PKL PPC 125

Automatic Chemistry Analyzer

User Manual

CE

Contents

Copyright: MR INTERNATIONAL HEALTHCARE TECHNOLOGY CO., LTD.

Thank you very much for your purchase of the MR Automatic Chemistry Analyzer.

All contents of this manual are complied with the related laws and regulations of the People's Republic of China, as well as the specific conditions of the MR Automatic Chemistry Analyzer. All the updated information is included in this manual before printing. MR is fully responsible for the revision and explanation of this manual, and reserves the right to renovate the relevant contents without separate notice. Some of the schematic pictures in this manual are for reference, if there is any difference, please according to the real object.

All instructions must be followed strictly during operation. In no event should MR be responsible for failures, errors and other liabilities resulting from user's noncompliance with the procedures and precautions described in this manual.

Guarantee of limited quality liability: The Operating Manual of MR Automatic Chemistry Analyzer has been clearly shown the guarantee of quality liability between MR and users, rights and duties in the after sale service and starting and ending of the agreement.

If a malfunction occurred under normal use because of the material and workmanship, MR will provide one year's warranty service from the date of installation to this instrument which sold by MR and agents. The using period of this instrument is 10 years.

Once the following situations occurred, MR assumes no liability to the safety, reliability and operation condition of the instrument, and all agreed right of free service is deem to be waived permanently and unconditionally.

- Instrument under improper use or not by maintenance or has been damaged.
- Using the reagents and accessories not supplied or approval by MR.
- Instrument damage caused by false operation or negligence because of user or others operates the instrument not comply with this manual.
- Replace accessories not specified by MR, maintaining, repairing by a personnel who does not authorized by MR.
- Components are discounted, drawing and readjusted not approved by MR.

NOTE

MR makes no warranties, either express or implied, as to product quality, performance, and value as a commodity or applicability for any particular purpose.

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CE

Version: 01/2017

PREFACE

This document is the operating manual for MR Automatic Chemistry Analyzer. It describes the structure, operation, maintenance and troubleshooting concerning the instrument in details. Users should read carefully the manual and get special training before operating to guarantee instrument precision, normal operation and personal safety.

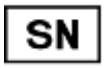
Safety Symbol

Following are the safety symbols which used together with character in the manual.

Marking	Meaning
 **Warning**	Operator should operate under the manual otherwise serious injury maybe caused or even lost life. Serious injury involving go blind, trauma, burn (excess temperature), electric shock, cataclasis, toxication and other sequela.
 **Caution**	System damage or incorrect result may cause if not comply with the manual to operate.
 **Note**	Following the manual to avoid personal injury, physics damage and a series of adverse impact on test results. Also point out source of infection. Personal injury involving mild burns, electric shock or drug allergy. Physical damage involves damage to building, animal and pet.
 **Biohazard**	Biohazard means the biological factor may be caused hazard to the environment and organism.

Sign Illustration

Meaning of the signs used in Automatic Chemistry Analyzer is as following.

	Caution. Refer to the accompanying document		Caution. Electric shock
	Caution. Hot surface		Biohazard
	Protective earthing		Power on
	Power off		In vitro diagnostic medical device
	Environmental protection lifetime		Keep away from heat and radioactive source
	Serial number		Manufacturer
	Recovery		May cause personal injury

	Refer to the operating manual		

Safety Cautions

Please comply with the following rules for safety and effective use.

Prevent Breakage and Flammability

Please comply with the following precaution to prevent breakage.

CAUTION

1) Installation should be complied with installed instruction of the manual.
2) If relocation is necessary, contact your local distributor or MR firstly.

Prevent Electric Shock

Please comply the following precaution for preventing electric shock.

CAUTION

1) Users other than the servicing personal authorized by our company must not open the rear cover and left/right cover when turn on the power.
2) If a spill occurs or liquid gets into the instrument, please contact MR. Neglecting the liquid may cause electric shock.

Prevent Personnel Injury

Please comply the following precautions for preventing injury.

CAUTION

1) While the instrument is in motion, DO NOT touches the moving parts, such as aspirating probe and stirrer, etc.
2) DO NOT put your finger or hand into the open part of instrument.

Eyes Protection

Please comply with the following precaution for eyes protection.

CAUTION

1) DO NOT directly look at the light emitting from the lamp source when the instrument is in motion.
2) Turn off the power and wait for at least 15 minutes until the light source is cooling before replacing light source to prevent scald.

Precision and Accuracy of Data

Please attention the following matters for getting the accurate data.

CAUTION

1) DO NOT open the top cover, rear cover and reagent tray when the instrument is under analyzing condition.

2) Please check the accuracy of instrument by quality-control before using.

3) Please comply with the manual to maintain, check and replace the assembly unit.

4) Please comply with the corresponding explanation to handle the reagent, quality-control materials and reference materials.

5) Please handle the sample according to the requirements in the manual.

Chemical and Biological Safety

Please comply with the following matters for chemical and biological prevention.

Biological Hazard

If chemical adheres to the human body, contagion may occur. DO NOT touch the sample, mixed solution and waste solution directly. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the sample splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

CAUTION

Some reagents are strong acid or alkaline. Please use them carefully avoiding direct contact. If the reagent spill to the human body, immediately washes it off with water and soap. If the reagent splashes into eyes accidentally, wash it off with water and consult an oculist.

Handle Waste Solution

Please comply with the following matters when handle the waste solution in order to avoid personal injury and protect environment.

Biological Hazard

1) Some substances contained in QC solution, standard solution and waste solution are regulated by discharge standards and pollution control regulations, waste must be disposed according to the relevant environmental protection regulations.

2) Be sure to put on protective gloves, clothes, or even goggles if necessary when dispose waste solution.

System Dispose Hazards

Please comply with the following matters to dispose of the waste analyzer.

CAUTION

Materials of the analyzer are subject to contamination regulations. Dispose of the waste analyzer in accordance with your local or national rule for waste disposal.

Fire and Explosion Hazards

Observe the following instructions to prevent fire and explosion.

CAUTION

Alcohol is flammable substance. Please exercise caution while using alcohol.

Using Precaution

Systematic Usage

CAUTION

1) Automatic Chemistry Analyzer is intended use for medical institution and laboratory to analyze some specific chemical composition of human body fluid. If the instrument to be used beyond this scope, consult MR firstly.

2) Please consider together with the clinical symptom or other analyzing result when make the clinical judgment.

Operator

CAUTION

The instrument is operated only by technicians, doctors and laboratory personnel that trained by MR.

Operational Environment

CAUTION

1) Please install the instrument according to the specified installed instruction in the manual. Otherwise, the results may not reliable even may cause system damage.

2) Please contact MR if system state is changed.

Caution on Electromagnetic Wave Interference

CAUTION

1) Keep the instrument away from strong noise source and electromagnetic wave. Turn off mobile phones and transmitter-receiver when operating the instrument since the electromagnetic wave may cause an adverse effect on instrument.

2) Do not use other medical instrument around the system that may generate electromagnetic wave interfere with their operations.

Indication for System Use

CAUTION

1) The operator must training before operating the instrument. Please follow the instruction of manual to operate. Improper operation may cause personal injury, system damage and improper result.

2) Please make a calibration and quality-control test before use the system for the first time to ensure it can be used normally.

3) A quality-control test must be done when use the system. Otherwise, the reliability of the result could not be guaranteed.

4) Do not open the sample/reagent cover while in the analyzing process.

5) The communication joint of analytical part is set to connect with the communication joint of operational part. Please use the cables of MR for connecting.

6) The operation part is an external computer which is installed the specified operational software. The computer should be for the instrument exclusive use. DO NOT run any other software when it is connected with the instrument. Inappropriate manner may result in computer virus infection

7) DO NOT touch the keyboard, indicator and mouse when your hands is wet, also includes the chemistry.

System Maintenance

CAUTION

1) Maintaining according to the instruction. Incorrect maintenance may lead to wrong result even caused system damage and personal injury.

2) Dust may be there after long-time placement. Cleaning the surface by soft cloth or little soap solution if necessary. Never use organic solvent such as alcohol. Wipe the surface after cleaning. Please turn off all the power supply and pull up the plug before cleaning. Take measures to prevent water into the system, otherwise, will cause system damage or personal injury.

3) Calibration analyses must be done when changed the light source, optical system, sample needle, reagent needle, stirrer and any other major component.

4) Please turn off the power and wait the light is cooled down to avoid scald.

Setup of Parameters

CAUTION

To define such parameters as sample volume, reagent volume and wavelength, follow the instructions in this manual and the instruction of reagents.

Precaution for Handling Samples

CAUTION

1) Sample must not contain insoluble substances such as fibrin and dust. Coagulation and imply may block the aspirating probe thus causing bad effect on tests. Medicine, anticoagulant, preservative exist in sample may influence test result, hemolytic, icterus and cycle also will cause incorrect result. Suggest do background test.

2) Store the sample correctly. Sample structure will change and even caused incorrect result in wrong storage.

3) DO NOT expose samples in the air for a long time because they may be contaminated or boiled off and thus erroneous test result may occur.

4) Certain sample cannot be analyzed please contact reagent supplier for details.

5) Certain sample need to be preprocessed please contact reagent supplier or distributor.

6) Consult manual for sample volume when do the test.

7) Ensure sample positioned correctly before test, if not bad result may occur.

Handling Reagents, Calibration and Control

CAUTION

1) Proper reagent, calibration solution and control solution are needed for analyses.

2) Please choose correct reagent. Consult the manufacturer or distributor if uncertain about the usage of reagent

3) For storage, handling and usage of reagent, standard solution and control serum, refer to the Instruction for Use provided by their manufacturers. Improper storage may not guarantee the accuracy of test result even though they are not expired.

4) Be sure to perform calibration when replacing reagent. Otherwise, inexact test result may occur.

5) Cross-contamination among reagents may influence test results. Contact your reagent supplier for details.

Data Back Up

CAUTION

Please backup the analysis data and measurement parameters regularly.

Other Cautions

CAUTION

1) DO NOT touch the keyboard, indicator and mouse when your hands is wet, also includes the chemistry.

2) Check samples for contamination (dust, or fibrinogen) and air bubble before analyses.

3) For replacements of major parts, such as light source lamp, aspirating probe, reaction cuvette, etc., please contact MR.

4) For settings of sample volume, reagent volume, wavelength, standard values, etc., Please refer to the instruction in reagent kit as well as this operating manual. Checking the quality of distilled water and detergent, check calibration results, control results, and sample results after analyses. Make sure there is no air bubble in the flow paths.

Chapter One Installation

1.1 Preparation

CAUTION

Only the MR technician can perform the installation of instrument.

Only the MR technician can perform the installation of instrument, users shall make preparation for satisfying the installation requirements in accordance with this manual before installation. If relocation is necessary, please contact your local distributor or MR.

1.1.1 Pre-installation Checking

When you receive the system, carefully inspect the package .If you see any signs of damage，file a claim immediately with our Customer Service Department or your local distributor.

After opening the package, check the delivered goods against the packing list as well as the appearance of the system. If you find anything missing or damaged, alert our Customer Service Department or your local distributor immediately.

1.1.2 Installation Requirements

Caution：

●The analyzer should be installed in place to meet the following conditions. Otherwise, it can not guarantee that the analytical performance.

1) Installation Environment Requirements

Instrument is for indoor use only.

Bearing platform (or ground) should be level (gradient less than 1/200).

Bearing platform (or ground) should be able to bear 30Kg weight.

Site of installation should be well ventilated

Notice：

●Working environment of instrument should be well ventilated to ensure that heat, if necessary, ventilation can be used. But should avoid direct airflow blowing analyzer, or may affect the reliability of data.

The installation site should be free of dust as possible.

The installation site should avoid direct sunshine.

The site should not be near a heat or draft source.

Site of installation should be free of corrosive gas and flammable gas.

Bearing platform (or ground) should be free of vibration

The site should not be disturbed by large noise or power supply.

The system should not be placed near brush-type motors and electrical contacts that are frequently turned on and off.

Do not use such devices as mobile phones or radio transmitters near the system.

The altitude height of the installation site should be lower than 3000 meters.

Caution：

●The current direction of inclination greater than 8 degrees, the analyzer of the dumping of hazardous and may cause damage. You should take the necessary protective measures in the storage, handling and other process

2) Power Requirement

Power supply：100-240V，50/60Hz，the power should be more than 300W

Three-wire power cord should be grounding properly.；

Instrument should be connected to a properly-grounded power socket. to provide the required power.

The distance between the power socket and the system should be less than 3 meters.

Caution：

●Power should be properly grounded. Improper grounding may cause electric shock and analyzer damage

●You should confirm that the power outlet output voltage meet the requirements of the analyzer, and has installed the appropriate fuse.

3) Temperature and Humidity Requirements

3.1) Storage Temperature and Humidity

Storage temperature: -10℃~55℃,with fluctuation less than ±2℃/H;；

Storage relative humidity: ≤95%RH, no dew.

Notice：

●Exceeds the instrument storage temperature range may result in damage to the analyzer.

3.2) Working Temperature and Humidity

Working temperature: 10℃~35℃, with fluctuation less than ±2℃/H;

Working relative humidity: ≤90%RH, no dew.

Notice：

●You must operate analyzer within the specified environment, humidity, temperature range; otherwise the results may not be reliable.
●If the ambient temperature, humidity exceeds the above range, can be used the air conditioning equipment

4) Water Supply and Drain Requirements

The water must meet requirements of the GB-6682 Ⅲ grade water.；

The water temperature should be 5-50 ℃；

If water-purifying equipment is used, the pressure at water source should be within 49kPa-392kPa.

Bio-hazard：

●Liquid waste discharged by instrument should be handled according to local emission standards.

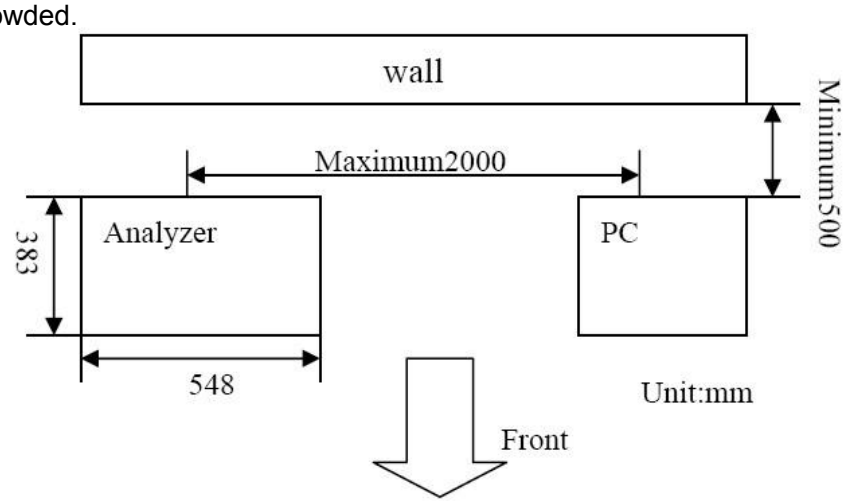
Notice：

●The water quality must meet the requirements of the GB-6682 three-grade water, otherwise the lack of water pMRy may interfere with test results.

5) Space and Accessibility requirements

The system should be installed and used meeting the space and accessibility requirements as shown below.

The laboratory should be large enough, so that the analyzer and computer will not be crowded.



1.2 Installation

After unpacking, please take out the chemistry analyzer from the packing, and put it in a flat surface.

1.2.1 Connecting Water Supply Bucket

Bio-hazard：

●While operating, you must wear gloves, wear overalls to prevent them from being infected, if necessary, wear protective glasses.

Caution：

- When placing distilled water bucket, the bucket can not be higher than the bottom of the upper cabinet at the top of the analyzer.
- Ensure that the water conductivity of the deionizer liquid pipe flow does not bend, twist.
- Note: there are two plastic pipes in the distilled water sensor subassembly; the tube which is connected with long plastic pipe should connect with water interface which is making up arrow. And the tube which is connected with short plastic pipe should connect with water interface which is marked down arrow. Like the up pictures.

1.2.2 Connecting Waste Bucket

 **Bio-hazard:**

●While operating, you must wear gloves, wear overalls to prevent them from being infected, if necessary, wear protective glasses.

 **Caution:**

●When placing waste water bucket, the bucket can not be higher than the bottom of the upper cabinet at the top of the analyzer.
●Ensure that waste catheters are all located above the waste container, and smooth, does not bend, twist. Otherwise may be due to drain poor result of the waste liquid overflow from the panel of analysis division, can cause serious damage to the analyzer.

1 Confirm that the Analysis Division of the power is turned off
2 Make the waste liquid bucket to a right place which is under work desk.
3 Lotus head on the barrel plug in side panel of the lotus throne.
4 Let the liquid level sensor into waster liquid bucket.

1.2.3 Installing/Removing Sample-Reagent Disk

 **Warning:**

●Before inserting or removing the sample / reagent tray please make sure that the analyzer stops working or is turned off, the sample / reagent tray is stopped.

 **Bio-hazard:**

●While operating, you must wear gloves, wear overalls to prevent them from being infected, if necessary, wear protective glasses.

Be sure the two pins of disk is insert to the position.

1.2.4 Installing/Removing Sample Tubes

Warning:

●Before installing or removing the sample test tube / cup, you should confirm that the sample / reagent tray, sampler needle are in the stopped state.
●Do not use the sample containers but only specified.

Bio-hazard:

●While operating, you must wear gloves, wear overalls to prevent them from being infected, if necessary, wear protective glasses.

To load sample tubes, insert the tube into the tube holder until the bottom of the tube contacts the groove of the tube rack.

To remove sample tubes, grab the tube and pull it upward to remove it from the tube holder.

1.2.5 Installing/Removing Reagent Bottles

Warning:

●When installing the reagent bottle, you should confirm that the sample / reagent tray, sampler needle are in the stopped state.

●Do not use the sample containers but only specified.

Bio-hazard:

●While operating, you must wear gloves, wear overalls to prevent them from being infected, if necessary, wear protective glasses.

To load reagent bottles, insert the bottle into the bottle holder until the bottom of the bottle contacts the groove of the holder to remove reagent bottles, grab the bottle and pull it upward to remove it from the bottle holder..

1.2.6 Installing/Removing Reaction Cuvette

Bio-hazard:

●While operating, you must wear gloves, wear overalls to prevent them from being infected, if necessary, wear protective glasses.

●Abandoned reaction cup shall comply with the relevant provisions for proper handling.

Align the positioning column in a row on the reaction cup bracket holes on the reaction plate, and then tighten the set screw to mount joint reaction cuvettes by Installed one by one.

Rotary positioning screws, pick up reaction cuvette bracket, you can take out a joint reaction cuvette, then replace the cuvettes.

Chapter 2. Introduction

2.1 Working Principle

Working principle of analyzer: conduct qualitative and quantitative analysis for certain substance by testing the light absorbance of it in certain wavelength or wavelength range. When a bunch of monochromatic light emitting from a certain photo source radiates into the liquid to be tested, some of the optical signal of transmitting light are absorbed, and others are transferred into electric signal. Through operation and transition, the amount absorbed by the material is in proportion to the concentration and the thickness of liquid layer (the light path length), thereby we get the concentration (A) of the material tested.

The relation is as following formula:

$A=-\log(I/I.)=-\lg T=kCL$

In this formula: A is absorbance;

I.is the strength of monochromatic light radiated into the material;

I is the strength of monochromatic light of transmitting light;

T is the transmittance of material;

k is absorption coefficient;

L is the optical path of the material tested;

c is the concentration of the material.

Below is the construction of the raster, the spectral style of PPC175 is optical filler

2.2 General Introduction

Design Philosophy of Biochemistry Analyzer: the reaction generated substance absorb the special spectrum created by reaction resultant in ultraviolet radiation and visible light region on the basis of Lambert—Beer law, compare the sample with unknown concentration and standard substance with known concentration, or carry out quantitative analysis according to Moore coefficient method

When a monochromatic light pass the colored solution, a part of incident light is reflected by the vessel and a part is absorbed by the liquid and another part permeates the liquid. The relations are as follow:

Io=Ia+Ir+It……（1）

Io—incident intensity

Ia—Absorbing light intensity

Ir—intensity of reflected light

It—intensity of permeation light

All the cuvettes are of same material and specification in the actual test, so the intensity of reflected light is a fixed value, and it won't cause test error. So we don't need consider the influence of reflected light. And the above formula can be simplified as:

Io=Ia+It……（2）

We can know from formula (2) that: when "Io" value is fixed, if "Ia" is bigger, then "It" is smaller; that is to say, the recede of the light intensity is only related with the absorbance of the colored solution.

Then what factors are related with the light absorbance of the solution? experimental evidence: C（concentration of the solution） is bigger, then the L (thickness of the liquid) is thicker. Then the solution can absorb more light. The relationship between them is decided by the following formula:

lg= KCL……（3）

This is "Lambert---Beer" law, K means light absorption coefficient; it means the absorption of the colored solution in unit consistence and unit thickness. If wavelength of the incident

light, the solution type and temperature are fixed, then “K” value is fixed. Absorption coefficient is an important feature of colored chemistry compound, and it has important function in colorimetric analysis. If K is bigger, then it means the substance have stronger absorption power of light. And the change of consistence will cause significant change of absorbance, so the sensitivity will be higher during the colorimetric testing.

“Lambert---Beer” law means the absorbency of colored solution to the light. It is direct ratio with the liquid thickness and consistency of the colored substance in the solution. “Lambert” law explains the relationship between light absorbing and thickness, Beer law explains the relationship between light absorbing and consistency.

2.2.1 Appearance

PKL PPC125 Biochemistry analyzer【Please see below picture】

2.2.2 Main parts

1）Lamp: halogen lamp, 20W,12V, running time more than 2000hours.

2）Syringe pump: sample and reagent aspiration, 500ul volume.

3) Aspirating mechanism: aspirating quantitative volume of reagent from reagent bottle and inject to cuvette; then aspirating quantitative sample from sample cup and inject to cuvette. The aspirating is mechanism with liquid level sensing function.

4) Stirring Mechanism: Stirs the reaction solution contained in reaction cuvettes.

5) Sample Tray: Convey sample cup to sample aspirating point and place cup.

6) Reagent Tray: Convey reagent to aspirating arm, with cooling function.

7) Washing Pool: Omni directionally wash the stirrer and aspiration probe.

8) Reaction Tray: Fixed the cuvette. Sample and reagent reacted in the fixed cuvette in 37℃ thermostat meanwhile colorimetric directly.

9) Barcode scanning function (Optional): to indentify the sample test tube and reagent bottle, and coding for the tube and bottle.

2.2.3 Technical Parameter

Test speed	200test/h
Chemistry on board	39items，one diluent position.
Analysis method	End points, Fix-time (two points) , Kinetic, Colorimetry, Turbidimetry, Two wavelength, Double reagent, multi-standard etc.
Sample disc	40 sample positions，sample can be placed randomly , including standard QC, emergency , can use original tube or serum cup
Reagent disc	39 reagent positions, 1 diluent position, 20ml reagent bottle, with water cycle refrigerated compartment function.
Sample volume	1.5-50μl，0.1μl step
Reagent volume	R1 150μl～300μl， R2 10μl～250μl， 1μl step
Reaction volume	180μl～350μl
Emergency sample	Insert emergency sample randomly and can be tested with priority
Sample probe	Liquid level detection; system could test automatically the surplus in the reagent bottle; collision protection; trace facility;
Cleaning system	Automatic 7-step cleaning, cuvette drying automatically, spring style internal/external auto cleaning
Automatic syringe and retest supported.	
With independent stirring arm, stirring immediately when sample is added; for double reagent, stirring immediately after R2 is added. And using the aspirator needle sucking up and down to mix optional if stirrer not work.	
Reaction disc	60 reusable UV plastic cuvettes
Reaction Tem.	37±0.1˚C，temperature fluctuating should be ±0.1˚C
Reaction cuvette	5mm×6mm×25mm, optical path 5mm
Reaction liquid total volume	180~350μl
Max. reaction time	12minutes
Optical system	Static optical fiber transit system, optical filter style , multi-wavelength spectrophotometer; back light style
QC	Multi QC function, can insert QC randomly; QC diagrams can be stored, displayed and printed; Can pre-set up different QC material; every test can take 3 different QC material.
Light source	12V, 20W halogen lamp, halogen lamps, tungsten iodine lamp
Wavelength （The actual Wavelengths of each machine are with √ ones at right table.)	With 9 wavelengths 340nm ,405nm,450nm, 510nm,546nm,578nm, 620nm,660nm,690nm
Detecting cycle	18 seconds

Absorbency linearity	0.0000～4.0000Abs
Wavelength accurate	±2nm
Repeatability	CV ≤ 2.5% (CV stands for coefficient of variation.)
Stability	within one hour , absorbance change is less than 0.01
Power supply	110 or 220V,50/60Hz, three-cores power cord, well grounded
Fuse	T10A, 250V
Input power	300VA
Operating system	Windows XP or Windows 7,8,10
Data processing	Can edit and store more than 300 testing parameter. And the patients' information can be stored infinitely, depends on the volume of the computer hard disk
Printing	Multi-format printing modes are available for choosing
Storage environment	Tem.: -10˚C～55˚C
	Humidity: ≤95%RH, no dewdrops
	Atmospheric pressure: 50kPa～106kPa
	Altitude : below 3000m
Working environment	Tem.: 10˚C～ 30˚C
	Humidity: ≤90%RH, no dewdrops
	Atmospheric pressure: 70.0kPa～106.0kPa
	Altitude: below 3000m
Dimension	415mm(W)*565mm(L)*385mm(H)
Weight	N.W.:28kg
Input and output devices	PC keyboard
	PC mouse
	Printer
	Screen
Communication interface	Instrument / computer : RS-232C, network port (can be expanded))

2.3 Reagent

Please refer to the user manual about the usage of reagent, and here we will give a brief introduction on classification and principle of reagent.

2.3.1Reagent Classification

Reagent can be classified into:

1) Powder Reagent

It needs to be dissolved with buffer solution or distilled water (deionized water) in operation, then start testing.

2) Single Liquid Reagent

It can be directly used without any prior treatment and only one type is enough

3) Double (multi) Reagent

It can be directly used without any prior treatment, but two or more types of reagents are needed.

The superiority of double reagent:

3.1) Storage stability can be improved because of separate storage of reagent I (R1) and reagent II (R2).

3.2) Accuracy of testing result is ensured. The double reagents method can eliminate interfere of non-specified chemistry:

For example: when testing serum ALT, the original keto-acid in serum can react with reagent LDH to lead to result on the high side. However, you add non α-ketoglutaric acid reagent (R1) firstly getting the original keto-acid reacting with LDH, then you add reagent with α-ketoglutaric acid (R2) and ALT enzyme catalysis begins and pyruvic acid is created. The pyruvic acid will react with LDH, and the consumed NAD+ can reflect the ALT activity, so the side reaction will be eliminated.

2.3.2Reaction Principle of Reagent

1）End Point

1.1) Common Reagent for this method

Total bilirubin, conjugative bilirubin, total protein, albumin, glucose, uric acid, CHOL(cholesterol), triglyceride, high density lipoprotein cholesterol, low density lipoprotein, calcium, phosphorus, magnesium etc.

Analyte turns to product in the reaction, and when it reaches reaction end point, we could get the concentration of this substance based on the magnitude of absorbance. This is called end point.

Actually, it would be more proper to name it balancing method. In the curve of time—absorbance, when it reaches end point or balancing point, the absorbance does not change any more. It is easy to set parameter, and the longer the time of reaction, the more accurate the result is.

1.2) Determination of time of end point

Based on curve of time—absorbance

Based on reaction endpoint of analyte integrating with the reaction situation of distractors

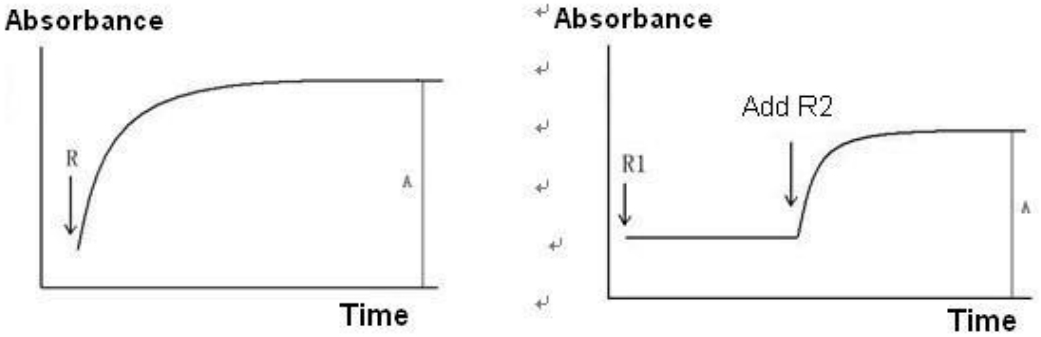
One Point End Assay

When the reaction reaches the end point, the absorbance does not change any more on the curve of time—absorbance, choose a value of end point absorbance on the curve to calculate the result.

The formula is: the concentration of analyte CU= (analyte absorbance AU—reagent blank absorbance AB) ×K

K—calibration factor

Chart 1 Reaction Curve of One Point End Assay



A: Single Reagent **B: Double Reagent**

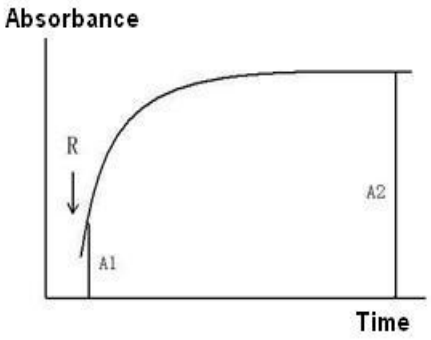
Two Points End Assay

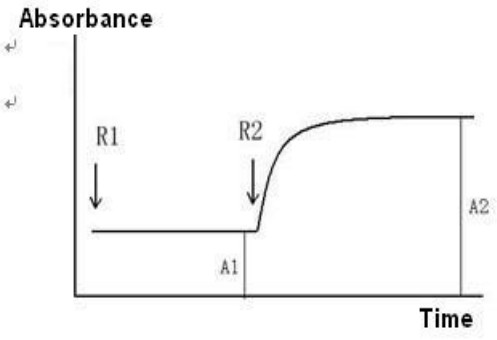
Before the reaction of analyte, choose the first absorbance, and when the reaction reaches end point or balancing point, choose the second absorbance, calculate the result based on the difference between the two points.

The formula is: the concentration of analyte CU= (absorbance to be tested A2—absorbance to be tested A1) ×K

K—calibration factor

Chart 2 Reaction Curve of Two Point End Assay





A: Single Reagent **B: Double Reagent**

This method can effectively eliminate the interference caused by the light absorption of such samples as hemolysis, icterus and lipo-turbid.

2) Two points

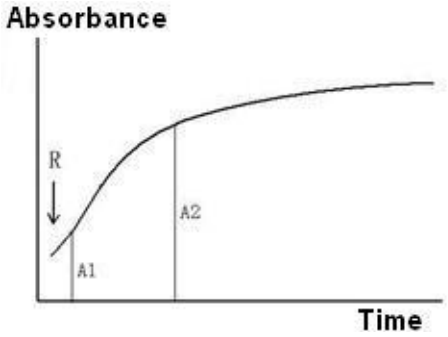
Reagent for this method: creatinine, urea, bile acid.

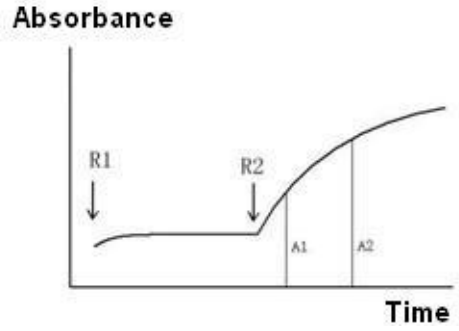
Choose two photometry point on the curve of time—absorbance. The two points are neither beginning absorbance nor end point absorbance. The difference between absorbance of the two points is used to calculate the result. This method is sometimes called two points. Formula is the same with two points end assay:

CU=(A2-A1) ×K

K—calibration factor

Chart 4 Reaction Curve of Fixed Time



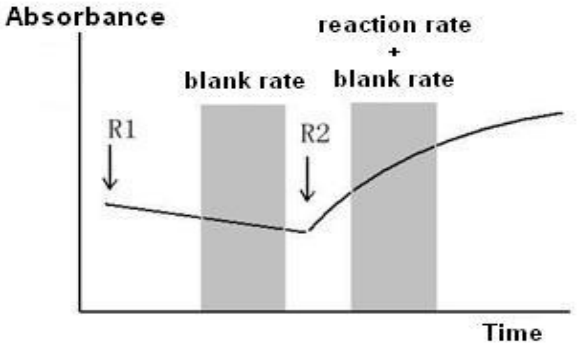


A: Single Reagent **B: Double Reagent**

(This method helps to solve the problem of some reaction non-specificity)

For example: the creatinine test of picric acid. Set blank rate to eliminate the influence of bilirubin. If set the reagent blank rate within a period of time after adding the first reagent, due to the picric acid hasn't react with creatinine yet in this period, and the bilirubin has been converted by oxidation in the alkaline environment of the 1st reagent, so can eliminate the negative influence of bilirubin after the rate change of 2nd reagent minus the change of reagent blank rate. Please refer to the following chart:

Chart 5 Blank rate method eliminate the influence of creatinine test caused by bilirubin

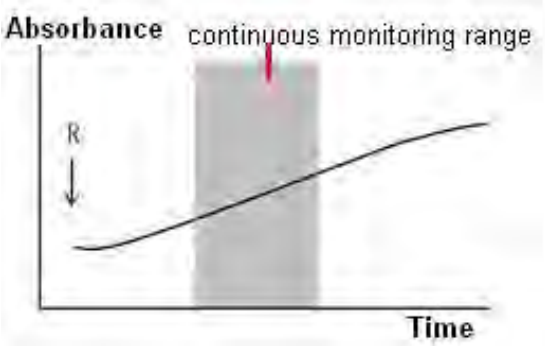


3) Kinetic Method

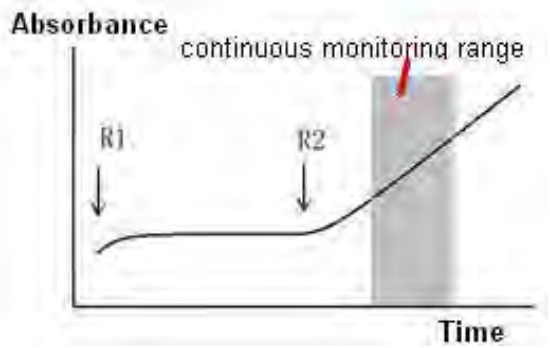
Generally adopt continuous monitoring method (also called rate method) for enzyme assay, such as alanine aminotransferase, aspartic transaminase, lactic dehydrogenase, alkaline phosphatase, Pancreatic enzyme acyl transfer γ ammonia, amylase, HBDH, cholinesterase, acid phosphatase, CKMB and creatine kinase and so on.

Rate method, is to choose the absorbance value continuously in time-linearity section in the absorbance curve (the D-value between every two point is the same) when test enzymatic activity or test the metabolin by enzyme, and calculate result based on the change rate of unit absorbency(ΔA/min).

Chart 6 Reaction curve of rate method



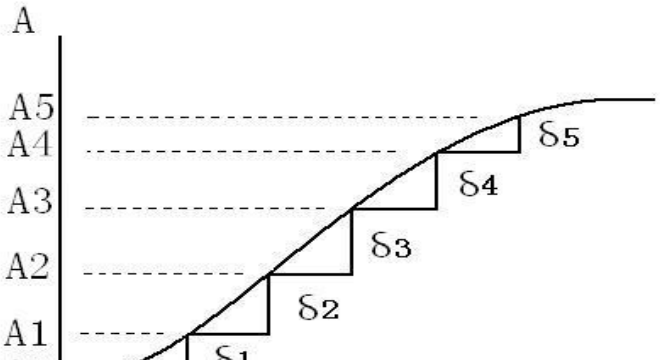
A: Single reagent



B: Double reagent

① Linearity section of enzymatic reaction

Chart 7 Linearity section of enzymatic reaction



② Advantages of rate method:

Can confirm the linearity period and calculateΔA/min, and to calculate the enzymatic activity accurately according to this value; so this make the automatic chemistry analyzer observably superior to the manual method when test the enzymatic activity. Continuous monitoring method is also used for testing the concentration of linearity reaction metabolin which are normally resulted by some enzyme test.

enzymatic activity（U/L）＝ΔA/min× theory（o calibration）K value

concentration of metabolin CU =ΔA/min×calibration K value

③ Theory K value

It is usually used for enzyme assay, for there have no recognized calibration substance for enzymatic activity. We can get the formula of enzymatic activity according to the international definition of unit enzymatictivity:

enzymatic activity（U/L）＝ΔA/min×calibration K value

In this formula use K, theory K value, as analysis parameter to input to the analyzer equipment

a.The premise of adopting theory K value:

The dosage of sample and reagent must be accurate; the light diameter of the colorimetric cuvette is accurate; the temperature control is accurate and the wavelength is accurate. But actually, due to the difference of the stepping motor accuracy and width of the optical filter between different models instruments, this may cause the error of sample and reagent volume and absorbance testing; and the influence of temperature is large sometimes.

b. Actual Moore absorptivity and K value testing

Due to the Moore absorption coefficient is influenced by cuvette light diameter and wavelength, so the Moore absorptivity in this manual or which is provided by the reagent manufactory maybe are a little different from the actual Moore absorptivity tested by instrument. So it is necessary to get the actual Moore absorptivity, and then calculate the theory K value accordingly.

NADH（NADPH）Moore absorptivity testing:

NADH（NADPH）has no standard pure product, and the stability of the solution is not so good, so we can't directly use NADH or NADPH standard liquid to calibrate the instrument. Must do NAD+(NADP+) reaction.

When use hexokinase (HK) or glucose-6-GD method to test the glucose, the consumption of glucose keeps equal Moore relations with NADH. The glucose has standard pure product. According to the formula A=εbC, the cuvette's light diameter and glucose standard liquid's concentration, to test the absorbance of glucose standard liquid A, and then to calculate t he NADH's (NADPH) Moore absorptivity εis A/bC.

The concentration of the glucose standard liquid is 1Ommo1/L(0.01mol/L), the adding volume of the standard liquid is 3.5μL, the add volume of enzyme reagent is 335μL, the light diameter of the cuvette is 0.7cm, the absorbance is 0.465 at the 340nm, then the actual tested NADH Moore absorptivity is 6424. That means at the wavelength of 340nm on this instrument, the tested Moore absorptivity is 6424, but on theory NADH's (NADPH) εis 6220.

The Moore absorptive test of "Chromogen" substrates at 405mm wavelength

Many enzymes substrates are synthetic "chromogen" substrate by artificially synthesized, they are colourless. And they will liberating out colored reaction product after enzyme action, at the wavelength of 405mm, it has absorption peak. ALP substrate: phosphoric acid p-nitroaniline (4-Nitrophenyl phosphate，4-NPP) liberate out yellow p-nitrophenol (4-Nitrophenol，4-NP) after enzyme reaction; GGT substrate: γ-L- glutamyl- p-nitroaniline (γ-L-Glutamyl-p-nitroanilide) oγ-L- glutamy-3- oxhydryl-p-nitroaniline(γ-L-Glutamyl-3-carboxyl-p-nitroan) liberate out yellow p-nitrophenol after enzyme action(p-Nitroaniline ， 4-NA) o p-nitryl-5- benzaminic acid (2-amino-nitrobenzoicacid， ANBA).

Take the Moore absorptivity test of p-nitroaniline as a sample:

a. 4-NPstandard stored liquid (1Ommo1/L)

b. 4-NP stardard application liquid (2.5mmo1/L，produced by diluting 0.84mol/L AMP buffer solution)

c. Substrate buffer solution (l5mmol/L 4-NPPdispensed in 0.84mol/L AMP-HCL buffer solution，37℃,pH l0.09 ± 0.02)

Test method: 4-NP standard liquid qty. is 5μL, Substrate buffer solution qty. is 350μL, wavelength is 405nm,light diameter is 0.7cm, temperature is 37℃,absorbency tested is A1;and use distilled water instead of 4-NP standard liquid, then can get absorbency is A2 and absorbency of 4-NP standard liquid isΔA= A1- A2, according to above method. If getΔA 为 0.460, thus get real test 4-NP Moore absorptive =18662

④ Calibration K value:

Analyzer calculates automatically after enzyme activity calibration substance be calibrated. During enzyme testing, if the testing terms change, such as temperature, sample reagent qty. and absorptive test error etc. all can affect calibration substance and sample untested, thus remedy with calibration substance. Generally, better use calibration K value, but should satisfy with two preconditions: ①must use matched reagents; ②must use matched and high qualified calibration substance, which should be traceable.

5) Transmittance Turbidimetry

It can be used for testing the items which generates turbidity reaction, and most are immune turbidity methods, apolipoprotein, immune globulin, alexin, antibody “O”, rheumatoid factors, and other protein in serum such as prealbumin, hoptoglobin, transferrin and so on.

The immune complex ,which is formed by the antigen combined with the relative antibody ,has certain turbidity in the reaction liquid, can be tested by common spectrophotometry method with transmittance turbidimetry testing; can used for some protein and drug concentration testing. This method need multi points calibration, and then conduct non linear regression to calculate the content of the antigen and antibody.

2.3.3Automatic monitoring of the testing procedure

1) Reagent Blank Monitoring

1.1) Each bottle reagent should automatically test its reagent blank absorbency before

testing;

1.2) Each sample should test the reagent blank absorbency. (For some analyzers that add reagent before sample.)

2) Monitoring the Rate of the Reagent Blank

By set-up this function of Rate_B, analyzer will deduct the reagent blank rate in calculating the result. In monitoring the activity of the enzyme testing which use NAD (p) H decreasing as indication, rate-blank can be monitoring and eliminate the effects of absorbency reducing which caused by the NADH's self oxidation reaction.

3) Sample Information Monitoring

Hemolysis, icterus, lipid of the sample will interface the non-chemical reaction, so usually sample will be justed its affecting level of the hemolysis, icterus, lipid at 600nm/570nm、700nm/660nm and 505nm/480nm, then automatically deduct this part to improve the reliability.

4) Reliability Monitoring

① End point monitoring

② Linearity monitoring

A: Conduct linear regression for all kinds of continuously monitored absorbance value. Calculate variance of all points. Judge whether it presents linearity according to magnitude of variance:

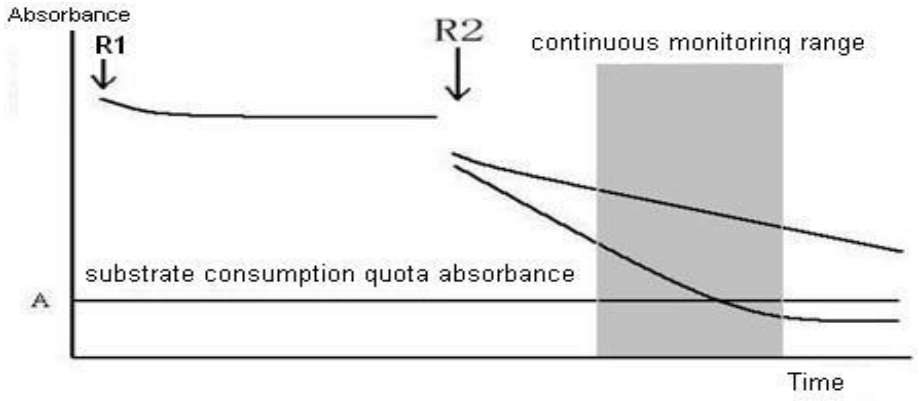
B: Compare the shift of some points at the beginning of continuous monitoring with that in the end to judge whether it is linear phrase.

5) Substrate Consumption Monitoring

When determining the enzymatic activity by continuous monitoring assay, if during the monitoring period, the up or down of absorbance exceeds its substrate consumption value, it means that enzymatic activity of this sample is very high. When the substrate is to be used up, absorbance during the monitoring period will deviate the linear, which will

make the result unreliable. This monitoring is vital for analyzing enzymatic activity by negative reaction.

Chart 8 Substrate Consumption Monitoring



6) Method Range of Linearity Monitoring

Every kind of analysis has a measurable concentration and activity range, if the result of sample exceeds the range, analyzer will give clues that result exceeds the linearity range. Most analyzers would automatically retest the sample decrement or dilution.

2.3.4. Single Wavelength & Dual Wavelength

1) Conception

By using a wavelength to detect the light absorption strength of analyte is called single wavelength. It can be employed when the reaction liquid contains a kind of component or the absorption peak of analyte component in the mixed reaction liquid is nonoverlapping with the absorption wavelength of other coexistence material.

The method using a dominant wavelength and secondary wavelength is called dual wavelength. It would be better to employ this method when reaction liquid occur large absorption of interferent, which would affect the accuracy of testing result.

2) Function of Dual Wavelength

2.1) Eliminate the disturbance of noise;

2.2) Reduce the impact of stray light;

2.3) Reduce the impact of light absorption of sample: when sample contains interferent beyond chemical reaction, such as triglyceride, hemoglobin, bilirubin etc, nonspecific

light absorption would be generated. But dual wavelength can eliminate this kind of disturbance.

3) Determination of Secondary Wavelength

When the dominant wavelength of analyte is decided, choose secondary wavelength according to the features of interferent absorption spectrum. Make interferent show similar light absorption value at the dominant and secondary wavelength, whereas analyte show obviously different light absorption value.

Generally speaking, secondary wavelength should be 100nm longer than dominant wavelength. Result is calculated based on the absorbance difference between dominant wavelength and secondary wavelength.

2.3.5. Reagent Package and Service Life

1) Concerning reagent package, attention should be paid to the manufacturer mark, which is supposed to meet the requirements of law and regulations.

2) Package should meet the requirements of industrial standard and enterprise standard.

3) Reagent should have proper service life, which should be indicated clearly and conspicuously on the package.

2.3.6 Precautions of Reagent

1) Reagent should be used within the expiration date.

2) Reagent should be used together with analyzer to form integrated system.

3) Reagent should be stored properly under the storage condition required by manufacturer.

4) Reagent should be used in accordance with service conditions and range of application required by manufacturer.

5) Reagent is only for in vitro diagnostic use.

2.4 Calibrators and quality control material

2.4.1 Conception

Calibrator: Calibrate with 2nd standard substance, decide value with conventional method. It is

used for calibration of conventional method and instrument.

Control: it is characterized with brought in line with detection process. Its ingredients is the same or similar to matrix of detection sample. Control should be of good stability. The variation between several bottles should be less than expectant variation of observation system. Its conventional detection helps to confirm the report range.

Potential difference of result is likely to occur due to different detection principles and reagent quality adopted by analyzers produced by different manufacturers. Especially for some special specimen, the value got from different detection systems sometimes would be different with the true value. Therefore, manufacturer and distributor of analyzer have the responsibility to chronically and stably provide the special specimen of this detection system, detection result and other relevant information. Besides, to keep this traceability for good, all detection systems in this traceability system should be ensured under stable state every year, day and hour. So once all detection systems enter traceability system, it is necessary to actively conduct control indoor and among doors.

2.4.2 Packages and Expiration Date of Calibrator and Control

1) Concerning reagent package, attention should be paid to the manufacturer mark, which is supposed to meet the requirements of law and regulations.

2) Package should meet the requirements of industrial standard and enterprise standard.

3) Reagent should have proper service life, which should be indicated clearly and conspicuously on the package.

2.4.3 Precautions of Calibrator and Control

1) Reagent should be used within the expiration date.

2) Reagent should be used together with analyzer to form integrated system.

3) Reagent should be stored properly under the storage condition required by manufacturer.

4)Reagent should be used in accordance with service conditions and range of application required by manufacturer.

5)Reagent is only for in vitro diagnostic use.

Chapter 3. Instrument Description

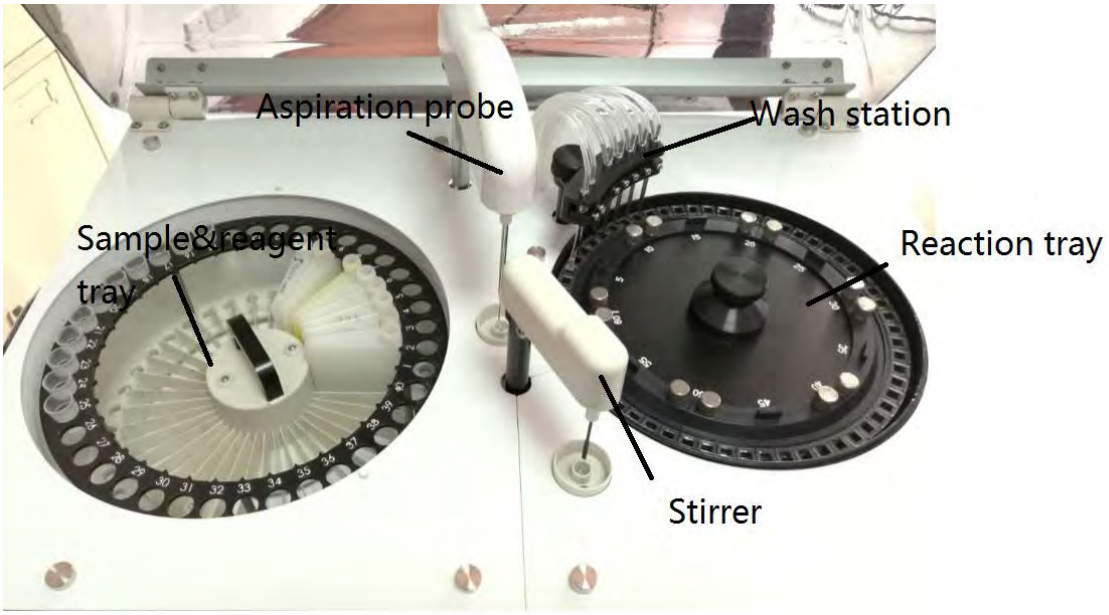
3.1 System Structure

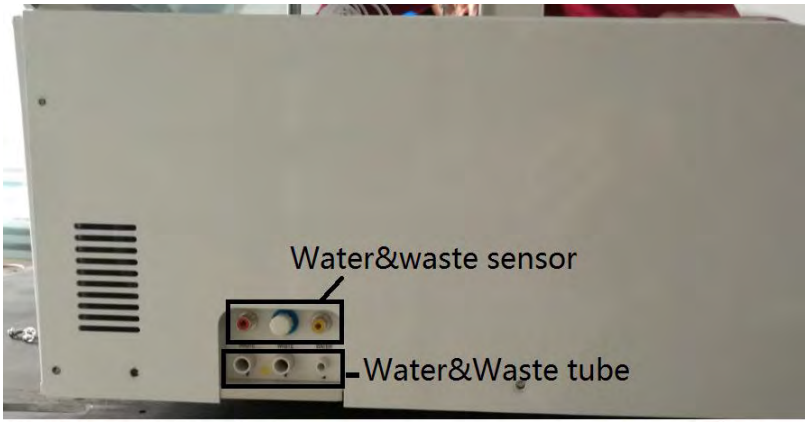
This Part mainly describes the structure and interface and other basic operations of PPC125 automatic chemistry analyzer

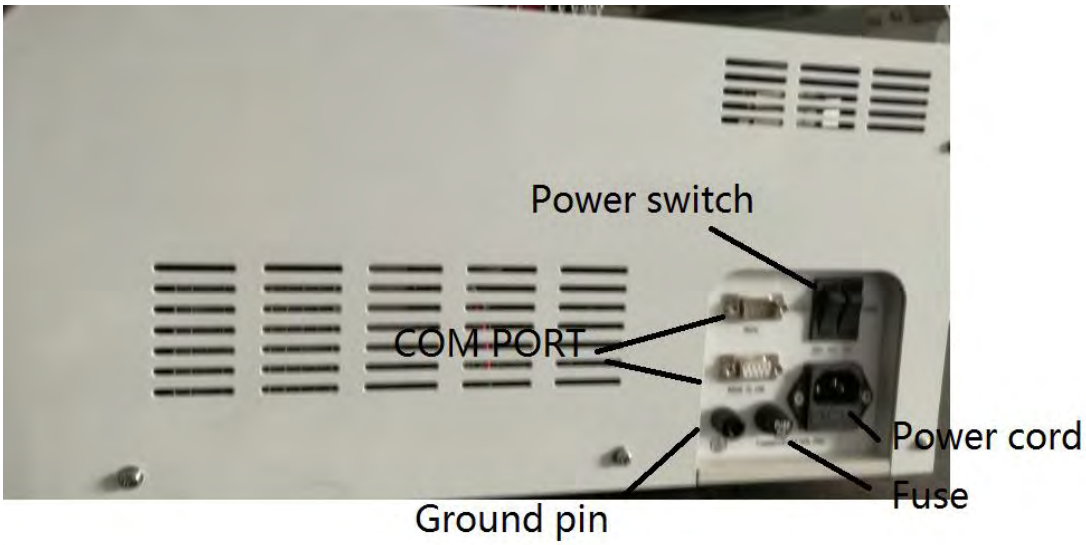
The full name of the system is PPC125 Automatic Chemistry Analyzer, It is intended for in vitro diagnostic use and quantitative determination of clinical chemistries samples, such as serum, plasma, urine or cerebrospinal or pleural effusion and ascite.

Note：

●Some samples may not be analyzed on the system based on parameters and the testing reagents. For these sample, you can consult the reagent manufacturer or distributor for details.







3.1.1 Analyzing Unit:

The analyzing unit consists of the sample-reagent disk, aspiration system, reaction disk, photometer for analyzing operation.

1) Sample-reagent disk

Sample-reagent disk holds sample and reagent.

The sample position can holds the following container:

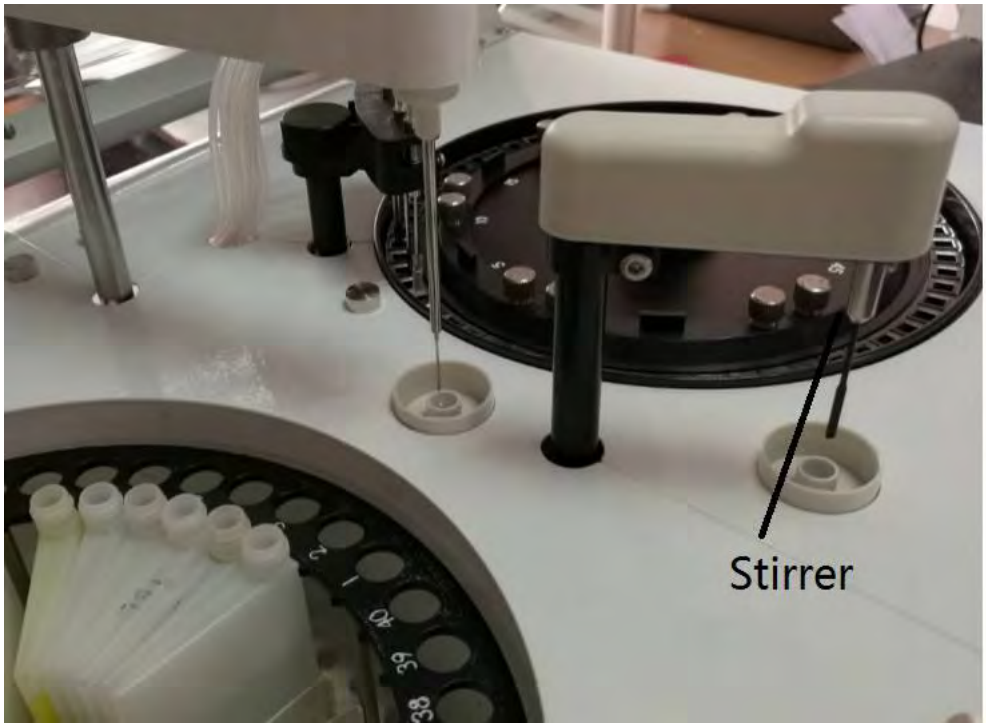
- Micro sample tube, Centrifugal tube
- Blood collecting tube Φ12×100

MR reagent tubes are used only. The volume of PPC125 reagent container is 20ml. Sample disk and reagent disk place in the sample and reagent storage respectively. The storage supports refrigeration to keep temperature between 5~14℃.

Note：

●The reagent positions are for MR reagent bottles only. Please use specified sample tubes; otherwise, it may cause system damage.

2) Mixer Assembly



The mixer assembly is used for mixing the biochemistry reactant liquid or fluids in the reaction cuvette. It has to fixed straight and its home position is at the Mixer washing station

For single-reagent test, the mixer is performing the mixing rotation for the particular test after adding the respective reagents and samples.
For double-reagent test, the mixer works after adding Reagent R1 + Sample and then after adding the Reagent R2 respectively. When stirring is finished, than mixer moves automatically to the wash well position i.e. the home position of mixer and then get washed up the stirrer and get stop.

Warning：

●When the analyzing unit is in operation, do not place any part of your body or any obstacle in the route the arm moves. Otherwise, it may lead to personnel injury or equipment damage.

3) Reaction Disk Assembly

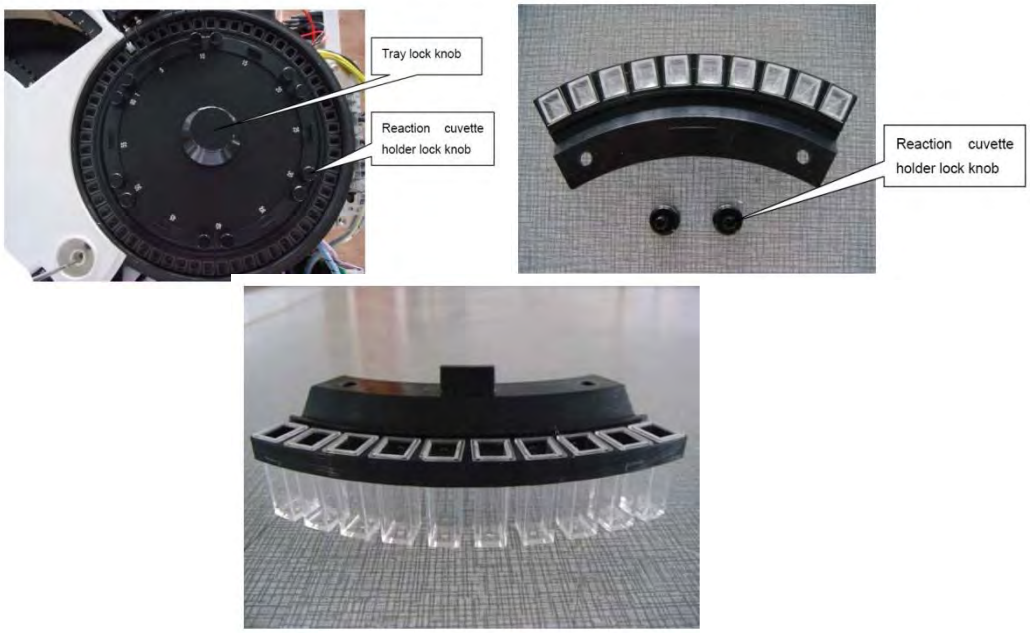
The reaction disk holds the cuvettes. Total 60 cuvette are present on the reaction disk. The cuvettes are designed for reaction container and colorimetric measurement.

During analyzing, specified cuvette moves to sample loading position or mixing position for sample loading or stirring, and then carries it to the axis of corresponding light path for absorbency measurement.

The cuvette is able to use permanently and is replaced manually if necessary.

The reaction disk is placed in temperature-controlled room, which provides the steady temperature at 37±0.1℃.

The exchange of Cuvette cup:



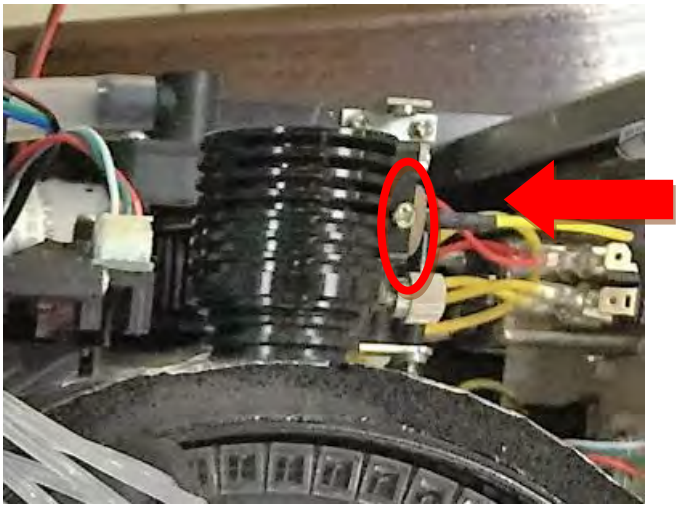
BIOHAZARD：

●Wear gloves and lab coat is a must to replace reaction cup to avoid infected. ●Be sure to dispose the used cuvette according to the local regulations.

4) Photometer Assembly

The photometer assembly, which locates inside the analyzing unit, measures the absorbance of the reaction mixture in cuvette.

The exchange of Halogen Lamp:



Loose this screw to remove the lamp

Biohazard:

- Do not stare into the lamp when the system is in operation. Light sent by the photometer lamp may hurt your eyes.
- If you want to replace the photometer lamp, first switch off the MAIN POWER and then wait at least 30 minutes for the lamp to be cooled down before touching it. Do not touch the lamp before it cools dow, or you may get burned.

3.1.2 Operation System

The operation system is a computer, installing control software for running, operation and data processing.

Warning:

- **External device connected to the system, e.g. computer, printer, must be complied with the requirement of IEC 60950 or EN 60950.**

3.1.3 Output System

Output System is a printer for printing data.

Warning:

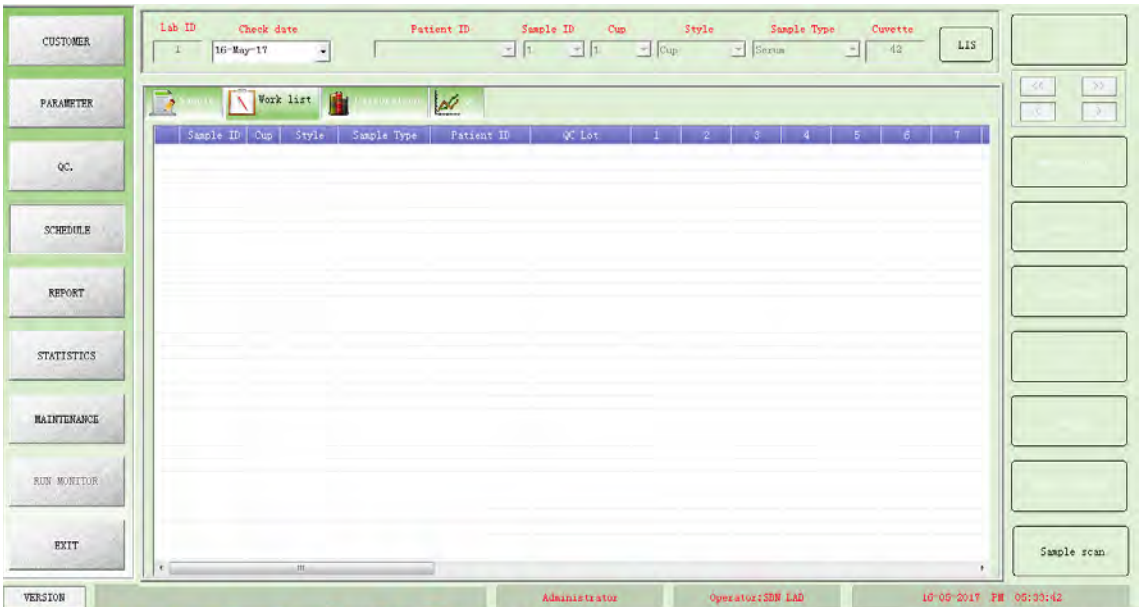
●External device connected to the system, e.g. computer, printer, must be complied with the requirement of IEC 60950 or EN 60950.

3.2 Interfaces and Basic Operation of Software

When user double click on the PKL PPC 125 software icon, the above screen will gets open and ask user to enter the Login id and password to access the instrument software. Before opening the software make sure that the PKL engineer had completely installed the instrument parameter setting for the lab/user and also provided the training to operate the software. PKL Engineer will generate the Login ID and required password for the end user.

3.2.1 Screen Layout

After entering the valid user id and password, the software will get open and following main screen will be displayed:



Software main interface: (For Version 5.1)

Group button area

It is on the left hand side of software main home screen display. Basically it is used for the following operation parameter like: 1.Customer 2.Parameter 3.QC 4.Schedule 5.Report 6.Statistics. 7. Maintenance 8.Run monitor 9.Exit.

When operator click on any of the group button, then relevant working software interface will get operated and respective screen is displayed on the monitor.

Working status area

The working status area is visible on the bottom of main screen, which will going to display the computer real time and date, operator or Admin detail, Laboratory name and software information.

Biochemical test area

It is on the center of screen, designed for user to monitor and run the sample, control, standard and perform the reagent test.

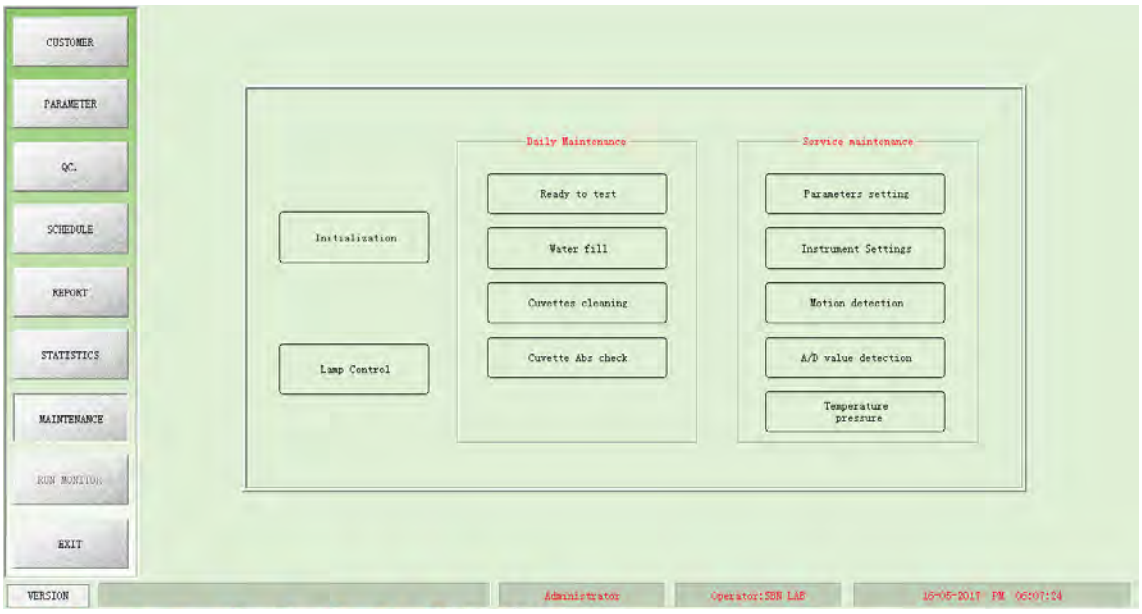
Working interface area

It displays the value and graph of parameters, process, result and etc on the interface of selected button. At the bottom of the interface is the note area, where the items listed on the current interface are described.

3.2.2 Screen Elements

Dialog box

The dialog box is one of the most common interfaces for man-machine interaction. Please see the following example.



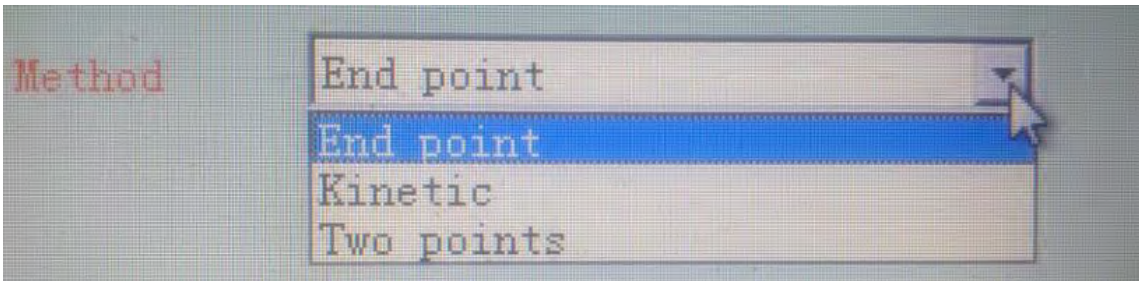
Dialog box

Tab

Click a tab and you will enter its corresponding index working interface. See the picture below for an example. This is a example, when user click on PARAMETER on the main widow, than software will open new page. These tabs are visible on the top of the screen. Then depending upon the functionality and requirement of work the user we go in the respective Tab by single clicking on the corresponding index name. Here if users want to do the task of REFLEX test than on the Tab user will single click on the REFLEX test.

Drop-down list box

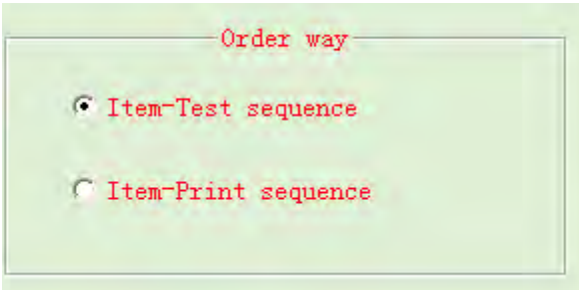
Click  , and a list will display, as the picture below shows. Click the desired item to select it.



Button

The function of button is to open a dialog box or execute other defined function. Click a button, it will do corresponding operation. See below picture.

Option button



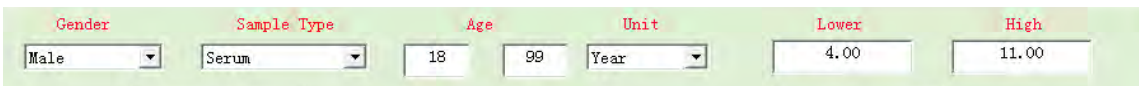
In one group of option buttons, you can only choose one option button. Click a radio button to select the option it represents. See below picture.

Note that for a given group of radio buttons, you can only select one of them. See the figure below.

.

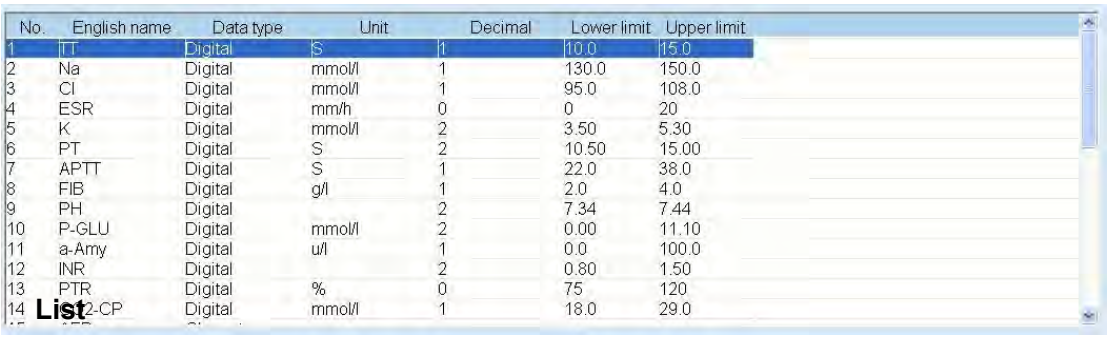
Edit box

Edit box is used to edit the character i.e. in the following picture you can see Age in the edit box, and lower and higher box. Basically edit box is used to edit and write any character. Also in the other box, apart from input of character, the left button of the mouse can be used to click the right icon of edit box or to select



Scroll bar

When the content is beyond the size that screen can display, scroll bar will appear. Move the pointer on the scroll bar, press left button of the mouse and hold it, then you move the mouse to drag the scroll bar to see the hidden contents. See below picture.



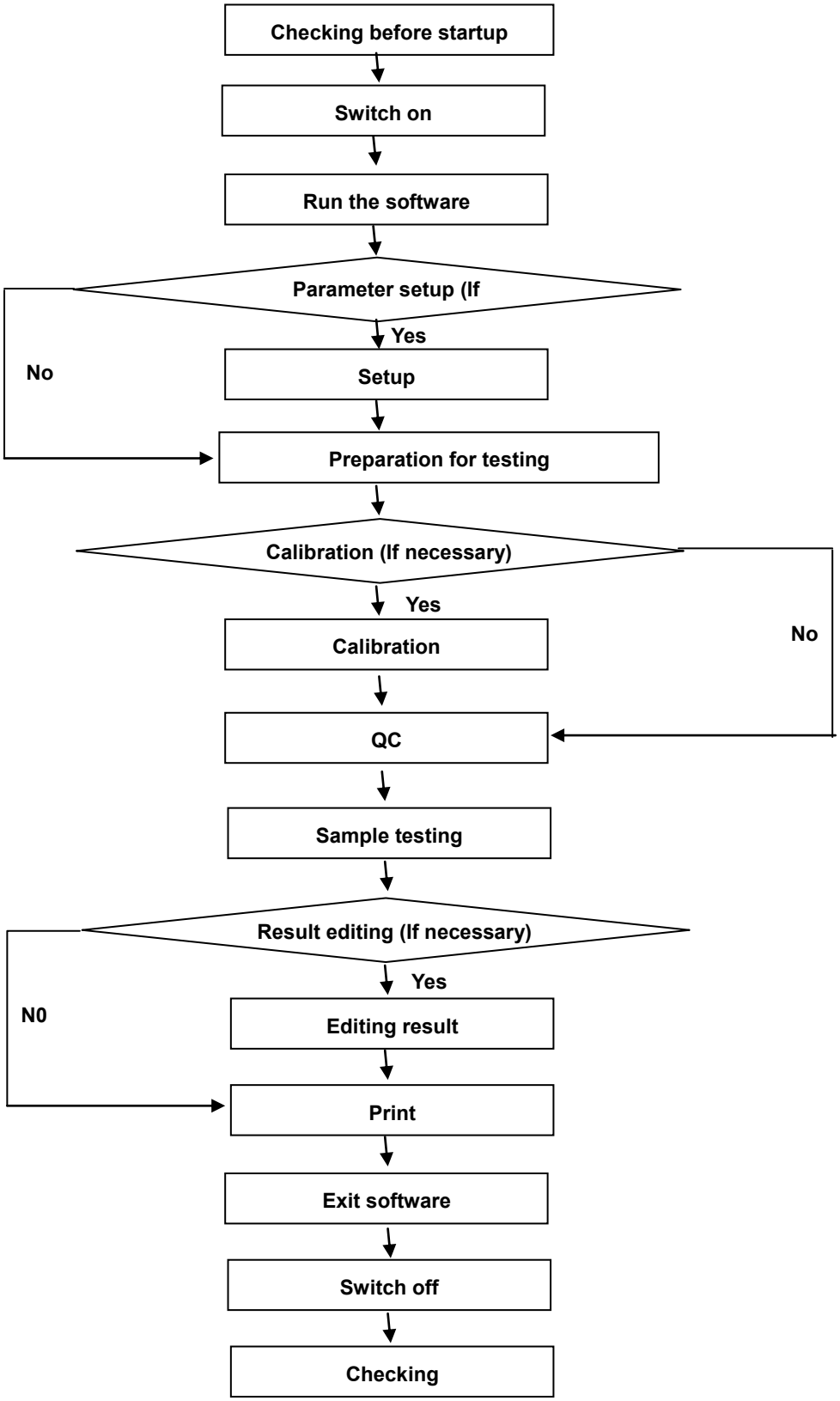
No.	English name	Data type	Unit	Decimal	Lower limit	Upper limit
1	TT	Digital	S	1	10.0	15.0
2	Na	Digital	mmol/l	1	130.0	150.0
3	Cl	Digital	mmol/l	1	95.0	108.0
4	ESR	Digital	mm/h	0	0	20
5	K	Digital	mmol/l	2	3.50	5.30
6	PT	Digital	S	2	10.50	15.00
7	APTT	Digital	S	1	22.0	38.0
8	FIB	Digital	g/l	1	2.0	4.0
9	PH	Digital		2	7.34	7.44
10	P-GLU	Digital	mmol/l	2	0.00	11.10
11	a-Amy	Digital	u/l	1	0.0	100.0
12	INR	Digital		2	0.80	1.50
13	PTR	Digital	%	0	75	120
14	2-CP	Digital	mmol/l	1	18.0	29.0

List

The list displays the name of one or multi items or combination of them. The example is showed as below. Click to select it, and click it again to cancel your selection. Number stands for the position of reagent.

Chapter 4. Basic Operations

4.1 General Operation Procedure



4.2 Operation Rule

4.2.1 Preparation for Testing

1) Checking before Startup

To ensure that the system can works normally after switching on, please check what stated below before startup.

BIOHAZARD:

● Wear gloves and lab coat and when doing the following inspections; if necessary, please also wear goggles.

⚠

1)	Check the power supply, ensure power supply and voltage is ok.
2)	Check the communication cable (which connect the analyzer, computer and printer) line and the power line, ensure they are ok and not loose.
3)	Check whether the printing paper is enough; please add printing paper if necessary.
4)	Make sure the sample probe is at the right position (cleaning position).
5)	For PPC175, make sure the stirring probe is at the right position (cleaning position).
6)	Make sure there is enough distilled water in the water bucket.
7)	Emptying the waste bucket.
8)	Prepare enough reagents for tests.

2) Switch On

Connect the power supply and switch on each part orderly as follows:

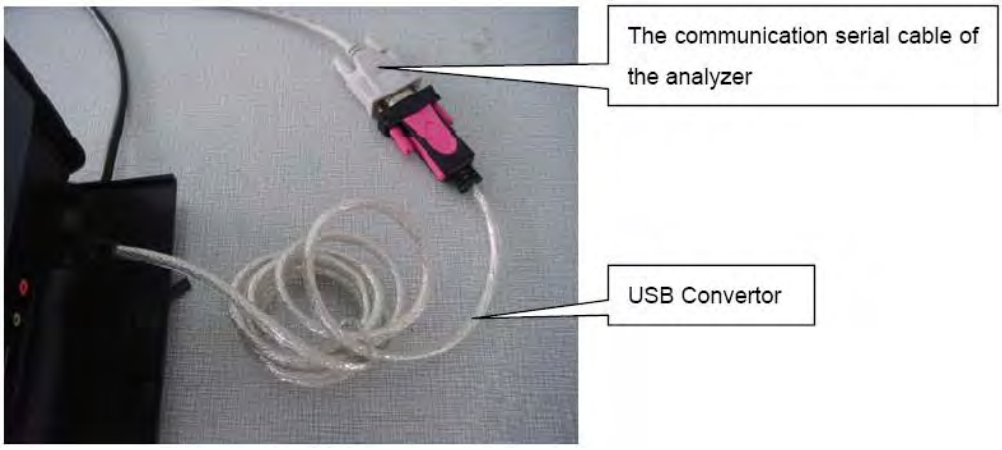
1	Analyzer Power Supply
2	Computer Screen Power Supply
3	Computer (Mac Pro) Power Supply
4	Printer Power Supply

Note: Please switch on analyzer power supply at first, and then run software.

3) Run Software

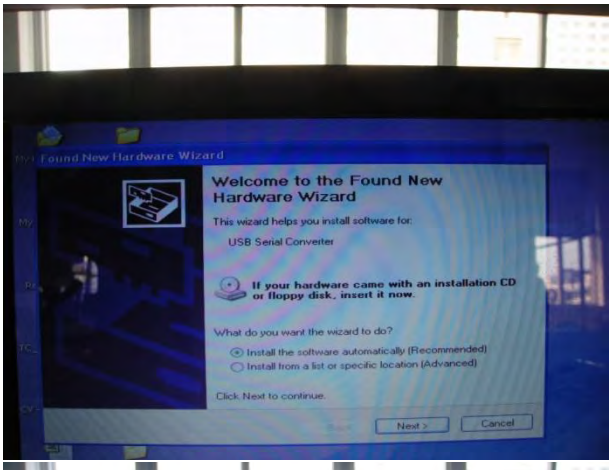
3.1)	Connection between computer and instrument. There is a piece of USB to serial port convertor in the accessories of machine, and if there is not 9-pins serial port in the computer, the convertor should be used, otherwise it is not needed. **How to install the convertor?** **Step1**: there are two ports in the USB convertor: one is USB port, the other is male

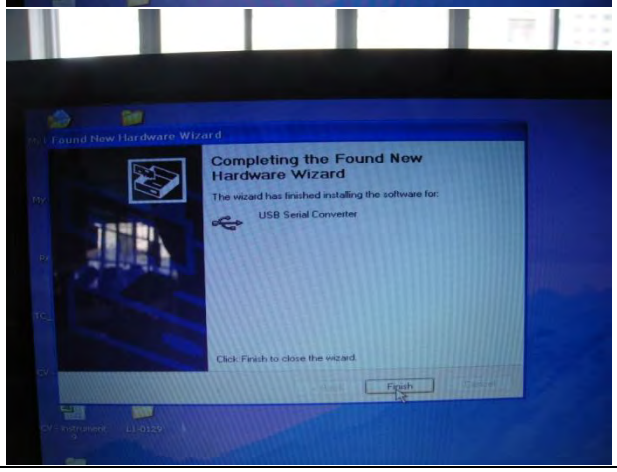
9-pins serial port.

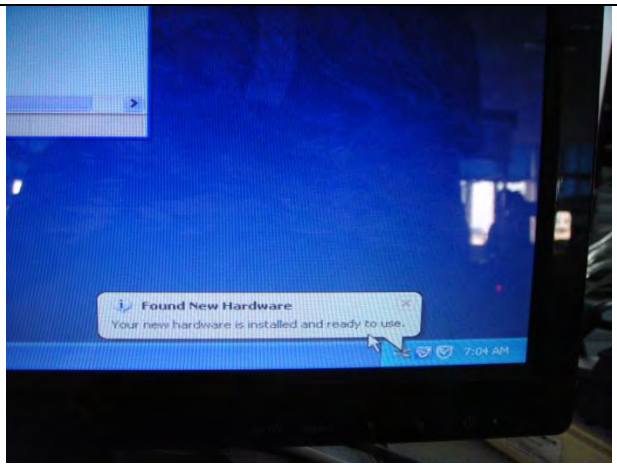


Step 2: connect the serial cable with male 9-pins port of convertor,

Step 3: Connect the USB port of convertor with computer. The computer will indicate the new hardware is found. The screen will indicate “Found new hardware wizard” see the following picture. then always click next button to perform next process.

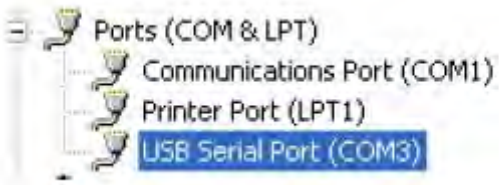






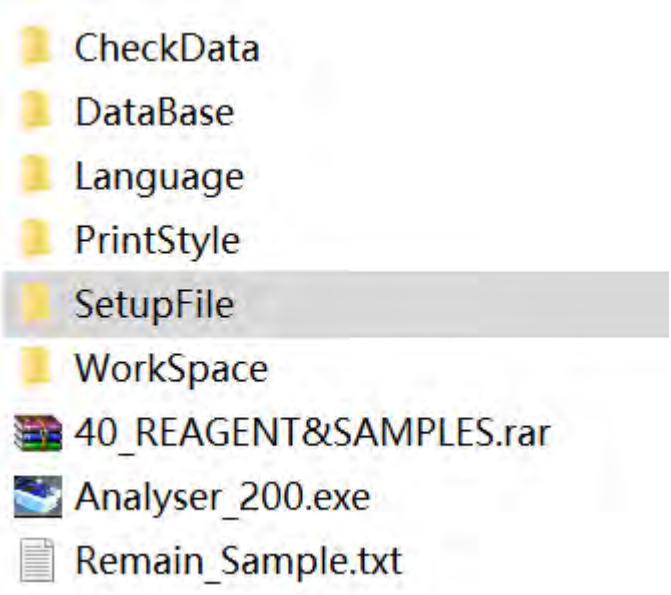
Finish the driver installation.

Step 4: after install the driver of convertor, enter the hardware information menu which is in the control panel to check whether the added com number is 1 to 3 or not. If not, it should be done to modify it through advanced properties menu of the added com port.



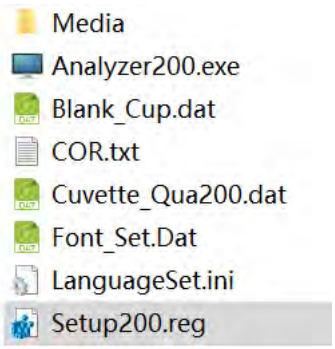
Step 5: the operator can use the convertor to connect the communication cable of machine.

3.2) Go to software folder, open the [SetupFile]

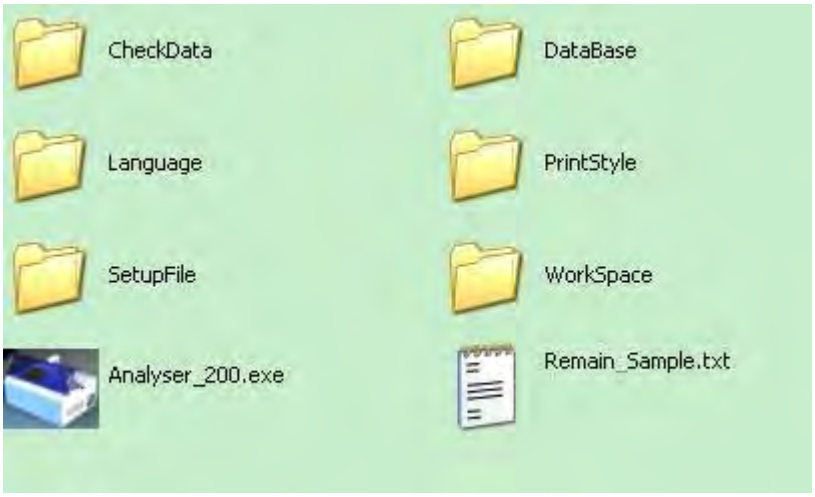


Run the file [Setup200.reg] to register the instrument parameters to

windows system regidit.



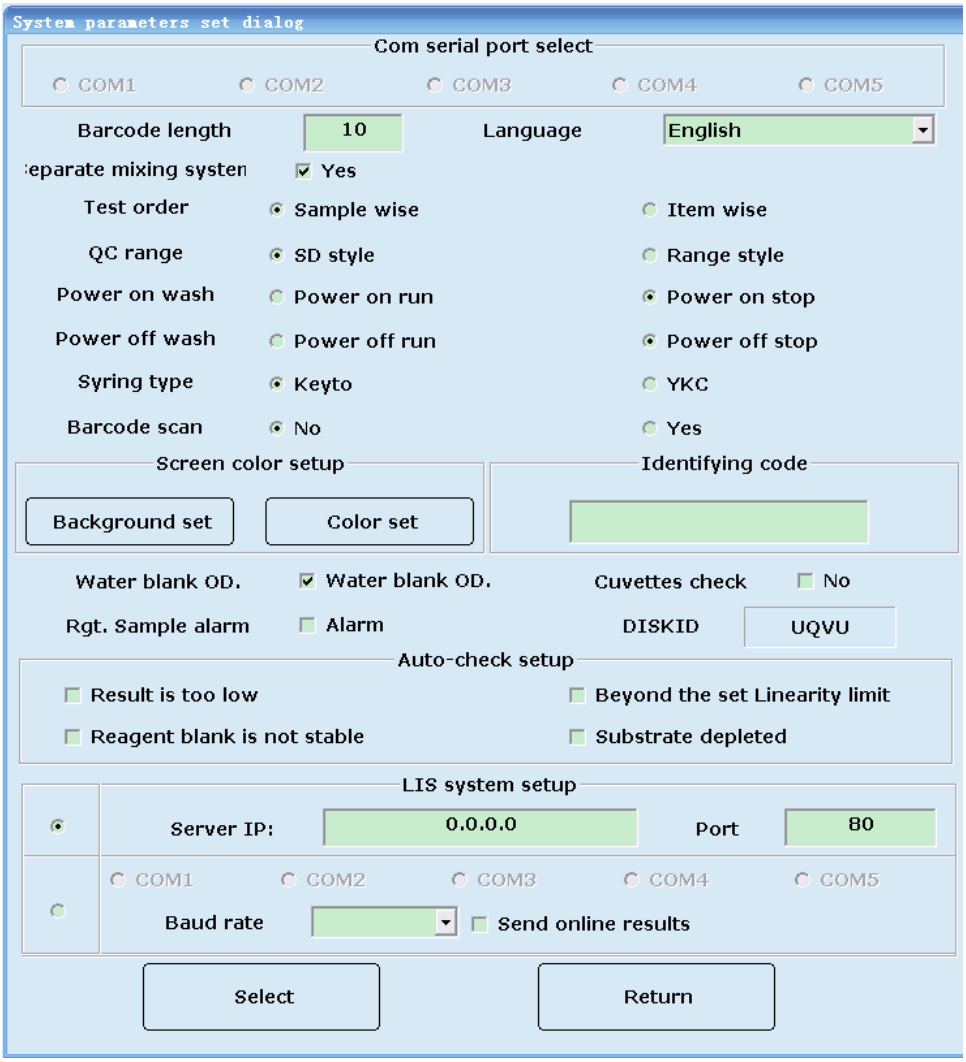
After startup Windows Operation System, you can startup control software by double clicking the shortcut icon of the software on the desktop or from software package.



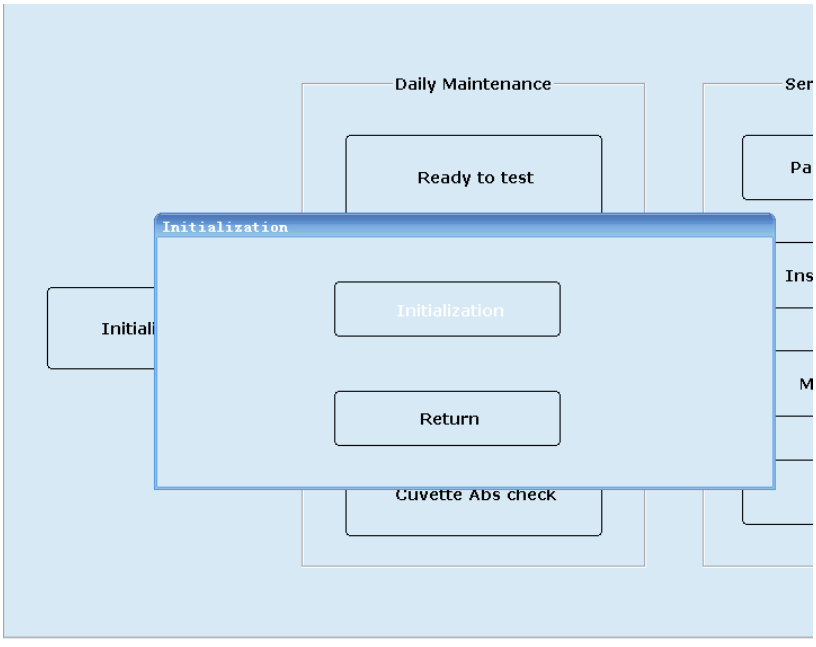
When startup, system will check automatically the operation system, screen resolution, close screen protection program, check color configure, initial database, check printer.

After checking, a dialog box will pop-up and then you can input administrator name operator and password 123456 and click "OK" to enter the software.

	 **Note:**
3.3)	This software can be used on PPC175. How can we setup machine type? **Maintenance → Parameter setting (Password sages) →Separate mixing system** 1. Pls select Yes ,and then click Select.



Click “MAINTENANCE” button, and then click “Initialize” button to reset the moving parts and the screen is shown as below.



Note:

● To ensure accurate testing results, please power on the system for at least half an hour before starting analysis.

4) Parameters Setup

Only when the parameters are set properly and rationally, the analyzer can carry out the testing and other functions.

Please setup the parameters when first time operates the analyzer. During the daily operation, the user can setup the parameters according to the specific needs.

Before the testing, please at least setup the following parameters:

1) Hospital data setup

2) Doctor data setup

3).Calibration Setup

4) QC setup

5) Parameter setup

Note: Details please read the chapter 5.

5） Preparing the Reagent

Load the reagent bottles to their designated positions on the reagent disk, and then open the bottle covers.

Warning:

● Exercise caution to prevent puncture wound by the probe tip.
BOHAZARD： ●Wear gloves and lab coat are must to avoid to be infected and, if necessary, goggles.

4.2.2 Start Testing

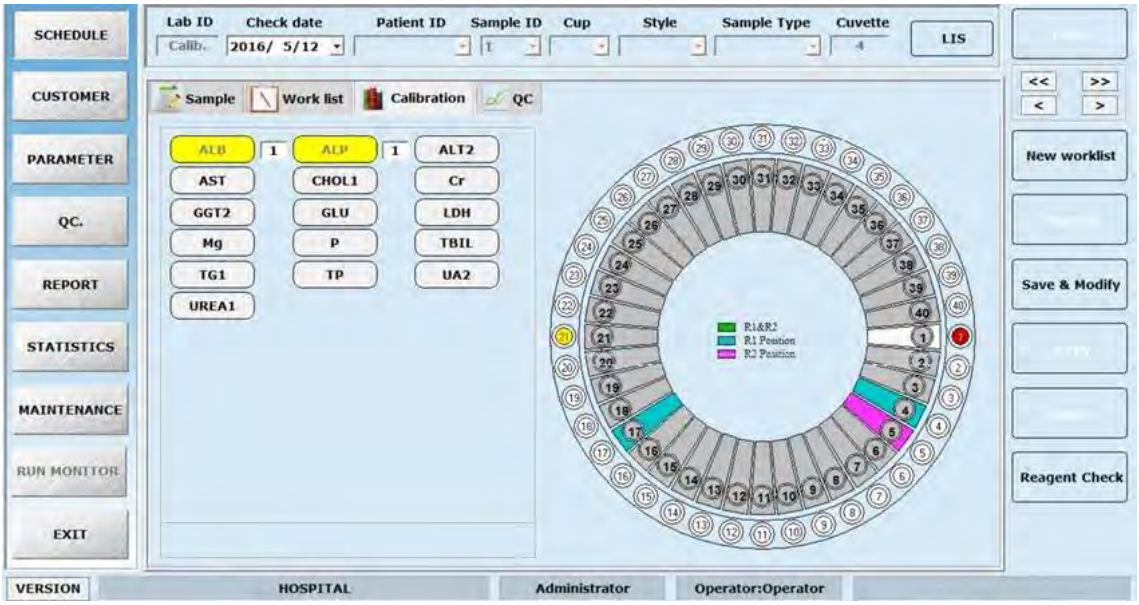
Note: Before any sample test the software will ask for the calibration, So user should make sure to calibrate the instrument before running the sample. Also it is required to refill all the reagents before the calibration.

1) Calibration

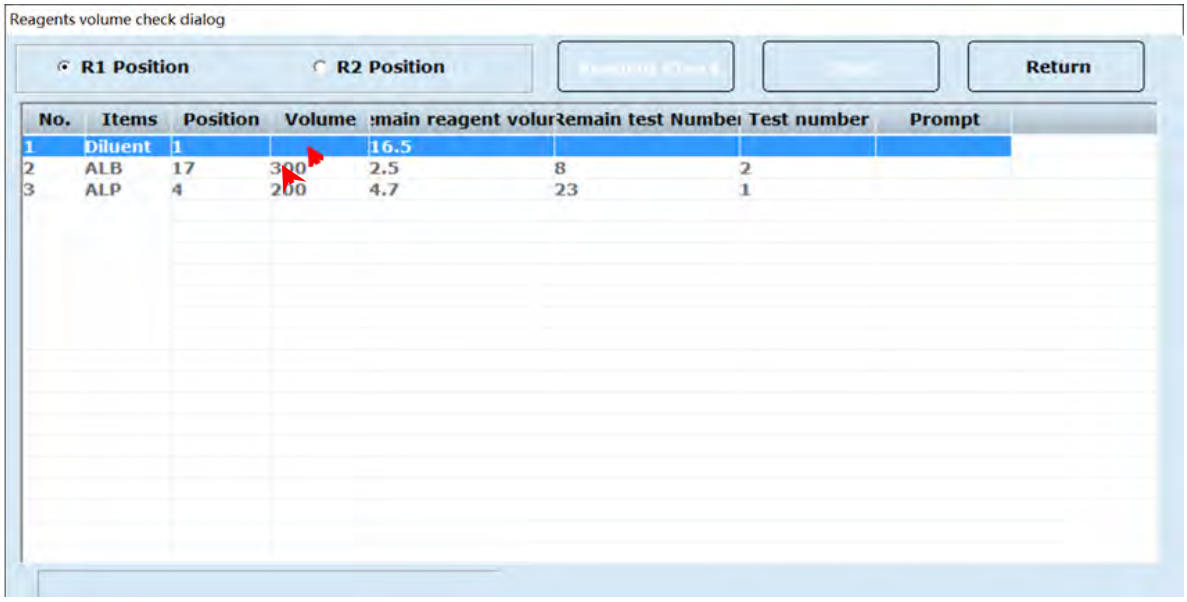
Be sure the parameter setup and calibration setup already finished.

SCHEDULE →Calibration

Select the calibration items and press [Save&Modify]



Press [Reagent Check], firstly, press [Reagent Check] to check the reagent level, and then press [Start] to start calibration procedure. In Reagent check there are two option button R1 position and R2 position, The user can check the reagent volume by selecting the corresponding option button. If user will click on Reagent Check button than instrument will start performing the reagent volume check of R1, R2, DW and Cleaner solution. After Reagent check instrument is ready for the calibration. Note: User can skip the reagent check option also.



Note:

- Please re-perform the calibration if you change the reagent lot No., test parameter, lamp (or other analysis conditions will result in measurement situation change).

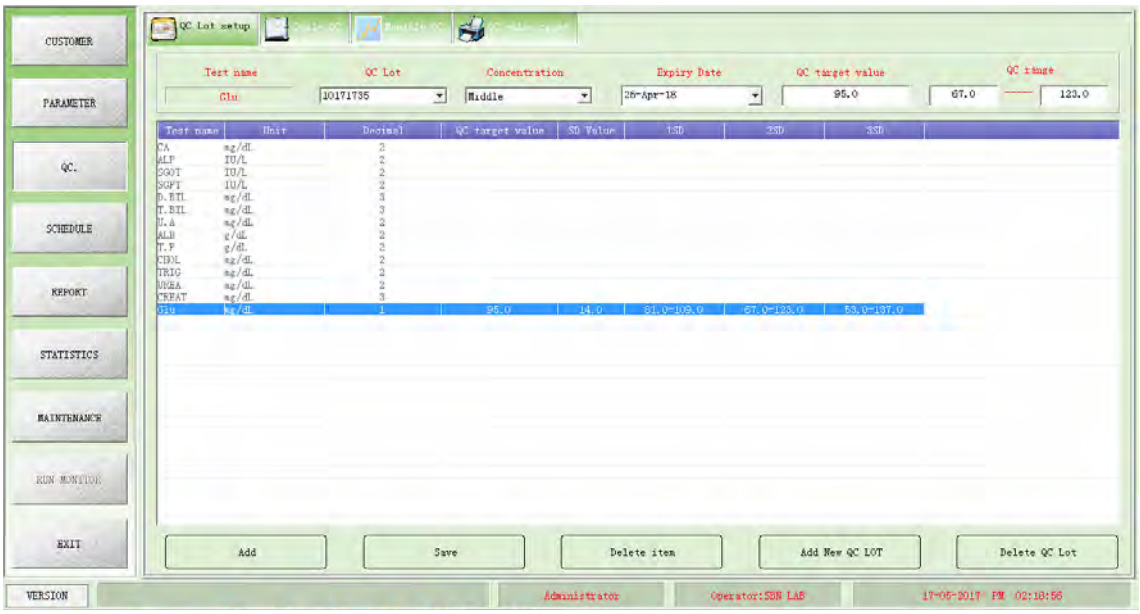
2)QC

Quality Control →QC lot setting

Before starting with the Quality control, User should make sure the lot number and expiry date of the control should be valid. Here user has to define Low, High and Normal control with there QC Ranges. For Example in the following picture, User is making a QC for Glucose test.

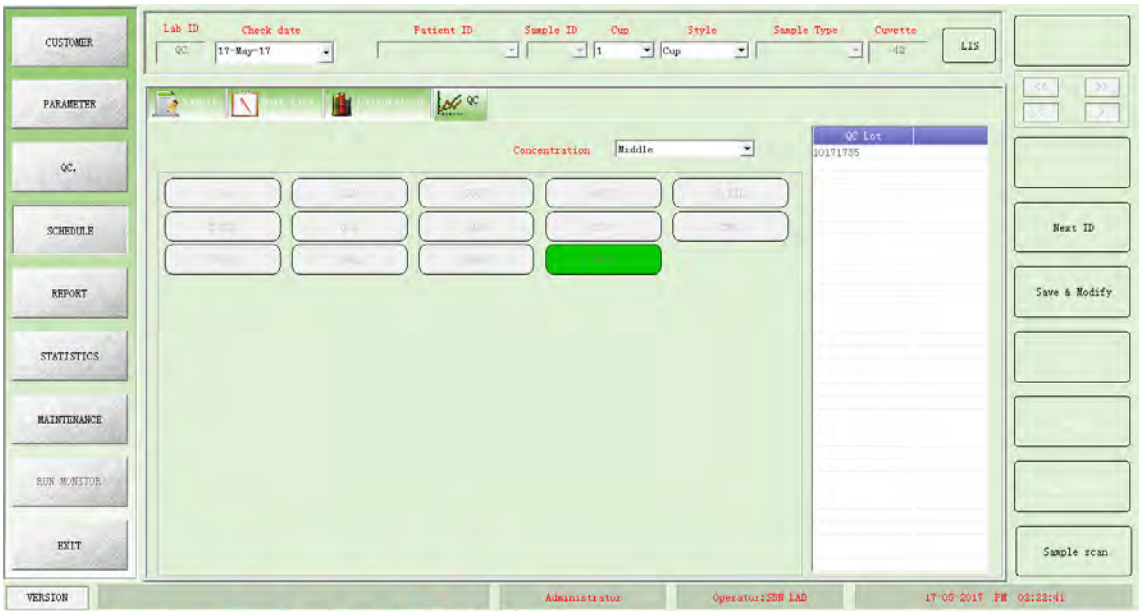
Here in example: User had enter the QC Lot no. 10171735, Concentration: Middle, Expiry date: 25 Apr 2018, QC target valve: 95 and than reference range .

Than user will select the desired name in the item list, and then Click [ADD] and [SAVE].



3) SCHEDULE →QC

For running the QC, First user has to click on the Schedule than on the QC button as shown in the following picture. Than depending upon the level of concentration of control, user will select the desired concentration.



① **Select Concentration of QC.**

② **Select QC Lot No. in the QC Lot.**

③ **Select the desire item in the item list, and it will become yellow after being selected.**

④ **Input Sample Cup**

Press [Save&Modify], then press [Reagent Check] to start QC test.

4) Sample Testing

SCHEDULE →Sample

Before Adding any sample make sure user should take a sufficient amount of sample is a cup or tube. Make sure the sample serum/Plasma should not contain any fibrin on it.
Than take the sample and load on the vacant position of the sample disk. After loading the sample on the sample disk please make a note of sample position and correspondingly select the position of that sample in the software and also give a name to sample id edit box.

Click ADD, then please check Test →Work List, now you can click **[Reagent Check]** and

then [**Start**] to start sample test.

Note:

- The requesting of emergency testing is similar with the requesting of common samples; the only difference is to click" emergency testing" at requesting time in necessary.
- Ensure the samples are placed in the correct positions, otherwise it may cause unreliable testing results.

4.2.3 Result Follow-up

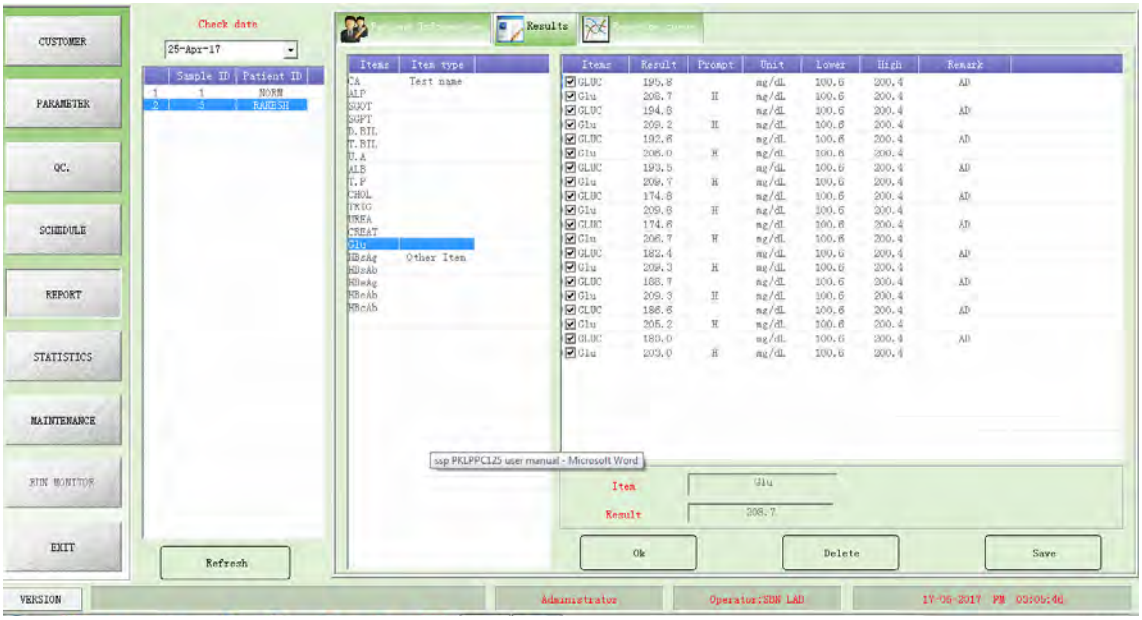
Result of the desired sample are displayed by clicking on the [Report] than by selecting the date on which that sample is tested on the instrument as shown in the following picture. After selecting the date, all the result for the particular date will get visible to the user with all the details.

User can also edit the sample by the selecting the desire test in the item list and then modify the result and click OK to save the modification.

1) Editing the Sample Testing Results

Report → Results

Select the desire item in the item list, and its information will display on the right. You can modify the result and click OK to save the modification.



Note:

- The testing results can only be edited when guided by authorized superior doctors.

2) Printing the Testing Results and editing the patient information.

User can edit and fill the patient detail in the following window. After entering all the details user can save the details by clicking on the save button.. Than clicking on the print button user can take a print out of the details.

Report → Patient information

You can print the test result by checking the date.

Important：

- The system automatically stores the data to the built-in hard disk. However, data loss is still possible due to deletion or physical damage of the hard disk or other reason. We recommend you to regularly back up the data to such medium as CDs.

4.2.4 Finishing the Testing

1) Exit the Operation Software

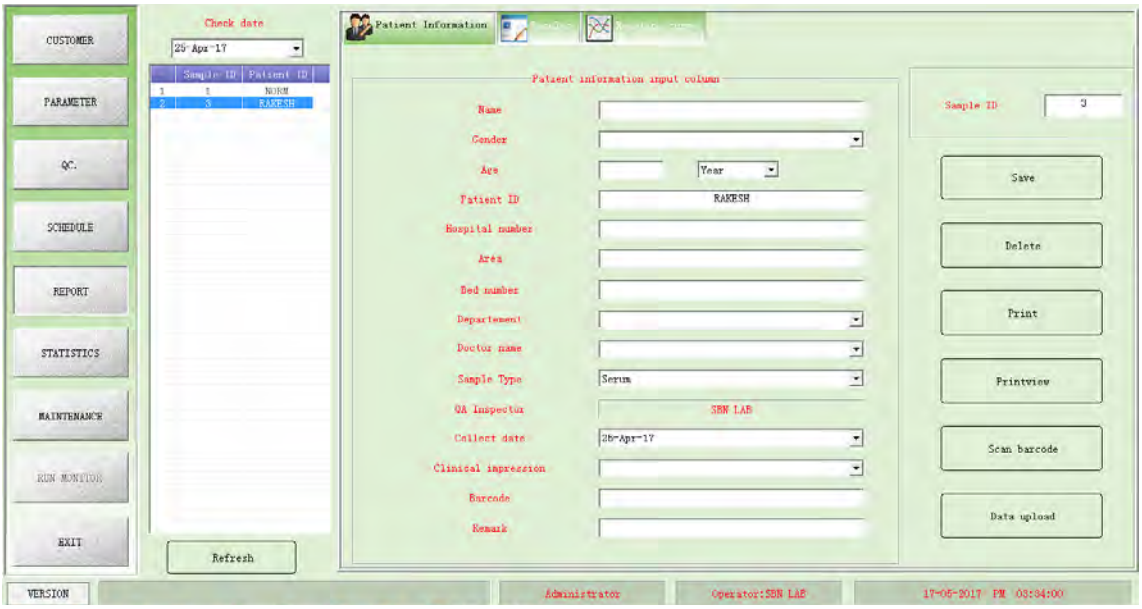
When all tests are finished and the system is in standby status, the user can click ”EXIT” button to exit the operation software.

2) Shut down the Analyzer

After exiting the Windows operating system, please switch off the powers orderly as below:

1)	Printer Power Supply
2)	Computer Power Supply
3)	Analyzer Power Supply

3) Checking after Powering Off



 **BIOHAZARD:**

● Wear gloves and lab coat are must to avoid to be infected and, if necessary, goggles.

 **Note:**

● If the MAIN POWER of the analyzer is power off, please take the reagents from the reagent disk and put them into an external refrigerator.

1)	Cap the sample/reagent tube/bottle on sample/reagent disks and cover the disks.
2)	Remove the calibrators, QCs, samples and reagents in the sample/reagents disc.
3)	Empty the waste bucket.
4)	Check the surface of the analyzer, if any stain, wipe them off with clean soft cloth.

Chapter5. Advanced Operation

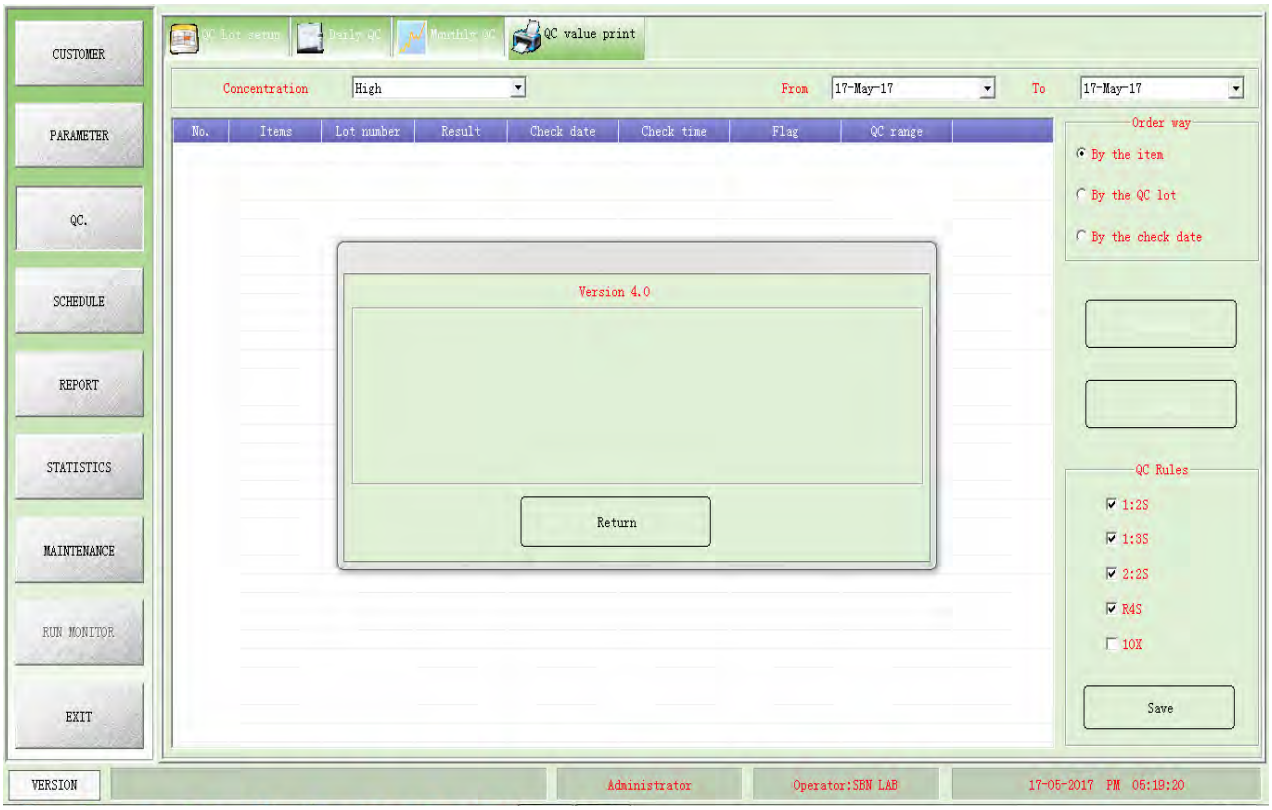
This chapter will explain each shortcut and button as per the software interface.

5.1 Menu

Main Menu	One-level Menu	Second-level Menu	Remark
1.Customer	Customer details entry		To display hospital name when print
	Operator set up		To display operator's name when login or print
	Data Dictionary set up		To data units, sample cup, sample type, reagent supplier name and clinical impression
2. Parameter	Test Parameter	Basic parameter Reference range Calibration	For setting chemistry parameter
	External parameter		For add on item which was tested by other analyzer when print
	Calculation item		For adding item by calculate
	Profile		For quick select batch items
	Test sequence		To avoid carry over.
	Item-print sequence		For printing the item details
3.QC.	QC. Lot setup		To enter the control details like expiry date, lot number and

			Reference range
	Daily QC		To run daily QC for a particular test
	Monthly QC		To run monthly QC for a particular test
	QC value print		To take a printout from the desired date
4.Report	Patient information		To entire the patient details
	Results		To see the desired result
	Reaction curve		To see the reaction curve of a sample
5. Statistics	Results modification		To revise test result
	Historical data display		To search the past result
	Charge statistics		To calculate money charge price of a test
	Search		To search the sample depending upon various given option
6.Maintenance	Initialization		To initialize the instrument
	Parameter setting		To set the computer setting
	Ready to test		For washing and checking all the cuvettes before testing
	Instrument setting		Set up movement parameter of instrument.
	Water fill		For washing and filling water to cuvettes before shutdown.
	Motion detection		For checking valves and pumps condition.
	Cuvettes cleaning		For washing cuvettes
	Cuvette Abs check		For checking signal value
	Temperature pressure		To set up and display temperature and pressure.
7.Schedule	Sample		To Run the desired sample
	Work list		To make a group of tests to be perform in a desired sample
	Calibration		Used for the calibration of Particular parameter
	QC.		Used for the Quality check
8. Urgent	Sample		To select a sample position
	Work list		To make a group of tests to be perform in a desired sample
	Calibration		Used for the calibration of Particular parameter
	QC.		Used for the Quality check
9.Run monitor	Sample info.		To monitor running sample
	Reagent info.		To monitor running reagents
	Cuvettes info.		To monitor running Cuvette
10.Exit			Exit software

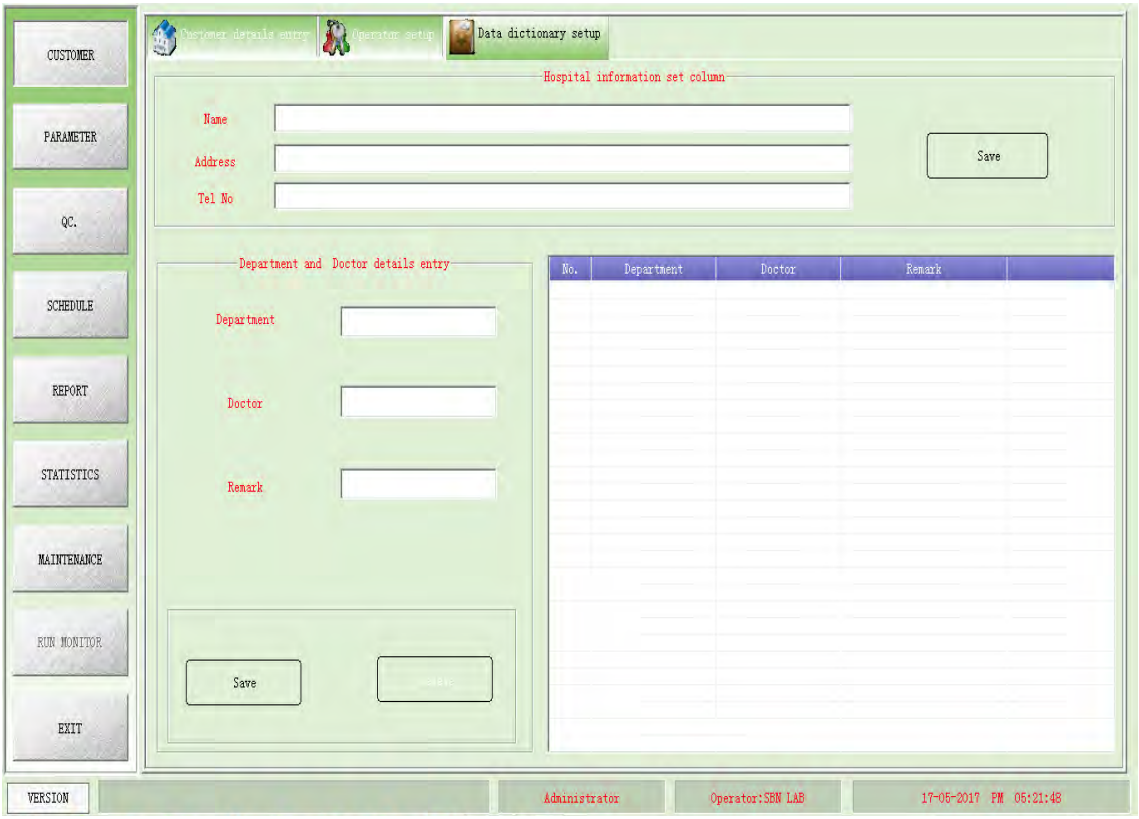
To check software version: please click “version” on the lower right corner, it will pop out version information, see below.



5. 2 Operation menu

5.2.1Customer data

Click the “Customer details entry” button, then goes to the below interface, it’s for editing hospital data, operator data and data dictionary.



Here to explain each tab.

1) Customer unit setting

The interface is showed as upper chart, it’s for editing hospital details such as name, address and contact, etc.

Parameters:

Parameters	Meaning
Hospital name	After input, it will display on printed report.
Hospital address	The address where instrument installed.
Tel No.	Hospital telephone.
Department	The department where sample from
Doctor	Doctor’s name
Remark	Future comments when the upper parameters cannot explain.

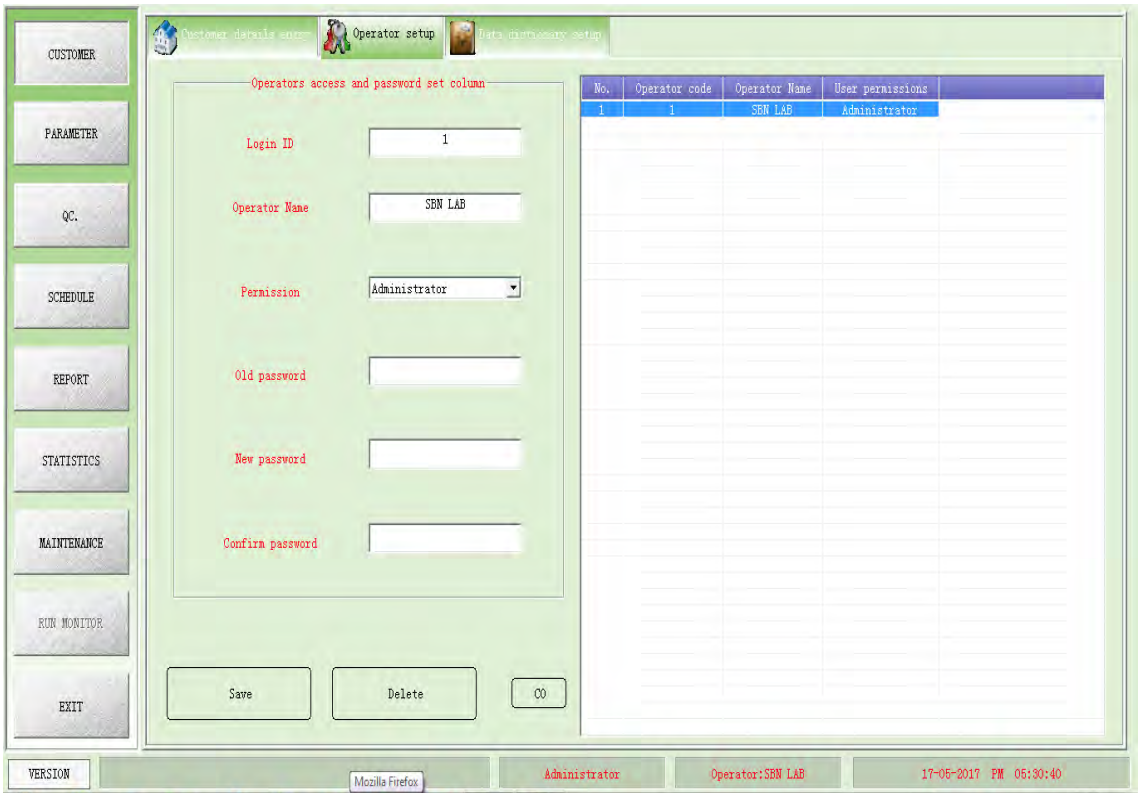
Buttons:

Button	Function
Save	To save input information
Delete	To delete input information

2) Operator setup

Click “Operator setup” to see the below interface:

The super user can modify item parameter, and the generally user cannot.



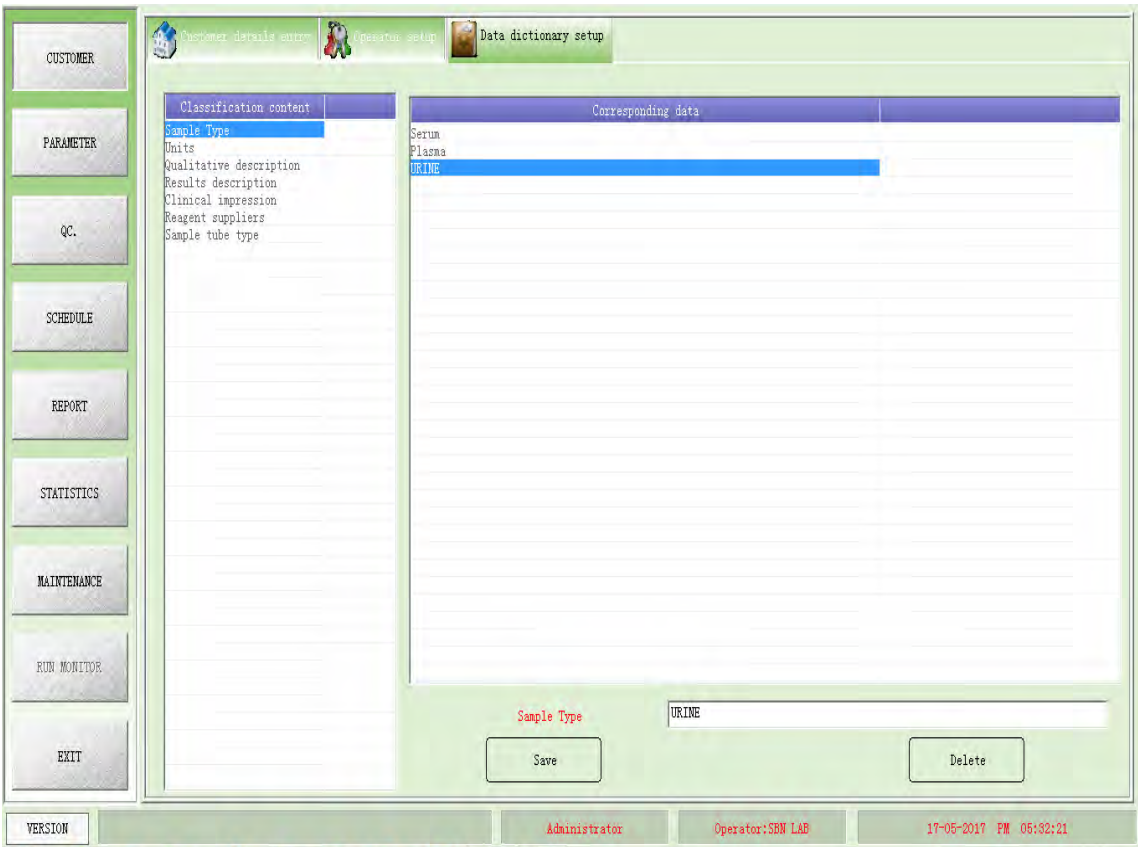
Parameter	Meaning
Login ID	Set operator’s code to instead of name.
Operator name	Set up operator name
Permission	Allowance
Old password	The old password set up by operator
New password	The new password to replace old one.
Confirm password	To confirm the new password again.

Button:

Button	Function
Save	To save the input information
Delete	To delete the input information

3) Data dictionary setup

Click “Data dictionary setup” ,it shows as below:



Parameter:

Parameter	Meaning
Sample type	Type of the sample,eg：serum、plasm、urine
Units	Unit of the result
Qualitative description	Result qualitative description，eg：Masculine、Negative etc
Results description	H=H;L=L
Clinical impression	Sample clinical impression，eg：hemolysis,lipemia,icterus etc
Reagent suppliers	Company name of the reagent

Parameter	Meaning
Sample tube type	Cup;Tube

Button:

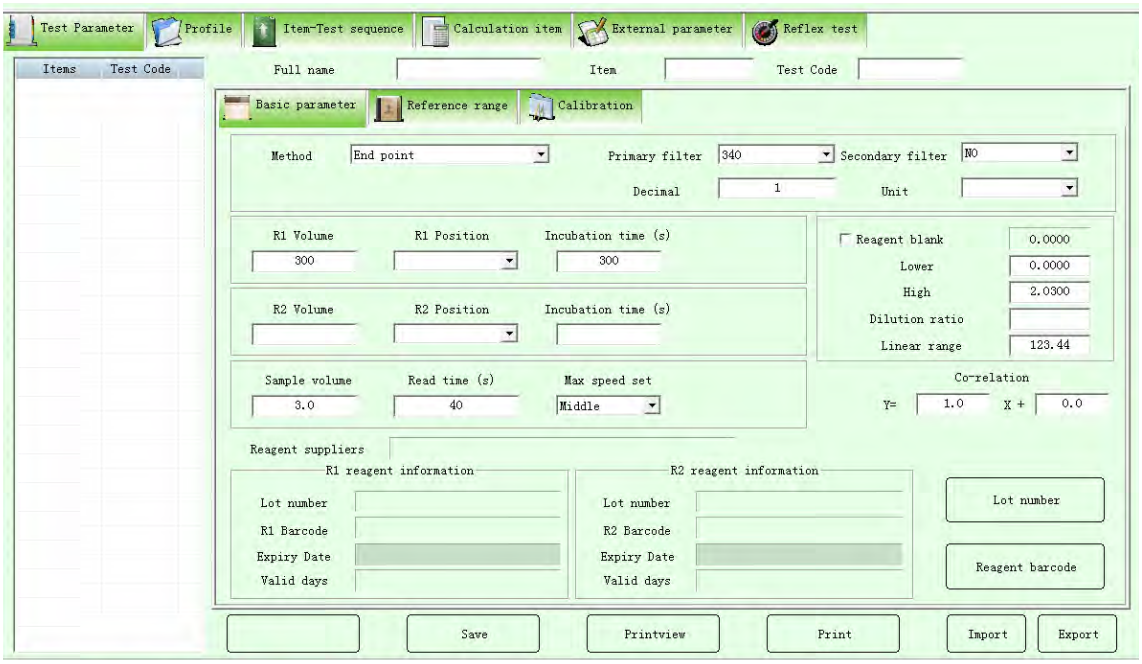
Button	Function
Save	Save the changes
Delete	Delete selected content

5.2.2 Parameter

“Parameter” is the main execution command for making a application program for a biochemistry reagent. Each biochemistry reagents comes with the programming literature chart inside the kit. Depending upon the programming literature chart User or Application engineer is supposed to make a program in instrument. For adding the program the User has to first Click “Parameter” button then goes to the below interface, it’s for setting up parameter of testing items. This is the key step to ensure instrument to get accurate result.

As there are many items, while editing parameter; please in according with chemistry reagent instruction.

Here explain each tab:



Attention:

- This system requires to set up parameters like sample volume, reagent volume and testing wave length, etc, when setting this, please comply with related description in the User Manual, also refer to reagent instruction.

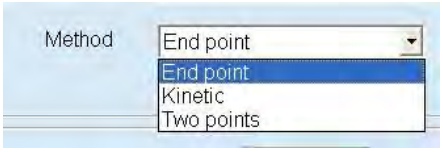
1）Test parameter

Showed as the upper graphic, it for setting up the chemistry item's basic parameter, reference range and calibration.

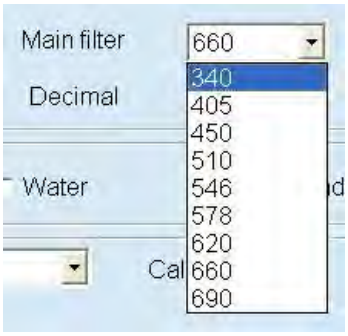
1.1）Basic parameter

Here can set up test method, main filter, sub filter, decimal and unit.

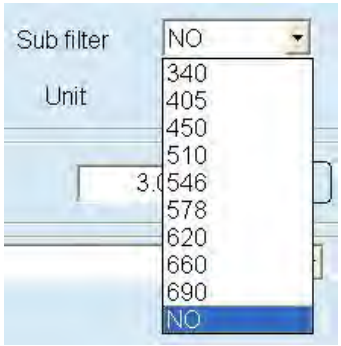
Select the correct method according to instruction.



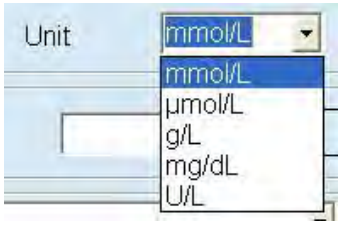
Click the combo box and select the correct method.



Click the combo box and select the correct wave length.



Click the combo box and select the correct wave length.



Click the combo box and select the correct unit.

Parameter,

Parameter	Meaning
Method	To select correct method as per specific item. For example , ALT use Kinetic
Main filter	It means the primer wave length, must be setting.
Sub filter	It means the wave length to eliminate interference, set up when needed.
Decimal	It refers to the result the decimal place be retained. For example, when set up “0”, means no decimals.
Unit	It can be selected that you set up in “Customer Data”
Linear range	The maximum testing valve. It will dilute and re-test while the result exceed range.
Distilled water / Reagent	For distilled water blank, it will not record reagent absorbance, while reagent blank will record that.
Reagent blank	When select reagent blank, the programme will record reagent absorbance during test and record here.
Lower-High Limit	The range of reagent blank absorbance.
Reagent manufacturer	Select the reagent manufacturer that you set up in “Customer Data”
Reagent Lot No.	Input the lot number of reagent
Dilution ratio	To set the default ratio of dilution when auto retest
Sample volume	To display the sample volume when auto test. It will calculate automatically by software.
Distilled water	To display the distilled water volume. It will calculate automatically by software.

Button,

Button	Function
Add	Add a new item to setting parameter.

Button	Function
Delete	Delete current item.
Save	Save the changes.
Print	Print the complete test parameter
Import	To Import the new reagent and parameter from computer
Export	To export the program from the computer

1.2) More details

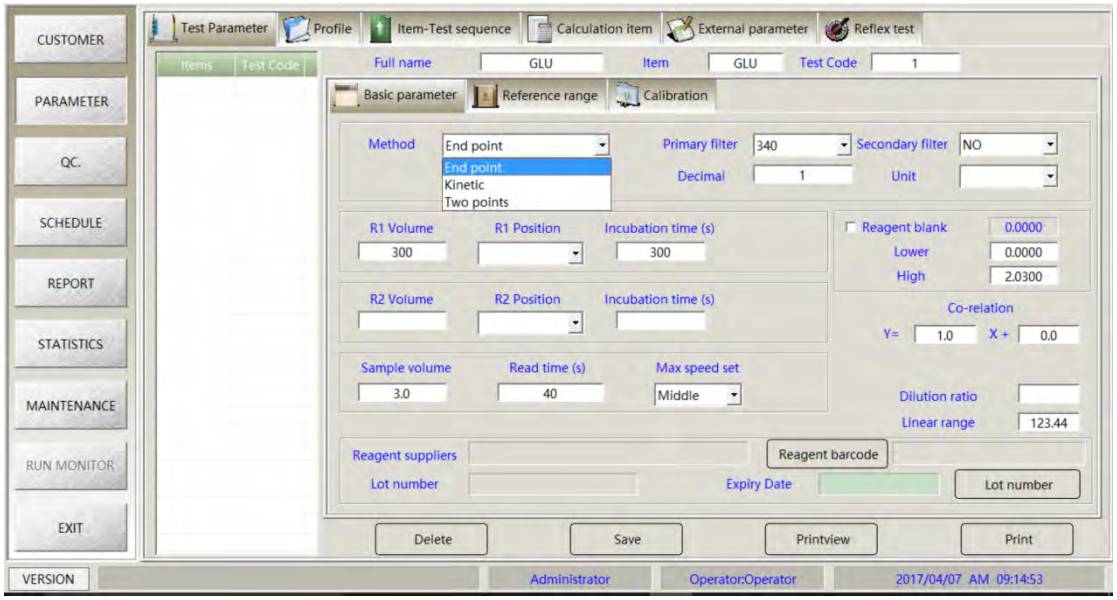
1.2.1 [Item] please use the logogram, it is for Test name display in the [SCHEDULE] screen.

1.2.2 [Test code] it only can use 1~99 number, so the total program parameter can up to 99 items.

1.2.3 [Method]

Software with 3 method: End point, Kinetic, Two point

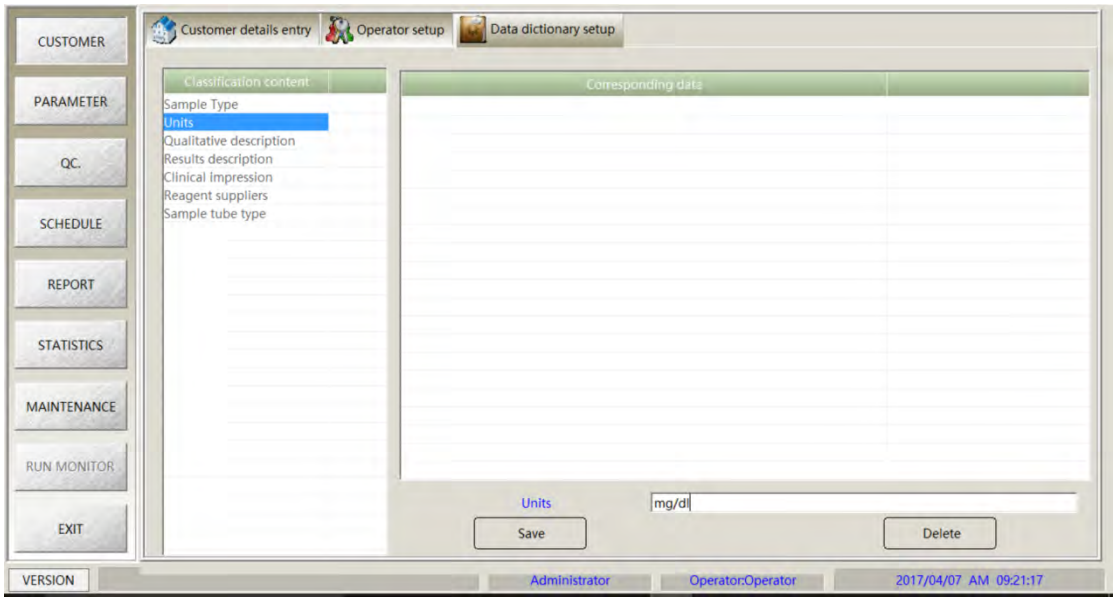
Two point also is Fixed time assay.



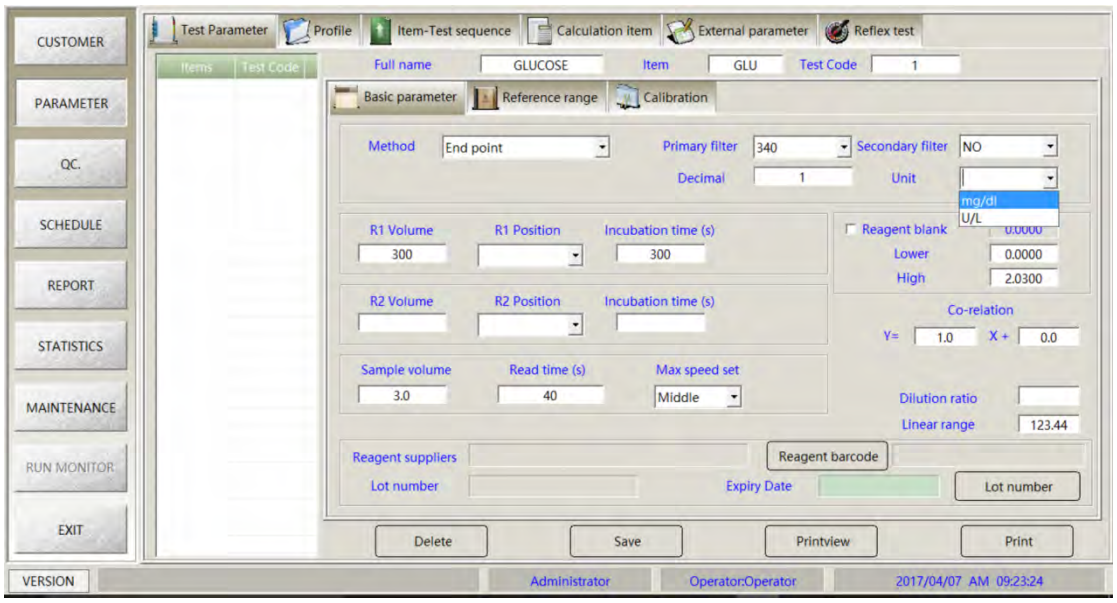
1.2.4 [Unit]

We can manual input the unit for each parameter directly.

Or we go to [CUSTOMER] –[Data dictionary setup]-input unit and press [SAVE]



Then restart the software, you can select the unit in the list.



1.2.5 [R1 volume] [R2 volume]

R1 volume can input only from 150ul ~300ul.

But if the two reagent item, the total reagent volume R1+R2 should be less than 300ul also.

1.2.6 [R1 position] [R2 position]

The position 1 is only for dilution water, so for reagent we can select the 2 to 40.

1.2.7 [Incubation time(s)]

The instrument will add reagent 1 (R1) firstly, then incubation R1 and incubation time is fixed, it is 108 seconds (6cycle* 18seconds, 1 cycle is 18seconds)

The incubation time after R1 position: This is the incubation time after add reagent 1(R1) and sample and mixed. And for One reagent parameter, the setup range is 30~662seconds.For two reagent parameter, this incubation time also fixed to 144 seconds (8cycles).

The incubation time after R2 position: This is the incubation time after add reagent 2 (R2), the setup range is 18~518seconds.

1.2.8 [Sample volume]

The sample volume setup range is 1.5~50ul.

1.2.9 [Read time(s)]

The read time, for Endpoint, we can use 40seconds (that means instrument will read 2points)

And for Kenetic, the read time suggest more than 180seconds(that means more than 10points.

Please noted, the whole reaction time can not more than 13minutes.

1.2.10 [Dilution ratio]

It is setup dilution ratio for auto dilution procedure, the instrument will aspiration water from no.1 reagent position. This position only input the number from 2~10, it means dilution ratio is 1:2 to 1:10.

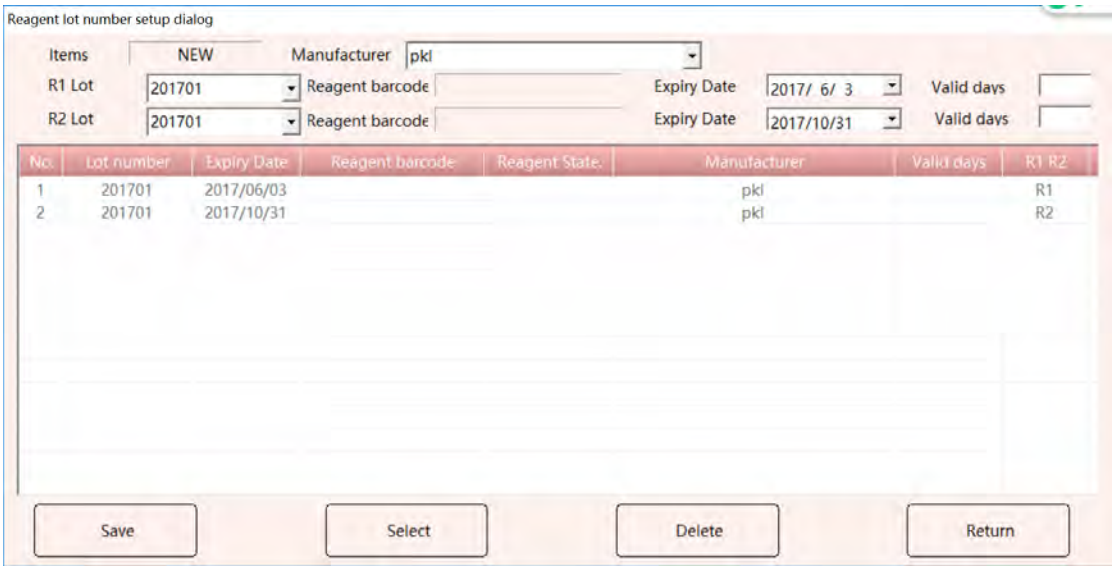
1.2.11 [Max speed set]

This is setup the stirrer rotate speed, normally only setup to Middle is okey.

1.2.12 [Lot number]

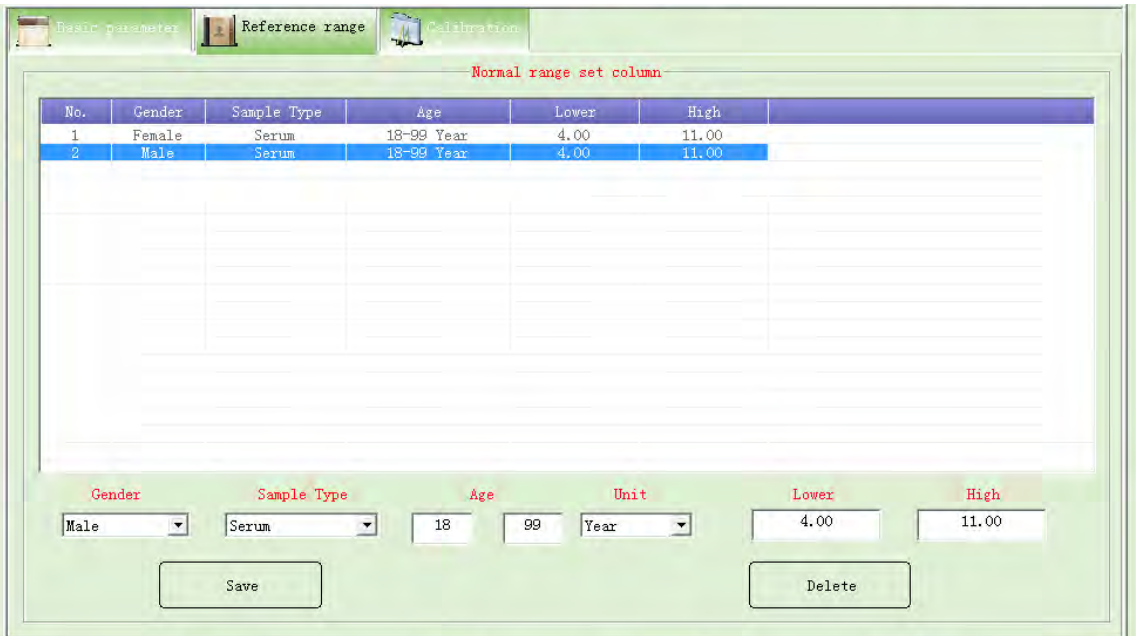
Press it to setup the reagent lot number for R1 and R2, Expiry date, Manufacturer, also can setup the Valid days to bottle open time (on board time)

After setup, press [Save] and then [select] it for current use.



1.3) Reference range

For entering the reference range, click “Reference range” tab. In reference range window you can add the reference range for male, female and child. First user has to select the gender, than type of sample like serum, plasma or urine. With respect to reagent kit literature, user has to enter the lower and higher valve.



Parameter:

Parameter	Meaning
Gender	The patient's gender.
Sample type	The type of sample, for example: serum or urine.
Age	The patient's age.
Unit	The unit of age,eg：Year,Month,Days
Lower limit	The lower limit of normal value.
High limit	The upper limit of normal value.

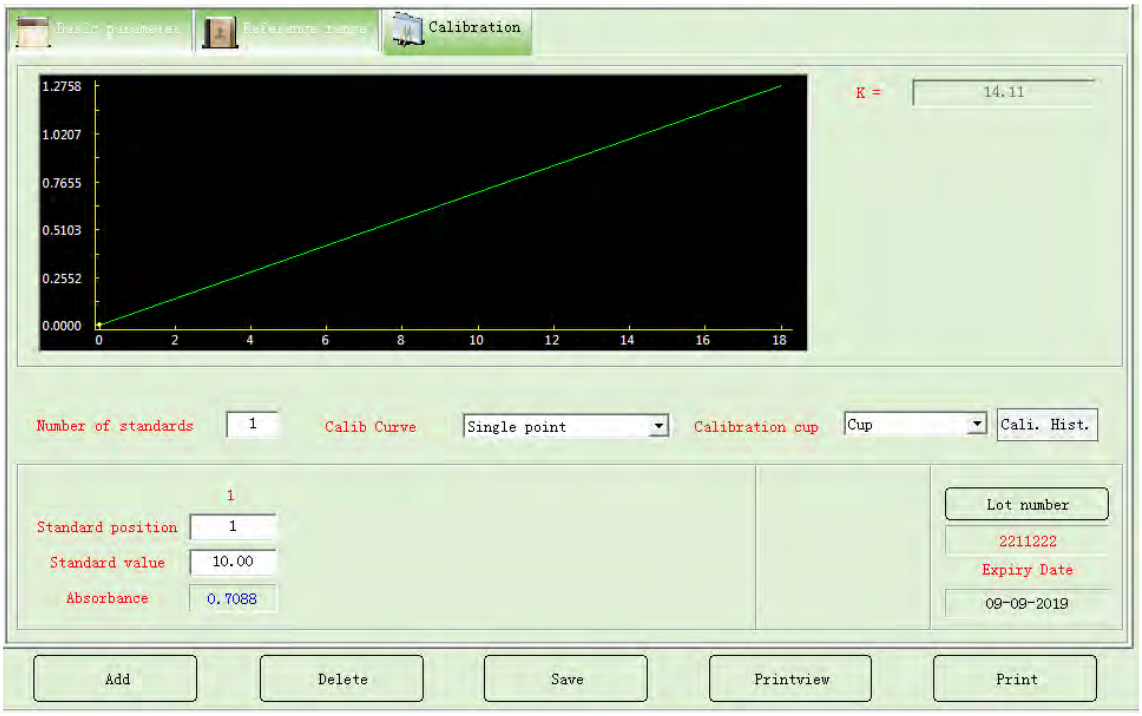
Button:

Button	Function
Save	Save the setting
Add	Add the patient's parameter
Delete	Delete the setting

Note: [Sample Type] should setup in [CUSTOMER] –[Data dictionary setup]-select the Sample Type and setup to save it. And we must be setup the age range and then save it.

1.4) Calibration

Calibration is used to calibrate the reagent on the instrument. For calibrating the instrument the User is suppose to calibrate with respect to Standard or Multi cal of known value.



Parameter:

Parameter	Meaning
Number of standards	When choose calibrate method, it will show corresponding number of calibrator.
Calibration curve	The rule for calibration.
Calibration cup	The type of calibrator cup
Standard position	The position to place calibrator.
Standard value	The value of calibrator.
Absorbance	The absorbance value of calibrator.

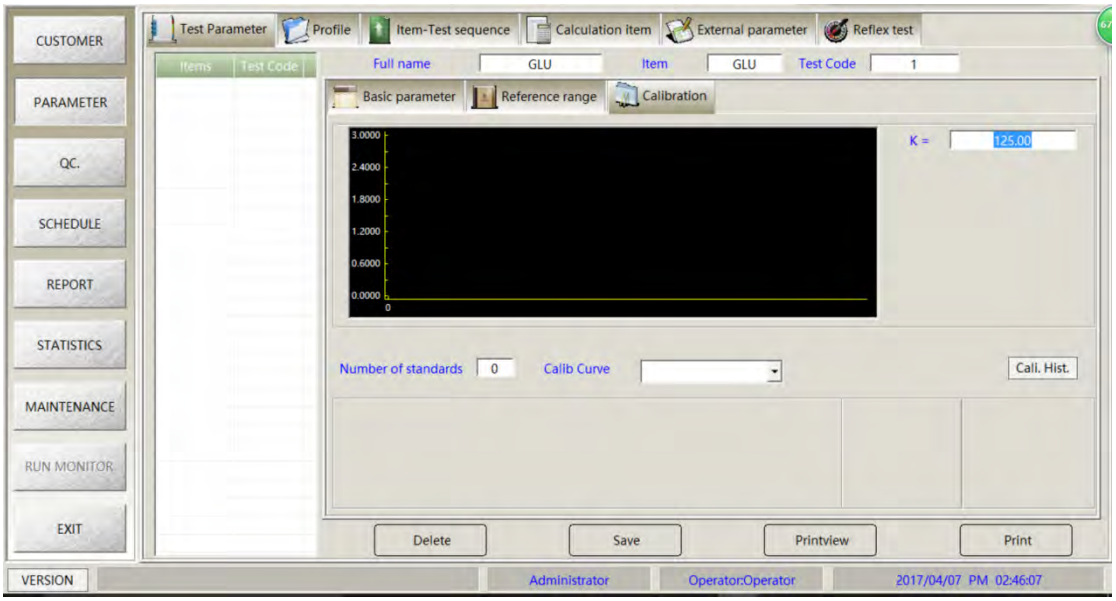
Button:

Button	Function
Save	Save the setting
Add	Add the patient's parameter
Delete	Delete the setting

Calibrate method:

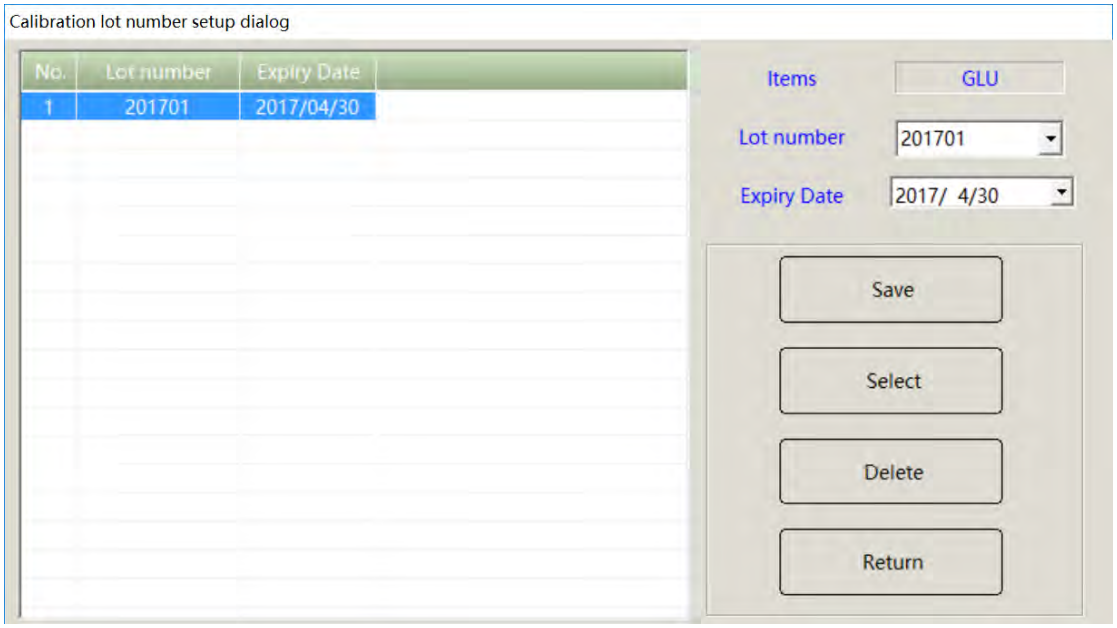
No.		Calibration type	Number	Calibration parameters
Linear	1	Single point	1	K
	2	Two point	2	a、b
	3	Multiple point	3～6	a、b
Non-linear	1	Logistic-Log 4P	4	K、R_0、a、b
	2	Logistic-Log 5P	5	K、R_0、a、b、c
	3	Polynomial	5	a、b、c、d
	4	Parabola	3	a、b、c
	6	Spline	4	R_0、a、b、c

1.4.1 If we want manual setup the factor K value, we should setup the [Number of standards] to 0, then input the K value



1.4.2 For normal calibration, we input the Number of standard, calib Curve (This is calibration method), input standard position and standard value.

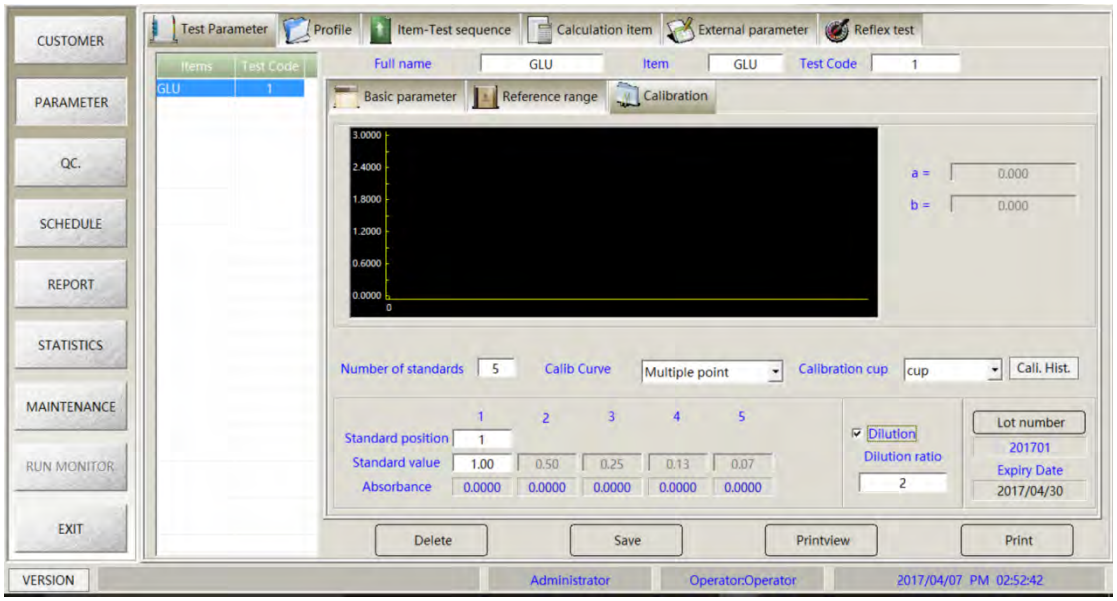
Then we must be press [Lot Number]



Setup the Lot number and Expiry date for the calibrator, press [Save] and then [Select] it.

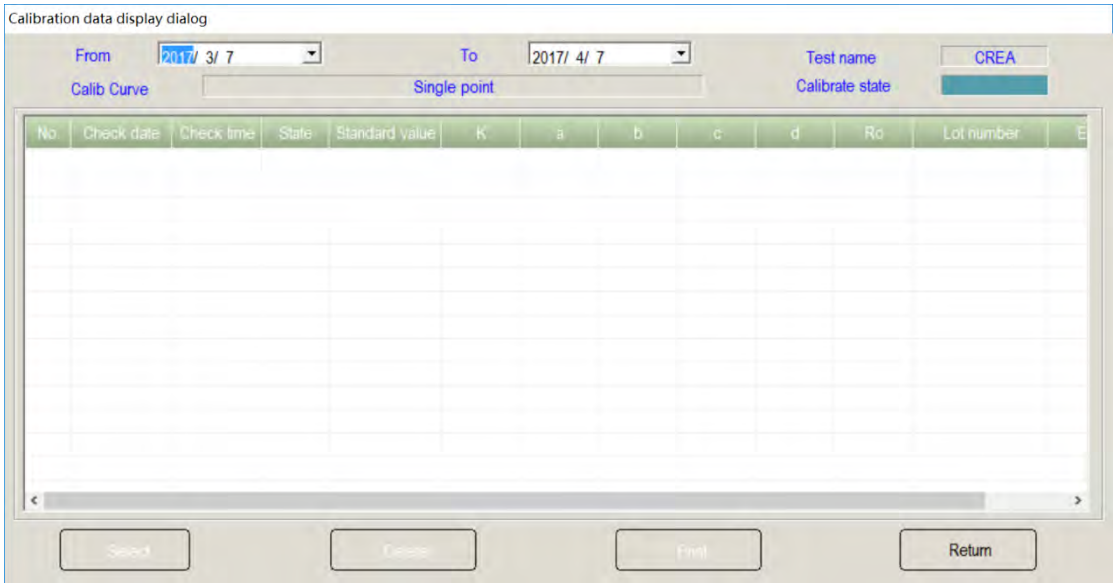
1.4.3 For multiple point method, if we want perform auto dilution calibration, we can select

the Dilution, then input the dilution ratio for calibrator. Also setup range is 2~10, it means the dilution ratio is 1:2 to 1:10.



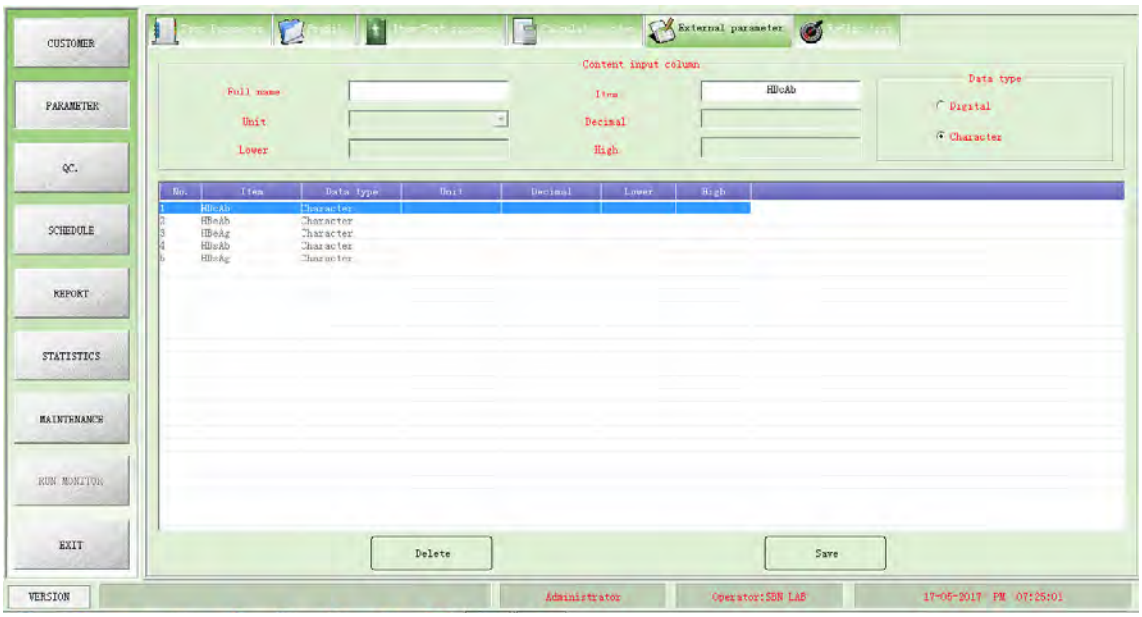
1.4.4 [Cali.Hist]

It is check the calibration history, also we can select the old calibration data for test.

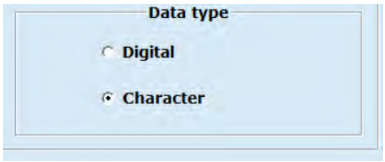


2) External parameter

Click “External parameter“, then edit item as below :



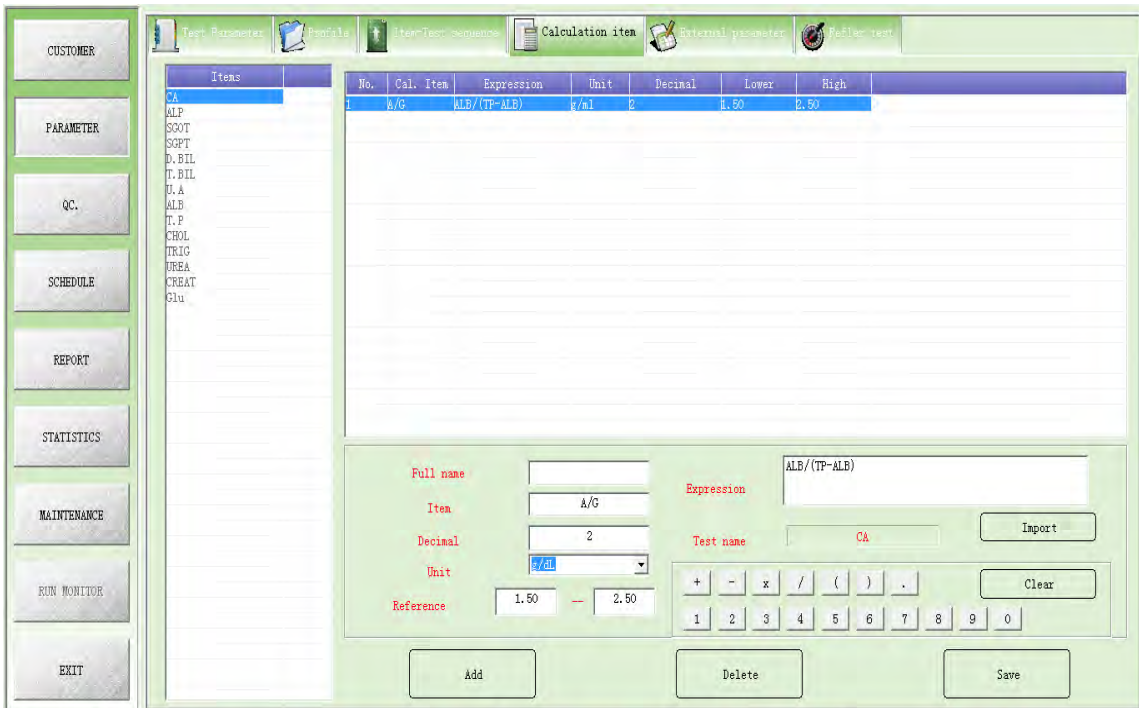
This is for the result which tested by other instruments and need to print on a same report.



It can select digital or character for displaying result.

3) Calculation item

Some items' result can be calculated by other result, no need test. For example: Globulin=TP-Albumin



Parameter:

Parameter	Meaning
Full name	Code name of calculating item
Item	English name of calculating item.
Decimal	Result of decimal point.
Unit	Unit of item
Reference	Normal value reference range
Expression	Calculate formula.
Test name	Select related calculate item on list.
Clear	Clear the current formula.
Import	Import item to formula.
0~9	Input numbers to formula.
+ - * /	Calculate symbol
.（）	Decimal point and bracket

Button:

Button	Function
Save	Save the setting
Add	Add new calculate item
Delete	Delete selected item

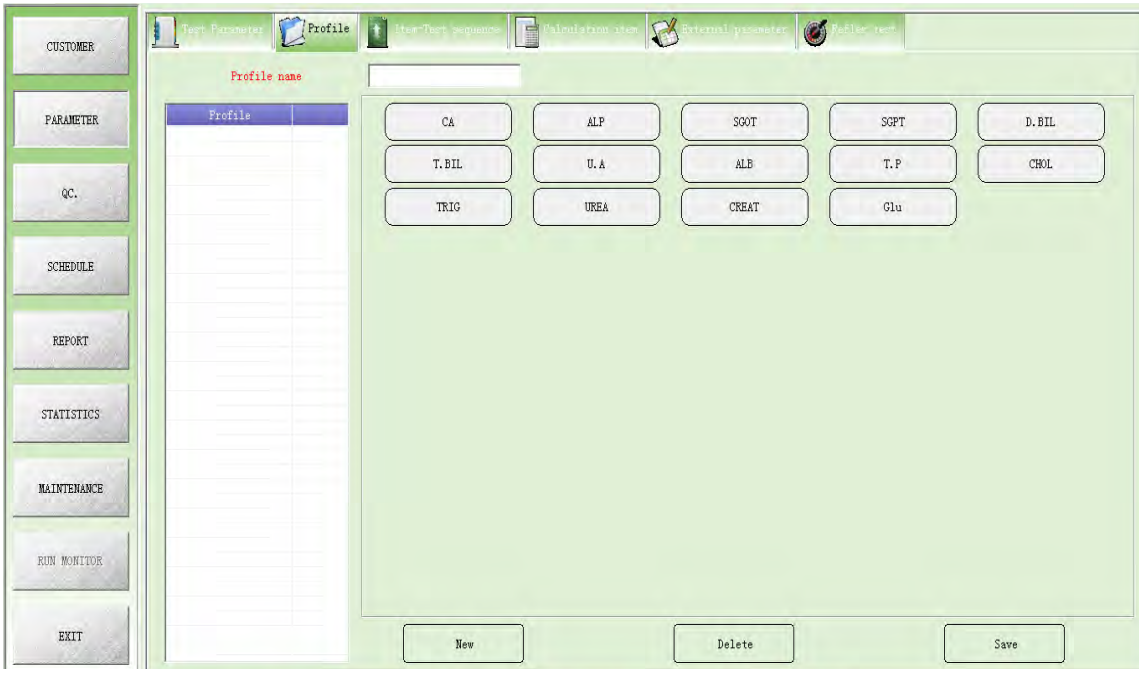
4) Profile setting:

4.1) Click “Profile”, and then edit items.

4.2) Click “New”, input the group name, and select combo items, then save.

4.3) It’s simply to operate combo item test, by click group name, can test the required items.

See details on “Test Parameter

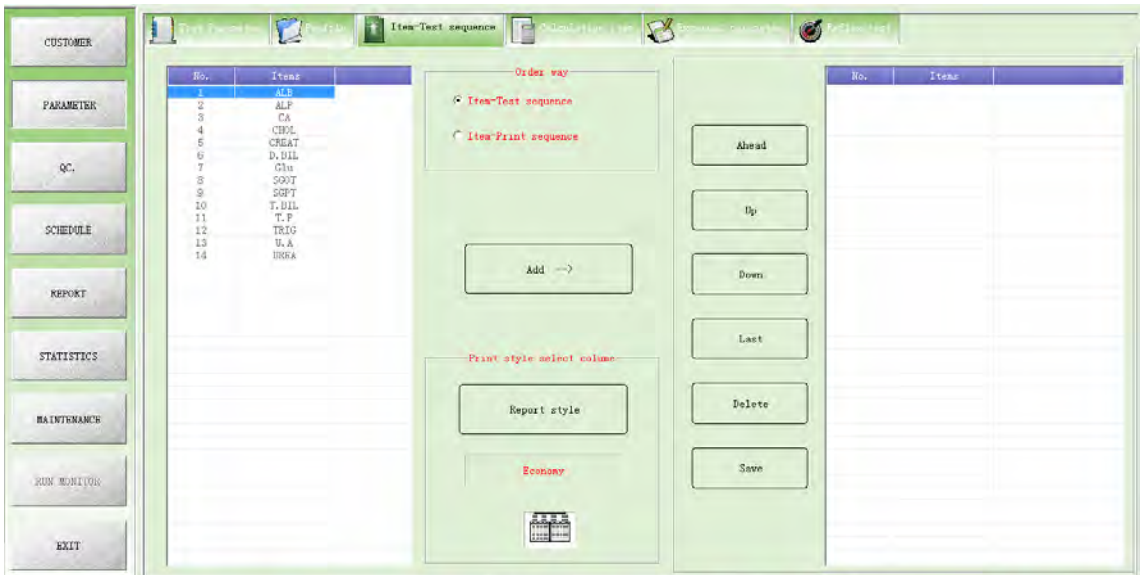


5)Test sequence setting:

5.1) Here can set up testing sequence. Left list is for all items and the right list is for ready test item.

5.2) Select item on the left list and click “Add”, this item will add on the bottom of right list; by setting the order of right item, select certain item, then click buttons such as : “up”, “down”, “Ahead” and “Last”

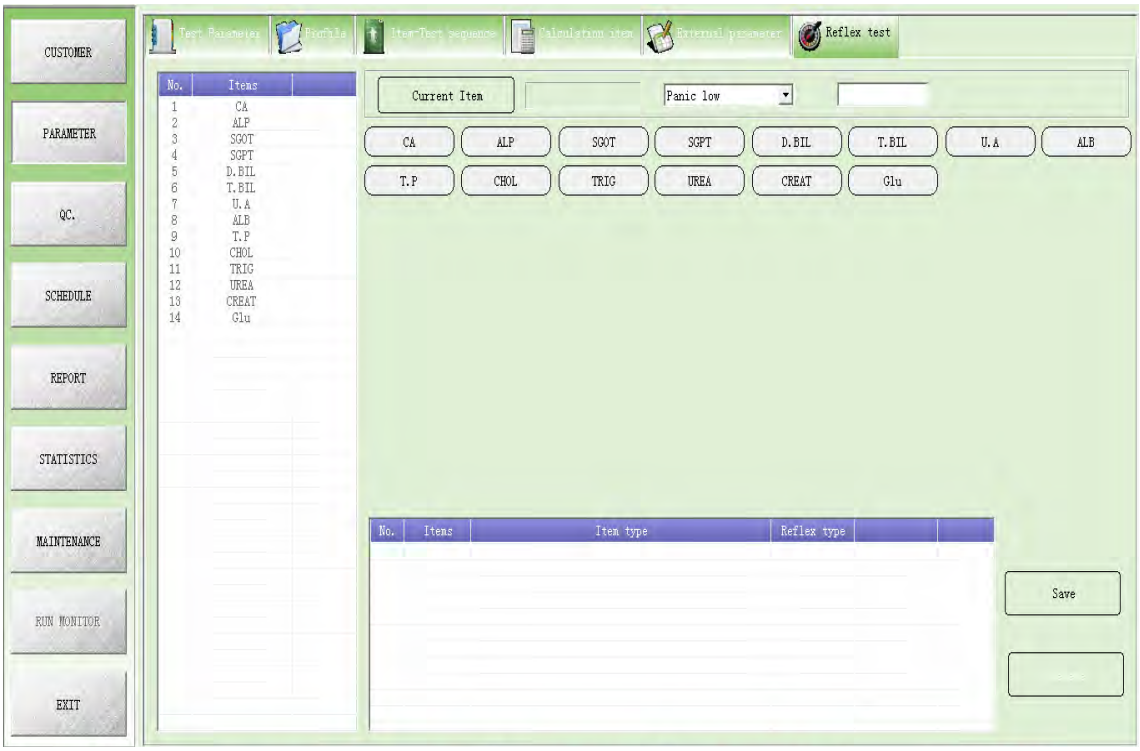
5.3) The test start from the No.1 item.



5) Reflex Test

Reflex test are test depend upon the panic high or panic low result of any particular

biochemistry test. For example: In case of renal profile, if the result of CREAT is greater than panic high, than user no need to run UREA separately. So in reflex test, user can program a panic high range for CREAT, So if the sample results of CREAT exceed panic high than instrument will automatically run UREA.

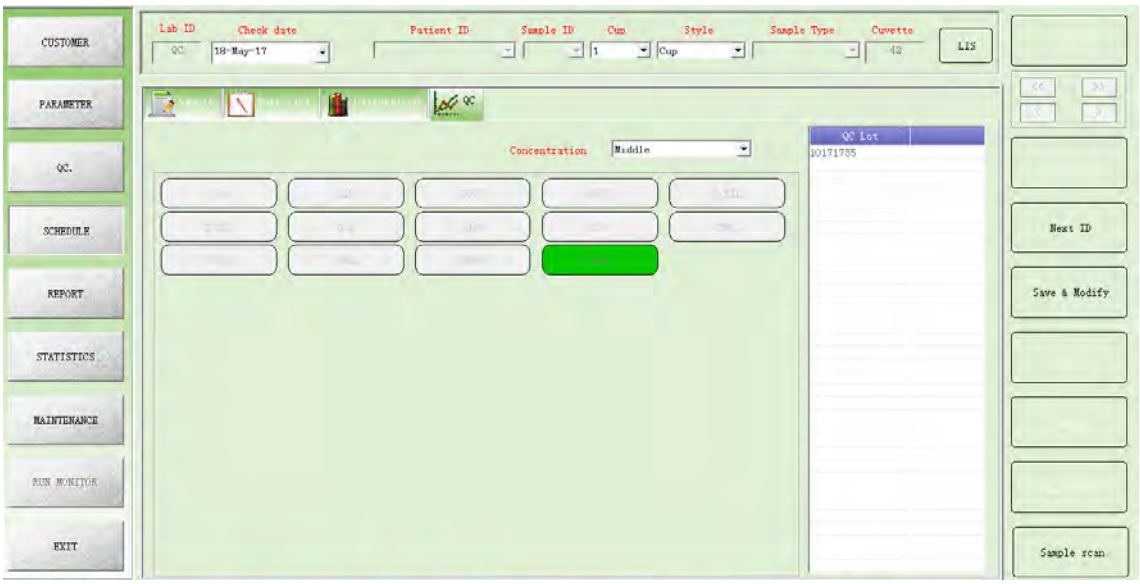


5.2.3 Quality Control

1) Input Control sample

1.1) Sample input on the testing interface:

Click Schedule button to go to test interface, then click “QC” tab. After select concentration type, then choose testing Lot No., then select test-item on the left column. The background will turn into green color after selecting. After set up information like sample position, cuvettes position, click “add”, then undergoing control test. Before starting with the Quality control, User should make sure the lot number and expiry date of the control should be valid. Here user has to define Low, High and Normal control with there QC Ranges. For Example in the following picture, User is making a QC for Glucose test.



Attention:

- The background color of item indicates the current condition.
- Green means the item is selected.

2) Quality Control

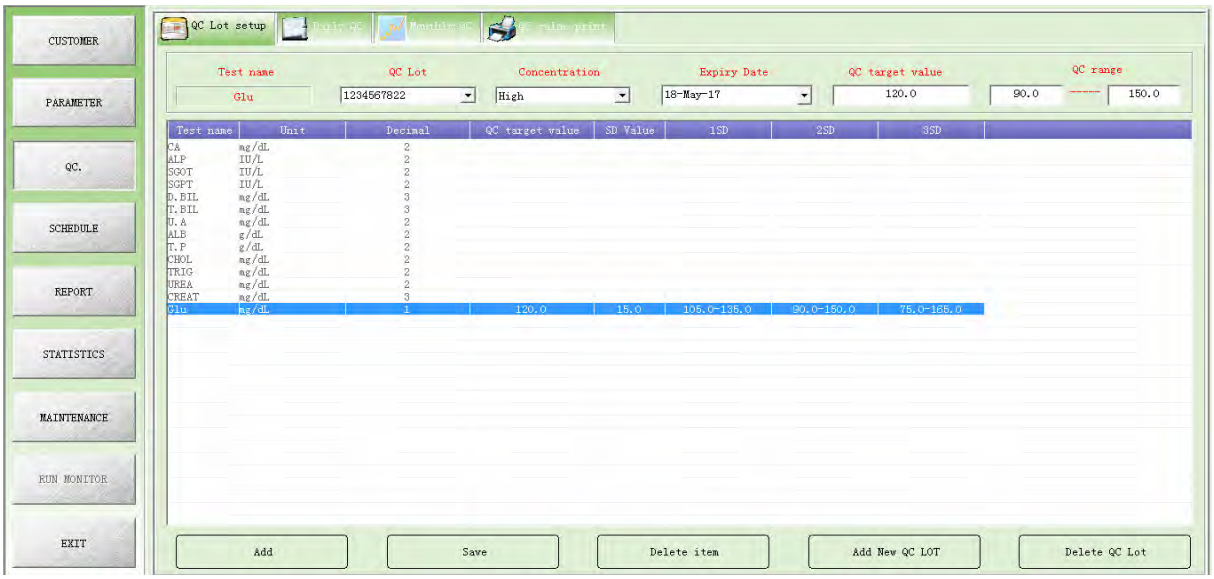
Click “QC”tab to enter control interface. It’s for setting control and review control result and chart.

2.1) QC. Lot setting

Set up each item’s information such as QC. Lot No., target value,expiry date and concentration.

Then input at least one item’target value and SD,then click “Add” and “Save”.

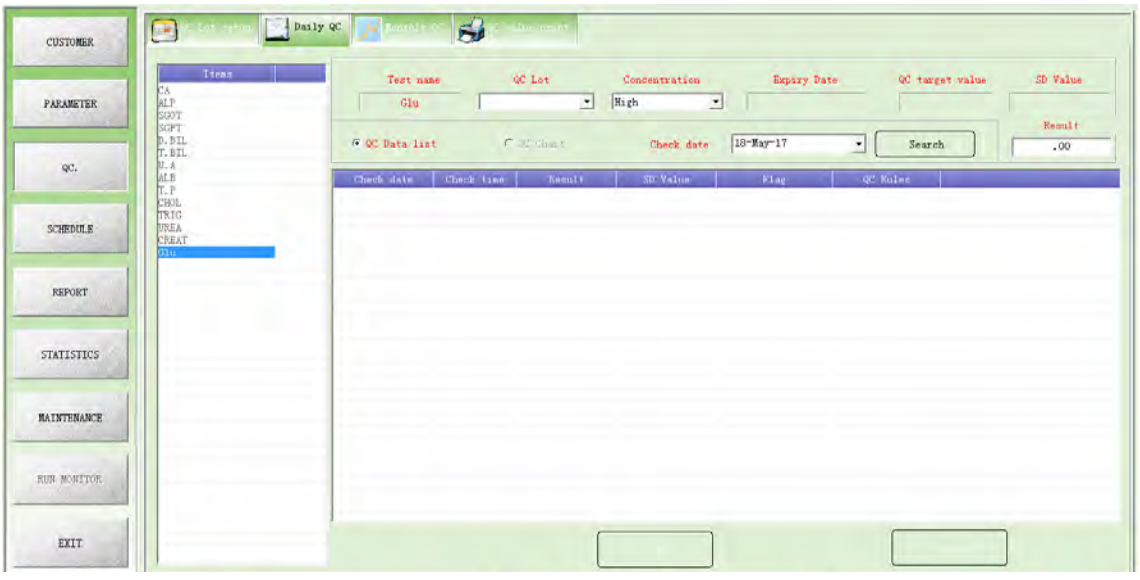
See chart below:



2.2)QC. Daily QC.

Review control value by clicking “Daily QC” tab.

Select “Daily QC”



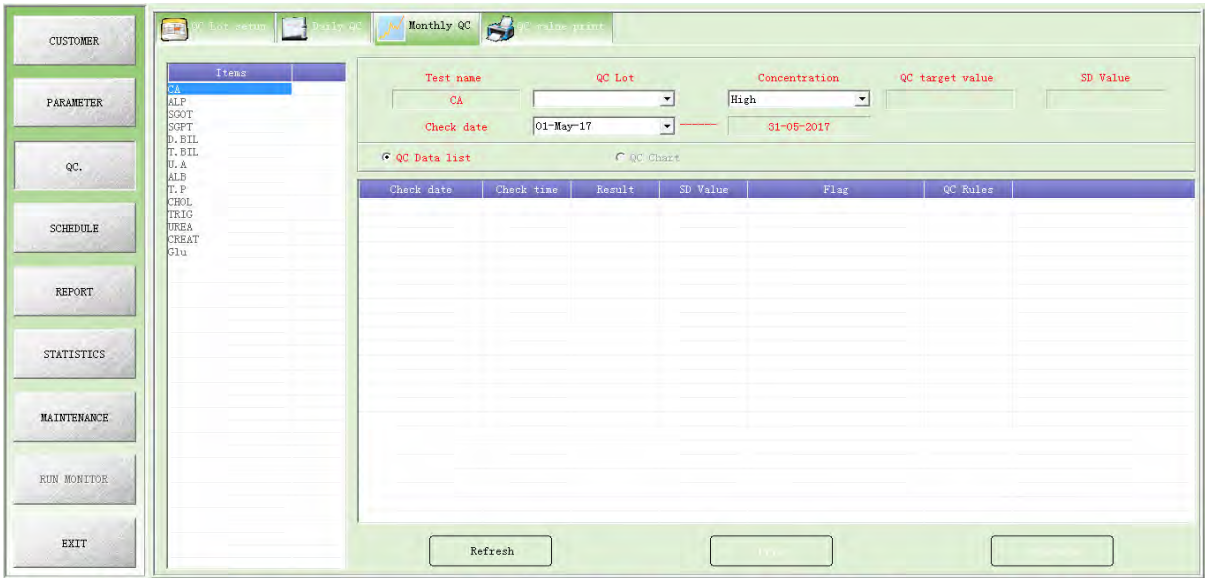
Click “Monthly QC” to see Control curve.

Button:

Button	Function
Add	Modify the value of control
Save	Save the modification
Delete	Delete the value of control

2.3) Monthly QC. analysis:

First, select QC. Lot No. and concentration type under "Monthly QCs" list, then choose the date which need analyze in "Check date" column, it will display the all control information in whole month. The control information will display by "QC date list " and "QC Chart". See as below:



Button:

Button	Function
Refresh	Refresh the control chart
Print	Print control chart
Printview	Printview the control chart

Attention:

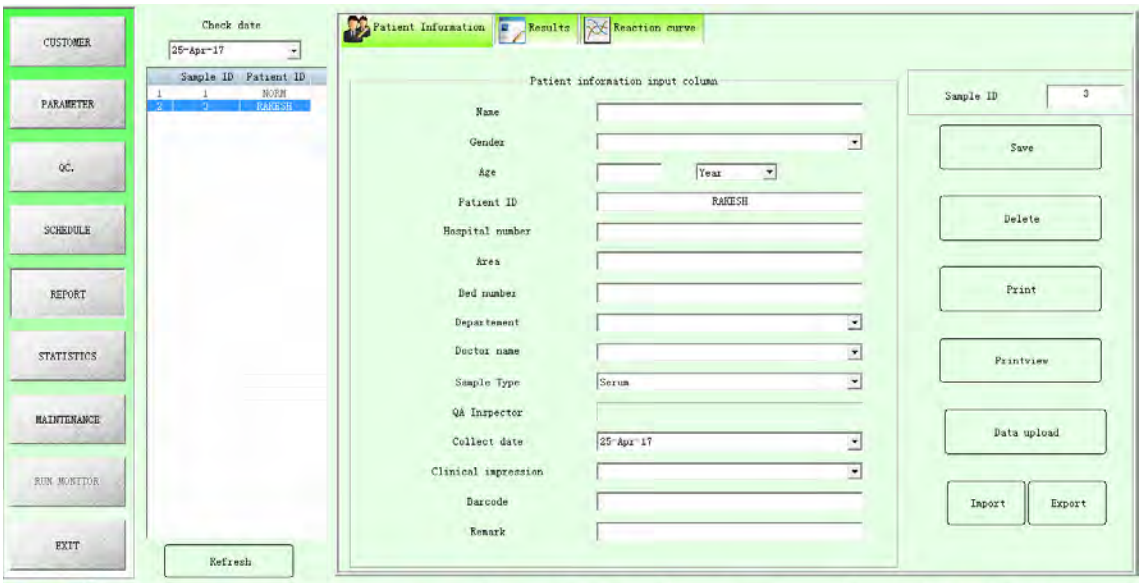
● Make sure to set up control's validity correctly, so that enable the software to judge whether within validity.

5.2.4Report

Click“report”button, enter interface, input patient detail information, “Save”inputed information, user can “Preview”print format, select suitable style,“Print”, print patient report.

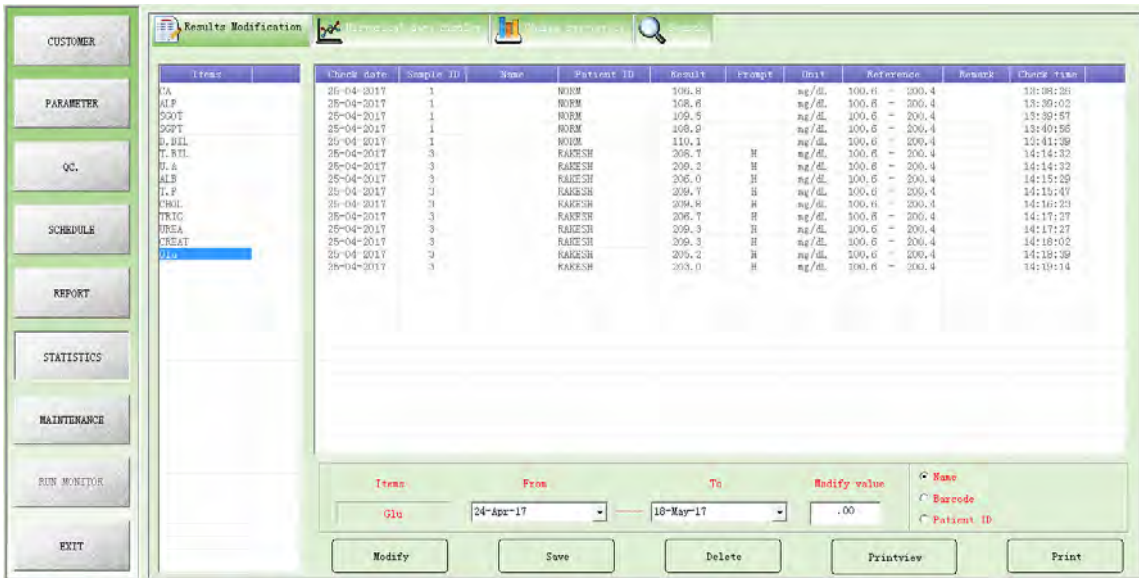
1) Patient information register

During test, can input patient detail information, click”Report”button, enter into “Patient information”input interface,see below picture.This interface display and edit sample detail information.



Also in this interface can check patient test result, and display real test graph.

2) Print format setting



2.1）Print-Print view: Select print format, click will display select format dialoge.

2.2）Save: After click, will save at present revised into format.

2.3）Preview: Click print or print view, select print format, click then will see preview.

2.4) Import: Import is used to collect the patient details into the system.

2.5) Export: Export is used to send back the data into the computer

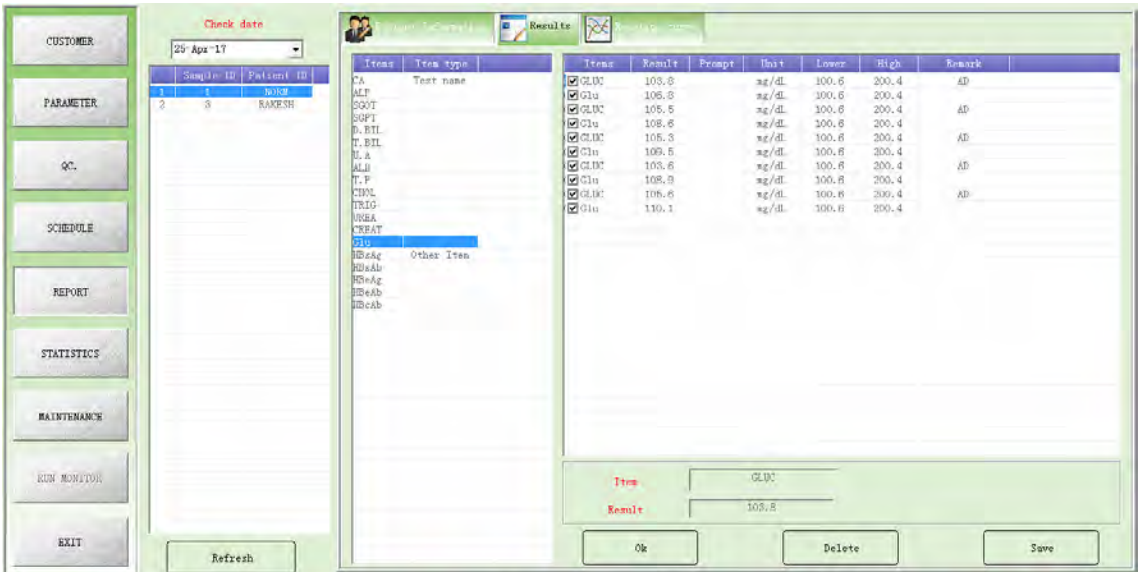
2.4）Exit: After click will exit interface.

Below introduce “sample information”dialog’s parameter.

Parameter	**Meaning**
Sample ID	Operator input ID No., for identifying different samples
Print	Print condition identification, “No” not printed, “Yes” printed
Name	Patient name
Gender	Patient sex
Age	Patient age
Outpatient No.	Patient case history No.
In-patient No.	Patient in-patient No.
Area No.	Patient sick area.
Bedroom No.	Patient sickbed No.
Submitting department	Inspector’s department.
Submitting doctor	Inspector name
Sample type	“Serum”、“Plasma”、“Urine”、“Others”
Inspected doctor	Operator name
Submitting date	Revise submitting date manually
Clinic impression	Basic description of patient samples.
Barcode No.	Samples barcode information.

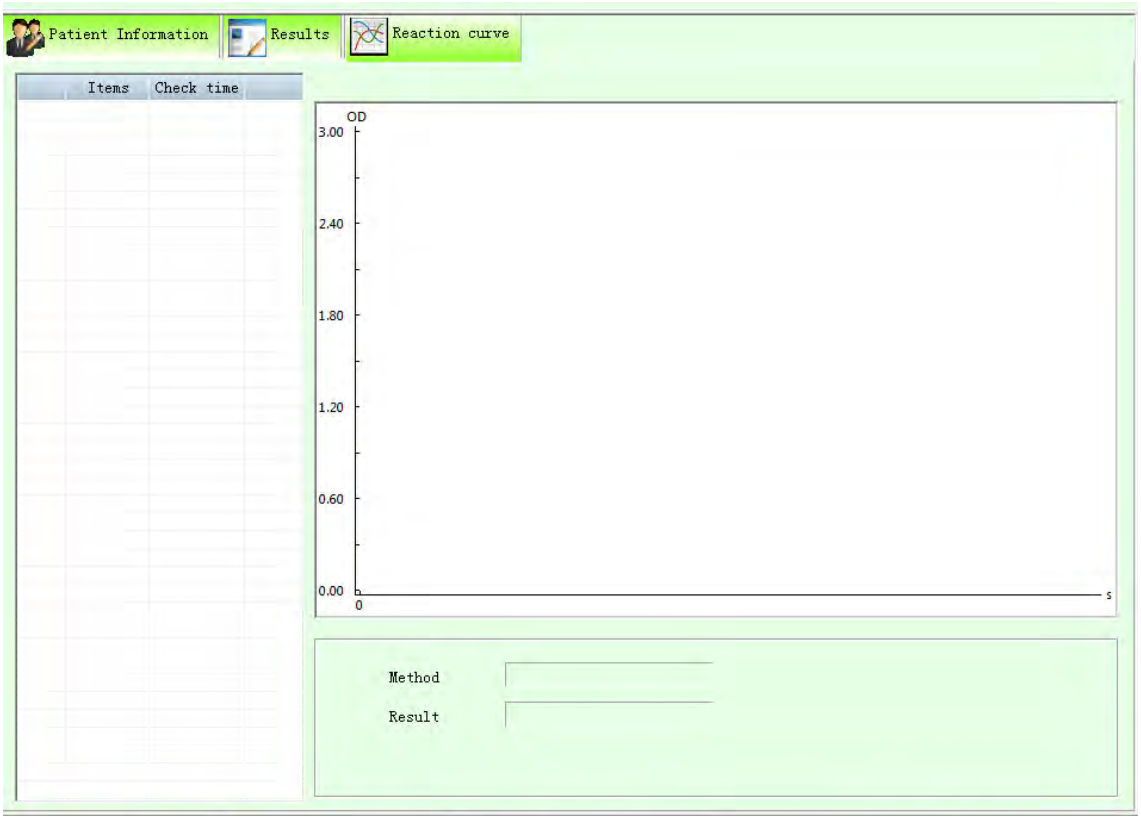
3) Test results display

Here can check patient test results and revise.



4) Reaction curve

4.1) Inspector can check reaction curve here，and according to reaction curve to confirm instruments or reagents have problem or not，patients test results trustiness or not.



4.2) Inspector can use real-time chart to check reagents parameter setting right or not, if not correct, change test points and resetting.

5.2.5 Statistics

Click“Statistics” button enter to main interface. See below picture.

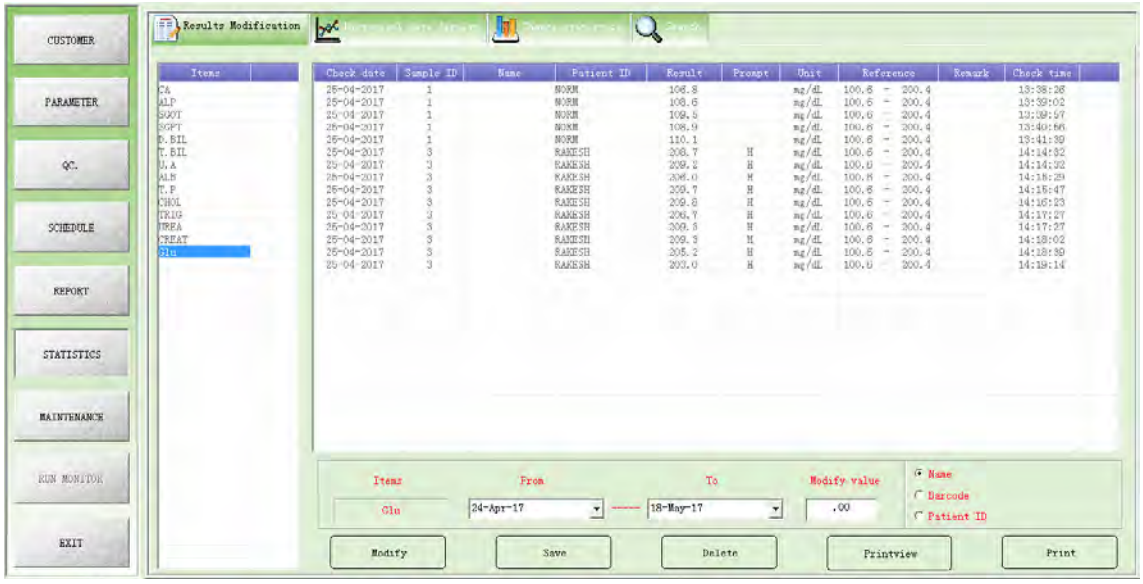
●In menu can check historical data.

●In menu can edit historical data.

●In menu can make charge statistic for test items.

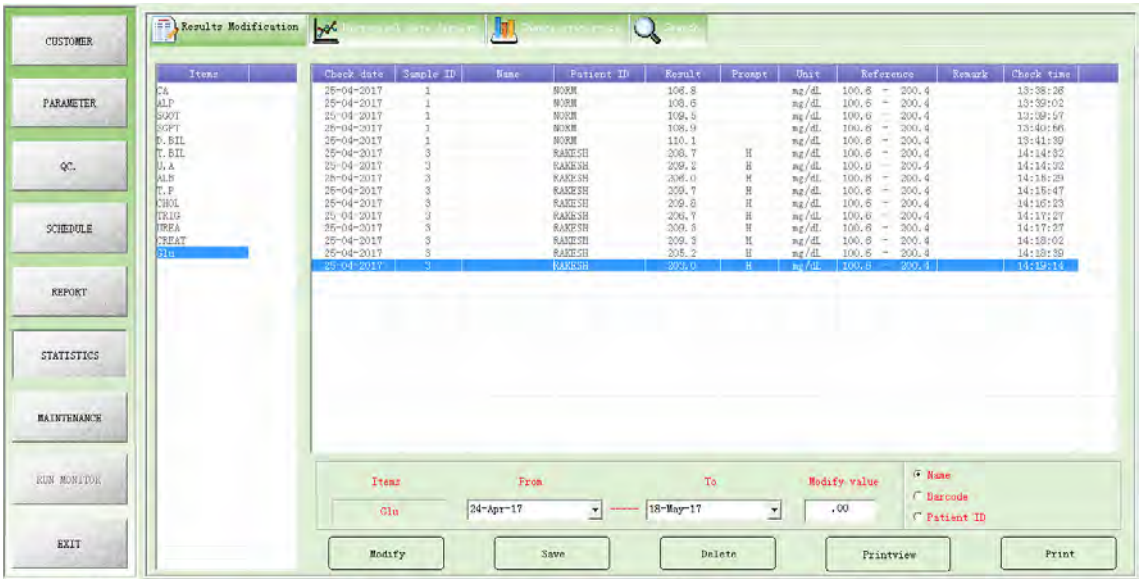
●Have different kinds of query mode.

●Query and edit results can print.

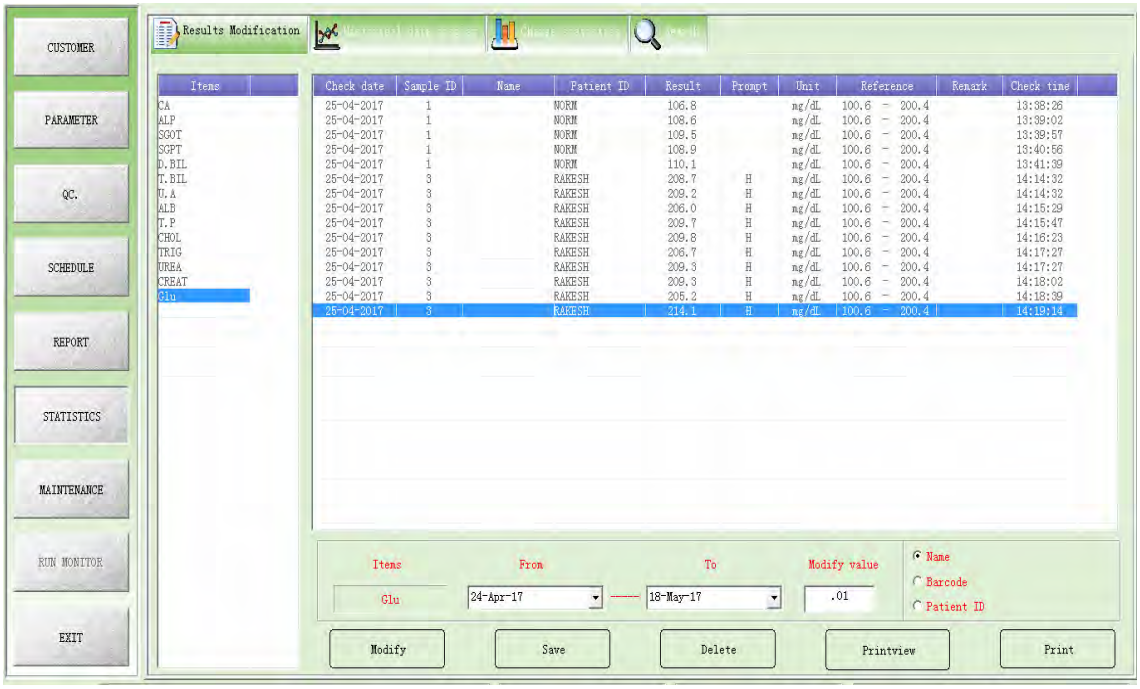


1) Results modification

1.1) Click “Results modification”, then enter to interface below. This is use for editing results.



1.2) Select needed revised item in chemistry items column, fill in revised factor, click“Modify”, and “Save”,this item all results will multiply revised factor.See below picture.

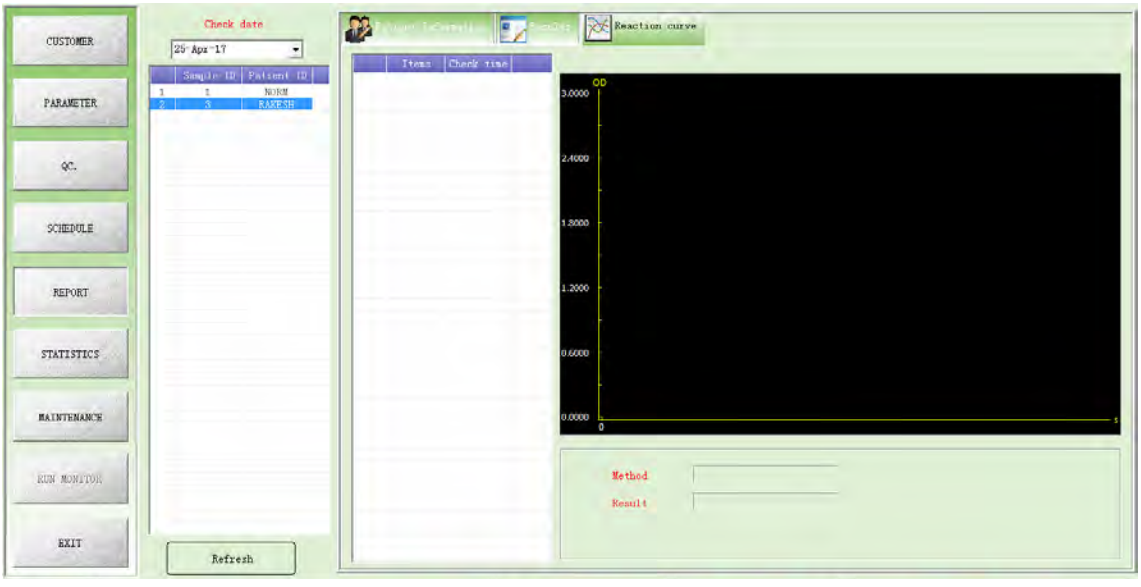


Parameters in this interface:

Parameter	Meaning
Items	This box shows all the biochemistry items. You can check and edit them by selecting items.
Check date	Show the done biochemistry items orderly at testing date.
Modify value	Selecting test items, all results will multiply revised factor,can revise batch results.

2) **Historical Data Display**

2.1) In “Historical Data” page, the sample、QC and calibrator results tested in specified day can be displayed below.



2.2) Display the reaction curve of item result, and the reaction curve can be edited and

calculated

Parameters in this interface:

Parameter	Meaning
Check date	Only when testing date is set, you can query the testing items on that day
Search style	There are three methods: sample、QC and Calibrator
NO. and ID	Show the S.N. and sample ID of biochemistry items done on that day. Select by mouse.
Items	After choose sample ID, testing ID will be shown. Showing reaction curve of that detection item by mouse.
Results	By setting parameters, the results tested by analyzer
Start point	When you need to re-edit the results, it is the testing point which is used for calculating the time the reaction begins
End point	When you need to re-edit the results, it is the testing point which is used for calculating the time the reaction finishes
New result	The new results after editing the beginning and end testing points

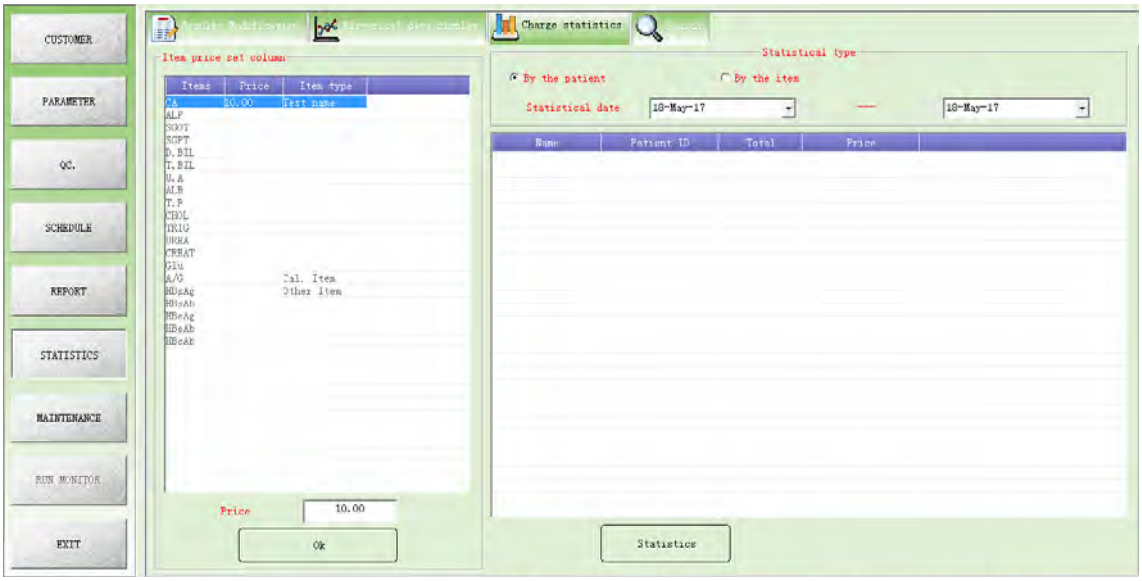
Buttons in this interface:

Button	**Function**
Refresh	Refresh the historical data
Calculate	Calculation results will display the edited results by clicking “calculation” button
Save	To save the edited results by clicking this button

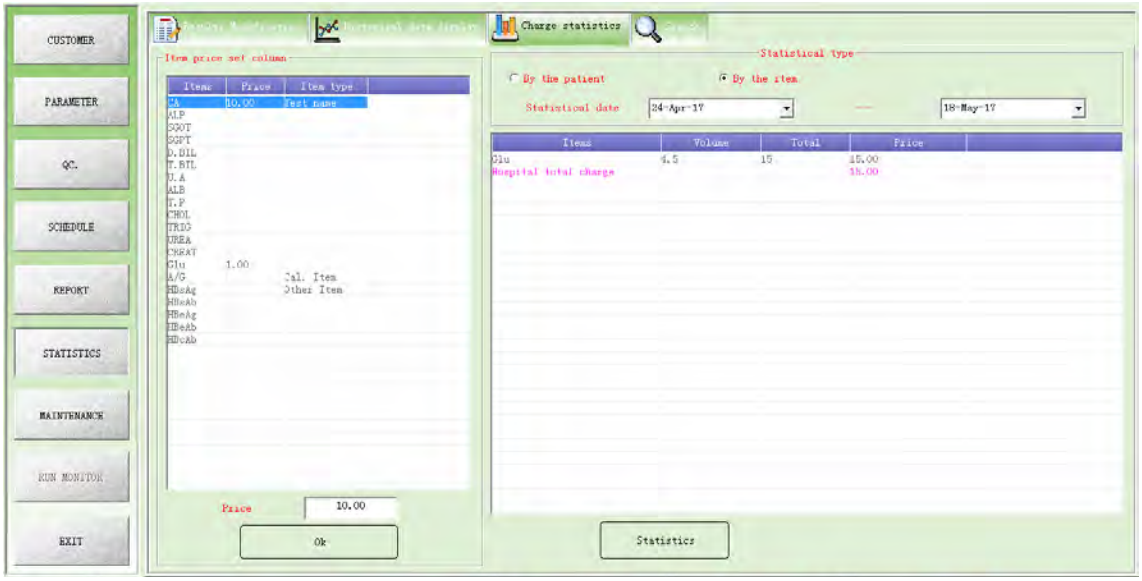
3) **Charges Statistics**

Click “Charges Statistics” tab to check total charge. It helps to get charge statistics.

3.1) Statistics-charges statistics-Patient charges statistics



3.2) Statistics—Charges Statistics—Item charge Statistics



Parameters in this interface:

Parameter	**Meaning**
By the patient	Show the testing items of a patient, and the charges he has to pay
By the item	The charge of certain items in the statistics date
Statistics date	Query charge statistics according to statistics date
Price	Input the price of selected item into the price box

Buttons in this interface:

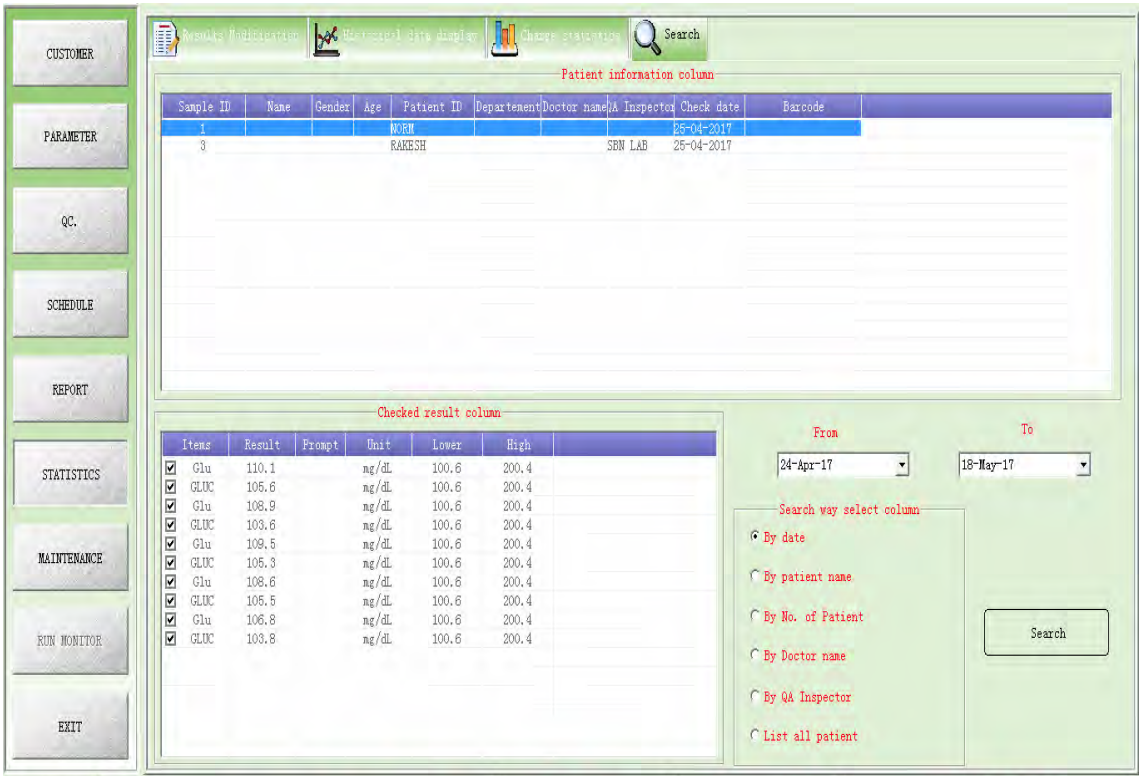
Button	**Function**
OK	Confirm the inputted price

Button	Function
Statistics	Statistics the prices

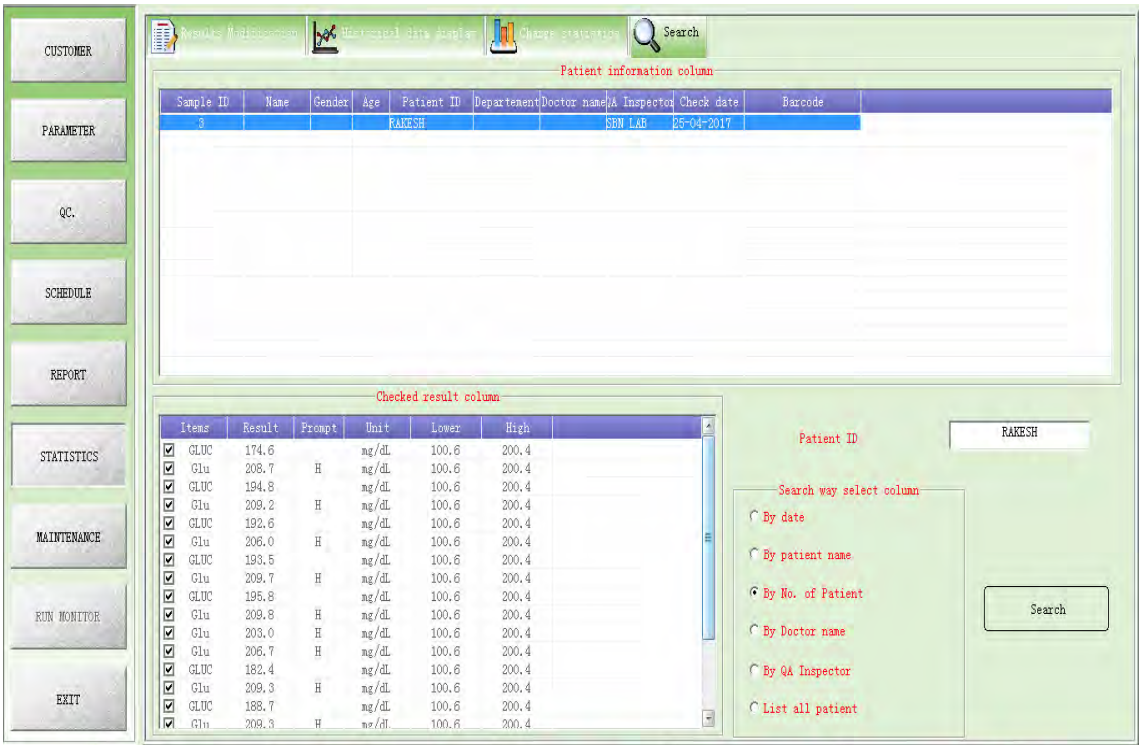
4) **Search**

Select a desired query way and click “Search” to index to results.

4.1) Statistics — Search — Search way select— Check date



4.2) Statistics —Search — Search way select— patient name:



Parameters in this interface:

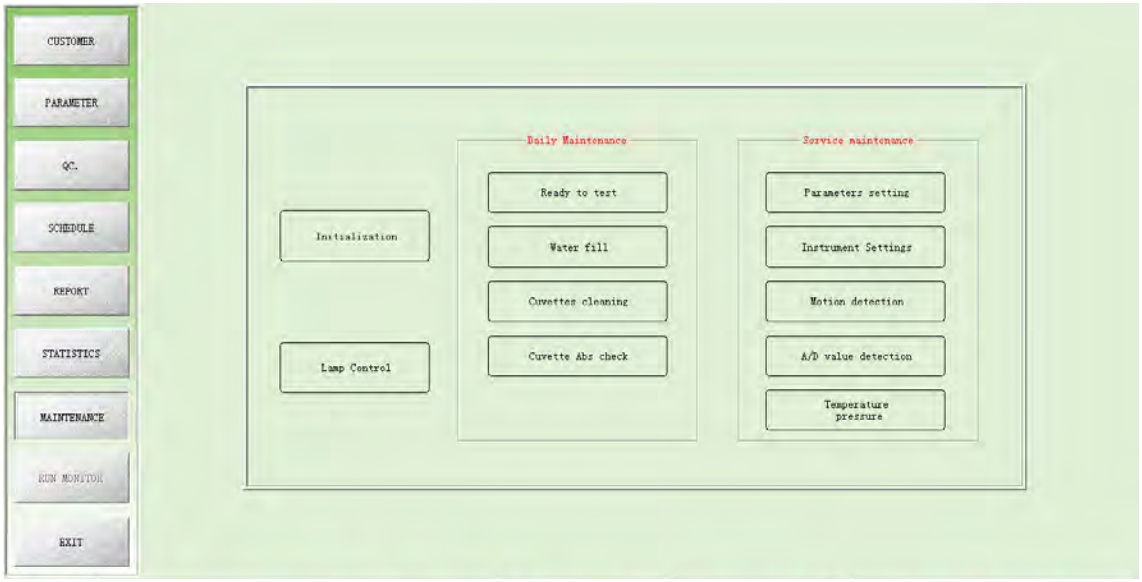
Parameter	Meaning
Patient information column	Click the items in “Patient information column” to show in the “Checked result” column
Checked result column	Display the results from the “Patient information column”
Search way select column	Six methods: date、patient name、No. of patient、doctor name、QA inspector 、List all patient.

Buttons in this interface:

Button	Function
Search	After selecting “Search way”, click it to search the results that meet your requirements

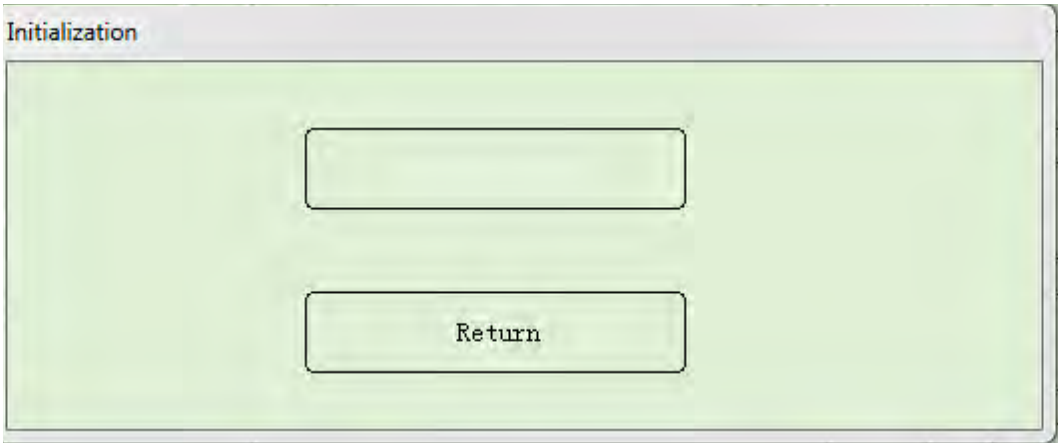
5.2.6 Maintenance

Click “Maintenance” button to enter into the below interface. This is mainly used for maintaining the system and data.



1) Initialization

Click “Initialization” button to get the following dialog box; and then click “Initialization” button again to initialize the instrument; it is adopted when the user can’t ensure whether the instrument has returned to the beginning point.

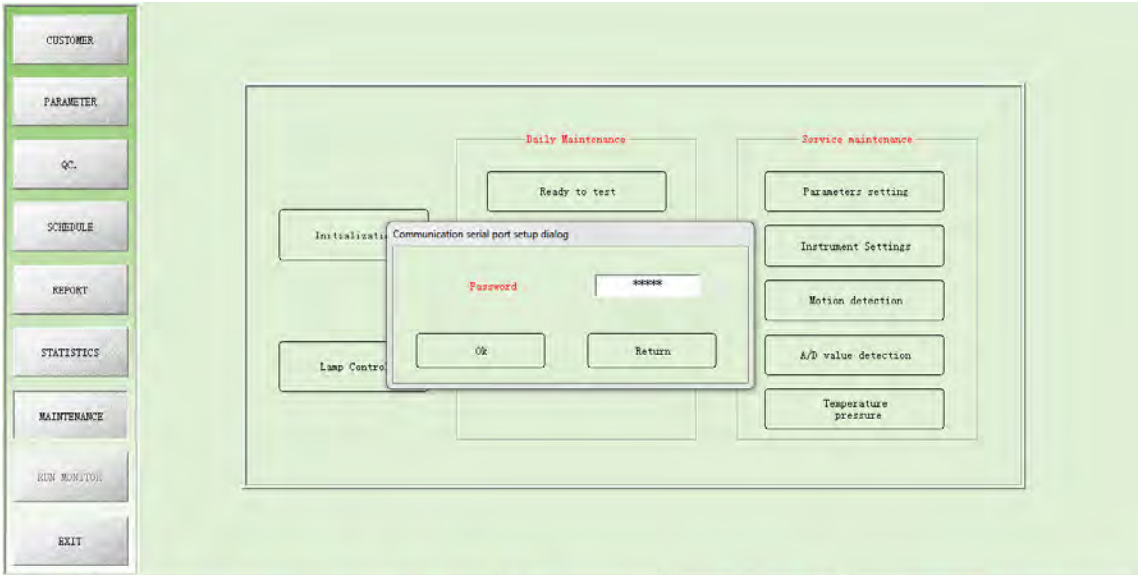


Buttons in this interface:

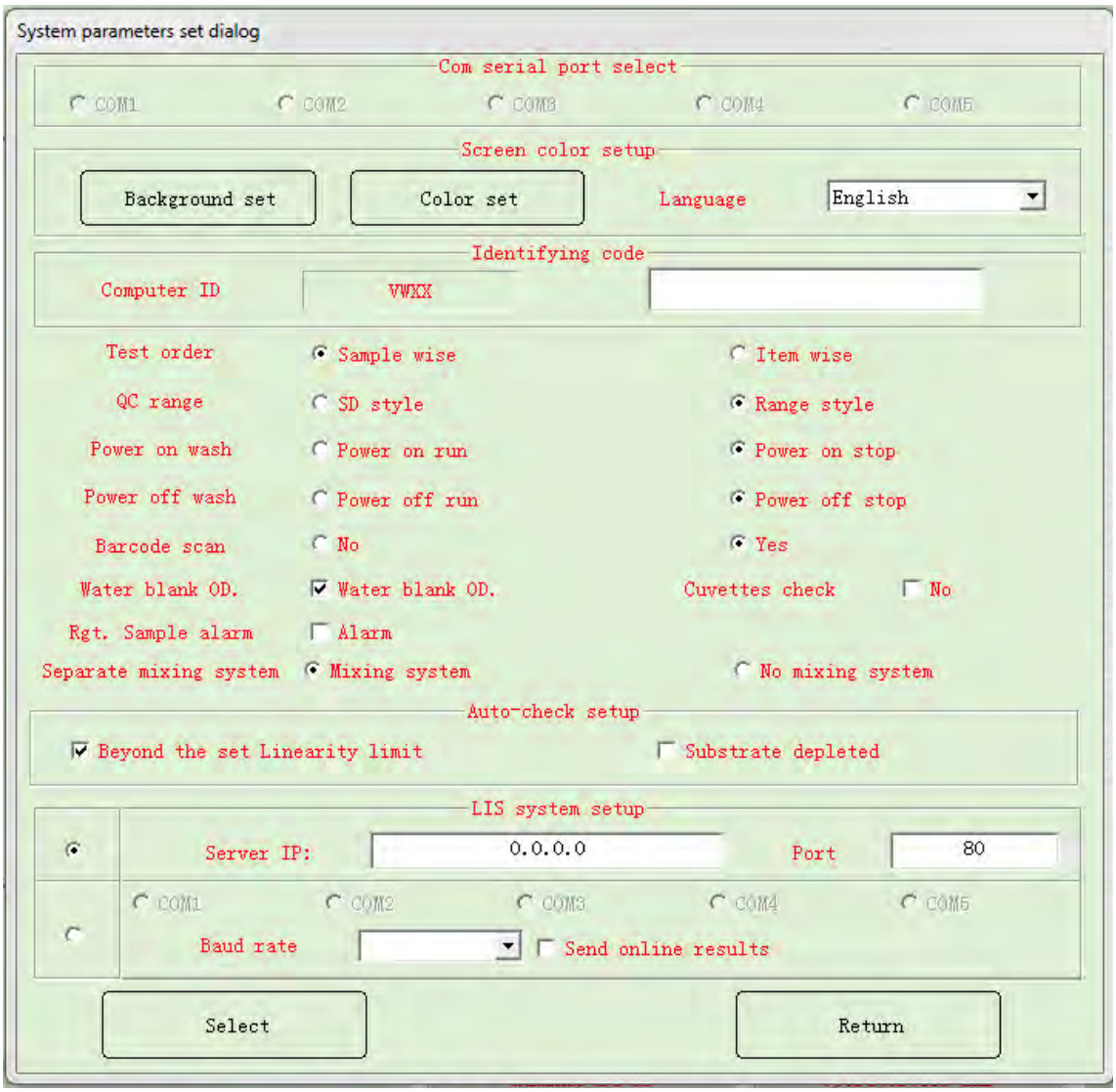
Button	Function
Initialization	To initialize the instrument by clicking this button, and the moving parts will return to start position
Return	To return to the maintenance main interface by clicking this button

2) Parameters setting

Click “Parameters setting” button to enter into the following interface, It is used for system setup:



Input password “sages” to enter into the interface. Choose instrument model and software language, and set communication serial port.

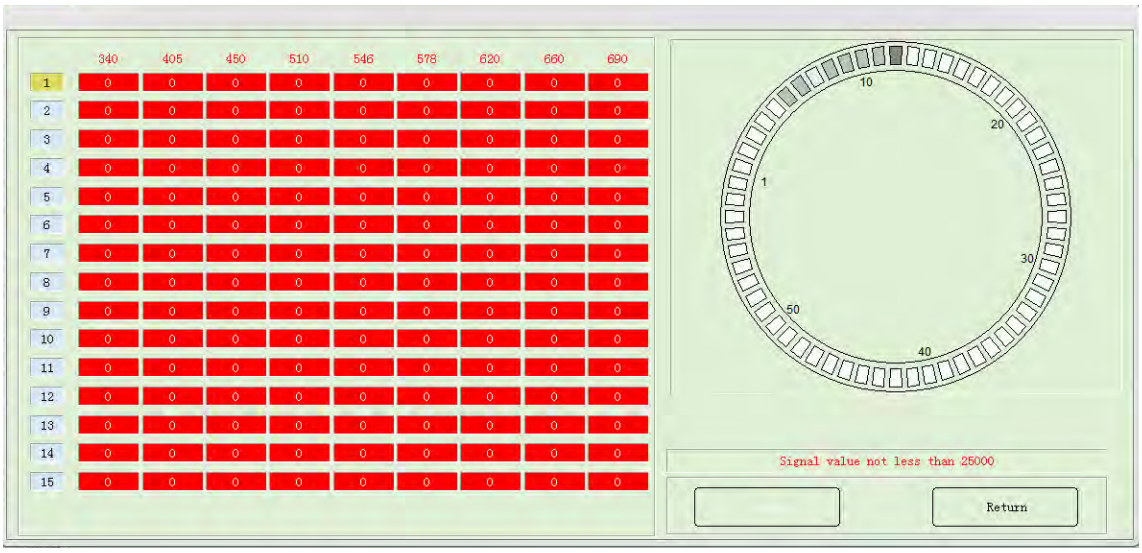


Parameter	Meaning
Com serial port	The serial port between analyzer and computer, which is usually set by engineer
Barcode length	Setting scan barcode length
Language	English and Chinese are available here ，more languages are available by support of language database .
Test order	When you select the option “ sample first”, the analyzer will carry out the test according to the sample sequences; When you select the option “ item first”, the analyzer will carry out the test according to the item sequences
QC range	Select the style of QC value:SD style or Range style, according to user requirement
Screen color setup	User can choose software interface color.
Sample and reagent remain alarm	Check reagent volume not enough two times, instrument stop add reagent for this item, sample volume check as setting times not enough, instrument stop add this sample for all item, system alarm.

Parameter	Meaning
Auto-check setup	Choose will according your setting to auto retest.
Result is too small	Choose means when test result < 1/3 normal lower value, auto retest.
Test no balance points	Only valid for “End point method”:Choose means during reaction process can’t test balance points, auto retest.
Beyond the scope of linear	Choose means when over linearity range limit by setting, auto retest.
Substrate depleted	Only valid for “Kinetic method”:Choose means during reaction process appears substrate exhaustion,auto dilute and retest.
Server IP	Server IP address for LIS

3) Ready to test

“Ready to test” interface see below picture, used for check each cuvette different wavelength water blank signal.



In this interface, you can input signal threshold value(25000~40000), if below this ,it will mark red color,that means the cuvette may be dirty or damaged,you should replace the red one.By correct setting,if all the cuvette mark red color,you should check there is water in reaction groove,if not ,please ask for our engineer or contact our Customer Service Department.

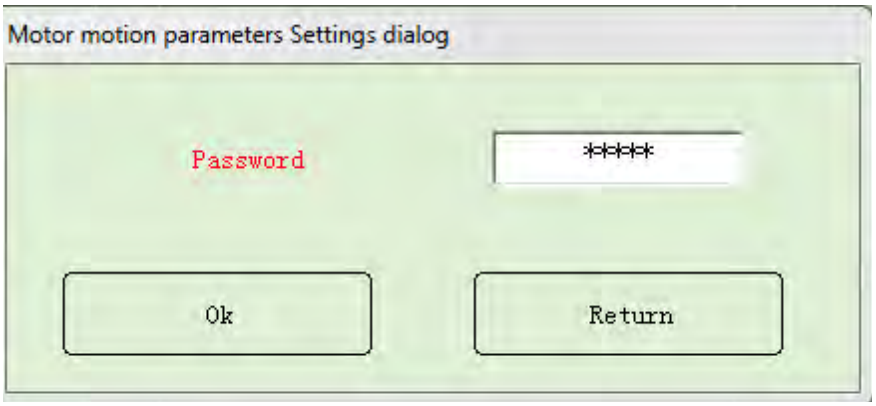
Buttons in this interface:

Button	Function
Begin	Click this button,instrument check each cuvette different wavelength signal automatically.
Return	Click this button, software return up one level function.

4) Instrument Setting

Clicking “Instrument setting” button to enter into the following interface; Input password

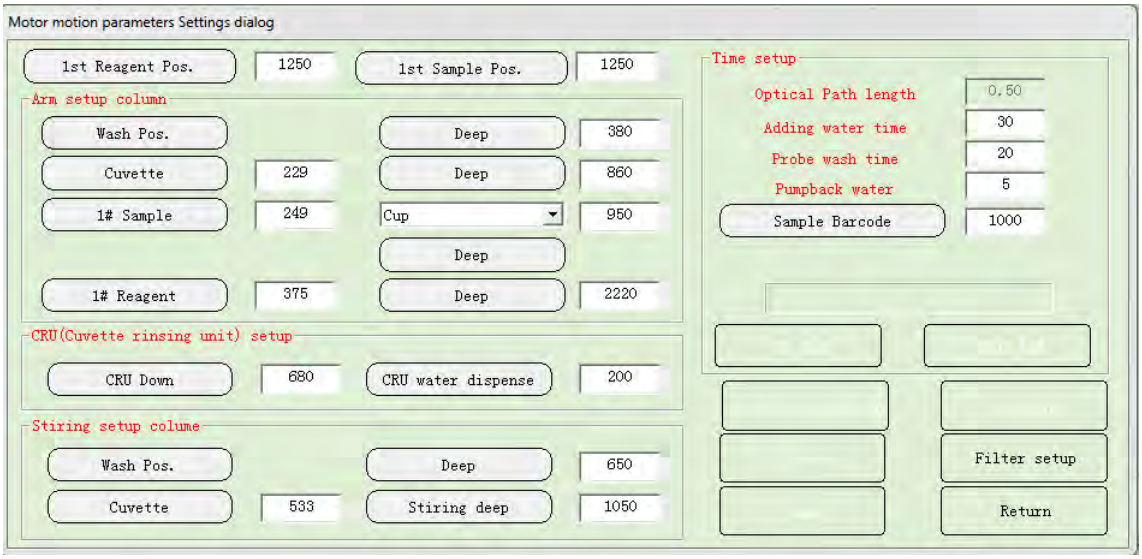
"sages" to enter into the "Motor motion parameters setting" dialog box. Here the user can setup the parameters of the mechanical arm, and detect the mechanical arm. This is usually done by engineer authorized by our company



NOTE:

●The parameter setup must be done by engineer authorized by our company. Otherwise, it may lead to unexpected damage

Input the password and enter into the following interface. It is used to modify the settings when first time installation, mechanical arm replacement or site changes.



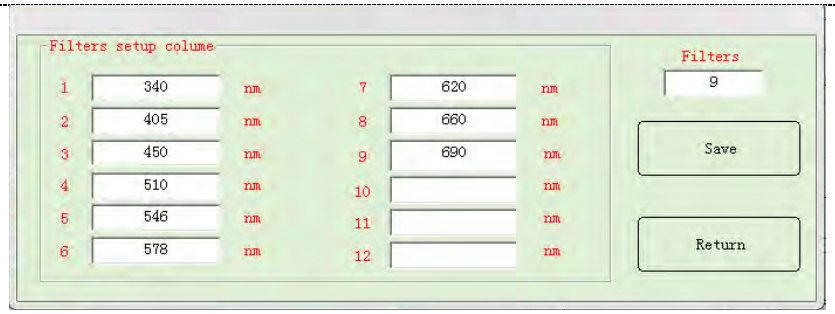
Parameters in this interface:

Parameter	Meaning
Arm setup	
Washing position	Use sample mechanical arm at the washing position as the

Parameter	Meaning
	starting point
Deep	Sample needle in washing pool ‘s wash depth
Cuvette	The steps numbers of sample mechanical arm probe start from washing position to reaction cuvette in reaction disk
Deep	The steps numbers of Sample needle get into the depth of the cuvette bottom
1# sample	The steps numbers of sample mechanical arm probe start from washing position to No.1 sample position
Deep	The steps numbers of Sample needle get into the depth of serum cups or tubes bottom
1# reagent	The steps numbers of sample mechanical arm probe start from washing position to No.1 reagent position
Deep	The steps numbers of Sample needle get into the depth of reagent bottle bottom
Washing arm setup	
Washing deep	The steps numbers of washing needle get into the depth of the cuvette bottom
Water deep	The steps numbers of washing needle get into the depth of the cuvette when adding water
Stiring arm setup	
Wash position	Use stirring mechanical arm at the washing position as the starting point
Deep	The steps numbers of stirring mechanical arm probe get into the depth of washing position
Cuvette	The steps numbers of stirring mechanical arm probe start from washing position to reaction cuvette in reaction disk
Stiring deep	The steps numbers of String arm move to the bottom of cuvettes.
Time setup	
Adding water time	Time of injecting distilled water
Probe wash time	Time for sample needle wash tube in washing pool
Optical Path length	Optical path length of the cuvette

Buttons in this interface:

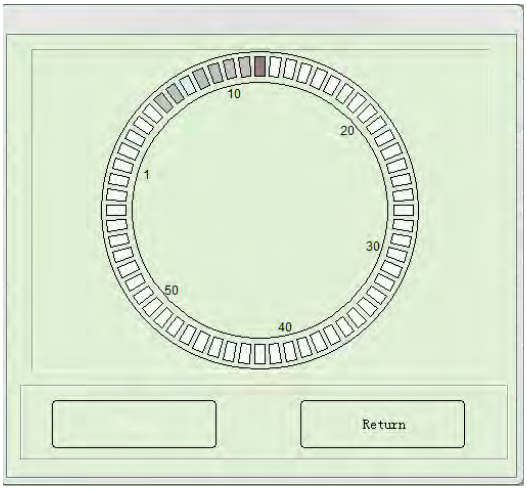
Button	Function
Save	To enter into the dialog box by clicking this button after input the password
Return	To return to the “maintenance “ main interface by clicking this button
Filter setup	To get the below dialog box to setup the wavelength by clicking this button:

Button	Function
	
Arm reset	To make the arm moving right and left by clicking this button, and stop at the original position
Arm hoist	To make the mechanical arm moving up
Test	Select a certain moving parameter setup of the mechanical arm at the left side, click “test” button to test the correctness of the selected moving motion.

5) Water fill

“Water Fill” interface see below picture, wash all cuvettes, add full distilled water.

	Caution:
	Analysis not in test condition, allow operation.

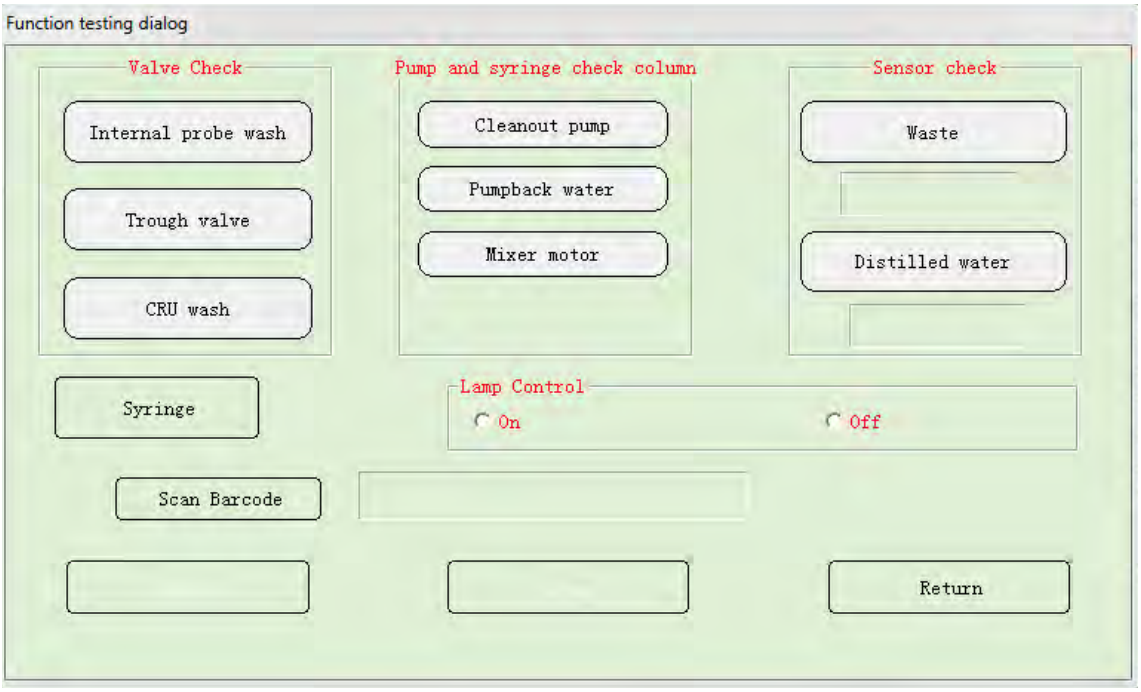


Buttons in this interface:

Button	Function
Begin	Click this button, instrument will wash all cuvettes and add distilled water into each cuvette.
Return	Click this button, software return up one level function.

6) Motion detection

Click“motion detection”, see below interface, can detect moving parts.



⚠

Warning:

- When system working, don’t touch system moving parts.These parts include sample needle、mix arm and wash arm.
- When system working, don’t allow fingers or hand stretch into open assembly unit.

Parameters in the interface

Parameter	**Meaning**
Valve check column	
Internal probe wash	Click”test” button, water spray from sample needle. If not, consider reagent valve work or not.
Trough valve	Click”test”bitton, water gush from the middle of washing pool.If not, consider washing needle valve work or not.
CRU wash	Click”test”bitton,water spray from wash needle .If not, consider water valve work or not.
Pump and syringe check column	
Cleanout pump	Click “test” button, hear the voice of cleanout pump.If not, consider cleanout pump work or not.
Pumpback water	Click “test” button, hear the voice of backing-water pump.If not, consider backing-water pump work or not.
Syring	Click “Syring”, the syring will work up and down.If not, check syring work or not.

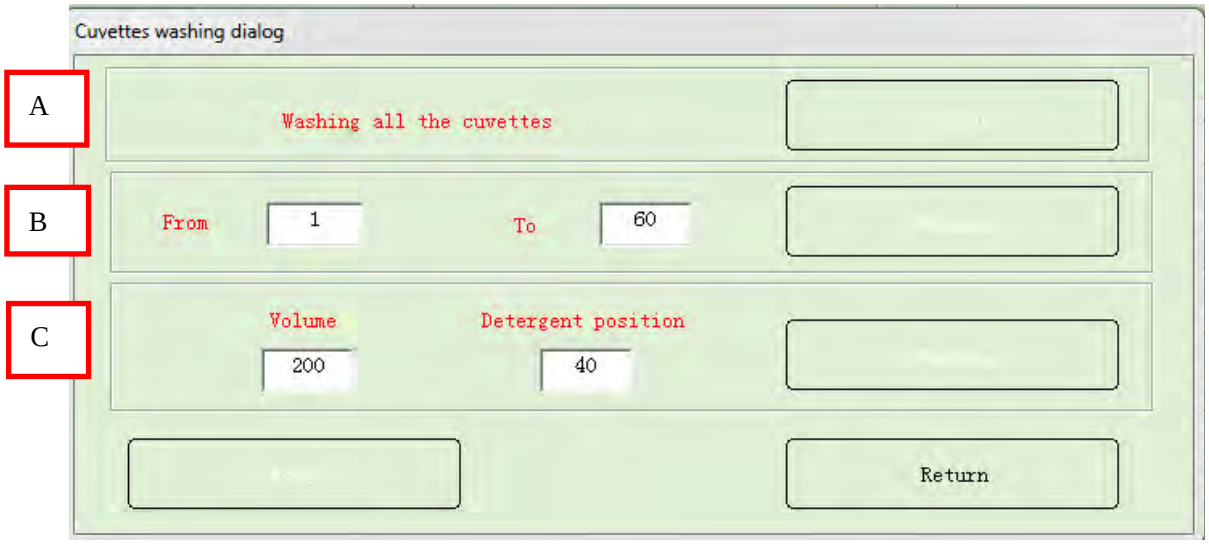
Parameter	Meaning
Sensor check column	
Mixer motor	Click “Test” button, see stiring paddle twirl or not.If not, consider mixture motor work or not.
Waste	Click “Test” button, move up and down float switch in the waste bucket, see screen have character or not.If not, check floater and connection.
Distilled water	Click “Test” button, move up and down float switch in the distilled water bucket, see screen have character or not.If not, check floater and connection.

Buttons in the interface

Button	Function
Test	Choose moving part, click “test can check assembly unit movement.
Stop	Moving parts restoration.
Return	Click return maintenance main interface

7) Cuvettes cleaning

Click “cuvettes cleaning”, see below dialog.



Parameters in the interface

Parameter	Meaning
A area	Washing all the cuvettes
B area	Washing appointed position cuvettes
C area	Input detergent in reagent (tray)rack’s position, sample

Parameter	Meaning
	needle firstly inject detergent into each cuvette, waiting reaction cup finish add detergent, washing all cuvettes.During add detergent, needle check wash condition automatically.

Buttons in the interface

Button	Function
Washing	Click this button, operate corresponding area function.
Pause	Pause instrument movement
Return	Click this button, back to “Maintenance”

9) Cuvette Abs check

Click “Cuvette Abs check” enter into below interface:

Cuvettes singal:“cuvettes signal” interface, used for check cuvettes signal.

Parameters in the interface:

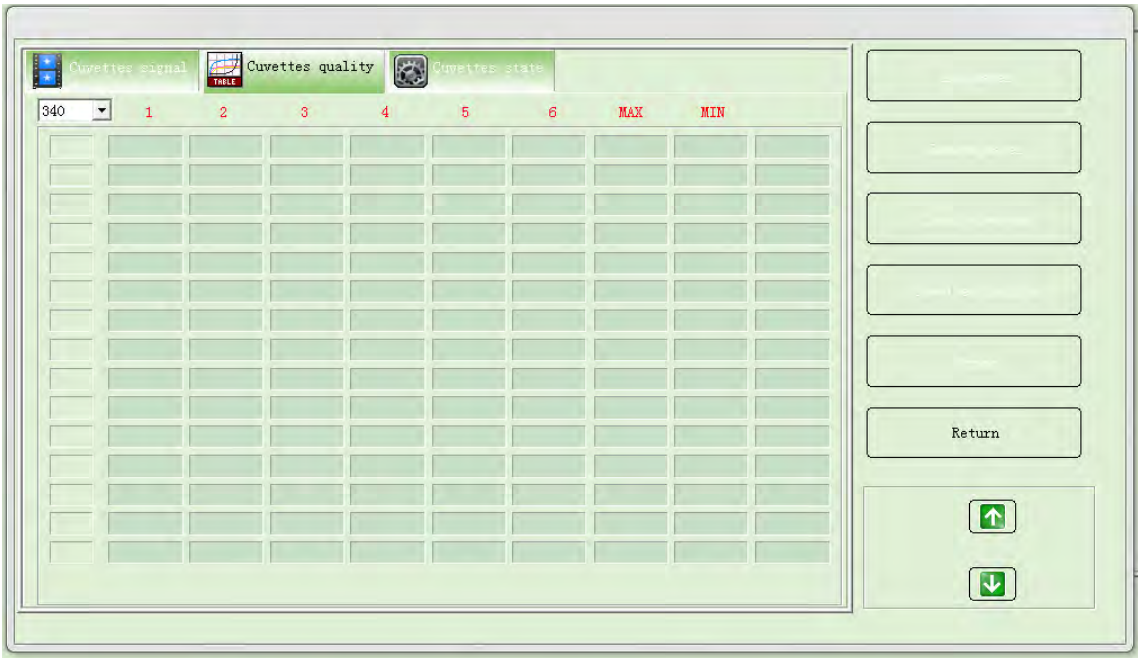
Parameter	Meaning
Absorbance	Display different wavelength data by absorbance way.
Signal value	Display different wavelength data by A/D way.

Buttons in the interface

Button	Function

Button	Function
Add water	Click this button, wash arm add distilled water into all cuvettes.
remove water	Click this button, wash arm extract each cuvette liquid.
Check cuvettes	Click this button, reaction tray rotate one circle, and check 60 cuvettes different wavelength A/D value(absorbance).
Check quality	Click this button, reaction tray rotate 8 circles continuously, check same cuvette different wavelength 8 times.
Return	Click this button, software return up one level function.

Cuvettes quality: “cuvettes quality” interface see below picture, used for check same cuvette continously different wavelength signal difference .



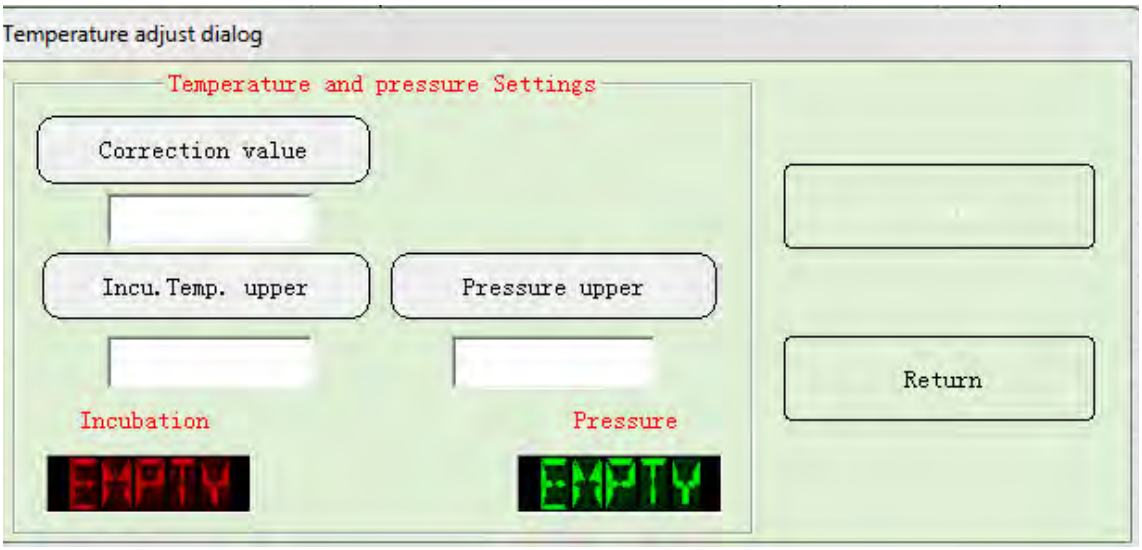
Parameters in the interface

Parameter	Meaning
1-6	Choose wavelength, display no.1-6 circle A/D signal.
MAX	Same cuvette rotate 6 circles continuously get max A/D signal.
MIN	Same cuvette rotate 6 circles continuously get min A/D signal.
	Counting each cuvette same wavelength max A/D valve-min A/D value, if >200 display in red.

10)Temperature and Pressure

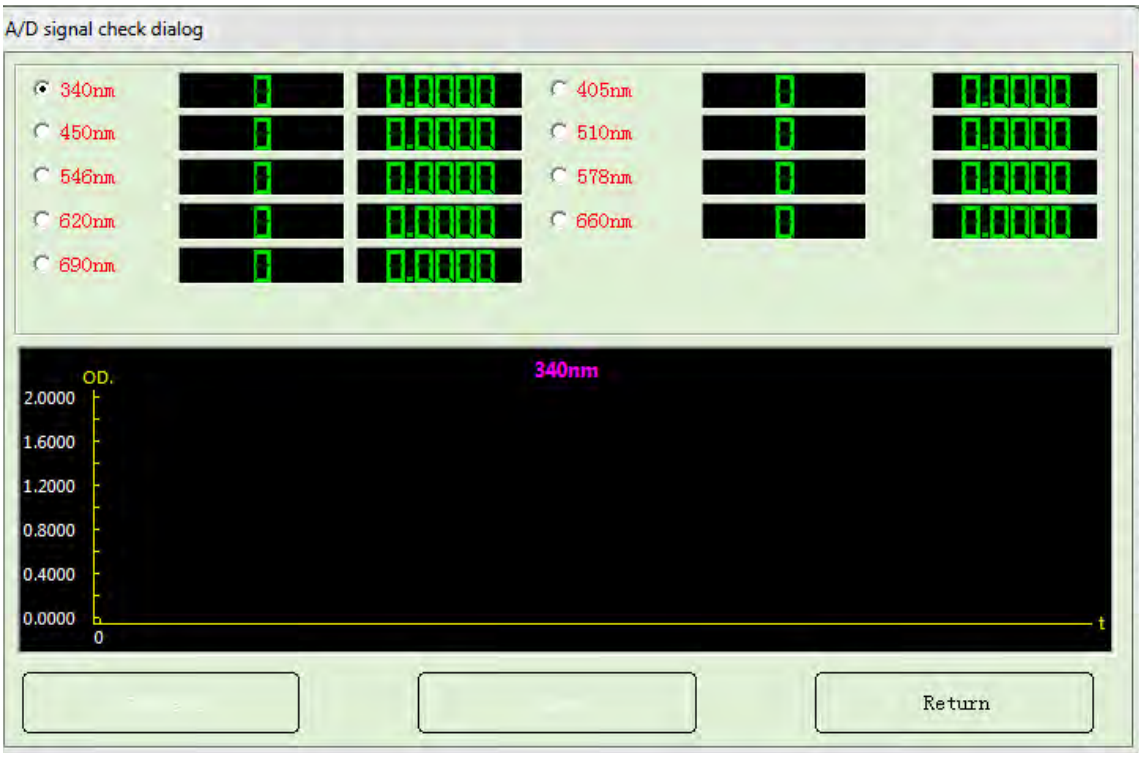
Click “temperature and pressure” button to setting the temperature and pressure
The correction factor is used for calibrating the temperature value when there is any error between the temperature in the instrument and the thermometer.
And only when the temperature is balanced, then the correction factor can be modified.
Please set the correction factor to “0” if you don’t have micro thermometer for measuring.

The temperature displayed = instrument temperature measured + correct coefficient



11) AD valve detection:

AD valve detection is used for checking the lamp quality and strength. All the filter show some OFFset valve and OD.



5.2.7 TEST

All sample information edit and test operation process in TEST interface which including four sub-interface.

1) Sample applying

Showing as above picture,Edit sample ID,sample cup number and initiative cuvette number(software will increse automatically).Choose item(s) being test and click Add

button.If need test more item,click New,ID will plus 1 automatically.Choose item(s) being test and click Add button.Do not input same ID number.Otherwise it will cover previous result by letter one.

Note：

- In TEST interface, each button status reflect its working status.
  - Button sunken sysbols be choosen
  - Button convex sysbols optional
- In reagent item list and reagent item group list, button color will turn blue when choosen

1.1) schedule-Sample-Copy

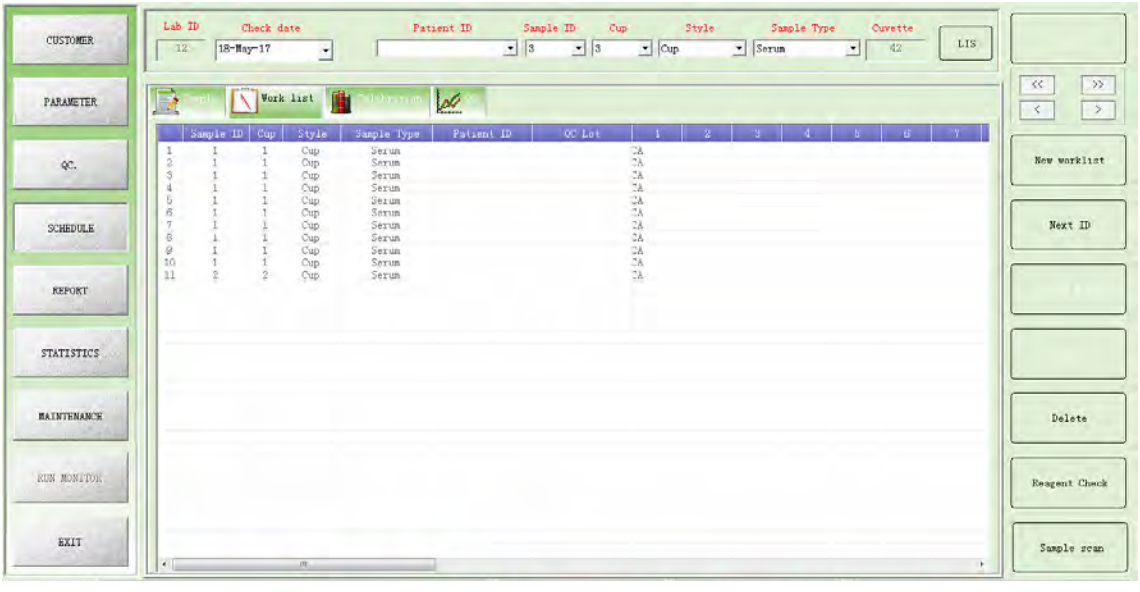
After choose reagent item, click Copy to enter interface as following picture. It can achieve operation that to do same item test with different sample or to do several tests with same sample in one time. Please refer to detail funtion of Copy button in this section 1.4.

1.2) Schedule--Sample-Test

After choose reagent item, click Test to enter interface as following pictures. It is a recheck interface before test including sample test, QC test and calibrator test. It can also check if reagent quantity enough or not for test(s) to be done. Machine will check reagent quantity after click Reagent Ckeck button, and it will give you the prompt if some reagent is not enough. Then, you can click “Test” to enter interface as following picture, and click “Test” again to start test.

1.3) Work List

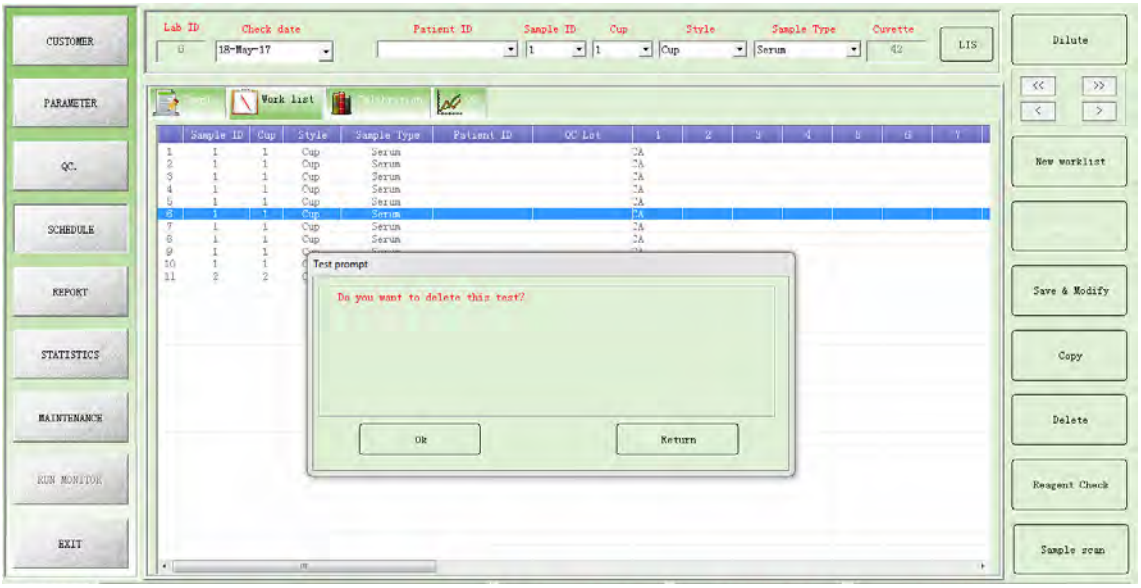
As a accessorial menu, Work List interface is to list all test items to be test. Before choose reagent item and start test,it is necessary to check if Work List leave test list.Delete all if have.



Note：

●Before choose reagent item and start test,it is necessary to check if Working List leave test list.Delete all if have.Otherwise item on test list will test again.

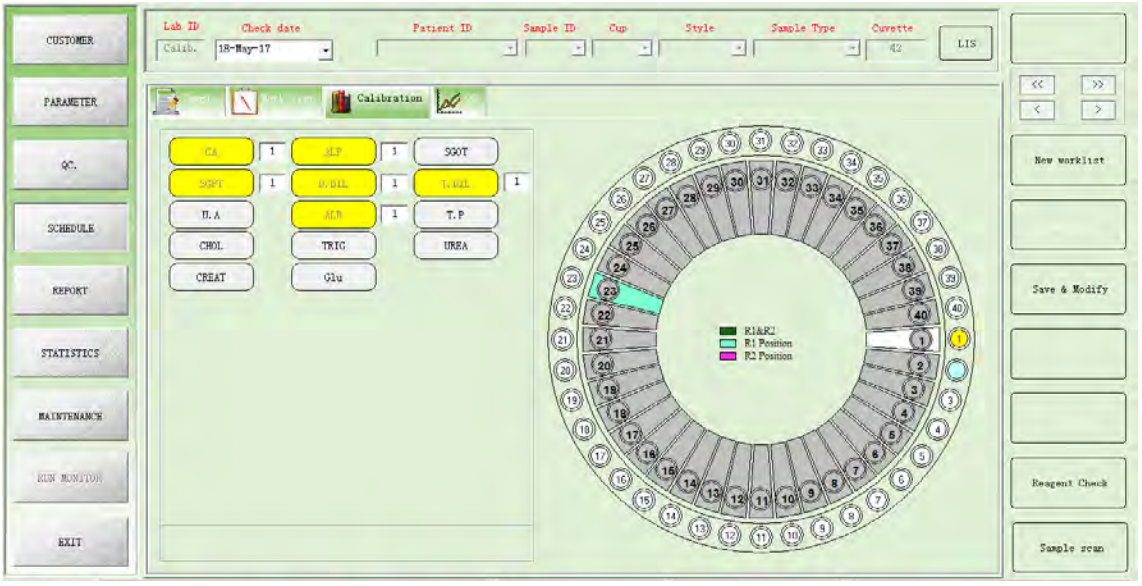
1.3.1) Click “Delete” button to enter interface as following pictures. Click “OK” to finish deleting, and click “Cancel” to cancel the delete.



Select one ID in “work list”, you can modify the test item for this sample, and click “Add” button, it will save the new item you choose. The sample position、 cup type and sample type are also can be modified.

1.4) Calibration applying

It is used for editing the items which need calibration running.



1.5) QC applying

It is used for editing the items which need QC running,.

Please refer to the following explanations for the parameters and buttons in this interface:

Parameter/Funtion	Meaning
ID	Each sample has one ID number. Each ID number should be unique in one day
Cup	To choose sample cup position to be put
Style	Cup or Tube
Sample style	Serum,urine etc.
Cuvette	To edit first cuvette to be used.All cuvette is optional
New	To add ID No. for edit new test item
Add	To add to Work list after choose test item
Copy	To achieve same reagent item to be test under several samples, click copy button after choosing item and input copy time. If choose “same sample cup” simultaneously, software will detect one sample with same reagent item for required time.
Delete	To Delete test list choosen in Work list interface
Delete all test	To Delete all test list in Working list interface
Save	To save test list(s) in Work list interface
Test	To start test
Diluent	To start test To setup multiple for diluent reagent item

1.6) Sample Test

1.6.1) Sample Test Interface

After inputting sample and QC in the “Work list” and “emergency test” menu, click “Test” button, biochemistry detection interface will be shown as below.

NOTE:

- Before clicking Test button, please ensure that sample, calibrator, QC and reagent are placed at the right positions.

1.6.2) Sample testing interface

Test will begin after click “Test” button in this interface.“Sample, Reagent, Cuvette” taps will

appear on this interface. click any tap, you can know each its working status, For example, click Cuvette tap, then click any reaction cuvette on the virtual chart, you may know the current status of the cuvette.

1.6.3) Test result inquiry in the testing interface

When test finish, Result list under Sample tap will show test result as well as the state of reaction disc cleaning.

Also the washing status of reaction disc can be shown here.

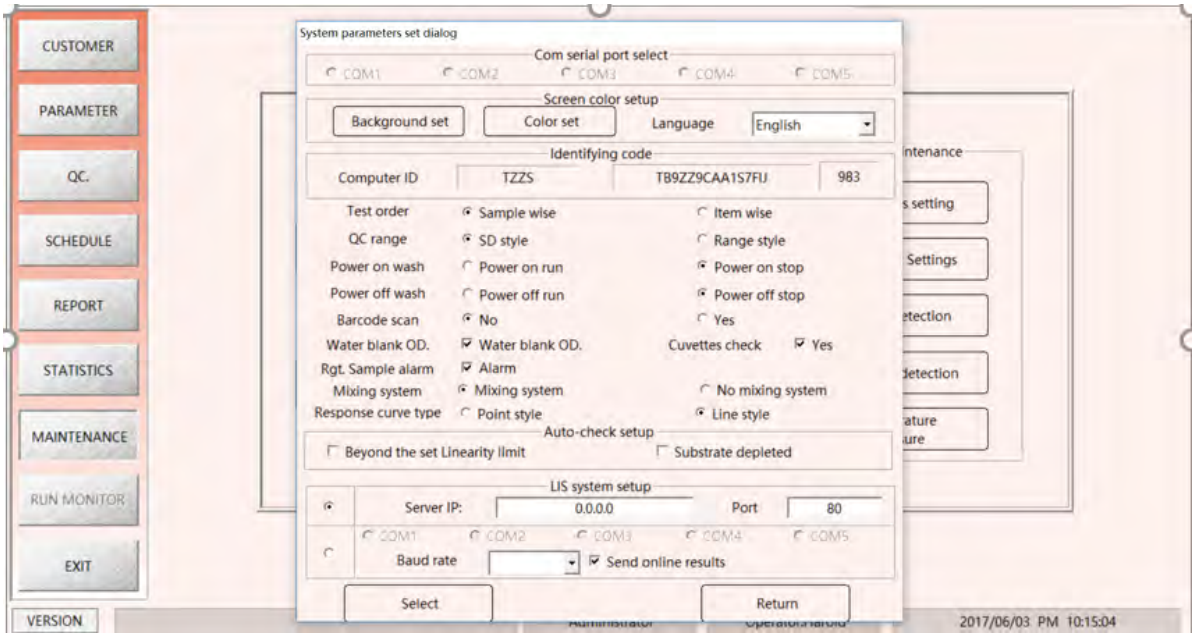
Beside, you can also check the current result under “Statistics” function tap.

Please refer to the following explanations for the taps and buttons in this interface:

Taps/Button	**Funtion**
Sample	To show each sample information
Reagent	To show each reagnt information
Cuvette	To show each cuvette information
Pause/Continue	To pause or continue test.Please don’t click pause button facilely as biochemistry reaction is in process all the time
Exit	To exit test
Distilled Water	Liquid level detection and alarm.Button will turn orange color with letter “Over” on it when lack of distilled water
Waste	Liquid level detection and alarm.Button will turn orange color with letter “Full” on it when waste water full

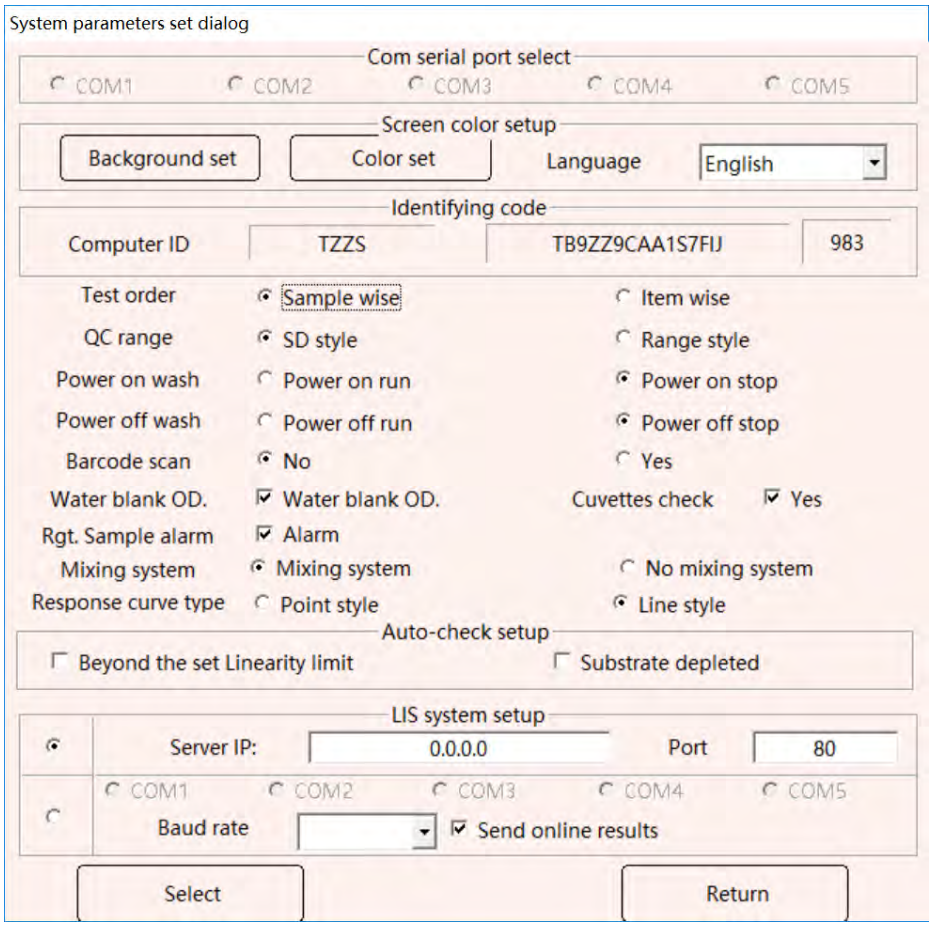
1.7) Diluent re-test

1.7.1) Parameter setup



NOTE:To choose diluent liquid position. Software will acquiescence No.1 reagent position.Diluent liquid can be pure

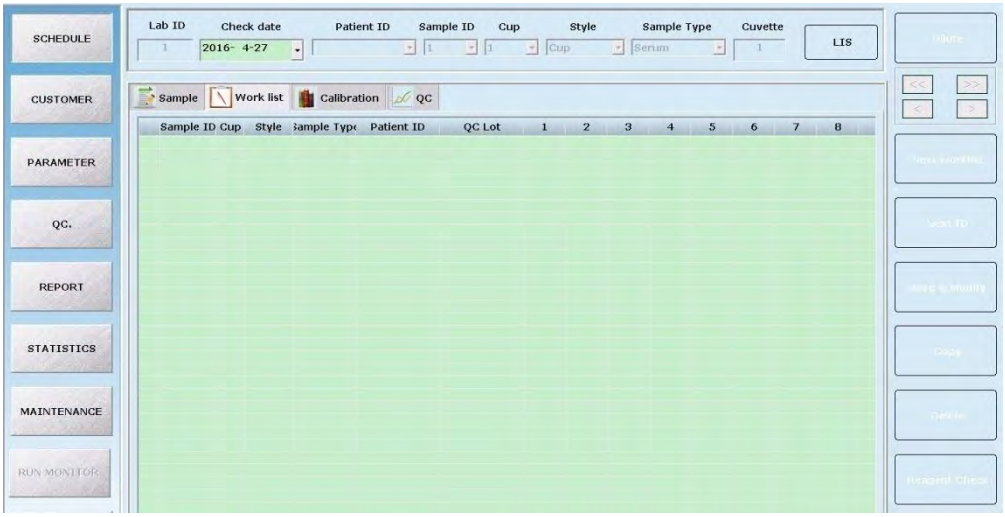
1.7.2)Dilution ratio setup:

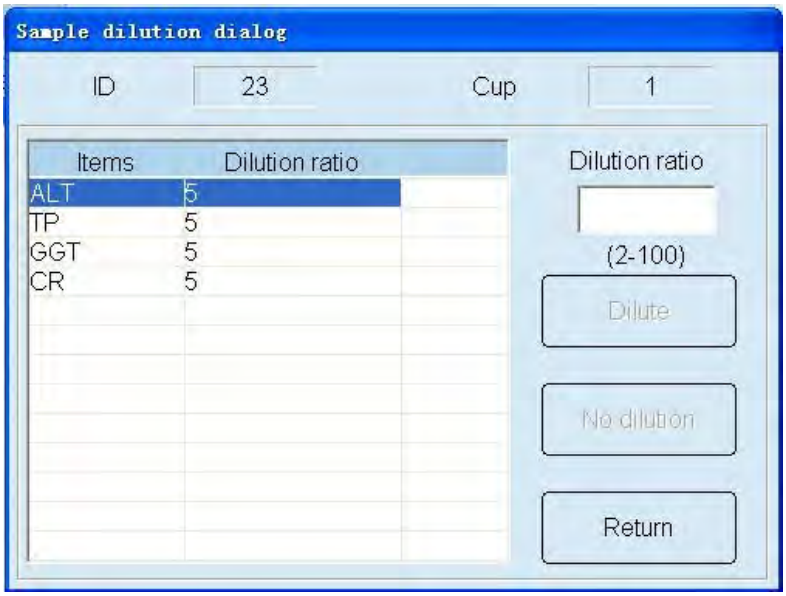


Linear Range

Method for judgment: please setup parameter according to reagent user manual. when test result beyond linear range, it will automatically dilute for retest

1.7.3)Operation method for prediluent





1、Dilution ratio：input the pre-dilution multiples with range from 2 to150 times

2、No Dilution：To cancel dilute for current sample. you can quickly cancel the pre-dilution that you have already chosen

3、Return：Return to the previous interface

1.7.3) Re-test

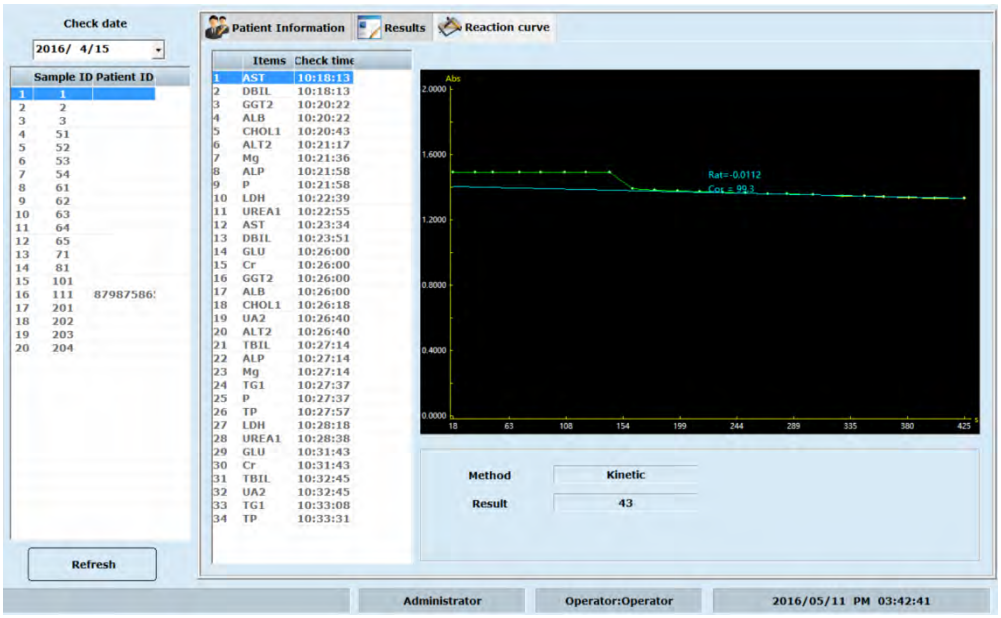
If user don't want to auto-retest and no select Auto-check setting in "Paraneter, you can recheck the result in "Check information" according to your needs.

In test Screen-Check information interface, machine will restest items chosed to be retest

and click CHECK bottom.To those result which out of Linearity range or Substrate depleted,machine will diluent and retest based on diluent multiple setting, or only retest the sample when other condition.

1.7.4) Retest result selectness

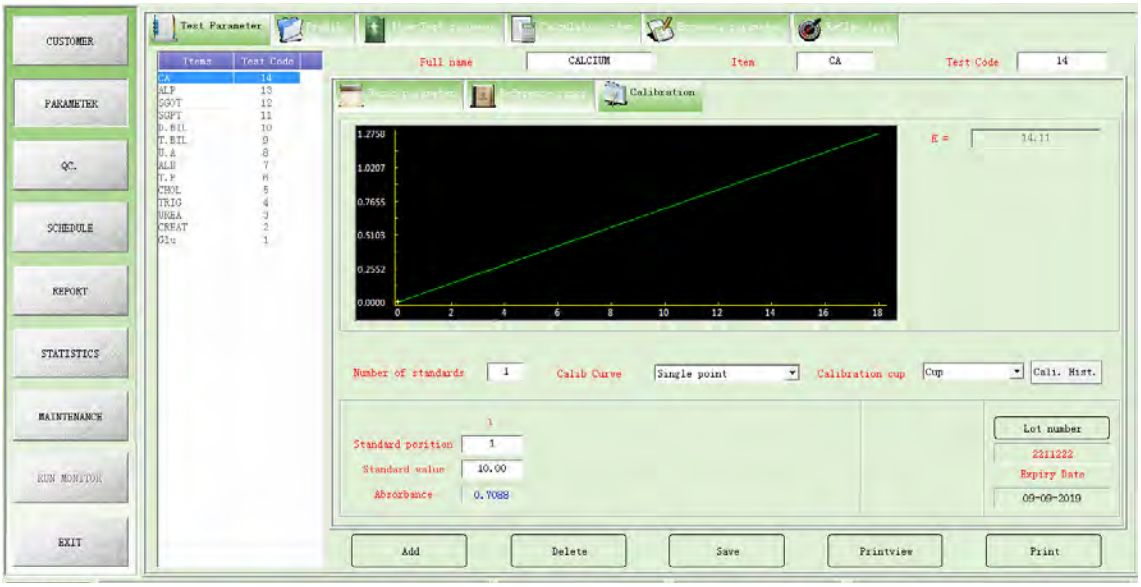
Retest result will cover last result once retest finish. If user prefer to previous result, they can check last test result in reaction curve and revise test result in Report interface by hand.



2) Calibration

2.1) Calibration parameter setup

Click PARAMETER-- Test parameter --Calibration to enter calibration parameter setup interface.Shown as following picture.



Choose the item to run Calibration in item list. Edit Standard number, Calibration rule,

Standard position and Standard value. The initial value of absorbance is “0.0000”.Absorbance value and K factor will calculate and input automatically after calibration. To modify absorbance value, click Calculate button and K factor will calculate again.

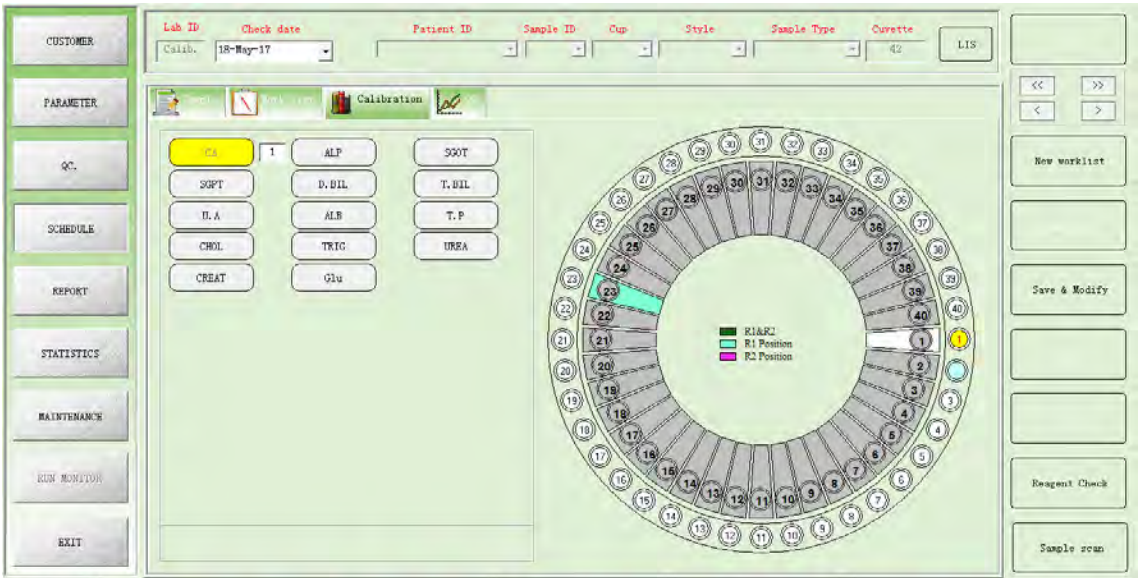
Please refer to the following explanations for each parameter name in this interface:

Parameter	Meaning
Number of standards	Calibrator number for item. More than one is acceptable
Standard position	Calibrator position in sample disk
Standard value	Standard value of calibrator
Absorbance	The absorbance value of calibrator test
Calib Curve	There are 3 Linear Calibration and 6 Non-Linear Calibration which different in standard nunmber and calibration factor.Pls refer to following chart

Number		Calibration Rule	Standard number	Calibration factor
Linear Calibration	1	Single point	1	K
	2	Two point	2	a、b
	3	Multiple point	3～6	a、b
Non-linear Calibration	1	Logistic-Log 4P	4	K、R_0、a、b
	2	Logistic-Log 5P	5	K、R_0、a、b、c
	3	Exponential 5P	5	K、R_0、a、b、c
	4	Polynomial	5	a、b、c、d
	5	Parabola	3	a、b、c
	6	Spline	4	R_0、a、b、c

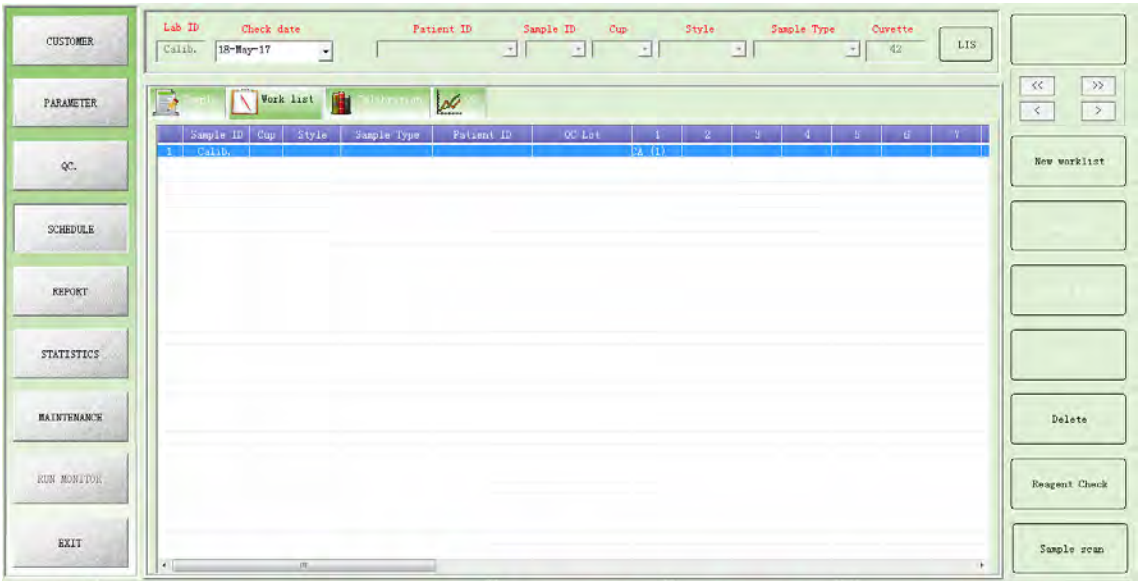
2.2) Calibration Test

Click TEST-Calibration to enter calibration test interface show as following picture



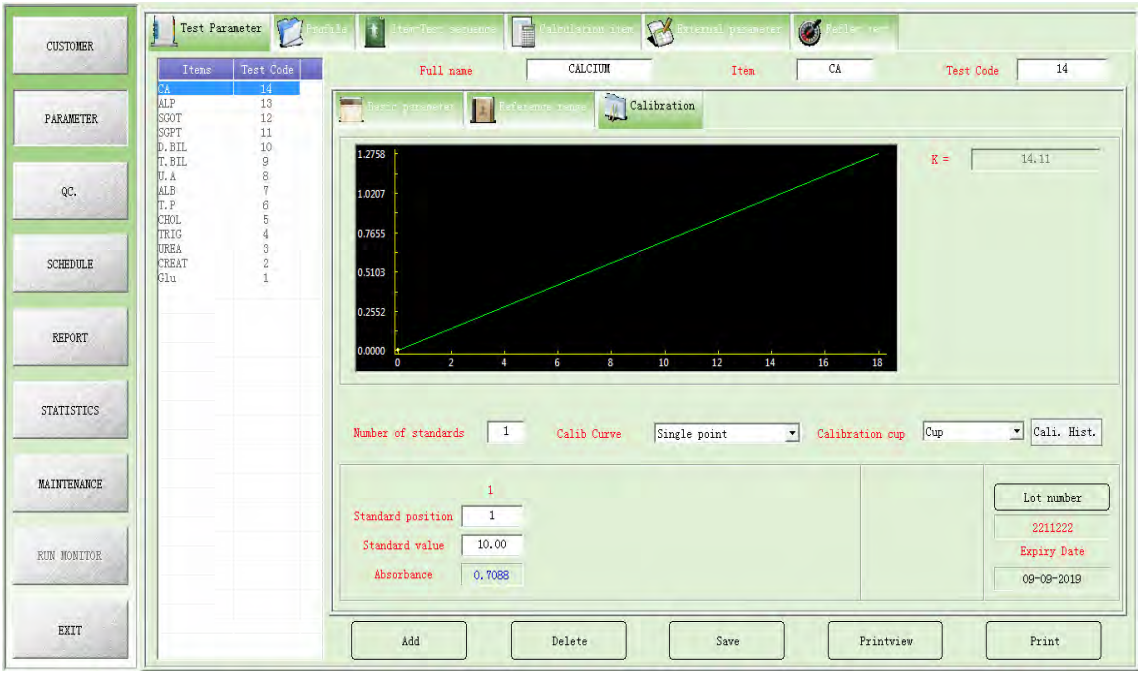
After choose item to be calibration,click “Add”.Test list will be list at Working list interface.Click Test button to start calibration.

Note： The number after parameter, it is how many test times for this calibration



2.3) Result checking

The results from calibration is new K factor which in PARAMETER-- Test parameter - Calibration interface. Please refer to following picture.



Note：

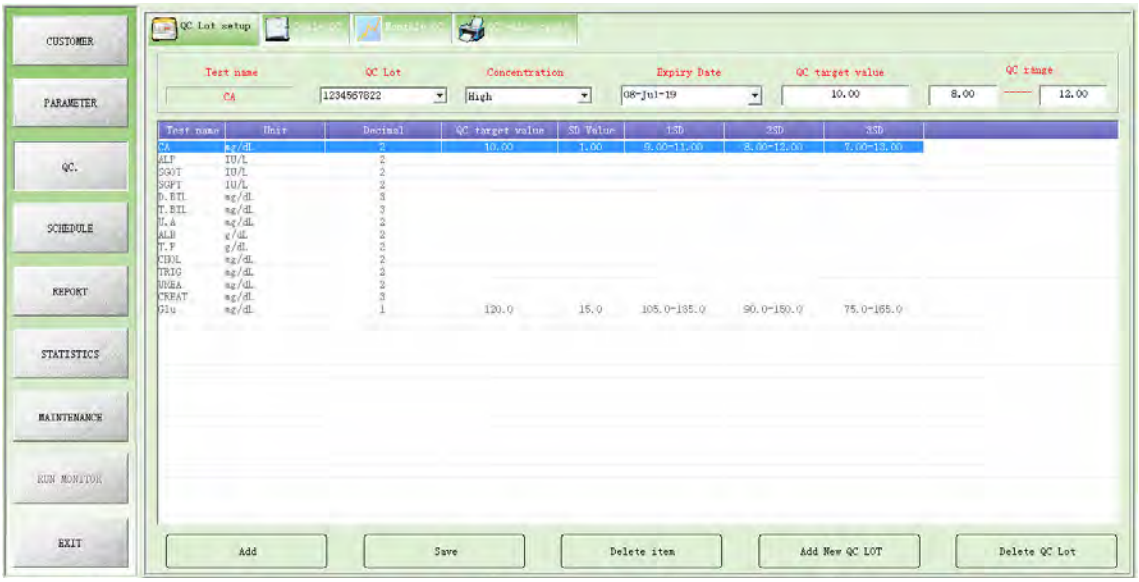
- The system will adopt the current default calibration factor to calculate the concentration of the sample.
- The system will set the latest calibration factor (including the calibration factors which are got from calibration test and calibration edit) as the default factor.

3) Quality Control

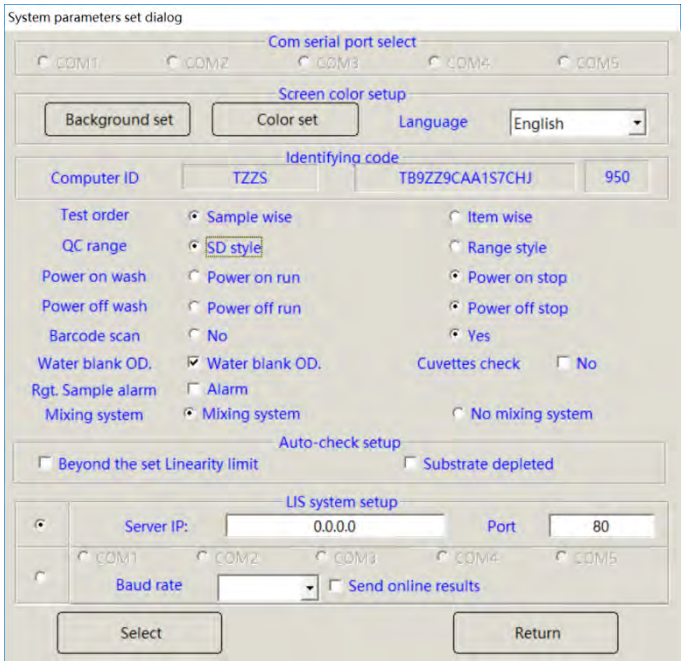
3.1) QC Setup

Enter QUALITY CONTROL-QC. Lot Setting interface to setup QC information such as lot number,concentration and expiry time.

Choose item going to do QC.Input relative target value and SD value.Item unit and name already set in PARAMETER interface.Click Add than Save button.

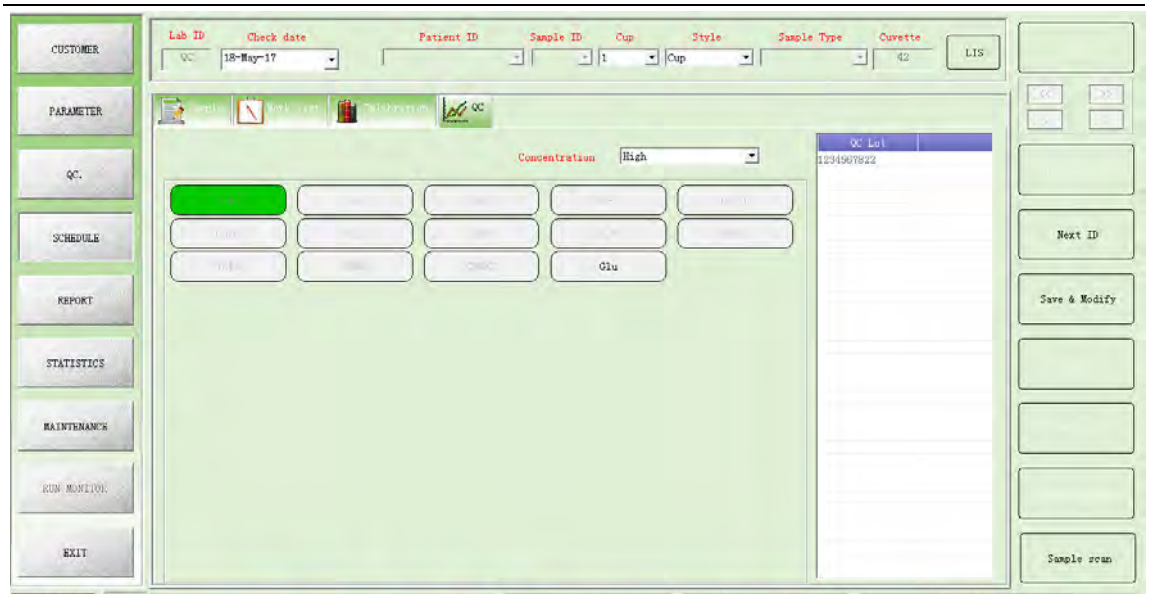


This is range setting, if we want use SD mode, we need go to [MAINTENANCE] MENU—select [Service maintence]—[Parameter setting]—input password ‘sages’, the QC range setup to SD style



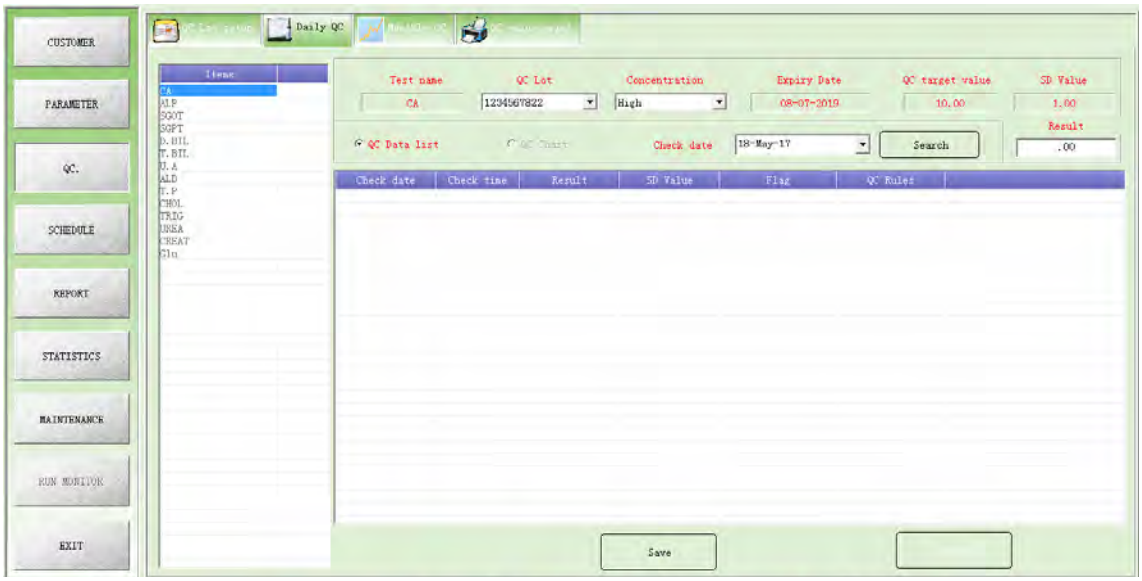
3.2) QC Test

Enter TEST-QC interface.Choose item going to do QC test and Lot number.Click Add to add test list to Working List interface.Click Test to start QC test.

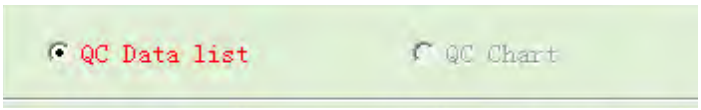


3.3) QC Test Result Checking

QC test result can be check in QUALITY CONTROL-QC.data display interface in which show all QC test result.



QC test result can be show in two form.That is data list and chart.



Please refer to the following explanations for each parameter name in this interface:

Parameter	Meaning
QC Lot.	Lot number of QC
Concentration	Concentrate of QC including Low,Middle and High
QC Target value	Target value of QC
SD value	1 SD value of QC
Expiry Date	Expiry date of QC
Result	Result for QC test

Parameter	Meaning
Check date	QC test date
Check time	QC test time
QC.data display	To show all QC test result in figure form
QC.chart analysis	To show all QC test result in chart form

Please refer to the following explanations for the buttons in this interface:

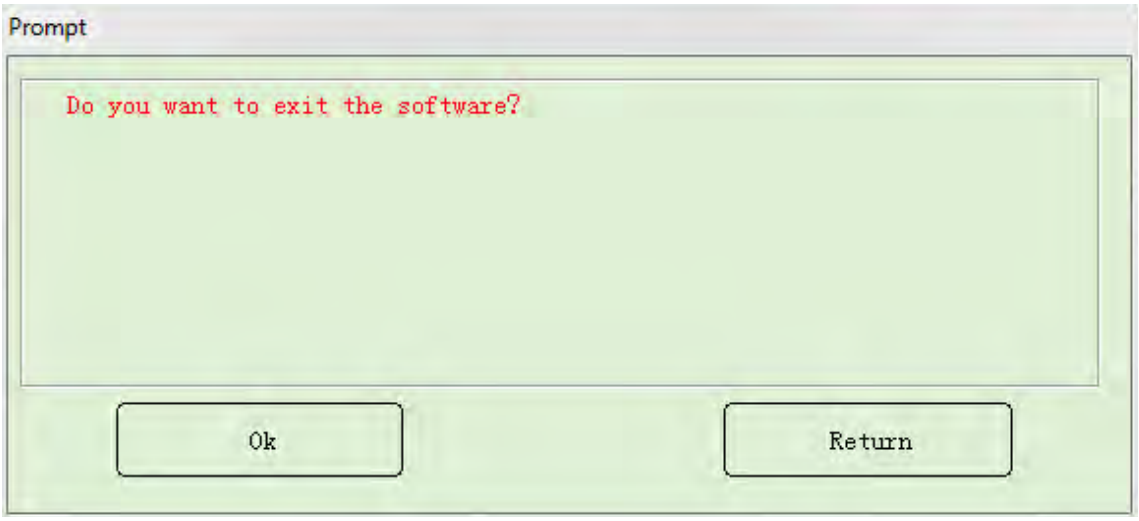
Button	Function
Save	To save for all operation
Print	To print test result chart
Delete	To delete result data

5.2.9 Test Screen

Test screen is the interface to show testing status which including Samples,Reagents,Cuvettes and check information four interface.

5.2.10 Exit

Click Exit button in main menu will exit software and in sub menu will back to previous interface.



Chapter 6. Maintenance

To ensure reliability, good performance and service life of the system, regular maintenance is required.

6.1 Maintenance

6.1.1 Method and instruction for operating and maintaining

1) Keep the instrument power on for 30 minutes before analysis every morning.

2) Check and make sure the reagent and serum are enough. Check and make sure the pump pipe is at the bottom of the distilled water bucket, and can pump enough water for analysis. After emptying the waste and moving the waste bucket back, make sure that the drain pipe is in the waste bucket

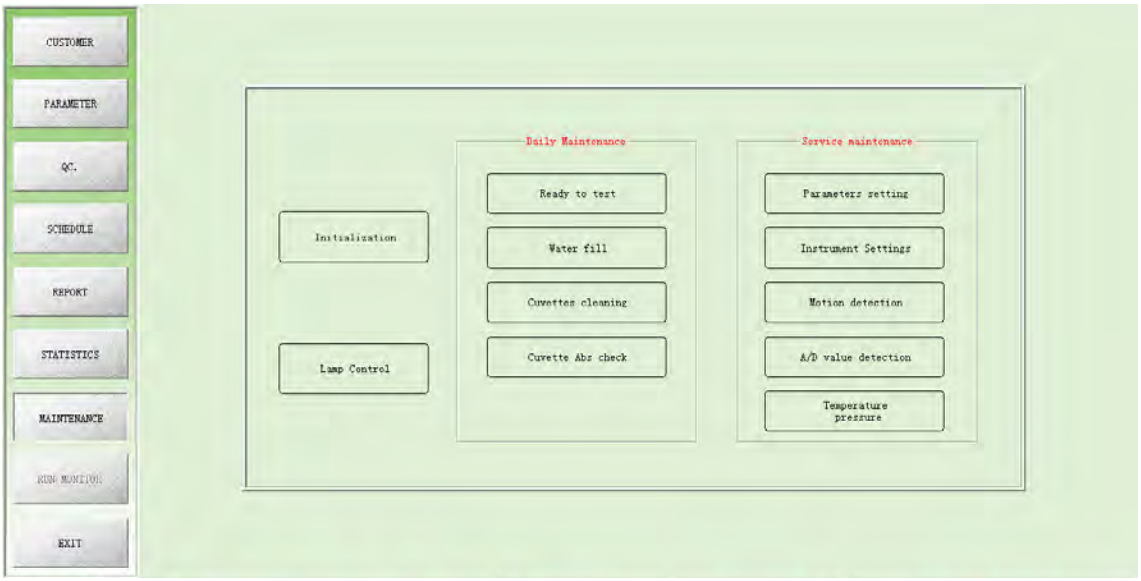
3) Do the program “Ready to test” before testing every day,and do the program “End to test” after testing every day.

4) Put the reagent, standard substance and QC serum to external refrigerator after tests every day.

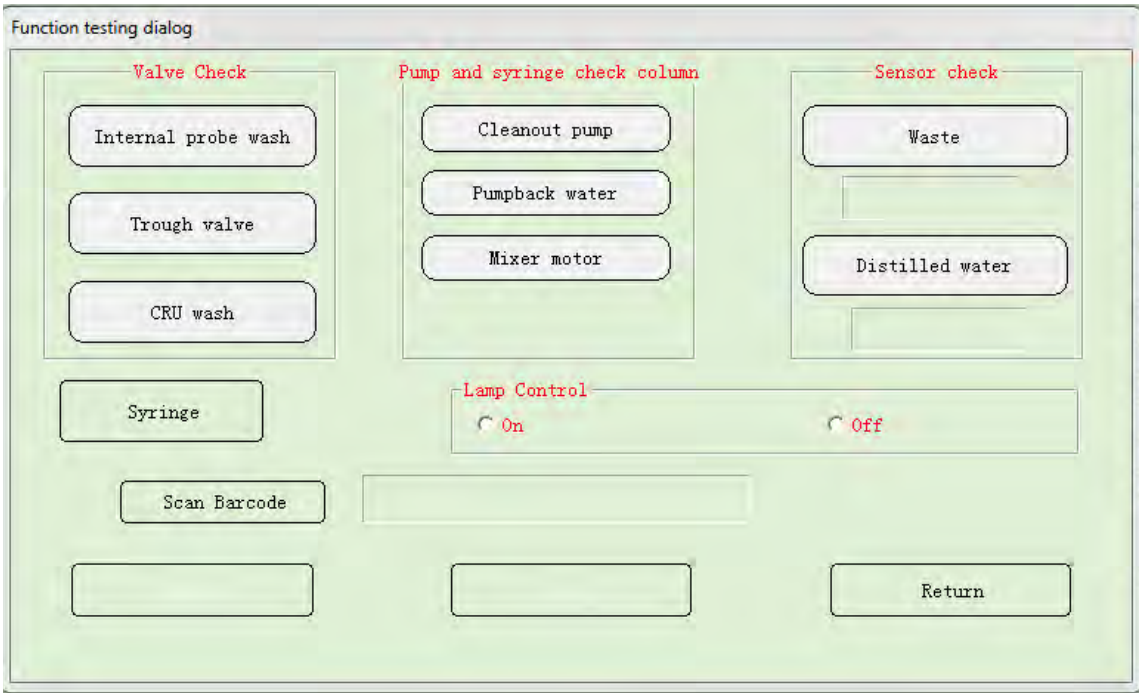
5)To prevent injury and damage，please do not touch the moving arm (moving parts) during the test.

6) Check to ensure that the distilled water in buckets are enough and waste bucket is not overflow every day.

7) Check whether the probe is blocked or not periodically by clicking Maintenance→ Motion detection.



Then you can see the following interface:



Please click Reagent valve, Needle valve, Water valve respectively, if no water coming out from Reagent needle and sample needle, please use acupuncture to make them clear. If still does not work, pls contact us.

8)If you find that wash unit can not drain the cuvettes completely or no water is injected in, please contact us.

9) The flaw or stain on the light-pass surface of the cuvettes will influent the measurement

of absorbency; please replace it with a new one.

10) QC serum should be tested to calibrate the precision of the instrument.

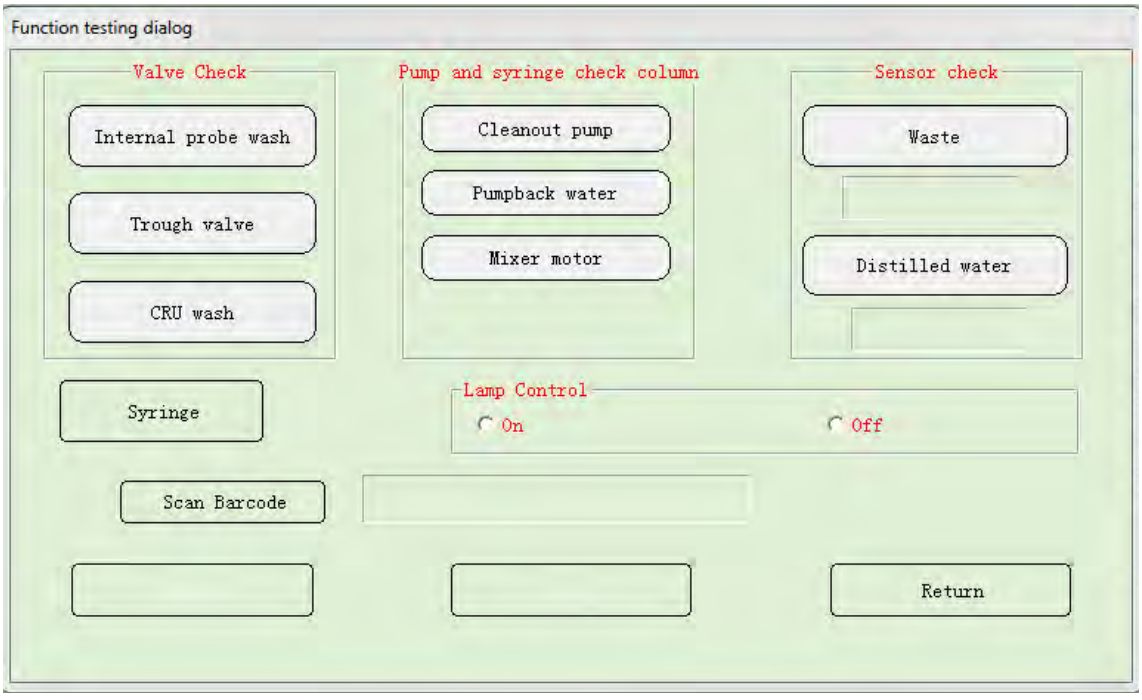
11) Do not switch the instrument power on and off frequently, it should cause damage to the power module.

12) Stabilized voltage supply should be used when the net voltage is not steady or on the low side.

13) The reagent stored in the refrigerator should be waited to warm up to the room temperature before test.

14) Cap the reagent bottles in the disk when the instrument is in the idle status and uncap it before test.

15) Check the electrical valves under the menu of “Motion Detection” of “Maintenance” regularly.



Please click Reagent valve, Needle valve, Water valve respectively, if the sound “pa” can be heard, then the valves are in good condition; otherwise, please contact us.

16) Click “Mixer motor” to check if mix needle is rotating, otherwise contact us.

17) Do not press “SPACE” and “Enter” on computer keyboard during testing; otherwise,

test will stop immediately.

Chapter 7.Troubleshooting

7.1 Initialization

Faults	Causes analysis	Solutions
1.Can not initialize after start the system	a. The serial port wire is not connected rightly b. The serial port is not selected rightly c. Software setting faults	a. Check whether the serial port line is connected. b. Select the serial port in communication setting. Select the needed serial port in computer device manager if there is not serial port in communication setting. c. Re-setting the software
2.The reaction disc can't rotate when initialize, and act on other actions after a period of time	a. the 0# motor signal wire is not inserted rightly b. The main control board is broken, or the line contact is not good c. Software program faults	a. Re- insert and extract 0# motor signal wire b. Replace the main control board, weld the serial port wire c. Replace the software
3.The motor lock is not tight after initialization	a. The voltage of 5V power supply is not stable or not enough b. The drive board of motor is broken	a. Replace the power board b. Replace the drive board of motor
4.the reaction disk position are differents between initializing and parameter setting	a. The installation position of optocoupler of the reaction disc is wrong	a. Re-adjust the optocoupler of the reaction disc
5.Friction noise from the colorimetric disc when initialize	a. The colorimetric disc is not assembled rightly, or the rotary axis is not in	a. Disassemble the colorimetric disc and reposition

7.2 Mechanical

Faults	Causes analysis	Solutions
1.The mechanical arm can't detect initial position	a. The signal wire of optocoupler sensor is not connected to motor pinboard well. b. The retainer ring of optocoupler is not installed rightly c. Weld position of optocoupler is	a. Check and connect to right position b. Re-adjust the position and fix c. Take down the optocoupler and re-weld

	loosen	
2.The mechanical arm can't uplink and downlink smoothly	a. There is a wire on the bottom side, or the upper and under mechanical arms are caught on the pipeline b. The friction between the axis and components is too big	a. Check and re-arrange the light path b. Daub silicone grease lubrication on the axis
3.The mechanical arm rock	a. The rotary synchronousbelt is too lax b The synchronizing wheel and motor rotary axis do not occlusion tightly c. The voltage of 5V lock motor is not enough	a. Adjust the synchronousbelt to suitable tightness value b. Tighten the fastening screw on the rotary synchronizing wheel c. Check and replace 5V power supply
4.Obvious noise from the motor when running	a. Stepping motor line is loosened b. Dialing error of motor drive board	a. Electrode Cable. Find out the uncompacted parts and re-press the connecting plug b. Re-adjust the dialing of motor drive board
5.Reagent arm can't reach the designated position when testing	a. Motor board faults b. The rotary belt is too lax	a. Replace the No. 8 and 9 motor boards b. Adjust the synchronousbelt to suitable tightness value
6.Mechanical arm can't work normally	a. Motor board faults b. The optocouplers is broken c. Mechanical arm faults d. Internal 3P data lines burn up, external 232O data line is fall off	a. Replace the motor board b. Replace the optocouplers c. Replace the sample mechanical arm d. Replace the 3P data line and weld

7.3 Waterway System

Faults	Causes analysis	Solutions
1.Can't draw water but inject water when cleaning	a. The plus-minus of peristaltic pump power line is inversed	a. Swop the power-supply wiring heads of the peristaltic pump
2.Obvious residual water stain at the bottom of cuvette after cleaning	a. The apocenosis pump can't work b. The bottom of cleaning probe is projecting in the rinse block	a. Repair and replace the apocenosis pump b. Re-adjust the position of the cleaning piece c. Re-adjust the steps numbers of

	c. The cleaning needle can't reach to the bottom of the cuvette	fluctuation to make the cleaning piece reach the bottom of the cuvette in "motion parameter settings"
3.Can't inject water well-distributed	a. The magnetic valve or water inlet are blocked	a. Replace the magnetic valve or clean the pipeline
4.The water level of pressure tank rise ceaselessly	a. The sealed cap of pressure tank is not tightened b. The seal ring of pressure tank leak air	a. Tighten up the sealed cap b. Replace the seal ring and sealed cap
5.The pressure of apocenosis pump is not enough	a. The apocenosis pump is blocked by foreignmatter b. The heating tank leak air	a. Disconnect the apocenosis pump and eliminate the foreignmatter b. Reassemble the heating tank
6.During clean the cuvette, the clean probe crash it	a. The cleaning arm is not well adjusted b. The installation angle of optocoupler is wrong c. Reaction discis loosen(a. the three fixing bolts on the reaction disc are not tightened; b. the cuvette bracket is not clasped; c. The bottom bearing of reaction disc is not tightened） d. The coded disc of reaction disc is unqualified	a. Adjust the clean arm to the centre of the cuvette b. Adjust the position of optocoupler slightly to make the green and red lights are bright c. Find out the reason of looseness and eliminate it d. Replace with qualified coded disc
7.The cleaning probe drip water	a. The magnetic valve is not closed well b.Backwater peristaltic pump performance reduction c.Channel air leakage d.Infusion pump trouble	a. Disconnect and clean, calibrate the optic parameters b.Reassemble peristaltic pump or change channel c.Inspect the channel of whole cleaning system d. Inspect property of infusion pump.

7.4 Light Path

Faults	Causes analysis	Solutions
The signal value is lower than the allowed range	a. The voltage of lamp is not enough b. The voltage of AMP is too low c. The fiber optic is not installed correctly.	a. Adjust the lamp to suitable voltage b. Adjust the voltage of AMP to 3.6V after inject the distilled water c. Re-install the fiber optic

2.The signal is unqualified when the gain is on the max. or min. value	a. The fiber optic is break off b. Circuit board faults	a. Replace the fiber optic b. Check the weld condition of the circuit board to confirm whether the fuse is wrong selected
3.The signal value is not stable	a. The voltage is not stable b. The lamp is unqualified c. The photosensitive diode Is unqualified d. The fiber optic is not installed correctly. e.The circuit board is not grounded well f. The power source is unqualified	a. Adjust the lamp's voltage to rated voltage, we suggest to use stabilized voltage supply， b. Replace the lamp c. Replace the photosensitive diode d. Shorten the light path of the optic fiber to enhance the light intensity. And put the light beam (which is with the strongest light intensity) at 340nm wavelength e. The oxidation treatment at the junction of the screws may cause bad contact; Polishing the screw junctions of each circuit boards. And weld another grounding wire if necessary. f. Replace with qualified power supply

7.5 Test

Alarm prompt	Causes analysis	Solutions
1.Test results are not correct	a. The voltage is not stable b. The stirring depth is not enough c. The circuit board is not grounded well d. The voltage of AMP is too low e. The colorimetric cuvette is dirty f. The reagent is invalid g. Software faults h. The parameter settings of reagents are wrong	a. Adjust the lamp's voltage to rated voltage, we suggest to use stabilized voltage supply b. Re-adjust the stirring depth c. The oxidation treatment at the junction of the screws may cause bad contact; Polishing the screw junctions of each circuit boards. And weld another grounding wire if necessary d. Adjust the AMP's voltage to 3.6V after adding distilled water e. Replace the reaction cuvette f. Replace the reagents g. Re-install computer system and software h. Re-inspect the parameters settings

7.6 Temperature and Pressure

Faults	Causes analysis	Solutions
1.No heat	a. Check whether the	a. Check +24V heating power source

	heating power supply is inputted b. Check whether the reaction disc and water-heating temperature sensor are in normal condition c. The main control board is connected to temperature control board d. Check whether the wire is ok	b. Check reaction disc and water-heating temperature sensor c. Check the connector wire between main control board and temperature control board d. Check whether the temperature setting is in normal condition
2. No pressure	a. Liquid inlet pump b. Pressure sensor	a. Check whether the pressure setting of the operation software is in normal condition b. Replace the waterway board
3.No refrigerate	a. Refrigeration power supply b. Refrigeration piece trouble	a. Check +12 refrigeration power supply b. Change refrigeration piece

NOTE: The user can solve the problems/faults (which are mentioned in the user manual) according to the user manual. If there is any problems/faults that can't be solved or not mentioned in the manual, please contact our company or your local distributor.

CHAPTER 8 STORAGE AND TRANSPORTATION

8.1 Storage

The wrapped instrument should be stored at a ventilated room, with temperature range from -40℃ to 55℃, ambient humidity not exceeding 95%. DO NOT store the instrument along

with any poison or corrosive. The instrument stored for over one year may fall short of the precision of measurement. Therefore, it is suggested to perform mechanical calibration and alignment procedure when using the instrument.

CAUTION

Please contact URIT to perform calibration for mechanism of the instrument.

8.2 Transportation

The transportation must strictly follow the terms and conditions specified in the order contract.

Do not ship the instrument along with any poison or corrosive.

CAUTION

Under the packing sound condition, the transport temperature is -40℃~55℃ and the relative Humidity is ≤95%.