

LiDA500

Random Access Analyzer

User Manual



LiNEAR

LiNEAR Chemicals S.L.

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How to use the Manual

Thank you for using LIDA 500 Automated Chemistry Analyzer. Before operating the instrument, be sure to read the Manual carefully. To get the best results, you must be aware of our instrument and its performance before clinical diagnosis and testing.

This is the User's Manual for LiNEAR Chemicals S.L. LIDA 500 Automated Chemistry Analyzer. It describes the installation, daily use and maintenance, etc. of the instrument. After reading the Manual, please keep it properly for future reference.

The functions may vary depending on the version or configuration of the instrument.

Please keep all packing materials for future storage, transportation or return to the manufacturer for repair.

If you have any questions, contact your dealer.

Meaning of Symbols

Warning: When the user ignores this symbol and misuses the instrument, casualties, serious injury or serious property loss may be caused to the user.

Caution: When the user ignores this symbol and misuses the instrument, injury, wrong output results or property loss may be caused to the user.

Precautions for Diagnosis

Caution: The product is a clinical examination instrument for inspection. Clinical diagnosis based on testing results should be conducted by doctors according to the clinical symptoms of the patients by combining other inspection results.

Representation

LiNEAR Chemicals S.L. reserves the right for the final explanation of the User's Manual.

The illustrations in the Manual give typical examples only and may not be completely consistent with the actual displaying on the product. Take practicality as standard. Never use the illustrations for other purposes.

Without written consent of LiNEAR Chemicals S.L., no individual or organization may duplicate, modify or translate the contents of the Manual.

LiNEAR Chemicals S.L. will be responsible for the safety, reliability and performance of the product only when all the following requirements are met:

- Assembly, re-debugging, expansion, improvement and repair should be conducted by persons recognized by LiNEAR Chemicals S.L.;
- The product is operated according to the Manual;
- The related electrical equipment complies with the national standards.

Caution

- The instrument must be used by medical examination professionals or trained doctors, nurses or laboratory technicians.



Warning

- If no satisfied maintenance/repair plan is achieved, the instrument may fail abnormally and may endanger personal health.
- Ensure to use the instrument in the conditions specified in the Manual. Otherwise, it may cause the instrument's failure to function normally and unreliable measurement results, damage the components of the instrument, and endanger personal safety.



Major Icons Used in the Instrument



Temperature Limit

The temperature limit of the transport package.



Fragile Objects

The transport package contains fragile objects. Be careful in handling.



Upward

The correct position of the transport package is straight up.



Prevent Rain

Protect the transport package against rain.



Prevent Sunshine

Avoid direct sunshine.



Do Not Roll

Do not roll the transport package.



Biohazard.



Caution. Refer to the document supplied with the product.



In vitro diagnostic equipment.



Warning and Safety Instruction

For in vitro diagnosis only. Carefully read the following warning before use and strictly follow it.

Warning: Read the following precautions carefully before using the instrument.

- In case of peculiar smell, smog or abnormal noise during use, immediately turn off the power and remove the plug from the socket, and immediately apply for inspection with the dealer or our agent. If you continue to use the instrument in that case, fire, electric shock or casualties may be caused.
- Prevent blood, reagent or metal pieces, such as staple, etc., from entering the instrument. Otherwise short circuit or fire may be caused. In case of abnormality, immediately turn off the power and unplug the plug from the socket, and immediately apply for inspection with the dealer or our agent.
- Do not touch the electronic circuit in the instrument. Particularly, touch with wet hand may cause electric shock.
- Wear rubber gloves and use the specified tools, parts and components when maintaining and inspecting the instrument. When the operation is ended, wash hands with disinfectant. Otherwise the skin in contact with blood may be infected or scalded or get an electric shock.
- Be very careful when treating samples. Be sure to wear rubber gloves, otherwise infection may be caused. In case the sample enters the eye or wound, immediately rinse with plenty of clear water and receive examination by a doctor.

Use and Disposal of Reagent

- Prevent the reagent from being contact with skin and clothing during operation.
- In case the reagent enters the eye, immediately rinse with plenty of clear water and receive examination by a doctor.
- If you swallow the reagent, immediately consult a doctor and drink water generously to spit the reagent.
- If your hand or skin is stained with the reagent, immediately rinse with clear water.
- The cleaning solution supplied with the instrument is highly alkaline, and should not be in contact with skin or clothing. In case your skin or clothing is stained with it, immediately rinse with plenty of water to prevent injury.
- Used test tubes and other consumables for the instrument should be disposed properly as medical waste or infectious waste. If contaminated by blood, etc., they may be infected by pathogen.

Voltage, Connection and Grounding of Power Supply

- Ensure the power supply and grounding environment of the instrument are good and stable.
- Never insert the power plug into a socket outside the allowed voltage range. Otherwise fire or electric shock may be caused.
- Be sure to use the three-core electric cable supplied with the instrument in installation, ensure good grounding, and put the instrument in a place for easy power off operation. Otherwise fire or electric shock may be caused.
- Never damage the insulating covering of the electric cable. Do not jerk the cable or hang heavy objects with the cable. Otherwise short circuit or open circuit may be caused, thus causes electric



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shock or fire.

- **Be sure to turn off the power before connecting peripheral equipment. Otherwise electric shock or failure may be caused.**

In accordance with the Pharmaceutical Affairs Law, modification of medical instruments is prohibited.

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Chapter 1 Introduction

1.1 Introduction

1.1.1 Product Name

1.1.2 Model : LIDA 500

1.1.3 Features

LIDA 500 is a discrete automated chemistry analyzer that tests sample data with the colorimetry, turbidimetry, ion electrode (optional) method, etc. for quantitative analysis of chemical composition of clinical samples of blood serum, blood plasma, urine, cerebrospinal fluid, etc.

- 1) Automated, random, optional, discrete, priority given to emergency treatment, and fully open analysis parameters and reagents;
- 2) Up to 78 colorimetric items and 3 ISE items (K, Na and Cl; optional) in progress at the same time;
- 3) The analysis methods include end-point method, two-point method, kinetics method, etc. Single/dual-wavelength test and three/four-reagent test support;
- 4) One point calibration, two-point calibration, multi-point linear calibration or nonlinear calibration;

1.2 Composition and Structure of the Instrument



Figure 1-1 LIDA 500 Automated Chemistry Analyzer

LIDA 500 Automated Chemistry Analyzer is composed of the analysis section (main machine), operation section (computer system), result output section (printer), accessories and consumables.



1.2.1 Analysis Section

The analysis section is mainly composed of the sampling system (including sample tray, sample probe, reagent tray, reagent probe, etc.), mixing and reaction system (including mixer, reaction tray, etc.), optical measurement system (including optical and signal processing module), test cuvette cleaning mechanism (including automatic cleaning station, etc.), liquid line system connected to the whole machine, control system that drives various modules (hardware and low-level driver software), etc. The barcode scanning system and electrolyte module are optional.

The front view of the analysis section is shown in the figure below.

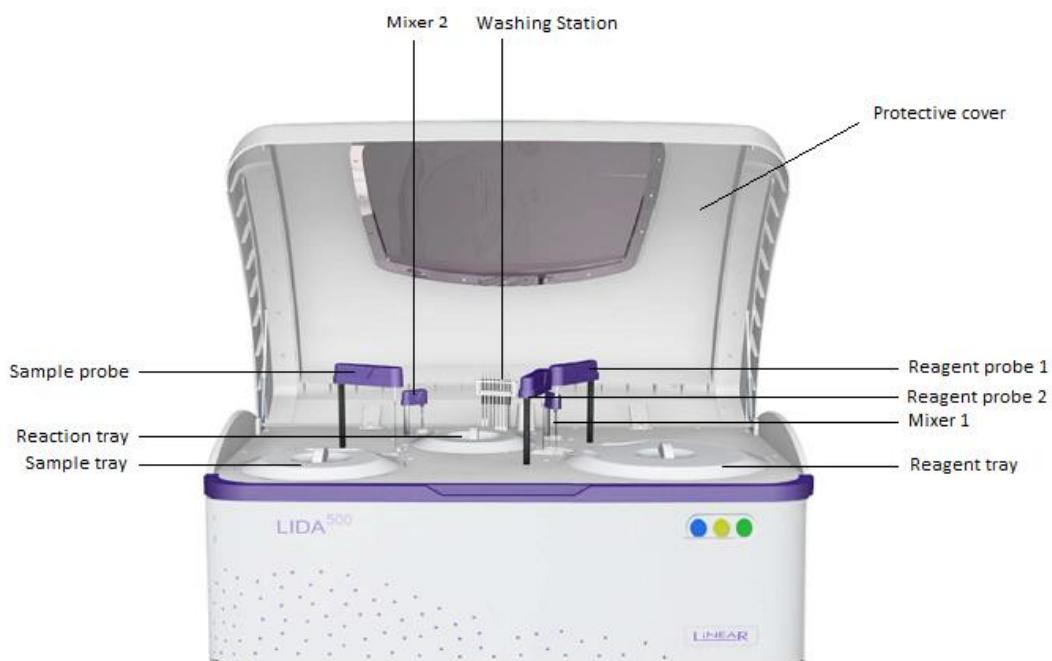


Figure 1-2 Front View of Analysis Section

The connectors of the liquid lines on the back of the analysis section include:

- High Concentration Waste Liquid Sensor: Connected to the signal wire of the level sensor for the high concentration waste liquid tank;
- Cleaning Agent Sensor: Connected to the signal wire of the level sensor for the cleaning agent tank;
- Low Concentration Waste Liquid 1 Sensor: Connected to the level sensor for the low concentration waste liquid 1 tank. The connection is not needed when the low concentration waste liquid is directly discharged to the trough;
- High Concentration Waste Liquid: Outlet of high concentration waste liquid, connected to the



high concentration waste liquid tube;

- Cleaning Agent: Inlet of cleaning agent for the analysis section, connected to the cleaning agent entry tube;
- Low Concentration Waste Liquid 1: Connected to the fat low concentration waste liquid tube;
- Low Concentration Waste Liquid 2: Connected to the slim low concentration waste liquid tube;
- Deionized Water: Main inlet of deionized water for the analysis section, connected to the deionized water entry tube.

The layout of the connectors of the liquid lines on the back of the analysis section is shown in the figure below.

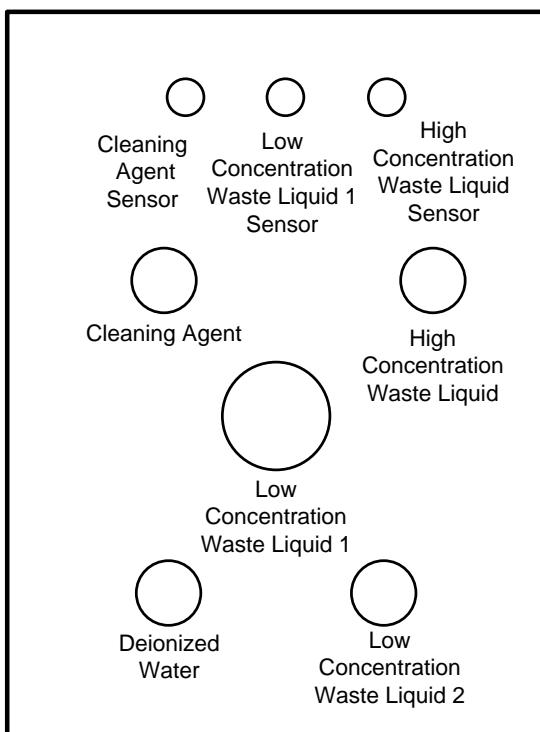


Figure 1-3 Connectors of Liquid Lines on the Back of Analysis Section

The serial ports and power jacks on the back of the analysis section are shown in the figure below.

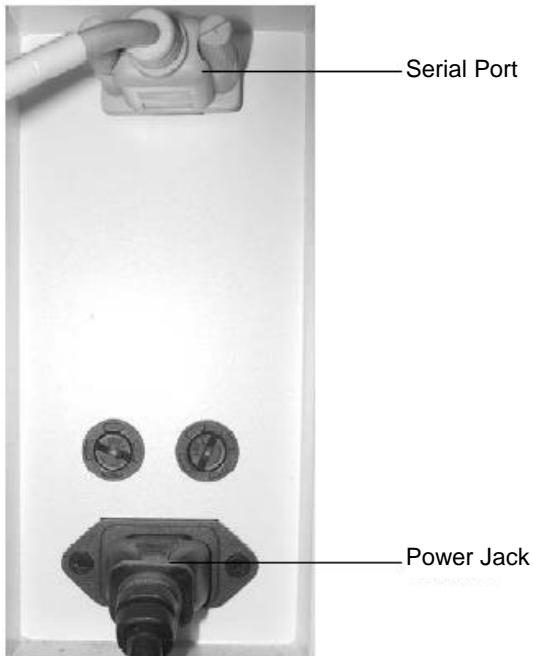


Figure 1-4 Serial Port and Power Jack on the Back of Analysis Section

- Serial Port: Connected to the data cable, through which the analysis section is communicated with the operation section;
- Power Jack: Connected to the electric cable.

1.2.1.1 Sampling System

The LIDA 500 sampling system mainly includes the sample probe module, reagent probe module, sample tray module, reagent tray module, etc.

Structure of Sample Probe Module



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Figure 1-5 Structure of Sample Probe Module

The sample probe module is mainly used to analyze the collection and delivery of samples for analysis and is composed of the sample probe, sample probe rocker arm, sample probe drive shaft, sample syringe, corresponding liquid lines, etc.

Functions of Sample Probe Module

- **Sample Collection:** The sample probe module is mainly used to absorb quantitative sample from the sample test tube and deliver the sample to the test cuvette, with the sample size of:
 - For biochemical items: $2\mu\text{l} \sim 45\mu\text{l}$, increasing progressively by $0.1\mu\text{l}$;
 - For electrolyte items: $70\mu\text{l}$ (blood serum or blood plasma), $140\mu\text{l}$ (diluted urine) (added twice, $70\mu\text{l}$ each).
- **Cleaning of Sample Probe:** The sample probe module includes a cleaning system that cleans the outer wall of the probe in the fountain type way, cleans the inner wall of the probe with high pressure water, and supports strong acid and alkali cleaning;
- **Anti-collision Test:** The sample probe has the horizontal and vertical collision protection function. When it encounters an obstacle in the horizontal or vertical direction, the anti-collision function will be started to prevent the sample probe from being damaged;
- **Liquid Level Detection and Tracking Depending on Volume:** The sample probe can detect the liquid level automatically and determine the depth of the sample probe below the liquid level



according to the volume of liquid absorbed to realize the function of tracking depending on volume.

Structure of Reagent Probe Module



Figure 1-6 Structure of Reagent Probe Module

LIDA 500 includes two reagent probe modules - R1 and R2 which have exactly the same structure. They are mainly used to collect and deliver reagents. A reagent probe module is composed the reagent probe, reagent probe rocker arm, reagent probe drive shaft, reagent syringe, corresponding liquid lines, etc.

Functions of Reagent Probe Module

- **Reagent Collection:** The reagent probe module is mainly used to absorb quantitative reagent from the reagent bottle and deliver the reagent to the test cuvette. The reagent probe module moves repeatedly in the order of reagent bottle, reaction tray, and reagent probe cleaning tank to complete reagent adding, in which,
 - R1 is used to absorb reagent No. 1(3), with the volume of 150 μ l~350 μ l, increasing progressively by 1 μ l;
 - R2 is used to absorb reagent No. 2(4), with the volume of 20 μ l~250 μ l, increasing progressively by 1 μ l.
- **Cleaning of Reagent Probe:** The reagent probe module includes a cleaning system that cleans the outer wall of the probe in the fountain type way, cleans the inner wall of the probe with high



pressure water, and supports strong acid and alkali cleaning;

- Anti-collision Test: The reagent probe has the horizontal and vertical collision protection function. When it encounters an obstacle in the horizontal or vertical direction, the anti-collision function will be started to prevent the reagent probe from being damaged;
- Liquid Level Detection and Tracking Depending on Volume: The reagent probe can detect the liquid level automatically and determine the depth of the reagent probe below the liquid level according to the volume of liquid absorbed to realize the function of tracking depending on volume.

Structure of Sample Tray Module



Figure 1-7 Structure of Sample Tray Module

The sample tray module mainly includes the sample tray and its drive system, sample pot, sample barcode scanner, etc.

Functions of Sample Tray Module

- The sample tray is a support where the sample test tubes are carried. It can rotate counterclockwise according to the set position when it is driven by its drive system. During the work, each sample test tube rotates to the sampling position of the sample probe to wait for the sample probe to absorb the sample.

Caution: To add sample during the operation of the whole machine, be sure to stop the rotation of the sample tray first, and do not add sample to the rail where the sample probe moves back and forth, otherwise, the sample probe may



be collided.

- The sample tray is divided into the outer, middle and inner circles. Each of the outer and middle circles has 35 sample positions, and the inner circle has 30 sample positions;
- The sample tray has a total of 100 sample positions, in which, sample positions 97-100 are for ISE cleaning solution (D1), acid cleaning solution (D2), alkaline cleaning solution (D3), and deionized water (W);
- Virtual Sample Tray: The LIDA 500 system software allows the setup of up to 7 virtual sample trays at the same time, one of which can be selected as the current sample tray.
- Sample containers, such as original blood collection tube, centrifuge tube, plastic test tube, small sample cup, etc., can be put on the sample tray. The following sample containers are compatible with the sample tray:
 - Standard Test Tubes: $\Phi 12 \times 68.5$, $\Phi 12 \times 99$, $\Phi 12.7 \times 75$, $\Phi 12.7 \times 100$, $\Phi 13 \times 75$, and $\Phi 13 \times 100$;
 - Original Blood Collection Tubes: $\Phi 12 \times 68.5$, $\Phi 12 \times 99$, $\Phi 12.7 \times 75$, $\Phi 12.7 \times 100$, $\Phi 13 \times 75$, and $\Phi 13 \times 100$;
 - Small Sample Cups: $\Phi 10 \times 37$ and $\Phi 12 \times 3$.
- The body of the sample tray can be picked and placed freely for you to replace the whole tray of samples easily.
 - Pick: Loosen the two fixing screws on the sample tray, hold the handle of the tray, and lift and take it out vertically.
 - Place: Hold the handle of the sample tray, aim the pin hole on the tray at the pin position on the tray base, place down the tray vertically, and tighten the two fixing screws on the tray.
- The sample barcode scanner is optional.
 - The sample barcode has 3~27 digits, supports the NCCLS standard, and is compatible with various barcode application environments.
 - You can set the format of sample barcode and select the barcode system.
 - When the fixed barcode scanning fails, the handheld barcode identification system can be used for supplementary scanning or manual barcode input can be used to perfect the scanning of sample barcode.



Structure of Reagent Tray Module

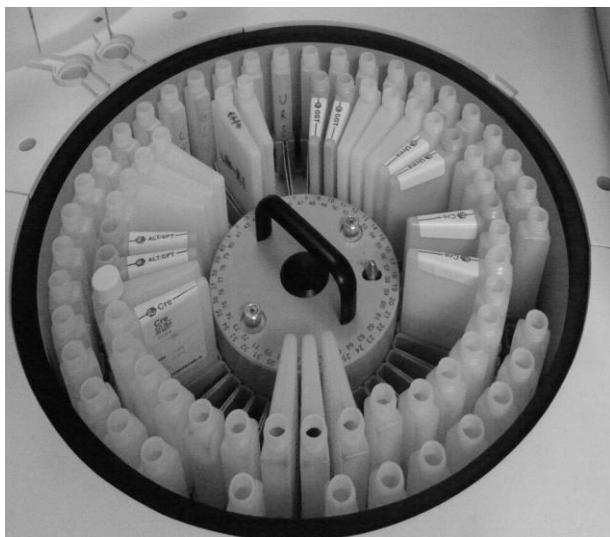


Figure 1-8 Structure of Reagent Tray Module

The reagent tray module mainly includes the reagent tray and its drive system, reagent pot, reagent refrigeration system, reagent barcode scanner, etc.

Functions of Reagent Tray Module

- The reagent tray is a support where the reagent bottles are carried. Its drive system can rotate each reagent bottle to the sampling position of the reagent probe according to the system setting to wait for reagent absorption.
- The reagent refrigeration system is used to guarantee the reagent in the reagent bottle is always stored in the low temperature environment to keep the reagent stable and reduce volatilization.
- The reagent tray is divided into the inner and outer circles, each of which includes 40 reagent positions. The compatible reagent bottles are: LiNEAR Chemicals S.L. outer circle bottle 25ml, LiNEAR Chemicals S.L. inner circle bottle 70ml, and Hitachi 60~70ml reagent bottle.
- The reagent tray has a total of 80 reagent positions, in which, reagent positions 79 and 80 are for strong cleaning solution (D) and deionized water (W);
- Any type of reagent (R1/R2/R3/R4) of a test item is allowed to be put at any reagent position in the reagent tray;
- Two virtual reagent trays (80 positions) can be set. During a test, the system can dynamically prompt for replacement of reagent tray;
- The reagent refrigeration system can provide 24-hour uninterrupted refrigeration, with the storage temperature of 2~10°C;
- The body of the reagent tray can be picked and placed freely for you to replace the whole tray of



reagents easily.

- Pick: Loosen the two fixing screws on the reagent tray, hold the handle of the tray, and lift and take it out vertically.
- Place: Hold the handle of the reagent tray, aim the pin hole on the tray at the pin position on the tray base, place down the tray vertically, and tighten the two fixing screws on the tray.
- The reagent barcode scanner is optional.
 - The reagent barcode has 10~30 digits, supports the NCCLS standard, and is compatible with various barcode application environments.
 - You can set the format of reagent barcode and select the barcode system.
 - When the fixed barcode scanning fails, the handheld barcode identification system can be used for supplementary scanning or manual barcode input can be used to perfect the scanning of reagent barcode.

1.2.1.2 Mixing and Reaction System

The mixing and reaction system is used to promote the full mixing of the sample and reagent and provides a constant temperature reaction environment. The system includes the mixer module, reaction tray module, etc.

Structure of Mixer Module

LIDA 500 has two mixer modules - M1 and M2 which have exactly the same structure. A mixer module is mainly composed of the mixer, rocker arm, and drive shaft.



Figure 1-9 Structure of Mixer Module



When the mixing is finished, the mixer automatically moves to the mixer cleaning pool for cleaning to prevent carrying contaminants.

Functions of Mixer Module

- For a single-reagent item test, M1 begins to mix the contents after the sample is added, and M2 does not move;
- For a double-reagent item test, M1 begins to mix the contents after the sample is added, and M2 begins to mix the contents after reagent 2 is added;
- For a three-reagent item test, M1 begins to mix the contents after the sample is added, and M2 begins to mix the contents after reagents 2-3 are added;
- For a four-reagent item test, M1 begins to mix the contents after the sample is added, and M2 begins to mix the contents after reagents 2-4 are added.

Structure of Reaction Tray Module

The reaction tray module includes the reaction tray and its drive mechanism, test cuvette, and heating film. The test cuvette is mounted on the reaction tray and is heated for warm bath with the heating film under the reaction tray. Its structure is shown in the figure below:



Figure 1-10 Structure of Reaction Tray Module

Functions of Reaction Tray Module

- The reaction tray has a total of 100 test cuvettes that are arranged on a single circle. During the test and analysis, the reaction tray rotates counterclockwise only and stops the specified test cuvette at the sample adding position, reagent adding position, mixing position, and automatic



cleaning position according to the setting of the software.

- The test cuvettes are put on the reaction tray and are used as reaction containers and for colorimetric measurement. The optical diameter of the test cuvettes is 5mm. The standard test cuvettes are made of organic glass. Quartz test cuvettes of the same specification are compatible.
- The total volume of reaction liquid is 150~500 μ l. When each test is ended, the test cuvettes are automatically cleaned by stage;
- The reaction tray heats the test cuvettes in the direct solid heating way, with the reaction temperature of 37±0.3°C.

1.2.1.3 Optical Measurement System

The optical measurement system is used to measure the absorbance of the reaction liquid in the test cuvette and includes the optical module, signal processing board, etc.

Structure of Optical Module

The optical module is located inside the machine of the analysis section and includes the light source base, light splitting box, focusing barrel, grating module, receiver board, etc., as shown in the figure.

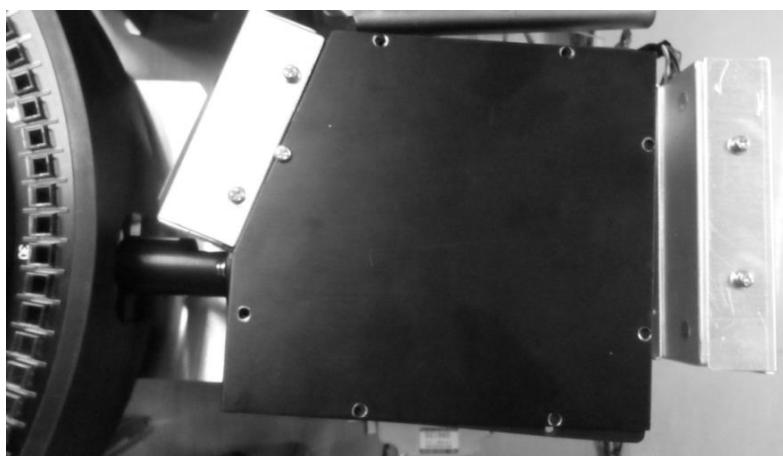


Figure 1-11 Structure of Optical Module

Functions of Optical Module

- The light path is measured with the flat-field holographic concave grating in the rear light splitting way. The absorbance of up to 12 wavelengths can be measured;
- The lamp is a 12V/20W halogen tungsten lamp, with water cooling type heat dissipation to guarantee stable light source;
- Range of Absorbance: 0~3A; Resolution: 0.0001A;
- 12 wavelengths: 340nm, 405nm, 450nm, 505nm, 540nm, 570nm, 600nm, 635nm, 670nm, 700nm, 760nm, and 795nm.



1.2.1.4 Automatic Test Cuvette Cleaning Mechanism

There is a multi-stage automatic test cuvette cleaning mechanism above the reaction tray of LIDA 500 that is used to clean and dry the test cuvettes after testing.

Composition of Automatic Cleaning Mechanism

The automatic cleaning mechanism includes the wiping head, cleaning needle, running gear, tube system coordinating liquid absorption and discharge, etc., as shown in the figure:

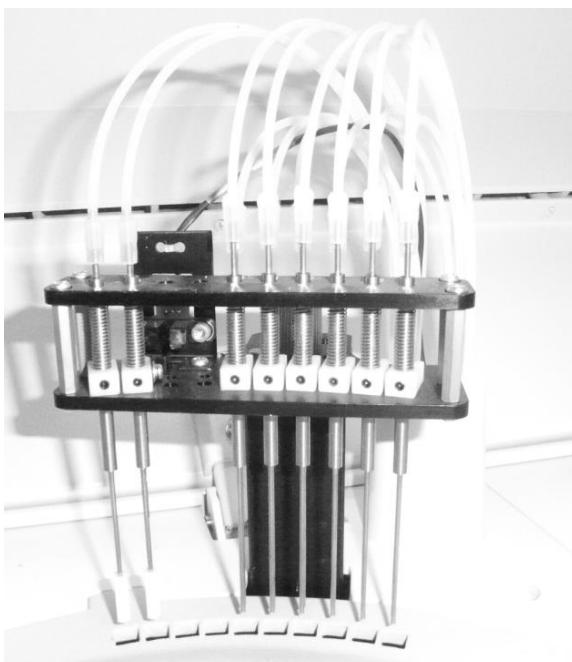


Figure 1-12 Automatic Test Cuvette Cleaning Mechanism

Functions of Automatic Cleaning Mechanism

- The automatic test cuvette cleaning mechanism can clean and dry the test cuvettes after testing during the analysis and test to ensure there is no cross contamination of the test cuvettes during the test;
- The test cuvettes are cleaned by stage, i.e. cleaning with cleaning solution, cleaning with deionized water, and drying with wiping head;
- The cleaning solutions include alkaline cleaning solution and deionized water which are preheated;
- The cleaning wastewater of different concentrations flow separately to effectively control environmental pollution.



1.2.1.5 Liquid Line System

The liquid line system is used to deliver the liquid inside the whole machine and control the flow and direction of the liquid. It is composed of various pumps and valves.

Layout of Liquid Line Separator

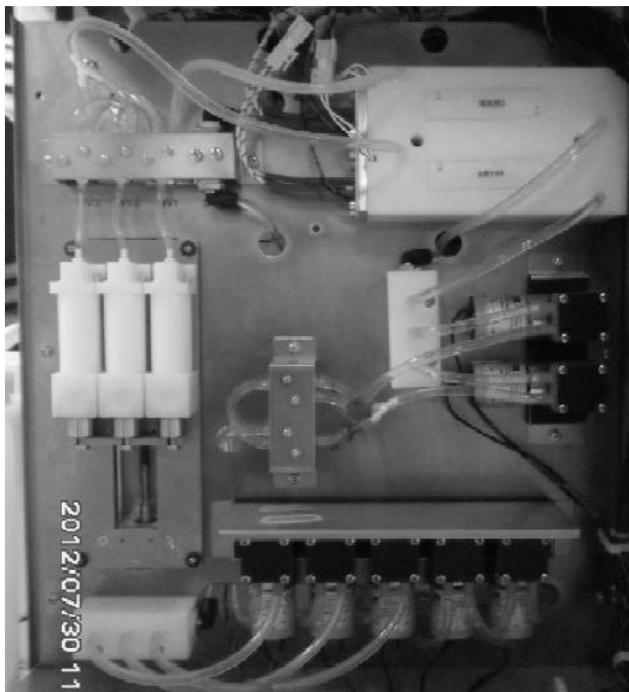


Figure 1-13 Layout of Liquid Line Separator

Functions of Liquid Line System

- The liquid line system is mainly used to deliver cleaning solutions for the test cuvettes, sample probe, mixer, etc. and absorb and discharge cleaning wastewater;
- The liquid pump and syringe module in the liquid line system provide driving force for liquid delivery;
- The valves in the liquid line system are mainly used to control the direction of liquid or air.

1.3 Scope

Applicable to quantitative analysis of various samples with liquid reagents.

1.4 Technical Parameters

Type	Automated, random, optional, discrete; priority given to emergency treatment; fully open analysis parameters and reagents
Principles of Analysis	Colorimetry, turbidimetry, ISE module (optional)
Analysis Method	End-point method, two-point method, kinetics method; single/ dual-wavelength test and three/four-reagent test support
Calibration Method	One point calibration, two-point calibration, multi-point linear calibration, nonlinear calibration, etc.



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Items in Simultaneous Analysis	Up to 78 colorimetric items and 3 ISE items (K, Na and Cl; optional) in progress at the same time
Sample Positions	100 sample positions
Spec. of Test Tube	Standard test tube, original blood collection tube, and small sample cup
Sample Size	2~45μl, increasing progressively by 0.1μl
Sample Barcode	Optional fixed barcode scanner
Sample Adding Technology	Automatic liquid level detection, tracking depending on volume, 3D collision protection
Automatic Sample Retest	Equivalent, increment and decrement retests, and 3~150 times dilution retest
Carry-over of Sample Probe	Cleaned automatically, carry-over ≤ 0.1%
Reagent Probe	Two reagent probes for R1(R3) and R2(R4) respectively; liquid level detection, tracking depending on volume, 3D collision protection
Reagent Position	80 reagent positions
Spec. of Reagent Bottle	25ml and 70ml support; compatible with Hitachi reagent bottles
Volume of Reagent	R1: 150~350μl, R2: 20~250μl, increasing progressively by 1μl
Refrigeration of Reagent	2~10°C, 24-hour uninterrupted refrigeration
Reagent Barcode	Optional fixed barcode scanner
Carry-over of Reagent Probe	Cleaned automatically, carry-over ≤ 0.1%
Test cuvette	100 test cuvettes made of organic glass with the optical diameter of 5mm. Quartz test cuvettes of the same specification are compatible.
Volume of Reaction Liquid	150~500μl
Temperature Control of Reaction Tray	Direct solid heating, free from daily maintenance
Temperature of Reaction	Room temperature, 30°C, 37°C, temperature fluctuation ±0.2°C
Way of Mixing	Two mixers that begin to mix the contents after the sample and reagent are added respectively.
Cleaning of Test cuvettes	8-stage automatic cleaning, preheating of cleaning solution, warning of minimal volume of cleaning solution
Light Source	Halogen lamp
Way of Light Splitting	Flat-field holographic concave grating, in the rear light splitting way
Wavelength	12 wavelengths, precision ±2nm
Detector	Photodiode array



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Linear Range	0~2.5A
Input Equipment	Branded PC, English versions of multimedia analysis and control software
Output Equipment	Wide-screen LCD, printer
Interface	RS232 serial port
Tube Connector	Connected to specific water machine, waste liquids of different concentrations discharged separately, with the minimal volume warning function
Power Supply	a.c.100V-240V, 50Hz/60Hz
Peak Water Consumption	≤ 20L/H
Working Environment	Temperature: 10°C~30°C; RH: 40%~85%, altitude below 2000 meters
Storage Environment	Well-ventilated environment with temperature of 0°C~40°C, RH ≤ 85%, without corrosive gas

Chapter 2 Installation and Correction

2.1 Unpacking

2.1.1 Steps of Unpacking

Unpack the instrument and remove the materials for transport, such as EPE, etc. Keep the packing case and packing materials properly for future repacking.

1) Steps for Moving out the Machine

- Open the packing case with tools.
- Take out the pallet and put it beside the packing case as a slope.
- Remove the fixing angle iron.
- Suspend the four foot margins with a wrench.
- Push the machine out of the packing case stably.

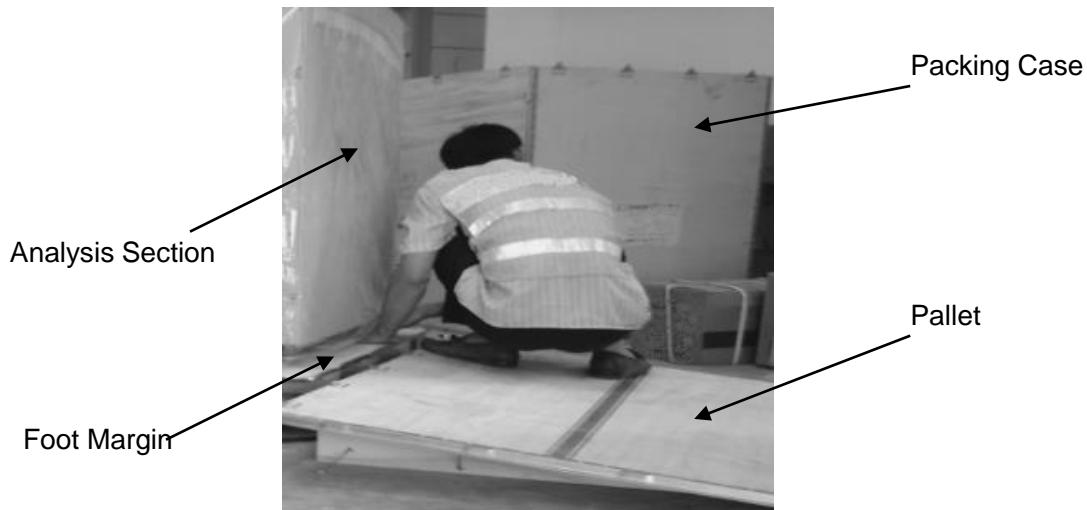


Figure 2-1 Packing

-
- 2) Take out the accessories and check the objects against the accessories list. If any object is missing, immediately inform LiNEAR Chemicals S.L.'s After Service Unit or the retailer.
-

Caution: The accessories packed should be consistent with the packing list. If any component is missing or damaged or inconsistent with the packing list, please contact the retailer.

2.1.2 Handling Method

Use the pallet to move the machine out of the packing case; keep the machine stable.

Caution: Keep the packing case for packing before long distance transport. The



instrument must be put on a level operation desk, rather than angular surface.

2.2 Installation and Use Environment

LIDA 500 Automated Chemistry Analyzer must be installed by professionals. In order to ensure the instrument works normally, put it in a workplace meeting the following requirements:

- Level ground or table (inclination < 1/200); load bearing ≥ 300Kg;
 - No direct sunshine;
 - No large amounts of dust;
 - No strong electromagnetic radiation;
 - Easy power off operation;
 - With good ventilation;
 - Avoid moist and high temperature; avoid violent vibration and collision;
 - Difference in height between waste liquid discharge outlet (higher) and ground ≤ 100mm;
 - The quality of water supplied must meet CAP Class II Water Requirements;
 - If a water purification unit is used, the pressure of water supply must be in the range of 0.05MPa~0.4MPa.
-

Caution:

- ◆ ***The normal working environment for the instrument is temperature of 10 °C~30 °C and HR of 40%~85%.***
 - ◆ ***After installation, try to avoid frequent movement. To move the instrument, use a stable cart. The angle of inclination should not be greater than 15° when the instrument is being moved.***
 - ◆ ***It must be installed and moved by authorized professionals.***
 - ◆ ***Please dispose the waste liquid discharged by the system in accordance with the local standards.***
-

2.3 Requirement of Power Supply

- Voltage: a.c.100 V - 240V;
- Frequency: 50Hz/60Hz;
- Power: 1500W;
- Fuse: T10AL 250V, Φ5X20.



Warning:

- ◆ The AC power supply must be grounded properly (*zero to earth voltage < 5 V*).
 - ◆ Check that the input voltage complies with the requirement of the instrument. The AC power supply must be stable. Sharing a power supply with high power electrical appliances is prohibited. It is better to be equipped with a regulated power supply.
 - ◆ Before connecting the electric cable, check that the switch of the instrument is off.
 - ◆ In case of smog, peculiar smell or abnormal noise, immediately turn off the power and contact the retailer.
 - ◆ To unplug the electric cable, grasp the plug, rather than the cord.
-

2.4 Requirements of Temperature and Humidity

- Ambient Temperature: 10~30°C;
 - Ambient Humidity: 40%~85%, no condensation.
-

Caution:

- ◆ Be sure to operate the system within the specified range of ambient temperature and humidity, otherwise the results may not be reliable.
 - ◆ If the ambient temperature and humidity exceed the specified range, please use an air conditioning equipment.
-

2.5 Requirements of Water Supply and Discharge

- The quality of water supplied must meet CAP Class II Water Requirements;
 - The temperature of water supplied is 5~30°C;
 - Flow: ≥20L/hour, continuous flowing;
 - An external pressurizer is provided to make the pressure of water supplied to the whole machine in the range of 0.1 ~ 0.4MPa;
 - The outlet of the pressurizer is quick adapter type and can be connected to Ø 6mm ebonite hose or 1/4" tube.
-

Risk of Biological Pollution:

- ◆ Please dispose the waste liquid discharged by the system in accordance with the local standards.

Caution:



- ◆ **The quality of water must meet the requirements of water supply, otherwise the test results may be impacted due to insufficient purity of water.**

2.6 Installation

2.6.1 Space Requirement

Please place the analysis section and operation section as shown in the figure below. The gap between the analysis section and wall must not be less than 0.5m.

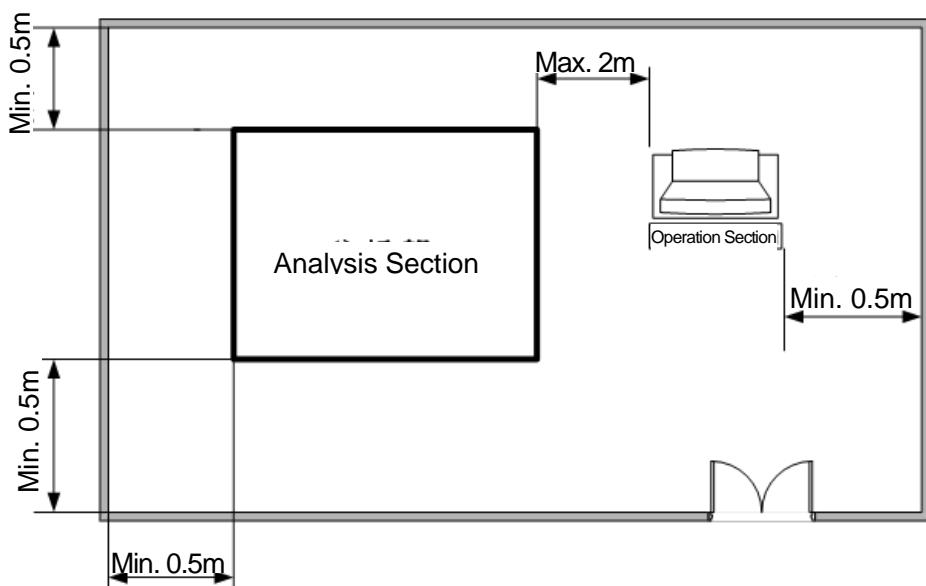


Figure 2-2 Space Requirement

2.6.2 Liquid Line Connection

Connect the liquid lines correctly as shown in the figure below. If there is a water discharge system in the room, the low concentration waste liquid can be directly discharged to the water discharge system.

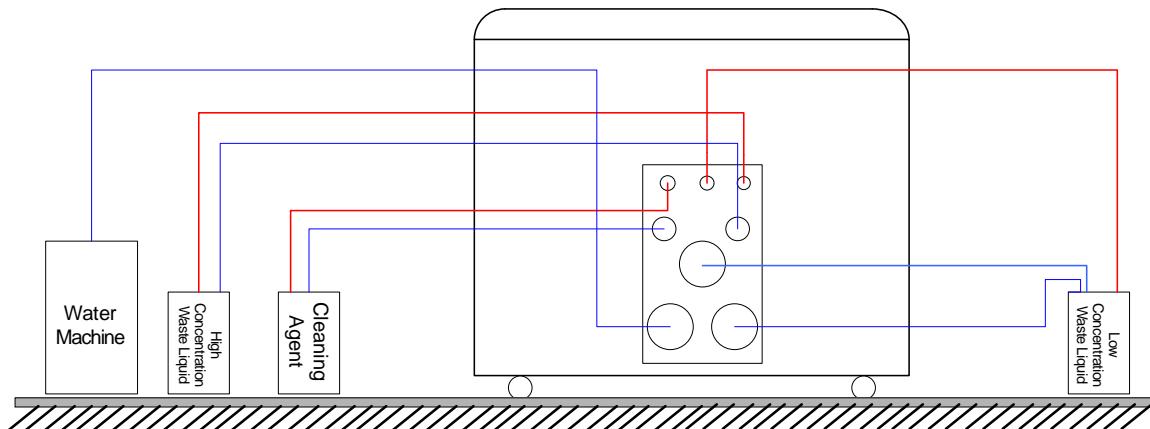


Figure 2-3 Liquid Line Connection

Warning: When connecting the drain tube, do not fold or compress the drain tube.

Caution: The high concentration waste liquid outlet joint on the back of the analysis section must be inserted in place, otherwise the automatic cleaning system will overflow.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

2.6.3 Mounting and Removing the Sample Tray

Mounting the sample tray:

Hold the handle on the sample tray, aim the big hole in the center of the tray and kidney shape hole at the tray base, mount the tray onto the base in place, and manually tighten the two screws on the tray.

Removing the sample tray:

Manually loosen the two screws on the sample tray, hold the handle on the tray, and lift the tray. Use even force. Do not overexert yourself to prevent spilling the sample.

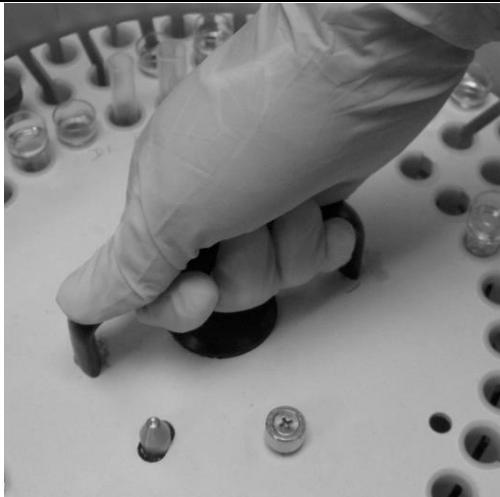


Figure 2-4 Mouting and Removing Sample Tray

Warning: Before mouting the sample tray, confirm the system is in the standby mode and the tray has stopped.

Caution: Before the system runs, confirm the sample tray cover has been closed, otherwise the sample adding probe may be damaged. When placing the tray cover, make sure the positioning boss clicks in place.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

2.6.4 Mounting and Removing the Reagent Tray

Mounting the reagent tray:

Hold the handle on the reagent tray, aim the big hole in the center of the reagent tray and kidney shape hole at the tray base, mount the tray onto the base in place, and manually tighten the two screws on the tray.

Removing the reagent tray:

Manually loosen the two screws on the reagent tray, hold the handle on the tray, and lift the tray. Use even force. Do not overexert yourself to prevent damaging the components or spilling the reagent.



Figure 2-5 Mouting and Removing Reagent Tray

Warning: Before mouting the reagent tray, confirm the system is in the standby mode and the reagent tray has stopped.

Caution: Before the system runs, confirm the reagent tray cover has been closed, otherwise the sample adding probe may be damaged. When placing the tray cover, make sure the positioning boss clicks in place.

Biohazard: Be sure to wear gloves and work clothes during operaton to prevent infection.

2.6.5 Mounting and Removing the Sample Test Tube

Mount the test tube onto the rubber base at the bottom till the tube clicks in place.

Warning: Before mouting the test tube, confirm the system is in the standby mode and the sample tray has stopped.

Caution: Do not use test tubes of specifications other than specified.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

2.6.6 Mouting and Removing the Reagent Bottle

Mount the reagent bottle onto the bottle base till the bottle clicks in place.

Warning: Before mouting the reagent bottle, confirm the system is in the



standby mode and the reagent tray has stopped.

Caution: Do not use reagent bottles of specifications other than specified.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

2.6.7 Mouting and Removing the Electrolyte Module (Optional)

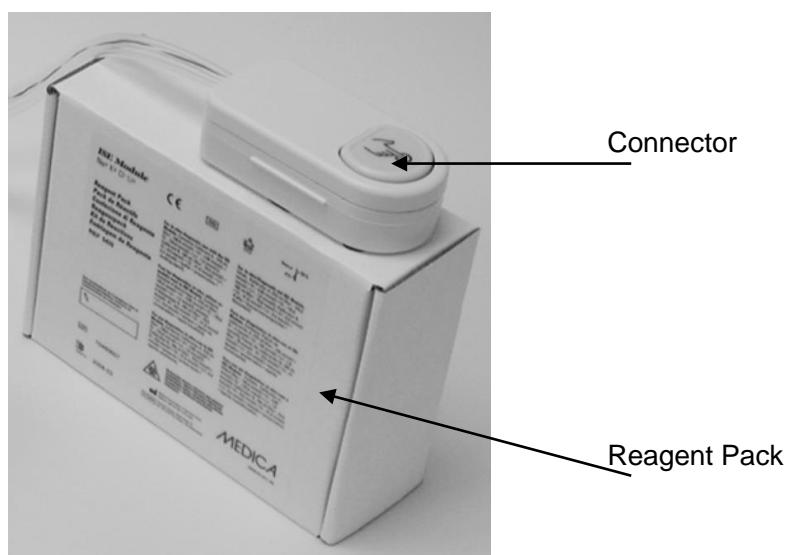


Figure 2-6 Electrolyte Module

Mounting/removing the reagent pack:

To mount the reagent pack, as shown in the figure below, remove the red cap on the reagent pack and push up the connector on it. Ensure the connector aims at the reagent pack and press down the connector.

To remove the reagent pack, press the button the connector and lift the connector.





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Figure 2-7 ISE Reagent Pack

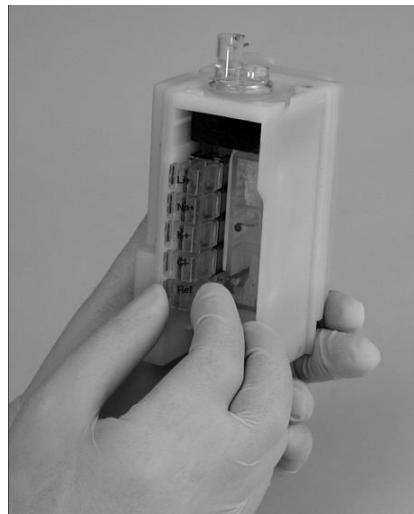


Figure 2-8 Schematic of Electrolyte Module Mounting

Warning: Properly dispose removed waste components in accordance with the local laws.

Before removing the reagent pack, ensure the power supply of the instrument has been turned off.

Caution: Please use the consumables recommended by LiNEAR Chemicals S.L., otherwise the performance of the system may reduce.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

2.6.8 Connecting the Control Computer

- Insert the mouse and keyboard into the corresponding interfaces on the back of the control computer.
- Insert one end of the electric cable of the display into the signal interface of the display and the other end into the display interface on the back of the control computer. Connect the display and AC power supply with the electric cable.
- Insert one end of the electric cable of the printer into the signal interface of the printer and the other end into the printer port on the back of the control computer.
- Connect the printer and AC power supply with the electric cable supplied with the printer.



- Connect the control computer and AC power supply with the electric cable.

2.6.9 Connecting the Instrument and Control Computer

Insert one end of the serial cable into the serial interface of the instrument and the other end into the serial interface COM1 of the control computer (the port setting can be changed to use other serial interfaces).

2.6.10 Connecting the Instrument to the Power Supply

Connect the instrument and AC power supply with the electric cable.

2.6.11 Sequence for Turning on/off the Instrument

- Turn on the instrument: Turn on the power supply of the instrument and the control switch of the analysis section, turn on the computer, and turn on the instrument control software.
- Turn off the instrument: Turn off the instrument control software and then turn off the power switch of the instrument.

2.7 Correction

Standard can be used to correct the instrument. The instrument needs not to be calibrated for each test. However, for items requiring calibration, at least one calibration test is needed. The changes in the system environment may impact the tests to a certain extent, so a calibration test is suggested each time the machine is switched on to ensure the accuracy of test results.

For the calibration test method, refer to “Chapter 4 Parameter Setup” and “Chapter 7 Tests”.

Chapter 3 Start

3.1 Precautions before Starting the Machine

Before you start the machine each time, pay attention to the following to ensure the system is ready:

- 1) Check the status of the instrument before starting the machine.
 - Check that the three plate covers on the workbench have been closed;
 - Check that there is no obstacle in the motion region of the various components on the workbench;
 - Check that the deionized water machine has been turned on;
 - Check that the high concentration waste liquid tank and low concentration waste liquid tank have been emptied;
 - Check that the minimal volume of cleaning solutions (including the cleaning solution for test cuvettes, cleaning solution in the reagent tray, and cleaning solution in the sample tray) is sufficient;
 - Check that the minimal volume of deionized water for the reagent tray and sample tray is sufficient;
 - Check that all tubes are correctly connected;
 - Check that the serial control cables are properly connected;
 - Check that the electric cables are properly connected.
- 2) Check whether the printing paper is sufficient and whether they are inserted in place.
- 3) Keep the User's Manual in a handy place.
- 4) Operate and maintain the computer according to the instructions of the computer.

3.2 Logging on to the System

Start the machine and run the LIDA 500 software, and the system will enter the user login screen, as shown in the figure:

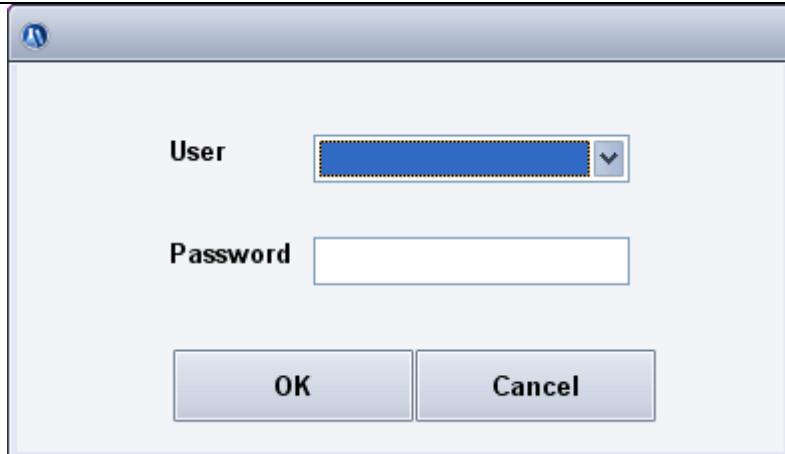


Figure 3-1 Login

Select a user name and input the password, and click the Login button to login, or click the Cancel button to quit the software.

Caution: The user name of the system administrator is "Admin", and the initial password is "888888". You can change the password freely. Please keep the changed password in mind!

After login, the system will enter the initialization screen and conduct self-check and initialization automatically, as shown in the figure:

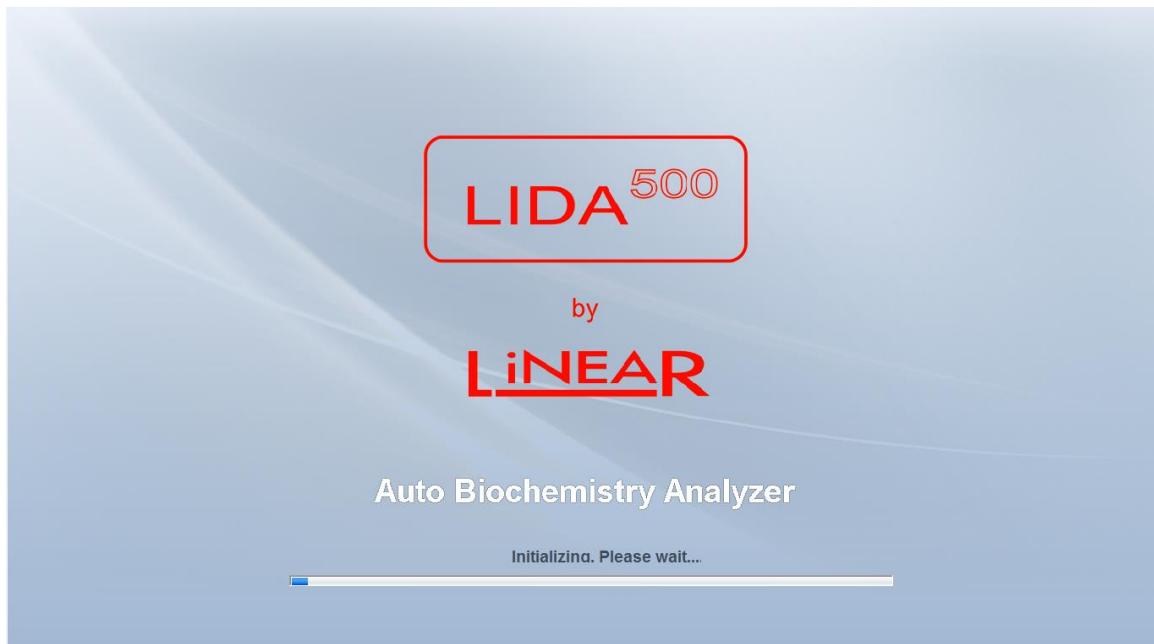


Figure 3-2 Initialization

Self-check and initialization include the following contents:

- **Connecting front end:** Test whether the communication between the control software and



middle computer software is normal.

- **Units shaking hands:** Test whether the status of the various units is normal.
- **Sending parameters:** Read system parameters from the middle computer.
- **System reset:** Conduct whole machine reset and liquid line filling to prepare for testing.

3.3 Main Screen

After login, the main screen will appear, and the system will enter the “waiting for the light source to become stable” mode. Here, “Wait for the light source to become stable” is displayed on the left top corner of the screen. The test can be commenced only when the light source becomes stable and “Ready” is displayed on the left top corner of the screen, as shown in the figure:

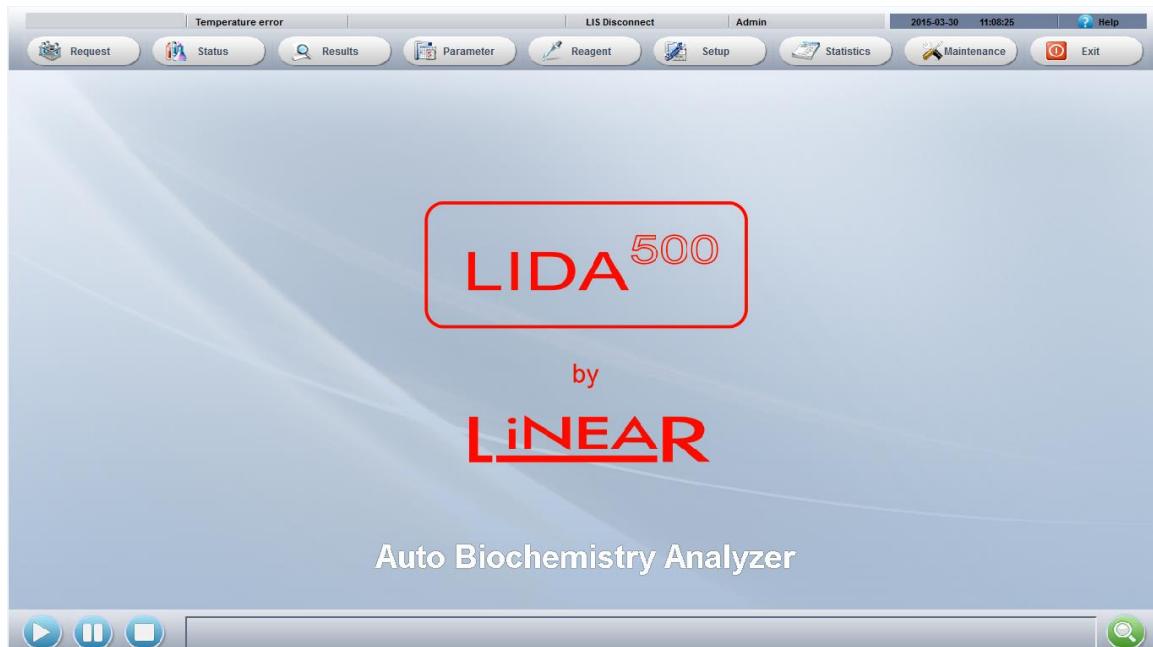


Figure 3-3 Main Screen

Caution: Each time the power is switched on, it takes 30 minutes for the light source to become stable. If the test is commenced before the light source becomes stable, the accuracy of the results may be impacted.

3.4 Function Modules

The function modules on the main screen are as follows:

- **Status Display Area:** Displays the system status, current temperature of reaction tray, remaining test time, LIS connection status, ISE status, operator, and current time.
- **Help:** Click the Help icon to display the About and Help selection box.



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- **Function Button Area:** Displays the function buttons, including Sample, Reagent, Calibration, QC, Status, Statistics, Parameter, Setup, Maintenance, and Off. Click a function button, and the working page corresponding to the button will appear.
- **Shortcut Button Area:** Includes the Start, Pause, and Stop buttons. Click a shortcut button to operate the system accordingly.
- **Function Window Area:** Displays the values and graphs of the parameters, processes, results, etc. corresponding to the selected function button.
- **Prompt and Alarm Message Display Area:** Displays alarm, warning or error messages. Click the Inquire button to inquire the details of the alarm, warning or error messages.

3.5 Help

Function Brief: When you encounter any question during the use of the software, you can find the information on the instrument in the help file.

Click the Help icon on the main screen to enter the About and Help selection box. Click the Help button, and the help file will pop up, as shown in the figure:

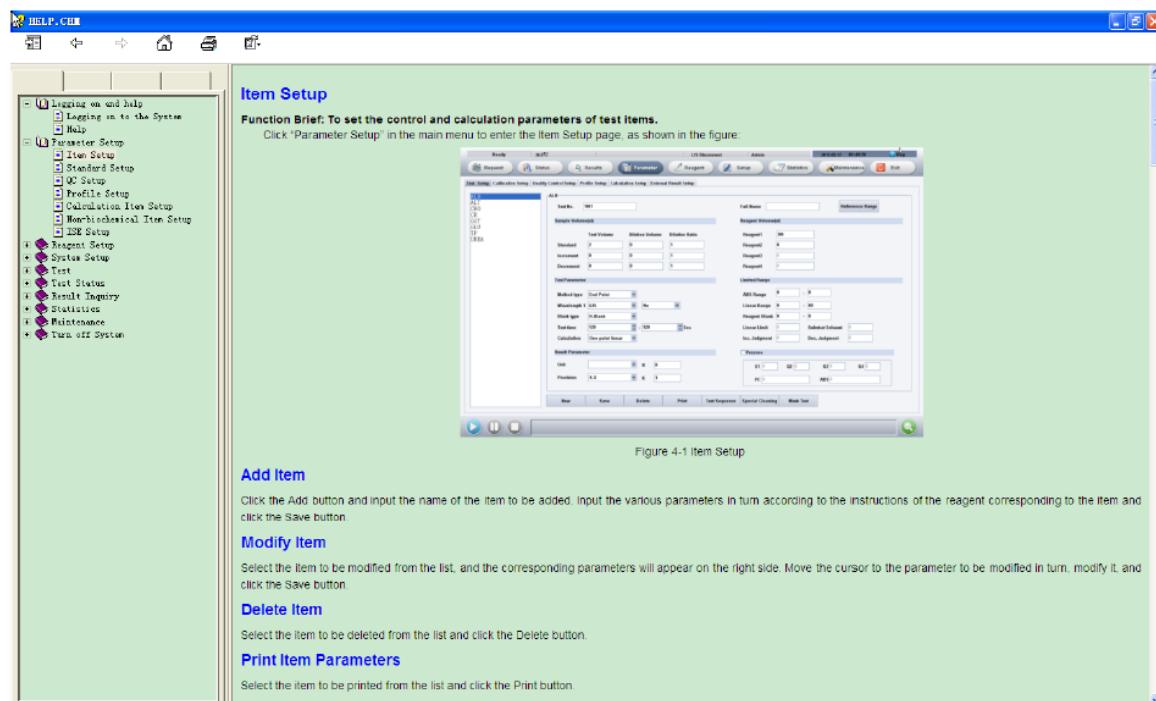


Figure 3-4 help

Chapter 4 Parameter Setup

4.1 Item Setup

Function Brief: To set the control and calculation parameters of test items.

Click “Parameter Setup” in the main menu to enter the Item Setup page, as shown in the figure:



Figure 4-1 Item Setup

4.1.1 Add Item

Click the Add button and input the name of the item to be added. Input the various parameters in turn according to the instructions of the reagent corresponding to the item and click the Save button.

4.1.2 Modify Item

Select the item to be modified from the list, and the corresponding parameters will appear on the right side. Move the cursor to the parameter to be modified in turn, modify it, and click the Save button.

4.1.3 Delete Item

Select the item to be deleted from the list and click the Delete button.

4.1.4 Print Item Parameters

Select the item to be printed from the list and click the Print button.

4.1.5 Meaning of Item Parameters

- 1) Item Number:** The unique number of the item. If the system adopts the barcode scanning to



identify reagents and obtain sample information, the item number must be consistent with the definition of the information system, otherwise the reagent may be wrongly positioned or the sample information may be wrong!

- 2) **Full Name of Item:** Input the full name or description information of the item. When printing the general report on a patient, you can select whether to print the information according to the needs.
- 3) **Reference Range:** Specify the division criterion of the reference range and the corresponding values of reference range according to the instructions of the reagent, as shown in the figure:

A screenshot of a software window titled "Reference Range". The window is for the protein ALB. It has three main sections: "Age (A)" on the left, "By age" in the middle, and "By sex" on the right. The "Age (A)" section contains dropdown menus for age ranges: <= 3, < 16, < 35, < 60, and "Above". The "By age" section shows five pairs of input fields for reference ranges, all currently set to 0-0. The "By sex" section also shows five pairs of input fields for reference ranges, all currently set to 0-0. At the bottom are "Save" and "Cancel" buttons.

Figure 4-2 Reference Range

- 4) **Sample Size – Standard:**
 - **Test Sample Size:** The volume of sample to be added during a standard test. Range: 2-45 μ l, increasing progressively by 0.1 μ l;
 - **Dilution Sample Size:** The volume of original sample used for dilution during a dilution test. Range: 2-80 μ l, increasing progressively by 0.1 μ l;
 - **Dilution Ratio:** The dilution ratio of the original sample during a dilution test. Input "10" to indicate a 10 times dilution, i.e. 1 part of sample + 9 parts of diluent; input "1" to indicate no dilution.
- 5) **Sample Size - Increment:**
 - **Test Sample Size:** The volume of sample to be added during an increment test. Range: 2-45 μ l, increasing progressively by 0.1 μ l;



-
- **Dilution Sample Size:** The volume of original sample used for dilution during an increment dilution test. Range: 2-80 μ l, increasing progressively by 0.1 μ l;
 - **Dilution Ratio:** The dilution ratio of the original sample during an increment dilution test. Input "10" to indicate a 10 times dilution, i.e. 1 part of sample + 9 parts of diluent; input "1" to indicate no dilution.
- 6) **Sample Size - Decrement:**
- **Test Sample Size:** The volume of sample to be added during a decrement test. Range: 2-45 μ l, increasing progressively by 0.1 μ l;
 - **Dilution Sample Size:** The volume of original sample used for dilution during a decrement dilution test. Range: 2-80 μ l, increasing progressively by 0.1 μ l;
 - **Dilution Ratio:** The dilution ratio of the original sample during a decrement dilution test. Input "10" to indicate a 10 times dilution, i.e. 1 part of sample + 9 parts of diluent; input "1" to indicate no dilution.
- 7) **Reagent Volume:** Input the volume of reagent used. (Input 0 for a reagent not used.)
- 8) **Method Type:** Select End-Point Method, Two-Point Method, or Kinetics Method.
- 9) **Main/Secondary Wavelength:** Set the wavelength used according to the instructions of the reagent. If the single-wavelength test is adopted, set wavelength 1 only, and select None for wavelength 2. However, in order to eliminate external interference, it is suggested to use the dual-wavelength test.
- 10) **Blank Test:** Select None, Reagent Blank, Sample Blank, or Pre-Blank.
- **None:** The blank value needs not to be reduced;
 - **Reagent Blank:** The reagent and sample volumes for normal tests are used, and the sample is substituted with deionized water;
 - **Sample Blank:** The reagent and sample volumes for normal tests are used, and the reagent is substituted with deionized water;
 - **Pre-Blank:** The pre-blank measurement point should be set. The blank value of the set measurement point should be reduced from the measurement results.

Caution:

- ◆ ***With the end-point method, the absorbance value of the reagent blank test is reduced; with the two-point method and kinetics method, the variation per minute of the reagent blank test is reduced.***
- ◆ ***When Pre-Blank is selected, the start point and end point shall be in the***



corresponding range. Input range for single-reagent tests: 10-150; input range for double-reagent tests: 170-450; input range for three-reagent tests: 460-1000; input range for four-reagent tests: 1020-1450.

- 11) **Measurement Time:** To set the start time and end time of measurement respectively. For single-reagent items, the range of measurement time is 20-600 seconds; for double-reagent items, 20-300 seconds; for three-reagent items, 20-750 seconds; for four-reagent items, 20-300 seconds. With respect to the two-point method and kinetics method, the interval between the start time and end time should not be less than 30 seconds.
 - 12) **Calculation Method:** Select the corresponding calculation method according to the actual needs. When the Factor Method is selected, you can input factor values provided in the instructions of the reagent.
-

Caution: The signs of the factors of items tested with the kinetics method reflect the change directions of the curve. If it is downward reaction, the factor is negative, otherwise the factor is positive.

- 13) **ABS Range:** To set the measurement range of absorbance value, with a maximum range of -30000-30000. Input 0 to indicate this judgment is not made.
- 14) **Linear Range:** Test range of the instrument or reagent. When the test results exceed the range, the results are unreliable and should be marked to prompt you for dilution retest, decrement retest or increment retest. Input 0 to indicate this judgment is not made.
- 15) **Reagent Blank:** The valid range of reagent blank. When the reagent blank exceeds the range, the system will treat the reagent as failure. The unit is 1/10000 absorbance.
- 16) **Linear Limit (Linearity Limit):** Effective for the kinetics method only. The system calculates the linearity in the test period automatically. When the linearity of the reaction curve exceeds the set range, the results will have the corresponding sign. The setup range of linearity limit is 0-300. The default is 20. The calculation formula of linear limit is:
 - Number of test points > 9
$$\text{Linearity} = 100 * (\text{Change rate of the first 6 points} - \text{Change rate of the last 6 points}) / \text{Change rate of all points}$$
 - $4 \leq \text{Number of test points} \leq 8$
$$\text{Linearity} = 100 * (\text{Change rate of the first 3 points} - \text{Change rate of the last 3 points}) / \text{Change rate of all points}$$
- 17) **Substrate Exhaust Limit:** Effective for the two-point method and kinetics method only. Some high concentration (active) samples exhaust the substrate, which makes the reaction no longer a



kinetic method reaction. In order to correctly reflect the determination results, the substrate exhaust limit (a certain absorbance) needs to be set which should be exactly the critical point between linear zone and nonlinear zone in the reaction curve, the minimum (the reaction curve bends downward) or maximum (the reaction curve bends upward) absorbance value before the substrate is exhausted within the reaction time. The substrate exhaust limit of an item is closely related to the reagent kit used. The unit is 1/10000 absorbance. The setting 0 indicates no judgment.

- No Linear Interval: Number of points with no substrate exhausted in the measurement time < 3. (The check is started only when the substrate is exhausted.)
- No Calculation Interval: Number of points with no substrate exhausted including the delay time < 3. (The check is started only when there is no linear interval.)

18) Increment Judgment: Increment judgment is a judgment limit in the increment test. When the absorbance is less than (the reaction curve bends upward) or greater than (the reaction curve bends downward) the limit after the reaction is ended, the increment test is conducted automatically.

The input range of increment judgment is -30000 ~ 30000; input 0 to indicate this judgment is not made.

Caution: Be sure to set the increment sample before setting increment judgment.

19) Decrement Judgment: Decrement judgment is a judgment limit in the decrement test. When the absorbance is greater than (the reaction curve bends upward) or less than (the reaction curve bends downward) the limit after the reaction is ended, the decrement test is conducted automatically.

The input range of decrement judgment is -30000 ~ 30000; input 0 to indicate this judgment is not made.

Caution: Be sure to set the decrement sample before setting decrement judgment.

20) Unit of Results: To set the unit of test results. The options displayed are the information set in "System Setup" -> "Data Dictionary" -> "Unit of Results".

21) Precision of Results: To select the number of decimal places of the results of the items in the general report to be printed, with a maximum of 3 decimal places.

22) Correction Factor: Linear correction factor of system test results: Result = Measurement result * Slope K + Intercept B. In general, no correction is needed: K=1, B=0. However, for items tested



with the factor method, the factor can be used to correct the error of the instrument.

23) Prozone Check: Q1, Q2, Q3 and Q4 are the photometric points for prozone check; PC is the prozone limit; ABS is the absorbance limit for prozone check. The above prozone parameters are valid only when “Prozone Check” is selected.

The reaction rate method is adopted in the prozone check, that is, the antibody excess reaction curve can reach balance and the antigen excess reaction curve cannot reach balance in the same period time. The specific judgment method is as follows:

- Set the photometric points for prozone check [Q1], [Q2], [Q3], and [Q4]
- Set the prozone limit [PC] and lower limit of absorbance for prozone check [ABS]
- Calculate the PC_M value of the sample: $PC_M = \text{Change slope } [Q3, Q4]/\text{Change slope } [Q1, Q2]$. If $PC_M > PC$, the “Prozone Check Exception” warning sign is given.
- Requirements of photometric point input:
 - Single-reagent items: $16 < q1 < q2 < q3 < q4 \leq \text{End point of reaction} \leq 76$
 - Double-reagent items: $46 < q1 < q2 < q3 < q4 \leq \text{End point of reaction} \leq 76$
 - Three-reagent items: $102 < q1 < q2 < q3 < q4 \leq \text{End point of reaction} \leq 176$
 - Four-reagent items: $146 < q1 < q2 < q3 < q4 \leq \text{End point of reaction} \leq 176$
- The prozone check is no longer conducted in the following two cases:
 - Absorbance of end point of sample A < abs.lowlimit (upward reaction) or A > abs.lowlimit (downward reaction)
 - Absolute value of reactivity of sample R > RCMAX (Absolute value of reactivity of standard of maximum concentration)

4.1.6 Test Sequence Setup

Click the Test Sequence Setup button to enter the screen as shown in the figure:



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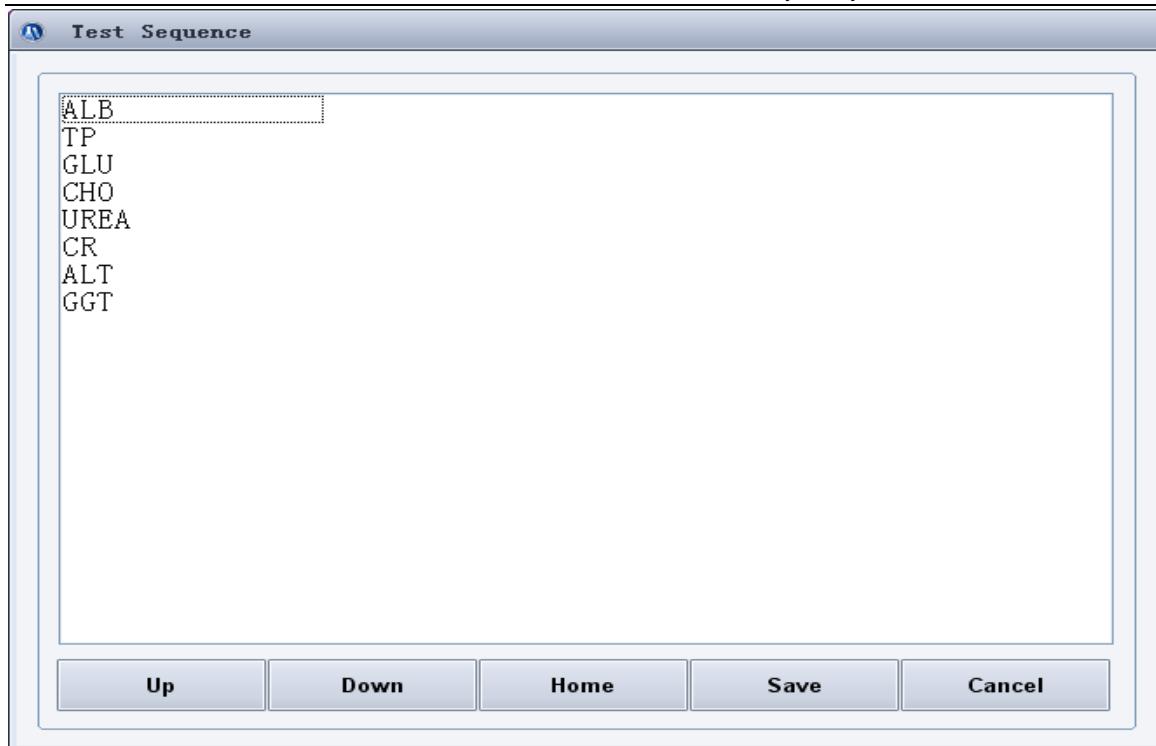


Figure 4-3 Test Sequence Setup

The function is used to set the test priority of items. Select the item for which the test sequence needs to be adjusted, use the Up and Down keys or the mouse to adjust it to the proper position, and click the Save button after adjusting all items.

To restore the default test sequence, click the Restore button and save the setting.

Caution: The default test sequence is in alphabetical order of item names.

4.1.7 Special Cleaning Setup

The cross contamination of reagents for some items may impact the test results, and such impact should be reduced or eliminated with special cleaning treatment. Use “Special Cleaning Setup” to specify in which case the system should conduct which type of special cleaning. Click the Special Cleaning Setup button to enter the screen as shown in the figure:



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A screenshot of the 'Special Cleaning Setup' software window. The window title is 'Special Cleaning Setup'. It contains two main sections: 'Reagent Probe Cleaning' and 'Cuvette Cleaning'. Under 'Reagent Probe Cleaning', there are two tables labeled 'Reagent Probe 1' and 'Reagent Probe 2'. Each table has columns for Contaminant test, Contaminated item, Contaminant Reagent, Solution type, and Solution Volume. Below each table are dropdown menus for Contaminant test and Contaminated item, and input fields for Contaminant Reagent, Solution type, and Solution Volume. At the bottom of each section are 'Save', 'Delete', and 'Delete All' buttons. A 'Cancel' button is located at the bottom right of the entire window.

Figure 4-4 Special Cleaning Setup

4.1.7.1 Reagent Probe Cleaning Setup

- **Contaminating Item:** The item producing cross contamination;
- **Contaminating Reagent:** The polluting reagent corresponding to the item producing cross contamination;
- **Contaminated Item:** The item contaminated by the contaminating item;
- **Contaminated Reagent:** The reagent contaminated by the contaminating reagent;
- **Type of Cleaning Solution:** Including deionized water and cleaning solution;
- **Volume of Cleaning Solution:** Setting range: 150-350µl.

To delete a set special cleaning item, select a set item from the list and click the Delete button. To delete all set items, click the Delete All button.

Caution: The special cleaning consumes the normal test cycle, therefore the testing speed of the instrument will be lowered. Unless it is necessary, do not set the special cleaning!



4.1.7.2 Test Cuvette Cleaning Setup

In addition to the cross contamination of reagents that impact the test results, some tests may cause cross contamination between different tests due to the residue in the test cuvette, thus causes inaccurate test results. Therefore, anti-cross contamination cleaning setup should be set for test cuvettes, as shown in the figure:

A screenshot of the 'Special Cleaning Setup' software window. The title bar says 'Special Cleaning Setup'. Below it is a tab bar with 'Reagent Probe Cleaning' and 'Cuvette Cleaning' (which is selected). A large table has five columns: 'Contaminant test', 'S Solution', 'S Volume', 'R1 Solution', and 'R1 Volume'. Below the table is a dropdown menu labeled 'Contaminant te'. To the left is a 'Sample Probe' section with 'Solution type' (set to 'Water') and 'Solution Volume' (set to '40 ul'). To the right is a 'Reagent 1' section with 'Solution type' (set to 'Water') and 'Solution Volume' (set to '300 ul'). At the bottom are four buttons: 'Save', 'Delete', 'Delete All', and 'Cancel'.

Figure 4-5 Special Cleaning Setup

- **Contaminating Item:** To select the item contaminating test cuvettes;
- **Sample Probe:** To set the actions of the sample probe during the cleaning of test cuvette, including type and volume of cleaning solution;
- **Reagent Probe 1:** To set the actions of the reagent probe 1 during the cleaning of test cuvette, including the type and volume of cleaning solution.

The process of special cleaning of test cuvette is the same as that of a normal single-reagent test, that is, when the first cleaning is finished, add R1 cleaning solution, wait about 2.5 minutes and then add the sample cleaning solution and mix the contents, and wait about 10 minutes and then conduct the second cleaning. As the test cuvette has undergone the special cleaning process of “automatic cleaning – add cleaning solution and soak - automatic cleaning”, thus eliminates cross contamination between items.

4.1.8 Item Masking Setup

Click the Item Masking Setup button, as shown in the figure:



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Figure 4-6 Item Masking Setup

Select the item to be masked, and the system will prohibit the application for test of the masked item.

Click the Mask All button to mask all items. Click the Unmask button to cancel the masking of the item.

Click the Save button to save the modification, or click the Back button to give up saving.

4.2 Standard Setup

Function Brief: To set the parameters of the standard used by the system.

Select the Standard Setup page as shown in the figure:

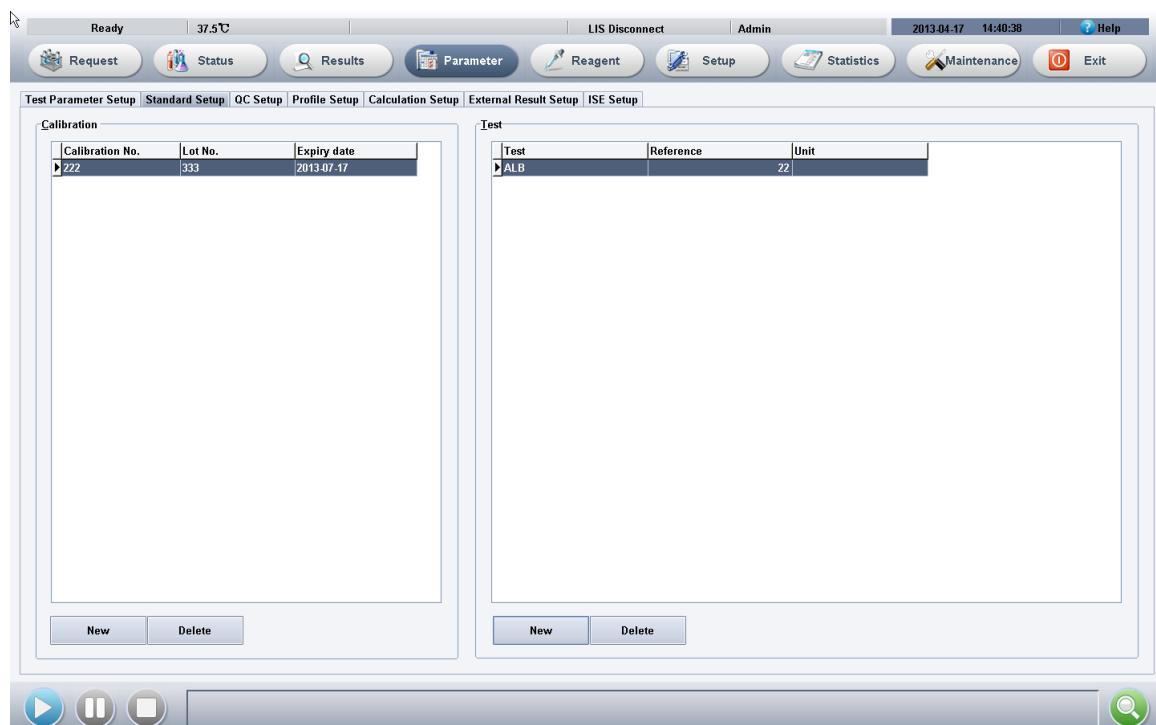


Figure 4-7 Standard Setup



4.2.1 Add Standard

A screenshot of a Windows-style dialog box titled "Input a new standard". It contains three text input fields: "No." with the value "Standard2", "Lot." with the value "555", and "Expiry date" with the value "2013-05-17" and a dropdown arrow. At the bottom are two buttons: "OK" and "Cancel".

No.	Standard2
Lot.	555
Expiry date	2013-05-17

OK Cancel

Figure 4-8 Add Standard

Click the Add Standard button, input the Number, Batch Number and Expiry Date on the screen that appears, and select OK to save the setting. Add the calibration items included for the standard in turn.

4.2.2 Delete Standard

Select the standard to be deleted from the standard list and click the Delete Standard button.

4.2.3 Add or Modify Calibration Item



Standard1 - Add Standard Test

ALB
ALT
CHO
CR
GGT
GLU
TP
UREA

Test Reference

ALB	55
-----	----

Save **Cancel**

Figure 4-9 Add Calibration Item

Specify a standard and click the Add Item button. Select Add or the calibration item to be modified on the screen that appears, input the reference value, and click the Save button.

4.2.4 Delete Calibration Item

Select a standard from the standard list, and the calibration items included will be displayed on the list on the right side. Select the calibration item to be deleted and click the Delete Item button.

Caution: When an existing standard is deleted, the calibration results corresponding to the standard will also be deleted. When an existing calibration item is modified or deleted, the calibration results corresponding to the calibration item will also be deleted.



4.3 QC Setup

Function Brief: To set parameters of QC substances used by the system.

Select the QC Setup page as shown in the figure:

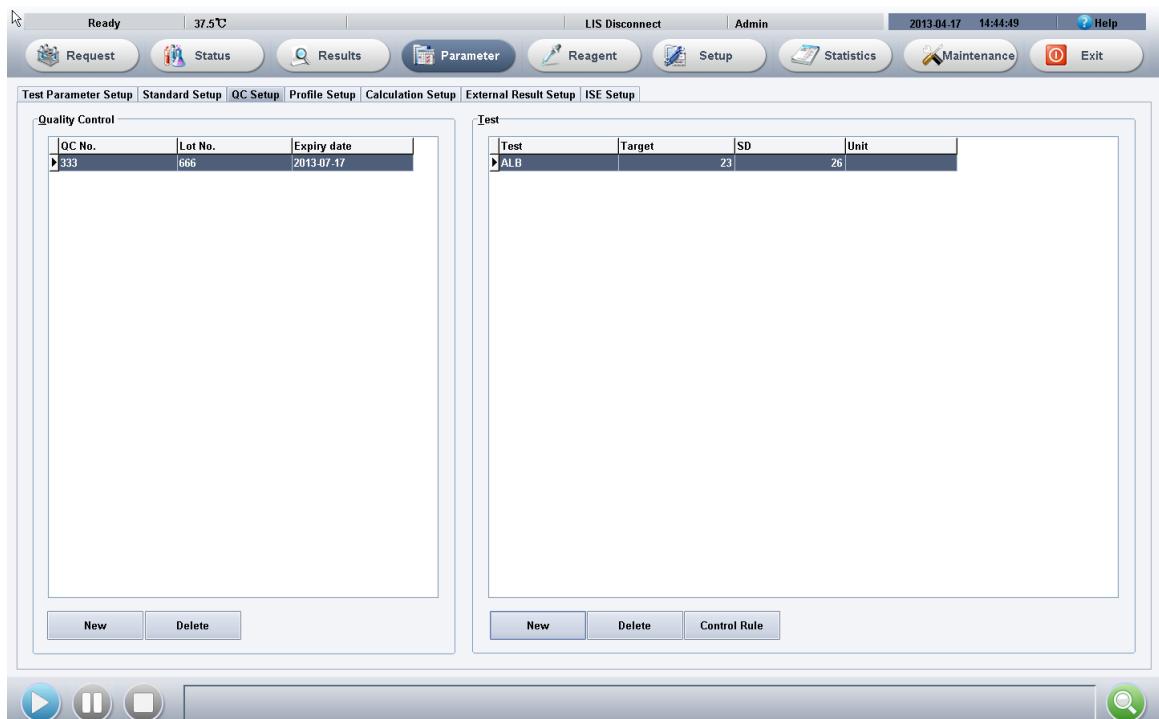


Figure 4-10 QC Setup

4.3.1 Add QC



Figure 4-11 Add QC

Click the Add QC button, input the Number, Batch Number and Expiry Date on the screen that



appears, and click OK to save the setting. Add the QC items included for the QC substance in turn

4.3.2 Delete QC

Select the QC substance to be deleted from the QC substance list and click the Delete QC button.

4.3.3 Add QC Item

A screenshot of a computer dialog box titled "QC1 - Add Quality Control Test". On the left, a vertical list of test names is shown: ALB, ALT, CHO, CR, GGT, GLU, TP, and UREA. The first item, "ALB", is highlighted with a blue selection bar. At the bottom of the dialog, there are four input fields labeled "Test", "Target", "SD", and "Unit". The "Test" field contains "ALB", the "Target" field contains "88", the "SD" field contains "99", and the "Unit" field is empty. To the right of these fields are two buttons: "Save" and "Cancel".

Test	Target	SD	Unit
ALB	88	99	

Save Cancel

Figure 4-12 Add QC Item

Specify a QC substance and click the Add Item button. Select Add or the QC item to be modified on the screen that appears, input the target value and SD, and click the Save button.

4.3.4 Delete QC Item

Select a QC substance from the QC substance list, and the QC items included will be displayed on the list on the right side. Select the QC item to be deleted and click the Delete Item button.

4.3.5 Set QC Rule

Select a QC substance from the QC substance list, and the QC items included will be displayed on the list on the right side. Select the time for which you want to set the QC rule and click the QC Rule



button to enter the screen as shown in the figure:

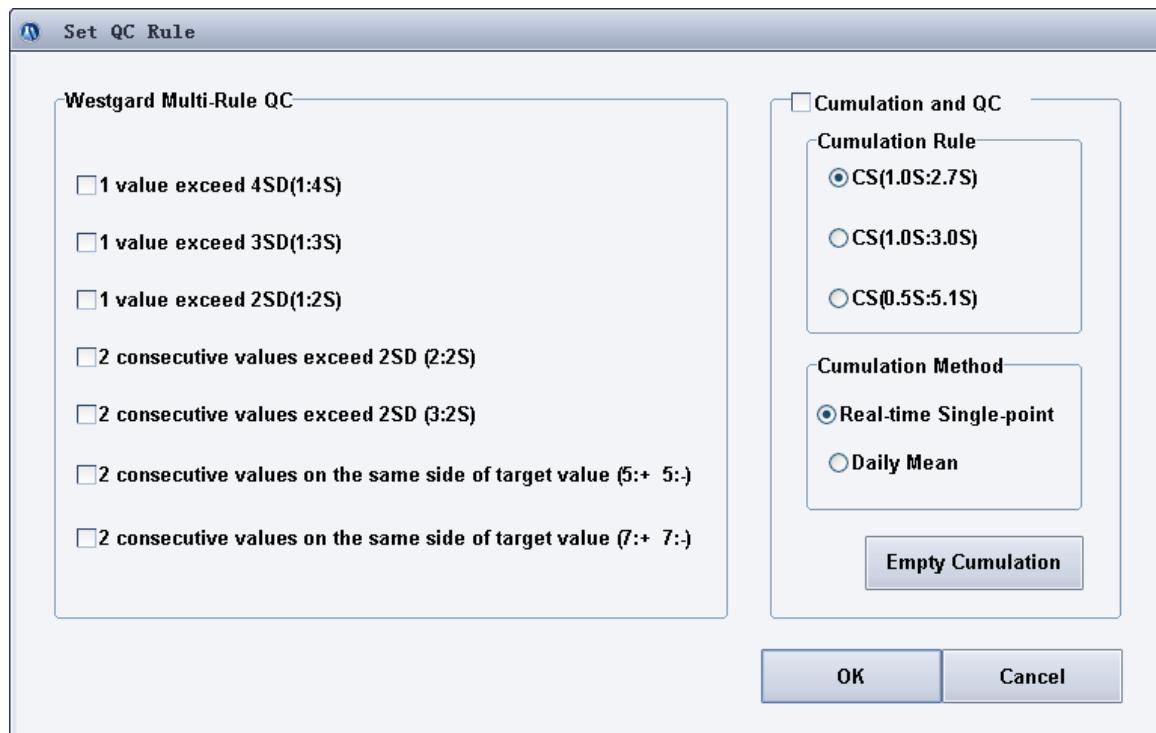


Figure 4-13 QC Rule Setup

- **Westgard Multi-rule QC:** Select the QC warning rule for the item from the 7 rules and click the OK button to save the selection.
- **Cumulation and QC:** Whether the cumulation and rule are used. Select it to cumulate the QC substance and make rule judgment.
- **Cumulation Rule:** To set the QC rule for cumulative sum, such as CS(1.0S:2.7S), in which, 1.0S is the threshold K that starts cumulation and calculation, and 2.7S is the QC limit H.
- **Cumulation Method:** For daily QC chart, Real-time Single-point Cumulation means the cumulative data are the actual results of each test; Daily Mean Cumulation means the cumulative data are the mean of test results of every day.
- **Empty Cumulative Sum:** After calibration and correction of the out-of-control instrument, click the Empty Cumulative Sum button to restart cumulation and QC. After the cumulative sum is emptied, the current value of cumulative sum is 0.

4.4 Profile Setup

Function Brief: Used to assist a number of test items of a diagnosis to in forming a set.



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Select the Profile Setup page as shown in the figure:

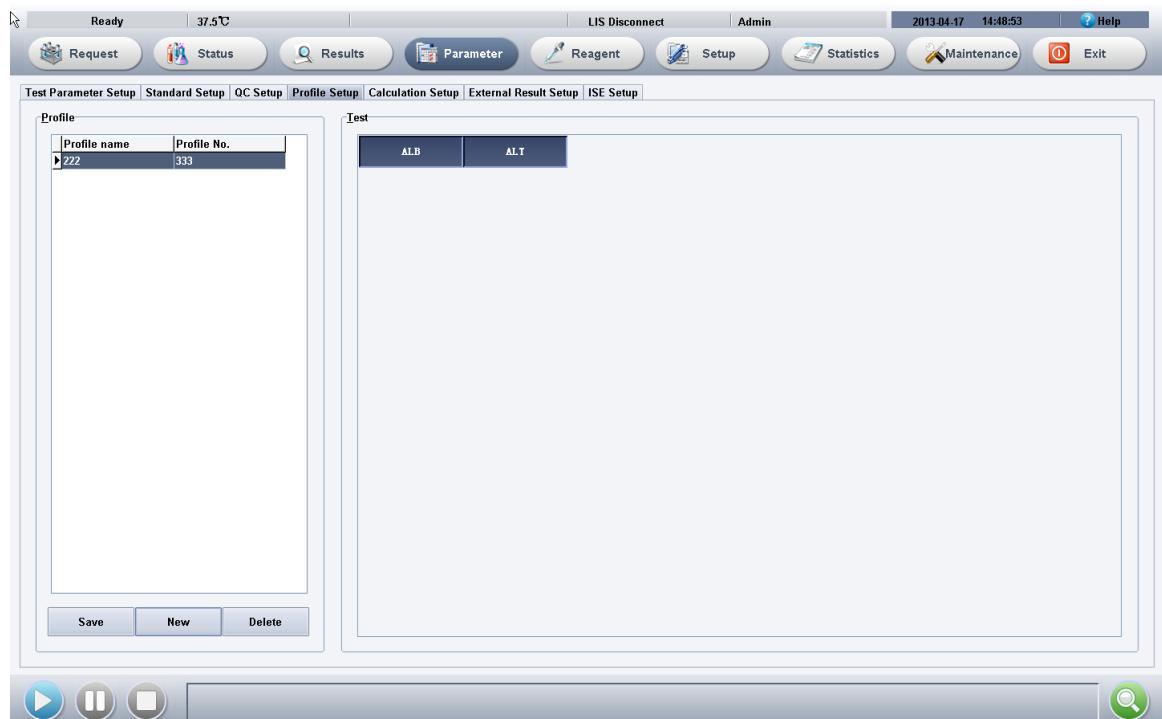


Figure 4-14 Profile Setup

4.4.1 Add Profile



Figure 4-15 Profile Setup

Click the Add Profile button, input the name and number of the new profile, and click the OK button. Select the items to be included in the profile and click the Save button.

4.4.2 Modify Profile

Select the profile to be modified from the profile list, modify the items included in the profile, and click the Save button.



4.4.3 Delete Profile

Select the profile to be deleted from the profile list and click the Delete Profile button.

4.5 Calculation Item Setup

Function Brief: To set the item the results of which are obtained through calculation of test items.

Select the Calculation Item Setup page as shown in the figure:

A screenshot of the LIDA 500 software interface showing the 'Calculation Setup' tab selected. The main window displays a table with columns: Test, Test No., Full name, Unit, Decimal, and Formula. A row is selected for 'TPR' with '33' in the Test No. field and '(ALB){ALT}' in the Formula field. To the right of the table is a dropdown menu listing various calculation items: ALB, ALT, CHO, CR, GGT, GLU, TP, and UREA. Below the table are input fields for 'Test' (TPR), 'Test No.' (33), 'Unit' (dropdown), 'Decimal' (x), 'Full Name' (empty), and 'Formula' ((ALB){ALT}). There is also a note about input expression including '+,-,*,/ and {Test}'. At the bottom are buttons for 'New', 'Save', 'Delete', and 'Ref. Range'. The bottom navigation bar includes icons for play, pause, stop, and search.

Figure 4-16 Calculation Item Setup

4.5.1 Add Calculation Item

Click the Add button, input the Item Name, Full Name, Unit, Decimal Places and Calculation Formula of the calculation item added in turn, click the Save button, and input the reference range of the calculation item added.

4.5.2 Modify Calculation Item

Select a calculation item from the list, modify the Full Name, Unit, Decimal Places and Calculation Formula, and click the Save button. Or modify the reference range of the item according to Reference Range.

4.5.3 Delete Calculation Item

Select a calculation item from the list and click the Delete button.



Caution: A calculation formula is composed of +, -, *, /, (,), digits and {Item Name} only. Otherwise the formula is regarded as invalid.

4.6 Non-biochemical Item Setup

Function Brief: To input the results of a non-biochemical item tested by other equipment to the system, set the parameters of the non-biochemical item to be input first.

Select the Non-biochemical Item Setup page as shown in the figure:

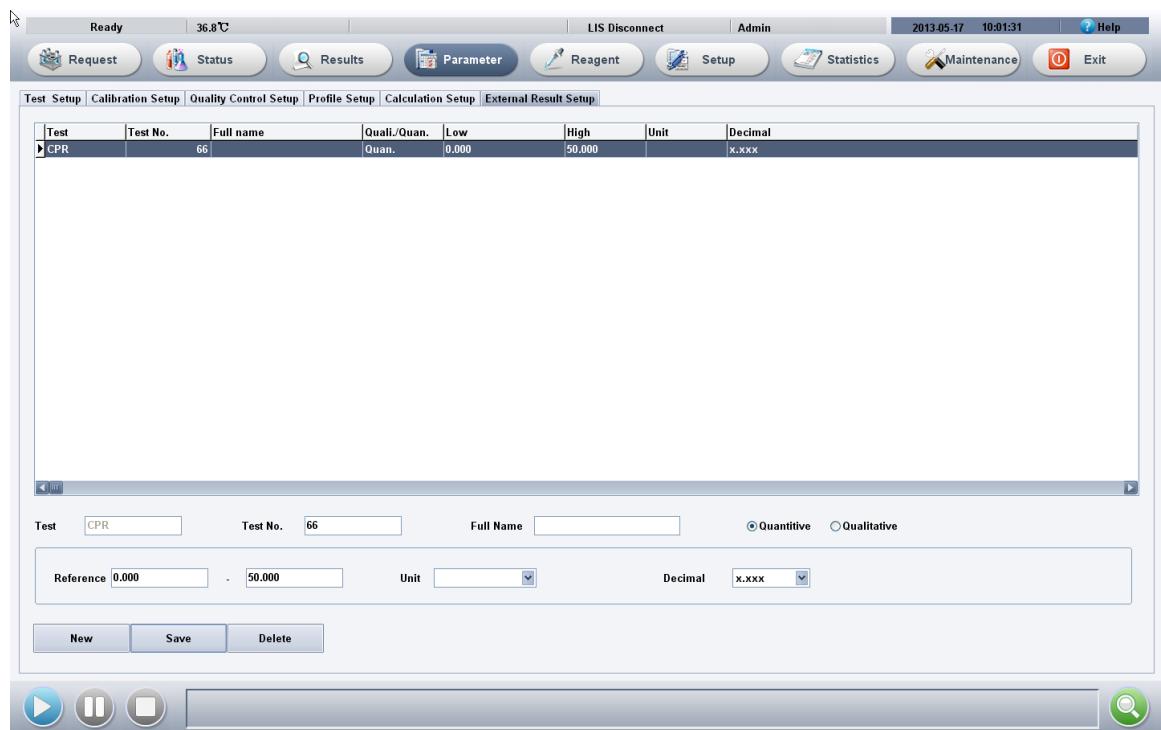


Figure 4-17 Non-biochemical Item Setup

4.6.1 Add Non-biochemical Item

Click the Add button, input the Item, Full Name, Qualitative or Quantitative and Reference Value of the non-biochemical item added in turn, and click the Save button.

4.6.2 Modify Non-biochemical Item

Select the non-biochemical item to be modified from the list, modify the Full Name, Qualitative or Quantitative and Reference Value, and click the Save button.



4.6.3 Delete Non-biochemical Item

Select the non-biochemical item to be deleted from the list and click the Delete button.

4.7 ISE Setup

Function Brief: In this screen, you can observe and set the basic parameters, reference range, standards, and QC rules of each ISE item.

Select the ISE Setup page as shown in the figure:

The screenshot shows the ISE Setup software interface. At the top, there is a menu bar with various buttons: Ready, Request, Status, Results, Parameter, Reagent, Setup, Statistics, Maintenance, and Help. The date and time are displayed as 2013-05-17 10:03:16. Below the menu bar, there is a toolbar with icons for Save, Print, and Search. The main window has a title bar "ISE Parameters" and a sub-title "ISE-K". On the left, there is a sidebar titled "ISE Test" with three items: ISE-K (selected), ISE-Na, and ISE-C1. The main content area is divided into two sections: "Serum/Plasma" and "Urine". Both sections contain fields for Slope, Intercept, Range, Unit, and Precision. The "Serum/Plasma" section has a range of 1 to 8 and a unit of mmol/L. The "Urine" section has a range of 5 to 200 and a unit of mmol/L. A "Ref. Range" button is located above the "Urine" section. At the bottom left is a "Save" button, and at the bottom right is a "Search" icon.

Figure 4-18 ISE Setup

4.7.1 Meaning of ISE Parameters

Under the ISE Setup page, select the ISE Parameter Setup page as shown in the figure:



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A screenshot of the LIDA 500 software interface. At the top, there is a toolbar with various icons and buttons like 'Ready', '36.0°C', 'LIS Disconnect', 'Admin', '2013.05.17 10:03:16', 'Help', 'Request', 'Status', 'Results', 'Parameter', 'Reagent', 'Setup', 'Statistics', 'Maintenance', and 'Exit'. Below the toolbar, a navigation bar includes 'Test Setup', 'Calibration Setup', 'Quality Control Setup', 'Profile Setup', 'Calculation Setup', 'External Result Setup', and 'ISE Setup'. The main window is titled 'ISE Parameters' and shows 'ISE-K' selected. It contains two main sections: 'Serum/Plasma' and 'Urine'. In the Serum/Plasma section, fields include 'No.' (1), 'Full Name' (K), 'Slope' (1.0517), 'Intercept' (0.046), 'Range' (1 - 8), 'Unit' (mmol/L), and 'Precision' (X.XX). In the Urine section, fields include 'Slope' (1.0754), 'Intercept' (0.6186), 'Range' (5 - 200), 'Unit' (mmol/L), and 'Precision' (X). A 'Save' button is located at the bottom left of the parameter setup area. The bottom of the window features standard operating system-style buttons for minimize, maximize, and close, along with a search icon.

Figure 4-19 ISE Parameter Setup

- **Number:** The unique number of the item. If the system adopts the barcode scanning to obtain sample information, the item number must be consistent with the definition of the information system, otherwise the sample information may be wrong!
- **Full Name of Item:** The full name of the ISE item. It may be empty;
- **Slope and Intercept:** The linear correction coefficient for the test results of the system. $\text{Results} = \text{Measured value} * \text{Slope} + \text{Intercept}$. In general, no correction is needed: Slope = 1, Intercept = 0;
- **Measurement Range:** The test range of the ISE item. When the test results exceed this range, the corresponding results will be marked with the sign A> or A<;
- **Unit of Results:** The unit of results of the ISE item. It cannot be modified;
- **Precision of Results:** The precision of results of the ISE item. It cannot be modified.

4.7.2 ISE QC Setup

Under the ISE Setup page, select the ISE QC Setup page as shown in the figure:



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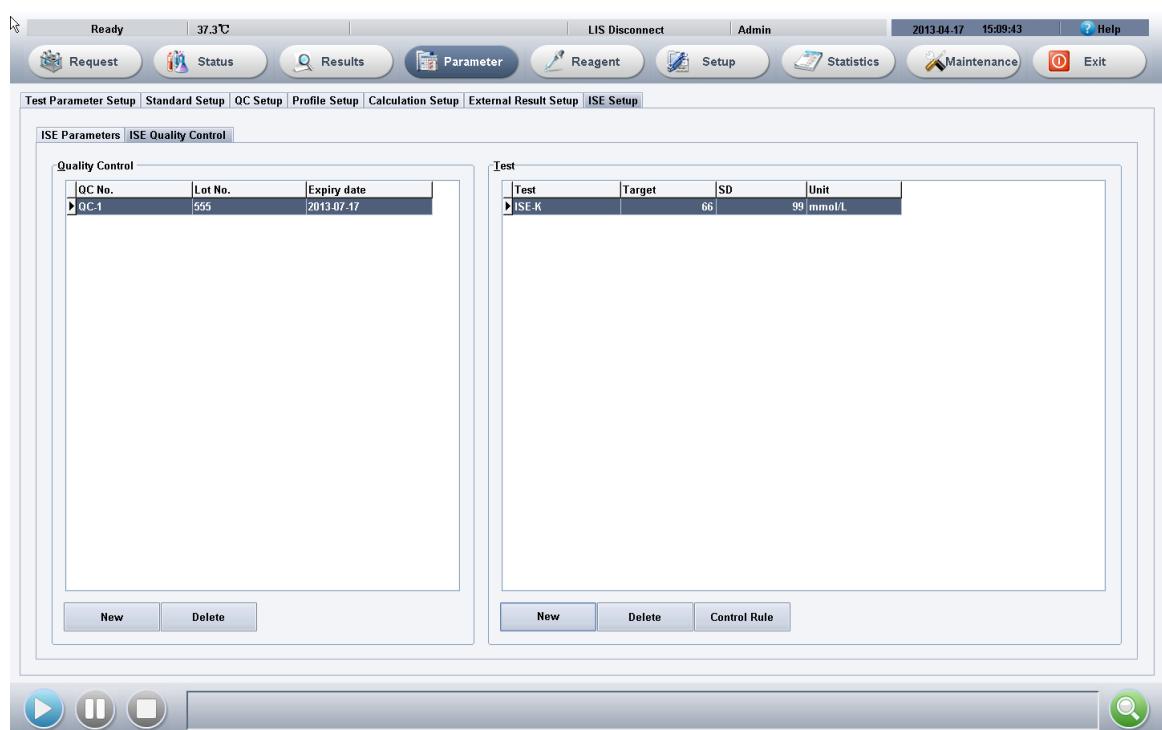


Figure 4-20 ISE QC Setup

4.7.2.1 Add ISE QC

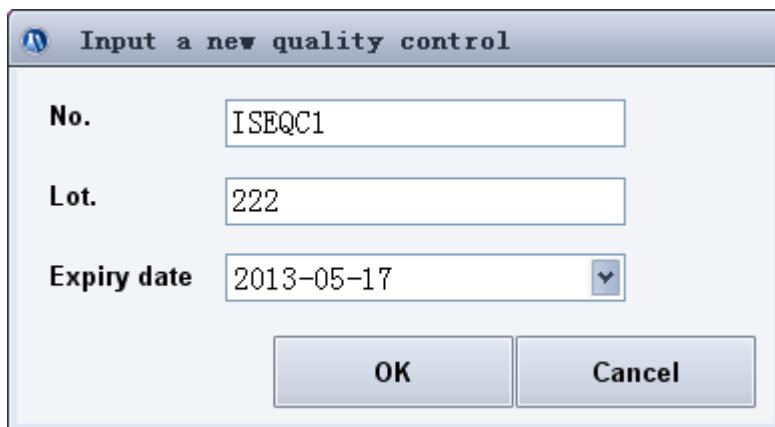


Figure 4-21 Add QC

Click the Add QC button, input the Number, Batch Number and Expiry Date on the screen that appears, and click OK to save the setting. Add the QC items included for the QC substance in turn.

4.7.2.2 Delete ISE QC

Select the QC substance to be deleted from the QC substance list and click the Delete QC button.



4.7.2.3 Add ISE QC Item

The screenshot shows a software interface titled "ISEQC1Input a new quality control". On the left, a vertical list displays three items: "ISE-K" (selected), "ISE-Na", and "ISE-Cl". Below this list is a large empty rectangular area. At the bottom of the window, there is a horizontal row of four buttons labeled "Test", "Target", "SD", and "Unit". Under "Test", "ISE-K" is selected. Under "Target", the value "55" is entered into a text box. Under "SD", the value "66" is entered into a text box. Under "Unit", the unit "mmol/L" is selected. To the right of these fields are two buttons: "Save" and "Cancel".

Figure 4-22 Add QC Item

Specify a QC substance and click the Add Item button. Select Add or the QC item to be modified on the screen that appears, input the target value and SD, and click the Save button.

4.7.2.4 Delete ISE QC Item

Select a QC substance from the QC substance list, and the QC items included will be displayed on the list on the right side. Select the QC item to be deleted and click the Delete Item button.

4.7.2.5 Set ISE QC Item

Select a QC substance from the QC substance list, and the QC items included will be displayed on the list on the right side. Select the item for which you want to set the QC rule and click the QC Rule button to enter the screen as shown in the figure:

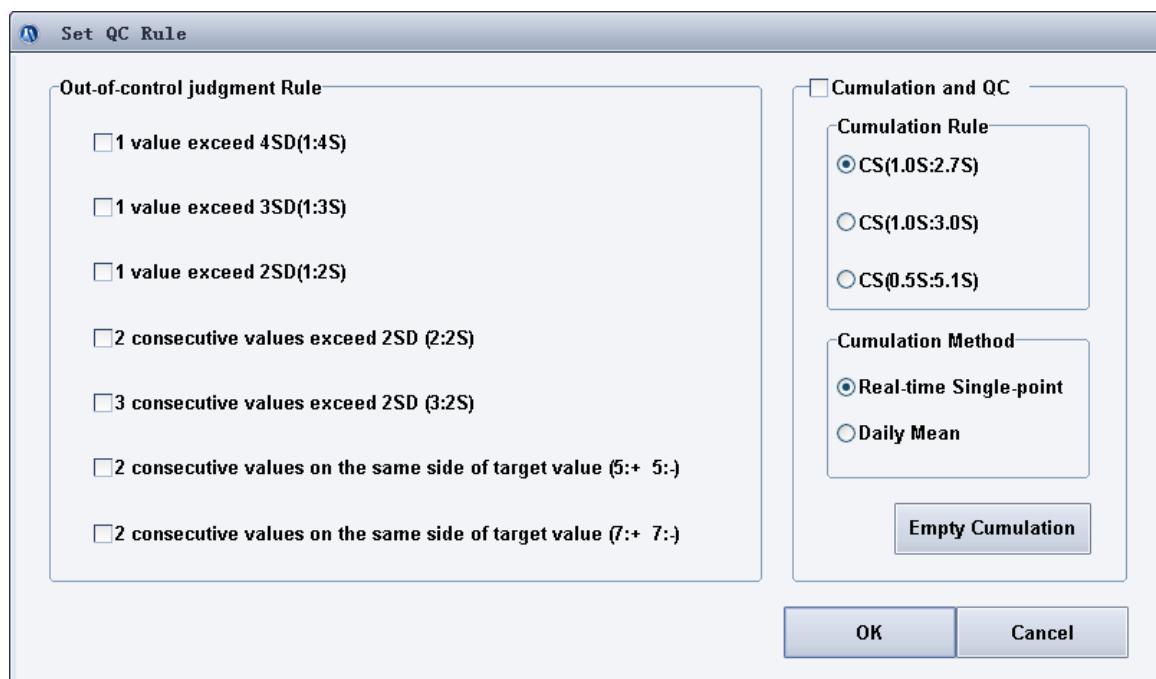


Figure 4-23 QC Rule Setup

- **Westgard Multi-rule QC:** Select the QC warning rule for the item from the 7 rules and click the OK button to save the selection.
- **Cumulation and QC:** Whether the cumulation and rule are used. Select it to cumulate the QC substance and make rule judgment.
- **Cumulation Rule:** To set the QC rule for cumulative sum, such as CS(1.0S:2.7S), in which, 1.0S is the threshold K that starts cumulation and calculation, and 2.7S is the QC limit H.
- **Cumulation Method:** For daily QC chart, Real-time Single-point Cumulation means the cumulative data are the actual results of each test; Daily Mean Cumulation means the cumulative data are the mean of test results of every day.
- **Empty Cumulative Sum:** After calibration and correction of the out-of-control instrument, click the Empty Cumulative Sum button to restart cumulation and QC. After the cumulative sum is emptied, the current value of cumulative sum is 0.



Chapter 5 Reagent Setup

5.1 Reagent View

Function Brief: To view the reagent information corresponding to the test item.

Click Reagent Setup in the main menu to enter the Reagent Setup page as shown in the figure:

The screenshot shows the Reagent View interface. At the top is a toolbar with buttons for Request, Status, Results, Parameter, Reagent, Setup, Statistics, Maintenance, and Exit. The date and time are displayed as 2013.05.17 10:15:43. Below the toolbar is a table titled "By Position" with columns: Position, Test, Type, Volume(ml), Bottle Type, Barcode, Batch No., Bottle No., and Expiry Date. The table lists positions from 58 to 80. Positions 79 and 80 are highlighted in blue. Below the table are several input fields: Position (79), Test (Solution), Type (R1), Volume(ml) (79), Bottle Type (79 ml), Barcode, Batch No., and Expiry Date (2014.05.17). There are also buttons for Save, Delete, Delete All, Check, and Scan. At the bottom are playback controls (Play, Stop, Pause) and a search icon.

Figure 5-1 Reagent View

Two virtual reagent trays can be set in the system. Select “View by Position” or “View by Item” to view the reagent list in different display ways.

5.1.1 Related Information in Reagent View

- **Reagent Tray:** The virtual reagent tray where the reagent is.
- **Reagent Position:** The position of the reagent on the reagent tray.
- **Item Name:** To set the name of the item corresponding to the reagent.
- **Reagent Type:** The type of the reagent corresponding to the item, including “R1”, “R2”, “R3”, and “R4”;
- **Minimal Volume of Reagent:** To manually input the minimal volume of reagent or use the Minimal Volume Detection function to detect the minimal volume of reagent after setting the type of reagent bottle and saving the setting.
- **Bottle Type:** The type of the reagent bottle. Options include the option information set in Data Dictionary;
- **Reagent Barcode:** The barcode information on the reagent bottle which can be input manually or obtained with the barcode scanner.



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- **Reagent Batch Number:** The batch number of the reagent which is the identification to determine the batch leaving factory.
- **Expiry Date of Reagent:** The expiry date of the reagent. When the expiry date of the reagent has passed, the “Reagent Setup” and “Test Status – Reagent Tray” screens will prompt you with yellow.
- **Volume Used Each Time:** To display the volume of the reagent used in each test of the set item.
- **No. of Items Tested with Minimal Volume:** The number of items that can be tested with the minimal volume of reagent calculated according to “Minimal Volume of Reagent” and “Volume Used Each Time”.

5.2 Reagent Setup

Function Brief: To specify reagent positions and other reagent information for test items.

Enter the Reagent Setup screen, and select “View by Position” or “View by Item” to view the reagent list in different display ways, as shown in the figure:

The screenshot shows a software application window titled "Reagent Setup". The top menu bar includes "Ready", "36.0°C", "LIS Disconnect", "Admin", "2013.05.17 10:15:43", "Help", "Request", "Status", "Results", "Parameter", "Reagent", "Setup", "Statistics", "Maintenance", and "Exit". A dropdown menu "RD01" is open. Below the menu is a toolbar with buttons for "By Position" and "By Test". The main area contains a table with columns: Position, Test, Type, Volume(ml), Bottle Type, Barcode, Batch No., Bottle No., and Expiry Date. Rows 58 through 78 are empty. Row 79 is highlighted in blue, showing values: Test = Solution, Type = R1, Volume(ml) = 79, Bottle Type = 79 ml, Barcode = (empty), Batch No. = (empty), and Expiry Date = 2014.05.17. Row 80 shows Water as the test, R1 as the type, and 79 as the volume. At the bottom of the table are input fields for "Position", "Test", "Type", "Volume(ml)", "Bottle Type", "Barcode", "Batch No.", and "Expiry Date". Below these fields are buttons for "Save", "Delete", "Delete All", "Check", and "Scan". A status message "Used Volume(ml): No. of Items tested with Minimal Volume:" is displayed. The bottom of the window features standard operating system controls (Minimize, Maximize, Close) and a search icon.

Figure 5-2 Reagent Setup

5.2.1 Set and Modify Reagent Information

Select an item, set the related reagent information, and click the Save button.



Caution: The reagent positions 79 and 80 are used for cleaning solution and deionized water respectively. Other reagents are prohibited.

5.2.2 Delete Reagent Information

Select an item and click the Delete button to delete the reagent information of the item. Click the Delete All button to delete the reagent information of all items.

5.3 Detection of Minimal Volume of Reagent

Function Brief: To detect the minimal volume of reagent corresponding to the reagent position on the reagent tray.

The minimal volume of reagent can be detected only when the system is ready. Click the Minimal Volume Detection button to pop up the Minimal Volume Detection dialogue box as shown in the figure:



Figure 5-3 Minimal Volume Detection

- **Detect the minimal volume of reagent at the selected position:** Detect the minimal volume of reagent at the selected position in the reagent list for the current reagent tray. If no reagent information is set at this position, it cannot be detected;
- **Detect the minimal volume of reagent of all set reagents:** Detect the minimal volume of all set reagents in the current reagent tray.
- **Detect the minimal volume of reagent of set reagents in the specified range:** Detect the minimal volume of set reagents in the specified range in the current reagent tray.



Caution: Before reagent detection, input and save the Bottle Type information corresponding to the reagent positions first. Otherwise detection of minimal volume of reagent is impossible.

5.4 Reagent Scanning

Function Brief: To scan the reagent barcode corresponding to the reagent position in the reagent tray to obtain reagent information.

If no reagent barcode system is installed in the instrument, the Reagent Scanning button is disabled. Only when the reagent barcode scanning system has been installed in the instrument, “Apply Reagent Barcode” is ticked in the barcode setup, and the system is ready, can the reagent barcode be scanned. Click the Reagent Scanning button to pop up the Reagent Scanning dialogue box as shown in the figure:



Figure 5-4 Reagent Scanning

- **Scan all positions:** To scan all positions on the current reagent tray.
- **Scan the specified position range:** You can input the start and end reagent positions, and the system will scan the specified reagent position range. The “Scan the specified position range” radio must be selected before you can input the start and end positions. When the input is finished, the end reagent position must be greater than the start reagent position.



Caution: When any position cannot be scanned normally during the scanning of reagent barcode, view the prompt message at the bottom of the screen to inquire the abnormal reagent position and the cause of scanning failure.

Chapter 6 System Setup

The system parameters of LIDA 500 Automated Chemistry Analyzer have been initialized when it leaves factory. When the machine is started for the first time, what you see on the screen are all system defaults. In order to guarantee the security of product setup and data and meet different needs in actual application, the privilege levels for common users and administrator can be set for system setup.

6.1 System Control Parameter

Function Brief: Basic parameter setup, automatic retest setup, system temperature and default input method.

Click System Setup in the main menu to enter the System Setup page as shown in Figure 6-1:



Figure 6-1 System Control Parameter Setup

6.1.1 Basic Parameter Setup

- **Wait for the light source to become stable:** To set whether to wait for the light source to become stable after the machine is started;
- **Wait for temperature to become stable:** To set whether to wait for temperature to become stable after the machine is started;
- **Do a retest automatically when the test fails:** To set whether to do a retest automatically when the test fails (for example, in case of collision of the sample probe or reagent probe);



- **Automatic Sleep Time:** To set the automatic sleep time. As long as the idle time of the system exceeds the set time, the system will enter the sleep mode automatically. In the sleep mode, the light source protection function will be activated. To use the machine again, execute the Awake operation;
- **Automatic QC Setup:** To set the interval of QC. 0 indicates no automatic QC is conducted;
- **Automatic Calibration Setup:** To set the interval of calibration. 0 indicates no automatic calibration is conducted;
- **Upper Limit of No. of Dirty Cups:** To set the maximum number of dirty test cuvettes when you are prompted to replace the test cuvettes;
- **Alarm Limit of Minimal Volume of Reagent:** To set the minimal volume of reagent when the reagent tray marks the corresponding reagent as “Reagent Insufficient”.

6.1.2 Automatic Retest Setup

To set the retest methods in various cases. The options in the drop-down box are the retest methods that can be set. The related parameters must be set in the item setup for each retest method. The option None indicates that no automatic retest is conducted.

Exceeding Upper Limit of Reference: When the test results exceed the upper limit of the reference range, the system will do a retest for the test with the results exceeding the limit according to the retest method.

- **Nonlinear:** When the calculated linearity is greater than the linear limit set for the item, the system will do a retest for the test with the results exceeding the limit according to the retest method.
- **No Linear Interval:** When the number of photometric points within the substrate exhaust limit is less than 3, the system will do a retest for the test with the results exceeding the limit according to the retest method. It is effective for the kinetics method only.
- **Substrate Exhaust Appears:** When substrate exhaust appears during the reaction, the system will do a retest for the test with the results exceeding the limit according to the retest method. It is effective for the two-point method only.
- **Less than Lower Limit of Reference:** When the test results are less than the lower limit of reference range, the system will do a retest for the test with the results exceeding the limit according to the retest method.
- **Exceeding Upper Limit of Reference:** When the test results exceed the upper limit of reference range, the system will do a retest for the test with the results exceeding the limit according to the retest method.
- **Exceeding Upper Limit of Linear Range:** When the test results exceed the upper limit of linear range set for the item, the system will do a retest for the test with the results exceeding the limit according to the retest method.



- **Less than Lower Limit of Linear Range:** When the test results are less than the lower limit of linear range set for the item, the system will do a retest for the test with the results exceeding the limit according to the retest method.
- **No Calculation Interval:** When the number of photometric points in the linear range is less than 3 during the highly active enzyme inspection, the enzyme linear range expansion function will be activated. In such case, when the number of all photometric points including the delay time is less than 3, the system will do a retest for the test with the results exceeding the limit according to the retest method. It is effective for the kinetics method only.
- **Prozone Check Exceeding Limit:** When prozone appears during the reaction, the system will do a retest for the test with the results exceeding the limit according to the retest method. It is effective for the end-point method only.
- **Exceeding Max. Calibration Reactivity:** When the reactivity tested exceeds the reactivity of the calibration solution of the maximum concentration, the system will do a retest for the test with the results exceeding the limit according to the retest method.
- **Less than Zero Concentration Calibration Solution:** When the reactivity tested is less than the reactivity of the calibration solution of zero concentration, the system will do a retest for the test with the results exceeding the limit according to the retest method.

6.1.3 System Temperature Setup

To set the target temperature when the system is running.

6.2 Printing Setup

Function Brief: To set the title, annotation and printing format of a general report.

Select the Printing Setup page to enter the screen as shown in the figure:



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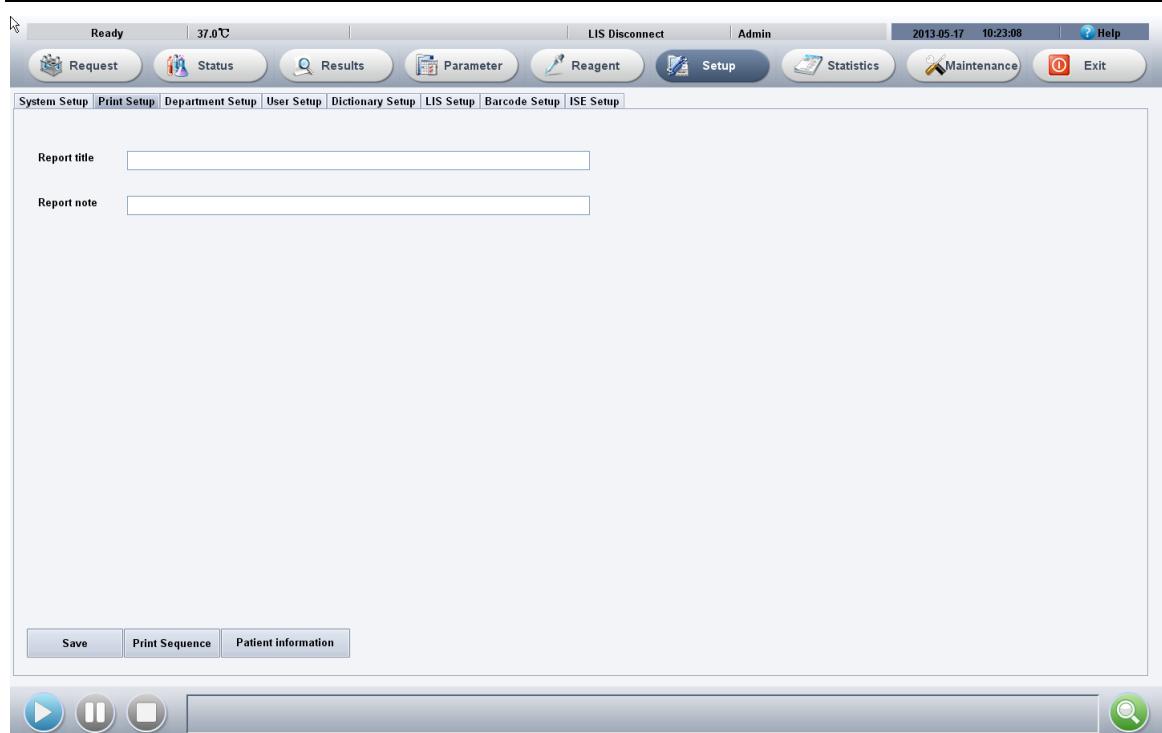


Figure 6-2 Printing Setup

The meanings of the various functions on the Printing Setup page are as follows:

- **Report Title:** Set the title of the patient report, such as “Inspection Report of xxxx Hospital”.
- **Report Annotation:** Set the remark of the patient report, such as “Note: The inspection results are for the sample only”.
- **Printing Sequence Setup:** Set the printing sequence of the items in the general report.
- **Patient Information Setup:** Set the default, printing display setup, and printing sequence setup of patient information newly recorded.



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Set patient information

Set default value

Sample No.	Name	Sex
Clinic No.	Bed No.	Age
Nation	Blood	Sample traits
Department	Sent by	Sent Date
Patient type	Ward	Diagnosis
Charge type	Medicare	Medical No.
Birthday	Country	Nationality
Address	Zip Code	Telephone
Blood No.	Therapy Dept.	Doctor
Barcode	Note	

Set Print Display

<input checked="" type="checkbox"/> Sample No.	<input checked="" type="checkbox"/> Name	<input checked="" type="checkbox"/> Sex	<input checked="" type="checkbox"/> Clinic No.	<input checked="" type="checkbox"/> Bed No.
<input checked="" type="checkbox"/> Age	<input type="checkbox"/> Nation	<input type="checkbox"/> Blood	<input checked="" type="checkbox"/> Sample traits	<input type="checkbox"/> Department
<input type="checkbox"/> Sent by	<input checked="" type="checkbox"/> Sent Date	<input type="checkbox"/> Patient type	<input type="checkbox"/> Ward	<input type="checkbox"/> Diagnosis
<input type="checkbox"/> Charge type	<input type="checkbox"/> Medicare	<input type="checkbox"/> Medical No.	<input type="checkbox"/> Birthday	<input type="checkbox"/> Country
<input type="checkbox"/> Nationality	<input type="checkbox"/> Address	<input type="checkbox"/> Zip Code	<input type="checkbox"/> Telephone	<input type="checkbox"/> Blood No.
<input type="checkbox"/> Therapy Dept.	<input type="checkbox"/> Doctor	<input type="checkbox"/> Barcode	<input type="checkbox"/> Note	<input checked="" type="checkbox"/> Tested by
<input checked="" type="checkbox"/> Checked by	<input checked="" type="checkbox"/> Print time			

Set Print Display

Header Order	Name
1	Name
2	Sex
3	Age
4	Sample No.
5	Sample traits
6	Clinic No.
7	Department
8	Bed No.
9	Sent by
10	Sent date
11	Blood
12	Nation
13	Charge type
14	Patient type
15	Ward
16	Diagnosis
17	Medical No.
18	Address
19	Birthday

Footer Order	Name
1	Print time
2	Tested by
3	Checked by

Buttons: Select All, Clear All, Save, Cancel

Figure 6-3 Patient Information Setup

- **Default Setup:** The default obtained with the default function when details are set for a newly generated or applied patient;
- **Printing Display Setup:** Set the patient information to be displayed in the patient report;
- **Printing Sequence Setup:** Set the printing sequence of the header and footer information in the report.

6.3 Hospital Setup

Function Brief: To set the hospital information and the departments and doctors involved in patient information input.

Select the Hospital Setup page to enter the screen as shown in the figure:



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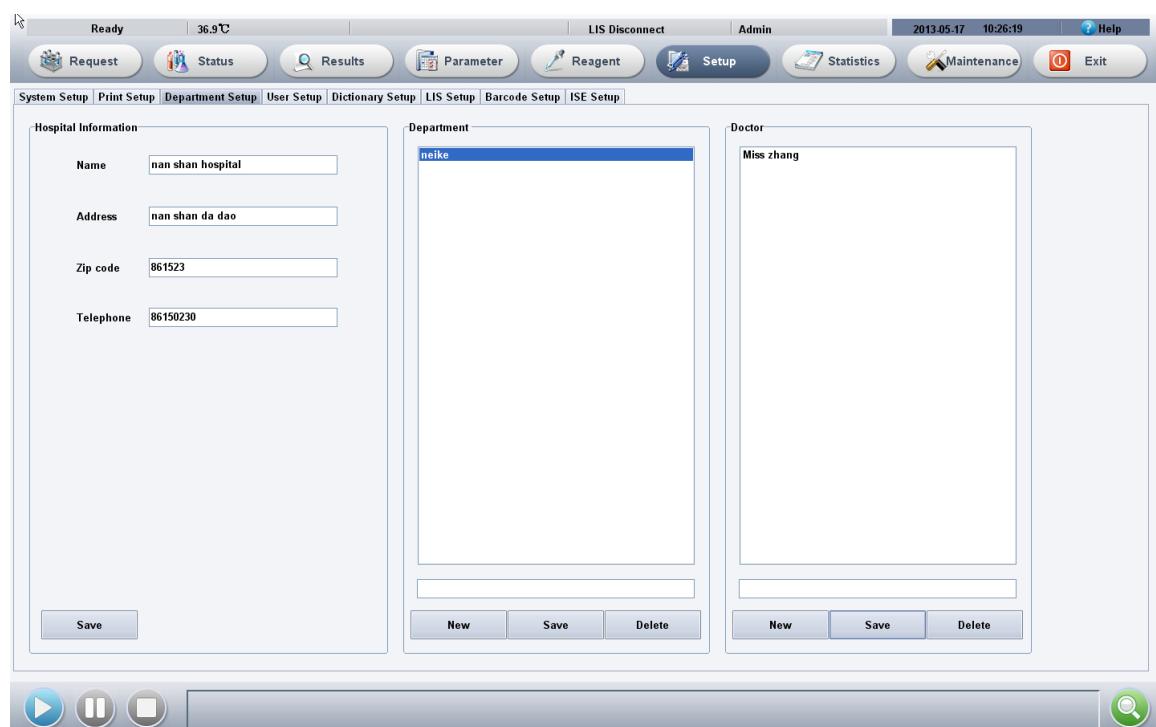


Figure 6-4 Hospital Setup

6.3.1 Hospital Information Setup

Set the information on the hospital: name, mailing address, postal code, and phone number.

Click the Save button.

6.3.2 Department Setup

- **Add Department:** Under the department list, click the Add button, input the department name, and click the Save button.
- **Delete Department:** Select the department to be deleted from the department list and click the Delete button.

6.3.3 Doctor Setup

- **Add Doctor:** Select a department, and all doctors of the department will appear in the doctor list. Under the doctor list, click the Add button, input the doctor name, and click the Save button.
- **Delete Doctor:** Select a department, and all doctors of the department will appear in the doctor list. Select the doctor to be deleted from the doctor list and click the Delete button.



6.4 User Management

Function Brief: To set the privilege and password of a user.

Select the User Management page to enter the screen as shown in the figure:

The screenshot shows the User Management screen of the LIDA 500 software. At the top, there is a toolbar with various icons and buttons: Ready, 36.0°C, LIS Disconnect, Admin, 2013.05.17 10:26:50, Help, Request, Status, Results, Parameter, Reagent, Setup, Statistics, Maintenance, and Exit. Below the toolbar is a navigation bar with links: System Setup, Print Setup, Department Setup, User Setup, Dictionary Setup, LIS Setup, Barcode Setup, and ISE Setup. The main area displays a table of users:

User	Daily Testing	Parameter Setup	Calibration Setup	Control Setup	Result Edit	Result Check	System Setup
Admin	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Below the table, there is a search bar labeled "User" with "Admin" typed in. Under "Access Setup", there is a list of checkboxes: Daily Testing (checked), Parameter Setup (checked), Calibration Setup (checked), Control Setup (checked), Result Edit (checked), Result Check (checked), and System Setup (checked). At the bottom of the screen are buttons for New, Save, Delete, and Password, along with standard window control buttons (Minimize, Maximize, Close) and a magnifying glass icon for search.

Figure 6-5 User Management

6.4.1 Add User

Click the Add button, input the user name in the User Name input box, select and set the privilege, and click the Save button.

6.4.2 Modify User Privilege

Select a user from the list, reselect and set the privilege, and click the Save button.

6.4.3 Delete User Privilege

Select a user from the list and click the Delete button.

Caution: Only the administrator “Admin” can add, delete and modify user privilege.

6.4.4 Modify Password



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Select a user from the list and click the Modify Password button. The screen as shown in the figure will appear:

The screenshot shows a 'Change Password' dialog box. It has four input fields: 'User' (Admin), 'Password' (*****), 'New Password' (*****), and 'Input Again' (empty). Below the fields are two buttons: 'Revise' and 'Cancel'.

User	Admin
Password	*****
New Password	*****
Input Again	

Revise Cancel

Figure 6-6 Modify Password

Input the password and new password, input the new password again for confirmation, and click the Modify Password button.

6.5 Data Dictionary

Function Brief: To set the data frequently used by the operating software, including Unit of Results, Sample Type, etc.

Select the Data Dictionary page to enter the screen as shown in the figure:



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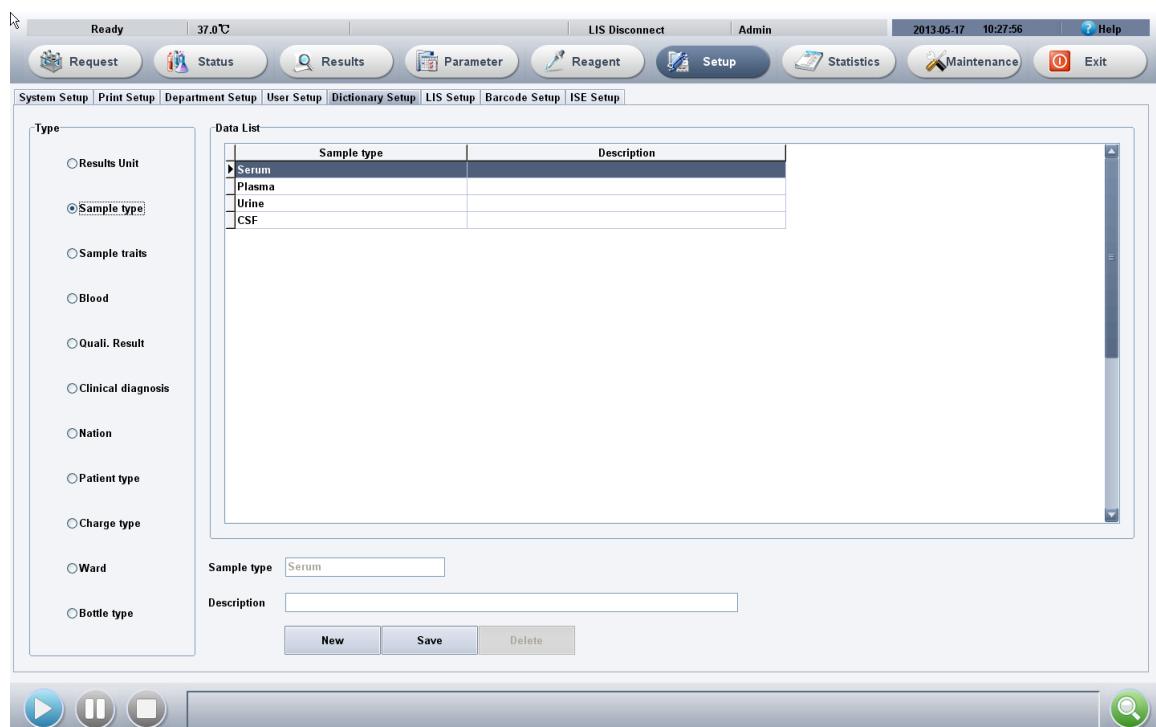


Figure 6-7 Unit Setup

From the type selection box, select the data dictionary entry to be observed and edited, and all data of the selected type will appear in the data list, including Unit of Results, Sample Type, Specimen Character, Blood Type, Qualitative Results, Clinical Diagnosis, Nation, Patient Type, Charge Type, Inpatient Area, and Reagent Bottle Type. The data dictionary entry is character type, with the maximum length of 30 characters.

- **Description:** The description of a data dictionary entry, which indicates the meaning of the data dictionary entry. It can be empty.
- **Add:** Select a data type, click the Add button, add a new entry to the selected data type, and click the Save button;
- **Modify:** Select a data type, edit the related entry, and click the Save button;
- **Delete:** Select a data type, select the entry to be deleted, and click the Delete button.

Caution: On the Data Dictionary screen, the system will pre-input some entries. If Prohibit Deletion or Prohibit Modification is selected for the pre-input entry, deletion or modification will be prohibited.



6.6 LIS Setup

Function Brief: To set the LIS communication mode.

Select the LIS Setup page to enter the screen as shown in the figure:

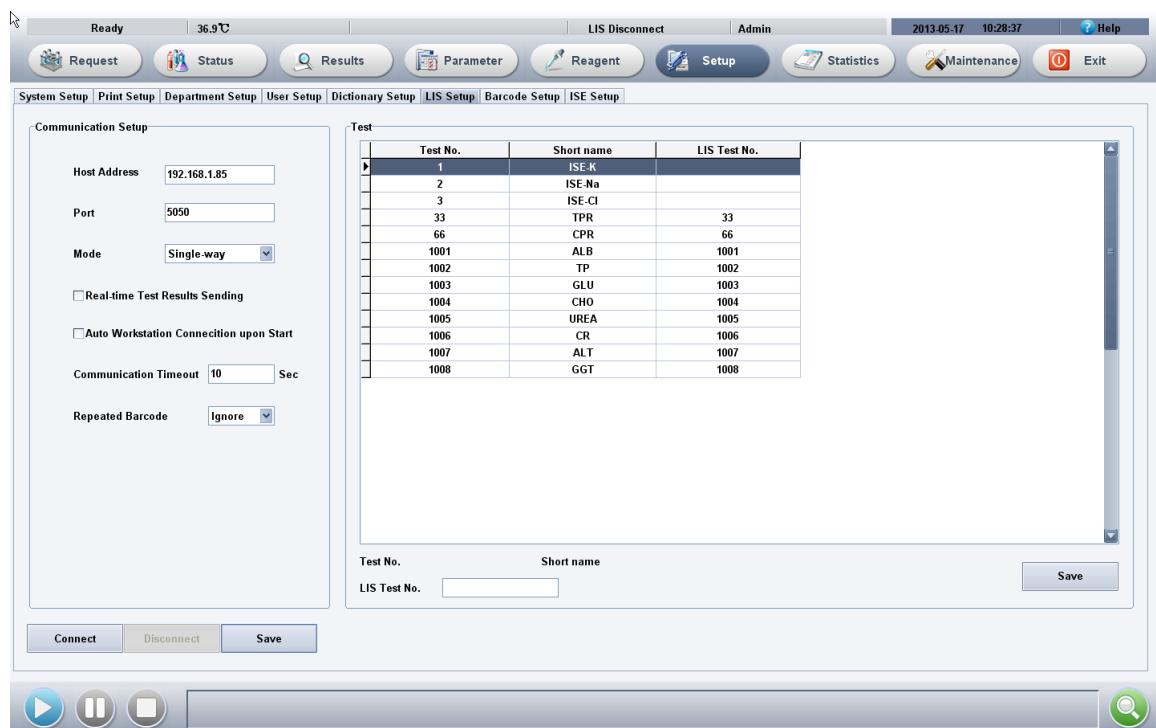


Figure 6-8 LIS Setup

6.6.1 LIS Host Address

Set the IP address of LIS host connected to the system.

6.6.2 LIS Communication Port

The communication port number of LIS host.

6.6.3 LIS Communication Mode

Set the communication modes of the operating software and LIS host, including single-way and two-way.

- **Single-way:** Only test results and other information are sent to the LIS host and no sample application information is obtained from the LIS.
- **Two-way:** Test results and other information are sent to the LIS host and sample application information is obtained from the LIS.

6.6.4 LIS Real-time Test Results Sending



When it is selected, after all tests of each patient sample are finished, the test results will be sent to the LIS host automatically.

6.6.5 Automatic Workstation Connection upon Start

When it is selected, after the operating software is started, the LIS workstation host is connected according to the address and port number of the LIS host automatically.

6.6.6 Communication Timeout Setup

Set the timeout limit for response of the LIS host for obtaining application, sending results, and network connection. Range: 1~200 seconds.

6.6.7 Repeated Sample Barcode Setup

When a sample barcode obtained is the same as an existing one, the later may be treated in three ways:

- **Ignore:** The existing sample will be retained, and the newly obtained sample will be ignored.
- **Overwrite:** No matter whether the original sample has been finished or not, the related information of the original sample will be deleted, and the information of the newly obtained sample will be used.
- **Add:** The existing application items of the original sample will be unchanged, but the items newly applied for the new sample will be added to the original sample.

6.6.8 Setup of Corresponding Items of LIS System and Operating Software

Software

As the item name and number in the LIS system may be different from those in the instrument, in order to correctly match the items during sample application information obtaining and results transmission, the correspondence of item parameters between the LIS system and instrument must be set, with the corresponding code as the link.

From the corresponding item list, select an item and directly edit the code in the corresponding "LIS Item Code" column. The information input is character type, with the length of 0~20 characters, which indicates the code of the item in the LIS host.

6.7 Barcode Setup

Function Brief: To set the work mode, barcode system and coding rule of the sample barcode scanning system and reagent barcode scanning system.



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Select the Barcode Setup page to enter the screen as shown in the figure:

The screenshot shows the 'Barcode Setup' page of the LIDA 500 software. The interface is divided into two main sections: 'Sample Barcode Setup' on the left and 'Reagent Barcode Setup' on the right. Each section contains a 'Format' table and a 'Barcode System' table.

Sample Barcode Setup:

- Format:** Includes fields for Median, Start, and End, and dropdowns for Sample No., Sample type, Profile No., and Container type.
- Barcode System:** Contains checkboxes for CODE128 (checked), CODE39, CODABAR, UPC/EAN, and CODE93 (checked).
- Sample Information Source:** A dropdown menu set to 'No'.
- Buttons:** 'Save' button at the bottom.

Reagent Barcode Setup:

- Format:** Includes fields for Median, Start, and End, and dropdowns for Test No., Test name, Reagent type, Bottle type, Lot No., and Expiry Date.
- Barcode System:** Contains checkboxes for CODE128 (checked), CODE39, CODABAR, UPC/EAN, and CODE93 (checked).
- Barcode:** A dropdown menu set to 'Reagent Barcode'.

Figure 6-9 Barcode Setup

6.7.1 Apply Sample Barcode

The sample barcode is applied in the operating system. All buttons related to the sample barcode function are active.

6.7.2 Sample Information Source Setup

Select how to obtain the related sample information after the system scans the sample barcode.

- **None:** The system will not obtain sample information. When there is no setup information in the worksheet related to the scanning position and scanned barcode, the default sample information will be used.
- **Obtain from LIS System:** When the barcode is scanned and the system has been connected to the LIS host, the system will obtain sample information from the LIS system on a real-time basis.
- **Obtain from Sample Barcode:** After scanning the barcode, the system will automatically obtain the sample information according to its constituent fields. When the information is being obtained, any invalid constituent information will cause failure of sample barcode scanning. Take the profile number as an example: all profile numbers of barcodes must be profile numbers predefined in the operating software.



6.7.3 Sample Barcode Format Setup

The sample barcode scanned or manually input must have the sample barcode format set before it is regarded as a sample barcode of the system. Otherwise, it will be judged as a wrong barcode. The barcode scanned will be discarded and will not be saved. The check bit is not counted in the number of digits of a barcode. Do not input the check bit when manually inputting a barcode.

- **Total No. of Digits:** The total number of digits of a sample barcode. Options: 10-30.
- **Test Type:** Regular and Stat. Options: 0 or 1 digit.
- **Submission Date:** Year-Month-Day. Options: 0, 6 or 8 digits.
- **Sample No.:** The number of the sample. Options: 0-10 digits.
- **Sample Type:** The sample type defined in the data dictionary (for example, blood serum: 1; blood plasma: 2, etc.) Options: 0 or 1 digit.
- **Profile No.:** The number of the item profile. Test items are applied with profile numbers. Options: 0-5 digits.
- **Container Type:** The specification of a sample container. Options: 0 or 1 digit.
- **Default of sample barcode information:**

Name	Default
Test Type	Regular
Submission Date	Current day
Sample No.	Generated automatically
Sample Type	Blood serum
Profile No.	Empty
Container Type	Standard tube

Caution: During information obtaining, the system will first obtain sample information from the sample barcode source; detect whether there is setup information of the barcode in the current worksheet and obtain the information if any; detect whether there is setup information at the scanning position and obtain the information if any. If no necessary sample information is obtained, the system will fill the missing necessary information with the default. If the information obtained is repeated, the system will save the information obtained first and then clear the repeated information.

6.7.4 Sample Barcode System Setup



- **Barcode System:** Set the category of sample barcode currently used, including Code128, Code39, Codabar, UPC/EAN, and Code93.
- **Check:** Set whether to check the sample barcode information.

6.7.5 Apply Reagent Barcode

Application of reagent barcodes in the operating system. All buttons related to the reagent barcode function are active.

6.7.6 Reagent Barcode Format Setup

The reagent barcode scanned or manually input must have the reagent barcode format set before it is regarded as a reagent barcode of the system. Otherwise, the scanning will fail. The barcode scanned will be discarded and will not be saved. The check bit is not counted in the number of digits of a barcode. Do not input the check bit when manually inputting a barcode.

When scanning a reagent barcode, the item information of the barcode must be consistent with the item number or item name (abbreviation) of the system, otherwise, the scanning will fail. In barcode setup, either the item number or item name must be input. If both are input, make sure the item number corresponds to the item name, otherwise the scanning will fail.

Caution: If "Apply Reagent Barcode" is selected, when the system is scanning a reagent, it will obtain reagent information from the reagent barcode.

- **Total No. of Digits:** The total number of digits of a reagent barcode. Options: 10-30.
- **Item Number:** The number of the tested item. Options: 0-5 digits.
- **Item Name:** The name of the item. Options: 0-10 digits.
- **Reagent Type:** R1/R2/R3/R4. Option: 1 digit.
- **Bottle No.:** The number of the reagent bottle. Options: 0 or 3-5 digits.
- **Bottle Spec.:** The bottle specification defined in the data dictionary. Options: 0 or 1 digit.
- **Batch No.:** The production batch number of the reagent. Options: 0 or 3~5 digits.
- **Expiry Date:** Year-Month or Year-Month-Day. Options: 0, 4, 6 or 8 digits.
- **Default of reagent barcode information:**

Name	Default
Item Number	None
Item Name	None
Reagent Type	R1
Bottle Type	25ml
Batch No.	Empty



	Expiry Date	Current day

Caution: During information obtaining, the system will first obtain reagent information from the reagent barcode information; detect whether there is setup information of the barcode in the current reagent tray and obtain the information if any; detect whether there is setup information at the scanning position and obtain the information if any. If no necessary reagent information is obtained, the system will fill the missing necessary information (except the item name and item number of the reagent) with the default. If the information obtained is repeated, the system will save the information obtained first and then clear the repeated information.

6.7.7 Reagent Barcode System Setup

- **Barcode System:** Set the category of reagent barcode currently used, including Code128, Code39, Codabar, UPC/EAN, and Code93.
- **Check:** Set whether to check the reagent barcode information.

6.8 ISE Control

Function Brief: To set the ISE control information in daily tests, including ISE calibration and cleaning mode.

Select the ISE Control page to enter the screen as shown in the figure:



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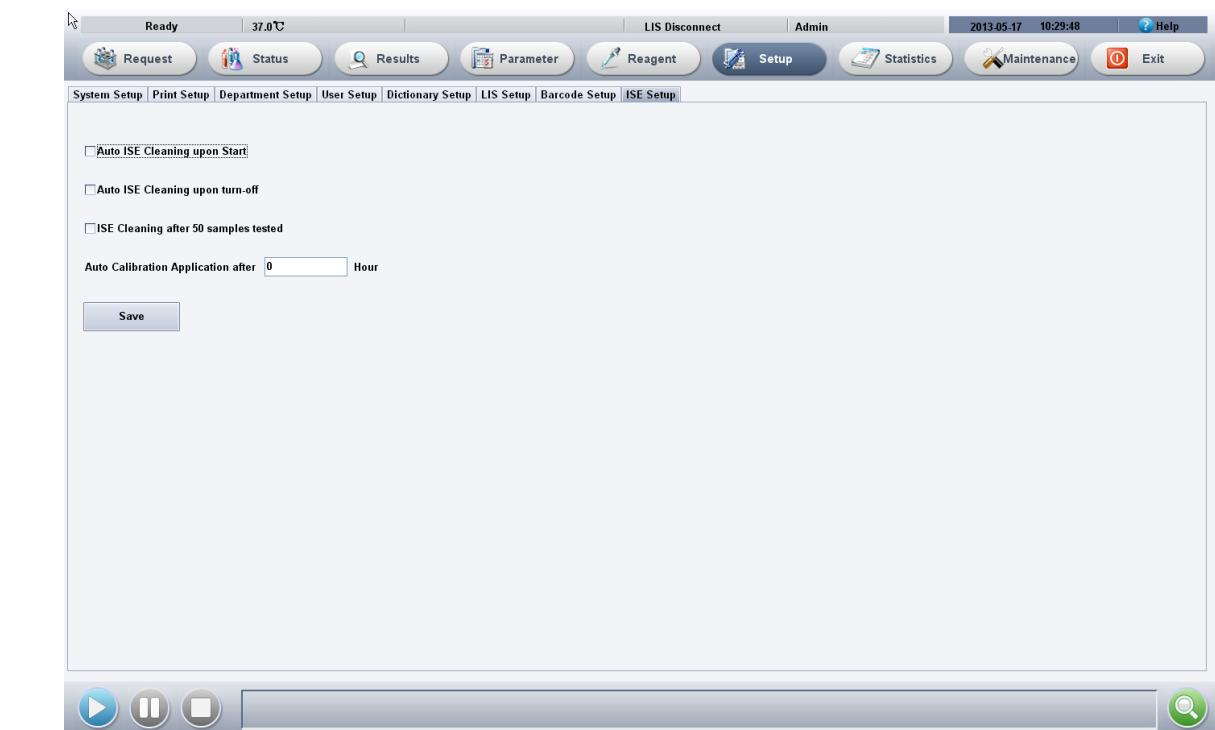


Figure 6-10 ISE Setup

The meanings of the setup information on the ISE Setup page are as follows:

- **Automatic ISE Cleaning upon Start:** If it is selected, the ISE will be cleaned automatically when the machine is started.
- **Automatic ISE Cleaning upon Turn-off:** If it is selected, the ISE will be cleaned automatically when the machine is turned off.
- **ISE Cleaning after 50 Samples Tested:** If it is selected, the ISE will be cleaned once automatically after every 50 samples are tested.
- **Automatic Calibration Application after Certain Hours:** The ISE unit conducts an ISE calibration automatically after the set interval. The range of interval is 0-8 hours. 0 indicates no automatic calibration is conducted.



Chapter 7 Test

7.1 Sample Application

Function Brief: To set test items for samples according to the editing of the worksheet.

Click Sample Application in the main menu to enter the Sample Application screen as shown in the figure:

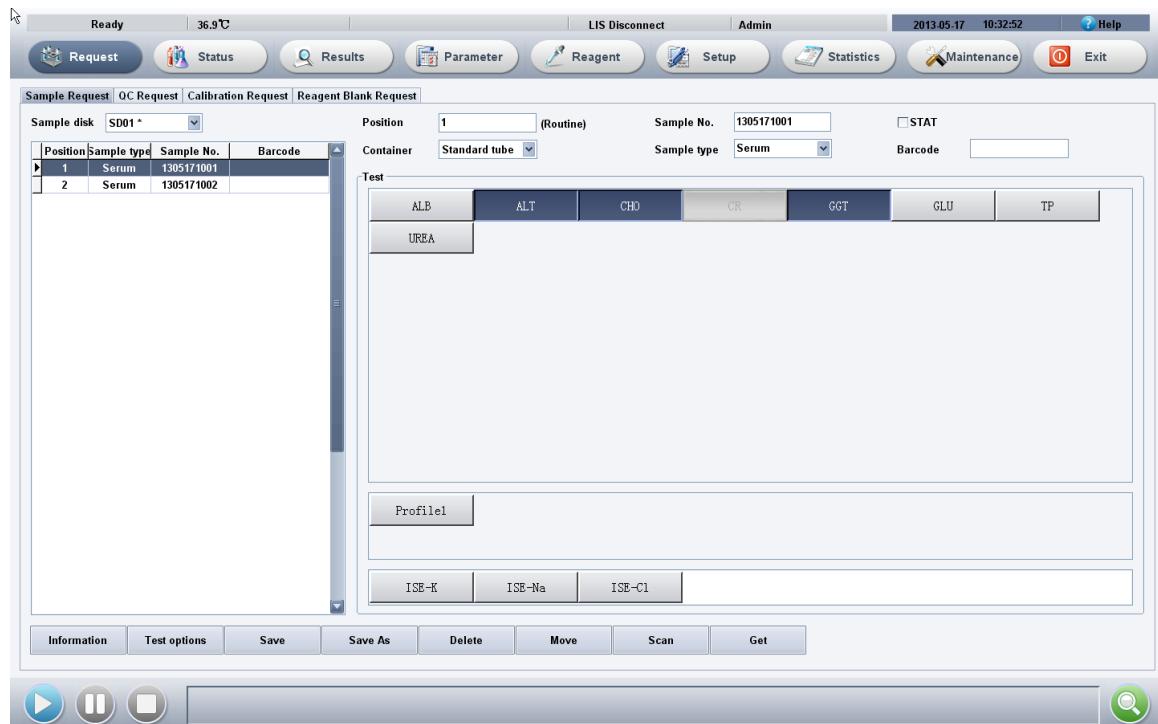


Figure 7-1 Sample Application

7.1.1 Meanings of Setup Parameters in Sample Application

- **Select Worksheet:** The system provides 7 worksheets with the test editable and a temporary sample list. 96 test samples can be input to each worksheet, and total 672 test samples can be input. You can virtualize the 7 worksheets as 7 sample trays. The temporary sample list is mainly used to for sample application for which the test is not conducted for the time being and the samples obtained from the LIS system.
- **Sample Position:** Set the position of a sample in the selected worksheet. The range of editable positions is 1-96. Positions 97-100 cannot be edited, in which, position 97 is for ISE cleaning solution; position 98 is for acid cleaning solution; position 99 is for biochemical analyzer specific cleaning solution; position 100 is for deionized water. If the system applies barcode scanning, the sample positions with the number greater than 100 are barcode



identification positions which can be repositioned through barcode scanning after the barcodes are input and saved.

- **Sample No.:** The maximum length of a sample number is 15 digits. The sample number can be input manually or generated by the system automatically. If the worksheet has not any sample, the system will generate 10-digit sample numbers automatically, including 2-digit year number + 2-digit month number + 2-digit day number + 1-digit worksheet number +3-digit serial number, such as 1109232001. If the worksheet has samples saved, the system will generate new sample numbers automatically according to the format of the existing sample number.
-

Caution: No matter whether the sample number is input manually or generated by the system automatically, it must have at least three digits and the last three digits must be figures.

- **Sample Container:** The type of sample container used, including Standard Tube and Small Cup.
- **Sample Type:** The options in the sample type are the options set in the data dictionary.
- **Sample Barcode:** The barcode information of the sample which can be obtained with the barcode scanning system or input manually.
- **Test Item:** The test item table includes all items that can be tested on the instrument, including, from top to bottom, items set in Item Setup, item profile, and ISE items. For items that cannot be applied for due to certain reason, this option will be disabled. When an item profile is selected, the corresponding items will all be selected. When an item of the item profile in the item list is cancelled, the profile will also be deselected. As long as an item in the item profile is disabled, the profile will be disabled. The ISE item list is displayed only when the ISE module has been installed in the instrument, otherwise, the ISE item list is invisible.

7.1.2 Sample Information

Click the Sample Information button to pop up the Sample Information dialogue box where the sample information is displayed and can be edited, as shown in the figure:



Sample Information

Sample No.	1305171001	Name		Sex	Unknown
Clinic No.		Bed No.		Age	
Nation		Blood		Traits	
Department		Sent by		Date	2013-05-17

Buttons: Show Detail, Get Default, Save, Cancel

Figure 7-2 Sample Application

- **Display Details:** Display all information on the sample for you to view and edit.
- **Obtain Default:** Obtain default information according to the default set in “Setup -> Printing Setup”. For details, see Printing Setup.
- **Save:** Save the set information and return to the previous screen.
- **Back:** Return to the previous screen without saving the information.

7.1.3 Item Options

Click the Item Options button to pop up the Item Options dialogue box where the details of the test items related to the sample are displayed. The default information of item options is filled in according to the item parameter setup and can be edited by you, as shown in the figure:



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Item option

Set All test

<input type="checkbox"/> Sample blank	Not test	<input type="button" value="▼"/>	<input type="checkbox"/> Repeat	1	<input type="button" value="OK"/>
Test	Sample Volume	Test Volume	Dilution Volume	Sample blank	Dilution Ratio
ALT	Standard	20	0	Not test	1
CHO	Standard	3	0	Not test	1
GGT	Standard	20	0	Not test	1

ALT

Sample Volume	Standard	<input type="button" value="▼"/>	Test Volume	20	ul	Dilution Volume	0	ul	
Sample blank	Not test	<input type="button" value="▼"/>	Dilution Ratio	1	<input type="button" value="Repeat"/>	1	<input type="button" value="Next"/>	<input type="button" value="Up"/>	<input type="button" value="Cancel"/>

Figure 7-3 Item Options

The default settings can be modified on the Item Options Setup screen. The meanings of the test information are as follows:

- **Sample Size:** Set the sample size mode in item testing, including Standard, Dilution, Increment, Increment Dilution, Decrement, and Decrement Dilution (displayed only when the related test information has been set in Item Parameter Setup). The system will read the test sample size, dilution sample size and dilution ratio according to the selected sample size mode. You can further adjust the above information according to the specific needs.
- **Test Sample Size:** Specify the volume of sample used in a test. The default is obtained according to Sample Size. You can further edit it as needed.
- **Dilution Sample Size:** Specify the volume of dilution sample used in a dilution test. The default is obtained according to Sample Size. You can further edit it as needed.
- **Sample Blank:** You may select to test or not to test sample blank. The default is "Not To



Test". You can further edit it as needed.

- **Dilution Ratio:** Set the dilution ratio of sample in a test. The default is obtained according to Sample Size. You can further edit it as needed. Input "10" to indicate 10 times dilution, i.e. 1 part of sample + 9 parts of diluent. Input "1" to indicate no dilution.
- **Repeat Count:** Set the times of repetition of a sample test. The default is 1. You can further edit it as needed.
- **Set All Items:** To select the same sample blank or set the same repeat count for all items applied for the sample, tick and set the corresponding options, and click OK to realize batch setup.

7.1.4 Move Sample

Click the Move button to pop up the Move Sample dialogue box. It is used to change the position of the sample on the sample tray or move it to another worksheet, as shown in the figure:



Figure 7-4 Move Sample

- **Source Worksheet:** Select the worksheet where the sample to be moved is located.
- **Sample Position:** Select the position of the sample to be moved. Multiple positions can be input according to the prompt of the system, such as 1-9, 11, and 60.
- **Destination Worksheet:** Select the new worksheet to which the sample is to be moved.
- **Sample Position:** Input the start position in the new worksheet to which the sample is to be



moved. The samples will be inserted to the destination worksheet in turn according to the start position.

7.1.5 Scan

Click the scan button to pop up the Sample Scanning dialogue box. It is used to scan the sample barcode in the sample tray, as shown in the figure:

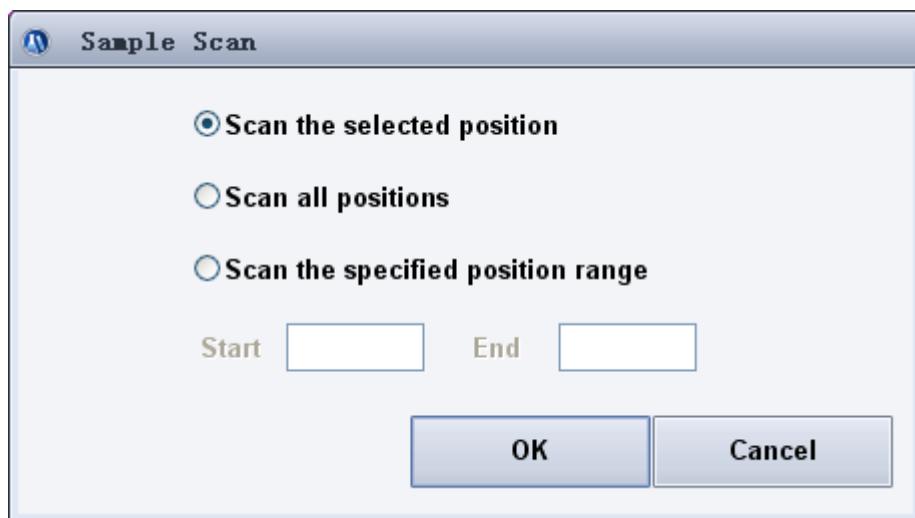


Figure 7-5 Sample Scanning

- **Scan All Positions:** Select “Scan All Positions” and click the OK button, and the system will scan positions 1-96 in the selected worksheet;
- **Scan Specified Position Range:** Select “Scan Specified Position Range”, and the “Start” and “End” fields will be available. The range of input is positions 1-96, and the start position must be less than or equal to the end position. Click OK, and only the sample positions in the range input will be scanned.

After the barcode is scanned, the corresponding sample information will be obtained according to “Sample Information Source” in Barcode Setup. For details, see “Barcode Setup”.

Caution:

- ◆ ***During barcode scanning, when the barcode scanned is the same as one in another worksheet, a prompt message will be given, and the saving of the barcode scanned will be given up.***
-



- ◆ When the barcode scanned is the same as one in the current worksheet, the system will move the repeated barcode in the current worksheet to the current scanning position and save the information obtained according to the barcode.
- ◆ If, during sample barcode scanning, there is any position where scanning is abnormal, please view the prompt message at the bottom of the screen to inquire the abnormal sample position and cause of scanning failure.

7.1.6 Get

"Get" can be operated when the system is ready and has been connected to the LIS host, and the communication mode has been set to Two-way in "LIS Setup". Click the Get button to pop up the Sample Scanning dialogue box. It is used to scan the sample barcode in the sample tray, as shown in the figure:

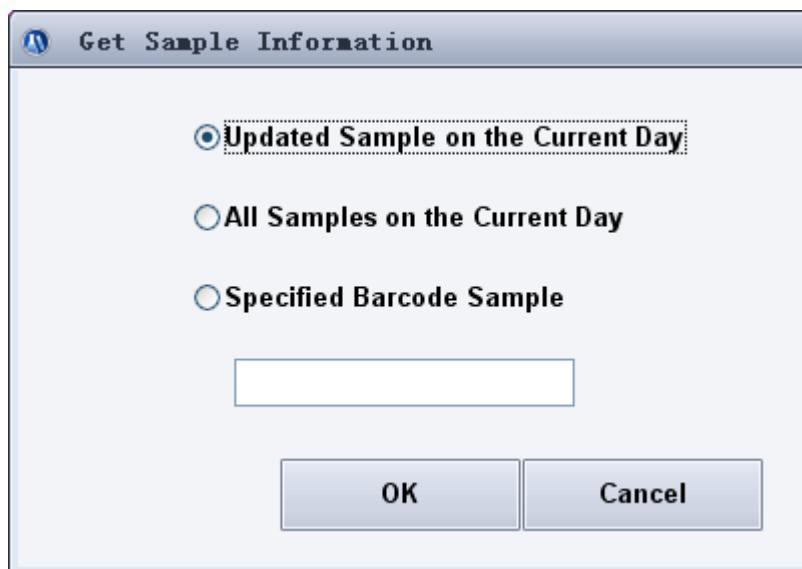


Figure 7-6 Get Sample Information

- **Updated Sample on the Current Day:** The operating software will obtain all sample information that has not been obtained on the current day from the LIS system.
- **All Samples on the Current Day:** The operating software will obtain all sample information on the current day from the LIS system.
- **Specified Barcode Sample:** Select this option, and the sample barcode textbox below it will be available. Input a valid barcode, and the LIS system will retrieve the sample information of the barcode and send it to the operating software.

For the treatment of repeated information, see "LIS Setup" in "System Setup".



7.1.7 Sample Application Process

1) Edit a Single Sample

Step 1: Specify "Sample Position" (input a sample position, and the information corresponding to the sample position will appear);

Step 2: Input the sample number (click the Patient Info button to input the basic patient information corresponding to the sample);

Step 3: Select the test type Regular or Stat;

Step 4: Select the sample cup type Standard Tube or Small Cup;

Step 5: Select the sample type. The options in Sample Type are the options set in Data Dictionary;

Step 6: Select the test items and test profile;

Caution: Items that cannot be applied for due to certain reasons are disabled. When the cursor floats over such items, the reasons why the item cannot be selected will be displayed.

Step 6: Click the Save button;

Step 7: Click the Item Option button to set the specific settings for item testing.

Step 8: Click the Save button to finish a sample application.

Caution: Input any figures among 1-96 at the sample position, and the sample editing information will be displayed automatically. If the sample position has not been defined, the system will generate a new sample number automatically.

2) Batch Editing of Multiple Samples

Step 1: Select an edited sample or edit a new sample;

Step 2: Click the Save As button, and the dialogue box as shown in the figure will appear:

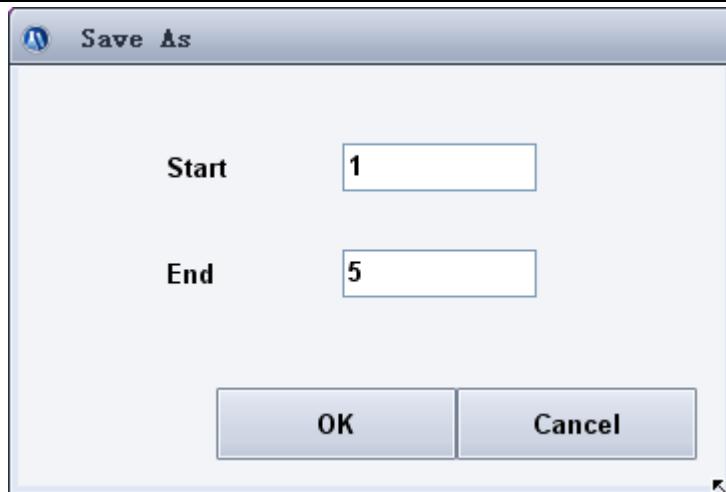


Figure 7-7 Save As

Step 3: Input the start sample position and end sample position, and click the OK button.

Step 4: Finish the batch sample application.

Caution:

- ◆ *In batch sample application, the rule for the system to automatically generate sample numbers increasingly is starting with the sample number input and increasing in turn. For example, when ***018 is input, the sample numbers in batch application are ***018, ***019, ***020...*
 - ◆ *When the application is finished, you can modify it manually.*
-

7.2 QC Application

Function Brief: To edit the QC test information and apply for QC test items for sample testing.

7.2.1 QC Application

Click “Sample Application” in the main menu to enter the sample application screen. Select the QC Application page as shown in the figure:



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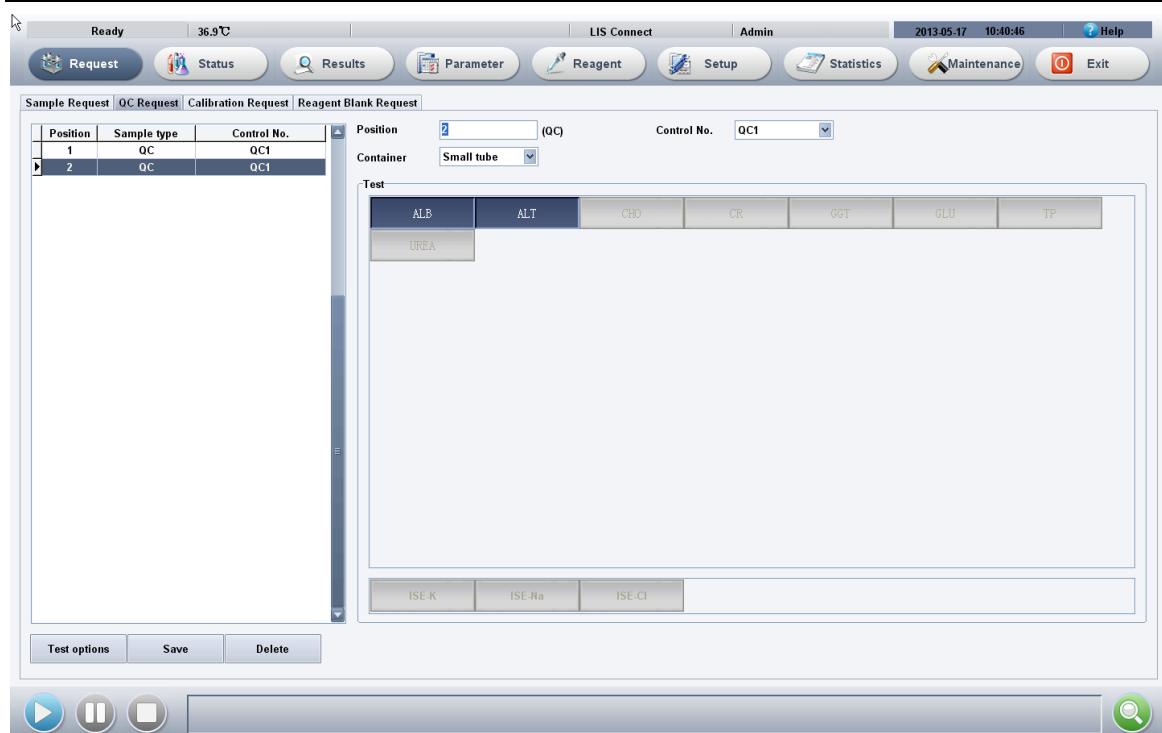


Figure 7-8 QC Application

- **Sample Position:** Set the position of the sample in the selected worksheet. The range of editable positions is 1-96. Positions 97-100 cannot be edited, in which, position 97 is for ISE cleaning solution, position 98 for acid cleaning solution, position 99 for biochemical analyzer specific cleaning solution, and position 100 for deionized water.
- **Sample Container:** The type of sample container used, including Standard Tube and Small Cup.
- **Test Item:** The test item table includes all items that can be tested on the instrument, including items set in Item Setup and ISE items. Items that cannot be applied for due to certain reasons are disabled. The ISE item list is displayed only when the ISE module has been installed in the instrument, otherwise, the list is invisible.

7.2.2 Item Options

Click the Item Options button to pop up the Item Options dialogue box which displays the times of test repetition of QC test items, as shown in the figure:

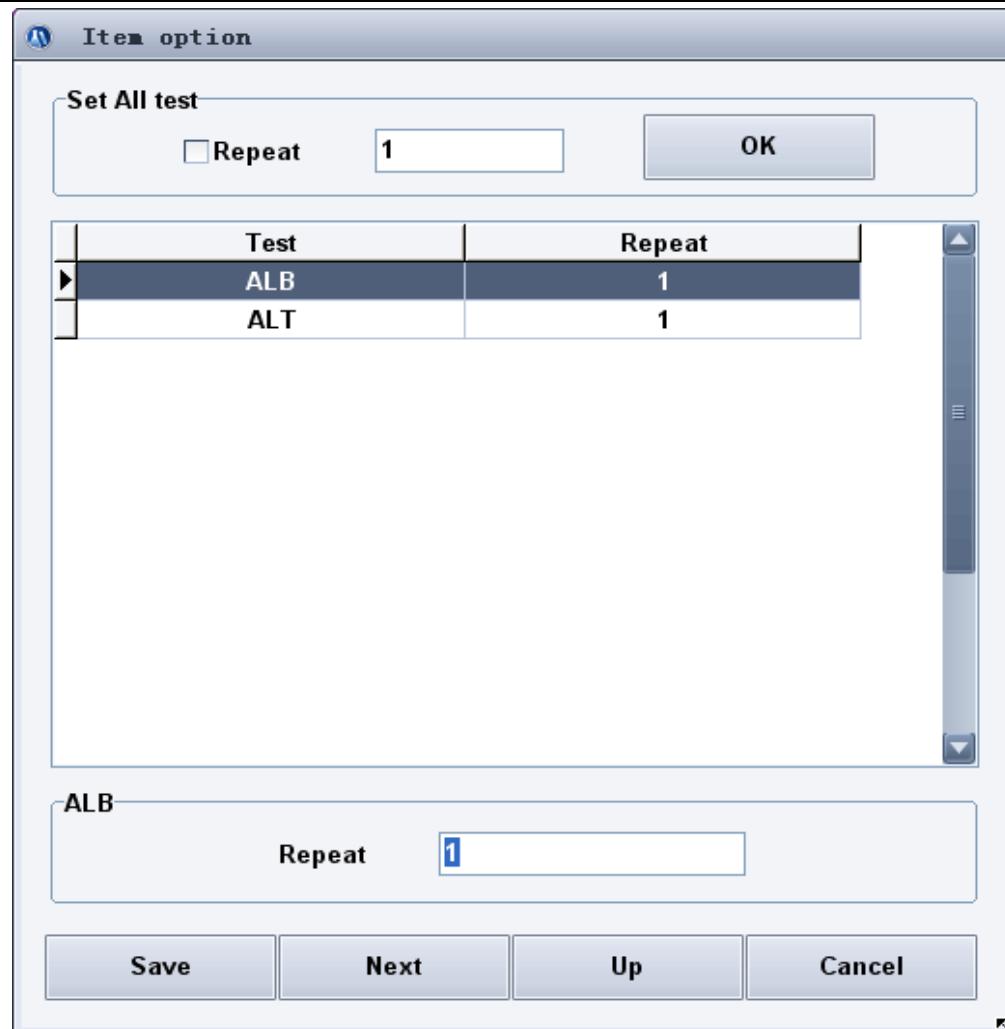


Figure 7-9 Item Options

The default settings can be modified in the Item Options setup screen. The meanings of test information are as follows:

- **Repeat Count:** Set the times of repetition of a QC test. The default is 1. You can further edit it as needed.
- **Save:** Save the setting and return to the previous screen.
- **Next:** Display the item information of the next QC sample position.
- **Previous:** Display the item information of the previous QC sample position.
- **Back:** Return to the Setup page without saving the setting.

7.2.3 QC Application Process

Step 1: Specify "Sample Position";

Step 2: Select the QC substance number. The optional QC items included in the QC substance will



be displayed in the item list;

Step 3: Select the QC item from the test item list;

Step 4: Click the Save button;

Step 5: Click “Item Options” to set the times of repetition;

Step 6: Finish a QC substance application.

Caution: Items that cannot be applied for due to certain reasons are disabled. When the cursor floats over such items, the reasons why the item cannot be selected will be displayed. ISE items can be applied for only when the ISE QC parameters are set in “ISE Setup”.

7.3 Standard Application

Function Brief: To edit the standard test information and apply for standard test items for sample testing.

7.3.1 Standard Application

Click “Sample Application” in the main menu to enter the Sample Application page. Select the Standard Application page, as shown in the figure:



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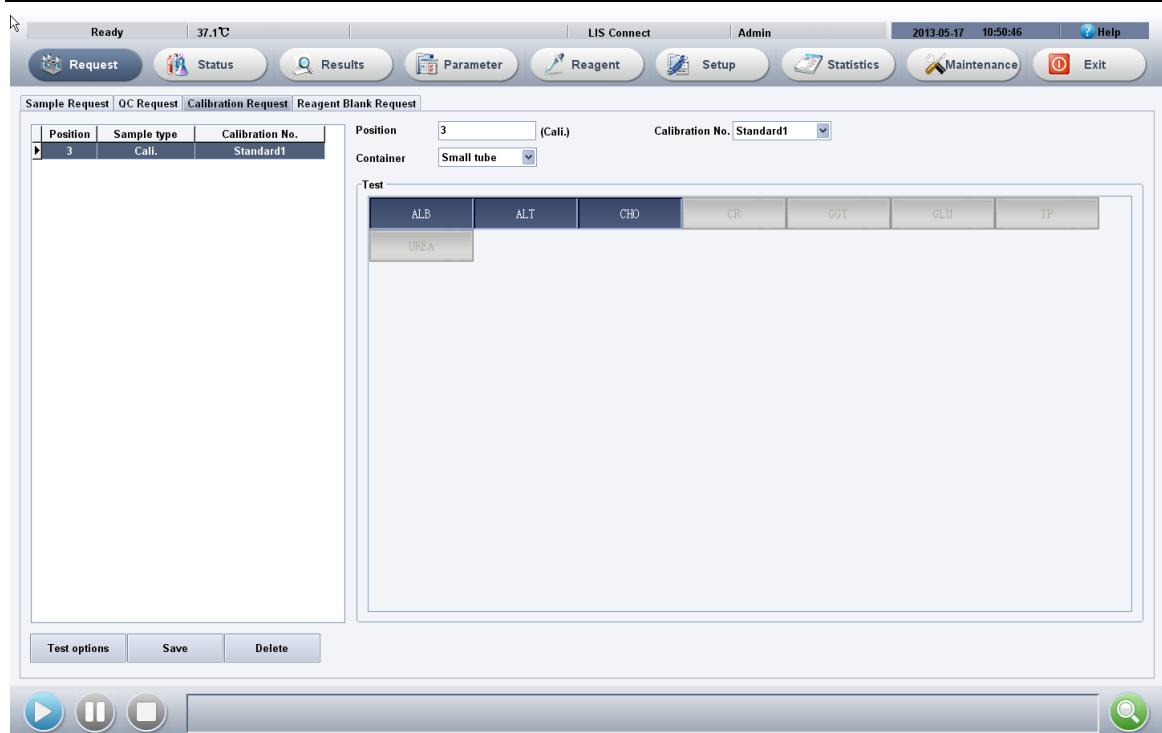
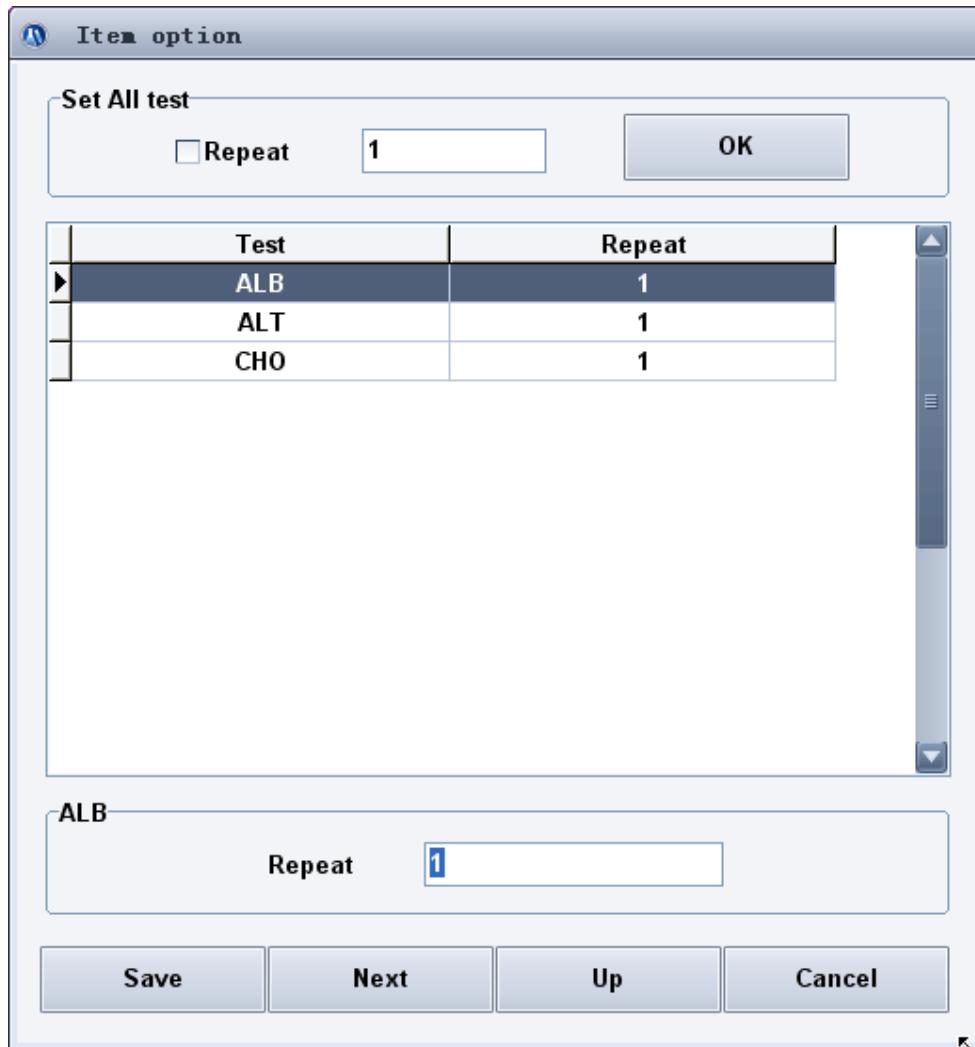


Figure 7-10 Standard Application

- **Sample Position:** Set the position of the sample in the selected worksheet. The range of editable positions is 1-96. Positions 97-100 cannot be edited, in which, position 97 is for ISE cleaning solution, position 98 for acid cleaning solution, position 99 for biochemical analyzer specific cleaning solution, and position 100 for deionized water.
- **Sample Container:** The type of sample container used, including Standard Tube and Small Cup.
- **Test Item:** The test item table includes all items that can be tested on the instrument Items that cannot be applied for due to certain reasons are disabled.

7.3.2 Item Options

Click the Item Options button to pop up a dialogue box which displays the times of test repetition of standard test items, as shown in the figure:



The screenshot shows the 'Item option' setup screen for the LIDA 500. At the top, there is a header 'Item option' with a gear icon. Below it, a sub-header 'Set All test' is displayed. A checkbox labeled 'Repeat' is checked, and the value '1' is entered in a text input field next to it. An 'OK' button is located to the right of the input field. Below this, a table lists three tests: ALB, ALT, and CHO. Each row has a 'Test' column and a 'Repeat' column. The 'ALB' row is selected, indicated by a dark blue background. The 'Repeat' values for ALB, ALT, and CHO are all set to 1. A vertical scroll bar is visible on the right side of the table. At the bottom of the screen, there is a section for the 'ALB' test, which includes a 'Repeat' input field containing '1'. Below this are four buttons: 'Save', 'Next', 'Up', and 'Cancel'.

Figure 7-11 Item Options

The default settings can be modified in the Item Options setup screen. The meanings of test information are as follows:

- **Repeat Count:** Set the times of repetition of a standard test. The default is 1. You can further edit it as needed.
- **Save:** Save the setting and return to the previous screen.
- **Next:** Display the item information of the next standard sample position.
- **Previous:** Display the item information of the previous standard sample position.
- **Back:** Return to the Sample Application page without saving the setting.

7.3.3 Standard Application Process



- Step 1: Specify "Sample Position";
 - Step 2: Select the repeat count;
 - Step 3: Select the standard number, and the calibration items included in the standard will be displayed in the list on the right side;
 - Step 4: Select calibration items from the list;
 - Step 5: Click the Save button;
 - Step 6: Finish a standard application.
-

Caution: Items that cannot be applied for due to certain reasons are disabled. When the cursor floats over such items, the reasons why the item cannot be selected will be displayed.

7.4 Sample Test

Function Brief: To start the test applied for in the current worksheet.

Click the Start button at the bottom of the screen to pop up the Test Selection dialogue box. It is used to select sample application, calibration application and QC application for which a test will be conducted soon, as shown in the figure:

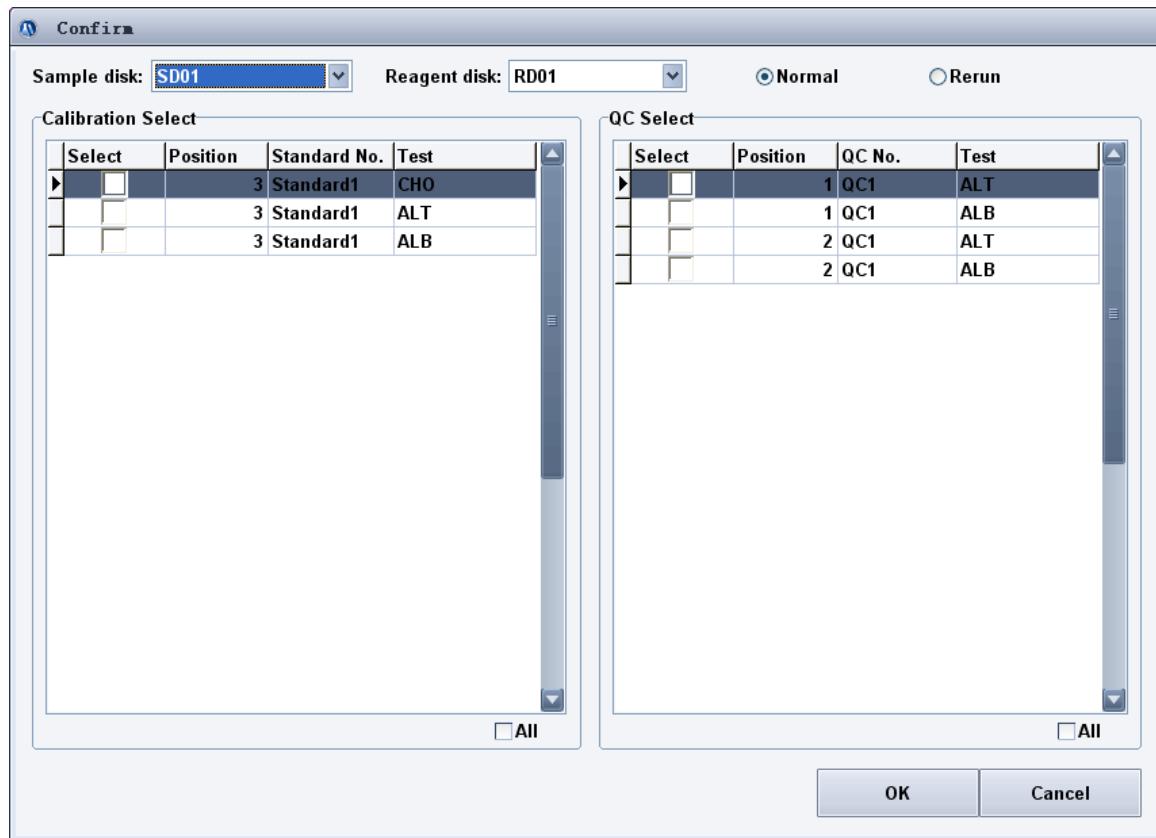


Figure 7-12 Test Selection

- **Worksheet:** Select the worksheet for which a test will be conducted soon. If the system is conducting a test, the worksheet has been fixed.
- **Reagent Tray:** Select the reagent tray for which a test will be conducted soon. If the system is conducting a test, the reagent tray has been fixed.
- **Initial Test:** To conduct initial test for the tests not finished or retests in the current worksheet. If the system is conducting a test, this option is read only.
- **Retest:** To conduct retest for the finished tests the results of which need retest in the current worksheet. If the system is conducting a test, "Retest" cannot be selected.
- **Calibration Selection:** Select the calibration test required this time. Calibration tests commenced cannot be edited.
- **QC Selection:** Select the QC test required this time. QC tests commenced cannot be edited.

Caution: If the selected reagent tray does not include the reagents required for calibration and QC item tests, the calibration and QC items will be disabled.



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Before confirming the commencement of the test, please confirm the above information and check that the sample, calibration solution, QC solution, reagent, etc. have been put at the correct positions. To modify them, click the Cancel button. Or click the OK button, and the Test Sequencing screen will appear, as shown in the figure:

Test sorting (Normal)

Chemistry Test | ISE Test

Position	Sample No.	Test	Repeat	Type	Status	Remark
1	1305171001	ALB	1	Routine	Completed	
1	1305171001	ALT	1	Routine	Completed	
2	1305171002	ALB	1	Routine	Completed	
2	1305171002	ALT	1	Routine	Completed	
5	1305171003	ALB	1	Routine	Unloaded	
5	1305171003	ALT	1	Routine	Unloaded	

By Test By Sample Total: 6

Test All Samples Test Specified Samples Check reagent volume
 Clear Sample Results Clear Standard Results Clear QC Results

OK Cancel

Figure 7-13 Test Sequencing

- **Test All Samples:** Select all sample tests not finished.
- **Test Specified Samples:** Specify which samples for which the test has been applied for will be tested. Multiple sample positions can be input according to the prompt of the system, such as 1-9, 11, and 60.
- **Detection of Minimal Volume of Reagent:** Detect the minimal volume of the items applied for in this test. If the reagent is insufficient, a prompt box will be popped up to prompt that



some reagents are missing and whether to continue the test. Select Yes to continue the test; select No to give up the test.

- **Clear Tested Sample Results:** Clear the sample results tested in the current worksheet and restart all sample tests.
- **Clear Tested Standard Results:** Clear the standard results tested in the current worksheet and restart all standard tests.
- **Clear Tested QC Results:** Clear the QC results tested in the current worksheet and restart all QC tests.
- **No. of Tests:** Prompt the total number of tests, including finished, loaded and unloaded items, but excluding items that cannot be tested for which “Reagent Tray Should be Replaced”.

The meanings of the Status and Prompt columns in the list are shown in the table below:

Status	Description
Unloaded	Test applied for and unloaded.
Loaded	Test applied for and loaded.
Finished	Test applied for and finished.

Prompt	Description
Reagent Tray should be Reselected	The setting of the selected virtual reagent tray does not include the reagents required for the item test.

By default, the system uses the sequence specified in “Test Sequence Setup” (see “Item Setup”). To adjust the sequence, click the “Sort by Item” button or “Sort by Sample” button or drag the tests in the list. After the test sequence is adjusted, click the OK button to start the test, or click the Cancel button to give up the test.

Caution: Test items with the prompt “Reagent Tray should be Reselected” in the list will not be loaded as the selected virtual reagent tray does not include the reagent for the item. After completing all current tests, you can replace the reagent tray, press the Start button again, and select the corresponding reagent tray to test it.



7.5 Add Sample

New test applications can be added during a test. Enter the Sample Application screen, select an empty sample position, edit the sample application to be added, and click the Start button on the left bottom corner of the screen to enter the screen as shown in the figure:

The screenshot shows a software interface titled "Test sorting (Normal)" with a sub-tab "Chemistry Test". A table displays the test sequence:

Position	Sample No.	Test	Repeat	Type	Status	Remark
1	1305171001	ALB	1	Routine	Loaded	
1	1305171001	ALT	1	Routine	Loaded	
2	1305171002	ALB	1	Routine	Loaded	
2	1305171002	ALT	1	Routine	Loaded	
5	1305171003	ALB	1	Routine	Unloaded	
5	1305171003	ALT	1	Routine	Unloaded	

At the bottom, there are buttons for "By Test" and "By Sample", with "By Test" selected. To the right, it says "Total: 6". Below the table are several checkboxes and buttons:

- Add all untested sample
- Add specified sample
- Check reagent volume
- Clear Sample Results
- Clear Standard Results
- Clear QC Results

At the bottom are "OK" and "Cancel" buttons.

Figure 7-14 Add Sample – Test Sequencing

Confirm the test sequencing, and the system will test all samples according to the new sequence.

7.6 Emergency Treatment Test

Emergency treatment tests can be added during a test. Enter the Sample Application screen, select an empty sample position, edit the stat sample to be added, and mark it as "Stat". Click the Start button on the left bottom corner of the screen to enter the screen as shown in the figure:



Test sorting (Normal)

Position	Sample No.	Test	Repeat	Type	Status	Remark
1	1305171001	ALB	1	Routine	Completed	
1	1305171001	ALT	1	Routine	Completed	
2	1305171002	ALB	1	Routine	Completed	
2	1305171002	ALT	1	Routine	Completed	
5	1305171003	ALB	1	Routine	Unloaded	
5	1305171003	ALT	1	Routine	Unloaded	

By Test By Sample Total: 6

Test All Samples Test Specified Samples Check reagent volume
 Clear Sample Results Clear Standard Results Clear QC Results

OK Cancel

Figure 7-15 Add Emergency Treatment – Test Sequencing

Confirm the test sequencing, and the system will test all samples according to the new sequence. All stat samples will be tested first.

7.7 Pause Test

During a test, click the Pause button on the left bottom corner of the screen, and the system will enter the Pause for Adding Sample mode. All tests not started will be paused, but all tests in progress will continue. To restore the test, click the Start button again.

7.8 Stop Test

During a test, click the Stop button on the left bottom corner of the screen, and the system will enter the Stop Test mode. All tests not finished will be stopped, and tests in progress will be cancelled



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automatically, but the cleaning of test cuvettes will continue. To give up the cleaning of test cuvettes and stop the test immediately, press Ctrl+Shift+Q.

Chapter 8 Test Status

Click the Test Status button in the main screen of the software to enter the Test Status screen. The Status screen is divided into four pages, i.e. "Sample Tray", "Reagent Tray", "Reaction Tray" and "Test List", as shown in the figure:

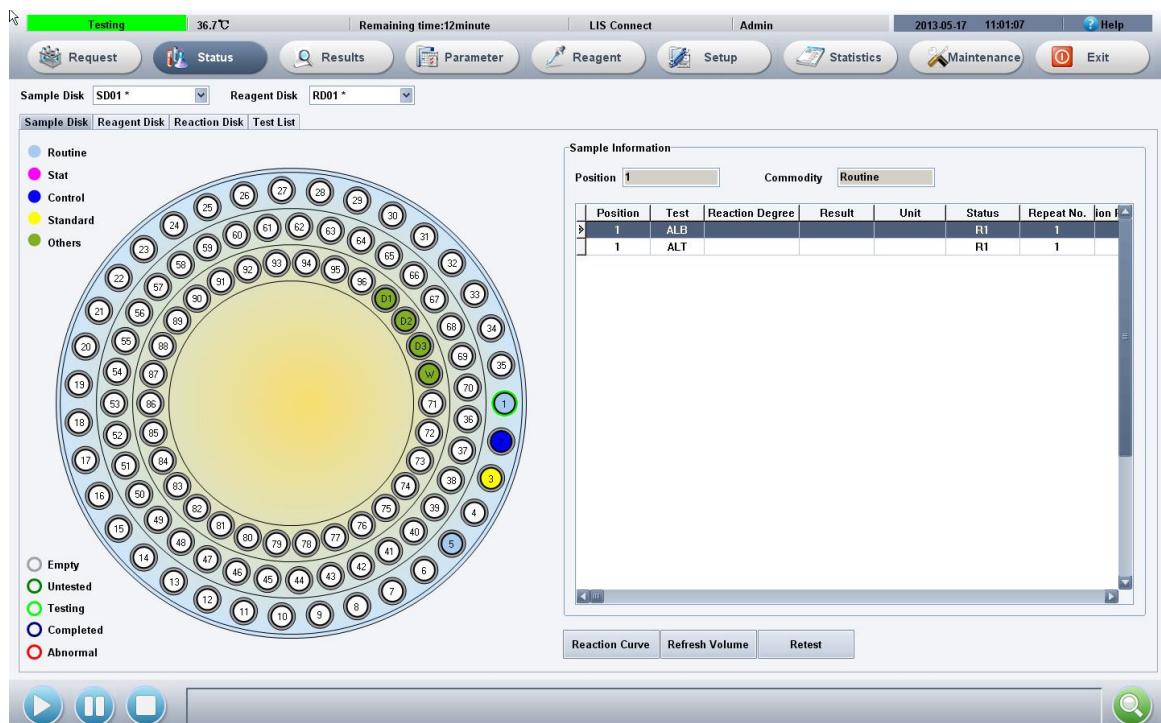


Figure 8-1 Status

- **Worksheet:** Including 7 test worksheets in the system, in which, the worksheet with an asterisk (*) at the end is the current worksheet.
- **Reagent Tray:** Including 2 virtual reagent trays in the system, in which, the reagent tray with an asterisk (*) at the end is the current reagent tray.

8.1 Sample Tray

Function Brief: To view the test status of the sample tray of the current worksheet.

On the Test Status screen, select the Sample Tray page as shown in the figure:



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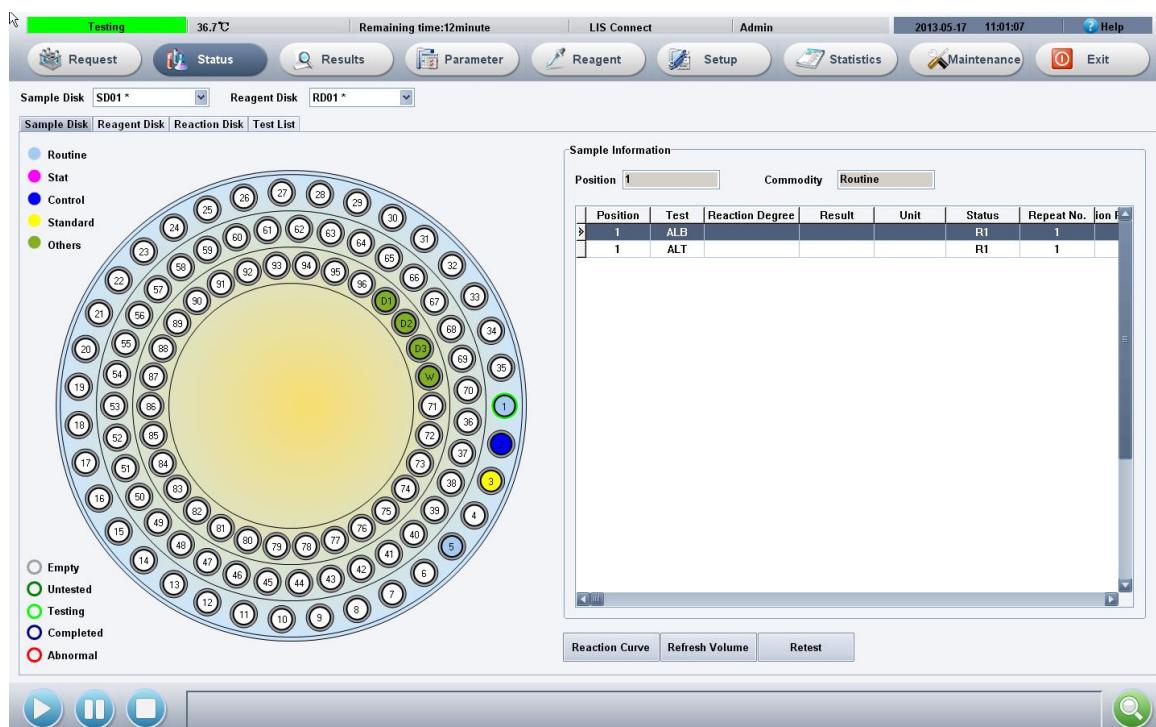


Figure 8-2 Sample Tray

8.1.1 Sample Tray Status

Select the sample position in the sample tray, and the sample information of the position will be displayed on the right side of the screen.

The meanings of the status information on the left side of the sample tray graph are as follows:

Substance Type	Color	Description
Regular sample	Light blue	For regular sample
Stat sample	Pink	For stat sample
QC substance	Dark blue	For QC substance
Standard	Yellow	For standard
Others	Light green	For cleaning solution and deionized water
Test Status	Color	Description
Idle	Light grey	Not sample is set or a sample is set but the system will not test it (for example, when the reagent tray required for the sample is different from the current reagent tray)
Not tested	Green	A sample is set at the sample position, but it is in the application or pending test mode.
Testing	Light green	A sample is set at the sample position and is in the test mode.



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Finished	Blue	A sample is set at the sample position and has been tested.
Abnormal	Red	A sample is set at the sample position, but any abnormality is encountered during the test (for example, the sample has been used up, etc.)

8.1.2 Reaction Curve

Select a sample position in the Sample Tray status graph, select a test in the test list of the sample information, and click the Reaction Curve button to pop up the Reaction Curve dialogue box. It is used to view the reaction curve of the selected test, as shown in the figure:

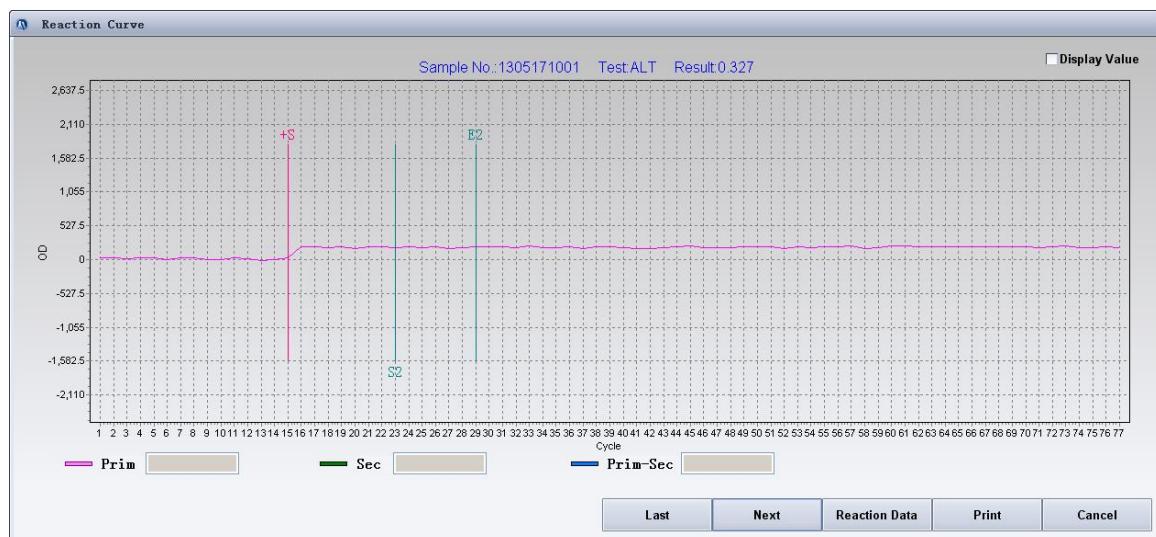


Figure 8-3 Reaction Curve

- **Stage Prompt Line:** The current stage of the curve data. The meanings of the stage prompt lines are as follows:

Stage Line	Meaning	Color
S	Add sample	Light red
R2	Add reagent 2	Light blue
R3	Add reagent 3	Light blue
R4	Add reagent 4	Light blue
S1	Start point of pre-blank	Light green
E1	End point of pre-blank	Light green
S2	Start point of	Light green



	calculation	
E2	End point of calculation	Light green

- **Analysis Line:** When the cursor is at a test point, the red prompt line of the point will appear, and the current number of periods and OD value will be displayed on the right side of the cursor.
- **Prim:** The measured absorbance of the primary wavelength, indicated with red points.
- **Sec:** The measured absorbance of the secondary wavelength, indicated with green points.
- **Prim-Sec:** The absorbance of the primary wavelength minus that of the secondary wavelength, indicated with blue points.
- **Reaction Data:** Click this button to pop up the Reaction Curve Data prompt box which displays the reaction data corresponding to the current reaction curve.
- **Print:** Print the reaction curve graph.

8.1.3 Minimal Volume Refreshing

When any sample is missing during a test, the system will automatically skip all tests corresponding to the sample and mark it with the “Sample Missing” sign. After adding a sample, select this sample position on the Sample Tray page and click the Minimal Volume Refreshing button to pop up the Minimal Volume Refreshing dialogue box. Select the corresponding options, and the system will refresh the sample status of the specified position, as shown in the figure:

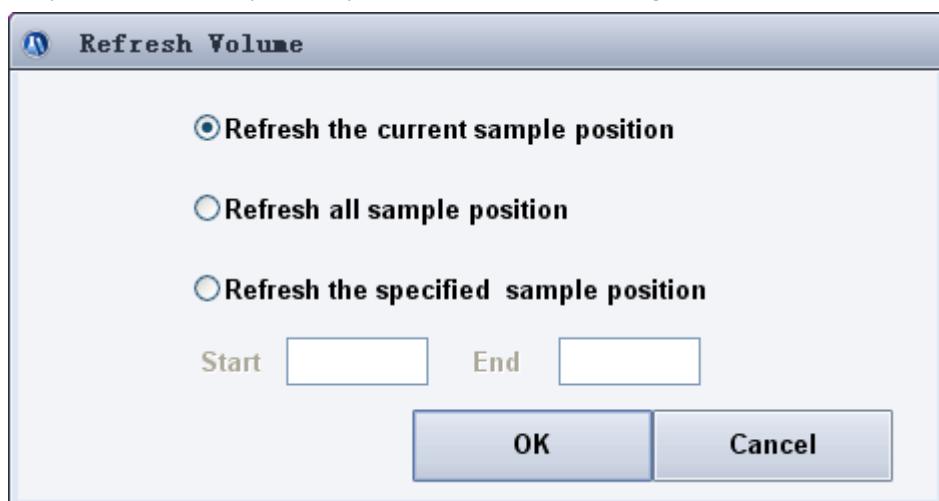


Figure 8-4 Minimal Volume Refreshing

- **Refresh Minimal Volume of Selected Sample Position:** Cancel the missing sign of the selected sample position.



- **Refresh Minimal Volume of All Sample Positions:** Cancel the missing sign of all sample positions.
- **Refresh Minimal Volume of Specified Sample Position:** Cancel the missing sign of the sample positions in the specified range.

Caution: If any sample is missing during a test, the system will automatically skip all tests corresponding to the sample. Execute “Minimal Volume Refreshing”, and the system will automatically continue the test of the sample.

8.1.4 Retest

Select a tested sample in the sample tray status graph and click the Retest button to pop up the Retest dialogue box as shown in the figure:

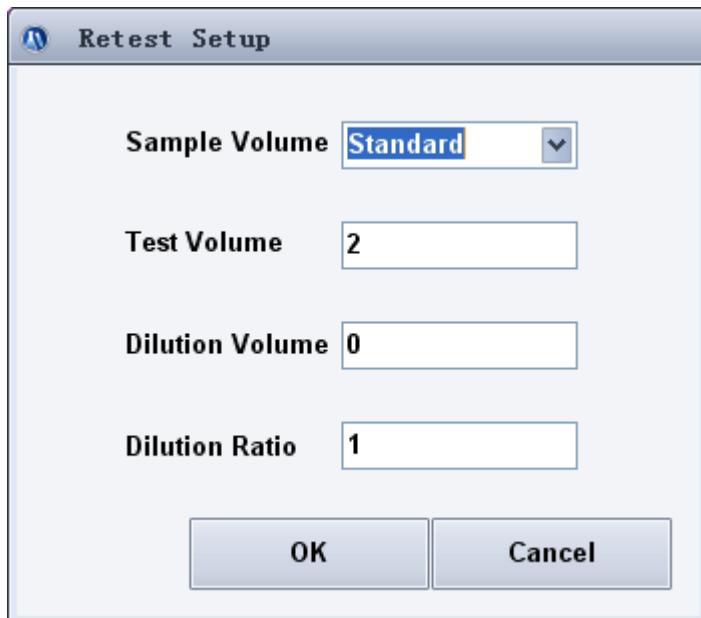


Figure 8-5 Retest Setup

- **Sample Size:** Set the sample size mode in item testing, including Standard, Dilution, Increment, Increment Dilution, Decrement, and Decrement Dilution (displayed only when the related test information has been set in Item Parameter Setup). The system will read the test sample size, dilution sample size and dilution ratio according to the selected sample size mode. You can further adjust the above information according to the specific needs.
- **Test Sample Size:** Specify the volume of sample used in a test. The default is obtained



according to Sample Size. You can further edit it as needed.

- **Dilution Sample Size:** Specify the volume of dilution sample used in a dilution test. The default is obtained according to Sample Size. You can further edit it as needed.
- **Dilution Ratio:** Set the dilution ratio of sample in a test. The default is obtained according to Sample Size. You can further edit it as needed. Input "10" to indicate 10 times dilution, i.e. 1 part of sample + 9 parts of diluent. Input "1" to indicate no dilution.

8.2 Reagent Tray

Function Brief: To view the status of the current reagent tray.

In the test status screen, select the Reagent Tray page as shown in the figure:

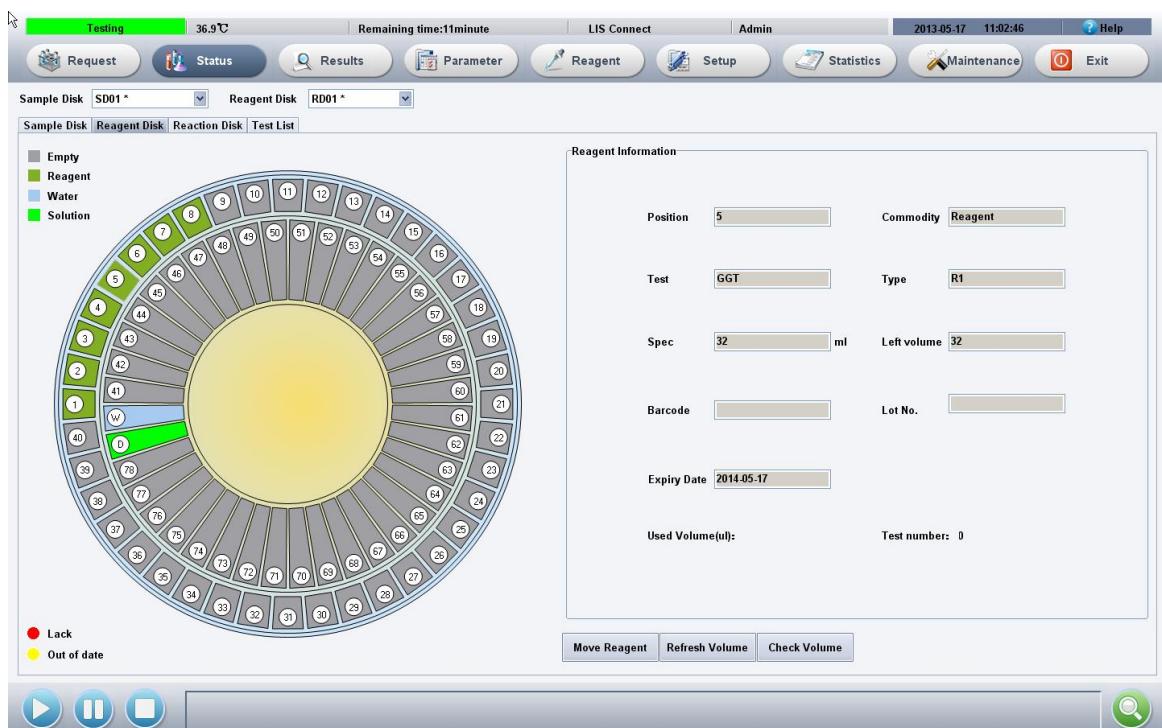


Figure 8-6 Reagent Tray

8.2.1 Reagent Tray Status

In the Reagent Tray screen, the reagent tray graph displays the current status of each reagent position. Click a reagent position, and the reagent information of the position will be displayed on the right side of the screen.

- **Liquid Volume:** The volume of reagent used for each test of the item corresponding to the reagent.
- **Samples that can be Tested:** The number of samples that can be tested with the minimal



volume of reagent.

The status information on the left side of the reagent tray graph is shown in the table below:

Status	Color	Description
Empty position	Grey	No reagent is put.
Deionized water	Light blue	For deionized water
Cleaning solution	Light green	For cleaning solution
Reagent	Green	For reagent
Reagent insufficient	Red	The minimal volume of reagent is insufficient to finish the test or less than the alarm limit set.
Reagent out of date	Yellow	The reagent is out of date.

8.2.2 Move Reagent

On the Reagent Tray page, select a reagent position in the reagent tray status graph, and click the Move Reagent button to pop up the Move Reagent dialogue box as shown in the figure:



Figure 8-7 Reagent Movement

- **Original Reagent Position:** The reagent position of the reagent selected in the reagent tray status graph on the current reagent tray. It is a read only field.
- **New Reagent Position:** Input the position that is empty on the reagent tray.

Caution:

- ◆ ***The deionized water and cleaning solution positions are fixed and cannot be***



moved.

- ◆ **If items corresponding to the reagent have been applied for, movement is prohibited.**

8.2.3 Minimal Volume Refreshing

If any reagent is missing during a test, the system will automatically skip all tests corresponding to the reagent and mark it with the “Reagent Missing” sign. After adding a reagent, select this reagent position on the Reagent Tray page and click the Minimal Volume Refreshing button to pop up a dialogue box as shown in the figure. Select the corresponding options, and the system will refresh the reagent status of the specified position, with the default of “Fill Up”.

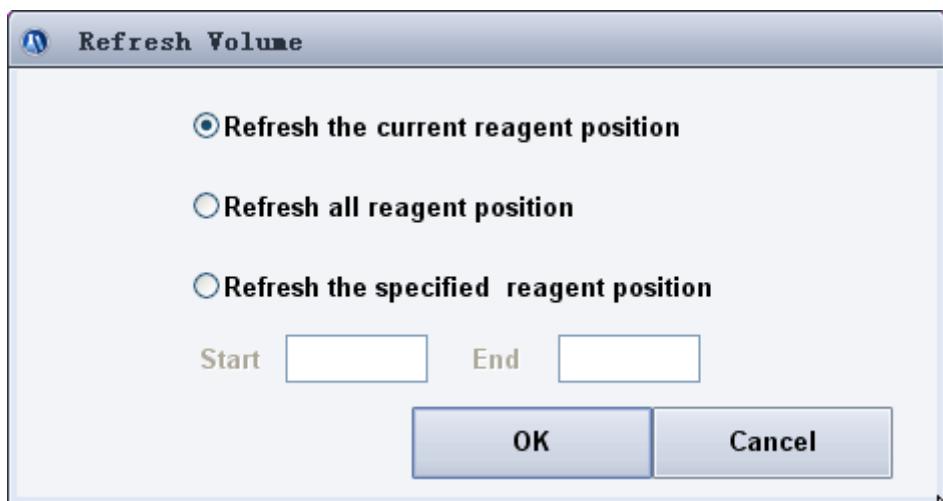


Figure 8-8 Minimal Volume Refreshing

- **Refresh Minimal Volume of Selected Reagent Position:** Cancel the missing sign of the selected reagent position.
- **Refresh Minimal Volume of All Reagent Positions:** Cancel the missing sign of all reagent positions.
- **Refresh Minimal Volume of Specified Reagent Position:** Cancel the missing sign of the reagent positions in the specified range.

Caution: If any reagent is missing during a test, the system will automatically skip all tests corresponding to the reagent. Execute “Minimal Volume Refreshing”, and the system will automatically continue the test of the reagent.



8.2.4 Minimal Volume Detection

When the system is ready, click the Minimal Volume Detection button to detect the minimal volume of the reagent. When the detection is finished, the minimal volume displayed will be refreshed, as shown in the figure.

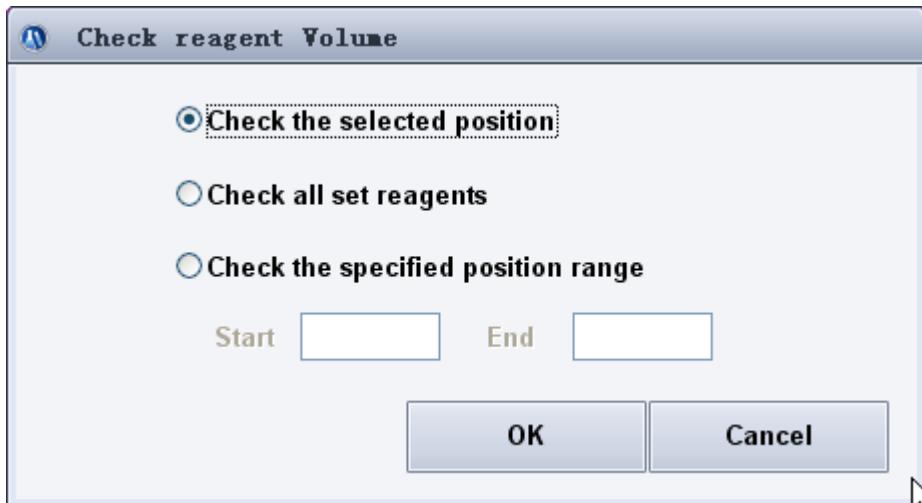


Figure 8-9 Minimal Volume Detection

- **Detect the minimal volume of reagent at the selected position:** Detect the minimal volume of reagent at the selected reagent position.
- **Detect the minimal volume of all set reagents:** Detect the minimal volume of all set reagents in the current reagent tray.
- **Detect the minimal volume of set reagents in the specified range:** Detect the minimal volume of set reagents in the specified range.

8.3 Reaction Tray

Function Brief: To view the status of the current reaction tray.

On the Test Status screen, select the Reaction Tray page as shown in the figure:



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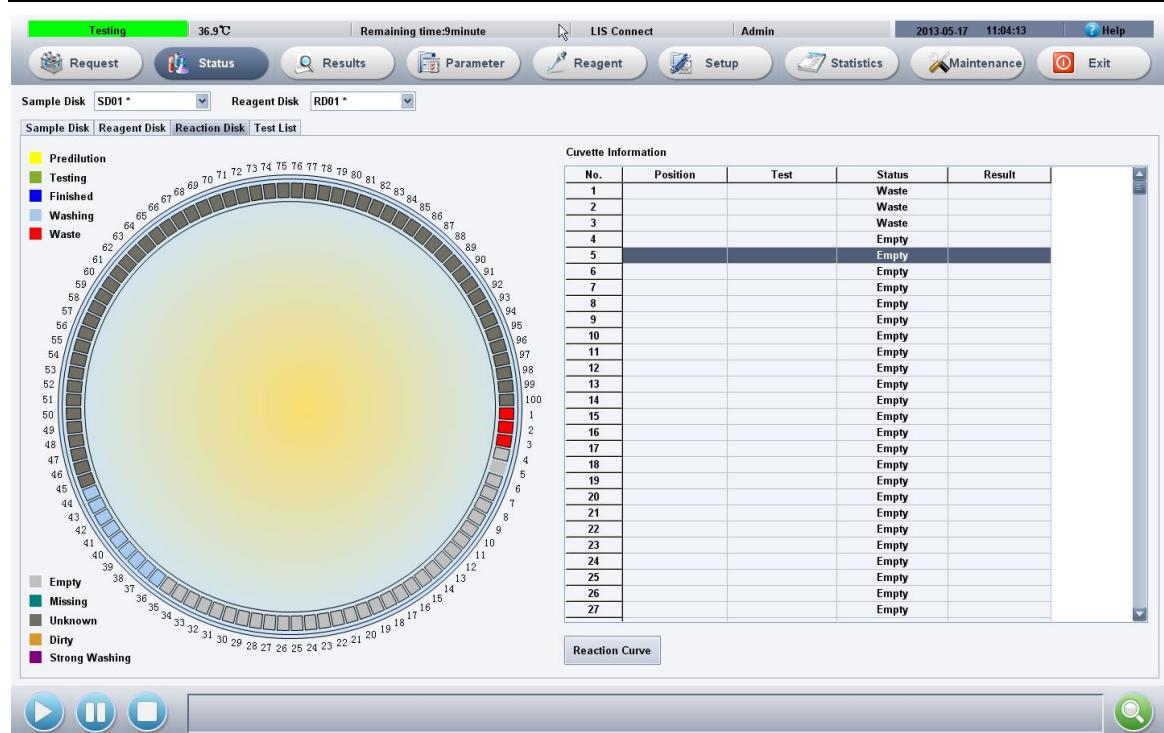


Figure 8-10 Reaction Tray

8.3.1 Reaction Tray Status

The status of test cuvettes can be viewed with the graph on the left side or the list on the right side of the screen. The system displays the status information of all test cuvettes on a real-time basis.

The meanings of the status information on the left side of the reaction tray graph are shown in the table below:

Status	Color	Description
Prediluted	Light yellow	Prediluted in the test cuvette
Testing	Light green	Testing in the test cuvette
Finished	Dark blue	The test in the test cuvette is finished, and the test cuvette is pending cleaning.
Cleaning	Light blue	The test cuvette is being cleaned. After the water blank is tested, the test cuvette can be used again.
Cancelled	Red	The test in the test cuvette has been cancelled, and the test cuvette is pending cleaning.
Empty	Light grey	The clean test cuvette can be added for testing.
Missing	Green	The blank value of the test cuvette exceeds the allowed upper limit. Maybe the test cuvette has not been put.
Unknown	Black	When the machine is started, the test cuvette has not been cleaned or the status of the test cuvette is not detected. The



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		test cuvette can be used only after it is cleaned.
Dirty test cuvette	Earthy yellow	The blank value of the test cuvette exceeds the allowed lower limit. Maybe the test cuvette has not been cleaned or has been stained.
Strong cleaning	Purple	The test cuvette is being strongly cleaned.

8.3.2 Reaction Curve

Select a test cuvette position in the Reaction Tray status graph or test cuvette information list, and click the Reaction Curve button to pop up the Reaction Curve dialogue box. It is used to view the reaction curve in the selected test, as shown in the figure:

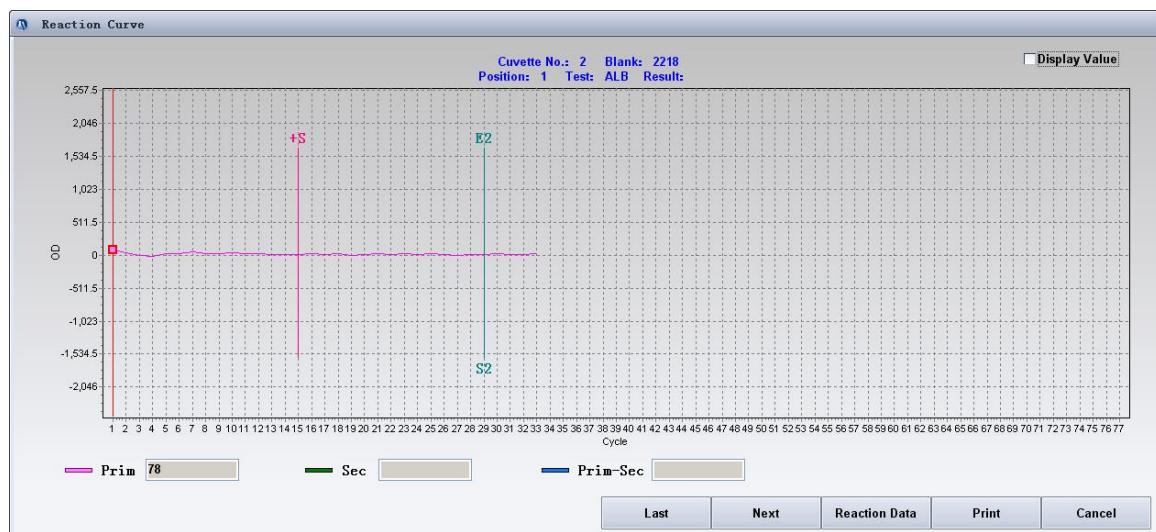


Figure 8-11 Reaction Curve

- **Stage Prompt Line:** The current stage of the curve data. The meanings of the stage prompt lines are as follows:

Stage Line	Meaning	Color
S	Add sample	Light red
R2	Add reagent 2	Light blue
R3	Add reagent 3	Light blue
R4	Add reagent 4	Light blue
S1	Start point of pre-blank	Light green
E1	End point of pre-blank	Light green
S2	Start point of	Light green



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	calculation	
E2	End point of calculation	Light green

- **Analysis Line:** When the cursor is at a test point, the red prompt line of the point will appear, and the current coordinate position will be displayed on the right side of the cursor.
- **Prim:** The measured absorbance of the primary wavelength, indicated with red points.
- **Sec:** The measured absorbance of the secondary wavelength, indicated with green points.
- **Prim-Sec:** The absorbance of the primary wavelength minus that of the secondary wavelength, indicated with blue points.
- **Reaction Data:** Click this button to pop up the Reaction Curve Data prompt box which displays the reaction data corresponding to the current reaction curve.
- **Print:** Print the reaction curve graph.

8.4 Test List

Function Brief: To view the status of the current reaction tray.

On the test status screen, select the Test List page as shown in the figure:

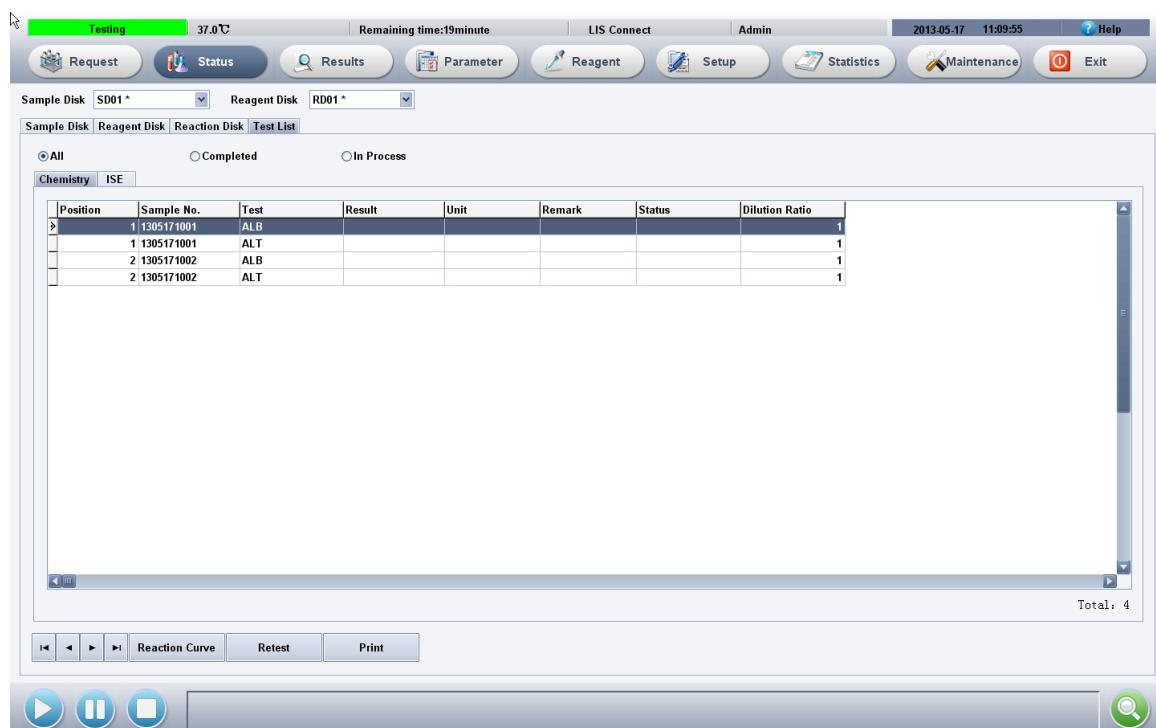


Figure 8-12 Test List

- **Display Type:** Select “Display All”, “Display Finished” or “Display Unfinished”, and the



system will automatically screen the test records as required.

- **Reaction Curve:** Select a test from the list and click the Reaction Curve button to view the reaction curve corresponding to the test.
- **Retest:** Select the results to be retested from the list and click Retest to mark the selected record as "Retest". For the detailed retest setup, see 7.1.3. If the system is conducting a test, tests marked with "Retest" will be added automatically; otherwise, in the next test, the system will automatically respond to the Retest request.
- **Print:** Print the results of a finished patient sample test.

8.4.1 Test List Signs

The Sign column in the test list will display the signs related to the results of sample tests. The meanings of the signs are as follows:

Sign	Meaning
L	On the low side
H	On the high side
A<	Exceeding the lower linear limit
A>	Exceeding the upper linear limit
OL	Exceeding the linearity range (nonlinear)
SE	Substrate exhaust
AR	Less than the increment retest limit
DR	Greater than the decrement retest limit
NLN	No linear interval
ENC	No calculation interval
PRO	Prozone check exceeding limit
RRZ	Exceeding reactivity of zero concentration
RRN	Exceeding reactivity of maximum calibration
**	Still abnormal after retest

8.4.2 Test List Status

The Status column in the test list will display the status related to the sample test process. The meanings of the status signs are as follows:

Sign	Meaning
Ready	The test will begin soon.
S	Add sample
R1	Add reagent 1
R2	Add reagent 2



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R3	Add reagent 3
R4	Add reagent 4
Unloaded	The test has been applied for, but has not been loaded.
Finished	The test has been finished.
Reagent Tray should be Reselected	The selected reagent tray does not include the reagent required for the item test.
Abnormal	Any abnormality appears during the test of the item, such as reagent missing or collision.

Caution: Test items with the prompt “Reagent Tray should be Reselected” in the status will not be loaded as the selected reagent tray does not include the reagent for the item. After completing all current tests, you can replace the reagent tray, click the Start button again, and select the corresponding reagent tray to test it.

Chapter 9 Result Inquiry

9.1 Patient Record Inquiry

Function Brief: To inquire the patient records meeting the specified criteria. The basic information and test results of the selected patient can be edited and viewed one by one.

Click “Result” in the main menu to enter the Patient Record page as shown in the figure:

The screenshot shows a software interface for managing patient samples. At the top, there's a toolbar with icons for Request, Status, Results (which is highlighted), Parameter, Reagent, Setup, Statistics, Maintenance, and Help. The date and time are displayed as 2013-05-17 11:34:37. Below the toolbar, a navigation bar includes Patient, Test, Calibration, Quality Control, Reagent Blank, ISE Calibration, and ISE Quality Control. The main area has two main sections: a large table on the left and a smaller table on the right.

Left Section (Patient List):

Sample No.	Name	Sex	Clinic No.	Bed No.	Age	Dept.	Sent by	Tested by	Checked by	Sent Date
1305171001		Unknow			Year		Admin	Admin		2013-05-17
1305171002		Unknow			Year		Admin	Admin		2013-05-17
1305171003		Unknow			Year		Admin	Admin		2013-05-17
1305171004		Unknow			Year		Admin	Admin		2013-05-17
1305171005		Unknow			Year		Admin	Admin		2013-05-17
1305171006		Unknow			Year		Admin	Admin		2013-05-17

Right Section (Detailed View):

Test	Result	Unit	Remark
ALB	ERK		
ALT	0.487		

Below the tables are search and filter fields. The search bar contains "1305171002". Other fields include Name, Sex (Unknown), Clinic No., Detail, Bed No., Age (Year), Nation, Blood, New, Sample traits, Dept., Sent by, Sent Date (2013-05-17), and Save. There are also Find, Delete, Print, Send, Calculate, Check, Setup, and Select All buttons. At the bottom are playback controls (Play, Stop, Pause) and a search icon.

Figure 9-1 Patient Record

9.1.1 Inquire Patient Record

Click the Inquire button, and the screen as shown in the figure will appear:



Find Patient

History sheet	Default
Sample No.	
Clinic No.	
Bed No.	
Name	
Sex	
Age	
Department	
Sent by	
Tested by	
Checked by	
Date From	2013-05-17
To	2013-05-17

OK Cancel

Figure 9-2 Patient Record Inquiry Criteria

Input the inquiry criteria and click the OK button, and the list will display all patient records meeting the criteria.

9.1.2 Edit Patient Information

Select a patient from the list, and the corresponding basic information will be displayed at the bottom of the list. Edit and modify the information as required, and click the Save button.

9.1.3 Edit Patient Test Results

Click a patient record, and the test results corresponding to the patient will appear in the list on the right side. You can add, modify or delete test results.



Caution: Only operators with the “Result Editing” privilege may edit patient test results.

9.1.4 Add Patient Record

Click the Add button, directly input the basic information of the patient at the bottom of the list, and click the Save button.

Caution:

- ◆ ***Retested, manually added or modified test results are prompted with “*” at the end.***
 - ◆ ***Results on the high side and low side are prompted with “↑” and “↓” respectively.***
 - ◆ ***The test date of the newly added patient is the current day. The sample number of the newly added patient must not be the existing patient sample number on the day of test, otherwise the system will inquire whether to overwrite the existing patient information.***
 - ◆ ***When the system is saving test results, if there is no patient information of the sample number on the current day, the system will automatically generate a new patient according to the sample number and test date.***
-

9.1.5 Delete Patient Record

Select the record to be deleted or “Select All” from the patient record list and click the Delete button, and the system will delete the specified patient record and all corresponding test records.

9.1.6 Audit Patient Record

Before auditing the results, the auditor should login first. Select the Setup button from the Patient Record screen, and the screen as shown in the figure will appear:



The screenshot shows a software interface titled "Setup". At the top, there are two tabs: "Report Format" and "Checker". The "Checker" tab is selected. Below the tabs, there is a section labeled "Checker" with a dropdown menu showing "Admin". Next to it is a password input field. At the bottom of the screen are three buttons: "Login", "Log out", and "Cancel".

Figure 9-3 Audit Login

Select the auditor, input the password, and click Login. After the identity passes the verification, the selected user will become the current auditor automatically. The Status column will display the current auditor.

From the patient record list, select the audited patient record or “Select All”, and click the Audit button to finish the audit of the selected patient.

Caution: In order to protect the validity of the audit, after finishing the audit, the auditor should timely enter the Setup screen to log out.

9.1.7 Indirect Calculation

From the patient record list, select the patient record for which indirect calculation will be conducted or “Select All” and click the Calculate button. The system will automatically calculate the results of calculation items of the selected patient according to the system setup parameters.

9.1.8 Send Patient Test Results

If the software has been connected to the LIS system server, from the patient record list, select the patient record to be sent or “Select All” and click the Send button. The system will send the test results of the selected patient to the LIS server.



9.1.9 Print Patient Report

Before printing the patient report for the first time, the report format should be set. Select the Set button on the Patient Record screen, and the screen as shown in the figure will appear:

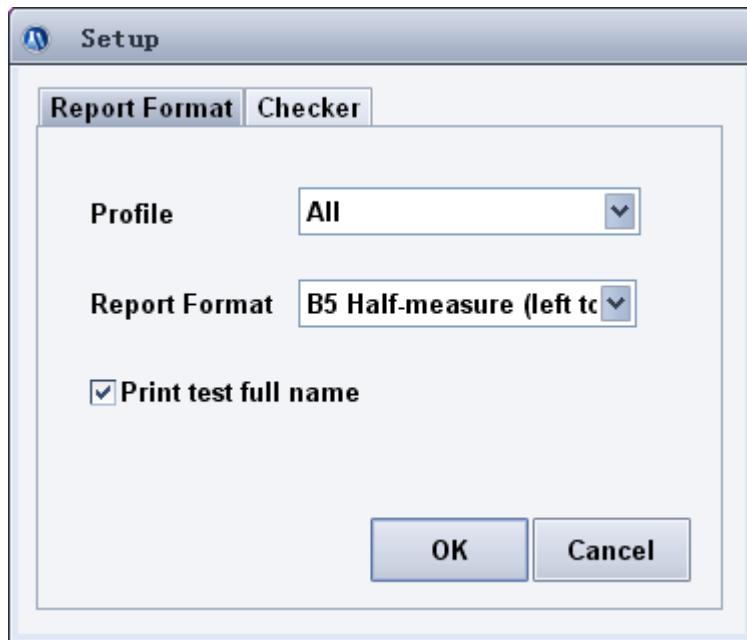


Figure 9-4 Report Setup

Select "Profile" and "Report Format" to specify the content and format of the patient report.

Caution: The report settings will be saved automatically after the operation, and the report needs not to be set each time before it is printed.

From the patient record list, select the patient record to be printed or "Select All" and click the Print button. The system will generate the patient report automatically.

9.2 Test Record Inquiry

Function Brief: To inquire the test records meeting the specified criteria.

Select the Test Record page as shown in the figure:



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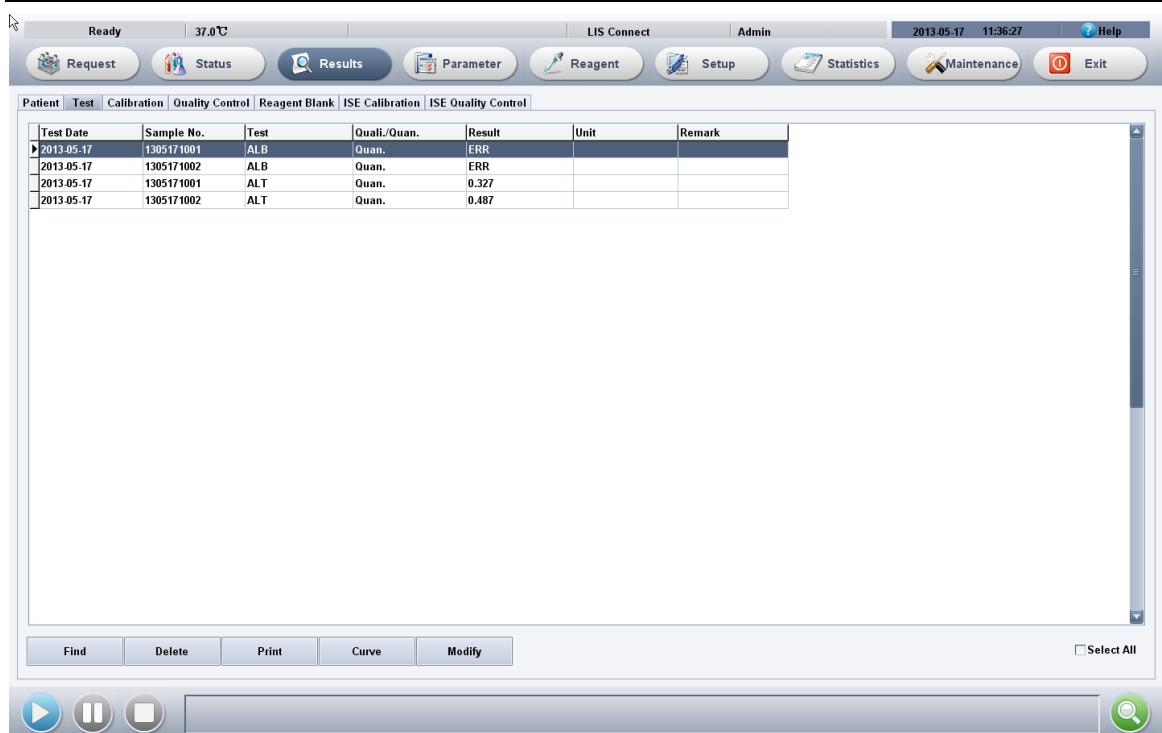


Figure 9-5 Test Record

9.2.1 Inquire Test Record

Click the Inquire button, and the screen as shown in the figure will appear:

This is a modal dialog box titled "Find histroy result". It contains several input fields and dropdown menus:

- History sheet: A dropdown menu set to "Default".
- Test: A dropdown menu currently empty.
- Sample No.: An empty text input field.
- Data From: A dropdown menu set to "2013-05-17".
- To: A dropdown menu set to "2013-05-17".
- OK and Cancel buttons at the bottom.

Figure 9-6 Test Record Inquiry Criteria



Input the inquiry criteria and click the OK button, and all test records meeting the criteria will appear in the list.

Caution: Retested, manually added or modified test results are marked with “*” at the end.

9.2.2 Delete Test Record

From the test record list, select the record to be deleted or “Select All”, and click the Delete button.

9.2.3 Print Test Record

From the test record list, select the record to be printed or “Select All”, and click the Print button.

9.2.4 View Reaction Curve

Click the test record to be viewed and click the Reaction Curve button, and the system will display the reaction curve of the test, as shown in the figure:



Figure 9-7 Reaction Curve

- **Stage Prompt Line:** The current stage of the curve data. The meanings of the stage prompt lines are as follows:

Stage Line	Meaning	Color
------------	---------	-------



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S	Add sample	Light red
R2	Add reagent 2	Light blue
R3	Add reagent 3	Light blue
R4	Add reagent 4	Light blue
S1	Start point of pre-blank	Light green
E1	End point of pre-blank	Light green
S2	Start the sample result test	Light green
E2	End the sample result test	Light green

- **Analysis Line:** When the cursor is at a test point, the red prompt line of the point will appear, and the OD value corresponding to the current test period will be displayed on the right side of the cursor.
- **Prim:** The measured absorbance of the primary wavelength, indicated with red points.
- **Sec:** The measured absorbance of the secondary wavelength, indicated with green points.
- **Prim-Sec:** The absorbance of the primary wavelength minus that of the secondary wavelength, indicated with blue points.
- **Reaction Data:** Click this button to pop up the Reaction Curve Data prompt box which displays the reaction data corresponding to the current reaction curve.
- **Print:** Print the reaction curve graph.

9.3 Standard Inquiry

Function Brief: To inquire the calibration results of the specified item.

Select the Standard Inquiry page as shown in the figure:



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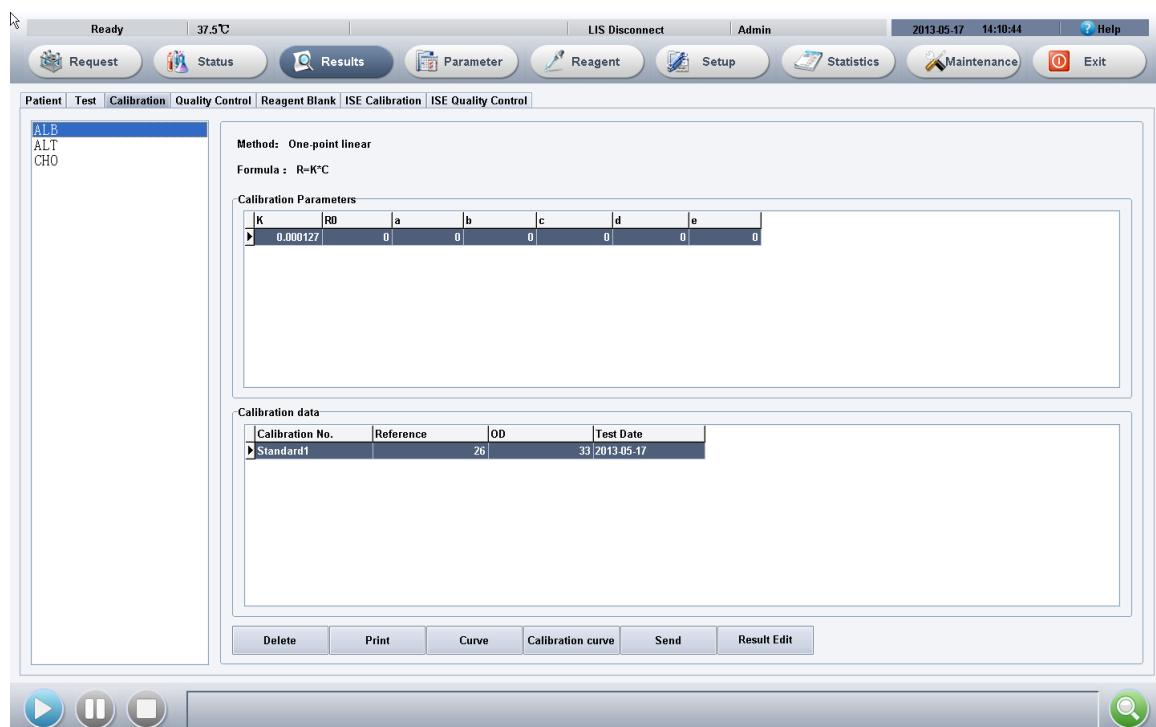


Figure 9-8 Standard Inquiry

9.3.1 View Calibration Results

The list on the left side displays all items for which the calibration test has been conducted.

Click one of the items, and the calculation method, calculation formula, calibration parameter and calibration data corresponding to the item will appear on the right side. (In which, the calibration parameters are calculated according to the calculation method and calibration data of the item.)

9.3.2 Delete Calibration Results

From the calibration data list, select the calibration results to be deleted, and click the Delete button.

9.3.3 Modify Calibration Data

From the calibration data list, select the OD value of the calibration data to be modified and directly input a new OD value. Click once outside the list of calibration data modified.

Caution: After the calibration data are deleted or modified, the system will calculate the new calibration parameter automatically. The system will automatically set the newly calculated calibration parameter as the default calibration



parameter of the item and refresh the display of the calibration parameter list. If the calculation fails, the system will give the prompt “Calibration invalid. Parameter calculation impossible” at the right bottom corner.

9.3.4 Print Calibration Results

Select the item for which the calibration results will be printed from the list on the left side, and click the Print button.

9.3.5 View the Reaction Curve of Standard

Select the calibration item to be viewed from the list of the left side, select the standard from the calibration data list, and click the Reaction Curve button to view the standard reaction curve corresponding to the item.



Figure 9-9 Reaction Curve

9.3.6 View the Calibration Curve of Item

Select the calibration item to be viewed from the list on the left side and click the Reaction Curve button to view the calibration curve corresponding to the item, as shown in the figure:



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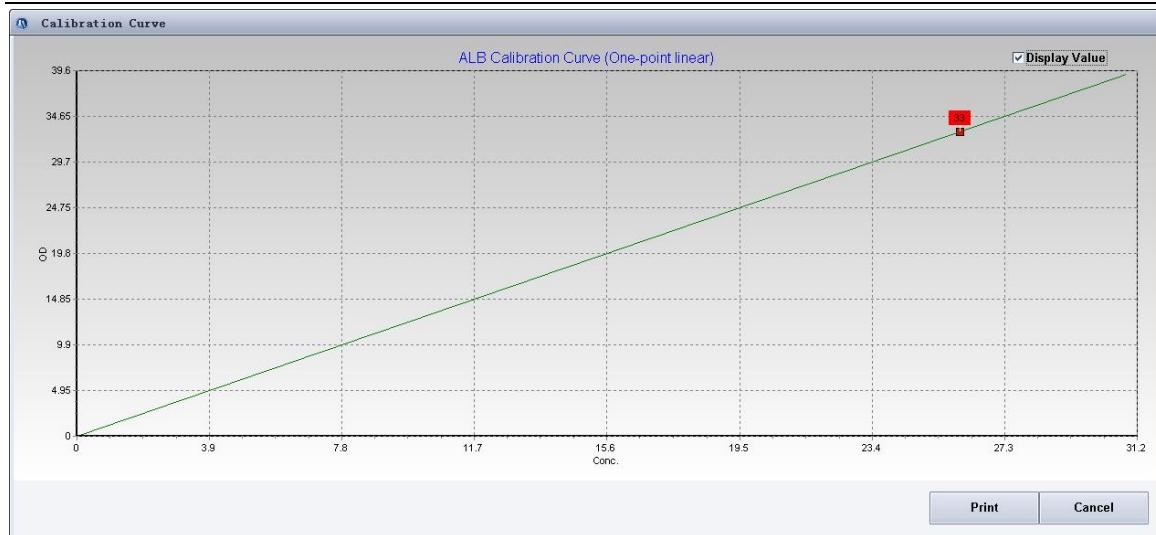


Figure 9-10 Calibration Curve

- **Analysis Line:** When the cursor is at a position, the red prompt line of the point perpendicular to the X axis will appear, and the concentration and corresponding OD value of the intersection of the current prompt line and standard curve will be displayed on the right side of the cursor.
- **Print:** Print the calibration curve graph.

9.3.7 Send Calibration Data

Click the Send button, and the system will pop up the Send dialogue box as shown in the figure:

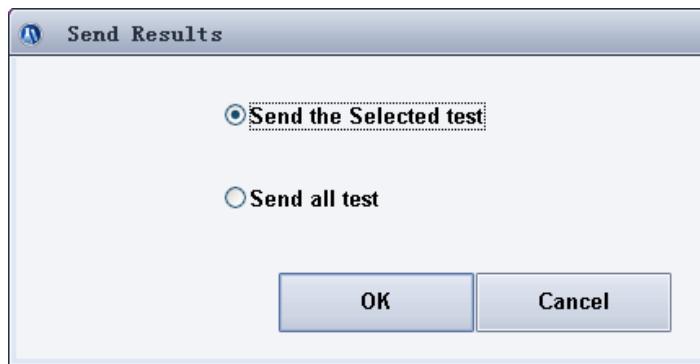


Figure 9-11 Send

- **Send the Selected Item:** Send the calibration parameters and results of the selected item to the LIS host;
- **Send All Items:** Send the calibration parameters and results of all items in the list to the LIS



host.

9.4 QC Inquiry

Function Brief: To view the test results in the specified time range of the specified QC item.

Select the QC Inquiry page as shown in the figure:

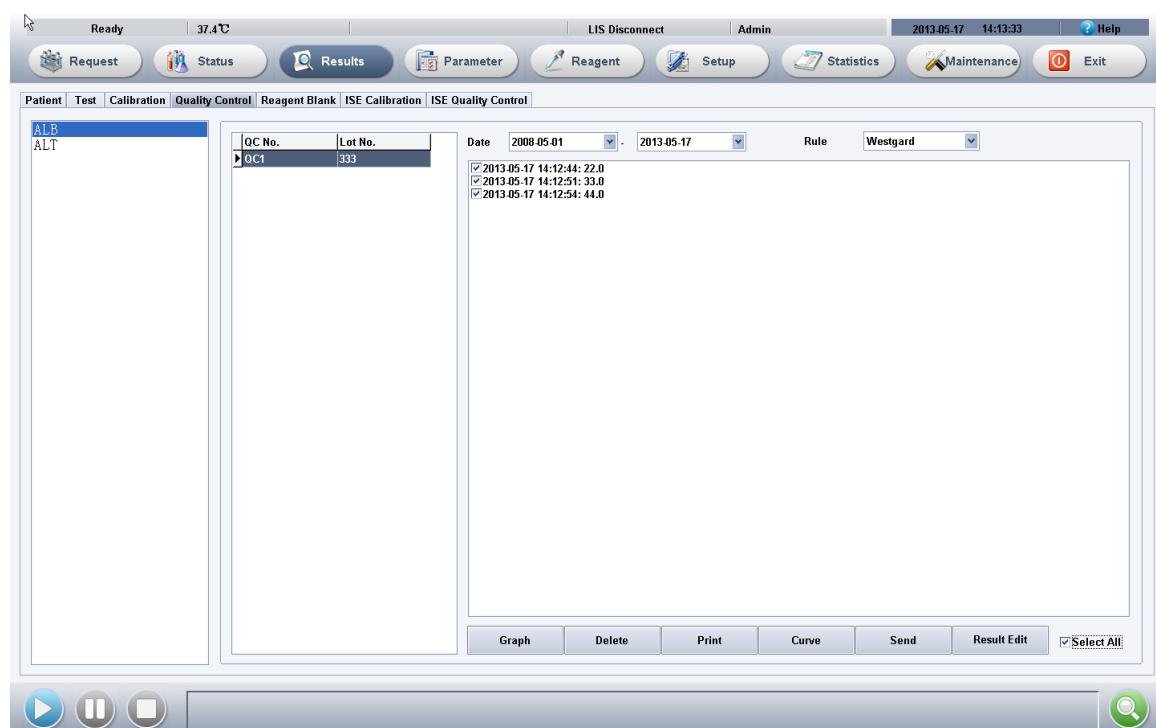


Figure 9-12 QC Inquiry

9.4.1 View QC Data

Select the QC item to be viewed from the list on the left side and specify the range of inquiry dates, and the data list on the right side will display all test data meeting the criteria.

- **Date:** Inquire the start date and end date of QC data. The end date must be greater than the start date.
- **QC Graph Rule:** Select the type of QC graph to be viewed, including Westgard multi-rule, cumulation & rule, and Youden rule.



Caution: When the Youden rule is selected, 2 QC solutions must be selected (to select multiple QC solutions in the QC list, press and hold the Ctrl key). The Youden rule does not judge the QC results automatically.

9.4.2 View QC Graph

Select the data point to be drawn from the data list, select the QC graph rule, and click “QC Graph”.

The QC graph will appear:

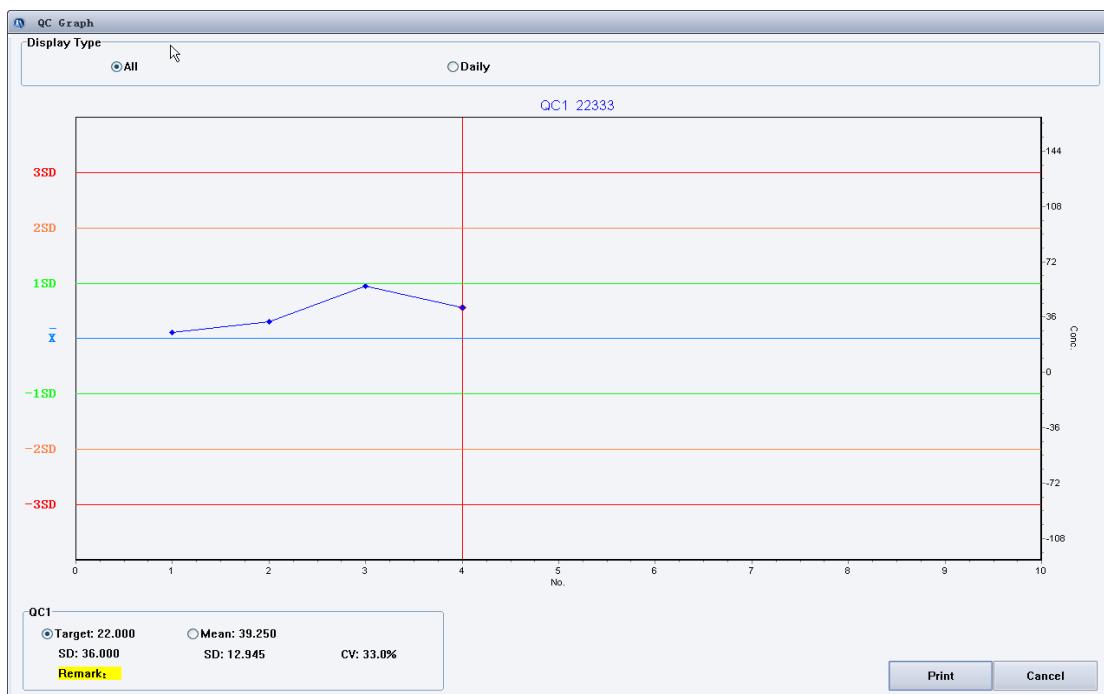


Figure 9-13 QC Graph

The screen displays the target value and SD value of the QC item as well as the statistical results of the selected data: mean, SD, and CV. The system can change the QC graph automatically according to the drawing method specified by you. Click the Print button to print the QC graph shown on the Graph screen.

- **Real-time QC Graph:** Draw all data. Each QC datum corresponds to the X-coordinate value on the graph.
- **Daily QC Graph:** Average the data for the same day and draw the point corresponding to the mean for each day only. The mean for each day corresponds to the X-coordinate value.
- **Display QC Point Time:** Select the Display QC Point Time option, and the QC test time will



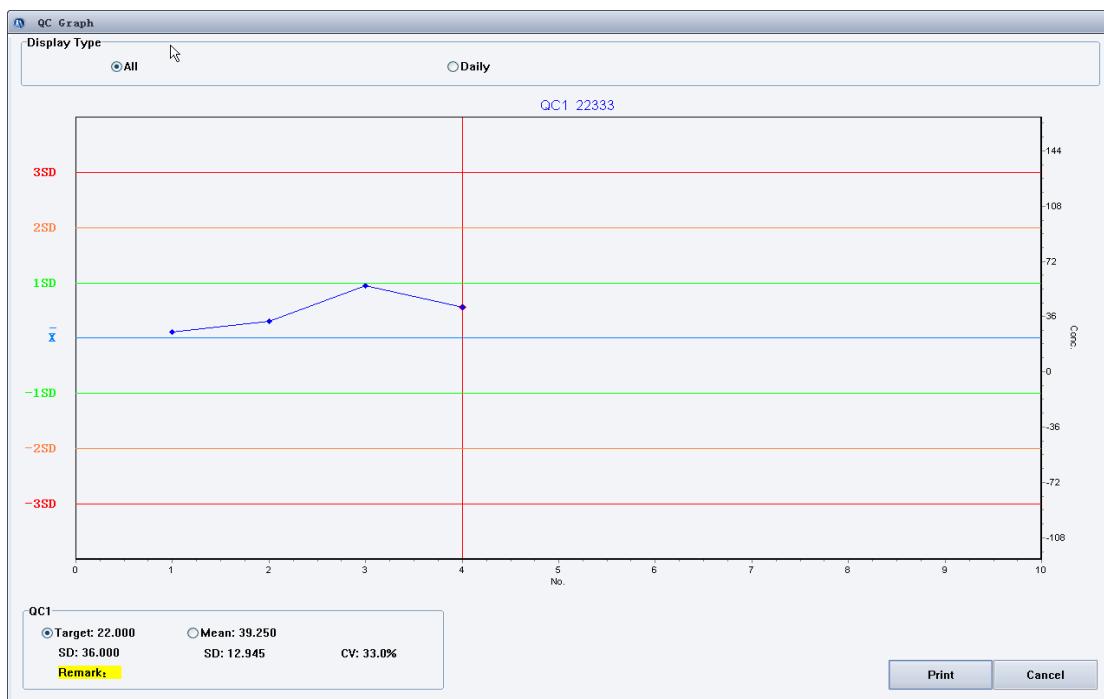
be displayed on the QC point.

- **Target Value and SD Value:** The fixed target value and SD value set for the QC substance.
- **Mean and SD Value:** The mean and SD value obtained through statistics of data actually tested for the QC substance.
- **Out-of-control Prompt:** Prompt the out-of-control QC solution according to the set QC rule.
- **Print:** Print the QC graph.

Caution: The numbers on the right side of the cursor on the Westgard QC graph and cumulation & rule graph are the X-coordinate and Y-coordinate data of the current QC point. Youden QC graph may have multiple QC points on the same Y-coordinate, therefore the numbers on the right side of the cursor are the X-coordinate and Y-coordinate data of the current cursor. When viewing the data points on the Youden QC graph, locate the cursor following the corresponding QC point to view its coordinate data.

9.4.3 Westgard Multi-rule QC Graph

Select the data point to be drawn from the data list, select “Westgard Multi-rule” in “QC Rule”, and click QC Graph. The Westgard multi-rule QC graph will appear:





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Figure 9-14 Westgard Multi-rule QC Graph

On the Westgard multi-rule QC graph, the X-coordinate is the serial number of the QC point, and the Y-coordinate is the concentration. For QC test points violating the QC rule, in addition to prompting which rules are violated in “Out-of-control Prompt”, the out-of-control QC points will be displayed in pink. The values on the right side of the cursor are the X-coordinate and Y-coordinate values of the current QC point.

9.4.4 Cumulation & Rule QC Graph

Select the data points to be drawn from the data list, select “Cumulation & Rule” in “QC Graph Rule”, and click “QC Graph”. The Cumulation & Rule QC graph will appear:

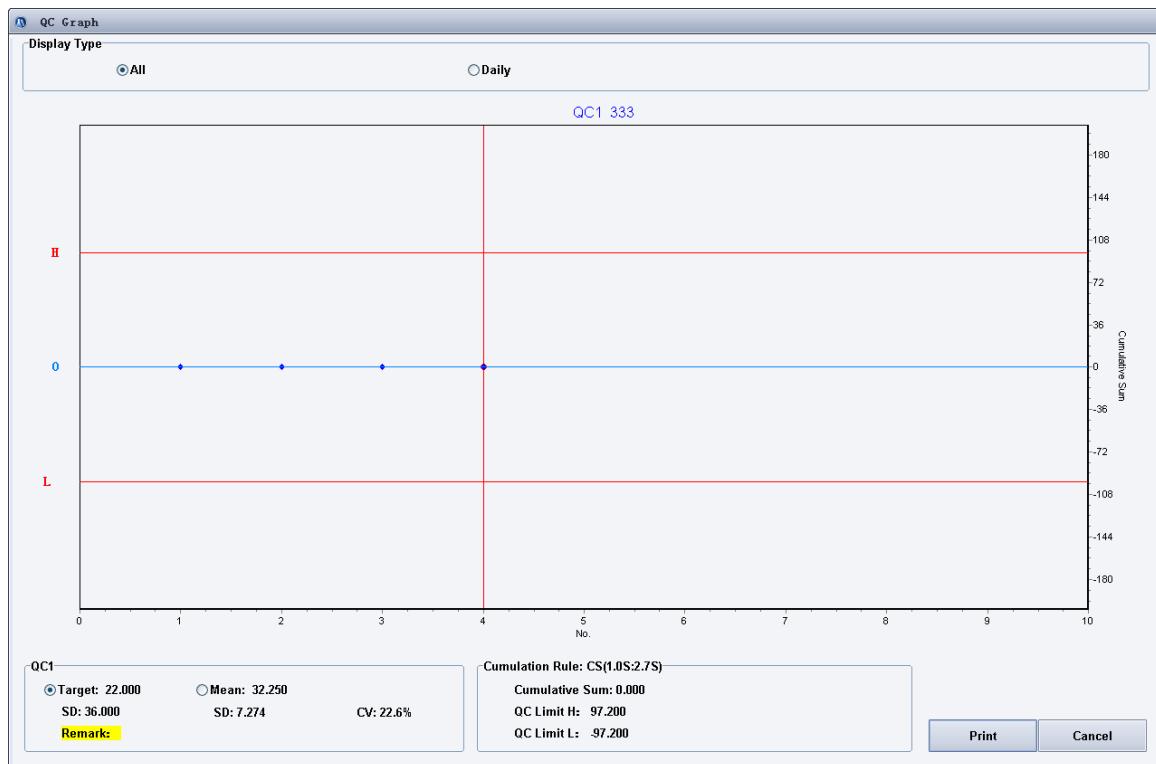


Figure 9-15 Cumulation & QC Graph

On the Cumulation & Rule QC graph, the X-coordinate is the serial number of the QC point, and the Y-coordinate is the specific value corresponding to the cumulative sum of the QC point. For QC test points violating the QC rule, in addition to prompting which rules are violated in “Out-of-control Prompt”, the out-of-control QC points will be displayed in pink.



- **Cumulative Sum:** Display the total cumulative sum of the QC substance.
- **QC Limit H:** Display the upper limit of cumulative QC of the QC substance.
- **QC Limit L:** Display the lower limit of cumulative QC of the QC substance.

Caution: The cumulation method of the real-time QC graph is real-time single point cumulation. The cumulation method of the daily QC graph is daily mean cumulation. For the meanings of real-time single point cumulation and daily mean cumulation, see 4.3.5 Set QC Rule.

9.4.5 Youden Rule QC Graph

Select two QC solutions to be drawn from the QC solution list and select the data points from the data list, select “Youden Rule” in “QC Graph Rule”, and click “QC Graph”. The Youden Rule QC graph will appear:

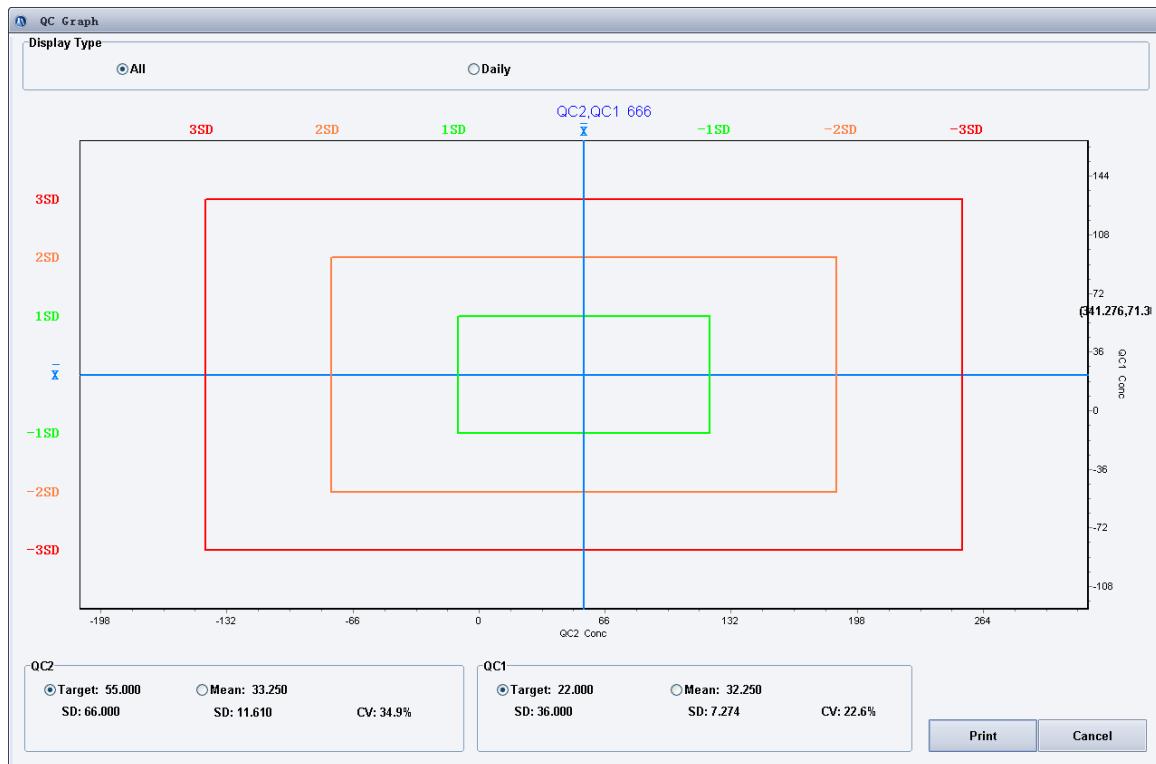


Figure 9-16 Youden QC Graph

For the Youden rule, the mean and SD of the corresponding QC solution are displayed on the left and upper sides of the QC graph respectively. Move the cursor on the QC point to observe the specific



data of each point in the graph. In the two boxes under the QC graph, the statistical data of the X-coordinate item are displayed on the left side, and the statistical data of the Y-coordinate item are displayed on the right side.

Caution: If the Youden rule has been selected, when the Youden QC graph is viewed, the QC results will not be judged and no out-of-control prompt will appear. For the QC point Youden graph for a day, only points with both QC solutions tested will be displayed. If two QC solutions are tested multiple times in a day, the number of points displayed on the Youden real-time QC graph are the number of points of the QC solution lesser tested.

9.4.6 Delete QC Data

Select the QC data to be deleted from the QC data list and click the Delete button.

9.4.7 Print QC Data

Select the QC data to be printed from the QC data list and click the Print button.

9.4.8 View QC Test Reaction Curve

Select the QC item to be viewed from the list on the left side, select the test data of which the reaction curve will be viewed from the data list on the right side, and click the Reaction Curve button to inquire the reaction curve of the QC test.

9.4.9 QC Data Sending

Click the Send button, and the system will pop up the Send dialogue box as shown in the figure:



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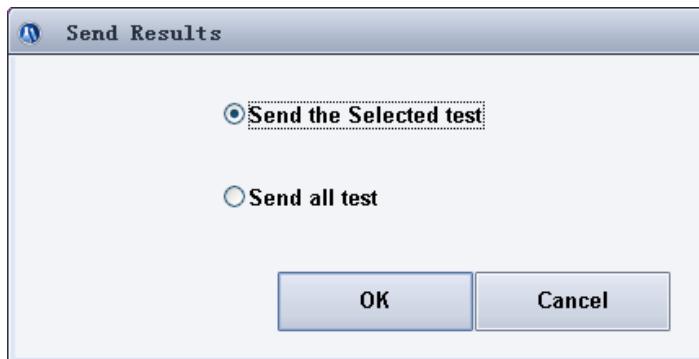


Figure 9-17 Send

- **Send Selected Item:** Send the QC data of the selected item to the LIS host;
- **Send All Items:** Send the QC data of all items in the list to the LIS host.

9.5 Reagent Blank Inquiry

Function Brief: To inquire the historic reagent blank record of the specified item.

Select the Reagent Blank Inquiry page as shown in the figure:

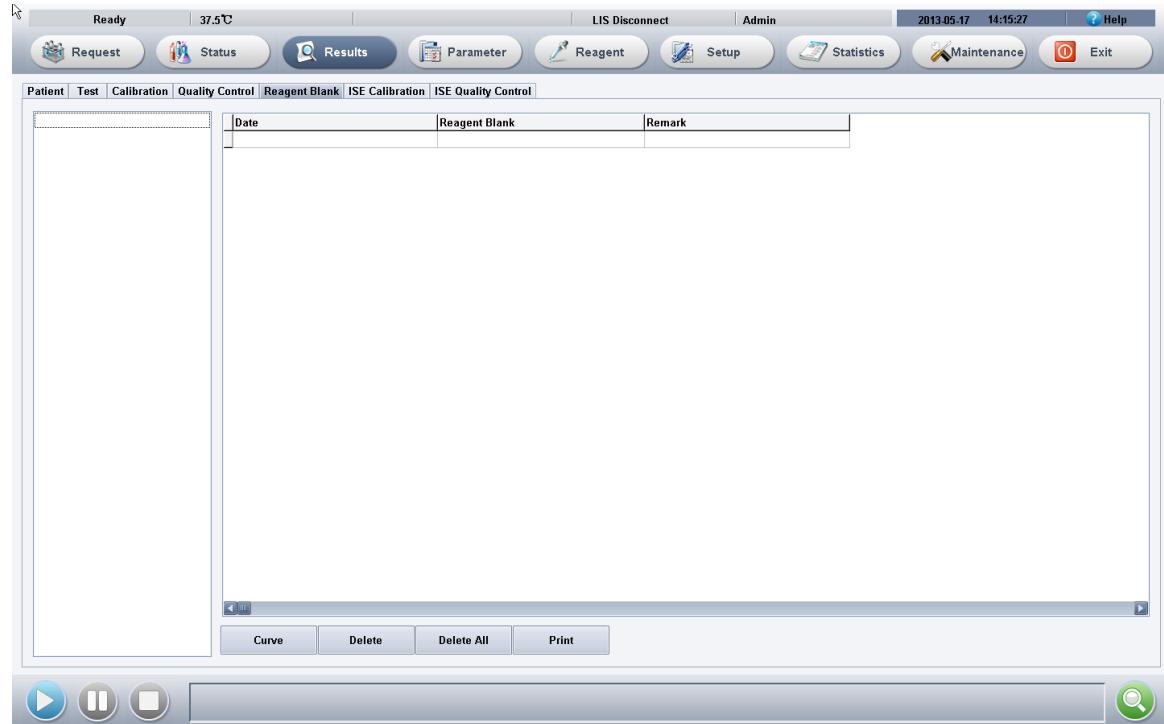


Figure 9-18 Reagent Blank Inquiry

All items with reagent blank tested are displayed on the list on the left side. Click the item to be



inquired, and the historic reagent blank record will be displayed on the list on the right side.

- **Reaction Curve:** View the reaction curve graph of the reagent blank test.
- **Delete:** Delete the selected reagent blank record in the list.
- **Delete All:** Delete all reagent blank records in the list.
- **Print:** Print all reagent blank records in the list.

Caution: Blank results exceeding the reagent blank range are marked with "OR".

9.6 ISE Calibration Inquiry

On the Results screen, select the ISE Calibration Inquiry page as shown in the figure:

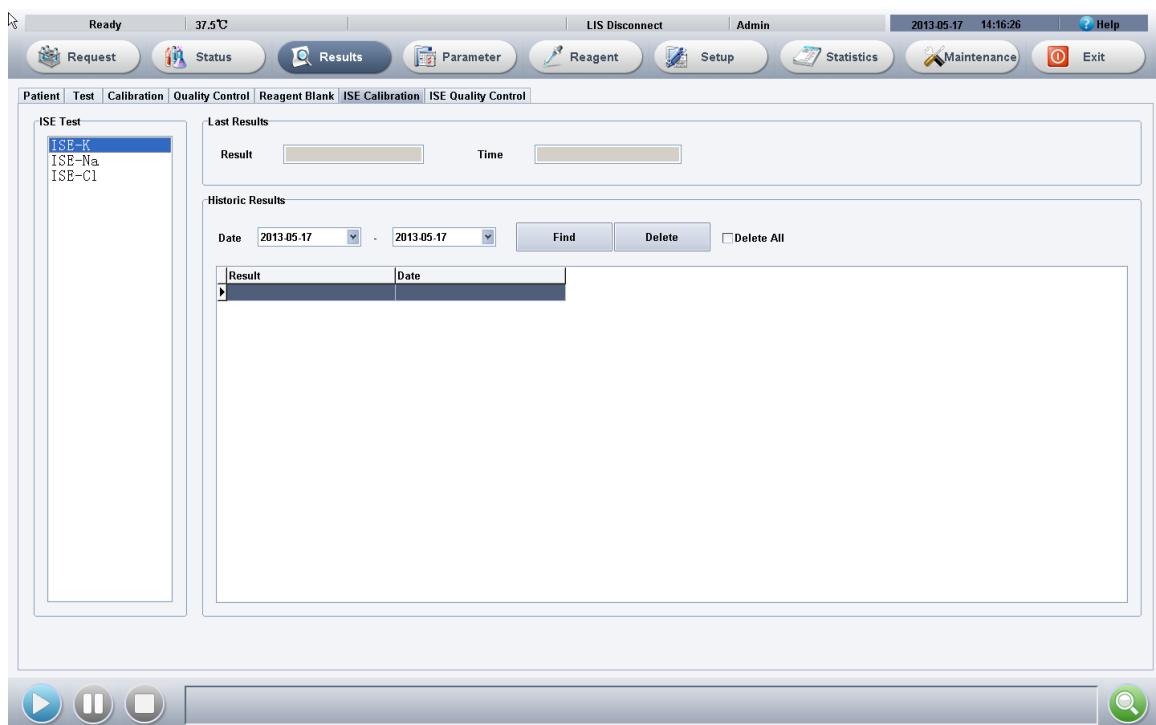


Figure 9-19 ISE Calibration Inquiry

- **Last Results:** Display the results of the last calibration, including calibration results and calibration reagent.
- **Historic Results:** Inquire the historic calibration results in the date range.
- **Inquire:** Inquire the calibration results in a time period of the selected ISE item according to the date range.
- **Delete:** Delete the specified ISE calibration results.



9.7 ISE QC Inquiry

On the Results screen, select the ISE QC Inquiry page as shown in the figure:

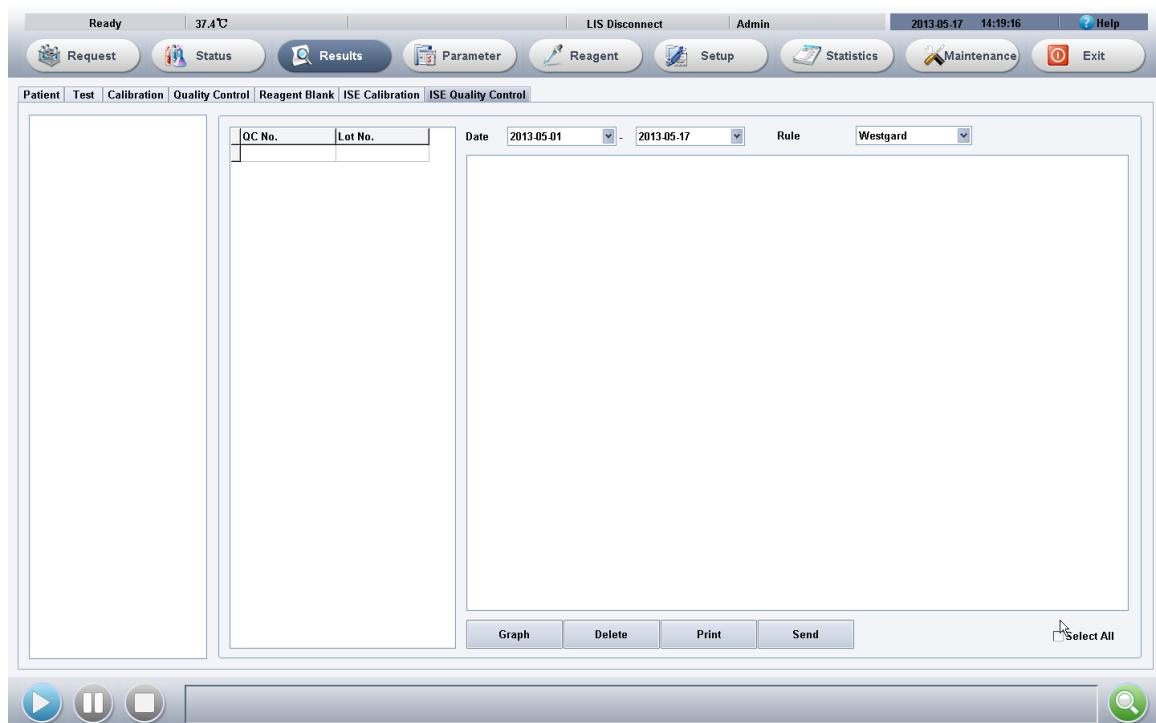


Figure 9-20 ISE QC Inquiry

- **QC Graph:** Display the QC graph according to the selected time and QC rule.
- **Delete:** Delete the selected QC data.
- **Print:** Print the QC data of the selected time.
- **Send:** Transmit the data of QC results.

Caution: The ISE Calibration Inquiry and ISE QC Inquiry pages are displayed only when the ISE module has been installed in the instrument.



Chapter 10 Statistics

10.1 Worksheet Statistics

Click "Statistics" in the main menu to enter the Statistics page as shown in the figure:

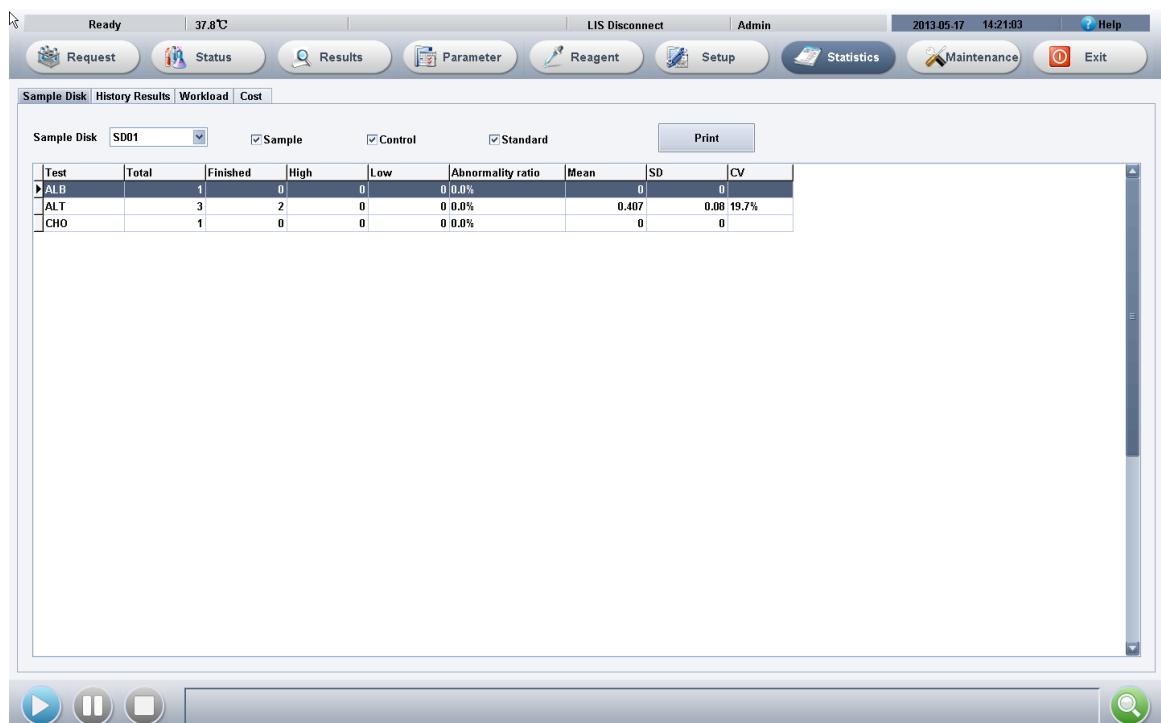


Figure 10-1 Worksheet Statistics

Select the worksheet for which statistics will be conducted from the pull-down list, and the statistical results of the worksheet will be displayed in the list below. The statistical results include Total, Finished, On The High Side, On The Low Side, Abnormality Rate, Mean, SD, and Variable Coefficient.

10.2 Historic Record Statistics

Select the Historic Record Statistics page as shown in the figure:



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The screenshot shows the LIDA 500 software interface. At the top, there is a toolbar with various icons and buttons: Ready, 37.2°C, LIS Disconnect, Admin, 2013.05.17 14:22:00, Help, Request, Status, Results, Parameter, Reagent, Setup, Statistics, Maintenance, and Exit. Below the toolbar, a search bar allows users to filter results by Date (2011-05-17 to 2013-05-17), Sex, Age (Year range), and Test. There are also Statistics and Print buttons. The main area displays a table of test records with columns: Sample No., Sex, Age, Test, Result, and Remark. To the right of the table, a 'Statistics results' panel provides summary statistics: Total, High, Low, Abnormality ratio, Mean value, SD, and CV. At the bottom, there are navigation buttons (Back, Forward, Home) and a search icon.

Figure 10-2 Historic Record Statistics

Specify the inquiry criteria as needed (Date, Sex, Age, and Item), and click the Statistics button. The system will display the test records meeting the criteria in the list, and conduct statistics of the results automatically.

The statistical results include Total, On The High Side, On The Low Side, Abnormality Rate, Mean, SD, and Variable Coefficient.

10.3 Workload Statistics

Select the Workload Statistics page as shown in the figure:



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Figure 10-3 Workload Statistics

Specify the time range and click the Statistics button. The system will conduct statistics of workload of each submitting doctor, testing doctor and auditing doctor in the statistical time respectively.

10.4 Cost Statistics

Select the Cost Statistics page as shown in the figure:



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The screenshot shows the software interface for the LIDA 500. At the top, there is a header bar with various buttons: Ready, 37.6°C, LIS Disconnect, Admin, 2013-05-17 14:23:23, Help, Request, Status, Results, Parameter, Reagent, Setup, Statistics, Maintenance, and Exit. Below the header is a navigation bar with tabs: Sample Disk, History Results, Workload, and Cost (which is currently selected). A condition selection dropdown is set to 'By Patient'. Date pickers show '2013-05-17' for both start and end dates. A sample number input field is empty. To the right are 'Statistics' and 'Print' buttons. The main area is divided into two sections: 'Price' and 'Statistics results'. The 'Price' section contains a table with columns: Test, Cost, and Price. It lists several items: ALB, ALT, CHO, CPR, CR, GGT, GLU, TP, TPR, and UREA, all with values 0. Below this table are input fields for 'Cost' (0), 'Price' (0), and a 'Save' button. The 'Statistics results' section contains a table with columns: Sample No., Clinic No., Name, Test Date, Test times, Total cost, Total charge, and Total profit. It shows two entries: 1305171001 and 1305171002, both dated 2013-05-17, with test times of 2, total costs of 0, total charges of 0, and total profits of 0. Below this table are summary statistics: Sum cost:0, Sum charge:0, and Sum profit:0. At the bottom of the window are standard control buttons: play, pause, stop, and a search icon.

Figure 10-4 Cost Statistics

10.4.1 Statistical Criteria

Specify the statistical criteria of costs and click the Statistics button. The system will conduct statistics of costs, charges and profits in the criteria range.

- **Statistics by Patient:** Input the date and sample number range and click the Statistics button for statistics of all patient samples in the statistical range.
- **Statistics by Item:** Input the date and item and click the Statistics button for statistics of all items in the range.

10.4.2 Price Setup

In the price list, select the item to be set, input the cost and price, and click the Save button.

Chapter 11 Turn off System

Click “Off” in the main menu to log out or exit the system, as shown in the figure:

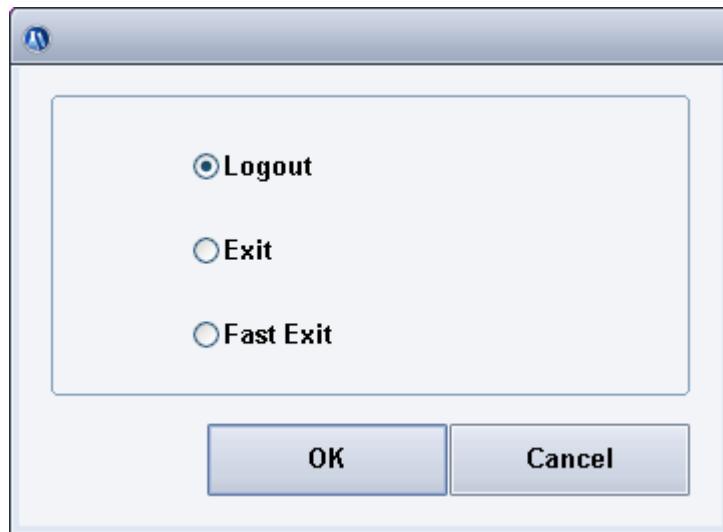


Figure 11-1 Logout and Exit

- **Logout:** Log out and then login again.
- **Exit:** The system conducts necessary cleaning of the tube, sample adding probe and mixer, and turn off the software system automatically.
- **Quick Exit:** The system turns off the software system without cleaning.



Chapter 12 Instrument Maintenance

In order to guarantee the accurate and reliable operation of the instrument and prolong the useful life of the parts and components, you need to conduct daily maintenance as required. The chapter will describe the required daily maintenance, suggestions on troubleshooting, and calibration and replacement of frequently used components, etc. of the instrument.

Caution:

- ◆ *There is potential biological contamination on the surface of the components of the instrument, proper safety measures should be taken for operaiton and maintenance;*
- ◆ *Improper maintenance may cause damage of the insturment. Be sure to conduct maintenance according to the instructions;*
- ◆ *If any failure or problem not listed in the instructions is encountered, please contact LiNEAR Chemicals S.L.'s User Service Department, and the professional designated by LiNEAR Chemicals S.L. will give suggestions on maintenance;*
- ◆ *Be sure to use the parts and components supplied by LiNEAR Chemicals S.L. for maintenance;*
- ◆ *If you have any question, please contact LiNEAR Chemicals S.L.'s User Service Department.*

12.1 Preparation for Maintenance

The following tools, cleaning solutions, alcohol, etc. may be used during maintenance.

- Tools: A set of internal hexagonal wrench, cross screwdriver, syringe (30ml), tweezers, and gauze;
- Cleaning Solutions: Cleaning solutions designated by LiNEAR Chemicals S.L.;
- Others: alcohol.

12.2 Regular Maintenance

12.2.1 Daily Maintenance

1. Check deionized water connection

- Check that the water machine or other external water container has sufficient deionized water;



- Check that the tubes are correctly connected and are not folded or leaking;
 - Check that the switch of the water machine is on.
- 2. Check waste liquid connection**
- Check that the tubes are correctly connected and are not folded or leaking;
 - Check whether the waste liquid is timely disposed.
- 3. Check serial cable connection**
- Check whether the serial cable is normally connected.
- 4. Check printer**
- Check whether the power indicator and data cable connection of the printer are correct;
 - Check whether the primer has sufficient printing paper.
- 5. Check mixers**
- Make visual inspection to see whether the reagent and sample mixers are normally connected;
 - Remove any stain on the mixers with a clean gauze;
 - Use the operating software to make the mixers enter the cleaning status, and observe whether the water outlet of the cleaning pool is normal and whether the rotation of the mixers is normal.
- 6. Check reagent probe and sample probe**
- Remove any stain on the mixers with a clean gauze;
 - Use the operating software to make the reagent probe and sample probe enter the cleaning status, and observe whether the water outlet of the cleaning pool is normal;
 - Observe whether the water outlet of the inner wall is normal. If not, clean the sample probe (use the fine needle supplied for dredging).
- 7. Check reagent/sample syringe**
- There are total three syringes which have similar structures.
- Observe whether the connection of the syringe tubes is leaking. If yes, replace the related tube and connector;
 - Observe whether the piston at the bottom of the syringe is leaking. If yes, replace the piston.



Figure 12-1 Syringe Maintenance

8. Table Surface Cleaning

- Wipe the dirt on the workbench with a cloth soaked with neutral cleaning solution;
 - Wipe the dirt on the facepiece of reagent probe and sample probe and the facepiece of mixers;
 - Wipe the dirt on the facepiece of reagent probe and sample probe and the rotation axis of mixers.
-

Warning: Properly dispose the removed waste components according to the local laws.

Before mounting/removing the reagent pack, ensure the power supply of the instrument has been turned off.

Caution: Please use the consumables recommended by LiNEAR Chemicals S.L., otherwise the performance of the system may reduce.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

12.2.2 Weekly Maintenance

1. Cleaning the sample probe and reagent probe

- 1) Make sure the power supply of the analysis section has been turned off;
- 2) Pull the sample probe/reagent probe to the highest point and then rotate the probe to the position for convenient operation:



Figure 12-2 Sample Adding Probe Maintenance

- a) Gently wipe the point of the probe with a gauze soaked with alcohol till the surface becomes smooth and oil-free;
- b) Clean the point of the probe with a gauze soaked with deionized water;
- c) Turn on the power supply of the analysis section, enter the Maintenance – Daily Maintenance page, and execute the Reset Whole Machine operation.

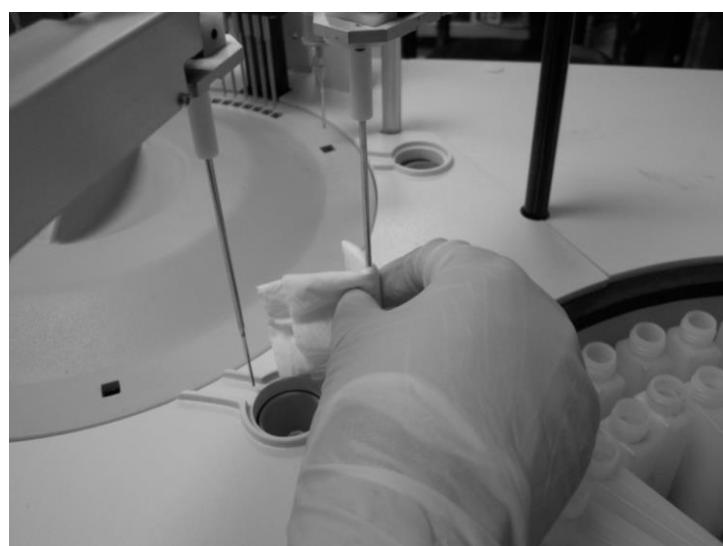


Figure 12-3 Sample Adding Probe Maintenance

Warning: Operate carefully to avoid scratching the hand.

Caution: Do not overexert yourself during wiping, otherwise the point of the probe will be distorted, which impacts the performance of the machine.



Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

Never discard gauzes used for cleaning at will.

2. Cleaning the Sample/Reagent Mixers

- 1) Make sure the power supply of the analysis section has been turned off;
- 2) Pull the mixer to the highest point and then rotate it to the position for convenient operation (outside the cleaning pool);
- 3) Gently wipe the mixer with a gauze soaked with alcohol till the surface becomes smooth and oil-free;
- 4) Clean the point of the probe with a gauze soaked with deionized water;
- 5) Turn on the power supply of the analysis section, enter the Maintenance – Daily Maintenance page, and execute the Reset Whole Machine operation.

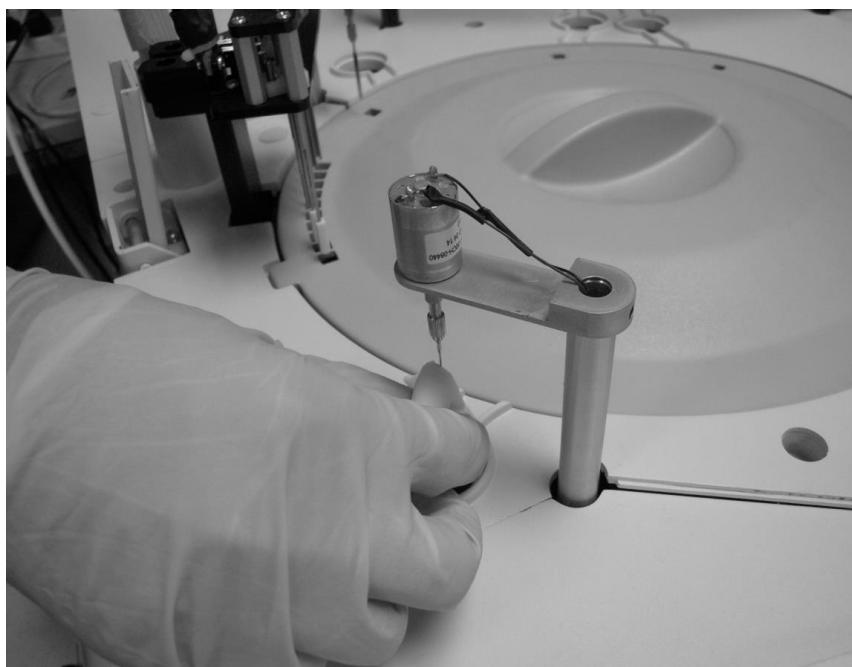


Figure 12-4 Mixer Maintenance

Warning: Operate carefully to avoid scratching the hand.

Caution: Do not overexert yourself during wiping, otherwise the point of the probe will be distorted, which impacts the performance of the machine.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.



Never discard gauzes used for cleaning at will.

3. Cleaning the barcode scanning window (with the optional fixed barcode scanning)

- 1) Make sure the power supply of the analysis section has been turned off;
- 2) Remove the sample tray cover and reagent tray cover, and take out the sample tray and reagent tray;
- 3) Clean the glass window with a gauze soaked with deionized water;
- 4) Mount the reagent tray and sample tray, and close the tray covers.

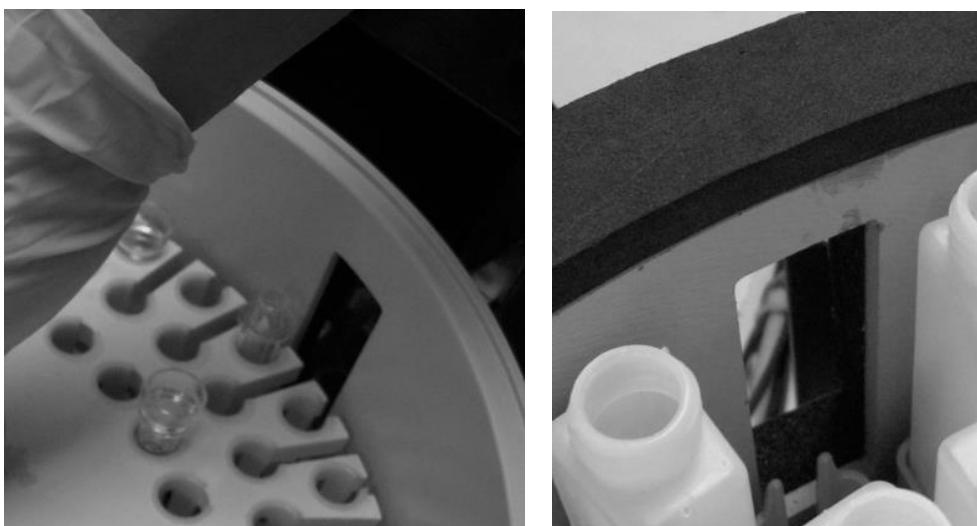


Figure 12-5 Scanning Window Maintenance

Caution: Do not directly look at the laser of the barcode scanner.

Do not wipe the glass window with a sharp object.

4. Cleaning the reagent/sample tray bin

- 1) Make sure the power supply of the analysis section has been turned off;
- 2) Rotate the sample probe and reagent probe off the sample tray and reagent tray;
- 3) Remove the sample tray cover and reagent tray cover, and take out the sample tray and reagent tray.

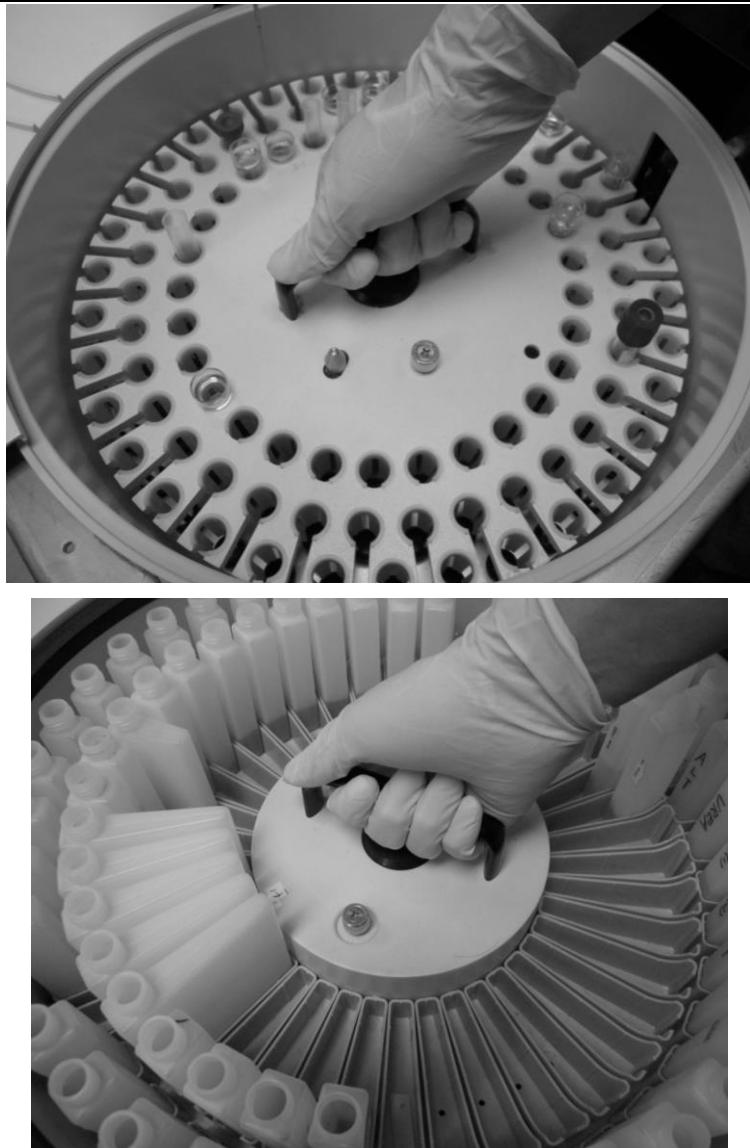


Figure 12-6 Reagent Tray Maintenance

- 4) Clean the sample bin and reagent bin with a cloth soaked with cleaning agent;
- 5) Mount the reagent tray and sample tray, and close the tray covers.



Figure 12-7 Reagent Tray Maintenance

Warning: Operate carefully to avoid scratching the hand.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

5. Cleaning the panel of analysis section

- 1) Make sure the power supply of the analysis section has been turned off;
 - 2) Wipe the panel with a clean cloth soaked with clear water. To wipe extremely dirty areas, a small amount of cleaning agent can be added.
-

Warning: Operate carefully to avoid scratching the hand.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

Never discard gauzes used for cleaning at will.

6. Strong cleaning of test cuvettes

- 1) Put the specified cleaning solution at the specified positions on the sample tray and reagent tray respectively;



-
- 2) Enter the Maintenance – Daily Maintenance screen, execute the Strong Cleaning operation to realize strong cleaning of the sample probe, reagent probe and test cuvettes. Then execute the “Strong Cleaning of Test Cuvette” command.

12.3 Monthly Maintenance

1. Cleaning the sample probe and reagent probe cleaning pool

- 1) Make sure the power supply of the analysis section has been turned off;
- 2) Rotate the sample probe and reagent probe off the cleaning pool;
- 3) Clean the inside and periphery of the cleaning pool with a clean cotton swab.

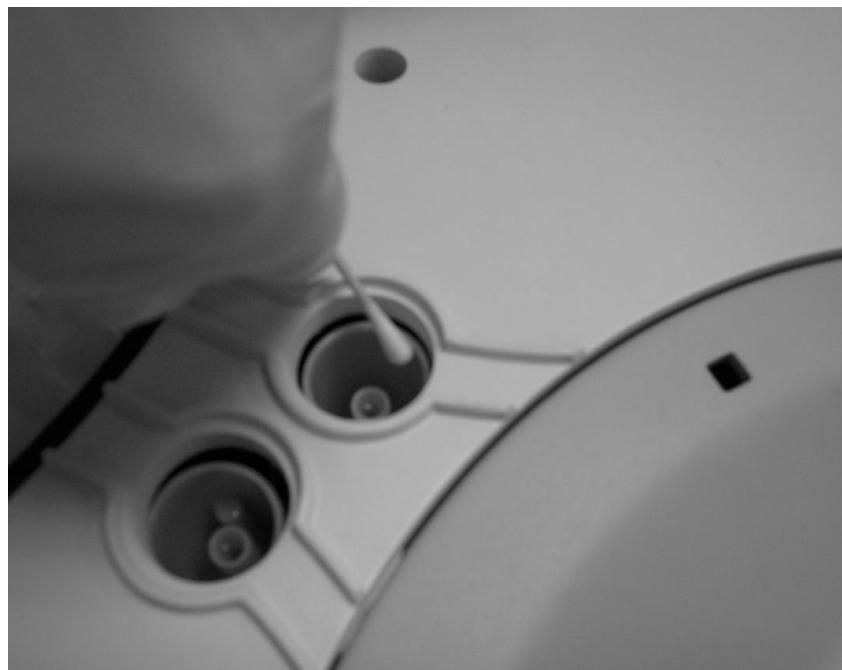


Figure 12-8 Cleaning Pool Maintenance

Warning: Operate carefully to avoid scratching the hand.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

Never discard cotton swabs used for cleaning at will.

2. Cleaning the mixer cleaning pool

- 1) Turn off the power supply of the analysis section;
- 2) Grasp the rocker arms of the sample probe, reagent probe and mixer with hand respectively



- and move them out of the respective cleaning pool;
- 3) Wipe the inside and outer side of the cleaning pool with a soft gauze soaked with alcohol to ensure the cleaning pool is clean;
 - 4) After the wiping, move the sample probe, reagent probe and mixer over the cleaning pool.

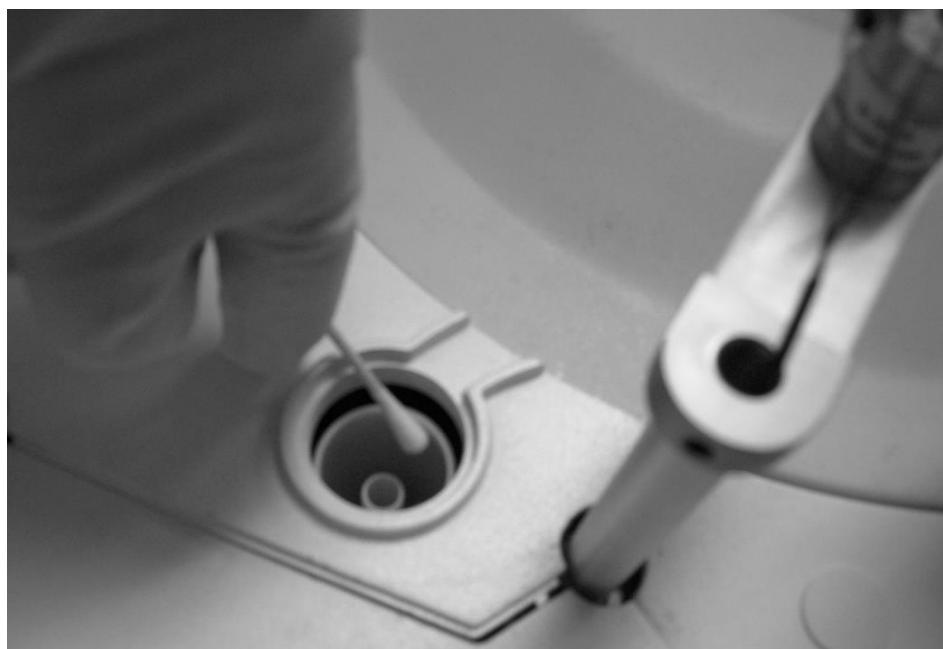


Figure 12-9 Cleaning Pool Maintenance

Warning: Operate carefully to avoid scratching the hand.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

Never discard cotton swabs used for cleaning at will.

3. Automatic cleaning mechanism maintenance

- 1) Start the machine and open the reaction tray cover;
- 2) Enter the Maintenance – Daily Maintenance screen, operate “Automatic Cleaning Station Maintenance”, and aim the cleaning mechanism at the test cuvette;
- 3) Loosen the adjusting nut of the automatic cleaning station and remove the automatic cleaning mechanism from the support;
- 4) Wipe the surface of the steel probe and wiping head with a soft gauze soaked with deionized water;
- 5) Check whether the surface of the wiping head is smooth. If it is worn, replace it;



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- 6) Mount the automatic cleaning mechanism onto the support and adjust the position to make the steel probe and wiping head at the center of the test cuvette;
 - 7) Fix the nut.
-

Warning: Operate carefully. Do not overexert yourself when rotating the wiping head.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

Never discard gauzes used for cleaning at will.

4. Replacing the test cuvette

- 1) Turn off the power supply of the analysis section;
 - 2) Open the reaction tray cover;
 - 3) Carefully remove all fixing clips of the test cuvette to be replaced with the tweezers;
 - 4) After the clips are removed, clamp the two sides of the test cuvette with the thumb and index finger to take the test cuvette out of the reaction tray (do not touch the light-passing surface of the test cuvette);
 - 5) Clamp the two sides of the clean test cuvette with the thumb and index finger and put it in the reaction tray vertically (do not touch the light-passing surface of the test cuvette; the light-passing surface should face the inner side of the reaction tray);
 - 6) Carefully insert the clips in the gap on the left side of the test cuvette with the tweezers and vertically press it down;
 - 7) Check that all test cuvettes and clips are correctly put;
 - 8) Close the reaction tray cover.
-

Warning: Operate carefully. During the process, do not touch other components (probe or mixer) on the machine.

Caution: When mounting a new test cuvette, do not touch the optical surface of the test cuvette.

After the mounting, check whether any clip or test cuvette is missing.

Biohazard: Be sure to wear gloves and work clothes during operation to prevent infection.

Removed test cuvettes should be properly disposed.



The test cuvettes can also be replaced in 1-3 months according to the actual application effect.

5. Cleaning the water-in tank

- 1) Make sure the power supply of the analysis section has been turned off;
- 2) Loosen the screws on the support for water-in tank with the screwdriver;
- 3) Rotate off the plastic shell and clean the tank with clear water 3 times to make the inner wall of the tank no longer satiny;
- 4) Wipe the shell dry and mount it again;
- 5) Turn on the power supply of the analysis section and observe whether water enters the tank normally.



Figure 12-10 Water-in Tank Maintenance

12.4 Other Maintenance

1. Replacing the halogen lamp:

Check or replace it every 1000 hours.

2. Replacing the mixer:



Check or replace it once a year.

3. Replacing the dust screen

Clean it every 3 months.

4. Replacing the wiping head

Clean it every 6 months.

Caution: The replacement of wiping head and mixer must be allowed by the engineer of LiNEAR Chemicals S.L..

12.5 Maintenance Guide

12.5.1 Liquid Line Check

- Whether the air tightness of the connection between the probe and syringe and the tube is good;
- Whether the air tightness of the connection between the steel probe and tube of the automatic cleaning station is good;
- Whether the tube connection is consistent with the graph on the rear panel; whether the tube is bent;
- Whether the waste liquid tank is full;
- Whether the deionized water machine works normally;
- Whether the cleaning solution is sufficient;
- Whether the liquid in the cleaning pool flows evenly and smoothly.

12.5.2 Regular Check

- Whether the sample probe and reagent probe are at the center of the cleaning pool during the cleaning;
- Whether the sample probe and reagent probe are at the center of the test cuvette during the cleaning;
- Whether the mixer is at the center of the cleaning pool during the cleaning;
- Whether the automatic cleaning station is at the center of the test cuvette during the cleaning.



12.5.3 Regular Cleaning

- Wipe the outer walls of the sample probe and reagent probe with an alcohol prep pad;
- Wipe the mixer with an alcohol prep pad;
- Wipe the workbench surface of the instrument with an alcohol prep pad.

12.5.4 Daily Maintenance

When manual interface is needed during the use of the instrument, enter the Maintenance - Daily Maintenance screen as shown in the figure:

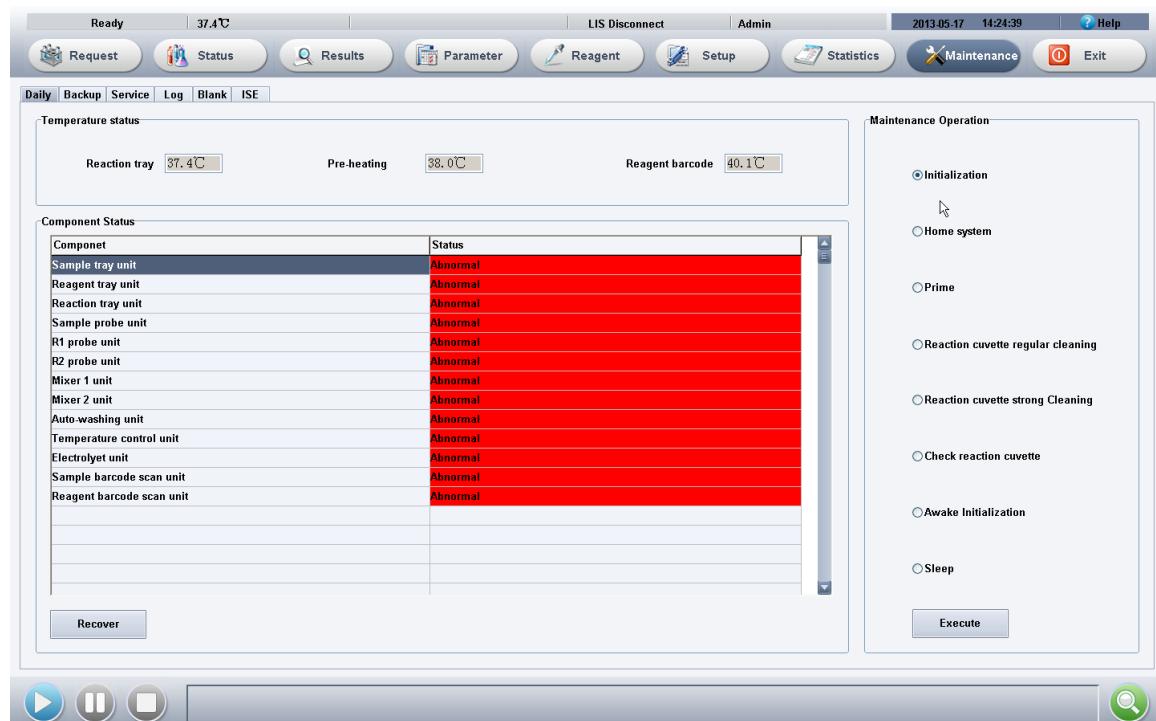


Figure 12-11 Daily Maintenance

- Instrument Temperature Inquiry: Display the current temperature status of the system.
- Component Status: Display the current status of the various units and components. Select any unit and click the Failure Restoration button to restore the operation.
- Maintenance Operation: When the instrument is in the non-testing mode, you can select the desired maintenance operation and click the Execute button.

12.5.5 Data Maintenance

To make backup or restore data, enter the Maintenance - Data Maintenance screen as shown in the figure:



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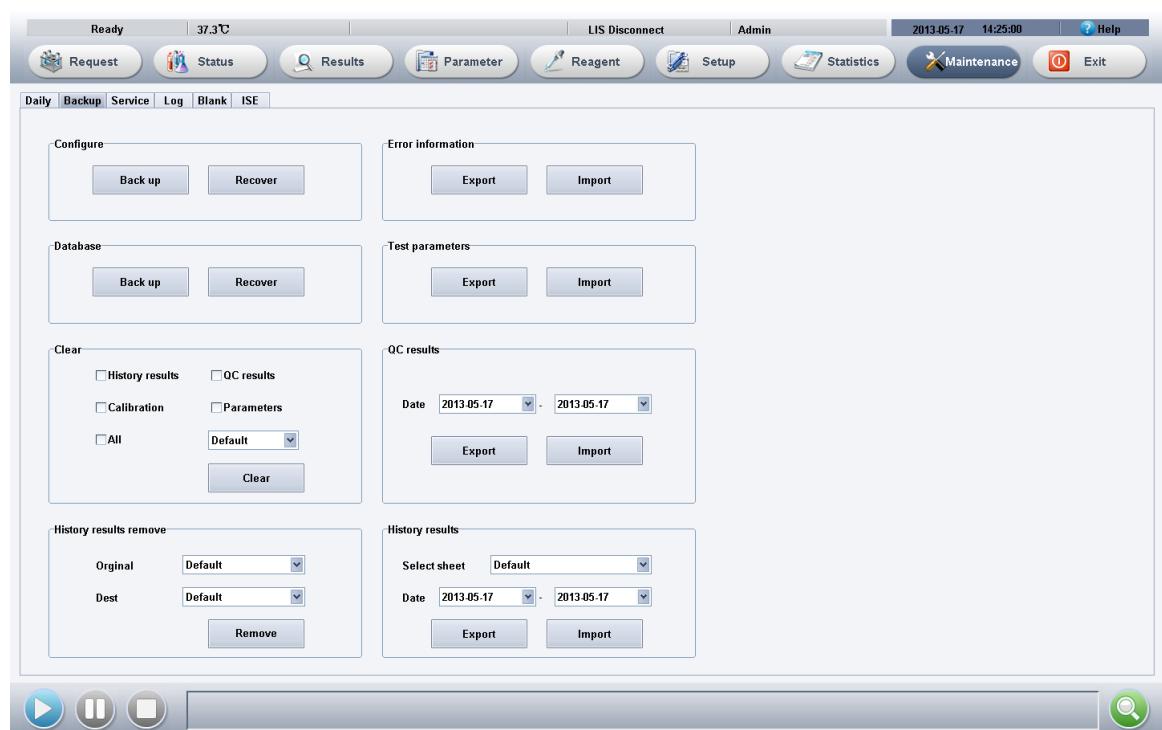


Figure 12-12 Data Maintenance

■ Backup and Restoration of Configuration Parameters

Configuration parameters are the best correction parameters obtained after commissioning during the machine production that are suitable for the hardware system. In order to prevent the configuration parameters from being damaged or lost, which causes abnormality of the equipment, please make backup of configuration parameters in the normal mode so as to restore the configuration parameters to the backup state with the Restore function when necessary.

■ Backup and Restoration of Database

Database is the data file used to store setup parameters and historic test results. Make regular backup of database so as to restore the database to the backup state in case data are damaged or lost.

■ Data Deletion

Used to delete the specified type of data in the database. The data type can be selected according to the actual needs. Once deleted, the data cannot be restored!

■ Export and Import of QC Results

Export all QC results tested in the specified time range. Data exported will be saved in the specified directory. When they are needed, the QC results in the specified time range can be imported from the file.



■ Export and Import of Historic Data

Export the patient sample test results in the specified time range. Data exported will be saved in the specified directory. When they are needed, the patient sample test results in the specified time range can be imported from the file.

■ Export and Import of Setup Parameters of Item

Export the setup parameters of the current item in the system. Data exported will be saved in the specified directory. When they are needed, the setup parameters of the item can be imported from the file.

Caution: Only the administrator can maintain data!

12.5.6 Repair Record

Record all maintenance records of the instrument.

12.5.7 Log

Record the user login log and major failure log of the instrument.

12.5.8 Test Cuvette Blank

View the water blank value of the test cuvette. In normal cases, the water blank value of the test cuvette should be between 40000-60000. If it is less than the lower limit, the test cuvette may be contaminated or worn, or the lamp may be aged. You can judge whether to replace with a new test cuvette according to the actual circumstances.

12.5.9 ISE Maintenance (Optional)

If the ISE module has been installed in the instrument, enter the Maintenance – ISE Maintenance screen for maintenance, as shown in the figure:



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The screenshot shows the LIDA 500 software interface with the following details:

- Top Bar:** Ready, 37.7°C, LIS Disconnect, Admin, 2013.05.17 14:25:32, Help.
- Middle Left:** Navigation tabs: Request, Status, Results, Parameter, Reagent, Setup, Statistics, Maintenance, Exit.
- Middle Center:** A table titled "Component Status" showing the following data:

Component	Rated test time	Rated test times	Last replace time	Test time (h)	Test times	Remark
Na Electrode	100	10000	2013.05.17 09:31:56	0	0	
K Electrode	100	10000	2013.05.17 09:31:56	0	0	
Cl Electrode	100	10000	2013.05.17 09:31:56	0	0	
Reference Electrode			2013.05.17 09:31:56	0	0	
A liquid line			2013.05.17 09:31:56	0	0	
B liquid line			2013.05.17 09:31:56	0	0	
waste liquid line			2013.05.17 09:31:56	0	0	
A liquid regular line			2013.05.17 09:31:56	0	0	
B liquid regular line			2013.05.17 09:31:56	0	0	
Waste liquid regul:			2013.05.17 09:31:56	0	0	

- Middle Right:** "Maintenance operation" section with radio button options:
 - Two points calibration
 - Cleaning Cycle
 - Maintenace cycle
 - Pump Calibration cycle
 - Bubble inspection calibration cycle
 - ISE Error Recover
 - Deionized A cycle
 - Deionized B cycle
 - Cleaning profile
- Bottom:** Buttons for Replace component, Find reagent, Replace reagent, and Execute.

Figure 12-13 ISE Maintenance

- Daily cleaning
 - After starting the machine, enter the Maintenance – ISE Maintenance screen for maintenance every day to execute the Cleaning Period operation and execute “Two-point Calibration”. When the test is finished or the number of samples with the ISE test finished exceeds 50 samples, an ISE Cleaning operation is required. You can also enter the System Setup - ISE Setup screen to make the corresponding setup to make the software complete the above operations automatically;

 - Pump Calibration
- After starting the machine, enter the Maintenance – ISE Maintenance screen every day to execute the Pump Calibration Period operation.



Chapter 13 Failure Treatment

13.1 Failure Classification

When the system fails, you can see the failure and warning prompt messages intuitively from the failure information table and test list. A number of failures may appear during a test. Different failures may have different severity degrees and are treated in different ways. Failures are divided as follows according to the severity: warning level, cancel level, pause level, stop level, restrict level, and turn off level. In which, the failure information of pause level, stop level and restrict level will be written in the log.

1. Warning Level Failure

Failure that does not impact the action and test results of the instrument but requires you to know the error (such as invalid test cuvette blank or abnormal test results).

Invalid Test Cuvette Blank: During the cleaning of cuvette, deionized water is poured into the cuvette after the sixth cleaning is finished. When the cuvette is passing the photoelectric acquisition position, the water blank of the cuvette is measured. If the water blank value exceeds the set range, the system will prompt you that “the blank of x# cuvette is invalid” and give up the use of the cuvette automatically.

When the test results are abnormal, the system will prompt you with a sign. For abnormal results, you can conduct manual retest or recheck. If the automatic retest rule has been set, the system will finish the retest automatically. Abnormalities of test results include:

- | | |
|--|-----|
| ■ On the low side | L |
| ■ On the high side | H |
| ■ Exceeding the lower linear limit | A< |
| ■ Exceeding the upper linear limit | A> |
| ■ Exceeding the linearity range (nonlinear) | OL |
| ■ Substrate exhaust | SE |
| ■ Less than the increment retest limit | AR |
| ■ Greater than the decrement retest limit | DR |
| ■ No linear interval | NLN |
| ■ No calculation interval | ENC |
| ■ Prozone check exceeding limit | PRO |
| ■ Exceeding reactivity of zero concentration | RRZ |



- Exceeding reactivity of maximum calibration RRN
- Still abnormal after retest **

2. Cancel Level Failure

As some criteria are not met in this test, the test cannot be continued and a retest is required, or a reagent cannot be used any longer (such as Reagent Missing, Sample Missing, Probe Collision, and Reagent Blank Exceeding Range).

- Reagent Missing: When a certain reagent is missing during a test, the instrument will skip the test corresponding to the reagent. If you need to restore the test of the item, please supplement the reagent, enter the Test Status – Reagent Tray screen, and click the Refresh Reagent button to refresh the range.
- Sample Missing: When a certain sample is missing during a test, the instrument will skip the test corresponding to the sample. If you need to restore the test of the sample, please supplement the sample, enter the Test Status – Sample Tray screen, and click the Refresh Sample button to refresh the range.
- Probe Collision: When the sample adding probe is collided horizontally or vertically during movement, the test will be cancelled automatically. For automatic retest, before starting the test, enter System Setup, select the System Control Parameter page, and select “Conduct retest automatically when the test fails”.
- Reagent Blank Exceeding Range: The setup parameters of each test item include the setting of Reagent Blank. This value is provided in the reagent instructions and represents the value range of absorbance of the reagent blank test when the reagent is valid. You can fill in the value according to your experience. If Reagent Blank is selected in Blank Type of the item and the reagent blank exceeds the set range, the software will prompt you that “xx reagent blank exceeds the range” and cancel all tests of the item.

3. Pause Level Failure

When the reagent probe, sample probe, mixer or automatic cleaning unit fails during the test, the tests involved will be cancelled automatically.

Reagent Probe Failure: When the reagent probe is collided and cannot be restored or the syringe of the reagent probe is abnormal during the test, thus the reagent probe cannot be used for adding sample any longer, the software will prompt “Reagent Probe Failure” and enter the pause mode, but the test with reagent added will continue:

- Reagent Probe Failure: When the reagent probe is collided and cannot be restored or the



syringe of the reagent probe is abnormal during the test, thus the reagent probe cannot be used for adding sample any longer, the software will prompt “Reagent Probe Failure” and enter the pause mode, but the test with reagent added will continue;

- Sample Probe Failure: When the sample probe is collided and cannot be restored or the syringe of the sample probe is abnormal during the test, thus the sample probe cannot be used for adding sample any longer, the software will prompt “Sample Probe Failure” and enter the pause mode, but the test with sample added will continue;
- Mixer Failure: When the mixer cannot work normally during the test, the software will prompt “Mixer Failure” and enter the pause mode, but the test with mixing finished will continue;
- Automatic Cleaning Unit Failure: When the automatic cleaning unit cannot work normally during the test, the software will prompt “Automatic Cleaning Unit Failure” and stop the adding of R1, but the test having been started will continue.

4. Stop Level Failure

When any failure to operate occurs during the test, such as photoelectric acquisition failure, reaction tray failure or any liquid line device failure, the system will cancel all tests and enter the stop mode. The software will prompt “the status of xx unit is abnormal”.

5. Ban Level Failure

If, when the machine is started, the test criteria are not met, the test operation will be banned, such as photoelectric acquisition failure, reaction tray failure, reagent tray failure, sample tray failure, sample probe failure, reagent probe failure, mixer failure or any liquid line device failure. The software will prompt “the status of xx unit is abnormal”.

6. Restrict Level Failure

The LIS interface or LIS connection has any problem, and reconnection is required. If the ISE module has been installed in the instrument, but ISE cannot work normally, the ISE test will be banned. The sample barcode system has been installed in the instrument, but the sample barcode system cannot work normally. The reagent barcode system has been installed in the instrument, but the reagent barcode system cannot work normally. The software screen can display the status corresponding to the various function modules.

7. Turn Off Level Failure



Also called "No Starting Level". When the starting self-check is not passed, the software will prompt you and turn off the control system automatically (such as damage of database, software failure, insufficiency of system resources, and invalidity user's privilege).

13.2 Failure Summary Table

The following are the common failures and treatment methods of the instrument. If the failure cannot be cleared according to the tip or more detailed information is required, contact LiNEAR Chemicals S.L.'s Customer Service Department.

Unit	Failure Code/Content	Failure Level	Treatment Measure
Main Processing Unit	001: Command error	Stop level	Check the connection of serial cables. Restart the instrument and PC; Check whether the board matches with the program version; If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	002: Parameter error	Stop level	
	003: Abnormality of self-check	Stop level	
	004: Communication failure	Stop level	
	005: The system is busy and cannot respond to other operations.	Stop level	
	006: Error of host memory	Stop level	
	007: The command sent to the upper computer is not responded or the response is wrong.	Stop level	
	008: The command sent to the lower computer is not responded or the response is wrong.	Stop level	
	009: Error of communication frame sent by upper computer	Stop level	
	010: Error of communication frame sent by lower computer	Stop level	
	101: Time out sending command to R1 module	Stop level	Check the connection of the control line of the reagent probe 1 module; check whether the board matches with the program version.
	102: Time out R1 module executing command	Stop level	
	201: Time out sending command to R2 module	Stop level	Check the connection of the control line of reagent probe 2 module; check whether the board
	202: Time out R2 module	Stop level	



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	executing command		matches with the program version.
	301: Time out sending command to sample probe module	Stop level	Check the connection of the control line of the sample probe module; check whether the board matches with the program version.
	302: Time out sample probe module executing command	Stop level	
	401: Time out sending command to M1 module	Stop level	Check the connection of the control line of the sample mixer module; check whether the board matches with the program version.
	402: Time out M1 module executing command	Stop level	
	501: Time out sending command to M2 module	Stop level	Check the connection of the control line of the reagent mixer module;
	502: Time out M2 module executing command	Stop level	Check whether the board matches with the program version.
	601: Time out sending command to reaction tray module	Stop level	Check the connection of the control line of the reaction tray module; check whether the board matches with the program version.
	602: Time out reaction tray module executing command	Stop level	
	701: Time out sending command to sample tray module	Stop level	Check the connection of the control line of the sample tray module; check whether the board matches with the program version.
	702: Time out sample tray module executing command	Stop level	
	801: Time out sending command to reagent tray module	Stop level	Check the connection of the control line of the reagent tray module; check whether the board matches with the program version.
	802: Time out reagent tray module executing command	Stop level	
	901: Time out sending command to automatic cleaning module	Stop level	Check the connection of the control line of the automatic cleaning module;
	902: Time out automatic cleaning module executing command	Stop level	Check whether the board matches with the program version.
	951: Time out sending command to temperature control module	Stop level	Check the connection of the control line of the temperature



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	952: Time out temperature control module executing command	Stop level	control module; Check whether the board matches with the program version.
Sample Probe	1001: Command error	Stop level	Restart the instrument PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	1002: Parameter error	Stop level	
	1003: Abnormality of self-check	Stop level	
	1004: Communication failure	Stop level	
	1005: Command cannot be executed normally	Stop level	
	1006: Abnormality of vertical movement (in test cuvette, not restored)	Stop level	Check whether the cover of the sample test tube is removed; Check whether the sample is missing in the sample cup;
	1007: Abnormality of vertical movement (in sample cup, not restored)	Pause level	Check whether the covers of reaction tray and sample tray are closed;
	1008: Abnormality of vertical movement (in cleaning pool, not restored)	Pause level	Check whether there is any foreign object on the movement trace of the sample probe;
	1009: Abnormality of vertical movement (in ISE sample adding opening, not restored)	Pause level	Check whether the appearance of the sample probe is normal;
	1010: Abnormality of vertical movement (other positions, not restored)	Pause level	Check whether the positions of the sample probe are in the center;
	1011: Abnormality of vertical movement (restored)	Cancel level	After the sample probe is vertically jacked up and loosened, check whether the sample probe can be reset freely.
	1012: Vertical probe collision (not restored)	Stop level	
	1013: Vertical probe collision (restored)	Cancel level	
	1014: Vertical reset signal not detected	Stop level	Turn off the power supply of the analysis section, hold the rocker arm of the sample probe, and move the sample probe to the intermedial height. Then turn on the power supply of the analysis section. If, after the instrument and software are restarted, the failure still appears, contact the After



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			Service Unit.
	1015: Abnormality of horizontal movement (not restored)	Pause level	Check whether there is any foreign object on the movement trace of the sample probe.
	1016: Abnormality of horizontal movement (restored)	Cancel level	
	1017: Horizontal probe collision (not restored)	Pause level	Check whether there is any foreign object on the movement trace of the sample probe.
	1018: Horizontal probe collision (restored)	Cancel level	
	1019: Horizontal reset signal not detected	Pause level	Turn off the power supply of the analysis section, hold the rocker arm of the sample probe, and move the sample probe to above the cleaning pool. Then turn on the power supply of the analysis section. If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	1020: Abnormality of syringe	Pause level	Open the front cabinet door of the machine to see whether the syringe is abnormal. If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	1021: No liquid	Cancel level	Check, when the sample probe is being cleaned, whether the flow rate of the deionized water in the sample probe cleaning pool is normal; Check whether there is sufficient sample in the sample cup.
Reagent Probe 1	2001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	2002: Parameter error	Stop level	
	2003: Abnormality of self-check	Stop level	
	2004: Communication failure	Stop level	
	2005: Command cannot be executed normally	Stop level	



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	2006: Abnormality of vertical movement (in test cuvette, not restored)	Stop level	Check whether the reagent bottle cover is opened; Check whether reagent is missing in the reagent bottle;
	2007: Abnormality of vertical movement (in reagent bottle, not restored)	Pause level	Check whether the covers of the reaction tray and reagent tray are closed;
	2008: Abnormality of vertical movement (in cleaning pool, not restored)	Pause level	Check whether there is any foreign object on the movement trace of the reagent probe;
	2009: Abnormality of vertical movement (other positions, not restored)	Pause level	Check whether the appearance of the sample probe is normal;
	2010: Abnormality of vertical movement (restored)	Cancel level	Check whether the positions of the reagent probe are in the center;
	2011: Vertical probe collision (not restored)	Stop level	After the reagent probe is vertically jacked up and loosened, check whether the reagent probe can be reset freely.
	2012: Vertical probe collision (restored)	Cancel level	
	2013: Vertical reset signal not detected	Stop level	Turn off the power supply of the analysis section, hold the rocker arm of the reagent probe, and move the reagent probe to the intermedial height. Then turn on the power supply of the analysis section. If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	2014: Abnormality of horizontal movement (not restored)	Pause level	Check whether there is any foreign object on the movement trace of the reagent probe.
	2015: Abnormality of horizontal movement (restored)	Cancel level	
	2016: Horizontal probe collision (not restored)	Pause level	Check whether there is any foreign object on the movement trace of the reagent probe.
	2017: Horizontal probe collision (restored)	Cancel level	
	2018: Horizontal reset signal not detected	Pause level	Turn off the power supply of the analysis section, hold the rocker arm of the reagent probe, and



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			move the reagent probe to above the cleaning pool. Then turn on the power supply of the analysis section. If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	2019: Abnormality of syringe	Pause level	Open the front cabinet door of the machine to see whether the syringe is abnormal. If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	2020: No liquid	Cancel level	Check, when the reagent probe is being cleaned, whether the flow rate of the deionized water in the reagent probe cleaning pool is normal; Check whether there is sufficient reagent in the reagent bottle.
Reagent Probe 2	3001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	3002: Parameter error	Stop level	
	3003: Abnormality of self-check	Stop level	
	3004: Communication failure	Stop level	
	3005: Command cannot be executed normally	Stop level	
	3006: Abnormality of vertical movement (in test cuvette, not restored)	Stop level	Check whether the reagent bottle cover is opened; Check whether reagent is missing in the reagent bottle;
	3007: Abnormality of vertical movement (in reagent bottle, not restored)	Pause level	Check whether the covers of the reaction tray and reagent tray are closed;
	3008: Abnormality of vertical movement (in cleaning pool, not restored)	Pause level	Check whether there is any foreign object on the movement trace of the reagent probe;
	3009: Abnormality of vertical movement (other positions, not restored)	Pause level	Check whether the appearance of the reagent probe is normal;
	3010: Abnormality of vertical	Cancel	Check whether the positions of the



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	movement (restored)	level	reagent probe are in the center; After the reagent probe is vertically jacked up and loosened, check whether the reagent probe can be reset freely.
	3011: Vertical probe collision (not restored)	Stop level	
	3012: Vertical probe collision (restored)	Cancel level	
	3013: Vertical reset signal not detected	Stop level	Turn off the power supply of the analysis section, hold the rocker arm of the reagent probe, and move the reagent probe to the intermedial height. Then turn on the power supply of the analysis section. If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	3014: Abnormality of horizontal movement (not restored)	Pause level	Check whether there is any foreign object on the movement trace of the reagent probe.
	3015: Abnormality of horizontal movement (restored)	Cancel level	
	3016: Horizontal probe collision (not restored)	Pause level	Check whether there is any foreign object on the movement trace of the reagent probe.
	3017: Horizontal probe collision (restored)	Cancel level	
	3018: Horizontal reset signal not detected	Pause level	Turn off the power supply of the analysis section, hold the rocker arm of the reagent probe, and move the reagent probe to above the cleaning pool. Then turn on the power supply of the analysis section. If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	3019: Abnormality of syringe	Stop level	Open the front cabinet door of the machine to see whether the syringe is abnormal. If, after the instrument and software are



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			restarted, the failure still appears, contact the After Service Unit.
	3020: No liquid	Cancel level	Check, when the reagent probe is being cleaned, whether the flow rate of the deionized water in the reagent probe cleaning pool is normal; Check whether there is sufficient reagent in the reagent bottle.
Sample Tray Unit	4001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	4002: Parameter error	Stop level	
	4003: Abnormality of self-check	Stop level	
	4004: Communication failure	Stop level	
	4005: Command cannot be executed normally	Stop level	
	4006: Reset impossible	Pause level	
	4007: Lost step in movement	Pause level	
Reagent Tray Unit	5001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	5002: Parameter error	Stop level	
	5003: Abnormality of self-check	Stop level	
	5004: Communication failure	Stop level	
	5005: Command cannot be executed normally	Stop level	
	5006: Reset impossible	Pause level	
	5007: Lost step in movement	Pause level	
Assay Tray Unit	6001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	6002: Parameter error	Stop level	
	6003: Abnormality of self-check	Stop level	
	6004: Communication failure	Stop level	
	6005: Command cannot be executed normally	Stop level	
	6006: Reset impossible	Pause level	
	6007: Lost step in movement	Pause level	



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		level	
Sample Mixer	7001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	7002: Parameter error	Stop level	
	7003: Abnormality of self-check	Stop level	
	7004: Communication failure	Stop level	
	7005: Command cannot be executed normally	Stop level	
	7006: Abnormality of vertical movement (in test cuvette, not restored)	Stop level	
	7007: Abnormality of vertical movement (in cleaning pool, not restored)	Pause level	
	7008: Abnormality of vertical movement (other positions, not restored)	Pause level	
	7009: Abnormality of vertical movement (restored)	Cancel level	
	7010: Vertical reset signal not detected	Stop level	
Reagent Mixer	7011: Horizontal reset signal not detected	Pause level	If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	8001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	8002: Parameter error	Stop level	
	8003: Abnormality of self-check	Stop level	
	8004: Communication failure	Stop level	
	8005: Command cannot be executed normally	Stop level	
	8006: Abnormality of vertical movement (in test cuvette, not restored)	Stop level	
	8007: Abnormality of vertical movement (in cleaning pool, not restored)	Pause level	
	8008: Abnormality of vertical movement (other positions, not restored)	Pause level	
	8009: Abnormality of vertical movement (restored)	Cancel level	
	8010: Vertical reset signal not detected	Stop level	If, after the instrument and



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	detected		software are restarted, the failure still appears, contact the After Service Unit.
	8011: Horizontal reset signal not detected	Pause level	
Automatic Cleaning Unit	9001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	9002: Parameter error	Stop level	
	9003: Abnormality of self-check	Stop level	
	9004: Communication failure	Stop level	
	9005: Command cannot be executed normally	Stop level	
	9006: Abnormality of vertical movement (not restored)	Stop level	Check whether the cover of the reaction tray is closed;
	9007: Vertical collision	Stop level	Check whether there is any foreign object in the test cuvette;
	9008: Abnormality of vertical movement (restored)	Cancel level	Check whether the position of the wiping head in the test cuvette is in the center. Check whether the bounced steel probe can be reset freely at the various stages of automatic cleaning.
	9009: Vertical reset signal not detected	Stop level	If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	9010: Abnormality in automatic cleaning of syringe	Pause level	If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
Temperature Control Unit	10001: Command error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	10002: Parameter error	Stop level	
	10003: Abnormality of self-check	Stop level	
	10004: Communication failure	Stop level	
	10005: Command cannot be executed normally	Stop level	
	10006: Overheat of reaction tray	Warning level	Turn off the instrument and contact the After Service Unit.
	10007: Abnormality of reaction tray temperature sensor	Warning level	
	10008: Overheat of cleaning	Warning	



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	solution	level	
	10009: Overheat of cleaning solution temperature sensor	Warning level	
	10010: Preheating temperature of reagent 1 too high	Warning level	
	10011: Abnormality of reagent 1 preheating temperature sensor	Warning level	
	10012: Preheating temperature of reagent 2 too high	Warning level	
	10013: Abnormality of reagent 2 preheating temperature sensor	Warning level	
	10014: Temperature fluctuation of reaction tray too big	Warning level	
	10015: Reaction tray temperature cannot become stable for too long	Warning level	
	10016: Abnormality of reagent cooling fan	Warning level	Check whether the cooling fan runs normally. If it is abnormal, turn off the instrument and contact the After Service Unit.
ISE Unit	11001: Command error	Restrict level	Restart the instrument and PC; Check whether the board matches with the program version; if, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	11002: Parameter error	Restrict level	
	11003: Abnormality of self-check	Restrict level	
	11004: Communication failure	Restrict level	
	11005: Command cannot be executed normally	Restrict level	
	11006: Na electrode slope exceeding standard range	Pause level	If, after recalibration, the failure still appears, check whether the electrode needs replacement or contact the After Service Unit.
	11007: K electrode slope exceeding standard range	Pause level	
	11008: Cl electrode slope exceeding standard range	Pause level	
	11009: Na electrode noise error	Pause level	
	11010: K electrode noise error	Pause level	



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	11011: Cl electrode noise error	Pause level	
	11012: Noise error of all electrodes	Pause level	
	11013: Voltage drift error of Na electrode	Pause level	
	11014: Voltage drift error of K electrode	Pause level	
	11015: Voltage drift error of Cl electrode	Pause level	
	11016: Voltage drift error of all electrodes	Pause level	
	11013: Voltage overflow error of Na electrode	Cancel level	
	11014: Voltage overflow error of K electrode	Cancel level	
	11015: Voltage overflow error of Cl electrode	Cancel level	
	11016: Voltage overflow error of all electrodes	Cancel level	
	11017: Na electrode sample test exceeding measurement range	Cancel level	
	11018: K electrode sample test exceeding measurement range	Cancel level	
	11019: Cl electrode sample test exceeding measurement range	Cancel level	
	11020: Sample has air	Cancel level	Check whether there is air leakage in the tube of the sample probe;
	11021: Calibration solution A has air	Cancel level	Check whether there is bubble in the sample or cleaning solution;
	11022: Calibration solution A has air	Cancel level	If the same failure appears repeatedly, contact the After Service Unit.
	11023: Cleaning solution has air	Cancel level	
	11024: No liquid in tube	Cancel level	Check whether the pump module of ISE works normally; Check whether the pump line is damaged or loose.
	11025: Calibration failure	Cancel level	If, calibration failure still appears after repeated calibrations, check whether the ISE reagent is used up



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			or out of date; Check whether the electrode needs replacement.
	11026: Calibration value storage error	Cancel level	Check whether the ISE reagent is used up;
	11027: Failure of bubble detector	Restrict level	Check whether the ISE tube and peristaltic pump are normal; If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	11028: Command execution error	Restrict level	If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	11029: Reagent module does not exist	Restrict level	Check whether the ISE reagent pack is connected normally.
Sample Barcode Unit	12001: Command error	Restrict level	Restart the instrument and PC; Check whether the board matches with the program version; If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	12002: Parameter error	Restrict level	
	12003: Abnormality of self-check	Restrict level	
	12004: Communication failure	Restrict level	
	12005: Barcode check error	Cancel level	Check whether the sample barcode is affixed correctly;
	12006: Barcode information error	Cancel level	Check whether the barcode is stained; Check whether the sample barcode setup is correct.
Reagent Barcode Unit	13001: Command error	Restrict level	Restart the instrument and PC; Check whether the board matches with the program version; If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	13002: Parameter error	Restrict level	
	13003: Abnormality of self-check	Restrict level	
	13004: Communication failure	Restrict level	
	13005: Barcode check error	Cancel level	Check whether the reagent barcode is affixed correctly;
	13006: Barcode information error	Cancel level	Check whether the barcode is stained; Check whether the reagent barcode setup is correct.



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Other Failures	14001: Photoelectric acquisition error	Stop level	Restart the instrument and PC; Check whether the board matches with the program version; If, after the instrument and software are restarted, the failure still appears, contact the After Service Unit.
	14002: Abnormality of photoelectric data	Stop level	
	14003 Abnormality of photoelectric acquisition communication	Stop level	
	14004: Cleaning solution insufficient	Warning level	Check whether the cleaning solution is sufficient and the tube is connected normally.
	14005: Deionized water insufficient	Warning level	Check whether the deionized water machine works normally and the reading of the pressure gauge is normal.
	14006: High concentration waste liquid full	Warning level	Empty the high concentration waste liquid.
	14007: Low concentration waste liquid full	Warning level	Empty the low concentration waste liquid.
Software System Failure	20001: Exceeding 4SD once	Warning level	Check whether the QC setup parameters are reasonable;
	20002: Exceeding 3SD once	Warning level	Check whether the item setup parameters are correct;
	20003: Exceeding 2SD once	Warning level	Check whether the QC sample is valid;
	20004: Two results in a row exceeding 2SD	Warning level	Check whether the reagent is valid;
	20005: Three results in a row exceeding 2SD	Warning level	Check whether the calibration results are accurate.
	20006: Five results in a row on one side of the target value	Warning level	
	20007: Seven results in a row on one side of the target value	Warning level	
	20008: Invalid calibration	Warning level	Check whether the standard setup parameters are correct; Check whether the item setup parameters are correct; Check whether the standard sample is valid; Check whether the reagent is valid.



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	20009: Error saving data	Warning level	
	20010: Barcode same as barcode in another worksheet	Warning level	
	20011: Scanning failure. Error obtaining information from LIS system!	Warning level	
	20012: Scanning failure. Time out of LIS system's transmission!	Warning level	
	20013: Scanning failure. No corresponding sample information obtained!	Warning level	
	20014: Scanning failure. Abnormality of LIS system's information transmission!	Warning level	
	20015: Scanning failure. Test type not matching!	Warning level	
	20016: Scanning failure. Submission date format error. Judgment impossible!	Warning level	
	20017: Scanning failure. Submission date format error. Judgment impossible!	Warning level	
	20018: Scanning failure. Sample type cannot be judged!	Warning level	
	20019: Scanning failure. Sample type not matching with data dictionary. Judgment impossible!	Warning level	
	20020: Scanning failure. Profile number cannot be judged!	Warning level	
	20021: Scanning failure. Container type not matching!	Warning level	
	20022: Scanning failure. Total length of barcode not matching with system setup!	Warning level	
	20023: Scanning failure. Abnormality of barcode scanning!	Warning level	
	20024: Scanning failure. Item number type not matching!	Warning level	
	20025: Scanning failure. Reagent	Warning	



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	type cannot be judged!	level	
	20026: Scanning failure. Reagent type > 4. Judgment impossible!	Warning level	
	20027: Scanning failure. Reagent bottle type cannot be judged!	Warning level	
	20028: Scanning failure. Reagent bottle type not matching with data dictionary. Judgment impossible!	Warning level	
	20029: Scanning failure. Expiry date format error. Judgment impossible!	Warning level	
	20030: Scanning failure. Expiry date format error. Judgment impossible!	Warning level	
	20031: Scanning failure. Item number not matching with item name!	Warning level	
	20032: Scanning failure. Reagent type information not matching with reagent setup of item!	Warning level	
	20033: Minimal volume detection failure!	Warning level	
	20034: Scanning failure. Item number and item name of this barcode does not exist in item setup!	Warning level	
	20035: Scanning failure. No reagent item information obtained!	Warning level	
	20036: Cumulation and out-of-control. Please find cause of out-of-control. After correction, clear cumulative sum in QC rule setup.	Warning level	

Warning:

- ◆ ***In case of failure of the instrument, contact the agent immediately so as to obtain technical support!***
-



- ◆ ***Only professionals recognized by LiNEAR Chemicals S.L. may repair the instrument.
To replace accessories, contact the manufacturer or agent.***
-



Chapter 14 Safety Protection Device and Accident Treatment

- Ensure the grounding is normal when using the machine.
- After moving the machine, be sure to put down the fixing anchor to support the machine to prevent the machine from sliding.
- Do not remove any component of the machine at will to prevent electric shock or crush injury.
- Do not open the front door to adjust the syringe at will.
- Do not put any sundries on the cleaning platform of the machine or closely hold the platform with hand to prevent crush injury or sticking.
- Do not replace the power fuse at will.
- Do not put any container with water or other water sources near the power switch.
- Before the test, make sure there are no other sundries on the workbench to prevent colliding the moving probe of the machine.
- Before the test, close the cover of each tray; do not lean or tilt the cover.
- When the machine is conducting a test normally, be sure to close the top cover properly; do not open the top cover or touch the working moving part at will.
- To replace the lamp, switch off the machine and wait half an hour to prevent heating components from scalding the operator
- If any accident occurs when the machine is running, such as probe collision, mixer collision, abnormal noise of motor, water leakage or peculiar smell, switch off the power immediately. Contact the customer service staff for treatment.
- Turn off the power when the machine will not be used for a long time to prevent fire.
- In case of fire of the machine, use powder fire extinguisher to put out the fire.



Appendix I: Names and Contents of Toxic/Hazardous Substances or Elements

1. Names and Contents of Toxic/Hazardous Substances or Elements

Component	Toxic/Hazardous Substance or Element					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr (VI))	Polybrominated Biphenyls (PBB)	Polybrominated Diphenyl Ethers (PBDE)
Built-in circuit board	✗	○	○	○	○	○
Shell	✗	○	○	✗	○	○
Display	✗	○	○	○	○	○
Photoelectric components	✗	○	○	○	○	○
Internal electronic wire	○	○	○	○	○	○
Accessories	✗	○	○	○	○	○

○: Indicates the content of the toxic/hazardous substance in all homogeneous materials of the component is below the limit specified in the SJ/T11363-2006 standard.
✗: Indicates the content of the toxic/hazardous substance in at least one homogeneous material of the component exceeds the limit specified in the SJ/T11363-2006 standard.

2. Description of Mark

Environmental protection use period mark



Meaning of the mark: The electronic information product contains certain toxic/hazardous substances, with the environmental protection use period of 20 years. You can use it within this period. When this period expires, the product should enter the recycling system.

