Baso®

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Plasma Freezing System
with Full Temperature Control
BSSD-IV-02

Operating Manual

Before using device, please carefully read this operating manual for its efficient operation and safety.

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Application and Contraindications

Intended purpose

The product is mainly used for quick freezing treatment of plasma products by blood stations or medical institutions.

Intended use environment

The device is used in blood stations or medical institutions.

The device is stationary type device and must not be used outdoors.

The devices are designed to operate at an ambient temperature range of 5°C~40°C with a maximum relative humidity of 80%.

Additional environmental requirements for the safe operation of the devices are documented in the operating instructions and must be observed.

During transport and storage, the ambient temperature must be maintained between -40°C and 55°C, with a humidity level below 95%.

Intended patient population

Patients do not come into direct contact with the devices.

Indications

Plasma infusion or treatment with plasma products, such as coagulation disorders treatment, supplement coagulation factors.

Contraindications

There are no known contraindications.

Intended users

●Pharmacists, doctors, laboratory staff or other staff who are trained and/or experienced in dealing with whole blood and blood components

●Service technicians with a recognized license or certificate as required by local authorities for installation, servicing and repair of refrigeration systems and equipment, and properly trained in the use of the contact shock freezer models.

Note: The device must be operated by individuals in organizations with knowledge of applicable regulations and guidelines governing the storage and distribution of blood and blood components. The organization must implement and validate procedures in accordance with these regulations and guidelines. These procedures should address the required storage temperature and a appropriate storage duration for blood and blood components.

Clinical benefit

Plasma quality assurance: Rapid freezing reduces ice crystal formation and protects the activity of coagulation factors.

Efficiency optimization: Shorten the freezing time.

Chapter One: General Remarks

1. General safety instructions

Please observe the following rules when using to avoid accidents:

1.1 Ensure reliable grounding when the freezing system is installed;

1.2 Do not touch the power switch with wet hands;

1.3 Do not touch the LCD screen with sharp objects;

1.4 When abnormal equipment occurs (such as abnormal sound or peculiar smell, etc.), immediately disconnect the power supply and interrupt the power supply;

1.5 Please wear protective gloves to prevent frostbite if you want to take and put things during operation of the equipment;

1.6 Please do not open the freezing chamber for a long time in freezing;

1.7 Operators must be operated by professional trained personnel;

1.8 Staff operating the equipment must have a comprehensive understanding of the operator's instructions, safety information, health measures, legal provisions and technical rules;

1.9 See attachment 1 for the EMC information of the equipment;

1.10 The user is responsible for ensuring the electromagnetic compatible environment of the equipment so that the equipment can work normally;

1.11 Do not use the equipment near the high-intensity radiation source, or it may interfere with the normal operation of the equipment;

1.12 See attachment 1 for the minimum anti-interference requirements of medical equipment;

1.13 It is recommended to evaluate the electromagnetic environment before using the equipment;

1.14 This product is intended for use in industrial premises;

1.15 For the temporary operation of the instrument, it must be conducted under the technical instructor of Baso or under the guidance of the related trained personnel;

1.16 Before using this equipment, confirm the quick-freezing effect and monitor the equipment when using;

1.17 If the equipment fails, please follow the related items in the instruction manual for troubleshooting. If the failure cannot be solved, please contact the after-sales service unit.

1.18 In order to ensure the safety and reliability of the equipment, only parts provided by the company or its agent can be used in fault maintenance;

1.19 For questions that you feel are not adequately addressed in the instructions, please consult the company directly for an accurate response;

1.20 Instructions are subject to change without prior notice.

1.21 National language versions, Chinese version with the final right of interpretation;

1.22 Please place the operation manual nearby to view safety instructions and important operation information.

1.23 On-site training will be provided by the Baso or authorized distributor.

2. Warranty

The operating safety and operation warranty conditions of the freezing system are as follows:

2.1 The use and service of the equipment is in accordance with the functions and instructions described in the operation instructions. The expected service life of the product is 7 years.

2.2 No changes have been made to the equipment.

2.3 Use original spare parts supplied by Baso.

2.4 Carry out inspection and maintenance work regularly, and maintenance is valid from the date of delivery.

3. Labeling definitions

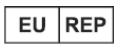
3.1 Safety warning symbols

	General Warning Warning notes indicate conditions or practices that, if not strictly observed, could result in personal injury. ✧ Danger of crushing injury! ✧ Danger of frostbite! ✧ Danger of scalding! ✧ Do not touch or place any objects on the moving cold plate to avoid damage or malfunction. ✧ Do not forcefully lift the cold plate. ✧ Do not touch the cold plate during defrosting to avoid scalding.
	Warning: Risk of hand-crushing hazard! Keep hands away from the cold plate while it is in motion.
	Always wear protective gloves during operation! ✧ The cold plate is extremely cold and may cause frostbite. ✧ Do not push or remove the frozen tray without wearing protective gloves. ✧ Wear protective gloves and keep sleeves secure to prevent frostbite while operating the freezer. ✧ Wear protective gloves when cleaning melted water to avoid scalding.
	Warning: Risk of electric shock Hazard! ✧ Do not handle the power cord or operate the POWER switch with wet hands to void electrical shocks. ✧ Do not extend the power cord.
	Warning: Moderate frostbite hazard due to low temperatures and freezing conditions.
	Caution: Operational Guidance ✧ Do not keep the freezing chamber open for extended periods during freezing, as it may affect system performance. ✧ Ensure an interval of more than 3 minutes between compressor shutdown and restart.

3.2 Device tagging

	Warning: Risk of hand-crushing hazard! ✧ Keep hands away from the cold plate while it is in motion.
	Always wear protective gloves during operation! ✧ The cold plate is extremely cold and may cause frostbite. ✧ Do not push or remove the frozen tray without wearing protective gloves. ✧ Wear protective gloves and keep sleeves secure to prevent frostbite while operating the freezer. ✧ Wear protective gloves when cleaning melted water to avoid scalding.
	Warning: Risk of electric shock Hazard! ✧ Do not handle the power cord or operate the POWER switch with wet hands to void electrical shocks. ✧ Do not extend the power cord.
	Warning: Moderate frostbite hazard due to low temperatures and freezing conditions.

3.3 Label Instruction

	Manufacturer
	Authorized representative in the European Community/European Union
	Date of manufacture
	Use by date
	Batch code
	Serial number
	DISPOSAL: Do not dispose this product as unsorted municipal waste. It must be collected separately for special treatment.
	Consult instructions for use.
	Medical device

UDI	Unique device identifier
CE 2797	CE Mark: conforms to the essential requirements of the Regulation (EU) 2017/745 (2797: BSI Group The Netherlands B.V.)

4. Quality criterion

In order to ensure the best and maximize the preservation of blood coagulation factors and biological activities of inhibiting factor, collect fresh plasma should be quickly frozen (ideal within six to eight hours, not more than 24 hours), storage temperature below -30℃.

Plasma product should be frozen to -30℃ within 60min.

The freezing system supplied by Baso ensures high speed freezing quality plasma and maximum daily plasma output.

5. Application of equipment

5.1 Proper usage

Caution - plasma professional marking

For other purposes, contact Baso or local distributor.

Operation and storage temperature:

- Operation temperature of freezing system is set around -60℃ to ensure efficient refrigeration. The operating temperature can be reached after pre-cooling for 15min.
- After completion of frozen, automatically turn to economic model, the temperature up to -30℃.
- Continuously refrigerate multiple batches of cargo without defrost.

Operation Mode:

- It is suitable for use in blood donation center or hospital.

5.2 Incorrect use

Do not use the following materials as part of the equipment

- Inflammable and explosive materials
- Steam contact with air produces a mixture that is flammable and explosive
- Release of noxious gas
- Gradually consumed

Caution: failure to use the equipment in the manner specified by the manufacturer may damage the protection provided.

6. Equipment protection

Several safety protections matter of the freezing system.

Compressor protection:

- The function of compressor is monitored during freezing operation.

Plasma bag protection in freezing:

- The pressure controller limits the contact force and protects the blood bag from bursting due to excessive force.

When the freezer is used continuously at an ambient temperature of 40°C, the power cord temperature is 50°C.

Chapter Two: Naming Rules and Product Structure

Product name: Plasma Freezing System with Full Temperature Control

Separate type freezing system is composed of the following structure: and the house and the connecting pipe, indoor machine including electronic parts, machinery parts, cold plate, simulated plasma bags, remote monitoring system (optional), the scanning gun (optional), including outdoor refrigeration components such as compressor, condenser, and the house through the copper pipe connection. The environment-friendly R507 is used as the refrigerating medium, and the semi-closed double-stage refrigeration piston compressor is used. Two identical cold plates are used for conducting refrigeration, and both the upper and lower cold plates are mobile cold plates.

Model: BS SD–IV–02

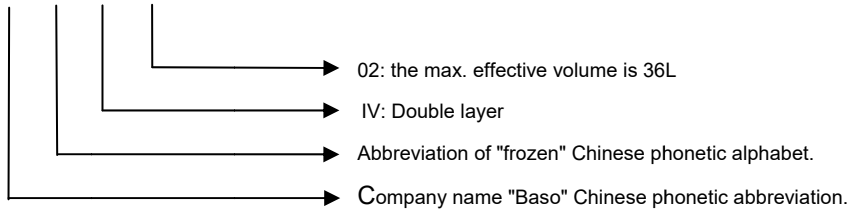


Fig 2: Product structure diagram (ABS shell type)

Caution: 1. Caster; 2. Defrosting Button of B System; 3. Close Button of B System;
4. Open Button of B System; 5. Defrosting Button of A System;
6. Close Button of A System; 7. Open Button of A System;
8. Emergency stop switch; 9. PLC touch screen; 10. Freezing Chamber

Table 1: Specification list

Product name	Plasma Freezing System with Full Temperature Control
Model	BSSD-IV-02

Catalogue number	BX7005
Enclosure	Inside machine ABS/Outside machine metal plate
Type	Separated type
Dimensions Contact Plate	1100 x 630mm * 2
Min. Temperature	≤-60℃
Pre-cooling	No-load: From normal temperature to -60℃ for 15min or less
Min. Temp of Cold Plate	No-load: -68℃
Freezing Time (To reach Core Temp. of -30℃)	≤30min (80 bags 200ml)
Compressor	Two-stage reciprocating compressor
Refrigerant	R507/R507A
Freezing Capacity (plasma bags)	120 at 100ml; 80 at 200ml; 40 at 600ml
Power Supply	3Ph~; AC380-415V 50/60Hz 12000VA
Defrosting time	≤8min
Operation Condition	5℃~40℃, ≤80%RH
Storage condition	-40℃~55℃, ≤95%RH
Weight of inside machine	570KG
Weight of outside machine	275KG * 2
Dimensions of inside machine	1581*784*1924mm (L* W* H)
Dimensions of outside machine	1300*520*1245mm (L* W* H) * 2

Chapter Three: Installation

1. Environmental condition

1.1 The freezing system must meet the following environmental conditions:

1.1.1 Air dry and ventilated places, easy to heat;
1.1.2 The environment temperature 5℃ to 40℃;
1.1.3 Freezing system should not be exposed to direct sunlight;
1.1.4 It is prohibited to install or use a radiator near the device.

1.2 During continuous operation, the energy output of the freezing system may change the room climate

1.2.1 It is prohibited to use in an unventilated environment;
1.2.2 The air conditioner should be opened at room temperature over 25℃.

1.2.3 For the BSSD-III-01 model, the standard filling amount of the refrigerant R507/507A is 12kg for pipelines up to 10 meters in length, adding 400g for each additional meter of pipeline.

2. Transport and packing requirements (hoisting as per drawing)

2.1 Packing

Air and sea transport, the freezing system for solid wooden packaging, all packaging materials can be separated and reused.

The package of freezing system of Baso is made of packing film and corner protection.

Packing material:

- Quality wood
- Plastic packaging film

2.2 Examine cargo

After opening the package, check whether all parts of the freezing system are complete and whether there is any transportation damage. If any damage or omission is found, please contact the supplier.

2.3 Outdoor transportation

The freezing system (Net weight: about 1120KGS) is transported to the truck by lifting equipment or transported to the designated installation site by special lifting belt.

General Warning
Do not forcefully lift the cold plate.

Caution-transport damage
The driver should fill out the form to confirm the transportation damage

2.4 Indoor transportation

Push the pulley on the bottom of the freezing system to the designated installation place. When the installation is completed, step on the brake block for fixation.

2.5 Installation

2.5.1 Refer to section 1 for installation environmental conditions;
2.5.2 The freezing system is installed in a stable plane to the ground of the 25 kg/cm^2 under pressure;
2.5.3 At least 0.5m space should be reserved on the back and right side of the freezing system or at least 0.5m away from the wall; the front is at least 1.5m away from the wall to ensure that the operating distance is enough;
2.5.4 Do not cover the air-vent of the enclosure; A good circulation of air around the unit is a prerequisite for it to operate perfectly. Air circulation at the top, rear and lower sides of the machines must not be restricted under any circumstances
2.5.5 For the separated type of plasma freezing system, it includes two parts: inside machine (Main System) and outside machine (Cooling Unit). The outside machine must be connected with the inside machine and installed by BASO or an authorized professional team.

3. Power supply

The equipment needs to be connected with the AC 380~415V 50Hz power supply of the three-phase five-wire. The power cord is copper core wire of more than 6 square millimeters, and configuring a 40A air switch with leakage protector. Ensure the reliability of grounding.

Note: For the connection of the equipment, it is not allowed to transfer equipment. If it is used forcibly, it will cause power loss and the start of the compressor will failed.

Caution

Wires cannot be extended: the wires of power supply connect with the device cannot be extended, and appropriate connecting wires can be used if necessary.

Chapter Four: Operation and Commissioning

1. Function Brief

1.1 Freezing method
Adopts directly contact method, the plasma bag is placed in the middle of two cold plates through heat transfer to pre-cooled to -60℃, and then the plasma bag will be quickly frozen.

1.2 The freezing system has two modes of operation for users to choose, including regular mode and economic mode.

1.3 Temperature control and record management system:
1.3.1 The lowest freezing temperature of the freezing system can be reached to -60℃, can quickly be frozen core temperature of plasma bag to -30℃.
1.3.2 Adopt automatic temperature control program, frozen plasma process control precision of ±0.5℃.
1.3.3 Monitoring function: it can display the curve of the core temperature of simulated bag (QC bag) and the operating temperature of the cooling plate during the freezing process in real time, and has the function of audible and visual double alarm.

1.4 Quality management system:
1.4.1 The temperature change during plasma freezing was monitored and stored by inserting a temperature probe into the simulated bag (QC bag) with the same state as plasma.
1.4.2 The quality index of plasma freezing can be traced through the storage management of monitoring data.
1.4.3 The power is turned on for the first time every day, the equipment automatically checks sensors of the upper and lower cold plate. If the temperature difference between the upper and lower cold plates exceeds ±1°C, it will alarm. The device automatically saves the daily inspection results and the data could be exported by user at any time. Also print it as a quality management form. (Temperature detection can be done manually).
1.4.4 The freezing time could be preset by the user through the simulated bag (QC bag) to facilitate continuous production.
1.4.5 Multiple protections prevent the occurrence of hazardous conditions of equipment and ensure the safety of users' personal safety and property.

1.5 The function of automatic fault detection shows the cause of fault directly, which is convenient for product maintenance.

2. Operating Instruction

2.1 Regular mode

Fig 4.1 Main Interface

The equipment is double layer plasma freezing system, which is divided into the upper and lower freezing chamber. The upper freezing chamber is defined as “A System”, and the lower freezing chamber is defined as “B System”. Both systems can be used at the same time, also can be used separately.

Step 1: Start Up: open the air switch, and rotate the emergency button clockwise. Then enter into the main interface (Fig 4.1).

Step 2: Login: for the initial operation, automatically enter into the user login interface (Fig 4.2). Choose “Admin” and enter the password “999999” (the password cannot be changed.), then click “OK” to login (The following steps can be operated only after entering the password.); More information about the login, please see “Chapter Four: 6. Settings Function”.

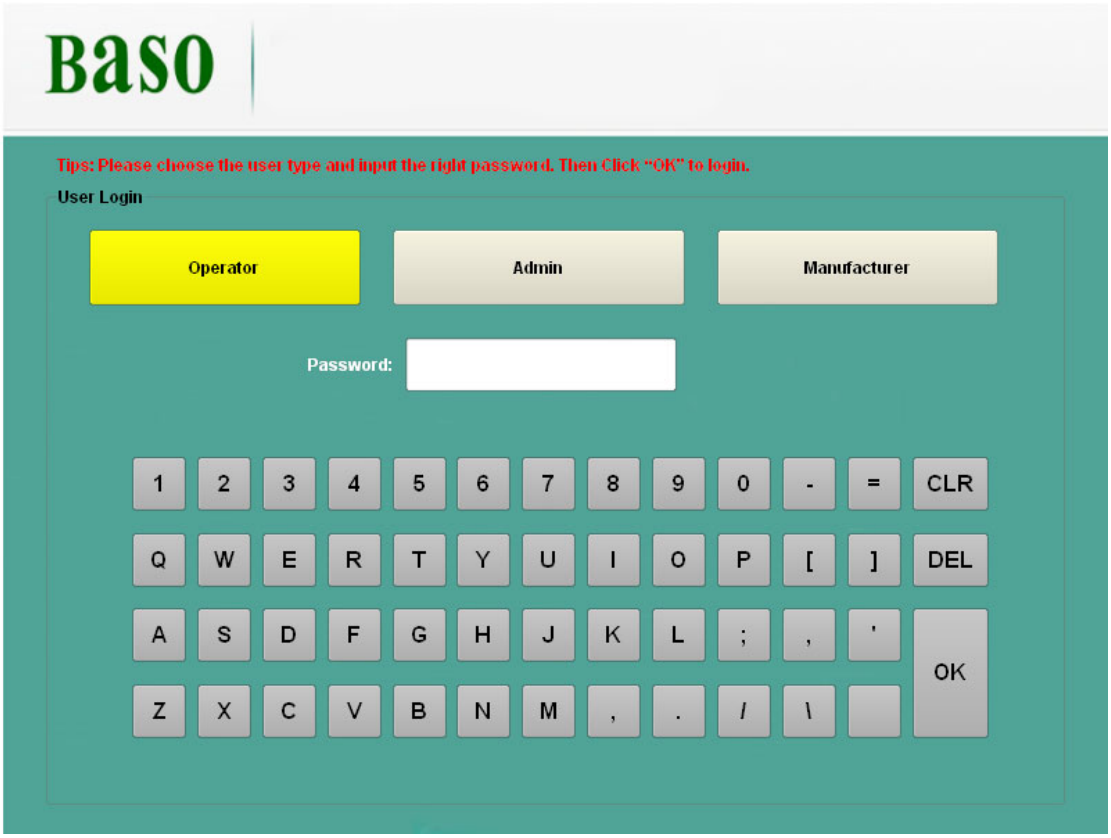


Fig 4.2 User Login Interface

Step 3: QC; the device automatically starts "QC" (Fig 4.3) and detects the temperature difference between the upper and lower cold plates, the temperature difference is within ±1°C, otherwise the device alarms and a warning shows in the touch screen. After the completion of QC, the equipment will record the temperature verification value during the detection of the temperature control system and save it in the solid-state disk of the industrial computer. The QC data could be directly reviewed on the touch screen by the users according to the date and print it to a quality management form.

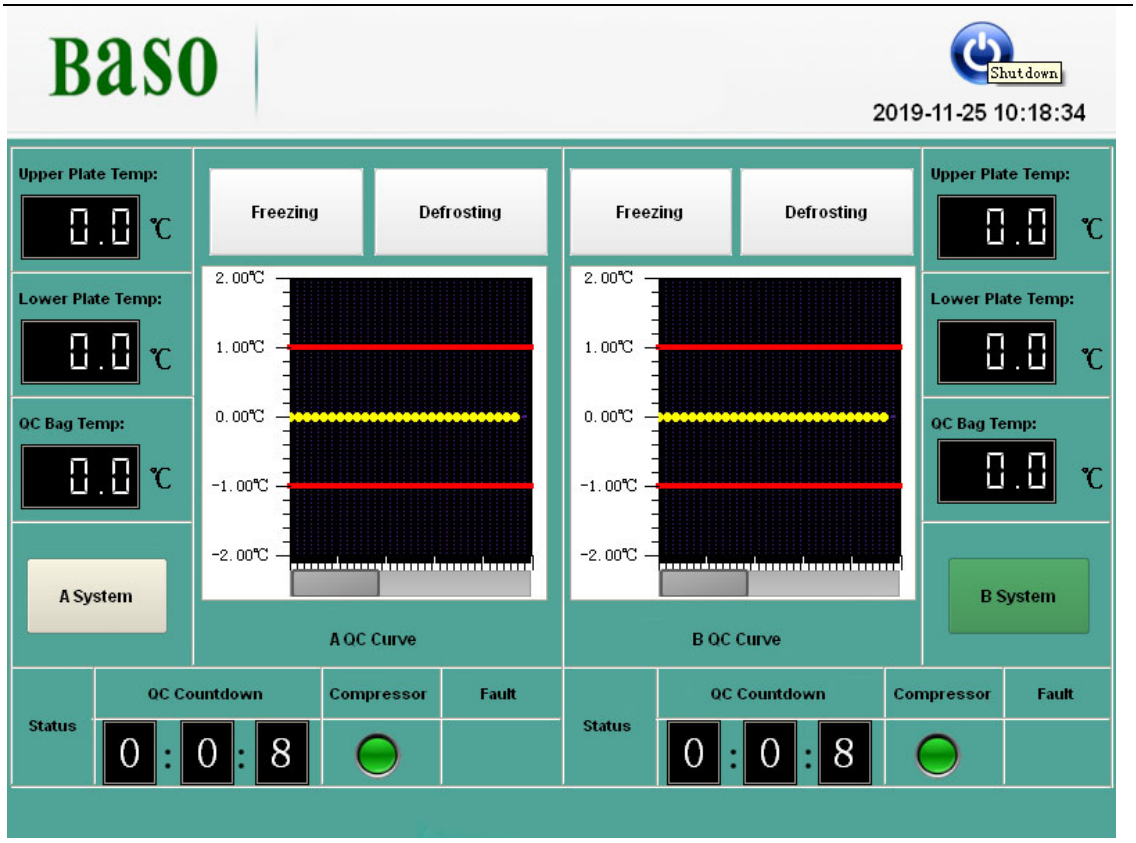


Fig 4.3 QC in Main Interface

Step 4: Pre-cooling; keep the freezing chamber of A/B System closed, then click “Freezing” in Fig 4.4 to start. (If the compressor is on and off for less than interval 3min, the delay light will flash). The pre-cooling time is about 15min.

A System Interface

B System Interface

Fig 4.4 A/B System Interface

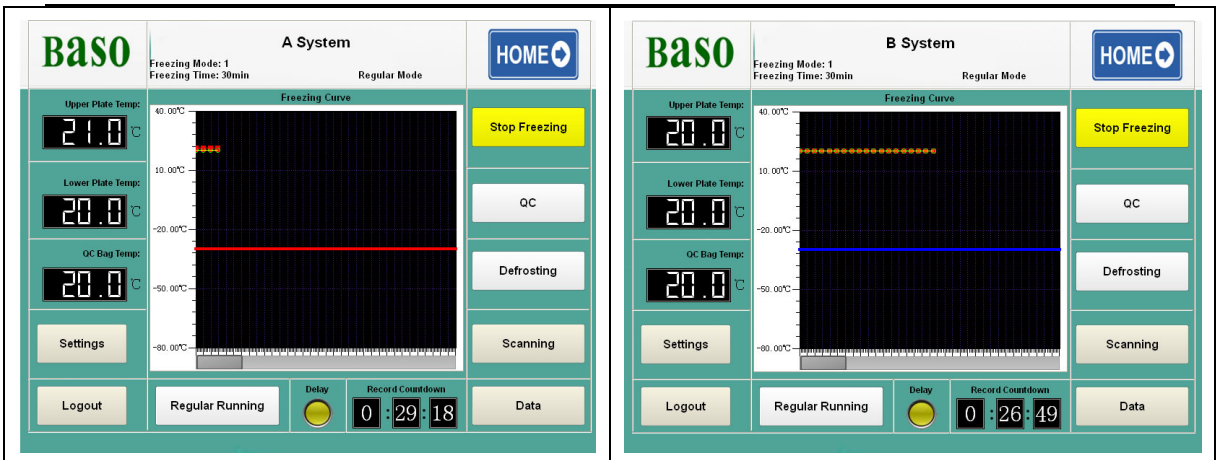
Caution

1. The freezing chamber must be closed while pre-cooling.

2. The pre-cooling time is about 15min and there is no warning when it finished. The operator needs to pay more attention to it.

3. Do not place your hand or others near the door of freezing chamber during closing, otherwise it will stop.

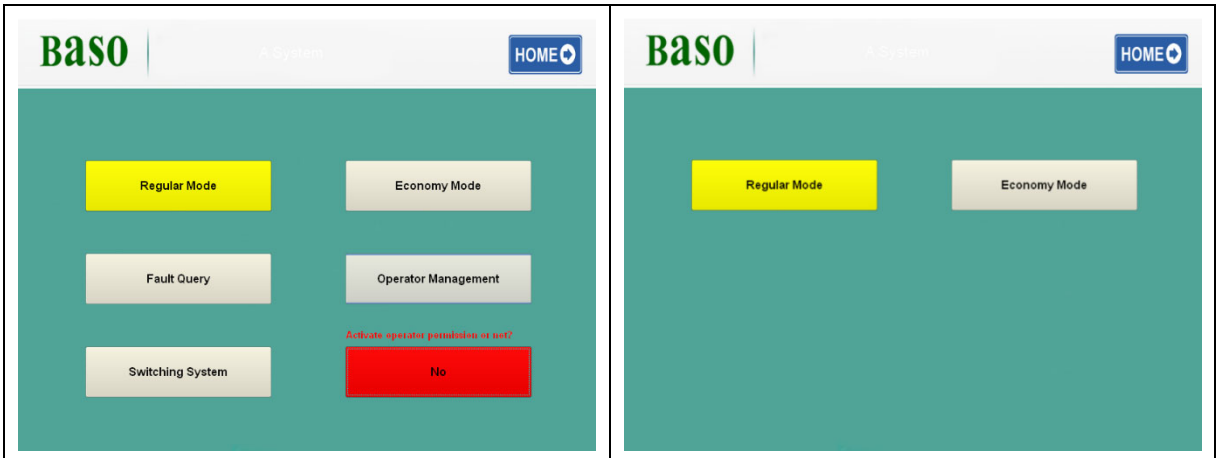
Step 5: Freezing; after pre-cooling, click "Stop Freezing" > “Scanning” in Fig 4.5, scan the barcode of plasma bag and place evenly and neatly on the transport tray, then click “HOME” back to the A/B System Main Interface.



A System: Freezing Interface | B System: Freezing Interface

Fig 4.5 Freezing interface

Press “Open” button at the right of A/B System freezing chamber. When the freezing chamber is open and the cold plate stop, the transporting tray could be pushed into the freezing chamber and press “Close”. At last, click “Settings” > “Regular Mode” (Fig 4.6); Regular mode and economy mode for choosing, the regular mode is default) > Time Setting (Fig 4.7); According to the Table 2 to choosing) > “OK” > "Freezing".



Freezing Mode (Admin) | Freezing Mode (Operator)

Fig 4.6 Settings Interface

A System: Time Setting (Operator) | B System: Time Setting (Operator)

Fig 4.7 Time Setting

Note:

1. The barcode of plasma bag will be automatically saved in freezing data of curve.

2. It is recommended to use the conductive pad to improve the freezing efficiency.

Table 2 List of frozen mode

Mode	Bag capacity	Quantity of plasma bags
Mode 1	200ml / 500ml / 600ml	25bags / 16bags / 8bags
Mode 2	200ml / 500ml / 600ml	30bags / 20bags / 12bags
Mode 3	200ml / 500ml / 600ml	35bags / 24bags / 16bags
Mode 4	200ml / 500ml / 600ml	40bags / 28bags / 20bags

	General Warning Danger of crushing injury!
	Warning: Risk of hand-crushing hazard! Keep hands away from the cold plate while it is in motion.
	General Warning Danger of frostbite!
	Wear protective gloves! It is prohibited to push r remove the frozen tray without wearing protective gloves, which is at risk of frostbite.

Caution

1. If the "Stop Freezing" is not clicked before press “Open”, the freezing chamber also can be open. But please try not to do this to prevent serious frost formation on the cold plate and affect the freezing effect.

2. The interval time must be more than 3min between start-up and stop of the compressor

3. Please do not open the freezing chamber for a long-time during freezing, which will cause frost on the cold plate and affect the freezing effect.

4. The freezing curve is in the middle of the main interface (Fig 4.8), which can be viewed by the operator at any time. If the user wants to review the curve, it is shown in “Data” interface of A/B System.

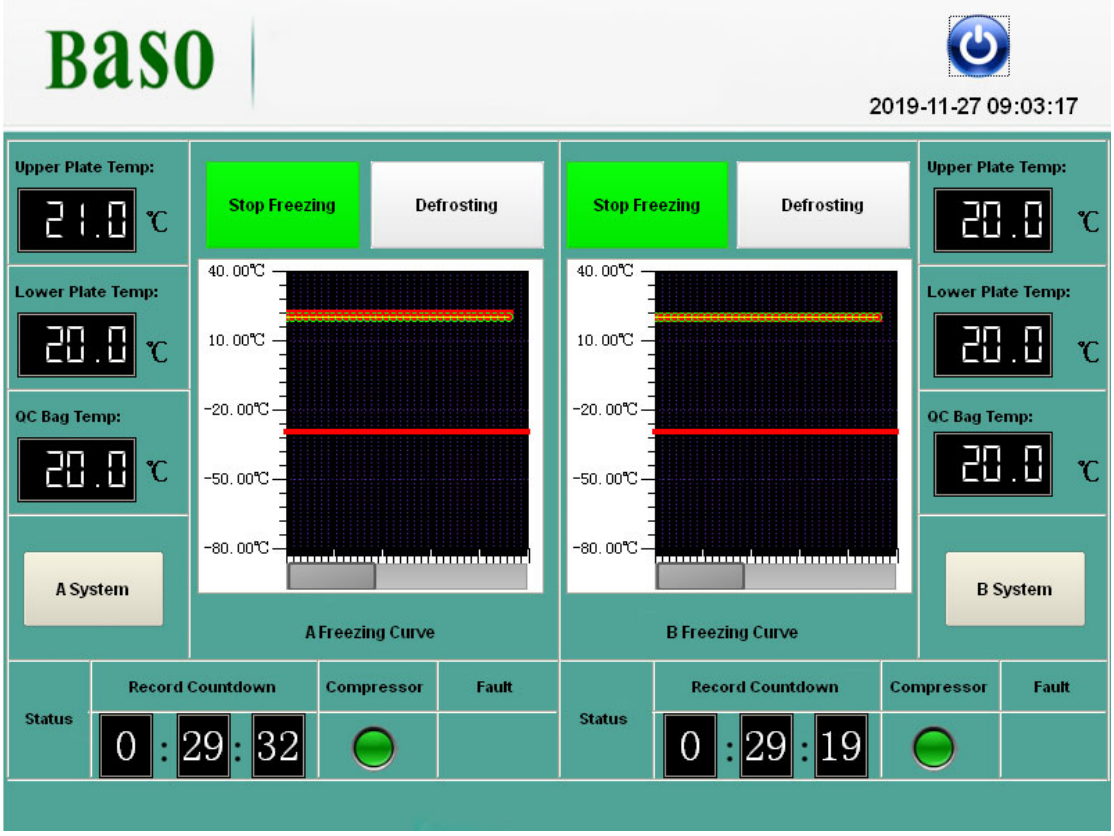


Fig 4.8 Freezing Curve in Main Interface

Step 6: Freezing completed; When it goes back to “0.0.0”, there is a prompt window and warning sounds for reminder. At this time, press “Open”, take out the freezing tray. Press “Close” to complete a whole process for quick freezing.

- Now you can choose to freeze another batch of plasma bag. This process is the same as described above, but there is no need to pre-cool.
- If you do not want to freeze again, close the freezing chamber. The device is now in standby and maintains the selected settings until you want to freeze the next batch of plasma bags. However, the device should not be operated in standby mode for longer than 2 hours because of the risk of ice formation

	General Warning Danger of frostbite!
	**Wear protective gloves!** **When operating in the freezer, wear protective gloves and tighten sleeves to prevent frostbite.**

Caution

1. Please don’t do any other operation during freezing.

2. When the timer goes back to “0.0.0” and the temperature at -60℃, the freezer will automatically switch to economy running for saving energy.

2.2 Economy mode

a) Step 1, step 2, step 3 and step 4 are same as regular mode operation.

b) After pre-cooling, click "Stop Freezing" > “Scanning” in Fig 4.5, scan the barcode of plasma bag and place evenly and neatly on the transport tray, then click “HOME” back to the A/B System Main Interface.

c) Press “Open” button at the right of A/B System freezing chamber. When the freezing chamber is open and the cold plate stop, the transporting tray could be pushed into the freezing chamber and press “Close”.

d) Click “Settings” > “Economy Mode” (Fig 4.9) > “OK” > Time Settings (Fig 4.7; According to the Table 2 to choosing) > “OK” > "Freezing".

e) When the timer goes back to “0.0.0”, there is a prompt window and warning sounds for reminder. At this time, press “Open”, take out the freezing tray. Press “Close” to complete a whole process for quick freezing.

f) After finished the freezing process and the compressor stopped, the freezer will automatically switch to economy running for saving energy.

Caution

1. In the economy mode, the QC bag should be placed in the freezing chamber together with the plasma products during freezing process, and the temperature probe should be inserted into the QC bag

2. The compressor is turned on at -30℃ and turned off at -35℃ in economy mode. The plasma bag in the freezer can be kept warm for a long time by using this mode, which guarantee its core temperature is always below -30℃.

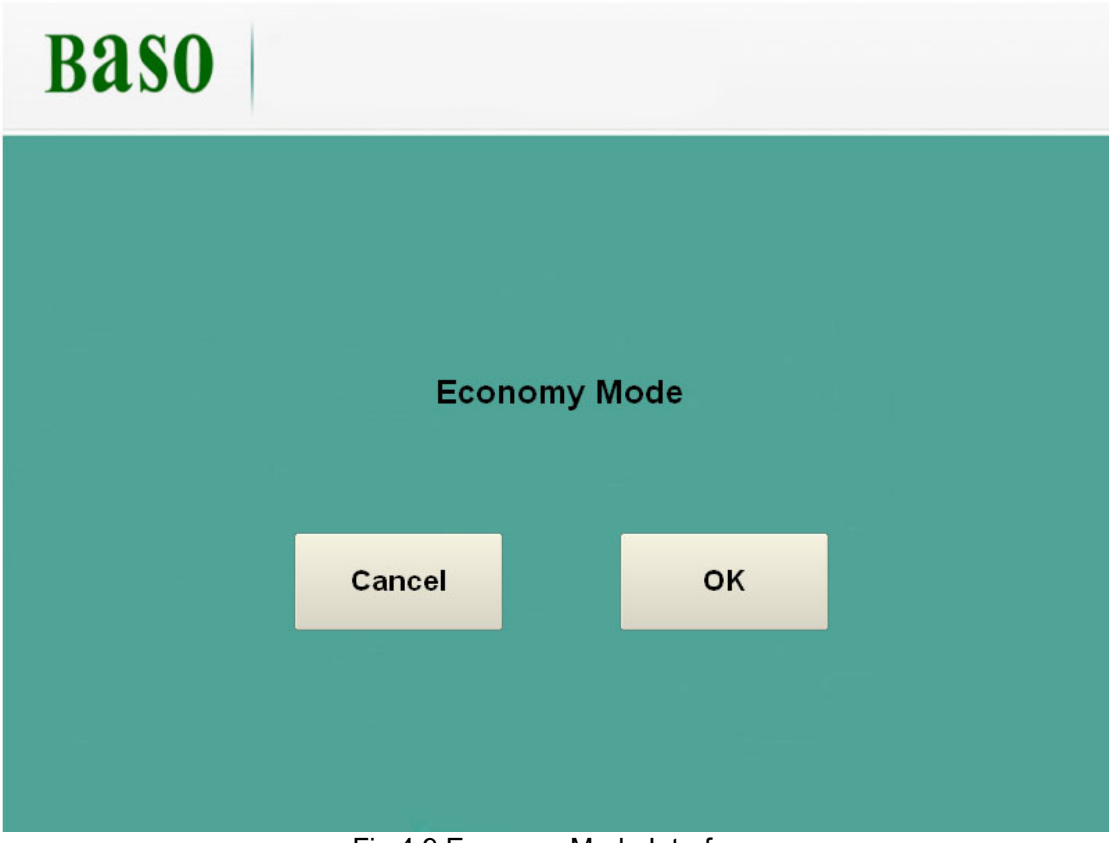


Fig 4.9 Economy Mode Interface

3. Defrosting function

Step 1: Press "Open" in A/B System to open the freezing chamber

Step 2: Click the "Defrosting" on the main interface (Fig 4.1), or press the "Defrosting" button for 3s on the right side of the A/B System, then automatically turn to the defrosting interface (Fig 4.10). It takes 8min for defrosting and the temperature of both cold plates reaches 40°C.

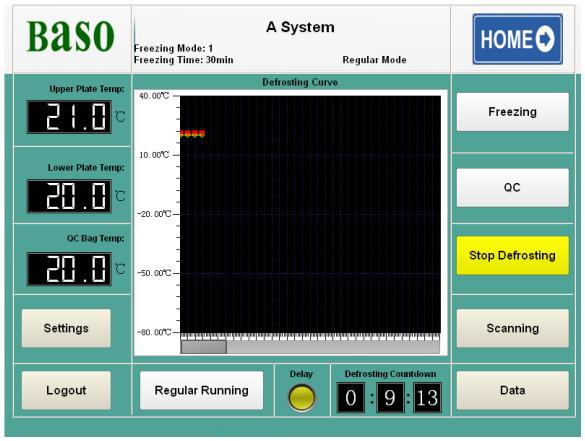
Step 3: When the defrosting was finished, there is a warning signal sounds, and then clean the residual water with a clean cloth.

Caution

1. No other operations during defrosting.

2. Keep the freezing chamber open during defrosting

	General Warning Danger of scalding!
	**Wear protective gloves!** **In the process of defrosting, please do not touch the cold plate to avoid scalding.** **Wear protective gloves before cleaning the residual water to avoid scalding.**



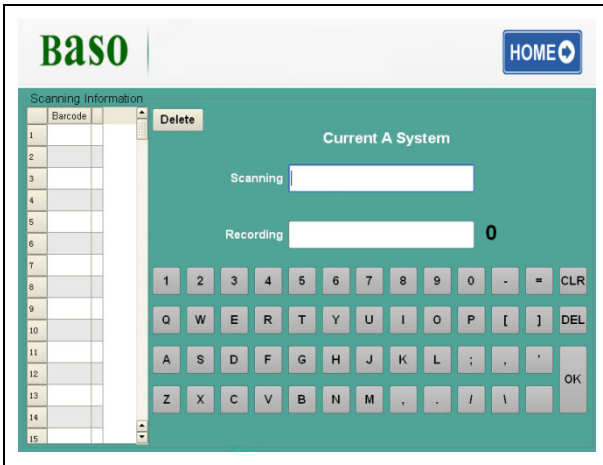
A System: Defrosting Interface | B System: Defrosting Interface

Fig 4.10 Defrosting Interface

4. Scanning function

a) Click “A/B System” in the main interface (Fig 4.1) to enter, then click “Scanning” in A/B system (Fig 4.11)

b) Directly scan the barcode of plasma bag and the data will be automatically recorded in the database.

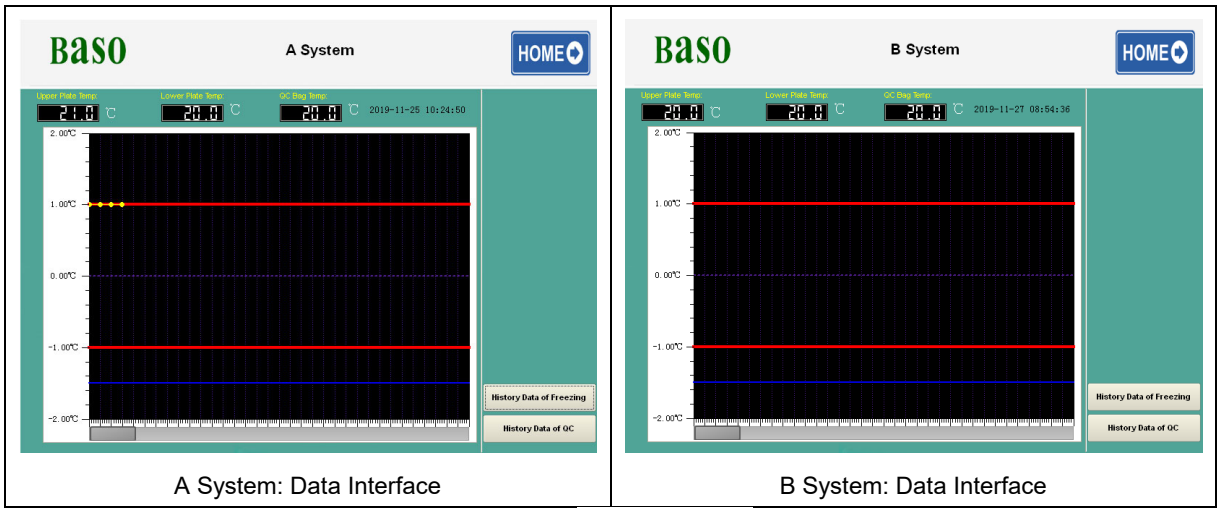


A System: Scanning Interface | B System: Scanning Interface

Fig 4.11 Scanning Interface

5. Record function

Confirm the authorization first, click "A/B System" in the main interface (Fig 4.1) to enter, then click “Data” to enter the data interface of A/B System (Fig 4.12) for searching data. After finished, click "Home" to go back to the A/B System interface.



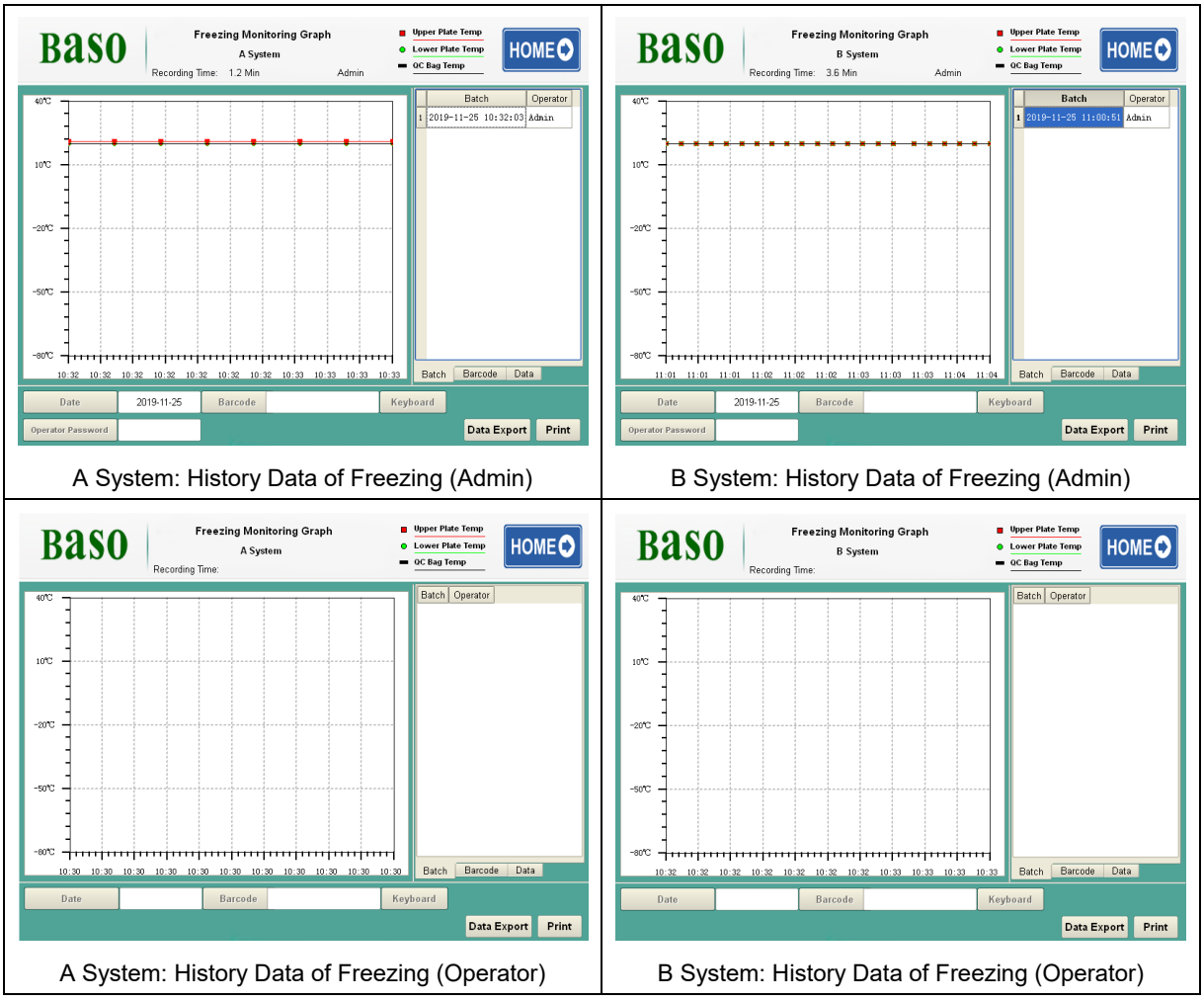
A System: Data Interface | B System: Data Interface

Fig 4.12 Data Interface

Caution

Click the "Data" in A/B system interface, and it shows the real-time curve and data. In the QC operation, it will show QC curve; in the freezing operation, it will show freezing curve.

5.1 Searching freezing data



A System: History Data of Freezing (Admin) | B System: History Data of Freezing (Admin)

A System: History Data of Freezing (Operator) | B System: History Data of Freezing (Operator)

Fig 4.13 History Data of Freezing Interface

Click "History Data of Freezing" in data interface (Fig 4.12) to enter Fig 4.13. Select “Date or Operator Password” and click "OK", the data will be shown in the blank space on the right side of the interface, also you could select one record to review the temperature/time curve, barcode etc.

When the plasma bags are placed in freezing chamber, and the temperature of the cold plate is below -30°C, the data will be started to record. Press the "Stop Freezing" or the freezing chamber is fully opened to terminate the data saving.

- There are 3 recording curves in the interface, respectively representing the temperature of the upper cold plate (red), lower cold plate (green) and QC bag (yellow).

Note:

1. In the recording function, the device will automatically collect data for every 10s.

2. Its curve will be automatically saved on the solid-state disk. The data will be directly read or searched it by users on the touch screen or using the software provided by Baso, and also directly connect to the printer for printing.

3. To enable the recording function, the QC bag should be placed in the freezing chamber together with the plasma products during the freezing process, and the temperature probe should be inserted into the QC bag. Otherwise, it collects temperature is not the data of QC bag.

5.2 Searching QC data

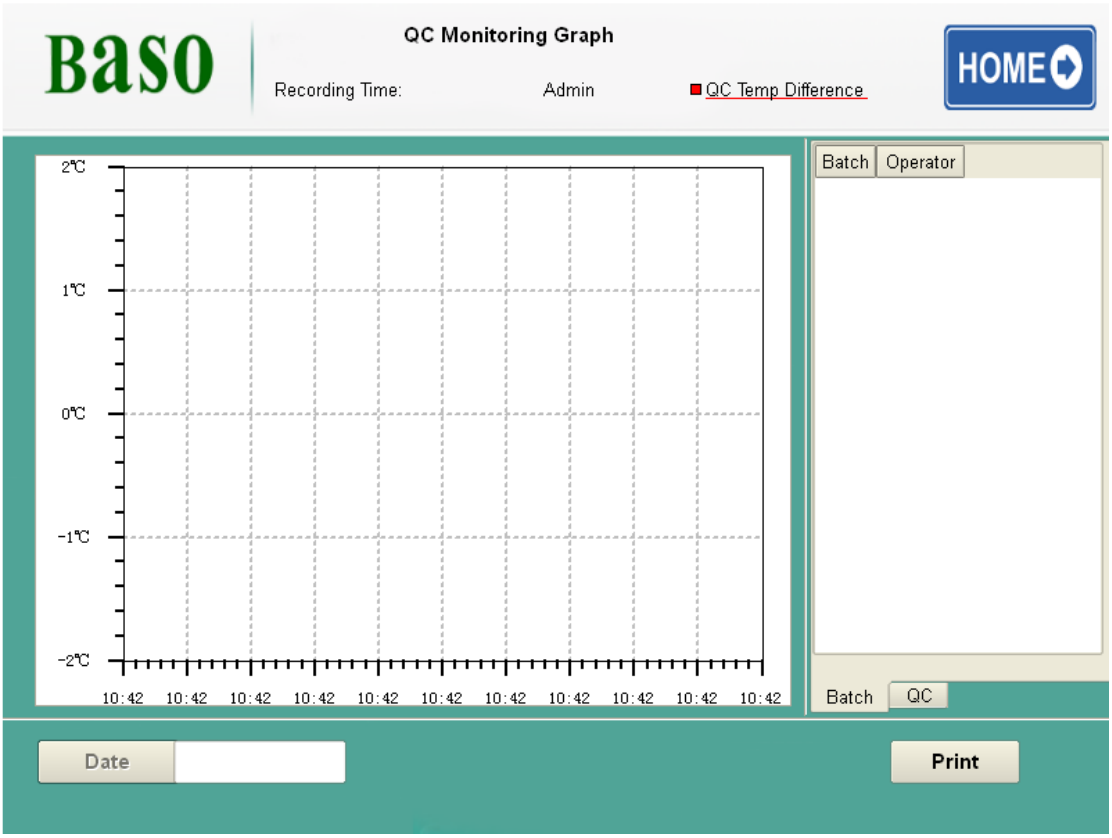


Fig 4.14 History Data of QC Interface

Click "History data of QC" in data interface (Fig 4.12) to enter Fig 4.14. Select “Date” and click "OK", the data will be shown in the blank space on the right side of the interface, also you could select one record to review the QC data.

The QC data will be started to record by pressing “QC” and press “Stop QC” to save the data in the solid-state disk of micro-computer.

The QC data is qualified within ±1℃, otherwise the device will alarm.

Caution

In the recording function, the device will automatically collect data for every 10s.

Caution

The curve from the data collected by recording function will be automatically saved on the solid-state disk. The data will be directly read or searched it by users on the touch screen or using the software provided by Baso, and also directly connect to the printer for printing and archiving.

Reading and management of data:

The industrial computer is equipped with solid-state disk. The data storage capacity is 128GB. It can save about 60000 sets of data. The user could read and save the data periodically by using the management software provided by Baso.

6. Settings Function

Click "Settings" of A/B System interface (Fig 4.1) to enter into the settings interface (Fig 3.6).

6.1 Administrator rights

For the administrator login, the “Regular Mode, Economy Mode, Fault Query, Operator Management, Switching System” are all available.

6.1.1 Fault Query

Back to the A/B System (Fig 4.1), confirm “Admin” login (if no, click “Log out” of A/B System), and click “settings”, then click the “Fault Query” to enter as shown in Fig 4.15; the users could view the “Current Fault” and “History Fault” to maintenance.

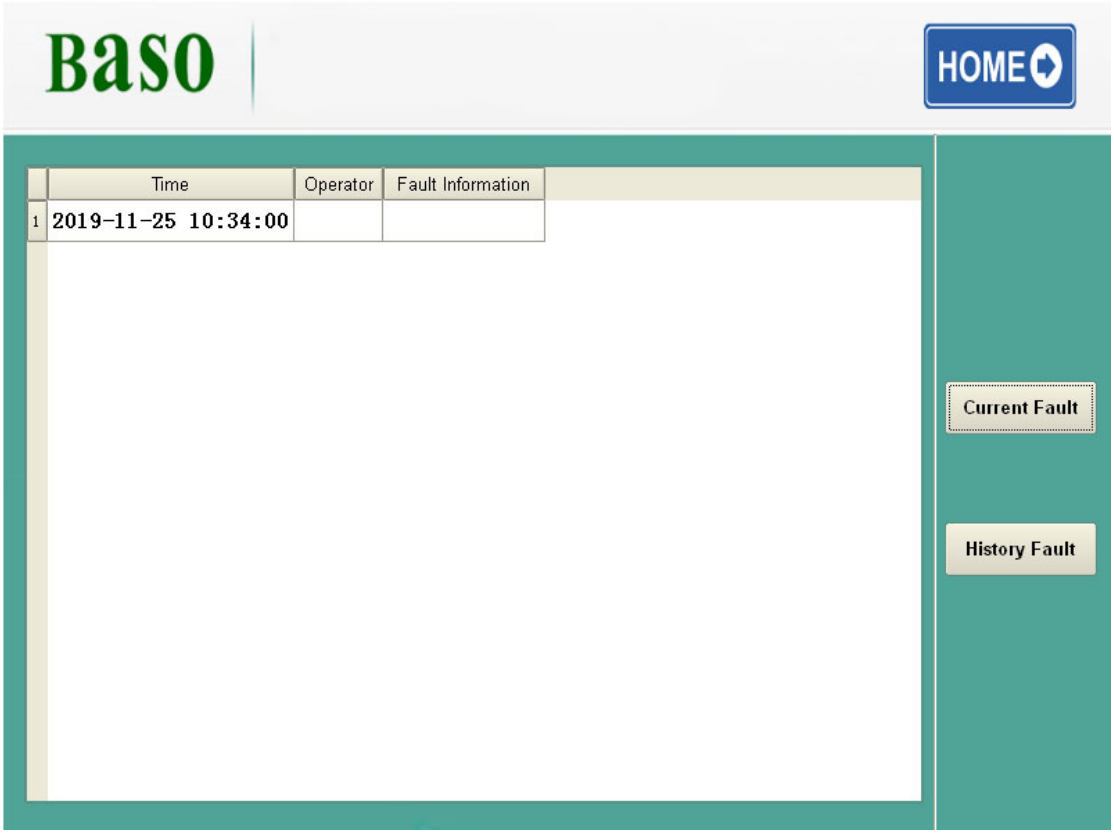


Fig 4.15 Fault Query Interface

6.1.2 Operator Management

Back to the A/B System (Fig 4.1), confirm “Admin” login first (if no, click “Log out” of A/B System), and click “Settings”, then click “Operator Management” as shown in Figure 4.16. Enter a password to authorize the operator.

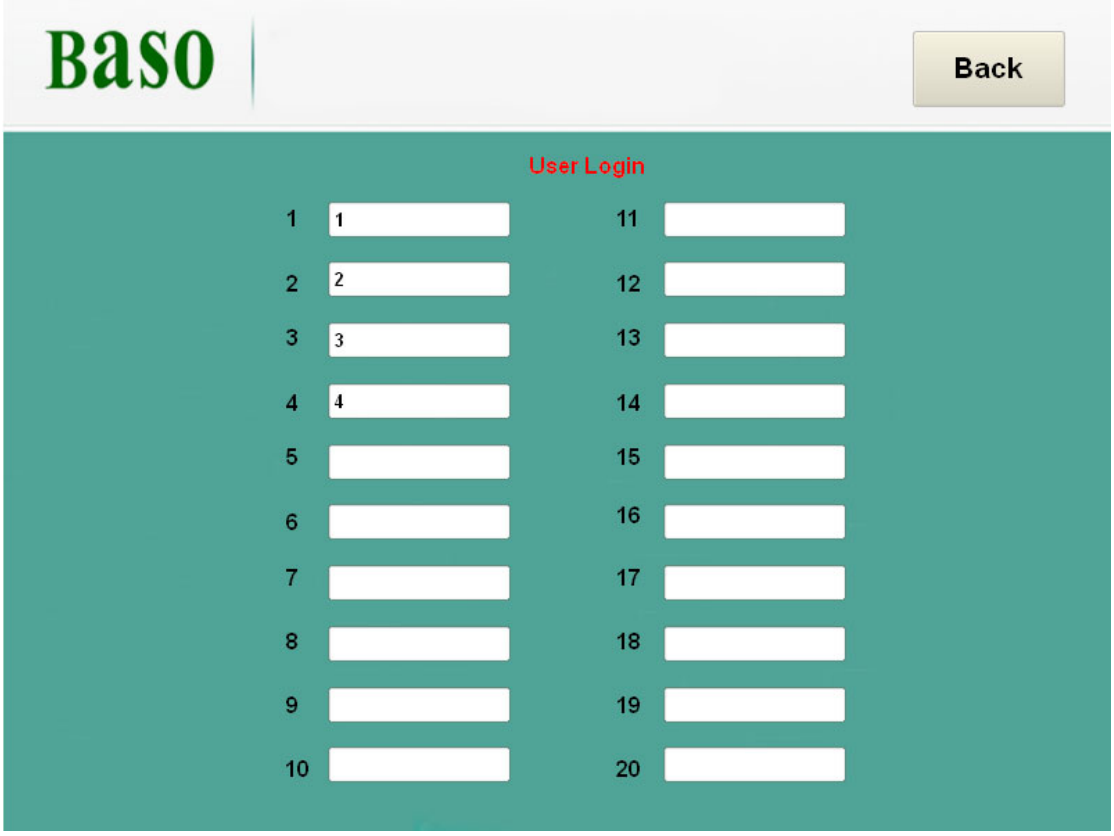


Fig 4.16 Operator Management Interface

6.1.3 System switching

Back to the A/B System (Fig 4.1), confirm “Admin” login first (if no, click “Log out” of A/B System), and click “settings”, then click "Switching System" to enter into the computer operating system and the freezer could be connected to a printer. The relevant data and curve will be printed directly.

6.2 Operator rights

Back to the A/B System (Fig 4.1), confirm “Operator” login first (if no, click “Log out” of A/B System), and click “settings”, then enter as shown in Fig 4.6. For the operator Authority, the freezing mode is only available in the settings, including regular mode and economy mode (Eco mode).

7. User authorization

The user authorization function mainly aims to build the traceability of database. Different user will use a different ID for operation.

The user including: Operator, Admin and Manufacturer; operator is the normal user; Admin is the administrator; Manufacturer is used for manufacturer maintenance.

For the operator, the freezing mode is only available in the settings, including regular mode and economy mode.

For the administrator, the “Regular Mode, Economic Mode, Fault Query, Operator Management, Switching System” are all available. In operator management, there are 20 operators for authorization.

Detailed operation:

Enter into the “A/B System” interface, confirm the authorization first (if no, click “Log out” of A/B System), then enter into the user login interface as shown in Fig 4.2. Choosing the user type, enter “password” to login.

8. Protection system

8.1 Phase-sequence protection: the soft start of the equipment is equipped with phase-sequence protection function. If the equipment is connected to the power supply and the power is switched on, the phase-sequence protection power can be displayed.

8.2 Pressure protection: when the refrigeration system of exhaust pressure lower than 0MPa or more than 2.5MPa, the compressor will stop working.

8.3 Compressor overheating protection: when the motor temperature of compressor is higher than the temperature limit by setting, the compressor stops working.

8.4 Compressor overcurrent protection: when the current of compressor exceeds the rated current, the compressor stops working.

8.5 QC warning: When “QC” is activated, when the temperature difference between the cold plate temperature and the QC bag probe exceeds 1°C.

8.6 Leakage protection: the air switch adopted by the equipment is equipped with leakage protection device. When the leakage current exceeds 30mA, the power supply will be automatically disconnected.

Chapter Five: Maintenance

Cleaning

1.1 Defrosting first

1.2 Power off

Caution

Cleaning agents are easy to corrode plastic parts, strong acid and strong alkali may lead to brittle plastic, easy to break.

Caution

When cleaning, do not use carbohydrate materials containing more than 10% alcohol or strong acids and bases.

Caution

Use general purpose cleaner and warm water for cleaning.

1.3 Cleaning the heat sink of the condenser in the freezing system.

Under normal maintenance conditions, the refrigerator condenser needs to be cleaned once a year.

Chapter Six: Trouble Shooting

1. Fault Alarm

If a fault occurs during the operation of device, the buzzer will prompt for repeat and automatically switch to the fault interface. It will be automatically recovered and the fault interface will be closed when the fault removes.

2. Troubleshooting

Fault, cause and solution are shown in Table 3.

Table 3: General Troubleshooting

Fault	Cause	Solution
High pressure alarm	Poor ventilation of condenser and environment	Clean the condenser and improve ventilation
The motor of Compressor overheating	Compressor return gas, poor environment cooling	Automatically reset after 30min. If not, the compressor will break down
Compressor overcurrent	The compressor current is too large, environment poor heat dissipation	After detecting the fault cause, reset by thermal overload
Sensor of the upper cold plate	Sensor error or not available	Contact Baso
Sensor of the upper cold plate	Sensor error or not available	Contact Baso

Caution: The maximum working pressure under normal working condition of equipment is 2.5MPa.

Chapter Seven: Supplementary Instruction

1. Instruction of simulated plasma bags

The simulated plasma bag (QC bag) is one of our patents which is used in the equipment to monitor the temperature change of the plasma freezing process. Its heat capacity ratio is similar to that of plasma, and it can effectively simulate the process of plasma temperature change in the same environment.

During freezing, a simulated plasma bag (QC bag) is placed in the freezer with the blood products to be frozen. The temperature probe in the freezer is inserted into a probe tube that simulates a plasma bag and its depth is limited by the positioning plastic sleeve on the probe.

Following the above steps, the temperature monitoring interface during the freezing process will display the temperature change process simulating the plasma bag, provide users with the parameters of plasma freezing, and the equipment will record the series data to the solid-state hard disk for future traceability and management.

If the plasma bag temperature probe is not used, the probe can be placed in a designated position in the freezer.

The simulated plasma bag shall be filled by the user. The simulated load package shall be filled with 0.9% sodium chloride (normal saline) solution, and the filling volume shall

correspond to the maximum filling capacity specified for the respective plasma bag type. The deviation of the actual filling volume from the nominal capacity shall not exceed ±3%.

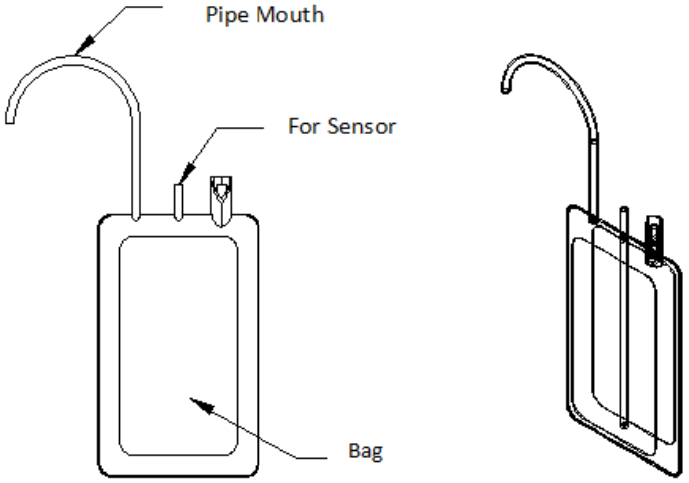


Figure 7.1 Schematic diagram of simulated plasma bag structure

2. Instruction of USB interface

The device is equipped with a USB port, which is mainly used for scanning gun or USB disk, providing working power for scanning gun or USB disk and supporting data transmission after scanning. Power supply cannot be provided to equipment other than the scanning gun and U disk.

Chapter Eight: Warranty

Warranty period: One year from the date of acceptance.

Shelf life: 5 years

The expected service life of the product is 7 years.

Warranty scope: provide repairing service or replaced new parts for the failure parts.

But for the following faults, even within the warranty period is paid repair.

1. Failure to comply with the scope of use specified in this manual.

2. Improper installation.

2.1 Damage caused by improper operation during installation.

2.2 Failure caused by failure to comply with the setting location, temperature and voltage range specified in this product.

3. Faults caused by lightning, fire, earthquake, flood and other natural disasters.

4. Used abroad.

Note:

1. The contents of this product manual are subject to change without prior notice.

2. All replacement components must be disposed of in accordance with local environmental requirements.

3. Disposal of equipment after the expiration date should meet local environmental requirements.

Packing list

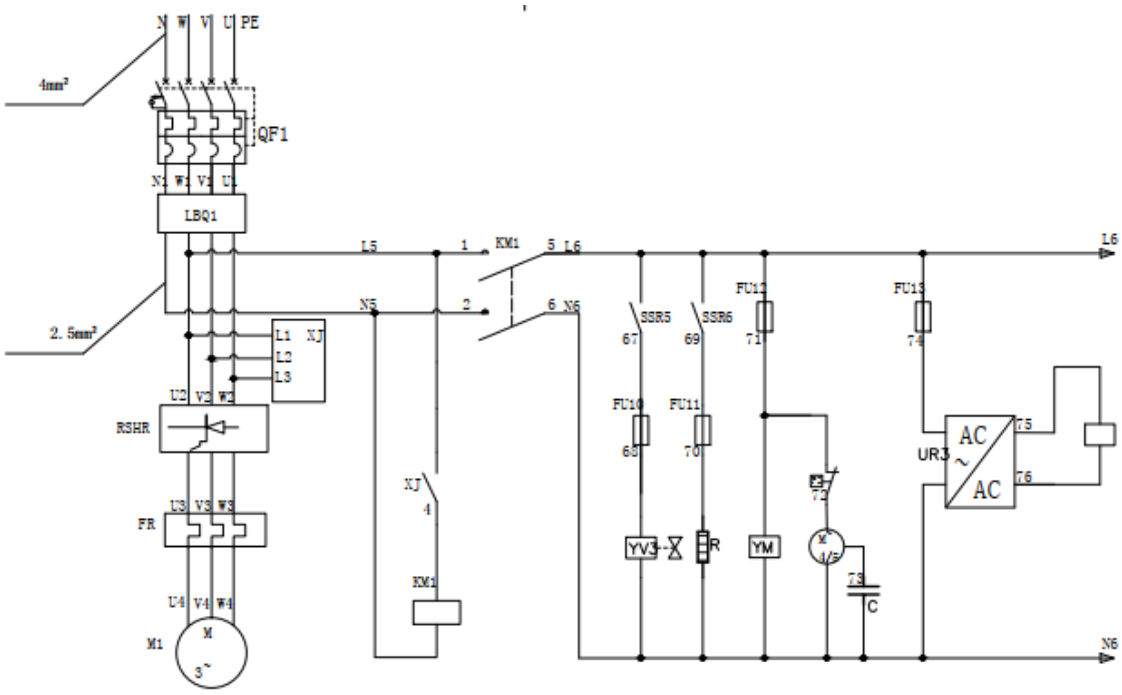
Name	Specification	Quantity	Remark
Plasma Freezing System with Full Temperature Control	BSSD-IV-02	1 set	
Barcode Reader		1pc	
Operating manual		1 copy	
Brief operation procedure		1 copy	
Certificate of Conformity		1pc	

Option List

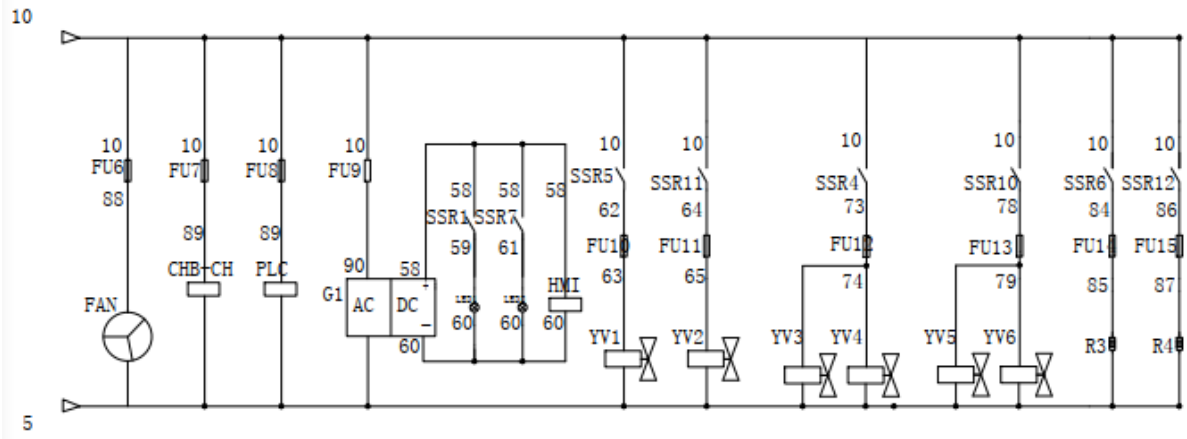
Name	Specification	Quantity	Remark
Anti-adhesion Pad (Soft Pad)		2pcs	
Cart		1 set	
Freezing Tray		2pcs	
Simulated plasma bag (QC bag)	200ml/500ml/600ml	1 package	5 bags/package
QC Bag	200ml	1 package	5 bags/package
QC Bag	100ml	1 package	5 bags/package

Caution: Considering the relevant safety regulations for the transportation of chemicals or liquids, it is recommended that customers purchase QC bags locally.

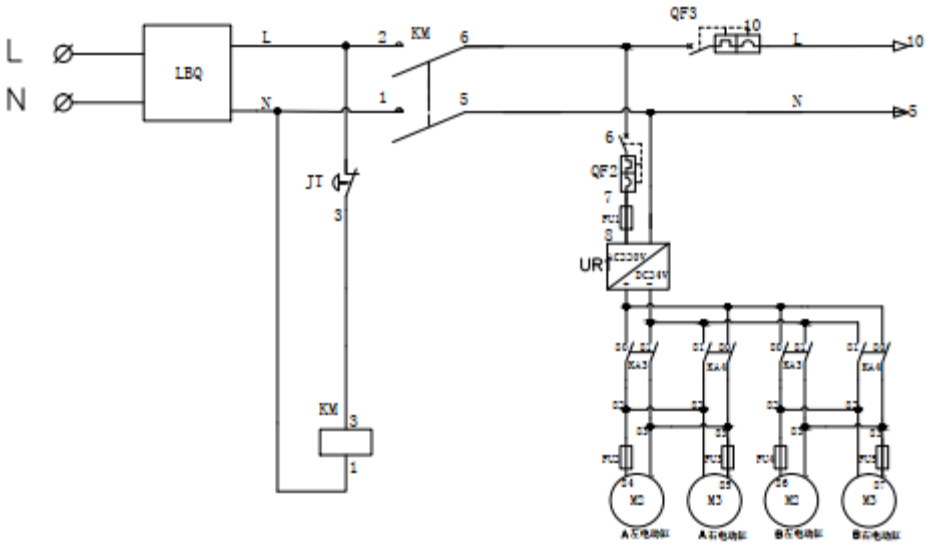
Circuit Diagram 1



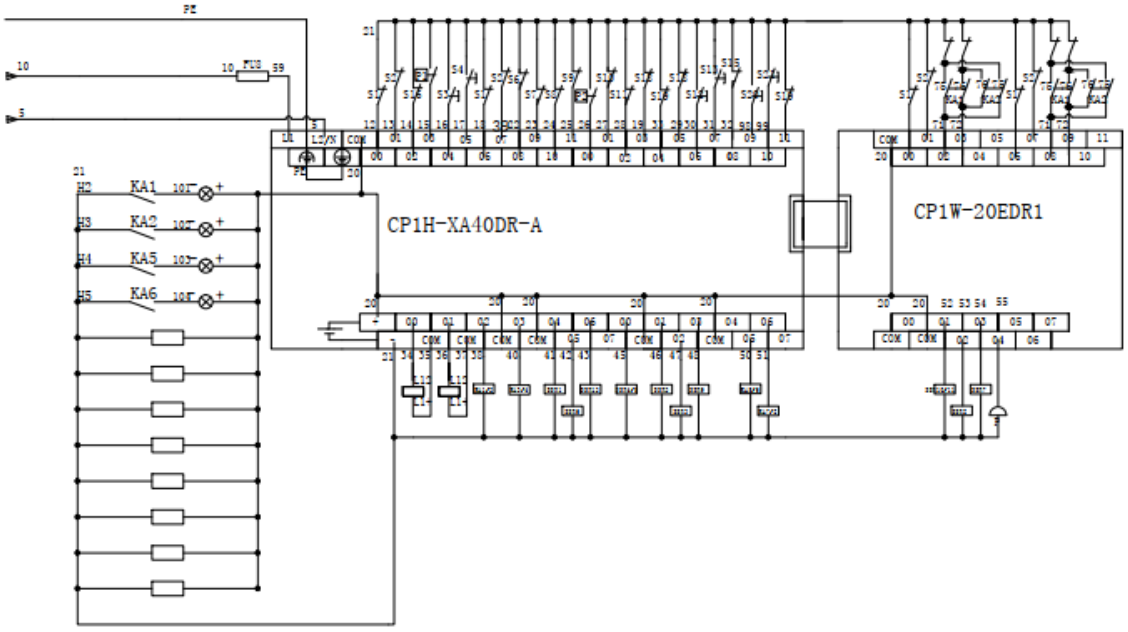
Circuit Diagram 2



Circuit Diagram 3



Circuit Diagram 4



Attachment 1

Test requirements for anti-disturbance of equipment used in industrial premises

Port	Test item	Basic Standard	Trial value	Performance criterion
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	Contact discharge:4kV， Air discharge: 8kV	B
	Radiofrequency electromagnetic radiation	IEC 61000-4-3	10V/m (80MHz~1.0GHz) 3V/m (1.4GHz~2.0GHz) 1V/m (2GHz~2.7GHz)	A
	Rated power frequency magnetic field	IEC 61000-4-8	30A/m[e]	A
AC power supply	Voltage sags	IEC 61000-4-11	0%1 cycle 40%10/12[h] cycle 70%25/30[h] cycle	B C C
	Short interruption	IEC 61000-4-11	0%250/300[h] cycle	C
	Pulse group	IEC 61000-4-4	2kV (5/50ns,5kHz)	B
	Surge	IEC 61000-4-5	1kV[a]/2kV[b]	B
	Radiofrequency field induced conduction disturbance	IEC 61000-4-6	3V[f] (150kHz~80MHz)	A
DC power supply	Pulse group	IEC 61000-4-4	2kV(5/50ns,5kHz)	Not Applicable
	Surge	IEC 61000-4-5	1kV[a]/2kV[b]	
	Radiofrequency field induced conduction disturbance	IEC 61000-4-6	3V[f] (150kHz~80MHz)	
I/O signal/ control (A cable that includes a functional grounding port)	Pulse group	IEC 61000-4-4	1kV (5/50ns,5kHz)d	Not Applicable
	Surge	IEC 61000-4-5	1kV[b,c]	
	Radiofrequency field induced conduction disturbance	IEC 61000-4-6	3V[d,f] (150kHz~80MHz)	
I/O signal/control port directly connected to the power supply network	Pulse group	GB/T 17626.4 IEC 61000-4-4	2kV (5/50ns,5kHz)	Not Applicable
	Surge	IEC 61000-4-5	1kV[a]/2kV[b]	
	Radiofrequency field induced conduction disturbance	IEC 61000-4-6	3V[f] (150kHz~80MHz)	

a Line to line
b Line to ground
c Only for long distance lines.
d Applicable to the case of line length exceeding 3m only.
e For equipment sensitive to magnetic fields only, the display interference of the cathode ray tube is allowed when the magnetic field strength is greater than 1A/m.
f The test level of conducting rf test is lower than that of the radiation rf test, which is a more rigorous test because the conducting rf test simulates the resonant state at each frequency.
g DC connections between parts of the equipment/system, if not connected to the dc distribution network, should be treated as I/O signal/control port.
h "25/30 cycle" means that 25 cycles are applicable to tests with rated frequency of 50Hz and 30 cycles are applicable to tests with rated frequency of 60Hz.

IEC 61326-1:2012, EN 61326-1:2013 article 6.4 performance criteria grade
Performance criterion A: during the test, the performance is normal within the limit value of the specification.
Performance criterion B: during the test, the function or performance is temporarily reduced or lost, but can be restored by itself.
Performance criterion C: during the test, the function or performance is temporarily reduced or lost, but operator intervention or system reset is required.
This product is classified as group 1 class A equipment according to IEC/CISPR 11:2009/A1:2010.

CE 2797

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