XL 1000Series
Automatic Blood Coagulation Analyzer

Beijing Zonci Technology Development Co., Ltd.

Revised table

Document No.	Edition	Date
XL1000	1. 2. 3	2018/04/09

CONTENTS

Warning and Attention Symbols

Warning:
Must be observed so as not to harm the human body

☆ **Note:**
Important information and helpful hints in operation or maintenance.

Various signs used by this instrument:

 fuse mark

 shut off(from main power supply)

 turn on(with main power supply)

alternating current

attention

biological hazard

Packing label:

 stacking layers

 keep dry

 up

 Handle with care

no roll

Important safety guidelines

Before starting installation work and first use, read the following instructions carefully.

◆ The power must be Protective grounding. Ground Protection port inside instrument is marked with  , safe earth-connection through socket is necessary. Electrical leakage protecting device is required in moist places.

◆ The nameplate of the instrument shall include name, type No., manufactrurer, factory No., norminal voltage and frequence of power supply and input power.

◆ Outside instrument is marked with  indicates that strict enforcement of regulations is required.

◆ Protective measures are taken inside package during transportion. Do not move once installed. To avoid electrical shock, do not open the instrument. Refer to operation manual or qualified personnel only.

◆ The instruments produced by us are merely for indoor use except special purpose instruments.

a) There should be no severe electromagnetic interference, strenuous vibration, aggressive gas around the device;

b) Room temperature should be kept between at 10 ℃ to 30 ℃. The relative humidity should be kept below 70%. And the atmospheric pressure shouble be 86.0kPa ~ 106.0kPa;

c) Transportation and storage conditions the packaging intact is between -40 ℃ to 55 ℃, relative humidity of not more than 93%, no corrosive gas and ventilated room.

d) The grounding tap of the instrument must be reliably grounded through power outlets. Electrical leakage protector shall be used in damp conditions.

e) The instrument is equipped with power regulator, an external regulator is unnecessary. If the external voltage fluctuations have gone beyond 220V ± 22V, UPS voltage regulator is necessary, common regulator is not allowed;

- **Be sure to cut off the power supply instrument installed in a convenient place；**
- Turn off the power, unplug the power plug and turn to professionals upon any of the following events

a) When the power cord, signal cable or plug is damaged or broken

b) Instrument is exposed to rain or water

c) Instrument or the shell is broken or damaged;

d)The instrument can't be operated normally even according to guideline of the instruction.

e) The instrument can not function correctly, or there is obvious change in character, exclude the factors of samples, accessories, manual operation error.

1. Summary

1.1 Purpose and components

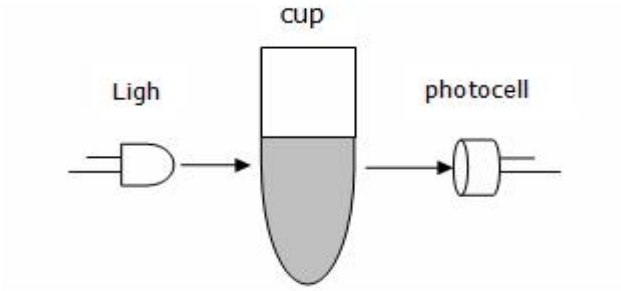
XL Series automatic blood coagulation analyzer is used for rapid detection of blood coagulation. It is suitable to the hospital clinical test, laboratories and scientific research institutes. The instrument tests the coagulation function with optical method. Testing items include prothrombin time, PT; activated partial thromboplastin time, APTT; thrombin time, TT; fibrinogen, FIB; and other special items. Results can be displayed in different units upon calibration of instrument.

Components: Rotary synchronous feeding arm, test tube tray, testing unit, cleaning unit, heating and refrigeration unit, operating and displaying unit, data transfer unit.

1.2. Testing principle

1.2.1 Coagulation Method

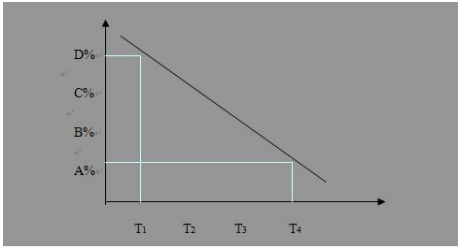
This method is to determine the end of coagulation through the change of absorbance during coagulation. Parallel lights from light source passed the sample to be tested will irradiate to a photocell, which will change the light signal to an electric signal. The signal will be sent to the processing center after enlarge. Then the testing result will be given by the microprocessor.



Mix the plasma and the reagent rapidly. At the moment of mixing, the absorbance is very weak. The absorbance will increase with the generation of fibrinogen coagulation in the specimen. When the specimen is entirely coagulated, the absorbance is the stable. At the moment of mixing, the absorbance is weakest, 0%, while the absorbance is strongest, 100% after entire coagulation. Here the coagulation time is set, corresponds to the point 50% on the curve.

Calculation of percentage of activity: First calculate the coagulation time according to the known concertration or activity. Then draw a curve of the concentration or activity to coagulation

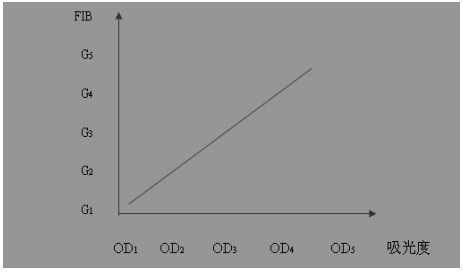
time . The curve shall include more than three points. The activity can be obtained from the curve according to the coagulation time.



T1, T2, T3, T4, represents coagulation time, A%, B%, C%, D% is for activity

1.2.1.1 Derived FIB

PT of derived FIB: The concentration of derived FIB is calculated by the difference value of absorbance in start and end points of the coagulation during PT test. Before testing, calibration curve FIB density--absorbance is required.



OD1, OD2, OD3, OD4, OD5 represent absorbance
G1, G2, G3, G4, G5 represent FIB density

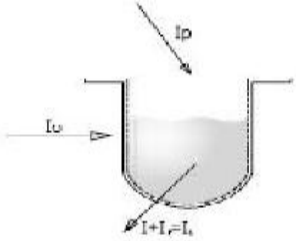
1.2.2 Immunoturbidimetry

The immunoturbidimetric method, is to use the antibody which is corresponding to the testing substance, to connect on a latex particle with diameter of 15 to 16 nm, so that the volume of the antigen-antibody conjugate is creased. After light passing through, the intensity of transmission light increase largely so as to improve the checking sensitivity.

The XL1000 series uses a dynamic method to detect changes in absorbance caused by antigen and antibody reactions. When the antibody is added to the test substance, the concentration of free antigen and antibody is large, and the reaction speed of antigen and antibody is faster. That is, the formation speed of the agglomerated particles is faster and the absorbance changes drastically. This is the unstable phase of the reaction. As the antigen-antibody reaction continues, the reaction rate is gradually stable, and the change in absorbance is also maintained at a stable level, which is the straight line of the reaction. In this linear stage, the rate of change in absorbance is in a quantitative relationship with the amount of antigen in the sample to be examined. Based on this principle, the coagulometer measures the amount of antigen in the sample to be examined by detecting the change in absorbance per unit time during the straight-line phase.

The schematic of the light absorption method is as follows. The incident light （I0） pass into the cuvettes and is absorbed by the reactants. Scattered light （I+IP） is measured and the absorbance value is calculated by the following formula:

$A = - \log (I_1 / I_0)$



The disturbing light Ip is eliminated by subtracting another identical reference value that only detects the scattered light.

I1 = I+IP (initial measured value, including scattered light and interference light)

I2 = IP (reference measurement, blocking incident light, measuring interference light only)

Subtracting I，from I1 is I, and interference light IP is used as a reference constant between measurements.

Incident light is provided by a monochromatic wavelength (405 nm or 540 nm) high-precision laser diode. After the absorbance changed, the absorbance is converted into the concentration by Beer-Lambert's law.

$$A = \varepsilon I C$$

A = Absorbance

ε = molecular dissipation coefficient

I = length of optical path

C = concentration of the color concentration and the absorbance is proportional to the relationship

During the detection process, due to reaction of antigens and antibodies in the sample to be

testing, complexes are formed, so that particles of solute are increased and light scattering is enhanced. The intensity of the scattered light and the amount of antigen are in a quantitative relationship. The blood coagulation analyzer automatically calculates the amount of change in absorbance per unit time, and then calculates the content of the substance to be detected based on the standard curve.

1.3 Instrument Overview

1.3.1 Performance

1. size： XL1000C/1000p/1000i/1000: 350mm×370mm×510mm
2. weight： XL1000C/1000p/1000i/1000 35KG
3.

Function / Model	Test speed （Ts/h）	Test position (unit)	Sample position (unit)	Warm position	Slant Reagent position	Sample probe (unit)	Test method
XL1000C	160	4	6	4	11	1	coagulation immunoturbidimetry
XL1000P	100	4	4	4	9	1	
XL1000	120	4	4	4	6	1	
XL1000i	140	4	4	4	6	1	coagulation

Instrument's function: a) continuous batch sample test; and emergency first test function; b) software provides routine and special test item of measurement function selection in menu mode; c) automatic positing of sample probe and liquid surface detection function; d) PT-derived Fib function; measuring special items with immunoturbidimetric assays such as D-dimer; e) Multi-point calibration function; f) Instrument software for reagent and quality control management functions; g) With open custom report mode;report/data network transmission; h) abnormal alarm function for test results; insufficient cleaning fluid and reagents alarm function; i) work function with LED light; j) Tilt room temperature or cool reagent unit; k) arbitrary combination detection of test items; l) rotary sampling arm and sampling needle to continuous adding, cleaning and testing functions; m)automatic and manual loading for double mode test functions;

5. Test items: prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (FIB), thrombin time (TT), D-dimer and FDP. The reporting unit for PT, APTT, and TT is the second (S). The PT measurement results should also report the International Normalized Ratio (INR); the FIB reporting unit is g/L or mg/dL;

6. Carrying Contamination Rate

6.1 contamination rate of samples' concentration: FIB (g/L) contamination rate should be ≤ 10%; D-dimer (ug/ml) contamination rate should be ≤ 10%;

6.2 contamination rate of FIB or TT to PT or APTT should be ≤10%; D-dimer of contamination rate to APTT and APTT of contamination rate to D-dimer should be ≤10%;

7. Channel consistency: The consistency of the channel should be ≤ 5%.

8. Test Speed

The numbers for single PT test within 1h shall not be less than 80Ts/h.

9. The preheating time for starting up machine shall not exceed 30 minutes;

10. Temperature Control

The temperature of the reaction system on the detection and incubation thermostats is controlled within the range of 37°C±1°C;

10. Repeatability

Item	CV	
	Normal samples	Abnormal samples
PT(s)	≤3.0%	≤8.0%
APTT(s)	≤4.0%	≤8.0%

FIB(g/L)	≤8.0%	≤15.0%
TT(s)	≤10.0%	≤15.0%
D-dimer (ug/ml)	≤15.0% (0-1ug/ml)	≤10.0% (≥5ug/ml)

12. Measurement Accuracy: The relative bias of the FIB measurement does not exceed ±10.0%; The D-dimer measurement relative bias does not exceed ±15.0%.

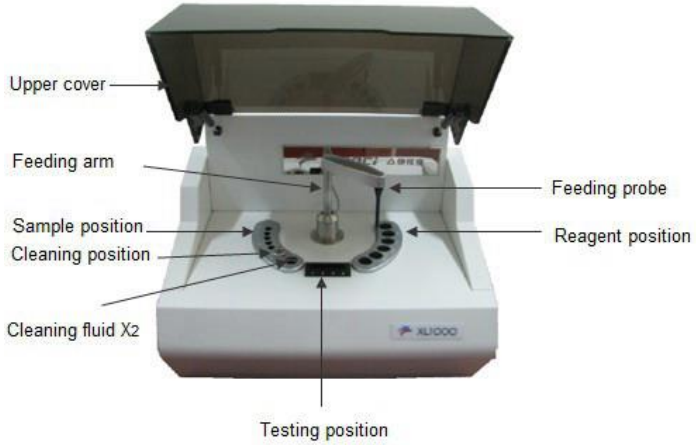
13. Linearity: the linear range of FIB measurement is 1-10g/l and the correlation coefficient is r≥ 0.975.

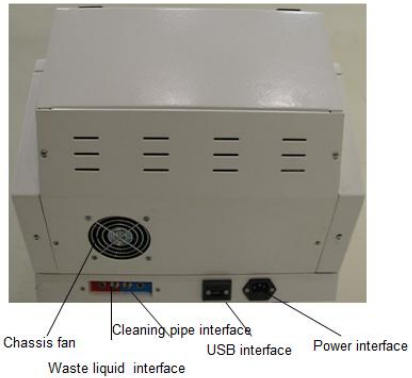
linear range of instrument measuring D-dimer linear range 0-30ug/ml, correlation coefficient r ≥ 0.975.

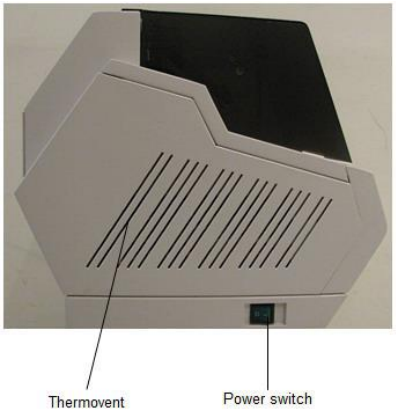
14. continuous working time: not less than 24 hours.

1.3.2 Instrument structure

XL 1000series automatic blood coagulation analyzer is comprised with the sample feeding arm, testing system, reagent loading system, cleaning system, heating & refrigerating system, injection pump system, PC system and printing system as shown below.

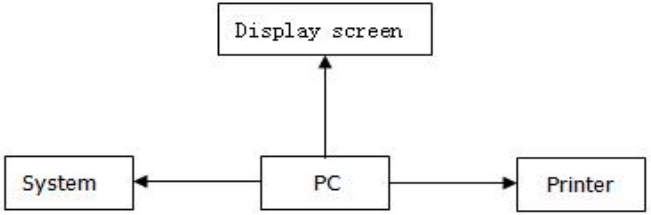



Chassis fan
Waste liquid interface
Cleaning pipe interface
USB interface
Power interface


Thermovent
Power switch

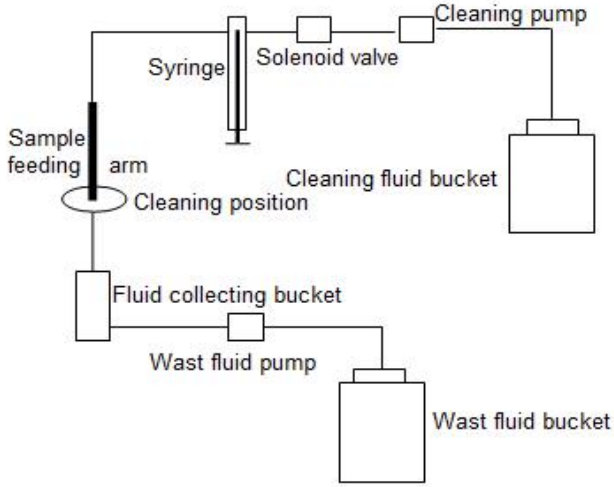
1.3.3 Instrument connection

The system of XL series automatic blood coagulation analyzer is composed of the analyzer, computer, screen and printer.



1.3.4 Pipeline connection

The pipeline system is composed of cleaning pipelines and waste fluid pipelines, as shown below.



Cleaning system consists of cleaning position, solenoid valve, waste fluid pump, flushing pump, cleaning fluid bucket, fluid collecting bucket, and waste fluid bucket.

1.3.5 Basic operating principle

*Sample feeding system consists of micro-syringe, rotating sample feeding arm and 5 sample positions.

While testing is started, the feeding syringe turns to sample position to absorb and then feed test samples. After feeding, the feeding syringe turns to the cleaning position for cleaning.

* Pre-heating system is composed of testing cup pre-heating and temperature controller. The working temperature shall be controlled at 15—30°C for regular running.

* Cooling system: The reagent position cools the reagent at 16℃ by semiconductor.

* Reagent feeding syringe can be controlled at 37℃ continuously and can heat the cooled reagent to 37℃ in a short time.

* Once the testing cup is fed, it will stay at the preheating area for 3 minutes. After the reagent is extracted and fed to the testing cup, the test starts.

* The data will be reported and the test is over if the relative change of the sample's turbidity is up to 50%.The software will prompt the operator to change the testing cup.

1.4 Notes

Before use, read the instruction carefully.

To ensure the reliability of testing results, advise to use the reagent and consumption provided by Zonci.

If the electricity is shut off unexpectedly, the ongoing testing result would lose, finished ones could be saved.

1.4.1 general notes

* Automatic blood coagulation analyzer of XL1000 series can be operated by the person authorized by Beijing Zonci. Please read the instruction carefully and operator the analyzer according it. Beijing Zonci is not responsible for any damage caused by non-compliance to the instruction.

* Before any operation, read the instruction carefully.

1.4.2 notes for biological products be used

For all biological products like reagent, calibration, quality control plasma and patient's plasma, see the notes related to potential pollution.

* Don’t eat, drink and smoke in place of biological products.

* Please wear single-use gloves when use biological products, polluted or hazardous things.

* If your wound of skin or mucosa has contact with the biological products, please sterilize it immediately.

* Dispose the biological products after use according to the medical regulations.

1.4.3 Notes about instrument

* Automatic blood coagulation analyzer of XL1000 series can be operated by the person authorized by Beijing Zonci.

* To avoid electronic shock, the user must comply with the related instruction.

* To ensure the safety, unwanted goods should not be put on operating platform during operating.

* Do not add testing cup, cleaning fluid or sample tube when the feeding arm is working.

* Maintain the instrument pipe several times before using when the unit is not in use for extended periods.

2. Operation of the instrument

2.1 Installation

To obtain a reliable result, it is necessary for Automatic blood coagulation analyzer of XL 1000series

to be operated according to the instruction.

2.1.1 Environment

Temperature 10-30℃

Humidity Not more than 75%

Atmospheric pressure 86.0kPa ~ 106.0kPa；

Keep the instrument away from interfering sources like corrosion and electromagnetism, avoid direct sunlight, and keep ventilation.

2.1.2 Space and Power

Space：height×width×depth＞100cm×120cm×100cm

Power：220V(±10%), 50Hz (±5Hz), 250VA

2.1.3 Requirements and procedure

Automatic blood coagulation analyzer of XL1000 series can be operated by the person

authorized by Beijing Zonci.

* Connect the power cord
* Connect the instrument to computer
* Insert the card reader into the USB interface of the computer.
* Connect inlet and outlet pipes, cleaning fluid, waste fluid buckets

The connectors of inlet and outlet pipes are on the back of the instrument. The red one is for waste liquid and the blue one is for cleaning liquid.

* Before starting, the operator should check whether X1 and X2 cleaning fluid are sufficient.

* After starting, click “reset” and “washing” to conduct the cleaning procedure for feeding syringe.

*Before starting, the operator should check the waste liquid bucket and empty it. The disposal of waste liquid shall comply with the national regulations.

2.2 Starting up

2.2.1 Connection

Connect the power supply and data lines of coagulation analyzer, computer, printer, and turn on the power supply. Login to the testing software of the instrument; if there is no abnormal information and the instrument conduct resetting operation, it shows that all the devices are successfully connected.

If fail connection is reminded on the screen, please check the connection and interface setting.

After the devices are successfully connected, the instrument will conduct resetting operation

automatically.

2.2.2 Reagent preparation.

* Prepare reagents provide by Bejing Zonci according to the use instructions.
* The maximum diameter of reagent bottle is 22mm with a height of less than 45mm.
* Put reagent bottles in relevant positions.

*Estimate reagents dosage of the day according to test quantity and the data below.

Reagent	Dosage/Ts	Dosage of sample
PT Reagent	100ul	50ul
APTT Reagent CaCL2	50ul 50ul	

		50ul
FIB Reagents Buffer Solution	50ul 90ul	10ul
TT Reagents	100ul	100ul

2.2.3 Sample preparation

* Sample position: 5 fixed sample positions which can be used repeatedly.
* Sample tube: standard anticoagulant blood collection tube.
* Anticoagulants selection and dosage: 105-109mmol / L sodium citrate. The ratio of anticoagulants and blood is1:9.
* If patients' hematocrit is above 55% or below 20%, the dosage of anticoagulant should be adjusted. Anticoagulant dosage can be calculated according to the following formula:

  0.00185×Blood Volume（ml）×（100 –Patient's hematocrit）
* The devices, such as testing tubes, pipets and syringes that contact with the blood must be plastic.

* The volume of extracted sample should be more than 2ml.

* Collection of sample

- time: Morning fasting blood。
- Location: Normally vein blood from anterior cubital region
- The blood should be collected by one prick. To avoid hemolysis, platelet aggregation due to stimulation, repeated pricks is forbidden. The blood and blood anticoagulant should be mixed gently.

* Preparation of samples

Centrifuge the mixed anti-coagulation blood at 25℃ -32℃ with the rotate speed of 2000-2500 r / min for about 20 minutes. Put out the sample after the centrifuge stops. (If there is hemolysis, the blood shall be sample again.)

* Storage of samples

The sample should be tested within 4 hours. If the test can't be done immediately, the sample can be preserved for 2 hours at 4℃, two weeks at -20℃ and six weeks at -70℃. Frozen samples should be thawed rapidly at 37 ℃, and tested immediately. Frozen samples may affect the testing results.

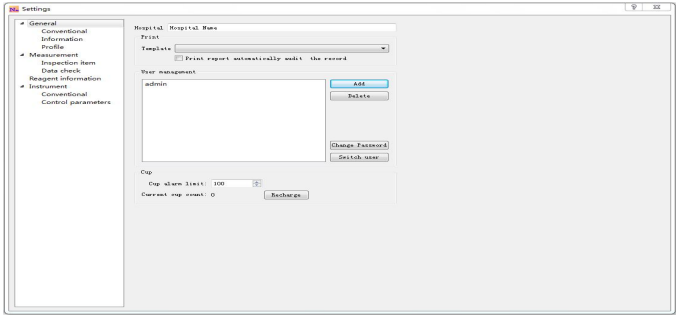
2.2.4 Test Cup loading

* Automatic blood coagulation analyzers of XL1000 series are designed to load the testing cups manually.

* Once the instrument is started, the software will prompt the operator to loading the testing cup. After loading, click OK.

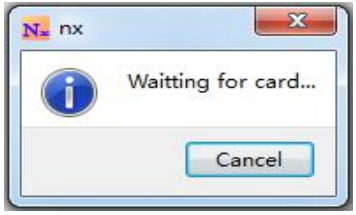
* Testing number shall be input for normal running. The instrument can't perform the testing direction without input of testing number. Click 

to enter the setting interface. Recharge in the regular window as follow.

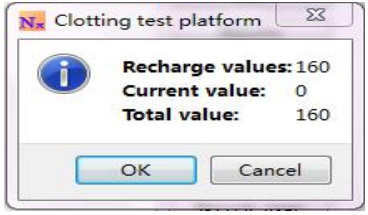


When there are 100 (it can be set by user) left to be tested, there will be a Popup Window for alarm to remind the user to recharge. The user should recharge. Otherwise, if the test number left is zero, the instrument will stop testing.

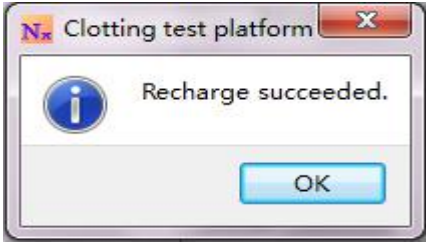
- Click Recharge, there will be a Popup window as follow：



◆ Put the recharge card on the reader. When there is a popup window as follow and a sound of “di”, the information of the card is read.



◆ Click [OK] ，when there is a sound of “di” and there is a popup window as follow，Click [OK] to exit recharge interface. If recharge operation is not needed, click [Cancel] exit。

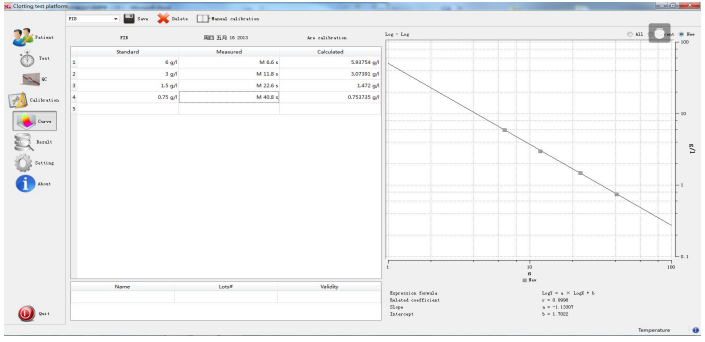


◆If there is a popup window as follow, it shows those recharge fails, click [OK] to recharge again.

◆If there is a popup window as follow when the card is read, it shows that recharge fails.

2.2.5 Standard curve

* View the calibration curve, click  to enter the standard curve interface as follow:



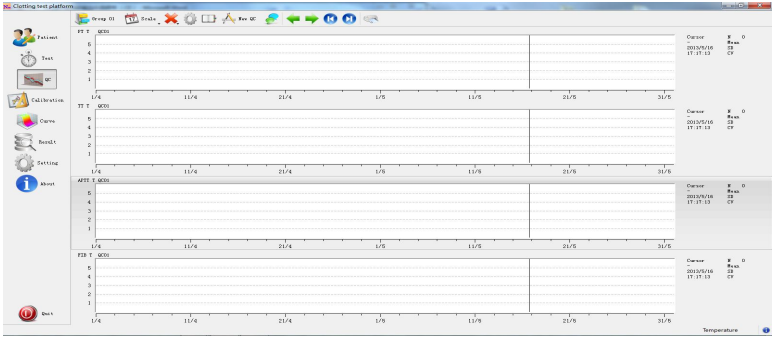
* Click PT to choose the calibration items such as PT, FIB, PT-FIB.
* Click Delete to delete the calibration data.
* Click Save to save the current calibration data.
* Click Manual calibration to input manually when the current calibration curve is revised.
* After each calibration, the operator can enter the curve interface to review the data and curve.

Click Current or New , the current curve and new curve will be shown alternately.
Click All , the current curve and new curve will be shown at the same time.

* ISI value of the reagent is the international sensitivity index for reagents, which is provided by the reagent manufacturer and shown on the reagent container or instruction. The sensitivity of the reagent is perfect if the value is approximately 1. ISI value and PT value are input by operator, the instrument will obtain the patient's PTR and INR value. The PT value is a control value.

2.2.6 Control Chart

* Click  to enter the interface of quality control curve as follow. There will be no more than four control charts at one interface. In order to get reliable data, the quality control is necessary. The data will be saved in quality control folder after quality control analysis.



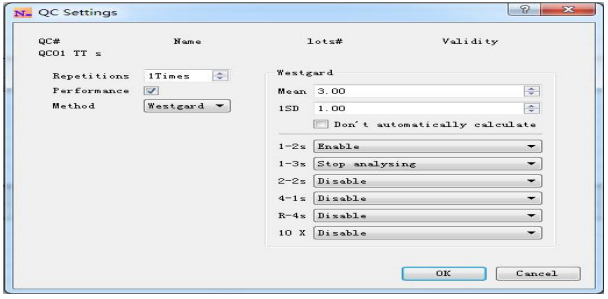
* Click  to choose the quality control combination to be reviewed. As to XL 1000 series, there are 100 combinations quality control combinations, 6 items and 10 quality control files. Unlimited data can be saved for each file.

*Click  to review the quality control result in some stage. Four kinds of period can be chosen, such as one month, two months, three months and all the time.

* Click  to delete the quality control data partly or completely.

* Click  to review the quality control data.

* Click  to set the quality control as follow.



2.3 Turn off

* Conduct the maintenance and cleaning program according to the prompt once day's work is finished.

* Put the reagents to refrigerator.

* Clear waste fluid and clean surface of instrument.

* Close the cover.

* turn off printer, computer, coagulation analyzer power in turn.

2.4 Replacement of cleaning liquid

* Twist-off lid of waste fluid, take the pipe and detector to new cleaning fluid bucket.

* Put the cleaning liquid and detector in to a new bucket.

The waste cups and liquid shall be treated according to the national or local regulations. The replacing method is as same as cleaning liquid.

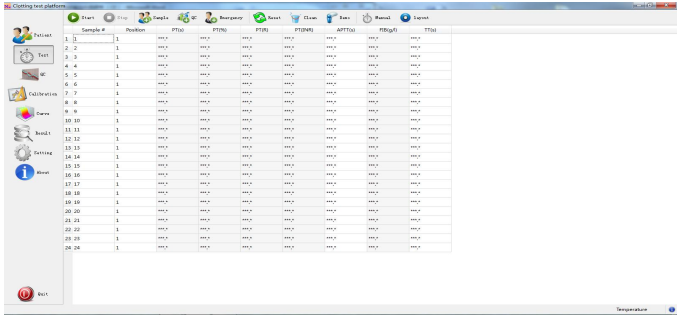
Don't drain the waste liquid into the environment directly.

Collect the waste liquid into a safe container to dispose. It can be burned in a incinerator or buried in an approved position.

3. Testing

3.1 Testing interface

Click the shortcut icon  . After the software is opened, there will be a testing interface as follow:



Explanation：

* Click  to set the testing of patient (See to 3.2).

* Click  to start to test.

* Click  to stop feeding.

* Click  to set quality control.

* Click  to set emergency testing。

* Click  to system reset; include the feeding arms and syringes.

* Click  to clean the feeding syringes. The pumps of waste liquid and cleaning liquid start to work to remove the waste liquid from the collecting bucket to a special bucket for waste bucket.

* Click  to demonstrate the testing process. The syringe doesn't work.

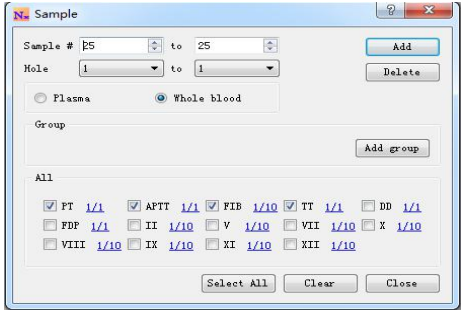
* Click  to enter the manual testing mode. In this mode, only the testing parts of the instrument work.

There is a window for temperature display in the lower right corner of the testing interface. The temperature display flashes in red during 30 minutes preheating. Test can't be done. When the temperature reaches to the set value, the display stops flashing and test can be done.

3.2 Testing setting

3.2.1 Batch tests

Click  to enter setting interface as follow:



* Put the centrifuged plasma into the sample position（5 test tubes can be placed at one time）.

* Put the reagent into the reagent position.

* Set position number, sample number and testing items in the dialog box.

* Setting of sample number：Input the initial number and last number of the samples. The

sample number can't be set repeatedly for each day.

* The initial number and last number of the positions shall be homologous with the sample numbers. 5 test tubes can be placed at one time.

* Select the testing mode, plasma testing or whole blood testing.

* Select the item to be tested.

* Click Add group to enter the setting interface; and click Close to exit.

* Check the information set. The sample number can't be duplicated each day.

* Click Start to start testing.

Software can be edited on project team.

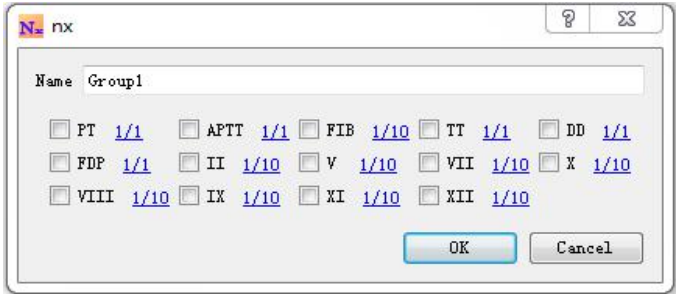
* Click Add group ; there will be a popup window as follow. Click☐ before the item to select.

* Click Close to cancel.

* Click OK to shut off the dialog box.

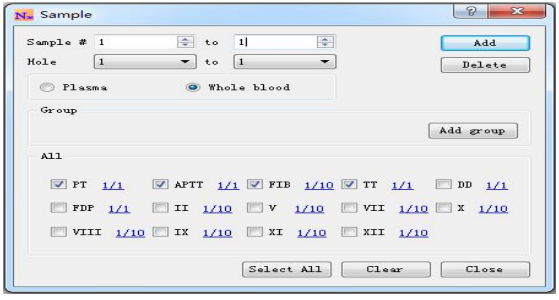
Revision of item combination：

* Click Modify ; there will be a popup window as follow. Click ☐ before the item to select the item again.



3.2.2 Single test

* Put the centrifuged plasma into the sample position.
* Put the reagent into the fixed reagent position.
* Set position number, sample number and testing items in the dialog box.
* Setting of sample number: input the sample number. The sample number shall be single for each day.



* Select the item to be tested.

The user can set combination of testing items. Click combination Add to select or click to select testing item.

* Click Add , all the information is displayed on the testing interface. Click Close to exit.
* Check the information set. The sample number can't be duplicated each day.
* Click Start to start testing.

3.3 Emergency treatment

Click 

to go to Emergency interface. The sample number for Emergency is S1, S2, and S3... Emergency test is given top priority.

Once the emergency testing is running, the feeding arms will feed the sample of emergency. Other testing will be done after the emergency testing.

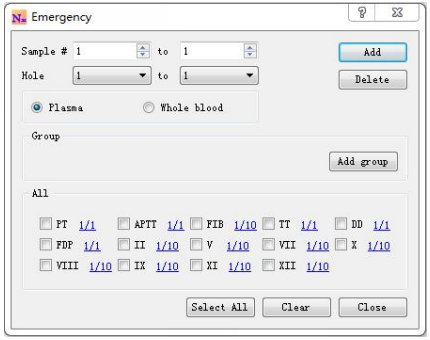
Input sample number and hole site number of emergency, choose the item combination, then click “add”.

Setting of emergency treatment：

* Put the centrifuged plasma into any position of sample tray.
* Click 

and there will be a popup window as follow.
* Input the sample number.
* Input the position number.
* Select the item combination.

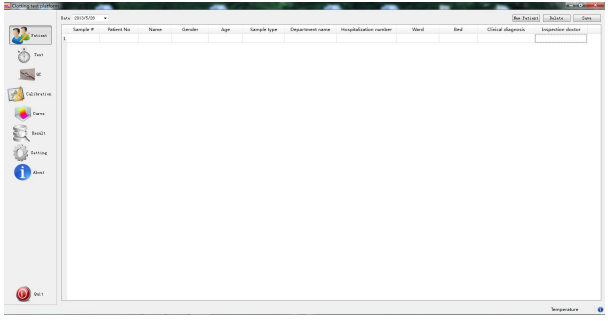
* Click 、 to complete the setting.



3.4 Information input：

Click 

to view the input window as follow. The patients' information can be input in this window and they will be displayed on the report.



Input method of information：

* Input year, month and date in the date column as follow. Click ← or → to choose.

* Click New Patient or N ， the sample number will increase automatic.

* Input the patient's information such as name, number, sex, age etc.

* Click Save or S ， the information will be displayed in the statistic chart.

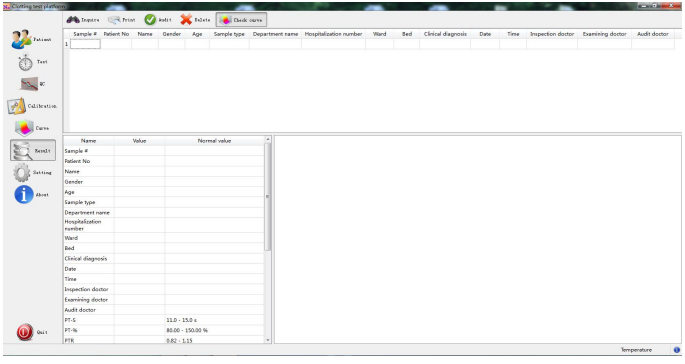
* Click Delete or D to delete the information.

* Click New Patient or N to input the information of the next patient.

* Click New Patient or N， the sample number will increase automatic.

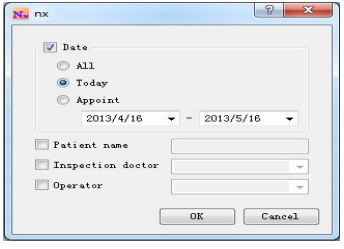
3.5 Result

Click Result to the saving interface. In this interface, you can review the result, print and check the curve.



3.5.1Results

In the result interface, click  ; and there will be a popup window as follow.



All：all the results

Today：results of today

Appointed：Input the appointed date and click OK, the results of the date will be displayed.

Patient name: Inquire according to the patient name.

Inspection doctor: Inquire according to the inspection doctor.

Operator ：Inquire according to the operator.

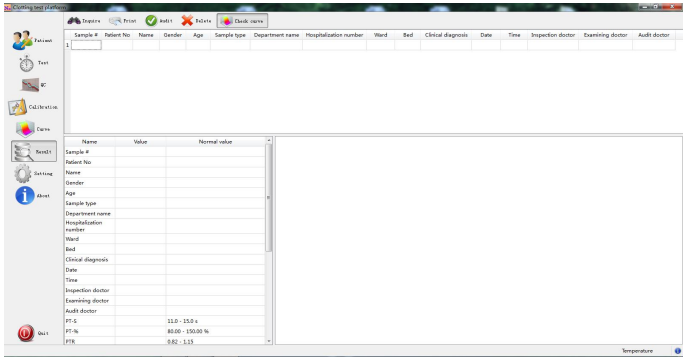
3.5.2 Printing

The results can be printed in the result interface.

Click 

to print a single result.

Batch printing：Select the option of batch printing. Select the first result, and press “ shift”, then select the last result. All the results to be printed are selected.

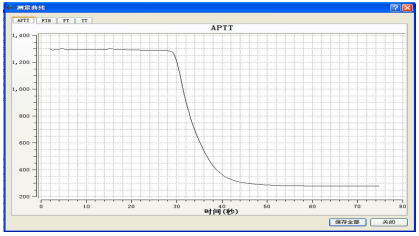


3.5.3 Review of coagulation curve

After choosing patient's testing result, click  to view the curve as follow:

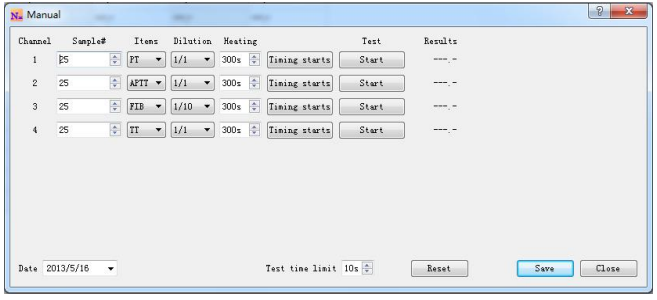
* Select the different options, the curve will change.

* Click save, the curve will be saved.



3.6Manual testing

When the automatic feeding arms can't work, the manual testing mode can be started. In this mode, the operator can test manually. The testing results can be input to the database and be printed.



Explanation:

Channel: Number of testing route.

Sample: Number of sample to be tested.

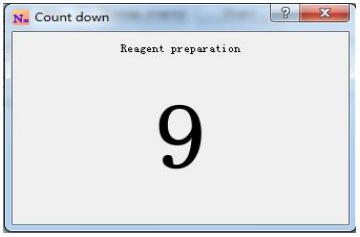
Items：To select the item to be tested in the pull-down menu.

Dilution: Whether the item needs diluted or selects the dilution ratio. 1/1 is not diluted.

Heating：Time setting of pre-heating.

Time starting ：Click Timing starts to start the clock of pre-heating.

Testing：Click Start ，to countdown for testing. As follow, 10 seconds is set. When countdown ends, the alarm will make a sound of “du”.



Result ： Testing data of each route.

Testing time ： Time of sample tested.

Reset：If the testing result of some route can't be accepted, click 

to test again.

Save：After the testing of one sample is completed, click 

to save the result.

Close：Click 

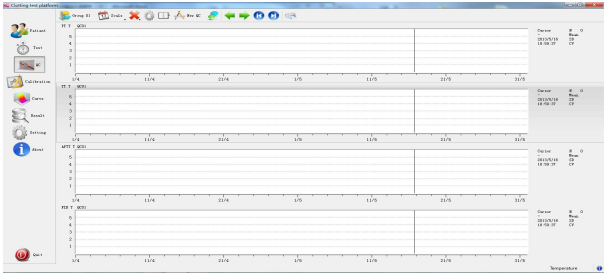
to exit the interface of manual testing.

While adding reagents, do not touch testing cups. Add reagents quickly and accurately.

4. Quality Control

4.1 Brief introduction

To obtain reliable analytical data, quality control analysis is necessary. Once quality control testing is finished, click  to the review interface. Four quality control charts can be displayed in on interface at most as follow.

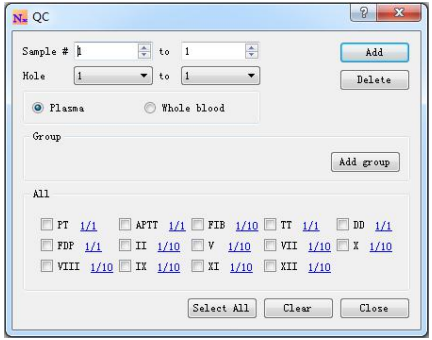


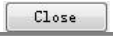
Interface description:

* Quality control combination 
* The Time Group 
* Delete 
* Quality control settings 
* Choose quality control data 
* View new quality control data 
* Switch quality control lot number 
* Choose the data point 
* Page up or page dowr 
* Print quality control data 

4.2 Running of quality control

Click  in the testing interface, and there will be a popup dialog box as follow:



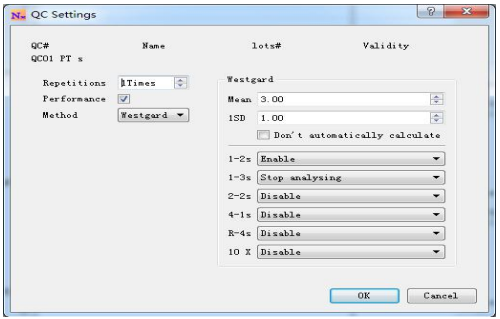
* Put quality control samples in any sample position.
* Input quality control sample No.
* Input the sample position No.
* Choose quality control items (single or combination)
* Click  to add the chosen items to the testing interface.
* Click  to exit the dialog.

* Check the testing cup.
* Click Start to start the quality control testing.

4.3 Quality control parameter settings

Only after the quality control is set, the function of quality control can be performed. The quality control can't be performed if the set is not completed.

Click QC to the quality control interface. Then click , the quality control setting window will pop up as follow. The related information of quality control can be input in this interface. If the information can't be input completely, the information will not be displayed in the window.



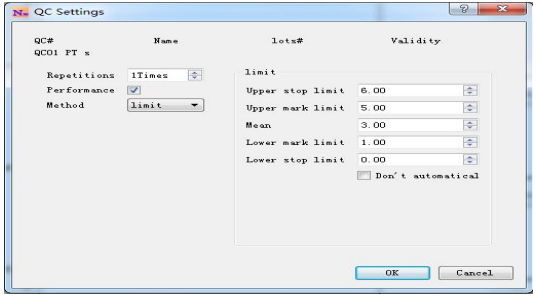
In this interface, the quality control function can be set. Control is divided into two types: multi-rule control and limits control.

4.4 check of error information

Two checking ways of quality control, such as limits control mode and multi-rules mode, can be selected in the setting dialog box.

4.4.1 Limit control mode

This inspecting way is to control by upper/lower limit as follow. In the dialog box, the target value is the reference. The marking limit and stopping limit can be set according to SD value by the operator. If the quality control result is beyond marking limit, the result will be marked; if the quality control result is beyond stopping limit, the test will be stopped. The reasons for abnormal value may include expired quality control samples, expired reagents or instrument error.



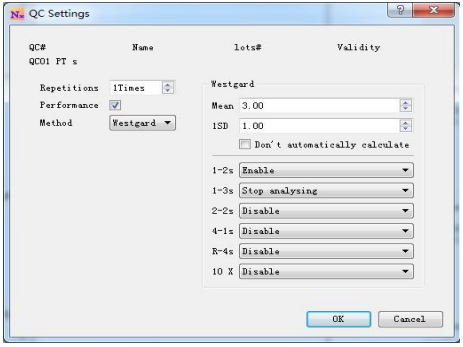
Inspection of quality control results, based on control conditions set as below:

Control conditions	Inspection ways
Upper stopping limit	The instrument stops analyzing if the quality control result exceeds this value
Upper marking limit	Quality control result will be marked if it exceeds this value
Target value	The target value of quality control
Lower marking limit	Quality control result will be marked if it exceeds this value
Lower stopping limit	The instrument stops analyzing if the quality control result exceeds this value

4.4.2 Multi-rules mode

Quality control inspection is based on average value and SD (Standard deviation). The average

value is target value of quality control.

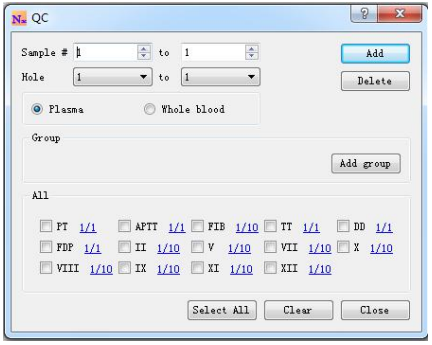


The target values in the below chart are the average values. The inspection ways and rules are as below:

Rules	Inspection ways
1-2s	Unit quality control result exceeds the range of ± 2SD
1-3s	Unit quality control result exceeds the range of ± 23D
2-2s	2 consecutive quality control results exceed the range of ± 2SD
4-1s	4 consecutive quality control results exceed the range of ± 1SD
R-4s	The Current quality control result is beyond 4SD compared with previous results
10x	10 consecutive quality control results are located at the same side of average value

4.5 Quality Control Analysis

Click  in the testing interface to quality control setting window. In this interface, the quality control sample can be set as follow:



Quality control analysis operating processes:

* Put the dissolved quality control plasma in the tube, and then put the tube in any position of the sample tray.

* Check whether the reagents are sufficient for quality control test.
* Check if the cleaning fluid is sufficient, if the waste fluid bucket is full.
* Click  to set quality control items.
* Select plasma mode.

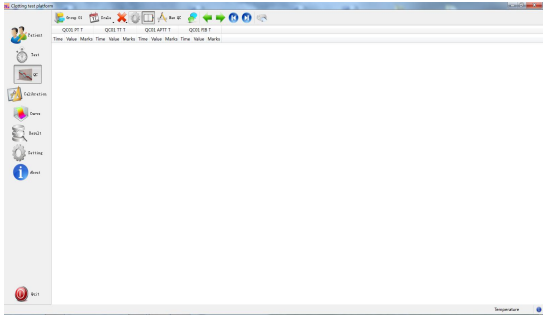
* Click  , the testing items will be displayed.
* Click  to exit settings.
* Click  , to start quality control analysis. Results will be saved in quality control files.

4.6 Quality control data query

Select  in the main interface to enter the interface of quality control charts. Then click to the interface of the quality control date querying. In this interface, all the quality control data can be reviewed as follow:

* Click  to select the quality control combination.
* Click  to select the quality control time.
* Click  to display the quality control data.

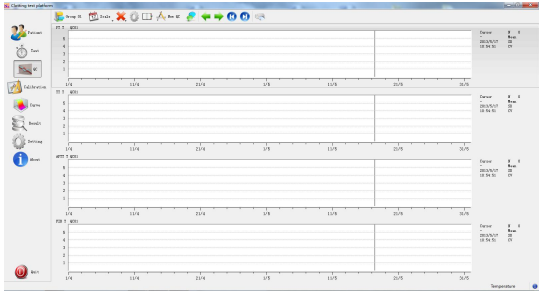
* Click  to display the new quality control data.



4.7 Quality control chart

Click  to view the quality control window. Four kinds of quality control charts could be displayed each screen at most. The cursor line in the quality control chart can move. Relevant

information is displayed at right side of the chart, such as quality control time, type, average value, SD and CV value.



Control limit, Cursor, quality control data graph, quality control data are displayed in quality control chart.

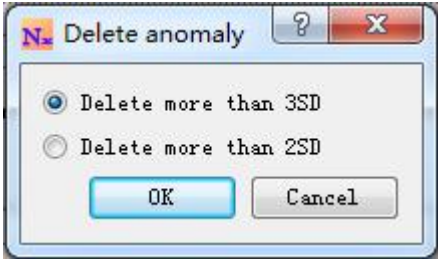
* Control limit: set according to target value.
* Cursor: move around to select the graphic interval.
* Quality control data chart: Previous data for quality control.
* N: number of repetitions

* Mean: quality control target value
* SD: standard deviation of quality control results
* CV: coefficient of variation of quality control results

4.8Deletion of quality control

By this function key, the quality control data can be deleted according to the demand of user.

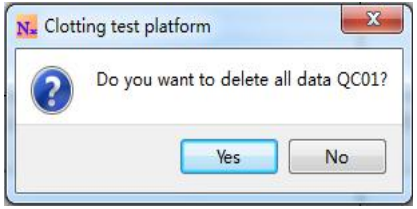
In quality control chart window, click , the window for details of deletion will pop up. There are three options: abnormal data, all data and appointed data. Click abnormal data, a window will pop up as follow.



Select Delete more than 3SD， and click OK， the data that exceed 3SD will be deleted.

Select Delete more than 2SD , and click OK, the data that exceed 2SD will be deleted.

* Click all data, a window as follow will pop up.



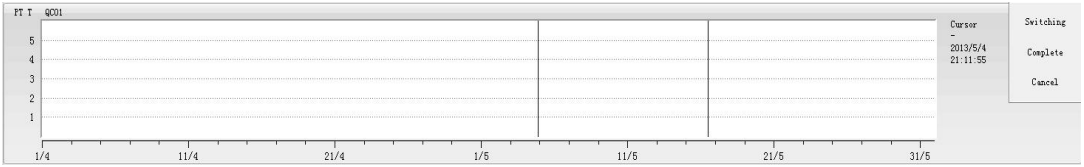
Click Yes , all quality control data of QC01will be deleted.

* Select quality control chart and click the appointed data, a moving cursor will appear on the chart.

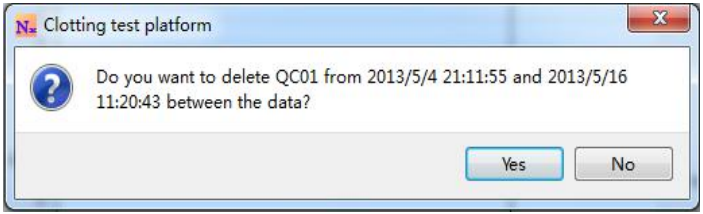
* Cursor conversion: two cursors will converse.

* Completion

* Cancel：Cancel the selected target and the window will shut off.



Select the object and click OK, a window as follow will pop up. It can be done according to the demand of user.



The appointed data can be deleted according to the demand of user. After the data of some

period is deleted, other data will move forward.

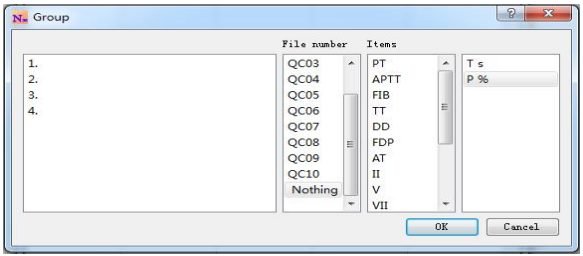
4.9 Edition of quality control group

Click 

to edit the quality control group. At most 100 groups are displayed in this editing window.

Editing procedure:

* Click the group number, a window as below will pop up.



* Select No.1, click the file number in the column and select the item number.

* Select unit and the unit selected will be displayed after the item.

* Repeat the operation above.

* Click OK , the set quality control files will be displayed in the window.

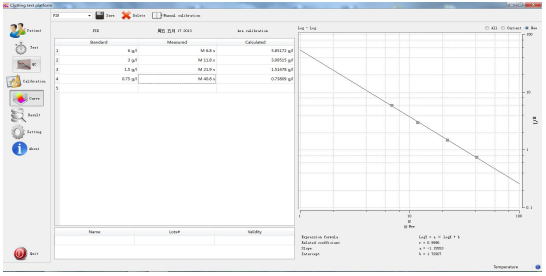
Units available for choosing:

PT	T represents time, s,	P represents degree of activity %
APTT	T represents time, s	
TT	T represents time, s	
FIB	T represents time, s	P represents content g/l or mg/dl
D-D	OD represents absorbance	P represents content ug/ml 或 ng/ml
FDP	OD represents absorbance	P represents content ug/ml
AT	OD represents absorbance	P represents content %
Factor	T represents time, s	P represents degree of activity %

5. Standard curve

5.1 Brief introduction

Click  in the main interface to open quality control curve window. Operators can review or modify the standard curve.



Click function keys to complete corresponding operation:

* Click FIB to select curve
* Click Save to save the curve
* Click Delete to delete curve
* Click Manual calibration to input manually.
* Click All to display all the curves.
* Click Current to display the current curve.
* Click New to display the new curve.

The information shown in the window includes the following contents.

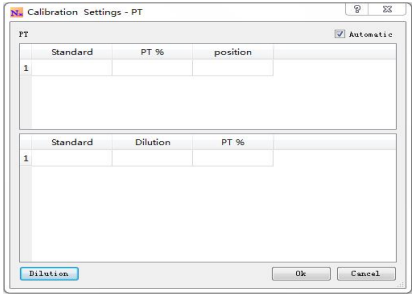
* Items: items curves available to be chosen.
* Time: Establishing time of the curve.
* Related value of the current curve: standard value, measured value, calculated value.
* ISI: International sensitivity index of PT reagent.
* Normal reference value: PT testing result of normal reference plasma.
* The name, lot number, validity of calibration plasma.
* Curve equation: logy=alogx+b

* r= Correlation coefficient
* a= Slope of the curve
* b= Intercept of the curve

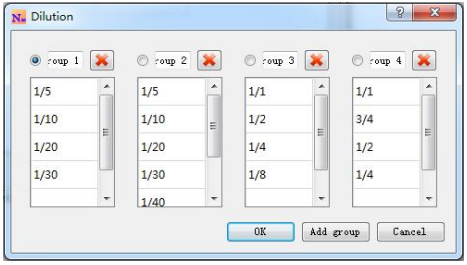
5.2 Curve Settings

The calibration of XL1000 automatic coagulation analyzer includes PT activity, FIB derived from PT, FIB calibration. The analyzer can be calibrated by the user.

Click Setting in item setting window, the setting window for the selected item will pop up. Below is setting window of PT%.

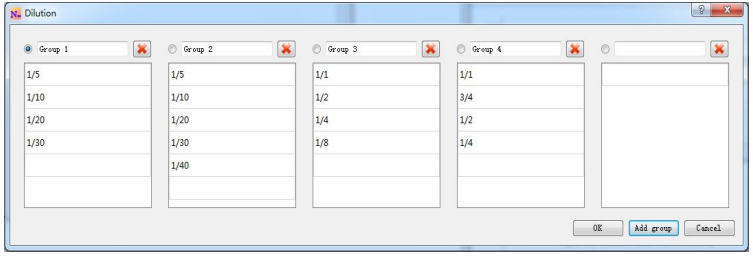


The settings of PT% curves are divided into automatic dilution and manual dilution. In the automatic dilution mode, click Dilution to select dilution ratio as follow.



In the dialog box of dilution ratio, after the dilution ration is selected, click OK , the gradient will be displayed in the window. And the related calculation can be performed automatic.

In the chart above, click Add group to add the dilution ratio, and a window as follow will pop up.In this window, after the dilution ratio is input, click OK to save the ratio or click Cancel to shut off the window. The added dilution ratio will be saved in the window.



Procedure to add dilution gradient

* Input the No. of dilution gradient in column Group5

* Select the dilution ratio in the space below.

* Input the dilution ration continuously.

* Click 

to save the added dilution ration gradient.

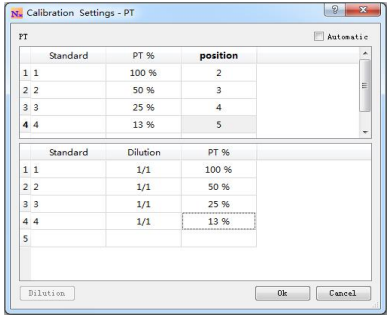
* Click  to delete the added dilution ration gradient.

* Click 

to shut off the window.

5.2.1 Manual dilution

Select manual dilution mode, then put the diluted plasma in specified position in the sample tray. Select dilution ratio of 1/1, which means no dilution.



Standard represents 5 standard samples in five different concentrations; position represents the position for the five standard samples on the tray. Dilution 1/1 means no dilution. Repeat time represents number of measurements for each concentration.

Procedure：

* Click the input box under Standard to select the number of standard sample.

* Click the input box under PT%, enter the diluted concentration, 100% represents the original plasma.

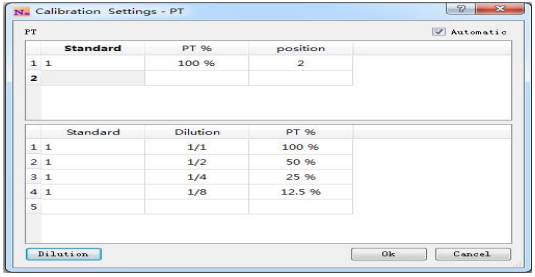
* Click the input box under Position, enter the position of diluted standard sample.

Move the mouse to the input table below:

* Click the input box under Standard to select the number of standard sample.
* Click the input box under dilution, select1/1, which means no dilution.
* Click the input box under PT%, enter the diluted concentration.
* Click the input box below Repeat time to enter the number of measurements for each standard sample.
* Save the settings.
* Put five diluted standard samples in Specified position in sample tray and click Add .
* Click Close to exit the setting window.
* Click Start to start PT% calibration.

5.2.2 Automatic Dilution

Choose Automatic Dilution mode, then put standard samples in specified positions in the sample tray. Define the number of standard sample, of which the concentration is 100%. Select dilution ratio in the dilution gradient, click ok to save settings.

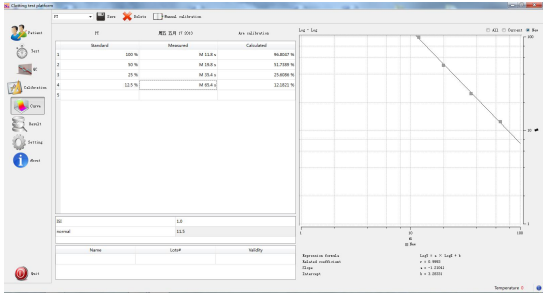


Procedure：

* Once dilution ratio is set, click Ok to exit the window.
* Put the dilution cup in specified position in the sample tray, and click Add .
* Click Close to exit the setting window.
* Click Start to start PT% calibration.

5.2.3 Manual Calibration

Click Curve in main interface, and then select Manual calibration to view the manual input window as follow.



Procedure of manual Input：

* Click PT to select calibration item.
* Click the input box under Standard value , input the value of the first standard sample.
* Input the first coagulation time.
* Input value and coagulation time of second, third, fourth, fifth standard sample in turn.
* After the value and coagulation time of the second sample is input, there will be two points in one coordinate.
* There will be a more point as per standard sample. The coagulation time can be revised in the coordinate.
* After input, view the standard curve. It is can be accepted if r> 0.975.

* Click Save to save changes. The current curve will be covered by the new curve.

5.3 Standard Curve Analysis

The calibration curve of series XL1000 automatic blood coagulation analyzer can be done automatic. After the item is set; exit the setting window to the calibration window, and click , then Start calibration procedure will run automatic. The results will be saved in calibration files automatic and standard curves will be established.

5.3.1 Operation

Exit setting window when calibration settings are finished. Follow the instructions below:

For manual dilution:

* Dilute calibration plasma manually according to the concentration being set.
* Put diluted calibration plasma in specified position of sample tray.
* Check the remaining reagents.
* Check the position of diluted plasma again.
* Click Start and start calibration program.

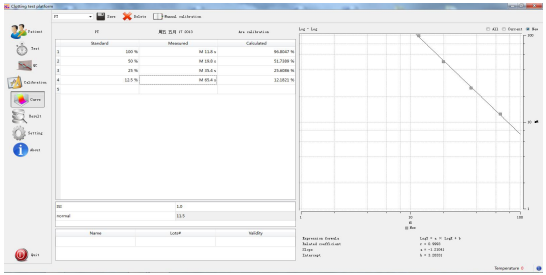
For automatic dilution:

* Put calibration plasma in specified position in sample tray.
* Check remaining reagents and buffer solution.

* Check the position of diluted plasma again.
* Click Start and start calibration program.

5.3.2 Review standard curve

After the calibration is completed, the calibration result can be review. Click Curve in the main interface, the curve window will pop up. Select items in pop up window and the related curves will be displayed as follow.



Click PT to review the curve. Then click New to switch to a new curve. The correlation coefficient of curve, r below the coordinate is the criteria to determine whether the curve can be accepted. The curve is accepted when r > 0.975.

5.3.3 Saving

A new standard curve can be accepted if it is acceptable.

If one curve can be accepted after review, click 

. The current curve will be replaced by the new curve.

5.3.4 Deletion

Delete the new curve if it is unacceptable. Make new standard curve again. Click 

to delete the new curve.

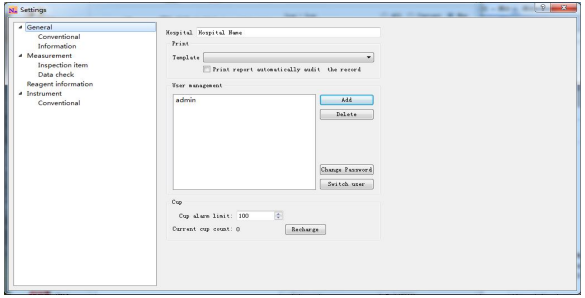
6. Settings

6.1. Common settings

To ensure the normal running of the analyzer, it is very important to set it properly.

Click 

to go to setting interface as follow.



6.1.1 General settings

Input hospital name in General Settings, the name will be displayed on printed report.

For example: XXX Hospital

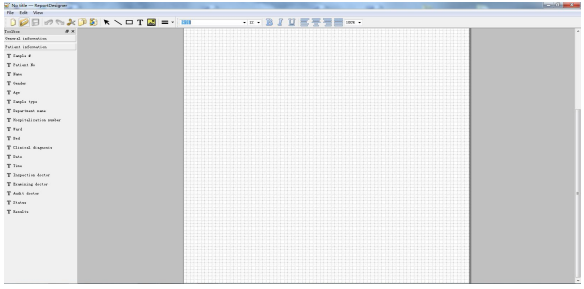
User-defined report format:

The report of series XL1000 automatic blood coagulation analyzer can be defined according to the habit of user.

Setting procedure:

Open folder ReportDesigner , and there will be a popup window as below.

Click the information of patient, the report setting content will pop up. The user can move the selected item by click the item. The format of the report can be designed by the user.



After design, the report can be named and saved as a template.

Recharge of testing cups

See 2.2.4.

6.1.2 Information Database：

The information database is convenient for the user to input the patients' information. When inputting information, the patients' information can be selected according to window.

Patient's information can be input in advance so that it is convenient for operating.

The information inputting window is as follow:

Select type in 

,

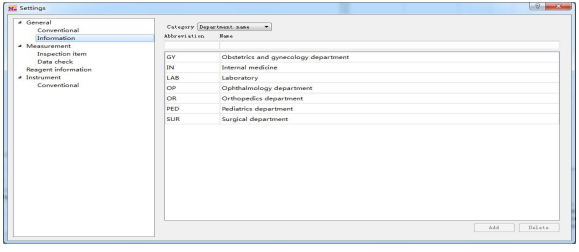
Input the abbreviate name of type in capital letter.

Input the type name in column of name.

Click 

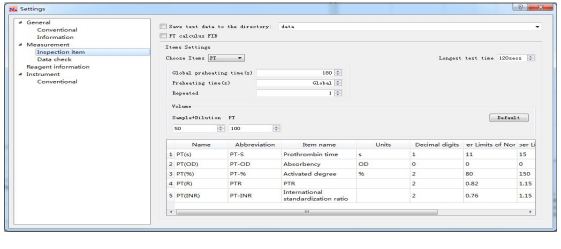
to add input column. Click 

, the information can be inputted again.



6.2 Testing

Click “Test” in the setting interface, the interface will change to a window as follow.



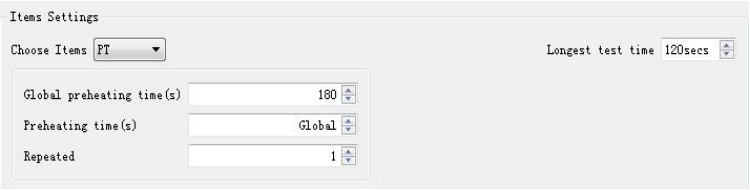
6.2.1 Testing items：

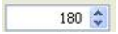
All testing results will be saved in folder “data” if the testing results are saved to catalogue

"data". If the FIB is set to be derived from PT, FIB will not be tested; the instrument can get derivative FIB during PT testing.

The preheating time, repetitions, maximum testing time can also be set.

In the following window, the testing items can be set.



Click  to select item. Click  to set pre-heating temperature.

Input the testing times by clicking 

	Name	Abbreviation	Item name	Units	Decimal digits	er Limits of Nor	er Li
1	PT(s)	PT-S	Prothrombin time	s	1	11	15
2	PT(OD)	PT-OD	Absorbency	OD	0	0	0
3	PT(%)	PT-%	Activated degree	%	2	80	150
4	PT(R)	PTR	PTR		2	0.82	1.15
5	PT(INR)	PT-INR	International standardization ratio		2	0.76	1.15

The upper limit and lower limit inputted can be displayed in the report.

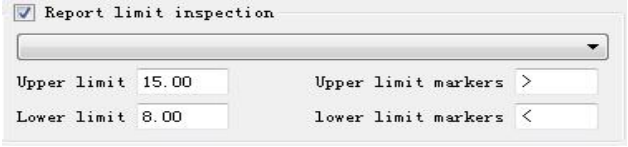
6.2.2 Data inspection：

Select data checking, click 

to select items.

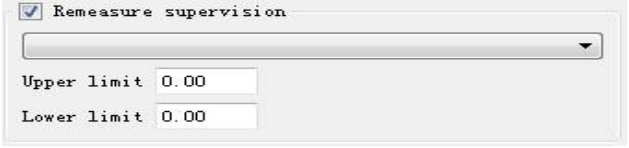
Report limits check：

If the testing results exceed the report limit, "<" ">" will be marked on report.



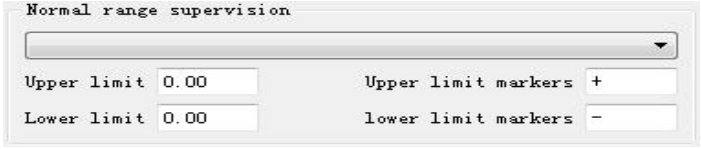
Re-test check:

If the testing results exceed normal value, the instrument will re-test automatically if re-test limits are set.



Scope check of normal value:

If the testing results exceed set normal limits, "+" "-" will be marked in front of testing result.



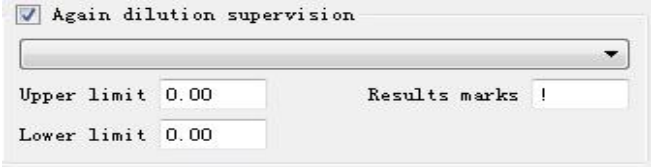
Again dilution check：

XL1000 series automatic blood coagulation analyzer dilutes plasma at ratio of 1:10 when FIB is tested. The linear range of test result is 1—10g/l

There are two kinds of dilution definitions if FIB test result is less than 1g/l or more than 10g/l

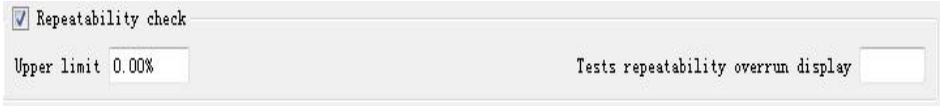
If again dilution inspection is set for FIB, when the test result is less 1g/l, the instrument retests at dilution ratio of 1:5, result is divided by 2 for reporting. When test result is more than 10g/l, instrument retests at dilution ratio of 1:20, result is multiplied 2 for reporting

If again dilution inspection is not set for FIB, when the test result is less than1g/l or more than 10g/l, the operator can choose new dilution ratio to test. The instrument converts the result at 1:10 to report. The result will be marked with “！”



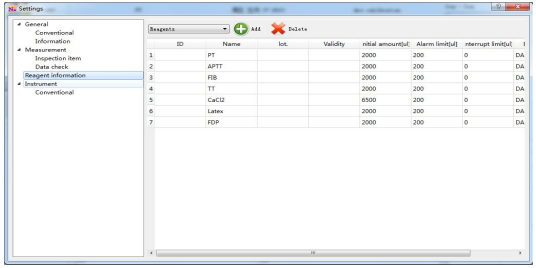
Repetition check:

If the repetition limits is set for testing result, it will be marked in the report when multiple testing results exceed the limits. Limits definition: the ratio of difference and average value between two tests.



6.3 Reagent Information：

In this interface, user can input the information of reagent. The following items of reagent can be set.



I D：Reagent number

Name：Name of reagent

LOT No.：Lot number of reagent

EXP date：EXP date of reagent

Initial volume：Loading volume of reagent

Alarming limit：Reagent volume of alarming

Interruption volume：Reagent volume of interruption

Type of bottles：Type of reagent bottle

Setting procedure：

* Click 

，and there will be a popup window. Select the reagent name to be set.

* Click 

，and the input frame will pop up. Input the ID No., name, Lot No., expiry data, initial volume, alarming limits, stopping limit and bottle type of reagent.

* While the information of QC plasma is input, the type of quality control shall be input, such as normal QC （N）, abnormal QC （P）. The QC No. shall be input such as QC01etc.

* Click 

to delete the input frame。

7. Maintenance and repair

7.1 Daily maintenance

* Daily maintenance of pipeline

Start pipeline cleaning program after the whole day work.

* Check the cleaning fluid and drain the waste liquid

Before starting the instrument, check whether the cleaning liquid is enough for use of the same day and supplement the cleaning liquid. Check whether the waste liquid bucket is empty.

Wear rubber gloves when pouring waste fluid. Then wash hands with disinfection solution. Medical sewage should be treated in accordance with relevant provisions.

* Cleaning of feeding pinhead

Start syringe-cleaning program after the whole day work. If there are stains out of the syringe, clean the sample tray with wet cotton.

* Cleaning of the sample tray with cotton swabs

After the whole day work, clean the sample tray with moistened cotton swabs.

* Cleaning of condensate water in reagent cooling position.

When the temperature of reagent position is kept below 16℃, condensate water may be produced.

After the whole day work, clean the condensate water with cotton balls.

* Cleaning of the instrument surface with wet cotton

After the whole day work, clean the surface of instrument with wet cotton.

Don't clean the pinhead, sample tray and surface of instrument with corrosive liquid.

Wear rubber gloves when cleaning waste cup. Then wash hands with disinfection solution. It should be treated in accordance with relevant provisions.

7.2 Weekly maintenance and inspections

* Maintenance of pipelines

Inspect whether the pipeline is jammed and whether there is sediment in the cleaning bucket. Check whether the alarming system works well and whether there is leakage in the pipeline.

* Check whether the feeding syringe is blocked.

When the syringe is cleaned, observe whether the cleaning liquid is unblocked. If the pinhole is blocked, unblock it with a steel wire （φ0.5）and re-clean it.

Wear rubber gloves when cleaning the syringe. Wash hands with disinfectant after cleaning. When cleaning the pin of feeding syringe, take care of your fingers.

* Cleaning of holes for testing cups

* Clean the holes for testing cups with wet cotton balls after the whole day work. Remove the

Check if the syringe is blocked. Clear it first if blocked.

Clean testing cup trough with wet cotton. Remove the particles left in the holes to avoid blocking the running of testing cups.

* Maintenance of feeding syringe:

click  to start syringe cleaning program.

7.3 Common trouble shooting

Fault	Causes and solutions
Failed to connect	1、Check whether the power supply is on. 2、Check whether the connection of 232 is normal. 3、Check whether the communication ports of the software are set correctly. 4、Contact the local authorized engineer.
Inlet, outlet fault	1、Contact authorized engineers if the flushing pump does not work. 2、Contact authorized engineers if the waste fluid pump does not work. 3、Check whether the pipe is blocked, or whether the plug is sloughing when no cleaning fluid outflows from the syringe. 4、If the waste fluid pump is working without waste fluid outflowing, check whether the pipe is blocked, or whether the plug is sloughing 5、If the pump is working properly, but there is no cleaning fluid in the pipeline, conduct the cleaning program. 6、In life, drainage pipe shall not exceed 12 months, within this range should be replaced by manufacture or the local authorized engineer once a year.

Fault	Causes and solutions
Liquid sensor fault	1、The pinhead of syringe contact the bottom of the bottle. 2、The volume of sample is less than 3ml. 3、The detecting board failure or connecting fault 4、Contact the local authorized engineer.

Testing results fault	1、 The feeding syringe can't be washed normally. Check the specimen of cleaning system. The sample wasn't centrifuged enough and the sample volume was not enough or there was coagulation. 2、 Check whether the reagent is contaminated, invalid, wrong solvent or whether the reagent is placed properly. 3、 The volume of feeding is not enough due to the bubbles in the cleaning pipes. 4、 Test panel fault, testing route fault or temperature controller fault. 5、 Abnormal specimen. 6、 Contact the local authorized engineer.

Feeding fault	1、 The volume of plasma or samples is not correct due to the leakage of connecting pipes. 2、 The plasma or reagent can't be sucked because of fall-off of connecting pipes. 3、 The syringe doesn't work. 4、 Contact the local authorized engineer.

Other fault	1、The power line is not connected. Connect the power line. 2、The power outlet has no electricity. Replace the outlet. 3、The fuse of power supply blew. Replace the fuse. 4、Communication error. Far away from the electromagnetic radiation. 5、The environmental temperature shall be kept at10-30°C. 6、The main engine shall be grounded. 7、Contact the local authorized engineer.

7.4 Important notes

The equipment complies with the emission and immunity requirements described in the IEC61326-1 and IEC 61326-2-6.

The user should be ensuring that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

The electromagnetic environment should be evaluated prior to operation of the automatic blood coagulation analyzer.

Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

8. Transport storage

The automatic coagulation analyzer should be stored at -20 ° C ～ 55 ° C in the state of transport and storage, and the relative humidity should not exceed 85%. It should be transported without corrosive gas and in a well-ventilated environment.

During the transmission, it must be protected from severe impact, rain, and sun exposure.

9. Service Life

product life: 10 years from the date of installation

production date: see the instrument’s nameplate

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