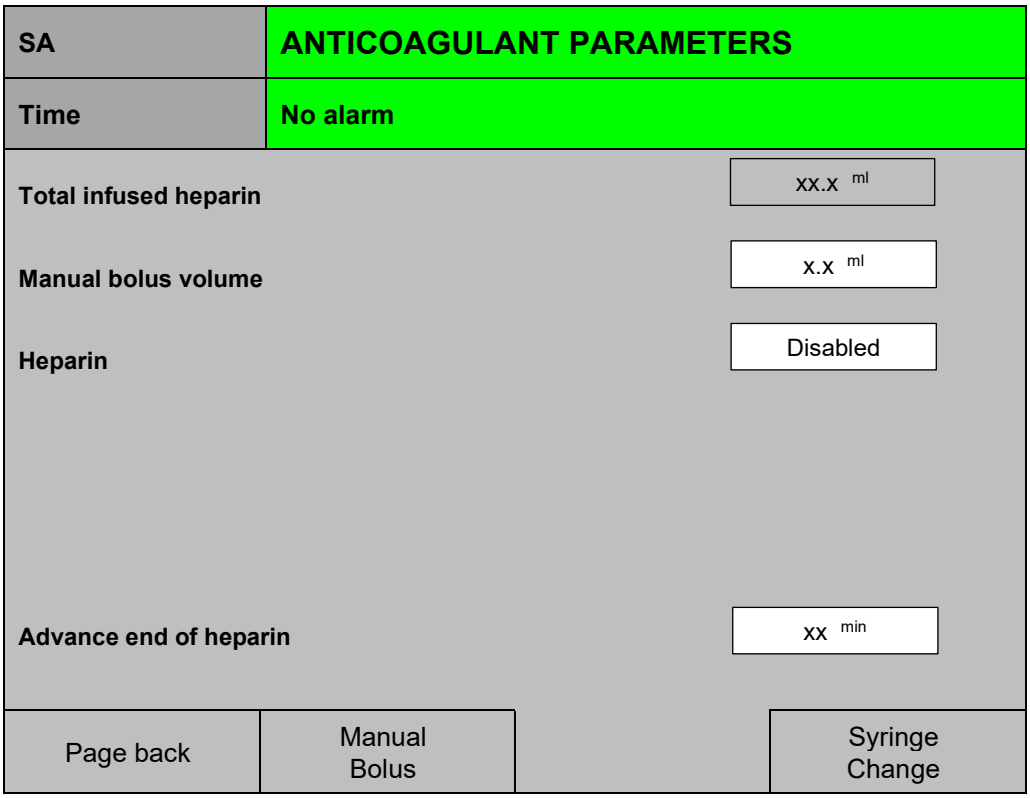
WARNING

Raising the alarm threshold of blood in plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

Heparin XXXX:

On this page it is possible to check and change the operating status/mode of the heparin pump:



The screen above shows the "Disabled" heparin mode.

- **Total Infused Heparin:** Volume in ml of heparin injected into the extracorporeal circuit (not modifiable)
- **Manual Bolus Volume**: It indicated the heparin bolus volume that the user can manually injected into the extracorporeal circuit
  - Range: [0.1 – 5.0] ml
  - Default: 1.0 ml
  - Step: 0.1 ml/min

  Press the "Manual Bolus" key to inject this bolus.
- **Heparin:** This parameter indicates the operating status/mode of the heparin syringe; the pump operating mode can be changed during treatment.
- **Advance end of heparin:** It indicates the time in minutes when the heparin infusion should be stopped before the end of the treatment.

NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

From this screen it is possible to access various functions through the menu located at the bottom:

Manual Bolus: trough this function it is possible to administering an additional heparin bolus of 1 ml respect the normal heparin operating mode.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Manual Bolus	Confirm

Syringe Change: trough this function it is possible to replace the anticoagulant syringe .
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Confirm	Syringe Change

Confirmed the "Change Syringe" appear the following screen with reported the instructions to replace the syringe.

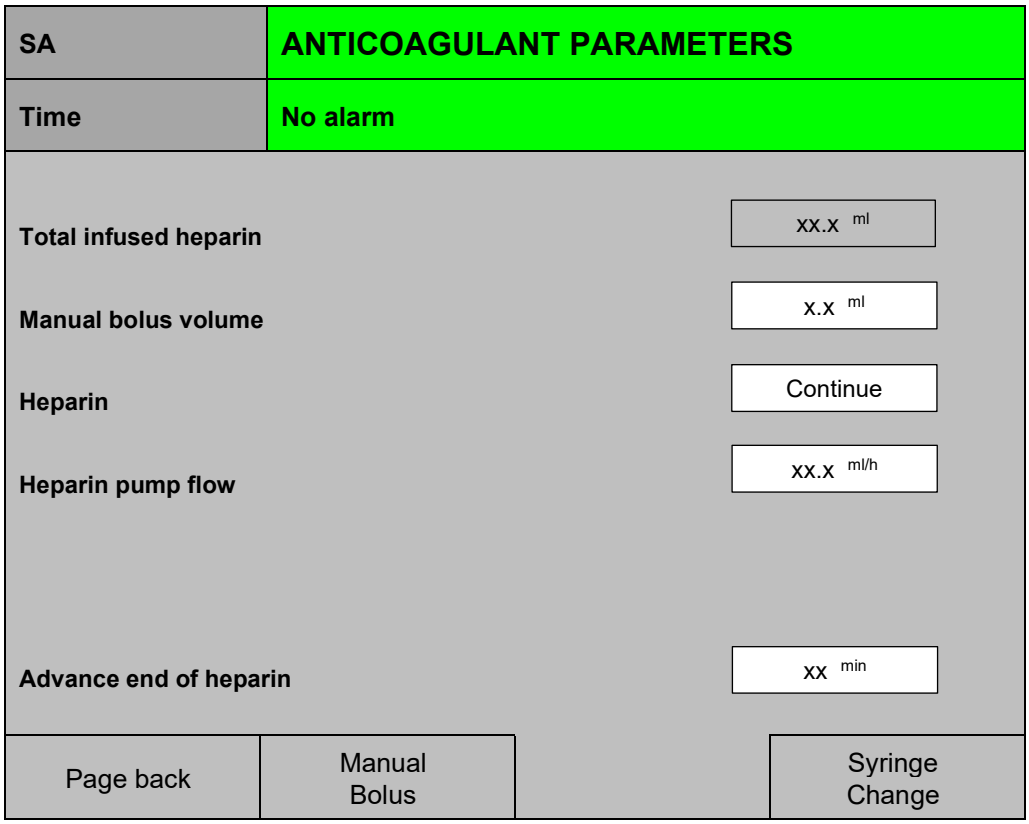
SA	**TREATMENT IN PROGRESS**		
Time	**CHANGE SYRINGE**		
*** Close the syringe line clamp** *** Remove the empty syringe** *** Set syringe cursor** *** Introduce new syringe** *** Open syringe line clamp** *** Confirm syringe change**			
Page back	Syringe < - -	Syringe - - >	Change Syringe

Follow the on-screen instructions and confirm "Change Syringe" key.

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Other Heparin Modes available:

- **Heparin Continue:**

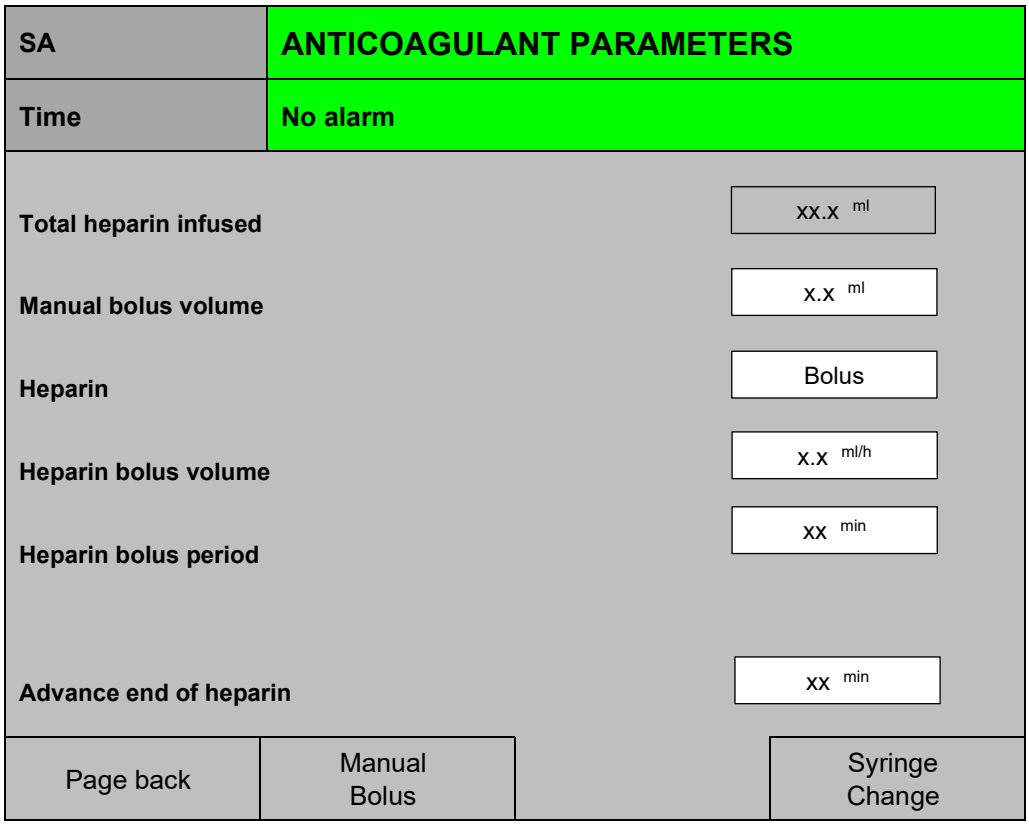


Compared with the heparin disable screen the only add parameter is:

Heparin pump flow: It indicated the anticoagulant flow in ml/min .

- Range: [0.1 – 20.0] ml
- Default: 0.4 ml
- Step: 0.1 ml

- **Heparin Bolus:**



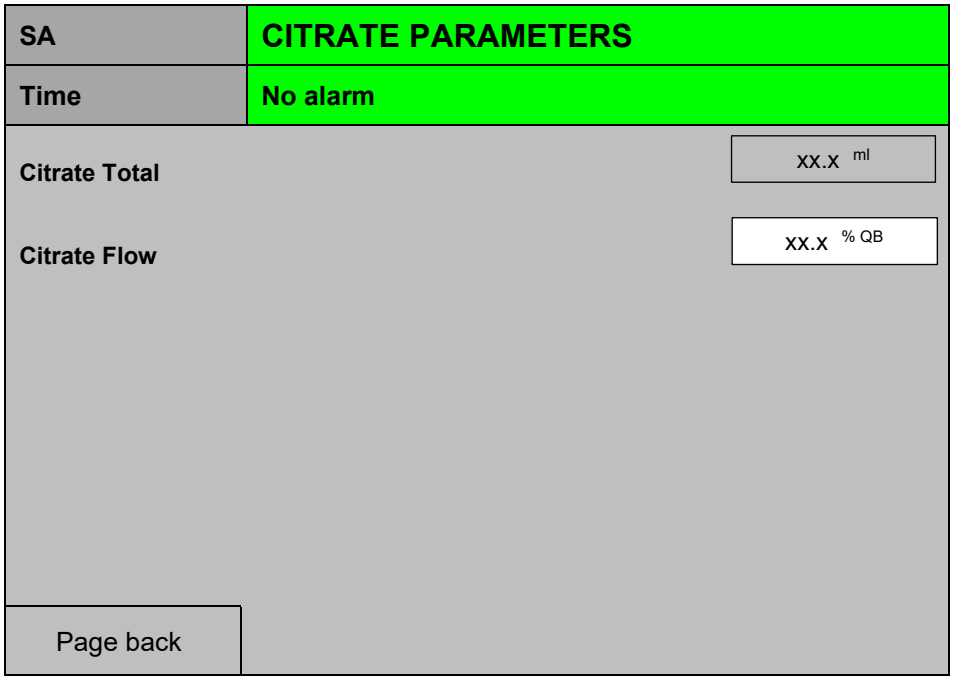
Compared with the heparin disable screen the only add parameter is:

Heparin bolus volume: It indicated the anticoagulant bolus volume regularly injected.
- Range: [0.1 – 5.0] ml
- Default: 0.1 ml
- Step: 0.1 ml

Heparin bolus period: It indicated the time between two consecutive bolus anticoagulant injection.
- Range: [5 – 60] min
- Default: 20 min
- Step: 1 min

Citrate (if selected before Priming):

On this page it is possible to check and change the operating status/mode of the citrate pump:



- **Citrate Total:** Volume in ml of citrate infused into the extracorporeal circuit (not modifiable)
- **Citrate Flow**: It indicated the citrate pump speed respect the blood pump flow rate
  - Range: [0.0 – 10.0] % QB
  - Default: 3.0 % QB
  - Step: 0.1 % QB

End Treatment

See End Treatment chapter 19.3.2.4.

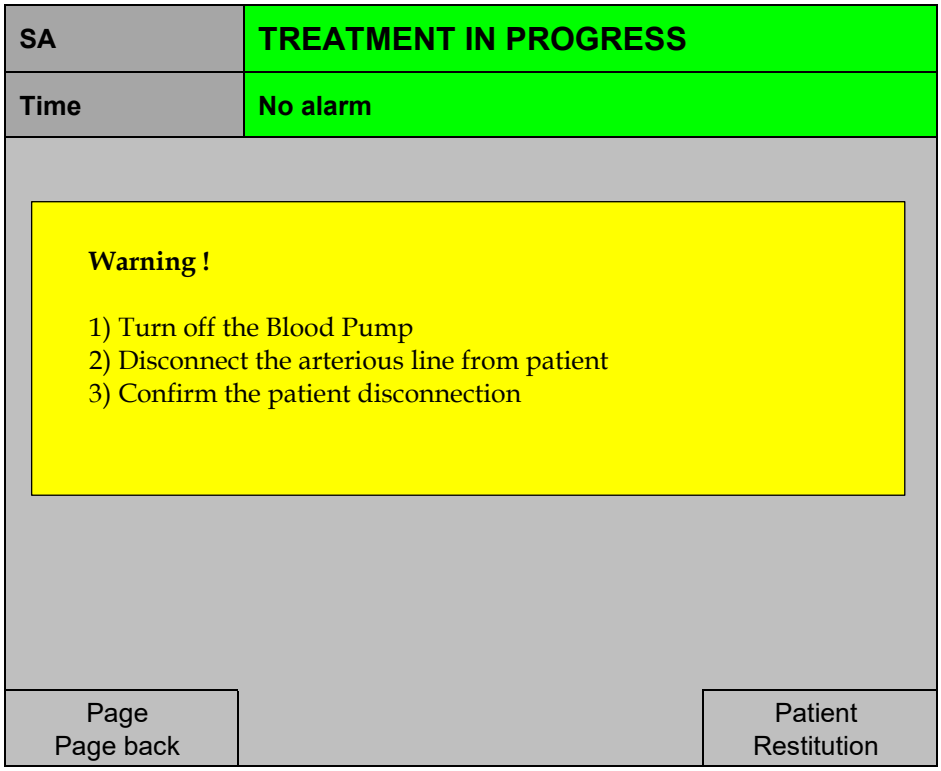
19.3.2.4. End Treatment

When AFERSMART PLUS has reached the target of treated blood volume, the message "501 END TREATMENT" appears on the screen.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the treatment at any time by pressing "End Treatment" key also if the treatment is not completed.

Select "End Treatment" and perform the operations that appear on the display to proceed.

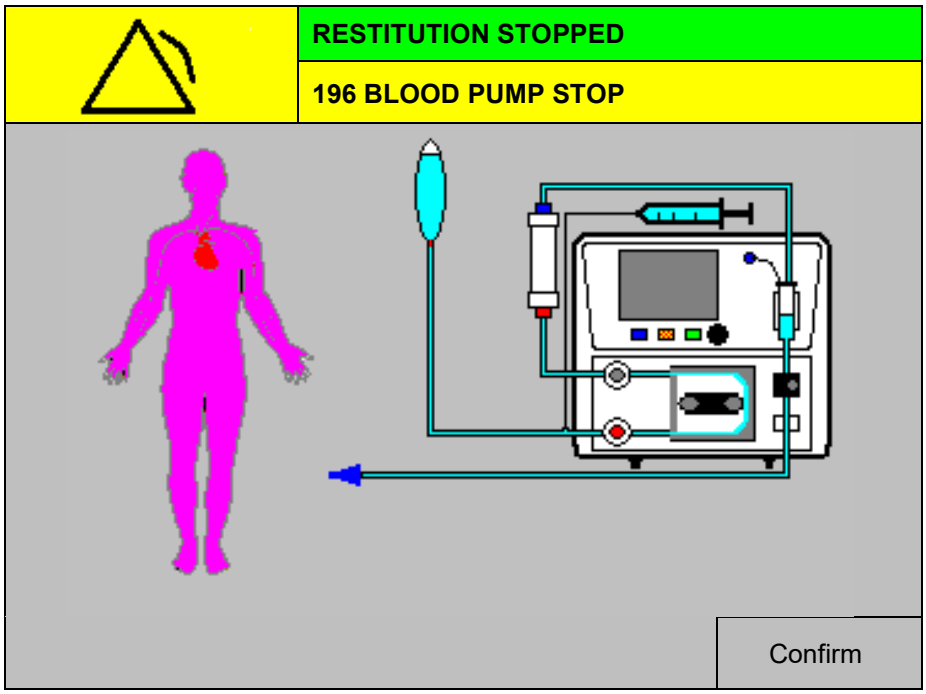


Press "Patient Restitution" key to start the blood restitution phase.
Press "Page back" key to return the treatment phase.

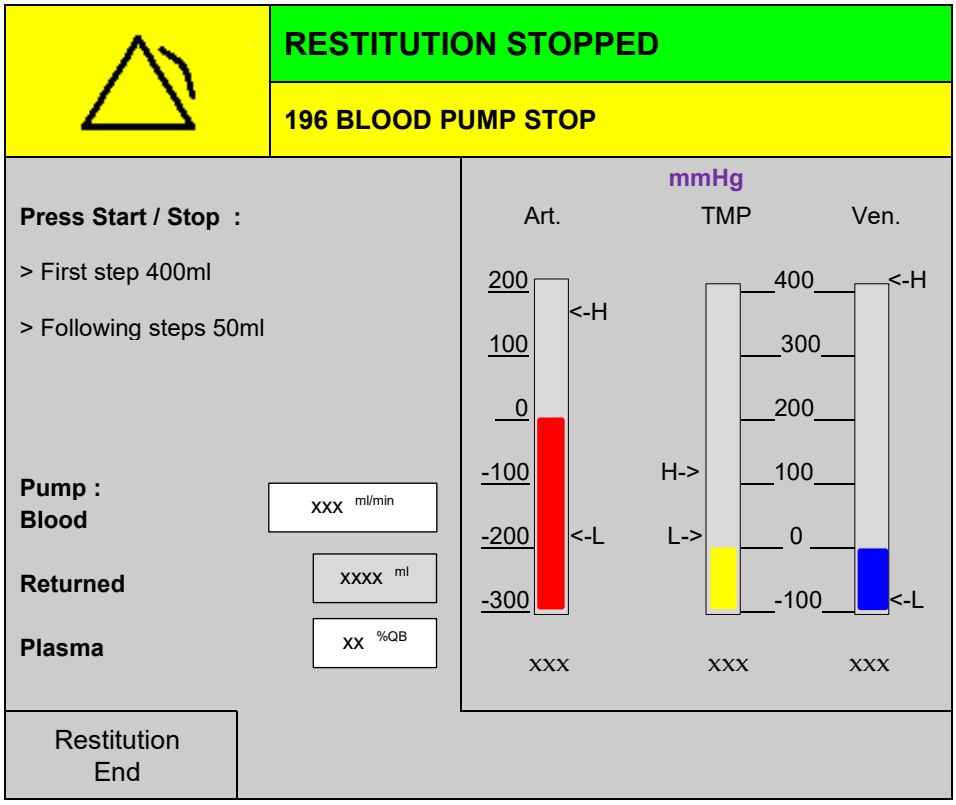
19.3.3. BLOOD RESTITUTION

19.3.3.1. Restitution

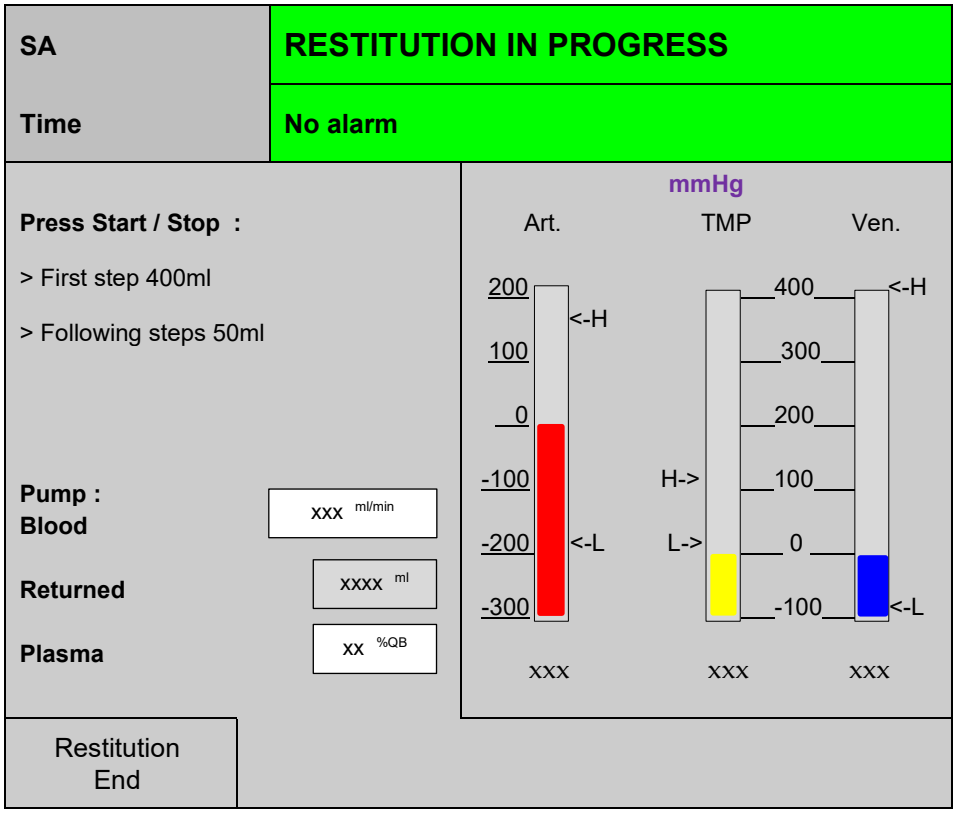
The restitution phase allows the patient to re-infuse most of the blood remaining in circulation in the lines.
Disconnect the arterial line from the patient and connect it to the NaCl solution (1000 ml container).



When entering the page above, the blood pump stops to allow to connect the aspiration line to saline solution bag.
Press "Confirm" key to enter the main page of restitution phase.



Press the <START / STOP> button to start the blood REINFUSION phase.



The first time the START/STOP button is pressed and 400 ml of blood are returned.
The next times the button is pressed 50 ml at a time are returned.
During standard or additional reinfusion, it is always possible to stop the blood pump by pressing <START / STOP>

Available setting parameters:

- Pump: Blood (flow)[ml / min].
  - Range: [0 - 100] ml / min
  - Default: 30ml / min
  - Step: 5ml / min

- **Plasma** (flow) [%QB].
  - Range: [0 - 50] %QB
  - Default: 30 %QB
  - Step: 1 %QB

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Returned [ml]:** It indicates the total blood returned.
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The TMP pressure is the pressure that work over the filter fibers. The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

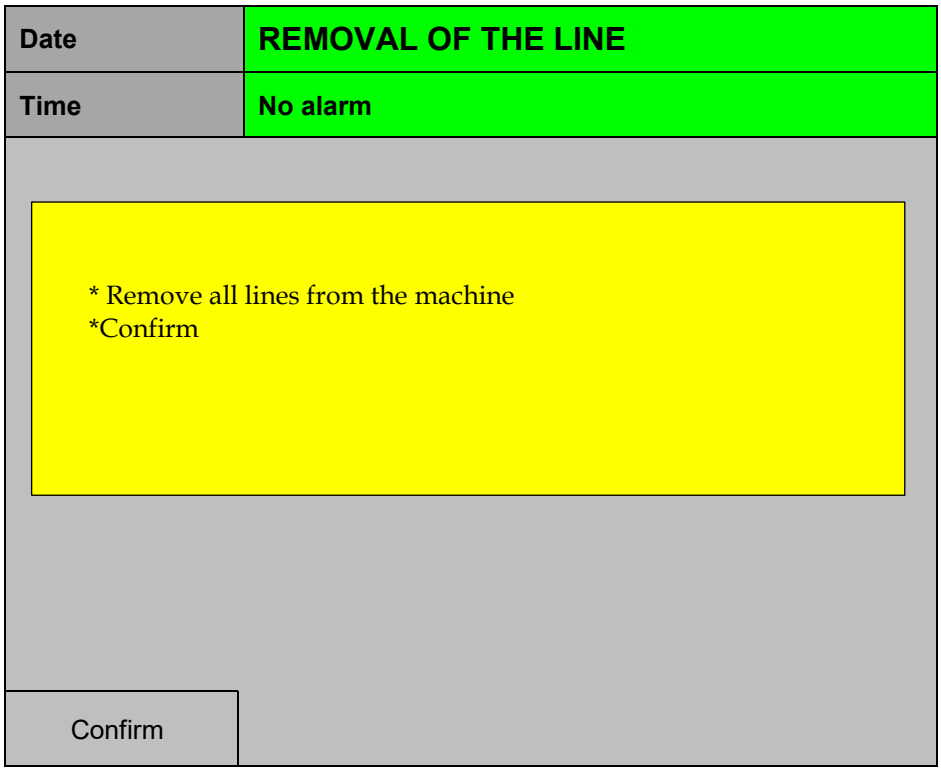
In this phase, only the air bubble detector and the pressure and safety alarms (covers, etc.) are active.
Once the restitution has been completed, select "Restitution End" to disconnect the circuit from the machine.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the restitution at any time by pressing "Restitution End" key also if the blood restitution is not completed.
If you do not confirm the "Restitution End" before turning off the machine. The next time you turn it on, it will restart from this page and not from the INTRODUCING page. In this case, confirm the "Restitution End" after turning on

19.3.3.2. Removal of the lines

The patient can be disconnected from the venous line.
It is possible to remove the lines and the plasma filter and proceed with disposal them.



After the uninstallation of the lines, push "Confirm" to go to the "INTRODUCING" page.

The AFERsmart PLUS can now be turned off.

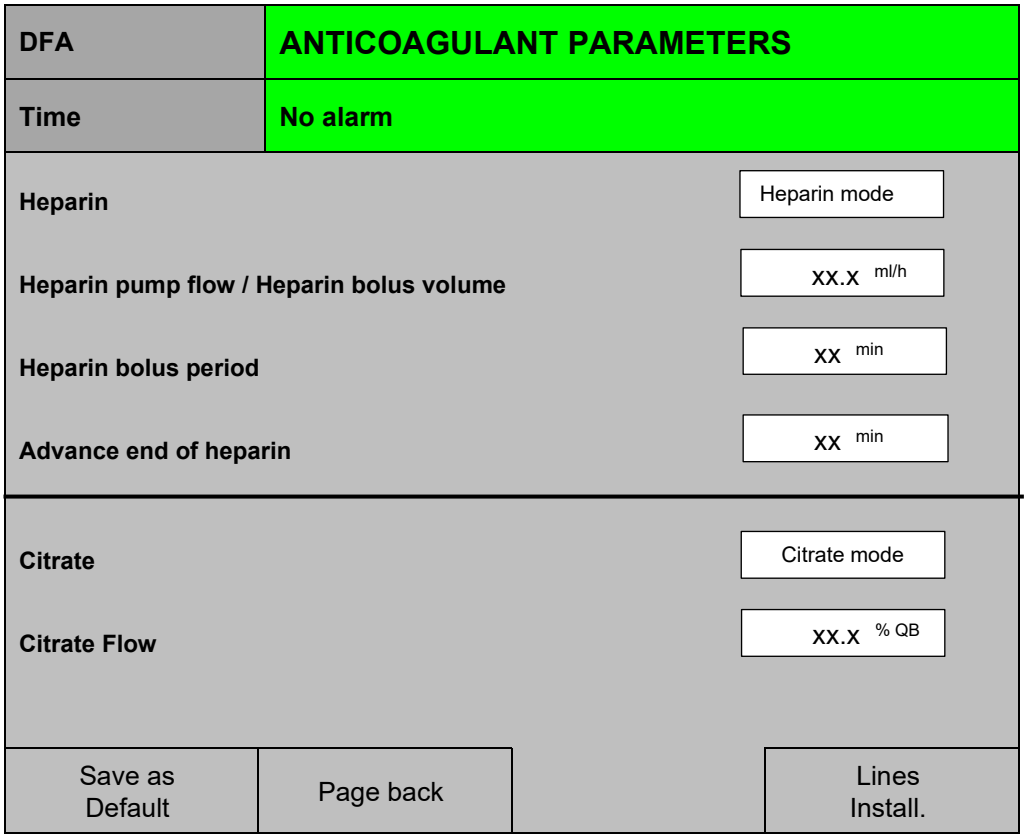
19.4. DOUBLE FILTRATION ADSORBTION

19.4.1. PREPARATION

19.4.1.1. Anticoagulant Parameters

It is possible to set / modify the parameters related to the anticoagulant before entering in the priming procedure. These parameters can be modified even during the treatment phase, by pressing < Parameters> key.

- Heparin: Disabled/ Continue/ Bolus
- Heparin pump flow (available only in "Continue" mode): [0.1 – 20.0] [ml/h]
- Heparin bolus volume (available only in "Bolus" mode): [0.1 – 5.0] [ml/h]
- Heparin bolus period (available only in "Bolus" mode): [5 – 60] [min]
- Advance end of heparin: [0 – 30] [min]
- Citrate: Disabled/ Enabled
- Citrate Flow (available only in "Enabled" mode) : [0.5 – 10.0] [% QB]



NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

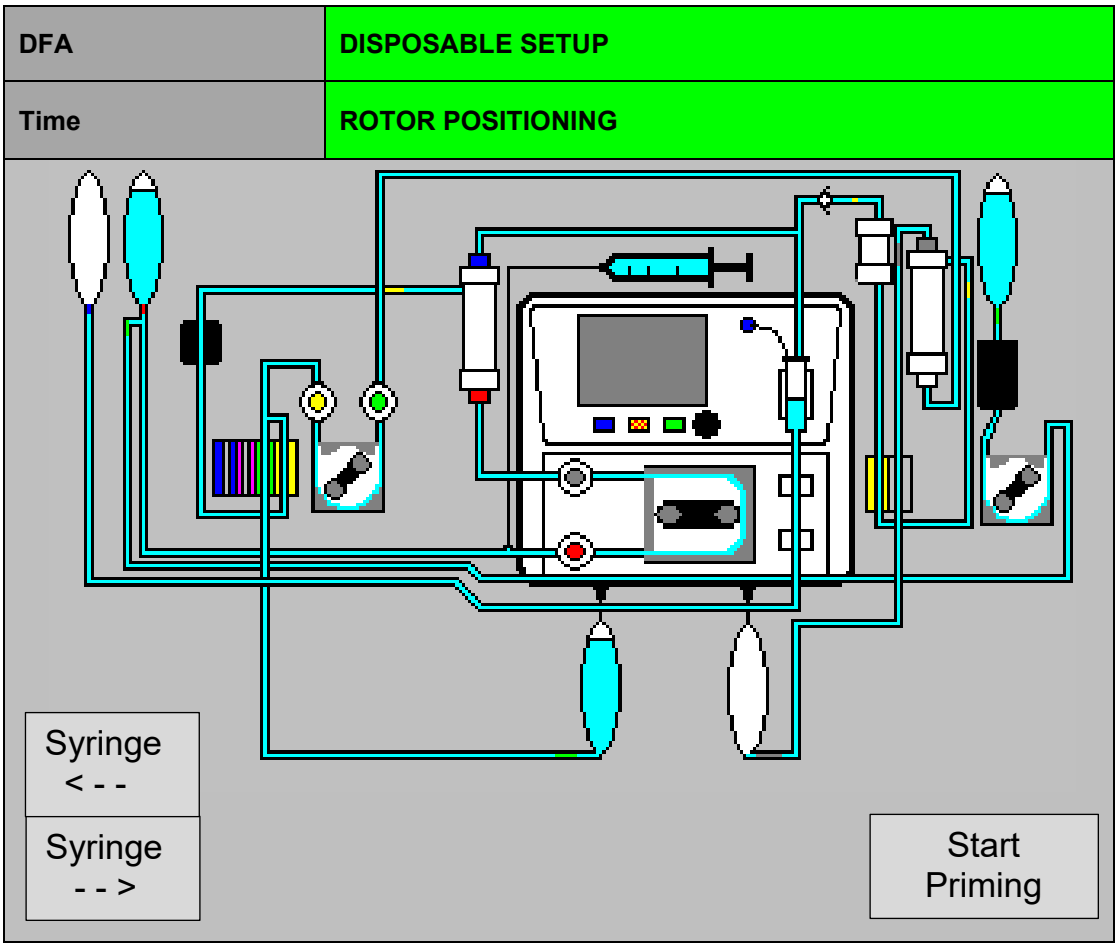
Press ”Save as Default” to save set parameters and make them available for the next treatments

Press the <Page back> key to return to the “INTRODUCING” page

Press the <Lines Install.> key to proceed to the “DISPOSABLE SETUP” page

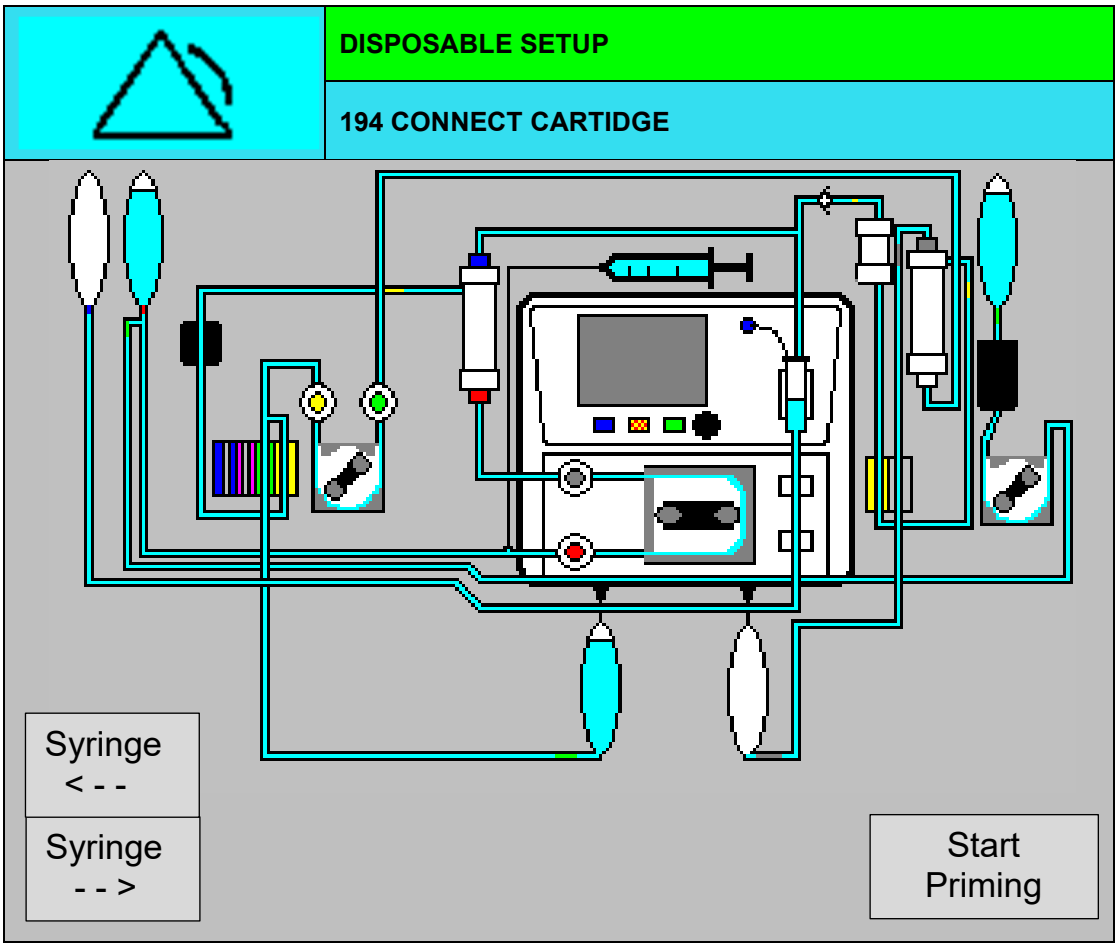
19.4.1.2. DISPOSABLE SETUP

On this page it is possible to install the disposable, the Plasmafilter and the bags needed to perform the DFA treatment and its priming



Once entering in this page AFERsmart PLUS will execute the automatic pump rotors positioning (both Blood and Plasma) needed to ease the installation of Blood and Plasma tubing set.

After the "Rotors positioning" phase the "194 CONNECT CARTRIDGE" message will appear, the venous electroclamp will open and the red light over the clamp will switch off.
and it will be possible to install the disposable kit, the Plasmafilter and the bags as shown on the screen



At this phase make sure that the hooks of the scale are completely free.

The AFERSMART PLUS Kit is enclosed in a paper-film envelope, inside are:

Semi-finished arterial line and ACD (identified with red- and green-coloured components)
Semi-finished venous line (identified with blue-coloured components)
Semi-finished plasma line (identified with yellow components)
Semi-finished drainage line (identified with grey components)

- Hang the Priming Solutions and the citrate solution (if Citrate anticoagulation was set) on the stand pole.
- Hang to the washing scale the washing solution container
- Hang to the drain scale the waste container
- Place the plasma filter in its support (ref. 6 Chapter 2.3)
- Place the plasma fractionator in its support (ref. 2 Chapter 2.4)
- Remove the plasma line from the bag

- Open the plasma pump cover (ref. 1 Chapter 2.3)
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  Close the plasma pump cover

- Open the UF pressure transducer and connect the relevant UF DOME (ref. 3 Chapter 2.3)

- Open the plasma pressure transducer and connect the corresponding plasma DOME (ref. 2 Chapter 2.3)

- Insert the washing section of the plasma line into the clamp n°3 (ref. 4 Chapter 2.3) and connect it to the washing solution container on the washing scale (ref. 1 Chapter 2.6)

- Insert the plasma section of the plasma line into the clamp n°4 and successively insert the cuvette into the BLD with the nose pointing outward (ref. 5 Chapter 2.3)

- Connect the yellow Hansen connection of the plasma section of the plasma line to the upper lateral plasma compartment port of the plasma filter

- Connect the fractionator section of the plasma line (outgoing from plasma DOME) to the inlet (lower part) of the fractionator filter

WARNING

Take great care when inserting each line inside each selection clamp. Make sure that all the lines are firmly in place and that the color on the line corresponds to the color on the clamp.

- If Citrate anticoagulation was set:
  - Place the ACD chamber in the appropriate support (ref. 4 Chapter 2.4), inserting it from top to bottom
  - Open the ACD pump cover (ref. 3 Chapter 2.4),
  - Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  - Close the cover of the ACD pump
  - Connect the ACD inlet, with the white clamp to the citrate bag positioned on the stand pole

- Open the blood pump cover (ref. 2 Chapter 2.1),
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth.
  Close blood pump cover.

- Open the arterial pressure transducer and connect the relative arterial DOME (ref. 5 Chapter 2.1),

- Open the prefilter pressure transducer and connect the relative prefilter DOME (ref. 6 Chapter 2.1),

- Connect the red adapter outgoing from the prefilter DOME to the inlet (lower part) of the plasma-filter.

- If heparin anticoagulation was set:
  - Connect the heparin tube fitting to the 30-cc syringe previously filled with heparinized solution Insert the syringe in its seat, using the arrows < ← > and < → > to position the cursor
- Connect the inlet connector of the arterial line to the priming solution bag positioned on the stand pole
- Take the venous line from the envelope
- Place the venous chamber in the appropriate support (ref. 8 Chapter 2.1), by inserting it from top to bottom
- Connect the hydrophobic Venous Pressure Transducer Protector Luer Lock to the Venous Pressure Transducer (ref. 7 Chapter 2.1),
- Connect the blue adapter, at the inlet of the venous line, to the outlet (Upper part) of the plasma-filter.
- Insert the tube outgoing from the venous chamber into the air / blood sensor (ref. 3 Chapter 2.1) and, successively, into the venous electroclamp (ref. 4 Chapter 2.1)
- Place the venous waste bag already connected to the venous line on the stand pole (ref. 2 Chapter 2.6)
- Take the drainage line from the envelope
- Connect the blue adapter of the waste section of the drainage line to the outlet (upper part) of the fractionator filter, insert it in the clamp n°6 and successively connect it to the waste bag positioned on the drain scale
- Connect the white Hansen connector of the plasma section of the drainage line to the upper lateral plasma compartment port of the fractionator filter, insert it in the clamp n°5 and successively connect it to the inlet (lower part) connector of the adsorber.
- Connect the outlet (upper part) of the adsorber to the return plasma section of the venous line

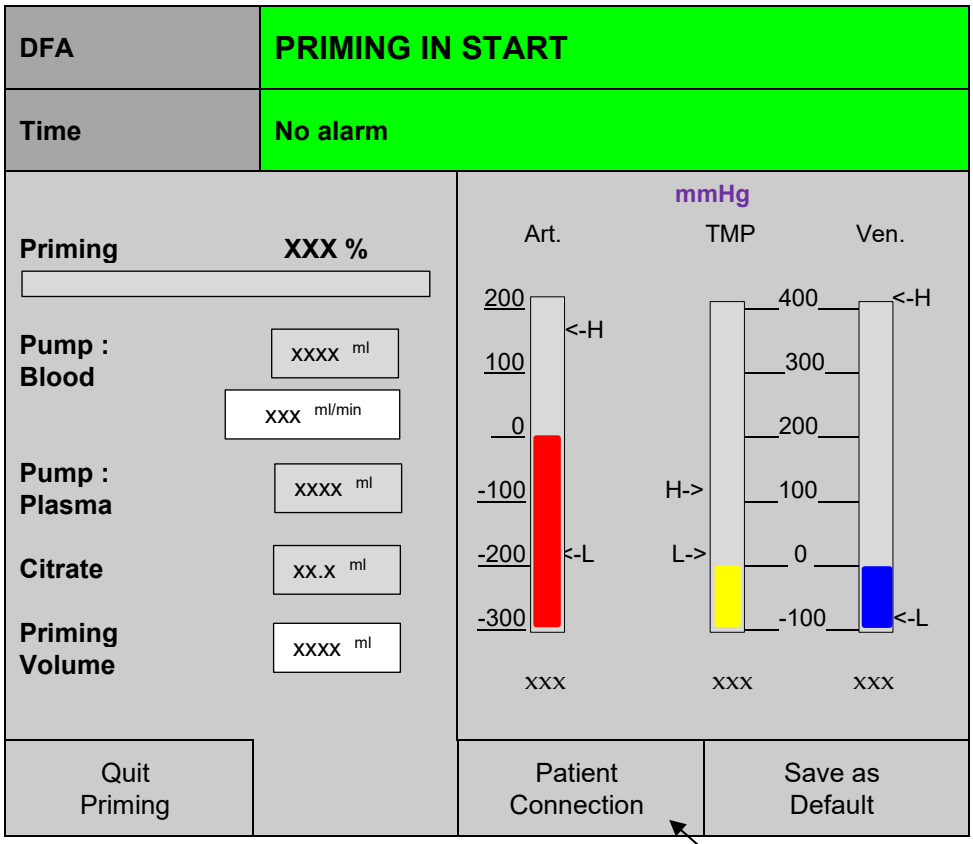
NOTE

To correctly mount the venous pressure transducer protector to the conical connections of the pressure transducers, it is necessary to:

- **Fully insert the venous pressure transducer protector by making it make a slight rotational movement until it locks.**
- **Turn the ring anticlockwise to prevent it from disconnecting.**

19.4.1.3. Priming

Make sure you have connected the circuit as described above.
Select and confirm the <Priming Start> function; this takes you to the "PRIMING IN START" screen.



If no anomalies have occurred, this button appears at the end of the Priming.

The page displays:

- Pump: Blood (volume)[ml];
- Pump: Blood (flow)[ml/min]: adjustable from 5 to 250;
- Pump: Plasma (volume)[ml];
- Citrate (volume)[ml];
- Priming Volume (total)[ml]: adjustable from 1600 to 4000;
- The current value of the Arterial (RED), TMP (YELLOW) and Venous (BLUE) pressures and the related alarm thresholds.

AFERSMART PLUS then begins the automatic priming procedure.

NOTE

To temporarily stop priming, simply press the <START / STOP> button once. Press this button again to restart priming.

Press "Save as Default" to save set parameters and make them available for the next treatments

During Priming it is advisable to adjust the level in the restitution drip chamber. To do this, operate as follows:

- Close the clamp on the restitution line to the patient.
- Open the service line on the restitution drip chamber.
- When the desired level has been reached, normally 2/3 the volume of the drip chamber, close the service line and reopen the clamp on the restitution line to the patient.

If you want to end PRIMING before it has been completed, select and confirm "Quit priming". You will be asked for confirmation that you want to quit PRIMING:

Quit Priming	Confirm

After selecting and confirming "Quit Priming" return to the "INTRODUCING" page.

Once the Priming of the disposables has been successfully completed, the Priming status bar is at 100% and the "Patient Connection" key will appear and the warning "500 END PREPARATION" rise up.

Quit Priming		Patient Connection	Save as Default

A further flushing phase can be performed by pressing the "START STOP" physical button located below the display.

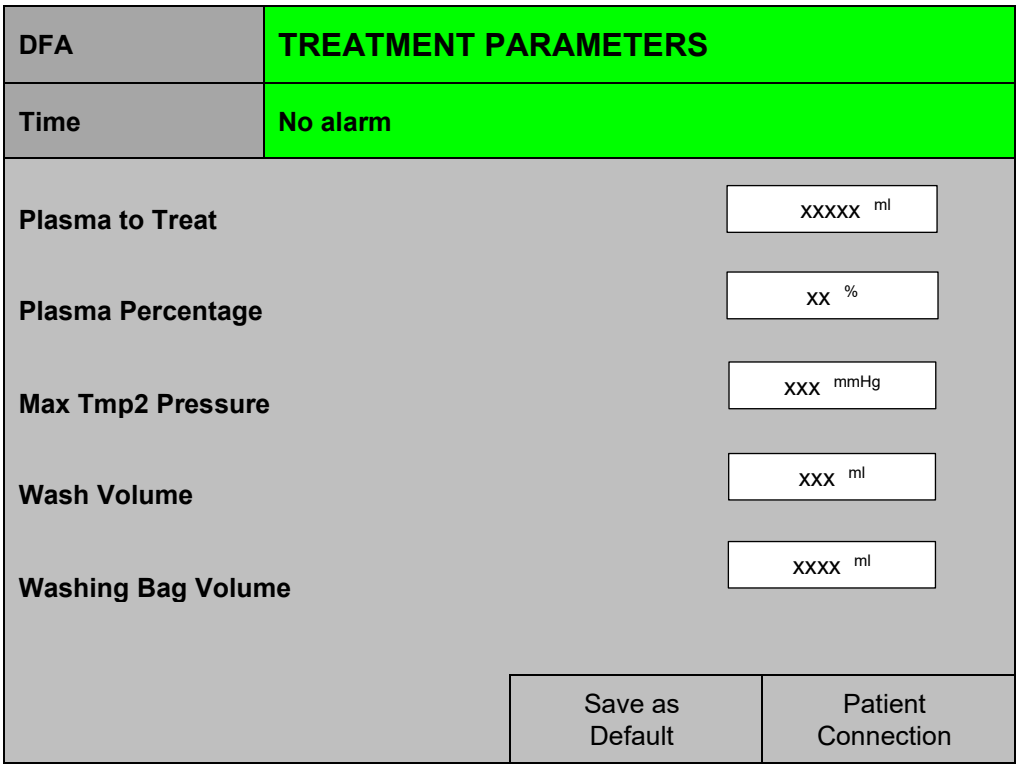
In this phase a total of one litre of priming solution will be processed by the Blood pump.
This operation can be repeated several times.

Press "Patient Connection" key to proceed to the clinical parameters settings before the treatment.

19.4.2. TREATMENT

19.4.2.1. TREATMENT PARAMETERS

The TREATMENT PARAMETERS screen allows you to set the parameters relating to the treatment.
Check and, if necessary, modify the parameters relating to the treatment, then press <Patient Connection>.



Available setting parameters:

- **Plasma to Treat [ml]:** Total plasma volume to treat.
  - Range: [500 - 20000] ml
  - Default: 500 ml
  - Step: 50 ml
- **Plasma Percentage [%]:** Plasma pump speed.
  - Range: [1 – 30] %QB
  - Default: 10 %QB
  - Step: 1 %QB
- **Max Tmp2 Pressure [mmHg]:** it indicates the pressure threshold at which the machine starts the washing cycle of the fractionation filter.
  - Range: [50 – 350] mmHg
  - Default: 200 mmHg
  - Step: 10 mmHg
- **Wash volume [ml]:** it indicates the quantity of washing solution per cycle.
  - Range: [10 – 500] ml
  - Default: 100 ml
  - Step: 10 ml
- **Washing bag volume [ml]:** it indicates the volume of the washing solution bag.
  - Range: [500 – 5000] ml
  - Default: 1000 ml
  - Step: 500 ml

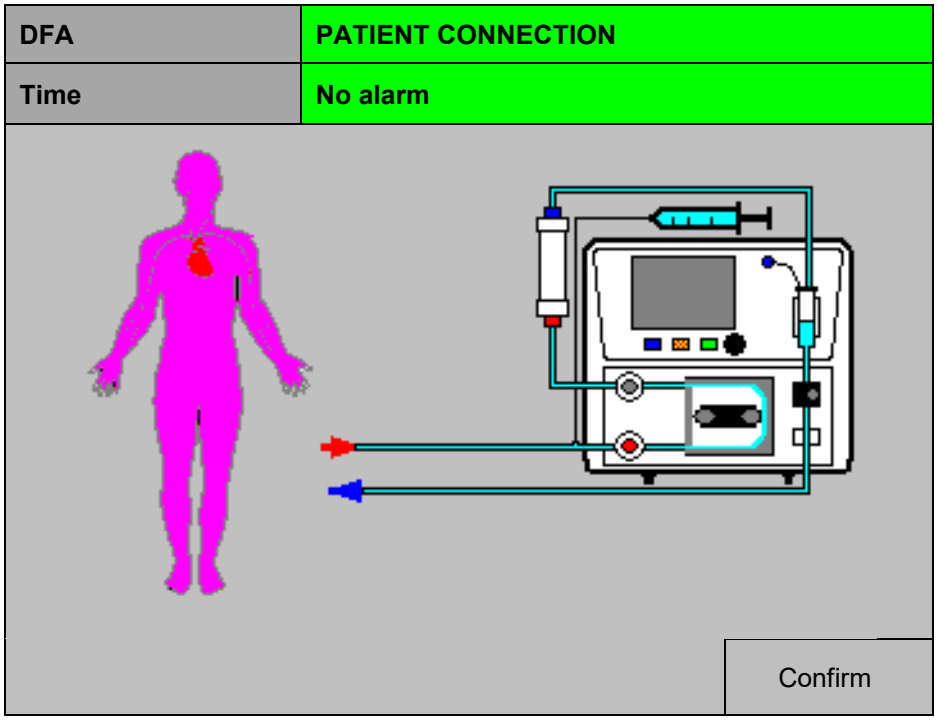
Press "Save as Default" to save set parameters and make them available for the next treatments

19.4.2.2. PATIENT CONNECTION

After setting the treatment parameters, select <Patient Connection>.

Disconnect the priming lines from the arterial line, remove the priming bags from the stand and connect the arterial and the venous line to the patient.

When done, press <Confirm>.



WARNING

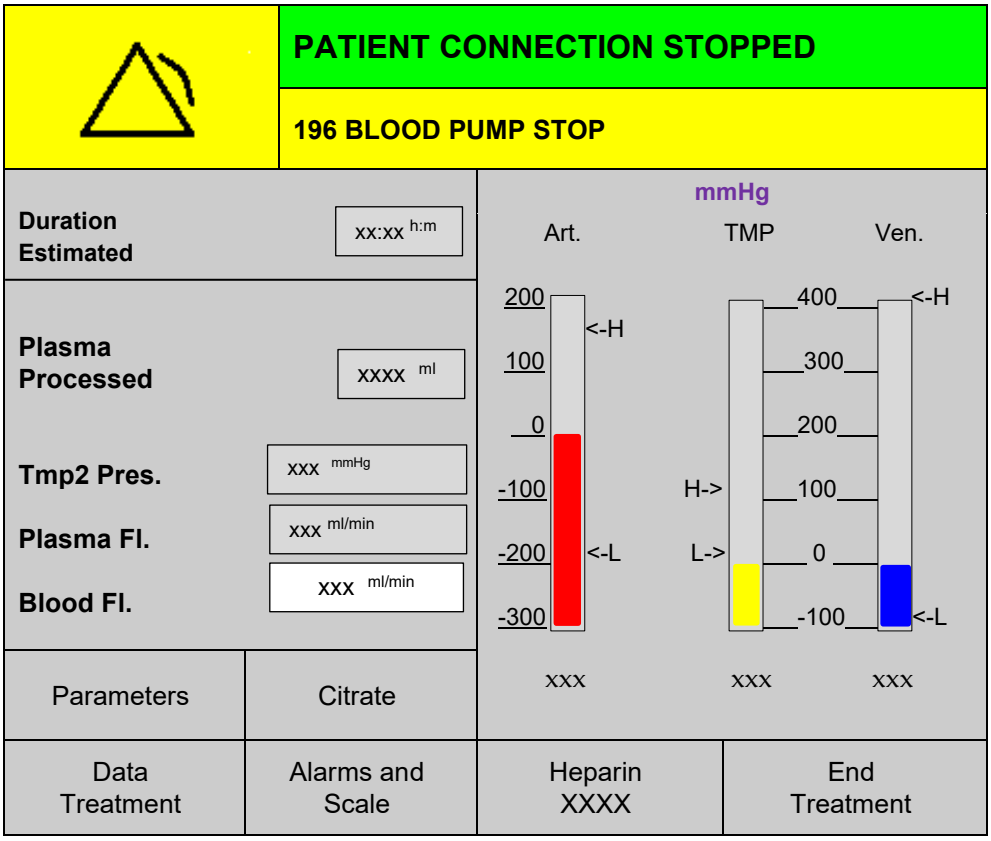
- **Risk of embolism due to air in the lines**
- **Risk of haemolysis due to kinking or crushing of lines**
- **Risk of blood loss due to not hermetically sealed connection points**

Before starting a treatment, check the following:

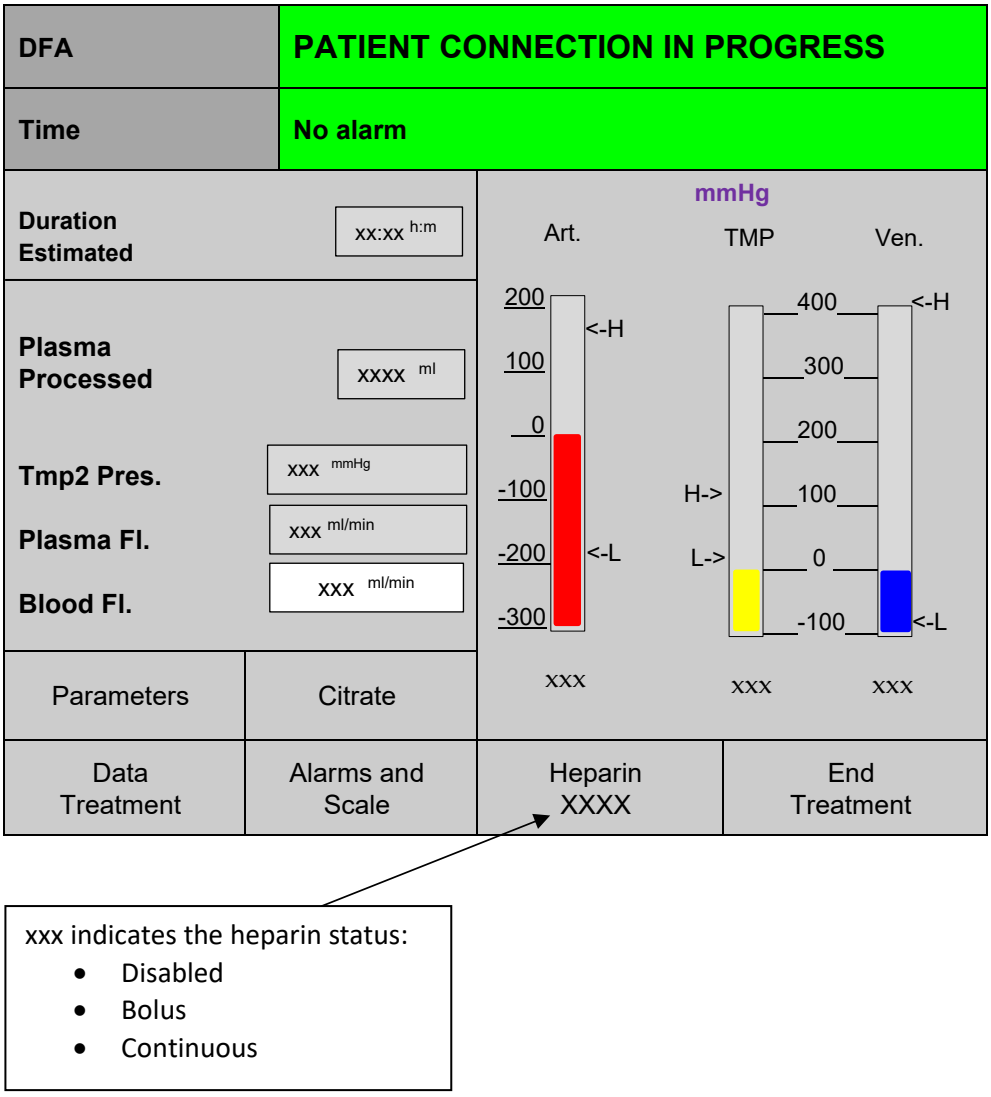
- All line joints are firmly connected
- There are no noticeable leaks in the lines, neither during nor after filling
- If leaks are found, tighten the relevant connections as needed.
- If necessary, replace the entire disposable.
- Lines are airless, inserted cleanly with no kinks, line tension or twisting and
- all fluid levels are correct.

19.4.2.3. TREATMENT

When start the treatment is show the "PATIENT CONNECTION STOPPED" screen, like reported in the following picture.



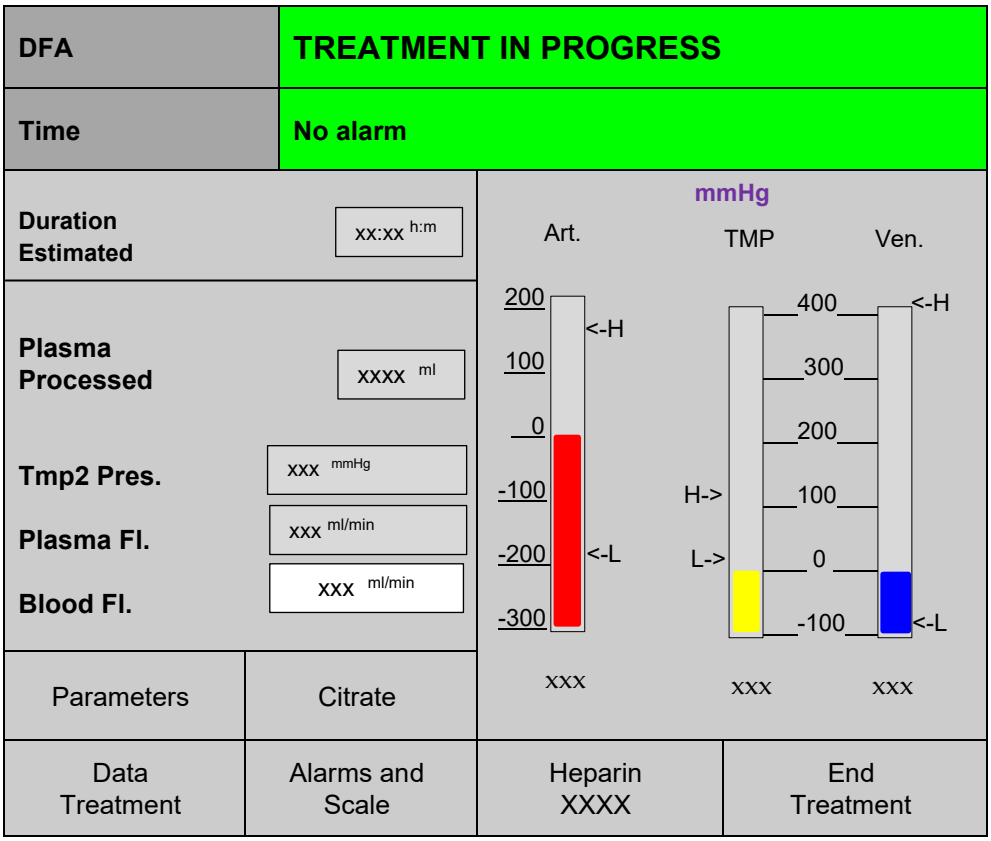
Push the START/STOP button (rif.16) to switch on the blood pump and enter in the patient connection phase.



For the first 100 ml of processed liquid by the blood pump, the machine considers the treatment as being in the connection phase and hence does not activate the infusion pump.

At the end of the patient connection phase AFERsmart PLUS automatically enters the treatment phase.

From the main screen it is possible to monitor the status of the treatment, by setting and / or monitoring the main treatment parameters.



Available setting parameters:

- **Blood Fl.** (flow) [ml / min].
  - Range: [5 - 250] ml / min
  - Default: 50ml / min
  - Step: 5ml / min

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Duration Estimated [h:m]**: It indicates the treatment time estimated.
- **Plasma processed [ml]:** It indicates the volume of plasma treated.
- **Tmp2 pres. [mmHg]**: It indicates the pressure of in the adsorber filter.
- **Plasma Fl**.: It indicates the actual plasma pump flow rate
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The TMP pressure is the pressure that work over the filter fibers.
  The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

NOTE

If Citrate was previously selected in the anticoagulant to be used, the range of the blood pump speed will be set in relation to the citrate percentage set and vice versa. AFERsmart PLUS automatically reject any incorrect value of Blood pump speed or citrate percentage that will be set.
The maximum value the citrate pump can reach is 5 ml/min.

Example of work situation:

- **If Blood Pump is set at 250 ml/min the citrate percentage must be 2% or less**
- **If Citrate percentage set is 5% the blood pump speed must be 100 ml/min or less**

From the main screen it is possible to access various functions through the menu located at the bottom:

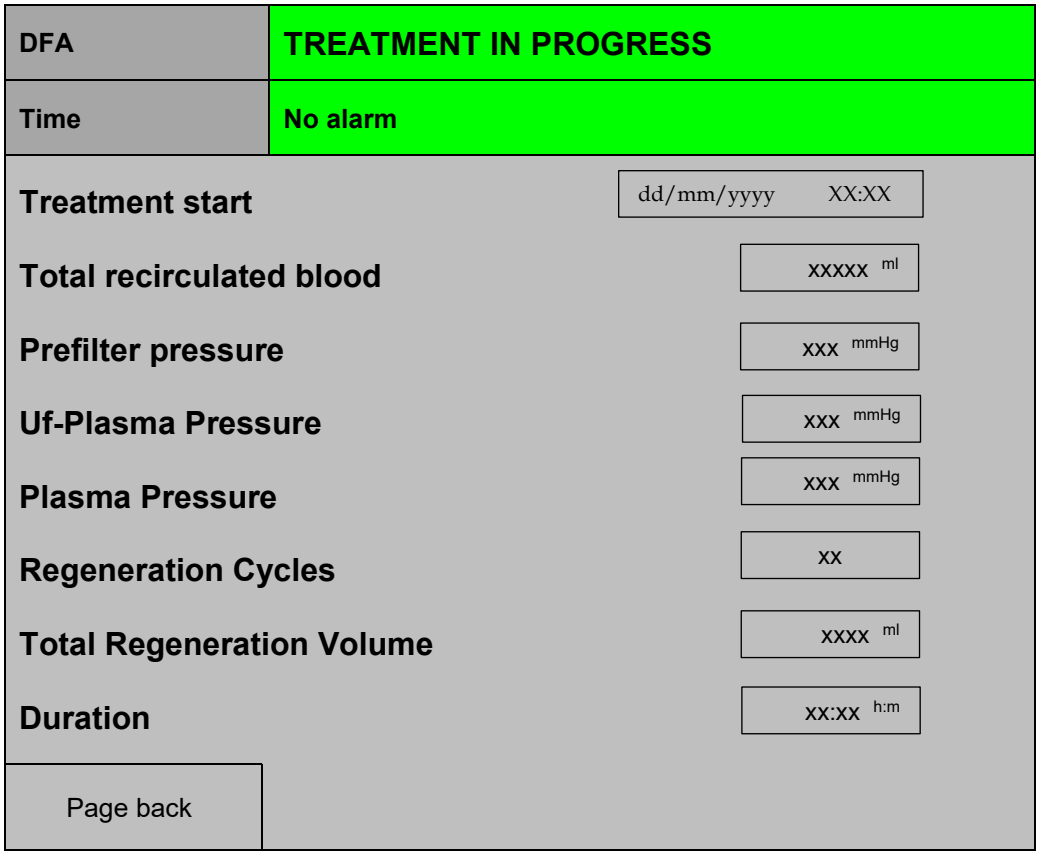
Parameters

See the TREATMENT PARAMETERS chapter 19.4.2.1

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Data Treatment

The DATA TREATMENT screen shows the data relating to the treatment:



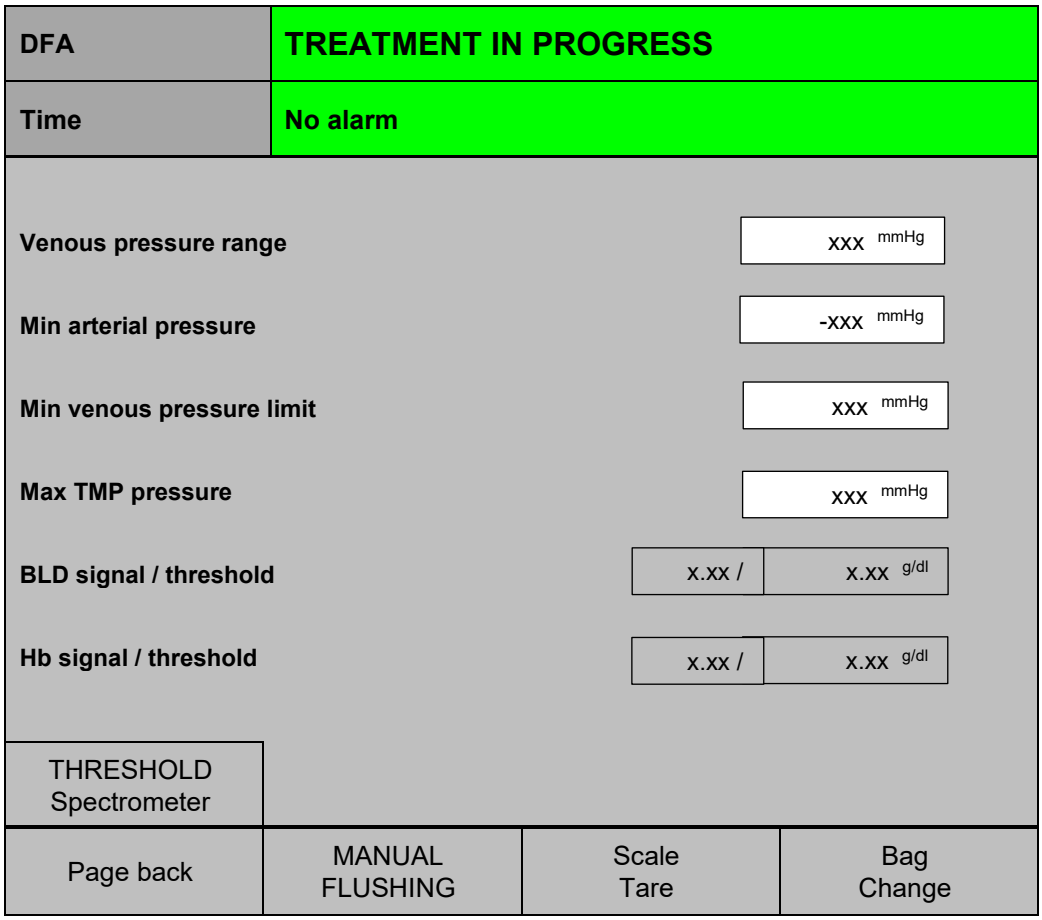
Allows accessing to the page where the following data are shown:

- Treatment start: Date and time of the treatment;
- Total recirculated blood[ml];
- Prefilter pressure [mmHg];
- Uf-Plasma Pressure [mmHg];
- Plasma Pressure [mmHg];
- Regeneration Cycles;
- Total Regeneration Volume [ml] ;
- Duration [h:m]

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Alarms and Scale:

The "ALARMS AND SCALE" screen allows you to set / view the alarm thresholds:



On this page, you can view and change the following values:

- **Venous pressure range**: It indicates the range of values within which the restitution pressure must be maintained during the treatment; if the value read is not within this range
  - Range: [40 - 200] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min arterial pressure**: It indicates the aspiration pressure alarm threshold value.
  - Range: [-250 - 0] mmHg
  - Default: -200 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min venous pressure limit**:Indicates the minimum value alarm of venous/restitution pressure
  - Range: [-30 - 5] mmHg
  - Default: 5 mmHg
  - Step: 1 mmHg

  The relative alarm will be displayed.

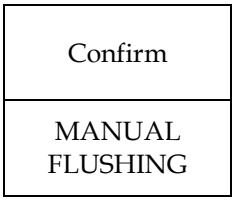
- **Max TMP pressure**: Sets the maximum transmembrane pressure on the plasma filter
  - Range: [0 - 300] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

When this value is reached, the plasma pump automatically starts decelerating until reaching the minimum value available

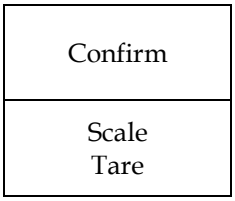
- **BLD signal / threshold:** It indicates the value of blood in the plasma read by the spectrometer and the related alarm threshold
- **Hb signal / threshold:** It indicates the value of haemolyzed plasma read by the spectrometer and the related alarm threshold

From this screen it is possible to access various functions through the menu located at the bottom:

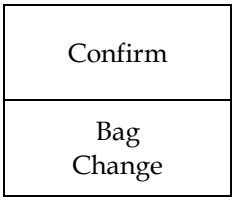
MANUAL FLUSHING: if the TMP2 is growing up or it is necessary to clean the plasma fractionator it is possible to start a plasma fractionator flushing phase.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:



Scale Tare: if one of the bags hanged to the scales is accidentally moved and it is necessary to continue the treatment it is possible to tare the scales.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:



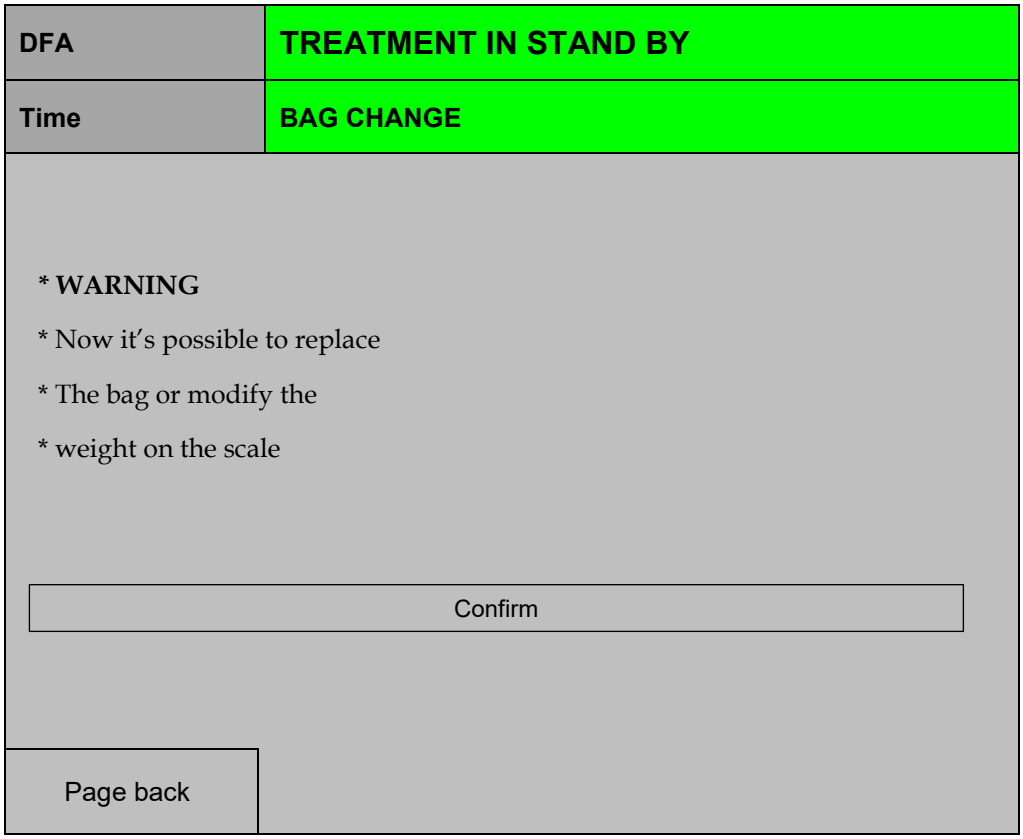
Bag Change: if it is necessary to replace one or more bags located on one or both scales, it is possible to activate the associated replacement procedure.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:



After correctly performing the Functions described above, it is necessary to follow the instructions that appear on the display.

NOTE

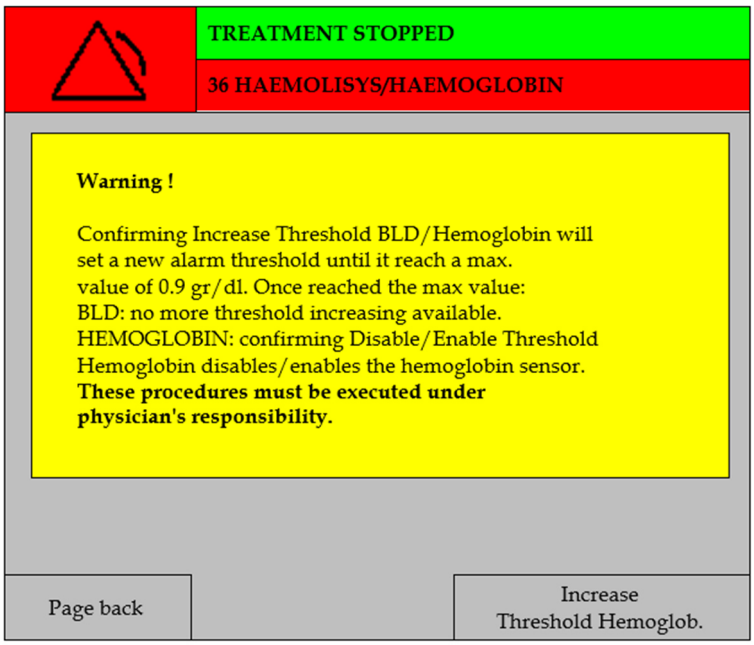
During the Change bag procedure the Treatment phase change automatically to "TREATMENT IN ST-BY" (Stand By phase)



Press "Confirm" when connect at the scale the new bag.
With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

THRESHOLD Spectrometer: if the value read by the spectrometer of blood in plasma or plasma haemolyzed exceeds the value of the related threshold this function key appears.
By selecting and confirming the function key the following pages will be shown.
In particular, if the alarm raised up is:

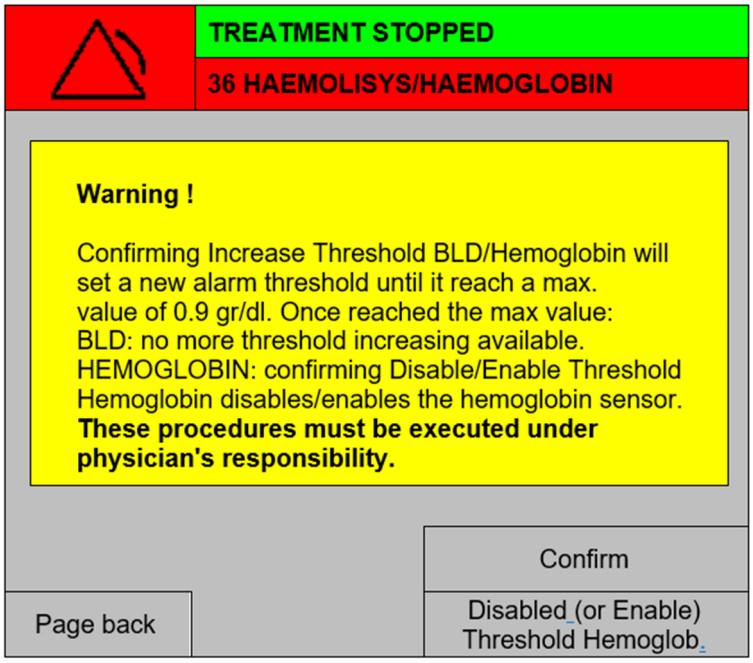
- **36 HAEMOLISYS/HAEMOGLOBIN**



Press "Increase Threshold Hemoglob." to increase of 0.2 g/dl the value of the threshold of the alarm and come back in the "TREATMENT STOPPED" page.

With the "Page back" button it's possible to come back in the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl and the alarm rise up or the reading of haemolyzed plasma by the spectrometer is disabled following page will be shown by pressing on "THRESHOLD Spectrometer" function key.



Press "Disabled Threshold Hemoglob." and "Confirm" to disable the reading of haemolyzed plasma by the spectrometer and come back in the "TREATMENT STOPPED" page.

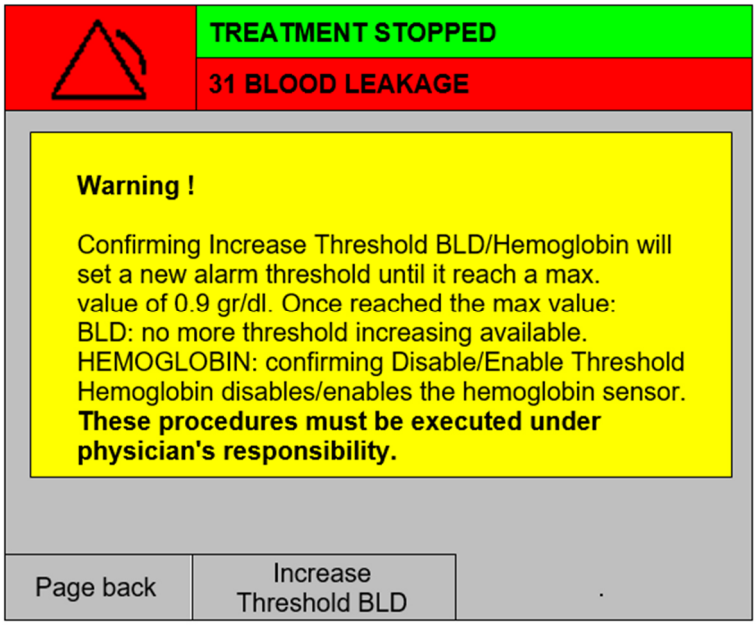
Press "Enable Threshold Hemoglob." and "Confirm" to enable the reading of haemolyzed plasma by the spectrometer and come back in the "TREATMENT STOPPED" page.

WARNING

Raising the alarm threshold and deactivating the spectrometer's reading of haemolysed plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

- **31 BLOOD LEAKAGE**



Press "Increase Threshold BLD" to increase of 0.2 g/dl the value of the threshold of the alarm and come back in the "TREATMENT STOPPED" page.

With the "Page back" button it's possible to come back in the "TREATMENT STOPPED" page.

If the threshold of the alarm is 0.9 g/dl the "THRESHOLD Spectrometer" function key will not appear

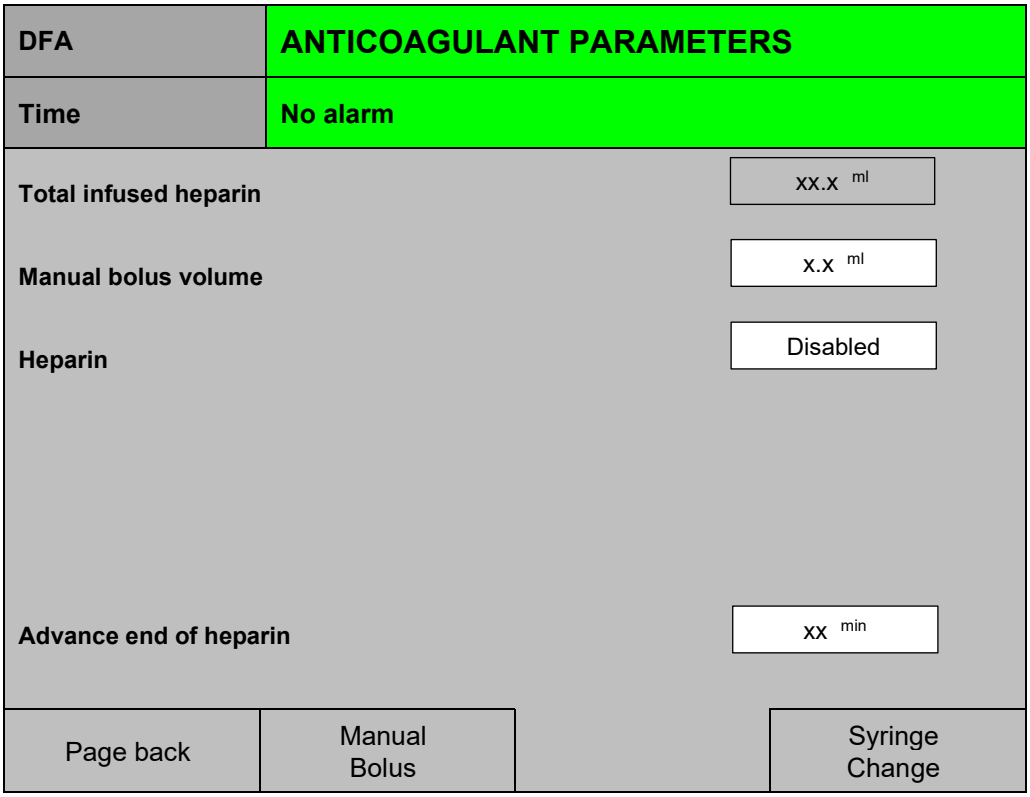
WARNING

Raising the alarm threshold of blood in plasma can lead to dangerous situations for the patient and must only be carried out under the guidance and supervision of a physician.

The threshold can not be increased more than 0.9 g/dl

Heparin XXXX:

On this page it is possible to check and change the operating status/mode of the heparin pump:



The screen above shows the "Disabled" heparin mode.

- **Total Infused Heparin:** Volume in ml of heparin injected into the extracorporeal circuit (not modifiable)
- **Manual Bolus Volume**: It indicated the heparin bolus volume that the user can manually injected into the extracorporeal circuit
  - Range: [0.1 – 5.0] ml
  - Default: 1.0 ml
  - Step: 0.1 ml/min

  Press the "Manual Bolus" key to inject this bolus.
- **Heparin:** This parameter indicates the operating status/mode of the heparin syringe; the pump operating mode can be changed during treatment.
- **Advance end of heparin:** It indicates the time in minutes when the heparin infusion should be stopped before the end of the treatment.

NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

From this screen it is possible to access various functions through the menu located at the bottom:

Manual Bolus: trough this function it is possible to administering an additional heparin bolus of 1 ml respect the normal heparin operating mode.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Manual Bolus	Confirm

Syringe Change: trough this function it is possible to replace the anticoagulant syringe .
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Confirm	Syringe Change

Confirmed the "Change Syringe" appear the following screen with reported the instructions to replace the syringe.

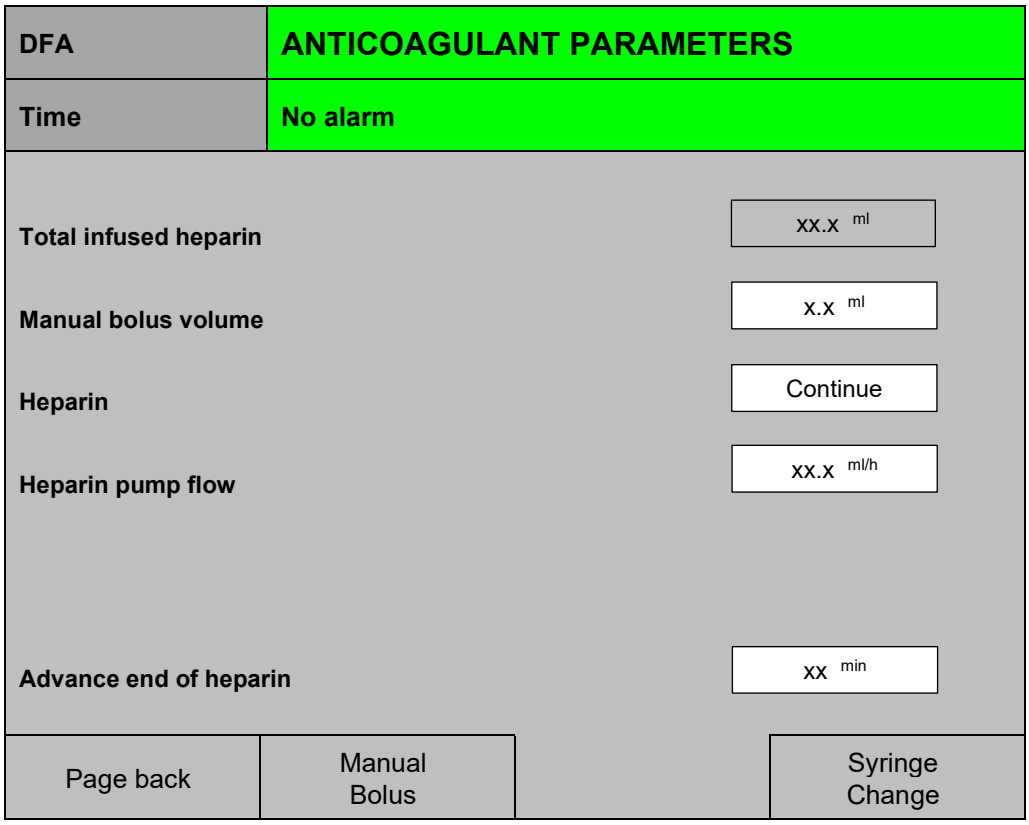
DFA	**TREATMENT IN PROGRESS**		
Time	**CHANGE SYRINGE**		
*** Close the syringe line clamp** *** Remove the empty syringe** *** Set syringe cursor** *** Introduce new syringe** *** Open syringe line clamp** *** Confirm syringe change**			
Page back	Syringe < - -	Syringe - - >	Change Syringe

Follow the on-screen instructions and confirm "Change Syringe" key.

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Other Heparin Modes available:

- **Heparin Continue:**

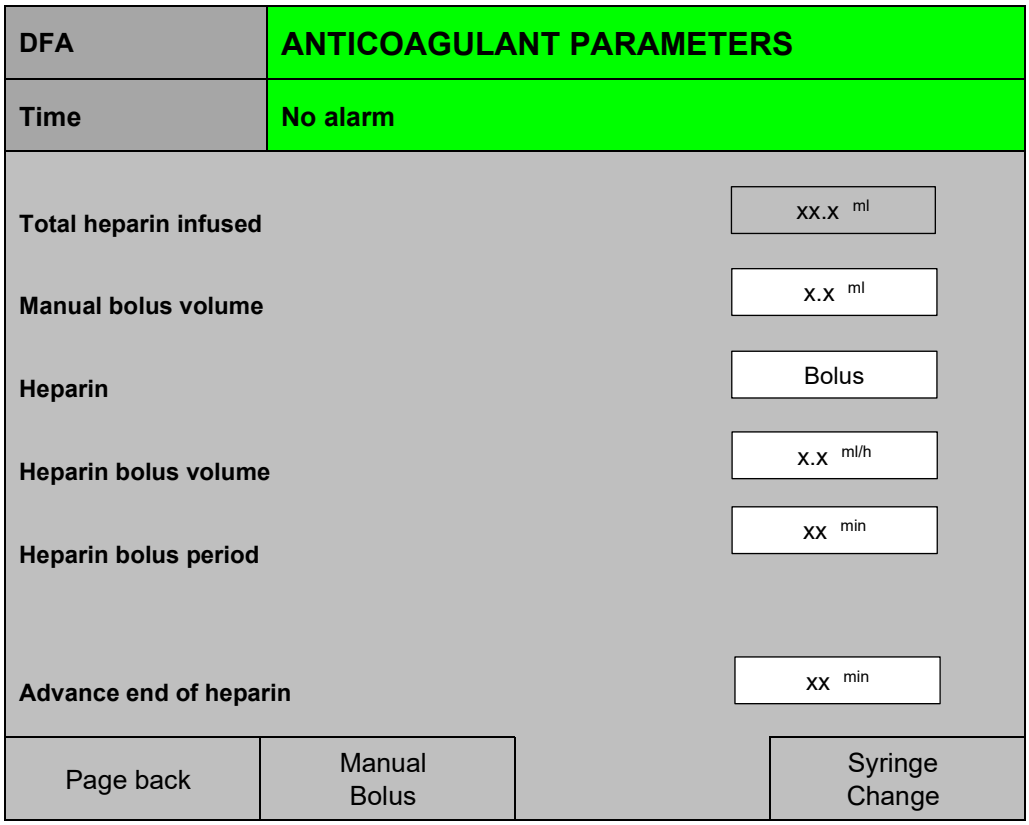


Compared with the heparin disable screen the only add parameter is:

Heparin pump flow: It indicated the anticoagulant flow in ml/min .

- Range: [0.1 – 20.0] ml
- Default: 0.4 ml
- Step: 0.1 ml

- **Heparin Bolus:**



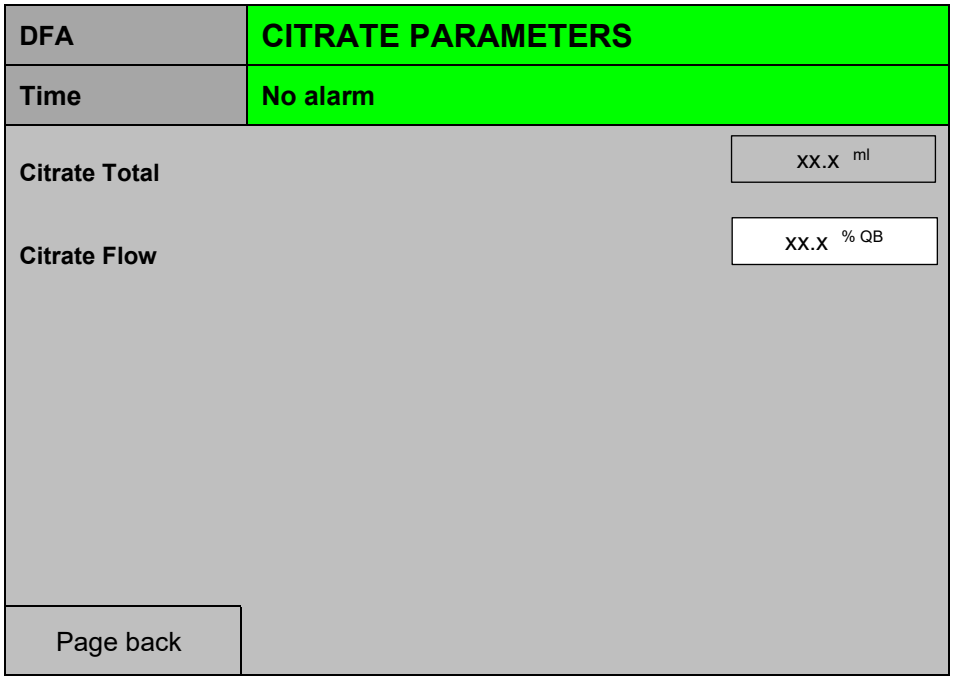
Compared with the heparin disable screen the only add parameter is:

Heparin bolus volume: It indicated the anticoagulant bolus volume regularly injected.
- Range: [0.1 – 5.0] ml
- Default: 0.1 ml
- Step: 0.1 ml

Heparin bolus period: It indicated the time between two consecutive bolus anticoagulant injection.
- Range: [5 – 60] min
- Default: 20 min
- Step: 1 min

Citrate (if selected before Priming):

On this page it is possible to check and change the operating status/mode of the citrate pump:



- **Citrate Total:** Volume in ml of citrate infused into the extracorporeal circuit (not modifiable)
- **Citrate Flow**: It indicated the citrate pump speed respect the blood pump flow rate
  - Range: [0.0 – 10.0] % QB
  - Default: 3.0 % QB
  - Step: 0.1 % QB

End Treatment

See End Treatment chapter 19.4.2.4.

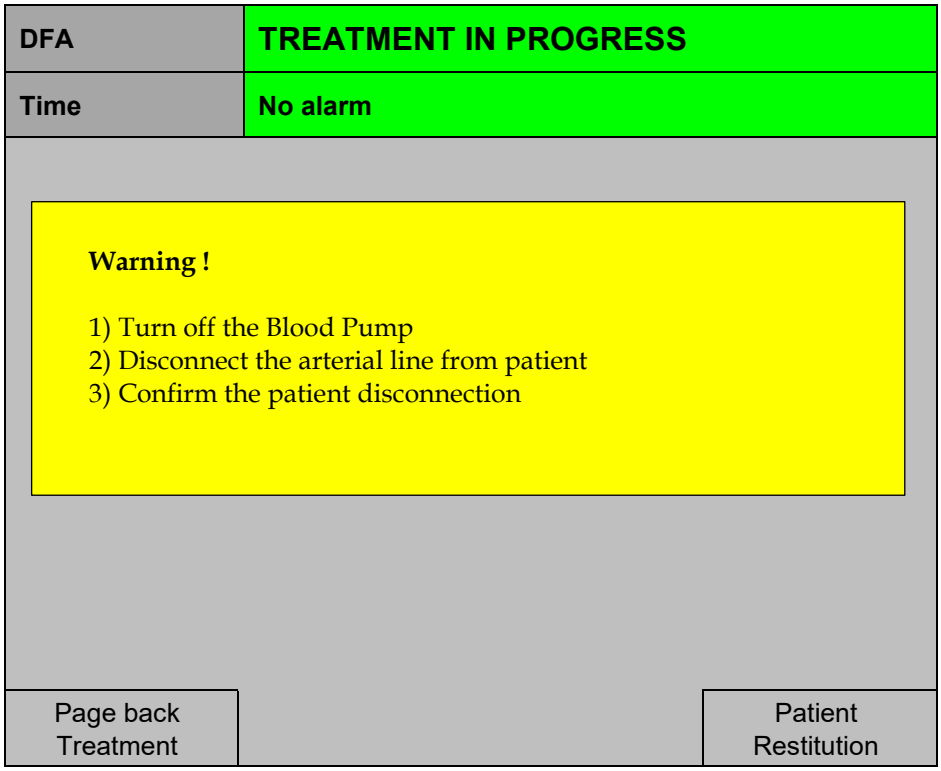
19.4.2.4. End Treatment

When AFERSMART PLUS has reached the target of treated blood volume, the message "501 END TREATMENT" appears on the screen.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the treatment at any time by pressing "End Treatment" key also if the treatment is not completed.

Select "End Treatment" and perform the operations that appear on the display to proceed.

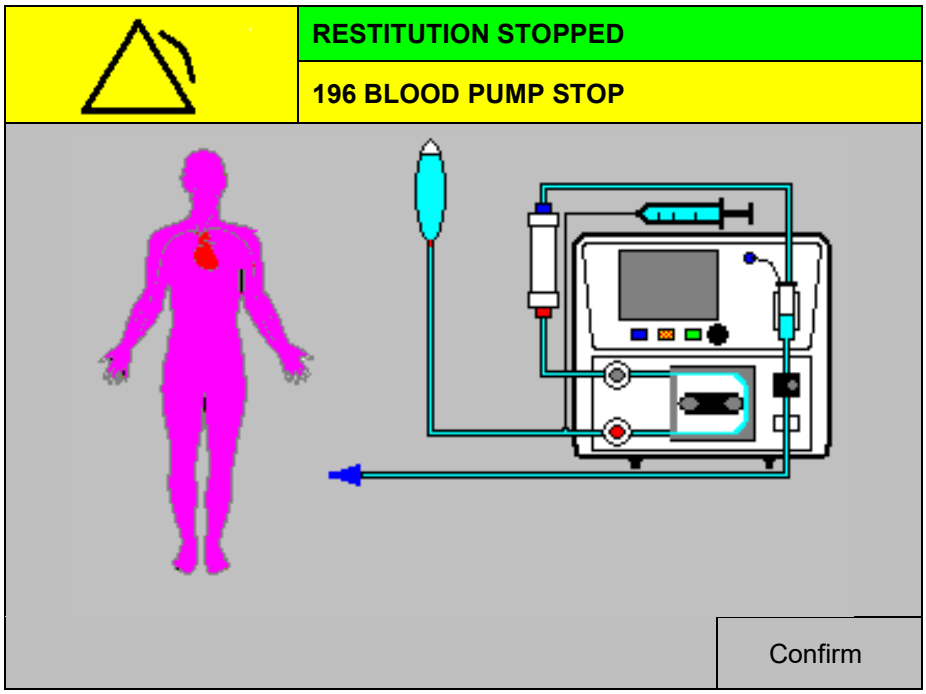


Press "Patient Restitution" key to start the blood restitution phase.
Press "Page back Treatment" key to return the treatment phase.

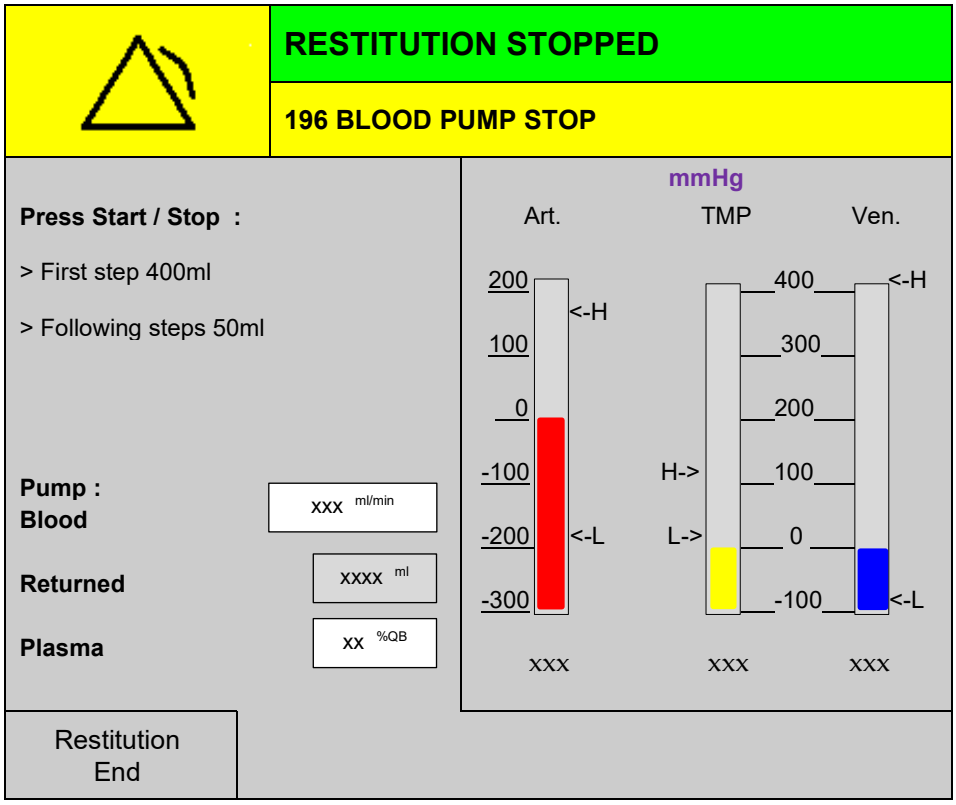
19.4.3. BLOOD RESTITUTION

19.4.3.1. Restitution

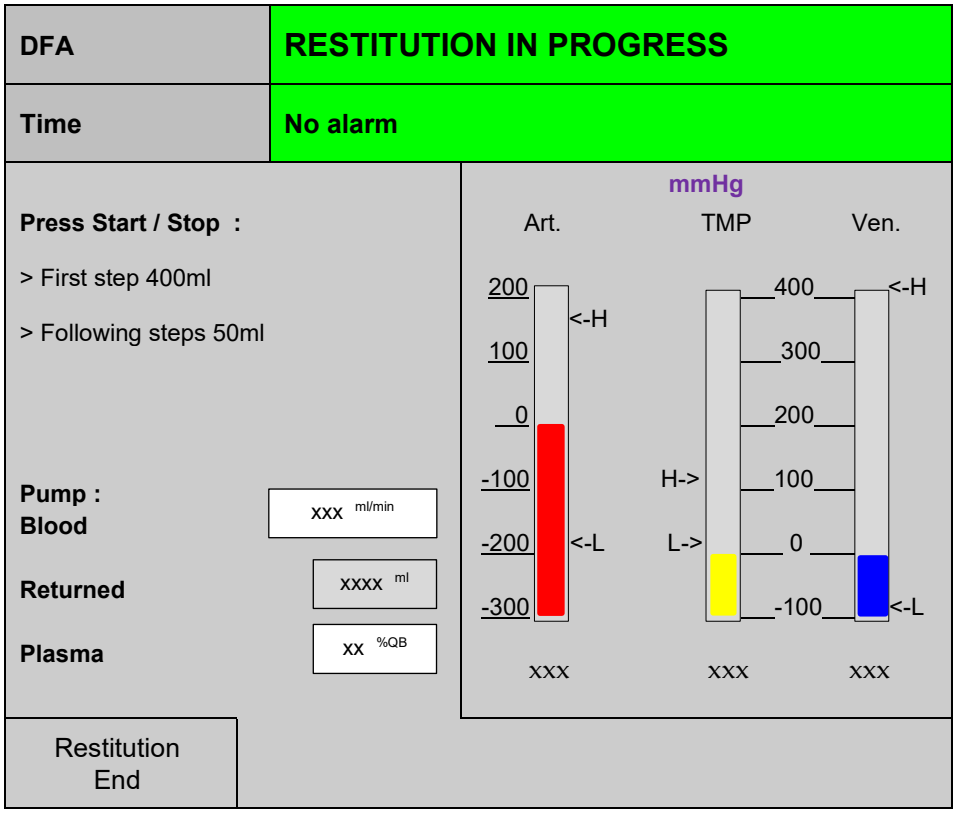
The restitution phase allows the patient to re-infuse most of the blood remaining in circulation in the lines.
Disconnect the arterial line from the patient and connect it to the NaCl solution (1000 ml container).



When entering the page above, the blood pump stops to allow to connect the aspiration line to saline solution bag.
Press "Confirm" key to enter the main page of restitution phase.



Press the <START / STOP> button to start the blood REINFUSION phase.



The first time the START/STOP button is pressed and 400 ml of blood are returned.
The next times the button is pressed 50 ml at a time are returned.
During standard or additional reinfusion, it is always possible to stop the blood pump by pressing <START / STOP>

Available setting parameters:

- **Pump: Blood** (flow)[ml / min].
  - Range: [0 - 100] ml / min
  - Default: 30ml / min
  - Step: 5ml / min

- **Plasma** (flow) [%QB].
  - Range: [0 - 50] %QB
  - Default: 30 %QB
  - Step: 1 %QB

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Returned [ml]:** It indicates the total blood returned.
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The TMP pressure is the pressure that work over the filter fibers. The value is obtained from the following formula:

$$P_{TMP} = \frac{P_{PREFILTER} + P_{VENOUS}}{2} - P_{UF}$$

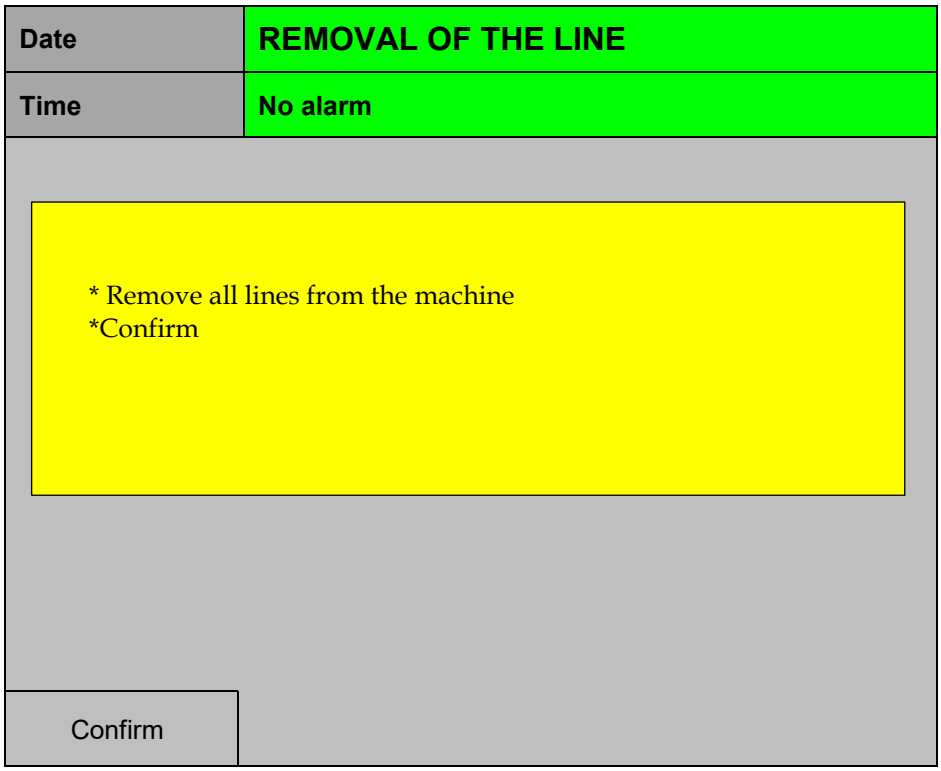
In this phase, only the air bubble detector and the pressure and safety alarms (covers, etc.) are active.
Once the restitution has been completed, select "Restitution End" to disconnect the circuit from the machine.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the restitution at any time by pressing "Restitution End" key also if the blood restitution is not completed.
If you do not confirm the "Restitution End" before turning off the machine. The next time you turn it on, it will restart from this page and not from the INTRODUCING page. In this case, confirm the "Restitution End" after turning on

19.4.3.2. Removal of the lines

The patient can be disconnected from the venous line.
It is possible to remove the lines and the plasma filter and proceed with disposal them.



After the uninstallation of the lines, push "Confirm" to go to the "INTRODUCING" page.

The AFERsmart PLUS can now be turned off.

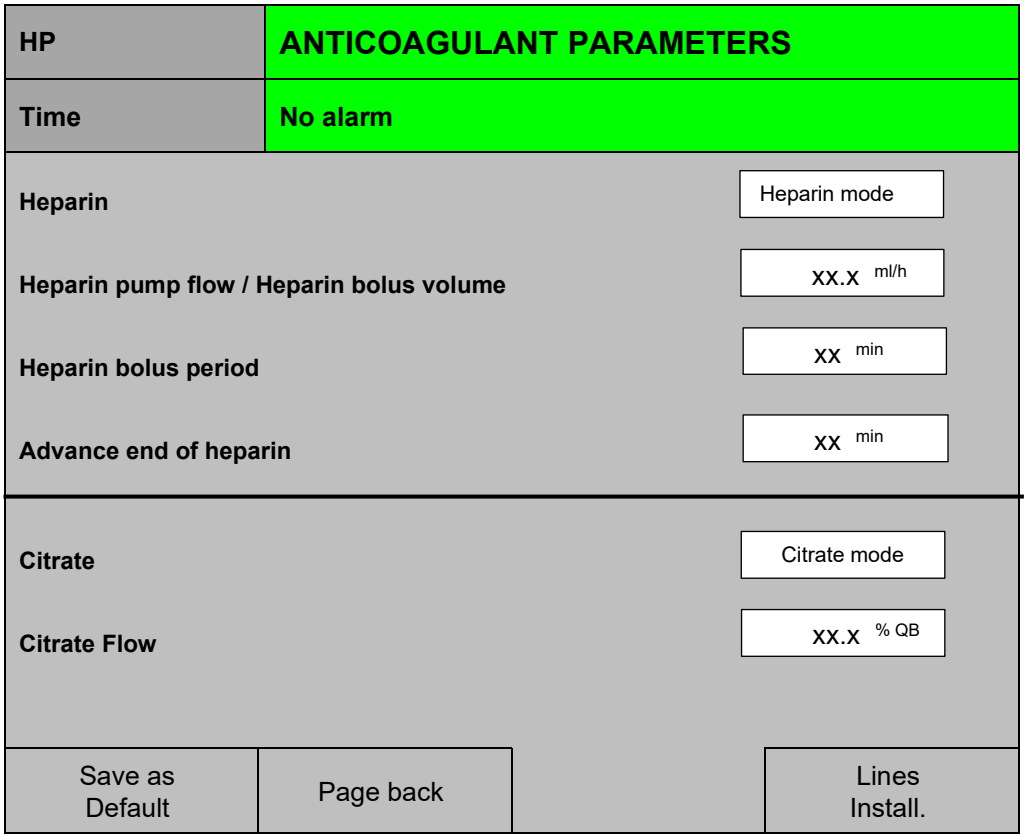
19.5. HEMOPERFUSION

19.5.1. PREPARATION

19.5.1.1. Anticoagulant Parameters

It is possible to set / modify the parameters related to the anticoagulant before entering in the priming procedure. These parameters can be modified even during the treatment phase, by pressing < Parameters> key.

- Heparin: Disabled/ Continue/ Bolus
- Heparin pump flow (available only in "Continue" mode): [0.1 – 20.0] [ml/h]
- Heparin bolus volume (available only in "Bolus" mode): [0.1 – 5.0] [ml/h]
- Heparin bolus period (available only in "Bolus" mode): [5 – 60] [min]
- Advance end of heparin: [0 – 30] [min]
- Citrate: Disabled/ Enabled
- Citrate Flow (available only in "Enabled" mode) : [0.5 – 10.0] [% QB]



NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

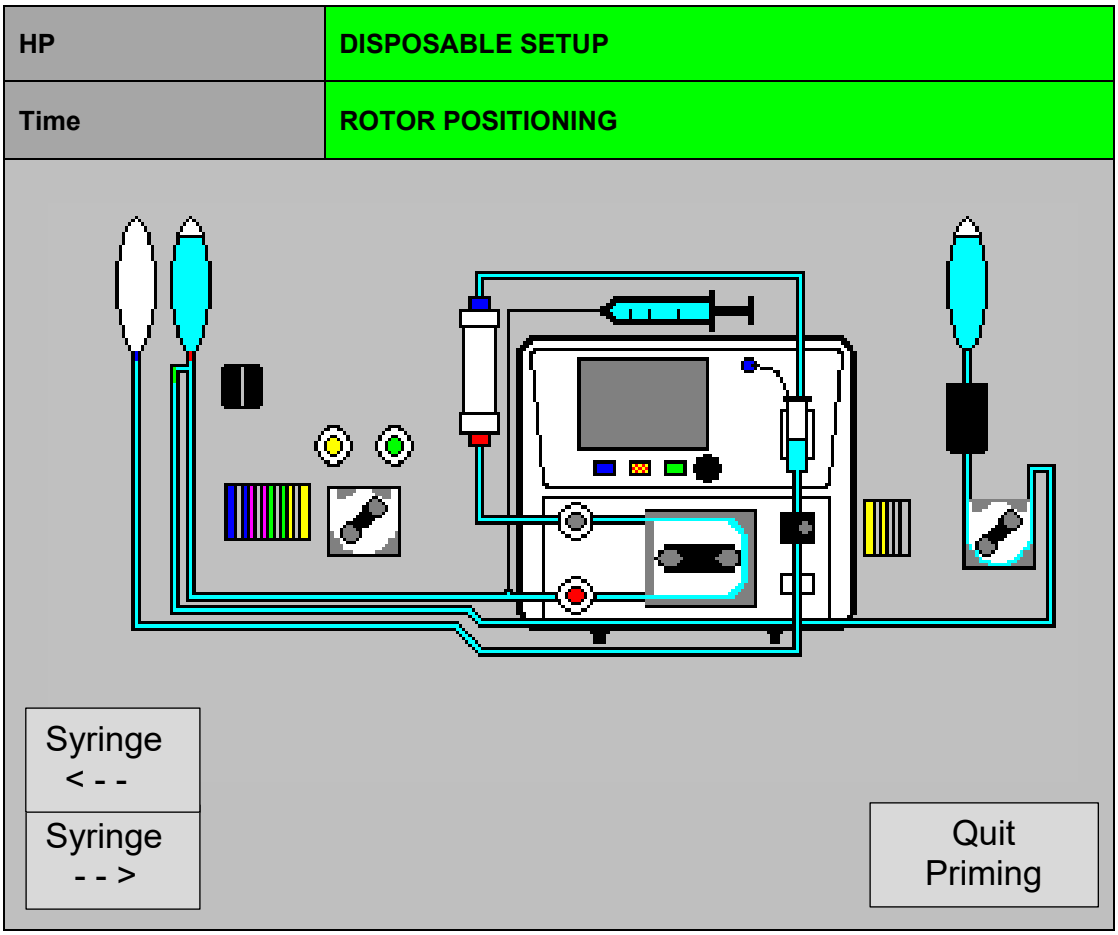
Press ”Save as Default” to save set parameters and make them available for the next treatments

Press the <Page back> key to return to the “INTRODUCING” page

Press the <Lines Install.> key to proceed to the “DISPOSABLE SETUP” page

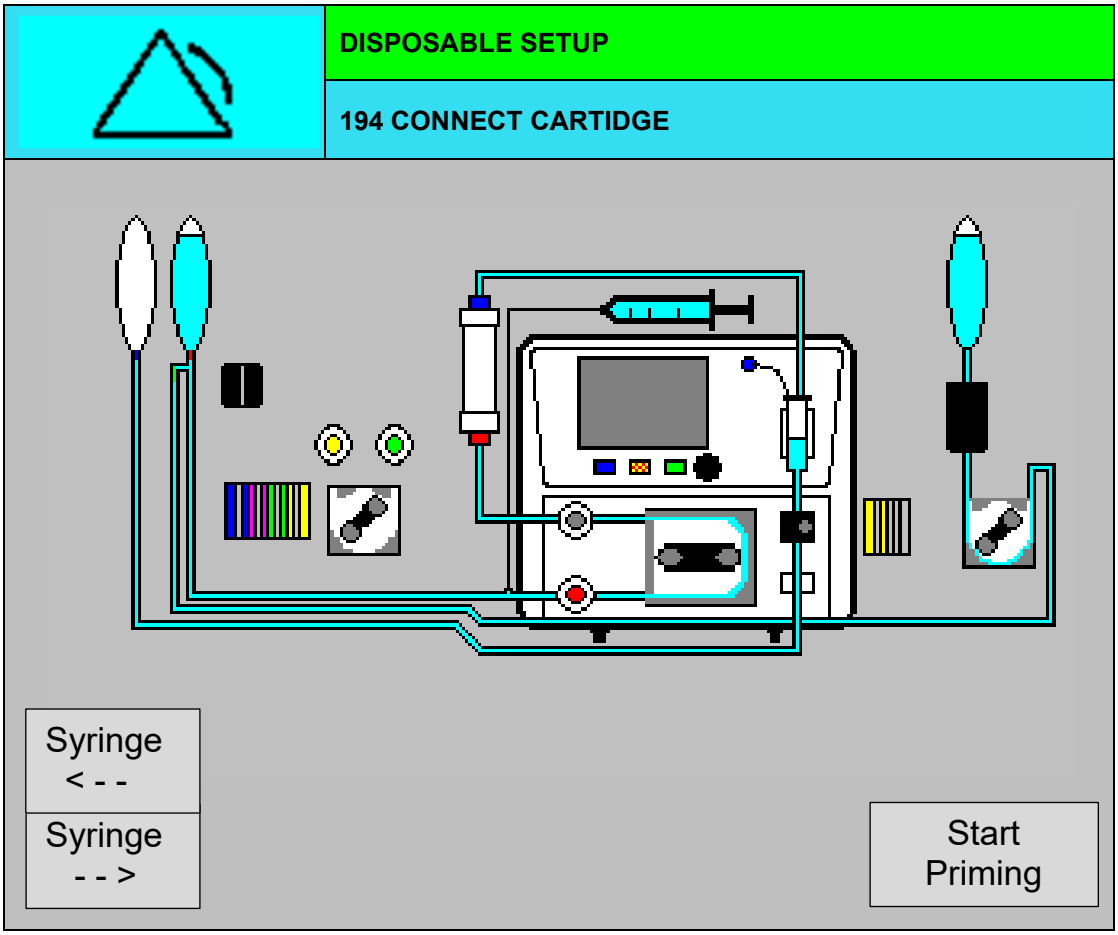
19.5.1.2. DISPOSABLE SETUP

On this page it is possible to install the disposable, the haemofilter and the bags needed to perform the HP treatment and its priming



Once entering in this page AFERsmart PLUS will execute the automatic pump rotors positioning (both Blood and Citrate) needed to ease the installation of Blood and Citrate tubing set.

After the "Rotors positioning" phase the "194 CONNECT CARTRIDGE" message will appear, " the venous electroclamp will open and the red light over the clamp will switch off.
and it will be possible to install the disposable kit, the Haemofilter and the bags as shown on the screen



At this phase make sure that the hooks of the scale are completely free.

The AFERSMART PLUS Kit is enclosed in a paper-film envelope, inside are:

Semi-finished arterial line and ACD (identified with red- and green-coloured components)
Semi-finished venous line (identified with blue-coloured components)

- Hang the Priming Solutions and the citrate solution (if Citrate anticoagulation was set) on the stand pole.
- Place the filter in its support (ref. 6 Chapter 2.3)
- If Citrate anticoagulation was set:
  - Place the ACD chamber in the appropriate support (ref. 4 Chapter 2.4), inserting it from top to bottom
  - Open the ACD pump cover (ref. 3 Chapter 2.4),
  - Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth
  - Close the cover of the ACD pump
  - Connect the ACD inlet, with the white clamp to the citrate bag positioned on the stand pole

- Open the blood pump cover (ref. 2 Chapter 2.1),
  Place the pump section in the pump cradle, taking care to position the tube of the section between the rotor teeth.
  Close blood pump cover.

- Open the arterial pressure transducer and connect the relative arterial DOME (ref. 5 Chapter 2.1),

- Open the prefilter pressure transducer and connect the relative prefilter DOME (ref. 6 Chapter 2.1),

- Connect the red adapter (outgoing from the prefilter DOME) to the inlet (lower part) of the filter.

- If heparin anticoagulation was set:

  - Connect the heparin tube fitting to the 30-cc syringe previously filled with heparinized solution
  Insert the syringe in its seat, using the arrows < ← > and < → > to position the cursor

- Connect the inlet connector of the arterial line to the priming solution bag positioned on the stand pole

- Take the venous line from the envelope

- Place the venous chamber in the appropriate support (ref. 8 Chapter 2.1), by inserting it from top to bottom

- Connect the hydrophobic Venous Pressure Transducer Protector Luer Lock to the Venous Pressure Transducer (ref. 7 Chapter 2.1),

- Connect the blue adapter, at the inlet of the venous line, to the outlet (Upper part) of the filter.

- Insert the tube outgoing from the venous chamber into the air / blood sensor (ref. 3 Chapter 2.1) and, successively, into the venous electroclamp (ref. 4 Chapter 2.1)

- Place the venous waste bag already connected to the venous line on the stand pole (ref. 2 Chapter 2.6)

NOTE

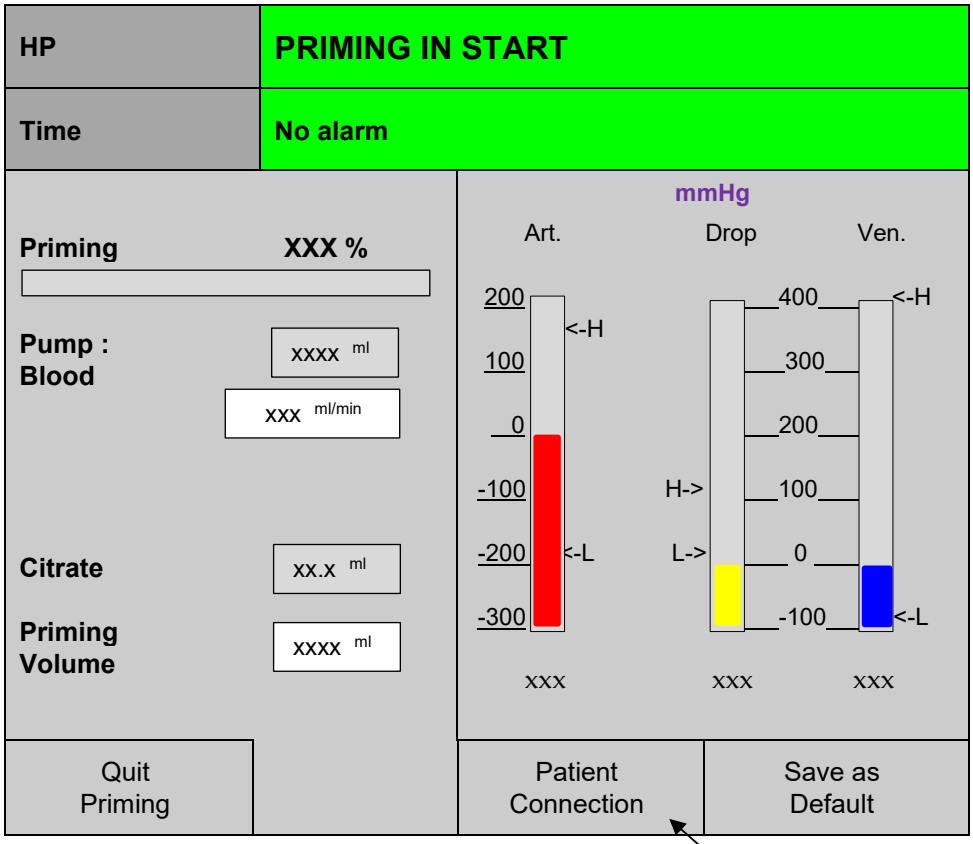
To correctly mount the venous pressure transducer protector to the conical connections of the pressure transducers, it is necessary to:

- **Fully insert the venous pressure transducer protector by making it make a slight rotational movement until it locks.**
- **Turn the ring anticlockwise to prevent it from disconnecting.**

19.5.1.3. Priming

Make sure you have connected the circuit as described above.

Select and confirm the <Start Priming > function; this takes you to the "PRIMING IN START" screen.



If no anomalies have occurred, this button appears at the end of the Priming.

The page displays:

- Pump: Blood (volume)[ml];
- Pump: Blood (speed)[ml/min]: adjustable from 5 to 250;
- Citrate (volume)[ml];
- Priming Volume (total)[ml]: adjustable from 1000 to 4000;
- The current value of the Arterial (RED), Drop (YELLOW) and Venous (BLUE) pressures and the related alarm thresholds.

AFERSMART PLUS then begins the automatic priming procedure.

NOTE

To temporarily stop priming, simply press the <START / STOP> button once. Press this button again to restart priming.

Press "Save as Default" to save set parameters and make them available for the next treatments

During Priming it is advisable to adjust the level in the restitution drip chamber. To do this, operate as follows:

- Close the clamp on the restitution line to the patient.
- Open the service line on the restitution drip chamber.
- When the desired level has been reached, normally 2/3 the volume of the drip chamber, close the service line and reopen the clamp on the restitution line to the patient.

If you want to end PRIMING before it has been completed, select and confirm "Quit priming". You will be asked for confirmation that you want to quit PRIMING:

Quit Priming	Confirm

After selecting and confirming "Quit Priming" return to the "INTRODUCING" page.

Once the Priming of the disposables has been successfully completed, the Priming status bar is at 100% and the "Patient Connection" key will appear and the warning "500 END PREPARATION" rise up.

Quit Priming		Patient Connection	Save as Default

A further flushing phase can be performed by pressing the "START STOP" physical button located below the display.

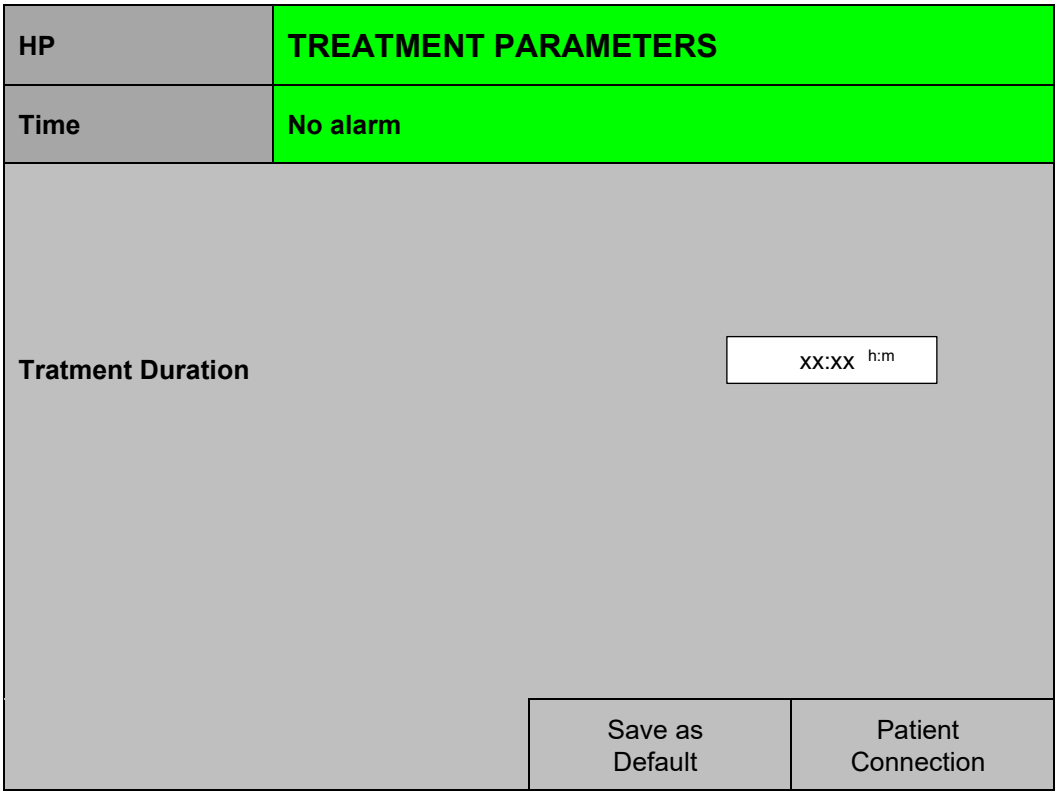
In this phase a total of one litre of priming solution will be processed by the Blood pump.
This operation can be repeated several times.

Press "Patient Connection" key to proceed to the clinical parameters settings before the treatment.

19.5.2. TREATMENT

19.5.2.1. TREATMENT PARAMETERS

The TREATMENT PARAMETERS screen allows you to set the parameters relating to the treatment.
Check and, if necessary, modify the parameters relating to the treatment, then press <Patient Connection>.



Available setting parameters:

- **Treatment Duration [h:m]:** Total treatment time.
  - Range: [01:00 – 24:00] h:m
  - Default: 01:00 h:m
  - Step: 00:10 h:m

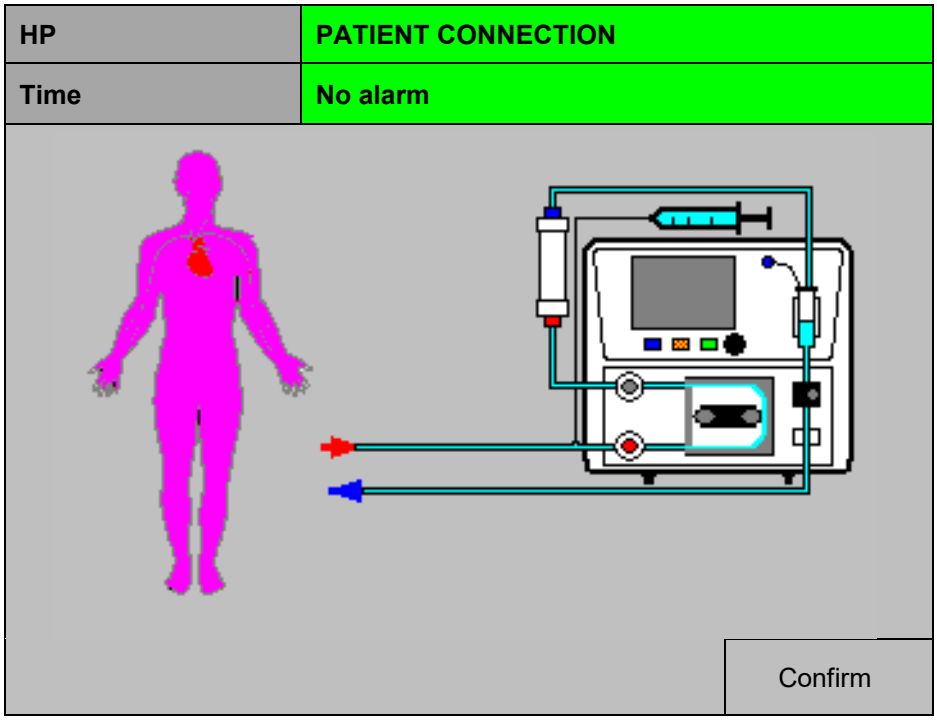
Press ″Save as Default″ to save set parameters and make them available for the next treatments

19.5.2.2. PATIENT CONNECTION

After setting the treatment parameters, select <Patient Connection>.

Disconnect the priming lines from the arterial line, remove the priming bags from the stand and connect the arterial and the venous line to the patient.

When done, press <Confirm>.



WARNING

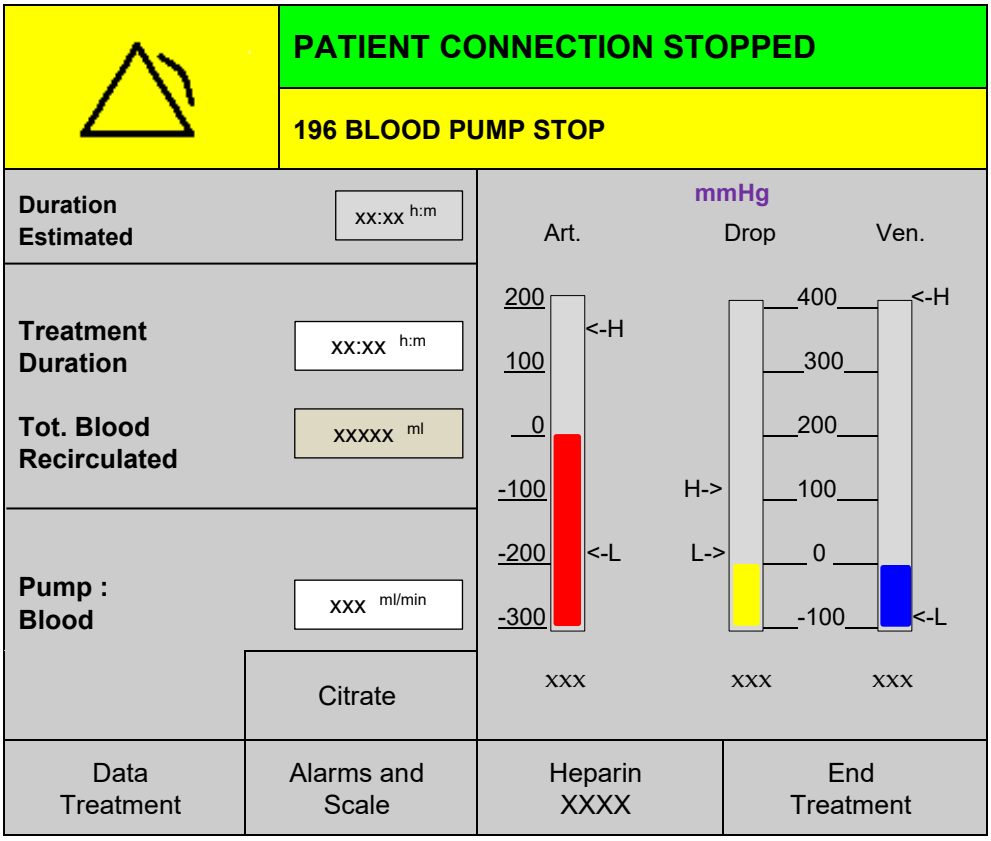
- **Risk of embolism due to air in the lines**
- **Risk of haemolysis due to kinking or crushing of lines**
- **Risk of blood loss due to not hermetically sealed connection points**

Before starting a treatment, check the following:

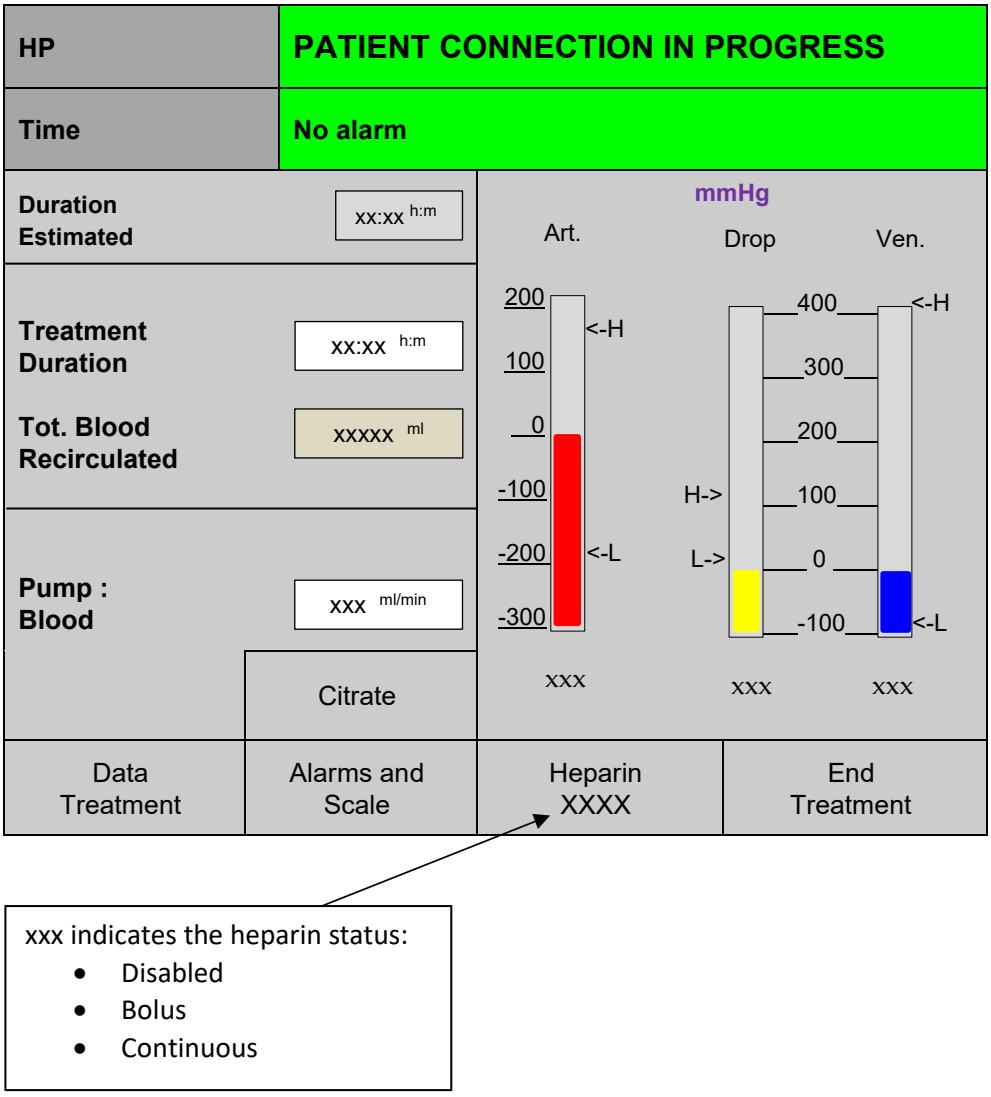
- All line joints are firmly connected
- There are no noticeable leaks in the lines, neither during nor after filling
- If leaks are found, tighten the relevant connections as needed.
- If necessary, replace the entire disposable.
- Lines are airless, inserted cleanly with no kinks, line tension or twisting and
- all fluid levels are correct.

19.5.2.3. TREATMENT

When start the treatment is show the "PATIENT CONNECTION STOPPED" screen, like reported in the following picture.



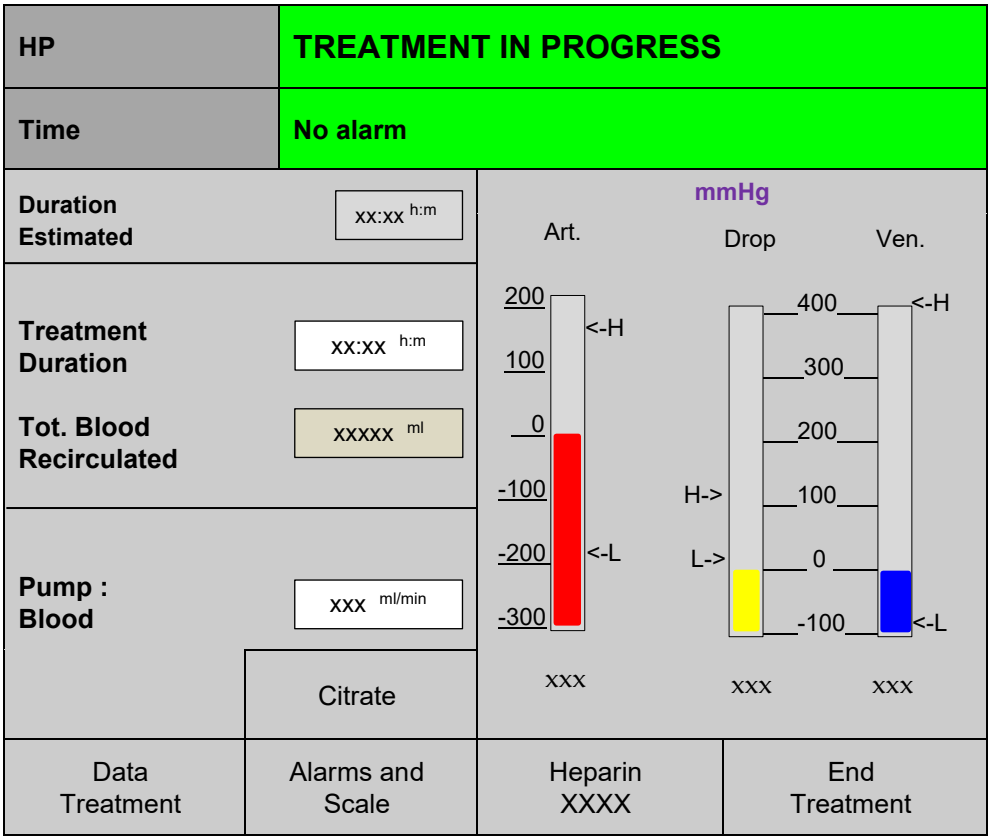
Push the START/STOP button (rif.16) to switch on the blood pump and enter in the patient connection phase.



For the first 100 ml of processed liquid by the blood pump, the machine considers the treatment as being in the connection phase and hence does not activate the infusion pump.

At the end of the patient connection phase AFERsmart PLUS automatically enters the treatment phase.

From the main screen it is possible to monitor the status of the treatment, by setting and / or monitoring the main treatment parameters.



Available setting parameters:

- **Pump: Blood** (flow)[ml / min].
  - Range: [5 - 250] ml / min
  - Default: 50ml / min
  - Step: 5ml / min

- **Treatment Duration** [h:m].
  - Range: [01:00 – 24:00] h:m
  - Default: 01:00 h:m
  - Step: 00:10 h:m

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Duration Estimated [h:m]**: It indicates the treatment time estimated.
- Tot. Blood Recirculated [ml] It indicates the total amount of blood processed
- The instant value of the arterial (RED), Drop (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]
  The Drop pressure is the pressure that work over the filter fibers.
  The value is obtained from the following formula:

P.Drop = P.Pre-Filter - P.Venous

NOTE

If Citrate was previously selected in the anticoagulant to be used, the range of the blood pump speed will be set in relation to the citrate percentage set and vice versa. AFERsmart PLUS automatically reject any incorrect value of Blood pump speed or citrate percentage that will be set.
The maximum value the citrate pump can reach is 5 ml/min.

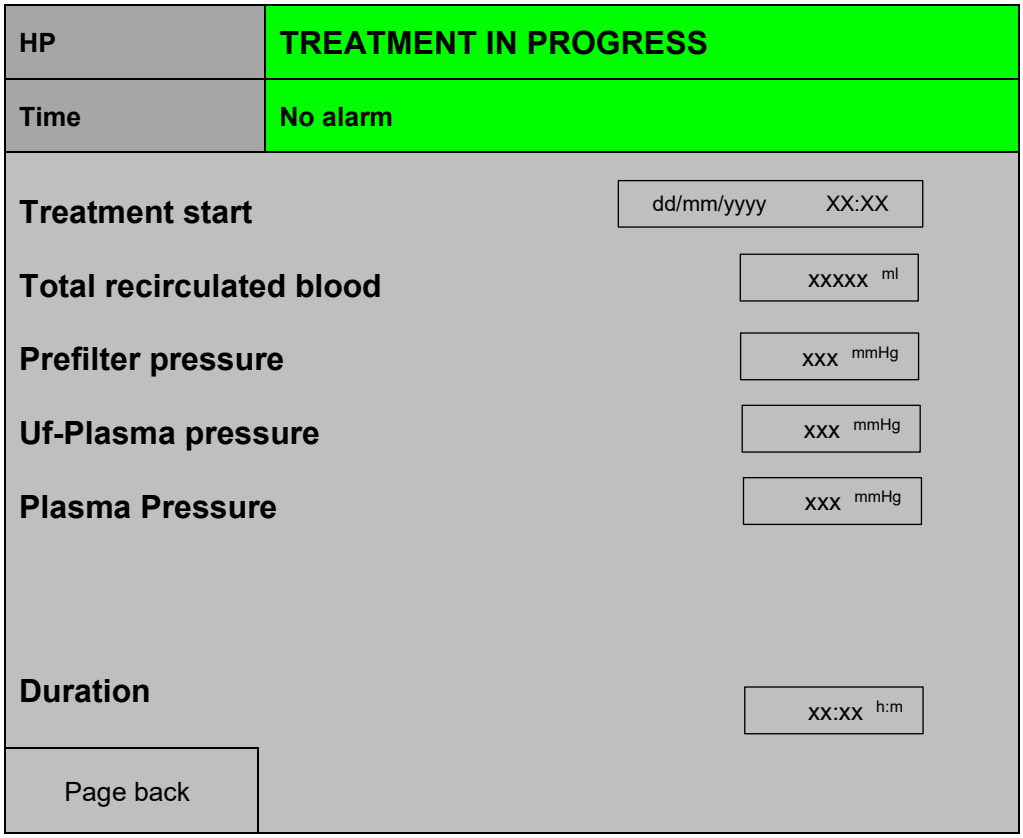
Example of work situation:

- **If Blood Pump is set at 250 ml/min the citrate percentage must be 2% or less**
- **If Citrate percentage set is 5% the blood pump speed must be 100 ml/min or less**

From the main screen it is possible to access various functions through the menu located at the bottom:

Data Treatment

The DATA TREATMENT screen shows the data relating to the treatment:



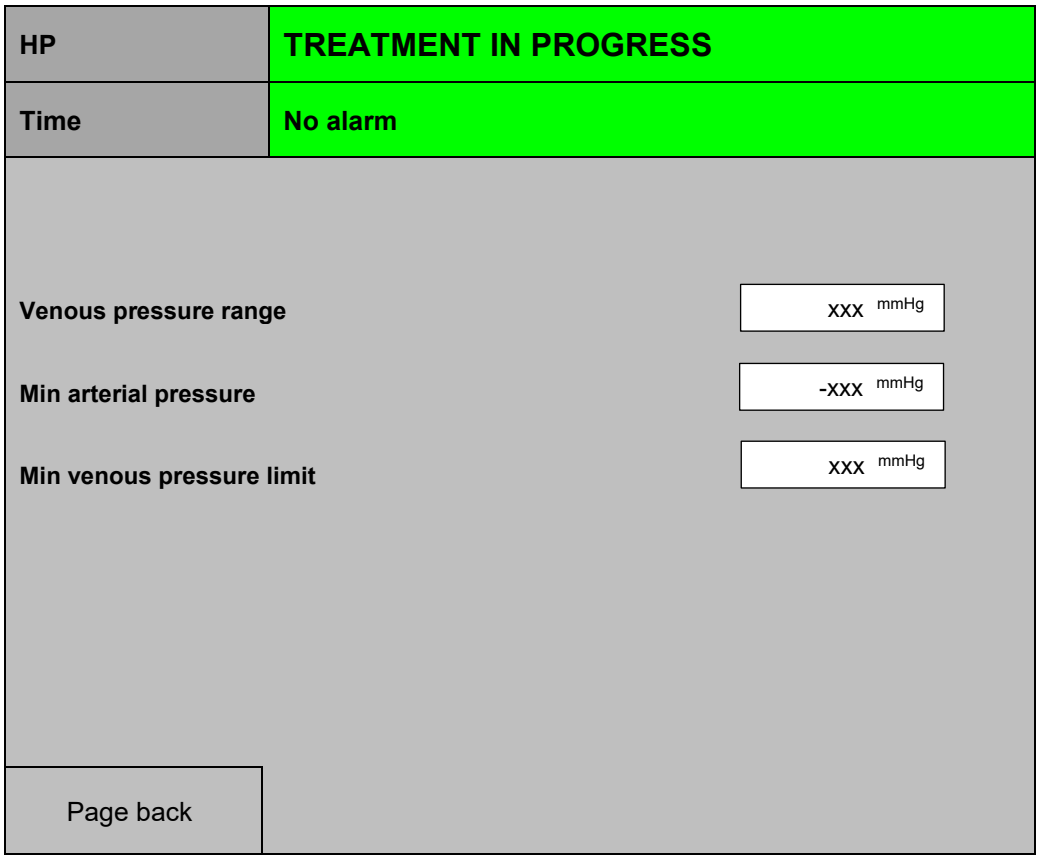
Allows accessing to the page where the following data are shown:

- Treatment start: Date and time of the treatment;
- Total recirculated blood[ml];
- Prefilter pressure [mmHg];
- Uf-Plasma Pressure [mmHg];
- Plasma Pressure [mmHg]
- Duration [h:m]

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Alarms and Scale:

The "ALARMS AND SCALE" screen allows you to set / view the alarm thresholds:



On this page, you can view and change the following values:

- **Venous pressure range** It indicates the range of values within which the restitution pressure must be maintained during the treatment; if the value read is not within this range
  - Range: [40 - 200] mmHg
  - Default: 100 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

- **Min arterial pressure**: It indicates the aspiration pressure alarm threshold value.
  - Range: [-250 - 0] mmHg
  - Default: -200 mmHg
  - Step: 10 mmHg

  The relative alarm will be displayed.

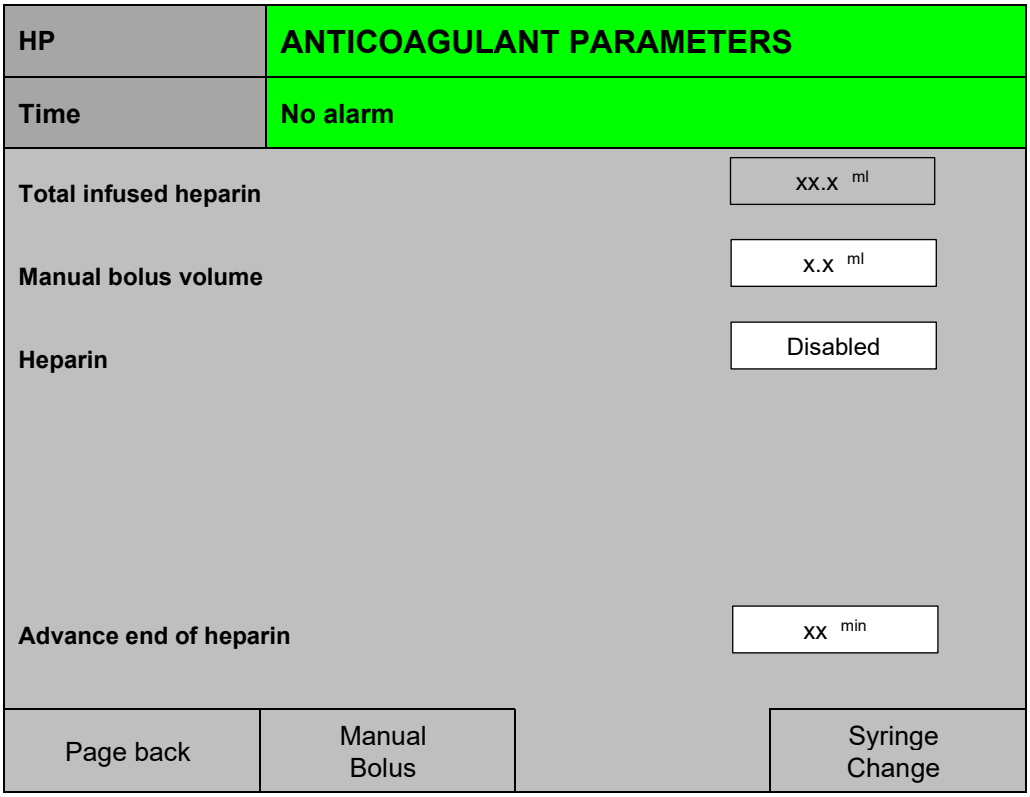
- **Min venous pressure limit**:It indicates the minimum value alarm of venous/restitution pressure
  - Range: [-30 - 5] mmHg
  - Default: 5 mmHg
  - Step: 1 mmHg

  The relative alarm will be displayed.

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Heparin XXXX:

On this page it is possible to check and change the operating status/mode of the heparin pump:



The screen above shows the "Disabled" heparin mode.

- **Total Infused Heparin:** Volume in ml of heparin injected into the extracorporeal circuit (not modifiable)
- **Manual Bolus Volume**: It indicated the heparin bolus volume that the user can manually injected into the extracorporeal circuit
  - Range: [0.1 – 5.0] ml
  - Default: 1.0 ml
  - Step: 0.1 ml/min

  Press the "Manual Bolus" key to inject this bolus.
- **Heparin:** This parameter indicates the operating status/mode of the heparin syringe; the pump operating mode can be changed during treatment.
- **Advance end of heparin:** It indicates the time in minutes when the heparin infusion should be stopped, before the end of the treatment.

NOTE

By setting the "Advance end of heparin" value at "0 min" the infusion of heparin continues until the restitution phase is started.

From this screen it is possible to access various functions through the menu located at the bottom:

Manual Bolus: trough this function it is possible to administering an additional heparin bolus of 1 ml respect the normal heparin operating mode.
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Manual Bolus	Confirm

Syringe Change: trough this function it is possible to replace the anticoagulant syringe .
To activate this function, it is necessary to select it, confirm it and also confirm the operation by means of the "Confirm" function that will be displayed as follows:

Confirm	Syringe Change

Confirmed the "Change Syringe" appear the following screen with reported the instructions to replace the syringe.

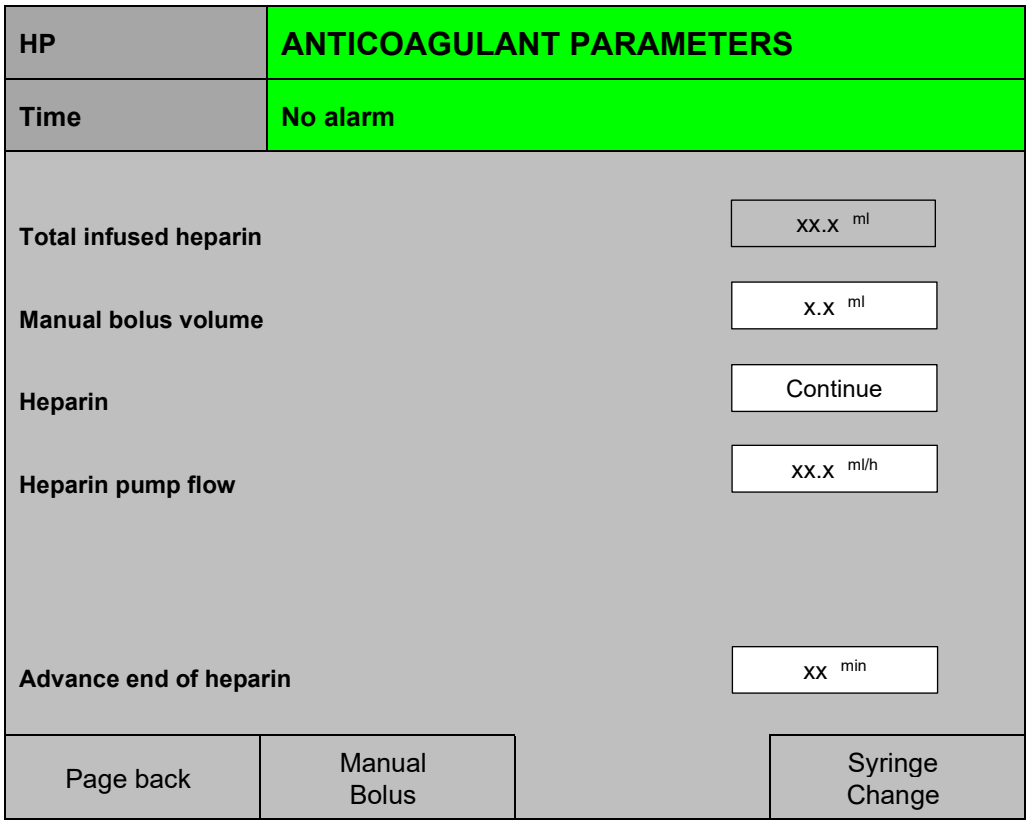
HP	**TREATMENT IN PROGRESS**		
Time	**CHANGE SYRINGE**		
*** Close the syringe line clamp** *** Remove the empty syringe** *** Set syringe cursor** *** Introduce new syringe** *** Open syringe line clamp** *** Confirm syringe change**			
Page back	Syringe < - -	Syringe - - >	Change Syringe

Follow the on-screen instructions and confirm "Change Syringe" key.

With the "Page back" button it's possible to come back in the "TREATMENT IN PROGRESS" page.

Other Heparin Modes available:

- **Heparin Continue:**

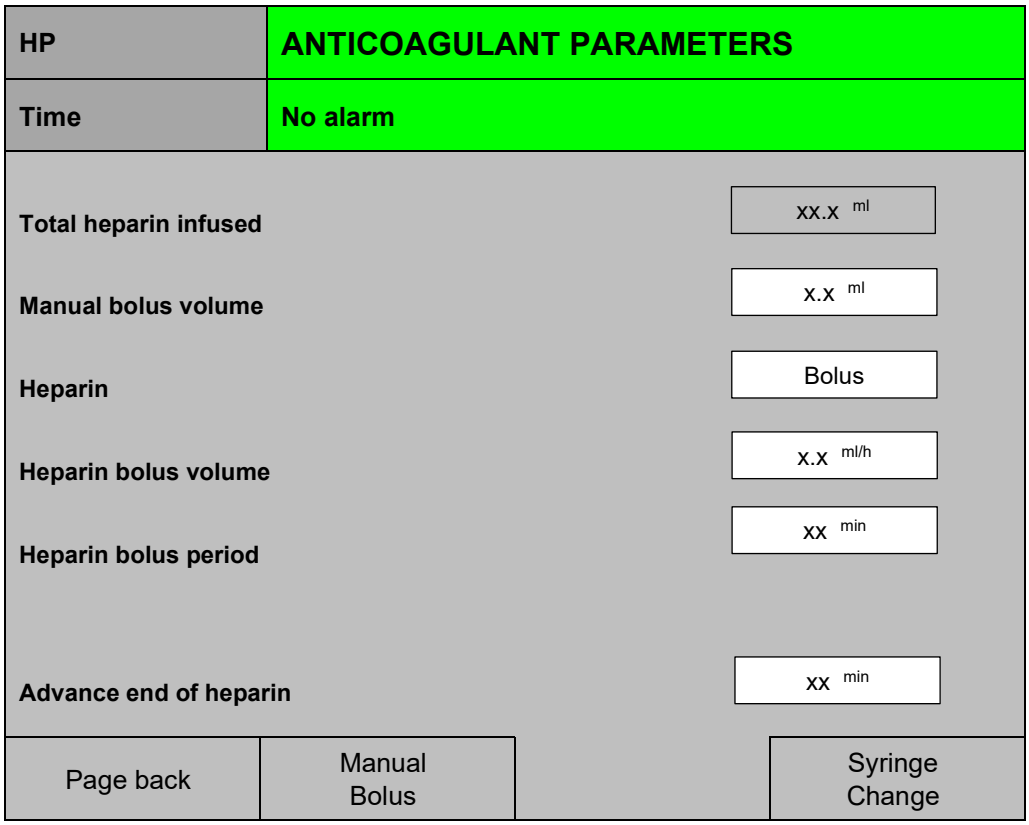


Compared with the heparin disable screen the only add parameter is:

Heparin pump flow: It indicated the anticoagulant flow in ml/min .

- Range: [0.1 – 20.0] ml
- Default: 0.4 ml
- Step: 0.1 ml

- **Heparin Bolus:**



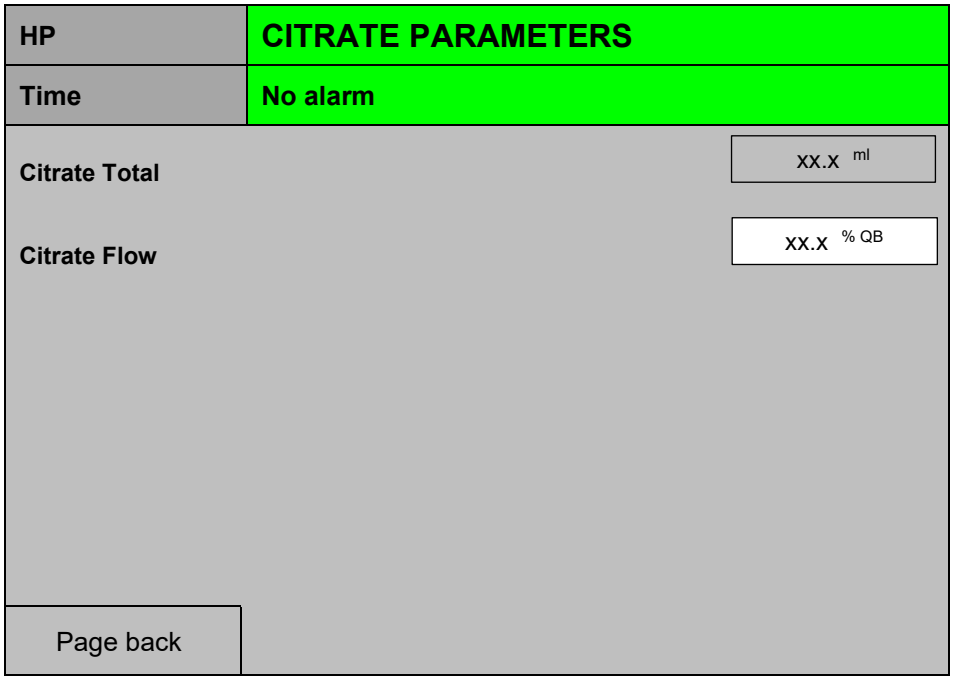
Compared with the heparin disable screen the only add parameter is:

Heparin bolus volume: It indicated the anticoagulant bolus volume regularly injected.
- Range: [0.1 – 5.0] ml
- Default: 0.1 ml
- Step: 0.1 ml

Heparin bolus period: It indicated the time between two consecutive bolus anticoagulant injection.
- Range: [5 – 60] min
- Default: 20 min
- Step: 1 min

Citrate (if selected before Priming):

On this page it is possible to check and change the operating status/mode of the citrate pump:



- **Citrate Total:** Volume in ml of citrate infused into the extracorporeal circuit (not modifiable)
- **Citrate Flow**: It indicated the citrate pump speed respect the blood pump flow rate
  - Range: [0.0 – 10.0] % QB
  - Default: 3.0 % QB
  - Step: 0.1 % QB

End Treatment

See End Treatment chapter 19.5.2.4.

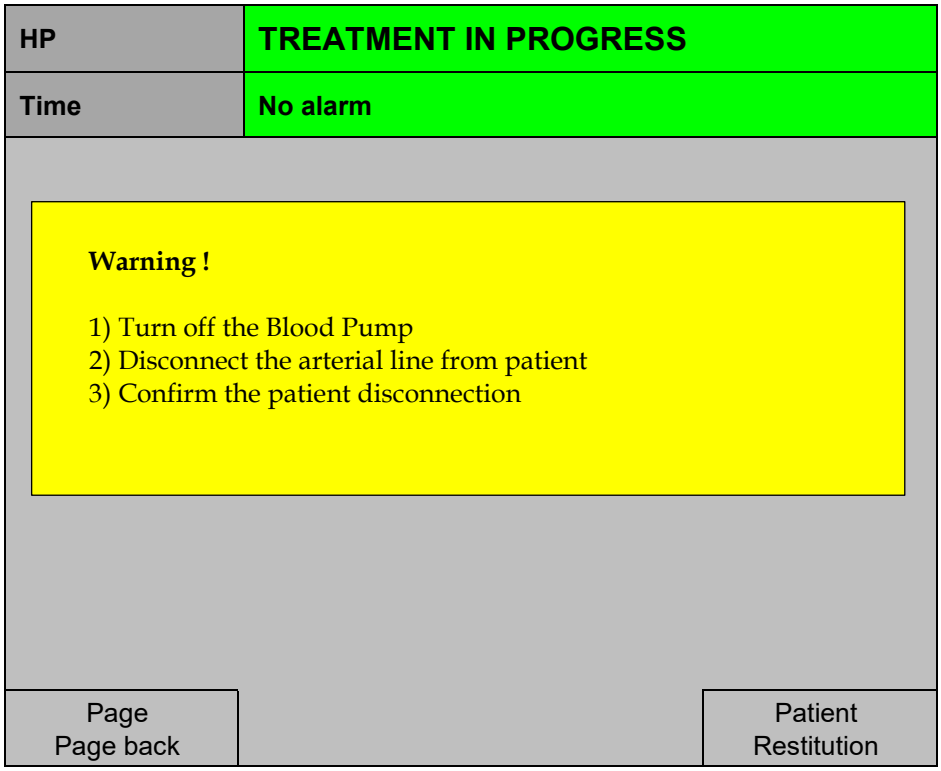
19.5.2.4. End Treatment

When AFERSMART PLUS has reached the target of treatment duration, the message "501 END TREATMENT" appears on the screen.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the treatment at any time by pressing "End Treatment" key also if the treatment is not completed.

Select "End Treatment" and perform the operations that appear on the display to proceed.

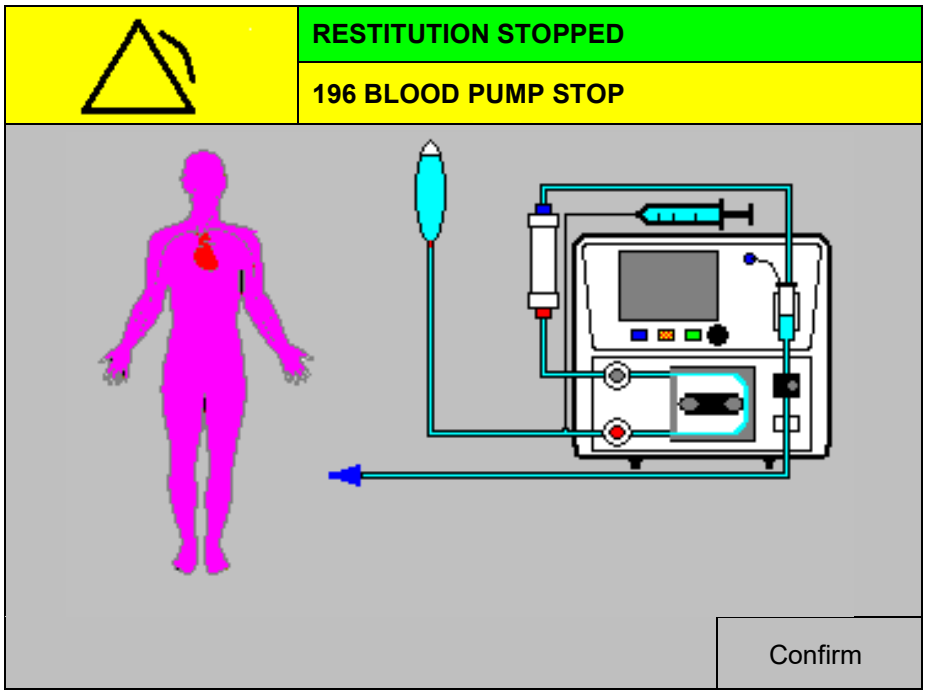


Press "Patient Restitution" key to start the blood restitution phase.
Press "Page back" key to return the treatment phase.

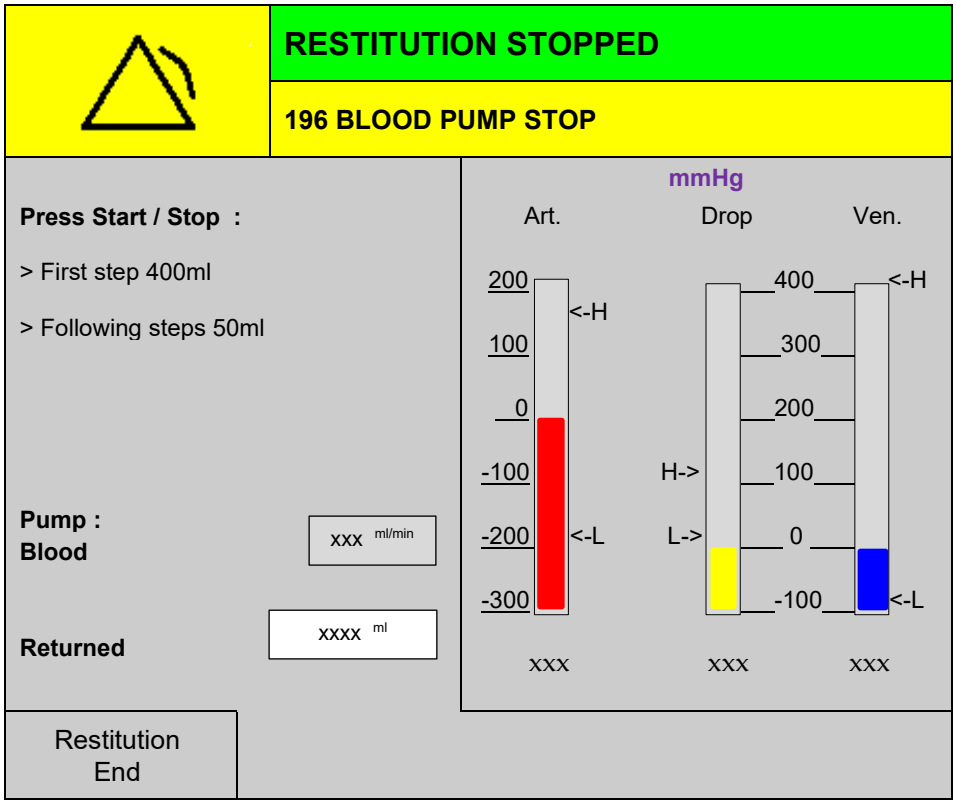
19.5.3. BLOOD RESTITUTION

19.5.3.1. Restitution

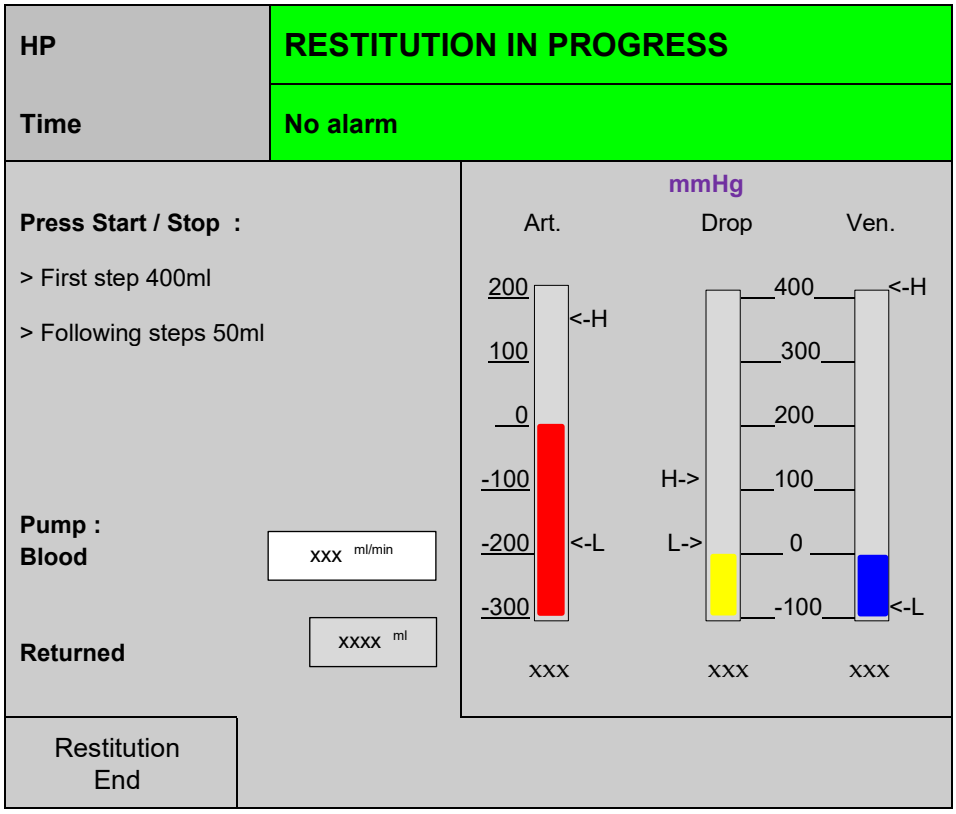
The restitution phase allows the patient to re-infuse most of the blood remaining in circulation in the lines. Disconnect the arterial line from the patient and connect it to the NaCl solution (1000 ml container).



When entering the page above, the blood pump stops to allow to connect the aspiration line to saline solution bag.
Press "Confirm" key to enter the main page of restitution phase.



Press the <START / STOP> button to start the blood REINFUSION phase.



The first time the START/STOP button is pressed and 400 ml of blood are returned.
The next times the button is pressed 50 ml at a time are returned.
During standard or additional reinfusion, it is always possible to stop the blood pump by pressing <START / STOP>

Available setting parameters:

- Pump: Blood (flow)[ml / min].
  - Range: [0 - 100] ml / min
  - Default: 30ml / min
  - Step: 5ml / min

Once you have selected and confirmed the box you can adjust the flow rate directly with the knob.

Other parameters displayed:

- **Returned [ml]:** It indicates the total blood returned.
- The instant value of the arterial (RED), TMP (YELLOW) e venous (BLUE) pressures and the related alarm thresholds [mmHg]

The Drop pressure is the pressure that work over the filter fibers. The value is obtained from the following formula:

P.Drop = P.Pre-Filter - P.Venous

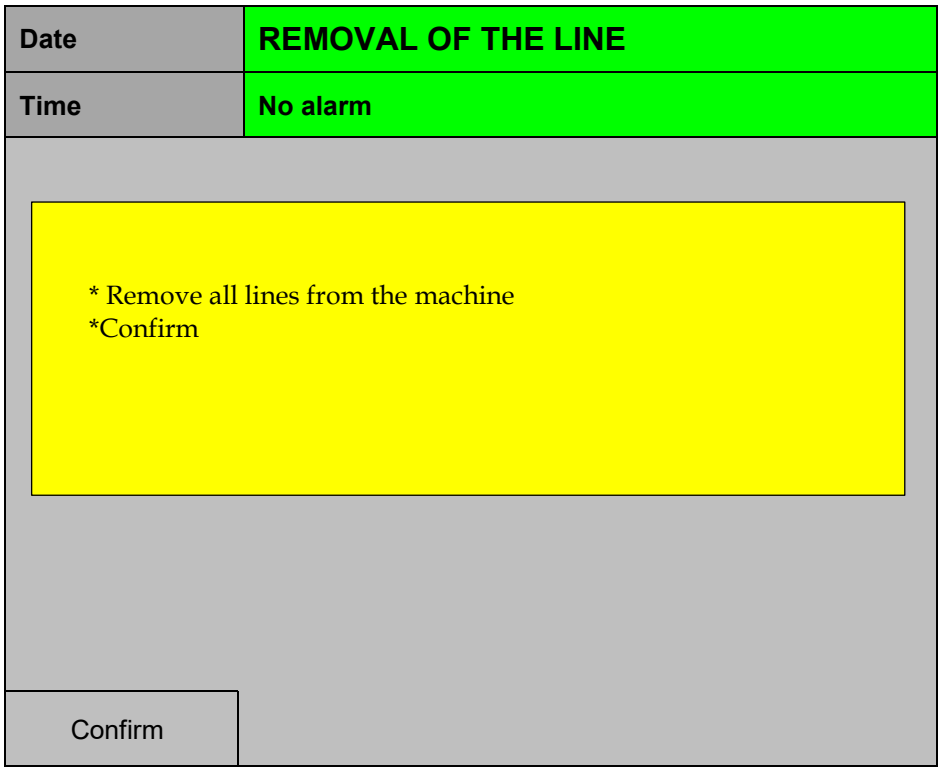
In this phase, only the air bubble detector and the pressure and safety alarms (covers, etc.) are active.
Once the restitution has been completed, select "Restitution End" to disconnect the circuit from the machine.

NOTE

If it is needed to disconnect the patient from the extracorporeal circuit it is possible to end the restitution at any time by pressing "Restitution End" key also if the blood restitution is not completed.
If you do not confirm the "Restitution End" before turning off the machine. The next time you turn it on, it will restart from this page and not from the INTRODUCING page. In this case, confirm the "Restitution End" after turning on

19.5.3.2. Removal of the lines

The patient can be disconnected from the venous line.
It is possible to remove the lines and the plasma filter and proceed with disposal them.



After the uninstallation of the lines, push "Confirm" to go to the "INTRODUCING" page.

The AFERsmart PLUS can now be turned off.

20. SYSTEM SHUT DOWN

At the end of treatment, once you have returned to the PROTOCOL SELECTION screen, to turn off AFERSMART PLUS, simply press the main switch, moving it to the "0" position.

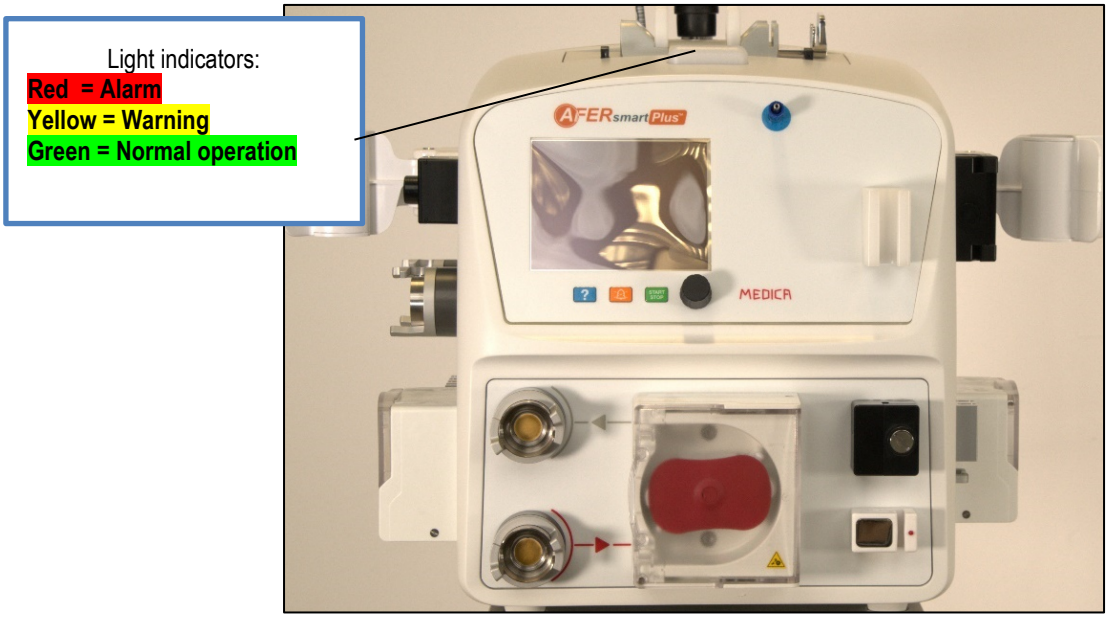
The main switch is located on the rear panel of the machine (ref. 8, paragraph OPERATING MODULE REAR VIEW).

21. ALARM SYSTEM DESCRIPTION

To diversify alarm signalling, the colour of the message displayed on the alarm line will be different, depending on the type:

- Each high priority alarm requires immediate intervention by the caregiver.
- Each medium priority alarm requires intervention by the caregiver, even if not immediate.
- Each low priority alarm is an operator information or message that does not require intervention by the caregiver or that does not require it in an immediate time frame.

Message colour	Identified alarms	Alarm priority
Red	Security Malfunctioning Operational	High priority
Yellow	Warning	Medium priority
Cyan	Attention	Low priority



Two different types of acoustic alarm signals are emitted in the event of an alarm.

The acoustic signals are generated by the MALLORY buzzer ref. SBS300PC in accordance with the requirements of IEC 60601-1-8.

The medium priority audible alarm has a different emission frequency from the high priority audible alarm.

The medium priority audible alarm has an emission amplitude equal to that of the high priority audible alarm.

Audible alarm sound level: 72 dB at 1m (operator distance in normal DMA use): The volume of the buzzer is not adjustable.

In the event of a power failure to the DMA, the audible alarm is activated after less than 1 second.

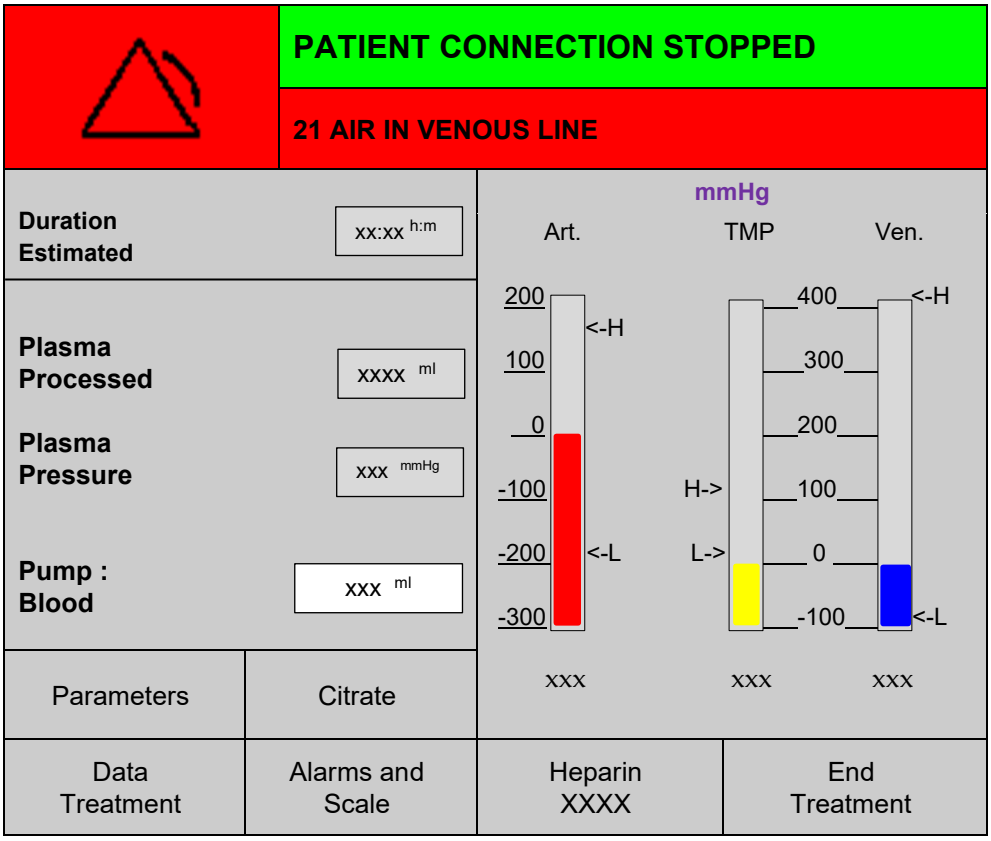
During treatment, when the power supply is restored, the DMA restarts in the pre-existing situation, but in a situation of blocked operation while waiting for a command from the operator to restart treatment.
When the battery is charged, the audible alarm is maintained for 1 minute.

Alarms can be reset by pressing the ALARM RESET button.

If the cause of the alarm is not resolved, the alarm will be repeated.

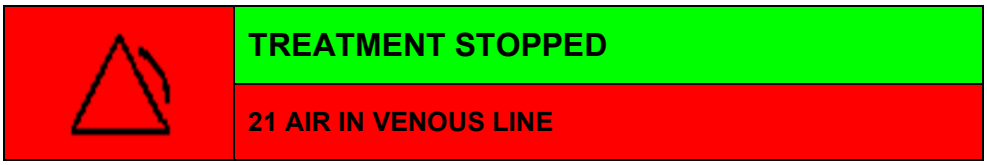
Even if muted, the alarm remains visible. After 1 minute, the sound will resume.
The alarm silencing period can be interrupted by another alarm condition.

A description of the alarm type is shown in the "Alarm Bar" as shown in the following figure.



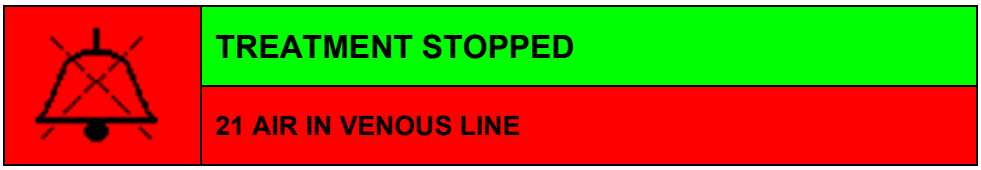
Whenever a high priority alarm appears the following symbol appears on the screen.

The 'Alarm' symbol appears next to the alarm.



Each time the button to silence the alarm is pressed the following symbol appears

The symbol "Alarm paused" appears next to the alarm description.



A list of possible causes and solutions of alarms are given later in this chapter.

The main alarm information, regarding the main causes and possible solutions, is always available in the HELP ON LINE screen.
The HELP ONLINE function can be obtained from any screen by pressing the<?> button (ref.1fig.8).
When an alarm occurs, the HELP ONLINE screen can be obtained directly by pressing the<?>) button; in fact, you enter the page relating to that alarm directly.
The information page remains active even if the alarm should cancel itself; in this case the alarm title disappears from the alarm line and the rest of the screen remains as before.
If the alarm exits independently, processing will resume normally.
When consulting the on-line manual, if a different alarm occurs than the previous one, the MAIN screen will reopen, otherwise the HELP ON LINE "page" remains enabled for 20 seconds.
The information screen provides a list of possible causes for the alarm to have exited, as well as a set of possible solutions to resolve the problem.

The alarm limits automatically determined by the software using an algorithm are as follows:

- Maximum and minimum venous pressure limits.

The pressure values are indicated with the following-coloured bars:

- Red for arterial pressure
- Yellow for Drop/TMP pressure
- Blue for venous pressure;

For each pressure the values of the alarm limits are indicated as follows:

- The maximum pressure limit: <-H
- The minimum pressure limit: <-L

Blood losses from the extracorporeal circuit to the environment are signalled by the AMD through the minimum venous pressure alarm.

Blood loss from the extracorporeal circuit due to coagulation is signalled by the AMD via the maximum pre-filter / pre-adsorber pressure or maximum pressure drop alarm.

Operator position during treatment:

- If the operator is working on the AMD or the patient, the operator should be at a distance of approximately 50 cm from the AMD.
- If the operator is not working on the AMD or the patient, he/she should be in the same room as the device or at a distance that allows him/her to hear the audible alarm and/or see the visual alarm.

WARNING

To guarantee the functioning of the alarm system, the user must verify it by pressing the "Lights and Buzzer Test" button on the technical parameters page.
Once the button is pressed, the buzzer starts sounding a high priority alarm and the lights turn on in all available colours.
If the buzzer emits a high priority alarm sound and the lights show colours, the test is considered passed, otherwise the machine must not be used and technical assistance must be contacted.
It is recommended to test the alarm system every time the machine is turned on.

22. ALARM MESSAGES LIST, CAUSES AND SOLUTIONS

Alarms require the immediate intervention by the operator.

The following indications are intended as a guide to determine possible causes of alarm and of AFERSMART PLUS non-operation.
For each alarm a number of possible solutions are listed, the choice of which is up to the clinician.
AFERSMART PLUS displays all the alarms on the special signalling line on the display, warning the user by means of the indicator light and buzzer sound.
During normal operation, the message NO ALARMS appears.
Each alarm is shown on the signal line on the display. The signal will correspond to the type of alarm detected by AFERSMART PLUS's self-diagnosis system, which intervenes in the event of a malfunction. However, if there is more than one alarm at the same time, AFERSMART PLUS will display the one with the highest priority, keeping all the other alarms in memory.
Blocking alarms, i.e., those that cause the blood pump to stop and close the venous electroclamp on the venous line, cause a change in the status of the treatment, which will be indicated on the line on the display by the message TREATMENT STOPPED.

As regards the blood pump and plasma pump opening alarm, with the words "70 BLOOD PUMP DOOR OPEN", "80 PLASMA PUMP DOOR OPEN" and “90 ACD PUMP DOOR OPEN” , AFERSMART PLUS will restart automatically, i.e. without pressing the alarm reset button; if the condition is restored by itself, i.e. if the pump door is closed; in this case no alarm will be displayed, as the machine does not store these types of alarm, which are called "automatic restart alarms".

For all remaining alarms AFERSMART PLUS stores the alarm and allows the treatment to be reactivated by pressing the alarm reset key; the treatment is restarted if the cause of the alarm has been resolved, otherwise the alarm status persists.

The main information on alarms, their causes and possible solutions is always available in the HELP ONLINE screen.

Messages are a separate category of alarms that handle purely signalling situations (Green background).
These situations are different but have as their common denominator the fact that they seek to draw the attention of the operator to a particular warning or an impending situation.
During 'test in progress' messages, it is important that the operator does not interfere with the progress of the test by changing programme parameters or by acting on the extracorporeal circuit.

22.1. AFERSMART PLUS ALARMS TABLES

22.1.1. MEANING OF THE ALARM TABLES

Alarm:	indicates the name, with the related number, displayed in the Alarm Row of AFERsmart MS screen
Priority:	indicates the priority of the Alarm displayed. It can be of three different type: ▪ HIGH (red coloured) ▪ MEDIUM (yellow coloured) ▪ LOW (blue coloured)
Possible causes:	indicates a list of probable faults or errors that have triggered the alarm
Possible solutions:	indicates a list of probable solutions that could solve the alarm situation

22.1.2. HIGH PRIORITY ALARMS

These are alarms that interrupt the course of treatment, require immediate operator intervention.

WARNING

Failure to take immediate action during a high priority alarm could result in serious harm to the patient

For all the alarms in the following table, proceed as described before proceeding to the possible solutions described individually:

- Press the MUTE/RESET button
- Switch the DMA off and on again (only if the alarm does not reset in the previous step).

Alarm	Priority	Possible causes	Possible solutions
01 CONTROL FATAL ERROR		Software anomalies.	- Reset the alarm. - Turn-off AFERsmart and turn-on again. - If the problem persists, contact the Service Department.
02 PROTECTION SYSTEM FAILURE		Electronic anomalies.	- Reset the alarm. - Turn-off AFERsmart and turn-on again. - If the problem persists, contact the Service Department.
03 PROTECTION FATAL ERROR		Software anomalies.	- Reset the alarm. - Turn-off AFERsmart and turn-on again. - If the problem persists, contact the Service Department.
04 CONTROL SYSTEM FAILURE		Electronic anomalies.	- Reset the alarm. - Turn-off AFERsmart and turn-on again.

Alarm	Priority	Possible causes	Possible solutions
			- If the problem persists, contact the Service Department.
05 CONTROL CALIB. ERROR		- Memory error during the calibrate data loading in the control circuit.	- Recalibrate all sensors. - If the problem persists, contact the Service Department.
06 PROTECTION CALIB. ERROR		- Memory error during the calibrate data loading in the control circuit.	- Recalibrate all sensors. - If the problem persists, contact the Service Department.
07 DATA ERROR		- Memory error during data loading.	- If the problem persists, contact the Service Department.
10 DIFFER. CP VENOUS PRES.		Data exchange error between microprocessors.	- Calibrate venous pressure. - If the problem persists, contact the Service Department.
11 DIFFER. CP ARTERIAL PRES.		Data exchange error between microprocessors.	- Calibrate arterial pressure. - If the problem persists, contact the Service Department.
13 DIFFER. CP PRE-FILTER PRES.		Data exchange error between microprocessors.	- Calibrate prefilter pressure. - If the problem persists, contact the Service Department.
14 DIFFER. CP WASHING SCALE		Data exchange error between microprocessors.	- Calibrate washing scale. - If the problem persists, contact the Service Department.
15 DIFFER. CP DRAIN SCALE		Data exchange error between microprocessors.	- Calibrate drain scale. - If the problem persists, contact the Service Department.
17 DIFFER. CP BLD		Data exchange error between microprocessors.	- Calibrate drip detector. - If the problem persists, contact the Service Department.
20 AIR TEST FAILED		The continuous test of air sensor was not successful.	- Reset the alarm. - If the problem persists, contact the Service Department.
21 AIR IN VENOUS LINE		- Air presence in tube controlled by air sensor. - Tube controlled by air sensor is out of place.	- Unscrew slightly the cap of venous level regulation tube. Push manually venous electroclamp for air bubble went up into the venous chamber. - Correctly reposition the tube into the air sensor. - If the problem persists, contact the Service Department.
22 BATTERY VOLTAGE		- The 9V battery has discharged.	- Connect AFERsmart PLUS to the power supply for ten hours.

Alarm	Priority	Possible causes	Possible solutions
			- If the problem persists, contact the Service Department.
23 VOLTAGE OUT OF TOLERANCE		- Error in regulation of voltage supply.	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
25 ELECTROCLAMP RELAY FAULT		- An anomaly on the electroclamp power supply circuit has been detected during test.	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
26 BLOOD PUMP RELAY FAULT		- An anomaly on the blood pump power supply circuit has been detected during test.	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
27 PLASMA PUMP RELAY FAULT		- An anomaly on the plasma pump power supply circuit has been detected during test.	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
31 BLOOD LEAKAGE		- Air presence in tube controlled by BLD sensor. - Leakage into the membranes of the hemofilter.	- Press slightly the U.F. tube on the top of the BLD sensor to allow the air bubbles to go inside the U.F. bag. - Replace the tubing set and the filter, according to the medical procedure. - If the problem persists, contact the Service Department.
32 TUBE NOT INSERTED IN BLD		- Tube controlled by BLD sensor is out of place.	- Correctly reposition the tube into the BLD sensor. - If the problem persists, contact the Service Department.
34 BLD DRIVER FAULT		- Anomalies on the BLD command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.

Alarm	Priority	Possible causes	Possible solutions
36 HAEMOLISYS/HAEMOGLOBIN		- Air presence in tube controlled by BLD sensor. - Leakage into the membranes of the hemofilter.	- Press slightly the U.F. tube on the top of the BLD sensor to allow the air bubbles to go inside the U.F. bag. - Replace the tubing set and the filter, according to the medical procedure. - If the problem persists, contact the Service Department.
40 MIN VENOUS PRESSURE		- Presence of leakage in the extracorporeal circuit. - The blood flow is not suitable for the extracorporeal circuit.	- Verify the connections of the extracorporeal circuit. - Verify the value of the blood pump flow. - If the problem persists, contact the Service Department.
41 MAX VENOUS PRESSURE		- Obstruction present in the venous blood circuit. - Blood pump setting is not suitable for the extracorporeal circuit. - Blood with high Hct. - High patient blood pressure.	- Verify if the blood flow is suitable for the extracorporeal circuit. - Verify if whether the patients venous access is clotting free. - If the problem persists, contact the Service Department.
42 MIN ARTERIAL PRESSURE		- Obstruction present in the arterial blood circuit. - Blood pump setting is not suitable to the extracorporeal circuit according to patients vascular access condition and needle size.	- Decrease arterial alarm threshold in Menu setting. - Check for any closures on the arterial circuit. - Verify if the blood flow is suitable for the circuit. - Verify whether the patients arterial access is clotting free. - If the problem persists, contact the Service Department.
43 MAX ARTERIAL PRESSURE		- Possible mistakes during circuit placing. - Possible anomaly on the arterial pressure detector.	- Verify the correct placing of the circuit according to the PRIMING procedure. - Contact the SERVICE department.
46 MIN PRE-FILTER PRESSURE		- The filter pressure reading line was disconnected. - Possible anomaly on the prefilter pressure detector.	- Verify the correct placing of the circuit according to the PRIMING procedure. - Contact the SERVICE department.
47 MAX PRE-FILTER PRESSURE		- Blood pump speed too high.	- Reduce blood pump speed. - Substitute kit-line end filter

Alarm	Priority	Possible causes	Possible solutions
		- Blood coagulation in the filter.	according to the Medical Protocol. - If the problem persists, contact the Service Department.
48 MIN UF PRESSURE		- Suction line occlusion fresh plasma bag. - The fresh plasma bag is empty.	- Open suction line clamp fresh plasma bag. - Fresh plasma bag replacement. - End treatment. - If the problem persists, contact the Service Department.
51 MAX PLASMA PRESSURE		- Occlusion on the plasma delivery line.	- Remove occlusion. - If the problem persists, contact the Service Department.
53 MAX DROP PRESSURE		- Presence of a closure on the arterial pre-filter tubing. - Presence of a closure on the venous post-filter tubing. - Presence of a clotting inside the filter.	- Remove closures on the arterial pre-filter tubing. - Remove closures on the venous post-filter tubing. - Replace the tubing set and the filter, according to the medical procedure. - If the problem persists, contact the Service Department.
54 MAX TMP2 PRESSURE		- Occlusion on the adsorber filter line.	- Remove occlusion. - Start a manual flushing - If the problem persists, contact the Service Department.
58 MAX TMP PRESSURE		- Obstruction filter. - Presence of a clotting inside the filter.	- Replace the tubing set and the filter, according to the medical procedure. - If the problem persists, contact the Service Department.
60 ELECTROCLAMP NOT CLOSED		- The safety electroclamp is not closed	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
61 ELECTROCLAMP NOT OPEN		- The safety electroclamp is not properly open	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.

Alarm	Priority	Possible causes	Possible solutions
67 VENOUS PRESSURE BLOCKED		- The venous pressure reading line is full of liquid. - A closure on the venous reading line is present. - The venous reading line, is disconnected from the machine.	- Remove with a syringe the liquid inside the pressure line then connect the line to the machine. - Remove the closure. - Remove with a syringe, the liquid inside in the pressure line, then connect the line to the machine. - If the problem persists, contact the Service Department.
70 BLOOD PUMP DOOR OPEN		- The pump cover is open. - The pump rotor is not properly fixed. - The cover sensor is out of its place.	- Close the cover. - Fix the screw completely. - If the problem persists, contact the Service Department.
73 BLOOD PUMP FLOW RATE		- Anomalies on the blood pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
74 BLOOD PUMP DRIVER FAULT		- Anomalies on the blood pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
75 BLOOD PUMP POSITION		- Anomalies on the blood pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
76 BLOOD PUMP STOPPED		- AFERsmart has stopped for two minutes.	- Press START-STOP to restart. - If the problem persists, contact the Service Department.
80 PLASMA PUMP DOOR OPEN		- The plasma pump cover is open. - The pump rotor is not properly fixed. - The cover sensor is out of its place.	- Close the cover. - Fix the screw completely. - If the problem persists, contact the Service Department.
83 PLASMA PUMP FLOW RATE		- Anomalies on the plasma pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again.

Alarm	Priority	Possible causes	Possible solutions
			- If the problem persists, contact the Service Department.
84 PLASMA PUMP DRIVER FAULT		- Anomalies on the plasma pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
85 PLASMA PUMP POSITION		- Anomalies on the plasma pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
90 CITRATE PUMP DOOR OPEN		- The citrate pump cover is open. - The pump rotor is not properly fixed. - The cover sensor is out of its place.	- Close the cover. - Fix the screw completely. - If the problem persists, contact the Service Department.
93 CITRATE PUMP FLOW RATE		- Anomalies on the citrate pump command system	- Reset the alarm. - Turn-off AFERsmart,and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
94 CITRATE PUMP DRIVER FAULT		- Anomalies on the citrate pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
95 CITRATE PUMP POSITION		- Anomalies on the citrate pump command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
100 WASHING CLAMP TIMEOUT		- Positioning timeout washing clamp.	- Repeat the step. - If the problem persists, contact the Service Department.
101 DRIVER WASHING CLAMP		- Anomalies on the washing clamp command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
104 WASHING CLAMP ERROR		- Positioning error washing clamp.	- Reset alarm and repeat Start.

Alarm	Priority	Possible causes	Possible solutions
			- If the problem persists, contact the Service Department.
110 DRAIN CLAMP TIMEOUT		- Positioning timeout washing clamp.	- Repeat the step. - If the problem persists, contact the Service Department.
111 DRIVER DRAIN CLAMP		- Anomalies on the drain clamp command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
114 DRAIN CLAMP ERROR		- Positioning error drain clamp.	- Reset alarm and repeat Start. - If the problem persists, contact the Service Department.
120 HEPARIN PUMP OVERLOAD		- Presence of a closure on the anticoagulant line. - There is an excessive pressure by the extracorporeal circuit.	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
121 HEPARIN MOTOR LOCKED		- Anomalies of the motor which manages the anticoagulant pump motor.	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
122 SYRINGE RUN OUT		- The anticoagulant solution in the syringe is finished.	- Proceed to replace it. - If the problem persists, contact the Service Department.
130 ARTERIAL DOME OPEN		- Arterial pressure dome block is open.	- Close the dome lock. - If the problem persists, contact the Service Department.
131 BLD CALIBRATION FAILED		The autocalibration of the BLD was not successful	- Reset the alarm. - Restart the AFERsmart - If the problem persists, contact the Service Department.
133 PRE-FILTER DOME OPEN		- Prefilter pressure dome block is open.	- Close the dome lock. - If the problem persists, contact the Service Department.
134 UF DOME OPEN		- UF pressure dome block is open.	- Close the dome lock. - If the problem persists, contact the Service Department.

Alarm	Priority	Possible causes	Possible solutions
135 PLASMA DOME OPEN		- Plasma pressure dome block is open.	- Close the dome lock. - If the problem persists, contact the Service Department.
145 EXCESSIVE WEIGHT VARIANCE		- Protection sistem error, of the weight loss.	- Reset the allarm. - End the treatment. - Calibrate the scale. - If the problem persists, contact the Service Department.
146 DIFFERENT WEIGHT LOSS		- Control sistem error, of the weight loss.	- Reset the allarm. - End the treatment. - Calibrate the scale. - If the problem persists, contact the Service Department.
147 SCALE WEIGHT VARIATION		- The Ultrafiltrate bag has been removed from the load cell, without following the right procedure. - The weight read by the UF. Load cell is not stable. - Reposition the bag on the plate.	- Reposition the bag on the plate. - Remove the vibrations. - If the problem persists, contact the Service Department.
148 EXCESSIVE SCALE WEIGHT		- Overload on the drain scale. load cell.	- Remove or reduce, the weight. - If the problem persists, contact the Service Department.
170 BLOOD NOT DETECTED		The Air/Blood sensor has not detected blood during patient connection	- Check the venous line - If in the venous line is present the blood press Start Treatment to proceed - If the problem persists, contact the Service Department.
174 BLOOD SENSOR DRIVER FAULT		- Anomalies on the spectrometer command system	- Reset the alarm. - Turn-off AFERsmart PLUS, and after ten seconds turn-on again. - If the problem persists, contact the Service Department.
180 CITRATE FLOW ERROR		- Empty citrate bag. - Citrate line occlusion. - Drip tray full.	- Citrate bag replacement. - Check citrate line occlusion. - Check the drip tray - If the problem persists, contact the Service Department.
181 LIGHT ON DRIP DETECTOR		- Tube controlled by drip sensor is exposed to excessive light source.	- Limit light source. - Turn the equipment in different direction as respect to light.

Alarm	Priority	Possible causes	Possible solutions
			- If the problem persists, contact the Service Department.
190 BAG EMPTY		- Ultrafiltration bag not hang in the scale. - Fresh plasma bag empty or not hang in the scale - Uncalibrate scale. - Disfunction scale.	- Hang the ultrafiltration bag in the scale - Replace or hang the fresh plasmabag in the scale - Calibrate the scale. - If the problem persists, contact the Service Department.
191 DRAIN BAG FULL		-The drain liquid bag is full.	-Proceed to replace it. - If the problem persists, contact the Service Department.
211 PRESSURISATION FAILED		- The blood circuit is probably open (arterial line, venous and filter). - Pump segments are not correctly inserted. - The rollers of the pump rotor are not properly calibrated.	- Verify all the caps and the connectors on the line. - Pump segment are not correctly inserted. - Verify if the venous line is correctly inserted in the electro clamp - If the problem persists, contact the Service Department.
212 UNCALIBRATED PRESSURES		- The venous and filter pressure reading lines are not mounted correctly or they are fully of saline solution. - The transducer does not work. - The pressure are not properly calibrated.	- Check the line on the pressure connector. - In case the line is fully of liquid, proceed to emptying using a syringe. - If the problem persists, contact the Service Department.
230 UF LINE OUT OF CLAMP		- Line outside the UF clamp	- Reposition the line in the UF clamp - If the problem persists, contact the Service Department.
231 MIN U.F. FLOW		The flow rate of the plasma pump is to low	Increase the Blood pump flow rate or the Plasma pump flow rate - If the problem persists, contact the Service Department.
232 OCCLUDED PLASMA LINE		The line between the fresh plasma bag and the plasma pump is occluded	- Remove occlusions in the fresh plasma path. - If the problem persists, contact the Service Department.
303 PRESSURE NOT ZERO		One of the pressure sensors is reading a pressure different by	- Remove the disposable and start the line installation phase

Alarm	Priority	Possible causes	Possible solutions
		0 mmHg before to enter the line installation phase The disposable is connected before the line installation phase	- If the problem persists, contact the Service Department.
307 WEIGHT ON SCALES		One or both the scales are reading a weight different by 0 gr before enter the line installation phase One or more bags are hooked to the scales before the line installation phase	- Remove the bags from the scales and start the line installation phase - If the problem persists, contact the Service Department.
308 VENOUS LINE INSERTED		- The circuit has been placed before performing the PRIMING procedure. - The sensor does not work.	Remove tube from the air sensor and perform correctly PRIMING procedure. - If the problem persists, contact the Service Department.
309 BLD DOOR OPEN		-The Spectrometer sensor door is open - The sensor does not work.	-Close the Spectrometer sensor door - If the problem persists, contact the Service Department.

22.1.3. MEDIUM PRIORITY ALARMS

Alarm	Priority	Possible causes	Possible solutions
24 LINE OUTSIDE OF AIR SENSOR		- Air detected in the air sensor.	-Insert the line properly If the problem persists, contact Technical Service
192 WASHING BAG EMPTY		- The wash bag is empty.	- Replacement of washing bag.
193 CHANGE DISPOSABLE		- The disposable used working for 24 hours!	- It would be better to replace it.
195 BLOOD PUMP MIN. SPEED		- The blood pump has reached the minimum speed Set due to a slow down caused by a drop in Suction pressure.	- Verify kinking in the intake tract. - Lower the minimum speed threshold blood pump
196 BLOOD PUMP STOP		- Blood pump has stopped.	-Press START/STOP to restart
200 VENOUS PRESSURE OVERRIDE		- The venous pressure's alarm is bypass for 10 seconds	-Wait 10 seconds where the minimum venous pressure alarm threshold is -50mmHg. If the minimum venous pressure leads to values greater than 20mmHg, the alarm disappears even before the end of the 10 seconds, otherwise reappears to the minimum venous pressure alarm.
201 BLD OVERRIDE		- The BLD alarm is bypass for 30 seconds	-Wait for the alarm to disappear. If the cause of the alarm does not end up a BLD alarm rise up again.
202 HEMOGLOBIN OVERRIDE		- The HEAMOGLOBIN alarm is bypass for 30 seconds	-Wait for the alarm to disappear. If the cause of the alarm does not end up a HEMOGLOBIN alarm rise up again
203 REACHED THE MAX FLUSHING		-The number of suggested plasma fractionator flushing cycles has been reached	- Reset the alarm - Consider to end the treatment
501 TREATMENT COMPLETED		- Target of the treatment achieved	To continue : 1) increase weight loss or target 2) select weight loss in continuous mode 3) finish the treatment

22.1.4. LOW PRIORITY ALARMS

Alarm	Priority	Possible causes	Possible solutions
194 CONNECT CARTRIDGE		- Connect line in progress.	- Is necessary to arrange kit the lines to edge of the machine.
198 DISCONNECT RESTIT. DISABLE		- The minimum venous pressure limit has been set to a lower value at 5 mmHg.	Change the value of the related field in "Alarms and Scale" page
199 REGENERATION IN PROGRESS		-The plasma fractionator flushing phases is in progress	Wait until the alarm disappear and the treatment phase restarts
500 PRIMING COMPLETED		- Priming completed.	-Continue with the treatment settings

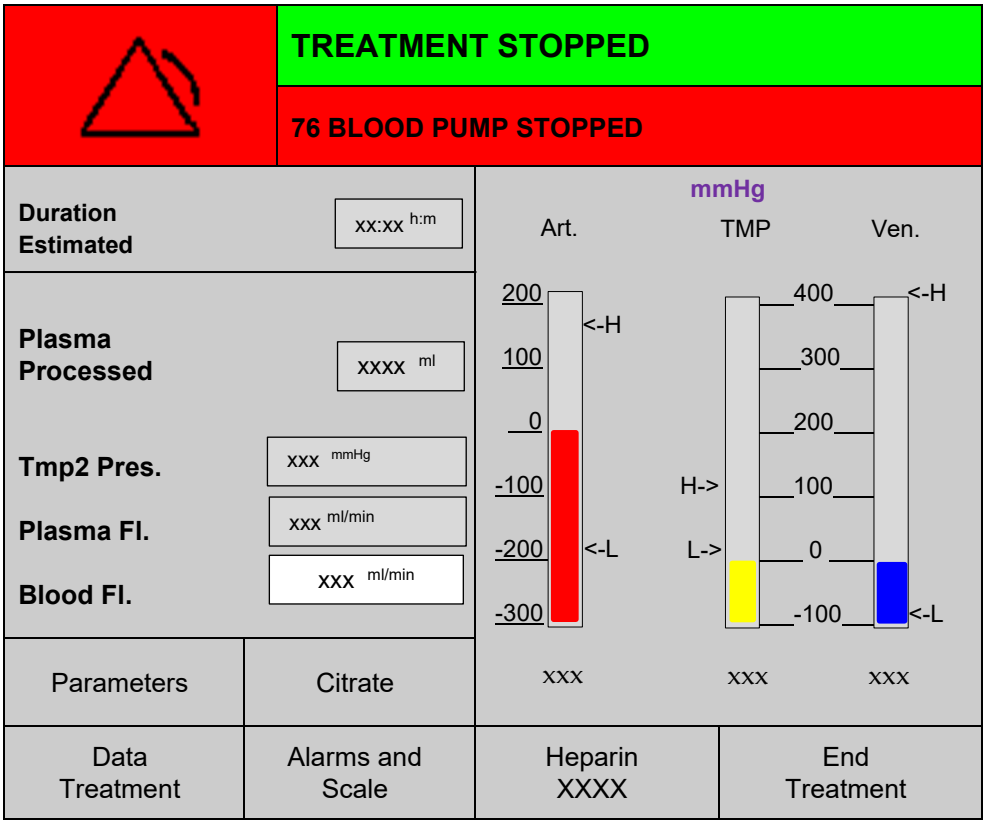
22.2. POWER FAILURE ALARM

An audible alarm indicates that there is no power and the device has switched off, interrupting treatment.
If the power is not restored in a short time, the treatment must be abandoned.

When power is restored, the system restarts, the alarm is automatically reset and any treatment interrupted by the lack of power is resumed from the point of interruption.

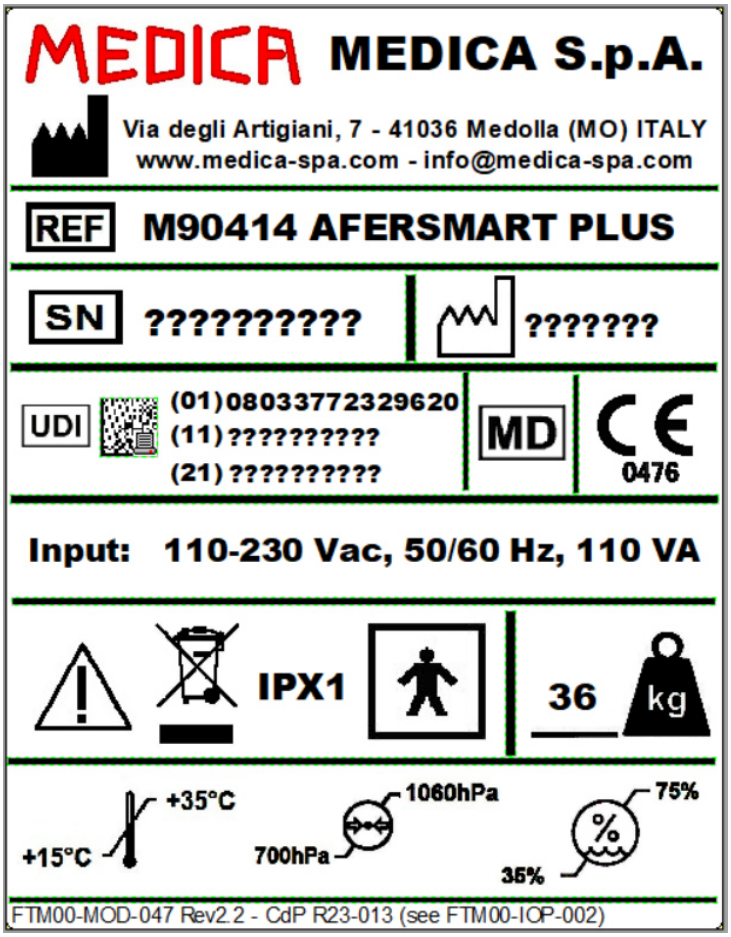
22.3. RECOVERY FROM POWER FAILURE DURING TREATMENT

In case of automatic restart, after a short period of power failure, the system goes into suspended treatment status (message TREATMENT STOP), the blood pump is stopped and the high priority alarm "76 BLOOD PUMP STOPPED " is activated. Press the START-STOP button to restart.

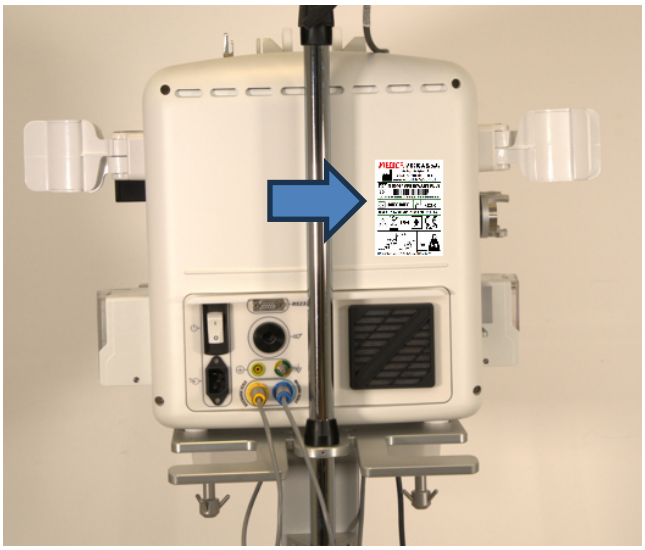


23. DEVICE LABELS

23.1. DEVICE DATA LABEL ON OPERATING MODULE



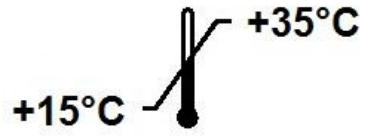
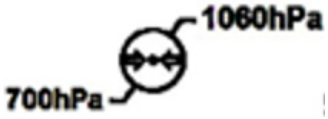
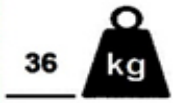
23.1.1. Positioning



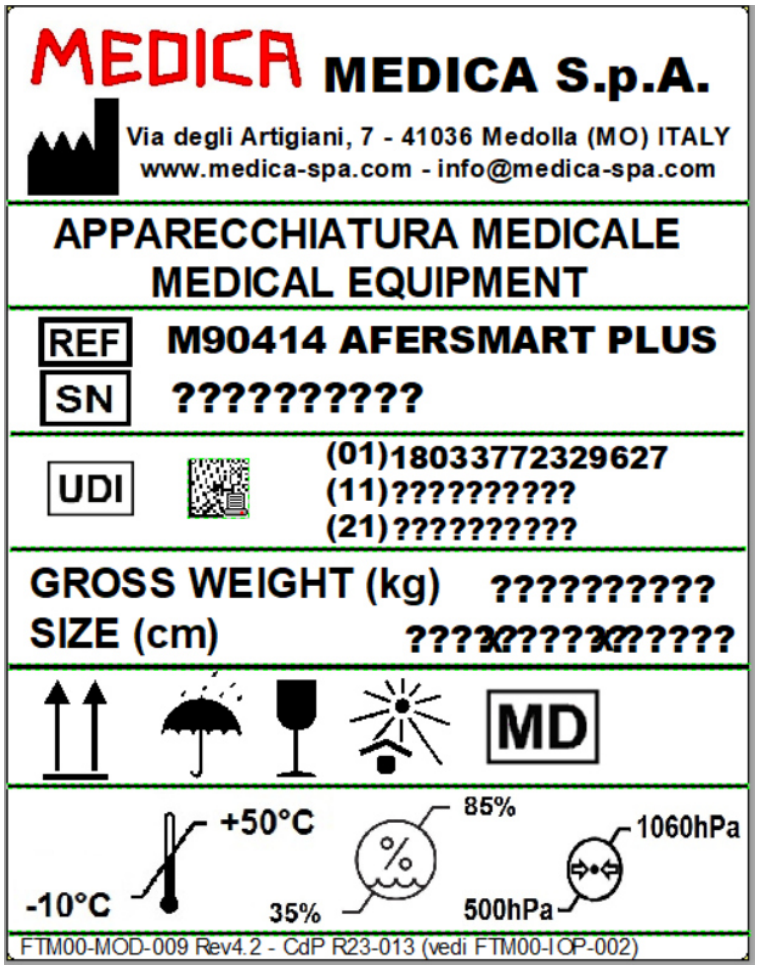
23.1.2. Meaning of the symbols

Meaning of information and symbols on the rating plate label:

Information and symbols	Description
MEDICA	Manufacturer's logo
	Symbol indicating the manufacturer of the device
MEDICA S.p.A.	Company name of manufacturer
Via degli Artigiani, 7 - 41036 Medolla (MO) ITALY www.medica-spa.com - info@medica-spa.com	Address and contact details of manufacturer
	Device model
	Device serial number
	Date of manufacture (YYYY-MM)
Input: 110-230Vac, 50/60Hz, 110VA	Indicates the following input parameters: supply voltage, supply voltage frequency, maximum power absorbed by the device.
	Indicates to the user that there are dangers to the patient or operator when using the device if the operator does not read the manual before use.
	Indicates the separate collection of electrical and electronic equipment.
IPX1	Indicates the level of protection of the enclosure.
	Indicates the grade of protection against electrical hazards of applied parts: type BF in accordance with medical device safety standard IEC 60601-1.

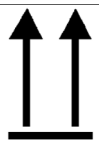
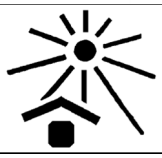
Information and symbols	Description
CE 0476	Indicates that the device complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council regarding medical devices. It refers to the machine only.
	Indicates the ambient temperature limits to which the medical device may be safely exposed during use.
	Indicates the relative humidity limits to which the medical device may be safely exposed during use.
	Indicates the limits of atmospheric pressure to which the medical device may be safely exposed during its use.
	Indicates the weight of the equipment.
UDI	It identifies the UDI carrier, including the AIDC (Automatic Identification and Data Capture) and human readable information. The information include: - Global Trade Item Number (GTIN), with the prefix (01) - Production date (YYMMDD), with the prefix (11) - Serial number, with the prefix (21)
MD	Indicates that the product is medical device according to the regulation (EU) 2017/745

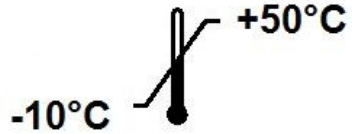
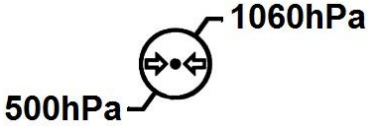
23.2. PACKAGING LABEL



23.2.1. Meaning of the symbols

The following table shows the meaning of the symbols on the packaging label:

Symbol	Meaning
	Keep the packed device dry.
	It indicates that at the time of storage, packaging must be placed in the direction indicated by the arrows.
	Fragile, handle with care the packaged medical device.
	It indicates that the packed medical device should not be exposed to direct sunlight or bright light.

	It indicates the temperature limits at which the packed medical device can be exposed safely during transport and storage.
	It indicates the relative humidity limits to which the packed medical device may be exposed safely during transport and storage.
	It indicates the atmospheric pressure limits which the packed medical device can be exposed safely during transport and storage.
	It identifies the UDI carrier, including the AIDC (Automatic Identification and Data Capture) and human readable information. The information include: - Global Trade Item Number (GTIN), with the prefix (01) - Production date (YYMMDD), with the prefix (11) - Serial number, with the prefix (21)
	Indicates that the product is medical device according to the regulation (EU) 2017/745

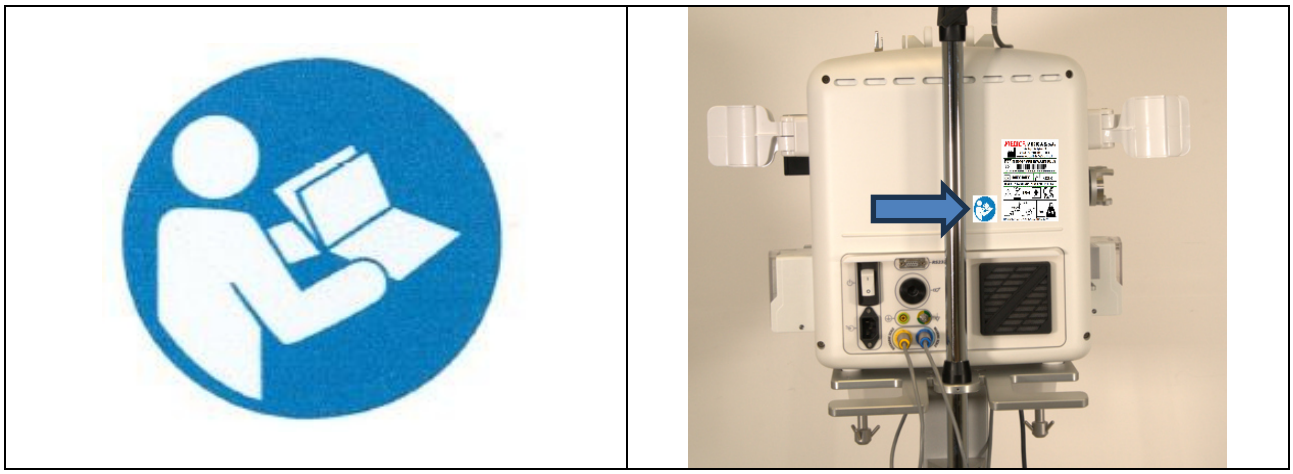
23.3. STERILE ACCESSORIES PACKAGING LABEL

An explanation of the symbols on the packaging label for sterile accessories follows.

Symbols	Meaning
	Sterile device. The sterile device must only be used if the packaging is undamaged and the expiry date has not passed.
	Device sterilised by ethylene oxide
	Radiation sterilised device
	Do not re-sterilise or re-use the device. The device is intended for single use only. Reuse, reprocessing, or re-sterilisation could compromise the structural integrity of the device and/or lead to device failure which, in turn, could result in patient injury, illness, or death.
	This symbol indicates the sterilisation expiry date. Do not use the device beyond the expiry date

23.4. MANDATORY MANUAL READING M70221 LABEL

Next to the rating plate label there should also be the following label in colour on a blue background indicating to the user the need to read the manual before using the device:



Mandatory manual reading label M70221

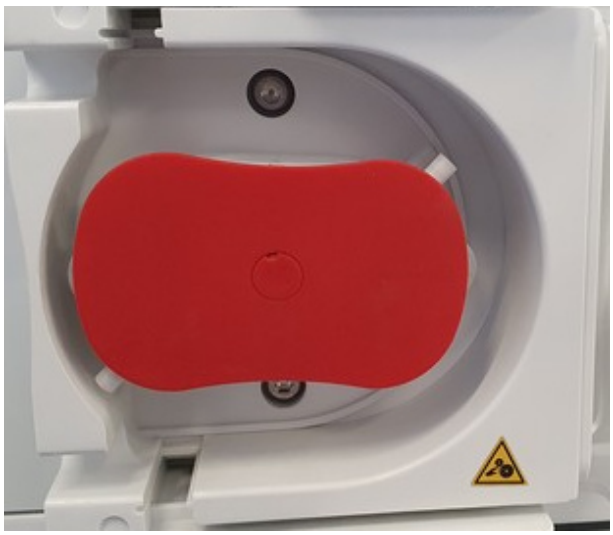
23.5. NO PUSHING M70222 LABEL

No pushing label on both sides of the device M70222

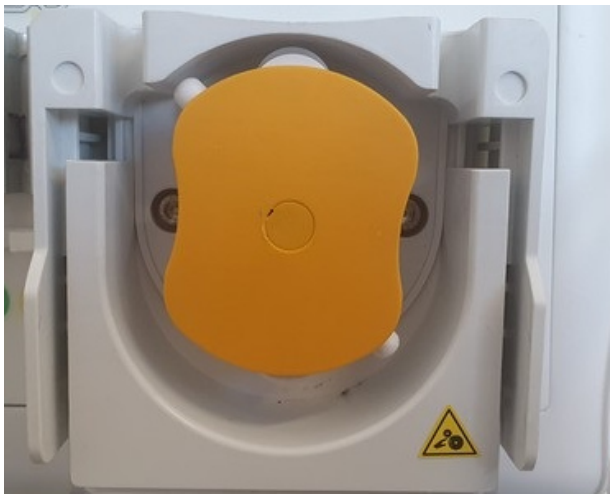
23.6. SYMBOLS ON THE SIDE OF THE POWER INPUT PANEL

Information and symbols	*Description*
I	Device power supply On.
0	Device power supply Off.

23.7. LABELS ON PERISTALTIC PUMPS CRADLES – BLOOD, PLASMA AND ACD PUMPS



Blood pump

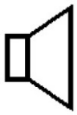


Plasma pump

ACD pump

Information and symbols	*Description*
	This symbol warns the user that, after opening the cradle cover, he must ensure that the rotor is stationary, before accessing the moving parts, to avoid the risk of crushing his fingers.

23.8. PROTECTIVE GROUND, POTENTIAL EQUALISATION TERMINAL AND BUZZER LABELS

Symbol	Description
	This symbol is located near the ground connection point of the device.
	This symbol is located near the equipotential connection point of the device.
	This symbol identifies the buzzer.

The DMA is equipped with a potential equalisation terminal with the following features:

- The terminal for connecting the potential equalisation conductor is accessible to the operator in any position in which the DMA is normally used.
- The terminal allows the potential equalisation conductor to be connected without the use of a tool.

The terminal for connecting the potential equalisation conductor must not be used for a protective earth. Function and use of the potential equalisation conductor: If more than one active medical devices are used on the same patient, the operator must connect all terminals for the potential equalisation conductor connection of the active medical devices.

23.9. RS232 PORT LABEL

The device has an input/output port with a serial interface: the port is labelled RS 232 and has a software update function and/or console connection port

WARNING

The RS 232 port must only be used by authorised service personnel. In any version provided, it is forbidden to connect any device not provided for in this manual.

WARNING

Do not connect or disconnect anything during the preparation, execution or termination of a patient treatment.

23.10. SERIAL NUMBER DEFINITION

The serial number, defined in the table below, consists of 8 alphanumeric characters:

1	2	3	4	5	6	7	8

The first and second (alphanumeric) characters identify the device family.
The third character identifies the equipment model.
The fourth, fifth and sixth characters (numeric) identify the progressive registration number starting with 001 at the beginning of each year.
The seventh and eighth characters (numeric) identify the year of manufacture.

24. PERFORMANCE AND TECHNICAL CHARACTERISTICS

Operating conditions	Temperature from 15°C to 35°C Relative humidity from 35% to 75% Avoid direct exposure to sunlight. Atmospheric pressure 700 to 1060 hPa
Transport conditions	Temperature -10°C to +50°C Relative humidity 35% to 85%. Atmospheric pressure 500 to 1060 hPa If the transport period is longer than 15 weeks, please refer to "Operating conditions".
Power supply	230 VAC (±10%) 110 VAC (±10%) 50Hz/60Hz
Device life	10 years
Power Adsorption	Power absorption in worst case conditions is 110VA
Mechanical structure	Polyurethane machine case, rigid and structural, with aluminium panels. Stainless steel trolley. Stainless steel pole with a maximum load of 10Kg External case dimensions: Height: 365mm; Width 375mm; Depth: 300mm Trolley dimensions: Base: 440 x 500 mm Height of the trolley (at the top of IV pole at the maximum extension): 1970 mm Weight with trolley: 36Kg
Blood pump	Peristaltic pump, front side. Pump Segment: 6,36x9,54 PVC Maximum flow range: [0 to 450]ml/min Selectable flow range: Limited by software (see IFU) Resolution: 5ml/min Accuracy: 10%. Colour code: red Minimum suction pressure: -300mmHg Maximum delivery pressure: +600mmHg Sensor for cover closure Easy-loading system
Plasma pump	Peristaltic pump, lateral side. Reachable flow range : [0 to 200] ml/min Adjustable flow range (by the operator) : [0 to 30] % related to blood pump speed Pump segment: PVC 4.77x7.95

	Resolution: 1ml/min Accuracy: 10%. Minimum suction pressure: -300mmHg Maximum delivery pressure: +600mmHg Sensor for cover closure. Easy-loading system for tube insertion.
Citrate pump	Peristaltic pump, lateral side. Reachable flow range : [0 to 2000] ml/h Pump Segment: 2,0x5,5 PVC Resolution: 1 ml/min Accuracy: 10% Minimum suction pressure: -300mmHg Maximum delivery pressure: +600mmHg Sensor for cover closure. Easy-Loading system for tube insertion.
Syringe pump	Syringes supported: 30ml. Flow rate: [0, 20]ml/h Sensitivity: 0,1ml Accuracy: +/-0,2ml or 2%. Maximum pressure: 600mmHg Occlusion detection.
Venous pressure	Front panel, top-right corner TPE type Color Code: Blue Range: [-100, +500] mmHg Sensitivity: 1 mmHg Displayed Resolution: 5mmHg Accuracy: ±5mmHg or ± 5%
Arterial pressure	Front pump panel. Type DOME Colour code: Red Range: [-300, +300] mmHg Sensitivity: 1mmHg Display resolution: 5 mmHg Accuracy: ±5mmHg or ±5%. Sensor to detect incorrect closure.
Prefilter pressure	Front pump panel. Type DOME Colour code: Grey Range: [-100, +500] mmHg Sensitivity: 1mmHg Display resolution: 5 mmHg Accuracy: ±5mmHg or ±5%. Sensor to detect incorrect closure.
Plasma pressure	Plasma pressure. Lateral panel DOME type Colour code: Green Range: [-100, +500] mmHg

	Sensitivity: 1mmHg Display resolution: 5mmHg Accuracy: ±5mmHg or ±5%. Sensor to detect incorrect closure.
UF pressure	UF pressure Lateral panel DOME type Colour code: Yellow Range: [-300, +500] mmHg Sensitivity: 1mmHg Resolution displayed: 5 mmHg Accuracy: ±5mmHg or ±5%. Sensor to detect incorrect closure.
Bubble detector	Ultrasound sensor. Sensitivity: 0.1 mL (at a flow rate of 100 mL/min)
Venous electroclamp	Closes the venous line to immediately cut off the flow to the patient in the event of a safety problem. Closing pressure: > 98,1 kPa Normally closed
Washing Scale	Range: [0, 6]Kg Sensitivity: 1 g Accuracy: ±20g or ±1%. Maximum overload: 30Kg
Drain scale	Range: [0, 6]Kg Sensitivity: 1g Accuracy: ±20g or ±1%. Maximum overload: 30Kg
Switch clamp 4-ways	Switch clamp with 4 independent ways Maximum clamping pressure: 600mmHg
Switch clamp 2-ways	Switch clamp with 2 independent ways Maximum clamping pressure: 600mmHg
Blood and haemoglobin detector	Detects traces of blood or haemoglobin in the ultrafiltrate liquid. • Optical sensor based on spectroscopy analysis. • Tube: 3.5x5.5 PVC • Sensitivity: 0.5% blood or 0.5% haemoglobin
Blood detector	Optical sensor capable of detecting blood inside the venous line Tube: PVC, transparent, 4.6x6.4mm Sensitivity: 0.5%.
Drip sensor	Check the citrate flow by optical identifications of the drops Drop volume = 50uL +- 10%.
Buzzer	Piezo-ceramic type. Complies with IEC60601-1-8. Maximum sound pressure level at 1 m from the front of the machine: 72db
Buzzer backup battery	A back-up battery is used to keep the buzzer running, for at least 1 minute, in the event of a power failure. Permanently under recharge when the device is in on.
Human-Machine Interface	HMI is made of an integrated 5.7", colour display; a rotary selector with confirmation click and three buttons for the most critical actions: start/stop the blood pump, Reset alarms, get help about the current active alarm
RS232 serial port	Used for communication with external console and for software upgrades.
External console (optional)	10" external console. Reads treatment Data from the device and displays relevant information to the operator. Read only: does not send any commands to the device.

	Stores information in an internal log and provides automatic download of the log to a USB pen drive. Power supply: 24V Mounted on the rear pole of the stand. Connected to the RS232 port of the device.
UPS (optional)	Supports loads up to 350VA At least 20 minutes half load runtime Compliance to IEC 60601-1 Ground Potential Equalization Connector Resistant to electrostatic discharge

25. COMPATIBLE DEVICE

25.1. UNINTERRUPTIBLE POWER SUPPLY (UPS)

The AFERSmart PLUS works normally without the need for a UPS.

25.1.1. DESCRIPTION OF THE UNINTERRUPTIBLE POWER SUPPLY

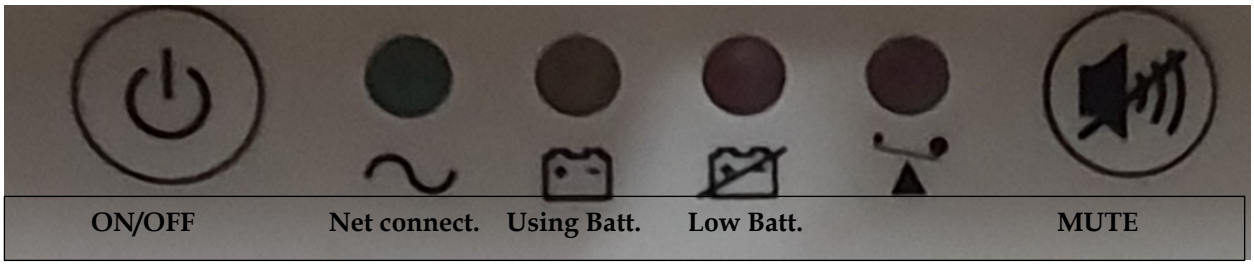
Eventually, in order to keep the equipment operational in situations of mains power failure, it is possible to install an uninterruptible power supply (UPS) that can guarantee operation for approximately 20 minutes. The uninterruptible power supply (UPS) is housed in a dedicated support that is fixed at the bottom of the trolley column without the need for any mechanical work. (See photo).

To activate the UPS simply press the <ON / OFF> button for a few seconds.
If the power supply is connected, the green light indicating normal operation and the status of the battery charging will light up.
If not, check the mains connection.

The yellow light will come on when mains power is not available, the UPS will power the equipment using the batteries and will emit a "beep" sound that can be muted by pressing the <MUTE> button on the UPS.

WARNING:

Once the <MUTE> button is pressed, the "beep" sound will be muted until mains power is restored.



For further information on the operation of the UPS, please read its user manual.

26. HOW TO ORDER

The main codes for the machine and the medical devices required for its use are summarised at Chapter 6.
If it is needed to replace any components of AFERsmart PLUS device or for further information on spare parts or technical problems, please contact :

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27. WARNINGS CONCERNING ELECTROMAGNETIC COMPATIBILITY

AFERSMART PLUS equipment is designed and manufactured to comply with the IEC 60601-1-2 standard on Conformity and Electromagnetic Compatibility (EMC) requirements for electromedical equipment.

Tab. 1 - Guidance and manufacturer's declaration - Electromagnetic emissions		
EMISSIONS TEST	**TEST LEVEL IEC 60601-1-2**	**INFORMATION ON THE ELECTROMAGNETIC ENVIRONMENT**
RF emissions CISPR 11	Group 1	*AFERSMART PLUS* only uses RF energy for its internal operation. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of voltage fluctuations / flicker IEC 61000-3-3	Compliant	

Despite this, the AFERSMART PLUS may interfere with other devices in the vicinity.
The device should not be used near, or stacked with, other equipment.
Install the device away from other equipment that radiates high frequencies (short waves, microwaves, electrosurgical equipment, mobile phones).
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are under control. The customer or operator can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communications equipment (transmitters) and the medical device, as recommended below, relative to the maximum output power of the radio communications equipment.

Tab.2

Maximum transmitter output power (W)	**Separation distance (m) depending on transmitter frequency**		
	from 150kHz to 80MHz d = 1,2 √P	**from 80MHz to 800MHz d = 1,2 √P**	**from 800MHz to 2,5GHz d = 2,3 √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 with a maximum rated output power not shown above, the recommended separation distance "d" in metres (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

(1) At 80 MHz and 800 MHz the highest frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Tab 3 – Guidance and manufacturer's declaration - Electromagnetic immunity			
AFERSMART PLUS equipment is intended for use in the electromagnetic environment specified below. The customer or the user of AFERSMART PLUS must ensure that it is used in such an environment.			
Immunity test	**Level in accordance with IEC 60601-1-2**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±15 kV air - ±8 kV contact	±15 kV air, level 3 - ±8 kV contact, level 2	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast electrical transients/trains IEC 61000-4-4	±2 kV common mode - ±1 kV differential mode	±2 kV common mode - ±1 kV differential mode	The mains voltage quality should be that of a typical commercial or hospital environment.
Over voltages IEC 61000-4-5	±1 kV differential mode - ±2 kV common mode	±1 kV differential mode - ±2 kV common mode	The mains voltage quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%U_T (>95% drop in U_T) for 0.5 cycles. 40%U_T (60% drop in U_T) for 5 cycles – 70%U_T (30% drop in U_T) for 25 cycles – <5%U_T (95% drop in U_T) for 5s	<5%U_T (>95% drop in U_T) for 0,5 cycles - 40%U_T (60% drop in U_T) for 5 cycles – 70%U_T (30% drop in U_T) for 25 cycles – <5%U_T (95% drop in U_T) for 5s	The mains voltage quality should be that of a typical commercial or hospital environment. If the user requires normal performance even in the event of a power failure, the use of a power source with backup is recommended.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields must have levels characteristic of a typical location in a commercial or hospital environment.

Tab. 4 – Guidance and manufacturer's declaration - Radiofrequency			
AFERSMART PLUS equipment is intended for use in the electromagnetic environment specified below. The customer or the user of AFERSMART PLUS must ensure that it is used in such an environment.			
Immunity test	**Level in accordance with IEC 60601-1-2**	**Compliance level**	**Electromagnetic environment**
Conducted RF	3 Veff	3 Veff	d = 1.17 √P. Where P is the maximum nominal output power of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended operating distance expressed in meters (m).
Radiated RF	10 V/m (26 MHz -1GHz) …….. 3 V/m (1GHz –2.5GHz)	10 V/m 3 V/m	d = 0.35 √P from 80 MHz to 800 MHz d = 0.70 √P from 800 MHz to 1 GHz d = 2.33√P from 1GHz to 2.5 GHz Where P is the maximum nominal output power of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended operating distance expressed in meters (m).

27.1. WARNINGS AND INSTRUCTIONS FOR LIMITATION OF USE

If the electromedical device is used near other devices, the operator must check that it works correctly: if the device is subjected to proximity electromagnetic fields, emitted by wireless radio frequency communication devices (see following table) , its functionality is not guaranteed. The biological value measurement system may be conditioned, leading to unwanted alarms that limit the use of the device, even if the essential performance indicated is guaranteed.
The feedback systems implemented, in fact, detect unexpected changes in the parameters and block the treatment to avoid risks to the patient.
In this context, there are no risks for the operator, other than those already dealt with.

Immunity to proximity EM fields, linked to RF wireless communication devices (EN 61000-4-3):			
Service	**Field power (V/m)**	**Frequency**	**Signal modulation**
TETRA 400	27	380MHz÷390MHz	18Hz PM 50%
GMRS 460 FRS 460	28	430MHz÷470MHz	18Hz PM 50%
LTE Band 13, 17	9	704MHz÷787MHz	217Hz PM 50%
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	28	800MHz÷960MHz	18Hz PM 50%
GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3, 4, 25 UMTS	28	1700MHz÷1990MHz	217Hz PM 50%
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	28	2400MHz÷2570MHz	217Hz PM 50%
WLAN 802.11 a/n	9	5100MHz÷5800MHz	217Hz PM 50%

WARNING

For reasons of electromagnetic compatibility, the electro-medical device must only be used with the following power cable:
Power cable: SCHURTER cod. 6051.2154 - length: 5 meters

WARNING

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of AFERSMART PLUS, as replacement parts for internal components, may result in increased emissions or decreased immunity of AFERSMART PLUS