CE

Coagulation Analyzer
Instruction for Use
（Type：MC100）

Zhejiang PushKang Biotechnology Co.,Ltd.

Content

Preface

1. Description

Thank you for purchasing the MC100 coagulation analyzer! Read all product manuals and consult with Pushkang trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the recommendation from the manufacturer. For more information, contact Pushkang.

2. Basic Information

- Product name: Coagulation analyzer
- Specifications and models：MC100
- Size：270mm×180mm×155mm
- Weight：3kg
- Range of application: The MC100 coagulation analyzer adopts the coagulation method for clinical determination of prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB) indicators; adopts immunoturbidimetric method for clinical determination Determine D-Dimer (D-Dimer) index. This instrument is suitable for laboratories with professional testing capabilities in medical institutions, such as central laboratories, outpatient and emergency laboratories, clinical departments, physical examination centers. For in vitro diagnostic use only.
- Contraindication: none

3. Index of Symbols

The following symbols are used on the coagulation analyzer, related components and accessories, labels or in the text of this user manual:

	Warning; Electricity
	Warning; Biological hazard
	Warning; Caution!
IVD	In vitro diagnostic medical device
SN	Serial number

	Date of manufacture
	Consult instructions for use
	Manufacturer
	Authorized representative in the European Community
	This way up
	Fragile, handle with care
	Keep away from rain
	Stacking limit by number

4. Warnings and Precautions

Pay attention to and observe all warning labels attached to this instrument, do not cover or remove labels. If the label falls off or is blurred, please inform the after-sales service agency or agent of Pushkang to replace it.

【Waste Management】

- All used reagent disks should be treated as infectious waste.
- Some wastes may need special treatment before they are discarded. For waste treatment methods, please follow the relevant guidelines for medical waste, infectious waste and industrial waste implemented by the competent authorities of the country and region.
- Instruments may require special treatment before they are scrapped. For waste treatment methods, please follow the relevant guidelines for medical waste, infectious waste and industrial waste implemented by the competent authorities of the country and region.

Note: MC100 instruments should be regarded as industrial waste after being discarded, it should be specially managed as infectious waste in accordance with the waste treatment and public

cleaning law. Before the instrument is discarded, it must be handled properly according to the relevant laws of the country and region where it is located.

【Prevent Fire and Damage】

- Install the instrument correctly according to the installation environment and conditions described in this manual.
- This instrument shall be installed by authorized personnel of Pushkang.
- If you need to change the installation of this instrument, please contact the after-sales service agency or agent.
- Do not use any flammable or flammable gas near the instrument to avoid explosion.
- Do not trample, twist, pull wire and cable, avoid to cause fire.
- If the equipment is not used according to the method specified by the manufacturer, the protection provided by the equipment may be destroyed.

【Prevent Infection】

- Please wear appropriate protective equipment when handling samples, performing maintenance operations, and handling waste.
- All patient samples should be treated as a potential source of infection. Please wear protective gear and follow general precautions in local or national regulations.
- If the user's skin touched the patient's sample, rinse the contact area with water. If necessary, go to the hospital in time.
- Wipe away any contaminants sprinkled on the instrument in time
- If you accidentally swallow any reagent or sample, please go to the hospital immediately.
- If hazardous substances (pollutants such as reagents or samples) leak on the surface or enter the inside of the equipment, should take appropriate disinfection measures.
- It is not allowed to use cleaning agents or disinfectants, such as alcohol, gasoline and other flammable organic solvents, which cause danger due to chemical reaction with equipment parts or materials contained in the equipment.
- If you have any questions about the compatibility of disinfectant or cleaning solvent with equipment parts or materials contained in the equipment, please contact our after-sales service agency or agent.

【Prevention of Personal Injury and Serious Injury】

- You can't start operating instruments until the cabin covers are closed
- Do not put your fingers or hands inside any opening.
- Do not touch any moving parts while the instrument is running.
- Do not look directly at the lens of the scanner. Looking directly at the scanner can cause eye injury.

【Instrument Operation Instructions】

- Install and operate instruments according to instructions, the instrument model applicable to this manual is: MC100.
- The operator of the instrument shall be the professional trained inspection personnel of medical and health institutions, and the relevant personnel shall be professionally trained to operate the instrument.
- Do not place the instrument in a position that is difficult for personnel to operate.
- When handling the instrument, it should be gently picked up by both sides and released after being placed in the predetermined position.
- The instrument should be installed on a stable operating table and close to a power socket with good ground connection.
- Dust may accumulate on the surface of the instrument after long-term storage. Wipe the surface gently with a clean soft cloth, and use a small amount of cleaning solvent if necessary. Cut off the power before cleaning the instrument. Cover the instrument when it is not in operation.
- This instrument is a closed type, please use it together with the matching detection reagent produced by Pushkang.
- Refer to the relevant instructions for the use and storage of reagents, quality control products and calibration products. In order to ensure the stability and reliability of the results, please use the reagents, quality control products and calibration products within the expiry date.
- Please follow the procedure described in this manual to operate the instrument, improper operation may produce incorrect results or lead to instrument failure.
- The instrument should be regularly maintained in strict accordance with the provisions of this manual, otherwise it may lead to instrument failure or affect the accuracy and precision of instrument testing.
- Users are not allowed to disassemble or replace any parts of the instrument by yourselves. If you need to replace or repair, please contact our after-sales service agency or agent for operation by the after-sales service engineer.
- If the result of retest is still out of control, please contact our after-sales service agency or agent immediately.

【Electromagnetic Compatibility and Noise】

- Don't place the instrument beside the equipment that produces great electrical noise.
- Electromagnetic waves will be generated during the use of the instrument. Please keep away from the instrument sensitive to electromagnetic waves.
- The instrument meets the emission and immunity requirements specified in this part of EN61326-1：2013 and EN 61326-2-6：2013, as shown in the table below.
- The users have the responsibility to ensure the EMC environment of the equipment, so that the equipment can work normally.
- It is recommended to evaluate the electromagnetic environment before using the equipment.
- The instrument is designed and tested according to group 1, class A equipment in CISPR 11：2016. In the home environment, this equipment may cause radio interference, so it is necessary

to take protective measures.

- It is forbidden to use the equipment near strong radiation sources (such as unshielded RF sources), otherwise it may interfere with the normal operation of the equipment.

The instrument electromagnetic compatibility disturbance test shall meet the following requirements:

Table 4 EMC emission test requirements

Electromagnetic emission		
Normative Reference	Test Item	Compliance
CISPR 11：2016	Conducted emission	Group 1, class A
CISPR 11：2016	Radiated emission	Group 1, class A
IEC 61000-3-2：2018	Harmonic current emission	NA
IEC 61000-3-3：2017	Voltage fluctuation and flicker	NA

The EMC immunity test of the instrument shall meet the following requirements:

Table 5 EMC immunity test requirements

Electromagnetic Immunity			
Test Item	Normative Reference	Trial value	Compliance with performance criteria
Electrostatic discharge (ESD)	IEC 61000-4-2-2008	±2kV,±4kV contact discharge ±2kV, ±4kV, ±8kV air discharge	B
Electromagnetic field	IEC 61000-4-3:2010	3V/m（80MHz～1GHz） 3V/m（1.4GHz～2GHz） 1V/m（2GHz～2.7GHz）	A
Burst	IEC 61000-4-4:2012	AC power : ±1kV(5/50ns,5kHz)	B
Surge	IEC 61000-4-5:2017	Line to ground: ±2kV Line to line: ±1kV	B
Conducted RF	IEC 61000-4-6:2013	3V，150kHz～80MHz, 80%AM	A
Power frequency magnetic field	IEC 61000-4-8:2009	3A/m，（50 Hz，60Hz）	A
Voltage dip and interruption	IEC 61000-4-11:2017	1 cycle 0%; 5/6 cycle 40%; 25/30cycle70%; 250/300 cycle 5%;	B C C C

Performance criterion:

A. The equipment shall continue to operate as intended during and after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer,when the equipment is used as intended.The performance level may be replaced by a permissible loss of performance.lf the minimum performance level or the permissible performance loss is not specified by the manufacturer,either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended.

B. The equipment shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the equipment is used as intended.The performance level may be replaced by a permissible loss of performance. During the test. degradation of performance is however allowed. No change of actual operating state or stored data is

allowed.lf the minimum performance level or the permissible performance loss is not specified by the manufacturer, either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended

C. Temporary loss of function is allowed, provided the function is self-recoverable or can be restored by the operation of the controls

1. Summary of Instrument

Thank you for choosing the MC100 blood coagulation analyzer ! Our company will send engineers to install and train the users. The operators should be the inspectors of medical and health institutions who have received professional training. The relevant personnel must receive professional training to operate the instrument.

1.1 Intended Use

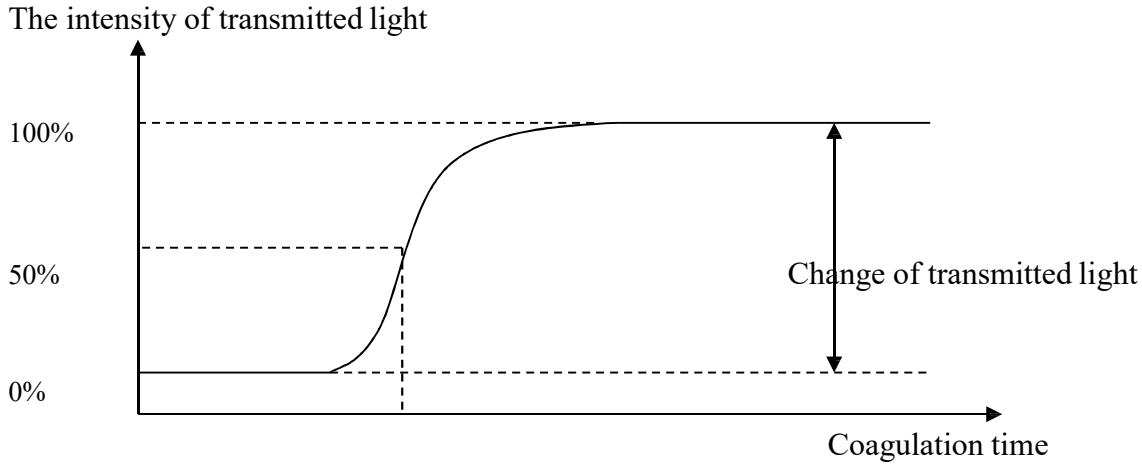
The MC100 coagulation analyzer adopts the coagulation method for clinical determination of prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB) indicators; adopts immunoturbidimetric method for clinical determination Determine D-Dimer (D-Dimer) index. This instrument is suitable for laboratories with professional testing capabilities in medical institutions, such as central laboratories, outpatient and emergency laboratories, clinical departments, physical examination centers. For in vitro diagnostic use only.

1.2 Operating Principle

Coagulation test (percentage test)

Simulate physiological blood coagulation conditions, add the reagent to start blood agglutination reaction, make fibrinogen in the sample into cross-linked fibrin then cause the coagulation of sample. The end point of the reaction is determined by continuously monitoring the change of the absorbance characteristics of the reaction system in this process, and it is used as the conversion time of fibrinogen. This method is used to determine the coagulation characteristics or fibrinolysis characteristics of blood samples.

The transmittance level is 0% just before the solidification reaction is added and 100% after the solidification reaction is completed. The solidification time is obtained from the solidification curve when the transmission level reaches 50% of the predetermined detection.



Turbidimetric inhibition immunoassay

The D-dimer in the sample reacts with the D-dimer antibody latex enhanced particles to form immune complex, resulting in agglutination and increase of turbidity. When light passes through the solution, it can be absorbed by immune complex, and the amount of light absorbed is proportional to the amount of immune complex in a certain range. Under certain wavelength, the content of D-dimer in the sample can be obtained by measuring the change of light absorption caused by turbidity.

1.3 Working Conditions

Power voltage:	~220V-240V, 50/60Hz
Rated power:	100VA
Environment temperature:	15℃~30℃
Relative humidity:	40%~85%
Atmospheric pressure:	85.0kPa～106.0kPa
Stay away from interference source of strong electromagnetic field;	
Avoid direct exposure to strong light;	
Well-ventilated environment;	
With good grounding;	

1.4 Performance

<table>
<tr><td>Appearance</td><td>

The appearance should be clean without scratch, burr and other defects;
The graphic symbols and words on the panel shall be accurate, clear and uniform;
The connection of fasteners shall be firm and reliable without looseness
The moving parts should be stable, and should not be stuck, jump and significant empty return. The key group should be flexible.

</td></tr>
<tr><td>Pre-heating time</td><td>The start-up pre-heating time should not exceed 30min.</td></tr>
<tr><td>Temperature</td><td>The temperature of detection position is controlled in the range of 37℃±1.0℃.</td></tr>
<tr><td>Test items and report units</td><td>Test items: plasma prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (FIB), thrombin time (TT) and D-dimer.

Reporting units: the reporting of PT, APTT and TT are seconds (s), among which the test results of PT should also be reported in international normalized ratio (INR); the reporting unit of FIB is g/L or mg/dL; the reporting unit of D-dimer is μg/mL; the reporting unit of coagulation factor activity is U/L or percentage (%).</td></tr>
<tr><td>Testing speed</td><td>The constant test speed should not be less than 8 tests/h.</td></tr>
<tr><td>Repeatability</td><td>Table 1 Repeatability requirements
<table>
<tr><td rowspan="2">Items</td><td colspan="2">CV</td></tr>
<tr><td>Normal sample</td><td>Outlier samples</td></tr>
<tr><td>PT</td><td>≤5.0%（Sample Requirements:</td><td>≤10.0%</td></tr>
<tr><td>APTT</td><td>≤5.0%（Sample Requirements:</td><td>≤10.0%</td></tr>
<tr><td>FIB</td><td>≤10.0%（Sample Requirements:</td><td>≤20.0%</td></tr>
<tr><td>TT</td><td>≤15.0%（Sample Requirements:</td><td>≤20.0%</td></tr>
<tr><td>D-Dimer</td><td>≤15.0%</td><td>≤10.0%</td></tr>
</table>
</td></tr>
<tr><td>Accuracy</td><td>The relative deviation of FIB measurement result should be less than ± 10.0%.
The relative deviation of D-Dimer measurement result should be less than ± 15.0%.</td></tr>
</table>

<table>
<tr><td>Linear</td><td>Within the linear range of FIB, R≥0.980. The linear deviation of FIB shall meet the requirements of Table 2.
Table 2 FIB linear range deviation requirements
<table>
<tr><th>Item</th><th>Linearity range/(g/L)</th><th>Allowable deviation range</th></tr>
<tr><td rowspan="2">FIB</td><td>(0.5~2.0]</td><td>Absolute deviation not more than±0.2g/L</td></tr>
<tr><td>[2.0~8.0)</td><td>Relative deviation should not more than±10%</td></tr>
</table>
Within the linear range of D-dimer, R > 0.980. D-Dimer deviation within the linear range shall meet the requirements of table 3.
Table 3 D-dimer linear range deviation requirements
<table>
<tr><th>Item</th><th>linear range/(μg/mL)</th><th>Allowable deviation range</th></tr>
<tr><td rowspan="2">D-Dimer</td><td>[0.22~5.0]</td><td>Absolute deviation not more than±0.5μg/mL</td></tr>
<tr><td>(5.0~20.0]</td><td>Relative deviation should not more than±10.0%</td></tr>
</table></td></tr>
<tr><td>Continuous working hours</td><td>The deviation of continuous working for 8h shall meet the requirements of Table 4.
Table 4 Continuous working hours requirements
<table>
<tr><th>Items</th><th>Allowable deviation range</th></tr>
<tr><td>PT/s</td><td>Relative deviation should not more than±15%</td></tr>
<tr><td>APTT/s</td><td>Relative deviation should not more than±10%</td></tr>
<tr><td>FIB(g/L)</td><td>Relative deviation should not more than±10%</td></tr>
<tr><td>TT/s</td><td>Relative deviation should not more than±10%</td></tr>
<tr><td>D-Dimer(μg/mL)</td><td>Relative deviation should not more than±15%</td></tr>
</table></td></tr>
<tr><td>Limit of blank</td><td>D-Dimer limit of blank≤0.2μg/mL.</td></tr>
<tr><td>Function</td><td>◆ Software Function
The instrument software consists of five parts: quality control, record, setting, help and test.
◆ Communication Function
Equipment shall have 2 RS232 serial port， 1 USB connector and 1 LAN connector；with WIFI connection function.
◆ User Access Control
User identification method: user name and password.
User type and permissions: it is divided into two levels: administrator and ordinary user. The administrator has all the operation permissions of the system, and ordinary users can only carry out test related operations.</td></tr>
<tr><td>Safety Requirements</td><td>Should meet the requirements of EN61010-1: 2010+A1： 2019、EN61010-2-101：2017.</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>Should meet the requirements of EN61326-1：2013 and EN 61326-2-6：2013.</td></tr>
</table>

1.5 Software System

Software Edition Number：

Name of the software: MC100 coagulation analyzer software, software edition number: V1.0.

Operating Condition：

Operating system:	Android5.1 or above
Ramer:	1024M
Internal storage memory:	8G
Monitor resolution:	1280×720
Lower computer system:	dsPIC33
Random access memory:	1M

Data Interface：

RS232 serial port, USB connector, LAN port.

User Access Control：

User identification method	User name, password
User types	Administrator and ordinary user
User permissions	The administrator has all the operation permissions of the system, and ordinary users can only carry out test related operations.

1.6 Sample Type

Sodium citrate plasma, whole blood.

1.7 Applicable Reagents

It should be used together with the coagulation kit produced by Zhejiang Pushkang Biotechnology Co., Ltd.

Kit Name	Items	Methodology
Coagulation 4 Test Panel	Prothrombin time (PT)	Coagulation method
	Activated partial thromboplastin time(APTT)	Coagulation method
	Fibrinogen (FIB)	Coagulation method
	Thrombin time (TT)	Coagulation method
Coagulation 5 Test Panel	Prothrombin time (PT)	Coagulation method
	Activated partial thromboplastin time(APTT)	Coagulation method
	Fibrinogen (FIB)	Coagulation method
	Thrombin time (TT)	Coagulation method
	D-Dimer (D-Dimer)	latex immunoturbidimetric method

1.8 Transportation and Storage Requirements

Transportation Requirement:

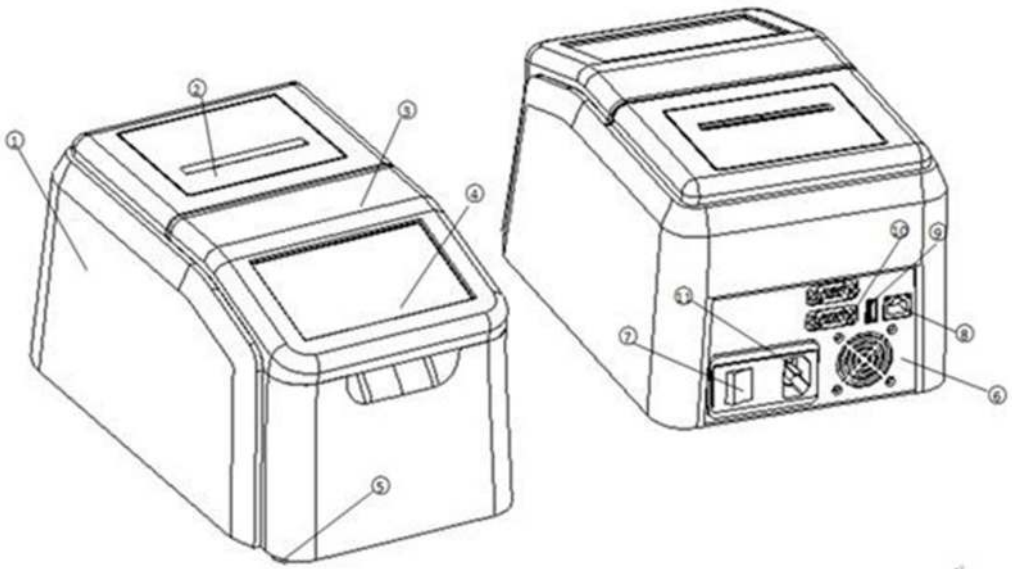
The packed MC100 Coagulation analyzer can be transported by general means to prevent violent vibration, moisture and sun exposure. It is strictly forbidden to turn upside down and tilt. It should be moved gently during transportation to ensure that the products are delivered to customers in good condition.

Storage Requirements:

After packaged, the instrument should be stored in a well ventilated environment with - 20℃~ 55℃, relative humidity no more than 70%, no corrosive gas.

1.9 Product Structure

MC100 Coagulation analyzer is composed of a detection module, a pre-temperature module, a touch screen and a printer.



1.7-1 Integral structure

1. body shell 2. printer 3. top cover 4. touch screen 5. foundation
6. back plate 7. power switch 8. LAN connector 9. USB connector
10. RS232 connector 11. power port

2. Installation Instructions

When you receive the instrument, follow the instructions below to receive and install it:

2.1 Receiving Guide

- Please check whether there are visible cracks, dents or possible damage caused by transportation around the packing box of the instrument. If you find any visible cracks, dents or possible damage caused by transportation, please contact our after-sales service agency or agent in time.
- After receiving the instrument, please check whether the package is in good condition. If the instrument may be damaged, please contact the person in charge of the entrusted transportation company immediately.
- When you receive the instrument, please inform our after-sales service agency or agent immediately, and make an appointment for application engineer or maintenance engineer to open and install it.

2.2 Packing List

After opening the package of biochemical analyzer, please check whether the items are damaged according to the list in table 2.

Table 2 Packing list

Items	Quantity
Coagulation analyzer	1
Power line	1
Barcode scanner	1
Thermal printing paper	1
Production certificate	1
Instruction for use	1
Warranty card	1

2.3 Installation Environment

2.3.1 Requirements for Using Environment

- Environment temperature: 15℃~30℃;
- Relative humidity: 40%~85%;
- Altitude: Below 2000 meters;
- Atmospheric pressure: 85.0kPa～106.0kPa；
- It should be placed in a stable worktable, far away from the interference source of strong electromagnetic field, avoid direct illumination of strong light, and in a well-ventilated environment with good grounding.

2.3.2 Peripheral Environmental Requirements

In order to facilitate the operation, maintenance and repair of the instrument, the installation of Coagulation analyzer should meet the following conditions:

- The distance between the left and right sides of the instrument and the wall should not be less than 20cm;
- The distance between the back panel of the instrument and the wall should not be less than 20cm;
- The distance between the front of the instrument and other instruments should not be less than 20cm;
- The load-bearing capacity of the operating table for placing the instrument shall not be less than 10kg.

2.3.3 Power Requirement

- Power voltage: ~220V-240V;
- Rated frequency: 50/60Hz;
- Rated power: 100VA;
- The instrument should be close to the power socket and have good grounding.

2.4 Installation

2.4.1 Instrument Placement

When the instrument is placed on the horizontal console lightly, it should be ensured that the console is flat and the bearing capacity is not less than 10kg.

2.4.2 Computer Connection

If you need to connect the computer, use the communication cable to directly connect the RS232-1 interface.

2.4.3 WIFI Connector

If you need to connect to WIFI, the engineer should connect in the network setting interface under administrator mode.

2.4.4 Power Connection

The power socket used by the instrument must have grounding wire, and the socket must be stable and reliable in contact; all the required grounding points must be compulsorily grounded. First connect the interface of the power cord with the power interface of the instrument, and then plug one end of the power cord into the AC power socket.

2.4.5 Scanner Gun Connection

Before starting the instrument, connect the RS232 interface of the connecting line of the code scanning gun directly with the RS232-2 interface of the instrument.

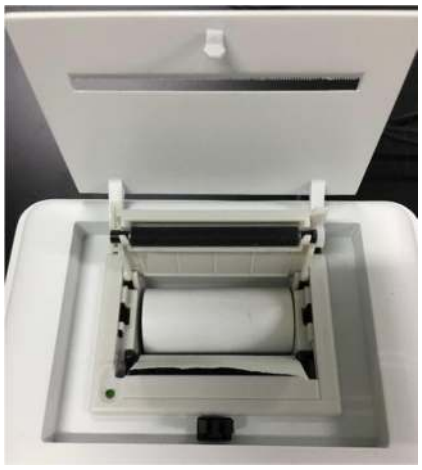
Note: If the scanning gun is connected after the instrument is turned on, the scanning gun will not be able to identify the barcode.This scanning gun only supports the use of connected instrument, does not support wireless use after charging.

2.4.6 Installation of Thermal Printing Paper

Gently press the bottom of the printer cover, open the printer cover and the green indicator light is always on; pull up the left buckle and open the paper bin cover, and the green indicator light is flashing; take out the empty paper roll and put in the new thermal printing paper roll, pull out a small section of it and insert it into the printer cover slot; close the paper bin cover and the printer cover in turn.

Note: When installing the thermal printing paper, the paper output end is close to the display screen. Please confirm that the installation is correct, or the instrument will not be able to print the test results normally.

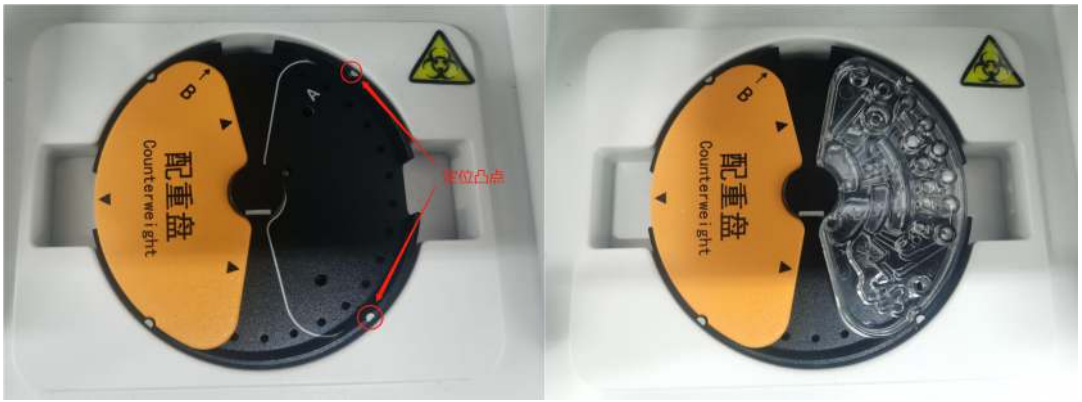
The installation style is shown in 2.4-1：



2.4-1 Printing paper installation diagram

2.4.7 Installation of Reagent Disk

Align the groove of the reagent disk with the groove of the tray rack, and gently press to fix the reagent disk.



2.4-2 Diagram of reagent disk installation

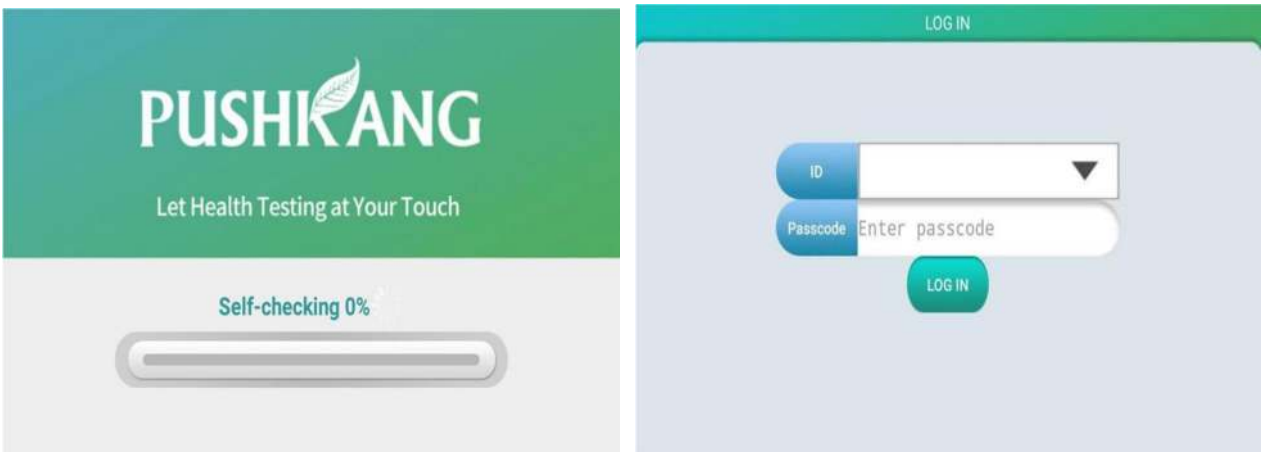
3. Operating Instructions

3.1 Pre-startup Inspection

- Make sure the power cord is properly connected.
- Make sure the scanning gun is connected correctly.
- Confirm thermal printing paper allowance.

3.2 Start-up System

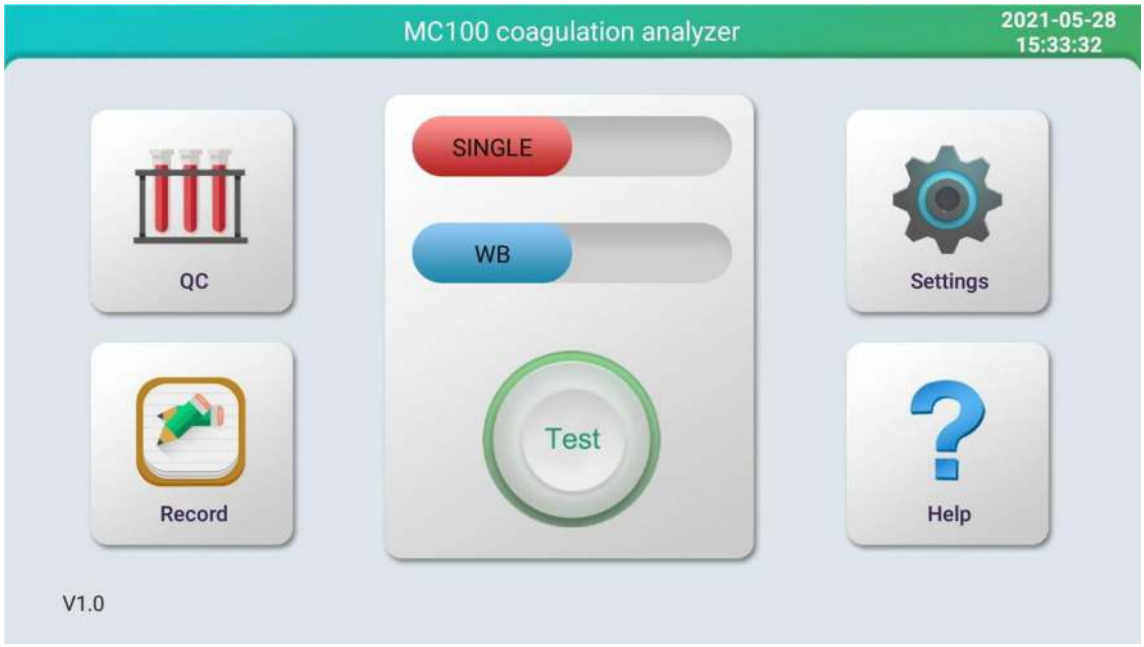
After correctly connecting the power cord and the code scanning gun, turn on the power switch on the back of the instrument. The company logo will appear on the interface of the instrument and enter the self-inspection procedure, as shown in figure 3.2-1. Please wait patiently for the instrument to complete the self-inspection. After the instrument self-test is successful, it will enter the login interface. Please enter the ID and password and click “LOG IN” to enter the main interface, as shown in figure 3.3-1. If the self-test fails, please restart the instrument and make it self-test again. If it still fails, please contact our after-sales service agency or agent.



3.2-1 Instrument self-check and login interface

3.3 Main Interface

The top right part of the main interface is the time and date, the bottom left part is the software version number, and the middle part is the function area, which includes five parts: “QC”, “Record”, “Test”, “Settings” and “Help”.



3.3-1 Main interface

3.4 Test

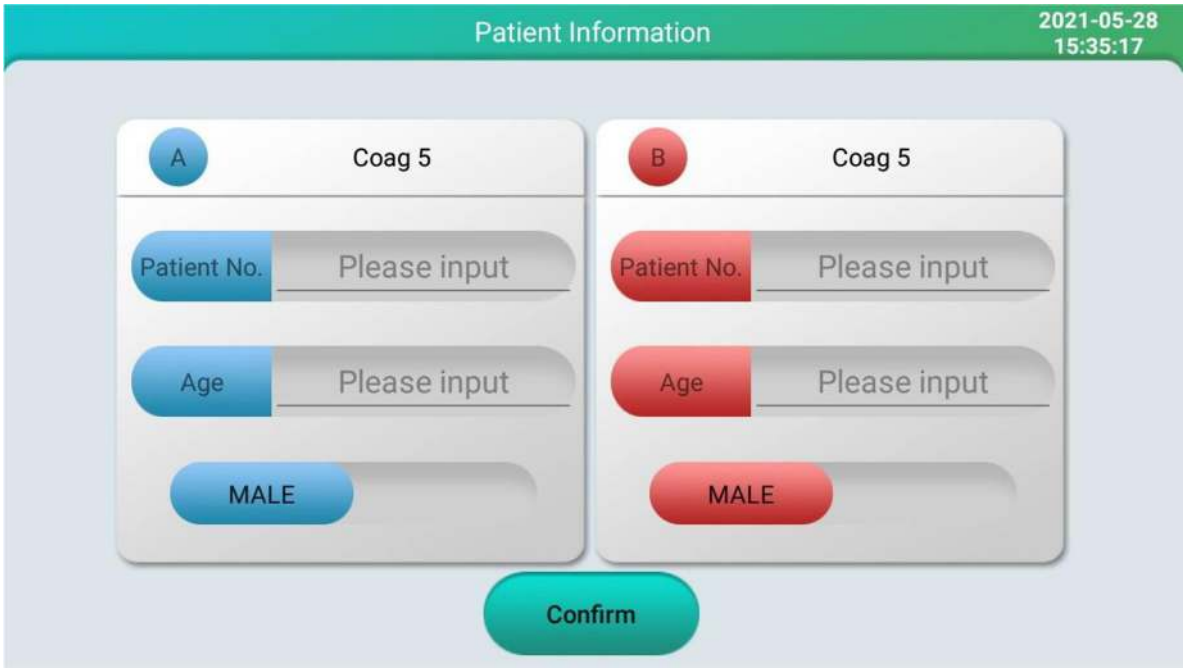
Before the formal test, please preheat the instrument for about 30 minutes. If the temperature does not reach the expected temperature due to insufficient preheat or other reasons, the instrument will alarm and cannot start the test.

3.4.1 Normal Test

After preheating, select "SINGLE /DOUBLE " and "WB / PLASMA" by dragging the button. After selection, click the "Test" button. The interface will have the prompt of "Scan ning", as shown in figure 3.4-1. Scan according to the prompt. To return, please click the return button in the upper left corner.

3.4-1 Scan reagent disk bar code prompt

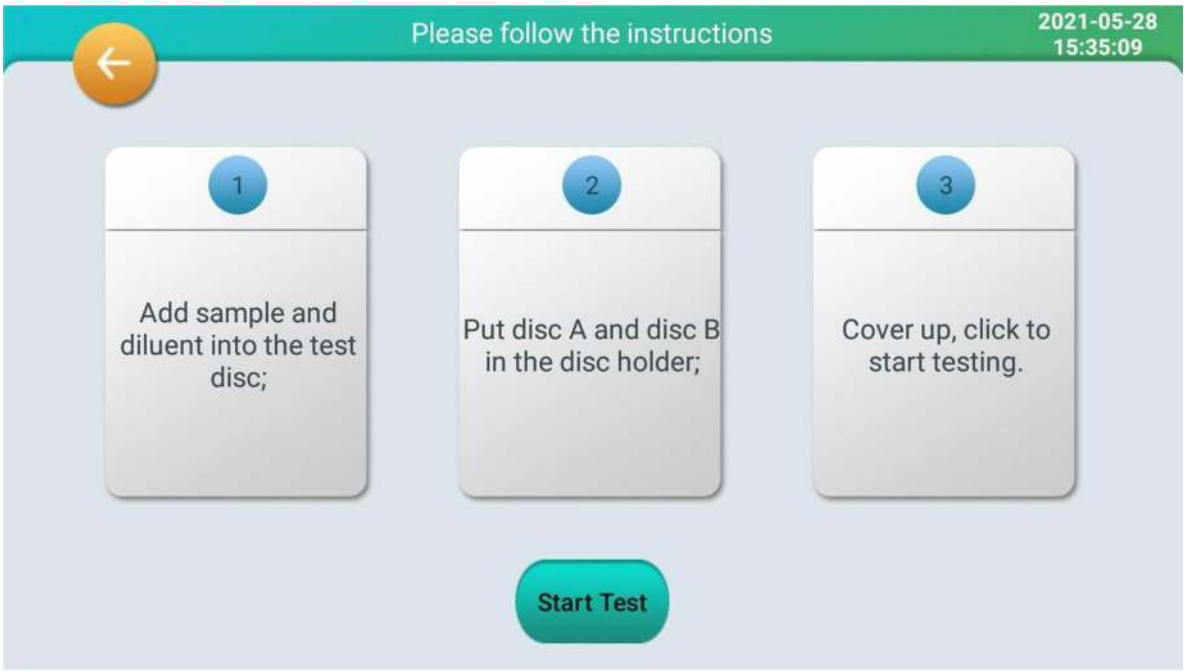
After scanning, the system will automatically read the reagent disk information and jump to the patient information input interface, as shown in figure 3.4-2. Input the patient information according to the prompt.



3.4-2 Test item determination interface

After clicking the "Confirm" button, the system will enter the test preparation promptinterface, as shown in figure 3.4-3, then operate according to the interface prompt.

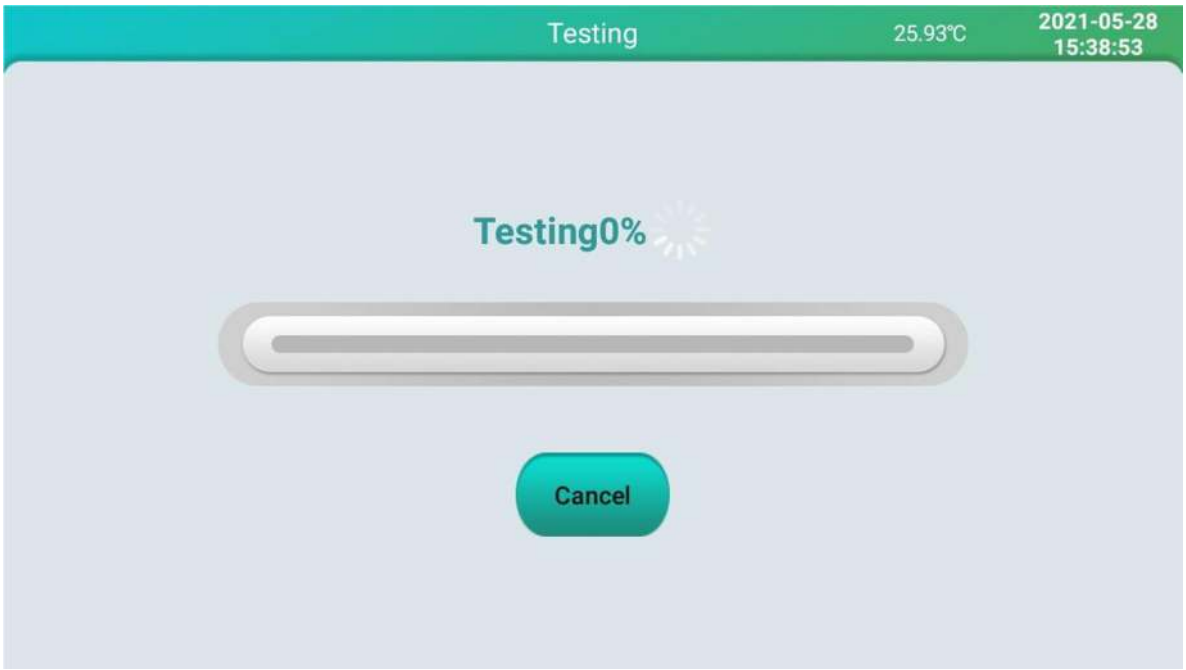
Take out the reagent disc from the aluminum sealed bag, open the upper cover of the instrument, and put the test disc horizontally to the tray rack, then use the micro-pipette or other sample adding equipment, inject the sample into the reagent disc through the "Sample" sampling hole; inject the diluent into the reagent disc through the "Diluent" sampling hole; please refer to the reagent manual for the sample amount. Close the upper cover and click the "Start Test" button to test.



3.4-3 Test preparation prompt interface

Warning: Please wear dust-free gloves for operation, as the dust will cause destructive effects on the optical elements of the instrument. During and after sample addition, the test disk must be kept horizontal. Please place the reagent disk on the horizontal desktop for sample addition. When placing the test disk, please hold the edge of the disk and do not touch other parts of the disk.

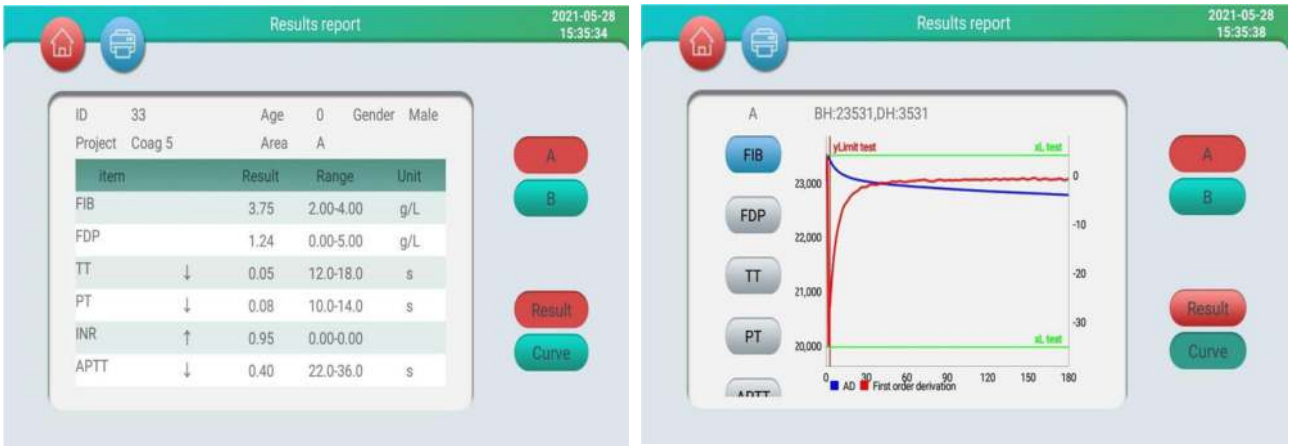
After confirmation, wait for test results. The interface is shown in Figure 3.4-4.



3.4-4 Testing process interface

After the test is completed, the test results will be displayed, as shown in figure 3.4-5, and the test results will be automatically saved in the internal memory of the analyzer. Click the print button on the top left of the interface to print the test results directly; click the "Result" and "Curve" buttons to

switch the description form of the test results; click the "A" and "B" buttons to switch the test results of samples.



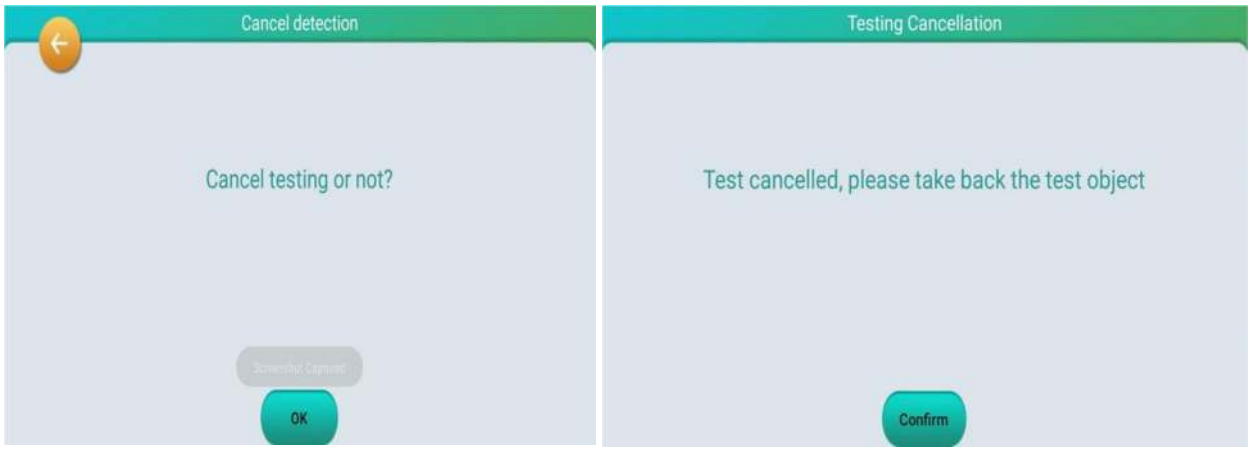
3.4-5 Test result interface

Note: Do not open the upper cover during the test. If the upper cover is opened due to mis-operation, the disk will stop running and the screen will display an alarm. This test will be invalid. Please take back the disk and dispose it as scrap. If you need to continue the test, please restart the test according to the normal test process.

3.4.2 Cancel Detection

In the detection process interface, click the "Cancel" button, and "Cancel testing or not?" will pop up in the dialog box, click "OK" to cancel to cancel the detection, as shown in figure 3.4-6. The user takes out the disk and processes it according to the waste requirements, and then click "Conform" to return to the main interface; click "return" to return to the detection process interface.

Note: The reagent disk is a disposable product. The disk after use should be specially managed as infectious waste according to the waste treatment and public cleaninglaw.



3.4-6 Whether to cancel the detection interface

3.5 Quality Control

If it is necessary to conduct quality control test on the reagent disk, you can select the "QC" button in the main interface and use the quality control products provided by our company to replace the samples for test. The follow-up operation process is consistent with the routine test. The quality

control chart can be viewed after the quality control test is completed.

3.6 Record

If the user needs to check the previous test data, click the "Record" button in the main interface to enter the historical data query interface, as shown in figure 3.6-1. The query results of "QC", "DATE" or "ID" can be selected according to the requests.

3.6-1 Record interface

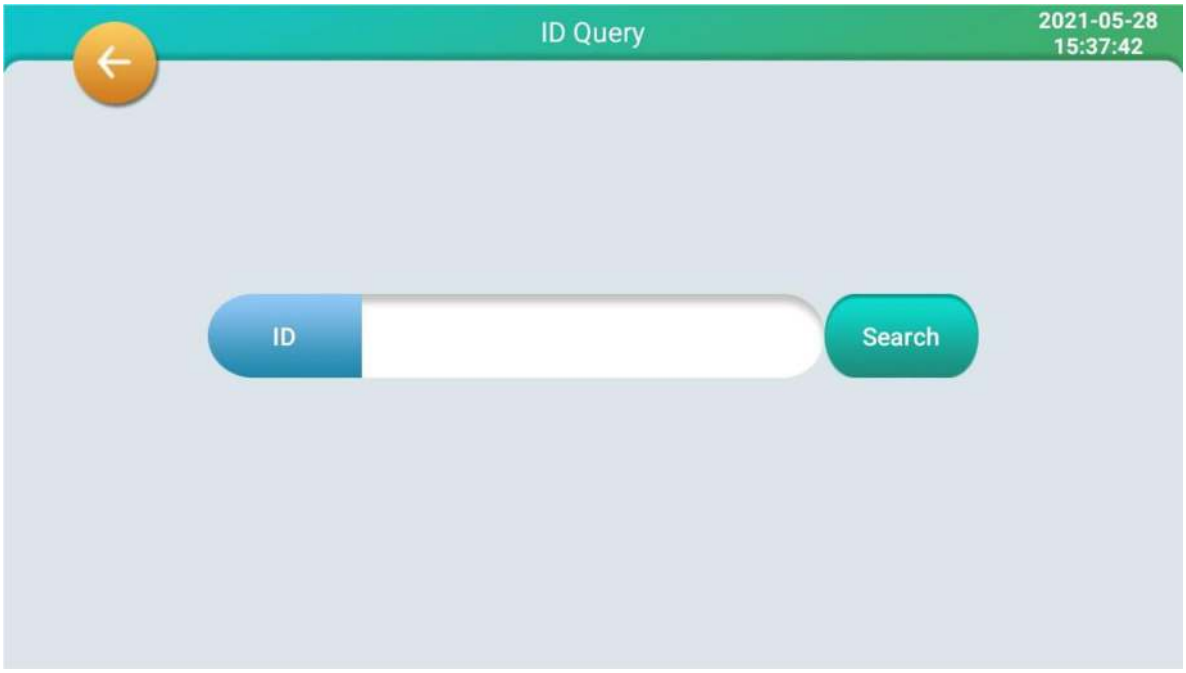
3.6.1 Date Query

In the record interface, click the "DATE" button to enter the test result query interface, as shown in figure 3.6-2. The query time range includes today, recent week and recent month ect. Users can set the start date and end date to query according to their needs in the user-defined interface. The specific operation is the same as quality control query.

3.6-2 Date query

3.6.2 ID Query

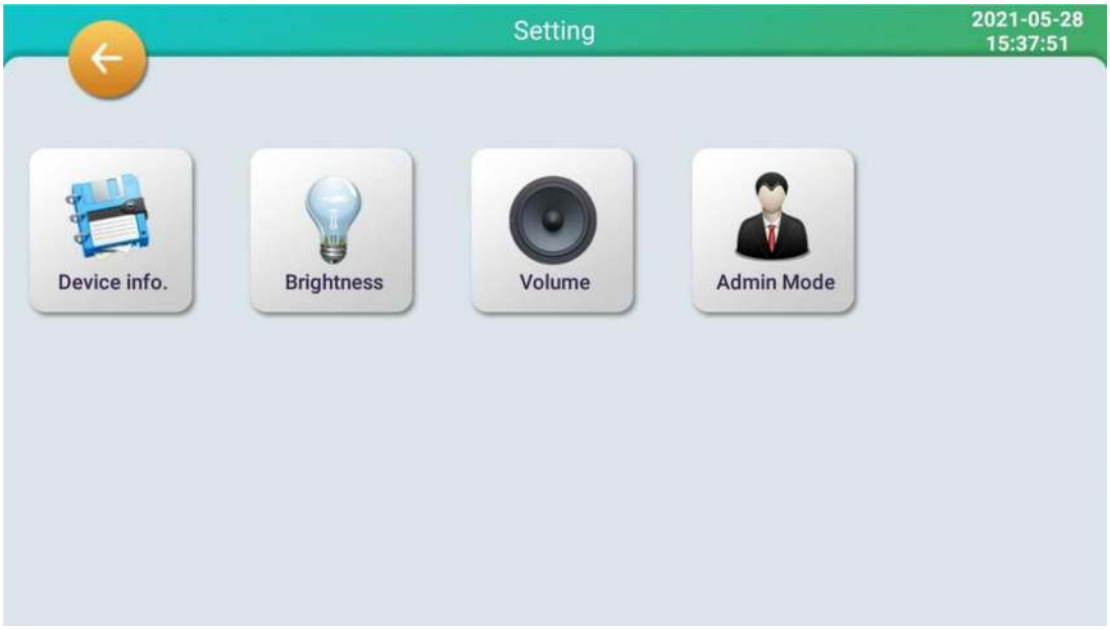
Click the "ID" button in the record interface to enter the ID query interface, as shown in figure 3.6-3. You can input the ID to accurately query the test results.



3.6-3 ID query

3.7 Setting

Click the "Settings" button in the main interface to enter the settings interface, where you can view "Device info", "Brightness", "Volume" and "Admin Mode", as shown in figure 3.7-1.



3.7-1 Setting interface

View Device Information

Click the "Device info." button in the setting interface to enter the device information interface to view the device information.

Adjust Brightness

Click the "Brightness" button in the setting interface to enter the screen brightness adjustment interface to adjust the screen brightness

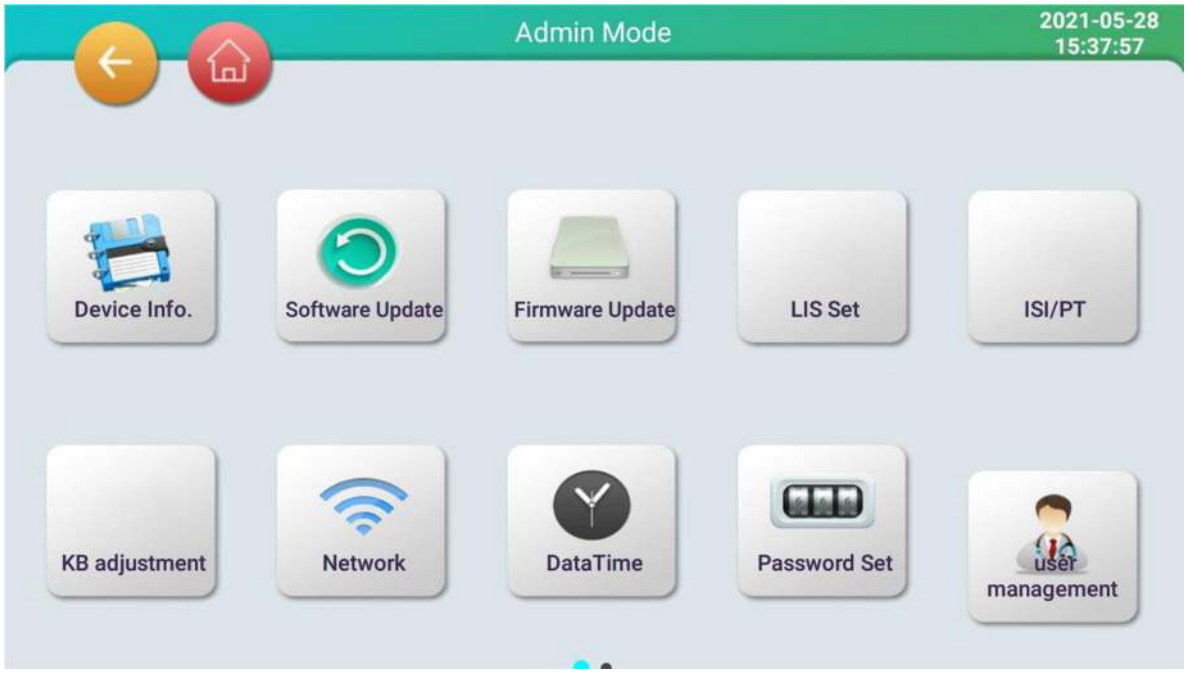
Adjust the Volume

Click the "Volume" button in the setting interface to enter the volume adjustment interface to adjust the instrument volume.

Administrator Mode

If you want to enable the administrator mode, you can log in by selecting the engineer account in the login interface and enter the password to enable. Please click the "administrator mode" button in the setting interface to enter the administrator mode. In the administrator mode, engineers can maintain the instrument and set the bottom system, as shown in figure 3.7-2.

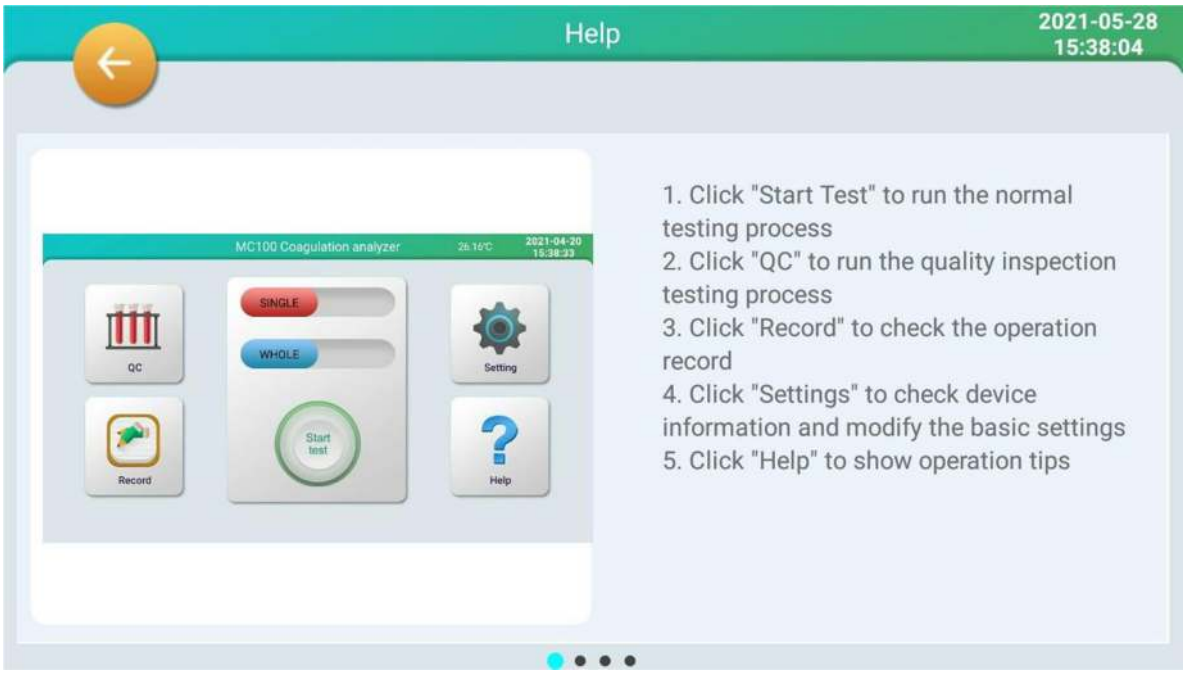
Note: Ordinary users cannot enable administrator mode



3.7-2 Administrator mode interface

3.8 Help

Click the "Help" button in the main interface to view the operation method of the instrument, as shown in figure 3.8-1.



3.8-1 Help interface

Note: The software interface is for reference only, subject to the actual display situation.

4. Maintenance

4.1 Daily Maintenance

Temperature Control Device Detection

Before starting work every day, after 30 minutes of preheating, touch the tray rack with your hand to feel whether there is obvious temperature rise. If so, it indicates that the temperature control device is running normally, and the test can be carried out normally. If not, the temperature control device may be damaged. Please contact the after-sales service agency or agent of Pushkang in time.

Cleaning Tray Rack

At the end of the work each day, clean the residue on the tray rack with a wet alcohol cotton.

Waste Disposal

After the test, the waste materials such as reagent disk and pipette tips should be cleaned up in time.

Note: during daily maintenance, please wear rubber gloves, wash hands with disinfectant after maintenance, and dispose reagent disk and pipette tips according to relevant regulations of medical waste.

4.2 Monthly Maintenance

Shell Cleaning

Wipe the surface of instrument shell with clean cloth dipped in purified water to remove dust and dirt. It is forbidden to use alcohol, gasoline and other flammable organic solvents to wipe the surface of the instrument, so as not to cause danger. When wiping, do not place the water container around the instrument to avoid the liquid flowing into the instrument. To avoid moisture, after the shell surface is dry, then turn on the power supply to use the instrument

Touch Screen Cleaning

Use a hairless soft cloth dipped in glass cleaning solution for wiping. Do not spray the cleaning solution directly on the surface of the touch screen. Do not use alcohol, gasoline and other flammable organic solvents to wipe the surface of the instrument to avoiddanger.

4.3 Six Months or Annual of Maintenance

In order to keep MC100 working normally, the following maintenance isrequired:

- Add lubricating oil to the moving parts of the instrument.
- Wipe and maintain the optical components and mirrors.

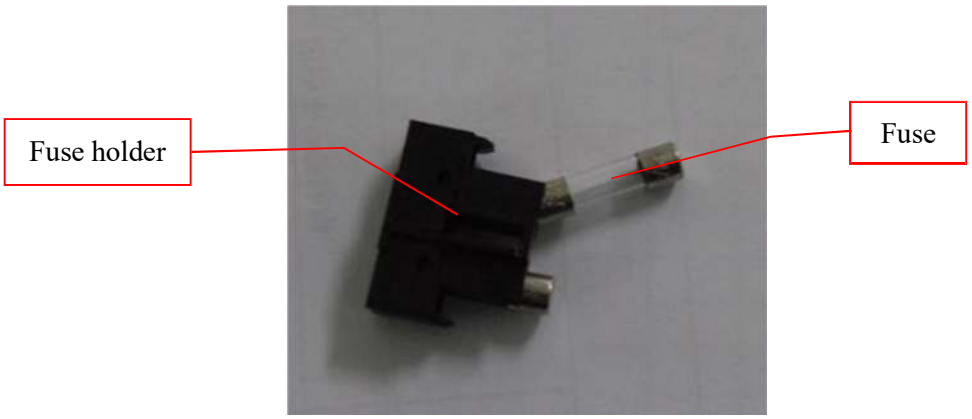
4.4 Replace the Fuse

Type of fuse: T1AL250V. The position of fuse holder is shown in Figure 4.4-1, and the replacement process is as follows:

Place the power switch in the "O" position and pull out the power connector of the power cord assembly. Use a tool (such as a screwdriver) to remove the fuse holder from the filter socket (in the direction of the arrow).

4.4-1 Power connector

The removed fuse holder is shown in figure 4.4-2. Remove the damaged fuse, replace the fuse of the same model, and re-install it on the filter socket. (the fuse holder is unidirectional insertion mode, please pay attention to the direction when installing it back to the original position of the filter socket!)



4.4-2 Fuse

5. Common Faults and Treatment Methods

This chapter lists the system fault and warning information, please deal with it in time according to the information. If the alarm status cannot be removed after taking measures, please contact the after-sales service agency or agent of Pushkang.

5.1 Common Faults and Treatment Methods

When the following faults occur, the user can take corresponding actions to solve the faults according to the description in the column of user handling measures. If it cannot be solved, please contact the after-sales service agency or agent of Pushkang in time.

No	Details	Measures
01	Light source fault	Restart the machine, if there is still a problem, please contact the manufacturer's after-sales service department
02	Motor fault	
03	Communication failure	
04	Instrument crash	
05	Quality control lose control	Repeat the test. If there are still problems, please contact the manufacturer's after-sales service department
In case of other faults, please contact the after-sales service agency or agent of Pushkang in time!		

5.2 Common Error and Handling Methods

When the following errors appear, the user can take corresponding actions to solve it according to the description in the column of processing method. If it cannot be solved, please contact the after-sales service agency or agent of Pushkang in time.

No	Error warning	Treatment Methods
1	Number input cannot be empty	The patient number must be entered
2	Open the cover, the test is invalid, please take back the test object	Do not open the cover during the test
3	Please check if the panel is placed correctly	Please make sure the panel is in the correct position

6. After-sales Service

6.1 Warranty Period

The packaged instrument shall be guaranteed within 12 months from the date of installation under the condition of complying with the rules of transportation, storage and use. (Start from the record date of the product warranty card when the instrument is installed.)

Content of the Warranty

If the instrument fails to operate normally according to the instruction manual due to product quality problems, the company is responsible for repairing the instrument, replacing parts or products for users within the warranty period free of charge.

Non Warranty Items

Even within the warranty period, if the faults of the instrument belong to the following contents, the company will carry out paid repair:

- Failure and damage caused by failure to use according to the method recorded in
- the instruction manual;
- Failure to use in accordance with the method recorded in the operation manual, resulting in failure and damage;
- Failure and damage caused by fire, earthquake and other force majeure;
- Failure and damage caused by using non specified power supply (voltage, frequency) or abnormal voltage;
- Failure caused by repair, adjustment and modification not carried out by our company or designated after-sales service organization.

Note: consumable goods indicated in the instruction manual are not covered by the warranty. Maintenance beyond the warranty period is paid service.

6.2 Production Date and Service Life

Production date: See the label.

Service life: the service life specified in the operation manual refers to 5 years after the implementation of regular maintenance, replacement of consumables, repair of components and necessary overhaul.

6.3 After-Sales Service Company Information

- Company name: Zhejiang Pushkang Biotechnology Co., Ltd
- Address: C408, Science and Technology Innovation Park NO.398, Mahuan Road, Binhai new Area, 312366 Shaoxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA.
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