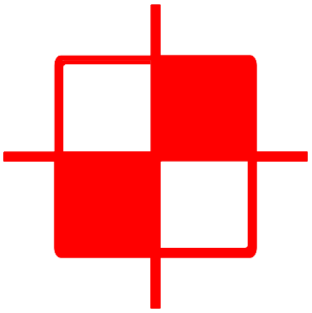
AU150

Auto Chemistry Analyzer

Operation Manual



Shenzhen HETO Medical Tech Co., Ltd.

Stable
The must for a lab

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Declaration

The current version number of this manual is B/3, released in 2019-06. This manual should be used for the following models: AU150-P (Without auto wash function), AU150-PW (With auto wash function). This manual may be modified as needed without prior notice.

For product safety, reliability and performance provided , the following requirements are met:

1) Installation, use, operation, maintenance and repair are performed by personnel authorized by HETO;

2) Any associated electrical equipment complies with national standards;

3) Use and operation of the instrument are performed in strict accordance with this manual.

Shenzhen HETO Medical Tech Co., Ltd. shall have the right of final interpretation for this manual

Introduction

We would like to sincerely thank you for choosing to purchase HETO auto chemistry analyzer.

Please read this manual carefully in order to ensure correct use of the apparatus.
After carefully reading this manual, please keep it safely stored so that you can refer to it when necessary.

Product Name: Auto Chemistry Analyzer

Model: AU150-P, AU150-PW

Safety Classifications: Class II Overvoltage, Pollution Grade 2.

Management Classification: This device is classified as a Biochemical Analysis System under the Clinical Testing Apparatus (6840) class; management classification: Class II.

Product Composition: The product primarily comprises an analysis unit, operating unit and results output unit as well as various accessories, and supplies.

Scope of Product Application: This product is suitable for use in the quantitative analysis of different samples using liquid reagents.

Manufacturer: Shenzhen Heto Medical Tech Co., Ltd.

Address: 4th Floor, Building No.4, Shenzhen Environmental Protection Industrial Park, No.31 Makan South Road, Nanshan District, Shenzhen, 518055, P.R.China

Manual Overview

This manual is focused on helping users to understand several aspects of this auto chemistry analyzers, including safety, installation, structure and function, analysis principles, operating procedures, maintenance and repair, alarms and treatment. Please operate the apparatus in strict accordance with this manual in order to ensure proper use.

Symbols

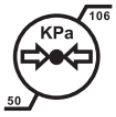
The following is a list of symbols used in this manual.

Symbols	Meaning
	Warning! May cause damage to the analyzer or affect test results.
	May result in biological contamination.
	May result in electric shock.
	May cause corrosive damage.
	High temperatures which may cause injury.
	Glare which may cause eye injury.
	May result in bodily injury.
	Flammable substance which may result in a fire.

Screen Printing and Labels

The screen printings and labels listed below are used in this manual.

Labels	Meaning
SN	Product Serial Number
	Protective Conductor Terminal
	Manufacturing Date
	Manufacturer
IVD	The product is an *in vitro* diagnostic device
REF	The product serial number of company
EC REP	The abbr. of European representative
~	AC
|	Power On
○	Power Off
CE	CE Mark
ON	Power On
OFF	Power Off
Serial Port	Communication Port
Waste Liquid Outlet	Waste Liquid Outlet
Purified Water Inlet	Purified Water Inlet
	Upward

	Fragile , handle with care
	Avoid sunlight
	Do not roll
	Temperature limit
	No Stacking
	Temperature limit
	Keep dry
	Atmospheric pressure level for storage
	The analyzer, after being scrapped, should not be disposed with other household garbage, instead, it should be collected and recycled following the WEEE regulations for scrapped electronic and electrical equipment
	Recyclable materials

Figures

All pictures included in this manual are used for descriptive purposes or as examples only, and are not intended to be used for any other purposes.

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1. Safety and Precautions

The following are warning symbols used in conjunction with this auto chemistry analyzers. Ignoring these symbols may result in death or serious injury. The order in which the symbols are given is in no way indicative of importance and all symbols are of equal importance.

1.1. Safety



1.1.1. Glare

Do not look directly into any beams of light, including those produced by light sources and barcode scanners, as these beams can harm your eyes.



1.1.2. Combustibles

Do not use any dangerous flammable substances, such as alcohol, ether, etc. near the analyzer.



1.1.3. Explosion

Do not use any potentially explosive dangerous articles near the analyzer.

1.1.4. High Temperature



1) Before replacing any lamps, turn off the power switch of the apparatus, and wait at least 30 minutes until the lamp has cooled down;
2) Contact with the heater or metal objects around the heater may cause burns.

1.1.5. Electric Shock

1) Non-authorized service personnel should not open the analyzer's paneling or side and back covers while the device's power is turned on;
2) Spillage of liquid on the device's countertop should be avoided and in the event that a spill does occur, please power off the device immediately and contact service promptly;
3) The internal parts of computers, printers and other components are under high voltage, so please do not touch the interior of these devices.



1.1.6. Bodily Injury



1) Please be careful with the sharp elements of the analyzer, such as reagent probe tips, sample probe tips, mixers, and the steel piping of the device's self-cleaning mechanism, as a failure to do so can result in injury;

2) When the analyzer is running, do not touch any of its moving parts, including the sample probe tips, reagent probe tips, mixer, automatic cleaning mechanism or fans.

1.1.7. Biological Contamination

1) All test samples, calibrators, controls, etc., should be considered contagious and protective gloves should be worn when coming into contact with these objects; additionally, work clothes should be worn to avoid infection and eyewear should be worn if necessary;



2) All waste liquid should be considered contagious and protective gloves should be worn when coming into contact with it; additionally, work clothes should be worn to avoid infection and eyewear should be worn if necessary;

3) All device components that have been in contact with test samples, such as reagent probes, sample probes, mixers, cleaning mechanisms, waste liquid tubing, waste liquid containers and reaction cuvettes should be regarded as contagious, and protective gloves should be worn when coming into contact with these objects; additionally, work clothes should be worn to avoid infection and eyewear should be worn if necessary.

1.1.8. Corrosion



1) Wash solution and some reagents are strongly acidic or alkaline, and protective gloves should be worn when coming into contact with these substances; additionally, work clothes should be worn to avoid infection and eyewear should be worn if necessary; Measures should be taken to prevent contact between the user's hands and clothing; In case of contact, immediately wash the affected area with plenty of soap and rinse thoroughly with water;

2) In the event that any of the aforementioned fluids enter the user's eye, rinse the affected eye immediately with plenty of water and consult an ophthalmologist.

1.2. Precautions

1.2.1. Scope of Use:



1) This product is suitable for use in the quantitative analysis of different samples (including serum, plasma, urine, cerebrospinal fluid, etc.) using liquid reagents.

2) When making a clinical diagnosis using test results, a comprehensive determination should be made that also incorporates the patient's clinical symptoms, as well as the results of other clinical examinations and tests.

1.2.2. Device Operator



1) This device may only be operated and used by authorized personnel who have undergone training provided by HETO or authorized representatives of HETO.

1.2.3. Operating Environment



1) Please install the device properly in an environment that conforms to the specifications outlined in this manual. The installation or use of the device under conditions other than those specified may result in reduced reliability as well as harm to the analyzer;

2) If the operating environment of the analyzer needs to be modified, please contact HETO or the authorized HETO agent for your region.

1.2.4. Electromagnetic Interference



1) The analyzer is susceptible to electromagnetic interference during operation which may affect measurement results and lead to operational errors. Please do not use devices that emit electromagnetic radiation, such as electric drills, mobile phones or walkie-talkies while the analyzer is running;

2) The analyzer will emit electromagnetic radiation during operation. Do not install or use electromagnetically-sensitive devices near the analyzer.

1.2.5. Improper Grounding



1) The power supply unit must be properly grounded. Failure to ground the power supply presents a risk of electric shock;

2) Ground impedance must be less than 0.1Ω; poor grounding can cause instability in measurement results and electrical leakage from the enclosure, producing a shock hazard.

1.2.6. Loss of Label Stickers

1) When stickers on the instrument become faded or fall off, please contact HETO for a replacement.

1.2.7. Liquid Leakage

1) Fittings for all tubing should be carefully checked before each test to check for any leaks. Liquid leakage can cause inaccurate suction and emission;

2) To avoid liquid spills and leaks, do not put reagents and samples on the analyzer table.

1.2.8. Probe Obstruction

1) Carefully check reagents and samples to ensure that no insoluble compounds, such as cellulose or fibrin, are present. Failure to do so may result in obstruction of the reagent or sample probes.

1.2.9. Water Quality

1) Water quality should meet Class 2 national standards for laboratory water. Use of lower-grade water can easily lead to valve or pump damage as well as difficulty cleaning the apparatus.

1.2.10. System Use

1) Follow the instructions contained in the manual when using the system. Incorrect use may result in incorrect measurement results, and furthermore may even result in system damage or personal injury.

2) Before using the system for the first time, please first perform a system calibration followed by the relevant quality control procedures in order to verify that the system is working properly.

3) When using the system on a regular basis, it is recommended that quality control procedures are used to ensure the reliability of measurement results.

4) During analysis, do not open the reaction disk cover.

5) Before performing an analysis, close the reaction disk cover and reagent / sample disk cover.

6) During the analysis process, make sure there are no obstructions in the probe or in the path of the mixer.

7) In order to prevent injury, do not touch the reaction disk and sample and reagent disk while they are spinning.

8) Do not install any hardware or software onto the computer comprising the operating unit other than the software and hardware specified by HETO. The installation of non-specified hardware or software may interfere with the normal operation of the system. Do not run other software while the system is working.

9) Do not use the computer comprising the operating unit for any other purposes. Improper use may result in viral infection of the computer. Computer viruses can be propagated via USB thumb drives, programs and networks, as well as via other means.

1.2.11. System Maintenance

1) Please follow the instructions in this manual when performing system maintenance. Incorrect maintenance procedures may result in incorrect measurement results, and furthermore may even result in system damage or personal injury.

2) After replacing major system components, such as the light photometer, pipetting probe or syringe piston assembly, a calibration should be performed.



3) When using the instrument in South Asian countries which feature high temperatures, low humidity, and extremely dry conditions (including India, Pakistan, Bangladesh, Sri Lanka, etc.). As these do not fall within the range of normal operating conditions for the instrument, maintenance such as dust removal and add coolant into coolant pump should be performed regularly.

4) If use of the instrument is stopped due to malfunction and repairs or treatment are needed, please contact HETO or the authorized HETO agent for your region and concurrently take the following measures:

Use other devices or methods to complete unfinished tests in order to avoid delays.

5) Please remove reagents from the instrument and store them according to the reagent instructions after the testing, such as returning one or more reagents to a refrigerator for cold storage, in order to prevent reagent deterioration.

1.2.12. Samples



1) Please use completely separated serum samples and urine samples which do not include any suspended solids. If a serum sample contains fibrin or a urine sample contains suspended solids, the Sample probe may become obstructed, affecting the accuracy of analysis results.

2) Drugs, anticoagulants, preservatives, etc. which are present in a

sample may interfere with some analysis results.

3) Lipemia, jaundice and hemolytic samples may affect analysis results so it is recommended that a blank sample analysis be performed.

4) Please store samples correctly. Incorrect sample storage conditions may alter the composition of samples, thus affecting the accuracy of analysis results.

5) In order to prevent sample evaporation, do not leave the sample open for an extended period of time. Failure to do so may affect the accuracy of analysis results.

6) There are requirements concerning sample volume when performing an analysis with the system. When taking a sample, make sure that the sample size is appropriate based on the instructions given in this manual.

7) Prior to analysis, make sure the sample is positioned correctly. Failure to do so will make it impossible to obtain accurate results.

1.2.13. Reagents, Calibrators and Control Fluids

1) When using the system to perform an analysis, please use the appropriate reagents, calibrators and control fluids.

2) Please select and use reagents that are suited to the system. In the event that the suitability of a reagent cannot be determined, please contact the HETO or distributor of the reagents, HETO or one of HETO's distributors.

3) For information concerning the use and storage of reagents, calibrators and control fluids, refer to the HETO or distributor's instructions.



4) If reagents, calibrators, or control liquids are improperly stored, correct test results may not be obtained, even prior to the corresponding expiration date.

5) Please perform a calibration after replacing reagents. Failure to perform calibration and a quality control analysis may result in inaccurate test results.

6) The presence of reagent cross contamination during analysis may affect test results. For more information concerning reagent cross-contamination, please consult the reagent Manufacturer or distributor.

7) Prior to analysis, make sure the sample is positioned correctly. Failure to do so will make it impossible to obtain accurate results.

1.2.14. Cuvettes



This analyzers employ semi-permanent rigid cuvettes. Please use cuvettes designated by HETO and change them regularly (3 months). Or it may result in a failure to obtain the desired level of performance.

1.2.15. Analysis Parameters



Incorrect analysis parameters can lead to erroneous measurement results. Please consult HETO or your reagent supplier for more information.

1.2.16. Data Backup



The system performs automatic backups which are stored on the computer's hard drive. If data on the computer's hard disk are deleted or the hard drive is otherwise damaged, data loss will result. Please periodically backup analysis data and analysis parameters to other mobile storage devices.

1.2.17. Disposing of the Instrument



Some substances contained in the analyzer are subject to anti-pollution regulations during disposal. Please adhere to local waste disposal standards when disposing of the analyzer.

2. Installation

2.1. Installation

This auto chemistry analyzers should only be installed by HETO or an authorized HETO agent and the customer must provide an appropriate environment and space for the installation. When the analyzer needs to be relocated, please contact HETO or an authorized HETO agent. When you receive your analyzer, please immediately notify HETO and the authorized local HETO agent in your area..

Contact information for HETO:

1) Contact Address: 4/F Building No.4, Shenzhen Environmental Protection Industrial Park, No.31 Makan South Road, Nanshan District, 518055, Shenzhen, P.R.China

2) Telephone: +86-755-28935967,

3) Email: sales@hetomedical.com,

4) Website URL: www.hetomedical.com

2.2. Damage Inspections

All analyzers are subject to a strict inspection by HETO before packing and shipping. After you have received your analyzer, before opening the packaging, perform a thorough inspection and note whether any of the following damage is present:

1) Packaging is inverted or misshapen;

2) Packaging has obvious signs of water damage;

3) Packaging has obvious signs of being hit;

4) Packaging shows signs of having been previously opened:

If you notice any of the above instances of damage, please immediately notify HETO and the authorized local HETO agent in your area..

If the packaging is intact, open the box while HETO staff and/or authorized agent personnel are present, and perform the following checks once the packaging has been opened:

1) Verify that all equipment parts are present using the packing list contained inside the box;

2) Carefully check the appearance of all equipment, noting any cracks, impacts or deformation.

2.3. Installation Requirements

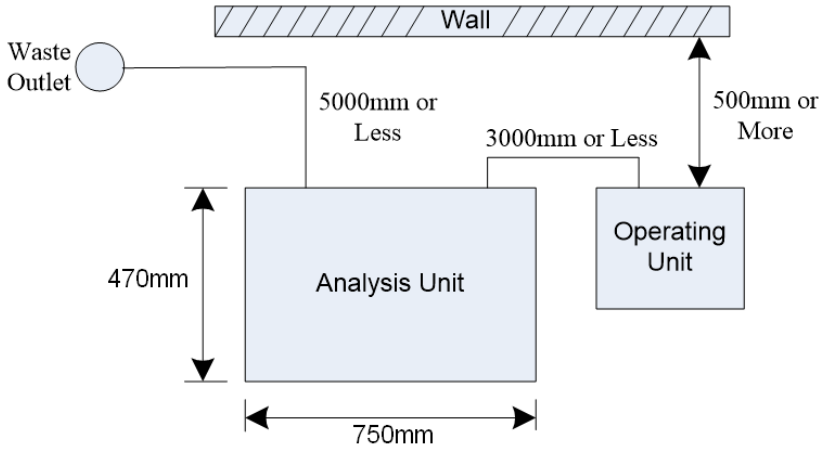
2.3.1. Environmental Requirements

2.3.1.1 Power Supply

1) 100-240V, 50/60Hz±1 Hz(recommended that the customer should use a UPS);
2) Proper grounding; grounding resistance less than 10mΩ; If the power supply is poorly grounded, a copper wire of impedance less than 0.1Ω should be connected to the rear of the device's analysis unit and buried directly in the ground.

2.3.1.2 Site and Space

1) The ground on which the device is placed should be level with an incline gradient of less than 1/200 and sufficient strength to withstand a weight of 75kg;
2) The environment should be free of dust as well as corrosive and flammable gases, heat and air sources, and mechanical vibration;
3) Avoid exposure to direct sunlight;
4) Air exchange with the outside with smooth circulation should be present; the ventilation source should not blow directly onto the analysis unit of the device;
5) The device should not be positioned close to brush-type motors and electrical contact equipment that is regularly switched on and off;
6) Space Requirements:



2.3.1.3 Temperature, Humidity and Atmospheric Pressure

1) Environmental Temperature: 10 °C - 30 °C.
2) Relative Humidity: 30% - 85%, non-condensing.
3) Atmospheric Pressure: 86.0 kPa - 106.0kPa.

2.3.2. Computer Requirements

The computer must meet the relevant safety requirements and be preloaded with Windows 7/10, with a CPU clock speed of 2.0 GHz or greater and more than 4.0GB of RAM. More than 40G hard space disk space.

Operation system : Win7 / Win 10

2.4. Water Supply and Drainage Requirements

2.4.1. Water Supply Requirements

1) The quality of water supplied to the device should comply with CAP Class 2 water standards;

2) Water Supply Volume: No less than 10 L/h;

3) If using water purification equipment, the water supply must be gravity-based;

4) The distance between the water supply device and biochemical analyzer inlet should not exceed 10 meters.

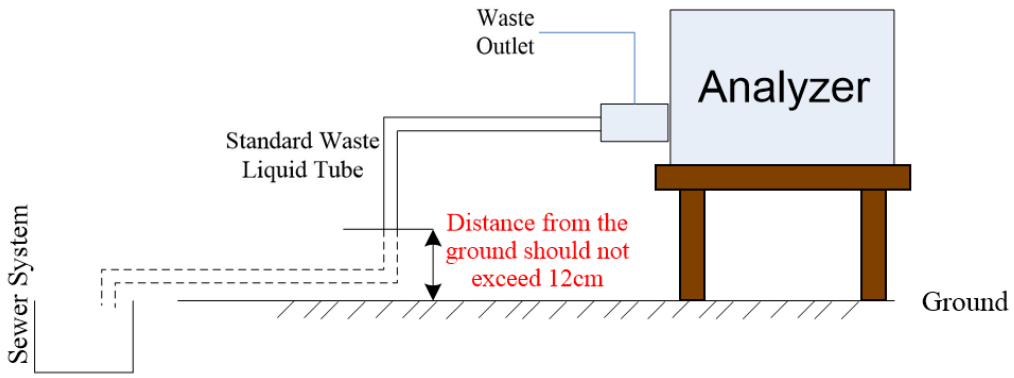
Notes:
The quality of water supplied to the device should comply with CAP Class 2 water standards.

2.4.2. Drainage Requirements

1) Please follow local environmental regulations when discharging waste liquid;

2) Connection to Waste Collection Container: The waste collection container can be on a horizontal surface below the instrument; it is important to ensure that the waste collection container be positioned lower than the waste liquid outlet on the left door of the device;

3) Connection to sewer system: The waste liquid discharge port should not be more than 12 cm from ground level;



4) Waste liquid tube length should not exceed 5 meters.

Biological Contamination:
During operation, be sure to wear protective gloves and clothing to prevent contamination.
Please process waste discharged by the biochemical analyzer according to your local waste emission standards.

2.5. Connecting Fluid Lines

For analyzer using internal cooling pump, please connect fluid lines as shown in the following Figure. A description is given below:

1) Connect the waste outlet tubes with the waste outlet connectors in the back side of analyzer, connect the other ends of tubes into waste container (please leave proper length and cut the waste tube before connecting). Waste Outlet discharges wastewater used to clean the device's probe, mixer and cuvettes; output from this outlet may be directly discharged to a municipal sewer system or waste liquid container;
2) Connect waste detector line with the waste detector connector, put the waste detector into waste container.
3) Connect the deionized water inlet tube with the water inlet connector in the left side of analyzer, put the end of the tube together with a filter which is connected with the tube into the water container. Deionized Water Inlet provides the analyzer with deionized purified water to wash the probe and mixer; this inlet may be directly connected to a purified water bucket.
4) Connect deionized water detector line with the deionized water detector connector, put the detector into water container.
5) The concentrated waste is combined by waste reagent and sample which need to be discharged into waste bucket. The “waste” from another port is the liquid from wash well which can be discharged to sewer or waste bucket.

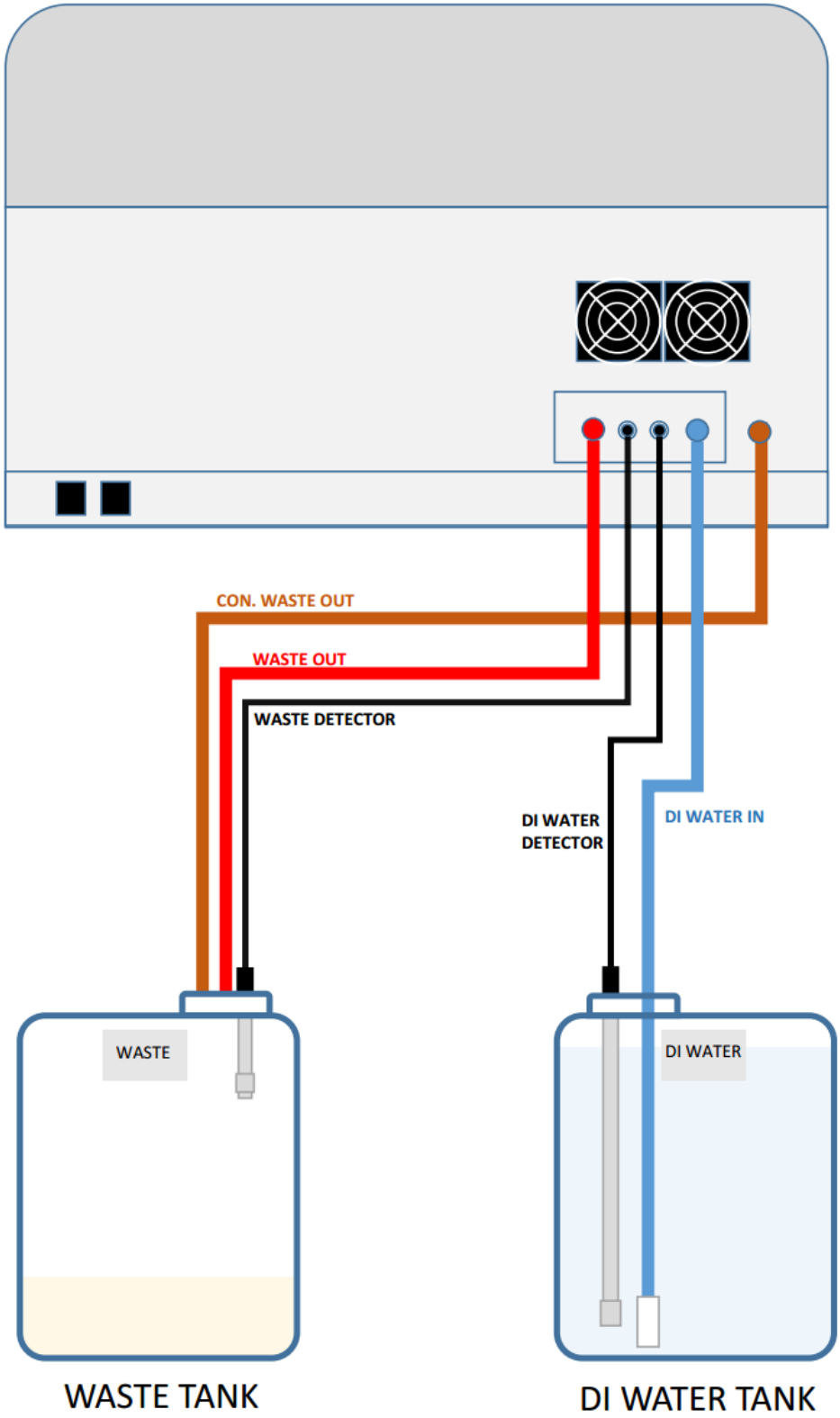


Notice:

Both DI water container and waste container should be set down to a lower place than the analyzer.

The DI water container opening should not be higher than the analyzer DI water inlet port, their distance should be within 1 meter.

The waste container opening should be lower than the analyzer waste outlet port.



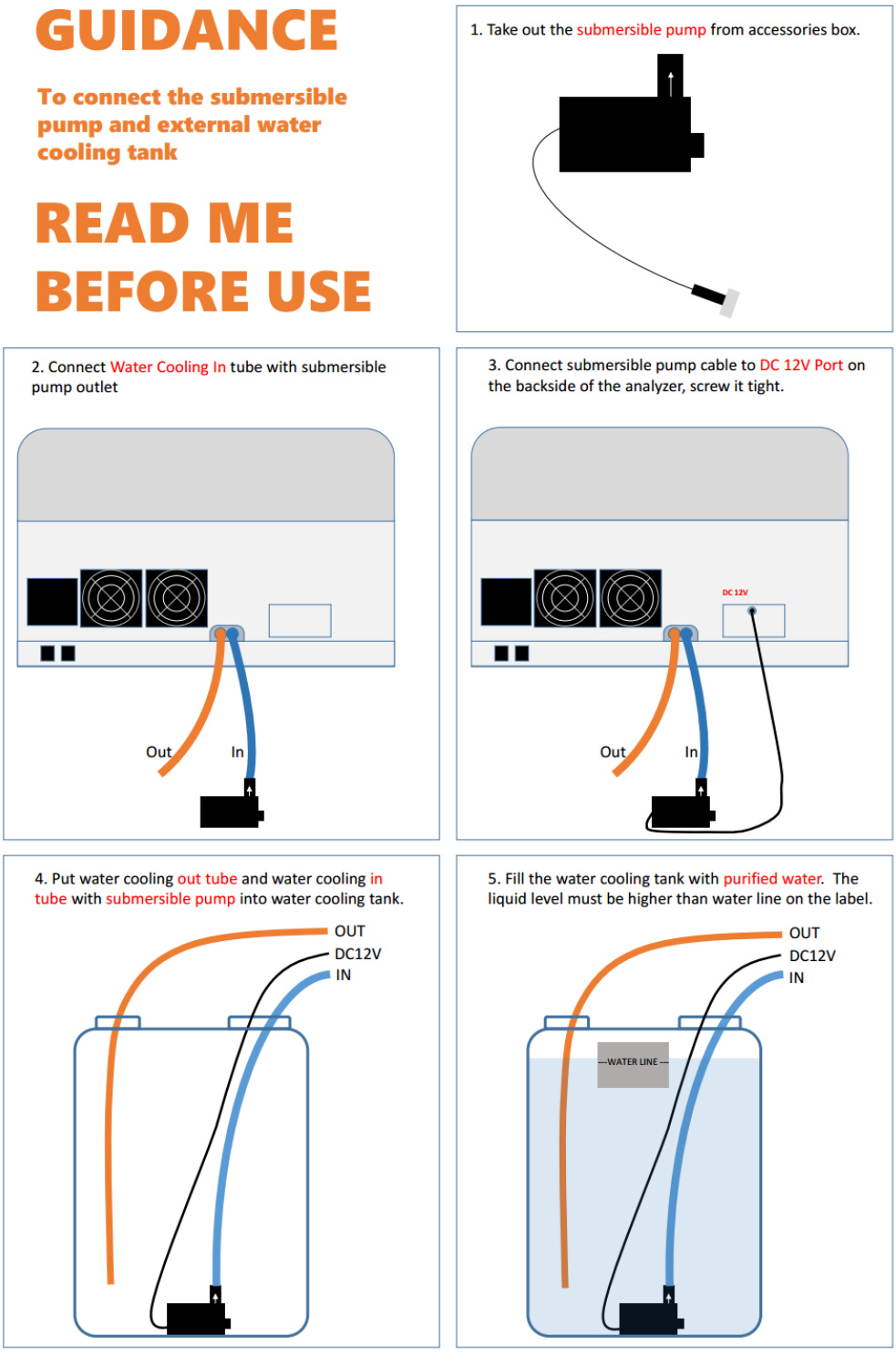
Notice:

For analyzer without auto wash function, there is no CON.WASTE OUT.

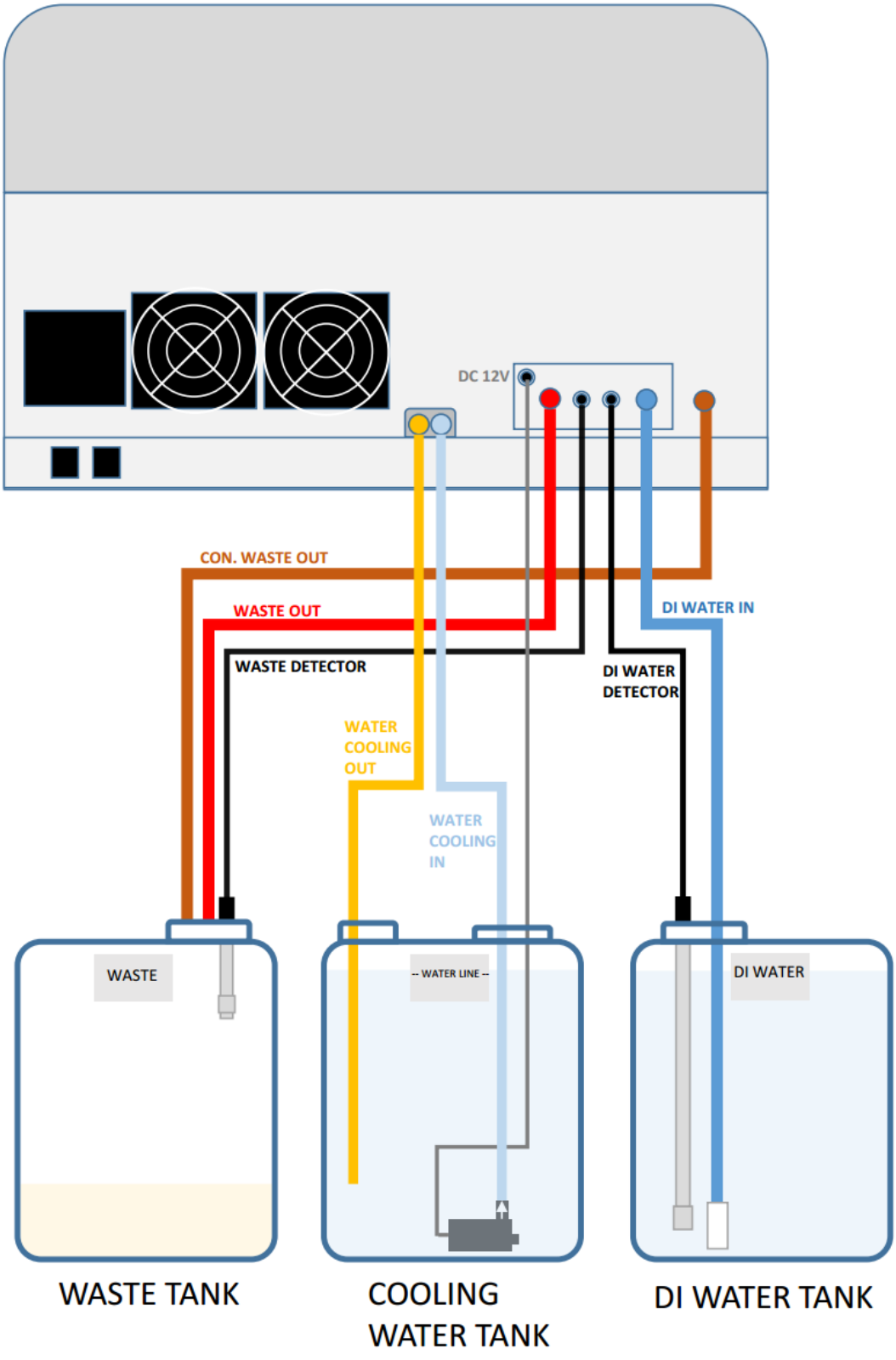
For analyzer using external submersible pump, please follow the instruction in Section 2.6.

2.6. Connect External Submersible Pump

For analyzer using external submersible pump only:



External tanks connection is shown as below:



Notice:

For analyzer without auto washing function, there is no CON.WASTE OUT.

2.7. Installing or Removing Sample /Reagent Disk

Operation

1) To load the reagent / sample disk, hold the handle in the middle of the reagent / sample disk firmly with your hand and align the alignment hole underneath the handle with the alignment pin in the middle of the reagent / sample refrigeration unit and place it down gently.

2) To remove the reagent / sample disk, pull to loosen the two lockers, raise the handle of the reagent / sample disk to the vertical position and remove the disk.

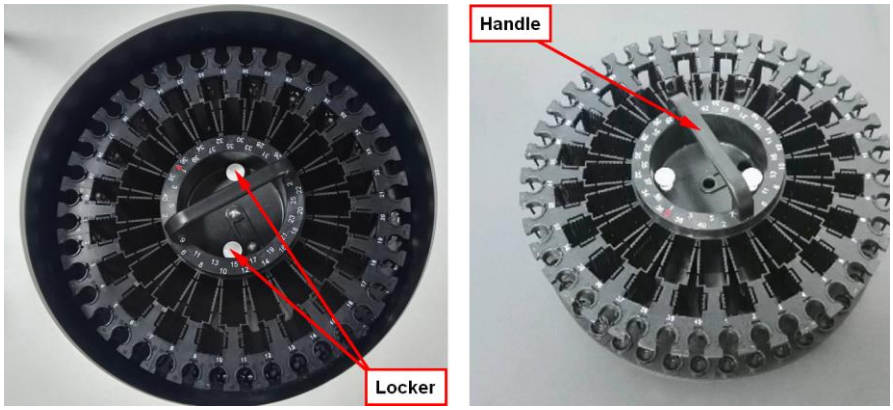


Figure 2-1: Diagram of the Reagent / Sample disk

Warning:

When inserting or removing the reagent / sample disk, first verify that all operating parts of the instrument, such as the Sample probe, mixer, cleaning mechanism, reaction disk and reagent / sample disk, have ceased operating.

Biological Contamination:

During operation, be sure to wear protective gloves and clothing to prevent contamination.

Notes:

1) When using the instrument, ensure that the reagent / sample disk cover is closed. Failure to do so may adversely affect the cooling system's functionality and result in damage to the sample probe.

2) The reagent / sample disk and refrigeration unit may be contaminated by samples during use. When a sample or reagent splashes onto the reagent / sample disk or refrigeration unit, wipe the affected area with a cloth or towel soaked in water or disinfectant after turning off the power supply of the analysis unit.

2.8. Loading and Unloading Sample Test Tubes

Operation

1) When loading vials, place the vials containing the desired samples in the sample apertures of the sample disk until they are fully inserted in their respective sample apertures.

2) When loading sample test tubes, place test tubes containing the desired samples in the sample apertures of the sample disk until they are fully inserted in their respective sample apertures.

3) When removing vials or sample test tubes, pinch the vial or sample test tube with your hand, raise it to the vertical position and remove.



Warning:
Before inserting or removing a sample tube, you should verify that the sample probe and sample disk of the analyzer have both ceased operating. Please do not use sample test tubes other than those within the specified size range.



Biological Contamination:
During operation, be sure to wear protective gloves and clothing to prevent contamination.

2.9. Loading and Unloading Reagent Bottles

Operation

1) When loading a reagent bottle, place the reagent bottle containing the desired reagent in the reagent bottle slot of the reagent disk until the bottom of the reagent bottle makes contact with the bottom of the reagent bottle slot.

2) When removing a reagent bottle, pinch the opening of the reagent bottle, raise it to the vertical position and remove.



Warning:
Before inserting or removing a reagent tube, you should verify that the reagent probe and reagent disk of the analyzer have both ceased operating.

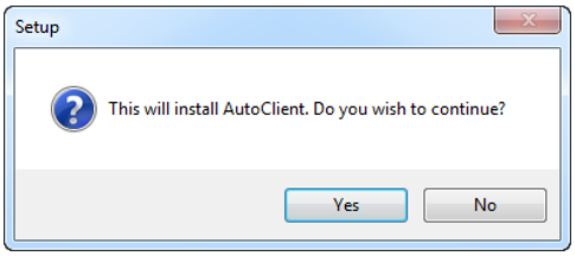


Biological Contamination:
During operation, be sure to wear protective gloves and clothing to prevent contamination.

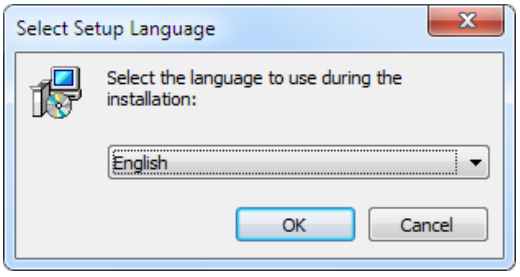
2.10. Installing the System Software

Operation

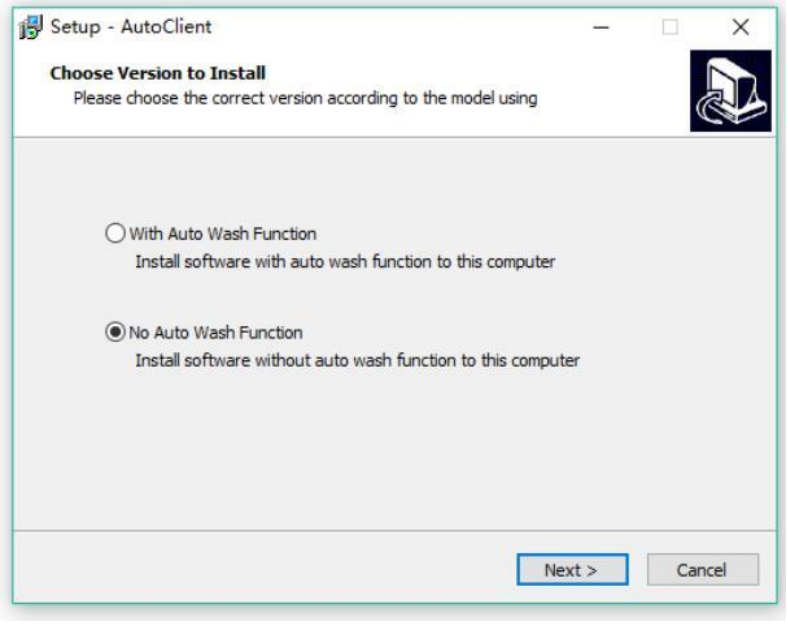
1) Turn off windows firewall and exit all antivirus program. Open the software CD and click on the exe file to begin the software program installation process. The following windows will appear.



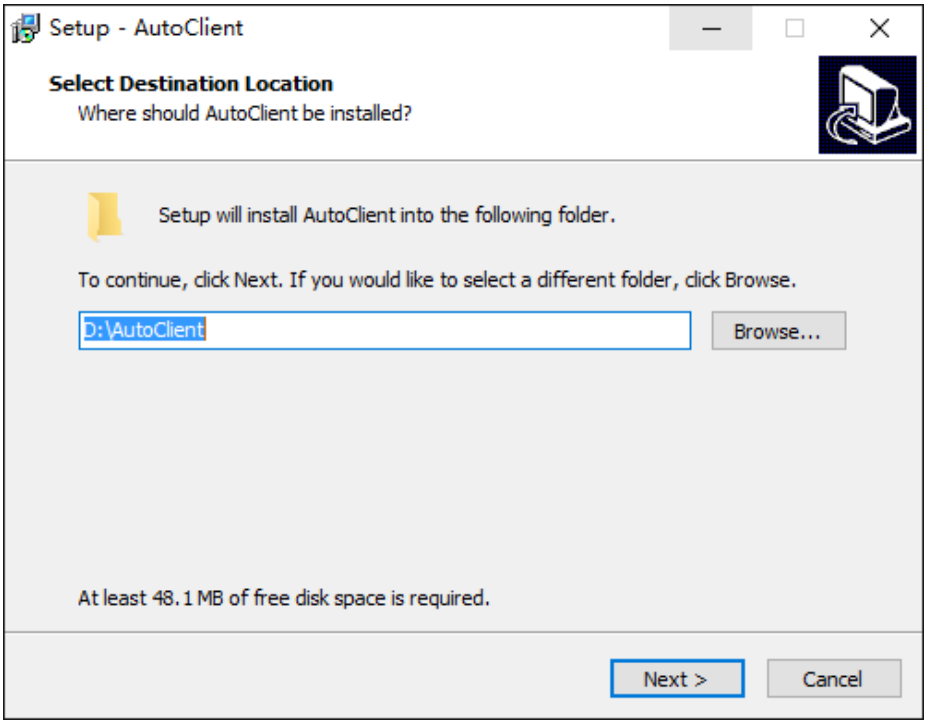
2) The following screen appears, select a language and click "OK" to continue. Select “English” first, later in the program you can change to other display language.



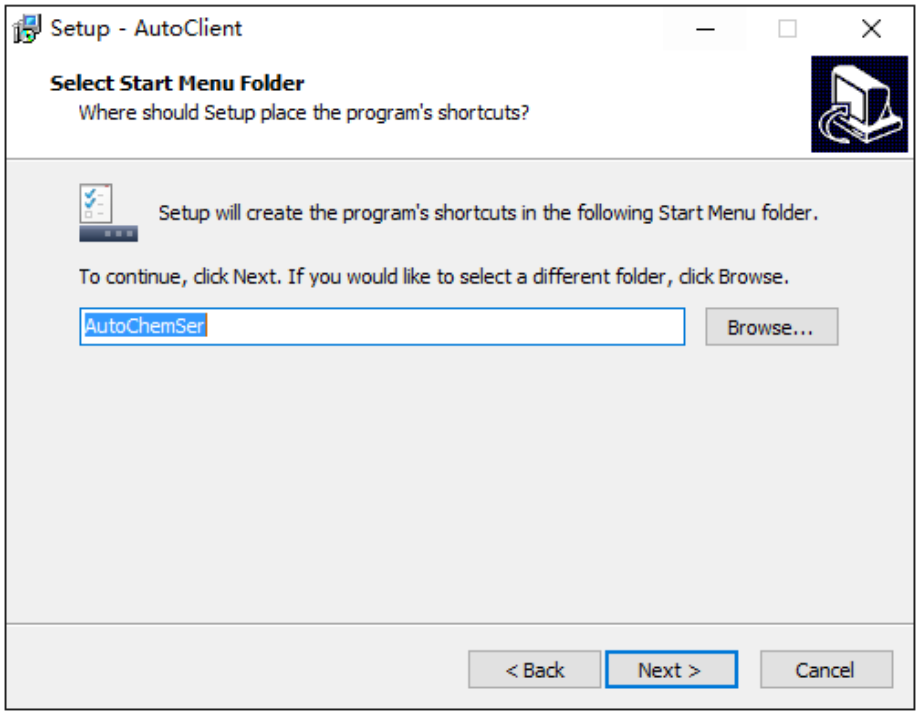
3) Choose the correct version according to whether the analyzer has auto wash function or not, click “Next” button.



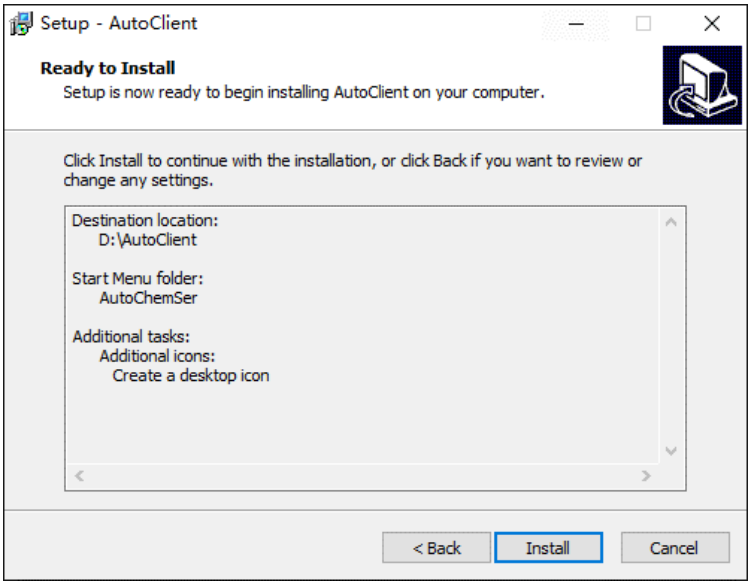
4) Click "Next" after choosing a folder to install the program. Default folder is recommended. .



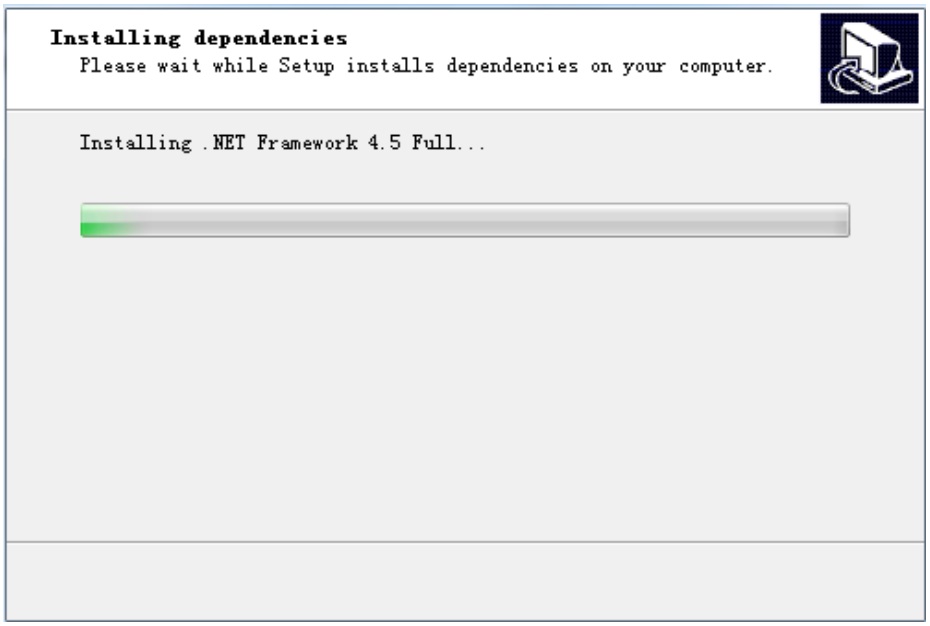
5) Click "Next" to continue.



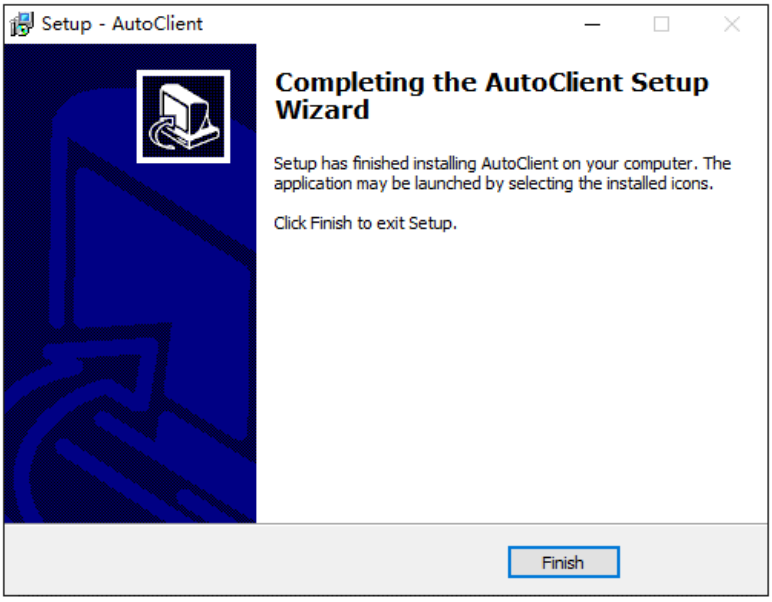
6) Click “Install”.



7) For the first time installation, it will automatically install .net framework 4.5 which may take a while for installation. Please wait.



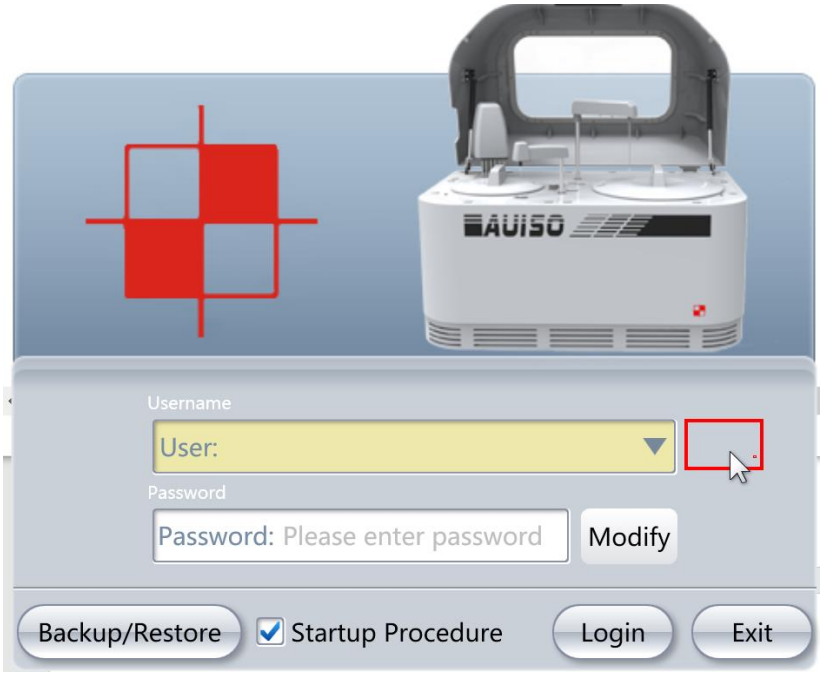
8) At the end of the installation, the following window will appear. Simply click the "Finish" button.



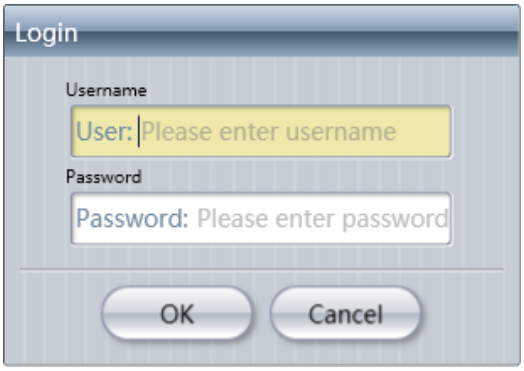
9) Once the above installation process is complete, the software is successfully installed. Double-click the software icon on the desktop to run the software.



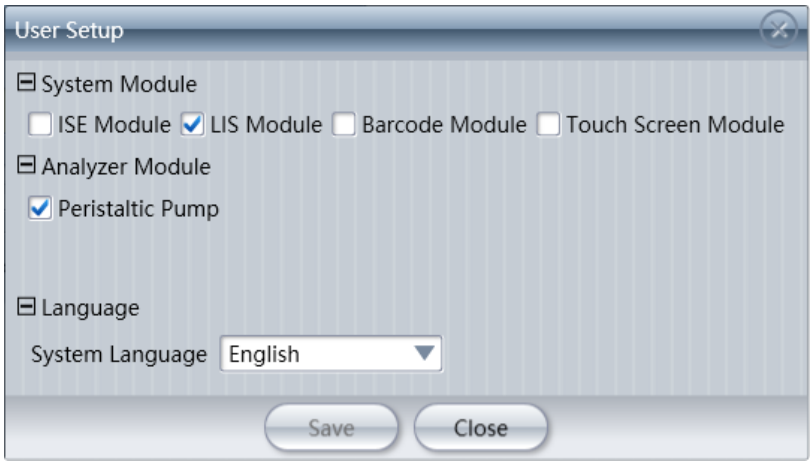
10) If you need to adjust optional modules or the display language, run the software and at the login screen, move the mouse to the area which is to the right side of the username box, and double click.



Use an account with rights to change the module configuration to log in.



11) Select the desired modules and functions, click “Save”. Peristaltic Pump must be selected for analyzer with auto wash function



Note:

1) The files in the disk is recommended to be copied to local disk. During software installation, the installation “AutoClient.exe” program and the “Dependencies” folder must be in the same directory.

2) For the analyzer which is configured with ISE module, Barcode scanner or Touch Screen Module, please tick to choose the corresponding modules in above step 10), otherwise the module will

3. Structure and Functions

This auto chemistry analyzer consists of two major components: one is the analysis unit and the other is the operating unit. The analysis unit automatically completes the operational process for each test, including washing reaction cuvettes, loading of the first reagent, sample loading, sample stirring, loading of the second reagent, stirring of the second reagent and absorbance measurements performed during the reaction process. The operating unit drives and controls the analysis unit during the completion of all analysis procedures.

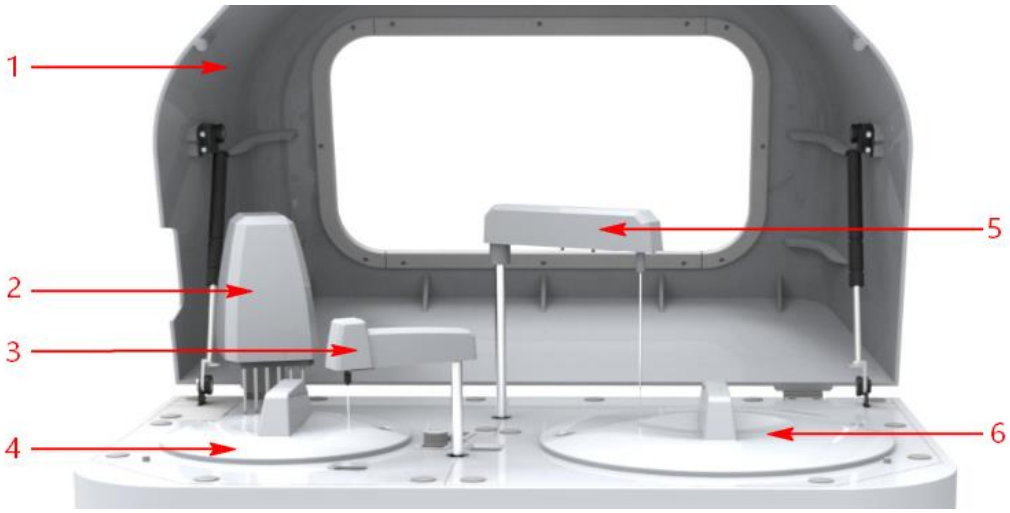
3.1. Composition of the Analysis Unit

3.1.1. Overall Structure



1 Main Enclosure 2 Front Cover 3. Tray

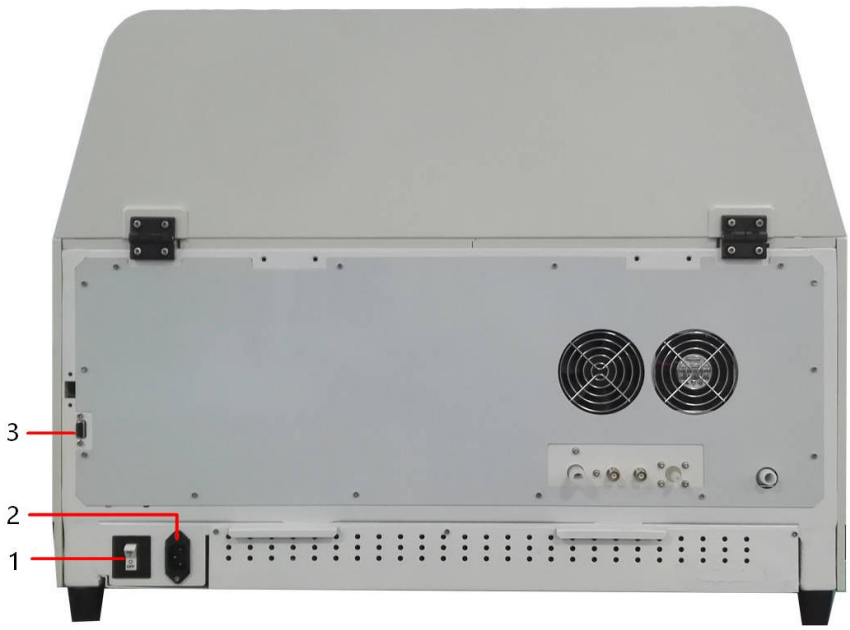
3.1.2. Top Structure



1: Main Enclosure
2: Automatic Cleaning Mechanism
3: Mixer
4: Reaction Disk
5: Reagent/Sample Probe
6: Reagent/Sample tray

3.1.3. Rear Structure

For analyzer with internal cooling pump:



For analyzer with external submersible pump:



1: Main Power Switch 2: Main Power Port 3: Communication Port (RS232)

3.1.4. Structure of the Left Side of the Analysis Unit



3.1.5.Structure of the Right Side of the Analysis Unit



1. Analysis Unit Power Switch

3.2. Function Module

3.2.1. Concentrate Wash Solution

For analyzer with auto wash function only:



Concentrated Wash solution

a) Function

Wash Concentrated Solution:

Used for cleaning the reaction cuvette, cleaning the reaction cuvette after prepared according to an automatic online dilution of concentrated wash solution : washing water = 1: 9 by volume.

Insert the tube left on the panel into wash concentrate wash solution bottle to use it directly.

b) Specification

Concentrated Cleaning Solution: 1000 ml

3.2.2. Wash Solution



c) Function

Alkaline Cleaning Solution:

Used to clean sample probe and the mixer.

Fill the bottle with Wash Dilution and put it in this slot.

d) Specification

Alkaline Cleaning Solution: 60 ml

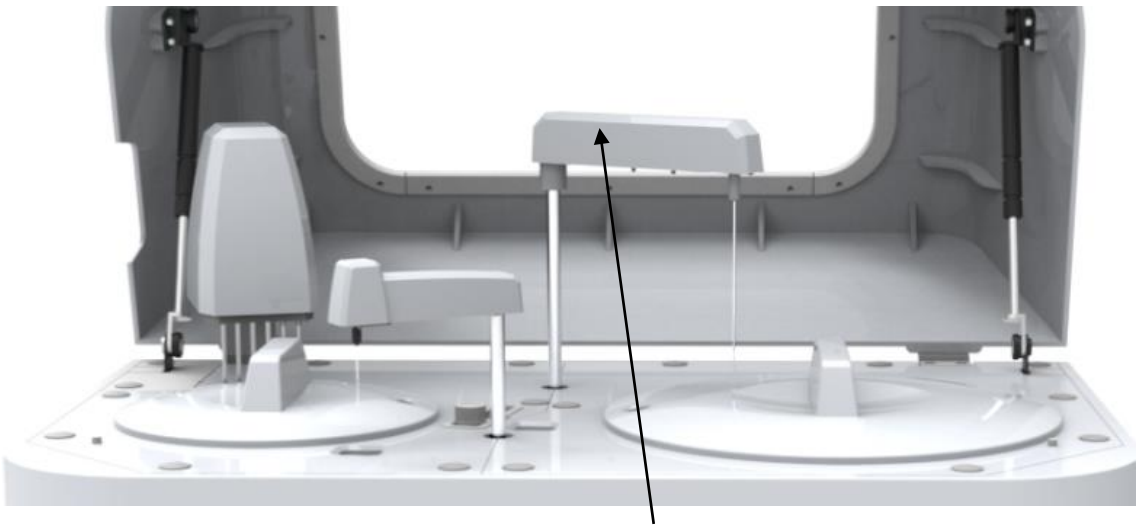
Notes:

1) We recommend using the following wash solutions: Alkaline Wash solution WASH DILUTION;
2) Acidic Enhanced Wash solution: 0.1 mol/L hydrochloric acid;
3) Alkaline Enhanced Wash solution: Sodium hypochlorite solution with an effective chlorine content of 0.5%.

We recommend daily use of HETO's proprietary WASH DILUTION alkaline cleaning solution for cleaning, as well as weekly use of both an acid enhanced cleaning solution and alkaline enhanced cleaning solution (one wash each).

Please use only cleaning solutions recommended by HETO. Failure to do so may result in a failure to obtain expected test results.

3.2.3. Sample Probe Mechanism



Sample probe mechanism

a) Function

Aspirates a predetermined amount of reagent/sample from a reagent/sample tube and dispenses the reagent/sample into a cuvette.

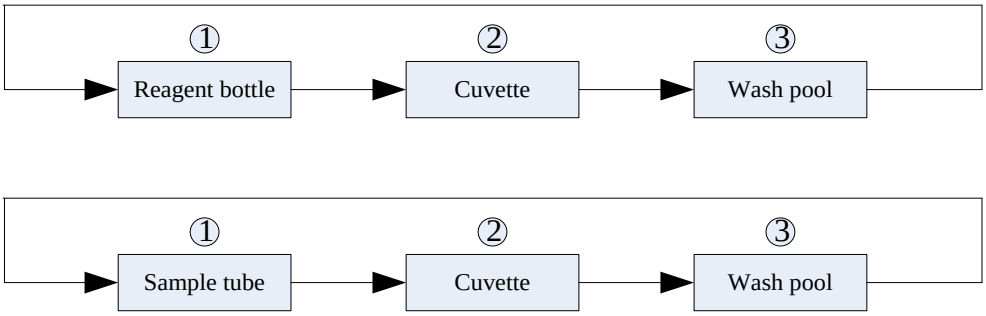
b) Specification

Reagent: 10 - 450 µL in 1 µL increment

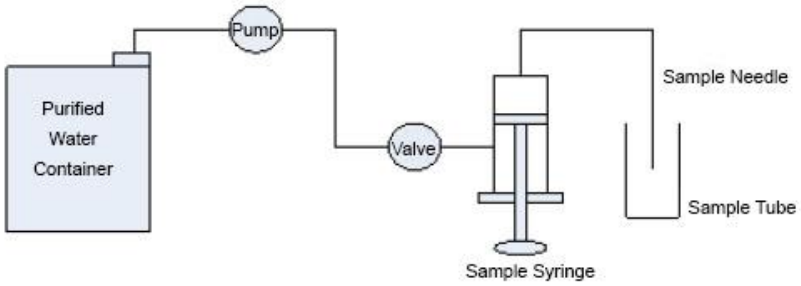
Sample: 2 - 50 µL in 0.1 µL increment

c) Action

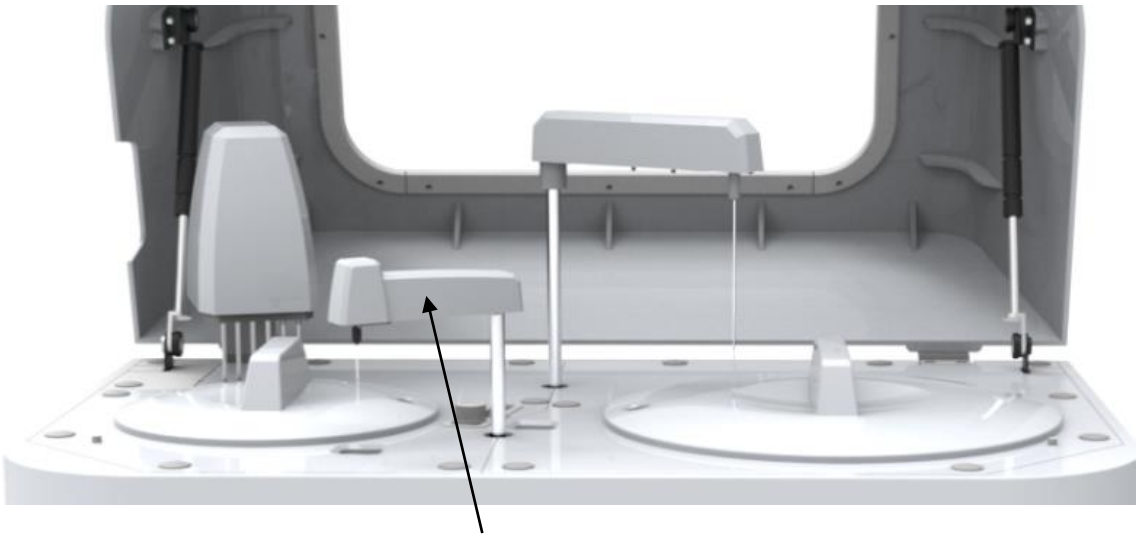
Raises and lowers in the following positions.



d) Fluid Line Diagram



3.2.4. Stirring Mechanism



Stirring Mechanism

a) Function

Stirs the reaction solution inside the cuvette.

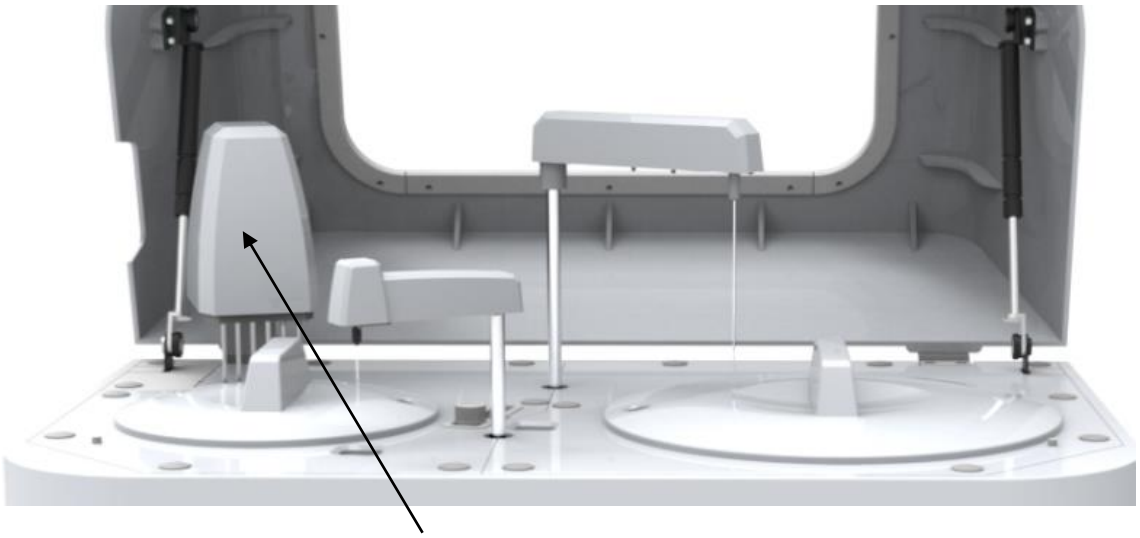
b) Action

Raises, lowers and rotates in the following positions.



3.2.5. Automatic Cleaning Mechanism

For analyzer with auto washing function only:



Automatic Cleaning Mechanism

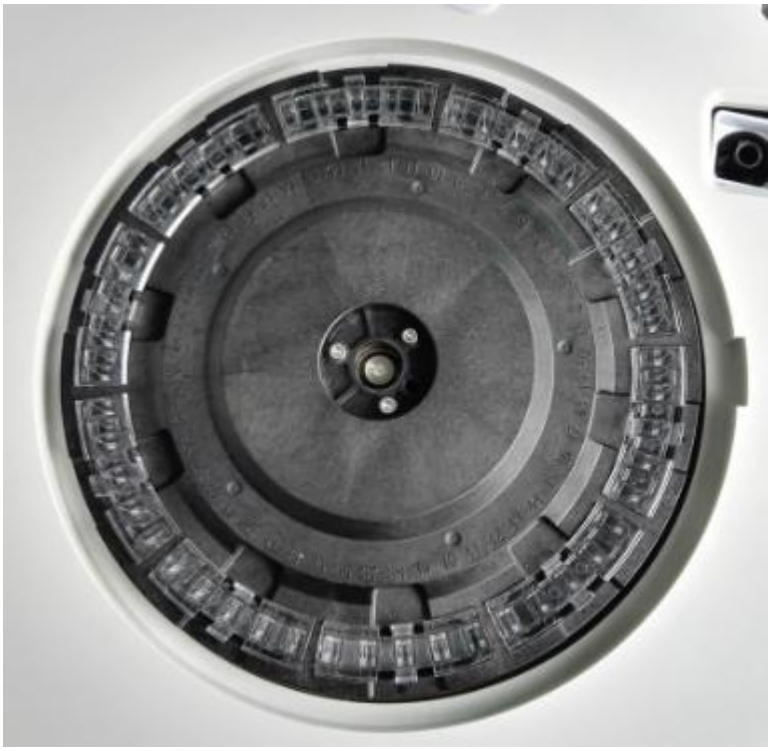
a) Function

automatically cleans cuvettes.

b) Action

Moves up and down in the reaction cuvette, drawing up the reaction solution completely and filling the cuvette with deionized water and concentrated wash solution.

3.2.6. Reaction Disk



Reaction disk

a) Function

Load the cuvette and allow the sample and reagents to react at 37°C in the reaction Compartment. Colorimetric measurements are carried out directly using the cuvette.

b) Specification

Number of Cuvettes: 50;

Cuvette Materials: Semi-permanent Ultraviolet transmission specialty plastic;

Specification 5*5*30 (mm);

Optical Path Length: 5 mm;

c) Action

Clockwise rotation.

3.2.7. Thermostatic Groove



Reaction Compartment Structure

a) Function

Maintains a temperature of 37°C for the reaction solution contained in the cuvette.

b) Specification

Rated Temperature: 37°C;

Temperature Accuracy: 37°C ± 0.3°C;

Temperature Fluctuation: ± 0.2°C.

3.2.8. Reagent / Sample Disk



Reagent / Sample disk

a) Function

Various reagent bottle / sample tube carriers can be used to move reagent bottles / sample tubes over to the Sample probe Sample location via rotation.

b) Specification

Disc with three concentric circles for a total of 40 reagent / 40 sample positions.

The sample disk is compatible with the following sample containers:

Miniature Sample Vials: Φ12×37mm, Φ14×25mm;

Traditional Blood Collection Tubes: Φ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13 × 75 mm, Φ13 × 95 mm, Φ13 × 100 mm;

Plastic Test Tubes: Φ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13 × 75 mm, Φ13 × 95 mm, Φ13 × 100 mm.

The sizes of reagent bottles which can be used with the reagent disk are 30 ml and 15 ml for the inner and outer rings respectively.

Notes:

1) Sample Position No. 40 is used exclusively for reagent blank samples. Please only insert sample tubes containing de-ionized water or saline solution to provide a blank sample for use during reagent blank testing.

c) Action

Clockwise and counterclockwise rotation.

3.2.9. Reagent Refrigerator



Reagent Refrigerator

a) Function

Insert the reagent and sample disks to refrigerate reagents.

b) Specification

Refrigeration of all reagents at a temperature of 4 - 12°C.

3.2.10. Optical System

a) Function

Measure the absorbance of the reaction solution inside the cuvette during rotation of the reaction disk.

b) Specification

Wavelengths: 340, 405, 450, 510, 546, 578, 630 and 670 nm; total 8 wavelengths;

Number of simultaneously detectable wavelengths: One or two wavelengths can be simultaneously measured;

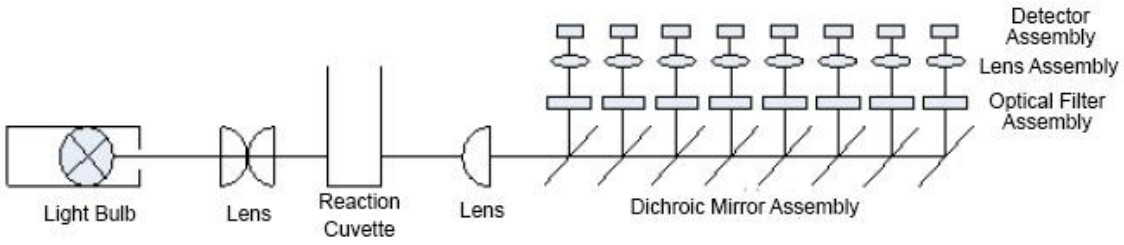
Wavelength Accuracy: ± 2nm;

Half-Wave Width: Less than 12nm;

Inspection Element: Photodiode array;

Source: Tungsten halogen lamp, 12V 20W;

c) Diagram



4. Detailed Operating Procedure

All pictures in this section show examples only; please perform operations according to the actual interface displayed.

4.1. Operating Software

4.1.1. Basic Procedure for Logging In

The basic procedure is as follows:

1) Find the shortcut for the operating software as shown below and double-click it to start the software:



Figure 4-1: The shortcut icon of the operating software

2) In the software login screen that pops up (see Figure 4-2), enter an appropriate username and password to log into the software. In the login screen, you can also select the startup procedures, change the login password and perform database backup / restore operations.

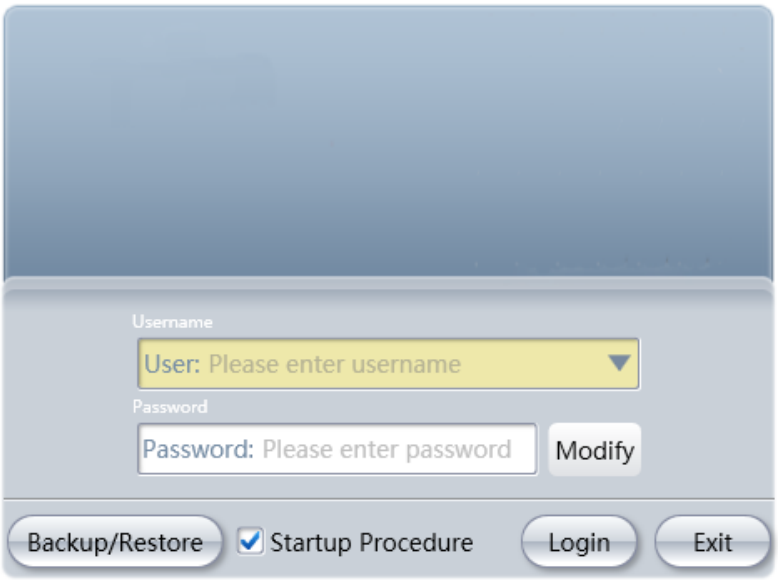
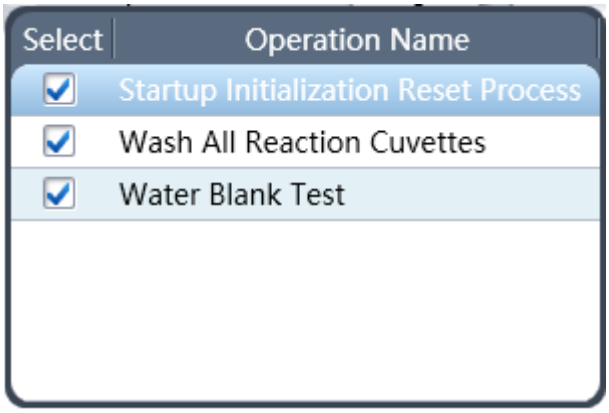


Figure 4-2: Main interface of the operating software

Note: The first time log in this program, in the “Startup Procedure”, please choose all procedures then click “Login” button.



Startup Initializtion Reset Process: To reset all mechanism parts, must be selected everytime log in the program.

Wash All Reaction Cuvettes: For analyzer with auto washing function only. To wash all 50 cuvettes after all mechanism parts reset.

Water Blank Test: For analyzer with auto washing function only. To perform a water blank test after washing all cuvettes.

4.2. Interface Layout

The operating interface of this auto chemistry analyzer includes a function menu area, function display area, status bar and alert message area, as shown below:

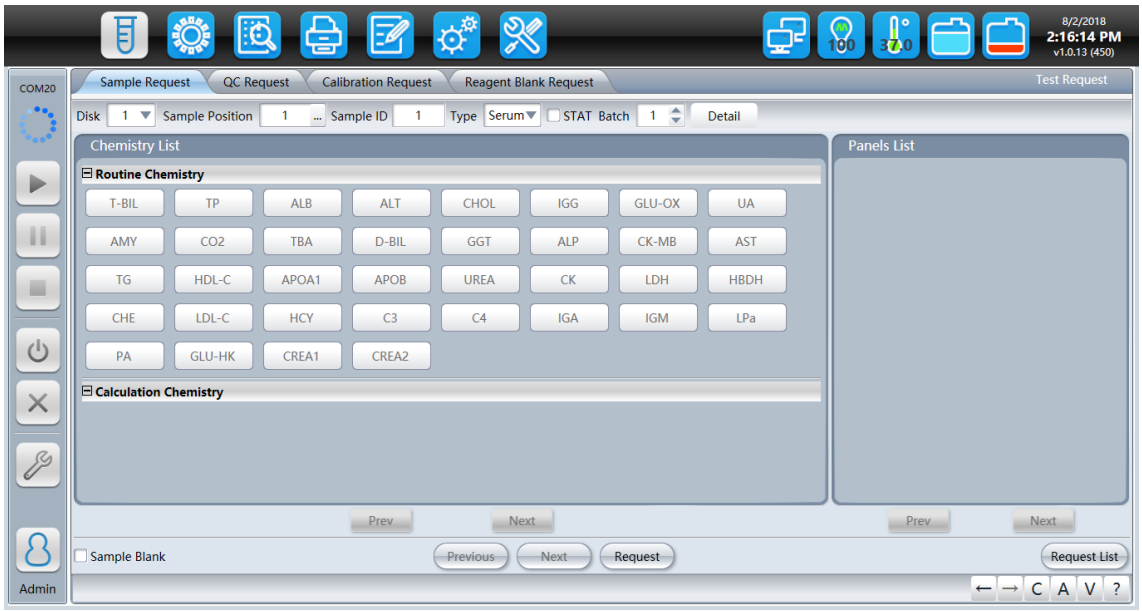


Figure 4-3: Main interface of the operating software

4.2.1. Function Menu Area

There are seven major menus within the operating system and each major menu includes submenus organized by function for changing corresponding settings and performing corresponding operations. A detailed description is provided below:

1) Test Request Include 4 submenus: sample request, QC request, calibration request and reagent blank request. Also supports functions such as the input of patient information as well as the release of sample position and sample ID.
2) Online Status Include 4 submenus: sample disk, reagent disk, reaction disk and test list.
3) Result Include 4 submenus: sample, QC, calibration and reagent blank.
4) Statistics Include 4 submenus: test statistics, workload statistics, charge statistics and result statistics.
5) Parameter Include 6 submenus: routine chemistry, calculation chemistry, Panels, Carryover, calibrator setup and QC setup.
6) Function Setup Include 5 submenus: system setup, hospital setup, user manage, print setup, and barcode setup.
7) System Maintenance Include 5 submenus: routine maintenance, log management, temperature curve, AD curve and probes parameters.

4.2.2. Submenu Function Key Area

Each submenu is assigned different function keys according to their different functions. The specific features of each submenu will be discussed in detail in each submenu's section in this manual.

4.2.3. Shortcut Button Area

4.2.3.1. Start

Button: 

Description of Function: Initiates tests that need to be started.
Basic operational steps:

1) Click on the Start  button in the Shortcut Button Area to bring up the test start dialog box as shown below:

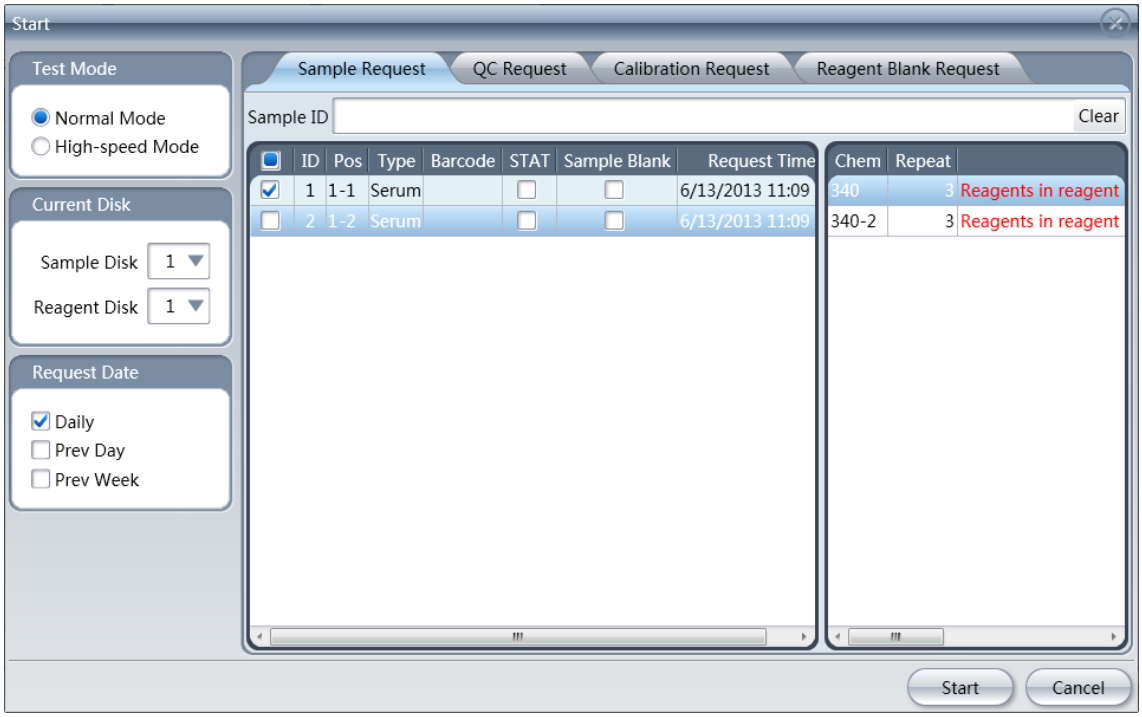


Figure 4-4: "Start Test" Screen

2) Select the required test modes, sample disk, reagent disk, and the date of the application;

3) Select the type of test;

4) Enter the test sample number range needed to start the test or directly enter a sample number; in the event that no input is given, the software will start all tests by default (including calibration, quality control and sample tests for which an application was made);

5) Click the "Start" button to confirm that you want to start the test or click the "Cancel" button to cancel starting the test.

4.2.3.2. Suspension of Pipetting

Button: 

Description of Function:

Suspends all ongoing tests for which R1 has not yet been added. Tests for which R1 has already been added will continue with the addition of S (sample) and R2 to complete the test. When pipetting is suspended, the reaction disk will continue to run; The sample disk and sample probe stop, after which operations such as the addition of reagent can be performed.

Basic Operational Steps:

Click on the "Pause" button in the right shortcut button area; Click "Yes" in the dialog box that pops up; The instrument will perform a pipetting suspension operation; After pipetting is suspended, click the "Start" button on the right side of the screen to resume testing.

4.2.3.3. Stop

Button: 

Description of Function:

The system will stop all ongoing testing and unfinished tests will be voided.

Basic Operation:

Click on the "Stop" button in the right shortcut button area and click the "OK" button in the dialog box that pops up. The analyzer will stop immediately; If you do not want to stop current testing, click the "Cancel" button.



Notes:

After performing a stop operation, tests for which test results have not been calculated will be voided.

4.2.3.4. Shut Down

Button: 

Description of Function: Performs a system shutdown

Basic operational steps:

Click on the "shutdown" button in the right shortcut button area to bring up the following dialog box and select a shutdown mode as needed:



Figure 4-5: The shutdown screen

For analyzer with auto wash function:

If you wish to perform a standard routine shutdown, click on the "OK" button directly;

If you anticipate that the machine will not be turned on for a long period of time (several days), first click on the "Long holiday shutdown" radio button and then click the "OK" button.

Notes:

When a standard routine shutdown is performed the system cuvette will be filled with purified water; When a "Long holiday shutdown" shutdown is performed all water in the system cuvette will be drawn out. Select "Turn off computer" to automatically turn off the computer after system shutdown. (For analyzer without auto wash function, only “Turn Off Computer” option is displayed)

4.2.3.5. Emergency Shutdown

Button: 

Description of Function:

This operation should only be performed when the analyzer malfunctions during operation or there is an error which requires an emergency stop of the instrument. During an emergency shutdown, the analyzer does not perform any shutdown process before exiting - the instrument stops running and all incomplete tests will be voided.

Basic Operational Steps:

Click the "Emergency Shutdown" button and click the "Yes" button in the dialog box that pops up to immediately exit the software; If you do not want to perform an emergency shutdown, click the "No" button.

4.2.3.6. Routine Maintenance

Button: 

Description of Function:

Using the routine maintenance shortcut, you can quickly enter the routine maintenance interface and perform routine maintenance operations on the instrument.

Basic Operational Steps:

Click "Routine Maintenance" and, after entering the "Routine Maintenance" menu, select the maintenance operations that need to be performed in order to execute them.

4.2.3.7. Lock System

Button: 

Description of Function:

While the system is running, the user can lock the system or switch the user operating the machine.

Basic Operational Steps:

Click the button to enter the "Lock system" screen and the system will be locked; If you need to unlock the machine or switch users, enter the appropriate username and password.

4.2.4. Function Display Area

Displays information such as various data for corresponding menus when you click on a function menu or submenu.

4.2.5. Status Bar

Displays the lamp, temperature, purified water container, waste liquid container and LIS connection status. Purified water container and waste liquid container statuses are directly displayed as icons and cannot be interacted with;

Lis icon : Double click the LIS icon to open the LIS Settings dialog box where you can setup and connect to LIS.

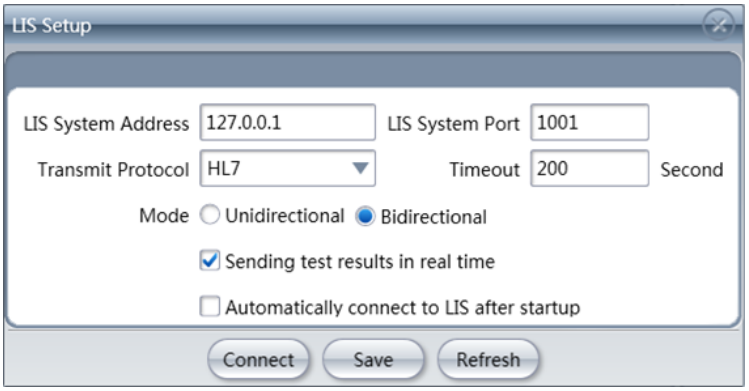
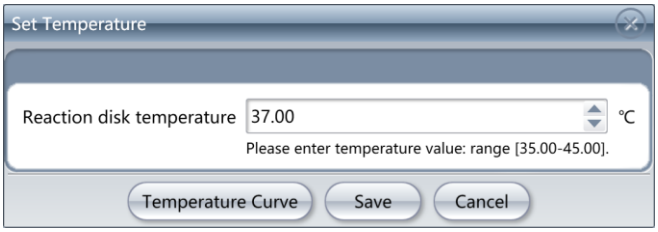
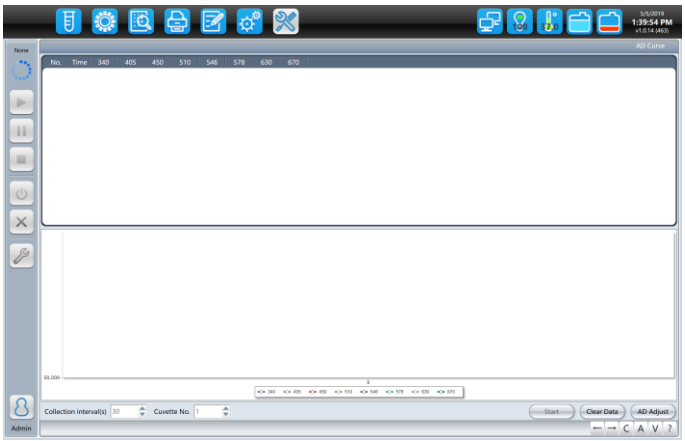


Figure 4-6: "LIS" Setup Interface Screen

Temperature icon : Double click temperature icon to set target temperature of reaction disk.



Lamp icon : Double click the lamp icon to open AD curve detection screen.



DI water icon : The sensor will detect signal after DI water used out, and it will show

exclamation mark in the DI water icon.

Waste icon : The sensor will detect the signal after waste tank is full, and it will show exclamation mark in the waste icon.

4.2.6. Message Alert Area

When using certain functions such as requesting tests, etc. or if the system malfunctions or experiences an error, the information bar will display corresponding information or warnings; the following function buttons are available:

"C": Clear the current message.

"A": Alarm/Error. Click to view information recorded by the system related to various errors.

"V": Version. Check the software name and version information

: View the "previous" or "next" message

: View help information

4.3. Test Request

Requests for sample, quality control, calibration and reagent blank testing can be made via the Test Request menu. The menu also supports various functions such as the entry of patient information, selection of sample numbers, batch requests, retesting, dilution testing, etc.

4.3.1. Sample Request

In the Sample Request menu, the user can request sample tests and can specify emergency or batch sample requests based on the actual requirements of the user. At the same time, special functions such as sample blank testing, repeat testing and repeated dilution and automatic dilution testing can also be requested; The history of requested items can be checked or cleared in the Request List Menu.

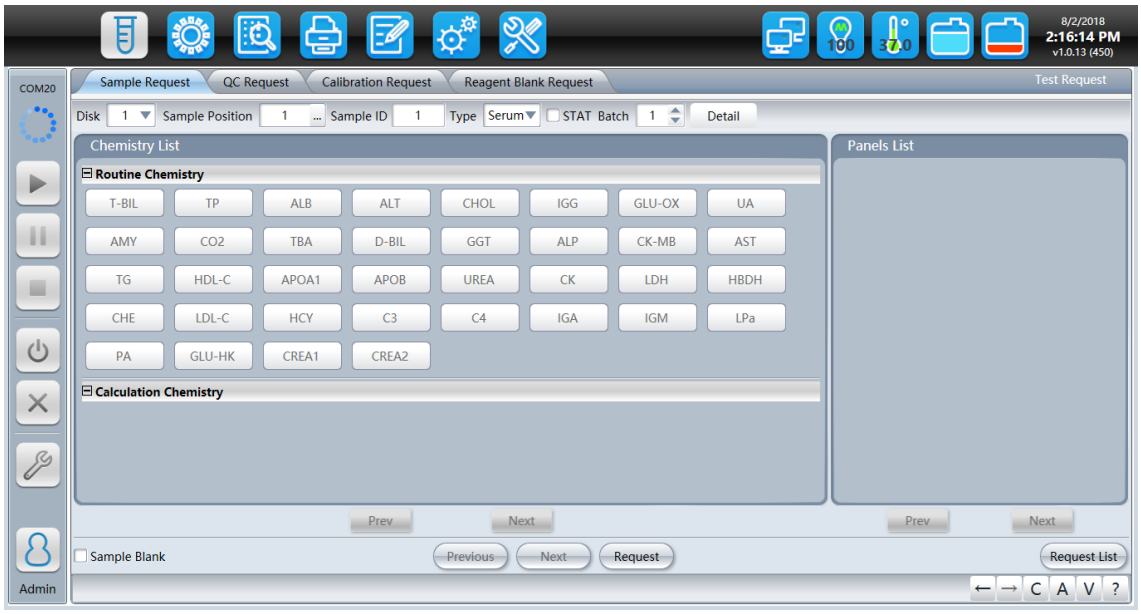


Figure 4-7: The "Sample Request" Screen

4.3.1.1. Introduction of Basic Parameters

For an explanation of the meanings of various "Sample Request" screen parameters, consult the following table:

Parameter	Meaning
Disk	Set to 5 by Default. Selection is made via a drop-down menu.
Sample Position	Refers to the disk position number (total of 40 possible) of the selected sample. The number can be entered directly or you can click ... on the right of the screen to select a number from the sample disk empty vial list

Parameter	Meaning
Sample ID	Refers to the number of the test sample. This parameter can be entered directly into the corresponding box and once the request is successful it increases in ascending order; can enter a prefix and suffix
Type	Allows the user to select the sample type; selection is made via a drop-down menu
STAT	When checked, the currently requested sample is designated as an emergency sample and given priority during testing
Batch	Enter the batch number directly into the corresponding box to simultaneously request multiple samples
Detail	Click to enter the detailed information input interface and enter detailed information regarding a specific sample
Chemistry List	Show all items and directly select specific requests based on your testing needs
Panels List	Show panels and directly select specific requests based on your testing needs
Prev	Click to look at the item list on the previous page
Next	Click to look at the item list on the next page

4.3.1.2. Details

Detailed information on the sample and patient corresponding to the sample.

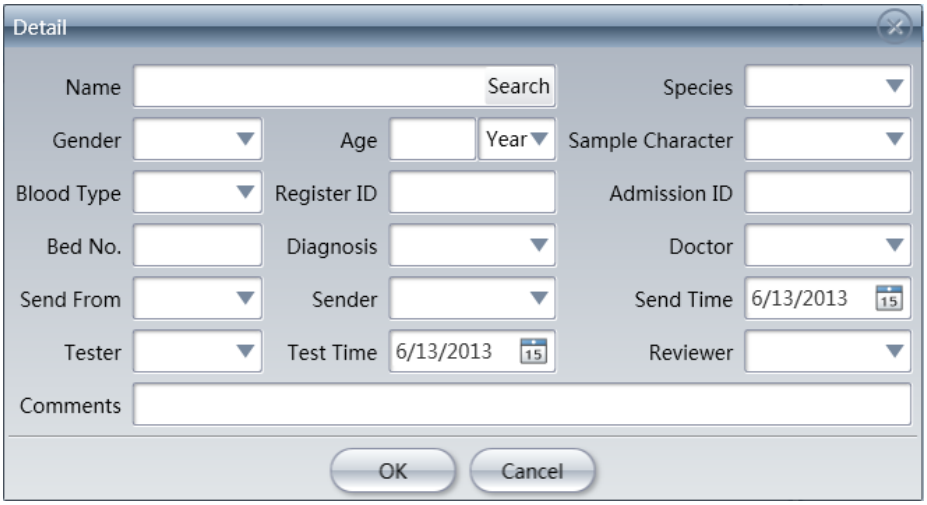


Figure 4-8: "Details" Screen

For explanations of different parameters and operations corresponding to the "Details" screen, see the following table:

Parameter	**Meaning**	**Operation**
Name	Current patient information	Input directly into the box
Gender	Gender of the current patient	Selected from the drop-down box
Age	Age of the current patient	Data is directly entered into the first box and a selection from a drop-down menu is made for the second box
Species	Current sample source type	Selected from a drop-down box
Blood Bag	Number of the blood bag corresponding to the current sample	Input directly into the box
Sample Character	Outward appearance of the sample	Selected from the drop-down box
Blood Type	Blood type of the current patient	Selected from the drop-down box
Register ID	Outpatient number of the current patient	Input directly into the box
Admission ID	Inpatient number of the current patient	Input directly into the box
Bed No.	Bed number of the current patient	Input directly into the box
Diagnosis	Clinical diagnosis of the current patient	Can select from the drop-down box or enter data directly
Doctor	Current patient's attending physician	Can select from the drop-down box or enter data directly
Send From	Department where the current patient resides	Can select from the drop-down box or enter data directly
Sender	Physician who requested the current sample	Can select from the drop-down box or enter data directly

Parameter	Meaning	Operation
Test Time	Time of sample testing	Can enter data directly or select by clicking
Send Time	Time of sample submission	Can enter data directly or select by clicking
Tester	Physician responsible for testing the patient's sample	Can select from the drop-down box or enter data directly
Reviewer	Person making an audit and inspection report	Can select from the drop-down box or enter data directly
Comments	Indicates special circumstances concerning the present sample or other related information	Input directly
OK	Saves patient information	Click to save the patient's information
Cancel	Cancels the registration of patient information	Click to return to the previous screen

4.3.1.3. Introduction to Application Features

The Sample Request screen features a number of function buttons including sample blank and repeated testing as well as dilution testing. The user can request each sample independently based on their specific requirements; The user can also set default conditions in order to perform default requests for all samples. After a corresponding default function is checked, it becomes valid for all items, but can be modified manually.

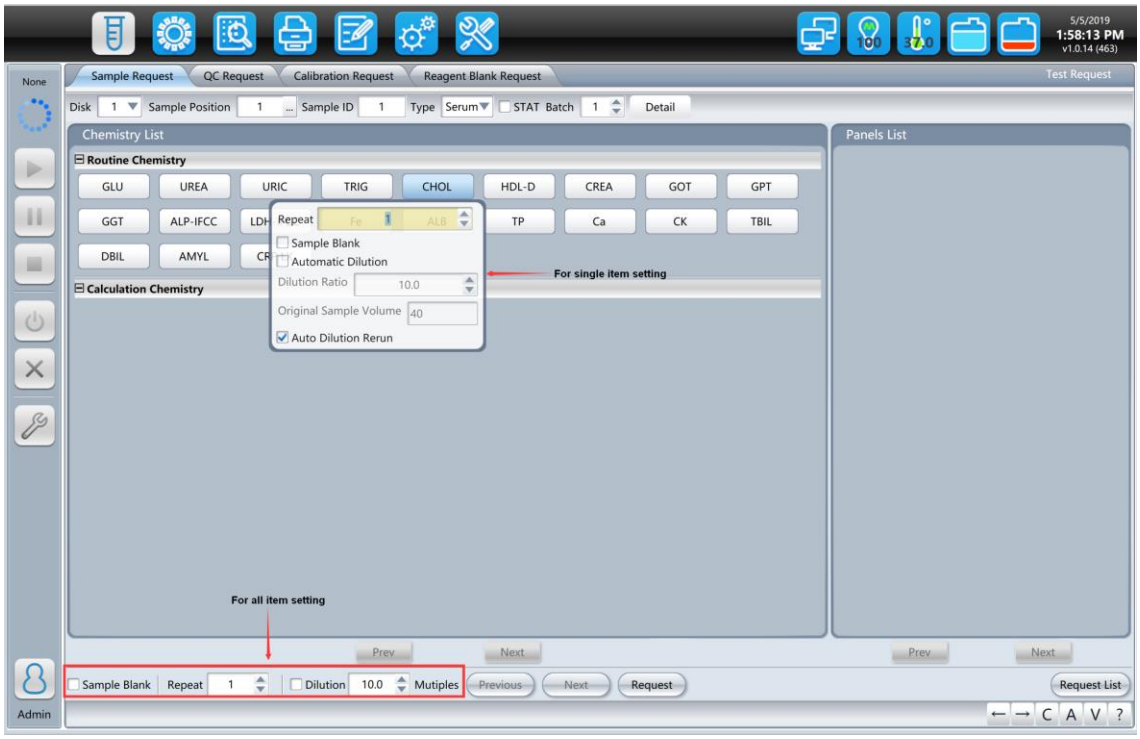


Figure 4-9: "Sample Application" Screen Function Key Schematic

Each function button and a corresponding explanation is given below:

Button	**Explanation and Operation of Function**
Sample Blank	When checked, a sample blank test is requested by default
Repeat	Indicates the number of times a test is repeated; can enter the desired number of repetitions after checking
Dilution	Sample dilution test; can set the dilution parameters according to specific requirements
Auto Dilution Rerun	When checked, the system will automatically determine whether or not the test results necessitate a dilution retest based on the automatic dilution rerun conditions specified.
Request	Sample Test Request

Button	Explanation and Operation of Function
Request List	View already-requested samples and the project; can perform delete operations

4.3.1.4. Sample Program

Basic operational steps:

1) Enter the "Test Request - Sample Request" menu;
2) Select the sample disk number, sample position and sample type;
3) Enter the sample ID;
4) Choose whether or not the sample corresponds to an emergency or is a batch sample and input detailed information according to actual clinical conditions;
5) Click the item that needs to be measured in the in the Chemistry List. Click once to select and click again to cancel the selection. Or, click the specified combination in the Panels Selection Screen. Click once to select and click again to cancel the selection.
6) Click the "Request" button to open up a pop-up box;
7) View or delete application records in the request list.

4.3.1.5. Repeat Test

When requesting a sample, enter the number of times a given test is to be repeated into the "Repeat" function selection for the relevant project. Takes effect once the request is successful.

4.3.1.6. Sample Blank

When requesting a sample, select whether or not to test a "Sample Blank" for the relevant project. Takes effect once the request is successful.

4.3.1.7. Dilution Test

Dilution functionality is divided into automatic dilution and manual dilution. "Multiple" refers to the factor by which the dilution is performed (also called the post-dilution factor). Must be set to equal to or greater than 2; When performing an automatic dilution, the "Original Sample Volume" which refers to the amount of original sample drawn by the Sample probe during dilution, needs to be set. It is recommended when performing an automatic dilution that the product of the dilution factor and the dilution amount falls between 200 - 400 ul, in order to achieve the best dilution results; When performing a manual dilution, the user should first dilute the sample, select manual dilution and enter the dilution factor. An already-diluted sample is used to perform testing.

4.3.1.8. Auto Dilution Rerun

After selecting automatic dilution rerun functionality for a given project, the software will evaluate the results according to the automatic dilution retest parameters specified in the project parameters to ensure that an automatic dilution retest needs to be performed. Takes effect after a request is successful.

4.3.2. QC Request

In the QC Request menu, the user can request quality control testing. Any of the preset quality control items can be selected to request a test based on the user's specific requirements. Both repeat testing and dilution testing functions can be tested; Quality control application records can be viewed and deleted in the Request List menu.

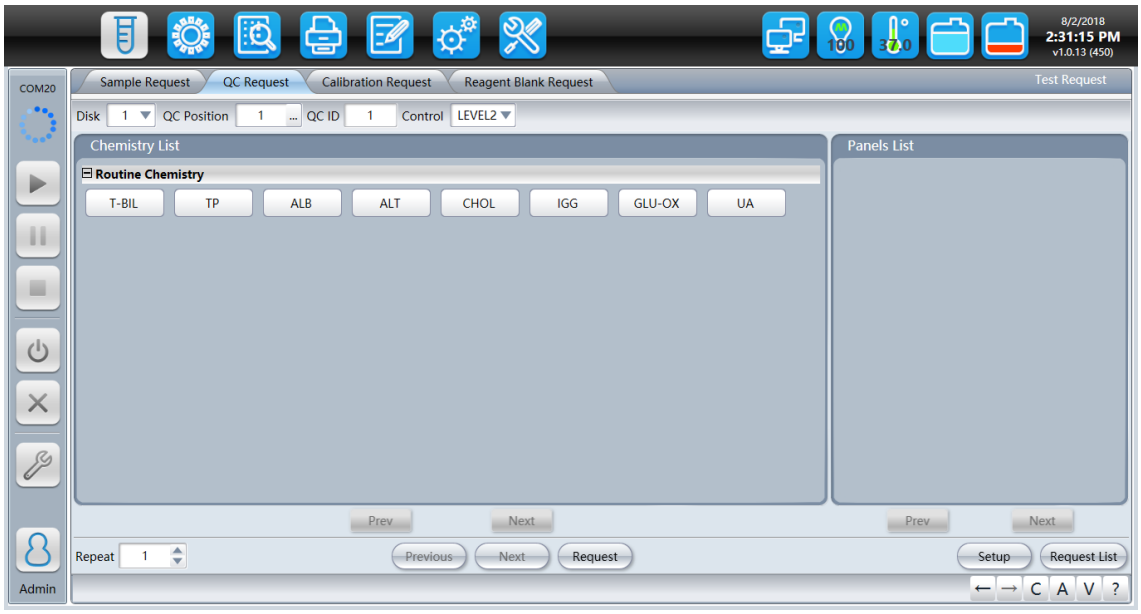


Figure 4-10: "QC Request" Screen

4.3.2.1. Introduction of Basic Parameters

For an explanation of the meanings of various "QC Request" screen parameters, consult the following table:

Parameter	Meaning
Disk	Selects the number of the sample disk for quality control testing (there are 5 by default) via a drop-down box
QC Position	Refers to the disk position number (total of 40 possible) of the selected sample. The number can be entered directly or you can click ... on the right of the screen to select a number from the sample disk empty vial list

Parameter	Meaning
QC ID	Number of the QC sample; entered directly in ascending order
Control	Refers to the quality control liquid which was been set; selected from a drop-down box

4.3.2.2. Introduction to Application Features

For an overview and explanation of the meanings of the "QC Request" screen functional buttons, consult the following table:

Button	Explanation and Operation of Function
Repeat	Number of project test repetitions; enter the number of repetitions for a repeat test
Dilution	QC dilution test; click Dilution and then select a dilution method and input the corresponding dilution parameters
Request	Request QC Test
Setup	Sets QC parameters; click to enter the QC setup interface
Request List	List of quality control tests already requested; click to enter the list viewer screen

4.3.2.3. QC Request

The basic QC request procedure is as follows:

1) Enter the "Test Request - QC Request" menu;

2) Select a disk number, QC position and control solution and enter the QC ID;

3) Click the item that needs to be measured. Click once to select and click again to cancel the selection. Or, click the specified combination in the Panels Selection Screen. Click once to select and click again to cancel the selection.

4) Choose whether or not to perform repeat testing and dilution testing based on the actual requirements of the project;

5) Click the "Request" button after which the software should indicate that the request was successful. View or delete application records in the request list.

4.3.3. Calibration Request

A calibration test can be requested on the calibration request screen where the user can also check the list of requests as well as set up the calibration.



Figure 4-11: The "Calibration Request" Screen

4.3.3.1. Introduction of Basic Parameters

For an explanation of the meanings of various "Calibration Request" screen parameters, consult the following table:

Button	**Meaning**
Disk	Sample disk number where the calibrator resides
Chemistry List	Shows all items
Prev	View the previous item list
Next	View the next item list
Details Setup	Detailed settings concerning the number of repetitions, reagent blanks and calibrators for the calibration test; effective for a single project

4.3.3.2. Introduction to Application Features

See the following table for explanations concerning the function of the various "Calibration Request" buttons and the operation thereof:

Button	**Explanation and Operation of Function**
Repeat	Default number of calibration test repetitions; valid for all requests
Rgt Blk	Default selection for reagent blank testing; valid for all projects
Setup	Calibration Parameter Settings
Request	Calibration Test Request
Request List	List of calibration tests already requested; click to enter the list viewer screen

4.3.3.3. Calibration Request

The basic calibration request procedure is as follows:

1) Enter the "Test Request - Calibration Request" menu;
2) Click the item that needs to be calibrated. Click once to select and click again to cancel the selection.
3) Select the calibrator that needs to be tested in the detailed settings box on the right hand side of the screen;
4) Set the number of calibration repetitions and the reagent blank in the detailed settings box on the right hand side of the screen according to the needs of the project;
5) Click the "Request" button until the request is shown as successful;
6) View or delete application records in the request list.

4.4. Online Status

The "Status" menu primarily shows information such as the current state of the sample disk, reagent disk and reaction disk as well as tests currently being performed; The menu also includes a test list submenu which shows the status of the invalid tests. These are described in detail below.

4.4.1. Sample Disk Status

In the "Sample Disk" menu, you can view the test status and sample information of test samples that have already been requested, as well as a list of requested items; additionally, basic operations can be performed using this menu.

Different shapes and colors for a sample position on the disk on the left side of the Function Display Area indicate different types of samples and different test statuses; The Sample Information display box is shown in the upper right of the Function Display Area; shows basic information regarding selected samples; A list of tests for the selected samples is shown in the area below; The Estimated Time Remaining box shows the time required to complete testing of the current sample batch.

The function key area includes Barcode Scan, Rerun, Release Positions, Release All, Add and Reaction Curve function keys, allowing the user to select an appropriate action.

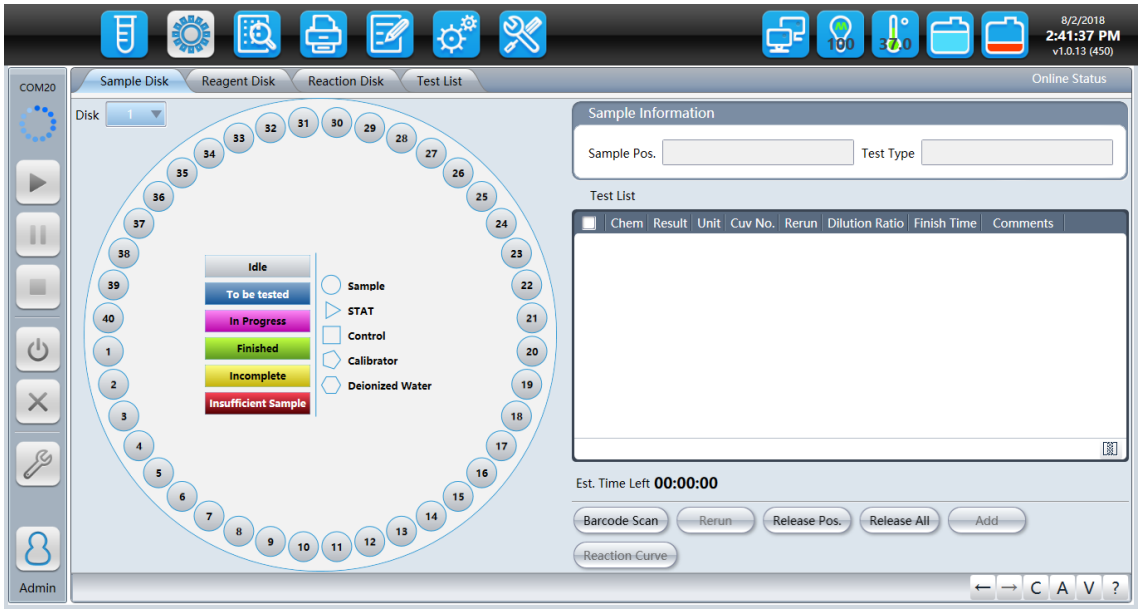


Figure 4-12: The "Sample Disk" Screen

4.4.1.1. Status Explanation

For information concerning the meaning of various sample colors shown in the "Sample Disk" screen, see the following table:

Status	**Color**	**Meaning**
Idle	Blank	Unoccupied position; can request a sample
To be tested	Blue	A sample has been requested but the test has not been started
In Progress	Pink	Sample currently being tested
Finished	Green	All tests for the sample have been completed
Incomplete	Yellow	Test completed, but, due to various causes, a result cannot be computed
Insufficient Sample	Red	Insufficient sample margin

For the meanings of different sample position shapes in the Sample disk Status Screen Function Display Area, see the table below:

Sample Position Shape	**Meaning**
Circle	The sample is a standard sample
Triangle	The sample is an emergency sample
Square	The sample is a control solution
Pentagon	The sample is a calibrator
Hexagon	Deionized water is in the corresponding position

4.4.1.2. Introduction of Basic Parameters

For an explanation of the meanings of various "Sample disk Status" parameters, consult the following table:

Parameter	**Meaning**
Disk	Current sample disk number
Sample Information	Information concerning the sample in the current sample position, including sample position, number, test type, patient name, sample type and bar code information
Test List	Displays a list of tests, results and additional notes for the currently selected sample

4.4.1.3. Introduction to Application Features

The "Sample disk" status screen includes Barcode Scan, Rerun, Release Positions, Release All, Add and Reaction Curve function buttons (total of 7 buttons);
for a description of the function and basic operation of each button, see the table below:

Button	**Explanation of Basic Operation and Functions**
Barcode Scan	Click to enter the bar code scanning interface, select the location you want to scan and the desired scan mode and, after verifying the input, start scanning the sample
Rerun	Select samples and items requiring a retest; click rerun button to perform a repeat test
Release Positions	Release the location of the selected sample
Release All	Release all samples on the current disk
Add	Click after selecting a sample to enter the Sample Request screen and add additional test items to already-requested samples
Reaction Curve	After selecting a sample and test(s), click to view the corresponding reaction curve(s)

Notes:

1) The retest function can only be used for chemistries where testing has already been completed;

2) Samples that are currently being tested cannot be deleted and released;

3) Release of the entire disk can only be performed when the instrument is stopped.

4.4.2. Reagent Disk Status

The status of all reagents can be viewed in the "Reagent Disk" screen, and operations such as setting the reagent position and monitoring residual volume can be performed.



Figure 4-13: The "Reagent Disk" Screen

Detailed information corresponding to all reagent positions is shown in the left side of the Function Display Area. Different colors indicate different reagent types and statuses as well as other information; The Chemistry List Area on the right-hand side shows abbreviations for all items and the user can page through the list using the Next and Previous buttons; The two boxes on the lower right part of the screen show the position of the currently selected reagent or detailed reagent classification, positioning and residual volume information corresponding to the item currently selected; The different colored circles in the middle of each reagent position indicate different reagent statuses: normal, insufficient reagent, reagent depleted and expired.

The Function Key Area contains 6 major function keys: Barcode Scan, Inventory, Reset, Release Positions, Release All and Reagent Status, which can be used to perform corresponding operations.

4.4.2.1. Status Explanation

The meaning of various statuses and parameters which appear on the "Reagent Disk" screen are as shown below:

Status	Color	Meaning
Empty	Blank	The current reagent position is empty
Diluent	Blue	A dilute solution is in the corresponding position
R1	Light Green	Reagent 1 is in the current position
R2	Orange	Reagent 2 is in the current position
Shared	Pink	The current reagent position is shared by reagents across multiple projects
Unrelated	Yellow	The current reagent position is not associated with a project

In addition, the circle area in the center of a given reagent position will appear blank, yellow, red or gray to indicate whether the reagent is normal, insufficient, completely depleted or expired (4 possible states) respectively.

4.4.2.2. Introduction of Basic Parameters

For the meanings of various parameters and operations associated with the "Reagent disk Status" screen, refer to the following table:

Parameter	Meaning	Operation
Chemistry List	List of abbreviations for all items. Move the mouse or click to make a selection	Move the mouse or click to make a selection
Reagent Name	Chem. Abbreviation	Select an item in the item list
Exp Date	Expiration date of the reagent	Default is 1 year. Use the drop-down box to select a date
Uncap Time	The number of days remaining until the reagent expires	No action required. The software automatically calculates the remaining number of days based on the reagent's expiration date
Lot No.	Lot Number Information for the Reagent Kit	The user need only enter the lot number information provided with the reagent kit

Parameter	Meaning	Operation
Volume	Reagent bottle specification	Inner Ring: Including two sizes: 40ml and 20ml, with 40 ml the default size; the user can select the corresponding size in the drop-down box based on the specification of the reagent used. Outer Ring: Size is fixed at 20ml and cannot be selected.
Remaining	Refers to the number of days until the reagent expires after the reagent bottle is opened. The number of days after the reagent bottle is opened is calculated from the time the reagent position is set.	Blank by default; the user can set a value as needed; The cumulative number of days following opening of the reagent bottle will be cleared after a refresh or residual volume detection operation is performed, and the calculation of the number of days following opening of the reagent bottle is restarted.
Diluent	Set this position as diluent position	First click one position, and then tick the check box and input related information, save.

4.4.2.3. Introduction to Application Features

It is possible to perform 7 major functions in the Reagent disk Status Screen: reagent position setup, barcode scan, residual volume detection, residual volume reset, release position, release of the entire disk and reagent status view.

4.4.2.4. Reagent Position Settings

The basic procedure is as follows:

1) Left-click to select a reagent bottle position;
2) Move the mouse to the item that needs to be set in the item list area;
3) In the dialog box that pops up, select the reagent category that you wish to set: R1 or R2;
4) Reagent Information Settings Name is displayed by default by the system based on the project and reagent type selected. Specifications, expiration date, time to expiration after opening, residual volume and number of days remaining are set to their default values when set up for the first time and any of these parameters can be adjusted manually according to the needs of the user;

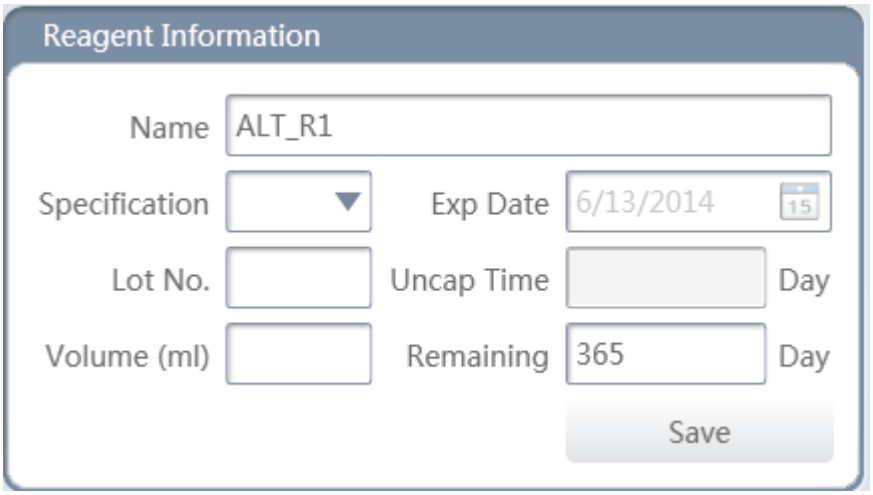


Figure 4-14: The "Reagent State disk - Reagent Information" Screen

5) Click on the Save button in the reagent information box to save the corresponding reagent information;

Notes:

1) The two reagent items R1 and R2 must be set to the same reagent disk;
2) When a change in reagent location is necessary, the user need only release the reagent position (for specific operating instructions, see "Release Position").

4.4.2.5. Reagents Scan

The basic procedure is as follows:

1) Click the "Barcode Scan" button;
2) In the pop-up dialog box, select the position you want to scan and click on the "OK" button or click "Cancel" to exit.

4.4.2.6. Inventory

The basic procedure is as follows:

1) Select the reagent disk;
2) Click the " Inventory " button to open up the residual volume detection interface;
3) Choose the reagent for which residual volume detection needs to be performed;
4) Click the "OK" button to start residual volume detection or click the "Cancel" button to cancel residual volume detection.

Notes:

Reagent residual volume monitoring can only be performed in standby mode.

4.4.2.7. Reset Volume

The basic procedure is as follows:

1) Select the reagent position that needs to be reset in the Reagent disk Screen on the left;
2) Click the "Reset " button to reset the reagent residual volume and expiration date;
3) If you need to reset residual volumes for all reagents or residual volumes for multiple reagents;
4) First, left-click on the chemistry list area;
5) Click the "Reset " button to bring up the following screen:

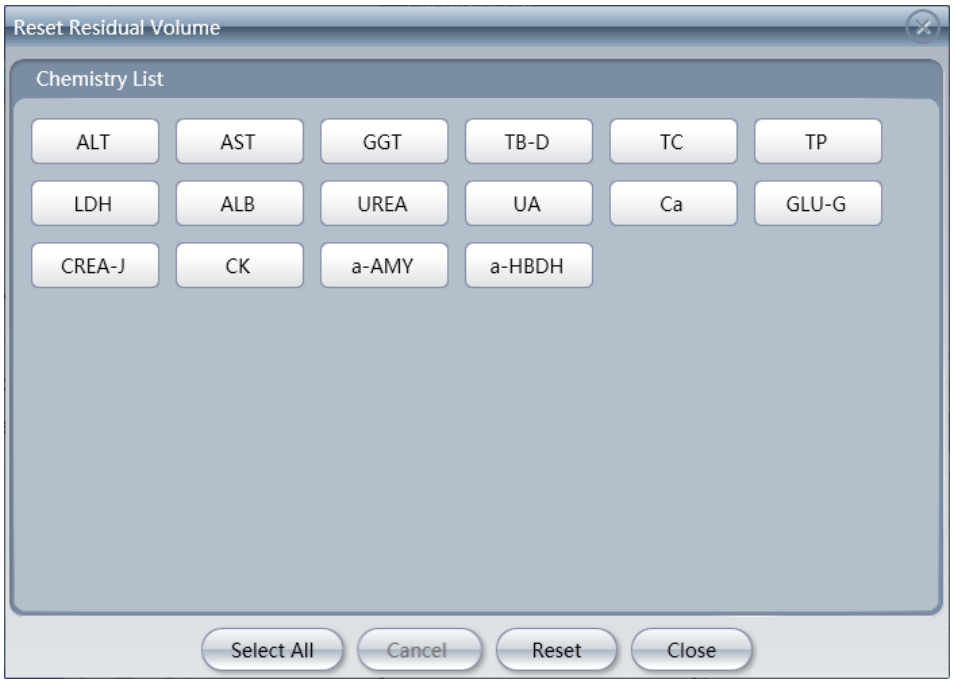


Figure 4-15: The "Reset" Screen

6) Select items that need to be reset. If all items need to be refreshed, click "Select All"
7) Click the "Reset" button to reset the residual volume and expiration date of the reagent corresponding to the selected item. Once the reset is successful, a status message will pop up;
8) Otherwise, click the "Back" button to cancel resetting the residual volume.

Notes:

When an item is missing a reagent, a residual volume reset must be performed after adding the required reagent before the testing with the reagent can be performed.

4.4.2.8. Release Positions

The basic procedure is as follows:

1) Select the reagent disk number;
2) Click on a reagent in the reagent disk that requires a position change and click "release position" to release the reagent position;
3) Click Whole disk Release to release all positions on the reagent disk.

Notes:

The release of a reagent position is not permitted for items still undergoing testing and the instrument does not allow a whole disk release to be performed when in testing mode.

4.4.2.9. Reagent Status

Click the "Reagent Status" button to open the Reagent Status screen and see detailed information regarding all reagents on the reagent disk, including their positions, lot numbers, residual volumes, number of viable tests, expiration dates, reagent specifications, and calibration status for corresponding items; it is possible to perform residual volume detection and reset operations on this screen. Enter the appropriate conditions in the filter conditions box and the system will automatically filter for reagents which meet the conditions specified, allowing for easy examination and operation of reagents.

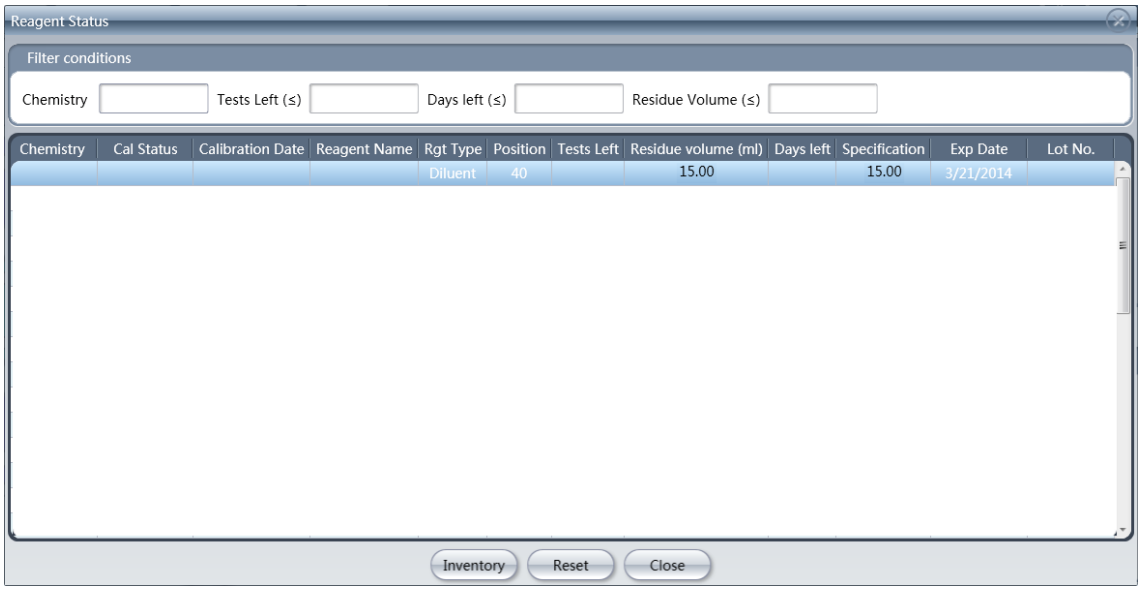


Figure 4-16: The "Reagent Status" Screen

4.4.3. Reaction Disk Status

Enter the "Reaction Disk" screen from "Online Status" to view the overall condition of the reaction disk as well as the status of reaction cuvettes. Colors are used to display in real-time the current status of each reaction cuvette, including the cleaning status and sample loading status of each reaction cuvette as well as observe the reaction curve of valid tests (samples, calibration, quality control, sample blank and reagent blank); Clicking on a reaction cuvette will display testing information for the location indicated on the right-hand side of the screen.

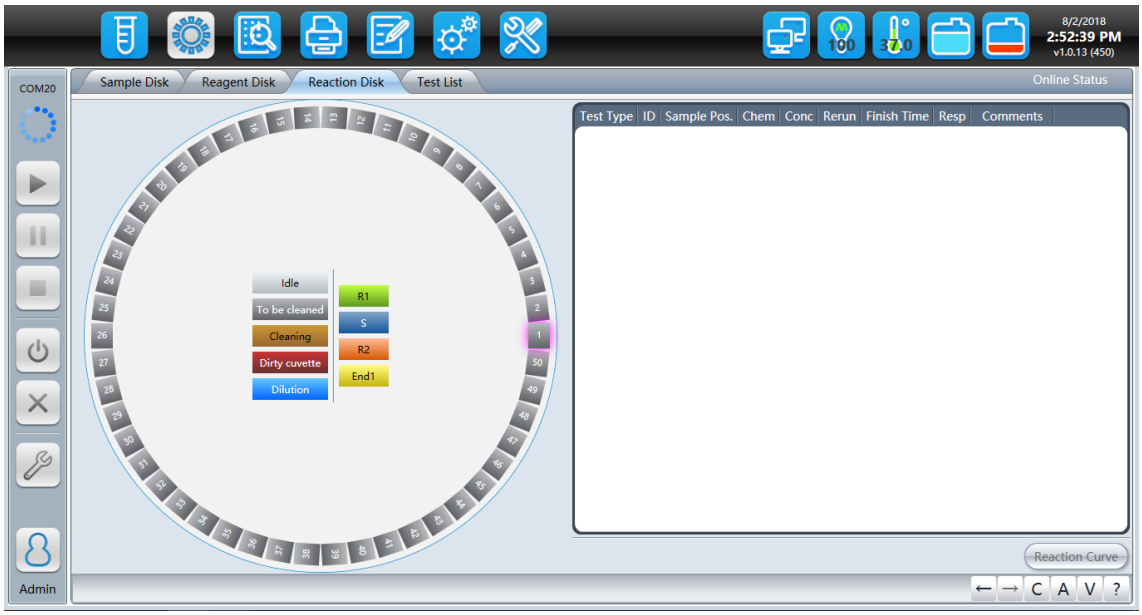


Figure 4-17: The "Reaction Disk" Screen

4.4.3.1. Status Explanation

There are a total of 10 different reaction cuvette statuses which may be displayed in the "Reaction Disk" screen, different colors are used to display the current status of each reaction cuvette in real time and status information displayed in the center of the virtual reaction disk schematic includes the following:

Status	Color	Meaning
Idle	Blank	Clean cuvette - can be used for a new test
To be cleaned	Dark Gray	For analyzer with auto wash function only. Indicates cuvettes that have not been cleaned or reserved immediately following startup of the device; a cleaning operation may be performed on cuvettes of this type

Cleaning	Brown	For analyzer with auto wash function only. The cuvette is currently undergoing cleaning and once cleaning is completed a cuvette blank test can be used to determine whether the cuvette is clean or dirty
Dirty cuvette	Dark Red	The cuvette is not clean, or the cuvette is already occupied with waste product (e.g. voided test)
Dilution	Blue	Dilution is currently being performed in the current cuvette position
R1	Light Green	Addition of a first reagent for a given test
S	Dark Blue	Addition of a sample for a given test
R2	Orange	Addition of a second reagent for a given test
End	Yellow	The current test ended normally and the corresponding results have been computed

4.4.3.2. Introduction of Basic Parameters

For an explanation of the meanings of various "Reaction Disk" parameters, consult the following table:

Parameter	**Meaning**
ID	Cuvette number
Test Type	Automatically displays the type of test corresponding to the selected cuvette, including calibration, quality control, sample tests, sample blank, reagent blank and dilution (total of 6 classes)
Sample Pos.	Position of the sample corresponding to the current test
Chem	Abbreviation for the test being carried out in the reaction cuvette
Conc	Results of the test being carried out in the reaction cuvette
Rerun	Indicates whether or not the current test is a retest; if so, a ☑ mark is displayed in the box

Parameter	Meaning
Finish Time	The time to completion for tests carried out in the selected reaction cuvettes
Comments	Shows error information related to testing performed in the selected cuvette

4.4.3.3. Introduction to Application Features

For an explanation of the functions and basic operation of buttons on the "Reaction disk Status" screen, see the following table:

Button	Explanation of Basic Operation and Functions
Reaction Curve	Select a reaction cuvette on the reaction disk which is currently undergoing testing during a cyclical test and click on it This button will call up a "Reaction Curve" screen which shows the reaction curve for tests performed in the reaction cuvette **Notes:** When the selected reaction cuvette contains a diluted sample or is empty, this button is disabled.
Replace Cuvette	For analyzer without auto wash function only. After replacing new cuvettes, click this button so that the system will detect and refresh the cuvette status.

4.4.4. Test List

You can view information for tests that are invalidated.

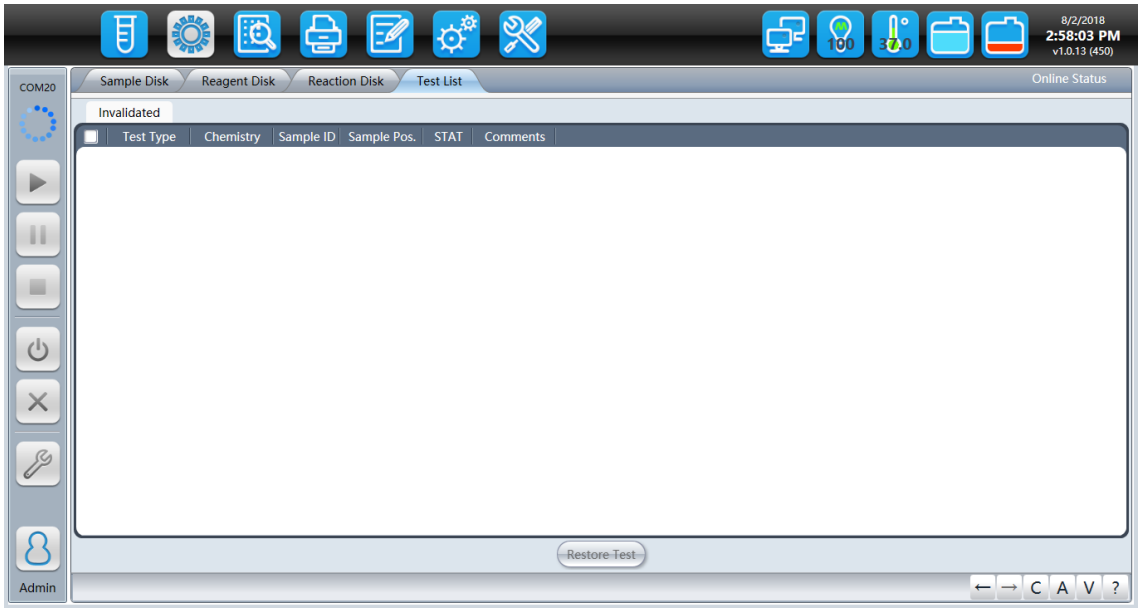


Figure 4-18: The "Test List" Screen

4.4.4.1. Explanation of Status and Functions

When a test is listed as invalid, a retest can be performed. Details regarding each status are given in the table below:

Status	Description of Status and Functions
Invalidated	An item for which the corresponding test was rendered invalid due to an error such as malfunction or lack of samples / reagents; the user can select the corresponding item and initiate a retest as needed

4.5. Query Results

The Query Results screen allows the user to query sample, calibration, quality control and reagent blank results. These will be described in the following section.

4.5.1. Sample Result Query

The left side of the Function Display Area on the Sample Result Query Screen shows sample records which meet the current query criteria (samples for the current day are displayed by default) including request time, sample ID, sample position, patient name and barcode; Detailed information corresponding to the sample is shown in the upper right section of the screen. The contents of this information are identical to the "Test Request - Sample Request" screen and can be edited and saved for later; A list of tests for the selected samples is shown in the lower right section of the screen;

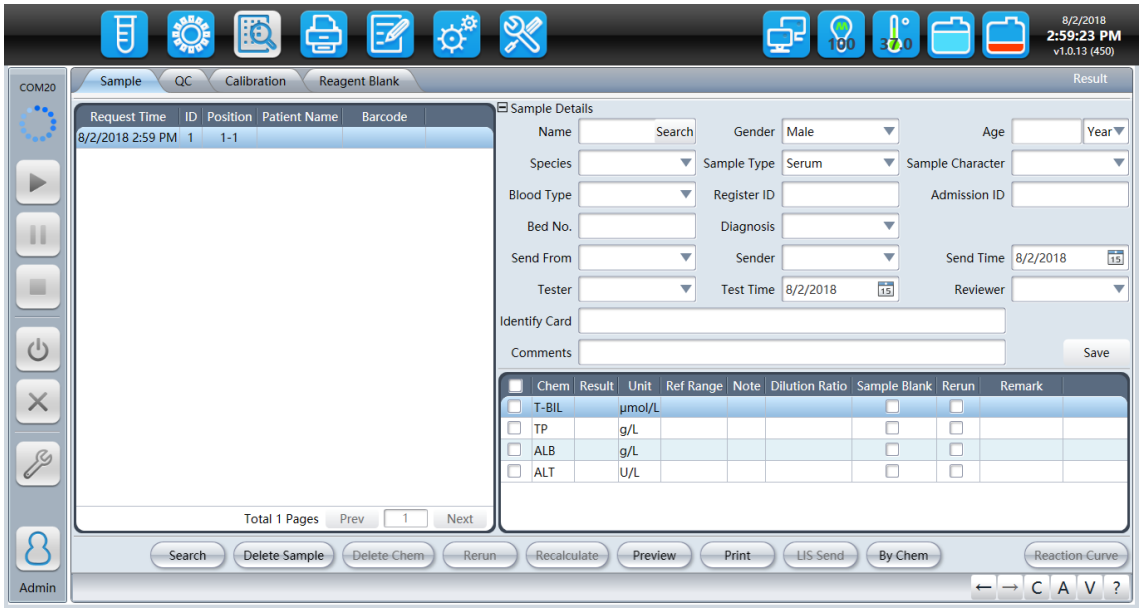


Figure 4-19: The "Sample Result Query" Screen

4.5.1.1. Introduction to Application Features

Queried sample results can be arranged based on sample or based on corresponding item. The sample-based view includes multiple function buttons, including search, delete sample and delete chem allowing the user perform corresponding operations.

4.5.1.2. Search Conditions

By default, the Sample Results Query interface displays a record of tests performed on the current day. If you need to check older results, click the "Search" button to bring up the "Sample Query" dialog box and, after entering your query criteria, a corresponding sample record should be displayed; Click "Close" to end the query.

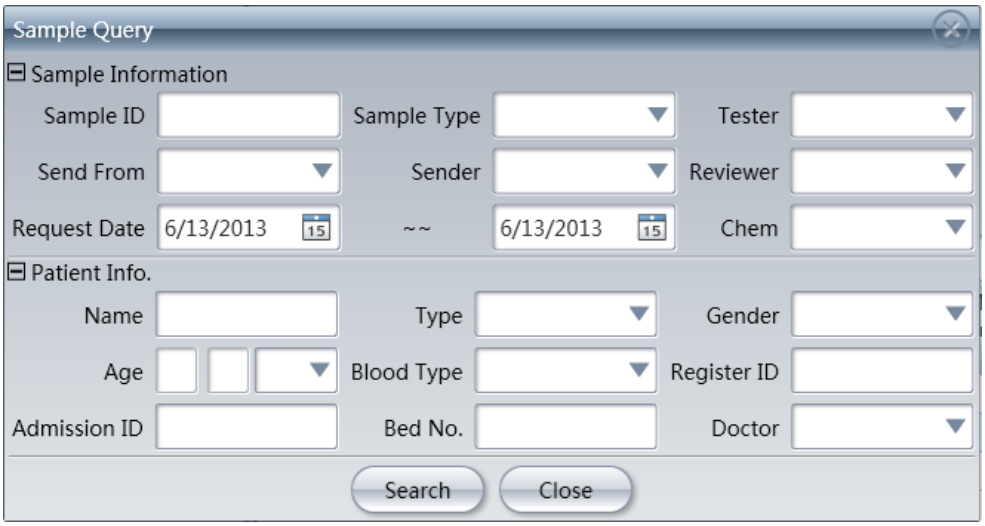


Figure 4-20: The "Sample Query Criteria" Screen

4.5.1.3. Delete Sample

Select the sample you want to delete, click the "Delete Sample" button to bring up the confirm deletion prompt and confirm the deletion.



Notes:
Samples that are currently being tested cannot be subject to a "Delete Sample" operation.

4.5.1.4. Delete Chem

Select the sample that needs to be deleted and select the items you want to delete from the Item List Area. Then, click the "Delete Chem" button to bring up the confirm deletion prompt and confirm the deletion.



Notes:
Samples that are currently being tested cannot be subject to a "Delete Chem" operation.

4.5.1.5. Rerun

Select the item requiring a retest to bring up the retest confirmation prompt and click "Yes" to start a retest or click "No" to cancel.



Notes:
Only unreleased items for which testing has been completed may be subject to a retest; unreleased samples include "samples requested on the same day as well as samples requested on a previous day but which were saved and not released from the sample disk as a result of not exiting the software for an extended period of time."

4.5.1.6. Recalculate

"Recalculate" allows you to recalculate results and you can recalculate test results under various conditions depending on your needs.

4.5.1.7. Preview / Print

After selecting a sample, click on "Preview" to display the results of the current sample and print a preview image; Click Print to print the results directly.

4.5.1.8. LIS Send

After selecting a sample, click on LIS Send to directly send the selected sample results to an LIS system.

4.5.1.9. Reaction Curve

After selecting a sample and test item, click the "Reaction Curve" button to bring up the

reaction curve corresponding to the current results record.

4.5.1.10. By Chem

Click the "By Chem" button to enter the View Results by Item screen which includes the following 5 functional buttons: Search, Delete Chem, Recalculate, By sample and Results chart. The Search, Delete Chem, Recalculate and Results chart are functionally equivalent to corresponding features of the View By Sample screen and the View By Sample screen allows the user to switch to viewing the results by sample.

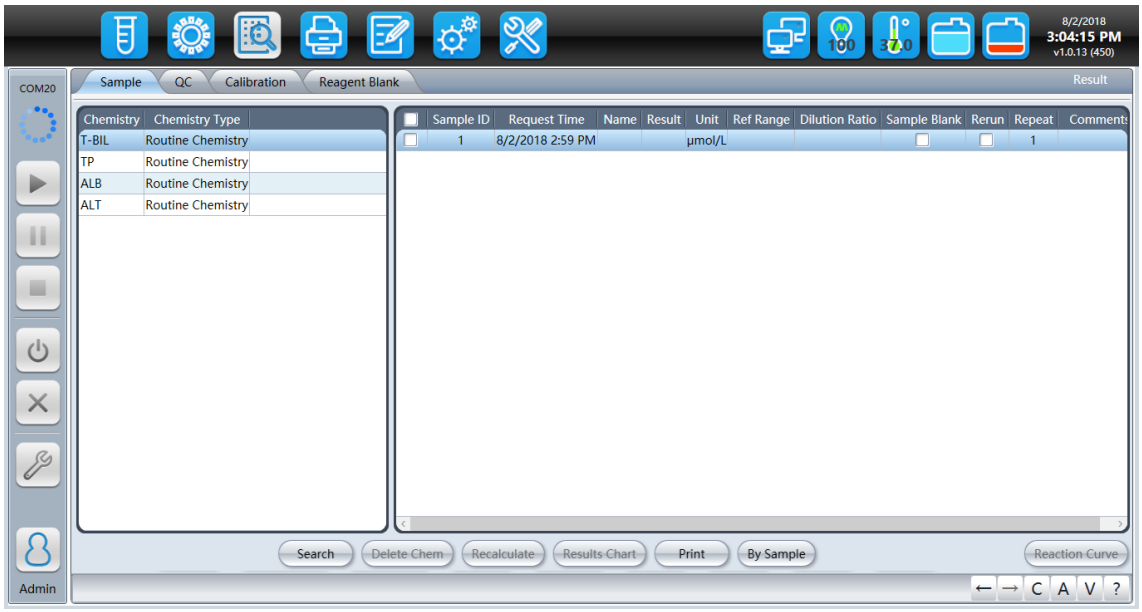


Figure 4-21: The "Sample Results Query - View by Chem" Screen

4.5.2. Quality Control Result Query

The Quality Control Results Query function provides three quality control modes: real-time QC, Daily QC, and Day-to-day QC. A detailed explanation of quality control modes is given in Section 6.6.2; Provides three different quality control chart types: Westgard, Cum-sum-check and Twin Plot; Quality control data can be displayed by either quality control or item.

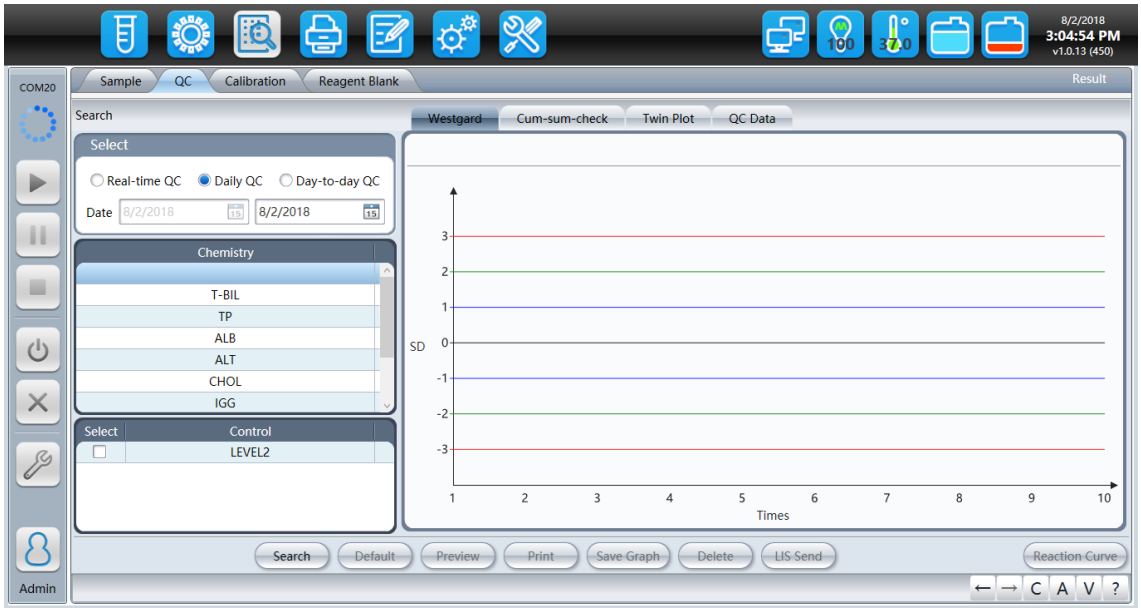


Figure 4-22: The "Quality Control Result Query" Screen

4.5.2.1. Introduction of Basic Parameters

For explanations of different parameters and operations corresponding to the "QC Result Query" screen, see the following table:

Parameter	**Explanation and Operation of Parameters**
Select	Provides three quality control modes: real-time QC, Daily QC, and Day-to-day QC; can be selected directly
Date	Date on which quality control data needs to be examined; can be selected directly
Chemistry	List of abbreviations for quality control items; can directly select the desired item; when nothing is selected, defaults to showing quality control data for all items
Control	List of control solutions; can be selected and viewed directly
Westgard	Click to view a quality control chart created based on quality control data for the selected project and within the selected time period based on preset Westgard quality control rules.
Cum-sum-check	Click to view a quality control chart created based on quality control data for the selected project and within the selected time period based on pre-set cumulative sum quality control rules.
Twin Plot	Click to view a twin plot chart created based on quality control data for the selected project and within the selected

Parameter	Explanation and Operation of Parameters
	time period.
QC Data	Click to display quality control data filtered based on specific quality control conditions.

4.5.2.2. Introduction to Application Features

For explanations regarding the function of buttons on the "QC Result Query" screen as well as the operation thereof, see the following table:

Button	Explanation and Operation of Function
Search	Click directly to query corresponding quality control data based on the conditions selected
Default	Quality control data is selected by default - the system automatically treats the last successful result for a given day and a given item as the default result. When there are multiple successful results for a given day, the default result can be selected manually
Preview	Click to initiate a print preview of quality control data and corresponding quality control charts
Print	Click to print quality control data and corresponding quality control charts
Save Graph	Saves the quality control chart
Delete	Delete quality control data. Click after selecting the data you would like to delete. By default, quality control data cannot be deleted
LIS Send	Send quality control data to a LIS system
Reaction Curve	Click to view reaction curves corresponding to the selected quality control test results

4.5.2.3. Quality Control Result Query

The basic procedure is as follows:

1) Select the type of quality control you want to view on the left-hand side and select the start and end dates you wish to query;

2) Select the desired item and control solution name and the system will automatically

bring up the corresponding quality control data;

3) Select the "Quality Control Data" menu to show all test results for the current item for the selected time period;

4) Select the "Westgard", "Cum-sum-check" or "Twin Plot" menu to view the corresponding chart for the given item and time period

4.5.3. Calibration Result Query

After selecting an item in the Calibration Results Query menu, enter the appropriate date and the system will automatically find calibration records for all items. Furthermore, functions such as blank correction and calibration copying can be invoked as needed.

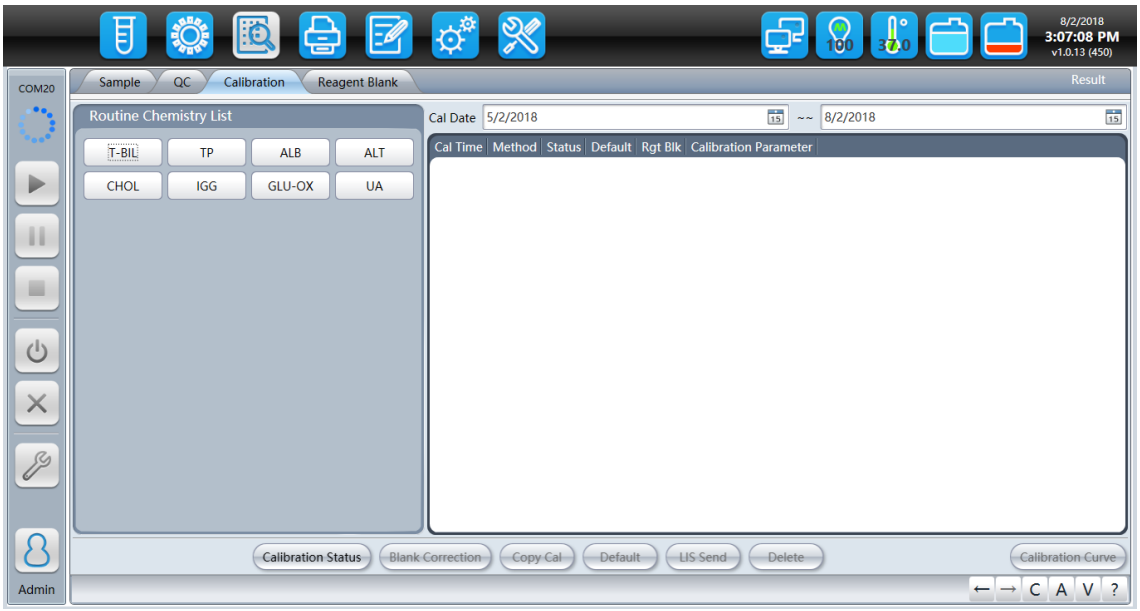


Figure 4-23: The "Calibration Result Query" Screen

4.5.3.1. Introduction of Basic Parameters

For explanations of different parameters and operations corresponding to the "Calibration Result Query" screen, see the following table:

Parameter	**Meaning and Basic Operation**
Routine Chemistry List	Shows all standard items directly. Directly select the item you wish to view
Cal Date	The date of the calibration data you wish to view. Directly selected
Cal Time	Time at which the calibration test was requested
Method	Calibration method for the current item
Status	The recorded status of each calibration. Can be either "test complete" or "request pending"

Parameter	Meaning and Basic Operation
Default	Signs the current default calibration results
Rgt Blk	Reagent blank data used during calibration
Calibration Parameter	Displays calibration parameters derived from linear calibration results

4.5.3.2. Introduction to Application Features

Using the Calibration Results Query screen, you can view the calibration results for each item. Five buttons - blank correction, calibration copy, Send to LIS, delete and calibration curves - are available on this screen for performing corresponding functions.

4.5.3.3. Blank Correction

Click "Blank Correction" to bring up a dialog box and, after selecting the appropriate date, check the reagent blank results. Select the reagent blank that needs to be used for the correction and click "Correction" to start the correction process; Click "Close" to exit.

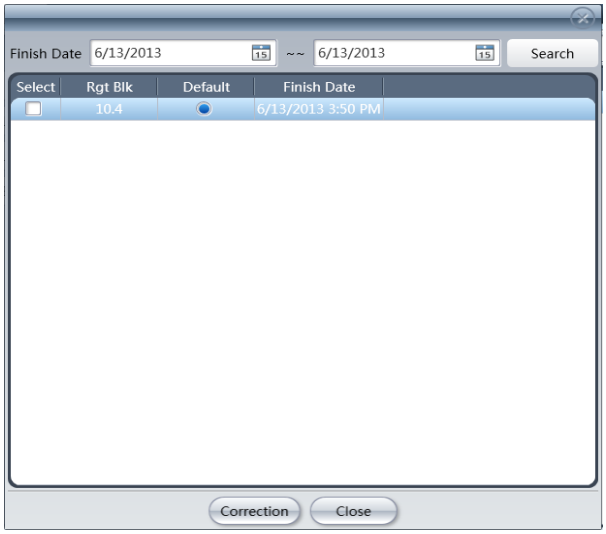


Figure 4-24: The "Blank Correction" Function Screen

4.5.3.4. Copy Cal

Select the calibration results that need to be replicated, click on the "Copy Cal" button to bring up the "Copy Calibration Data" dialog box, select the target item to which you want to copy the calibration parameters, click "reset" and make another selection, click "Copy" to start the copying process and click "Close" to exit.

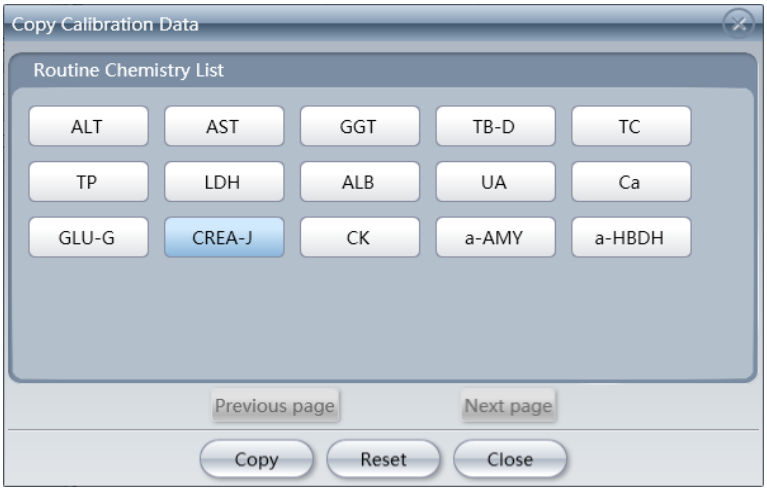


Figure 4-25: The "Copy Calibration" Function Screen

4.5.3.5. Delete

Directly delete the selected calibration results; default results cannot be deleted.

4.5.3.6. Send to LIS

Users can use this function when an LIS connection is present. Click to send data to a connected LIS system.

4.5.3.7. Calibration Curve

Select record corresponding to a single instance of successful calibration, click on "Calibration Curve" to view the calibration curve corresponding to the selected result as shown in the Figure below:

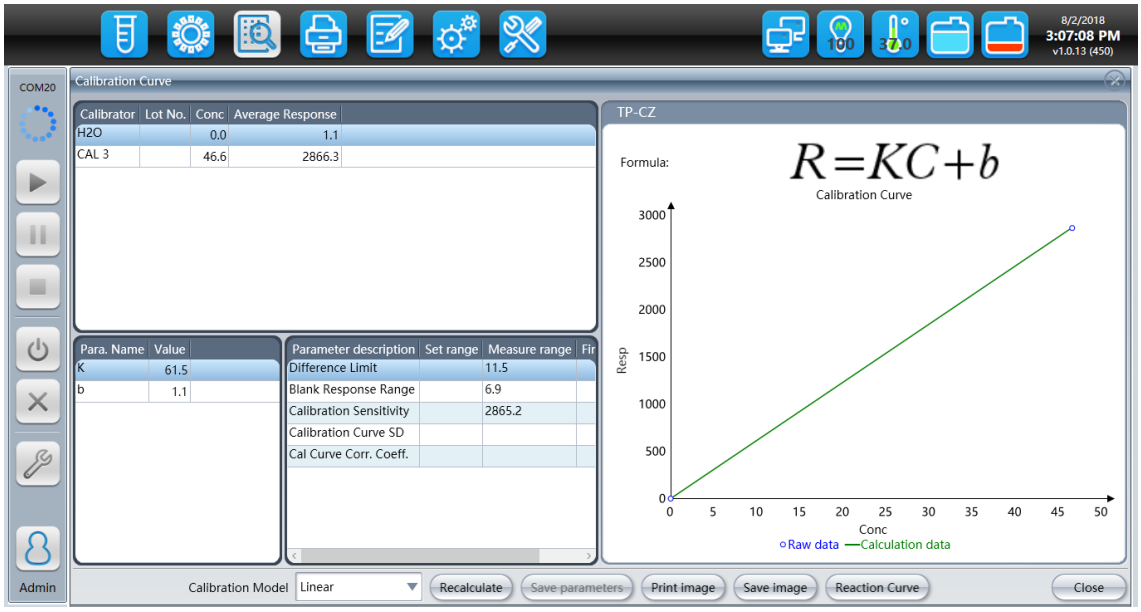


Figure 4-26: The "Calibration Curve" Screen

Using the Calibration Curve interface, you can take advantage of functions such as modify calibration parameters, recalculate, save parameter, print graphic, save graphic and view reaction curve view. See the following table for explanations concerning the function of the various buttons:

Button	**Explanation and Operation of Function**
Recalculate	Using existing calibration data, you can choose different calibration methods to recalculate calibration parameters. Click directly to use. **Notes:** The use of different calibration methods to recalculate calibration parameters is predicated on existing calibration data meeting the computational conditions of the method used to recalculate the calibration.
Save parameters	Saves new calibration parameters after calibration curve parameters have been modified or a recalculation has been performed
Print Image	Prints a calibration curve
Save Image	Saves a calibration curve
Reaction Curve	Click to view reaction curves corresponding to the selected calibration test results
Close	Closes the current screen. Click directly to close

4.5.4. Reagent Blank Query

While querying a reagent blank, it is possible to view reagent blank results and a reagent blank trend graph on an item-by-item basis.

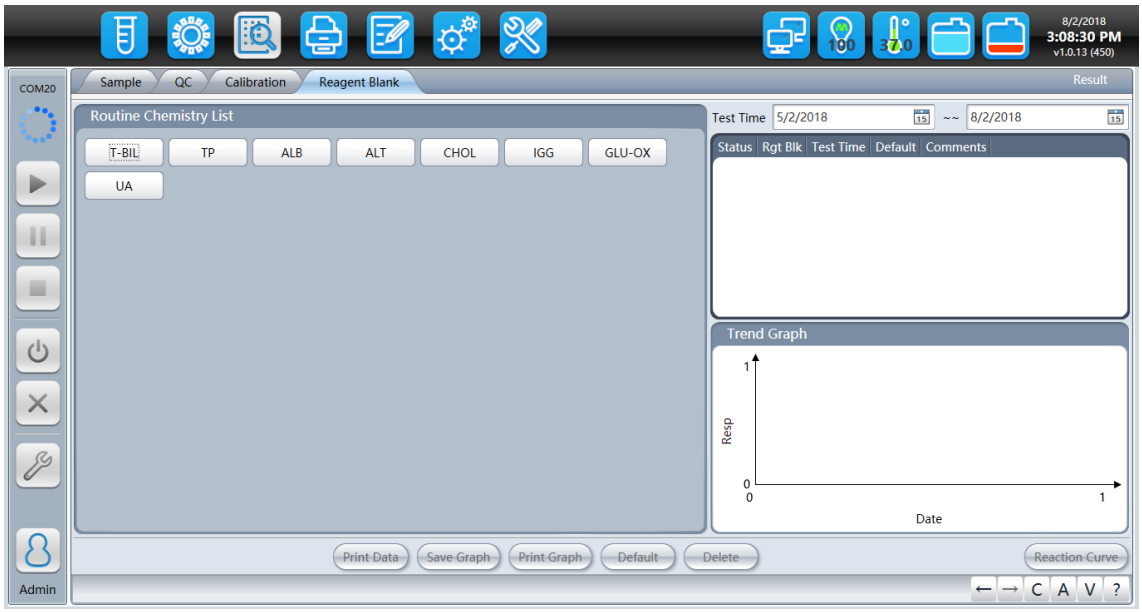


Figure 4-27: The "Reagent Blank" Screen

4.5.4.1. Basic Operation:

1) In the chemistry list box, select the chemistries you wish to query;
2) Choose the start and end dates of the reagent blank you wish to query;
3) The system will automatically find corresponding reagent blank data and produce a trend graph.

4.5.4.2. Introduction to Application Features

For explanations regarding the function of buttons on the "Reagent Blank Query" screen as well as the operation thereof, see the following table:

Button	**Explanation and Operation of Function**
Print Data	Prints reagent blank data found under the current query. Click to use
Save Graph	Saves the reagent blank trend graph. Click to use
Print Graph	Prints the reagent blank trend graph. Click to use
Delete	Deletes reagent blank data. Select the data you wish to delete and click to delete **Notes:** Default reagent blank data cannot be deleted
Reaction Curve	View a reaction curve corresponding to the selected reagent blank results. Click to view

4.6. Para. Setup

Includes the Routine Chemistry, Calculation Chemistry, Panels, Carryover, ISE Settings, Calibrator Setup and QC Setup menus. Each menu can be used to invoke corresponding functions.

4.6.1. Routine Chemistry

When including basic parameters, monitoring parameters, QC parameters and standard item parameter settings, setting are performed preferentially in the following order: “Basic Parameters” → “Monitoring Parameters” → “QC Parameters”. These are described in detail below:

4.6.1.1. Basic Parameters

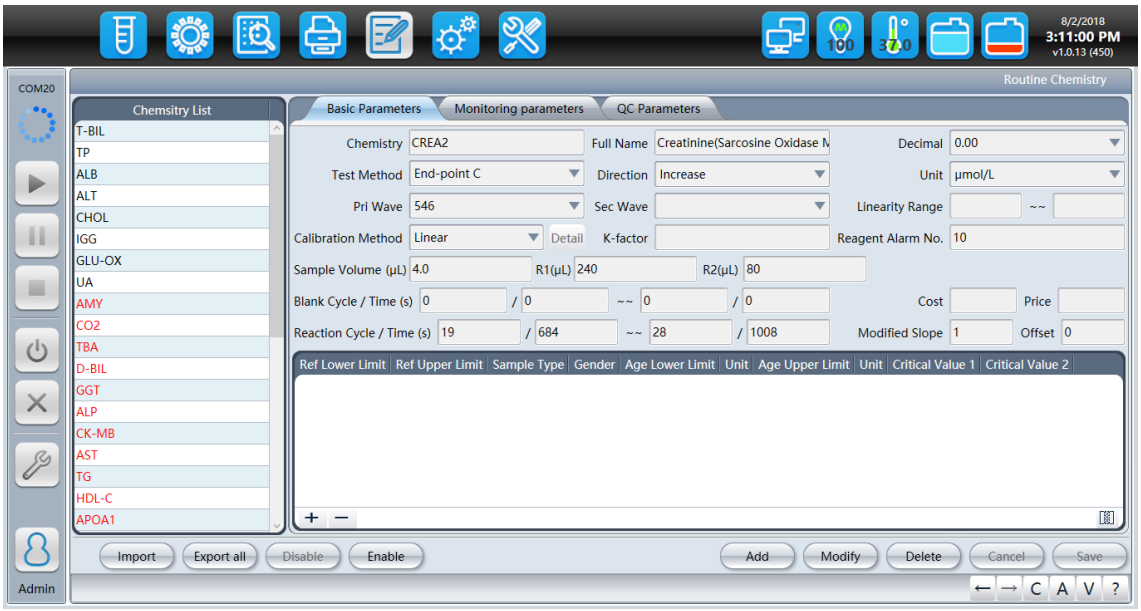


Figure 4-28: Parameter Settings Screen #1

Introduction of Basic Parameters

For explanations of different parameters and operations corresponding to the "Basic Parameters" screen, see the following table:

Parameter	Meaning	Operation
Chemistry	Item abbreviations	Data can be entered directly into the input box. Supports entry of up to 20 English characters or 20 Chinese characters (supports the input of any characters, including special characters such as punctuation and Greek letters)
Full name	The full name of the item	Data can be entered directly into the input box. Supports entry of up to 20 English characters or 20 Chinese characters (supports the input of any characters, including special characters such as punctuation and Greek letters)

Parameter	Meaning	Operation
Decimal	Number of decimal places with which results are saved	Can select one of five settings from the drop down box: 0, 0.0, 0.00, 0.000 and ... Select the ... button to enter the "Data Dictionary Maintenance" menu and click on the "Add" button. You can specify any number of decimal places with which results will be retained. Click the "Save" button once you have finished editing your selection to save or click "Cancel" if you do not need to save your selection
Test Method	Sets the measurement method for a given item	Select from the drop-down box. The following five options are available: end-point method A, end-point method B, end-point method C, two-point method and kinetic method
Direction	The direction of any change in absorbance which occurs during the reaction	Select from the drop-down box. There are two options: increase and decrease
Unit	Units of the test results	Selected from a drop-down box Select the ... button to enter the "Data Dictionary Maintenance" menu and click on the "Add" button. You can specify any number of decimal places. Click the "Save" button once you have finished editing your selection to save or click "Cancel" if you do not need to save your selection
Pri Wave	Main wavelength of the measurement	Select from the drop-down box. Eight wavelengths are available: 340, 405, 450, 510, 546, 578, 630 and 670 nm
Sec Wave	Secondary wavelength of the measurement	Select from the drop-down box. Eight wavelengths are available: 340, 405, 450, 510, 546, 578, 630 and 670 nm
Linearity Range	Linear range of the reagent kit	Directly enter the upper and lower concentration limits for the reagent's linear range as indicated in the reagent kit instructions

Parameter	Meaning	Operation
Calibration Method	Set the calibration method for a given item	Select from the drop-down box. There are ten options available: K-factor method, linear scaling, Logistic-Log4P, Logistic-Log5P, Exponential-5P, Polynomial-3P, Polynomial-4P, Polynomial-5P, spline and Com4P If you choose the K-factor method, you will also have to enter specific corresponding K-factor values in the corresponding box Click on the "Details" button to edit specific calibration parameters, including the repeated measurements differential limit, blank solution reaction range, calibration sensitivity, calibration curve standard deviation and calibration curve correlation coefficient. If you need to save your changes after editing is complete click on the "OK" button or click "Cancel" if you do not wish to save your changes
Reagent Alarm No.	Number of remaining tests for a given reagent kit	Input directly into the box. During test once the remaining reagent is less than the number input, an alarm will come up.
Sample Volume	The amount of sample loaded for a normal test. Value is expressed in units of microliters	Enter values directly into the box. Entries can range from 2 - 50 μl and can be adjusted in 0.1 μl increments
R1	The amount of Reagent 1 loaded for a normal test. Value is expressed in units of microliters	Enter values directly into the box. Entries can range from 150 - 450 μl and can be adjusted in 1 μl increments
R2	The amount of Reagent 2 loaded for a normal test. Value is expressed in units of microliters	Enter values directly into the box. Entries can range from 10 - 300 μl and can be adjusted in 1 μl increments

Parameter	Meaning	Operation
Blank Cycle / Time (s)	The blank cycle time. For a single reagent, this refers to the cycle time before the sample is loaded while for two reagents this refers to the cycle time after the sample is loaded prior to the loading of R2	Input directly into the box
Reaction Cycle / Time (s)	Used for computed optical metering start and end points	Input directly into the box
Cost	Cost of the item	Input directly into the box
Price	Item price	Input directly into the box
Modified Slope	Uses the formula y = ax + b to correct measurement results, where x is the actual measured result, y is the corrected result, a is the slope of the correction formula and b is the intercept of the correction formula	Enter directly into the box, 1 by default
Offset		Enter directly into the box, 0 by default
Ref Lower Limit	Enter the default lower limit of the reference range	Enter a number in the box based on the reference range provided by the reagent's manual or other professional reference book
Ref Upper Limit	Enter the default upper limit of the reference range	Enter a number in the box based on the reference range provided by the reagent's manual or other professional reference book Click "+" to set the upper and lower limits of the reference range; Click "-" to delete all content related to the reference range; Click "" to add additional conditions for a reference range, including classification, gender, sample type, age lower limit, age upper limit, and age units

Parameter	Meaning	Operation
Import	Imports item-related parameters from an external source	Click the "Import" button, select item-related parameters you want to import and initiate the import operation
Export all	Exports all current item-related parameters	Click the "Export All" button to export all item-related parameters to an external storage device
Selectively export	Select a subset of available item-related parameters for export	Click the "Selectively Export" button to export a subset of available item-related parameters to an external storage device
Enable	Disable the selected item	Select the disabled item that you want to active. Click the "Enable" button to activate the item.
Disable	Enable the selected item	Select the item that you want to diable. Click the "Disable" button to diable the item.

Basic Operations

Add Item Parameters

1) Click the "Add" button;
2) Enter parameter data directly into the corresponding item parameter box or make a selection from the drop-down box;
3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

Change Item Parameters

1) Select the item you wish to modify in the list of standard items;
2) Click the " Modify " button to modify parameter data for the current project;
3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

Delete Item Parameters

1) Select the item you wish to delete from the list of standard items;
2) Click the "Delete" button to open up a warning dialog box ("Are you sure you want to delete the currently-selected standard project(s)?")and click the "Yes" button to delete the item or click "No" to cancel deletion of the item.

Note: have tested data items not allowed to delete.

4.6.1.2. Monitoring Parameters

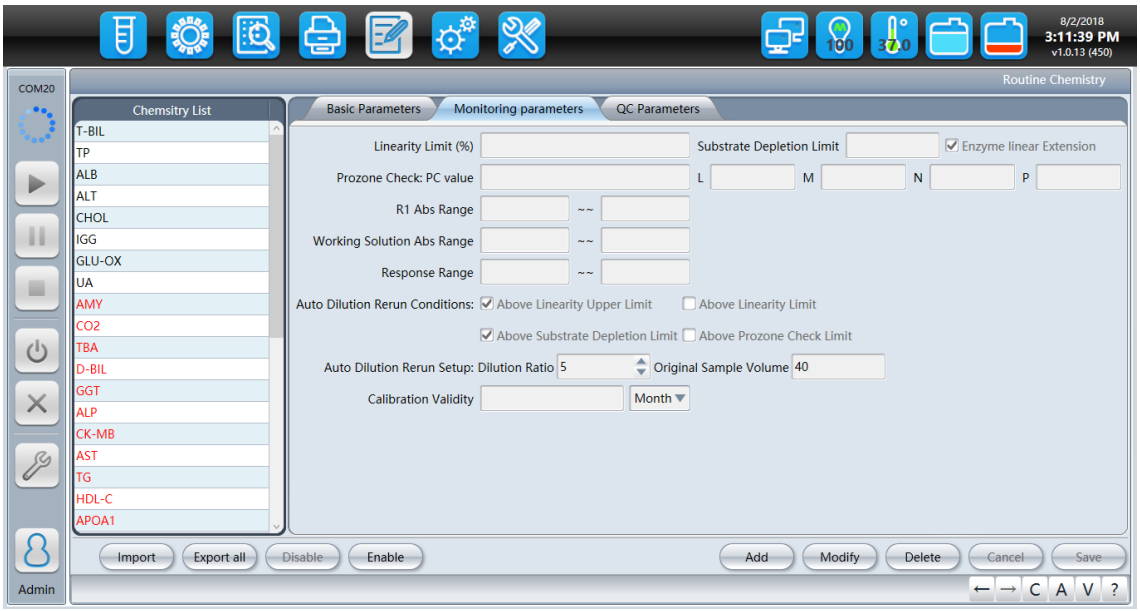


Figure 4-29: Parameter Settings Screen #2

Introduction of Monitoring Parameters

For explanations of different parameters and operations corresponding to the "Standard Item Settings" screen, see the following table:

Parameter	Meaning	Operation
Linearity Limit (%)	Determines the linearity of the reaction curve. Only used for the kinetic method	Enter an integer value between 0 - 100
Substrate Depletion Limit	The limit set to determine substrate depletion during the reaction process. Must be an absorbance value multiplied by 10000. Only used for the kinetic method and two-point method	Enter an integer value between -40000 - 40000
Enzyme Linear Extension	When the optical metering point in a zero-order kinetics interval is n ≤ 2, enzyme linear range expansion functionality can be activated to calculate the reaction rate based on all optical metering point data for which substrate depletion has not occurred, including delay times	Place a √ in the selection box or click the √ to cancel your selection

Parameter	Meaning	Operation
	(⊿ Amax) as an indicator of the sample's reactivity	
Prozone Check PC value L M N P	Prozone check limit Reaction time optical metering point	Enter an integer value between 0 and 100 Enter a corresponding optical metering point in accordance with the instructions contained in the section on the specific prozone check PC value algorithm
R1 Abs Range	Enter the lower / upper limits of the first reagent's absorbance. Values must be absorbance values multiplied by 10000.	Enter specific values between -40000 and 40000 directly into the box without exceeding the upper absorbance limit for the first reagent
Working Solution Abs Range	Enter the lower / upper limits of the working solution's absorbance. Values must be absorbance values multiplied by 10000.	Enter specific values between -40000 and 40000 directly into the box without exceeding the upper absorbance limit for the working solution
Response Range	Reaction amplitudes corresponding to the upper and lower limits of the linear range. Values must be absorbance values multiplied by 10000.	In the box, enter a specific value between -40000 and 40000
Auto Dilution Rerun Conditions	Includes Above Linearity Upper Limit, Above Linearity Limit, Above Substrate Depletion Limit and Above Prozone Check Limit	Place a √ in the selection box or click the √ to cancel your selection
Auto Dilution Rerun Setup	Includes dilution factor and stock liquid dosage	Enter specific values in the box
Calibration Validity	The valid period of calibration	Input the defined number and select a unit

Basic Operations

Set or Modify Monitoring Parameters

1) Select the item you wish to set or modify in the list of standard items;
2) Enter corresponding data into each monitoring parameter input box;
3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

4.6.1.3. QC Parameters

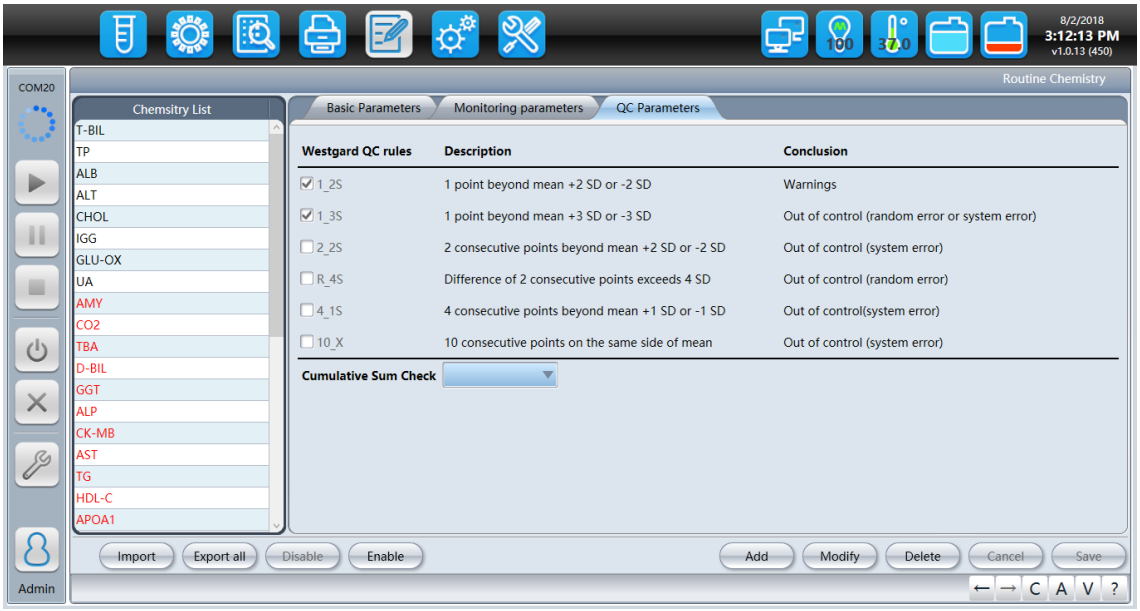


Figure 4-30: Parameter Settings Screen #3

Explanation of QC Parameters

For explanations of different parameters and operations corresponding to the "QC Parameters" screen, see the following table:

Parameter	Meaning	Operation
Westgard QC rules	Set an item's Westgard multi-rule quality control	Select a rule by checking it.
Description	Explanation of the conditions for determining whether or not a loss of control has occurred under the Westgard rules	No operation
Conclusion	Indicates determination regarding sources of error for Westgard loss-of-control rules. Should only	No operation

Parameter	Meaning	Operation
	be used as a guide	
Cumulative Sum Check	Set an item's cumulative sum quality control rules	Select directly from the drop-down box

Basic Operations

Set or Modify Quality Control Parameters

1) Select the item you wish to set or modify in the list of standard items;
2) Select or modify Westgard multi-rule quality control rules;
3) Select or modify cumulative sum quality control rules;
4) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

4.6.2. Calculation Chemistry

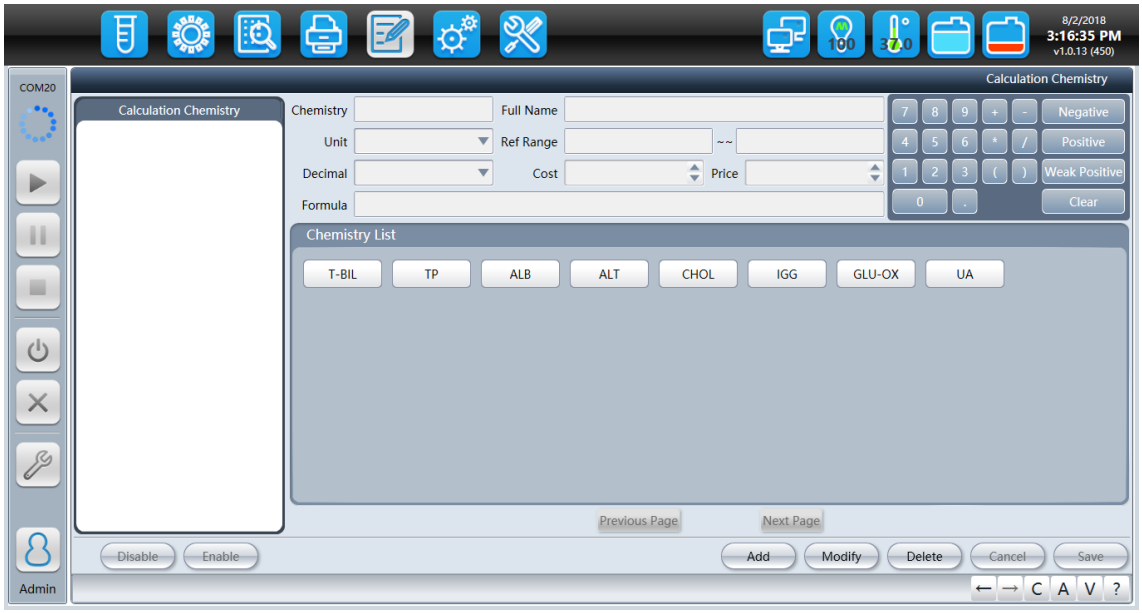


Figure 4-31: "Calculation Chemistry" Parameter Settings Screen

4.6.2.1. Explanation of Basic Parameters

For parameter meanings and basic operations associated with the Computational Item menu, see the following table:

Parameter	Meaning	Operation
Chemistry	Item abbreviations	Data can be entered directly into the input box. Supports entry of up to 20 English

Parameter	Meaning	Operation
		characters or 20 Chinese characters (supports the input of any characters, including special characters such as punctuation and Greek letters)
Full name	The full name of the item	Data can be entered directly into the input box. Supports entry of up to 20 English characters or 20 Chinese characters (supports the input of any characters, including special characters such as punctuation and Greek letters)
Unit	Units of the test results	Select the ... button from the drop-down menu to enter the "Data Dictionary Maintenance" menu and click on the "Add" button. You can specify any kind of result units as desired. Click the "Save" button once you have finished editing your selection to save or click "Cancel" if you do not need to save your selection
Ref Range	Enter the default reference range	Enter a specific value in the box based on the reference range provided by the reagent's manual or other professional reference book
Decimal	Number of decimal places with which results are saved	Users can select one of five settings from the drop down box: 0, 0.0, 0.00, 0.000 and ... Select the ... button to enter the "Data Dictionary Maintenance" menu and click on the "Add" button. You can specify any number of decimal places with which results will be retained. Click the "Save" button once you have finished editing your selection to save or click "Cancel" if you do not need to save your selection
Cost	Cost of the item	Input directly into the box
Price	Item price	Input directly into the box
Formula	Use the Formula Editor area buttons and calculation formula criteria to complete formula editing operations.	Input directly into the box

4.6.2.2. Basic Operations

Add Computational Item

1) Click the "Add" button;

2) Enter or select parameter data corresponding to the current computational and use the Formula Editor area buttons and calculation formula criteria to complete the expression

3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

Modify Computational Item

1) Select the item you wish to modify in the list of computational items;

2) Click the "Modify" button to modify corresponding parameter data for the current item;

3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

Delete Computational Item

1) Select the item you wish to delete from the list of computational items;

2) Click the "Delete" button to open up a warning dialog box ("Delete current calculation chemistry?") and click the "Yes" button to delete the item or click "No" to cancel deletion of the item.

4.6.3. Panels

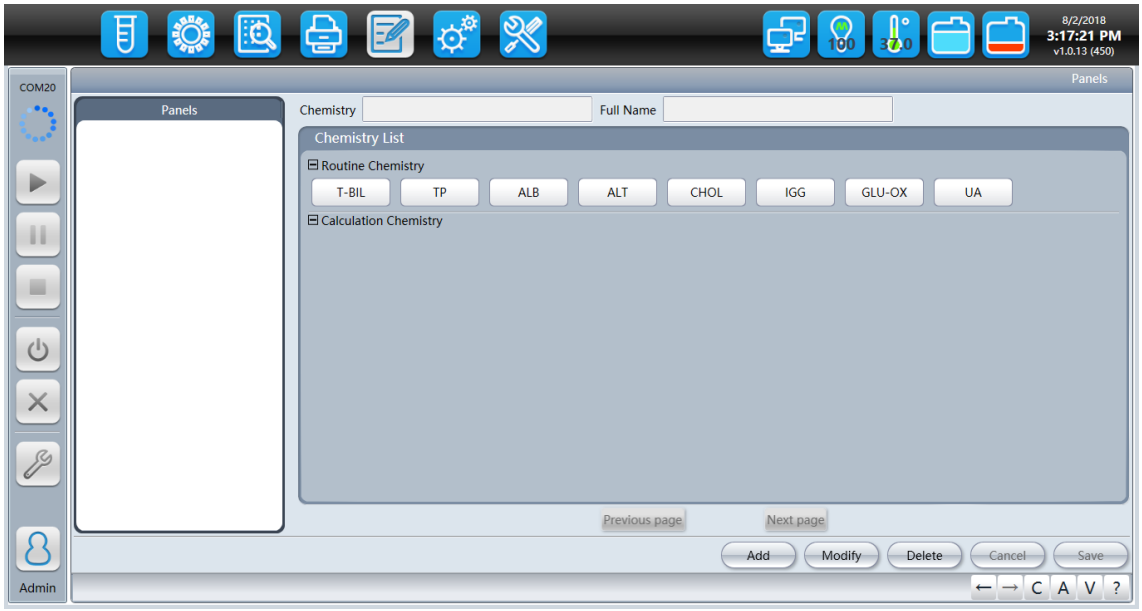


Figure 4-32: "Panels" Parameter Settings Screen

4.6.3.1. Explanation of Basic Parameters

Parameter	Meaning	Operation

Parameter	Meaning	Operation
Chemistry	Panel abbreviations	Data can be entered directly into the input box. Supports entry of up to 20 English characters or 20 Chinese characters (supports the input of any characters, including special characters such as punctuation and Greek letters)
Full name	Panel full names	Data can be entered directly into the input box. Supports entry of up to 20 English characters or 20 Chinese characters (supports the input of any characters, including special characters such as punctuation and Greek letters)

4.6.3.2. Basic Operations

Add Panel

1) Click the "Add" button;
2) Select the desired panel from the standard item and computational item lists;
3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

Modify Panel

1) Select the panel you wish to modify in the list of panels;
2) Click the " Modify " button to modify items corresponding to the current panel;
3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.

Delete Panel

1) Select the panel you wish to delete from the list of panels;
2) Click the "Delete" button to open up a warning dialog box ("Delete current panel?") and click the "Yes" button to delete the item or click "No" to cancel deletion of the item.

4.6.4. Carryover

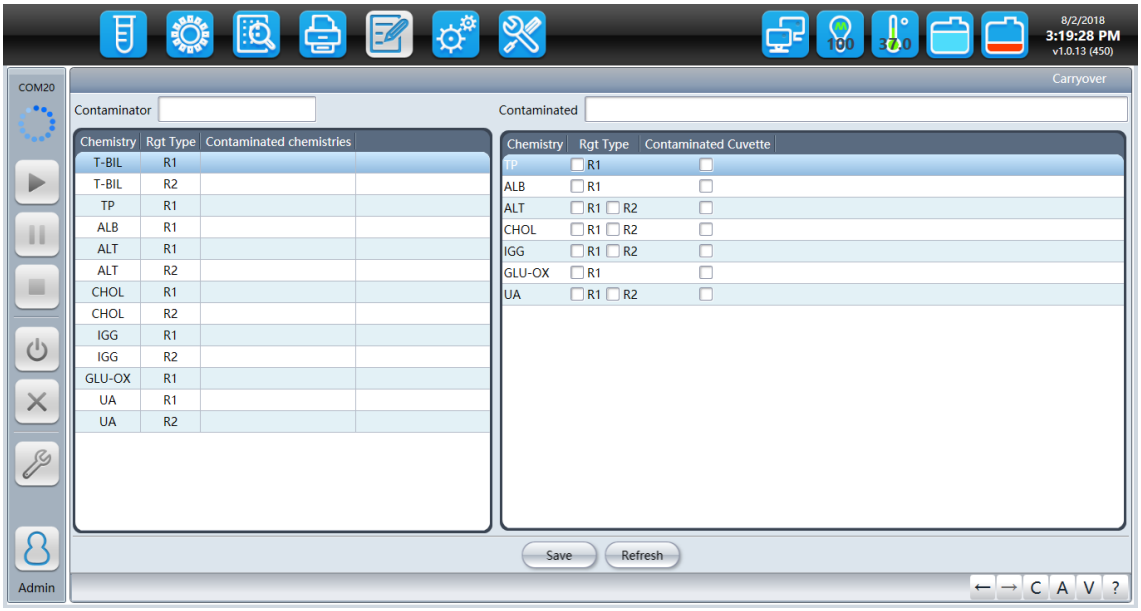


Figure 4-33: "Carryover" Parameter Settings Screen

4.6.4.1. Explanation of Basic Operations

For explanations of different parameters and operations corresponding to the "Carryover " screen, see the following table:

Parameter	Meaning	Operation
Contaminator	Contamination source item abbreviations	Input directly into the box
Contaminated	Contaminated item abbreviations	Input directly into the box

4.6.4.2. Basic Operations

Carryover Settings

1) Select a contaminator from the contamination source item list and enter the item abbreviation in the box to quickly find the item;

2) Select a contaminated item from the contaminated item list and enter the item abbreviation in the box to quickly find the item; once a selection has been made place a √ in the box next to the reagent class. If there is contamination of the reaction cuvette, place a √ in the box next to "Contaminated Cuvette". Once complete, click the "Save" button;

3) If you need to modify or delete a cross-contamination pair that has already been set, select a contaminator from the contamination source item list, remove the √ in the box next to the reagent class for the contaminated item and, once complete,

click the "Save" button.

4.6.5. Calibrator Setup

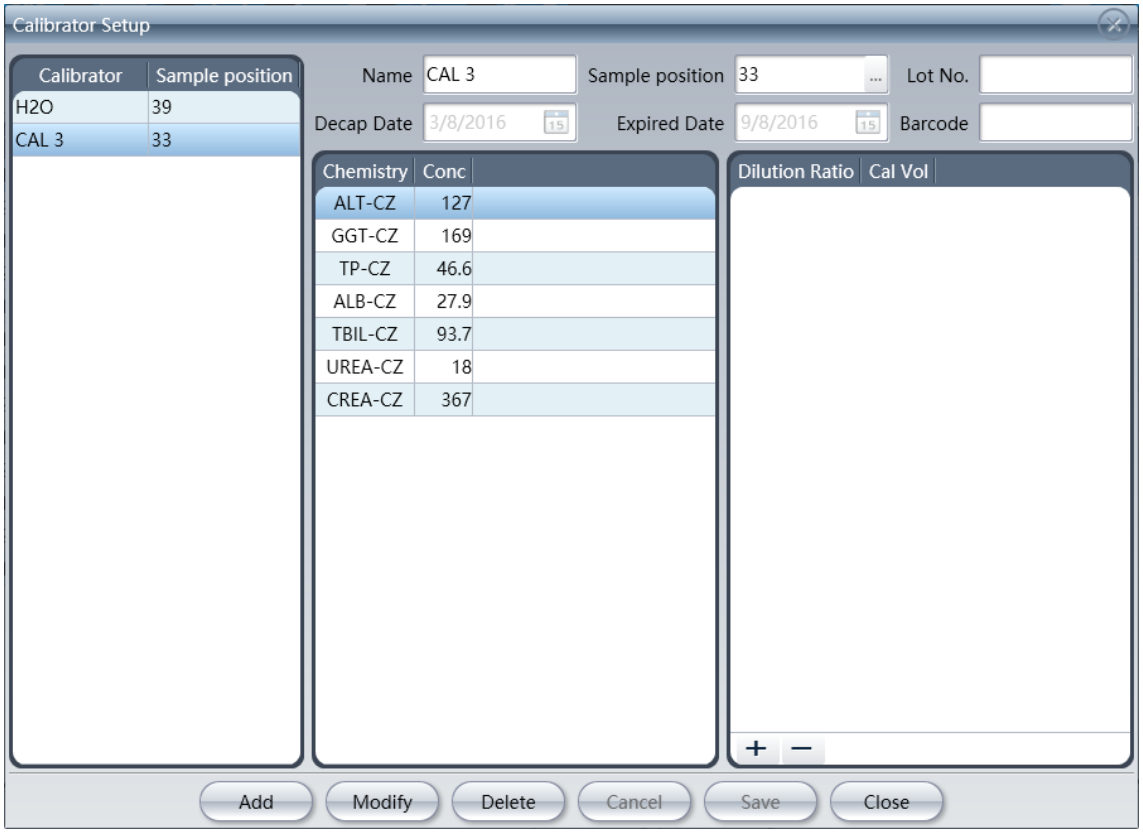


Figure 4-34: "Calibrator Setup" Screen

4.6.5.1. Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Calibrator Setup" screen, see the following table:

Parameter	Meaning	Operation
Name	Name of the calibrator	Input directly into the box
Sample Position	The position of the calibrator on the sample disk	Select the ... button to enter the sample tray status and select a sample position in which to place to the selected calibrator
Lot No.	Lot number of the calibrator	Input directly into the box
Decap Date	Date on which the calibrator was opened and a solution was prepared	Select by clicking on the calendar icon to the right of the box
Expired Date	Calibrator expiration date	Select by clicking on the calendar icon to the right of the box

Parameter	Meaning	Operation
Barcode	Barcode of the calibrator	Enter directly in the box or click on the "Scan" button in the sample disk screen to display directly

4.6.5.2. Basic Operations

Add calibrator, Set project calibrator concentration, Set project calibrator dilution factor

1) Click "+" to set the dilution factor and dosage for the item corresponding to the current calibrator; Click "-" to delete the dilution factor and dosage for the item corresponding to the current calibrator;
2) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.
3) When finished, click the "Close" button to exit the calibrator setup screen.

Modify a Calibrator

1) Select the calibrator that you want to modify from the calibrator name list;
2) Click the "Modify" button to modify information corresponding to the current calibrator;
3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.
4) When finished, click the "Close" button to exit the calibrator settings screen.

Delete a Calibrator

1) Select the calibrator that you want to delete from the calibrator name list;
2) Click the "Delete" button to open up a warning dialog box ("Delete selected calibrator?") and click the "Yes" button to delete the calibrator or click "No" to cancel deletion of the calibrator.
3) When finished, click the "Close" button to exit the calibrator setup screen.

4.6.6. QC Setup

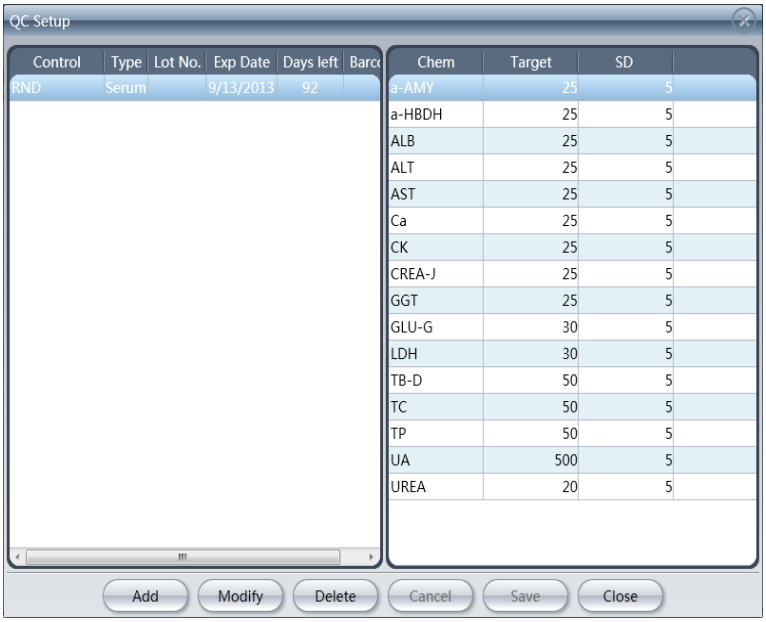


Figure 4-35: The "QC Setup" Screen

4.6.6.1. Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "QC Setup" screen, see the following table:

Parameter	**Meaning**	**Operation**
Control	Name of the quality control solution	Input directly into the box
Type	Type of quality control solution, including serum, plasma, urine and cerebrospinal fluid	Selected from a drop-down box
Lot No.	Lot number of the quality control solution	Input directly into the box
Exp Date	Expiration date of the QC solution	Select by clicking on the calendar icon to the right of the box
Days Left	The number of remaining days until QC solution expires	Enter the expiration date of the QC solution and the system will automatically display the number of days remaining until expiration

Parameter	Meaning	Operation
Barcode	QC solution lot number	Enter directly in the box or click on the "Scan" button in the sample disk screen to display directly
Target	Target value for item corresponding to a given calibrator	Input directly into the box
SD	Standard deviation value for item corresponding to a given calibrator	Input directly into the box

4.6.6.2. Basic Operations

Add a quality control solution or set the quality control solution concentration for a given item

1) Click the "Add" button;
2) Set parameter information corresponding to a control solution;
3) Enter a target value and standard deviation value in the target value and standard deviation fields which follow the same of the item corresponding to the current quality control solution;
4) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.
5) When finished, click the "Close" button to exit the QC Setup screen.

Modify a Calibrator

1) Select the QC solution that you want to modify from the QC solution list;
2) Click the "Modify" button to modify information corresponding to the current quality control solution;
3) If you need to save the data after completing the above, click the "Save" button, or click the "Cancel" button if you do not wish to save your data.
4) When finished, click the "Close" button to exit the QC Setup screen.

Delete a Calibrator

1) Select the quality control solution that you want to delete from the quality control solution list;
2) Click the "Delete" button to open up a warning dialog box ("Delete selected control?") and click the "Yes" button to delete the quality control solution or click

"No" to cancel deletion of the quality control solution.

3) When finished, click the "Close" button to exit the quality control solution settings screen.

4.7. Statistical Reports

Includes four subsections: test statistics, workload statistics, charge statistics and result statistics. These will be described in detail in corresponding chapters.

4.7.1. Test Statistics

The "Test Statistics" menu is as shown below:

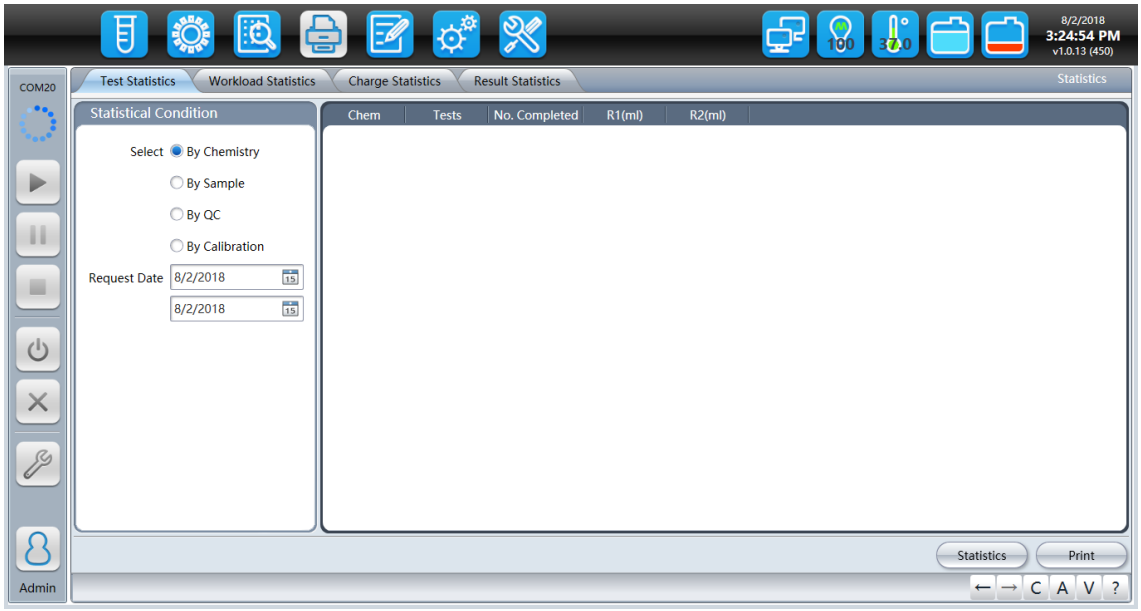


Figure 4-36: The "Test Statistics" Screen

4.7.1.1. Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Test Statistics" screen, see the following table:

Parameter	Meaning	Operation
Select	Includes "By Chemistry", "By Sample", "By QC", "By Calibration"	No operation
By Chemistry	Generates statistics concerning the amount of tests performed, number of tests completed, R1 consumption and R2 consumption for each item over a requested period of time as well as totals for tests performed, number of tests completed, R1 consumption and R2 consumption across all items	Click the circle next to the item statistics option until it turns blue

Parameter	Meaning	Operation
By Sample	Generates statistics concerning the amount of samples processed, number of items processed, number of tests completed, statistical items, manual items and ISE items for each day over a requested period of time as totals for tests performed, number of tests completed, R1 consumption and R2 consumption across all days	Click the circle next to the item statistics option until it turns blue
Request Date	Generates statistics concerning a requested date range with the range set to the current day only by default. Enter the start date in the first box and the end date in the second box. The start date cannot be later than the end date.	Select by clicking on the calendar icon to the right of the box

4.7.1.2. Basic Operations

Statistics

Allows the user to check data for test statistics according to the statistical criteria entered.

Print

Prints a test statistics information table.

4.7.2. Workload Statistics

"Workload Statistics" are used to evaluate the user's workload with respect to a specific physician or department.

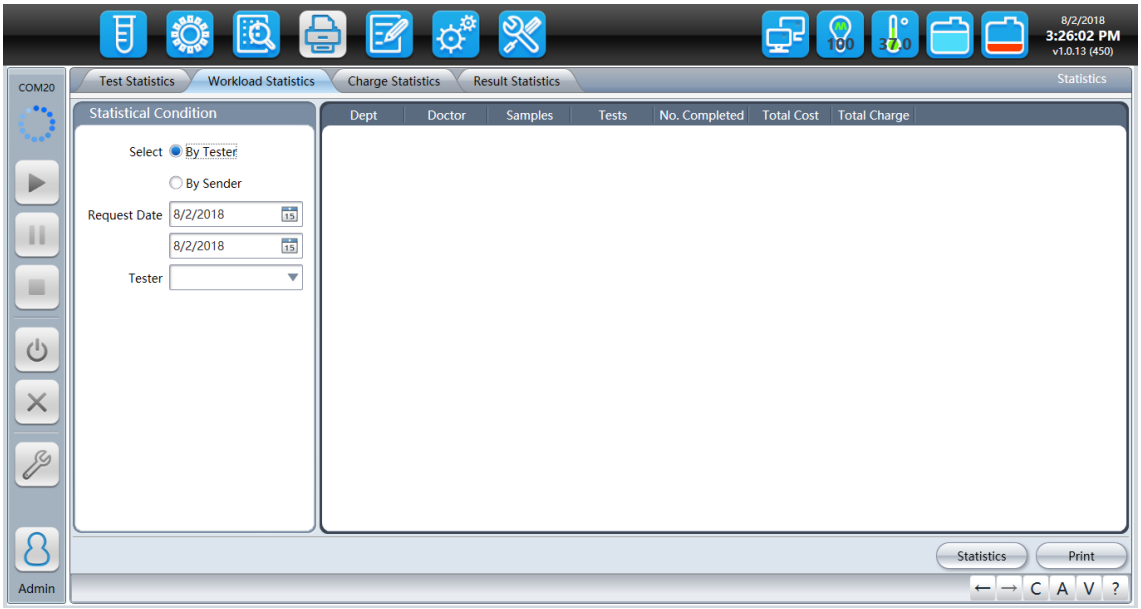


Figure 4-37: The "Workload Statistics" Screen

4.7.2.1. Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Workload

Statistics" screen, see the following table:

Parameter	Meaning	Operation
Select	Includes "By Tester" and "By Sender"	No operation
By Tester	Selects Examining Physician Statistics. If nothing is entered into the boxes corresponding to the examining department and the examining physician, then the total workload of all examining physicians in the examining department will be computed; When an examining physician is entered into the box corresponding to the examining physician, then only the workload of the physician in question is computed	Click the circle next to the item statistics option until it turns blue
By Sender	Selects Submitting Physician Statistics. If nothing is entered into the boxes corresponding to the submitting department and the submitting physician, then the total workload of all submitting physicians not in the examining department will be computed; If a department is entered into the box corresponding to the submitting department, then the total workload of all submitting physicians in the indicated department will be computed; If both a submitting department and submitting physician are entered into the corresponding boxes, then the total workload of the indicated physician in the indicated department will be computed;	Click the circle next to the item statistics option until it turns blue
Request Date	Generates statistics concerning a requested date range with the range set to the current day only by default. Enter the start date in the first box and the end date in the second box. The start date cannot be later than the end date.	Select by clicking on the calendar icon to the right of the box

4.7.2.2. Basic Operations

- **Statistics**

  Allows the user to check data related to workload statistics according to the statistical criteria entered.

- **Print**

  Prints a workload statistics information table.

4.7.3. Charge Statistics

The "Charge Statistics" menu is shown below:

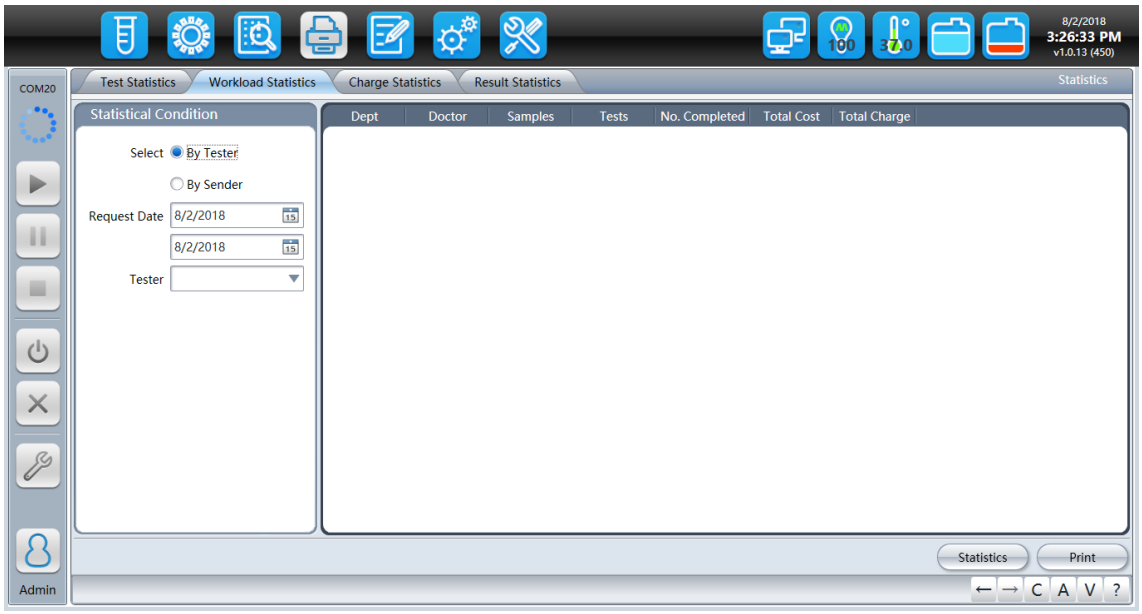


Figure 4-38: The "Charge Statistics" Screen

4.7.3.1. Explanation of Basic Parameters

An explanation of basic parameters found in the "Charge Statistics" menu is provided in the following table:

Parameter	Meaning	Operation
Select	Includes "patient cost statistics" and "cost accounting statistics." Cost statistics include the number of items, number of items completed, total costs, total receipts, and total revenue	No operation
By Price	Selects the patient cost statistics. A range of sample serial numbers to be incorporated in patient cost statistics needs to be set.	Click the circle next to the item statistics option until it turns blue
By Cost	Selects cost accounting statistics. The user must set items included in cost account statistics	Click the circle next to the item statistics option until it turns blue
Request Date	Generates statistics concerning a requested date range with the range set to the current day only by default. Enter the starting day in the first box and the ending day in the second box. The starting date cannot be later than the ending date.	Select by clicking on the calendar icon to the right of the box
Sample ID	Test sample serial number range.	Input directly into the box
Item	Name of the test item	Selected from a drop-down box

4.7.3.2. Basic Operations

- **Statistics**

Allows the user to check data for charge statistics according to the statistical condition entered.

■ **Print**

Prints a costs statistics information table.

4.7.4. Result Statistics

The "Result Statistics" menu is shown below:

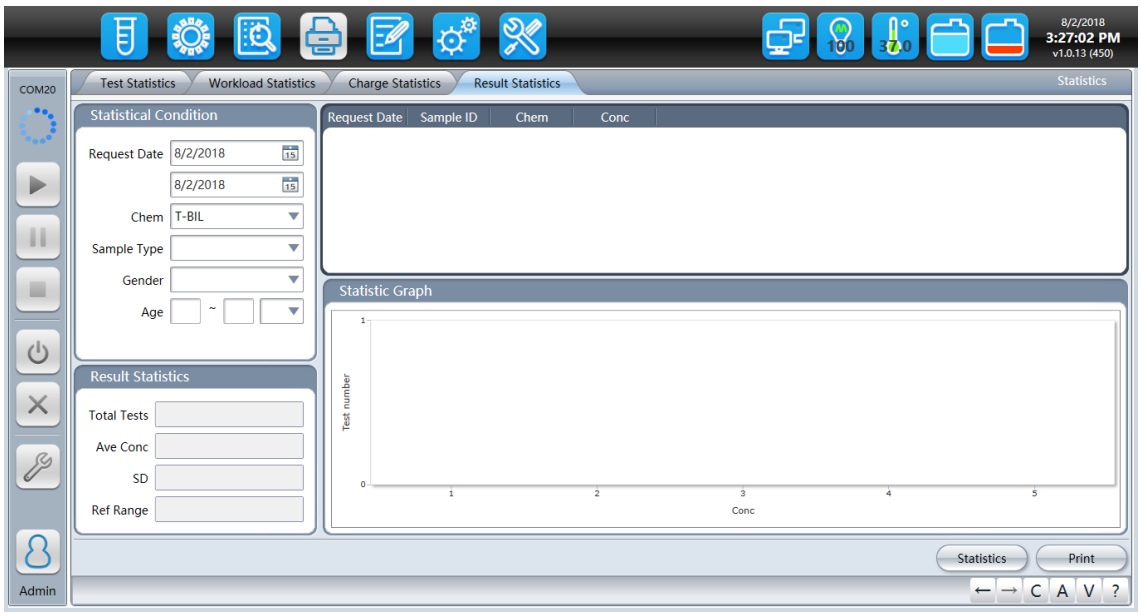


Figure 4-39: The "Result Statistics" Screen

4.7.4.1. Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Result Statistics" screen, see the following table:

Parameter	Meaning	Operation
Request Date	Generates statistics concerning a requested date range with the range set to the current day only by default. Enter the start date in the first box and the end date in the second box. The start date cannot be later than the end date.	Select by clicking on the calendar icon to the right of the box
Item	Name of the test item	Selected from a drop-down box
Sample Type	Sample type of the result statistics.	Selected from a drop-down box
Gender	Patient gender of the results statistics.	Selected from a drop-down box

Parameter	Meaning	Operation
Age	Patients age range and units of the result statistics.	The patient age range is entered directly into the corresponding box and age units are selected from a drop-down box
Total Tests	The total number of tests that have been completed and produced results under the given statistical condition	No operation
Ave Conc	The average concentration of all test results under the given statistical criteria	No operation
SD	The average standard deviation of all test results under the given statistical criteria	No operation
Ref Range	Statistical item reference range	No operation

4.7.4.2. Basic Operations

- **Statistics**

  Allows the user to check data for result statistics according to the statistical criteria entered.

- **Print**

  Print a result statistics information table.

4.8. Function Settings

In the operating software main interface, click the "Function Setup" button to bring up a drop-down menu which includes the following 5 options: system Setup, hospital Setup, user manage, print Setup, and barcode Setup. These options will be introduced in separate sections to follow.

4.8.1. System Setup

Click the "Function Setup" button to pull up a drop-down menu, click on the "System Setup" button and enter the system setup screen. This screen is used primarily for function activation settings and settings concerning the sharing of reagent positions and rules concerning the removal of reagents.

4.8.1.1. Function Enable

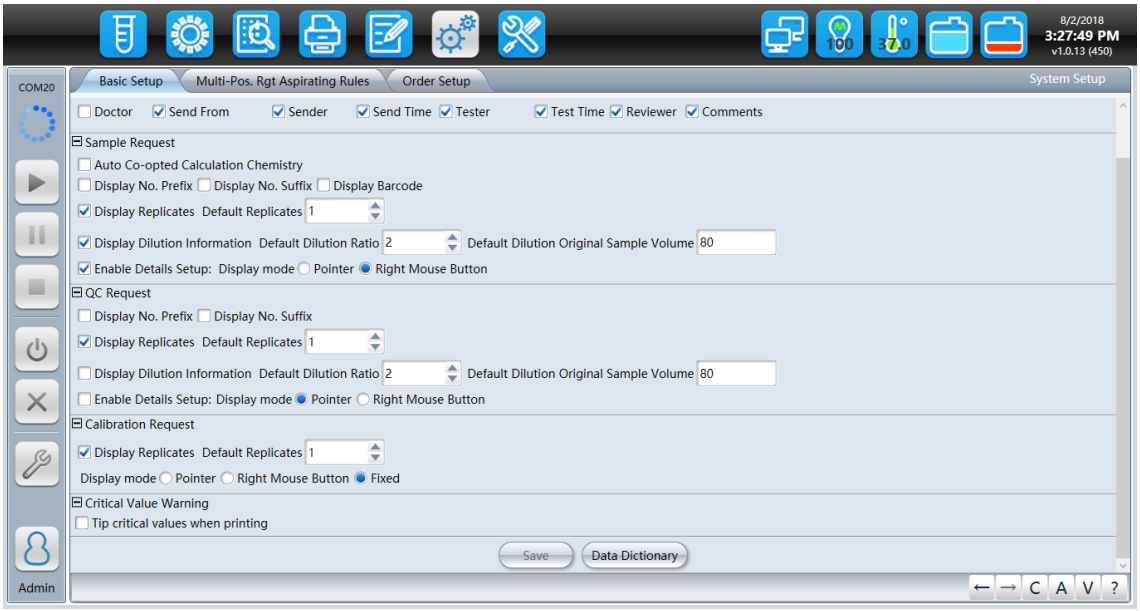


Figure 4-40: The "Function Enable" Screen

Explanation of Basic Parameters

- **For explanations of different parameters and operations corresponding to "Sample Request" parameters, see the following table:**

Parameter	Meaning	Operation
Display No. Prefix	When this option is selected, the sample request screen will display sample numerical prefixes	Click save after checking
Display No. Suffix	When this option is selected, the sample request screen will display sample numerical suffixes	Click save after checking
Display Barcode	When this option is selected, after a sample's barcode has been scanned in and the sample is selected on the sample request screen, the sample's barcode will be displayed	Click save after checking
Display Replicates	When this option is selected, a box showing the number of repeated requests will be displayed on the sample request screen	Click save after checking this option and use the input box on the right side to set the default number of replicates
Display Dilution Information	When this option is selected, the sample request screen will display sample dilution information	Click save after checking this option and use the input box on the right side to set the default dilution factor and sample dilution amount

Parameter	Meaning	Operation
Enable Details Setup	Method for showing detailed settings: 1. Select "mouse over" to have the sample application interface display detailed settings information when the mouse cursor is placed over a standard item; 2. Select "right click" to have the sample application interface display detailed settings information when the user right clicks an item;	Click save after checking this option and select the detailed settings display mode on the right side of the screen

■ **For an basic explanation of "QC Request" parameters, see the following table:**

Parameter	Meaning	Operation
Display No. Prefix	When this option is selected, the sample request screen will display numerical prefixes for QC samples	Click save after checking
Display No. Suffix	When this option is selected, the sample request screen will display numerical suffixes for QC samples	Click save after checking
Display Replicates	When this option is selected, a box showing the number of repeated requests will be displayed in the QC sample request screen	Click save after checking
Display Dilution Information	When this option is selected, the QC sample request screen will display sample dilution information	Click save after checking
Enable Details Setup	Method for showing detailed settings: 1. Select "mouse over" to have the quality sample application interface display detailed settings information when the mouse cursor is placed over a standard item; 2. Select "right click" to have the sample application interface display detailed settings information when the user right clicks an item;	Click save after checking

■ **For an basic explanation of "Calibration Request" parameters, see the following table:**

Parameter	Meaning	Operation
Display Replicates	When this option is selected, a box showing the number of repeated requests will be displayed in the calibration request screen	Click save after checking this option and use the input box on the right side to set the default number of replicates
Enable Details Setup	Method for showing detailed settings: 1. Select "mouse over" to have the calibrator application interface display detailed settings information when the mouse cursor is placed over a standard item; 2. Select "right click" to display detailed settings information when the user right clicks an item; 3 Select "fixed" to have the calibration request interface display detailed information on the selected item on the right-hand side of the screen	Click save after checking this option and select the detailed settings display mode on the right side of the screen

4.8.1.2. Multi-Pos. Rgt Aspirating Rules

When a reagent has been assigned multiple reagent positions, you can use this screen to set a Sample sequence for multiple reagent positions.

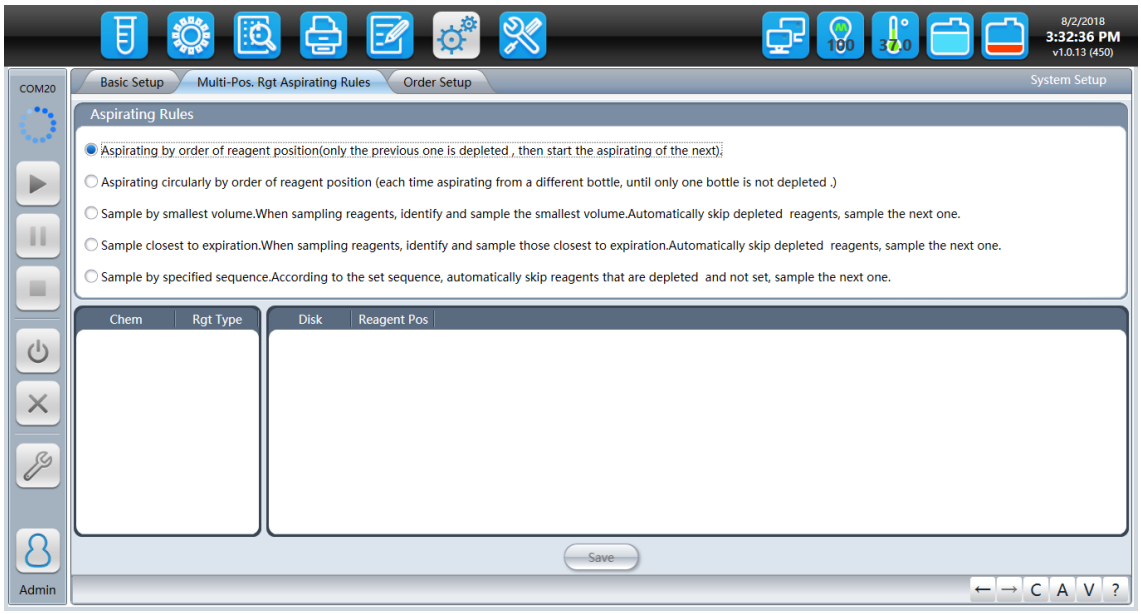


Figure 4-41: The "Multiple Reagent Position and Aspirating Rules" Settings Screen

4.8.1.3. Order Setup

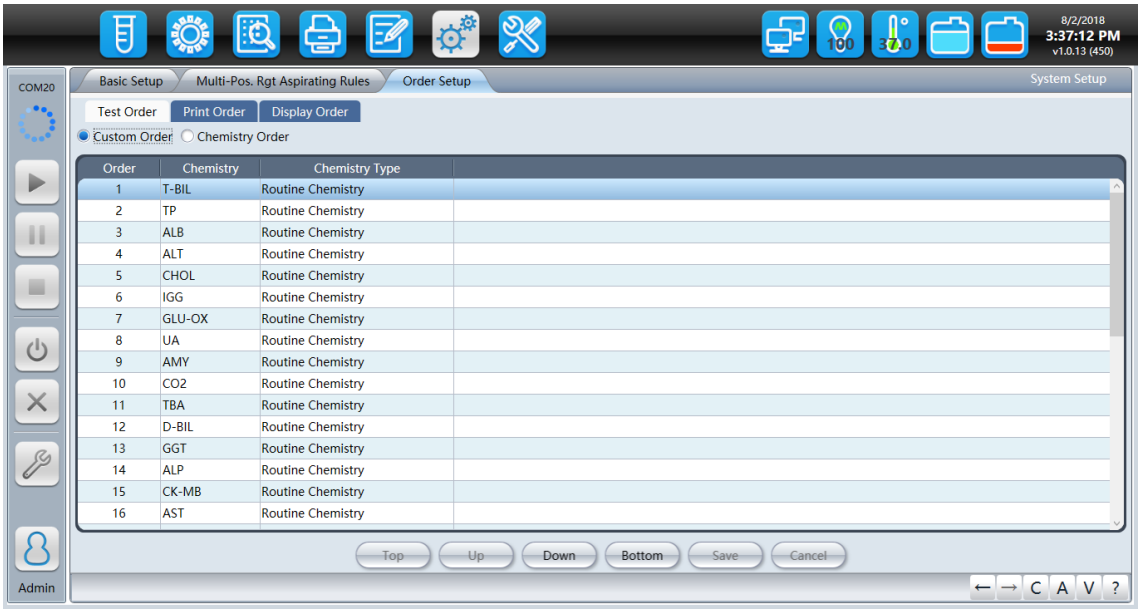


Figure 4-42: The "Order Setup" Settings Screen

You can setup test order, print order and display order by click related tabs.

Function Description

For an explanation of the function of the "Order Setup" screen buttons and the operation thereof, see the following table:

Button	**Explanation and Operation of Function**
Top	Move the selected item directly to the top
Up	Move the position order of the selected item up by one
Down	Move the position order of the selected item down by one
Bottom	Move the selected item directly to the bottom
Save	Save the modified order list
Cancel	Cancel the modified order list

4.8.2. Hospital Setup

Click the "Function Setup" button to bring up a drop-down menu, click on the "Hospital Setup" button to enter the Hospital Setup screen which is used to set hospital-related information.

4.8.2.1. Hospital Information

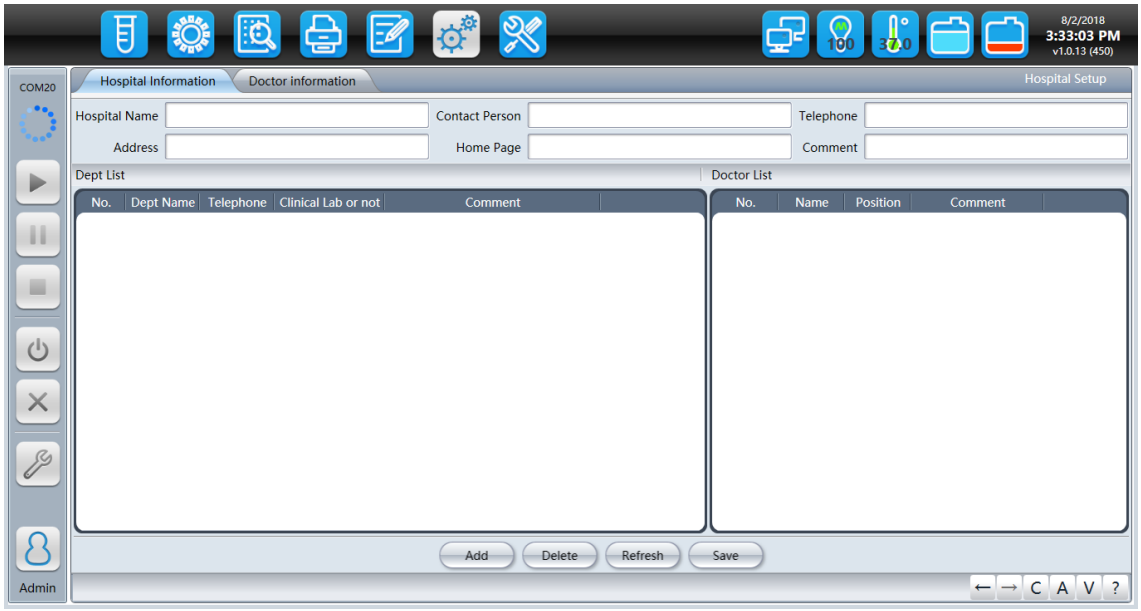


Figure 4-43: The "Hospital Information" Settings Screen

Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Hospital Information" screen, see the following table:

Parameter	Meaning	Operation
Hospital Name	Name of the hospital	Input directly into the box
Contact Person	Names of the hospital personnel in charge	Input directly into the box
Telephone	Hospital phone number	Input directly into the box
Address	Hospital address	Input directly into the box
Home Page	Hospital website	Input directly into the box
Comment	Explanation and description of the hospital	Input directly into the box
Dept List	Shows the department number, department name, telephone number, whether the department is the examining department and additional remarks	Click to add a new department
Doctor List	Shows the physician's number, name, rank and additional remarks	None

Introduction to Application Features

For an explanation of the function of the "Hospital Information" screen buttons and the operation thereof, see the following table:

Button	Explanation and Operation of Function
Add Department	Click this button to add an additional input box to the department list. The user can then enter corresponding departmental information
Delete	Choose a department and click on this button to delete the selected department
Refresh	Click this button to have the screen display department and physician information saved in the system database
Save	After adding or modifying records in the data list, click this button to save the changes.

4.8.2.2. Doctor Information

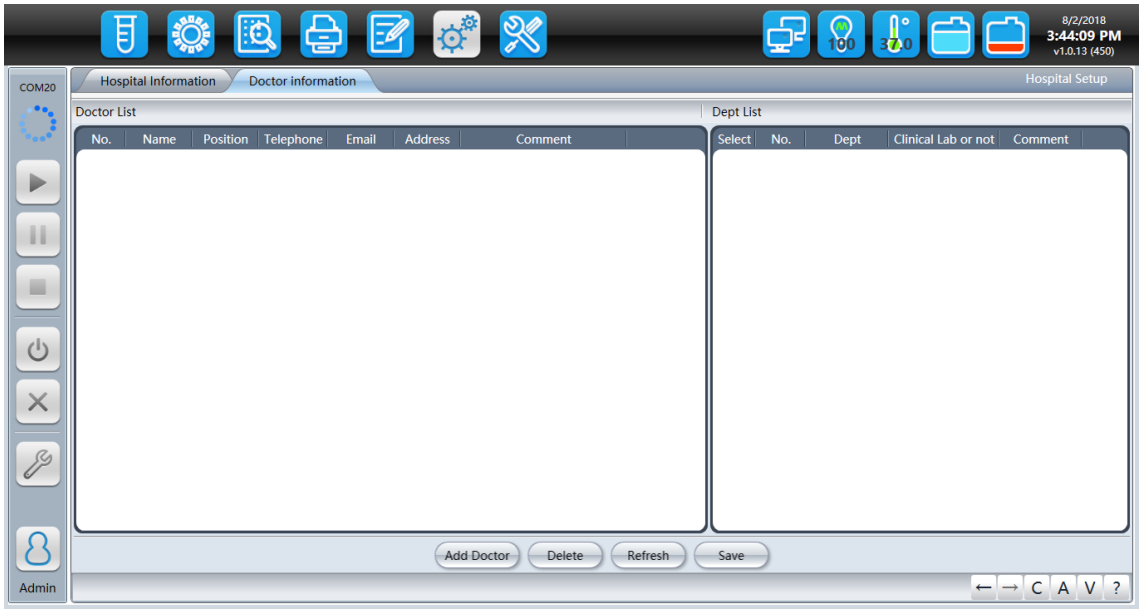


Figure 4-44: The "Doctor Information" Settings Screen

Explanation of Basic Parameters

For a basic explanation of the parameters of the "Doctor Information" screen, see the following table:

Parameter	Meaning	Operation
Doctor List	Shows the physician's number, name, position and additional comments	Click to add a new physician

Parameter	Meaning	Operation
Dept List	Shows the department number, department name, telephone number, whether the department is the examining department and additional remarks	None

Introduction to Application Features

For an explanation of the meaning of the function buttons found on the "Doctor Information" screen, see the following table:

Button	Function Description
Add Physician	Click this button to add an additional input box to the physician list. The user can then enter corresponding physician information
Delete	Select a physician and click on this button to delete the selected physician
Refresh	Click this button to have the screen display department and physician information saved in the system database
Related Departments	Select a physician and select a department from the department list on the right to associate the physician with the selected department
Save	After adding or modifying records in the data list, click this button to save the changes.

4.8.3. User Management

Click the "Function Setup" button to bring up a drop-down menu, click on the "User Manage" button to enter the User Management screen which includes role management and user management. These are described separately below:

4.8.3.1. Role Management

The "Role Management" interface is used to set appropriate permissions for a given role:

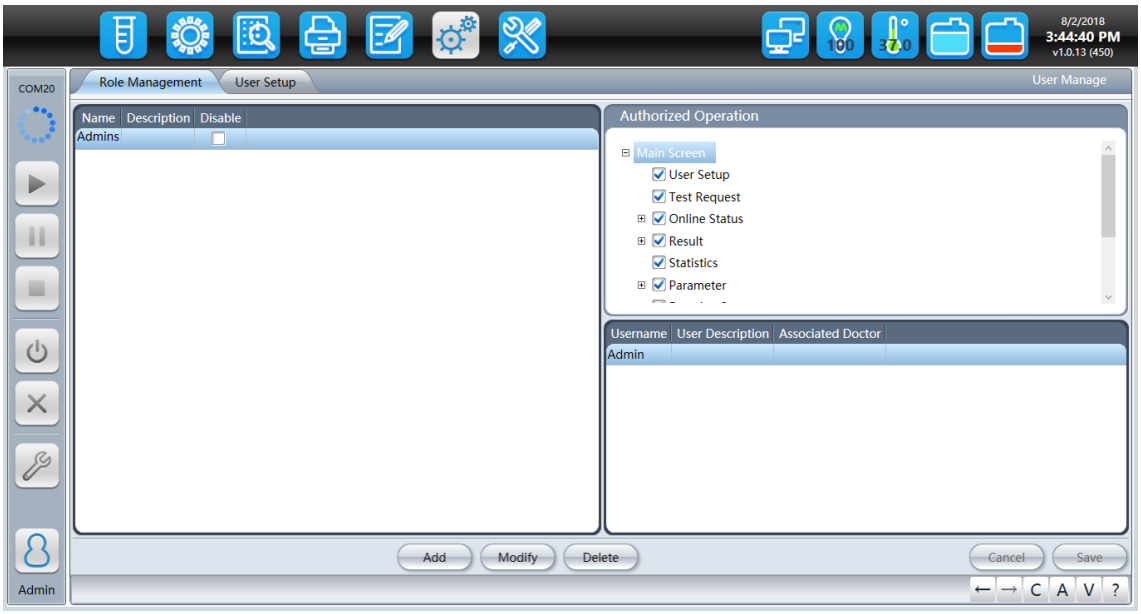


Figure 4-45: The "Role Management" Settings Screen

Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Role Management" screen, see the following table:

Parameter	Meaning	Operation
Name	Name of set role	Click to add and enter information into the corresponding box
Description	Detailed description of the set role	Click to add and input into the corresponding box
Disable	Disables the current role	Check the corresponding box

Introduction to Application Features

For an explanation of the function of the "Role Management" screen buttons and the operation thereof, see the following table:

Button	Function
Add	Adds a new role
Modify	Modifies permissions for the selected role
Delete	Deletes the selected role
Cancel	Cancels the current operation
Save	After adding or modifying records in the data list, click this button to save the changes.

4.8.3.2. User Setup

Used to assign appropriate roles to the user:

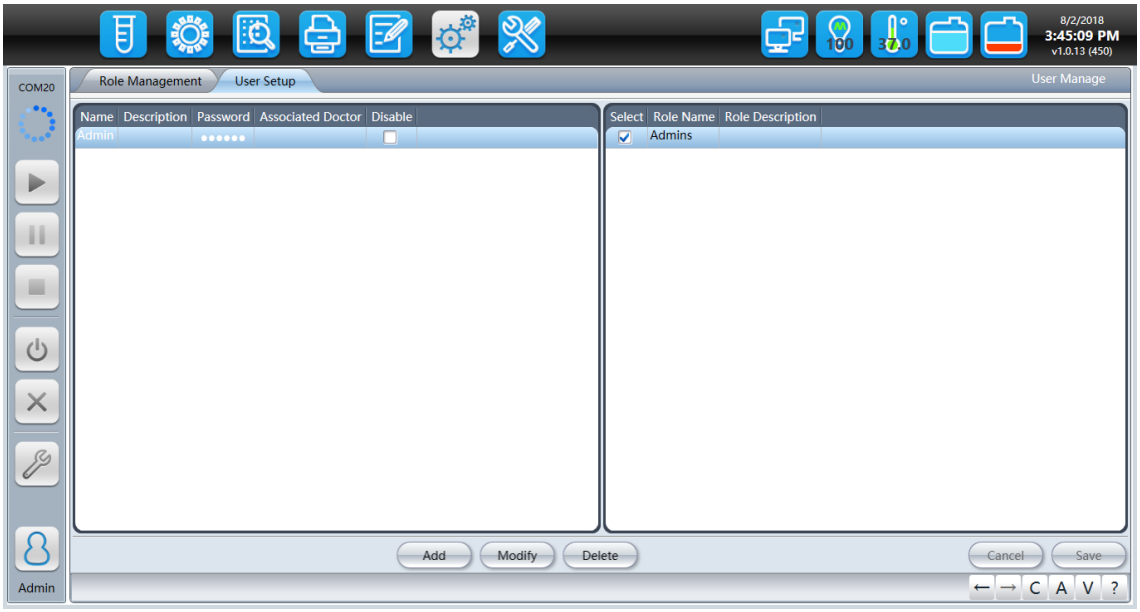


Figure 4-46: The "User Setup" Settings Screen

Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "User Setup" screen, see the following table:

Parameter	Meaning	Operation
Name	Username used to log into the software	Click to add and input into the corresponding box
Description	Detailed description of the selected account	Click to add and input into the corresponding box
Password	The password of the selected account	Click to add and input into the corresponding box
Associated Doctor	Name of the physician using the selected account	Click to add and input into the corresponding box
Disable	Disables use of the selected account	Check the corresponding box

Introduction to Application Features

For an explanation of the function of the "Role Management" Screen buttons and the operation thereof, see the following table:

Button	Function Explanation
Add	Adds a new user
Modify	Modify the role assigned to the selected user
Delete	Deletes the user currently selected
Cancel	Cancels the current operation
Save	After adding or modifying records in the data list, click this button to save the changes.

4.8.4. Print Setup

Click the "Function Setup" button to bring up a drop down menu, click on the "Print Setup" button to enter the Print Setup interface which includes Template Setup, Print Order and the Print List. See below for more details.

4.8.4.1. Template Setup

In the Template Setup menu, the user can set corresponding print formats and templates for different printing categories based on their specific needs.

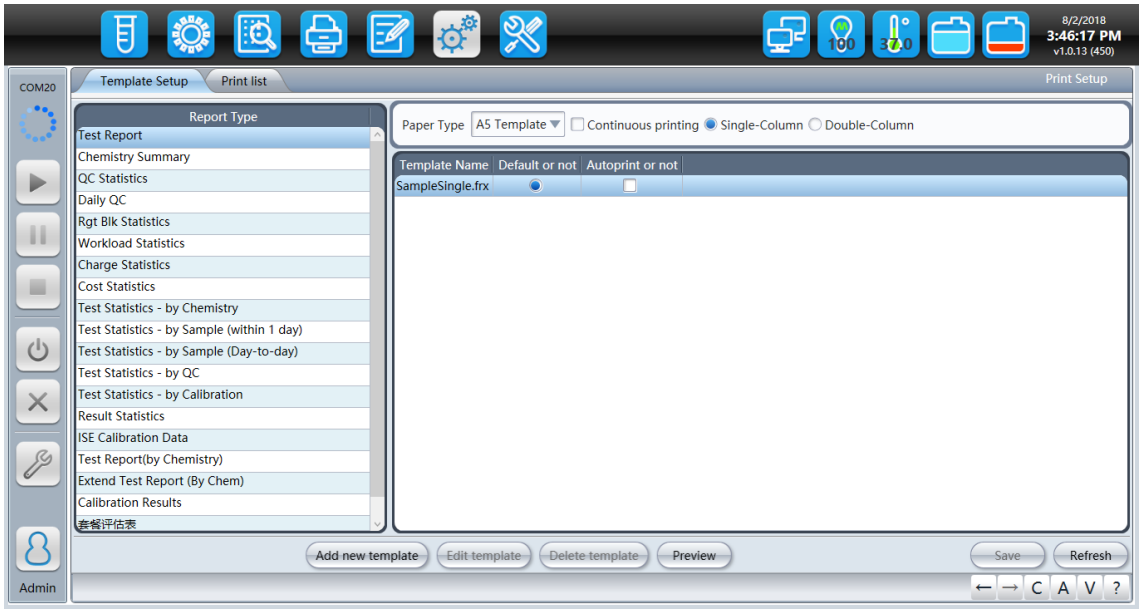


Figure 4-47: The "Template Setup" Screen

Explanation of Basic Parameters

For a detailed explanation of the various "Report Type" in the "Template Setup" screen, see the table below:

Report Type	Detail
Test Report	Individual patient's inspection report, including a summary of patient

Report Type	Detail
	information, sample information, test results and diagnostic information
Chemistry Summary	Summarizes test results obtained over a given period by item, including a summary of the item's information and test results
QC Statistics	Print interday quality control curves and quality control data for a given item
Daily QC	Print real time quality control curves and quality control data for a given item
Rgt Blk Statistics	Provides summary information for reagent blanks, including the blank's absorbance, reactivity and blank limit
Workload Statistics	Prints statistics for the total testing workload of tester within a given period of time, including sample amounts and number of tests
Charge Statistics	Prints information regarding test fees for some or all samples within a given period of time
Cost Statistics	Print the statistics concerning the total cost, receipts and profits of all test items within a given period of time
Test Statistics - by Chemistry	Print information concerning the total number of tests and level of reagent use for all items within a given period of time
Test Statistics - by Sample (within 1 Day)	Print the number of samples requested, the corresponding number of tests, test information and serum information for a single day
Test Statistics - by Sample (Day-to-day)	Print the number of samples requested, the corresponding number of tests, test information and serum information for a given period of time (multiple days)
Result Statistics	Print out a test results distribution trend chart and trend information for a given item for a given period of time
ISE Calibration Data	Prints out ISE calibration results for a given period of time

Function Description

For an explanation of the function of the buttons present in the "Template Setup" screen, see the table below:

Button	Function Description
Add new template	Adds new printing templates
Edit Template	Allows the user to edit template formats that already exist within the

Button	Function Description
	system
Delete Template	Deletes templates that already exist within the system. Default templates cannot be deleted
Preview	View a preview for the selected template
Save	Saves the selected information after adjustments to template information are made
Refresh	There is no need to save after editing template information. Use the refresh option to restore the template to its pre-edited state

4.8.4.2. Print List

Used to display the sample currently printing (automatic printing only) as well as display the reasons for, and number of, print failures for a given sample.

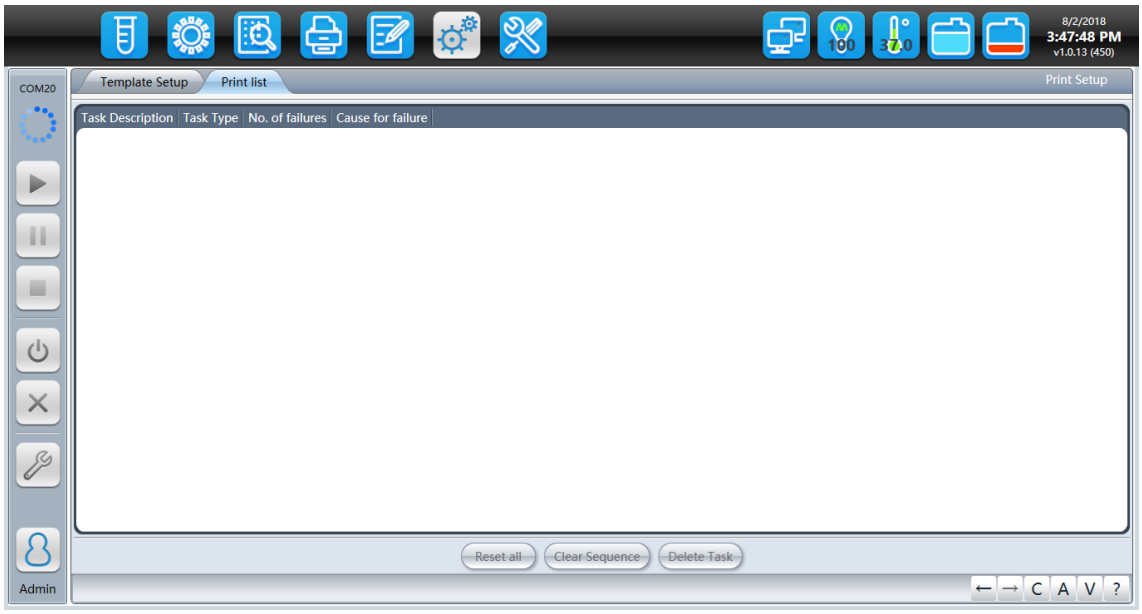


Figure 4-42: The "Print List" Settings Screen

Introduction to Application Features

For an explanation of the function of the "Print List" screen buttons and the operation thereof, see the following table:

Button	Explanation of Functions and Operation
Reset all	Clears the number of failed attempts for all failed print jobs shown in the print list so that failed jobs can be re-attempted

Button	Explanation of Functions and Operation
Clear Sequence	Deletes all failed print jobs currently on the print list
Delete task	Deletes the selected failed print job

4.8.5. Barcode Setup

Click the "Function Setup" button to bring up a drop-down menu, click on the "Barcode Setup" button to enter the barcode setup interface. This interface is mainly used to set up working modes for the sample and reagent barcode scanning systems, barcode symbology and encoding rules.

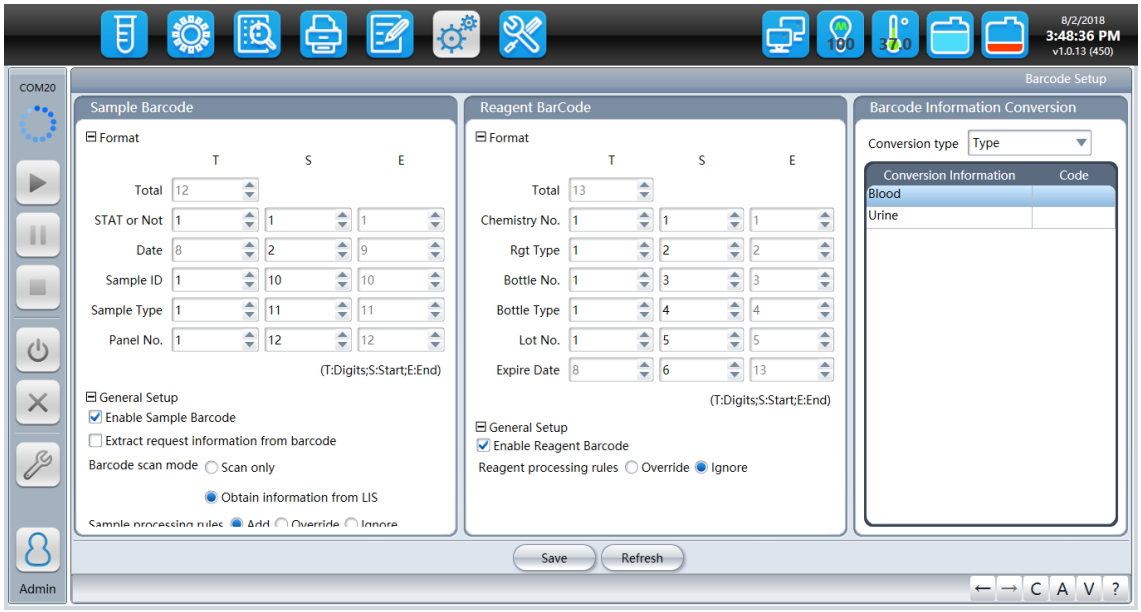


Figure 4-43: The "Barcode Setup" Screen

4.8.5.1. Explanation of Basic Parameters

Sample Barcode

For an explanation of the function and operation of the "Barcode Setup - Sample Barcode" screen, see the table below:

Parameter	Meaning
Sample Barcode	Select this option to indicate that sample barcodes can be used within the operating system. All buttons associated with sample barcode functions are active. If, on the other hand, this option is not selected, the corresponding buttons are inactive.
Extract Request Information from Barcode	This option can only be selected when the link to the LIS host has been terminated. If this option is selected, when the system scans a barcode, sample information will be automatically obtained according to the associated constituent fields rather than from the LIS system.

Parameter	Meaning
	For example: If a sample barcode only includes the serial number and date of the sample, then when the barcode is analyzed, the number and date contained in the barcode will be automatically parsed and added to the sample information. The appearance of any invalid composition information during the parsing process will without exception result in the sample corresponding to the barcode being declared invalid. In particular, care should be taken with panel serial numbers as the serial number must conform to the operating software's predefined composition serial number.
Total	The total number of digits in a sample barcode. Can be changed by the system automatically but may not be modified manually. The "S" and "E" read-only fields indicate the sample barcode's start and end positions respectively.
STAT or Not	Routine and emergency. Can be set to 0 or 1 bit.
Date	Year - Month - Day; this option defaults to 8 bits.
Sample ID	Sets the number of digits in a sample serial number.
Sample Type	The sample type (serum, etc.) defined in the data dictionary.
Panel No.	Panel serial number. If the user is unable to obtain request information for an LIS host but does not wish to enter request information manually, information for the requested item can be included in the barcode; Thus, the group contains a definition of panels for which a request is possible.

Reagent Barcode

For explanations of the meanings of different parameters and operations corresponding to the "Barcode Setup - Reagent Barcode" screen, see the following table:

Parameter	Meaning
Enable Reagent Barcode	Select this option to indicate that reagent barcodes can be used within the operating system. All buttons associated with reagent barcode functions are active. If, on the other hand, this option is not selected, the corresponding buttons will be inactive.
Bar Code Symbology	Includes Code128, Code39, Codabar, ITF, UPC / EAN and Code93. CODE128 is selected by default.
Total	The total number of digits in a reagent barcode. Can be changed by the system automatically but may not be modified manually. The "S" and "E" read-only fields indicate the reagent barcode's start

Parameter	Meaning
	and end positions respectively.
Chemistry No.	Serial number of the test item
Rgt Type	R1 / R2. This option is 1 bit.
Bottle No.	Reagent bottle serial number.
Bottle Type	Outer 15ml, inner 30ml. This option is 1 - 3 bits.
Lot No.	Reagent production batch.
Expire Date	Year - Month or Year - Month - Day; this option defaults to 8 bits.

Bar Code Conversion

Barcode data conversion. The user can convert sample types, combination serial numbers, item serial numbers, reagent types and bottle sizes to corresponding barcode values.

4.9. System Maintenance

4.9.1. Routine Maintenance

4.9.1.1. Routine Maintenance Commands

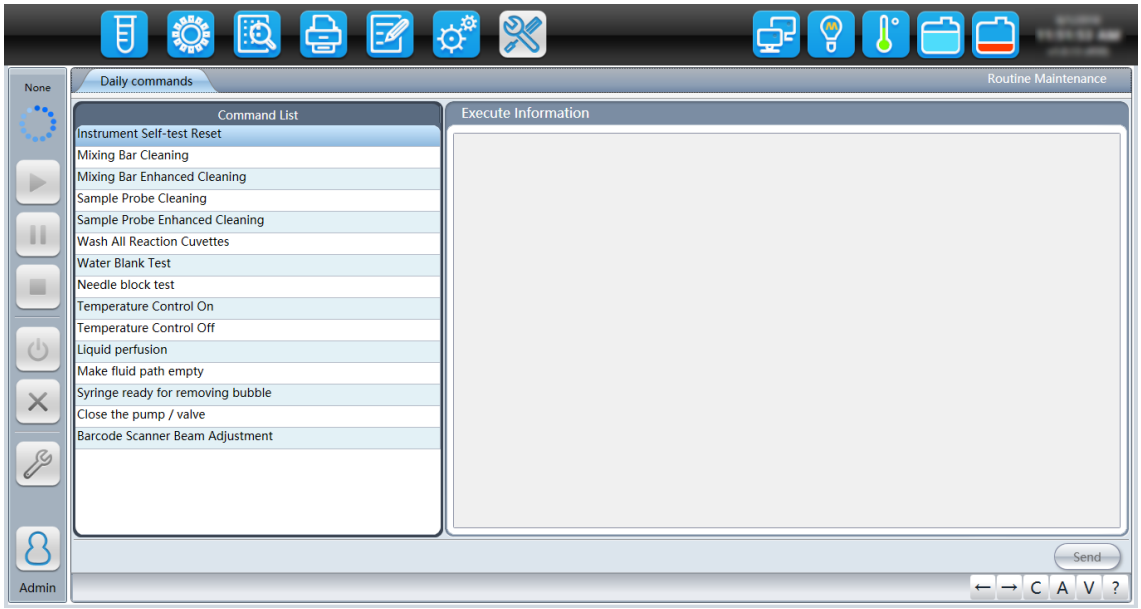


Figure 4-44: The "Daily Commands" Screen

Description of Command Functions

Parameter	Meaning	Operation

Parameter	Meaning	Operation
Instrument Self-test Reset	Self-test retest of the whole machine	Click send after selecting the command to execute
Mixing Bar Cleaning	Cleaning of the mixer	Click send after selecting the command to execute
Mixing Bar Enhanced Cleaning	Uses an alkaline cleaning solution to perform an intensive cleaning of the mixer	Click send after selecting the command to execute
Sample Probe Cleaning	Ordinary cleaning of the sample probe	Click send after selecting the command to execute
Sample Probe Enhanced Cleaning	Uses an alkaline cleaning solution to perform an intensive cleaning of the sample probe	Click send after selecting the command to execute
Wash All Reaction Cuvettes	Clean All Reaction Cuvettes	Click send after selecting the command to execute
Water Blank Test	Performs a water blank test and replaces the water blank data currently being used	Click send after selecting the command to execute
Needle Block Test	Check water coming out from probe is normal or not	Click send after selecting the command to execute
Temperature Control On	Reaction disk heater is turned on	Click send after selecting the command to execute
Temperature Control Off	Reaction disk heater is turned off	Click send after selecting the command to execute
Liquid Perfusion	All the tubes will be filled with liquid	Click send after selecting the command to execute
Make Fluid Path Empty	All the tubes will be empty	Click send after selecting the command to execute
Syringe ready for removing bubble	Syringe pulls down and probe interior pump is turned on	Click send after selecting the command to execute

Parameter	Meaning	Operation
Close the pump/valve	Pump is turned off and valve is close	Click send after selecting the command to execute
Barcode Scanner Beam Adjustment	Barcode scanner beam on and reagent disk rotate to barcode scanning position	Click send after selecting the command to execute

4.9.2. Log Management

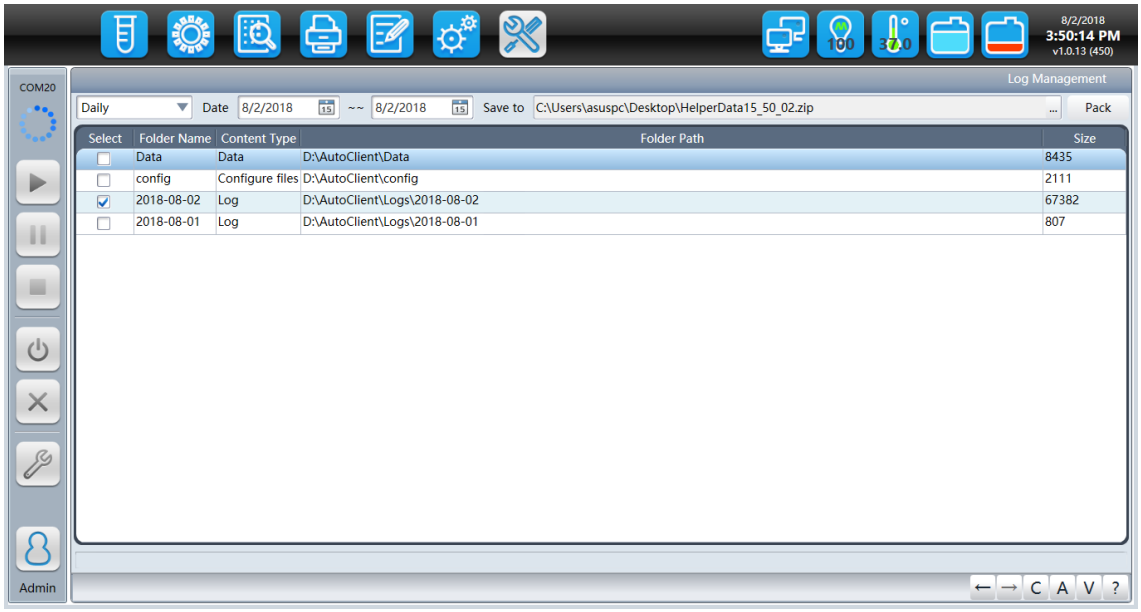


Figure 4-45: The "Log Management" Screen

4.9.2.1. Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Log Management" screen, see the following table:

Parameter	Meaning	Operation
Date	Select the time range of the log you would like to export	The date range can be selected from the drop-down box to the left of the "Date" field: daily, three days, five days, ten days and one month for a total of five options; Alternatively, you can click on "" to the right of the "Date" field to select a date range yourself;
Save to	Select the directory to which you want to export the specified log	Enter the file storage directory in the box to the right of the "Export File" text or click on

Parameter	Meaning	Operation
	contents	the "" icon to selecting a storage path
Pack	Allows the user to export a file to the export directory in the form of a zip file	Click the "Export" button to execute the export operation
Select	Select the files you would like to export by inserting a "☑" in the appropriate boxes in the lower part of the screen	Select a given file for export by placing a "☑" in the box on the same line as the name of the file you would like to export
Folder name	Name of the folder corresponding to files designated for export	/
Content Type	Refers to the type of data contained in files designated for export, including raw data, configuration files, and logs	/
Folder Path	The path of the directory in which exported files are stored	/
Size	The size of the data contained in files designated for export	/

4.9.3. Temperature Curve

Click the "Temperature Curve" button to enter the Temperature Status screen where you can check and monitor the temperature of the reaction disk.

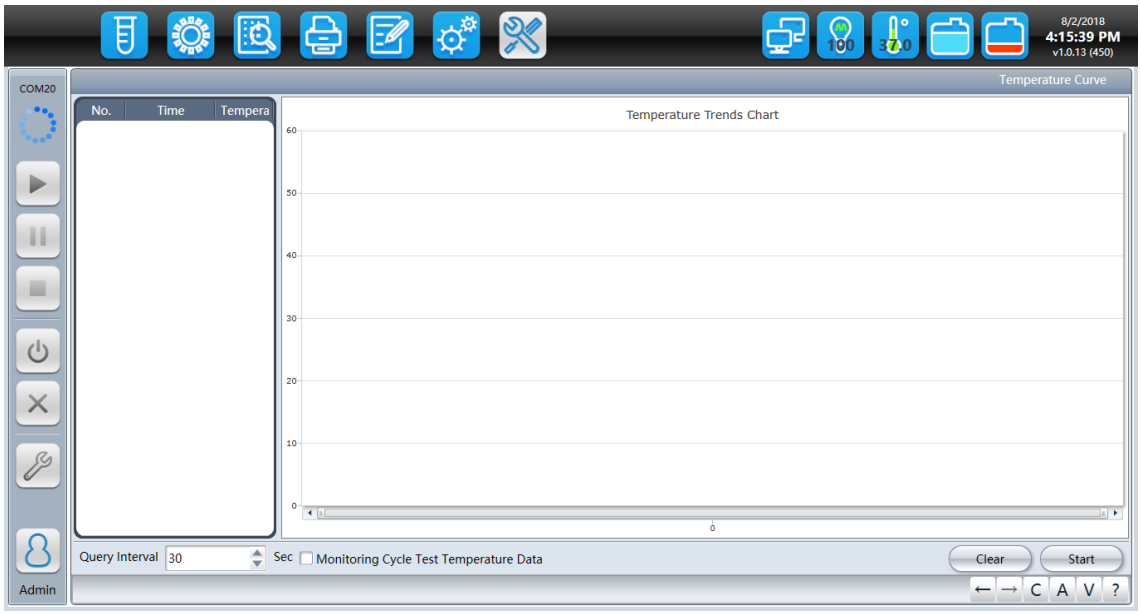


Figure 4-46: The "Temperature Curve" Screen

4.9.3.1. Explanation of Basic Parameters

For explanations of different parameters and operations corresponding to the "Temperature Curve" screen, see the following table:

Parameter	**Meaning**	**Operation**
No.	Indicates the serial number of monitoring data	/
Time	The time at which monitoring data was created	/
Temperature	Indicates the temperature of monitoring data	/
Temperature Trends Chart	A trend chart showing temperature monitoring data	/
Interval Time / Monitoring Cycle Test Temperature Data	Select the interval mode for monitoring data	The default interval is 30s between temperature measurements; The user can opt to have temperature monitoring performed according to cyclical testing, by placing a "☑" in the box next to "Monitoring Cycle Test Temperature Data."
Start	Start monitoring of temperature data	Click "Start Monitoring" and the software will monitor the reaction disk temperature according to the selected data monitoring interval method

4.9.4. AD Curve

Click to enter the lamp AD value monitoring screen.

Input collection interval time and cuvette number, click “Start” button, the system will rotate reaction disk and that cuvette will stop at light detecting position. The upper area will display the real time AD values of each channel of this cuvette. Click “Stop” button to stop monitoring.

To clear the display values, click “Clear Data” button.

To adjust the lamp AD value, you need take out one cuvette and rotate to the position, click “AD Adjust” button to start photometer adjustment tool.

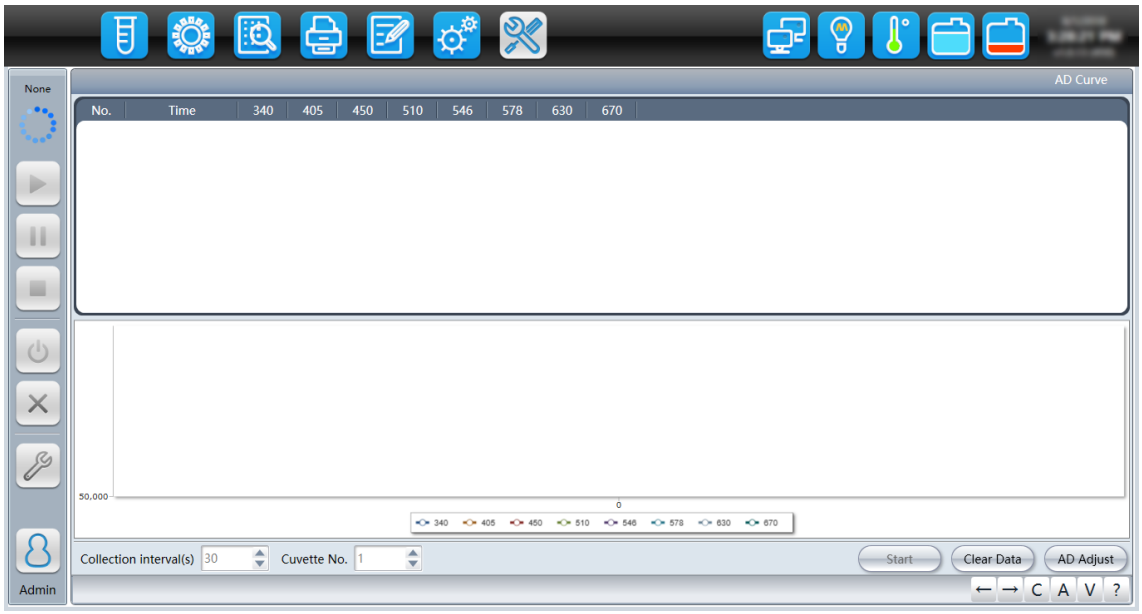


Figure 4-47: The "AD Curve" Screen

Parameter	Meaning	Operation
No	Wavelength sequence	/
Collection intervals	Time gap between collecting optical data	/
Collection intervals	Time gap between collecting optical data	Input directly
Cuvette No.	Cuvette position that rotates to the light path	Input directly

4.9.5. Probe Parameter Configuration

Click to enter the Probes Parameters screen which includes: Sample Probe Parameters,

Mixing Bar Parameters, Reaction disk Optical System Parameter and Peristaltic Pump/ Sample probe wash pump/ Mixing bar wash pump/ Cuvette wash pump Parameter. Users can adjust and set sample probe, mixer and reaction disk optical and electrical parameters as well as pump operating parameters to ensure normal operation of the instrument.

4.9.5.1. Sample Probe Parameter Configuration

See section 4.9.5.8 for a detailed description of the various parameters and function buttons in this menu.

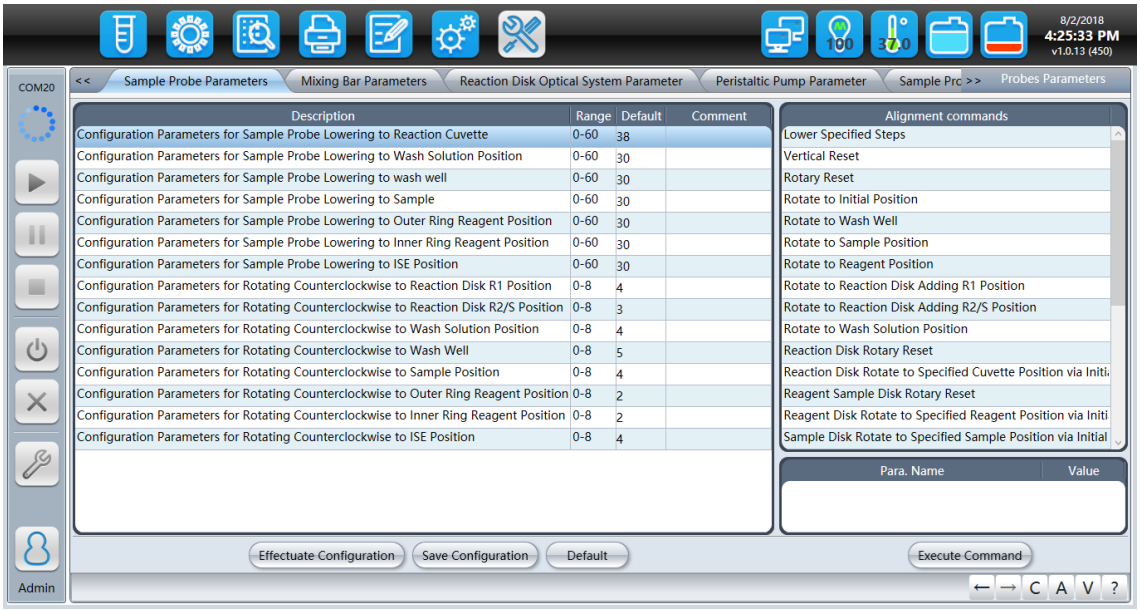


Figure 4-48: The "Sample Probes Parameters" Screen

4.9.5.2. Mixing Bar Parameter Configuration

See section 4.9.5.8 for a detailed description of the various parameters and function buttons in this menu.

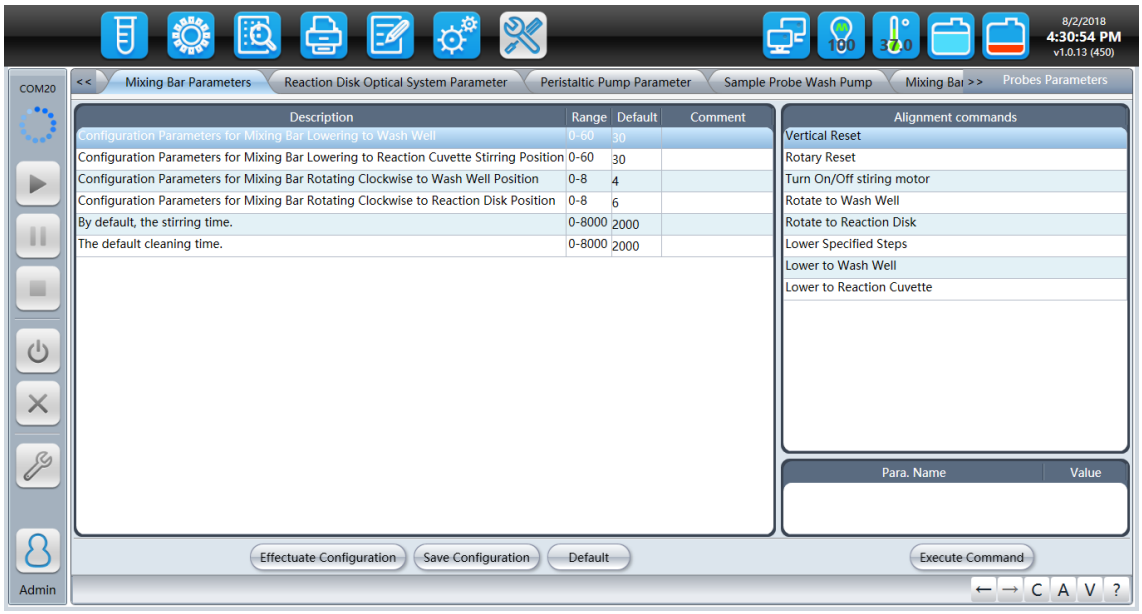


Figure 4-55: The "Mixing Bar Parameters" Screen

4.9.5.3. Reaction Disk Optical System Parameters Configuration

See section 4.9.5.8 for a detailed description of the various parameters and function buttons in this menu.

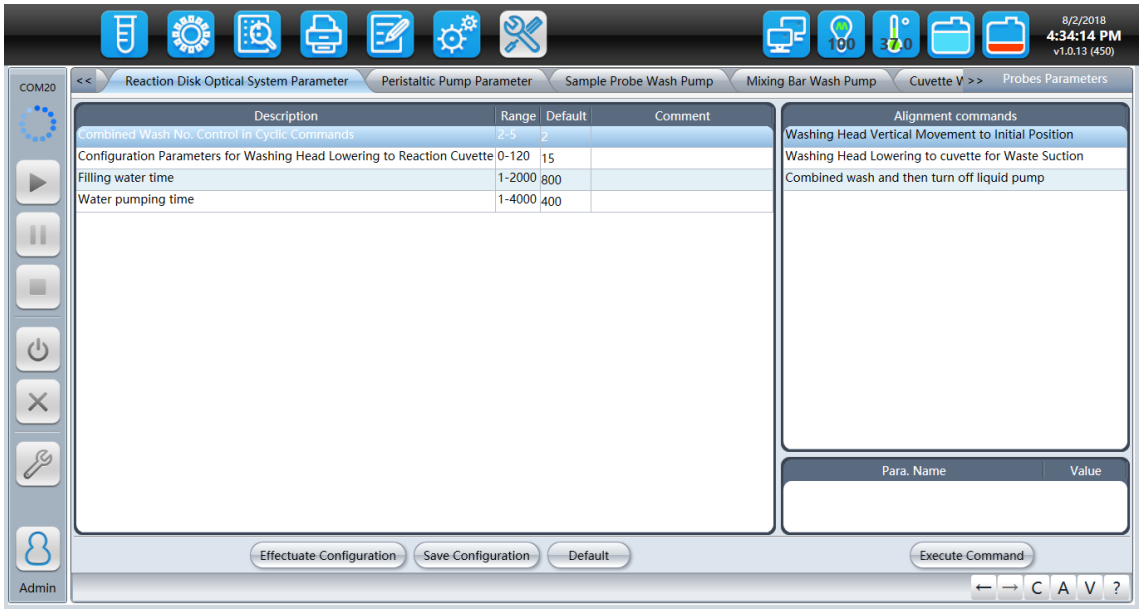


Figure 4-56: The "Reaction disk Optical System Parameter" Screen

4.9.5.4. Peristaltic Pump Parameters Configuration

For analyzer with auto wash function only. See section 4.9.5.8 for a detailed description of the various parameters and function buttons in this menu.

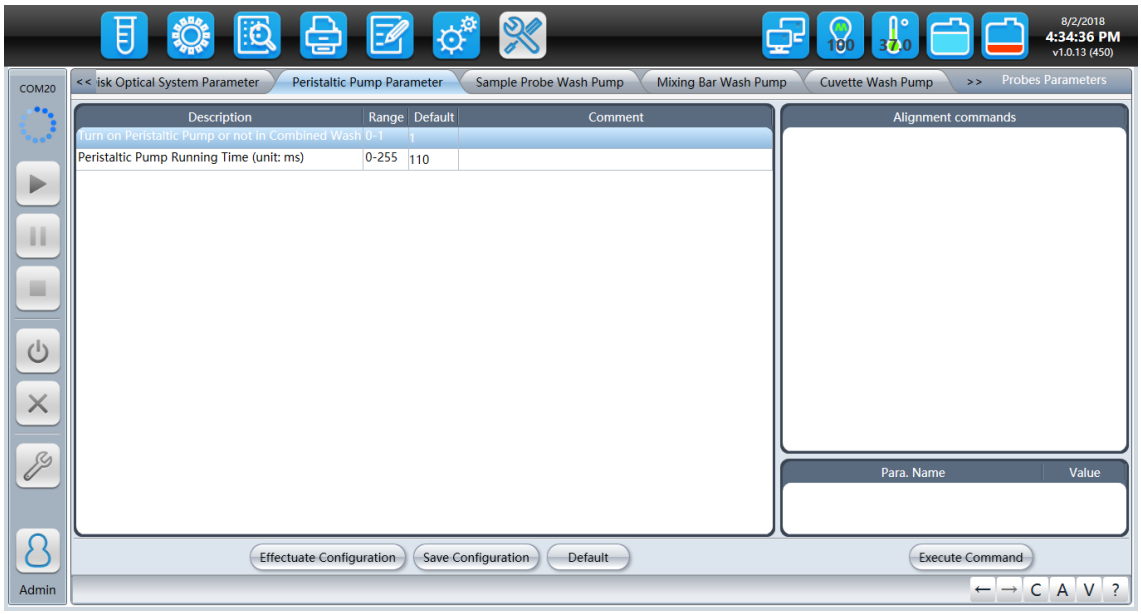


Figure 4-57: The "Peristaltic Pump Parameter" Screen

4.9.5.5. Sample Probe Wash Pump Parameters Configuration

See section 4.9.5.8 for a detailed description of the various parameters and function buttons in this menu.

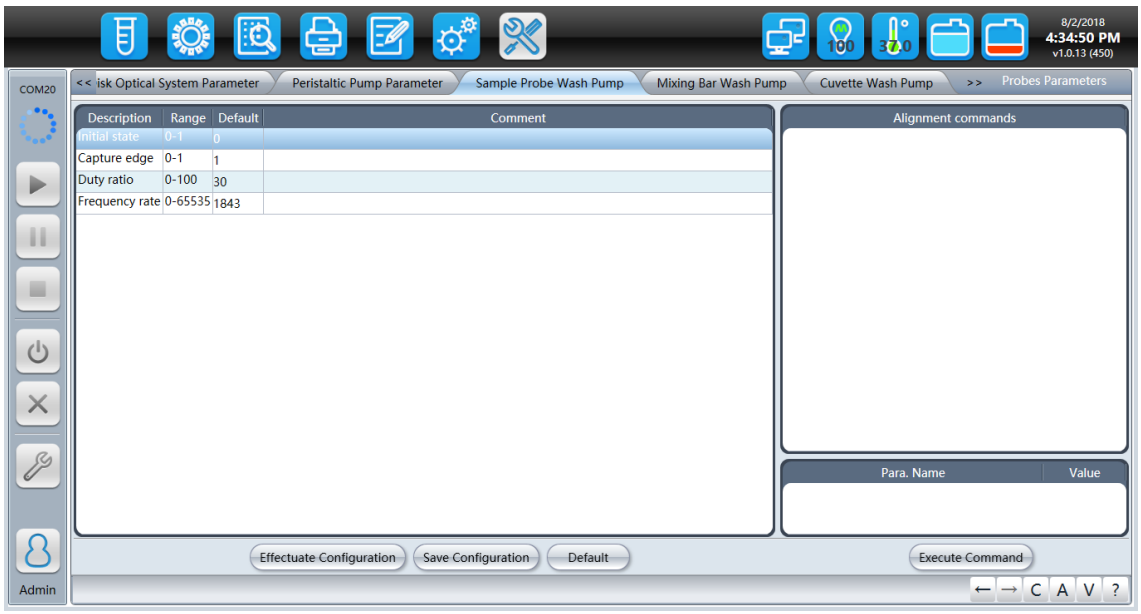


Figure 4-58: The "Sample Probe Wash Pump Parameter" Screen

4.9.5.6. Mixer Bar Wash Pump Parameters Configuration

See section 4.9.5.8 for a detailed description of the various parameters and function buttons in this menu.

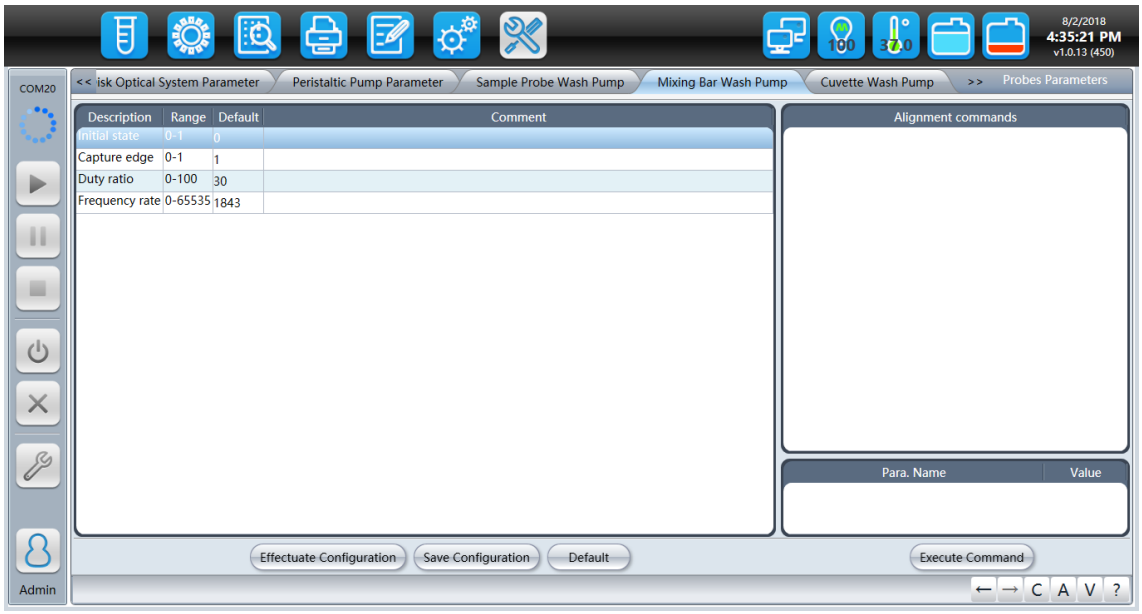


Figure 4-59: The "Mixing Bar Wash Pump Parameter" Screen

4.9.5.7. Cuvette Wash Pump Parameters Configuration

For analyzer with auto wash function only. See section 4.9.5.8 for a detailed description of the various parameters and function buttons in this menu.

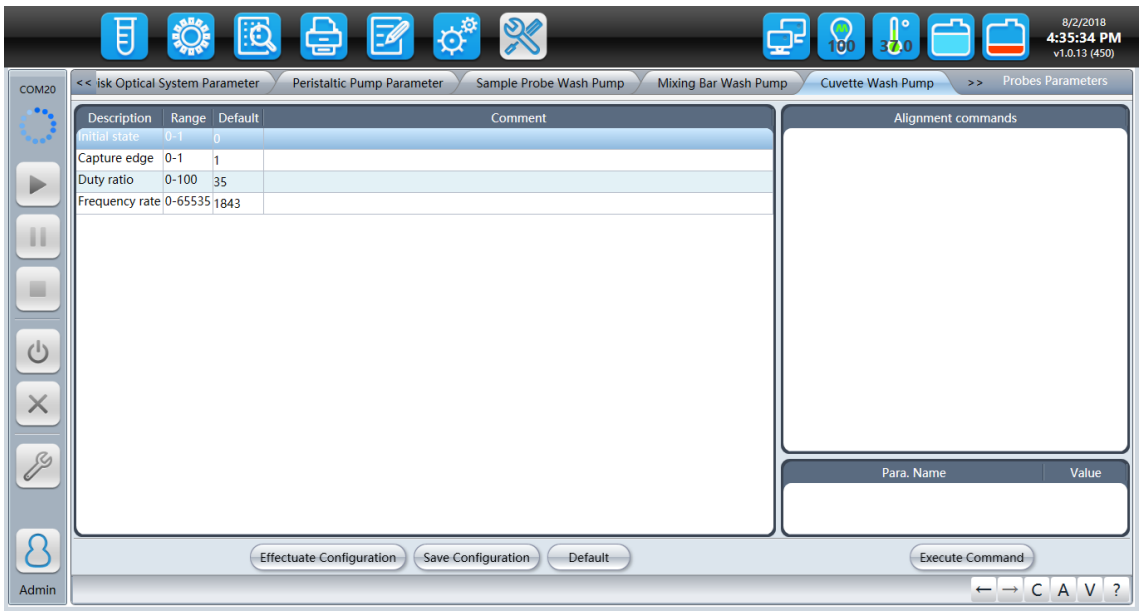


Figure 4-60: The "Cuvette Wash Pump Parameter" Screen

4.9.5.8. Introduction to Parameters and Features

Explanation of Basic Parameters

Parameter	Meaning	Operation

Parameter	Meaning	Operation
Description	Detailed description of parameter settings names	/
Range	Adjustable parameter range	/
Default	The software's default configuration parameter value	/
Default	The set parameter value. The value must be within the adjustable range for the parameter	Enter a modified value into the set value box corresponding to the selected "Description"
Comment		Input directly
Alignment Commands	List of commands for debugging the instrument	/
Para. Name	Names of parameters required for debug commands	/
Value	Specific values corresponding to parameters required for debug commands	Can be input directly into the blank space below

Introduction to Application Features

Button	Function
Effectuate Configuration	Send modified configuration parameters to a slave machine. The configuration parameters will be used in subsequent operations by the instrument
Save configuration	Stores modified configuration parameters on the computer
Execute Command	Select the desired command from the available debug commands, click "Execute Command" and the instrument will carry out the corresponding action

5. Simplified Operating Procedures

5.1. Operational Procedures for Basic Functions

5.1.1. Add Item

1) Left click the **Parameter** button  on the Main Screen;

2) Choose **Routine Chemistry** to enter the item parameter editing screen;

3) Click the **"Add"** button, and enter the desired parameters for each item in the **Basic Parameters, Monitoring Parameters** and **QC Parameters** interfaces according to the significance of each item and applicable reagent manuals;

4) Click the **"Save"** button to save the new item's parameters.

5.1.2. Change Item Parameters

1) Left click the **Parameter** button  on the Main Screen;

2) Choose **Routine Chemistry** to enter the item parameter editing screen;

3) Select the item you wish to modify in the **item list** on the left hand side of the screen;

4) Click the **"Modify"** button to edit the parameters of items you wish to modify, according to the significance of each item and applicable reagent manuals;

5) After editing, click the **"Save"** button.



Notes:

1) A recalibration analysis needs to be performed after modifying the following parameters; failure to do so may prevent you from obtaining accurate results: measurement method, reaction direction, main wavelength, sub-wavelength, sample volume, R1, R2, blank time and reaction time.
2) Do not modify an item's parameters during the testing process. Failure to adhere to this rule may prevent you from obtaining accurate results:

5.1.3. Delete Item

1) Left click the **Parameter** button  on the Main Screen;

2) Choose **Routine Chemistry** to enter the item parameter editing screen;

3) Select the item you wish to delete from the **item list** on the left hand side of the screen;

4) Click the **"Delete"** button;

5) In the dialog box that appears, select the **"Yes"** button to confirm the deletion, or click the **"No"** button to cancel.



Notes:

1) Once an item is deleted, all the information contained in the item will be deleted, including test results and other information.

2) The deletion of item parameters is prohibited during the testing process.

5.1.4. Add Control Solution

1) Left click the **Parameter** button  on the Main Screen;

2) Select **QC Setup** to enter the quality control solution editing screen;

3) Click the "Add" button to add a new row to the left screen, left click a blank input box to activate input of the control solution name, batch number and expiration date information and then enter the corresponding information;

4) Enter target value and standard deviation information for each item in the right screen;

5) Click the "Save" button to save information pertaining to the newly-added control solution.

5.1.5. Modify Control Solution

1) Left click the **Parameter** button  on the Main Screen;

2) Select **QC Setup** to enter the quality control solution editing screen;

3) Select the quality control solution you wish to modify from the control solution display area on the left hand side of the screen;

4) Click the "Modify" button to edit the information you wish to modify;

5) Click the "Save" button to save the modified information.

5.1.6. Delete Quality Control Solution

1) Left click the **Parameter** button  on the Main Screen;
2) Select **QC Setup** to enter the quality control solution editing screen;
3) Select the quality control solution you wish to delete from the control solution display area on the left-hand side of the screen;
4) Click the "Delete" button;
5) In the dialog box that appears, select the **"Yes"** button to confirm the deletion, or click the **"No"** button to cancel.

5.1.7. Add New Calibrator

1) Left click the **Parameter** button  on the Main Screen;
2) Select **Calibrator Setup** to enter the Calibrator editing screen;
3) Click the "Add" button and, at the top of the screen, left click a blank input box to activate input of the calibrator name and sample position and then enter the corresponding information;
4) Enter the corresponding concentrations and activity values for the current calibrator for each item in the Concentration Input field;
5) Click the "Save" button to save information pertaining to the newly-added calibrator.

5.1.8. Modify a Calibrator

1) Left click the **Parameter** button  on the Main Screen;
2) Select **Calibrator Setup** to enter the Calibrator editing screen;
3) Select the calibrator solution you wish to modify from the calibrator solution display area on the left-hand side of the screen;
4) Click the "Modify" button to edit the information you wish to modify;
5) Click the "Save" button to save the modified information.

5.1.9. Delete a Calibrator

1) Left click the **Parameter** button  on the Main Screen;

2) Select **Calibrator Setup** to enter the Calibrator editing screen;

3) Select the calibrator solution you wish to delete from the calibrator solution display area on the left-hand side of the screen;

4) Click the "Delete" button;

5) In the dialog box that appears, select the "Yes" button to confirm the deletion, or click the "No" button to cancel.

5.1.10. Set Reagent Positions

1) Left click on the **Online Status** button  on the Main Screen;

2) Select the **Reagent disk** interface;

3) Select an empty reagent position, move the mouse over the item in the "Chemistry List" for which you want to set the position, and select either R1 or R2;

4) Input reagent information in the "Reagent Information" display area in the lower right of the screen, including the reagent name, size, expiration date, batch number and other information;

5) Click the "Save" button to save the edited information.

5.1.11. Modify Reagent Information

1) Left click on the **Online Status** button  on the Main Screen;

2) Select the **Reagent disk** interface;

3) click on the reagent position you wish to modify on the reagent disk on the right of the screen;

4) Modify the reagent information in the "Reagent Information" display area in the right of the screen, including the reagent name, size, expiration date, batch number and other information;

5) Click the "Save" button to save the modified information.

5.1.12. Release Reagent Positions

1) Left click on the **Online Status** button  on the Main Screen;

2) Select the **Reagent disk** interface;

3) Click on the reagent position you wish to release on the reagent disk on the right of the screen;
4) Click the "Release Position" button;
5) Click the "Yes" button on the screen that pops up to confirm release of the position or click "No" to cancel the release of the position.

Notes:

To release all locations, simply click the "Release All" button.

5.1.13. Reagent Blank Test Procedure

5.1.13.1. Request

1) Left click the Test Request button  on the Main Screen;
2) Click " Reagent Blank Request " to enter the Reagent Blank Request interface;
3) Select an item for which you want to perform a reagent blank test;
4) Click the "Request" button to complete the request process.

5.1.13.2. Testing

1) Place a reagent blank sample (typically deionized water or saline) in Sample Position 40;
2) Click on the **Start** button in the shortcut button area on the right side of the main interface;
3) Select the sample disk and reagent disk where the current test will be performed;
4) Click "OK" to start the test.

5.1.14. Calibration Test Procedure

5.1.14.1. Request

1) Left click the Test Request button  on the Main Screen;
2) Click " Calibration Request " to enter the Calibration Request screen;
3) Select the item for which the calibration test needs to be performed as well as the number of repetitions and the corresponding calibrator;
4) Click the "Request" button to complete the request process.

5.1.14.2. Testing

1) Place all calibrators in their corresponding sample positions;

2) Click on the start button in the shortcut button area on the right side of the main interface;
3) Select the sample disk and reagent disk where the current test will be performed;
4) Click "OK" to start the test.

Notes:

When performing a calibration for a new chemistry, make sure a reagent blank is tested.

5.1.15. Quality Control Test Procedure

5.1.15.1. Request

1) Left click the Test Request button  on the Main Screen;
2) Click " QC Request " to enter the QC Request screen;
3) Select a sample disk and sample position;
4) Enter the quality control sample number and select a quality control solution;
5) Select a quality control test item;
6) Click the "Request" button to complete the request process.

5.1.15.2. Testing

1) Place all quality control solutions in their corresponding sample positions;
2) Click on the Start button in the shortcut button area on the right side of the main interface;
3) Select the sample disk and reagent disk where the current test will be performed;
4) Click "OK" to start the test.

5.1.16. Sample Testing Procedure

5.1.16.1. Request

1) Left click the Test Request button  on the Main Screen;
2) Click " Sample Request " to enter the Sample Request screen;
3) Choose whether or not the sample is an emergency room sample and select a sample disk and sample position;
4) Enter the sample serial number and other information;

5) Select a test item;

6) Click the "Request" button to complete the request process.

5.1.16.2. Testing

1) Place all test samples in their corresponding sample positions;

2) Click on the start button in the shortcut button area on the right side of the main interface;

3) Select the sample disk and reagent disk where the current test will be performed;

4) Select the range of samples to be tested. If you only want to test some of the samples, enter a corresponding sample range;

5) Click "OK" to start the test.

5.2. Operating Procedures for Opening a New Item

1) Add new in **item parameters;**

2) Set the item's **reagent position;**

3) Add **calibrators** for the current item or add a concentration for the current project in addition to an existing calibrator;

4) Add **quality control solutions** for the current item or add a target value and standard deviation for the current project in addition to an existing quality control solution;

5) Submit a **Calibration Request** for the current item (select a reagent blank);

6) Start the **calibration test;**

7) After calibration is successful, perform a **quality control** request and start the quality control test;

8) Once the integrity of the quality control has been confirmed, a standard sample test can be carried out.



Notes:

When performing a calibration for a new item, make sure to test a reagent blank.

5.3. Routine Operational Procedures

5.3.1. Pre-Startup Check

1) Check that sufficient printer paper is available and, if not, add printer paper;

2) Check that there are no issues with the power supply and that the connection is stable;

3) Check that the connection of the communications cables between the printer and the computer as well as the connection between the computer and the analysis unit are stable;

4) Place a tube with deionized or distilled water or saline in Sample Position 40 on the sample disk;

5) Place a sufficient amount of ISE wash solution, deionized water or other wash solution in Reagent Position 39 (Please ignore this if no ISE module);

6) Check that purified water is available and, if not, supplement immediately; If a water supply machine is being used, please make sure the water supply machine is switched on and running;

7) Check that enough wash solution is present and supplement if necessary;

8) Check that the system probes, mixer are free of bending, dirt and excess water;

9) Check that there are no bubbles or leaks in the instrument's syringe;

10) Open the reagent bottle caps;

11) Check that the reaction disk cover, reagent disk cover and sample disk cover are closed.

Notes: Biological Contamination



1) All waste should be considered a source of contagion and gloves should be worn during handling;

2) All parts of the apparatus are subject to potential biological contamination, and protective gloves should be worn during operation.

5.3.2. Powering On the System

Turn on each power supply in the following order:

1) Flip the main power switch on the left-hand side of the back of the analysis unit to the ON position;

2) Press the power switch on the right-hand side of the analysis unit (an indicator light should come on after pressing the switch);

3) Power on the monitor;

4) Turn on the computer;

5) Turn on the printer.

5.3.3. Order of Operational Procedures

Double-click the software shortcut icon on the desktop to log into the system and start up the system using the following operational procedures. After approximately 2 minutes the system will show the Main Screen for operating the software:

1) Reset all operating parts;

2) Open the thermostat and heat up the reaction disk;

3) Turn on the system lamp;

4) Prime the system fluid lines;

5) Check the lamp status;

6) Wash all cuvettes and do water blank test. (For analyzer with auto wash function: If these 2 options are selected, it takes 15 minutes more)



Notes: Alarms and Dirty Cuvettes

1) If an alarm is issued during system startup, click the alarm to view detailed information and solutions;
2) The system will automatically monitor the status of the system lamp during startup and if the system indicates that the luminous intensity of the lamp is insufficient, investigate the reason immediately and replace the lamp if necessary.

5.3.4. System Setup

1) Set hospital, department and physician-related information;

2) Set a username, preliminary password and operating privileges;

3) Set patient-related information and select or edit the print format for different reports.

5.3.5. Item Parameter Settings

Enter analysis parameters for each item based on the significance of each parameter as well as the instructions included with your reagent kit.



Notes: Analysis Parameters

Incorrect analysis parameters can lead to erroneous measurement results. Please consult HETO or your reagent supplier for more information.

5.3.6. Reagent Position Settings

Set the position of each item in the reagent disk.



Notes:

For two-reagent items, R1 and R2 must be set to the same reagent disk;

5.3.7. Calibrator Setup

1) Add New Calibrator;
2) Set the position of the calibrator on the sample disk;
3) Set the concentration for each item corresponding to a given calibrator.

5.3.8. QC Settings

1) Add Control Solution
2) Set the target value and standard deviation for each item corresponding to a given control solution;
3) Set quality control rules for each item.

5.3.9. Test Request

1) Reagent blank request;
2) Calibration request;
3) QC request;
4) Sample test request.

5.3.10. Test Preparation

1) Place reagents on the reagent disk according to the set reagent positions and supplement immediately if reagent levels are low;
2) Place the calibrator on the sample disk according to the set calibrator position;
3) Place the quality control solution on the sample disk according to the requested quality control solution position;
4) Place the test sample on the sample disk according to the requested sample position;
5) Check the clean cuvette is enough or not, if not, place new cuvettes into reaction disk and click “Replace Cuvette” button(For analyzer without auto wash function).

Notes:

1) Carefully check the reagents and samples to ensure that no insoluble compounds, such as cellulose or fibrin, are suspended in solution. Failure to do so may result in obstruction of the reagent or sample probes.

2) If the sample contains suspended insoluble matter, the supernatant should be aspirated off and transferred to a clean sample tube.

5.3.11. Start

1) Click the "Start" shortcut;
2) Select the reagent disk and sample disk with which you want to start the test (No. 1 by default);
3) Enter the sample range for the test you wish to start;
4) Click the "Confirm" button.

Notes:

You can also start a reagent blank test, calibration test, quality control test or standard test at the same time, in accordance with the following priority levels.

1) Reagent Blank Test;
2) Calibration Test;
3) Quality Control Test;
4) Standard Test.

Note:

1) An unstable reaction disk or light source may adversely impact the test results. Do not perform any tests until the reaction disk or light source are stable;
2) Always ensure that the reaction disk cover is closed during the testing process. Failure to do so may result in poor thermoregulation of the reaction disk, abnormal noises and damage to the apparatus probes.
3) Always ensure that the reagent disk cover is closed during the testing process. Failure to do so may result in poor refrigeration of the reagent disk, abnormal noises and damage to the apparatus probes.

5.3.12. Test Result Query

5.3.12.1. Calibration Result Query

1) Left click the Results button  on the Main Screen;
2) Click **"Calibration"** to enter the calibration results query page;
3) Select an item and calibration time period to perform a query;

4) Click "Calibration Curve" after selecting a particular calibration record to enter the detailed calibration screen corresponding to the calibration record.

5.3.12.2. Quality Control Result Query

1) Left click the Results button  on the Main Screen;

2) Click **"QC"** to enter the quality control results query page;

3) Select the quality control query type, project, time, and quality control solution conditions to perform a query;

4) On the right side page you can view the quality control status, quality control results and quality control graphics for a given item.

5.3.12.3. Sample Results Query

1) Left click the Results button  on the Main Screen;

2) Click **"Sample"** to enter the sample results query page;

3) Click the "Query Conditions" button to select search criteria for performing your query.

5.3.12.4. Reagent Blank Query Results

1) Left click the Results button  on the Main Screen;

2) Click **"Reagent Blank"** to enter the reagent blank query results page;

3) Select an item and start and end time period to view your results;

4) Reagent blank reactivity and a trend graph for a given item can be viewed on the reagent blank page on the right side of the screen.

5.3.13. Adding Tests

1) Add standard sample tests;

2) Add emergency sample tests;

3) Add quality control tests;



Notes:

1) During a test, an unlimited number of samples and quality control tests can be added;

2) During the test process, do not add calibration tests for items for which calibration parameters are already available and for which testing is currently in progress, as this may result in some samples

being calculated according to previously set calibration parameters while other samples are calculated according to newly set calibration parameters.

5.3.14. Shutdown

Click on the "Shutdown" shortcut button on the right side of the main screen and select routine shutdown in the menu that pops up to perform a shutdown in the following order:

1) Reset all the units and for analyzer with auto wash function: wash all cuvettes;
2) Exit the operating software.



Notes:

1) If a test stops abnormally, then all cuvettes must be washed once before draining (will require approximately 16 minutes).
2) For analyzer with auto wash function, if you choose the long holiday shutdown option then system will dry all the cuvettes.
3) If you need to turn off the computer, simply select Shutdown Computer and the computer will shut down automatically after you close the software.

5.3.15. Powering Off the System

Turn off each power supply in the following order:

1) Analysis unit power supply;
2) Computer power supply;
3) Monitor power supply;
4) Printer power supply.



Notes:

1) The main power supply is located on the back of the analysis unit. If reagents need to be refrigerated, then do not turn off the main power supply; you need only turn off the analysis unit;
2) If you need to turn off the main power supply, switch the main power switch from ON to OFF.

5.3.16. Post-Shutdown Inspection

1) Remove all samples, calibrators and quality control solutions from the sample disk;
2) Cap all reagent bottles; If the analyzer main power is off, reagents in the reagent disk should be stored in a refrigerator;
3) Wipe down the analyzer countertop;
4) Wipe off any contaminants or water droplets present on the apparatus probe, mixer, or cleaning mechanism nozzles.

6. Analysis Principles and Computational Methods

6.1. Analysis Principle

The instrument operates by establishing a formal relationship between absorbance and concentration or activity using the law of absorbance for solutions exposed to a light source (the Beer–Lambert law), or the law governing the opacity of suspensions to a light source; The biochemical analyzer's optical system can be used to monitor the absorbance of a specific item throughout the reaction process and, based on changes to absorbance following the reaction or the rate of change of absorbance throughout the reaction process, in conjunction with corresponding calibration parameters and computational factors, the software is able to compute the concentration and activity of the substance examined.

6.2. Analysis Procedure

The procedure will be described in terms of the machine's actions, the position where each action occurs, the testing process and the system's optical metering point.

6.2.1. Actions Performed by the Device

For analyzer with auto wash function, the system performs the following actions in a test cycle to complete all assigned tests:

1) A cuvette is placed below the first washing and automatic cleaning is performed. The reaction disk turns by 51 cuvette positions (absorbance measurements are carried out during the rotation) and the system pauses; The disk rotates to the cuvette position currently being used for R1 and the system pauses; The disk rotates by 51 cuvette positions and the system pauses. This is referred to as a single cycle;

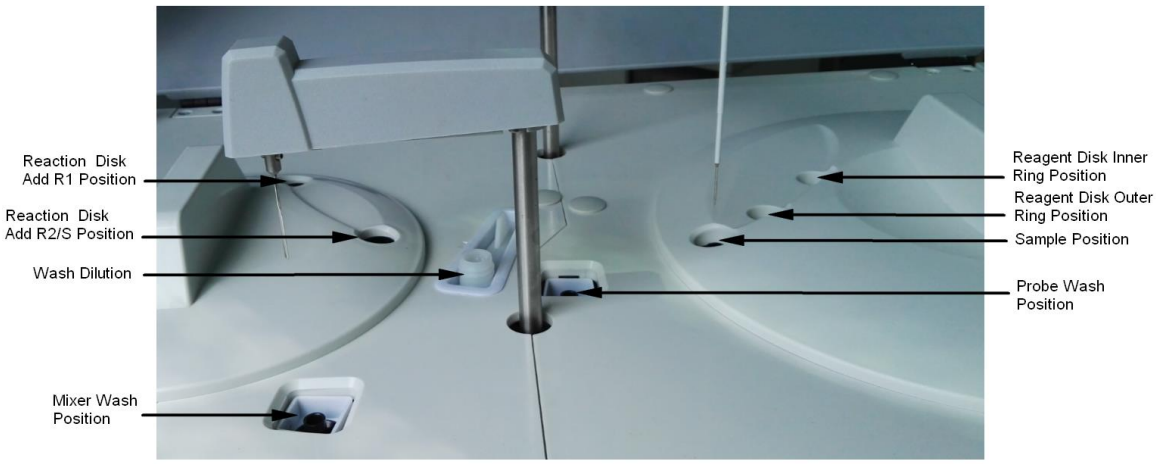
2) From the 1st to the 40th cycle, addition of the first reagent, sample and second reagent as well as reaction monitoring are carried out and absorbance is measured once during each cycle; With each cycle, the position of the reaction cuvette is moved forward by one position;

For analyzer without auto wash function, the system performs the following actions in a test cycle to complete all assigned tests:

1) The reaction disk turns by 51 cuvette positions (absorbance measurements are carried out during the rotation) and the system pauses; The disk rotates to the cuvette position currently being used for R1 and the system pauses; The disk rotates by 51 cuvette positions and the system pauses. This is referred to as a single cycle;

2) From the 1st to the 40th cycle, addition of the first reagent, sample and second reagent as well as reaction monitoring are carried out and absorbance is measured once during each cycle; With each cycle, the position of the reaction cuvette is moved forward by one position;

6.2.2. Operating Position



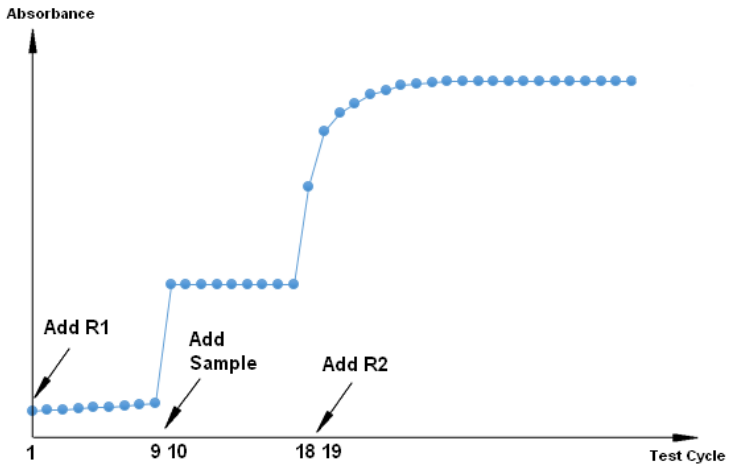
6.2.3. Testing Process

This system feature fixed testing procedures with each reaction including a total of 40 test cycles. In high speed mode, each cycle lasts 24 seconds while in standard mode each cycle lasts 36 seconds.

6.2.4. Optical Metering Point

For a given reaction, a single optical measurement is taken once every cycle for a total of 40 optical metering points. In high speed mode, the time interval between two adjacent optical metering points is 24 seconds; In standard mode, the time interval between two adjacent

optical metering points is 36 seconds, as shown in the Figure below:



6.3. Analysis Methods and Reactivity Calculations

6.3.1. Absorbance Calculation

The formula used to calculate absorbance (A) by the analyzer is as follows:

$$A = \log \frac{AD_{H2O} - AD_{dark}}{AD_{solution} - AD_{dark}} \times 20000$$

Where:

1) "Log" refers to a common logarithm of base 10;

2) "AD" indicates the value of the intensity of the transmitted light following photoelectric conversion and digital to analog conversion;

3) "AD_{dark}" refers to the AD value when the system lamp is not on, "AD_{H2O}" refers to the AD value of Purified water in the cuvette and "$AD_{solution}$" indicates the AD value of the test solution in the cuvette;

4) The absorbance data shown in reaction curves generated by the system is amplified by a factor of 20,000.

Description:

Reaction classification is performed based on the characteristics of a particular reaction's speed during the reaction process. The analyzer divides all reactions into three categories: end-point method, two-point method (fixed time method) and kinetic method. These are described in detail separately below:

- Test Methods, Test methods include the end-point method, two-point method (fixed time method) and kinetic method.
- Reaction time [N] [P]: The period of time from when a reaction is started to the time when monitoring of the reaction ends.

  1) For single reagent items, the reaction time refers to the time which elapses after the addition of the sample S;

  2) For double reagent items, the reaction time refers to the time which elapses after the addition of R2;

  3) This section includes two input boxes into which the reaction monitoring start time and reaction monitoring end time are entered. These quantities are represented by N and P.

- Blank Time [L] [M]: The time before a reaction for a given test is started.

1) For single reagent items, blank time refers to the time interval from the time R1 is added to the time the sample S is added;

2) For double reagent items, blank time refers to the time interval from the time the sample S is added to the time R2 is added;

3) This section also includes two input boxes into which the blank monitoring start time and blank monitoring end time are entered. These quantities are represented by L and M.

- For dual-wavelength items, absorbance A is the difference in absorbance at the main and sub-wavelengths; For single wavelength items, A is the absorbance at the primary wavelength.

6.3.2. Endpoint Method

The endpoint method, also known as the "equilibrium method" is a method in which, once the reaction in question has reached an equilibrium and there are no longer any changes to be observed absorbance values after a certain period of time and the increase (or decrease) in absorbance precipitated by the reaction is proportional to the concentration of the substance being measured.

6.3.2.1. Single Reagent Endpoint Method

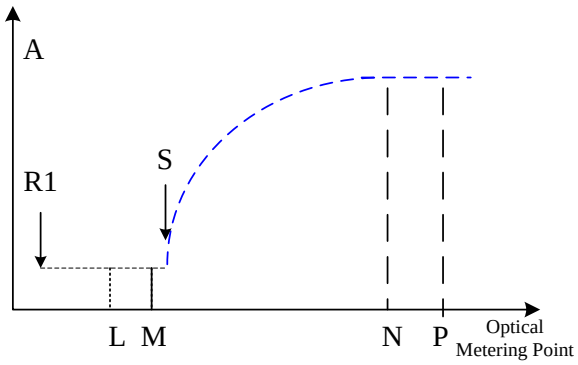


Figure 0-1 Single Reagent Endpoint Methods A and B Reaction Curves

Endpoint Method A

Reaction time [N] [P], 10 ≤ N ≤ P ≤ 40, where P ≤ N +4;

Blank time [L] [M], 1 ≤ L ≤ M ≤ 9, where M ≤ L +4; L and M default to 7-9.

The formula by which reactivity (R) is calculated is as follows:

$$R = A_i - kA_b$$

Where:

1) $k = \frac{V_{R1}}{V_{R1} + V_S}$ is a single reagent volume correction factor and V_{R1} and V_S represent the volumes of the first reagent and sample.
2) The second term in the equation, kA_b, represents the reagent blank correction value. Real-time deduction of the reagent blank is possible while deduction of the sample blank is not possible. If you need to perform a sample blank correction, you must request separately a sample blank test and the formula for computing the sample blank reactivity, R_{Sb}, is the same as the above formula used to calculate R - that is, $R_{sb} = A_i - kA_b$. Reactivity following sample blank correction is computed as $R' = R - R_{Sb}$.
3) A_i indicates absorbance at the reaction endpoint, calculated as follows:
   a) If N = P, then the corresponding input is [P] [P] and only one point is used. That is: $A_i = A_P = A_N$.
   b) If P = N +1, then the corresponding input is [N] [N+1] and two points are used. That is: $A_i = \frac{A_N + A_{N+1}}{2}$.
   c) If P = N +2, then the corresponding input is [N] [N+2] and three points are used. Thus, A_i is the average of the two absorbance data points remaining after the largest outlier is removed.
   d) If P = N +3, then the corresponding input is [N] [N+3] and four points are used. Thus, A_i is the average of the two absorbance data points remaining after the largest and smallest outliers are removed.
   e) If P = N +4, then the corresponding input is [N] [N+4] and five points are used. Thus, A_i is the average of the three absorbance data points remaining after the largest and smallest outliers are removed.
4) A_b refers to the absorbance during blanking and this value is calculated using the same method as that used for absorbance A_i.

Endpoint Method B

Endpoint Method B is also sometimes called the non-volume-corrected two-point blank endpoint method and the method is primarily intended to eliminate the effects of R1 blank absorbance or S blank absorbance on concentration for certain clinical samples. The only difference between this method and Endpoint Method A is that in this method there is no need to multiply by a volume correction factor when calculating reactivity. All other requirements are identical to Endpoint Method A.

Reaction time [N] [P], 10 ≤ N ≤ P ≤ 40, where P ≤ N+4;

Blank time [L] [M], 1 ≤ L ≤ M ≤ 9, where M ≤ L +4; L and M default to 7-9.

The formula by which reactivity (R) is calculated is as follows:

$$R = A_i - A_b$$

In the above formula, the calculation of A_i and A_b are exactly the same as with Endpoint Method A.

Endpoint Method C

Endpoint Method C is also sometimes called the "post-reaction two-point endpoint method" and does not include a blank time setting. It is primarily intended to eliminate the effects of S or R2 blank absorbance on concentration for certain clinical samples. It differs from Endpoint Method A in that:

1) There is no need to multiply by a volume correction factor when calculating reactivity;

2) At the same time, there is no need to set a blank time. Only a reaction time needs to be set;

3) The requirements of the two methods in terms of start and end points of the reaction time interval are different;

All other requirements are fully consistent with Endpoint Method A.

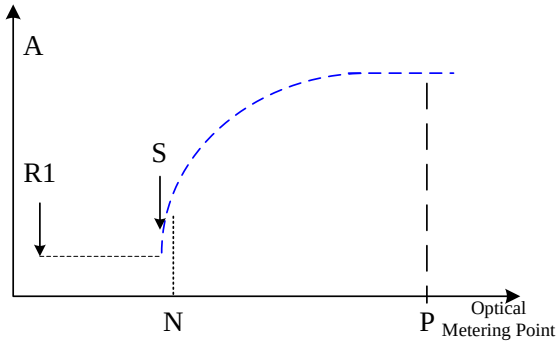


Figure 0-2 Single Reagent Endpoint Method C Reaction Curves

Reaction time [N] [P], 10 ≤ N ≤ 12 < P ≤ 40;

Blank time [L] [M], empty by default, input is prohibited.

Reactivity Calculation:

$$R = A_P - A_N$$

A_P represents the absorbance of the Pth cycle and A_N represents the absorbance value of the Nth cycle. There is no need to perform a sample blank correction.

6.3.2.2. Double Reagent Endpoint Method

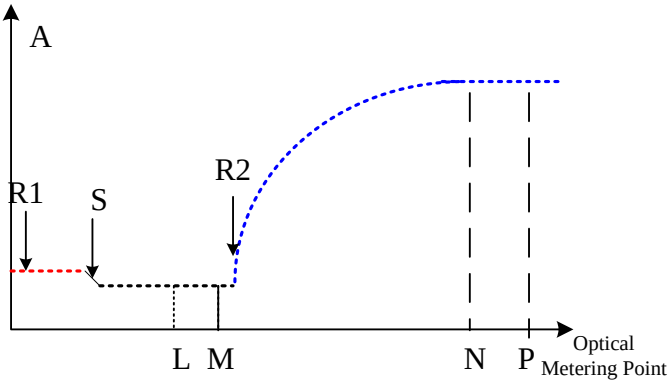


Figure 0-3 Double Reagent Endpoint Methods A and B Reaction Curves

Endpoint Method A

Reaction time [N] [P], 19 ≤ N ≤ P ≤ 40, where P ≤ N +4;

Blank time [L] [M], 10 ≤ L ≤ M ≤ 18, where M ≤ L +4; L defaults to 16 while M defaults to 18.

The calculation of reactivity (R) is performed as follows:

$$R = A_i - k' A_b$$

Where:

1) $k' = \dfrac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$ is a double reagent volume correction factor and V_{R1}, V_S and V_{R2} represent the volumes of the first reagent, sample and second reagent.

2) The second term in the equation, $k' A_b$, indicates the mixed blank correction value for reagent R1 and sample S. The mixed blank of the first reagent R1 and the sample S, can be deducted in real time but the R2 (second reagent) blank cannot be deducted. If you need to perform a correction for R2, you must request separately a reagent blank test and the formula for computing the R2 blank reactivity, R_{R2}, is the same as the above formula used to calculate R - that is, reactivity following sample blank correction is calculated as $R' = R - R_{R2}$.

3) Calculation of A_i: Equivalent to the method for calculating A_i using the single reagent endpoint method as described in 6.3.2.1.

4) Calculation of A_b: Equivalent to the method for calculating A_i using the single reagent endpoint method as described in 6.3.2.1.

Endpoint Method B

Reaction time [N] [P], 19 ≤ N ≤ P ≤ 40, where P ≤ N +4;

Blank time [L] [M], 10 ≤ L ≤ M ≤ 18, where M ≤ L +4; L defaults to 16 while M defaults to 18.

Reactivity Calculation:

$$R = A_i - A_b$$

The second term in the equation for R above, A_b indicates the mixed blank correction value for the sample and the first reagent without a volume correction. The mixed blank of the first reagent and the sample, can be deducted in real time but the R2 (second reagent) blank cannot be deducted. If you need to perform a correction for R2, you must request separately a reagent blank test and the formula for computing the R2 blank reactivity, R_{R2}, is the same as the above formula used to calculate R - that is, $R_{R2} = A_i - A_b$. Thus reactivity following sample blank correction is calculated as $R^{'} = R - R_{R2}$.

Endpoint Method C

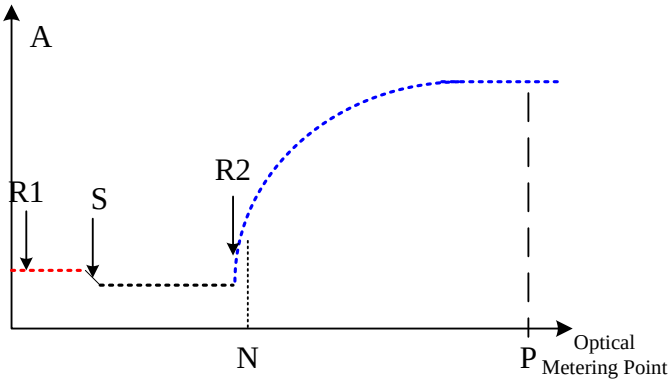


Figure 0-4 Double Reagent Endpoint Method C Reaction Curve

Reaction time [N] [P], 19 ≤ N ≤ 21 < P ≤ 40;

Blank time [L] [M], empty by default, input is prohibited.

Reactivity Calculation:

$$R = A_P - A_N$$

A_P represents the absorbance of the Pth cycle and A_N represents the absorbance value of the Nth cycle. There is no need to perform a sample blank correction.

6.3.3. Two-Point Method (Fixed-Time Method)

The Two-Point Method, also known as the first-order kinetic method, two-point rate method and fixed-time method, refers to a first order correlation between reaction rate and substrate concentration over a defined period of time, expressed formally as v = k[S]. Since the substrate is constantly being consumed during the reaction, the overall reaction speed is constantly decreasing and this is manifested as a reduction in the rate of increase (or decrease) in absorbance. Within the specified reaction time, the reaction solution absorbance increase (or decrease) (△ A / min) is proportional to the concentration and the measured substance.

Two-point methods are divided into single interval and double interval two-point methods depending on whether or not deduction of a sample blank is necessary. For double interval two-point methods, real time deduction of the sample blank is possible. That is, the rate of change in absorbance between the two points within the sample blank period is taken as the sample blank deduction.

Two-point method allows the user to check for substrate depletion and in the event that substrate depletion has occurred, corresponding markings will be provided in the results.

6.3.3.1. Single Reagent Two-Point Method

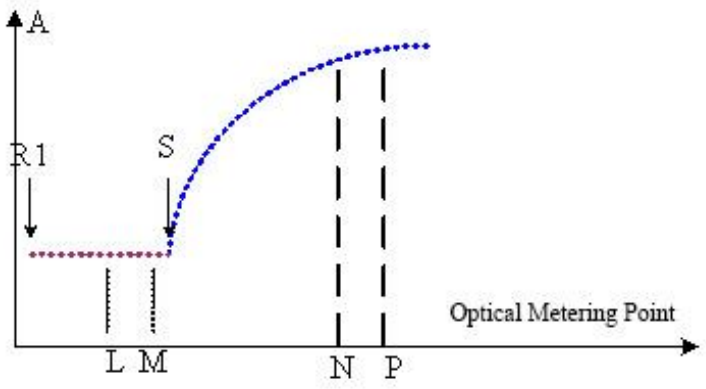


Figure 0-5: The Single Reagent Two-Point Method Reaction Curve

Reaction time [N] [P], 10 ≤ N < P ≤ 40;

Blank time [L] [M], 1 ≤ L ≤ M ≤ 9, where L and M are empty by default; a blank correction is not performed.

The calculation of reactivity (R) is performed as follows:

$$R = \frac{A_P - A_N}{t_P - t_N}$$ (R must be converted to a per-minute reaction rate)

Where:

1) A_p and A_N represent the absorbance values during the Pth cycle and Nth cycle respectively;

2) t_p and t_N represent the cycle times of the Pth cycle and Nth cycle respectively;

3) Blank Reactivity R_b: $R_b = \frac{A_M - A_L}{t_M - t_L}$ (R_b must be converted to R_b in per-minute units)

A_M and A_L represent the absorbance values during the Mth cycle and Lth cycle respectively;

t_M and t_L represent the cycle times of the Mth cycle and Lth cycle respectively;

Note:

If a blank time has been set, a blank correction must be performed and the blank-corrected reactivity is calculated as $R' = R - K \times R_b$ where K is the single reagent volume correction factor, $K = \frac{V_{R1}}{V_{R1} + V_S}$.

6.3.3.2. Double Reagent Two-Point Method

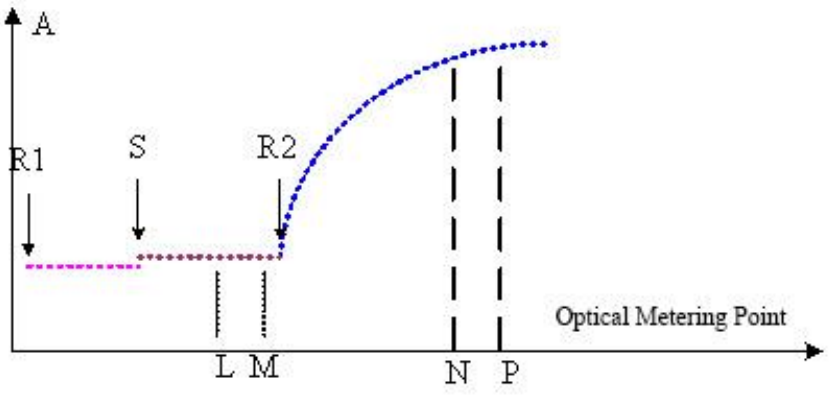


Figure 0-6: The double Reagent Two-Point Method Reaction Curve

Reaction time [N] [P], 19 ≤ N < P ≤ 40;

Blank time [L] [M], 10 ≤ L < M ≤ 18, where L and M are empty by default; a blank correction is not performed.

The calculation of reactivity (R) is performed as follows:

1) Response R: computation is identical to the single reagent method discussed in 6.3.3.1.

2) Blank Reactivity R_b: calculation is identical to the single reagent method discussed in 6.3.3.1.

If a blank time has been set, a blank correction must be performed and the blank-corrected reactivity is calculated as $R' = R - K' \times R_b$ where K' is the double

reagent volume correction factor, $K' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$ .Using the blank time settings, the instrument can only automatically deduct the first reagent and sample mixed blank and cannot deduct the second reagent blank. If you need to deduct the second reagent blank, you will need to separately request a reagent blank test. The reactivity of the second reagent blank R_{R2} is calculated in the same way as reactivity R above. The second reagent blank corrected reactivity is expressed as $R'' = R - R_{R2}$.

6.3.4. Kinetic Method

Also known as the zero-order rate method, rate method, or continuous monitoring method, the Kinetic Method implies a zero-order correlation between the reaction rate and substrate concentration; that is, there is no relationship to substrate concentration. Thus, during the entire reaction process, the reactant can uniformly (at constant speed) generate a product, causing the absorbance of the testing solution to uniformly decrease or increase under a given wavelength. The rate of decrease or increase (△A/min) and the testing substance's (catalytic substance) activity or concentration are directly correlated. This method is mainly used for enzyme activity measurement.

In practice, because the substrate concentration cannot be infinitely large, as the reaction proceeds, after the substrate has been consumed to a certain degree, the reaction will no longer be zero order. Thus, the zero-order rate law is applicable for specific time periods and one must choose zero-order reaction time periods over which to conduct monitoring in order to ensure the accuracy of the test results.

Kinetic methods are divided into single interval and double interval kinetic methods depending on whether or not deduction of a sample blank is necessary. For double interval kinetic methods, real time deduction of the sample blank is possible. That is, the rate of change in absorbance between the two points within the sample blank period is taken as the sample blank deduction.

The kinetic method allows the user to check for substrate depletion and, in the event that substrate depletion has occurred, corresponding markings will be provided in the results.

The kinetic method allows the user to check for linear limits and if the linear limit has been exceeded, corresponding markings will be provided in the results.

6.3.4.1. Single Reagent Kinetic Method

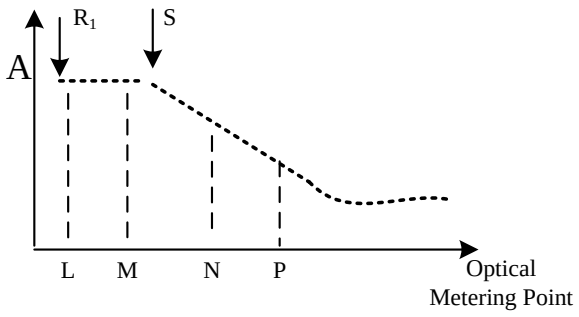


Figure 0-7: Single Reagent Kinetic Method Reaction Curve

Reaction time [N] [P], 10 ≤ N ≤ P ≤ 40 and P ≥N+2, so at least 3 optical metering points are needed;

Blank time [L] [M], 1 ≤ L ≤ M ≤ 9, where M ≥ L +2, so at least 3 optical metering points are needed; L and M are blank by default, and no blank correction is performed.

The calculation of reactivity (R) is performed as follows:

1) Reactivity R : R = ΔA_{NP} , Δ represents using a least square calculation to obtain the rate of change in absorbance per minute between the optical metering points (N, P).

   Least Square Formula:

$$R = \frac{\sum_{i=N}^{P}(t_i - \bar{t}) \cdot (A_i - \overline{A})}{\sum_{i=N}^{P}(t_i - \bar{t})^2}$$

Where N is the start point of the zero-order kinetics reaction interval, P is the end point of the zero order kinetics reaction interval, Ai is point i's absorbance, $\overline{A}$ is the average absorbance between N and P, ti is time at point i, and $\bar{t}$ is the average time from N to P.

2) Blank Reactivity R_b : The calculation is the same as that described for R above, R= ΔA_{LM}

If a blank time has been set, a blank correction must be performed and the blank-corrected reactivity is calculated as $R' = R - K \times R_b$ where K is the single reagent volume correction factor, $K = \frac{V_{R1}}{V_{R1} + V_S}$.

6.3.4.2. Double Reagent Kinetic Method

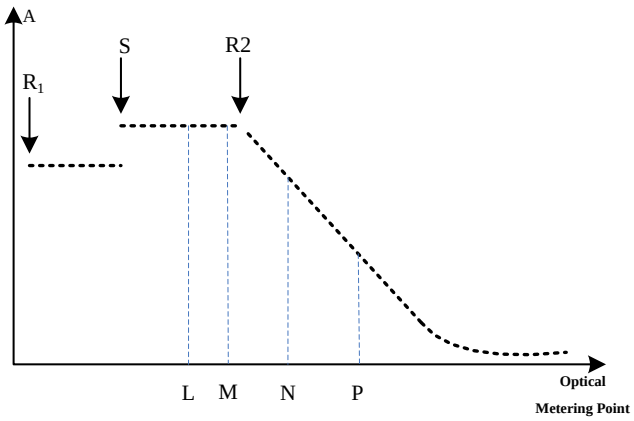


Figure 0-8: The Double Reagent Rate Method Reaction Curve

Reaction time [N] [P], 19 ≤ N ≤ P ≤ 40 and P ≥N+2, so at least 3 optical metering points are needed;

Blank time [L] [M], 10 ≤ L ≤ M ≤ 18, where M ≥ L +2, so at least 3 optical metering points are needed; L and M are blank by default, and no blank correction is performed.

The calculation of reactivity (R) is performed as follows:

1) Reactivity R : The calculation is identical to the single reagent kinetic method discussed in 6.3.4.1.

2) Blank Reactivity R_b : The calculation is identical to the single reagent kinetic method discussed in 6.3.4.1.

If a blank time has been set, a blank correction must be performed and the blank-corrected reactivity is calculated as $R^{'} = R - K^{'} \times R_b$ where $K^{'}$ is the double reagent volume correction factor, $K' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$ .Using the blank time settings, the instrument can only automatically deduct the first reagent and sample mixed blank and cannot deduct the second reagent blank. If you need to deduct the second reagent blank, you will need to separately request a reagent blank test. The reactivity of the second reagent blank R_{R2} is calculated in the same way as reactivity R above. The second reagent blank corrected reactivity is expressed as $R^{''} = R - R_{R2}$.

6.4. Calibration

6.4.1. Calibration Types

For this analyzer, calibration is either classified as linear or non-linear. Linear calibration also includes single point, dual point, and multi-point linear scales which are principally used when the reaction takes place in a solution; Non-Linear calibration mainly includes Logit-4P, Logit-5P, Exponential-P, Polynomial-5P and Spline methods which are principally used when the reaction solution is a suspension, such as for turbidimetric immunoassays.

6.4.2. Calculation of Calibration Parameters

There are different calibration parameter numbers and calculation methods for different calibration types, as described separately below.

1) Single-Point Linear Calibration

The formula R = KC includes one calibration parameter, K.

$$K = \frac{R_{\text{Standard}}}{\text{C}_{\text{Standard}}}$$

Where: The C term is the concentration of the standard and the R term is the standard's reaction amplitude.



Notes:

A single-point linear calibration must be simultaneously performed with a reagent blank test.

2) Dual-Point Linear Calibration

The formula R = KC + b includes two calibration parameters, K and b.

$$K = \frac{\text{R}_{2-}\text{R}_1}{C_2 - \text{C}_1}$$

$$b = R_1 - \frac{C_1(R_2 - R_1)}{C_2 - C_1}$$

Where: C1 and C2 represent the concentrations of the standards 1 and 2 and R1 and R2 represent the reaction amplitudes of standards 1 and 2.

3) Multi-Point Linear Calibration

The formula R = KC + b includes two calibration parameters, K and b.

Calculates calibration parameters using a multi-point linear regression.

4) Logit-4P

The calibration formula R = R0 + K / [1 + e - (a + blnC)] features 4 parameters, R0, K, a and b. Use of this formula requires the provision of 4 standards. The first standard's concentration (activity) is zero and its corresponding R is R0. All other parameters can be obtained using an iterative method.

5) Logit-5P

The calibration formula R = R0 + K / [1 + e - (a + blnC + c*C)] features 5 parameters, R0, K, a, b and c. Use of this formula requires the provision of 5 standards. The first standard's concentration (activity) is zero and its corresponding R is R0. All other parameters can be obtained using an iterative method.

6) Exponential-5P

The calibration formula R = R0 + Ke [alnC + b(lnC)2 + c(lnC)3] features 5 parameters, R0, K, a, b and c. Use of this formula requires the provision of 5 standards. The first standard's concentration (activity) is zero and its corresponding R is R0. All other parameters can be obtained using an iterative method.

7) Polynomial-5P

The calibration formula LnC = a + b(R - R0) + c(R - R0)2 + d(R - R0)3 features 5 parameters, R0, a, b, c and d. Use of this formula requires the provision of 5 standards. The first standard's concentration (activity) is zero and its corresponding R is R0. All other parameters can be obtained using an iterative method.

8) Spline

The calibration formula C - Ci = R0i + ai(C - Ci) + bi(C - Ci) 2 + ci(C - Ci)3 - R features 4 i parameters, R0i, ai, bi and ci. Use of this formula requires the provision of 2 standards. With parameters for all intervals obtained using an iterative method.

6.5. Results Calculation

1) Calculation Factor: When using the calculation factor to calculate results, you can directly enter calculation factor F without performing a calibration.

   Results can be calculated using the following calculation formula:

$$C = \frac{F \times R}{10000}$$

   Where: F is the calculation factor entered and R is the reaction amplitude of the test sample.



Notes:

When using the calculation factor to calculate results, the chemistry in question needs to have at least one effective reagent blank result, meaning that the project must have at least one successful reagent blank test.

2) When using other calibration types, calibration parameters and reaction amplitude R can be used to calculate the results.

6.6. QC

6.6.1. Quality Control Rules and Determination

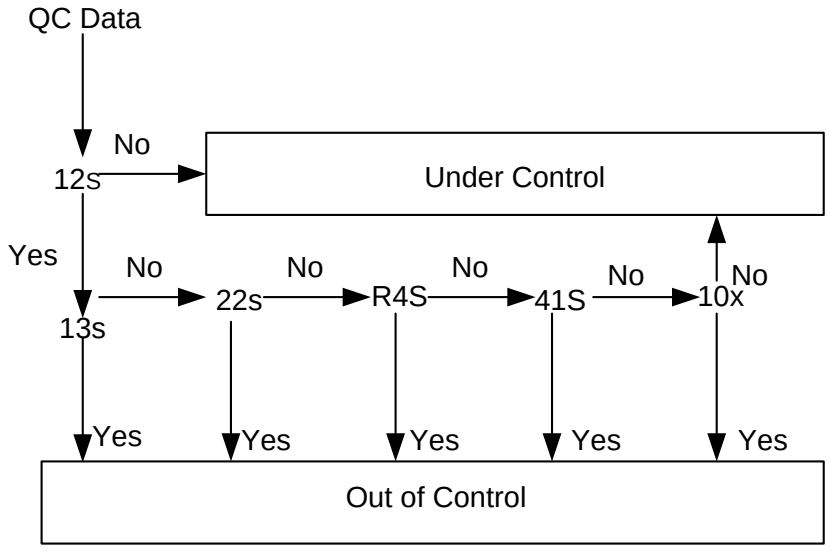
The system supports the Westgard multi-rule standard (L-J), cumulative sum quality control and Twin Plot quality control rules. The default quality control rule is the Westgard multi-rule standard and the user can choose one or more rules with which to perform a quality control status determination for different items as appropriate.

6.6.1.1. Westgard Multi-Rule

Westgard multi-rule quality control rules include 6 sub-rules; the definition of each sub-rule is given below:

Rule	Explanation	QC determination
1-2S	1 point falls beyond mean +2 SD or -2 SD	Warnings
1-3S	1 point falls beyond mean +3 SD or -3 SD	Outliers (random error, system error)
2-2S	2 consecutive points fall beyond mean +2 SD or -2 SD	Outliers (system error)
R4S	The difference between two values within the same batch exceeds 4SD	Outliers (random error)
4-1S	4 consecutive points fall beyond mean +1 SD or -1 SD	Outliers (system error)
10X	10 consecutive points fall on the same side of mean	Outliers (system error)

A flow chart for determining the aforementioned sub-rules is as follows:



6.6.1.2. Cumulative Sum

6.6.1.3. Twin Plot

6.6.2. Quality Control Query

There are a total of three quality control search modes: real-time QC, intraday QC and inter-day QC. An analysis of quality control status is performed using preset QC rules.

Real-time QC Used to perform a quality control status analysis on 10 consecutive quality control data points in a day;

Daily QC Used to perform a quality control status analysis on all quality control data points in a given day;

Day to Day QC Used to perform a quality control status analysis on all quality control data points across different days;

6.6.3. QC Charting

There are three types of quality control charts: L-J (Westgard Multi-Rule), cumulative sum, and Twin-Plot QC charts.

1) LJ Quality Control Chart

Using the quality control data value measured as the vertical axis, a horizontal line is drawn from the quality control target value and 6 parallel lines are drawn to the mean line at the upper +1SD (Standard deviation, abbreviated as SD), +2SD, +3SD and at the lower -1SD, -2SD, -3SD. Furthermore, ±1SD、±2SD and ±3 SD are marked clearly and each quality control product test result is marked on the quality control chart. Adjacent points are connected with a thin line.

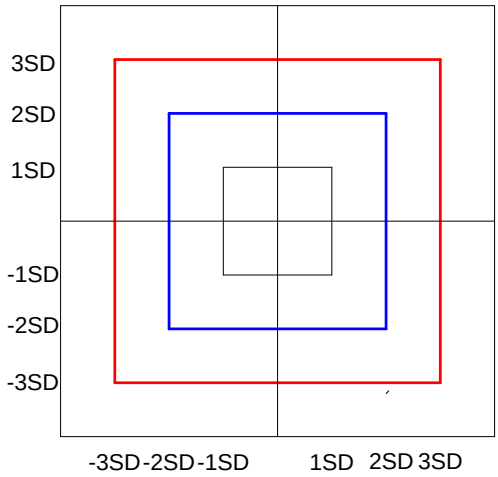
2) CUMSUM Control Chart

In calculating the cumulative sum of a control solution, the cumulative sum value is taken as the vertical axis, and the number of tests as the horizontal axis. A horizontal line is drawn from 0 and at the upper and lower cumulative sum's control limit point h (this limit is automatically calculated according to the quality control rules that the user has entered in the QC setup), two parallel lines are drawn to the horizontal, each cumulative sum point is labeled on the chart and the adjacent points are connected via a thin line to yield a cumulative sum quality control chart. Any points that are outside the upper and lower parallel lines are regarded as outliers.

3) Twin-Plot QC chart

When simultaneously analyzing control solutions of two concentrations under a single item, the Twin-Plot QC chart can be displayed. According to each quality control solution's target value and standard deviation SD (entered by the user in the QC set up) and taking one of the quality control solution's test values as the horizontal axis (usually the lower-concentration quality control solution), the other quality control solution's test

values as the horizontal and vertical axes (usually the higher-concentration quality control solution), and the mean value as the center line, ±1SD、±2SD and ±3SD lines are labeled and one point is established using the test results of the two quality control solutions corresponding to the same test. The point lies on the coordinates as shown in the Figure below:



This chart can sensitively reflect systematic and random errors. Data that falls within the blue circle (±2SD) is regarded as nominal; Data that falls within the first or third quadrant between the red and blue circles is regarded as affected by systematic error; Data that falls within the second or fourth quadrants between the red and blue circles is regarded as arising from random errors and data that falls outside the red circle is also regarded as indicative of random errors.

6.7. Other Related Calculations

6.7.1. Calibration Curve-Related Calculations

1) Calibration Sensitivity

Refers to the difference in reactive amplitude between the maximum concentration calibration liquid and the minimum concentration calibration liquid during the calibration process. If this value is smaller than the value set by the user, it will be regarded as invalid.

2) Blank Solution Reaction Amplitude

Refers to the reaction amplitude of a calibration solution with concentration zero. If this value is greater than the value set by the user it will be regarded as invalid.

3) Calibration Reproducibility

If the difference between the minimum and maximum tested reaction amplitude for a single calibrator tested multiple times exceeds a set value, the calibration will be regarded as invalid.

4) Standard Deviation of the Calibration Curve

Applies only to multi-point linear and nonlinear calibration curves. Refers to the sum of squares of the difference in the calibrator reaction amplitude (R) and the amplitude calculated based on the corresponding calibration curve (Ri') divided by the number of degrees of freedom, which is then squared again. The specific formula for the calculation is as follows:

- Multi-Point Linear Calibration

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri'\right)^2}{Nn-2}}$$

Where: Rij is the reaction amplitude for calibrator i during a particular test (valid test), Ri' is the reaction amplitude of calibrator i calculated based on the corresponding calibration curve, N is the number of calibrators and n is the effective number of repeated measurements made.

- Logit-4P

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri'\right)^2}{Nn-4}}$$

Where: Rij is the reaction amplitude for calibrator i during a particular test (valid test), Ri' is the reaction amplitude of calibrator i calculated based on the corresponding calibration curve, N is the number of calibrators and n is the effective number of repeated measurements made.

- Logit-5P

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-5}}$$

Where: Rij is the reaction amplitude for calibrator i during a particular test (valid test), $Ri^{'}$ is the reaction amplitude of calibrator i calculated based on the corresponding calibration curve, N is the number of calibrators and n is the effective number of repeated measurements made.

- Exponential-5P and Polynomial-5P

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-5}}$$

Where: Rij is the reaction amplitude for calibrator i during a particular test (valid test), $Ri^{'}$ is the reaction amplitude of calibrator i calculated based on the corresponding calibration curve, N is the number of calibrators and n is the effective number of repeated measurements made.

- Spline

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-4}}$$

Where: Rij is the reaction amplitude for calibrator i during a particular test (valid test), $Ri^{'}$ is the reaction amplitude of calibrator i calculated based on the corresponding calibration curve, N is the number of calibrators and n is the effective number of repeated measurements made.

5) Calibration Curve Correlation Coefficient

Applies only to multi-point linear and nonlinear calibration curves. The formula for calculating the coefficient is given below:

$$R^{2}=\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Cij-\overline{C}\right)^{2}\left(Rij-\overline{R}\right)^{2}}{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Cij-\overline{C}\right)^{2}\sum_{i=1}^{N}\left(Rij-\overline{R}\right)^{2}}$$

Where: C is the concentration of calibrator, R is the reaction amplitude, N is the number of calibrators and n is the effective number of repeated measurements made.

6.7.2. Substrate Depletion Determination

Only applied for the kinetic method and two-point method. Some high concentration (activity) samples quickly deplete their substrate such that the reaction rate is not what is desired (zero-order or single-order). In order to correctly reflect the measurement results obtained, there is a need to determine a substrate depletion threshold. The specific method for making this determination is described below:

1) Upward Reaction

   When the absorbance of one or more points within the established time range is greater than a set value, a determination of substrate depletion is made.

2) Downward Reaction

   When the absorbance of one or more points within the established time range is less than a set value, a determination of substrate depletion is made.

6.7.3. Linearity Test

Only applies to the kinetic method. Whether or not the linearity of the reaction curve examined satisfies a pre-set value within the established time range is determined using data derived from all optical metering points. The specific calculation is performed as follows:

1) Assuming the number of optical metering points within the established time range is greater than 9:

   Linear limit = (the rate of change in absorbance for the first six points - the rate of change in absorbance for the last six points) / the rate of change in absorbance for all points

2) Assuming that the number of optical metering points within the established time range is greater than or equal to 4 and less than or equal to 8:

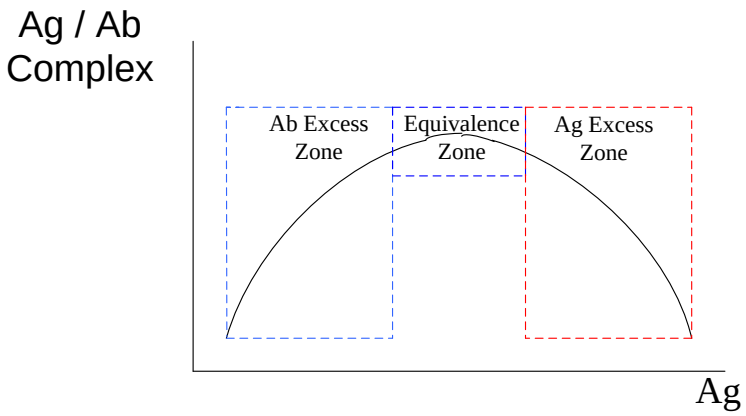
   Linear limit = (the rate of change in absorbance for the first three points - the rate of change in absorbance for the last three points) / the rate of change in absorbance for all points

3) Linearity is not calculated under the following conditions:

   - Number of optical metering points ≤ 3
   - The rate of change in absorbance is less than 0.006 / min or the differential of the rate of change in absorbance is less than 0.006 / min
   - Reagent blank testing, sample blank testing and zero concentration calibrator testing

6.7.4. Prozone Check

In an antigen-antibody reaction, the amount of resulting insoluble antigen-antibody complex is closely associated with the antigen-antibody ratio. If an appropriate ratio is maintained, the amount of insoluble antigen-antibody complex generated is maximized and when this happens the amount of transmitted light is minimized and (necessarily) absorbance is maximized; When this ideal ratio is exceeded or not met, the resulting amount of insoluble antigen-antibody complex produced will be reduced and transmitted light increases so absorbance decreases as shown in the Figure below. If a prozone check is not performed beforehand, two samples which differ greatly in concentration can produce equal amounts of insoluble antigen-antibody complexes and the measurement result will be the same.

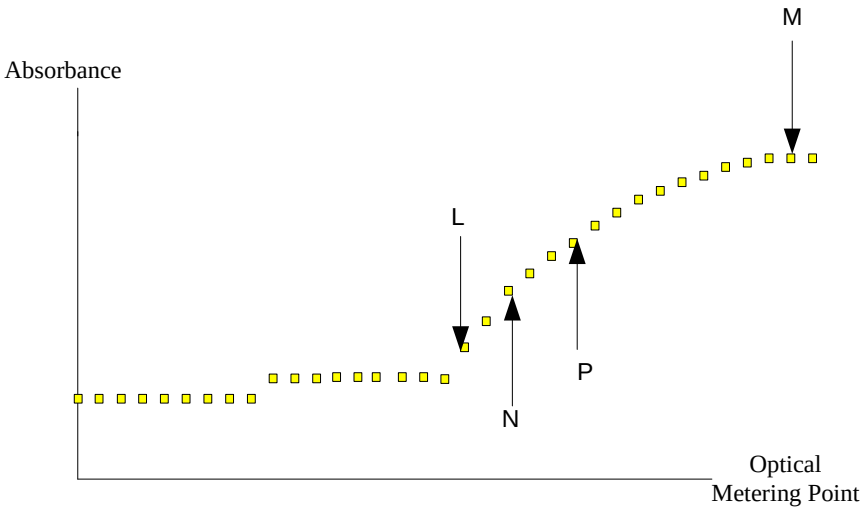


A prozone check is performed according to the following method:

1) Double Reagent End-Point Method

   As shown in the Figure below, L is the starting point of the reaction, M is the beginning of the reaction time interval, N and P are the prozone check points. L, M, N and P must satisfy the following relationship:

$$19 \leq L < N < P < M \leq 40$$



The prozone check (PC) value is equal to:

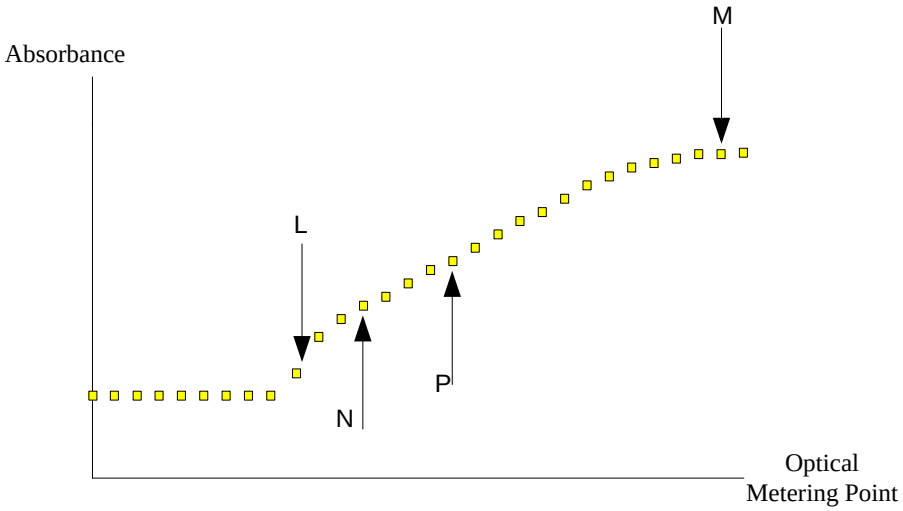
$$PC = \frac{\frac{A_M - A_P}{M - P}}{\frac{A_N - A_L}{N - L}} \times 100\%$$

If PC > the set prozone check value limit, then the existence of a prozone effect is affirmed;

2) Single Reagent End-Point Method

As shown in the Figure below, L is the starting point of the reaction, M is the beginning of the reaction time interval, N and P are the prozone check points. L, M, N and P must satisfy the following relationship:

$$10 \le L < N < P < M \le 40$$



The prozone check (PC) value is equal to:

$$PC = \frac{\frac{A_M - A_P}{M - P}}{\frac{A_N - A_L}{N - L}} \times 100\%$$

If PC > the set prozone check value limit, then the existence of a prozone effect is affirmed;

6.7.5. Determination of Lamp State

After each startup, before starting a test, the reaction disk is rotated such that the reaction cuvette stays in between positions 50# - 1#. When this happens, photoelectric collection is performed for each wavelength and a total of 10 data points are collected for each wavelength. The maximum and minimum values for each wavelength are excluded and the average of the remaining 8 data points is taken as the current photoelectric value for each wavelength as a basis for determining the light intensity of the system lamp. When a photoelectric value for any given wavelength is less than 25,000, the system will alert the user that "Light source intensity is low; please replace the lamp." The user will then be permitted to continue the current test but before each subsequent test a warning will appear which states "Insufficient light intensity may affect results. Continue test?" and the user can make a decision regarding whether or not to proceed with the test; When the photoelectric value for any given wavelength decreases below 15,000 an alarm will be issued to the user stating "Light source intensity is very low; please replace the lamp immediately" and the user will be prohibited from continuing the test. The user will be required to replace the light source bulb and carry out a light source intensity test as required before testing can be continued.

6.7.6. Examination of Cuvette Cleanliness

After starting up the machine and before starting a test, the reaction disk is rotated such that the reaction cuvette stays in between positions 50# - 1#. When this happens, photoelectric collection is performed for each wavelength and a total of 10 data points are collected for each wavelength. The maximum and minimum values for each wavelength are excluded and the average of the remaining 8 data points is taken as the current photoelectric value for each wavelength as a basis for determining the cleanliness of the system's reaction cuvettes.

During the test, if the AD of the cuvette blank for any one of the 8 tested wavelengths is smaller than 50% of its initial value, the user is alerted to the presence of a dirty cuvette. Each time the blank of a cuvette is tested, the apparatus will attempt to determine whether or not the cuvette is dirty. The determination of dirtiness is based on the ratio of the blank AD value of the cuvette at the tested wavelength to the corresponding initial value.

7. Care and Maintenance

To maximize the performance of the analyzer, ensure its reliability and extend its life, maintenance should be performed in strict accordance with the requirements outlined in this section.

7.1. Preparation of Tools

1) M1.5, M2.0, M2.5, M3.0 hex wrenches;
2) Phillips screwdriver (large, medium and small);
3) Stainless steel wire (of 0.3 mm and 0.5 mm diameters);
4) Plastic syringe (approx. 10ml, without probe);
5) Clean gauze;
6) Clean cotton swabs;
7) Brush (used to clean containers);
8) Non-ionic surfactant cleaner;
9) Anhydrous ethanol;
10) 84 Disinfectant;
11) Medical latex gloves;
12) Lubricating grease.

7.2. Daily Maintenance

7.2.1. Wiping Down the Analyzer Countertop

The analyzer countertop can easily become dirty due to spilling of reagents, reaction solution and serum, and should be cleaned promptly. The instrument should be cleaned every day after shutdown, in accordance with the following steps:

1) Wet a towel with cleaning solution and wipe the analyzer countertop until all visible dirt is wiped clean;
2) Wet a towel with disinfectant and wipe down the analyzer countertop;
3) After fifteen minutes, wring out a wet towel and wipe down the countertop to remove any residual disinfectant.



Notes: Corrosion
Wash solution is chemically corrosive and protective gloves should be worn during use.



Notes: Biological Contamination

The countertop should be considered a source of contagion and gloves should be worn during handling.

7.2.2. Cleaning the Sample Probe / Mixer

When the exterior and tip of the sample probe or surface of the mixer are dirty, they may contain serum, reagent or cleaning water and should be checked daily after system shutdown. If any of the above issues are observed, cleaning should be carried out promptly.



Notes: Combustibles

Ethanol is flammable. When cleaning with ethanol, ensure that the analyzer has been shut down and the amount of ethanol within proximity to the analyzer should be kept to within 10ml or less.



Notes: Biological Contamination

All analyzer parts should be considered a source of contagion and gloves should be worn during handling;

7.2.2.1. Cleaning the Sample Probe



Figure 7-1: Wiping Down the Sample probe

1) Move the Sample probe to the appropriate position;

2) Soak a piece of clean gauze in ethanol and gently wipe the sample probe tip until nothing remains on the probe tip.

7.2.2.2. Cleaning the Mixer



Figure 7-2: Wiping Down the Mixer

1) Move the mixer to the appropriate position;
2) Soak a piece of clean gauze in ethanol and gently wipe the flat part of the mixer until nothing remains on the rod.

7.2.3. Inspecting the Reagent / Sample Syringe

Open the cover on the left side of the analysis unit. The syringe should be visible on the right.

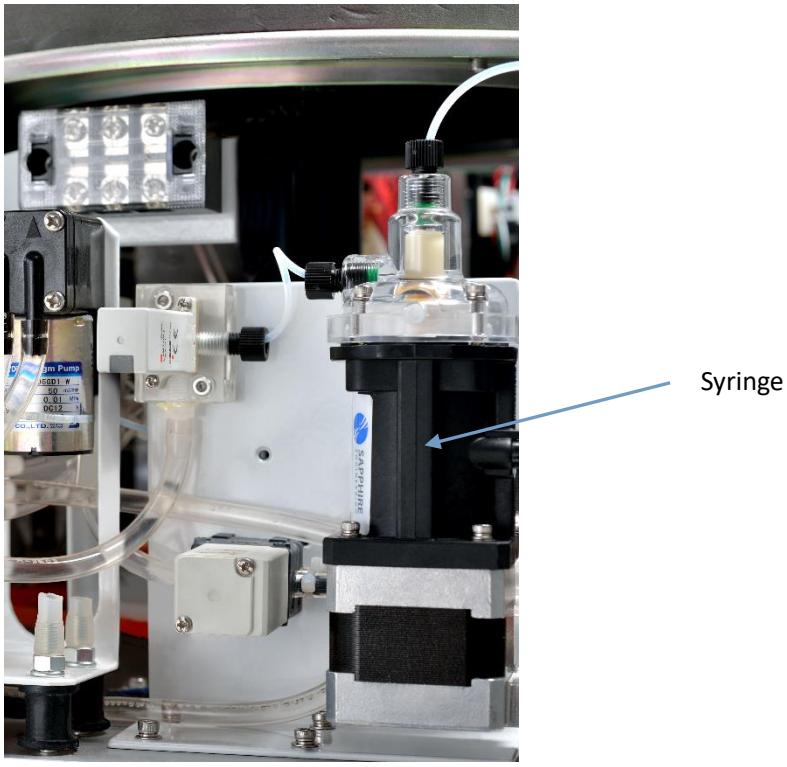


Figure 7-3: The Syringe

Check the knob of the Finger-tight fitting, if syringe any leaks are identified, tighten it. If bubbles inside, please remove all bubbles. If not be solved, please contact HETO; When finished, close the cover on the left side of the analysis unit.

7.2.4. Inspecting the Purified Water Bucket

A purified water bucket should be present on the left side of the analysis unit:



Figure 7-4: The Purified Water Bucket

Check the clean water bucket in accordance with the following procedure:

1) Check whether or not the bottom of the bucket is clean;

2) If the bottom of the bucket is dirty, clean the bucket thoroughly before continuing use.

7.2.5. Inspecting the Waste Liquid Container / Tubing

A waste liquid container should be present next to the purified water bucket on the left side of the analysis unit:



Figure 7-5: Waste Liquid Container / Tubing

Check the waste liquid container in accordance with the following procedure:

1) Check whether or not there is any fluid leakage at the joints connecting the analyzer to the system's waste liquid tubing.

2) If a leak is identified, wipe off any liquid on the connector with gauze and unscrew the connector in the counterclockwise direction. Check whether or not the waste liquid tubing is blocked and, after removing any blockage, screw the connector back on. If the leak persists, contact HETO for service.

3) Check whether or not the system's waste liquid tubing is bent. If there are any kinks, straighten them out.



Notes: Biological Contamination

1) All waste liquid should be considered a source of contagion and gloves should be worn during handling;

2) The disposal of any liquid waste should comply with the requirements of your local regulatory agency for environmental protection.

7.3. Weekly Maintenance



Note: Combustibles

Ethanol is flammable. When handling ethanol, ensure that the analyzer has been shut down and that the amount of ethanol within proximity to the analyzer is kept to within 10ml or less.



Note: Biological Contamination

All analyzer parts should be considered a source of contagion and gloves should be worn during handling;

7.3.1. Cleaning the Cuvette Cleaning Probes

For analyzer with auto wash function, when the cuvette cleaning mechanism probe is dirty, it may contain reaction solution or excess water and should be checked daily after system shutdown. If any of the above issues are observed, cleaning should be carried out promptly.

1) Soak a piece of clean gauze in ethanol and gently wipe the drainage probe and tip until no foreign matter remains on the probe.

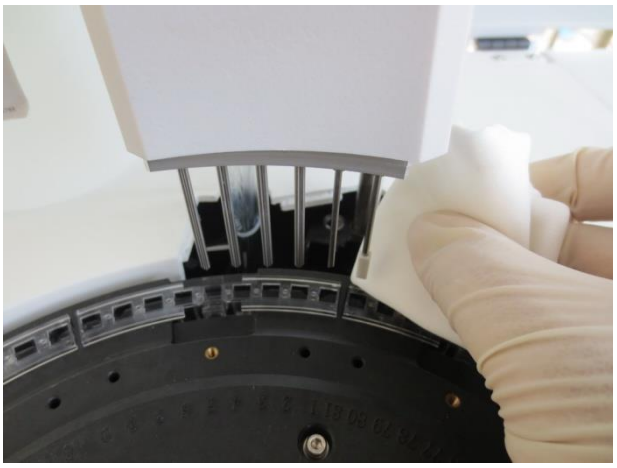


Figure 7-6: Wiping Clean the Cuvette Cleaning Mechanism Nozzle

2) Soak a piece of clean gauze in ethanol and gently wipe all four sides and the top and bottom of the nozzle until no foreign matter remains on the rod.

Notes:
When cleaning, it is important to note that there is a risk that cotton swab fibers may become stuck between the drainage and suction probes.
If found, these should be promptly removed.

7.3.2. Cleaning the Primary Purified Water Filter



Figure 7-7: Removing the Filter



Figure 7-8: Replacing the Filter

Notes:
When installing the filter, it is important to ensure that the filter and the purified water detector have sunk to the bottom of the container. Failure to do so may result in inaccurate results!

Remove the tubing connected to the purified water bucket and remove the filter, as shown in Figures 7-7 and 7-8;

Check that the filter to be placed in the purified water bucket is completely clean. If it is dirty:

First rinse off the filter thoroughly in tap water then rinse once again using purified water until completely clean;

Connect the filter to the connecting tubing and place it in the clean water bucket;

7.3.3. Cleaning the Waste Liquid Container

If waste liquid is discharged directly into a sewer system, this maintenance step may be omitted. Otherwise, cleaning should be performed in the following order:

1) Open the waste liquid container lid and remove the waste liquid tubing;
2) Clean the tubing thoroughly with a brush and place it back in the container.

Notes: Biological Contamination
All waste liquid should be considered a source of contagion and gloves should be worn during handling;

7.3.4. Cleaning the Reagent / Sample Disk Refrigeration Unit

1) Turn off the analysis unit's power supply;
2) Remove the reagent / sample disk lid and remove the reagent / sample disk. Use a piece of clean gauze dipped in wash solution to clean the internal walls of the refrigeration unit until there are no visible stains present. Next, use a clean piece of gauze to wipe the interior dry as shown in the following Figure :



Figure 7-9: Clean and dry reagent tray

3) Reinstall the reagent / sample disk

4) Place the cover back on the reagent / sample disk



Notes: Biological Contamination
All stains encountered should be considered a source of contagion and gloves should be worn during handling;

7.4. Monthly Maintenance



Notes: Biological Contamination
All analyzer parts should be considered a source of contagion and gloves should be worn during handling;

7.4.1. Cleaning the Cleaning Pool

The cleaning pool should be cleaned in the following order:

1) Turn off the analysis unit's power supply;
2) Remove the reagent probe / sample probe from the cleaning position;
3) Use a cotton swab dipped in cleaning solution to gently wipe the interior of the reagent probe / sample probe cleaning pool until no stains are visible, then wipe the surface dry with clean gauze;
4) Remove the mixer from the cleaning position;
5) Use a cotton swab dipped in cleaning solution to gently wipe the interior of the mixer cleaning pool until no stains are visible, then wipe the surface dry with clean gauze;
6) Move the Sample probe and mixer to the tops of the corresponding cleaning pools.

7.4.2. Cleaning the Thermostatic Groove of the Reaction Disk

The thermostatic groove of the reaction disk should be cleaned in the following order:

1) Turn off the analysis unit's power supply;
2) Remove the reaction disk cover;
3) Loosen the screws that fix the reaction disk in place, as shown below:



Figure 7-10: Loosen screws

4) Take out the reaction disk, as shown below:



Figure 7-11: Take out reaction disk

5) With a clean gauze dipped in wash solution, clean each part of the inner wall of the reaction Compartment until no stains are visible. Then, wipe the inner wall dry with clean gauze, as shown below:

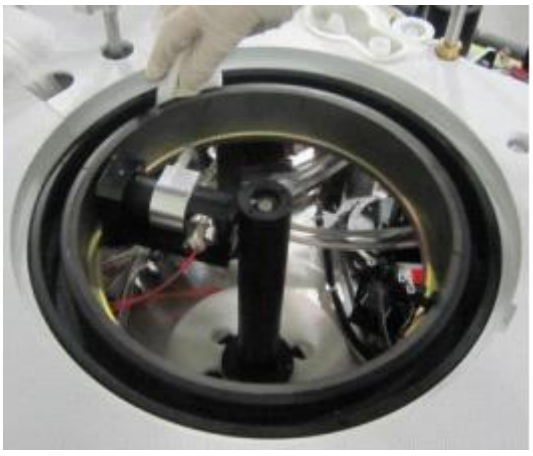


Figure 7-12: Clean and dry

6) Reinstall the reaction disk and fix in place with the corresponding fastening screws;

7) Place the cover on the reaction disk;

7.4.3. Wiping the Driving Rod

Wipe the driving rod in the following order:

1) Turn off the analysis unit's power supply;

2) Move the mixer such that the driving rod is at an angle suitable for wiping;

3) Gently use a piece of clean gauze to wipe the driving rod up and down in the vertical direction until no stains are visible.

4) Use the same method to wipe the Sample probe driving rod;

5) Move the Sample probe and mixer to the tops of the corresponding cleaning pools.

7.4.4. Check and Replace Cooling Water

For analyzer with external submersible pump: the cooling water inside the external water cooling tank should be checked:

1) Turn off the analysis unit's power supply;

2) Disconnect the power cable of submersible pump, take out the *water cooling in tube* with the submersible pump from the external water cooling tank.

3) Take out the *water cooling out tube* from the tank.

4) Clean the external water cooling tank and make sure no dust left inside.

5) Put back the *water cooling in tube* with submersible pump into the tank.

6) Put back the *water cooling out tube* into the tank.

7) Refill the tank with purified water.

8) Connect the power cable for submersible pump to the DC12V port.

7.4.5. Clean the Dust Filter

1) Turn off the analysis unit's power supply;

2) Remove the dust filter from the backside of the analyzer and wash it by using purified water;

3) Put the dust filter back when it is dry.

7.5. Semi-Annual Maintenance

7.5.1. Replacing the Primary Filter

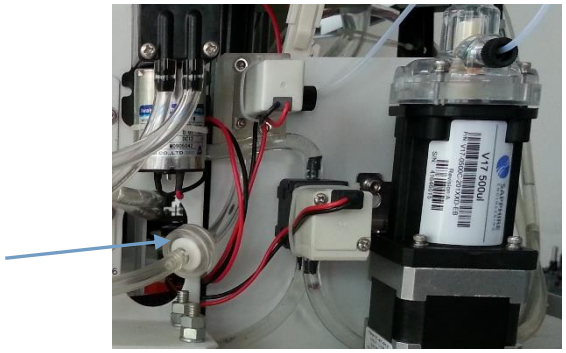
The method for replacing the primary stage filter is the same as the method described in

Section 7.3.1.

7.5.2. Replacing the 45 Micron Filter

When the 45 micron filter is obviously dirty or the amount of clean water on the interior is obviously reduced, the filter needs to be replaced. The replacement should be performed according to the following sequence:

1) Turn off the analysis unit's power supply;
2) Open the left door of the analysis unit and locate the 45 micron filter. Release the clips on either side of the second stage filter and simply remove the old filter as shown in the Figure below:



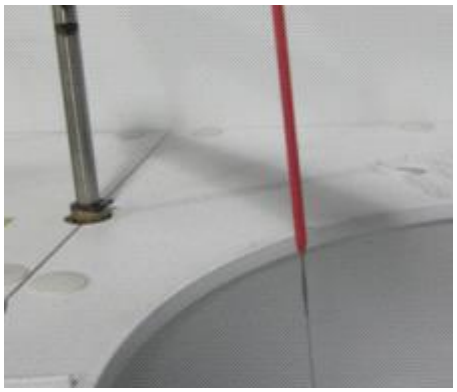
3) Install a new filter and reinstall the clips on either side of the filter.
4) Close the left door of the analysis unit.

7.6. Unscheduled Maintenance

7.6.1. Unblocking the Sample and Reagent Probes

When clogging of a probe occurs, it should be cleared immediately in the following sequence:

1) Turn off the analysis unit's power supply;
2) Remove the reagent disk vertically;
3) Manually pull the sample probe's rocker arm to its uppermost position and then rotate it towards the interior of the reagent disk;
4) Use the space available in the reagent disk to insert a standard acupuncture probe into the Sample probe to unblock it as shown in the Figure below:



5) Rotate the reagent probe or Sample probe into the space above the cleaning pool and install the reagent disk.



Notes: Biological Contamination

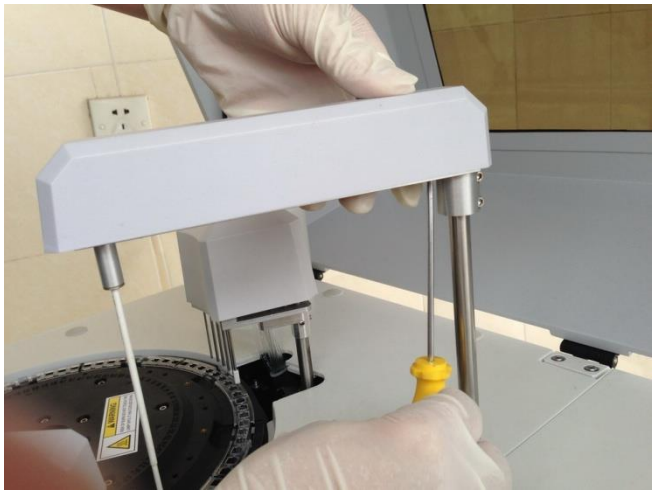
The reagent probe and Sample probe should be considered a source of contagion and gloves should be worn during handling.

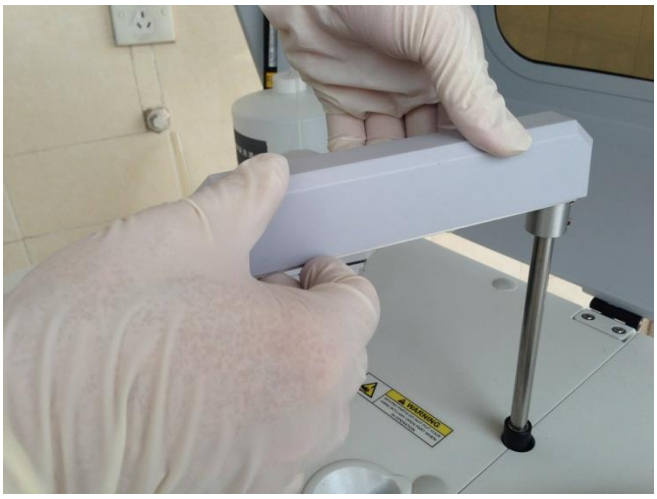
7.6.2. Replacing the Sample Probe

In the event that the probe becomes irreversibly clogged, broken or bent, you will need to replace it immediately in accordance with the following sequence:

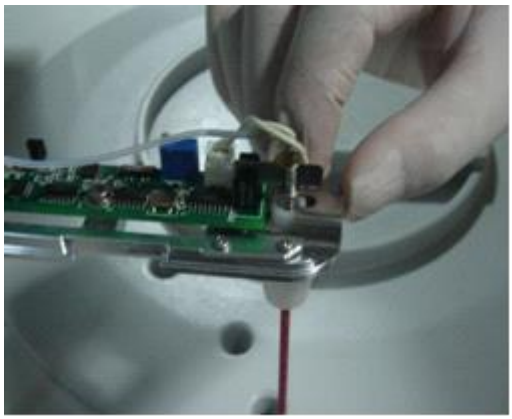
1) Turn off the analysis unit's power supply;

2) Rotate the Sample probe to an appropriate location and open the Sample probe rocker arm cover, as shown below:

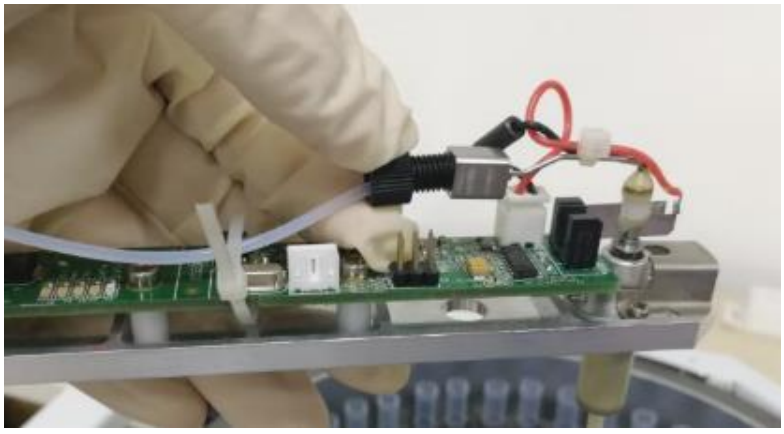




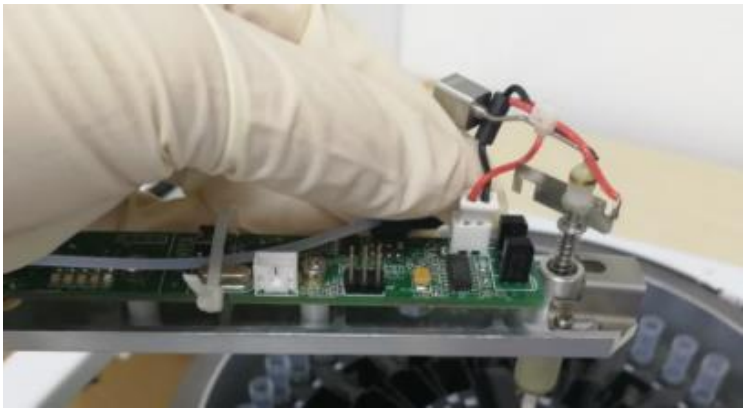
3) Loosen the compression spring, as shown below:



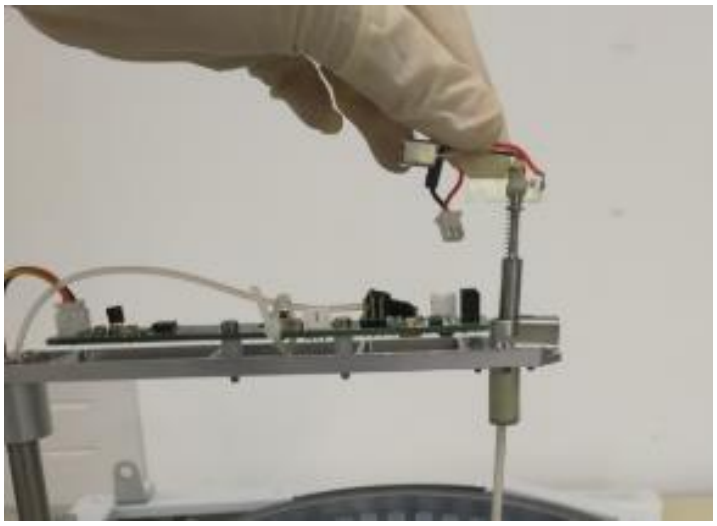
4) Loosen the Teflon tube connected to the Sample probe, as shown below:



5) Unplug the connection to the liquid level detection plate, as shown below:



6) Remove the reagent probe or Sample probe in the upward direction as shown in the Figure below:



7) Install the new probe on the rocker arm, reapply the spring, connect the Teflon tube, plug in the liquid level detection sensor leads and close the rocker arm cover;

8) Move the Sample probe to the space above the cleaning pool.



Notes: Biological Contamination
The Sample probe should be considered a source of contagion and gloves should be worn during handling.

7.6.3. Replacing the Mixer

In the event that the mixer probe becomes broken or bent or frequently holds onto liquids, you will need to replace it immediately in accordance with the following sequence:

1) Turn off the analysis unit's power supply;

2) Move the mixer to the appropriate position;

3) Loosen the two top wire screws fixed to the stirring motor shaft, as shown below:



4) Remove the mixer.

5) Install the new mixer upward in the motor shaft until you meet with resistance;

6) Use two top wire screws to fix the mixer onto the stirring motor shaft;



Notes: Biological Contamination
The mixer should be considered a source of contagion and gloves should be worn during handling.

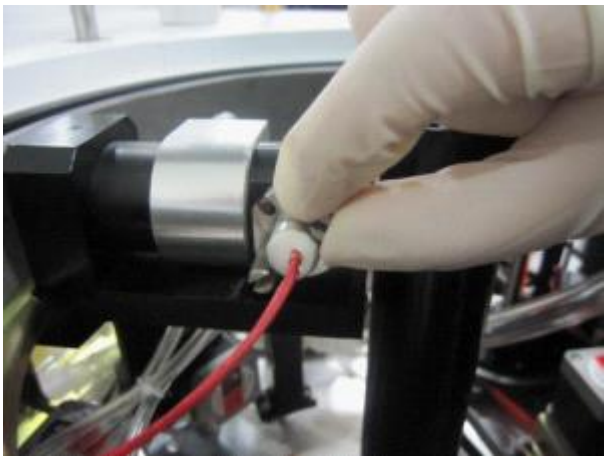
7.6.4. Replacing the Lamp

When the lamp has been in use for more than six months or the analyzer prompts you to replace the lamp, the lamp should be replaced immediately according to the following sequence:

1) Turn off the analysis unit's power supply and perform the subsequent steps after waiting for 30 minutes;

2) Remove the reaction disk cover and remove the reaction disk using steps 2 to 4 of Section 7.4.2;

3) After removing the reaction disk, unscrew the 2 screws on either side of the lamp base, as shown below:



4) After removing the lamp, disconnect the lamp power cord, as shown below:



5) Insert the new lamp, apply the fixing screws and tighten the lamp power cord to power connector;
6) Put the reaction disk back into place and apply the fixing screws;
7) Place the cover on the reaction disk.
8) Adjust the AD again to keep it in the range 57000 ~ 59000



Notes: High temperature. Take care to avoid burns
Before replacing the lamps, turn off the power switch of the apparatus, and wait at least 30 minutes until the lamp has cooled down.



Notes: Glare
Before replacing the lamp, make sure the analysis unit is turned off, as light beams emitted by the bulb can damage your eyes.



Note: Dropping of Screws
When loosening and tightening the screws that secure the lamp, take care to avoid dropping the screws.

7.7. Replaceable Part List

7.7.1. The following is a list of items that can be replaced by the user

1) Sample probe and mixer;
2) Lamp;
3) The second stage filter.



Replacing the Fuse
1) The fuse that is integrated into the main power switch is an overcurrent release fuse and does not need to be replaced by the user;
2) If you need to replace the fuse, please notify HETO maintenance

engineer.

7.7.2. List of Parts that Require a Maintenance Engineer for Replacement

1) Main power supply switch;
2) Analysis unit power supply switch;
3) Other parts.

7.8. Maintenance Log

The following table lists components that need maintenance and provides a recommended maintenance schedule. Please make a copy of these tables monthly and record when maintenance is performed using the corresponding column of the maintenance log.

_____Year__Month

	Maintenance Performed (Daily)	Maintenance Record																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Wiping Down of the Analyzer Countertop																															
	Cleaning of the Sample probe / Mixer																															
	Inspection of the Reagent / Sample Syringe																															
	Inspection of the Purified Water Bucket																															
	Inspection of the Waste Liquid Container / Tubing																															

	Maintenance Performed (Weekly)	Maintenance Record																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Cleaning of the Cleaning Head Mechanism																															
	Cleaning of the Purified Water Filter																															
	Cleaning of the Waste Liquid Container																															
	Cleaning of the Reagent / Sample disk Refrigeration Unit																															

_____Year__Month

	Maintenance Performed (Monthly)	Maintenance Record																														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Cleaning of the Wash well																															
	Cleaning of the Reaction Compartment																															
	Wiping the of Driving Rod																															
	Check and Replace Cooling Water																															
	Clean Dust Filter																															

_____Year__Month

	Maintenance Performed (Semi-Annually)	Maintenance Record																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Cleaning of the Wash well																															
	Cleaning of the Reaction Compartment																															
	Wiping of the Driving Rod																															
	Maintenance Performed (Unscheduled)	Maintenance Record																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Unblocking of the Sample / Reagent probes																															
	Replacement of the Sample / Reagent probes																															
	Replacement of the Mixer																															
	Replacement of the Lamp																															
	Replacement of the Syringe																															
	Replacement of the 45 micron Filter																															

8. Alarm Information and Processing

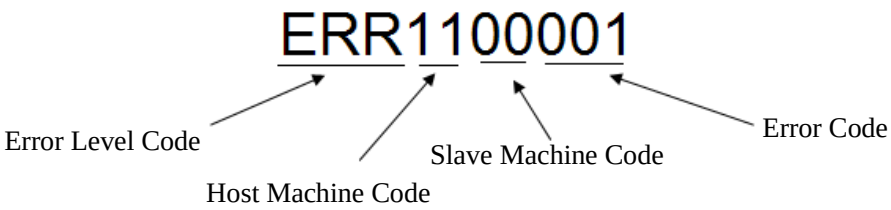
8.1. Overview

This chapter lists all system fault alarm information and corresponding troubleshooting measures. Please implement corresponding troubleshooting measures as soon as possible based on the measures provided here. In the event that the alarm status cannot be resolved after performing the required steps, please contact HETO.

8.2. Alarm Information Inquiry

When the system gives a warning message, click on the lower right corner of the error log view button to find the message and to view the corresponding message code which can be used to find corresponding appropriate user actions using the table below. Detailed information concerning potential runtime errors are summarized below:

8.2.1. Error Code Definition



8.2.1.1. Error Level Code Definitions

Level Code	Error Class	Class Definitions
INF	1	Reminder: The malfunction will not affect the operation of the instrument or the calculation of test results, but the user should be aware of the error.
WAR	2	Warning: The malfunction will not affect the operation of the instrument or the calculation of test results, but the user should take responsive measures as appropriate, as failure to do so may affect subsequent tests.
ERR	3	Error: The current malfunction may affect the current testing process or corresponding results.
FAT	4	Fatal: The system may not be able to continue operation due to the issue in question or may turn off automatically.

8.2.1.2. Host Machine Code Module Definitions

Host Machine Code	Code Definition
11	Cycle test module
21	Machine task logic module

8.2.1.3 Slave Machine Unit Code Definitions

Slave Machine Code	Code Definition
00	Main control unit
01	ISE unit

8.2.2. Instrument Runtime Error Table

Error Code	Level	Description	Solution
ERR1100001	ERR	Failed to obtain dilution cuvette number	Restart the system. If the problem persists, please contact HETO's technical support department.
ERR1100002	ERR	Communication abnormal	Check the communication cable and restart the system. If the problem persists, please contact HETO's technical support department.
ERR1100003	ERR	Cycle command response timeout	1. Turn on the system power; 2. Check the cable and restart the system. If the problem persists, please contact HETO's technical support department.
ERR1100004	FAT	Processing cycle command results frame data abnormal	If the system receives abnormal data, please contact the HETO technical support department.
ERR1100005	FAT	Cycle command results frame data abnormal	If the system receives abnormal data, please contact the HETO technical support department.
ERR1100006	FAT	Precompiled cycle command abnormal	Restart the system. If the problem persists, please contact HETO's technical support department.
ERR1101001	ERR	A unit of the recovery cycle has malfunctioned and the test will be immediately terminated	Exit the host computer and restart. Perform a power on self-test

ERR1101002	ERR	Sample probe rotation prohibited alert	Check the wiring and connectors. First perform a sample probe vertical reset command and then re-execute the corresponding rotate command. If the error reoccurs, please contact the HETO technical support department.
ERR1101003	ERR	The sample probe has detected that the acid-base cleaning solution is low	Add acid-base cleaning solution. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101008	ERR	Insufficient acid-base cleaning solution error	1) Add acid-base cleaning solution; 2) Check all applicable wires and sensors. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101009	ERR	Cycle command response timeout	1) Turn on the system power; 2) Check all connected cables and restart the system. If the problem persists, please contact HETO's technical support department.
ERR1101010	ERR	Cycle command results frame data abnormal	If the system receives abnormal data, please contact the HETO technical support department.
ERR1101011	ERR	The sample probe is unable to detect the initial vertical position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101012	ERR	Sample probe collision	1) Check whether or not the reagent bottle is open and whether or not the reagent is misplaced; 2) Check whether or not the sample tube lid is open and whether or not the sample is misplaced; 3) Place the reagent / sample disk cover and reaction disk cover in the correct positions; 4) Remove possible electromagnetic interference factors. If the problem persists, please contact HETO's technical support department.

ERR1101013	ERR	The sample probe is unable to leave the initial vertical position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101014	ERR	Sample probe detects the reagent level incorrectly	1) Check the water level in the cleaning solution container. If there is insufficient water in the container, add more immediately; 2) Check the tip of the sample probe. If it is dirty, wipe gently with cotton wool dipped in ethanol; 3) Remove possible source of electromagnetic interference. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101015	ERR	The sample probe has detected that the amount of reagent is insufficient	Add reagent. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101016	ERR	The Sample probe has detected a complete lack of reagent	1) Check the placement of the reagent; 2) Add reagent, 3) Check all applicable wires and sensors. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101017	ERR	Sample probe unable to descend to specified position error	1. Execute a Sample probe vertical reset command, then execute the relevant descend command. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101018	ERR	Although there was no sample drawn during the current cycle, when moving down toward the reaction cuvette, the Sample probe was not in the initial vertical position.	First, execute a Sample probe vertical reset command and eliminate strong sources of photo or electromagnetic interference, then restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101019	ERR	Although there was a sample drawn during the current cycle, when moving down toward the	First, execute a Sample probe vertical reset command, and eliminate strong sources of photo or electromagnetic interference then

		reaction cuvette, the Sample probe was not in the initial vertical position.	restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101020	ERR	Although a sample was drawn, when cleaning of the Sample probe was started, it was discovered that the Sample probe was not in the initial position, so it cannot be lowered and cleaning cannot be completed.	First, execute a Sample probe vertical reset command and eliminate strong sources of photo or electromagnetic interference, then restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101021	ERR	Although a sample was not drawn, when starting cleaning of the Sample probe, it was discovered that the Sample probe was not in the initial position, so it cannot be lowered and cleaning cannot be completed.	First, execute a Sample probe vertical reset command and eliminate strong sources of photo or electromagnetic interference, then restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101022	ERR	The Sample probe is not in the initial position and cannot be lowered to the specified position in order to complete the enhanced Sample probe cleaning process.	First, execute a Sample probe vertical reset command and eliminate strong sources of photo or electromagnetic interference, then restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101023	ERR	Although a sample was drawn, the Sample probe was not in the initial position and the Sample probe could not be completely lowered into the cleaning pool solution and the cleaning operation could not be completed.	First, execute a Sample probe vertical reset command and eliminate strong sources of photo or electromagnetic interference, then restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101024	ERR	Although no sample was drawn, the Sample probe was not in the initial position and the Sample probe could not be completely lowered into the cleaning pool solution and the cleaning operation could not be completed.	First, execute a Sample probe vertical reset command and eliminate strong sources of photo or electromagnetic interference, then restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101025	ERR	The initial position sensor was not detected when the sample probe was horizontally rotated into the initial position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error

			reoccurs, please contact the HETO technical support department.
ERR1101026	ERR	The sample probe is unable to leave the initial position when performing a rotation reset in the initial position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101027	ERR	Sample probe error when rotating to cleaning position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101028	ERR	The sample probe experienced an error when rotating to specified reagent position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101029	ERR	The sample probe experienced an error when rotating to specified sample position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101030	ERR	Sample probe horizontal position unknown error	Execute a sample probe rotation reset command, then execute the relevant rotation command. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101031	ERR	Sample probe error when rotating to reaction disk position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.

ERR1101032	ERR	Sample probe detection error: sample liquid level detected incorrectly	1) Check the water level in the cleaning solution container. If there is insufficient water in the container, add more immediately; 2) Check the tip of the sample probe. If it is dirty, wipe gently with cotton wool dipped in ethanol; 3) Remove possible source of electromagnetic interference. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101033	ERR	Turn On error	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and valve and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101034	ERR	Turn on pump error	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and valve and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101035	ERR	Turn on pump and close solenoid valve error	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and valve and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101036	ERR	There were errors when closing the pump and solenoid valve	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and valve and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101037	ERR	Turn Off error	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and valve and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101038	ERR	Turn off pump error	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and valve and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101039	ERR	Sample probe error when opening the cleaning valve on the inner wall	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and valve and

			reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101040	ERR	Syringe is out of step	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101042	ERR	Sample probe unit command reception efficacy and error	1) Perform a check after shutting down the machine and fix the serial cable in place; 2) Eliminate strong electromagnetic interference, reboot the system. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101043	ERR	The Sample probe has detected that the amount of sample is insufficient	Add additional sample. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101044	ERR	The Sample probe has detected a complete lack of sample	1) Check the placement of the sample; 2) Add sample; 3) Check all applicable wires and sensors. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101045	ERR	Incorrect reagent cuvette position	The reagent cuvette number is out of range. Please issue a cuvette number from 1 - 40.
ERR1101046	ERR	Sample probe moves to the initial vertical position early error	Check for light interference; otherwise contact the HETO and handle accordingly.

ERR1101047	ERR	The syringe has moved to the initial vertical position too early	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101048	ERR	Sample syringe unable to leave initial vertical position error	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101049	ERR	Incorrect sample cuvette position	The sample cuvette number is out of range. Please issue a cuvette number from 1 - 40.
ERR1101051	ERR	Sample probe unit invalid command	Please issue a correct unit command.
ERR1101052	ERR	Sample probe error when rotating to reaction disk Add S position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101053	ERR	Sample probe error when rotating to acid-base cleaning position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101054	ERR	Sample probe error when rotating to ISE position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101055	ERR	During an online dilution, the sample probe detected an insufficient amount of sample	Add additional sample. If the problem continues to reoccur, please contact HETO's technical support department.

ERR1101056	ERR	During an online dilution, the sample probe detected a complete lack of sample	1) Check the placement of the sample; 2) Add sample; 3) Check all applicable wires and sensors. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101057	ERR	Clockwise rotation error when performing a sample probe initial position reset	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101058	ERR	Insufficient sample in cuvette during online dilution	Please contact the HETO technical support department.
ERR1101110	ERR	Reagent disk unit command reception efficacy and error	1) Perform a check after shutting down the machine and fix the serial cable in place; 2) Eliminate strong electromagnetic interference, then reboot the system. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101113	ERR	Vacuum pump turn off error	Please contact the HETO technical support department.
ERR1101114	ERR	Vacuum pump turn on error	Please contact the HETO technical support department.
ERR1101115	ERR	Encoding disk error when reagent sample disk is rotating	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101116	ERR	Initial position sensor error when reagent sample disk is rotating	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.

ERR1101118	ERR	There was an error with the reagent disk when rotating to specified sample position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101119	ERR	Reagent disk error when rotating to initial position or when passing through the initial position when rotating to a specified cuvette	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101120	ERR	Mixer vertical reset error	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101121	ERR	Mixer unable to leave initial vertical position error	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101122	ERR	Mixer unable to descend to specified position error	Check the wiring or plug. Execute a mixer vertical reset command. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101123	ERR	Mixing motor turn on error	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and board and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101124	ERR	Mixing motor turn off error	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and board and reboot the machine. If the error reoccurs, please contact the HETO technical support department.

ERR1101125	ERR	Pump turn off error (cleaning of the outer wall of the mixer was stopped)	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and board and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101126	ERR	Error when closing the cleaning valve on the outer wall of the mixer and turning off the mixing motor	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and board and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101127	ERR	Pump turn on error (cleaning the outer wall of the mixer)	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and board and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101128	ERR	Error when opening the cleaning valve on the outer wall of the mixer and turning on the mixing motor	After eliminating strong sources of photo or electromagnetic interference, check the guidewire and board and reboot the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101129	ERR	Initial position not found error when performing a mixer horizontal rotation reset	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101130	ERR	Mixer not left initial position error when performing a horizontal rotation reset	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101131	ERR	Mixer error when rotating to cleaning position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.

ERR1101132	ERR	Mixer error when rotating to cleaning position during deceleration interval	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101133	ERR	Mixer error when rotating to reaction disk position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101134	ERR	Mixer error when rotating to reaction disk position during deceleration interval	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101135	ERR	Mixer horizontal position unknown error	To complete this operation, please issue a mixer horizontal rotation reset command and then carry out this operation.
ERR1101136	ERR	Mixer moves to the initial vertical position early error	Check for light interference; otherwise contact the HETO and handle accordingly.
ERR1101137	ERR	Mixer rotation prohibited alert	First perform a mixer vertical reset command, check the wiring and connectors, and then re-execute the corresponding rotate command. If the error reoccurs, please contact the HETO technical support department.
ERR1101143	ERR	Mixer unit command reception efficacy and error	1) Perform a check after shutting down the machine and fix the serial cable in place; 2) Eliminate strong electromagnetic interference, then reboot the system. If the problem continues to reoccur, please contact HETO's technical support department.

ERR1101153	ERR	Reaction disk rotation prohibited alert	First perform a cleaning nozzle vertical reset command, check the wiring and connectors, and then re-execute the corresponding rotate command. If the error reoccurs, please contact the HETO technical support department.
ERR1101154	ERR	Reaction disk command reception efficacy and error or invalid command	1) Perform a check after shutting down the machine and fix the serial cable in place; 2) Eliminate strong electromagnetic interference, then reboot the system. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101155	ERR	Cuvette encoding disk error	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101156	ERR	Reaction disk initial position not found error	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101157	ERR	Cuvette encoding disk error during deceleration interval	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101158	ERR	Unconfirmed reaction disk stop position error	Perform a reaction disk rotation reset operation. Once the reset operation has been completed normally, re-execute the current operation. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101159	ERR	Incorrect Sample channel no.	Please enter the correct Sample channel number.
ERR1101160	ERR	Cleaning solution valve opening error	Please contact the HETO technical support department.

ERR1101161	ERR	Cleaning solution valve closing error	Please contact the HETO technical support department.
ERR1101162	ERR	Vacuum valve opening error	Please contact the HETO technical support department.
ERR1101163	ERR	Vacuum valve closing error	Please contact the HETO technical support department.
ERR1101164	ERR	Waste valve opening error	Please contact the HETO technical support department.
ERR1101165	ERR	Waste valve closing error	Please contact the HETO technical support department.
ERR1101166	ERR	Initial position sensor error or motor step loss when performing a vertical reset operation on the cleaning head	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101167	ERR	The cleaning head reaches the initial position while moving up 185 steps	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101168	ERR	Cleaning head has not left the initial position	Eliminate strong photo or electromagnetic interference factors and check that the sensor plug is not loose. If it is not loose, check that the sensor wires are not disconnected and restart the machine. If the error reoccurs, please contact the HETO technical support department.
ERR1101169	ERR	The cleaning head is not in the initial position prior to moving	First, execute a cleaning head vertical reset then execute other cleaning head operations. If the issue persists, please contact the technical support department.
ERR1101170	ERR	Cleaning head moves into the initial position early	Perform a cleaning head vertical reset, move the cleaning head into the waste liquid suction position and re-execute this operation. If the error reoccurs, please contact the HETO technical support department.
ERR1101171	ERR	Peristaltic pump waiting times exceed the permissible range	Reset peristaltic pump waiting times

ERR1101172	ERR	Cleaning head vertical reset error	Check the cleaning head sensor, connector and wiring then re-execute the operation. If the problem persists, please contact the HETO technical department.
ERR1101173	ERR	Pump turn on error	Please contact the HETO technical support department.
ERR1101174	ERR	Pump turn off error	Please contact the HETO technical support department.
ERR1101208	ERR	High temperature alarm	Eliminate strong electromagnetic interference. Check wiring. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101209	ERR	First abnormal temperature alarm after establishing temperature	Eliminate strong electromagnetic interference. Check wiring. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101210	ERR	Abnormal temperature alarm	Eliminate strong electromagnetic interference. Check wiring. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101211	ERR	Continuously high temperature alarm	Eliminate strong electromagnetic interference. Check wiring. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101212	ERR	Unable to change execution parameters	Stop analyzer and put into standby mode.
ERR1101213	ERR	Target temperature value is too high	Reset the target temperature value
ERR1101214	ERR	Cooling fan turn on error	Check the guide wire; If the problem persists, please contact HETO's technical support department.
ERR1101215	ERR	Cooling fan turn off error	Immediately contact the HETO technical support department.
ERR1101216	ERR	High temperature alarm	Immediately contact the HETO technical support department.

ERR1101236	ERR	Temperature control unit command reception efficacy and error	1) Perform a check after shutting down the machine and fix the serial cable in place; 2) Eliminate strong electromagnetic interference, then reboot the system. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101239	ERR	Incorrect channel no.	1) Perform a check after shutting down the machine and fix the serial cable in place; 2) Eliminate strong electromagnetic interference, then reboot the system. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101244	ERR	Main control unit command efficacy and error	1) Perform a check after shutting down the machine and fix the serial cable in place; 2) Eliminate strong electromagnetic interference, then reboot the system. If the problem continues to reoccur, please contact HETO's technical support department.
ERR1101252	ERR	Main control unit control error	Perform a malfunction recovery command. If the problem continues to reoccur, please contact HETO's technical support department.
WAR2100001	WAR	Optical data returned by all channels is zero.	1) Turn on the system lamp 2) Please contact the HETO technical support department.
WAR2100002	WAR	The channel background value is equal to the set maximum	1) Adjust the AD value of each channel to within the standard range; 2) Replace the lamp; 3) Please contact the HETO technical support department.
WAR2100003	WAR	The channel background value is lower than the alarm value	1) Adjust the AD value of each channel to within the standard range; 2) Replace the lamp; 3) Please contact the HETO technical support department.

WAR2100004	WAR	The channel background value is lower than the warning value	1) Adjust the AD value of each channel to within the standard range; 2) Replace the lamp; 3) Please contact the HETO technical support department.
WAR3200602	WAR	The remaining reagent volume of Item [{0}] is {1} insufficient. disk No.: {2}, Cuvette No.: {3}	Add reagent.
WAR3200603	WAR	The remaining measurements [{1}] of chemistry [[0}] are less than warning limits [{2}].disk No.: {3}, Cuvette No.: {4}	Add reagent.
WAR3200606	WAR	Prozone check point P of chemistry [{0}] is abnormal	Retest after diluting the sample; Check whether or not the limit settings are suitable.
WAR3200607	WAR	The light source intensity is very low	Replace the lamp.
WAR3200608	WAR	The the light source intensity is low	Replace the lamp.
WAR3200609	WAR	Channel {0} configuration is not found in dark current configuration	There was an error in the photoelectric module configuration file. Please contact HETO technical support.
WAR3200610	WAR	Dark current value [{1}] of channel {0} exceeds alarm value [{2}]	There was a malfunction in the photoelectric module. Please contact HETO technical support.
WAR3200611	WAR	Deionized water level is low. disk No.: {0}, Cuvette No.: {1}	Add deionized water

Appendix A

A.1. Common Terms

A.1.1. AD Value

The photocurrent generated by light reaching the sensor. The current passes through a fixed resistor and, after amplification, is converted into a photoelectric voltage (analog signal). This voltage is then subject to an AD conversion (digital-analog conversion) to create a value of corresponding size (the size is correlated with the bit value of the selected AD). This value is the AD value.

A.1.2. Dark Current

The value output by the electrical circuit when the light source is not on (i.e., when there is no signal light). Expressed as an AD value. Dark current is effectively equivalent to the background current of the circuit and this value must be deducted when calculating absorbance.

A.1.3. Water Blank

The absorbance when purified water is loaded into the cuvette being examined. Since absorbance values are relative - that is, they are based on an arbitrary absorbance base value - the absorbance of a water blank is defined as 0. That is, all other absorbance values must have the absorbance value of the reaction cuvette containing a water blank subtracted from their initial values. In analyzers which has not the auto wash station, the water blank value is the cuvette blank value (The absorbance value of an empty cuvette).

A.1.4. Optical Metering Point

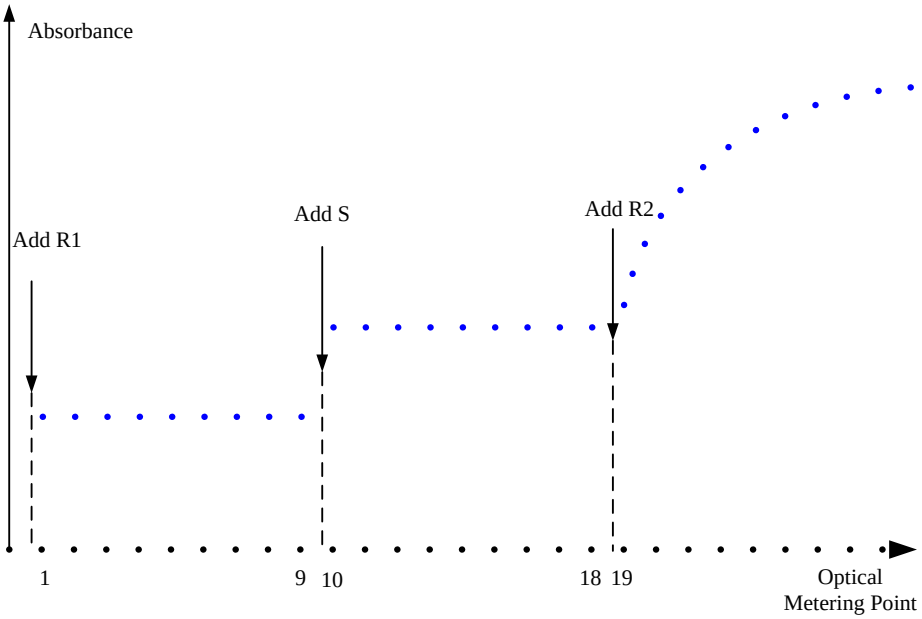
This value is typically shown as a specific cyclical value when performing a photoelectric test on a reaction solution. There are strict and fixed relationships between each optical metering point; Each reaction features 40 optical metering points, and in high-speed mode the time intervals between two adjacent optical metering points is 24 seconds; In standard mode, the time interval between two adjacent optical metering points is 36 seconds.

A.1.5. Absorbance

The value obtained by taking the negative common logarithm (base 10) of the transmitted light intensity divided by the incident light intensity. The incident light intensity is the AD value of a reaction cuvette filled with distilled water. The absorbance value shown is the computed absorbance × 20000.

A.1.6. Reaction Curve

The series of points plotted on a plane where optical metering points are plotted on the horizontal axis and absorbance is plotted on the vertical axis. In high-speed mode, a single cycle lasts 24 seconds; In standard mode, a single cycle lasts 36 seconds.



A.1.7. Reactivity

The change or rate of change following the reaction or during the course of the reaction.

A.1.8. Calibration

Also referred to as alignment. The reaction amplitude of one or more calibrators with known concentration (or activity) is measured and, based on the calibration method selected by the user (linear or nonlinear), a best-fit curve is fit to the data set (concentration, reactivity) and a mathematical expression for this curve is computed. By using this curve and determining the reactivity of a sample of unknown concentration (or activity), it is possible to calculate the concentration (or activity) of the sample.

A.1.9. Calibration Curve

Points are arranged on a coordinate plane with concentration (or activity) displayed on the horizontal axis and reactivity displayed on the vertical axis. A fit for the curve is then computed using an optimal mathematical formula.

A.1.10. Calibration Parameter

Refers to all terms present in the relational expression governing calibration with the exception of concentration and reactivity.

A.2. Technical Parameters

Para. Name	Parameter Values
Instrument Type	Random optional discrete type, emergency insertion, all reagents permitted
Central Wavelength Deviation	±2nm
Half-Wave Width	≤12nm
Stray Light	≥ 4.5 (in absorbance)
Test Speed	150 tests/hour (high speed mode); 100 tests/hour (standard mode);
Analysis Principle	colorimetry, turbidimetry
Test Method	Endpoint method, two-point method, kinetic method, support for single and double reagents, turbidimetric immunoassay method and linear and nonlinear calibration methods
Cal Method	Linear (single-point, two- and multi-point), logit-log4p, logit-log5p, spline, exponential functions, etc., ≥ 6 types
Number of Items for which Simultaneous Analysis is Possible	40 single reagents or 20 double reagents; reagents unrestricted, supports domestic and imported reagents
Maximum Reaction Time	18.6 min for single reagent test, 13.2min for dual reagent test
Sample Disk	40 sample positions, compatible with variety of differently sized miniature sample vials, original blood collection tubes, plastic tubes, etc.
Sample Probe	1 probe which includes a liquid level sensor, volume tracking, three-dimensional anti-collision protection and automatic cleaning functionality
Sample Vol	2 ~ 50 ul in 0.1ul increments
R.Crsl	1 disk containing 40 reagent positions, 20 on the inner ring and 20 on the outer ring
Reagent Probe	probe is shared with the Sample probe which includes a liquid level sensor, volume tracking, three-dimensional anti-collision protection and automatic cleaning functionality
Reagent Volume	R1：150~450μL，R2:10~300μL，1μL in 1μL increments
Reagent Refrigeration	4 - 12 ℃, 24-hour continuous refrigeration
Mixer	Independent mixer

Minimum reaction volume	160 μL
Cuvettes	50 semi-permanent Ultraviolet transmission rigid cuvettes
Cuvette wash	6-step auto cuvette washing (For analyzer with auto wash function)
Carryover Contamination Rate	≤ 0.005%
Thermostat System	Solid thermostat, reaction disk temperature maintained at 37 ± 0.3 °C, free routine maintenance
Light Source	Halogen lamp, 12V / 20W, minimal current with high stability
Wavelengths	8 wavelengths: 340, 405, 450, 510, 546, 578, 630 and 670 nm
Spectrophotometry Method	Post-sample splitting, maintenance-free
Detector	Fully enclosed photodiode array, maintenance-free for life
Linear range of absorbance	0～3.5A
Resolution	0.0001Abs

A.3. Power Requirements

Power Supply Requirements	AC 100 - 240V, 50/60Hz ± 1 Hz
Input Power (VA)	350

A.4. Operating Ambient Temperature and Humidity Requirements

Work Environment	Environmental Temperature: 10 - 30 °C; Relative Humidity Range: 30% - 85% RH

A.5. Computer and Printer Configuration

Computer Configuration	CPU of 2.0 GHz or greater, more than 4.0 GB of RAM, Hard disk more than 40G free space, preloaded with the Windows 7 , win 10 operating system; Display resolution should be above 1280*768

Printer	Supports laser, inkjet and dot matrix printers

A.6. Communication Interface

Communication Interface for Biochemical Analyzer Host Machine and Computer	RS-232 serial interface
Interface for Computer and Printer / Handheld Barcode Scanner	USB interface
Computer Network Interface	Network port

A.7. Dimensions and Weight

Bare Dimensions (mm, length*depth*height)	750*470*580
Net Weight (kg)	45

A.8. Options

Options	Purified water dispenser capable of dispensing ≥ 10L water / hour; UPS: ≥ 30 minutes uptime; Barcode module

A.9. Other

Overall water consumption	< 2 L / h
Operating noise (dB)	< 65
Total Power (VA)	350

A.10. Transport and Storage Requirements

Temperature	0°C - 40°C
Humidity	Relative humidity of 30% - 90%, non-condensing.

A.11. Safety Classifications

Electric Shock Prevention Class	Class I externally-powered equipment
Overvoltage Class	Class II

Pollution Class	Class 2

A.12. After-Sales Service

After-sales service is provided by Shenzhen HETO medical Tech Co., Ltd.

Address: 4th Floor, Building No.4, Shenzhen Environmental Protection Industrial Park, No.31 Makan South Road, Xili, Nanshan District, Shenzhen, 518055, China

Telephone: +86- 755-28935967

Fax: +86- 0755-28937587

Postal Code: 518055

Website URL: www.hetomedical.com

A.13. Warranty Service

The entire machine is covered by a comprehensive warranty for a full year from the date of installation. However, damage occurring under the following conditions shall not be covered by this warranty:

1) Environment in which the machine is used does not meet the requirements indicated in the manual;

2) Damage caused by use of an unspecified power supply or any other abnormality in the power supply;

3) Artificial damage;

4) Damage caused as a result of maintenance performed by personnel not authorized by HETO;

5) Other damage caused by uncontrollable natural factors such as earthquakes, fires or war;

In the event you have any inquiries or questions while using the instrument, you can always call our customer support call center by phone or contact Shenzhen HETO Medical Tech Co., Ltd.

A.15. EMC Description

Attention :

- This equipment complies with the emission and immunity requirements of the GB/T 18268.26
- Users have responsibility to guarantee the EMC environment so that machine can

work normally

- It’s recommend to evaluate the EMC environment before use machine

Cautions :

- The AU150 is designed and tested according to GB 4824. The device may cause radio interference in home environment , in which case , you may need to take measures to mitigate the interference.
- It’s forbidden to use machine near strong radiation source which may disturb the use of machine

Table 1

EMC emission	
Applied test	**Performance Criteria**
GB 4824 Conducted Emission	1Mode-Class A
GB 4824 Radiated Emission	
GB 17625.1 Harmonic Currents Emission	n.a.
GB 17625.2 Voltage Fluctuations/Flicker Emission	n.a.

Table 2:

EMC immunity

Test item	Test Standard	Test Requirment	Performance Criteria
ESD Immunity	GB/T 17626.2	Contact discharge：±2kV、±4kV Air discharge：±2kV、±4kV、±8kV	B
Radiated Electromagnetic Filed Immunity	GB/T 17626.3	3V/m，80MHz～2.0GHz，80%AM	A
EFT Immunity	GB/T 17626.4	Power cable： ±1kV(5/50ns,5kHz)	B
Surge	GB/T 17626.5	L-PE , N-PE：±2kV L-N：±1kV	B
Conducted Immunity	GB/T 17626.6	Power cable：3V，150kHz～80MHz，80%AM	A
Power Frequency magnetic field	GB/T 17626.8	3A/m，50/60Hz	A
Voltage Dips and interruptions Immunity	GB/T 17626.11	1 cycle , 0%； 5/6 cycle, 40%； 25/30 cycle , 70%；	B C C C

		250/300 cycle, 5%	

Definition:

A. The performance is normal in the limit during test

B. The performance or function decline or lose but it can automatically recover during test.

C. The performance or function decline or lose that operator need to intervene or system reset during test

A.16. Removal of equipment from use for repair or disposal

1) All test samples, such as calibrator and control, are infectious . Please use cotton dipped in 75% alcohol to clean if there are sample spilled on the instrument surface , otherwise it may cause biohazard like infection by touching. If there is plenty of liquid spilled and enter the internal machine, please stop using and disconnect the power cable. Contact with HETO or distributor.。

2) The instrument surface should be disinfected completely to minimize the biohazard when the instrument is carried , being changing location , delivery , maintenance , etc. Please stop using machine when there is collision , fall on instrument no matter there is obvious damage on the surface or inside . And please contact with HETO or distributor.

3) Please contact with HETO or distributor when there is problem of machine.

4) It's suggested to stop use machine or HETO do full inspection and maintenance of instrument when it reaches its life (5 years)

5) This device may only be operated and used by authorized personnel who have undergone training provided by HETO or authorized representatives of HETO.

A.17. Toxic or Hazardous Substances and Elements

Item		Toxic or Hazardous Substances and Elements					
		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Hose	Host shell	○	○	○	○	○	○
	Host PCBA	×(1)	○	○	○	○	○
	Host sheet metal parts	○	○	○	○	○	○
	Host machine processing part	○	○	○	○	○	○
	Host plastic parts	○	○	○	○	○	○

	Host hardware	○	○	○	○	○	○
	Host connecting cable	○	○	○	○	○	○
	Host hydraulic parts	○	○	○	○	○	○
Accessory	Label	○	○	○	○	○	○
	Cable	○	○	○	○	○	○
	Maintenance tool	○	○	○	○	○	○
	Inlet/Outlet tube	○	○	○	○	○	○
	Tank	○	○	○	○	○	○
Packaging	Packing material	○	○	○	○	○	○

○：Indicates that this toxic or hazardous substance contained in all the homogeneous materials for this part is below the limit requirement in SJ/T 11363-2006.

×：Indicates that this toxic or hazardous substance contained in all the homogeneous materials for this part is above the limit requirement in SJ/T 11363-2006.

(1)：Some part of circuit board involves Pb. During process , Leaded soldered is used.

Note：The place which marked "×" is because currently there is no replaceable technology or unit. There is no leak or mutation in 5 years for normal use of machine. It also won't cause pollution to the environment or harm to people and property.

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Model	REF No.
AU150-P	03000001
AU150-PW	04000001