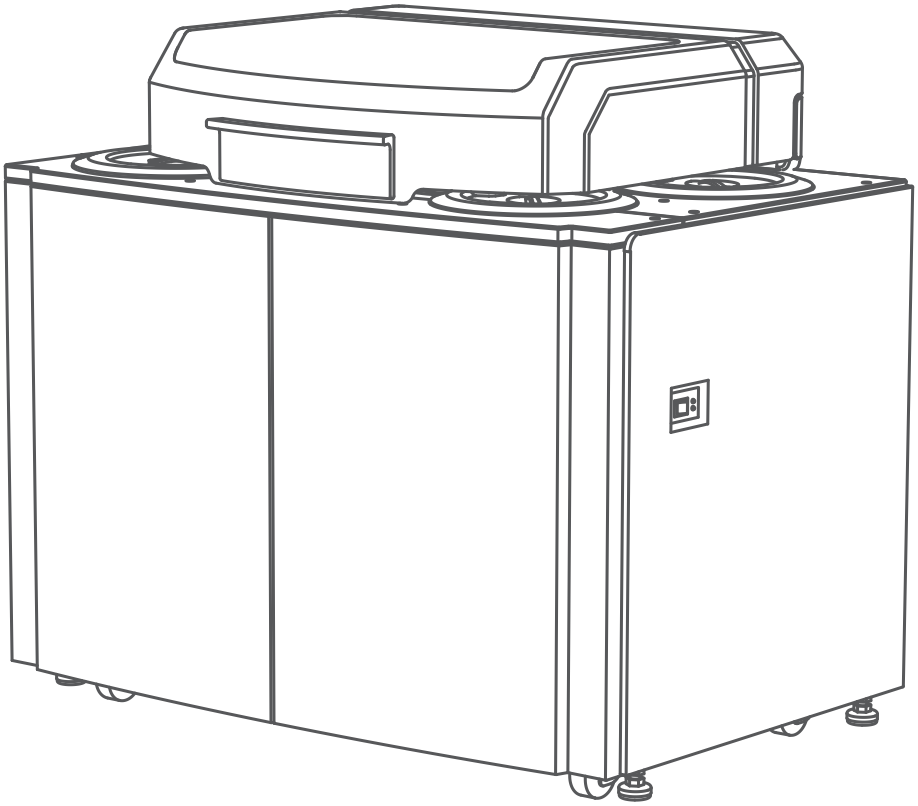
Auto-Chemistry Analyzer



User Manual

This manual is applicable for Auto-Chemistry Analyzer, hereinafter called "analyzer".

Instructions

Dear users, thanks for purchasing this Auto-Chemistry Analyzer.

Carefully read this User Manual for correct operation. Any incorrect operation may affect the precision and accuracy of test results, and damage the analyzer or even put users in danger.

Please keep User Manual safe for future use.

Date Revised: REV.02-2015.

Configuration No.:001.

Precaution

● The analyzer should be operated by medical laboratorial specialists, or physicians, nurses and lab assistants who are specially trained.

● The analyzer should be controlled by dedicated software. Please install the software that is appointed by our company. Installation of other software/hardware may affect normal running. Don't run other software when the analyzer is running.

● Dust may accumulate on the surface of the analyzer after long-time storage. Soft cloth or gauze can be used for cleaning, and with a little detergent when necessary. Please turn the power off before cleaning. Shut the top cover when the analyzer is not used.

● Please observe the relevant instructions for the usage and storage of samples, reagents, Control and Calibrator.

● Users should comply with the local regulation when discharging and disposing reagent, waste liquid, waste samples, consumables, etc. Please dispose the waste liquid and analyzer consumables according to the regulation of medical, infective and industrial wastes.

● Connect with a local printer to print reports, diagrams, etc.

● The chemical parameters mentioned in the software application introductions of this manual are only examples. Please refer to the reagent instructions on chemical parameters.

●When outdoor temperature is low during the winter, the new arrived analyzer shall be placed in room temperature for 24 hours before using.

Warning

● If the user do not operate the analyzer according to the manual, the safety measures provided by the analyzer may be invalid.

● The analyzer should be operated in a good grounding condition with independent power supply. The input power should be conformed to analyzer requirements.

● Do not pull the electrical wires with wet hand, as this may cause electric shock.

● Do not stamp on, twist or drag the wires and cables, as this may break the cables and cause fire.

● Do not open the back and side cover board before cutting the main power supply except service staff.

● In case that liquid enters the analyzer or there is an internal pipeline leakage, immediately cut off the main power supply, and contact service dept.

● Do not touch the sample probe, reagent probe and mixer, etc during running, as this may cause body injury or analyzer damage.

● Cut off the power supply before replacing lamps. Do not touch the lamp before cooling. Burning may happens.

● Periodic maintenance should be performed in strict accordance with User Manual. Otherwise, it may cause analyzer malfunction, inaccurate and imprecise test results.

● Make sure that the Analyzer is operated according to the User Manual. Or unreliable test results, analyzer damage or danger may happen.

● Combustible material should not be used around the analyzer.

Statements

The manufacturer has the final right of interpretation.

The manufacturer is responsible for the security, reliability and capability of analyzer only when all the following requirements are satisfied.

(1)Installation, adjustment, improvement and repair are conducted by professionals.

(2)Relevant electric equipments meet national standards.

(3)Analyzer operation is in accordance with User Manual.

Software interface is subject to change without prior notice.

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Chapter 1 Brief Introduction

1.1 Summary

Auto-Chemistry Analyzer is an modularized analyzer with a discrete system, emergency priority and externalized computer.

The analyzer can automatically finish sample adding, reagent adding, anti-interference, mixing, pre-heat, reaction monitoring, rinsing, calculation, display and print of results. The automatic operation serves as simulation and substitution of manual operation. As a result, it enhances efficiency, diminishes errors, and thus improves the accuracy and precision of test results.

The Analyzer can perform different routine biochemical analysis such as liver function, renal function, ion-metabolization, blood sugar, blood fat, myocardium enzymogram, immunoglobulin, etc.

1.2 Main Technical Specifications

Specifications		
Basic Properties	Wavelengths	rear spectrophotometry system with holographic concave flat-grating, 12 wavelengths can be collected and measured simultaneously. Wavelengths: 340 nm, 380 nm, 405 nm, 450 nm, 480 nm, 505 nm, 546 nm, 570 nm, 600 nm, 660 nm, 700 nm, 750 nm or 800 nm
	Reaction Temp.	37℃
	Control Precision	±0.1℃
	Test Items	132 colorimetric items at most, 3 ISE items(optional): K, Na, Cl
	Test Methods	1-point end assay, 2-point end assay, 2-point rate assay, rate A assay
	Speed*	800 items/h, 1260 items/h (for ISE)
Reagent System	Reagent Disk, Position	two reagent disks with refrigeration function, 67×2 positions
	Reagent Vol.	15μL ~ 350μL
	Reagent Bottle Vol.	20mL,70mL,100mL
	Reagent Storage Temp.	5℃ ~ 15℃
	Reagent Level Sensor	digital liquid level sensor，volume tracking，probe blocking detection and dimensional anti-crash function
Sample System	Sample Disk, Position	140 samples(80 routines, 10 stats, 8 controls, 39 standards, 3 detergents)with refrigeration function
	Sample Types	blood, serum, urine, CSF, ascites
	Sample Vol.	1.5μL ~ 35μL
	Sample Barcode Rading System	4 built-in barcode reader(optional routine sample, stat sample, reagent 1 and reagent 2)
	Liquid Level Sensor	digital liquid level sensor，volume tracking，probe blocking detection and dimensional anti-crash function
Data System	Interface	RS 232
	Computer Configuration	optional computer and printer
	LIS/HIS Connection	can be connected

Specifications		
Analysis System	Cuvette Type	discrete
	Cuvette Optical Diameter	5mm
	Reaction Positions	8 sets, 20 pos./set, 160 in total
	Reaction Solution Vol.	120μL ~ 450μL
	Light Source	20W/12V long service life quartz halogen lamp
	Absorbance Range	0Abs ~ 3.3Abs
	QC	linear/non-linear calibration，manual/auto calibration; real-time QC by double-concentration method; daily QC, monthly QC and out of control analysis
	Auto Rinse	cuvette auto rinsing
	Mix System	separate mixing after reagent adding
Overall System	Weight	370kg approximately
	Dimensions	1282mm*870mm*1127mm (L×W×H)
	Power Consumption	2500VA



- **When the reaction solution volume is 120μL, result accuracy might be affected.**
- **Due to different test conditions, analyzer processing capability sometimes is lower than 800 T/H.**

Test Condition	Processing Capability Lower Degree(estimated)
Pre-diluted sample	180T/H(when all tested samples are pre-diluted)
Avoiding cross-contamination conducted	450 T/H (reaction cuvette)
	450 T/H (sample probe)
	600 T/H((reagent probe)
22-minute test applied to all items	450 T/H

Normal Working Conditions:

(1)Power Supply: 220/230VAC 50Hz.

(2)Ambient Temperature: 15℃~32℃.

(3)Relative Humidity: no more than 75%.

(4)Keep away from magnetic field.

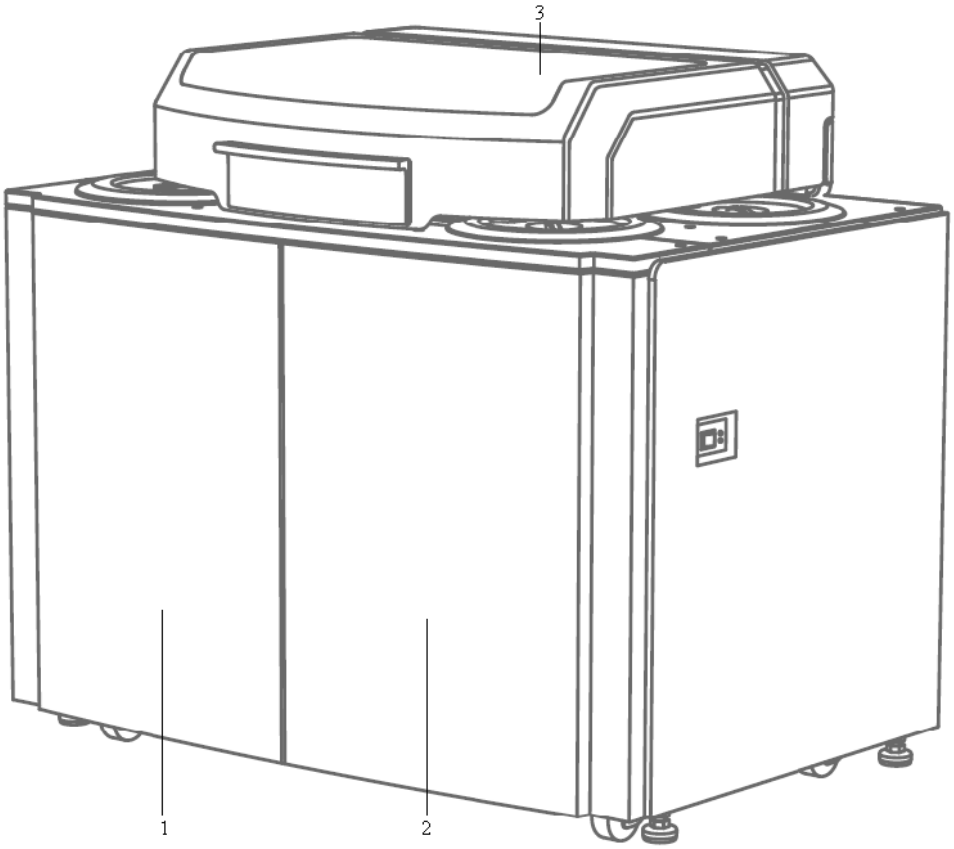
(5)Avoid direct sunlight.

(6)Atmospheric pressure: 75kPa~106kPa.

1.3 Analyzer Composition

1.3.1 Analyzer Appearance

1.3.1.1 Analyzer Front View



1 Front Left Cover 2 Front Right Cover 3 Upper Cover

Figure 1-3-1

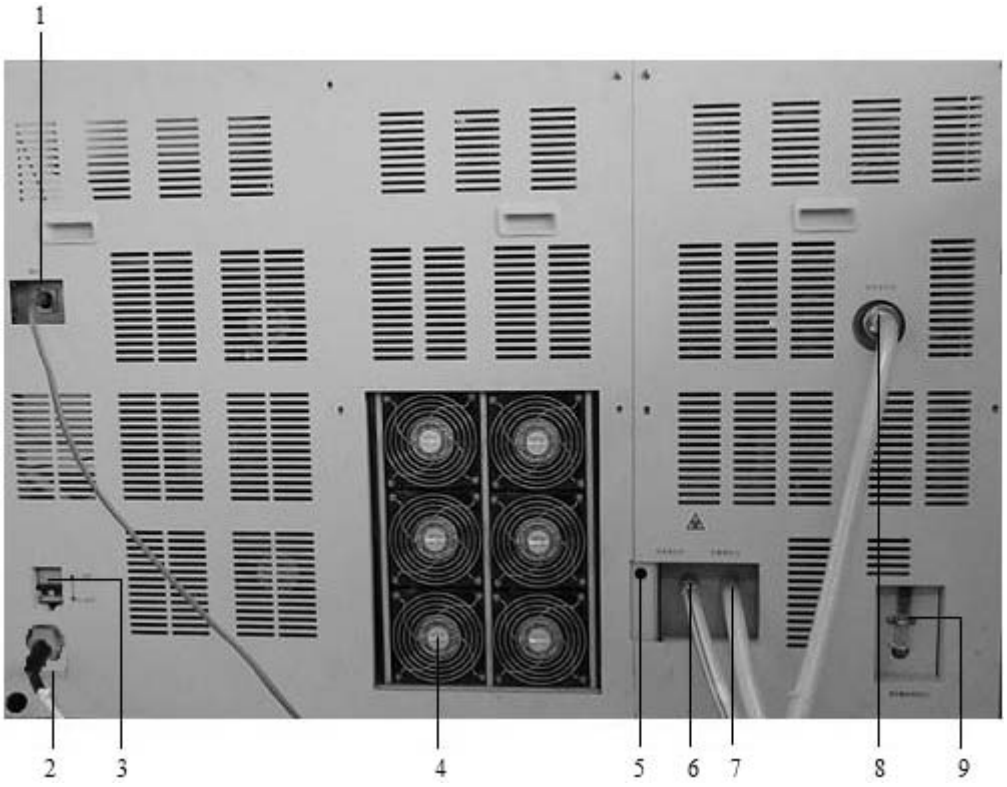
1.3.1.2 Front Door Open



1 ISE Proportioning Peristaltic Pump 2 ISE Internal Standard Peristaltic Pump 3 ISE Diluent Syringe Pump
4 Sample Syringe Pump 5 R2 Syringe Pump 6 R1 Syringe Pump 7 Left Alkaline Detergent Box
8 Right Alkaline Detergent Box

Figure 1-3-2

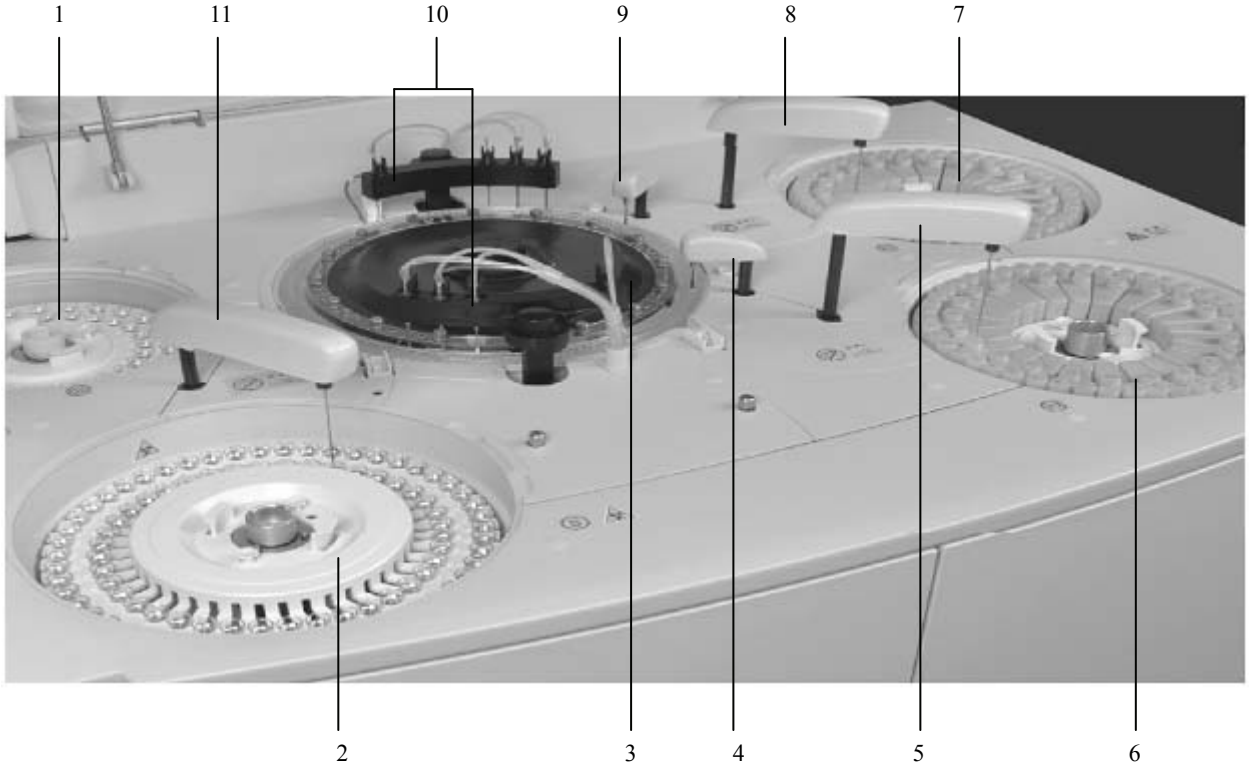
1.3.1.3 Back View



1 Internet Port 2 Power Inlet 3 Power Switch(circuit breaker) 4 Cooling Fan
5 Concentrated Waste Liquid Level Sensor Port 6 Concentrated Waste Liquid Outlet
7 Diluted Waste Liquid Outlet 8 Purified Water Inlet 9 Vacuum Container Waste Liquid Outlet

Figure 1-3-3

1.3.1.4 Upper View



1 QC Disk 2 Sample Disk 3 Reaction Disk 4 R2 Mixer 5 R2 Reagent Probe 6 R2 Reagent Disk
7 R1 Reagent Disk 8 R1 Reagent Probe 9 R1Mixer 10 Reaction Cuvette Rinsing Mechanism
11 Sample Adding Unit

Figure 1-3-4

1.3.1.5 Right View



1 Switch for Analysis Part(excluding refrigeration power)

2 Refrigeration Power Indicator(Green)

3 Power Indicator(Red)

Figure 1-3-5

1.3.2 Systematic Composition

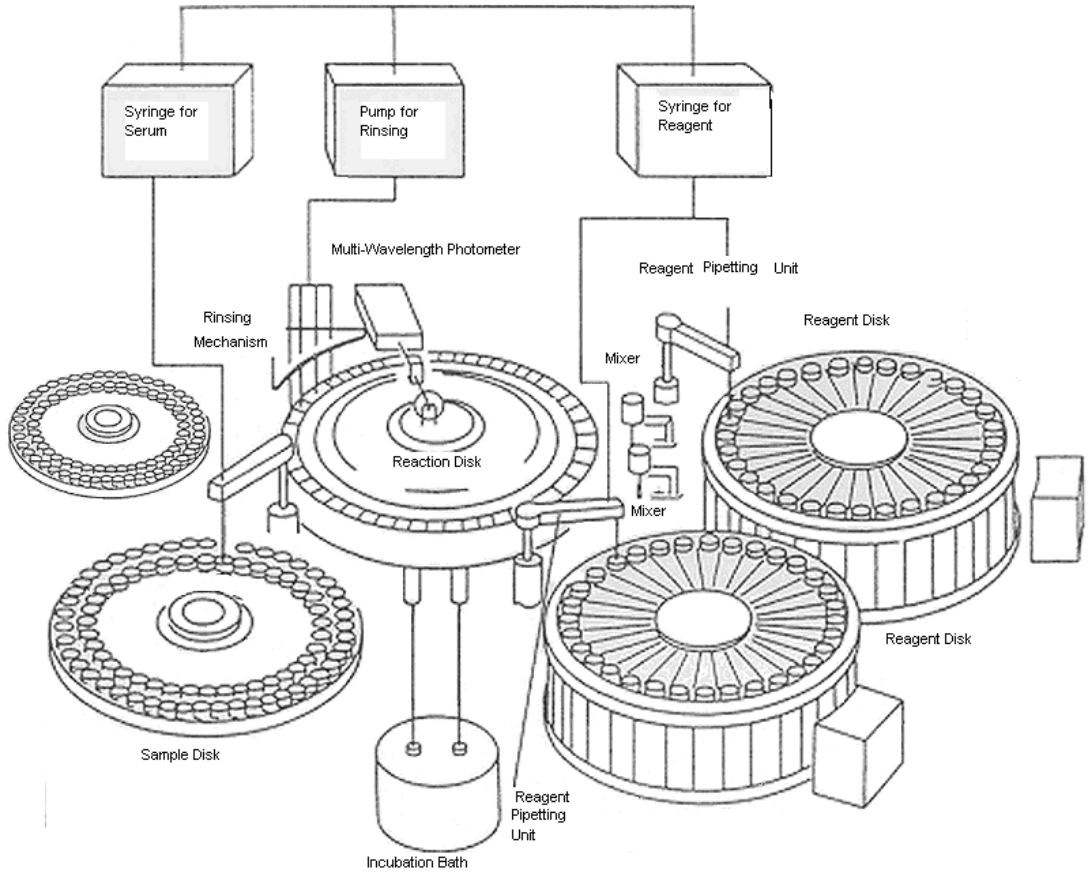


Figure 1-3-6 Systematic Composition

1.4 Analyzer Structure and Function

Auto-Chemistry Analyzer is composed of two main parts: analytical system and operating system. The analytical system includes optical system, mechanism system, pipeline system, and electronic control system. And the computer installed with system software system makes up the operating system.. The two parts are connected by network cable.

1.4.1 Operating System

Operating system consists of host computer, display device, keyboard, mouse and printer.

Host Computer: Windows 7 operating system, dedicated application software and database.

Computer Configuration: CPU basic frequency≥2.8GHz, hard disk≥120G, memory≥1G, 100Mbps network interface, USB interface, and printer interface.

Display Device: Display all windows, curves and detection data of Analyzer software. Resolution ratio ≥1024 ×768.

Keyboard: Operation control and data input of Analyzer.

Mouse: Software operation.

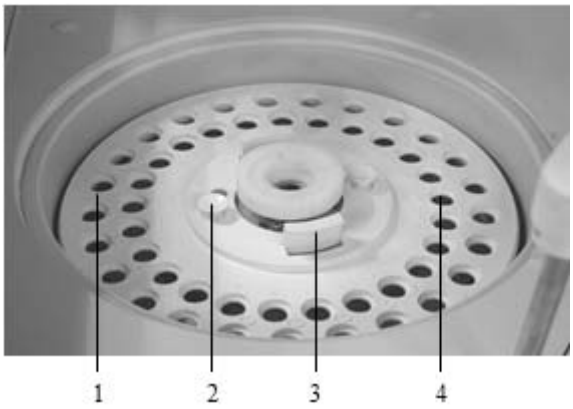
Printer: Detection data and charts printing.

1.4.2 Analytical System

Analytical system includes sample disk, QC disk, sample adding mechanism, reagent disk, reagent adding mechanism, reaction disk, mixing mechanism, cooling system, rinsing mechanism, optical system etc.

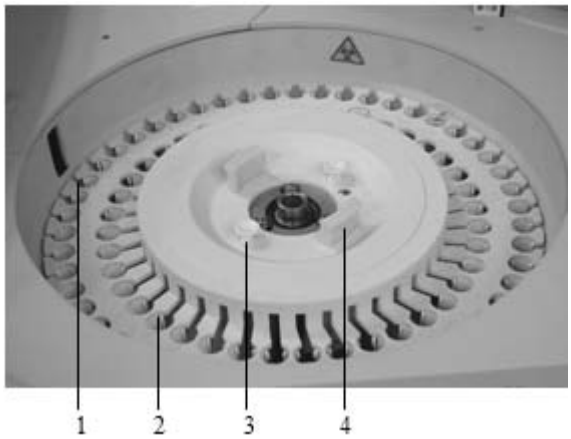
1.4.2.1 Sample Disk

The sample disk and QC disk must be covered when the analyzer is running.



1 QC Disk Outer Circle 2 QC Disk Lock Buckle 3 QC Disk Handle 4 QC Disk Inner Circle

Figure 1-4-1 QC Disk



1 Sample Disk Outer Circle 2 Sample Disk Inner Circle
3 Sample Disk Lock Buckle 4 Sample Disk Handle

Figure 1-4-2 Sample Disk

(1)Composition and Function

Routine sample can be placed in both outer circle and inner circle(10 positions for emergent samples in inner circle). QC disk is with refrigeration function which can keep the temperature between 5℃～15℃.

Place the tubes with sample, calibrator, control in the corresponding position of sample disk and QC disk. The rotate mechanism will send the tubes to sampling position.

There is a button on the upper left of the sample disk and on the lower left of the QC disk. When the indicator lamp is burning, users can make the sample disk or QC disk rotate by pressing the button of the sample disk or QC disk, and then replace a sample.

(2)Specifications(Sample No.)

Sample disk (90 positions):

(Outer Circle)Routine (1~50) ……... 50 positions

(Inner Circle)Routine (51~80) …….. 30 positions

(Inner Circle)Emergent(E81~E90)…… 10 positions

QC disk (50 positions)

(Outer Circle)Detergent(W1~W3) ……... 3 positions

(Outer Circle)Control(C1~C8) …….. 8 positions

(Outer Circle)Standard (S1~S14) ……. 14 positions

(Inner Circle)Standard (S15~S39)……. 25 positions

(3)Movements

When power on: Rotate counter-clockwise to send No.1 sample to sampling position.

When analyzing: The action is same as power on in the beginning. The movement will towards the short distance during analyzing.

When resetting: Same as power on.

(4)Mounting/dismounting

When mounting the sample disk, be sure to set the sample disk matching with the guide pin. The sample disk should be level and can not be moved by slight strength.

● In order to change the sample in disk, be sure that sample probe has stopped sampling or been under the stand-by status.

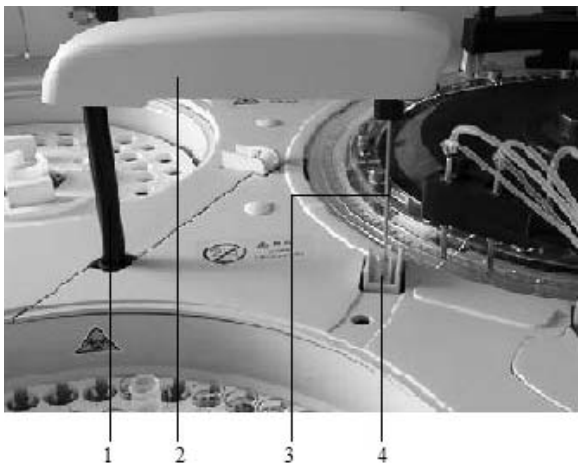
● Before tests, check whether the position for the QC disk cover and sample disk cover is correct.

(5)Movements check

In "Mechanism Check" of "Maintenance" window, select "Mechanism Action Checkup", input the check times, single-click "Execute" button. Alarm will be prompted when abnormality presents.

1.4.2.2 Sample Adding Mechanism

Do not touch the sampling mechanism when the analyzer is working, otherwise physical injury or analyzer damage may be caused.



1 Sample Probe Elevating 2 Rotational Sampling Arm

3 Sample Probe 4 Rinsing Bath for Sample Probe

Figure 1-4-3

(1)Functions

Aspirate quantitative sample from sample container and dispense it into reaction cuvette. Meanwhile, sample probe can detect liquid level. When sample probe is collided, blocked, or with blood clot, alarm is given.

(2)Specifications

The sample volume that the sample adding mechanism can aspirate is 1.5μL ~ 35μL, with 0.1μL increment.

(3)Movements

When power on: Sample probe goes above reaction cuvette, and then goes above sample probe rinsing bath.

When analyzing: Sample probe rotates and goes up and down in the following order: sample container→ reaction cuvette →sample probe rinsing bath. Automatic sample probe rinsing is carried out after each sampling. The movement of starting analysis is same as power-on movement. Above the rinsing bath, inner and outer wall of the probe is rinsed. At the same time, detection will be made to make sure whether sample probe is clogged.

When resetting: Same as power on.

When aspirating sample: Sample is aspirated when sample probe descents to about 3 mm below the liquid level.

(4)Automatic rinsing

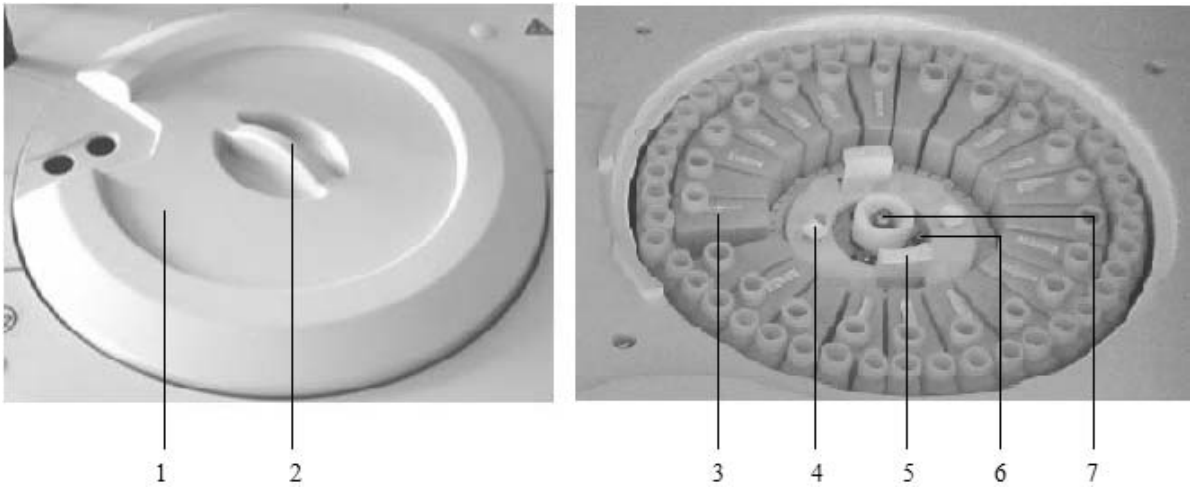
Automatic rinsing of sample probe: After each sampling, sample probe will return above the rinsing bath to wash the inner and outer wall. When all dispensing steps are finished, Alkaline Detergent will be aspirated from W1 position of QC disk.

(5)Movement check

In "Mechanism Check" of "Maintenance" window, select "Mechanism Action Checkup", input the check times, single-click "Execute" button. Alarm will be prompted when abnormality presents.

1.4.2.3 Reagent Disk

Make sure the reagent disk is covered. Do not touch the reagent disk cap during tests, otherwise physical injury or analyzer damage may be caused.



1 Reagent Disk Cover 2 Handle of Reagent Disk Cover 3 Reagent Bottle 4 Reagent Disk Lock Buckle
5 Reagent Disk Handgrip 6 Reagent Disk Guide Pin 7 reagent disk check switch

Figure 1-4-4

(1)Functions

Reagent disk accommodates reagent bottles and carries specific reagent and Anti-Bacterial Phosphor-Free Detergent to the adding position for adding mechanism. Cooling system can keep the reagent disk in lower temperature to store reagent. There is a barcode reader window on the wall of reagent cooling unit, which can scan the barcode on reagent bottle.

(2)Specifications

Reagent disk 1 (R1 disk): To place R1, R4 and Anti-Bacterial Phosphor-Free Detergent. There are 67 bottle positions, No.45 position is used for placing Anti-Bacterial Phosphor-Free Detergent.

Reagent disk 2 (R2 disk): To place R2, R3 and Anti-Bacterial Phosphor-Free Detergent. There are 67 bottle positions, No.45 position is used for placing Anti-Bacterial Phosphor-Free Detergent.

Reagent bottle capacity: 100mL, 70mL, 20mL, or user-defined

Single reagent usage: Single reagent can be used as R1 or R2, which means single reagent can be placed in both two reagent disks.

(3)Movements

When power on: Reagent disk turns clockwise and carries Position 1 of R1 and R2 disks to the reagent adding position.

When analyzing: Reagent disk firstly conducts resetting movements, and then turns to closer direction to carry next reagent bottle.

When resetting: Same as power on.

(4)Movements check

In “Mechanism Check” of “Maintenance” window, select “Mechanism Action Checkup”, input the check times, single-click “Execute” button. Alarm will be prompted when abnormality presents.

(5)Dismounting/Mounting

The 2 lock buckles in the center of disk are used for fixing reagent disk. When dismounting disk, loose the lock buckles. When mounting, make sure to align position hole with the guide pin.

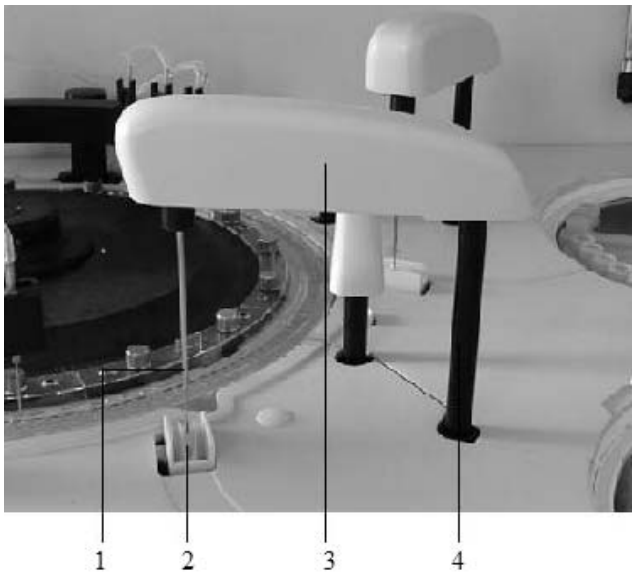
The reagent disk must be covered unless replacing disk or reagent to keep the temperature. When the reagent probe moves during running, do not open the reagent disk cover.

● If the user opens the disk cover during stand-by or running state, an alarm will be given.

● To replace reagent, uncover the QC disk. Press the button of the reagent disk to rotate it to a convenient position. Then replace the reagent.

1.4.2.4 Reagent Adding Mechanism

Do not replace reagent when reagent probe mechanism is adding. Otherwise physical injury or analyzer damage will be caused.



1 Reagent Probe 2 Reagent Probe Rinsing Bath

3 Rotation Arm of Reagent Probe 4 Reagent Probe Elevating

Figure 1-4-5

(1)Functions

Reagent probe aspirates 10μL~20μL more than specified volume of reagent from reagent bottle, and dispenses the specified volume into reaction cuvette. The reagent probe serves as a liquid level sensor. The remaining amount in reagent bottle is calculated by the descending distance of reagent probe, and is displayed on the “Reagent Info.” window.

Note:

To avoid diluted reagent, surplus volume should be aspirated and added into set volume each time.

Set Volume(μL)	Surplus Volume(μL)
0＜V＜50	10
50≤V＜100	12
100≤V＜150	14
150≤V＜200	16
200≤V＜250	18
250≤V＜350	20

The available test times of remaining reagent is calculated according to "Set Volume+Surplus Volume".

(2)Specifications

Specified reagent volume: 15μL ~ 350μL, with 1μL increment.

(3)Movements

When power on: Reagent probe goes up and turn to reaction cuvette side. Then return above reagent probe rinsing bath.

When analyzing: Reagent probe rotates repeatedly in the following sequence: reagent bottle, reaction cuvette, reagent probe rinsing bath.

When resetting: Same as power on.

(4)Automatic rinsing

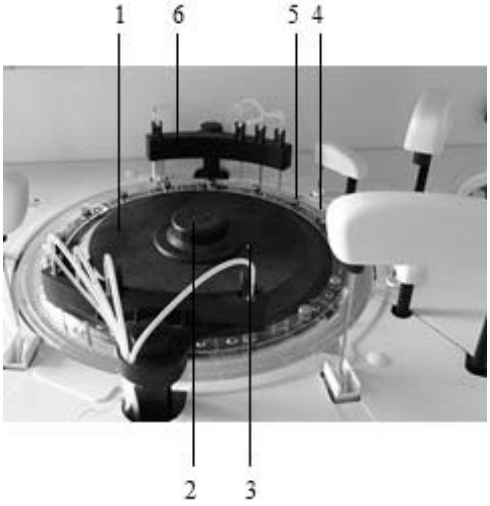
After adding reagent, reagent probe automatically aspirates Anti-Bacterial Phosphor-Free Detergent, dispenses detergent into reaction cuvette and gets washed in reagent probe rinsing bath. The inner and outer wall is rinsed. This serial movements will be conducted for three times.

(5)Movements check

In "Mechanism Check" of "Maintenance" window, select "Mechanism Action Checkup", input the check times, single-click "Execute" button. Alarm will be prompted when abnormality presents.

1.4.2.5 Reaction Disk

Do not touch the reaction disk during tests, as it may cause malfunction.



1 Reaction Disk　2 Fix Knob of Reaction Disk　3 Guide Pin and Hole
4 Handgrip of Reaction Cuvette Assembly　5 Fix Screw of Cuvette Rack
6 Reaction Cuvette Rinsing Mechanism

Figure 1-4-6

(1)Functions

Reaction cuvettes are fixed on reaction disk by fix screw. Reaction solution is kept and reacts at 37℃ in thermostatic bath. Absorbance is determined during rotation of reaction disk.

(2)Specifications

Reaction cuvettes in total: 20 cuvettes/set×8 sets, namely 160 cuvettes.

Optical diameter: 5mm

Material of reaction cuvette: Optical plastic

(3)Movements

Reaction disk usually rotates counterclockwise.

When power on: Reaction disk rotates, and then stops at the starting position. At this moment, No.1 reaction cuvette is under rinse nozzle.

When analyzing: Power on movements will be conducted first. Then reaction disk rotates anticlockwise for 90 degrees and adds a cuvette as a movement (41 cuvettes), 4 times as a circle. The reaction disk running one circle takes 18 seconds.

When resetting: The movement is same as power on.

(4)Reaction cuvette rinsing

Place Alkaline Detergent at No.45 position of R1 and R2, open the reagent bottle. Conduct “Reaction Cuvette Rinsing” in “System Maintenance” window. During analyzer working, Alkaline Detergent in the analyzer(1 for left side and 1 for right side) will be used, thus, daily maintenance is not required.

(5)Movements check

In “Mechanical Check” of “System Maintain” key, select “Mechanical Action Check” and input check times. Then click “Execute”. Alarm will be given when abnormality exists.

(6)Dismounting/Mounting

Reaction disk: When demounting, remove two rinse mechanisms of reaction disk, and loosen the fix knob in the center. Thus reaction disk can be lifted up. When mounting, align guide pin with guide hole of the reaction disk and tighten fix screw to ensure reaction disk fixed firmly.

Reaction cuvette: Remove cuvette fix screw and pull up reaction cuvette pack by holding the handgrip, and then reaction cuvette pack can be removed from reaction disk.



Keep removed reaction cuvettes immersed in pure water. Besides, if machine powers off for more than 3 days, reaction cuvettes should also be removed and immersed in 2％ Anti-Bacterial Phosphor-Free Detergent.

1.4.2.6 Incubation Bath



● Keep the cleanness of pure water in incubation bath, or test accuracy may be affected.

● When startup or rinsing incubation bath, make sure that there is enough Anti-Bacterial Phosphor-Free Detergent in position No.45.

(1)Functions

Keep the reaction solution thermostatic in the reaction cuvette.

(2)Movements

When starting up: Thermostatic water is renewed once automatically. R1 probe and R2 probe aspirate Anti-Bacterial Phosphor-Free Detergent from respective detergent bottle. Then detergent will be dispensed into incubation bath.

When analyzing: Thermostatic water circulates. Analyzer automatically supplements water when shortage occurs during operation process.

Thermostatic water renewal: In “System Maintain” window, thermostatic water is renewed when “Rinse Incubation Bath” is conducted. R1 probe and R2 probe aspirate Anti-Bacterial Phosphor-Free Detergent from

respective detergent bottle. Then detergent will be dispensed into incubation bath. 500μL Anti-Bacterial Phosphor-Free Detergent will be dispensed every time of total six times. Every startup consumes about 6mL detergent.



After running for continuous 24 hours, the analyzer will give prompt information "Incubation bath needs renewing water". Then the user should conduct "Rinse Incubation Bath" function in "Maintenance" window.

1.4.2.7 Stirring Mechanism



Do not touch stirring mechanism during its operation. Otherwise physical injury or analyzer damage may be caused.

(1)Functions

To stir reaction solution in reaction cuvette.

(2)Movements

When starting up: After rotating to reaction cuvette side, mixer returns above rinsing bath. Then mixer again comes to reaction cuvette side, again returns above rinsing bath, and finally stops.

When analyzing: Stirring mechanism rotates in the following sequence: reaction cuvette—rinsing bath of mixer. Above the two positions, mechanism descends, mixer rotates, mechanism rises and mixer stops rotating successively.

When resetting: The movement is same as power on.

R1 and R4 reagent will be mixed by R1 mixer. R2 and R3 reagent will be mixed by R2 mixer.

(3)Automatic rinsing

Automatic rinsing of mixer: When mixer descends in rinsing bath, mixer rotates and is rinsed automatically with pure water.

Dispensing finished: Mixer stirs in reaction cuvette with detergent. Thus mixer is also rinsed.

(4)Movements check

In "Mechanical Check" of "System Maintain" key, select "Mechanical Action Check" and input check times. Then click "Execute". Alarm will be given when abnormality exists.

1.4.2.8 Reaction Cuvette Rinsing Mechanism



●Do not touch rinsing mechanism during its operation. Otherwise physical injury or analyzer damage may be caused.

●Direct physical contact with solution spurted from rising mechanism nozzle must be avoided, otherwise infection or skin injury may be caused. Protective measures must be taken. In case of direct contact with skin or eyes, the area must be rinsed immediately with plenty of water and sterilized.

(1)Functions

To suck reacted reaction solution, rinse reaction cuvette, inject and suck pure water used for testing cuvette blank.

(2)Composition of rinsing nozzle

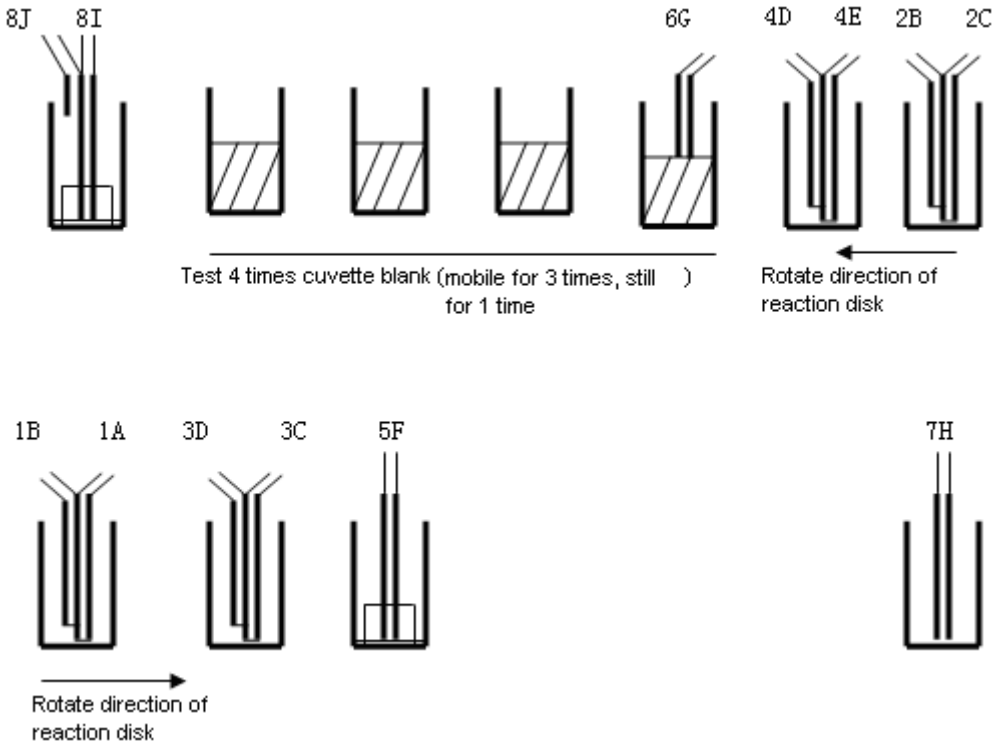


Figure 1-4-7

The above figure shows that 2 rinsing mechanisms are used in cuvettes rinsing, 8 processes are needed (4 times cuvette blank tests are added), therefore, 11 steps are conducted for rinsing 1 cuvette.

Step 1: Nozzle 1A aspirates reaction mixture, and then Nozzle 1B dispenses Alkaline Detergent into cuvette.

Step 2: Nozzle 2C aspirates Alkaline Detergent from cuvette, and then Nozzle 2B dispenses Alkaline Detergent into cuvette.

Step 3: Nozzle 3C aspirates Alkaline Detergent from cuvette, and then Nozzle 3D dispenses pure water into cuvette.

Step 4: Nozzle 4E aspirates pure water from cuvette, and then Nozzle 4D dispenses pure water into cuvette.

Step 5: Nozzle 5F aspirates pure water from cuvette and wipe it.

Step 6: Nozzle 6G dispenses pure water into cuvette. Conduct cuvette blank once.

Step 7, 8 and 9: Photometry starts from the fifth nozzle. Cuvette filled with pure water can determine absorbance of cuvette blank for 3 times(3 mobile cuvette blank tests)

Step 10: Nozzle 7H aspirates pure water used when cuvette blank absorbance is determined.

Step 11: Nozzle 8I wipes the reaction cuvette. And 8J dispenses pure water to rinse the swab just before sample dispensing.

13 nozzles' function:

A aspirating the reacted solution……. 1

B dispensing detergent……. 2

C aspirating detergent…….. 2

D dispensing pure water used for rinsing…… 2

E aspirating pure water…… 1

F aspirating pure water from reaction cuvettes and wipe them……... 1

G dispensing pure water used for cuvette blank testing…….. 1

H aspirating pure water used for cuvette blank testing……..……. 1

I wipe reaction cuvettes……..... 1

J dispensing pure water (during the rinse just before sample dispensing)……..... 1

(3)Movements

When starting up: Mechanism descends for 5mm and then rises.

When analyzing: Mechanism rinses reaction cuvette and tests cuvette blank in the rotational direction of Figure 1-4-7.

When resetting: The movement is same as power on.

(4)Movements check

In “Mechanical Check” of “System Maintain” key, select “Mechanical Action Check” and input check times. Then click “Execute”. Alarm will be given when abnormality exists.

(5)Dismounting/Mounting

When dismounting, loosen fix screw counterclockwise, and then rinsing mechanism can be lifted. When mounting, align rinsing mechanism with guide pin, press tightly and fasten fix screw.

1.4.2.9 Reagent Refrigeration

(1)Composition and functions:

Refrigeration system consists of reagent refrigeration system, control and calibrator refrigeration system. The systems respectively refrigerate reagent, control and calibrator.

(2)Specifications

Cooling temperature: 5℃~15℃.

● Even analytical system powers off, refrigeration system is still working. Refrigeration system won’t stop working until general power supply is cut off.

● The usage, storage and disposal of reagent must be performed rigorously in accordance with instruction.

● Clean the reagent refrigeration storage periodically.

1.4.2.10 Optical System

(1)Functions

When reaction disk rotates, absorbance of pure water and reaction solution is determined in reaction cuvette. As the figure below shows.

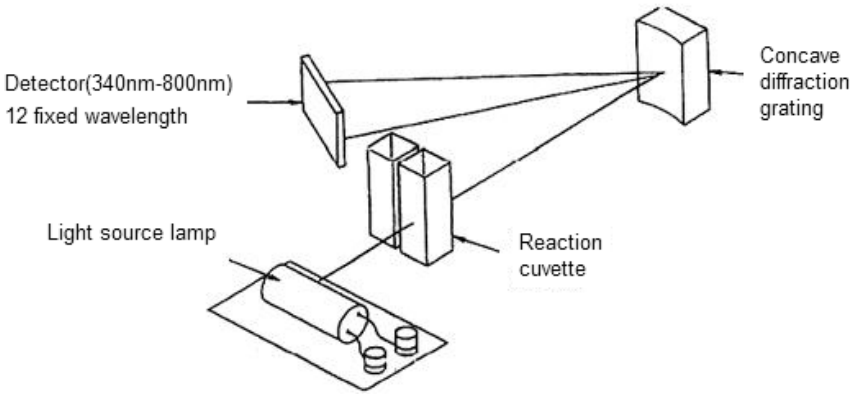


Figure 1-4-8 Photometer

(2)Specifications:

Photometry is conducted by dual-wavelength or single-wavelength at wavelengths of 340nm, 380nm, 405nm, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm and 800nm.

Wavelength accuracy: ±2nm.

Measuring range: 0Abs ~3.3Abs.

Spectral bandwidth: FHW 8nm to 10nm.

Detector: Silicon photodiode.

Light source: 12V, 20W halogen lamp.

1.5 Symbol

Table 1-5-1

Symbol	Meaning
	Biohazard symbol, reminding the user to pay attention; otherwise it may cause biological infection
	Laser mark
	Alternating current symbol
	Only for in vitro diagnostic use
	Storage at temperature range of
	Lot number
	Valid date
	Serial number
	Date of Manufacture
	Protective ground
	Manufacturer
	Meeting IVDD requirements
	Refer to the accompanying file or mark the detail warning or notice
	Classification code
	“ON”(power)
	“OFF”(power)

The above symbol information will be included on the analyzer, reagent, Control, and Calibrator.

1.6 Analyzer Working Principle

1.6.1 Mechanical Movement Position

The relative position of reaction cuvettes and probes are as Figure 1-6-1 shows.

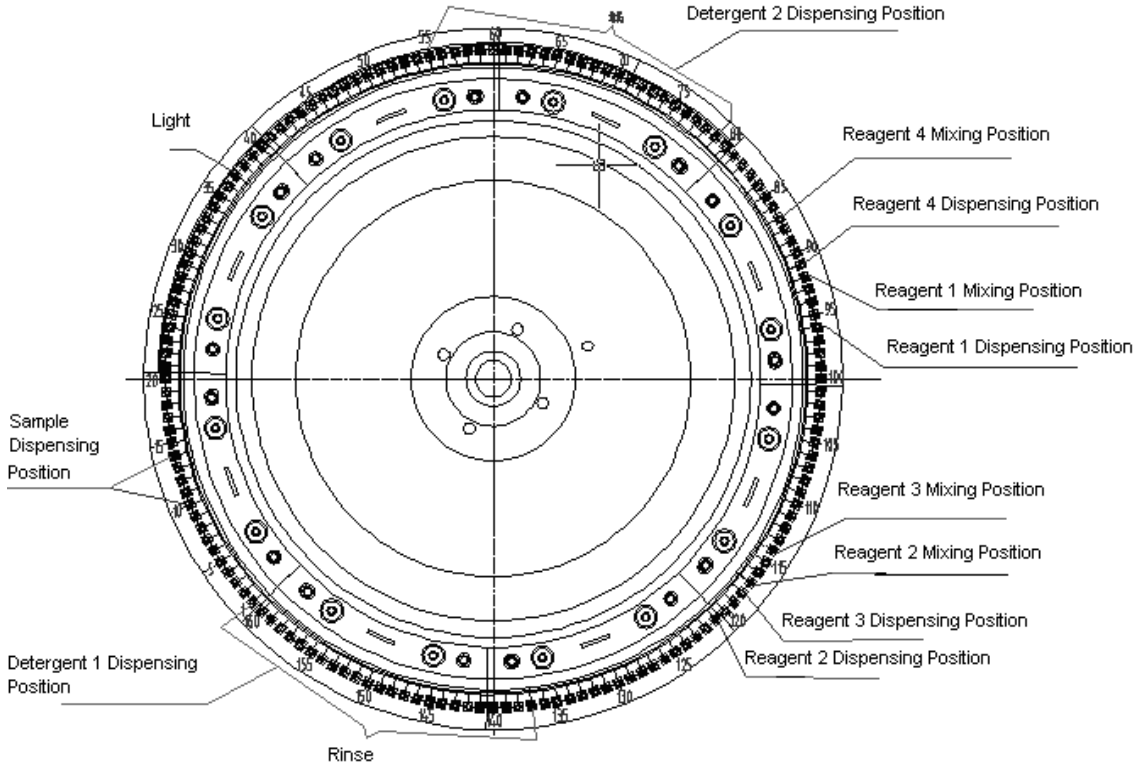


Figure 1-6-1

1.6.2 Analytical Procedures

The analytical procedures of Auto-Chemistry Analyzer are shown in the following figure:

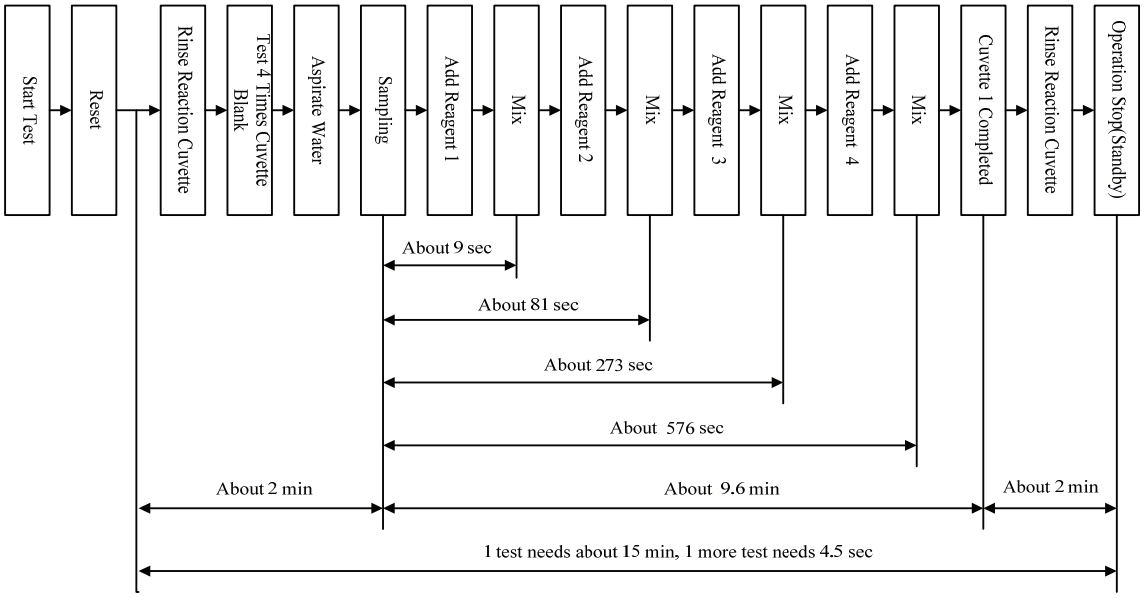


Figure 1-6-2 Analytical Flow

Note:

Take 10-minute reaction time as an example.

1.6.3 Photometric Features

Analyzer adopts whole-course photometry, which means absorbance of reaction solution is determined constantly during 10-minute reaction time. 160 reaction cuvettes are determined with absorbance value when passing by optical axis of photometer. Every reaction cuvette is measured for 34 times(because of 34 measuring positions) during 10 min.

If 22 min mode is selected, which means reaction cuvette is measured for 74 times(because of 74 measuring positions). When emitted from the light source lamp, white light is focalized by lens and then grated by concave diffraction. Grated wavelength components are simultaneously received on the 12 fixed photoelectric detectors and amplified by respective 12 amplifiers. Finally, the absorbencies and absorbance change rate are calculated. In dual-wavelength photometry, concentration is measured by absorbance change rate or absorbance difference between dominant wavelength and complementary wavelength. Because of that, dual-wavelength photometer compensates for not only lipemia, hemolysis and icterus testing, but also for impact from voltage fluctuation. In this way, measured value is more accurate and stable.

Chapter 2 Analyzer Installation

Only authorized technicians can install the analyzer and software.

2.1 Installation Requirement

The analyzer should be installed in a place meeting the following conditions; otherwise the performance cannot be guaranteed.

2.1.1 Space Requirements

The installation and use of the analyzer should meet the following requirements:

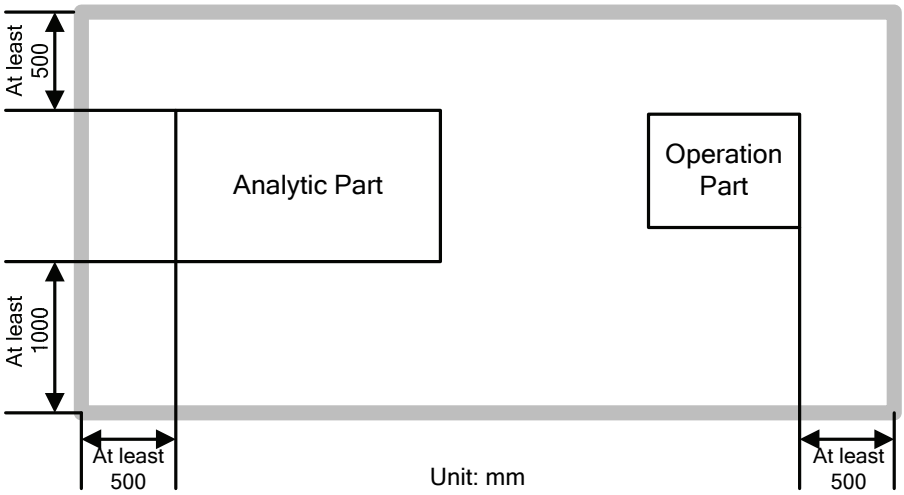


Figure 2-1-1 Installation Space

Do not install the analyzer at the place where the power-cut device is far away.

2.1.2 Environmental Requirements

(1)Ambient temperature: 15℃~32℃.

(2)Relative humidity: 30%~75%.

(3)Atmospheric pressure: 75kPa~106kPa.

(4)Analyzer should be placed in the room without dust, mechanical vibration, noise source and power interference.

(5)Do not put the analyzer in the vicinity of brush motors, flicker fluorescent tubes and other constant on-off electrical equipments.

(6)Avoid direct sunlight, do not put the analyzer in front of heat source and wind source.

(7)The maximum volume at the distance of 1 meter around the equipment shall be 70dB during normal work.

(8)The ground should be flat, and with intensity, such as cement and tiles, which can bear more than 370kg. (The analyzer cannot be disassembled to several discrete parts, not displaying the total weight of main component.)

● If the temperature and humidity cannot meet the above requirements, use air-conditioning.

●During work, heat will be generated and discharged from the rear of the analyzer. The working environment should be well ventilated. Utilize ventilating device if necessary. Avoid direct flow towards

the analyzer. Otherwise, the accuracy will be affected.

2.1.3 Power Requirements

(1)Power supply: 220/230VAC, 50Hz.

(2)Rated power: 2500VA.

(3)Circuit breaker: 250V, 20A.

(4)For reliable analysis, at least one switchboard of 20A should be prepared. Three 5A sockets are used to supply display device, host computer and printer. Other electrical equipments with large loads should not be connected on the same socket, such as air conditioner, refrigerator etc.



● The power supply should be safely grounded. Incorrect grounding may cause electric shock and system damage.

● The input voltage of the analyzer should be up to standard. It's suggested the hospitals make 6kVA online UPS power supply themselves.

2.1.4 Pure water equipment requirements

Peak water consumption of the analyzer is approximately 35L/h. Pure water equipment should meet the following requirements:

(1)Water should be obtained from the faucet.

(2)Conductivity of pure water should be less than 1μs/cm.

(3)Water supply capacity should be ≥60L/h.

(4)The hydraulic pressure should be within 50kPa ~ 200kPa.

(5)Water should be installed.



For the usage and maintenance of the pure water equipment, refer to the instruction or consult the distributor or manufacturer.

2.2 Unpacking

2.2.1 Unpacking Procedures

Check if there is any physical damage on the pack when analyzer arrives. If so, contact the manufacturer or local distributors. If not, open the package according to procedures below:

(1)Make sure that the arrow on the package is up when placing on the ground.

(2)Open the accessory box and mainframe box, check if parts in box are complete according to packing list; if not, contact the manufacturer or local distributors.

(3)Check the package and appearance of analyzer, if there is any damage, please contact the manufacturer or local distributors.

2.2.2 Transportation Method

(1)Take out all reagent bottles and the samples, Calibrators, Controls on the sample disk prior to transportation.

(2)Make sure that the liquid in the syringe pump and tubing is drained prior to transportation.

(3)Do not move analyzer until water in water tank of cooling system and incubation bath is drained. For detailed operation please refer to "10.4.8".

(4)If the distance is short and the ground is smooth, you can just drain the water in the incubation bath, and then push the analyzer to move.

(5)Make sure the analyzer stands upright during transportation.

(6)Avoid vibration during transportation. Before use, check and debug the analyzer.

2.3 Installation Procedures

2.3.1 Analyzer Installation

(1)Place the analyzer in a proper position. Adjust the analyzer to a horizontal level. Open the left and right front cover plate of the analyzer. Check whether the connecting line of the syringe pump is loose.

(2)Fix the reagent probe and sample probe. Check whether the reagent probe and sample probe can move up and down smoothly.

(3)Add 500mL pure water into the incubation bath. Fix the reaction cuvettes.

(4)Open the front door of the analyzer. Add Alkaline Detergent to the two detergent boxes on the left and right. Place a reagent bottle (70mL reagent bottle) of Alkaline Detergent in Position 45 of R1 and R2.

(5)Pure water pipeline connection

Use the pure water supply pipe to connect the outlet of the pure water equipment and “pure water inlet” (8 in Figure 2-3-1) on the right rear cover plate of the analyzer.



Figure 2-3-1

If a booster pump is selected, refer to “Booster Pump Instructions” for the connection of the pure water machine and analyzer.

(6)Waste liquid pipeline connection

a)Outlet pipeline of concentrated waste: connect one end of the concentrated waste pipeline carried with analyzer with the concentrated waste liquid outlet connector (6 in Figure 2-3-1) in analyzer. Then place the other end into the waste liquid collector.

Please dispose the waste liquid in accordance with local laws and regulations.

b)Outlet pipeline of diluted waste: connect one end of the diluted waste pipeline carried with analyzer with the diluted waste liquid outlet connector (7 in Figure 2-3-1) in analyzer. Then place the other end into the waste liquid collector or sewer.

c)Concentrated waste liquid level sensor connection: connect one end of the sensor carried with analyzer with the concentrated waste liquid level sensor connector (5 in Figure 2-3-1) at the right side of refrigeration system. Then place the other end into the concentrated waste liquid collector.

(7)ISE waste liquid collector (optional) installation

a)Remove the two screws on the right of the fans in the middle of the rear panel of the analyzer, as the following figure shows:

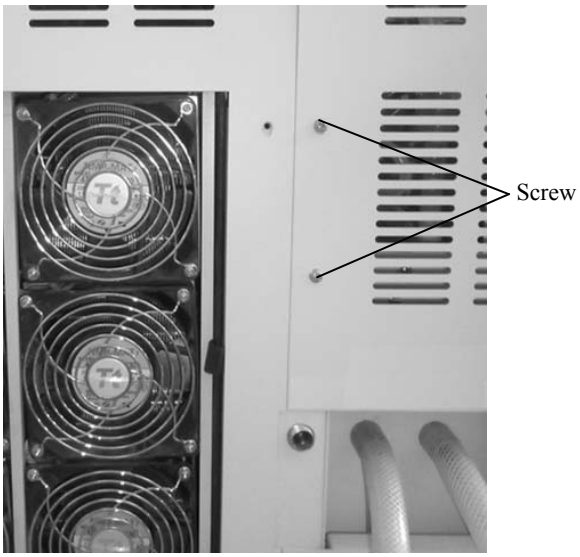


Figure 2-3-2

b)Use fixing screws to fix the ISE waste liquid collector onto the rear panel of the analyzer, as the following figure shows:

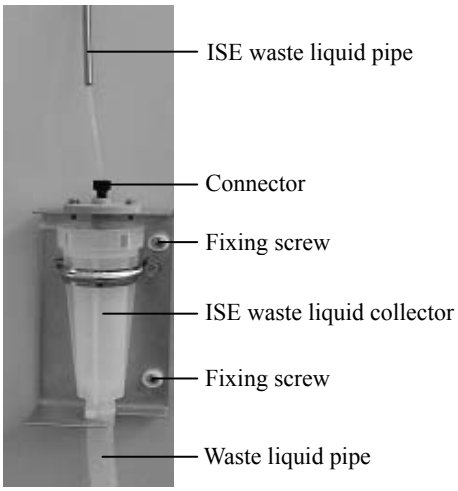


Figure 2-3-3

c)Insert the ISE waste liquid pipe into the ISE waste liquid collector. The inserted length of the pipe is about 20mm, as the following figure shows:

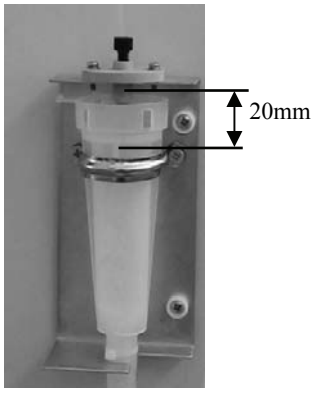


Figure 2-3-4

d)Tighten the connector. Connect the lower waste liquid pipe of the ISE waste liquid collector to the waste liquid discharge device (waste cask or sewer pipe).

The installed ISE waste liquid pipe should be in the center of the waste liquid collector, not in contact with the container wall.

(8)ISE electrode (optional) installation

Make sure the electrode storage temperature is within 1℃~51℃.

a)Remove the 2 screws fixing the ISE electrode replacement cover on the worktable, and open the cover:

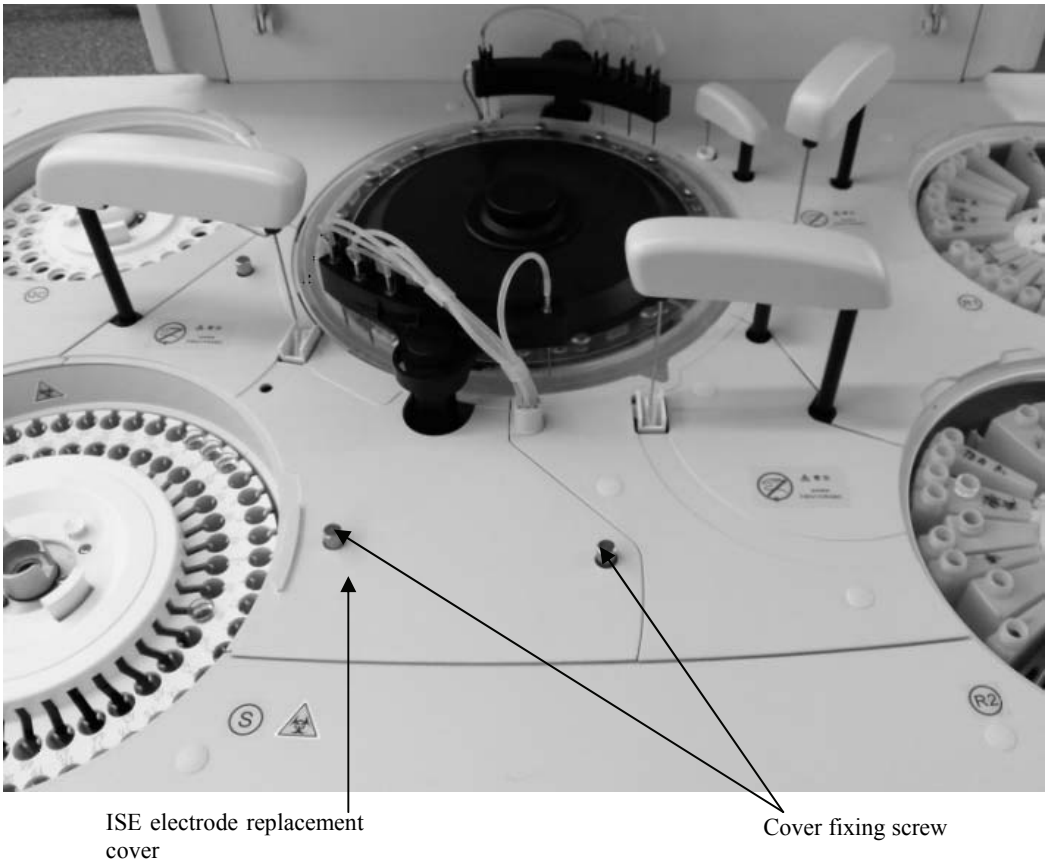


Figure 2-3-5(a)

b)Remove the fixing screw form the electrode assembly, and lift up the electrode assembly, as the following figure shows:

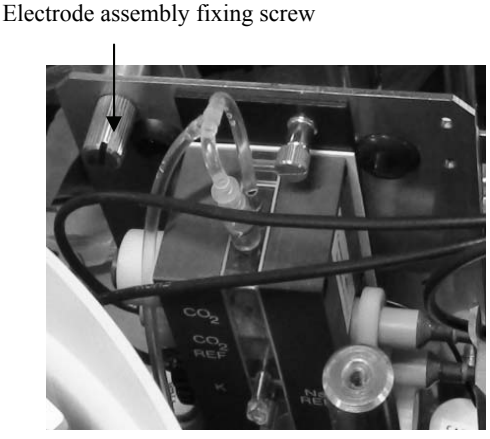
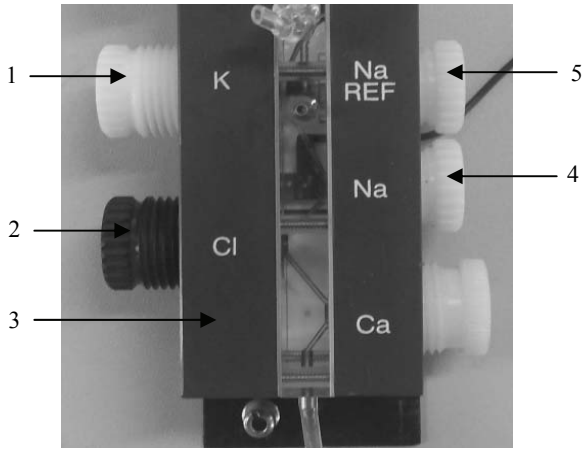


Figure 2-3-5(b)

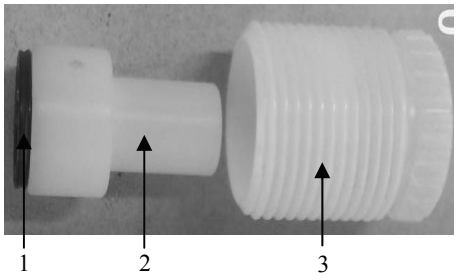
c)Unscrew the nut of K, Cl, Na and NaREF on the flow cell (as Figure 2-3-6 shows), and take out each seal plug and ring. Save the K, Cl, Na, and NaREF nut for the installation of Cl, K, Na, and NaREF electrode. The seal plugs and rings can be disposed of for other use. (Refer to Figure 2-3-7 for the removed seal plugs and seals):

If any seal ring on a seal plug falls in the flow cell. Use cotton swabs to take it out (do not use hard tools to take it out).



1 K nut, seal plug, and seal ring 2 Cl nut, seal plug, and seal ring
3 Flow cell 4 Na nut, seal plug, and seal ring 5 NaREF nut, seal plug, and seal ring

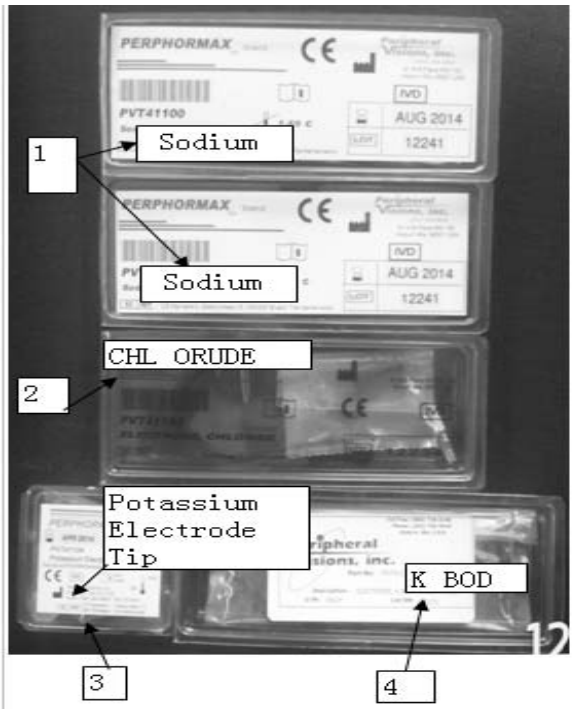
Figure 2-3-6



1 Seal ring 2 Seal plug 3 Nut

Figure 2-3-7

d)The following figure shows the packaging of Cl, K, Na, and NaREF electrode. When installing the electrodes, pay attention to the letters on the packaging to avoid incorrect electrode installation.



1 Na electrode packaging (NaREF electrode) 2 Cl electrode packaging

3 K electrode tip packaging 4 K electrode packaging

Figure 2-3-8

e)Install the electrode of CL, K, Na and NaREF(same to Na electrode) onto the flow cell according to the following steps:

During installation, keep the O-shaped seal ring (4 in Figure 2-3-9) safe.

➢Open the packaging of K electrode tip, and K electrode, and take out the electrode and accessories.

➢Fix the O-shaped seal ring (4 in Figure 2-3-10) on the electrode well. Screw the K electrode tip (10 in Figure 2-3-10) onto the K electrode, and then fix the electrode seal ring (9 in Figure 2-3-10) onto the K electrode tip evenly.

➢Use cotton swabs to wipe the liquid in the electrode holes in the flow cell. Use cotton swabs to wipe the electrode.

➢Thread the K electrode (as Figure 2-3-10 shows) through the nut. Make sure the electrode seal ring is fixed onto the K electrode tip evenly. Screw the mentioned electrode assembly onto the flow cell.

When installing an electrode, use proper strength to tighten the nut with hands.

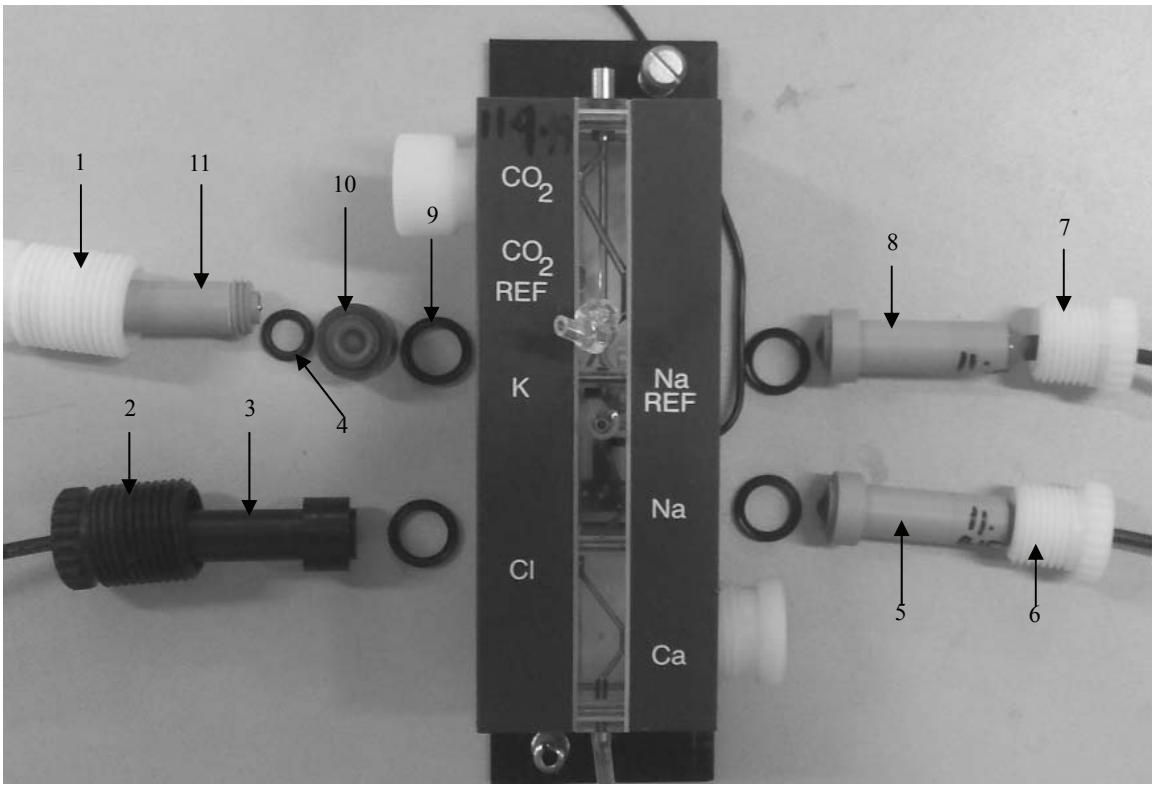


Figure 2-3-9

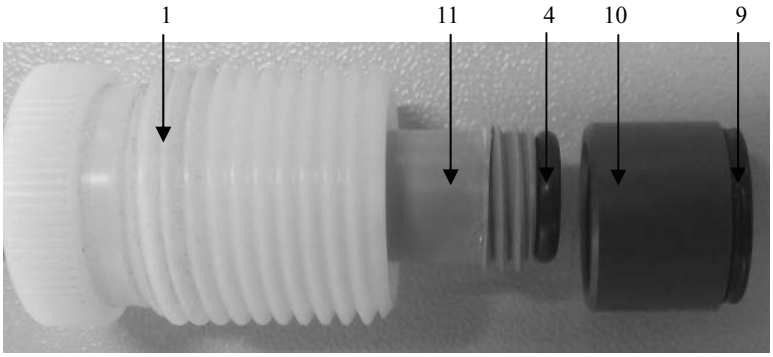
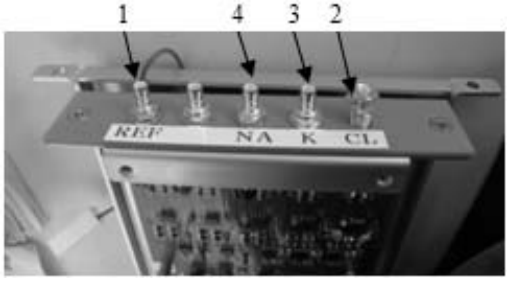


Figure 2-3-10

1 K nut 2 Cl nut 3 Cl electrode 4 O-shaped seal ring 5 Na electrode 6 Na nut
7 Na nut 8 Na electrode 9 electrode seal ring 10 K electrode tip 11 K electrode wire

➢According to the above method, fix the Cl electrode, Na electrode, and NaREF to the flow cell respectively.

f)Connect the other end of the Cl, K, Na and NaREF electrode that has been fixed to the flow cell to the amplifier board connectors, as the following figure shows:



1 NaREF electrode tip 2 Cl electrode tip 3 K electrode tip 4 Na electrode tip

Figure 2-3-11

Note:

The differences are as follows:

- **K electrode can be disassembled;**
- **The surface of Na electrode is glass;**
- **The surface of Cl electrode is metal.**

g)Push the electrode assembly back to the original place, and tighten the fixing screws.

h)Fix the ISE electrode replacement cover on the worktable and tighten the fixing screws.

2.3.2 Power connection

Before power connection, make sure the main switch (circuit breaker) of the analyzer is OFF.

The analyzer is equipped with a three-core power cable; the red wire is the live wire, the blue wire is the neutral wire, and the yellow green wire is the earth wire. The rated temperature of the three-core power cable is 70℃.

To realize the reliable connection between the analyzer and the power supply, do not use a power cable socket, and connect the power cable to the switchboard during installation. Make sure there is no much distance between the switchboard and the analyzer for the convenience of cutting off the power once emergency occurs.

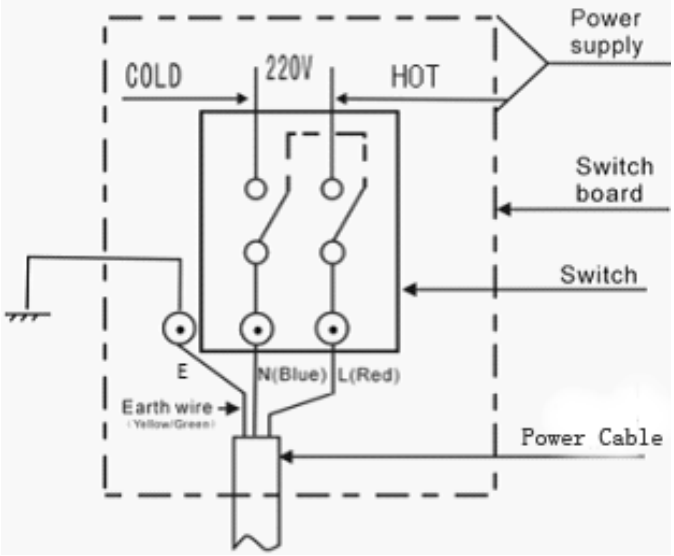


Figure 2-3-12

The distance between the switchboard and analyzer should be no more than 3 meters.

2.3.3 Peripheral device connection

(1)Install and connect the computer, display and printer, and check:

a)whether the printer driver is installed;

b)the specifications of the printer paper.

(2)Connect one end of the accompanying network cable to the network port of the analyzer, and the other end to the main case network port of the computer.

2.3.4 Software installation and un-installation

2.3.4.1 Software installation

Place analyzer applied software CD into CD driver of computer and run “setup.exe”. Installation program initializes as the figure below shows:



Figure 2-3-13

Select a language, and click the “OK” key. The following figure pops up:

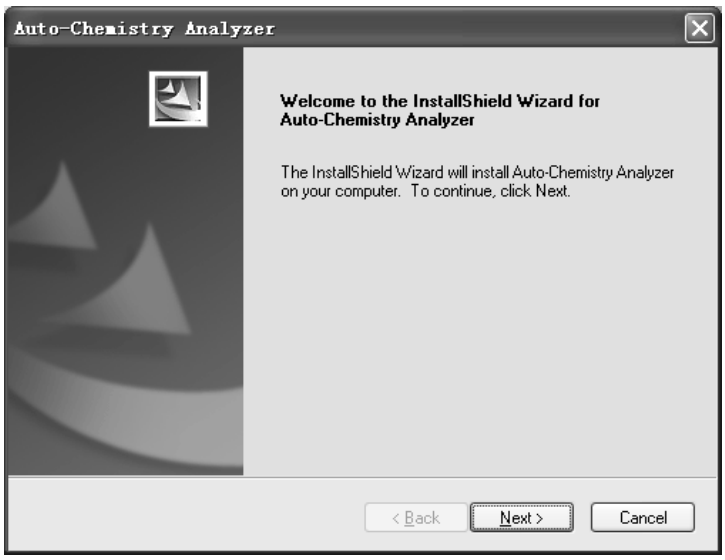


Figure 2-3-14

Click the “Next” key, and the following figure pops up:

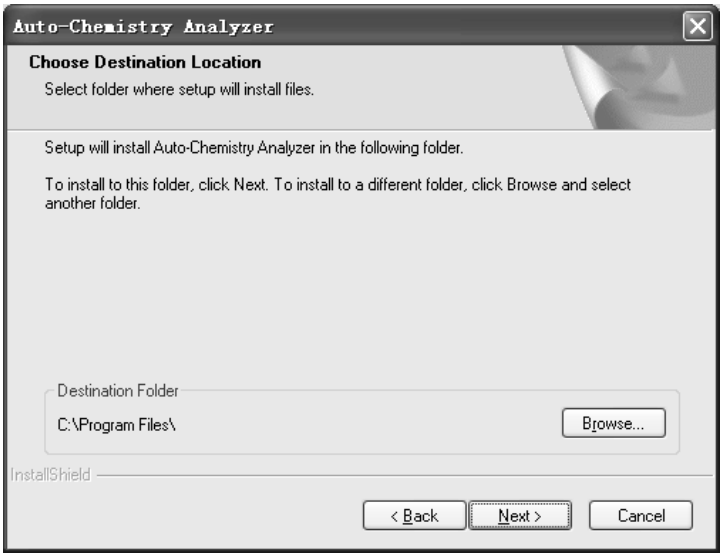


Figure 2-3-15

To change the installation path, click the “Browse” key in the above figure to select an installation path; To use the default path, click the “Next” key, and the following figure pops up:

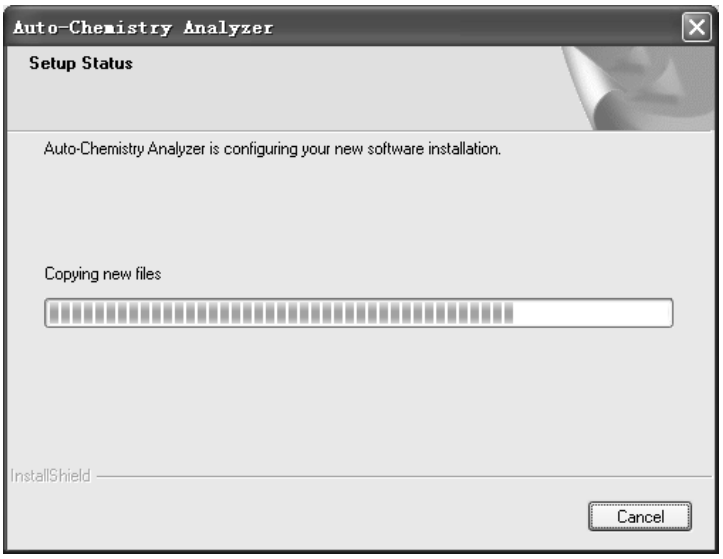


Figure 2-3-16

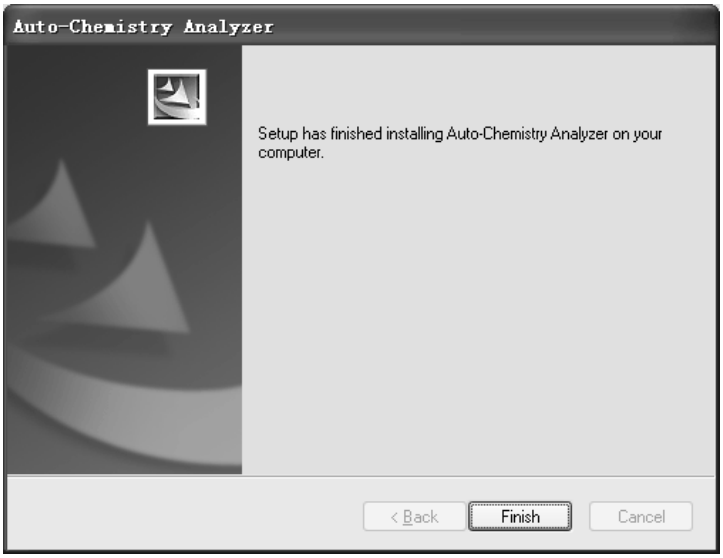


Figure 2-3-17

Click “Finish” to finish the installation; meanwhile, the software icon will be displayed on the computer desktop.

2.3.4.2 Un-installation of Software

Method 1: Enter “Add or Remove Programs” in Control Panel. Select “Analyzer” and then click “Modify/Delete” button. “Add or Remove Programs” confirmation window will be displayed as follows:

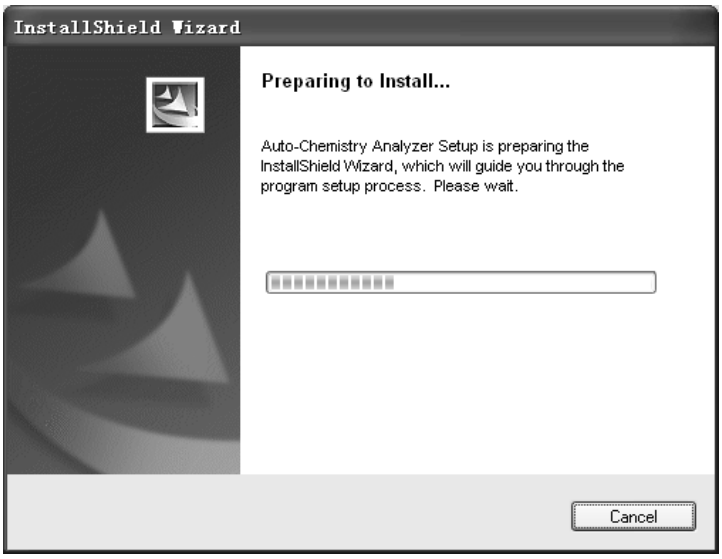


Figure 2-3-18

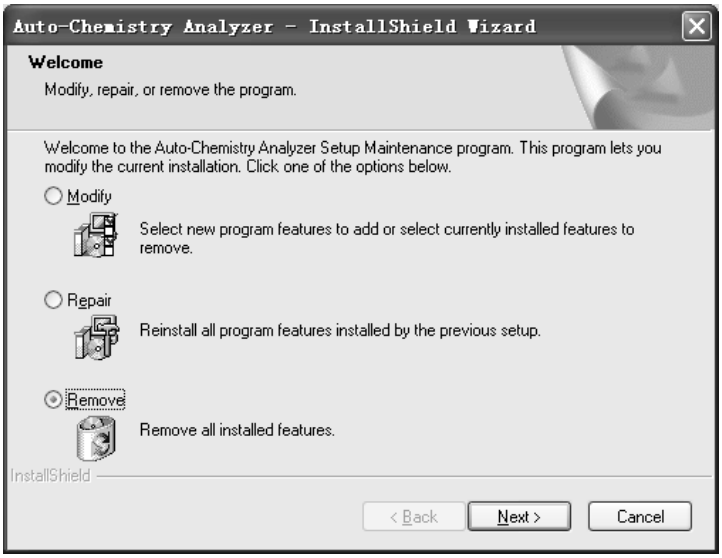


Figure 2-3-19

Click “Next” to uninstall the software.

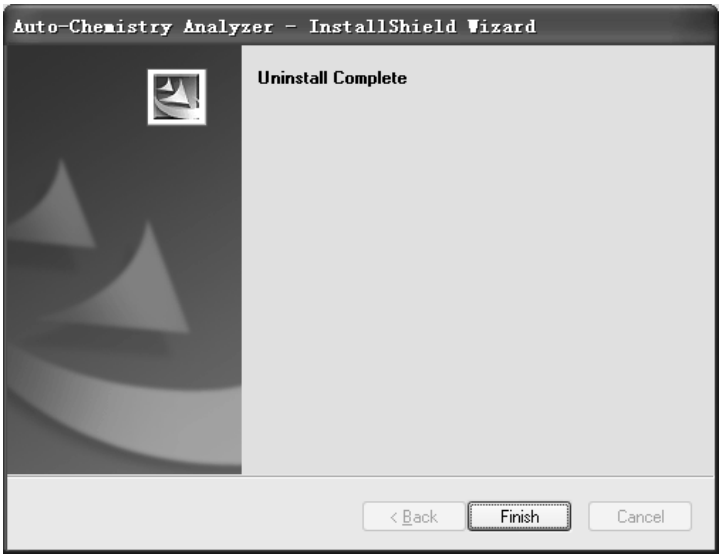


Figure 2-3-20

Method 2: Click “Start → Program →Auto-Chemistry Analyzer—Uninstall Auto-Chemistry Analyzer”, then confirmation window will be displayed.

Click “Next” in Figure 2-3-19 to finish the un-installation.

Click “Finish” in Figure 2-3-20 to close the window.

2.3.5 Add water to cooling system water tank

(1)Turn off the main switch of the analyzer.

(2)Remove the left front cover plate of the analyzer, as the following figure shows:



Figure 2-3-21

(3)Pull out the plug of the two rubber hoses that connect the water tank of the cooling system, as the following figure shows:

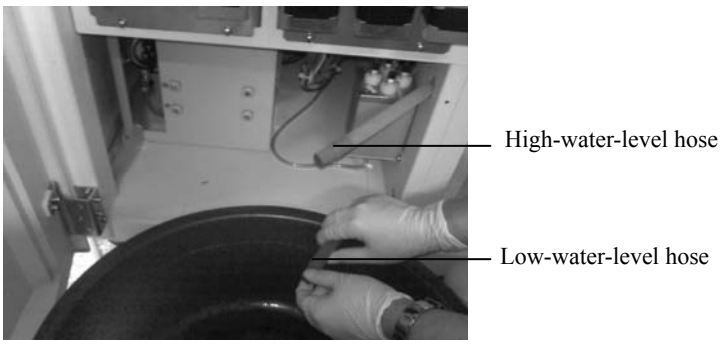


Figure 2-3-22

(4)Keep injecting pure water into the hose of the low water level until water flows out the hose of the high water level.

(5)Turn on main switch of the analyzer. After a few minutes, continue injecting pure water into the low-water-level hose until there is water flowing out the high-water-level hose. It takes approximately 3L water.

(6)Insert the rubber plugs into the hoses again. Fix the analyzer cover plate well.

2.3.6 System Login

Turn on power supply as follows: pure water equipment power, computer case power, computer display power, printer power, analyzer power, and analytic unit power.

Then double click the icon “” of Analyzer Software application software on desktop, or click “Start → Program → Auto-Chemistry Analyzer”. “System login” window will be displayed as follows.

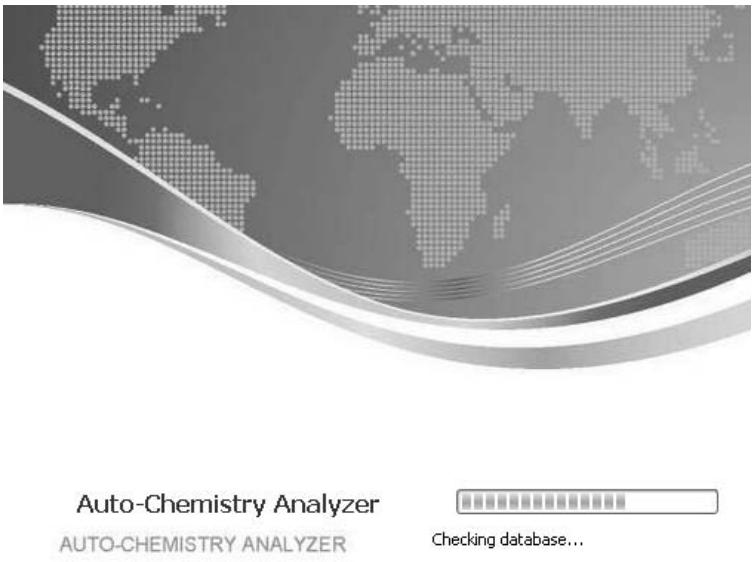


Figure 2-3-23



Figure 2-3-24

Input the user name and password (initial software user name: 1; initial password: 1), and click “Login” to get into the main menu of the software, as Figure 2-3-25 shows.

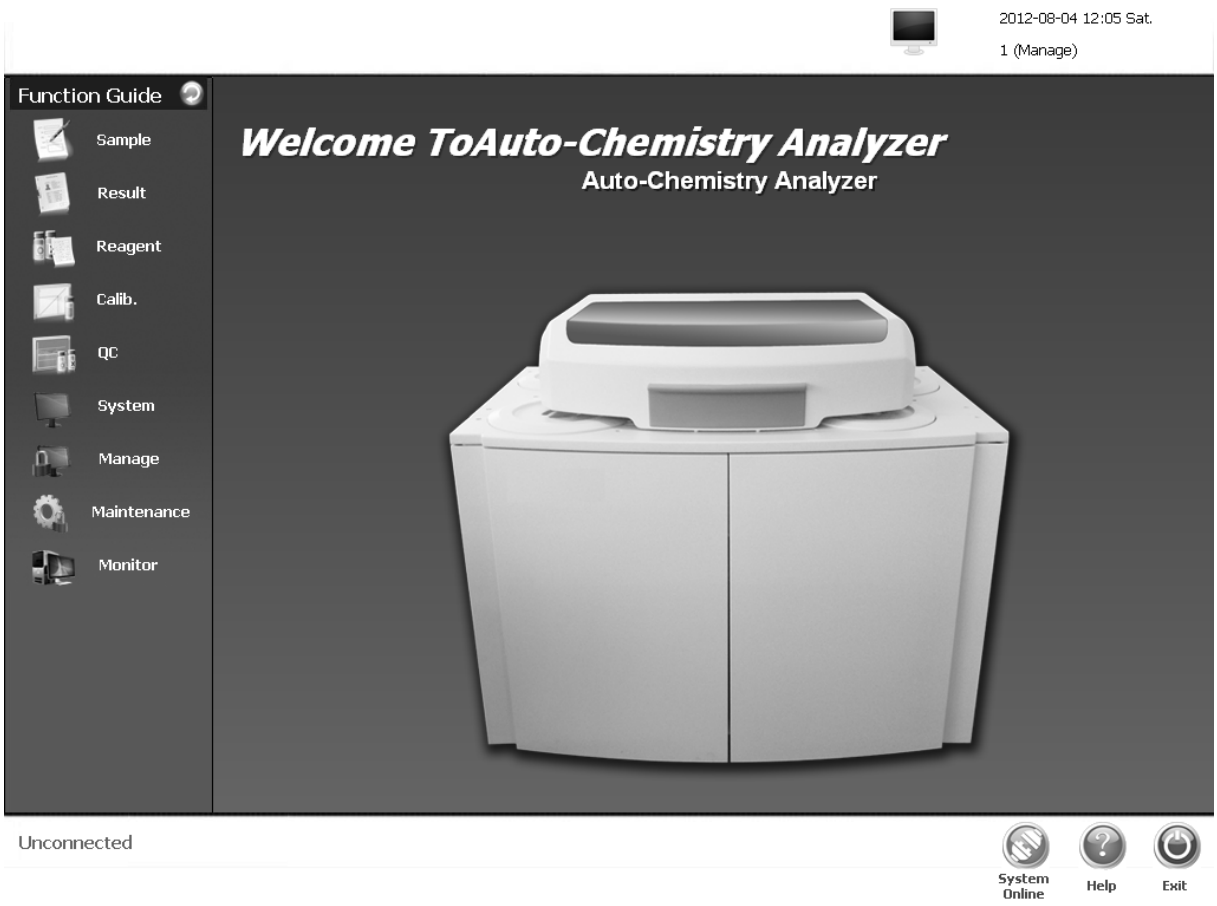


Figure 2-3-25

After login, the analyzer is in the off-line state . At this time, the user can browse functional windows, check alarm information, logoff and exit.

On the interface of "System Login", screen will notify login errors when wrong user name and password were input. See the following figure:



Figure 2-3-26

If incorrect user names or passwords are input for consecutive 3 times, the program will exit automatically.

All functional buttons in the main window of the software are explained as follows:



a)On-line: Click "", After access, the status bar will display "analyzer status: 37.0 ℃ standby". At this time, all operation and tests can be carried out.

After login, if analytical system is not connected with power supply or data wire, click the "On-line Connection", the screen will display "Connecting failed" (lower left of the screen).

If it shows on the screen, start on-line service after connecting power supply.

b)Exit: Click “ Exit ” among shortcut keys, then confirmation window will show as follows:

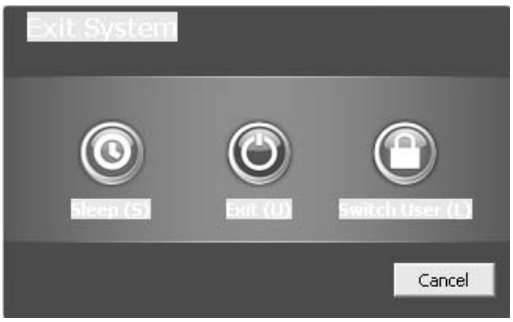


Figure 2-3-27

Click “” to exit this software.

Exit is carried out only in off-line state. If analyzer is on-line, click “” and then exit the system.

c)Switch User: Click “” among shortcut keys, and screen will display the following figure:



Figure 2-3-28

● When laboratory physician rests, it is suggested to exit software, avoiding non-user from damaging it or modifying data. The user should back up database periodically, so data can be kept despite accidents.

● Input initial user name and password when logging in for the first time. Click “User info.” in “System management” window to set up user name, password and permission. Then you can use renewed information to log in next time.

System enters into standby mode after power on for 20 mins (time for the temperature and light source to be stable).

2.3.7 Debug analyzer

Carry out the following operation in the “System Maintenance” window.

(1)Syringe pump exhaust

Carry out syringe pump exhaust to exhaust the air in the pipeline. For detailed operation, refer to Section 10.2.3.

(2)Rinsing detergent pipeline exhaust

Carry out “Rinsing detergent pipeline exhaust” to fill the pipeline with detergent to exhaust. For detailed operation, refer to Section 10.2.3.

(3)Reagent probe horizontal check

Make sure the reagent probe is above the reaction cuvette, rinsing path, and reagent bottle correctly. For detailed operation, refer to Section 10.2.5.

(4)Sample probe horizontal check

Place a standard cup in Position 1 and 51 of the sample disk, and W1 and S15 of the QC disk respectively. Carry out the sample probe horizontal check to make sure the sample probe is above the reaction cuvette, rinsing bath, and standard cup (outer circle, inner circle). For detailed operation, refer to Section 10.2.5.

(5)Stirring rod horizontal check

Carry out the stirring rod horizontal check to make sure the stirring rod is above the reaction cuvette, and rinsing bath. For detailed operation, refer to Section 10.2.5.

(6)Mechanical action check

Carry out the mechanical action check 20 times to check whether the swab of the rinsing nozzles rub against the reaction cuevette. For detailed operation, refer to Section 10.2.5.

(7)Rinse reaction cuvette and ISE

Carry out reaction cuvette rinsing in the "System Maintenance" window. For detailed operation, refer to Section 10.2.4. If ISE is equipped, ISE pipeline rinsing and ISE matching cuvette rinsing need to be carried out in the ISE maintenance window. For detailed operation, refer to Section 10.2.7.

(8)Light intensity check

Carry out the light intensity check, and attach the results to the installation acceptance report. The check values should be no more than 18000. For detailed operation, refer to Section 10.2.2.

(9)Cuvette blank test

Carry out the cuvette blank test. The check value of Cuvette 1 should be no more than 18000. The check value of Cuvette 2~160 should be within -800~800.

(10)ISE check

Carry out the ISE check 50 times. The difference between two neighboring results should be no more than 0.2 units. The difference between the maximum and minimum of Na and Cl is no more than 3 units. The difference between the maximum and minimum of K is no more than 0.2 units. For detailed operation, refer to Section 10.2.7.

(11)Sample probe blockage removal

The sample probe has been cleaned before leaving the factory. However, it still can be blocked by dusts during transportation. If a "sample blockage" alarm is issued during the above tests, remove the blockage. For detailed operation, refer to Section 10.4.1.

2.3.8 Clinical item test

Edit chemistry parameters, register reagent information, and test rate assay ALT, end point assay TP, and two-point rate BUN. Calculate CV. And fill the test results in the Installation Acceptance Report.

2.3.9 Medical personnel training

Offer training in operation and maintenance to the medical personnel, and fill the records in the Installation Acceptance Report.

2.3.10 Fill installation acceptance report

Fill out the installation report in detail and mail it to the manufacturer or the distributor.

2.4 Accessory Devices

2.4.1 Sample Disk Barcode Reader

2.4.1.1 Barcode Reader Scanning Range

The barcode reader in the outer circle of sample disk reads the barcode of sample 1~50. The barcode reader in the inner circle of sample disk reads the barcode of sample 51~90(sample No.51~80 are emergent samples).

2.4.1.2 Sample Container Requirements

(1)Specifications:

Tube: Φ10mm×75mm, Φ10mm×100mm, Φ13mm×75mm, Φ13mm×100mm(±1 mm)

Standard cuvette: Φ14mm×37mm(±1 mm)

(2)Tube mouth should be regular without extrusion and deformation.

2.4.1.3 Barcode Requirements

(1)Barcode type: Code 128, Code 39, Code 93, Codebar, I2 of 5.

(2)Label size: Width within 8mm~12mm; valid length≤40mm. Start margin & end margin are required to be≥3mm when barcode is cut as follows:

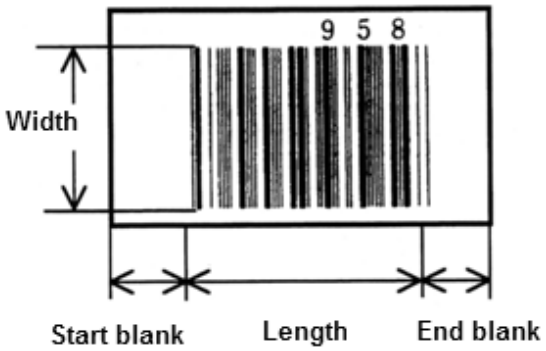


Figure 2-4-1

(3) Barcode digits

Table 2-4-1

Sample Barcode Type	Digits
Code39	3~18
Code93	3~18
Code128	3~18
I2of 5	3~18
Codebar	3~18

● Barcode with such characters as‘’, “”, and ( ) cannot be identified normally. Please avoid them. Codebar start and stop character should be A, B, C, and D.

● The length of the barcode with “NR” at the end cannot be less than 5.

2.4.1.4 Pasting Requirements

(1)When pasting label, make sure no cockle or contamination on it. Incomplete print should be avoided. Otherwise the barcode cannot correctly read.

(2)Pasting barcode:

In order to read barcode correctly, the distance between lower edge of barcode and tube bottom is required to be 15mm~20mm. Make sure barcode is in the notch of sample position when placing tube on rack as the following figure shows:

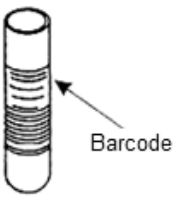


Figure 2-4-2 Pasting Sample Barcode

When the barcode is the lowercase of CODE39, the ID in display of the screen and the printed report will be marked with “+” and corresponding capital letter.

2.4.1.5 Barcode Reader Usage

If “Sample Barcode No.” is selected in the sample test mode from the “Other Info.” interface under the “System” window before analysis, the sample disk will stop at the barcode reader for scanning after sample tests begin. For the barcode which can not be identified, scanning will be conducted for continuous 3 times. Tests will be conducted after barcode scanning. For the added samples, scanning will be conducted after last sample sampling is finished. The scanned information will be displayed in “Sample Registration” and “Test Result” window.

In sample disk barcode reader check of “System Maintenance”, samples in position No.1 of outer circle and position No.51 of inner circle will be scanned, and the scanning result will be displayed after scanning.

Make sure barcode is in the notch of sample position when placing tube on rack.

2.4.2 Reagent Barcode Reader

2.4.2.1 Scanned Range

Reagent disk barcode reader is used for identifying barcodes on reagent bottles of reagent disk 1 and reagent disk 2.

2.4.2.2 Reagent Bottle Requirements

Specifications: 100mL, 70mL, 20mL, or user-defined.

2.4.2.3 Usage Requirements

(1)Type: Code 128(17- digit).

(2)Label size: Width within 12 mm~25mm; valid length≤40mm.

(3)Start margin & end margin are required to be ≥3mm(as Figure 2-4-1).

2.4.2.4 Pasting Requirements

(1)When pasting label, make sure no cockle or contamination on it. Incomplete print should be avoided. Otherwise the barcode cannot correctly read.

(2)Pasting barcode: In order to read barcode correctly, the distance between lower edge of barcode and tube bottom is required to be 15mm~25mm.

2.4.2.5 Usage

Carry out “barcode scanning” in “reagent info.” window, then reagent disk barcode readers will automatically and continually scan two reagent disks. If barcode cannot be identified when scanning, reader will scan continuously for three times.

When barcode reader checks of reagent disks are conducted in the “Maintenance” window, the reader identifies barcode information of Position1 on reagent disk1&2, and then displays pass or fail.

2.4.2.6 Rules

The user can prepare their own barcodes according to circumstances. Rules are as shown in Table 2-4-2.

Table 2-4-2

Barcode digits	Information	Barcode value range	Detailed explanation of barcode implication	Remarks
1~2	Item name	0~94	Chemical reagent item code (representing different item name)	
		95	ISE Concentration Quantitative Determination Internal standard solution	
		96	ISE Concentration Quantitative Determination Diluent	
		97	ISE Concentration Quantitative Determination Reference solution	
		98	Anti-bacterial & phosphor-free detergent	
		99	Alkaline Detergent	
3	Bottle specifications	1	20mL	
		2	70mL	
		3	100mL	
		4	500mL	
		5	2000mL	
4	Reagent type	1	R1	
		2	R2	
		3	R3	
		4	R4	
		5	Null	Reagent type must be 5 if item code is ISE reagent or detergent.
5~9	Manufacture date (LOT)	0~9	Year	
		01~12	Month	
		01~31	Day	
10	Expiry date	1	2 weeks	
		2	1 month	
		3	3 months	
		4	6 months	
		5	12 months	
		6	18 months	
		7	2 years	
		8	3 years	
		9	5 years	
11~14	Bottle code	0001~9999	The XXXXXth bottle	
15~17	Parity bit	Numeric or alphanumeric (automatically generated)		

Reagent barcode information is read by barcode reader, and couples with chemistry parameters which have been saved. This process is called reagent auto registration, which means reagent information can be confirmed through barcode scanning.

The read information is showed in “reagent information” window, with the forms of “disk No.”, “position”, “reagent name”, “reagent type” .

Reagent name: Chemical name of analyzed item.

Position: Each reagent disk has 1~45 positions to place reagent. But automatic barcode scanning can not be conducted for inner circle.



Periodically clean reading windows of sample disk and reagent disk barcode readers.

Chapter 3 Software Operation

3.1 Software Interface Instruction

3.1.1 Main Interface Composition

Software interface mainly consists of status bar, main functional guide area, work area, indication bar, shortcuts area.

(1)Status bar: Status bar immediately displays analyzer status on the top of window. It is real-time information. As Figure 3-1-1 shows:



Figure 3-1-1

Function explanation:



: The temperature and status is displayed immediately. Displayed statuses include “standby”, “testing”, “emergency stop”, “suspend dispensing” and “system sleep”.

: LIS status. Display means open, while disappear means close.

: Signal of communication monitoring. With ball means normal communication while no ball means no communication.

: Alarm icon. Only when there is alarm information will this icon appear. The operator should click the “Alarm Info.” Key F8 in shortcuts area, or directly click alarm icon to check. Abnormalities can be disposed according to indications.

1 (Manage): To show ID information of current user. The information can be set up, modified or deleted in “User Info.” options page under “System Manage” window.

2012-08-04 12:08 Sat. : To show system time(YMD-HMW).

(2)Main functional guide area: Click to select functional keys as Figure 3-1-2 shows. Click “” to change window color and style.

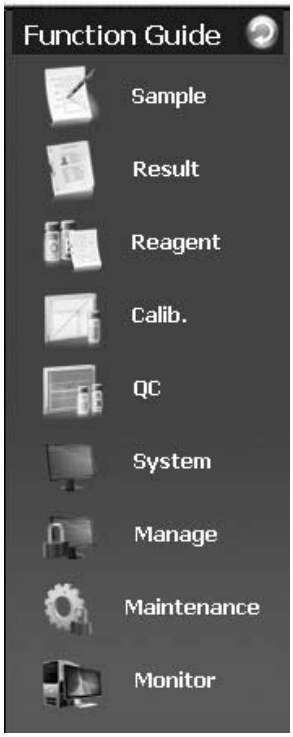


Figure 3-1-2

(3)Work area: Click corresponding keys to enter work area, when functional key is clicked, its border color will change. If the user click "System" under Function Guide, "System Setting" window will show as Figure 3-1-3.

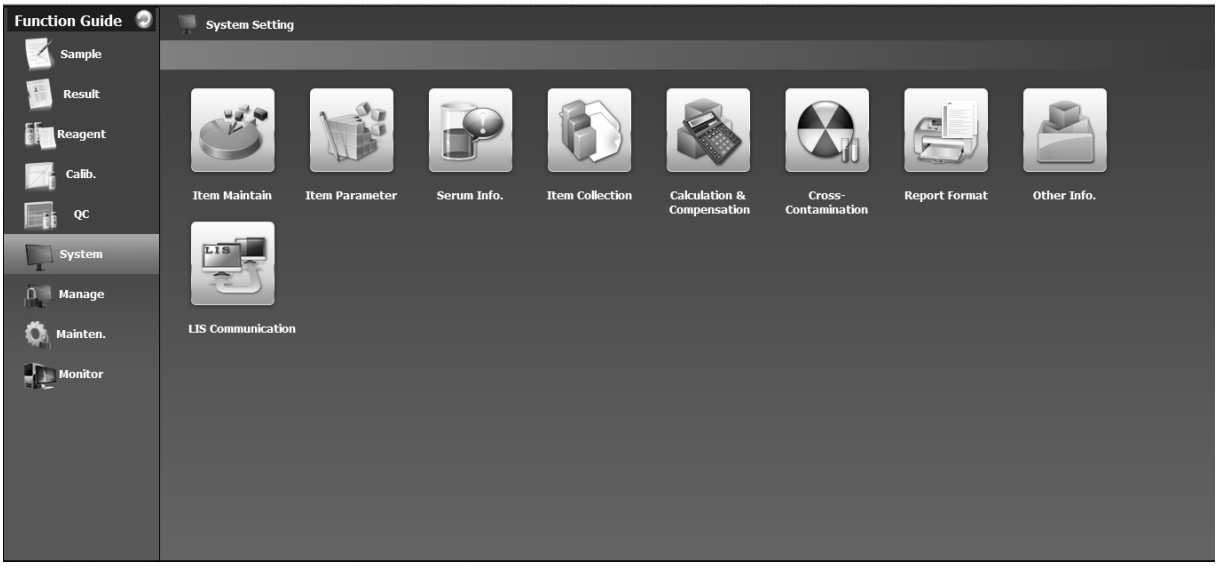


Figure 3-1-3

(4)Indication bar: Indication bar is on the lower edge of interface, providing corresponding hints to most operation. It helps the user to know operation methods. For example, it indicates input range and method, or incorrect operation, as Figure 3-1-4 shows:

Please input the range of routine sample No.: 1 - 9000

Figure 3-1-4

(5)Shortcuts area: To facilitate software operation as Figure 3-1-5 shows.



Figure 3-1-5

To complete software operation, the user can click the keys above, or press F2~F8 on the keyboard. Besides, F1 is defaulted to “Help” key.

Click the blank before “Analyzer Status” to display the software version information.

3.1.2 Keypad Function

(1)Num Lock

To check if numpad is activated.

(2)Caps Lock

To set an uppercase input mode. The keypad remains in caps lock mode until the key is pressed again.

(3)Frequently used shortcuts:

F1: System help shortcut

F2: Sending test shortcut

F3: Sampling pause shortcut

F5: Emergence stop shortcut

F6: On-line/off-line shortcut

F7: Exiting system shortcut

F8: Alarm information shortcut.

3.1.3 Software Functional Keys List

Table 3-1-1

Sample Registration	To edit info. on samples, patients, and test items, and edit sample summary sheets and manual LIS application.	
Test Result	Result Query	Modify result, add item, reaction curve, send data to LIS, audit, print
	History Query	Query history data and compare history result
	Result Statistic	Repetitiveness statistic, positive result statistic, item statistic, workload statistic
	Check Item	Check condition setting, lot registration
Reagent Information	Reagent Registration	Set or print reagent information, scan reagent remaining volume, and scan reagent barcodes
	Browse Reagent	Monitor and print reagent information status
Calibration Information	Calibration Registration	Register calibration types and items, and delete the setting of calibration information, and calibrator concentrations and positons
	Calibration Result	Calibration curve, calibration tracing, reaction process, calibration data
	ISE calibration	Set calibration parameters, check ISE calibration results, and print ISE calibration results
QC Management	QC Registration	Edit QC rules, register QC items, set QC positions and set QC dilution
	Daily QC	Reaction curve, QC chart, QC deleting, and monthly QC accumulation
	Monthly QC	QC icon, QC result printing, QC deleting, and result editing
System Setting	Item Maintenance	Register, add, modify, delete, print item information
	Item Parameter	Analysis parameter, calibration parameter, range parameter
	Serum Information	Serum information setting
	Item Combination	Edit item combination
	Calculation and Compensation	Calculation item and compensation item setting
	Cross-contamination	Set avoid cross-contamination of reagent probe, reaction cuvette, sample probe
	Report Format	Report information and print format setting
	Other Information	Sample test mode, setting of clot detection, ISE setting, setting of reagent alarm, setting of timing wakeup, setting of sample rinsing alarm, linearity check, setting of user-defined reagent bottle type, and setting of automatic sleep
	LIS Communication	LIS communication setting
	Reagent Recharge	Reagent recharge setting
System Management	Data Dictionary	User information, hospital information, other information setting
	System Log	Check login log, operation log, maintenance log, and alarm log
System Maintain	Analyzer Reset	Probes return to original position
	Cuvette Blank and Light Quantity	Maintain and test cuvette blank, light quantity check
	Exhaust	Syringe pump exhaust
	Rinse	Rinse water tank, incubation bath, reaction cuvette, sample probe, automatic concentrated waste liquid rinsing.
	Unit Check	Sample probe, reagent probe, mixing unit, mechanical action
	Barcode	Barcode check
	Sleep	Sleep status setting
System Monitor	Sample Disk	Sample disk status
	Reagent Disk	Reagent disk status
	Reaction Disk	Reaction disk status
	LIS Status	LIS communication status
	Test Sample	Sample test list
	Analyzer Status	All units status

3.2 Software Operation

Click to select functional keys with a mouse. Input number and character with a keypad (Switch character input mode by shift + control in Windows system.)

3.2.1 Move Mouse Cursor

Mouse cursor moves as long as the user clicks to change input area or item.

3.2.2 Select a Key

Click to select a needed key.

3.2.3 Open a Window

Click window key to open one. Windows consist of modal and non-modal ones.

Modal window: No other operation can be conducted until modal window is closed. Click “Close” key to close it. Figure 3-2-1 shows the “Patient Info.” window in Sample Registration.

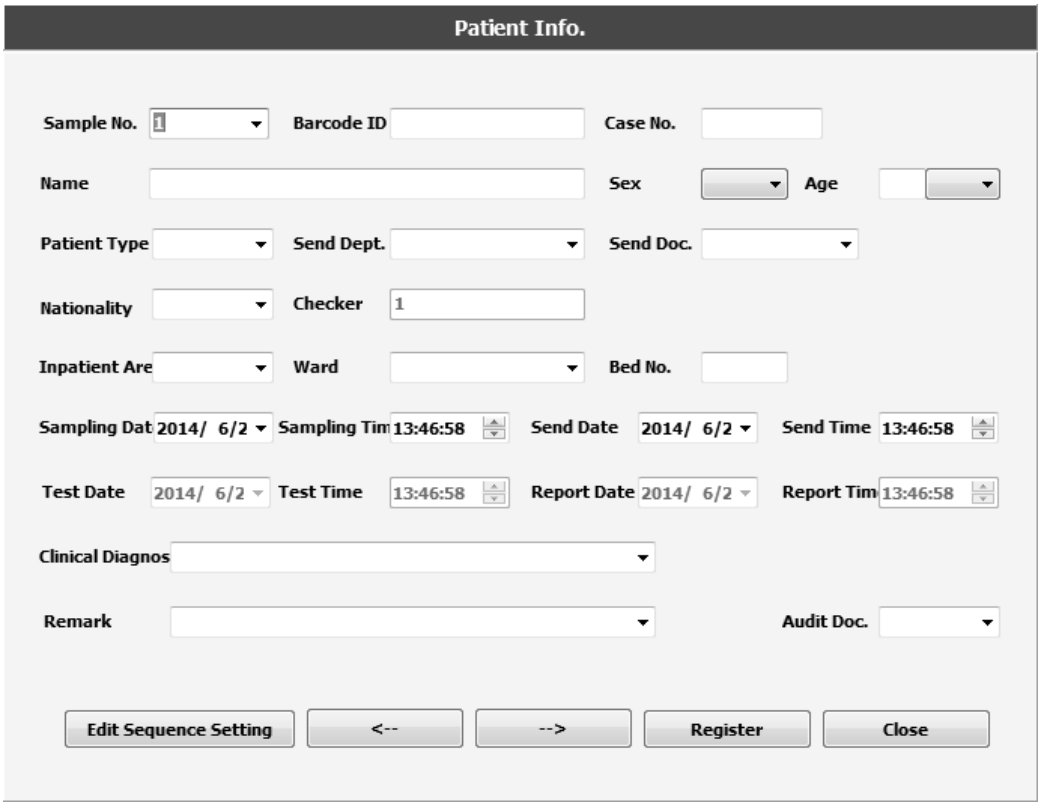


Figure 3-2-1

Non-modal window: Other operation can be conducted when non-modal window is open. Figure 3-2-2 shows “Analysis Parameter” window in Item Parameter.

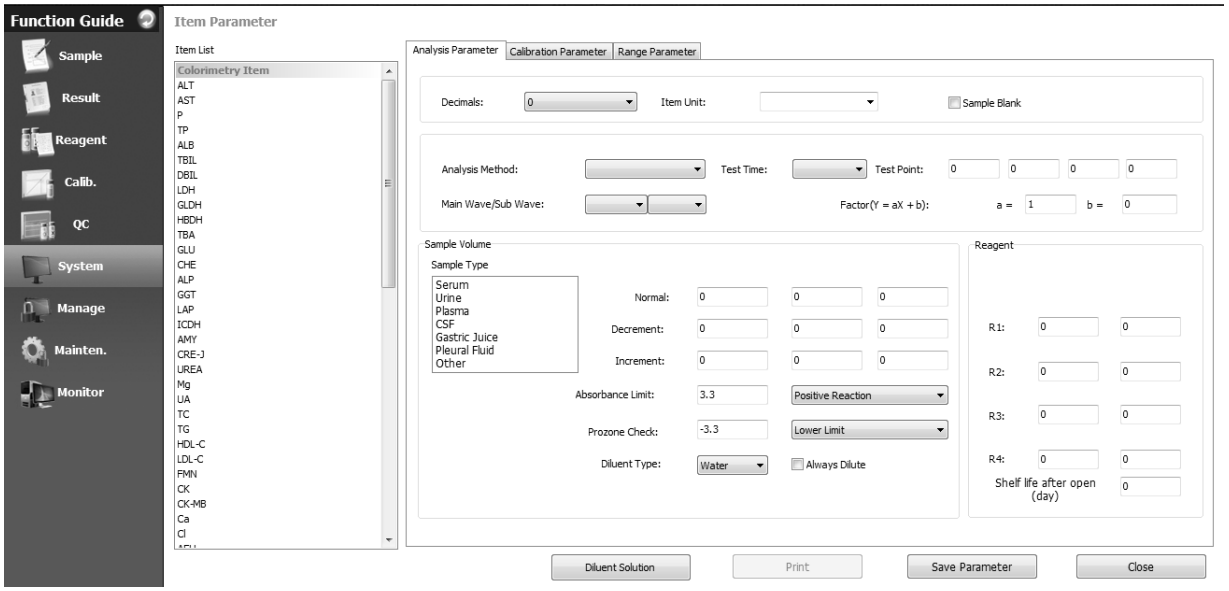


Figure 3-2-2

3.2.4 Operate List Box and Scroll Bar

(1)List box

List box is used for displaying information. Users can select intended information in list box, as Figure 3-2-3 shows:

Item Maintain

Total number of item:70

Item No.	Item Abb.	Item Type	Item Full Name	Print Sequence	Barcode No.
1	ALT	Colorimetry Item		1	01
2	AST	Colorimetry Item		2	02
3	P	Colorimetry Item		27	27
4	TP	Colorimetry Item		3	30
5	ALB	Colorimetry Item		4	31
6	TBIL	Colorimetry Item		5	03
7	DBIL	Colorimetry Item		6	04
8	LDH	Colorimetry Item		15	22
9	GLDH	Colorimetry Item		7	09
10	HBDH	Colorimetry Item		16	23
11	TBA	Colorimetry Item		8	05
12	GLU	Colorimetry Item		19	20
13	CHE	Colorimetry Item		9	06
14	ALP	Colorimetry Item		10	07
15	GGT	Colorimetry Item		11	08
16	LAP	Colorimetry Item		12	10
17	ICDH	Colorimetry Item		13	11
18	AMY	Colorimetry Item		14	12
19	CRE	Colorimetry Item		25	32
20	BUN	Colorimetry Item		24	13

Figure 3-2-3

(2)Scroll bar

Scroll bar is used for adjusting display range in list box. Scroll bar is often composed of vertical scroll bar(on the right edge of list box) and horizontal scroll bar(on the lower edge of list box), as Figure 3-2-3 shows:

Click "▼" to check displayed content in list box, or press "▤" and move.

3.2.5 Pull-down List Box

Click "▼" on the right edge of pull-down list box to open or close it. More information can be displayed in pull-down list box. The selected item will show on the top column, meanwhile box will disappear.

3.2.6 Radio Box and Check Box

Radio box: The user can only select one function in multiple functions. For example in Figure 3-2-4, "Sample Volume" options in "Sample Registration" window consist of "Normal", "Decrement" and "Increment". The three options can not be selected simultaneously:

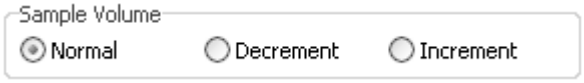


Figure 3-2-4

Check box: More than two functions can be selected simultaneously. For example in “Item List” interface in Figure 3-2-5, several options can be selected at the same time:

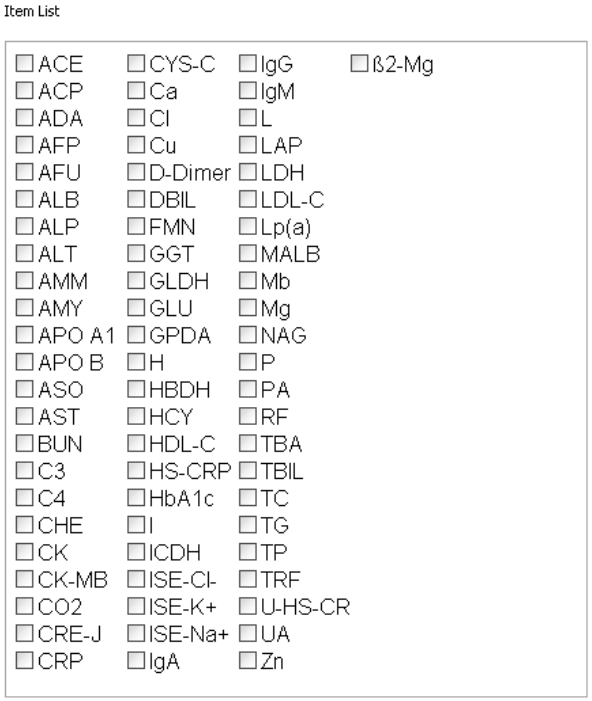


Figure 3-2-5

3.2.7 Width Adjustment of Grid Table

Generally, the width of tables in a software can be changed. The width will be back to the original state if you access this interface again after width changing.

Chapter 4 System Management

4.1 System Management

The user with administrator permission can add, delete or modify the user information.

Click the "

" key under Function Guide, as the following figure shows:

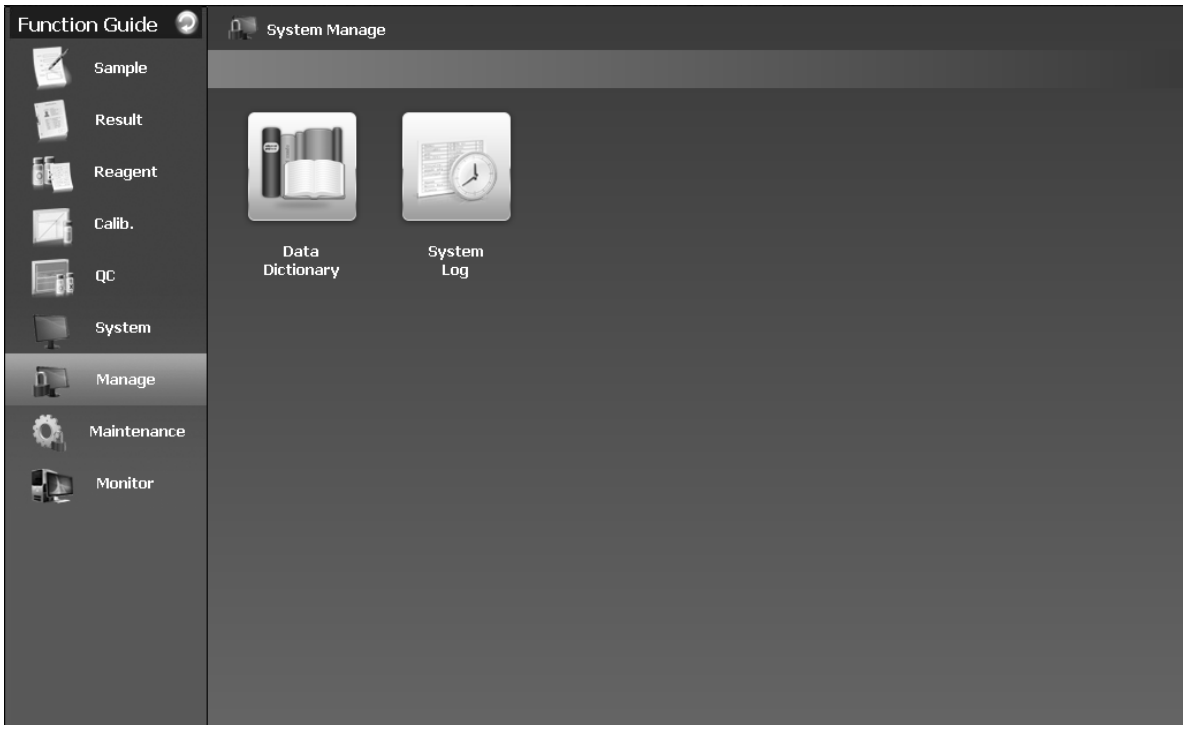
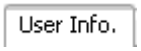


Figure 4-1

4.1.1 User Information

Click "

" in "System Management", 

will be displayed. As the following figure shows:

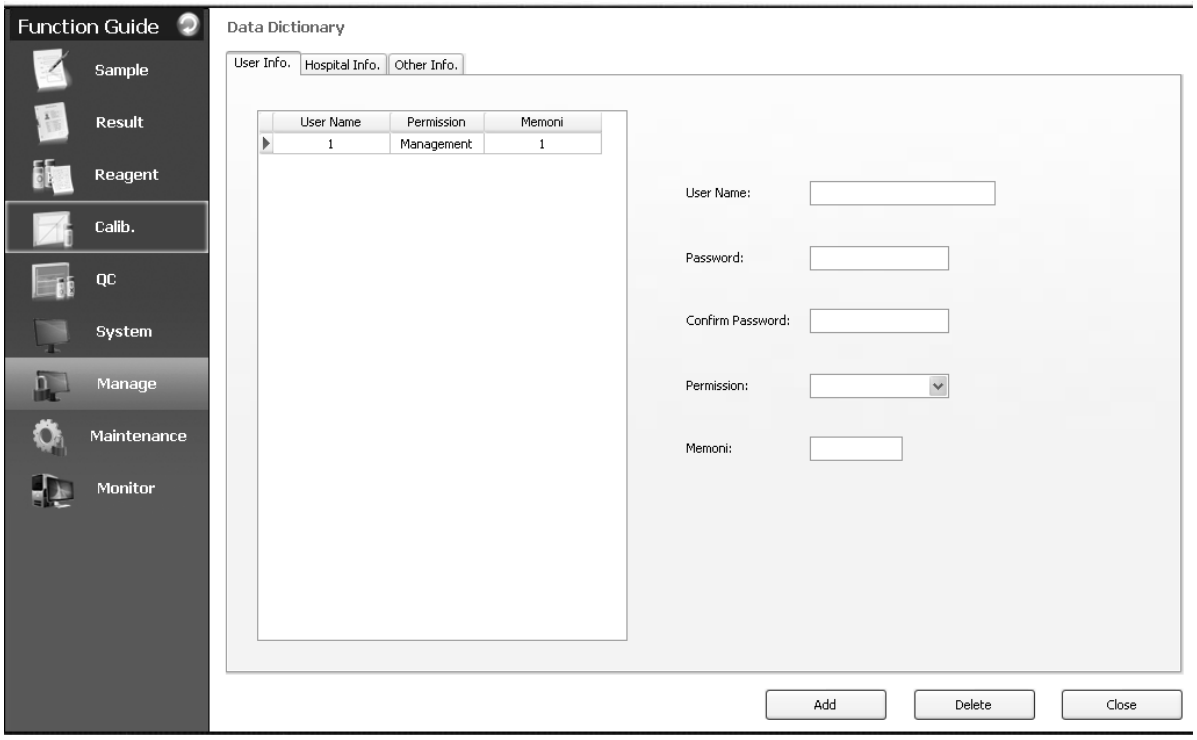


Figure 4-1-1

(1)Username: Enter a username in the input box.

(2)Password: Enter a password in the input box.

(3)Confirm Password: Enter the password again.

(4)Permission: Select the corresponding permission from the drop-down menu of permission in Figure 4-1-1.

a)Query: Select "Query", the user can query some function window instead of conducting setting, test and connection.

b)Operator: Select "Operation", the user can set, check all functions excluding user information, system setting. The user can also register, modify and delete the sample records tested by himself.

c)Administrator: Select "Management", the user can set, delete, check and test all functions.

(5)Mnemonic: The function of mnemonic is to help the user inputting information in a convenient and time-saving way, e.g. The mnemonic of username can be set as JXL or number, such as 001. Mnemonic can be input in login area.

Click Add after information input. The user information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete user information if needed. Click Close to exit "User Info." window.

4.1.2 Hospital Info.

Click the "Hospital Info." to set the send dept. send doctor, inpatient area, ward, as Figure 4-1-2 shows :

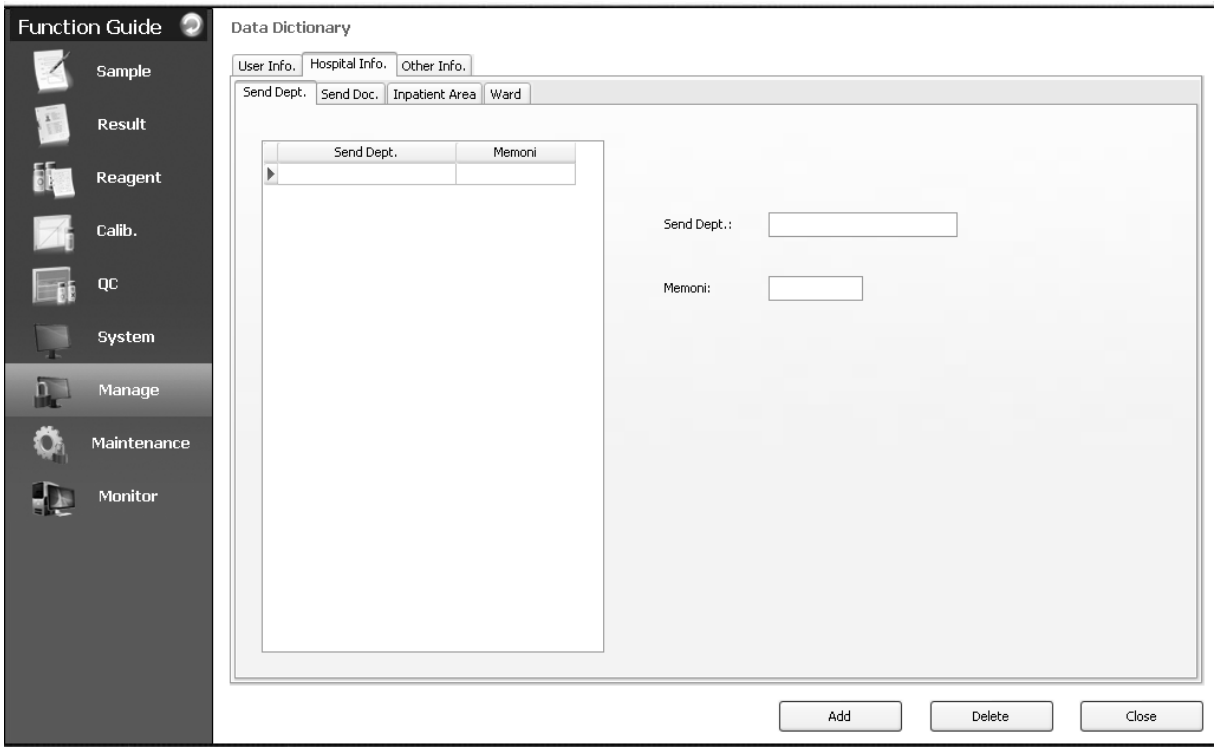


Figure 4-1-2

Click "Close" key to exit the current window.

These items will be displayed automatically after setup in "Patient Info." from corresponding pull-down block.

4.1.2.1 Send Dept

Click the "Send Dept." to set department name and mnemonic.

(1)Send Dept.: Input the dept name in the input box. The information will be displayed in the drop-down list of "Patient Information" window.

(2)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of send department can be set as WGK, or number, e.g.001.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.2.2 Send Doc.

Click "Send Doc." to set "Send Dept.", "Doctor Name", "Mnemonic" etc. information. As Figure 4-1-3 shows:

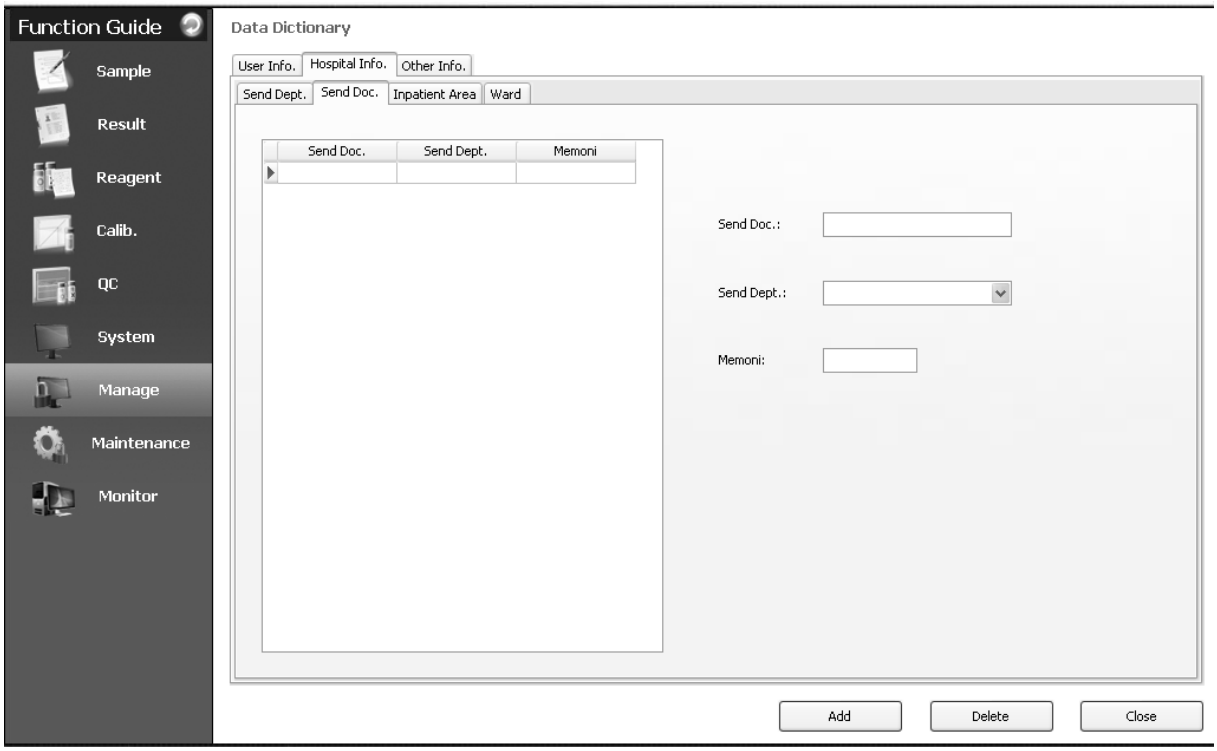


Figure 4-1-3

(1)Send Doc.: Input the doctor name in the input box. The information will be displayed in the drop-down list of "Patient Info." window.

(2)Send Dept.: Select the department from the pull-down menu.

(3)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of send doctor can be set as YS, or number, 001. In information input area, YS or 001 can be used instead of doctor name. Press enter key to input the doctor number automatically.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.2.3 Inpatient Area

Click Inpatient Area to add or delete inpatient area, as Figure 4-1-4 shows:

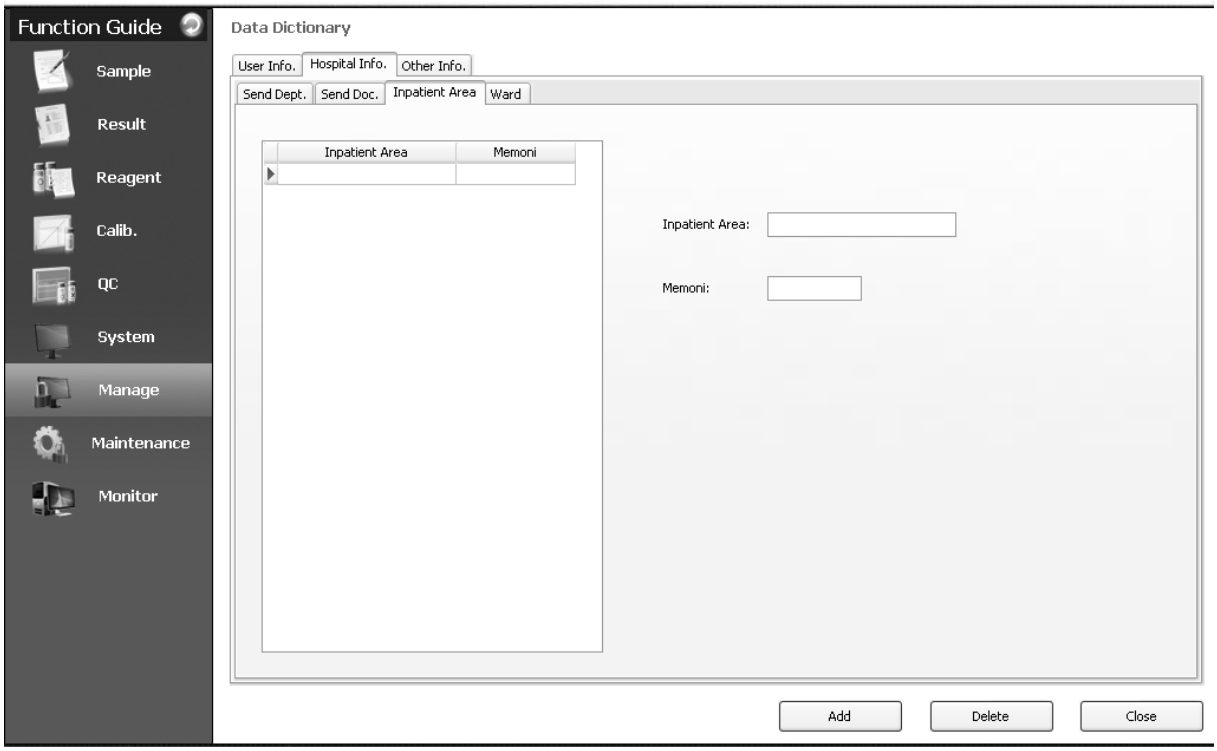


Figure 4-1-4

(1)Inpatient Area: Input the inpatient area name in the input box. The information will be displayed in the drop-down list of "Patient Information" window.

(2)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of inpatient area can be set as XZB, or number 001. In information input area, XZB or 001 can be used instead of inpatient area. Press enter key to input the number automatically.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.2.4 Ward

Click Ward to add and delete the ward, as Figure 4-1-5 shows:

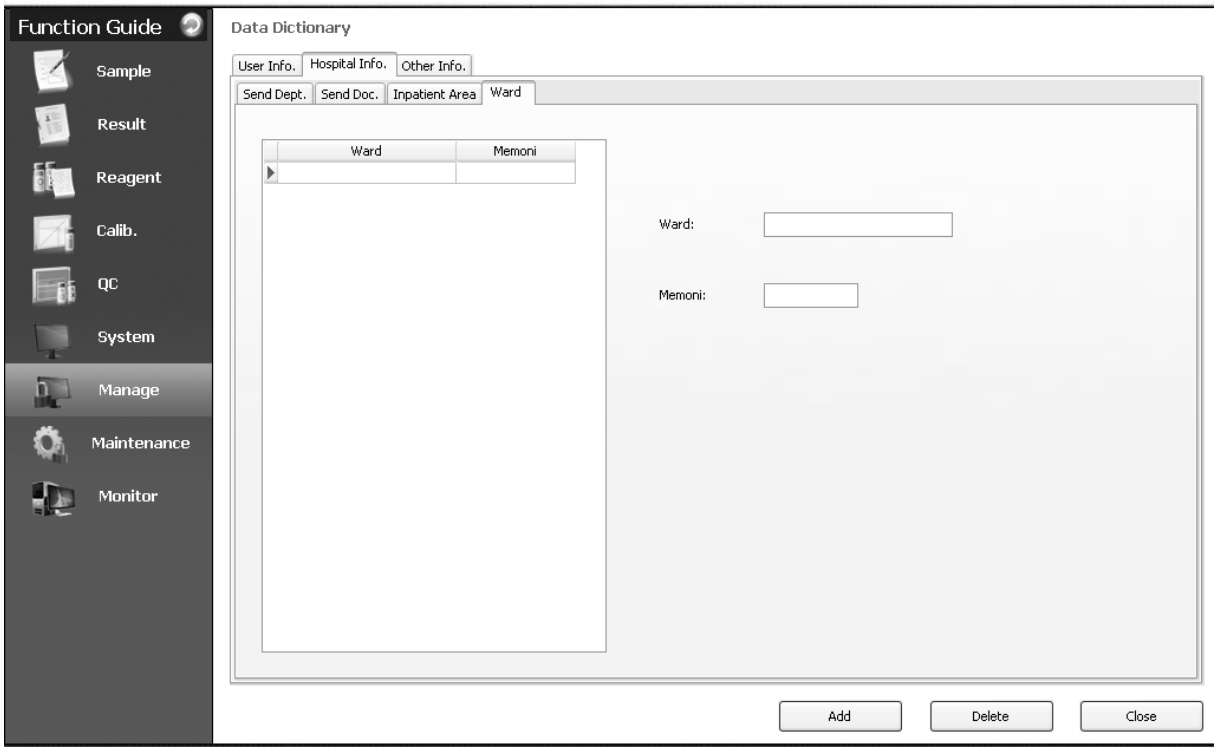


Figure 4-1-5

(1)Ward: Input the ward name in the input box. The information will be displayed in the drop-down list of "Patient Info." window.

(2)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of ward can be set as BF, or number 001. In information input area, BF or 001 can be used instead of ward. Press enter key to input the number automatically.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.3 Other Information

4.1.3.1 Patient Type

Click "Patient Type" key in other information to set patient type, mnemonics, etc. as the Figure 4-1-6 shows:

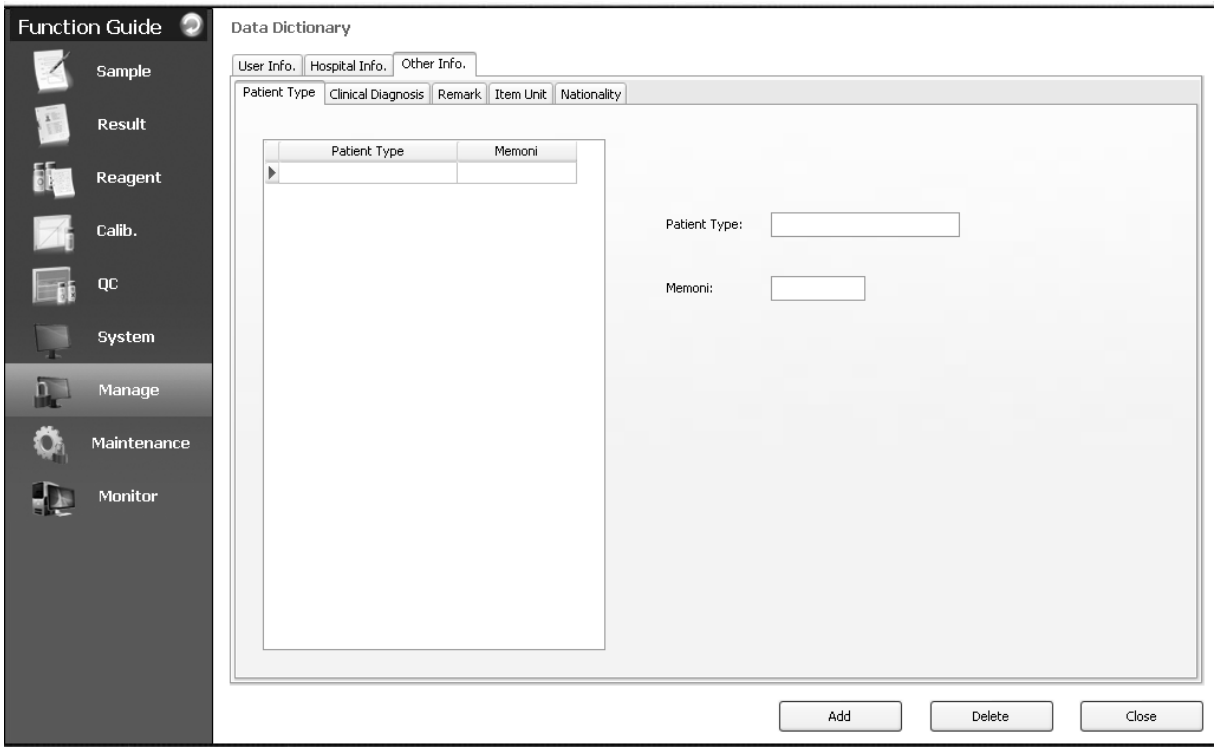


Figure 4-1-6

(1)Patient Type: Input the patient type in the input box. The information will be displayed in the drop-down list of "Patient Information" window.

(2)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of patient type can be set as GF, or number 001. In information input area, GF or 001 can be used instead of patient type. Press enter key to input the number automatically.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.3.2 Clinical Diagnosis

Click "Clinical Diagnosis" key to set the clinic diagnosis, and mnemonics. As Figure 4-1-7 shows:

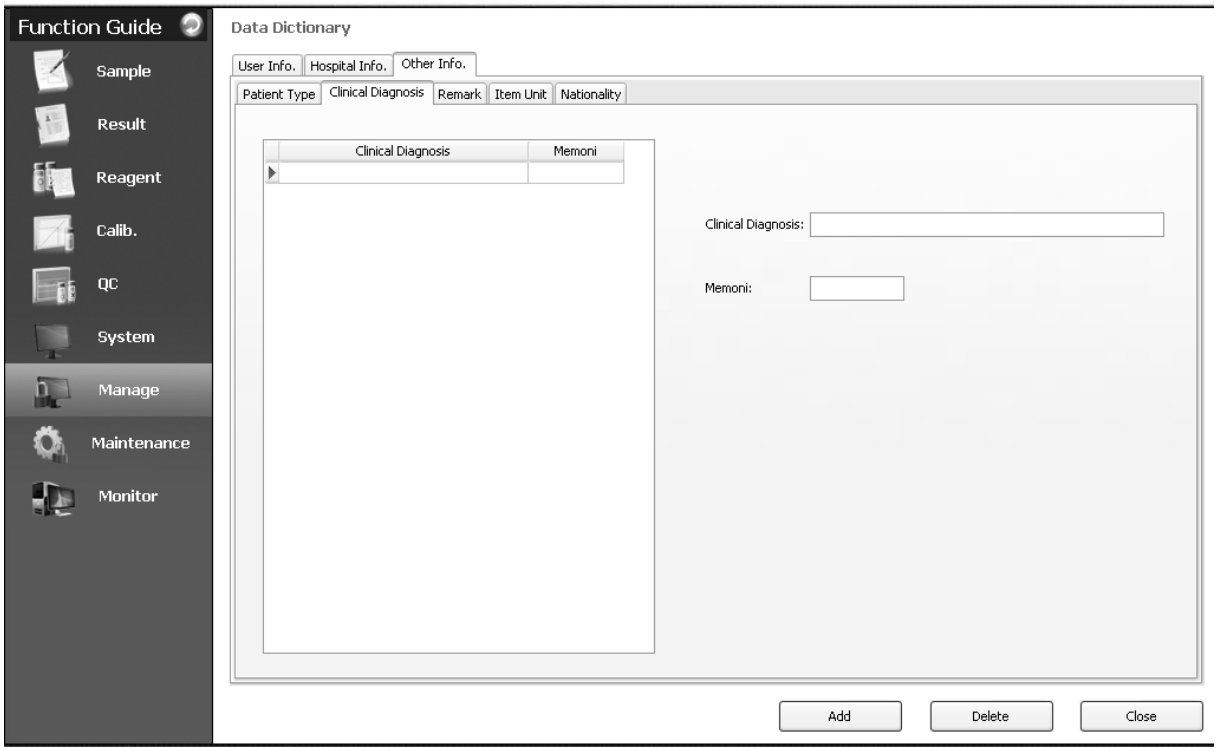


Figure 4-1-7

(1)Clinical Diagnosis: Input the clinical diagnosis in the input box. The information will be displayed in the drop-down list of "Patient Info." window.

(2)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of clinical diagnosis can be set as GM, or number 001. In information input area, GM or 001 can be used instead of clinical diagnosis. Press enter key to input the number automatically.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.3.3 Remark

Click "Remark" key in working area to set the report remark, mnemonic, as the Figure 4-1-8 shows:

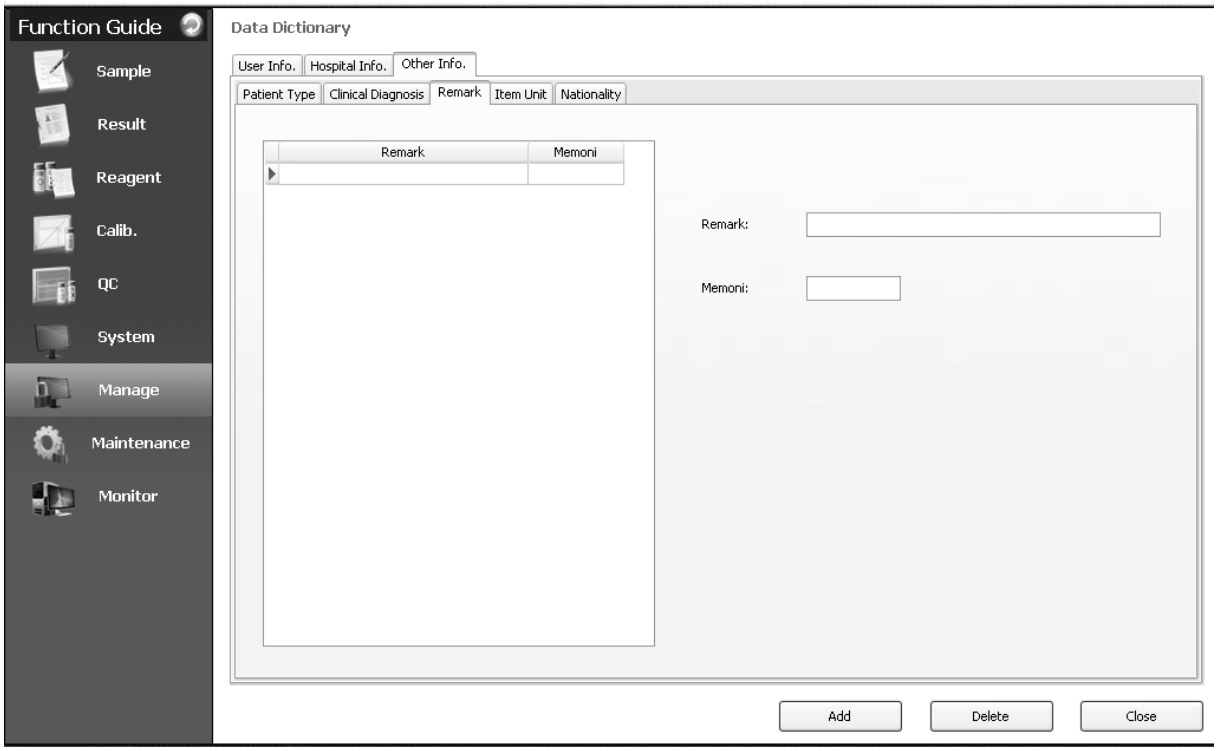


Figure 4-1-8

(1)Remark: Input the remark in the input box. The information will be displayed in the drop-down list of "Patient Information" window.

(2)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of remark can be set as XXX, or number 001. In information input area, XXX or 001 can be used instead of remark information. Press enter key to input the number automatically.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.3.4 Item Unit

Click "Item Unit "key to set the item unit, as Figure 4-1-9 shows:

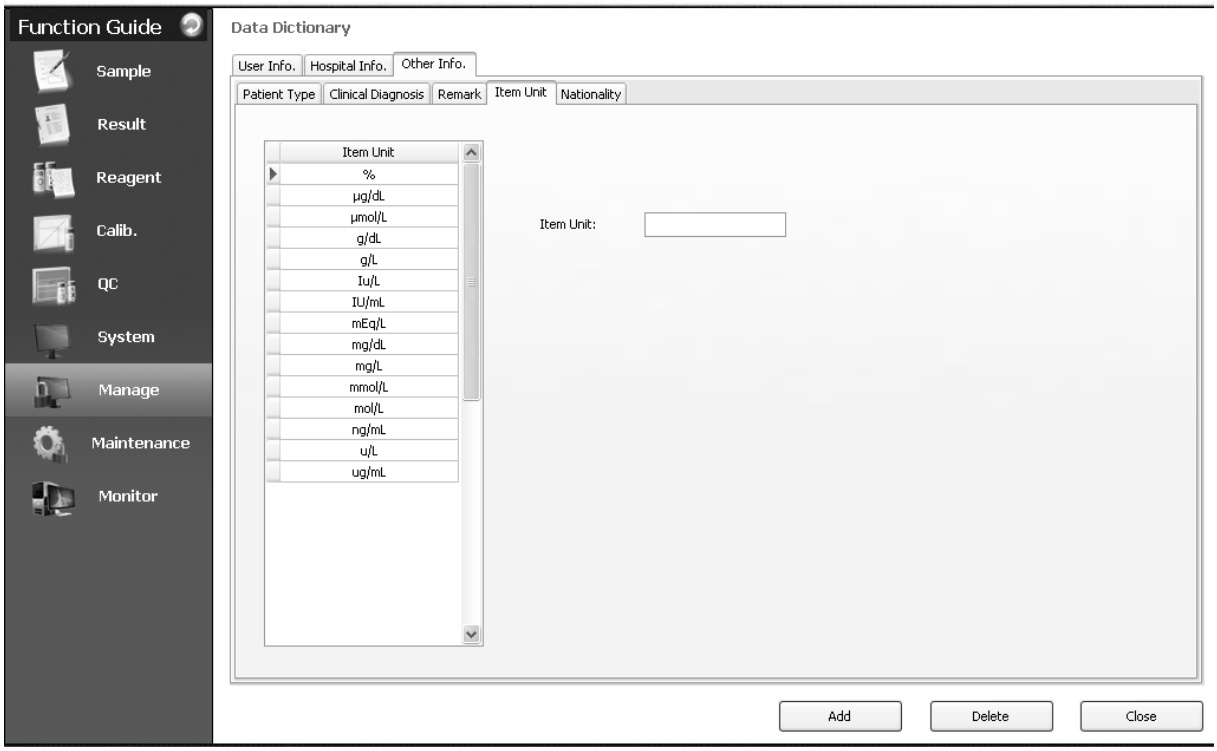


Figure 4-1-9

Item Unit: Input the character of item unit in the input box. The information will be displayed in the corresponding drop-down list.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.1.3.5 Nationality

Click "Nationality "key to set the nationality, mnemonic, as Figure 4-1-10 shows:

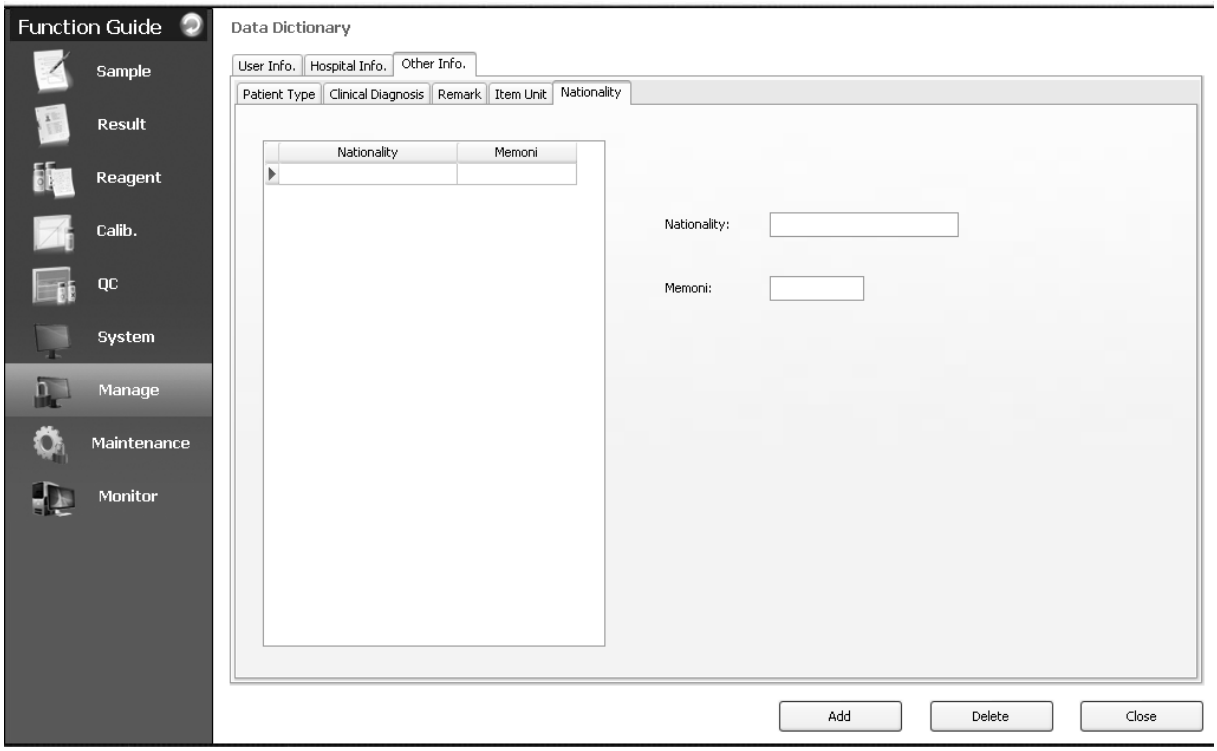


Figure 4-1-10

(1)Nationality: Input the nationality in the input box. The information will be displayed in the drop-down list of "Sample Registration" window.

(2)Mnemonic: Help the user to input the information quickly. For example: the mnemonic of nationality can be set as HZ, or number 001. In information input area, HZ or 001 can be used instead of nationality information. Press enter key to input the number automatically.

Click Add after information input. The information setting is completed and edited information will be displayed in work area. Select the information and click Delete to delete if needed. Click Close to exit.

4.2 System Log

Click "

" in "System Management". As Figure 4-2-1 shows:

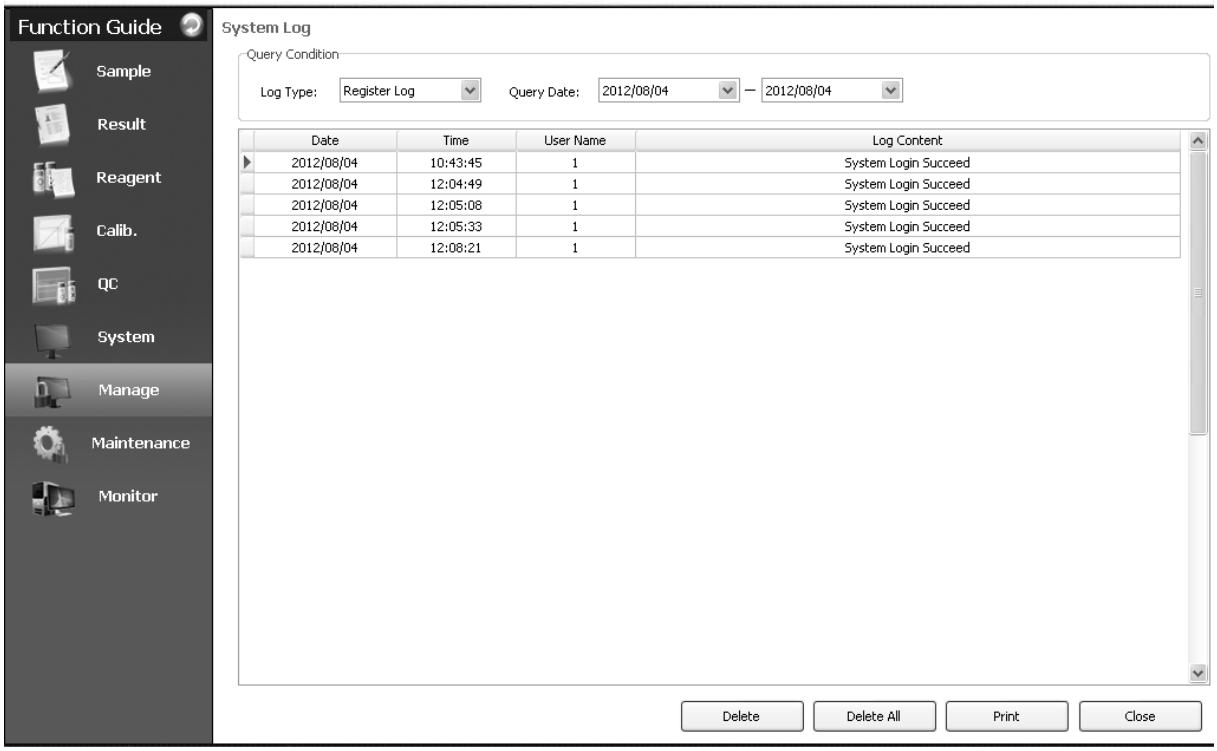


Figure 4-2-1

System log including login log, operation log, maintenance log and alarm log.

Select one log type from the "Log Type" pull-down menu, and select the start date and end date from the "Query Date" pull-down menu. All the relevant log information will be listed.

Click Delete All to delete all logs displayed in log list.

Click Delete after selecting one log to delete it.

Click Print to print current log list.

Click Close to exit current window.

Chapter 5 System Setting

Click 

to enter into system setup window. “System Setting” window includes: Item Maintenance, Item Parameter, Serum Info., Item Collection, Calculation & Compensation, Cross-Contamination, Report Format, Other Info., LIS Communication. As shown in Figure 5-1:

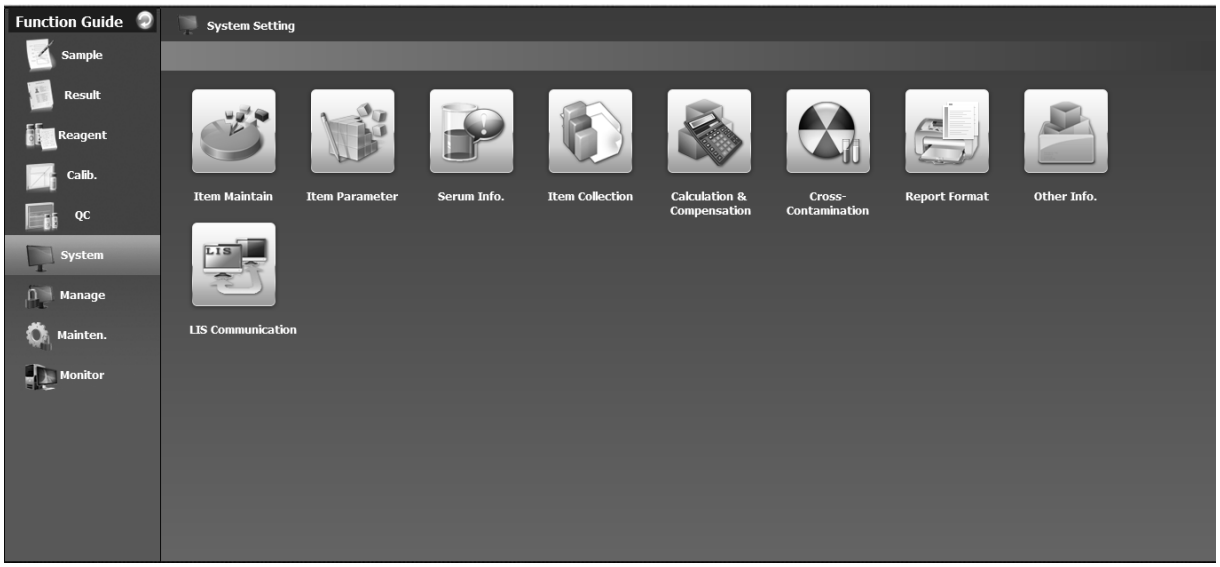


Figure 5-1

5.1 Item Maintenance

Click 

to enter the “Item Maintenance” window, as shown in Figure 5-1-1:

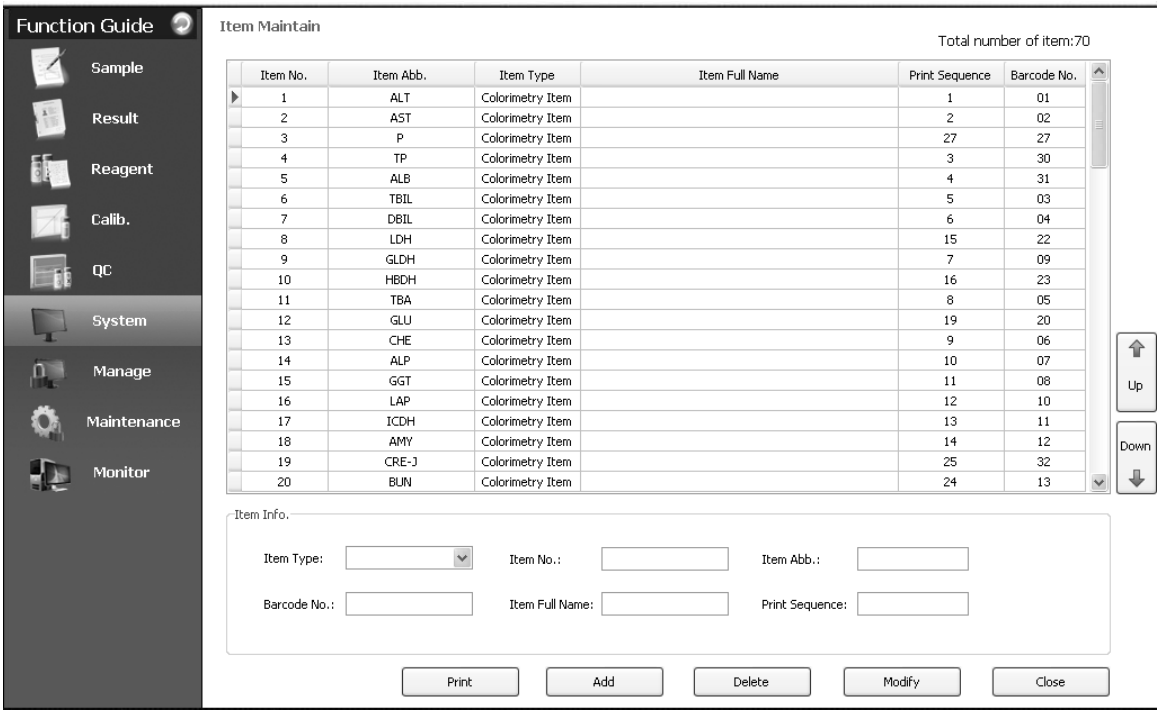


Figure 5-1-1

For new item addition, the information can be set in “Item Info.” work area:

Print: For all item maintenance information printing.

Add: New item information is added into worklist after clicking.

Delete: Select one item and click Delete to delete the item.

Modify: Select one item to modify it. The modified information will be displayed in item list.

Close: Click it to exit.

5.1.1 Add Colorimetry Item

(1)Item Type: Select “Colorimetry Item” from the pull-down menu, as Figure 5-1-2 shows:

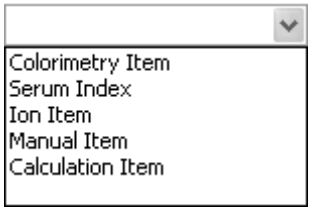


Figure 5-1-2

(2)Item No.: Input new item No. in the input box, such as 25. The item number can not be blank and can not duplicate with the existed number.

(3)Item Abb.: Input new item Abb. in the input box, e.g. ALT. Colorimetric item abb. can not be blank and can not duplicate with the existed information.

(4)Barcode No.: It is the item No. used for identifying item name in automatic barcode scanning. 01~99 represents different item name. Colorimetric item barcode No. can be blank but can not duplicate with the existed information.

(5)Item Full Name: Input the full name in the input box, e.g. The full name of ALT is alanine aminotransferase. Colorimetric item full name can be blank and can duplicate with the existed information.

(6)Print Sequence: Item sequence in report. The sequence is default to same as item No. which can not be blank but can duplicate with existed information.

5.1.2 Modify Serum Index

(1)Item Type: Select “Serum Index” from the pull-down menu.

(2)Item No.: The item No. of serum index is fixed which can not be modified.

(3)Item Abb.: The item abb. of serum index is fixed which can not be modified.

(4)Barcode No.: The barcode No. of serum index is fixed which can not be modified.

(5)Item Full Name: Input the full name in the input box. The full name of serum index can be blank and can duplicate with existed information.

(6)Print Sequence: Item sequence in report. The sequence is default to same as item No. which can not be blank but can duplicate with existed information.

5.1.3 Modify Ion Item

(1)Item Type: Select “Ion Item” from the pull-down menu.

(2)Item No.: The item No. of ion item is fixed which can not be modified.

(3)Item Abb.: The item abb. of ion item is fixed which can not be modified.

(4)Barcode No.: The barcode No. of ion item is fixed which can not be modified.

(5)Item Full Name: Input the full name in the input box. The full name of ion item can be blank and can duplicate with existed information.

(6)Print Sequence: Item sequence in report. The sequence is default to same as item No. which can not be blank but can duplicate with existed information.

5.1.4 Modify Manual Item

(1)Item Type: Select “Manual Item” from the pull-down menu.

(2)Item No.: Input new item No. in the input box, such as 25. The item number can not be blank and can not duplicate with the existed number.

(3)Item Abb.: Input new item Abb. in the input box. The item abb. can not be blank and can not duplicate with the existed number.

(4)Barcode No.: Barcode No. of manual item is not available.

(5)Item Full Name: Input the full name in the input box. Manual item full name can be blank and can duplicate with the existed information.

(6)Print Sequence: Item sequence in report. The sequence is default to same as item No. which can not be blank but can duplicate with existed information.

5.2 Item Parameter

Click 

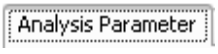
in “System Setting” to enter into parameter setting window. The analysis parameter, calibration parameter and range parameter can be set in this window.

The parameters must be saved after each page editing.

5.2.1 Colorimetry Item Analysis Parameter

Wavelength, reagent volume, sample volume, analysis method, photometry point, decimal places, item unit, etc. can be set in “Analysis Parameter” interface.

5.2.1.1 Set Analysis Parameter

Click 

to set the analysis parameters of colorimetric items. Click “Save Parameter” after setting. As shown in Figure 5-2-1:

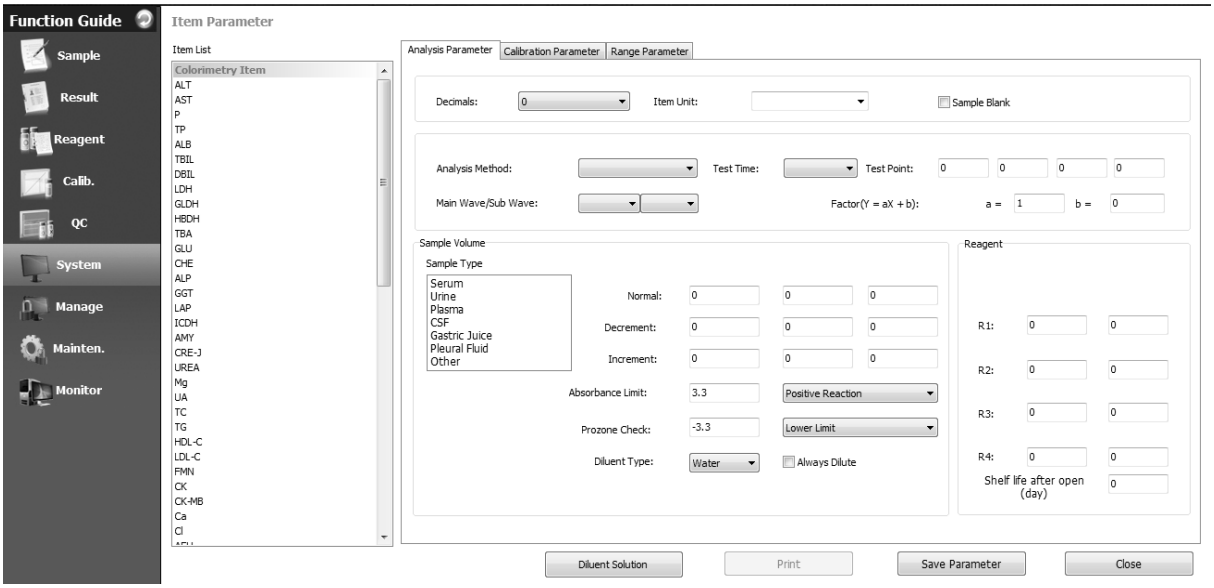


Figure 5-2-1

Select the intended item name needs parameters setting on the left for item setting.

(1)Decimals: The user can select the decimal places of test result and print out result as set.

(2)Item unit: Choose the chemistry item unit from the pull-down menu, for the add and delete of item unit, please refer to chapter “4.1.3.4 ”.

(3)Sample Blank: Sample blank test will be conducted only when this “Sample Blank” is selected and “Sample Blank” is selected in corresponding item registration of “Sample Registration”.

(4)Analysis Method: Select one method from the pull-down menu which is conform to reagent requirement, 1 point assay, 2 point assay, rate A assay and 2-point rate assay. For detailed introduction, please refer to 5.2.1.3.

(5)Test Time: Test time can be selected from the “test result” pull-down menu.

(6)Test Point: Analyzer will record one time absorbency every 18 seconds. Please input proper photometry point according to reagent instruction. Effective photometry point should be inputted within 2 to 74 (0 represents no input). Tested absorbency value of each test light point can be searched from reaction curve.

(7)Main Wave /Sub Wave: There are 12 optional wavelengths in pull-down menu, select them according to reagent instruction: 340nm,380nm,405nm,450nm,480nm,505nm,546nm,570 nm,600nm,660nm,700nm and 800nm. If double wavelength test is used, then the difference of the absorbance value between main wavelength and sub wavelength is used for calculating result. When select single wavelength test, select “0” for sub wavelength.

(8)Factor (Y=a X + b): Carry out relation calibration. The test result will be higher or lower than expected result or result from other analyzer. In order to make result in accordance with expected result or result from other analyzer, add the calibration relation in result calculation. Relation equation:

$$Y = aX + b$$

Y : Result after calibration

X : Real result from analyzer

a : Slope value (multiplication calibration factor)

b : Intercept value (compensation calibration factor)

When test result of the analyzer is the same as expected value, or when results of any two analyzer are accordant, let a=1, b=o.

When results from two analyzers are different, analyzer can get an accordant result by calibration of slope value and intercept value. Slope value is a positive number, which is less than 8 digits. Intercept value is a real number, which is less than 8 digit.

(9)Sample Volume

a)Sample Type: Select the sample type.

b)Sample Volume: Sample volume includes normal volume, increased value and decreased value, as Figure 5-2-2 shows:

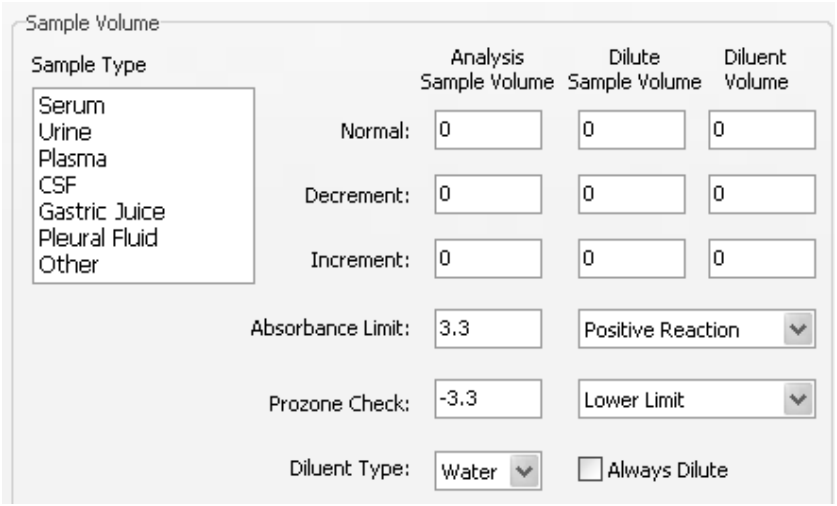


Figure 5-2-2

Normal

In normal volume setting, the user can specify sample normal volume. This work area are divided into three functional key field: Analysis Sample Volume, Dilution Sample Volume, and Diluent Volume.

[Normal/Analysis Sample Volume] : The sample volume, 1.5μL~35μL, aspirated from sample container

(standard cuvette or tube). The total volume of sample and reagent should be greater than or equals to 120μL, smaller than or equals to 450μL.

[Normal/Dilute Sample Volume] : If dilution is required, the parameter is used to set up diluted sample volume which is aspirated from the sample container and infuse to reaction cuvette that is used for analyze sample. The input value is within 1.5μL~35μL. Input 0, if the sample does not need diluting.

[Normal/Diluent Volume]: If dilution is required, the parameter is used for set up diluent volume for dilute sample. The input value is within 15μL~350μL. Input 0, if the sample does not need diluting.

Decrement (sample volume decreases)

Decrement setting is used for specify sample volume when sample concentration exceed the upper limit of reagent linearity range. (lower than normal volume). This area is divided into 3 functional key field: sample volume, diluted sample volume, diluent volume. After test, analyzer will automatically change decreased test result into normal volume and display on result information.

[Decrement/Analysis Sample Volume]: Select a sample volume 1.5μL~35μL, which is aspirated from sample container (standard cuvette or tube). Regardless of sample whether to be diluted, the total volume of sample and reagent should be greater than or equals to 120μL, smaller than or equals to 450μL.

[Decrement/Dilution Sample Volume] : If dilution is required, the parameter is used for set up diluted sample volume which is aspirated from dilute cup and infuse to reaction cuvette that is used for analyze reagent. The input value is within 1.5μL~35μL, Input 0, if the sample does not need diluting.

[Decrement/Diluent Volume] : If dilution is required, the parameter is used for set up diluent volume for dilute sample. The input value is within 15μL~350μL. Input 0, if the sample does not need diluting.

Increment (Sample Volume Increases)

Increment setting is used to specify sample volume when sample concentration exceed the lower limit of reagent linearity range. (more than normal volume). This area is divided into 3 functional key field: sample volume, diluted sample volume, diluent volume.

[Increment/Analysis Sample Volume] : Select the sample volume, 1.5μL~35μL, which is aspirated from sample container (standard cuvette or tube). Regardless of sample whether to be diluted , the total volume of sample and reagent should be greater than or equals to 120μL, smaller than or equals to 450μL.

[Increment/Dilute Sample Volume] : If dilution is required, the parameter is used for set up diluted sample volume which aspirated from dilute cup and infuse to reaction cuvette that is used for analyze. The input value is within 1.5μL~35μL. Input 0, if the sample does not need diluting.

[Increment/Diluent Volume] : If dilution is required, the parameter is used to set up diluent volume for dilute sample. The input value is 15μL~350μL. Input 0, if the sample does not need diluting.

Note:

The injection range of sample probe is 1.5μL~35μL. The injection range of reagent probe is 15μL~350μL. When the sample volume is 35μL, the injection diluent volume of reagent probe is 70μL, the minimum dilution ratio is 1:2, the total volume of sample and diluent is 105μL. When the sample volume is 1.5μL, the injection diluent volume of reagent probe is 350μL, the maximum dilution ratio is 1: 233.3.

The equal of sample volume for dilution and dilution volume must be larger than the sample volume for test. The total volume of sample volume and diluent used for dilution must not be smaller than 60μL.

(10)Absorbance Limit: Input the range of absorbance check, select positive reaction or negative reaction.

For analysis items of rate A assay and 2-point rate assay, correct data can not be obtained when concentration exceeds set range. Therefore, the upper limit and lower limit of absorbency should be set. And corresponding alarm will be prompted. Input check value in “Absorbency Limit” window. Input 0 (Negative Reaction)or 3.3(Positive Reaction) when check is not conducted.

When 4 or more than 4 tested absorbency is not in accordance with the set value, alarm will be prompted. As Figure 5-2-3 shows:

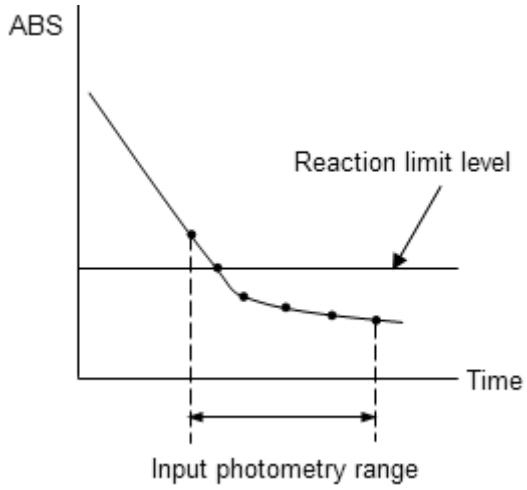


Figure 5-2-3

(11)Prozone Check: Set the prozone check range in input box, and select upper limit, lower limit.

In immunoreaction, working curve descends if antigen concentration is abnormally high beyond the suitable range. This is called zone phenomenon. This analyzer can check whether concentration is in the absorbance decreasing range.

For prozone checks, the following 2 methods are available: antigen re-addition method and reaction rate method. Refer to Figure 5-2-4 and 5-2-5.

a)Antigen adding method

Applicable to one-point method. Start analysis from reagent n-1. Add a small amount of samples with antigen (about 50μL), like serum diluent, to reagent n. Compare the absorbance difference (PC value) between the values after the reagent n-1 adding and reagent. Then compare the difference with the input value (LIMIT). n: 2~4.

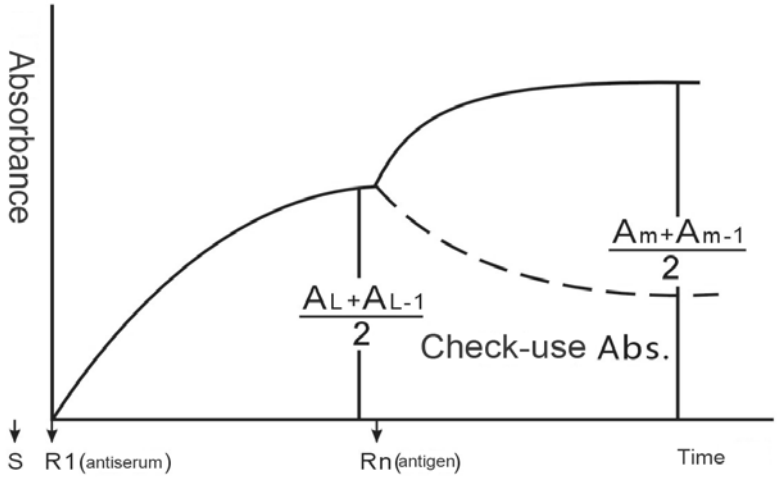


Figure 5-2-4 Prozone check(antigen re-addition method)

In the figure: A_L: absorbance at photometric point L.

➢In the analysis parameter interface, enter the check limit, upper limit or lower limit: if the prozone check value is higher than the upper limit or lower than the lower limit. Data alarms will occur.

➢Prozone check method

Compare prozone check value (PC) with limit value:

$$PC = \frac{A_m + A_{m-1}}{2} - k \times \frac{A_L + A_{L-1}}{2}$$

In which: m, L mean photometric points; k is the volume calibration coefficient. But, when 1≤L, m≤5 or 6≤L, m≤16 or 17≤L, m≤33, 34≤L, k=1.

b)Reaction rate method

Applicable to the two-point method. Compare the ratio (PC) of the reaction rate after adding reagent n to the overall reaction rate from reagent n addition to the absorbance photometric point with the input value (LIMIT). n: 2~4.

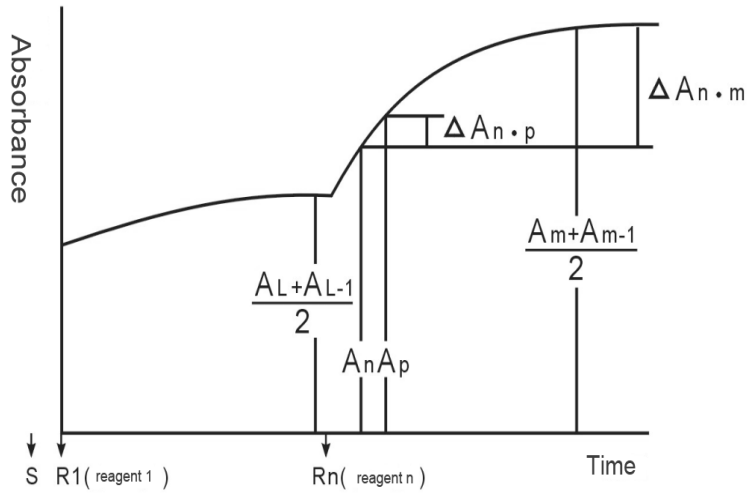


Figure 5-2-5 Prozone Check (Reaction rate method)

In the figure: $\Delta A_{n\cdot p}$ and $\Delta A_{n\cdot m}$ mean respective mean reaction ratio of photometric point n to p, and n to m.

- In the analysis parameter interface, enter the prozone check limit, upper limit or lower limit
- Prozone check method

Compare prozone check value (PC) with limit value:

$$PC = \frac{\frac{A'_m - A_n}{m' - n}}{\frac{A_p - A_n}{p - n}} \times 100$$

- Note: prozone checks will not be carried out for calibration tests.

When not carrying out prozone checks, enter "-3.3 lower limit" in the check value column.

(12)Diluent Type: The diluent used for sample dilution. Select the diluent type from the pull-down menu of water(pure water dispensed by probe), diluent. Diluent is the type selected by the user, such as physiological saline, buffer, etc. which is placed in R1 disk. Its position should be set in reagent information. R1 probe aspirates diluen automatically during sample dilution, multipoint linear calibration and non-linear calibration..

(13)Always Dilute: ☑ Always Dilute (always dilute is selected) indicates this item of all samples will be diluted.

(14)Reagent: Reagent includes R1, R2, R3 and R4, as Figure 5-2-6 shows:

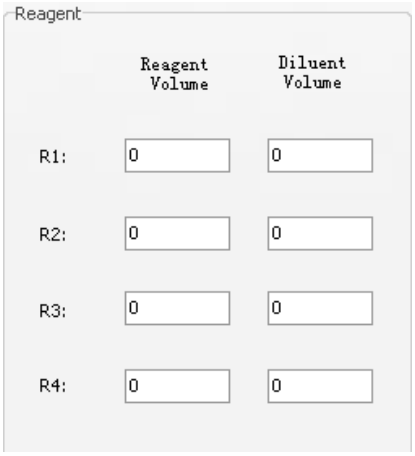


Figure 5-2-6

a)Reagent Volume: The unit is μL. R1, R2 probe can aspirate 15μL~350μL, with increment of 1μL. "0"indicates no reagent will be dispensed.

b)Diluent Volume: If concentrated reagent is used, input the diluent volume used for diluting in "Diluent Volume". Diluent volume should not be larger than 250μL, the total volume of reagent and diluent should not be larger than 350μL.

(15)Shelf life after open(/day): Enter a shelf life after open in the box. The unit: day. The input range is 0~999. After the setting, the expiry date is calculated from the current day, and displayed in the "Expiration Date" column in "Reagent Register" window under "Reagent Info." window. If reagent passed the expiry date, an alarm will be given after login.

(16)Diluent Solution

Click the button "Diluent Solution" which is in the bottom of "Analyzer Parameters" interface, as shown in the 5-2-6(a):

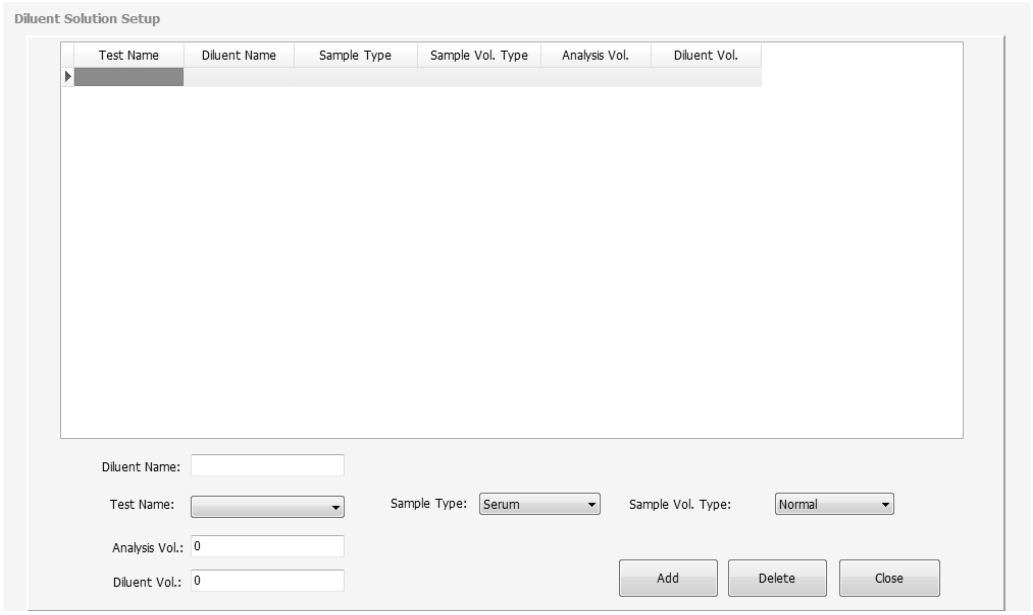


Figure 5-2-6(a)

Input the diluent name in the "Diluent Name" text entry box, select the items to be diluted in the "Test Name" drop list, and input the sample needed in the diluent progress in the "SampleVol. Type", the volume range is 1.5μL~35μL; input the diluent sample volume in the "Diluent VoL." drop list, the volume range is 15μL~350μL; select the sample type in the "Sample Vol." drop list; the "Normal", "Increment" or "Decrement" in the "Sample Vol. Type" drop list. The user can add or remove the diluent ratio according to the diluent requirement.

Each individual test can set seveal diluent names. After select the "Dilution" and "Test Name" in the sample signing interface, the diluent name which is already has been setup will popup automaticly.

5.2.1.2 Test Principle

The test principle of Analyzer is based on the Beer-Lambert law that the material selective light absorption.

The main principle is: When monochromatic light with specific wavelength passes through the cuvette with sample, the monochromatic light absorbency and sample liquid concentration are varies directly as the distance which is passed through sample liquid by light:

$$A = \lg\left(\frac{1}{T}\right) = \lg\left(\frac{I_o}{I_t}\right) = \varepsilon bc$$

A — Absorbency of the light when passing through liquid

T — Transmitted intensity and incident intensity ratio: transmittance I_t/I_o

I_o — Incident intensity

I_t — Transmitted intensity

ε — Molar absorption coefficient of solution($mL\times mmol^{-1}\times cm^{-1}$)

c — Mol concentration of the solution(mmol/mL)

b — Solution layer thickness(cm)

Solution layer thickness (b): Optical path, which is fixed by analyzer. Molar absorption coefficient (ε) is the correlation coefficient of the wavelength, solution and solution temperature. Linear relationship is displayed between solution thickness and absorbency when in stable temperature and single wavelength (ε value is given on the reagent bottle by factory).

If the sample liquid adequate distribution, interaction between liquid and incidence monochromatic light only happens during absorbing process. No fluorescence, disperse and photochemical appear. No interaction between substances in the solution while absorbing process. The absorbency possess conducts nature, and this condition conforms to the Beer-Lambert law.

5.2.1.3 Assay Mode Variety

As to how to set the assay parameter, please refer to User Manual. Assay mode is showed as the following table (Reaction time is 10 minutes):

Method	Analysis Item	Photometry Point	Cuvette Blank	Formula	Note
1-point Assay	ALB	L–0–0–0 1＜L≤74	$\frac{B_1+B_2+B_3}{3}$	$\frac{A_L+A_{L-1}}{2}$	
2-point Assay	GLU	L–M–0–0 1＜L＜M≤74	$\frac{B_1+B_2+B_3}{3}$	$\frac{(A_M+A_{M-1})-k(A_L+A_{L-1})}{2}$	
2-point Rate Assay	BUN	L–M–0–0 1＜L＜M≤74	$\frac{B_1+B_2+B_3}{3}$	$\frac{\frac{A_M+A_{M-1}}{2}-\frac{A_L+A_{L-1}}{2}}{t}$	t: time (minute) between photometry point L,m
Rate A Assay	ALT	L–M–0-0 1＜L＜M≤74 L+2＜M	$\frac{B_1+B_2+B_3}{3}$	$\triangle A_{(M-L)}$	

Explanation of symbols:

L, M, N, P, Q, r : Photometric points

Rn : Volume of nth reagent ,n=1 to 4

SB : Cuvette blank tested while still

B_1, B_2, B_3 : Cuvette blanks test while mobile

$(B_1+B_2+B_3)/3$: Mean value of 3 times cuvette blank tested while mobile

Ax : Absorbance at photometric point x

$\Delta A_{(M-L)}$: Change in absorbance per minute between photometric points L and M

k : Liquid volume correction factor

$$k=\frac{S+\sum_{j=1}^{a}R_j}{S+\sum_{i=1}^{b}R_i}$$

S : Sample volume

R_j ,R_i : Reagent volume; a means reagent number not corrected; b means reagent number corrected.



● Liquid in the reaction cuvette should be more than or equals to 120μL, less than or equals to 450μL.

● Do input 0 if the photometric point is not used.

(1)1-point Assay

Endpoint assay in which absorbance is measured at a designated photometric point (specific time point when reaction reach balance) after addition of reagents. Figure 5-2-7 explains the 1-point assay.

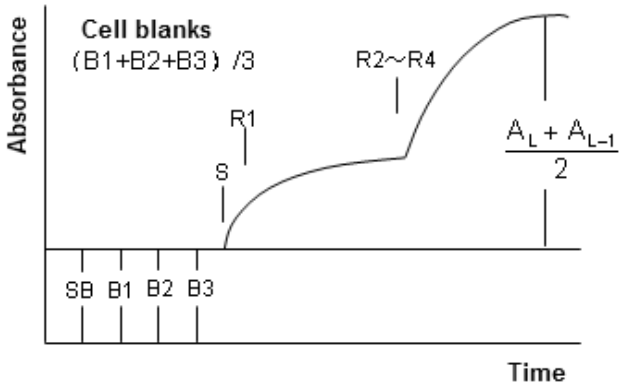


Figure 5-2-7 1-point Assay

a)Photometric point : 【L】- 【0】- 【0】- 【0】 ($1< L \leq 74$)

b)Calculation of absorbance:The average of absorbance at measurement points Land L-1 is used.

$$A_x = \frac{A_L + A_{L-1}}{2}$$

c)Calculation of concentration

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

SB: Cuvette blank tested while still

B_1~B_3: Cuvette blank tested while mobile

R1~R4: Reagent adding position

Cx: Concentration of standby sample

C_1: Concentration of calibrator 1(reagent blank)

K: Factor

B: Absorbance of blank

IFA and IFB: Analyzer constants, representing slope and intercept

d)Analytical items: TP, ALB, etc.

(2)2-point Assay

Endpoint assay in which measurement is made twice at different points to obtain the difference in absorbance. One point is measured as the action initial, the other point is measured when the action reach endpoint or balance. The difference between the absorbance of two photometric points is used for calculation sample concentration. Figure 5-2-8 explains the 2-point assay:

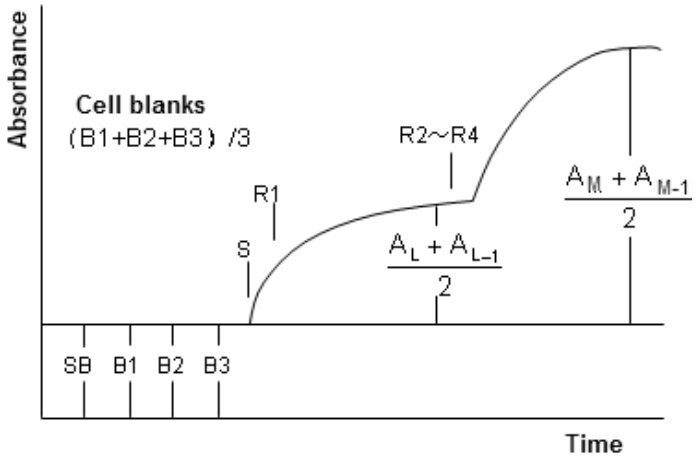


Figure 5-2-8 2-point Assay

a)Photometric point : 【L】- 【M】- 【0】- 【0】 ($1 < L < M \leq 74$)

b)Calculation of absorbance

The difference between the average of absorbance at measurement point M and M-1 and that at measurement point L and L-1 is used.

$$A_X = \frac{(A_M + A_{M-1}) - k(A_L + A_{L-1})}{2}$$

$$k = \frac{S + \sum_{j=1}^{a} R_j}{S + \sum_{i=1}^{b} R_i}$$

a: No. of reagents at Al measurement

b: No. of reagents at Am measurement

c)Calculation of concentration

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

SB: Cuvette blank tested while still

B_1~B_3: Cuvette blank tested while mobile

R1~R4: Reagent adding position

Ax: The deference between the photometric point M and L

Cx: Concentration of standby sample

C_1: Concentration of calibrator 1(reagent blank)

K: Factor

B: Absorbance of blank

IFA and IFB: Analyzer constants, representing slope and intercept

d)Analytical items: CRE, etc.

(3)2-point Rate Assay

Measurement is made twice at different measurement points (The two point are neither measured initial nor endpoint) to determine the change in absorbance per minute in order to calculate sample concentration. For check of reaction limit level, refer to Figure 5-2-9:

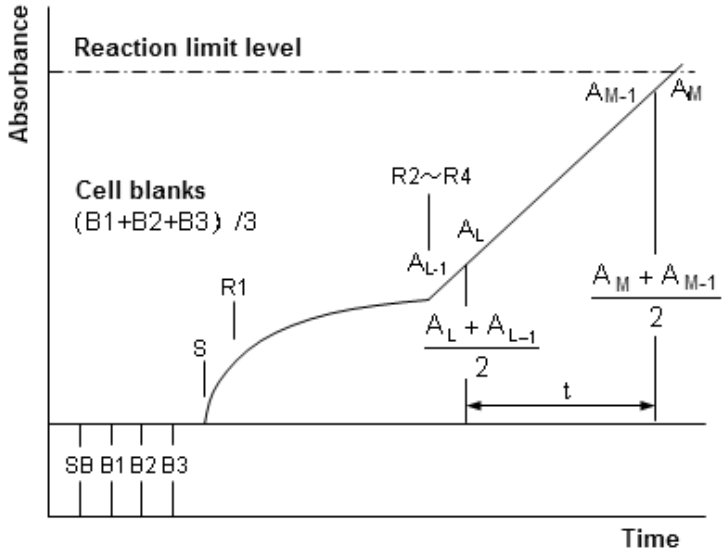


Figure 5-2-9 2-point Rate Assay

a)Photometric point : 【L】-【M】-【0】-【0】 (1< L <M≤ 74)

b)Calculation of absorbance

The difference between the average of absorbance at measurement points M and M-1 and that at measurement points L and L-1, then divide the result by time.

$$A_X = \frac{\frac{(A_M + A_{M-1})}{2} - \frac{(A_L + A_{L-1})}{2}}{t}$$

t: Time (minute) between test points L and M

c)Calculation of concentration

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

SB: Cuvette blank tested while still.

B_1~B_3: Cuvette blank tested while mobile.

R1~R4: Reagent adding position

Ax: Average change in absorbance per minute between measurement points L and M

Cx: Concentration of standby sample

C_1: Concentration of calibrator 1(reagent blank)

K: Factor

B: Absorbance of blank

IFA and IFB: Analyzer constants, representing slope and intercept.

d)Analytical items: BUN, CRE etc.

(4)Rate A Assay

The concentration or activity level is obtained from the change rate in absorbance between the specified measurement points. Figure 5-2-10 explains the Rate A Assay.

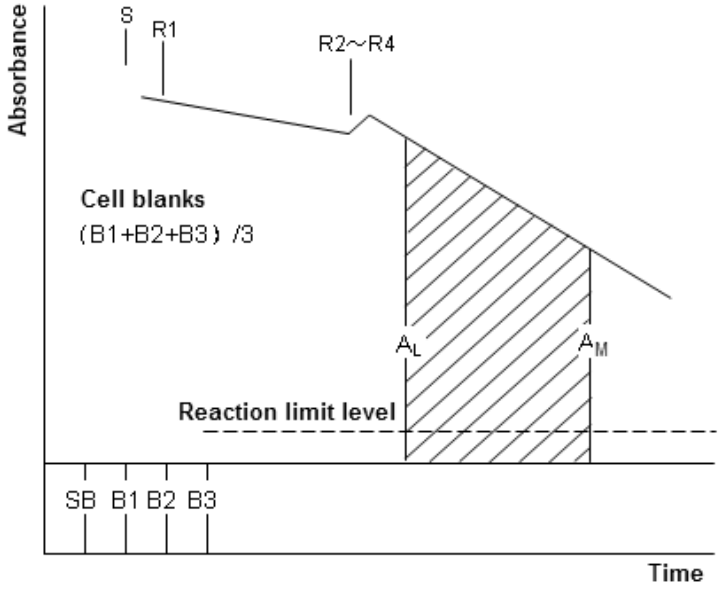


Figure 5-2-10 Rate A Assay

a)Photometric point : 【L】-【M】-【0】-【0】 (1<L <M≤ 74, L+2<m)

b)Calculation of absorbance

The change rate in absorbance per minute between measurement point L and M is obtained by the least squares method.

$$A_X = \Delta A_{(M-L)}$$

c)Calculation of concentration

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

SB: Cuvette blank tested while still.

B1~B3: Cuvette blank tested while mobile.

R1~R4: Reagent adding position

$\triangle A_{(M-L)}$: Change in absorbance per minute between measurement point L and M

Cx: Concentration of standby sample

C1: Concentration of calibrator 1(reagent blank)

K: Factor

B: Absorbance of blank

IFA and IFB: Analyzer constants, representing slope and intercept.

d)Analytical items: AST, ALT, etc.

5.2.2 Calibration Parameter

5.2.2.1 Calibration Parameter Setup

Click "Calibration Parameter", as shown in Figure 5-2-11:

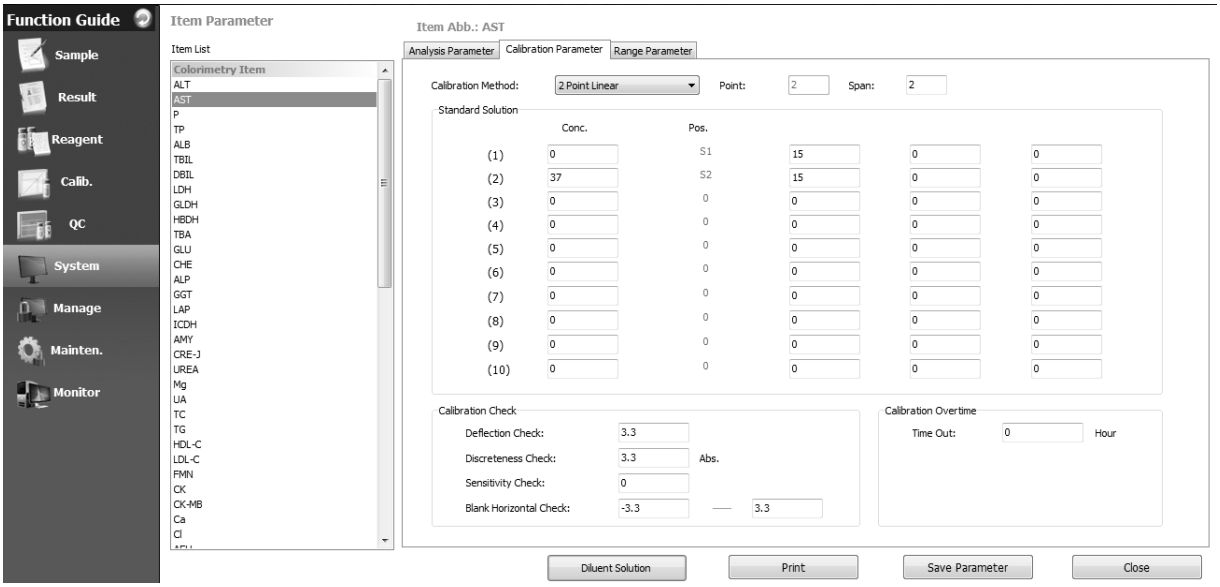


Figure 5-2-11

Parameters related to calibration can be set in "Calibration Parameter" window.

(1)Item List: Select an item name from the left(color will change after selection).

(2)Calibration Method: Select the calibration method in its drop down list according to reagent instruction. Calibration method includes: 1-point linearity , 2-point linearity, multi-point linearity, Logit-Log3P, Logit-Log4P, Logit-Log5P, exponential function method, spline function method, polygon method.

(3)Point: Input the quantity of Calibrator in functional field. (among 1~10).

(4)Span: Input the relevant span point in functional field. (among 2~10, 0 indicates invalid range calibration).

(5)Standard Solution: Input the calibrator concentration, sample volume used for analysis, sample volume used for dilute, diluent in calibrator setting.

(6)Calibration Check: If sensitivity, drift rate, discrete, etc. check need to be conducted during calibration, input check value. The newly added items are default as not conducting above check.

(7)Calibration Overtime: Input the overtime whose The unit is hour. If calibration time comes when stand-by, alarm will be prompted. Click "0" in time position to avoid automatic calibration.

After checking the parameters, click "Save".

5.2.2.2 Calibration Method

(1)1-point linearity (K factor)

The absorbance and input K value of blank (or calibrator 1) is measured to prepare a working curve. Figure 5-2-12 explains the linear method.

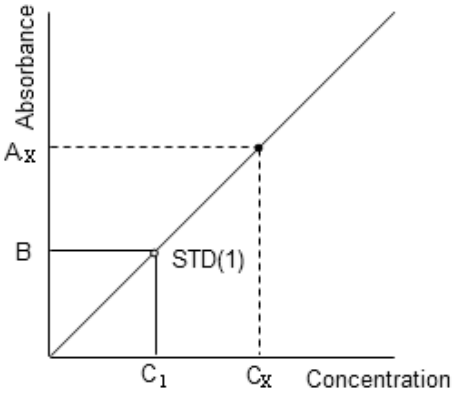


Figure 5-2-12

a)Calibration Parameter input

Calibration type:【1-point linear】

Calibration point:【1】 (number of calibrator)

Span point:【0】

b)Confirm K factor

Input K factor in "Calibration Result " window

c)Calculation of parameters for working curve

S1ABS (B): Change in absorbance per minute of blank (calibrator 1)

K: Input value.

C_1: Concentration of calibrator 1(reagent blank), input value.

d)Calculation of concentration

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

Cx: Concentration of standby sample.

Ax: Absorbance or change of absorbance per minute.

IFA and IFB: Analyzer constants, representing slope and intercept.

e)Applicable assay

1-point assay, 2-point rate assay, 2-point assay, rate A assay.

(2)2-point linearity

Blank (or calibrator 1) and calibrator 2 are measured to prepare a linear working curve Figure 5-2-13 explains the linear method.

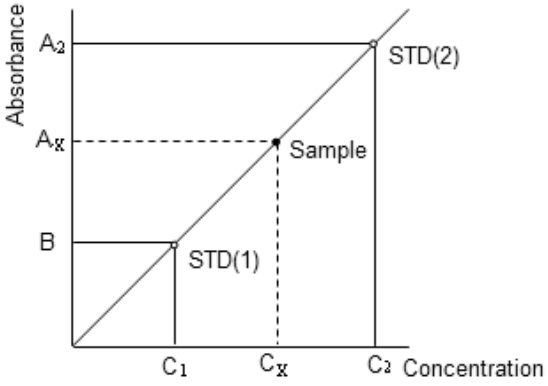


Figure 5-2-13

a)Calibration Parameter input

Calibration type:【2-point linearity】

Calibration point:【2】 (number of calibrator)

Span point:【2-10】

b)Calculation of parameters for working curve

S1ABS (B): Absorbance or change in absorbance per minute of blank (calibrator 1)

K: Calculated from measured values and input values of blank (calibrator 1) and calibrator 2.

C_1: Concentration of calibrator 1(reagent blank)

C_2: Concentration of calibrator 2

A_2: Absorbance or change in absorbance per minute of calibrator 2.

$$K = \frac{C_2 - C_1}{A_2 - B}$$

c)Calculation of concentration

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

Cx: Concentration of standby sample

Ax: Absorbance or change in absorbance per minute

IFA and IFB: Analyzer constants, representing slope and intercept.

d)Applicable assay

1-point assay, 2-point rate assay, 2-point assay, rate A assay.

(3)Multi-point linearity

Blank (or calibrator 1) and calibrator(calibrator 2 and calibrator 10) are tested and preparing linear working curve. Figure 5-2-14 explains the linear method.

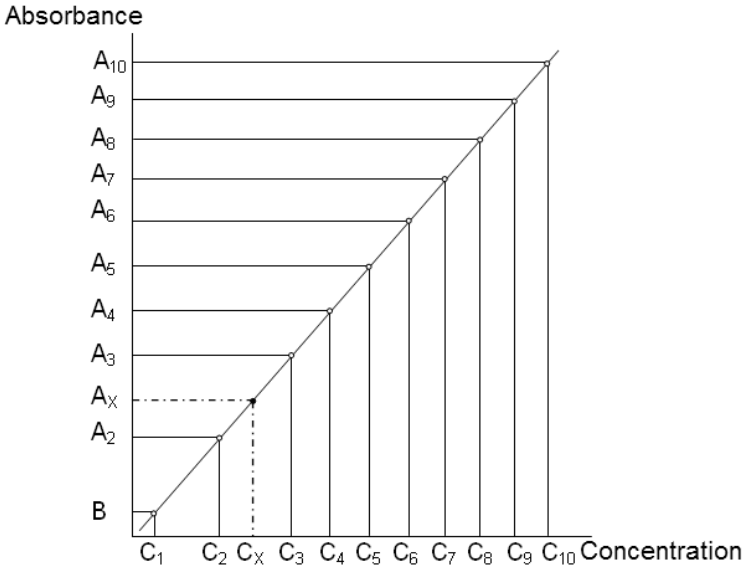


Figure 5-2-14

a)Calibration Parameter input

Calibration type:【multi-point linearity】

Calibration point:【3-10】(number of calibrator)

Span point:【2-10】

b)Calculation of parameters for working curve

S1ABS (B):Linear primary regression intercept for absorbance or change in absorbance per minute of blank (calibrator)

K: Inverse number of working curve slope in the result of linear primary regression.

B(S1ABS) and K values can be calculated by the formulas below:

$$B(\text{SlABS}) = \bar{A} - \frac{X \times \bar{C}_r}{Y}$$

$$K = \frac{Y}{X}$$

$$X : \sum_{i=1}^{n} (C_{ri} - \bar{C}_r) \times (A_i - \bar{A})$$

$$Y : \sum_{i=1}^{n} (C_{ri} - \bar{C}_r)^2$$

$$\bar{A} : \frac{\sum_{i=1}^{n} A_i}{n}$$

$$\bar{C}_r : \frac{\sum_{i=1}^{n} C_{ri}}{n}$$

A_1, A_2: Test value of calibrator

n: No. of calibrators (N) ×2

Cri: Concentration of calibrator (i)

c)Calculation of concentration

$$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$$

Cx: Concentration of standby sample

Ax: Absorbance of sample or its change per minute.

IFA and IFB: Analyzer constants, representing slope and intercept.

d)Applicable assay

1-point assay, 2-point rate assay, 2-point assay and rate A assay.

(4)Logit-Log3P (Non-linearity Method 1)

This is applied to a working curve in which the absorbance converges as the concentration increase. As the following figure shows:

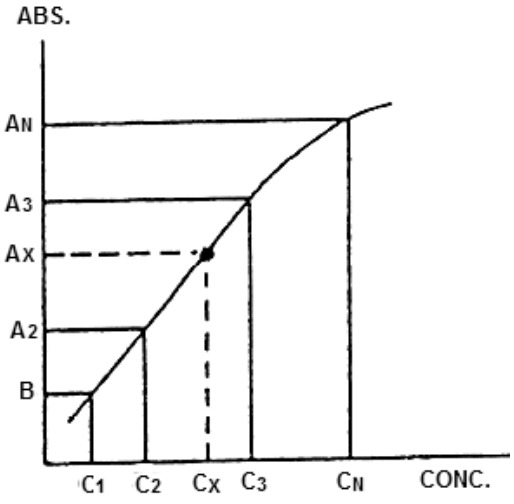


Figure 5-2-15

a)Calibration Parameter input

Calibration type:【Logit-Log3P】

Calibration point:【3-10】(number of calibrator)

Span point:【0】span calibration invalid

b)Calculation of parameters for working curve

B: The absorbance or approximate value of the absorbance change per minute when CX approaches ∞.

K: Blank (calibrator 1) absorbance or value calculate by the approximation formula of the absorbance change per minute subtraction B.

a: Constants in approximation formula. Automatically calculated.

S1ABS, K, a are displayed on the Calibration Result screen.

c)Calculation of concentration

$$C_X = (C + C_1) \times IFA + IFB$$

$$A_X = B + \frac{K}{1 + aC}$$

$$C = \frac{1}{a} \times \left\{ \frac{K - (A_X - B)}{A_X - B} \right\}$$

Cx: Concentration of standby sample.

C_1: Blank concentration.

Ax: Absorbance of sample or its change per minute.

K: Constants in approximation formula. The more Cx approaches ∞, AX approaches B.

When K＜0, AX≤B+K or K＞0, AX≥B+K, C=C1

IFA, IFB Analyzer constants, representing slope and intercept.

d)Calculation of SD value

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij} - A_i'\right)^2}{2N - 3}}$$

(N=3~10, j=1or 2)

(A_{ij}~A_i'): Difference between approximate absorbance A_i' and tested value A_{ij} or A12. Each calibrator is tested twice, so the number of points A_{ij} is 12 at maximum.

e)Applicable assay

1-point assay, 2-point rate assay, 2-point assay, Rate A assay.

(5)Logit-Log4P (Non-linearity method 2)

It is applied to a working curve in which the absorbance converges as the concentration increases. The following figure explains the non-linearity method.

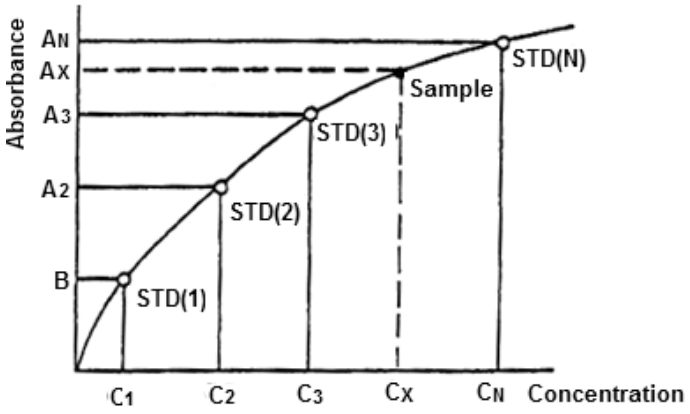


Figure 5-2-16

a)“Calibration Parameter” input

Calibration type:【Logit-Log4P】

Calibration point:【4-10】(number of calibrator)

Span point:【0】range calibration is invalid

b)Calculation of parameters for working curve

B: approximation for the absorbance or its change per minute when CX approaches ∞.

K: Blank (calibrator 1) absorbance or value calculate by the approximation of the absorbance change per minute subtraction B.

a ,b : Constants in approximation formula. Automatically calculated.

S1ABS, K, a , b are displayed on the Calibration Result screen.

c)Calculation of concentration.

$$C_X = (C + C_1) \times IFA + IFB$$

$$A_X = B + \frac{K}{1 + aC^b}$$

$$C = b \times \sqrt{\frac{1}{a} \times \left\{ \frac{K - (A_X - B)}{A_X - B} \right\}}$$

Cx: Concentration of standby sample

C_1: Blank concentration.

Ax: Absorbance of sample or its change per minute.

K: Constants in approximation formula. The more Cx approaches ∞, AX approaches B

When K＜0, $A_X \leq B+K$ or K＞0, $A_X \geq B+K$ C1=0

IFA,IFB Analyzer constants, representing slope and intercept.

d)Calculation of SD value

$$SD = \sqrt{\frac{\sum_{i=1}^{N} \sum_{j=1}^{2} (A_{ij} - A_i')^2}{2N - 4}}$$

(N=4~10,j=1or 2)

(A_{ij}~A_i'): Difference between approximate absorbance A_i' and tested value A_{ij} or A_{12}. Each calibrator is tested twice, so the number of points A_{ij} is 12 at maximum.

e)Applicable assay

1-point assay, 2-point rate assay, 2-point assay, Rate A assay.

(6)Logit-Log5P (Non-linear method 3)

Logit-Log5P has the same feature as Logit-Log4P. Compared with Logit-Log4P, Logit-Log5P is more accurate in some condition for the 1 more calculation parameter.

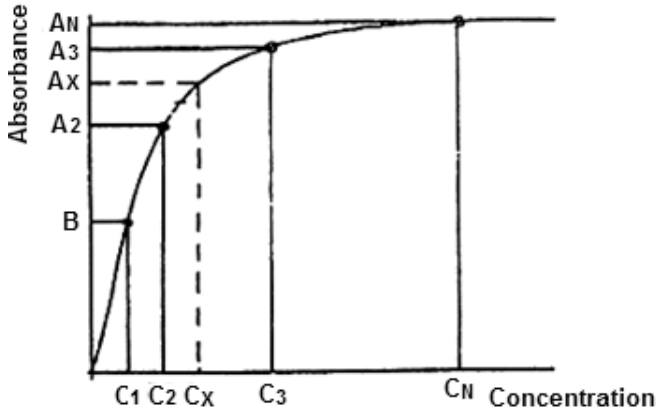


Figure 5-2-17

a) “Calibration Parameter” input

Calibration type :【Logit-Log5P】

Calibration point:【5-10】(number of calibrator)

Span point:【0】Span calibration is invalid.

b)Calculation of parameters for working curve

B: approximation for the absorbance or its change per minute when CX approaches ∞.

K,a,b,c: Constants in approximation formula. Automatically calculated.

S1ABS, K, a,b,c are displayed in the Calibration Result screen.

c)Calculation of concentration

$$a + b \times \ln C + c \times C - \ln\left\{\frac{A_X - B}{K - (A_X - B)}\right\} = 0$$

Calculate C according to the Newton approximation formula.

$$C_X = (C + C_1) \times IFA + IFB$$

$$A_X = B + \frac{K}{1 + \exp(-a - b \times \ln C - c \times C)}$$

Cx: Concentration of standby sample

C_1: Blank concentration.

Ax Absorbance of sample or its change per minute.

K: Constants in approximation formula. The more Cx approaches ∞, AX approaches B

When K＜0, AX≤B or when K＞0, AX≥B, C=0

IFA,IFB Analyzer constants, representing slope and intercept.

d)Calculation of SD value

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij} - A_i'\right)^2}{2N - 5}}$$

(N=5~10,j=1 or 2)

(A_{ij}~A_i'): Difference between approximate absorbance A_i' and measured value A_{ij} or A_{12}. Each standard sample is measured in duplicate so the number as measurement points A_{ij} is 12 at maximum.

e)Applicable assay

1-point assay, 2-point rate assay, 2-point assay, Rate A assay.

(7)Exponential function method (Non-linear method)

Exponential function method prepares a working curve in which the absorbance disperses as the concentration increases. The following figure explains the exponential function method.

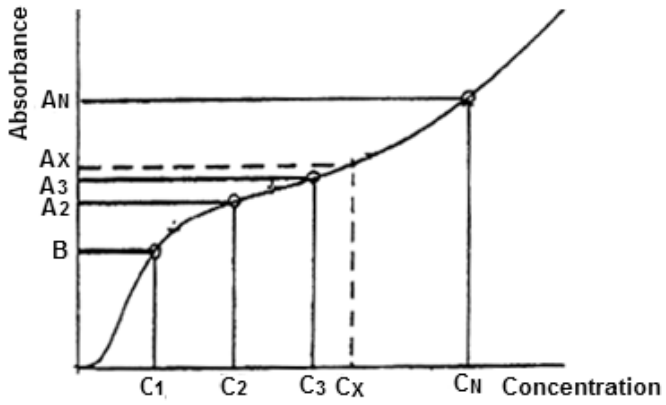


Figure 5-2-18

a)Calibration Parameter input

Calibration type:【exponential function】

Calibration point:【5-10】(number of calibrator)

Span point:【0】Span point calibration invalid.

b)Calculation of parameters for working curve

B: approximation formula for the absorbance or its change per minute of blank (calibrator1)

K,a,b,c: Constants in approximation formula. Automatically calculated.

S1ABS, K, a,b.c are displayed in the Calibration Result screen.

c)Calculation of concentration.

$$A_X = B + K \times \exp\left\{a \times (\ln C) + b \times (\ln C)^2 + c \times (\ln C)^3\right\}$$

$$a \times (\ln C) + b \times (\ln C)^2 + c \times (\ln C)^3 - \ln\left(\frac{A_X - B}{K}\right) = 0$$

Calculate C according to the Newton approximation formula.

$$C_X = (C + C_1) \times IFA + IFB$$

Cx: Concentration of standby sample

C1, C2~CN: Blank and calibrator concentration.

Ax: Absorbance of sample or its change per minute.

When K>0, AX≤B or when K<0, AX≥B, C=0

IFA,IFB Analyzer constants, representing slope and intercept.

d)Calculation of SD value

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij} - A_i'\right)^2}{2N - 5}}$$

(N=5~10,j=1 or 2)

(A_{ij}~A_i'): Difference between approximate absorbance A_i' and measured value A_{ij} or A_{12}. Each calibrator is measured in duplicate so the number as measurement points A_{ij} is 12 at maximum

e)Applicable assay

1-point Assay, 2-point Rate assay, 2-point Assay, Rate A assay.

(8)Spline function method (Non-linear method)

In this method, line is connected in each section so as to form a curve as a whole. Since each section is smoothed including the error in measured value, more accurate approximation is possible than the polygonal line approximation. Figure 5-2-19 explains this method.

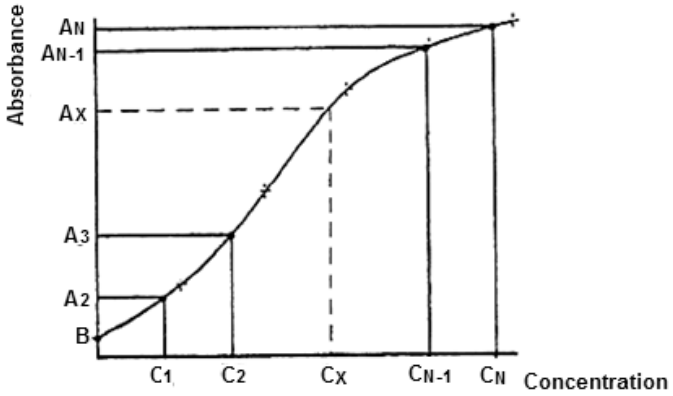


Figure 5-2-19

a)"Calibration Parameter" input

Calibration type:【Spline function】

Calibration point:【5-10】(number of calibrator)

Span point:【0】Span point calibration invalid.

b)Calculation of parameters for working curve

a(I),b(I),c(I),d(I): Constants in approximation formula, I=1～N

In the "calibration" menu, S1ABS show as a (1) (intercept of absorbance axis).

c)Calculation of concentration.

$$A_X = a(I) + b(I) \times (C_X\text{-}C(I) + c(I)) \times (C_X\text{-}C(I)^2) + d(I) \times (C_X\text{-}C(I))^3$$

$$f \times (C_X\text{-}C(I)) = a \times (I) + b \times (I) \times (C_X\text{-}C(I)) + d \times (I) \times (C_X\text{-}C(I))^2 + d(I) \times (C_X\text{-}C(I))^3\text{-}A_X$$

Calculate C according to the Newton approximation formula.

$$C_X = (C + C_1) \times IFA + IFB$$

Cx: Concentration of standby sample

C_1~C_N: Blank and calibrator concentration.

A_X, A_2~A_N: Absorbance of sample and calibrator or its change per minute.

IFA, IFB Analyzer constants, representing slope and intercept.

d)Calculation of SD

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij} - A_i'\right)^2}{2N-4}}$$

(N=5~10 ,j=1 or 2)

(A_{ij}~A_i'): Difference between approximate absorbance A_i' and measured value A_{ij} or A_{12}. Each calibrator is measured in duplicate, so the number as measurement points A_{ij} is 12 at maximum

e)Applicable assay

1-Point Assay, 2-Point Rate Assay, 2-Point Assay, Rate A Assay.

(9)Polygon method (Non-linear method)

The range between calibrator 1 to 5 or 10 is subject to approximation in consideration of measured values across them and line is connected in each section so as to form a curve as a whole.

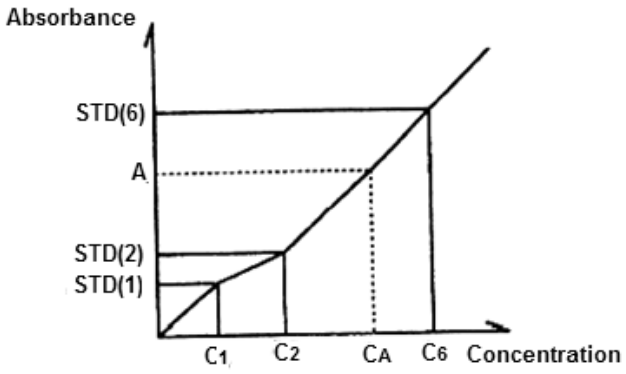


Figure 5-2-20

a) "Calibration Parameter" input

Calibration type:【polygon】

Calibration point:【5-10】(number of calibrator)

Span point:【0】Span point calibration invalid.

b)Calculation of parameters for working curve

S1ABS is the mean of two measure value (absorbance or it's change) of calibrator (1)

$$K = \frac{C_2\text{-}C_1}{A_2\text{-}B}$$

B: Absorbance or it's change of calibrator (1)

A_2: Absorbance or it's change of calibrator (2)

C_1: Calibrator (1) concentration (input value)

C_2: Calibrator (2) concentration (input value)

Calculate K2, K3, K4, K5 as using calibrator 2~10.

c)Calculation of concentration.

$$C_X = \{K_N \times (A_X - A_N) + C_N\} \times IFA + IFB$$

d)Applicable assay

1-Point Assay, 2-Point Rate Assay, 2-Point Assay, Rate A assay.

5.2.2.3 Calibration Types

According to the number of calibration points, calibration can be affected in different ways. Blank calibration: Only reagent blank (standard 1) is calibrated. Span calibration: Only one standard solution other than the reagent blank is calibrated. 2-point calibration: Reagent blank and a single standard solution are calibrated. Full-point calibration: All standard solutions specified on the Chemistry Parameters screen are calibrated. These are selectively usable so as to meet your analytical purpose. Each calibration is explained below.

(1)Blank Calibration

Only reagent blank (calibrator 1) is calibrated. Table 5-2-1 lists the calculation method for each calibration type.

a)S1ABS calculation

Table 5-2-1 S1ABS Calculation

Calibration Type	SIABS Calculation
1 point linearity	$(A_{11}+ A_{12})/2$
2 point linearity	$(A_{11}+ A_{12})/2$
Multi-point linearity	$\{(A_U+ A_{12})/2-(A_U'+ A_{12}')/2\}$+SIABS′
Logit-Log3P	$\{(A_{11}+ A_{12})/2-(A_{11}'+ A_{12}')/2\}$+SIABS′
Logit-Log4P	$\{(A_{11}+ A_{12})/2-(A_{11}'+ A_{12}')/2\}$+SIABS′
Logit-Log5P	$(A_{11}+ A_{12})/2$
Exponential function	$(A_{11}+ A_{12})/2$
Spline function	$\{(A_{11}+ A_{12})/2-$ SIABS′$\}$+a(I)
Polygon method	$(A_{11}+ A_{12})/2$

A_{11}, A_{12}: 1st and 2nd absorbance value of calibrator (1) measured presently.

A_{11}', A_{12}': 1st and 2nd absorbance value of calibrator (1) measured previously.

SIABS′: Previous SIABS value

a(I): I=1~N, N representing the number of calibrator and factor of the curve(refer to Logit-Log5P method).

Only blank calibration can be carried out in case 1 is entered for the number of calibrator (K factor method).

b)Applicable calibration types

Linear (2-point), Linear (multi-point), Linear (1-point: K factor) , Logit-Log3P, Logit-Log4P, Logit-Log5P, Exponential, Spline. Polygon.

(2)Span Calibration

Only one calibrator other than reagent blank is calibrated. As shown in Figure 5-2-2:

a)K factor and S1ABS calculation

Table 5-2-2 S1ABS, K value calculation

Calibration Type	K Factor Calculation	S1ABS
Two-point linearity	$(C_2-C_1)/(A_2-S1ABS)$	Previous value
Multi-point linearity	$(C_N-C_1)/(A_N-S1ABS)$	Previous value

C_2: Concentration of calibrator (2)

C_1: Concentration of calibrator (1)

C_N: Concentration of calibrator N (N represents span point)

A_2: Average of absorbance values of calibrator (2)

A_N: Average of absorbance values of calibrator (N)

b)Applicable assay

Linear (2-point), Linear (multi-point),

(3)2-point Calibration

Reagent blank and a single calibrator are calibrated. As shown in Figure 5-2-3:

a)K factor and S1ABS calculation

Table 5-2-3 S1ABS, K value calculation

Calibration Type	S1ABS Calculation	K Factor Calculation
Two-point linearity	$(A_{11}+A_{12})/2$	$(C_2-C_1)/(A_2-S1ABS)$
Multi-point linearity	$(A_U+A_{12})/2$	$(C_N-C_1)/(A_N-S1ABS)$

A_{11}, A_{12}: 1st and 2nd absorbance values of calibrator (1) tested presently.

C_2: Concentration of calibrator (2)

C_1: Concentration of calibrator (1)

C_N: Concentration of calibrator N (N represents span point)

A_2: Average of absorbance values of calibrator (2)

A_N: Average of absorbance values of calibrator (N)

b)Applicable assay

Linear (2-point), Linear (multi-point).

(4)Multi-point Calibration

All calibrators (including reagent blank) specified on the “Calibration Parameters” screen are calibrated. After this calibration, the results are updated.

a)Calculation formula

The calculation varies from the calibration methods.

b)Applicable calibration types

Linearity (multi-point), Logit-Log3P, Logit-Log4P, Logit-Log5P, Exponential, Spline, Polygon.

5.2.2.4 Calibration Check

Various checks are performed to enhance the reliability of measured results. Below are check description.

(1)Blank Level check

In calibration, a “reagent blank level check over” alarm (warning–level) is issued when the mean of twice measured Calibrator 1 (reagent blank) absorbance is outside the set blank level check range. Meanwhile, the calibration result list displays calibration failure.

If the alarm happens to an analytic item, the calibration reaction curve will be updated. Value K will not be updated. To avoid the check, enter “-3.3~3.3”.

(2)Discrete Check

In calibration, each Calibrator (include reagent blank: Calibrator 1) is tested twice, and calculate the mean. A

"discreteness check value over" alarm (warning level) is issued if the absorbance difference between measurement of two times is larger than the set value. Meanwhile, the calibration result list displays calibration failure.

If the alarm happens to an analytic item, the calibration reaction curve will be updated. Value K will not be updated. To avoid the check, enter "3.3".

Discrete check is performed by the below formula:

$$\left|A_{liquid(N)}\text{First} - A_{liquid(N)}\text{Second}\right| \leq \text{Absorbance Discrete Check(ABS)}$$

(3)Sensitivity Check

In calibration, a "sensitivity check value over" alarm (warning level) will occur If the difference between Calibrator 1 absorbance (absorbance mean of two times measurement) and highest-concentration Calibrator absorbance (absorbance mean of two times measurement of highest-concentration Calibrator in non-linearity and multi-point linearity). Meanwhile, the calibration result list displays calibration failure.

If the alarm happens to an analytic item, the calibration reaction curve will be updated. Value K will not be updated. To avoid the check, enter "0".

Check sensitivity by the below formula:

$$A_{calibrater(N)} - A_{calibrater(1)} \geq \text{Sensitivity Check Value (ABS)}$$

(4)K Factor Check

If the difference between previous Factor K and current one is more than 20% of their mean (fixed value), a "Factor K check abnormal" alarm (warning level) will occur. The working curve and Factor K will be updated, but calibration status will not be updated. It's suggested that the reason for the alarm be found out before testing samples.

Check the K factor by the below formula:

$$\frac{K_{this} - K_{last}}{(\frac{K_{this} + K_{last}}{2})} \times 100\% \leq 20\%$$

(5)Drift Rate Check

In non-linearity working curve and multi-linearity working curve, a "drift rate check value over" alarm (notice-level) is issued if the difference between each calculated absorbance (through approximate expression) and tested absorbance has exceeded the set drift rate value. Meanwhile, calibration failure is displayed in the calibration result list. The working curve and K factor will be renewed and testing can be carried out. Be sure to check the reason for the alarm before sample analysis.

To avoid the check, enter "3.3".

5.2.3 Range Parameter

Click "Range Parameter" to setup the reference value range , linearity range and critical value. Click "Save Parameter" button to save the parameters. As Figure 5-2-21 shows:

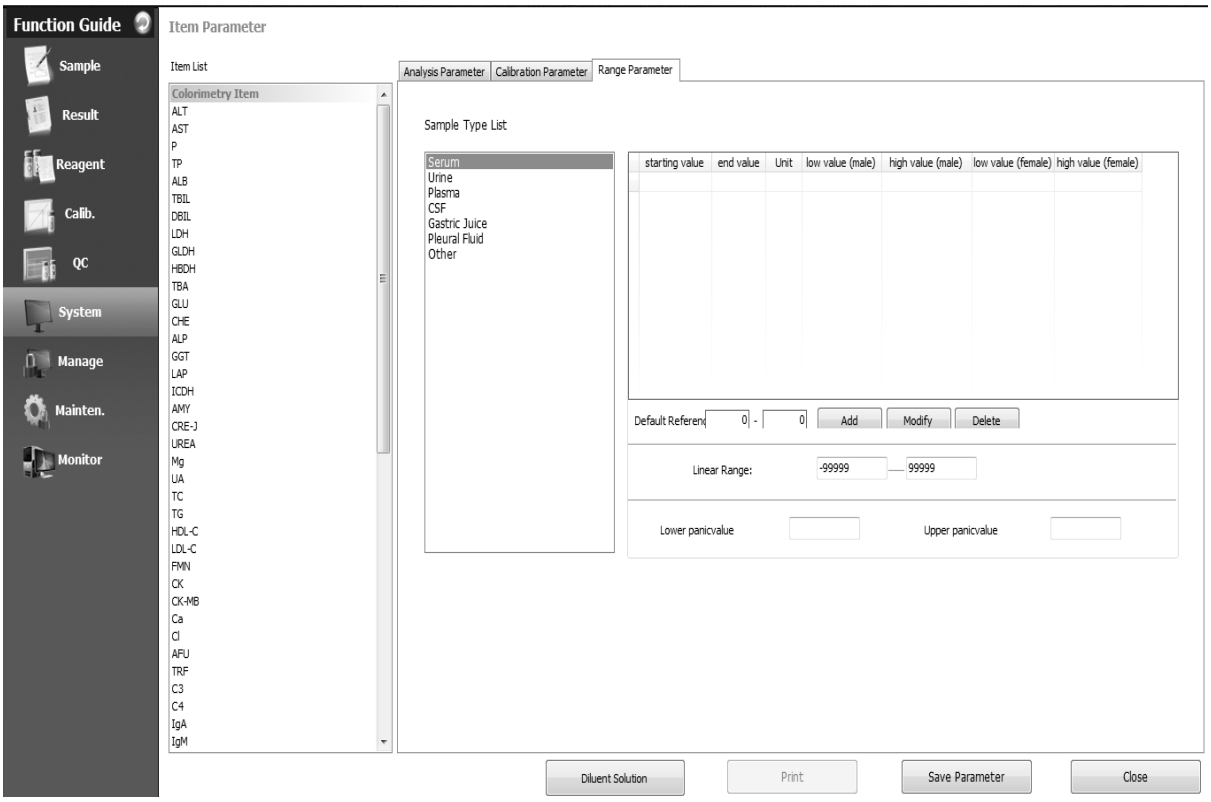


Figure 5-2-21

(1)Specific Reference: If patient age, and patient gender are different, then the reference range are different. Click "Specific Reference:" key.

a)Click "Add" to switch to "reference range setting" window as the following figure shows:

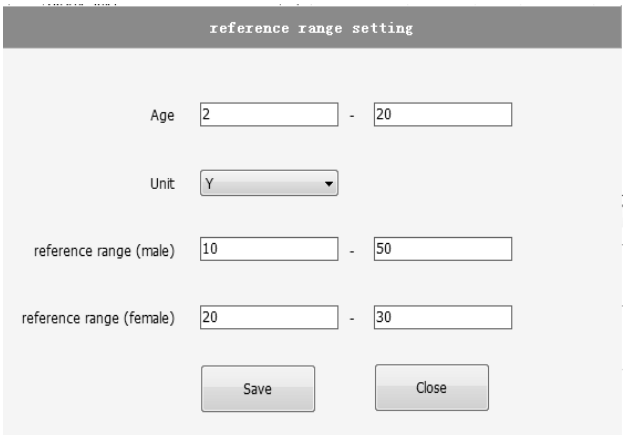


Figure 5-2-22

The age unit is optional, including "year", "month", "day" and "hour". Input a value to set an age, and then click "Save" to save the setting, or you can click "Close" to cancel settings and exit.

If you want to set the reference range, you need to set before the test result is calculated. Otherwise, the test result will display a default reference range.

b)Click "Modify" to modify the values already set.

c)Click "Delete" to delete the specific reference value already set.(2)Default Reference: select default

reference range "Default Reference:" when the reference range are the same despite the difference in patient age and gender.

For example, the default reference range of urine amylase is 0U/L ~640U/L , as Figure 5-2-23 shows.

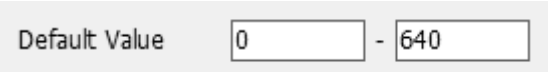


Figure 5-2-23

(3)Linear Range: Input the upper limit and lower limit of reagent linearity in functional field. Alarm is issued when test result exceeds the range.

(4)Crisis value range: Input the upper limit and lower limit of crisis value according to both the clinic and application environment. An alarm will be issued when the test results are out of the range.

5.2.4 Manual Item Parameter

Select the parameters need to be set in "Manual Item" in "Item List", and click "Save Parameter" after setting, as Figure 5-2-24 shows:

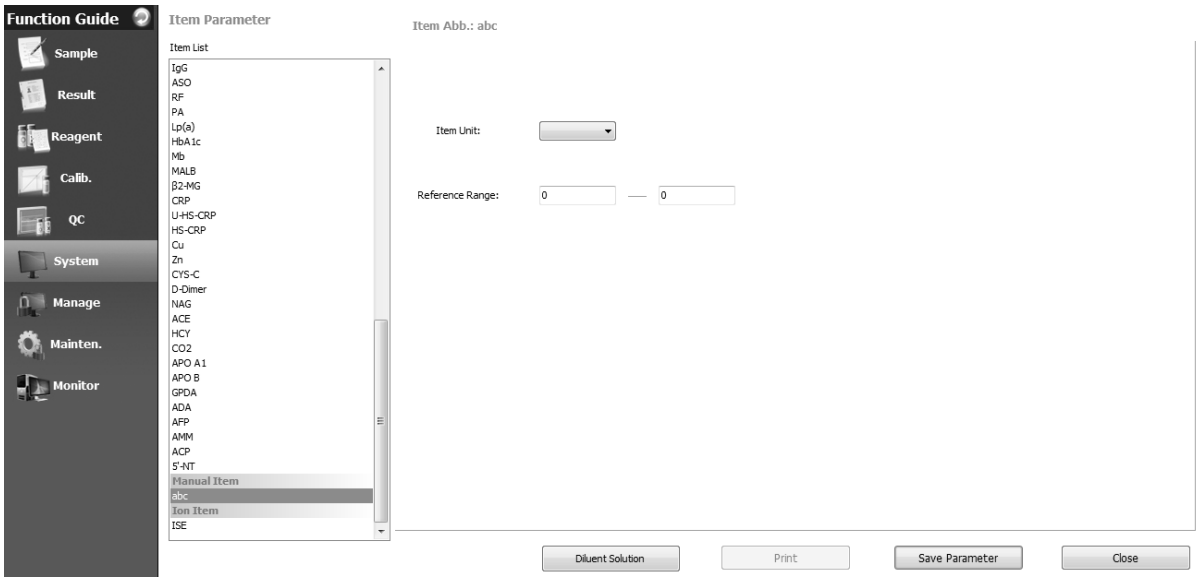


Figure 5-2-24

(1)Item Unit: Select the item unit from the pull-down menu.

(2)Reference Range: Input the reference range in the input box.

5.2.5 Ion Item Parameter

Select the items need to be set in "Ion Item" in "Item List", and click "Save Parameter" after setting, as Figure 5-2-25 shows:

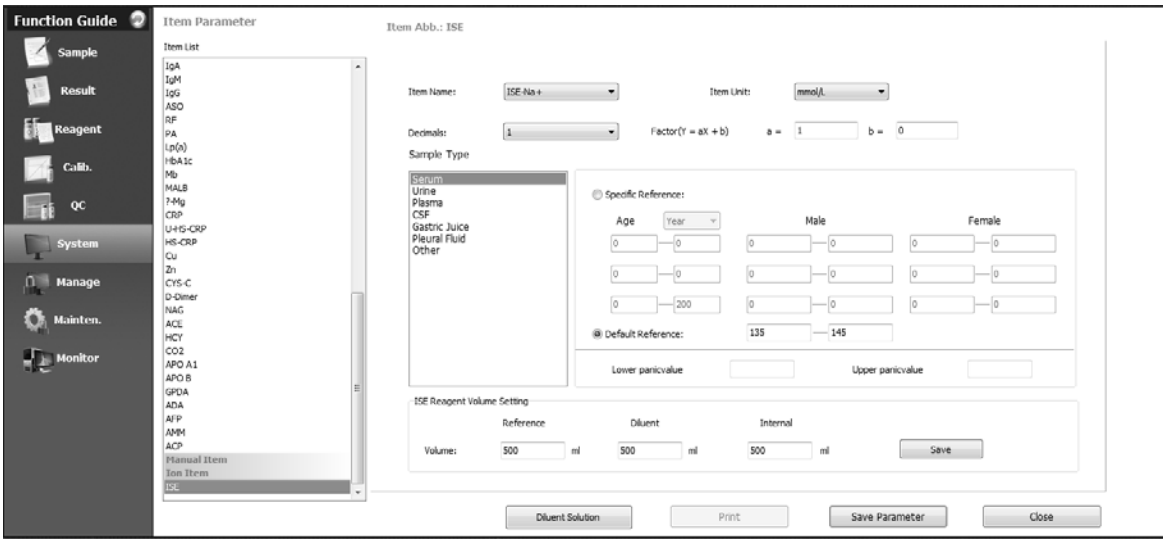


Figure 5-2-25

(1)Item Abb.: Select item abb. from the pull-down menu.

(2)Item Unit: Select item unit from the pull-down menu.

(3)Decimals: Select decimal places from the pull-down menu.

(4)Factor(Y=aX+b): Input a,b value in the input box. Refer to "Chapter 5.2.1.1 (8)" for detail.

(5)Sample Type: Select the sample type.

(6)Specific Reference: If patient age, and patient gender are different, then the reference range are different. Click "Specific Reference:".

If this, the user must set patient age and gender first, otherwise the default reference range will be displayed.

(7)Default Reference: select default reference range "Default Reference:" when the reference range are the same despite the difference in patient age and gender.

(8)Crisis value range: input the upper limit and lower limit of crisis value according to both the clinic and application environment. An alarm will be issued and the test result will be displayed with an "E", when the test results are out of the range.

(9)ISE Reagent Left Volume Setting: Input the reagent volume, and set the corresponding reference solution, diluent, and internal standard solution alarm volume. Click "Save" to save the parameter.

The chemistry parameters in the manual are taken as an example, not real test parameters. The user should set parameters according to the reagent instructions.

5.3 Serum Information

Click 

in "System Setting" to enter into serum information setting window, as Figure 5-3-1 shows:

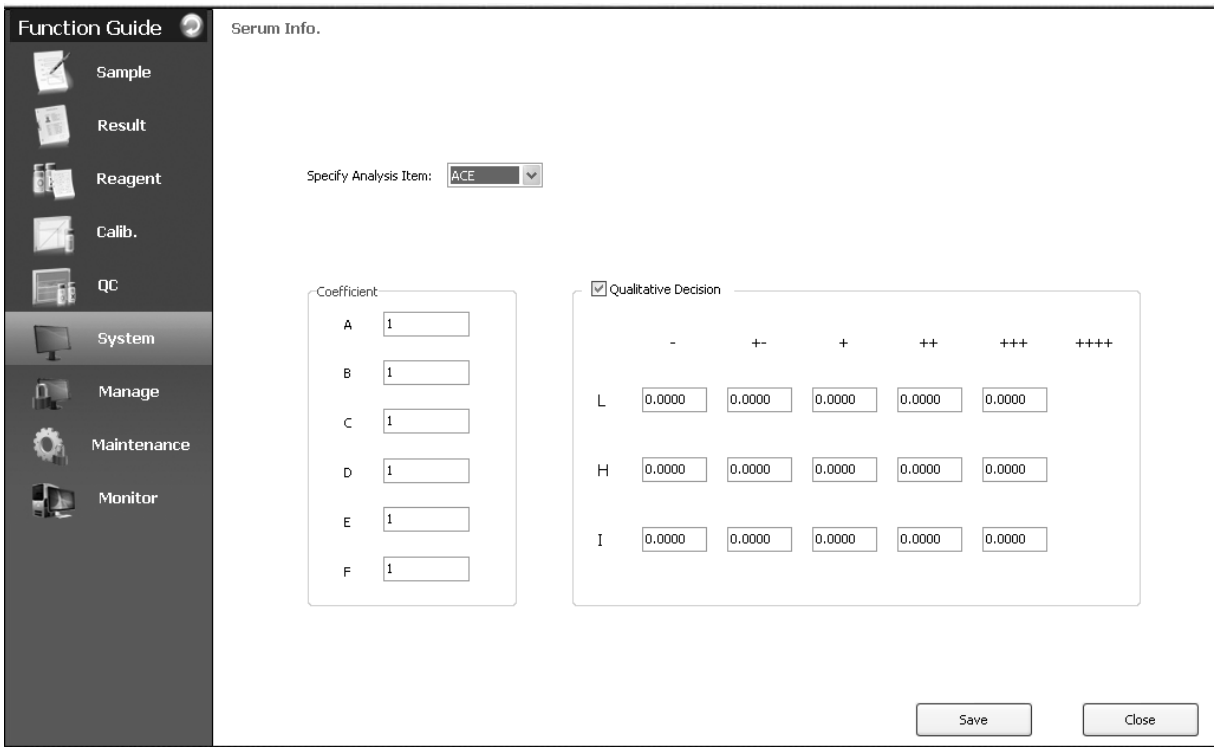


Figure 5-3-1

Serum Info. is the function of obtaining serum index through testing degree of Lipemic (L), Hemolytic (H) and Icteric (I) in serum .

Item Name	Serum Information
L	Lipemic
H	Hemolytic
I	Icteric

The use of serum information (Lipemic, Hemolytic, Icteric) can compensate analysis result. Qualitative result can be obtained through the test result. Different analysis method may cause rise in bilirubin, etc. Medicine or its metabolite may also affect the test results.

Serum information test indicates the degree of Lipemic, Hemolytic, Icteric in serum. The reagent used is colorless transparent, such as ALT, AST, LDH, etc. and is tested in non-analysis time of rate A (test point $5 \leq L < m \leq 34$). Therefore, serum information and item are tested separately.

(1)Test Wavelength of Serum Information

Lipemic : Main wavelength is test at 660nm, sub wavelength is tested at 700nm, which will not be affected by Hemolytic, Icteric.

Hemolytic: Main wavelength is test at 570nm, sub wavelength is tested at 600nm, which will not be affected by Lipemic, Icteric.

Icteric: Main wavelength is test at 480nm, sub wavelength is tested at 505nm, which will not be affected by Lipemic, Hemolytic.

(2)Test Value and Test Point

Test serum index, each tested absorbency minus reagent blank absorbency.

Icteric: $\Delta E_I = \Delta E_4 - \Delta E_{B4}(\lambda_{Main} / \lambda_{sub} = 480nm / 505nm)$

Hemolytic: $\Delta E_H = \Delta E_4 - \Delta E_{B4}(\lambda_{Main} / \lambda_{sub} = 570nm / 600nm)$

Lipemic: $\Delta E_L = \Delta E_4 - \Delta E_{B4}(\lambda_{Main} / \lambda_{sub} = 660nm / 700nm)$

ΔE represents the absorbency of Icteric, Lipemic, Hemolytic at test point 4 by main wavelength minus sub wavelength.

ΔE_{B4} represents reagent blank value tested at test point 4.

(3)Calculation Formula of L, H, I and A~F Setting

$$L = \frac{1}{C} \times \Delta E_L$$

$$H = \frac{1}{A} \times (\Delta E_H - B \times \Delta E_L)$$

$$I = \frac{1}{D} \times (\Delta E_I - E \times \Delta E_H - F \times \Delta E_L)$$

L, H, I is the index of Icteric, Lipemic, Hemolytic.

C,A,D is the coefficient of turning absorbency into serum information.

B,E,F is coefficient obtained from spectrum absorption used for calibrating Icteric, Lipemic, Hemolytic.

Input "coefficient A ~F". The input information can be modified manually.

B, E, F should be input in times of 10^5

B=121000

E=15000

F=170000

C, A, D should be input in its 10 times.

C=320

A=1271

D=4350

The default C,A,D value is taking sample volume as 10μL, R1 volume is 200μL. C,A,D value should be corrected when volume of R1 and sample is changed. The corrected C′, A′, D′ are:

$$C' = C \times K$$

$$A' = A \times K$$

$$D' = D \times K$$

Input "coefficient A~F". Test item and coefficient of L, H, I is connectable, The input information of one item is valid for other serum information.

In qualitative determination, input the determine benchmark after selecting "qualitative determination". Determination is output in 6 levels. Input the result value range in left column. Input "+" "-" symbol in right column.

Press the "Save Parameter" after input.

5.4 Item Combination

Click "

" key in the "System Setting" window, set up item combination, as Figure 5-4-1 shows:

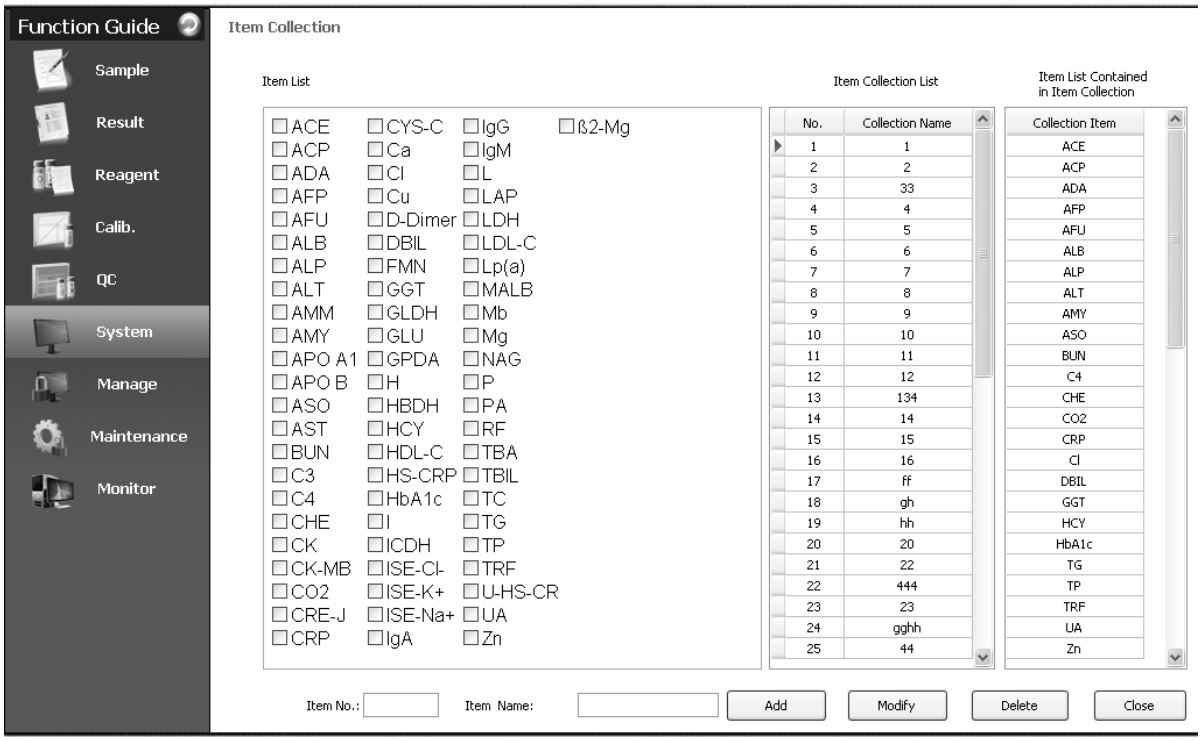


Figure 5-4-1

(1)No. : Input the number of combination item in "number" functional field, the number can't be repeated, should be within 0~99, or it cannot be saved.

(2)Item Name: Input the name of item combination in "Item Name" box. Character and number are all allowed, but can't be repeated, or it can not be saved.

(3)Item Collection List: Select item of item combination, click check box in front of item name, "☑" indicate that is selected. Click check box again, and "☐" indicate that it is cancel.

The added manual items will be displayed in the item list.

(4)Click "Add" key, combination item number, name will be displayed in the right side of functional field. Click the number or name, all items will be automatically showed in functional field.

(5)Click the item No. or name, and select the items of this item combination again, click Modify to save the modified item.

(6)Select the number or name of desired combination item, click "Delete" key to delete the combination item.

5.5 Calculated /Compensated Item

Calculated and compensated item are on the base of two or more item test results, using special calculation method to get a new item, such as A/G..

Click "Calculation & Compensation" as Figure 5-5-1 shows:

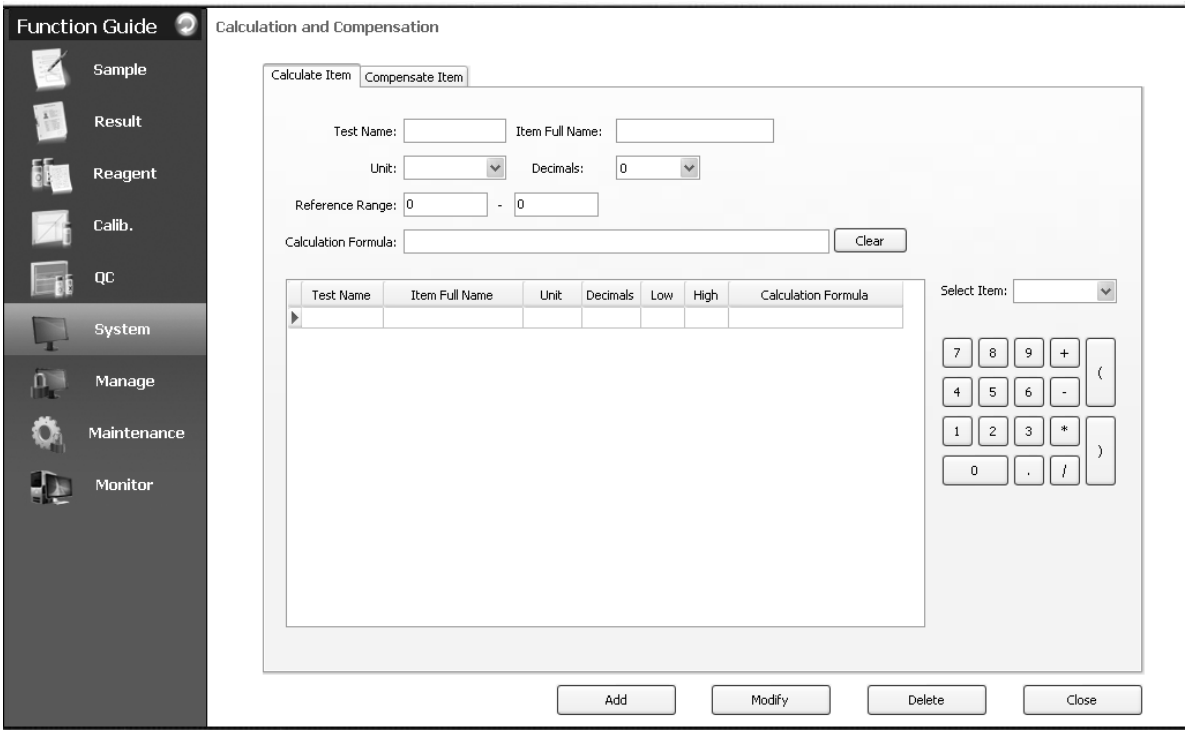


Figure 5-5-1

5.5.1 Calculate Item

Click "Calculate Item" in the "Calculation and Compensation" window.

(1)Test Name: Input test name in the "Test Name" box.

(2)Item Full Name: Input item name in the "Item Full Name" box.

(3)Unit: Select the unit of new calculated item from the "Unit" pull-down menu.

(4)Decimals: Select the decimal places of new calculated item from the "Decimals" pull-down menu.

(5)Reference Range: Select the reference range of new calculated item from the "Reference Range" pull-down menu.

(6)Calculation Formula: Edit the calculation formula, the edited information will be shown in the "Calculation Formula" box.

Click "Add" key to finish edition work. Click Clear to clear the edited calculation formula.

Select the item to be modified if calculation item needs to be modified, reset in input box of calculation formula and click "Modify".

Select the item to be deleted if calculation item needs to be deleted, and click "Delete".

Edition method of calculation formula (for instance: A/G):

Set the shortened item name, item full name, unit, decimal place, and reference range according to the above procedures. Select "ALB" from the "Select Item" pull-down menu, click symbol "/" and "(", select "TP" from the "Select Item" pull-down menu, click symbol "-", select "ALB" from the "Select Item" pull-down menu, and click symbol ")". Every edit of the formula can be shown in "Calculation Formula". If there are some numbers in the formula, click any number among 0, 1, 2, 3, 4, 5, 6, 7, 8, and 9. After the input, click the "Add" key, the formula will be shown in the functional field, as the following figure shows:

Test Name	Item Full Name	Unit	Decimals	Reference Value Low	Reference value High	Calculation Formula
A/G	A/G		2	0	0	<ALB>/(<TP>-<ALB>)

Figure 5-5-2

Click "Clear" key beside the calculation formula functional field to delete the wrong content.

5.5.2 Compensated Item

Click "Compensate Item" in "Calculation and Compensation" window, as Figure 5-5-3 shows:

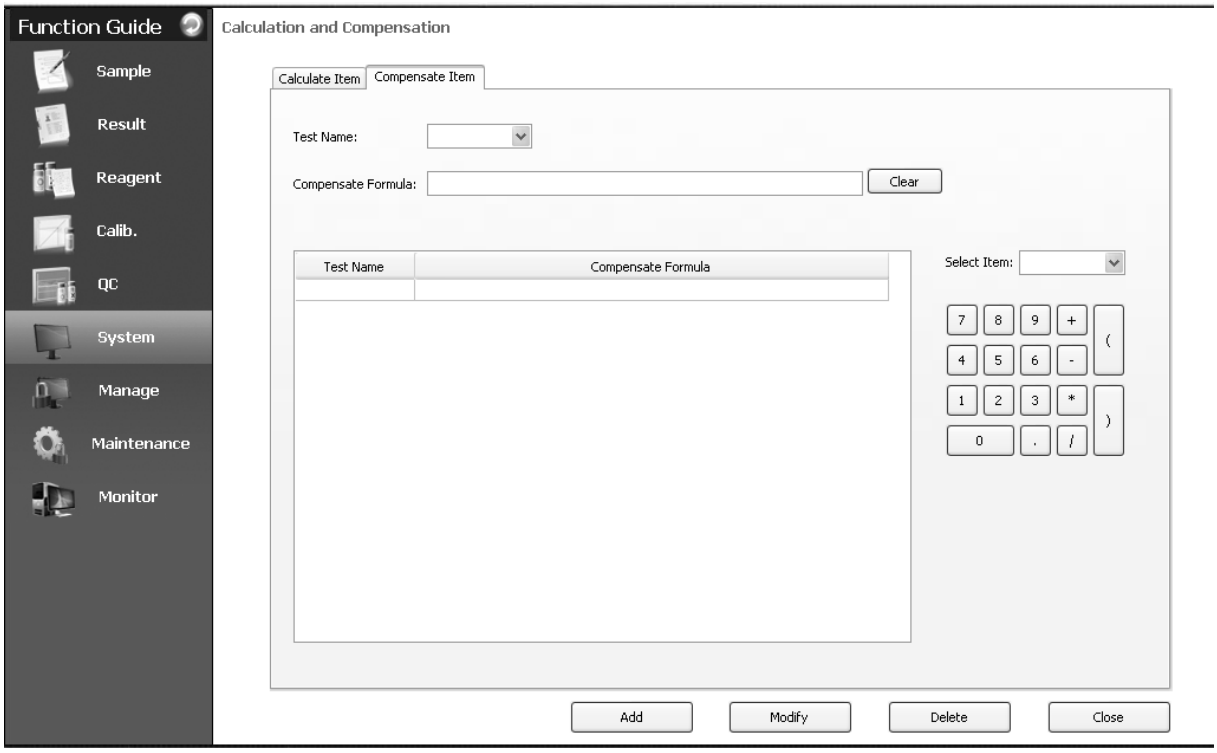


Figure 5-5-3

The editing of compensate item is same as calculation item setting. Refer to "5.5.1 Calculate Item" for detail.

5.6 Cross-Contamination

Cross-contamination obviation is a function to avoid cross-contamination among analyzing items. The degree of cross-contamination is different due to different reagent ingredient. For avoiding cross-contamination among reagents, we strongly suggest separate the items with cross-contamination and the items without cross-contamination. If all items cannot be separated, cross-contamination obviation can be selected in order to decrease the cross-contamination in maximum extent.

But the cross-contamination function may decrease the test speed.

Cross-contamination occurs among reagent probes, reaction cuvettes, and sample probes.

Click "Cross-Contamination" key in "System Setting" the window.

5.6.1 Reagent Probe Cross-contamination

Click "Reagent Probe" to set avoid cross-contamination of reagent probe. As Figure 5-6-1shows:

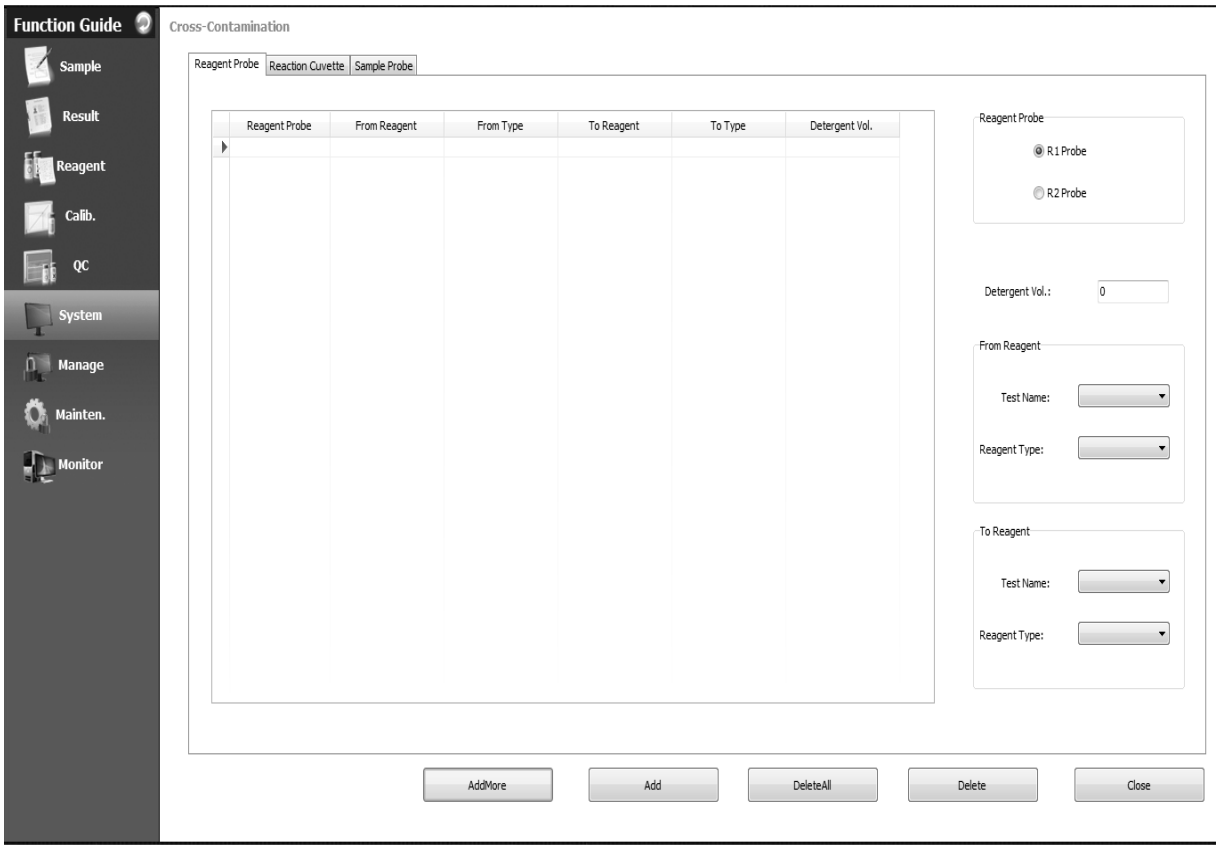
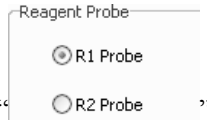


Figure 5-6-1

(1)Add

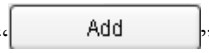


a)Reagent Probe: Select Probe R1 or R2 under "Reagent Probe". "" indicates R1 probe has been selected. Input the detergent volume (μL). The unit is μL.

b)From Reagent: Select the item causing cross-contamination; select the corresponding reagent type from the pull-down menu of "Reagent Type".

c)To reagent: Select the item tend to be contaminated, select the corresponding reagent type from the pull-down menu of "Reagent Type".

Detergent is located at position 45 in reagent disk 1 and reagent disk 2.

d)Click "

" key, the information you set will be displayed, representing cross-contamination obviation of reagent probe has been set successfully.

(2)Add More

Click "AddMore" to enter the batch adding screen as the figure below shows:

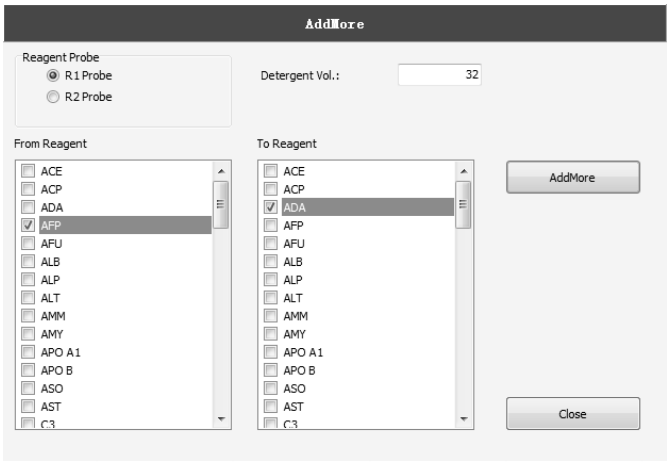


Figure 5-6-1(a)

a)Select a reagent probe type;

b)Specify the volume of detergent;

c)Select a "From Reagent" type from the left drop-down list, and then select the item in the "From Reagent" column;

d)Select a "To Reagent" type from the right drop-down list, and then select the item in the "To Reagent" column;

e)Click the button "AddMore" to fulfill the batch adding.

(3)Click "Delete", the relevant information will be deleted.

The items whose cross-contamination function is set must be registered in reagent information.

5.6.2 Reaction Cuvette Cross-contamination

Click "Reaction cuvette" key to set avoiding cross-contamination. As Figure 5-6-2 shows:

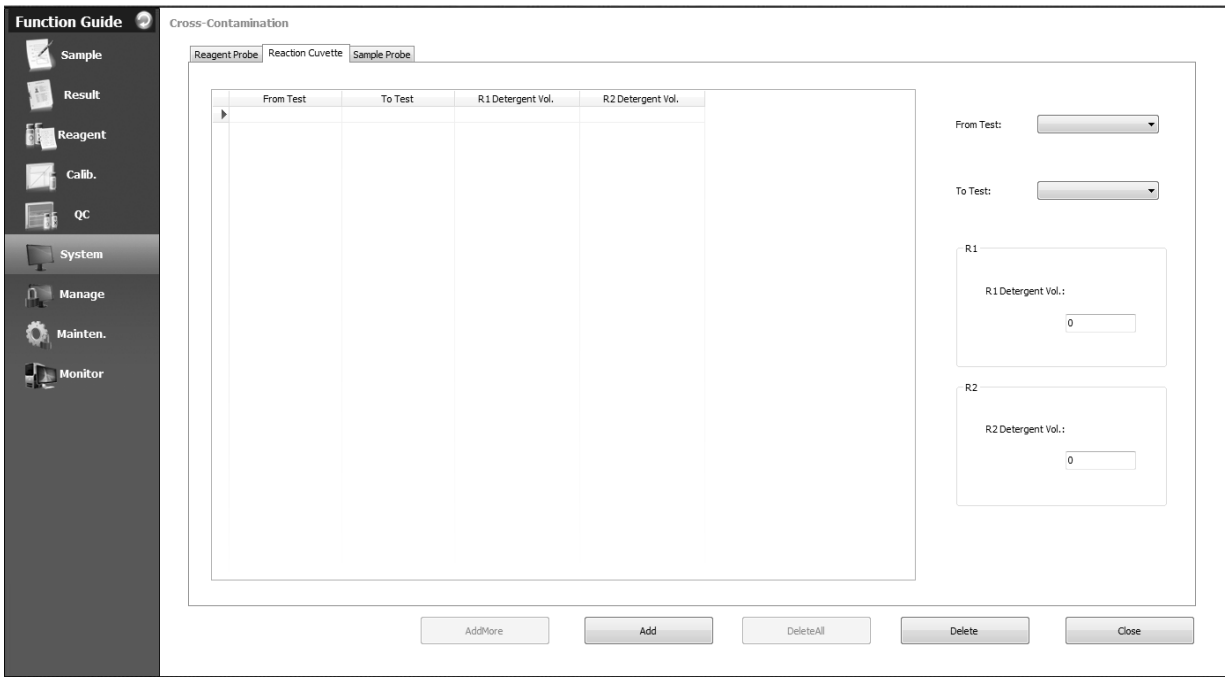


Figure 5-6-2

(1)Item Abb.: Select items causing cuvette contamination from the pull-down menu.

(2)R1: Input R1 detergent volume (μL) in "R1 Detergent Vol." work area.

(3)R2: Input R2 detergent volume (μL) in "R2 Detergent Vol." work area.

Detergent is located at position 45 in reagent disk 1 and reagent disk 2.

Click "Add" key, the set information will be displayed.

Click "Delete" key, information will be deleted.

5.6.3 Sample Probe Cross-contamination

Click "Sample Probe" key to set sample cross-contamination obviation, as Figure 5-6-3 shows:

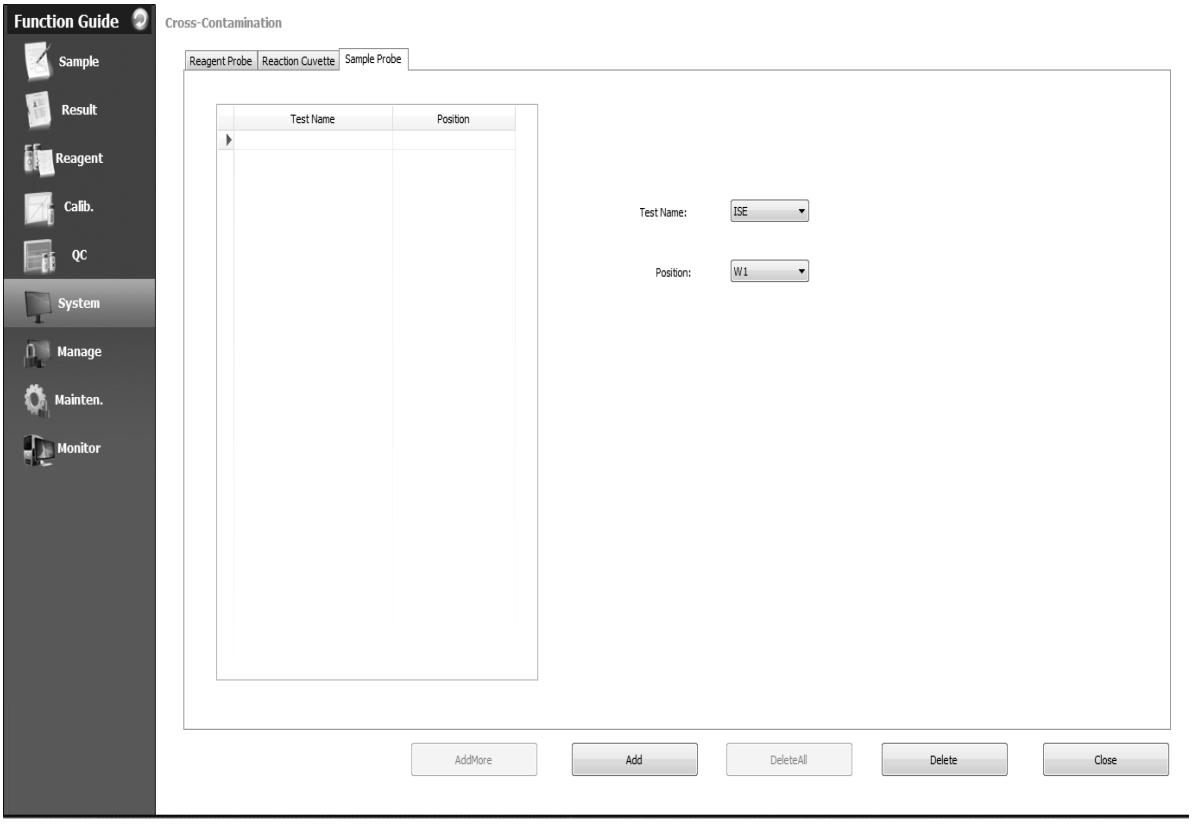


Figure 5-6-3

(1)Test Name: Select the items to be set in "Test Name" drop-down list, including colorimetric items and ISE items.

(2)Position: Select detergent position from W1, W2, and W3.

Click "Add" key, the set information will be displayed.

Click "Delete" key, information will be deleted.

5.7 Report Format

Click "

" key to set printing info., as Figure 5-7-1 shows:

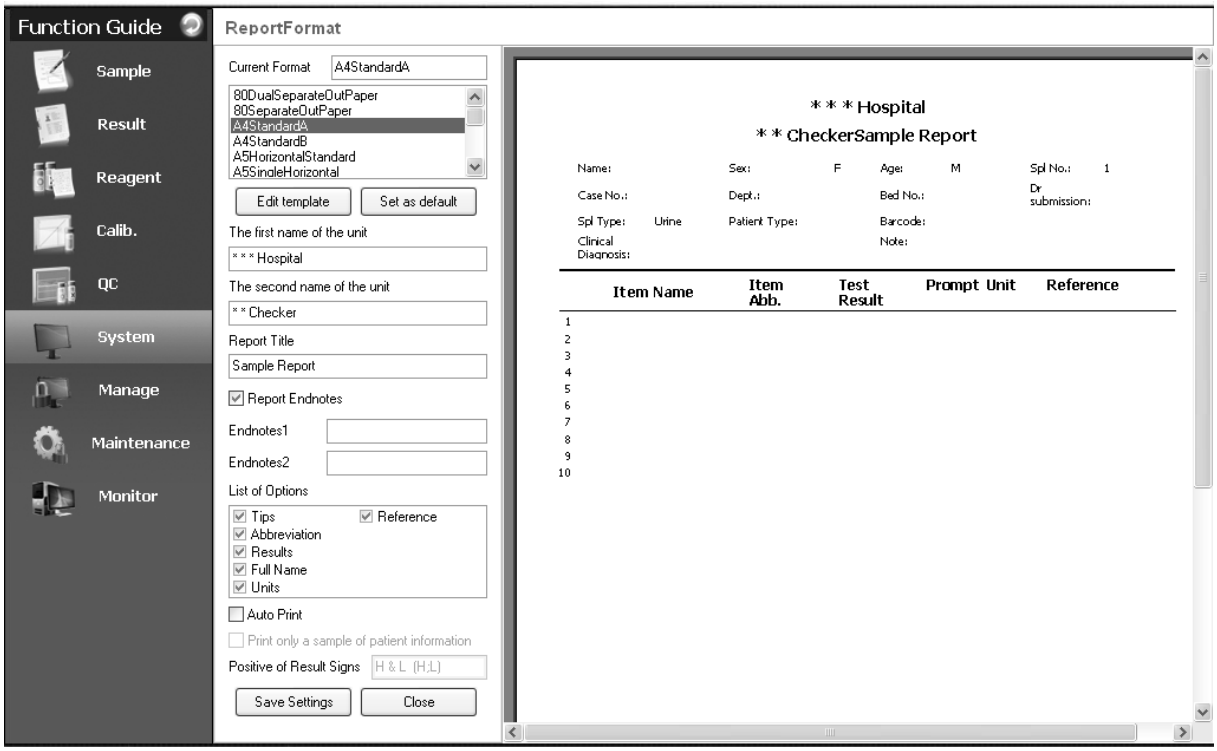


Figure 5-7-1

(1)Current Format: Select one print type from "Report Format", and click "Set as default ".

(2)The first name of the unit: Input the unit name in the input box.

(3)The second name of the unit: Input the unit name in the input box.

(4)Report Title:Input the report title in the input box.

(5)Report Endnotes: If endnote of report is used, please select it "☑ Report Endnotes ". Related contents can be entered in "Endnote 1" and "Endnote 2". The user can select not to tick "Report Endnotes" if there is no need to use it.

(6)List of Options: Select the items need to be printed, " ☑ " indicates selected, "☐" indicates not. The items include: Tips, Abbreviation, Results, Full Name, Units and Reference.

(7)Auto Print: Select "Auto print". The analyzer can automatically print the report after the test.

(8)Positive of Result Signs: The positive mark of print results can be set as (↑;↓) or (H;L).

Click "Save Settings" key to save basic information of report.

5.8 Other Info.



Click "Other Info." key to set the test mode, clot detection, ISE, linear check, regent alarm etc. function. As Figure 5-8-1 shows:

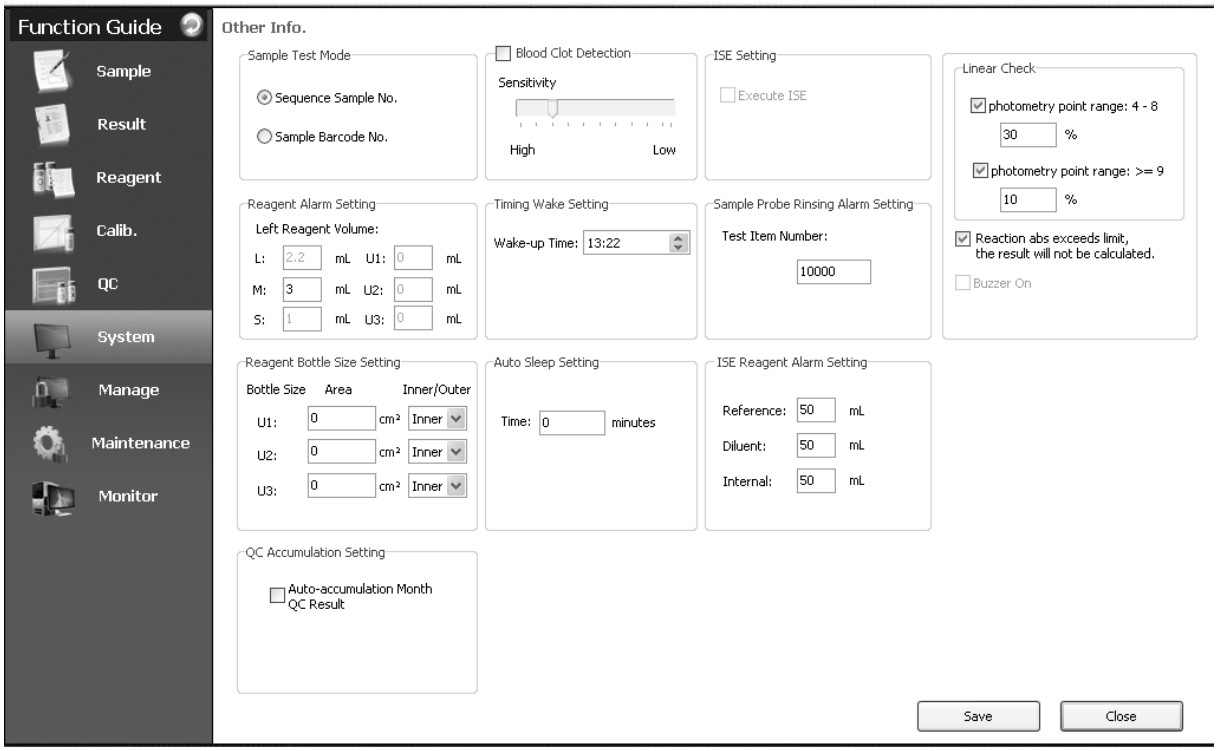


Figure 5-8-1

(1)Sample analysis method: There are 2 registration methods.

Sequence Sample No.: Place the waiting samples in the disk according to registered sequence.

Sample Barcode No.: The analyzer will register the sample barcode information according to the scanned result.

Sample test mode can not be changed when waiting samples are not tested.

(2)Blood Clot Detection:

Set blood clot detection sensitivity when clot detection is necessary. Use the mouse to move the slider to set sensitivity. If the sample probe detects clots when aspirating a sample, it will skip the sample and test the next sample. Alarm information of the sample number will be displayed.

(3)ISE Setting:

Sign "√" in ISE setup if any test required ISE test.

The hardware of ISE liquid level sensor needs to be equipped.

(4)Reagent alarm setting: After inputting the remaining volume for a reagent alarm into the "M" box, the volume in "S" and "L" will change automatically. When the analyzer detects the remaining volume is less than set value, an alarm will be issued. (L: 100mL, M: 70mL, S: 20mL, U1, U2, U3 are self-defined reagent bottle type. Refer to "User-define reagent bottle type setting" for volume.)

(5)Timing Wake Setting: Input the wakeup time in the input box, the analyzer will automatically be awakened in specified time. The analyzer can be wakened manually by clicking "Wake".

(6)Sample Probe Rinsing Alarm Setting: Input a number into "Test Item Number". After reaching the numbers of test items, alarm prompts will be given.

(7)Linear check: In reaction of rate A assay, absorbency change and time is in linear correlation. Thus, linear check is needed, alarm will be prompted in limit exceeding. Input limit check value in corresponding box, as shown in Figure 5-8-2:

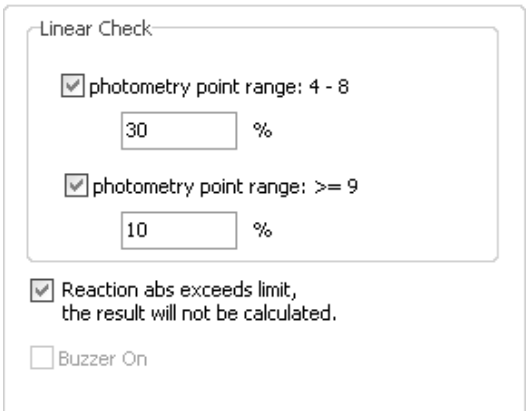


Figure 5-8-2

"☐"indicates note selected. Analyzer will not conduct linear check though value is input in the corresponding box.

a)When number of test points (N) more than 9 (N>9)

The principle of linear check is least squares technique. When N≥9, linearity is checked by dividing the difference in absorbance change between the first and last 6 measurement points by the average absorbance change for all. If the value thus obtained is beyond the limit linearity value, alarm is prompted. As the following figure shows:

$$\frac{|\Delta Af-\Delta Ab|}{|\Delta A|}\times 100 > \text{Limit linearity value(\%)}$$

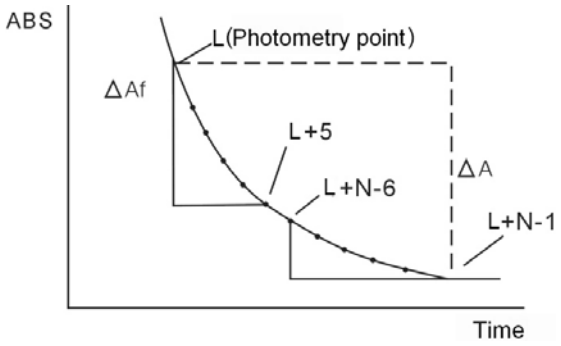


Figure 5-8-3

b)When number of test points (N) between 4 and 8 (4≤N≤8)

Linearity is checked by dividing the difference in absorbance change between the first and last 3 measurement points by the average absorbance change for all. If the value thus obtained is beyond the limit linearity value, alarm is issued as the following figure shows:

$$\frac{|\Delta Af'-\Delta Ab'|}{|\Delta A'|}\times 100 > \text{Limit linearity value(\%)}$$

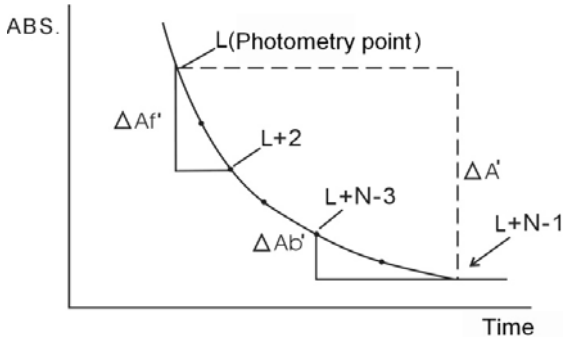


Figure 5-8-4

Linearity check will not be conducted in the following conditions:

a)The test points within absorbency limit should be less than 3.

b)ΔA/ΔA′≤0.006 or |ΔAf-ΔAb|≤0.006.

(8)User-defined reagent bottle type: If the reagent bottle is prepared by the user, sectional area should be input in corresponding input box, and select the position(inner or outer circle).

(9)Automatic sleep: If automatic sleep after certain time is required, input the time(1~999min) in the corresponding box. If the analyzer is on standby, automatic sleep will be conducted after certain time(standby time span is counted) .

(10)ISE Reagent Alarm Setting: Enter a remaining reagent alarm volume in the box of reference solution, diluent, and internal standard solution. When ISE reagent volume is smaller than the set value, an alarm will be given in Alarm Info.

(11)QC Accumulation: Click to select "Automatically accumulate monthly QC results". The last test result of the current day for all the QC items will be accumulated to monthly QC.

(12)Database Automaticly Back-up Setting: Click and select " Run database automaticly back up" and type the day intervals in the time interval strip, and the software will backup the data automaticly according to the set-up. When the database is wrecked, the user can restore the database to the last one through the backup database. The time intercal range: 1~180.

Click "Save" for saving. Click "Close" to exit.

5.9 LIS Communication

This setting should be conducted on disconnection.

LIS communication setup is needed in system setup interface for the connection between the analyzer and other LIS systems. Standard RS-232 serial communication is adopted, and the ASTM1394 protocol standards are observed. Or adopt TCP/IP network interface communication, and follow HLT2.3.1 protocol standards, as Figure 5-9-1 shows:

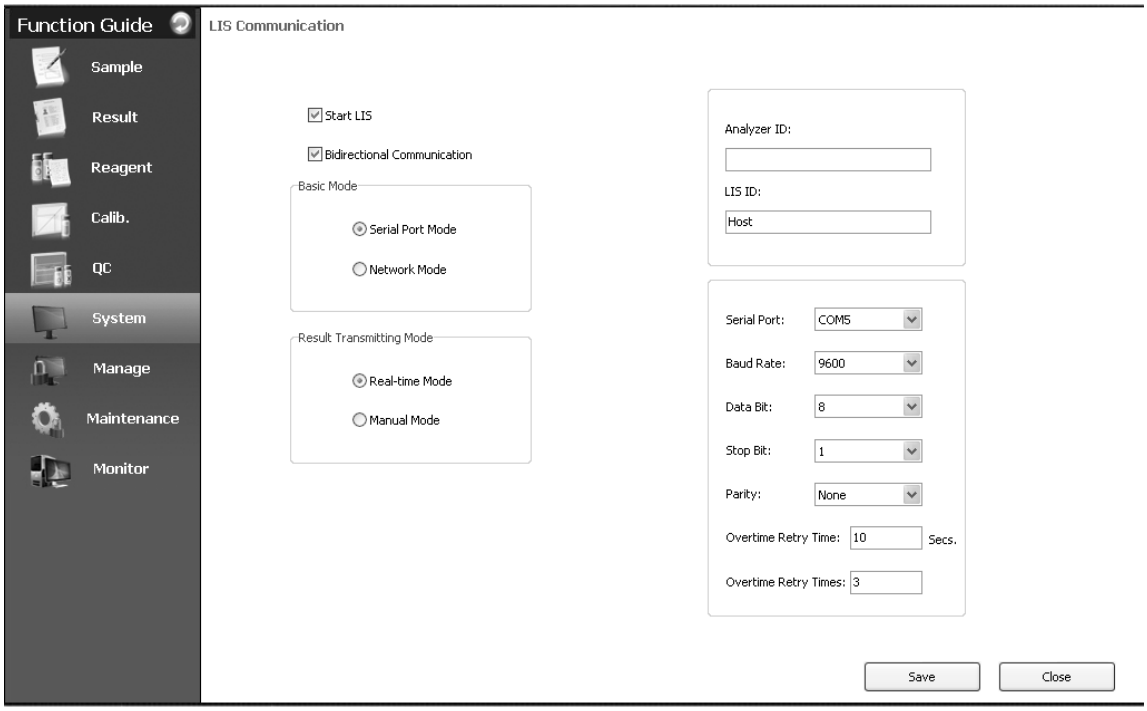


Figure 5-9-1

(1)Start LIS: Select this option, start communication with LIS, whereas, LIS communication fails.

When LIS communication status is changed, login again after exit is required.

(2)Bidirectional Communication: Select this option to fulfill bidirectional communications with the LIS.

(3)Basic mode: Serial Port Mode, which means analyzer connected with LIS through RS-232 port. Network Mode, which means analyzer communicates with LIS through IP address.

(4)Result Transmitting Mode: Two modes, real-time mode, namely, when all the items of each sample are completed, real-time transmission is carried out in the unit of sample. And manual mode, namely, manual transmission can be only conducted after the completion of the analysis.

When Serial Port Mode is selected, the parameters are set as follow:

(5)Analyzer ID: It is communication mark used in the transmission with LIS.

(6)LIS ID: It is the LIS system mark of communication with analyzer.

(7)Serial Port: Select a serial port for communication. No default value. The user should conduct setting according to the actual situation.

(8)Baud Rate: Select the serial baud rate of communications among 4800,9600,19200.

(9)Data Bit: Select the data bit of communications among 5,6, 7 or 8.

(10)Stop Bit: Select stop bit of communication among 1, 1.5, and 2.

(11)Parity: Select the communication parity bit among N, M, E, O, and S.

(12)Overtime Retry Time: Time for overtime retry.

(13)Overtime Retry Times: Times for overtime retry.

The default value for equipment communication protocol are 19200, N, 8,1. Please contact distributor for the detailed information of LIS online.

When “Network Mode” is selected, the parameters are set as follow :

(14)Mainframe IP: Input the IP of analyzer. The user should conduct setting according to the actual situation.

(15)Mainframe Port: Mainframe port No.

(16)Overtime Retry Time: Conduct communication overtime retry setting.

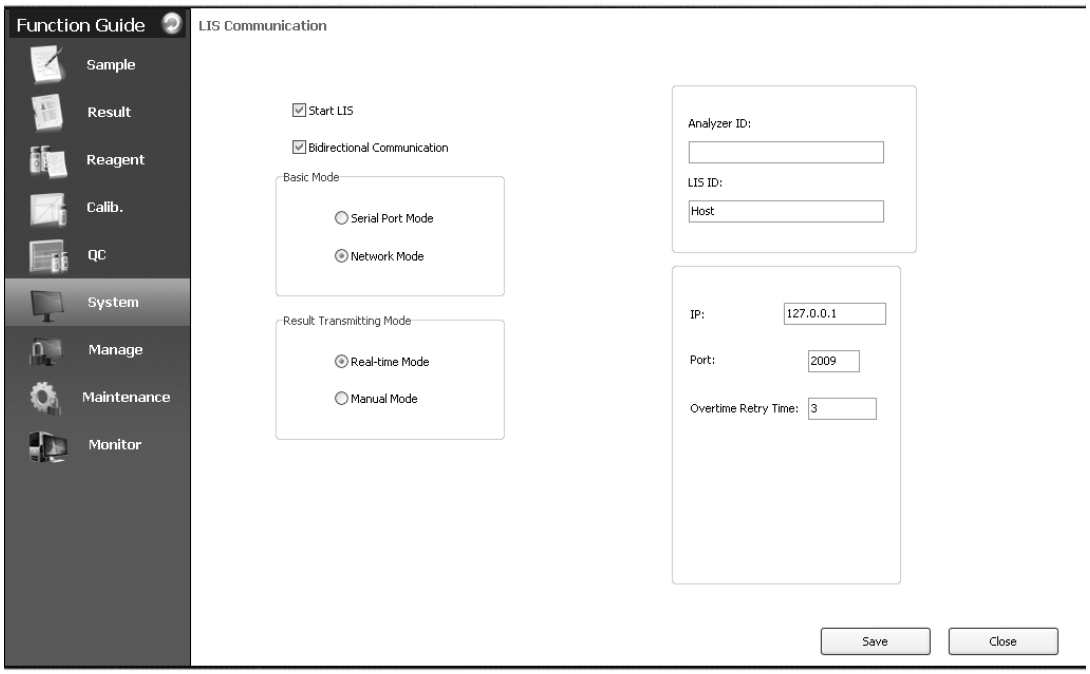


Figure 5-9-2

Chapter 6 Calibration Information

Click "

" key to register calibration information and check calibration result. Then interface displays as follow:



Figure 6-1

6.1 Colorimetric Item Calibration

6.1.1 Register Calibration for Colorimetric Item

Click "

" key in calibration information window as Figure 6-1-1 shows:

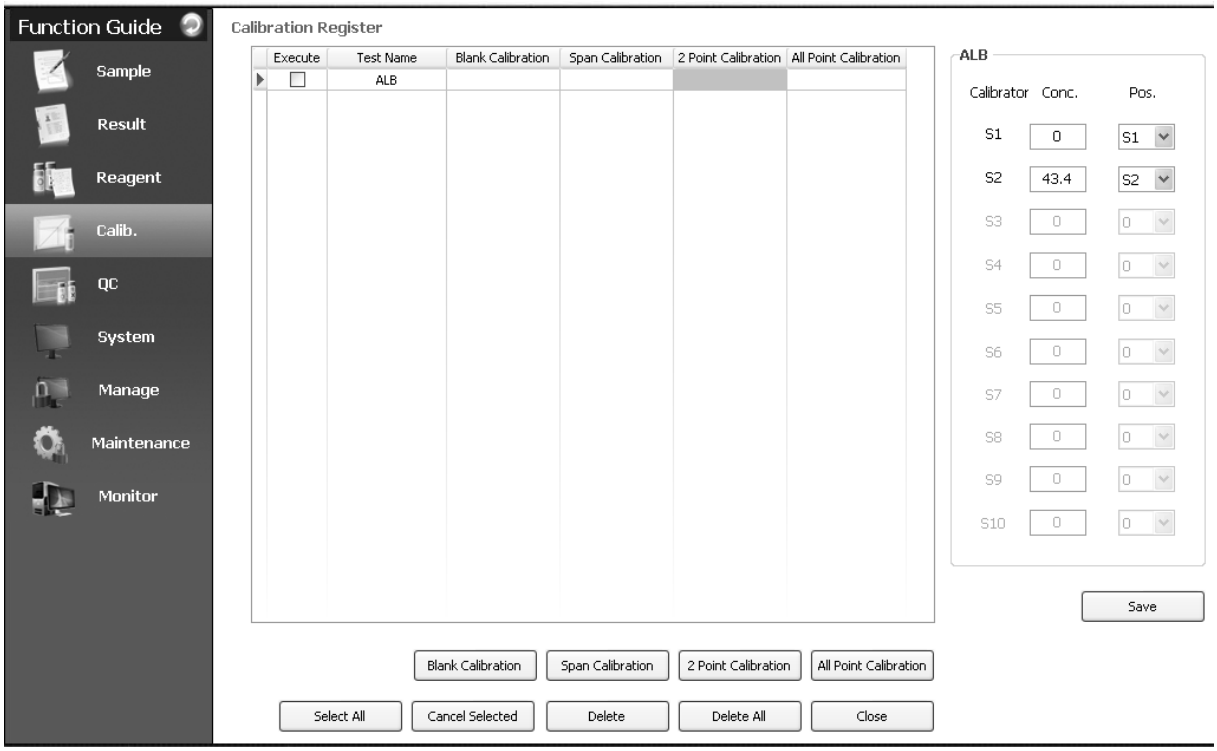


Figure 6-1-1

(1)To register calibration of colorimetric item, first select a proper calibration type. There are four types: blank calibration, range span calibration, two-point calibration, all-point calibration.

Table 6-1-1

Calibration Type	Calibrator volume	Calibration result	Calibration method	Application example
Blank calibration	Blank solution	Only reagent blank value is renewed.	All calibration methods	When K factor method is applied and calibrator test is omitted.
Range span calibration	One point out of blank solution.	Only k value is renewed.	Two-points linearity and multi-point linearity	Recheck calibrator point 1
Two-point calibration	Blank solution and span points	Reagent blank value and K value are renewed.	Two-points linearity and multi-point linearity	Linear 2-point method to make standard curve. Multi-point method is applied and the quantity of calibrator is omitted.
All-point calibration	All registered calibrator	Standard curve is renewed by all points	multi-point linearity, nonlinearity	Multi-point standard curve

Click calibration type button, e.g. Click “Two-point Calibration” button if two-point calibration of BUN needs to be conducted. As Figure 6-1-2 shows:

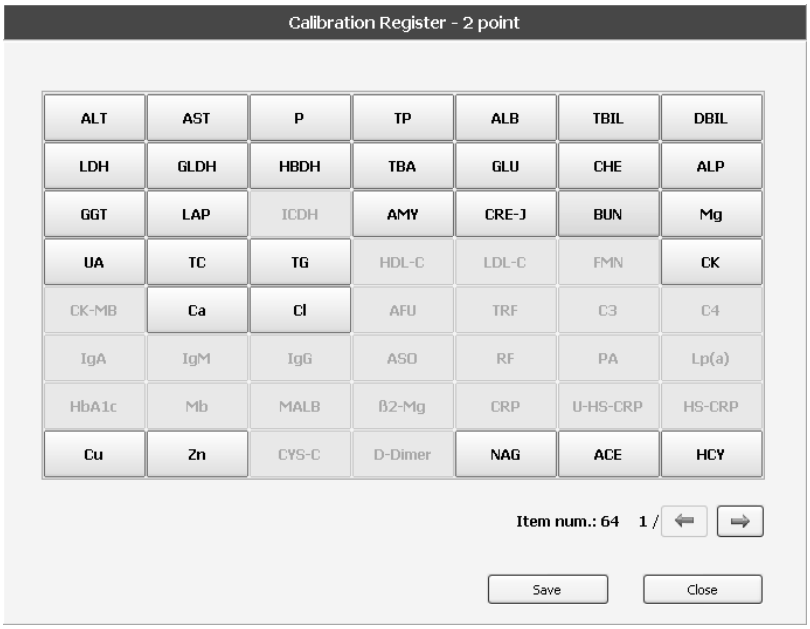


Figure 6-1-2

Select “BUN”, and click “” key. Registered item will be displayed in calibration registration area. Click “Close” key to shut down selection window of calibration items.

Successful registration of calibration item is shown in the following figure:

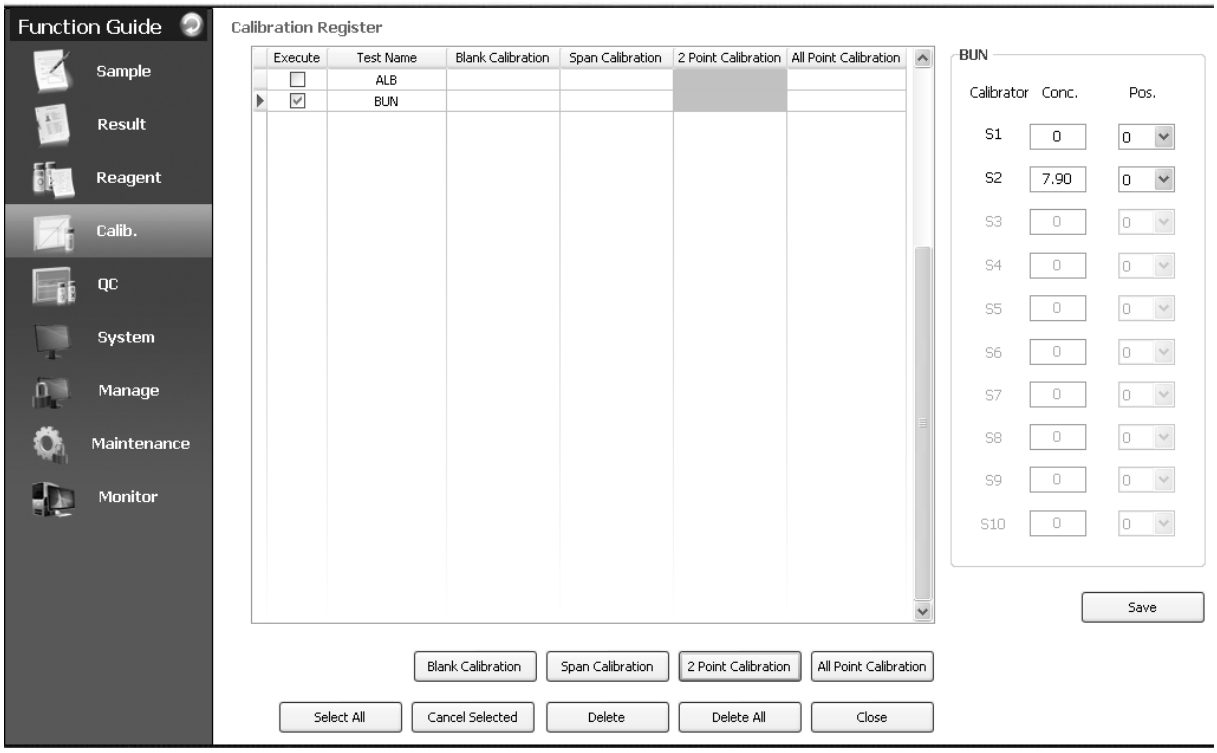


Figure 6-1-3

(2)To delete a single calibration item, select intended registration info. and click “Delete”. Or click “Delete All” to remove all registered calibration items.

(3)After registering calibration item, the user should continue to set up calibration position and concentration. Select disk number and position(0~39, 0 indicates no setup) of calibrator in pull-down box. Set up concentration of standard solution in input box according to calibrator parameters. Click “Save” after setup.

6.1.2 Calibration Result

(1)Result calibration



Click “ ” key in “Calibration Info.” area, and confirm calibration results such as reagent blank(S1ABS), K factor, approximate function of constant A.B.C from multi-points calibration curve etc. as the following figure shows:

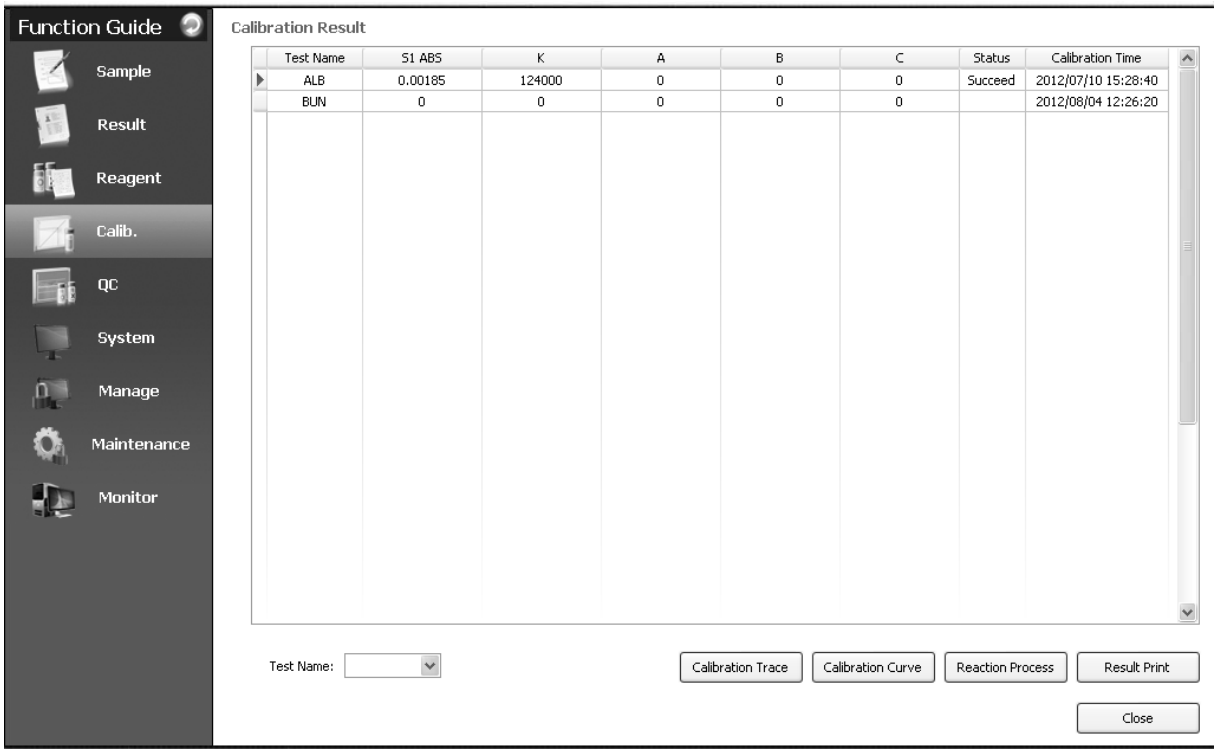


Figure 6-1-4

To change calibration result of certain item: when analyzer is in standby status, move cursor to intended box and input modified result. Then click “Enter” key.

To check calibration result of certain item. Item can be selected from the drop down list of “Test Name”. As Figure 6-1-5 shows:

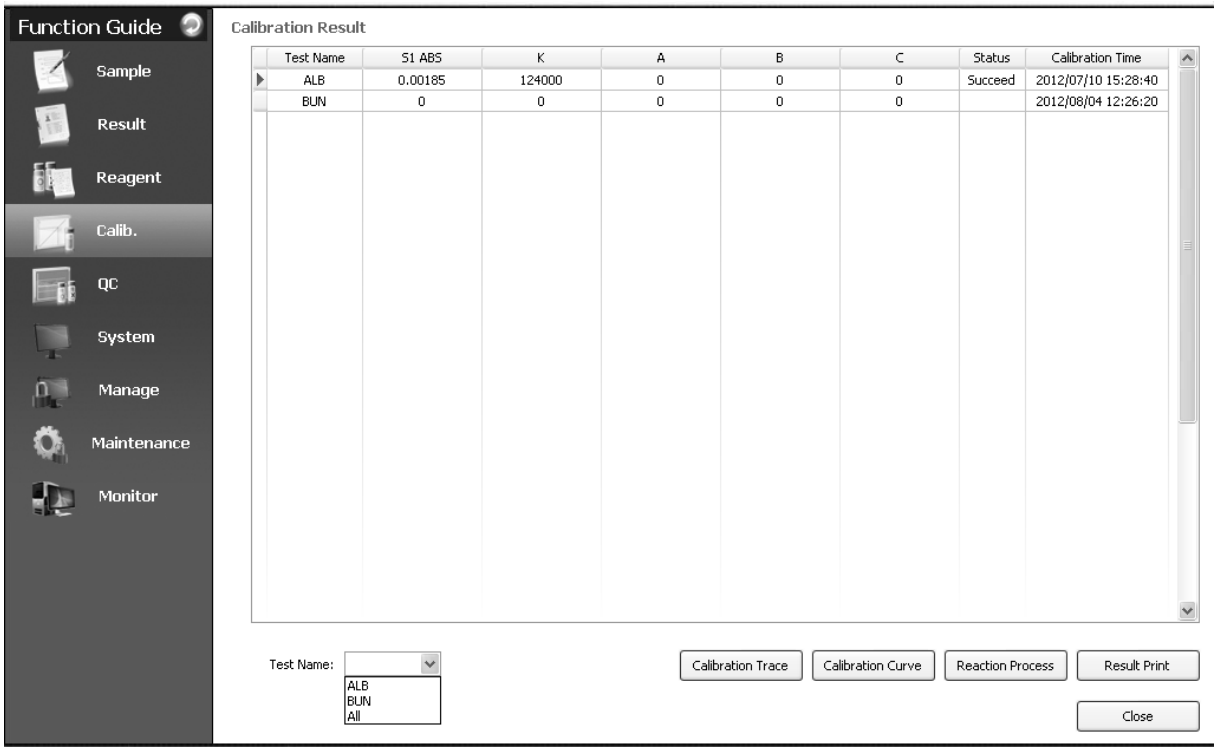


Figure 6-1-5

(2)Trace calibration

Analyzer will save absorbances of each calibration automatically. In calibration tracing interface, the absorbance change can be checked, thus confirm the calibration accuracy.

Click "Calibration Trace" as the following figure shows:

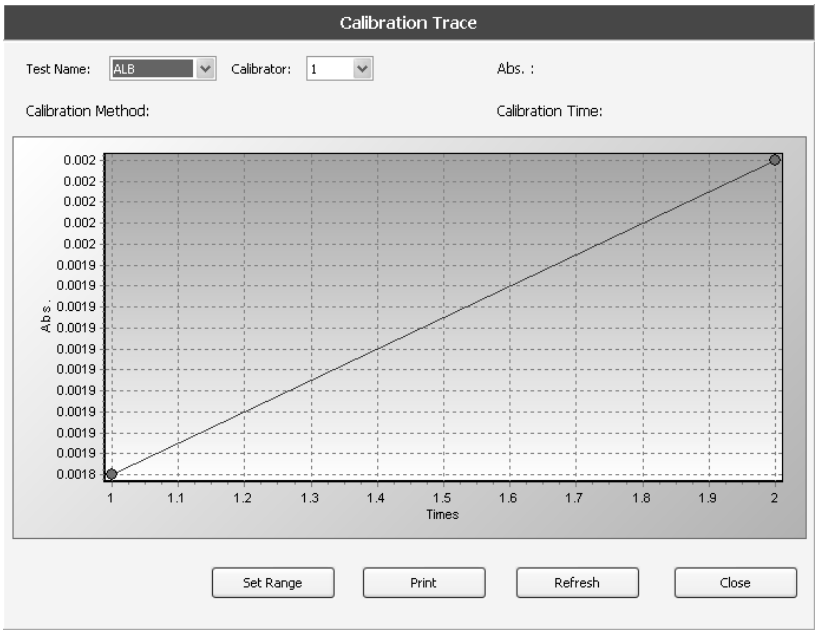


Figure 6-1-6

Select the intended item name, standard solution from the pull-down menu, the latest 50 times absorbance will be displayed. Meanwhile, the calibration method and calibration time will be displayed.

Click "Set Range" to set up absorbency range.

Click "Print" to print calibration tracing curve.

Click "Refresh" to display reaction curve of intended calibration item, in which horizontal ordinate represents calibration times while vertical ordinate represents absorbency of standard solution.

Click "Close" to shut down the window.

(3)Calibration curve

Click "Calibration Curve" in calibration result interface, as Figure 6-1-7 shows:

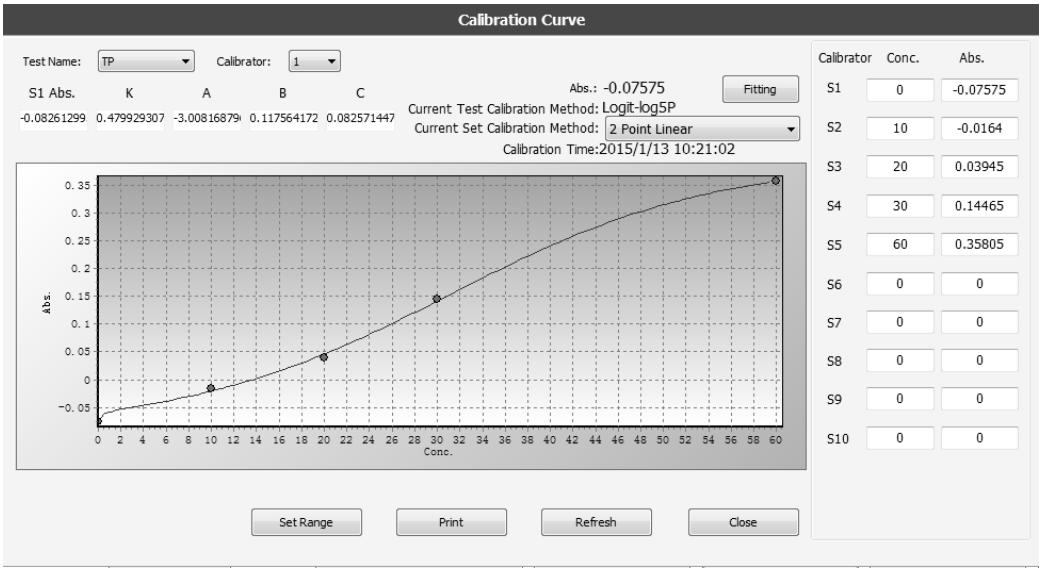


Figure 6-1-7

Select name and standard solution of intended item in pull-down box. The S1ABS, K, A, B, C value, absorbance, calibration method of current test, calibration method of current setting, calibration time will be displayed.

a)Click "Set Range" to set up absorbency range.

b)Click "Print" to print calibration tracing curve.

c)Click "Refresh" to display reaction curve of intended calibration item, in which horizontal ordinate represents calibrator concentration while vertical ordinate represents absorbency of calibrator.

d)Select the calibrator (calibrator 1~10) to be viewed from the pull-down menu to check the absorbance. The absorbance values will be shown in the Calibration Curve screen.

e)When the calibration method was set non-linear, the Abs. and calibration method can be edited. After calibration with non-linear method, if you select a calibration method from the drop-down of "Current Set Calibration Method" on the Calibration Curve screen and modify the Abs, and then click "Fitting", a new calibration curve will be generated; If you click "Save Fitting", the Abs., calibration method and related curve will be saved. The "Calibration Method" in "Item Parameters" will be changed as well.

"Current Set Calibration Method" can only be changed from multi-point calibration to single point calibration.

Click "Close" to shut down the window.

(4)Reaction process

The absorbance change can be checked in "Reaction Process" window. Through the reaction curve, the reaction status and absorbance stability can be checked.

Click Reaction Process in Figure 6-1-5, as Figure 6-1-8 shows:

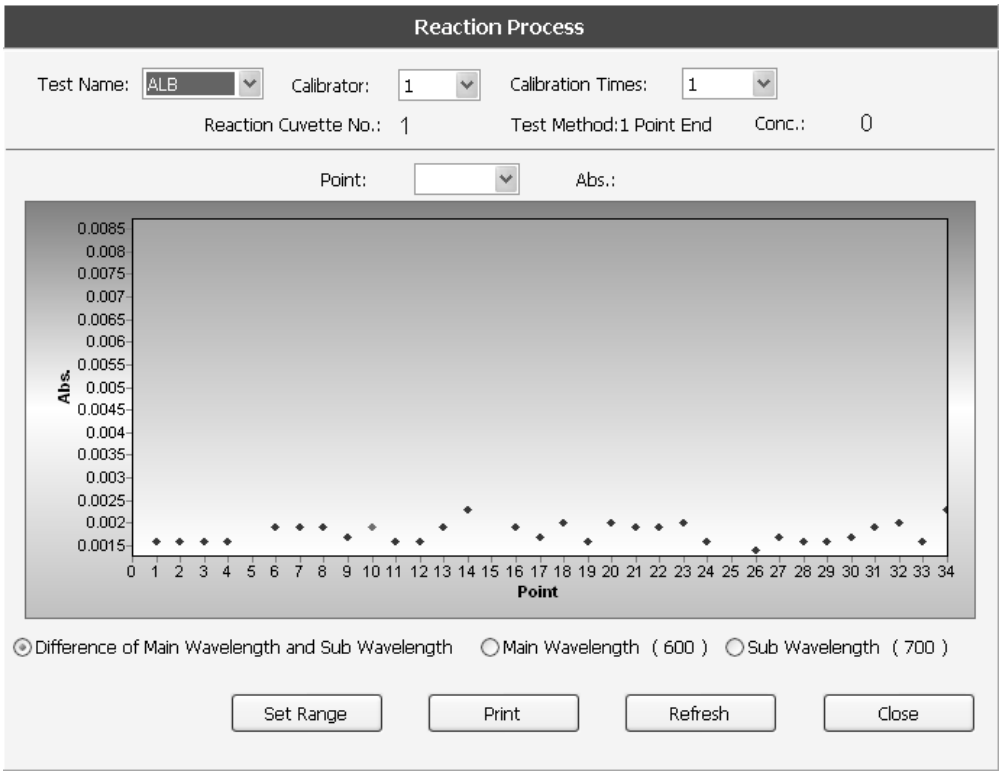


Figure 6-1-8

Select item name, calibrator number and calibrator tested time (each calibrator is tested for two times), main wavelength, sub wavelength or difference of main wavelength and sub wavelength, the curve will be displayed, in which horizontal ordinate represents photometry point while vertical ordinate represents absorbency.

a)Main wavelength minus secondary wavelength: To display the reaction curve of main wavelength minus secondary wavelength.

b)Main wavelength: To display the reaction curve of main wavelength.

c)Sub wavelength: To display the reaction curve of sub wavelength.

Select the intended point to check the absorbance.

Click "Set Range" to set up absorbency range.

Click "Print" to print calibration tracing curve.

Click "Refresh" to display reaction curve of intended calibration item, in which horizontal ordinate represents photometry point while vertical ordinate represents absorbency of calibrator.

Click "Close" to shut down the window.

The newly added items should be calibrated before test, for the inaccurate calibration result may affect the test result.

(5)Print result

Calibration result of colorimetric item can be previewed after the user clicks "Result Print". For example, click "Print" key on the top of preview window to print calibration result.

6.2 ISE Calibration

6.2.1 ISE Calibration Registration

Click ISE Calibration in "Calibration Information" window to register ISE calibration items and check the results, as Figure 6-2-1 shows:

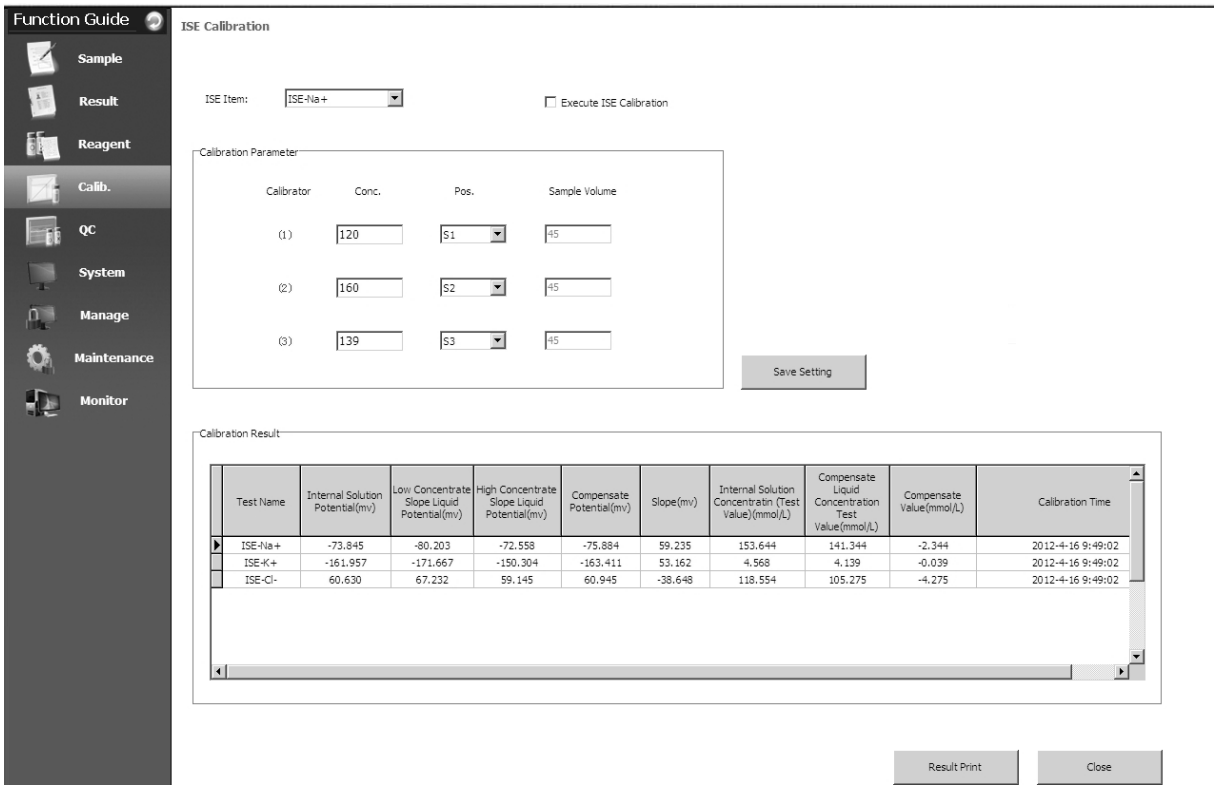


Figure 6-2-1

(1)Calibration Registration

For ISE item calibration, select item name from the pull-down menu, input the concentration and position of corresponding calibrator, click “Save Setting”, select “Execute ISE Calibration”, click “Send Test”, select “Calibration Test” in “Start Test” interface to execute calibration.

(2)Calibration test

In electrolyte test calibration, analyzer will calculate and display the result automatically. Alarm will be prompted if abnormity occur.

When conducting ISE calibration, calibrator(low, high, blood calibrator) will be tested for 3 times each. The average of the second time and the third time will be used in calculation.

6.2.2 Calibration Result of ISE Item

In “Calibration Result” work area, confirm internal standard solution potential, low concentrate slope liquid potential, high concentrate slope liquid potential, compensate potential, slope, internal standard solution concentration(test value), compensate liquid concentration test value, compensate value.

Click “Result Print” for result preview, and click “Print” for result printing.

6.2.3 ISE Determination Principle

6.2.3.1 Determination Principle

Ionic selective electrode (ISE) is an electrochemical sensor, in which there is a sensitive membrane selectively responding to a specific ion, turning ionic activity into a potential signal. In a specific range, its potential has linear relations with the logarithm of the ionic activity in the solution. Ionic activity of unknown solution can be obtained by making a comparison with solution of known ionic concentration.

Electrode potential is obtained through Nernst formula:

$$E = E_o + 2.303 \times \frac{RT}{nF} \times \log(ai) \quad \text{..... (1)}$$

$$ai = f \times C_i \quad \text{.....(2)}$$

In which:

E_o: standard potential of the determined system

R: Gas constant (8.314510 $J\times mol^{-1}\times K^{-1}$)

T: Absolute temperature (t℃+273.15)(K)

F: Faraday Constant (9.6485309×10^{4} $C\times mol^{-1}$)

ai: Ionic (i) Activity

f: Activity Coefficient

C_i: Concentration

n: Electric charge number of the given Ion (i) (Cation is positive; Anion is negative)

6.2.3.2 Determination Method

(1) Preparation for Working Curve

Determine the low-concentration slope solution (S1) and high-concentration slope solution (S2), and determine the slope values (sensitivity) of K, Na and Cl electrodes respectively.

$$SL=\frac{E(H)-E(L)}{\log\frac{C(H)}{C(L)}} \quad \text{(3)}$$

In which:

SL: slope

E(H): Difference between potentials of high-concentration slope solution and reference solution

E(L): Difference between potentials of low-concentration slope solution and reference solution

C(H): Concentration of high-concentration slope solution (Input Value)

C(L): Concentration of low-concentration slope solution (Input Value)

(2)Determining concentration of internal standard solution

$$C(IS)=C(L)\times10^{\frac{E(IS)-E(L)}{SL}} \quad \text{(4)}$$

In which:

C(IS): Concentration of internal standard solution

E(IS): Potential of internal standard solution

(3)Concentration Calculation

Use the concentration of the low-concentration slope liquid as a benchmark, and figure out the concentration of routine samples, emergency samples, and Control.

$$C(S)=C(L)\times10^{\frac{E(S)-E(L)}{SL}} \quad \text{(5)}$$

In which:

C(S): Sample concentration

E(S): Sample potential

(4)Result correction

After calibration, determine calibration solution of the serum type (namely S3 calibration), and figure out its concentration. Use the difference between this determined concentration and the input value as a compensation value, and make the value plus and minus the sample quantitation value.

$$C(VALUE)=C(C)-C(X) \quad \text{(6)}$$

In which:

C(VALUE): Compensation Value

C(C): Input value of Serum Calibration Solution Concentration

C(X): Actual Measurement of Serum Calibration Solution Concentration

$$C'(S)=IF\{C(S)+C(VALUE)\} \quad \text{(7)}$$

In which:

C′(S): Sample Concentration After Correction

IF: Analyzer Constant (usually 1.0)

(5)Standard Specifications of Electrolyte

Table 6-2-1 Standard Specification of Electrolyte

Item	Specification
Sample volume	45μL
Diluent Volume	900μL
Processing Capacity	150T/H (electrolyte determination only)
Determination Range(Serum)	Na^+ 80~200mmol/L K^+ 1.0~9.0mmol/L Cl^- 50~200mmol/L
Reagent Consumption Volume	Reference Solution 400μL/Sample Diluent 900μL/Sample Internal Standard Solution 1100μL/Sample

Chapter 7 QC Management

Quality control in lab is to guarantee reliable result of each sample. The reliability includes two aspects. One is precision: precision means good repeatability. Precision control is mainly to eliminate or reduce impact caused by random error. The other one is accuracy: accuracy means test result is correct and close to truth value. Accuracy control is mainly to eliminate or reduce impact caused by systematic error.

Random error: The difference between mean value of numerous test results of same target under repetitious conditions is called random error.

Systematic error: The difference between true value and mean value of the same target tested repetitiously is called systematic error. It is the component expected not to be zero in test results.

Accuracy: The combination of systematic error and random error in the test result is called accuracy. It indicates the accordance degree between test result and true value.

Precision: The magnitude of random error in test results is called precision. It means the accordance degree among test results in specified conditions.

L-J (Levey Jennings) QC chart: QC chart is a graph with quality control limits. QC limit is confirmed by the mean value ($\overline{X}$) and the standard deviation (SD), which are acquired through detecting known sample repetitiously with controlled analysis. $\overline{X} \pm 2SD$ is the warning limit while $\overline{X} \pm 3SD$ is the out of control limit.

Click "

" key under Function Guide as the following figure shows:

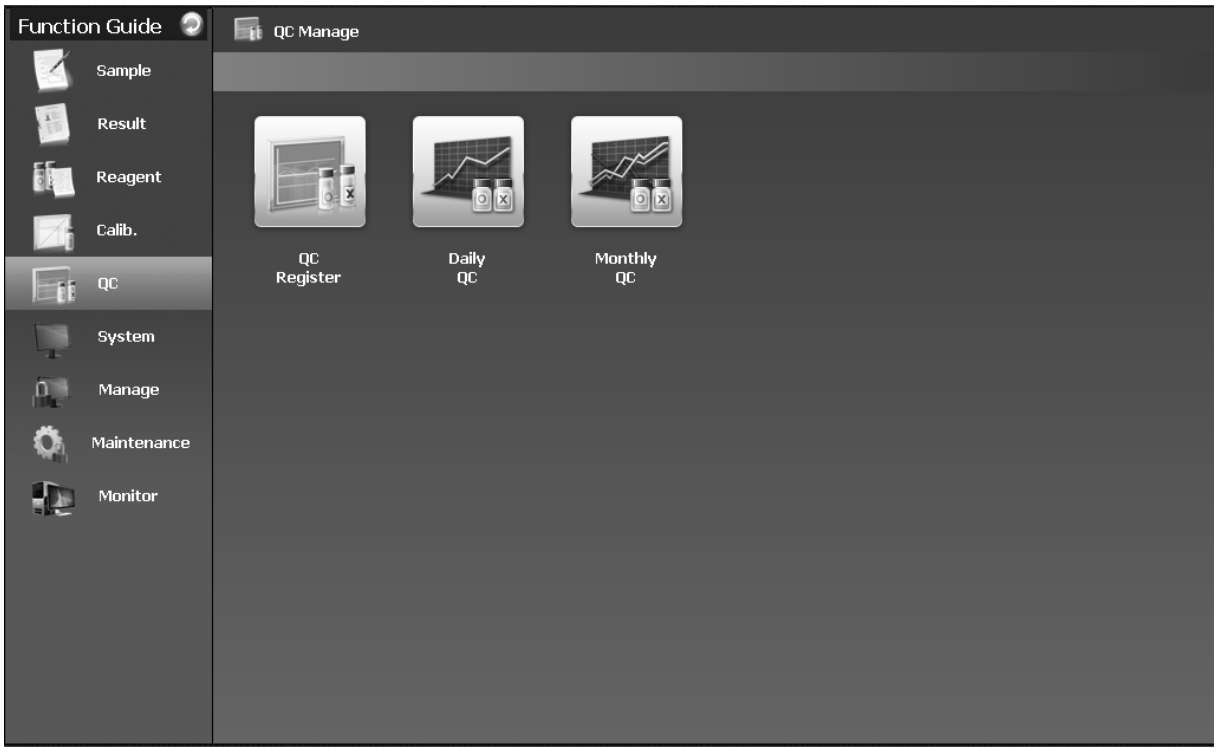


Figure 7-1

7.1 QC Registration

Click "

" key in working area, and then QC registration window pops up as the following figure shows:

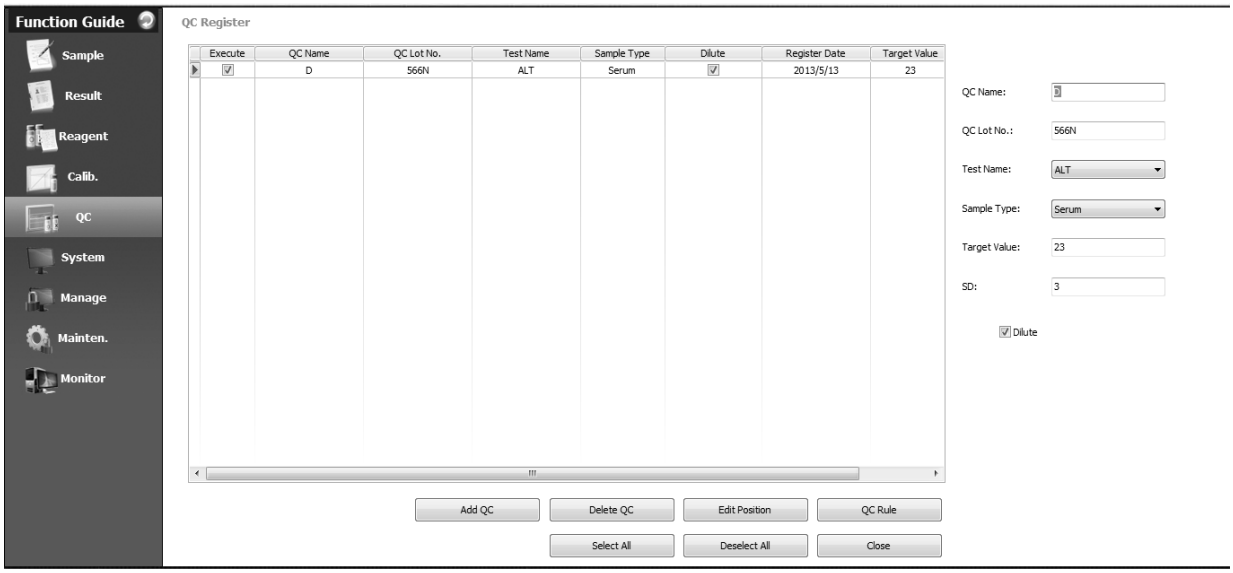


Figure 7-1-1

In QC registration window, the user can add and delete QC items, and set up QC position and rule. Maximum 8 kinds of Controls can be used at the same time.

7.1.1 QC Multirules

(1)Click “QC Rule” key in “QC Register”, and the Westgard QC rules will be showed as the following figure:

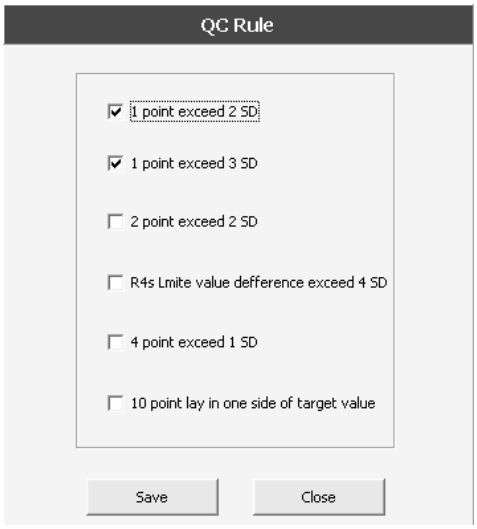


Figure 7-1-2

The user selects proper QC rules, and clicks “Save” for saving, and click “Close” to return to QC registration window. After setup, uncontrollable analysis for QC data will be conducted in accordance with QC rules in “Monthly QC” windows.

According to Westgard multi-rule benchmark for judgment, the uncontrollable analysis will be carried out. The logical chart of Westgard multirules is showed as follows:

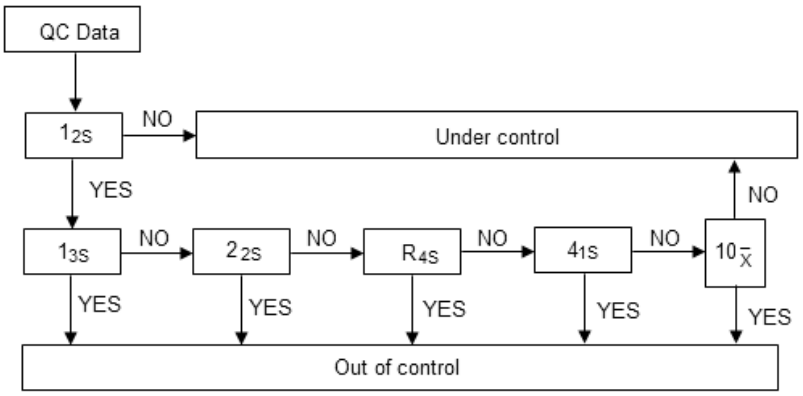


Figure 7-1-3 Logical Chart of Westgard Multirules

(2)Instruction for judgment benchmark:

1_{2S}: When one QC result exceeds mean value ±2 SD, this can be judged as warning rule and starting to check QC data by other rules.

1_{3S}: When one QC result exceeds mean value ±3 SD, this can be judged as out of control. This rule is mainly sensitive to random error.

2_{2S}: When two consecutive QC results exceed mean value +2 SD or -2 SD at the same time, this can be judged as out of control. This rule is sensitive to systematic error.

R_{4S}: When one control result exceeds mean value +2 SD and another exceeds -2 SD, this can be judged as out of control. This rule is sensitive to random error.

4_{1S}: When four consecutive QC results exceed mean value +1 SD or -1 SD at the same time, this can be judged as out of control. This rule is sensitive to systematic error.

$10_{\bar{x}}$: When ten consecutive QC results fall on the same side of mean value (higher or lower than mean value, without requirement of deflection degree), this can be judged as out of control. This rule is sensitive to systematic error.

7.1.2 Add QC Parameters

On the right side of "QC Register" window, QC item information can be set up.

(1)Input QC name in "QC Name".

(2)Input Control lot No. in "Lot No.".

(3)Select items from the pull-down menu of "QC Item".

(4)Select type of samples in "sample type" pull-down menu.

(5)Input target value and standard deviation.

(6)Put a tick in the check box of "Dilution" to set whether to dilute Control ("☑" means selected; "☐" means not)

QC tests cannot be carried out until "Sample volume for dilution" and "Diluent volume" are set up in "Analytic Parameters" after selecting "Dilution".

Click "Add" key when above parameters are correctly inputted. All inputted parameters are saved in the left work area.

After registering the QC item, make sure check which item may carry out QC test, click "Execute" key in front of QC item.

Execute	QC Name	QC Lot No.	Test Name	Sample Type	Dilute	Register Date	Target Value
☑	D	566N	ALT	Serum	☑	2013/5/13	23

7.1.3 QC Parameter Modification

If registered parameters need modify, click the desired items in the left side of file, the color will change. Saved QC parameter will display in the right side of field. Directly input the parameter on the item, then click "Add" key to finish this procedure.

7.1.4 Delete QC Item

Click the item to be deleted in the left side of field to eliminate the registered information, color changes after being clicked. Click "Delete" key to finish this operation. All information of this item will be deleted.

7.1.5 Set QC Position

Click "Edit Position" in "QC Registration", edit widow will pop up ,as Figure 7-1-4 shows:

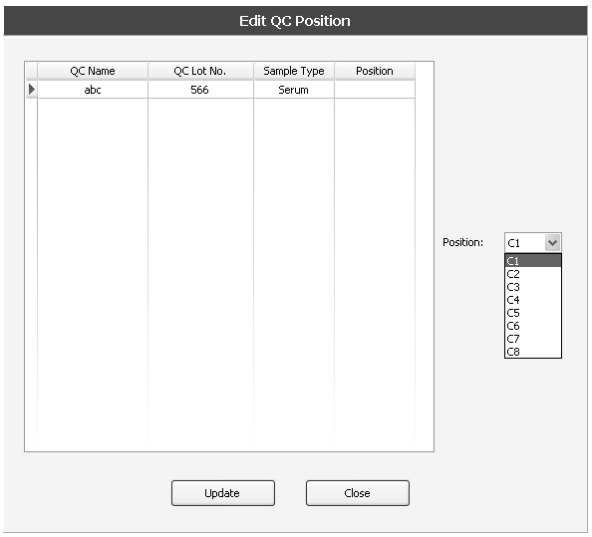


Figure 7-1-4

Click the QC information needs position registration. The color will change after selection. Select the position No. and click "Update" to finish registration. Click "Close" for exit.

Same item with different QC name at same QC position can not be tested simultaneously.

7.1.6 QC Test

Check the reagent placement after QC registration, execute reagent horizontal scanning. Place the Control in corresponding position, click "Start Test", select "QC Test" in "Start Test", as shown in Figure 7-1-5:

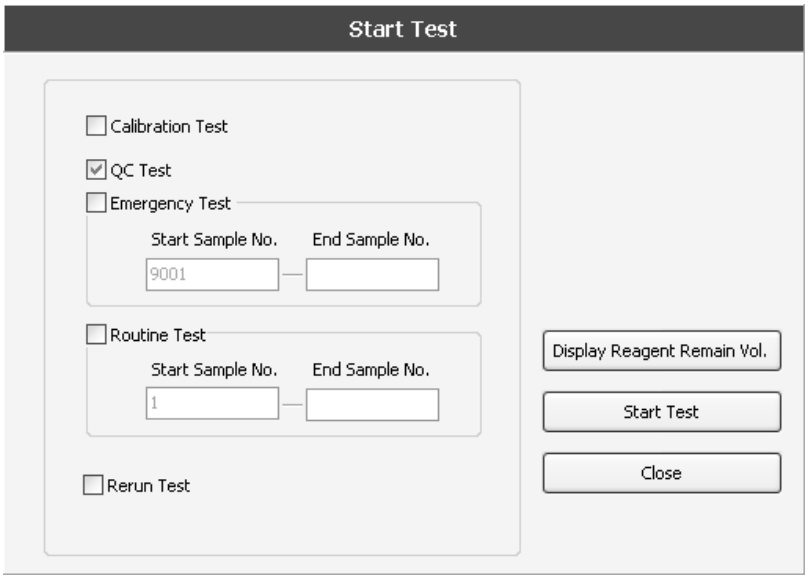


Figure 7-1-5

Click “Start Test”.

7.2 QC Interval

After QC test finish, analyzer will automatically calculate real test QC target value (mean value), standard deviation, coefficient of variation, etc. .

Target value $(\overline{X})$: $\frac{\sum_{i=1}^{N} X_i}{N}$

Standard deviation(SD): $\sqrt{\frac{\sum_{i=1}^{N}(X_i - MV)^2}{N-1}}$

Coefficient variation(CV%) : $\frac{SD}{mv} \times 100\%$

Deviation: $X_i - (MV)$

% Error: $\frac{Deviation}{mv} \times 100\%$

N: test times

Xi : test result.

Click “Daily QC” in “QC Management” window, as Figure 7-2-1 shows:

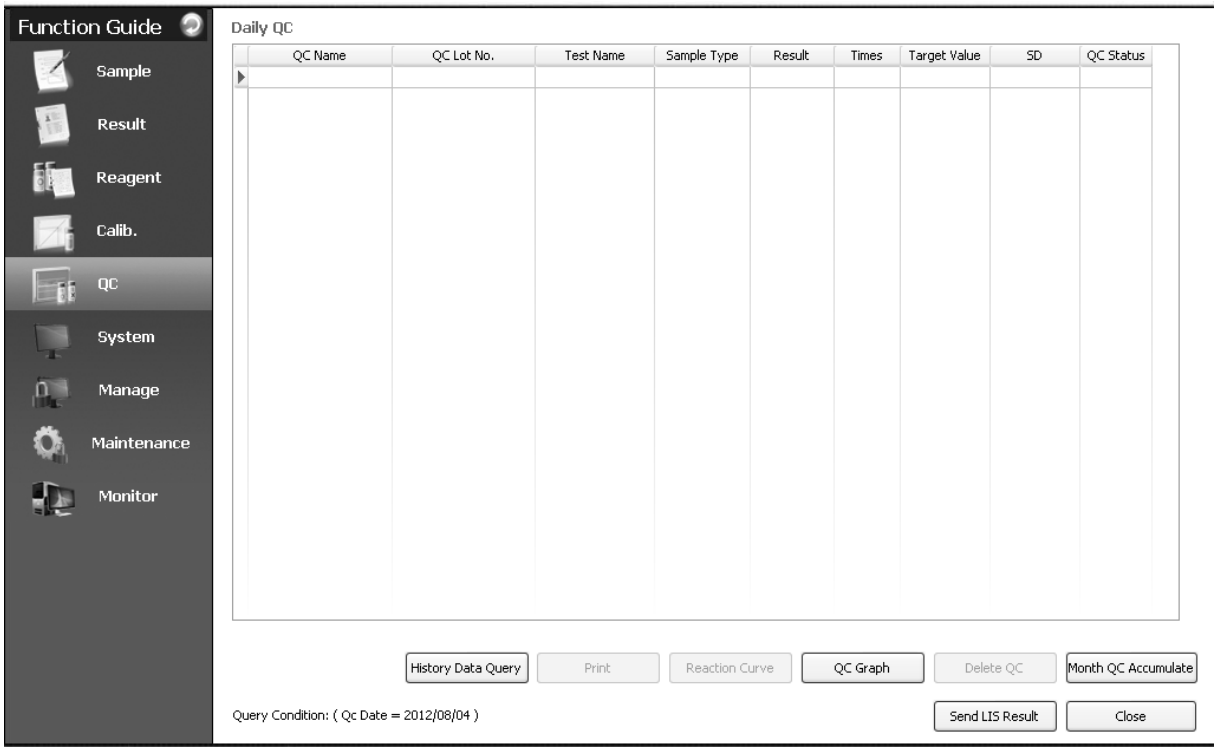


Figure 7-2-1

Daily QC result will be displayed in QC list.

(1)Click “Print” to print the QC result of the day.

(2)Click “Reaction Curve” to check the reaction process.

(3)Click “QC Graph” to switch between “QC Data” and “QC Chart”. If the current status is “QC Chart”, click “Print” to print the report of the day.

(4)Select the QC result in QC list, click “Delete QC” to delete this information.

(5)Monthly QC Accumulation

a)Manual Accumulation: Click the “Monthly QC Accumulate” key, select QC information according to items, and click “Accumulate” key to accumulate the mean of the daily QC results of the current day tests to QC account. After QC information accumulation, the user can choose whether to delete daily QC results.

b)Automatic Accumulation: To conduct automatic accumulation of monthly QC results of all QC items, select “Automatically Accumulate Monthly QC Results” from the “Other Info.” window under “System Setting”. The last result of the QC tests of the current day will accumulate to monthly QC automatically.

If the above 2 modes of monthly QC accumulation are not selected, the QC results of the current day will not accumulate to monthly QC.

(6)Click “Send LIS Result” to send the displayed result to LIS system.

(7)Click “History Data Query” key, and Figure 7-2-2 is shown:

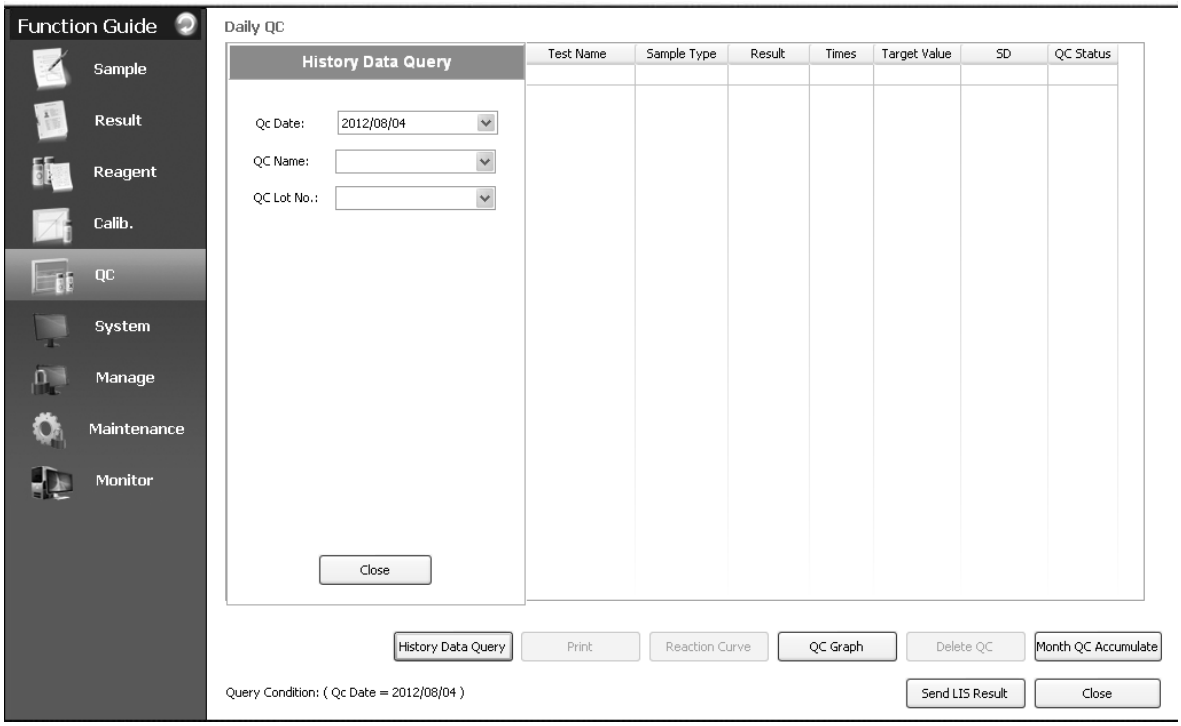


Figure 7-2-2

Select a QC date, QC name and QC lot No., and all the QC data corresponding to the selected information will be displayed in the right list.

7.3 Monthly Quality Control

Click 

in "QC Management" window, as shown in Figure 7-3-1:

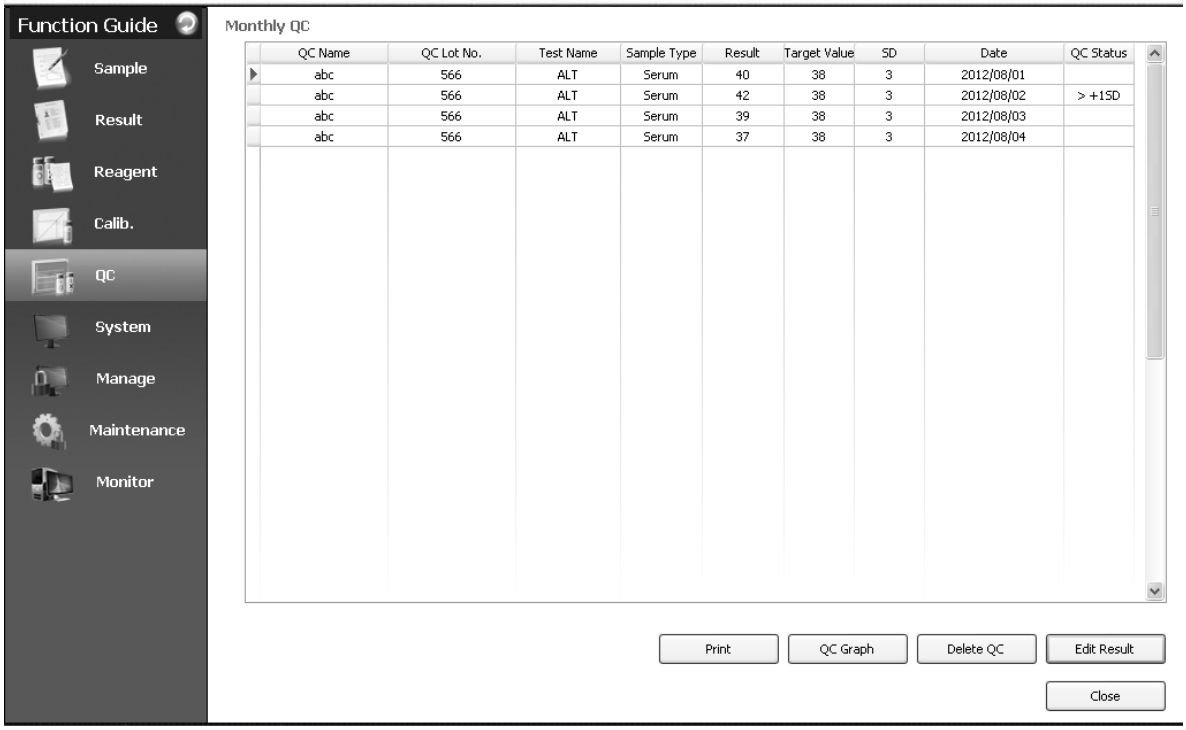


Figure 7-3-1

Display monthly QC information and result in “QC” list.

(1)Click “Print” to print the monthly QC result list.

(2)Click “QC Graph” in “Monthly QC” window, to switch between “QC Data” and “QC Graph”, as shown in Figure 7-3-2:

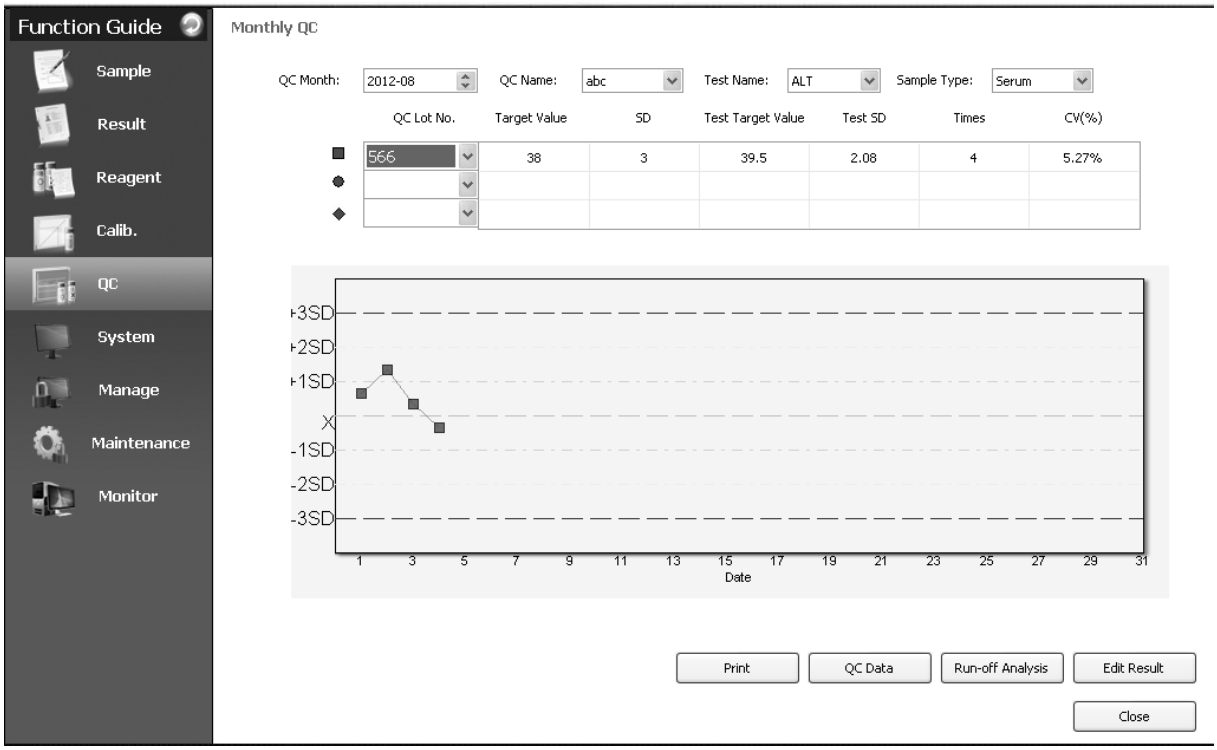


Figure 7-3-2

Select “QC Month”, “QC Name”, “Test Name”. And select QC lot No. in . The QC results will be displayed in “QC Graph” in the form of points.

Click “Print”, as shown in Figure 7-3-3:

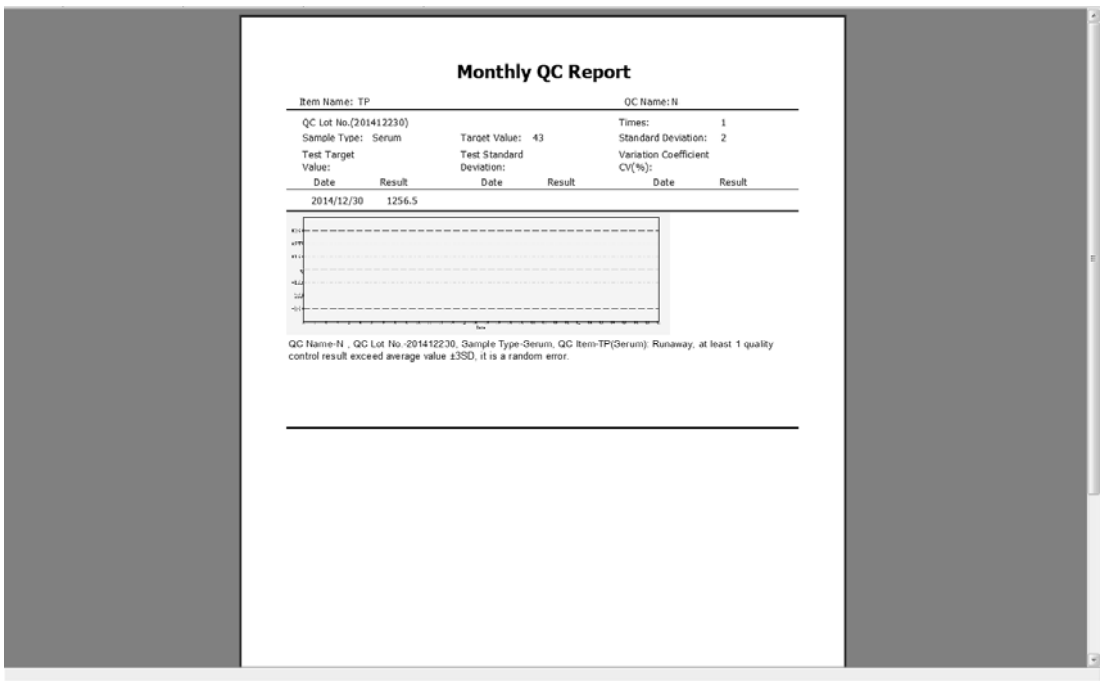


Figure 7-3-3

Click “Print” to print monthly QC report.

Click “Run-off Analysis”, as shown in Figure 7-3-4:

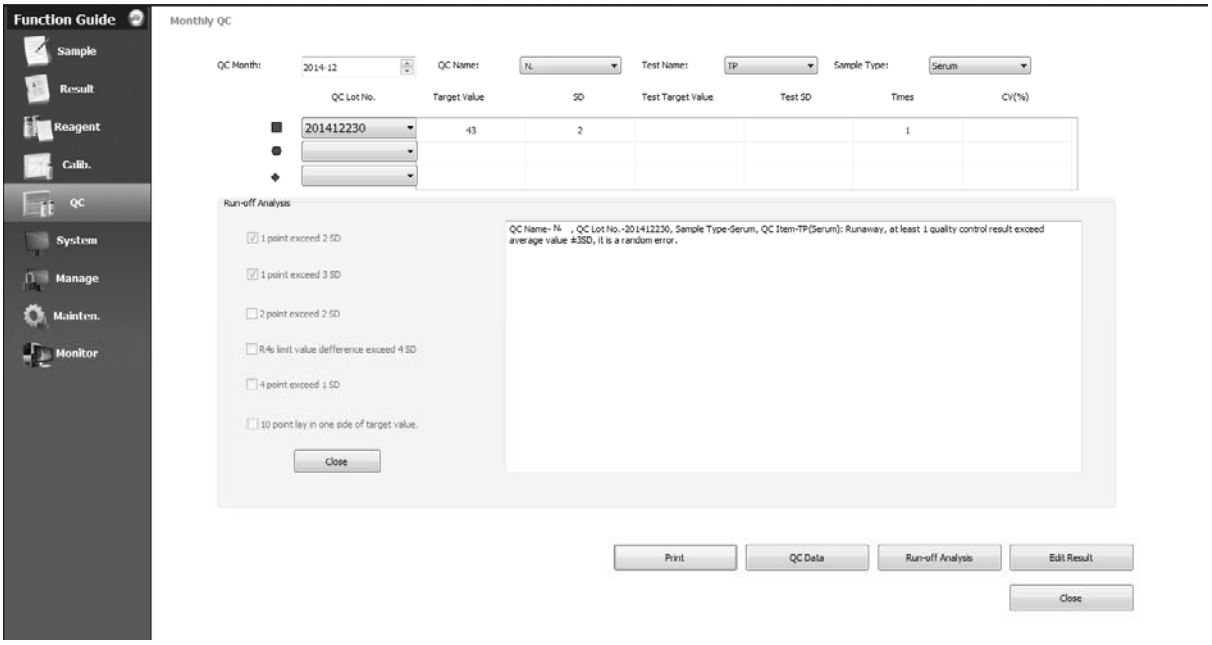


Figure 7-3-4

Conduct out of control analysis according to Westgard multi-rules and display the analysis contents.

Click “Edit Result”, and Figure 7-3-5 will be shown:

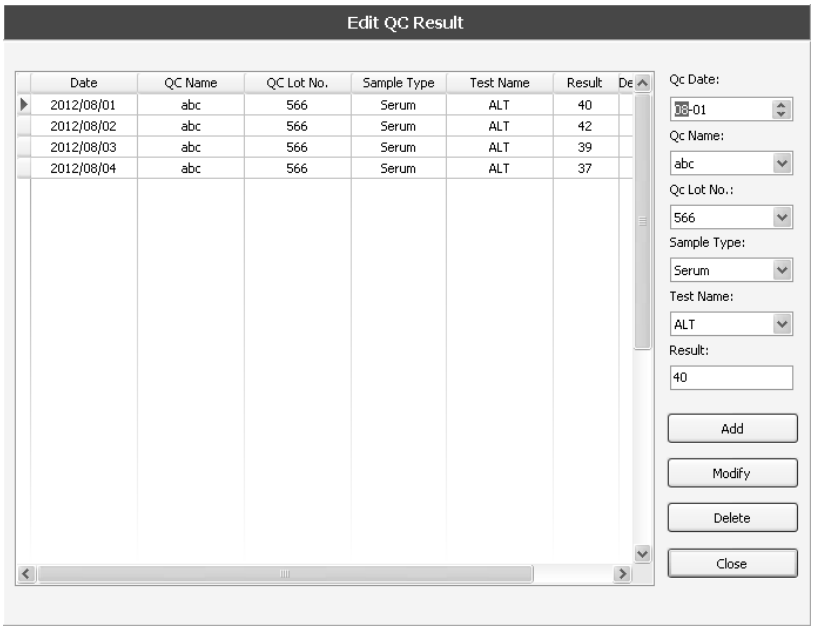


Figure 7-3-5

Select “QC Date”, “QC Name”, “QC Lot No.” and “Test Name” of the intended result needs to be modified in corresponding drop down list. Input QC result in “Result”, and click “Add” to add QC result.

Select “QC Date”, “QC Name”, “QC Lot No.” and “Test Item” of the intended result needs to be modified in corresponding drop down list. Input QC result in “Result”, and click “Modify” to modify QC result.

Select the intended result needs to be deleted in list. And click “Delete” to delete QC result.

You can input, modify or delete the content shown in the right column of Run-off Analysis. After edition, the content will be displayed under the QC diagram by clicking “Print”. Once you exit the Run-off Analysis screen, the content you edited will not be saved. Click 

to close the window.

Chapter 8 Analyzer Operation

8.1 Operation Overview

Table 8-1-1 describes brief sequence of operation. Users can refer to "Chapter 8.2 Detailed operation" for details.

Operation Step	Window / Key	Operation	Cross Index
1. Check before test	——	Check before power-on.	8.2.1
2. Connect pure water unit and power on Software login	 System Login	Turn on the water faucet, connect the pure water unit, and power on the analyzer Input user's name and password.	8.2.2
3. Confirm analyzer status 1) Confirm alarm 2) Confirm incubation bath temperature	Alarm information Status bar	Refer to "Chapter 11 Alarm and disposal of analyzer malfunction". Confirm if incubation bath temperature is within (37.0±0.1)℃	8.2.3
4. Confirm analytical parameters 1) Add items 2)Set and confirm chemical parameters 3) Check K value	 System setup System setup Calibration info.	 Add chemical items Set and confirm chemical parameters Confirm calibration curve and K factor	8.2.4
5. Prepare reagent (reagent info.) 1)Confirm reagent remaining volume 2)Prepare reagent for photometric and ISE items	 Reagent info. Reagent info.	 Confirm reagent remaining volume and remaining test times. Place the needed reagent at the corresponding position on the reagent disk.	8.2.5
6. Setup of calibration and QC items	Calibration info. Quality control	Confirm item name of calibration analysis Confirm item name of QC test	8.2.6
7. QC registration and test	QC management Send test	Confirm item name and Control position of QC test Send test	8.2.7
8. Start test (1)Prepare sample, Calibrator, and Control (2)Send test instruction	Start test	Place sample, Calibrator and Control in sample disk Conduct "Start Test" to make analysis	8.2.8
9. During test (1)Monitor system (2)Stop and continue sample adding (3)Emergency stop (4)Sample complementing	 System monitoring Sample adding pause /continuing Emergency stop Sample registration	 Real-time monitoring of analyzer test mode During test, edit sample and click "Start Test"	8.2.9
10. Confirm test result	Test result	To inquire, modify, delete, verify and print test result. Check sample reaction curve.	8.2.10
11. Determination of recheck sample	Test result	Confirm conditions for recheck item, click "Start Test", and send instruction of recheck test.	8.2.11
12 Complete analysis 1)Recheck result 2)Backup database 3)System sleep 4)Power off 5)Prepare next operation	 Test result System management	 Confirm, verify and print recheck result. Periodically backup database. Once a month is suggested. Analyzer automatically wakes up at the set time. Cut off all the power of analyzer, computer and pure water unit Clean up analyzer for next operation.	8.2.11

8.2 Detailed Operation

8.2.1 Check Before Test

Before test, check the following aspects:

(1)Check if power is on.

(2)Check communication wires among analyzer, computer and printer. Ensure correct connection and fastening.

(3)Check if print paper is enough. Add paper if necessary.

(4)Check if there are water drops, contamination or bending on reagent probe, sample probe, mixer and rinsing nozzle.

(5)Check if detergent is enough. Anti-Bacterial Phosphor-Free Detergent must be placed in position 45 of reagent disk 1 and 2; Alkaline Detergent in the detergent box in the front of the analyzer should be enough; Detergent in position W1, W2, and W3 of the sample disk should be enough. Choose which sample disk detergent to use in accordance with the actual situation. Refer to Chapter "10.1.3 Detergent" for detailed information on detergent.

(6)Check if the waste liquid barrel is emptied. Users don't have to do this, if the waste liquid discharging device is connected with a sewer.

(7)Check if there are bubbles in syringe pump. (Leakage and bubbles can cause incorrect data).

Detergent should be considered as corrosive liquid. Once in contact with skin and eyes, rinse with a large quantity of clear water.

8.2.2 Power on and Software Login

(1)Turn on the water faucet. Power on pure water device with exclusive power supply.

(2)Power on general power supply, analysis system power supply, refrigeration power supply. In order to ensure stable reagent, it is suggested to switch on refrigeration system and general power supply when reagent disk is loaded with reagent.

(3)Login Analyzer software. Submit online order before starting test.

8.2.3 Confirm Analyzer Status

8.2.3.1 Confirm Alarm

(1)Buzzer Setting

Select "☑ Buzzer On " from "Other Info." under the "System Setting" window. The buzzer will buzz to give an alarm.

When the analyzer gives an alarm and the buzzer buzzes, click the alarm icon to enter the alarm information window. Click "Turn Buzzer Off" to stop the buzzing. Buzzing can also be stopped, if the alarm information is deleted.

(2)Alarm Information Seeing

When the analyzer gives an alarm, the alarm icon "" will flash. To see alarm information, click the alarm icon to enter the alarm information window. To see the alarm information of the past, enter "System Log" under the "System Management" window.

(3)Words of Alarm Information

When the analyzer gives an alarm, the alarm code, alarm level, brief description of alarm information, and alarm time will be displayed. As shown in Figure 8-2-1:

	Code	Level	Content	Time
▶	0-50	Warning	Sample Rack-N001: Sample rack placing error.	2011-7-25 18:14:05

Figure 8-2-1

To see the detailed information of alarm records, click information strips, and the detailed description of alarm information will be displayed in the following textbox. As shown in Figure 8-2-2:



Figure 8-2-2

Meanwhile, solutions will be displayed in the textbox beneath "Detailed Description". As shown in Figure 8-2-3:



Figure 8-2-3

Users can deal with problems by referring to the solutions. If the malfunction cannot be solved, contact maintainers of after-sales service.

(4)Alarm Information Deleting

Click "Refresh", the alarm information of the current status will be displayed.

Click "Delete All", all alarm records under the "Alarm Information" window will be deleted. After selecting the alarm information that is to be deleted, click the "Delete" key. The alarm code record corresponding to the selected record will be deleted.

(5)Alarm Information Setting

Click "AlarmSetup", a window will pop up as the figure below shows:

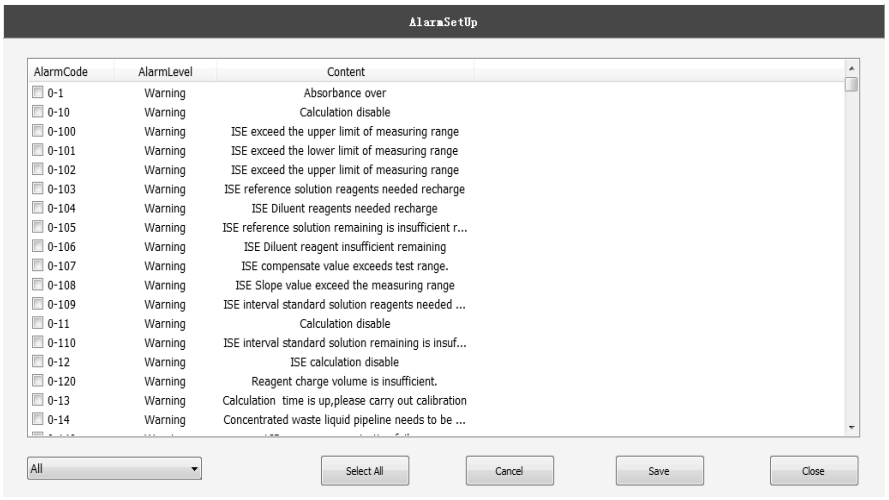


Figure 8-2-3(a)

Select the alarms to be set or click "Select All" to select all the alarm info., then click "Save" to save the current selection.

After the settings are saved successfully, the Alarm Info. screen will not show the alarms you selected when the testing process triggers the related alarm.

- **All the alarms shown on the AlarmSetup screen are the warning level, you can select as required.**
- **The "AlarmSetup" button will be shown only when you login as the administrator.**

(6)To exit the "Alarm Information" window, click the "Close" key in the alarm information working area.

8.2.3.2 Check on Light Intensity

In the "Maintenance" window, click "Cuvette Blank & Light Intensity" to conduct checks on cuvette blank and light intensity.

In the "Cuvette Blank & Light Intensity" window, select Light Intensity Check, namely "Light Intensity Check", as shown in Figure 8-2-4:

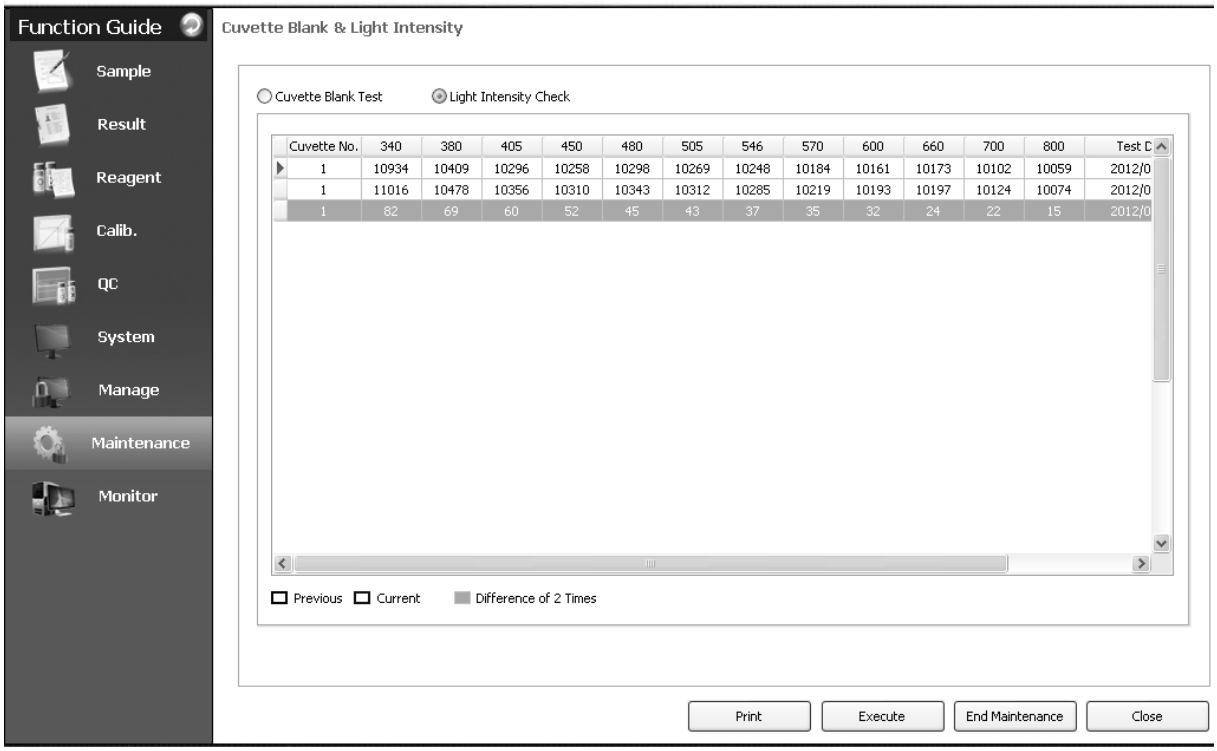


Figure 8-2-4

Click "Execute". Then analyzer will automatically conduct the power test of light source. And previous and current test values of light intensity will be displayed together, and the difference value will be calculated automatically. Users can decide whether to print or not.

Halogen tungsten lamps will be old gradually, and check values will increase gradually. AD value of each wavelength in every check on light intensity should be smaller than or equal to 18000. Usually, 340nm is the largest value. For light source replacing, refer to Chapter "10.4.3 Light Source Lamp".

8.2.3.3 Confirm Cuvette Blank

In the "Maintenance" window, click "Cuvette Blank & Light Intensity" to conduct cuvette blank tests. In the "Cuvette Blank & Light Intensity" window, select "Cuvette Blank Test", namely "Cuvette Blank Test". Click "Execute", the analyzer will automatically conduct cuvette blank tests of 160 reaction cuvettes, and the results will be displayed in "Cuvette Blank Test" window, as shown in Figure 8-2-5:

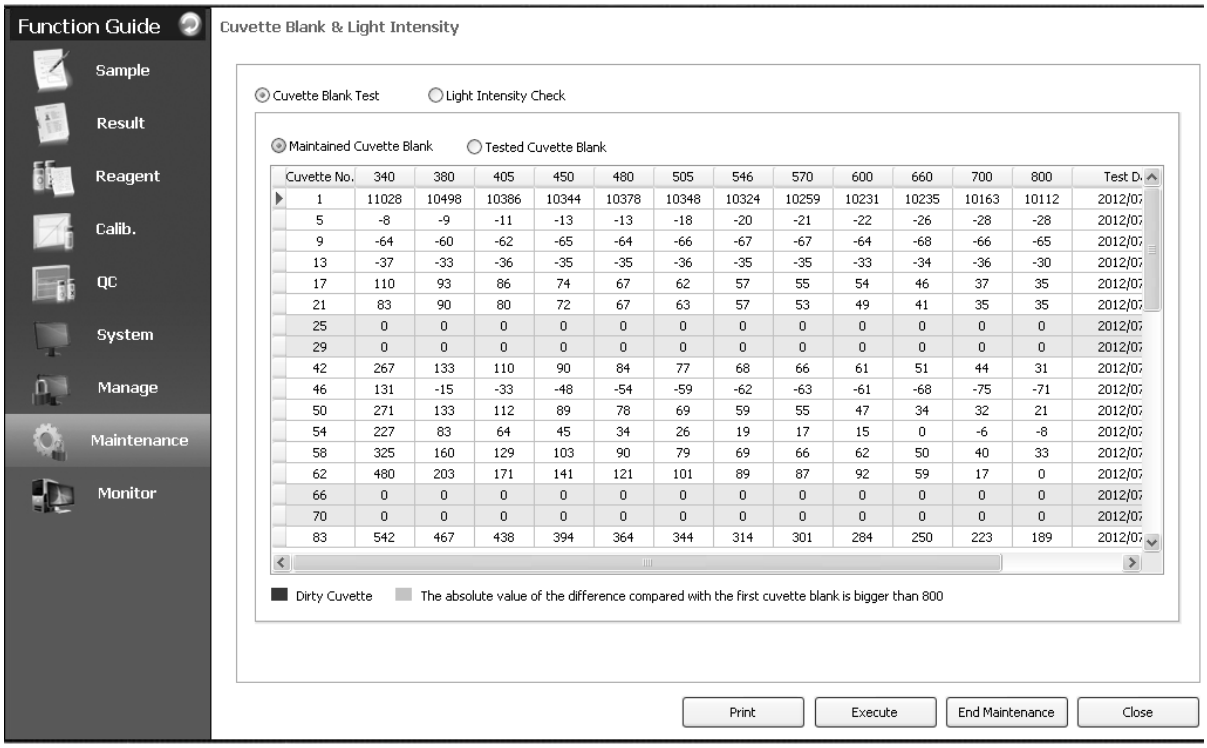


Figure 8-2-5

To print values of cuvette blank, click "Print". Preview them before printing.

The cuvette blank check value of the first reaction cuvette should be less than 18000. The value difference between other reaction cuvettes and the first reaction cuvette should be -800~800. If the value difference cannot meet this standard, replace the light source by referring to Chapter "10.4.3 Light Source Lamp".

Immerse new reaction cuvettes in Anti-Bacterial Phosphor-Free Detergent (2%) for more than 8 hours, before fixing them. Then use tap water to rinse them again and again and use pure water to rinse them before placing them in the reaction disk. Conduct cuvette blank tests. If the values are normal, sample tests can be conducted.

8.2.3.4 Confirm the temperature of incubation bath

Observe the temperature in status bar on the top of screen, and confirm if incubation bath temperature is within 37℃±0.1℃. During test, a notice-level alarm will be given when temperature exceeds 37℃±0.5℃. Yet analyzer will continue analysis. During standby, a notice-level alarm will be given when temperature exceeds 45℃.

After power on, it takes about 20 minutes to ensure constant (37±0.1)℃ of incubation bath; it also takes several minutes to stabilize light source. Therefore when waiting for standby after startup, users can browse window information, input item parameter, and check alarm info.. Only status bar displays standby can sample test be carried out.

8.2.4 Confirm Analytic Conditions

Before a test, first, conduct item maintenance; then set analytic parameters, calibration parameters, and range parameters.

For information about parameters setting, usage, notice, and storage of reagent, Calibrator and Control used for analysis, refer to the instructions or consult the manufacturers and sellers.

8.2.4.1 Confirm analytic conditions for colorimetric items

(1)Item Maintenance (Item Adding and Deleting)

Before setting up parameters, the user should maintain items, namely adding items. Click "System" key in main functional navigation area, and then click "item maintenance" key. In

"item maintenance" window, the user adds, modifies and deletes colorimetric items, manual items, serum information and ionic items. Detailed operation can be obtained in "Chapter 5.1 Item Maintenance".

Item name is forbidden to overlap its number. Mark off item names with letter or number if same item from different companies is added. Identical sample will be tested from small to large item codes.

(2)Confirm Item Parameters

Set up/confirm reagent chemistry parameters according to reagent instructions. Some parameters are necessary, such as: tested item name, analytic method, test time, test light point, dominant/secondary wavelength, sample volume, reagent volume, reagent position, calibration type, calibration position and calibration density etc. Some parameters have no actual impact on test result, such as linearity range and absorbancy limit. However, they serve as reliable index for test precision. It is suggested to input correct parameters one by one before test.

In the "System Setting" window, click "Item Parameter". Set up chemistry, calibration and range parameters according to reagent instructions. Refer to Section "5.2.1" for detail operation.

(3)Set up item combination

Item combination means to combine related items. For example when liver or kidney function tests are needed, the user just clicks item combination names to register multiple items. This enables convenient and rapid input of sample registration.

In "System Setting" window, click "Item Combination". Detailed operation can be obtained in "Chapter 5.4 Item combination".

(4)Set up item calculation/compensation

Item calculation is to calculate another item result by two or more results. Compensation item is conducting compensation calculation upon one result by using number or other results.

In "System Setting" window, click "Calculation and Compensation". Detailed operation can be obtained in "Chapter 5.5 Item calculation and compensation".

(5)Set up cross-contamination

"Cross-contamination" is to decrease or avoid cross-contamination among different tested items, namely on reagent probe, reaction cuvette and sample probe.



Due to different reagent composition, some items may affect other analysis result. Contamination differs in different reagents. Detailed information can be acquired from manufacturers and distributors. It is suggested to separately set reagents which can cause cross-contamination. If complete separation fails, set up "Cross-contamination" to reduce cross-contamination among tests.

In "System Setting" window, click "Cross-contamination". Detailed operation can be obtained in "Chapter 5.6 cross-contamination".

(6)Confirm calibration K factor

If 1 point linearity method is used for calibration, click "Calib." under Function Guide. Then click "Calibration Result", as shown in Figure 8-2-6:

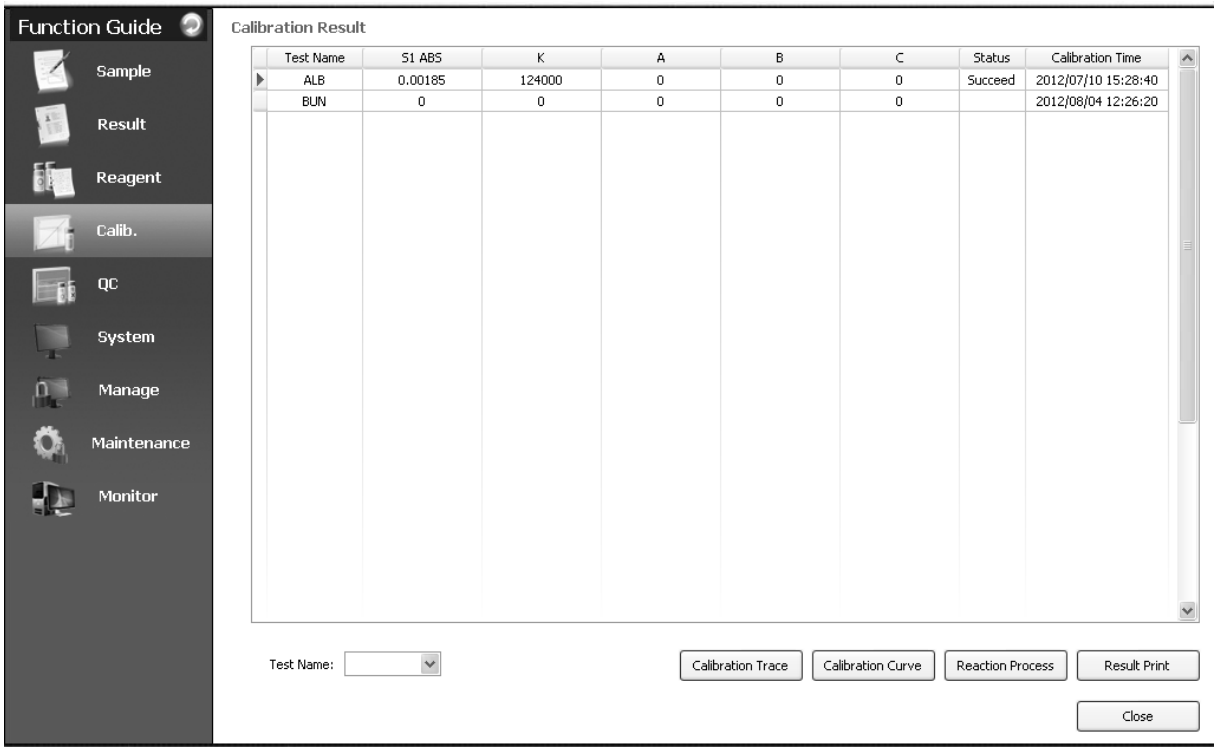


Figure 8-2-6

Input factor in “K” field, and press “Enter” key on the keyboard to save modified value.

8.2.4.2 Confirm ISE Analytic Conditions

(1)Activate ISE

If the analyzer is equipped with ISE modules and ISE tests are needed, click the “System” key under Function Guide to enter the “Other Info.” window. Tick “Use ISE” in “ISE” setting.

(2)Set ISE parameters

Select items from “ISE List” of the “Item Parameter” window in “System” to set the ISE unit, decimal place, sample type, reference values of specific parameters, alarm volume of ISE reference solution, and alarm volume of ISE diluent.

Click the “ISE Calibration” option in the “Calibration Info.” window. Select an name of an ISE calibration item, and input the concentration and position of its corresponding Calibrator. 45μL is the set value of sample-aspirating volume. Tick ☑ Execute ISE Calibration .

8.2.5 Reagent Preparation (Reagent Information)

8.2.5.1 Preparation for colorimetric item

(1)Reagent usage and note

a)Confecting, using and storing reagent is required to be conducted rigorously in accordance with reagent instruction. Avoid bubbles in reagent. When reagent is shaken violently, surfactant in it can cause bubbles. In addition, liquid level sensor will misjudge bubbles as reagent, and thus inaccurate aspiration volume and test result.

b)Adding reagent of different manufactures or LOT numbers is forbidden.

If the user adds reagent from different plants or different lots of the identical plant, reagent composition will be changed, and thus affects test result.

c)Turn the reagent cover counter-clockwise, open the lid, and put reagent bottles on corresponding positions on reagent disk. Table 8-2-1 shows reagent types:

Table 8-2-1 Reagent Type and Corresponding Disk

Reagent Type	Reagent Disk
Reagent 1	Reagent disk 1
Reagent 4	
Reagent 2	Reagent disk 2
Reagent 3	

If there is a bar code on the reagent bottle, the user should confirm whether the bar code label has fallen off or been contaminated.

Before barcode is read, analyzer conducts resetting movements, which means sample probe, reagent probe and stirring mechanism will start up. As a result, cover the reagent disk and avoid stretching hand into mechanical movement range. Otherwise physical injury may be caused.

(2)Manual Registration of Reagent

Under Function Guide, click "

", as shown in Figure 8-2-7:

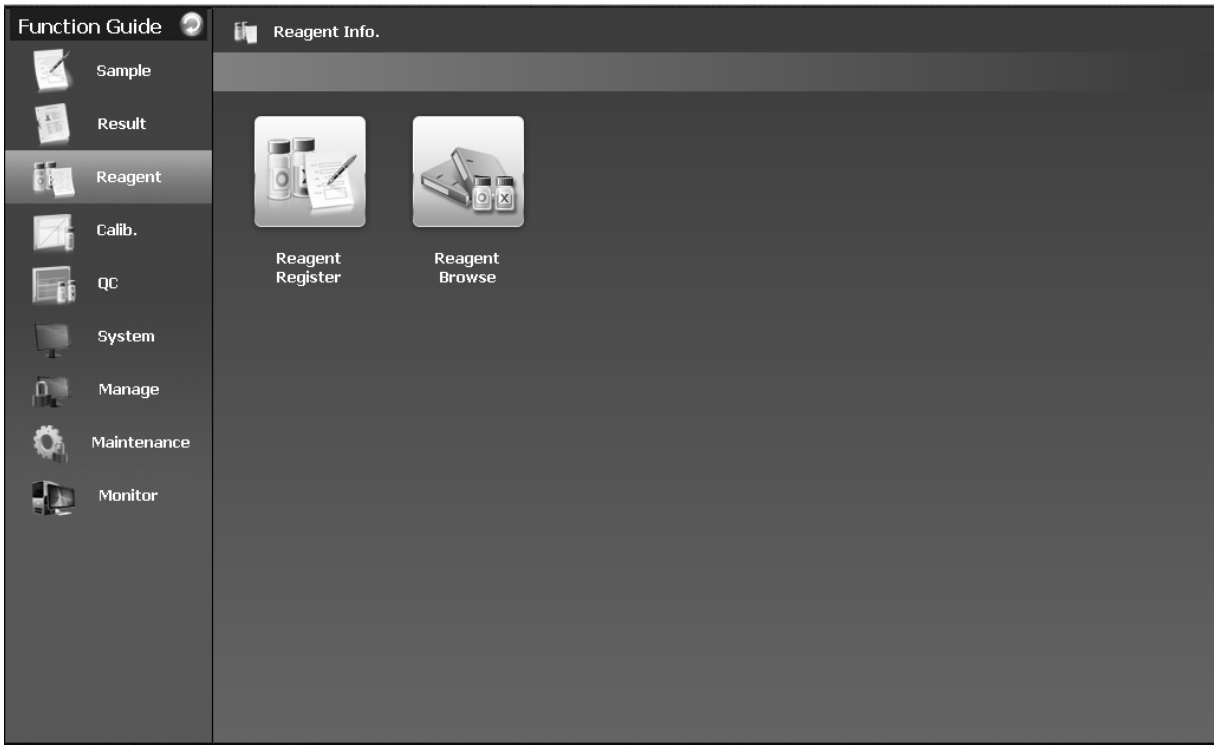


Figure 8-2-7

In "Reagent Info.", click "

", as shown in Figure 8-2-8:

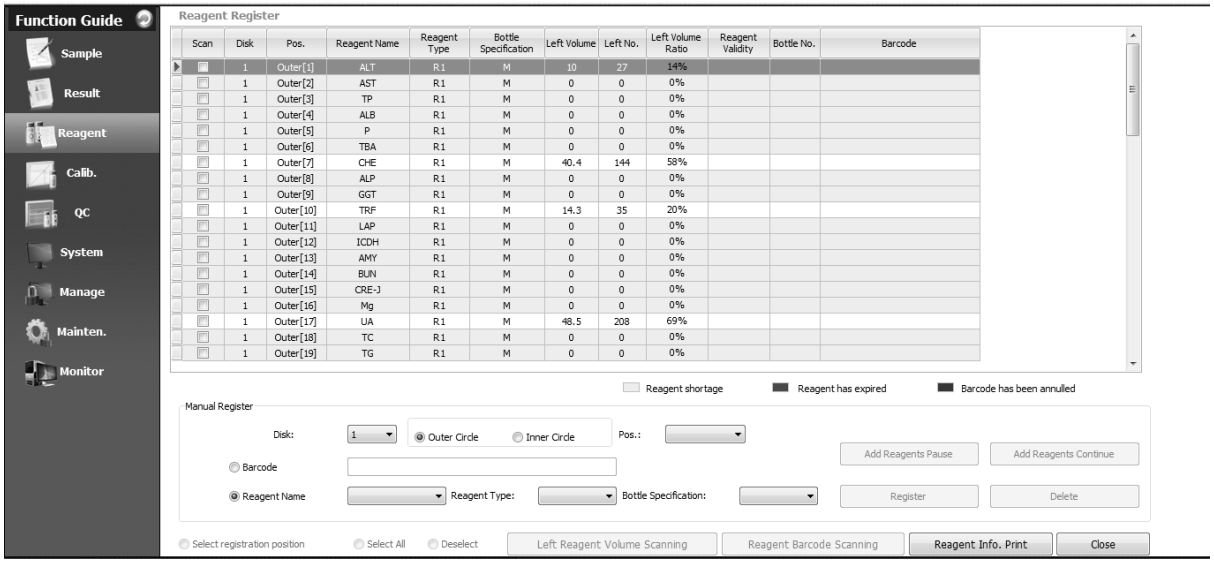


Figure 8-2-8

a)Select 1 (R1 reagent disk), or 2 (R2 reagent disk) from the "Disk" pull-down menu.

b)Select Outer Circle or Inner Circle. "

" means Outer Circle is selected.

c)From the "Pos." pull-down menu, select a position for reagent. Position 1~44 of Outer Circle is available; Position 2~44 of Inner Circle (even number) is available.

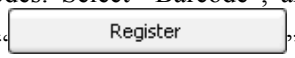
To conduct manual registration by using item names, select "Reagent Name". Select a reagent name from the "Reagent Name" pull-down menu. Select a reagent type from the "Reagent Type" pull-down menu. Select a bottle specification from the "Bottle Specification" pull-down menu. Then click the "

" key. Reagent information will be displayed in the area of the reagent registration list.

When registering reagent, make sure the analyzer is online, and in the standby mode. Don't delete reagent information while the analyzer is conducting tests.

(3)Barcode Scanning

a)Register reagent by manually inputting barcode

If reagent information cannot be read as barcodes of reagent bottles have been contaminated or fallen, users can register reagent information by manually inputting barcodes. Select "Barcode", and input 17 valid reagent barcode numbers in the barcode input box. Click the "

" key. The reagent name, type, reagent bottle specifications and other information will be registered automatically.

The present reagent can be recharged during sample tests. From "Reagent Register", select the reagent disk number and position of the reagent that is to be recharged. Select "Barcode", input the reagent barcode, and click "

" to finish reagent recharging.

b)Register reagent by automatic barcode scanning (Mainly used in reagent close mode)

When barcodes and their information pasted on reagent bottles are clear and complete, users can use "Reagent Barcode Scanning" to conduct automatic registration of reagent information.

Barcode items should be set before reagent barcodes are read. Click "System" under Function Guide. Select the "Item Maintenance" interface. Input item codes used to identify item names in the "Barcode" input box. 01~99 stands for difference item names respectively.

In the reagent path close mode, place reagent bottles with barcode pasted on in any position in the reagent disk. Make sure they are put in the correct reagent disk according to reagent types. Select correct reagent

positions from the "Reagent Register" window. Conduct "Reagent Barcode Scanning", and the analyzer will automatically conduct barcode scanning, identifying barcode information which will be registered automatically in the area of reagent registration list. If the analyzer fails to read a barcode, it will be scanned three times. If the last scanning still fails, this situation will be shown in alarm information.

(4)Reagent Remaining Volume Scanning

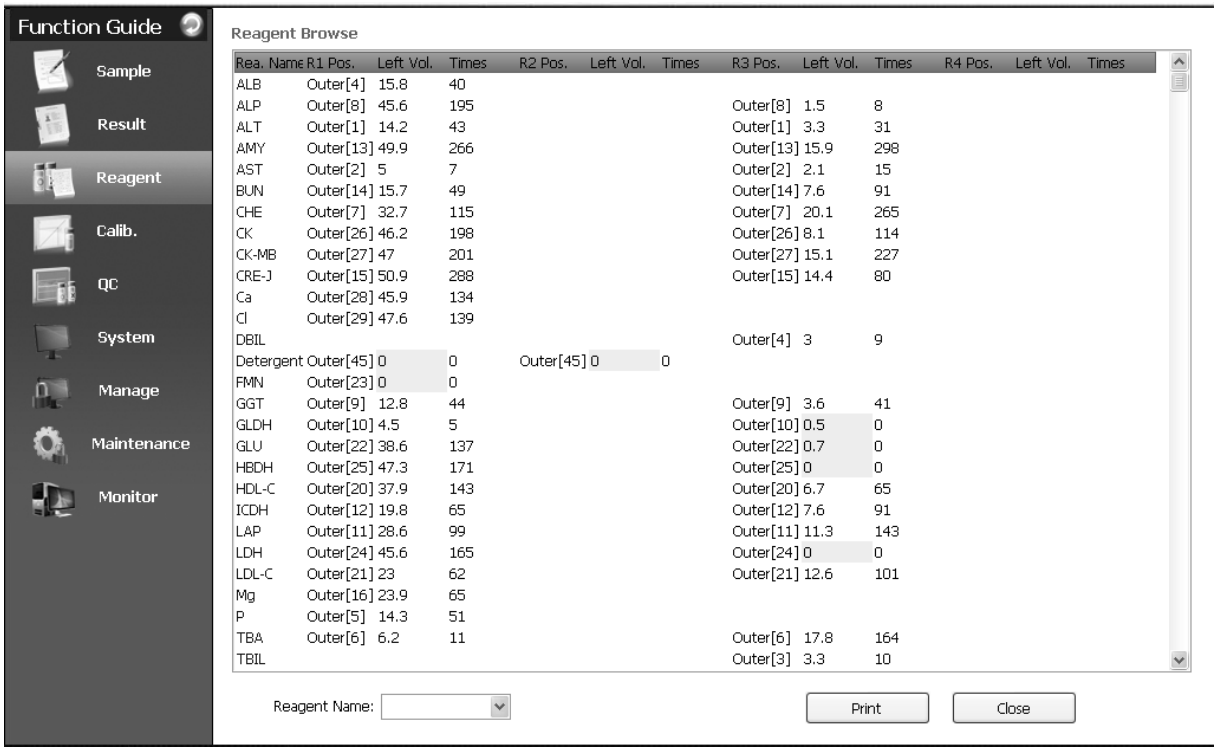
Conduct reagent remaining volume scanning after registration of reagent information. Click an item corresponding to the "Scan" column, namely "

Scan	Disk	Pos.	Reagent Name
☑	1	Outer[27]	CK-MB

". Select an item that is to be scanned, and click the "Left Reagent Volume Scanning" key. The analyzer will automatically scan the remaining volume of the reagent in the position that has been selected. If users want to scan all the registered reagents, click "Select registration position". If "Select All" is clicked, all the reagents, including those in the positions that has not been registered, will be scanned. Click "Deselect", and all the selected items will be canceled.

(5)Remaining reagent volume displaying

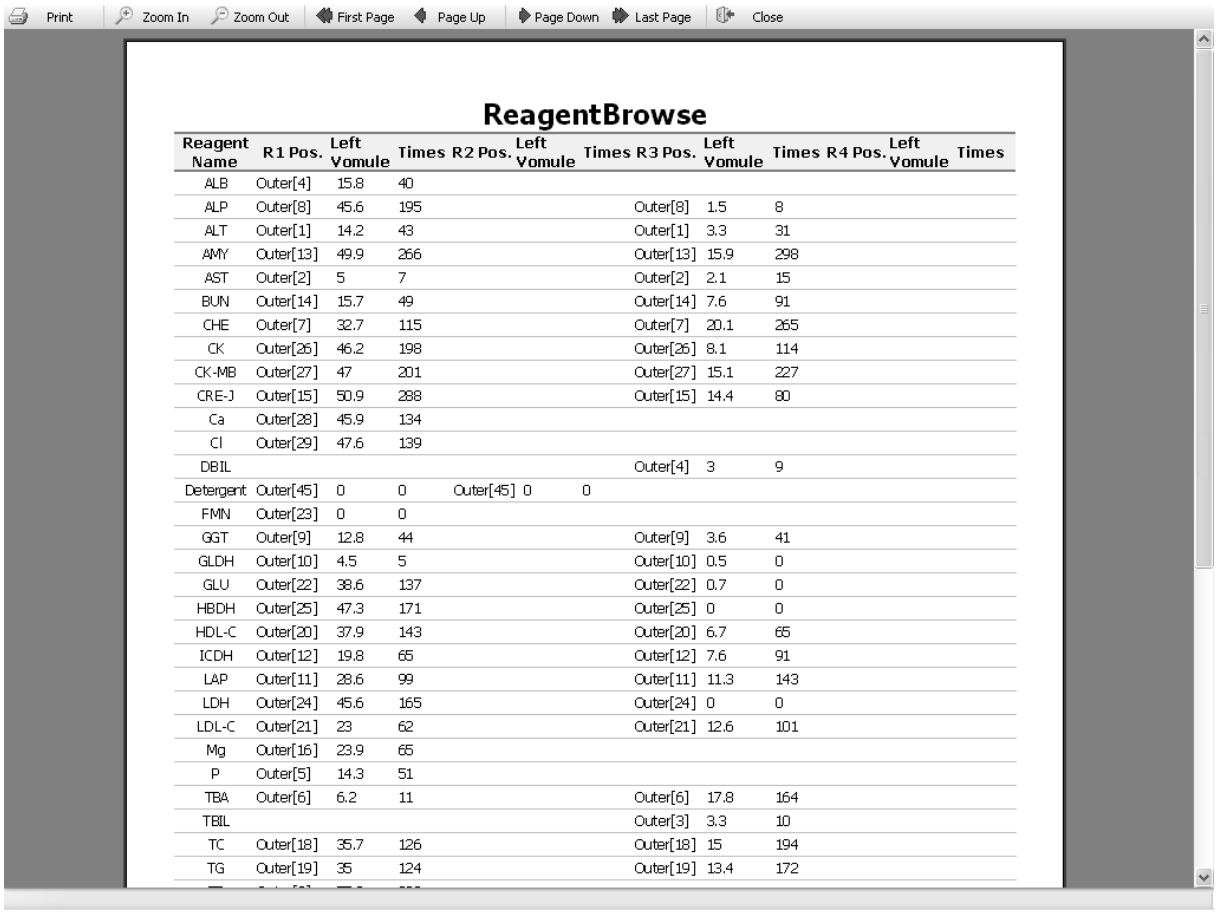
In the "Reagent" window, click "Reagent Browse" to enter the reagent browse window, as shown in Figure 8-2-9:



Rea. Name	R1 Pos.	Left Vol.	Times	R2 Pos.	Left Vol.	Times	R3 Pos.	Left Vol.	Times	R4 Pos.	Left Vol.	Times
ALB	Outer[4]	15.8	40									
ALP	Outer[8]	45.6	195				Outer[8]	1.5	8			
ALT	Outer[1]	14.2	43				Outer[1]	3.3	31			
AMY	Outer[13]	49.9	266				Outer[13]	15.9	298			
AST	Outer[2]	5	7				Outer[2]	2.1	15			
BUN	Outer[14]	15.7	49				Outer[14]	7.6	91			
CHE	Outer[7]	32.7	115				Outer[7]	20.1	265			
CK	Outer[26]	46.2	198				Outer[26]	8.1	114			
CK-MB	Outer[27]	47	201				Outer[27]	15.1	227			
CRE-J	Outer[15]	50.9	288				Outer[15]	14.4	80			
Ca	Outer[28]	45.9	134									
Cl	Outer[29]	47.6	139									
DBIL							Outer[4]	3	9			
Detergent	Outer[45]	0	0	Outer[45]	0	0						
FMN	Outer[23]	0	0									
GGT	Outer[9]	12.8	44				Outer[9]	3.6	41			
GLDH	Outer[10]	4.5	5				Outer[10]	0.5	0			
GLU	Outer[22]	38.6	137				Outer[22]	0.7	0			
HBDH	Outer[25]	47.3	171				Outer[25]	0	0			
HDL-C	Outer[20]	37.9	143				Outer[20]	6.7	65			
ICDH	Outer[12]	19.8	65				Outer[12]	7.6	91			
LAP	Outer[11]	28.6	99				Outer[11]	11.3	143			
LDH	Outer[24]	45.6	165				Outer[24]	0	0			
LDL-C	Outer[21]	23	62				Outer[21]	12.6	101			
Mg	Outer[16]	23.9	65									
P	Outer[5]	14.3	51									
TBA	Outer[6]	6.2	11				Outer[6]	17.8	164			
TBIL							Outer[3]	3.3	10			

Figure 8-2-9

Select an item name from the "Reagent Name" pull-down menu at the bottom of the window, which means that users can browse information on items they have selected. To print the information of the browse window, click "Print", as shown in Figure 8-2-10:



ReagentBrowse

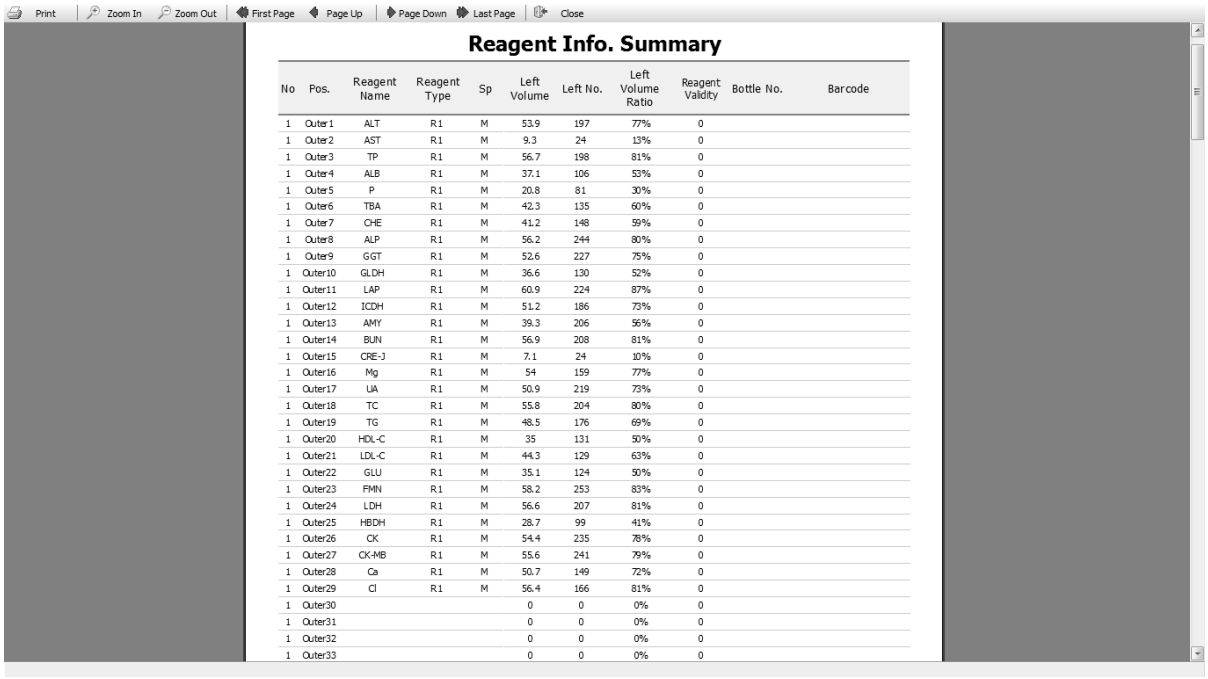
Reagent Name	R1 Pos.	Left Vomule	Times	R2 Pos.	Left Vomule	Times	R3 Pos.	Left Vomule	Times	R4 Pos.	Left Vomule	Times
ALB	Outer[4]	15.8	40									
ALP	Outer[8]	45.6	195				Outer[8]	1.5	8			
ALT	Outer[1]	14.2	43				Outer[1]	3.3	31			
AMY	Outer[13]	49.9	266				Outer[13]	15.9	298			
AST	Outer[2]	5	7				Outer[2]	2.1	15			
BUN	Outer[14]	15.7	49				Outer[14]	7.6	91			
CHE	Outer[7]	32.7	115				Outer[7]	20.1	265			
CK	Outer[26]	46.2	198				Outer[26]	8.1	114			
CK-MB	Outer[27]	47	201				Outer[27]	15.1	227			
CRE-J	Outer[15]	50.9	288				Outer[15]	14.4	80			
Ca	Outer[28]	45.9	134									
Cl	Outer[29]	47.6	139									
DBIL							Outer[4]	3	9			
Detergent	Outer[45]	0	0	Outer[45]	0	0						
FMN	Outer[23]	0	0									
GGT	Outer[9]	12.8	44				Outer[9]	3.6	41			
GLDH	Outer[10]	4.5	5				Outer[10]	0.5	0			
GLU	Outer[22]	38.6	137				Outer[22]	0.7	0			
HBDH	Outer[25]	47.3	171				Outer[25]	0	0			
HDL-C	Outer[20]	37.9	143				Outer[20]	6.7	65			
ICDH	Outer[12]	19.8	65				Outer[12]	7.6	91			
LAP	Outer[11]	28.6	99				Outer[11]	11.3	143			
LDH	Outer[24]	45.6	165				Outer[24]	0	0			
LDL-C	Outer[21]	23	62				Outer[21]	12.6	101			
Mg	Outer[16]	23.9	65									
P	Outer[5]	14.3	51									
TBA	Outer[6]	6.2	11				Outer[6]	17.8	164			
TBIL							Outer[3]	3.3	10			
TC	Outer[18]	35.7	126				Outer[18]	15	194			
TG	Outer[19]	35	124				Outer[19]	13.4	172			

Figure 8-2-10

Click "Print" to print the current list. Click "Close" to return to the menu of reagent registration.

(6)Print reagent information

If reagent information needs to be printed, click "Reagent Info. Print". Disk No., position, reagent name, reagent type, bottle type, remaining volume, ratio, validity, bottle No. and barcode will be displayed in "Reagent Info. Summary". As shown in Figure 8-2-11:



Reagent Info. Summary

No	Pos.	Reagent Name	Reagent Type	Sp	Left Volume	Left No.	Left Volume Ratio	Reagent Validity	Bottle No.	Barcode
1	Outer1	ALT	R1	M	53.9	197	77%	0		
1	Outer2	AST	R1	M	9.3	24	13%	0		
1	Outer3	TP	R1	M	56.7	198	81%	0		
1	Outer4	ALB	R1	M	37.1	106	53%	0		
1	Outer5	P	R1	M	20.8	81	30%	0		
1	Outer6	TBA	R1	M	42.3	135	60%	0		
1	Outer7	CHE	R1	M	41.2	148	59%	0		
1	Outer8	ALP	R1	M	56.2	244	80%	0		
1	Outer9	GGT	R1	M	52.6	227	75%	0		
1	Outer10	GLDH	R1	M	36.6	130	52%	0		
1	Outer11	LAP	R1	M	60.9	224	87%	0		
1	Outer12	ICDH	R1	M	51.2	186	73%	0		
1	Outer13	AMY	R1	M	39.3	206	56%	0		
1	Outer14	BUN	R1	M	56.9	208	81%	0		
1	Outer15	CRE-J	R1	M	7.1	24	10%	0		
1	Outer16	Mg	R1	M	54	159	77%	0		
1	Outer17	UA	R1	M	50.9	219	73%	0		
1	Outer18	TC	R1	M	55.8	204	80%	0		
1	Outer19	TG	R1	M	48.5	176	69%	0		
1	Outer20	HDL-C	R1	M	35	131	50%	0		
1	Outer21	LDL-C	R1	M	44.3	129	63%	0		
1	Outer22	GLU	R1	M	35.1	124	50%	0		
1	Outer23	FMN	R1	M	58.2	253	83%	0		
1	Outer24	LDH	R1	M	56.6	207	81%	0		
1	Outer25	HBDH	R1	M	28.7	99	41%	0		
1	Outer26	CK	R1	M	54.4	235	78%	0		
1	Outer27	CK-MB	R1	M	55.6	241	79%	0		
1	Outer28	Ca	R1	M	50.7	149	72%	0		
1	Outer29	Cl	R1	M	56.4	166	81%	0		
1	Outer30				0	0	0%	0		
1	Outer31				0	0	0%	0		
1	Outer32				0	0	0%	0		
1	Outer33				0	0	0%	0		

Figure 8-2-11



● Reagent information deletion should be conducted in the standby mode.

● If reagent disk cover is opened in the standby mode, alarm will be set off (notice level).

● Manual registration is needed if barcode scanning failed.

● Conduct reagent horizontal check to confirm remaining reagent volume and times after reagent information registration.

(7)Reagent information deleting

To delete the information of an item that has been registered, select the reagent information and click "Delete".



Reagent information is not allowed to be deleted while the analyzer is testing samples.

8.2.5.2 ISE item preparation

(1)Place reagents

Open the front door of the analyzer, and place reference solution, diluent, and internal standard solution in the downside.

(2)Conduct ISE reagent pipeline rinsing in the "Maintenance" window.

8.2.5.3 Pause to add reagent

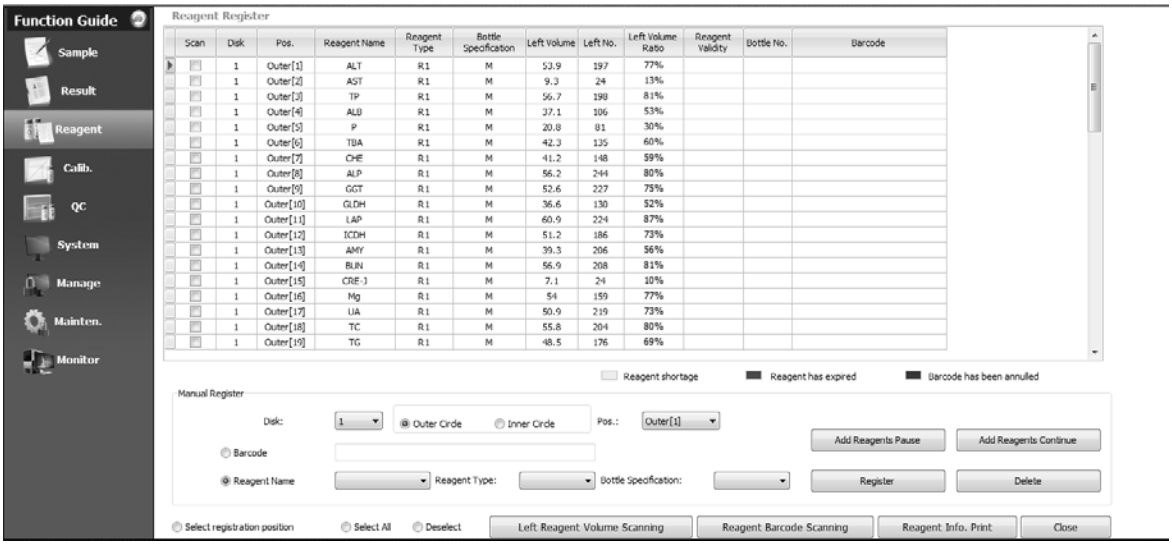


Figure 8-2-11(a)

During testing, if reagent is insufficient, the user can add reagent during testing, the following shows the detail:

(1)Click "Add Reagents Pause" button, and the analyzer prepares to enter the mode of stopping to add reagent. "Analyzer Status: 37.0°C Ready to pause reagent adding" is displayed.

(2)When the mode switches to "Analyzer Status: 37.0°C Reagent adding pause", the user can do the operation of adding reagent and the subsequent operation, such as reagent remaining volume scanning, and reagent bar code scanning.

(3)After reagent adding, click "Add Reagents Continue" to continue testing.

8.2.5.4 Reagent Recharge

Login the system as a supervisor on reagent sealing mode, then select "Activate recharge function by item" from "Other Info" interface. Click "reagent" from the navigation column, and then enter to the "Reagent Register" interface, as shown in the following figure:

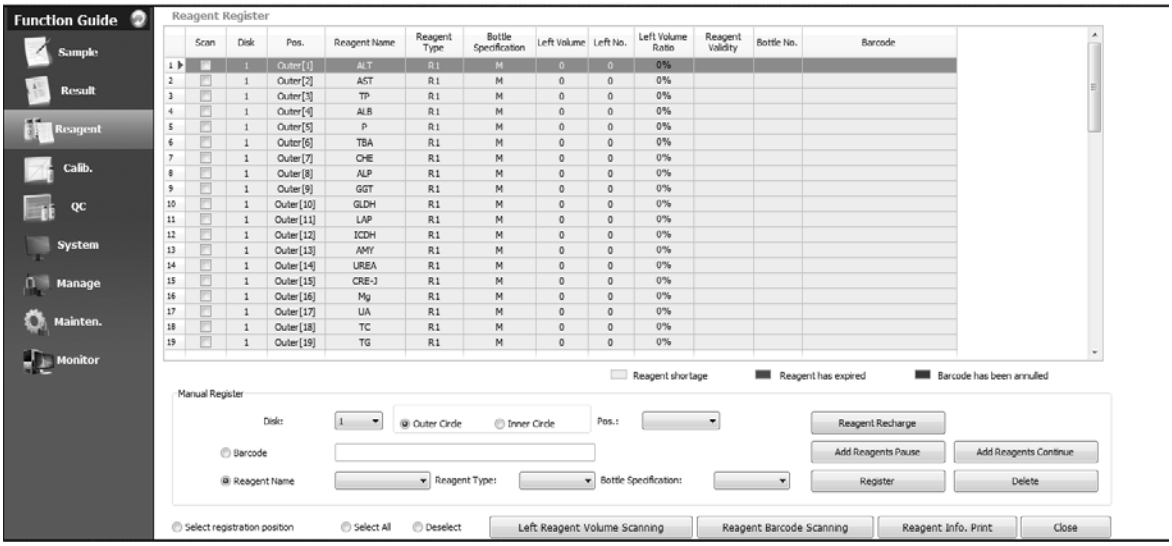


Figure 8-2-11(b)

(1)Reagent Recharge for Colorimetric Items

Click "Reagent Recharge", as shown in the following figure:

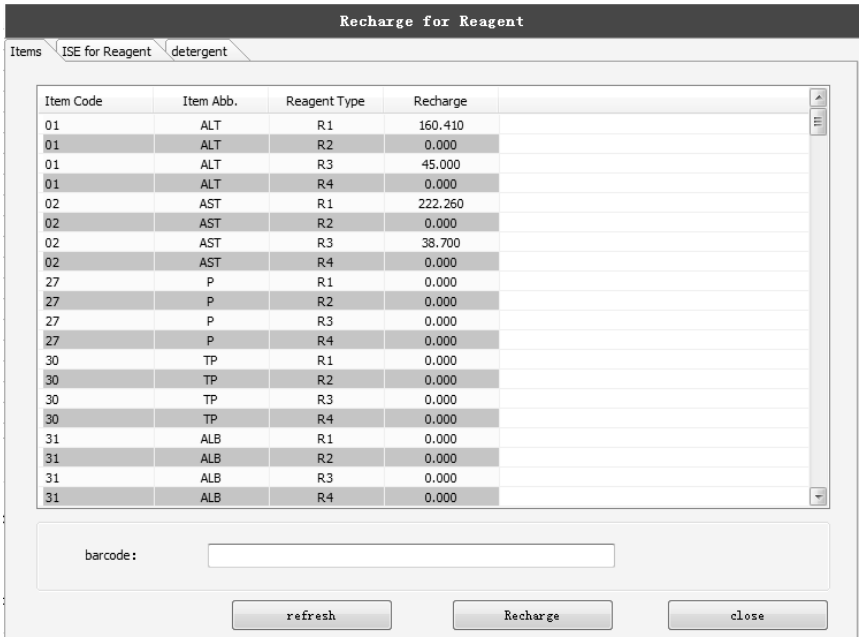


Figure 8-2-11(c)

Input the reagent barcode info, then click “Recharge”to finish the setting of the reagent recharge.

(2)ISE Reagent Recharge

Click “Reagent Recharge” and select “ISE” as shown in the following figure:

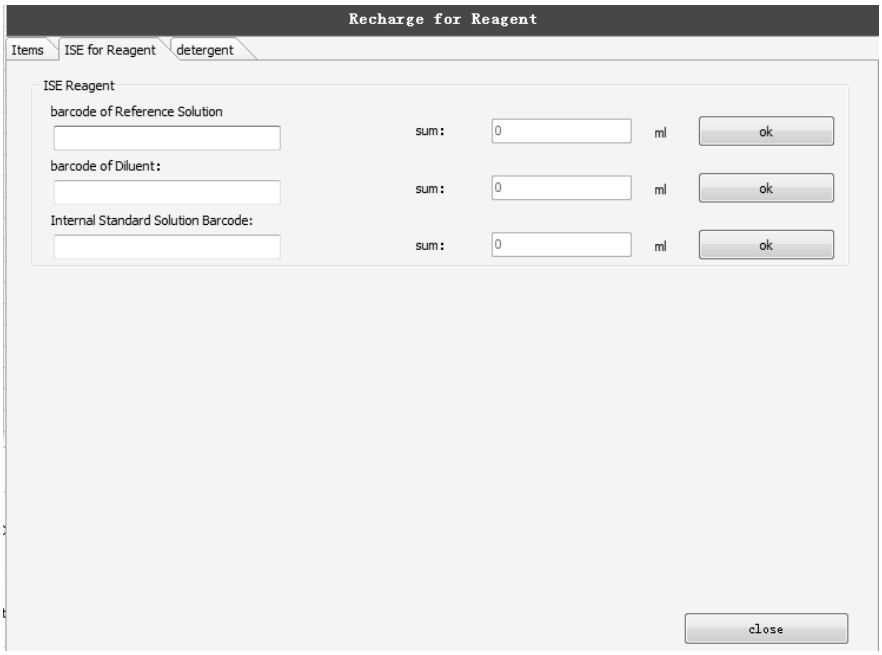


Figure 8-2-11(d)

Input the ISE barcode info into the related field, then click “OK” to finish the setting of the reagent recharge.

(3)Detergent Recharge

Click “Reagent Recharge” and select “Detergent”as shown in the following figure:

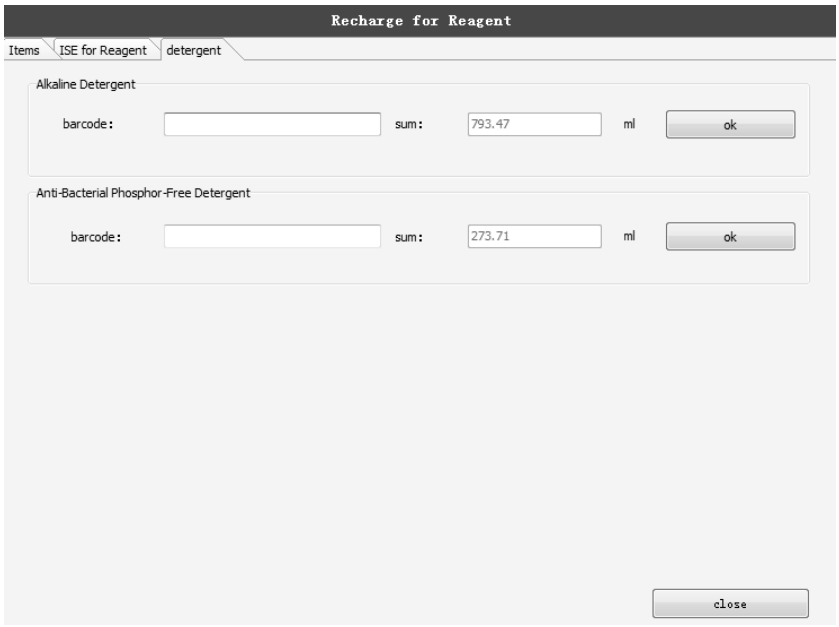


Figure 8-2-11(e)

Input the detergent barcode info. into the related field, then click "OK" to finish the setting of the reagent recharge.

8.2.6 Registration of calibration and QC item

(1)Registration of calibration item

Under Function Guide, click "Calibration". In the calibration information interface, click "Calibration Registration". Select calibration items according to calibration types. Click "Register". After successful registration, calibration information will be displayed in the area of calibration registration list. Click a piece of calibration information, and set the concentration and position of Calibrator on the right of the list. For detailed operation, refer to "Chapter 6 Calibration Information".

The mode for calibration items should be "Execute".

Execute	Test Name
☑	BUN
☑	CRE

(2)Registration of QC item

Under Function Guide, click "QC". Then click "QC Registration" to register QC names, QC LOT numbers, QC items, sample types and other information, and set QC target values and standard deviation. For detailed information, refer to Chapter "7.1 QC Registration".

8.2.7 Sample Registration and Test (Sample Registration)

Under Function Guide, click "

". Then click "

" as shown in Figure 8-2-12:



Figure 8-2-12

Click "Close" to close the window.

(1)Single sample registration

a)Select test type: routine, emergency

For routine sample registration, click Routine. For emergency sample registration, click Stat.

b)Input sample number, barcode ID

Sample Number: input sample numbers in the "Sample Number" input box, or click "<--", "-->" to select sample numbers. Routine sample number: 1~9000; emergency sample number: 9001~9999. These numbers are of uniqueness in one day.

Barcode ID Number: barcode numbers pasted on test tubes. When the sample barcode scanning function is in use, the scanned barcode number will be displayed in the "Barcode ID Number" input box. If users don't use the sample barcode scanning function, or the function fails, they can input valid sample barcode numbers in the "Barcode ID Number" input box. "??" shown in the input box means that no valid barcode information is scanned when the reader is scanning a sample barcode.

c)Input sample disk No., position

Select a disk number (1~9) from the "Disk No." pull-down menu for sample tests. Input a sample position No. in the input box of "Position No." (Routine sample registration: 1~80; emergency sample registration: 81~90). After emergency sample registration, users can click "Send Test" directly. After selecting "Stat Test", input the initial sample number of Stat tests to start Stat tests.

The analyzer will go into the mode of sample-adding pause, if the disk No. changed, but the analysis will continue. Single click "Sampling Continue" to continue dispensing samples.

d)Select sample type, cuvette type

From the pull-down menu, select a sample type and cuvette type for tests. means default setting.

e)Select sample blank

To conduct sample blank tests, click "Sample Blank". Sample blank is only suitable for 1 end point items.

f)Input times of test repetition

Test repetition times of the same sample. The default is 1. The biggest number that users can input is 100.

g)Item name of sample test

From the working area, select item names for the sample test. (Colors of test items will change after being chosen)

h)Select sample volume: Normal, decrement, increment

i)Select whether dilution is needed

If samples (hemolysis, lipemia, jaundice and other samples) need diluting, click "Always Dilute" in the "Analysis Parameter" interface under "Item Parameter" of "System", and all samples for the test item will be diluted during the test. If some items require dilution while some don't, first, click the "Dilute" option, namely "Dilute", in the "Sample Registration" interface, select test item names, and then the diluent solution interface pops up, and select the diluent solution in need and then push the "OK" button. The interface will be showen as follows:

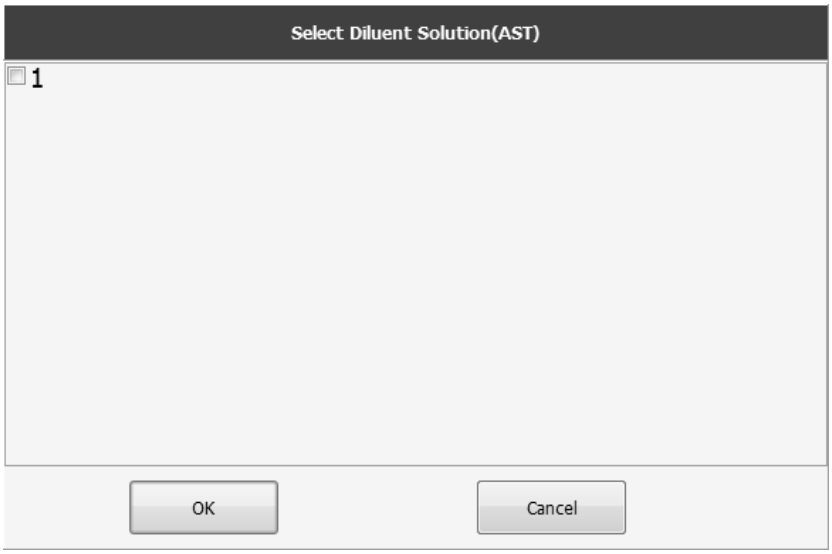


Figure 8-2-12(a)

Click the "Sample Register" key. The button color will change after dilution item selection.

To use the dilution function, users have to set valid sample volume for analysis, sample volume for dilution, and diluent volume in the "Analysis Parameter" interface.

During registration, first click "Dilute" (Dilute), and then select items.

j)Select item. Single item or combined item registration can be conducted. The button color will change after item selection. Refer to "5.4 Item Combination" for item combination setting.

If users didn't set the parameter in the "Analysis Parameter" interface under "Item Parameter" of "System", the item in "Item Information" of "Sample Registration" will be gray and cannot be selected.

k)Click "Sample Register" after sample information editing. The registered information will be displayed on the right. Click the information bar to check the registered information.

(2)Registration of batch routine sample

When various samples are registered in the same test item, batch sample registration can be used.

a)Select a test type, input a sample number and barcode ID number (the sample number here is the initial sample number of batch registration), input a disk number and position, select a sample type and cuvette type, select whether to conduct sample blank, select an item name for sample tests, select sample volume, and select whether to dilute the sample to register the initial sample information of batch routine sample

registration according to the contents in a), b), c), d), e), g), h), and i) of (1) Single sample registration.

b)In the "Sample Registration" window, click the "Lot Register" key, as shown in Figure 8-2-13:

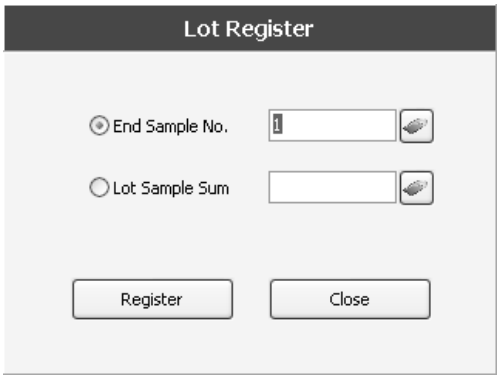


Figure 8-2-13

Input the final sample number in the "End Sample No." input box. The final sample number should be larger than the initial sample number.

Or choose to input a number in "Lot Sample Sum": Input the number of the batch sample test in the "Lot Sample Sum" input box.

c)Click the "Register" key to finish batch sample registration.

If one of the batch registration samples is the same as a single registration sample, the analyzer will remind the user that batch registration failed, as shown in Figure 8-2-14:

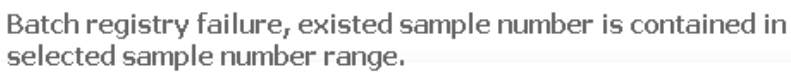


Figure 8-2-14

Restart the batch sample registration.

d)Click the "Close" key to exit the present window.

To conduct batch registration of routine samples, users must first register sample information, and then patient information.

(3)Edit patients' information

In the "Sample Registration" window, click the "Patient Info." key to switch to the patient information inputting mode, as shown in Figure 8-2-15:

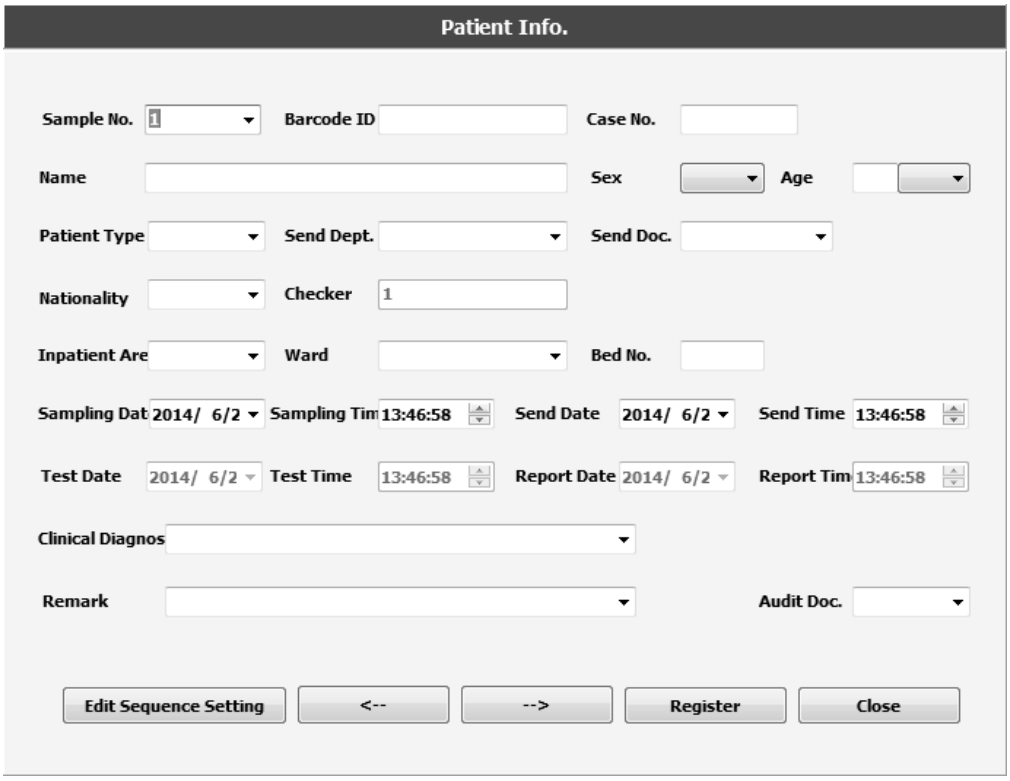


Figure 8-2-15

a)Input a sample number in the "Sample No." input box, or click "<--", "-->" to select a sample number.

b)Select or input a case number, patient name, age, gender, patient type, send department, send doctor, nationality, checker, inpatient area, ward, bed number, sampling date, sampling time, clinical diagnosis, remark, audit doctor, etc. Mnemonics can be used in registration. Press the "Enter" key in the keyboard.

Users must input a patient's name when editing Patient Info.. Otherwise the analyzer will refuse patient information registration.

c)After the editing, single-click the "Register" key, and the patient's name will be automatically displayed in the browse area.

d)Users can click "<--", "-->" to switch to the previous or next "Patient Info." and edit.

e)Click the"Edit Sequence Setting" key, as shown in Figure 8-2-16:

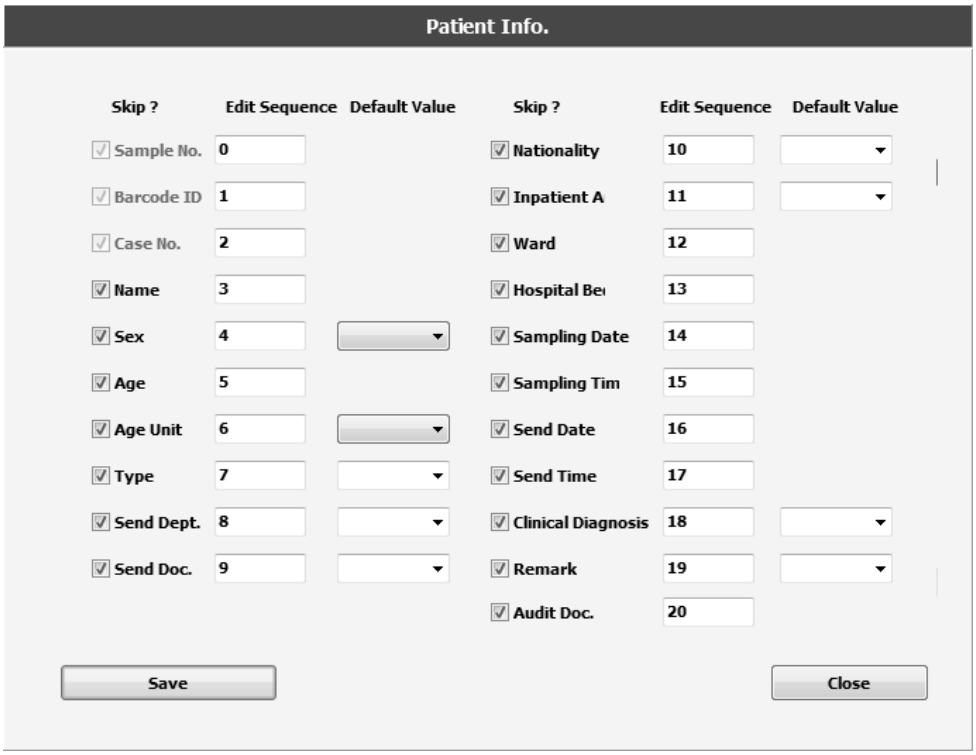


Figure 8-2-16

Input numbers in the "Edit Sequence" boxes to set the edit sequence of patients' information.

f)To exit the "Patient Info." window, click the"Close"key.

The test results can still display the default normal reference range if no patient information is input.

(4)Manual LIS Application

"Manual LIS Request"Used to start up LIS Communication.

(5)Modify and delete sample information

To modify sample information, click information in the browse area, or use the "<--" and "-->" keys. Users can also input the number of the sample that is to be modified in the "Sample No." input box. To delete sample information, click the "Sample Delete" key in the "Sample Registration" window. A box will pop up, as shown in Figure 8-2-17:



Figure 8-2-17

Input the number of the initial sample that is to be deleted in the "Start Sample No." input box. Input the number of the final sample that is to be deleted in the "End Sample No." box. To delete one piece of sample information, input the same number in the "Start Sample No." and "End Sample No." boxes. The initial sample number should be smaller than or equal to the final sample number.

● Information on samples that have been registered but not yet sent to be tested can be modified and deleted in the standby mode or during tests. But information on samples that have been sent to be tested can be deleted only in the standby mode.

● If users have registered sample information but not registered patient information, the records will be blue in the browse area. If users have registered patient information but not registered sample information, the records will be red in the browse area. If both sample and patient information has been registered, the records will be black in the browse area.

● In sample registration, different samples cannot use the same position. To use the position that has been selected, the previous position selection should be canceled.

(6)Sample Summary

When samples are registered for tests, registration situations will be displayed. After tests, results will be shown in a report form, shown in Figure 8-2-18:

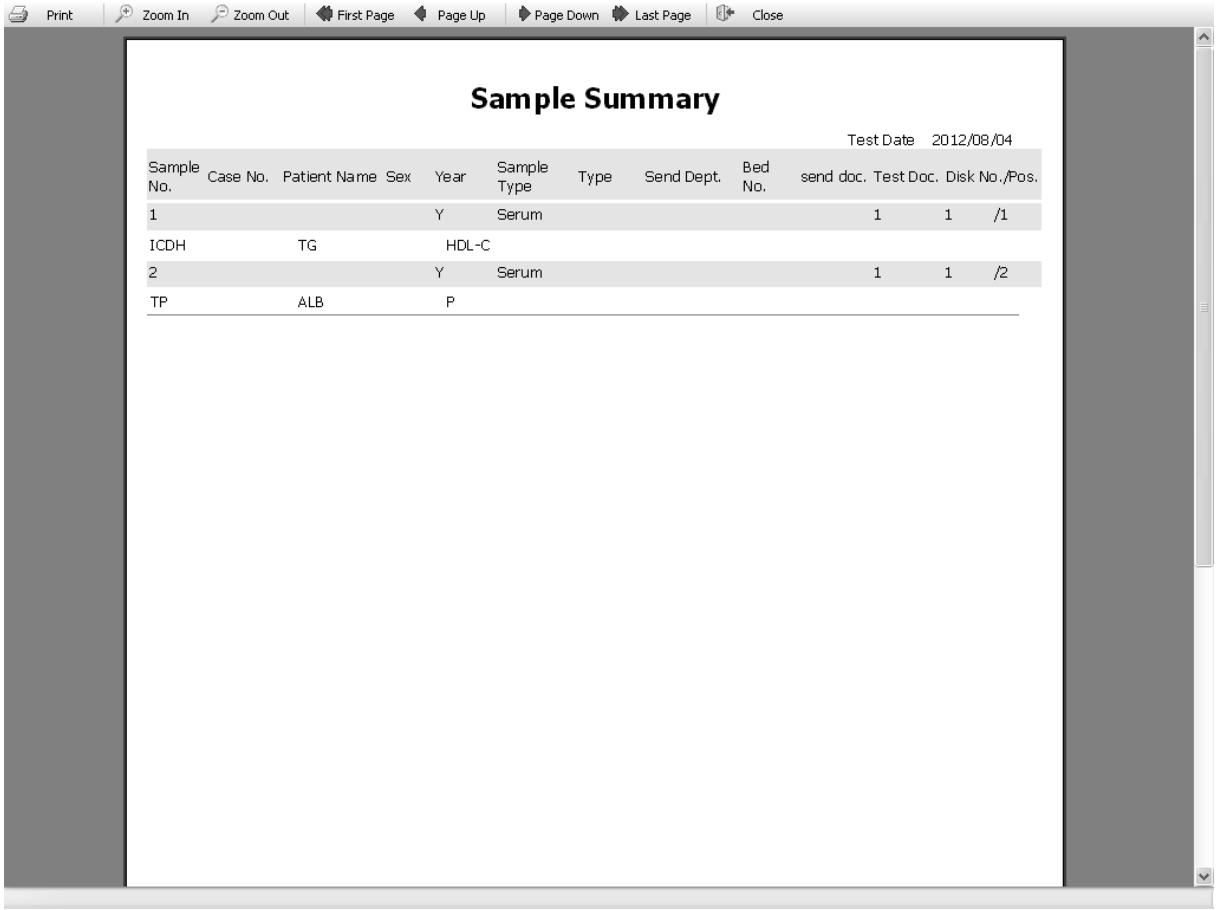
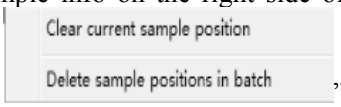


Figure 8-2-18

(7)Clear sample position

Move the cursor to a certain piece of sample info on the right side of the "Sample Register" screen, then right-click the mouse, the options box" 

" will appear. If you choose "Clear current sample position(Y)", the disk No. and position of the sample info you selected will be cleared. If you choose "Clear sample positions in batch", a window will pop up as the figure below shows:

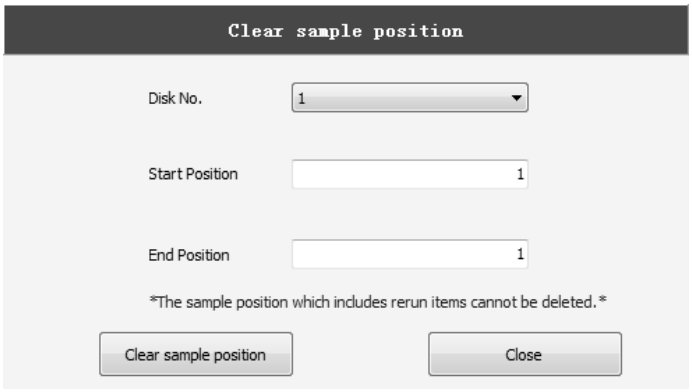


Figure 8-2-18(a)

Select a disk no. from the drop down list and input the start position and end position, and then click “Clear sample position”, the disk no. and positions within the range you set will be deleted.

8.2.8 Preparation for Tests

(1)Prepare Detergent, Calibrator, Control, and samples

Place routine samples, emergency samples, Calibrator, Control, Detergent used for analysis in the corresponding positions of the sample disk or QC disk.

a)Place Detergent

Before tests, put Alkaline Detergent in the W1 position in the QC disk; If ISE tests are needed, put ISE Detergent in the W2 position in the QC disk. To avoid sample probe cross-contamination, put Alkaline Detergent in the set position in the QC disk.

b)Place Calibrator

Put Calibrator in the corresponding position in the QC disk, in the Calibrator position set by the “Calibration Registration” window.

c)Place Control

Put Control in the corresponding position set by the “QC Registration” window.

d)Place samples

Put routine samples in Position 1~50 in the outer circle, or Position 51~80 in the inner circle of the sample disk. Put emergency samples in Position E81~E90 in the inner circle of the sample disk.



Control and Calibrator should be put into standard cuvettes or micro-cups during tests.

(2)Start Test

After sample registration, click the “Send Test” key in the shortcut key area to sent instructions to conduct tests, as shown in Figure 8-2-19:

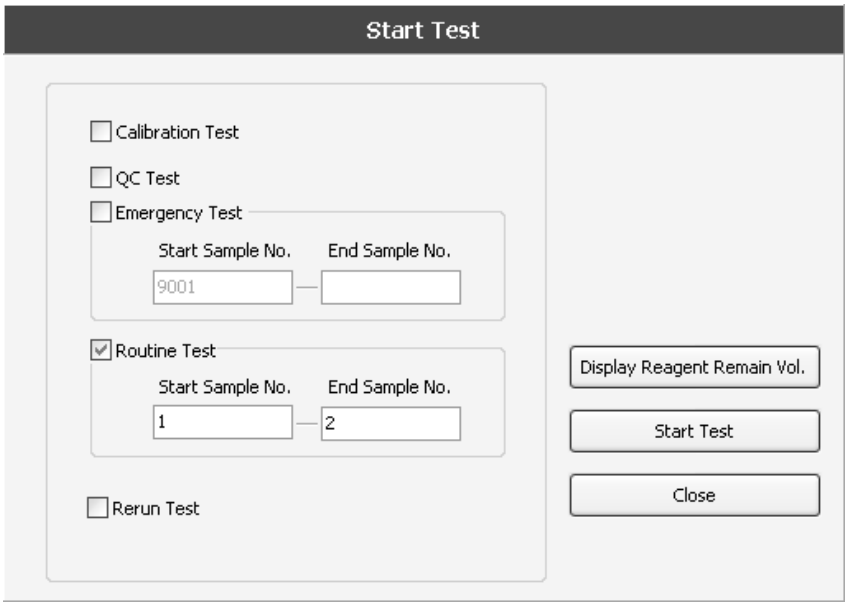


Figure 8-2-19

Select a test type, and click the "Start Test" key to start the test.

8.2.9 During Test

(1)System monitoring

As the analyzer is running, users can monitor the sample disk, reagent disk, reaction disk, LIS mode, and sample testing in real time.

Under Function Guide, click the "

" key, as shown in Figure 8-2-20:



Figure 8-2-20

a)Click "

" to check the real-time status of the sample rack, as shown in Figure 8-2-21:

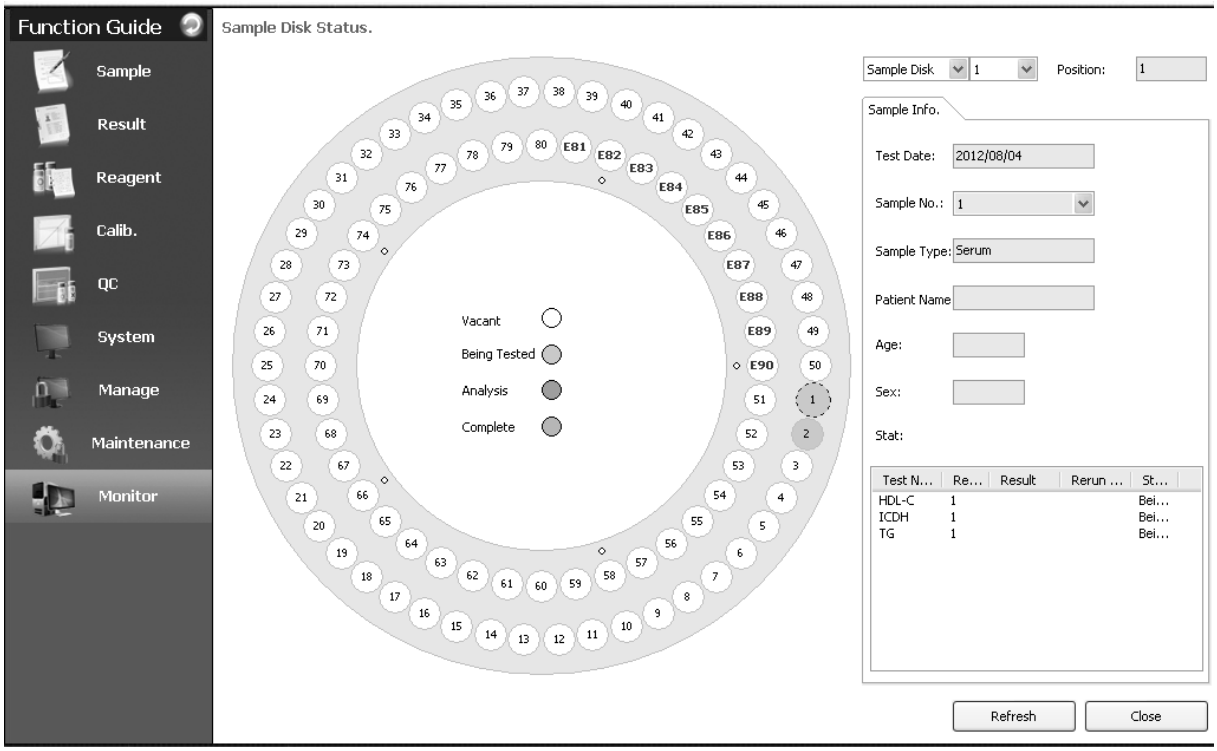


Figure 8-2-21

The sample disk status is shown on the left of the window. "1 2 3 ... 10 ..." is the sequence of the sample cuvettes. If a sample is tested in the corresponding position by the analyzer, it will be shown in the status area. Its sample number and test status will be displayed. Click a certain sample, and its position number will be displayed on the right.

Status Explanation:

- Vacant: The sample in the position is not registered. The color shown is white.
- Being tested: The sample in the position is already registered, but not dispensed. The color is light blue.
- Analysis: The analyzing status is shown in pink.
- Complete: All the test results of the sample in the position has been calculated. The color is green.

b)Click "

" to check the real-time status of the reagent disks, as shown in Figure 8-2-22:

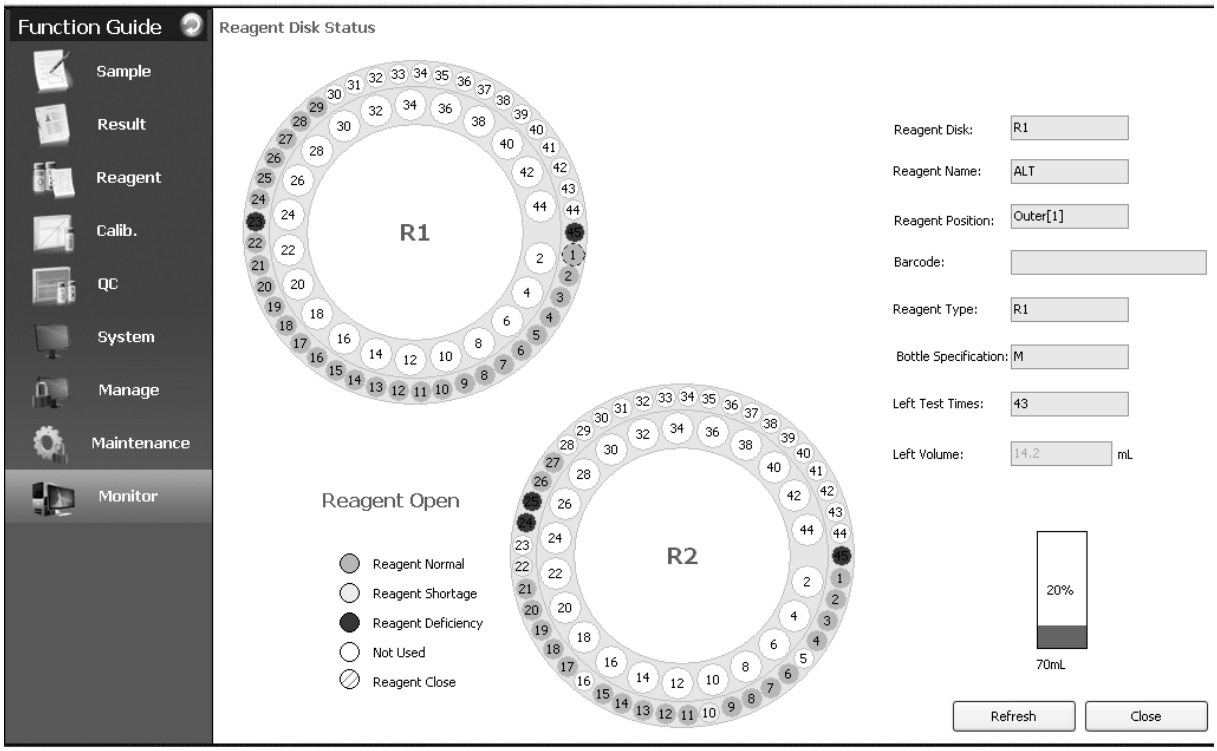


Figure 8-2-22

This window displays the information on 2 reagent disks and reagent probe detergents.

Click the corresponding reagent position, the relevant information will be displayed on the right.

Left Test Times: According to the remaining volume of the reagent and the set volume of reagent-dispensing in chemistry parameters, the software will automatically calculate the number of the remaining tests.

Left Volume: The remaining volume of the reagent in the current position will be displayed in a number. The The unit is mL.

Reagent Disk Status: Different colors indicate different reagent status.

- ➢Reagent Normal: The reagent volume for tests meets the test requirement. Green shown.
- ➢Reagent Shortage: The remaining volume of the reagent is smaller than the set volume in "Reagent Alarm Setting". Yellow shown.
- ➢Reagent Deficiency: The reagent volume is 0mL. Red shown.
- ➢Not Used: No reagent is registered in the position. White shown.
- ➢Reagent Close: The position requires reagents of a specific brand. Shadow shown.

c)Click "

" to check the real-time status of the reaction disk, as Figure 8-2-23 shows:

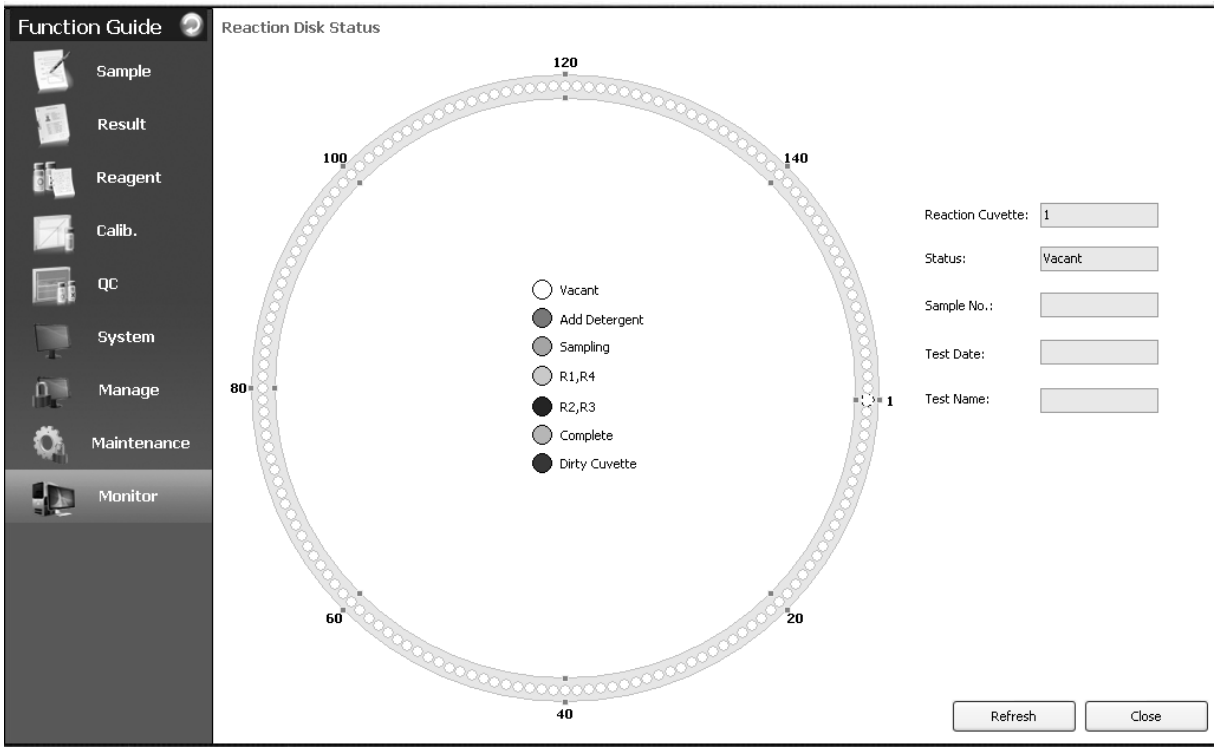


Figure 8-2-23

Click a reaction cuvette position that is to be check, and the related information will be shown on the right.

Status: Words will be displayed to show the status of the current reaction cuvette. Different colors mean different status of reaction cuvettes.

Status Explanation:

- Vacant: The reaction cuvette is not used for the current test. White shown.
- Add Detergent: Detergent is being dispensed into the reaction cuvette. Blackish green.
- Sampling: A sample is being dispensed into the reaction cuvette. Pink.
- R1, R4: Reagent 1 or 4 is being dispensed into the reaction cuvette. Light blue.
- R2, R3: Reagent 2 or 3 is being dispensed into the reaction cuvette. Purple.
- Complete: The test is finished. Green.
- Dirty Cuvette: The blank difference between the reaction cuvette and standard cuvette exceeds ±1000. Red.

Sample No.: The number of the sample tested in the reaction cuvette. 0 means a QC test or calibration test.

Test Name: The name of the analytic item tested in the reaction cuvette.

d)Click "

" to check the status of LIS communication, as shown in Figure 8-2-24:

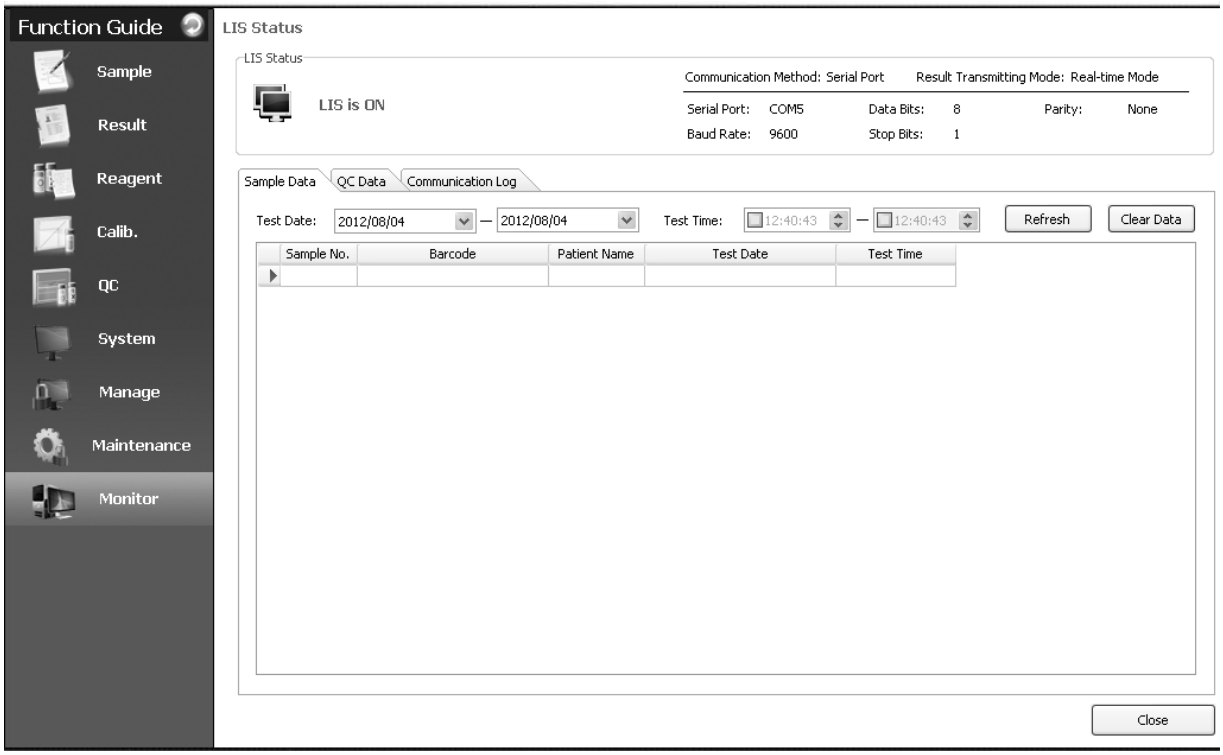


Figure 8-2-24

LIS system connecting status is displayed in this window.

➢Sample Data

Click "Sample Data", and select a range of "Test Date".

Select a range of "Test Time".

To update sample information, click "Refresh".

Click "Clear Data", and the sample data list in the window will be deleted.

The deleted data cannot be recovered.

➢QC Data

Click" QC Data", and select a range of "Test Data".

Select a range of "Test Time".

To update sample information, click "Refresh".

Click "Clear Data", and the sample data list in the window will be deleted.

The deleted data cannot be recovered.

➢Communication Log

Click" Communication Log", and select a "Date".

Click" Refresh" to update log information.

Click" Clear Data", and the log information will be deleted.

The deleted data cannot be recovered.

e)Click "

" to check the statistics of the tested samples, as shown in Figure 8-2-25:

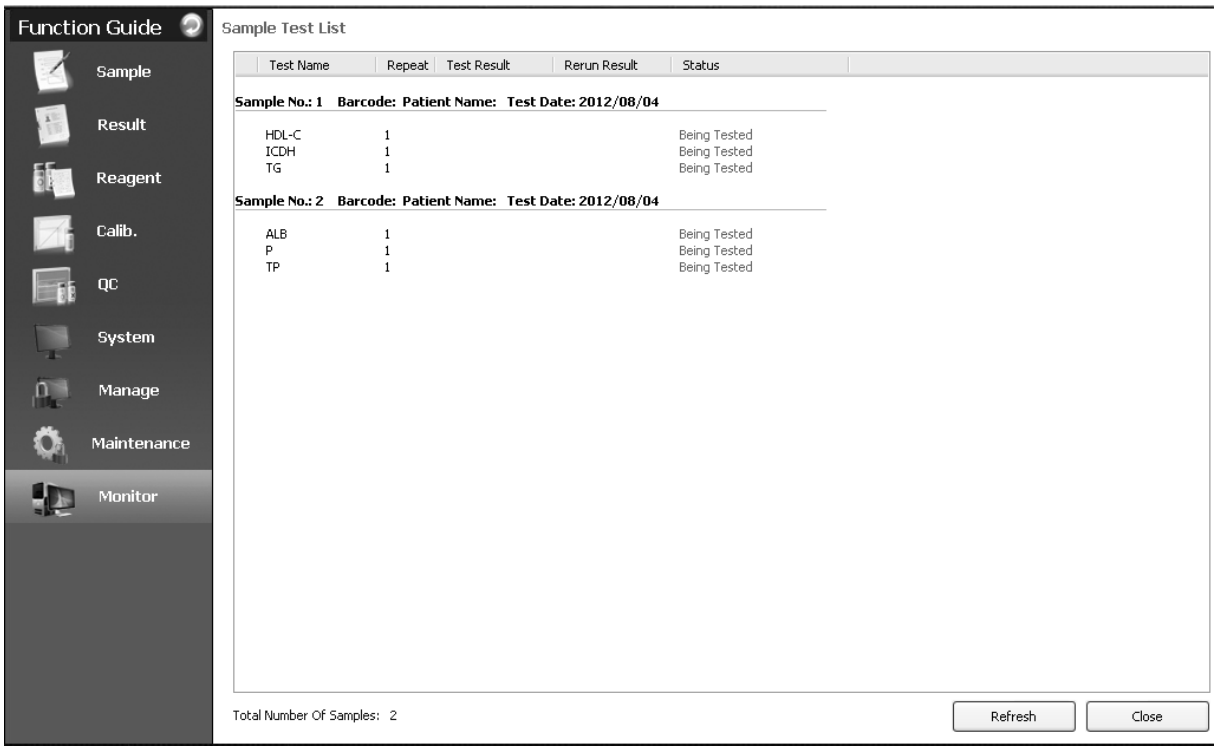


Figure 8-2-25

Click the "

" key to update the list of test information.

f)Click "

" to check the real-time status of each system of the analyzer, as shown in Figure 8-2-26:

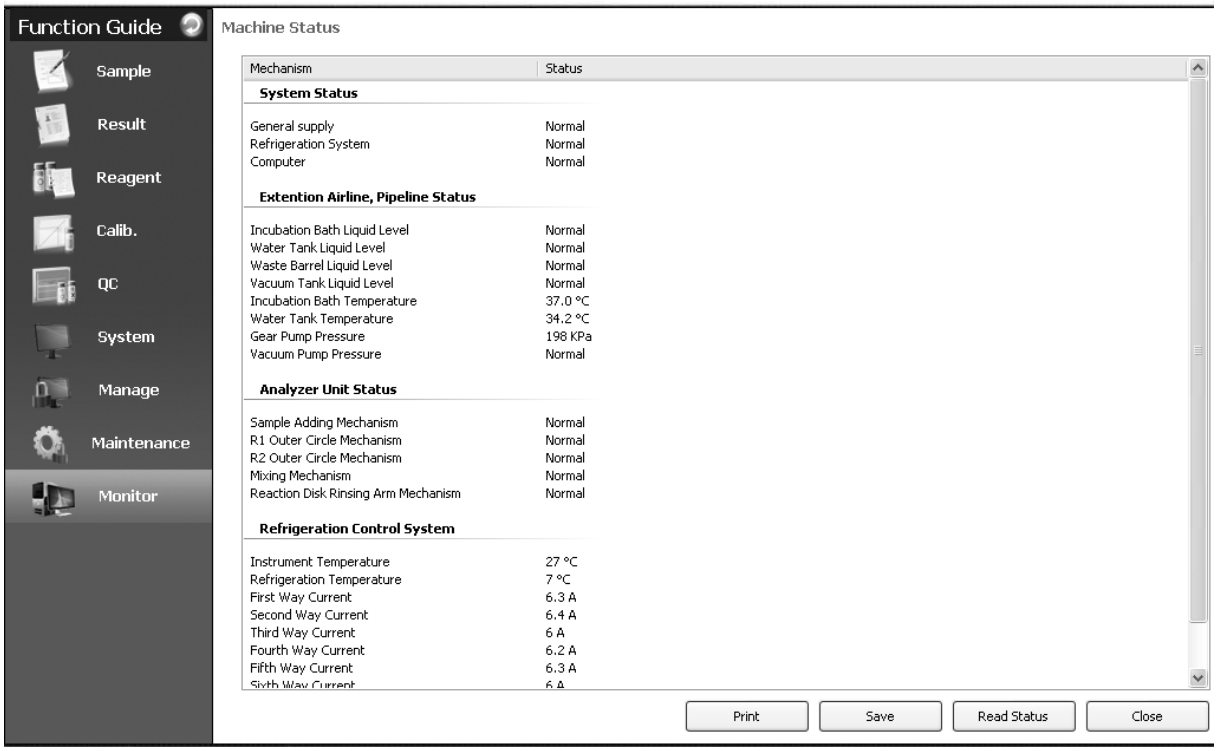


Figure 8-2-26

Under the window, users can monitor the status of the analyzer in real time: system status, gas and liquid path status, analyzer unit status, refrigeration control system status, etc.

Status can be read only in the stand-by mode.

(2)Stop or continue sample dispensing

Users can stop sample dispensing only when the analyzer is conducting tests. To continue tests, click the "" key.

If the disk number changes during tests, the analyzer will stop dispensing samples. After sample replacement, click "" to continue sample dispensing.

When an sample-dispensing-stop-level alarm sounds, the sample probe will also stop dispensing samples.

(3)Emergency Stop

If "" key is clicked during tests, the analyzer will stop current action immediately.

(4)Add samples

a)Add new samples

During tests, users can register other samples in the "Sample Registration" window. After registration, click the "Send Test" key to send the analyzer to add new samples.

b)Add new items to the existing sample No.

Click "Add Item" in "Test Inquiry" under the "Test Result" window. Select a range of sample numbers, sample volume, item name, and whether to dilute from "Analysis Item" boxes. Click "Add". Then click " " to send the instruction to add tests.

Users can add items to the existing sample No. in the stand-by mode or during tests.

8.2.10 Confirm test results (Check results)

● Lipemia, homolysis and icterus samples can affect test results.

● Make sure samples are not cloudy or with clots. Otherwise the sample probe can be blocked, which will badly affect test results.

● Such substance as medicine, anticoagulant, and preservative in samples can disturb some test results.

● Samples should not be in long-time contact with air. Otherwise they will volatilize, and thus affects test results.

● Incorrect parameter setting will affect test results.

● System maintenance should be conducted in accordance with User Manual. Otherwise, analyzer contamination or damage may be caused. As a result, test results will be affected.

● Modifying or adding test results is not recommended. The manufacturer takes no responsibilities for any results caused by modifying or adding test results.

Under Function Guide, click "

", as shown in Figure 8-2-27:

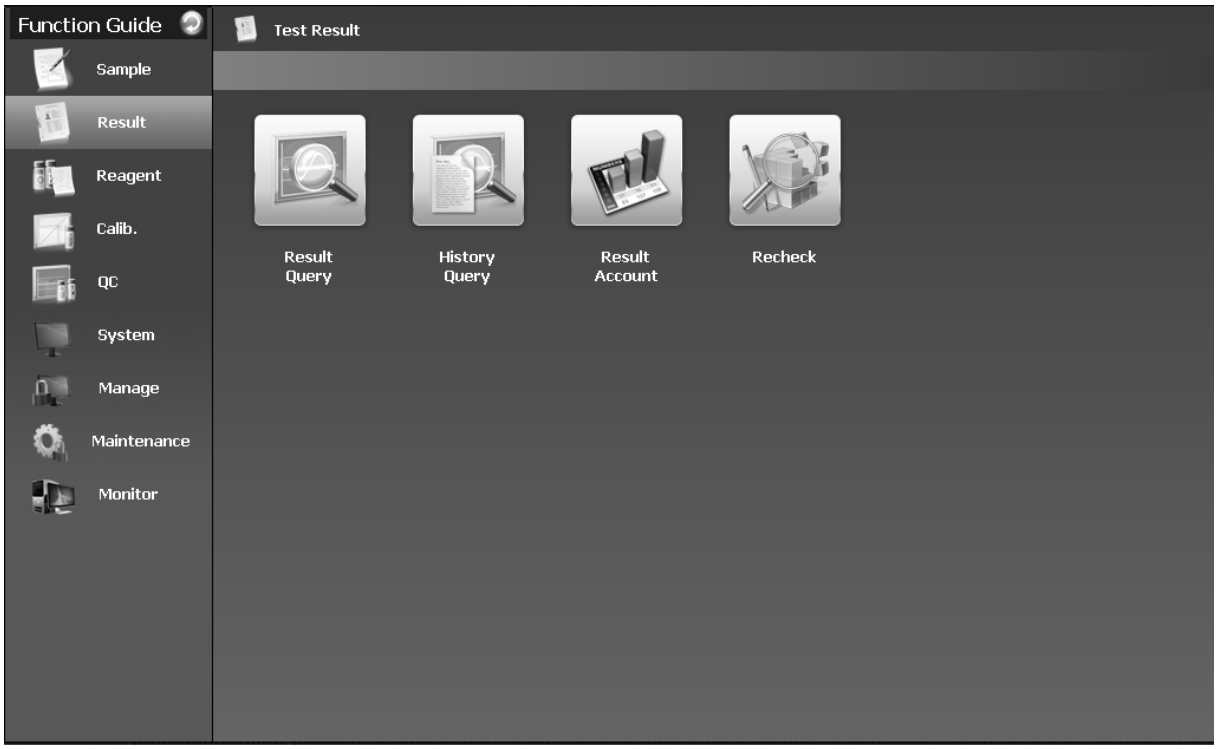


Figure 8-2-27

8.2.10.1 Result Query

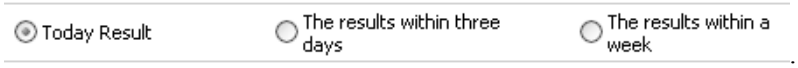
Click "

" to check, delete, modify, audit, preview, print, etc. test results.

(1)Today's results

To check today's results, click "Today Result" in the "

" window:



. All the information on today's samples will be displayed, as shown in Figure 8-2-28:

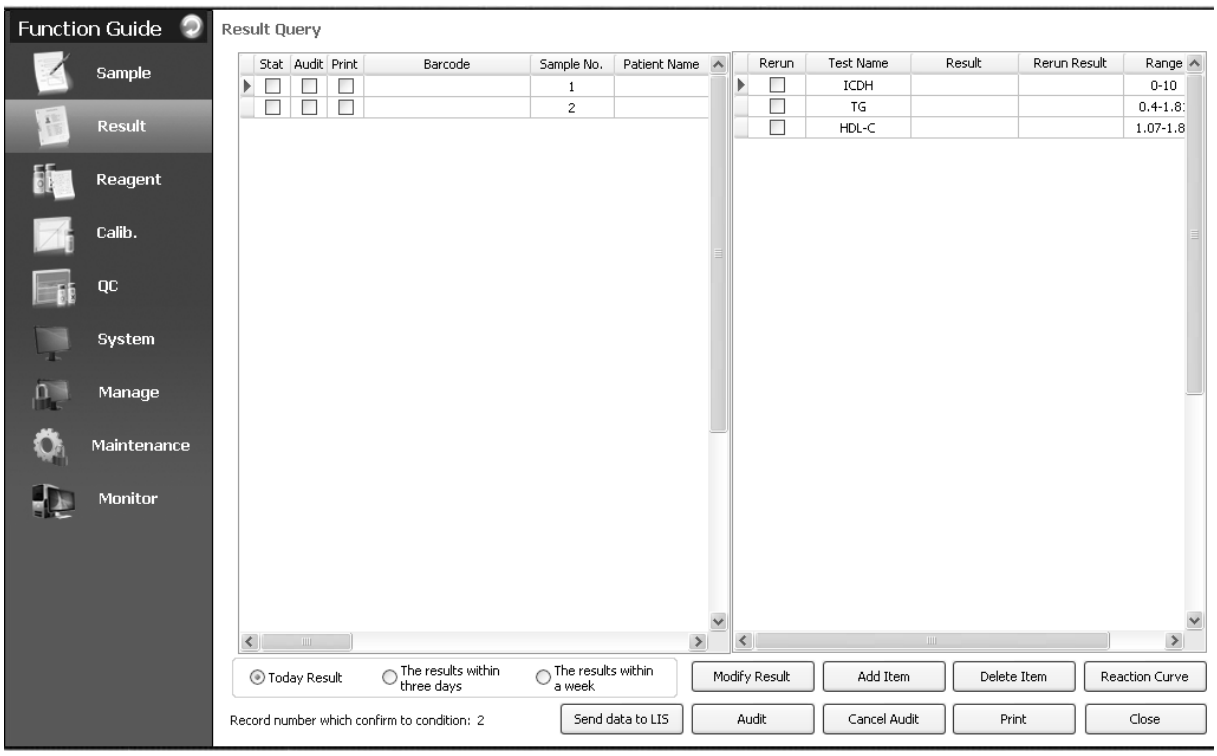


Figure 8-2-28

The left displays sample information, and the right displays test results.

Sample or reagent shortage indicating the aspirated volume is not sufficient. Therefore, the result is not reliable. "S" indicates no sample. "R" indicates no reagent. "!" indicates no sample and reagent. And the result will be colored. There will be no calibration; the test result is blank, and an alarm will be set off.

a)Modify Results

To modify a sample result, one way is to click the result in the result area. The position will be gray. Input another result, and press "Enter" in the keyboard.

Right-click an item, as shown in Figure 8-2-29:

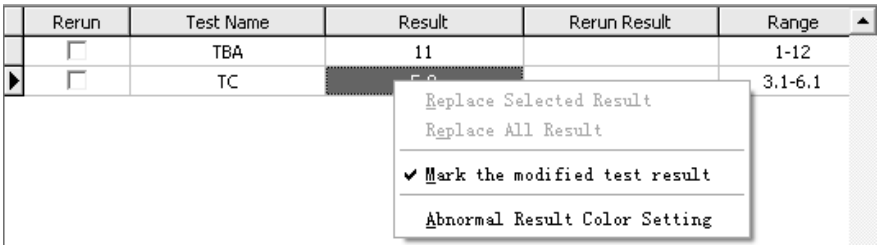


Figure 8-2-29

If "Mark the modified test result" is ticked, " * " will be displayed after result modification. If not ticked, no mark of modification will be made. As Figure 8-2-30 shows:

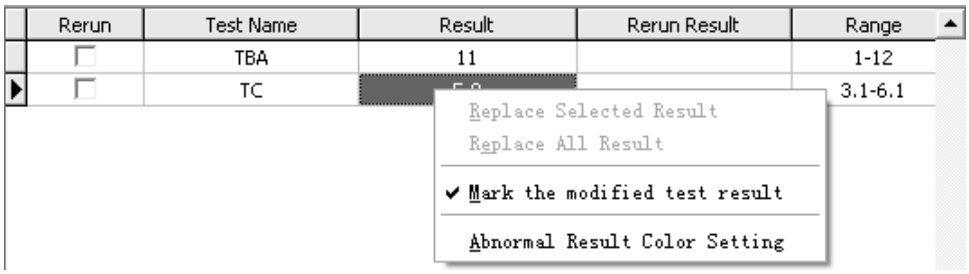


Figure 8-2-30

The other way is to click the "Modify Result" key, and Figure 8-2-31 will be shown:

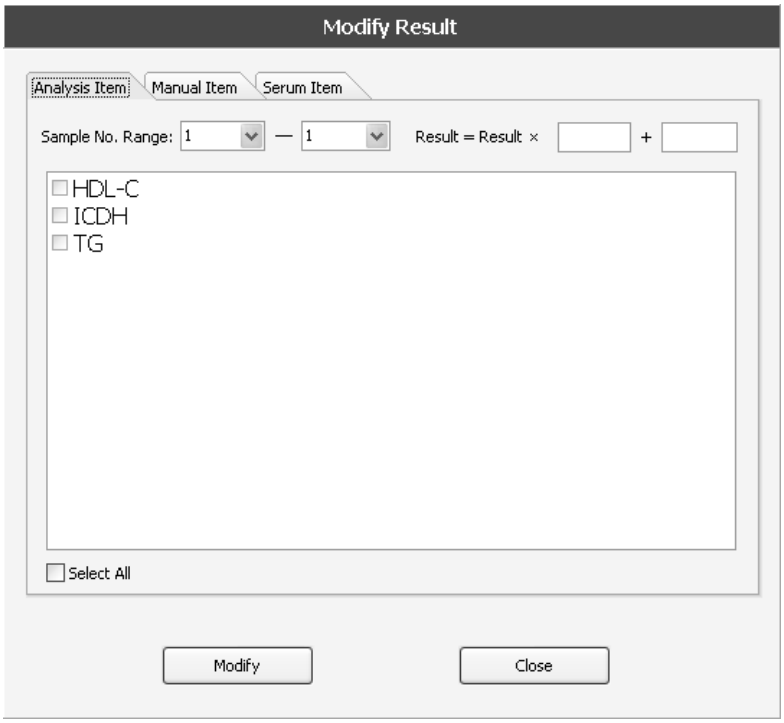


Figure 8-2-31

To modify results of analysis items, select "Analysis Item". Select a range of sample numbers from the pull-down menu. After selecting an item that is to be modified, input numbers for modification in "Result = Result × + ".

Click the "Modify" key to save the result.

To modify manual item results, select "Manual Item", and select a sample number range. After selecting an item that is to be modified, a modified number in the "Result" column. As Figure 8-2-32 shows:

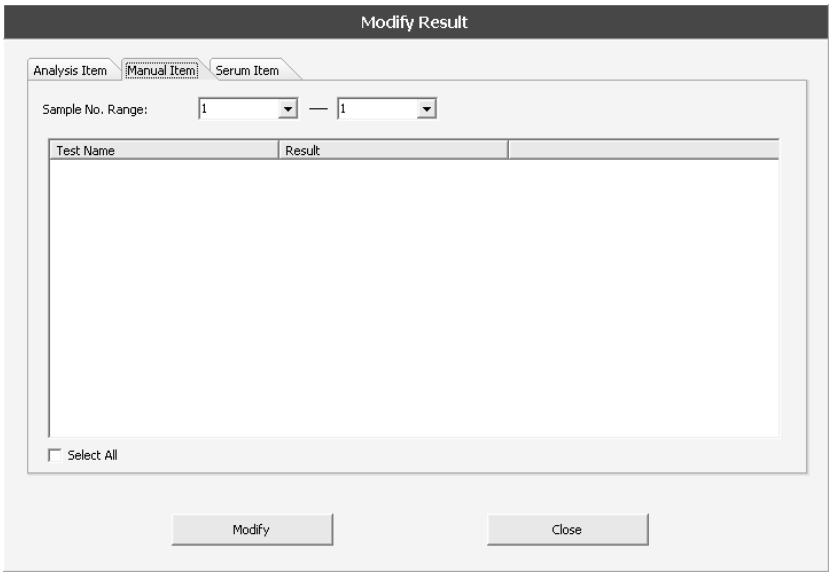


Figure 8-2-32

Click“ Modify ”to save the result.

To modify serum item results, select“ Serum Item ” and select a sample number range from the pull-down menu. After selecting the information to be modified, input a modified number in “ Result ”, as Figure 8-2-33 shows:

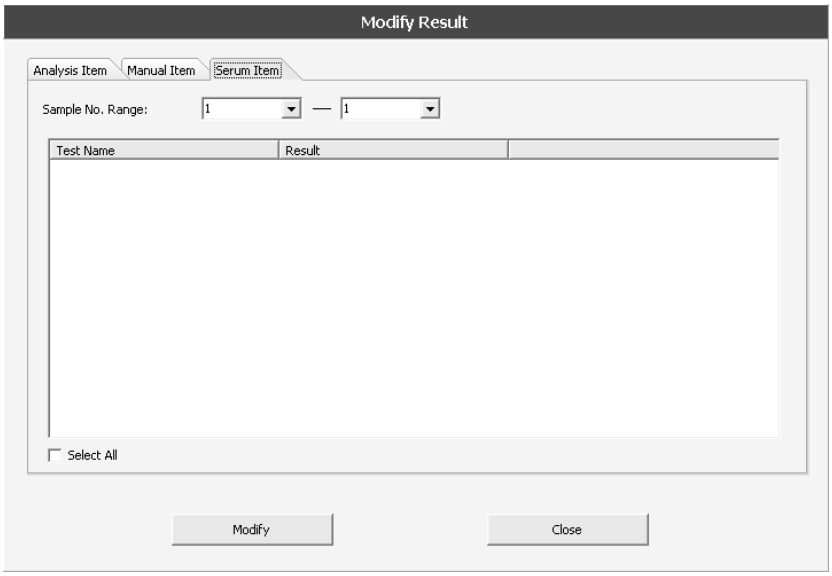


Figure 8-2-33

Click“ Modify ”to save the result.

b)Add items

Analysis items and manual items can be added to already-registered samples, no matter whether test results have been obtained. Click “ Add Item ” in the “Result Query” window to enter the item-adding window. Select “ Analysis Item ” to add items, as shown in Figure 8-2-34:

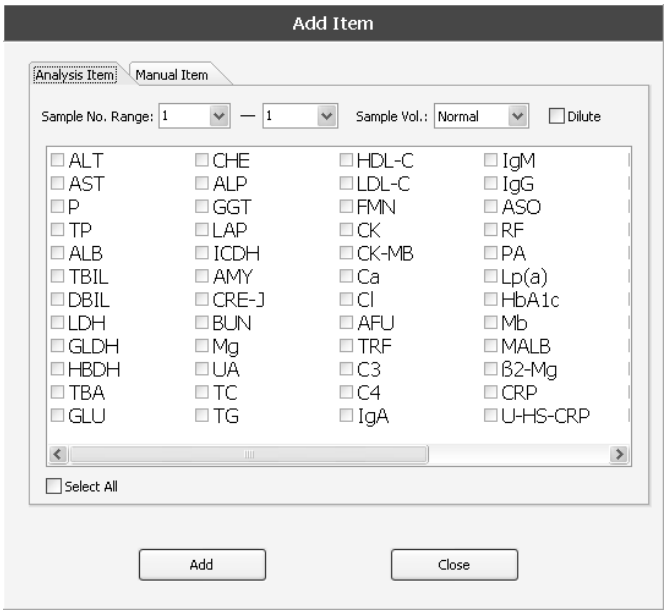


Figure 8-2-34

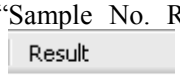
Select an initial sample number and final sample number from the "Sample No. Range" boxes. Select a sample volume type, and decide whether to dilute. 

means being selected. Select abbreviations of the analysis items to be added from the list. Click "

" to finish adding items.

If the added items need to be tested, click "Send Test", select "Routine Test" and initial sample number, and then click "Start Test".

In the "Add Item" window, click "

" to conduct manual item adding. Select a range from the "Sample No. Range" boxes. After selecting a test item that is to be added, input a result in the "

" column, as Figure 8-2-35 shows:

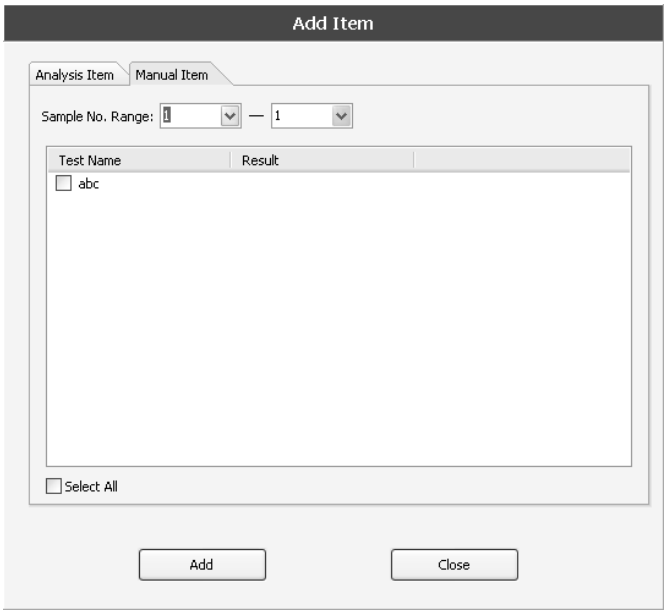
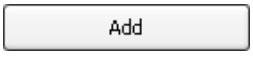


Figure 8-2-35

Click "

" to finish the item adding. Users can also directly click

“Add” after selecting an item without inputting a result in the result column; but input a result in the Manual Item result area which has been add to the “Result Query” window. As Figure 8-2-36 shows:

	Rerun	Test Name	Result	Rerun Result	Range
	☐	TBA	11		1-12
▶	☐	TC	5.8		3.1-6.1

Figure 8-2-36

Press “Enter” in the keyboard to save the result.

Adding manual item results must be conducted based on the item information (item number, item abbreviation, printing order) having been registered in the “Item Maintenance” window.

c)Delete Items

Click the result needing to be deleted in the “Result Query” area. Then click the “Delete Item” key. A dialogue box will pop up. As shown in Figure 8-2-37:

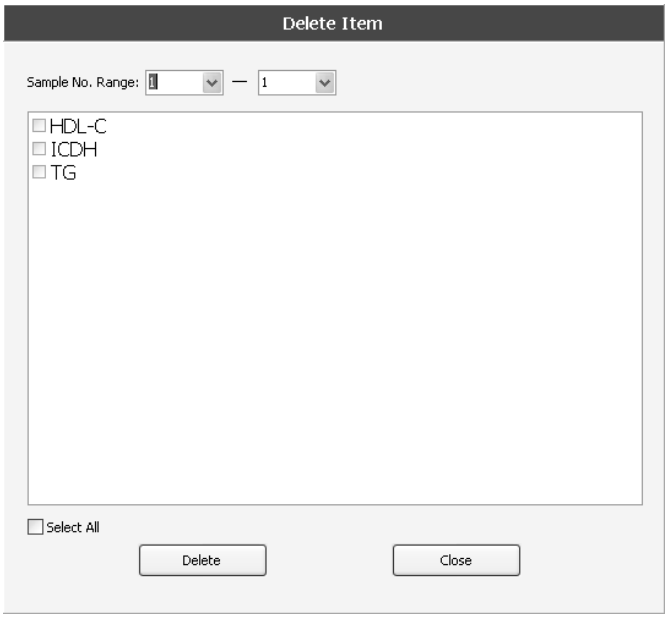


Figure 8-2-37

After range and item selection, click “Delete” to delete the records. To delete all the items, tick “Select All”.

If all items of a certain sample have been deleted, the sample is also deleted.

d)Reaction curve

To check the reaction curve of a certain test item, click the “Reaction Curve” key. After entering the window, make selection from the Test Date, Sample No., Test Name, Repeat Times, Curve Type, and Test Point pull-down menu. As Figure 8-2-38 shows:

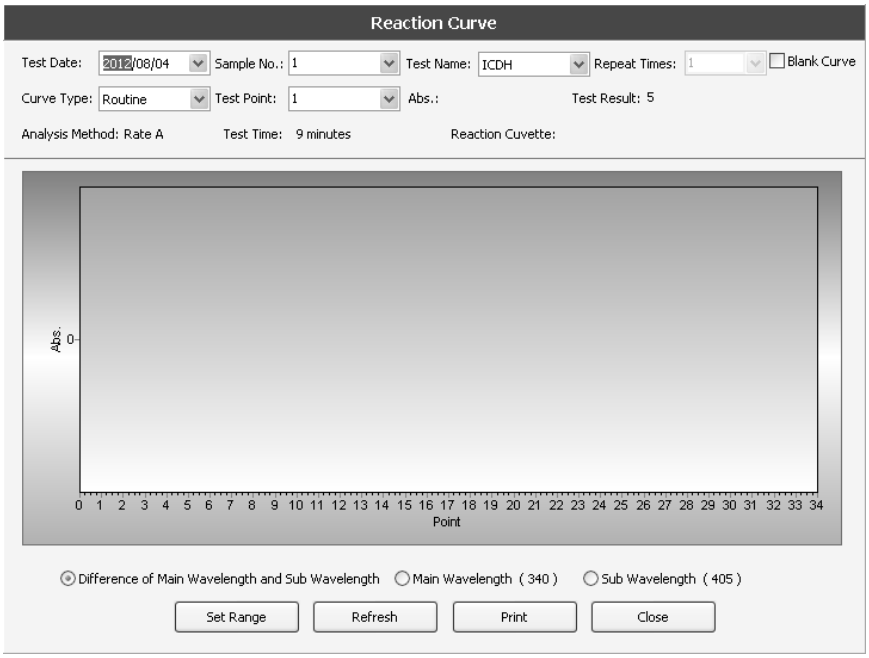


Figure 8-2-38

Select a test point from the pull-down menu of "Test Point", the absorbancy value will be displayed.

e)Send data to LIS

When LIS communication starts up, users can click "Send data to LIS", and Figure 8-2-39 will be shown:

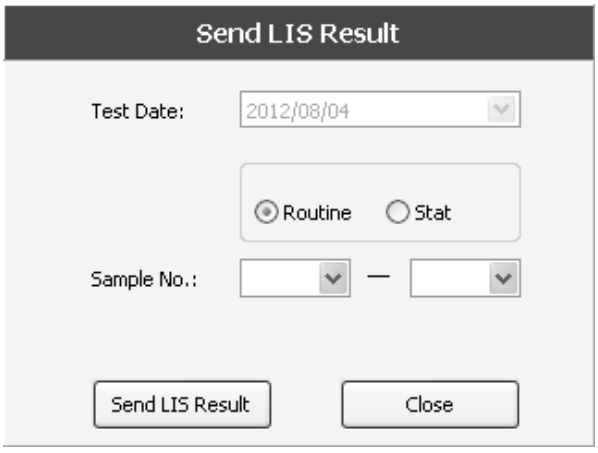


Figure 8-2-39

Select a test date from the "Test Date" pull-down menu. Select "Routine" or "Stat" sample. Select an initial sample number and final sample number. Then click the "Send LIS Result"key, and the test result will be sent to LIS system. If the LIS function is not in use, the function key won't be shown.

f)Audit

To audit sample results, click the "Audit" key. Select a range from the "Sample No. Range" pull-down menu. To audit a single sample, the initial and the final sample number should be the same; To audit a batch of samples, select an initial sample number and a final sample number. Then click the "Audit" key. For example, to audit No. 4 sample, select the sample number as Figure 8-2-40 shows:

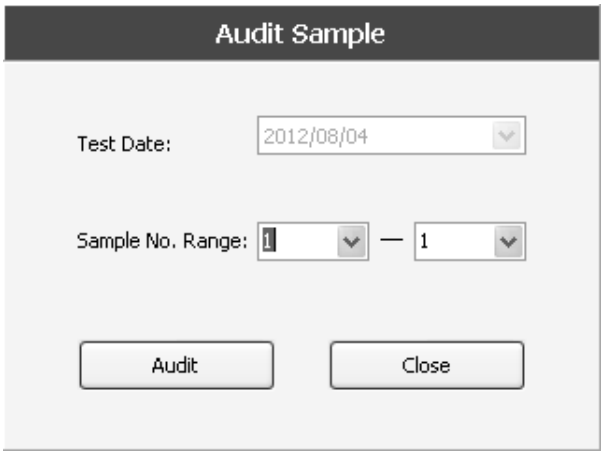


Figure 8-2-40

Click the "Close" key to exit from the "Audit Sample" window.

● Only sample information with results and names can be audited.

● The initial sample No. should be smaller than or equal to the final sample No. for batch audit.

● Users with checking and operator permission can not modify or delete audited samples. Users with administrator permission can cancel the audit of the audited sample and then modify it.

● Users with administrator permission can modify all test results. While Users with operator permission can only modify results of today.

g)Cancel Audit

If the audited samples need to be canceled, click "Cancel Audit". Select numbers from the "Sample No. Range" pull-down menu, as Figure 8-2-41 shows:

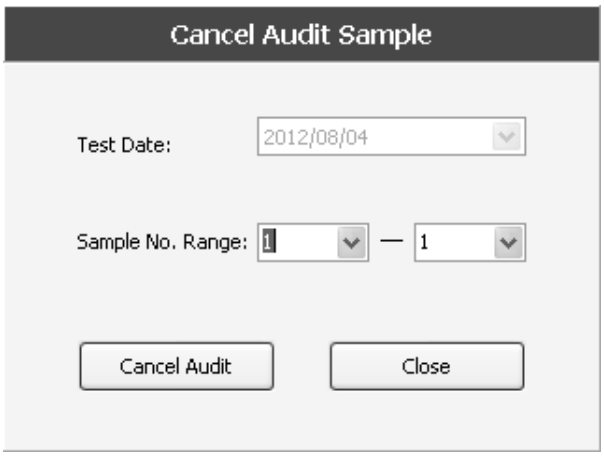


Figure 8-2-41

Click "Cancel Audit" to cancel the audited sample.

Click "Close" key to exit from the window.

h)Print report

Click the "Print" key. Make selection from "Test Date", "Sample No. Range", and "Print audited patient report", as Figure 8-2-42 shows:

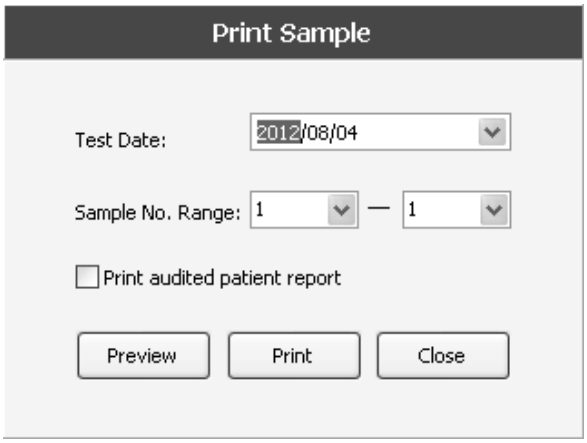


Figure 8-2-42

Click "Preview" and Figure 8-2-43 will be shown:

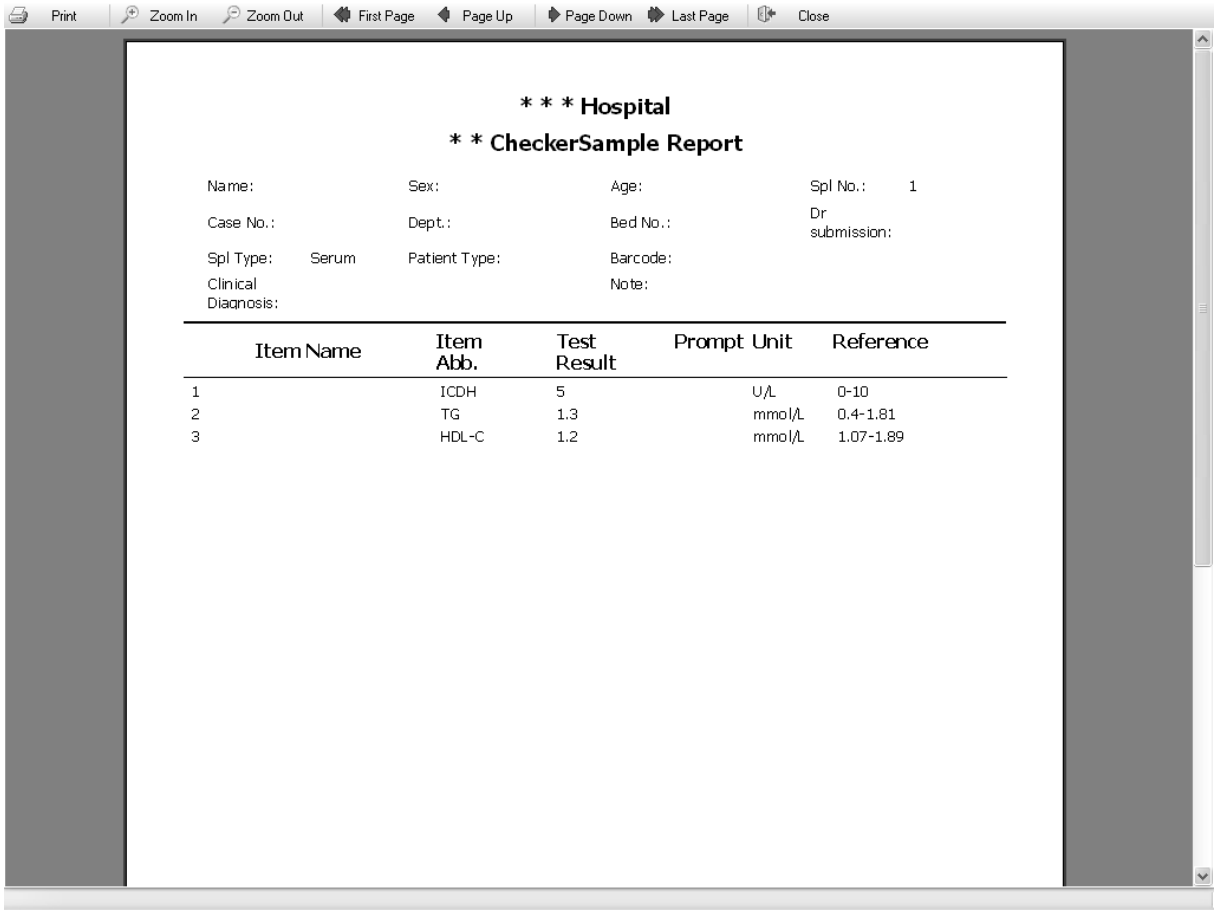


Figure 8-2-43

To print the report, click "Print" in Figure 8-2-43.

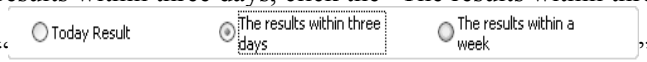
If preview is not needed, directly click the "Print" key in the "Print Sample" window to print the report.

If "Print audited patient report" is ticked, only the audited samples will be printed. If not selected, all reports will be printed.

Click "Close" to exit from the window.

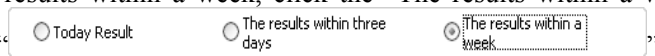
The initial sample number must be smaller than or equal to the final sample number in batch printing.

(2)Results within three days

To check results within three days, click the "The results within three days" radio button in the "Result Query" window: "

". For detailed operation, refer to Chapter "8.2.10.1(1) Today's Results" .

(3)Results within a week

To check results within a week, click the "The results within a week" radio button in the "Result Query" window: "

". For detailed operation, refer to Chapter "8.2.10.1(1) Today's Results" .

8.2.10.2 History Query

In the "Result" window, click the "

" key to enter the following window:

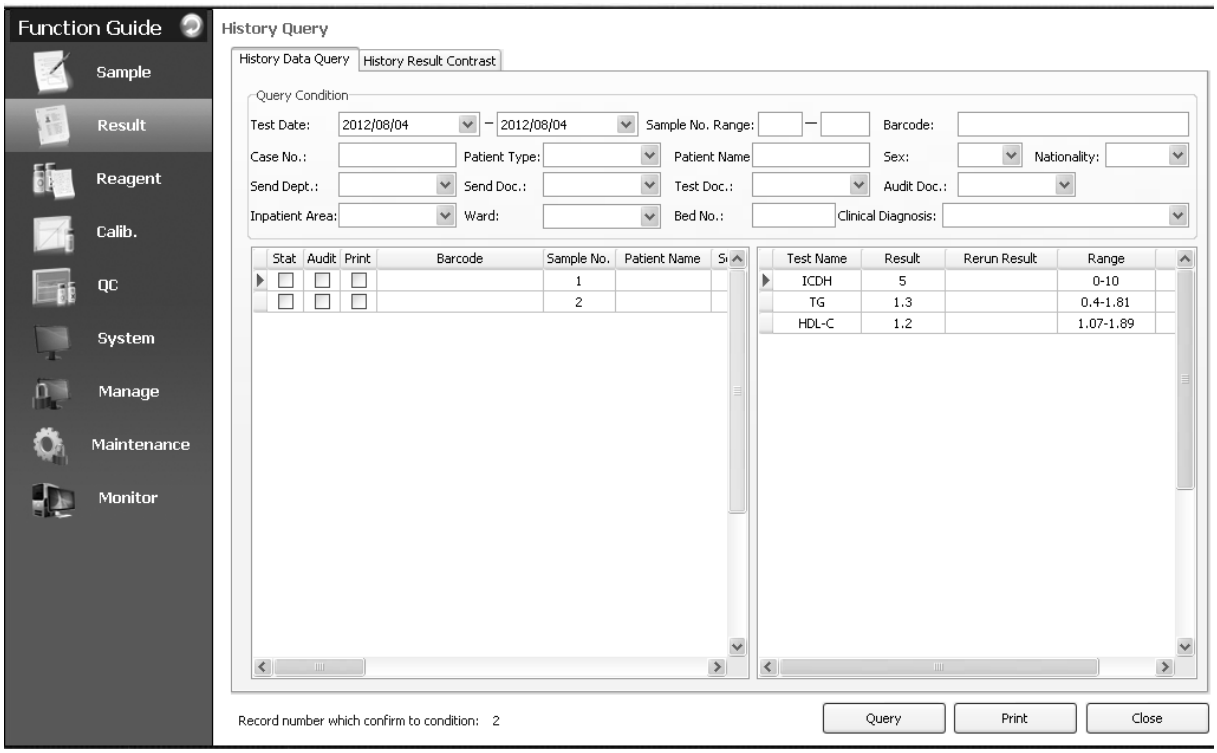
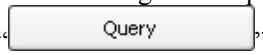


Figure 8-2-44

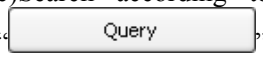
(1)History data query

a)Search according to "date": Select a date range from the "Test Date" pull-down menu. Then click "

". All the records that meet the requirement will be displayed in the result box. To check sample records of a certain day, the initial and the final date should be the same.

b)Search according to "sample number": Input sample numbers in the "Sample No. Range" input box. Then click "

". The results that meet the requirement will be displayed in the result box.

c)Search according to "barcode": Input a barcode number in the "Barcode" box. Then click "

". The results that meet the requirement will be displayed in the result box.

d)Search according to "case number": Input a case number in the "Case No." box. Then click

“Query”. The results that meet the requirement will be displayed in the result box.

e)Search according to “patient type”: Select a patient type from the “Patient Type” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

f)Search according to “patient name”: Input a patient name in the “Patient Name” box. Then click “Query”. The results that meet the requirement will be displayed in the result box.

g)Search according to “gender”: Select gender from the “Gender” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

h)Search according to “nationality”: Select a nationality from the “Nationality” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

i)Search according to “send department”: Select a send department from the “Send Dept.” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

j)Search according to “send doctor”: Select a send doctor from the “Send Doc.” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

k)Search according to “test doctor”: Select a test doctor from the “Test Doc.” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

l)Search according to “audit doctor”: Select an audit doctor from the “Audit Doc.” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

m)Search according to “inpatient area”: Select an inpatient area from the “Inpatient Area” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

n)Search according to “ward”: Select a ward from the “Ward” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

o)Search according to “bed number”: Input a bed number in the “Bed No.” box. Then click “Query”. The results that meet the requirement will be displayed in the result box.

p)Search according to “clinical diagnosis”: Select a clinical diagnosis from the “Clinical Diagnosis” pull-down menu. Then click “Query”. The results that meet the requirement will be displayed in the result box.

Click “Print”, and Figure 8-2-45 will be shown:

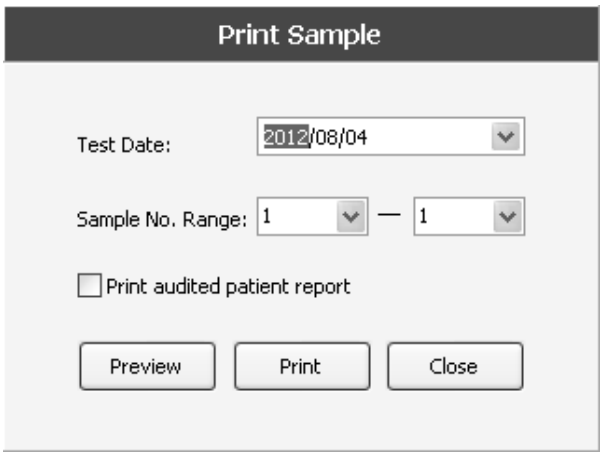


Figure 8-2-45

Click "Preview" and Figure 8-2-46 will be shown:

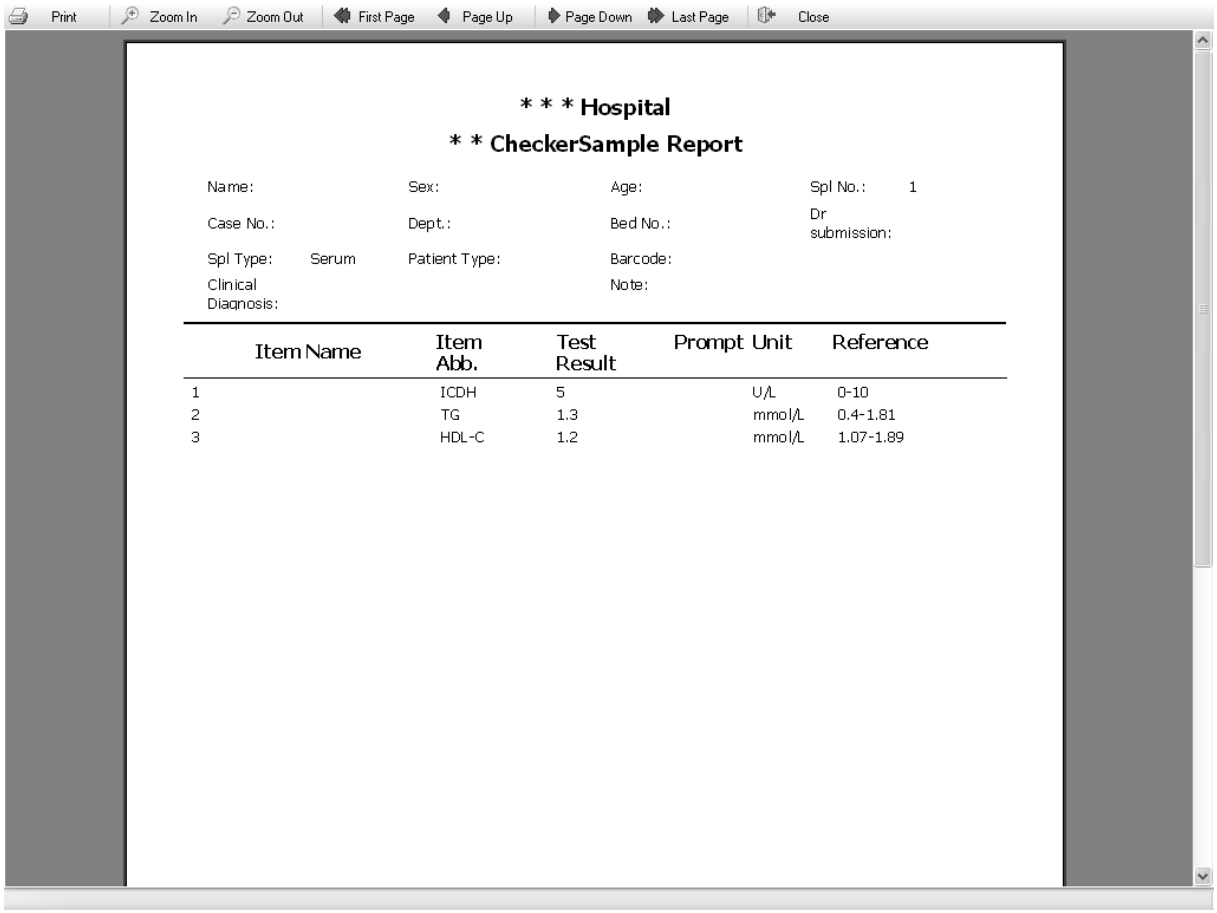


Figure 8-2-46

To print the report, click the "Print" key in Figure 8-2-46.

If preview is not needed, click the "Print" key in the "Print Sample" window.

If "Print audited patient report" is ticked, only the audited samples will be printed. If not selected, all reports will be printed.

Click "Close" to exit from the "Print Sample" window.

"Result Query" is a model window. After using the function, users must click the "Close" key to exit.

(2)History result contrast

In the "History Query" window, click "History Result Contrast", and Figure 8-2-47 will be shown:

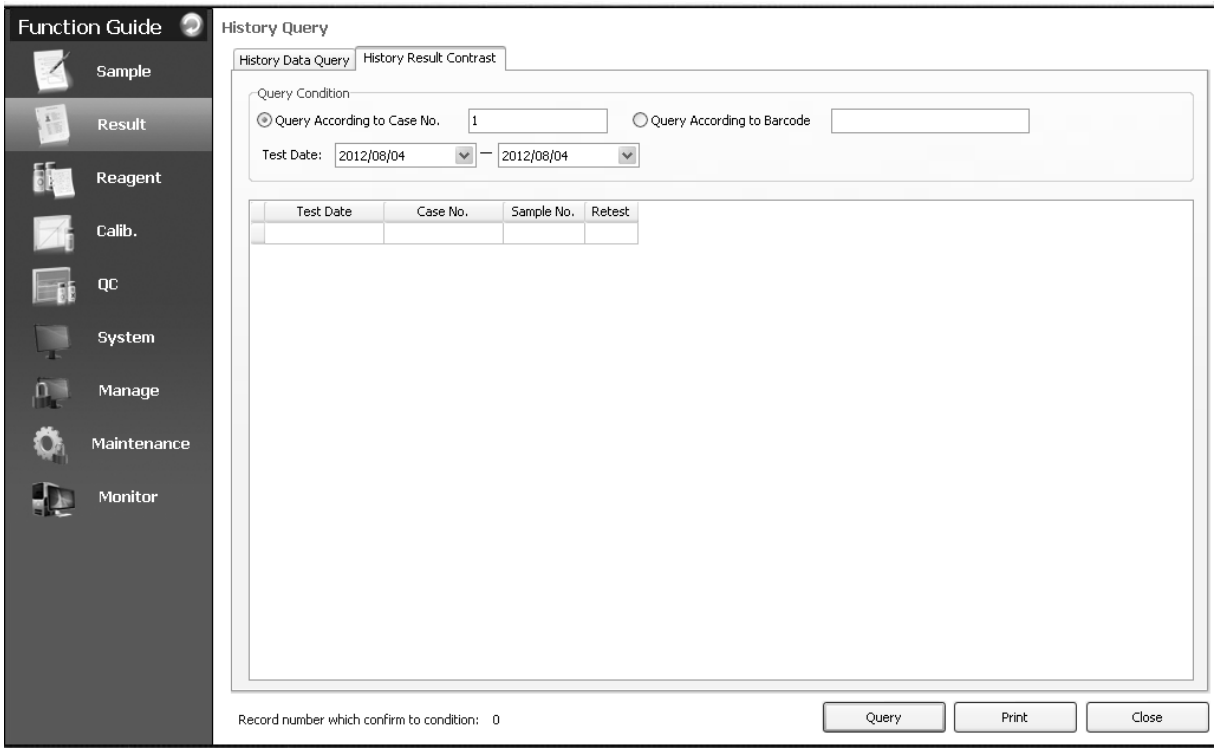


Figure 8-2-47

There are two methods for query, namely according to "case number" and "barcode number".

In "Query Condition", select "Query According to Case No. ". Input a case number and select a date range from the "Test Date" pull-down menu.

In "Query Condition", select "Query According to Barcode ". Input a barcode number and select a date range.

Click "Query" and Figure 8-2-48 will be shown:

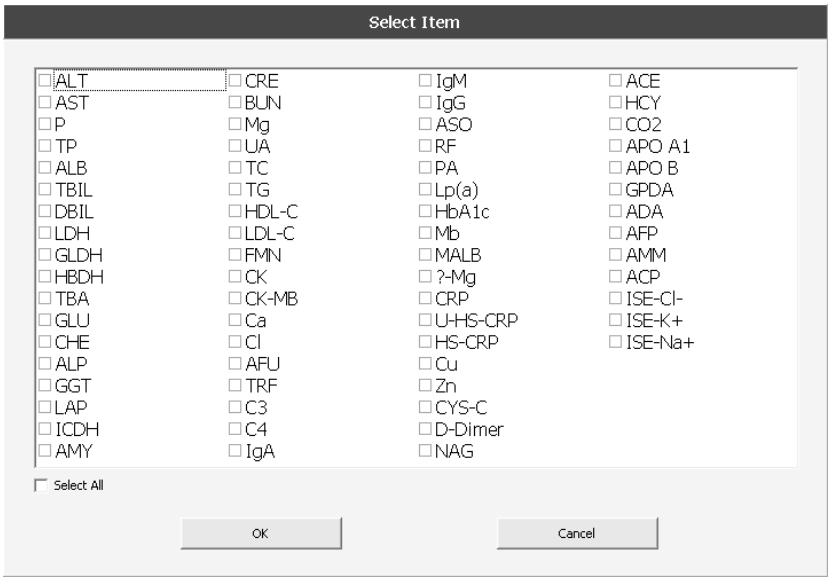


Figure 8-2-48

Users can select several items (5 at most), or click "Select All" (Select All) and the analyzer will select the first 5 items automatically. Then click the "OK" key, and the result will be displayed.

After the query, click "Print" to print the list.

8.2.10.3 Result Account

In the "Result" window, click the "

" to enter the following window:

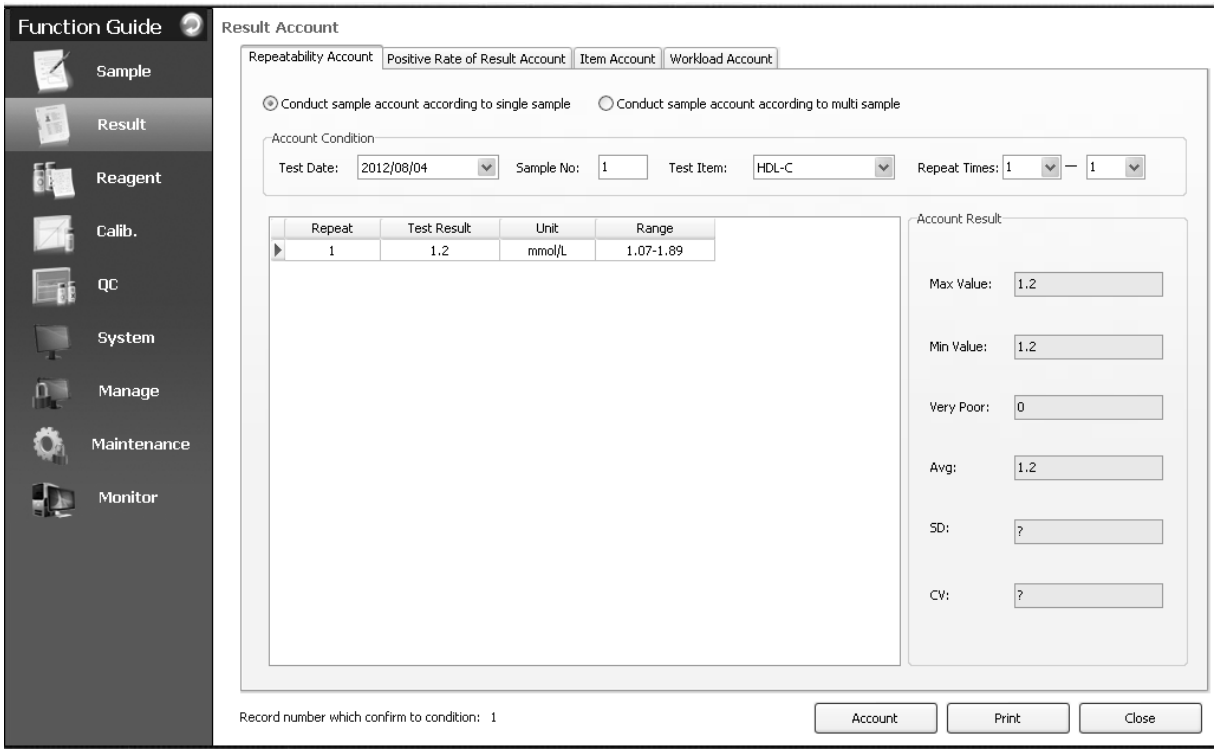


Figure 8-2-49

(1)Repeatability Account

a)Account a single sample

In the "Repeatability Account" window, to account repeatability of a single sample, select "

", and input account condition contents: test date, sample number, test name, and repetition times. Then click the "

" key to have the result displayed on the right of window. The maximum, minimum, extreme difference, average value, standard deviation and coefficient of variation can be checked, which facilitates confirming repeatability.

To print the report, click "

", as shown in Figure 8-2-50:

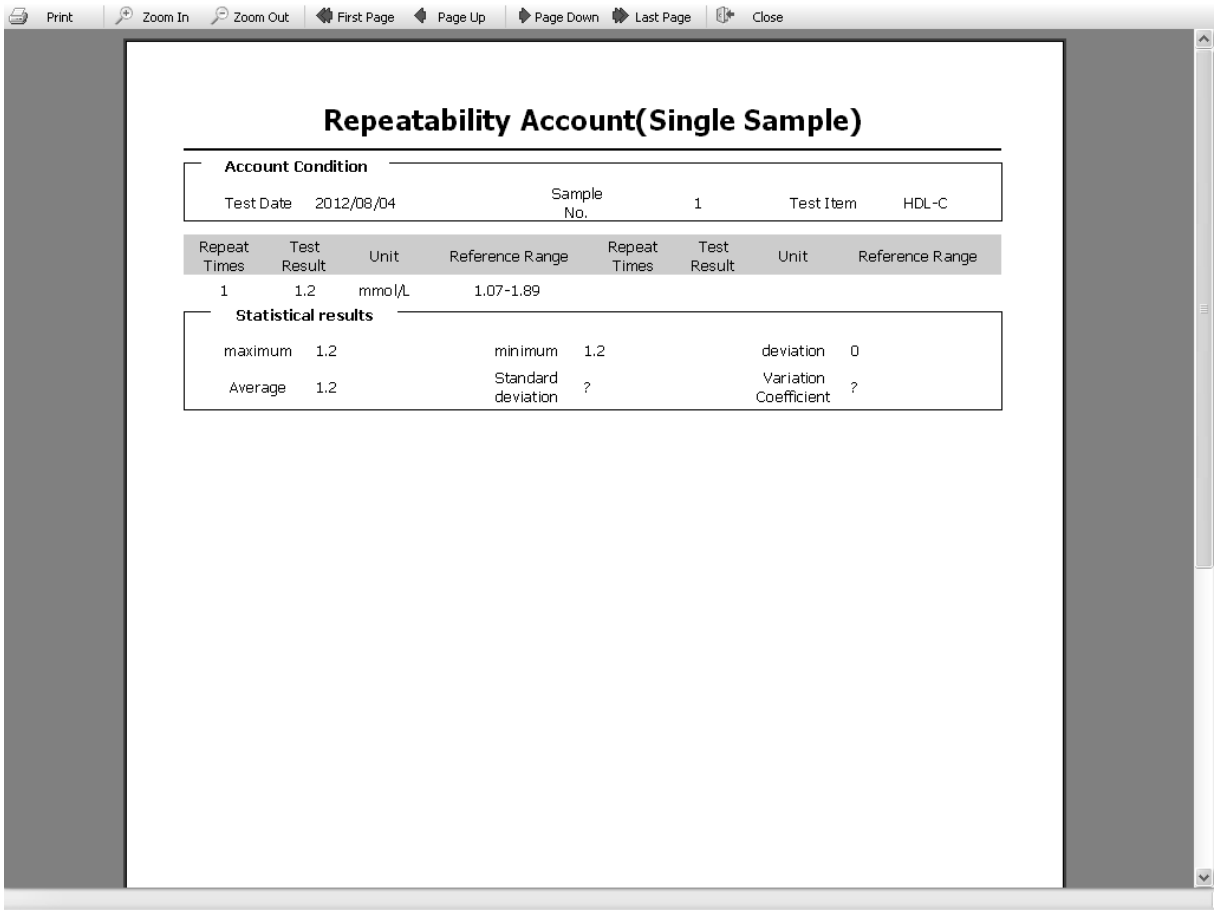


Figure 8-2-50

Click the "Print" key to print the report form.

No repeatability account can be conducted if a single sample has not been tested repeatedly.

b)Account several samples

In the "Repeatability Account" window, to account repeatability of several samples, select "Conduct sample account according to multi sample" as the following figure shows:

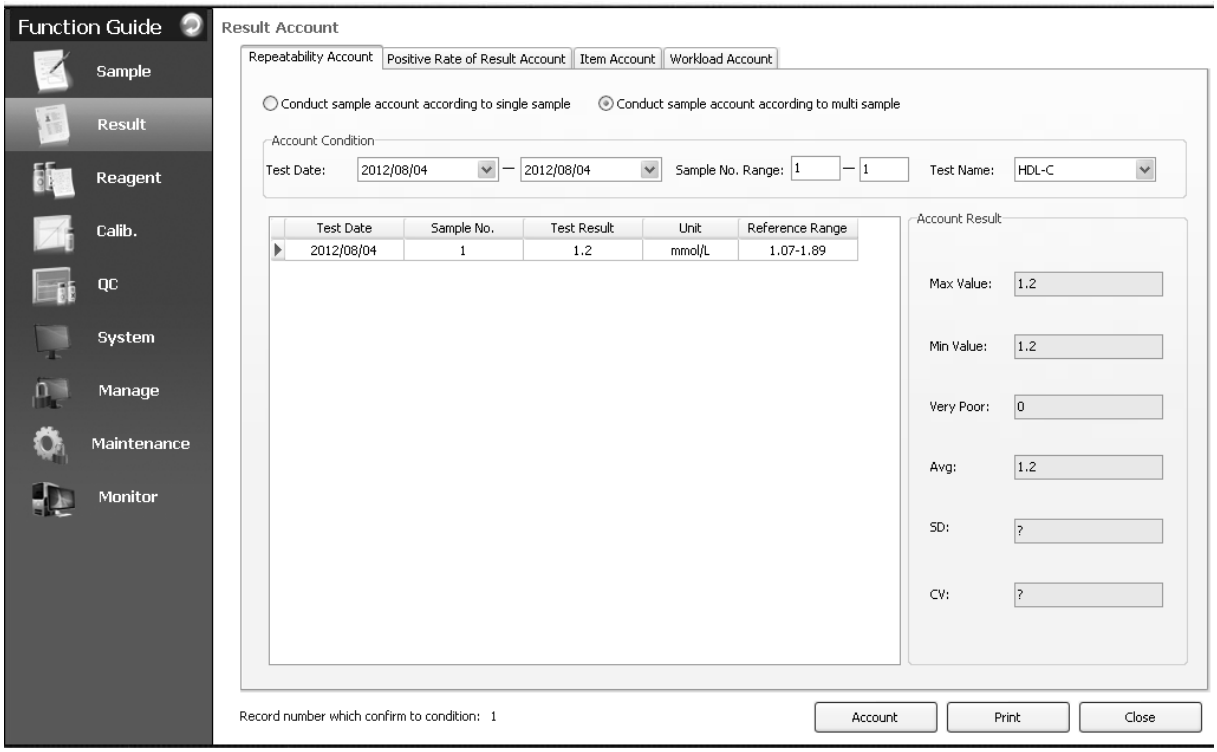


Figure 8-2-51

Input account condition contents: test date, range of sample number, and test name. Then click the "Account" key to display the result on the right of window. The maximum, minimum, extreme difference , average value, standard deviation and coefficient of variation can be checked, which facilitates confirming repeatability.

If the account report needs printing, click the "Print" key, and Figure 8-2-52 is shown:

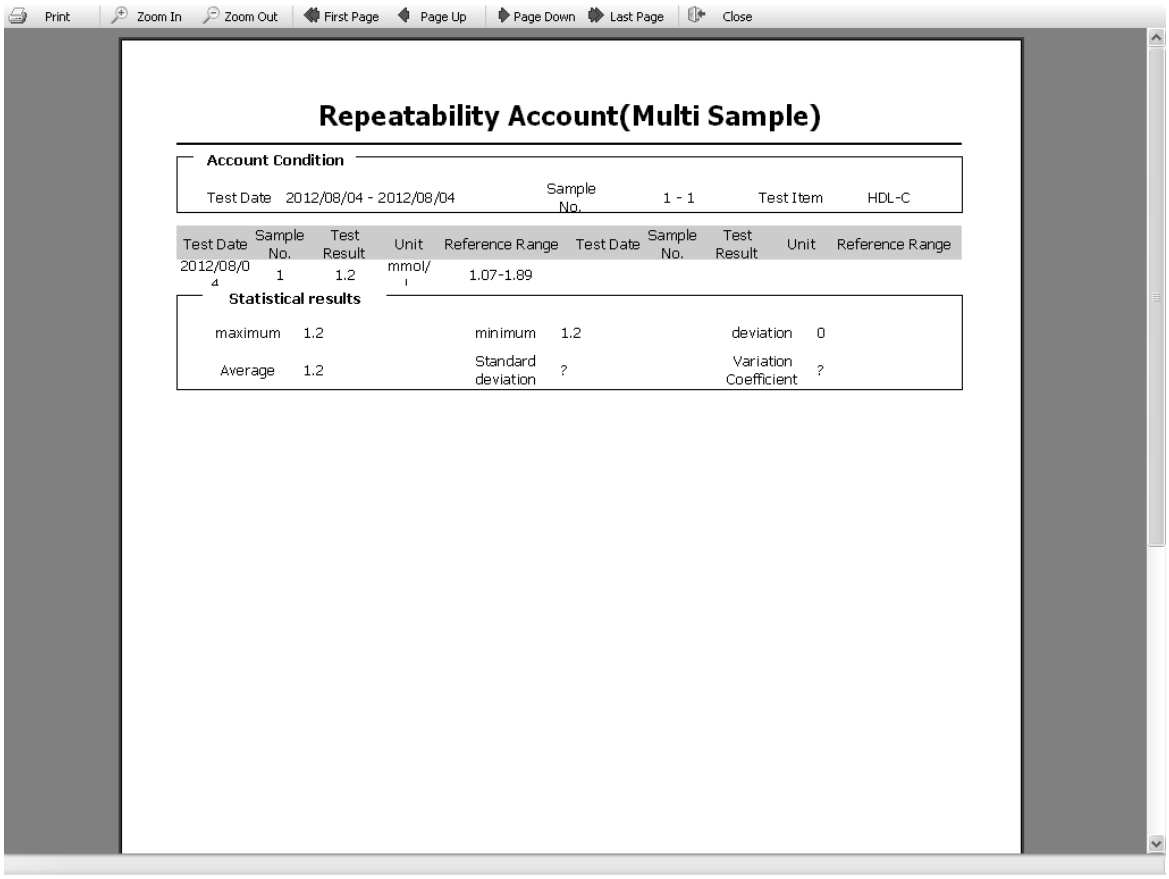


Figure 8-2-52

Click "Print" to print the report form.

(2)Account of positive result rate

Enter the "Positive Rate of Result Account" window that Figure 8-2-53 shows:

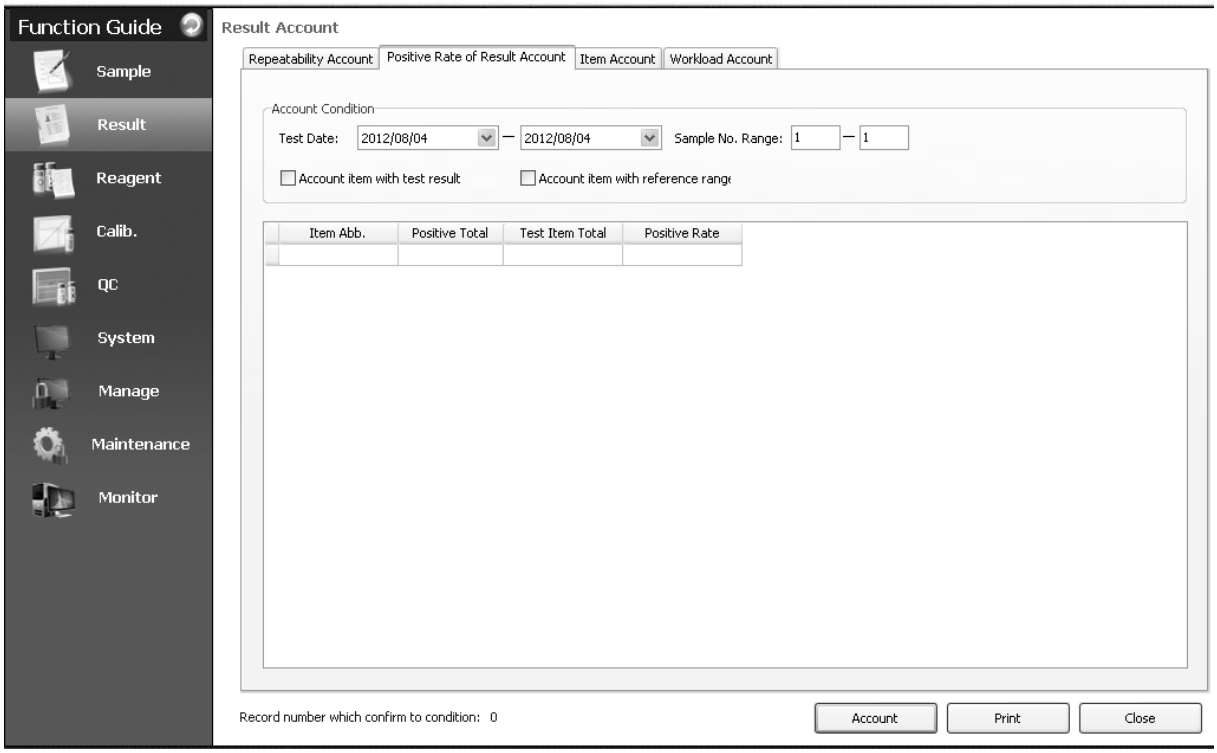


Figure 8-2-53

Under “Account Condition”, input a test date and sample number range.

Users can select “Account item with test result” or “Account item with reference range”, or select both at the same time to conduct account of test results that meet the requirements.

Click the “Account” key, and Figure 8-2-54 is shown:

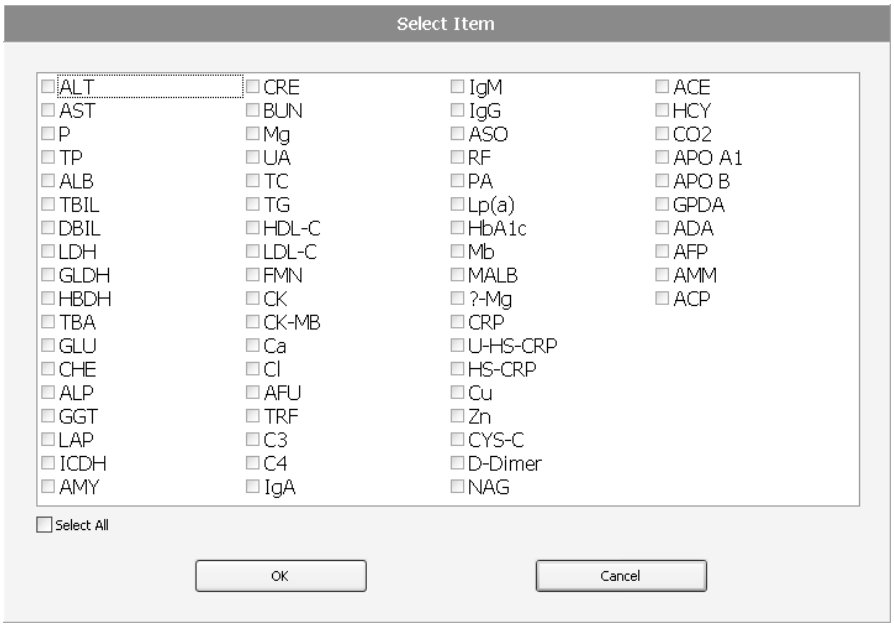


Figure 8-2-54

Select account items, or click “Select All”. Then click “OK”, and the result will be shown in the list box.

To print the account report, click “Print” and Figure 8-2-55 will be shown:

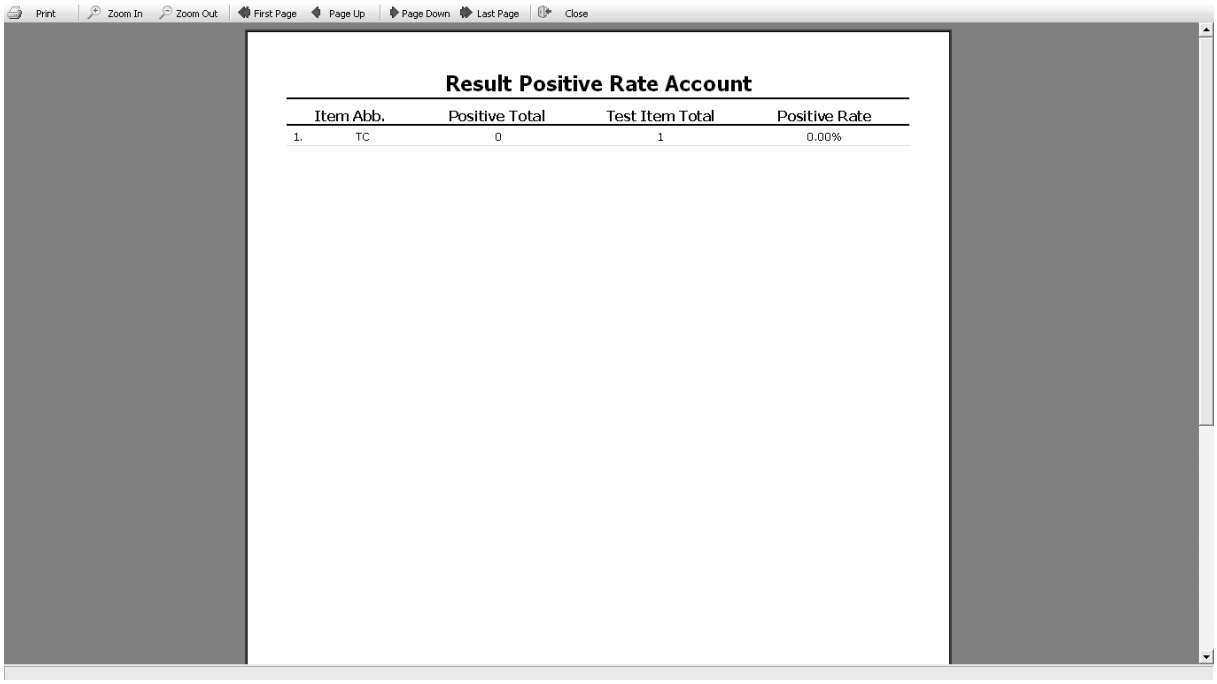


Figure 8-2-55

Click “Print” to print the report form.

(3)Item Account

Enter the “Item Account” window, and conduct setting under the “Account Condition”: select a test date range. Then click the “Account” key, as shown in Figure 8-2-56:

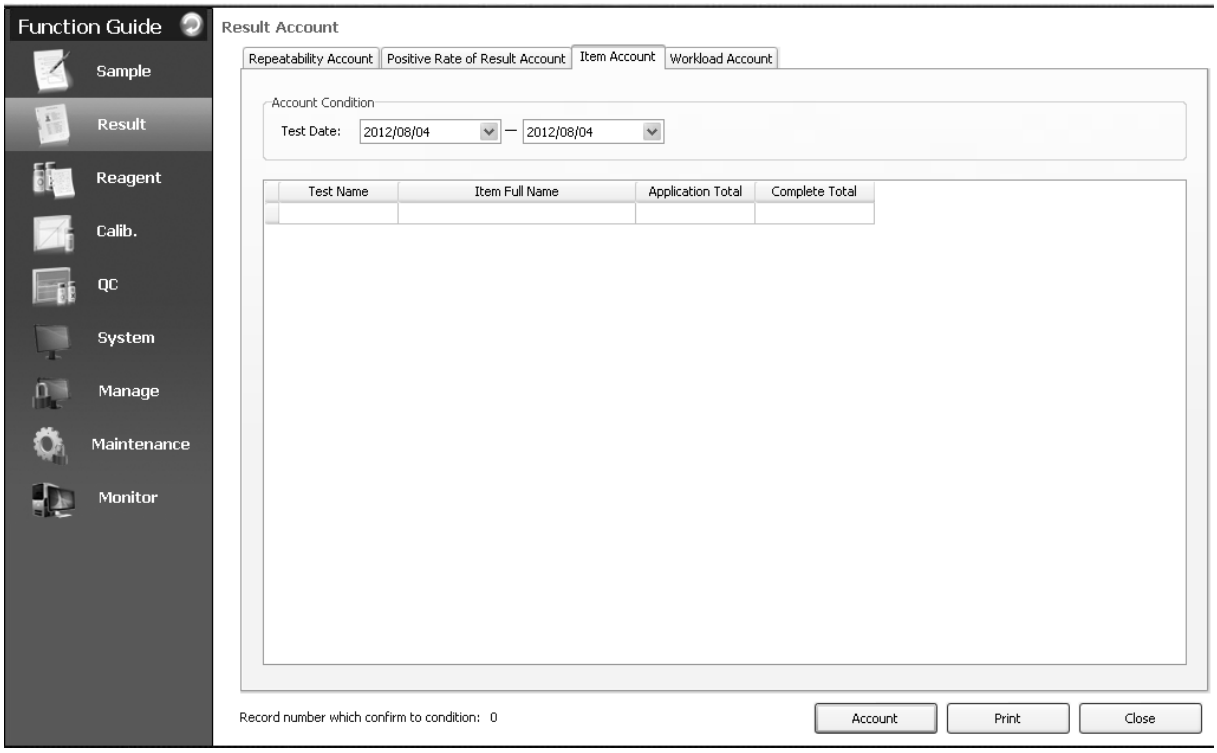


Figure 8-2-56

Click the “Print” key to print the account report.

(4)Workload Account

Enter the “Workload Account” window, as shown in Figure 8-2-57:

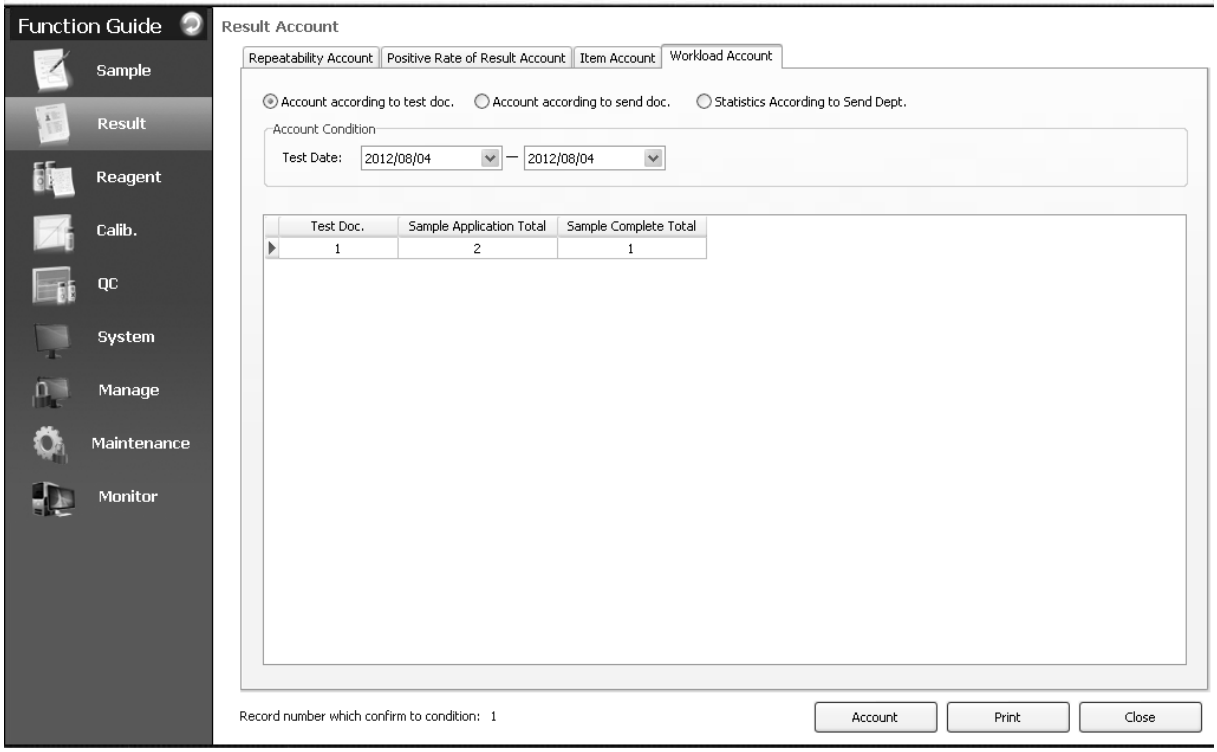


Figure 8-2-57

Users can conduct "Workload Account" to account the workload of a test doctor, send doctor and send department. According to needs, select a test date range under "Account Condition". Click the "Account" key to finish account analysis. Users can also click the "Print" key to preview and print the account report form.

8.2.11 Item Recheck

There are two recheck methods: automatic recheck and manual recheck. The rechecks won't change sample numbers.

(1)Automatic recheck

In the "Result" window, click the "

" key, as shown in Figure 8-2-58:

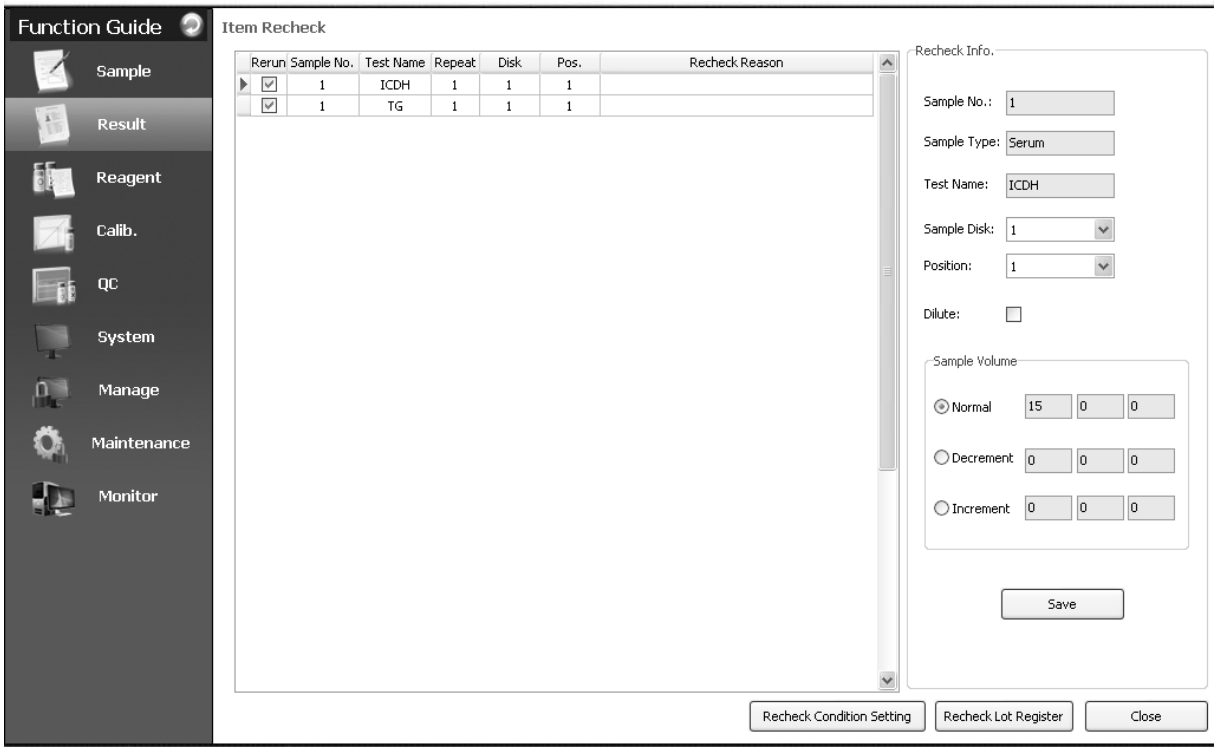


Figure 8-2-58

Click "Recheck Condition Setting" to set Recheck Condition, as shown in Figure 8-2-59:



Figure 8-2-59

Tick corresponding items and click the "Save" key. After sample tests, the analyzer will automatically add the sample information that meet the requirement of "Recheck Condition" to the recheck window, according to the set "Recheck Condition".

(2)Manual Recheck

a)Manual recheck on a single sample

If a sample needs recheck after a test, click the "Recheck" key in its corresponding "Result Query" window. Then the sample to be rechecked will be automatically displayed in the Item Recheck list as Figure 8-2-60 shows:

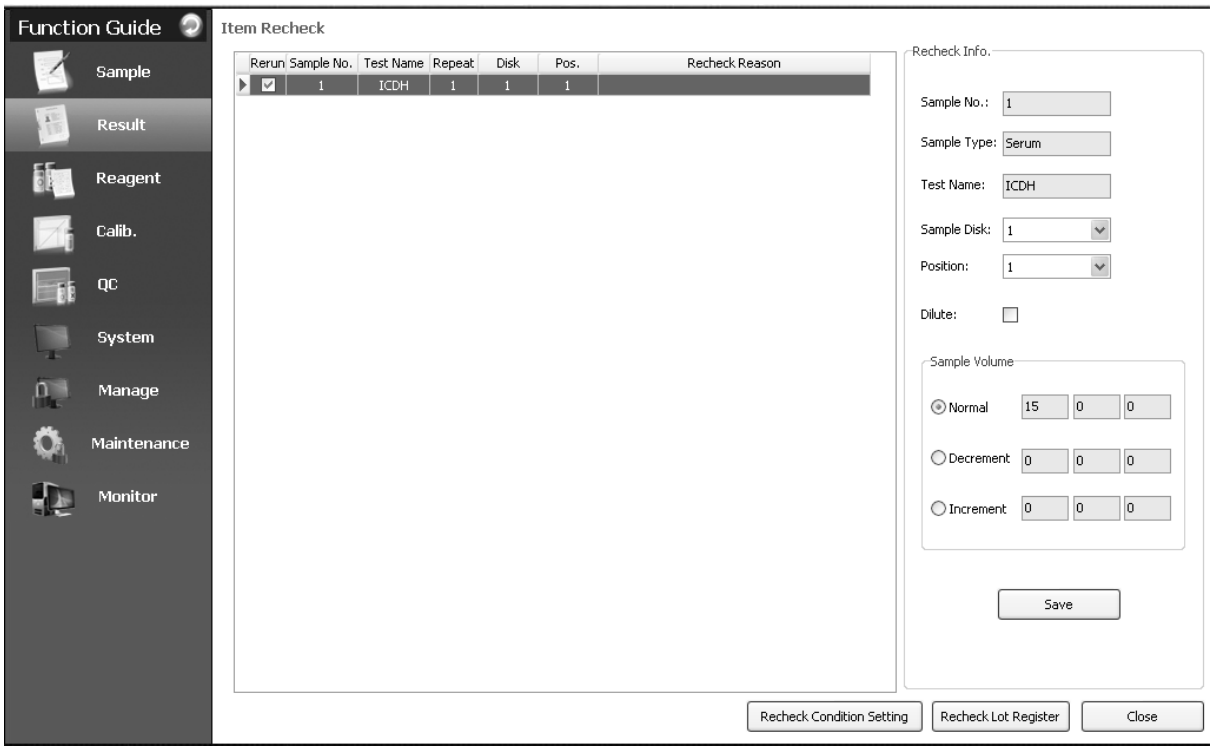


Figure 8-2-60

Under "Recheck Info." on the right, set the sample number, sample type, test name, sample disk, position,

and "dilute". Then click the "Save" key. If the recheck setting is conducted successfully, the modified disk number and position of the recheck item will be displayed in the "Item Recheck" area.

Users can manually modify sample volume (normal, increment, decrement), and can set the dilution of a sample. The following table shows the relation between recheck conditions and sample volume.

Conditions for automatic recheck	Sample volume type
Exceed technical lower limit	increment
Exceed technical upper limit	decrement
Exceed reaction absorbancy limit	decrement
Exceed prozone test value	decrement
Absorbancy of reaction solution exceeds 3.3Abs	decrement

● When a test meets auto-recheck conditions, and the dilution, increment, decrement of the items are set, a re-test will be conducted automatically. The recheck result will be displayed in "Result Query".

● Place a sample in the set disk and position to conduct the manual recheck test.

b)Manual recheck on a batch of samples

In the "Item Recheck" window, click the "Recheck Lot Register" key, and Figure 8-2-61 will be shown:

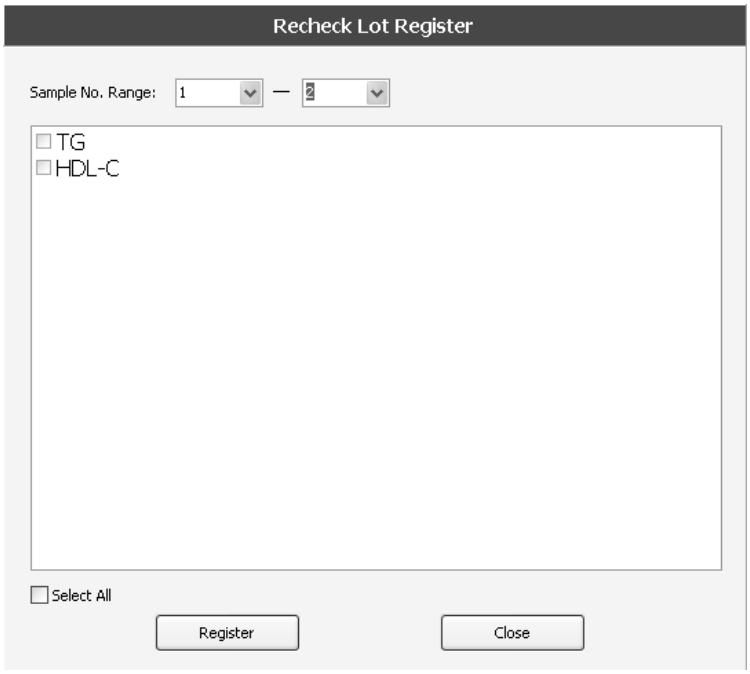


Figure 8-2-61

Select a range of sample numbers.

Select recheck items, or click "Select All". Then click the "Register" key, and the samples will be added to the recheck list.

Under "Recheck Info." on the right, set the sample number, sample type, test name, sample disk, position, and "dilute". Click the "save" key, the information will be added to the recheck window.

Users can manually modify sample volume (normal, increment, decrement), and can set the dilution of samples.

Before sample volume setting, "sample volume" should be set in "Analysis Parameter" of "System

Setting".

(3)Recheck Test

After recheck registration, click "  " in the shortcut key area. Select "Recheck Test". Then click the "Start Test" key to start the test.

Only tests of today can be rechecked.

8.2.12 Analysis Complete

(1)Reconfirm results

After sample recheck tests, left-click the results. Right-click, and select "Replace Selected Result". The recheck results will be displayed in the "result" column, as shown in Figure 8-2-62:

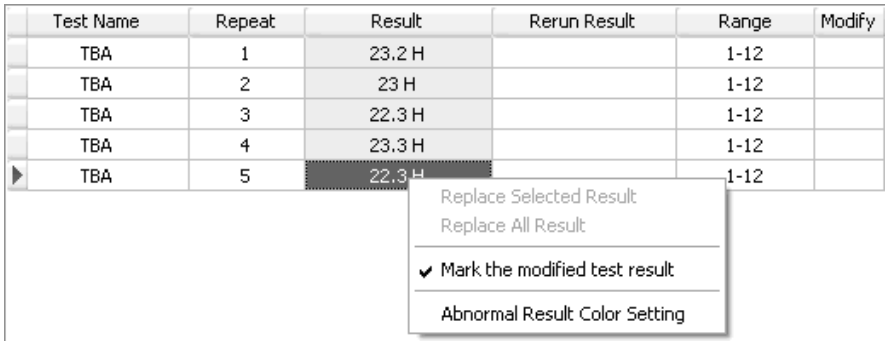


Figure 8-2-62

If the recheck item is more than one, users can click "Replace All Result". All the recheck results will be added to the "result" column.

After audit, recheck results will replace previous test results.

(2)Back up database

The backup and recovery of database must be done in the off-line mode.

In the "not log on" status, right-click "" on the desktop. Select "Attribute", and then click "Search Target". The "C:\Program Files\Auto-Chemistry Analyzer\Auto-Chemistry Analyzer" interface will pop up, as shown in Figure 8-2-63:

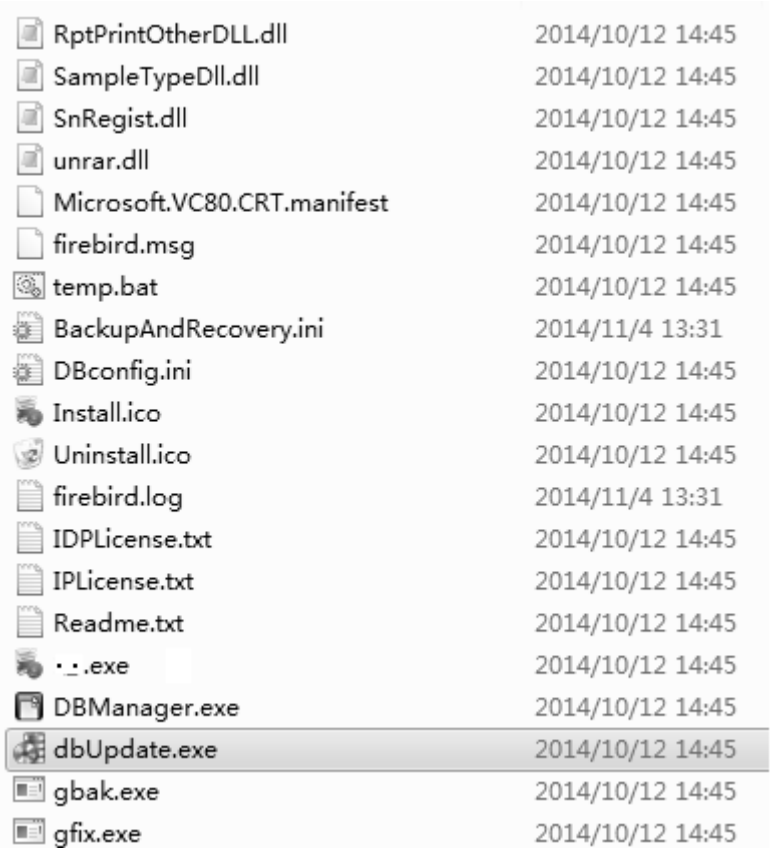


Figure 8-2-63

Double-click “ dbUpdate.exe ”, and Figure 8-2-64 will be shown:

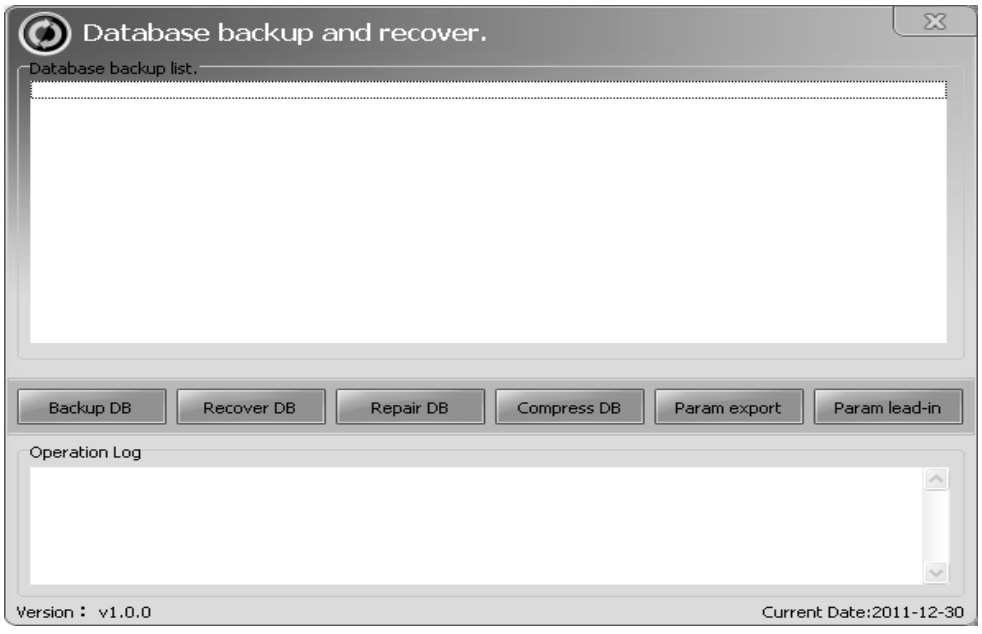


Figure 8-2-64

Click “ Backup DB ”, and finish the database backup.

(3)Recover database

For detailed operation, refer to (2) Back up database. In “Database backup List” in Figure 8-2-64, click the file name of the database that is to be recovered, and then click “Recover Database” to finish the database recovery according to the prompts.

(4)System Sleep

Sleep means that the analyzer is in a semi-stop status. Only cooling system and master control board are at work. The analyzer will automatically be standby when awakened.

When standby, click “Other Info.” of “System” to set time for timed wakeup, and then click the “Sleep” key, and the following figure pops up:

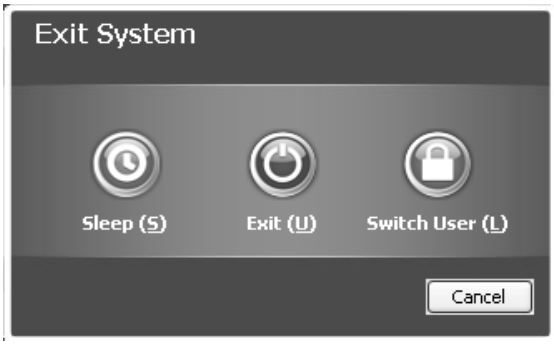


Figure 8-2-65

After clicking “Sleep”, and Figure 8-2-66 pops up:



Figure 8-2-66

After clicking the “OK” key, the analyzer goes into the sleeping mode. The analyzer will cut off all power supply except for that of the cooling system and master control board. The status bar displays “Machine Sleeping”. The analyzer will start up at the set wakeup time. After that, log in again.

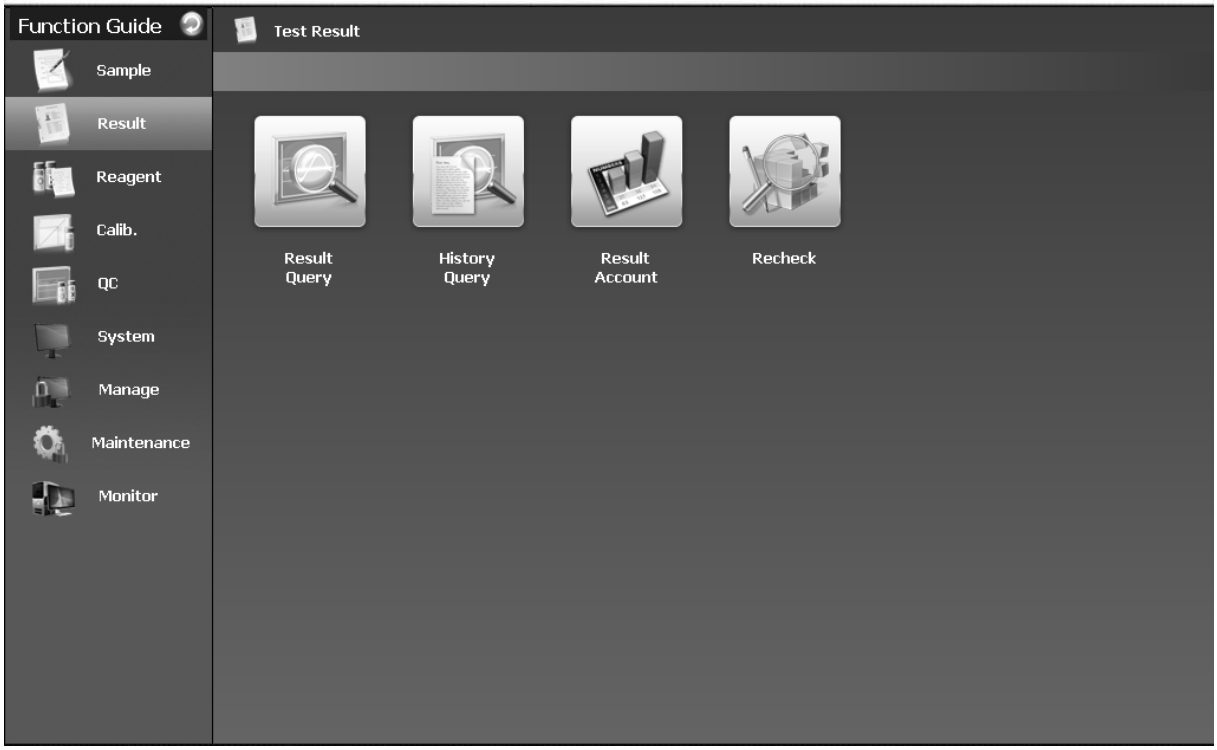


Figure 8-2-67

The software will automatically go into the offline status after sleep. "Machine Sleeping" will be displayed in the status bar if it is connected.

Before the set time, users can click the " Wake-up" key to cancel sleep manually. Then the analyzer will conduct resetting movements, and users can start a test after the status bar displays "standby".

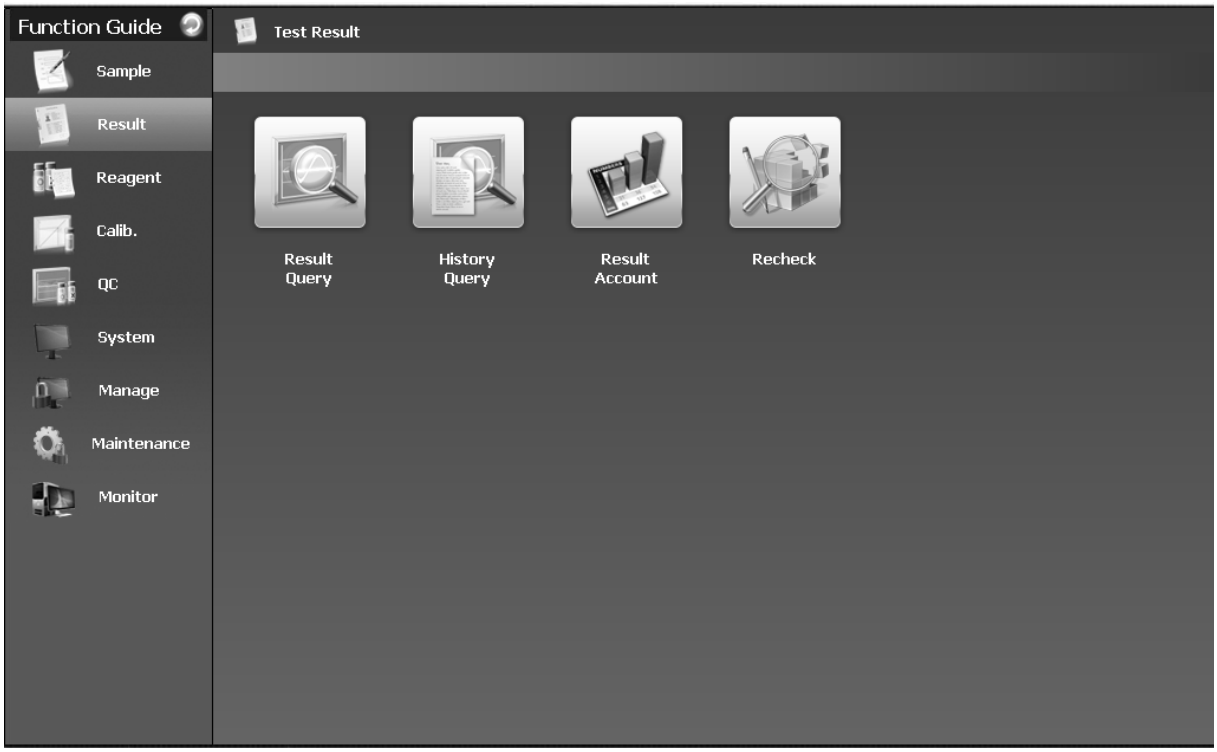


Figure 8-2-68

(5)Power off

Exit from the software, and turn off the power supply according to the following sequence: printer, host computer, display, analytical system, and general power. (General power cannot be cut off when reagents need cooling.)

Users don't have to cut off analytical system power and general power when system sleep is conducted.

(6)Prepare for next operation

Check if the reagent disk is covered. Take away tubes or standard cuvettes that hold Calibrator, Control, and samples. Drain the waste barrel. Check if the reagent probe, sample probe and mixer are contaminated or bent. Check if the analytical system and operating system is dirty, and clear up the surface.

Chapter 9 System Help

If users have any questions about some functions or the operation, click " Help " or press "F1" to enter the following window:

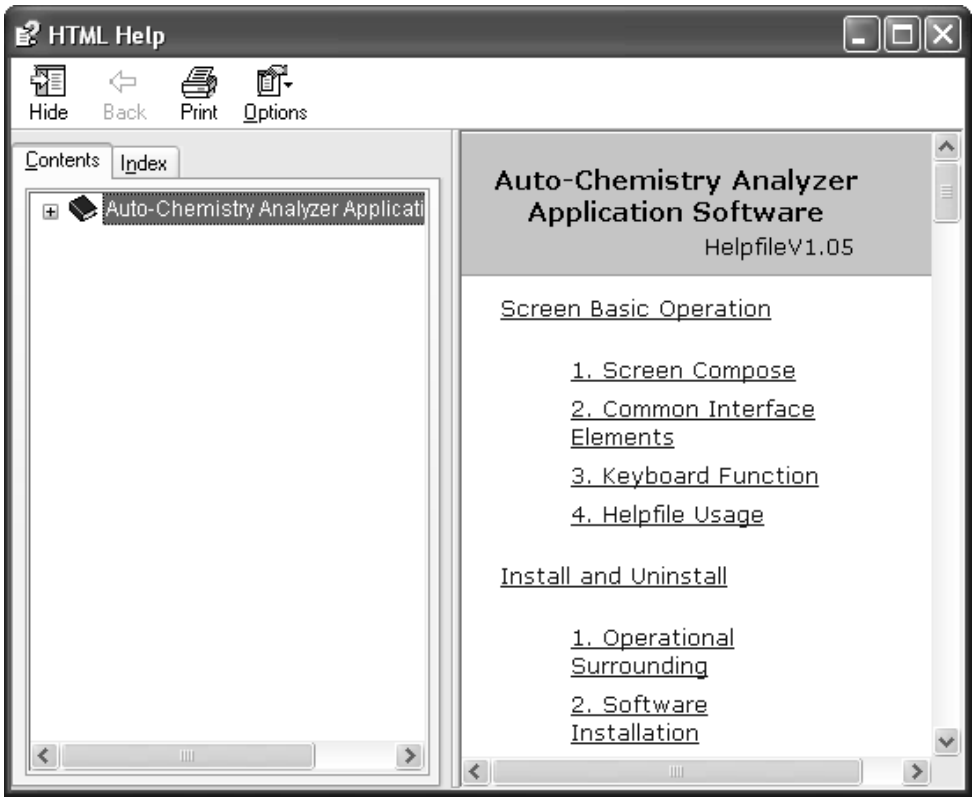


Figure 9-1

9.1 Usage of System Help

(1)In the help contents, click the titles to browse the corresponding operation. Click "previous page" and "next page" to turn pages. Click "back to title" to return to the previous catalogue. If the instructions are not displayed completely, pull the scroll bar to browse the rest.

(2)Click "Close" to exit.

Chapter 10 System Maintenance

10.1 Preparation for System Maintenance

To ensure the accuracy and precision of Analyzer, users should conduct operation in strict accordance with this User Manual, and maintain the analyzer periodically. Only in this way can it ensure reliable results and long-life usage.

Prepare the following items before carrying out system maintenance:

10.1.1 Tools

(1)Accessories (carried with the analyzer)

Cross screwdriver…….…….…….. (for demounting/mounting cover)

Unblocking needles…….……. (for cleaning sample probe and reagent probe)

Probe unblocking tool…….……...… (for removing probe clog)

Fixing block……. (for adjusting the height of mixer)

(2)User's preparation

Clean gauze…….. (for cleaning every part)

Swab……. (for cleaning sample probe and reagent probe)

Vacuum cleaner…… (for cleaning cooling fan)

Barrel (two)…….. (for discharging waste liquid)

Test tube brush……. (for cleaning the cleaning tank)

Graduated cylinder or breaker (3L or 5L)…… (for injecting water into bank of cooling system)

10.1.2 Pure water

For routine operation and maintenance, pure water with conductivity under 1 μs/cm should be provided. Periodic maintenance of pure water equipment is also a necessity. For detailed operation, refer to instructions on pure water equipment, or contact the supplier or distributor of pure water equipment.

10.1.3 Detergent

Detergents are used for rinsing all parts of the analyzer. Detergents should be purchased from the manufacturer. Using detergents from other companies may cause the uncleanness of the reaction cuvettes, reagent probe, sample probe, mixer and pipeline. Then inaccuracy and imprecision of test results will be caused. the manufacturer claims no responsibility for inaccuracy and imprecision caused by not using the manufacturer detergents.

There are three kinds of detergents:

(1)Anti-Bacterial Phosphor-Free Detergent: Place the detergent in the No. 45 position in the R1 disk and R2 disk. In the incubation bath, a water exchange needs 6mL Anti-Bacterial Phosphor-Free Detergent. If the detergent is not added, air bubbles can be attached to the reaction cuvettes, and bacteria can grow in the incubation bath. After reagents are dispensed during tests, the reagent probe will automatically aspirate Anti-Bacterial Phosphor-Free Detergent from the No. 45 position for rinsing the reagent probe and mixer. To wipe all parts of the analyzer or immerse cuvette, users should use Anti-Bacterial Phosphor-Free Detergent of 2% concentration.

(2)Alkaline Detergent : Placed in the detergent boxes in the lower front part of the analyzer (both the left and right boxes need Alkaline Detergent) to rinse the reaction cuvettes; Placed in the W1 position of the QC disk to rinse the sample probe.

(3)ISE Detergent: placed in the W2 position of the QC disk, for ISE matching cuvette, flow cell, and ISE pipeline rinsing.

10.2 The Application of System Maintenance

Click "

" under Function Guide. Conduct daily maintenance according to needs. As shown in Figure 10-2-1:

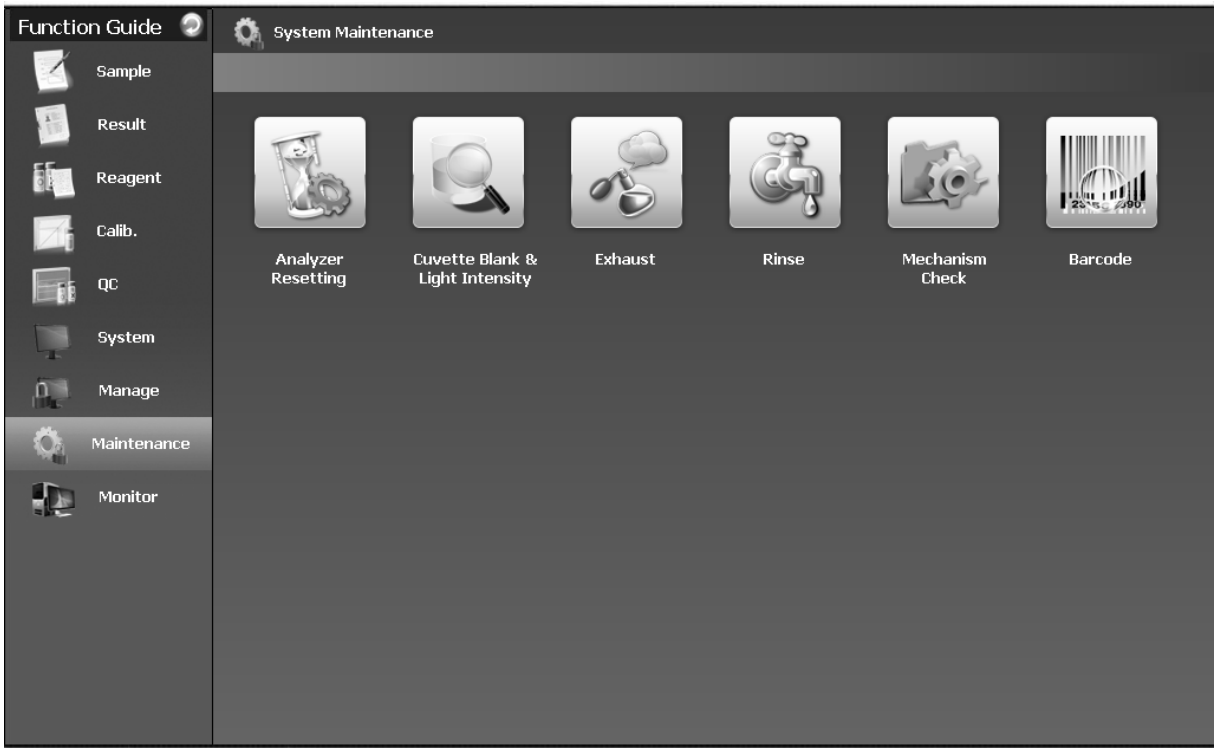


Figure 10-2-1

During maintenance, some movements can be suspended. Click "End Maintenance" to end maintenance movements. However, some maintenance movements cannot be suspended. After maintenance is finished, other operation can be conducted. The first step of maintenance is resetting the analyzer. Any abnormality during maintenance will cause alarm in the "Alarm Info." window.

To exit from a maintenance window, click the "Close" key.

10.2.1 Reset Analyzer

In the "Maintenance" window, click "

" as shown in Figure 10-2-2:

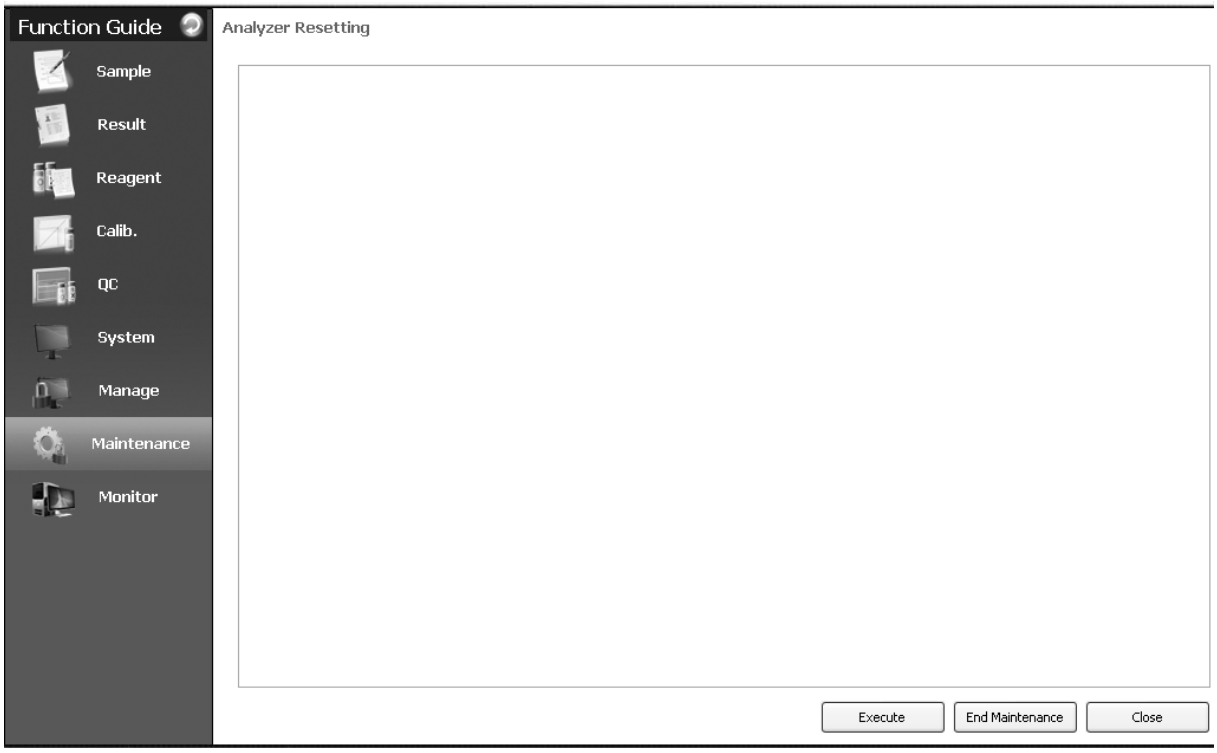


Figure 10-2-2

Click "Execute". All mechanisms will automatically return to initial positions. Emergency stop is forbidden during analyzer resetting. Only when in standby can other operation be conducted.

Analyzer resetting needs to be conducted when alarm information indicates that users reset the analyzer, emergency stop happens, or single step movement of the reagent probe, sample probe and mixer is adjusted.

10.2.2 Check on Cuvette Blank and Light Intensity

In the "Maintenance" window, click "Cuvette Blank & Light Intensity" to conduct a check on cuvette blank and light intensity.

(1)Cuvette Blank Test

In the "Cuvette Blank&Light Intensity" window, select Cuvette Blank Test, and click "Execute". Then the analyzer will automatically conduct cuvette blank tests for 160 reaction cuvettes. Results will be shown in the cuvette blank window as Figure 10-2-3 shows:

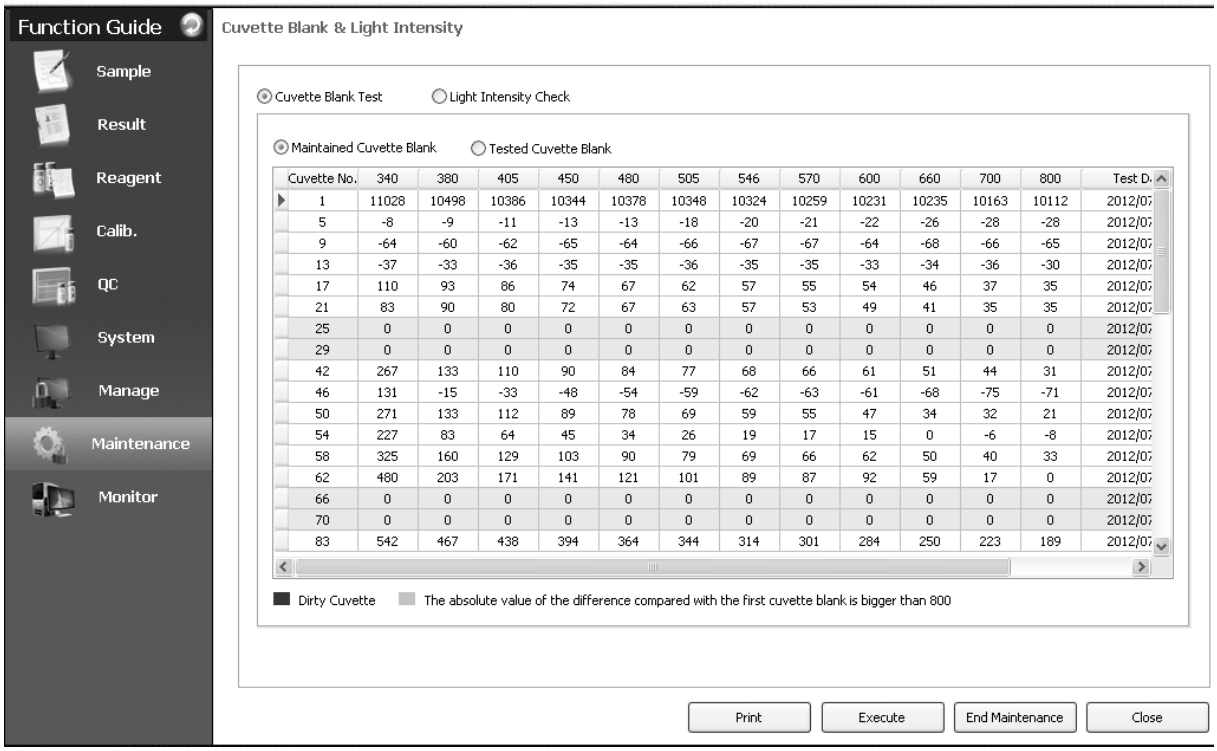


Figure 10-2-3

To print the cuvette blank values, click "Print". Then preview and print them. When the analyzer is testing cuvette blank, users can click "End Maintenance" to stop the test movement.

It is normally suggested to conduct a cuvette blank test once a week. Cuvette blank should be tested every time users replace cuvettes. Cuvettes with blank values that meet the requirement can be used for tests. It is not suggested to conduct sample tests when blank values are abnormal. Otherwise, test results may be inaccurate.

a)"Cuvette No." vertical line: displaying the cuvette number 1~160.

b)"340-800" vertical line: respectively displaying the blank values of the 160 cuvettes detected by waves of 340nm, 380nm, 405nm, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm, and 800nm.

c)Horizontal line "1" (cuvette): displaying blank values of Cuvette 1 detected by 12 waves. The values that meet the requirements should be smaller than 18000.

d)Horizontal line "2~160" (cuvette): Displaying blank differences between Cuvette 1 and Cuvette 2~160. The between-cuvette difference should meet the requirement "-800~800".

(2)Check on Light Intensity

In the "Cuvette Blank&Light Intensity" window, select "Light Intensity Check", as shown in Figure 10-2-4:

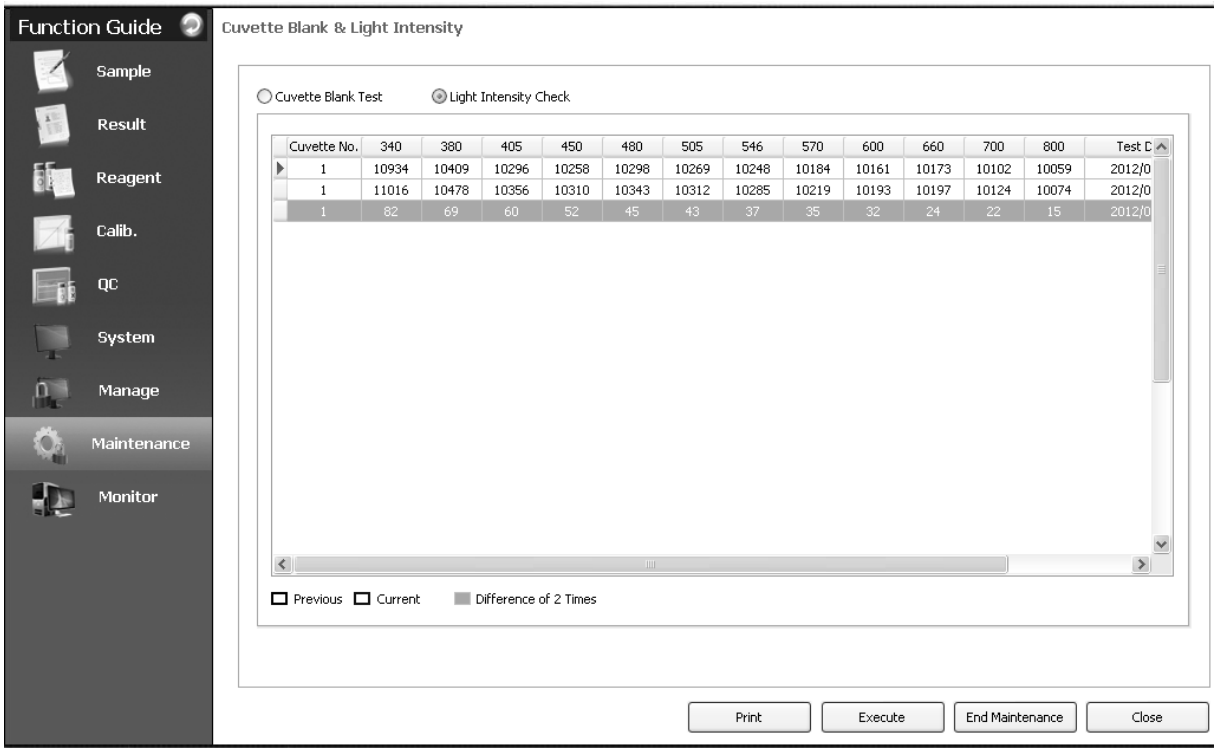


Figure 10-2-4

Then the analyzer will automatically conduct the check on the power of the light source. The previous and current test values of the light intensity will be displayed together, and the difference will be calculated. Users can decide to print or not according to needs. Light intensity values should be smaller than or equal to18000.

When the analyzer is testing light quantity, users can click "End Maintenance" to stop check movement of light intensity.

It is normally suggested to conduct light intensity check once a month. Light intensity check should be conducted every time users replace halogen lamps. Lights with values that meet the requirement can be used for tests.

10.2.3 Expel Air

In the "Maintenance" window, click "

" to expel air from syringe pumps and rinsing detergent pipeline, as shown in Figure 10-2-5:

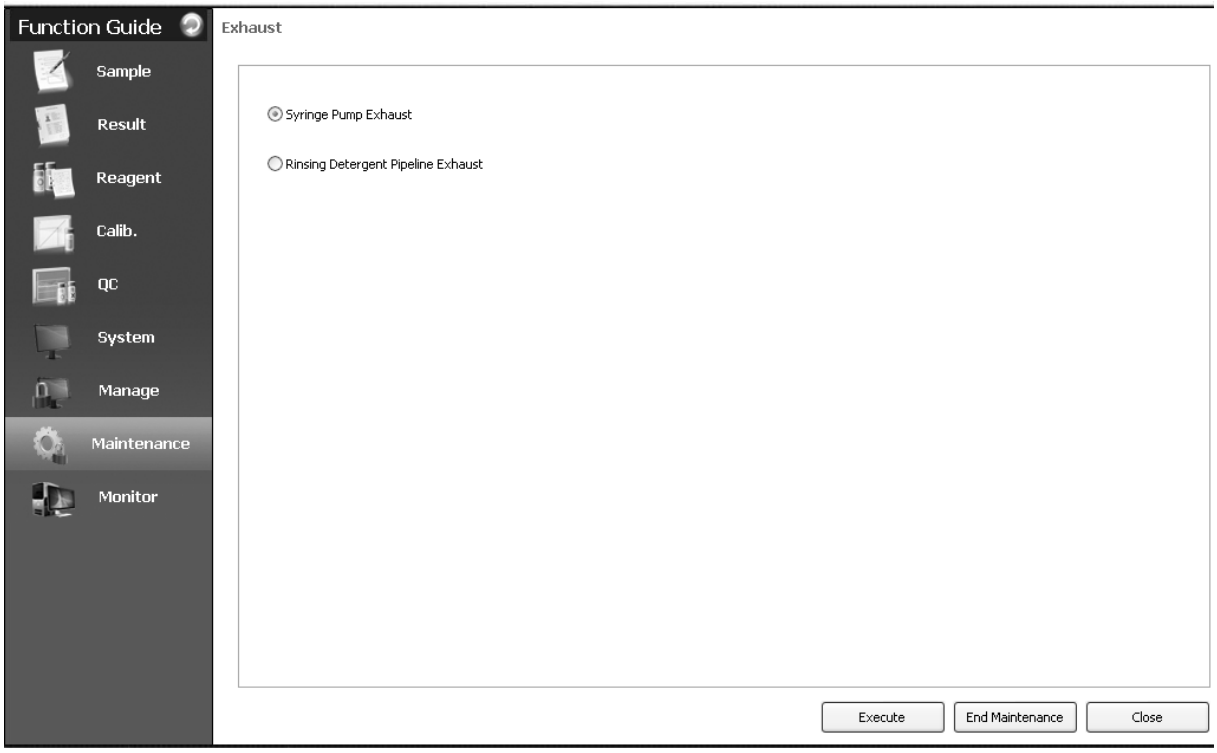


Figure 10-2-5

(1)Expel Air from Syringe Pumps

In the "Exhaust" window, select " Syringe Pump Exhaust " and click "Execute". The pistons of the syringe pumps will move up and down to expel air from syringe pumps or pipeline. During the process, emergency stop is forbidden. Other operation can be conducted when in standby.

Expel air for several times when replacing syringe pumps or their pipeline, or installing the analyzer for the first time.

(2)Expel Air from Rinsing Detergent pipeline

In the "Exhaust" window, select " Rinsing Detergent Pipeline Exhaust ", and click "Execute". The analyzer will automatically expel air from the pipeline that connect the detergent box. During the process, emergency stop is forbidden. Other operation can be conducted when in standby.

This function should be put in use when the Alkaline Detergent in the detergent box is used up, or air goes into the bottom of the pipeline because of the joint problems.

10.2.4 Rinse

In the "Maintenance" window, click "Rinse" to rinse the water tank, incubation bath, reaction cuvettes, sample probe, pipeline of high concentration waste liquid, as shown in Figure 10-2-6:

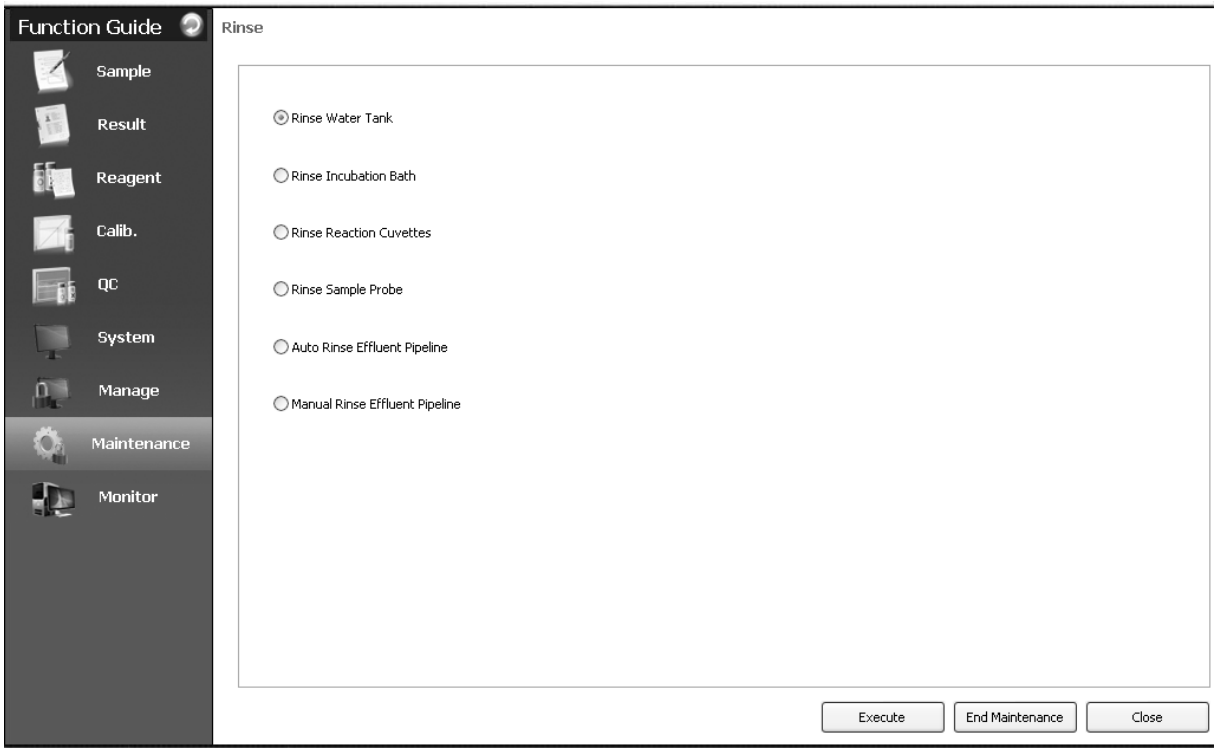


Figure 10-2-6

(1)Rinse Water Tank

In the "Rinse" window, select "Rinse Water Tank" and click "Execute". The analyzer will automatically circulate pure water in the tank and discharge some water to rinse the tank. Emergency stop can be conducted during the process. Bacteria or uncleanness in the tank can affect the quality of the thermostatic water. This contributes to inaccuracy of test results and blockage in pipeline.

It's suggested that water tank rinsing be conducted once three months.

(2)Rinse Incubation Bath

In the "Rinse" window, select "Rinse Incubation Bath", as shown in Figure 10-2-7:

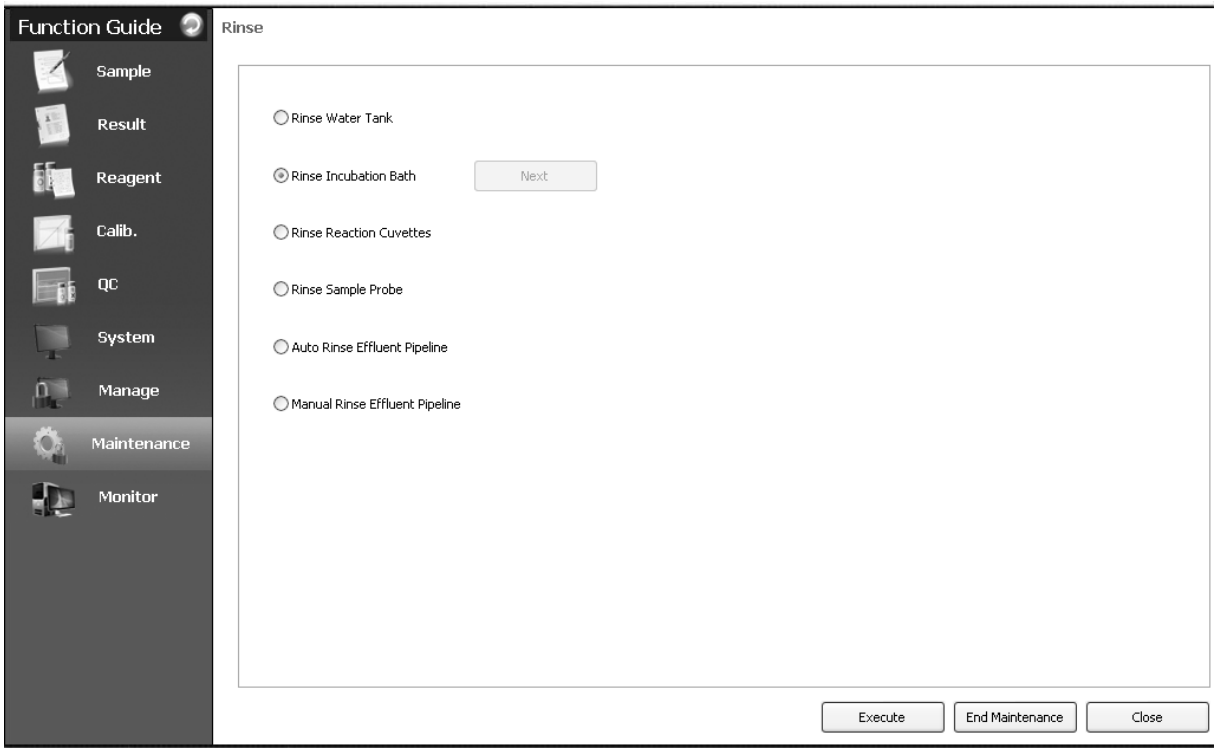


Figure 10-2-7

Click "Execute". The analyzer will automatically discharge the water in the incubation bath. When the status bar shows "finish discharging water in incubation bath", wipe the inside of the incubation bath with clean gauze if there is dirt. Then click "Next", and new pure water will be injected into the incubation bath. At the same time, R1 and R2 probes aspirate the Anti-Bacterial Phosphor-Free Detergent from the No. 45 position in the R1 and R2 disk respectively. Every probe aspirates detergents 6 times, 500μL each time. Finally 6mL detergents are dispensed into the incubation bath. Stop is forbidden during the process.

Rinse the incubation bath when the thermostatic water is dirty.

(3)Rinse Reaction Cuvette

In the "Rinse" window, select " Rinse Reaction Cuvette ", as shown in Figure 10-2-8:

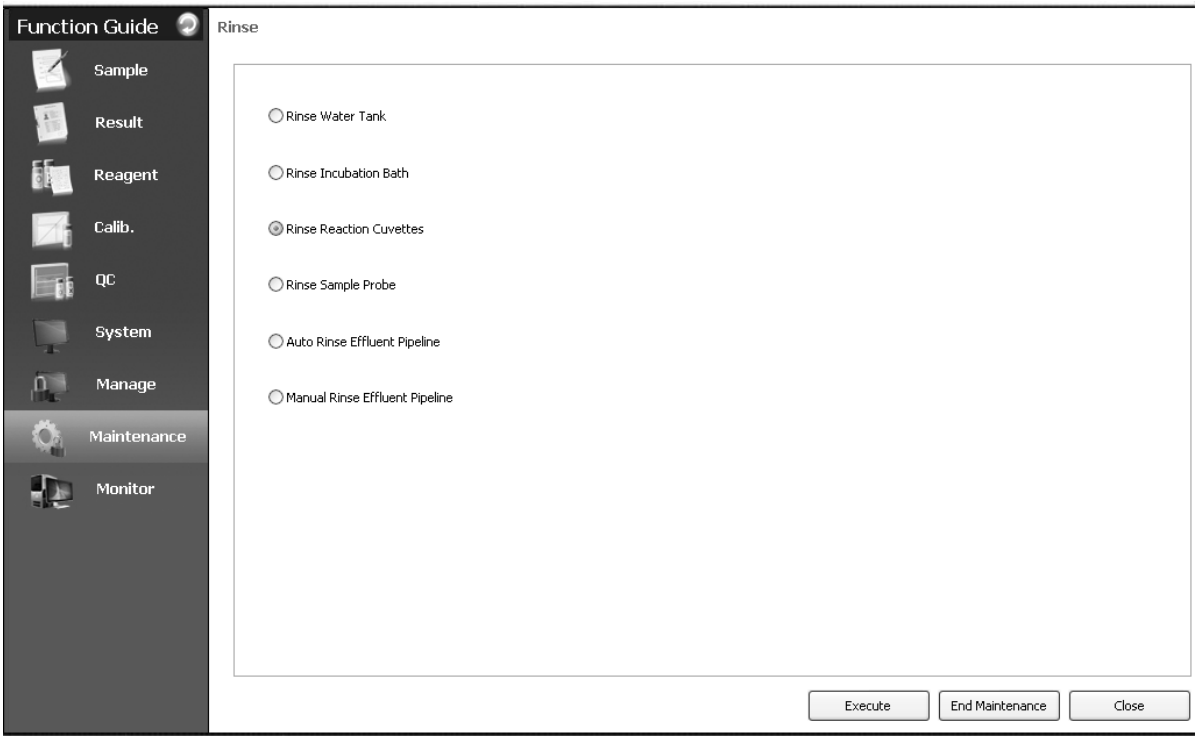


Figure 10-2-8

Click "Execute". The analyzer will automatically rinse the 160 reaction cuvettes.

When the reaction cuvettes are rinsed, users can click "End Maintenance" to stop the rinse.

Rinse reaction cuvettes when cuvette blank values are abnormal. It is suggested to rinse reaction cuvettes once a week to prevent test results from being affected by uncleanness.

(4)Rinse Sample Probe

In the "Rinse" window, select "Rinse Sample Probe", as shown in Figure 10-2-9:

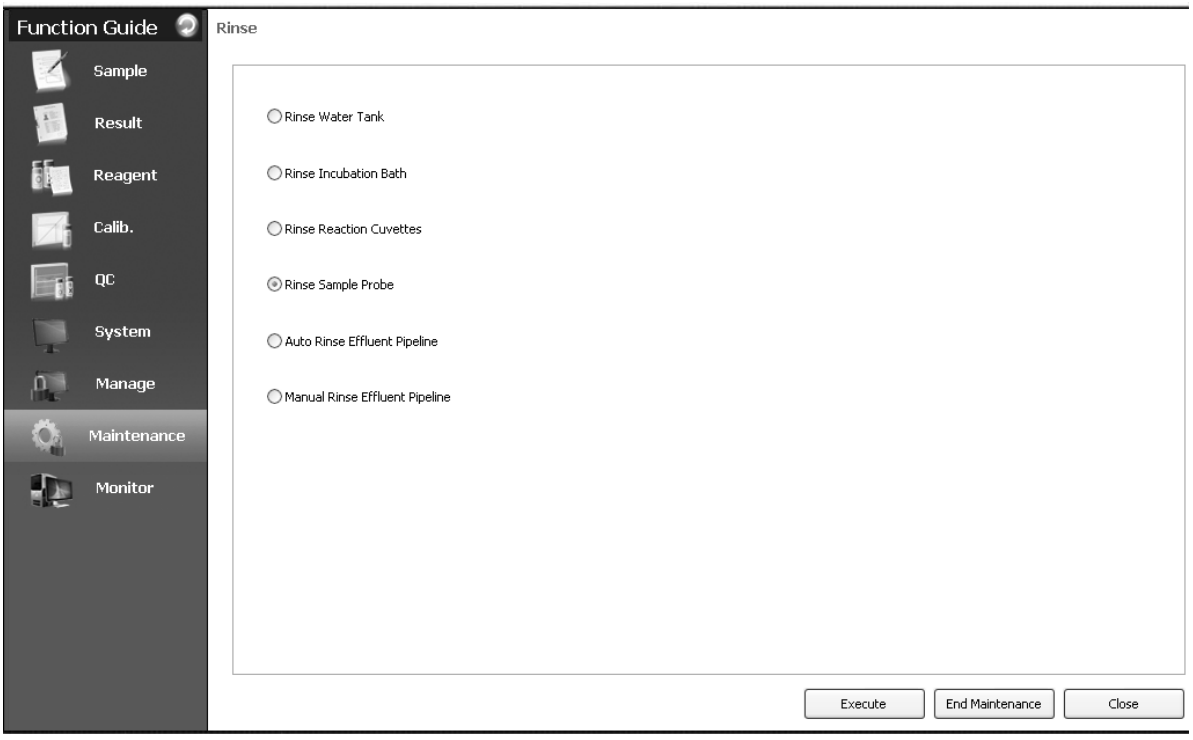


Figure 10-2-9

Click "Execute". The analyzer will automatically rinse the sample probe, which takes thirty minutes. Users can click "End Maintenance" to stop the rinse. It is suggested to rinse the sample probe weekly after tests.

(5)Automatic Rinse of High-concentration Waste Liquid pipeline

If serum samples don't coagulate completely during tests, serum after centrifugation may contain fibrin which can cause blockage in high-concentration waste liquid pipeline. Bacteria may also cause blockage in the pipeline. After 10,000 tests, the host computer will display "Please rinse high-concentration waste liquid pipeline". The following shows the method:

In the "Rinse" window, select " Auto Rinse Effluent Pipeline ", as shown in Figure 10-2-10:

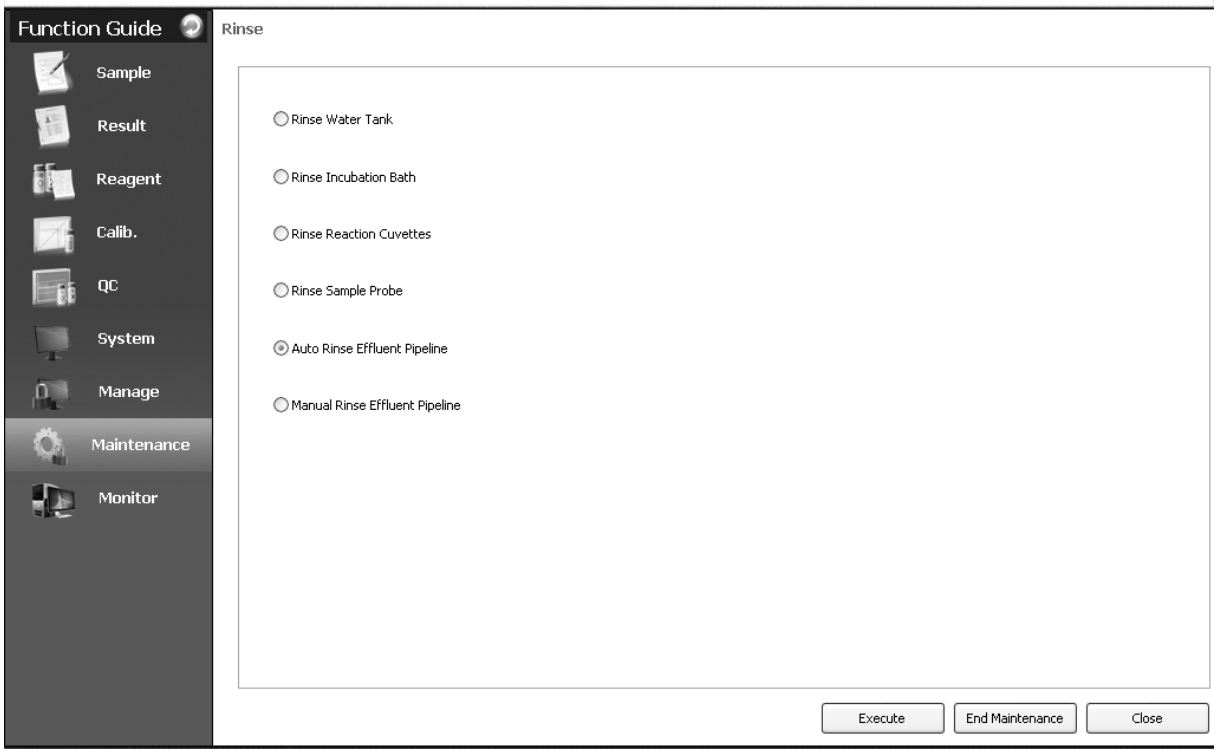


Figure 10-2-10

Click "Execute", and the analyzer will automatically rinse the high-concentration waste liquid pipeline. During the process, users can click the "End Maintenance" to end the rinse.

(6)Manual Rinse of High-concentration Waste Liquid pipeline

When the high-concentration waste liquid pipeline are dirty, rinse them manually according to the following steps:

a)Remove No. 2 nozzle, as shown in Figure 10-2-11:

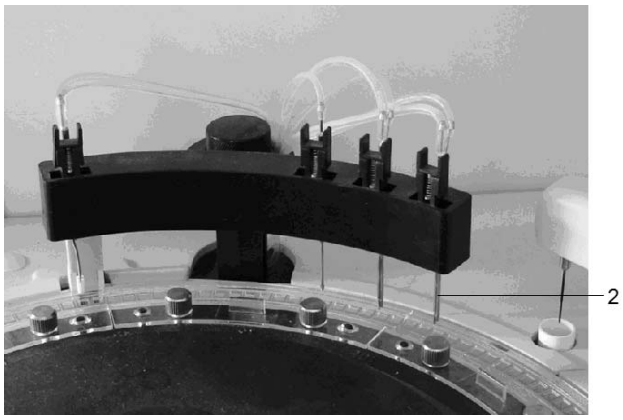


Figure 10-2-11

b)Put Alkaline Detergent in a reagent bottle of 70mL. Make sure the distance between the liquid level and the bottle mouth is 20mm. Insert the No. 2 nozzle in the reagent bottle. Then click "Manual Rinse Effluent Pipeline" in the "Rinse" window, as shown in Figure 10-2-12:

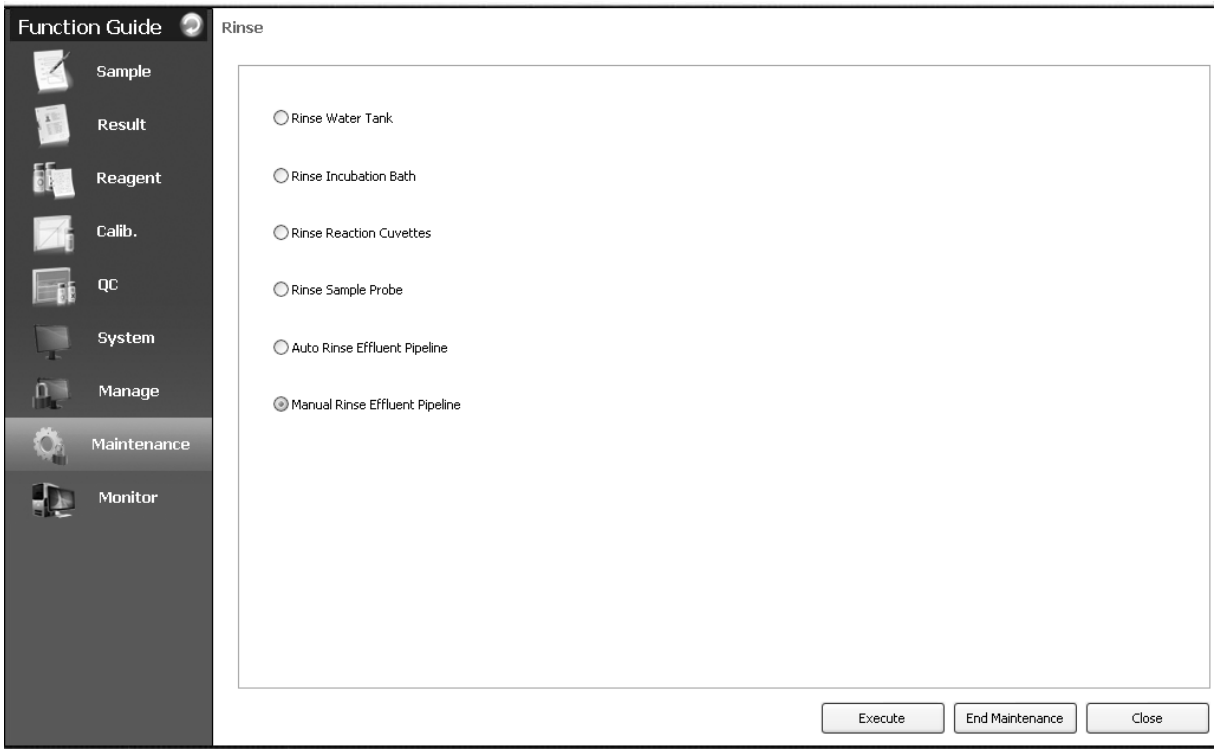


Figure 10-2-12

Click "Execute", and the analyzer will rinse the high-concentration waste liquid pipeline, which takes about 4 minutes. After the rinse, the high-concentration waste liquid will be discharged automatically. During the rinse, users can click "End Maintenance" to stop it in advance.

c)Replace the Alkaline Detergent in the reagent bottle of 70mL with pure water, and repeat the above steps.

10.2.5 Mechanism Check

In "Maintenance" window, click "Mechanism Check" to conduct a vertical check for the sample probe, a horizontal check for the sample probe, a vertical check for the reagent probe, a horizontal check for the reagent probe, a check for the stirring mechanism and a check for the mechanical movement. To check or adjust probe positions,

users should conduct corresponding maintenance.

(1)Vertical Check on Sample Probe

In the “Mechanism Check” window, select “ Sample Probe Vertical Check ”, as shown in Figure 10-2-13:

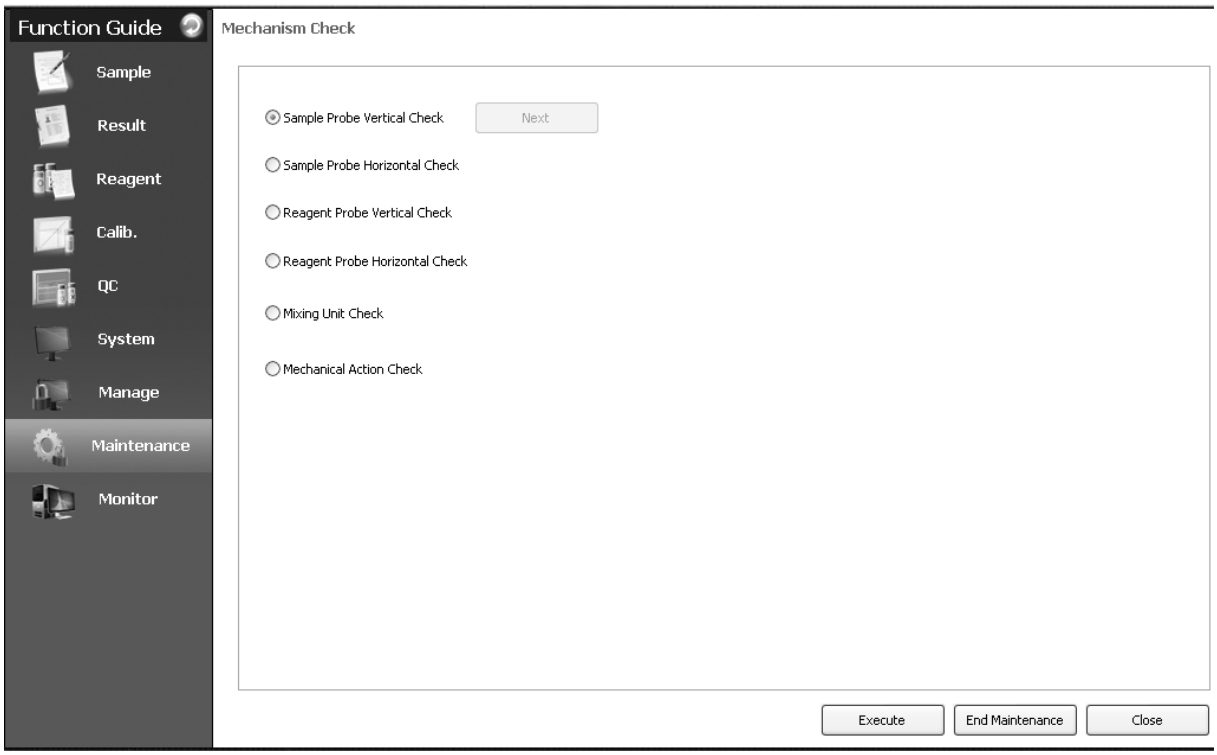


Figure 10-2-13

Click “ Execute ”. The analyzer will carry out the single-step vertical movement of the lifting mechanism of the sample probe. Click “ Next ” to conduct the next movement. Users can click “ End Maintenance ” to stop the maintenance movement.

For detailed information on the sample probe vertical check, refer to Chapter “10.4.1 (4)”.

(2)Horizontal Check on Sample Probe

In the “Mechanism Check” window, select “ Sample Probe Horizontal Check ”, as shown in Figure 10-2-14:

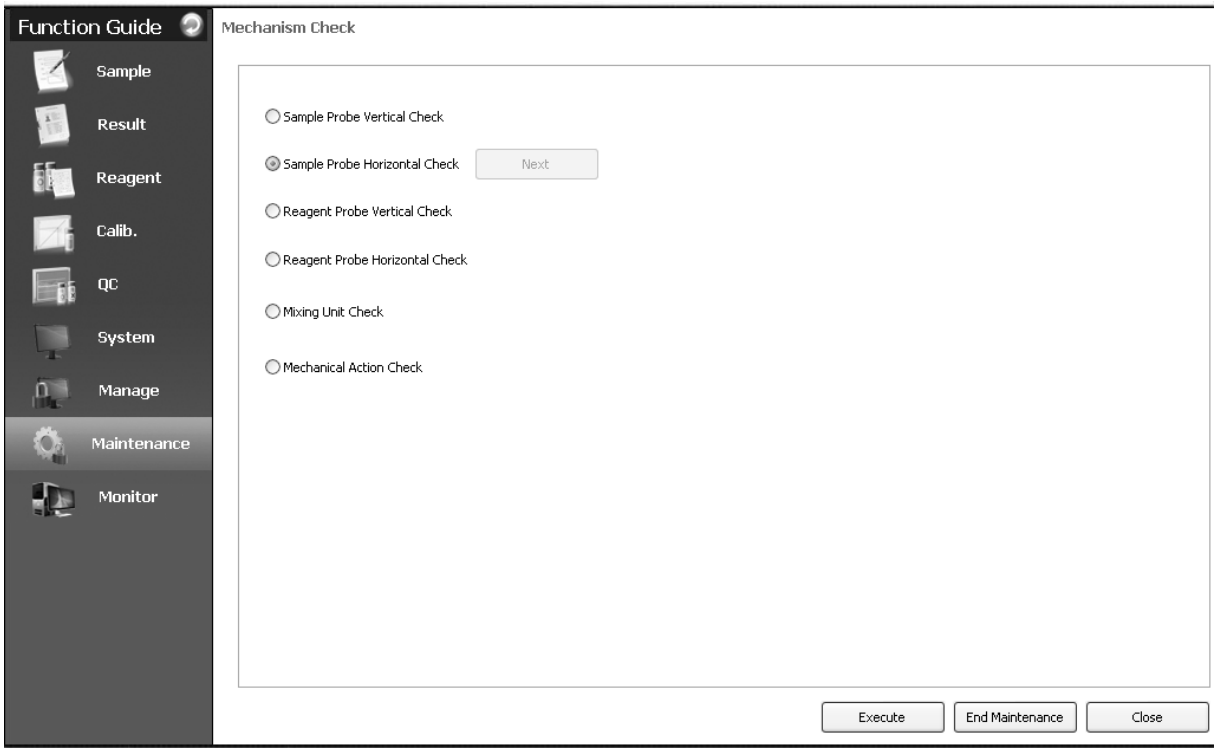


Figure 10-2-14

Click "Execute". The analyzer will carry out the single-step horizontal movement of the lifting mechanism of the sample probe. Click "Next" to conduct the next movement. Users can click "End Maintenance" to stop the maintenance movement.

For detailed information on the sample probe horizontal check, refer to Chapter "10.4.1 (4)".

Conduct the movement when adjusting or checking the sample probe position.

(3)Vertical Check on Reagent Probe

In the "Mechanism Check" window, select "Reagent Probe Vertical Check", as shown in Figure 10-2-15:

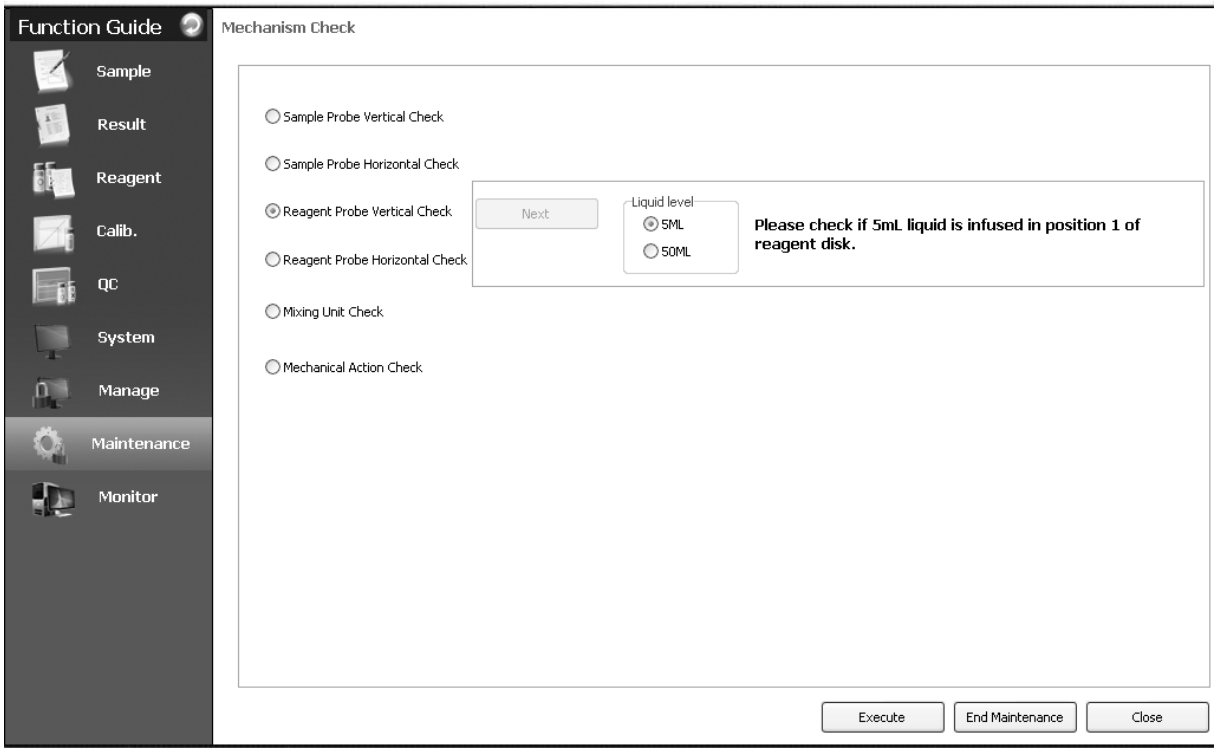


Figure 10-2-15

Select " 5ML " from "Liquid Level"; Put a 70mL bottle that holds 5mL normal saline in the No.1 position of the R1 and R2 reagent disk. Click "Execute", and the analyzer starts the single-step vertical movement of the lifting mechanism of the reagent probe. Click "Next" to conduct the next movement. Click "End Maintenance" to stop the maintenance movement.

Select " 50ML " from "Liquid Level"; Put a 70mL bottle that holds 50mL normal saline in the No.1 position of the R1 and R2 reagent disk. Click "Next" to conduct the next movement. Click "End Maintenance" to stop the maintenance movement.

During tests, the analyzer will automatically remember the testing height as a benchmark value for calculating the remaining volume of the reagent.

5mL and 50mL normal saline must be used to conduct the reagent vertical check. "5mL 50mL reagent bottle placement error" alarm will be set off if the reagent volume is inaccurate.

For detailed information on the reagent probe vertical check, refer to Chapter "10.4.1 (4)".

(4)Horizontal Check on Reagent Probe

In the "Mechanism Check" window, select " Reagent Probe Horizontal Check", as shown in Figure 10-2-16:

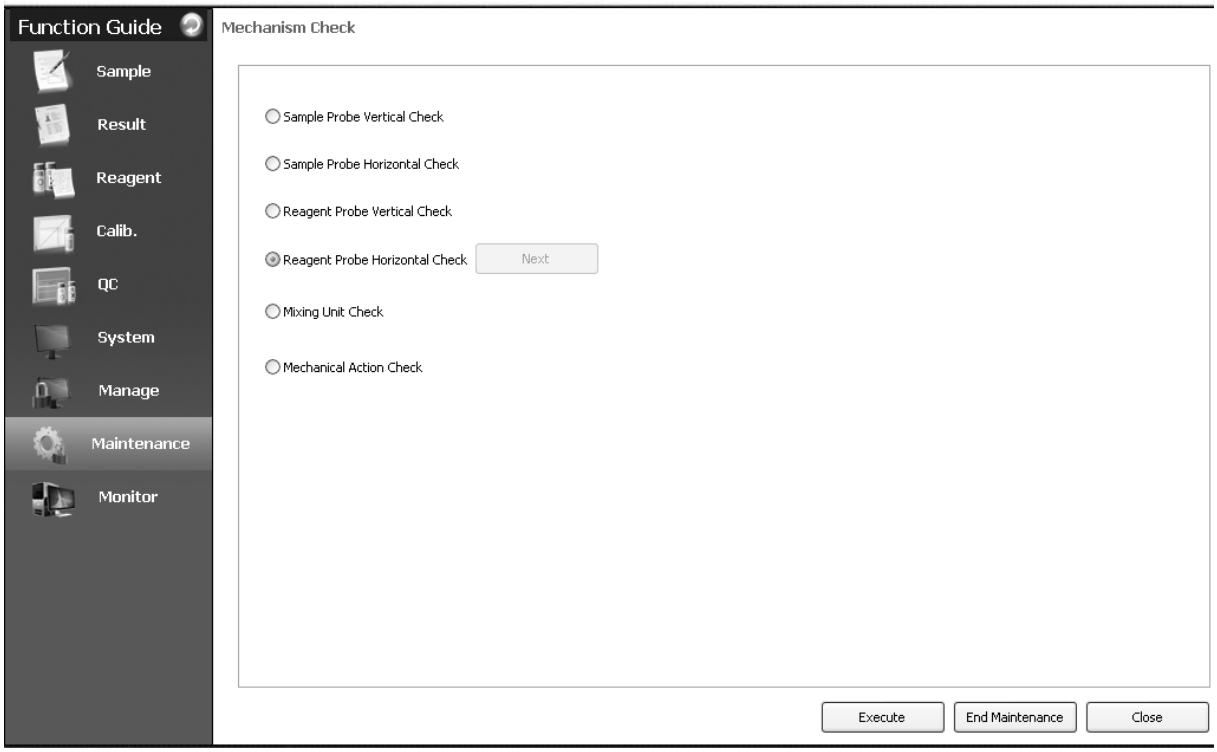


Figure 10-2-16

Click "Execute". The analyzer will carry out the single-step horizontal movement of the lifting mechanism of the reagent probe. Click "Next" to conduct the next movement. Users can click "End Maintenance" to stop the maintenance movement.

For detailed information on the reagent probe horizontal check, refer to Chapter "10.4.1 (4)".

Conduct the movement when adjusting or checking the reagent probe position.

(5)Check on Mixing Unit

In the "Mechanism Check" window, select "Mixing Unit Check", as shown in Figure 10-2-17:

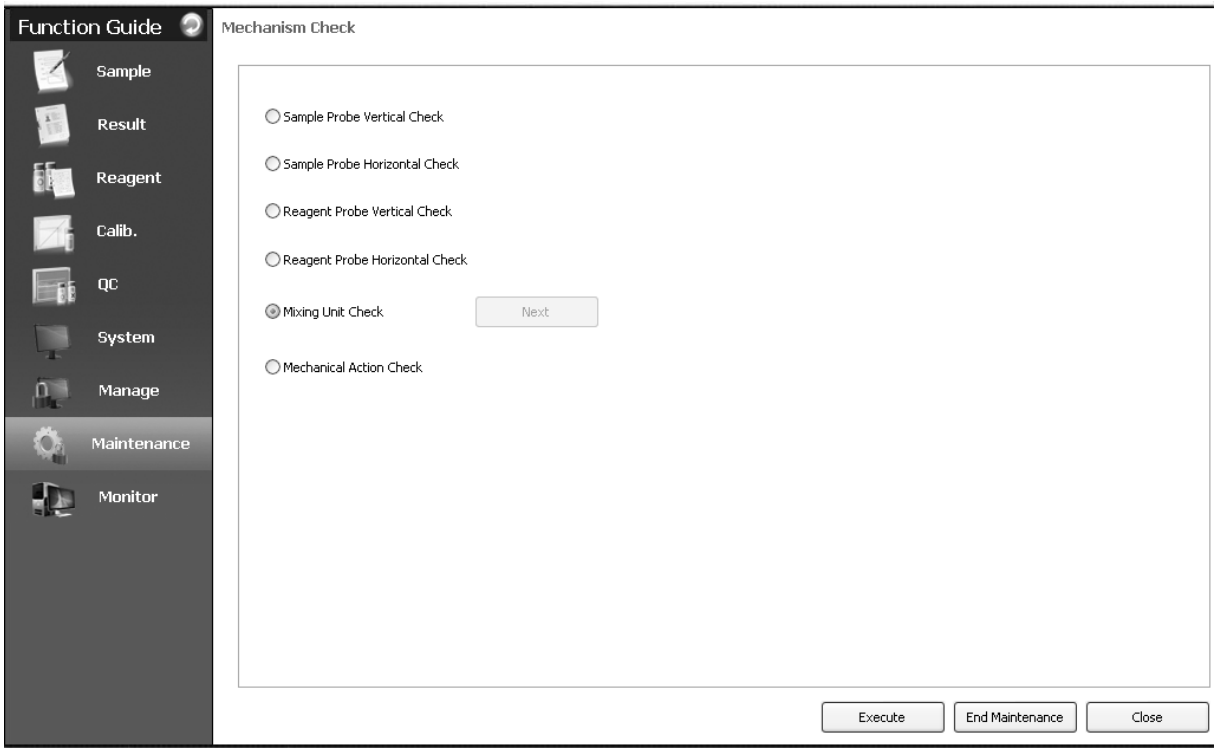


Figure 10-2-17

Click "Execute". The analyzer will carry out the single-step movement of the mixer. Click "Next" to conduct the next movement. Users can click "End Maintenance" to stop the maintenance movement.

To adjust the position (beside the reaction cuvettes, above the rinsing bath) of the stirring mechanism, users should conduct the above maintenance.

(6)Check on Mechanical Action

In the "Mechanism Check" window, select " Mechanical Action Check " as shown in Figure 10-2-18:

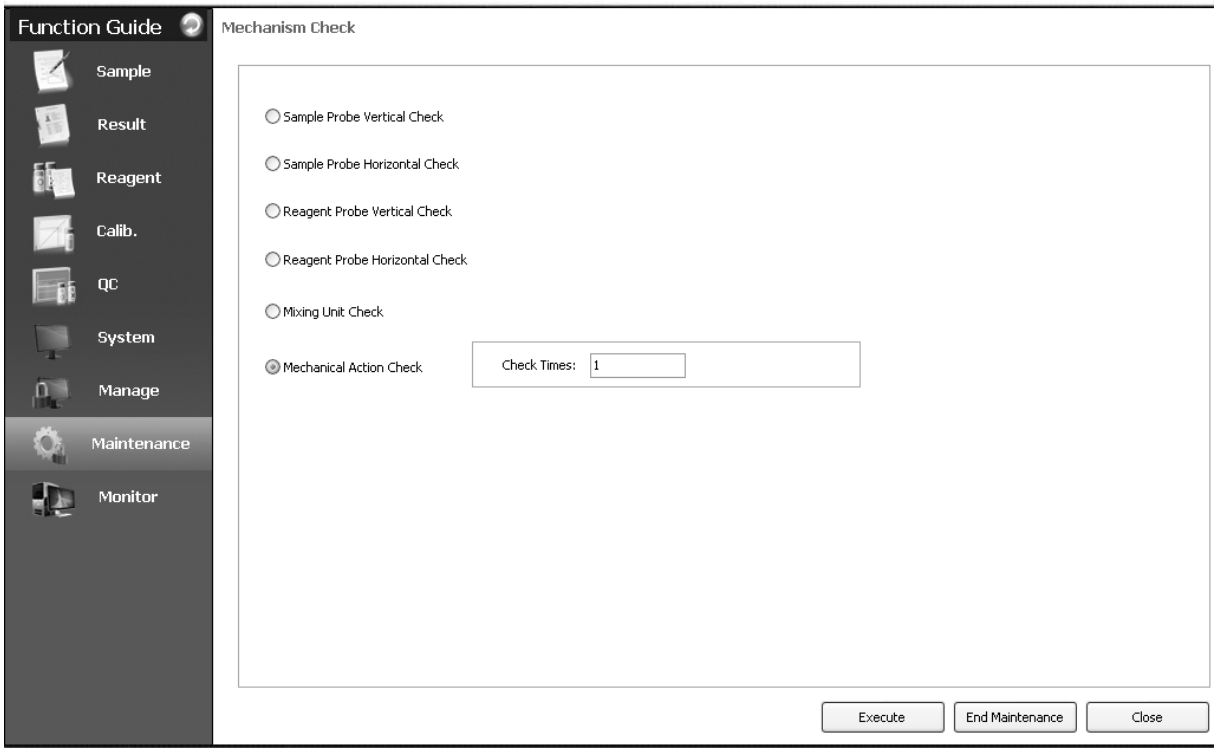


Figure 10-2-18

Input check times (the range is 1~65535), and click "Execute". The analyzer will automatically check the movement of all the mechanisms.

10.2.6 Barcode

In the "Maintenance" window, click "Barcode" to check reagent and sample barcodes.

(1)Reagent disk barcode

In the "Barcode Reader Check" window, select "Reagent Disk Barcode", as shown in Figure 10-2-19:

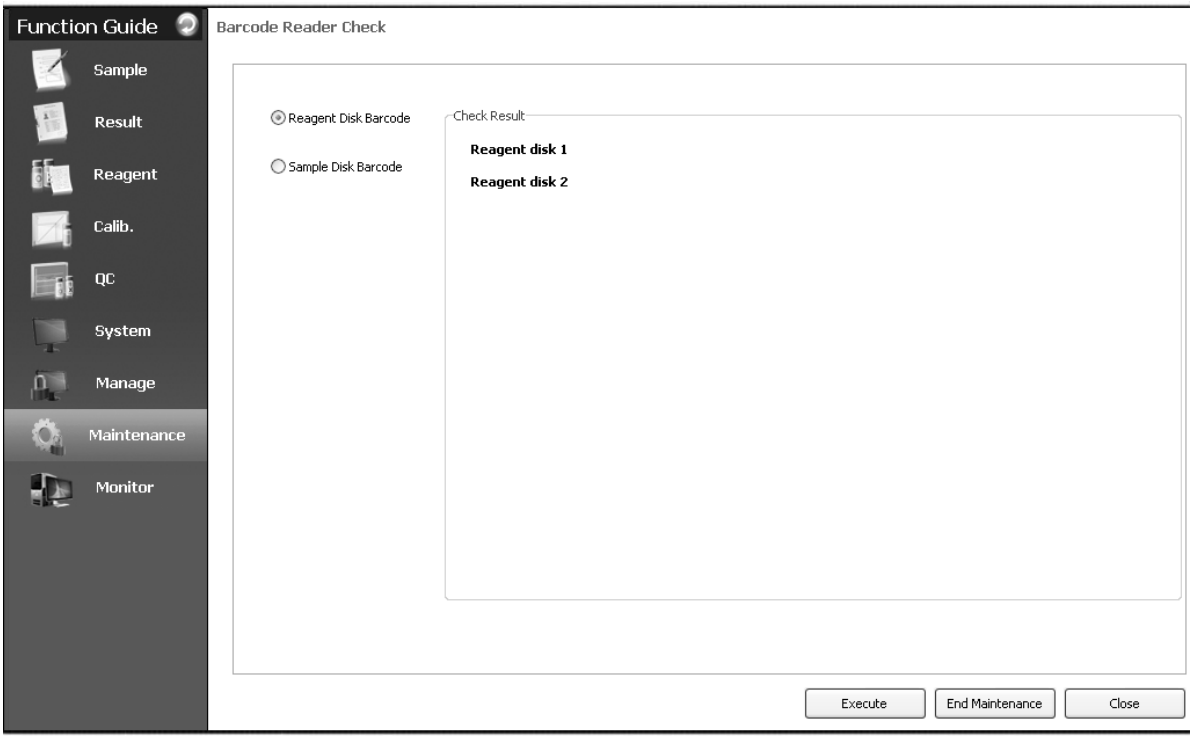


Figure 10-2-19

Click "Execute". The analyzer will scan Position 1 of the reagent disk, and display the result.

Before the test, place a reagent bottle with a barcode in Position 1 in the reagent disk.

(2)Sample Disk Barcode

In the "Barcode Reader Check" window, select "Sample Rack Barcode", as shown in Figure 10-2-20:

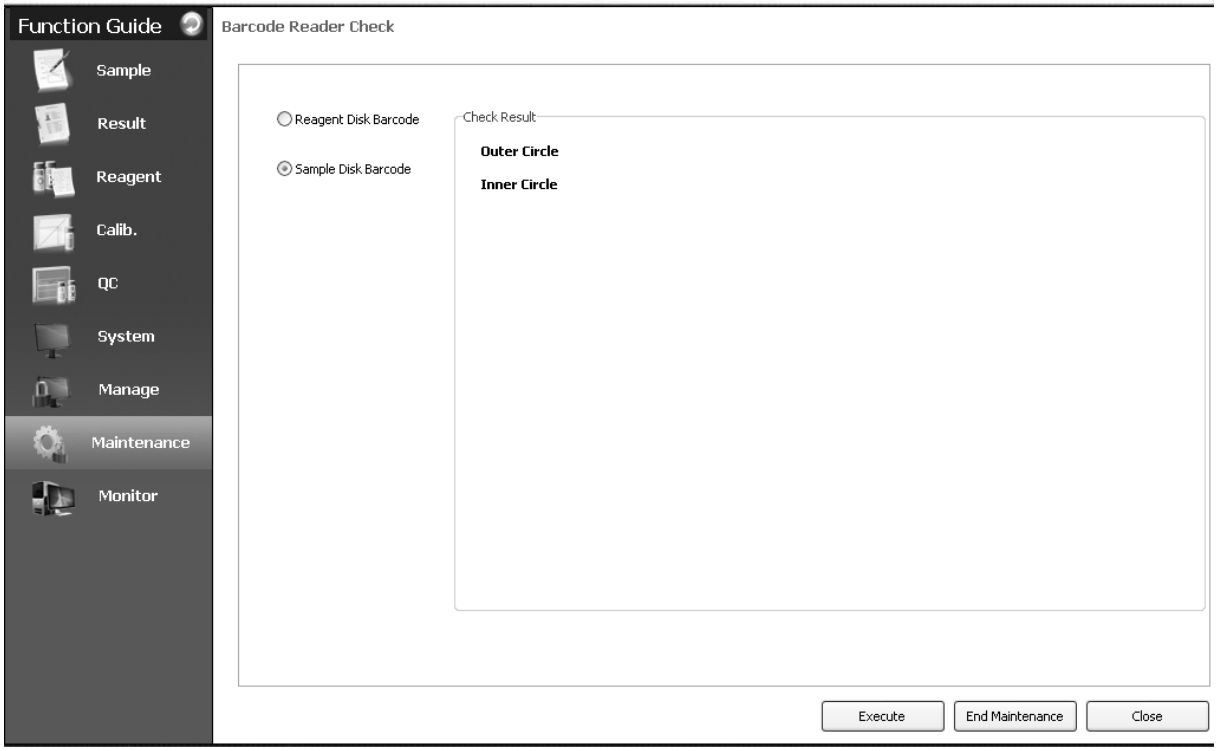


Figure 10-2-20

Click "Execute". The analyzer will scan the barcode of Position 1 and 51 in the sample disk, and display the results.

Place a tube pasted with a barcode in Position 1 and Position 51 respectively before tests.

10.2.7 ISE

In the "Maintenance" window, click the "ISE" key to enter the ISE window shown in Figure 10-2-21:

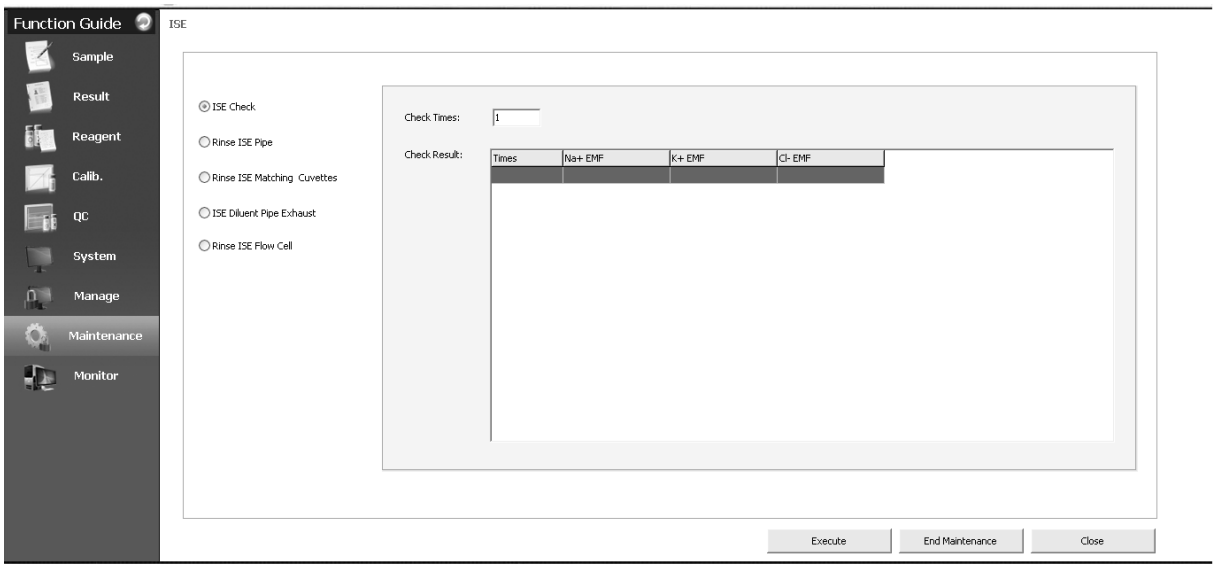


Figure 10-2-21

(1)ISE Check

Click "ISE Check" in the "ISE" window and input a number in the "Check Times" box. The range is 1~999. Click the "Execute" key, and the check value will be shown in the "Check Result" area. To end the movement, click "End Maintenance".

ISE checks need conducting after ISE alarm, ISE rinsing or electrode replacing.

● **Normal range of ISEcheck result:**

Item Name	Normal Range (Unit: mV)
Na^+	-200~200
K^+	-300~100
Cl^-	-200~200

● **The value difference of two checks on the same electrode should be less than 0.2mV.**

(2)ISE pipeline rinsing

Click "Rinse ISE pipe" in the "ISE" window, as Figure 10-2-22 shows:

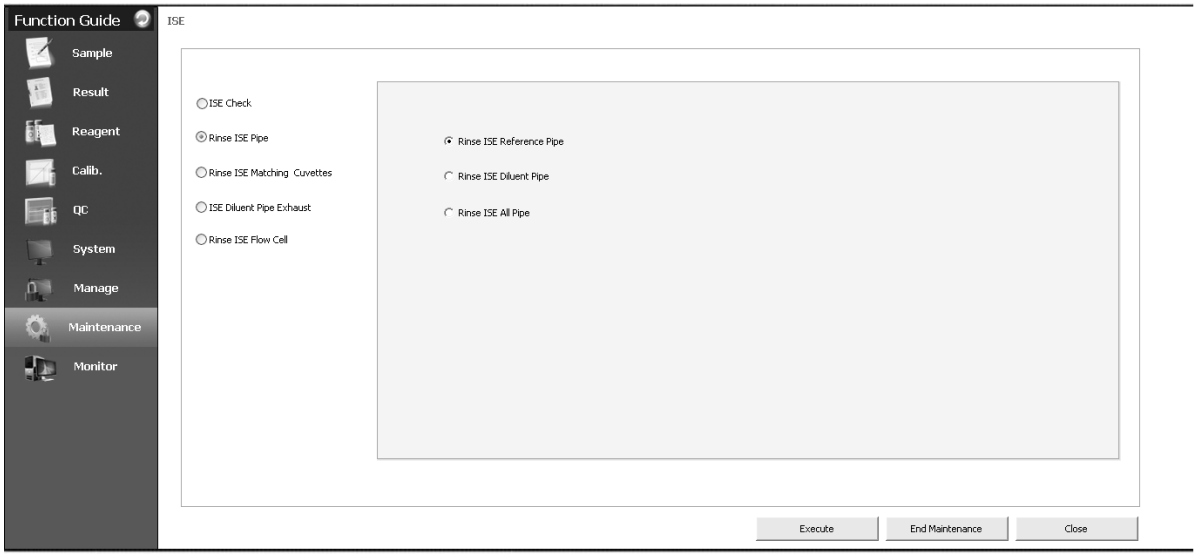


Figure 10-2-22

Select a pipeline type from the working area of ISE pipeline rinsing according to actual situations, and click the “Execute” key. The analyzer will conduct pipeline rinsing automatically. To end the movement, click “End Maintenance”.

It's suggested that users conduct “Rinse ISE All Pipeline” once a month.

(3)ISE matching cuvette rinsing

Click “Rinse ISE Matching Cuvette” in the “ISE” window, as Figure 10-2-23 shows:

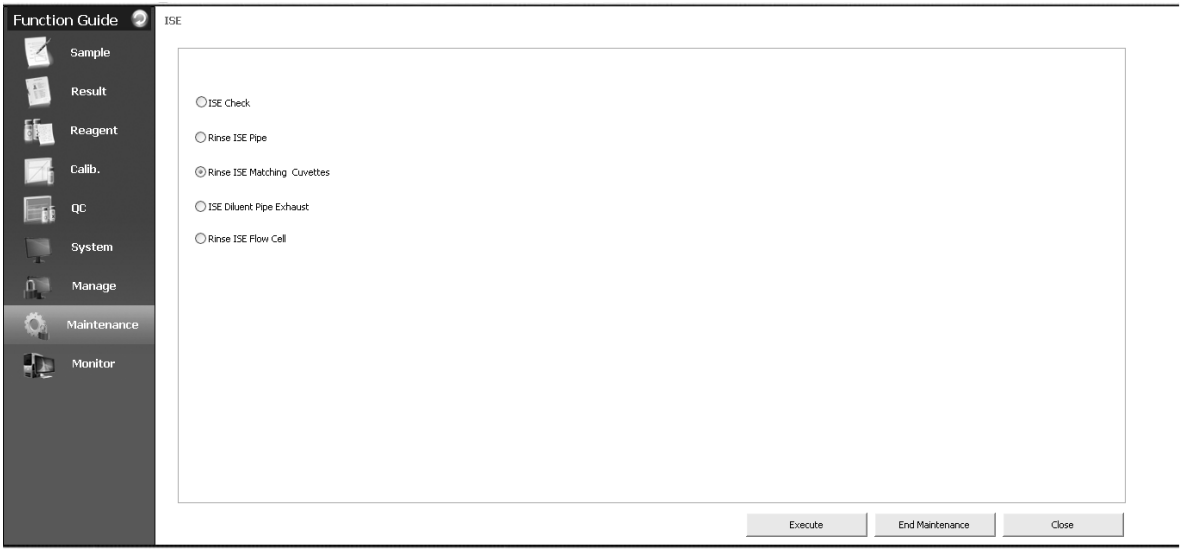


Figure 10-2-23

Place newly poured-out ISE Detergent in the rinse position of W2, and click “Execute”. The analyzer will rinse ISE matching cuvettes automatically. Users can click “End Maintenance” to end the movement.

It's suggested that users conduct “Rinse Matching Cuvette” once a week. Conduct ISE calibration once every time after matching cuvette rinsing.

(4)Expel air from ISE diluent pipeline

Click “ISE Diluent Pipe Exhaust” in the “ISE” window, as Figure 10-2-24 shows:

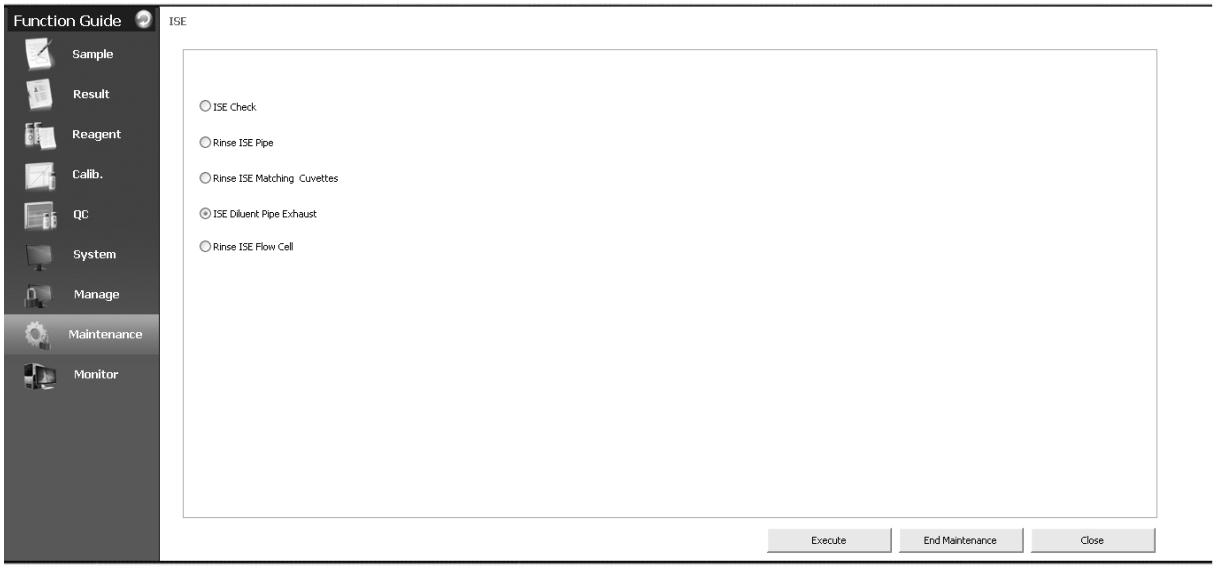


Figure 10-2-24

When there are bubbles in ISE pipeline, or ISE syringe pumps, click the “Execute” key. The analyzer will expel air automatically. During the process, emergency stop is forbidden. Other operation cannot be conducted before the analyzer goes into the standby mode.

(5)ISE flow cell rinsing

Click “Rinse ISE Flow Cell” in the “ISE” window, as Figure 10-2-25 shows:



Figure 10-2-25

Place new ISE Detergent in the rinse position of W2, and then click the “Execute” key. The analyzer will rinse the ISE flow cell automatically. To end the movement, click the “End Maintenance” key.

It's suggested to conduct “Rinse ISE Flow Cell” monthly.

10.3 Positions and Spare Parts of System Maintenance

10.3.1 Periodic Cleaning and Check, and Periodic Replacement of Spare Parts

Periodic cleaning and check, and replacement of spare parts is shown in Table 10-3-1 (based on 5-hour usage daily):

(○: Periodic cleaning and check; ●: Periodic replacement and addition.)

Table 10-3-1 List of Periodic Cleaning and Check, and Periodic Replacement of Spare Parts

No.	Item	Necessary Quantity for one time	Yearly Quantity	Period					Refer to
				Daily	Timely	Weekly	Monthly	Annually	
1	Sample cuvette				●				——
2	Sample probe (manually)			○					10.4.1
	Sample probe (automatically)					○			10.2.4
3	Reagent probe			○					10.4.1
4	Rinsing bath of reagent probe; Rinsing bath of sample probe; Rinsing bath of mixer						○		10.4.1
5 (Note a)	Reaction cuvette (20pcs*set)	8 sets	96 sets		●	○			10.4.2
6	Incubation bath and its drain filter						○		10.4.2
7 (Note b)	Halogen lamp (light source lamp)	1	2		●				10.4.3
8	Rinsing mechanism nozzle			○					10.4.4
9	Mixer			○					10.4.5
10	Syringe pump of sample probe; Syringe pump of reagent probe				●				10.4.11
11	Water supply filter						○		10.4.6
12	Anti-Bacterial Phosphor-Free Detergent; Alkaline Detergent				●				10.1.3
13	Vacuum tank						○		10.4.7
14	Water storage tank of cooling system							○	10.4.8
15	Reagent cooling unit; Sample cooling unit						○		10.4.9
16	Cooling fan and dust proof cover						○		10.4.10
17 (Note c)	Paper, ribbon, ink and toner cartridge of printer				●				The instructions
18 (Note d)	Cuvette blank confirmation					○			10.2.2
19 (Note e)	Pure water equipment			○	●				The instructions
20	Waste liquid discharging				○				——
21	Detergent box						○		10.4.2
22	High-concentration waste liquid pipeline rinsing						○		10.2.4

Note:

a)The list shows the statistics of the maximum use. If the blank values still meet the requirement after 1

month, continue using them; if the blank values are abnormal after the reaction cuvette rinsing, replace them.

b)To ensure the result accuracy and precision, replace the halogen lamp as soon as the photometer check value (340nm wavelength) exceeds 18,000, or the lamp has been used for 750 hours, although the life span of the lamp is about 2000 hours.

c)The analyzer can be equipped with a stylus, ink jet, or laser printer. Users choose consumables accordingly.

d)A blank alarm may occur if blank is not executed every week.

e)If the electrical productivity of the pure water exceeds 1μs/cm, consult the water supplier.

10.3.2 List of Spare Parts for Periodic Replacement or Maintenance

Always prepare the following spare parts for malfunctions:

Table 10-3-2 List of spare parts for maintenance

No.	Name of Spare Part	Remarks	Recommended Quantity / Year
1	Halogen Lamp	12V 20W	2
2	Reaction cuvette (20pcs/set × 8)		96 sets
3	3603 ethylene tube	1/8 inch ×1/4 inch	5m
4	3603 ethylene tube	1/16 inch ×1/8 inch	5m
5	Teflon FEP rigid tube	1.5mm×2.5mm	5m
6	Teflon FEP rigid tube	0.03 inch×1/16 inch	3m
7	Silicone tube	8mm×14mm	10m
8	Ribbon, ink and toner cartridge	For stylus, ink jet, and laser printer	Proper
9	Printer paper	For printing	Proper
10	Water supply filter	For water supply pipe	1
11	Sample probe	For sample aspirating	1
12	Reagent probe	For reagent aspirating	2
13	Mixer	For mixing	2
14	White block of rinsing mechanism	For colorimetric cuvette rinsing	2 each
15	Syringe pump of R1 probe	For reagent aspirating by R1 probe	1
16	Syringe pump of R2 probe	For reagent aspirating by R2 probe	1
17	Syringe pump of sample probe	For sample aspirating by sample probe	1

10.4 Maintenance Method



● Spilling water, reagents, detergents or other liquids over the analyzer or the mechanical /electrical parts may cause damage to the analyzer.

● Do not touch the aspirating mechanism, dispensing mechanism, stirring mechanism, and reaction cuvette rinsing mechanism when the analyzer is running, or there will be a risk of infection or injury.

● Users should take protective measures while working, such as wearing protective gloves, glasses and work cloths. Otherwise, they may get infected when in contact with the contaminated areas and contaminated liquid. Corrosive liquids may cause skin injury. If in contact with contaminated or corrosive liquids accidentally, please rinse the contact part with water immediately.

10.4.1 Sample Probe and Reagent Probe

If the inner walls and outer walls of the probes are contaminated, serum, reagents and water can easily adhere to them, which can also cause blockage inside easily. Consequently, test results will be affected. Thus, they

need checking and cleaning regularly and timely.

(1)Daily, automatic rinse of the analyzer

a)Place about 1mL Alkaline Detergent in the W1 position of the QC disk, as Figure 10-4-1 shows:

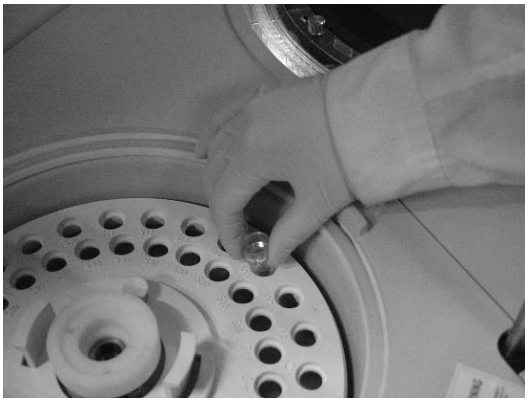


Figure 10-4-1

To conduct a rinse to avoid cross-contamination between the sample probes, place about 1mL Alkaline Detergent in the W3 position that quality control disk has set-up. Take the actual rinse frequence into consideration while deciding on the quantity of the detergent. If the analyzer is equipped with an ISE equipment, place about 1mL ISE Detergent in the quality control disk W2 position.

b)Put 70mL Anti-Bacterial Phosphor-Free Detergent in No. 45 position in the R1 and R2 disk respectively, as Figure 10-4-2 shows:

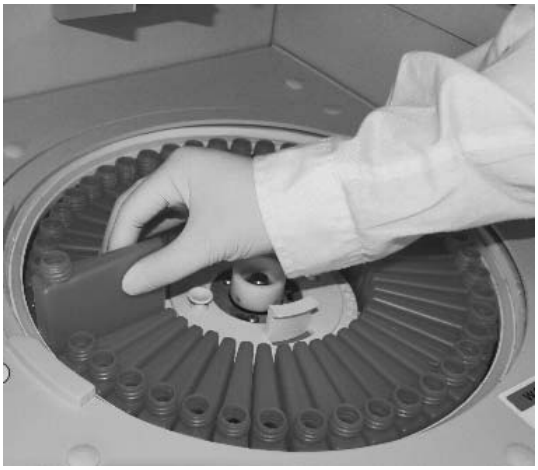


Figure 10-4-2

The reagent probe and sample probe will automatically aspirate Anti-Bacterial Phosphor-Free Detergent or Alkaline Detergent to conduct rinses, after finishing their each movement of dispensing.

Place detergents in the specific positions when rinsing the reaction cuvettes and reagent probe to avoid cross-contamination.

(2)Probe outer wall cleaning

a)Turn off the POWER switch of the analyzer.

b)Remove the cover of the reagent disk. Move the probe arm to the top of the disk by hand. As shown in Figure 10-4-3:

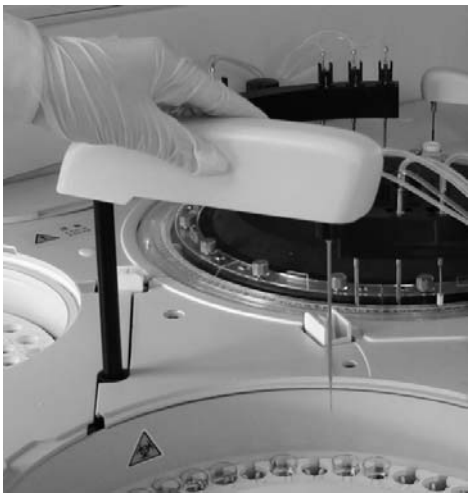


Figure 10-4-3

c)Use cotton swab dipped with alcohol to clean the outer wall of the probe, as shown in Figure 10-4-4:



Figure 10-4-4

As alcohol is flammable, pay attention to it and do not place large amount of alcohol in the vicinity of the analyzer.

d)Restart the analyzer, and the sample probe and reagent probe will return to the home positions.

(3)Clear blockage in probe

Clear blockage when an alarm of blockage in the sample probe is set off, or the water is not discharged from the probe continuously, vertically, or in a stream.

a)Turn off the POWER switch of the analyzer.

b)Hold the upper shell of the probe, lift it and remove it, as shown in Figure 10-4-5:

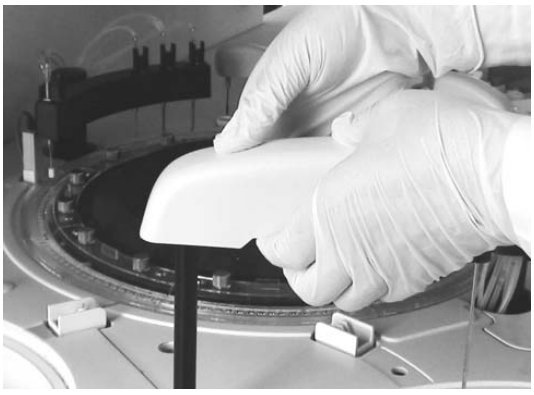


Figure 10-4-5

Unscrew the pipe joint, as shown in Figure 10-4-6:

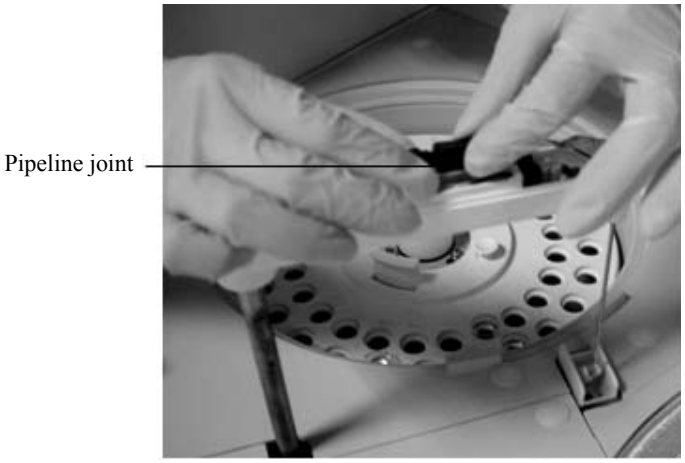


Figure 10-4-6

c)Remove the needle of the probe.

d)Connect the joint of an end of the needle cleaner with the joint of the probe well, as shown in Figure 10-4-7. Inject sodium hypochlorite detergent into a clean standard tube. Put the probe tip into the solution and pull the syringe piston to aspirate the detergent which should be discharged after it retains in the needle for 5 minutes. If the probe is still clogged, repeat the action of pulling and pushing the syringe piston after 5 minutes of immersing the probe in hot water.

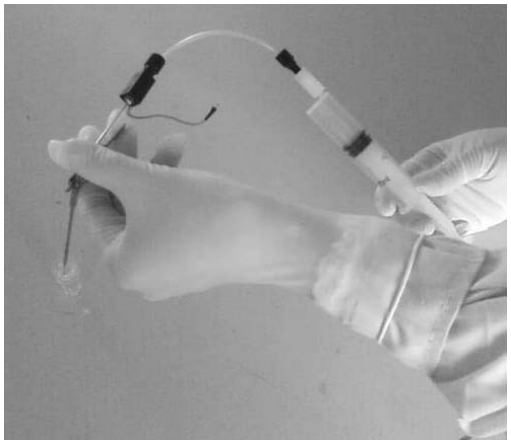


Figure 10-4-7

e)After the operation of d), if no liquid comes out of the probe tip, the probe is severely clogged, which needs the penetration of an acupuncture needle through the probe tip as shown in Figure 10-4-8:

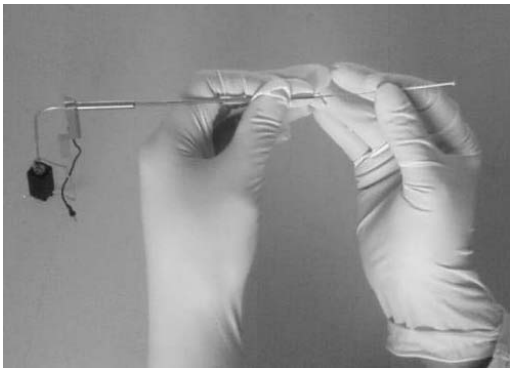


Figure10-4-8

Repeat Step d) with the needle cleaner assembly after the clean-up.

(4)Adjust and check the position of the reagent probe and sample probe

a)Turn on the POWER switch of the analyzer.

b)Click the "Maintenance" key under Function Guide.

c)From the "Mechanism Check" list, select "sample probe horizontal check", "reagent probe horizontal check" or "stirring mechanism check". Click "Execute". Then click "Next".

d)Conduct "sample probe horizontal check". When the sample probe stops above the reaction cuvette, check if the probe tip is in the center of the reaction cuvette, as shown in Figure 10-4-9. If not in the center, contact the maintainer.

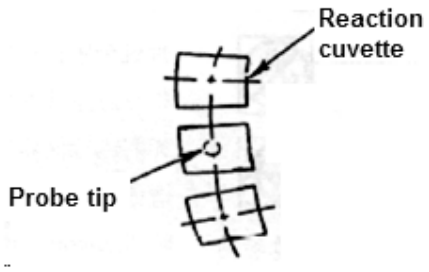


Figure 10-4-9

e)Conduct "reagent probe horizontal check". When the reagent probe stops above the reaction cuvette, check if the probe tip is in the center of the reaction cuvette. If not in the center, contact the maintainer.

f)Conduct "stirring mechanism check". When the mixer stops above the reaction cuvette, check if the mixer tip is in the center of the reaction cuvette. If not in the center, contact the maintainer.

From overlooking angle to see the sample probe, reagent probe and mixer (stirring rod), as shown in Figure 10-4-10:

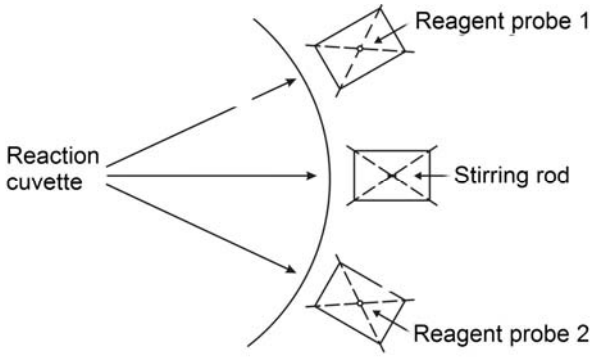


Figure 10-4-10

Click "End Maintenance" to end the maintenance.

The procedure of a horizontal check on the lifting mechanism of the sample probe:

Sample probe resetting→ above the reaction cuvette of the sample probe →rinsing bath(stop for a while) → No.1 position of the outer circle of the sample disk (descending) → above the reaction cuvette →the rinsing bath (stop for a while) →No.51 of the inner circle of the sample probe (descending)→ above the reaction cuvette →rinsing bath (stop for a while) → W1 position of the outer circle of QC disk→above the reaction cuvette→the rinsing bath (stop for a while) →Position S15 of the inner circle of the QC disk (descending) →above the reaction cuvette→the rinsing bath→ Repeat the procedure

The procedure of a check on the lifting mechanism of the reagent probe:

Reagent probe resetting→above the reaction cuvette→the rinsing bath (stop for a while) →reagent bottle(descending) →above the reaction cuvette→repeat the procedure. The movement of the R1 probe is the same as the R2 probe.

The procedure of a check on the mixer:

Mixer resetting→above the reaction cuvette→the rinsing bath→above the reaction cuvette→repeat the

procedure. The movement of R1 mixer and R2 mixer is the same.

g)Vertical check on the sample probe

In the "Maintenance" window, select "sample probe vertical check". Click the"Execute" key, and the sample probe descends until the bottom of sample tube is detected.

h)Vertical check on the reagent probe

When conducting a reagent probe vertical check, prepare two 70mL bottles that hold 5mL normal saline, and prepare two 70mL bottles that hold 50mL normal saline. Place the 70mL bottles with 5mL normal saline in the No. 1 position of the outer circle of R1, R2 disk respectively. Select the corresponding reagent volume in the window. Click "Execute". After the movement, place the 70mL bottles with 50mL normal saline in the No. 1 position of the outer circle of R1, R2 disk respectively. Select the corresponding reagent volume in the window. Click "Execute". During the procedure, the analyzer will automatically remember testing height as a benchmark value for calculating the remaining volume of the reagent.

(5)Rinsing bath cleaning

a)If the rinsing baths are contaminated, use a tube brush to clean them with 2% Anti-Bacterial Phosphor-Free Detergent as Figure 10-4-11 shows:

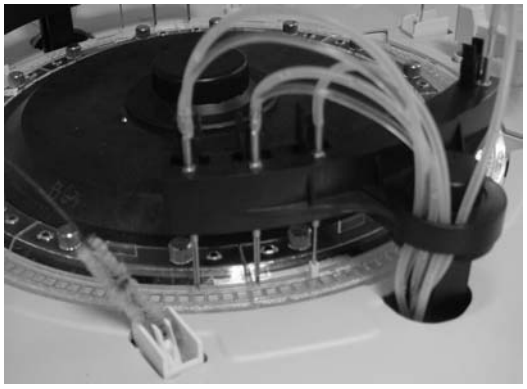


Figure 10-4-11

b)Inject 10mL 2% Anti-Bacterial Phosphor-Free Detergent into a rinsing bath. As Figure 10-4-12 shows:



Figure 10-4-12

c)Then, inject about 100mL water into a rinsing bath to rinse it.

After cleaning, contamination can be eliminated and bacterial can be restrained. Cleaning can be taken every month. If the analyzer is contaminated while the operation, please clean it in time.

10.4.2 Reaction Disk

If the reaction cuvettes or incubation bath are contaminated, the test results may be inaccurate. After long-time use, the reaction cuvettes will age. Thus, rinse them periodically, and check the cuvette blank values. When the values are abnormal and an alarm is set off, rinse them immediately.

(1)The confirmation of the contamination of the reaction cuvettes

a)Turn on the POWER switch of the analyzer.

b)Select “blank” function in the “Maintenance” menu, click “Execute”, the analyzer will carry out the blank check automatically.

c)The blank value of No.1 reaction cuvette should be smaller than or equal to 18,000, the blank value of No.2 ~160 should be within the range of “-800~800”.

d)If the blank values don't meet the above requirement, rinse the reaction cuvettes before tests. After the cleaning, If the blank values still exceed the range, replace the cuvettes.

The current blank value can be displayed or printed. However, the analyzer do not save the tested blank values.

(2)Reaction cuvette rinsing

When the between-cuvette difference exceeds the range of -800~800, the reaction cuvettes may have been contaminated. Rinse them. But if they still can't meet the requirement after the rinsing, replace them at once.

a)Place the Alkaline Detergent (70mL/bottle) in the No. 45 position of the R1 and R2 disk.

b)Conduct “Rinsing reaction cuvette” in “Maintenance” window.

c)After cleaning the reaction cuvettes, carry out the blank check again. If the blank values still exceed the range of -800~800, please the cuvettes.

In order to avoid the uncleanness due to long time use, immerse the reaction cuvettes in 2% Anti-Bacterial Phosphor-Free Detergent for more than 8 hours every week. After that, rinse the immersed reaction cuvettes with clean tap water, and then rinse them with pure water, and then fix the cuvettes on the reaction disk. Carry out blank checks, and conduct sample tests after the blank check values meet the requirement.

(3)Reaction cuvette replacing

If the blank values still cannot meet the requirement after cleaning, replace the reaction cuvettes with new ones.

New reaction cuvettes should be immersed in the 2% Anti-Bacterial Phosphor-Free Detergent for more than 8 hours. Clean the surface of the cuvettes with pure water, mount the cuvettes on the reaction disk, and carry out a blank check. If the values meet the requirement, continue to do sample tests.

a)urn off the power switch.

b)Wear protective gloves, and remove the set screws of the reaction cuvettes as Figure 10-4-13 shows:

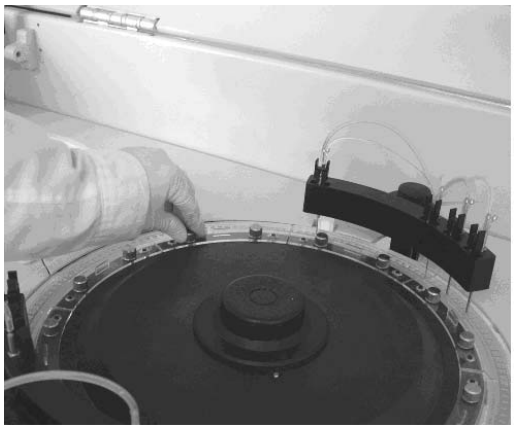


Figure 10-4-13

c)Take out the cuvettes, as Figure 10-4-14 shows:



Figure 10-4-14

d)Rotate the reaction disk to make the place where the reaction cuvettes were removed move to the area below the rinsing mechanism, as Figure 10-4-15 shows:



Figure 10-4-15

e)Remove other reaction cuvettes, place the immersed new reaction cuvettes in the reaction disk. 8 sets of reaction cuvettes can be replaced at the same time.

f)Turn on the power of the analyzer.

g)Select “blank test” in “Maintenance” menu. Make sure carry out the blank check after replace reaction cuvettes. Testing can be carried out after the blank values meet the requirement.

● A once-employed reaction cuvette might be contaminated heavily if allowed to dry. Immerse it in pure water to store it. If the analyzer will be left unemployed for 3 days or more, remove the reaction cuvettes from the reaction disk and keep them immersed in Anti-Bacterial Phosphor-Free Detergent of 2%. If emergent stop occurs during testing, the un-rinsed cuvettes should be rinsed to avoid liquid residue.

● Never use any organic solvent (benzene, alcohol) to clean or immerse the reaction cuvettes.

(4)Clean incubation bath and its drain filter

A clog on the drain filter or incubation bath contamination will cause the inaccuracy of the test results. Thus, clean the incubation bath periodically. (Once a month).

a)Select “Rinse incubation bath” from the “Rinse” window under the “Maintenance”, and click “Execute”. After turning off the light source lamp and the circulating pump of thermostatic water, the thermostatic water will be discharged from the incubation bath.

b)Loosen the set screws of the rinsing mechanism, as Figure 10-4-16 shows:

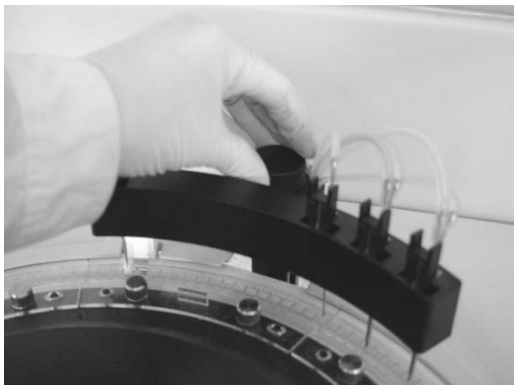


Figure 10-4-16

c)Take out the 8 sets of reaction cuvettes and put them into pure water. Or loosen the set screws of the reaction disk, take out the reaction disk. Put it in a dry and clean place.

Never allow the water on the outside of the reaction cuvettes to drop in the analyzer. Otherwise, malfunctions may occur.

d)Use clean, wet gauze to gently clean the photometric window of the reaction bath as Figure 10-4-17 shows.



Figure 10-4-17

Don't scratch the photometric window, or make impurities attach to them.

e)Take out the drain filter of the incubation bath as Figure 10-4-18 shows. Rinse it with water, and then place it in the original position.

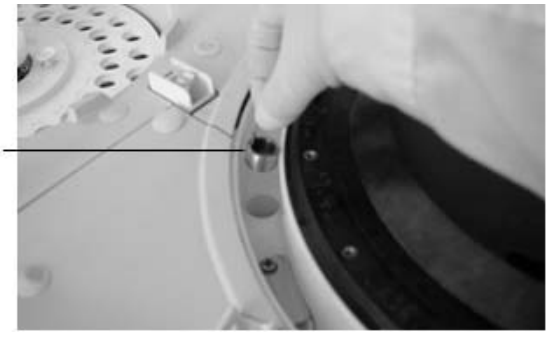


Figure 10-4-18

f)Click the “Next” key under the “Rinse” window of “Maintenance”. Inject pure water into the incubation bath, and turn on the light source lamp and circulating pump.

g)Mount the reaction disk and reaction cuvettes after incubation bath rinsing.

h)Put the rinsing mechanism back in the original place, and fix it.

i)Conduct cuvette blank checks. Sample tests can be carried out after the blank values meet the requirement.

The fixed screws of the reaction disk must be tightened in the installation to ensure its firmness.

(5)Liquid level sensor of the incubation bath

Take out the sensor out of the incubation bath, wipe the surface of the sensor probe with gauze moisturized with 2% Anti-Bacterial Phosphor-Free Detergent. In order to prevent water from being contaminated by the sensor probe, rinsing it once a month is advised.

(6)Detergent box cleaning

After long-time use, there will be dirt and crystal in the Alkaline Detergent box. It's suggested to clean it monthly.

a)Take out the detergent box from the analyzer, and loosen the box cap, as shown in Figure 10-4-19. Clean a detergent box when there is a little detergent inside.

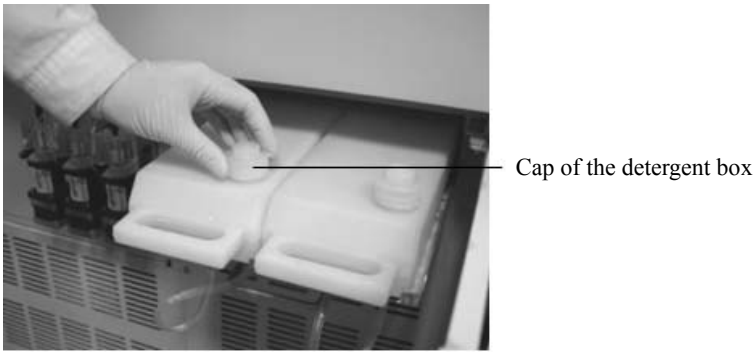


Figure 10-4-19

b)Prepare a gauze. Pull out the pipeline joint under the detergent box, as Figure 10-4-20 shows. Use a container to hold the detergent discharging from the detergent box.

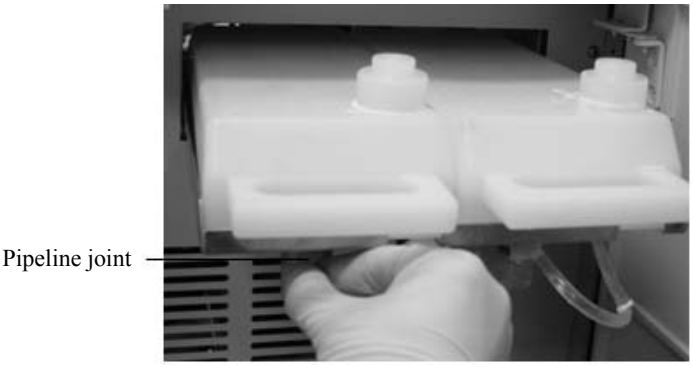


Figure 10-4-20

c)After removing the detergent box, clean the inner and outer surfaces of the detergent box. Rinse it with tap water. Then rinse it with pure water.

d)Discharge the water from the detergent box, wipe the outer surface of the box with dry gauze, put the box back in its original place, and add Alkaline Detergent (a detergent box requires about 1.3L Alkaline Detergent).

e)Conduct “Rinsing Detergent pipeline Exhaust” in the “Exhaust” window under “Maintenance”.

10.4.3 Light Source Lamp

After the aging of the light source lamp, the light power is weakened, and the precision of the analyzer will be affected. When conducting a check on the light intensity, if the check value exceeds 18000, replace the lamp.

(1)Check on light intensity

Select the “Cuvette Blank &Light Intensity” function from the “Maintenance” window. Conduct “light intensity check”. The analyzer will automatically test the power of the light source. The results will be displayed in AD values or printed out. Usually the maximum value is at 340nm.

(2)Light source lamp replacing

Method 1:

a)Prepare a new lamp, as Figure 10-4-21 shows:



Figure 10-4-21

Do not touch the glass surface of the new lamp. Otherwise its value of light intensity may be affected. If the glass surface is found stained with fingerprints, etc, wipe them off with gauze dipped with alcohol.

b)Conduct “Rinse incubation bath” in the “Rinse” window under “Maintenance”. After turning off the light source lamp and circulating pump of the thermostatic water, the thermostatic water in the incubation bath will be discharged automatically.

c)Turn off the power of the analyzer. Wait to let the light room cool completely (for about 30 minutes) to avoid get burned.

d)Loosen the set screws of the rinsing mechanism, and remove the rinsing mechanism. Remove the set knob of the reaction disk, and take out the reaction disk.

If remove the reaction disk and reaction cuvettes at the same time, the water on the reaction cuvettes may drop into the analyzer, which may lead to a malfunction. So, first remove the reaction cuvettes, then the reaction disk.

e)Unscrew the two set wiring terminals of the halogen lamp, and remove the leads, as Figure 10-4-22 shows:

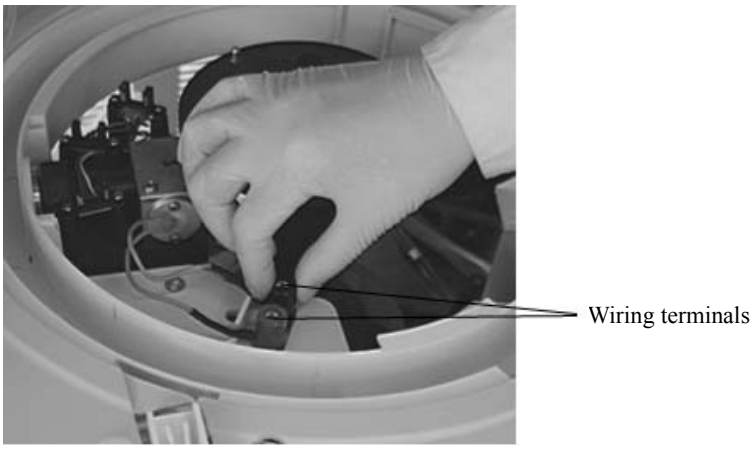


Figure 10-4-22

f)Unscrew the two set screws of the light source seat, and remove the halogen lamp, as Figure 10-4-23 shows:

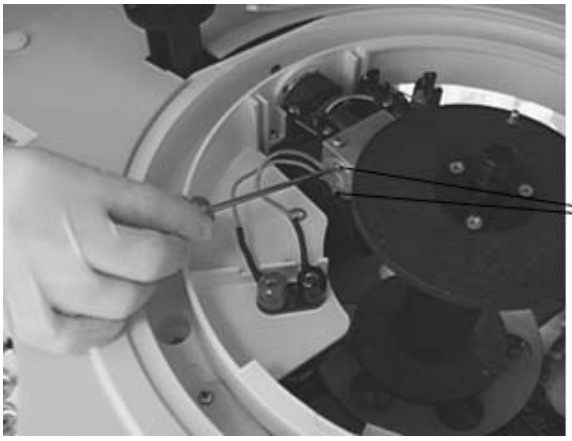


Figure 10-4-23

g)According to the opposite of the above steps, replace the old halogen lamp with a new one. The screws should be tightened; The rubber hose used for light room cooling should not be twisted; The leads should not be loosened or stick out.

h)Put the reaction disk, reaction cuvettes, and rinsing mechanism back in their original places. Turn on the analyzer. After going into the standby mode, click the "Next" key in the "Rinse" window under "Maintenance" to inject new pure water into the incubation bath. After standby, conduct "light intensity check". If the value meets the requirement, fix the halogen lamp and conduct sample tests.

Method 2:

Step a) ~ c) is the same as the above.

d)Users don't have to remove the rinsing mechanism. Remove 2 sets of reaction cuvettes under the 2 rinsing mechanism. Keep the reaction cuvettes clean. Rotate the reaction disk by the set knob, and move the places where the reactions have been removed to the area below the rinsing mechanism. Unscrew the set knob of the reaction disk and remove the reaction disk. Don't scratch the reaction cuvettes.

The next steps are the same as those of Method 1.

10.4.4 Rinsing nozzle cleaning

If the rinsing nozzle is clogged, the reaction cuvettes may not be cleaned adequately or water may flow over the cuvette mouths, which may cause data errors or other analyzer malfunctions.

(1)Loosen the rinsing mechanism screw by turning it counterclockwise, and remove the rinsing mechanism of the reaction cuvettes.

(2)Wipe the outside of the nozzle with gauze that has been dipped in the 2% Anti-Bacterial Phosphor-Free Detergent as Figure 10-4-24 shows:

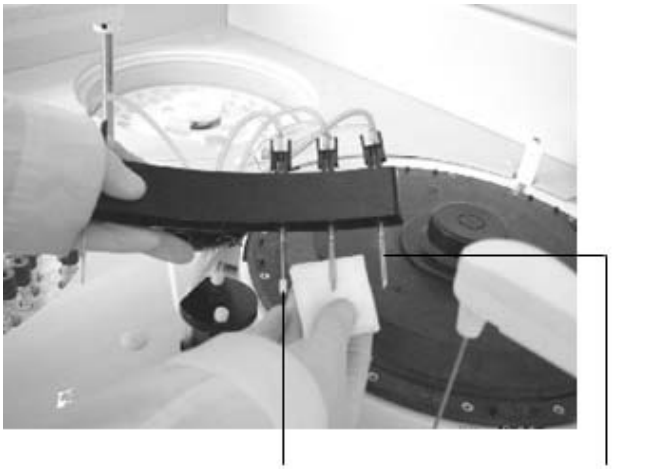


Figure 10-4-24

Don’t bend the nozzle during the operation. Replace the sponge if it’s badly contaminated or worn out.

(3)Gently take out the sponge. When fixing it, (as Figure 10-4-25 shows) do not install it in the opposite direction, and the lower surface of the sponge should be parallel to the reaction cuvettes.

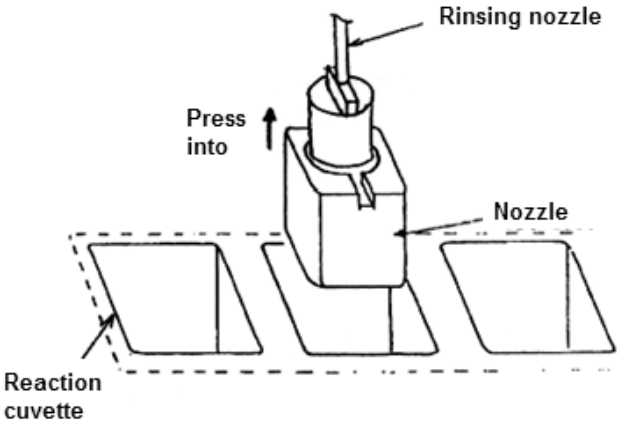


Figure 10-4-25

(4)Put the rinsing mechanism back in its original place.

(5)Carry out “Mechanism Check” 10 times. The sponge should not come into contact with the reaction cuvettes and the rinsing water is filled up to the upper limit level in the reaction cuvettes and it does not overflow from the reaction cuvettes.

10.4.5 Mixer

A contaminated mixer would cause cross-contamination so that influence the accuracy and precision of the test results. So clean the mixer periodically. In addition, the mixer should be replaced when bent.

(1)Mixer cleaning

Wipe the mixer using gauze moistened with alcohol. Then wipe off the liquid on the surface of the mixer with gauze moistened with pure water as Figure 10-4-26 shows. Do not bend the mixer during the process.



Figure 10-4-26

(2)Mixer replacing

a)Turn off the analyzer.

b)Loosen the 2 screws, as Figure 10-4-27. Pull out the mixer downwards.



Figure 10-4-27

c)Prepare a new mixer. Wipe the front end of the new mixer with gauze moisturized with alcohol.

d)Insert the new mixer until its end touches the bottom of the shaft of the motor. Then, fix it using M2 screw as Figure 10-4-28 shows:

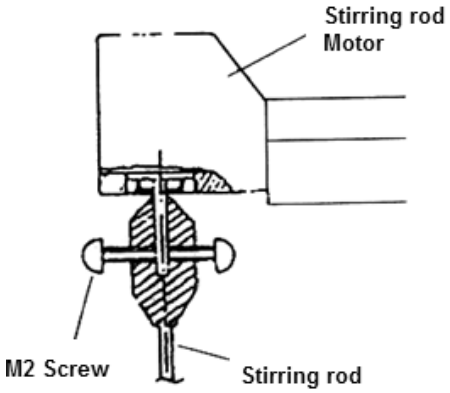


Figure 10-4-28

e)Place the adjusting block of the mixer on the rack of the reaction cuvettes, and then move the mixer above the adjusting block as Figure 10-4-29 shows.

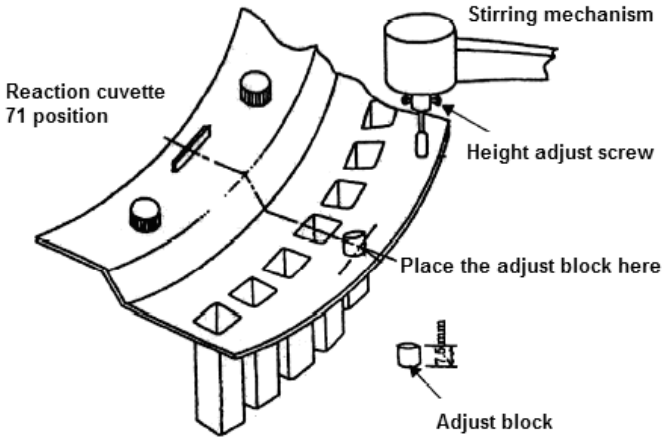


Figure 10-4-29

f)Loosen the M2 screw, and adjust the position of the mixer to make its tip in contact with the upper surface of the adjusting block, as Figure 10-4-30 shows. Tighten the M2 screw.

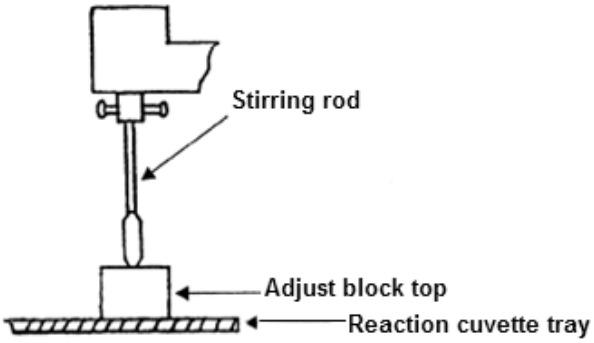


Figure 10-4-30

g)Select "stirring mechanism horizontal check" from the "Mechanism Check" window of "Maintenance". Click "Execute" and then "Next" to check if the position of the mixer is proper. Please contact the after-service people if it's not in the center of the reaction cuvette.

h)Execute "mechanism movement check" 10 times to confirm no abnormality exists.

10.4.6 Water Supply Filter

The main function of the water supply filter is to prevent ion exchange resin and rubber particles from getting into the internal pipeline of the analyzer. If the filter is clogged, there will be a shortage of water supply for the normal operation of the analyzer. So clean it monthly.

(1)Turn off the pure water equipment.

(2)Turn off the analyzer.

(3)Use gauze as a pad to hold the filter cap. Loosen the filter cap and pull it out as Figure 10-4-31 shows. Prepare a container to hold the water flowing out.

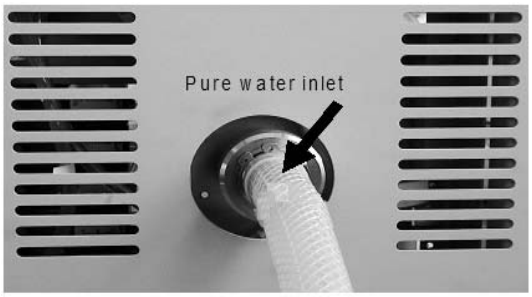


Figure 10-4-31

(4)Take out the filter, rinse it with clean water and put it back in its original place.

10.4.7 Vacuum tank

If waste liquid flows into the vacuum tank, discharge the liquid. Otherwise, malfunctions of other parts may occur (Contact us if abnormality occurs due to the above reason).

(1)Turn off the analyzer.

(2)Unscrew the two screws that fix the rubber hose on the back of the analyzer, and remove the hose, as Figure 10-4-32 shows:



Figure 10-4-32

(3)Pull out the plug of the hose, and use a container to hold the waste liquid flowing out.

(4)After discharging the waste liquid in the vacuum tank, insert the plug in the hose well, and fix the rubber hose on the rear plate of the analyzer with screws.

10.4.8 Water tank

The water tank of the cooling system is at the left front of the analyzer. The thermostatic water tank is on the lower left.

(1)Add pure water into the water tank of the cooling system

If water in the cooling water tank is used for a very long time, it will be dirty and result in bad water circulation, and the volume will reduce due to evaporation and influence the normal working of the cooling system. So change the water annually.

a)Turn off the analyzer.

b)Open the front left door of the analyzer, and remove the lower front plate of the analyzer. As Figure 10-4-33 shows:



Figure 10-4-33

c)Pull out the plug of the two rubber hoses that connect the water tank of the cooling system. Place a container to hold the water discharging from the water tank, as Figure 10-4-34 shows:

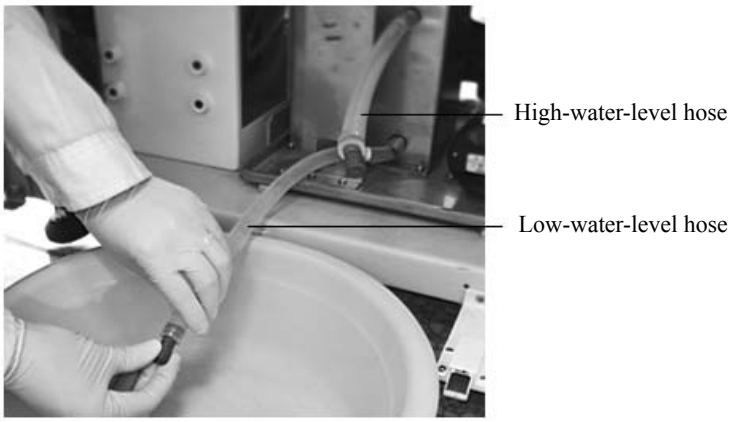


Figure 10-4-34

d)Keep injecting pure water into the hose of low water level until water flows out the hose of high water level.

e)Turn on the analyzer. After a few minutes, continue injecting pure water into the low-water-level hose until there is water flowing out the high-water-level hose. It takes approximately 3L water.

f)Insert the rubber plugs into the hoses again.

g)Fix the analyzer cover plate well.

(2)Drain the water tank of the cooling system

Before moving the analyzer, discharge the pure water in the water tank of the cooling system.

a)Turn off the analyzer.

b)Demount the left front cover of analyzer.

c)Pull out the plugs of the high-water-level and low-water-level hoses. When the water is completely discharged, insert the plugs and mount the cover.

(3)Drain the thermostatic water tank

Before moving the analyzer, discharge the pure water in the thermostatic water tank.

a)Turn off the analyzer.

b)Demount the left cover plate of the analyzer.

c)Pull out the rubber plug of the hose, as Figure 10-4-35 shows:

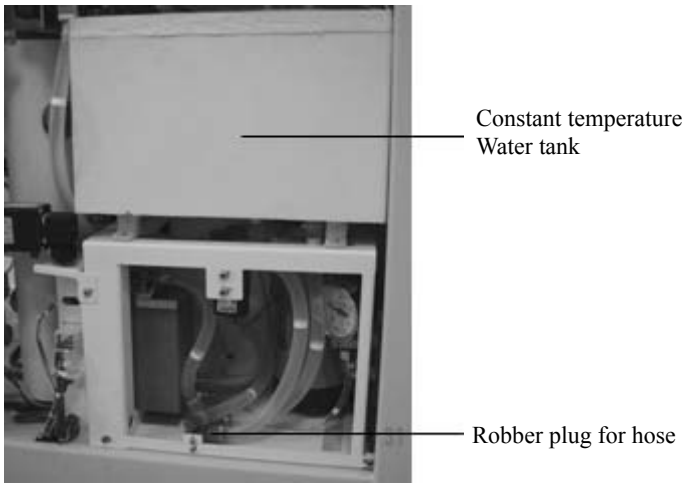


Figure 10-4-35

d)After draining the water tank, insert the plug and mount the cover plate of the analyzer.

10.4.9 Reagent Cooling Unit, Sample Compartment, and QC Compartment

The reagent cooling unit, sample compartment and QC compartment will be contaminated by samples or dust. Clean them at least once a month.

(1)Remove the reagent disk and clean the inside of the reagent cooling unit with gauze as Figure 10-4-36 shows:

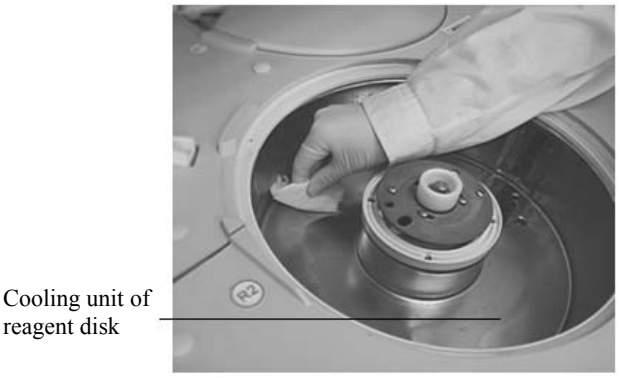


Figure 10-4-36

(2)Then, with lens paper, clean the reading window of the reagent barcode reader, as Figure 10-4-37:

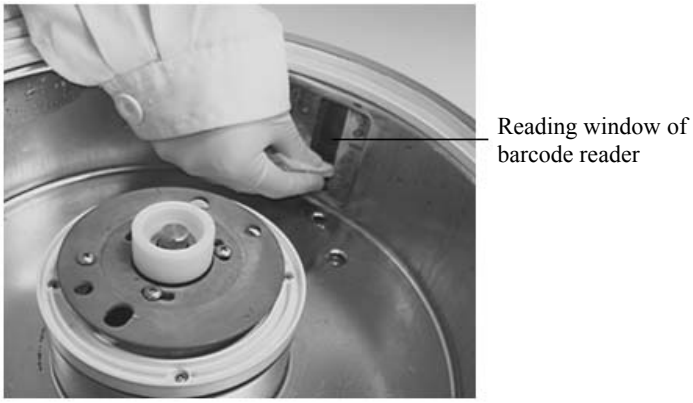


Figure 10-4-37

(3)Remove the sample disk or QC disk, and clean the inside with gauze, as Figure 10-4-38 shows:



Figure 10-4-38

Laser barcode reader is adopted in the analyzer. Please do not look at the reading window when the analyzer is working.

10.4.10 Cooling Fan and Dustproof Cover Cleaning

Long-term usage of the analyzer will accumulate dust on the cooling fans and dustproof cover, so clean them every month. There are 6 cooling fans on the back of the analyzer.

(1)Cooling fan cleaning

a)Turn off the analyzer.

b)Clean the dust on the fans with a vacuum cleaner.

(2)Dustproof cover cleaning

a)Hold the side handles of the cooling fan, and pull out the two dustproof covers, as Figure 10-4-39 shows:

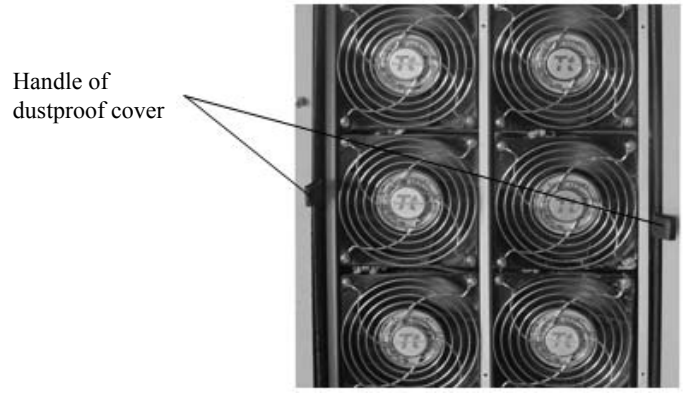


Figure 10-4-39

b)Clean the dust with a vacuum cleaner.

c)Rinse the covers with clear water.

d)Wipe the covers and put them back in the original places.

10.4.11 Syringe Pump

The syringe pumps include the syringe pump of the sample probe, the syringe pump of R1 probe, and the syringe pump of R2 probe. If connected with ISE equipment, they also include SIP syringe pump, DIL syringe pump, and IS syringe pump. The working life of a syringe pump is 1 million times. Normally, a syringe pump needs replacing every 15 months. Contact the after-service workers for replacement of syringe pumps.

The surface of the syringe pump only can be cleaned by pure water, alcohol and other organic solutions are not acceptable.

10.4.12 Cooler

The cooler is at the back of the analyzer as Figure 10-4-40 shows:

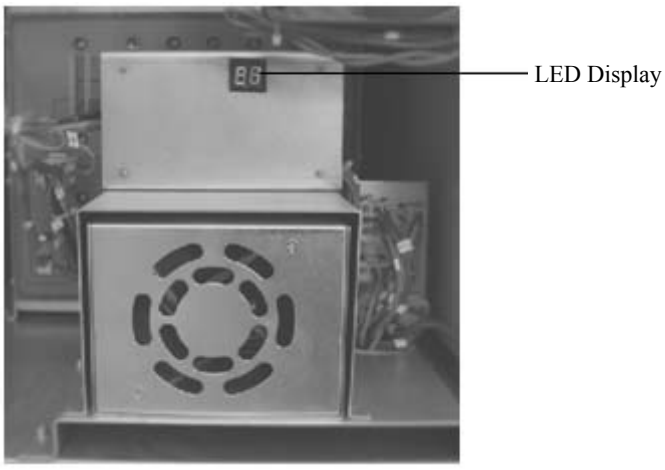


Figure 10-4-40

The LED screen of the cooler will cyclically display the current values of the semiconductor chilling plate 1~6, the temperature of the water tank of the cooling system, and the internal temperature of the analyzer.

When the temperature of the water tank of the cooling system is lower than 5℃~15℃ or the C1~C6 current values are smaller than 5A~7 A, an alarm will be set off. Contact after-service workers.

10.5 Maintenance of ISE Equipment

10.5.1 Periodically clean, check and replace spare parts

Table 10-5-1 shows the list of positions periodically cleaned and spare parts periodically replaced (based on using the analyzer 5 hours a day).

(○:Periodically clean and check ●:Periodically replace spare parts)

Table 10-5-1

No.	Item	Period					Refer to
		Daily	Timely	Weekly	Monthly	Every 3 months	
1	Syringe Pump (diluent, sample)		●				10.4.11
2	Matching Cuvettes			○			10.5.2
3	Reagent pipeline				○		10.5.3
4	Na Electrode		●				10.5.4
5	K Electrode		●				10.5.4
6	Cl Electrode		●				10.5.4
7	Reference Electrode		●				10.5.4
8	Hose of Pinch Valve (suction hose)					●	10.5.5
9	Flow Cell				○		10.5.6

10.5.2 Clean ISE matching cuvettes

After ISE tests, the matching cuvettes may be contaminated by protein, fat and bacteria. So after a time, clean the cuvette for future use.

(1)Place a standard cuvette with ISE Detergent in the W2 position of the QC disk.

(2)After a week of tests, conduct “Rinse ISE Matching Cuvettes” in the “ISE” window of “Maintenance”.

10.5.3 Clean ISE reagent pipeline

After longtime use, ISE reagent pipeline will be contaminated, resulting in inaccurate data. So clean them monthly according to the following steps:

(1)Conduct the rinse of ISE reagent pipeline

a)Dilute the ISE Detergent to 20-fold with pure water, and put 200mL of it into an open container for use.

b)Pull out the reagent pipettes of the reference solution, diluent, and internal standard solution from the reagent bottles, and insert them into the container which holds the diluted detergent. Conduct the rinsing of all the pipeline three times in the “ISE” window of “Maintenance”.

c)After the rinse, take out the reagent pipettes of the reference solution, diluent and internal standard solution from the detergent container, use pure water to rinse the ISE Detergent adhering to the pipettes, wipe them dry with gauze, and put them back in the reagent bottles of the reference solution, diluent and internal standard solution.

d)In the “ISE” window of “Maintenance”, conduct twice “Rinse all ISE pipeline”.

e)Conduct ISE calibration after the conduct of rinsing all the pipeline.

(2)ISE check conducting

Conduct “ISE check” 30 times in the “ISE” window of “Maintenance”. The check results will be displayed.



The value difference of the two checks on the same electrode should be less than 0.2 mV.

10.5.4 Electrode Replacing

● Usually, don't open the ISE cover. Otherwise, it may lead to bad temperature control, resulting in inaccurate test results.

● Finish replacing the electrode and checking the analyzer within one hour.

● The lifespan of an ISE electrode is 6 months or 15000 tests.

● Make sure electrode storage temperature is 1℃~51℃.

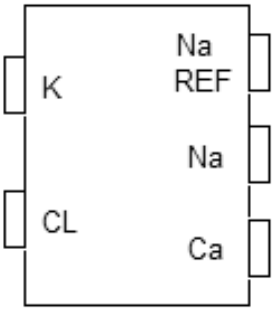


Figure 10-5-1 Electrode Arrangement

10.5.4.1 Replacement of Na, K and Cl electrodes

After long-time use, ISE electrode potential will become smaller gradually, and cause unfavorable responses. At this moment, the existing electrodes need to be replaced by new ones.

(1)Time to replace electrodes

When abnormality happens to calibration slopes, an alarm will go off. See Table 10-5-2:

Table 10-5-2

Slope Value			Alarm Info.
Na	K	Cl	
40mV~70mV	40mV~70mV	-70mV ~ -40mV	Normal Range
35mV~40mV	35mV~40mV	-40mV ~ -35mV	ISE preparation abnormal
Below 35mV	Below 35mV	Above -35mV	ISE slope abnormal

When abnormality happens to ISE preparation and an alarm goes off, analysis can be conducted normally that day. The existing electrodes need to be replaced by new ones the next day. But when an alarm goes off because of an abnormal ISE slope, electrode replacement should be done at once.

If still an alarm goes off or QC tests cannot meet the requirements when the slope values remain in the normal range, it shows that the responses of electrodes are not favorable. Such conditions are the results of pipeline contamination, and can be settled by rinsing pipeline.

If the calibration values of the day before were normal but the present slope value changes dramatically, other causes besides the electrodes cannot be ruled out. Check whether leak happens, and whether there are blockages or air bubbles in the pipeline.

(2)Way to replace electrodes

a)Unscrew the upper cover plate, open it, unscrew the electrode components, and lift the electrode components. For detailed operation, refer to Section 2.3.1.

b)Choose an electrode that is to be replaced, pinch the jacket with one hand, and unscrew the electrode as the following figure shows:




Figure 10-5-2

c)Pull out the electrode wire as Figure 10-5-3 shows:



Figure 10-5-3

d)After removing the electrode, use cotton swabs to wipe dry the liquid on the place where the electrode was installed, as Figure 10-5-4 shows:



Figure 10-5-4

e)Install the new electrode and fix it onto the corresponding position in the flow cell, and connect the other end of the electrode to the connector of the front amplifier board. For detailed operation, refer to 2.3.1.

(3)Electrode reconditioning

After old electrodes are replaced by new ones, the reconditioning of electrodes needs to be conducted according to the following, before analysis.

a)Conduct the rinsing of all the ISE pipelines once, in the “ISE” window of the “Maintenance” interface.

b)Let it stand for 10 minutes, and then conduct the ISE check 10 times in the “ISE” window of the “Maintenance” interface. The test results will be displayed in the system maintenance working area.

c)Conduct ISE calibration once, and check whether the slope is in the normal range.

10.5.4.2 Replacement of reference electrodes

(1)Time to replace reference electrodes

The electrodes need replacing when all the slope values of the Na, K and Cl electrodes are low or not stable.

(2)Replacing method

Choose the reference electrode (Na REF). The replacing method and notice are the same as “(2)Way to replace

electrodes" in "10.5.4.1 Replacement of Na, K and Cl electrodes".

(3)Confirmation after replacement

a)Conduct the rinsing of all the ISE pipeline once, in the "ISE" window of the "Maintenance" interface.

b)Let it stand for 10 minutes, and conduct the ISE check 10 times in the "ISE" window of the "System Maintenance" interface. The test results will be displayed in the system maintenance working area. The value difference of the two checks on the same electrode should be less than 0.2 unit.

c)Conduct ISE calibration once, and check whether the slope is in the standard range.

10.5.5 Replacement of pinch valve hoses

(1)Open the ISE cover plate of the analysis unit of the analyzer.

(2)Pull out the old hoses, and replace them with new ones. In fixing the hoses, avoid making them hang down loosely, as Figure 10-5-5 shows:

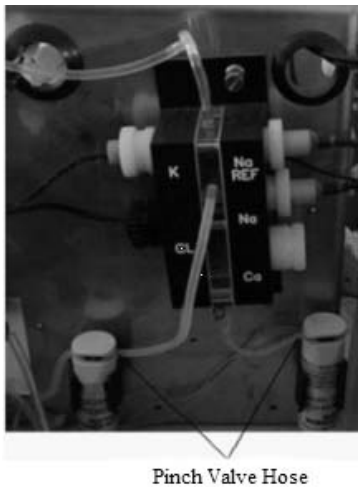


Figure 10-5-5

(3)If liquid drops, wipe it with gauze that has been dipped in pure water.

(4)Fix the ISE cover well.

10.5.6 Rinse flow cell

(1)Put a cup of newly poured-out ISE Detergent in the W2 position of the QC disk.

(2)After a week of tests, conduct "Rinse ISE Flow Cell" in the "ISE" window under "Maintenance".

10.5.7 Cl electrode maintenance

(1)Remove the Cl electrode that is to be maintained. Refer to "10.5.4.1 (2)" for the method.

(2)Place a piece of polishing paper on the table (as the following figure shows). Drip 3 to 5 drops of pure water on the paper. Remove the electrode seal ring on the front of the electrode, hold the electrode tip, and keep polishing the electrode tip in the 8-shaped route within the area of dripped water for 5-10 times, while making the electrode tip perpendicular to the paper, until the electrode tip renders luster.

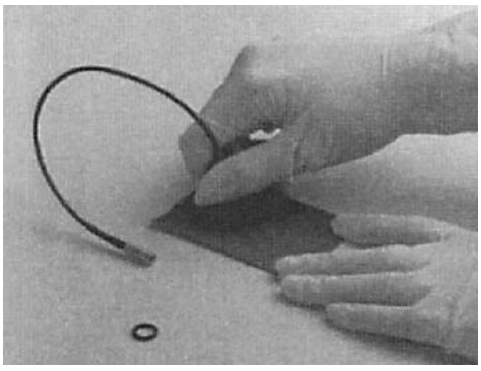


Figure 10-5-6

● Be sure to make the electrode tip perpendicular to the paper while polishing it.

● Do not polish the electrode tip using overmuch strength.

(3)Gently wipe the electrode tip to remove impurities using cotton swabs that have been dipped in pure water. Then let the tip dry.

(4)Drip a small drop of silicone mixture on the surface of the electrode tip. Use cotton swabs to evenly spread the silicone mixture on the surface of the electrode tip; a thin layer is all right. Then use cotton swabs to wipe the redundant silicone.

(5)Reinstall the electrode for use.

● The Cl electrode needs maintenance once a month.

● If the Cl electrode has been maintained several times and the electrode seal ring cannot be fix on the tip evenly, replace the electrode with a new one.

10.5.8 ISE waste unit cleaning

The crystal substance attached on the ISE waste interface may cause inaccuracy of the test result. Clean it once a week.

(1)Wash the crystal attached on the ISE waste interface into waste container by purified water, and then wash the waste container by purified water, as Figure 10-5-7 shows:

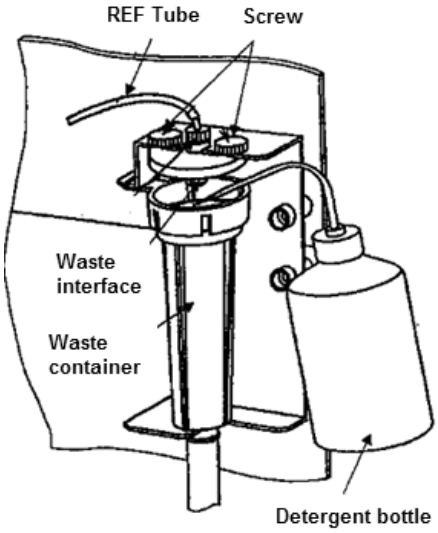


Figure 10-5-7

(2)Wipe out the liquid by gauze with purified water. Thus there will be no conductive components on the waste interface and outside of the waste container.

Touching the waste tube may cause noise jamming while testing.

Chapter 11 Alarm Handling

11.1 Alarm Information Type

Alarm information consists of data alarms and malfunction alarms according to the different contents. The data alarm is “notice level”; while the malfunction alarm includes “notice level”, “feeding sample stops level” and “stop level”. After alarms are given, the movements of the analyzer are shown in Table 11-1:

Table 11-1 Analyzer Movement after Alarm

Alarm Type	Analyzer Movement
Data alarm	Alarm for testing results. Operation continues.
Notice alarm	Notice alarm appears both in data alarm and analyzer malfunction. Buzzer buzzing, but the operation continues as usual. Whether the analysis is stopped is decided by the user.
Feeding sample stops alarm	Alarm for analyzer malfunction. Stop feeding new samples. Samples already in reaction cuvettes continues being analyzed.
Stop alarm	Alarm for malfunction. Buzzer buzzing. The analyzer stops immediately. Test results not reliable.

11.2 Solution to Malfunction without Alarm

11.2.1 Data Abnormality Without Alarm

Some data abnormality cannot be displayed as alarms. They can be found out through QC test, recheck and analyzer status check.

For the solutions, see Table 11-2-1:

Table 11-2-1

Malfunction	Main Reason	Solution
Repeatability badness	1.Maintenance is not carried out periodically. 2.Reagent deteriorates; insoluble substance exists: impurity blends. 3.The quality of pure water is poor. 4.Anti-Bacterial Phosphor-Free Detergent, Alkaline Detergent shortage. 5.Crystal occurs in reagent cooling unit. (Repeatability of low value runs error.) 6.Cross-contamination exists between analysis items. 7.Sample is unqualified. Fibrin exists in sample. 8.Surface of sample probe with dirt or liquid.	1.Maintain according to User Manual. 2.Replace with new reagent. Use and preserve it correctly. 3.Water conductivity should be within 1μs/cm. 4.Add detergent, and carry out rinsing reaction cuvette in “Maintenance”. 5.Use detergent produced by the manufacturer. 6.Separate reagents causing cross -contamination. Or use avoidance function for cross -contamination. 7.Separate unqualified sample, or collect sample again. 8.Wipe it with cotton swab moistened by alcohol.
Accuracy error	1.Calibrator is concentrated or invalid. 2.Reagent ingredient is incorrect. 3. Analytical condition is set up incorrectly.	1.Immediately use it as long as put into the sample cuvette. Preserve it correctly. 2.Replace with new reagent. 3.Correct the parameter.



The above examples are not comprehensive. Solve practical problems according to actual conditions.

11.2.2 Analyzer Malfunction without Alarm

For the solutions, see Table 11-2-2:

Table 11-2-2

Malfunction	Main Cause	Solution
Sample probe with water droplet	1.Sample probe contaminated. 2.Sampling system (pipeline, syringe) leakage.	1.Wipe it with cotton swabs with alcohol. 2.Carry out maintenance check.
Water drops from rinsing mechanism	1. Anti-Bacterial Phosphor-Free Detergent for cleaning reaction cuvette is used up. 2.Rinsing mechanism pipeline leaks. 3.Nozzle and pipeline blocked.	1.Add the detergent. 2.Check the joint. 3.Clean it through maintenance check. For replacement purpose, contact service department.
Thermostatic water does not flow out	1.Air in water supply pipeline. 2.Incubation bath filter blocked. 3.Pure water unit powers off.	1. Expel the air in pump. 2.Clean it. 3.Connect with power supply. Do not use the same circuit with analyzer.
Water cannot flow out from rinsing nozzle	Nozzle or pipeline blocked.	Clean it through maintenance check. For replacement purpose, contact the service department.
Water cannot flow out from rinsing bath (sample probe, reagent nozzle, stirring rod)	Outlet port or pipeline blocked.	Rinsing outlet port. For replacement purpose contact the service department.
Thermostatic water (from rinsing mechanism to reaction cuvette) overflows.	Nozzle, pipeline block.	Clean it through maintenance check. For replacement purpose, contact the service department.
Incubation bath has bubble inside.	1.Incubation water level is over low or incubation bath is contaminated. 2.Incubation water exchange carried out before Pure water unit power on.	1.Carry out water exchange in incubation bath. 2.Carry out water exchange after pure water unit electrified.
Sample syringe mechanism leaks	Joint installation error	Re-install after leakage confirmed.
Sample syringe mechanism has bubble inside	1. Joint installation error 2.Sample syringe degas insufficient	1.Re-install after place from which air entered confirmed. 2.Carry out again. If small air bubbles exist, tap the syringe pump while reagent or detergent flows to remove them.

11.3 Alarm and Solution

Alarm code	Level	Brief description	Description	Countermeasure
0-1	Warning	Absorbance over	The absorbance to be used for calculation after cell blank correction exceeds 3.3Abs	(1)Check if the reagent is confected or positioned in the right way. (2)Check if water in incubation bath is contaminated. (3)Check if there is the impurity interfuse in sample. (4)Check if the reaction cuvette is blurred. (5)Check if there is an obstacle on
0-10	Warning	Calculation disable	1.The denominator becomes zero in calculation. 2.An over flow occurs in logarithmic or exponential calculation. 3.The absorbance of test item is less than the absorbance of standard liquid.	(1)Check if there is a logical error in calculation formulas. (2)Check the concentration setup of standard liquid when multi-point calibration. (3)Check the absorbance value of photometry point of the test.(4)Check if reagent and sample is enough and in right
0-11	Warning	Calculation disable	In all-point calibration, the absorbance of standard liquid do not increase when concentration increase.	(1)Check if calibration liquid is put in the right place . (2)Check if absorbance value of different concentrations increase. (3)Please rerun the calibration.
0-12	Warning	ISE calculated error	In calculation the denominator became zero	Please check if ISE reagent and sample are enough, and in right position.
0-13	Warning	Overtime calibration time arrive, please execute calibration.	Overtime calibration time arrive in the setting of calibration parameter, please execute calibration.	
0-14	Warning	Concentrated waste liquid pipeline need to Rins	Concentrated waste liquid pipeline need to Rins	Call up the system maintenance menu, carry out the program “Auto Rinsing Concentrated waste liquid pipeline”
0-15	Warning	Calculation disable	The test item is not calibrated.	First please calibrate the test item.
0-16	Warning	Drift rate check exceeds ...	When the nonlinear standard curve and linear (multipoint) calibration is carried out, the difference between the absorbance of each concentration obtained through the fitting formula and the absorbance of the actual measurement exceeds the allowable deviation.	(1)Check whether the set value of the drift rate of the calibration item is correct. (2)Check whether the reagent deteriorates. (3)Check whether the input value of the concentration of the calibration solution is correct.
0-18	Warning	Calibration test unable to complete	No standard sample cuvette is placed or the sample volume in the standard sample cuvette is insufficient, so the calibration test is unable to complete.	After the check, send calibration again in the standby mode.
0-19	Warning	QC test unable to complete	No quality control sample cuvette is placed or the sample volume in the quality control sample cuvette is insufficient, so the quality control test is unable to complete.	After the check, send quality control again in the standby mode.

Alarm code	Level	Brief description	Description	Countermeasure
0-2	Warning	Check on the first standard absorbance exceeds ...	The average value of the two determinations of standard 1 is greater than the set value of the blank level determination.	(1)Check the set value of the blank level determination. (2)Check whether the reagent is effective.
0-20	Warning	Reagent barcode of R1 disk already used	When the reagent barcode is registered in R1 disk, it's found that the reagent barcode is already used.	(1)Check the barcode stick information. (2)Scan barcode again after check.
0-21	Warning	R2 reagent found in R1 disk	R2 or R3 reagent is found in R1 disk.	(1)Check the barcode stick information. (2)Scan barcode again after check.
0-23	Warning	R1 disk barcode blank out.	(1)when reagent residual volume is less than setup reagent residual volume, the barcode is blank out. (2)barcode is used after blank out.	(1)Check the barcode stick information. (2)Scan barcode again after check.
0-24	Warning	R1 disk barcode invalid.	(1)The check on the reagent barcode fails. (2)The reagent name of the barcode is not added in “Setting of Reagent Item”. (3)An error in the check on the reagent type of the barcode is made.	(1) Check the information about the pasting of the barcode. (2) Scan the reagent barcode again after the check. (3)Add a corresponding item to the setting of the barcode item.
0-25	Warning	R2 disk barcode repeats	R2 disk barcode repeats	(1)Check the barcode stick information. (2)Scan barcode again after check.
0-250	Warning	Reception of data overruns	The incorrect header information that has been received makes the reception of data overruns.	(1)Please contact the maintainer.
0-251	Warning	Network card not available or network cable pulled out	The sending or receiving of data fails because the network card is not available or the network cable is pulled out.	(1)Please check whether the network connection is normal. (2)Please check whether the network functions well.
0-252	Warning	Instrument data sending or receiving fails	The malfunction of the network, server, etc. leads to the failure of the sending or receiving of data.	(1)Please check whether the net connection is normal. (2)Please contact the maintainer. (3)The meanings of error codes: 10050-The socket operation meets with an unavailable network; 10053-The software in your host computer gives up an already-established connection; 10054-The remote host is forced to close a present connection; 10055-The socket operation cannot be conducted because of the insufficient buffer space or the full queue; 10064-The socket operation fails because the target host does not function.
0-253	Warning	Sending data to the instrument overruns	No identification order is received within the designated interval.	(1)Please check whether the network connection is normal. (2)Please check whether the instrument functions normally. (3)Please contact the maintainer.

Alarm code	Level	Brief description	Description	Countermeasure
0-254	Warning	Reception of instrument mode data overruns	No instrument mode data are received within the designated interval.	(1)Please check whether the network connection is normal. (2)Please check whether the instrument functions normally. (3)Please contact the maintainer.
0-255	Warning	Communication connection with the instrument malfunctions	No communication data of the instrument are received within the designated interval.	(1)Please check whether the network connection is normal. (2)Please check whether the instrument functions normally. (3)Please contact the maintainer.
0-26	Warning	Reagent of R1 or R4 type found in R2 disk	Reagent of R1 or R4 type is found in R2 disk.	(1)Check the barcode stick information. (2)Scan barcode again after check.
0-28	Warning	R2 disk barcode blank out.	(1)when reagent residual volume is less than setup reagent residual volume, the barcode is blank out. (2)barcode is used after blank out.	(1)Check the barcode stick information. (2)Scan barcode again after check.
0-29	Warning	R2 disk barcode invalid.	(1)Barcode checkup failure. (2)Barcode reagent name do not occur in “barcode item setup”. (3)Barcode reagent type checkup error.	(1)Check barcode stick information. (2)Scan barcode again after check. (3)Corresponding item is added in barcode item setup.
0-3	Warning	Divergence checkup over	The difference between two times test standard solution absorbance is larger than deviation permissible absorbance.	(1)Check if the value of deviation permissible absorbance is correct. (2)Check if sample syringe is leakage and if the incubation bath is contaminated. (3)Check if there is a cross-contamination.
0-31	Warning	ISE exceed the lower limit of measuring range	ISE QC exceed the lower limit of measuring range.	Please check if Controls volume and reagent volume is enough, if the position is right.
0-32	Warning	ISE exceed the upper limit of measuring range	ISE QC exceed the upper limit of measuring range.	Please check if Controls volume and reagent volume is enough, if the position is right.
0-33	Warning	ISE exceed the lower limit of measuring range	ISE calibration exceed the lower limit of measuring range.	Please check if Controls volume and reagent volume is enough, if the position is right.
0-34	Warning	ISE exceed the upper limit of measuring range	ISE calibration exceed the upper limit of measuring range.	Please check if Controls volume and reagent volume is enough, if the position is right.
0-35	Warning	ISE exceed the measuring range	ISE sample exceed the upper/lower limit of measuring range.	Please check if sample volume and reagent volume is enough, if the position is right.

Alarm code	Level	Brief description	Description	Countermeasure
0-4	Warning	K factor check value over	The difference between calculate K factor and previous one is more than plus or minus 20%	(1)Check if K factor is proper. (2)Check if the standard solution is deteriorate. (3)Check if reagent is deteriorate.
0-40	Warning	Remaining volume in R1 disk insufficient	The remaining volume of reagent is smaller than the setting value of the remaining volume of reagent in the system setting interface.	(1)Open the reagent information window to check whether there is reagent smaller than the setting value of the remaining reagent volume. (2)Check whether the setting value of the remaining reagent volume is reasonable.
0-41	Warning	Remaining reagent volume in R2 disk insufficient	The remaining reagent volume is smaller than the setting value of the remaining reagent volume in the system setting interface.	(1)Open the reagent information window to check whether there is reagent smaller than the setting value of the remaining reagent volume. (2)Check whether the setting value of the remaining reagent volume is reasonable.
0-42	Warning	Detergent low(R1)	The detergent volume is less than 5mL.	(1) Call up “Reagent information”screen to check if detergent is enough.
0-44	Warning	Detergent low(R2)	The detergent volume is less than 5mL.	(1) Call up “Reagent information”screen to check if detergent is enough.
0-46	Warning	Reagent information setting in R1 disk incorrect	R1 reagent volume in analytic parameters ≤0	Please check whether the setting of analytic parameters is correct.
0-47	Warning	R2 disk reagent information setting incorrect	R2 reagent volume in analytic parameters ≤0	Please check whether the setting of analytic parameters is correct.
0-48	Warning	Automatic check on sample volume parameters setting ineffective	When the automatic check is conducted, no sample volume parameters of the check item that meet a certain condition is set or the setting is ineffective.	Please check whether the setting of item sample volume parameters satisfies the requirement of the automatic check.
0-5	Warning	Linearity limit over	The measured value is out of the linearity limit range of test item.	(1)Dilute the sample and rerun the test. (2)Check setup value.
0-52	Warning	Sample barcode not recognized	The barcode reader cannot recognize the sample barcode.	(1)Please check whether the sample is correctly placed. (2)Please check whether the information about the pasting of the sample barcode is effective.
0-56	Warning	Sample barcode ineffective	Sample information corresponding to the barcode is not found in the database.	(1)Please check whether the sample is registered. (2)Please check whether the barcode is pasted in a correct way.
0-57	Warning	Sample application from the LIS-side overruns	The sample application from the LIS-side overruns.	(1)Please check whether the LIS is started. (2)Please check whether the LIS communication setting is correct. (3)Please check whether there is any sample to be tested in the LIS-side.

Alarm code	Level	Brief description	Description	Countermeasure
0-58	Warning	No sample to be tested found from the LIS-side	No sample to be tested is found from the LIS-side.	(1)Please check whether the barcode is pasted in a correct way. (2)Please check whether there is sample information in the LIS system.
0-6	Warning	Linearity abnormal	Calculation in the specified photometric range, and there is a different exceeding the linearity limit value.	(1)Check if there is impurity in the sample. (2)Check if there is impurity and bubble in the reagent. (3)Dilution the sample and rerun the test. (4)Check Stirring mechanism.
0-60	Warning	Calculation result overflows	The result of the related formula calculation overflows.	(1)Check whether the calculation formula is reasonable. (2)Check the absorbance value of the calculation photometry point of the test item. (3)Check whether the reagent and samples are enough and whether the positions are correct.
0-61	Warning	Expression in calculation formula incorrect	The calculation formula is an irregular math expression.	(1)Check whether the calculation formula is correct.
0-62	Warning	Item test result in compensation formula abnormal	The test result in the compensation formula cannot be converted into effective floating-points.	(1)Please check whether the decimal point separator of the present operating system is consistent with that used by the software.
0-63	Warning	No item test result in compensation formula	The compensation formula includes the item of no test result.	(1)Check whether the compensation formula is reasonable. (2)Check the absorbance value of the calculation photometry point of the test item. (3)Check whether the reagent and samples are enough and whether the positions are correct.
0-64	Warning	Test item in compensation formula not exists	The compensation formula includes nonexistent test items.	(1)Check whether the compensation formula is reasonable.
0-7	Warning	Sensitivity abnormal	Sensitivity is checked for linear(2-6 points), non-linear calibration. This error is indicated if the difference in mean absorbance between standard solution 1 and standard solution (N) is smaller than the sensitivity limit (input value).	(1)Call up main screen, check if sensitivity limit value is properly setup. (2)Check if reagent is deteriorated. (3)Check the input concentration value of standard solution is properly setup. (4)Check if standard solution is deteriorated.
0-70	Warning	Please conduct operation of rinsing sample probes in standby mode	The number of the test items is larger than that of the setting items of sample probe rinsing.	Please conduct the operation of rinsing sample probes.

Alarm code	Level	Brief description	Description	Countermeasure
0-71	Warning	Incubation bath water temp abnormal	The water temperature in the incubation bath is over 45C	(1)Check if cooling fan is operate normally. (2)check if colling fan dustproof cover is clogged by dirt. (3)Trouble can not be restored, contact the service department
0-72	Warning	Incubation bath water temp abnormal	The water temperature in the incubation bath is over the range of 37 plus or minus 0.5C.(check in operating)	(1)Check if the room temperature is within a range of 15-32C. (2)Check if cooling fan is operated normally. (3)Check if cooling fan dustproof cover is clogged by dirt. (4)Check if the incubation bath water is circulation. (5)Trouble can not be restored, contact
0-73	Warning	Concentration exceeds the reference crisis value range	The test results exceeds the crisis value range of the item.	Make sure the crisis value range setting
0-8	Warning	Prozone check value over	In the Antigen addiction assay and reaction assay, the prozone check value (PC value),exceeds the specified upper/lower limit.	(1)Dilution the sample and rerun the test. (2)Check if the reagent is confected or positioned in the right way. (3)Check if the specified upper/ lower limit is properly set up.
0-81	Warning	Alkaline detergent needs adding	The remaining volume of the alkaline detergent used as the supplement is 0. Please add some.	First add reagent in “Reagent Supplement” in “System Setting”.
0-82	Warning	Anti-bacterial phosphor-free detergent needs adding	The remaining volume of the anti-bacterial phosphor-free detergent used as the supplement is 0. Please add some.	First add reagent in the “Reagent Supplement” in the “System Setting”.
0-85	Warning	ISE-Na+ LEVEL Error	The mean electromotive force of internal standard solution (EAV) is out of the following range at 3 of 5 measuring points(internal standard solution) Na:-90.0mV=EAV=-10mV	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-86	Warning	ISE-K+ LEVEL Error	The mean electromotive force of internal standard solution (EAV) is out of the following range at 3 of 5 measuring points(internal standard solution) K:-90.0mV=EAV=-10mV	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-87	Warning	ISE-Cl- LEVEL Error	The mean electromotive force of internal standard solution (EAV) is out of the following range at 3 of 5 measuring points(internal standard solution) Cl:-90.0mV=EAV=-10mV	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.

Alarm code	Level	Brief description	Description	Countermeasure
0-88	Warning	ISE-Ca+ LEVEL Error	The mean electromotive force of internal standard solution (EAV) is out of the following range at 3 of 5 measuring points(internal standard solution) Ca:-90.0mV=EAV=-10mV	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-9	Warning	Absorbency reaction limit over	In Rate A assay and 2 points rate assay, The check value of absorbency limit is larger than the setup limit value.	(1)Test after dilute the sample. (2)Check if the reagent is confected or put in the right position. (3)Check the setup value of absorbency limit.
0-91	Warning	ISE Slope Error	1.Upon calibration, the slope level is within the following range. 2.The electrode response is degraded (the carryover rate A is as follows). Na: (1)SLOPE<35mV.	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-92	Warning	ISE Slope Error	1.Upon calibration, the slope level is within the following range. 2.The electrode response is degraded (the carryover rate A is as follows) K: (1)SLOPE<25mV.	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-93	Warning	ISE Slope Error	1.Upon calibration, the slope level is within the following range. 2.The electrode response is degraded (the carryover rate A is as follows). Cl: (1)SLOPE>-25mV .	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-94	Warning	ISE Slope Error	1.Upon calibration, the slope level is within the following range. 2.The electrode response is degraded (the carryover rate A is as follows). Ca: (1)SLOPE>-25mV	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-95	Warning	ISE concentration error	The concentration of internal standard solution C(IS)is within the following range. Na:C(IS)<150.0mmol/L or 300.0mmol/L<C(IS)	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.

Alarm code	Level	Brief description	Description	Countermeasure
0-96	Warning	ISE concentration error	The concentration of internal standard solution C(IS)is within the following range. K:C(IS)<4mmol/L or 10mmol/L<C(IS)	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-97	Warning	ISE concentration error	The concentration of internal standard solution C(IS)is within the following range. Cl:C(IS)<100mmol/L or 200mmol/L<C(IS)	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-98	Warning	ISE concentration error	The concentration of internal standard solution C(IS)is within the following range. Ca:C(IS)<80mmol/L or 120mmol/L<C(IS)	(1)Carry out “ISE Check” on the Mechanisms Check screen. (2)If it is not easy for the user to remove the cause of trouble, contact the service department. (3)For details refer to “electrolyte device maintenance” in “User manual”.
0-101	Warning	ISE exceed the lower limit of measuring range	ISE QC exceeds the lower limit of measuring range.	Please check if controls volume and reagent volume is enough, if the position is right.
0-102	Warning	ISE exceed the upper limit of measuring range	ISE QC exceeds the upper limit of measuring range.	Please check if controls volume and reagent volume is enough, if the position is right.
0-103	Warning	ISE reference solution reagents needed recharge	Used to recharge the ISE reference solution remaining is 0, please recharge.	Please go to “System” in the “Reagent recharge” in the recharge kit.
0-104	Warning	ISE Diluent reagents needed recharge	ISE is used to recharge the remaining amount of dilution is 0, please recharge.	Please go to “System” in the “Reagent recharge” in the recharge kit.
0-105	Warning	ISE reference solution remaining is insufficient reagent	Reagent remaining less than the amount of remaining reagent system settings interface settings.	(1) to confirm whether there are less than the amount of reagent remaining settings reagents. (2) to confirm the amount of reagent remaining settings are reasonable.
0-106	Warning	ISE Diluent reagent insufficient remaining	Reagent remaining less than the amount of remaining reagent system settings interface settings.	(1) to confirm whether there are less than the amount of reagent remaining settings reagents. (2) to confirm the amount of reagent remaining settings are reasonable.
0-107	Warning	ISE compensate value exceeds test range.	ISE compensation value exceed the measuring range	Please check the calibration fluid volume, reagent volume is adequate, the location is correct.

Alarm code	Level	Brief description	Description	Countermeasure
0-108	Warning	ISE Slope value exceed the measuring range	ISE Slope value exceed the measuring range, Calibration failed, do not update the calibration results.	Please check the calibration fluid volume, reagent volume is adequate, the location is correct.
1-1	Stop	Time sync failure	Time sync instruction transmitting failure.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored . Contact the service department.
1-10	Warning	R1 liquid level detect failure	R1 probe cannot detect the liquid level when adding detergent.	(1)Check if there are water in incubation bath. (2)Restart the instrument. (3)Various malfunctions or trouble can not be restored. Contact the service department.
1-11	Warning	R2 liquid level detect failure	R2 probe cannot detect the liquid level when adding detergent.	(1)Check if there are water in incubation bath. (2)Restart the instrument. (3)Various malfunctions or trouble can not be restored. Contact the service department.
1-14	Warning	Barcode scanning overtime.	Barcode scanning overtime.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-15	Warning	Degas overtime	Degas overtime	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-16	Stop	Reaction disk initialize failure	Reaction disk initialize failure	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-17	Stop	Reaction disk stop failure	Reaction disk stop failure	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-19	S. Stop	Add sample failure	Last add sample failure	(1)After testing upon added sample, call up system maintenance menu, carry out “Reset”. (2) Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
1-2	Warning	Add water to water tank overtime	Water tank liquid path system error, add water overtime.	(1)check the supplying pipe whether air exists in.check the height of water tank whether it is more than 1.5 meters (distance from ground)if it will be used. (2)Call up the system maintenance menu and carry out the program "Reset". (3)Various malfunction.
1-20	S. Stop	Add R1 failure	Last add R1 failure.	(1)After testing upon added sample, call up system maintenance menu, carry out "Reset". (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-21	S. Stop	Add R2 failure	Last add R2 failure.	(1)After testing upon added sample, call up system maintenance menu, carry out "Reset". (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-22	S. Stop	Add R3 failure	Last add R3 failure.	(1)After testing upon added sample, call up system maintenance menu, carry out "Reset". (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-23	S. Stop	Add R4 failure	Last add R4 failure.	(1)After testing upon added sample, call up system maintenance menu, carry out "Reset". (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-24	S. Stop	R1 stirring failure	Last R1 stirrer failure	(1)After testing upon added sample, call up system maintenance menu, carry out "Reset". (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-25	S. Stop	R2 stirring failure	Last R2 stirrer failure	(1)After testing upon added sample, call up system maintenance menu, carry out "Reset". (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-26	S. Stop	R3 stirring failure	Last R3 stirrer failure	(1)After testing upon added sample, call up system maintenance menu, carry out "Reset". (2) Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
1-27	S. Stop	R4 stirring failure	Last R4 stirrer failure	(1)After testing upon added sample, call up system maintenance menu, carry out “Reset”. (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-3	Warning	AD board reset failure	Error occurs when AD board reset, AD board reset failure.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-30	Warning	Reagent horizontal scanning overtime.	Reagent horizontal scanning overtime.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-32	Warning	Barcode scanning overtime.	Mechanical disfunction causes barcode scanning overtime when testing.	(1)After testing upon added sample, call up system maintenance menu, carry out “Reset”. (2) Various malfunctions or trouble can not be restored. Contact the service department.
1-33	Stop	ISE resetting failure	Error occur in ISE resetting process, and the resetting do not accomplish.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-34	Warning	ISE check operation overtime	ISE check operation overtime	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-35	Warning	ISE pipeline rinsing overtime	ISE pipeline rinsing overtime.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-36	Warning	ISE testing error	Error occur when ISE testing, ISE testing stop.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
1-4	Warning	Reaction disk reset failure	Error occurs when reaction disk resetting and reaction reset failure.	(1)Check if there is waterdrop on the code wheel. (2)Call up the system maintenance menu and carry out the program "Reset". (3)Various malfunctions or trouble can not be restored. Contact the service department.
1-42	Stop	Mapping information transmit failure	Transmit reagent mapping information failure and add reagent may failure too.	(1)Call up the system maintenance menu and carry out the program "Reset". (2)Various malfunctions or trouble can not be restored. Contact the service department.
1-43	Warning	Cooling overtime	When water tank temperature exceed 36.5 degree, infuse cold water into water tank, and water tank temperature cannot reduce to 35.5 degree in 1 minute or cold water temperature is too high.	(1)Room temperature is too high or water supply equipment error occur. (2)Please contact the maintenance department.
1-44	Stop	Instrument module error	Error occurs between instrument modules.	(1)Power off and restart the instrument. (2)Various malfunctions or trouble cannot be restored. Contact the service department.
1-45	Stop	Continue contaminated cup occur	Continually 5 contaminated cup occur.	(1)Check if halogen lamp are normal in stand-by status, if the lamp are off, please change lamp. (2)Carry out cell blank test to judge cup states. If cell blank value is abnormal, please change reaction cuvette cup, if cell blank value is normal please con
1-46	Stop	Data receiving of data acquisition panel overtime.	Data of data acquisition panel is not received within 6 seconds during test.	(1)Conduct resetting in maintenance interface. (2)Contact the maintenance staff if problem can not be solved.
1-49	Warning	Illegal test item	Illegal test number and reagent volume	Please contact the service department.
1-5	S. Stop	Sample disk reset failure	Error occurs when sample disk resetting and sample disk reset failure.	(1)Check if there is substance in sample container. (2)Call up the system maintenance menu, carry out the program "Reset". (3)Various malfunctions or trouble can not be restored. Contact the service department.
1-52	Stop	Stirring mechanism reset failure	Stirring mechanism Trouble reset when detected, the failure of the Stirring mechanism reset.	(1) Please check whether Stirring mechanism collision. (2)Call up the system maintenance menu, carry out the program " reset." (3)Various malfunctions or trouble can not be restored. Contact the service department.
1-57	Warning	Sample contains blood clot	Sample contains blood clot	Please check whether the sample contains clots or other low solid constituents.

Alarm code	Level	Brief description	Description	Countermeasure
1-59	Warning	Obtaining reaction tank temperature overruns	The reaction tank temperature sent by AC is not received within the given time.	(1)Switch to the system maintenance window, and conduct “resetting”. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
1-6	Warning	R1 disk reset failure	Error occurs when R1 disk resetting and R1 disk reset failure.	(1)Check if there is substance in reagent R1 container. (2)Call up the system maintenance menu and carry out the program “Reset”. (3)Various malfunctions or trouble can not be restored. Contact the service department
1-60	Warning	Manually rinsing high-concentration waste liquid pipeline overruns	The manual rinsing of high-concentration waste liquid pipeline is not finished within the given time.	(1)Check whether there is water in the reaction tank. (2)Restart the instrument (3)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
1-61	Warning	The refrigeration system communication overruns.	No refrigeration system working information is received within the designated time.	(1)Observe the alarm information window to check whether there is an alarm from breakdown units. (2)Start the instrument again and observe whether the breakdown still exists. (3)If it can't return to normality or there are other breakdowns, please contact the maintainer.
1-62	Warning	The reaction tank needs a water change.	The water in the reaction tank hasn't been changed for 24 hours.	(1)Execute the order for the water in the reaction tank to be changed.
1-63	Warning	Main control board updating program over large	Contents of the main control board updating program S19 file exceed 488KB.	(1)Stop updating it.
1-64	Stop	Basic value of cuvette blank obtaining error.	Blank values of cuvette 1, 42, 83 and 124 which are used for calculating basic value can not meet the standard of difference smaller than 800 and values among 8000-16000.	(1)Conduct Cuvette Blank Check in maintenance window. Observe whether the blank values can meet the standard of difference smaller than 800 and values among 8000-16000. Replace the cuvette if the blank value can not meet the requirements. (2)Contact the maintenance staff if problem can not be solved.
1-65	Warning	Resetting AC fails	In resetting AC, a malfunction is detected; Resetting fails.	(1)Switch to the system maintenance window, and conduct “resetting”. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
1-66	Warning	No reagent for test item	The remaining reagent volume is over small or none	Please supplement reagents in the stand-by mode or the add reagent pause mode.

Alarm code	Level	Brief description	Description	Countermeasure
1-67	Warning	No reagent for test item; Skip sample	The sample-related reagent volume is over small or none	Please supplement reagents in the stand-by mode or the add reagent pause mode.
1-68	Warning	ISE test overruns	The ISE test results are not uploaded within the designated time	(1)Switch to the system maintenance window, and conduct “Reset”. (2)If it cannot return to normality or other malfunctions occur, please contact the maintainer.
1-69	Warning	ISE reference pipeline rinsing overruns	The ISE reference pipeline rinsing is not finished within the designated time	Finish rinsing the ISE reference pipeline within the designated time.
1-7	Warning	R2 disk reset failure	Error occurs when R2 disk resetting and R2 disk reset failure.	(1)Check if there is substance in reagent R2 container. (2)Call up the system maintenance menu and carry out the program “Reset”. (3)Various malfunctions or trouble can not be restored. Contact the service department
1-70	Warning	ISE dilution pipeline rinsing overruns	The ISE dilution pipeline rinsing is not finished within the designated time	(1)Switch to the system maintenance window, and conduct “Reset”. (2)If it cannot return to normality or other malfunctions occur, please contact the maintainer.
1-71	Warning	ISE reference and dilution pipeline rinsing overruns	The ISE reference and dilution pipeline rinsing is not finished within the designated time	(1)Switch to the system maintenance window, and conduct “Reset”. (2)If it cannot return to normality or other malfunctions occur, please contact the maintainer.
1-72	Warning	ISE matching cuvette rinsing overruns	The ISE matching cuvette rinsing is not finished within the designated time	(1)Switch to the system maintenance window, and conduct “Reset”. (2)If it cannot return to normality or other malfunctions occur, please contact the maintainer.
1-75	Stop	Data acquisition panel start failure.	Data acquisition panel respond is not received after sending start command to the panel before test.	(1)Conduct resetting in maintenance interface. (2)Contact the maintenance staff if problem can not be solved.
1-76	Debug	Data acquisition panel data packet header error.	Invalid data of data acquisition panel is received.	(1) Contact the maintenance staff if problem can not be solved.
1-77	Debug	Data acquisition panel data packet body error.	Invalid data of data acquisition panel is received.	(1) Contact the maintenance staff if problem can not be solved.
1-78	Warning	ISE injection pump exhaust overtime.	ISE did not finish exhaust within specified time.	(1)Alarm window check will lead to the alarm of ISE can not finish exhaust. Refer to the relevant description for trouble shooting. (2)Conduct resetting in maintenance interface. (3)Contact the maintenance staff if problem can not be solved.

Alarm code	Level	Brief description	Description	Countermeasure
1-79	Stop	Upper cover open	No operation can be conducted when upper cover open	(1)Close the upper cover.
1-8	Warning	Water discharge failure	Water discharge failure	(1)Check if incubation filter and diluent waste pipeline is clog. (2)Please restart the instrument. (3)Various malfunctions or trouble can not be restored. Contact the service department.
1-80	Stop	R1 reagent disk outer cover open	No operation can be conducted when R1 reagent disk cover open	(1)Close R1 reagent disk cover.
1-81	Stop	R1 reagent disk inner cover open	No operation can be conducted when R1 reagent disk cover open	(1)Close R1 reagent disk cover.
1-82	Stop	R2 reagent disk outer cover open	No operation can be conducted when R2 reagent disk cover open	(1)Close R2 reagent disk cover.
1-83	Stop	R2 reagent disk inner cover open	No operation can be conducted when R2 reagent disk cover open	(1)Close R2 reagent disk cover.
1-84	Stop	Sample disk outer cover open	No operation can be conducted when sample disk cover open	(1)Close sample disk cover.
1-85	Stop	Sample disk inner cover open	No operation can be conducted when sample disk cover open	(1)Close sample disk cover
1-86	Stop	QC disk outer cover open	No operation can be conducted when QC disk cover open	(1)Close QC disk cover
1-87	Stop	QC disk inner cover open	No operation can be conducted when QC disk cover open	(1)Close QC disk cover
1-9	Warning	Adding detergent overtime	Detergent is not added completely in specified time by reagent probe 1 and reagent probe 2.	Contact the service department.
1-92	Stop	Network data receiving overtime	Communication data is not received within specified time	(1)Check the network connection. (2)Check the analyzer working status. (3)Please contact maintenance staff.
1-93	debug	Upper computer disconnect	Upper computer disconnect	(1)Whether upper computer is disconnected normally.
1-94	Stop	Network cable is pull out.	Network cable is pull out.	(1)Check the network connection. (2)Check the analyzer working status. (3)Please contact maintenance staff.
112-1	S. Stop	R1 Stirrer mechanism abnormal	The stirring mechanism(R1)does not reach the upper dead point in ascending motion,(at the rinsing bath side)	(1)Please restart the instrument (2)Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
112-10	Stop	R1 Stirrer mechanism abnormal	The stirring mechanism (R1) has sway error	Contact the service department.
112-11	S. Stop	R1 Stirrer mechanism abnormal	The circuit of the electric stirrer in R1 stirring mechanism is open.	Contact the service department.
112-12	S. Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2)does not reach the upper dead point in ascending motion (at the rinsing bath side)	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-13	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2)does not reach the upper dead point in ascending motion(at reaction cuvette side)	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-14	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2)does not leave the upper dead point in descending motion.	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-15	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2)does not leave the upper dead point in descending motion.	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-16	S. Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2)does not reach the rinsing bath position in movement to the rinsing bath side	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-17	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2) does not reach the reaction cuvette position in movement to the reaction cuvette side	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-18	Stop	R2 Stirrer mechanism abnormal	In resetting, the stirring mechanism (2) does not reach the rinsing bath position	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-19	S. Stop	R2 Stirrer mechanism abnormal	In resetting, the stirring mechanism (2) does not leave the rinsing bath position	(1)Call up the system maintenance menu,first carry out the program "Reset",then go on "mechanism check" (2)Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
112-2	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (1) does not reach the upper dead point in ascending motion(at the reaction cuvette side)	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-20	Stop	R2 Stirrer mechanism abnormal	In rotation of stirring mechanism (2), it is not set at the upper dead point.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-21	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2) has ascend /descend error	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-22	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2) sway abnormal	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-23	S. Stop	R2 Stirrer mechanism abnormal	The circuit of the electric stirrer in R2 stirring mechanism is open.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-24	S. Stop	Electromagnetic valve abnormal	The circuit of the electromagnetic cleanout valve SV6 is open.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-25	S. Stop	R1 stirring failure	Last R1 stirrer failure	(1)After testing upon added sample, call up system maintenance menu, carry out “Reset”. (2) Various malfunctions or trouble can not be restored. Contact the service department.
112-26	S. Stop	R2 stirring failure	Last R2 stirrer failure	(1) After testing upon added sample, call up system maintenance menu, carry out “Reset”. (2) Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
112-27	S. Stop	R3 stirring failure	Last R3 stirrer failure	(1) After testing upon added sample, call up system maintenance menu, carry out “Reset”. (2) Various malfunctions or trouble can not be restored. Contact the service department.
112-28	S. Stop	R4 stirring failure	Last R4 stirrer failure	(1)After testing upon added sample, call up system maintenance menu, carry out “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-29	Stop	Stirring mechanism reset failure	Stirring mechanism Trouble reset when detected, the failure of the Stirring mechanism reset.	(1) Please check whether Stirring mechanism collision. (2)Call up the system maintenance menu, carry out the program “ reset.” (3)Various malfunctions or trouble can not be restored. Contact the service department.
112-3	S. Stop	R1 Stirrer mechanism abnormal	The stirring mechanism(R1)does not reach the upper dead point in ascending motion,(at the rinsing bath side)	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-30	Stop	R1 Stirrer mechanism abnormal	The stirring mechanism (1) does not reach the upper dead point in ascending motion(at the reaction cuvette side)	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-31	Stop	R1 Stirrer mechanism abnormal	The stirring mechanism (1) ascend /descend overtime	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-32	Stop	R1 Stirrer mechanism abnormal	The stirring mechanism (1) has sway error	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-33	Stop	No optocoupler signal	Mixer 1 is not at rinsing position.	(1)Check the real position of mixer 1. (2)Check optocoupler status and its connection. (3)Conduct resetting in maintenance interface, contact the maintenance staff if problem can not be solved.
112-34	Stop	No optocoupler signal	Mixer 1 is not at position 1 of reaction disk.	(1)Check the real position of mixer 1. (2)Check optocoupler status and its connection. (3)Conduct resetting in maintenance interface, contact the maintenance staff if problem can not be solved.

Alarm code	Level	Brief description	Description	Countermeasure
112-35	Stop	No optocoupler signal	Mixer 1 is not at position 4 of reaction disk.	(1)Check the real position of mixer 1. (2)Check optocoupler status and its connection. (3)Conduct resetting in maintenance interface, contact the maintenance staff if problem can not be solved.
112-4	Stop	R1 Stirrer mechanism abnormal	The stirring mechanism (1)does not reach the rinsing bath position in movement to the rinsing bath side	(1)Call up the system maintenance menu,first carry out the program “Reset”, then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-41	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2) ascend /descend error	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-42	Stop	R2 Stirrer mechanism abnormal	The stirring mechanism (2) has sway error	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-43	Stop	No optocoupler signal	Mixer 2 is not at rinsing position.	(1)Check the real position of mixer 1. (2)Check optocoupler status and its connection. (3)Conduct resetting in maintenance interface, contact the maintenance staff if problem can not be solved.
112-44	Stop	No optocoupler signal	Mixer 2 is not at position 2 of reaction disk.	(1)Check the real position of mixer 2. 2.Check optocoupler status and its connection. 3.Conduct resetting in maintenance interface, contact the maintenance staff if problem can not be solved.
112-45	Stop	No optocoupler signal	Mixer 2 is not at position 3 of reaction disk.	(1)Check the real position of mixer 2. (2)Check optocoupler status and its connection. (3)Conduct resetting in maintenance interface, contact the maintenance staff if problem can not be solved.
112-5	Stop	R1 Stirrer mechanism abnormal	The stirring mechanism (1) does not reach the reaction cuvette position in movement to the reaction cuvette side	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-51	S. Stop	R1 Stirrer mechanism abnormal	R1 stirring mechanism cleanout and Position 4 swing steps exceed the limit.	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check “. (2)Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
112-52	S. Stop	R1 Stirrer mechanism abnormal	R1 stirring mechanism cleanout and Position 1 swing steps exceed the limit.	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check “. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-53	S. Stop	R1 Stirrer mechanism abnormal	The steps are abnormal when R1 stirring mechanism's up and down returns to zero.	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-6	Stop	R1 Stirrer mechanism abnormal	When resetting is conducted, R1 stirring mechanism cannot reach the cleaning tank position.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-61	S. Stop	R2 Stirrer mechanism abnormal	R2 stirring mechanism cleanout and position 4 swing steps exceed the limit.	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-62	S. Stop	R2 Stirrer mechanism abnormal	R2 stirring mechanism cleanout and position 1 swing steps exceed the limit.	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-63	S. Stop	R2 Stirrer mechanism abnormal	The steps are abnormal when R2 stirring mechanism's up and down returns to zero.	(1)Call up the mechanism check screen ,first carry out the “Reset” program, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-7	S. Stop	R1 Stirrer mechanism abnormal	When resetting is conducted, R1 stirring mechanism cannot leave the cleaning tank position.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-8	Stop	R1 Stirrer mechanism abnormal	When R1 stirring mechanism is rotating, it's not in the top point.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
112-9	Stop	R1 Stirrer mechanism abnormal	R1 stirring mechanism's up and down is abnormal.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
128-1	Warning	Irregular order received	An order (except the set orders) is received.	If it occurs repeatedly, please contact the maintainer.
128-10	Warning	Reaction tank water letting out fails	Letting out reaction tank water fails.	(1)Check whether the reaction tank filter gauze and the low-concentration waste liquid pip are clogged. (2)Please start the instrument again. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
128-11	Stop	Reaction tank water feeding overruns	Reaction tank water feeding overruns.	(1)Check whether the sensor in the reaction tank position is clean, or there is water in the reaction tank. (2)Start the instrument again. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
128-12	Stop	Over high water temperature in the reaction tank	The water temperature in the reaction tank exceeds the top limit.	(1)Check whether the cooling fan of the instrument is functioning normally. (2)Check whether the dustproof of the cooling fan in the refrigeration system is clogged with dust. (3)Please contact the maintainer if it cannot return to normality.
128-13	Warning	Over low water temperature in the reaction tank	The water temperature in the reaction tank exceeds the lower limit.	(1)Check whether the 37℃ constant temperature heating circuit and the control circuit of the instrument are functioning normally. (2)Please contact the maintainer if it cannot return to normality.
128-14	Warning	Water temperature in reaction tank abnormal	Water temperature in the reaction tank exceeds the range (37℃±0.5℃). Note: Check only in operation.	(1)Check whether the room temperature is between 15—32℃. (2)Check whether the cooling fan of the instrument is working normally. (3)Check whether the dustproof of the cooling fan in the refrigeration system is clogged with dust. (4)Check whether the water in the reaction tank is circulating. (5)Please contact the maintainer if it cannot return to normality.
128-16	Warning	Reaction tank temperature abnormal	Reaction tank temperature exceeds 38℃.	(1)Over high room temperature. (2)Please contact the maintainer if it cannot return to normality.
128-17	Stop	Temperature sensor of reaction tank abnormal	The temperature sensor of the reaction tank has short-circuited or open-circuited.	Please contact the service department
128-18	Warning	Waste liquid mixed in vacuum tank	There is water accumulation in the vacuum tank.	Remove the water accumulated in the vacuum tank according to the maintenance part of “User Manual”.
128-19	Warning	Vacuum pump goes wrong	The negative pressure of the vacuum pump is too low.	Please contact the maintainer.

Alarm code	Level	Brief description	Description	Countermeasure
128-2	Stop	Water tank float goes wrong	The upper float of the water tank has detected a flowing up signal, but the lower float hasn't.	(1)Please restart the instrument. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
128-20	Stop	Gear pump goes wrong	The gear pump pressure of the sampling mechanism probe liquid path is abnormal.	(1)Please restart the instrument. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
128-21	S. Stop	Sample probe clogged	The sample probe is clogged.	Please remove the clot according to Chapter 12.4.1 of “User Manual”.
128-24	Stop	Alternating current electromagnetic valve abnormal	The electromagnetic valve has short-circuited or open-circuited, or the driving chip is overheating.	Please contact the service department
128-25	Warning	alkaline detergent shortage(left)	alkaline detergent place in front of instrument is shortage.	Please add alkaline detergent in detergent bottle.
128-26	Warning	alkaline detergent shortage(right)	alkaline detergent place in front of instrument is shortage.	Please add alkaline detergent in detergent bottle.
128-27	Warning	Alternating current mode reading overruns	No alternating current mode is read within the designated time.	Please check whether it's in upgrading mode, or communication is abnormal.
128-28	Warning	Incorrect water flume temperature coefficient setting	The water flume temperature coefficient setting is incorrect.	(1)Please set the water flume temperature coefficient again.
128-29	Warning	Incorrect water tank temperature coefficient setting	The water tank temperature coefficient setting is incorrect.	(1)Please set the water tank temperature coefficient again.
128-3	Stop	Insufficient water supply for the water tank	The water tank lower float floating up overruns.	(1)Check whether the water supply system, like the water supply pipe or pure water equipment, is working normally. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
128-30	Warning	Waste liquid tank full	The waste tank is full	Please empty it.
128-31	Stop	Water tank heating abnormal	The water tank heating rod or temperature sensor is abnormal	Please contact the maintainer.
128-32	Stop	Constant temperature tank heating abnormal	The constant temperature heating rod or temperature sensor is abnormal	Please contact the maintainer.

Alarm code	Level	Brief description	Description	Countermeasure
128-33	Warning	Waste liquid is mixed into vacuum container during test.	There is water in vacuum container during test.	1.Refer to the maintenance part of User Manual to drain the vacuum container during non-test. 2.Contact the maintenance staff if there is no water in vacuum container.
128-34	Warning	Halogen lamp has been used for more than specified time.	Halogen lamp has been used for more than 2000 hours.	Please replace the lamp and clear the lamp using time in “Other” of adjust software.
128-4	Warning	Low water level in the water tank	The water tank upper float floating up overruns.	(1)Check whether the liquid path from the main water tank to the module is abnormal. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
128-5	Stop	Water tank temperature higher than top limit	The water tank heating rod or the temperature control interface has open-circuited.	Please contact the service department
128-6	Warning	Water tank temperature lower than lower limit	The water tank heating rod or the temperature control interface has open-circuited.	Please contact the service department
128-7	Stop	Water tank temperature sensor abnormal	The water tank temperature sensor has short-circuited or open-circuited.	Please contact the service department
128-8	Warning	Water tank temperature abnormal	Water tank temperature exceeds 36.5℃.	(1)Room temperature is too high. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
128-9	Warning	Water tank water cooling overruns	When water temperature in the water tank exceeds 36.5℃, inject cold water into the water tank to lower the temperature, but it cannot be lowered to 35.5℃ within one munite or the cold water temperature is too high.	(1)Room temperature is too high or the water supply equipment malfunctions. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
176-10	Warning	Path 3 cooling chip error	Path 3 cooling circuit is less than 5A	Please contact the service department
176-11	Warning	Path 4 cooling chip error	Path 4 cooling circuit is less than 5A	Please contact the service department
176-12	Warning	Path 5 cooling chip error	Path 5 cooling circuit is less than 5A	Please contact the service department
176-13	Warning	Path 6 cooling chip error	Path 6 cooling circuit is less than 5A	Please contact the service department

Alarm code	Level	Brief description	Description	Countermeasure
176-2	Warning	Cooling system abnormal	Abnormal refrigeration liquid level, damaged refrigeration water tank float, or lack of water in the refrigeration water tank	(1)Please add water to the water storage tank of the refrigeration system by referring to “User Manual”.
176-3	Warning	Cooling system abnormal	Abnormal refrigeration water tank temperature: below 5℃ or exceeding 15℃	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
176-4	Warning	Cooling system abnormal	Abnormal refrigeration current: exceeding 8A	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
176-5	Warning	Cooling system abnormal	Abnormal refrigeration communication	Please contact the service department
176-6	Warning	Ambient temperature exceeds the limit	Ambient temperature goes beyond the range of 15 to 32℃	(1)Control the ambient temperature in the range of 15 to 32℃. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
176-7	Warning	Refrigeration system abnormal	The refrigeration fan is running abnormally.	Please contact the service department
176-8	Warning	Path 1 cooling chip error	Path 1 cooling circuit is less than 5A	Please contact the service department
176-9	Warning	Path 2 cooling chip error	Path 2 cooling circuit is less than 5A	Please contact the service department
208-1	Stop	Dilution pump abnormal	ISE module A dilution pump cannot reach the zero position	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
208-2	Stop	Dilution pump abnormal	ISE module A dilution pump cannot leave the zero position	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
208-3	Stop	Dilution pump abnormal	Writing ISE module A dilution pump motor chip fails.	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
208-8	Stop	Waiting for sample probe to add samples overruns	ISE The sample adding of the module A sample probe overruns.	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
208-9	Stop	ISV1 valve mode abnormal	ISE Module A ISV1 open-circuits	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
208-10	Stop	ISV2 valve mode abnormal	ISE Module A ISV2 open-circuits	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
208-11	Stop	ISV3 valve mode abnormal	ISE Module A ISV3 open-circuits	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
208-12	Stop	ISV4 valve mode abnormal	ISE Module A ISV4 open-circuits	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
208-17	Stop	Stirring motor mode abnormal	ISE module A stirring motor open-circuits.	(1)Restart the instrument. (2)Please contact the maintainer if it cannot return to normality or other malfunctions occur.
224-1	Debug	Illegal command is received.	Command other than specified is received.	(1)Contact the maintenance staff if problem can not be solved.
224-2	Warning	Communication with sample control panel overtime in sample disk rotation.	Sample control panel respond overtime.	(1)Conduct resetting in maintenance interface, observe whether the sample disk can reset normally, if not,contact the maintenance staff.
224-3	Warning	Communication with sample control panel overtime in QC disk rotation.	Sample control panel respond overtime.	(1)Conduct resetting in maintenance interface, observe whether the sample disk can reset normally, if not,contact the maintenance staff.
224-4	Warning	Communication with reagent 1 control panel overtime in R1 disk rotation.	Reagent 1 control panel respond overtime.	(1)Conduct resetting in maintenance interface, observe whether the sample disk can reset normally, if not,contact the maintenance staff.
224-5	Warning	Communication with reagent 2 control panel overtime in R2 disk rotation.	Reagent 2 control panel respond overtime.	(1)Conduct resetting in maintenance interface, observe whether the sample disk can reset normally, if not,contact the maintenance staff.

Alarm code	Level	Brief description	Description	Countermeasure
48-1	Stop	Reaction disk abnormal	The reaction disk cannot detect the stop position.	(1)After washing the reaction disk, please wipe the water drop in the inner side of disk. (2)Check if water drop stick to the light coupler and code wheel under the disk. (3)If the trouble cannot be restored, please contact the service department.
48-10	Stop	Reaction Board Rinsing mechanism 1 abnormal	The rinse mechanism does not reach the upper dead point in ascending motion	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
48-11	Stop	Reaction Board Rinsing mechanism 1 abnormal	The rinse mechanism does not leave the upper dead point in the descending motion.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
48-12	Stop	Reaction Board Rinsing mechanism 1 abnormal	It's detected that the electric motor has a severe out-of-step, when the reaction cuvette rinsing mechanism returns to the top point.	(1)Check whether the installation of the rinsing mechanism and the electric motor connection are abnormal. (2)Check whether there are obstacles below the rinsing mechanism. (3)Open the system maintenance window; First conduct “Reset”, and then conduct “Check on Mechanical Motion”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-13	Stop	Reaction Board Rinsing mechanism 2 abnormal	The rinse mechanism does not reach the upper dead point in ascending motion	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
48-14	Stop	Reaction Board Rinsing mechanism 2 abnormal	The rinse mechanism does not leave the upper dead point in the descending motion.	(1)Call up the system maintenance menu and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
48-15	Stop	Reaction Board Rinsing mechanism 2 abnormal	It's detected that the electric motor has a severe out-of-step, when the reaction cuvette rinsing mechanism returns to the top point.	(1)Check whether the installation of the rinsing mechanism and the electric motor connection are abnormal. (2)Check whether there are obstacles below the rinsing mechanism. (3)Open the system maintenance window; First conduct “Reset”, and then conduct “Check on Mechanical Motion”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
48-17	Stop	Reaction board abnormal	Reaction board executes invalid instruction	(1) Please contact the maintenance staff if it fails repeatedly.
48-18	Stop	Abnormal reaction disk data	Great data fluctuation in the tooth width and pitch of the scanned reaction disk, exceeding 20 steps.	Conduct resetting again. Please contact the maintainer again if the malfunction occurs repeatedly.
48-2	Stop	Reaction disk abnormal	Signal error occurs where the reaction disk stops.	(1)Please contact the maintainer again if the malfunction occurs repeatedly.
48-3	Stop	Reaction disk abnormal	In resetting, the reaction disk cannot detect the home position	(1)Check whether the installation and signal of the return-to-zero OC are normal. (2)If it occurs after the reaction disk is rinsed, remove the drops of water in the inner side of the reaction disk. (3)Check whether there are water drops adhering to the inductor below the reaction disk. (4)Please contact the maintainer if it cannot return to normality.
48-40	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV30 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV30 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-41	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV21 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV21 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-42	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV15 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV15 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-43	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV14 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV14 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
48-44	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV12 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV12 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-45	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV11 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV11 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-46	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV43 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV43 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-47	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV42 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV42 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-48	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV31 malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV31 electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-49	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV12A malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV12A electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-5	Stop	Reaction disk abnormal	Reaction disk stuck	(1)Please check whether any barrier exists around the reaction disk. (2)Please contact the maintenance staff if it fails repeatedly.

Alarm code	Level	Brief description	Description	Countermeasure
48-50	Stop	Reaction Board Electromagnetic valve abnormal	Electromagnetic valve SV14A malfunctions.	(1)Open the system maintenance window; First, please conduct “Reset”, and then conduct “Check on Mechanical Motion”. (2)Check whether SV14A electromagnetic valve open-circuits or short-circuits. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-8	Stop	Reaction disk abnormal	When the reaction disk is rotating, rinsing mechanism 1 leaves the top point.	(1)Check whether rinsing mechanism 1 goes down and leaves the top point. (2)Check whether the installation and connection the electric motor of rinsing mechanism 2 are normal. (3)Open the system maintenance window, and conduct “Reset”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-80	Stop	Reaction board abnormal	No response instruction from the sample mechanism is received before the reaction disk is started.	(1)Open the system maintenance window, and conduct “Reset”. (2)Power it off and restart it; Open the system maintenance window, and first please conduct “Reset”. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-81	Stop	Reaction board abnormal	No response instruction from the stirring mechanism is received before the reaction disk is started.	(1)Open the system maintenance window, and conduct “Reset”. (2)Power it off and restart it; Open the system maintenance window, and first please conduct “Reset”. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-82	Stop	Reaction board abnormal	No response instruction from reagent 1 mechanism is received before the reaction disk is started.	(1)Open the system maintenance window, and conduct “Reset”. (2)Power it off and restart it; Open the system maintenance window, and first please conduct “Reset”. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-83	Stop	Reaction board abnormal	No response instruction from reagent 2 mechanism is received before the reaction disk is started.	(1)Open the system maintenance window, and conduct “Reset”. (2)Power it off and restart it; Open the system maintenance window, and first please conduct “Reset”. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
48-85	Stop	Reaction Disk Abnormal	Reaction disk anomalous rotation occur	(1)Check whether the reaction disk motor is locked. (2)Check whether the optocoupler installation under reaction disk is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.

Alarm code	Level	Brief description	Description	Countermeasure
48-9	Stop	Reaction disk abnormal	When the reaction disk is rotating, rinsing mechanism 2 leaves the top point.	(1)Check whether rinsing mechanism 2 goes down and leaves the top point. (2)Check whether the installation and connection of the electric motor of rinsing mechanism 2 are normal. (3)Open the system maintenance window, and conduct “Reset”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-1	S. Stop	Sample probe abnormal	The sample probe does not reach the upper dead point in descending motion.(at other than the reaction cuvette side)	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-11	S. Stop	Sample probe abnormal	The sample probe cannot detect the cell position in rotation to the reaction cuvette side.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-15	S. Stop	Sample probe abnormal	In rotation of reagent-1 probe, it is not set at the upper dead point.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-17	S. Stop	Sample probe abnormal	The probe cannot descend to the sample liquid level.	(1)Please check whether there are other obstacles in the sample disk. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-18	S. Stop	Sample disk abnormal	The sample disk does not detect the specified position on the outer track	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-19	S. Stop	Sample disk abnormal	The sample disk does not stop in the specified position on the outer track	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-22	S. Stop	QC disk abnormal	The QC disk cannot detect the stop position.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
64-23	S. Stop	QC disk abnormal	The QC disk cannot stop in the specific position.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-27	Warning	Sample barcode device of outer circle abnormal	Sample barcode reader cannot be found.	(1)Check if barcode device is well connected. (2)Trouble cannot be restored, Contact the service department.
64-29	Warning	Sample barcode scanning overtime.	Sample barcode scanning overruns during the test probably due to the instrument malfunction.	(1)After the samples that had been fed are tested and the instrument is in the standby mode, open the system maintenance window and conduct “Reset”. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-30	Warning	Sample barcode device of inner circle abnormal	Sample barcode reader cannot be found.	(1)Check if barcode device is well connected. (2)Trouble cannot be restored, Contact the service department.
64-33	S. Stop	Sample syringe abnormal	The sample syringe is not at the upper dead point.	(1)Call up the System Maintenance screen, first carry out the program “Reset” then go on the program “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-34	S. Stop	Sample syringe abnormal	The sample syringe does not leave the upper dead point.	(1)Call up the System Maintenance screen, first carry out the program “Reset” then go on the program “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-41	Warning	Sample probe abnormal	An abnormal occurs when the sample probe descends(over the sample cuvette).	(1)Check whether there is a sample in the sample cuvette. (2) Check whether the sample cuvette is in the correct position. (3) Check whether the sample cuvette is curved.
64-42	S. Stop	Sample probe abnormal	The sample probe is not in the return-to-zero position; The sample disk and QC disk cannot rotate.	(1)Open the system maintenance window, and first please conduct “Reset”. (2)Check whether the sample probe is in the return-to-zero position; Check whether the sample probe return-to-zero OC signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-43	S. Stop	Sample disk abnormal	Sample disk rotation overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the OC installation and signal below the sample disk are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
64-44	Stop	Sample probe abnormal	Sample probe ascending and descending over the reaction disk overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the sample probe elevating electric motor connection are normal, and whether the OC installation and signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-45	S. Stop	Sample probe abnormal	Sample probe swinging overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the sample probe swing electric motor connection is normal, and whether the OC installation and signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-46	S. Stop	Sample Syringe pump abnormal	Syringe pump return-to-zero overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the sample syringe pump electric motor connection is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-47	S. Stop	QC disk abnormal	QC disk rotation overruns	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the QC disk electric motor connection is normal, and whether the OC installation and signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-48	S. Stop	Sample disk abnormal	Sample disk waiting for sample-feeding triggering instruction(4) overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the circuit board is loose. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-49	S. Stop	Sample disk abnormal	Sample disk waiting for sample-feeding triggering instruction(37) overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the circuit board is loose. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-50	S. Stop	Sample cleanout valve abnormal	Sample probe inner wall cleanout valve opening fails.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the inner wall cleanout valve and the connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-51	S. Stop	Sample cleanout valve abnormal	Sample probe inner wall cleanout valve closing fails.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the inner wall cleanout valve and the connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
64-52	S. Stop	Sample cleanout valve abnormal	Sample probe outer wall cleanout valve opening fails.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the outer wall cleanout valve and the connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-53	S. Stop	Sample cleanout valve abnormal	Sample probe outer wall cleanout valve closing fails.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the outer wall cleanout valve and the connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-6	Stop	Sample probe abnormal	The sample probe does not leave the upper dead point in descending motion.(at the reaction cuvette side)	(1)Call up the system maintenance screen, first carry out the program “Reset”, then go on “mechanism check”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
64-60	Stop	Sample volume abnormal	The volume of the sample fed this time is too little, less than 1μL.	Contact the service department.
64-61	Stop	Sample volume abnormal	The volume of the sample fed this time is too much, more than 35μL.	Contact the service department.
64-62	S. Stop	Sample Disk position reception error	The received sample-feeding number is incorrect.	Contact the service department.
64-63	S. Stop	Sample Disk Add postion error	The verification of the received sample-feeding number fails.	Contact the service department.
64-64	Warning	Sample Board Ineffective instrucion received	The sample disk receives an unanalyzable instruction.	Contact the service department.
64-65	Warning	Sample Mode error	Conduct motion before resetting.	(1)Open the system maintenance window; First please conduct “Reset”.
64-66	Warning	Sample probe abnormal	The sample probe cannot find the sample cuvette.	(1)Please check whether there is a sample cuvette in the present position of the sample disk.
64-67	S. Stop	Sample probe abnormal	OC signal error occurs where the sample probe stops.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the sample probe swings normally. (3)Check whether the installation, connection and signal of the sample probe swinging OC are normal. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
64-68	S. Stop	Sample probe abnormal	The sample probe ascending and descending (not over the reaction disk) overruns	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the sample probe elevating electric motor connection, OC installation, and signal are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-69	S. Stop	Sample probe abnormal	The sample probe cannot leave the return-to-zero position when descending (not over the)	(1)Open the system maintenance window; First please conduct “Reset”. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-7	Stop	Sample probe abnormal	A collision signal is detected before the sample probe descends(over the reaction cuvettes).	Please contact the maintainer if the malfunction occurs repeatedly.
64-70	Stop	Sample probe abnormal	The sample probe cannot reach the return-to-zero position while ascending (over the reaction disk).	(1)Open the system maintenance window; First please conduct “Reset”. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-71	S. Stop	Sample Syringe abnormal	The syringe pump adding overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the syringe pump installation, connection, and the plug of the circuit board are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
64-72	S. Stop	Sample Syringe abnormal	The syringe pump dispensing liquid overruns.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the syringe pump installation, connection, and the plug of the circuit board are normal. (3)Please contact the maintainer if the malfunction occurs repeatedly, or other malfunctions occur.
64-73	S. Stop	Sample Syringe abnormal	Severe out-of-step is detected by the syringe pump.	(1)Open the system maintenance window; First please conduct “Reset”. (2)Check whether the syringe pump installation, connection, and the plug of the circuit board are normal. (3)Please contact the maintainer if the malfunction occurs repeatedly, or other malfunctions occur.
64-74	S. Stop	Sample adding volume abnormal	An error in the verification of the sample volume data occurs.	Please contact the maintainer.
64-75	S. Stop	Sample adding volume abnormal	An error in the verification of the dilution volume data occurs.	Please contact the maintainer.
64-76	Warning	Detergent in sample probe W1 position used up	The sample probe does not detect detergent when descending.	(1)Check whether there is detergent in the W1 position.

Alarm code	Level	Brief description	Description	Countermeasure
64-77	Warning	Detergent in sample probe W2 position used up	The sample probe does not detect detergent when descending.	(1)Check whether there is detergent in the W2 position.
64-78	Warning	Detergent in sample probe W3 position used up	The sample probe does not detect detergent when descending.	(1)Check whether there is detergent in the W3 position.
64-79	Warning	ISE Sampling Abnormal	Probe descending step is not enough when ISE sampling	(1)Check whether sample probe descends into the cuvette in ISE sampling. (2)Contact service staff if problem can not be solved.
64-80	Warning	ISE Sampling Abnormal	Probe collision occur when ISE descending for sampling	(1)Check whether there is block in descending position or other things may cause probe collision in ISE sampling. (2)Contact service staff if problem can not be solved.
64-81	Warning	ISE Sampling Abnormal	Probe can not detect the liquid level when ISE descending for sampling	(1)Check whether sample probe descends into the liquid level of cuvette in ISE sampling. (2)Contact service staff if problem can not be solved.
64-83	Warning	Sample probe abnormal	The lifting motor motion missed too many steps	Please contact the maintainer if it occurs repeatedly.
64-84	Warning	Sample probe abnormal	The two liquid level heights tested by the sample probe differ much	Please contact the maintainer if it occurs repeatedly.
64-85	S. Stop	Sample Disk Abnormal	Sample disk anomalous rotation occur	(1)Check whether the sample disk motor is locked. (2)Check whether the optocoupler installation under sample disk is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
64-86	S. Stop	QC Disk Abnormal	QC disk anomalous rotation occur	(1)Check whether the QC disk motor is locked. (2)Check whether the optocoupler installation under QC disk is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
64-87	Stop	Sample Probe Abnormal	Sample probe anomalous up and down occur	(1)Check whether the sample probe up and down motor is locked. (2)Check whether the sample probe up and down optocoupler installation is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
64-88	S. Stop	Sample Probe Abnormal	Sample probe anomalous swing occur	(1)Check whether the sample probe swing motor is locked. (2)Check whether the sample probe swing optocoupler installation is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.

Alarm code	Level	Brief description	Description	Countermeasure
80-14	S. Stop	Reagent 1 disk abnormal	The reagent disk R1 cannot detect the stop position	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
80-15	S. Stop	Reagent 1 disk abnormal	The reagent disk R1 does not stop at the specified position	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
80-16	S. Stop	Reagent 1 disk abnormal	The reagent disk R1 cannot detect the home position.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
80-17	Warning	Reagent 1 barcode device abnormal	The reagent 1 barcode reader is not found.	(1)Please check whether the barcode device is connected. (2)Please contact the maintainer if it can't return to normality.
80-18	Warning	Reagent 1 barcode device is abnormal.	The reagent 1 barcode reader returning data show that there is an inner error.	(1)Check whether the barcode device inside connection is normal. (2)Please contact the maintainer if it can't return to normality.
80-19	Warning	Reagent 1 barcode scanning overruns.	The reagent 1 barcode scanning overruns during the test probably because of the instrument malfunction.	(1)After the already-fed samples are tested and the instrument is in the standby mode, open the system maintenance window and conduct “Reset”. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-20	Stop	Reagent 1 NO.ineffective	R1 reagent number is ineffective.	Please contact the maintenance.
80-21	S. Stop	Reagent 1 Syringe abnormal	The reagent-1 syringe is not at the upper dead point.	(1)Call up the mechanism check screen ,carry out the “Reset” program, (2)Various malfunctions or trouble can not be restored. Contact the service department.
80-22	S. Stop	Reagent 1 Syringe abnormal	The reagent-1 syringe does not leave from the upper dead point	(1)Call up the mechanism check screen ,carry out the “Reset” program, (2)Various malfunctions or trouble can not be restored. Contact the service department.
80-3	S. Stop	Reagent 1 probe abnormal	R1 probe does not reach the upper dead point in ascending motion	(1)Call up the System Maintenance screen and carry out the program “Reset”. (2)Various malfunctions or trouble can not be restored. Contact the service department.
80-35	Stop	Reagent 1 board abnormal	Reagent 1 board receives invalid position position No. of sample adding	(1) Please contact the maintenance staff if it fails repeatedly.

Alarm code	Level	Brief description	Description	Countermeasure
80-36	Stop	Reagent 1 board abnormal	Reagent 1 board executes invalid instruction	(1) Please contact the maintenance staff if it fails repeatedly.
80-37	Warning	Reagent 1 probe does not find reagent bottle	R1 reagent probe does not find reagent bottle	(1)Check whether the current position of the R1 reagent disk exist reagent bottle. (2)Check whether the liquid level detecting board connection and signal are normal. (3)Please contact the maintainer if the malfunction occurs repeatedly.
80-38	S. Stop	Reagent 1 probe abnormal	The reagent volume is over little.	(1) Please contact the maintenance staff if it fails repeatedly.
80-39	S. Stop	Reagent 1 probe abnormal	The dilution volume is over much or little.	(1) Please contact the maintenance staff if it fails repeatedly.
80-4	S. Stop	Reagent 1 probe abnormal	R1 reagent probe cannot leave the top point while descending (not over the reaction cuvettes).	(1)Check whether the lifting mechanism leaves the top point. (2)Check whether the lifting mechanism zero point OC signal is normal. (3)Open the system maintenance window, and conduct “Reset”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-40	S. Stop	Reagent 1 probe abnormal	Waiting for the trigger signal to feed reagent overruns.	(1) Please contact the maintenance staff if it fails repeatedly.
80-41	Warning	Reagent 1 probe abnormal	The descending steps are not within the range of the 5mL liquid level.	(1)Please check whether the reagent volume of position 1 of R1 disk and R2 disk is 5mL. (2)Please contact the maintenance staff if it fails repeatedly.
80-42	Warning	Reagent 1 probe abnormal	The descending steps are not within the range of the 50mL liquid level.	(1)Please check whether the reagent volume of position 1 of R1 disk and R2 disk is 50mL. (2)Please contact the maintenance staff if it fails repeatedly.
80-43	S. Stop	Reagent 1 probe abnormal	Vertical check type error.	(1) Please contact the maintenance staff if it fails repeatedly.
80-44	Stop	Reagent 1 probe abnormal	The reagent probe is not in the ascending and descending zero position; the reagent disk cannot rotate.	(1)Check whether the reagent probe descends. (2)Check whether ascending and descending zero position signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-45	Stop	Reagent 1 probe abnormal	The reagent probe is not in the ascending and descending zero position; the reagent probe cannot swing.	(1)Check whether the reagent probe descends. (2)Check whether ascending and descending zero position signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
80-46	S. Stop	Reagent 1 Disk abnormal	The reagent disk rotation overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent disk electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-47	S. Stop	Reagent 1 probe abnormal	The reagent probe ascending and descending return-to-zero overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe elevating electric motor, connection and return-to-zero OC are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-48	S. Stop	Reagent 1 probe abnormal	The reagent probe swinging overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe swing electric motor, connection and return-to-zero OC are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-49	S. Stop	Reagent 1 Syringe pump abnormal	The syringe pump returning to zero overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-50	S. Stop	Reagent 1 Cleanout valve abnormal	Reagent probe inner wall cleanout valve opening fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the inner wall electromagnetic valve and connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-51	S. Stop	Reagent 1 Cleanout valve abnormal	Reagent probe inner wall cleanout valve closing fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the inner wall electromagnetic valve and connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-52	S. Stop	Reagent 1 Cleanout valve abnormal	Reagent probe outer wall cleanout valve opening fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the outer wall electromagnetic valve and connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
80-53	S. Stop	Reagent 1 Cleanout valve abnormal	Reagent probe outer wall cleanout valve closing fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the outer wall electromagnetic valve and connection open-circuit or short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-54	Stop	Reagent 1 board abnormal	Bottle number verification fails.	(1) Please contact the maintenance staff if it fails repeatedly.
80-55	S. Stop	Reagent 1 board abnormal	The reagent disk position cannot be found.	(1) Please contact the maintenance staff if it fails repeatedly.
80-56	S. Stop	Reagent 1 board abnormal	The position next to that for the reagent disk cannot be found.	(1) Please contact the maintenance staff if it fails repeatedly.
80-57	S. Stop	Reagent 1 board abnormal	Reagent disk motion needs conducting after a successful resetting.	(1) Please contact the maintenance staff if it fails repeatedly.
80-58	S. Stop	Reagent 1 board abnormal	Sample feeding position id error.	(1) Please contact the maintenance staff if it fails repeatedly.
80-59	Stop	Reagent 1 probe abnormal	OC mode error occurs where the reagent probe stops.	(1)Check whether the reagent probe swing position is correct. (2)Check whether the reagent probe swing electric motor, connection and return-to-zero OC are normal. (3)Open the system maintenance window, and conduct “Reset”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-6	Warning	Collision happens to R1 reagent probe	An abnormal occurs when R1 reagent probe descends.	(1)Check whether there is reagent in the reagent bottle. (2)Check whether the reagent bottle cap is opened. (3)Check whether the reagent disk cover is in the correct position. (4)Check whether the reagent probe is curved. (5)Check whether the reagent bottle is leaned.
80-60	Warning	Cover of reagent 1 disk open	The cover of the reagent disk is open.	
80-61	Warning	Cover of reagent 1 disk closed	The cover of the reagent disk is closed.	
80-62	S. Stop	Reagent 1 Syringe pump abnormal	Syringe pump adding overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
80-63	S. Stop	Reagent 1 Syringe pump abnormal	Syringe pump dispensing liquid overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-64	S. Stop	Reagent 1 Syringe pump abnormal	Syringe pump adding water overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-65	S. Stop	Reagent 1 probe abnormal	Reagent probe descending overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe elevating motor, connection and return-to-zero OC are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-66	S. Stop	Reagent 1 probe abnormal	Reagent probe ascending overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe elevating motor, connection and return-to-zero OC are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-67	S. Stop	Reagent 1 Syringe pump abnormal	Severe out-of-step is detected by the syringe pump.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump installation, connection and the plug of the circuit board are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-68	S. Stop	Reagent 1 disk abnormal	The reagent disk outer circle counting error.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent disk installation, connection and the plug of the circuit board are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-69	S. Stop	Reagent 1 disk abnormal	The reagent disk inner circle counting error.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent disk installation, connection and the plug of the circuit board are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
80-7	Warning	Reagent 1 probe abnormal	R1 reagent probe cannot reach the reagent liquid level while descending.	(1)Check whether there are other obstacles in R1 reagent disk. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
80-70	Warning	Reagent 1 probe abnormal	The reagent lifting motor motion misses too many steps	Please contact the maintainer if it occurs repeatedly.
80-71	Stop	Reagent 1 probe abnormal	The error in verification of dilution volume occurs during dilution	Please contact the maintainer.
80-72	Stop	Reagent 1 probe abnormal	The error in verification of reagent volume occurs during dilution	Please contact the maintainer.
80-73	S. Stop	R1 Reagent Disk Abnormal	R1 reagent disk anomalous rotation occur	(1)Check whether the reagent disk motor is locked. (2)Check whether the optocoupler installation under reagent disk is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
80-74	Stop	R1 Reagent Probe Abnormal	R1 reagent probe anomalous up and down occur	(1)Check whether the reagent probe up and down motor is locked. (2)Check whether the reagent probe up and down optocoupler installation is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
80-75	S. Stop	R1 Reagent Probe Abnormal	R1 reagent probe anomalous swing occur	(1)Check whether the reagent probe swing motor is locked. (2)Check whether the reagent probe swing optocoupler installation is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
80-76	Warning	Liquid Detection Abnormal of R1 Reagent Probe	The liquid level height difference detected by R1 reagent probe in one position for continuous two times is over normal value.	
96-14	S. Stop	Reagent 2 disk abnormal	The reagent disk stop position is unable to find.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
96-15	S. Stop	Reagent 2 disk abnormal	The reagent disk does not stop at the designated position.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.
96-16	S. Stop	Reagent 2 disk abnormal	The reagent return-to-zero position is unable to find.	(1)Call up the system maintenance menu,first carry out the program “Reset”,then go on “mechanism check” (2)Various malfunctions or trouble can not be restored. Contact the service department.

Alarm code	Level	Brief description	Description	Countermeasure
96-17	Warning	Reagent 2 barcode device abnormal.	The sample barcode reader is unable to find.	(1)Please check whether the barcode device is connected. (2)Please contact the maintainer if it cannot return to normality.
96-18	Warning	Reagent 2 barcode device abnormal	The sample barcode reader return data show that inner error occurs.	(1)Please check whether the barcode device inner connection is correct. (2)Please contact the maintainer if it cannot return to normality.
96-19	Warning	Reagent 2 barcode scanning overruns	During the test, the sample barcode scanning overruns probably because of the instrument malfunction.	(1)The samples that were fed have been tested; After the standby mode, open the system maintenance window, and conduct “Reset”. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-20	Stop	Reagent 2 No. ineffective	R2 reagent No. is ineffective.	(1) Please contact the maintenance staff if it fails repeatedly.
96-21	S. Stop	Reagent 2 Syringe abnormal	The reagent-2 syringe is not at the upper dead point.	(1)Call up the system maintenance menu,carry out the program “Reset” (2)Various malfunctions or trouble can not be restored. Contact the service department.
96-22	S. Stop	Reagent 2 Syringe abnormal	The reagent-2 syringe does not leave from the upper dead point	(1)Call up the system maintenance menu,carry out the program “Reset” (2)Various malfunctions or trouble can not be restored. Contact the service department.
96-3	S. Stop	Reagent 2 probe abnormal	R2 reagent probe cannot reach the top point while ascending (not over the reaction cuvettes).	(1)Check whether the lifting mechanism returns to the top point. (2)Check whether the lifting mechanism zero position OC signal is normal. (3)Open the system maintenance window, and conduct “Reset”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-35	Stop	Reagent 2 board abnormal	Reagent 2 board receives invalid position position No. of sample adding	(1) Please contact the maintenance staff if it fails repeatedly.
96-36	Warning	Reagent 2 board abnormal	Reagent 2 board executes invalid instruction	(1) Please contact the maintenance staff if it fails repeatedly.
96-37	Warning	Reagent 2 probe does not find reagent bottle	R2 reagent probe does not find reagent bottle	(1)Check whether the current position of the R2 reagent disk exist reagent bottle. (2)Check whether the liquid level detecting board connection and signal are normal. (3)Please contact the maintainer if the malfunction occurs repeatedly.
96-38	S. Stop	Reagent 2 probe abnormal	The reagent volume is over little.	(1) Please contact the maintenance staff if it fails repeatedly.
96-39	S. Stop	Reagent 2 probe abnormal	The dilution volume is over much or little.	(1) Please contact the maintenance staff if it fails repeatedly.

Alarm code	Level	Brief description	Description	Countermeasure
96-4	S. Stop	Reagent 2 probe abnormal	R2 reagent probe cannot leave the top point while descending (not over the reaction cuvettes).	(1)Check whether the lifting mechanism leaves the top point. (2)Check whether the lifting mechanism zero position OC signal is normal. (3)Open the system maintenance window, and conduct “Reset”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-40	S. Stop	Reagent 2 probe abnormal	Reagent feeding and other signals overrun.	(1) Please contact the maintenance staff if it fails repeatedly.
96-41	Warning	Reagent 2 probe abnormal	The descending steps are not within the range of 5mL liquid level.	(1)Please check whether the reagent volume of position 1 of R1 disk and R2 disk is 5mL. (2)Please contact the maintenance staff if it fails repeatedly.
96-42	Warning	Reagent 2 probe abnormal	The descending steps are not within the range of 50mL liquid level.	(1)Please check whether the reagent volume of position 1 of R1 disk and R2 disk is 50mL. (2)Please contact the maintenance staff if it fails repeatedly.
96-43	S. Stop	Reagent 2 probe abnormal	Vertical test type error occurs.	(1) Please contact the maintenance staff if it fails repeatedly.
96-44	Stop	Reagent 2 probe abnormal	The reagent probe is not in the ascending and descending return-to-zero position, and the reagent disk cannot rotate.	(1)Check whether the reagent probe descends. (2)Check whether the ascending and descending zero signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-45	Stop	Reagent 2 probe abnormal	The reagent probe is not in the ascending and descending return-to-zero position, and the reagent probe cannot swing.	(1)Check whether the reagent probe descends. (2)Check whether the ascending and descending zero signal is normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-46	S. Stop	Reagent 2 disk abnormal	Reagent disk rotation overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent disk electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-47	S. Stop	Reagent 2 probe abnormal	Reagent probe return-to-zero motion overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe elevating motor, connection and return-to-zero OC are abnormal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
96-48	S. Stop	Reagent 2 probe abnormal	Reagent probe swing overruns	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe elevating motor, connection and return-to-zero OC are abnormal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-49	S. Stop	Reagent 2 Syringe pump abnormal	Syringe pump return-to-zero overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-50	S. Stop	Reagent 2 Cleanout valve abnormal	Reagent probe inner wall cleanout valve opening fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether inner wall electromagnetic valve and connection open-circuit and short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-51	S. Stop	Reagent 2 Cleanout valve abnormal	Reagent probe inner wall cleanout valve closing fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether inner wall electromagnetic valve and connection open-circuit and short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-52	S. Stop	Reagent 2 Cleanout valve abnormal	Reagent probe outer wall cleanout valve opening fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether outer wall electromagnetic valve and connection open-circuit and short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-53	S. Stop	Reagent 2 Cleanout valve abnormal	Reagent probe outer wall cleanout valve closing fails.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether outer wall electromagnetic valve and connection open-circuit and short-circuit. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-54	Stop	Reagent 2 board abnormal	Bottle No. verification error occurs.	(1) Please contact the maintenance staff if it fails repeatedly.
96-55	S. Stop	Reagent 2 board abnormal	The reagent disk position is unable to find.	(1) Please contact the maintenance staff if it fails repeatedly.
96-56	S. Stop	Reagent 2 board abnormal	The next position for the reagent disk is unable to find.	(1) Please contact the maintenance staff if it fails repeatedly.

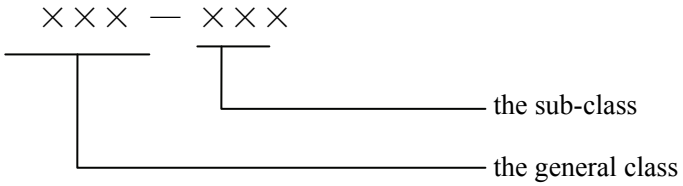
Alarm code	Level	Brief description	Description	Countermeasure
96-57	S. Stop	Reagent 2 board abnormal	The reagent disk motion needs conducting after a successful resetting.	(1) Please contact the maintenance staff if it fails repeatedly.
96-58	S. Stop	Reagent 2 board abnormal	Sample feeding position id error.	(1) Please contact the maintenance staff if it fails repeatedly.
96-59	Stop	Reagent 2 probe abnormal	OC mode error occurs where the reagent probe stops.	(1)Check whether the position where the reagent probe swing stops is correct. (2)Check whether the reagent probe swing motor, connection and return-to-zero OC are normal. (3)Open the system maintenance window, and conduct “Reset”. (4)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-6	Warning	Collision happens to R2 reagent probe	An abnormal occurs when R2 reagent probe descends.	(1)Check whether there is reagent in the reagent bottle. (2)Check whether the reagent bottle cap is opened. (3)Check whether the reagent disk cover is in the correct position. (4)Check whether the reagent probe is curved. (5)Check whether the reagent bottle is leaned.
96-60	Warning	Reagent 2 disk cover open	The cover of the reagent disk is open.	
96-61	Warning	Reagent 2 disk cover closed	The cover of the reagent disk is closed.	
96-62	S. Stop	Reagent 2 Syringe pump abnormal	Syringe pump adding overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-63	S. Stop	Reagent 2 Syringe pump abnormal	The syringe pump dispensing liquid overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-64	S. Stop	Reagent 2 Syringe pump abnormal	Syringe pump water adding overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump electric motor and connection are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.

Alarm code	Level	Brief description	Description	Countermeasure
96-65	S. Stop	Reagent 2 probe abnormal	Reagent probe descending overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe lifting motor, connection and return-to-zero OC are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-66	S. Stop	Reagent 2 probe abnormal	Reagent probe ascending overruns.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent probe lifting motor, connection and return-to-zero OC are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-67	S. Stop	Reagent 2 Syringe pump abnormal	Severe out-of-step is detected by the syringe pump.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the syringe pump installation, connection and the plug in the circuit board are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-68	S. Stop	Reagent 2 disk abnormal	The reagent disk outer circle counting error.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent disk installation, connection and the plug of the circuit board are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-69	S. Stop	Reagent 2 disk abnormal	The reagent disk inner circle counting error.	(1)Open the system maintenance window, and conduct “Reset”. (2)Check whether the reagent disk installation, connection and the plug of the circuit board are normal. (3)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-7	warning	Reagent 2 probe abnormal	R2 reagent probe cannot descend to the reagent liquid level.	(1)Check whether there are other obstacles in R2 reagent disk. (2)Please contact the maintainer if it cannot return to normality, or other malfunctions occur.
96-70	Warning	Reagent 2 probe abnormal	The reagent probe lifting motor motion missed too many steps	Please contact the maintainer if it occurs repeatedly.
96-71	Stop	Reagent 2 probe abnormal	The error in verification of reagent volume occurs during dilution	Please contact the maintainer.
96-72	Stop	Reagent 2 probe abnormal	The error in verification of reagent volume occurs during dilution	Please contact the maintainer.

Alarm code	Level	Brief description	Description	Countermeasure
96-73	S. Stop	R2 Reagent Disk Abnormal	R2 reagent disk anomalous rotation occur	(1)Check whether the reagent disk motor is locked. (2)Check whether the optocoupler installation under reagent disk is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
96-74	Stop	R2 Reagent Probe Abnormal	R2 reagent probe anomalous up and down occur	(1)Check whether the reagent probe up and down motor is locked. (2)Check whether the reagent probe up and down optocoupler installation is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
96-75	S. Stop	R2 Reagent Probe Abnormal	R2 reagent probe anomalous swing occur	(1)Check whether the reagent probe swing motor is locked. (2)Check whether the reagent probe swing optocoupler installation is loosened and whether the optocoupler signal is stable. (3)Contact service staff if problem can not be solved.
96-76	Warning	Liquid Detection Abnormal of R2 Reagent Probe	The liquid level height difference detected by R1 reagent probe in one position for continuous two times is over normal value.	

Note:

The alarm codes consist of the general class and the sub-class.



Chapter 12 Transportation and Storage

12.1 Transportation Requirements

Water proof and moisture proof are required during transportation. Do not extrude or vibrate the analyzer. The ambient temperature should be within -40℃~55℃. The relative humidity should not exceed 85%. The atmospheric pressure should be 75kPa~106kPa.

During transportation, the analyzer should keep upright, and meet the symbol requirements on the packaging. It should be transported, and loaded and unloaded gently.

12.2 Storage Requirements

Analyzer should be stored in clean and ventilated room without chemicals and corrosive gas. Ambient temperature at -40℃~55℃; relative humidity no more than 75%.

Appendix A Product Warranty

Dear users:

Thank you for purchasing Analyzer of our company. We can offer you the following services:

(1)Technical consultation at any moment.

(2)We provide one year warranty since the day of purchase. If analyzer malfunction is caused by design defects or manufacture defects, our company will offer free repair.

(3)Paid services are provided in the following conditions:

a)The warranty has expired.

b)Damage caused by accident or wrong operation.

c)Damage caused by use not in accordance with the manual requirements.

d)Damage caused by the repair without our permission.

(4)As our technique improves, we will offer Analyzer updating services.

Appendix B Product Statement

B.1 Product Classification

Analyzer is classified according to Product Classification Catalog of Medical Devices. It is a chemistry analysis system of clinical test analyzer(6840). Management Type: II.

B.2 Reagent Kit

See the following table.

Appendix C Parameter table of chemistry reagent frequently used

Item name	Analysis method	Measure wavelength (nm)		Photometric point	Sample volume	Reagent volume		Calibration method	Calibration point	Range point	Reaction direction	Deviation rate check	Discreteness check	Sensitivity check	Blank horizontal check
		Dominant wavelength	Secondary wavelength			R1	R2								
ALT	Rate A	340	405	20-31	15	240	60	2 point linearity	2	2	Negative	3.3	0.05	0	0.8-2.5
AST	Rate A	340	405	20-31	15	240	60	2 point linearity	2	2	Negative	3.3	0.05	0	0.8-2.5
ALP	Rate A	405	505	20-23	4	200	50	2 point linearity	2	2	Positive	3.3	0.05	0	0-1.0
GGT	Rate A	405	505	20-31	25	200	50	2 point linearity	2	2	Positive	3.3	0.05	0	0-1.2
TBA	2 point rate	405	505	20-28	4	270	90	2 point linearity	2	2	Positive	3.3	0.05	0	0-1.2
TBIL	1 point method	546	660	31	20	0	200	2 point linearity	2	2	Positive	3.3	0.05	0	-0.6
DBIL	1 point end method	546	660	31	20	0	200	2 point linearity	2	2	Positive	3.3	0.05	0	-0.6
TP	1 point end method	546	700	31	5	250	0	2 point linearity	2	2	Positive	3.3	0.05	0	-1
ALB	1 point end method	600	700	10	2	300	0	2 point linearity	2	2	Positive	3.3	0.05	0	0-0.5
LAP	Rate A	405	505	20-31	15	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	0-1.2

Item name	Analysis method	Measure wavelength (nm)		Photometric point	Sample volume	Reagent volume		Calibration method	Calibration point	Range point	Reaction direction	Deviation rate check	Discreteness check	Sensitivity check	Blank horizontal check
		Dominant wavelength	Secondary wavelength			R1	R2								
CHE	Rate A	405	505	20-25	3	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	0-1.0
ICDH	Rate A	340	405	20-31	15	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	-1.1
GLDH	Rate A	340	405	20-31	15	240	60	2 point linearity	2	2	Negative	3.3	0.05	0	0.1-2.5
AMY	Rate A	405	505	20-25	5	160	40	2 point linearity	2	2	Positive	3.3	0.05	0	-1.3
BUN	2 point rate	340	405	20-26	3	240	60	2 point linearity	2	2	Negative	3.3	0.05	0	0.8-2.2
CRE-E	2 point rate	546	700	10-31	8	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	-0.9
CRE-J	2 point rate	505	660	20-25	20	150	150	2 point linearity	2	2	Positive	3.3	0.05	0	0-1.2
GLU-E	2 point end method	505	660	10-31	2	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	0-0.8
GLU(HK)	2 point end method	340	405	10-31	2	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	-1.1
FMN	2 point end method	546	700	10-31	10	200	0	2 point linearity	2	2	Positive	3.3	0.05	0	-0.9
TC	2 point end method	505	660	10-31	3	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	-0.6

Item name	Analysis method	Measure wavelength (nm)		Photometric point	Sample volume	Reagent volume		Calibration method	Calibration point	Range point	Reaction direction	Deviation rate check	Discreteness check	Sensitivity check	Blank horizontal check
		Dominant wavelength	Secondary wavelength			R1	R2								
TG	2 point end method	546	700	10-31	3	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	-0.6
HDL-C	2 point end method	546	660	10-31	3	225	75	2 point linearity	2	2	Positive	3.3	0.05	0	0-0.8
LDL-C	2 point end method	546	660	10-31	4	300	100	2 point linearity	2	2	Positive	3.3	0.05	0	-0.9
CK-MB	Rate A	340	405	23-31	10	200	50	2 point linearity	2	2	Positive	3.3	0.05	0	0-0.8
CK	Rate A	340	405	21-31	5	200	50	2 point linearity	2	2	Positive	3.3	0.05	0	-1.3
HBDH	Rate A	340	405	20-31	6	240	60	2 point linearity	2	2	Negative	3.3	0.05	0	0.8-2.5
LDH	Rate A	340	405	20-31	5	240	60	2 point linearity	2	2	Positive	3.3	0.05	0	-1.1
UA	2 point end method	546	700	10-31	4	200	50	2 point linearity	2	2	Positive	3.3	0.05	0	-0.9
P	1 point end method	340	405	10	4	200	0	2 point linearity	2	2	Positive	3.3	0.05	0	-0.9
Ca-CPC	2 point end method	570	660	10-31	6	150	150	2 point linearity	2	2	Positive	3.3	0.05	0	-0.6
Cl	1 point end method	505	660	31	3	300	0	2 point linearity	2	2	Positive	3.3	0.05	0	-0.6

Item name	Analysis method	Measure wavelength (nm)		Photometric point	Sample volume	Reagent volume		Calibration method	Calibration point	Range point	Reaction direction	Deviation rate check	Discreteness check	Sensitivity check	Blank horizontal check
		Dominant wavelength	Secondary wavelength			R1	R2								
Ca-ARS	1 point end method	660	800	31	3	300	0	2 point linearity	2	2	Positive	3.3	0.05	0	0-0.8
Mg	1 point end method	546	800	10	3	300	0	2 point linearity	2	2	Positive	3.3	0.05	0	0-1.2

Note:

For specific parameters, please refer to the reagent instructions. In order to add items, please set the parameters according to the reagent instructions. To calculate sample results, calibration by calibration serum with the practical factor is advised if the items are tested by Rate A method.

Appendix D Cross-contamination Reference Table

Name	Principle		Contaminated Item	Principle
TG	Oxidase Method	→	TBA	Enzymatic Cycling Method
TC	Enzymic Method	→	TBA	Enzymatic Cycling Method
CHE	Substrate Hydrolysis Method	→	TG	Oxidase Method
LDL-C	Direct Method	→	GLU(OX)	Oxidase Method
HDL-C	Direct Method	→	GLU(OX)	Oxidase Method
CK	IFCC Recommend Method	→	Mg	Magnesium Blue Method
FMN	NBT Reduction Method	→	CHE	Substrate Hydrolysis Method

Note:

The above cross-contamination is only tested reagents from the manufacturer. If the recipe changes, the cross-contamination will also change. The above is only for reference.

Appendix E Abnormal Result Mark Reference Table

Sign	Meaning	Color
H or ↑	The result exceeds the upper limit.	Can be set
L or ↓	The result exceeds the lower limit.	Can be set
S	No samples are dispensed for sample tests. No Control are dispensed for quality control tests.	Can be set
R	No reagents are dispensed.	Can be set
C	Clots are detected in the sample.	none
!	Neither samples nor reagents are dispensed.	Can be set
>	The concentration exceeds the upper limit of the reagent linear range.	Can be set
<	The concentration exceeds the lower limit of the reagent linear range.	Can be set

Appendix F LIS Communication Setting Instruction (Version 1.0)

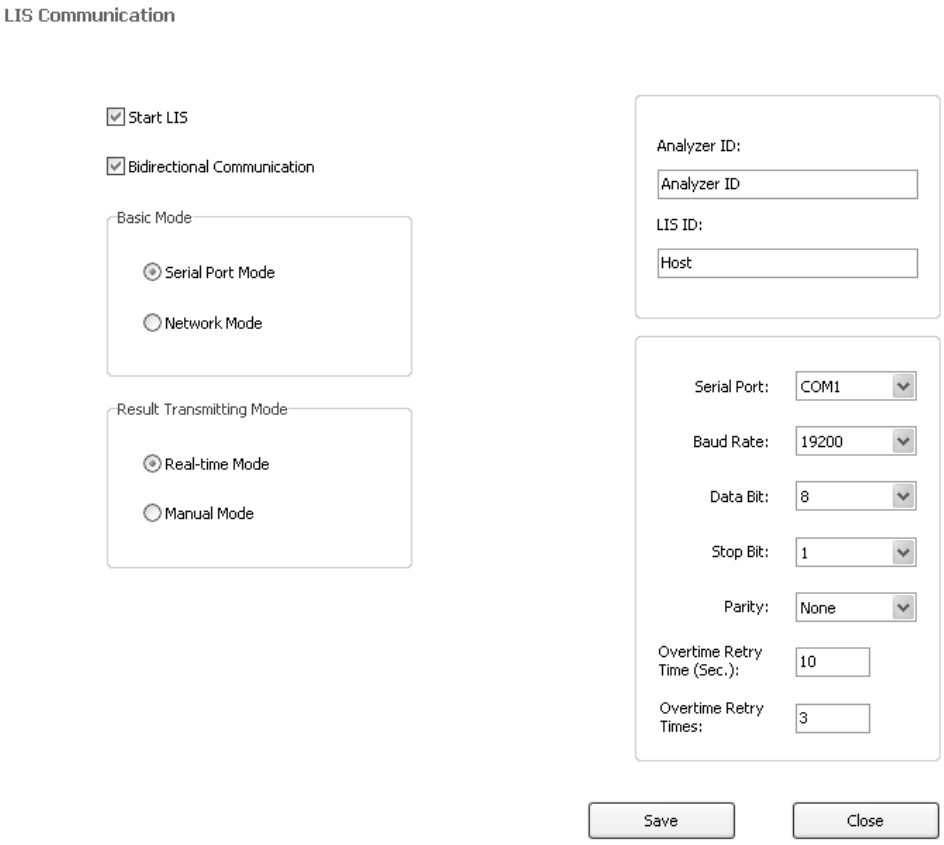
Analyzer and LIS Communication Interface Introduction

Analyzer and LIS communication interface adopts serial port communication mode, which has been adopted by most analyzers. This communication interface follows ASTM standard protocol (refer to section 6-13 of ASTM 1394). ASTM standard protocol provides a bi-directional communication channel for Analyzer and LIS workstation.

Through this interface, Analyzer can apply sample information registered in LIS workstation manually or automatically, and transmit test result and QC result to LIS workstation manually or automatically. The data transmitted through this interface all follow ASTM standard protocol format.

LIS Communication Setting Description

The setting interface is as follow:



Open Communication: In order to ensure the normal communication between Analyzer and LIS workstation, “Open Communication” must be selected, otherwise, Analyzer and LIS communication will be unavailable.

Bidirectional: “Bidirectional” must be selected when applying LIS data. This setting selection is not necessary when transmitting test result or QC result to LIS. When “Open Communication” is selected, “Bidirectional” is selectable.

Basic Setting: Only serial port mode is introduced here.

Data Transmission Mode: Including real time mode and batch mode. Those two modes are available when Analyzer transmitting test result or QC result of the day to LIS work station. On real time mode, when all items of the sample have results during test or the result of a QC item is obtained, Analyzer will transmit all information of the sample to LIS work station automatically. On batch mode, user can transmit the sample information or QC information from Analyzer to LIS work station.

Analyzer ID: Marking Analyzer

Host ID: Marking LIS work station

Serial Port: Selecting valid serial port No.

Baud Rate: Variation times of carrier parameter per unit time. 9600bps or 19200bps can be selected. Default as 19200bps.

Data Bits: 7 or 8. Default as 8.

Stop Bit: 1 or 2. Default as 1.

Parity: N, M, E, O, S. Default as N.

Timeout Retry Time: Time interval used for overtime retry in communication. The communication will stop when there is not effective communication during overtime retry time. The input range of overtime retry time is 1-15.

Timeout Retry Count: Count used for overtime retry in communication. The communication will stop when there is not effective communication during overtime retry count. The input range of overtime retry count is 1-6.

LIS Communication Data Format

1. Control Code

LF (Line Feed) (Hex 0A)

CR (Carriage Return) (Hex 0D)

STX (Start of Text) (Hex 02)

ETX (End of Text) (Hex 03)

EOT (End of Transmission) (Hex 04)

ENQ (Enquiry) (Hex 05)

ACK (Acknowledge) (Hex 06)

NAK (Not Acknowledged) (Hex 15)

2. Message Frame / Checksum Calculation

The end frame

[STX] FN Text first char. ..... Text last char. ETX CH CL [CR] [LF]

[STX]

The ASCII code 2, indicating the beginning of a frame transmission.

FN

The frame number modulo 8. Frames of a single Transmission Phase are consecutively numbered beginning with 1. So FN runs from 1 to 7, continues with 0, 1 and so on.

Text

Data content.

[ETX]

ASCII code 3, indicating the end of the text block of an end frame.

CH, CL

Represent the high nibble and the low nibble of the 8 bit checksum, respectively. CH and CL are represented as two digits of hex numbers. The checksum is the modulo 256 of the sum of ASCII values of the frame characters starting with and including “FN” and completing with [ETX].

Example for Checksum Calculation:

[STX]1Test[ETX]

Symbol	Character	Value (decimal)	Sum
[STX]	[STX]	002	0
FN	‘1’	049	49
Text	‘T’	+084	133
	‘e’	+101	234
	‘s’	+115	349
	‘t’	+116	465
[ETX]	[ETX]	+003	468
		468	= 468
		MOD 256	
		212	= 212
CH	‘D’	068	
CL	‘4’	052	
[CR]	[CR]	013	
[LF]	[LF]	010	

Therefore, frame will be transmitted in this form:

[STX]1Test[ETX]D4[CR][LF]

3. Delimiters

The Presentation Layer uses some characters as special delimiter codes. These characters may not be used as normal message text:

Delimiter	Character	Char.	ASCII decimal	ASCII hex.
Record delimiter	= carriage return	<CR>	13	0Dh
Field delimiter	= vertical bar	|	124	7Ch
Repeat delimiter	= backslash	\	92	5Ch
Component delimiter	= caret	^	94	5Eh
Escape delimiter	= ampersand	&	37	26h

4. Table of Record Message Type

Record Name	Identifier
Message Header Record	H
Patient Information Record	P
Test Order Record	O
Result Record	R
Message Terminator Record	L
Request Information Record	Q

5. Data Record Usage

(Refer to ASTM 1394, particularly sections 6 through 13)

1) Analyzer transmit message to LIS work station

Mandatory:

Y: Field is mandatory and have to be considered.

N: Field is not mandatory. The field have to be considered by the LIS, but it is transmitted only if information is available at Liaison. When the information is not available an empty field is transmitted.

Message Header Record (H)

Description:

The Message Header Record to LIS is the first record of each message.

Example:

<STX><FN>H|\^&|||Analyzer|||||Host|||1|20081124151206<CR><ETX>< Checksum><CR><LF>

Field No.	E1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	7.1.1	Record Type ID	'H'	1	Y
2	7.1.2	Delimiter Definition	'| \ ^ &'	4	Y
5	7.1.5	Sender Name or ID	'Analyzer'	20	Y
10	7.1.10	Receiver ID		20	Y
13	7.1.13	Version No.	'1'	1	Y
14	7.1.14	Date and Time of Message	'YYYYMMDDHHMMSS'	14	Y

Patient Information Record (P)

Description:

This record is used to transmit patient sex and age to LIS.

Example:

When transmitting sample result information:

<STX><FN>P|1||||ZhangDongdong|||M|||||40^Y<CR><ETX><Checksum> <CR><LF>

When transmitting Control result information:

<STX><FN>P|1||||QC|||||||^<CR><ETX>[Checksum] <CR><LF>

Field No.	E1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	8.1.1	Record Type ID	'P'	1	Y
2	8.1.2	Sequence Number		6	Y
6	8.1.6	Patient Name		30	N
9	8.1.9	Patient Sex	'M', 'F' or 'U'	1	N
15^1	8.1.15	Special Field 1	Age(1-200)	3	N
15^2			Age Unit ('Y','M','D')	1	

Test Order Record (O)

Description:

This record holds information regarding analysis request and sample information to LIS.

Example:

When transmitting sample result:

(1)Sample No. , Barcode Rack NO.Mode:

<STX><FN>O|1|^1^N001^10^N^1|||R|20081124151012||||||||1|||||||||O

<CR><ETX><CheckSum><CR><LF>

(2) Barcode ID Mode:

<STX><FN>O|1|CA2201320078^^N001^10^N^1|||R|20081124151012||||||||1|||||||||O<CR><ETX><Check Sum><CR><LF>

When transmitting Control result:

<STX><FN>O|1|^0^C001^1^N^1|LANDOX-1^2333^|||20110104172413||||||||1|||||||||O<CR><ETX><CheckSum><CR><LF>

Field No.	E1394	ASTM Field Name	Valid Contents	Max Length	Mandatory
1	9.4.1	Record Type ID	'O'	1	Y
2	9.4.2	Sequence Number		6	Y
3^1	9.4.3	Specimen ID (<Sample No>^ <Sample No>^ <Rack No>^ <Position No>^ <Diluent>^ <Replicate Number>)	Sample ID(ID Mode)	22	Y
3^2			Sample No.(S. No. Mode)	6	
3^3			Rack No.	4	
3^4			Position No.	2	
3^5			'Y' or 'N'	1	
3^6			Sample replicate number (1-100)	3	
4^1	9.4.4	Analyzer Specimen ID (<Qc Name>^ <Qc Lot No.>^ <Module>)	Qc Name	20	N
4^2			Qc Lot No.	15	
4^3			Module	1	
6	9.4.6	Priority	'S' or 'R'	1	Y
7	9.4.7	Requested/Ordered Date and Time	'YYYYMMDDHHMMSS'	14	Y
16	9.4.16	Specimen Descriptor	0 - Serum 1 - Urine 2 - Plasma 3 - CSF 4 - Gastric juice 5 - Ascites 6 - Other	1	Y
26	9.4.26	Report Types	'O', 'F', 'I', 'C' or 'X'	1	Y

Result Record (R)

Description:

The Result Record to LIS contains the result of a single analytical determination.

Example:

When transmitting sample result:

<STX><FN>R|1|^^^GGT|4.96|mg/dL|3^12\0^20|N||F|||20081124151012

<CR><ETX><CheckSum><CR><LF>

When transmitting Control result:

<STX><FN>R|1|^^^ALT|333|U/L|2^22|1-3s|>+3SD|||||20110104172413

<CR><ETX><CheckSum><CR><LF>

Field No.	E 1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	10.1.1	Record Type ID	R	1	Y
2	10.1.2	Sequence Number		5	Y
3	10.1.3	Universal Test ID		10	Y
4^1	10.1.4	Data or Measurement Value	Data result	10	N
4^2			Sample replicate number (1-100)	3	N
4^3			1-Out Cell 2-In Cell (Control)	1	
5	10.1.5	Units		10	N
6	10.1.6	Reference Ranges	(1) If send sample result, first range = normal range second range = critical range separated by repeat delimiter ('\') (2) If send QC result, first value=target mean second value=target SD. separated by repeat delimiter ('^').	30	N
7	10.1.7	Result Abnormal Flags	(1) If send sample result, 'L','H','N' or 'A' (2) If send QC result, QC regulation('','1-2s','1-3s')	1	N
8	10.1.8	Nature of Abnormality Testing	(1) If send sample result, '' (2) If send QC result, '+ 1SD', '- 1SD', '+ 2SD', '- 2SD', '+3SD', '- 3SD'		N
9	10.1.9	Result Status	'F' or 'C'	1	Y
13	10.1.13	Date/Time Test Completed	'YYYYMMDDHHMMSS'	14	N

2) Request Information Record to LIS

Description:

The Request Information Record to LIS is used to request sample program information from LIS. A query is typically performed when a sample bar code has been read on the analyzer and no sample program information is found locally. All queries are made by sample ID.

Example:

Sample NO. , Barcode Rack No. Mode:

<STX><FN>Q|1|^1^N001^1^N| |ALL|||||||O<CR><CTX><CheckNum><CR><LF>

Sample Barcode ID Mode:

<STX><FN>Q|1|AC2201023321^^N001^1^N| |ALL|||||||O<CR><CTX><CheckNum><CR><LF>

Field No.	E1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	10.1.1	Record Type ID	'Q'	1	Y
2	10.1.2	Sequence Number		6	Y
3^1	10.1.3	Starting Range ID Number (<Sample No>^ <Sample No>^ <Rack No>^ <Position No>^ <Diluent>)	Sample ID(ID Mode)	22	Y
3^2			Sample No.(S. No. Mode)	6	
3^3			Rack No.	4	
3^4			Position No.	2	
3^5			'Y' or 'N'	1	
5	10.1.5	Universal Test ID	'ALL'		Y
13	10.1.13	Request Information Status Codes	'A' or 'O'	1	Y

Message Terminator Record:

Description:

The Message Terminator Record to LIS is used with the Message Header Record to encapsulate related patient information.

Example:

<STX><FN>L|1|N<CR><ETX><CheckNum><CR><LF>

Field No.	E1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	13.1.1	Record Type ID	'L'	1	Y
2	13.1.2	Sequence Number		6	Y
3	13.1.3	Termination Code	'N'	1	Y

3)Message Transmitted to Analyzer from LIS Work Station

Mandatory: Y: Field is mandatory and have to be considered.

N: Field is not mandatory. The field have to be considered by the LIS, but it is transmitted only if information is available at Liaison. When the information is not available an empty field is transmitted.

Message Header Record (H)

Description:

The Message Header Record to the analyzer is the first record of each message.

Example:

<STX><FN>H|\^&<CR><ETX>< Checksum> <CR><LF>

Field No.	E1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	7.1.1	Record Type ID	'H'	1	Y
2	7.1.2	Delimiter Definition	'| \ ^ &'	4	Y

Patient Information Record (P)

Description:

This record is used to transfer patient sex and age to the analyzer.

Example:

<STX><FN>P|1||123456||ZhangDongdong|||M||||||40^Y<CR><ETX><Checksum> <CR><LF>

Field No.	E1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	8.1.1	Record Type ID	'P'	1	Y
2	8.1.2	Sequence Number		6	Y
4	8.1.4	Laboratory Assigned Patient ID	Sample ID or Sample No.	22	N
6	8.1.6	Patient Name		30	N
9	8.1.9	Patient Sex	'M', 'F' or 'U'	1	N
15^1	8.1.15	Special Field 1	Age(1-200)	3	N
15^2			Age Unit ('Y','M','D')	1	

Test Order Record (O)

Description:

This record holds information regarding analysis request and sample information to the analyzer.

Example:

Sample No., Barcode Rack No. Mode:

<STX><FN>O|1|^1^N001^10^N^1||^^^ALT|R|20081124151012||||||||1|||||||||O<CR><ETX><CheckNum><CR><LF>

Sample ID Mode:

<STX><FN>O|1|AB2201022318^^N001^10^N^1||^^^ALT|R|20081124151012||||||||1|||||||||O<CR><ETX><CheckNum><CR><LF>

Field No.	E1394	ASTM Field Name	Valid Contents	Max Length	Mandatory
1	9.4.1	Record Type ID	'O'	1	Y
2	9.4.2	Sequence Number		6	Y
3^1	9.4.3	Specimen ID (<Sample ID>^ <Sample No>^ <Rack ID>^ <Position No>^ <Diluent>^ <Replicate Number>)	Sample ID (ID Mode)	22	Y
3^2			Sample No. (S. No. Mode)	6	
3^3			Rack ID	4	
3^4			Position No.	2	
3^5			'Y' or 'N'	1	
3^6			Sample replicate number (1-100)	3	
5	9.4.5	Universal Test ID		10	Y
6	9.4.6	Priority	'S' or 'R'	1	N
7	9.4.7	Requested/Ordered Date and Time	'YYYYMMDDHHMMSS'	14	N
16	9.4.16	Specimen Descriptor	1 - Serum 2 - Urine 3 - Plasma 4 - CSF 5 - Gastric juice 6 - Ascites 7 - Other	1	N
26	9.4.26	Report Types	'O', 'F', 'I', 'C' or 'X'	1	N

Message Terminator Record

Description

The Message Terminator Record to the analyzer is used with the Message Header Record to encapsulate related patient information.

Example:

<STX><FN>L|1|N<CR><ETX><CheckNum><CR><LF>

Field No.	E1394	ASTM Field Name	Field Contents	Max Length	Mandatory
1	13.1.1	Record Type ID	'L'	1	Y
2	13.1.2	Sequence Number		6	Y
3	13.1.3	Termination Code	'N' or 'I'	1	Y

Notice:

When the double direction communication apply the testing from the Analyzer To LIS system, If when the LIS system didn't find the sample that should be applied, must send:

ENQ

EOT

Examples

1. Message Transmitted from Analyzer to LIS Work Station

Analyzer [ENQ]

HOST [ACK]

Analyzer [STX]1H|\^&||| Analyzer |||||Host||1|20090119131415[CR]

[ETX]24[CR][LF]

HOST [ACK]

Analyzer [STX] 2P|1|||||||||||^[CR][ETX]E9 [CR][LF]

HOST [ACK]

Analyzer [STX] 3O|1|128123^1^1^2|||R|20090119123027||||||||1|||||||||O
[CR][ETX]55[CR][LF]

HOST [ACK]

Analyzer [STX] 4R|1|^^^ALT|-2|U/L|^\^|N||F||||20090119123027[CR]

[ETX]32[CR][LF]

HOST [ACK]

Analyzer [STX] 5R|2|^^^AST|1|U/L|^\^|N||F||||20090119123027[CR]

[ETX]0D[CR][LF]

HOST [ACK]

Analyzer [STX] 6R|3|^^^ALB|-8.57|g/l|^\^|N||F||||20090119123027[CR]

[ETX]F6[CR][LF]

HOST [ACK]

Analyzer [STX] 7L|1|N[CR][ETX]0A[CR][LF]

HOST [ACK]

Analyzer [EOT]

2.Apply from analyzer to LIS

Single:

Analyzer [ENQ]

HOST [ACK]

Analyzer [STX]1H|\^&||| Analyzer |||||Host||1|20090119131335[CR]

[ETX]25[CR][LF]

HOST [ACK]

Analyzer [STX] 2Q|1|^130^5^45^N||ALL||||||||O[CR][ETX]B4[CR][LF]

HOST [ACK]

Analyzer [STX] 3L|1|N[CR][ETX]06[CR][LF]

HOST [ACK]

Analyzer [EOT]

Batch:

Analyzer [ENQ]

HOST [ACK]

Analyzer [STX]1H|\^&||| Analyzer |||||Host||1|20090119131335[CR]

[ETX]25[CR][LF]

HOST [ACK]

Analyzer [STX] 2Q|1|^11^2^11^N||ALL|||||||O[CR][ETX]78[CR][LF]

HOST [ACK]

Analyzer [STX] 3Q|2|^12^2^12^N||ALL|||||||O[CR][ETX]7C[CR][LF]

HOST [ACK]

Analyzer [STX] 4Q|3|^13^2^13^N||ALL|||||||O[CR][ETX]80[CR][LF]

HOST [ACK]

Analyzer [STX] 5Q|4|^14^2^14^N||ALL|||||||O[CR][ETX]84[CR][LF]

HOST [ACK]

Analyzer [STX] 6L|1|N[CR][ETX]09[CR][LF]

HOST [ACK]

Analyzer [EOT]

3.Test order from LIS to analyzer

Sample ID mode:

Single:

HOST [ENQ]

Analyzer [ACK]

HOST [STX] 1H|\^&[CR][ETX]E5[CR][LF]

Analyzer [ACK]

HOST [STX] 2P|1||||||||||||^[CR][ETX]E9[CR][LF]

Analyzer [ACK]

HOST [STX] 3O|1|3977777^4^1^1^N||^^^AST|R|20090119100534|||||||

|1|||||||||O[CR][ETX]51[CR][LF]

Analyzer [ACK]

HOST [STX] 4O|2|3977777^4^1^1^N||^^^TP|R|20090119100534|||||||

|1|||||||||O[CR][ETX]0F[CR][LF]

Analyzer [ACK]

HOST [STX] 5O|3|3977777^4^1^1^N||^^^ALB|R|20090119100534|||||||

|1|||||||||O[CR][ETX]3C[CR][LF]

Analyzer [ACK]

HOST [STX] 6L|1|N[CR][ETX]09[CR][LF]

Analyzer [ACK]

HOST [EOT]

Batch:

HOST [ENQ]

Analyzer [ACK]

HOST [STX] 1H|\^&[CR][ETX]E5[CR][LF]

Analyzer [ACK]

HOST [STX] 2P|1||||||||||||^[CR][ETX]E9[CR][LF]
Analyzer [ACK]
HOST [STX] 3O|1|128123^1^1^1^N||^^^ALT|R|20090119100417|||||||
|1|||||||||O[CR][ETX]F9[CR][LF]
Analyzer [ACK]
HOST [STX] 4O|2|128123^1^1^1^N||^^^AST|R|20090119100417|||||||
|1|||||||||O[CR][ETX]02[CR][LF]
Analyzer [ACK]
HOST [STX] 5L|1|N[CR][ETX]08[CR][LF]
Analyzer [ACK]
HOST [STX] 1H|\^&[CR][ETX]E5[CR][LF]
Analyzer [ACK]
HOST [STX] 2P|1||||||||||||^[CR][ETX]E9[CR][LF]
Analyzer [ACK]
HOST [STX] 3O|1|1281234^2^1^2^N||^^^ALT|R|20090119100425|||||||
|1|||||||||O[CR][ETX]2E[CR][LF]
Analyzer [ACK]
HOST [STX] 4O|2|1281234^2^1^2^N||^^^ALB|R|20090119100425|||||||
|1|||||||||O[CR][ETX]1E[CR][LF]
Analyzer [ACK]
HOST [STX] 5L|1|N[CR][ETX]08[CR][LF]
Analyzer [ACK]
HOST [STX] 1H|\^&[CR][ETX]E5[CR][LF]
Analyzer [ACK]
HOST [STX] 2P|1||||||||||||^[CR][ETX]E9[CR][LF]
Analyzer [ACK]
HOST [STX] 3O|1|3977777^4^1^3^N||^^^AST|R|20090119100534|||||||
|1|||||||||O[CR][ETX]53[CR][LF]
Analyzer [ACK]
HOST [STX] 4O|2|3977777^4^1^3^N||^^^TP|R|20090119100534|||||||
|1|||||||||O[CR][ETX]11[CR][LF]
Analyzer [ACK]
HOST [STX] 5O|3|3977777^4^1^3^N||^^^ALB|R|20090119100534|||||||
|1|||||||||O[CR][ETX]3E[CR][LF]
Analyzer [ACK]
HOST [STX] 6L|1|N[CR][ETX]09[CR][LF]
Analyzer [ACK]
HOST [EOT]

Appendix G LIS Network Interface Instruction V1.00

Preface

Please read this instruction carefully before using for correct operation.

Readers of this instruction are those who involved in LIS R&D and required to familiar with HL7 interface. This instruction is used for guiding LIS system manufacture to develop LIS interface and realizing LIS system & chemistry analyzer communication. The developers should be familiar with certain LIS, HL7 standard and network program knowledge. Network layer communication protocol is TCP/IP, application layer protocol is HL7, version 2.3.1. Interface development is recommended to be conducted by using Visual C++, Delphi, etc. on Windows.

1. Interface Overview

HL7 is standardized health information transmitting protocol which is used for electronic transmission among different applications in medical field. HL7 collects standard formats used by different manufactures to design interfaces among different application software and allows data communication among different systems. It is defined firstly by American and is widely used by many countries until now.

The transmission format in this interface is created according to HL7 version 2.3.1.

1.1 HL7 Message Structure

In HL7 communication protocol, message is basic unit of data transmitted among systems. Each message has its own message type, which is used for defining message purpose and contains trigger events. One message is composed of many segments. Each segment has its own name, which is used for defining its content or function. One segment is composed of many Data Field. The first segment of a message is always message head segment, it indicates sending and receiving program name, message type, and the only message ID, etc. the following segments are decided by message type. E.g. PID segment (Patient Identification Data) includes name, address, social insurance No. etc. One data segment can be composed of many parts and some messages may subdivided by event code.

This interface is defined upon HL7 v2.3.1, refer to HL7 Interface Standards Version 2.3.1 for detail.

1.2 HL7 Underlying Protocol

TCP/IP is a byte stream protocol, and it does not provide message boundaries. As upper layer protocol, HL7 is based upon message, but it does not provide message end facility. In order to confirm message boundary, we adopts the minimum underlying protocol(it is also described in HL7 Interface Standards Version 2.3.1.).The beginning of a message is single byte, the ending of a message is double byte.

Message will be transmitted in the following formats:

<SB> data <EB><CR>,

<SB> = Start Block character (1 wide char), ASCII <VT>,which is 0x0B.

data = Data (variable number of wide chars), data is HL7 message, only includes ISO 8859-1 character (hex decimal value 20 - FF) and <CR>, excludes other control and can not be printed characters.

<EB> = End Block character (1 wide char), ASCII <FS>, which is 0x1C.

<CR> = Carriage Return (1 wide char), ASCII Carriage Return, which is 0x0D.

Remark: This protocol adopts Unicode code, all send, received character strings are Unicode.

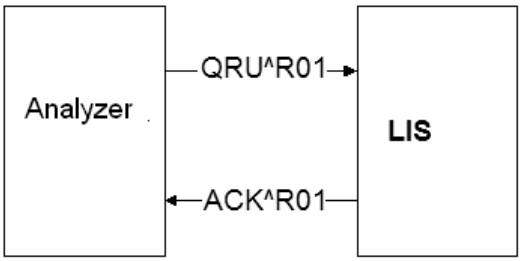
2. Communication Format

This communication interface includes test result transmission and sample information application. Test result transmission is to transmit sample information, test result and QC result of analyzer to outer system, such as LIS. The transmission method includes real time transmission during test and history result batch transmission. Sample information application is to obtain the required sample information from LIS.

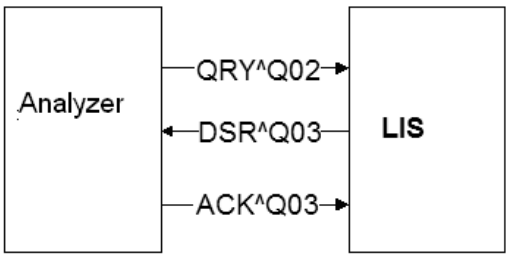
2.1 Support HL7 Message

All HL7 messages used in this interface are ORU, ACK, QRY and DSR.

The general view of test result transmission is as follow:



The general view of sample result application is as follow:



ORU/ACK: Non-request observe report /response. The main function of ORU^R01 message is transmitting lab results(sample information, test result, QC result) in HL7.

The transmitted information and test results include:

Patient information(patient name, sample No. etc.)

Doctor's advice information(sample type, send doctor, test doctor, clinical diagnosis, etc.)

Test result

It is a group of messages, one message corresponds to one sample information(one sample information may includes many item results) . LIS system can use these content according to requirements. The specific structure is as follow:

ORU Observational Results (Unsolicited)	Description
MSH	Message head
PID	Patient information
OBR	Observe report
{OBX}	Test result

The transmitted test result includes the following information:

Item information(item No., item name)

Control related information(QC times, QC name, QC lot No., etc.)

QC date, test result

One message will send one QC test. The send structure of QC result is as follow:

ORU Observational Results (Unsolicited)	Description
MSH	Message head
OBR	QC observe report

ACK^R01: Message is used for responding ORU message. The specific structure is as follow:

ORU Observational Results (Unsolicited)	Description
MSH	Message head
MSA	Message acknowledge

QRY/QCK: Query observe result /response. QRY^Q02 message query current data, used for query required sample information from LIS system. The specific structure is as follow:

QRY Query	Description
MSH	Message head
QRD	Query definition
QRF	Query screen

DSR/ACK: Response to QRY message, display/response of observe result. One function of DSR^Q03 message is to respond QRY message, the other function is send display of query result, which is sending sample information of LIS to analyzer. The specific structure is as follow:

DSR Display Response	Description
MSH	Message head
MSA	Message acknowledge
{DSP}	Display data

ACK^Q03 message is used for responding DSR message. The specific structure is as follow:

ACK Acknowledgment	Description
MSH	Message head
MSA	Message acknowledge

2.2 Message Segment

All fields used in message segments will be introduced in detail, in which, # behind No. is required segment specified by HL7. The unused segments will not be omitted for future expansion.

2.2.1 MSH Message Header

MSH is the head of HL7 message, which is in the front of message and all messages are started with MSH. MSH is used for defining message purpose, origin and grammar.

MSH of this interface uses the following fields:

No.	Segment Name	Length	Explanation
1#	Field Separator	1	Includes the separator between segment ID and the first real field, the left field separator (|).
2#	Encoding Characters	4	Includes assembly separator, repeat separator, transfer separator and subassembly separator(^~\&).
3	Sending Application	180	Application program of send end.
4	Sending Facility	180	Empty, keep. Facility of send end.
5	Receiving Application	180	Application program of receive end.
6	Receiving Facility	180	Empty, keep. Facility of receive end.
7	Date/Time Of Message	26	Time of current message. Adopt the time of the system.
8	Security	40	Empty, keep. Security
9#	Message Type	7	Message type, e.g.: ORU^R01.
10#	Message Control ID	20	Message control ID, unique marking one message, increase from 1 as message No. increases.
11#	Processing ID	3	Process ID, P(product).
12#	Version ID	60	Version ID, HL7 Protocol Version: 2.3.1.
13	Sequence Number	15	Empty, keep. Sequence No.
14	Continuation Pointer	180	Empty, keep. Continuation Pointer

No.	Segment Name	Length	Explanation
15	Accept Acknowledgment Type	2	Empty, keep. Accept Acknowledgment Type
16	Application Acknowledgment Type	2	Application Acknowledgment Type, as send result type. 0-patient sample test result; 1-calibration result; 2-QC result; In which, "1-calibration result" is not supported.
17	Country Code	2	Empty, keep. Country Code
18	Character Set	10	Character Set, take UNICODE.
19	Principal Language Of Message	60	Empty, keep. Principal Language Of Message
20	Alternate Character Set Handling Scheme	20	Empty, keep. Alternate Character Set Handling Scheme

Remark: This segment presents in all messages. In HL7 message send from LIS system to analyzer, the 3rd, 4th segment value will be decided by LIS manufacture, the 5th ,6th segment will be set by user in software. The 10th , 16th segment will use integer. Other segment will use character string type.

2.2.2 MSA - message acknowledgment segment

MSA of this interface use the following fields:

No.	Segment Name	Length	Explanation
1#	Acknowledgment Code	2	Acknowledgment Code, AA indicates accept; AE indicates error; AR indicates refuse, OK indicates data is queried. NF indicates data is not found. OK and NF are available in DSR^Q03.
2#	Message Control ID	20	Message Control ID, same as MSH-10 of sender.
3	Text Message	80	Text message, text description of a event in case of error or refuse. Corresponds with the 6th segment, and can be used to write wrong log.
4	Expected Sequence Number	15	Empty, keep. Intended sequence No.
5	Delayed Acknowledgment Type	1	Empty, keep. Delayed Acknowledgment Type
6	Error Condition	100	Error Condition(Status Code).

MSA-6 segment value is as follow:

Status Code(MSA-6)	Status Text(MSA-3)	Description/Remark
Succeed		AA
0	Message accepted	Succeed
Query Succeed		OK
0	Data found, not errors	Query Succeed
Data is not found in query.		NF
0	No data found, not errors	Data is not found in query.
Wrong status code		AE
100	Segment sequence error	Sequence of segments in message is incorrect, or necessary segment is lost.
101	Required field missing	Necessary segment is lost.
102	Data type error	Data type of segment is incorrect, such as character instead of number.
103	Table value not found	Table value is not found.
Refuse status code		AR
200	Unsupported message type	Unsupported message type

Status Code(MSA-6)	Status Text(MSA-3)	Description/Remark
201	Unsupported event code	Unsupported event code
202	Unsupported processing id	Unsupported processing ID
203	Unsupported version id	Unsupported version ID
204	Unknown key identifier	Unknown key identifier, such as non-exist patient information is transmitted.
205	Duplicate key identifier	Duplicate key identifier exists.
206	Application record locked	Event can not be carried out in application program storage level, such as database is locked.
207	Application internal error	Unclear internal error.

Remark: This message segment may present in ACK^R01, DSR^Q03, ACK^Q03. The 4th, 6th segment use integer, and other segments use character string type.

2.2.3 PID Patient Identification

PID mainly used for structure patient information. PID of this interface adopts the following fields:

No.	Segment	Length	Explanation
1	Set ID – PID	10	Acknowledge different patient message segment.
2	Patient ID	20	Empty, keep. Patient No. in hospital.
3#	Patient Identifier List	16	Case No.
4	Alternate Patient ID – PID	10	Bed No.
5#	Patient Name	30	Patient Name
6	Mother's Maiden Name	61	Inpatient Area and Ward. Area and ward are separated by ^.The inpatient area length is 30, ward length is 30.
7	Date/Time of Birth	26	Empty, keep. Patient date of birth.
8	Sex	1	Send M for male; F for female; O for other.
9	Patient Alias	48	Empty, keep. Blood type.
10	Race	80	Empty, keep. Empty, keep. Race
11	Patient Address	106	Empty, keep. Patient Address
12	County Code	4	Empty, keep. County Code
13	Phone Number -Home	40	Empty, keep. Phone Number
14	Phone Number -Business	40	Empty, keep. Empty, keep. Phone Number -Business
15	Primary Language	60	Empty, keep. Empty, keep. Primary Language
16	Marital Status	80	Empty, keep. Empty, keep. Marital Status
17	Religion	80	Empty, keep. Empty, keep. Religion
18	Patient Account Number	30	Patient type
19	SSN Number -Patient	16	Empty, keep. SSN Number -Patient
20	Driver's License Number – Patient	25	Empty, keep. Charge type.
21	Mother's Identifier	20	Empty, keep. Mother's Identifier
22	Ethnic Group	30	Ethnic Group
23	Birth Place	60	Empty, keep. Birth Place
24	Multiple Birth Indicator	1	Empty, keep. Empty, keep. Multiple Birth Indicator. Y indicates Yes, N indicates No.

No.	Segment	Length	Explanation
25	Birth Order	2	Empty, keep. Birth Order, which is whole number(larger than 0) .
26	Citizenship	100	Remark
27	Veterans Military Status	60	Empty, keep. Veteran status
28	Nationality	80	Empty, keep. Nationality
29	Patient Death Date and Time	26	Empty, keep. Patient Death Date and Time
30	Patient Death Indicator	1	Empty, keep. Patient Death Indicator. Y indicates Yes, N indicates No.
31	Patient Age	5	Age and age unit. Age and age unit are separated by ^. Age is whole number, length is 3. Age unit is character string, length is 1. Send Y for age, M for month, D for day, H for hour.

Remark: This message segment is only used in ORU^R01. The age segment of 1st ,25th ,31st segment use integer data type. Other segment use character string data type.

2.2.4 OBR Observation Request

OBR segment is used for transmitting doctor's advice related to test report. When transmitting test results of patient's sample,

(MSH-16 take 0), OBR of this interface uses the following fields:

No.	Segment	Length	Explanation
1	Set ID – OBR	10	Confirm different OBR segment.
2	Placer Order Number	22	Placer Order Number, used for sample barcode.
3	Filler Order Number	5	Filler Order Number, used for sample No.
4#	Universal Service ID	200	Universal Service identifier.
5	Priority	2	Priority or not ? Y indicates yes, N indicates No.
6	Requested Date/time	26	Empty, keep. Requested Date/time
7	Observation Date/Time	26	Observation Date/Time, used for test Date/Time.
8	Observation End Date/Time	26	Empty, keep. Observation End Date/Time
9	Collection Volume	3	Used for repeat test times, take 1.
10	Collector Identifier	8	Collector Identifier. Used for sample and position. this segment indicates sample disk No. and sample position.
11	Specimen Action Code	1	Empty, keep. Specimen Action Code
12	Danger Code	1	Danger Code. Used for dilute or not. Y indicates yes, N indicates No.
13	Relevant Clinical Info.	100	Related clinical information, used for patient clinical diagnosis information.
14	Specimen Received Date/Time	26	Send date/time.
15	Specimen Source	1	Specimen Source, used for sample type, such as serum, plasma, urine, etc. 0-Serum, 1-Urine, 2-Plasma, 3- CSF, 4-Gastric juice, 5-Ascites, 6-Other.
16	Ordering Provider	30	Ordering Provider, used for send doctor.
17	Order Callback Phone Number	30	Used for send dept.
18	Placer Field 1	60	Empty, keep. Sample character(jaundice, hemolysis, lipohemia).
19	Placer Field 2	60	Empty, keep. Blood bag No.

No.	Segment	Length	Explanation
20	Filler Field 1	30	Physician-in-charge, used for test doctor.
21	Filler Field 2	60	Empty, keep. Treatment dept.
22	Result Rpt/Status Change – Date/Time	26	Result report date/time.
23	Charge to Practice	40	Empty, keep. Charge to Practice
24	Diagnostic Serv Sect ID	10	Empty, keep. Diagnosis ID.
25	Result Status	1	Empty, keep. Result Status
26	Parent Result	200	Empty, keep. Parent Result
27	Quantity/Timing	200	Empty, keep. Quantity/Timing
28	Result Copies To	150	Empty, keep. Result Copies To
29	Parent	150	Empty, keep. Parent
30	Transportation Mode	20	Empty, keep. Transportation Mode
31	Reason for Study	300	Empty, keep. Reason for Study
32	Principal Result Interpreter	30	Principal Result Interpreter, used for checker.
33	Assistant Result Interpreter	200	Empty, keep. Assistant Result Interpreter
34	Technician	200	Empty, keep. Technician
35	Transcriptionist	200	Empty, keep. Transcriptionist
36	Scheduled Date/Time	26	Empty, keep. Scheduled Date/Time
37	Number of Sample Containers	4	Empty, keep. Number of Sample Containers
38	Transport Logistics of Collected Sample	60	Empty, keep. Transport Logistics of Collected Sample
39	Collector's Comment	200	Empty, keep. Collector's Comment
40	Transport Arrangement Responsibility	60	Empty, keep. Transport Arrangement Responsibility
41	Transport Arranged	30	Empty, keep. Transport Arranged
42	Escort Required	1	Empty, keep. Escort Required
43	Planned Patient Transport Comment	200	Empty, keep. Planned Patient Transport Comment
44	Ordering Facility Name	60	Empty, keep. Ordering Facility Name
45	Ordering Facility Address	106	Empty, keep. Ordering Facility Address
46	Ordering Facility Phone Number	48	Empty, keep. Ordering Facility Phone Number
47	Ordering Provider Address	106	Empty, keep. Ordering Provider Address

Remark: This message is only used in ORU^R01. Sample position segment of the 1st, 3rd ,9th, 10th segment. 15th , 37th segment use integer data type. Other segments use character string data type.

When transmitting QC results(MSH-16 is 2). Its segment definition is as follow:

No.	Segment	Length	Explanation
1	Set ID – OBR	10	Confirm different OBR segment.
2	Placer Order Number	22	Placer Order Number, used for sample barcode.
3	Filler Order Number	5	Filler Order Number, used for sample No.

No.	Segment	Length	Explanation
4#	Universal Service ID	200	Universal Service ID
5	Priority	2	Priority or not, Y indicates yes, N indicates No.
6	Requested Date/time	26	Empty, keep. Requested Date/time
7	Observation Date/Time	26	Observation Date/Time, used for QC date/time.
8	Observation End Date/Time	26	Empty, keep. Observation End Date/Time
9	Collection Volume	20	Empty, keep.
10	Collector Identifier	8	Collector Identifier. this segment indicates sample disk No. and sample position.
11	Specimen Action Code	5	Used for QC times.
12	Danger Code	3	Used for module and inner&outer circle mark. Module and inner&outer circle are separated by ^. 1 indicates outer circle. 2 indicates inner circle. 3 indicates inner & outer circle.
13	Relevant Clinical Info.	20	Used for QC name.
14	Specimen Received Date/Time	26	Empty, keep.
15	Specimen Source	1	Specimen Source, used for sample type, such as serum, plasma, urine, etc. 0-Serum, 1-Urine, 2-Plasma, 3- CSF, 4- Gastric juice, 5-Ascites, 6-Other.
16	Ordering Provider	15	Used for QC lot No.
17	Order Callback Phone Number	10	Used for mean.
18	Placer Field 1	10	Used for standard deviation.
19	Placer Field 2	10	Used for QC result.
20	Filler Field 1	12	Used for result unit.
21	Filler Field 2	10	Used for result mark. If the absolute difference between result and mean is not smaller than SD, and smaller than 2SD, return +1SD(or -1SD); If the absolute difference between result and mean is not smaller than 2SD, and smaller than 3SD, return +2SD(or -2SD); If the absolute difference between result and mean is not smaller than 3SD, return +3SD(or -3SD).
22	Result Rpt/Status Change – Date/Time	26	Empty, keep. Result report date /time.
23	Charge to Practice	10	Used for QC rule If the absolute difference between result and mean is not smaller than SD, and smaller than 2SD, return blank; If the absolute difference between result and mean is not smaller than 2SD, and smaller than 3SD, return 1-2s; If the absolute difference between result and mean is not smaller than 3SD, return 1-3s.
24	Diagnostic Serv Sect ID	10	Empty, keep. Diagnosis part ID.
25	Result Status	1	Empty, keep. Result status.
26	Parent Result	200	Empty, keep. Parent Result
27	Quantity/Timing	200	Empty, keep. Quantity/Timing
28	Result Copies To	150	Empty, keep. Result Copies To
29	Parent	150	Empty, keep. Parent

No.	Segment	Length	Explanation
30	Transportation Mode	20	Empty, keep. Transportation Mode
31	Reason for Study	300	Empty, keep. Reason for Study
32	Principal Result Interpreter	30	Empty, keep. Principal Result Interpreter
33	Assistant Result Interpreter	200	Empty, keep. Assistant Result Interpreter
34	Technician	200	Empty, keep. Technician
35	Transcriptionist	200	Empty, keep. Transcriptionist
36	Scheduled Date/Time	26	Empty, keep. Scheduled Date/Time
37	Number of Sample Containers	4	Empty, keep. Number of Sample Containers
38	Transport Logistics of Collected Sample	60	Empty, keep. Transport Logistics of Collected Sample
39	Collector's Comment	200	Empty, keep. Collector's Comment
40	Transport Arrangement Responsibility	60	Empty, keep. Transport Arrangement Responsibility
41	Transport Arranged	30	Empty, keep. Transport Arranged
42	Escort Required	1	Empty, keep. Escort Required
43	Planned Patient Transport Comment	200	Empty, keep. Planned Patient Transport Comment
44	Ordering Facility Name	60	Empty, keep. Ordering Facility Name
45	Ordering Facility Address	106	Empty, keep. Ordering Facility Address
46	Ordering Facility Phone Number	48	Empty, keep. Ordering Facility Phone Number
47	Ordering Provider Address	106	Empty, keep. Ordering Provider Address

Remark: This message is only used in ORU^R01. Sample position segment of the 1st, 10th segment. Module segment and inner&outer circle mark segment of 11st, 12th segment. The 15th segment uses integer data type. 17th,18th,19th segment use floating number. Other segments use character string data type.

2.2.5 OBX Observation

OBX mainly used for transmitting observed information in report message. If the transmitted data are sample information(MSH-16 is 0), one patient may with many OBX. The OBX segment of this interface use the following field:

No.	Segment	Length	Explanation
1	Set ID – OBX	10	Confirm different OBX segment.
2	Value Type	3	Value Type, used for mark test result type. NM (numeric) indicates numeric value, used for quantify item ST (string) indicates character string value, used for qualitative item.
3#	Observation Identifier	5	Observe identifier, used for item ID number.
4	Observation Sub-ID	16	Observe, Sub-ID, used for item name and repeat test times. Item name and repeat test times will be separated by ^, item name length 12, repeat test times length 3.
5	Observation Value	16	Observe value, used for test result value(result concentration or negative, positive, etc.)
6	Units	12	Unit, used as the unit of test result.
7	References Range	30	Reference range, test result normal range.
8	Abnormal Flags	5	Abnormal mark, whether test result is normal(description)L-low H-high N-normal.
9	Probability	5	Empty, keep. Possibility
10	Nature of Abnormal Test	5	Empty, keep. Used as result mark. F-test result, C-recheck result.
11#	Observe Result Status	1	Empty, keep. Observe result status.
12	Date Last Observe Normal Values	26	Empty, keep. Observe normal value date at last.
13	User Defined Access Checks	16	User-define access check, used for original result.
14	Date/Time of the Observation	28	Observe date/time, used for test date/time.
15	Producer's ID	30	Result producer’s ID.
16	Responsible Observer	30	Responsible observer, used for test doctor.
17	Observation Method	60	Empty, keep. Observe method.

Remark: This message segment presents only in ORU^R01 message. The repeat test segment of 1st, 3rd, 4th segments use integer data type. The 5th, 13rd segment use floating point data type. Other segments use character string data type.

2.2.6 QRD - query definition segment

The ORD segment of this interface use the following fields:

No.	Segment	Length	Explanation
1#	Query Date/Time	26	Time of this query, the system time.
2#	Query Format Code	2	Query format code, query method, take SN(indicates sample No. method)and BC(indicates sample barcode method)
3#	Query Priority	1	Query priority, take D(deferred),.
4#	Query ID	10	Query ID, represents different queries, it increase 1 as the query number increases.
5	Deferred Response Type	1	Empty, keep. Delay response type.
6	Deferred Response Date/Time	26	Empty, keep. Delay response date/time.
7#	Quantity Limited Request	10	Quantity Limited Request, take RD(Records).
8#	Who Subject Filter	30	Who Subject Filter, if QRD-2 is SN, this segment is used as sample No., if QRD-2 is BC, this segment is used as sample barcode.
9#	What Subject Filter	60	Empty, keep. What Subject Filter
10#	What Department Data Code	8	Used as sample rack and position. Sample rack and position will be separated by ^, sample rack length is 4, sample position length is 3. Sample rack and position require LIS to return original value in DSR^Q03.
11	What Data Code Value Qual.	1	Used for dilution, Y indicates conduct dilution, N indicates not conduct dilution. Whether to dilute require LIS to return original value in DSR^Q03.
12	Query Results Level	1	Empty, keep. Query result level, take T(Full results)

Remark: This message segment presents in QRY^Q02. The 4th segment is integer data type. Other segments use character string data type.

2.2.7 QRF - query filter segment

QRF segment and QRD segment shall be used together to further refine original query content. The QRF segment of this interface uses the following fields:

No.	Segment	Length	Explanation
1#	Where Subject Filter	20	Querier place filter.
2	When Data Start Date/Time	26	Record start date/time, used for start time of receiving sample in query.
3	When Data End Date/Time	26	Record end date/time, used for end time of receiving sample in query.
4	What User Qualifier	60	Empty, keep. User mark of conformity.
5	Other QRY Subject Filter	60	Empty, keep. Other QRF receive filter.
6	Which Date/Time Qualifier	12	Target type, take RCT.
7	Which Date/Time Status Qualifier	12	Target status, take COR.
8	Date/Time Selection Qualifier	12	Date/Time Selection Qualifier, take ALL.
9	When Quantity/Timing Qualifier	60	Empty, keep. Time interval segment.

Remark: This message segment presents in QRY^Q02. The 3rd and 4th segments are query zero point of the

day and query occurrence time, which are used for querying time interval condition. All segments use character string type.

2.2.8 DSP - display data segment

DSP segment used for displaying the queried sample information and test item, which can be duplicated. DSP shall repeat 3 times, the 1st DSP segment is patient information, DSP uses the following fields at this time:

No.	Segment	Length	Explanation
1	Set ID - DSP	4	Confirm different DSP segments.
2 - 31	The specific items are same as PID-2 to PID-31 of PID segment		Refer to PID explanation.

Remark: This segment only presents in DSR^Q03. The first segment uses integer data type. Other fields refer to PID-2 to PID-31 explanation.

The second DSP segment is doctor's advice information. DSP will use the following fields at this time:

No.	Segment	Length	Explanation
1	Set ID - DSP	4	Confirm different DSP segments
2 - 47	The specific items are same as OBR-2and OBR-47of OBR segment		Refer to OBR explanation.

Remark: This segment only presents in DSR^Q03. The first segment uses integer data type. Other segments refer to OBR-2 to OBR-47 explanation.

The third DSP is item information, refer to the following table for items and sequence:

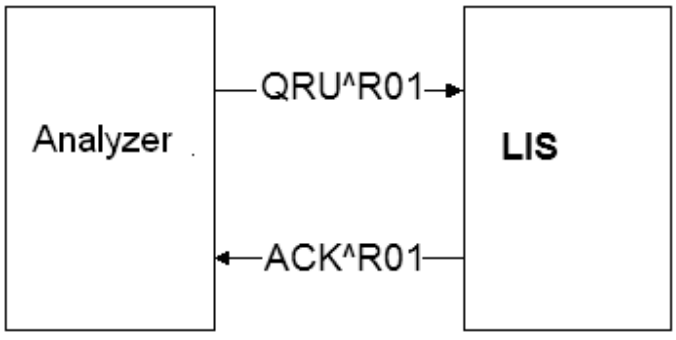
No.	Segment	Length	Explanation
1	Set ID - DSP	4	Confirm different DSP segment.
2	Item Count	4	Test item No.
3	Items	1000	Test item name. The items are separated by ^, such as ALT^ALB^BUN, character string type.

Remark: This message segment presents in DSR^Q03. The 1st, 2nd segments use integer data type. Other segments' type are character string.

3. Communication Demonstration

3.1 Test Data Sending Procedure

Analyzer transmits sample information and test results to LIS server in the unit of sample, namely one sample information and its test results are transmitted together as one message. LIS server will give corresponding response upon this message.

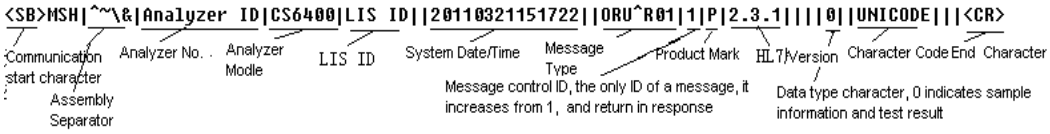


ORU message contains MSH, PID, OBR, OBX(There are many OBX segments if one sample contains many items.).MSH is message head, which presents in all messages.

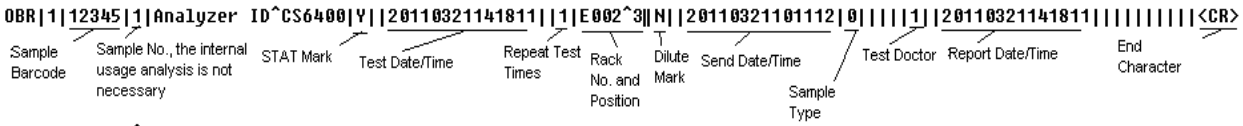
e.g. The following information of one patient:

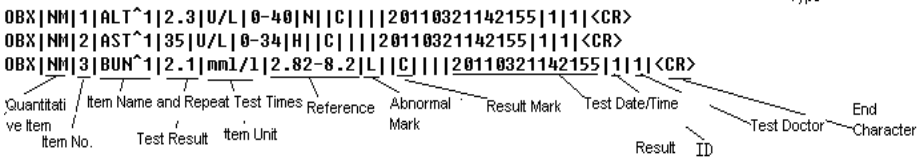
Meaning	Value
Patient Name	Jack
Case No.	002
Gender	Male
Send Date	March 21st, 2011
Send Time	10:11:12(H/M/S)
Sample Barcode	12345
Sample Type	Serum
Sample No.	10
Emergency or not	Yes
Sample Rack No., Position	E002, 3
Age	2
Item No.	1,2,3
Item Name	ALT,AST,BUN
Repeat Test Times	1,1,1
Test Result	2.3,35 ,2.1
Result Unit	U/L,U/L,mol/L
Reference Range	0-40,0-34,2.82-8.2

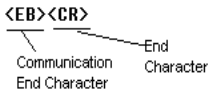
The ORU^R01 message send to LIS is as follow:







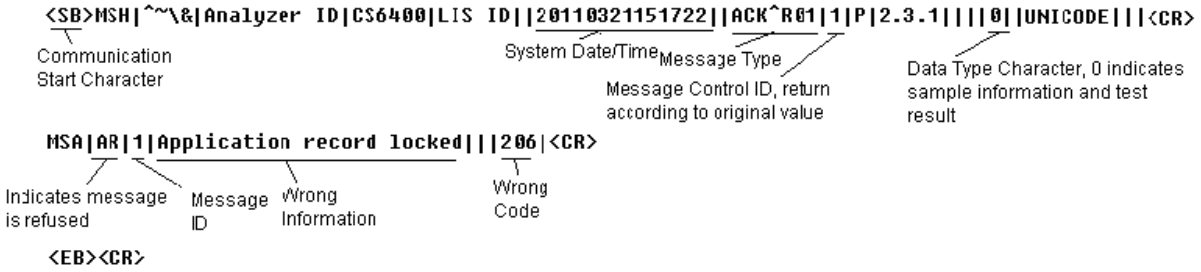




LIS server will judge the validity and type and give corresponding response upon receiving the message. The following is normal response:



If ORU message received by LIS server is incorrect, set corresponding code in MSA to back, analyzer software will conduct corresponding processing. Such as, LIS server found 206 refuse error, its response ACK message is as follow:



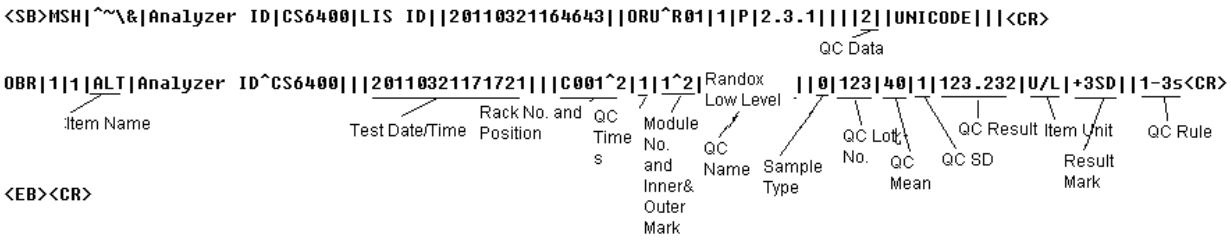
Analyzer transmits QC results to LIS server in the unit of one QC test. LIS server will give corresponding response upon this message.

ORU message includes MSH, OBR.

The following information is of one QC test:

Meaning	Value
Item No.	1
Item Name	ALT
QC Name	Randox Low Level
QC Lot No.	123
QC Times	1
Module No.	1
Sample Type	Serum
Sample Rack, Position	C001, 2
QC Mean	40
QC Standard Deviation	1
Tested Result(concentration)	123.232
Test Date/Time	2011.03.21 16:46:43

The ORU^R01 message send to LIS is as follow:



LIS server give corresponding response:

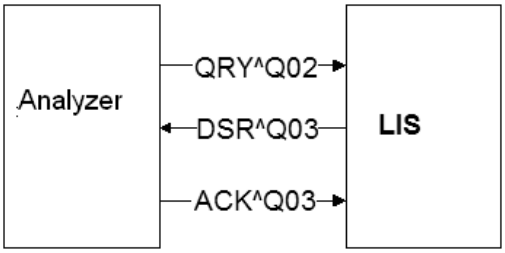
<SB>MSH|^~\&|Analyzer ID|CS6400|LIS ID||20110321164643||ACK^R01|1|P|2.3.1||||2||UNICODE|||<CR>

MSA|AA|1||||0|<CR>

<EB><CR>

3.2 Send Query Request Procedure

Analyzer send query request to LIS server. And obtain corresponding sample information, patient information, item information according to specified barcode.



Such as, download a sample with barcode 12345 from LIS server. Sample rack N003, position 4, no dilution, the send QRY^Q02 message is as follow:

<SB>MSH|^~\&|Analyzer ID|CS6400|LIS ID||20110321170353||QRY^Q02|1|P|2.3.1||||0||UNICODE|||<CR>

System Date/Time; Message Type; Message ID; 0 indicates sample information and test result

QRD|20110321170353|BC|D|1|||RD|12345||N003^4|N|T<CR>

System Date/Time; Query mode, BC indicates barcode mode; Query ID; Sample Barcode; Rack No. and Position,return according original value; Whether to dilute, return according to original value

QRF|CS6400|20110321000000|20110321170353|||RCT|COR|ALL||<CR>

Query Start Date/Time; Query End Date/Time

<EB><CR>

LIS server will return DSR^Q03 as response upon receiving this message. If there is corresponding sample, the message is as follow:

<SB>MSH|^~\&|AnalyzerID|CS6400|HostID|CS6400|20110321170353||DSR^Q03|1|P|2.3.1||||0||UNICODE|||<CR>

Message Type; 0 indicates sample information and test result

MSA|OK|1||||0|<CR>

Succeed Query Mark

DSP|1||002||Jack|^||M|||||||||||||||||||||2^Y<CR>

Case No.; Name; Gender; Age and Age Unit

DSP|2||12345|1|AnalyzerID^CS6400|N||20110321141811||1|N003^4||N||20110321101112|0|||||1||20110321141811||<CR>

Sample Barcode; Sample No.; Test Date; /Time; Repeat Test Times; Rack No. and Position, return according to original value; Whether to dilute, return according to original value; Send Date/Time; Sample Type; Send Doctor; Report Date/Time

DSP|3||3|ALT^AST^BUN|||<CR>

Test Item No.; Test Item List

<EB><CR>

If there is no corresponding sample, the return message is as follow:

<SB>MSH|^~\&|AnalyzerID|CS6400|HostID|CS6400|20110321170353||DSR^Q03|1|P|2.3.1||||0||UNICODE|||<CR>

MSA|NF|1||||0|<CR>

Data mark is not found

<EB><CR>

0 represents sample information and test result

If the QRY message received by LIS server is wrong, such as 206 refuse error presents, the return message is as follow:

<SB>MSH|^~\&|AnalyzerID|CS6400|HostID|CS6400|20110321170353||DSR^Q03|1|P|2.3.1||||0||UNICODE|||<CR>

MSA|AR|1|Error messages|||206|<CR>

<EB><CR>

Refuse Message, Error Message, Wrong Code

Analyzer will send ACK^Q03 as response upon receiving DSR message, the return message is as follow:

<SB>MSH|^~\&|AnalyzerID|CS6400|HostID|CS6400|20110321170353||ACK^Q03|1|P|2.3.1||||0||UNICODE|||<CR>

MSA|AA|1||||0|<CR>

<EB><CR>

Such as, download a sample with No.5 from LIS, sample rack N003, position 4, no dilution, the QRY^Q02 message is as follow:

<SB>MSH|^~\&|Analyzer ID|CS6400|LIS ID||20110321170353||QRY^Q02|1|P|2.3.1||||0||UNICODE|||<CR>

QRD|20110321170353 SN|D|1|||RD|5||N003^4 N|T<CR>

Query mode, SN indicates according sample No. mode

Sample No.

QRF|CS6400|20110321000000|20110321170353 ||RCT|COR|ALL||<CR>

<EB><CR>

LIS return DSR^Q03 message as response upon receiving this message, the message for response is as follow:

<SB>MSH|^~\&|AnalyzerID|CS6400|HostID|CS6400|20110321170353||DSR^Q03|1|P|2.3.1||||0||UNICODE|||<CR>

MSA|OK|1||||0|<CR>

DSP|1||002||Jack|^||M|||||||||||||||||||||2^Y<CR>

DSP|2||12345|5|AnalyzerID^CS6400|N||20110321141811||1|N003^4||N||20110321101112|0|||||1||20110321141811|||||<CR>

Sample No.

DSP|3||3|ALT^AST^BUN|||<CR>

<EB><CR>

Analyzer will send ACK^Q03 as response upon receiving DSR, the return message is as follow:

<SB>MSH|^~\&|AnalyzerID|CS6400|HostID|CS6400|20110321170353||ACK^Q03|1|P|2.3.1||||0||UNICODE|||<CR>

MSA|AA|1||||0|<CR>

<EB><CR>

Remark: During query request sending, analyzer send sample rack, sample position, dilution information at QRD of QRY^Q02 to LIS server. LIS server shall return the three segments according to original value from DSP of DSR^Q03.

Appendix H Reference Table of Reagent Consumption

Detergent Consumption (Unit: μL)

Detergent Name	Anti-Bacterial Phosphor-Free Detergent	Alkaline Detergent
Sample Testing	——	12800
When Each Test Finished	1386	——
Reaction Cuvette Rinsing	——	107900
Power on/Incubation Bath Rinsing	6000	——
Remarks: 80μl will be consumed for every one more test.		

ISE Detergent Consumption: (Unit: μL)

Detergent Name	ISE Detergent
Matching cuvette rinsing	55
Flow cell rinsing	500

ISE Reagent Consumption

Test type	Type of reagent/sample needed	Consumption (μL)
One-time Routine/Emergency	ISE Concentration Quantitative Determination Reference solution	400
	ISE Concentration Quantitative Determination Diluent	900
	ISE Concentration Quantitative Determination Internal Standard Solution	1100
	Sample	55/test
One-time Calibration Test	ISE Concentration Quantitative Determination Reference Solution	4000
	ISE Concentration Quantitative Determination Diluent	9000
	ISE Concentration Quantitative Determination Internal Standard Solution	11000
Electrode Check	ISE Concentration Quantitative Determination Reference Solution	200
	ISE Concentration Quantitative Determination Internal Standard Solution	1100
Internal Standard solution Pipeline Rinsing	ISE Concentration Quantitative Determination Internal Standard Solution	15500
Reference Solution Pipeline Rinsing	ISE Concentration Quantitative Determination Reference Solution	10000
Diluent Pipeline Rinsing	ISE Concentration Quantitative Determination Diluent	13500
All Pipeline Rinsing	ISE Concentration Quantitative Determination Reference solution	10000
	ISE Concentration Quantitative Determination Internal Standard Solution	15500
	ISE Concentration Quantitative Determination Diluent	13500
Matching Cuvette Rinsing	ISE Concentration Quantitative Determination Internal Standard Solution	2000
	ISE Concentration Quantitative Determination Diluent	1800
	ISE Detergent	55
Flow Cell Rinsing	ISE Concentration Quantitative Determination Internal Standard Solution	4000
	ISE Concentration Quantitative Determination Diluent	500
	ISE Detergent	500
Diluent Pump Exhaust	ISE Concentration Quantitative Determination Diluent	1800

Appendix I Accessories List

Name	Position	Replacement Cycle	Replacement Method	Remarks
Halogen Lamp	Optical Unit	2000 hours	10.4.3	
ISE Pinch Valve Tube(ISV3)	Flow Cell Assembly	3 months	10.5.5	
ISE Pinch Valve Tube(ISV4)	Flow Cell Assembly	3 months	10.5.5	
K Electrode Tip	Flow Cell Assembly	6 months/ 15000 tests	10.5.4	
NA Electrode/REF Electrode	Flow Cell Assembly	6 months/15000 tests	10.5.4	
CL Electrode	Flow Cell Assembly	6 months/15000 tests	10.5.4	
ISE Peristaltic Pump Tube	Peristaltic Pump	6 months	Contact the service staff.	Inspect or replace by the representative from the manufacturer or distributor only
Colorimetric Cuvette	Reaction Disk Mechanism	6 months	10.4.2	
Reagent Probe Assembly	Reagent Probe Mechanism	timely	10.4.1	
Sample Probe Assembly	Sample Probe Mechanism	timely	10.4.1	
Mixing Bar	Mixing Mechanism	timely	10.4.5	
Peltier	Cooling Unit	timely	Contact the service staff.	Inspect or replace by the representative from the manufacturer or distributor only
Rinsing Probe 2	Cleaning Mechanism	timely	10.4.4	
Rinsing Probe 3	Cleaning Mechanism	timely	10.4.4	
Wiping Probe 1	Cleaning Mechanism	timely	10.4.4	
Pressure Sensor Assembly	Syringe Pump Unit	timely	Contact the service staff.	Inspect or replace by the representative from the manufacturer or distributor only
Sample Syringe Pump	Syringe Pump Unit	timely	Contact the service staff.	Inspect or replace by the representative from the manufacturer or distributor only
R1 Syringe Pump	Syringe Pump Unit	timely	Contact the service staff.	Inspect or replace by the representative from the manufacturer or distributor only
R2 Syringe Pump	Syringe Pump Unit	timely	Contact the service staff.	Inspect or replace by the representative from the manufacturer or distributor only
ISE Electrode Sealing Ring	Flow Cell Assembly	timely	10.5.4	
Wiping Block	Cleaning Mechanism	timely	10.4.4	