



Chemistry Analyser

User Manual

CE

Contents

Copyright and Declaration	5
PREFACE	7
Safety Cautions	8
Using Precaution	11
Chapter 1 Installation	
1.1 Preparation	15
1.2 Installation	18
Chapter 2 Introduction	
2.1 Work Principals	22
2.2 General introduction	23
2.3 Reagent	27
2.4 Calibrators and quality control material	36
Chapter 3 Instrument Description	
3.1 System Structure	38
3.2 Interfaces and Basic Operation	43
Chapter 4 Basic Operation	
4.1 General Operation Procedure	47
4.2 Operation Rule.....	48
Chapter 5 Advanced Operation	
5.1 Work Menu	60
5.2 Operation menu	62
5.2.1 Customer date	62
5.2.2 Bio- parameter	65
5.2.3 Control	74
5.2.4 Test report.....	77
5.2.5. Query statistics	81
5.2.6. Instrument maintenance	87
1) Instrument initialisation	87
2) Instrument characteristic setting	88
3) Program Booting	90
4) Instrument parameter settings	90
5) Shutdown procedure	93
6) Moving parts detection	94
7) Cuvette washing	95
8) A / D signal detection	95
9) Cuvette checks	96
10) Temperature and pressure	98
5.2.7. Bio-Test	98
1) Item Edit.....	98
2) Calibration setup.....	107
3) Quality Control	110
5.2.8 Urgent	112
5.2.9 Test Screen	113

5.2.10 Exit	113
Chapter 6 Maintenance.....	114
Chapter 7 Failure Analysis and Troubleshooting	117
Chapter 8 Storage and transportation	121

Copyright and Declaration

Copyright: Woodley Equipment Company Ltd.

Thank you for purchasing the InSight DB Chemistry Analyser.

All contents of this manual comply with the related laws and regulations of the UK, as well as the specific conditions of the InSight DB Chemistry Analyser. All the updated information is included in this manual before printing. Woodley Equipment Company Ltd is fully responsible for the revision and explanation of this manual, and reserves the right to update the relevant contents without separate notice. Some of the schematic pictures in this manual are for reference, if there is any difference, please proceed according to the real object.

All the information of this manual is protected by Copyright Law. No part of this manual may be reproduced, stored or transmitted in any form, or by any means without the express written permission of Woodley Equipment Company Ltd.

All instructions must be followed strictly during operation. In no event should Woodley Equipment Company Ltd be responsible for failures, errors and other liabilities resulting from user's non-compliance with the procedures and precautions described in this manual.

Guarantee of limited quality liability: The Operating Manual of InSight DB Chemistry Analyser has been clearly shown the guarantee of quality liability between Woodley and users, rights and duties in the after-sale service and starting and ending of the agreement.

If a malfunction occurs under normal use because of the material and workmanship, Woodley Equipment Company Ltd will provide one year's warranty service from the date of installation to this instrument sold by Woodley Equipment Company Ltd and agents.

If the following situations occur, Woodley Equipment Company Ltd assumes no liability to the safety, reliability and operation condition of the instrument, and all agreed rights of free service are deemed to be waived permanently and unconditionally.

- Instrument under improper use, hasn't been maintained properly or has been damaged.
- Using reagents and accessories not supplied or approved by Woodley Equipment Company Ltd.
- Instrument damage caused by false operation or negligence as a result of the user or others not operating the instrument in compliance with this manual.
- Replace accessories not specified by Woodley Equipment Company Ltd, maintaining, repairing by personnel who are not authorised by Woodley Equipment Company Ltd.
- Components are discounted, drawing and readjusted not approved by Woodley Equipment Company Ltd.

NOTE



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



Woodley Equipment Company Ltd.

Old Station Park Buildings, St. John Street, Horwich, Bolton, Lancashire, BL6 7NY, UK

Tel: +44 (0) 1204 669033

Fax: +44 (0) 1204 669034

E-mail: sales@woodleyequipment.com

Web: www.woodleyequipment.com

Supplied by:

Woodley Equipment Company Ltd.







Version: 11/2018

PREFACE

This document is the operating manual for the InSight DB Chemistry Analyser. It describes the structure, operation, maintenance and troubleshooting concerning the instrument in detail. Users should carefully read the manual and receive special training before operating to guarantee instrument precision, normal operation and personal safety.

Safety Symbol











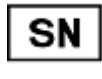




The following symbols are used to indicate danger and alert messages in this manual.

Marking	Meaning
 Warning	Follow the instruction below the symbol to avoid personal injury
 Caution	Follow the instruction below the symbol to avoid analyser damage and failure, or unreliable analysis results
 Note	Follow the instruction below the symbol. The symbol highlights the important information in operating procedures which call for special attention.
 Biohazard	Biohazard means the biological factor may cause a hazard to the environment and organism.

Sign Illustration

The analyser or the outer packaging may have the following labels or symbols.

All illustrations in this manual are provided as references only. They may not necessarily reflect actual analyser configuration or display.

	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 comply with the installation instructions of the manual.
 - 2) If relocation is necessary, contact your local distributor or Woodley Equipment Company Ltd.
-

Prevent Electric Shock

Please comply with the following precautions for preventing electric shock.

CAUTION



- 1) Users other than the servicing personnel authorised by our company must not open the rear cover and left/right cover when turning on the power.
 - 2) If a spill occurs or liquid gets into the instrument, please contact Woodley Equipment Company Ltd. Neglecting the liquid may cause electric shock.
-

Prevent Personal Injury

Please comply the following precautions for preventing injury.

CAUTION



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

Eyes Protection

Please comply with the following precautions.

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 burns.
-

Precision and Accuracy of Data

Please comply with the following to help ensure accurate data.

CAUTION



- 1) DO NOT open the top cover, rear cover and reagent tray when the instrument is under analysing condition.
 - 2) Please check the accuracy of the 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 samples 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 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 wash 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 handling the waste solution to avoid personal injury and protect the 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 goggles if necessary when disposing of waste solution.
-

System Dispose Hazards

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



CAUTION

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

Fire and Explosion Hazards

Observe the following instructions to prevent fire and explosion.



CAUTION

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

Using Precaution

Systematic Usage

CAUTION



- 1) The InSight DB Chemistry Analyser is intended for use in veterinary institutions and laboratories to analyse specific chemical composition of animal body fluid. If the instrument is to be used beyond this scope, consult Woodley Equipment Company Ltd first.
 - 2) Please consider together with the clinical symptom or other analysing result when making the clinical judgment.
-

Operator

CAUTION



The instrument is operated only by technicians, veterinarians and laboratory personnel that are trained by Woodley Equipment Company Ltd.

Operational Environment

CAUTION



- 1) Please install the instrument according to the specified installation instructions in the manual. Otherwise, the results may not be reliable and may cause system damage.
 - 2) Please contact Woodley Equipment Company Ltd if system state is changed.
-

Caution on Electromagnetic Wave Interference


CAUTION



- 1) Keep the instrument away from strong noise sources and electromagnetic waves. Turn off mobile phones and transmitter-receivers when operating the instrument since the electromagnetic wave may cause an adverse effect on the instrument.
 - 2) Do not use other medical instrument around the system that may generate electromagnetic waves and interfere with the operations.
-


Indication for System Use

CAUTION

- 1) The operator must receive training before operating the instrument. Please follow the instructions in the manual to operate. Improper operation may cause personal injury, system damage and improper results.
 - 2) Please run a calibration and quality-control test before using the system for the first time to ensure it can be used normally.
 - 3) A quality-control test must be done when using the system. Otherwise, the reliability of the result cannot be guaranteed.
- 
- 4) Do not open the sample/reagent cover while in the analysing process.
 - 5) The communication port of analytical part is set to connect with the communication port of operational part. Please use the InSight DB cables supplied for connecting.
 - 6) The operation port is an external computer which has installed the specified operational software. The computer should be exclusively used for the instrument. DO NOT run any other software when it is connected with the instrument. Inappropriate use may result in computer virus infection.
 - 7) DO NOT touch the keyboard, indicator and mouse when your hands are wet.
-

System Maintenance

CAUTION

- 1) Maintain according to the instructions in this manual. Incorrect maintenance may lead to inaccurate results and could cause system damage and personal injury.
- 
- 2) Dust may be found after a long-time placement. Clean the surface by using a soft cloth or little soap solution if necessary. Never use organic solvent such as alcohol. Wipe the surface after cleaning. Please turn off the power supply and pull out the plug before cleaning. Take measures to prevent water coming into contact with the system, otherwise, this will cause system damage or personal injury.
 - 3) Calibration analysis must be done when the light source, optical system, sample needle, reagent needle, stirrer and any other major component have been changed.
 - 4) Please turn off the power and wait until the light has cooled to avoid burns.
-

Setup of Parameters


CAUTION



To define parameters including sample volume, reagent volume and wavelength, follow the instructions in this manual and the reagent instructions.


Precaution for Handling Samples

CAUTION

- 1) Sample must not contain insoluble substances such as fibrin and dust. Coagulation may block the aspirating probe thus causing negative effects on tests. Medicine, anticoagulant, preservative which exist in a sample may influence the test result. Haemolysis, icterus and lipaemia may also cause incorrect results. Running a background test is recommended.
- 2) Store the sample correctly. Sample structure will change and may cause an incorrect result with incorrect storage.
-  3) DO NOT expose samples in the air for a long time because they may be contaminated or evaporated and inaccurate test results may occur.
- 4) Certain samples cannot be analysed, please contact the manufacturer or authorised distributor for details.
- 5) Certain samples need to be preprocessed please contact the manufacturer or authorised distributor for details.
- 6) Consult the manual for sample volume when conducting the test.
- 7) Ensure sample is positioned correctly before testing, otherwise an inaccurate result may occur.

Handling Reagents, Calibration and Control

CAUTION

- 1) Proper reagent, calibration solution and control solution are needed for analysis.
- 2) Please choose the correct reagent. Consult the manufacturer or distributor if uncertain about the usage of reagents.
-  3) For storage, handling and usage of reagent, standard solution and control serum, refer to the Instruction for Use provided by the manufacturer. Improper storage may not guarantee the accuracy of test results even though they are not expired.
- 4) Be sure to perform calibration when replacing reagent. Otherwise, inaccurate test results may occur.
- 5) Cross-contamination among reagents may influence test results. Contact the manufacturer or authorised distributor 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 are wet.
- 2) Check samples for contamination (dust, or fibrinogen) and air bubble before analysis.



- 3) For replacements of major parts, including light source lamp, aspirating probe, reaction cuvette, etc., please contact Woodley Equipment Company Ltd.
 - 4) For settings of sample volume, reagent volume, wavelength, standard values, etc., please refer to the instructions in the 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 analysis. Make sure there are no air bubbles in the flow paths.
-

Chapter One Installation

1.1 Preparation



CAUTION

Only the Woodley Equipment Company technician can perform the installation of the instrument.

Only the Woodley Equipment Company technician can perform the installation of the 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 Woodley Equipment Company.

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 analyser should be installed in place to meet the following conditions. Otherwise, it cannot guarantee 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:

- The working environment of the instrument should be well ventilated but should avoid direct airflow which may affect the reliability of data with the analyser.

The installation site should be as 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 devices such as mobile phones or radio transmitters near the system.

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



Caution:

- If the current direction of inclination is greater than 8 degrees, the analyser may spill hazardous material. You should take the necessary protective measures in storage, handling and other processes.

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.

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



Caution:

- Power should be properly grounded. Improper grounding may cause electric shock and analyser damage.
- You should confirm that the power outlet output voltage meets the requirements of the analyser, and has the appropriate fuse installed .

3) Temperature and Humidity Requirements

3.1) Storage Temperature and Humidity

Storage temperature: -10°C-55°C, with fluctuation less than $\pm 2^{\circ}\text{C}/\text{H}$;

Storage relative humidity: $\leq 95\% \text{RH}$, no dew.



Notice:

- Exceeding the instrument storage temperature range may result in damage to the analyser.

3.2) Working Temperature and Humidity

Working temperature: 10°C~35°C, with fluctuation less than $\pm 2^\circ\text{C}/\text{H}$;

Working relative humidity: $\leq 90\% \text{RH}$, no dew.



Notice:

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

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 °C;

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



Bio-hazard:

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



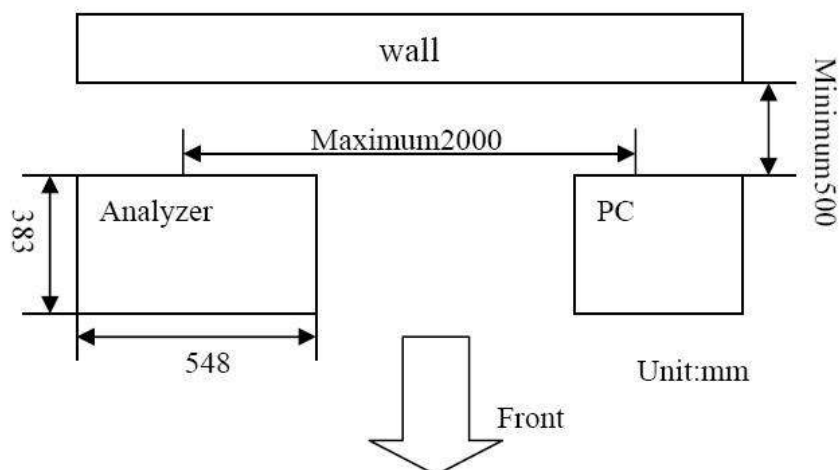
Notice:

- The water quality must meet the requirements of the GB-6682 three-grade water, otherwise the lack of water pressure 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 analyser and computer will not be crowded.



1.2 Installation

After unpacking, please remove the chemistry analyser from the packaging, and put it on a flat surface.

1.2.1 Connecting Water Supply Bucket



Bio-hazard:

- While operating you must wear gloves, protective clothing and if necessary protective eyewear to prevent infection.



Caution:

- When placing the distilled water bucket, the bucket cannot be higher than the bottom of the upper cabinet at the top of the analyser.
- Ensure that the water conductivity of the deioniser liquid pipe flow does not bend or twist.
- Note: there are two plastic pipes in the distilled water sensor subassembly; the tube which is connected with the long plastic pipe should connect with the water interface which is marked with an upwards pointing arrow. The tube which is connected with the short plastic pipe should connect with water interface which is marked with a downwards pointing arrow. Please see the above images for reference.

1.2.2 Connecting Waste Bucket



Bio-hazard:

- While operating you must wear gloves, protective clothing and if necessary protective eyewear to prevent infection.



Caution:

- When placing the waste water bucket, the bucket cannot be higher than the bottom of the upper cabinet at the top of the analyser.
- Ensure that waste catheters are all located above the waste container, are smooth, and do not bend or twist. Otherwise poor drainage of the waste liquid overflow can cause damage to the analyser.

- 1 Confirm that the Analysis Division of the power is turned off
- 2 Position the waste liquid bucket to the correct place under the work surface.
- 3 Let the liquid level sensor into waste liquid bucket.

1.2.3 Installing/Removing Sample-Reagent Disk



Warning:

- Before inserting or removing the sample / reagent tray please make sure that the analyser has finished working or is turned off and the sample / reagent tray has stopped.



Bio-hazard:

- While operating you must wear gloves, protective clothing and if necessary protective eyewear to prevent infection.

Be sure the two disk pins are inserted to the correct position as shown below



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, protective clothing and if necessary protective eyewear to prevent infection.

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, protective clothing and if necessary protective eyewear to prevent infection.

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, protective clothing and if necessary protective eyewear to prevent infection.
- 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 Two Introduction

2.1 Working Principle

Working principle of analyser: 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:

$$A = -\log(I/I_0) = -\lg T = kCL$$

In this formula: A is absorbance;

I₀ 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 InSight DB Chemistry Analyser is optical filler

2.2 General Introduction

Design Philosophy of Biochemistry Analyser: 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 coloured 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:

$$I_o = I_a + I_r + I_t \dots\dots\dots (1)$$

I_o —incident intensity

I_a —Absorbing light intensity

I_r —intensity of reflected light

I_t —intensity of permeation light

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

$$I_o = I_a + I_t \dots\dots\dots (2)$$

We know from formula (2) that: when “ I_o ” value is fixed, if “ I_a ” is bigger, then “ I_t ” is smaller; that is to say, the recede of the light intensity is only related with the absorbance of the coloured 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:

$$\lg = KCL \dots\dots\dots (3)$$

This is “Lambert---Beer” law, K means light absorption coefficient; it means the absorption of the coloured 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 coloured chemistry compound, and it has important function in colourimetric analysis. If K is bigger, then it means the substance have stronger absorption power of light. The change of consistence will cause significant change of absorbance, so the sensitivity will be higher during the colourimetric testing.

“Lambert---Beer” law means the absorbency of coloured solution to the light. It is direct ratio with the liquid thickness and consistency of the coloured 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

InSight DB Chemistry Analyser 【Please see below picture】



2.2.2 Main parts

- 1) Lamp: halogen lamp, 20W,12V, running time more than 2000 hours.
- 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 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°C thermostat meanwhile colourimetric directly.
- 9) Barcode scanning function (Optional): to identify 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	39 items, one diluent position.
Analysis method	End points, Fix-time (two points), Kinetic, Colourimetry, 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 24-hour water cycle refrigerated compartment function.
Sample volume	2-50 μ l, 0.1 μ l step
Reagent volume	R180 μ l~350 μ l, R2 10 μ l~250 μ l, 1 μ l step
Reaction volume	180 μ l~500 μ l
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, cross-contamination rate is less than 0.1%
Automatic syringe and retest supported.	
using the aspirator needle sucking up and down to mix. with independent stirring arm, stirring immediately when sample is added; for double reagent, stirring immediately after R2 is added	
Reaction disc	60 reusable plastic cuvettes
Reaction Tem.	37 \pm 0.1 $^{\circ}$ C, temperature fluctuating should be \pm 0.1 $^{\circ}$ C
Reaction cuvette	5mm \times 6mm \times 25mm, optical path 5mm
Reaction liquid total volume	180~500 μ l
Max. reaction time	12 minutes
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 \sqrt ones at right table.)	With 9 wavelengths 340nm <input type="checkbox"/> 、405nm <input type="checkbox"/> 、450nm <input type="checkbox"/> 、 510nm <input type="checkbox"/> 、546nm <input type="checkbox"/> 、578nm <input type="checkbox"/> 、 620nm <input type="checkbox"/> 、660nm <input type="checkbox"/> 、690nm <input type="checkbox"/> 、
Detecting cycle	18 seconds
Absorbency linearity	0.0000~4.0000Abs
Wavelength accurate	\pm 2nm
Repeatability	CV \leq 2.5% (CV stands for coefficient of variation.)
Stability	within one hour, absorbance change is less than 0.01
Power supply	~100-240V, 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	Temp.: -10°C~55°C
	Humidity: ≤95%RH, no dewdrops
	Atmospheric pressure: 50kPa~106kPa
	Altitude: below 3000m
Working environment	Temp.: 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))
Safety class	Type of prevent shock: I (Externally powered)
	Class of prevent shock: B
	Class of prevent harmful liquid inlet: common device (sealed device but can't prevent liquid inlet)
	The disinfect and sterilization methods recommend by the manufacturer: inapplicability
	Classify based on the safety standard under using flammable anaesthetic gas with air o oxygen o oxides of nitrogen: inapplicability in the place of flammable anaesthetic gas
	Operational condition: Continuous running equipment

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.

2.3.1 Reagent Classification

Reagent can be classified into:

1) Powder Reagent

It needs to be dissolved with buffer solution or distilled water (deionised 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 interference 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.

2.3.2 Reaction 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.

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

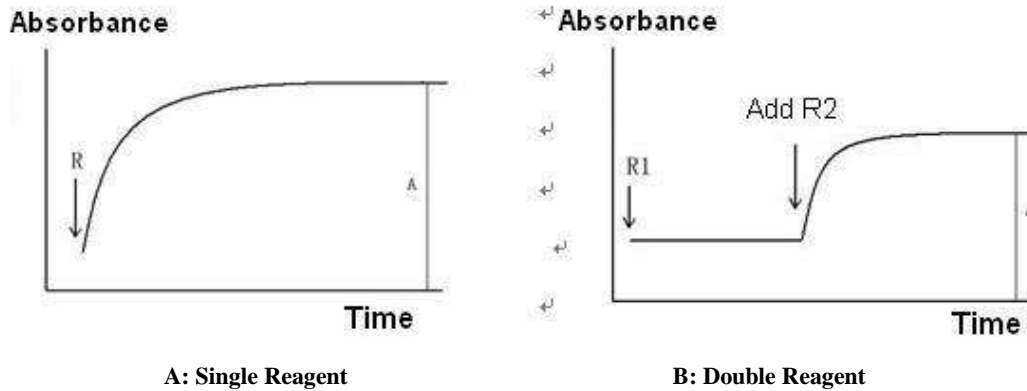
Based on reaction endpoint of analyte integrating with the reaction situation of distractors

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 $CU = (\text{analyte absorbance } AU - \text{reagent blank absorbance } AB) \times K$
 K—calibration factor

Chart 1 Reaction Curve of One Point End Assay

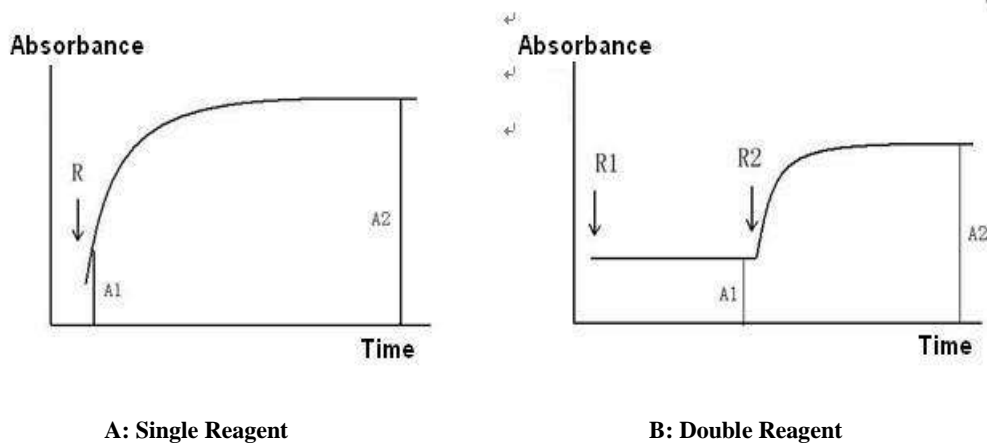


Two Points End Assay

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 $CU = (\text{absorbance to be tested } A2 - \text{absorbance to be tested } A1) \times K$
 K—calibration factor

Chart 2 Reaction Curve of Two Point End Assay



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

2) Two points

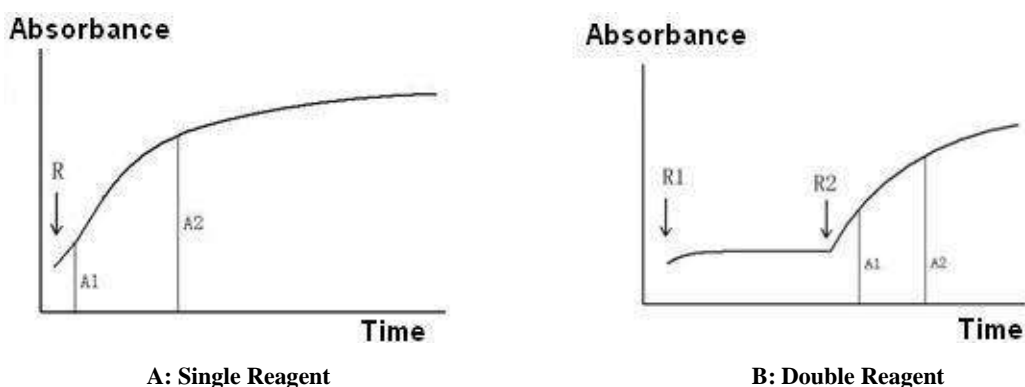
Reagent for this method: creatinine, urea, bile acid.

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:

$$CU=(A2-A1) \times K$$

K—calibration factor

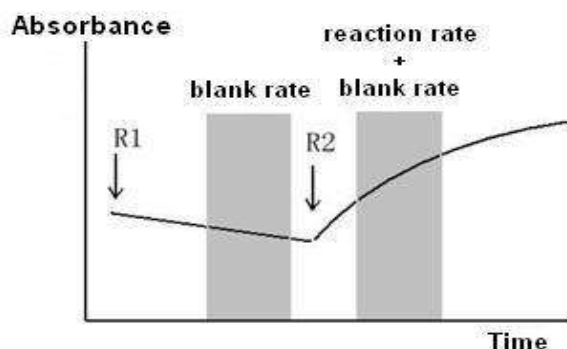
Chart 4 Reaction Curve of Fixed Time



(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

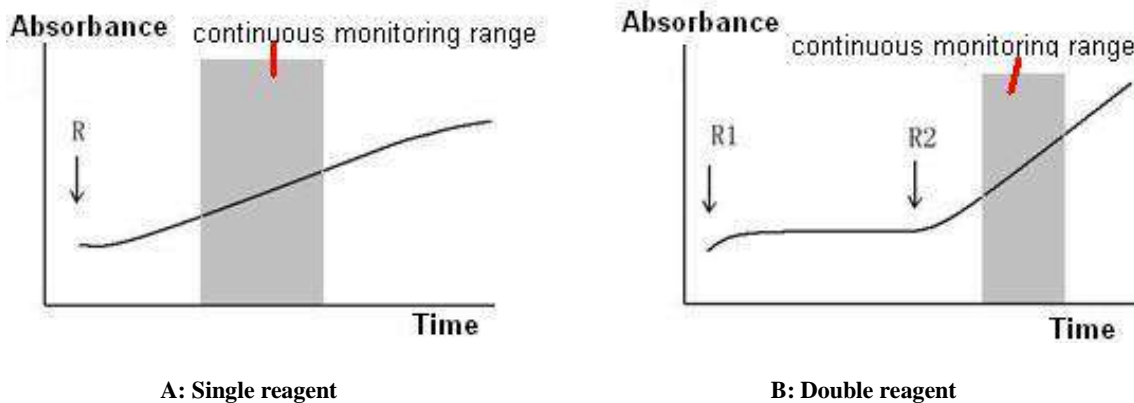


3) Kinetic Method

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.

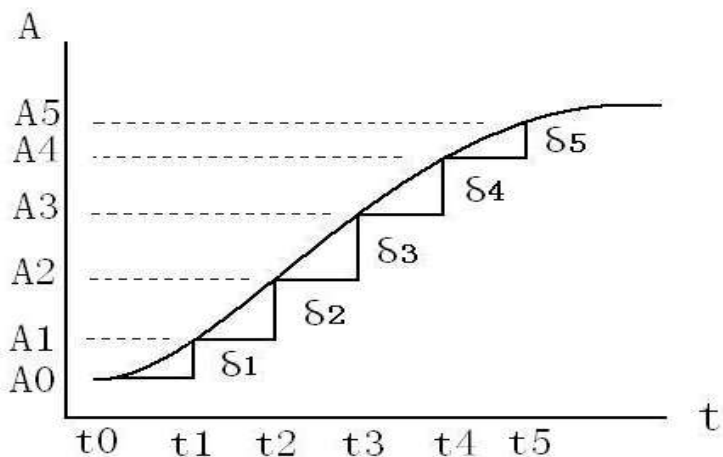
Rate method, is to choose the absorbance value continuously in time-linearity section in the absorbance curve (the D-value between every two points is the same) when test enzymatic activity or test the metabolite by enzyme, and calculate result based on the change rate of unit absorbency($\Delta A/\text{min}$).

Chart 6 Reaction curve of rate method



① Linearity section of enzymatic reaction

Chart 7 Linearity section of enzymatic reaction



② Advantages of rate method:

Can confirm the linearity period and calculate $\Delta A/\text{min}$, and to calculate the enzymatic activity accurately according to this value; so this make the automatic chemistry analyser observably superior to the manual method when test the enzymatic activity. Continuous monitoring method is also used for testing the concentration of linearity reaction metabolite which are normally resulted by some enzyme test.

enzymatic activity (U/L) = $\Delta A/\text{min} \times \text{theory (o calibration) K value}$

concentration of metabolite CU = $\Delta A/\text{min} \times \text{calibration K value}$

③ Theory K value

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

enzymatic activity (U/L) = $\Delta A/\text{min} \times \text{calibration K value}$

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

a. The premise of adopting theory K value:

The dosage of sample and reagent must be accurate; the light diameter of the colourimetric 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 instrument models, 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 manufacturer maybe are a little different from the actual Moore absorptivity tested by instrument. 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 $A = \epsilon b C$, the cuvette's light diameter and glucose standard liquid's concentration, to test the absorbance of glucose standard liquid A, and then to calculate the NADH's (NADPH) Moore absorptivity ϵ is A/bC .

The concentration of the glucose standard liquid is 10mmol/L(0.01mol/L), the adding volume of the standard liquid is 3.5 μ L, the add volume of enzyme reagent is 335 μ L, 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) is 6220.

The Moore absorptivity test of "Chromogen" substrates at 405nm wavelength

Many enzymes substrates are synthetic "chromogen" substrate by artificially synthesised, they are colourless. And they will liberating out coloured reaction product after enzyme action, at the wavelength of 405nm, 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) or γ -L-glutamyl-3-oxohydroxy- p-nitroaniline (γ -L-Glutamyl-3-carboxyl-p-nitroan) liberate out yellow p-nitrophenol after enzyme action (p-Nitroaniline, 4-NA) or p-nitryl-5-benzaminic acid (2-amino-nitrobenzoic acid, ANBA).

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

- a. 4-NP standard stored liquid (10mmol/L)
- b. 4-NP standard application liquid (2.5mmol/L, produced by diluting 0.84mol/L AMP buffer solution)
- c. Substrate buffer solution (15mmol/L 4-NPP dispensed in 0.84mol/L AMP-HCL buffer solution, 37°C, pH 10.09 \pm 0.02)

Test method: 4-NP standard liquid qty. is 5 μ L, Substrate buffer solution qty. is 350 μ L, wavelength is 405nm, light diameter is 0.7cm, temperature is 37°C, 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 is $\Delta A = A1 - A2$, according to above method. If get ΔA 为 0.460, thus get real test 4-NP Moore absorptivity = 18662

④ Calibration K value:

Analyser calculates automatically after enzyme activity calibration substance be calibrated. During enzyme testing, if the testing terms change, such as temperature, sample reagent qty. and absorptivity 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: ① must use matched reagents; ② must use matched and high qualified calibration substance, which should be traceable.

4) 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, haptoglobin, 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.

2.3.3 Automatic 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 analysers that add reagent before sample.)

2) Monitoring the Rate of the Reagent Blank

By set-up this function of Rate B, analyser 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

Haemolysis, icterus, lipid of the sample will interface the non-chemical reaction, so usually sample will adjust its affecting level of the haemolysis, 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.

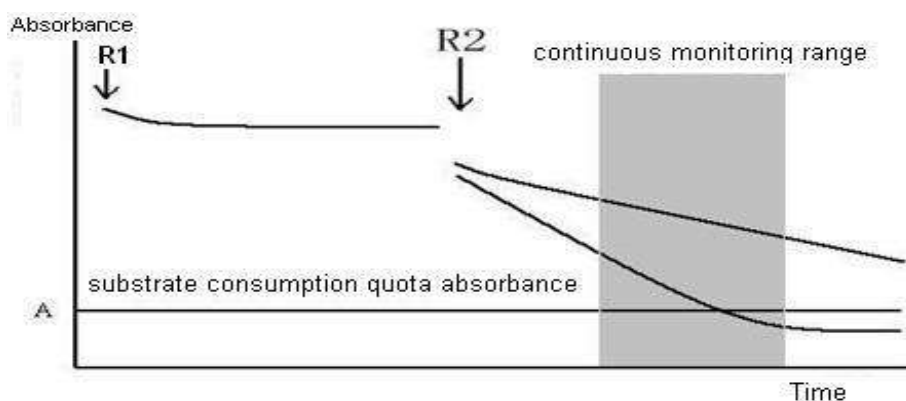
Calculate variance of all points. Judge whether it presents linearity according to magnitude of variance:

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 analysing 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, the analyser will give indications that results exceed the linearity range. Most analysers 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, haemoglobin, 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, secondary wavelength should be 100nm longer than dominant wavelength. The 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 the analyser to form an integrated system.

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

4) Reagent should be used in accordance with service conditions and range of application required by the 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 characterised with brought in line with detection process. Its ingredients are 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 results are likely to occur due to different detection principles and reagent quality adopted by analysers produced by different manufacturers. Especially for some special specimen, the value obtained from different detection systems would sometimes be different with the true value. Therefore, the manufacturer and distributor of the analyser have a responsibility to chronically and stably provide the special specimen of this detection system, detection result and other relevant information. To keep this traceability for good, all detection systems in the traceability system should be ensured under stable state every year, day and hour. Once all detection systems enter the traceability system, it is necessary to actively conduct control inside and outside.

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 the analyser to form an integrated system.
- 3) Reagent should be stored properly under the storage conditions required by the manufacturer.
- 4) Reagent should be used in accordance with service conditions and range of applications required by the manufacturer.
- 5) Reagent is only for in vitro diagnostic use.

Chapter Three Instrument Description

3.1 System Structure

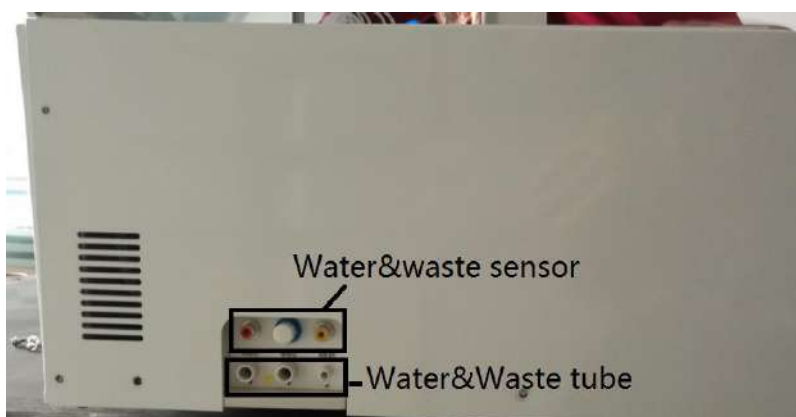
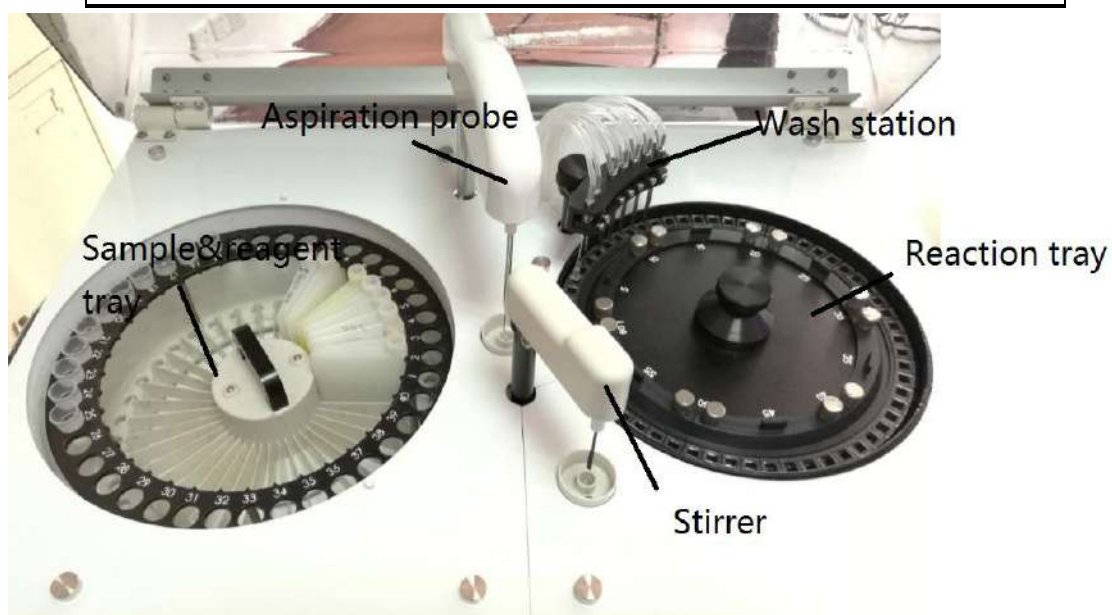
This Part mainly describes the structure and interface and other basic operations of the InSight DB Chemistry Analyser.

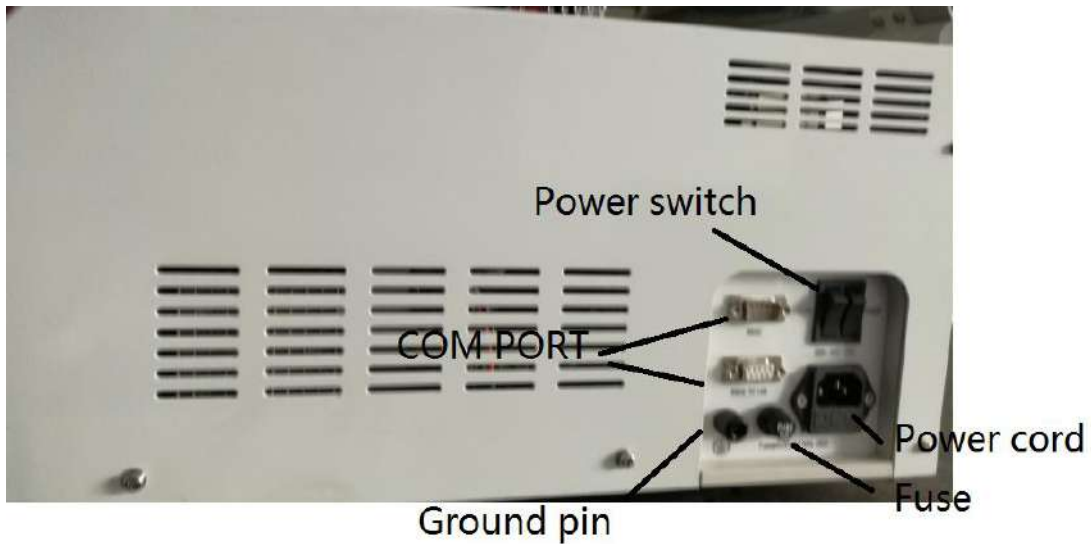
The InSight DB Chemistry Analyser is intended for in vitro diagnostic use and quantitative determination of clinical chemistry samples, such as serum, plasma, urine or cerebrospinal or pleural effusion and ascites.



Note:

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





3.1.1 Analysing Unit

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

1) Sample-reagent disk

Sample-reagent disk holds sample and reagent.

The sample position can hold the following container:

Micro sample tube, Centrifugal tube

Blood collecting tube $\Phi 12 \times 100$

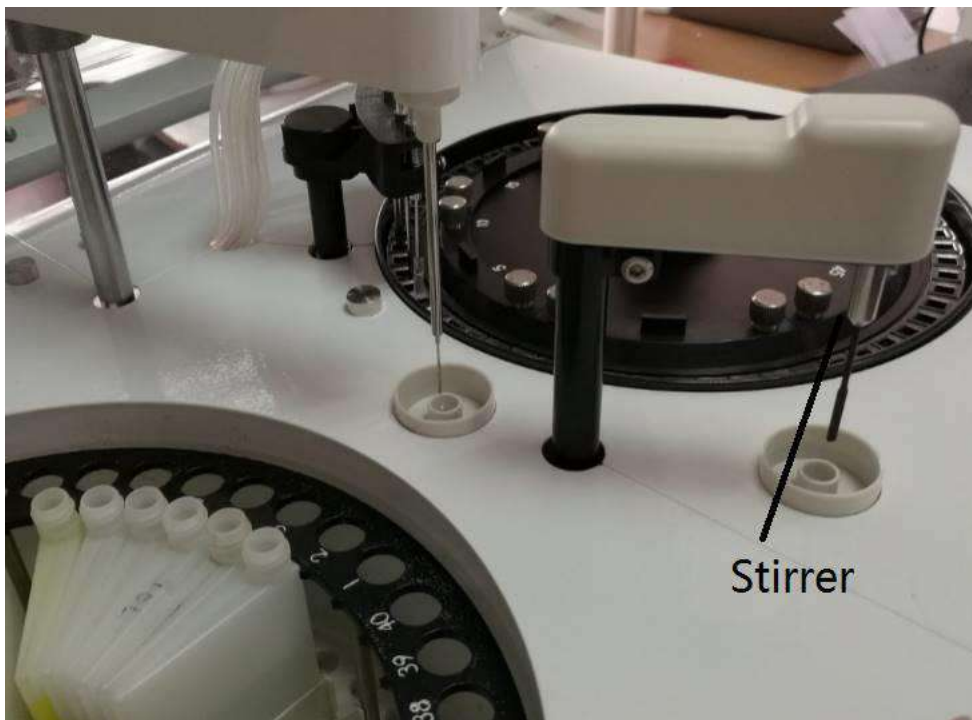
Woodley Equipment Company reagent tubes are only to be used. The volume of InSight DB Chemistry Analyser reagent container is 20ml. Sample disk and reagent disk place in the sample and reagent storage respectively. The storage supports refrigeration to keep temperature between 5~14°C.



Note:

- The reagent positions are for Woodley Equipment Company reagent bottles only. Please use specified sample tubes; otherwise, it may cause system damage.

2) Mixer Assembly



The mixer assembly mixes reaction liquid in the reaction cuvette.

For single-reagent test, the mixer works once sample adding is finished; for double-reagent test, the mixer works after adding sample and R2 respectively.

When stirring is finished, the mixer moves automatically to the wash well and washes.



Warning:

- **When the analysing 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 personal injury or equipment damage.**

3) Reaction Disk Assembly

The reaction disk holds the cuvettes. The cuvettes are designed for reaction container and colourimetric measurement.

During analysing, the specified cuvette moves to the 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 can be used permanently and is replaced manually if necessary.

The reaction disk is placed in a temperature-controlled room, which provides the steady temperature at $37\pm 0.1^{\circ}\text{C}$.

The exchange of Cuvette cup:



BIOHAZARD:

- Wearing gloves and a lab coat is a must to replace reaction cup to avoid infection.
- Be sure to dispose of the used cuvette according to the local regulations.

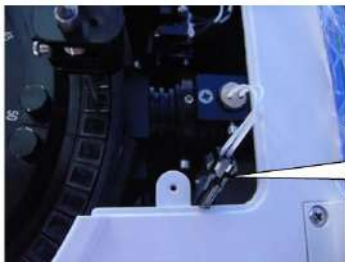
4) Photometer Assembly

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

The exchange of Halogen Lamp:



Unscrew the two screws and remove the cover



The connector of lamp



The retaining screw



Biohazard:

- Do not stare into the lamp when the system is in operation. Light sent by the photometer lamp may damage 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 cool before touching it. Do not touch the lamp before it cools down, 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.



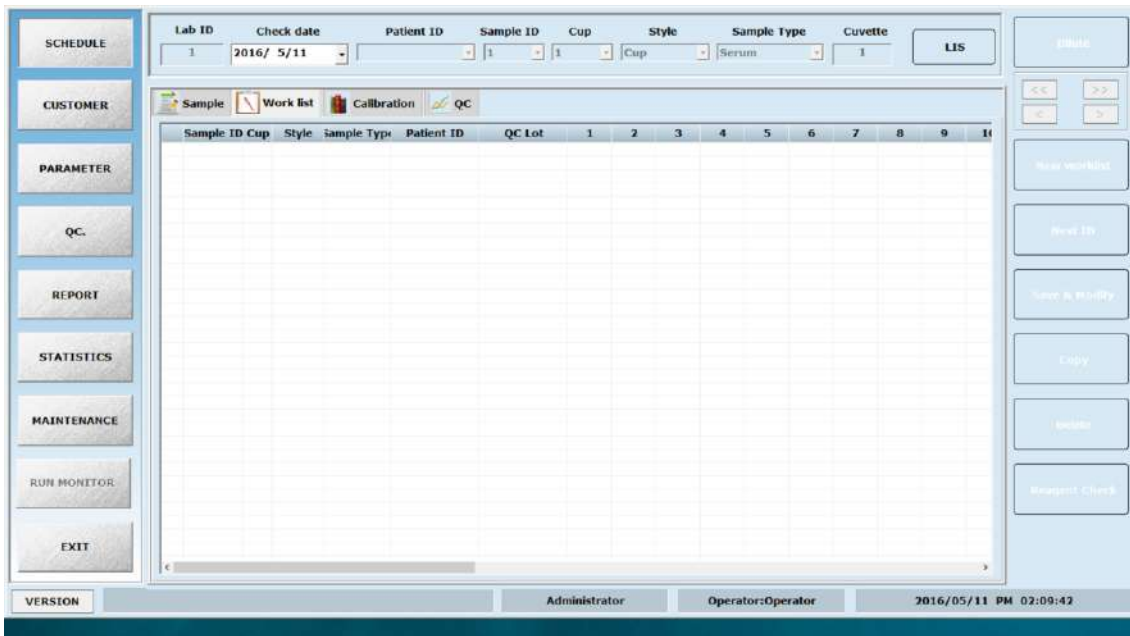
Warning:

- 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

3.2.1 Screen Layout

The main interface of the software are displayed below:



Software main interface

Group button area

It is on the right of interface, using for parameter setting, QC management, maintenance and history results query, and so on. When you click one of them, the relevant working interface will display.

Working status area

The area is on the low area of screen, which displays time, current user, laboratory name and software information

Biochemical test area

It is on the center of screen, designed for both regular and emergency test.

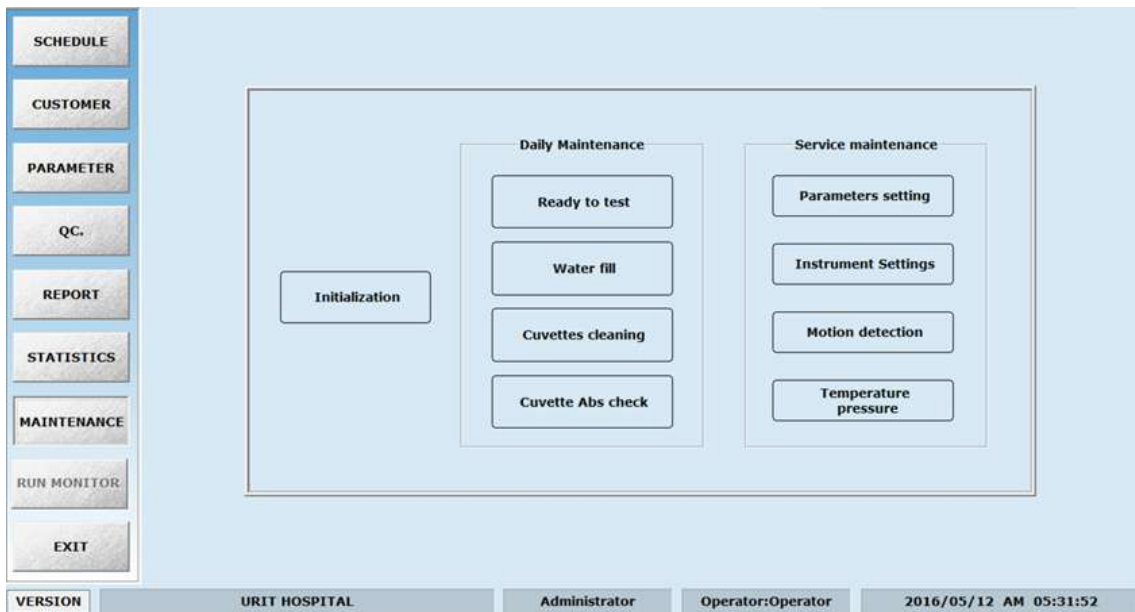
Working interface area

It displays the value and graph of parameters, process, result etc on the interface of the 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 human-machine interaction. Please see the following example.




Dialog box

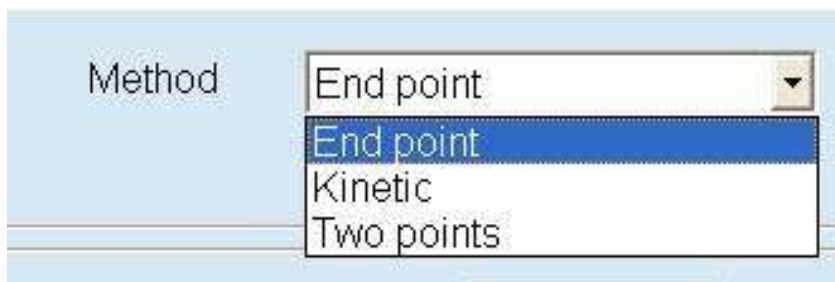
Tab

Click a tab and you will enter its corresponding index working interface. See the picture below for an example.



□ Drop-down list box

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



□ Button

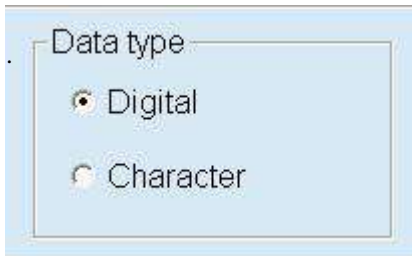
The function of button is to open a dialog box or execute other defined function. Click a button, it will conduct the corresponding operation. See below picture.





□ Option button

In one group button, you can only choose one each time, then it is called an 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.



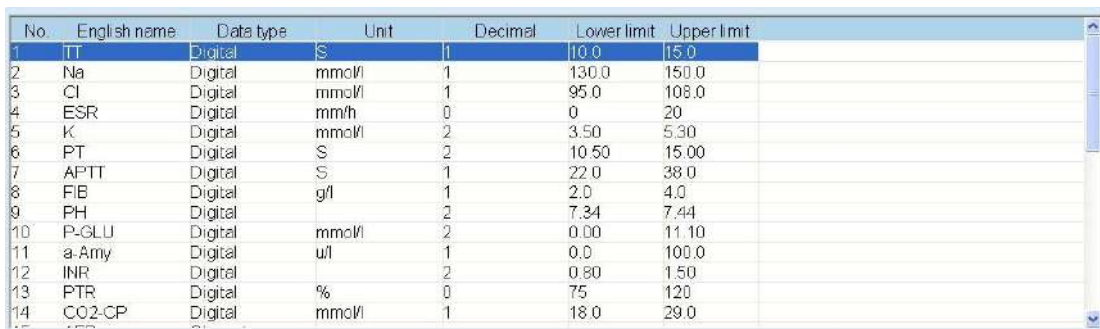
□ Edit box

Edit box can read and display characters input through the keyboard. See the picture below. Two edit boxes are provided, in one box, only character can be input, 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

Byname	<input type="text"/>	English name	<input type="text" value="TT"/>
Unit	<input type="text" value="S"/>	Decimal	<input type="text" value="1"/>
<input type="checkbox"/> Lower limit	<input type="text" value="10.0"/>	Upper limit	<input type="text" value="15.0"/>

□ Scroll bar

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



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	CO2-CP	Digital	mmol/l	1	18.0	29.0

□ **List**

The list displays the name of one or multiple items or combination of them. See the example below.

Click it to select and click it again to cancel your selection. Number stands for the position of reagent.

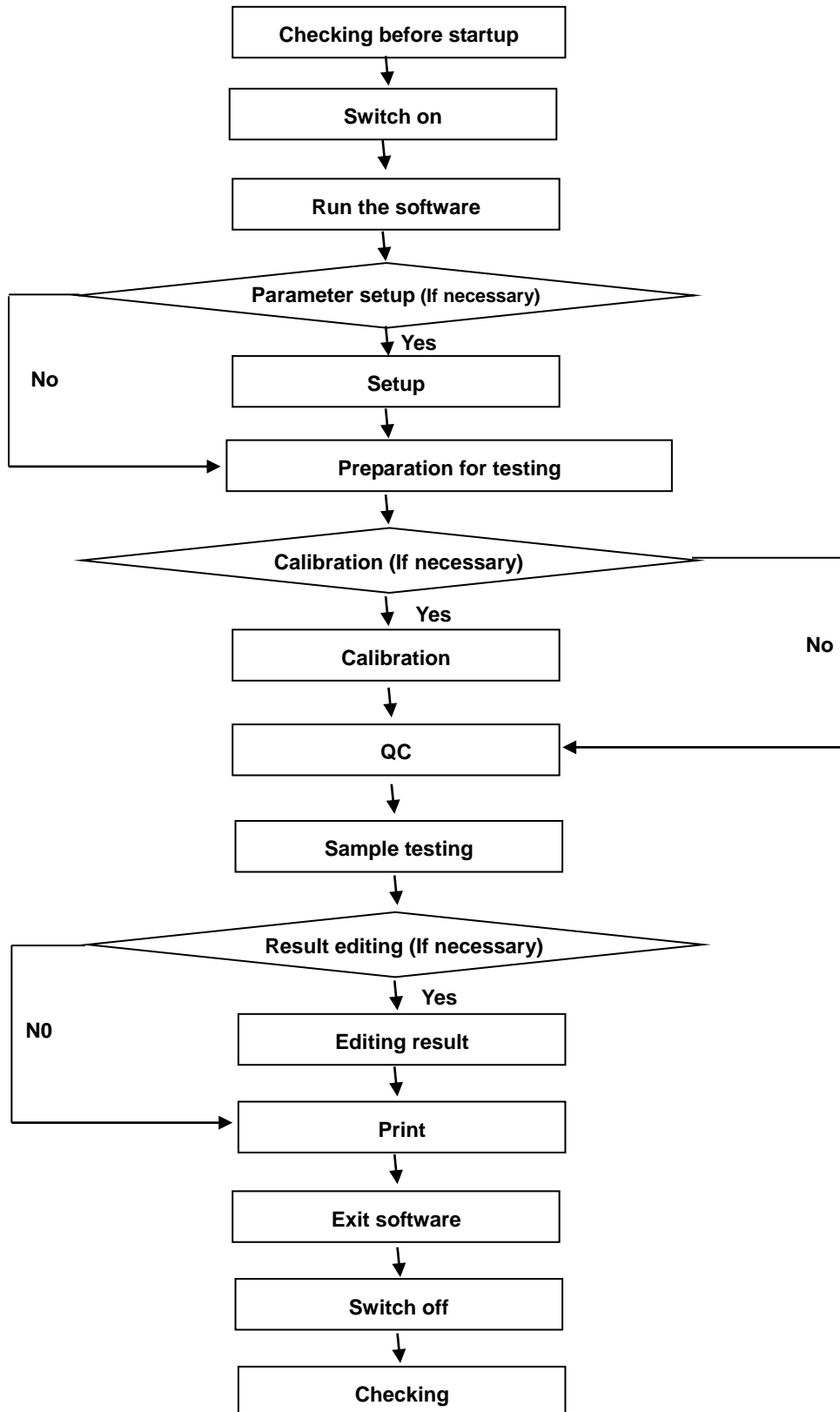
Sample | Work list | Calibration | QC

TB	9	ALB	12	ALP	5[6]	LDL_C	25[26]	DB	10
UA	20	AMY	25	TC	21[22]	TG	23[24]	LDH	14[15]
CK	16[17]	HDL_C	25[26]	ALT	2	TP	11	AST	3
GGT	7[8]	BUN	19	CR	18	GLU	13	CA	26

Test Group

Chapter Four 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 works normally after switching on, please check what is 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 analyser, computer and printer) line and the power line, ensure they are ok and not loose.
3)	Check whether there is enough printing paper and add printing paper if required.
4)	Make sure the sample probe is at the right position (cleaning position).
5)	For InSight DB Chemistry Analyser, 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 the tests to be carried out.

2) Switch On

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

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

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

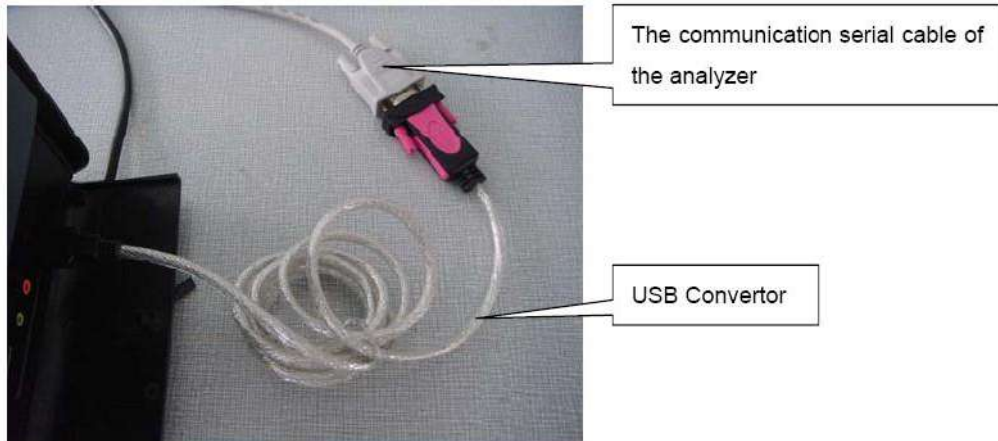
3) Run Software

3.1) Connection between computer and instrument.

There is a USB to serial port convertor in the accessories of the machine. If there is not a 9-pins serial port in the computer, the convertor should be used, otherwise it is not needed.

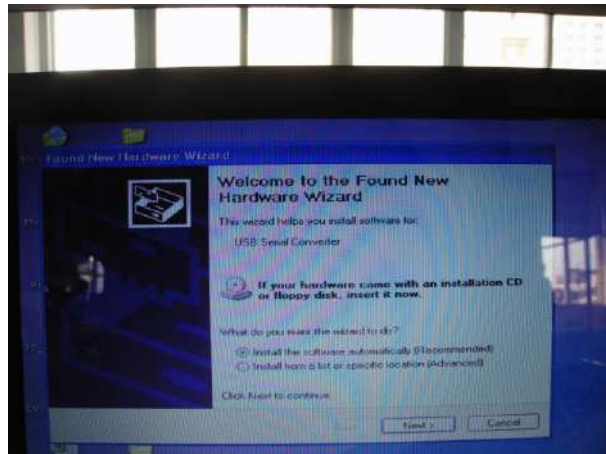
How to install the convertor?

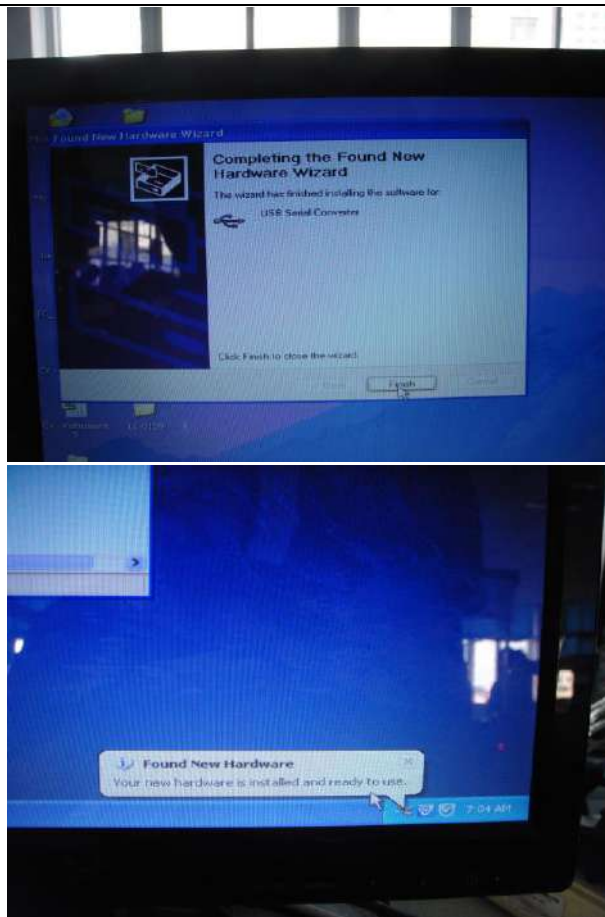
Step1: there are two ports in the USB convertor: one is a USB port, the other is a male 9-pins serial port.



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

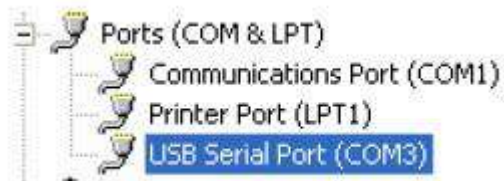
Step 3: Connect the USB port of convertor with the computer. The computer will indicate the new hardware is found. The screen will indicate “Found new hardware wizard” see the following picture. Always click the next button to perform the next process.





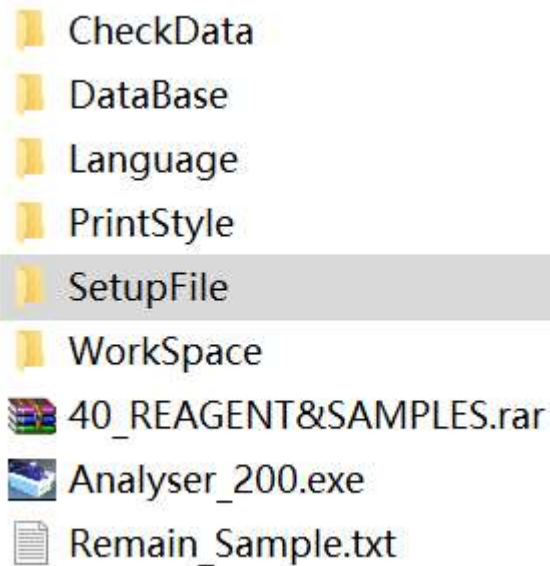
Finish the driver installation.

Step 4: after installing 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.

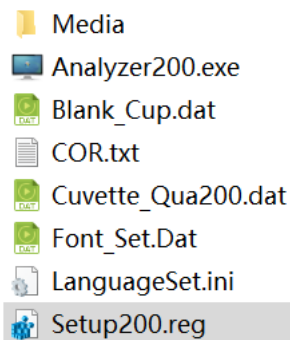


Step 5: the operator can use the convertor to connect the communication cable of machine.

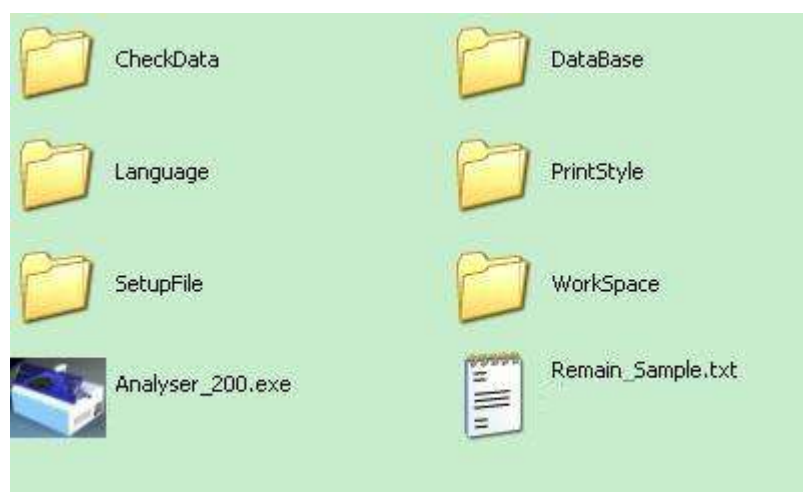
3.2)	Go to software folder, open the [SetupFile]
------	---



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



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



When starting up, the system will automatically check the operation system, screen resolution, close screen protection program, check colour configure, initial database and

check printer.

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



Note:

3.3) **This software can be used on the InSight DB Chemistry Analyser.**

How can we setup machine type?

Maintenance → Parameter setting (Password sages) →Separate mixing system

1. Please select Yes and then click Select.

System parameters set dialog

Com serial port select

COM1 COM2 COM3 COM4 COM5

Barcode length: Language:

Separate mixing system: Yes

Test order: Sample wise Item wise

QC range: SD style Range style

Power on wash: Power on run Power on stop

Power off wash: Power off run Power off stop

Syring type: Keyto YKC

Barcode scan: No Yes

Screen color setup

Background set Color set

Identifying code:

Water blank OD: Water blank OD. Cuvettes check: No

Rgt. Sample alarm: Alarm DISKID:

Auto-check setup

Result is too low Beyond the set Linearity limit

Reagent blank is not stable Substrate depleted

LIS system setup

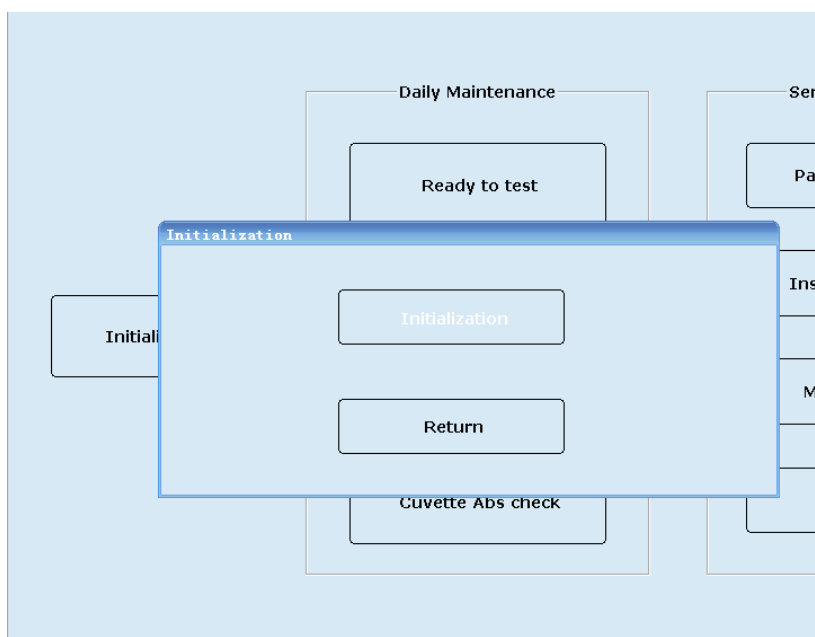
Server IP: Port:

COM1 COM2 COM3 COM4 COM5

Baud rate: Send online results

Select Return

Click “MAINTENANCE” button, and then click the “Initialise” 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, can the analyser carry out testing and other functions.

Please set up the parameters when operating the analyser for the first time. During the daily operation, the user can set up the parameters according to their specific needs.

Before testing, please 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 five.

5) Preparing the Reagent

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



Warning:

- | |
|--|
| <ul style="list-style-type: none">• Exercise caution to prevent puncture wound by the probe tip. |
|--|



BOHAZARD:

- | |
|--|
| <ul style="list-style-type: none">• Wearing gloves and a lab coat are required to avoid risk of infection and if necessary eye protection. |
|--|

4.2.2 Start Testing

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 the calibration procedure.

Reagents volume check dialog

R1 Position R2 Position

No.	Items	Position	Volume	main reagent volu	remain test Numbe	Test number	Prompt
1	Diluent	1	16.5				
2	ALB	17	300	2.5	8	2	
3	ALP	4	270	4.7	23	1	



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

Please select the Test name in the item list, and then input QC lot No., expiry date etc. Click [ADD] and [SAVE].

Test name	Unit	Decimal	QC target value	SD Value	1SD	2SD	3SD
DBIL	umol/l	1					
TP	g/l	1					
ALP	U/L	0					
UA2		2					
CHOL1	mmol/l	2					
TG1	mmol/l	2					
TBIL	umol/l	1					
GLU	mmol/L	2	56.00	2.00	54.00-58.00	52.00-60.00	50.00-62.00
Cr	umol/l	0					
UREA1	mmol/l	2					
ALB	g/l	1	23.0	1.00	22.0-24.0	21.0-25.0	20.0-26.0
Mg	mmol/l	2					
P	mmol/l	2					
ALT2	U/L	0					
GGT2	U/L	0					
AST	U/L	0					
LDH	U/L	0					

SCHEDULE →QC

Lab ID	Check date	Patient ID	Sample ID	Cup	Style	Sample Type	Cuvette	LIS
QC	2016/ 5/12		1	1	Cup	Serum	4	LIS

- 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.

3) Sample Testing

SCHEDULE → Sample

Setup the sample parameter. Load the sample into the corresponding position on the sample disk.

Click ADD, then please check Test → Work List, now you can click [Reagent Check] and then [Start] to start sample test.

Lab ID	Check date	Patient ID	Sample ID	Cup	Style	Sample Type	Cuvette	LIS
1	2016/ 5/12		1	1	Cup	Serum	4	

Sample	Work list	Calibration	QC	
ALB 17	ALP 4[5]	ALT2 21[22]	AST 20	CHOL1 8
Cr 14[15]	DBIL 2[10]	GGT2 23[24]	GLU 13	LDH 10[11]
Mg 10	P 19	TBIL 12[32]	TG1 9	TP 3
UA2 6[7]	UREA1 16			

TEST

VERSION HOSPITAL Administrator Operator:Operator 2016/05/12 AM 06:22:31



Note:

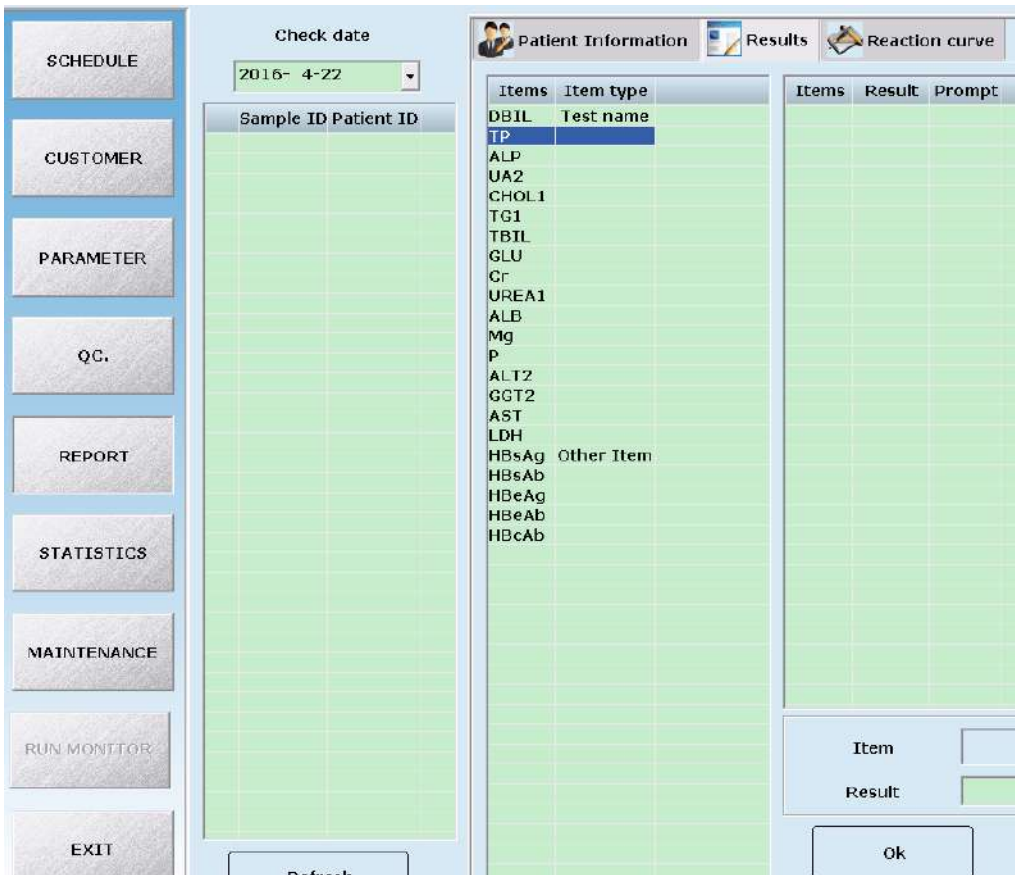
- The requesting of emergency testing is similar with the requesting of common samples; the only difference is to click "emergency testing" at requesting time in necessary.
- Ensure the samples are placed in the correct positions, otherwise it may cause unreliable testing results.

4.2.3 Result Follow-up

1) Editing the Sample Testing Results

Report → Results

Select the desired 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 authorised senior personnel.

2) Printing the Testing Results

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 regularly back up the data.
-

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 the “EXIT” button to exit the operation software.

2) Shut Down the Analyser

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

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

3) Checking after Powering Off



BIOHAZARD:

- | |
|---|
| <ul style="list-style-type: none"> ● Wear gloves and lab coat to avoid risk of infection and if necessary, protective eyewear. |
|---|



Note:

- | |
|---|
| <ul style="list-style-type: none"> ● If the MAIN POWER of the analyser is powered 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 analyser, if there are any stains, wipe them off with clean soft cloth.

Chapter Five Advanced Operation

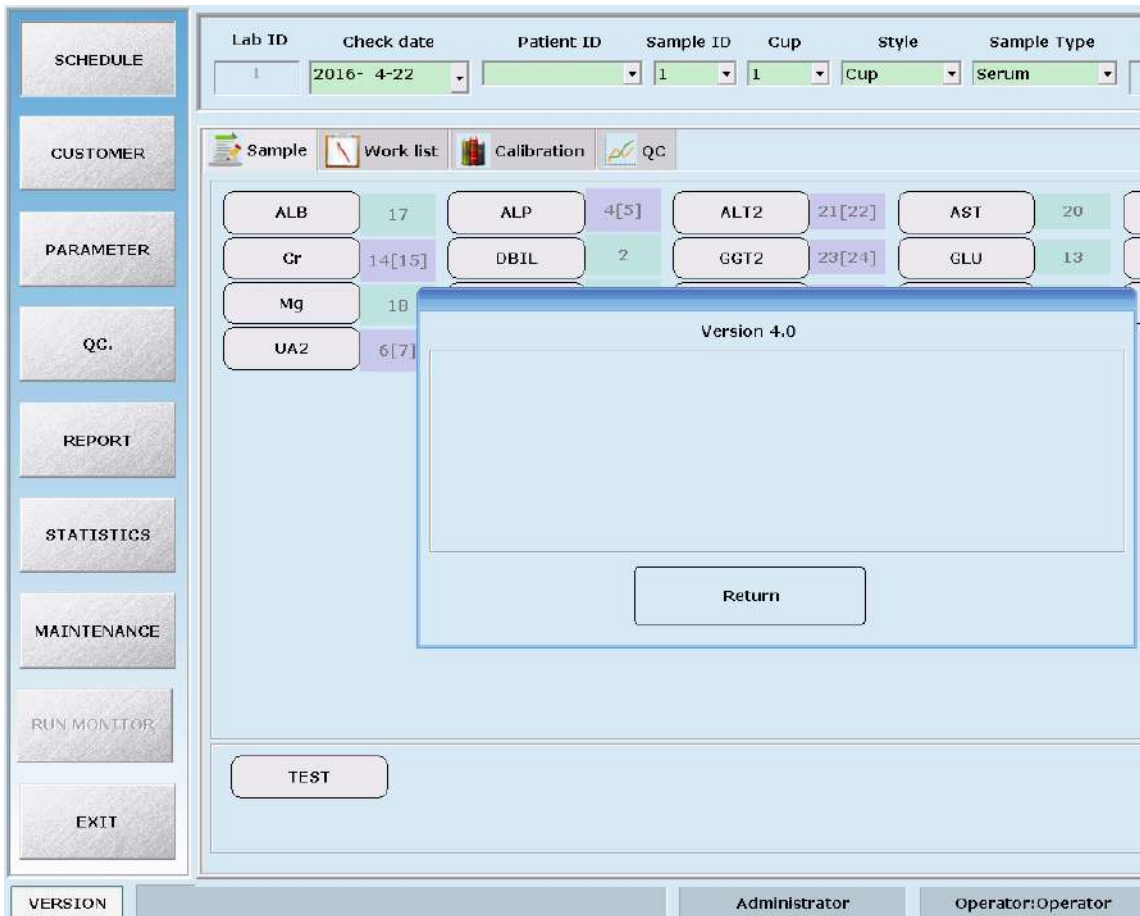
This chapter will explain each shortcut and button as per the software interface.

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 analyser 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
	QC. data display		Display QC data
	QC. chart analysis		Display QC chart
	QC value print		To take a printout from the desired date
4.Report	Patient information		To enter 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	Initialisation		To initialise 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 performed 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 performed in a desired sample
	Calibration		Used for the calibration of Particular parameter
	QC.		Used for the Quality check
9.Test Screen	Sample info.		To monitor running sample
	Reagent info.		To monitor running reagents
	Cuvettes info.		To monitor running Cuvette
	Check info.		Display analyser information
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

5.2.1 Customer data

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

The screenshot shows a software interface for 'Customer details entry'. On the left is a vertical menu with buttons for SCHEDULE, CUSTOMER, PARAMETER, QC, REPORT, STATISTICS, MAINTENANCE, RUN MONITOR, and EXIT. The main window has three tabs: 'Customer details entry' (active), 'Operator setup', and 'Data dictionary setup'. The 'Customer details entry' section is divided into two parts. The top part, 'Hospital information s', contains three text input fields for 'Name', 'Address', and 'Tel No'. The bottom part, 'Department and Doctor details entry', contains three text input fields for 'Department', 'Doctor', and 'Remark'. To the right of these fields is a table with two columns: 'No.' and 'Departme'. At the bottom of the main area are two buttons: 'Save' and 'Delete'.

To explain each tab.

1) Customer Unit Setting

The interface is shown 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 parameters, and the general user cannot.

No.	operator code	per
1	1	0
2	1	0

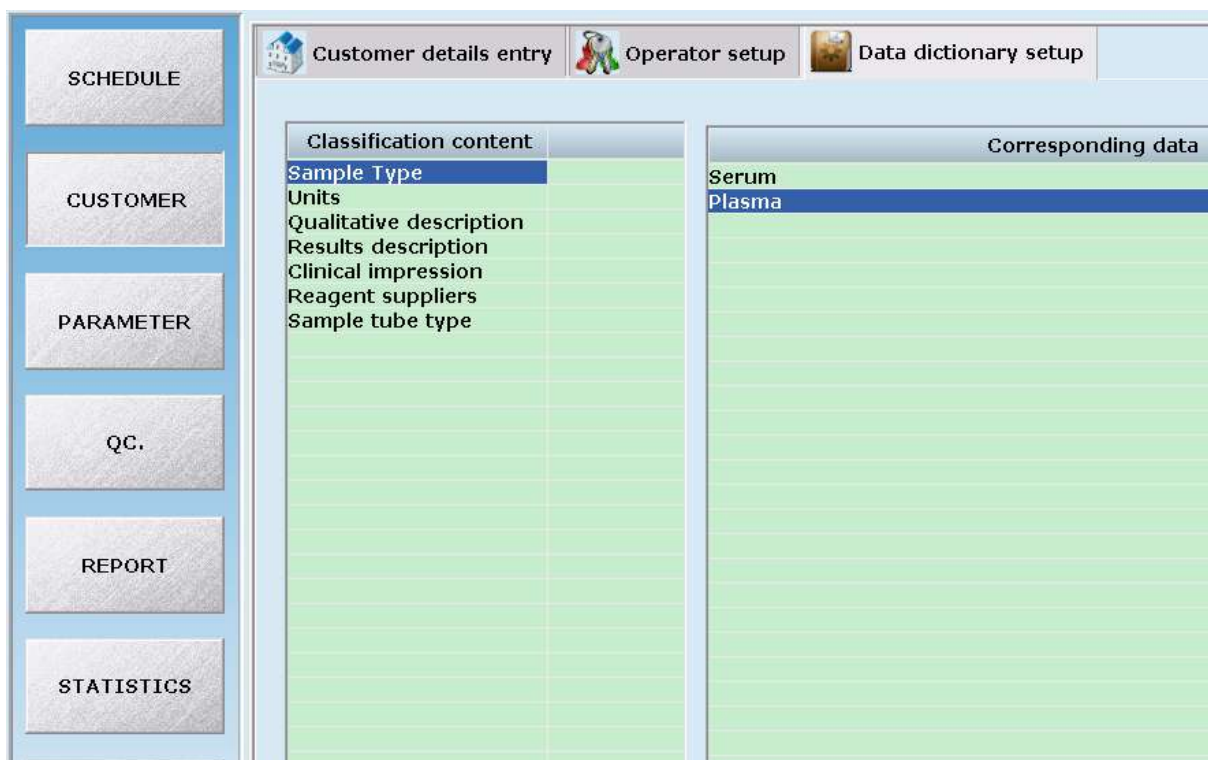
Parameter	Meaning
Login ID	Set operator’s code to instead of name.
Operator name	Set up operator name
Permission	Allowance
Old password	The old password set up by operator
New password	The new password to replace old one.
Confirm password	To confirm the new password again.

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、 plasma、 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: haemolysis, lipaemia, icterus etc
Reagent suppliers	Company name of the reagent
Sample tube type	Cup; Tube

Button:

Button	Function
Save	Save the changes

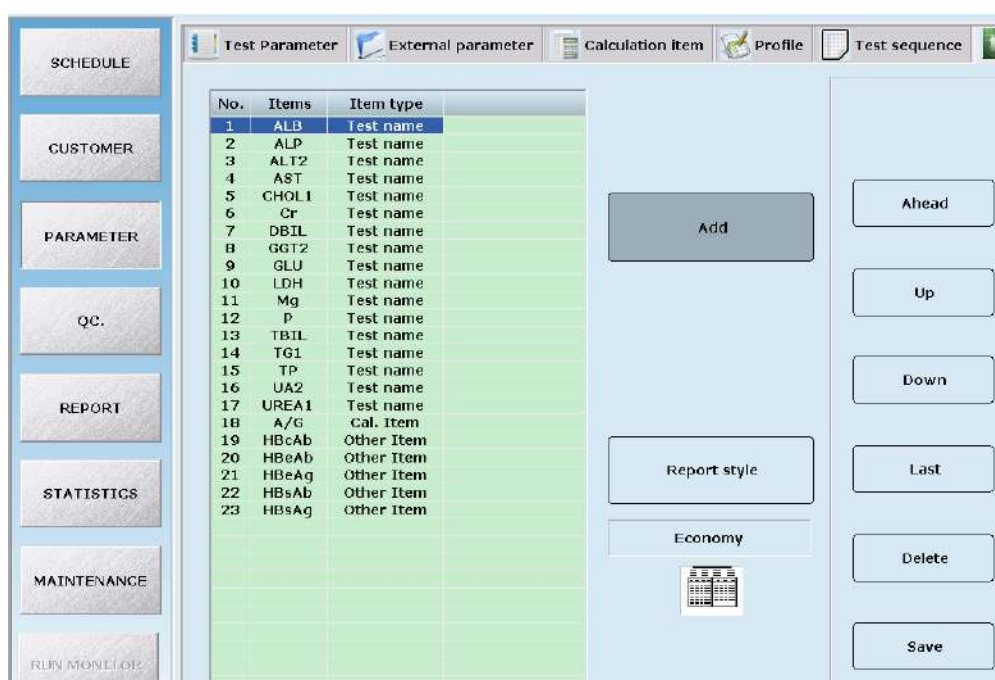
Button	Function
Delete	Delete selected content

5.2.2 Parameter

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 the instrument provides accurate results.

As there are many items, while editing parameter; please proceed in accordance with the chemistry reagent instructions.

Each tab is explained here:



Attention:

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

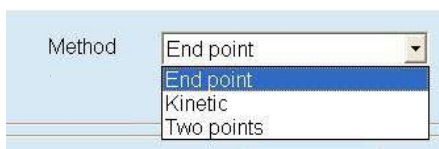
1) Test parameter

Displayed as the upper graphic, it is for setting up the chemistry item’s basic parameter, reference range and calibration.

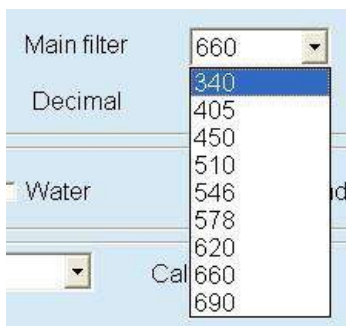
1.1) Basic parameter

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

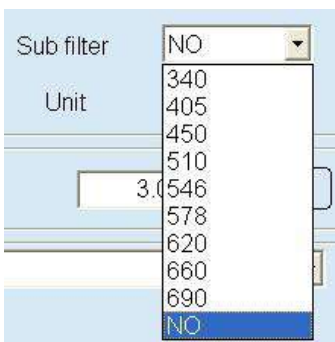
Select the correct method according to the instructions.



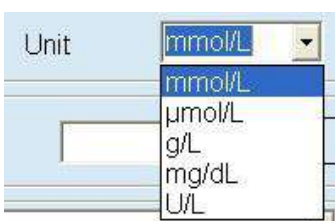
Click the combo box and select the correct method.



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 value. It will dilute and re-test while the result exceeds the range.
Distilled water / Reagent	For distilled water blank, it will not record reagent absorbance, while reagent

Parameter	Meaning
	blank will record that.
Reagent blank	When select reagent blank, the programme will record reagent absorbance during the test and record it 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 during auto test. It will calculate automatically by software.
Dilit water	To display the distilled water volume. It will calculate automatically by software.

Button,

Button	Function
Add	Add a new item to setting parameter.
Delete	Delete current item.
Save	Save the changes.

1.2) Reagent and sample volume

Here you can set up R1 and R2’s volume and position, its incubation time and check points.

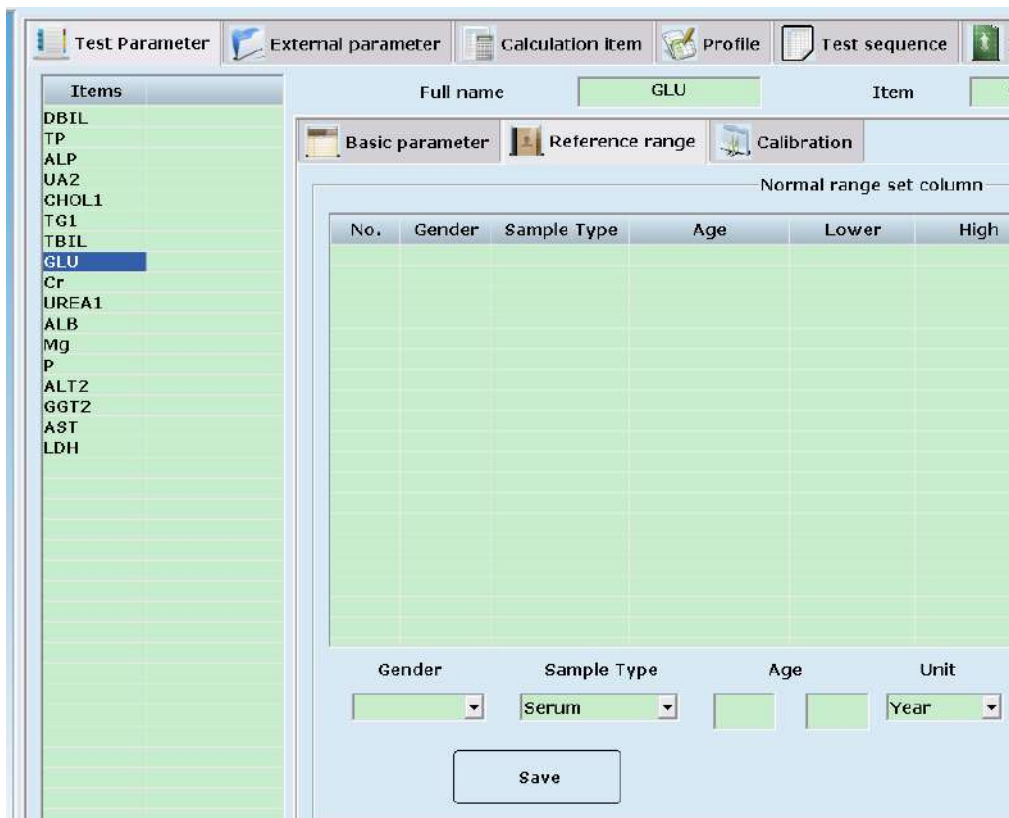
Parameters:

Parameter	Meaning
Setting of R1 and incubation time	
R1 Volume	It refers to volume for R1. The range is from 10 to 450, increase by 0.5 progressively. The unit is μl .
R1 position	Position for R1.
Incubation time	The total time for R1 and sample incubation time.
Setting of R2 and incubation time	
R2 Volume	It refers to volume for R2. The range is from 10 to 450, increase by 0.5 progressively. The unit is μl . Input “0” if no need R2.
R2 position	Position for R2.

Parameter	Meaning
Incubation time	The incubation time after adding R2
Sample volume and check point setting	
Sample volume	It refers to volume for sample. The range is from 1 to 50, increase by 0.1 progressively. The unit is μl .
Check time	Time for testing after incubation time

1.3) Reference range

Select a certain item, and click “Reference range” tab, then edit as below.



Parameter:

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

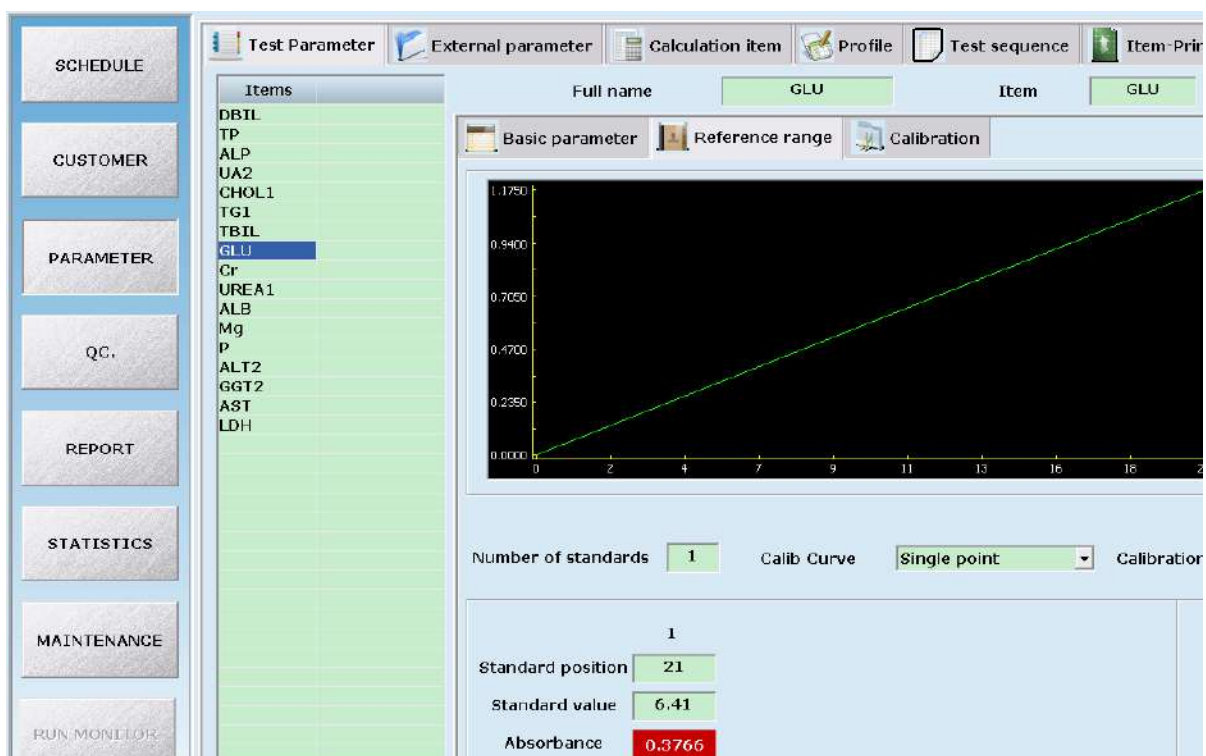
Parameter	Meaning
High limit	The upper limit of normal value.

Button:

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

1.4) Calibration

1.4.1) If you set up calibrator it will display the calibration result curve as below:



Parameter:

Parameter	Meaning
Number of standards	When choose calibrate method, it will show the 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:

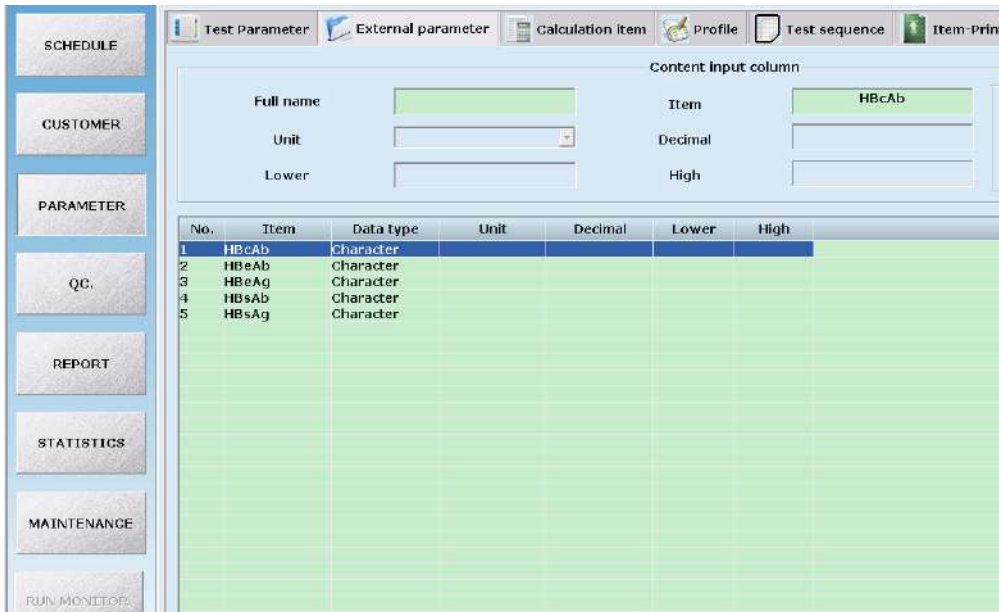
Button	Function
Save	Save the setting
Add	Add the patient's parameter
Delete	Delete the setting

Calibrate method:

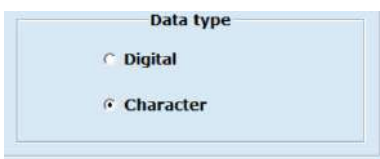
No.		Calibration type	Number	Calibration parameters
Linear	1	Single point	1	K
	2	Two point	2	a、 b
	3	Multiple point	3~6	a、 b
Non-linear	1	Logistic-Log 4P	4	K、 R ₀ 、 a、 b
	2	Logistic-Log 5P	5	K、 R ₀ 、 a、 b、 c
	3	Polynomial	5	a、 b、 c、 d
	4	Parabola	3	a、 b、 c
	6	Spline	4	R ₀ 、 a、 b、 c

2) External parameter

Click “External parameter” then edit item as below:



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



It can select digital or character for displaying the result.

3) Calculation item

Some items results can be calculated by other results, so there is no need to test separately. For

example: Globulin=TP-Albumin

Parameter:

Parameter	Meaning
Full name	Code name of calculating item
Item	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

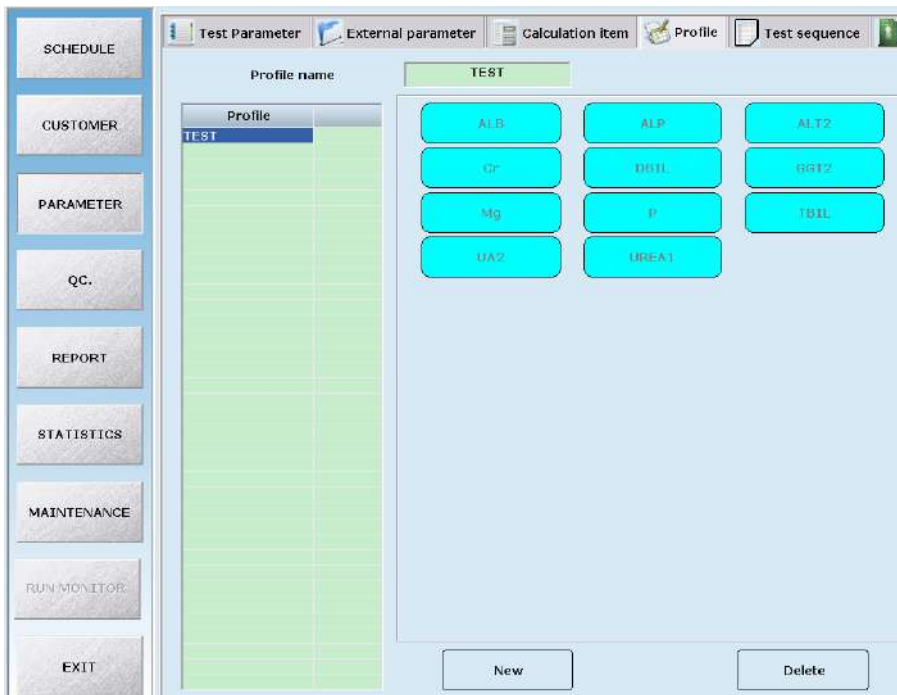
4) Profile setting:

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 simple to operate the combo item test, by click group name, you can test the required items.

See details on “Test Parameter

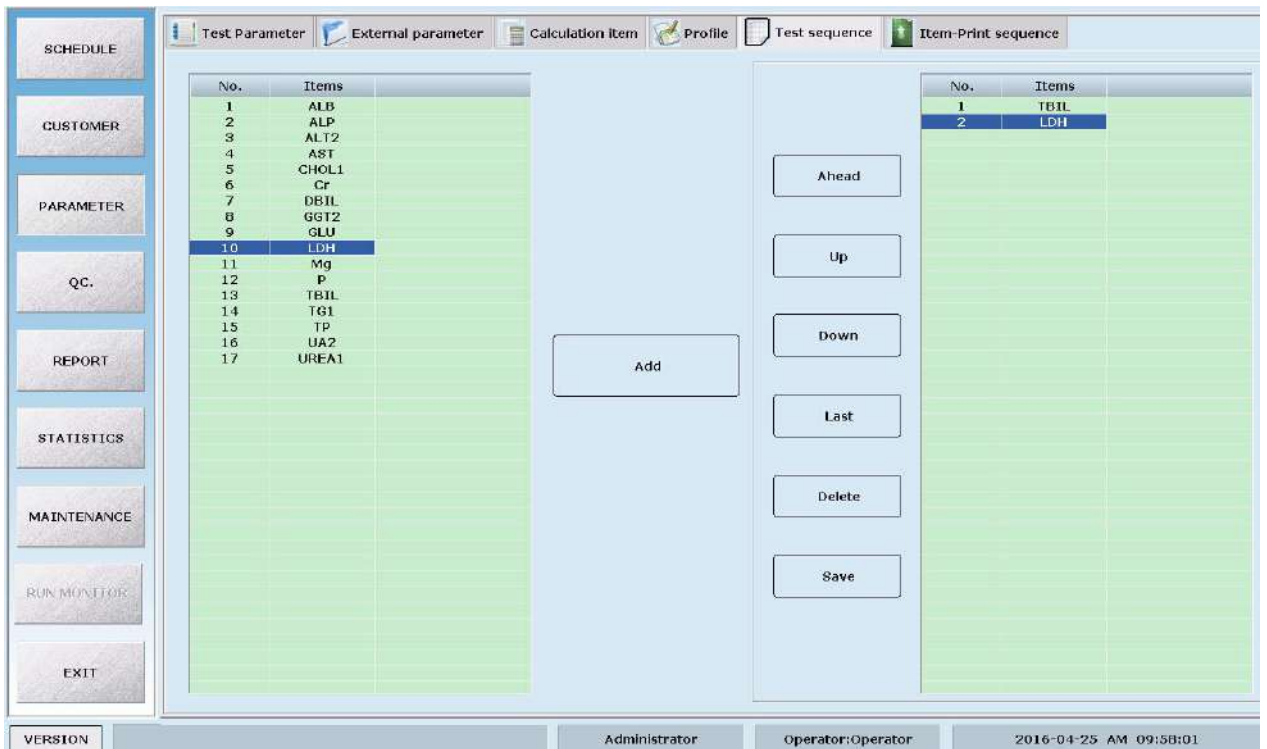


5) Test sequence setting:

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

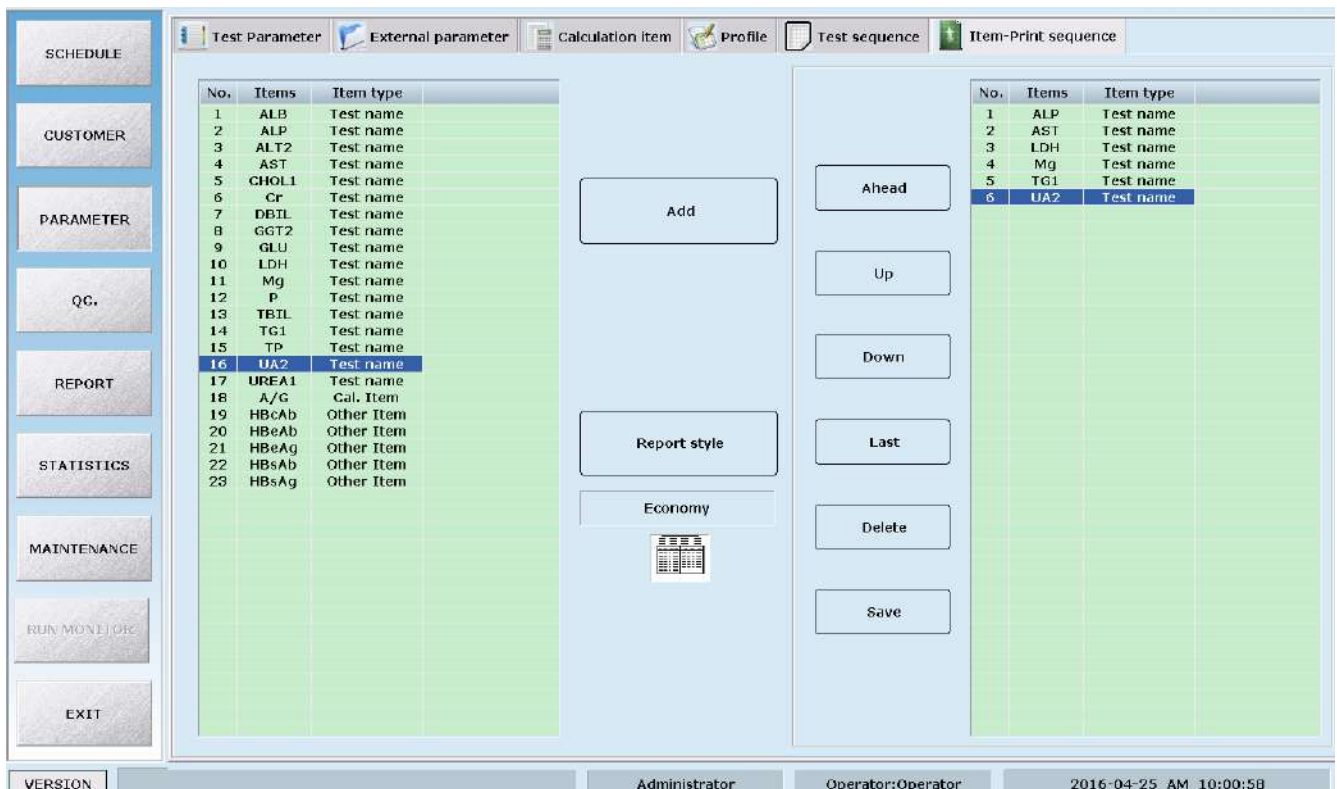
5.2) Select item on the left list and click “Add”, this item will add on the bottom of right list; by setting the order of right item, select certain item, then click buttons including: “Up”, “Down”, “Ahead” and “Last”

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



6) Item-Print sequence setting

This setting is the same as testing sequence. The left list is for all items, and the right list is for items to be printed. Select item on the left list and click “Add”, this item will add on the bottom of right list; by setting the order of the right item, select certain item, then click buttons such as : “Up”, “Down”, “Ahead” and “Last”



Button:

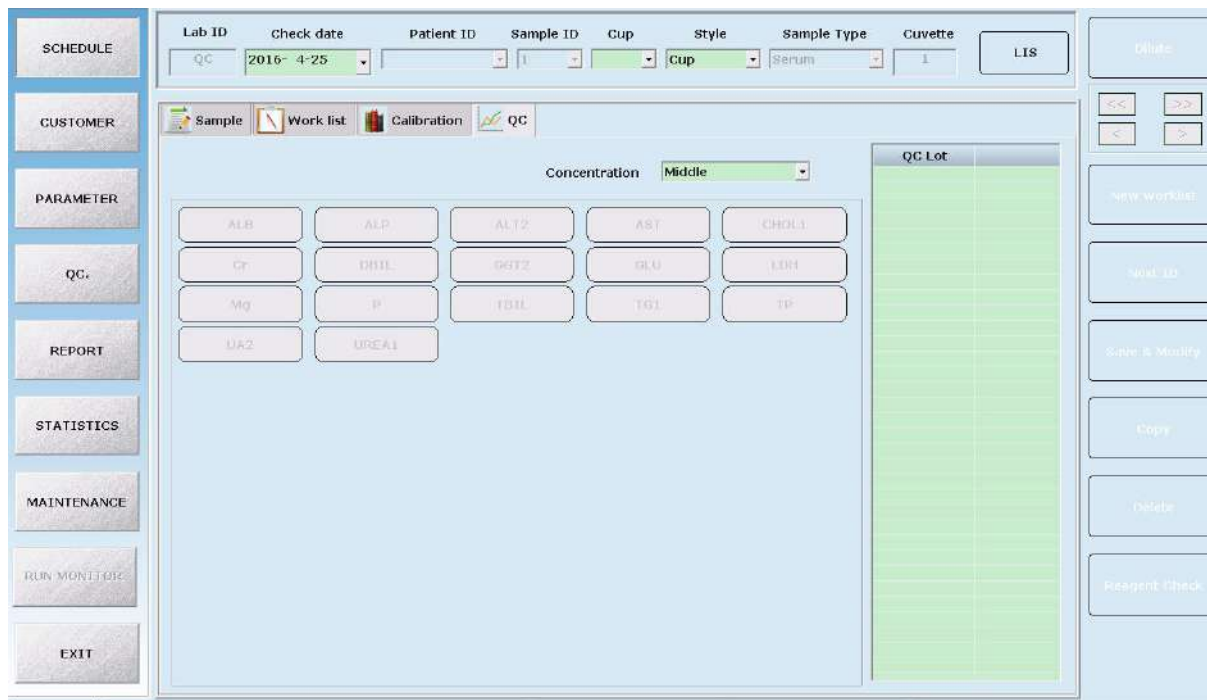
Button	Function
Add	Add new item
Delete	Delete selected item.
Save	Save setting after editing parameter.
Ahead	Move the selected item to top.
Up	Move up selected item.
Down	Move down selected item.
Last	Move the selected item to bottom.

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, choose testing Lot No., then select test-item on the left column. The background will turn into yellow after selecting. After set-up information like sample position, cuvettes position, click “add”, then undergoing control test.



Attention:

- The background colour of item indicates the current condition.
- Yellow 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’s target value and SD, then click “Add” and “Save”.

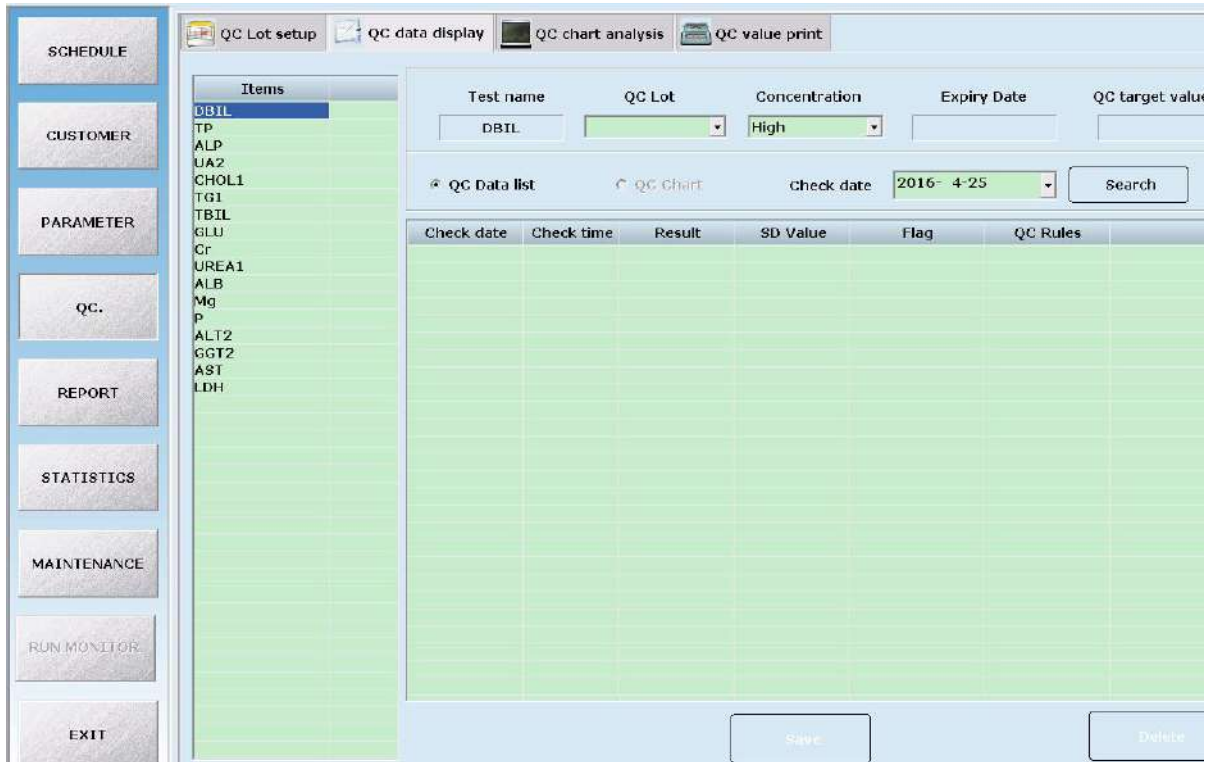
See chart below:

Test name	Unit	Decimal	QC target value	SD Value	1SD	2SD	3SD
DBTL	umol/l	1					
TP	g/l	1					
ALP	U/L	0					
UA2		2					
CHOL1	mmol/l	2					
TG1	mmol/l	2					
TBIL	umol/l	1					
GLU	mmol/L	2					
Cr	umol/l	0					
UREA1	mmol/l	2					
ALB	g/l	1					
Mg	mmol/l	2					
P	mmol/l	2					
ALT2	U/L	0					
GGT2	U/L	0					
AST	U/L	0					
LDH	U/L	0					

2.2) QC. data display

Review control value by clicking “QC data display” tab.

Select “QC Data list”



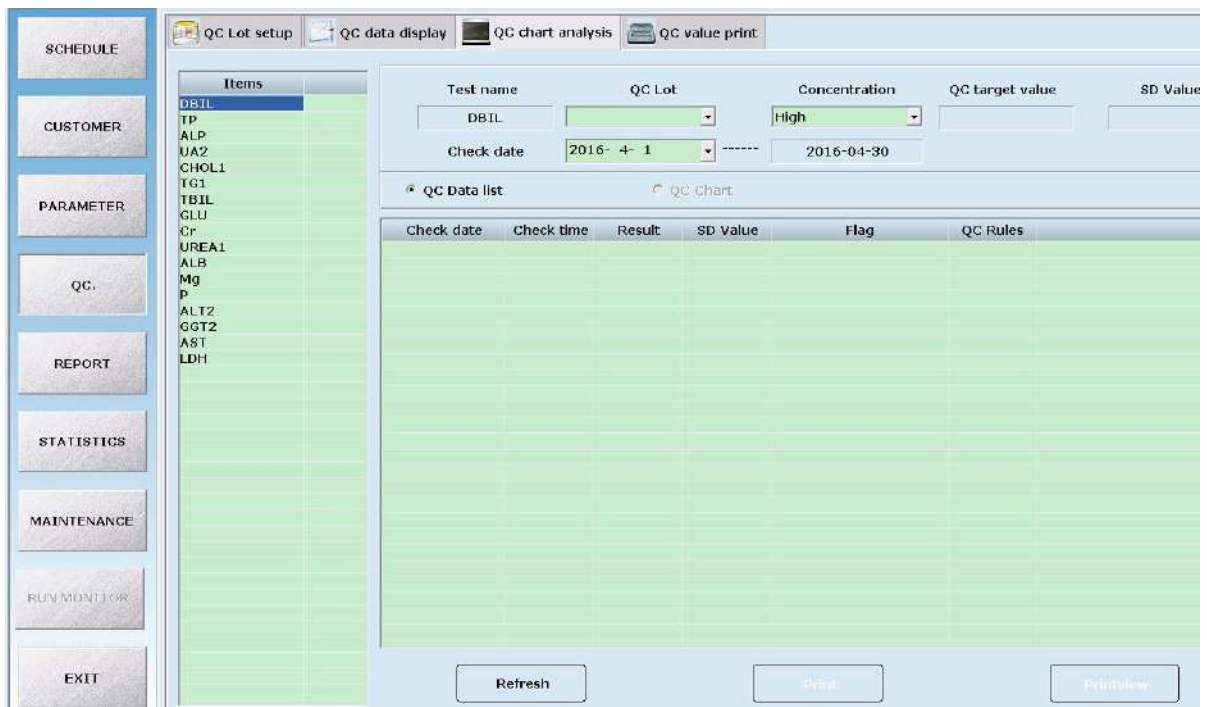
Click “QC chart” to see Control curve.

Button:

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

2.3) QC. chart analysis:

First, select QC., Lot No. and Concentration Type under “QC Chart analysis” list, then choose the date which need analysis 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	Print view the control chart



Attention:

- Please ensure you set up control's validity correctly, to enable the software to judge whether it is within validity.

5.2.4 Report

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

1) Patient information register

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

In this interface you can also check patient test results, and display real test graphs.

2) Print format setting

2.1) Print, Printview: select print format, click will display select format setting.

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

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

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	Species sex
Age	Species 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.

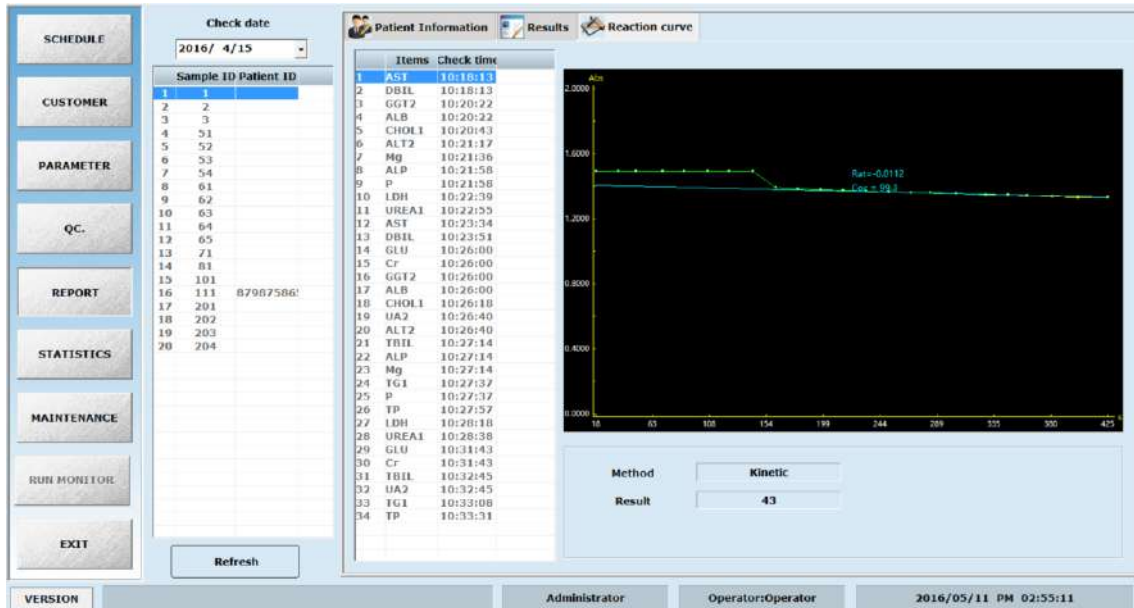
3) Test results display

Here can check patient test results and revise.

The screenshot displays a software interface for managing patient test results. On the left is a vertical sidebar with buttons for SCHEDULE, CUSTOMER, PARAMETER, QC, REPORT, STATISTICS, MAINTENANCE, RUN MONITOR, and EXIT. The main window has a 'Check date' dropdown set to 2016-4-25. Below this is a table with columns 'Sample ID' and 'Patient ID'. To the right, there are three tabs: 'Patient Information', 'Results', and 'Reaction curve'. The 'Results' tab is active, showing a list of test items and their types. The items listed are: TP, ALP, UA2, CHOL1, TG1, TBIL, GLU, Cr, UREA1, ALB, Mg, P, ALT2, GGT2, AST, LDH, HBSAg (Other Item), HBSAb, HBeAg, HBeAb, and HBcAb. To the right of this list is a large table with columns: Items, Result, Prompt, Unit, Lower, High, and Remark. At the bottom of the interface, there are input fields for 'Item' and 'Result', and three buttons: 'Ok', 'Delete', and 'Save'.

4) Reaction curve

4.1) The inspector can check the reaction curve here, to confirm whether instruments or reagents have problem or not, and whether patients test results can be trusted.

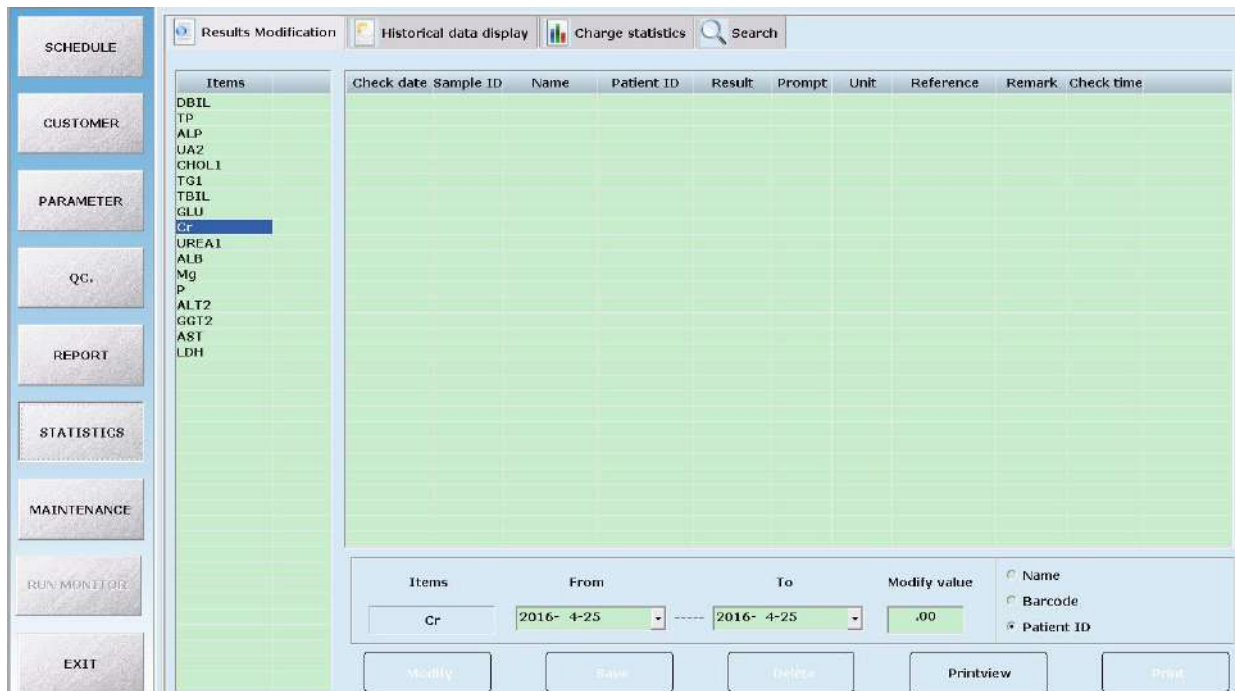


4.2) The inspector can use the real-time chart to check whether reagent parameter settings are correct or not, and if not correct, change test points and resetting.

5.2.5 Statistics

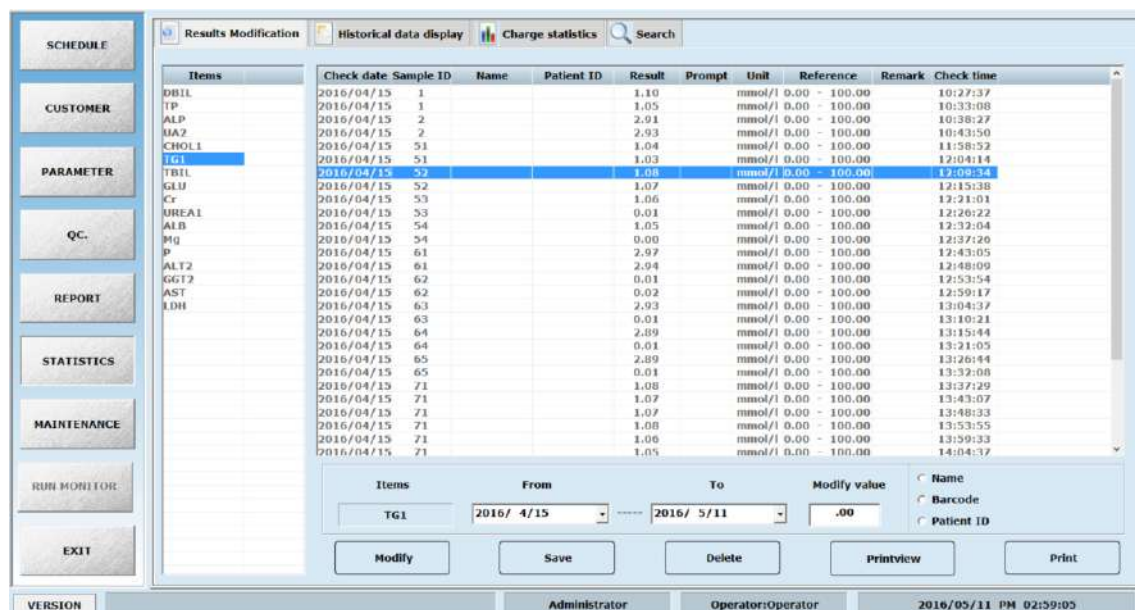
Click “Statistics” button to enter main interface. See below picture.

- In menu the user can check historical data.
- In menu the user can edit historical data.
- In menu the user can make charge statistics for test items.
- Have different kinds of query mode.
- Query and edit results the user can print.

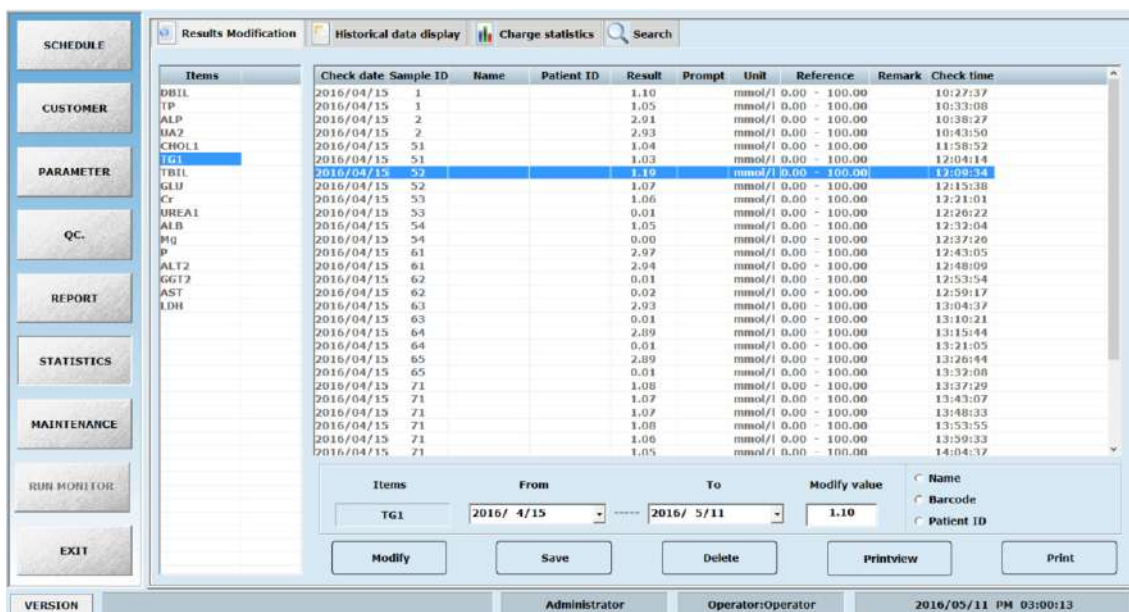


1) Results modification

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 will multiply revised factor for all results. See below picture.

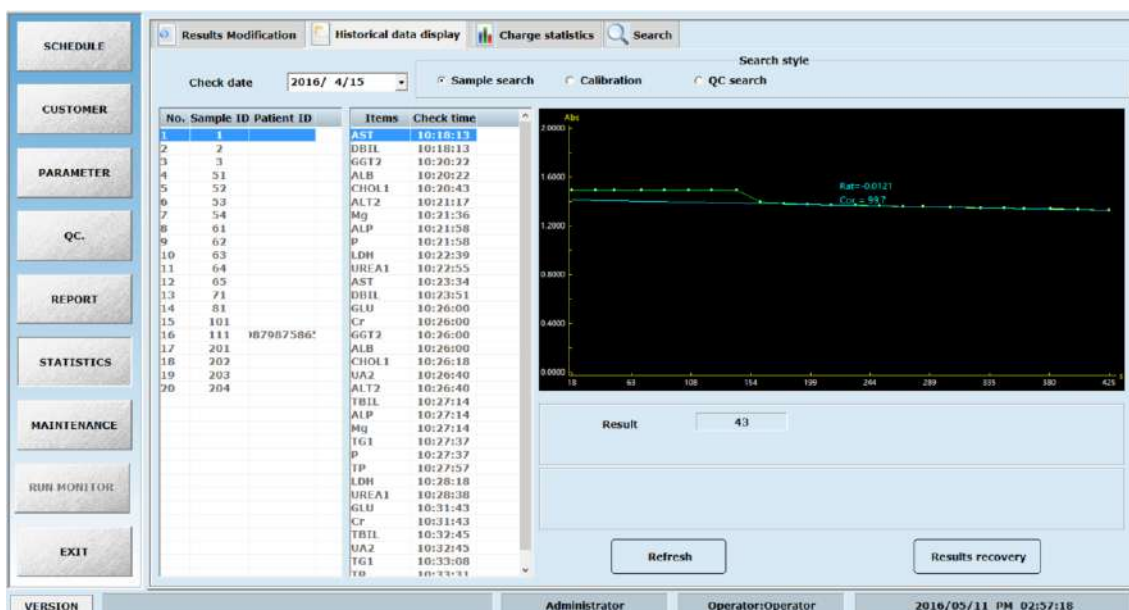


Parameters in this interface:

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 the testing date is set, can you 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 the analyser
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

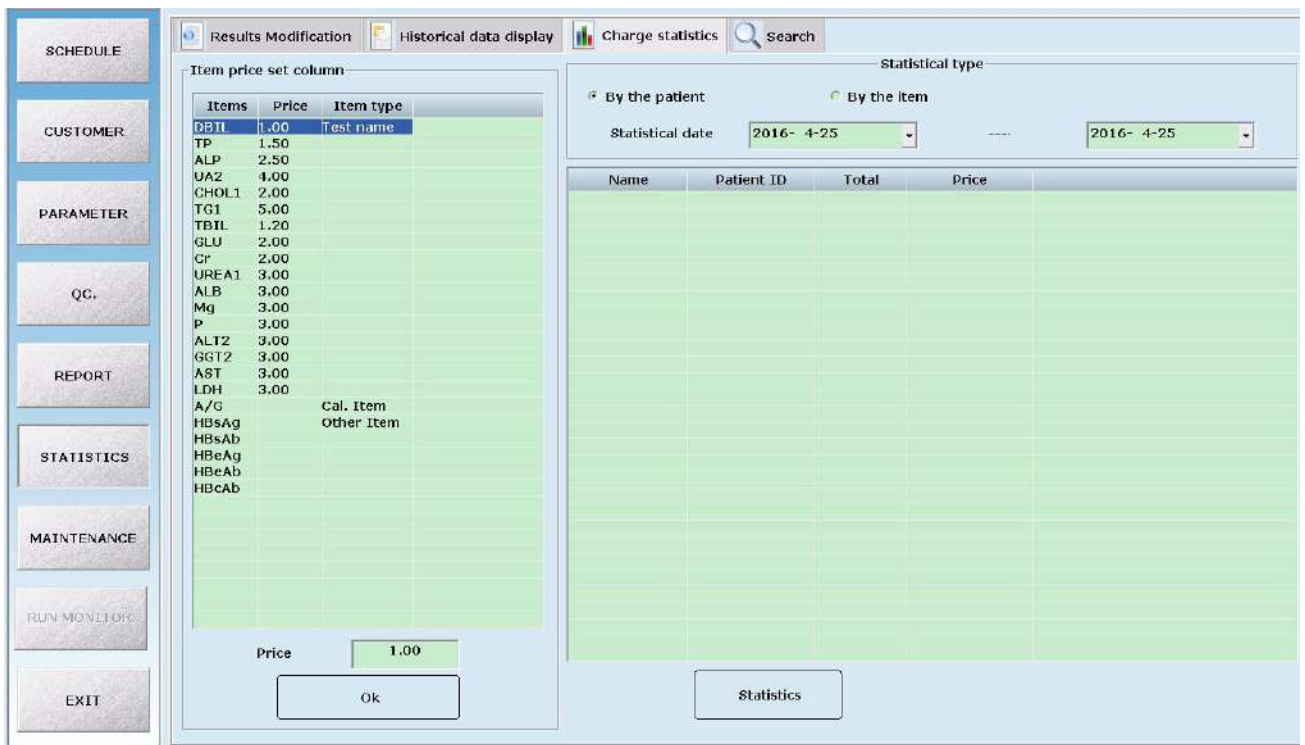
Buttons in this interface:

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

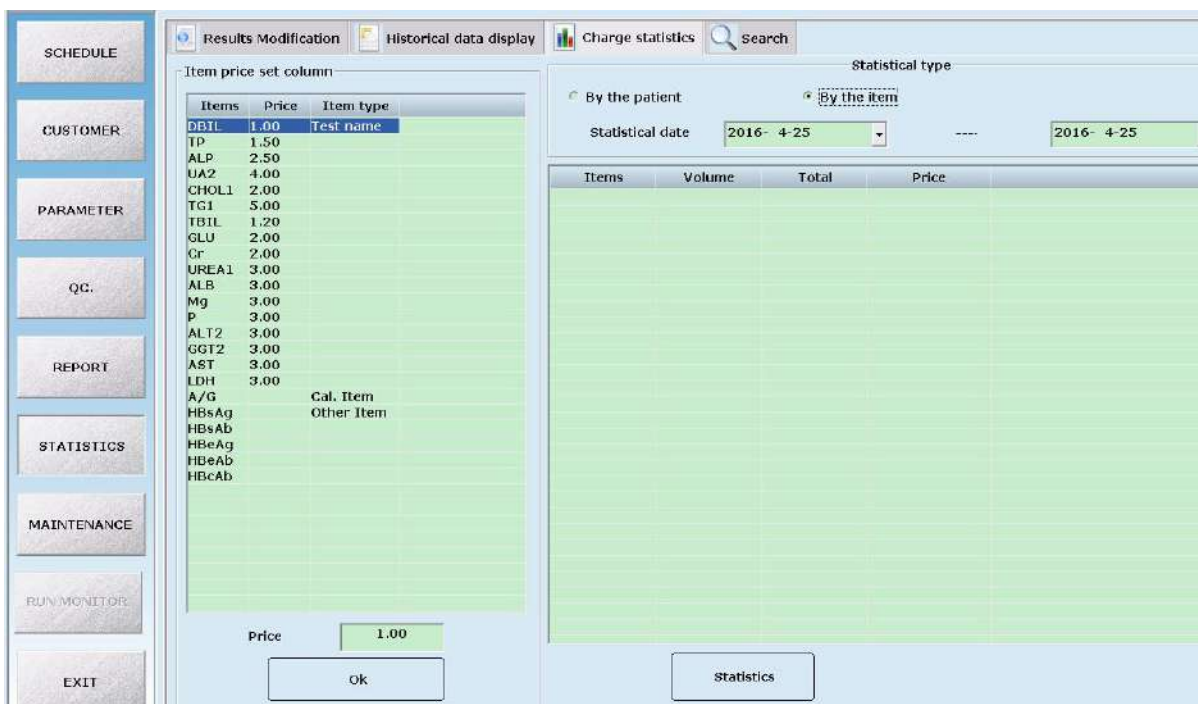
3) Charges Statistics

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 to pay
By the item	The charge of certain items in the statistics date
Statistics date	Query charge statistics according to statistics date

Parameter	Meaning
Price	Input the price of selected item into the price box

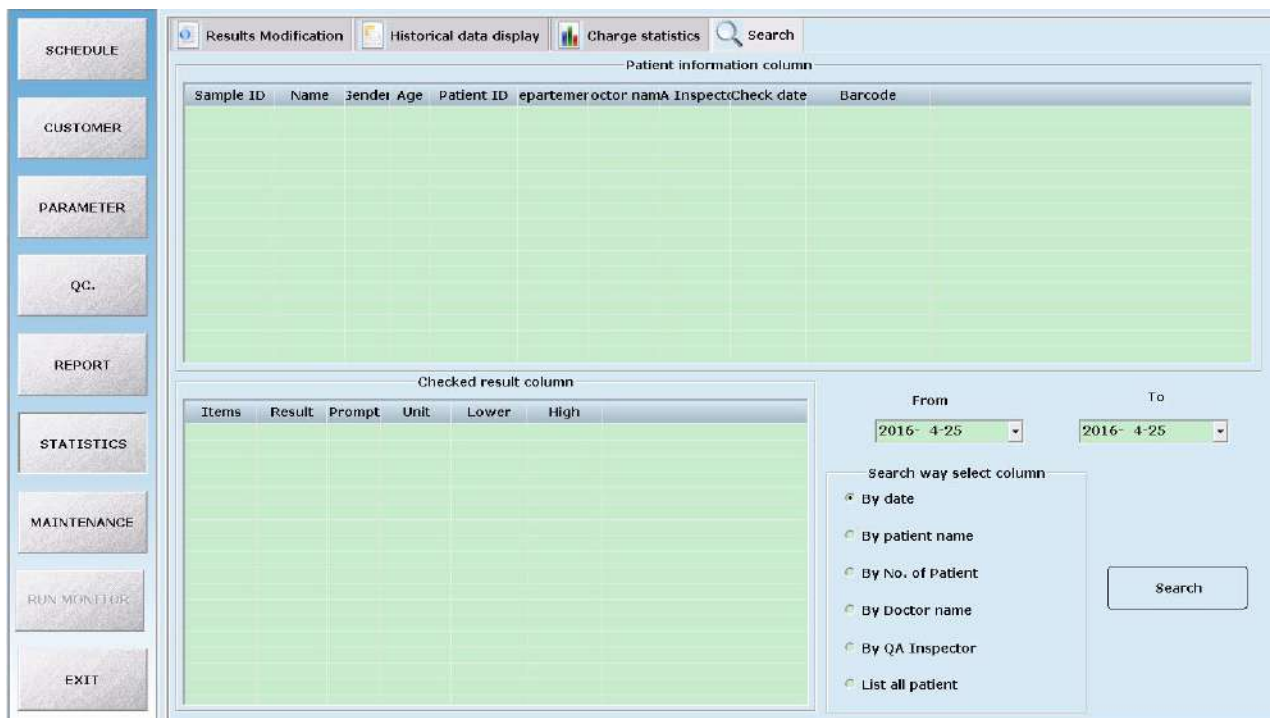
Buttons in this interface:

Button	Function
OK	Confirm the inputted price
Statistics	Statistics the prices

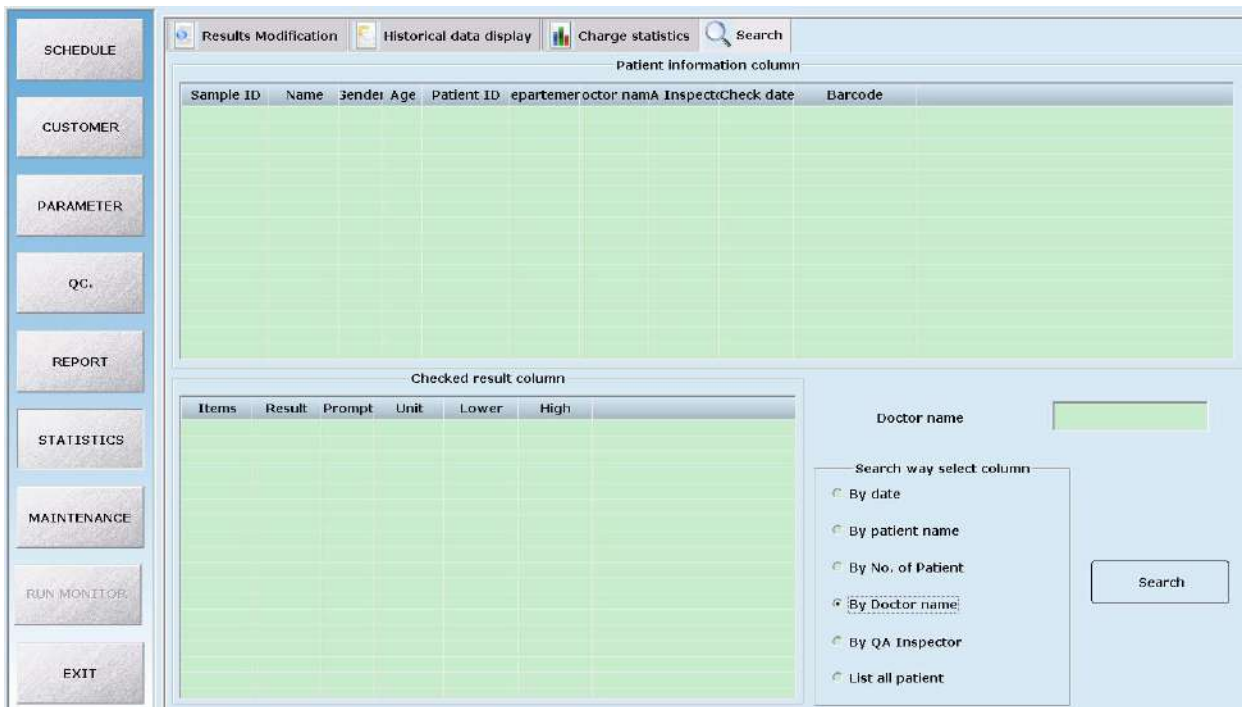
4) Search

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— Doctor name:



Parameters in this interface:

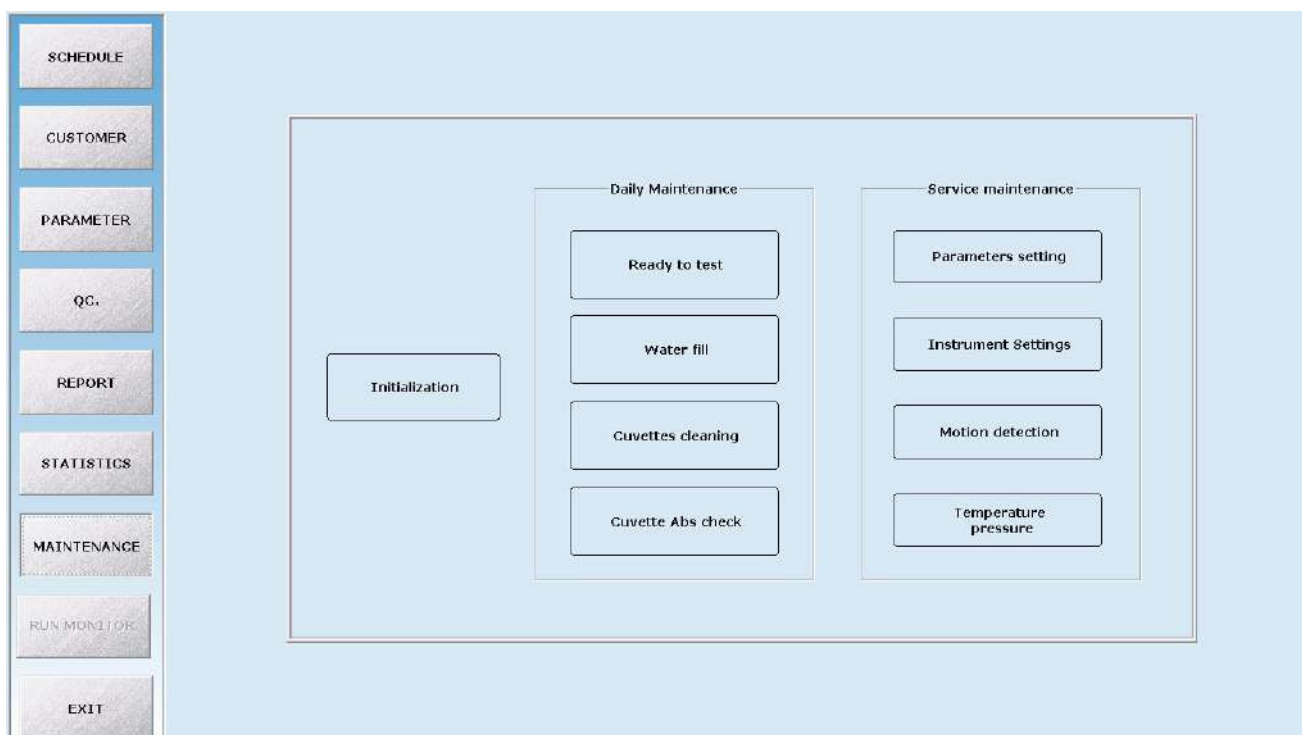
Parameter	Meaning
Patient information column	Click the items in “Patient information column” to show in the “Checked result” column
Checked result column	Display the results from the “Patient information column”
Search way select column	Six methods: date、 patient name、 No. of patient、 doctor name、 QA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

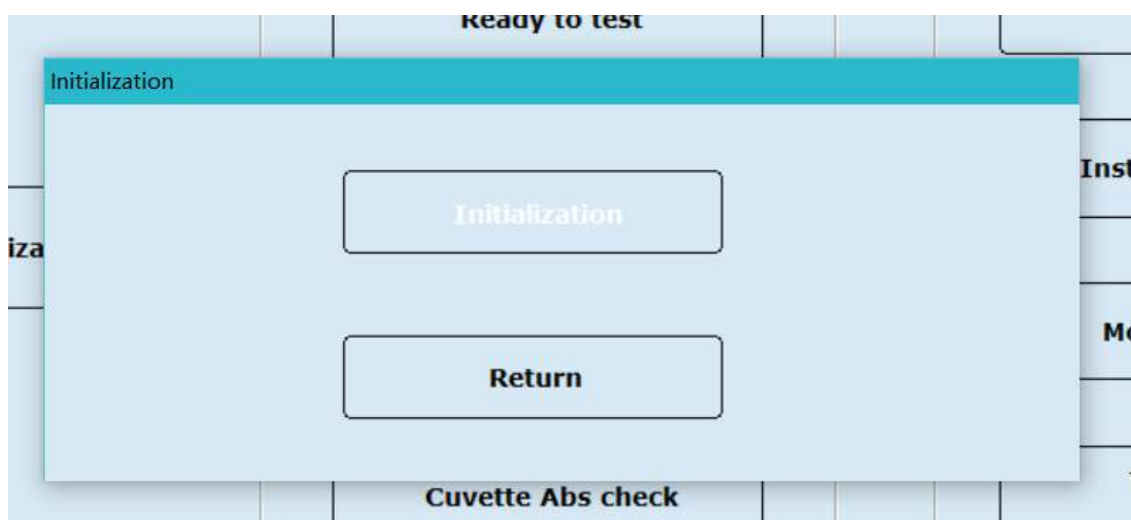
5.2.6 Maintenance

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



1) Initialisation

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

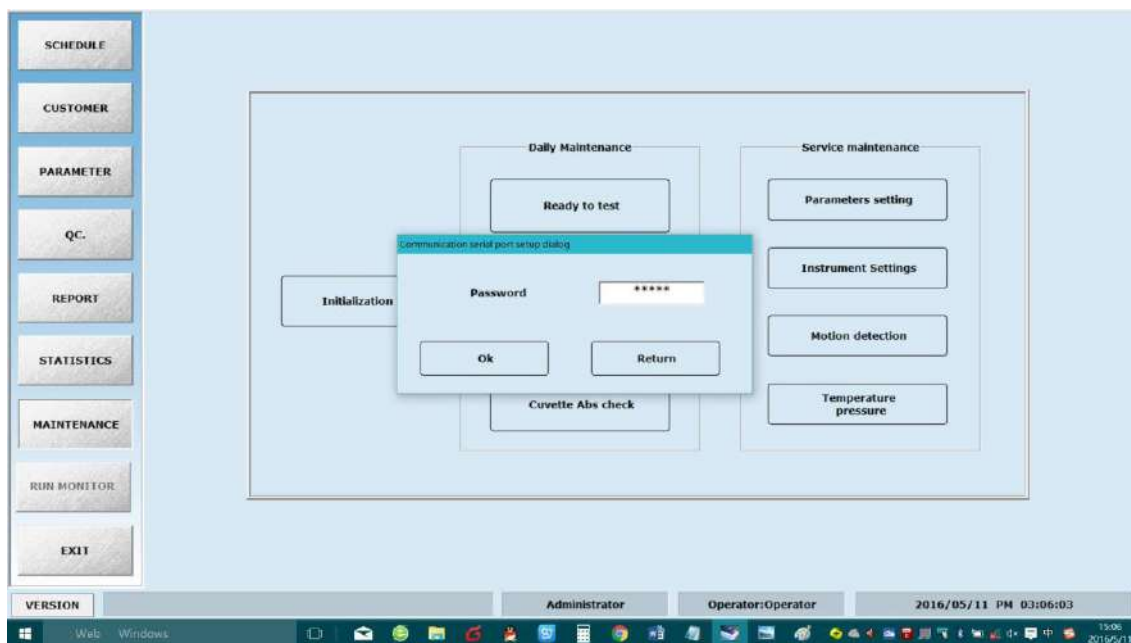


Buttons in this interface:

Button	Function
Initialisation	To initialise 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.

System parameters set dialog

Com serial port select

COM1 COM2 COM3 COM4 COM5

Barcode length: Language:

Separate mixing system: Yes

Test order: Sample wise Item wise

QC range: SD style Range style

Power on wash: Power on run Power on stop

Power off wash: Power off run Power off stop

Syring type: Keyto YKC

Barcode scan: No Yes

Screen color setup: Background set Color set

Identifying code:

Water blank OD: Water blank OD. Cuvettes check: No

Rgt. Sample alarm: Alarm DISKID:

Auto-check setup

Result is too low Beyond the set Linearity limit

Reagent blank is not stable Substrate depleted

LIS system setup

Server IP: Port:

COM1 COM2 COM3 COM4 COM5

Baud rate: Send online results

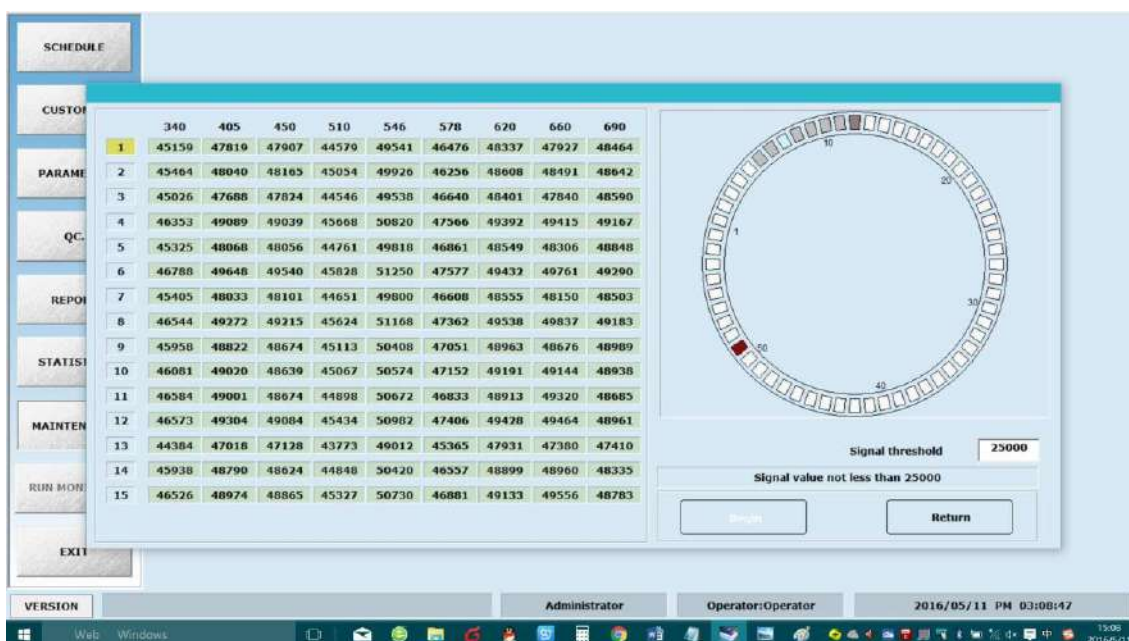
Select Return

Parameter	Meaning
Com serial port	The serial port between analyser and computer, which is usually set by engineer
Barcode length	Setting scan barcode length
Language	English available here, more languages are available by support of the language database.
Test order	When you select the option “sample first”, the analyser will carry out the test according to the sample sequences; When you select the option “item first”, the analyser 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 requirements.
Screen colour setup	User can choose software interface colour.
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.
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	Only valid for “End point method”: Choose means during reaction process can’t

Parameter	Meaning
points	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 a red colour, which means the cuvette may be dirty or damaged and you should replace the red one. By correct setting, if all the cuvette mark a red colour, you should check whether there is water in the 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 an

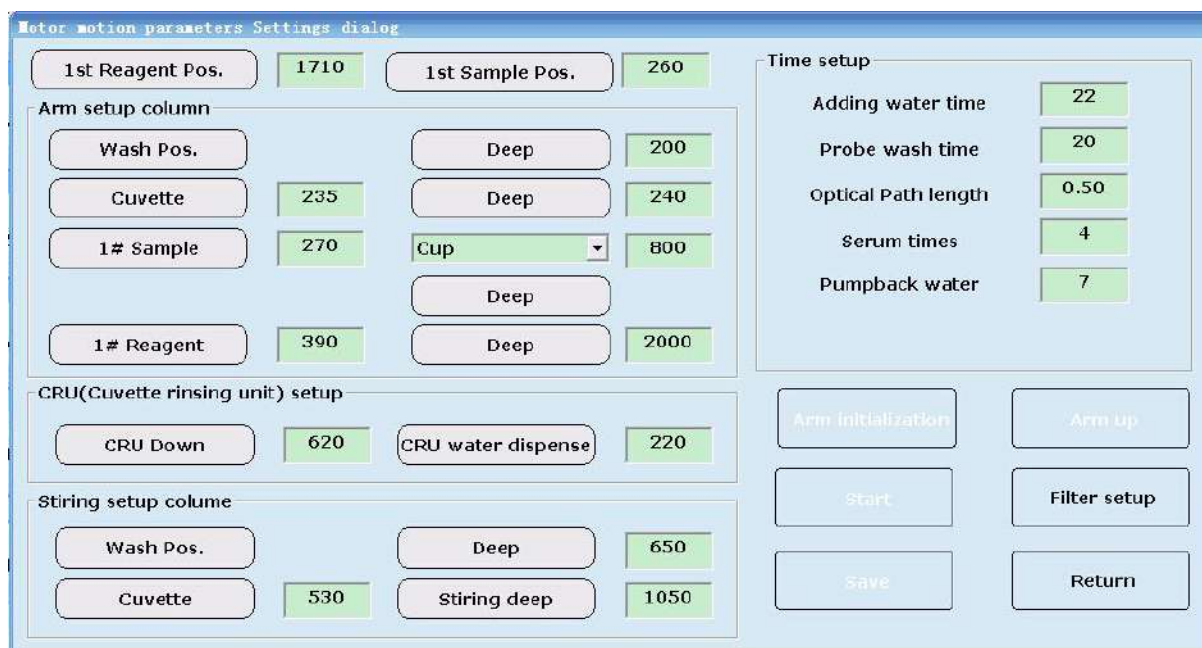
engineer authorised by our company



NOTE:

- The parameter setup must be done by engineer authorised 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.



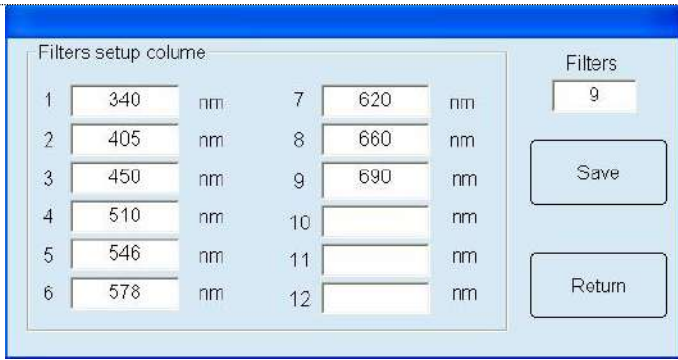
Parameters in this interface:

Parameter	Meaning
Arm setup	
Washing position	Use sample mechanical arm at the washing position as the starting point
Deep	Sample needle in washing pool 's wash depth

Parameter	Meaning
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
18# sample	The steps numbers of sample mechanical arm probe start from washing position to No.18 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
26 # reagent	The steps numbers of sample mechanical arm probe start from washing position to No.26 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
Stirring 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
Stirring 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	Input 0.62cm optical length according to the cuvette
Serum times	When sample cup alarm, no serum, at most add sample times

Buttons in this interface:

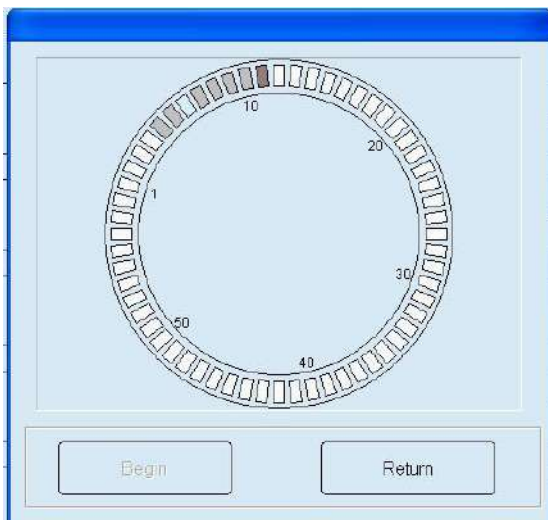
Button	Function
Save	To enter into the dialog box by clicking this button after input the password
Return	To return to the “maintenance” main interface by clicking this button
Filter setup	To get the below dialog box to setup the wavelength by clicking this button:

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) End to test

“End to test” interface see below picture, wash all cuvettes, add full distilled water.

Caution:
Analysis not in test condition, allow operation.

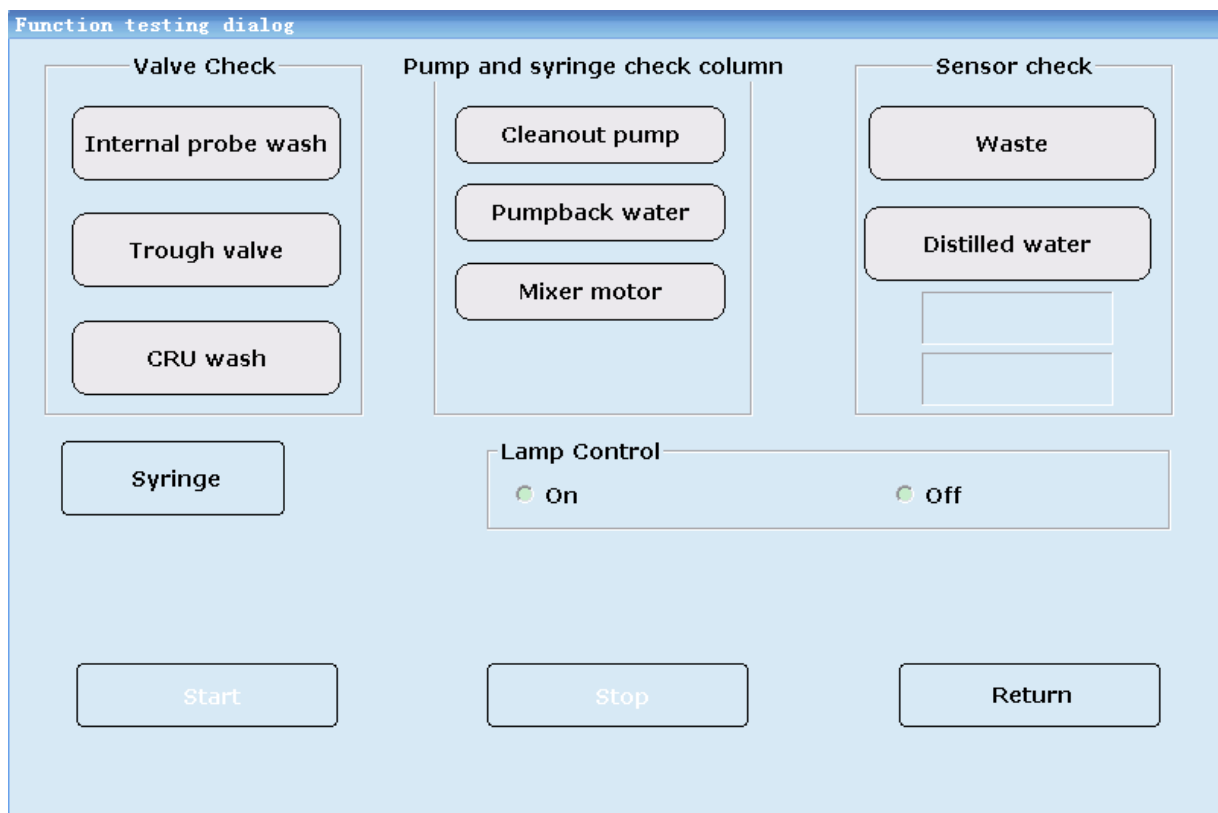


Buttons in this interface:

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 whether the reagent valve works or not.
Trough valve	Click “test” button, water gush from the middle of washing pool. If not, consider whether the washing needle valve works or not.
CRU wash	Click “test” button, water spray from wash needle. If not, consider whether the water valve works or not.
Pump and syringe check column	
Cleanout pump	Click “test” button, hear the voice of cleanout pump. If not, consider whether the cleanout pump works or not.

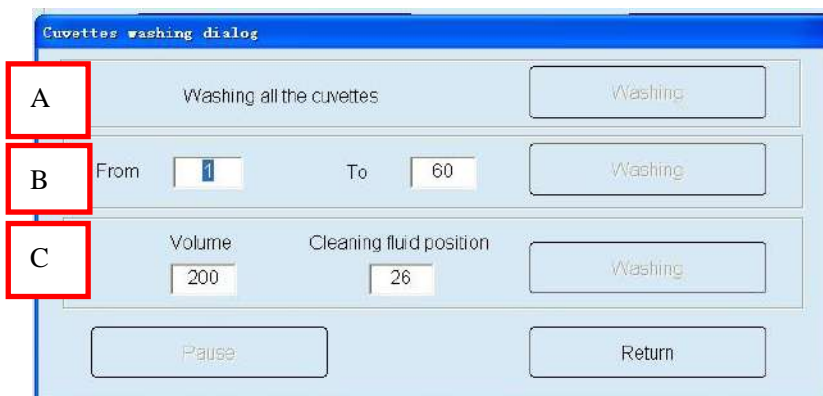
Parameter	Meaning
Pump back water	Click “test” button, hear the voice of backing-water pump. If not, consider whether the backing-water pump works or not.
Syringe	Click “Syringe”, the syringe will work up and down. If not, check whether the syringe works or not.
Sensor check column	
Mixer motor	Click “Test” button, see stirring paddle twirl or not. If not, consider whether the mixture motor works 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 needle firstly inject detergent into each cuvette, waiting reaction cup

Parameter	Meaning
	finish add detergent, washing all cuvettes. when adding 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 signal: “cuvettes signal” interface, used for check cuvettes signal.

The screenshot shows the 'Cuvettes signal' interface. It features a table with 15 rows and 9 columns of data. The columns are labeled with wavelengths: 340, 405, 450, 510, 546, 578, 620, 660, and 690. The rows are numbered 1 to 15. To the right of the table is a control panel with several buttons: 'Add water', 'Remove water', 'Check cuvettes', 'Cuvettes quality', and 'Return'. Below these buttons are two radio buttons for 'Absorbance' and 'Signal value', with 'Signal value' selected. At the bottom of the control panel are two green arrows, one pointing up and one pointing down.

	340	405	450	510	546	578	620	660	690
1	45159	47819	47907	44579	49541	46476	48337	47927	48464
2	45464	48040	48165	45054	49926	46256	48608	48491	48642
3	45026	47688	47824	44546	49538	46640	48401	47840	48590
4	46353	49089	49039	45668	50820	47566	49392	49415	49167
5	45325	48068	48056	44761	49818	46861	48549	48306	48848
6	46788	49648	49540	45828	51250	47577	49432	49761	49290
7	45405	48033	48101	44651	49800	46608	48555	48150	48503
8	46544	49272	49215	45624	51168	47362	49538	49837	49183
9	45958	48822	48674	45113	50408	47051	48963	48676	48989
10	46081	49020	48639	45067	50574	47152	49191	49144	48938
11	46584	49001	48674	44898	50672	46833	48913	49320	48685
12	46573	49304	49084	45434	50982	47406	49428	49464	48961
13	44384	47018	47128	43773	49012	45365	47931	47380	47410
14	45938	48790	48624	44848	50420	46557	48899	48960	48335
15	46526	48974	48865	45327	50730	46881	49133	49556	48783

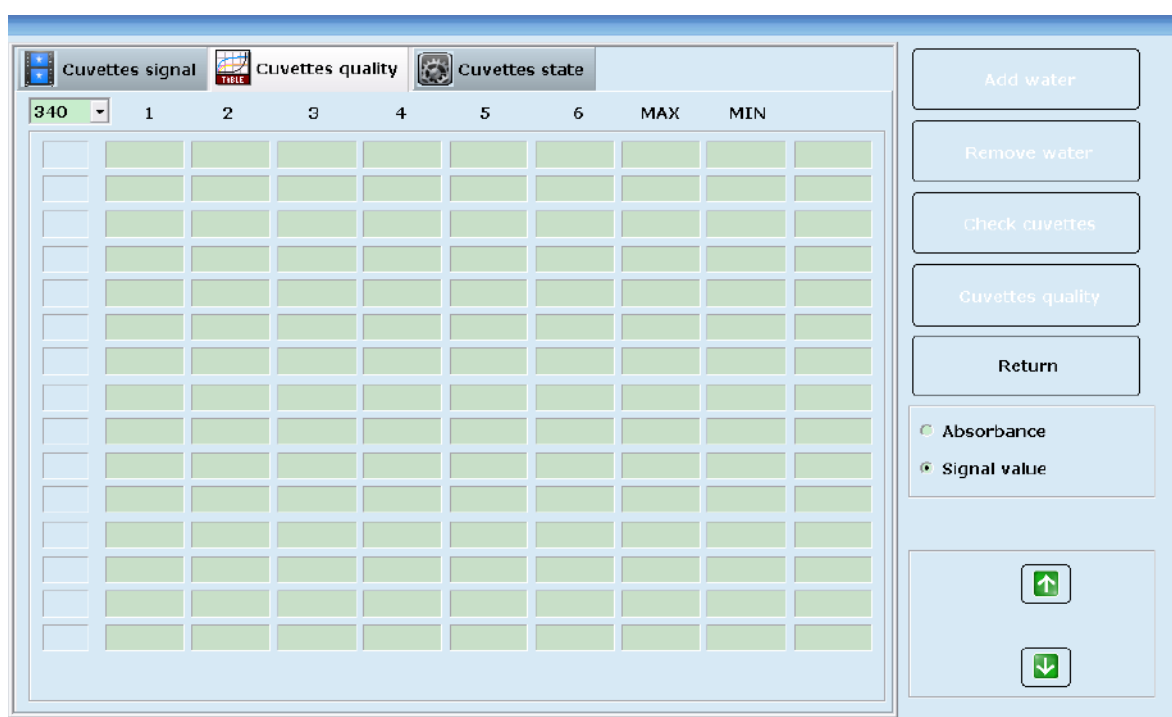
Parameters in the interface:

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
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 continuously 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 value-min A/D value, if >200 display in red.

10)Temperature and Pressure

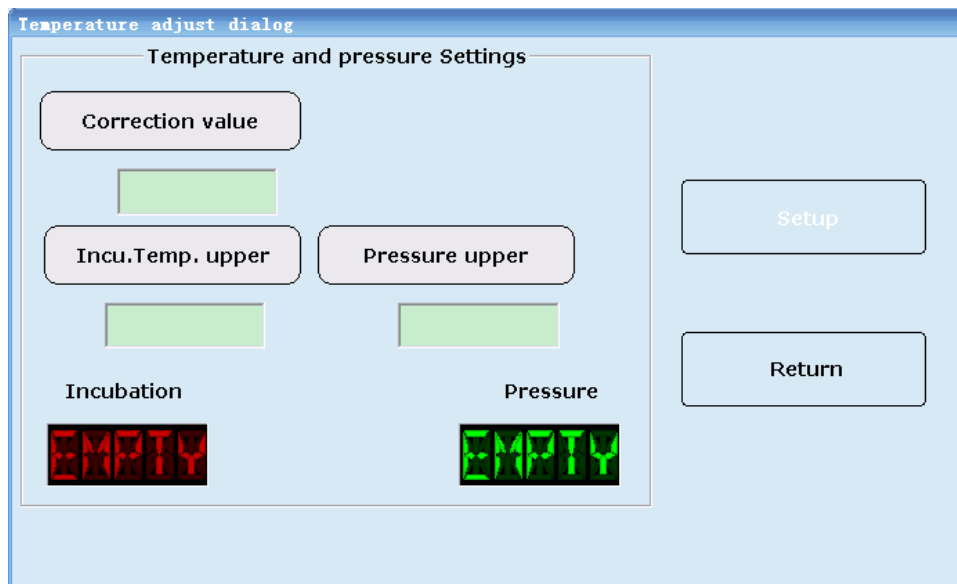
Click “temperature and pressure” button to set the temperature and pressure

The correction factor is used for calibrating the temperature value when there is any error between the temperature in the instrument and the thermometer.

Only when the temperature is balanced can the correction factor can be modified.

Please set the correction factor to “0” if you don’t have a micro thermometer for measuring.

The temperature displayed = instrument temperature measured + correct coefficient



5.2.7 TEST

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

1) Sample applying

Showing as above picture, Edit sample ID, sample cup number and initiative cuvette number (software will increase automatically). Choose item(s) being test and click Add button. If the user needs to 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 latter one.

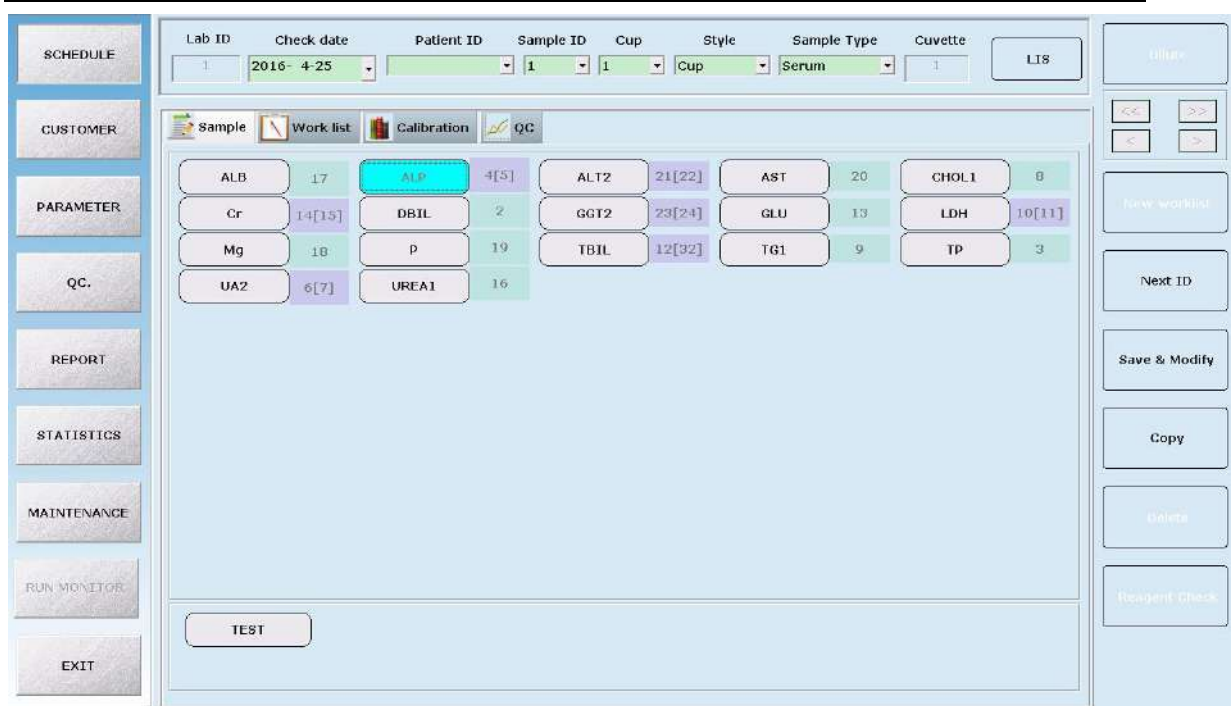


Note:

-
- In TEST interface, each button status reflects its working status.
 - Button sunken: symbols be chosen
 - Button convex: symbols optional
 - In reagent item list and reagent item group list, the button colour will turn blue when chosen
-

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 function 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.



The machine will check the reagent quantity after clicking Reagent Check button, and it will give you the prompt if some reagent is insufficient. Then, you can click “Test” to enter interface as shown in the following picture, and click “Test” again to start the test.

1.3) Work List

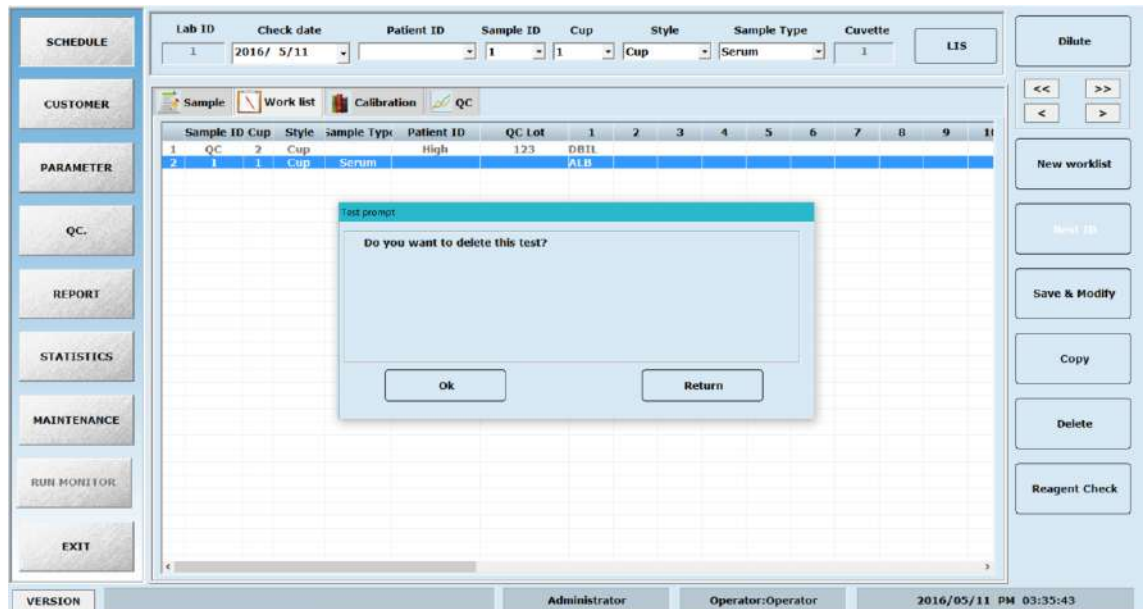
As an accessorial menu, Work List interface is to list all test items to be tested. Before selecting reagent item and start test, it is necessary to check if Work List leaves the test list. Delete all if it does.



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.

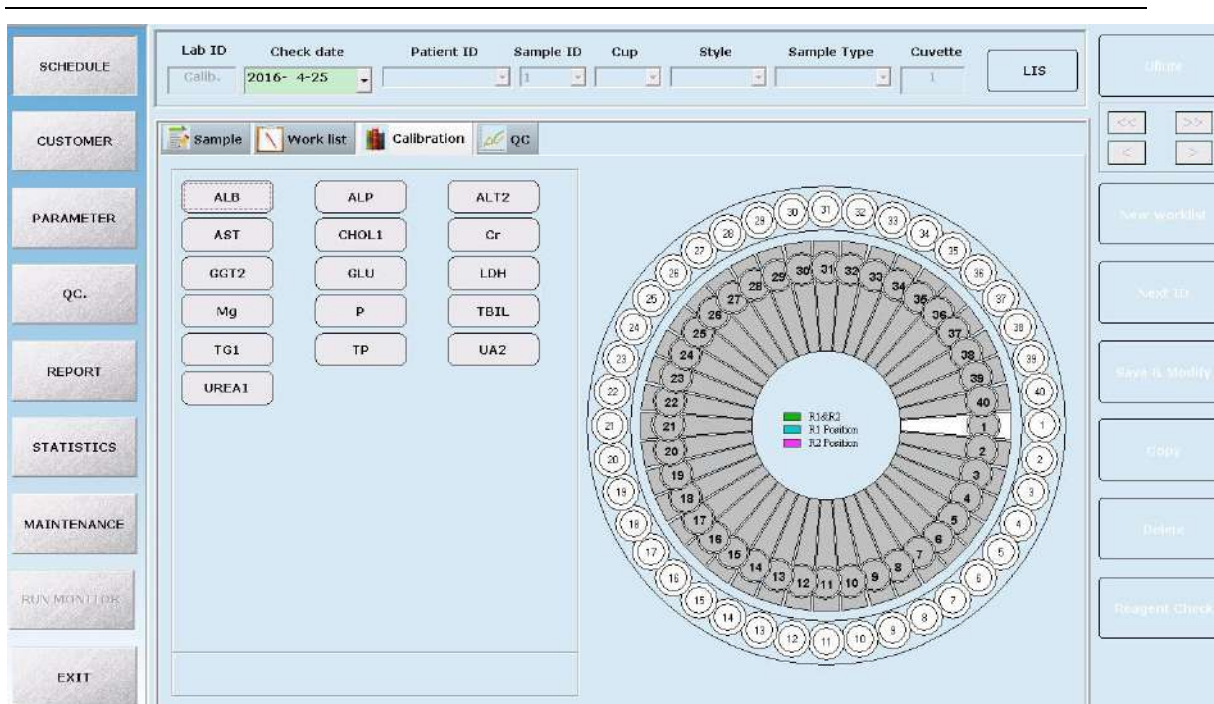


1.3.2)

1.3.3) By selecting one ID in “work list”, you can modify the test item for this sample. Click “Add” button and it will save the new item you choose. The sample position, cup type and sample type can also 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/Function	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 chosen 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.



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

1.6.2) Sample testing interface

The test will begin after clicking the “Test” button in this interface. “Sample, Reagent, Cuvette” tabs will appear on this interface. By clicking any tab, you can know its working status. For example, click Cuvette tab, then click any reaction cuvette on the virtual chart, and you will know the current status of the cuvette.

1.6.3) Test result inquiry in the testing interface

When the test has finished, Result list under Sample tab will show the test result as well as the state of reaction disc cleaning.

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

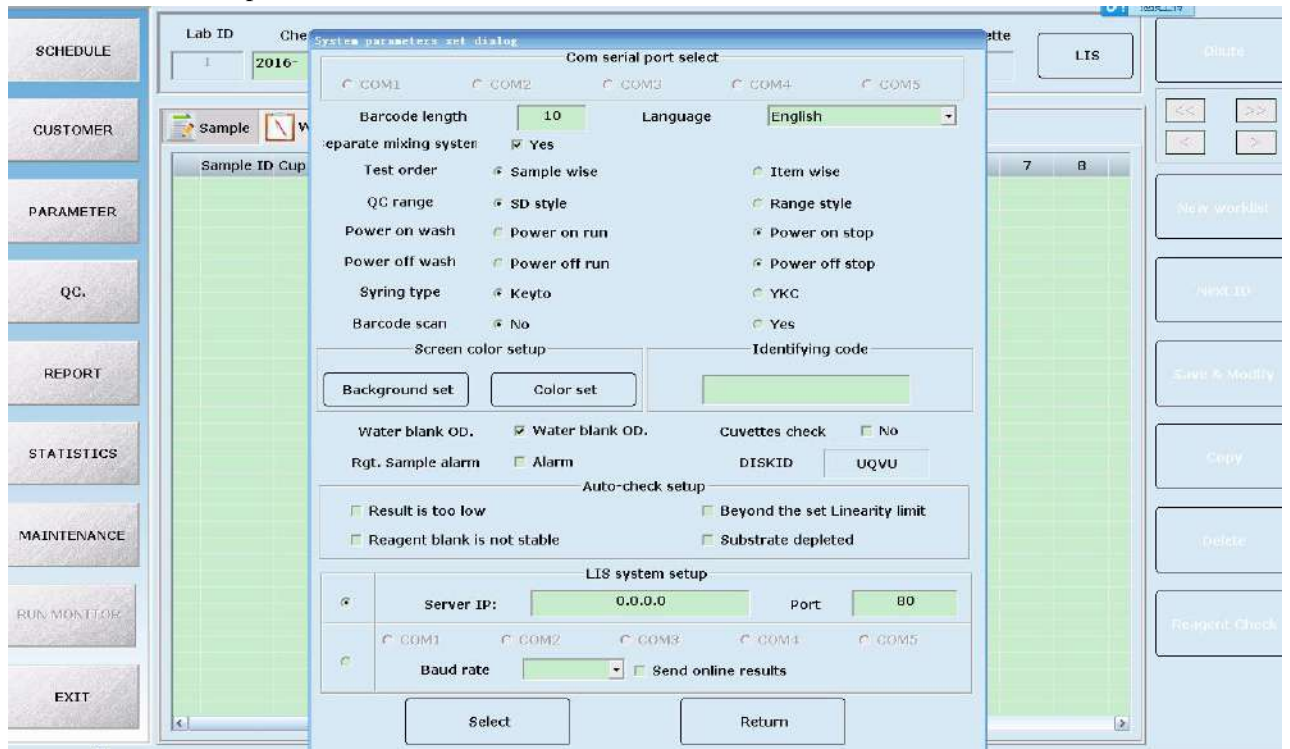
You can also check the current result under “Statistics” function tab.

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

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

1.7) Diluent re-test

1.7.1) Parameter setup



System parameters set dialog

Com serial port select

COM1 COM2 COM3 COM4 COM5

Barcode length: Language:

Separate mixing system: Yes

Test order: Sample wise Item wise

QC range: SD style Range style

Power on wash: Power on run Power on stop

Power off wash: Power off run Power off stop

Syringe type: Keyto YKC

Barcode scan: No Yes

Screen color setup

Background set Color set

Identifying code:

Water blank OD: Water blank OD. Cuvettes check: No

Rgt. Sample alarm: Alarm DISKID:

Auto-check setup

Result is too low Beyond the set Linearity limit

Reagent blank is not stable Substrate depleted

LIS system setup

Server IP: Port:

COM1 COM2 COM3 COM4 COM5

Baud rate: Send online results

Select Return

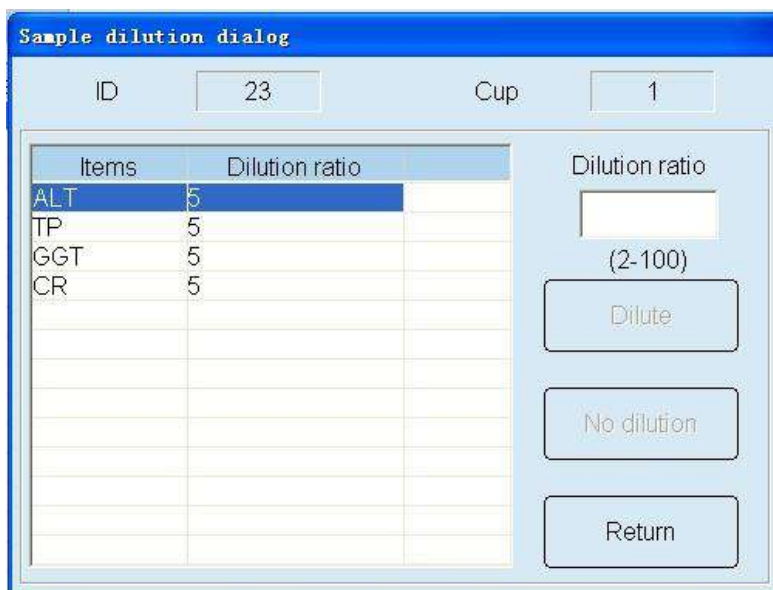
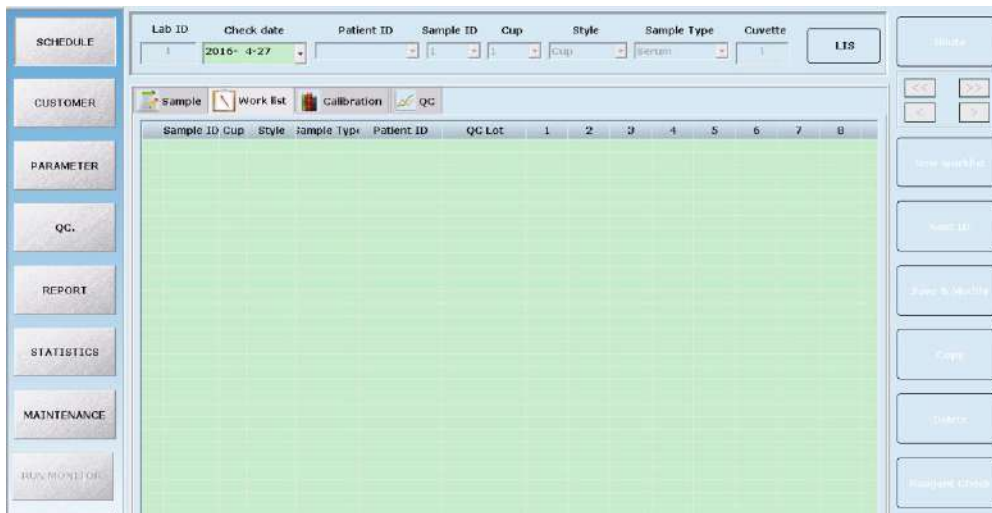
NOTE: To choose diluent liquid position. Software will select No.1 reagent position. Diluent liquid can be pure

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 pre-diluent



- 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

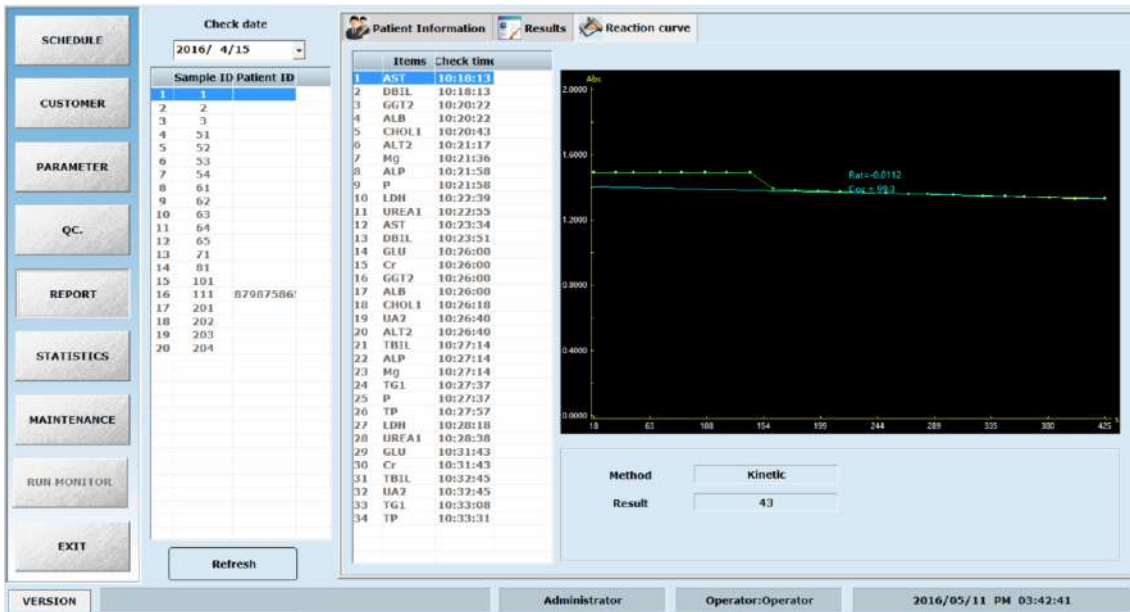
1.7.3) Re-test

If the user doesn't want to auto-retest and not select Auto-check setting in "Parameter, you can recheck the result in "Check information" according to your needs.

In test Screen-Check information interface the machine will retest items chosen to be retested and click the CHECK button. To those results which are 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.

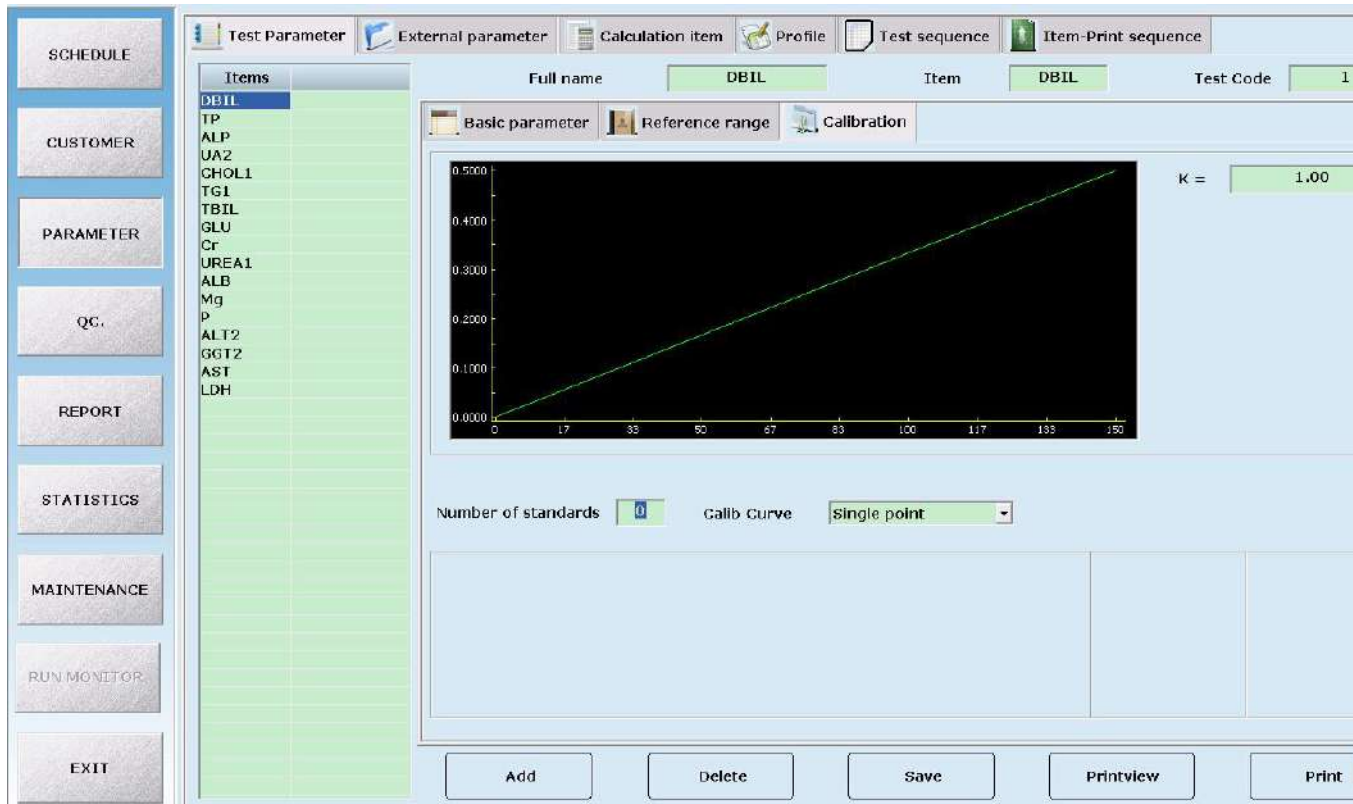


2) Calibration

2.1) Calibration parameter setup

Click PARAMETER-- Test parameter --Calibration to enter calibration parameter setup interface.

This is shown in the picture below:



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.

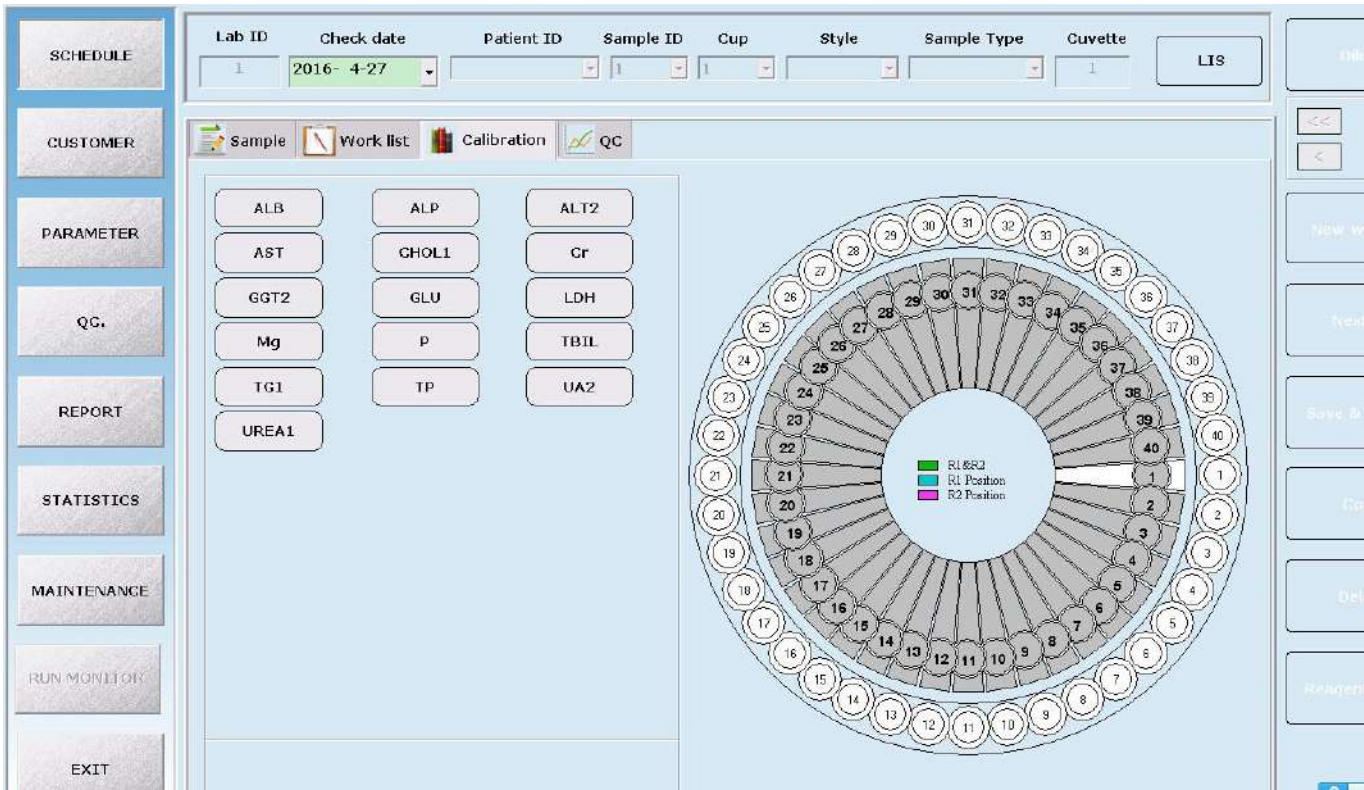
Please refer to the following explanations for each parameter name in this interface:

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
Cali. Curve	There are 3 Linear Calibration and 6 Non-Linear Calibration which different in standard number and calibration factor. Please refer to the following chart

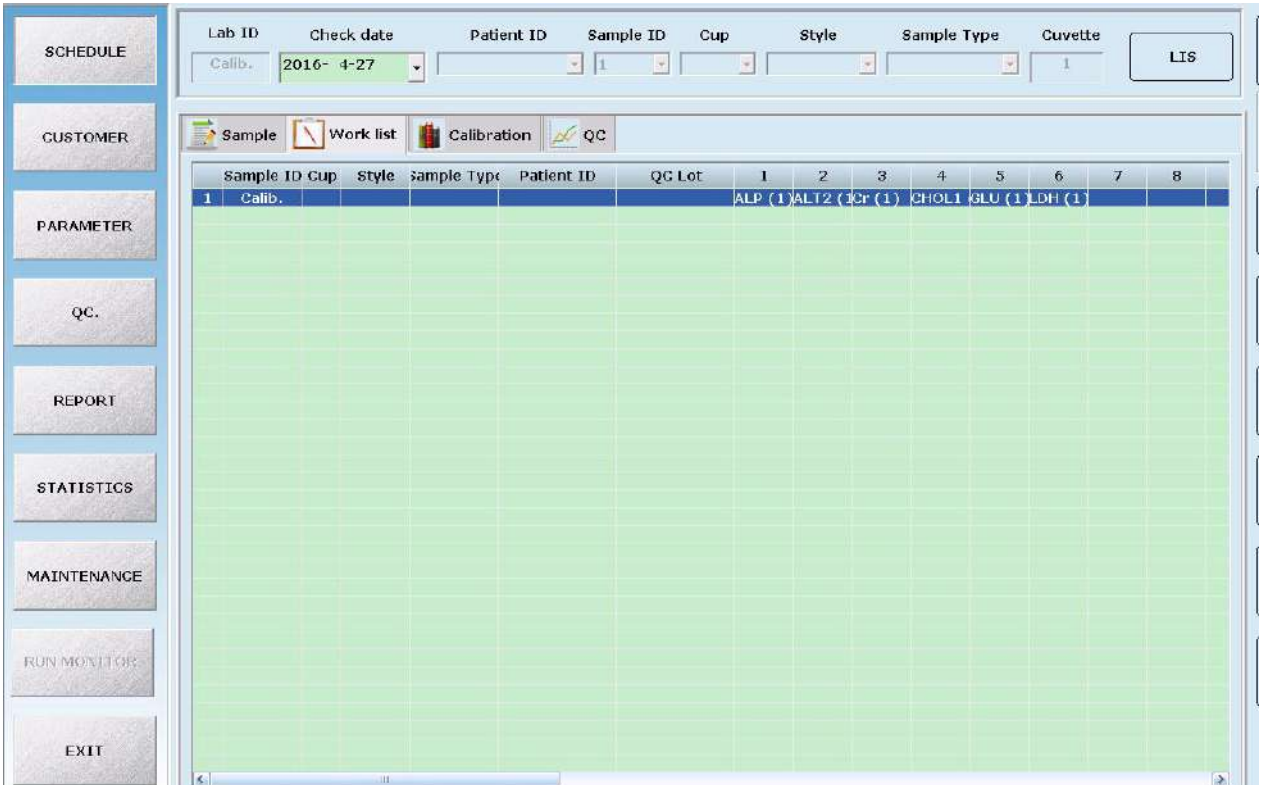
Number		Calibration Rule	Standard number	Calibration factor
Linear Calibration	1	Single point	1	K
	2	Two point	2	a、 b
	3	Multiple point	3~6	a、 b
Non-linear Calibration	1	Logistic-Log 4P	4	K、 R ₀ 、 a、 b
	2	Logistic-Log 5P	5	K、 R ₀ 、 a、 b、 c
	3	Exponential 5P	5	K、 R ₀ 、 a、 b、 c
	4	Polynomial	5	a、 b、 c、 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 selecting the item to be calibrated, click “Add”. The test list will be the list at Working list interface. Click Test button to start calibration.



2.3) Result checking

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

The screenshot shows the 'PARAMETER - Calibration' interface. On the left is a sidebar with menu items: SCHEDULE, CUSTOMER, PARAMETER, QC., REPORT, STATISTICS, MAINTENANCE, RUN MONITOR, and EXIT. The main window has tabs for 'Test Parameter', 'External parameter', 'Calculation item', 'Profile', 'Test sequence', and 'Item-Print sequence'. The 'Test Parameter' tab is active, showing 'Full name: DBIL', 'Item: DBIL', and 'Test Code: 1'. Below this are sub-tabs for 'Basic parameter', 'Reference range', and 'Calibration'. The 'Calibration' sub-tab is active, displaying a graph area (currently blank), input fields for 'a = 0.000', 'b = 0.000', and 'c = 0.000', and a table of standard values. The table has columns for 'Standard position' (1-5) and 'Standard value' (0, .00, .00, .00, .00). Below the table are 'Absorbance' indicators (red boxes) and a 'No dilution' checkbox. On the right, there are fields for 'Lot number' (2350) and 'Expiry Date' (2016-04-30).



Note:

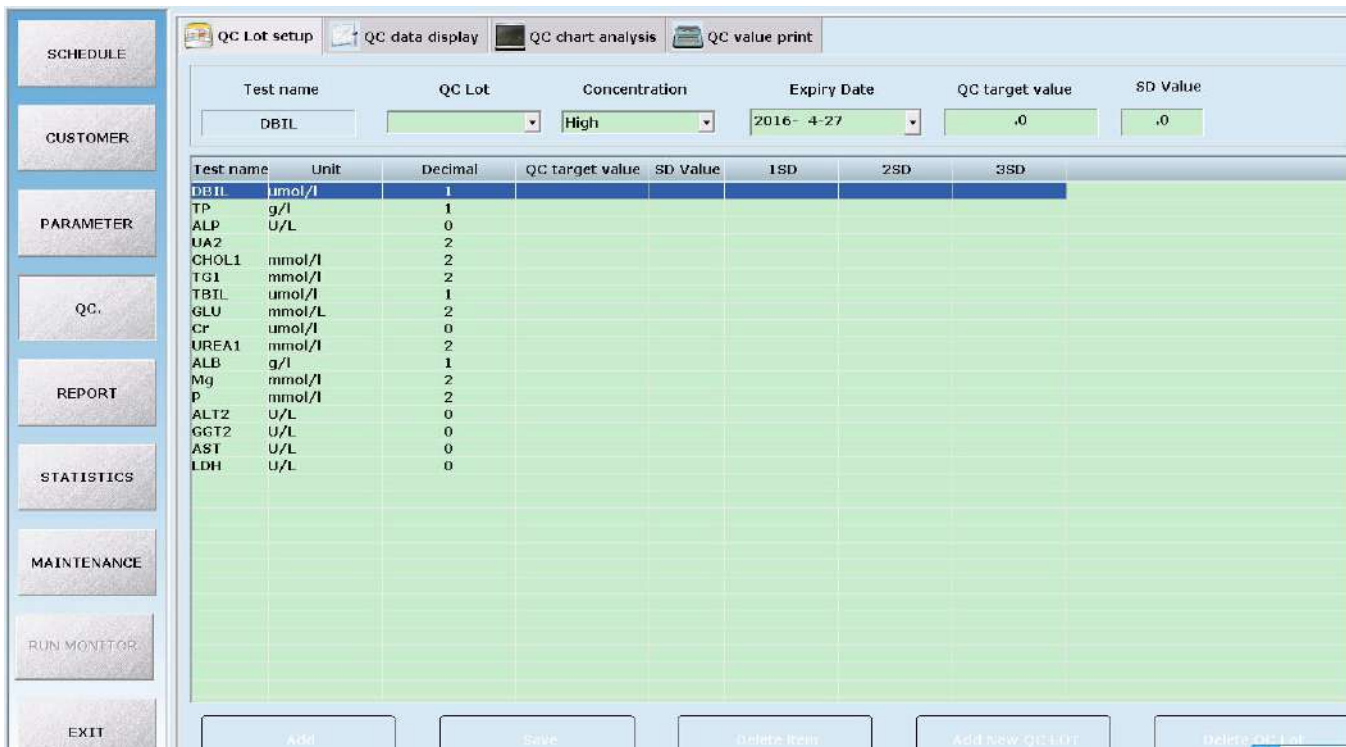
-
- The system will adopt the current default calibration factor to calculate the concentration of the sample.
 - The system will set the latest calibration factor (including the calibration factors which are from the calibration test and calibration edit) as the default factor.
-

3) Quality Control

3.1) QC Setup

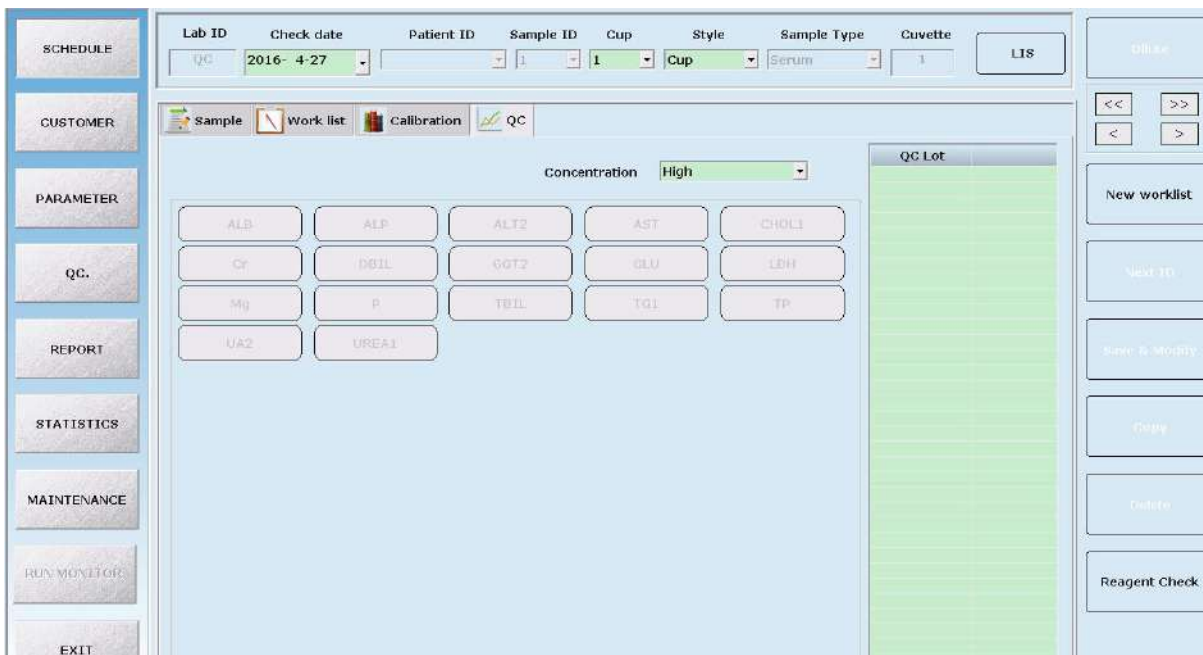
Enter QUALITY CONTROL-QC. Lot Setting interface to setup QC information such as lot number, concentration and expiry time.

Select the item to perform the QC. Input relative target value and SD value. Item unit and name already set in PARAMETER interface. Click Add then Save button.



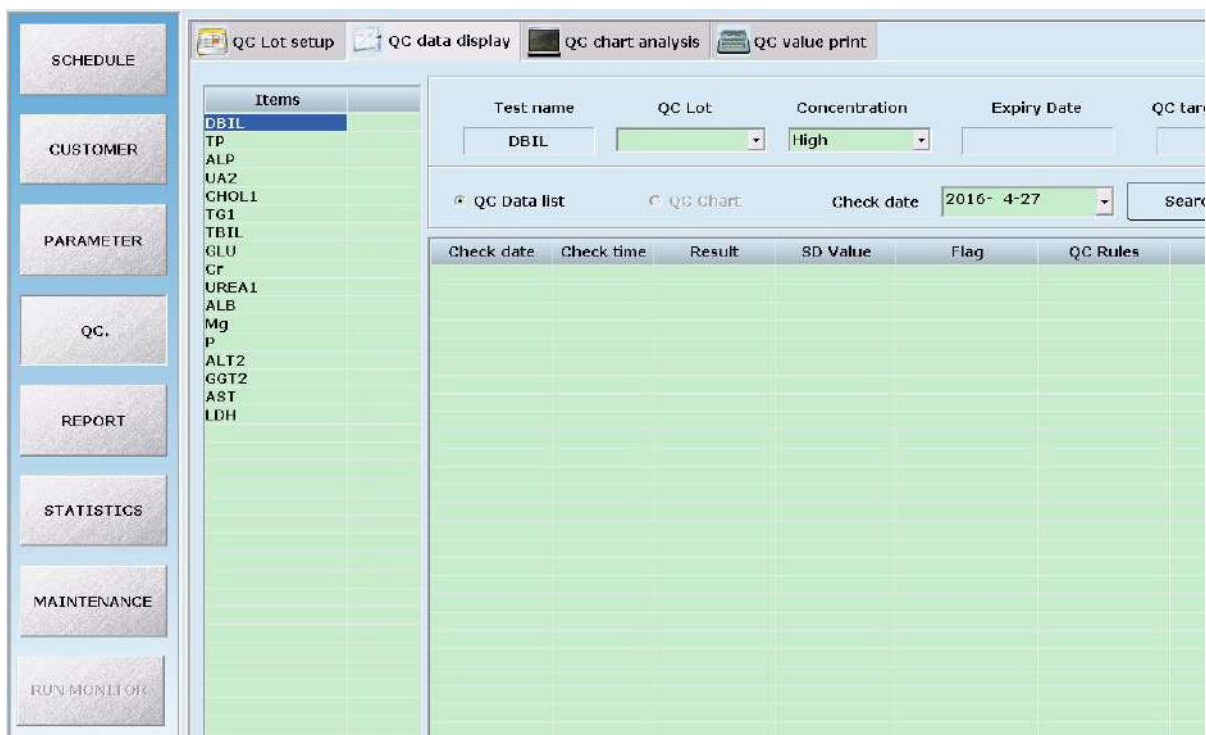
3.2) QC Test

Enter TEST-QC interface. Choose item going for 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 checked in QUALITY CONTROL-QC data display interface which shows all QC test results.



QC test result can be show in two forms - 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
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:

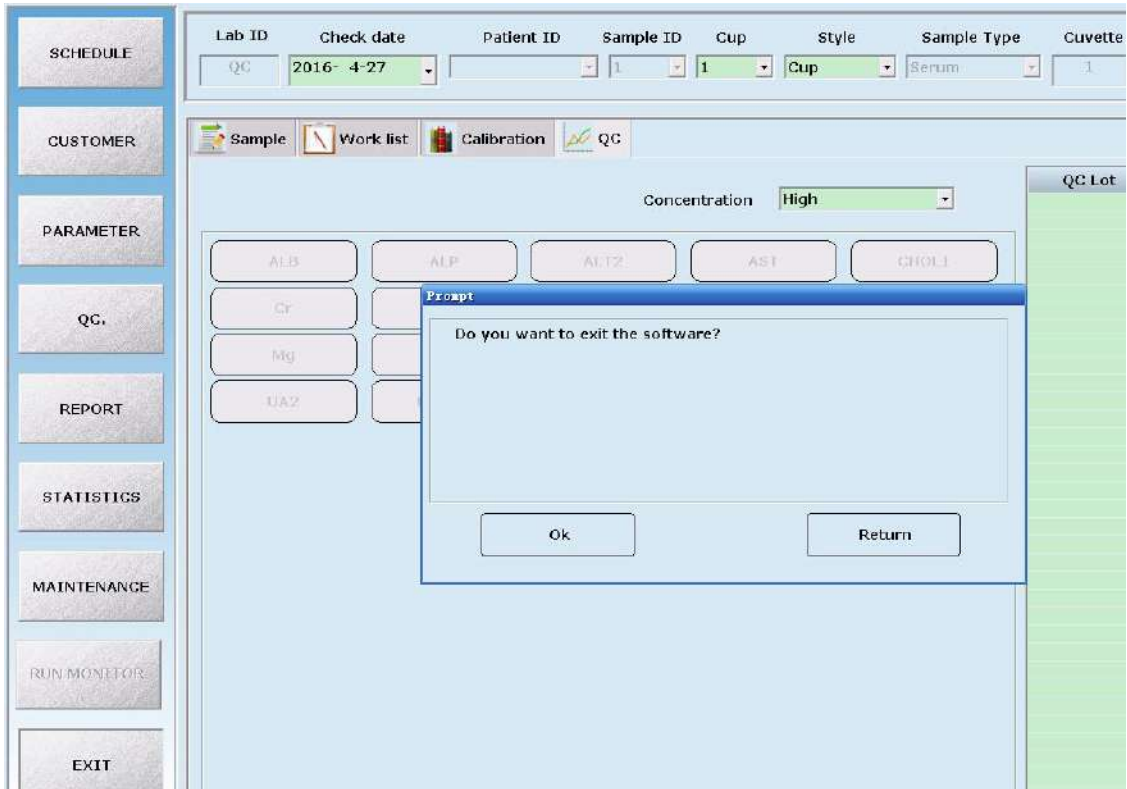
Button	Function
Save	To save for all operation
Print	To print test result chart
Delete	To delete result data

5.2.9 Test Screen

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

5.2.10 Exit

Clicking Exit button in the main menu will exit the software and in the sub menu will revert back to the previous interface.



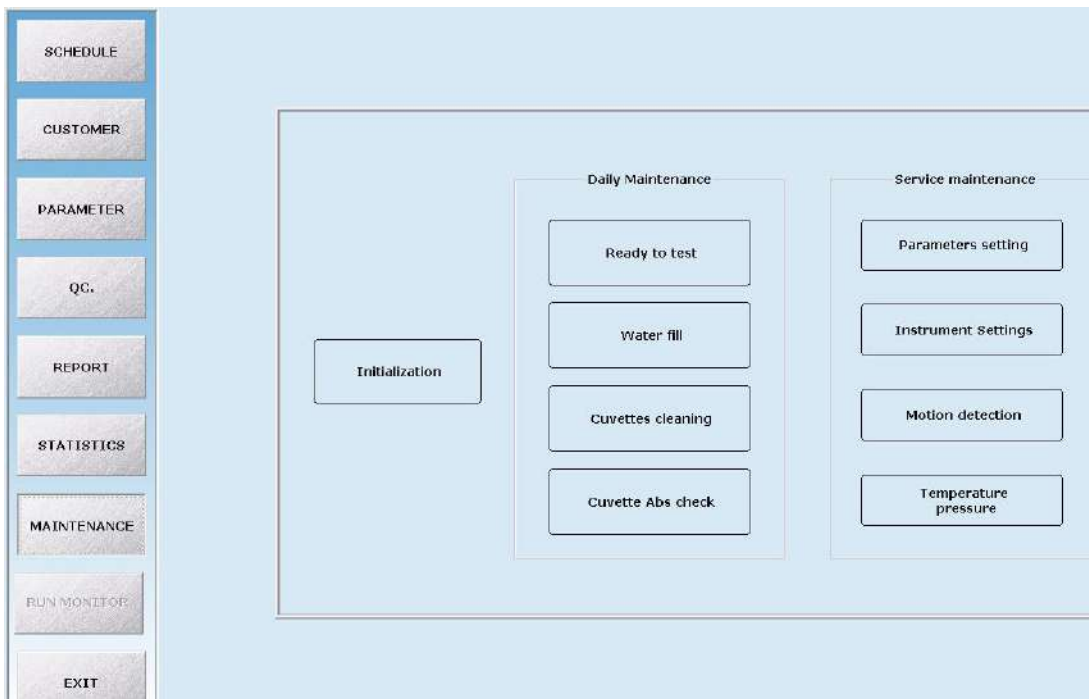
Chapter Six Maintenance

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

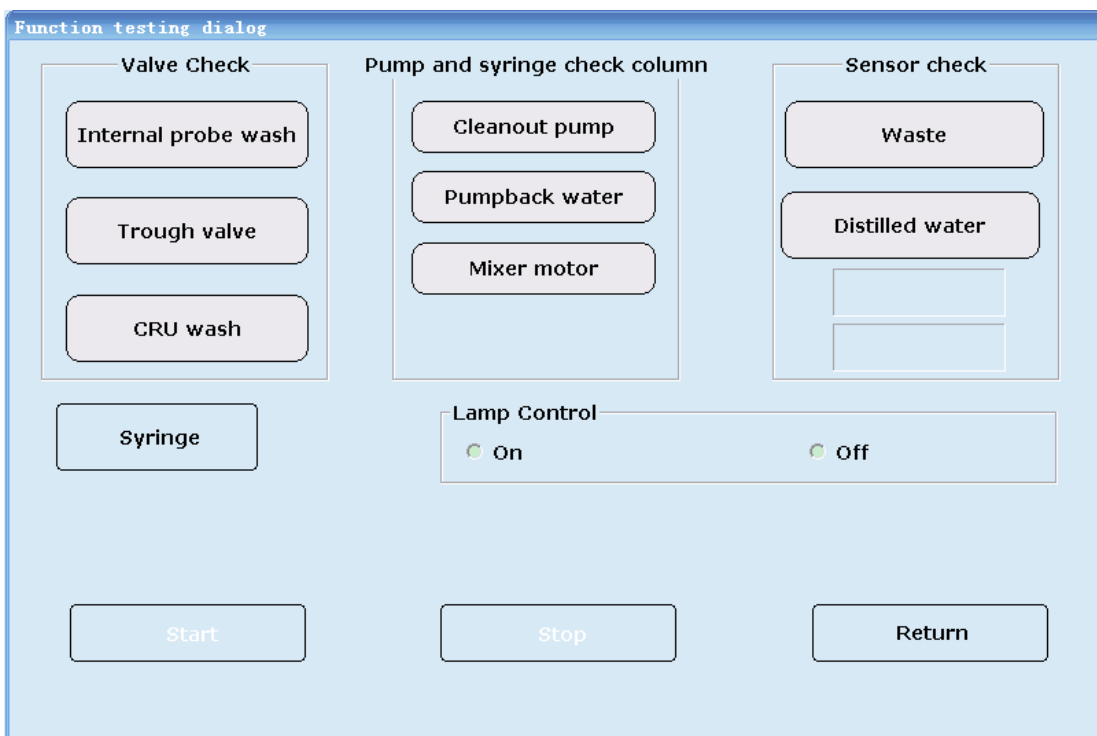
6.1 Maintenance

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 there are sufficient quantities of reagent and serum. 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) Conduct the “Ready to test” programme before testing every day, and conduct the program “End to test” after testing every day.
- 4) Put the reagent, standard substance and QC serum in an 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 sufficient and the waste bucket is not overflowing 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 water is not coming out from the reagent needle and sample needle, please clear obstruction. If this still does not work, please contact us.

8) If you find that the wash unit cannot 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 influence the measurement of absorbency; please replace it with a new one.

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

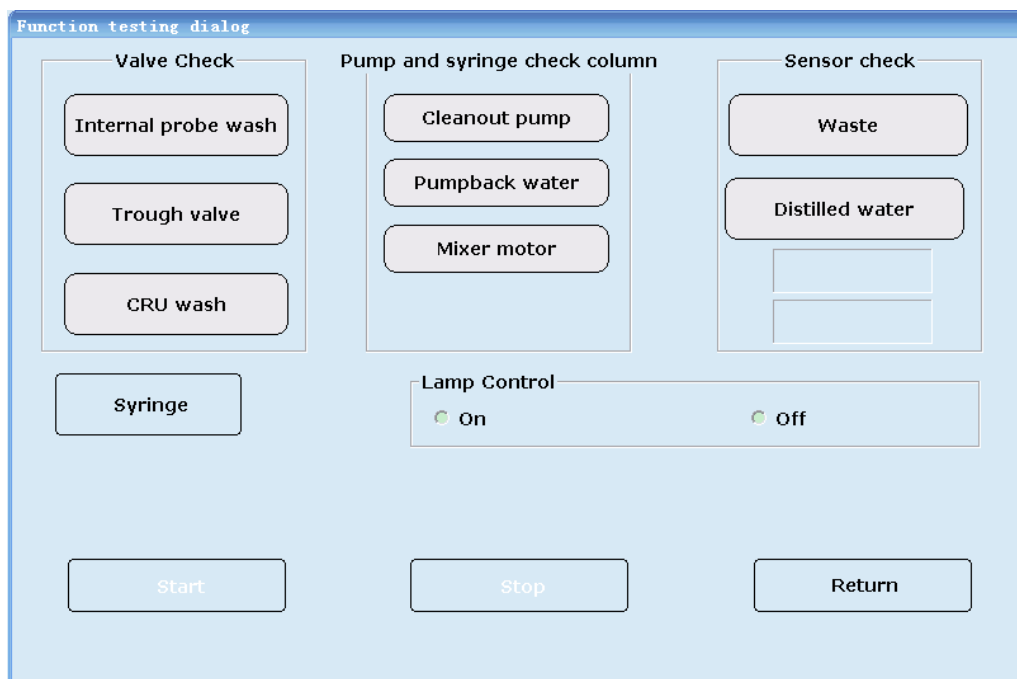
11) Do not switch the instrument power on and off frequently, it may cause damage to the power module.

12) Stabilised 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 warmed to room temperature before testing.

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

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 the test

will stop immediately.

Chapter Seven Troubleshooting

7.1 Initialisation

Faults	Causes analysis	Solutions
1. Cannot initialise after starting the system	<ul style="list-style-type: none"> a. The serial port wire is not connected correctly b. The serial port is not selected correctly c. Software setting faults 	<ul style="list-style-type: none"> 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 a serial port in communication setting. c. Re-setting the software
2. The reaction disc can't rotate when initialising, and act on other actions after a period of time	<ul style="list-style-type: none"> a. the 0# motor signal wire is not inserted correctly b. The main control board is broken, or the line contact is not good c. Software program faults 	<ul style="list-style-type: none"> 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 initialisation	<ul style="list-style-type: none"> a. The voltage of 5V power supply is not stable or not enough b. The drive board of motor is broken 	<ul style="list-style-type: none"> a. Replace the power board b. Replace the drive board of motor
4. the reaction disk position is different between initialising and parameter settings	<ul style="list-style-type: none"> a. The installation position of optocoupler of the reaction disc is incorrect 	<ul style="list-style-type: none"> a. Re-adjust the optocoupler of the reaction disc
5. Friction noise from the colourimetric disc when initialising	<ul style="list-style-type: none"> a. The colourimetric disc is not assembled correctly, or the rotary axis is not in 	<ul style="list-style-type: none"> a. Disassemble the colourimetric disc and reposition

7.2 Mechanical

Faults	Causes analysis	Solutions
1. The mechanical arm can't detect initial position	<ul style="list-style-type: none"> a. The signal wire of optocoupler sensor is not connected to the motor pinboard correctly. b. The retainer ring of optocoupler is not installed correctly c. Weld position of optocoupler is loosen 	<ul style="list-style-type: none"> a. Check and connect to right position b. Re-adjust the position and fix c. Take down the optocoupler and re-weld

2. The mechanical arm can't uplink and downlink smoothly	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> a. Check and re-arrange the light path b. Daub silicone grease lubrication on the axis
3. The mechanical arm rock	<ul style="list-style-type: none"> a. The rotary synchronous belt is too lax b. The synchronising wheel and motor rotary axis do not occlusion tightly c. The voltage of 5V lock motor is not enough 	<ul style="list-style-type: none"> a. Adjust the synchronous belt to suitable tightness value b. Tighten the fastening screw on the rotary synchronising wheel c. Check and replace 5V power supply
4. Obvious noise from the motor when running	<ul style="list-style-type: none"> a. Stepping motor line is loosened b. Dialing error of motor drive board 	<ul style="list-style-type: none"> a. Electrode Cable. Find out the uncompact 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	<ul style="list-style-type: none"> a. Motor board faults b. The rotary belt is too lax 	<ul style="list-style-type: none"> a. Replace the No. 8 and 9 motor boards b. Adjust the synchronous belt to suitable tightness value
6. Mechanical arm can't work normally	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> a. The plus-minus of peristaltic pump power line is inversed 	<ul style="list-style-type: none"> a. Swap the power-supply wiring heads of the peristaltic pump
2. Obvious residual water stain at the bottom of cuvette after cleaning	<ul style="list-style-type: none"> a. The apocenosus pump can't work b. The bottom of cleaning probe is projecting in the rinse block c. The cleaning needle can't reach to the bottom of the cuvette 	<ul style="list-style-type: none"> a. Repair and replace the apocenosus pump b. Re-adjust the position of the cleaning piece c. Re-adjust the steps numbers of fluctuation to make the cleaning piece reach the bottom of the cuvette in "motion parameter settings"
3. Can't inject water well-distributed	<ul style="list-style-type: none"> a. The magnetic valve or water inlet are blocked 	<ul style="list-style-type: none"> a. Replace the magnetic valve or clean the pipeline
4. The water level of pressure tank rise	<ul style="list-style-type: none"> a. The sealed cap of pressure tank is not tightened 	<ul style="list-style-type: none"> a. Tighten up the sealed cap b. Replace the seal ring and sealed cap

ceaselessly	b. The seal ring of pressure tank leak air	
5.The pressure of apocensis pump is not enough	a. The apocensis pump is blocked by foreign matter b. The heating tank leak air	a. Disconnect the apocensis pump and eliminate the foreign matter 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 disc is loose (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 injecting 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	a. Adjust the lamp's voltage to rated voltage, we suggest using stabilised voltage supply b. Replace the lamp c. Replace the photosensitive diode d. Shorten the light path of the optic fiber to

	<p>installed correctly.</p> <p>e. The circuit board is not grounded well</p> <p>f. The power source is unqualified</p>	<p>enhance the light intensity. And put the light beam (which is with the strongest light intensity) at 340nm wavelength</p> <p>e. The oxidation treatment at the junction of the screws may cause bad contact; Polishing the screw junctions of each circuit boards. Weld another grounding wire if necessary.</p> <p>f. Replace with qualified power supply</p>
--	--	---

7.5 Test

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

7.6 Temperature and Pressure

Faults	Causes analysis	Solutions
1. No heat	<p>a. Check whether the heating power supply is inputted</p> <p>b. Check whether the reaction disc and water-heating temperature sensor are in normal condition</p> <p>c. The main control board is connected to temperature control board</p> <p>d. Check whether the wire is ok</p>	<p>a. Check +24V heating power source</p> <p>b. Check reaction disc and water-heating temperature sensor</p> <p>c. Check the connector wire between main control board and temperature control board</p> <p>d. Check whether the temperature setting is in normal condition</p>
2. No pressure	<p>a. Liquid inlet pump</p> <p>b. Pressure sensor</p>	<p>a. Check whether the pressure setting of the operation software is in normal condition</p> <p>b. Replace the waterway board</p>

3. No refrigeration	a. Refrigeration power supply 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 are 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 in a ventilated room, with temperature range from -40°C to 55°C, 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 Woodley Equipment Company Ltd 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°C~55°C and the relative Humidity is $\leq 95\%$.



Woodley Equipment Company Ltd.

Old Station Park Buildings

St. John Street

Horwich

Bolton

Lancashire

BL6 7NY, UK

Tel: +44 (0) 1204 669033

Fax: +44 (0) 1204 669034

E-mail: sales@woodleyequipment.com

Web: www.woodleyequipment.com