NIGALE

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DigiPla 80/DigiPla 90

Plasma Separator

Operator's Manual

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Statement

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1) Assembly operation, expansion, re-adjust, improvement, and repair are conducted by personnel authorized by Nigale.
2) Relevant electrical equipment complies with national standards.
3) The product is operated in accordance with this operator's manual.

Service Police

Scope of free services:

All products according with the warranty service regulations can enjoy free services.

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2 Even under the warranty period, maintenance services caused by the following reasons will be charged: man-made damages. misoperation. network voltage exceeds the prescribed limit of product. irresistible natural disaster. replace parts or Disposable without permission of Nigale or maintain the product by personnel not authorized by Nigale.

⚠Warning:	**If each plasma station, hospital or organization responsible for using of this equipment cannot provide a satisfactory repair/maintenance plan, it may cause abnormal equipment failure, or even may endanger human health.**

Return Procedure

If there is a need to return goods, please follow the procedures below:

1. Obtain the right of return: Contact with sales service department of Nigale, and provide them with product model, which is marked on the outer packing case of the product. Please specify the product model and brief the return reasons.
2. Freight: Users shall bear the freight for delivering product to Nigale for maintenance (including customs fees).

Sales Service Department

Sales service department of Sichuan Nigale Biotechnology Co., Ltd.

Address: 4th F, No.2 Factory Building, Shiyang Industrial Park, No.55, Section 5th, Qingyun village, Hi-Tech District, Chengdu.

Zip Code：610041

24-hours Service Hotline (China Mainland Only)：400-606-9696

Fax: +86 28-85130655

Explanation

1 After purchasing the product, the customer is fully responsible for the maintenance and management of this device.

2 Even under warranty period, the quality guaranty does not include the following contents:

1) Damages or losses caused by wrong or rude operation.
2) Damages or losses caused by force majeure including fire, earthquake, flood or lightning.
3) Damages or losses caused by failing to meet the using conditions specified for the product, such as shortage of power supply, wrong installation, or unsatisfied environmental conditions.
4) Damages or losses caused by failing to use the product in the purchase place.
5) Damages or losses caused to products not purchasing from Nigale or its authorized dealers or agents.

3 Only medical personnel with professional certificates and having taken related operation training of the product can use the product.

4 It is prohibited to modify the software or hardware of the product without permission.

5 In any case, Nigale bears no responsibility for any problems, damages or losses caused by reinstallation, modify or repair conducted by unauthorized personnel of Nigale.

6 This product is intended to provide power equipment of plasma collection for health care personnel.

7 It is a must to back up important data to external storage medium, such as collection records, etc.

8 Nigale bears no responsibility for data loss stored in the product caused by fault of operators or abnormal conditions.

9 This operator's manual contains foreseeable warnings with potential risks. Maintain a high vigilance for those not-stated dangers at any time. Nigale bears no responsibility for damages and losses caused by neglecting or ignoring preventive measures stipulated in the operator's manual.

10 Once the owner of the product changes, this operator's manual shall also be transferred.

Preface

Thank you for buying DigiPla 80/DigiPla 90 plasma separator.

Before using this device, please carefully read the operator's manual for proper use of the devic.

After reading, please keep this manual properly and put it in a convenient and accessible location.

Product Information

Product name:	Plasma separator
Product model:	DigiPla 80/DigiPla 90
Product structure and composition:	Consists of host and pressurizing cuff. the host includes centrifuge, blood pump, anticoagulant pump, weigher, air detector, line pressure monitor, solenoid valve, control panel. Adapter of weigher can be bottle-type or bag-type. Pole can be of Φ10 or Φ12 type.
Application scope:	Applicable to plasma collection.
CE	No. G1 14 08 67972 003
Registered office:	No.28 KuiXing Road, 641400 Jianyang, Sichuan,
Production address:	4th F, No.2 Factory Building, Shiyang Industrial Park, No.55, Section 5th, Qingyun village, Hi-Tech District, Chengdu, China.

Description

This manual mainly describes the structure and composition, basic function, installation, operation, and maintenance, etc. of DigiPla 80/DigiPla 90 Plasma Separator.

Illustration

As the product model, software version, preset settings and option configurations may be different, the pictures in this manual may differ from the actual product purchased, please subject to the actual situation.

Pictures in this manual are only used as examples or explanations.

Issuing date of this manual: 2014-11, version No.: D

Contents

1. Important Information

1.1 Application Scope

DigiPla 80/DigiPla 90 plasma separator adopts advanced computer technology, peristaltic pump technology of transmitting pollution-free fluid and blood centrifugal separation technology, to complete raw material plasma collection for clinical and biological products.

1. Basic operating principle

In a closed single-use product, whole blood is collected into a centrifuge bowl through the blood pump. Various blood components have different density, and the centrifuge bowl rotates at high-speed in the centrifuge for blood components separation, to obtain high-quality plasma, and ensure that other components are free from damages and safely return to donors.

2. General operation process

Plasma separator is operated in single needle penetration. During the plasma collection process, the blood of donors and anticoagulant are mixed in an appropriate ratio in pipeline, and various components are separated from the anticoagulated whole blood in the centrifuge bowl. When the centrifuge bowl is full, the separated components will outflow from the bowl, the components need to be collected will enter into the plasma collection bottle/bag, and the remaining will return to donors.

The whole process is fully automated, just requiring the operator to install disposable and start the separator. The operating information is displayed on the screen of separator.

1.2 Symbols Meaning

This manual uses the following symbols as instructions regarding safety and other important matters. Specific meanings are as follows:

Symbol and vocabulary	Meaning
⚠ **Danger**	It indicates there will be an imminently hazardous situation, if not avoided, will result in death or serious injury.
⚠ **Warning**	Personal injury may occur in the place, including warn the operator against potential danger.

Caution	Provide additional information may be useful to the operator at different steps. Please note that it may include non-critical information, however, the operator should always review background information.
Prompt	Inform conditions that may damage the product, affect the result or cause unnecessary alarms.

1.3 Warning Message

1.3.1 Safety Warning

1. The storage and transportation and use of the separator must conform to the environmental conditions specified in the manual.

⚠ **Danger: Do not use the separator in environment with flammable gases (such as anesthetic gases, oxygen and hydrogen) or flammable liquid (such as ethanol), or there may cause an explosion.**

⚠ **Warning**: Keep the separator dry, avoid immediately starting up after quickly moving it from a cold place to a warmer place, or it may cause a short circuit due to condensation or water droplets.

⚠ **Warning**: The storage and transportation and operating conditions of the separator must meet the requirements (refer to chapter 7), and avoid storing and using in places with direct sunlight, sudden temperature change, condensation, dust, vibration-prone, or near a heat source.

2. It is necessary to connect the power plugs as well as its external connected devices to the power socket on the wall directly, and the socket must be well grounded and meet the rated power requirement.
3. Please use options provided or recommended with the separator, and use cables provided with the separator. Using other external devices or cables will reduce product performance, or even cause an electrical shock.
4. Do not use the separator in areas where water may enter the cabinet. To avoid risk of electric shock, do not pour any liquid on the product or let the liquid flow into the product.
5. Do not open cabinet. If the cabinet is opened in case of energization, it will cause a short circuit or electric shock.

6. Before cleaning the separator, please shut down the separator's power switch and unplug to avoid electrical shock hazard.
7. It is prohibited to directly unplug when the power is not shutting down, or this may cause damage to the separator or electrical shock.
8. If the fuse burned, it indicates that the separator or the external device breaks down, please contact our after-sale service department or the dealer. Do not handle the problem by yourself.
9. It is prohibited to use in environment with strong electric or magnetic fields (such as near transformer), or it will adversely affect the separator.
10. For disposal of the separator or any accessory, please contact our after-sale service department or the dealer. Do not dispose the product on your own. The Company bears no responsibility for any damage caused by not complying with this requirement.
11. Connection of power socket supplying power to the separator must conform to IEC standard, the fire wire and zero wire may not be reversely connected, and the zero wire and ground wire are not allowed to shortly connect. Moreover, the ground wire must be connected to the ground according to regulation.
12. Do not let any part of the body or clothes get twisted by the high-speed rotating device, so as to avoid serious injury.

1.3.2 Warning Related to donor

1. Before performing collection procedures, donors must be well selected and taken physical exam according to relevant national regulations, and shall be in good health on the date of collection.
2. Extracorporeal circulation is exposed to the risks of blood loss, hemolysis, air embolism, and/or blood clotting. In order to minimize these risks, do not deviate from the steps described in the operator's manual of the separator.

Caution: Donors should aware the basic knowledge of plasma collection process and the potential risks of air embolism and anticoagulant reactions.

3. Plasma collection volume should be conformed with national regulations.
4. Citrate and/or calcium metabolism may cause excessive anticoagulant reactions to donors.

Caution: Donors should understand that adverse reactions may occur during the return process, and if such reactions occur, he/she shall inform the operator immediately for timely processing.

1.3.3 Warning Related to Disposable

1. Disposable used in the separator include single-use pipeline supplies and various solutions, which cannot be reused.
2. All disposable shall be stored in a dry and ventilated place without chemical volatiles. When contacting the disposable, the hands or gloves should be kept clean and dry.

⚠ **Warning:** Single-use pipeline supplies used by the product shall be the series of single plasma separator produced by Nigale. Otherwise, the adverse effects caused thereby may be borne by the operator.

3. If liquid or particulate matter is found in the pipeline, centrifuge bowl or storage container, or the solution is found turbid, do not use it.
4. Operators shall ensure the correct hung of anticoagulant bag and saline bag. The red hook is used to hang anticoagulant, and the blue hook is used to hang saline.

⚠ **Warning:** Operators must ensure that the anticoagulant and saline are connected to the right position, otherwise, it will cause that the blood fails to coagulate or cause a large quantity of anticoagulant infuse into the donor's body during the return process, which can be dangerous. The spike of the anticoagulant is red, and the spike of saline is blue, white or transparent.

5. It is required to carefully check whether the pipeline is installed in the correct position on the device, and there shall be no twist and kink. Before using the pipeline for plasma collection, the operator should carefully check the suitability of pipeline and correctness of pipeline installation.

⚠ **Warning:** During the process of plasma collection, if the pipeline for plasma collection is blocked, the pressure inside the centrifuge bowl will rise significantly and thus cause hemolysis or leakage of blood.

⚠ **Warning:** It is necessary to correctly install the square pad on the stationary section of the centrifuge bowl to the cover bowl collar on the cover of centrifuge. Be sure this installation is correctly performed, otherwise the centrifuge bowl will rotate eccentrically, and the fixed and rotating parts around the sealing ring of centrifuge bowl will generate abnormal friction, which can overheat and cause hemolysis. If this happens, the blood in the disposable cannot be considered as safe blood and returned.

6. If the pipeline is found leakage at any time, operators shall terminate the collection. All out-leaked blood shall be cleaned according to relevant regulation for contamination handling

procedures.

7. The centrifuge bowl is filled with sterile air when leaving factory. During blood collection, this air is displaced to the plasma bag/bottle. During return, the air is transfered back to the bowl. The procedure of transfered air from the plasma bag/bottle back into the bowl is very important, which can avoid negative pressure generated to the empty bowl.

Prompt: The plasma valve is closed at the first seconds of return, thus generating slight negative pressure in the pipeline, so as to clear the collection pipeline when opening the plasma valve.

1.3.4 Warning Related to Operating Procedure

1. Ensure the entire operating procedures are pollution-free.
2. Before using the separator, ensure that the operator is trained, and the operator should carefully read this operator's manual.
3. Hemolysis will not occur based on design principle, but the operator should still follow the normal practices to avoid any hemolysis in plasma. If hemolysis is observed, the operator should immediately end the program before return to the body, and shall deal with such situation according to standard operating procedures.

Prompt: Red blood cells in the collection process should not enter the plasma storage container, if there is red blood cells overflow or free-hemoglobin, check immediately. If this reason cannot be determined, immediately stop the operation, and do not return the remaining to the donor.

4. Though the separator is operated automatically, the operator shall monitor the separator for the entire operating procedures. It is not allowed to make the donor uncared.
5. The system cannot detect foam by design. If a large number of foam appear in the return-blood vessel or in the filter of return-blood vessel, then end the program in advance and do not return.
6. Adjust and control the flow rate of saline, so as to avoid excessive saline infusing to the donor.

⚠ **Warning**: When infuse saline through gravity, or infuse saline manually, the operator shall check and monitor whether there is air in the pipeline.

1.3.5 Warning Related to Plasma Separator

1. In order to protect donor's and patient's safety, the separator -to-ground leakage current shall not exceed 100uA in the case of open circuit.
2. A defective bearing, seal ring, or lubricant failure can lead overheating to centrifuge bowl

holder, which will cause damage hemolysis.

Caution: If the centrifuge bowl holder is found significantly overheating during operation, the red blood cells shall be considered to be unsafe, and shall not return to the donor.

3. In order to ensure correctness of air detector, its surroundings and inside shall be kept dry.

1.4 Contraindication

It is prohibited to use this product when the blood is not fully anticoagulated.

1.5 Adverse Reaction

Adverse reactions may occur to the donor during the plasma collection process includes:

1. Same adverse reactions occurred in the conventional blood-collection process. These reactions include "dizziness", faint, vomit, hyperventilation, and hematoma formed at the venepuncture site. In addition, faint reactions may also occur caused by hypovolemia.
2. Abnormal reactions may also occur in the collection process. Allergy symptoms can be observed, including skin erythema, itching, and hives, etc. Low saline temperature or cooling of donor's blood can cause chill. The donor is infused with anticoagulant containing citrate, chelating a non-metabolizable citrate with calcium, which will cause moderate hypocalcemia symptoms to the donor. Such reactions have been proven by "tingling", often in the mouth or fingers. Other reactions may include muscle discomfort, muscle twitches or spasm, or abnormal sense of taste in mouth. If such symptoms occur, then the operator should temporarily stop or reduce blood-return speed.
3. Such complications as blood loss, hemolysis, air embolism, blood clot and the like may be related to incorrect operation.

⚠ **Warning:** The operator shall be quite familiar with the performance and doses of various medicines used in the blood processing procedures, as well as their application methods, packages and all other information.

1.6 Qualification and Care of Donor

1. The donor must conform to the requirements of relevant state laws and regulations.
2. After plasma collection is completed, the collection operator should instruct the donor to hold the venepuncture site with a sterile swab. If the donor's sleeve is found tight, it should be relaxed, to avoid hematoma or bleeding.
3. The donor shall be made to know and aware of that no obvious inadaptation phenomenon will occur to healthy person after plasma donation, and some phenomenon such as dizziness, weak,

nausea, vomit and palpitation may occur during plasma collection. The venepuncture site may occasionally appear hematopedesis, cyanoderma or mild discomfort in plasma collection, and it may take days to recover, very few donors may have phlebitis caused by improper clean, and very few donors may have adverse reactions and other related symptoms caused by plasma collection.

4. During the process for plasma donation, the operator should observe whether there is discomfort of the donor, timely inquiry and treat when necessary.
5. The adverse reactions of the donor shall be treated according to relevant regulations.

2. Composition and Structure

2.1 Composition

The separator is composed of host and pressure cuff.

2.2 Standard Configuration

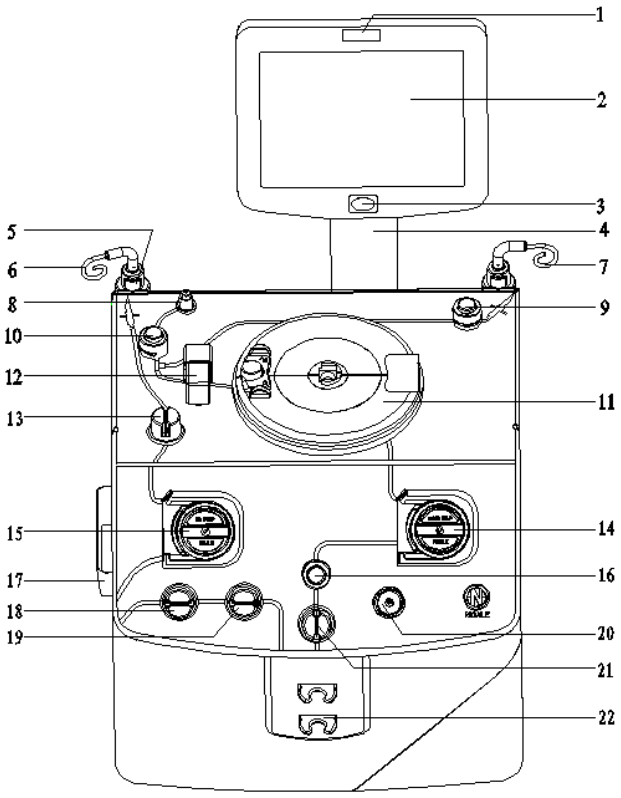
1 Host and its accessories (including options)

2 Standard pressure cuff.

3 Other accessories (including document)

2.3 Appearance Structure

2.3.1 Front View

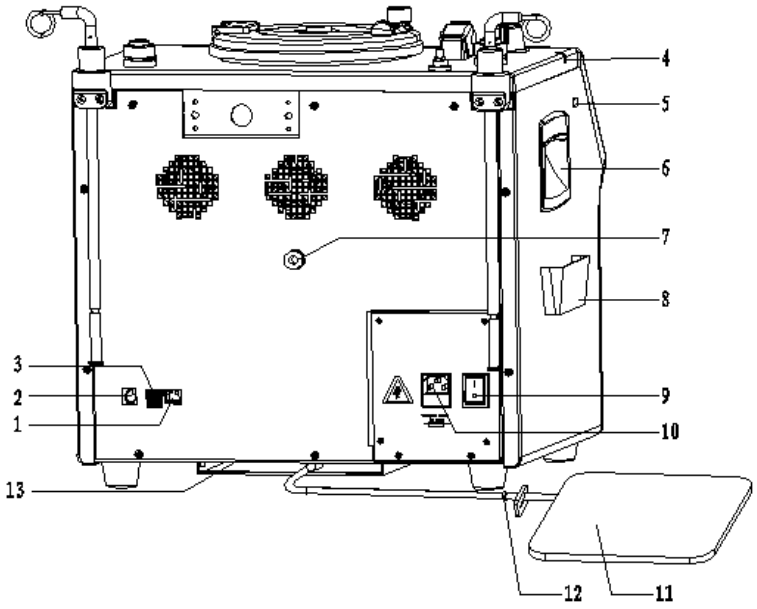


No.	Part Name	Purpose
1	Indicator light	Send light prompt when there is prompt information or an alarm, and it flash color is same with the alarm background color on the display. The high priority alarm is red, medium priority and low priority alarm is yellow, and prompt information is blue.
2	Display screen	Display image and parameters and other information.
3	Stop Key	Stop the separator operation, as well as the pump and centrifuge. In the running process of collection stage: click the button, a Dialog with **Return** and **Exit** pops out, double click the button, a Dialog with **Draw**, **Return** and **Exit** pops out. In the running process of return stage: click the button, a Dialog with **Draw** and **Exit** pops out, double click the button, a Dialog with **Draw**, **Return** and **Exit** pops out. Stop state (including alarming state): click the button and a Dialog with **Exit** pops out.
4	Display arm	Connect to the display and cabinet.
5	Pole button	Fix the pole.
6	Anticoagulant pole	Hang the anticoagulant container. Press the pole button and pull the pole out. The pole is fixed when you hear a sound and the button pops out. When lowering the pole, press the pole button to let the pole fall free.
7	Saline pole	Hang saline container, and the use is same as anticoagulant pole.
8	Weigher	Can be assembled with bottle or bag weigher, the plasma collection bottle is placed on the monitor and the plasma collection bag is hung on the bracket of the weigher. It can monitor the net weight of plasma in collection bottle/bag, and the unit is in g/ml. The weight is displayed in the display screen of plasma separator. During blood collection, the separator will automatically deduct the weight of collection bottle/bag

9	Saline valve	Control the open and close of saline pipeline. During return phase this valve is opened to refuse saline to the donor according to the setting value.
10	Plasma valve	Control the open and close of plasma pipeline. Plasma valve opens up when the draw phase and return phase without saline compensation, so that the plasma can flow from the centrifuge bowl exit to plasma collection bottle/bag or the sterile air can return to the centrifuge bowl.
11	Centrifuge	The centrifuge will drive the centrifuge bowl rotating at high speed when operating, and provide driving force for separating the liquid in the centrifuge bowl. When the centrifuge bowl leakage, the fluid sensor inside the centrifuge will give an alarm immediately, and stop the centrifuge and pump.
12	Line sensor	Detect the overflow of blood cells in plasma collection process, so as to stop the draw phase and shift to the return phase.
13	Anticoagulant line air detector (ALAD)	Monitor the air in the anticoagulant pipeline
14	Blood pump	Transfer anticoagulanted blood and blood components in the pipeline between donor and centrifuge bowl.
15	Anticoagulant pump	Transfer anticoagulant in the pipeline between anticoagulant bag and blood collection joints.
16	Blood valve	Control the open and close of blood pipeline. It is the last valve for blood pipeline connecting to the donor, thus working as a safe valve.
17	Donor line air detector 1 (DLAD1)	Monitor the air in the pipeline between the donor and blood filter. If air is detected in the pipeline, the separator will trigger an alarm and stop operating, so as to ensure the safety of donor.

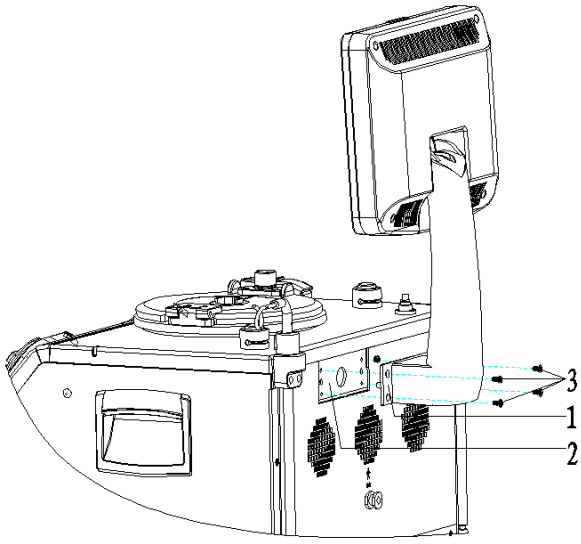
18	Donor line air detector 2 (DLAD2)	Monitor the air in the pipeline between the donor and blood filter. If air is detected in the pipeline, the separator will trigger an alarm and stop operating, thus become a backup of air detector for blood pipeline.
19	Cuff trough	Place cuff.
20	Donor pressure monitor (DPM)	Monitor the pressure in the blood pipeline of donor during draw and return phase, adjust the pump speed according to pressure, give an alarm when the pressure exceeds the specified range, and stop the separator. The pressure change is displayed on the LCD screen on bar chart.
21	Blood line air detector	Monitor the pipeline between the blood filter and centrifuge bowl. If air is detected in the pipeline, the separator will trigger an alarm and stop operating, so as to ensure the safety of donor.
22	Filter bracket for blood and blood components	Support and fix the blood filter.

2.3.2 Side Rear View



No.	Part Name	Purpose
1	Ethernet port	Connect with the network
2	Serial port	Maintain and test product
3	USB interface	Connect with external equipment such as code scanning gun
4	Protective cap slot	Fix the protective cap of needle
5	Blood pressure indicator light	Blood pressure indicator light ： green lamp on: moderate pressure. green lamp flashing: low pressure, the blood pump entering into the automatic speed control state, but in an acceptable range, reminding the donors making a fist. red lamp on: pressure too low, the blood pump stop and low pressure alarm, option.
6	Handle	Convenient for separator moving
7	Cuff Connector	Connect with pressure cuff
8	Cuff trough	Place cuff
9	Power switch	Turn on/off the power
10	AC power input socket	Connect with the system power line
11	Waste liquid bag	Collect the leaking liquid in centrifuge
12	Drain connector	Connect with waste bag at the leakage collector exit of separator
13	Waste bag holder	Place waste bag

2.3.3 Installation of Display

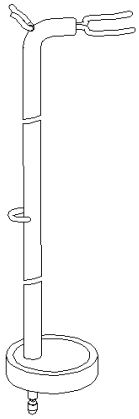


Install the display arm 1 on the installation hole 2 at the rear cover of the separator (install four M4 screws along the dotted line in alignment)

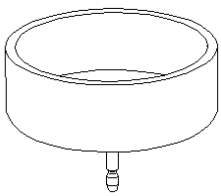
2.4 Installation Requirement for the Complete Machine

1. The complete machine is installed horizontally with proper height after installation: ensure the collection set are easy to install, and try to keep the centrifuge is in the same height with the heart of donor.
2. Ensure there is no foreign matter at the bottom of the separator, and the ventilated window is not blocked.
3. Ensure the separator identification (such as power input part) and the like are not overlapped after installation.

2.5 Options



Bag -type weigher collection adapter

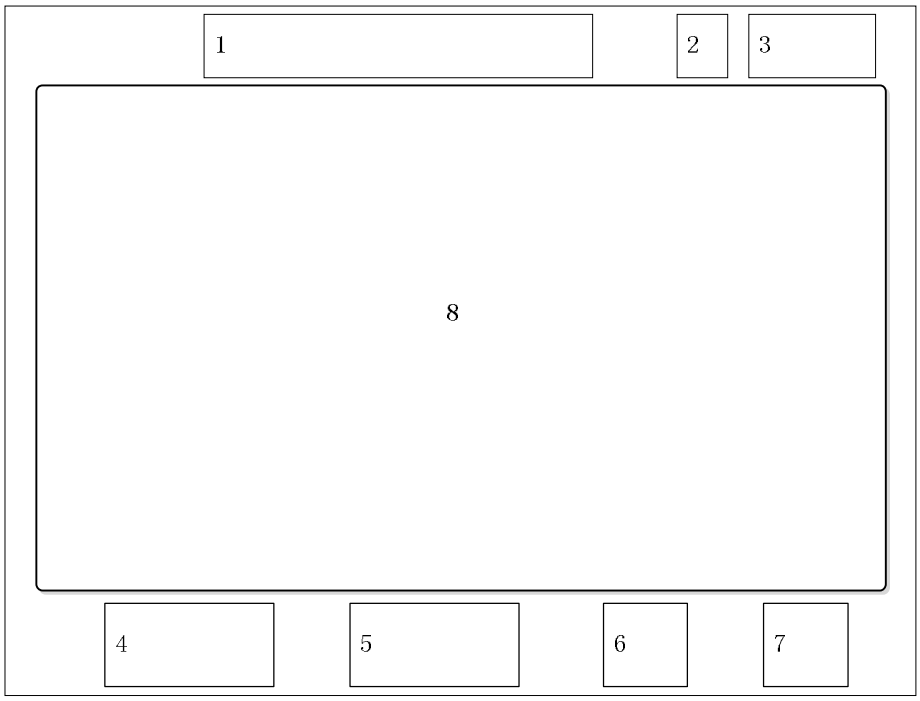


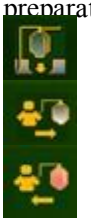
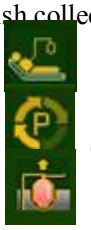
Bottle -type weigher collection adapter

2.6 Description of Screen interface and Operation

2.6.1 Interface content

The interface content is introduced by taking the plasma collection monitoring interface as an example.

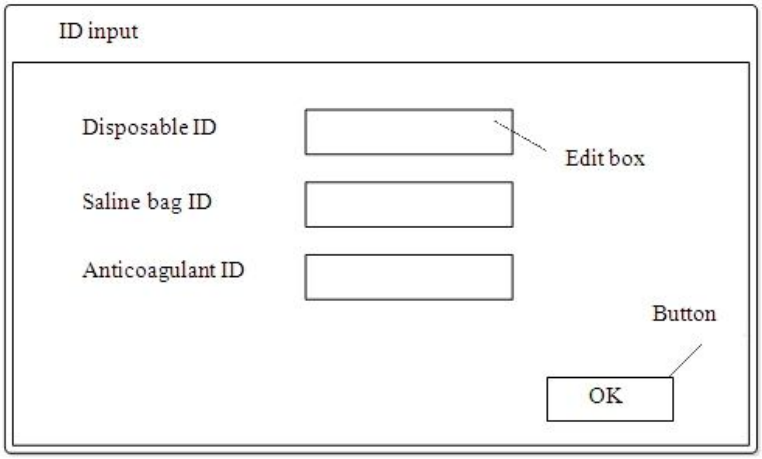


No.	Display Content Description
1	Current collection status of the system: Installation of Disposable -〉 collection preparation -〉 collection process -〉 finish collection  Disposable installation Draw phase Return phase  Collection preparation Centrifuge braking Disposable uninstallation The lighted icon represent the current state.
2	Current networking status of the system: wired connection success/failure / , wireless connection success/failure / .
3	Current date and time of the system.

No.	Display Content Description
4	Quick setting button of the **Pump** speed, including On/Off, and speed up/slow down (adjust the step is 5 ml/min).
5	Quick setting button of **Cuff** pressure, including On/Off, and add/reduce pressure (adjust the step is 5 mm Hg).
6	**ID** button. Pop up a window to query or modify the ID information of personnel, disposable and accessories and other information. The ID input is a configured item (see 4.3).
7	**Setting** button. Click this button to pop up a window for setting collection parameters: click here and the window pops out. Then set the current collection process parameter. See 4.3 for parameters.
8	Main interface. It displays a dialog box, real-time service data and status information.

2.6.2 Dialog Box

Take the disposable input as an example:



Generally, a dialog box has the following interface content:

- Button

A button is used for an action.

Operating method: Click the button area.

- Edit box

An edit box is used to input parameter and other information. It includes two types:

Type 1: Input ID (bar code)

Operating method: Click the edit box area, and click the **Enter** button in the pop-up soft button, and then trigger sweep by aligning the code scanning gun with the bar code to complete ID input.

Type 2: Input Number/Alpha

Operating method: Click the edit box area, and complete the ID input operation in the pop-up soft button.

2.7 Plasma Separator's Parameter Configuration

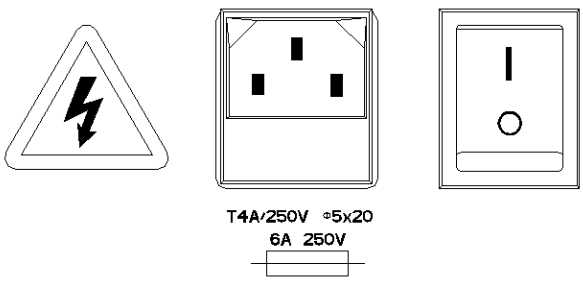
The following parameters are factory default values of the plasma separator.

Technical Parameters

Option	Range	Default	Precision
Cuff pressure	40～99mm Hg	50mm Hg	≤10 mm Hg
Collection per cycle (PLA Vol/Cycle)	100～400g	200g	≤10g
Total collection	100～1000g	600g	≤10g
Saline Compensation (Saline Compen.)	0～500ml	0	≤50ml
Draw speed	20～150ml/min	60ml/min	2ml/min
Return speed	20～150ml/min	60ml/min	2ml/min
AC/Blood Ratio	1:8 ～1:16	1:16	
Centrifuge speed	7000r/min	---	≤2.5%

The company can provide necessary information contributing to the qualified technical personnel of the user to repair the repairable parts designated by the company.

2.8 Power Input Section



1. Input power socket

IEC320 series of power socket is provided, and the dedicated power line will be provided with the separator.

⚠ **Warning**: If the power line must be replaced, its plug polarity must be consistent with the socket polarity of the separator. Otherwise it will affect the separator's safety.

2. Fuse

The replaced fuse must conform to the model and specifications marked on the separator, rated value of 4.0A, shape of Φ5×20

⚠ **Warning**: The cartridge fuse can be replaced only after unplugging the power plug.

3. Power switch

It is the main switch of the separator. In case of an emergency, turn off this switch can stop all operations of the separator. The symbol "○" on the switch represents on, and "|" represents off.

⚠ **Warning**: For the power socket that supplies power, the null line and the ground line are not allowed short connected. The ground line must be connected to the ground according to the specification, and must be reliably connected.

2.9 Waste Bag

Each plasma separator is provided with two waste bags, with one connecting to the leakage collector exit at the separator's bottom, and the other is individually packaged for backup. If liquid overflows from the centrifuge, the waste bag can be used for collection.

Caution: During the separator operation, the waste bag shall be connected with the leakage collector exit and hang freely. In addition, its clamp shall be opened.

Caution: The waste bag cannot be used for collection and storage of infusing product.

Caution: The company proposes to deal with or dispose of the waste may be contaminated in accordance with Regulations on the management of medical waste.

3. Product Specification

3.1 Operating Power Supply

- Supply voltage: ～230V
- Supply frequency: 50/60Hz
- Input power: ≤500VA
- Fuse: T 4A H 250V，Φ5×20

3.2Environmental Condition

3.2.1 Operating Environment

- Ambient temperature: 10°C～30°C
- Relative humidity: ≤70%
- Atmospheric pressure: 86kPa～106kPa
- Altitude: ≤2000m
- Environmental pollution grade: 2

3.2.2 Storage and Transportation Environment

- Ambient temperature: -20°C～55°C
- Ambient humidity: ≤93%
- Atmospheric pressure: 50kPa～106kPa

3.3Size and Weight

- External size: 540×510×770 mm (L x W x H)
- Weight (excluding the options): 29 Kg

3.4Label and Symbol Description

The separator includes the following labels and symbols, which are described as follows:

Label or Silk-screen	Definition
	Caution: Please operate according to the operator's manual, so as to avoid safety accidents.

	High voltage: There are high-voltage electric fields nearby the power supply, so keep away from the electrified part of the device or electrified maintenance device.
	Product's serial number
	Separator's manufacturing date
	BF-type device
	This electronic information product contains some toxic and harmful substances, and can be used assuredly within 20 years of environment-friendly use period, after which, it shall be recycled.
	AC (alternating current)
	Power off
	Power on
	Serial port
	Network interface
	USB interface
	Read the information after use
	Fuse
	Manufacturer information

4. Product Connection

This chapter describes the method of connecting the product with power supply, potential equalization connector, and external devices.

Caution: Before connecting the product, place it in a proper position, and spare at least 20cm on the back and both sides of the product. The storage and transportation and operating conditions of the product must meet the requirements (refer to chapter 3), and avoid storing and using the product in places with direct sunlight, sudden temperature change, condensation, dust, vibration-prone, or near a heat source.

4.1 Connecting with Power Supply

Plug the power plug of the product to the socket that meeting the following conditions:

- Supply voltage: ～230V
- Frequency: 50/60 Hz
- Output power: ≤500VA
- Three-core power cable: Well grounded

4.2 Network Connection

The DigiPla series of products support wired and wireless connection modes:

For wired connection, connect the Ethernet port on the back of plasma separator with the corresponding port of the router through network cable (twisted-pair). for wireless connection, communication is carried out by the WiFi module inside the plasma separator and the wireless router. The automatic management of collection results of the product is realized by the PC management software.

The network settings are as follows:

1. Click **Configuration** in the ready interface and input the maintenance password to enter the maintenance interface, and then click **Set Network** to enter the setting interface.
2. Only one of wired or wireless connection to a LAN can be chose at the same time.
3. For wired connection, connect the Ethernet port on the back of plasma separator with the corresponding port of the router through crossed network cable, and manually set IP address.

4. For wireless connection, choose the router to be connected in the available wireless router list and input the correct connection password for connection.
5. There are for connection status as shown in follows:

1) Wired connection, connection succeeded. The corresponding icon is 

2) Wired connection, connection failed. The corresponding icon is 

3) Wireless connection, connection succeeded. The corresponding icon is 

4) Wireless connection, connection failed. The corresponding icon is 

4.3 PC Data Management Software（DigiPla DMS）

The PC data management software is a software system used to manage the collection result data of the plasma separator. Click **Configuration** in the ready interface and input the maintenance password to enter the maintenance interface. Then use √ in front of the DigiPlaDMS. and its main functions are as follows:

1、 Monitor the status (offline, collecting or vacancy) of all plasma separators in LAN.

2、 Set parameters of all plasma separators in LAN in batch.

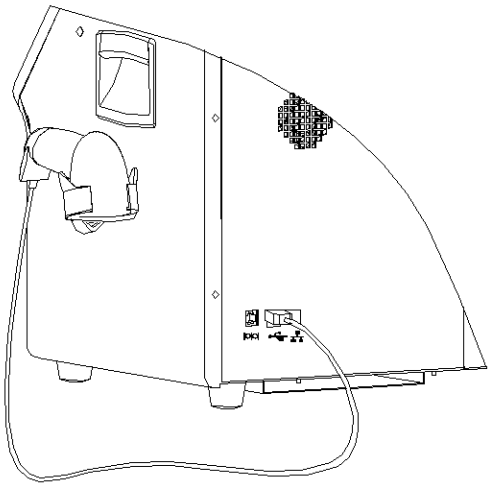
3、 Store the collection result data of the plasma separator, and provide an interface for users to query the database.

4、 Provide an interface for data communication with user's service management software, send collection result data and receive data of donor, thus making the collection and management process more standard.

DigiPla can connect with the PC data management software through wired and wireless modes, for connection method and settings of plasma separator, see section 4.2. For detailed use of PC data management software, see *Operating Manual of PC Data Management Software.*

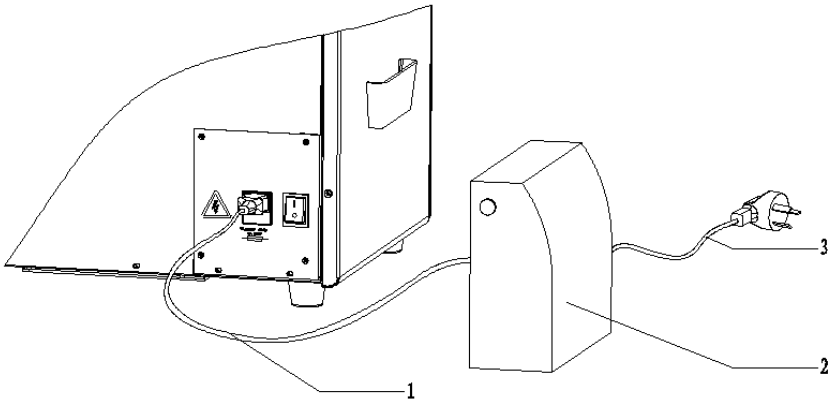
4.4 ID scanner

DigiPla series of products support to connect an ID scanner in USB connection mode, such as barcode scanning gun, which is used to complete the input of ID of personnel, Disposable and accessories configured in the system. The connection mode is as shown in the following figure:



4.5UPS (Uninterrupted Power Supply)

When the power supply system fails, the DigiPla series of products can be connected with the external device's UPS (Uninterrupted Power Supply), so as to continue the operation of plasma separator. For operating hours and use method of UPS, see the operator's manual of the product. The connection mode is as shown in the following figure:



Connect the power plug of power cable 1 of the plasma separator to the socket of UPS 2, and connect the power plug of power cable 3 of the UPS to the power socket on the wall.

5. Startup/Shutdown

This chapter describes the steps of startup and shutdown of the separator.

5.1 Startup

1 Check the following items before starting up:

- The ambient temperature, humidity and atmospheric pressure shall meet the requirements (see chapter 3).
- The separator shall be placed in a clean and steady place without direct sunlight, rapid temperature change, and condensation, and no heat source near the separator. There shall be at least 20cm left on the back and both sides of the separator.
- The separator and periphery are of no deformation, damages or stains, etc. If necessary, clean the separator according to Chapter 9 "Maintenance".
- There is no obstacle in movable area of the separator and near the cooling fans.
- All power cables and connecting cables are damage free.
- All connections are not loose.

2 Ensure the power plug of the separator is connected to a right socket. If an external device needs to be started up, ensure its power plug is connected to a right socket.

3 Turn on the separator's power switch. If a periphery needs to be started up, turn on its power switch.

4 The startup of the separator takes about 40 seconds, and the interface displays the startup screen.

5 After starting up, the separator will automatically check all parts, and the operator shall check the following items:

⚠ **Warning**: If any abnormity is found in the following checking items, please shut down the separator immediately and refer to section 8.3 "Troubleshooting". If this abnormity is described in section 6.3, solve the problem according to the listed solutions. Otherwise, contact our after-sale service department or the dealers.

- Observe whether the separator's startup is normal in the starting up process.
- Whether the separator has abnormal noises, smells or overheating phenomenon.

- Whether sound test is normal.
- Whether light test is normal.
- Whether there is an error message displayed.
- The separator's display date and time are in consistent with the current date and time. If it is not correct, modify the date and time (see section 6.3).

⚠ **Warning**: If the separator's display date and time are not in consistent with the current date and time, it will cause an error to the donor's information.

Prompt: The centrifuge cover must be closed in the process of starting-up self-test, otherwise the self-test cannot be done.

5.2 Shutdown

1 Fold the cuff and place it in the cuff trough on the side wall of the cabinet.

2 Turn off all power switches of the periphery connected with the separator.

3 Turn off the power switch of the separator.

4 If this separator will not be used for a long time, unplug the power plugs of this separator and of its peripheries.

5 Adjust the display vertical to the cabinet, so as to avoid the falling object damaging the display screen.

Caution:	After shutting down, the separator can be restarted after the centrifuge is fully stopped (40 seconds).

6. Collection Preparation

6.1 Disposable

1. The Plasma Apheresis Disposable Set includes unbundled set and closed set. When using the unbundled set, those disposables needed to be assembled shall be conducted in grade 100 cleaning environment with locally being grade 10000.
2. The plasma separator is mainly composed of needle, centrifuge bowl, plasma pipelines, and plasma collection bottle/bag.
   - Needle: The needle is of 15G or 16G, connecting with the joint of the plasma pipeline.
   - Centrifuge bowl: The centrifuge bowl is installed in the centrifuge bowl holder, which will drive the centrifuge bowl rotating at a speed of 7000rpm when operating. The centrifuge bowl fills or pumps blood through the inlet (high port) and feed tube, and the separated components flows out from the outlet (low port). The rotating centrifuge bowl generates centrifugal force, thus layering the blood filled in the centrifuge bowl. During blood collection, the blood fill into the bowl, making the sterile air inside the bowl discharged to the plasma collection bag/bottle. While during return, the sterile air is return to the bowl from the plasma collection bag/bottle and empties the centrifuge bowl.

Caution: If the blood flow and air flow between the centrifuge bowl and plasma collection bottle/bag are blocked during blood collection, it will cause damage to the rotating seal ring of the centrifuge bowl. The operator must constantly alert to any pipeline kink or block that might affect blood flow or air flow.

   - Plasma pipeline: Connect the harness of the pipeline with the inlet of the centrifuge bowl, and the anticoagulant spike(red) connects with anticoagulant bag, to implement the transfustion of anticoagulated blood, blood components and infuse saline (if any).
   - Plasma collection bag/bottle: Connect the harness of the pipeline of plasma collection bag/bottle with the outlet of the centrifuge bowl, and the saline spike (white/blue/transparent) connects with saline bag (if any), to implement the collection of separated plasma from the centrifuge bowl.
3. Anticoagulant (Sodium Citrate Injection for Anticoagulant or Anticoagulant Citrate Dextrose Solution I)

4. Sodium chloride injection for transfusion (if saline compensation is performed)
5. Disposable checking: disposable shall be well packed and within the validity period, the pipeline shall have no crack, the joint shall be not loose or disconnected, there shall be no foreign matters inside the centrifuge bowl, all protective covers are complete, and there is no kink, twist or dents on the pipeline that will influence the flow of liquid.

6.2 Separator Preparation

1. Raise the anticoagulant and saline poles (if any).
2. Check or adjust the weigher to the tighten state.
3. Connect the power, the startup screen is displayed, and enter to the self-check state after starting up.

Prompt: If the power fails during the collection process, the separator will not perform self-test automatically after restarting.

4. Pass self-check: The Ready interface is displayed.

Prompt: The ready interface provides two options of **Draw** and **Configuration**. Click **Draw** to enter disposable installation for safety check, and click **Configuration** to enter the user **configuration** interface (see chapter 6.3).

5. Self-check failure: Click Quit to restart self-check.
6. Pull out the waste bag at the bottom of plasma separator, check whether the waste bag is connected with the leakage collector exit and hangs freely, and the clamp shall be loose.

6.3 Configuration interface

In the ready interface, click **Configuration** to enter user configuration interface and then click **Set Params**, the following parameters can be set and the operator shall modify the pre-set values based on the actual condition of the donor.

Click **Configuration** in the ready interface, input the set password (initial password is 8888) to enter the user configuration interface, and the interface consists of the following:

No.	Setting Item	Purpose
1	Language	Choose the display language of the collection program in the drop-down list
2	Unit	Choose the display unit of the collection program in the drop-down list
3	Set time	Set and adjust the current time and date of the system

4	Set Params	Set the collection parameters, for setting method, see the setting of parameter table(2.7)
5	Set Password	Set and change the user configuration password
6	Set ID-input	Click to enter ID input setting menu, and select the ID items to be input When all or part of ID input of disposable and accessories are selected, the ID input interface will be popped up after safety check. when all or part of ID input of personnel are selected, the ID input interface will be popped up in the vein-puncture interface.
7	Quit	Exit the user configuration interface.

Setting of parameter table:

No.	Setting Item	Purpose
1	Plasma Target	Total plasma collection
2	PLM Vol/Cycle	Maximum collection per cycle
3	Saline Compen.	Total compensation of saline during the collection process
4	Saline Vol/Cycle	Compensation of saline per cycle
5	AC/Blood Ratio	Mixing ratio of anticoagulant and blood
6	Cuff Pressure	Pressure preset value of pressure cuff
7	Draw speed	Blood pump's rotation speed during the draw phase (counterclockwise)
8	Return speed	Blood pump's rotation speed during the return phase (clockwise)

For the setting range and precision of parameters and other information, see section 2.6.

7. Collection Procedure

7.1 Installation of Disposable

After starting up and self-check of the separator, enter to the ready interface.

7.1.1 Check before Installation of Disposable

- ID input of personnel (donor and operator), disposable, and accessories are configured items. For setting method, see chapter 6.3.
- Check whether the disposable meet with requirements according to section 6.1.
- The ready interface provides two options of **Draw** and **Configuration**. Click **Draw** to enter disposable installation for safety check, and click **Configuration** to enter the user **configuration** interface.

7.1.2 Installation of Disposable

7.1.2.1 Installation of Centrifuge Bowl

- After passing safety check, the interface will prompt to install centrifuge bowl, then open the centrifuge cover.
- The centrifuge inlet orientates to the right side of the separator, slightly press the centrifuge bowl to the bowl holder of the centrifuge.
- Close the centrifuge cover to enter the interface of installing pipeline.

Prompt: The centrifuge cover can be closed only when the centrifuge is correctly installed. If the cover cannot be fully closed, check the position and orientation of the bowl.

⚠ **Warning**: If the centrifuge bowl is not correctly installed, it will damage the seal ring during rotating for blood collection. Therefore, it is necessary to check whether the centrifuge bowl is correctly installed each time before blood collection.

7.1.2.2 Installation of Pipeline and DPM

1. Install the pipeline on the blood pump (red mark).
   - Find out the pump stop on the pipeline that connecting with the centrifuge bowl inlet, and put it in the tubing guide on the back of blood pump.

- Surround the pipeline from back to front to the ring slot on the head of blood pump.
- Ensure the other pump stop on the pipeline is in the tubing guide in the front of blood pump.
- Ensure the pump stop is fully stuck in the tubing guide.

2. Put the pipeline coming from the front of the blood pump in the blood valve, and spare enough pipeline between the tubing guide and the blood valve of the blood pump. Ensure the pipeline is installed in place in the blood valve, and no pipeline are allowed to slip outside.
3. Put the pipeline coming out from the blood valve in the slot of blood air detector, and spare enough pipelines between the blood valve and the blood line air detector.
4. Insert the dual tube upward and single tube downward of the blood filter to the bracket in the front cover of the separator. Spare enough pipeline between the blood line air detector and the blood filter, so as to prevent the pipeline from kinking or blocking.
5. Install the adapter of DPM
   - Hold the adapter of DPM by hand, insert it into the pressure monitor for blood pipeline, and press in the locking ring.
   - Rotate the adapter of DPM for 1/4 circle clockwise to fix.
   - Gently pull out the pressure monitor, so as to ensure it is correctly installed.
   - Relevant prompt will be displayed in the display screen.
6. Install the pipeline on the donor line air detector
   - Put the single tube of the blood filter in the following DLAD2.
   - Put the pipeline coming out from the left of DLAD2 in DLAD1.
   - Ensure to spare enough pipeline between the bottom of the blood filter and the right side of DLAD2, and spare enough pipeline between DLAD1 and DLAD2.
7. Install pipeline on the anticoagulant pump (blue mark)
   - Find out the pump stop near the anticoagulant, and put it in the tubing guide on the back of anticoagulant pump.
   - Surround the pipeline from back to front to the ring slot on the head of anticoagulant pump.
   - Ensure the other pump stop on the pipeline is in the tubing guide in the front of anticoagulant pump.
   - Ensure the pump stop is fully stuck in the tubing guide.

8. Put the pipeline coming from the front of anticoagulant pump in the slot of ALAD, and spare enough pipeline between the tubing guide and ALAD. Ensure the pipeline near the anticoagulant pump is free from kinking or blocking.
9. Close the clamp in the pipeline of blood collector.

7.1.2.3 Install Plasma Collection Bottle/Bag

1. Put the pipeline from the centrifuge bowl outlet in the notch on the top of line sensor, so as to ensure the pipeline is fully put in the bottom slot of line sensor.
2. Put the pipeline coming out from the line sensor in the plasma valve, and spare enough pipeline between the line sensor and the plasma valve, so as to prevent the pipeline from kinking or blocking. In addition, ensure the tube is installed in place in the plasma valve, and no pipeline is allowed to slip outside.
3. Ensure the infuse pipeline is in the front of the collection bottle or back of the collection bag, round the pipeline from the left of collection bag, and hang in the front of the bracket of weigher. Spare enough pipeline between the collection bottle/bags and the plasma valve, so as to ensure the pipeline is smooth.
4. If saline compensation is required, put the pipeline coming from the saline puncture in the saline valve. Ensure the tube is installed in place in the saline valve, and no pipeline is allowed to slip outside.

Caution: If the plasma infusing pipeline is not installed in place, it will influence the extracting of negative pressure at the initial return stage, and affect the plasma quality.

Caution: It is necessary to frequently check whether the pipeline is in the proper position of line sensor, ensure correct installation before operating, and the pipeline shall not be pulled after the separated plasma flowing out.

Caution: If there is saline compensation, and the pipeline is not well installed in the plasma valve and saline valve, it will influence the flow of saline to the centrifuge bowl, and thus causing error information of return overtime. Or the saline may be mixed into the plasma, making the plasma sample diluted, and thus influencing the check of virus marker for HIV and hepatitis.

7.1.2.4 Priming

After the pipeline installation is completed, click **OK**, and connect anticoagulant and saline according to the prompt on the interface. Then click **OK**, the separator will enter the stage of loading the lines of blood pump and anticoagulant pumps, as well as filling the line with anticoagulant. When the anticoagulant reaches the DLAD, the liquid filling and air exhausting is

completed, and the separator enters the vein- puncture interface.

Prompt: After spiking the anticoagulant bag, click **OK** to ensure normal liquid filling of anticoagulant as soon as possible.

7.2 Vein-puncture

1. Prepare vein-puncture part
   - Wrap the cuff on the arm of donor, and ensure the distance between the down edge of the cuff with the venepuncture site is longer than 9cm.
   - Click  of **Cuff** to increase pressure to the cuff to reach the preset cuff pressure value.
   - Prepare the venepuncture site according to the blood collection procedures.
2. Vein-puncture
   - Clamp the pipeline about 10-12cm from the needle.
   - Puncture according to the blood collection procedures and fix the needle to the arm of donor.
   - Open the clamp on the pipeline of blood collector.

7.3 Plasma Collection

1. Ensure the position of weigher's adapter and the plasma collection bottle/bag is correct.

Caution: When click **OK** on the vein-puncture interface, the measurement data in the weigher will be set to zero automatically, meanwhile pay attention to not touch the plasma collection bottle/bag and the weigher during plasma collection process.

2. Check the position of plasma pipeline in line sensor.

Prompt: Be sure to recheck the installation position of plasma pipeline in line sensor before plasma collecting. At this time, the lid of line sensor shall be down completely.

3. After vein-puncture is completed, click **OK** and starting plasma collection, and at this time, enter real-time monitoring interface.
4. In order to prevent red blood cells flow into the anticoagulant pipeline, hang firmly the double-lumen tube with Y-type interface vertically, the anticoagulant stretches upward from "Y", and the needle pipeline is under "Y".

Prompt: Make a circle of dual tubes around the arm of donor, so as to reduce the possibility of red blood cells falling to the anticoagulant owing to gravity in the return process.

7.4 Collection Monitoring

When starting collecting plasma, the separator will automatically start "blood collecting → centrifuge → return → blood collecting" cycle process until completing the total preset collecting amount. However, in this process, the operator should closely monitor the working conditions of separator and conditions of the donor, if any abnormity is found, it should be promptly handled.

1. In the collecting cycle process of plasma separator, click the setting button on the right bottom to modify the preset collection parameters, so as to adapt to the individual difference of donor. The operating method is same with section 6.3 "Collection Parameter Setting", and such modification is just valid for the current plasma collection.
2. Pay attention to the pump speed and pressure alarm, and check the blood flow of donor. The operator shall promptly correct the flow speed problem.

Prompt: The operator shall remind the donor pay attention to the blood pressure indicator on the side of plasma separator, if the indicator is green flashing, the donor shall make a fist.

- The operator shall take steps to solve flow speed problem according to the standard operating procedures.
- If the problem cannot be solved after taking measures (adjusting the pipeline, needle position and pressure), the blood collection shall be stopped or puncture again at the other arm.

3. The operator shall closely monitor the plasma separator in the whole plasma collection process, and promptly handle the problem when there is an alarm. If there is an air alarm, find out the air source and timely handled the problem. If no air is found in relevant pipeline, then check whether the pipeline is correctly placed in the air detector, and take out the pipeline for reinstallation when necessary.
4. The operator shall pay attention to the reactions of the donor in the whole plasma collection process.
5. Check the placement of pipeline in valve.
6. Observe the plasma color and pay attention to whether there is hemolysis.

Prompt: During the process of collection and return, if it is necessary to suspend or quit current operation, proceeding according to the following two ways:

- Click **Blood Pump** icon to stop the blood pump, temporarily stopping the collection or return process. At this time, the centrifuge will not stop if it is in collection process. After restarting the blood pump, the blood collection or return process will continue.
- The **Stop** button at the bottom of display can be pressed. After temporarily stopping the

collection process, when the content inside the centrifuge bowl exceeds 1/3 of the capacity, the collection process can be continued only after clearing the centrifuge bowl by click **Return.** After temporarily stopping the return process, click **Draw** to start the collection process or press **Stop** and click **Return** to continue the return process. In addition, you can click **Exit** to end the collection.

7.5 End of Operation

1. When the plasma separator completes the total preset collection and returns the content inside the centrifuge bowl, it will make a acoustic prompt and display the collection statistics on the screen.

The screen will display all or parts of the following collection results:

No.	Setting Item	No.	Setting Item
1	Donor ID	8	Start Time
2	Operator ID	9	End Time
3	Disposable ID	10	Duration
4	Saline ID	11	Total Plasma
5	Anticoagulant ID	12	Saline Compen.
6	Equipment No.	13	AC used
7	Num. of cycles	14	Blood Processed

Prompt: The ID input is configured items (for configuration method, see 6.3), if it is configured, relevant information will be displayed.

2. Uninstall disposable
   a. Remove the pressure cuff from the donor.
   b. Close the clamp in the tubes of needle.
   c. Disconnect the needle according to standard operating procedures.
   d. Open the clamp on the pipeline of blood collector with the needle upward, making the blood at least flow back to below the needle joint, and then close the clamp.
   e. Take down the anticoagulant bag from the pole and hang it upside down to the left of plasma separator.
   f. If saline compensation is used, perform the following operations:
      - Take down the saline bag from the pole, and hang it upside down to the right of plasma separator.

- Take out the saline pipeline from the saline valve.
- Clamp the saline pipeline.

g. Take out the pipeline from the blood valve and air detector for blood pipeline.

h. Close the pressure monitor tube with the clamp on the adapter of pressure monitor. Rotate the adapter for 1/4 to 1/2 circles, and take out the adapter.

i. Remove the pipeline from the blood pump.

j. Clamp the plasma pipeline, or raise the plasma collection bottle/bag, so as to ensure the content inside the centrifuge bowl and plasma collection bottle/bag is not flow to each other, and take out the plasma pipeline from the plasma valve and line sensor.

k. Take down the plasma collection bottle/bag from the weigher and handle according to standard operating procedures.

l. Remove the pipeline clockwise from the anticoagulant pump, and take out the pipeline from ALAD.

m. Take down the blood filter from the bracket on the front panel of plasma separator, and then take out the pipeline from DLAD.

n. Turn on centrifuge cover, and then take out the centrifuge bowl.

o. The contaminated disposable, anticoagulant and saline shall be processed in accordance with standard operating procedures.

p. The plasma shall be stored in accordance with standard operating procedures based on the product's using requirements.

3. Click **OK** to confirm the collection result and end the collection.

8. Fault Information and Handling

8.1 Alarm Signal

When the plasma separator sends prompt information or gives an alarm, the alarm will sound and the indicator light will flash, and meantime, the screen will give a visual alarm signal. The alarm level is represented by the frequency of alarm sound: sound for high priority is "CCC-CC CCC-CC", medium priority is "CCC", and low priority is "C". The flash color of the indicator light is same with the background color of alarm information bar in the screen: color for high priority alarm is red, medium priority and low priority are yellow. The priority of alarm is classified by different alarms at different stages in use. For details: see section 8.2.1-8.2.4.

Caution: When alarms of different priorities occur, the alarm information display and processing sequence is high priority – medium priority – low priority. When two or more alarms of the same priority occur, the system will display the alarm information according to the set internal (internal setting) sequence.

Prompt: The sound pressure level for alarm sound is no less than 60dB, and the sound pressure level for low priority alarm is lower than that of the high and medium priority alarm.

Interface item for alarm information:

Interface item		**Purpose**
Indicator light	Red	High priority alarm (including definition for background color of alarm information bar)
	Yellow	Medium and low priority alarm (including definition for background color of alarm information bar)
	Blue	Information signal indication (including prompt of startup and end of collection procedure)
Screen information	Mute	Click this key when an alarm occurs to shut down the alarm sound, when a new alarm occurs, the alarm sound will recover automatically.
		When a new alarm signal occurs, the alarm sound will open.

		When a new alarm signal occurs, the alarm sound will close.
		Icon for alarm signal
	!	Text prefix for low priority alarm information
	!!	Text prefix for medium priority alarm information
	!!!	Text prefix for high priority alarm information
	Written message	Content of alarm information
	Help>>	Click this key to pop up screen help information

8.2 Alarm Information and Processing

The operator shall be within 2 meters around the plasma separator, convenient to observe and process alarm information. If the following alarm information occurs, please remove the alarm according to the methods listed in the table. If the fault persists after taking measures in the table, please contact our after-sale service department or the dealers.

8.2.1 Installing Disposable and Prime

MESSAGE/Alert	Priority	Action
Air in the anticoagulant pipeline	Medium	● Check: ➢ The air detector for anticoagulant pipeline is clean. ➢ The anticoagulant bag is correctly connected. ➢ The anticoagulant pipeline is correctly installed between the anticoagulant pump and the air detector for anticoagulant pipeline. ● Perform the following operation to remove the fault: ➢ Manually rotate the anticoagulant pump clockwise to push the bubbles out from the air detector for anticoagulant pipeline. ● After troubleshooting, the operation will be recovered automatically.
Pressure too high	Low	● Check: ➢ The pipeline between the blood filter and the blood

		pump is free from kinking. ● Perform the following operation to remove the fault: ➢ Manually rotate the blood pump counterclockwise to recover the pressure to normal. ● After troubleshooting, the operation will be recovered automatically.
Pressure too low	Low	● Check: ➢ The pipeline between the anticoagulant pump and the blood filter is free from kinking. ● Perform the following operation to remove the fault: ➢ Manually rotate the blood pump clockwise to recover the pressure to normal. ● After troubleshooting, the operation will be recovered automatically.
DPM dropped	Low	● Check: ➢ DPM adapter is intact. ➢ DPM adapter is properly installed. ● After troubleshooting, the operation will be recovered automatically.

8.2.2 Veinpuncture

Message/Alert	Priority	Action
Centrifuge cover not closed	Low	● Check: ➢The centrifuge bowl is correctly installed. ➢No obstruction at the ON/ OFF for the cover of centrifuge. ● Perform the following operation to remove the fault: ➢The cover of centrifuge is tightened by force; turn the knob to ensure that the cover be tightened. ● After troubleshooting, the operation will be recovered automatically.

Leakage of the centrifugal bowl	Medium	● Check: ➢The monitor indicating leak in the centrifuge is clean. ● Perform the following operation to remove the fault: ➢Dip 70% of alcohol with cotton swab to clean the leakage liquid on the inner wall of centrifuge. ● After troubleshooting, the operation will be recovered automatically.
Air in the anticoagulant pipeline	Medium	● Check: ➢ The air detector for anticoagulant pipeline is clean. ➢ The anticoagulant bag is not empty. ➢ The anticoagulant pipeline is free from kinking. ➢ The anticoagulant pipeline is correctly installed between the anticoagulant pump and the air detector for anticoagulant pipeline. ● Perform the following operation to remove the fault: ➢ Manually rotate the anticoagulant pump clockwise to push the bubbles out from the air detector for anticoagulant pipeline. ● After troubleshooting, the operation will be recovered automatically.
Air in the donor's pipeline	Medium	● Check: ➢The air detector for donor's pipeline is clean. ➢The pipeline is correctly installed in the air detector for donor's pipeline. ➢The pipeline between the anticoagulant pump and the air detector for donor's pipeline is free from kinking. ● Perform the following operation to remove the fault: ➢ Manually rotate the blood pump counterclockwise to push the bubbles out from the air detector for donor's

		pipeline alone the blood filter direction. ● After troubleshooting, the operation will be recovered automatically.
Saline valve not close	Medium	● Check: ➢No obstruction in valve involved in action open/close. ● After troubleshooting, the operation will be recovered automatically. ● No way to resolve problem, then turn off the machine, restart the collection procedure.
Plasma valve not open	Medium	● Check: ➢No obstruction in valve involved in action open/close. ➢Press the button of the valve, open the valve manually. ● After troubleshooting, the operation will be recovered automatically. ● No way to resolve problem, then turn off the machine, restart the collection procedure.
Blood valve not open	Medium	● Check: ➢No obstruction in valve involved in action open/close. ➢Press the button of the valve, open the valve manually. ● After troubleshooting, the operation will be recovered automatically. ● No way to resolve problem, then turn off the machine, restart the collection procedure.
DPM dropped	Low	● Check: ➢ DPM adapter is intact. ➢ DPM adapter is properly installed. ● After troubleshooting, the operation will be recovered

		automatically.
Pressure too high	Low	● Check: ➢ The cuff pressure is right. ● Perform the following operation to remove the fault: ➢ Manually rotate the blood pump counterclockwise to restore pressure in normal condition. ● After troubleshooting, the operation will be recovered automatically.
Pressure too low	Low	● Check: ➢ The cuff pressure is right. ● Perform the following operation to remove the fault: ➢ Show how to clench one hand appropriate for donor. ● After troubleshooting, the operation will be recovered automatically.

8.2.3 Blood Collection

Message/Alert	Priority	Action
Centrifuge speed too high	High	● Check: ➢ The centrifuge bowl is correctly installed in the centrifuge. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Return** to enter returning process. ➢ Click **Exit** to end the collection process, and return by using the gravity returning method. ● Contact our after-sale service department.
Centrifuge speed too low	Medium	● Check: ➢ The centrifuge bowl is correctly installed in the centrifuge. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Return** to enter returning process. ➢ Click **Exit** to end the collection process, and return by using

		the gravity returning method. ● Contact our after-sale service department.
Wrong direction of the blood pump	High	● Check: ➢ The pipeline is correctly installed in the blood pump. ➢ The blood pump counterclockwise. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Draw** to continue collecting plasma. ➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method. ● Contact our after-sale service department.
Blood collection too fast/low	Medium	● Check: ➢ The pipeline is correctly installed in the blood pump. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Draw** to continue collecting plasma. ➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method. ● Contact our after-sale service department.
Anticoagulant ratio too low	Medium	● Check: ➢ The pipeline is correctly installed in the anticoagulant pump. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Draw** to continue collecting plasma. ➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method. ● Contact our after-sale service department.
Anticoagulant ratio too high	Medium	● Check: ➢ The pipeline is correctly installed in the anticoagulant pump. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Draw** to continue collecting plasma.

		➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method. ● Contact our after-sale service department.
Wrong direction of the anticoagulant pump	Medium	● Check: ➢ The pipeline is correctly installed in the anticoagulant pump. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Draw** to continue collecting plasma. ➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method. ● Contact our after-sale service department.
Leakage of the centrifugal bowl	Medium	● Check: ➢ The monitor indicating leak in the centrifuge is clean. ● Immediately perform the following operations: ➢ Cut off the power. ➢ Ensure the waste liquid bag is connected to the waste liquid pipe joint at the bottom of plasma separator. ➢ Dip 70% of alcohol with cotton swab to clean the leakage sensor on the inner wall of centrifuge. ● Clean the centrifuge according to the method described in section 9.1.3.2. ● After troubleshooting, suggest clicking **Exit** in the pop-up dialog box to end the collection.
Centrifuge cover not closed	Medium	● Check: ➢ The centrifuge bowl is correctly installed. ➢ No obstruction at the ON/ OFF for the cover of centrifuge. ● Perform the following operation to remove the fault: ➢ The cover of centrifuge is tightened by force, turn the knob to ensure that the cover be tightened. ● After troubleshooting, choose from the following operations: ➢ After troubleshooting, click **Return** in the pop-up dialog box to return, click **Exit** to end the collection.

Valve（Saline valve, Blood valve and Plasma valve） not closed	Medium	● Check: ➢ No obstruction in valve involved in action open/close. ● After troubleshooting, the operation will be recovered automatically. ● No way to resolve problem, press **Stop** and click **Exit** to end the collection, return by using the gravity return method.
Valve（Saline valve, Blood valve and Plasma valve） not open	Medium	● Check: ➢ No obstruction in valve involved in action open/close. ● Perform the following operation to remove the fault: ➢ Press the button of the valve, open the valve manually. ● After troubleshooting, the operation will be recovered automatically. ➢ No way to resolve problem, press **Stop** and click **Exit** to end the collection, return by using the gravity return method.
Weight abnormal	Medium	● Check: ➢ There is no foreign mater on the weight monitor. ● According to the interface prompt information, click **Continue** to continue plasma collection.
Too long blood collection process	Medium	● Check: ➢ The blood collector's joint is correctly connected. ➢ The donor has enough blood flow speed. ● According to the interface prompt information, perform the following operations: ➢ Click **Return** to enter returning process. ➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method.
Air in the anticoagulant pipeline	Medium	● Check: ➢ The air detector for anticoagulant pipeline is clean. ➢ The anticoagulant bag is not empty. ➢ The anticoagulant pipeline is free from kinking. ➢ The anticoagulant pipeline is correctly installed between the anticoagulant pump and the air detector for anticoagulant

		pipeline. ●Perform the following operation to remove the fault: ➢ Manually rotate the anticoagulant pump clockwise to push the bubbles out from the air detector for anticoagulant pipeline. ●After troubleshooting, the operation will be recovered automatically.
Air in the donor's pipeline	Medium	● Check: ➢The air detector for donor's pipeline is clean. ➢The pipeline is correctly installed in the air detector for donor's pipeline. ➢The pipeline between the anticoagulant pump and the air detector for donor's pipeline is free from kinking. ● Perform the following operation to remove the fault: ➢ Manually rotate the blood pump counterclockwise to push the bubbles out from the air detector for donor's pipeline alone the blood filter direction. ● After troubleshooting, the operation will be recovered automatically.
Air detected in the blood pipeline	Medium	● Check: ➢ The air detector for blood pipeline is clean. ➢ The pipeline is correctly installed in the air detector for blood pipeline. ➢ The pipeline between the air detector for donor's pipeline and the air detector for blood pipeline is free from kinking. ● Perform the following operation to remove the fault: ➢ Manually rotate the blood pump counterclockwise to push the bubbles out from the air detector for blood pipeline alone the centrifuge bowl direction. ● After troubleshooting, the operation will be recovered automatically.
DPM dropped	Low	● Check: ➢ DPM adapter is intact.

		➢ DPM adapter is properly installed. ● After troubleshooting, the operation will be recovered automatically.
High pressure of blood collection	Low	● Check: ➢ The blood pump speed is right. ➢ The cuff pressure is right. ➢ The pipeline between the blood filter and the blood pump is free from kinking. ● Perform the following operations to remove the fault: ➢ Manually rotate the blood pump counterclockwise to restore pressure in normal condition. ● After troubleshooting, the operation will be recovered automatically.
Low pressure of blood collection	Low	● Check: ➢ The blood pump speed is right. ➢ The cuff pressure is right. ➢ The pipeline between the anticoagulant pump and the blood filter is free from kinking. ● The donor clench and unclench. ● After troubleshooting, the operation will be recovered automatically.

8.2.4 Return

Message/Alert	Priority	Action
Air in the donor's pipeline	High	● Check: ➢ The air detector for donor's pipeline is clean. ➢ The pipeline is correctly installed in the air detector for donor's pipeline. ➢ The pipeline between the air detector for donor's pipeline and the blood pump is free from kinking. ● Perform the following operation to remove the fault: ： ➢ Manually rotate the blood pump counterclockwise to push

		the air out from the air detector for donor's pipeline until the bubbles enter into the blood filter. ● After troubleshooting, if air is observed in the air detector for blood pipeline, then: 1. If the blood is detained caused by blocking of screen at the bottom of blood filter, forcing the air on the top of screen exhausted too early, then manually rotate the blood pump counterclockwise to exhaust air to the blood filter, and gently tap the filter to force the air coming to the top of filter. 2. If the blood filter is completely empty, stop the operation and contact our after-sale service department.
Leakage of the centrifugal bowl	Medium	● Check: ➢ The centrifuge bowl is correctly installed in the centrifuge. ➢ The monitor indicating leak in the centrifuge is clean. ● Immediately perform the following operations: ➢ Cut off the power supply. ➢ Ensure the waste bag is connected to the waste liquid pipe joint at the bottom of plasma separator. ➢ Dip 70% of alcohol with cotton swab to clean the leakage sensor on the inner wall of centrifuge. ● Clean the centrifuge according to the method described in section 9.1.2.2.
Blood return too fast/low	Medium	● Check: ➢ The pipeline is correctly installed in the blood pump. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Return** to continue return process. ➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method. ● Contact our after-sale service department.
Wrong direction of the blood pump	High	● Check: ➢ The pipeline is correctly installed in the blood pump.

		➢ The blood pump clockwise. ● If the fault is unable to be handled on your own, choose from the following operations: ➢ Click **Return** to continue return process. ➢ Click **Exit** to end the collection procedure, and return by using the gravity returning method. ● Contact our after-sale service department.
Returning pressure too high	Medium	● Check: ➢ The blood pump speed is right. ➢ The pipeline between the blood collector and the blood pump is free from kinking. ● Perform the following operation to remove the fault: ➢ Adjust the pipeline and the needle position. ➢ Puncture the donor again when necessary. ● After troubleshooting, click **Continue** in the pop-up dialog box to recover the operation.
Valve（Saline valve, Blood valve and Plasma valve） not open	Medium	● Check: ➢ No obstruction in valve involved in action open/close. ● Perform the following operation to remove the fault: ➢ Press the button of the valve, open the valve manually. ● After troubleshooting, the operation will be recovered automatically. ➢ No way to resolve problem, press **Stop** and click **Exit** to end the collection, return by using the gravity return method.
Valve（Saline valve, Blood valve and Plasma valve） not closed	Medium	● Check: ➢ No obstruction in valve involved in action open/close. ● After troubleshooting, the operation will be recovered automatically. ● No way to resolve problem, press **Stop** and click **Exit** to end the collection, return by using the gravity return method.
Too long blood returning process	Medium	● Check: ➢ The pipeline is correctly installed in the air detector for blood

		pipeline. ➢ The pipeline is correctly installed in the blood pump. ➢ The pipeline is correctly installed in the saline valve. ➢ The pipeline between the centrifuge bowl and the blood pump is free from blocking. ➢ The pipeline between the collector needle and blood pump is free from kinking or knotting. ● According to the interface prompt information, perform the following operations: ➢ If the centrifuge bowl is not empty, click **Continue** to continue returning process. ➢ If the centrifuge bowl is empty, click **Stop** to continue collection or end collection.
DPM dropped	Low	● Check: ➢ DPM adapter is intact. ➢ DPM adapter is properly installed. ● After troubleshooting, the operation will be recovered automatically.
Air detected in the blood pipeline	Low	● Check: ➢ The air detector for blood pipeline is clean. ➢ The pipeline is correctly installed between the blood pump and the air detector for blood pipeline. ● Perform the following operation to remove the fault: ➢ Manually rotate the blood pump counterclockwise to push the bubbles out from the air detector for donor's pipeline alone the bowl direction. ➢ After troubleshooting, click **Continue** in the pop-up dialog box to recover the operation.
Air in the anticoagulant pipeline	Low	● Check: ➢ The air detector for anticoagulant pipeline is clean. ➢ The anticoagulant bag is not empty. ➢ The anticoagulant pipeline is free from kinking.

		➢ The anticoagulant pipeline is correctly installed between the anticoagulant pump and the air detector for anticoagulant pipeline. ● Perform the following operation to remove the fault: ➢ Manually rotate the anticoagulant pump clockwise to push the bubbles out from the air detector for anticoagulant pipeline. ● After troubleshooting, the operation will be recovered automatically.
Centrifuge cover not closed	Low	● Check: ➢ The centrifuge bowl is correctly installed. ➢ No obstruction at the ON/ OFF for the cover of a centrifuge. ➢ The cover of centrifuge is tightened by force; turn the knob to ensure that the cover be tightened. ● After troubleshooting, the operation will be recovered automatically.

8.3 Troubleshooting

User can remove the following faults.

If the following faults occur, please remove the fault according to the methods listed in the table. If the fault persists after taking measures in the table, please contact our after-sale service department or the dealers.

Starting Failure	Action
The product does not work after turn on the power switch.	Turn off the power switch, check: ● The power cable is correctly connected to the power supply. ● The power supply is normal. Turn on the power switch again.

8.4 Power Failure Recovery

If there is a power failure in the plasma collection process, the operating interface will provide three options (**Draw/Return/Exit**) after the recovery of the power supply and restart of the equipment. The plasma separator can automatically memorize the operating status and operating parameters, click the button of relevant procedure to continue to the next step. Or click **Exit** to summarize collection results.

⚠ **Warning:** Ensure the centrifuge bowl is empty before blood collection. If the capacity of centrifuge bowl exceeds 1/3, continuation of blood collection can interfere with blood collection or cause contamination of plasma by red blood cells.

8.5 Emergency Exit

If an emergency occurs or an error occurs to the plasma separator in the plasma collection process, press **Stop** button to stop current operation, and the operating interface will provide three options (**Draw/Return/Exit**). The plasma separator can automatically memorize the operating status and operating parameters, click the button of relevant procedure to continue to the next step.

⚠ **Warning:** Ensure the centrifuge bowl is empty before blood collection. If the capacity of centrifuge bowl exceeds 1/3, return the content in the centrifuge bowl before blood collection.

8.6 Gravity Returning

Due to some abnormal conditions, the plasma separator cannot return the content in the centrifuge bowl to the donor. It is recommended to return the content in the centrifuge bowl and pipeline to the donor as following methods, so as to significantly reduce the loss of blood cells of donor.

1. Turn off the power.
2. Inform the donor the procedure to be continued in advance, so as to avoid uneasiness.
3. Clamp three pipelines with clips or haemostatic forceps:
   - Dual-tube in the joint of blood collector.
   - Clamp the pipeline with the clip on the joint of pressure monitor, and take out the joint of pressure monitor from the pressure monitor of blood pipeline.
   - Saline pipeline (if any).
4. Move the pipeline away from the valve, air detector, and line sensor.
5. Remove the pipeline from the blood pump.
6. Take out the blood filter from the filter bracket.
7. Open the centrifuge cover, take out the centrifuge bowl and keep it upright.
8. Keep the centrifuge and blood filter above the heart of donor.
9. Take out the haemostatic forceps from the dual-tube of the joint of collector.
10. Return the content in the centrifuge and pipeline to the donor by gravity.
11. When content returning to the joint of collector, clamp the dual-tube with haemostatic forceps, reversely place the centrifuge bowl and blood filter on the platform of plasma separator.
12. Pull out the blood collection needle, and process in accordance with standard operating

procedures.

13. Discharging the liquid from the needle, and process the needle in accordance with standard operating procedures.
14. Clamp the pipeline for plasma collection and saline.
15. Take out the plasma collection bottle/bag and saline bag, and process in accordance with standard operating procedures.
16. Remove the pipeline from the anticoagulant pump, and take out the anticoagulant bag.
17. Process the contaminated pipeline, centrifuge bowl, anticoagulant bag and saline bag in accordance with standard operating procedures.

8.7 Power Failure Operation

- If power supply is failure, the plasma separator cannot return the content in the centrifuge bowl and pipeline to the donor.

Prompt: The plasma separator can be connected with periphery' UPS (Uninterrupted Power Supply), and supports continuous operating of plasma separator. For connecting method, see section 4.5.

- It is recommended to use the following method to handle or return the content in the centrifuge bowl and pipeline to the donor when there is a power failure.

1. Turn off the power supply.
2. Take out the pipeline from the blood valve, manually rotate the blood pump clockwise for five circles, letting the anticoagulant pass the needle pipeline and the needle, so as to ensure the blood in the needle is anticoagulated.
3. If the power supply does not recover in 5-7 minutes, return the content in the centrifuge bowl and pipeline to the donor by gravity.
4. If the power supply recovers immediately, restart the separator and continue the plasma collection process. For detailed operation, see section 8.4.

9. Product Maintenance

This chapter describes the product maintenance and common fault diagnosis.

⚠Warning:	**Product maintenance is commonly completed by the user and maintenance engineer. After purchasing the product, the user bears full responsibility to maintain and operate this product.** **For irresoluble problems encountered in use or maintenance and repair problems not covered by this chapter, please contact our after-sale service department or the dealers.**

Caution:	It is recommended to formulate a maintenance and regular inspection plan to regularly inspect the product. If any abnormity is found, please contact our after-sale service department or the dealers.

9.1 Maintenance by the User

The following maintenance is conducted by the user.

⚠Warning:	**Before cleaning the product, turn off the power switch of the product and unplug from the socket. Otherwise, it may result in electric shock.** **Do not pour any liquid in the product during cleaning. Otherwise, it may result in malfunction or electric shock.**

Prompt:	**It is necessary to refer to the instructions when using detergent.**

9.1.1 Routine Maintenance

The product is designed to require the minimum maintenance work, and the major maintenance must be carried out by the user is regular cleaning. Clean time and method depend on the use times. The minimum requirement is:

Daily cleaning	All external surfaces
	DPM
Weekly cleaning	Air detector

	Line sensor
	Inner wall of centrifuge
	Leakage sensor
Monthly cleaning	Cuff
	Air Filter

9.1.2 Cleaning

9.1.2.1 Cleaning Supplies

1. Cleaning solution (Specific to blood-borne pathogens is recommended)
2. Clean warm water
3. 70% alcohol
4. Hairless cleaning cloth
5. Screwdriver
6. Lubricant
7. Cotton swab

9.1.2.2 Cleaning Method

1. Cabinet surface

Regularly clean the external surface of plasma separator including the operating panel with cleaning solution.

2. Display screen

Wipe the display screen with a soft sloth immersing with glass cleaner and then air dry.

Caution: It is forbid to use cleaner with hydrocarbon or for OA devices to clean the display screen.

3. DPM

Clean the pressure monitor with clean water, and dry the monitor with a dry hairless cleaning cloth.

4. Air detector

Clean the pipe chase and surface of air detector with 70% medicinal alcohol and hairless cleaning cloth.

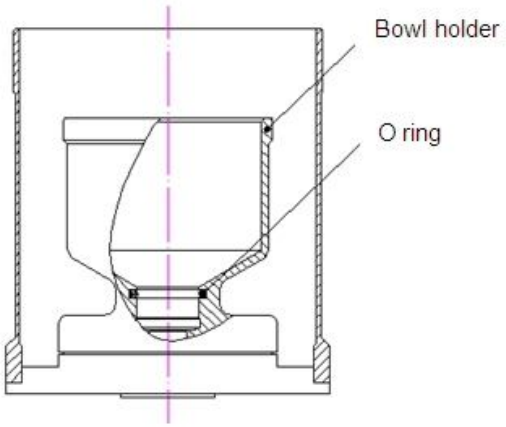
5. Line sensor

Clean the line sensor with clean water, and dry the detector with a dry hairless cleaning cloth.

6. Inner wall of the centrifuge

   a. Routine cleaning

- Clean the inner wall and bowl holder of the centrifuge with a cleaning cloth immersing with cleaning solution. For routine maintenance, no large quantity of cleaning solution is required.
- Clean the centrifuge cover with a cleaning cloth immersing with cleaning solution.
- Dry all surfaces with a dry cloth.
- Lubricate the O ring inside the bowl holder of centrifuge with a little vacuum grease every month. It is not necessary to take out the O ring when lubricating. See the figure below:



b. Cleaning when there is liquid leakage

- Turn off the power supply and pull the plug.
- Clean the centrifuge cover with a cleaning cloth immersing with cleaning solution, and then dry with a dry cloth.
- Clean the inner tank and bowl holder with a cleaning cloth immersing with cleaning solution.
- Clean the leakage sensor with a cotton swab dipping with 70% alcohol.

c. Cleaning when there is oozing of blood

- Turn off the power supply and unplug power cords, ensure the waste liquid bag is connected to the discharge pipe.
- Clean the centrifuge lid with a cleaning cloth immersed cleaning solution, and then dries with a dry cloth.
- Clean the inner wall and bowl holder with a cleaning cloth immersed cleaning solution.
- Fill cleaning solution with the injector of 50ml.
- Drain the cleaning solution from the discharge hole of centrifuge bowl holder, and rinse repeatedly until it is clean.
- Clamp the waste liquid bag, remove it for processing, and replace with a clean waste

liquid bag.

- Each time after oozing of blood, lubricate the O ring with a little vacuum grease without taking out the O ring.

7. Leakage sensor

Clean the leakage sensor with a cotton swab immersed 70% alcohol.

8. Air Filter

The air filter is at the bottom of cabinet, and shall be cleaned each month.

- Unscrew the filter-cover in the filter screen with a cross screwdriver.
- Pull out the filter.
- Rinse the filter screen with warm water.
- Put the filter in a soft cloth that is clean and dry it completely reinstall the filter screen and retainer at the bottom of case.

9. Cuff

Take out the outerwear of cuff, clean with cleaning solution, and put in a cool and ventilated place for drying.

9.2 Maintenance by the Engineer

The following checking items shall be conducted by professional maintenance engineers, so as to ensure the performance and safety of the product. For implement the following checks, please contact our after-sale service department or the dealers.

Checking Type	**Checking Item**
Cleaning	Inside the product Peripheral devices
Electrical safety	Impedance ground Ground leakage current Housing leakage current
mechanical safety	Control panel Mounting mechanism of peripheral devices Other mechanical parts

If the maintenance is conducted by the technical maintenance personnel approved by Nigale, please contact our after-sale service department to provide parts lists and circuit diagram and other relevant data of the product.

Appendix A Safety Classification

According to the stipulations of EN 60601-1：2006 Medical electrical equipment –Part 1:General requirements for basic safety and essential performance

According to the electric shock protection type: I type

According to the electric shock protection degree: BF type

According to the safety degree used where there is flammable anesthetic gas mixed with air (oxygen or nitrous oxide): Non AP/APG type

According to operating mode: Continuous operating

According to installation and using mode of the equipment: Non-permanent installation of equipment.

According to the protection against liquid inlet: IPX1

Annex B Toxic and Hazardous Substances and Elements Content

Part Name	Toxic and Hazardous Substances and Elements					
	Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Plastic structural parts	○	○	○	○	○	○
Metal structural parts	○	○	×	×	○	○
Rubber part	○	○	○	×	○	○
Display protection screen	○	○	○	○	○	○
Fan	○	○	○	○	○	○
PCB(including PCBA inside the display)	×	○	○	○	○	○
Wire	×	○	○	○	○	○

○：This toxic and hazardous substance or element if contained in any or all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006.

×：This toxic and hazardous substance or element contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006.