OPERATING MANUAL

LABSTAC

AUTO COAGULATION ANALYZER

ANA59-5SP

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INDEX

1. Summary

1.1 Purpose and components

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; 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 transfering unit.

1.2 Testing principle

1.2.1 Nephelometry

The absorbance changes during coagulation of the specimen. It is weak, 0% at the moment of plasma and reagent mixed, getting stronger while the fibrin clot is generated. When the specimen is entirely congealed, the absorbance is the strongest, 100%. Here the coagulation time is set, corresponds to the point 50% on the curve.

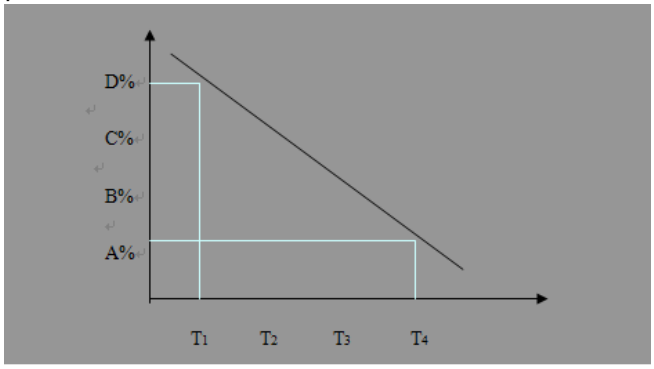


Figure 1
T1, T2, T3, T4, represents coagulation time, A%, B%, C%, D% is for activity

1.2.2 Derived FIB

FIB’s density is calculated by the difference value of absorbance in start and end points of the coagulation. Before testing, calibration curve of FIB density--absorbance is required.

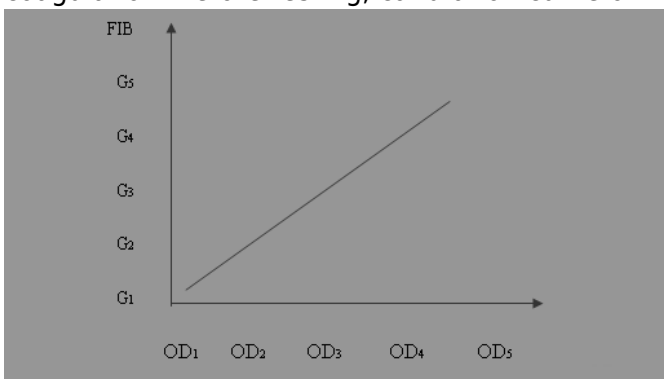


Figure 2
OD1, OD2, OD3, OD4, OD5 represent absorbance
G1, G2, G3, G4, G5 represent FIB density

1.3 Instrument Overview

1.3.1 System description

Automatic blood coagulation analyzer, with 5 sample positions,
Refrigerated position of reagent. Feeding probe with heating function. Every reagent position is strictly defined. One cleaning position.
Test cups are hand loading, one group of test cups can be loaded at one time. Under batch tests mode. the instrument will prompt to replace test cups after one test is finished.

1.3.2 Instrument structure

The sample feeding system, testing system, reagent position, cleaning system, heating & refrigerating system, injection pump system, PC system, print system comprise the automatic blood coagulation analyzer.

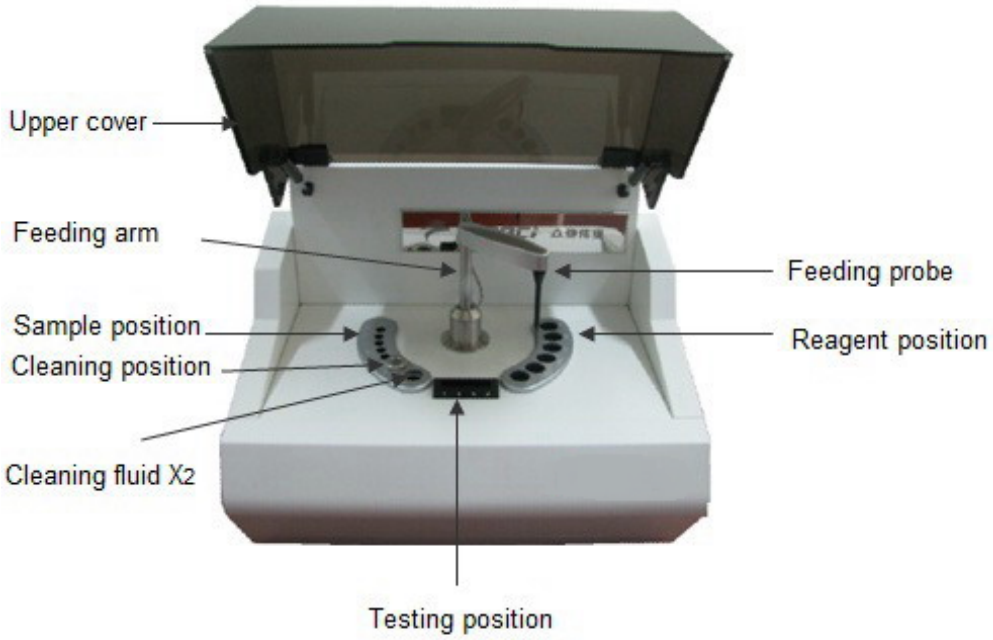


Figure 3

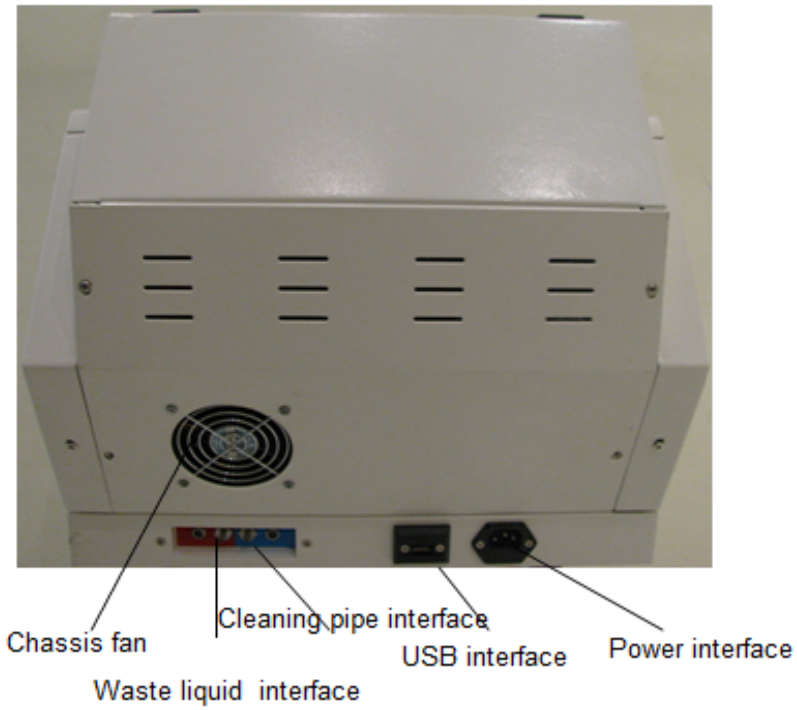


Figure 4

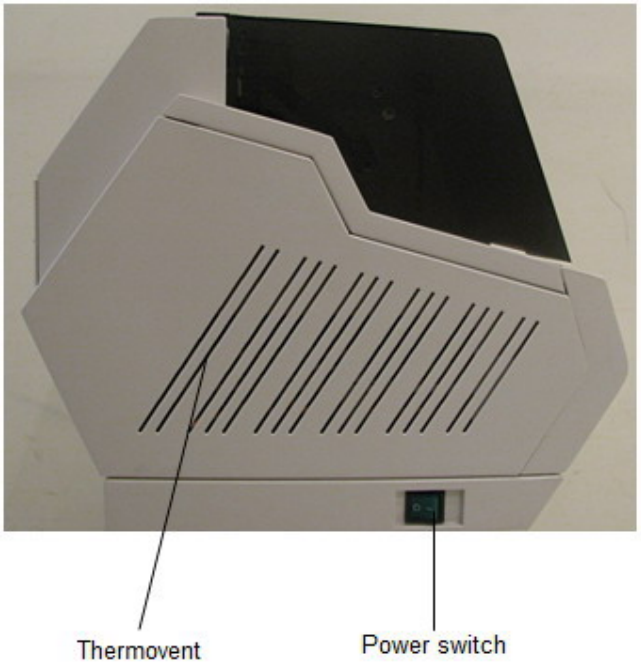


Figure 5

1.3.3 Instrument connection

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

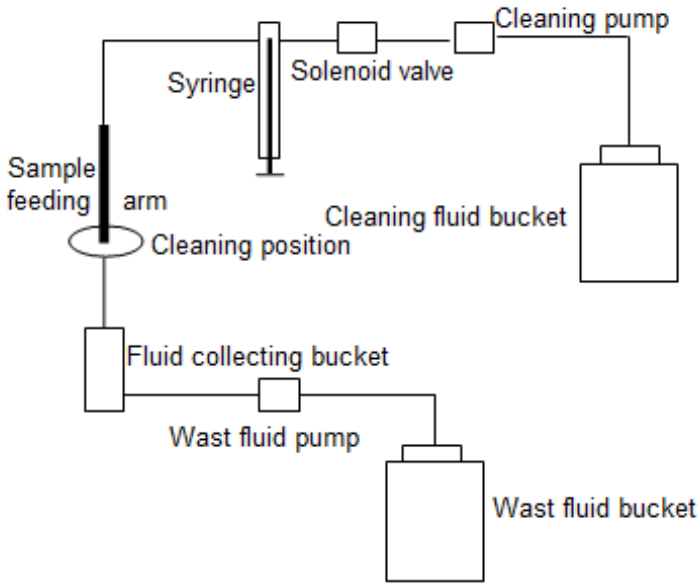


Figure 6

1.3.4 Pipeline connection

The pipeline system is composed of cleaning pipeline and waste fluid pipeline, as shown below. Cleaning system consists of cleaning position, solenoid valve, waste fluid pump, flushing pump, cleaning fluid bucket, fluid collecting bucket, waste fluid bucket.

1.3.5 basic operating principle

*Sample feeding system: consists of microsyringe, rotary sample feeding arm, 5 sample positions. While testing is started, the feeding arm turns to sample position, to absorb and feed test samples.
*Preheating system: consists of test cup preheating and temperature control. The environmental temperature should be between 15℃—30℃
*Cooling system: semiconductor refrigerating way for reagent cooling under 16℃
*Reagent feeding probe heats the cooled reagent to 37℃ in a short time, and keep the temperature at 37℃.
*Once the testing cup is fed, it stays 3 minutes at the preheating area, then is brought to testing area. The reagent is absorbed and fed to the preheated cup, test starts.
*The data will be reported if sample’s relative change of turbidity is up to 50%. The software will prompt to replace test cup once test is finished.

1.4 Notes

1.4.1 General Notes

Please follow the manual when operating the instrument. Any break of this manual may cause fault or loss, the producer accept no responsibility. We suggest using the reagent and consumable produced by Condor-Teco, so that the test result is reliable. If the electricity is suddenly cut off, the ongoing testing result would lose, finished ones could be saved.

1.4.2 Notes for biological products be used

For all biological products like reagent, calibration, quality control plasma and patient’s plasma, see to potential pollution. No smoking, wear disposable glove while using these biological products.

1.4.3 Notes about instrument

During testing, unwanted goods should not be put on operating platform. 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 Install

2.1.1 Environment

Temperature 15-30℃
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, keep ventilation.

2.1.2 Space and Power

Space：height×width×depth＞100cm×120cm×100cm
Power：220V(±10%), 50Hz (±5Hz), 250VA
(Power connection: NEUTRAL left and LIVE right. The socket with grounding protection, and case should be well earthed)

2.1.3 Requirements and procedure

* Connect the power cord.
* Connect the instrument to computer.
* Put card reader into computer USB interface. (Install card reader driver before using)
* Connect inlet and outlet pipes, cleaning fluid, waste fluid buckets. Inlet and outlet connectors are in the back of instrument. Red one is waste fluid connector, blue one is cleaning fluid connector.

2.2 Starting up

2.2.1 Connection

Connect the power and data lines of coagulation analyzer, computer, printer, turn on the power switches. Open software, if the host resets automatically, the connection is successful.
If on-screen prompts failed to connect, check the data lines and connectors.

2.2.2 Reagent preparation.

* Prepare reagents according to reagents user manual.
* The maximum diameter of reagent bottle is 22mm, height is 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
PT Reagent	100ul
APTT Reagent CaCL2	50ul 50ul
FIB Reagents Buffer Solution	50ul 90ul
TT Reagents	100ul

Table 1

2.2.3 Sample preparation

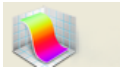
* Sample tube: Standard vacuum anticoagulant blood collection tube.
* Anticoagulants selection and dosage: 105-109mmol / L sodium citrate. Anticoagulants and blood in the ratio of 1:9.
* If patients' hematocrit is above 55% or under 20%, should adjust the dosage of anticoagulant.
Anticoagulant dosage can be adjusted according to the following formula:
0.00185×Blood（ml）×（100 –Patient's hematocrit）
* The extracted sample should be more than 2ml.
* Preparation of samples
Centrifuge mixed anti-coagulation blood at 25℃ -32℃ temperature, rotate speed should be 2000-2500 r / min, total 20 minutes.
* Storage of samples
The sample should be tested within 4 hours. But it can be preserved 2 hours under 4℃, two weeks under 20℃ and six weeks under -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

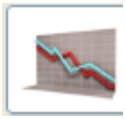
Load test cup by hand. Software will prompt operator to load test cup before testing. Please load test cup and click OK.

To input test numbers is required for automatic blood coagulation analyzer. Click  to view setting interface. Then click Recharge in conventional interface. Follow the software prompts to recharge with rechargeable card.
The cup alarm limit is 100(can be changed by operator). When test number is 0, the instrument will stop testing.

2.2.5 Standard curve

*View the calibration curve, click  to enter the standard curve interface, Choose and click the calibration items PT, FIB, PT-FIB.
* ISI value is the international sensitivity index for reagents, the sensitivity is perfect if the value is approximately 1. ISI value and PT value are input by operator, the instrument obtains patient's PTR and INR value

2.2.6 Control Chart

* Click  to view quality control interface. In order to get reliable date, quality control is necessary. The data will be saved in quality control folder.

* Choose the quality control combination, click  there are 100 combinations, 6 items, 1o quality control files. Unlimited data can be saved in each of the file.

*Click  for quality control settings.

2.3 Turn off

Start maintenance and cleaning program once day's work is finished. Put surplus reagents to refrigerator. Clear waste fluid and clean surface of instrument. Close the cover and turn off printer, computer, coagulation analyzer power in turn. Change waste bag in the waste box.

2.4 Cleaning fluid replacement

Twist-off lid of waste fluid, take the pipe to new cleaning fluid bucket. Waste cup and fluid should be environmental friendly treated.

3.Testing

3.1 Testing interface

Click desktop icon to open the software
Icons explanation:

 Test settings.

 Start to test.

 Feeding probe stop, fed testing cups keep working.

 Quality control set.

 Emergency set.

 System reset.

 Sample probe and reagent probe cleaning.

 Demonstrate testing process, the syringe does not work.

 Manual testing mode.

There is prompting window under the preheating interface. During 30 minutes preheating, there is red glittery.

3.2 Set

3.2.1 Single and Batch tests

Click  in the testing interface.
Put the sample at any hole site you want in sample tray. And put reagent to their position. Set the hole site, sample number, testing items, groups in the dialogue box.

3.3 Emergency treatment

Click  to go to Emergency interface. The sample number for Emergency are S1, S2, S3 ...
Input sample number and hole site number of emergency, choose the item combination, then click“add”. Emergency test is given top priority.

3.4 Information input

Click  to view the input window, patients’ information can be input and they will be displayed on the report.

3.5 Result

Click  to view memory area. Query result and curve, print the result. In this interface, click  to find all the testing results.

3.6 Manual test

During the course of feeding samples automatically, if there was unrecoverable failure, the operator can start manual test mode. Under this mode, the operator tests samples manually. The result can be saved and printed. 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 view the inquiring interface.
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 

* Print quality control data 

4.2 Running of quality control

Click  in the testing interface.
* 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 “Add”to add the chosen items to the testing interface.
* Click “Close” to exit the dialog.
* Click  to start the testing.

4.3 Quality control parameter setting

Click  in the quality control interface. Operator can set the quality control functions under this interface. Control is divided into two types: multi-rule control and boundary control

4.4 Error checking

The inspection way of quality control is divided into limit control mode and multi-rules mode, users can select as needed.

4.4.1 Limit control mode

The operator sets the marking limit and stopping limit according to SD(Standard deviation) value. If the quality control testing exceeds corresponding limits, Instrument will enter automatic control. For example, 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 maybe expired quality control samples, expired reagents or instrument error.
Inspection of quality control results, based on control conditions set as below:

Control conditions	Inspection way for errors
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

Table 2

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 inspection ways and rules are as below:

Rules	Inspection way
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

Table 4

4.5 Quality Control Analysis

Click  in the testing interface to go to quality control setting window.
Quality control analysis operating processes:
* Put the dissolved quality control plasma in the tube, then put the tube in any position of the sample tray.
* Check if the reagents are sufficient for quality control test.
* Check if the cleaning fluid is sufficient, if the waste fluid bucket is full.
* Click  to start quality control settings.
* Select plasma model.
* Click “Add”, the testing items will be displayed.
* Click “Close” to exit settings.
* Click  , to start quality control analysis. Results will be saved in quality control files.

4.6 Quality control data

Select  in the main interface, then click  to view the quality control date querying interface. Users can query all quality control date here.

4.7 Quality control chart

Click  to view the quality control window. Four kinds of quality control charts could be displayed each screen. 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

4.8 Editing quality control group

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

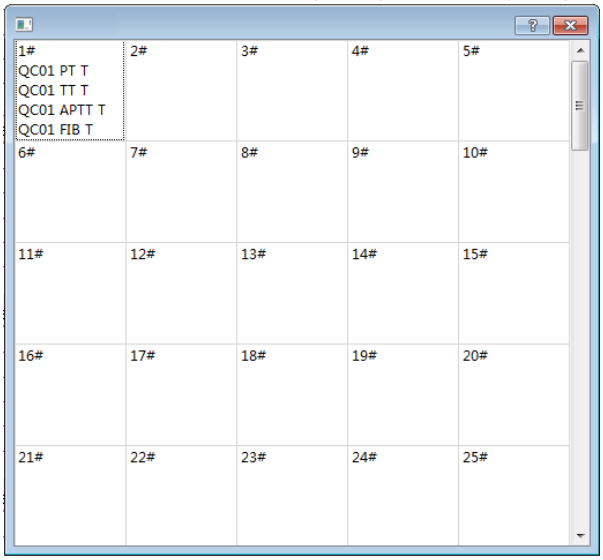


Figure 7
Click the group number, to see the pop-up window as below:

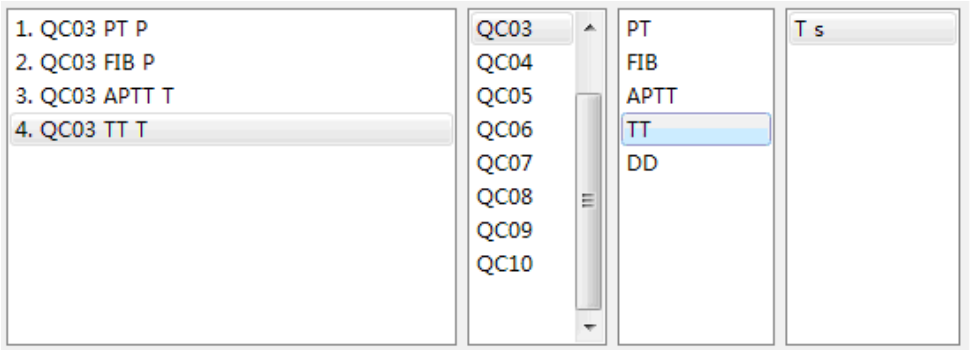
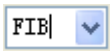


Figure 8
Click the number, file number, item, unit respectively, to display details. Repeat it until the four items are displayed. Then click OK.
Units available for choosing:
PT T represents time :s, P: represents degree of activity %
APTT T represents time :s
TT T represents time :s
FIB T represents time :s P: represents content g/l or mg/ml

5. Standard curve

5.1 Brief introduction

Click in the main interface to open quality control curve window. Operators can view or modify the standard curve. Click function keys to complete corresponding operation:

* To select curve 

* To save the curve 
* To delete curve 
* Manual input 

The information shown in the window including:
* PT items: items available for choosing.
* Time: Established 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 automatic coagulation analyzer includes PT activity, FIB derived from PT, FIB calibration. Click “Set” in the setting window to view the pop-up window, the chosen item could be set, for example PT%.
The settings of PT% are divided into automatic dilution and manual dilution. Under automatic dilution mode, click dilution gradient to select dilution ratio. The dilution ratio and dilution gradient can be added and saved.

5.2.1 Manual dilution

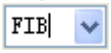
Select manual dilution mode, then put the diluted plasma in specified location in the sample tray. Select

dilution ratio of 1/1, which means no dilution.
“Standard” represents 5 standard samples in different concentration, “position” represents the position of standard samples on the tray. “Repetition” represents number of measurements for each concentration.
Operations：
* Click the input box under Standard，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，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.
* Save the settings.
* Put five diluted standard samples in Specified position in sample tray. Click “Add”
* Exit the setting window.
* Click  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 position number. The consistency is 100%. Select dilution ratio in the dilution gradient, click ok to save settings.
Operations：
* 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”
* Exit and close the setting window.
* Click  to start PT% calibration.
The calibration of FIB, PT-FIB is same as PT%.

5.2.3 Manual Calibration

Click in main interface, then select to view the manual input window.
Manual Input：
* Click 

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.
* While finished, view the standard curve. It is can be used if r> 0.975.
* Click to save changes. The current curve will be covered by the new curve.

5.3 Standard curve analysis

5.3.1 Operation

Exit setting window when calibration settings are finished. Follow 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 and test cup.
Check plasma's position.
* Click  and start calibration program.
For automatic dilution:
* Put calibration plasma in specified position in sample tray.
* Check remaining reagents and buffer solution.
* Click  and start calibration program.

5.3.2 View standard curve

Click  in the main interface. Select items in pop up window.
Click  to view the curve. Then click "New curve" to switch to the new curve.
The curve is qualified only when r > 0.975.

5.3.3 Saving

Save the new standard curve if it is acceptable.

Click  in the standard curve interface. The current curve will be replaced by new curve.

5.3.4 Deleting

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

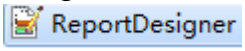
6. Settings

6.1 Common settings

Click  to go to setting interface.

6.1.1 General settings

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

User-defined report format: click 

in the software root directory to set the report format annually.
Save the setting for future report printing.

6.1.2 Information database：

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

6.2 Testing

Click “Test” in the setting interface.

6.2.1 Testing items：

All testing results will be saved in file “data” if operator chooses saving testing results to “data”. If operator chooses derive FIB from PT, FIB will not be tested, the instrument get derivative FIB from PT. The preheating time, repetitions, maximum testing time can also be set.

6.2.2 Data inspection：

Select data checking, click 

to select items.
Report limit check：
If the testing results exceed the report limit, "<" ">" will be marked on report.
Re-test inspection:
If the testing results exceed normal value, the instrument will re-test automatically if re-test limits are set.
Normal value scope inspection:
If the testing result exceed normal limit, "↑" "↓" will be marked in front of testing result.
Redilution inspection：
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
Two ways will be defined by instrument if FIB test result is under 1g/l or above 10g/l
If redilution inspection is set to FIB. When test result is under 1g/l, instrument retests at dilution ratio of 1:5, result is divided by 2 for reporting. When test result is above 10g/l, instrument retests at dilution ratio of 1:20, result is multiplied 2 for reporting
If redilution inspection is not set to FIB, test result is under 1g/l or above 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 “！”
Repetition inspection:
If the repetition limit is set for testing result, it will be marked in the report when multiple testing results exceed the limit. Limit definition: the ratio of difference between two tests and average value.

6.3 Reagent Information：

In this interface, the user could input and reagent information. Include reagent number, name, lot number, validity, initial volume, alarming volume, Interruption volume, types of reagent bottle, quality control type(N: normal; P Abnormal), quality control number, etc.

7. Maintenance and repair

7.1 Daily maintenance

Start pipeline cleaning program after the whole day work.
Check the cleaning fluid and pour waste liquid before starting the instrument. Wear rubber gloves when pouring waste fluid. Medical sewage should be treated in accordance with relevant provisions.
Start probe cleaning program after the whole day work. Clean sample tray with wet cotton.
Clean condensate water in reagent cooling position.
Clean instrument surface with wet cotton.
Clean the waste cup. Wear rubber gloves when cleaning waste cup. It should be treated in accordance with relevant provisions.

7.2 Weekly maintenance and inspections

Inspect pipeline, cleaning fluid bucket, cleaning fluid alarming system. Check if the probe is blocked. Clear it first if blocked. Wear rubber gloves when cleaning the probe, watch your fingers. Wash hands with disinfectant once finished.
Clean testing cup trough with wet cotton.
Probe maintenance: start probe cleaning program, click to clean repeatedly.

7.3 Common fault recovery

Fault	Failure causes and solutions
Failed to connect	check if the host power is on check the USB connection 3、check the software settings
Inlet, outlet fault	Contact authorized engineers if the flushing pump does not work Contact authorized engineers if the waste fluid pump does not work Check if the pipe is blocked, or if the plug is sloughing when no cleaning fluid outflows from probe The waste fluid pump is working, no waste fluid outflows, check if the pipe is blocked, or if the plug is sloughing 5、Pump is working properly, but there is no cleaning fluid in the pipeline. Execute cleaning program.
Liquid sensor fault	1、The probe hit bottom of the bottle 2、Insufficient amount of sample 3、The detecting board failure or connecting fault
Test result fault	1. The feeding probe can not be cleaned: inspect cleaning system, samples, check if samples are adequate, if clot or foreign object exists. 2. Check reagents: reagents maybe contaminated, disabled or wrongly placed. 3. There is bubble in cleaning fluid pipe, the amount is inadequate
Others	1. Working temperature is 10℃-30℃ 2. The host must be safely earthed

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