Labotronics

Blood Grouping Instruments

LB-10BGI

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1. Safety Measures

1.1 In this manual, symbols are taken as visual signals for conveying information.

Symbol	Title	Description
	Caution	This symbol indicates violating the operation guide or procedure may result in physical injury or even death and mayalso damage the instrument. The document should be consulted in any circumstances with this symbol to make clear the nature of the potential hazard as well as all necessary measures to be taken.
	Caution, hot surface	This symbol indicates the surface of the instrument may be very hot.
	Biological hazards	This symbol indicates keeping alert while using potentially contagious substances.
	Caution, possibility of electric shock	This symbol indicates there may be an electric shock hazard in the operation process and it should be kept alert.
	Beware of pinch points	This symbol indicates there may be hand-pinching hazards in the operation process and it should be kept alert.
	CAUTION, LASER	This symbol indicates there is a laser product. It should pay attention to protection from laser radiation and wearprotective goggles.

1.2 Electric Safety

	Protective Conductor terminal	The baseplate/housing of the instrument shouldbe safely grounded via earth wires. Breaking any grounding circuits, no matter whether inside or outside the instrument will cause danger.
	Caution	To prevent the danger of electric shock, choose aqualified power source for the instrument. In no case should the user try refitting or destroying the safety devices of the instrument. In case the power cord is fractured, worn, or broken, the local engineer to replace it at once. The back panel **MUST NOT** be opened when it is energized. The operator **MUST NOT** open the back panel byitself, and the engineer should disconnect the power source before opening the panel and pay attention to the live parts with an indication of "**CAUTION, ELECTRIC SHOCK**".

1.3 Emergency and Corrective Measures

To prevent personal injury or damage to the machine, timely disconnect the power source when this instrument occurs with danger or mechanical fault.

1.4 Disposal of Instrument

The instrument should be properly disposed of under local Measures for Administration of Medical Wastes when it reaches the end of service life, and it isconfirmed not serviceable by the engineer.

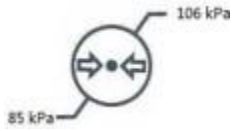
1.5 Electro-magnetic Compatibility (EMC)

- This equipment may be subjected to various kinds of electromagnetic disturbance.
- These kinds of disturbances are conducted via power sources, measure or control cables, or radiated in the environment.
- This equipment **MUST NOT** be used beside intense radiation sources such as non-shielded RF sources, otherwise normal functioning of the equipmentmay be interfered with.
    1) As professional IVD equipment, this instrument conforms to the radiation and anti-interference requirements outlined in EN IEC 61326-1.
    2) This equipment is designed and tested as per type A equipment in IEC/CISPR 11.
    3) This equipment may cause radio disturbance, so protective measures should be taken in the ambiance of the household.
    4) The user is suggested to evaluate the electromagnetic environment around the instrument before using the equipment.

	• The user must follow the information provided by the manufacturer. • The user is responsible for guaranteeing the EMC environment to enable the equipment to function normally • Do not place the equipment in a position where the equipment is hard to be disconnected. • The installation position should be stable. • Relocating the equipment must be done by a professional engineer and calibrated before use.

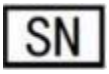
1.6 Packaging & Pictorial Marking for Handling

Symbol	Description	Explanation
	Upward	Indicating the package should be upright during handling.
	Fragile, handle with care	Indicating the package contains fragile articles and should be handled with care.
	Keep dry	Indicating the package should be kept dry.
	Do not roll	Indicating the package should not be rolled during handling.
	Temperature Limitation	Indicating the range of temperature in which the package should be kept. This instrument should be stored and handled at a temperature between -40°C~55°C.

	Humidity Limitation	This instrument should be stored and handled at relative humidity not greater than 85%.
	Atmospheric pressure limitation	This instrument should be stored and handled under barometric pressure of 85 kPa~106 kPa.

1.7 Instrument Labeling and External Markings

The label must include the product name, model, power connection requirements, input power, serial number, production date, service life, name, address, information, and the production facility address. Additionally, it shouldclearly state "**Consult the Manual for Additional Information**."

Marker	Explanation
	Power switch marking, down state of which is "ON"
	Power switch marking, ejected state of which is "OFF"
	In-vitro diagnostic medical device
	CE mark
	Serial number
	Date of manufacture

	Manufacturer
	Authorized Representative The European Community
	Consult Instructions for use
	Alternating Current
	Only for Hand support, and must not be used for moving equipment
	RS232 port 1
	RS232 port 2
	USB port 1

2. Introduction

Blood grouping instrument LB-10BGI is a fully automated multi-functional blood grouping device. It is characterized by a high-resolution image acquisition and interpretation system. The bi-directional LIS/HIS integrated connection promotes intellectual data analysis. Its synchronous operation and system refreshing feature enables rapid and errorless analysis.

3. Features

1. High-resolution image acquisition
2. Automatic interpretation of acquisition and recognition results
3. Display with a backlight system for visual monitoring of the processing and resulting data
4. Real-time monitoring and tracking function
5. Speed and time-adjustable centrifugation
6. Warning notification in malfunctioned situations
7. Disposable plastic tips
8. Efficient data storage to support rechecking of testing protocol

4. Specifications

Model	LB-10BGI
Testing throughput	Up to 30 cards/hour
Transfer card	1
Pipetting channels	1
Pipetting range	10 μL ~ 800 μL
Dispense tube volume	800 μL
Pierce module	12 cards position
Tips rack capacity	192 tips (2 positions, each can hold 96 tips)
Sample tube capacity	20 × 3 = 60
Sample tube dimensions	Diameter: Φ 13 mm
	Maximum height: 100 mm
Reagent module	2 diluent positions
	2 control positions
	3 cell suspensions
Dilution position	36 deep well plates
Centrifuge module	12 cards
Incubation module	12 cards
Incubation temperature	RT ~ 50 °C
Incubation temperatureincrement	0.1 °C
Maximum speed	3000 rpm
Dimensions	810 × 695 × 990 mm
Weight	126 kgs

5. Applications

Used for blood grouping, reverse grouping, phenotyping, crossmatching, antibody screening, identification, etc. in the fields of forensics, genetics, neonatology, pathology, etc.

6. Instrument Introduction

Structural Composition

The fully automated blood grouping system primarily comprises the main unit (which includes the pipette, incubator, centrifuge, and reader module), communication cables, power cord, and control software.

1. **Sample dispensing channel**
   The sample dispensing channel finishes the early dispensing process of human blood samples and relevant reagents for blood grouping gel cards. Its main functions are as shown in the below:
   - based on the gas-liquid displacement principle, regular disposable plastic tips are used to prevent cross-contamination and dilutive effect.
   - Operation of individual channels is independently controlled.
   - Non-equidistance probe and probe spacing is >9mm.
   - Dispensing range: 5-1000μL, with a step of 1μL.
   - With the liquid level detection function, it can monitor the level status (samplelevel and reagent volume status) in real-time.
   - Clot, bubble, empty tube, and collision detection function.
   - Tip status monitoring.

2. **Transfer arm**
   It displaces the physical locations of blood-grouping gel cards.

3. **Incubator**
   Consisting of a heating device, temperature sensor, and control circuit, it isused for precisely timed incubation of blood grouping gel cards.

4. **Centrifuge**
   It realizes speed-adjustable timed centrifugation to blood grouping gel cardsthrough the control circuit.

5. **Low noise**
   It has advanced automatic imbalance detection technology and an imbalance.

6. **Alarm function**
   It has safety protection functions such as precise locating and over-speedfeedback.

7. **Reader module**
   It photographs the centrifuged blood grouping gel cards and uploads theimages to the control software of the host computer.

8. **Piercer**
   It pierces the blood grouping gel card with the puncher for automatic sample dispensing.

9. **Card warehouse**
   It is for placing and temporarily storing the blood grouping gel cards to be used. Moving of the card warehouse is realized by the control system, so it canbe flexibly transferred in cooperation with the transfer arm.

10. **Barcode scanning**
    It realizes barcode scanning for the samples to be tested and provides the basis for determining what test to do to the current sample. It realizes barcode scanning for the blood grouping gel card to be tested and determinesthe type of the blood grouping gel card through the control software.

11. **Tip rack**
    It is used for loading and temporarily storing the tips to be used.

12. **Sample rack**
    It is used for placing the samples to be tested.

13. **Reagent rack**
    For loading the reagent vials for test and realizing the mixing of liquid withinthe vials.

14. **Dilution positions**
    For placing the deep-well plate for diluting the samples.

15. **To be determined (TBD) positions**
    For placing the blood grouping gel cards with uncertain test results, i.e. problematic cards.

16. **Balancing positions**
    For placing the balancing blood grouping gel cards; when the blood groupinggel cards are going to be centrifuged, they should be balanced in case there are odd number cards.

17. **Tip ejector**
    For getting the used tips ejected from the pipette channels.

18. **Wastes station**
    There is a waste card box and a waste tip box.

19. **Control software:**
    It generates corresponding reports by analyzing and disposing of the images.

7. Installation

7.1 Instruction on packaging, shipment, and storage

7.1.1 Packaging

Three-layer packaging is employed for the main unit, of which the outer layer is a wooden case for equipment packaging, marking, and protection; the medium layer is a plastic film for water and damp proofing, and the inner layeris bubble pad wrapping that is fixed by the stretch film for buffering.

7.1.2 Storage

The packaged equipment should be stored in such an environment that the temperature is -40°C~55°C, the relative humidity is not greater than 85%, the barometric pressure is 85 kPa~106 kPa, and well-ventilated without corrosivegases.

7.2 Packing List

Quantity	Assembly
1	Main unit and accessories
1	Power cord
1	Communication cable (USB
1	Control software
1	Operation Manual
1	Packing List

7.3 Installation

7.3.1 Installation Requirements

- The instrument should be uprightly placed on a horizontal plane.
- The instrument should be away from equipment with intense shocking orhigh electromagnetic radiation.
- The instrument comes with a certified power cord and a communicationcable (USB cable), which should not be replaced without authorization.
- The instrument shouldn't be exposed to direct, bright light such as sunlight.
- Installation of the instrument should be in the charge of the user's technicalengineer.
- After installation, the waste materials should be placed at the specifiedposition inside the equipment and put in a specified refuse bag.

7.3.2 Spatial and Power Requirements

<table>
<tr><th>Model</th><th colspan="3">120</th><th colspan="3">120</th></tr>
<tr><td rowspan="2">Size</td><td>L mm</td><td>W mm</td><td>H mm</td><td>L mm</td><td>W mm</td><td>H mm</td></tr>
<tr><td>1320</td><td>829</td><td>1780</td><td>800</td><td>700</td><td>1000</td></tr>
<tr><td>Weight</td><td colspan="3">375kg</td><td colspan="3">175kg</td></tr>
<tr><td>Bearing requirements</td><td colspan="3">Load bearing is not lower than 600 kg/m2</td><td colspan="3">Load bearing is not lower than 400 kg/m2</td></tr>
<tr><td>Floor</td><td colspan="6">Level floor</td></tr>
<tr><td>Electric power</td><td colspan="6">• Power connection conditions: AC 200-240 V; 50/60 Hz; typical transient overvoltage power appeared on the power grid in category II and rated pollution class 2 is applicable.
• To prevent electric shock hazards that may be caused by electric leakage, the external power source should be grounded.
• The instrument is not provided with UPS, but suitable UPS could be adopted according to the local condition of the electric supply, for which the user may consult a local engineer.
• The power outlet for the instrument should be a european standard
• 10A outlet with ground protection, and its position should be within 2 meters from the power inlet of the instrument.</td></tr>
<tr><td>Power</td><td colspan="3">800 VA</td><td colspan="3">500 V</td></tr>
<tr><td>Ventilation</td><td colspan="6">There is no other special requirement than the following:
• Do not block the air inlets.
• The horizontal spacing between theair inlets and surrounding walls or other obstacles should not be less than 5cm.
• Putting articles on the air inlets of fans is prohibited</td></tr>
<tr><td>Pass ways</td><td colspan="6">• An operation space of 50cm should be kept in front of the instrument to ensure convenient and safe operations.
• A space of20cm should be kept on the left of the instrument to turn off thepower switch easily.
• Putting articles in the power switch area is prohibited.</td></tr>
</table>

7.3.3 Environmental Requirements

- For indoor use in a controllable environment with an air-conditioner
- Clinically applies to professional test labs of medical service institutions such as hospitals and blood banks
- **Power supply environment**: AC200-240 V, 50/60 Hz
- **Ambient temperature**: 10°C~30°C
- **RH**: ≤85%
- **Baro. Pressure:** 85 kPa~106 kPa

7.3.4 Installation of Equipment

As a precise medical device, this instrument should be installed by professionals to ensure safety and effectiveness. Assist in supervising the installation process. (see the section of production information for details)

Instructions of instrument

USB-1	The connection port between the main unit and the PC
USB-2	The communication port between the camera and the PC
Power source	Power inlet, for input of power voltage.
Ground connection	Use a ground wire and make the grounding terminal on the instrument enclosure directly and reliably connect with the ground.

Installation process

Delivery	Transfer
• Inspect the completeness of the external package (whether it's broken, caught in the rain, tilted/inverted, or buckled under strain, etc.) and sign logistical delivery receipts. • Should the outer packaging be incomplete, refuse to sign in and a local sales rep or engineer.	The installation engineer of the user is responsible for safely handling the instrument to the specified location. • The installation engineer must pre-evaluate the environmental conditions for installation and confirm the feasibility. • Observe the precautions on instrument handling, it should not be tilted, inverted, or handled roughly, etc. • It strictly forbids handling the instrument by removing its fixing devices. • When handling the equipment, there should be at least 4 people on the four corners of the machine to make it in a balanced state.

Installation	Inspection &acceptance
• Adjust and fix the horizontalposition of the instrument. • Remove the devices for fixing the moving parts inside the instrument. • Connect the accessories and other devices and Install the software for the control system and the driver for each component. • Calibrate the position parameters, technical parameters, and functional requirements of each part. • Simulate the test running process and confirm the instrument running stats.	• Check the items against the packing list and sign the equipment handover list. • Both parties carry out inspection & acceptance according to the expected test plan and fill out the installation acceptance report / technical service report after acceptance. • The installation engineer should train the operators on SOP, instrument maintenance & alarms, and troubleshooting. • The operators should be assessed on-site after training and issued.

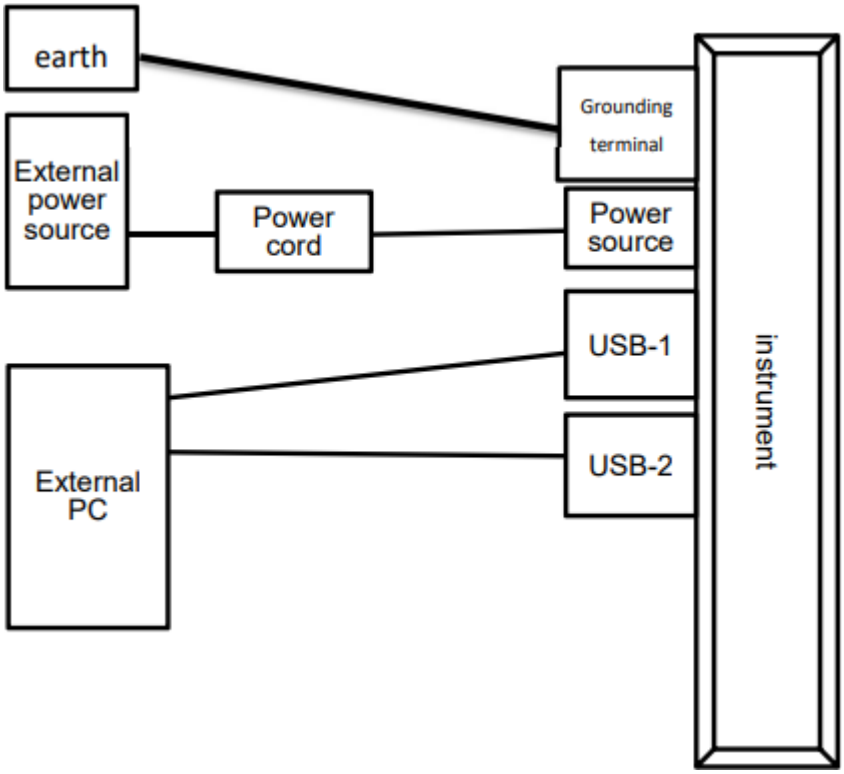


Figure-1

7.4 Centrifuge

The centrifuge exclusively applies to the matched blood grouping gel cards as required by the user's company and should not be used for centrifuging other substances.

7.4.1 Rotors and accessories of centrifuge

The centrifuge is fixed on the equipment and cannot be removed for use alone.Both the rotors and the card slots are non-removable.

7.4.2 Rated values of centrifuge

- The rotor rpm range is 0-3000 r/min.
- This device exclusively applies to the matched blood grouping gel cards as required by the user's company and should not be used for centrifuging other substances.
- There is no restriction on density and volume since the rotary module can only centrifuge the matched blood grouping gel card as required by the company.

7.4.3 Installation of centrifuge

- The equipment should be installed on a level ground.
- The four legs should beadjusted to such height that the worktop is measured level with a leveling instrument.
- There should be at least a 300mm gap on each side of the complete machine.
- The weight of an individual centrifuge is 8kg.
- The whole unit should be installed on a level ground.

- The centrifuge will be leveled by the engineer during installation.
- If it is foundimbalanced in later use, the user should not adjust by himself, but timely theengineer for maintenance.
- The centrifuge has been pre-installed in the equipment at the factory so thatno additional installation is required.

7.5 Instructions for Software

7.5.1 Basic functions of software

1) Run time environment

Hardware configurations

- **CPU**: Clock speed 1.5GHz and above
- **Storage**: Min. 256G HDD, 1G RAM
- **Peripherals**: USB or RS232
- Display resolutions 1024×768 pixels

Software environment

- **OS**: Windows (XP and above versions).
- **Supported software:** office 2003 and above versions; Anti-virus
- **software**:360 Anti-viruses.

Network conditions

- **Network architecture**: CS architecture
- **Network type**: LAN.
- **Band width**: 1M and above

2) Software Installation

Installation of the main program

The main program, as portable software, can be directly copied to a hard disk ofthe computer (recommended to install it to the disk D).

Installation of drivers

- The driver package includes a camera driver, CAN driver, RS232to USB driver, and net framework 2.0. The drivers should also be set.
- This software would not work without the drivers.
- In case of reinstalling the operation system, back up the database first to prevent loss of data.
- The user may consult local engineers for detailed driver installationmethods.

3) System Management

Login system

1. Double-click the  desktop icon to open the software interface below.

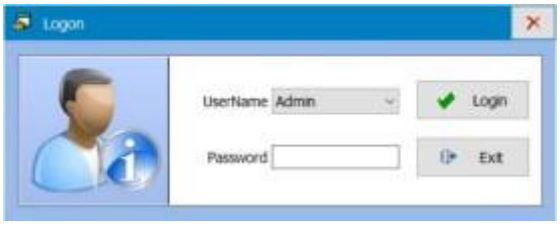


Figure-2

2. Select a username (e.g. Admin) and enter a password to log in.
3. The username Admin provides engineer authority, which can only be used by the User's professional engineers for changing the core parameters of this system.
4. It is forbidden to arbitrarily access this authority to change configuration parameters without permission, otherwise it will bring high risks.
5. The software generates a key to the password of this user to avoid this risk.
6. The user can single-click "**System Settings**" and select "**ChangePassword**" to change their password.

Figure-3

User management

1. Single-click "**System Settings**", and select "**User Management**" to add, change,or delete user settings.
2. The authority of specific users is set through a checkbox.
3. It suggests that the end user set only one ID with the highest authority.
4. The authority setting is shown in the following figure:

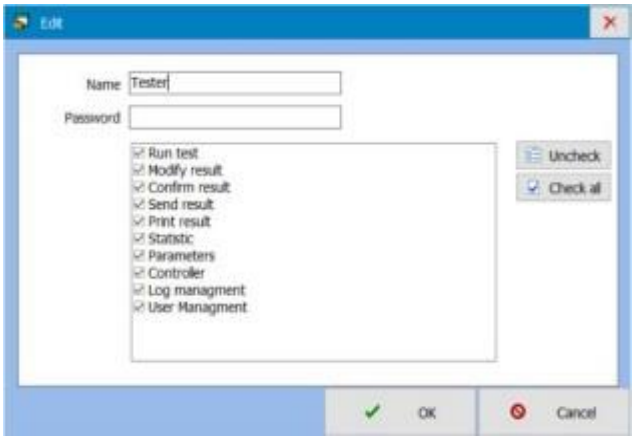


Figure-4

Log management

1. Single-click "**System Settings**" and select "**Log Management**" to query previous operation logs. See the following example:

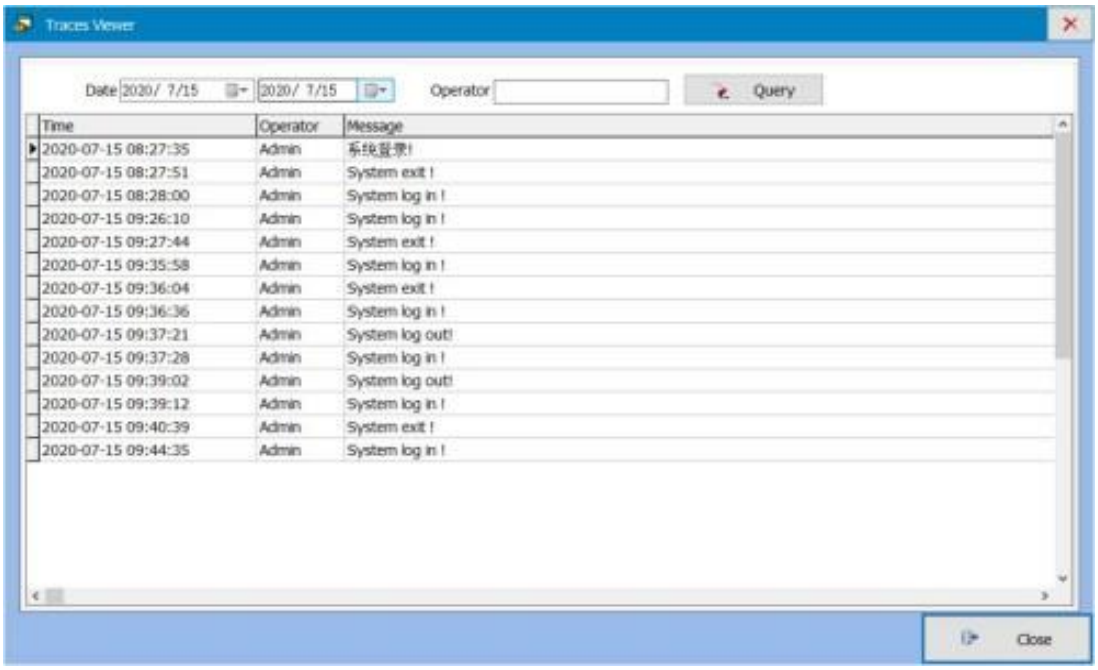


Figure-5

2. Single click "**Run Log**" to display the logs and running content in the operation process of the system**.**

Statistical analysis

Single-click "**System Settings**" and select "**Statistical Analysis**" to querystatistical information. See the following exam.

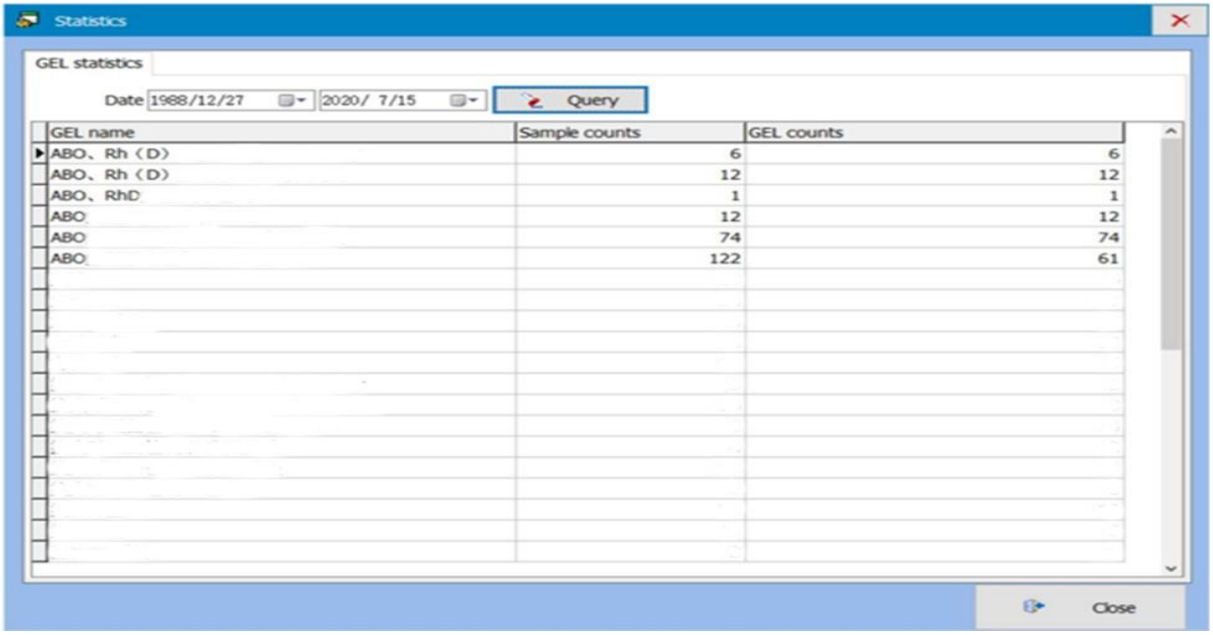


Figure-6

Dictionary Management

Single-click "**System Settings**" and select "**Dictionary Management**" to carryout the dictionary setting. See the following figure:

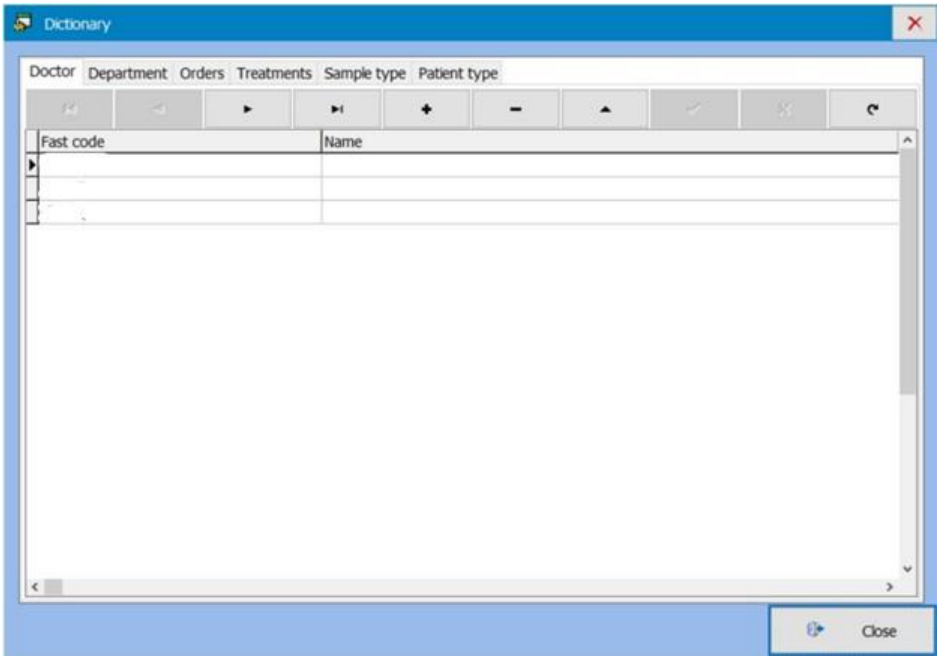


Figure-7

Debugging Tools

1. Single-click "**System Settings**" and select "**Component Controller**". See the following figure:

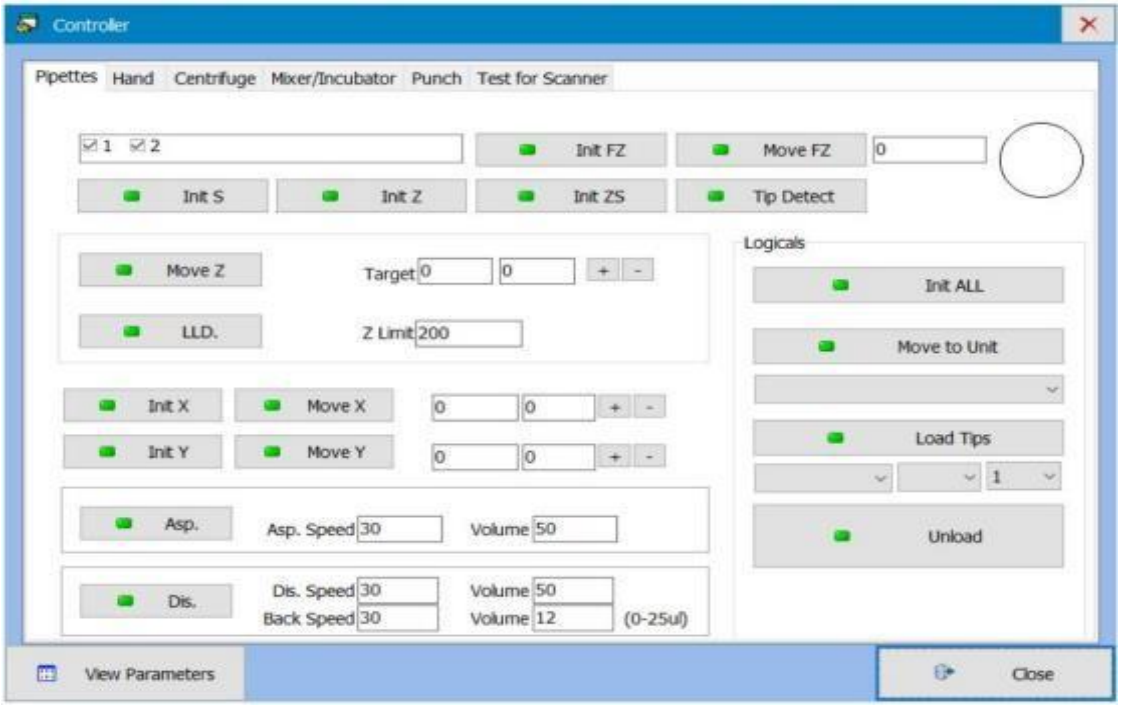


Figure-8

2. Parameters of the pipette, transfer arm, centrifuge, mixer/incubator, card warehouse/puncher, and barcode test can be adjusted within the component console.
3. The adjusted parameters will be set to the corresponding module of "**Component Coordinates**".

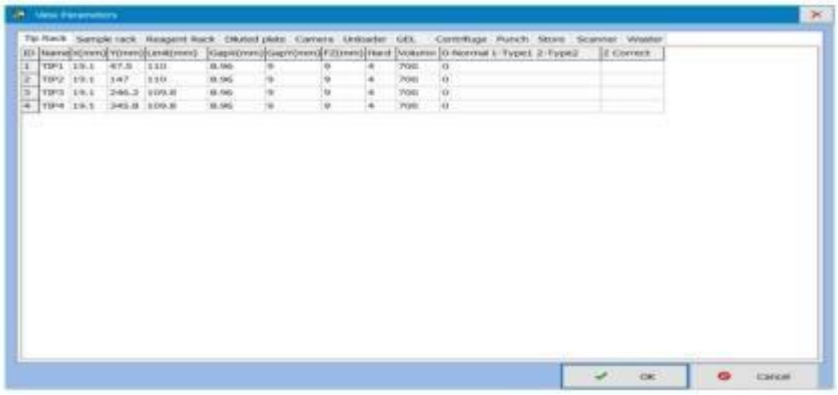


Figure-9

4. This debugging tool, as a specialized tool, is only for authorized users to use.

7.5.2 Software Applications

1) Instructions for Software Platform

1. The software interface is illustrated as

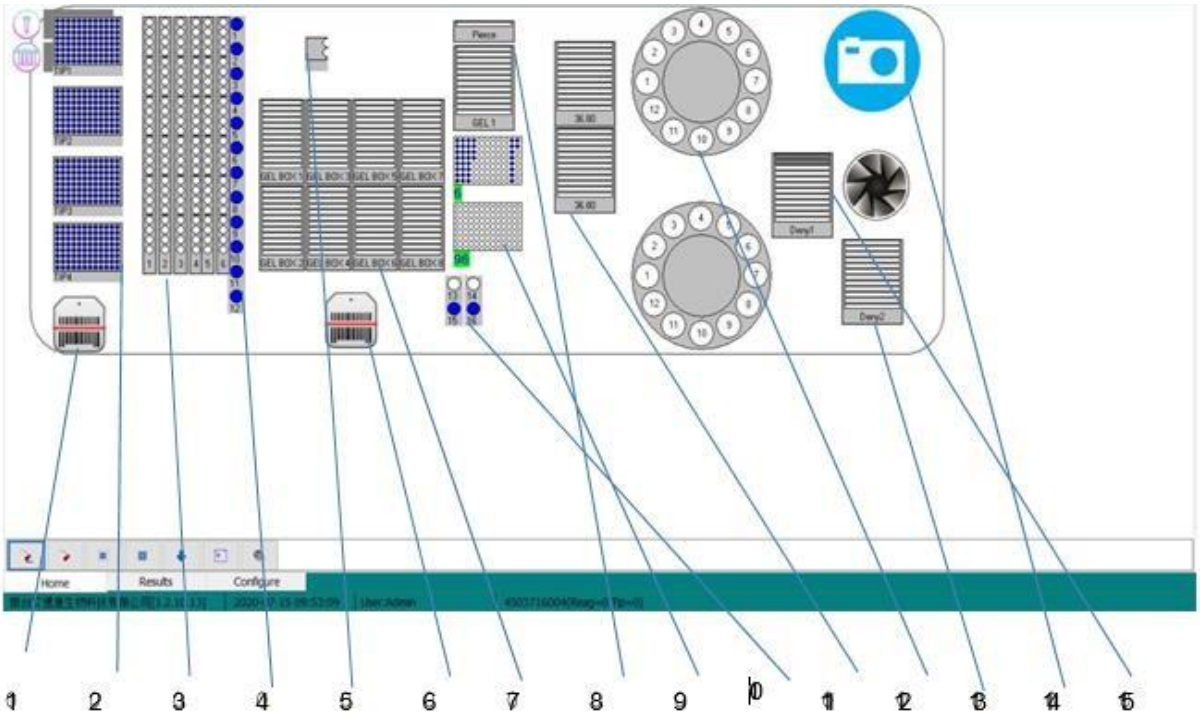


Figure-10

1. Sample /Reagent
2. Tip Rack
3. Sample Rack
4. Reagent Mixing Rack
5. Tip Ejector
6. Reagent Card
7. Reagent Card Warehouse
8. Sample Dispensing, Piercing Positions
9. Dilute Positions
10. Diluent Reagent Bin
11. Incubation Positions
12. Centrifuge
13. Waste Card Positions
14. Reader Module
15. TBD (Inc. Balancing Card)

2. The main interface displays the running conditions of system components and updates the working conditions of a data display devicein real-time, e.g. using/not using color change display, and centrifuge count down.
3. The buttons on the lower left corner are used to control the switch of the control system.

Figure-11

4. **From left to right**: turn on the fluorescent light, turn off the fluorescentlight, turn off the camera backlight, turn on the camera backlight, open the GEL card door, replace the deep-well plate, and turn off the sound alarm.
5. The buttons on the upper right corner are the system flow control buttons, which are used for duplex detection and non-duplex detection.

Figure-12

2) Test Operation Procedure

1. Startup

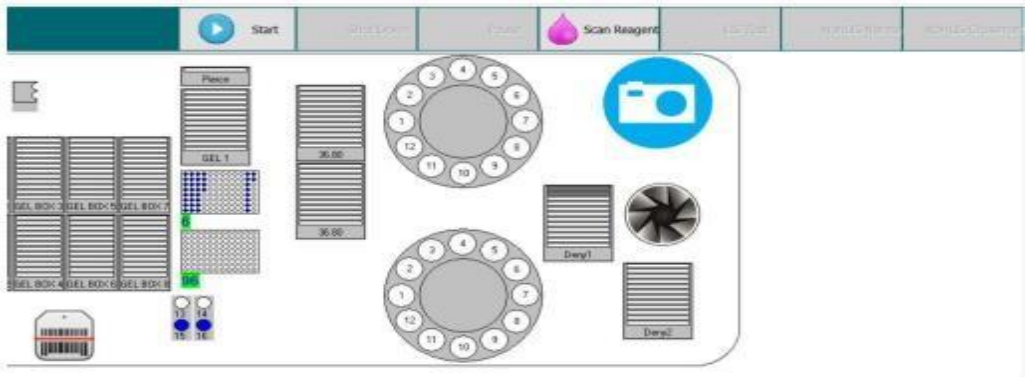


Figure-13

- Click the **'Start'** command in the home page options (starting is the self-checking process) before using this system.
- The equipment will always be in the standby state after starting up, in which regular or urgent tests can be performed at any time.
- Click the '**Start**' command in the main page options (starting is the self-checking process) before using this system.
- After starting up, the instrument will always be in the standby state, in which duplex communication or non-duplex tests can be performed at any time.
- After starting, the instrument will automatically grab the reagent cards, scan the barcode thereon, and then display the locations of the reagent cards on the software.

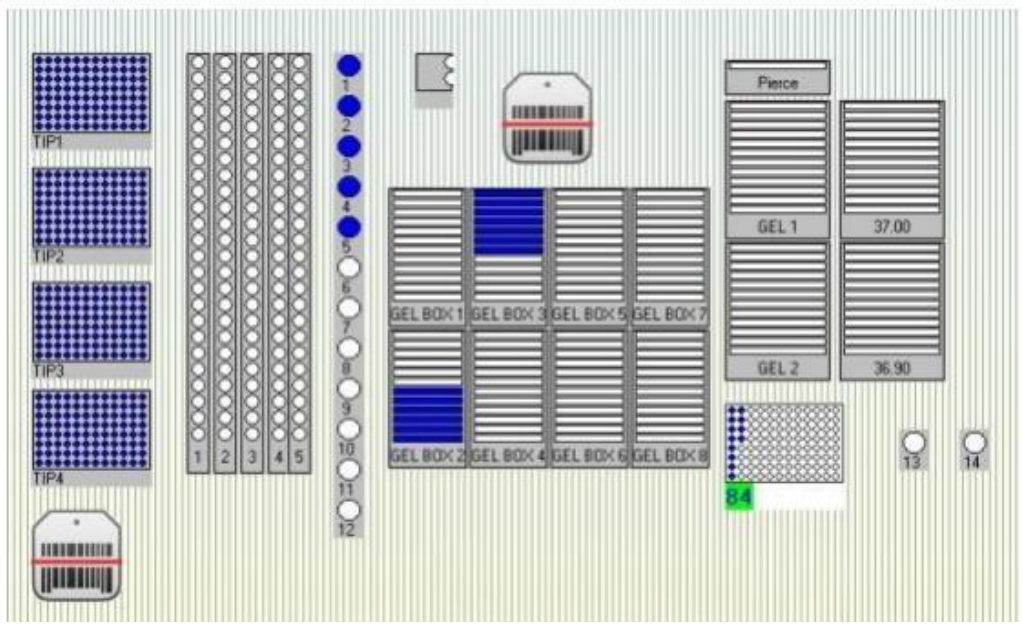


Figure-14

- The model is slightly different from other models in the automatic scanning of reagent card barcodes.
- After the model is started up, the device will automatically display the prompt window of reagent card scanning.
- The user enters the "**GEL Count**" box according to the number of reagentcards placed, clicks the "**Start Scanning**" button, and clicks the "**OK**"button after the code scanning is over.
- Pay attention that the barcode of the reagent card should be placed in the "**sample dispensing, puncher position"** facing the user.

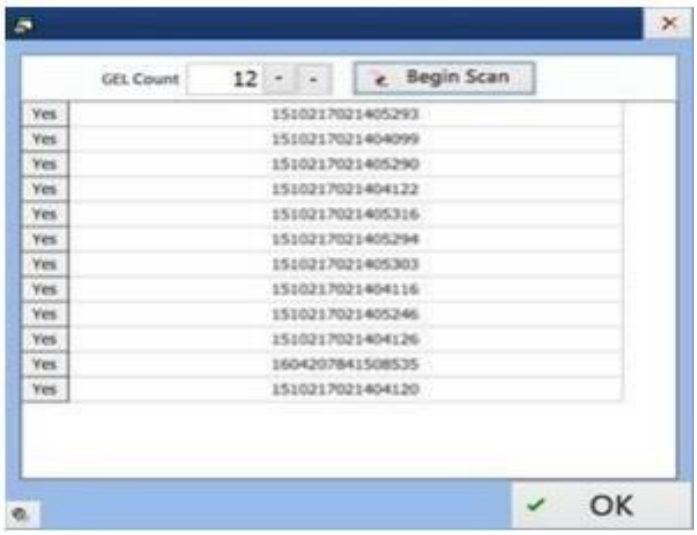


Figure-15

- After clicking OK, the equipment will display "The device is going to run, check and clear all the unused gel cards!", carefully check whether thereare misplaced reagent cards and whether the cards are in the correct positions.

Figure-16

- After the instrument is normally started, all the other buttons will be normally on and in clickable status except the "**Start**" button, see the following figure for details.

Figure-17

- Put the samples to be tested into the sample rack, the test tube barcode input dialog box will be displayed first, pull out the sample rack and put it back to the original position again, and then the device willautomatically scan the barcode of the samples to be tested and displays them on the software, see the following figure for details.

- At this time, either "**Normal Test**" or "**Emergency**" can be selected.
- For urgent samples to be tested, select "**Emergency**".
- The urgent samples will be given priority when the system generates a new batch.

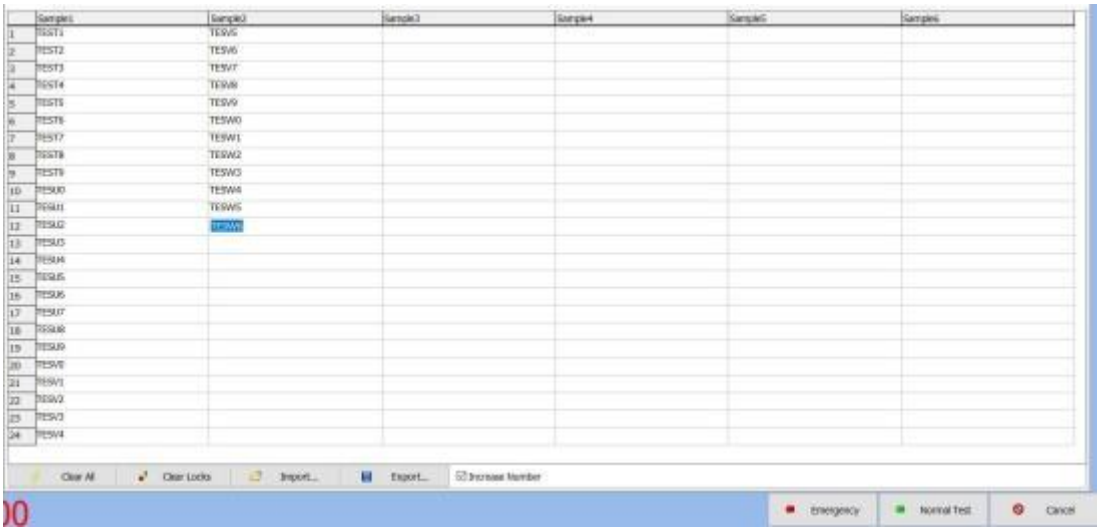


Figure-18

- After either "**Normal Test**" or "**Emergency**" is selected, the software automatically displays the edited "**blood grouping gel card**" method, and each sample can be tested by selecting one or more "**blood grouping gel card**" methods to be tested.
- Click OK upon determining the "**blood grouping gel card**" method, and then the device will automatically run the test.

1	1	1		Y	Y	
1	2	2		Y	Y	
1	3	3		Y	Y	
1	4	4		Y	Y	
1	5	5		Y	Y	
1	6	6		Y	Y	
1	7	7		Y	Y	
1	8	8		Y	Y	
1	9	9		Y	Y	
1	10	10		Y	Y	
1	11	11		Y	Y	
1	12	12		Y	Y	

Figure-19

Cross-matching of blood is a special option, and a matching setup table will be displayed upon confirming.

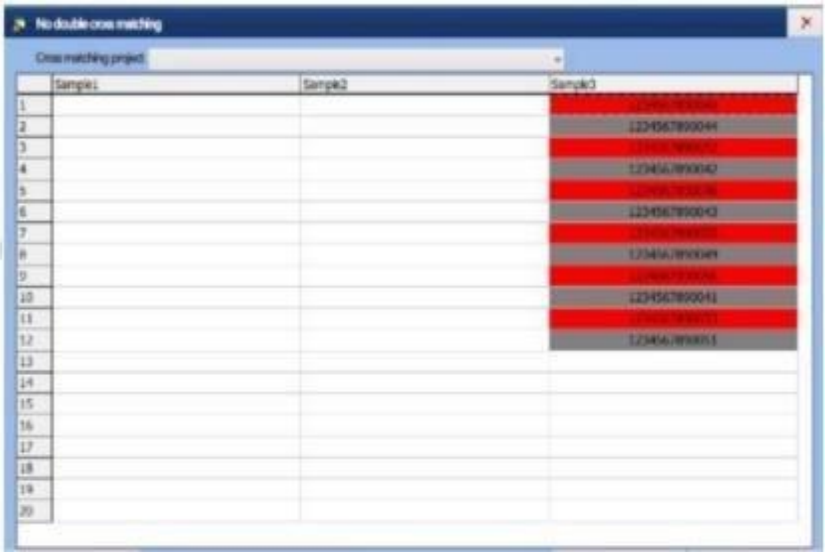


Figure-20

- For cross-matching items, the correspondence of blood matching shouldalso be specified.
- The red in the software represents patients' samples, and the grayrepresents the blood donors' samples.
- In this system, the patients' and blood donors' samples are uniformlyplaced on the test tube stand.
- The identity of the red and the gray can be switched by clicking thesample numbers with the mouse.
- For blood matching between the red and the following gray samples, it can realize one-to-one, one-to-multiple, multiple-to-one, and multiple-to-multiple.

Shut down

The system can be shut down by clicking the "**Shut down**" button after all tests have been finished.

Pause

It can click the "**Pause**" button during the running process, where upon the system will display the dialogue box of pause and suspend the actions of the pipette and the transfer arm.

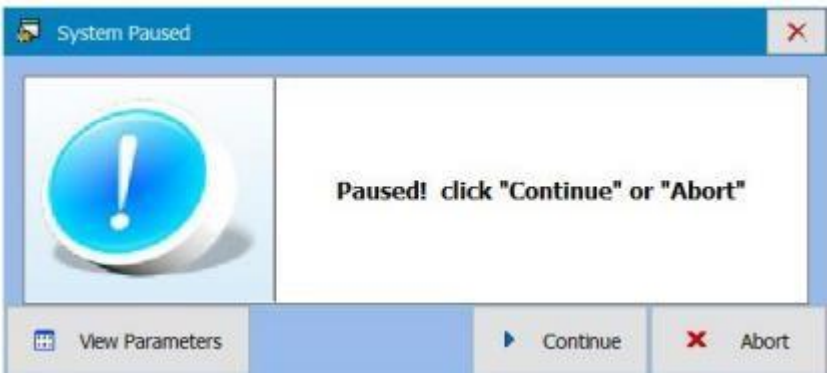


Figure-21

3) Result Analysis and Disposal

1. Single-click the "**Results**" option, as shown in the following figure:

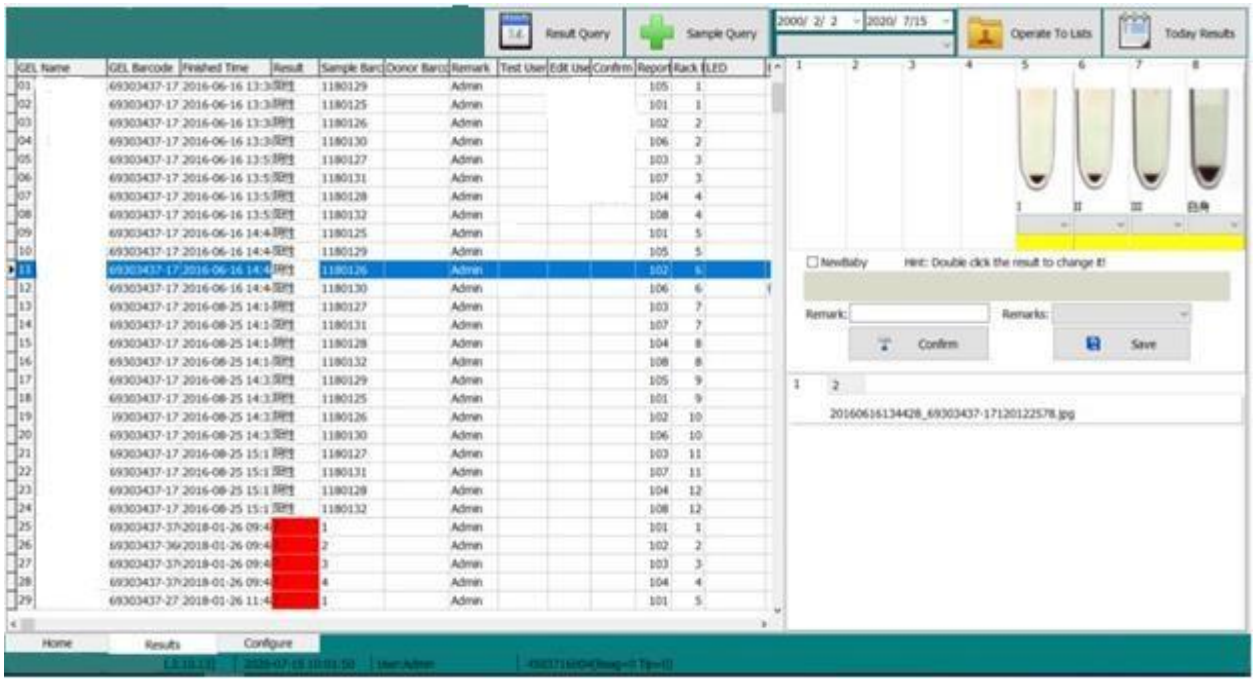


Figure-22

- The test result interface can display and query test results, andit can also edit and review the results.
- **Historical result query**: The results can be queriedaccording to period or test item.
- **Specific sample query**: The results can be directly queriedaccording to the sample number.
- **Today's results**: all test results of today can be displayed.
- **Result list management**: perform operations to the queried results such as 'Display Statistics', 'Print Test Records', 'Export Excel File', 'Batch Review', etc.
- **Display Statistics**: display the classified data of the querylist based on item/result.
- **Print Test Records:** Print the queried test results to lists.
- **Export Excel File:** Export the query list into an Excel file.
- **Batch review:** review the test results that have not been reviewed in batch**.**
- User ID and password must be entered for reviewing theresults, and the results can be reviewed only by users.

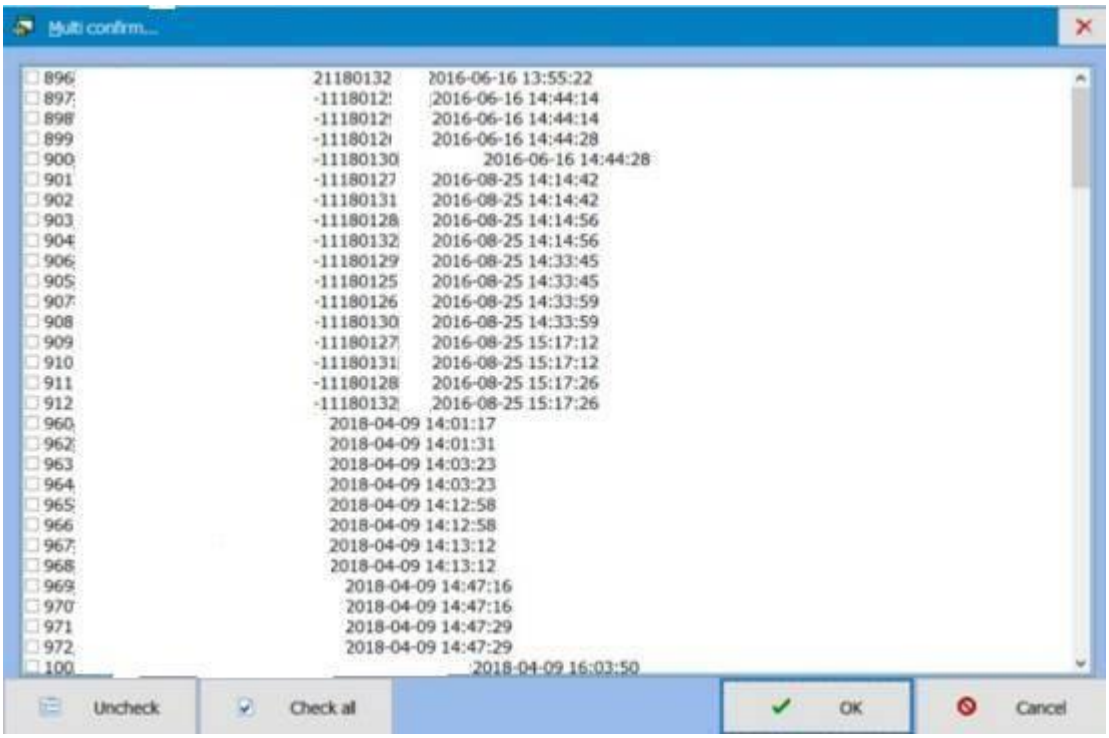


Figure-23

2. **Modify result**: the original photos can be viewed through the "Tab ofbrowsing original photos". The unknown (displayed as?) reagent cards can be manually determined by browsing the original photos.

3. **Method**: Double-click the GEL results with? in the gel column displayarea to switch the strength option, and then the software will determine the overall result. When the software calculates the result,the overall result is not directly determined for the strength below 2+. Reconfirm the current displayed result again. When saving the editing results, the username and the password must be entered, andit is accessible only to the users with authority can access.

4) Data Output

Report management

1. Single-click "**System Settings**", and select "**Report Management**", as shown in the following figure.

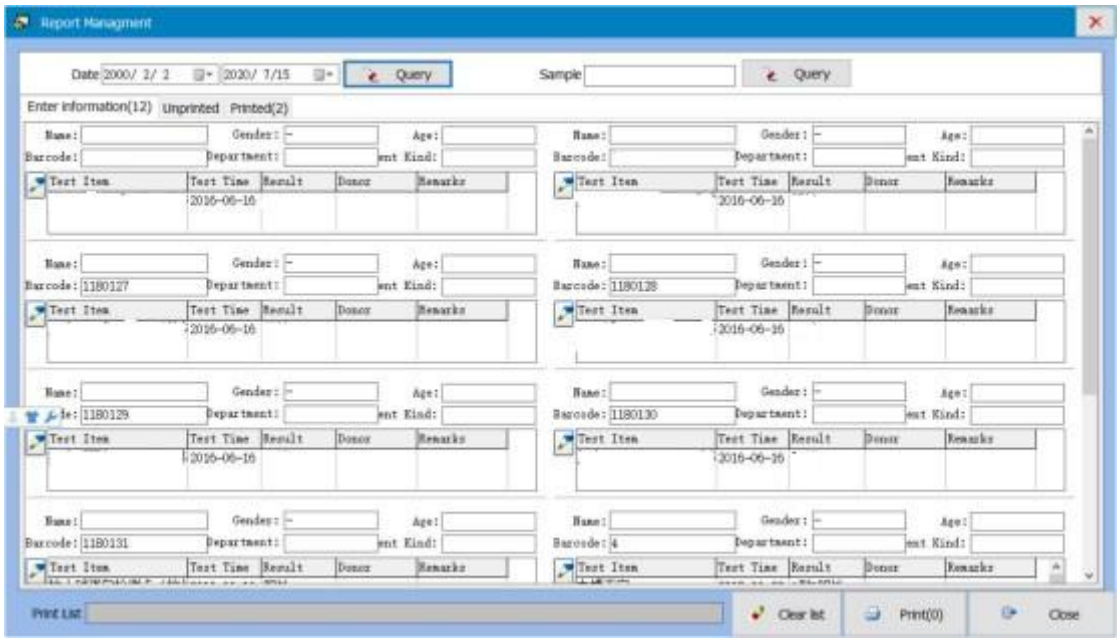


Figure-24

2. Data should be completed in case of shortage.
3. Click the 'Revise' icon andenter the patient's data.
4. The input window is as below:

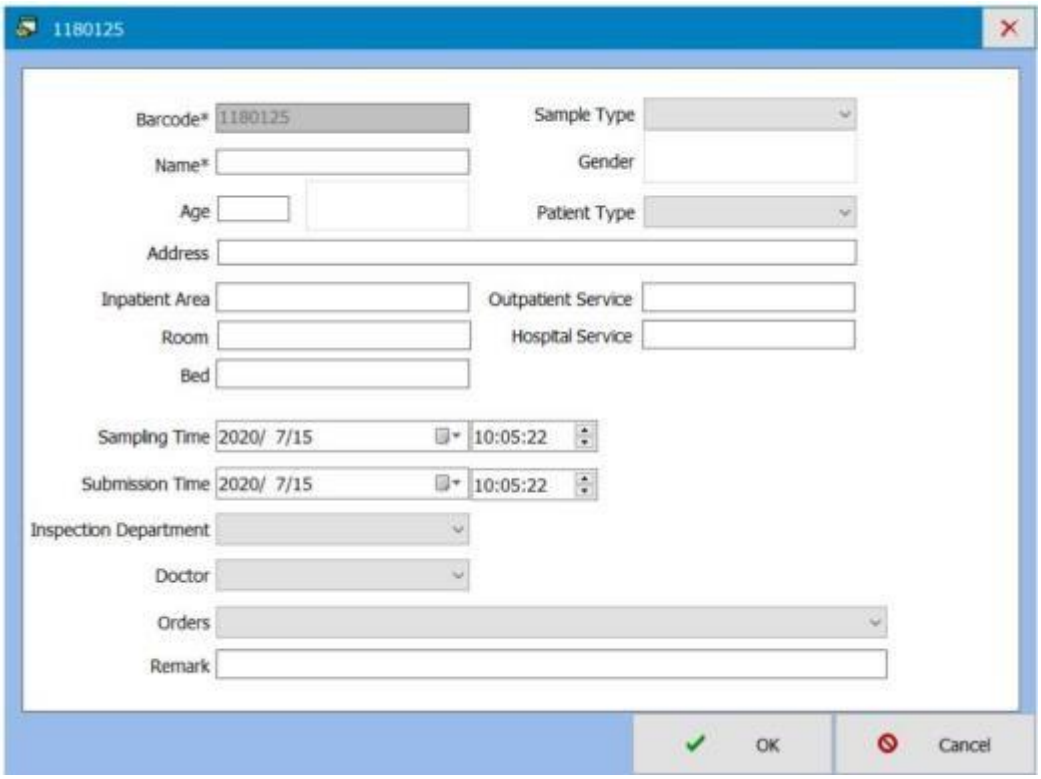
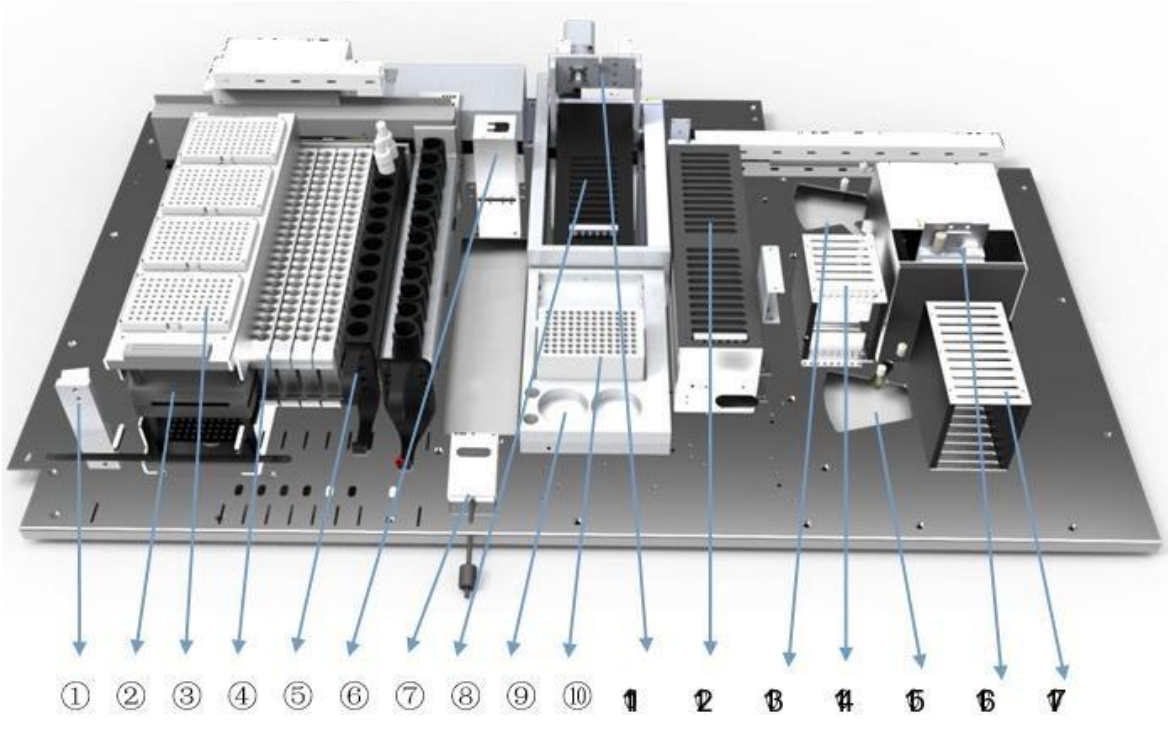


Figure-25

5. To print the review results, click the "**Print**" icon to enter the printqueue.

8. Operations

8.1 Sketch of Worktop Layout



1. Class 2 Laser Scanner
2. Tip Box Rack
3. Tip Box
4. Sample Rack
5. Reagent Rack
6. Tip Ejector
7. LED Scanner
8. Sample Dispensing Position
9. Diluent Positions
10. Deep-Well Plate
11. Puncher
12. Incubation
13. Centrifuge 1
14. TBD 1
15. Centrifuge 2
16. Camera
17. TBD 2

Replacement of consumables: add tips to the position of ③ tip box one by one

8.2 Operating Principle

The operating principle of the fully Automated Blood Grouping System is as below scan and transfer reagent card → Punching → Sample processing and dispensing → Cell reagent dispensing (N/A for cross-match) → Incubation → Centrifugation → Reading → Card recycle.

- The reagent cards are scanned by the barcode scanner; the reagent card transfer and recycle is finished by the transfer arm; the punching is finished by the puncher; sample disposal and dispensing and cell reagent dispensing is finished by the pipettes; incubation is finished by the incubator; centrifugation is finished by the centrifuge and reading is finished by the reader module.
- The control software generates corresponding reports by analyzing and disposingof the images.
- The entire process is automatically finished by the instrument without requiring manual operation.

8.3 Simple Flow Operation Card

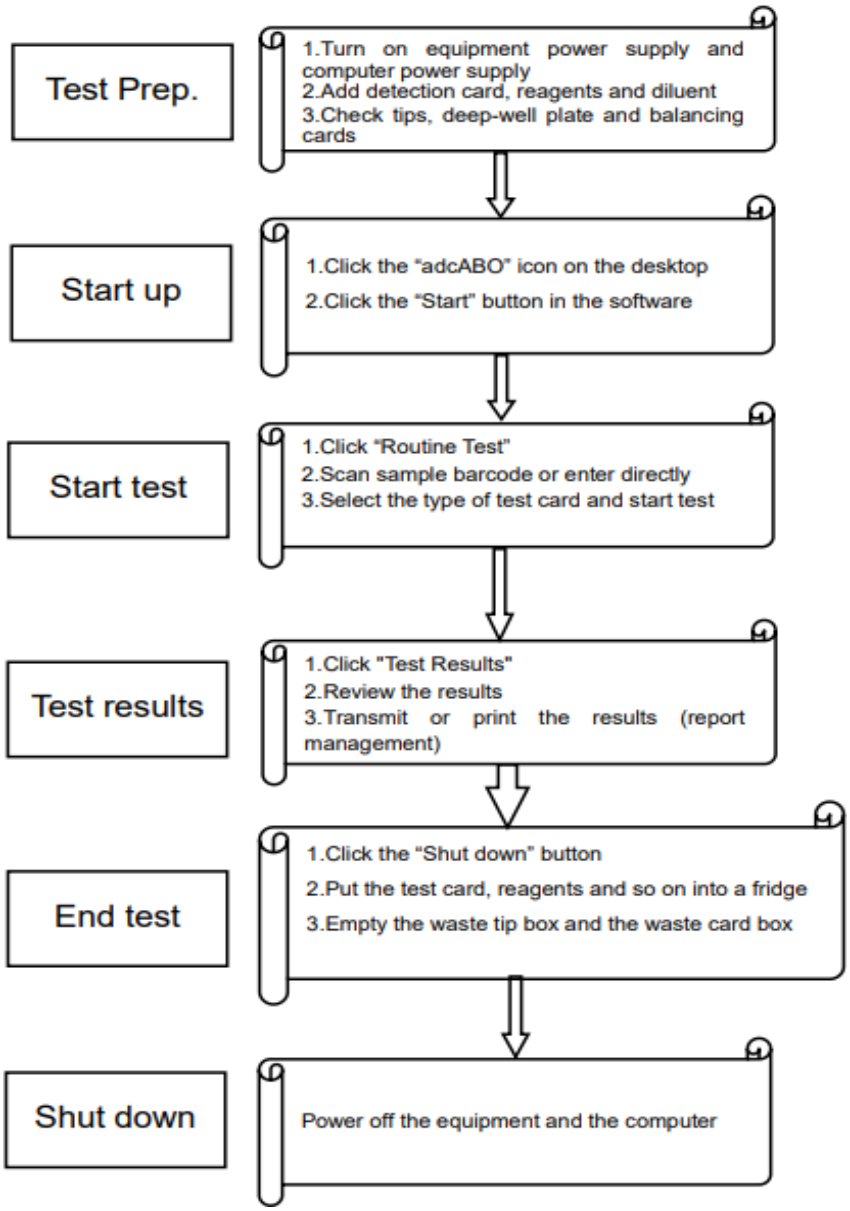


Figure-27

8.4 Operation of centrifuge

- Loading and unloading of the centrifuge cannot be operated manually but should be set in software and get it carried out by the transfer arm.
- The cardloading of the transfer arm is calculated by the algorithm. If the load tray is unbalanced, the centrifuge will not work normally.
- The rotors of the centrifuge cannot be replaced by the user.
- In the centrifuging process, the user should keep the front panel and other doors of the machine shut and locked.
- There is no restriction on the distancefrom the machine.
- The user should not lean on the machine when it is running.
- When the machine is running, there should be no substances irrelevant to thetest on the worktop of the instrument.
- When the machine is running, the user should neither open the machine door nor perform any operation on the worktop.
- For opening the centrifuge cover, must be operated in the software after thecentrifuge stops moving.
- There is no sealing ring or bio-protective shell on this machine.

8.5 Laser Barcode Scanner

- The equipment is equipped with a laser barcode scanner for identifying the barcodes on the sample rack and the reagent rack.
- This device is a class 2 laser product. DO NOT look directly into the beam when using it.
- Barcode scanner parameters: visible red semi-conductor laser, emissionwavelength 660nm, output power 85μW, pulse duration 112μs. 660nm visible radiation.
- Instantaneous irradiation is safe, but it may be harmful to stare at the beam intentionally.
- The laser beam produced by a class 2 laser product can causedazzling, flash blindness, and after-view images, especially in low-light environments.
- The user should not stare at the laser beam according to the instructions of the marking, i.e. finish initiative protective response by turning head or closing eyes and avoid continuous intentional looking into the beam.
- As a precision instrument, this laser barcode scanner may be damaged if it isimpacted or dropped onto the ground. It should be handled and installed with special care.
- When installing this equipment, the installation angle and distance need to be adjusted.
- **Installation angle:** Apply the laser beam along an angle ofapproximately 15°.
- It can stably read when the installation distance is120mm.
- The device has been pre-assembled on the rail fixed on the worktop of the machine at the factory so that no additional installation is required.

- The laser radiation emitted by this laser barcode scanner belongs to class 2laser, for adjustment, the engineer.
- In case of damage, the user should not repair it by himself.
- The maintenance staff should perform maintenance operations wearing goggles**.**
- **Caution:** Hazardous radiant exposure may be caused if the user doesn't use the control or adjustment devices or perform each step manually.
- The performance index of the laser barcode scanner should be marked onboth the barcode scanner and the front panel of the machine.
- The laser barcode scanner is provided with the following safety measures.
- **Laser radiation warning:** The "**LASER ON**" LED light will be on during the period of lasing and the status can be viewed through goggles.
- **Laser forced off command:** The laser emission can be prevented by sending the laser forced-off command to the barcode scanner.
- When working near the laser transmitter, make sure to use the laser forced-off command to prevent seeing the laser beam.
- When this command is selected, the **STABILITY LED** at the bottom will blink.

9. Maintenance

- The manual adequately elaborates on the preventive maintenance and inspectionthat the responsible person should take for safety purposes, the centrifuge rotorsare heavily used.
- The rise in temperature due to long-term high-speed rotation may easily cause the aging of components and shorten their service life, which possibly leads to damage to equipment and danger.
- Based on the fatigue test, the service life is determined ≥1 year, and itsuggests that the rotors are to be replaced after use for 1 year (original parts should be used, otherwise it will cause danger due to uncertain reasons).
- The recommended service life of the injection pump piston is not more than 2 years.
- Overuse will affect the accuracy of liquid aspiration and dispensing, and may cause miss dispensing, then seriously affect the test results.
- It is recommended the user local after-sales engineers for replacement after the service life ends.
- As this equipment is a professional instrument, improper maintenance is likely tocause equipment damage and uncertain failures, thus the operation instructions should be strictly followed, and the equipment should be maintained by professional engineers.
- The power source of the model is provided with an F6.3AL250V fuse, so replacement should be carried out in the power-off state.
- When replacing it, use a slot-type screwdriver to pry out the fuse slot, then remove the original fuse and replace it with a new one, finally push the slot back to its original position and get it installed up to standard before powering on.

9.1 Servicing

- This product is precision moving equipment.
- Running for a long time will causeincreased friction that results in an inaccurate moving position.
- To ensure the normal running of the equipment, the user should regularly lubricate the guide rails, bearings, and lead screws involved in this equipment.
- The recommended servicing period is once per month.
- The reagent mixing rack is a contact-type electrical module.
- The contacts should be cleaned every week to keep a favorable contact effect and to ensure a normal test process.
- Due to the pipette channel meeting samples, it suggests cleaning and sterilizing the needle adapter to ensure favorable air-tightness of the needle adapter.

9.2 Cleaning and Sterilization

The user of the blood grouping system should clean and sterilize the instrument regularly**.**

1) Cleaning:

- Be careful not to splash liquid onto the external surface, the worktop, and the inside of the instrument.
- The instrument can be wiped with soft, clean wet gauze or tissue.
- The acrylic housing and the worktop can be further wiped with 95% alcohol or special detergent for the instrument.

- Mechanical dead corners such as metal plate slits can be dusted with a soft brush.
- The areas of the pipette channels for matching the tips should be cleaned with 95% alcohol every day to ensure its favorable air-tightness.

2) Sterilization:

The following areas should be sterilized regularly as there are potential bio- hazards: The sample area, the reagent area, the tip ejectors, the waste card positions, the pipette, the transfer arm, the incubation positions, the centrifuge, the piercer, and the waste bin.

Ways of sterilization: key positions and dead corners should be treated with 75%medical alcohol. Remove the components with higher bio-hazards such as tip ejector and waste bin to soak in special disinfectant at a fixed time for sterilization.

9.3 Maintenance of centrifuge

- The centrifuge has been fixed on the worktop in the factory, and the user doesnot need to fix or install the centrifuge anymore.
- The centrifuge of this equipment is for blood grouping gel card, and the interiorneeds not to be cleaned. For routine maintenance, it only needs to wipe the centrifuge cover plate with 75% alcohol in the power-off state.
- Visually inspect whether the shell of the centrifuge is intact without protrusion, crack, or other abnormal conditions.
- Visually inspect whether the rotary assembly of the centrifuge is intact without breakage, imbalance due to curling up or other abnormal conditions.
- Inspect continuity of protective connection (N/a).
- There is no sealing part or other bio-protective shell.

9.4 Hazardous substances

- Centrifuge is prohibited from separating toxic, radioactive, or hazardousmicrobial-contaminated substances.
- Flammable and explosive materials are prohibited to use in the centrifuge.
- Chemical reactions are not allowed to prevent the production of large amounts of hazardous gaseous materials.

9.5 Cleaning and sterilization

- If this equipment is used following the manufacturer's instructions, it will not produce hazardous substances or get them spilled.
- If hazardous substances are sprinkled or find their way into the machine, disposed of according to the rules on disposal of hazardous substances.
- Sterilize with 75% medical alcohol. Before employing a cleaning and sterilization method that is not recommended by the manufacturer, the user needs to consult a professional to guarantee such a method will not impair theinstrument**.**

9.6 Chemical effect and environmental influence

- There is no impact on the environment, and the machine should not contactwith corrosive chemicals.
- The protective cover and other safety parts and structures are subject to inspection and replacement by engineers regularly.

10. Troubleshooting

Trouble phenomena	Cause analysis	Solutions
Motor Z continuously runs when pipettechannel Z reaches to the top after the equipment is energized.	The problem of proximity switch Zto the unit board	• Measure the output terminal of the proximity switch with amultimeter and determine whether the proximity switch is good or not by whether there is a change of voltage when a magnet draws near or moves away. • Measure if there is an open circuit on the lines between the proximity switch and the unit board.
The pump motor continuously runswithout stopping after the equipment isenergized.	The problem of proximity switch “s” to unit board	• Check if the proximity switch is damaged because the jack screw is too tight. • Measure the output terminal of the proximity switch with a multimeter and determine whether the proximity switch is good or not by whether there is a change of voltage when a magnet draws near or moves away. • The proximity switch lines including yellow FFC, etc.
A certain motor doesn’t move. When the software operates the motor to move to a specific position, the motor doesn’t respond, and the software doesn’t report errors.	It indicates there is no problem in communication between the main control board and the computer and that the software doesn’t report errors.	• First measure if the motor is damaged to preliminary determine whether A can be measuredWhether +A-, B+B- are close circuits. • Check whether the circuit from the main control board to the driver is open. • Check the 24V power supply of the driver is normal. • Test by replacing the driver and the mainboard is damaged, replace it and test again.
When the software is initialized, the part always moves forward once and stops.	The main control board alwaysreceives command from zero switch.	Replace the zero switch and test.
There is vibration and abnormal noise when a certain motor run	There aremechanical obstacles orlacunary	• Check whether there are mechanical obstacles in the tracks when such a component runs. • After clearing the mechanical obstacles, measure the motor circuit A Whether any of +A-, B+B- is an open circuit.

A certain pipette channel frequently detects in advance	Pressure detection error	• Check whether the steel needle is clogged. • If so, get it unclogged. • Check whether the pressure value is reasonably set. • If the pressure sensor is broken, if so, replace a new one. • The yellow FFC reaches the end of the service life, if so, replace a new one.
A certain pipette channel reaches the bottom at the time of detecting	Pressure detection error	• Check whether there is air leakage. • Check whether the current barometric pressure has changedand whether the value is normal. • Check whether the detection pressure value is reasonably set. • The yellow FFC reaches the end of the service life, if so, replace a new one. • If the pressure sensor is broken, if so, replace a new one.
A certain motor runs only in one direction nomatter software operates to increase or decrease.	The motordirection signals abnormal.	• Whether the DIR line between the main control board and the driver is an open circuit. • The driver or the mainboard is damaged
When loading tips, a certain channel rises before reaching to appointed position, which results in the tips not being loaded normally.	The encoder is abnormal, andstep-missing isdetected.	• First check whether there are mechanical obstacles in the Z direction. • Whether the jackscrew or the belt is loosened. • The encoder is out of order, replace a new one.
The tips have been well loaded, but it still alarms mounting fail.	Tip pick-updetection error.	• Check whether the tip pick-up detection piece is separated from the casing. • The photoelectric switch for pick- up detection is damaged. • Measure the output end with a multimeter. • Any circuit of the photoelectric switch is open, such as yellow FFT.
Communication failure	CAN card and bus	• Check if the driver is normal. • Inspect whether there is an open circuit. • CAN card failure.

Alarm Messages and Disposal

Alarm message	Message explanation	Alarm disposal
	The blood grouping system has a tip missing inspection function for inspecting TIPs loading status.	"Yes", confirm there are tips on the current positions and reload the tips. "No", skip the tip-loading step and enter the next step. If the next step is detecting aspiration, it will report "The tips are dropped, manually mount and click OK", and then the tips should be manually loaded and click "Yes".
	Inadequate liquid	"Retry", the user must replenish the liquid and ensure aspiration and dispensing. "Ignore", executechannel empty aspiration. The testcan still go on, but no liquid will bedistributed. "Abort", the software terminates the test.
	Communication failure	Check whether the driver has been installed. Click "Yes" after rechecking the connection. If there is still trouble, consult local sales engineers.
Probe loading fails, retry ornot? Error Message: sample dispensing -XY; 00000100 Send command pipette X initialization 01CAN Received: 88=True; AA0 1 02.	Pipette X failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Tip loading fails, retry or not Error Message:sample dispensing-XY; 00000100 send command: pipette Y initialization 02 CAN Received: 88=TrueAA20	Pipette Y failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Tip loading fails, retry or no Error Message: channel(S/N); 00000A (7,89)00 Send Command: Z initialization 01CAN Received: 881	Sample channel Z failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Error Message: channel (S/N);00000A00 Send Command: Sinitialization02 CAN Received: 88=TrueAA26	Sample channel failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Tip loading fails, retry ornot Error Message: sample dispensing-FZ; 00000F00 send Command: pipette FZinitialization 03 CAN Received: 88= True, AA36	Dispensing probe (FZ)failure	Click "Retry" If there is still trouble, consult a local sales engineer.

GEL card gripping fail, retryor not Error Message:Mechanical XYZ; 00000200 Sent Command: transfer arm X initialization 01 CAN Received: 88=True, AA21	Transfer arm X failure	Click "Retry" If there is still trouble, consult a local sales engineer.
GEL card gripping fail, retryor not Error Message.		Click "Retry"
Mechanical XYZ;00000200 Send Command: transferarm Y initialization 02CAN Received: 88=True; AA 22	Transfer arm Y failure	If there is still trouble, consult a local sales engineer.
GEL card gripping fail, retry or not Error Message: transfer arm XYZ; 00000200 Send Command: transfer arm Z initialization 03 CAN Received: 88=True, AA 32	Transfer arm Z failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Error Message:Centrifuge; 00000 400 Send Command: transfer arm1(2)initialization03(04)CAN Received: 88= True; AA 03(04) 02	Centrifuge failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Error Message: Centrifuge; 0000 0400 Send Command:70(71) 01 (02) CAN Received: 88=True; AA 70(71) 01	Centrifuge door failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Error Message: puncher; 00000500 Send Command:puncher Y initialization;01 CAN Received: 88=True AA0102	Puncher Y failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Error Message: puncher; 00000500 Send command:puncher Z initialization;02 CAN Received: 88=True, AA0202	Puncher Z failure	Click "Retry" If there is still trouble, consult a local sales engineer.
GEL card gripping fail, retry or not Error Message: puncher; 00000500 Send Command: card warehouse initialization; 03 CAN Received: 88=True； AA 0302	Card warehouse X failure	Click "Retry" If there is still trouble, consult a local sales engineer.
Error Message: barcode reading; 00001000 Send Command: barcode	Barcode scanner moving fail	Click "Retry"
Open;80 CAN Received: 88=True; AA 80		If there is still trouble,consult a local sales engineer.
Error Message: mixer;00000600 Send Command: mixer initialization 01 CAN Received: 88=True; AA 01,02	Mixer failure	Click "Retry" If there is still trouble, consult a local sales engineer.

Error Message: The centrifuge detects a signal of eccentricity and disposes of it manually.	Centrifuge imbalance	Click “Retry” after thecentrifuge is inspected. If there is still trouble, consult a local sales engineer.
Error Message: the panel is opened, and the system enters the pause state, close the panel.	The user opens the panel, and the device running is suspended. Interlock for protecting the user’s safety.	Close the user panel.
The error light of the laserbarcode is on.	There are barcode reading errors.	Consult a local sales engineer.

11. Accessories

Standard Accessories

Name of the accessory	Specification	Quantity
Disposable tips	300 µL	4608 pieces per carton
Disposable tips	800 µL	15000 pieces per carton

Optional Accessories

Sr. No.	Name of the accessory
1	Reagent tank (15 mL)
2	Tip rack
3	Reagent tank (60 mL)
4	Reagent tank (30 mL)
5	Reagent tank (100 mL)
6	Tube rack
7	Reagent rack
8	Reagent tank cover
9	Deep well plate