

C3100
AUTO COAGULATION ANALYZER

Operator's Manual



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- Product is used in accordance with the instructions for use.

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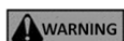
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- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
- Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.

NOTE

- This instrument must be operated by skilled/trained clinical professionals.
-

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Chapter1 Using This Manual

1.1 Introduction

This chapter explains how to use your operation manual, which is shipped with your Auto Coagulation Analyzer and contains reference information about the C3100 and procedures for operating, troubleshooting and maintaining the analyzer. Reading this manual carefully before operating your C3100 and operate your C3100 Auto Coagulation Analyzer strictly as instructed in this manual.

1.2 Who Should Read This Manual

This manual contains information written for clinical laboratory professionals to:

- Learn about the C3100;
- Customize system settings;
- Perform daily operating tasks;
- Perform system maintenance and troubleshooting.

1.3 How to Find Information

This operation manual comprises 10 chapters and 1 appendix. Refer to the table below to find the information you need.

If you want to...	See...
Learn about the intended use and test methods	Chapter 2 Understanding your analyzer
Learn about the installation requirements of the C3100	Chapter 3 Installing your analyzer
Learn about the software operation	Chapter 4 Setting your analyzer
Learn about the daily operation	Chapter 5 Operating your analyzer
Learn about the regular maintenance and parts replace	Chapter 6 Maintenance
Learn about how to solve the problem of the C3100	Chapter 7 Troubleshooting
Learn about the cautions	Chapter 8 Cautions
Learn about the storage and transport condition	Chapter 9 Storage and transport
Learn about the disposal of castoff	Chapter 10 Disposal castoff
Safe information	Appendix A safe information

1.4 Conventions Used in This Manual





This manual uses certain typographical conventions to clarify meaning in the text:

Form	Meaning
[× ×]	× × indicate a key name (either on the pop-up keyboard or the external keyboard), such as [ENTER]
“× ×”	× × indicate text you can find on the software

All illustrations in this manual are provided as examples only. They may not necessarily reflect your C3100 setup or data displayed.

1.5 Precautions, Limitations and Hazards

The following symbols are used to indicate danger and alert information in this manual.

Symbols	Meaning
	Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
	Read the statement below the symbol. The statement is alerting you to information that requires your attention.



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
 - If leakage happens to the analyzer, the leaked liquid is potentially biohazardous.
-







- Please check the firmness of all the doors and covers before running the analyzer.
 - Make sure all the safety measurements are adopted. Disabling any safety device or sensor is prohibited.
 - Please take action to any alarm and problem indication immediately.
 - Do not touch the moving parts.
 - Contact precil or precil-authorized distributors in time if any damaged part is found.
 - Be careful when opening/closing and removing/installing the doors, covers and boards of the analyzer.
 - Discard analyzer according to government regulations.
-



- Please use the analyzer strictly as instructed by this manual.
 - Make sure only pre-authorized software is installed on the computer.
 - Please install the original edition software to prevent the computer from being infected by virus.
 - Please adopt proper measurement to prevent the reagents from being polluted.
 - It is recommended that you install anti-virus software on the computer and scan for viruses periodically.
-

1.6 Symbols












The following symbols are used to indicate danger and alert information on the instrument.

Symbols		Meaning
Inside		Please notice the PCB, do not touch and measure it when electrified.
External		There is blood in the cuvette, please wear medical gloves. Used cuvette should be disposed as medical waste appropriately for the sake of avoiding potentially biohazardous condition.
		Caution, the running instrument has hot surface!
		Do not touch the instrument when it is operating!

You may find the following symbols of the analyzer system:



- During the daily use of the analyzer, especially the cleaning process, the operator shall ensure the intactness of the labels.
-

Symbols	Meaning
	CAUTION, RISK OF DANGER.
	The device is fully conformance with the council directive concerning in vitro diagnostic medical devices 98/79 EC.
	Serial number
	Date of manufacture
	Manufacture
	The following definition of the WEEE label applies to EU member states only: the use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.
	Alternating current
	On (power: connection to the mains)
	Off (power: disconnection to the mains)
	PROTECTIVE CONDUCTOR TERMINAL
	In vitro diagnostic medical device

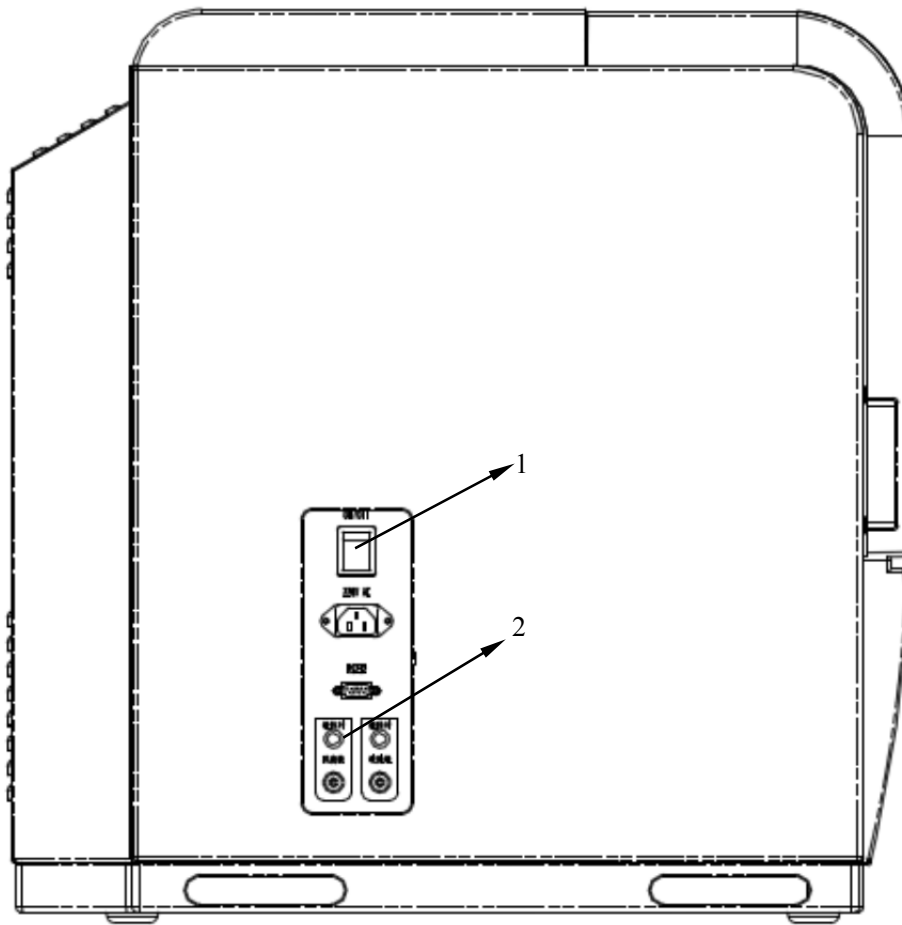


Figure 1-1 left of the analyzer

1

- Connect only to a properly earth grounded outlet.
- To avoid electric shock, cut off power supply before examine and repair.

2

- To avoid biohazardous, wear proper personal protective equipment (e.g. gloves, lab coat, etc.) before installing liquid device.

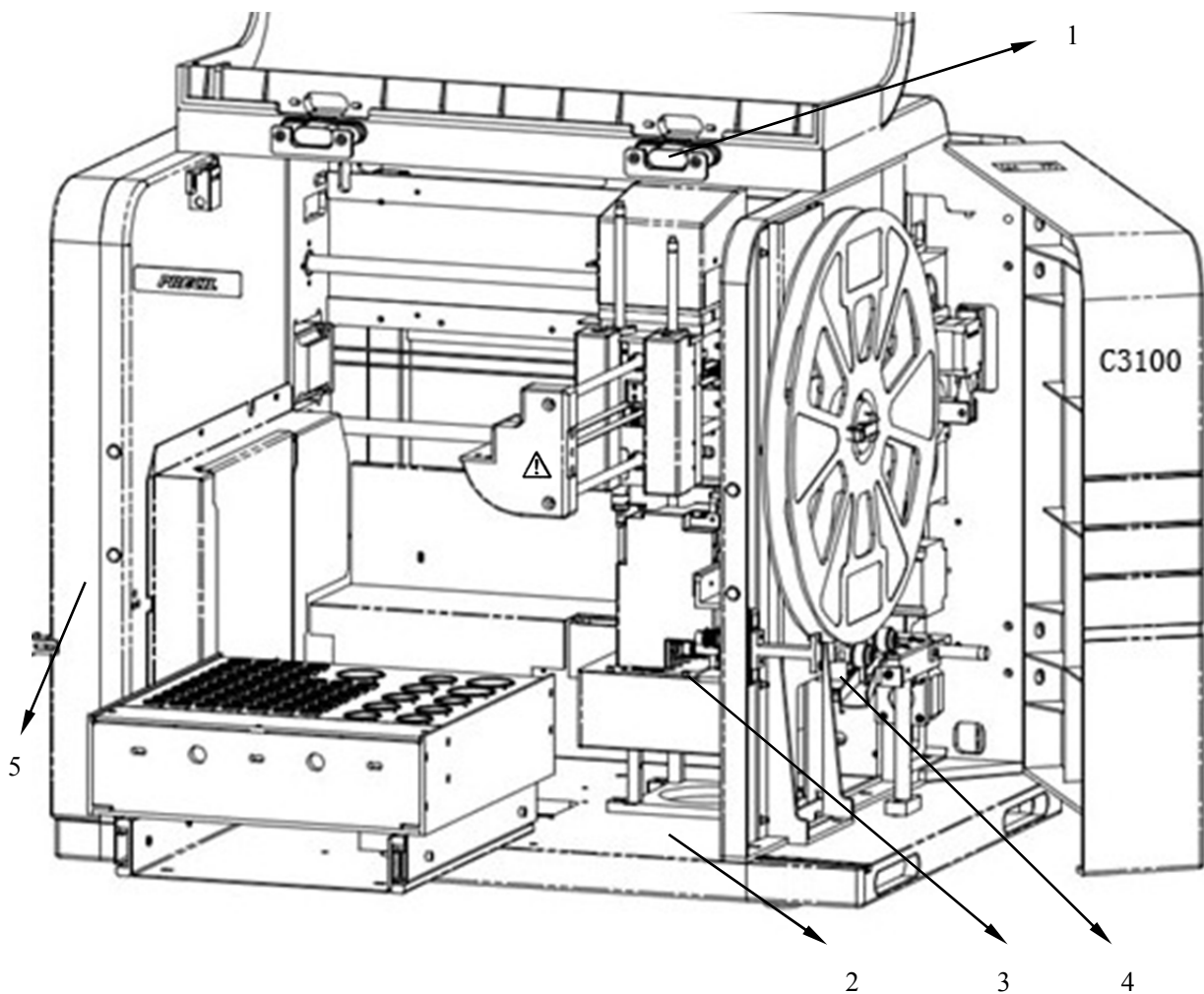


Figure 1-2 front of the analyzer

1

- To avoid personal injury, after you lift the cover, be sure to fix it with the stop bar exactly as the above figure shows.

2

- Waste cuvette (contain plasma and reagents), wear proper personal protective equipment (e.g. gloves, lab coat, etc.) before disposal.

3

- Heating area, do not touch.

4

- Mechanical and electricity risk may exist if the right door is opened.

5

- Mechanical risk may exist if the left door is opened.

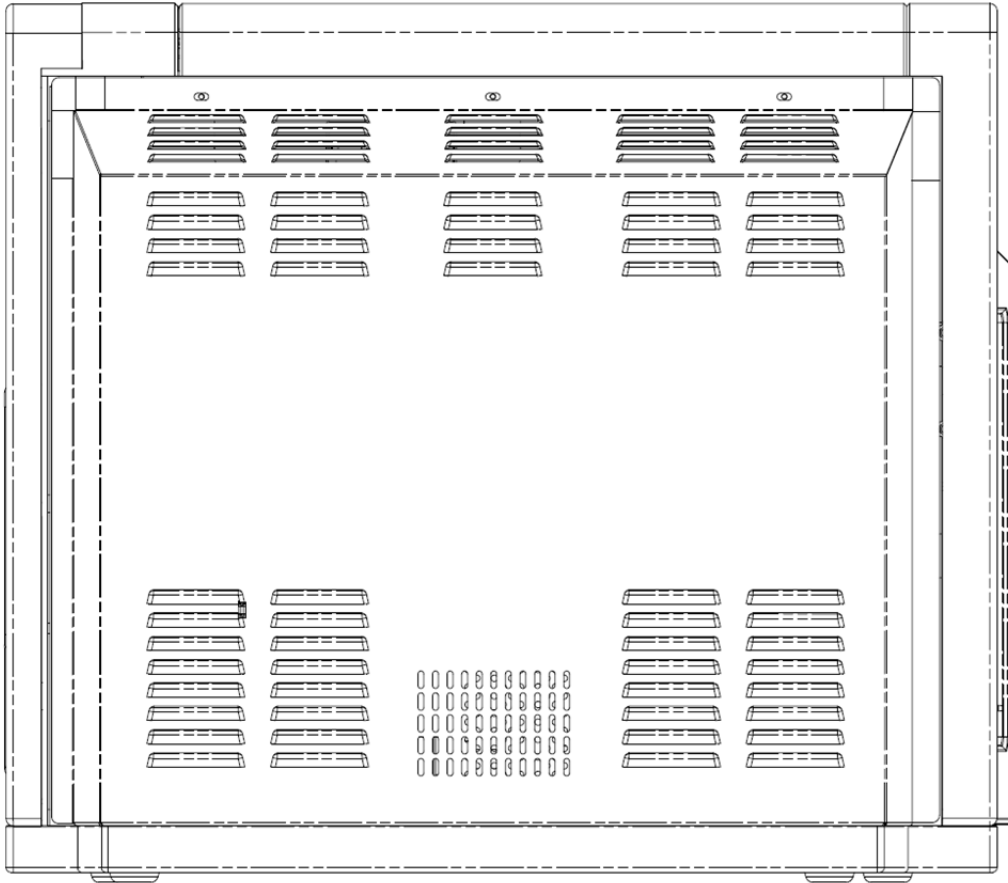


Figure 1-3 back of the analyzer

1 

- Set aside space behind analyzer for maintenance and shed heat.
- Do not put goods behind analyzer, to avoid fire.

1.7 Safe Cautions

For safe and right operation, this section lists some safe cautions.

Please read this section carefully before operation.

NOTE

- C3100 is used for in vitro diagnosis; the sample is mainly human plasma with anticoagulant. Please do not use it for others.
-

WARNING

- Do not touch the electricity and liquid parts inside the cover, especially wetting hands, it may cause electricity risk.
 - Make sure the input voltage meets the requirements and the analyzer is properly grounded.
 - Do not drag and put heavy thing on the wire.
 - Turn off the analyzer before installing the round device; otherwise it may cause risk and failure.
-

NOTE

- Installing
 1. Do not place the analyzer in a dry environment.
 2. Do not place the analyzer in direct sunlight or in front of a source of heat or drafts.
 3. Do not place the analyzer on a slope.
 4. The environment should be as free as possible from dust, mechanical vibrations, loud noises, pollution and electrical interference.
 5. The environment should be well-ventilated.
 6. Do not use this analyzer in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.
-



- Biohazardous

1. Do not touch the polluted parts, if touched please wash drastically.
 2. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) before operation and maintenance.
 3. If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.
 4. Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
-



- Reagent

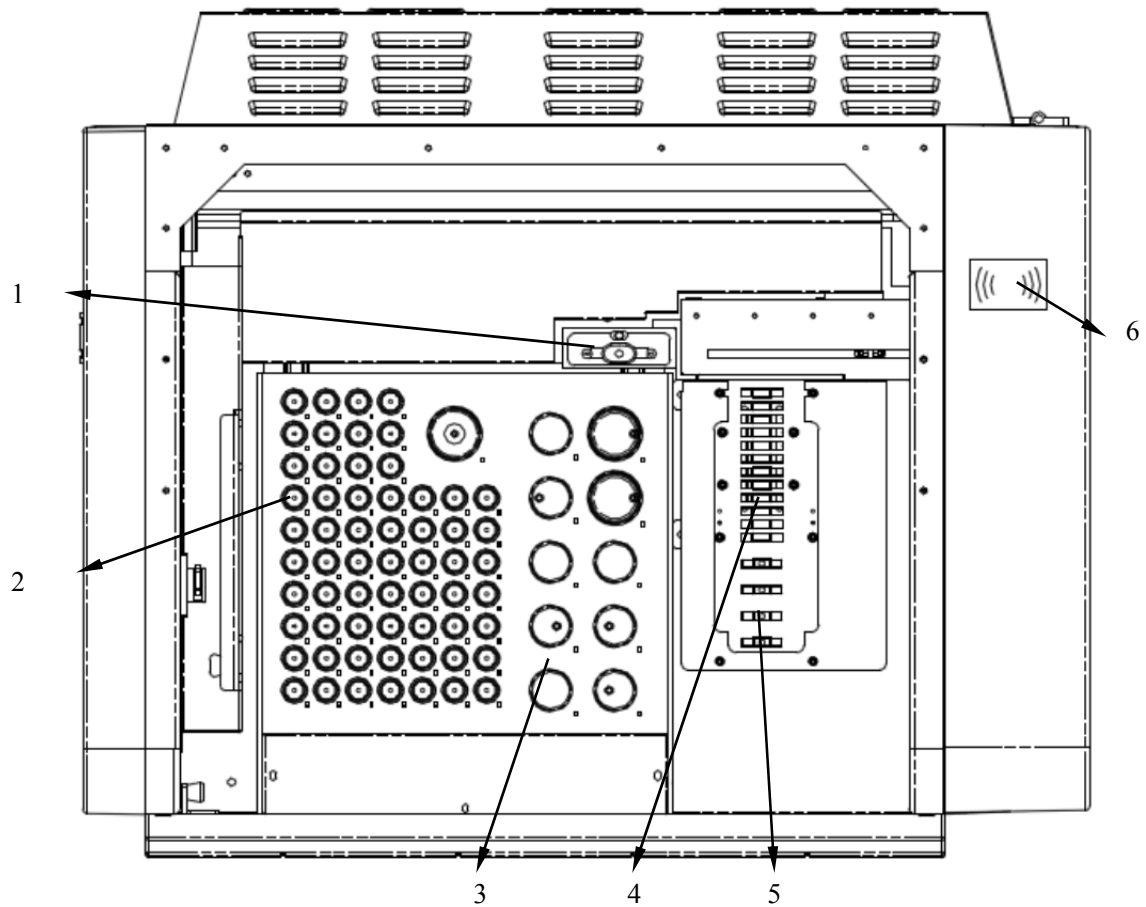
1. Operation according to reagent manual, do not use overdue reagents.
 2. Keeping it appropriately and be sure to dispose of reagent according to government regulations.
 3. Please wear gloves when using reagents; if the reagents accidentally spill on your skin, wash them off with plenty of water.
-

Chapter2 Understanding Your Analyzer

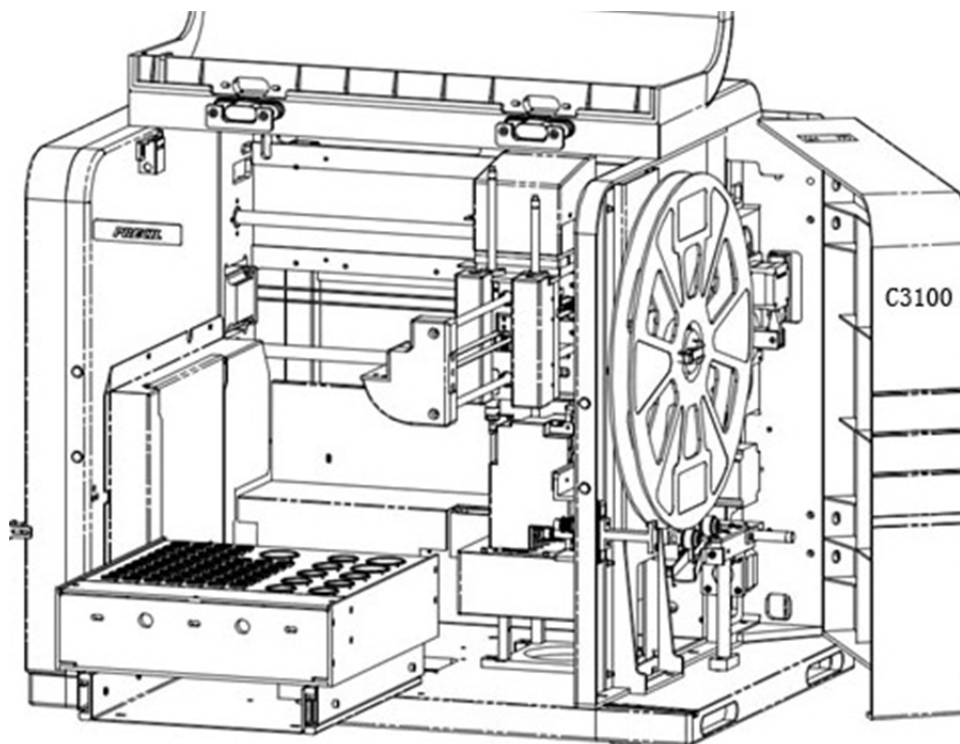
2.1 Introduction

C3100 Auto Coagulation Analyzer is a quantitative, Auto Coagulation Analyzer for in vitro diagnostic use in clinical laboratories; it provides Activated Partial Thromboplastin Time, Prothrombin Time, Thrombin Time, Fibrinogen , D-dimer and FDP etc..

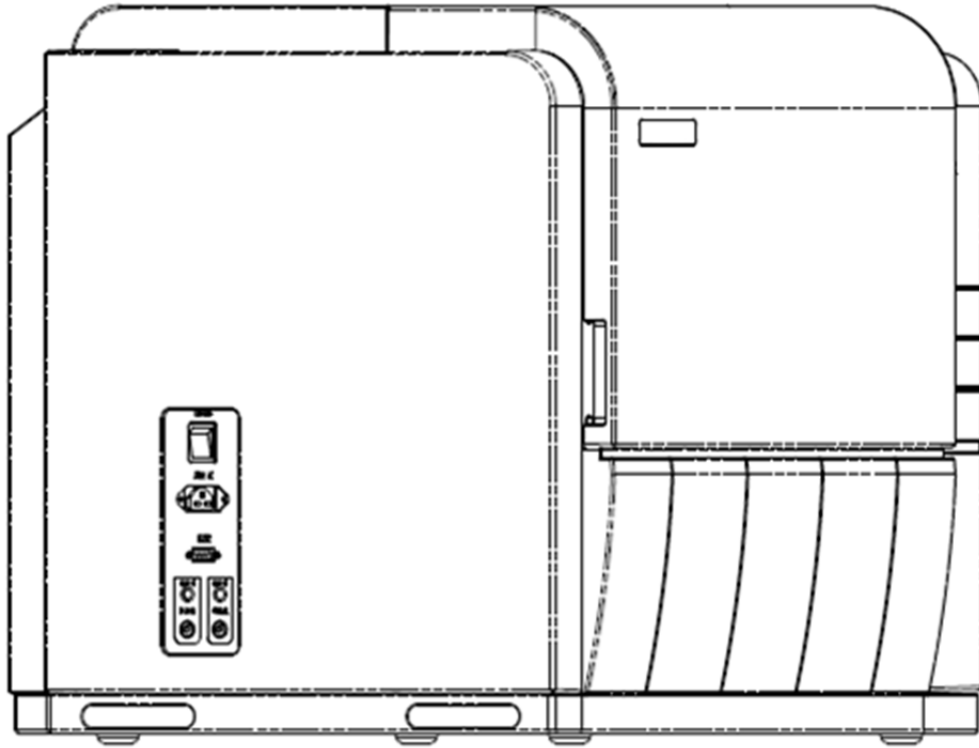
2.2 Overview



- 1 probe washing bath
- 2 sample position
- 3 reagents position
- 4 preheating position(contain optics method)
- 5 magnetic bead channel
- 6 swipe card position



- Push the right door lightly.
- How to installing the cuvette tray please reference to “chapter 3 installing of cuvette tray”
- Before install and disassemble the tray, please make sure the power of analyzer is cut off.



■ Power switch

On the left of analyzer; using to turn on / off the analyzer.



- To avoid damage, do not turn on / off the power of the analyzer continually in a short time.
-

■ Electrical outlet

Make sure the input voltage meets the requirements.

The analyzer is properly grounded.

■ Network interface

Connect the analyzer to PC;

Connect the scanner to PC.

■ Liquid outlet

Cleaning outlet, floater outlet;

Waste liquid outlet, floater outlet;

2.3 External Equipment

- PC
- keyboard
- mouse
- printer
- handset scanner (optional)

2.4 The System Principles

Simulating physiological blood coagulation conditions is the detection principle. Starting the coagulation by adding some reagents can make fibrinogen into cross-linked fibrin. We determine the reaction end point by continuous monitoring physical properties (dual bead magnetic method, plasma viscosity) of reaction system, and using process time as the fibrinogen conversion time. Using this principle, the coagulation characteristics of blood can be measured.

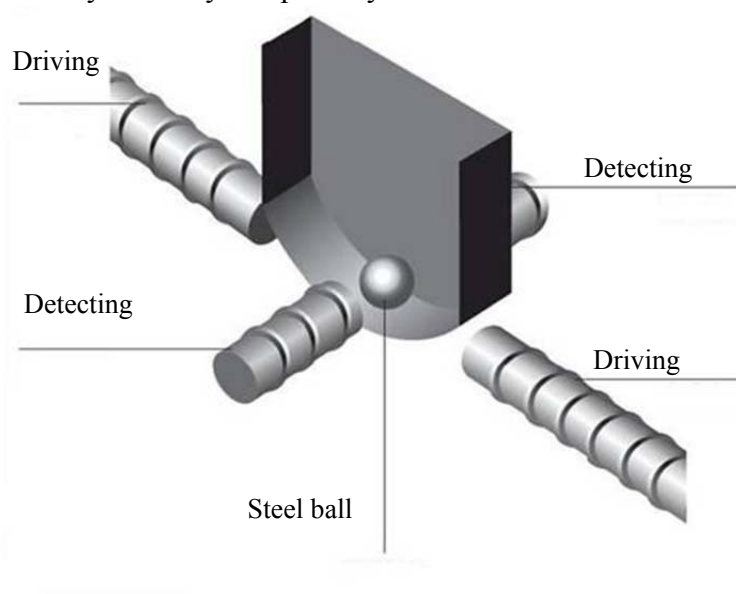
C3100 Auto Coagulation Analyzer use dual bead magnetic method and optical method.

2.4.1 Dual bead magnetic method

The detection system for clotting-time assays on the C3100 Auto coagulation analyzer is based on the increase of viscosity of the plasma being tested. This increase of viscosity is measured through the motion of a stainless steel ball that is made to affect pendular swings on the two curved rail tracks provided in the bottom of the cuvette containing the test plasma.

Constant pendular swings of the ball are created by an electromagnetic field that is applied alternately on opposite sides of the cuvette by two independent coils. The energy of the electromagnetic field can be varied depending on the test being performed. However, as soon as the plasma starts to clot (as a result of the coagulation process being initiated by the addition of the clot starting reagent), the viscosity of the plasma starts to increase, and this change in plasma viscosity affects ball movement, slowing it down. As the viscosity increases, the oscillation amplitude of the ball swing decreases. An algorithm uses these variations in oscillation amplitude to determine the clotting time.

- The interference caused by hemolysis, icterus or lipemia may be eliminated.
- The interference caused by air bubble may be eliminated.
- The interference caused by turbidity sample may be eliminated.



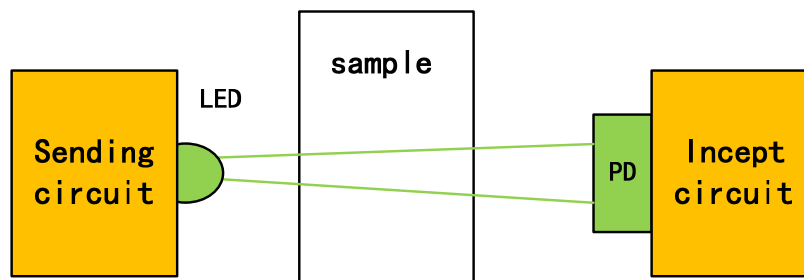
NOTE

- Cuvette and bead are patents. The camber on the cuvette bottom can affect the test result, please use the precil cuvette.
 - The cuvette tray should prevent magnetization from magnetic field.
 - The cuvette and bead is one-off products.
-

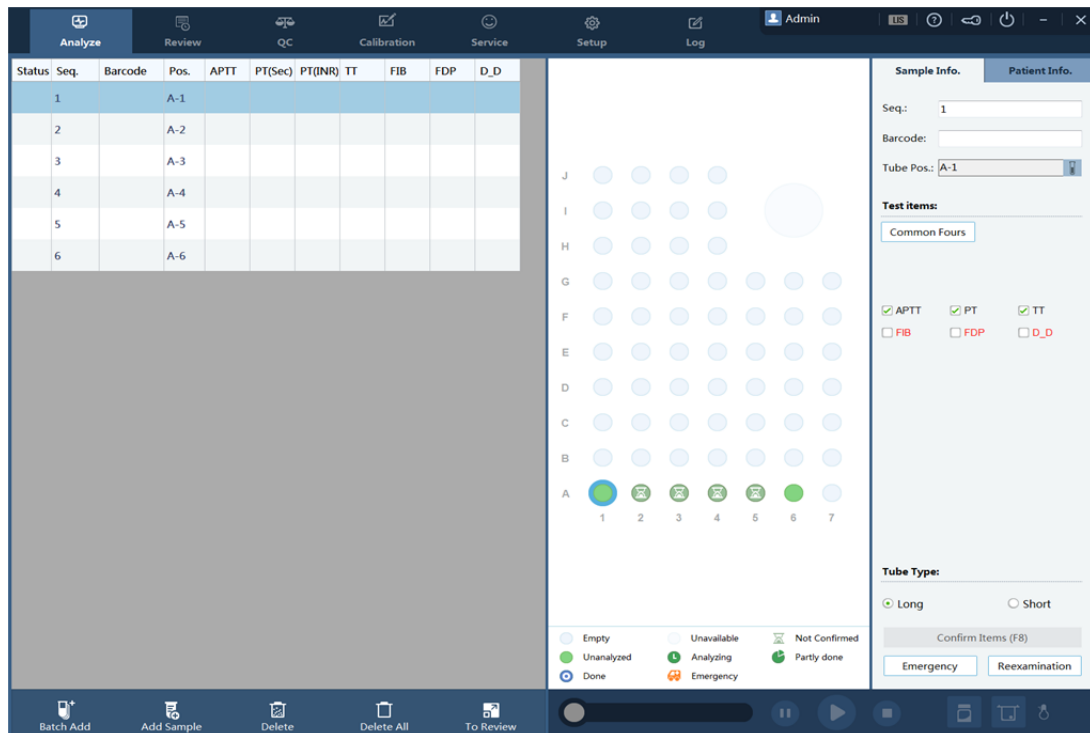
2.4.2 Optic method

There is a specifically bound characteristic between antigen and antibody; we use this feature to make test sample unite with Antibody particles. The content can be known through test the variation in light intensity.

The end point detection is determined by the change of the transmitted light. The optical source, sample and detector are in a straight line, the light intensity will gradually increase by reason of the formation of the fibrin clot.



2.5 Software Operation



■ Title area

Display the analyzer title and current interface.

■ Menu area

Level 1	Level 2		Level 1	Level 2
Sample Analyse				Analyze setup
Review				Items Combination
	QC Setting			Item Range
QC	QC Analyze			User Management
	QC Review			Item Parameter
Calibration				Print setup
	All logs			Com. Setup
	Parameter Modification			Data Dictionary
Log	Error Info.			Custom configure
	Other Logs		Service	

The PC software only shows the level 1 menus, and you can enter the level 2 screens by using the sub-menu buttons in the button area.

2.6 Reagents, Controls and Calibrators

As the analyzer, reagents, controls and calibrators are components of a system, performance of the system depends on the combined integrity of all components. You should only use the precisely specified reagents, which are formulated specifically for the fluidic system of your analyzer in order to provide optimal performance. Do not use the analyzer with reagents from multiple suppliers. In such use, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.

Each reagent package must be examined before use. Product integrity may be compromised in package that has been damaged. Inspect the package for signs of leakage or moisture. If there is evidence of leakage or improper handling, do not use the reagent.

NOTE

- Store and use the reagents as instructed by instructions for use of the reagents.
 - Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.
-

2.6.1 Reagent

Items	Reagent
Prothrombin Time (PT)	PT Kit
Activated Partial Thromboplastin Time (APTT)	APTT Kit
	CaCL ₂
Thrombin Time (TT)	TT Kit
Fibrinogen (FIB)	FIB Kit
	Buffer solution
D-dimer (DD)	D-dimer Kit
	Diluent
FDP	Trigger reagent
	Diluent

NOTE

- For precise result and normal function, please use precil probe cleanser and cleaning.
-

2.6.2 Controls and Calibrators

The controls and calibrators are used to verify accurate operation of and calibrate the analyzer.

The controls are used to verify that the analyzer is functioning properly. Daily use can verify the operation of the analyzer and ensures reliable results are obtained. Read and follow the instructions for use to use the controls and calibrators.

All references related to controls and calibrators in this manual refer to the controls and calibrators specifically formulated for this analyzer by precil. You should buy this controls and calibrators from precil and precil-authorized distributors.

Chapter 3 Installing Your Analyzer

3.1 Introduction



- Installation by personnel not authorized or trained by precil may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of authorized personnel.
 - The installation, test, update, and modification of the software associated with the analyzer shall only be performed by personnel authorized by precil.
-

The analyzer is checked and packed with care before it is shipped from the factory. Inspect the carton carefully after arrival. If you see any sign of damage is found, contact precil or your local distributor immediately.

After opening the package, check the delivered goods against the packing list, and then visually check the system appearance. If you find anything missing or damaged, contact precil or your local distributor immediately.

3.2 Installation Requirements

3.2.1 Space Requirements

While install your analyzer, make sure there is enough space left for service and maintaining operations, as well as for the analyzer to dissipate heat and for the fluidic tubing to be properly placed without extrusion. Specific requirements shown as follows:

- Proper high to place the analyzer;
- At least 500 mm to each side of the analyzer;
- At least 600 mm above the analyzer;
- At least 250 mm behind the analyzer;
- The supporting table where the analyzer is placed shall be able to withstand at least 100 Kg of weight.

3.2.2 Power Requirements



- Make sure the analyzer is properly grounded.
 - Before turning on the analyzer, make sure the input voltage meets the requirements.
-



- Using pinboard may bring electrical interference and the analysis results may be unreliable. Please place the analyzer near the electrical outlet to avoid using pinboard.
 - Please use the original electrical wire shipped with the analyzer. Using other electrical wire may damage the analyzer or cause unreliable analysis results.
-

- Voltage : AC 100-240 V
- Frequency : 50 / 60 Hz
- Power : 200 VA

3.2.3 General Environment

Working environment:

Ambient temperature	+10°C ~ +30°C
Relative humidity	≤70%
Atmospheric	86 KPa ~ 106 Kpa

- The environment should be as free as possible from dust, mechanical vibrations, loud noises, pollution and electrical interference.
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
- Do not place the analyzer in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.
- Do not place the analyzer near brush-type motors, flicking fluorescent lights, and electrical contacts that regularly open and close.
- Do not place the analyzer in direct sunlight or in front of a source of heat or drafts.
- The environment should be well-ventilated.
- Do not place the analyzer on a slope.

3.2.4 Transportation and Installation



- Installation by personnel not authorized or trained by precil may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of authorized personnel.
-

The transportation and installation shall be conducted by precil – authorized personnel. Do not transport or install the analyzer without contacting precil or your local distributor.

3.2.5 Cuvette Tray Installation

User can install the cuvette tray according to the figure 3-1.

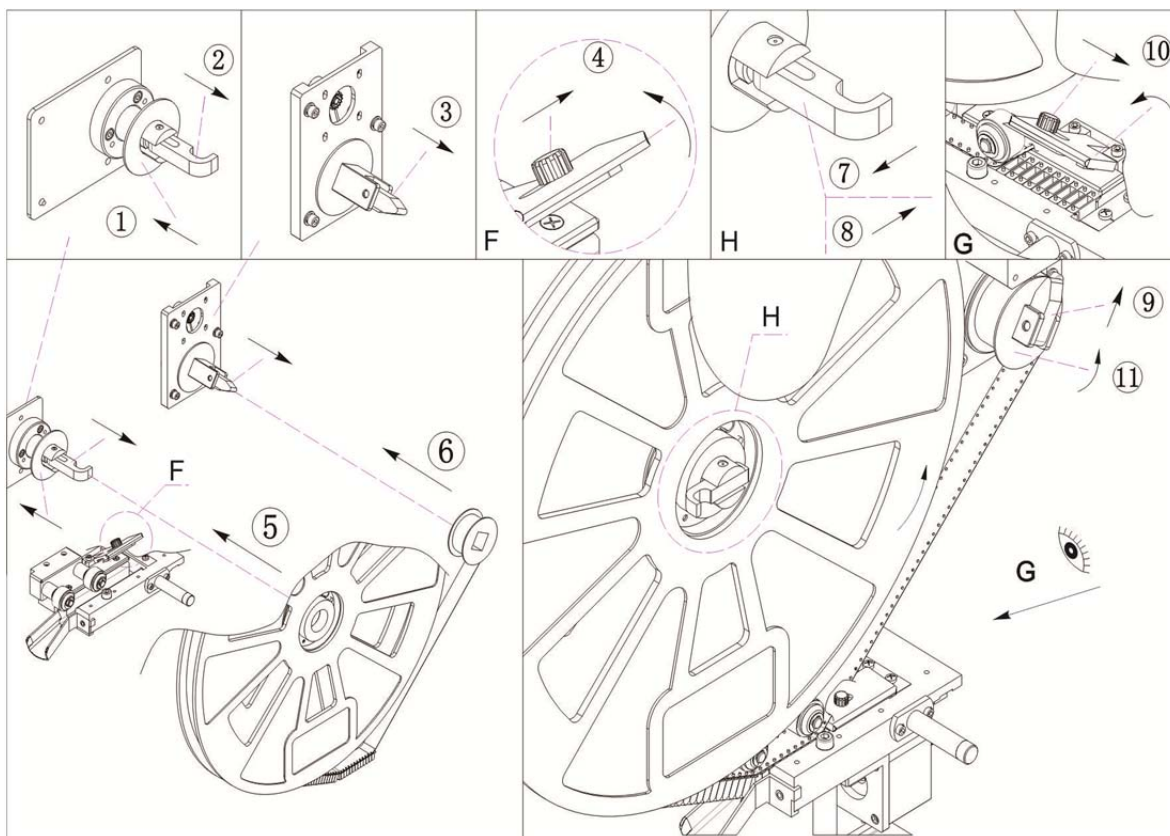


Figure 3-1 Install the cuvette tray

- Push the cushion to the rear, lift up the open plate and close plate.
- Open the cover plate
- Put the tray and scroll on the two gearwheels, straining the cuvette tape with counterclockwise.
- Lay flat open plate toward left and then push toward right to the bottom. Lay flat the close plate and cover plate.

NOTE

- The cuvette tape should be placed in the middle position.
- The cuvette tape should be extracted between cover plate and tape guide pin.
- Do not discard the cushion when change tray.

CAUTION

- Please push carefully when change the tray.
- Discard the cuvettes in the cup slot.
- Do not wreck cuvette tape.

3.3 Install the Analyzer

3.3.1 Liquid Line



- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
 - Wear proper personal protective equipment (e.g. gloves, lab coat, etc) and follow safe laboratory procedures when handling them in the laboratory.
 - If the waste accidentally spill on your skin, wash them off with plenty of water and if necessary, go to see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.
-

NOTE

- Please discharge the waste into a container and dispose it according to government regulations.
-

Connect the containers to the analyzer as shown in the following figure. Be sure to keep all connecting lines isolated from anything electrical.

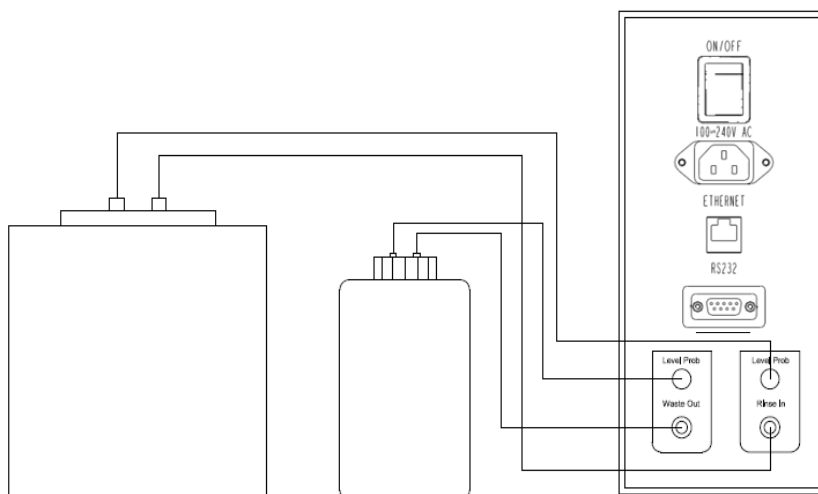






Figure 3-2 connecting line

- Rinse In  cleanser inlet, connect with cleanser bottle.
Level Prob  cleanser floater, connect with cleanser bottle.
- Waste Out  waste outlet, connect with waste bottle.
Level Prob  waste floater, connect with waste bottle.

3.3.2 Circuitry

- Power line: one end connects with the analyzer and the other connects with electrical outlet.



- To avoid electrical risk, the power should be properly grounded.
-

- Connect the analyzer with PC using wire.
- Connect with scanner using RS232 and USB wire.

3.4 Software

NOTE

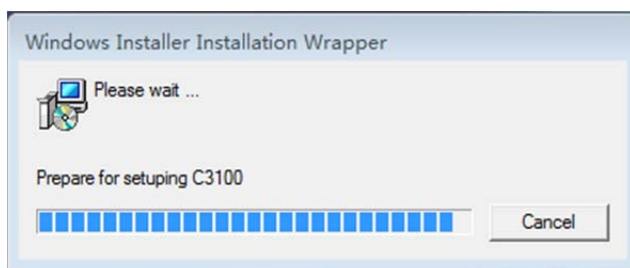
- Installation by personnel not authorized or trained by precil may cause error. Do not install software without the presence of authorized personnel.
 - The installation, test, update, and modification of the software associated with the analyzer shall only be performed by personnel authorized by precil.
 - Operating system should install not less than WIN7.
-

PC environment

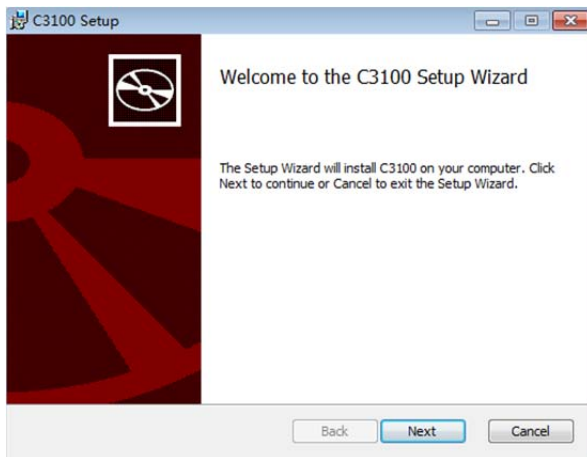
- 1、 Operation system: not less than 32 bit profesional Windows 7;
- 2、 CPU: not less than the intel[®] core Tmi3 processor
- 3、 RAM: not less than 4G
- 4、 Hard disk: not less than 500GB
- 5、 Indicator : resolution is not less than 1440×900
- 6、 Computer interface :
 - a) Network interface : at least 2 (connect the host and LIS system)
 - b) USB interface

The installation of software is shown as below:

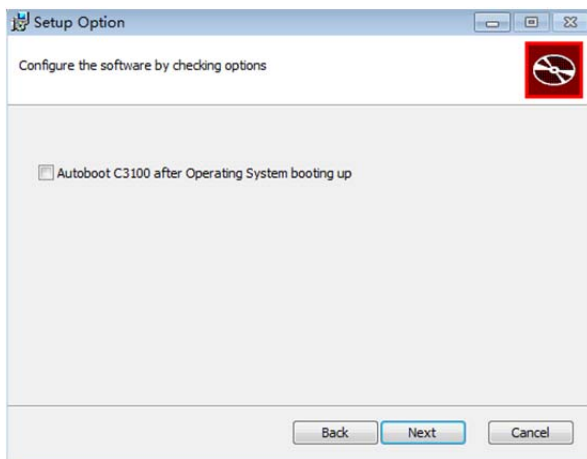
- Startup PC, put the CD in CD-driver; copy the setting procedure into PC hard disk, like D:
- Click setup icon to install software, and then process as the prompt.



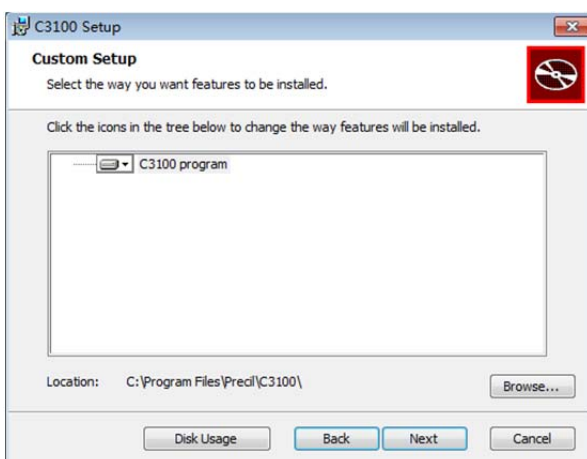
- Click the start button and choose procedure, you can found shortcut key of [Auto Coagulation Analyzer Control Software] on desk top.



Whether start-up the software automatically;



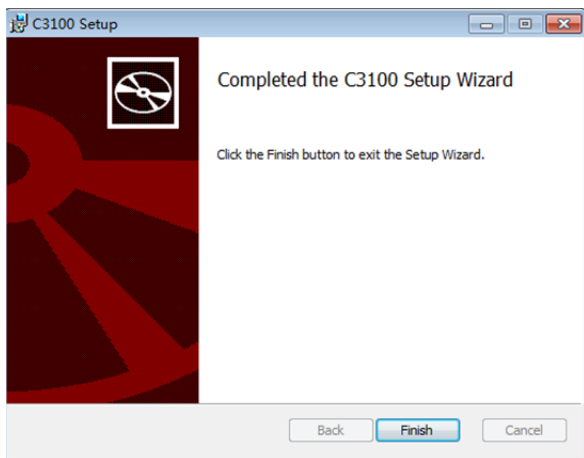
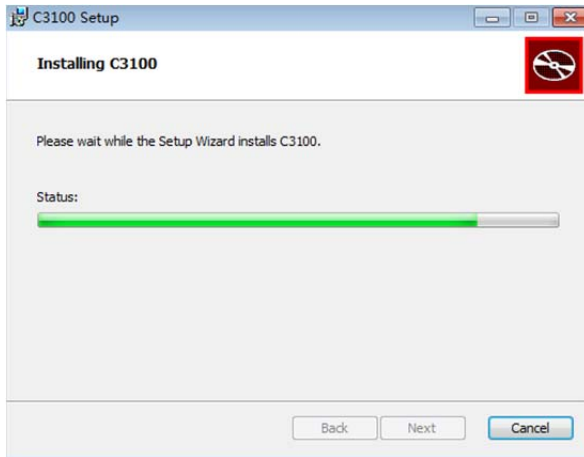
Choose the storage place of the date-base;



After the above setting, you can install the software;

There is shortcut key in desktop after installation.





After installation, we can check it as the follow procedure:

- Make sure the analyzer and PC are connected properly;
- Make sure the PC and printer are connected properly;
- Turn on the power switch and check whether the analyzer reposition and self-clean.
- On PC desk, double click the shortcut icon to enter login interface.

Chapter4 Setting Your Analyzer

4.1 Introduction

The C3100 is a flexible laboratory instrument that can be tailored to your work environment. You can customize the software options as introduced in this chapter.

For the security of the setting and data, two access levels are provided to the operator of the analyzer. The administrator access level provides the operator with access to more functions or settings, some of which can be configured to be accessible to operators.

This chapter introduces how to customize the settings of the analyzer and the PC, some of which will be performed only occasionally.

4.2 Analyzer Introduction

The appearance of C3100 is showed as figure 4-1.

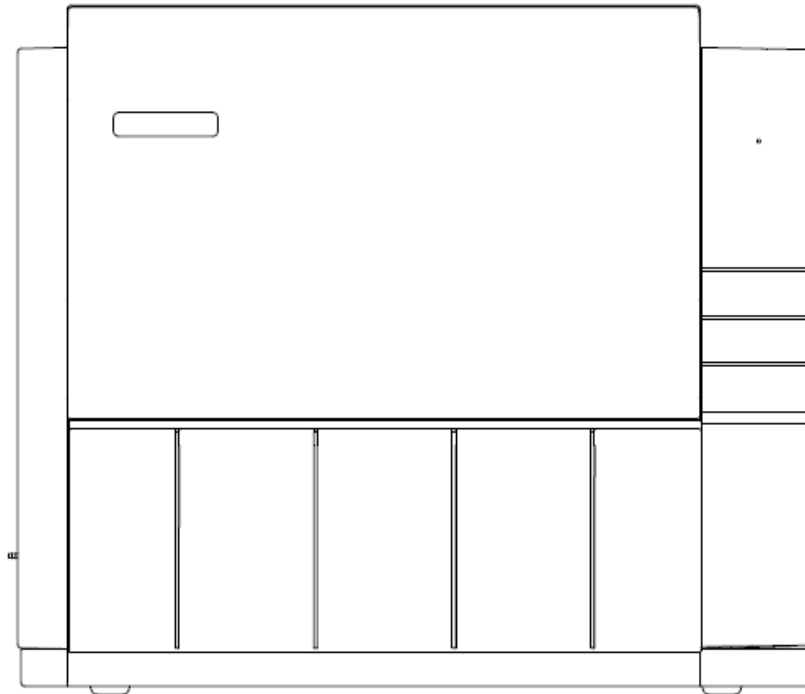


Figure 4-1 appearance

The left panel of analyzer is showed as figure 4-2:

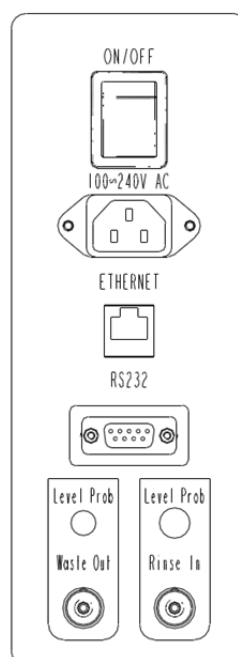
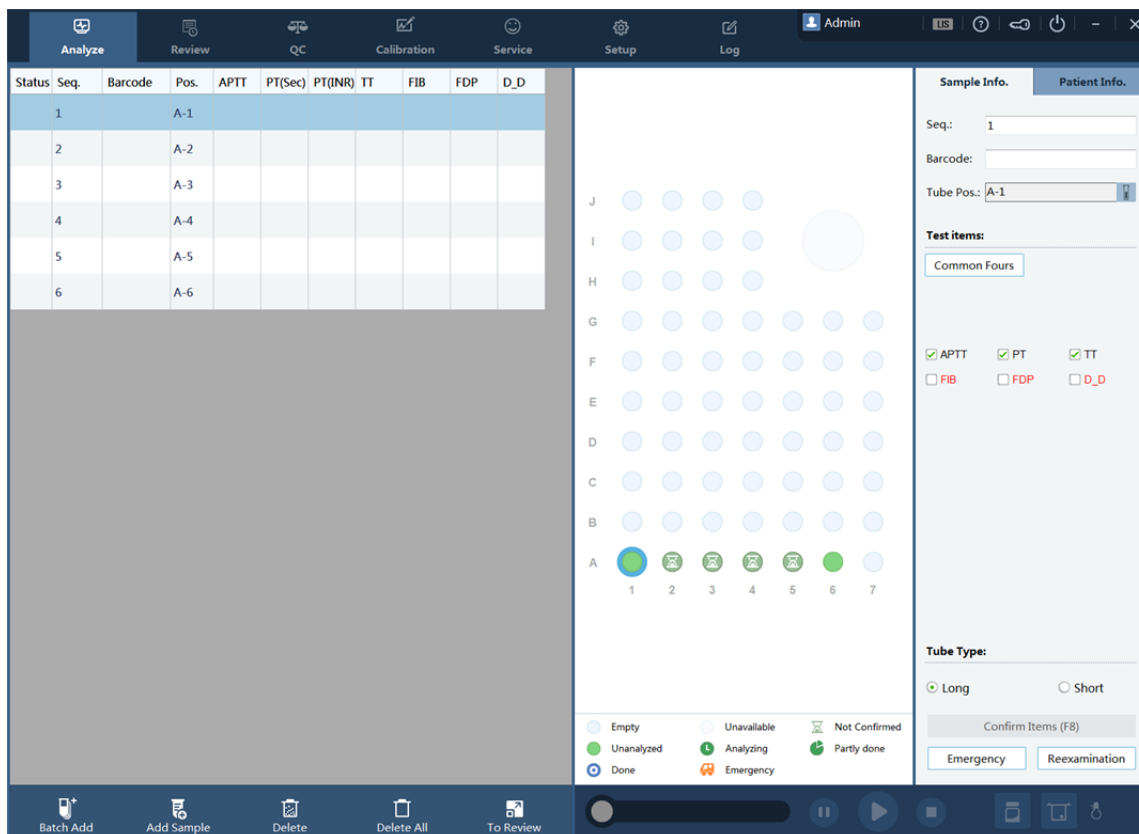


Figure 4-2 left panel

4.3 Software Introduction

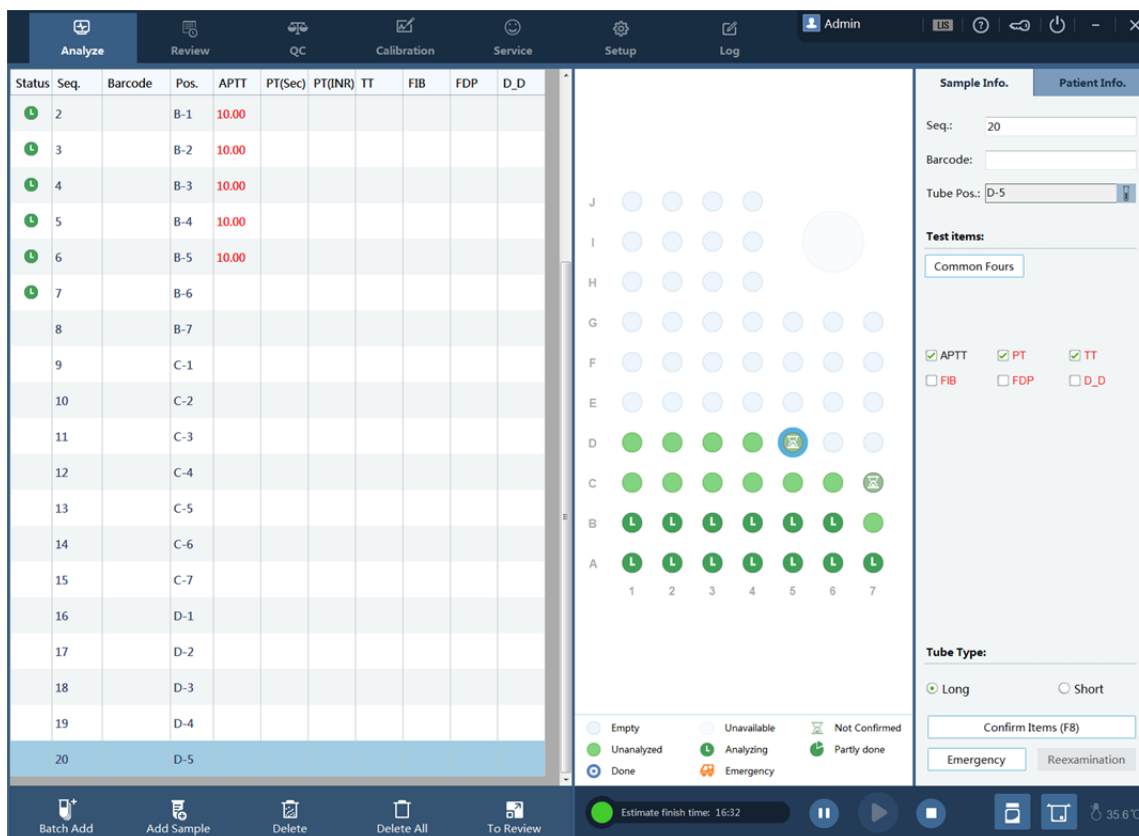
Combining menu options, function buttons and status bar information of the [Precil Auto Coagulation Analyzer Control Software]; this section states the use of the software. Access to the software interface leads to the access to the window interface as shown



4.3.1 Menu area

At the upper part of the software window are seven menu options: “Sample analyze”, “Review”, “QC”, “Calib”, “Service”, “Setup” and “Log”, all which are interpreted respectively as follows.

4.4 sample analyze



4.4.1 Work List

The Work List locates on the left of the screen. It includes the following main functions:

■ Sample testing state

The sample testing state and results are displayed on the left of the screen.

If the sample has a barcode and the LIS is connected properly, a worksheet is generated on the left.

■ Editing sample testing

You can edit the testing project when the generated worksheet is in non-testing state. You click a sample or select a sample location in the sample area to show experiment editing options in the sample information window on the right.

To edit testing projects of multiple consecutive samples at one time, you can select the required ones by dragging the cursor on the left or in the sample area, and edit the information in the sample information window on the right.

■ Data information









In the testing state area, you can double-click the target sample whose testing is complete to

return to the **Review** screen.

For details, see the introduction to Review.

4.4.2 Sample Area

You can view the information about inserted samples in the Sample area under **Sample Analysis**.

 Empty	No samples are added to the specified position in the test tube rack.
 Unavailable	Sample position is unavailable.
 Not Confirmed	Not confirm whether the sample has already place on the corresponding position.
 Unanalyzed	The testing worksheet of the corresponding position is set up, and no testing is carried out.
 Analyzing	The sample is being tested.
 Partly done	<p>The partly completed icon appears when one of the following situations occurs.</p> <ol style="list-style-type: none">1. The instrument is disconnected from the software.2. The sample is to be re-tested or re-diluted.3. The result is abnormal.4. The testing is stopped.
 Done	All the testing for the sample is completed.
 Emergency	The sample testing is an emergency testing, which is in high priority.

4.4.3 Sample Information

The **Sample Information** column shows the testing information and setup for samples.

Sample Info.
Patient Info.

Seq.:

Barcode:

Tube Pos.:

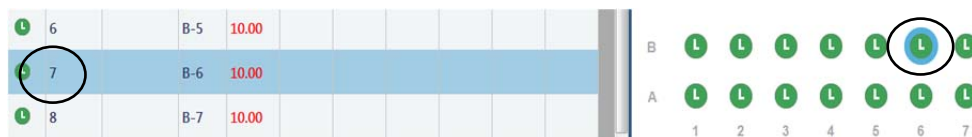
Serial No. A sample No. assigned by the software automatically. The serial No. is stored by day.

Bar Code Information read over the scanned bar code.

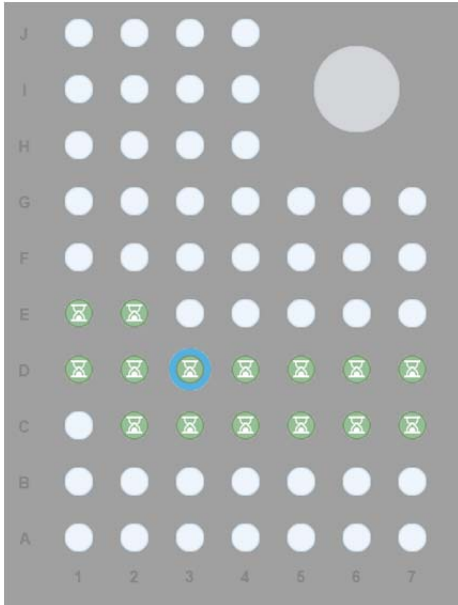
Tube Position Position of the sample.

To specify or change the tube position,

- Select a sample in the Worksheet column or sample area under **Sample Analysis**. The selected status is shown by "Sample 7" line in the following figure below:




- After you select a sample, click to show the position setup window.



- After the sample to be moved is selected, select the target position where no tube is placed. The sample is moved to the target position.

To perform a non-barcode sample testing, you need to perform the following operations first:

- Load the sample in the target position.

Choose **Add Sample**, select a sample, and click . Then, select a target position.

- No samples being loaded

If no samples have been loaded, choose **Add Sample** and load the sample in the automatically generated position.

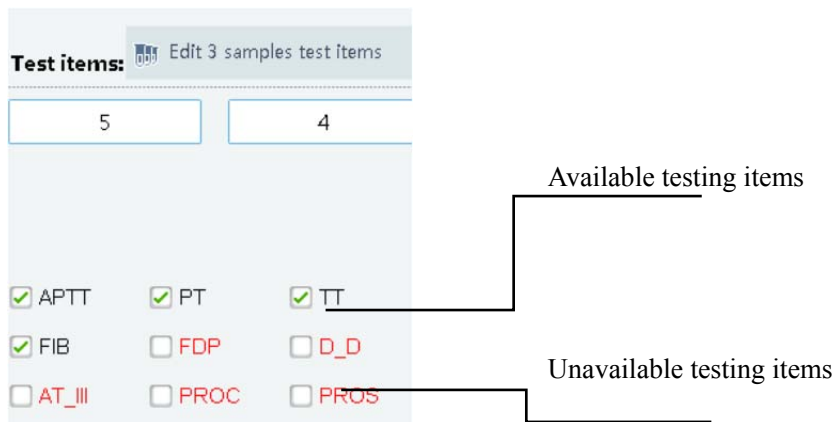
NOTE

- If the sample is being tested, do not change its position.
 - Make sure that the actual position is consistent with the one on the window after the position is changed; otherwise, erroneous results may be produced.
-

Testing item

- When multiple samples are selected for editing, corresponding messages are displayed.
 - You can select Four Normal Items to perform combined tests. You can also customize the combination of test items. For details, see “Test Combinations” under “Setup.”
-

- For unavailable testing items, the software shows corresponding notifications. You need to solve the problems as prompted before set up these testing items.



4.4.4 Tube Type

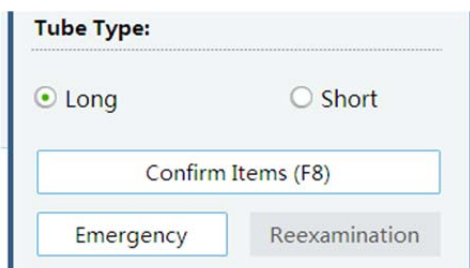
- The software takes by default that samples use long tubes. If short tubes are used to hold the samples, you need to click **Short Tube** after you select the sample.



- Make sure that the selected tube type is consistent with the actual one after the tube is replaced; if not, the instrument may be damaged and cannot be repaired.

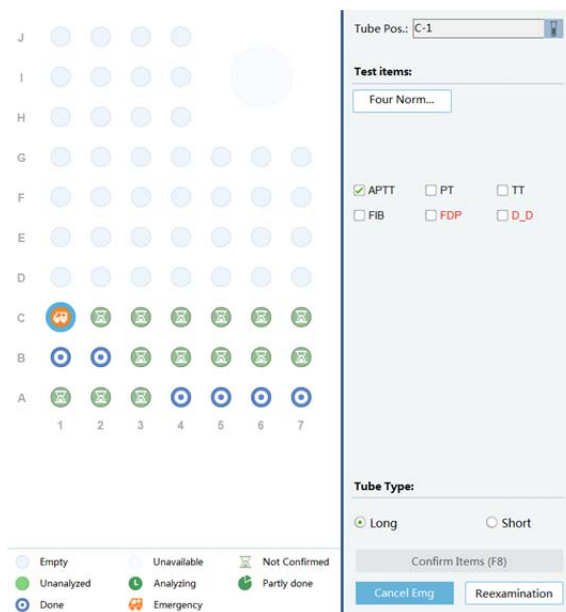
4.4.5 Emergency

- The samples from emergency clinic departments can be analyzed in higher priority than samples from other departments.



- During analysis and processing, perform the following steps to implement a sample analysis on emergency samples:
 1. Select a sample, for example, the sample in position E-1 in the figure below.

2. Click **Emergency**, and the sample in the position is changed to an emergency sample.
3. You can specify whether a sample is an emergency one before its testing is carried out.



NOTE

- When a sample is being tested, it cannot be set as an emergency sample.
- When an emergency sample is being tested, its sample type cannot be modified.

When you implement an emergency test for a non-barcode sample,

- The sample will be placed on the generated position after the sample is added. If the position does not meet with your requirement, change the tube position.
- Put the emergency sample in a specified position.

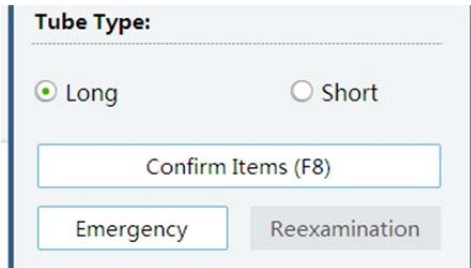


- Please confirm the type of the tube for emergency samples to avoid misoperation.
- Remove the tube cap before placing emergency samples to avoid damaging or jamming the sample probe.

- Click **Start** to carry out the testing.

Confirm Items

- You can click Confirm Items to confirm selected samples have been already placed on corresponding positions.
- You cannot start a test without confirm items.



Tube Type:

☒ Long ☐ Short

Confirm Items (F8)

Emergency Reexamination

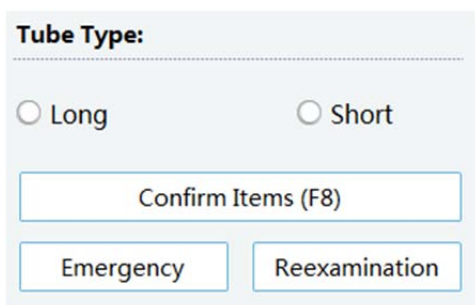
4.4.6 Retesting

- You can implement a retest on samples that are not removed from the instrument. The steps required are shown below:

NOTE

- The retest can be implemented on implemented testing items or testing items to be implemented for samples.
 - The sample status bar shows retest result, that is, analysis result of the second testing. You can query the two testing results over the **Review** menu.
-

Select a sample whose test is complete, and click **Reexamination**. Select the testing items for the retest, and click **Start**.



Tube Type:

☐ Long ☒ Short

Confirm Items (F8)

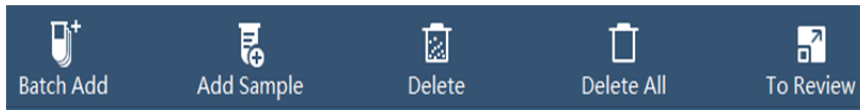
Emergency Reexamination

4.4.7 Patient Information

- After the LIS system connection is normal and the bar code is scanned successfully, the patient information is automatically loaded here.
- The information about the reviewer and review time is loaded automatically after the sample is reviewed.
- You can add quick inputs and new fields by choosing **Setup > Data Dictionary** and **Customized Setup**. For details, see “Data Dictionary” and “Customized Setup” under “Setup”.
- After the samples are reviewed under **Review**, the patient information cannot be modified.
You can click **Cancel Review** under **Review** to re-edit the patient information.
- You can press Enter in any edit area to shift sample.

Sample Info.	Patient Info.
Name	nike
Receive Time	2014年 8月 4日
Delivered by	doc. lee
Technologist	
Validator	
Checked at	
MR Number	123
Gender	Male
Date of Birth	1998年 8月11日
Age	24 Year
Payer	
Department	
Ward	
Bed No.	
Diagnosis	

4.4.8 Functional Buttons



■ Add Sample

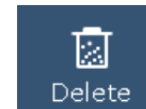


To add a new sample worksheet, you can click **Add Sample**.

NOTE

- By default, the new sample worksheet is generated on the first available position from A-1 from left to right.

■ Delete

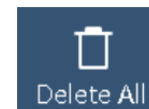


You can delete the testing in the worksheet column.

NOTE

- If you delete a delivered sample whose testing does not start, the sample information is not saved in **Review**.
- Samples in testing cannot be deleted.
- After a sample testing ends, you can click **Delete**. The testing information can be queried in **Review**.

■ Delete All



You can clear all the worksheets.

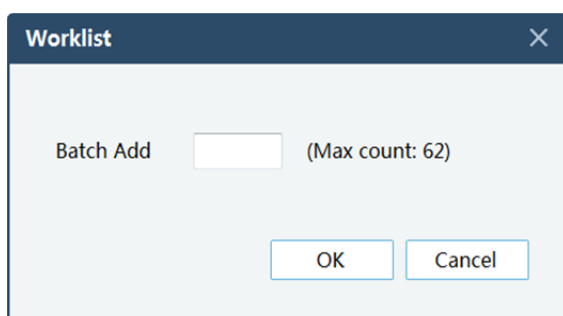
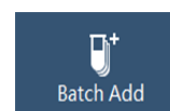
After you click **Delete All**, the sample status column on the left is cleared. You can check the history data in **Review**.



- The software does not implement clearance when the instrument is testing samples.
 - If there are still unreleased sample tube racks in the sample area after all the tests are completed, the clear operation is not available.
 - If the sample status column on the left does not contain samples in testing, all the undone sample worksheets in the column will be lost after you click **Clear**.
-



■ Batch Add



You can click this button to input batch add tubes, this number can not exceed the Max count appears on right.

NOTE

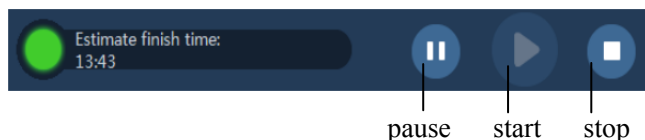
- The max count is a dynamic data according to currently available sample positions.
 - Improper number would be distinguished and rejected by software system.
-

■ To Review

You can press this button to switch to review interface.



4.4.9 Testing Buttons



■ Start

You can click **Start** to start the testing for a generated worksheet in the sample status column.

Status indicator:

The status indicator shows the running status of the instrument. The number in the indicator shows the number of alarms.

The software indicator shows the content of the alarms in rolling.

Grey	Not successfully connected to the instrument.	
Green	The instrument is ready.	
Flashing in green	A testing is being carried out. The system is being powered off or powered on. The system is in maintenance under service.	
Red	A level A or S fault occurs on the instrument.	
Yellow	A level B fault occurs on the instrument.	

■ **Pause:** You can click **Pause** if you need to change reagents or perform other operations.

NOTE

- You are recommended to quickly change the reagents or perform other operations after you click **Pause**,
- because the testing results may be affected if the process is paused for a long period.

■ Stop

The instrument cancels tests not started and carries on the ongoing ones to finish the analysis after you click **Stop**.



- After you click **Stop**, some of the ongoing testing items may be displayed as empty with their status shown as completed. If you click **Start**, you can get valid data only after you perform retest for those with empty testing results.
-

4.4.10 Reagent Setup



You can click **Reagent** to set up the reagents. The following screen is displayed:

When the reagents are used up, the icon changes into red.

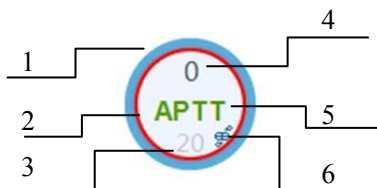


When the reagents are incomplete, the icon changes into yellow.





NOTE


- If the instrument lacks some of the reagents, the testing items will have no results. The testing items will go on after the reagents are replenished.
-



- 1 The reagent is selected.
- 2 The reagent is insufficient and must be replenished.
- 3 Reagent position No.
- 4 Remaining testing times of the reagent
- 5 Reagent projects and types

 Trigger Reagent

 Mixed Reagent 1

 Mixed Reagent 2
- 6 Stirrable reagent position

You can set up the reagents as follows:

To set up diluents, you need to place the corresponding diluent bottle in the normal temperature diluent position.

To set up normal reagents, you need to place them in the cooling reagent position.

Select a target reagent position, for example, position 23, and set the reagent information about the position.

Selecting testing items

Reagent type: You can select the reagent type based on the instructions of the reagent.

Reagent batch No.: Fill in the batch number of the reagent based on the reagent instructions or labels.

After the above information is filled in, click **Save**.

■ Update

To replenish the reagent, you need to:

Change the empty reagent bottle with one with the same reagent.

Select the reagent position on the software.

Click **Update**. The instrument reads the available remaining number of tests for the new reagent bottle, and clears the warning about the reagent bottle.

■ Clear

To clear the information about a selected reagent position, do as follows:

Select a target reagent position on the software.

Click **Clear**.

After the reagent position setup is complete, click **Exit**.

Reagent

Normal Temperature Area Dilution

54
D_D

452
PT

145
FIB

721
FDP

Cooling Area Reagent

532
FDP
5

211
D_D
12

429
Probe
Cleanser
24

52
D_D
11

52
XII
4

46
PT
22

257
FIB
3

442
TT
2

491
APTT
1

123
APTT
18

Item Color

Trigger Reagent

Mixed Reagent 1

Mixed Reagent 2

Reagent Information

Test Items

PT

Reagent Type

Mixed Reagent 1

Reagent LOT

Clear

Update

Save

Exit

4.4.11 Consumables

You can click **Consumables** to check the usage of the corresponding consumable.

Reagent amount: The software shows the remaining amounts of reagents for each testing item.

Cuvette amount: The software shows the updated remaining amount in the cuvette.

Remaining numbers of physical cuvettes: The software counts the number of online cuvettes.

You can check the remaining number of cuvettes on the software.

Consumables

Reagent Limit(μL):

APTT	PT	TT	FIB	FDP	D_D	AT_III
19940.0	19955.0	19945.0	19990.0	20000.0	20000.0	20000.0

Cuvette Limit:

4966

Swing card

Actual Cuvette Quantity:

166

Change cuvette

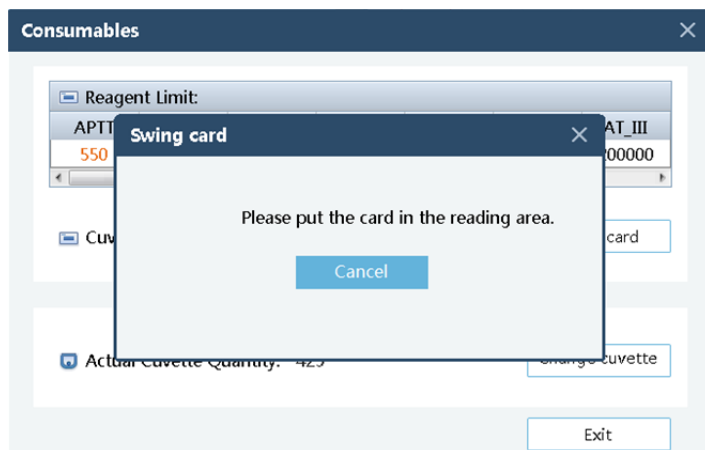
Exit

51

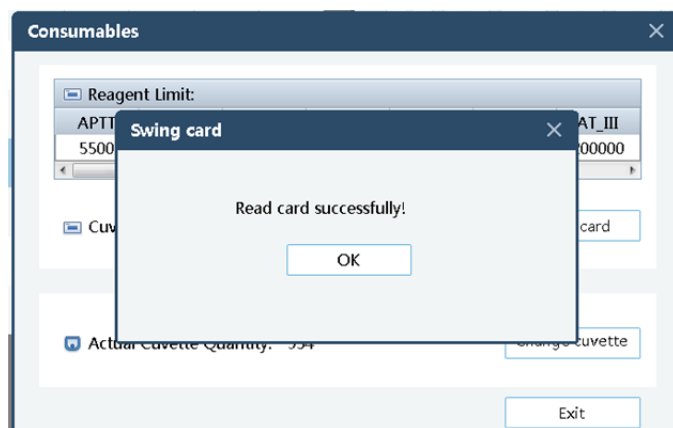
Swipe Card

When the reagent amount is low, you need to swipe the card.

Click **Swipe Card**, and follow the instructions.



After the instruction message appears, place the card on the card reading area on the instrument.



After the software indicates that the card is read successfully, click **OK** to end the card reading operation.

Replacing the cuvette tray

When there are few cuvettes left in the instrument, a yellow icon appears.



When there is no cuvette left in the instrument, a red warning icon appears.



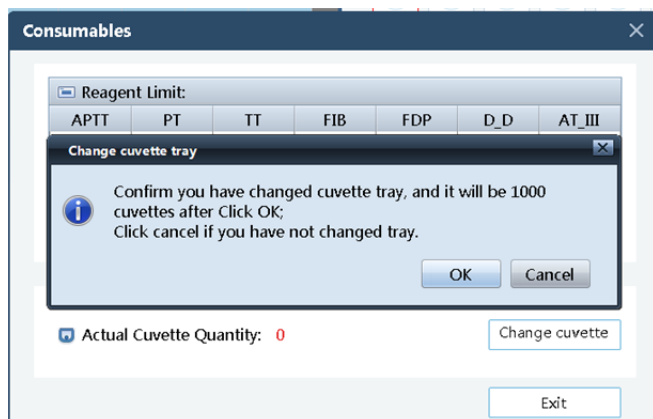


- It is recommended that you should replace the cuvette tray when the yellow warning icon appears.
 - If the cuvette tray is not replaced in time, the testing progress or even the testing result is affected.
-

You can replace the cuvette tray as follows:

If the yellow icon appears or the number of cuvettes is insufficient, click **Consumables**.
If the instrument is carrying on a testing, pause the testing first.

Replace and install the cuvette tray according to the instructions described in section 3.2.5.
After the cuvette tray is installed, click **Change Cuvette**.



Click **OK** at the prompt message.



- After you change the cuvette tray, you need to perform the above operations on the software. If you do not perform the setup operations on the software in time, the number of remaining physical cuvettes counted on the software may be inaccurate.
- Fault on the instrument or software, or improper user operation may lead to incorrectly counted number of remaining physical cuvettes. You are recommended to check the number of cuvettes before replacing the cuvette tray.
- Follow the instructions on cuvette tray replacing strictly to avoid damages caused by incorrect operation.

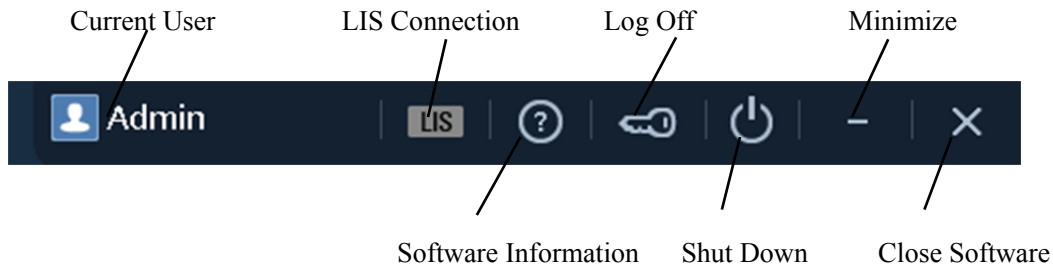
■ Temperature



The software shows the instrument measurement temperature. You are recommended to start testing when the temperature is at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$.



4.5 User Management

The software shows the current user account and allows you to close the software.



Current User	User name of the account currently logged in
LIS Connection	 Normal LIS connection  LIS connection failed
Software Information	Information about the software version and so on
Log Off	Logging off the current user account
Shut Down	Performing the shutdown operation
Minimize	Minimizing the software window
Close Software	Closing the software window

4.5.1 Log Off

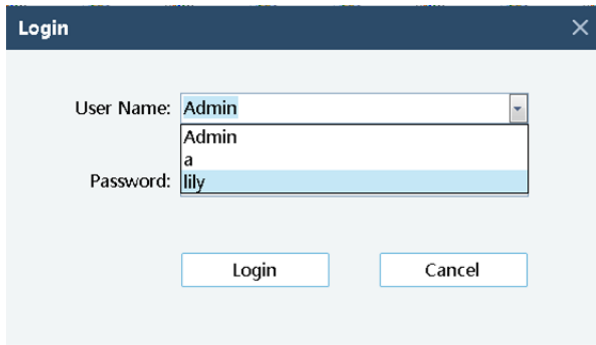
If you need to change the user account, you need to log out the current user account first. Do as follows:

Click the **Log Off** button.

In the dialog box as shown bellow, click **OK**.



Select another user account, enter the correct password, and click **Log On**.



4.5.2 Shut Down



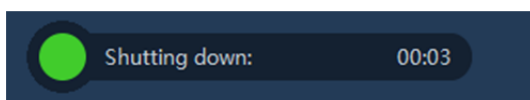
- Make sure that the software is shut down before powering off the instrument.
 - Incorrect power-off operation may cause anomalies or irrecoverable damages on the instrument.
-

You can shut down the software after the tests are complete.

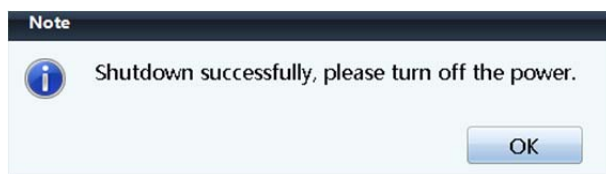
After you click **Shut Down**, a confirmation dialog box is displayed, asking whether you want to shut down the instrument.



After you click **OK** in the confirmation dialog box, the instrument turns into shutdown state.



Power off the instrument after the software is shut down.



After the clear operation is done, power off the instrument, dump the waste cuvette, recycle the reagents, and process the remaining samples properly as instructed.

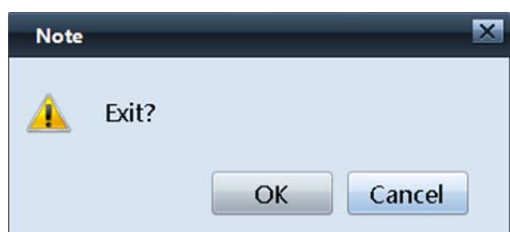


- All the articles (samples, quality control materials, calibrators, reagents, and wastes), and areas exposed to these articles possess potential biological danger in the form of infection. Operators in contact with these materials and areas in the laboratory must follow the laboratory safety operation process and regulations, and wear personal protective equipment (such as laboratory protective clothing and gloves) properly.
-

4.5.3 Close Software

This button is used to shut down the software.

After the shutdown process is complete, you can click **Close Software**.



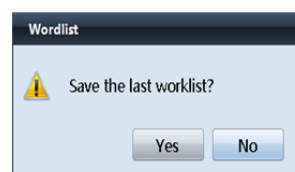
After you click **OK** in the confirmation dialog box, the software is closed.

NOTE

- When the instrument is carrying on tests, you cannot close the software.
-

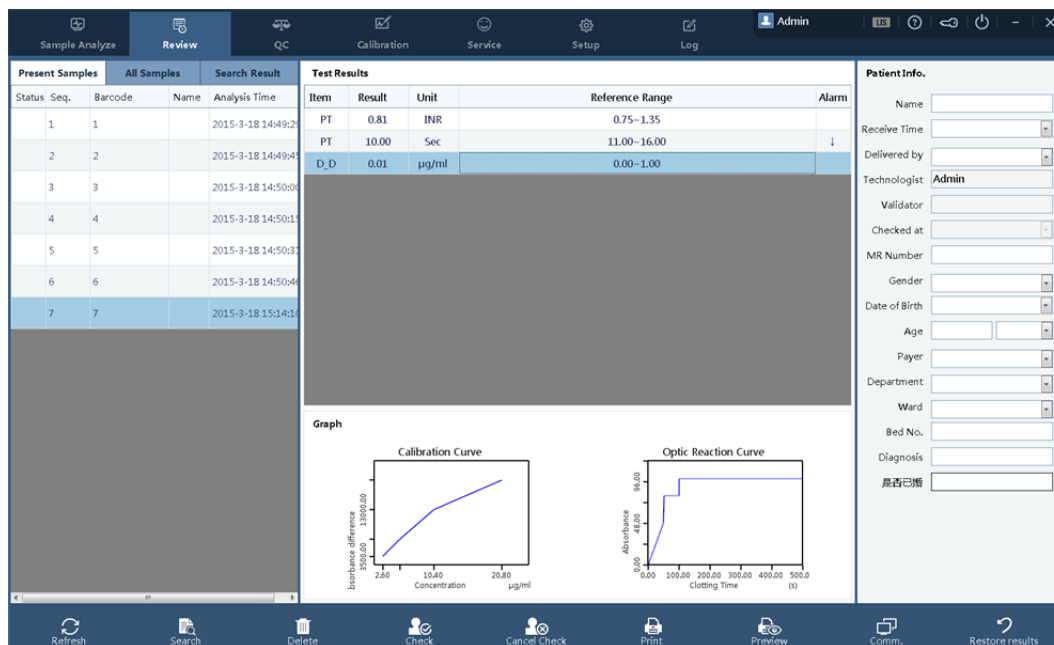
When all the tests are complete and there are no ongoing tests, the following prompt message is displayed after you close the software and restart it:

If you want to save the previous worksheets, click **Yes**.



4.6 Review

You can check, review, and print the testing results in the **Review** window.



4.6.1 Sample Results

You can check the testing results under **Current Samples**, **All Samples**, and **Search Result**.

Current Samples	Information about the testing samples in the current day
All Samples	Information about all the tests on the instrument
Search Result	Testing information about the samples queried by conditions.

■ Search Sample

You can filter the samples with querying conditions. Do as follows:

In the **Review** window, click **Search**.



Enter the query condition in the **Search** window.

To query samples by time, select a time point from **Testing Time**.

To query samples by other conditions, click **Advanced**.

You can select the query type as required.

After you select the query type and enter the query conditions correctly, click **OK** to query

samples.

The image shows a 'Search' dialog box with a dark blue header and a light blue body. At the top right of the header is a close button (X). Below the header, there is a 'Search' label followed by a text input field. Underneath that is the 'Analysis Time' section, which consists of two date pickers: 'Wednesday, February' and 'Wednesday, March', separated by a hyphen. Below the date pickers are three buttons: 'Advanced' (highlighted in blue), 'OK', and 'Cancel'. At the bottom of the dialog is a section titled 'Advanced' in bold. This section contains eight input fields arranged in two columns. The left column has 'Seq.', 'Name', 'Delivered by' (a dropdown), and 'Technologist'. The right column has 'Barcode', 'Department' (a dropdown), 'Ward' (a dropdown), and 'Validator'.

4.6.2 Testing Results

After you select a sample, the testing results and the reaction graphs are displayed in this area.

If a re-test is implemented on the sample, tests results and reaction graphs of both tests are displayed in this area.

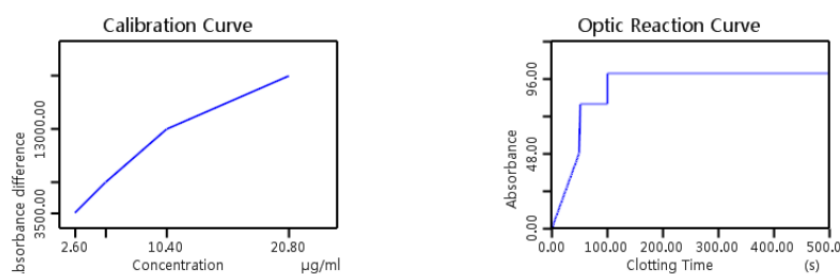
The average value is the arithmetic mean of the two testing results.

For an optical reaction testing program, the reaction graph is displayed in the graph area after you select the sample.

Test Results

Item	Result	Unit	Reference Range	Alarm
PT	0.81	INR	0.75~1.35	
PT	10.00	Sec	11.00~16.00	↓
D_D	0.01	μg/ml	0.00~1.00	

Graph



The following symbols may appear in the results:

- *** The instrument is faulty, the sample is not sucked, or the coagulation time is too short.
The instrument is short of reagents during the end of testing,
Stop is clicked when the instrument is short of reagents.
The instrument is stopped shut down by force during a testing.
- > The sample testing result is greater than the upper threshold.
- < The sample testing result is smaller than the lower threshold.

When the sample is not reviewed, you can correct the data in the following way:

Select a testing item for revision.

Click the data area that requires revision, and the data changes into the revisable state.

NOTE

- Do not change the data arbitrarily.
- Data revision is recorded in the logs.

■ Adding/Deleting Items

You can add or delete testing items in the testing results in the following ways:

To add a testing item:

Right-click the testing result area, and choose **Add Item**.

Select a required item and a desirable unit.

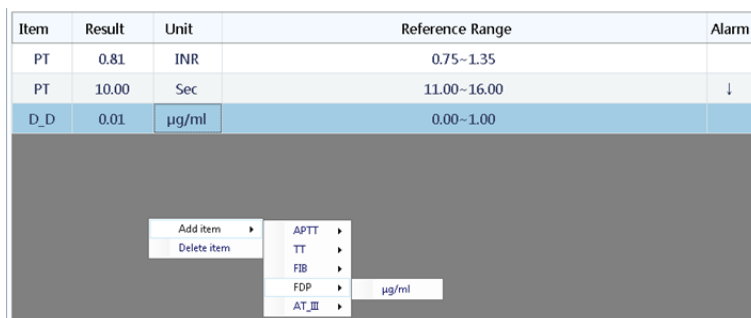
Fill in the testing results in the result sheet of the testing item.

To delete a testing item:

Select a target testing item to delete.

Right-click the testing item, and choose **Delete**.

In the dialog box as shown bellow, click **OK**.



■ Reference range

The reference range defines the normal range of a testing item.

You can set the range under **Setup > Item Parameters > Result Parameters > Reference Range Upper/Lower Limit**.

NOTE

- You are recommended to establish reference ranges of standard values for your laboratory.
-

■ Alarm

When the testing result is abnormal, the result is displayed in the **Alarm** area.



The testing result is ***.

The testing result is greater than the upper limit of the reference range, or longer than the maximum reaction duration.

The testing result is smaller than the lower limit of the reference range, or shorter than the minimum reaction duration.

■ Graph

The software supports the display of reaction graphs of optical testing items.

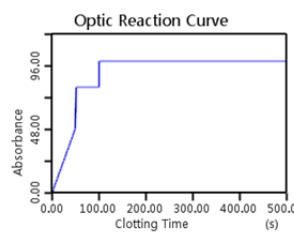
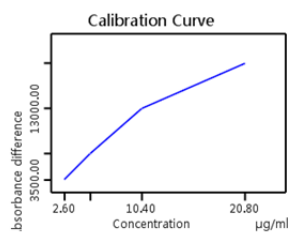
After you select an optical testing item, the software shows the reaction graph of the testing.

Calibration curve:

The calibration curve used by the testing.

Reaction curves of the first testing and the re-test.

To view the details of a curve, click the curve.



■ Patient information

You can view and record patient information.
For details, see section 4.4.7.

4.6.3 Functional Buttons

■ Refresh



You can update the selection/non-selection state of samples.

■ Delete



Select a sample, and click **Delete** to remove the sample.



- The testing results of deleted samples cannot be restored; therefore, exercise caution during operation.
- The operation of deletion will be recorded in the logs. You can check the basic information about the deleted samples by viewing the logs. However, the testing results are not included.

■ Check



After the tests are complete for the sample, you need to review the testing results of the sample.

You can drag the cursor to select multiple samples to review.

	21	11222		2015-1-5 10:38:5
	22	1		2015-1-5 13:13:0
	23	2		2015-1-5 13:13:2
	24	3		2015-1-5 13:13:5

NOTE

- You can print only the reviewed testing results.
 - The sample information cannot be edited after review.
 - You cannot restore the testing results after review.
 - After the samples are reviewed, you can click **Comm.** to upload the data.
-

■ Cancel Check



You can click cancel the review after a sample is reviewed.

You can drag the cursor to select multiple samples for cancelling review.

■ Print



You can print the testing report for reviewed samples.

NOTE

- The function is available only when the instrument is connected to a printer.
-

■ Print Preview

Before printing the report, you can preview the printing.

Coagulation Analyze Report				
Name:	Gender:	Age:	MR Number:	
Seq. : 3	Barcode:	Analysis Time: 2015/6/16 11:26		
Ward:	Department:	Bed No.:		
Diagnosis:				
Item Code	Result	Unit	Reference Range	Alarm
1 APTT	10.00	Sec	24.00~38.00	↓
2 PT	10.00	Sec	11.00~16.00	↓
3 INR	0.81		0.90~1.40	↓
4 TT	10.00	Sec	8.00~16.00	
Delivered by:	Technologist: service	Validator:	Admin	
Receive Time: 2015/6/16	Print Time:	2015/6/26 10:17		
This result is only responsible for the detected samples If you have any questions please consult the same day.				1 / 1

NOTE

- The print items of technologist and validator can be selected under **Print Setup**.
-

■ Comm.



After the tests are complete and testing results reviewed, you can click **Comm.** for LIS upload of testing data.

NOTE

- Make sure that the LIS is in normal connection.
-

■ Restore Results

When the testing results of a sample are not reviewed, you can restore the testing results for the sample.

Select a sample whose testing results are not reviewed.

Click **Restore Results**.

Click **Yes** in the popup window.



NOTE

- After you click **Restore Results**, the testing results are restored to those generated in the first testing. In addition, the add/modify/delete operations implemented on the sample are restored as well.
-

4.7 QC

NOTE

- Setting the Quality control blood plasma before QC. The setting details please see “Chapter 4 4.5.5 Quality control blood plasma”.

Analysis of the results with statistical methods allows the inference that sample results are reliable. Precil recommends you run the QC program daily with normal and high level controls. A new lot of controls should be analyzed in parallel with the current lot prior to their expiration dates. The QC files calculate the mean, standard deviation and coefficient of variation for each selected parameter.



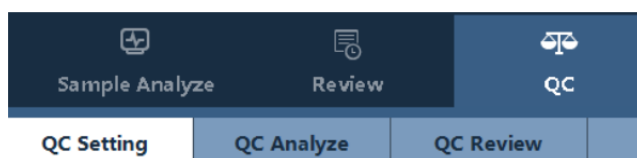
- Use and storage the calibrators according the calibrator introduction.



- Make sure the volume of controls is no less than 0.5 mL;
- Make sure the QC is taken when the analyzer is operated normally and error hint is cleared.
- Do not use the one-off product repeatedly.
- Inspect the controls before QC.



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.



4.7.1 QC Setup

■ QC grouping

The software provides five groups of QC configurations. You can set the QC configurations as required.

To make a clear distinction among groups, you can set the group names for them.

The screenshot shows the 'QC Setting' tab in the software interface. It features a table for configuring QC groups. The table has columns for Item Name, LOT, Target Value, Deviation Limit, Unit, and Entry time. The first row is for 'QC Group1' with a 'Group Name' input field and a 'Save' button. Subsequent rows show 'QC Group2' through 'QC Group5' with pre-filled data for various tests like APTT, PT(Sec), PT(INR), TT, FIB, FDP, D_D, and AT_III.

QC Group	Item Name	LOT	Target Value	Deviation Limit	Unit	Entry time
QC Group1	Group Name <input type="text"/> Save					
QC Group2	APTT	1	32.00	2.00	Sec	2015-1-14 13:55:14
QC Group3	PT(Sec)	1	12.00	2.00	Sec	2015-1-14 13:55:14
QC Group4	PT(INR)				INR	
QC Group5	TT				Sec	
	FIB				g/L	
	FDP				μg/ml	
	D_D				μg/ml	
	AT_III				%	

Batch No. Batch No. of the control.

Target value Target value of the measured control. You are recommended to establish target values of controls for your laboratory.

Range 1SD value of the QC data.

NOTE

- For four normal QC tests carried out at one time, their batch numbers must be consistent.
- You are recommended to establish target values and ranges of controls for your laboratory based on the QC testing data.



- To replace controls of different batches, you need to set the batch number.

4.7.2 QC Analysis

To ensure the analysis data reliability, you are recommended to implement QC analysis. Regular QC analysis helps you monitor the stability of the instrument and reagents.

NOTE

- To learn about how to use the control samples and reagents, see the corresponding instructions.

■ Steps to carry out QC analysis:

Set the new sample.

Select the required QC group type.

Select the target position for the control, and place the control in the corresponding position.

Select the QC item.

The instrument supports long-tube, bullet-head, and short-tube QC.

After the above configuration is made, click **Start** to implement the QC testing.

NOTE

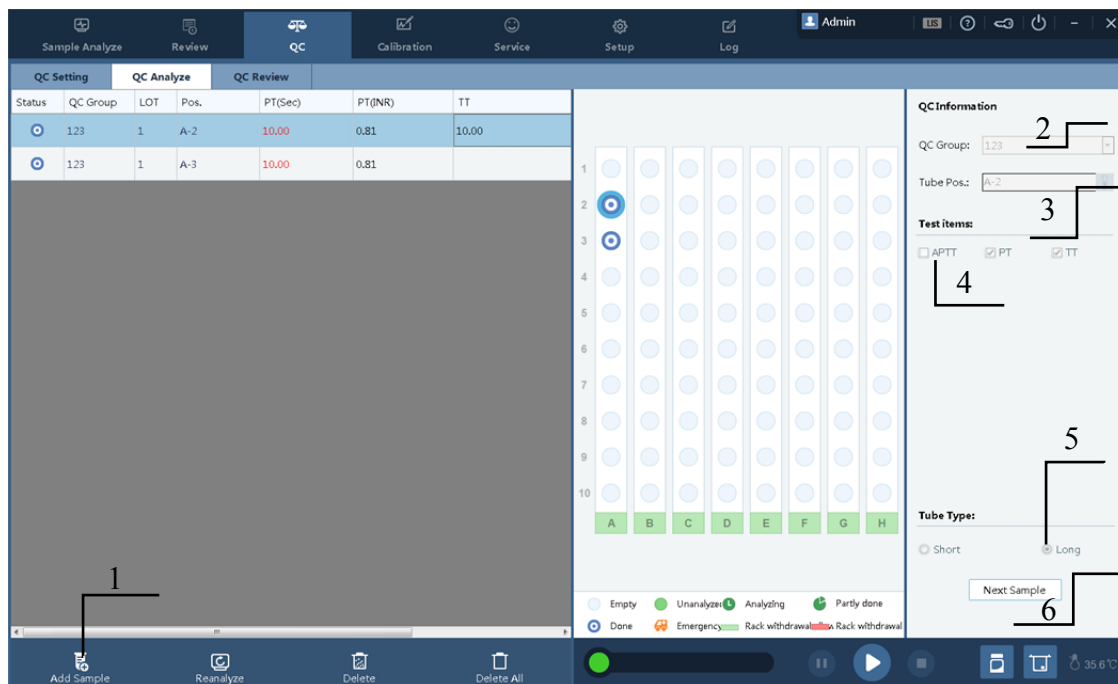
- The batch No. of one control in the same QC group must be the same.
- You need to set the tube type for the control.

NOTE

- You must use the controls and reagents specified by Precil, and follow the instructions for use of controls and reagents strictly during storage and usage.



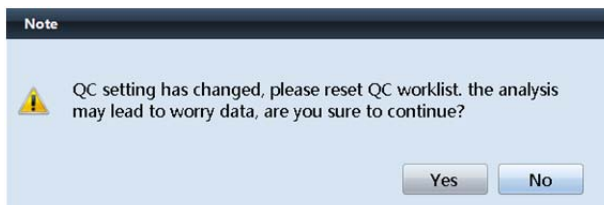
- When you click **Control Sample**, the instrument carries out daily QC analysis. During a QC testing, the plasma is stored in a short control tube (by default). Make sure that the tube type is correctly set; otherwise, the probe may be damaged.
-



■ Re-Analysis

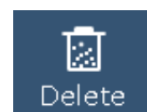
You can click **Re-Analysis** to carry out analysis operation on existing controls on the same sample again.

Check the accuracy of the QC worksheet when the QC configuration changes.



■ Delete

You can delete a selected QC analysis worksheet.

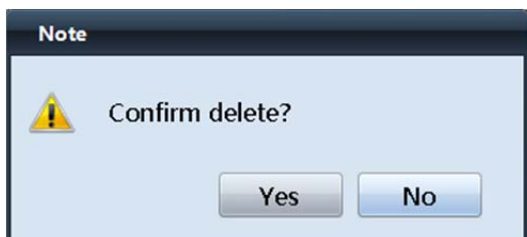


■ Delete All



You can clear the current worksheets if needed.

Click **Delete All**. In the displayed dialog box, click **Yes**.



4.7.3 QC Review

You can view the QC result of each analysis parameter in the QC analysis worksheet in **QC Review**.

You can monitor the stability of the instrument and reagents based on the QC graph at any time.

QC Group

Check the group of the QC analysis.

Measurement
Item

You can choose to view the QC data of different items.

Date

You can choose to view the QC plot of a certain period by specifying the start and end of the time period.

Delete

You can delete a selected QC data point.

Print

You can print the QC data plot.

Print Preview

You can preview the QC report to be printed.

QC Rules You can judge whether QC result is under control according to selected QC rules, there are at most 10 options.

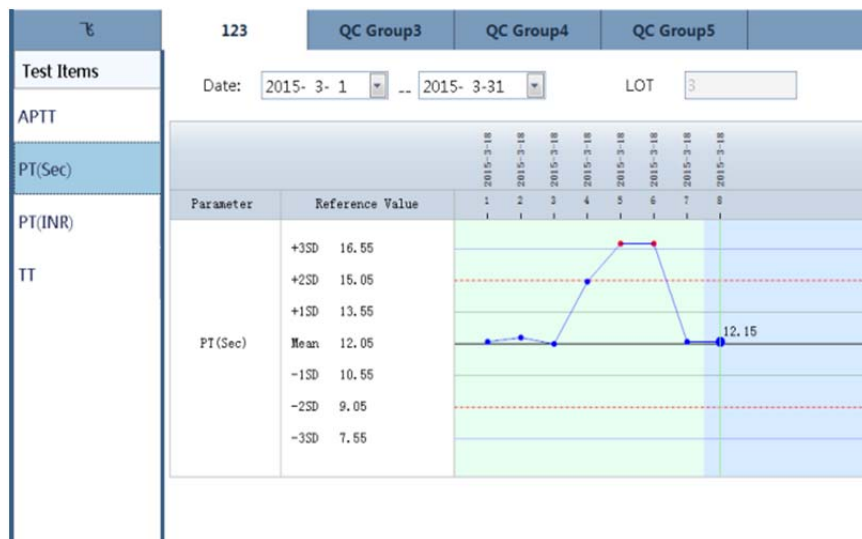
QC Analysis You can input QC analysis content in edit area.

■ QC plot

When the value of a QC data point exceeds 3SD, the corresponding data point is displayed in red in the plot.

After the batch No. of the control is sent for change, the background color of the corresponding area in the plot changes to a different one.

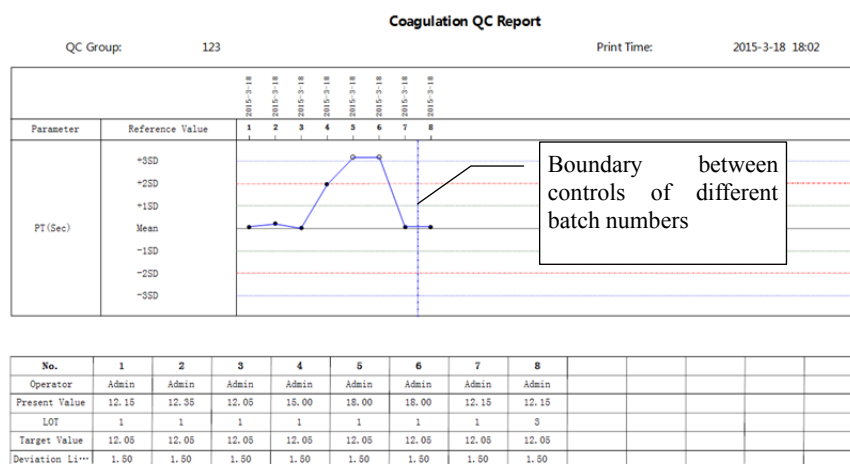
You can select any QC point to check the data value.



■ Print Preview

You can preview the QC report to be printed, and view the value and target value of each QC point.

Setting Your Analyzer



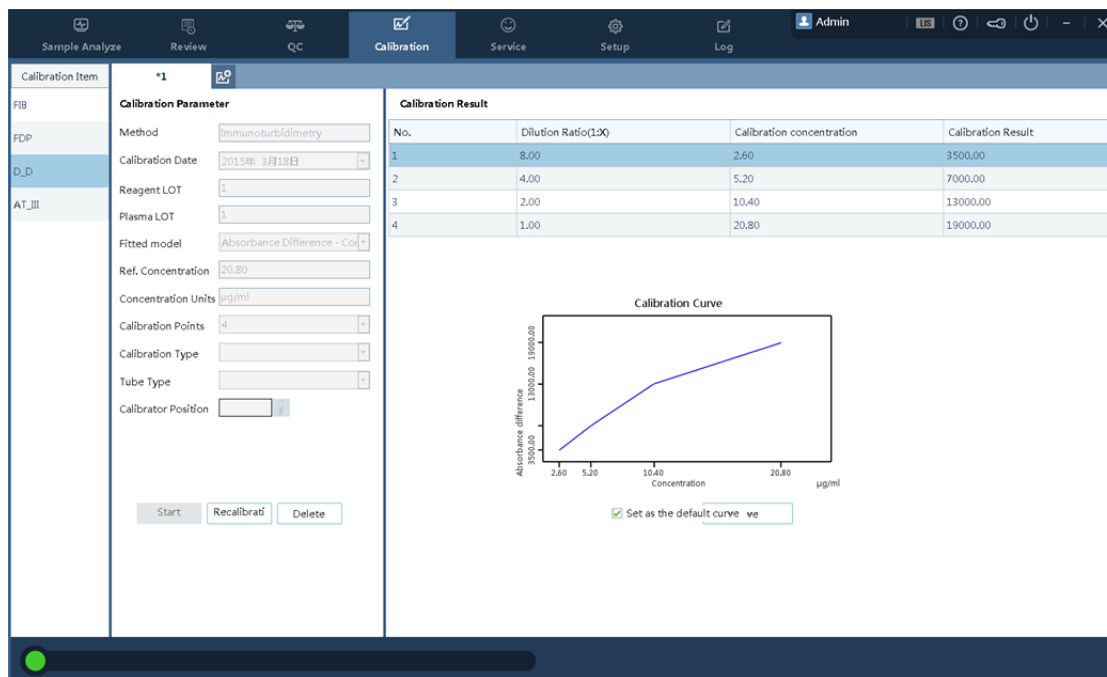
- The sampling probe is sharp and is potentially contaminated with hazardous biological substances. Therefore, be cautious when handling the main machine, and do not touch the sampling probe.
- A broken blood sampling cartridge may result in personal injury and/or biological contamination. Therefore, be careful when you load the blood sampling cartridge to the holder or remove it from the holder. Do not damage the blood sampling cartridge.

4.8 Calibration

This section describes the function of calibration. The process of calibration draws a function curve on the measured parameters based on the analysis results (for example, the coagulation time and optical density change rate dOD).

Each batch of reagents shall have a calibration curve. You can store a maximum of 10 calibration curves for each program.

You need to select the calibration curve of the reagents of the same batch number for the analysis. The software uses the verified curve to calculate the calculation parameter.



- Before changing the reagent batch, you need to calibrate the batch first.
- You need to select the calibration curve of the reagents of the same batch number for the analysis; otherwise, the testing results may be inaccurate.

NOTE

- You must use the calibrators and reagents specified by Precil, and follow the instructions for use of calibrators and reagents strictly during storage and usage.
- The calibration operation is valid only when the calibrator calculation is implemented in the **Calibration** window.

You can generate the calibration curve in the following ways:

- Auto calibration
- Manual calibration

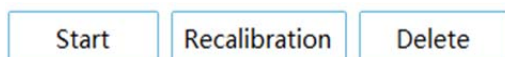
- 1 Button for creating a new calibration curve.
- 2 Area for calibration item selection.
- 3 Area for calibration parameter setup.
- 4 Area for calibration curve selection. You can save up to 10 calibration curves for each testing item.
*X is named by the reagent batch No. * marks the default curve.
- 5 Area of the calibration result.
- 6 Calibration curve

■ Calibration method

Click **Calibrate** to go to the **Calibration** window.

Select an item for calibration. Here, FIB is taken as an example.

To re-calibrate, (for example, when the batch number changes), click **Re-Calibrate**.



Enter the batch No. and standard plasma batch No. in the calibration parameter area.

For the fitting model FIB, select the double logarithmic, and set FDP and D-D to Absorbance difference – Concentration.

NOTE

- The default fitting model in the software is recommended for calibration.
-

Unit of concentration: g/L for FIB. The instruction of use for the calibrator shall prevail.

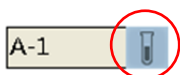
NOTE

- Use the default unit in the software for calibration.
 - If the unit recommended by the instruction of use for the calibrator differs from the default unit in the software, convert the unit before filling in the parameters.
-

Reference concentration		Filled in based on the instruction of use.
Number of calibration points	of	Number of dilution times.
Calibration type		Type of dilution times.
Number of calibration points	of	Number of tests during calibration
Tube type		Filled in based on the type of tubes used in the calibration testing.
Calibrator position		Position of the calibrator.

Setting up the calibrator position:

Click the **Calibrator Setup** button.



In the displayed screen as shown below, click the target position.

After the calibration parameters are set, click **Start Calibration**.

Tube Type: Long
Calibrator Position: A-1

Calibrating

Start Recalibrate Delete

Tube Type: Long
Calibrator Position: A-1

Calibrate successfully.

Start Recalibrate Delete

After the calibration ends, there appears a calibration curve with judgment by system automatically, if the curve is inaccurate, there appears following message:

The curve does not meet monotonicity requirement.

Click **Save** to keep the calibration result you want.

To save the curve as the default curve, select **Set as default curve**.

Save ☐ Set as the default curve

■ Manual calibration

If you choose manual calibration, you need to enter the dilution ration and calibration concentration.

After these parameters are set, click **Start Calibration**.



- You need to dilute the calibrator based on the reference concentration and dilution ratio.
 - Place the diluted calibrators in the correct positions. Incorrect positions may lead to serious error in the calibration curve.
 - For a bullet-head centrifugal tube, you need to place it in a proper adapter.
-

No.	Tube Pos.	Dilution Ratio(1:X)	Calibration concentration	Calibration Result
	A-1			
	A-2			
	A-3			
	A-4			

NOTE

- During a single-calibrator D-dimer calibration, put the calibrator in a bullet-head short tube, and put a clean bullet-head short tube in the position following the calibrator tube, so that the instrument can place the intermediate sample in the second short tube. To ensure the correctness of calibration, you need to prepare at least 500 μ L dilution for this type of calibration.
 - You are recommended to adopt manual calibration for D-dimer calibration.
-

4.9 Services

To help the analyzer operate effectively, you are recommended to take daily maintenance measures on the analyzer based on the description in this section. This analyzer provides multiple maintenance functions for your convenience.

This section describes these maintenance functions and handling measures for faults and alarms.



- The surfaces of all the parts of the analyzer is potentially contagious. Take protective measures during operation and maintenance.



- Improper maintenance may damage the analyzer. Follow the instructions strictly during maintenance.
- For problems not specifically clarified in the instruction, contact Precil Service Department for professional maintenance advices.
- Avoid the dangerous parts, such as the sharp point of a probe, during maintenance.

Item	Content	Reference	Unit
Temperature			
Preheating Z...	-4316...	35-39	℃
Reagent Probe	-4316...	>40	℃
Cooling Unit	-4316...	10-22	℃
Switch			
Shielding Co...	Close	/	/
Rack A	Rack I...	/	/
Rack B	Rack I...	/	/
Rack C	Rack I...	/	/
Rack D	Rack I...	/	/
Rack E	Rack I...	/	/
Rack F	Rack I...	/	/
Rack G	Rack I...	/	/
Rack H	Rack I...	/	/
Fluid Path			
Waste Bucket	Full	/	/
Cleaning Buc...	Full	/	/

■ Pipe refill

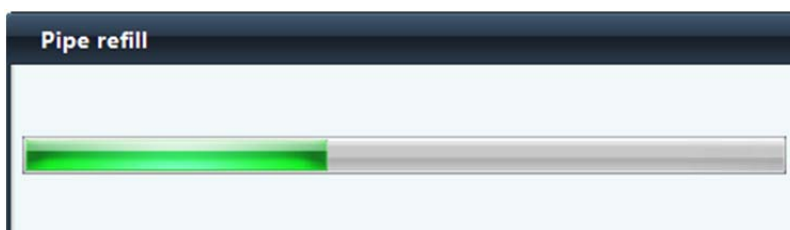
To ensure the accuracy of the testing results and the cleanness of the tube, carry out tubing perfusion periodically.

Click **Pipe refill** in the following circumstances:

- An air bubble is found in the tube. An air bubble may affect the accuracy of the added sample volume and reagent volume.
- The instrument is newly installed. Before implementing any testing, you need to carry out tubing perfusion first.
- Periodically implementing tubing perfusion for the cleanness of the tubes.



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
-



■ Examine liquid flow

Click **Service** and choose Examine liquid flow from the menu.

Observe the outlet of the sample needle and reagent needle, check whether the water outlet from the sample needle and reagent needle is continuous, whether the direction of the water outlet is consistent with the direction of the needles, and whether the volume of the outgoing water is normal.

If not, clean the sample needle. For details, see section 6.5 “Unscheduled Maintenance.”

■ Soak probes



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
 - If leakage happens to the analyzer, the leaked liquid is potentially biohazardous.
 - Areas contacted by sample, reagent etc are potentially biohazardous, please follow safe laboratory procedures.
-

Click **Soak probes** in the following circumstances:

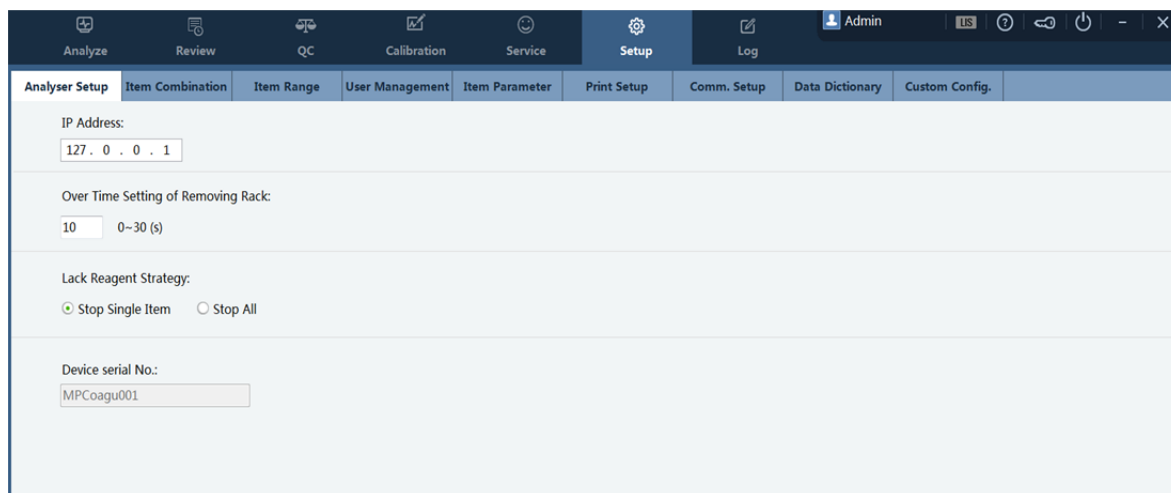
- The plasma is in small volume, which causes the sample needle dip too deep in the plasma and get contaminated with blood cells.
- The two needles have been used for a while.
- The sample needle and the reagent needle may be contaminated.

4.10 Setup

The analyzer has been initialized before delivery. The screens displayed at initial startup are system default screens. You can set some parameters of the analyzer to suit your demands.

To ensure production configuration and data security, the analyzer offers two types of users, namely, common users and administrators. (Administrators has all the user rights enjoyed by common users.)

The following describes how to configure the software at the PC end.



You can setting :

- Analyzer setup
- Items Combination
- Item Range
- User Management
- Item Parameter
- Print setup
- Comm. Setup
- Data dictionary
- Custom configure

4.10.1 Analysis setup

In the **Analysis setup** Window, you can set the following items:

- IP address
- Tube rack removing timeout settings
- Reagent shortage policy

The screenshot shows the 'Analysers Setup' window with the following fields and values:

- IP Address:** 127 . 0 . 0 . 1
- Over Time Setting of Removing Rack:** 10 (range 0~30 (s))
- Lack Reagent Strategy:** ☒ Stop Single Item, ☐ Stop All
- Device serial No.:** MPCoagu001

IP address

IP address of the host software

Lack
strategy

reagent

You can select one of the following reagent shortage policies:

Stop one testing item:

When you choose this option, the instrument does not stop other testing items except for the involved one when the instrument is short of the related reagent.

Stop all:

When you choose this option, the instrument stops all the testing items when it is short of one type of reagent.

Device serial No.

The serial No. of the connected analyzer. The content is read by the system automatically and cannot be modified.

4.10.2 Items combination

For your convenience in implementing a group of tests, you can set testing portfolios under **Setup** > Items combination as follows:

Click **New**.

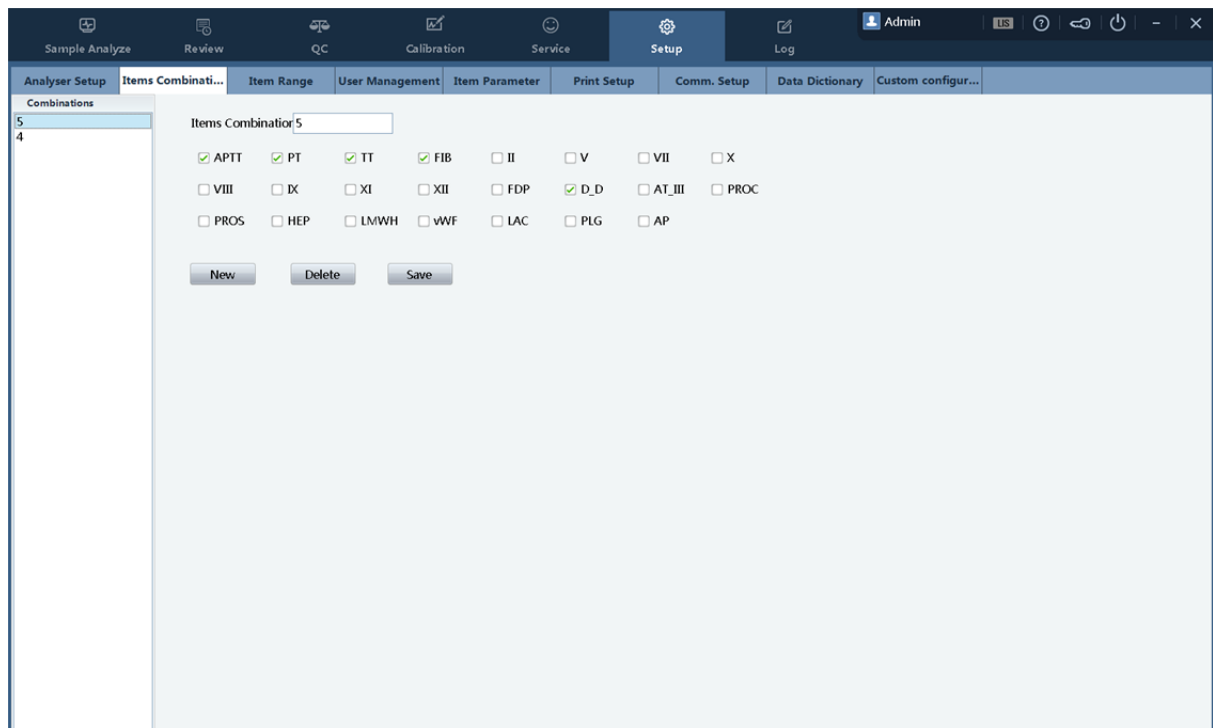
Fill in a name in Items combination. The parameter is mandatory.

Select the testing items for the portfolio. You can click the selected ones again to deselect them.

Click **Save**.

NOTE

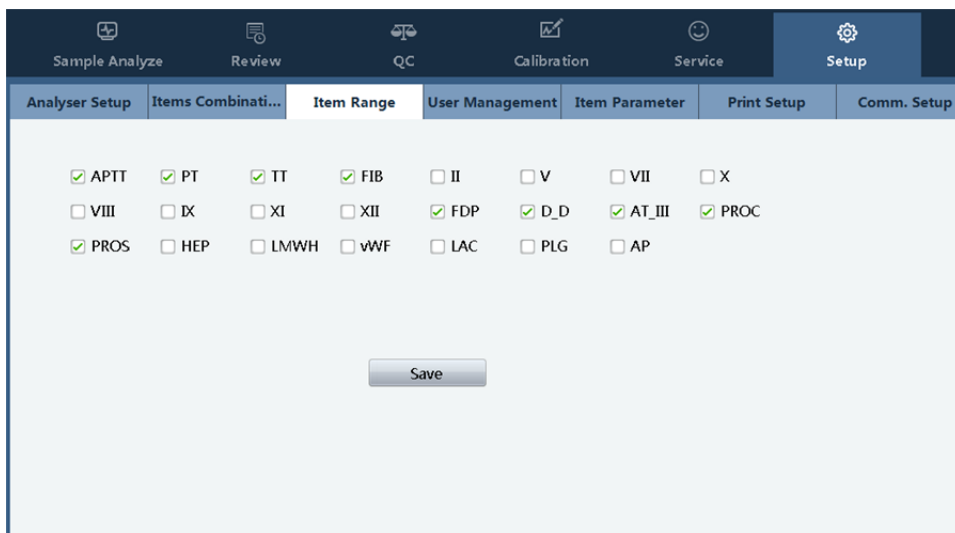
- You can only delete saved testing portfolios.
-



4.10.3 Item Range

You can select commonly used testing items so that they appear as testing items under **Sample Analysis**.

The deselected items do not appear in the common testing items list.



4.10.4 User Management

To prevent unauthorized access and to distinguish user rights, the software implements unified management on user login.

The functional user permissions are controlled based on the user rights. The factory default settings of the software is configured with a pre-registered user account. The pre-registered user account cannot be deleted or changed.

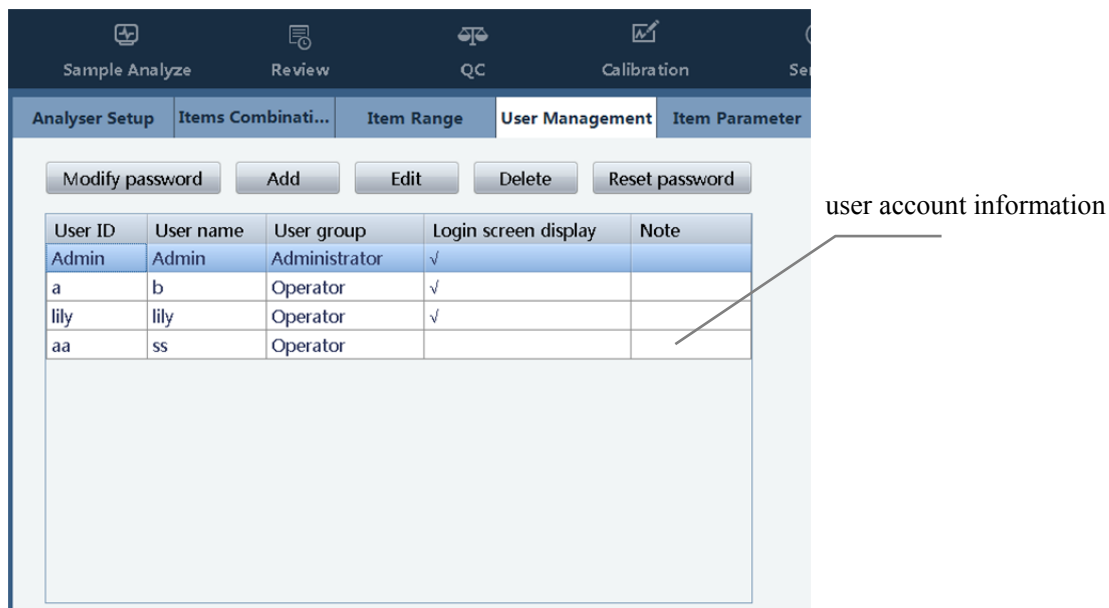
■ User registration/editing

Choose **User Management** in the **Setup** windows, and the following dialog box appears.

To edit registered user information, select a user account from the user account list. To add a new user, click **Add**.

Fill in the parameter values.

Click **Save** to save the modifications or the new user account information.



Default user account configured at delivery:

User ID	Admin
User name	Admin
Password	Admin
User group	Administrator
Display of login page	Yes
Remarks	(Blank)

The user registration form can hold information about up to 20 administrators and 100 common users, including the default user account.

The screenshot shows the 'Add new user' dialog box. It has a title bar with 'Add new user' and a close button. The form contains the following fields and controls:

- User Name: [Text input field] Login account
- User name: [Text input field]
- Password: [Text input field]
- Password: [Text input field]
- User group: [Dropdown menu] Operator
- Login screen display: ☒ Yes ☐ No
- Note: [Text input field]

At the bottom, there are 'OK' and 'Cancel' buttons.

User name	The user name contains at most 20 characters. You need to use the user name to access the software.
Real name	The real name contains at most 20 characters. The real name of the login user account is displayed on the user interface of the software after you access the software.
Password	The password supports a maximum of 20 characters. It is the credential of account login.
User group	The user group can be set to common users or administrators. User rights differ with the user group.
Login screen display	Yes: Users can select a user account from the login page. No: Users cannot select the user account from the login page and must enter the user name manually.

■ User Rights

Administrators and users differ in the following user rights:

- User management
- Testing portfolio
- Testing parameters
- QC setup

■ Delete User

Choose a user name from the user registration form.

Click **Delete**.

In the displayed confirmation dialog box, click **Yes**.

■ Reset Password

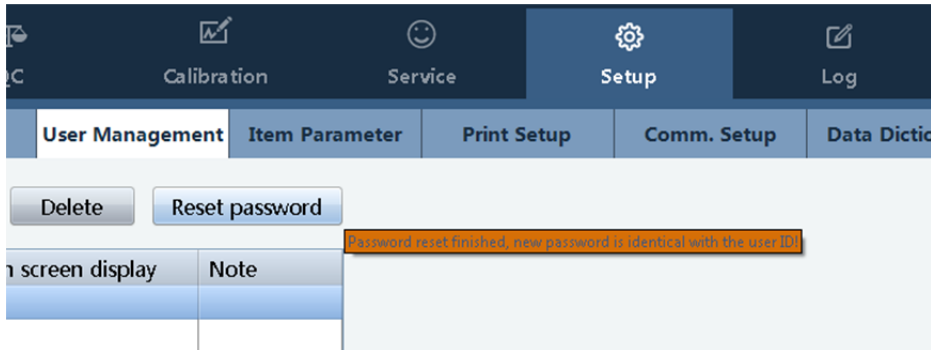
Choose a user name from the user registration form.

Click **Reset Password**.

In the displayed confirmation dialog box, click **Yes**.



After the password is reset, the following prompt message is displayed, saying that the new password is the same as the user name.



NOTE

- If the current login user is an administrator, you can reset the password of a common user.
- If the current login user is a common user, you can reset the password of your own account.

■ Reset Password

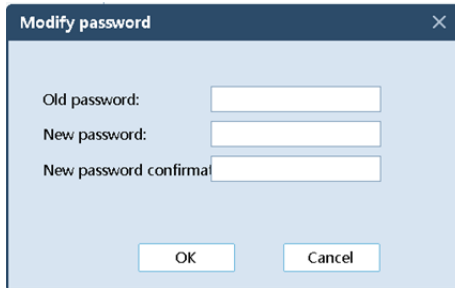
NOTE

- If the current login user is a common user, you can reset the password of your own account.

Select the user name of the current login account.

Click **Reset Password**.

In the displayed screen as shown bellow, enter the required information.



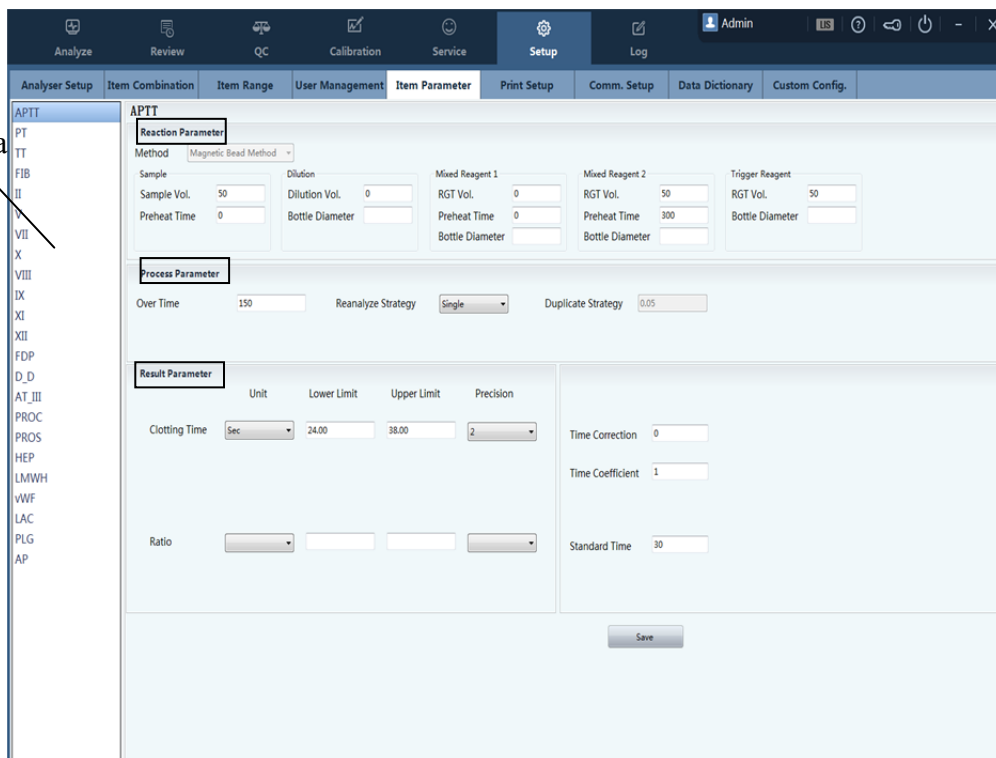
A dialog box titled "Modify password" with a close button (X) in the top right corner. It contains three input fields: "Old password:", "New password:", and "New password confirm:". At the bottom, there are two buttons: "OK" and "Cancel".

4.10.5 Testing Parameters

You can set the following parameters for each testing item.

- Reaction parameters
- Progress parameters
- Result parameters

Testing item
selection area



The "Testing Parameters" setup screen for the APTT testing item. The left sidebar shows a list of testing items: APTT, PT, TT, FIB, II, V, VII, X, VIII, IX, XI, XII, FDP, D.D, AT_III, PROC, PROS, HEP, LMWH, vWF, LAC, PLG, and AP. The main area is titled "APTT" and contains three sections: "Reaction Parameter", "Process Parameter", and "Result Parameter".

Reaction Parameter

Method: Magnetic Bead Method

Sample	Dilution	Mixed Reagent 1	Mixed Reagent 2	Trigger Reagent
Sample Vol. 50	Dilution Vol. 0	RGT Vol. 0	RGT Vol. 50	RGT Vol. 50
Preheat Time 0	Bottle Diameter	Preheat Time 0	Preheat Time 300	Bottle Diameter
		Bottle Diameter	Bottle Diameter	

Process Parameter

Over Time: 150 Reanalyze Strategy: Single Duplicate Strategy: 0.05

Result Parameter

Unit	Lower Limit	Upper Limit	Precision
Clotting Time Sec	24.00	38.00	2
Ratio			

Time Correction: 0
Time Coefficient: 1
Standard Time: 30

Save

NOTE

- The sample volumes are based on Precil reagents. Do not change the sample volumes if not necessary.
- The warm-up period is an optimal period for the instrument and reagents. Do not change it if not necessary.

Select a testing item from the testing item selection area.

■ Reaction parameters

Testing method	Methodology of the testing item. To ensure the testing accuracy, testing methodology is not configurable to users.
Sample volume	The sample volume is set taking Precil reagents as an example. Do not change it if not necessary.
Diluent volume	Volume of diluent required for each testing during a testing item. The unit is μL .
Triggering reagent volume	Volume of the triggering reagent required for each testing during a testing item. The unit is μL .
Volume of mixed reagent 1	Volume of mixed reagent 1 required for each testing during a testing item. The unit is μL .
Volume of mixed reagent 2	Volume of mixed reagent 2 required for each testing during a testing item. The unit is μL .
Warm-up period of mixed reagent 1	Warm-up period required for mixed reagent 1 during the testing. The unit is second.
Warm-up period of mixed reagent 2	Warm-up period required for mixed reagent 2 during the testing. The unit is second.
Bottle diameter	Bottle diameter of reagent or cleaning. The unit is mm.

■ Process parameter

Maximum reaction time	Longest testing period allowed for the reaction. The maximum value allowed is 9999 seconds.
Re-analysis policy	Single copy: one testing. Double copies: Two tests unconditionally.
Doublecopy policy	When double copies is selected as the re-analysis policy, this parameter is available.

$$x = \frac{|\text{Result of testing 1} - \text{Result of testing 2}|}{\text{Average of two results}}$$

If $x \leq \text{Double copy policy value}$, x is the testing result.
 If $x > \text{Double copy policy value}$, another two tests are carried out automatically.

■ Result parameters

	Unit	Lower Limit	Upper Limit	Precision
Clotting Time	Sec	24.00	38.00	2
Ratio				

Time Correction: 0
 Time Coefficient: 1
 Standard Time: 30

Save

Unit	Target report unit of the testing item.
Lower limit	Lower threshold of the normal reference range in the above testing unit. Values smaller than the lower threshold is considered abnormal.
Upper limit	Upper threshold of the normal reference range in the above testing unit. Values greater than the upper threshold is considered abnormal.
Precision	Number of digits reserved after the decimal place for the testing result.
Time correction	Adjusting the result in forms of addition.
Time coefficient	Adjusting the sec result in forms of multiplying.

Standard time Normal value in the INR calculation in PT testing.

NOTE

- You are recommended to establish normal reference ranges for your laboratory.
 - The time correction amount and time factor takes effect only for the values in the unit of second reported by magnetic beads tests.
 - Change the corresponding ISI value if the PT reagent batch changes. Fill in the ISI value based on the instruction of use or label.
-



- To report the INR value of a PT testing, you need to enter the ISI value and normal value of the reagent correctly.
-

After the above information is filled in correctly, click **Save**.

4.10.6 Print Setup

Analyser Setup	Item Combination	Item Range
Default Printer:		
<div> <div>\\PC_01\HP LaserJet 5200 PCL 6</div> <div>▼</div> </div>		
Copies:		
<div> <div>1</div> <div>1~100</div> </div>		
Report Title:		
<div>Coagulation Analyze Report</div>		
QCReport Title:		
<div>QC Report</div>		
<div> <input checked="" type="checkbox"/> Print Tetster <input checked="" type="checkbox"/> Print Auditor </div>		

Default printer	The software detects the default printer connected to the PC automatically. You can also choose a target printer from the drop-down list.
Copies	Number of print copies for each report. The value ranges from 1 to 100.
Report title	Title of the testing report.
QCReport title	Title of the QC report.
Print Technologis	Print option of technologist.
Print Validator	Print option of validator.

4.10.7 Comm. Setup

■ Communication method setup

- Terminal software as server
- ☐ The software at the PC end sends a connection request to the LIS system as the server.
 - ☒ LIS system send the connection request.

■ Network setup

- IP address IP address of the LIS system.
- Port Network port of the LIS system.

■ Protocol setup

Protocol type

HL7 and Astm are supported. You can select the protocol based on the LIS system in your laboratory.

Version

The supported protocol version is 1.0 and 2.0.
Serial No. can be sent out with testing results if you select protocol 2.0

ACK synchronized communication

If you select HL7 for the protocol type, ACK synchronized communication is available.

- ☐ The LIS system does not reply or provided feedback to the received worksheet.
- ☒ The LIS system replies to received worksheets one by one after you select ACK synchronized communication.

ACK timeout The worksheet communication command generates a prompt message after the configured ACK timeout period if ACK synchronized communication is selected.

■ **Transmit mode**

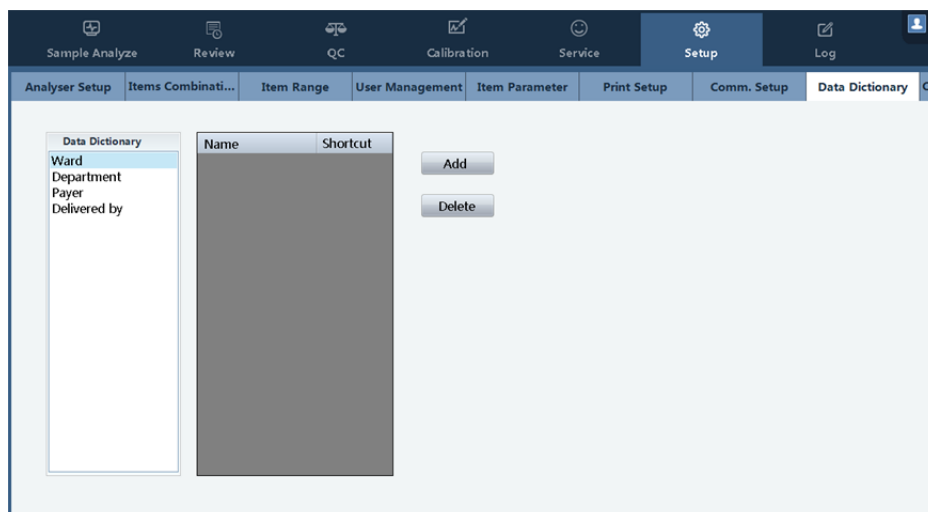
2-Way LIS/HIS ☐ Uni-directional LIS/HIS communication. You can only sent testing data to the LIS/HIS system.

☒ The PC end can communicate with the LIS/HIS system bi-directionally. That is, the PC end can read worksheets from and send testing results to the LIS/HIS system.

Auto transmit ☐ The PC end can transmit testing results to LIS/HIS system only after checking.

☒ The PC end can transmit those testing results which are implemented automatically to LIS/HIS system.

4.10.8 Data Dictionary



You can edit the following contents of patient information for quick edit

- Ward
- Department
- Payer
- Delivered by

To configure quick input:

Click **Add** to go to the quick edit window.

Name is mandatory and the quick code is optional.

NOTE

- Numbers are recommended for quick codes for your convenience in input.
-

To delete a quick input item, select it, and click **Delete**.

4.10.9 Custom configure

You can edit the customized fields under **Settings > Custom configure**.

The customized fields can appear in the patient information column. You can set the following information about the field as required.

Field name Serial No. of the field.

Text display Field title appeared in patient
information.

Enable Whether to use the customized field.

The screenshot shows a window titled 'Custom configure' with two sections: 'Sample Info.' and 'Patient Info.'. Each section contains a table with three columns: 'Field name', 'Enable', and 'Text Display'. In the 'Sample Info.' section, 'User defined field1' is enabled (checkbox checked) and 'User defined field2' is disabled (checkbox unchecked). In the 'Patient Info.' section, both 'User defined field1' and 'User defined field2' are disabled (checkboxes unchecked). Below each table is a large grey rectangular area for additional configuration.

Field name	Enable	Text Display
User defined field1	<input checked="" type="checkbox"/>	
User defined field2	<input type="checkbox"/>	

Field name	Enable	Text Display
User defined field1	<input type="checkbox"/>	
User defined field2	<input type="checkbox"/>	

4.11 Logs

Logs record the operations on the analyzer, allowing operators to query the operation history and maintenance personnel in troubleshooting.

The analyzer at the PC end can store one million entries of log records. If the number of log records exceed the threshold, the newly generated log records will overwrite the oldest ones.

Operators can view and print log records, but cannot delete them.

Choose **Logs** from the menu, and the screen as shown below is displayed:

No.	Source	Date/Time	Summary	Times	Details	Operator
1	C3100	2015/8/12 8:20:49	Startup complete	1	Startup complete	Admin(Admin)
2	C3100	2015/8/12 8:18:47	Login	1	Admin(Admin) login succeeded	Admin(Admin)
3	C3100	2015/8/11 17:14:15	Item Combination	1	Change Item CombinationCommon Fours:APTT,PT,TT,FIB to Item CombinationFour Normal It...	Admin(Admin)
4	C3100	2015/8/11 17:13:25	Login	1	Admin(Admin) login succeeded	Admin(Admin)
5	C3100	2015/8/11 17:12:37	Analyze	1	Pause	Admin(Admin)
6	C3100	2015/8/11 17:05:40	LIS communication fail...	1	Name;Gender;Age;Analysis Time:2015/8/11 17:05:27;Seq.;5;Barcode;Network connection error	Admin(Admin)
7	C3100	2015/8/11 17:00:53	Analyze	1	Continue	Admin(Admin)
8	C3100	2015/8/11 16:59:07	Analyze	1	Pause	Admin(Admin)
9	C3100	2015/8/11 16:32:37	Analyze	1	NormalStart	Admin(Admin)
10	C3100	2015/8/11 16:32:21	Login	2	Admin(Admin) login succeeded	Admin(Admin)
11	C3100	2015/8/11 16:31:28	Logout	1	Admin(Admin)log out successfully	Admin(Admin)
12	C3100	2015/8/11 16:31:19	Analyser Setup	1	IP Address:Change 127.0.0.0 to 127.0.0.1	Admin(Admin)
13	C3100	2015/8/11 15:36:06	Login	2	Admin(Admin) login succeeded	Admin(Admin)
14	C3100	2015/8/11 14:12:52	Item Combination	1	Change Item CombinationCommon 4:APTT,PT,TT,FIB to Item CombinationCommon Fours:AP...	Admin(Admin)
15	C3100	2015/8/11 14:10:41	Item Combination	1	Change Item CombinationCommon 4:APTT,PT,TT,FIB to Item CombinationCommon 4:APTT,P...	Admin(Admin)
16	C3100	2015/8/11 14:10:36	Item Combination	1	Change Item CombinationCommon Quadrinomial:APTT,PT,TT,FIB to Item CombinationComm...	Admin(Admin)
17	C3100	2015/8/11 14:09:57	Item Combination	1	Change Item CombinationCommon Fourth:APTT,PT,TT,FIB to Item CombinationCommon Qua...	Admin(Admin)
18	C3100	2015/8/11 14:08:10	Item Combination	1	Change Item Combination常规四:APTT,PT,TT,FIB to Item CombinationCommon Fourth:APTT...	Admin(Admin)
19	C3100	2015/8/11 8:40:43	Login	1	Admin(Admin) login succeeded	Admin(Admin)
20	C3100	2015/8/10 17:26:07	Analyser Setup	1	IP Address:Change 10.24.3.5 to 127.0.0.0	Admin(Admin)
21	C3100	2015/8/10 17:25:33	Login	1	Admin(Admin) login succeeded	Admin(Admin)
22	C3100	2015/8/10 17:25:03	登录	1	Admin(Admin)成功登录	Admin(Admin)
23	C3100	2015/8/10 17:23:57	注销	1	Admin(Admin)成功注销	Admin(Admin)
24	C3100	2015/8/10 17:23:36	登录	1	Admin(Admin)成功登录	Admin(Admin)
25	C3100	2015/8/7 10:09:24	通信设置	1	双向LIS/HIS通信：由关闭修改为打开，自动通信：由关闭修改为打开	Admin(Admin)

4.11.1 All Logs

■ Defining date range

You can enter or select a date range in the date configuration box above the log list.

■ Choosing the log source

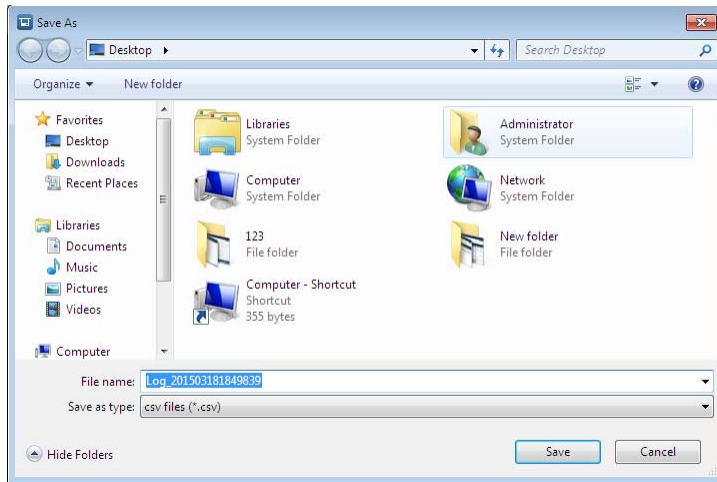
Click the **Source** drop-down list, and select a required log source from it.

■ Choosing log type

Click **All Logs**, **Parameter modify**, **Error Information**, and **Other Logs** to view lists of different types of logs.

4.11.2 Exporting Logs

Click **Export**. The dialog box as shown bellow is displayed:



Select a path and click **Save** to save the logs to the destination path.

Chapter 5 Operating Your Analyzer

5.1 Introduction

This chapter provides step –by step procedures for operating your analyzer on a daily basis. A flow chart presenting the common daily operating process is shown below.

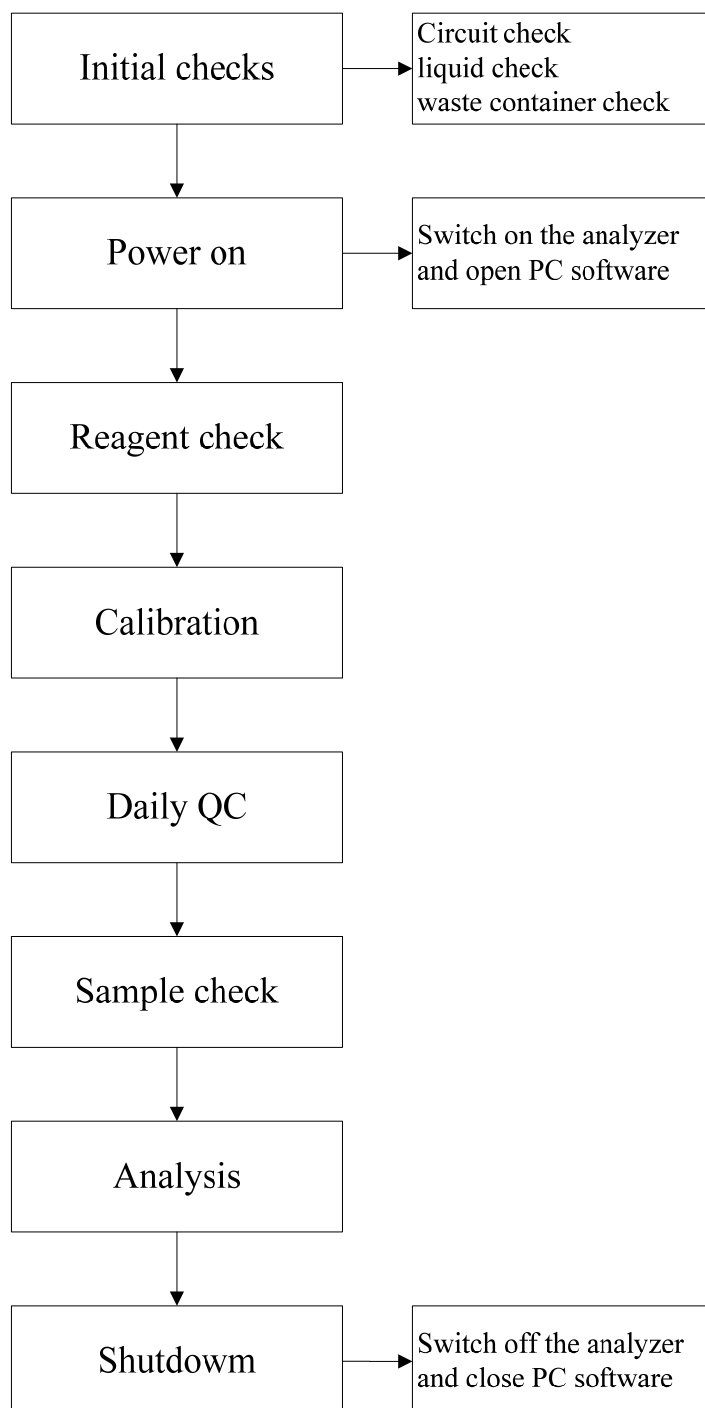


Figure 5-1 flow chart

5.2 Initial checks

Perform the following checks before turning on the analyzer.



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
-



- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
 - The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and following safe laboratory procedures when handling them in the laboratory.
 - If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go to see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.
 - Keep your clothes, hair and hands away from the moving parts to avoid injury.
-

NOTE

- You should only use the pre-specified reagents. Store and use the reagents as instructed by instructions for use of the reagents.
 - Before using the analyzer, make sure reagents are properly connected.
-

■ Checking waste bottle

Check and make sure the waste bottle is empty.

■ Checking waste container

Check and make sure the waste container is empty.

■ Checking tubing and power connections

Check and make sure the reagent, waste tubes are properly connected and not bent.

Check and make sure the power cords of the analyzer are properly plugged into the power outlet.
Check and make sure the barcode scanner is connected properly.

- Checking the printer (optional)
- Checking sample and reagent needle

Make sure sample and reagent needle without polluter and tip bend, in case of pollute, clean the sample and reagent needle. Specified operation please refer to “Chapter6 6.2 Daily maintenance Checking or cleaning the sample and reagent needles”. If the needle's tip is bent, please contact with precil customer service department to replace it.

5.3 Startup

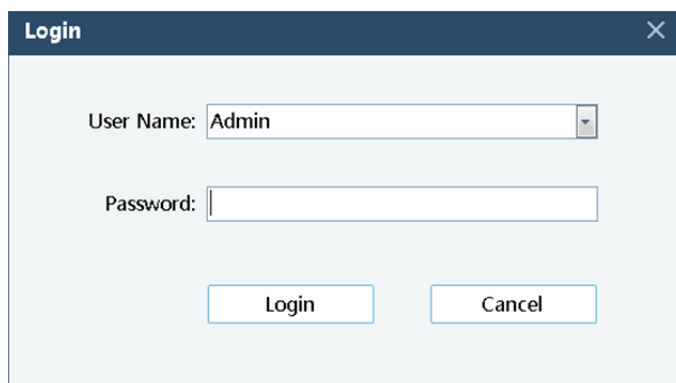
- Place the power switch at the left side of the analyzer in the ON position (I). The power indicator light will be on.

The analyzer will automatically perform the self-test procedure and initialize the systems.

- Open PC software

Open the PC and PC software.

Enter log on screen.



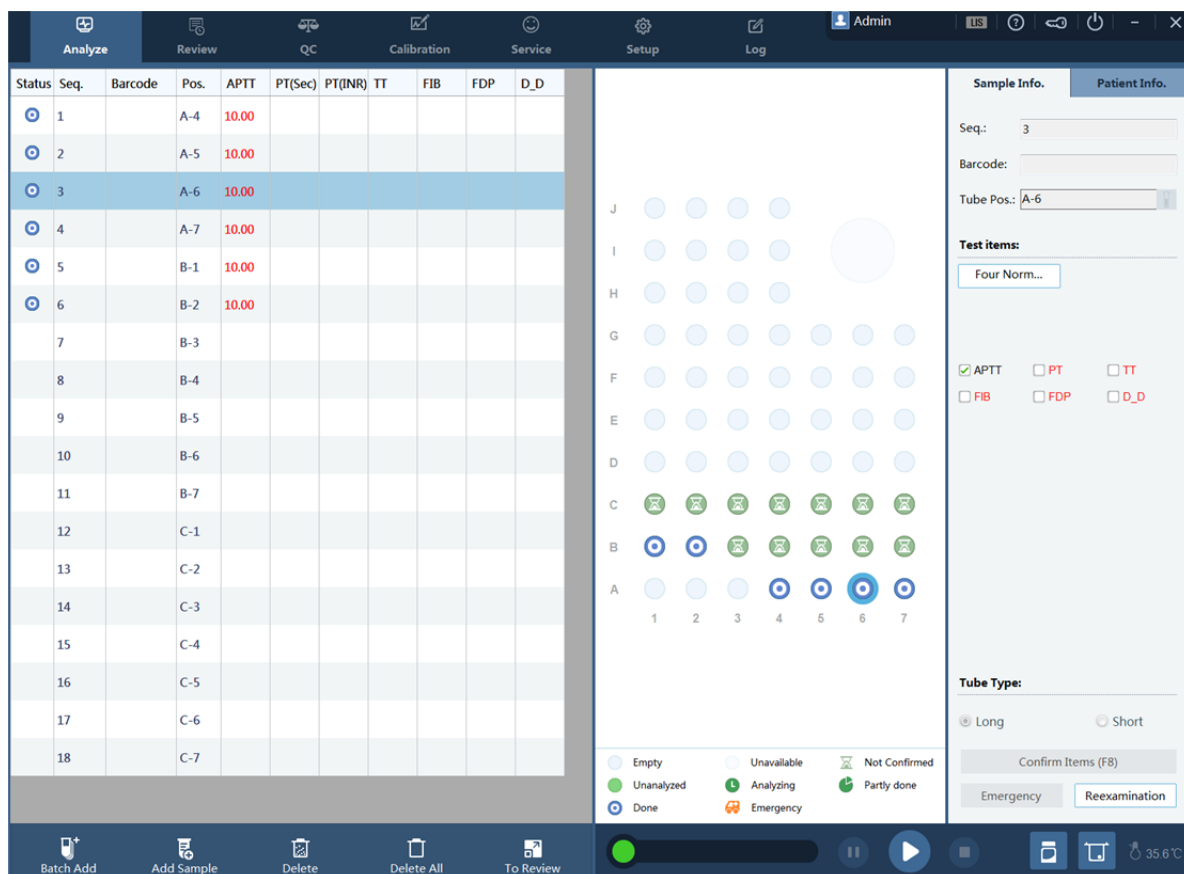
Choose the user and enter the password, then click “OK”.

First log on, please choose “Admin” and the password is “Admin”.

Click “Login” button or keyboard “Enter” to enter software interface.

NOTE

- If you fail to launch the software after tried for many times, please contact precil customer service department or your local distributor.
 - After the startup procedure completes, check if the data/time on the analyzer and the PC are correct.
-



5.4 Reagents

Prepare the reagents, buffer, diluents and probe cleaning according to the tests.

The reagent and aspiration volume:

Table 5-1 reagents and volume

Item	Reagent	Volume
Prothrombin Time(PT)	Prothrombin Time Kit	100 μL
Activated Partial Thromboplastin Time(APTT)	Activated Partial Thromboplastin Time Kit	50μL
	CaCl ₂	50μL
Thrombin Time(TT)	Thrombin Time Kit	75μL
Fibrinogen(FIB)	Fibrinogen Kit	50μL
	Buffer	90μL
D-dimer(DD)	Trigger reagent	70μL
	Diluent	210μL
FDP	Trigger reagent	70μL
	Diluent	210μL

Note: The volumes come from precil reagents, please refer to reagent manual.

Fit in enough reagents (calculate the volume according to the amounts of tests) and prepare more reagents (it will leave over reagent in every bottle).

Put mixer in PT and APTT reagent bottle (refer to reagent manual).

NOTE

- You can use the mixer repeatedly, clean and dry before reuse.
 - The tests number will change if mixer is used.
-

Setting the reagents as follow:

To set up diluents, you need to place the corresponding diluent bottle in the normal temperature diluent position.

To set up normal reagents, you need to place them in the cooling reagent position.

Select a target reagent position, for example, position 23, and set the reagent information about the position.

Selecting testing items

Reagent type: You can select the reagent type based on the instructions of the reagent.

Reagent batch No.: Fill in the batch number of the reagent based on the reagent instructions or labels.

After the above information is filled in, click **Save**.

■ Update

To replenish the reagent, you need to:

Change the empty reagent bottle with one with the same reagent.

Select the reagent position on the software.

Click **Update**. The instrument reads the available remaining number of tests for the new reagent bottle.

■ Clear

To clear the information about a selected reagent position, do as follows:

Select a target reagent position on the software.

Click **Clear**.

After the reagent position setup is complete, click **Exit**.

Reagent

Normal Temperature Area Dilution

54
D_D

452
PT

106
FIB

721
FDP

Cooling Area Reagent

532
FDP

211
D_D

350
Probe
Cleanser

52
XII

52
D_D

23

218
FIB

10

17

0
TT

8

16

0
APTT

7

15

23
PT

22

21

545
APTT

14

19

123
APTT

13

18

Item Color

Trigger Reagent

Mixed Reagent 1

Mixed Reagent 2

Reagent Information

Test Items

APTT

Reagent Type

Trigger Reagent

Reagent LOT

Clear

Update

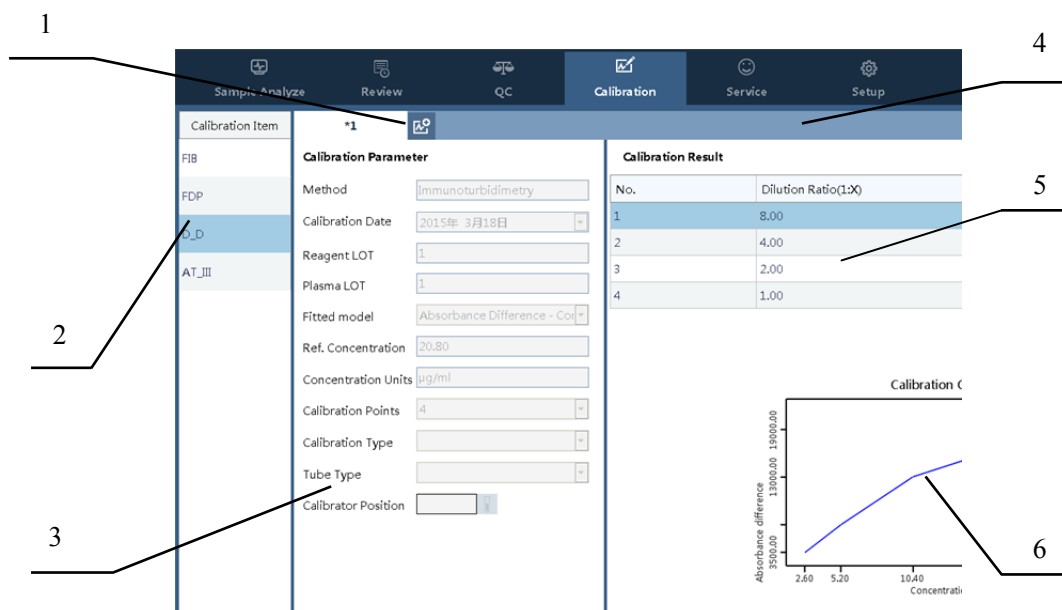
Save

Exit

5.5 Calibration curve

You can generate the calibration curve in the following ways:

- Auto calibration
- Manual calibration



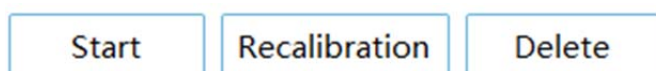
- 1 Button for creating a new calibration curve.
- 2 Area for calibration item selection.
- 3 Area for calibration parameter setup.
- 4 Area for calibration curve selection. You can save up to 10 calibration curves for each testing item.
*X is named by the reagent batch No. * marks the default curve.
- 5 Area of the calibration result.
- 6 Calibration curve

■ Calibration method

Click **Calibrate** to go to the **Calibration** window.

Select an item for calibration. Here, FIB is taken as an example.

To re-calibrate, (for example, when the batch number changes), click **Re-Calibrate**.



Enter the batch No. and standard plasma batch No. in the calibration parameter area.

For the fitting model FIB, select the double logarithmic, and set FDP and D-D to Absorbance difference – Concentration.

NOTE

- The default fitting model in the software is recommended for calibration.
-

Unit of concentration: g/L for FIB. The instruction of use for the calibrator shall prevail.

NOTE

- Use the default unit in the software for calibration.
 - If the unit recommended by the instruction of use for the calibrator differs from the default unit in the software, convert the unit before filling in the parameters.
-

Reference concentration Filled in based on the instruction of use.

Number of calibration type Number of dilution times.

Calibration type Filled in type based on dilution times.

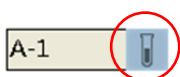
Number of calibration points Number of tests during calibration

Tube type Filled in based on the type of tubes used in the calibration testing.

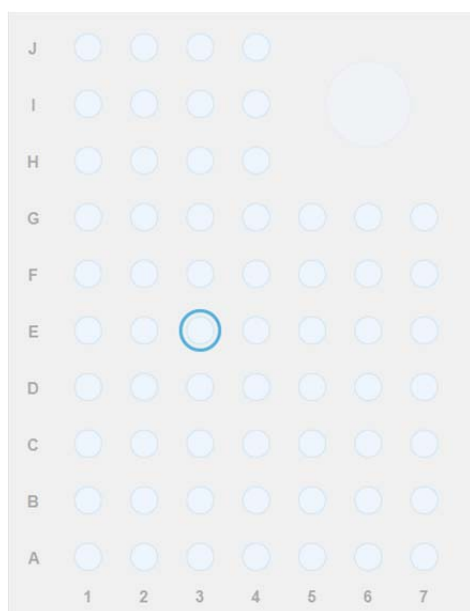
Calibrator position Position of the calibrator.

Setting up the calibrator position:


Click the **Calibrator Setup** button.



In the displayed screen as shown below, click the target position.



If **Manual Calibration** is selected, the position No. of the tube is displayed on the right in the calibration result area after the position of the first calibrator tube and the number of calibration points are specified.

New calibration 

Calibration Parameter

Method

Calibration Date

Reagent LOT

Plasma LOT

Fitted model

Ref. Concentration

Concentration Units

Calibration Points

Calibration Type


Tube Type

Calibrator Position

Calibration Result

No.	Dilution Ratio(1:X)	Calibration concentration

Calibration Curve





- Place the tubes of calibrators in different concentration according to the table on the right.
- For a bullet-head centrifugal tube, you need to place it in a proper adapter.


After the calibration parameters are set, click **Start Calibration**.


Tube Type

Tube Type

Calibrator Position

Calibrator Position

 Calibrating

 Calibrate successfully.

After the calibration ends, click **Save**.

To save the curve as the default curve, select **Set as default curve**.

☐ Set as the default curve

5.6 Quality Control

Before running any samples, run the controls. See “chapter 4 4.7 QC” for details.

■ QC Analysis

To ensure the analysis data reliability, you are recommended to implement QC analysis. Regular QC analysis helps you monitor the stability of the instrument and reagents.

NOTE

- To learn about how to use the control samples and reagents, see the corresponding instructions.
-

■ Steps to carry out QC analysis:

Set the new sample.

Select the required QC group type.

Select the target position for the control, and place the control in the corresponding position.

Select the QC item.

The instrument supports long-tube, bullet-head, and short-tube QC.

After the above configuration is made, click **Start** to implement the QC testing.

NOTE

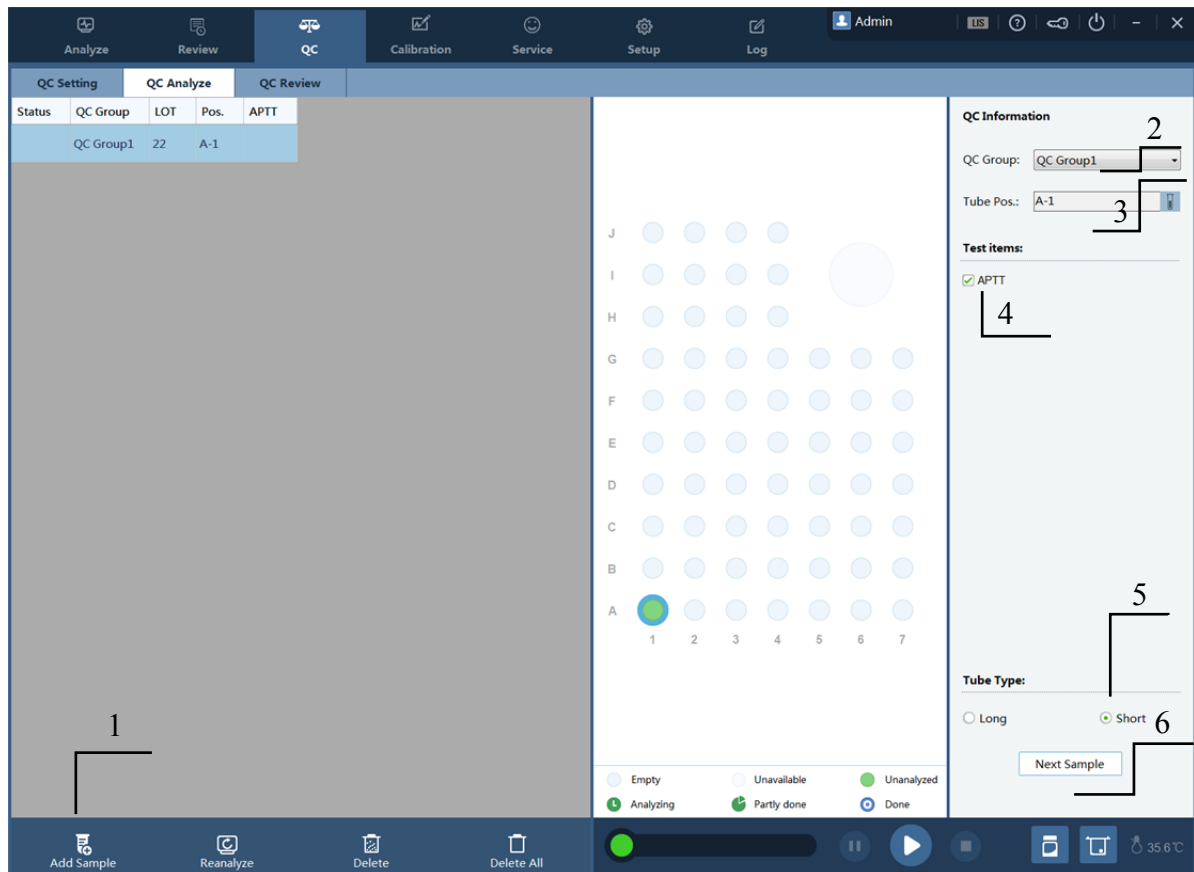
- The batch No. of one control in the same QC group must be the same.
 - You need to set the tube type for the control.
-

NOTE

- You must use the controls and reagents specified by Precil, and follow the instructions for use of controls and reagents strictly during storage and usage.
-



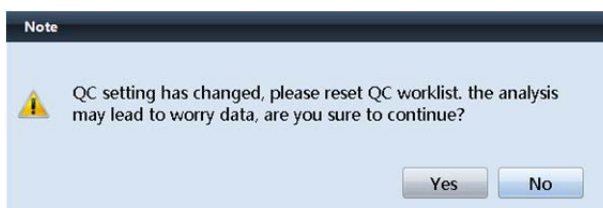
- When you click **Control Sample**, the instrument carries out daily QC analysis. During a QC testing, the plasma is stored in a short control tube (by default). Make sure that the tube type is correctly set; otherwise, the probe may be damaged.
-



■ Re-Analysis

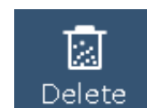
You can click **Re-Analysis** to carry out analysis operation on existing controls on the same sample again.

Check the accuracy of the QC worksheet when the QC configuration changes.



■ Delete

You can delete a selected QC analysis worksheet.

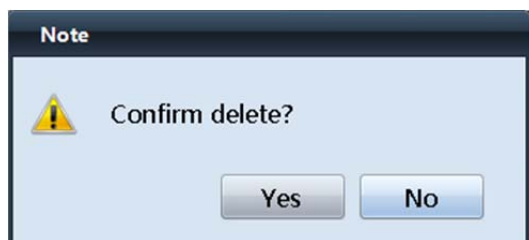


■ Delete All



You can clear the current worksheets if needed.

Click **Delete All**. In the displayed dialog box, click **Yes**.



5.7 Preparing Samples

Put sample tubes into sample racks.



- Do not contact patients' sample blood directly.
-



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
-



- Make sure the sample tube is uncapped before put into sample rack.
 - Do not re-use disposable products like cuvettes, reagent bottle, etc.
-



- To attain accurate analysis results, make sure the sample volume is no less than 1 ml.
 - Before running the refrigerated (2°C–8°C) samples, warm them at room temperature for at least 30 minutes.
-

NOTE

- Be sure to use clean fused silica glass/plastic as test tubes.
 - The proportion of blood and $\text{NaC}_6\text{H}_5\text{O}_7 \cdot 2\text{H}_2\text{O}$ is 9:1, improper proportion would lead to inaccurate results.
-

5.7.1 Samples

Prepare the samples according to the below procedures:

■ Plasma

Take a centrifugal separation for 10-15 minutes with 3000r or 2000 g of centrifugal force.

■ Stick sample barcode

■ Put the sample tube into rack of analyzer.

5.7.2 Sample volume

The sample volume for every item:

■ APTT	50μL
■ PT	50μL
■ TT	75μL
■ FIB	10μL
■ D-dimer	10μL
■ FDP	10μL

5.8 Sample Analysis

Pay attention on the below warnings, please stand to them severely; otherwise it may cause injury or analyzer damage.



- When the analyzer is processing, please:
 - ✓ Do not put the hand in analyzer.
 - ✓ Close the cover.
 - ✓ It may cause data missing and analyzer broken if turn off the analyzer.
 - ✓ Do not change analysis instruction of worksheet after experiment start.
-

NOTE

- Make sure the cover keep closed when the analyzer is processing, otherwise the instrument would alarm and pause work.
 - Open the cover would conduct to inaccurate testing results, especially for optical items.
-

NOTE

- If the analyzer is ready (working prompts and message prompts) and the temperature is $37\pm0.5^{\circ}\text{C}$, you can begin the analysis.
-

5.8.1 Clear up sample positions

When shutting down the software or starting it for the first time, a dialog box appears, asking whether you want to save the previous worksheet.

If the worksheet for the current experiment has been completed or a sample has been taken, click **No** to delete the worksheet that has expired.



- After the previous worksheet is deleted, make sure that the Sample area of the instrument does not contain a sample to be cleared.
-

5.8.2 Setting Experiments and Samples

An experiment sample can be set in two ways, depending on whether the sample has a barcode and whether the LIS system connection is normal.

- If a sample has a barcode and the bidirectional connection of the LIS system are normal
-

If all the test tubes on the tube rack have a barcode and LIS system connections are normal, you only need to put the tube on proper position.



- Make sure that the tube is put properly so that the software can read worksheet data correctly from the LIS system.
-

After the content of the worksheet of all the samples is read from the LIS system correctly, click **Start** to perform the experiment.



The software will estimate the time required for completing the experiment.

- If a sample does not have a barcode or the LIS system is not connected properly

If a test sample does not have a barcode or the LIS system is not connected properly, you can perform the following procedure to set the experiment:

1. Add samples

New Sample Add a blank sample. The software adds the sample to the first available position in A-1 to J-4.

Batch Add Add multiple blank samples. The software adds the sample to the first available position in A-1 to J-4.

2. Place the sample on the preset sample position.

Place the sample on the correct position on the correct tube rack.



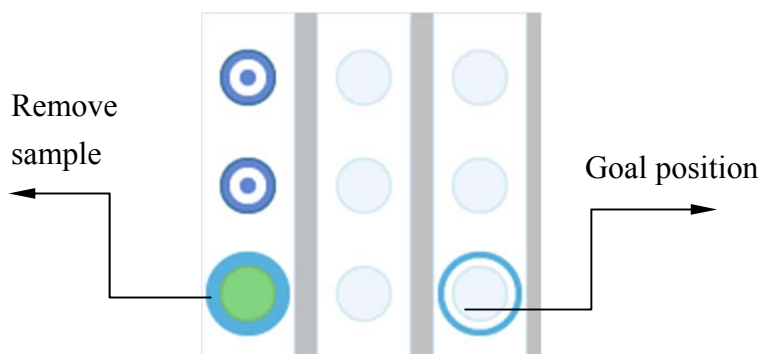
- Make sure that the actual sample position is the same as the preset position.
-

If the actual sample position is different from the default position:

After the sample is placed on the actual position, click **Tube Position** in the sample information on the right of the sample analysis screen.

The screenshot shows the 'Sample Info.' tab selected. It contains three input fields: 'Seq.', 'Barcode', and 'Tube Pos.'. The 'Tube Pos.' field is highlighted with a red circle, and a small icon of a test tube is visible next to it.

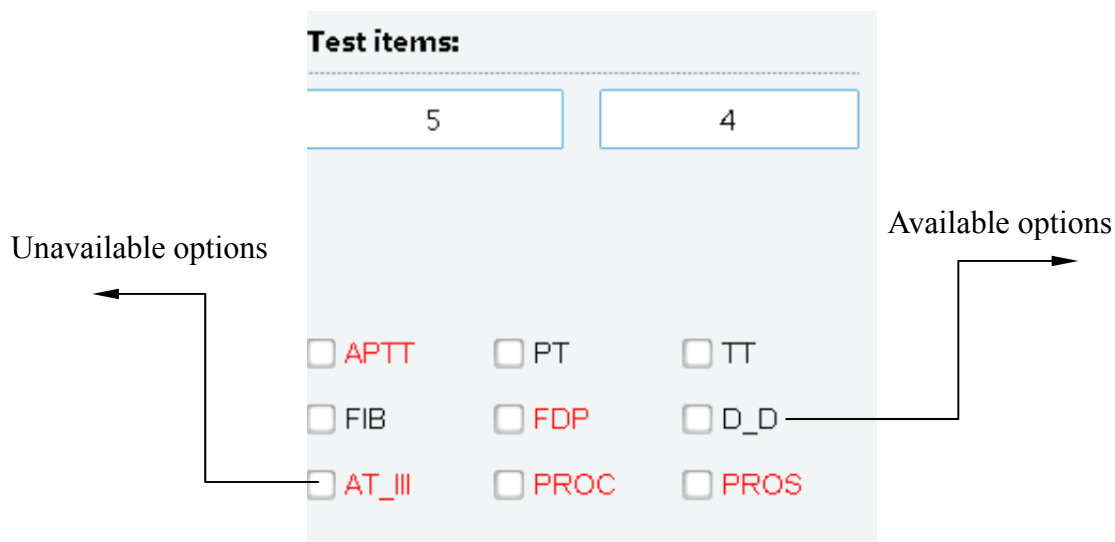
In the displayed screen as shown below, click the target position.



3. Select experiment options.

You can use a combination of keys to select multiple options. For the combination of options, see 4.10.2 "Testing Portfolio" in Chapter 4.

You can also click the required option to perform a single experiment.



NOTE

- An option may be unavailable because calibration is not performed, the related tube position is not set, or the related parameters are not set.

4. Select the tube type.

The instrument supports both long and short test tubes.

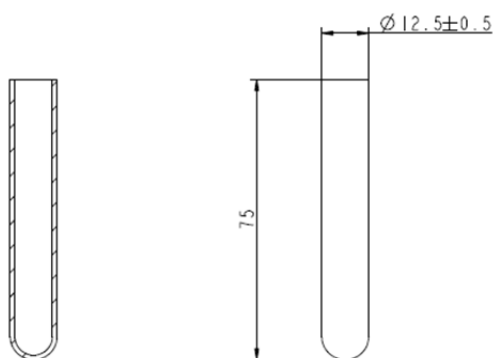
By default, the software uses long test tube settings. If a short test tube is used, enable the short test tube settings.

Tube Type:

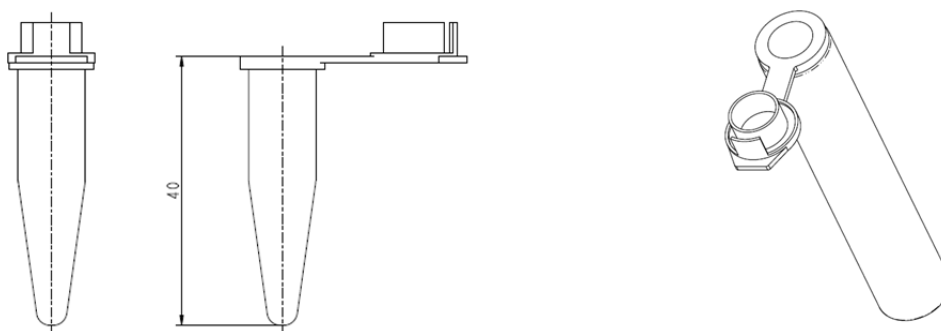
☐ Short ☐ Long

A long test tube refers to an anticoagulated blood sampling cartridge with 3.2% or 3.8% sodium citrate. After the anticoagulant is mixed with blood at a ratio of 1:9, the total volume is about 2 ml or 3 ml. After centrifugation and the cap is removed, insert the test tube on the standard tube rack of the instrument.

The instrument supports 75×12.5±0.5 standard blood coagulation tubes.



The short test tube shown in the following figure is supported. It is a 1.5 ml bullet-head centrifugal tube. If the sample is less than 1.0 ml, place plasma in a short test tube for tests or place whole blood that contains a certain proportion of sodium citrate anticoagulant in a short test tube for tests.



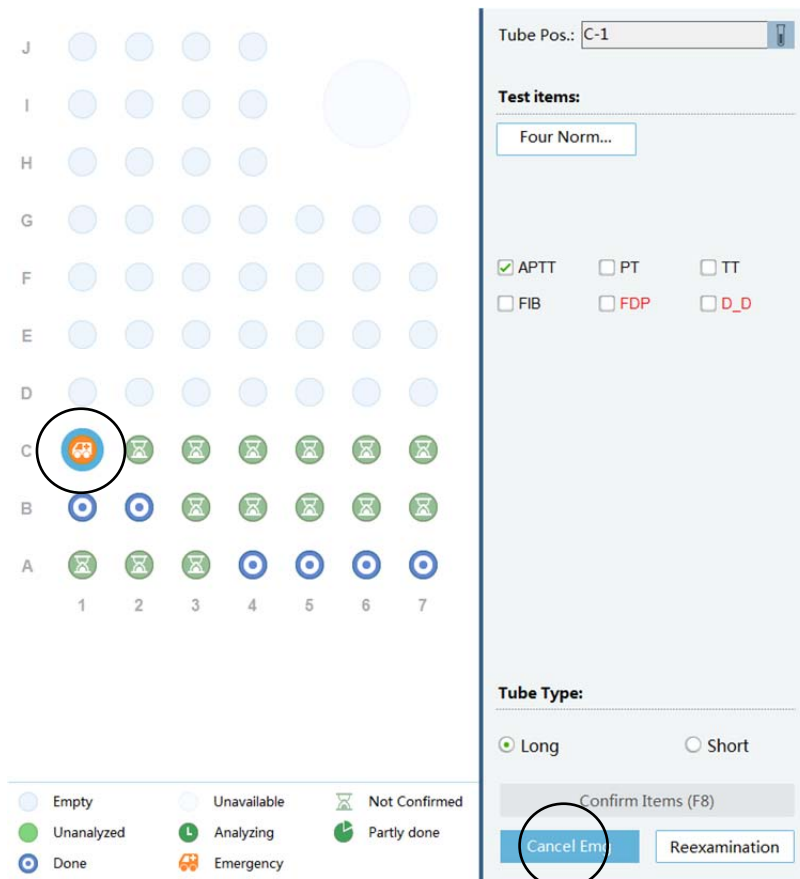
- It is recommended that you use standard short test tubes along with adapters. Do not place a short tube directly on a rack, so as to prevent inaccurate sample taking due to the inclined test tube.
 - The instrument does not support cap puncture. Before using a long test tube for tests, remove its cap to prevent probe damages.
 - When using a long test tube or a short test tube with an adapter, make sure that the tube is inserted to the bottom of the rack so that the tube will not collide with the moving probe and damage the probe.
-

5. Select the experiment type.

To perform a common experiment, click **Start** after the above configuration is made.



To set a sample for an emergency test, click **Emergency** and set the experiment.



If sample values are abnormal or other abnormal situation occurs, you can click **Retest** to perform the test again.

6. Delete or clear samples.

To delete a single sample: You can click **Delete** to delete a selected sample.

To clear all samples: You can clear the worksheet of all the samples in the sample area.

NOTE

- After **Clear** is clicked, you can query the information about the finished sample tests in the **Review** screen, but all the worksheets of unfinished tests are deleted.

5.8.3 Setting Reagents or Consumables



Red alarm for reagent or consumable: No reagent or cuvette is available, and the experiment will be stopped.



Yellow alarm for reagent or consumable: The reagent or cuvettes are insufficient, and the experiment will be stopped.

- Replace reagents or add new reagents.

When the instrument notifies you to replace a reagent, click the message to view the reagent usage.

 A screenshot of the 'Reagent' management window. The window is divided into two main sections: 'Normal Temperature Area Dilution' on the left and 'Cooling Area Reagent' on the right. The left section contains four circular buttons labeled '54 D_D', '452 PT', '106 FIB', and '721 FDP'. Below these are 'Item Color' options (Trigger Reagent, Mixed Reagent 1, Mixed Reagent 2) and 'Reagent Information' fields (Test Items: APTT, Reagent Type: Trigger Reagent, Reagent LOT). The right section displays a grid of reagent usage data with circular buttons showing values and labels like '532 FDP', '211 D_D', '350 Probe Cleanser', '52 XII', '52 D_D', '23 PT', '218 FIB', '0 TT', '0 APTT', '545 APTT', and '123 APTT'. At the bottom right is an 'Exit' button.

Before replacing a reagent, click **Pause**.



After the experiment is paused, click , place the new reagent on the correct position, and click **Update**.

Click **Exit**. The reagent is replaced.

To add a reagent for a new experiment, pause the instrument, and follow the instructions in 4.4.10 "Setting Reagents" in Chapter 4 to perform operations.

■ Set consumables.

NOTE

- To ensure accurate testing and reliable operation by the analyzer, this product requires dedicated cuvettes from Precil.
 - Cuvettes are not reusable products.
-



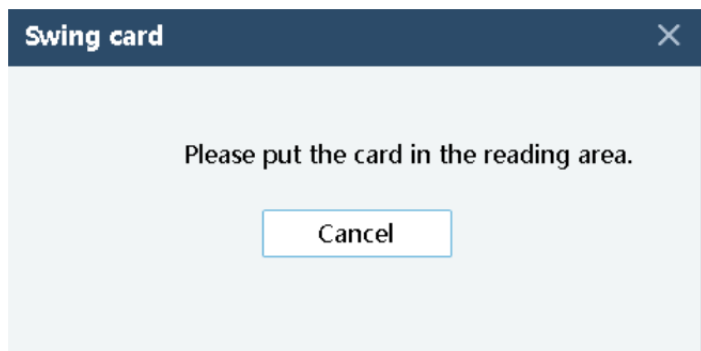
- Store cuvettes according to the requirements in their user manuals.
 - Keep cuvettes in dry environments and away from magnetic fields.
-

The instrument monitors and manages the volumes of reagents and cuvettes. You can check the usage of reagents and consumables in the consumables amount plan.

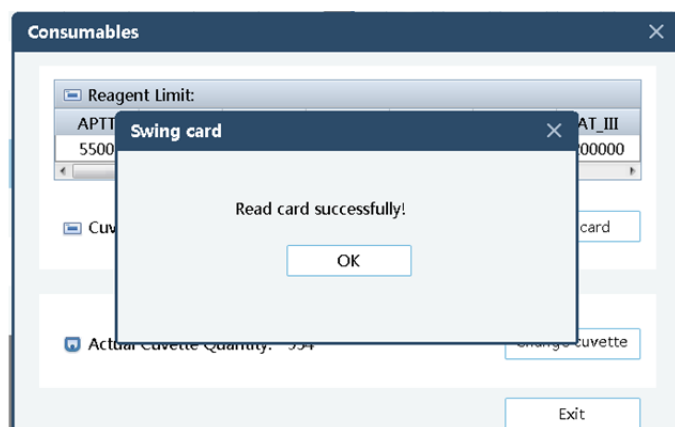
Swiping the card:

When the reagent amount is low, you need to swipe the card.

Click **Swipe Card**, and follow the instructions.



After the instruction message appears, place the card on the card reading area on the instrument.



After the software indicates that the card is read successfully, click **OK** to end the card reading operation.

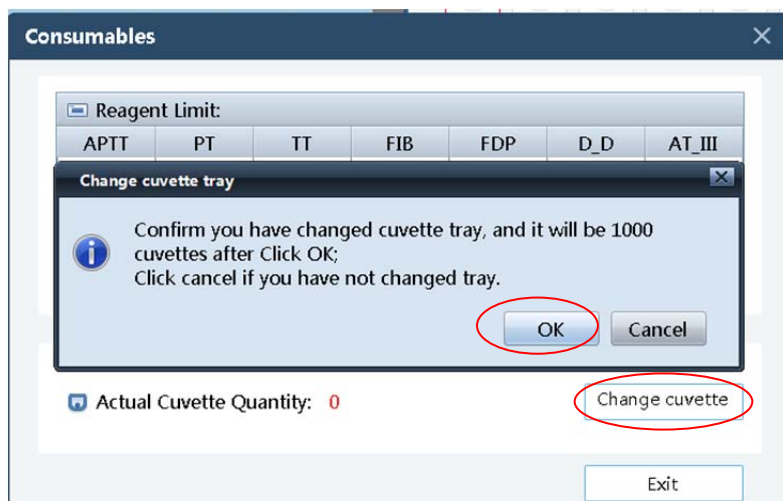
Replacing the cuvette tray:

When there are only a few cuvettes on the instrument, you need to replace the cuvette tray.

The replacement procedure is as follows:

Click **Pause** to pause the experiment. After the instrument is paused, follow the instructions in 3.2.5 "Installing the Cuvette Tray" in Chapter 3 to perform operations.

After the replacement, click **OK** and the software begins counting from 1000.



5.8.4 Report

After a patient's medical records are entered, an experiment report can be generated automatically. Before printing an experiment record, a doctor must confirm the experiment result and click Approve. Otherwise, the report cannot be printed (the **Print** button is unavailable).

■ Patient information

You can edit patient information on the **Review** screen.

For how to enter the information, refer to 4.4.7 "Patient Information" in Chapter 4.

After entering patient information and experiment information, approve the information.



After they are approved, you can print the worksheet or preview the worksheet to be printed.

To set a report title, choose **Settings > Printer Settings**.

Coagulation Analysis Report

Name:	Gender:	Age:	MR Number:	
Seq.: 1	Barcode:	Analysis Time: 2015/8/12 17:21		
Ward:	Department:	Bed No.:		
Diagnosis:				
Item Code	Result	Unit	Reference Range	Alarm
1 APTT	10.00	Sec	21.00~37.00	↓

Delivered by: Technologist: Admin Validator: Admin
 Receive Time: 2015/8/12 Print Time: 2015/8/13 9:33

This result is only responsible for the detected samples
 If you have any questions please consult the same day.

1 / 1

- *** The instrument is faulty, the sample is not sucked, or the coagulation time is too short.
 The instrument is short of reagents during the end of testing,
Stop is clicked when the instrument is short of reagents.
 The instrument is stopped shut down by force during a testing.
- > The sample testing result is greater than the upper threshold.
- < The sample testing result is smaller than the lower threshold.

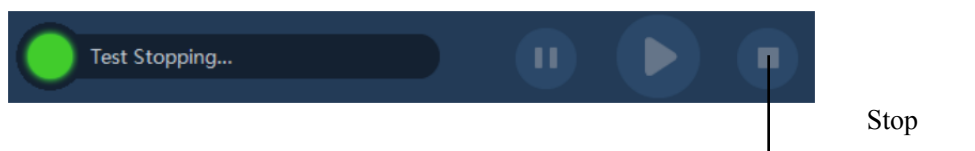
When the testing result is abnormal, the result is displayed in the **Alarm** area.

- ↑ The testing result is ***.
 The testing result is greater than the upper limit of the reference range, or is >.
- ↓ The testing result is smaller than the lower limit of the reference range, or is <.

5.9 Pause/stop analyzer

If reagent addition or reagent position change is required, you can press the **Pause** key to pause the experiment.

- Press the **Pause** key.
- After the instrument is paused, add reagents or other consumables.
- After the preparation, press the **Start** key to start the experiment.



When you click the **Stop** key, the instrument quickly stops the experiment.



- After you click **Stop**, some of the ongoing testing items may be displayed as empty with their status shown as completed. If you click **Start**, you can get valid data only after you perform retest for those with empty testing results.

5.10 Shutdown

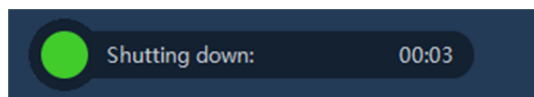
You can click the **Shut Down Host** key to shut down the instrument.



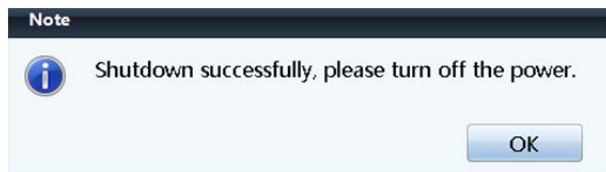
After clicking the **Shut Down Host** key, click **OK** to shut down the host.



When the software is performing host shutdown countdown, you can view the countdown in the area shown in the following figure.



You need to power off the instrument as instructed by the software.



NOTE

- Do not turn off the analyzer when processing and pausing.
 - Do not start up the analyzer immediately after shutdown. Wait at least 1 minute.
-



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
-

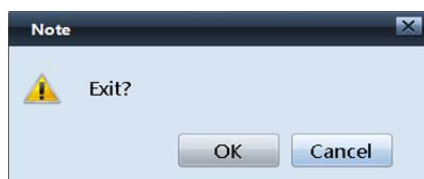


- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
-

You can close the software only after the instrument is powered off.



After the closing operation is performed, click **OK** in the dialog box that appears.



Chapter 6 Maintenance

6.1 Introduction

Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition.

This chapter introduces how to use the provided functions to maintain and troubleshoot your analyzer.

NOTE

- Only use precil cuvette, cleaning and reagents.
 - Do not mix the new container of reagent with the residue in the replaced container to ensure accurate measurement.
 - Do not reuse the one-off products.
-



- Performing unauthorized maintenance procedures can damage your analyzer. Do not perform maintenance procedures that are not described in this chapter.
 - In case of problems not specified in this manual, contact precil customer service department or your local distributor for assistance.
 - Only precil –supplied parts can be used for maintenance. For any questions, contact precil customer service department or your local distributor.
 - Exercise caution to avoid contact with the sharp sample probe when performing maintenance.
-

The tool or material used in maintenance:

- Clean duster cloth;
- Alcohol;
- Proper personal protective equipment, e.g. gloves, lab coat, etc.

6.2 Daily maintenance

■ Checking or cleaning the sample and reagent needles

1. Set the needle cleaning agent in the reagent position settings.
2. Press the **Clean Needle** key in the toolbar.



- The sample needle and reagent needle have sharp tips that may be contaminated by a blood sample, quality control material, or calibrator and become biologically infectious. Therefore, do not touch the needles.
-

Choose **Service > Maintenance** to access the maintenance menu.

Click the **Observe Twin-Needle Water Column** button.

Observe the outlet of the sample needle and reagent needle, check whether the water outlet from the sample needle and reagent needle is continuous, whether the direction of the water outlet is consistent with the direction of the needles, and whether the volume of the outgoing water is normal.

If not, clean the sample needle. For details, see section 6.5 “Unscheduled Maintenance.”

Tools and consumables:

Clean water

Deionized water

■ Checking or disposing cleaning agents, waste liquid, and used cuvettes

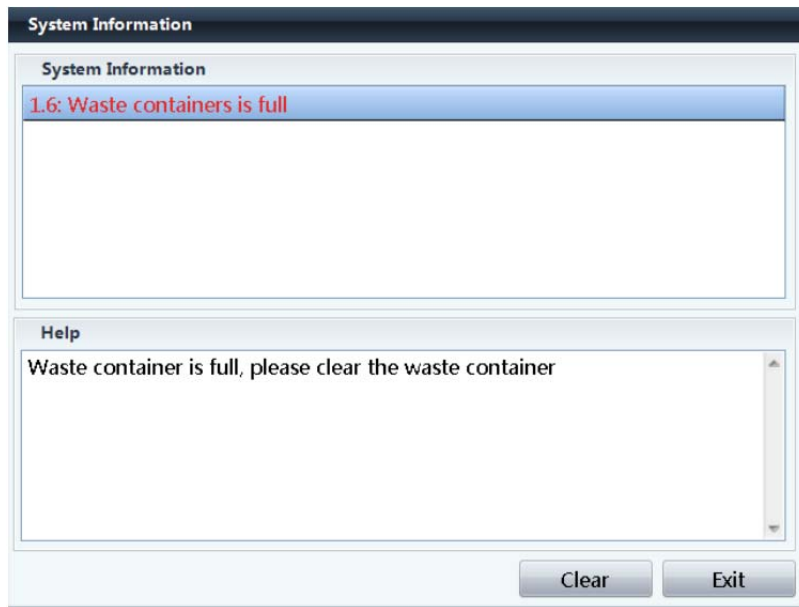
1. Check the connections for cleaning agents and waste liquid.

Check whether the analyzer cleaning agent and waste liquid connections are set up correctly according to the instructions on the panel.

Make sure that the hoses are not bent or leaking.

2. Dispose waste liquid.

When the waste liquid bucket is full during analysis, the software will generate a notification and pause the analysis. After the waste liquid is disposed, click **Clear** and **Exit**. The instrument continues the analysis.



Shut down or pause the instrument.

Open the cap of the waste liquid bottle and discharge the waste liquid.

Dispose the waste liquid and empty the waste liquid bottle.

Tighten the cap and make sure that the hoses are not bent.



- Wear rubber gloves when disposing waste liquid. Use a disinfectant to clean your hands after the operation.
- Dispose waste liquid in compliance with your local medical waste and infectious waste disposal regulations.

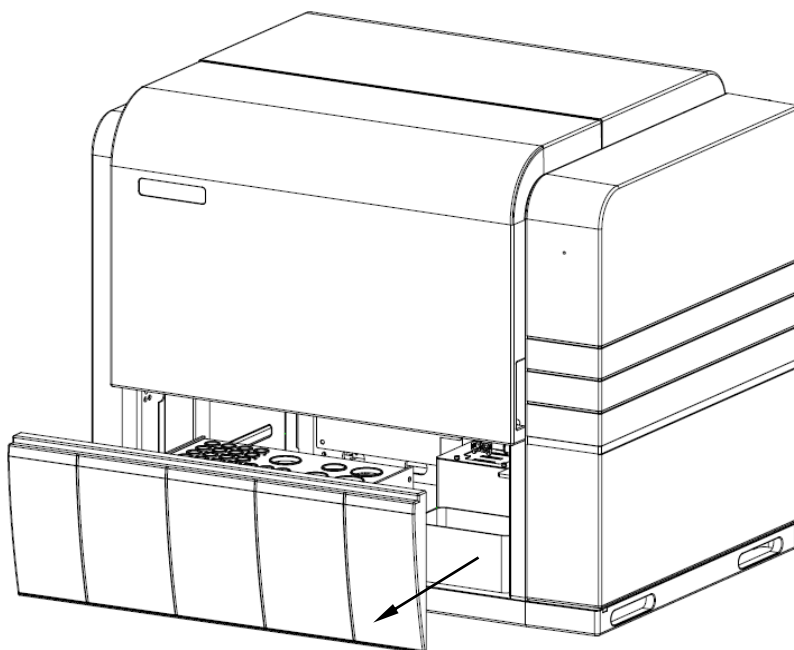
✓ Dispose waste cuvettes.

Used cuvettes will be automatically put into the waste cuvette box. After analysis in a day is finished, dispose the waste cuvettes and use running water to clean the box.



- Wear rubber gloves when disposing waste cuvettes. Use a disinfectant to clean your hands after the operation.
 - Dispose waste cuvettes in compliance with your local medical waste and infectious waste disposal regulations.
-

1. After the instrument is shut down or paused, open the right cover and take out the waste cuvettes. Close the cover after disposing the waste cuvettes.



2. Dispose the waste cuvettes following your local regulations.
3. Clean and dry the waste cuvette box.
4. Put the box back to the original position on the operation platform.

■ Shutting down the instrument

The instrument cannot be left operational for a long time. It is recommended that you shut it down after work every day. For detailed procedure, refer to 5.10 "Shutting Down the Instrument."

6.3 Weekly Maintenance

■ Cleaning the outer surface of sample and reagent needles

Make sure that the instrument has been powered off.

Move the sample needle and reagent needle up to the highest point.

Pull the probes to the end of the slideway.

Use a piece of gauze containing deionized water to scrub the outer surface of the sample needle and reagent needle from top to bottom, especially the tips, until the outer surface is clean. After the cleaning, close the instrument cover and power on the instrument. The instrument performs resetting.

Tools and consumables:

Gauze

Deionized water

NOTE

- Do not shake the probe when cleaning.
-

■ Cleaning the instrument

You must regularly clean the instrument, including its test tube rack, reagent panel, and reaction position panel.



- Before cleaning the instrument, make sure that it has been shut down and the power supply has been cut off.
 - The instrument surface may possess potential biological dangers in the form of infection. Wear gloves when cleaning it. Use a disinfectant to clean your hands after cleaning the instrument surface.
-

Make sure that the instrument has been powered off.

Use a piece of clean gauze to scrub the panels. When necessary, use a piece of gauze with a little clean water or disinfectant to scrub the panels.

Tools and consumables:

Gauze

■ Cleaning up the scrap on the cuvette tray

Use a piece of cloth to clean up the scrap on the cuvette tray.

6.4 Monthly Maintenance

■ Checking the cleaning pool

Check the cleaning pool every month.

If the cleaning pool contains unexpected objects, use tools to remove the objects to prevent them from blocking hoses.

Tools and consumables:

Tweezers and gauze



- Before cleaning the instrument, make sure that it has been shut down and the power supply has been cut off.
 - The instrument surface may possess potential biological dangers in the form of infection. Wear gloves when cleaning it. Use a disinfectant to clean your hands after cleaning the instrument surface.
-

■ Checking the waste liquid float

If a waste liquid bucket is used, remove the waste liquid bottle cap and check whether the waste liquid float is dirty. You can soak it in disinfectant liquid for 10 minutes for cleaning.

Tools and consumables:

Disinfectant liquid

NOTE

- Clean the float only after shutting down the instrument.
-

6.5 Annual Maintenance

■ Lubricating moving components

Check the moving components.

Check the X optical axis, Y optical axis, Z guide screw, and linear slideway of the twin-needle moving component and use a little grease to lubricate them.

Check the Y linear slideway and Z linear slideway of the jaw moving component and use a little grease to lubricate them.

Check and lubricate the linear slideway of the horizontal cuvette delivery component.

Check and lubricate the guide screw of the syringe component.

6.6 Irregular Maintenance

■ Perfusion

If the instrument has not been used for a long time, the cleaning liquid needs to be added for hoses before the instrument begins analysis.

1. Before perfusion, connect to the external cleaning liquid and waste liquid bucket.
2. Click the **Perfuse** key in the toolbar.

■ Cleaning the sample and reagent needles

If the flow at the tip of a needle is abnormal, use an acupuncture needle to pierce through the tip to remove unexpected objects from the needle.

Tools and consumables:

Acupuncture needle

NOTE

- Take caution to prevent damaging the sample or reagent needle.
 - Take caution to prevent being injured by the needles.
-

■ Replacing the sample and reagent needles

If the sample or reagent needle is damaged or its tip is bent, contact the user service personnel to replace it.

6.7 Change parts

■ Supply reagent

You should supply the reagent after the prompt show. See “Chapter 5 5.4 reagents” for details.



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
-



- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
 - The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and following safe laboratory procedures when handling them in the laboratory.
 - If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go to see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.
-



- Do not mix the new container of reagent with the residue in the replaced container to ensure accurate measurement.
-

Change and supply the reagents when lack, absence, overdue.

■ Cuvette supply

Please supply the cuvette according to “Chapter 3 3.2.6 cuvette tray installation”.



- Only use the cuvette once.
 - Only use precil cuvette of specified specification on the C3100.
-

■ Cleaning supply

The prompt will appear when the cleaning is in defect of. Please tap “YES” after supply the cleaning.

1. Open the cleaning bottle.
 2. Change the new one.
 3. Tighten the cup and make sure the liquid tube is not bended.
-



- Make sure the cleanness, Please use precil cleaning.
-



- Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) before change cleaning.

6.8 packing list

Component	Remarks
Power cable	Use the power cable delivered long with the instrument.
Network cable	Use the network cable delivered long with the instrument.
Cuvette tray	It is not reusable. For how to replace it, refer to 3.2.5 "Installing the Cuvette Tray."
Waste liquid bottle	Dispose waste liquid in the bottle following medical waste disposal regulations.
Short test tube cup	It is not reusable. Dispose it following medical waste disposal regulations.
External rubber hose	It must be installed by user service engineers or under the instruction of designated personnel.
Waste cuvette box lining	It is not reusable. Dispose it following medical waste disposal regulations.
Stirrer	It is reusable. After it is used, take it out from the reagent bottle where it is used, clean and dry it, and put it into a new reagent bottle. Take personal protection measures when taking it out from the bottle.

Note: The components specified on the packing list shall prevail.

Chapter 7 Troubleshooting

7.1 Introduction

This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analyzer.

NOTE

- This chapter is not a complete service manual and is limited to problems that are readily diagnosed and / or corrected by the user of the analyzer. If the recommended solution fails to solve the problem, contact precil or your local distributor.

NOTE

- Before maintain, please make sure the analyzer is turned off.
-

7.2 warning information and deal

No reagent	
Alarm cause	No reagent is detected during three consecutive detection attempts.
Alarm mode	An alarm window is displayed.
Solution	Click the alarm item, add reagents after an experiment pausing message appears, and click OK to continue the experiment.

No diluent	
Alarm cause	No diluent is detected.
Alarm mode	An alarm window is displayed
Solution	Click the alarm item, add diluent after an experiment pausing message appears, and click OK to continue the experiment.

No sample	
Alarm cause	No plasma is detected.
Alarm mode	The alarm bar displays information about the item for which no sample is provided.
Solution	After the experiment is ended, fetch plasma and perform the experiment again with a short test tube.

No cleaning liquid	
Alarm cause	No external cleaning liquid is provided.
Alarm mode	A dialog box containing the message "Empty cleaning liquid bottle" is displayed.
Solution	Add external cleaning liquid and perform perfusion on the hoses to exhaust air. Then, click OK in the dialog box.

No needle cleaning liquid	
Alarm	No needle cleaning liquid is provided.

cause	
Alarm mode	A dialog box containing the message "No needle cleaning liquid" is displayed.
Solution	Add needle cleaning liquid.

No cuvette	
Alarm cause	The cuvettes on the cuvette tray are insufficient.
Alarm mode	A dialog box is displayed.
Solution	Replace the tray and then choose Service > Replace Cuvette Tray in the menu bar of the software to update the number of available cuvettes.

Full waste liquid bottle	
Alarm cause	The waste liquid bottle is full.
Alarm mode	A dialog box is displayed.
Solution	Empty the bottle and click OK in the dialog box.

8005 error	
Alarm cause	The software is started repeatedly or the communication port is in use.
Alarm mode	A dialog box containing the message "Error: 8005" is displayed.
Solution	Restart the PC.

Inconsistency between the software and instrument	
Alarm cause	The communication between the software and instrument is faulty.
Alarm mode	A dialog box containing the message "Experiment status inconsistency between instrument and software" is displayed.
Solution	Restart the software and instrument.

Unable to create a new experiment	
Alarm cause	An experiment option is marked in red and cannot be selected, or a message indicating that no reagent for a specific experiment is detected is

	displayed when a combination of options is selected.
Alarm mode	The experiment option cannot be selected or the message indicating that no reagent is detected is displayed.
Solution	Click Reagent to view the usage of the reagent. If it is insufficient, swipe the card and add the reagent.

Preheating the instrument	
Alarm cause	The temperature of the preheating area of the instrument has not reached 37°C.
Alarm mode	The status bar displays a message, indicating that the instrument is preheating and no experiment can be created.
Solution	Wait for a few minute until the operating temperature is reached. If the temperature cannot be reached for a long time, modestly change the temperature compensation of the preheating area.

Insufficient reagent or cuvette	
Alarm cause	The reagent or cuvettes are insufficient.
Alarm mode	A dialog box is displayed.
Solution	Purchase the consumables and swipe the card.

Channel fault	
Alarm cause	The instrument seals the channel when the instrument is preheating or the cuvette cannot be picked up in the test channel.
Alarm mode	A dialog box is displayed.
Solution	Manually clean the channel.

7.3 Fault List

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
2	The glass cap is not closed.	Any	Fault	Close the glass cap.	---
5	No new cuvette can be picked up.	Experiment	Fault	1. Replace the cuvette tray. 2. Tighten the cuvette belt and skip the blank positions.	---
		Instrument startup	Alarm	1. Replace the cuvette tray. 2. Tighten the cuvette belt and skip the blank positions.	
6	The waste liquid bottle is full.	Instrument startup, experiment completion	Alarm	Empty the waste liquid bottle.	---
		Experiment	Fault		
		Experiment preparation, instrument shutdown	Fault		
7	The cleaning liquid bottle is empty.	Instrument startup, experiment completion	Alarm	Add cleaning liquid.	---
		Experiment	Fault		
		Experiment preparation, instrument shutdown	Fault		

Troubleshooting

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
9	No reagent is detected.	Experiment	Fault	Add reagents.	1. Reagent tube position number 2. -1 3. Project number of the current experiment
10	No diluent is detected.	Experiment	Fault	Add diluent.	1. Diluent tube position number. 2. -1 3. Project number of the current experiment
11	The jaw cannot pick up a cuvette.	Experiment	Alarm	Check the jaw.	1. Channel number 2. Tube position number of the current experiment 3. Project number of the current experiment
12	The jaw cannot put a cuvette.	Instrument startup, instrument shutdown	Alarm	Check the jaw.	1. Channel number 2. Tube position number of the current experiment 3. Project number of the current experiment If the instrument is not in the experiment status, the values of the three parameters are -1 .
		Experiment preparation, jaw test, experiment	Fault		
13	No needle cleaning liquid is	Experiment, experiment completion	Alarm	Add needle cleaning liquid.	1. Needle cleaning liquid tube position number.

Troubleshooting

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
	detected.	Instrument shutdown	Fault		1: Needle cleaning liquid tube position number. 2 and 3: -1
21	No plasma is detected.	Experiment	Alarm	Add plasma.	1. Reserved 2. Tube position number of the current experiment 3. Project number of the current experiment
		Calibration of predilution	Fault		1. Reserved 2. Tube position number of the current experiment
22	Z1 motor cannot be reset.	Any	Fault	It is a serious fault. Immediately shut down the instrument and contact user service personnel.	---
23	Z2 motor cannot be reset.	Any	Fault	It is a serious fault. Immediately shut down the instrument and contact user service personnel.	---
25	The optical channel is faulty.	Instrument startup	Alarm	1. Remove unexpected objected from the preheating area and restart the instrument. 2. Contact user service personnel.	---

Troubleshooting

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
26	X motor cannot be reset.	Any	Fault	It is a serious fault. Immediately shut down the instrument and contact user service personnel.	---
27	Y motor cannot be reset.	Any	Fault	It is a serious fault. Immediately shut down the instrument and contact user service personnel.	---
28	CX motor cannot be reset.	Any	Fault	You can try manually rectifying the fault and then click Rectify , or immediately shut down the instrument and contact user service personnel.	---
29	CY motor cannot be reset.	Any	Fault	You can try manually rectifying the fault and then click Rectify , or immediately shut down the instrument and contact user service personnel.	---
30	CZ motor cannot be reset.	Any	Fault	You can try manually rectifying the fault and then click Rectify , or immediately shut down the instrument and contact user service personnel.	---

Troubleshooting

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
31	The jaw drops a cuvette.	Experiment	Fault	Clean away the cuvette.	1. Reserved 2. Tube position number of the current experiment 3. Project number of the current experiment
32	No optical channel is available.	Experiment	Fault	No new optical experiment can be performed. Restart the instrument after the current experiment is complete.	---
33	No magnetic bead channel is available.			No new magnetic bead experiment can be performed. Restart the instrument after the current experiment is complete.	
34	No optical preheating channel is available.			No new optical experiment can be performed. Restart the instrument after the current experiment is complete.	
35	No magnetic bead preheating channel is available.			No new magnetic bead experiment can be performed. Restart the instrument after the current experiment is complete.	
36	A channel is faulty.	Experiment preparation	Fault	Remove unexpected objects from the channel and make sure that the fault is rectified.	---

Troubleshooting

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
37	P1 motor cannot be reset.	Any	Fault	It is a serious fault. Immediately shut down the instrument and contact user service personnel.	---
38	The cleaning liquid will soon be used up.	Experiment	Alarm	Replace the cleaning liquid bucket and click Rectify .	---
39	Dilution is not detected in the calibration of predilution stage.	Calibration of predilution	Fault	Add diluent.	1. Diluent tube position.
40	The test tube rack is not in position.	Experiment	Fault	Insert the test tube rack to the position corresponding to the newly created experiment.	1. Reserved 2. Test tube rack number of the current experiment
41	The immunoturbidimetry channel is faulty.	Instrument startup	Alarm	1. Remove unexpected objected from the preheating area and restart the instrument. 2. Contact user service personnel.	---
42	The chromogenic substrate channel is faulty.	Instrument startup	Alarm	1. Remove unexpected objected from the preheating area and restart the instrument. 2. Contact user service personnel.	---

Troubleshooting

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
43	No immunoturbidimetry channel is available.	Experiment	Fault	No new immunoturbidimetry experiment can be performed. Restart the instrument after the current experiment is complete.	---
44	No chromogenic substrate channel is available.	Experiment	Fault	No new chromogenic substrate experiment can be performed. Restart the instrument after the current experiment is complete.	---
45	No immunoturbidimetry preheating channel is available.	Experiment	Fault	No new immunoturbidimetry experiment can be performed. Restart the instrument after the current experiment is complete.	---
46	No chromogenic substrate preheating channel is available.	Experiment	Fault	No new chromogenic substrate experiment can be performed. Restart the instrument after the current experiment is complete.	---
47	The card swiping board cannot be connected.	Instrument startup	Alarm	1. Restart the instrument. 2. Contact user service personnel.	---

Troubleshooting

Fault No.	Fault Description	Scenario	Level	Solution	Parameter Description
48	The magnetic bead measurement board cannot be connected.	Instrument startup	Fault	1. Power off the instrument, wait for 30 seconds, and restart the instrument. 2. Contact user service personnel.	---
49	The optical receiver board cannot be connected.	Instrument startup	Fault	1. Power off the instrument, wait for 30 seconds, and restart the instrument. 2. Contact user service personnel.	---

Chapter 8 Cautions

8.1 Introduction

This chapter lists the cautions to make sure getting safe, availability and precise results.

8.2 Cautions

- 1) Clear the waste water bottle and add cleaning solution, reagents timely.
- 2) Please replace cuvette reel on the right of instrument timely, for the sake of avoiding cuvette lock.
- 3) The default test tube is short when having quality control test.
- 4) The power supply must be earthed.
- 5) Make sure to let the instrument on a stable operation table, no vibration and shaky is permitted. No electro-magnetic interference, no etching gas.
- 6) Do not disassemble the instrument privately; it should be permitted by engineer.
- 7) Precil cuvette and test tube should be used.
- 8) Wrapping box should be preserved for the sake of reuse.
- 9) A special computer should be equipped, for safeguard program and data, antivirus software is needed.
- 10) User should not touch the interior component when the instrument is operating.
- 11) User can only use the power line provided by Manufacturer, otherwise the instrument capability and personal safe cannot be guaranteed.
- 12) Any object cannot enter the air vents on the rear cover.
- 13) Input power: 200VA; Do not collinear with high-power electrical appliances.
- 14) The cleaning piping shall be connected tightly and should not have knots, for avoiding the cleaning solution leak, personal injury and instrument damage.
- 15) Please use the original electrical wire shipped with the analyzer.
- 16) Use precil or precil – authorized reagents. Refer to the reagent manual for using and storage.
- 17) Do not delete the current user.
- 18) Use the original or specific external equipment.
- 19) Use and storage the analyzer in specific environment.
- 20) This chapter is not a complete service manual and is limit to problems that are readily diagnosed and / or corrected by the user of the analyzer.

Chapter 9 Storage and Transport

Be sure to store the instrument in a room with the temperature of $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$, the relative humidity of less than 85%, no etching gas, and having good ventilation.

Please put the instrument in precil container when it is removed.

- Temperature $5^{\circ}\text{C} \sim 55^{\circ}\text{C}$
- Relative humidity $\leq 85\%$
- Atmospheric pressure $86 \text{ kPa} \sim 106 \text{ kPa}$

The transportation shall be conducted by precil authorized personnel. Do not transport the analyzer without contacting precil or your local distributor.

Chapter 10 Disposal of Castoff

NOTE

- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
 - Do not contact patients' sample blood directly.
-

The plasma used in test should be disposed according to the local law. The waste liquid contains biological and chemical composition; it is strongly recommended that gloves should be wearied before use the instrument. Used test cup should be treated as iatrogenic waste.

Appendix A Safe Information

1 Warning



- Please check the firmness of all the doors and covers before running the analyzer.
- Make sure all the safety measurements are adopted. Disabling any safety device or sensor is prohibited.
- Please take action to any alarm and problem indication immediately.
- Do not touch the moving parts.
- Contact precil or precil-authorized distributors in time if any damaged part is found.
- Be careful when opening/closing and removing/installing the doors, covers and boards of the analyzer.
- Discard analyzer according to government regulations.
- To avoid damage, do not turn on / off the power of the analyzer continually in a short time.
- Do not contact patients' sample blood directly.
- Store and use the reagents as instructed by instructions for use of the reagents.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.
- Installation by personnel not authorized or trained by precil may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of authorized personnel.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- Wear proper personal protective equipment (e.g. gloves, lab coat, etc) and follow safe laboratory procedures when handling them in the laboratory.
- If the waste accidentally spill on your skin, wash them off with plenty of water and if necessary, go to see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- If any tubing or part with fluid is found aging or wearing during when using the instrument, stop working with the instrument and contact customer service department or your local distributor for inspection or replacement.
- When the instrument is waiting for service, it is suggested that use applicable warning

measures to avoid potential biohazard or other hazards to people who contact it.

2 Caution



- Please use the analyzer strictly as instructed by this manual.
 - Make sure only pre-authorized software is installed on the computer.
 - Please install the original edition software to prevent the computer from being infected by virus.
 - Please adopt proper measurement to prevent the reagents from being polluted.
 - It is recommended that you install anti-virus software on the computer and scan for viruses periodically.
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3 Biohazardous



- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
 - If leakage happens to the analyzer, the leaked liquid is potentially biohazardous.
 - Areas contacted by sample, reagent etc are potentially biohazardous, please follow safe laboratory procedures.
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