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Operating Instruction

BLOOD COMPONENT SEPARATOR

NGL XCF 3000

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Preface

Intellectual Property

The intellectual property of this operator's manual and its corresponding products belongs to Sichuan Nigale Biotechnology Co., Ltd. (here in after refers to as "Nigale").

Statement

Nigale reserves the final explanation of this operator's manual.
In case all of the following requirements are met, Nigale will be responsible for the product safety, reliability and performance, that is:
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.

Explanation of Symbols and Abbreviations

To assist you during the reading of this operating instruction, the following symbols and abbreviations are used:


Warning


Practical tip


Non-ionizing radiation

DPM	Donor Pressure Monitor
ACAD	Anticoagulant Line Air Detector
DLAD1	Donor Line Air Detector 1
DLAD2	Donor Line Air Detector 2
BLAD	Blood Line Air detector

Adverse Reaction

Adverse reactions may occur to the donor during the platelet or 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.

Service Policy

Scope of free services:

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

Scope of paid services:

1 For all products exceeding the warranty service regulations, services will be charged by Nigale.

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.

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Contents

1. Brief Introduction

1.1 Summary

The NGL XCF 3000 Blood Component Separator was produced by Sichuan Nigale Biotechnology Co., Ltd. It applied advanced technologies of computer, sensing in multi-domains, peristaltic pump to transport liquid not to be polluted and blood centrifuge separation. All of these is to complete the separation and collection of blood components used in clinical.

A. Intended use

The NGL XCF 3000 Blood Component Separator is a medical equipment which takes advantage of density difference of blood components to perform the function of pheresis platelet or pheresis plasma through process of centrifugation, separation, collection as well as returning rest components to donor. This product is mainly used on the collecting and supplying blood sections or medical units which collect platelet and/or plasma.

B. Basic principle work

In a closed system, the device collects the whole blood into the centrifugal bowl through the pump. Due to the different densities of blood components, they can be separated through high speed rotation of the centrifugal bowl. Once the needed high-quality blood components are harvested, the rest will be returned back to the blood donor.

C. General operation process

The input of Blood Component Separator is only need venipuncture. In the process of collection, the blood from the donor will mix with the anticoagulant proportionally in tubing lines, then whole blood with anticoagulation solution will be separated into the different components in the centrifugal bowl. When the centrifugal bowl to be full of, the separated components flow from the bowl, so the needed components will be enter the collection bag and the other components return to the donor.

The device is completely automation in the whole separating process, the operator only needs to install the disposable and start the device. A friend display of operating status information will be shown on the screen.

D. Main features and functions

1. Use safety

The Blood Component Separator install several sensors, so the computer can make a real time monitoring within the whole separating process and possess high safety. The device will alarm in time, pause the play if it find a abnormality, and display the prompt message in the screen, then go on to work after waiting for being handled.

2. Adaptability

The pump speed can adjust according to the pressure in the line, in order to adapt the individual variation of the donor, and ensure the blood components separating can complete successfully.

3. Quality of the separating blood components

The advanced line sensor monitors the separating blood components precisely. Use with the corresponding disposable can control the infiltrate quantity of RBC and WBC strictly, then to ensure the collecting blood components can meet to the clinical use.

4. Use convenient

The Blood Component Separator has English or interrelated language for user display and graphical display. Every procedure in the whole process of the separating blood components has the screen prompt, furthermore have the audible alarm and screen prompt to the abnormal state. The man-machine interface is very friendly, convenient and easy to know. All of these can give the operator and trainer the enormously convenient.

1.2 Cautions

1. Requirements for product installation environment

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 2), and avoid storing and using the product in places with direct sunlight, sudden temperature change, condensation, dust, vibration-prone, or near a heat source.

⚠ **Notice: Mustn’t stack products or near the equipment with strong radiation, so as to avoid abnormal work.**

2. Request to the operator

Prior to using the NGL XCF 3000 Blood Component Separator, the operator must be the personnel have been trained, and read the operating instruction carefully.

3. Requirements for the blood donor

Before the blood collecting, the donor must be selected and take a physical check according to the related

country regulations. Meanwhile, educating the donor with the basic knowledge of the collecting process, possible latent risk of aeroembolism and anticoagulant reaction, etc is a mandatory.

⚠ **Notice: The donor must know that there has the latent risk of aeroembolism within return, although the Blood Component Separator have the air detectors to prevent the aeroembolism. The consequence of aeroembolism is very severe, may lead to die.**

⚠ **Notice: The donor must know that there has the latent risk of anticoagulant reaction within return. If this adverse effect occurred, he should tell to the operator so as to deal with promptly.**

4. Choosing and storage of the disposable

The disposable for the NGL XCF 3000 Blood Component Separator is the Disposable Blood Component Apheresis Set produced by Sichuan Nigale Biotechnology Co., Ltd.
All the disposables are stored in a dry, airy place without chemical volatiles. When deal with the disposables, hands or gloves should be maintained clean and dry.

⚠ **Notice: The disposable for the NGL XCF 3000 Blood Component Separator is the Disposable Blood Component Apheresis Set produced by Sichuan Nigale Biotechnology Co., Ltd (NGL). User is using non NGL produced kit, the user should be to assume the responsibility if the dys-consequence take place.**

5. Kink, crease and incorrect installation of tubing lines

Operator should check the line whether or not installation of kit is loaded at the correct position without kink of tubing lines on the device. Operator should check fitness of line and install correctness of line.

6. Centrifugal bowl malposition

If the device operates with the inexacting centrifugal bowl, the seal ring of the centrifugal bowl which is fixed will form off-normal frict which can create enough heat to result in hemolysis. The effluent blood is not regard the safety blood to return, if that occurs. It will have the minimum possibility if the operator make the locative head belong to the access panel on centrifuge clamp the square plate belong to stand head on the return.

⚠ **Notice: when the centrifugal bowl acutely sway, bias or incorrect location, do not operate device. The centrifugal bowl must block in the slot completely. If block non licet after trying several fittings, it will be regarded the defective disposable, and should not be use, then report according to some program.**

☞ **Prompt: bias >0.4mm is the standard of bias acutely, can find easily by eyes.**

7. Blood flow being hindered

If there have blocking between the centrifugal bowl and the collection bag, the pressure of the centrifugal bowl will rise during draw. This will result in that the revolving seal ring is pushed up and release pressure. It will cause to lose of air and the revolving seal ring will change function because its surface is steeped by blood. Under this state can't return safely. During return, the pressure in the centrifugal bowl will descend obviously and cause to haemolysis.

8. Ensure the store of air

The centrifugal bowl has been full of filtrated air when they leaved the company. During draw, air will be put into the collection bag and back to the centrifugal bowl during return. This process is very important. It will avoid the empty bowl generate negative pressure.

9. Plasma Hb

The blood pump will cause to haemolysis if it have very blockage during the operation. Because the free Hb is not very clear in the whole blood, it will be found by some inordinate indication. This pressure causing haemolysis will make the flow speed descend, then causes the collection speed descend and extend the emptying time of the centrifugal bowl anomaly. These changes can be known by the high pressure alarm in return.

⚠ **Notice: if there have free Hb visible in plasma, don't make the content in the centrifugal bowl return the donor. Must handle according to the standard operating procedure when suspect the happen of haemolysis.**

10. RBC spill

RBC spill is that RBC flow into plasma bag, and not happen in the normal station. The operator should notice the plasma collection state during collection and check immediately when the pink alarm (perhaps having RBC spill) or occur a free Hb fault. Operator should stop the operation immediately if he can't ensure the reason of pink alarm, and he must not to make these RBC return to donor.

11. WBC removal

The Blood Component Separator use disposable with WBC filter, it will remove the remain WBC in the product.

12. The quality of blood components product

Although the Blood Component Separator equipped sensors to precisely monitor the separating process, and ensure that the blood components meet the clinical requirement. But some effects from machine, disposable and donor, still cause blood product could not meet the intended purpose, such as deficiency quantity of platelet, too much leucocyte. So we suggest that operator should implement sampling test for the blood component product regularly to monitor its quality, to avoid the deficiency quality product cause

adverse effects to users.

13. Overheat

Overheat of the centrifuge's bowl base will damage RBC. This condition perhaps caused by the defective bearing.

⚠ **Notice: it will be regard to RBC is unsure if overheat of the centrifuge's bowl base occur in the operation, and not to return blood donor.**

14. Fire prevention

The station of the Blood Component Separator should prevent fire. And this equipment can not be used in the place of inflammable gas in it.

⚠ **Notice: Don't use the Blood Component Separator and connect or disconnect power at the station have inflammable gas.**

15. Danger of electrical shock

There is a risk of electrical shock if opening the device box before power plug is pulled out. This work is only done by the trained operator.
Because of the high conductibility of electrolytic, operator should avoid contact device with wet hand. Keep hand and gloves clean and dry during the operation.
The inner electronical connection of the mains power socket-outlet that supply the Blood Component Separator should conform to the ***International Electrotechnical Specifications***, the live wire and neutral line should not be connected reversely, and the neutral line cannot be connected with the ground. The ground wire should be connected to the ground according to the standards, and the electrodes contact is required to be reliable.

⚠ **Notice: To avoid the risk of electric shock, the device must only be connected to the supply mains with protective earth.**

16. Wheelwork

Any parts of the body or the clothes should not be intertwisted by the rotating machine at high speed, thus to avoid severe hurt. Therefore, a safety protection structure is designed for the NGL XCF 3000 Blood Component Separator, and centrifuge will not start to run if the centrifuge cover is not closed completely, so the personal safety can be guaranteed.

⚠ **Notice: operators or the people around this equipment should have basic safe guard knowledge about motive machine.**

17. Dissemination disease

The danger of blood transmissible disease is still exist although have several detections to hepatitis, HIV and syphilis. All blood outleakage should clean according to correlated require and step of medical treatment instrument's contamination handling regulations.
All outputs (equipment or disposable) which are produced by Sichuan Nigale Biotechnology Co., Ltd. can return to company because of any cause with repack under that protocol.

18. Contraindications

Not operation before blood have not anticoagulant thoroughly.

⚠ **Notice: Operators must set the appropriate AC/Blood Ratio according to the anticoagulants used. When AC/Blood Ratio is too low, less enough anticoagulant to be used will cause of coagulation, and safety hazard in return phrase.**

19. Environmental protection

The dispose of this waste equipment shall follow the local or regional regulations about Waste Electrical and Electronic Equipment.

20. Explanation

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

⚠ **Notice: It is prohibited to modify the software or hardware of the product without permission.**

⚠ **Notice: 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. It is prohibited to modify the software or hardware of the product without permission.**

2. Technical Specification

2.1 Equipment safety classification

1. The Blood Component Separator is conformity to the standard of **IEC 60601-1:2005/A1:2012.**
2. According to protection against electric shock**,** the Blood Component Separator is classified as Class Ⅰ and Type BF equipment.

   Applied parts: Cuff, The disposable set
3. The Blood Component Separator is not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
4. The Blood Component Separator is an equipment of continuous operation.

2.2 Electromagnetic compatibility

1. The Blood Component Separator is conformity to the standard of **EN60601-1-2:2015**.
2. The Blood Component Separator is classified as Group 1 and Class A according to CISPR 11.
3. The Blood Component Separator use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.

2.3 Normal working condition

1. Ambient temperature: ＋10℃～＋30℃
2. Relative humidity: ≤70%
3. Atmospheric pressure: 86kPa～106kPa
4. Altitude: ≤2000m
5. Use power supply: ～230V/～115V, 50/60Hz
6. Power input: ≤500VA
7. Fuse type and specs: T4.0A H250V Φ5×20 (Time delay, High breaking capacity)
8. Without electric conduction, explosion gas and active gases. Pollution degree 2.
9. Mains power quality should be that of a typical commercial or hospital environment.
10. Interference may occur in the vicinity of equipment marked with the following symbol:

11. The Blood Component Separator should avoid to be used in the vicinity of base station for radio (cellular/cordless) telephones and land mobile radios.

12. The operating panel of the Blood Component Separator should keep the same horizontal with the heart of donor.
13. The service lifetime of the Blood Component Separator is recommended as 5 years.
14. The Blood Component Separator is the portable medical electrical equipment.

☞ **Prompt: The ozone sterilization will damage the rubber material of cuff and the elastic cover of DPM. During the period of ozone sterilization, the equipment's cover should be closed up, and meanwhile take measures, such as using dust proof, to release the damage to cuff. Check the rubbery tube of cuff and elastic cover of DPM regularly. And change them timely if any crack or damage is found on them.**

2.4 Environmental conditions for storage and transport

1. Ambient temperature: －20℃～＋55℃
2. Relative humidity: ≤90%
3. without active gases.
4. Dark, cool, dry, ventilation fine and clean environment.

⚠ **Notice: because of using the liquid crystal display screen, the NGL XCF 3000 Blood Component Separator must store at lest －20℃. The low temperature will damage the liquid crystal screen's display function.**

2.5 Technique parameter

PARAMETER	RANGE	DEFAULT	Precision
Cuff	0～100mmHg(0～13.3kPa)	50mmHg(6.7kPa)	≤10 mm Hg
Plasma /cycle	0～500g	50g	≤10 g
Plasma collection	0～800g	200g	≤10 g
Draw Speed	20 r/min～100r/min	90r/min	2 r /min
Return Speed	20 r/min～120r/min	80r/min	2 r /min
AC/Blood Ratio	1:8～1:16	1:10	
Centrifuge Speed	5,500r/min	---	≤2.5％

⚠ **Notice: Operators must set the appropriate AC/Blood Ratio according to the anticoagulants used. When AC/Blood Ratio is too low, less enough anticoagulant to be used will cause of coagulation, and safety hazard in return phrase.**

2.6 Contour dimension

Turn-on:	Length	57 cm
	Width	54 cm
	Height	68 cm
Turn-off:	Length	57 cm
	Width	36 cm
	Height	45 cm

2.7 Accessories

Accessory: Cuff

2.8 Product Information

Product name: Blood Component Separator
Product type: NGL XCF 3000

Manufacturer:

Name: Sichuan Nigale Biotechnology Co., Ltd.
Address: NO.28 KuiXing Road, 641400 JianYang, SiChuan
PEOPLE'S REPUBLIC OF CHINA
Tel: +86-400-606-9696
Fax: +86-28-85137942

Authorized EC-representative:

Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Contact person: Mr. JIN LIANG

2.9 Service

Service department: Sichuan Nigale Biotechnology Co., Ltd.
Assigned distributor

Our company can provide the necessary data which is helpful for the qualified technician of our clients to repair the mendable part appointed by our company.

⚠ **Notice: Do not modify the device without authorization of the manufacturer.**

2.10 Symbolic interpretation

Type BF applied part

Power off

Power on

Alternating current

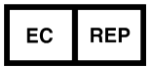
Refer to instruction manual

General warning sign

Safety warning in the vicinity of centrifuge cover reminds to protecting the operator from being intertwined by rotating part of the device.

Safety warning in the vicinity of equipment's inner power input socket reminds that there are live part near the warning sign, don't touch it when plug is connected with the equipment's socket.

Protective earth (ground)



Authorized EC-representative

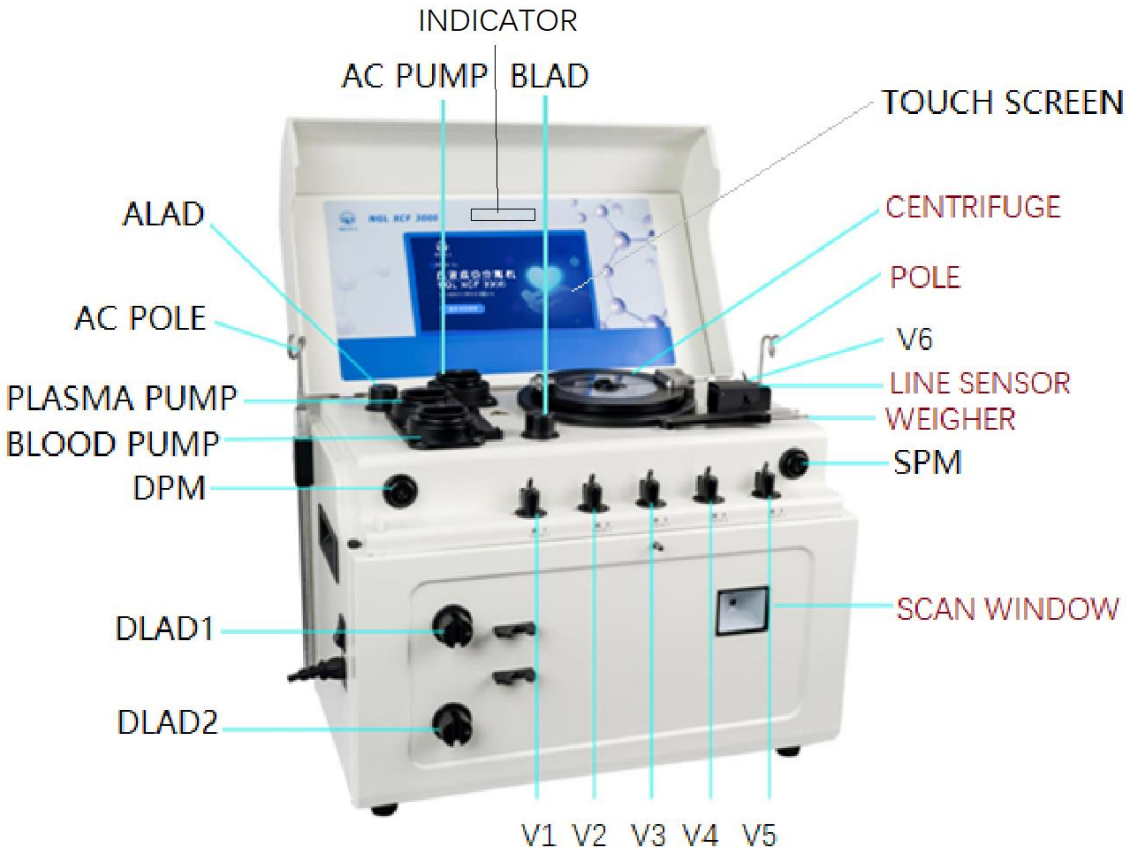
Manufacturer

Date of manufacture

Serial number

3. External Appearance Structure

3.1 Outline drawing



3.2 Functions of main part

1. Blood pump

Blood pump transports blood between the donor and centrifuge bowl.

During draw, the pump rotates clockwise and transfers the whole blood mixing with anticoagulant into the centrifuge bowl to centrifugal separation.

During return, the pump rotation inverse-clock transfers the remaining components (such as RBC and so on) in the centrifuge bowl back to donor.

2. Anticoagulant pump

Anticoagulant pump transports anticoagulant between the anticoagulant bag and needle adapter. During draw, anticoagulant pump can convey anticoagulant to needle adapter according to the parameter ratio of anticoagulant/whole blood, then mix with whole blood of donor.

3. Plasma pump

Plasma pump transports plasma between the plasma bag and centrifuge bowl.

4. Centrifuge

During draw, the anticoagulated whole blood enters the inlet and is directed down the feed tube to the bottom of the bowl. At this point, due to the presence of centrifugal forces generated by the spinning bowl at 5,500 rpm, the fluid migrates to the outer periphery of the bow.

5. Air detectors

During blood draw and return, the separator can detect air in the line, alarm and stop in order to ensure safety of the blood donor.

● Anticoagulant Line Air Detector (ACAD)
Anticoagulant Line Air Detector located at the left of anticoagulant pump, detect anticoagulant line.

● Donor Line Air Detector 1 (DLAD1)
Donor Line Air Detector 1 detect the line between the blood donor and blood filter.

● Donor Line Air Detector 2 (DLAD2)
Donor Line Air Detector 2 detect the line between the blood donor and blood filter, is the backlog of Blood Line Air Detector.

● Blood Line Air Detector (BLAD)
Blood Line Air Detector located at the right of the blood pump and detect the line between centrifugal bowl and blood filter.

6. Valves

The device has six valves in total. They can be turned on and off according to procedure of control open and close of corresponding line.
Valves marked with color, respectively corresponds to the color marked on the lines, it makes easy to check the correctness of the line installation.

7. Donor Pressure Monitor (DPM)

DPM is located at the left side of the device. During the process of drawing and returning, it can detect

the pressure of the blood line. The device can automatically adjust pump speed through supplying pressure information. In addition, it will alarm immediately if the pressure exceed defined scope and stop work. This pressure change can show on the right of liquid crystal display screen through computerized processing.

During draw, the superior of the bar chart is mean that pressure of ＋50mmHg, the inferior extremity of the bar chart is mean that pressure of －50mmHg. Over ＋80mmHg or below －80mmHg, pump will stop and alarm. The screen shows that "DPM PRESSURE HIGH" or "DPM PRESSURE LOW" in order to remind operator to adopt proper step.

During return, the superior of the bar chart is mean that pressure of ＋250mmHg, the inferior extremity of the bar chart is mean that pressure of 0mmHg. Over ＋250mmHg, pump will stop and alarm. The screen show that "DPM PRESSURE HIGH" in order to remind operator to adopt proper step.

⚠ **Notice: during normal work, don't clamp the DPM line using the clamp on the DPM adapter.**

⚠ **Notice: DPM adapter can't move when it plug in the Blood Component Separator because of its important function in detecting pressure. Operator can only pull out the DPM adapter after clamping the DPM line with sliding clipper, and the clipper can only be released after the adapter is inserted on DPM again.**

⚠ **Notice: during return, if pressure over ＋250mmHg, that is mean RBC perhaps haemolysis or venous injury, and should adopt proper step.**

☞ **Prompt: if pump stop and start again and again, accompany with the alarm that "DPM PRESSURE HIGH", should use pump － key to degrade the pump return speed in order to install stable transportation back.**

8．System Pressure Monitor (SPM)

SPM locates at the right side of the device. During the process of drawing and returning, it can detect the pressure of centrifugal bowl in order to ensure the filtrated air in bowl don't be destroyed by abnormal pressure.

If the pressure is over ＋115mmHg or below －90mmHg, the pump will stop and alarm. The screen will show that "SPM PRESSURE HIGH" or "SPM PRESSURE LOW" in order to remind operator to adopt proper step.

9．Weigher

Collection bag is hanged up the arm of weigher. The weigher can detect net weight of the content in bag and show at screen. The weigher automatically tares the bag weight when DRAW is initially pressed at

the start of a procedure.

⚠ **Notice: operator should ensure that the arm of weigher has no other weight after operate and can't move it during the collection.**

10. Line sensor

The line sensor locates at the superior part of the Blood Component Separator and right of the centrifuge. It is in charge of detecting blood components separation flow out from the bowl and send signal to CPU board to change the separation process..

11. Anticoagulant pole

It locates at the left side of the device and is used to hang anticoagulant bag. It can be tension. Rising to hear a gently sound means that the pole has been fixed. Degrading the pole is to extrude the knob and make it slip off.
After losing the locknut, the hook can be stretched, and direction of the hook can be changed. After getting the right position, screw down the locknut to fix it.

☞ **Prompt: The locknut must be screwed down after the hook is raised, and the hanged weight must be less than 1,000g.**

12. Pole

It locates at the right side of the device and is used to hang the air bag. It can be tension. Rising to hear a gently sound means that the pole has been fixed. Degrading the pole is to extrude the turn key and make it slip off.

13. Cuff

The cuff will maintain the pressure automatically preset during draw in order to keep the best flow. When return, the cuff will be deflated automatically. During draw, operator may press the **INFLATE/DEFLATE** key to manual control cuff's working or not working.

The cuff's joint locate at the back of the device.

☞ **Prompt: the actual cuff pressure should be within the scope of the preset value ±5 mmHg.**

3.3 Touch Screen

The screen will display a variety of related functional keys and information based on the working status, details of which will be explained in a later section.

An example of the screen when draw mode.

Notice: All values and colors in this manual are only for demo, maybe different values and colors during your operation.

1) Function Keys

Modify
To modify the parameter during procedure

DRAW
Start or recover the draw procedure.

RETURN
Start or recover the return procedure.

STOP
It stops the current work of the Blood Component Separator. The pump and centrifuge will stop, but it doesn't change any parameter or hamper volume calculation.

ESC
It makes a reset to the CPU, with high priority let the device to stop work, but all the data still in the memory.

START/STOP
It controls all pumps stop or start

INFLATE/DEFLATE
Cuff inflate or deflate, you can use the function before you make venipuncture, press "+" increase the pressure, press "-" decrease the pressure. During the draw phase, the cuff system inflate automatically, it deflate automatically when return phase.

⚠ **Notice: if the centrifugal bowl fill with over 1/3 when the centrifuge stop, continue the blood collection will interfere collection or result in RBC polluting. So, you should return the content in centrifugal bowl before draw.**

Operate census

Display Item	Illustration
PLM	Plasma weight in the plasma bag / default for total amount of plasma collected
PLM PUMP	The plasma pump speed during draw and return
PLT	The total quantity of platelet in the platelet collection bag
VOL	During draw, it means the accumulation of anticoagulation whole blood. During return, it means the accumulation of rest components transfused.
CUFF	Actual pressure of the cuff
CYCLE	CYCLE INDEX / COLLECTED PLT CYCLES

2) pump control key

pump + key

Use to increase the pump speed during draw and return. Press once is to add 5, the maximum is 100 when draw .and 120 when return.

pump — key

Use to decrease the pump speed during draw and return. Press once is to decrease 5 and the minimum is 20.

☞ **Prompt: During draw and return, don't use pump + key and - key when the device is regulating automatically pump speed.**

START/STOP

Control alone the working state of the blood pump, the plasma pump and the anticoagulant pump by making the pump stop or rotate. Press once, mean the working state of pump change once. Using **START/STOP** during draw can't effect operation of centrifuge.

⚠ **Notice: Don't keep the pump stop statue too long (>2~3min) while the centrifuge still running, it is harmful for RBC in the centrifuge bowl. If the pump stop over 2~3 minutes, operator should return the remaining blood component in centrifugal bowl back to donor before continuing draw blood.**

3) BACK

Go back to the last menu.

4) **ESC**

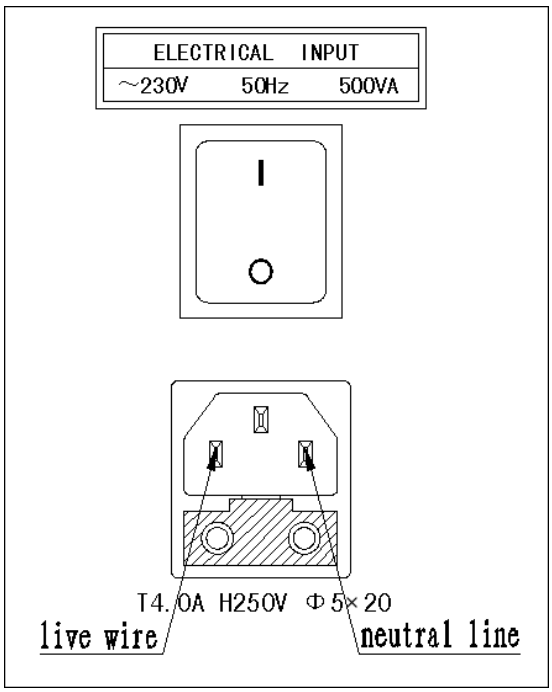
This key can make this working program sign off completely.

☞ **Prompt: use ESC can sign off if the device has being abnormal and help it to recovery normal. The parameter in this program will not be lost. New program can be start if continue allow the screen.**

⚠ **Notice: after having used ESC to sign off the program, it will interfere blood collection or make RBC polluter plasma if the content in centrifugal bowl has be over 1/3 and continue collection. So should return content before draw.**

3.4 Part of main input

Locate at the left of the device.



Power Entry

1. Appliance inlet

IEC320 series power socket are supplied, and exclusive power line is equipped with the device.

⚠ **Notice: the polarity of plug must match the appliance inlet of the device if change power line, otherwise effect safety of the device.**

2. Fuse tube

The fuse tube must match the type and size mark on the device. Time delay, High breaking capacity, rated value: 4.0A 250V, outline form: Φ5×20.

⚠ **Notice: changing fuse tube must after pull off the power plug.**

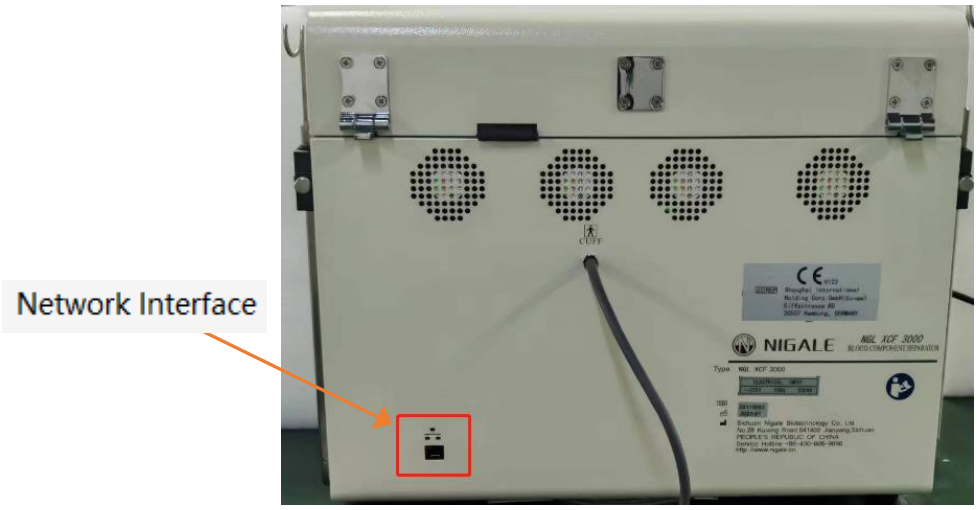
3. Power switch

Power switch for the device. That can stop all work of the device if have urgent situation. | represents power on, ○ represents power off.

⚠ **Notice: The inner electronical connection of the mains power socket-outlet that supply the blood component separator should conform to the *International Electrotechnical Specifications*, the live wire and neutral line should not be connected reversely, and the neutral line can not be connected with the ground. The ground wire should be connected to the ground according to the standards, and the electrodes contact is required to be reliable.**

3.5 Network Interface Connection

The back cover of the blood separator is equipped with a data input and output interface.



a) Purpose of connection: Upload and collect relevant data.

b) Network connection requirements: connect the device and the blood station or the local server of the hospital through the Ethernet interface, which can be used for reliable data transmission between the data management center through the router or hub according to the TCP/IP communication protocol. Remote control is not supported.。

c) Network connection configuration requirements：

1． Use crossover network cable to connect the Ethernet port of the product and the router

2．Click ADMIN on the device operation permission interface, enter the user password, and enter the ITEM SELECTION interface; Then click CONFIGURATION button and NETWOK PORT button to enter the network port configuration interface.

3． Configure server port , server IP address, subnet mask, gateway.

4． Configure the device IP address, device ID, port 10006 of the device, and the working mode to TCP_CLINET.

3.6 Waste bag

The Blood Component Separator has two waste bag. One link to the outlet of leakage collector at bottom of the device. Another is set at the shelf basis on device for be standby. Waste bag can collect liquid overflow

if liquid flow from centrifuge.

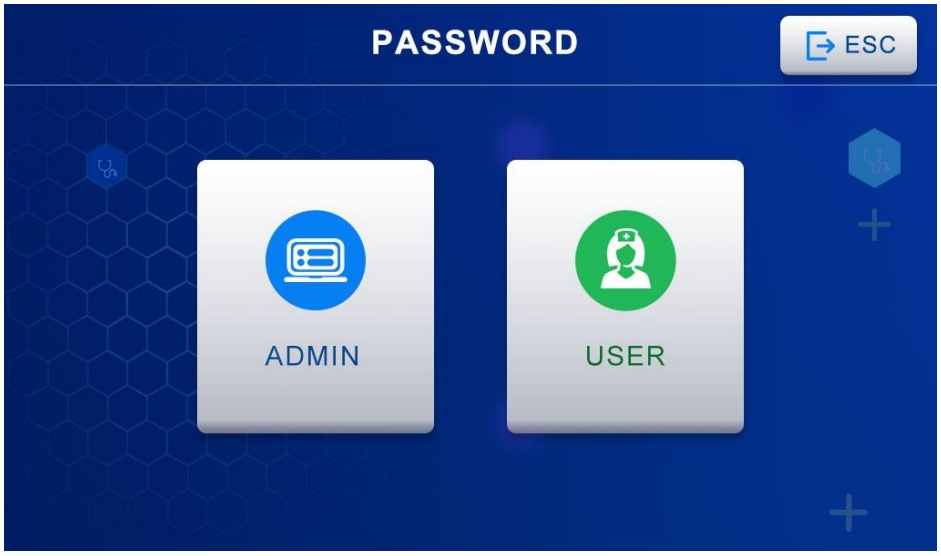
Notice: Waste bag should link with the outlet of leakage collector during operation and hang naturally with the clip open.

Notice: Waste bag can’t be used as collection and store of transport product.

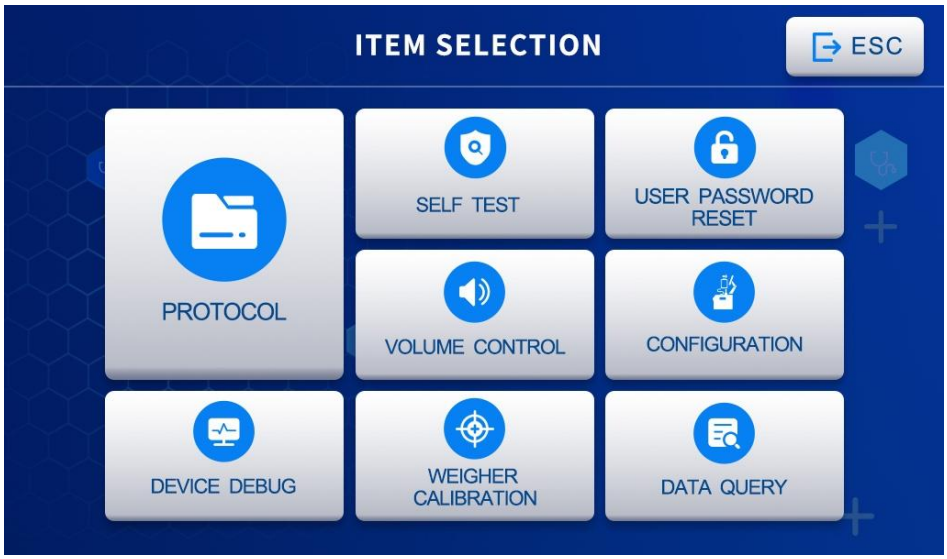
Notice: we suggest that must follow blood transfusion protocol when deal with or discard the waste contaminated possible.

4. Chapter Password and Interface Introduction

Press the touch screen, below menu appears, there are two options, ADMIN and USER, the ADMIN's password is 654321, the User's original password is 123456. The ADMIN has more function, and has high priority which can reset the User's password.



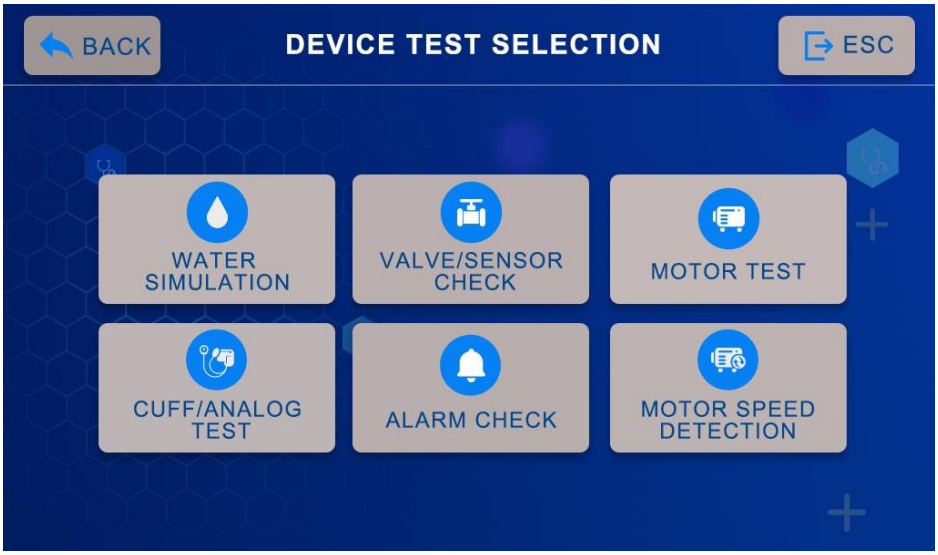
4.1 ADMIN menu and it's function introduction



4.1.1 PROTOCOL

At default configuration, we only provide PLT apheresis, others we are developing.

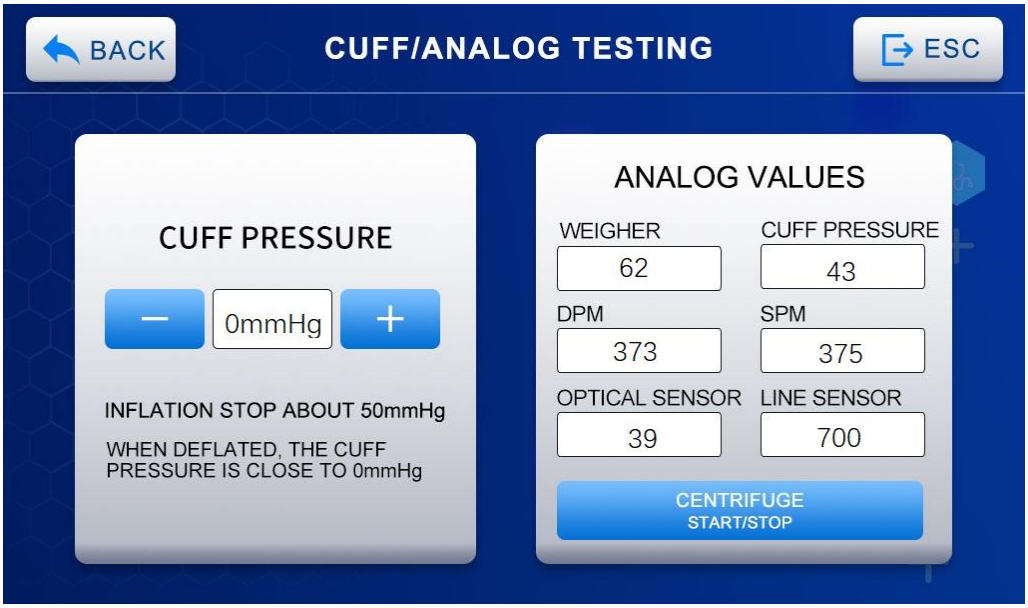
4.1.2 DEVICE DEBUG



4.1.2.1 WATER SIMLUATION

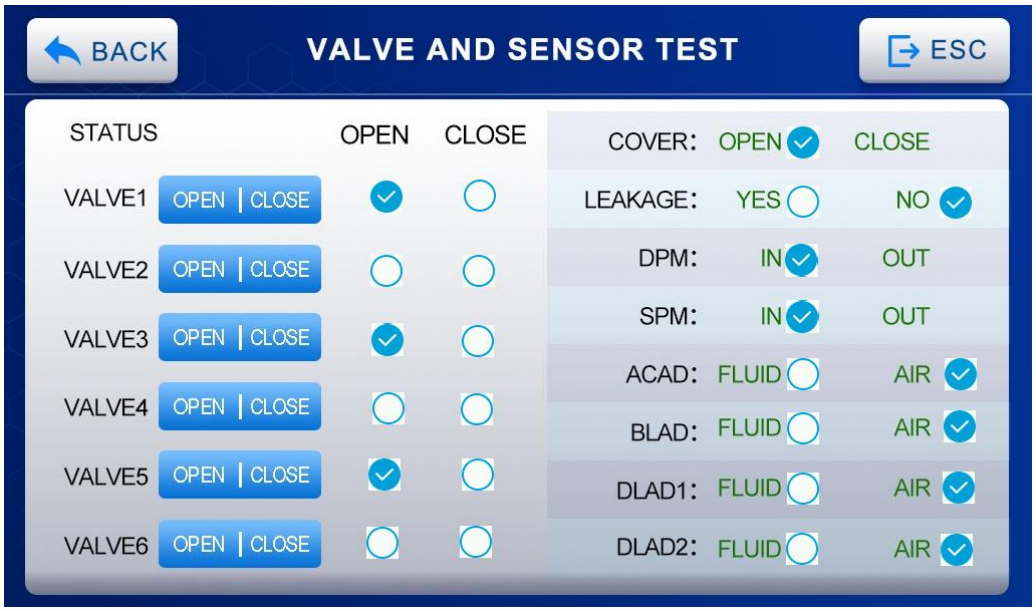
Water Simulation is special protocol which uses to simulate the PLT collection process, it can be used to train new operator or check the machine. It includes all the phase comparing the real collection, let new operator further know the process of PLT collection.

4.1.2.2 CUFF/ANALOG TEST



The picture on the left, use to check cuff pressure, press "+" inflate the cuff and increase the pressure , press "-" deflate the cuff and decrease the pressure.
The picture on the right, are the values which analog convert o digital, including weigher, cuff, DPM, SPM, optical sensor and line sensor.

4.1.2.3 VALVE AND SENSOR CHECK



The menu provide a check list for all valves, press OPEN, the valve open, press CLOSE the valve close normally, and the icon give a prompt.
COVER: The centrifuge cover can be checked, manually turn the switch clockwise until it shows

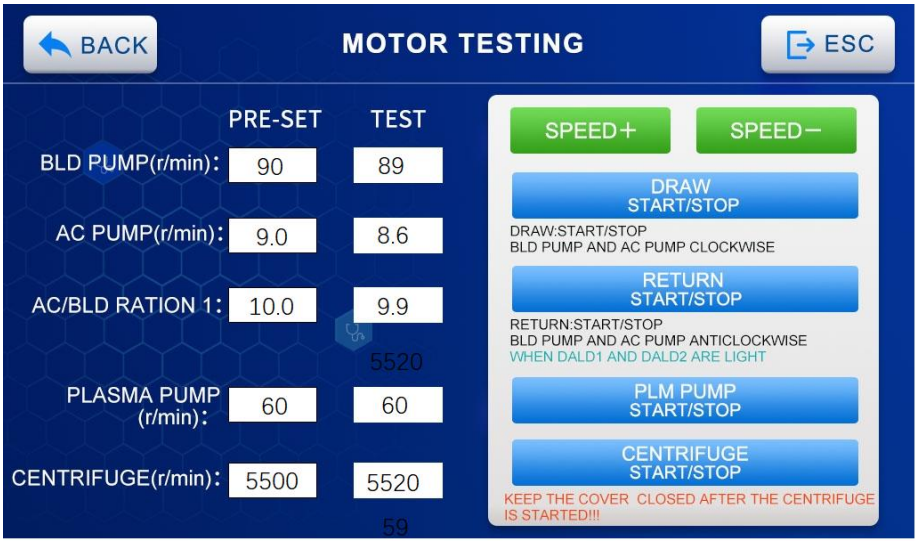
close, or turn it anticlockwise until it shows open.
LEAKAGE: To check the sensitivity of liquid sensor, use a cotton ball with water to scratch the sensor, you will get a YES icon. Clear the water on the surface of sensor, the icon will show NO.

4.1.2.4 ALARM CHECK

There are 6 different level alarms, the system give you corresponding icon and sound, an indicator also show different colors as showing below. Press OK to check them one by one.

4.1.2.5 MOTOR TEST

The menu below is to use tachometer of device itself to test the real speed of pumps and centrifuge.



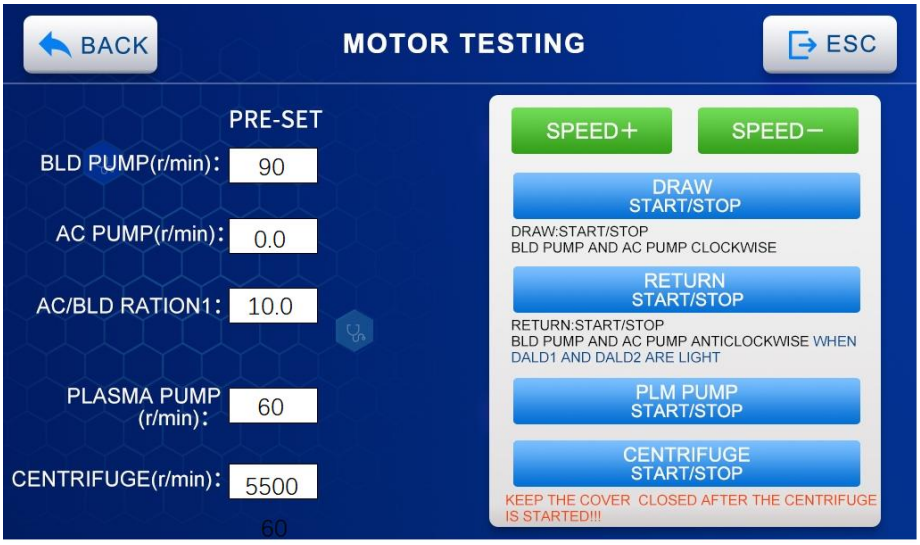
Press DRAW START/STOP, both blood pump and AC pump will run.
Press PLM PUMP START/STOP, the plasma pump will run.
The PRE-SET means the speed to be set, and press SPEED+ will increase the speed by 5 rpm, press SPEED- will decrease the speed by 5 rpm when the pumps are running.
Only the liquid be detected by DALD1 and DALD2, the RETURN mode can be activated.

The centrifuge speed was set to 5500 rpm before shipment, for safety, close the centrifuge lid before start the centrifuge.

Press BACK will stop all pumps and centrifuge, and go back to up-level menu.

4.1.2.6 MOTOR SPEED DETECTION

The menu intend to test the speed of pump and centrifuge by special instruments



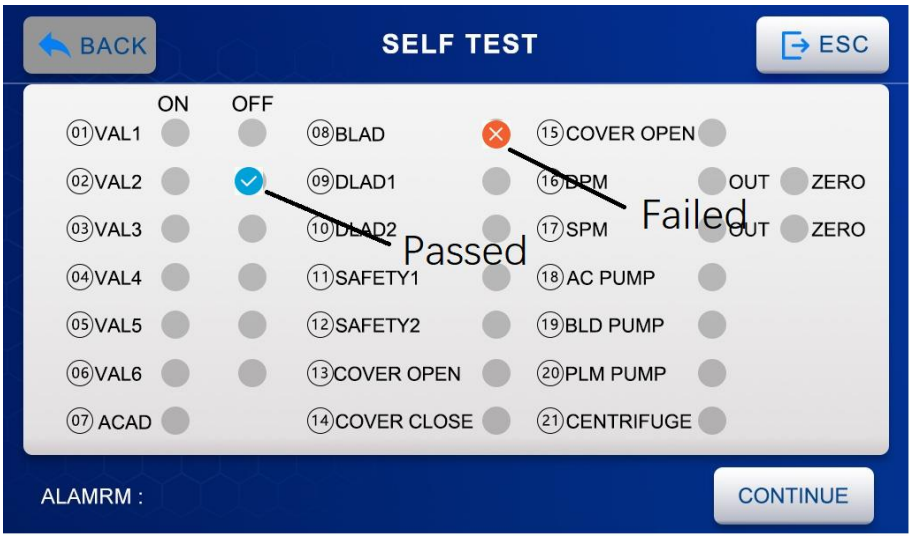
4.1.3 SELF TEST

There must be no any disposable on the machine while make a self-test, the below icon depicted test passed or failed.

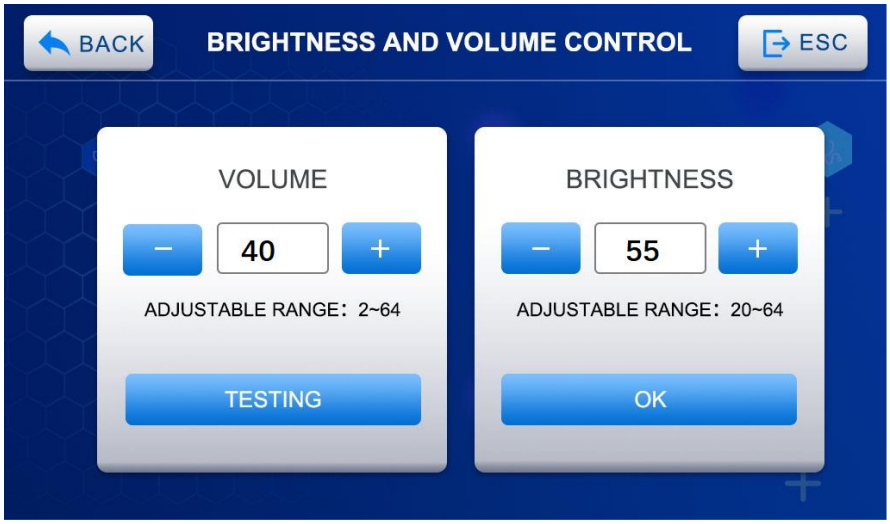
Both Open and Close of all valves will be checked..

The SAFETY1 and SAFETY2 check the function of safety when air detectors found air.

The cover of centrifuge must close before starting the centrifuge.



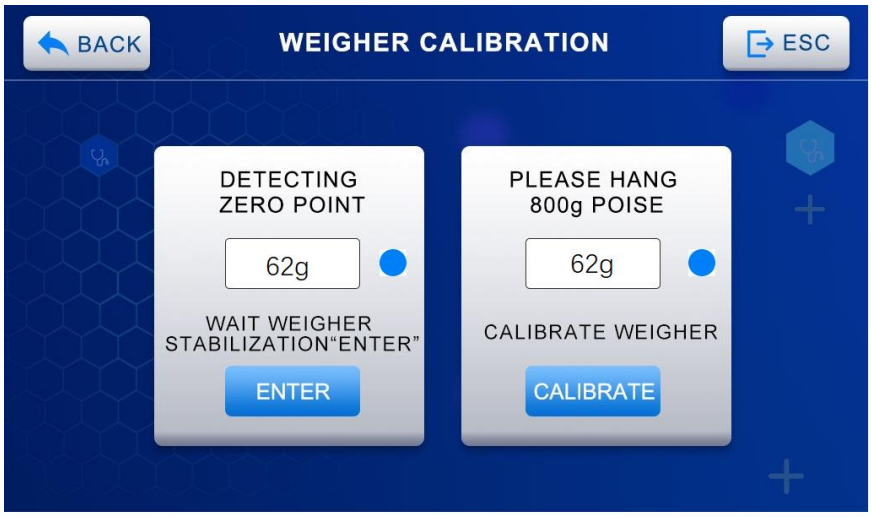
4.1.4 VOLUME AND BRIGHTNESS



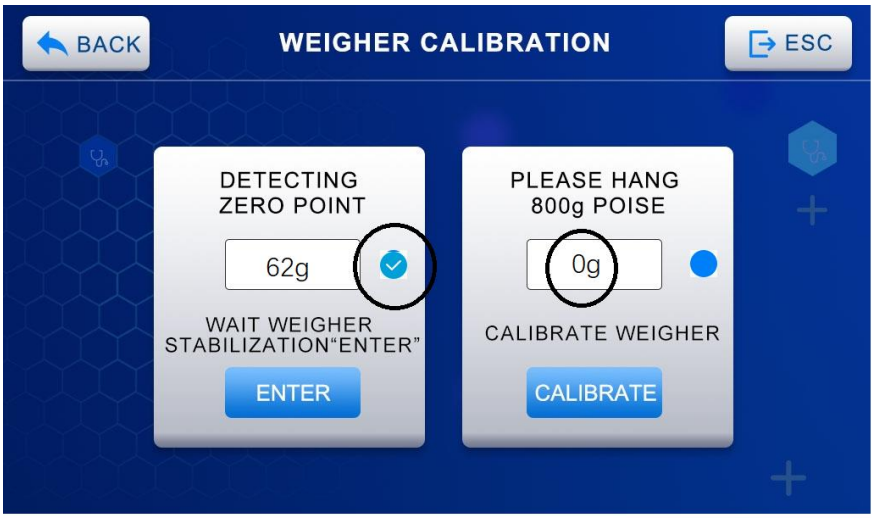
There are two functions on this menu, alarm volume on the left which the range from 2 to 64, press TESTING the give you a sound prompt, adjust the volume according you environment.

On the right can adjust the screen brightness from 20 to 64, press OK to confirm the brightness.

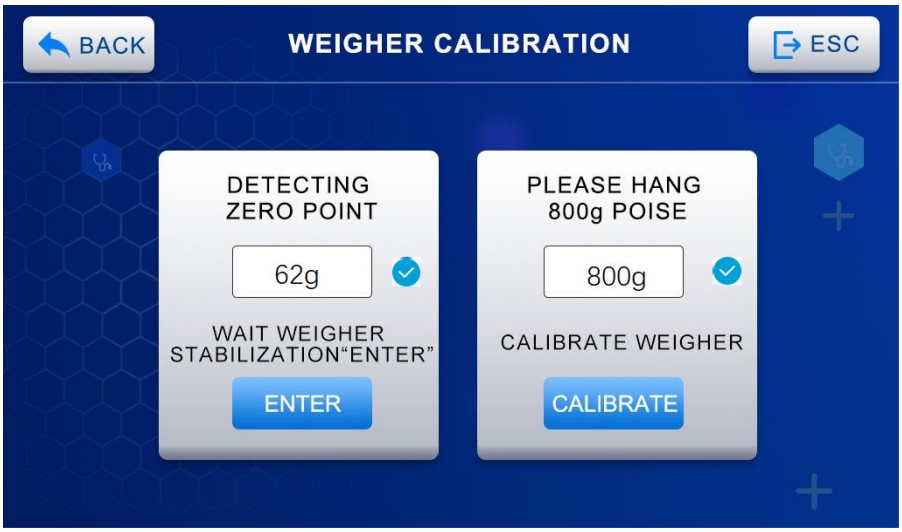
4.1.5 WEIGHER CALIBRATION



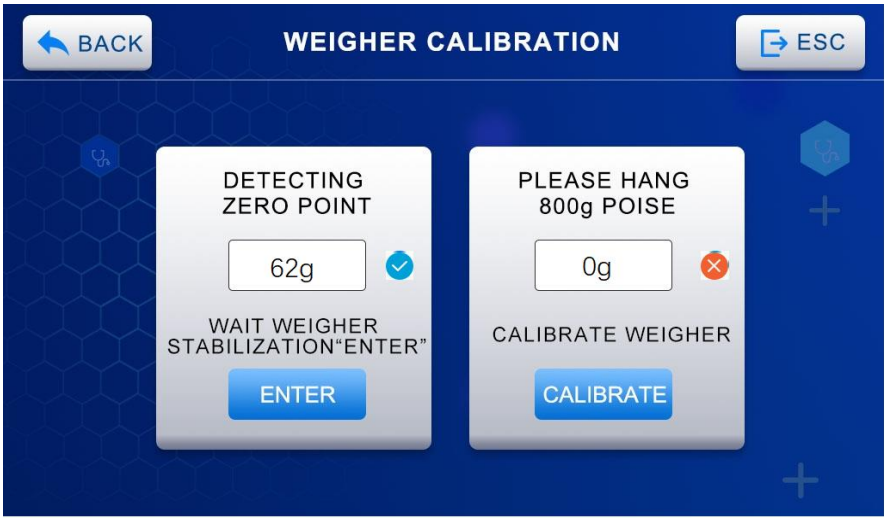
Please wait a moment until the value is stable, press ENTER, get the below menu：



Hang 800g poise on the arm of weigher, waiting until it become stable, then press the CALIBRATE, the weigher has been successfully calibrated if no alarm.

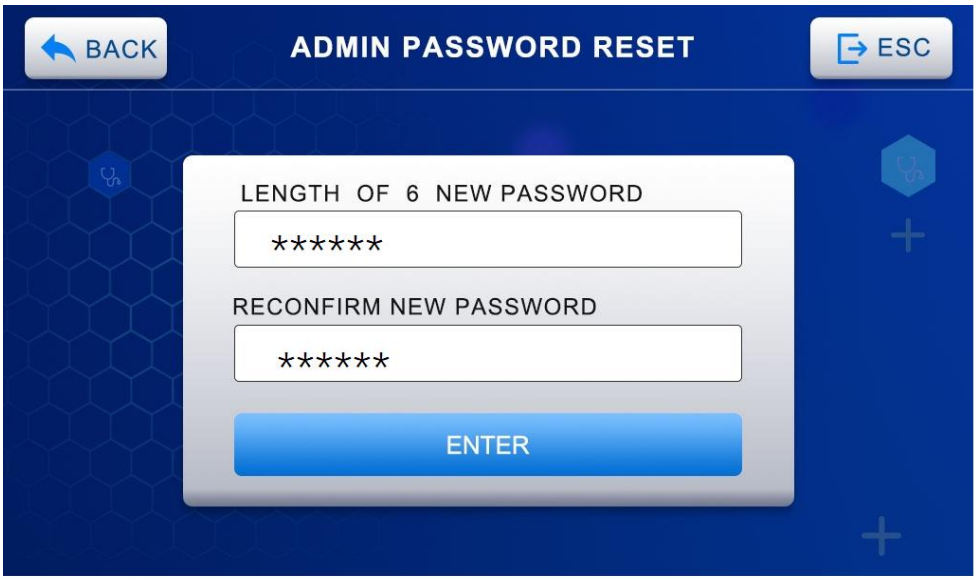


Error information: Fail information occur, when the weigher was damaged or give a wrong weight to the weigher's arm, the below information will appear.



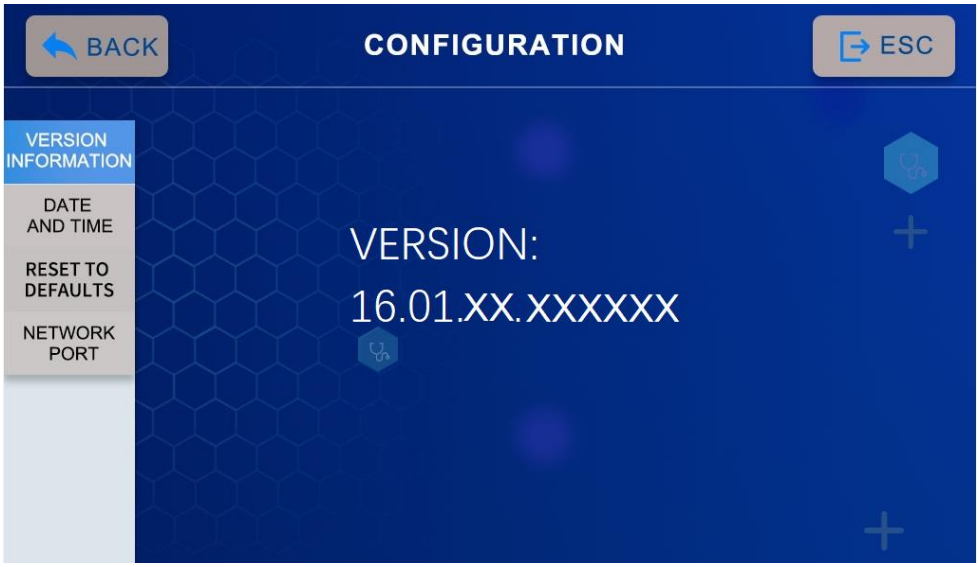
4.1.6 USER PASSWORD RESET

Click the USER PASSWORD RESET, you can modify user's password. Both letters and numbers can be entered as new password, but the length must be 6!



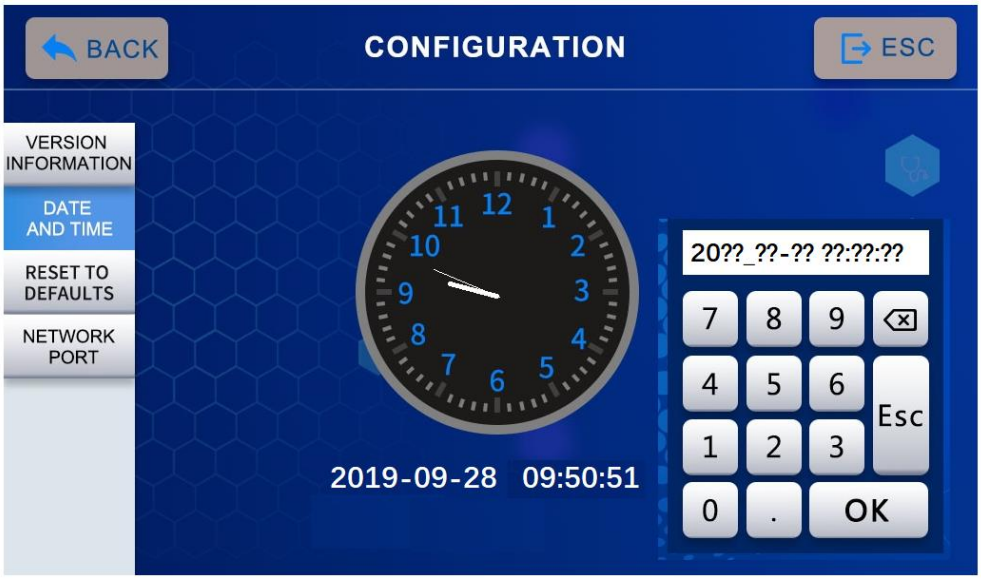
4.1.7 CONFIGUATION

4.1.7.1 Version Information



4.1.7.2 Date and Time

Click the clock, a keypad appears, you can enter the local date and time. The format is year-month-date, hour-minute-second. Press OK to store, Esc to abort.



4.1.7.3 RESET TO DEFAULTS Press “ENTER” to restore the defaults.

4.1.7.4 NETWORK PORT Check your local net system parameters to build net connection.

4.1.8 DATA QUERY

Both data query menu and statistic menu are shared; there are max 9 groups data stored in the local memory which can be checked for the operator if necessary. More collections will cause the old data be replaced by new one.
More information about this menu will explain in following chapters.

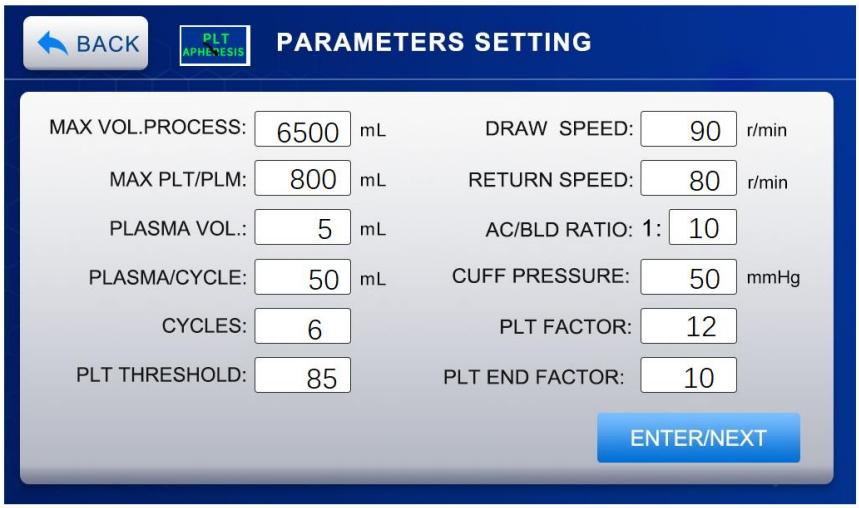
5. Parameters and Collection Calculator

5.1 USER interface

Press icon USER get interface below after you input the user password

5.2 Parameters setting

Press PLT APHERESIS, go to the parameters setting menu below. This menu is for machine



5.2.1 EXPLANATION

MAX VOL.PROCESS: It gives a limitation that the blood will be processed, the device will automatically stop draw and return the remaining blood component when it reaches the MAX VOL.PROCESS.

MAX PLT/PLM: The maximum platelet volume plus plasma volume to be collected from the donor, it will automatically return plasma to the donor if platelet volume is too big, thus keep the value equal to the setting.

PLASMA VOL: It is the quantity of plasma to be collected with the platelet, expressed in ml. The setting is 5 if concurrent plasma collection has not been selected because the injection port remaining about 5 ml. The device will not collect more than the maximum allowable volume of plasma and platelets.

PLT FACTOR: Delay surge start, the range is 0-25, default is 12. When the buffer coat be found by bowl optical sensor, that means the PLT close to the outlet of the bowl, the next phase SURGE will start.

PLT THRESHOLD: When surge start, as the speed of plasma pump increasing, more and more platelet be pushed out with plasma, back to the plasma bag, at same time the voltage of line sensor decreasing, when the value is equal to the PLT THRESHOLD, the plasma valve close and the PLT valve open, thus PLT goes into the platelet bag.

PLT END FACTOR: When most of platelet in the bowl has been pushed out, the voltage of line sensor will change from decreasing to increasing, the computer can automatically find the point and give a delay time. This value is what we called PLT END FACTOR.

5.2.2 Technique parameter

CYCLES is the number of cycles calculated as necessary to complete the collection procedure, based on the donor parameters and procedure information entered into the Calculator

AC Ratio signifies the volume of anticoagulant solution being administered to the donor line in comparison to the volume of whole blood being drawn from the donor.

Draw Speed is the targeted maximum pump rate used during the DRAW mode of the procedure. The device continuously regulates the Draw pump speed so that the pressure measured by the DPM in the donor line does not exceed safety limits.

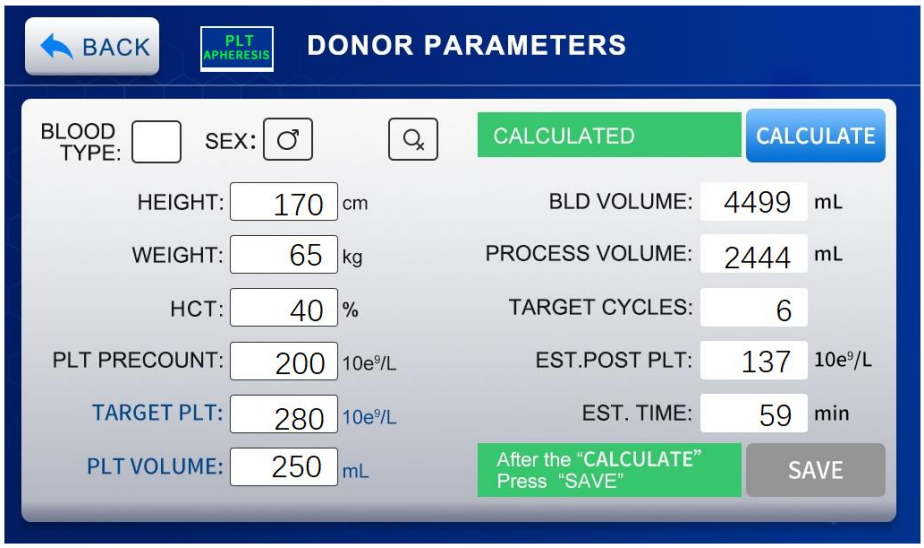
Return Speed is the targeted maximum pump rate applied during the RETURN mode of the procedure. The device continuously regulates the Return pump speed so that the pressure measured by the DPM in the donor line does not exceed safety limits.

Cuff adjusts the automatic inflation and deflation of the pressure cuff during the procedure expressed in mmHg.

PARAMETER	RANGE	DEFAULT
Cuff	0～100mmHg(0～13.3kPa)	50mmHg(6.7kPa)
Plasma /cycle	0～500g	50g
Plasma collection	0～800g	200g
Draw Speed	20 r/min～100r/min	90r/min
Return Speed	20 r/min～120r/min	80r/min
AC/Blood Ratio	1:8～1:16	1:10
Centrifuge Speed	5,500r/min	---

5.3 Donor Parameters

Click CALCULATE after you input all the parameters on the left, press SAVE go next menu.



5.3.1 EXPLANATION

Height is the height of the donor expressed in centimeters (cm).

Weight the weight of the donor expressed in kilograms (kg).

HCT is the hematocrit of the donor as determined by a pre-procedure blood sample, expressed as a percentage.

PLT PRECOUNT is the amount of platelets contained in a specific quantity of donor whole blood, as

determined by a pre-donation sample. The Calculator uses this measurement to determine the total volume of anticoagulated whole blood necessary to process in order to collect the programmed target yield of platelets.

TARGET PLT is the targeted number of platelets to be collected. Press CALCULATE, this volume is automatically calculated by the calculator, based on the donor characteristics and yield, as entered by the operator

PLT VOLUME PLT product volume, it is minimum volume. The program will automatically add plasma to the platelet bag at the beginning of plasma flow out when the volume of platelet cannot reach the PLT VOLUME. The platelet volume may over the PLT VOLUME when there are more cycles.

BLD VOLUME is the estimated total blood volume of the donor. Press CALCULATE, this volume is automatically calculated by the calculator, based on the donor characteristics, as entered by the operator

PROCESS VOLUME is the estimated blood volume will be processed. Press CALCULATE, this volume is automatically calculated by the calculator, based on the donor characteristics and the yield, as entered by the operator

EST.POST PLT is the estimated platelet count after the procedure, Press CALCULATE, this volume is automatically calculated by the calculator, based on the donor characteristics and the yield, as entered by the operator

EST TIME is the number of minutes elapsed since pressing the Draw key to initiate the first cycle, excluding the priming sequence.

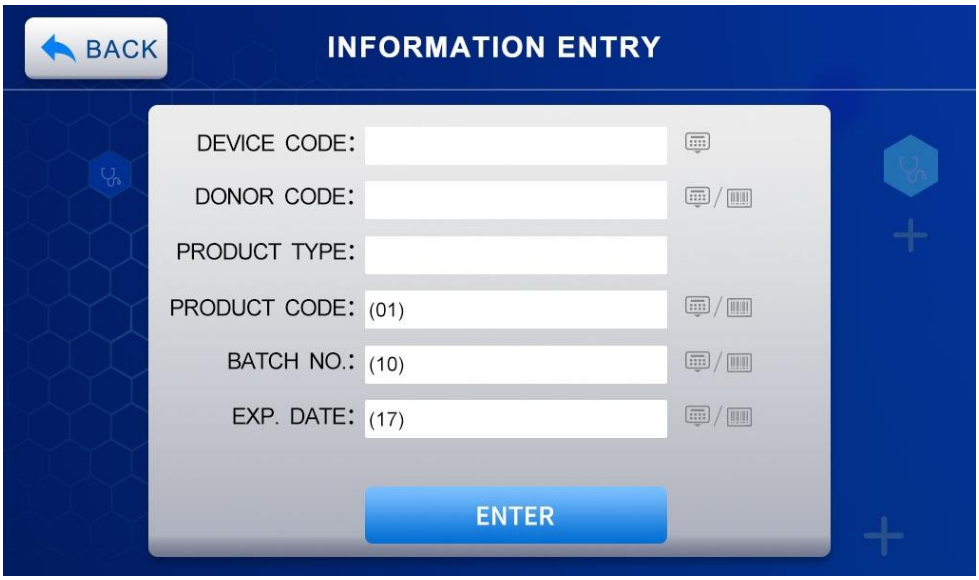
5.3.2 Technique parameter

PARAMETER	RANGE	DEFAULT
Height	120cm—210cm	170cm
Weight	40Kg--150Kg	65Kg
HCT	30—60 %	40%
PLT Precount	150—600 E9/L	200E9/L
Target PLT	150—700E9	280E9
PLT Volume	0-520ml	250ml

6. Install the Disposable, Priming

6.1 Data management information input

You can either scan the Bar code or RFID, then press ENTER; or you can also directly click ENTER to ignore the data input if you don't need or the network function not available.



6.2 Disposables Check

Disposables Check, carefully check appearance and expired date:

(1).Ensure that ACD is normal, spike port is not fallen, and that the connection line at the inlet of the centrifugal bowl is not fallen;

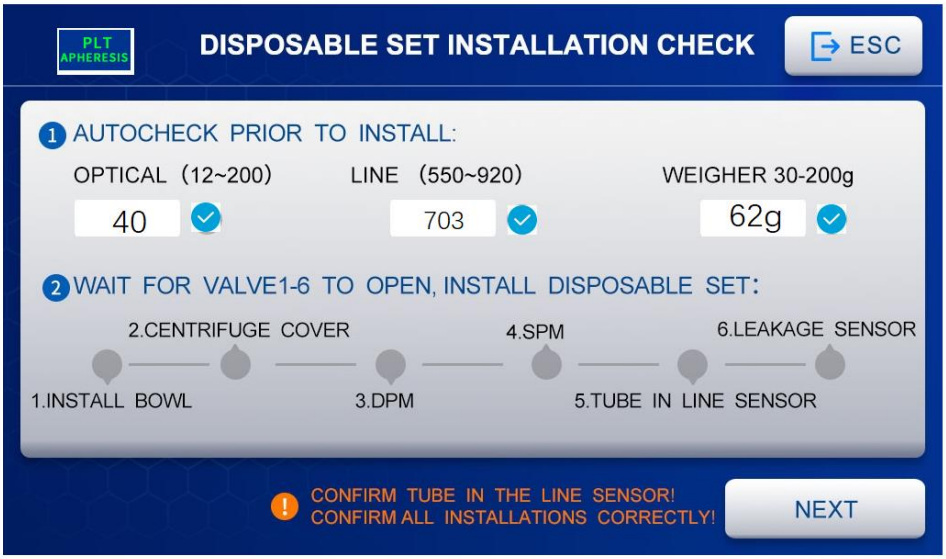
(2).The line shall not be twisted, twined, or pressed;

(3).The bag shall have no small holes or be broken;

(4).No crack shall occur on the surface of the centrifugal bowl, and no visible debris shall be seen in it;

(5).The bowl can revolve smoothly.

Device will display the sensors value and their ranges, see below. If one of them is out of the range, the device cannot go to next step.



6.3 Install the centrifugal bowl

(1) Open the centrifuge cover;

(2) Turn the outlet of the centrifugal bowl toward the right side of the centrifuge, and press it in the bowl seat lightly;

(3) Close the cover, screw tightly the cover switch, until a √ appears at the on the screen. The cover may be smoothly put down only the bowl is installed properly. If the cover cannot be closed well, check the location and direction of the centrifugal bowl.

⚠ **Notice: If the centrifuge bowl is installed improperly, the seal ring may be damaged during draw. Therefore, prior to draw each time, ensure whether the centrifuge bowl is installed properly.**

6.4 Install the line

(1) Install the connection line at the outlet of the centrifugal bowl at the line sensor, and place the “Y” joint connected with SPM between the line sensor and valve. Ensure the line is completely placed at the bottom of the line sensor.

⚠ **Notice: Often check the line is located properly in the line sensor, and ensure it is installed properly prior to operation. However, the line shall not be pulled after separating and collecting the plasma.**

(2) Install SPM adapter

a. Hold the SPM adapter with hand, and insert and press its lock ring into SPM;

b. Turn 1/4 circle clockwise, and fix it;
c. Tug lightly the SPM line, and ensure it is installed properly;

(3) Install the green line from the “T” joint along the connection line at the outlet of the centrifugal bowl to the platelet bag into the Green Valve 5, and install the other yellow line into the Yellow Valve 4. Ensure the line is installed properly in the valve, and shall not slip out of the valve.

(4) Hang the platelet bag on the pin at the right side of the Blood Component Separator, and open the clamp of the platelet bag.

(5) Hang the plasma bag on the weigher arm.

(6) Hang the air bag on the pole, line end downwards, load line in the black valve 6. Ensure the line is installed properly in the valve, and shall not slip out of the valve.

(7) If the kit has a transfer bag, hang the transfer bag on the pin of the front cover of the Blood Component Separator, install the line which connected to red line into the blue Valve 2, and install another line into the Valve 3. Ensure the line is installed properly in the valve, and shall not slip off the valve.

(8) Install the line at the blood pump and plasma pump as picture below, firmly push the cartridge until it goes to bottom.

(9) Put the line coming before the blood pump into the groove of the BLAD, and remain a little length of tubing line between the line guide of blood pump and the BLAD.

(10) Place the red line joint into the red Valve 1. Ensure the line is installed properly in the valve, and

shall not slip out of the valve.

(11) Take up the blood filter, with the double-tube downwards and the single-tube upwards, and insert into the bracket at the frontal panel of the device.

(12) Install the line into DLAD.

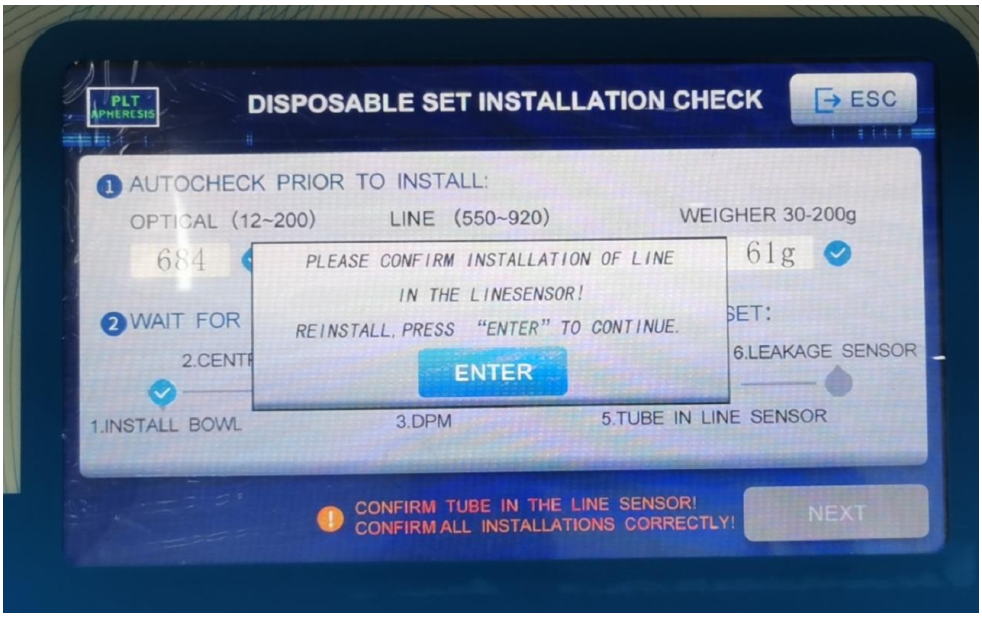
a. Place the single-tube of the blood filter into DLAD2;
b. Place the line from the top of DLAD2 into DLAD1;
c. Place the line form the top of DLAD1 into the tube nest at the left-front of the Blood Component Separator;
d. Ensure the line with extra length between the blood filter bottom and the bottom of DLAD2, between DLAD1 and DLAD2, and between DLAD1 top and the tube nest.

(13) Install the line at the anticoagulant pump with a blue sign.

a. Find the line stop seat closed to the anticoagulant spike, and put it into the line guide behind the anticoagulant pump;
b. Encircle the tubing line to the annular groove of the anticoagulant pump head from back to front;
c. Confirm another line stop seat put in the line guide before the anticoagulant pump;
d. Confirm the line stop seats block in the line guides entirely.

(14) Put the tubing line coming before the anticoagulant pump into the groove of ACAD, and remain a little length of line between the line guide of anticoagulant pump and ACAD.

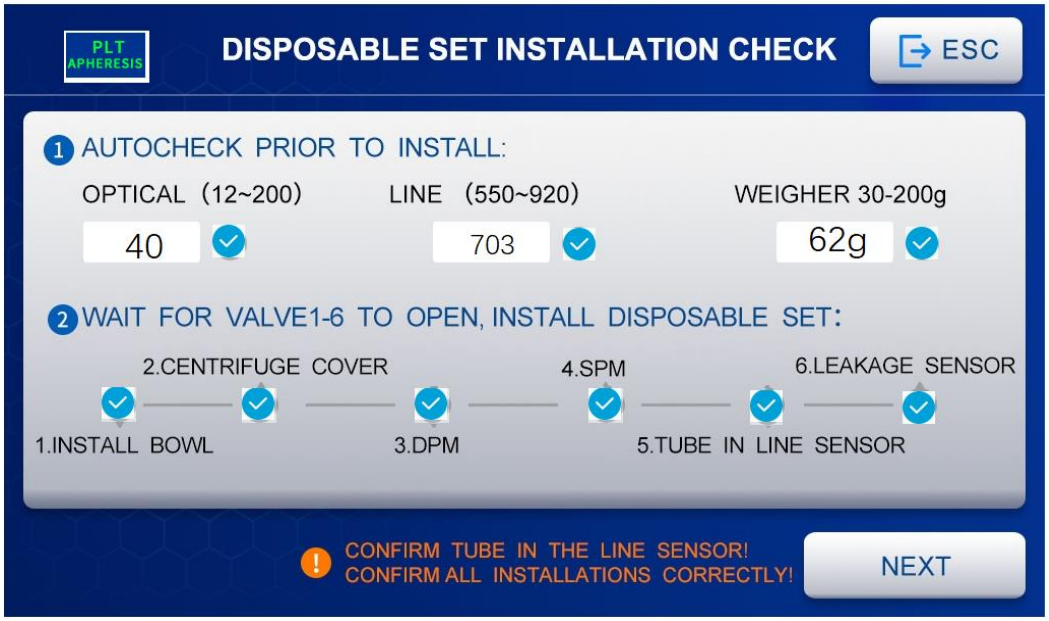
(15) Install the line of LINE SENSOR, insert it and pull it repeatly to confirm it correctly be installed.



(16)Install DPM adapter

a. Hold the DPM adapter with hand, and insert and press its lock ring into SPM;
b. Turn 1/4 circle clockwise, and fix it;
c. Tug lightly the DPM line, and ensure it is installed properly;

(17)Installation completion as below



(18)Close the clamps of the sampling bag and the needle line, and ensure the clamps of DPM line and SPM line, and of the platelet bag and plasma bag are open.
Press NEXT goes to next menu when disposable installation is right.

6.5 Load pump tube

1. Press **LOAD PUMP TUBE**, the three pumps turn 2 circles clockwise, and let the line into the pump. After the pump is stopped, if the line has not been completely placed into the pump, press **LOAD PUMP TUBE** install the line again, until the line is placed into the pump.

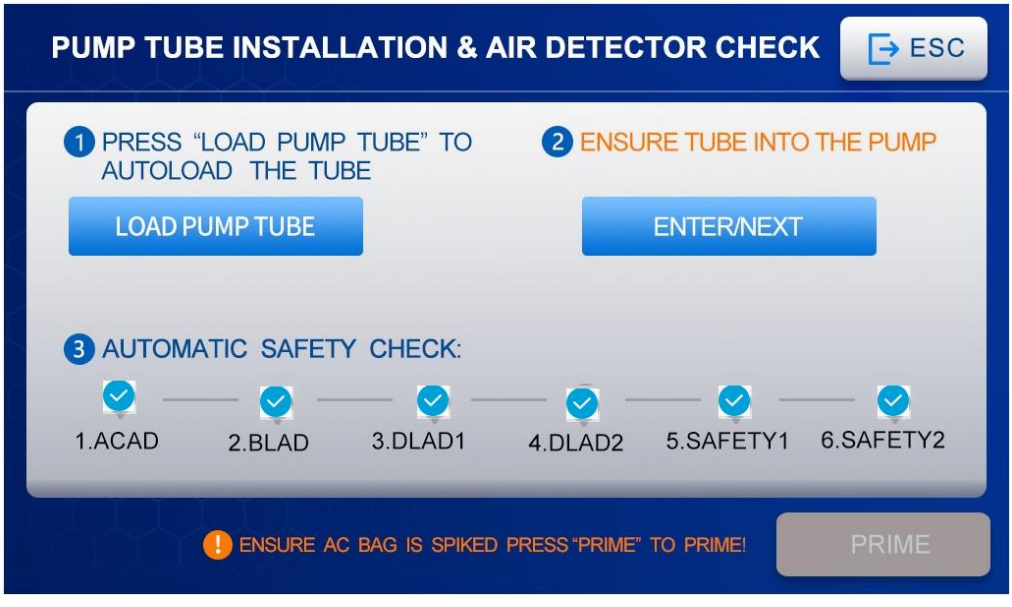
2. After completion of installation of the line, press **ENTER/NEXT** and continue the following operation.

3. Prime line with anticoagulant

(1)After completion of load line, the Blood Component Separator will conduct a self-check for safety items automatically.

a. If an item fails through check, the device may beep for warning and stop the check. Then please keep records for the item failed through check, press **ENTER** key, and return to the working menu, click CHECK DEVICE to determine the part in failure. Then, contact with the sales service department of the company.

b. A √ will appear at the up position of the each item that passes through check, or × if failed. All items pass through safety check, the screen displays:

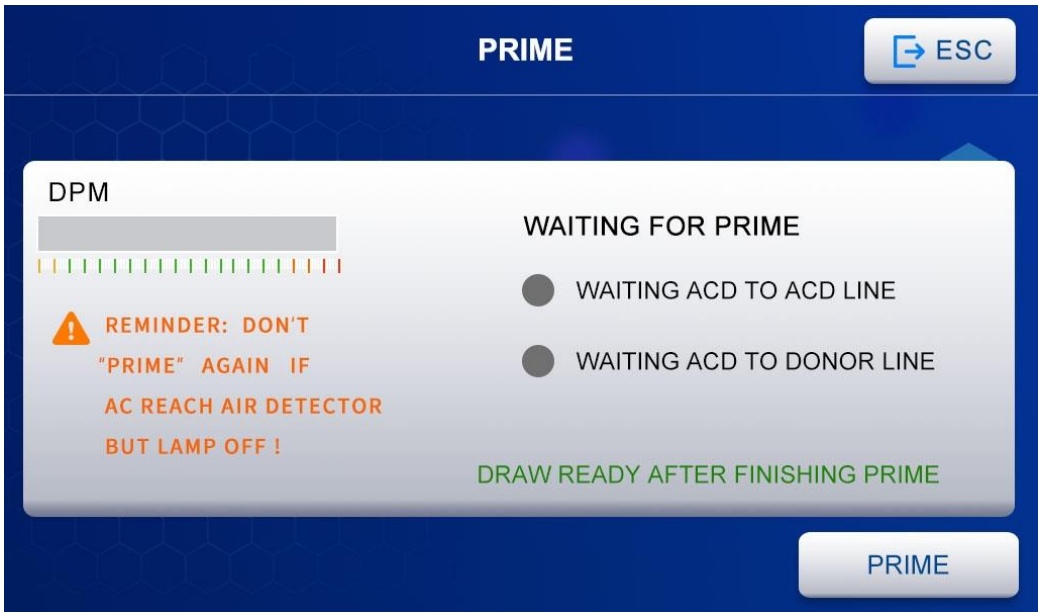


(2) Check whether each part is installed properly, according to requirements of installation of disposable.

(3) Get connected with the anticoagulant bag.

a. Hang the anticoagulant bag at the anticoagulant pole;
b. Pick off the caps from the bag and spike using asepticism;
c. Spike the bag using asepticism, ensure connect tightly.

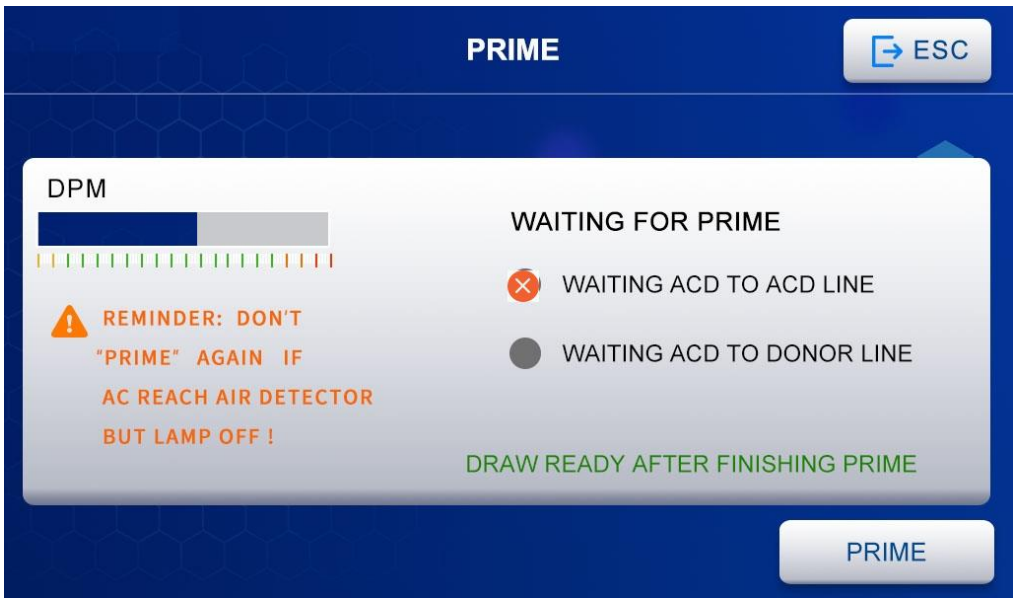
(4) Press **PRIME** key; then the two pumps rotate clockwise, and prime the line with anticoagulant.



(5) When anticoagulant reaches up to DLAD, then the prime are completed. The Blood Component Separator is ready to draw.

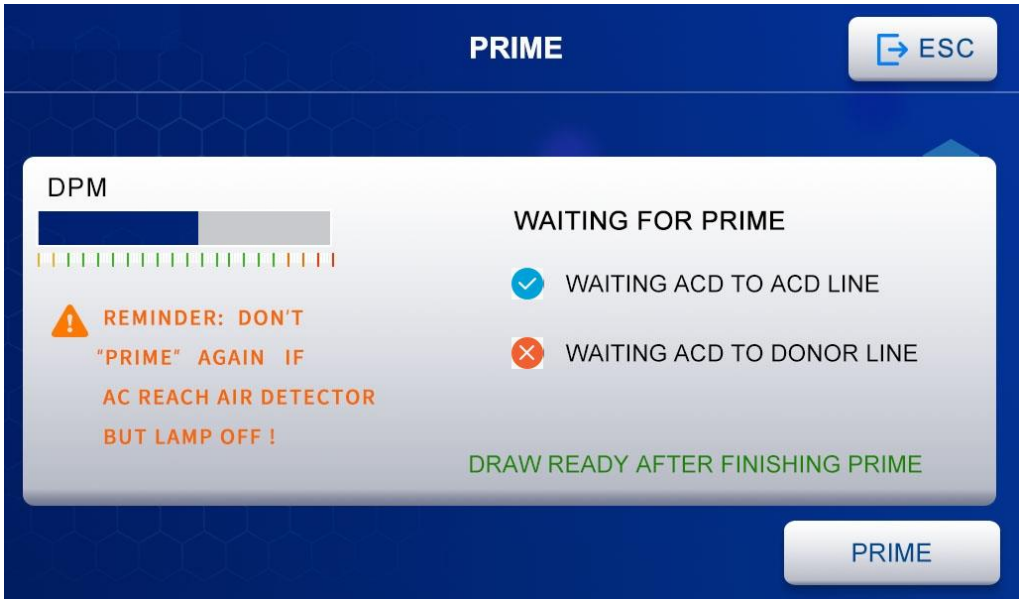
(6) Error messages:

a. If the line is installed improperly in ACAD, or the anticoagulant bag is not accessible, resulting in anticoagulant cannot be reached at ACAD, the screen displays:



Then check carefully, and correct the error.

b. If the line is not placed improperly in DLAD1, or the anticoagulant has no proper access into the line, resulting in anticoagulant cannot be reached at DLAD1, the screen displays:



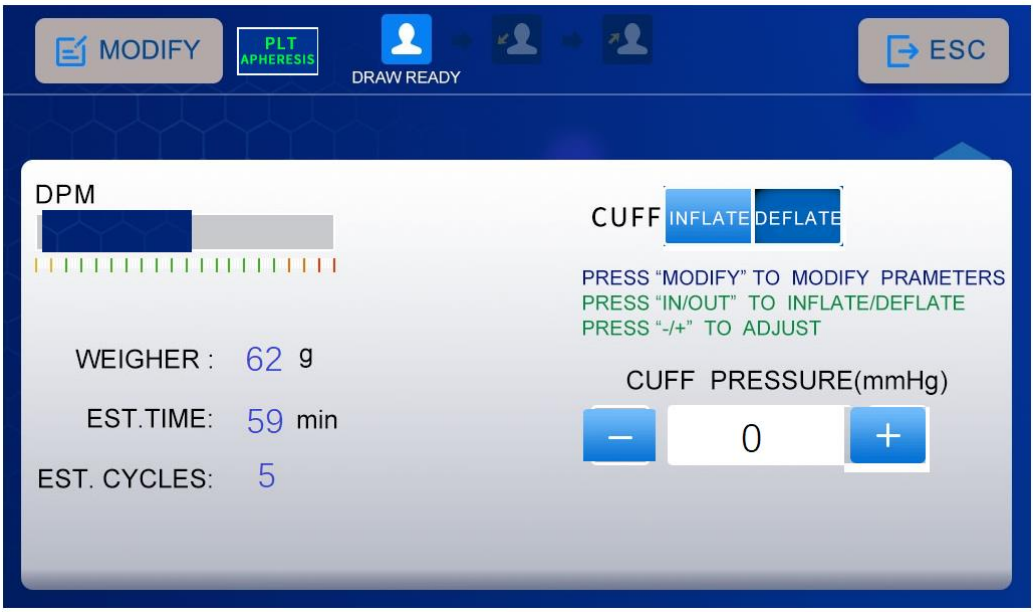
Then check carefully, and correct the error.

c. Then press **PRIME** again according to the screen prompt, and continue prime the line with anticoagulant.

7. Collection Procedure

7.1 Draw Ready

Once the parameters have been input on the Calculator screen, the disposable to be installed correctly and prime has completed.



When the READY mode is displayed, the operator should prepare the donor for the venipuncture, handling all biologically contaminated materials according to standard operating procedures.

a. Wrap the cuff around the arm of donor, the distance of the venipuncture site and the bottom of the cuff is not less than 9 cm;

b. Press INFLATE key, the cuff is inflated automatically, until the preset cuff pressure value; Temporarily adjust the cuff pressure by pressing the + and - keys to facilitate venipuncture, but does not change the preset cuff pressure values;

c. Clean the venipuncture site using aseptic technique.

d. Ensure that the donor line as well as the donor sample pouch tubing are clamped.

e. Perform the venipuncture respecting aseptic technique.

f. Unclamp the donor sample pouch line and allow a sufficient sample of blood to flow into the pouch, then re-clamp the line.

g. Seal the sample pouch tubing between the Y-connector and the sample pouch.

h. Fill the necessary donor blood sample containers with the contents of the sample pouch according to local standard operating procedures.

Warning: The injection port on the 4-way connector of the donor needle tubing must not be used

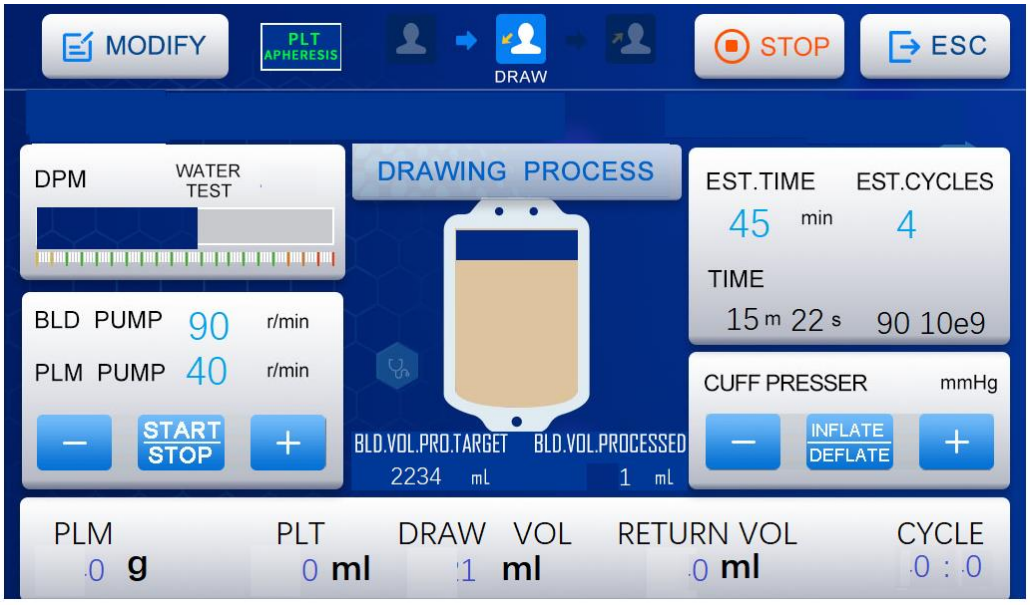
for any reason, and the needle itself should not be changed prior to hermetically sealing the collection products. Use of this port compromises the sterile fluid pathway and the system should be considered as "open".

The sterile pathway should be considered compromised, and the product life should be reduced to 24 hours.

7.2 Draw Mode

Press the Draw key to initiate the first collection cycle.

The pressure cuff automatically inflates, the pumps and centrifuge begin to spin, and all monitoring components used during the DRAW mode are activated. During the first Draw cycle the weigher is automatically tared to 0 to account for the initial weight of the bags.



A DEVICE collection protocol is the repetition of one basic cycle of operating states, or operating modes. The cycle is repeated until either the end procedure criteria are automatically reached, or the operator manually intervenes to terminate the procedure.

A basic collection procedure cycle consists of specific phases during each operating mode, occurring according to the following general sequence. The cycle repeats until the procedure is complete.

The DEVICE main display screen is composed of serval sections and continually updates information for the operator throughout the collection procedure.

Air/Plasma interface

When the optical bowl sensor has detected the air/plasma interface, the following screen appears:

Collecting plasma

Once the plasma be detected by line sensor, the v6 closes. The v4 valve opens to allow the plasma exiting the bowl to be collected in the plasma bag on the weigher, as indicated by the following display.

Transferring plasma

When a sufficient quantity of plasma is available in the plasma bag, the Transfer pump rotates to draw plasma from the plasma collection bag into the centrifuge bowl in order to maintain the critical flow.

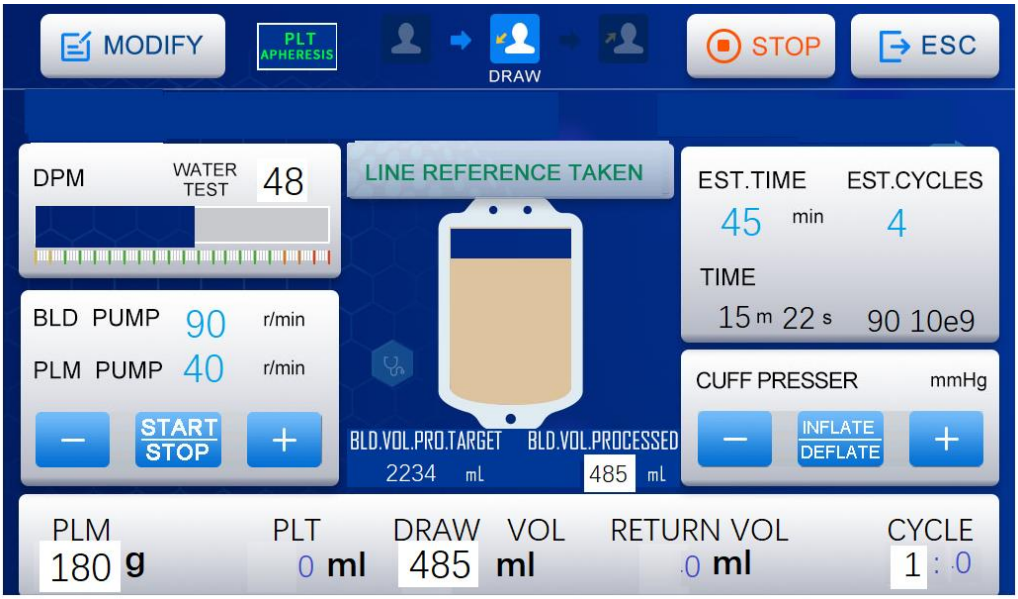
Note: Critical Flow refers to 100rpm rate of plasma flowing into the bowl. The critical flow process is used by the device to reduce the HCT and optimize the separation of blood cell layers within the centrifuge bowl, ultimately maximizing the platelet collection. The device adapts the speed of the plasma pump depending on the value of the donor hematocrit and donor flow during the DRAW mode.

Bowl optics reference

After a certain time, the optical bowl sensor measures the optical density of the donor plasma. The device uses this “bowl optics reference” to determine when to initiate the Surge phase.

Line sensor reference

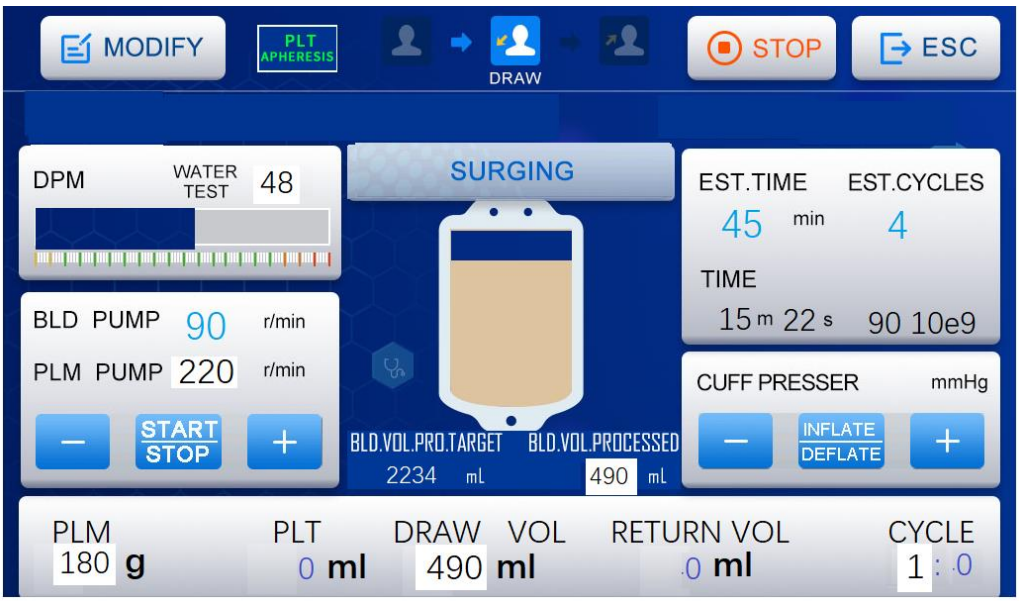
Once the bowl optical sensor detects the plasma/buffy coat interface, it records an optical reference for the line sensor and the following screen appears:



The Transfer pump rotates to circulate plasma from the plasma bag through the bowl at a constant flow rate. This clears the bowl feed tube of residual whole blood and stabilizes the separation between the blood cell layers within the bowl.

Surge

Once the Dwell phase is complete, plasma circulates at an increasing flow rate from the plasma bag into the bowl. This increasing flow rate elutriates the platelets out of the bowl. Optimal separation of blood cell layers contributes to obtaining high platelet recovery rates.



Collecting platelets

Once the line sensor detects the presence of platelets in the effluent tubing, the V3 closes and the V4 opens when the threshold value reaches, the platelet is collected into the PLT bag. At the end of surge phase, the platelet rich plasma will be collected into PRP bag.

During the second cycle, and subsequent cycles, platelet rich plasma collected into the PRP bag is reintroduced into the bowl during at beginning of draw.

The RETURN mode

Once the centrifuge stops, the RETURN mode begins automatically.

Returning cells

To ensure that blood components mix effectively prior to infusion to the donor, collected plasma from the plasma bag is simultaneously returned to the donor with red cells.

COMPLETING THE COLLECTION PROCEDURE

Automatic procedure ending

Once the selected end of procedure criteria have been met, the following screen appears and a prompt sounds.

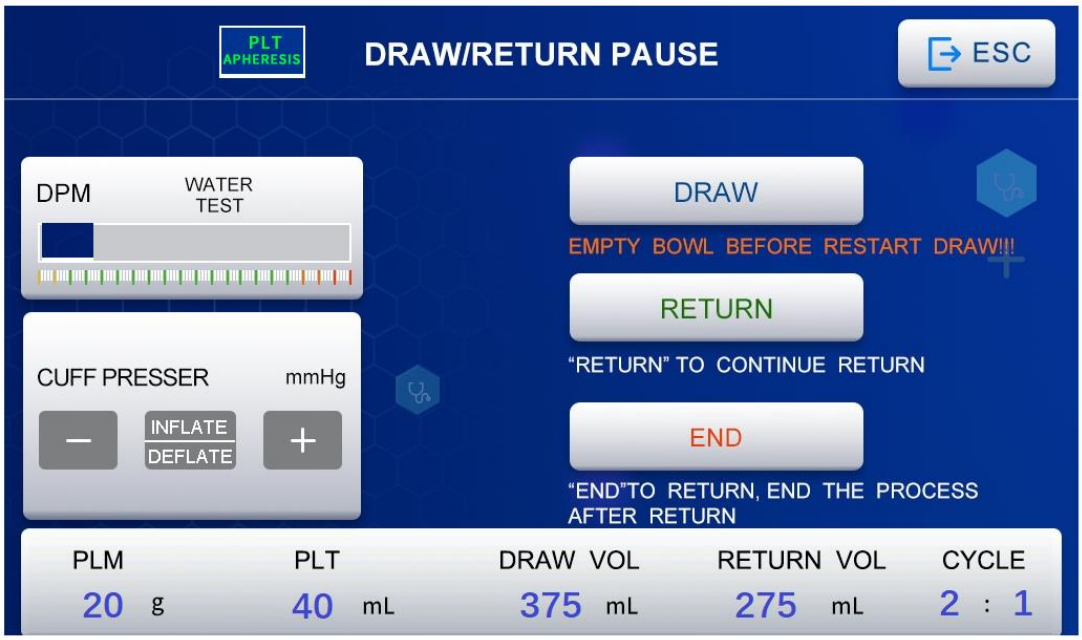
Manually ending a procedure

Certain situations may arise in which the operator may need to interrupt a procedure rather than allow it to end automatically. In these situations it is possible for a collection procedure to be terminated by manual operator intervention rather than by a DEVICE automatic procedure ending. The following two sections describe the possible interventions.

Interrupting the procedure with the STOP key

If necessary, the operator can press the STOP key from a Draw or Return cycle to discontinue the procedure.

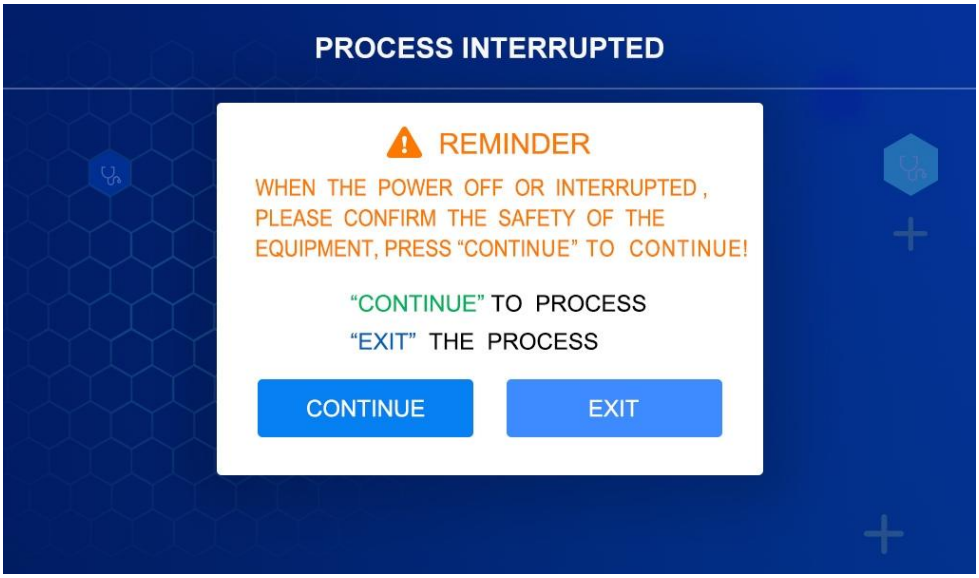
A sequence of messages will appear in which the STOP message appears, followed by the READY mode screen display:



Interrupting the procedure with the ESC key

If necessary, the operator can press the STOP key from a Draw or Return cycle to discontinue the procedure.

A sequence of messages will appear in which the STOP message appears, followed by the READY mode screen display:



Disconnecting the donor from the disposable set

When the collection procedure has been completed, the operator can disconnect the donor from the disposable set as follows:

1. Clamp the AC line and blood line tubing.
2. Draw a post-procedure donor sample if necessary.
3. Remove the venipuncture needle from the arm of the donor.
4. Apply a pressure dressing and discharge the donor according to the local standard operating procedures. Draw a product sample after the product has rested for one hour.

8. Status Messages

8.1 Trouble Information

When the blood component separator system appears the prompt message or the alarm, the alarm sound and the indicator light and the visual alarm signal of the display screen will be produced at the same time. The alarm level is represented by the different frequencies of alarm tones: the high priority tone is "ccc-cc ccc-cc", the middle priority tone is "CCC", and the low priority tone is "C". According to the alarm priority, the flashing color of the indicator light is also different: high priority alarm is red, medium priority and low priority alarm is yellow. The priority of alarm is classified according to the different alarms generated in different stages of product use.

In the work item menu, check the device option to verify that the alarm system is working, and it is recommended to check at least once a day at the start of work. If the alarm system does not work properly, it is recommended to suspend the use of the machine, and promptly contact the company sales service department.

Note: when different priority alarms appear, alarm information display and alarm processing sequence are high priority, medium priority and low priority. When two or more alarm signals with the same priority alarm status are generated, the system will display the alarm information recently generated according to the time sequence of alarm generation.

8.2 Fault information

The operator of the blood component separator shall be within 4m of the equipment to facilitate the observation and processing of alarm information. If the following alarm information appears, please exclude the alarm according to the method in the following table. If the failure cannot be eliminated after taking measures, please contact our after-sales service department or agents. Screen tips for each process and measures to be taken are listed in the table below

1. during prime

Message/Alert	Action
AIR IN ACD LINE	● Ensure the line is placed properly in ACAD; ● Ensure ACAD is clean; ● Ensure the line is properly installed in the anticoagulant pump; ● Ensure the anticoagulant is accessible; ● Ensure the line from the anticoagulant bag to the pump is not twisted or kinked; ● Rotate manually the anticoagulant pump clockwise to eliminate air bubble out of ACAD.
AIR IN DONOR LINE	● Ensure the line is placed properly in DLAD; ● Ensure DLAD is clean; ● Ensure the line from ACAD to DLAD is not twisted or twined; ● Rotate manually the blood pump clockwise to eliminate the air bubble out of DLAD.
DPM PRESSURE HIGH	● Ensure the line from the anticoagulant pump to the blood pump is not twisted, nipped, or obstructed; ● Hand turn-on valve 1 and clockwise rotate blood pump in order to make the pressure re-normal.
DPM PRESSURE LOW	● Ensure the line from the anticoagulant pump to the blood pump is not twisted, nipped, or obstructed; ● Hand turn-on valve 1 and clockwise rotate blood pump in order to make the pressure re-normal.
DPM OPENED	● Ensure DPM adapter is installed properly.

2. Period of Draw

Message/alert	Action
AIR IN ACD LINE	● Ensure the line in ACAD lay correctly; ● Ensure ACAD is clean; ● Ensure the anticoagulant bag is not empty; ● Ensure the line between anticoagulant bag and pump has no kink; ● Rotate anticoagulant pump clockwise by hand and pull air bubble out ACAD.

AIR IN DONOR LINE	● Ensure the line is placed properly in DLAD; ● Ensure DLAD is clean; ● Ensure the needle adapter is connected properly; ● Ensure the line from needle to DLAD is not kinked; ● Rotate manually the blood pump clockwise to eliminate the air bubble out of DLAD.
AIR IN BLOOD LINE	● Ensure the line in the BLAD lay correctly. ● Ensure the BLAD is clean; ● Ensure the donor has sufficient blood flow; ● Rotate blood pump clockwise by hand and pull air bladder out BLAD.
DPM PRESSURE LOW	● Ensure the line between anticoagulant pump and blood pump have no kink, clamping and obstructing; ● Ensure the donor have enough blood flow; ● Hand turn-on valve 1 and clockwise rotate blood pump in order to make the pressure re-normal.
DPM OPENED	● Ensure DPM adapter is installed correctly.
DRAW TIMEOUT “RETURN” TO RETURN	● Push **RETURN** to continue; ● Ensure the donor have enough blood flow.
COVER OPENED	● Draw have been pause and push **RETURN** to continue; ● Open the cover of the centrifuge and lock it; ● Return re-work automatic.
BOWL FLUID	● Turn off the power; ● Ensure the waste bag is connected with the joint locate behind the Blood Component Separator; ● Use the cotton swab with 70% alcohol to clean the fluid sensor locate on the centrifuge well; ● Clean the centrifuge follow with the centrifuge cleaning method (chapter 5).
VALVE NOT OPEN / VALVE NOT CLOSE	● Check the line in valve install correctly whether or not; ● Stop operation. Use the CHECK DEVICE check the valve and contact with marketing service department of our company.
The weight is abnormal	● Ensure there have no foreign object on the arm of weigher; ● Ensure not to touch the arm of weigher and press **ENTER** into the process of collection.

3. Period of Return

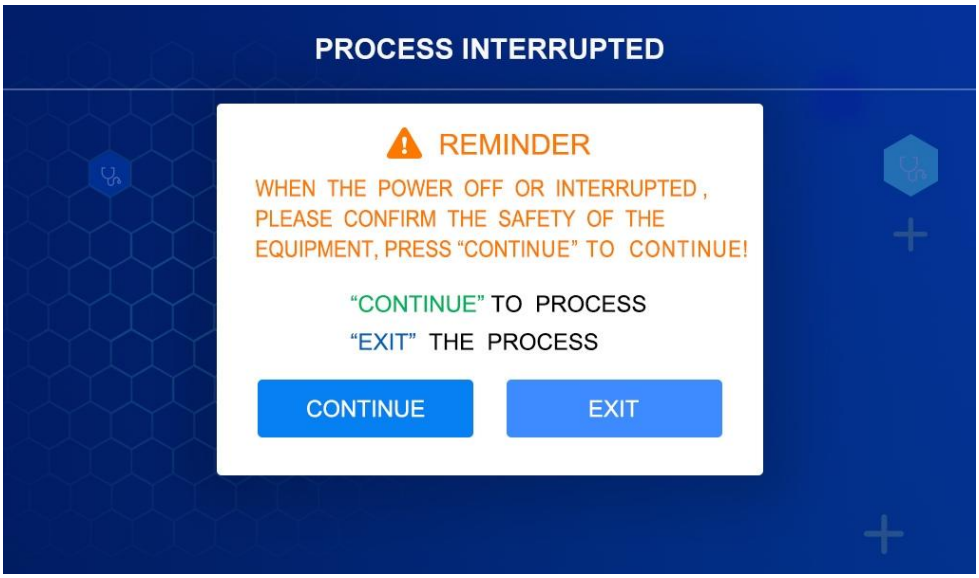
Message/alert	**Action**
AIR IN ACD LINE	● Ensure the line in the ACAD lay correctly . ● Ensure the ACAD is clean; ●Ensure the anticoagulant is enough to complete the operation process;

	● Rotate anticoagulant pump clockwise by hand and pull air bubble out ACAD.
AIR IN DONOR LINE AIR REMOVE "ENTER" TO RESUME	● Ensure the line in the DLAD lay correctly . ● Ensure the DLAD is clean; ● Rotate blood pump clockwise by hand and pull air bladder out blood filter; ● If there have air in the BLAD, so: 1. Rotate blood pump clockwise by hand and pull air bladder out blood filter if the basis of blood filter have part strainer blockage. Tap softly the filter and make air move to the top of the filter; 2. Stop operation if the blood filter have empty. Check the BLAD and contact with marketing service department of our company.
AIR IN BLOOD LINE	● Ensure the line is placed correctly in BLAD; ● Ensure BLAD is clean; ● Pause if the centrifugal bowl is empty and press **DRAW** into the next circle; Ensure centrifugal bowl and line link correct, if centrifugal bowl is not empty and hand move clockwise rotate blood pump and pull air back centrifugal bowl.
DPM PRESSURE HIGH	● Ensure there have no obstructing in the venipuncture site and the donor line ; ● Click **STOP** or **START/STOP** button; ● Ensure the venipuncture site have no errhysis and the pinhead is smoothly; ● Ensure there have no obstructing between the needle and blood pump; ● Degrade the speed of pump; ● Re-venipuncture if necessary.
DPM PRESSURE LOW	● Ensure the line between centrifugal bowl and plasma bag have no kink, clamping and obstructing; ● Ensure the DPM line is not clamped or obstructed.
RETURN TIMEOUT PAUSE PRESS "ENTER" TO RESUME	● Ensure the line in the BLAD lay correct; ● Ensure the line between centrifugal bowl and blood pump have no obstructing and kink; ● Ensure the line in the blood pump install correct; ● Ensure there have no obstructing and kink between the needle and blood pump; ● Ensure the centrifugal bowl have not empty and press **RETURN** to continue; If the centrifugal bowl is empty, then press **DRAW** into the next circle.
COVER OPENED	● Open the centrifuge cover and lock it, and device will

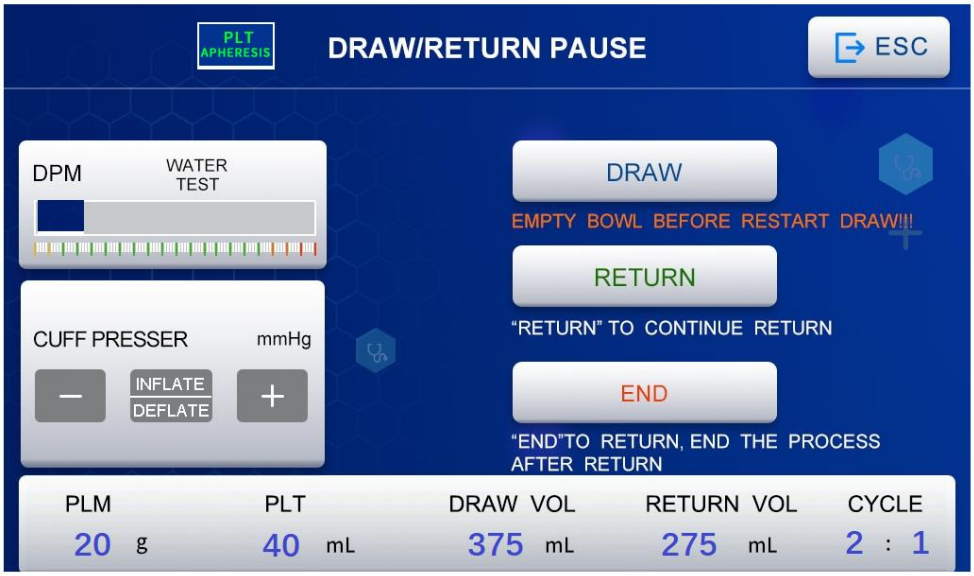
	re-operate.
BOWL FLUID	● Treat as Draw.
DPM FILTER NOT INSTALLED	● Ensure DPM adapter is installed correctly.
The valve gives a warning	● Check the line in valve install correct whether or not; ● Stop operation. Use the **SELF TEST** check the valve and composition with marketing service department of our company.

8.3 Power Failure Resume

The Blood Component Separator will automatically memory the working state and parameter if switching-off during the working process and recovery program when re-power supply. Show on the screen:



If you want to continue the last operation process, you should prepare and push **ENTER** key. Show as on screen



⚠ **Notice: ensure the centrifugal bowl have empty before blood collection. If the content over 1/3 in the centrifugal bowl and go on draw, it will interfere collection or cause RBC pollute plasma. So should return the content in the centrifugal bowl before draw.**

8.4 Exit Recovery Emergently

Press **ESC** to stop work when there is an emergency state in the working process or device in abnormal status. The Blood Component Separator can automatic memory the current working state and parameter, then carry out automatic recovery program and show on the screen.

When the urgent situation deals with completely, prepare to continue the last process and press **ENTER**. Show as on the screen.

8.5 Gravity Return

Because of some abnormal state, the Blood Component Separator can't return the content of the centrifuge bowl to the donor. We suggest that put the content in the centrifugal bowl and line return donor according to follow program in order to reduce significantly the lost of donor's cell.

1. Turn the power off.

2. Inform donor the program to be operate in order to avoid them upset.

3. Use the clip or haemostat to clamp 6 channels:
   - needle line;
   - Two pressure detector adapter line, and tack out the adapter;
   - Two lines on the plasma bag.
   - The green line beside the platelet bag.

4. Move line from valves, air detectors and line sensor.

5. Remove line from the blood pump and the plasma pump.

6. Move the blood filter from bearer.

7. Open the centrifuge cover and take out the centrifugal bowl and make it up.

8. Keep the centrifugal bowl and the blood filter above the heart of donor.

9. Open the clamp on the needle line.

10. Gravity transporting the content in the centrifugal bowl and line back to donor.

11. When return the needle adapter, clamp the needle line and put the centrifugal bowl and blood filter inverse on the desk.

12. Withdraw the needle, and handle according to the Standard Operation Procedure.

13. Empty the liquid from the needle, and dispose the needle according to the Standard Operation Regulation.

14. Take down the plasma bag, platelet bag and handle according to the Standard Operation Regulation.

15. Remove line from the anticoagulant pump and take down the anticoagulant bag.

16. Handle the polluted line, centrifugal bowl and anticoagulant according to the Standard Operation Regulation.

8.6 Operate When Power Failure

If power is failure, the Blood Component Separator can't return the content in the centrifugal bowl and line to donor. Follow protocol is suggested:

1. Turn power off

2. Put out the line from the valve 1 and rotate anticlockwise the blood pump 5 circles in order to anticoagulant pass through the needle line and needle and make them is anticoagulant.

3. If the power don't recovery in 5~7 min, so gravity return.

4. If the power is recovery in time, then re-start device and continue to work. Detail operation show as "**Power Failure Resume**".

9. Routing Clean &Maintenance

The NGL XCF 3000 Blood Component Separator is only need minimal preventive and maintenance. The operator is only to clean.

9.1 Common Maintain

The NGL XCF 3000 Blood Component Separator is same as every precision instrument need to be clean regularity. The time and way is decided by the using frequency. The minimum require is:

Clean/day	All external surfaces
	DPM
	SPM
Clean/week	Air detectors
	Line sensor
	Centrifuge
	Fluid sensor
Clean/month	Cuff
	Dust gauze

9.2 Clean Article

1. Cleaning solution (recommended for use on blood borne pathogens)
2. Clean, warm water
3. 70% rubbing alcohol
4. Clean cloth lint.
5. Screwdriver
6. 20ml syringe
7. Cotton bud
8. Aurilave

9.3 Clean Method

Cut-off the power and pull plug before clean the Blood Component Separator, or will electric shock.

1. External surfaces
   The panel and the surfaces of device should use the cleaning solution to clean frequency.

2. Pressure monitors

Use the pure water scrub pressure monitors and use the dry clean cloth nonlinting wipe dry them.

3. Air detectors

Use the clean cloth nonlinting to scrub the channel groove and surface of the air detector.

4. Line sensor

Use the clean cloth nonlinting to scrub the channel groove and surface of the line sensor. And clean the eyelet of the groove with the aurilave.

5. Centrifuge

The bowl optical be installed on centrifuge, the observation window is located on the centrifuge well.

The Blood Component Separator has two waste bag and locate on the tray below the device. One bag contact with the bleeder line of centrifuge, the other is the standby.

a. Normal clean

- ●Use the cleaning solution clean and polish the inner wall of centrifuge and bowl base. Note the observation window of bowl optical should be clean, no stains. Common maintain don't need a great quantity of cleaning solution;
- ●Use the clear water to clean and polish the cap of the centrifuge;
- ●Use the dry cloth to wipe dry each surface.

b. Clean when the centrifugal bowl have weeping

- ●Cut-off the power and pull off the plug ensure the waste liquid bag link to the bleeder line.
- ●Use the cleaning solution clean and polish the inner tube and bowl base of the centrifuge. Note the observation window of bowl optical should be clean, no stains;
- ●Use the cotton bud with 70% alcohol clean the weeping inductor;
- ●When the volume of leakage is too large, you should use 20ml syringe to flush the inner wall of the centrifuge with cleaning solution;
- ●Use the dry cloth wipe dry all the surface;
- ●Clip the waste liquid bag , move to handle and change the clean waste liquid bag.

6. Fluid sensor

Use the cotton bud with 70% alcohol clean the weeping inductor and use the dry clean cloth nonlinting wipe dry.

7. Dust gauze

The dust gauze locates at the basis of the device and need to clean on a monthly basis.

- ● Use the cross screwdriver put down the dust gauze cover on the strainer;
- ● Pull out the dust gauze;
- ● Flush the dust gauze with warm water;
- ● Put the dust gauze on the dry mull and make it dry thoroughly;
- ● Put the dust gauze and the dust gauze cover install into the device.

8. Cuff

Take off the cloth of the cuff and clean it use the cleaning solution. Then put it dry at the cool and ventilate station.

9.4 Precaution

1. The ozone disinfection will damage the rubber material of cuff and the elastic cover of DPM. When the ozone disinfection is ongoing in the room where Blood Component Separator is placed, the device's cover should be closed up and the cuff should be protected; therefore dust cover is suggested to cover the device in order to reduce damage. Meanwhile, the rubbery tube of cuff and elastic cover of DPM must be checked regularly, at least monthly, change them timely when any crack or damage is found.

2. The rubber roller in pump are abraded part that should be changed after the normal working time 2200hours. Check the pump rubber roller if there are some strange noise heard. And the rubber roller should also be changed timely if the powder or the phenomena of degumming is found. Changing rubber roller should be executed by the qualified technician or engineer.

3. Operator should often check waste bag and drain pipe, it must be replaced or handled when waste bag broken or pipe blocked.

Appendix A

Table 1 Electromagnetic emission level

Electromagnetic emission	
Electromagnetic requirements of this RF generator are given below and it is the responsibility of end user to meet these requirements.	
Emission test	**Compliance**
CISPR 11 Conducted emission	Group 1, Class A*
CISPR 11 Radiated emission	
* The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	

Table 2 ENCLOSURE PORT

Phenomenon	Basic EMC standard	Immunity compliant levels
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 4
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3 Input a.c. power PORT

Phenomenon	Basic EMC standard	Immunity compliant levels
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycle

Table 4 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13,17	Pulse modulation 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 – 5800	WLAN 802.11a/n	Pulse modulation 217 Hz	9
5500				
5785				

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Blood Component Separator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Appendix B

ELECTROMAGNETIC ENVIRONMENTS

The *NGL XCF 3000 Blood Component Separator* is intended for use in an typical health care environment. The customer or the user of *NGL XCF 3000 Blood Component Separator* should assure that it is used in such an environment.

Environment	Locations	General characteristics
Typical health care	Blood banks, Hospital	Controlled, health care professional present

Most environments and locations in the professional healthcare facility environment are considered to have a controlled ME ENVIRONMENT with regard to FIXED electromagnetic sources. In order to reduce the electromagnetic interference to The NGL XCF 3000 Blood Component Separator from the surrounding environment .After risk analysis, The NGL XCF 3000 Blood Component Separator should be operated away from the RF shielding chamber of a high frequency device, because there's a lot of electromagnetic interference around the device, which may interfere with the operation of The NGL XCF 3000 Blood Component Separator.

"Particular requirements for the safety of centrifugal blood separation devices". Through risk analysis, risk assessment, risk control and residual risk assessment, the performance of NGL XCF 3000 Blood Component Separator without failure will cause clinical safety risk. Therefore, there is no basic performance.

When NGL XCF 3000 Blood Component Separator is disturbed by electromagnetic interference and cannot work properly, follow the Gravity Return Transfusion requirements in chapter 8.

Appendix C

List of cables, transducers and accessories

List of transducers		
No.	**Item**	**Amount**
1	Donor pressure monitor	1
2	System pressure monitor	1
3	Weigher	1

List of cables and accessories		
No.	**Item**	**Amount**
1	Blood Component Separator	1
2	Cuff	1
3	Waste Bag	1
4	Jaw	1
5	Power Cable	1
6	Fuse （T4.0A H250V ø5×20 ）	2
7	Operating Instruction	1
8	Inspect. Certificate	1
9	Warranty Certificate	1
10	Service Manual	1
11	Dustproof Cover	1

CE 0123