Jafron Biomedical Co., Ltd.

Hemoadsorption equipment

User Manual

Description

In order to use this product correctly, please read the User Manual carefully prior to use. The contents of this User Manual are mainly for explaining the operation method of this device. For the use of disposable products, please refer to the special instruction manual or user manual of each product.

The company may not use the unit without the training or permission of the company, otherwise the company will not bear any responsibility for the adverse consequences.

Please keep this User Manual in a safe place for your reference.

Product name:	Hemoadsorption equipment
Specification & Model:	Future F20
Production license number:	Guangdong FDA 20010149
Product structure and composition:	This product belongs to the unit of blood purification system (including embedded software), which is composed of power system, anticoagulation system, heating system, monitoring system, alarm system, display and control system. Disposable tubing sets and other consumables used with it are not included.
Intended purpose:	This product provides extracorporeal circulation power and safety monitoring for blood purification treatment of hemoperfusion(HP), plasma adsorption(PA) and double plasma molecular adsorption system(DPMAS). The product is intended for use on adult patients who weight more than 40kg.
Registrant/manufacturer name:	Jafron Biomedical Co., Ltd.
Registrant/manufacturer residence:	No. 98, Technology Sixth Road, High-tech Zone, Zhuhai City, 519085 Guangdong, China
Registrant/manufacturer contact:	No. 98, Technology Sixth Road, High-tech Zone, Zhuhai City, 519085 Guangdong, China
Company website:	http://www.jafron.com/

Production date/service life: See product label for details

Release version of this User Manual: V1.3

File No.: CE-F20-07

Release date of this User Manual:

Software release version: V1

CE mark

CE 0123

EC Representative Name:

Shanghai International Holding Corp. GmbH (Europe)

EC Representative Address:

Eiffestrasse 80, 20537 Hamburg,Germany

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Jafron assumes no liability for software and equipment provided by non-Jafron or distributor.

Jafron is responsible for the safety, reliability, and performance of the product only if all of the

following requirements are met:

- Assembly, expansion, reconditioning, improvement and maintenance must be performed by Jafron approved professionals;
- All parts involved in the maintenance and replacement, as well as accessories and consumables for supporting use are Jafron original (original) or approved by Jafron;
- The relevant electrical equipment conforms to the national standards and the requirements of this User Manual;
- The operation of the product shall follow this User Manual.

Warranty and Maintenance Services

The warranty period of this product starts from the “installation date” filled in the “Product Warranty Card”, and the “Product Warranty Card” is the only certificate for calculating the warranty period. In order to safeguard your rights and interests, please urge the installation personnel to return the Product Warranty Card to Jafron within 30 days from the date of installation. If the Product Warranty Card corresponding to the product you purchased does not return to Jafron on time, the warranty period will be extended by 45 days from the “delivery date” marked on the product packaging box.

Within the warranty period, products can enjoy free after-sales services; however, please note that even within the warranty period, if the products need to be repaired due to the following reasons, Jafron will provide fee-based maintenance services, and you need to pay for maintenance and parts:

- man-made damages;
- improper use;
- the grid voltage is beyond the scope of the product;
- irresistible natural disasters;
- replace or use parts or accessories not approved by Jafron or maintained by non-Jafron authorized personnel; and
- other faults not caused by the product itself.

After the warranty expires, Jafron can continue to provide fee-based maintenance services. If you refuse to pay or delay in paying for the maintenance services, Jafron will suspend the maintenance services until you pay.

After-sales Service Organization

Jafron Biomedical Co., Ltd.

No. 98, Science and Technology Sixth Road, High-tech Zone, Zhuhai, Guangdong

Postal code: 519085

Service hotline: 0756-3619988

Fax: 0756-3619977

⚠Warning

- **This product shall be used by professional clinicians, medical electrical experts or trained clinical staff in designated occasions. Personnel using this product shall receive adequate training. No operation shall be carried out by any person without authorization or training.**
- **No modification of this equipment is allowed.**

Foreword

Description

This User Manual (hereinafter referred to as the “Manual”) describes in detail the use, function and operation of the product. Before using this product, please read and understand this Manual carefully to ensure the correct use of this product and ensure the safety of patients and operators.

This Manual describes the product in accordance with the most complete configuration, some of the contents may not be applicable to the product you buy. If you have any questions, please contact us.

Applicable Targets

This User Manual is only applicable to trained clinical staff.

Illustrations

All illustrations provided in this Manual are for reference only, and the settings or data in the illustrations may not be completely consistent with the actual display of the product.

Table of Contents

Chapter 1 Overview

1.1 Intended purpose

This product provides extracorporeal circulation power and safety monitoring for blood purification treatment of hemoperfusion(HP), plasma adsorption(PA) and double plasma molecular adsorption system(DPMAS). The product is intended for use on adult patients who weight more than 40kg.

1.2 Intended patient population, Indications and Contraindications

Intended patient population

Adult patients who weight more than 40kg

Indications

This product is used for the adult patients need blood purification treatment.

Contraindication

For the following diseases, the product shall be used with caution or forbidden:

- The active bleeding tendency is very obvious.
- The patients with disseminated intravascular coagulation (DIC), shock and unstable haemodynamics.
- The patients allergic to heparin.
- The patients with seriously systemic and local infection.
- The patients with unstable cardio-pulmonary function.
- The patients with obvious coma agitation or those that fail to coordinate due to other cause.

1.3 Side effects

Extracorporeal therapies occasionally cause following side-effects. Pay attention to the packing instructions. To reduce possible side effects, treatment should be personalized to the patient.

- Hypotension
- air embolism
- allergic reaction
- Hemolysis
- coagulation disorder
- puncture local hematoma

- Abnormal blood clotting,
- Elevated neutrophil count,
- Blood clotting disorder,
- Clotting failure,
- Excessive PT, ATPP, TT extension,
- Transient drop in blood pressure and slow heart rate
- Vomiting

1.4 Identifications and Symbols Used for Device and User Manual

⚠ Danger, ⚠ warning and ⚠ caution are used to indicate the hazardous situations that may occur if you do not follow the instructions and operating instructions for this device or this User Manual.

⚠Danger

- **Indicate an immediate danger that, if not avoided, may result in death, serious personal injury or property damage.**

⚠Warning

- **Indicate a potentially dangerous or unsafe operation that, if not avoided, may result in death, serious personal injury or property damage.**

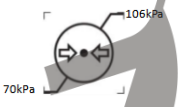
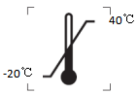
⚠Caution

- **Indicate a potentially dangerous or unsafe operation that, if not avoided, may result in minor personal injury, product failure, damage or property loss.**

Attention

- **Emphasize important notes, provide instructions or explanations for better use of the product.**

The identifications used for the device and this Manual and its meanings are as follows:

	Refer to instruction manual (dark blue sign, indicating a mandatory action, refer to ISO 7010-M002)	**IPX1**	Level of protection against liquid ingress
	Type CF applied part		DC power supply (DC)
	AC power supply (AC)		Non-ionizing radiation
	Production date		Manufacturer
	Medical device		Authorized Representative in the European Community/European Union
	Humidity limitation		Atmospheric pressure limitation
	Temperature limit		Use a pollution-free method for processing
	Sound pause		AC power supply
	Battery status		Blood pump start/pause
	Power on/off		USB interface
	Signal input and output interface		Equipotential end
	This way up		Keep dry
	Fragile, handle with care		Do not roll

	Do not stack	CE 0123	CE Mark
SN	Serial No.	**SN**	Serial No.
MFG	Manufacturing date	**EXP**	Expiry date

1.5 Storage and Transportation Requirements

1. Device storage conditions:

(1) It shall be stored in a clean, dry and non-corrosive environment.

(2) Storage ambient temperature: -20 ~ 40°C;

(3) Storage ambient humidity: relative humidity of 10% ~ 95%, with no condensation;

(4) Storage atmospheric pressure: 70 kPa ~ 106 kPa;

(5) Avoid direct sunlight;

(6) The storage location shall avoid drastic changes in the surrounding environment.

2. Device transportation requirements:

(1) In the process of handling, loading and unloading, it shall be civilized, strictly in accordance with the packaging identification code;

(2) During transportation, appropriate measures shall be taken for the packaging conditions and road conditions of medical devices to prevent damage to medical devices and to avoid severe vibration and impact.

1.6 Installment and Debugging

1. Unpacking

(1) After unpacking, the device shall be inspected for any damage caused by transportation. If any damage is found, please contact the company or the dealer immediately.

(2) Check if the spare parts are complete. The list of accessories is as follows:

Serial No.	Name	Unit	Quantity
1	Power cord	PCS	1
2	Infusion pole	Set	1
3	Filter holder	Set	3

2. Working conditions

The device shall be installed in the following working conditions:

(1) Ambient temperature: 10 ~ 40°C;

(2) Relative humidity: relative humidity of 20% ~ 75%, with no condensation;

(3) Working atmospheric pressure: 70 kPa ~ 106 kPa.

Do not place in the storage area of chemicals or places that will produce harmful gases.

Do not use when there is a mixture of gas and air and a mixture of oxygen and nitrous oxide.

3. Installment and debugging

This device must be installed by an authorized technician.

(1) Infusion support installation: Find the infusion pole assembly from the packaging box, insert the infusion pole assembly into the infusion pole mount, and use M5 hexagon socket screws to lock the lower end of the infusion pole mount.

(2) Perfusion cartridge clamp installation: Find the perfusion cartridge clamp from the packaging box, put the perfusion cartridge double-clamp assembly onto the infusion pole, and tighten the locking handle on the perfusion cartridge double-clamp assembly.

(3) Power cord installation: Find the power cord from the packaging box, and plug its output end into the power input socket of the device and its input end into the well-grounded power supply socket. The power plug must have a good grounding phase to ensure that the unit is well grounded during use, otherwise it may damage the unit and affect normal use, and thus bring adverse consequences to the patients being treated.

(4) Potential equalization conductor installation: Find the optional potential equalization conductor from the packaging box, and connect its two ends to the common grounding end of the device and the medical institution, respectively.

Attention

- **Do not connect the patient to the device during the installation test. Instead, a water container shall be used for the test.**

⚠Warning

- **The product shall be operated in a place that is not wet by water.**
- **The product shall be placed in a stable place without tilt, vibration or impact (including handling).**
- **The product shall be placed away from chemical libraries or where liquefied gases or gas are generated.**
- **The product shall be placed in a place where there is no direct sunlight and does not directly face the air vents, heating, ventilation ports, humidifiers, etc.**
- **The product shall be placed in a place where there is no electromagnetic wave or noise interference.**
- **Please check whether the voltage and frequency of the power supply and the permissible current (power consumption) are consistent with the rated value of this product. When inconsistent, it may lead to short circuit or fire, etc.**
- **Please use the supplied power cord. Electrical safety is not guaranteed without the use of the supplied power cord.**
- **Condensation is easy to produce when the device stored in the cold place is moved to a warm room, and thus it is necessary to start using it after confirming that there is no condensation. If condensation is present, the power shall be turned on after confirming that condensation has been removed.**

4. Fuse replacement

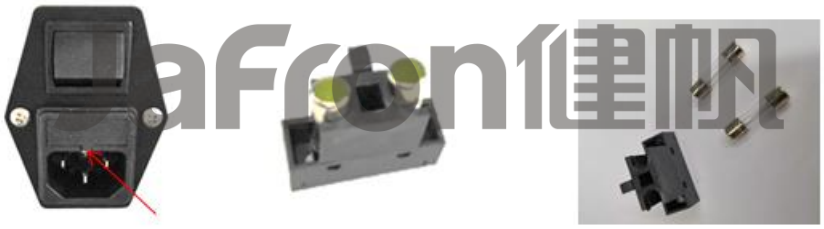


Figure 1-1 Fuse replacement diagram

Replace the fuse as shown in Figure 1-1. First turn off the power switch of the device, unplug the power supply, use a straight screwdriver to lift the fuse holder at the arrow in the above Figure (1); then pull out the fuse holder as shown in the above Figure (2); remove the old fuse and replace it with a new one, as shown in Figure (3) above; finally, put the fuse holder back into the power socket.

5. Training and instruction

This Instructions for Use is the main training material for operators of the Future F20 device. The

training for the operators is provided by the Jafron or Jafron authorized personnel.

Before the responsible organisation may begin operating the device for the first time, the individual responsible for operation must have been instructed by the Jafron or Jafron authorized personnel or personnel trained and qualified by the first two,on how to use the device, with certification of their instruction, and must be thoroughly familiar with the contents of the Instructions for Use. If they are operational difficulties or equipment malfunctions, employees of Jianfan Company or authorized personnel of Jianfan Company can be contacted for guidance. The device must only be operated by individuals who have been trained and certified in the proper operation of the device.

Attention

- **Be sure to turn off the power switch before replacing the fuse.**

1.7 Maintenance and Care

⚠Warning

- **Hospitals or medical institutions using this device shall establish a comprehensive maintenance plan, otherwise it may cause unpredictable consequences such as system failure and may endanger personal safety.**
- **All the safety inspection or maintenance that needs to dismantle the device shall be carried out by the professional maintenance personnel designated by the company. The operation of non-professional personnel may cause the system failure and may endanger personal safety.**
- **If the system is found to be abnormal, contact the dealer or manufacturer that sold the device to you.**
- **The circuit diagrams and list of components of this device are only provided to the professional maintenance personnel designated by the company.**
- **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.**

Use only the materials and methods listed in this section to clean or sterilize the product. The company does not provide any warranty for damage or accident caused by other materials or methods.

The chemicals or methods listed by the company are only used as a means of controlling infection and are not responsible for their effectiveness. For information on how to control infection, please consult the hospital’s infection prevention department or epidemiologist.

In order to prevent damage to the system, the following rules must be observed:

- Dilute cleaners and disinfectants as directed by the manufacturer or in the lowest concentration possible;
- The system shall not be immersed in liquid;
- Do not dump liquids on the system or accessories;
- Do not allow fluids to enter the body;
- Wear materials (such as steel wool or silver polish) and solvents such as xylene and acetone shall not be used to clean the system to avoid damage to the shell.

⚠Warning

- **Before cleaning the device, turn off the power and disconnect the power cord from the socket. When patients use the device, do not carry out the maintenance and cleaning of the device and other operations.**

⚠Caution

- **If you accidentally pour liquid onto the unit or accessories and the system does not work properly, please stop using it and contact the dealer or manufacturer who sold the product to you immediately.**
- **Device and its components must be inspected daily and regularly. If any abnormality is found, stop using it.**
- **When the device fails, do not repair it yourself. It shall be properly marked and must be carried out by maintenance personnel trained and authorized by the company.**
- **If daily inspections and periodic inspections are not carried out in accordance with the regulations, the performance and safety of the products cannot be guaranteed even during the service life.**

Regular cleaning:

The device shall be cleaned regularly, and the frequency of cleaning shall be increased in areas with serious environmental pollution or large sandstorm. Please consult or understand the regulations regarding the cleaning of medical devices before cleaning.

The recommended steps for cleaning and disinfecting this device are as follows:

(1) Turn off the power and disconnect the power cord from the socket;

(2) Wipe the surface of the device with a soft cloth dampened with warm water;

(3) Use 500mg/L ClO_2 disinfectant to wipe the surface of the device, when mental products have

been sterilized by ClO_2, the surface should be washed clean and dried in time with water that meets the requirements.

(4) After cleaning or disinfection, place the device in a ventilated and cool environment for air drying.

The above operations are for reference only and the disinfection effect shall be verified by appropriate methods.

Periodic inspection:

In addition to daily inspections, this device must be inspected once a year. Moreover, it is necessary to periodically replace consumable products such as parts. Also the components should be periodically check for performance and safety each year.

Regular inspections, periodic performance and safety check, and periodic parts replacement must be carried out by qualified service personnel designated by the company.

1.8 Battery Use and Maintenance

The device has a built-in rechargeable battery (hereinafter referred to as “battery”) to ensure that extracorporeal blood can be returned to the human body during a power outage. In the event of a sudden power outage, the device will continue to operate on battery power and the battery can only be powered for a period of time.

⚠Warning

- **Use only the battery specified by the manufacturer.**
- **Do not remove the battery, put it into fire or short circuit it. Battery combustion, explosion and leakage may cause personal injury.**

Attention

- **The service life of the battery depends on the frequency and time of use. If the battery is properly maintained and stored, the life of the lithium battery is approximately 500 charge and discharge cycles, and it is recommended to replace the battery for more than 500 charge and discharge cycles. If the battery is used improperly, its life will be shortened.**
- **When the battery is low, the device will start the battery exhaustion alarm, and the alarm indicator will flash and a sudden alarm will sound. The battery exhaustion alarm will only be eliminated after AC power supply is connected.**
- **When the battery runs out, it takes about six hours to recharge.**
- **A battery performance check must be performed once a year. A battery performance check is also required when you suspect that the battery is the source of the fault.**
- **If you do not use this product for a long time, please optimize the battery every 3 months to avoid battery damage.**
- **The battery is a consumable part and must be replaced when it is exhausted. If you need to replace the battery, please contact the dealer or manufacturer who sold you the product.**

When the product is not used for a long time, the battery shall be optimized. It is recommended to optimize every 3 months. A complete optimization cycle is: Continue charging until it is full, then unplug the power cord to discharge the device until the device is turned off, and then continue charging until it is full.

During battery use, it shall also be optimized periodically to maximize its service life.

If the battery has obvious damage (bulge, deformation, leakage) or when the battery capacity is exhausted, it shall be replaced and reasonably recycled. The disposal of used batteries shall comply with relevant laws and regulations.

1.9 Pollution-free Disposal and Recycling

After each treatment, dispose of disposable items such as tubing sets, sensor covers, and waste bags, and discard the residue and waste liquid after professional disinfection.

The service life of this product is about 8 years. When the device reaches the end of its life, it is best to contact the manufacturer for recycling. Otherwise continuing to use various data may be inaccurate, causing treatment errors.

Systems that exceed their service life shall be disposed of. Please contact the dealer or manufacturer that sold you the product for more information.

You can do the following:

1. Systems that have been scrapped can be returned to the dealer or manufacturer that sold you the product for appropriate recycling.
2. The used batteries can be returned to the dealer or manufacturer that sold you the product, or processed according to the appropriate regulations.
3. Disposable consumables such as used blood tubing sets and hemoperfusion cartridges may be cross-infected. Please follow the hospital regulations.

1.10 Description of network security

1. Operating environment

   ①Hardware configuration：

   CPU: AM3352

   Memory: IS43TR16

   Flash: 29F4G0

   Screen: 12-inch LCD touch screen

   ②Software environment:

   The operation environment of the main control software is Linux+Qt

   Linux: V3.2

   Qt: V4.7.3

   ③Network condition: none

2. Security software (such as antivirus software or firewall): none

3. Transport protocol / storage format of data interface:

   1) A RS232 serial port, which use the universal serial port RS232 communication protocol and complies with ANSI/EIA -232 standards.

   This serial port is only used for the development process and maintenance debugging. It does not have the function of data transmission or receiving.

   2) A USB port using USB 2.0 communication protocol, the storage format is customization log.

   Intended user of the interface: after sales engineers or professional equipment maintenance personnel designated by the manufacturer.

   Function requirements: ①Software upgrade: Data is received during software upgrade, and data is copied from the USB flash drive to the device during software upgrade. ②Data export: Record the

data of the device running status and the data of the device running status sensor without personal information when the device is running. To export data , copy the device data from the device to the USB flash drive.

4. User access control mechanism:

   a) User identification:A 6-digit password is used for user identification. Common user do not need a password. Engineers need to enter the password to obtain the corresponding permission.

   b) User types an permissions: User types are divided into two levels, namely ordinary users and engineer users. Ordinary users only have the permission to use the device. They can set and view the working parameters and mode of the device, and view the historical alarm records. In addition to the rights of common users, engineers have the rights to maintain equipment (calibrate key parameters), upgrade equipment software, and export equipment data.

5. Software environment

   Blood purification equipment control software..

6. Related requirement of software update

   When the software needs to be updated, the engineer designated by the manufacturer will operate on site. Other personnel have no right to carry out the work.

Attention

- **The correct passport is required for the interface to be invoked.**

Chapter 2 System Introduction

2.1 Product Composition

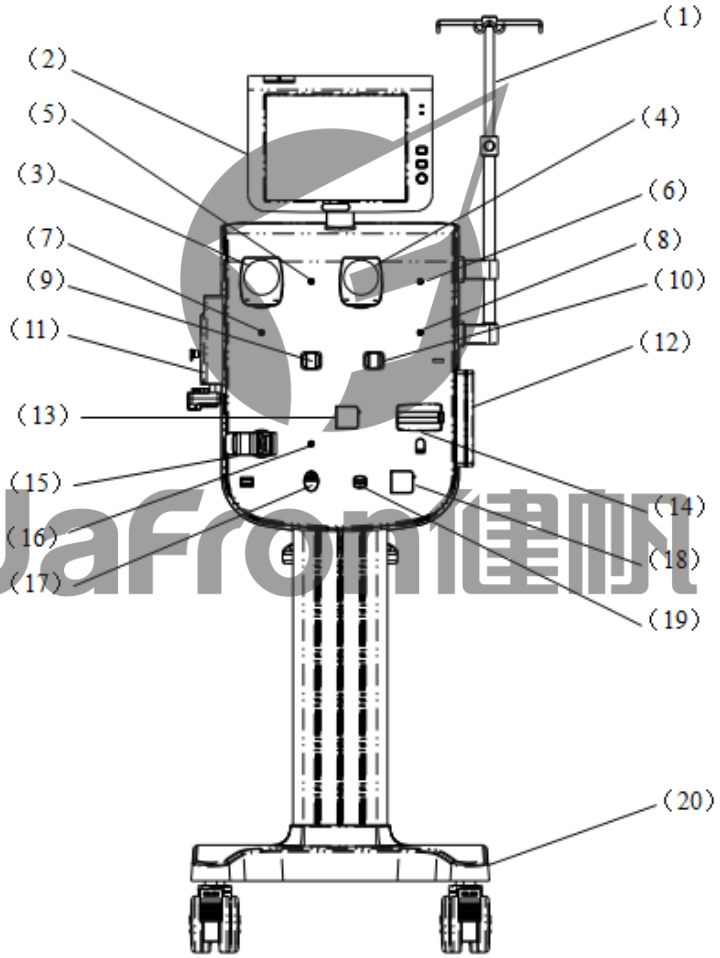
This product belongs to the unit of blood purification system (including embedded software), which is composed of power system, anticoagulation system, heating system, monitoring system, alarm system, display and control system. Disposable tubing sets and other consumables used with it are not included.

2.2 Principle of Action

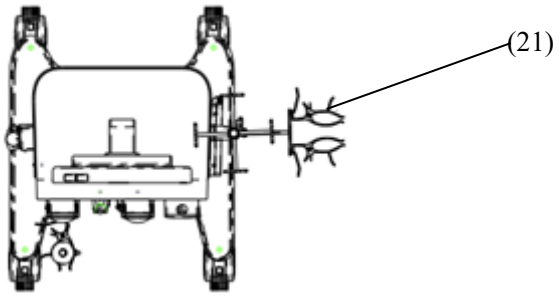
Blood is extracted from the patient end, driven by a blood pump to the extracorporeal circulation

tubing set, and the adsorption of harmful substances is completed in disposable hemoperfusion cartridge, plasma perfusion adsorption column and other devices. The purified blood flows through a liquid level detector, a blood heater, a bubble detector and a vein clamp, and then back into the patient. In the process of extracorporeal circulation, blood is automatically injected with anticoagulant by the heparin pump to prevent coagulation, and the blood insulation device is heated to improve the comfort of patients, and the monitoring of the treatment process is realized through the pressure monitoring, liquid level testing and bubble testing devices.

2.3 External View



Front view



Top view

Figure 2-1 Equipment appearance and parts drawing

No.	Name	No.	Name	No.	Name
(1)	Infusion support	(8)	Venous pressure interface	(15)	Filter holder
(2)	Display screen and touch screen	(9)	Arterial pot holder	(16)	Extramembranous pressure interface
(3)	Blood pump (BP)	(10)	Plasma pot holder	(17)	Vein clamp
(4)	Filter pump (FP)	(11)	Heparin pump	(18)	Blood detector
(5)	Inlet pressure 1 interface	(12)	Warmer	(19)	Bubble detector
(6)	Inlet pressure 2 interface	(13)	Blood leakage detector	(20)	Base
(7)	Arterial pressure interface	(14)	Liquid level detector	(21)	Extended filter holder

Table 2-1 Name of device appearance parts

2.4 Functional Description of Each Part

No.	Name	Function
(1)	Infusion support	A support and hooks for hanging fluid bags.
(2)	Display screen and touch screen	Display current working status, alarm information, prompt information, and provide an operation interface for human-computer interaction.
(3)	Blood pump (BP)	A roller pump that pumps blood out of the patient's body.
(4)	Filter pump (FP)	A roller pump that delivers plasma separated by a plasma separator into an adsorption plasma purifier.
(5)	Inlet pressure 1 interface	A connector for detecting pressure at the inlet of the plasma separator/perfusion cartridge.
(6)	Inlet pressure 2	During plasma adsorption therapy, the connector for

	interface	detecting pressure at the inlet of the adsorption column.
(7)	Arterial pressure interface	A connector for detecting arterial pressure.
(8)	Venous pressure interface	A connector for detecting venous pressure.
(9)	Arterial pot holder	Used to position and install an arterial pot.
(10)	Plasma pot holder	Used to position and install a plasma pot.
(11)	Heparin pump	A syringe pump that continuously injects heparin anticoagulant.
(12)	Warmer	The purified plasma/blood temperature is raised to near body temperature.
(13)	Blood leakage detector	Detect whether the plasma from the plasma separator is mixed with blood cells.
(14)	Liquid level detector	Used to install a venous pot, to detect and adjust the liquid level in the venous pot.
(15)	Filter holder	Used to hold a hemoperfusion cartridge or a plasma separator.
(16)	Extramembranous pressure interface	A connector for detecting extramembranous pressure of the plasma separator.
(17)	Vein clamp	Used to block the venous blood from flowing back to the patient.
(18)	Blood detector	Detect for blood flow through the venous tubing set.
(19)	Bubble detector	Detect for bubbles in the blood circuit that returns to the patient's veins.
(20)	Base	Include universal wheel for supporting and moving the unit.
(21)	Extended filter holder	During plasma adsorption and DPMAS therapies, it is used to clamp the adsorption column.

Table 2-2 Function of device appearance parts

2.5 Human-computer Interaction

1. Keys

(1) Power switch: Turn the system on or off.

(2) Sound pause: Pause the current alarm sound for 2 minutes.

(3) Start/Pause: Start or pause the current treatment.

2. Indicator

(1) AC indicator: It is always on after the system is connected to AC power supply.

(2) Battery indicator: The green indicator is always on during battery charging, and is off when fully charged.

(3) Alarm indicator: Red flashes when a high priority alarm occurs; yellow flashes when a medium priority alarm occurs; yellow is steady when a low priority alarm occurs.

3. Touch screen

(1) Various touch function keys, data, operation prompts and alarm contents can be displayed on the touch screen.

(2) After the touch control key displayed on the touch screen is operated, it is switched to the function representation content corresponding to the touched control key.

(3) In actual operation, the state of the corresponding function of the key can be controlled by tapping the control button displayed on the touch screen with a finger with appropriate force.

Please pay attention to the following aspects when operating the touch screen panel:

(1) When operating the touch keys on the touch screen, touch the screen vertically with a single finger, and the display state can be changed. There is no need to use too much force and multiple fingers on the keys, which is prone to misoperation.

(2) It is forbidden to use hard articles for operation, which will cause plane scratches and damage.

(3) Please follow the correct operation sequence during operation.

⚠Warning

- **No electrical equipment (non-ME equipment and ME equipment) with touch currents and patient leakage currents above the respective limits for type CF applied parts is used in the patient environment in combination with a central venous catheter whose tip is in the right atrium.**

2.6 Self-check

The system performs a comprehensive self-check at each startup, checking all operations, displays, sensors, alarms and other functions. Self-check status and progress can be displayed on the screen, as shown in the following figure:

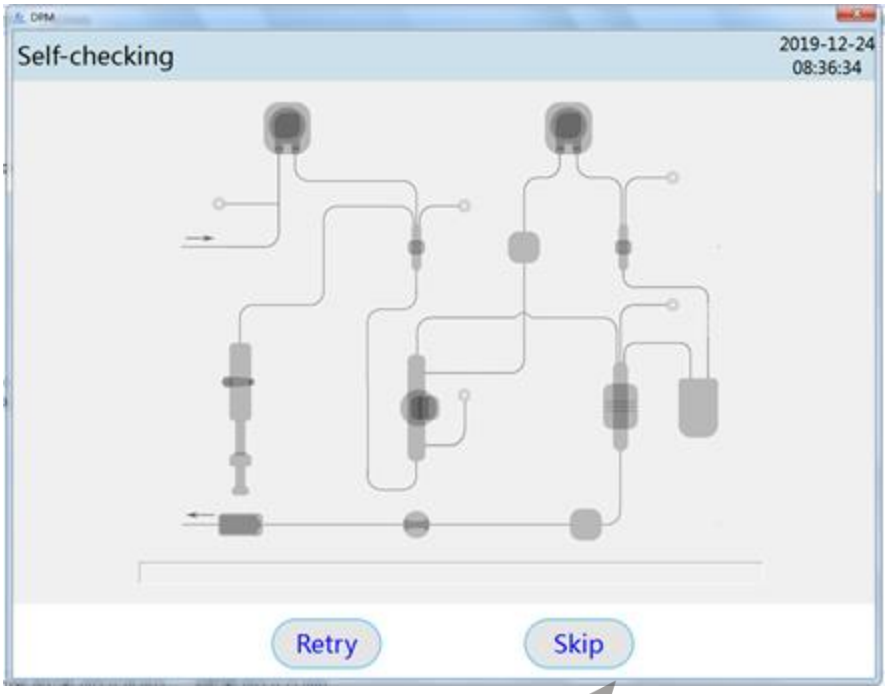


Figure 2-2 Self-check interface

The parts that pass the self-check will be represented by the green background color. If the self-check fails, self-check it again until it passes. After the self-check fails, select Skip to enter the main interface and the treatment function will be locked. If the self-check fails to pass, the self-check failure prompt shown in Figure 2-3 will pop up. Do not use this device in this case, and contact the manufacturer for maintenance.

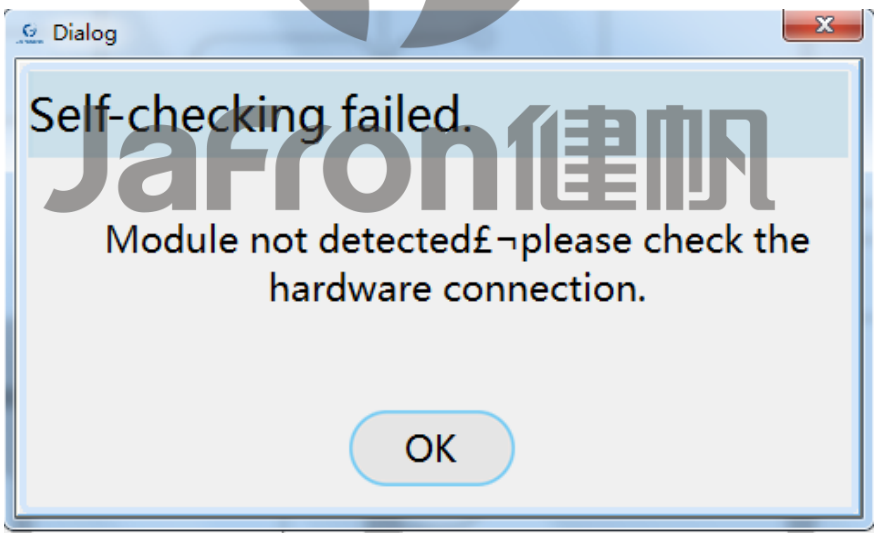


Figure 2-3 Self-check failure alarm window

The device self-check includes the items shown in the following table:

Blood pump	Arterial pressure sensor
Filter pump	Inlet pressure 1 sensor

Heparin pump	Inlet pressure 2 sensor
Bubble detector	Venous pressure sensor
Blood leakage detector	Extramembranous pressure sensor
Blood detector	Heater
Liquid level detector	Communication module
Vein clamp	Power supply

Table 2-3 Self-check list

2.7 Operating Procedures

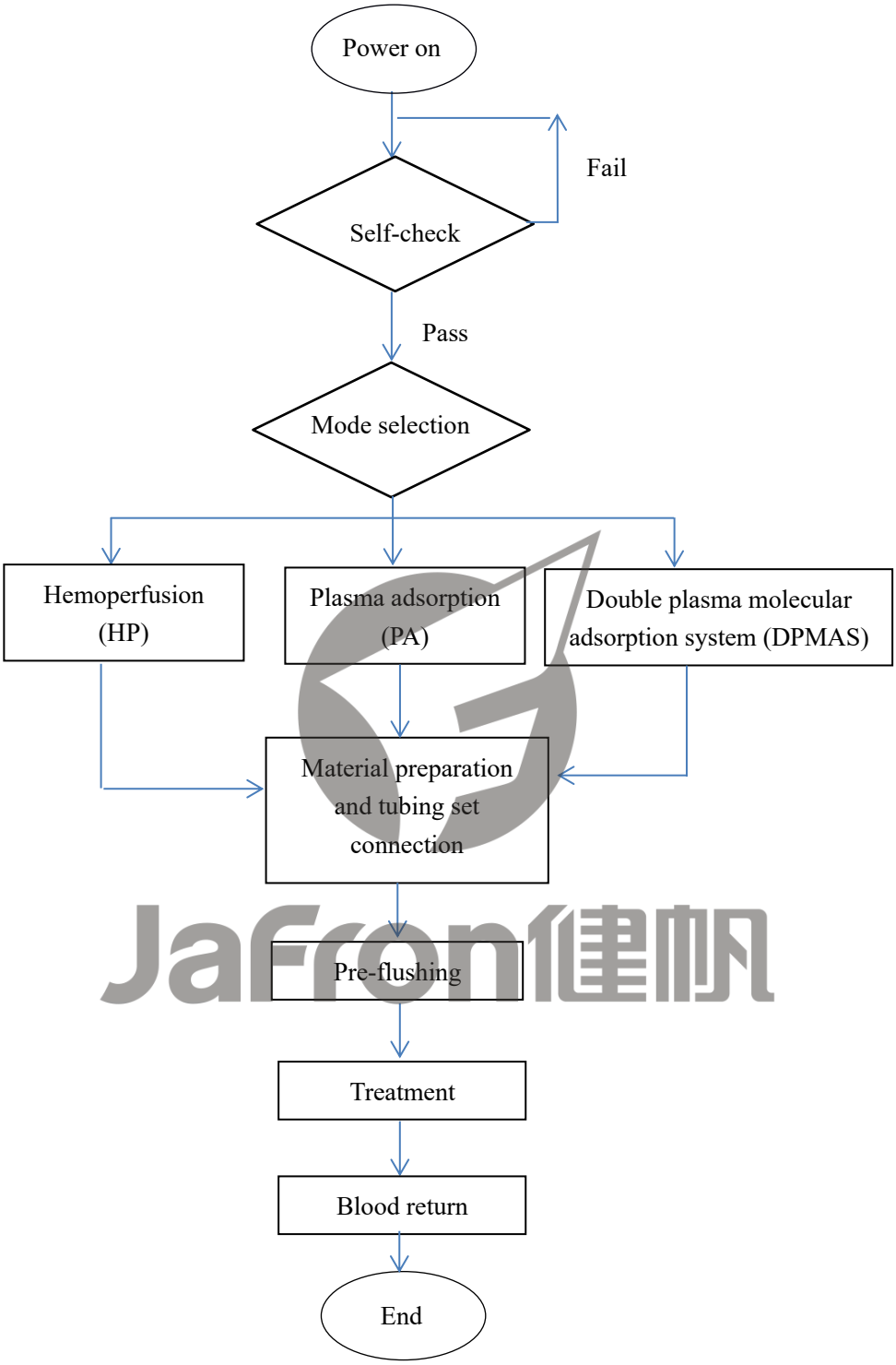


Figure 2-4 Device operation flow chart

A whole treatment will take about 6 hours which including self-check, tubing set installation, pre-flushing, treatment and blood return.

2.8 Recommended Consumables

Recommended consumables for treatment with this device are shown in the following table:

Consumable Name	Specification & Model	Brand	Mode
Disposable hemoperfusion cartridge	HA130	Jafron	HP, and PA and DPMAS
	HA230		
	HA280		
	HA330		
	HA330-II		
Disposable Hemoperfusion Cartridge	HA80, HA100, HA150, HA180, HA380, HA430, HA480		DPMAS
Disposable plasma bilirubin perfusion adsorption column	BS330, BS380		
Disposable tubing set	The type of appointed tubing set is BLS-121 which conforms to below requirements: EN ISO 11135, EN ISO 11607-1, EN ISO 11607-2, EN ISO 10993-1, EN 556-1, EN ISO 8638	Hanaco	All mode

Table 2-4 Recommended disposable consumables

Attention

- **This device supports heparin as the anticoagulant.**
- **After using this device for 24 hours, it is recommended to turn it off and then starting up again, use it after passing the self-check.**

⚠Warning

- **The blood circuit catheter shall be installed in the order of installation to ensure that it is properly installed.**

- **Make sure that there is no loose connection of the blood circuit catheter, and make sure that the blood circuit catheter is not folded or twisted.**
- **This device may not be able to detect the connection between the extracorporeal circulation tubing set and the patient, resulting in severe blood loss. Make sure that the patient's extracorporeal circulation tubing set is firmly connected.**
- **If the extracorporeal circulation tubing set is disassembled or removed while the patient is still connected, severe blood loss can result. When disassembling or removing the extracorporeal circulation tubing set from the device, ensure that the patient is disconnected from the extracorporeal circulation tubing set.**
- **If any consumables other than those recommended above are used for treatment, please consult the manufacturer.**
- **Consumables such as tubing sets and filters used on the device are guaranteed to be used at one time to prevent cross-infection.**

Chapter 3 Hemoperfusion

3.1 Preparation of Articles

When performing hemoperfusion therapy, you need to prepare the following articles:

(1) 1 hemoperfusion cartridge

(2) 1 syringe (20ml or 30ml or 50ml);

(3) Heparinized normal saline for rinsing (several);

(4) Normal saline for return blood (500ml);

(5) 1 set of supporting extracorporeal circulation tubing set;

(6) Other related materials.

⚠Warning

- **Please use the accessories recommended in Chapter 2.8 of this Manual, otherwise it may damage the health of the patient.**

3.2 Startup

Turn on the unit, after completing the self-check, enter the main interface, as shown below:

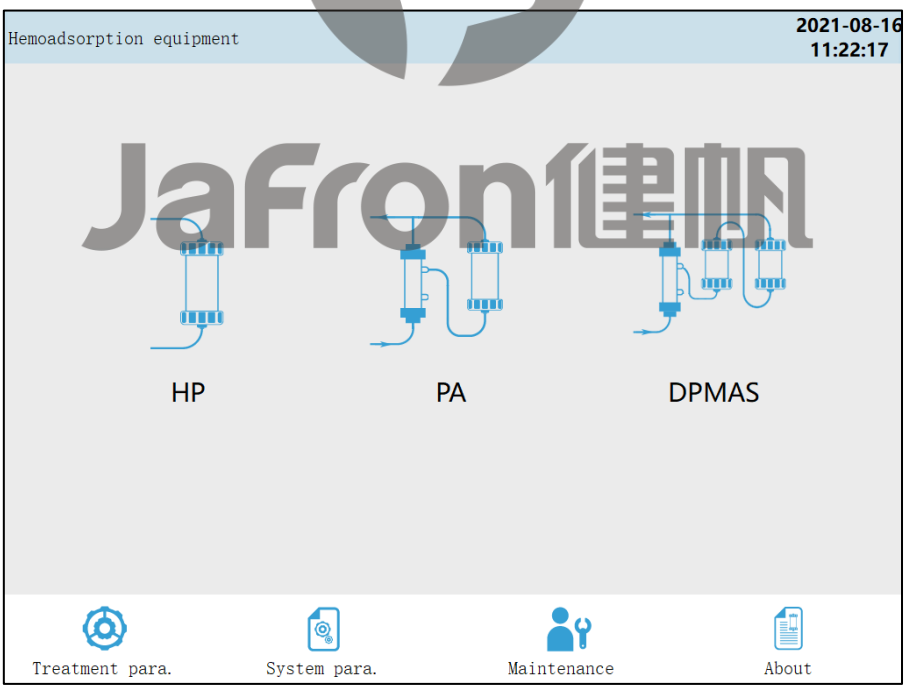


Figure 3-1 Main interface

After selecting the [Hemoperfusion] mode, it enters the hemoperfusion treatment tubing set installation interface.

3.3 Tubing Set Installation

The device provides a graphical and streamlined tubing set installation guide. Users can easily install the tubing set according to the instructions of the figures and text.

The main steps of the tubing set installation in the hemoperfusion treatment mode are:

1. Install the tubing set on the arterial side and the perfusion cartridge to connect the heparin pump;
2. Install the tubing set on the venous side;
3. Confirm the tubing set installation.

⚠Warning

- **It may cause tubing broken and blood losing from patient if user doesn't follow the right method of tubing set installation.**
- **Don't use the tubing which not appointed to use, otherwise the system can't provide well accuracy of flow rate or alarm function.**
- **The tubing set should be installed within right order on right position.**
- **Please make sure there is no loosen or folding on the connection of tubing.**
- **Please make sure there is no folding on the blood line.**
- **Please replace new pressure sensor cover when it's wet.**
- **The system can't detect the pressure if the pressure tubing is not connected to the system.**

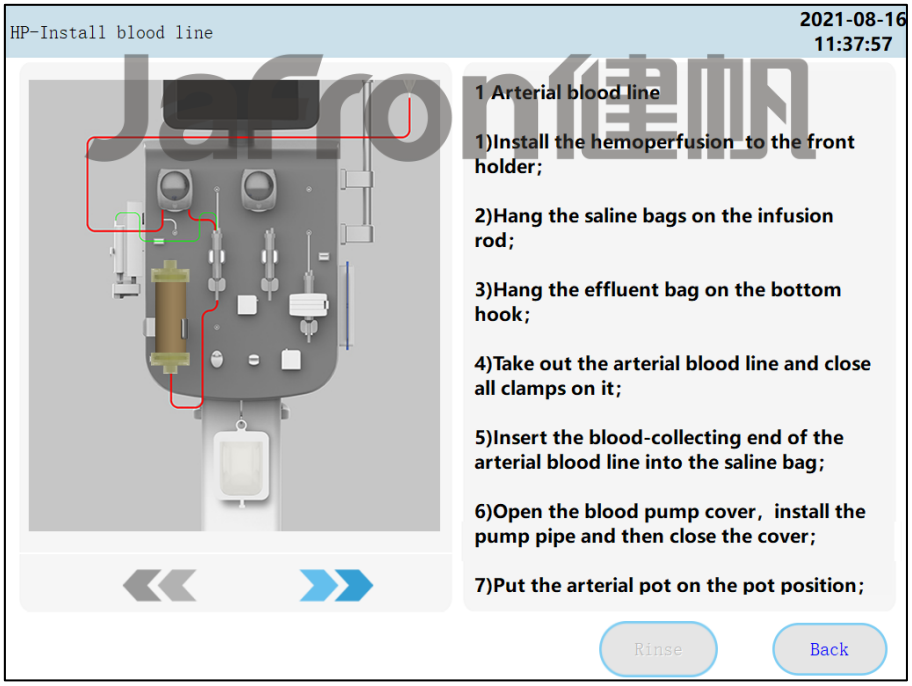


Figure 3-2 Connection diagram of the tubing set on the arterial side for hemoperfusion

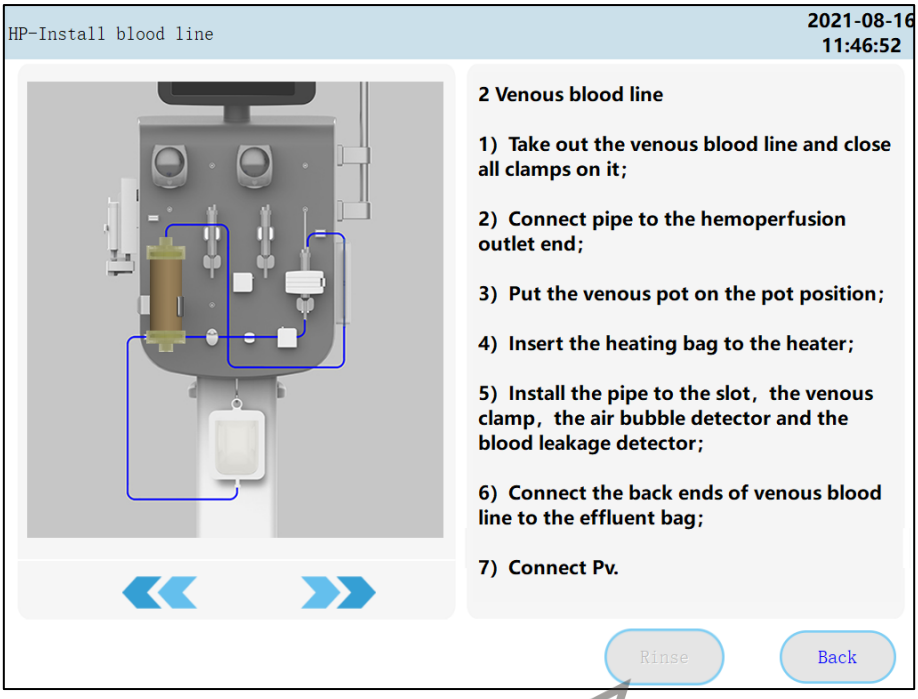


Figure 3-3 Connection diagram of the tubing set on the venous side for hemoperfusion

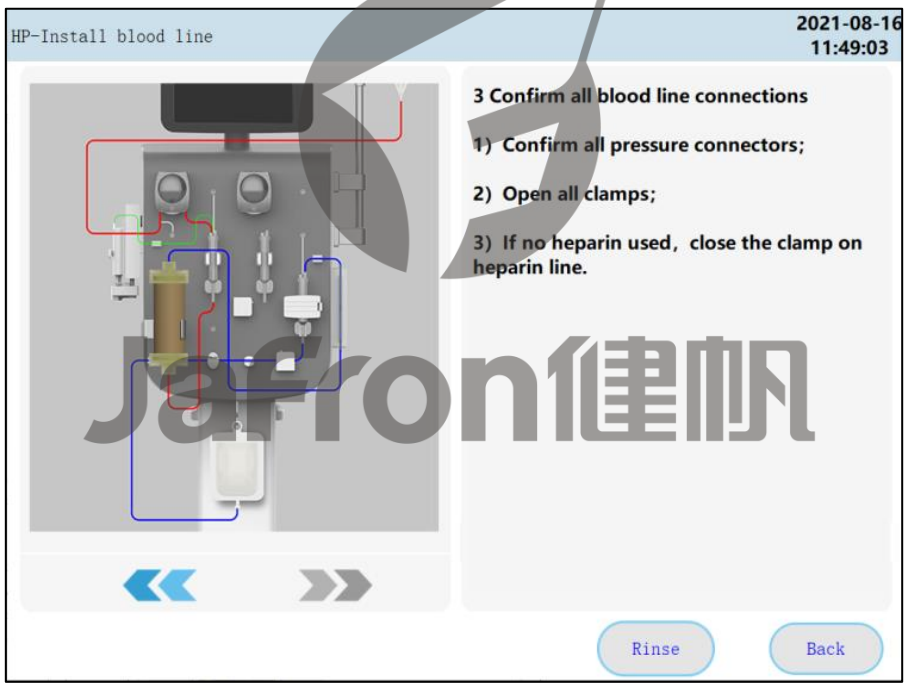


Figure 3-4 Overall tubing set connection confirmation diagram

3.4 Pre-flushing

This device can perform automatic pre-flushing. When the pre-flushing tubing set is installed and connected, click the [Pre-flushing] key to automatically complete the pre-flushing.

If the pre-flushing is completed, it is found that there are still some bubbles in the tubing set, you can press the [Re-pre-flushing] key to pre-flush again. After the pre-flushing is completed, click the [Treatment] key to enter the pre-flushing test.

⚠Warning

- **After pre-flushing, confirm that there is no residual air in the tubing set, otherwise air may be mixed into the patient.**

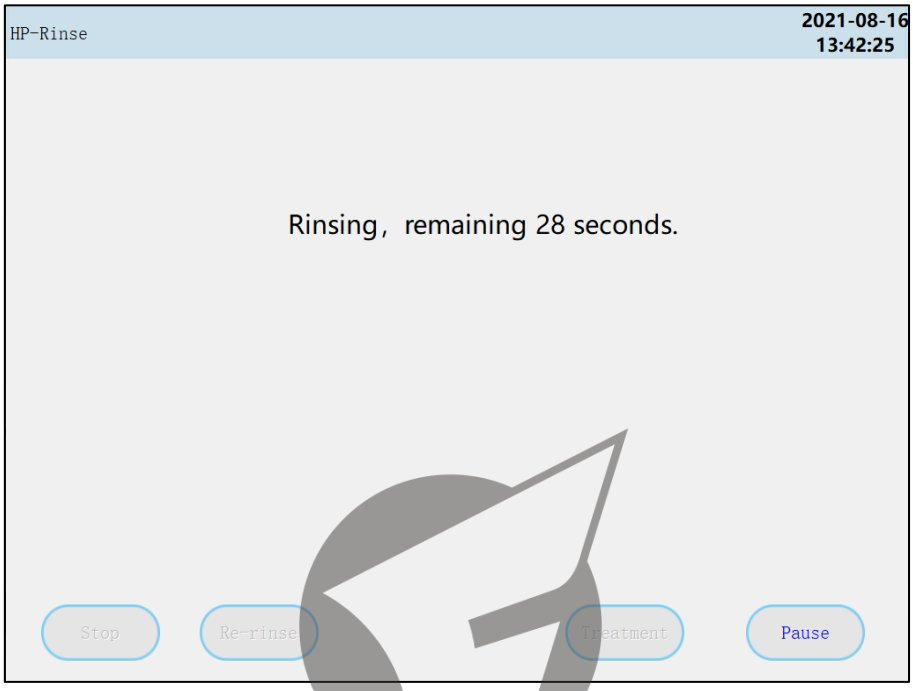


Figure 3-5 Hemoperfusion pre-flushing interface

3.5 Treatment

After the pre-flushing test is passed, enter the treatment interface, as shown in the figure below:

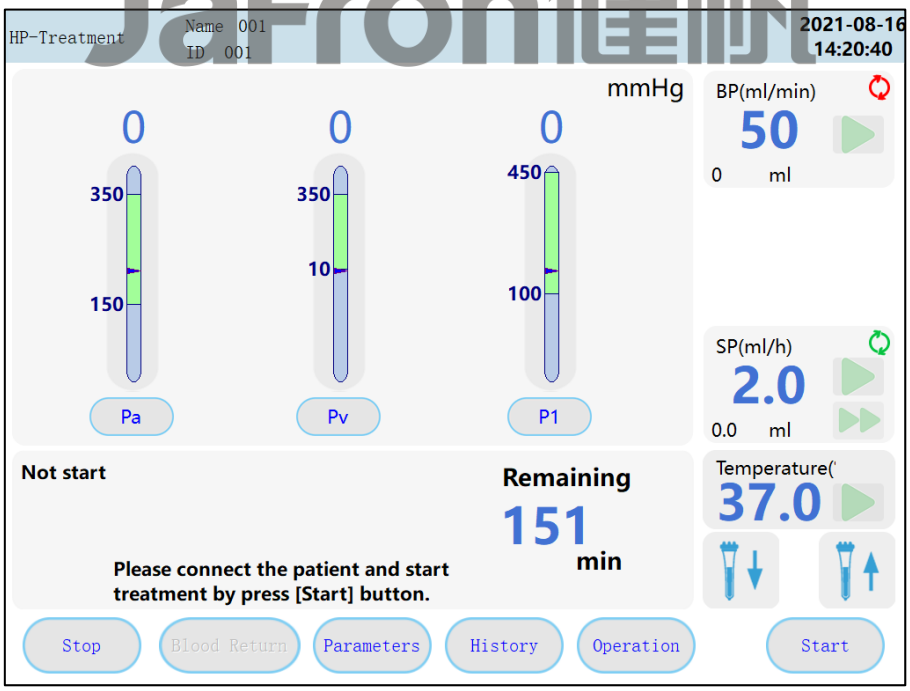


Figure 3-6 Hemoperfusion treatment interface

1. Connect the patient's ports on the arterial and venous ends, respectively.

2. Make sure that the arterial end, the venous end, and the syringe clamp are open (select the heparin tube clamp when the anticoagulation is not applied).

3. Press [Treatment Parameter] to set the relevant treatment parameters, or directly click the corresponding parameter icon on the interface to set the data.

4. Press the [Start/Pause] two-state button, the interface will pop up the treatment parameter interface, and start treatment after confirmation.

5. At the beginning of treatment, the blood pump will operate at the set "pumped BP speed". When the blood detector detects opaque liquid, the blood pump speed automatically switches to the set "blood pump speed".

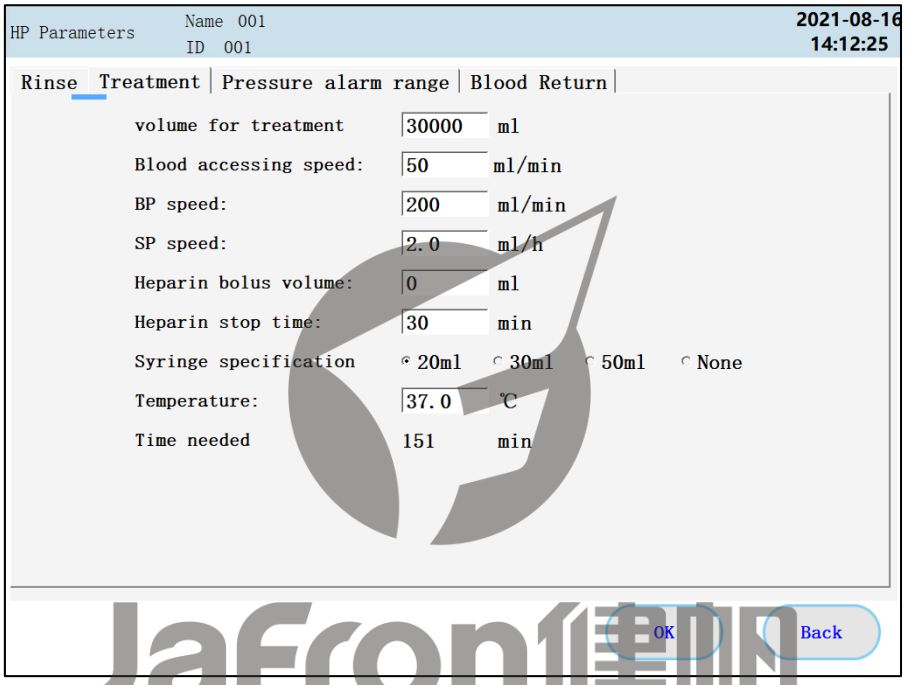


Figure 3-7 Hemoperfusion parameter interface

Parameter	Minimum	Maximum	Default	Unit
Volume for treatment	1000	90000	30000	ml
Blood accessing speed	15	100	50	ml/min
BP speed	15	400	150	ml/min
SP speed	0.5	15.0	2.0	ml/h
Heparin bolus volume	0	5	0	ml
Heparin stop time	0	120	30	min
Syringe specification	20ml/30ml/50ml/None		20ml	/
Temperature	35.0	39.0	37.0	°C

Table 3-1 Hemoperfusion parameter configuration

⚠Warning

- **Parameters in this screen can be configured, please select the configurations or explicitly confirm the default configuration before treatment.**
- **Future F20 can't detect all the condition that would cause hemolysis like the narrow passages of extracorporeal circuit. Please check carefully if there is any red or pink fluid in the plasma line during the treatment.**
- **The pressure monitor is a protect system to protect the patient from extracorporeal blood loss especially the venous pressure monitor. But it can't totally be relied upon for example during single needle treatment mode. So operator should always pay attention to the extracorporeal blood loss.**
- **Operator should consider the effective delivered blood flow rate recirculation of blood in the extracorporeal circuit before setting blood flow rate and treatment target when use single needle treatment mode.**
- **Any coagulum or ultrasound gel in the air detector or the extracorporeal line inside the air detector would cause the air detector failure.**
- **If pressure are negative, the air may enter into the extracorporeal circuit downstream of the air detector. Make sure the return line connected tightened with the patient.**
- **The blood flow rate and thus treatment efficacy may be reduced when the pre-pump arterial pressure is extremely negative.**
- **The use of low delivery rates of device-integrated anticoagulation means (e.g. use of undiluted anticoagulation solution) could lead to delayed and non-continuous delivery due to compliance in the delivery means or output pressure changes in the extracorporeal circuit.**
- **Please use aseptic processing during connect extracorporeal circuit with Disposable hemoperfusion cartridge or with patient.**

3.6 Blood Return

After the treatment is finished, press [Stop Treatment] on the main interface of the treatment, and press [OK] in the pop-up dialog box to terminate the treatment and enter the blood return interface:

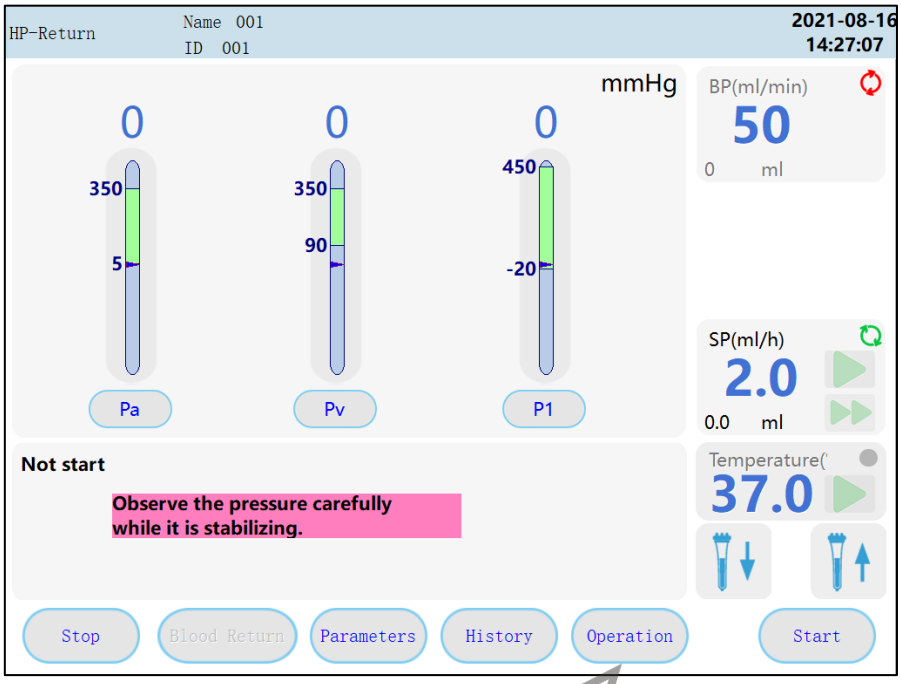


Figure 3-8 Blood return interface

1. Follow the interface prompts to connect the patient's arterial end and blood return to normal saline to ensure that all clamps are open;
2. Press [Treatment Parameter] to set the relevant blood return parameters, or directly click the corresponding parameter icon on the interface to set the data;
3. Press [Start] to start blood return;
4. When the blood detector detects a clear liquid or [End] is pressed, all pumps stop and the interface prompts the blood return to end;
5. Remove the arterial and venous tubing sets from the patient according to the interface prompts;

Chapter 4 Plasma Adsorption

4.1 Preparation of Articles

When performing plasma adsorption therapy, you need to prepare the following articles:

(1) 1 plasma separator;

(2) 1 hemoperfusion cartridge

(3) 1 syringe (20ml or 30ml or 50ml);

(4) Heparinized normal saline for rinsing (several);

(5) Normal saline for return blood (500ml);

(6) 1 set of supporting extracorporeal circulation tubing set;

(7) Other related materials.

⚠Warning

- **Please use the accessories recommended in Chapter 2.8 of this Manual, otherwise it may damage the health of the patient.**

4.2 Startup

Turn on the unit, after completing the self-check, enter the main interface, as shown in Figure 3-1.

After selecting the [Plasma Adsorption] mode, it enters the plasma adsorption treatment tubing set installation interface.

4.3 Tubing Set Installation

The device provides a graphical and streamlined tubing set installation guide. Users can easily install the tubing set according to the instructions of the figures and text.

The main steps of the tubing set installation in the plasma adsorption treatment mode are:

1. Install the tubing set on the arterial side, the plasma separator and the adsorption column to connect the heparin pump;
2. Install the tubing set on the plasma side;
3. Install the tubing set on the venous side;
4. Confirm the tubing set installation.

⚠Warning

- **It may cause tubing broken and blood losing from patient if user doesn't follow the right method of tubing set installation.**
- **Don't use the tubing which not appointed to use, otherwise the system can't provide well accuracy of flow rate or alarm function.**

- **The tubing set should be installed within right order on right position.**
- **Please make sure there is no loosen or folding on the connection of tubing.**
- **Please make sure there is no folding on the blood line.**
- **Please replace new pressure sensor cover when it's wet.**
- **The system can't detect the pressure if the pressure tubing is not connected to the system.**

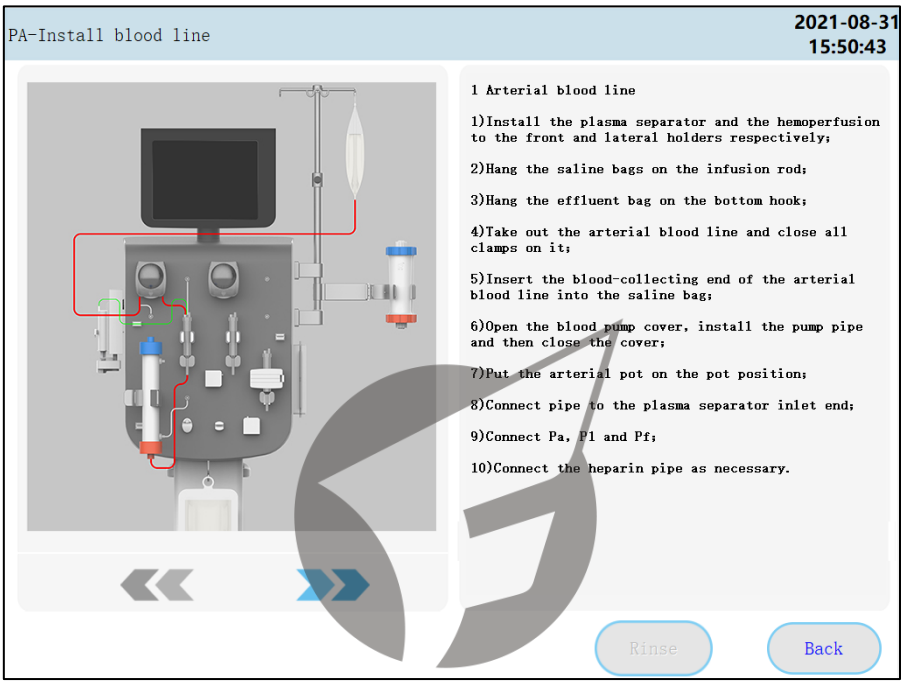


Figure 4-1 Connection diagram of the tubing set on the arterial side for plasma adsorption

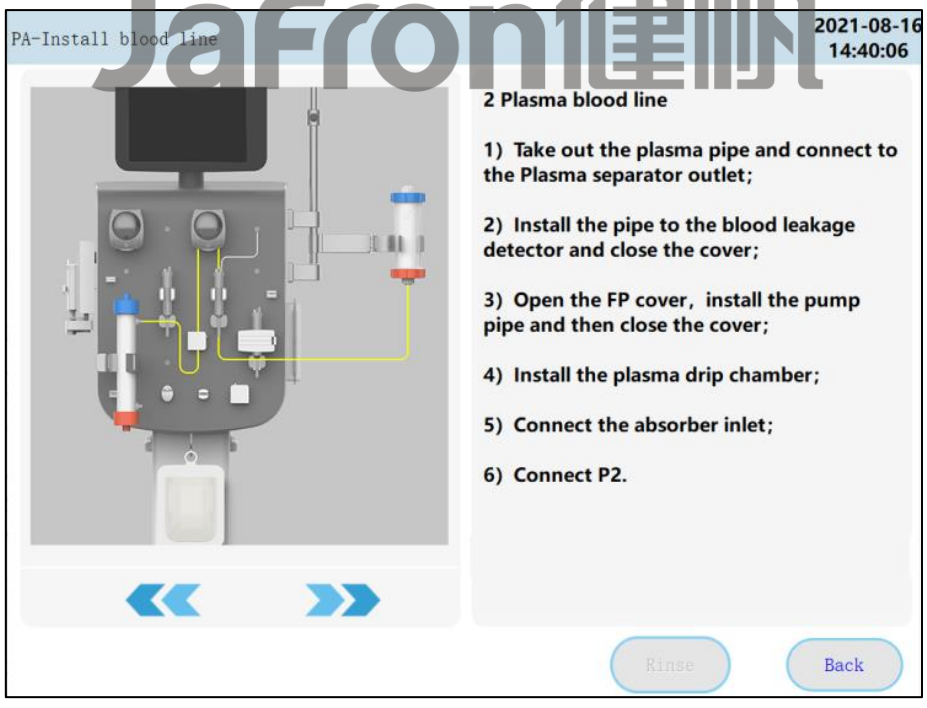


Figure 4-2 Connection diagram of the tubing set on the plasma side for plasma adsorption

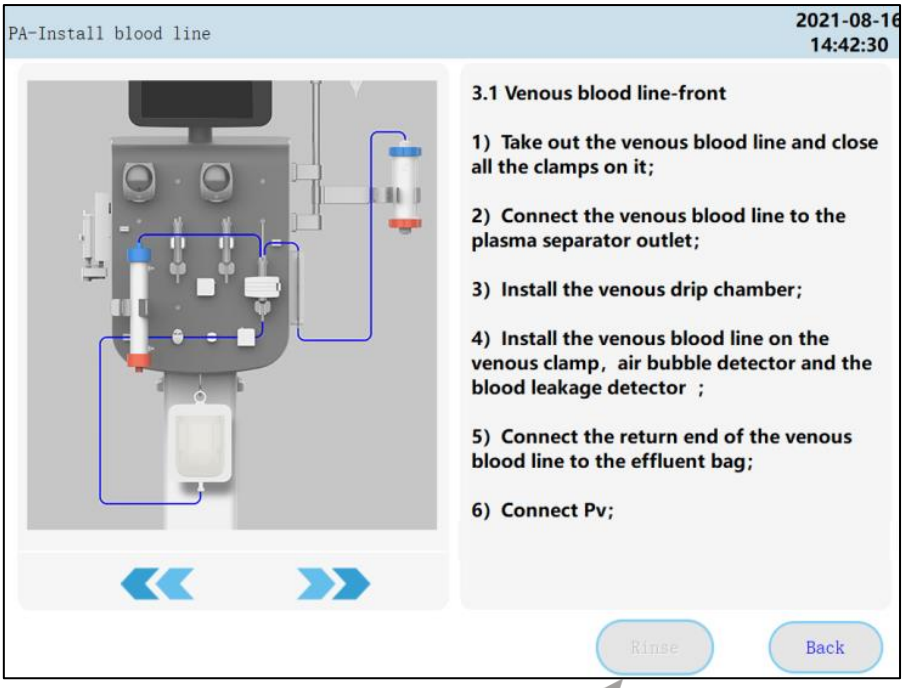


Figure 4-3 Tubing set on the venous side for plasma adsorption - Front connection diagram

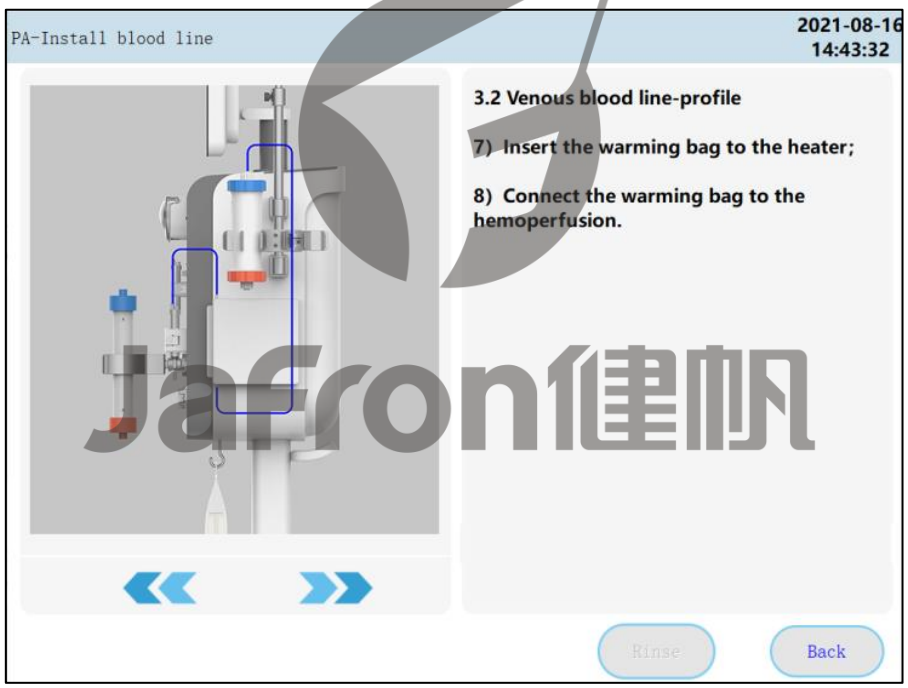


Figure 4-4 Tubing set on the venous side for plasma adsorption - Side connection diagram

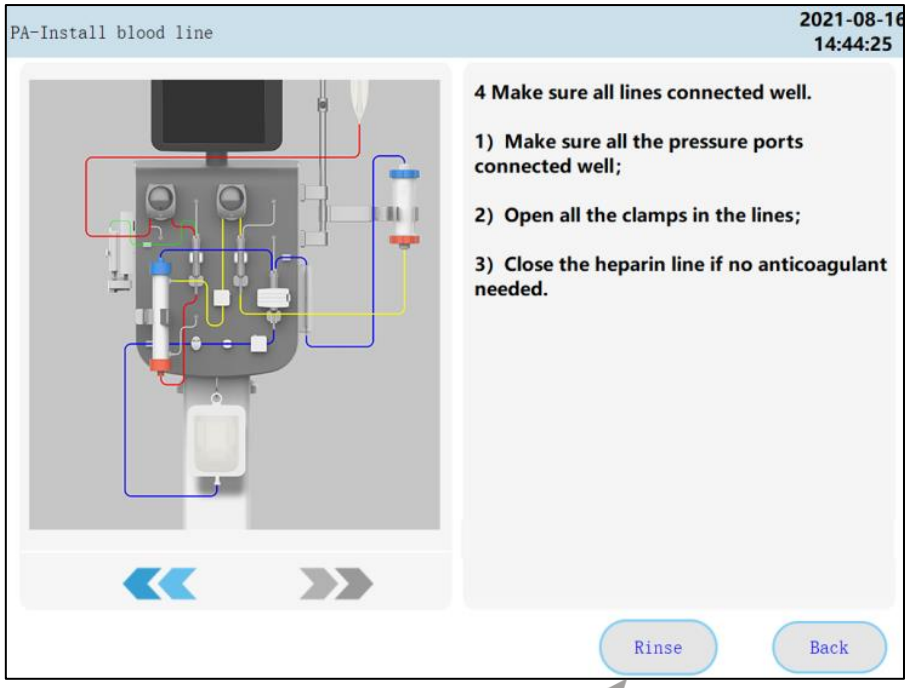


Figure 4-5 Overall tubing set connection confirmation diagram

4.4 Pre-flushing

This device can perform automatic pre-flushing. When the pre-flushing tubing set is installed and connected, click the [Pre-flushing] key to automatically complete the pre-flushing. The pre-flushing interface is shown in Figure 3-5.

If the pre-flushing is completed, it is found that there are still some bubbles in the tubing set, you can press the [Re-pre-flushing] key to pre-flush again. After the pre-flushing is completed, click the [Treatment] key to enter the pre-flushing test.

⚠Warning

- **After pre-flushing, confirm that there is no residual air in the tubing set, otherwise air may be mixed into the patient.**

4.5 Treatment

After the pre-flushing test is passed, enter the treatment interface, as shown in the figure below:

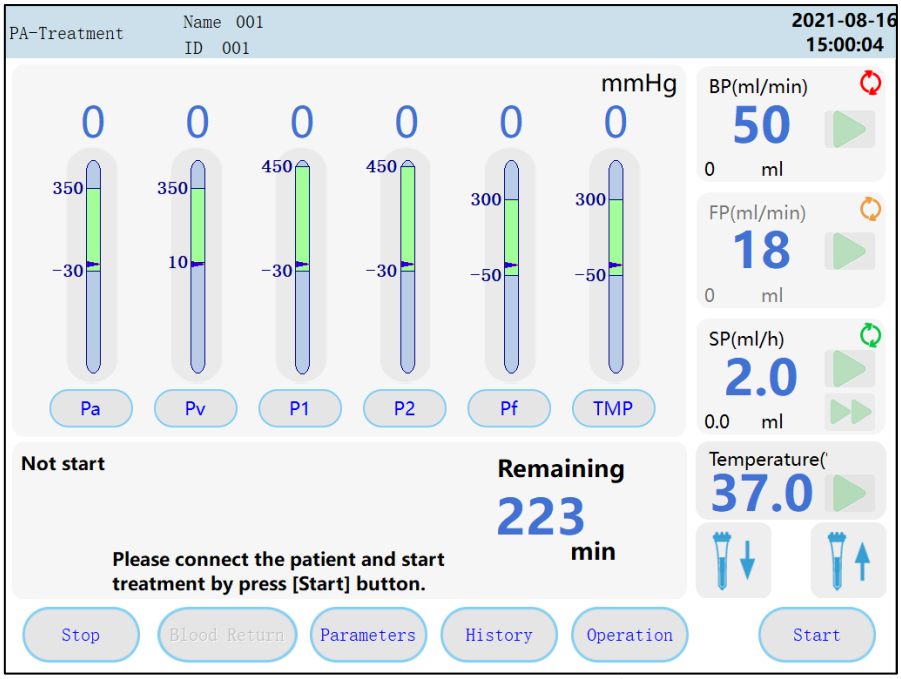


Figure 4-6 Plasma adsorption treatment interface

1. Connect the patient's ports on the arterial and venous ends, respectively;
2. Make sure that the arterial end, the venous end, and the syringe clamp are open (select the heparin tube clamp when the anticoagulation is not applied).
3. Press [Treatment Parameter] to set the relevant treatment parameters, or directly click the corresponding parameter icon on the interface to set the data.
4. Press [Start], the interface will pop up the treatment parameter interface, and start treatment after confirmation.
5. At the beginning of treatment, the blood pump will operate at the set "pumped BP speed". When the blood detector detects opaque liquid, the blood pump speed automatically switches to the set "blood pump speed". At this point, the filter pump starts running at the set speed.

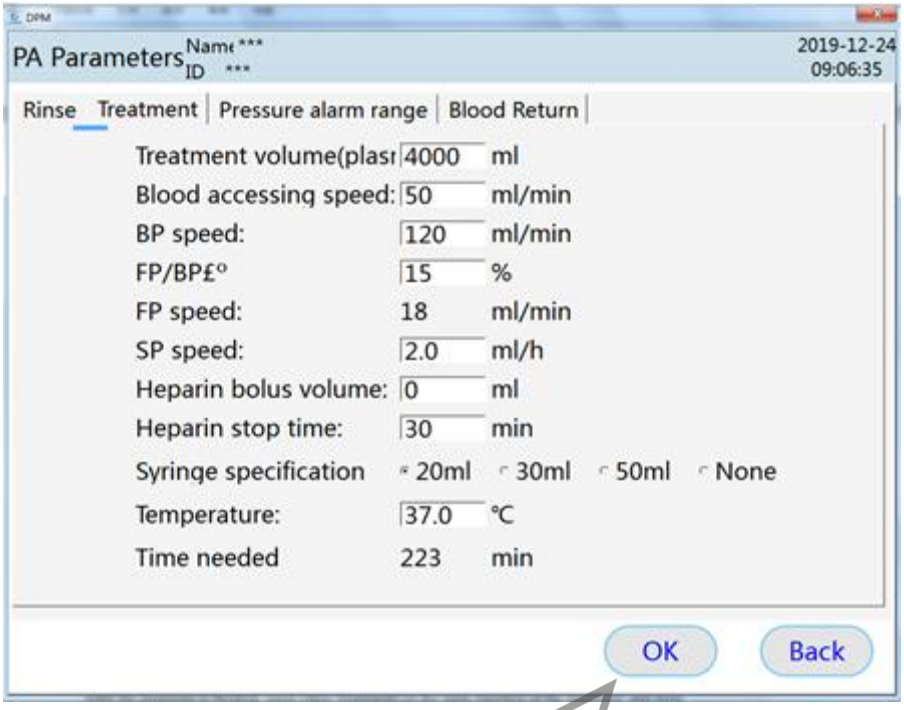


Figure 4-7 Plasma adsorption parameter interface

Parameter	Minimum	Maximum	Default	Unit
Volume for treatment	1000	90000	4000	ml
Blood accessing speed	15	100	50	ml/min
BP speed	15	400	150	ml/min
FP/BP	5	40	20	%
SP speed	0.5	15.0	2.0	ml/h
Heparin bolus volume	0	5	0	ml
Heparin stop time	0	120	30	min
Syringe specification	20ml/30ml/50ml/None		20ml	/
Temperature	35.0	39.0	37.0	°C

Table 4-1 Plasma adsorption parameter configuration

⚠Warning

- **Parameters in this screen can be configured, please select the configurations or explicitly confirm the default configuration before treatment.**
- **Future F20 can't detect all the condition that would cause hemolysis like the narrow passages of extracorporeal circuit. Please check carefully if there is any red or pink fluid in the plasma line during the treatment.**
- **The pressure monitor is a protect system to protect the patient from extracorporeal blood loss especially the venous pressure monitor. But it**

can't totally be relied upon for example during single needle treatment mode. So operator should always pay attention to the extracorporeal blood loss.

- **Operator should consider the effective delivered blood flow rate recirculation of blood in the extracorporeal circuit before setting blood flow rate and treatment target when use single needle treatment mode.**
- **Any coagulum or ultrasound gel in the air detector or the extracorporeal line inside the air detector would cause the air detector failure.**
- **If pressure are negative, the air may enter into the extracorporeal circuit downstream of the air detector. Make sure the return line connected tightened with the patient.**
- **The blood flow rate and thus treatment efficacy may be reduced when the pre-pump arterial pressure is extremely negative.**
- **The use of low delivery rates of device-integrated anticoagulation means (e.g. use of undiluted anticoagulation solution) could lead to delayed and non-continuous delivery due to compliance in the delivery means or output pressure changes in the extracorporeal circuit.**
- **Please use aseptic processing during connect extracorporeal circuit with Disposable hemoperfusion cartridge or with patient.**

4.6 Blood Return

After the treatment is finished, press [Stop Treatment] on the main interface of the treatment, and press [OK] in the pop-up dialog box to terminate the treatment and enter the blood return interface:

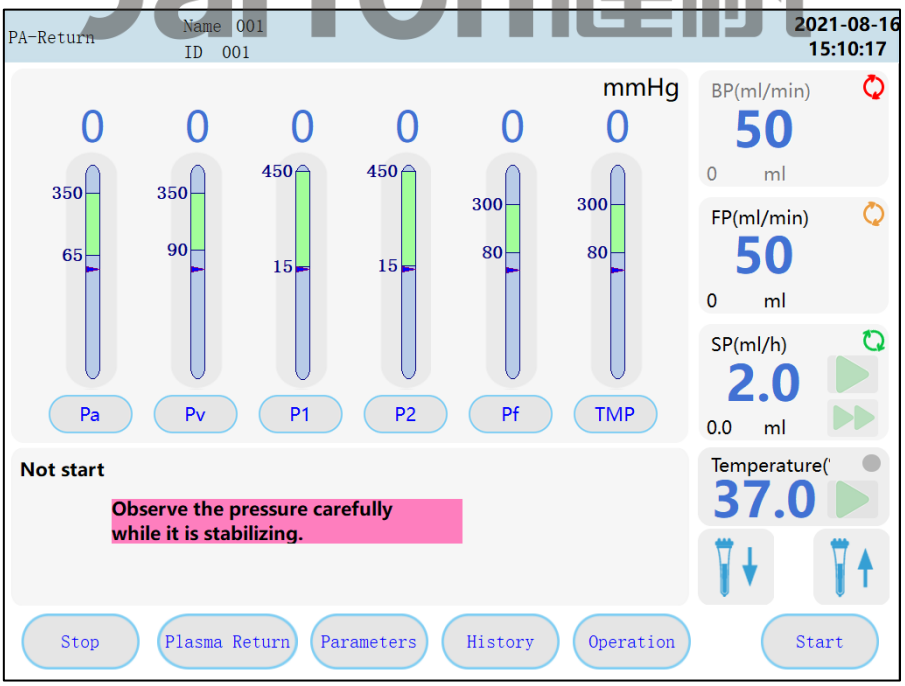


Figure 4-8 Blood return interface

1. Follow the interface prompts to connect the patient's arterial end and blood return to normal saline to ensure that all clamps are open;

2. Press [Treatment Parameter] to set the relevant blood return parameters, or directly click the corresponding parameter icon on the interface to set the data.

3. Press [Start] to start blood return. At this point, only the blood pump is running. When the blood detector detects the clear liquid, the filter pump starts to operate. Please observe it at this time.

4. When the plasma recovery is completed, press the [End] key, all the pumps stop, and the interface prompts the blood return to end;

5. Remove the arterial and venous tubing sets from the patient according to the interface prompts;

⚠Warning

- **During the blood return process, be careful not to allow air to enter the blood tubing set.**

Chapter 5 DPMAS

5.1 Preparation of Articles

When performing DPMAS therapy, you need to prepare the following articles:

(1) 1 plasma separator;

(2) 1 HA330-II hemoperfusion cartridge

(3) 1 BS330 bilirubin perfusion adsorption column;

(4) 1 syringe (20ml or 30ml or 50ml);

(5) Heparinized normal saline for rinsing (several);

(6) Normal saline for return blood (500ml);

(7) 1 set of supporting extracorporeal circulation tubing set;

(8) Other related materials.

⚠Warning

- **Please use the accessories recommended in Chapter 2.8 of this Manual, otherwise it may damage the health of the patient.**

5.2 Startup

Turn on the unit, after completing the self-check, enter the main interface, as shown in Figure 3-1.

After selecting the [DPMAS] mode, it enters the DPMAS treatment tubing set installation interface.

5.3 Tubing Set Installation

The device provides a graphical and streamlined tubing set installation guide. Users can easily install the tubing set according to the instructions of the figures and text.

The main steps of the tubing set installation in the DPMAS treatment mode are:

1. Install the tubing set on the arterial side, the plasma separator and the adsorption column to connect the heparin pump;
2. Install the tubing set on the plasma side;
3. Install the tubing set on the venous side;
4. Confirm the tubing set installation.

⚠Warning

- **It may cause tubing broken and blood losing from patient if user doesn't follow the right method of tubing set installation.**
- **Don't use the tubing which not appointed to use, otherwise the system can't**

provide well accuracy of flow rate or alarm function.

- The tubing set should be installed within right order on right position.
- Please make sure there is no loosen or folding on the connection of tubing.
- Please make sure there is no folding on the blood line.
- Please replace new pressure sensor cover when it's wet.
- The system can't detect the pressure if the pressure tubing is not connected to the system.

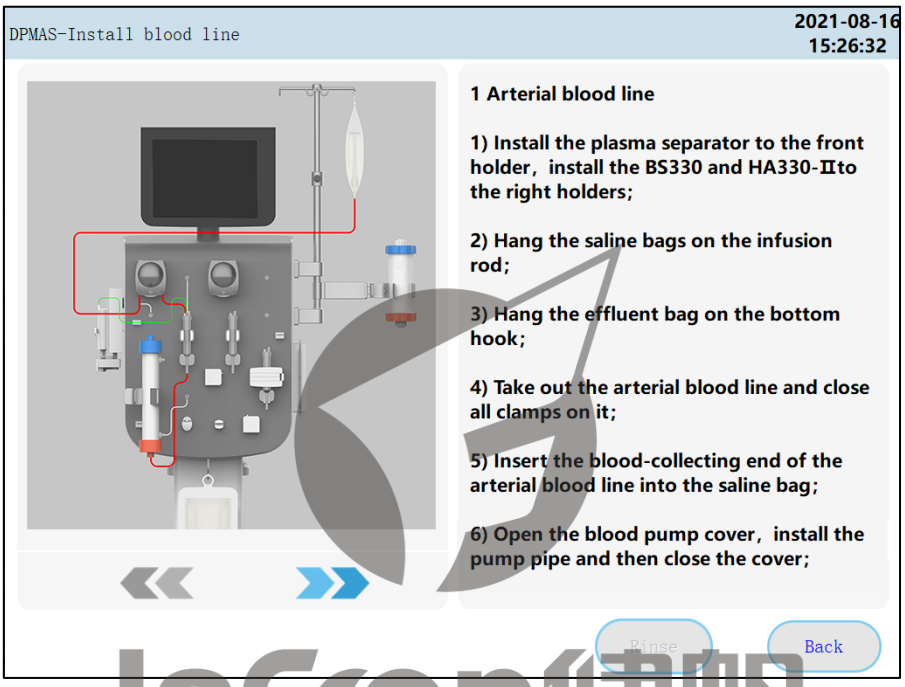


Figure 5-1 Connection diagram of the tubing set on the arterial side for DPMAS

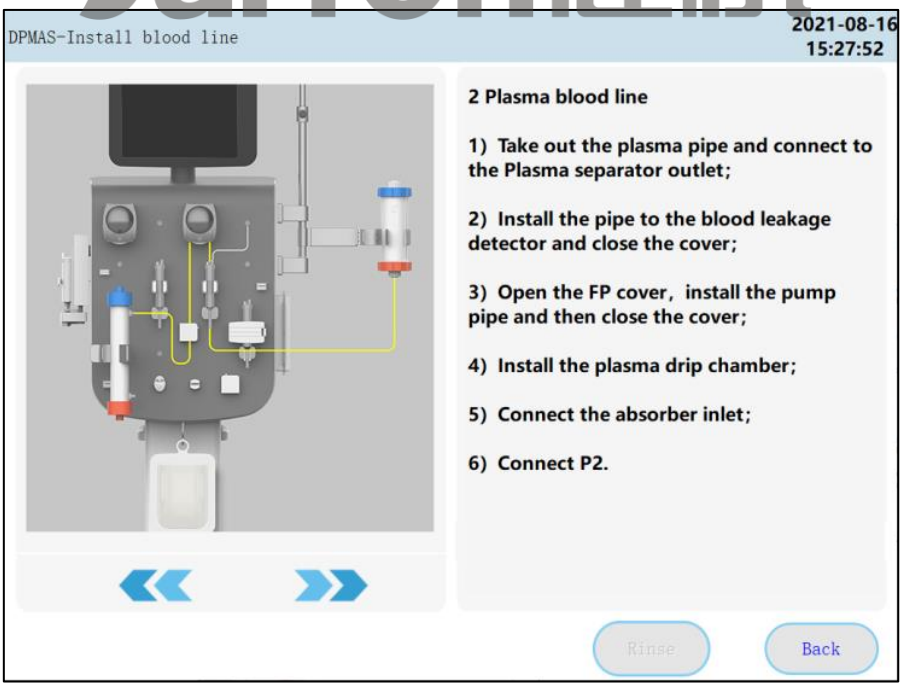


Figure 5-2 Connection diagram of the tubing set on the plasma side for DPMAS

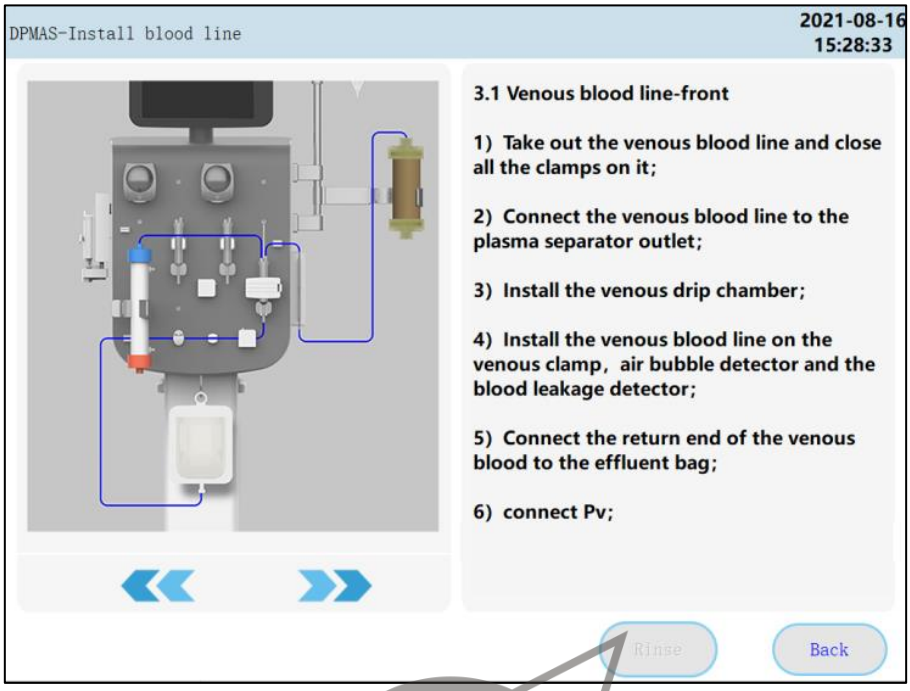


Figure 5-3 Tubing set on the venous side for DPMAS - Front connection diagram

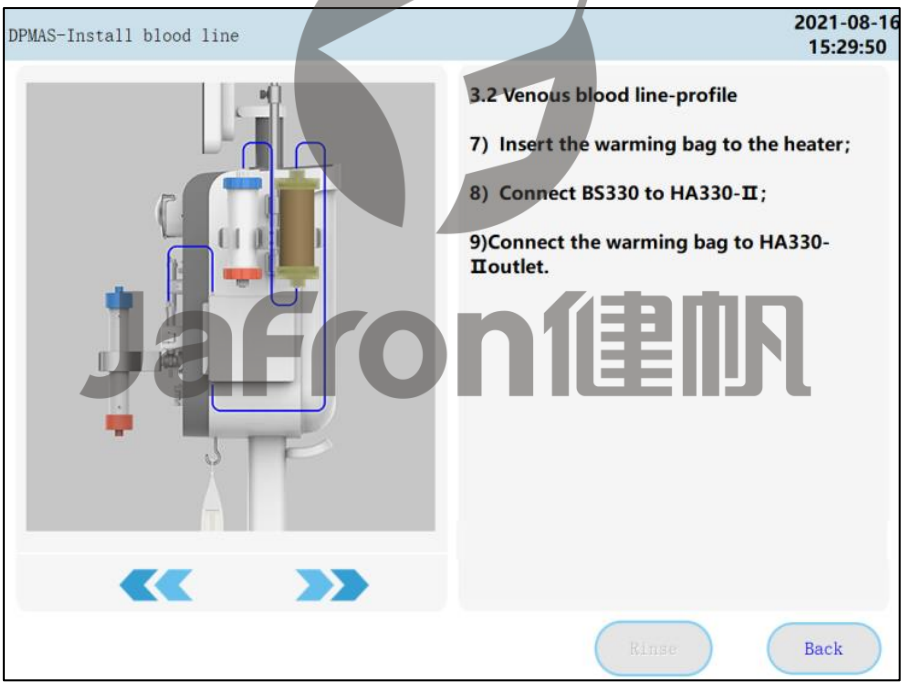


Figure 5-4 Tubing set on the venous side for DPMAS - Side connection diagram

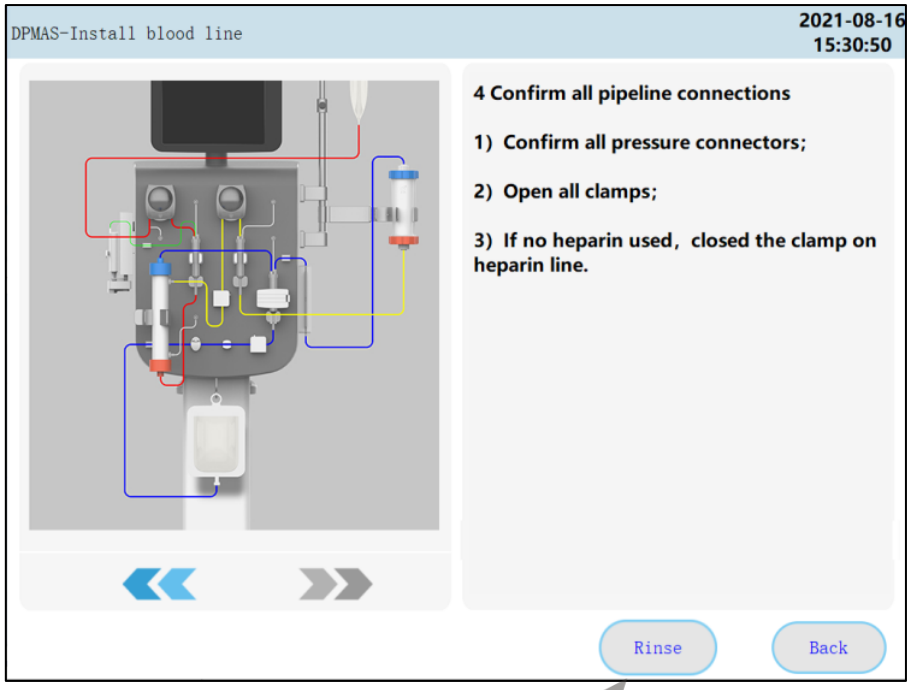


Figure 5-5 Overall tubing set connection confirmation diagram

5.4 Pre-flushing

This device can perform automatic pre-flushing. When the pre-flushing tubing set is installed and connected, click the [Pre-flushing] key to automatically complete the pre-flushing. The pre-flushing interface is shown in Figure 3-5.

If the pre-flushing is completed, it is found that there are still some bubbles in the tubing set, you can press the [Re-pre-flushing] key to pre-flush again. After the pre-flushing is completed, click the [Treatment] key to enter the pre-flushing test.

⚠Warning

- **After pre-flushing, confirm that there is no residual air in the tubing set, otherwise air may be mixed into the patient.**

5.5 Treatment

After the pre-flushing test is passed, enter the treatment interface, as shown in the figure below:

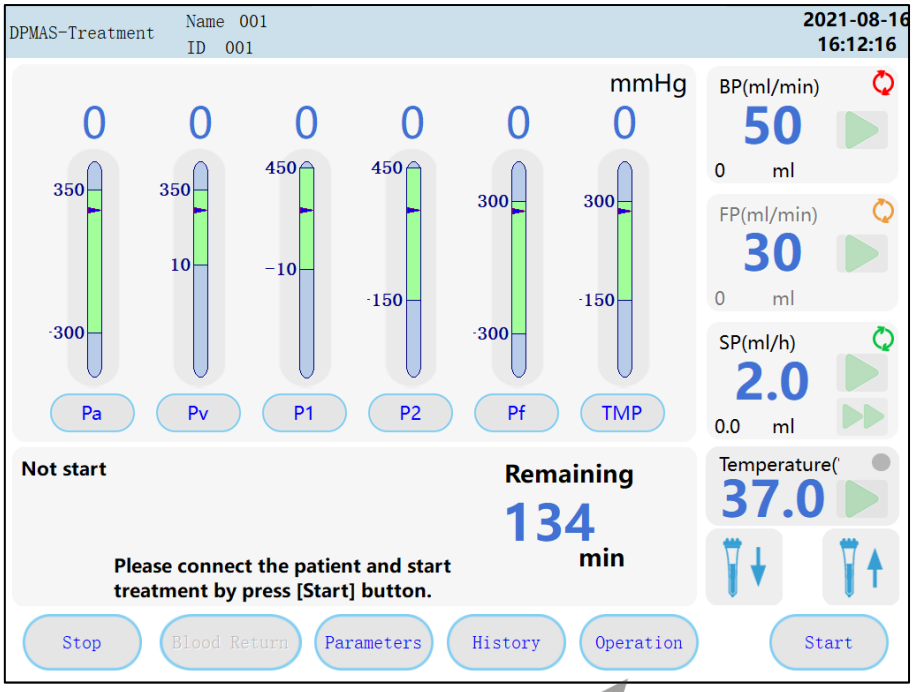


Figure 5-6 DPMAS treatment interface

1. Connect the patient's ports on the arterial and venous ends, respectively;
2. Make sure that the arterial end, the venous end, and the syringe clamp are open (select the heparin tube clamp when the anticoagulation is not applied).
3. Press [Treatment Parameter] to set the relevant treatment parameters, or directly click the corresponding parameter icon on the interface to set the data.
4. Press [Start], the interface will pop up the treatment parameter interface, and start treatment after confirmation.
5. At the beginning of treatment, the blood pump will operate at the set "pumped BP speed". When the blood detector detects opaque liquid, the blood pump speed automatically switches to the set "blood pump speed". At this point, the filter pump starts running at the set speed.

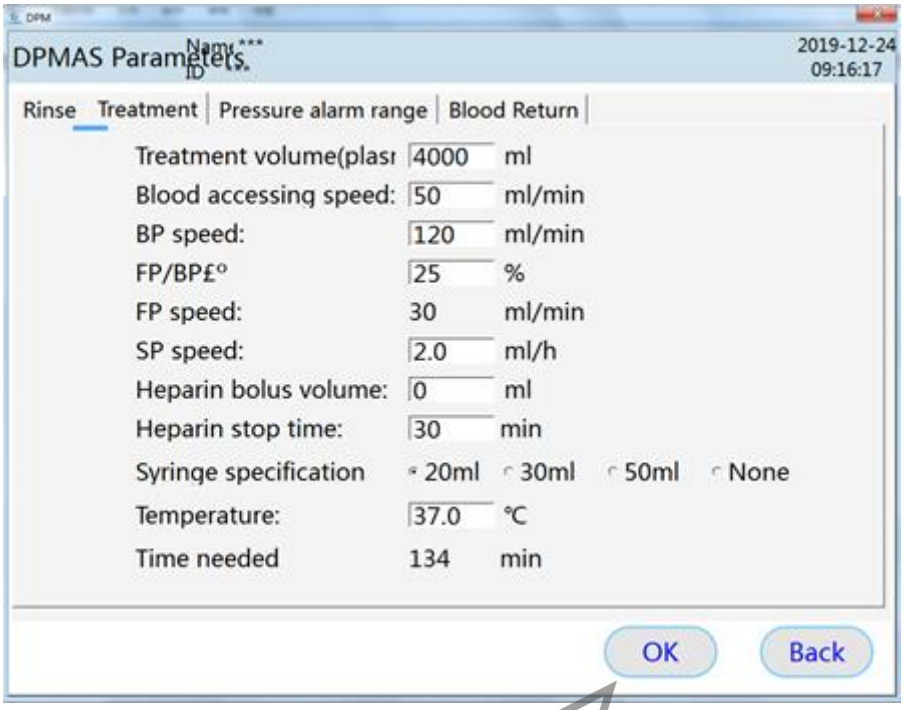


Figure 5-7 DPMAS parameter interface

Parameter	Minimum	Maximum	Default	Unit
Volume for treatment	1000	90000	4000	ml
Blood accessing speed	15	100	50	ml/min
BP speed	15	400	150	ml/min
FP/BP	5	40	20	%
SP speed	0.5	15.0	2.0	ml/h
Heparin bolus volume	0	5	0	ml
Heparin stop time	0	120	30	min
Syringe specification	20ml/30ml/50ml/None		20ml	/
Temperature	35.0	39.0	37.0	℃

Table 5-1 DPMAS parameter configuration

⚠Warning

- **Parameters in this screen can be configured, please select the configurations or explicitly confirm the default configuration before treatment.**
- **Future F20 can't detect all the condition that would cause hemolysis like the narrow passages of extracorporeal circuit. Please check carefully if there is any red or pink fluid in the plasma line during the treatment.**
- **The pressure monitor is a protect system to protect the patient from extracorporeal blood loss especially the venous pressure monitor. But it**

can't totally be relied upon for example during single needle treatment mode. So operator should always pay attention to the extracorporeal blood loss.

- **Operator should consider the effective delivered blood flow rate recirculation of blood in the extracorporeal circuit before setting blood flow rate and treatment target when use single needle treatment mode.**
- **Any coagulum or ultrasound gel in the air detector or the extracorporeal line inside the air detector would cause the air detector failure.**
- **If pressure are negative, the air may enter into the extracorporeal circuit downstream of the air detector. Make sure the return line connected tightened with the patient.**
- **The blood flow rate and thus treatment efficacy may be reduced when the pre-pump arterial pressure is extremely negative.**
- **The use of low delivery rates of device-integrated anticoagulation means (e.g. use of undiluted anticoagulation solution) could lead to delayed and non-continuous delivery due to compliance in the delivery means or output pressure changes in the extracorporeal circuit.**
- **Please use aseptic processing during connect extracorporeal circuit with Disposable hemoperfusion cartridge or with patient.**

5.6 Blood Return

After the treatment is finished, press [Stop Treatment] on the main interface of the treatment, and press [OK] in the pop-up dialog box to terminate the treatment and enter the blood return interface:

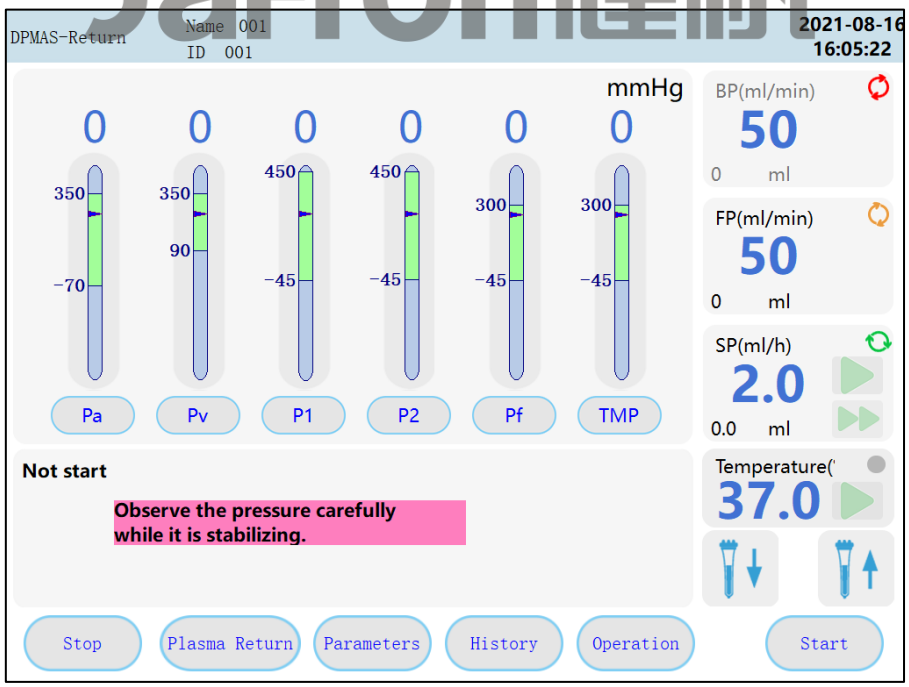


Figure 5-8 Blood return interface

1. Follow the interface prompts to connect the patient's arterial end and blood return to normal saline to ensure that all clamps are open;

2. Press [Treatment Parameter] to set the relevant blood return parameters, or directly click the corresponding parameter icon on the interface to set the data.

3. Press [Start] to start blood return;

4. When the blood detector detects a clear liquid or [End] is pressed, all pumps stop and the interface prompts the blood return to end;

5. Remove the arterial and venous tubing sets from the patient according to the interface prompts.

⚠Warning

- **During the blood return process, be careful not to allow air to enter the blood tubing set.**

Chapter 6 System Function

6.1 Data Storage and Review

The device provides storage and history review of treatment parameters. The data that can be stored and reviewed includes pressure data, heater temperature data, and alarm lists. It can store data within 120 hours.

The history review can be accessed and viewed by clicking the [History] button in the interface during the Treatment and Blood Returen stage.

Alarm information that has occurred will be recorded in the alarm list , including alarm time, alarm name, alarm number and other information. When the device is disconnected from the grid and/or internal battery, the alarm log is still saved and the contents remain unchanged. The alarm system discards the oldest data when the log becomes full.

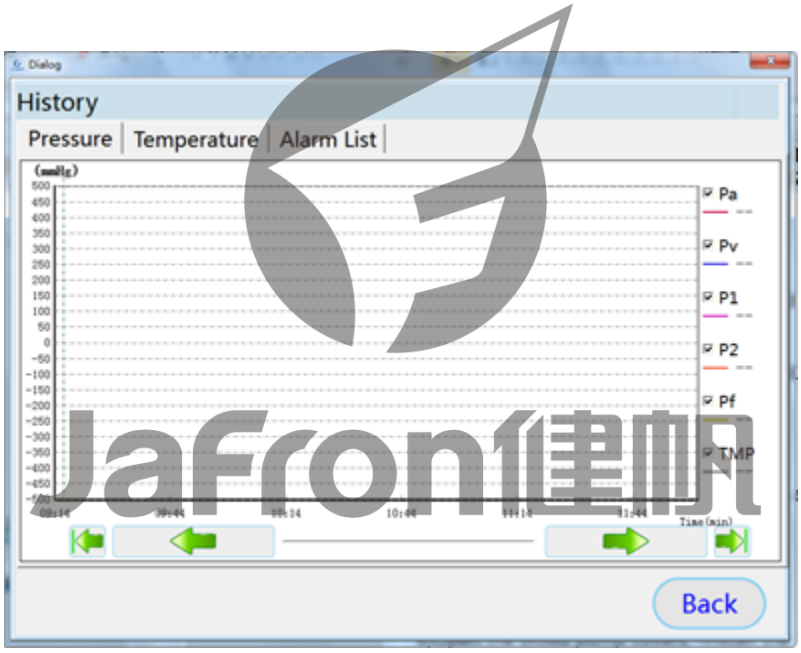


Figure 6-1 Data review interface

6.2 Liquid Level Adjustment Function

In order to prevent the liquid level in the venous pot from being too low or too high, the device provides liquid level detection and regulation. When the liquid level is too low, it may cause bubbles in the venous pot and may further enter the venous tubing set, posing a potential risk to the patient; when the liquid level is too high, blood may enter into the venous pressure joint, resulting in inaccurate measurement.

This device can automatically detect that the liquid level is too low. When this phenomenon is detected, the device will give an alarm. The operator can press and hold the “Liquid Level Up” key as shown in Figure 6-2, and release it after the liquid level rises to an appropriate position.

Figure 6-2 Liquid level up key

When the liquid level in the venous pot is too high, the device cannot automatically detect and needs to be confirmed by the operator. The operator can press and hold the “Liquid Level Down” key as shown in Figure 6-3, and release it after the liquid level drops to an appropriate position.

Figure 6-3 Liquid level down key

⚠Warning

- **When performing the liquid level adjustment, be sure to observe the liquid level to prevent the liquid level from being unnecessarily too high or too low.**

6.3 Heating Function

The device can heat the blood or plasma flowing back to the human body. The temperature setting range is shown in Appendix A, which can be set by the user according to the needs. And the user can start or stop heating by clicking the [ ] key in the temperature display area as needed.

6.4 One-time Additional Heparin

During the treatment, the operator may temporarily add heparin anticoagulant according to the patient’s condition, and the additional dose can be set in advance. And the user can start or stop the heparin injection by clicking the [ ] key in the heparin pump display area as needed; or by clicking the [ ] key in the heparin pump display area to start or stop the rapid heparin addition.

Chapter 7 Alarm Function

7.1 Overview

Alarm refers to the prompt given by the system to the operator through sound, light and other means when the device may cause danger to the patient, the system fails to monitor the safety of the patient due to fault, or the operator should pay attention to the situation.

When an alarm is generated, the operator is 4m away from the human-computer interface of the device and can accurately detect the flashing of the alarm light. The operator can accurately detect the display of alarm content within the range of 1m from the human-computer interface of the device.

⚠Warning

- **When an alarm occurs, please take prompt and appropriate measures to deal with it under the direction of your doctor.**
- **When repeated alarms occur during treatment, the treatment shall be stopped promptly and contact the manufacturer customer service.**
- **When an alarm is caused by a malfunction of this device, the use of the device shall be stopped for repair.**
- **Auditory alarm signal sound pressure levels which are less than ambient levels can impede OPERATOR recognition of ALARM CONDITIONS.**

7.2 Alarm Mode

When an alarm occurs, the device will prompt the user with a visual and audible alarm:

- Light alarm: The alarm indicator flashes when an alarm occurs, and different alarms display indicators of different colors or flashing characteristics.
- Audible alarm: When an alarm occurs, the device uses different sound characteristics to alert different levels of alarms. The alarm sound pressure range is: 65dB ~ 80dB.
- Alarm text: When an alarm occurs, the status bar prompts the corresponding alarm text message.

Among which, the light alarm and the audible alarm distinguish the level of the alarm in different ways.

7.3 Sound Pause

When there is an alarm in the active state in the system, you can enter the alarm sound pause state by pressing the [Sound Pause] key. In this state, the alarm sound is cleared, the alarm light and alarm text remain, and the sound pause icon and countdown are displayed on the right side of the alarm information bar.

The alarm sound is paused for 2 minutes. When the timeout is reached or a new alarm is generated, the

system automatically switches back to the normal alarm state. If the alarm is still active in the current system, the alarm sound will be triggered again.

7.4 Alarm Level

According to the urgency of the alarm and the possible risks, the device divides the alarm into three levels: high, medium and low. The corresponding sound and light representations are shown in the following table:

Alarm level	Alarm light	Alarm sound	Alarm text
High level	Red alarm indicator flashes at a frequency of 2Hz	A group of high-frequency alarm sounds are broadcast every 8 seconds, "beep-beep-beep--beep-beep----------beep-beep-beep--beep-beep----------".	Black font, and red background
Medium level	Yellow alarm indicator flashes at a frequency of 0.6Hz	A group of medium-frequency alarm sounds are broadcast every 12 seconds, "beep-beep----------beep----------".	Black font, and yellow background
Low level	Yellow alarm indicator is always on	A group of low-frequency alarm sounds are broadcast every 20 seconds, "beep----------".	Black font, and yellow background

Figure 7-1 Manifestations of different levels of alarm

⚠Warning

- **The setting of the alarm range shall be combined with the actual conditions of use and set reasonable values under the guidance of a professional doctor. If the set value is unreasonable, a false alarm may occur. Therefore, it is necessary to confirm the actual conditions of use before setting the alarm limit.**

7.5 Alarm Response Measures

⚠Warning

- **When an alarm occurs, the patient's condition shall be checked first.**

When the system has an alarm, please refer to the following steps to take the appropriate measures:

1. Check the condition of the patient;

2. Confirm the parameter or type of the alarm being alerted;

3. Identify the cause of the alarm;

4. For the reason of the alarm cancellation, some alarms need to click the [OK] key to exit the alarm information window prior to processing;

5. Check whether the alarm is eliminated. If it has been eliminated, click the [Retry] key in the alarm window to confirm.

Meanwhile, for the alarm, you can also ignore the alarm for 2 minutes by pressing the [Ignore] key, and the alarm sound and light temporarily disappear. After 2 minutes, if the alarm trigger condition disappears, the alarm no longer appears. Conversely, the alarm reappears.

When the network power and internal power supply are all interrupted, the set treatment alarm pressure parameters cannot be saved.

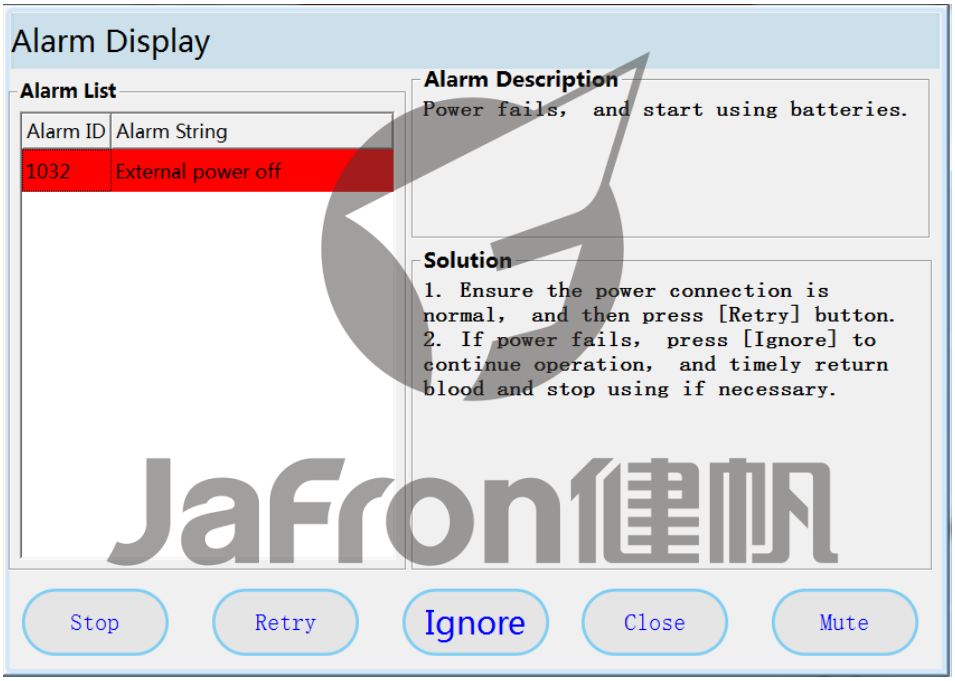


Figure 7-1 Alarm list diagram

Attention

- **For specific treatment measures of each alarm, please refer to Appendix C - *Alarm Information Table*.**
- **The latest data is written and the earliest data is discarded when the alarm log content of the device reaches its capacity.**

7.6 Heparin Pump Blocking Alarm Delay

Flow rate (ml/h)	Measured pressure value (Kpa)	Alarm delay time (min)	Heparin capacity (ml)
0.5	83.65±20	01:38:24	0.82
7.5	86.42±20	00:15:35	1.85
15	87.18±20	00:06:20	1.56

Attention:

1. Test conditions for the above data:

BSA224S-CW electronic balance;

MIK-Y190 pressure gauge;

PC894 stopwatch;

Syringe brand: Jierui.

2. The blocking alarm pressure, the longest delay time, and the maximum heparin capacity are affected by the test conditions.

Appendix A Product Specifications

A.1 Environmental Specifications

Parameter	Specification
Type of protection against electric shock	Class I, equipment with internal power supply
Degree of protection against electric shock	Type CF
Level of protection against liquid ingress	IPX1
Operating mode	Continuous operation

A.2 Environmental Specifications

Parameter	Specification
Operating temperature	10~ 40ºC
Operating humidity	Relative humidity of 20%~75%, with no condensation
Operating atmospheric pressure	70~106kPa
Storage temperature	-20~+40ºC
Storage humidity	Relative humidity of 10% ~ 95%, non-condensing
Storage atmospheric pressure	70~106kPa
Description of storage conditions	In a well-ventilated room with no corrosive gas

A.3 Power Specifications

Parameter	Specification
AC power supply	
Input voltage	AC 100～240V, 50/60Hz±1Hz
Input power	≤350VA
Battery	

Battery quantity	1
Battery type	Rechargeable lithium battery
Nominal battery voltage	DC 18.5V
Battery capacity	5200mAh
Usage time	After full charge, the running time of blood pump shall be no less than 30 minutes
Charging time	It takes about 6 hours to fully charge

A.4 Unit Specifications

Parameter	Specification
Unit dimensions	530×670×1560mm (length×width×height, excluding the infusion support)
Weight (excluding the power cord)	≈48kg
LCD	
Type	Color LCD
Size	12.1”
LED indicator	
Quantity	3 sets
Fuse	
Withstand voltage, and withstand current values	T6.3A H250V
AC power supply interface	
Quantity	1

A.5 Performance Parameters

Parameter	Specification
Blood pump (BP)	Speed: 15~400 ml/min Accuracy: ±10%
Filter pump (FP)	Speed: 15~200 ml/min Accuracy: ±10%
Heparin pump	Speed: 0.5~15 ml/min Accuracy: ± 5% or 0.2ml/h, whichever is greater, and the pressure does not exceed 500mmHg

	Syringe specifications: 20ml, 30ml, and 50ml
Heater	Temperature range: 35 ~ 39°C Power: ≤200W When the blood pump flow rate is 15~300ml/min (including 300ml/min), the accuracy is: ±1°C When the blood pump flow rate is 300~400ml/min, the accuracy is: ±2°C
Arterial pressure	Measuring range: -500~500 mmHg Accuracy: ±10 mmHg
Venous pressure	Measuring range: -500~500 mmHg Accuracy: ±10 mmHg
Inlet pressure 1	Measuring range: -500~500 mmHg Accuracy: ±10 mmHg
Inlet pressure 2	Measuring range: -500~500 mmHg Accuracy: ±10 mmHg
Extramembranous pressure	Measuring range: -500~500 mmHg Accuracy: ±10 mmHg
Transmembrane pressure	Measuring range: -500~500 mmHg Accuracy: ±20 mmHg
Bubble detection	Principle: Ultrasound Minimum bubble volume: 20μL (at a flow rate of 200ml/min)
Blood leakage detection	Principle: Optical Alarm limit: ≤0.35mL/min(if HCT≥32%)

A.6 Pressure Alarm Parameters (in treatment mode)

Parameter		Specification
Arterial pressure	Alarm limit range	-300~350 mmHg
	Alarm upper limit default value	350mmHg
	Alarm lower limit default value	-300mmHg
Venous pressure	Alarm limit range	-10~350 mmHg
	Alarm upper limit default value	350mmHg

	Alarm lower limit default value	10mmHg When the alarm limit setting is less than 10mmHg, the interface will prompt.
Inlet pressure 1	Alarm limit range	-150~450 mmHg
	Alarm upper limit default value	450mmHg
	Alarm lower limit default value	-150mmHg
Inlet pressure 2	Alarm limit range	-150~450 mmHg
	Alarm upper limit default value	450mmHg
	Alarm lower limit default value	-150mmHg
Extramembranous pressure	Alarm limit range	-300~300 mmHg
	Alarm upper limit default value	300mmHg
	Alarm lower limit default value	-300mmHg
Transmembrane pressure	Alarm limit range	-300~300 mmHg
	Alarm upper limit default value	300mmHg
	Alarm lower limit default value	-300mmHg

Attention:

Transmembrane pressure calculation formula:

Transmembrane pressure = (Inlet pressure 1 + Venous pressure)/2 - Extramembranous pressure

Appendix B Electromagnetic Compatibility

The basic performance of the product includes: blood pump flow, pressure monitoring system, air entry protection system, and liquid level monitoring and regulation.

Attention:

- Future F20 Hemoadsorption equipment meets the electromagnetic compatibility requirements of IEC 60601-1-2 and IEC 60601-2-16 standards.
- Users shall install and use the electromagnetic compatibility information provided in the accompanying file.
- Portable and mobile RF communication devices may affect the performance of the Future F20 Hemoadsorption equipment. Avoid strong electromagnetic interference when using, such as near mobile phones, microwave ovens, etc.
- See the Annex for the guidance and manufacturer's declaration.

Waring:

- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of Future F20 Hemoadsorption equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Hemoadsorption equipment (Future F20), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Class A equipment is intended for use in industrial environments. Due to conducted emissions and radiated emissions in Future F20 Hemoadsorption equipment, it may be potentially difficult to ensure electromagnetic compatibility in other environments.
- In addition to the cables sold by the manufacturer of Future F20 Hemoadsorption equipment as spare parts for internal components, the use of accessories and cables outside the regulations may result in increased emission or reduced immunity of Future F20 Hemoadsorption equipment.
- Future F20 Hemoadsorption equipment beyond the service life should be scrapped, otherwise it cannot guarantee the BASIC SAFETY and ESSENTIAL PERFORMANCE under electromagnetic

disturbances.

Cable Information Table

Serial No.	Name	Cable length (m)	Block or not
1	Power cord	1.8	No

Annex:

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Future F20 Hemoadsorption equipment is intended for use in the electromagnetic environments specified below. The purchaser or user of Future F20 Hemoadsorption equipment shall assure that it is used in such an electromagnetic environment:		
Emission test	**Compliance**	**Electromagnetic environment - Guidance**
RF emissions CISPR 11	Group 1	Future F20 Hemoadsorption equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Future F20 Hemoadsorption equipment is suitable for use in all non-domestic and domestic establishments not directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Future F20 Hemoadsorption equipment is intended for use in the electromagnetic environments specified below. The purchaser or user of Future F20 Hemoadsorption equipment shall assure that it is used in such an electromagnetic environment:			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact discharge ±2kV、±4 kV、±8kV、±15kV Air discharge	±8kV Contact discharge ±2kV、±4 kV、±8kV、±15kV Air discharge	Floors shall be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity shall be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	Power supply lines： ±2kV 100 KHz repetition frequency	Power supply lines： ±2kV 100 KHz repetition frequency	Mains power quality shall be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Line to Line ±2kV Line to Groud	±1kV Line to Line ±2kV Line to Groud	Mains power quality shall 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	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250/300 cycle	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250/300 cycle	Mains power quality shall be that of a typical commercial or hospital environment. If the user of Future F20 Hemoadsorption equipment requires continued operation during power mains interruptions, it is recommended that Future F20 Hemoadsorption equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	50Hz：30A/m 60Hz：30A/m	50Hz：30A/m 60Hz：30A/m	Power frequency magnetic fields shall be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T refers to the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Future F20 Hemoadsorption equipment is intended for use in the electromagnetic environments specified below. The purchaser or user of Future F20 Hemoadsorption equipment shall assure that it is used in such an electromagnetic environment:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Conduction RF IEC 61000-4-6	150 kHz to 80 MHz 3 Vrms 6 Vrms （ISM bands between） 80％Am at 1kHz	150 kHz to 80 MHz 3 Vrms 6 Vrms (in ISM bands) 80％Am at 1kHz	Portable and mobile RF communication equipment shall be used no closer to any part of FUTURE F20 Hemoadsorption equipment, including cables, than the recommended isolation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended isolation distance** $d = 1.2\sqrt{P}$
Radiation RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80％Am at 1kHz	3 V/m 80 MHz to 2.7 GHz 80％Am at 1kHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to2.7 GHz Where: P refers to the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; d refers to the recommended isolation distance in meters (m) [b].
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], shall be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol. 

Note 1: At 80MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey shall be considered. If the measured field strength in the location in which Future F20 Hemoadsorption equipment is used exceeds the applicable RF compliance level above, Future F20 Hemoadsorption equipment shall be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Future F20 Hemoadsorption equipment.

[b] Over the frequency range 150KHz to 80MHz, field strengths shall be less than 3V/m.

Recommended Isolation Distance between the Portable and Mobile RF Communication Equipment and Future F20 Hemoadsorption equipment

Future F20 Hemoadsorption equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The purchaser or the user of Future F20 Hemoadsorption equipment can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication equipment (transmitters) and Future F20 Hemoadsorption equipment as recommended below, according to the maximum output power of the communication equipment.

Test Frequency	**Band** (MHz)	**Service**	**Modulation**	**Maximum Power**(W)	**Distance** (m)	**IEC 60601-1-2**	**Compliance**
385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation	2	0.3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820,	Pulse modulation 18 Hz	2	0.3	28	28
1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation 217 Hz	2	0.3	28	28
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11	Pulse modulation 217 Hz	2	0.3	28	28
5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9

Guidance and manufacturer's declaration - electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation [a] 2,1 kHz	65 [b]
13,56 MHz	Pulse modulation [a] 50 kHz	7,5 [b]
a) The carrier shall be modulated using a 50% duty cycle square wave signal. b) r.m.s., before modulation is applied.		

Appendix C Alarm Information Table

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
1001	High	No module detected	Abnormal hardware connection.	The machine is faulty, please stop using it and contact customer service.
1002	High	Abnormal power output	1 24V-A voltage error 2 24V-B voltage error 3 12V-A voltage error 4 12V-B voltage error	Please press [Stop] to enter the shutdown and contact customer service.
1003	High	Bubble detection	1. The bubble detector detects the bubbles. 2. The blood tubing set is not properly installed in the sensor section.	1. If there are bubbles, remove the bubbles and press the [Retry] key. 2. If there is no bubble, please correct the position of the tubing set and press the [Retry] key.
1004	High	Heating bag bulging	Heating bag bulging	1. Please check the tubing set and clamp to ensure that the tubing set is sealed and unobstructed; 2. Slowly release the liquid in the heating bag by adjusting the liquid level; 3. Press [Retry] key after processing.
1005	High	Blood leakage detection	Blood leakage detected.	1. Press the [Ignore] key to check the tubing set in the blood leakage detector. (1) When there are bubbles in the tubing set, please remove the bubbles; (2) When there is liquid outside the tubing set, please dry the liquid; (3) Press the [Retry] key after processing. 2. If the alarm still occurs after processing, press [Ignore] key to sample and analyze the plasma. (1) When no blood leakage or hemolysis occurs, please perform the blood leakage detection calibration and press the [Retry] key.

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
				(2) When blood leakage or hemolysis occurs, press [Stop] to return blood and then replace the separator.
1006	High	No liquid level of venous pot detected	No liquid level of venous pot detected	1. Adjust the liquid level to a suitable position. 2. Press [Retry] key after processing.
1007	High	No tubing set detected in the vein clamp	No tubing set detected in the vein clamp	Make sure that the tubing set is correctly loaded into the vein clamp and then press the [Retry] key.
1008	High	Temperature is too high	The heater detects that the temperature is too high	1. Please lower the temperature. 2. Press [Retry] key after processing.
1009	High	Blood pump reversal	Blood pump reversal	1. Please press the [Retry] key. 2. If the same happens again, stop using it.
1010	High	Filter pump reversal	Filter pump reversal	1. Please press the [Retry] key. 2. If the same happens again, stop using it.
1011	High	Abnormal arterial pressure sensor	Arterial pressure is out of the range of possible measurements.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Press [Retry] key after processing. 3. If the same happens again, stop using it.
1012	High	Abnormal venous pressure sensor	Venous pressure is out of the range of possible measurements.	
1013	High	Abnormal extramembranous pressure sensor	Extramembranous pressure is out of the range of possible measurements.	
1014	High	Abnormal inlet pressure 1 sensor	Inlet pressure 1 is out of the range of possible measurements.	
1015	High	Abnormal inlet pressure 2 sensor	Inlet pressure 2 is out of the range of possible	

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
			measurements.	
1016	High	Upper limit of arterial pressure	The arterial pressure is higher than the upper alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
1017	High	Lower limit of arterial pressure	The arterial pressure is lower than the lower alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
1018	High	Upper limit of venous pressure	The venous pressure is higher than the upper alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
1019	High	Lower limit of venous pressure	The venous pressure is lower than the lower alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
1020	High	Upper limit of inlet pressure 1	The inlet pressure 1 is higher than the upper alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
1021	High	Lower limit of inlet pressure 1	The inlet pressure 1 is lower than the lower alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
1022	High	Abnormal running of blood pump	1. The blood pump running speed error exceeds the specified	1. Please press the [Retry] key. 2. If the same happens again, stop using it.

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
			value.□ 2. The blood pump encoder is abnormal;	
1023	High	Abnormal running of filter pump	1. The filter pump running speed error exceeds the specified value.□ 2. The filter pump encoder is abnormal;	1. Please press the [Retry] key. 2. If the same happens again, stop using it.
1024	High	Low battery	The main power supply is de-energized and the battery power is running out.	1. Please connect the power and press the [Retry] key.□ 2. If the power cannot be connected, press the [Stop] key to enter the shutdown.
1025	High	Syringe pole is detached	The syringe pole is detected to be detached from the slider during operation of the heparin pump.	1. Install the syringe correctly on the pole. 2. Press [Retry] key after processing.
1026	High	Check the syringe installation status	The syringe is detected to be improperly installed during operation of the heparin pump.	1. Please confirm whether the syringe capacity is correct. 2. Please confirm whether the syringe is installed properly.□ 3. Press [Retry] key after processing.
1027	High	Abnormal running of Heparin pump	The Heparin pump running speed error exceeds the specified value	1. Please press the [Retry] key. 2. Please stop using if the same situation occurs.
1028	High	Blood pump cover is open	Blood pump cover is open	1. Please confirm whether the pump tube is installed properly. 2. Please close the pump cover. 3. Press [Retry] key after processing.
1029	High	Filter pump cover is open	Filter pump cover is open	1. Please confirm whether the pump tube is installed properly. 2. Please close the pump cover. 3. Press [Retry] key after processing.
1030	High	Blood pump shutdown	Blood pump shutdown	1. Please press the [Retry] key. 2. If the same happens again, stop using it.

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
1031	High	Filter pump shutdown	Blood pump shutdown	1. Please press the [Retry] key. 2. If the same happens again, stop using it.
1032	High	The external power supply is disconnected	The power is turned off and the battery starts to be activated.	1. Please make sure that the power connection is normal and then press the [Retry] key. 2. If there is a power outage, please press [Ignore] key to continue the operation. If necessary, please return blood and stop using it.
1033	High	Inadequate blood drainage	The blood drainage is inadequate	1. Confirm the artery side lines and clamps are all open, and lines are not folded. 2. Confirm the blood drainage puncture is good. 3. Press [Retry] button after handling.
2001	Medium	Pause time is too long	In the state where the injection flow rate is zero, the stop state lasts for more than 2 minutes during the treatment and in the blood return mode.	When you forget to release the pause, start treatment.
2003	Medium	TMP upper limit	TMP is higher than the upper alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted.□ 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing. 4. Press [Retry] key after processing.

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
2004	Medium	TMP lower limit	TMP is lower than the lower alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
2005	Medium	Upper limit of extramembranous pressure	The extramembranous pressure is higher than the upper alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
2006	Medium	Lower limit of extramembranous pressure	The extramembranous pressure is lower than the lower alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
2007	Medium	Upper limit of inlet pressure 2	Occur when the inlet pressure 2 is higher than the upper alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water.

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
				2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
2008	Medium	Lower limit of inlet pressure 2	Occur when the inlet pressure 2 is lower than the lower alarm value.	1. Please check the tubing set, clamp and filter to ensure that the whole circuit is sealed, unobstructed, and free from coagulation and the protective cap is free from water. 2. Please confirm whether the pressure alarm limit needs to be adjusted. 3. Please confirm whether the pump speed needs to be adjusted; 4. Press [Retry] key after processing.
2009	Medium	Blood leakage detector cover is open	Blood leakage detector cover is open.	1. Please confirm whether the tubing set is installed properly. 2. Please confirm whether the blood leakage detector cover is closed properly. 3. Press [Retry] key after processing.
2010	Medium	Heparin pump blockage	During the operation of the heparin pump, the pressure on the pole is too high.	1. Please confirm whether the anticoagulant needs to be replenished; 2. Please check the heparin tubing set and clamp to ensure that the tubing set is sealed and smooth; 3. Please confirm that the syringe model is entered correctly; 4. Press [Retry] key after processing.
2011	Medium	Warming failure	Warming failure	If the heating fails, press [Retry] key to re-detect. If the alarm cannot be eliminated, consider stopping the treatment and returning blood, or turning off the

Alarm ID	Alarm level	Alarm information	Cause analysis	Countermeasure
				warming function and then continuing the treatment.
3001	Low	The syringe will be empty	The syringe will be empty	Add anticoagulant if needed.
3002	Low	The syringe has been empty	The syringe has been empty	Add anticoagulant if needed.
3003	Low	Not connected to battery	Not connected to battery	The battery is not connected, and there is a risk of power failure after continued treatment
3004	Low	Pre-flushing TMP is higher than 100mmHg	Pre-flushing TMP is higher than 100mmHg	If the filter transmembrane pressure limit is less than 100mmHg, please end the pre-flushing;
3005	Low	Blood detector cover is open	Blood detector cover is open.	1. Please confirm whether the tubing set is installed properly. 2. Please confirm whether the blood detector cover is closed properly. 3. Press [Retry] key after processing.