Operating Instructions

MAGLUMI Fully-auto chemiluminescence immunoassay analyzer

Maglumi 800

Shenzhen New Industries Biomedical Engineering Co.,Ltd

Dear users! Thank you for using our **MAGLUMI™** fully-auto chemiluminescence immunoassay analyzer!

To make sure you using the analyzer safely and skillfully, and improve your working efficiency, please read the instructions carefully before operating the analyzer.

Please properly keep the instructions after reading, and placed it in a readily accessible place in order to obtain easily at any time.

If you have any questions regarding your MAGLUMI fully-auto chemiluminescence immunoassay analyzer, please contact your local representative.

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REF

Device	Catalogue Number
Maglumi 800	23020003

Intellectual Property Statement

Information about the Product

Product Name: MAGLUMI Fully-auto chemiluminescence immunoassay analyzer
Model: Maglumi 800

Intended Use: This product is used to quantitatively or qualitatively analyze analytes in common clinical samples, including serum, plasma, urine, and whole blood.

List of accessories: See packing list

Information of operating instructions

Issued Date: 2018-05
Version: 3.4
Applicable Scope of Software: 2.14.10.15 and later versions

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Notes

This chapter covers all important information and regulations about safety and operation.

Read the operating instructions before you start using the analyzer.

Purpose

The **MAGLUMI™** series of fully automated chemiluminescent detectors and reagents are strictly limited to professional in-vitro diagnostic applications. Please use reagents and consumables manufactured by Shenzhen New Industries Biomedical Engineering Co., Ltd. Otherwise, measurement errors or product failure may occur.

The operating instructions are intended for the Maglumi 800 fully-auto chemiluminescence immunoassay analyzer. This instruction mainly helps users to understand the principle structure, operation, maintenance and troubleshooting of the Maglumi 800 fully-auto chemiluminescence immunoassay analyzer. Follow the instructions in this manual when operating the analyzer.

Safety Note

To ensure safe use of this system, read these instructions carefully before operating the analyzer. Any operation in violation of safety precautions may cause personnel injury or damage to the analyzer.

Production of the system complies with safety requirements for electronic analyzer and medical analyzer. There are related legal requirements for installation and operation of the system, and installation personnel and operators are obliged to comply with these legal provisions.

WARNING

1) If a user fails to perform analyzer maintenance required by the instructions, analyzer faults may occur and endanger personnel health.
2) To ensure analyzer safety and reliability, installation and maintenance of the analyzer can only be carried out by our authorized service engineers and personnel or upon their approval , and all analyzer parts must be checked and provided by our company or our authorized distributors.

1. Prevention of Injury Caused by Moving Parts

Observe the following precautions to prevent injury caused by moving parts when the analyzer is running.

WARNING

1) When the analyzer is running, do not touch its moving parts or the movement path. These moving parts include the pipetting needle, incubator, washer, washer loader, sample loader, back transport, and pusher.
2) When the analyzer is running, do not place any obstacle in the path of moving parts. Otherwise, it may cause injury or damage to the analyzer.
3) Caps on sample tubes will collide with the pipetting needle. Therefore, remove caps from all sample test tubes.
4) The analyzer has a cover with a lock. Close and lock the cover when the analyzer is running. If you need to open the cover, cut off the main power to avoid injury or damage to the analyzer.

Figure 1 Do Not Actuate During Operation

2. Electrical Hazard Prevention

Observe the following precautions to prevent electric shock.

WARNING

1) When the analyzer is powered on, non-authorized service personnel cannot open the analyzer rear cover and side cover.
2) If any liquid, such as the reagent and sample, flows into the analyzer, it may cause analyzer failure and electric shock. In this case, cut off the power immediately and contact our technical service department.
3) Cut off the power supply before opening the rear cover and side cover to replace parts.
4) Incorrect grounding may cause electric shock and damage to the analyzer.
5) Ensure that the input voltage meets the requirements of the analyzer.
6) Do not touch or conduct electrostatic discharge on components with static protection warning labels.

3. Fire Hazard Prevention

Observe the following precautions to prevent fire hazards when using organic solutions.

WARNING

1) Do not use organic solutions in the test.
2) The analyzer is not in explosion-proof design. Use any organic solution with caution to prevent fire or explosion.

4. Laser Hazard Prevention

Observe the following precautions to prevent laser burns caused by the barcode reader.

WARNING

Direct exposure of human retinas to lasers from the barcode reader will cause eye injury. Do not look directly to laser beams from the barcode reader.

Figure 2 Warning Symbol in the Sample Area

5. Waste Liquid Disposal

Observe the following precautions to prevent environmental pollution and injury when disposing of waste liquid.

WARNING

1) Certain substances in waste liquid are subject to pollution control regulations and emission standards. All departments shall comply with local emission standards and consult the manufacturer or distributor.
2) Discharge waste liquid of infectious patient samples to the infectious disease disposal device.

6. Chemical Hazard Prevention

Observe the following precautions to prevent chemical hazards caused by reagents and consumables.

WARNING

1) Read the reagent and consumable SDS carefully to understand safety instructions and preventive measures.
2) Prevent hands and clothes from direct contact with reagents and consumables. In case of accidental contact, wash hands or clothes with soap and water immediately. If any reagent or consumable contacts your eyes by accident, rinse your eyes with plenty of water immediately and consult an ophthalmologist.

7. Biochemistry Hazard Prevention

Observe the following precautions to effectively prevent biochemistry hazards.

WARNING

1) Incorrect use of samples may lead to infection. Do not touch samples, mixtures or waste liquid with hands or other body parts. During operation, always wear gloves and work clothes to prevent infection, and wear protective glasses when necessary.
2) Cuvettes will contact potentially infectious patient samples, and therefore used cuvettes must be disposed in waste bags to isolate the potential infection source.
3) Use reagents with caution to prevent direct contact with hands and clothes. In case of accidental contact, wash hands or clothes with soap and water immediately. If contacts your eyes by accident, rinse your eyes with plenty of water immediately and consult an ophthalmologist.
4) If a small amount of sample or reagent spills on the analyzer, use soft cloth and alcohol to clean it. If a large amount of sample or reagent spills on the analyzer, immediately stop using it and timely contact an authorized engineer for handling.
5) Before transporting the analyzer in a long distance, thoroughly disinfect the analyzer to prevent spread of a potential infection source.

Figure 3 Warning Symbol on the Waste Bag Bin

8. Waste analyzer Disposal

Adhere to the following requirements when disposing waste analyzer.

WARNING

Certain substances in waste analyzer are subject to pollution control regulations. Comply with local regulations in disposal.

9. Computer Virus Prevention

Observe the following precautions to prevent computer viruses.

WARNING

1) Use data movement and other data communication functions only in the permitted range to prevent computer viruses or software system damage caused by misoperation. Computer viruses can spread via floppy disks, USB disks, network and other channels.
2) Do not install any unspecified software or hardware that may affect normal operation of computer software systems. During system operation, do not run other software.

Operation Notes

Carefully read the following operation precautions for proper and effective use of this analyzer.

1. General Precautions

Before using this analyzer, understand application and general precautions of this analyzer. If you do not follow the methods specified in the instructions, protection provided by the analyzer may be undermined.

NOTE

1) The analysis results should be used with clinical symptoms or other experimental results for clinical judgment.
2) The Operating Instructions are subject to revision without prior notice. Please ask the customer service representative as needed.
3) This analyzer should only be used by medical laboratory professionals or trained doctors, nurses, and laboratory technicians.
4) Do not touch the computer monitor, mouse or keyboard using hands with chemicals.
5) Do not fold or compress the drainpipe, as this may result in poor drainage and cause the liquid to overflow elsewhere, and may cause instrument damage in severe cases.
6) The analyzer will generate heat during operation and the heat is discharged through the rear of the analyzer. Therefore, the working environment should be well ventilated to ensure cooling, and ventilation analyzer can be used if necessary. Avoid direct airflow blowing to the analyzer because it may affect reliability of results.
7) Before first use, adjust all parts of the analyzer to ensure the accurate parts parameters.
8) The starter and system liquid must be free of bubbles. Otherwise, reliability of test results cannot be ensured.
9) Ensure correct connection of starter bottles, and do not use the mixed starters. Otherwise, reliability of test results cannot be ensured.
10) Use new or pollution-free cuvettes to ensure analyzer operation safety and test result accuracy.
11) To ensure analyzer operation safety and test result consistency, do not use expired system liquid.
12) Start the analyzer at least 30 minutes before use so that the measurement system is stable. The temperature accuracy of the

incubator should be within ±0.5°C of the set value, with a deviation no more than 1.0°C.

13) Before the test, check whether consumables (system liquid, starters, cuvettes, control solution, etc.) are adequate.
14) Before the test, conduct at least one BGW and ensure the BGW results are within the normal range. Otherwise, reliability of test results cannot be ensured.
15) During pipetting, there should be no bubbles on the sample surface to avoid pipetting error. Please do not remove the reagent before the analyzer finish pipetting procedure.
16) When using this analyzer for sample analysis, quality control test must be carried out. Otherwise, reliability of test results cannot be ensured.
17) An alarm indicator is installed at the top of the analyzer. If any fault occurs in the analyzer, the alarm indicator flashes and the buzzer sounds. In this case, rectify the fault to ensure analyzer normal operation and accurate test results. For detailed troubleshooting methods, see Chapter 18.
18) Use our designated system tubing cleaning solution to clean and maintain pipes.

2. Operation Environment

NOTE

Correctly install this analyzer in the installation environment required by this manual. If the installation environment does not meet the requirements, test results may be inaccurate and the analyzer may be damaged.

3. Electromagnetic Compatibility

NOTE

1) Maglumi 800 fully-auto chemiluminescence immunoassay analyzer complies with emission and immunity requirements in IEC 61326-2-6-2012.
2) Users are responsible for ensuring the electromagnetic compatibility environment that allows the analyzer to work properly.
3) You are advised to assess the electromagnetic environment before using the analyzer.

WARNING

1) Maglumi 800 fully-auto chemiluminescence immunoassay analyzer is designed and tested according to requirements for Class A analyzer in IEC/CISPR 11:2010 . This analyzer may cause radio interference in the home environment, and therefore protective measures should be taken.
2) It is prohibited to use the analyzer next to a strong radiation source (for example, non-shielded RF source) because it may interfere with normal operation of the analyzer.

4. System Maintenance

CAUTION

1) Follow instructions in this manual to perform regular analyzer maintenance. Incorrect maintenance measures may affect accuracy and precision of test results, and may even lead to analyzer failure or injury.
2) Before maintenance and repair, cut off all power supplies to the system and disconnect the power plug. Otherwise, it may result in analyzer failure or injury.
3) The analyzer may be stained with potentially infected patient samples. During maintenance and repair, always wear gloves and work clothes to prevent infection.
4) The analyzer surface may be covered by dust after long-term placement. Use soft wet cloth to gently clean it. Take proper measures to prevent water drops from getting into the analyzer.
5) The analyzer does not contain user-serviceable parts. Do not attempt to remove the analyzer enclosure or dismantle parts. When you need assistance, call the company's authorized personnel.

5. Sample, Reagent and Control Solution

WARNING

1) Drugs, anticoagulants and preservatives in samples may affect certain test results.
2) Take correct sample storage measures. Incorrect sample storage measures may change sample composition and lead to incorrect test results.
3) To prevent sample volatilization, do not expose samples in the air for a long time. Volatilized samples may lead to incorrect test results.
4) Incorrect storage of reagents and control solutions may result in inaccurate test results and poor system performance, even when they are still within the validity period. Follow manufacturer instructions for using reagents and control solutions.
5) Carry out calibration analysis after replacing reagents. Without the calibration analysis, you may fail to get correct test results.

6. Data Backup

WARNING

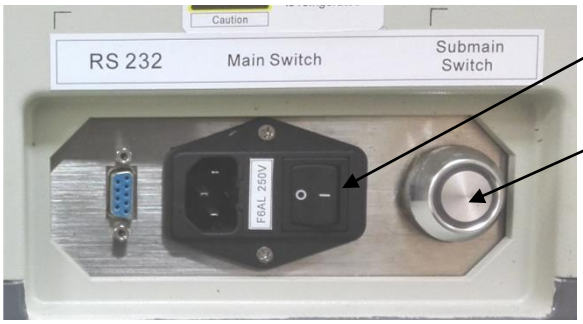
This system allows automatic data storage on the computer's hard disk. However, data cannot be restored if the data is deleted from the hard disk or the hard disk is damaged due to certain reasons. Regularly back up test results and analyzer parameters to other media, such as CD-ROM.

Other Notes

1. Input and Output Connection Terminals

RS232 port: used for communication and control between the analyzer and computer

2. Switches



Warning symbols

Warning infection
This symbol indicates the risk of biological infection and is located in all areas of the machine prone to biological risks, including:
The frontage of the waste container
The up side of the frontage of the waste tank
The up side of the panel of the sample area
The up side of the panel of the reagent area
The up side of the cover of the starter bottle

No Mixing
This sign is located in the area where the solution is placed to remind not mixing up the solution together. It is on
The cover of the starter container

Warning danger
This sign is located in the area where it is easy to get hurt to remind the safety. It is on
Interior of the reagent area
Interior of the sample area

Watch out for the laser
This sign is located in the area with laser beam to the danger of the laser beam. It is on
The shell of the machine

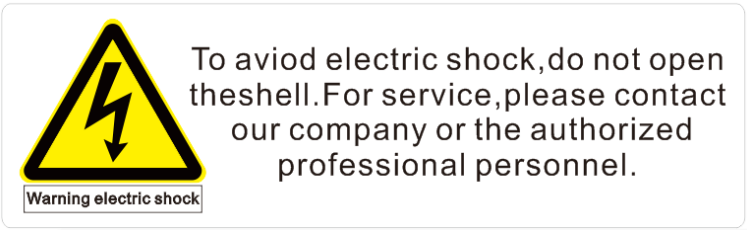
Laser window
This sign is located at the laser beam exit window. It is in
The right side of the interior of the sample area

Watch out for the movement of moving component
This sign is located in the moving part of the machine to remind not touching the moving component during operation. It is on
the shell of the pipetting arm

Watch out for your safety when opening the cover
This sign is to remind not opening the cover when the machine is working. It is on
The frontage of the upper cover

Warning hands pinching
This sign is located in the component with squeezing moving part to remind the danger of clamping hand. It is on
the plate covering the pipetting area

Warning electric shock
Pay attention the words on the sign. It is on
The top right side of the shell on the back side of the machine

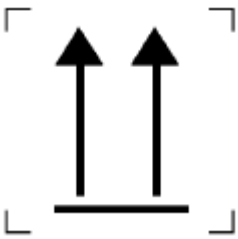


Other symbols

Symbols	Description
	**Manufactured**
	**Catalogue Number**
	**In Vitro diagnostic medical device**
	**Serial Number**
	**Authorized representative in the European Community**
	**Caution: Refer to attached documents**

The following definition of the WEEE label applies to EU member states only. The use of WEEE label indicates that it should not be treated as household waste. By ensuring this device is handed over to dispose correctly, you will help avoid the potential effects on the environment and human health as a result of the presence of hazardous substances. For further information, please contact the distributor from whom you purchased the product.

This way up
This sign is to remind the direction of the package should be upright during transport. It is on
The frontage of the package
The frontage of the wooden box



Keep away from rain
This sign is to remind keeping the package away from rain during transport. It is on
The frontage of the package
The frontage of the wooden box

Fragile
This sign is to remind fragile subject inside, moving carefully. It is on
The frontage of the package
The frontage of the wooden box

Rolling is forbidden
This sign is to remind not rolling the package during transport. It is on
The frontage of the package
The frontage of the wooden box

1 About This Instructions

1.1 Text conventions

To facilitate quick understanding and use of this manual, text styles occur in this document are defined as follows:

- Menu, interface and dialog names are boldfaced and put in the symbol **[ ]**. For example, **[Definitions]** menu, [**Test**] interface and **[User Specific Assay Data]** dialog.
- Button names are boldfaced and put in **<>**. For example, **<OK>** and **<Add>** button.
- Text in the interface or dialog is boldfaced. For example, **Assay Selection** area in the [**Patients**] interface.
- User input is boldfaced and appears in **""**. For example, **[Sample Pipetting Volume] "2" [μl]**.

1.2 Button

Common buttons explain:

Button	Description
	Red means the assay is not selected.
	Green means the assay is selected.
	Page front
	Page back
	Turn to the first page
	Page up
	Move to previous line
	Move to next line
	Page down
	Turn to the last page

1.3 Caution and Note

Symbols	Words	Description
	**WARNING**	Read the statement following the symbol. The statement is alerting you to an operating hazard that can cause personal injury.
	CAUTION	Read the statement following the symbol. The statement is alerting you to a possibility of system damage or unreliable results.
	NOTE	Read the statement following the symbol. The statement is alerting you to information that requires your attention.

1.4 Glossary

Glossary	Description
Analyzer	The instrument, but not PC, printer and connection cables
Back Transport	In second pipetting step, transfers cuvettes to proper positions in the incubator
Barcode Reader	Assembly to read the sample barcode
BGW	Background Wash, test to check quality of analyzer washing
Chamber	Assembly for measurement
Cuvette	Every cuvette has six cavities plastic module, in which immunometrical reaction can take place
CV%	Coefficient of variation, shows dispersion rate of measurements
Incubator	Assembly in which cuvettes are incubated and pipetted
LC	Light check of pipettor needle is used to test accuracy of pump volume and stability of the analyzer.
Loader	Including sample loader and washer loader.
Pipettor	Pipetting needle is used for pipetting samples and reagents
Pump system	For high-precision pipetting, washing and starter injection
Pusher	Exchanges cuvettes between washer and chamber.
Reader	Including Barcode reader and RFID reader
Reagent Area	Loading area for reagent
RFID	Radio Frequency Identification Devices, micro-chip present on reagent to allow recognition and data storage
RLU	Relative Light Unit (signal measurement unit)
Samples	Anything that can be introduced by operator into sample area racks, including patient samples, controls and external calibrators
Samples Area	Loading area for samples
Samples Rack	8 positions module to host sample tubes
Starter Reagents	Reagents dispensed during the reading to generate chemiluminescent signal
System Liquid	A solution used for washing arms and the reacted magnetic microbeads.
Washer	For washing unreacted material in cuvettes.
Waste Bag	Container for used cuvettes.

2Measuring Principle

2.1 Assay Procedure

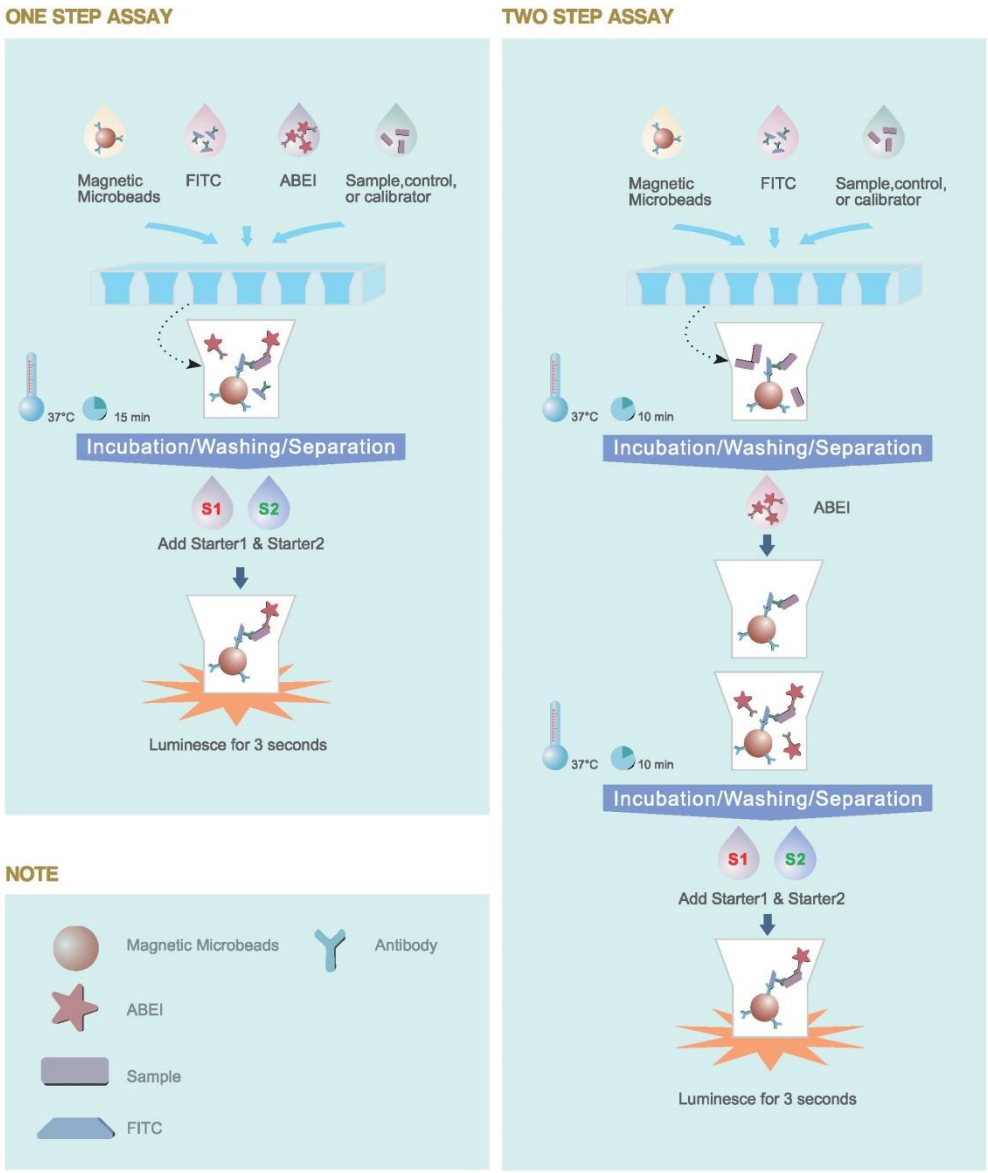


Figure 2.1-1 Assay Procedure

2.2 Measuring Principle

The analyzer's photomultiplier is used to detect light produced in chemiluminescence reaction, within the wavelengths range between 300nm to 650nm. The light peak of the chemiluminescence is emitted at a wavelength of 420nm The light produced in chemiluminescence reaction is emitted to the photomultiplier and reaches the photocathode plane through the incidence window, triggering photons on the photocathode plane emitting photoelectrons into a vacuum. Photoelectrons accumulate at the first dynode through the focusing electrode, pass subsequent dynodes for secondary electron multiplication, and then secondary electrons emitted from the last dynode are output through the anode. The photomultiplier anode collects secondary electrons after multiplication by dynodes and outputs current signals through an external circuit.

To eliminate differences between photomultipliers and ensure test result consistency between different analyzer, relative light unit (RLU) is used as the unit of measurement for original data.

After being pipetted to the cuvette, samples and reagents are blended, washed and separated before the cuvette is sent to the chamber. Starter 1 is injected into the first hole in the cuvette bar, and then Starter 2 is injected into the same hole after 2.5 seconds, triggering chemiluminescence reaction. Detection of optical signals starts 0.1 second after the chemiluminescence reaction and obtains optical signals of 3.0 seconds. Repeat this step to detect the other five holes in the cuvette bar.

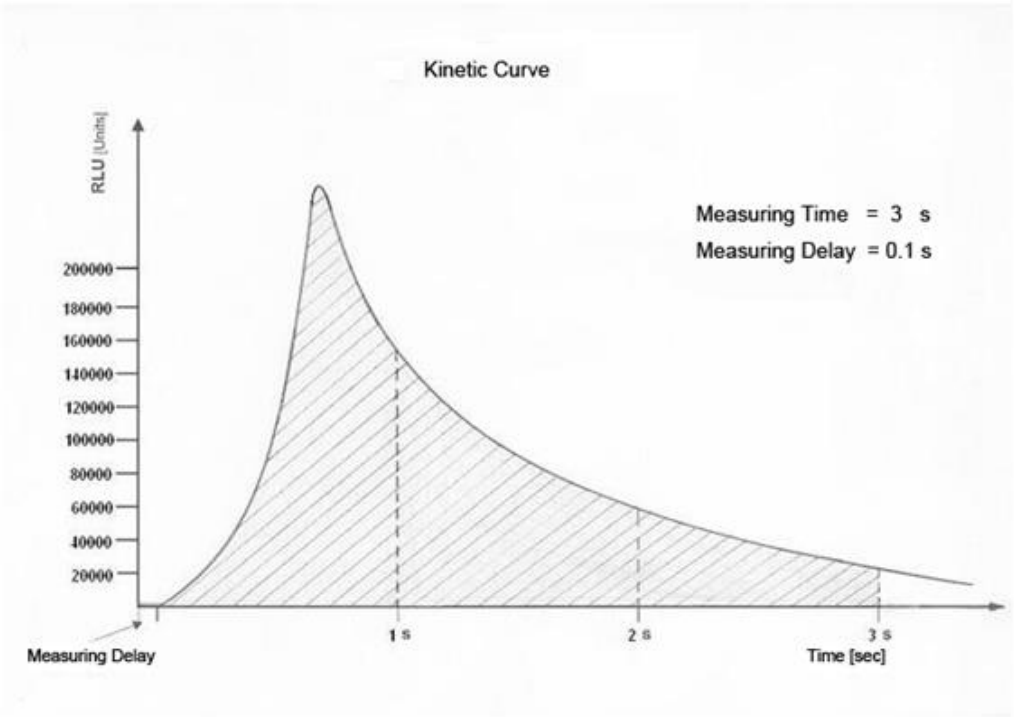


Figure 2.2-1 Kinetics Curve

2.3 Calibration

Because there are differences between the actual working environment and laboratory environment, the master curve should be adjusted to generate the working curve that meets the actual work environment.

Brief description:

- The master curve is determined by 10 standard calibrators.
- Compare two calibration RLUs obtained by calibrators with RLUs of related concentration on the master curve.
- Calculate the difference between two calibration RLUs obtained by calibrators and RLUs of related concentration on the master curve, and carry out linear inference using the recalculated RLU (Y-axis) and concentration (X-axis).
- Calculate RLU differences of other calibrators on the master curve with the correction carve and recalculate the RLU and concentration.
- The recalculated curve is a valid working curve (see Figure 2.3-1: Calibration Principle).

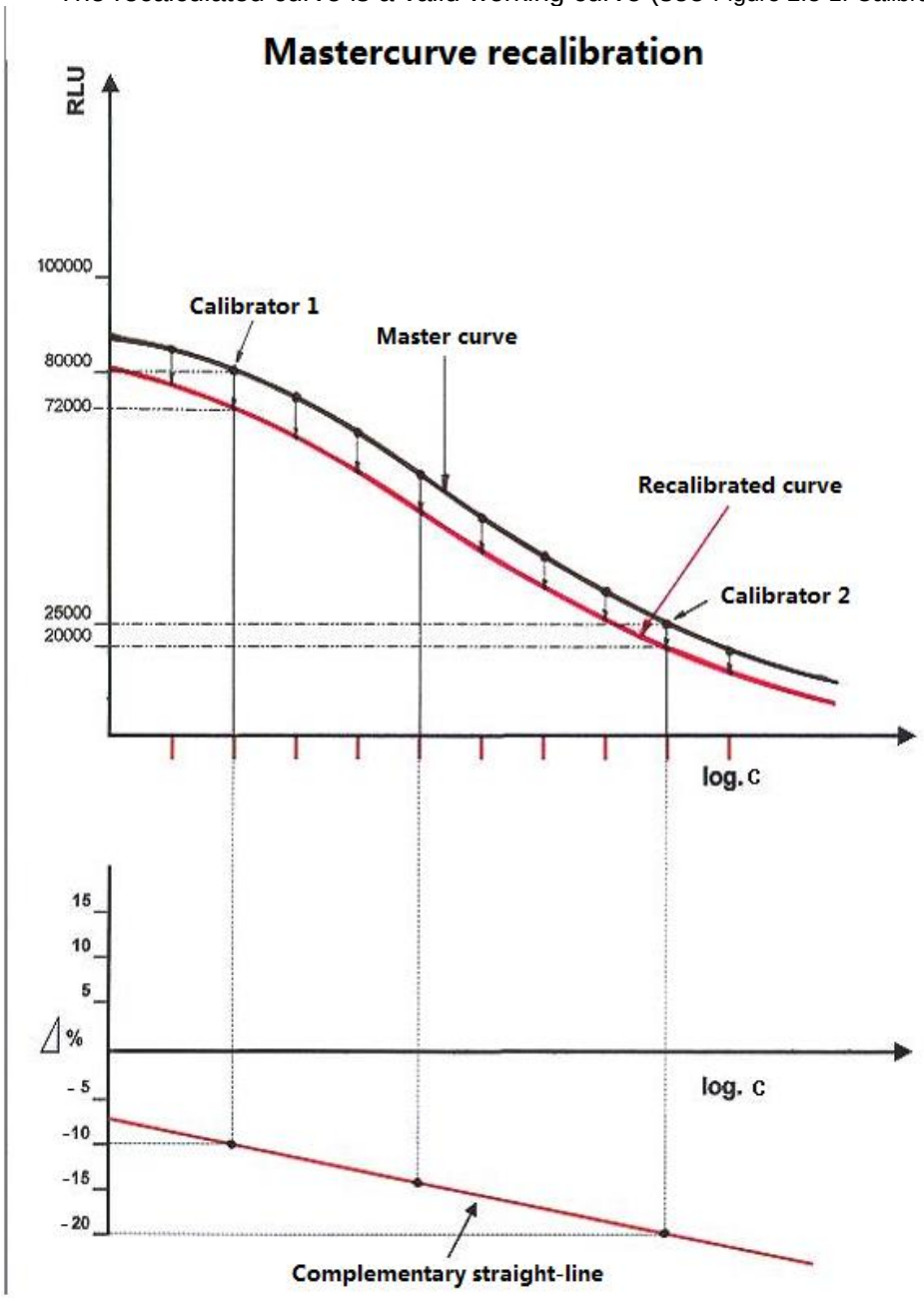


Figure 2.3-1Calibration Principle

3 System Description

Maglumi 800 fully-auto chemiluminescence immunoassay analyzer and a series of supporting diagnostic reagents constitute a precise trace assay system, which features direct chemiluminescence immunoassay based on magnetic separation of ABEI markers. It is used to quantitatively or qualitatively analyze analytes in common clinical samples, including serum, plasma, urine, whole blood. The analyzer automatically completes sample and reagent pipetting, incubation, washing, measurement and result calculation, reducing errors in test results and improving accuracy and precision of test results.

3.1 System Structure

The analyzer is composed of material supply module, tubing system module, temperature control module, mechanical transmission module, optical path detection module and circuit control module.

- The material supply module includes stacker, sample area module, reagent area module, the tray of system liquid and waste liquid module, starter module and cuvette Waste Bag Bin module.
- The tubing system module comprises a pipetting tubing system, system liquid tubing system, optical path detection tubing system and condensate water tubing system.
- The temperature control module consists of an incubator heating module, back transport pipetting area heating module, sample cooling module,reagent cooling module and photomultiplier cooling module.
- The mechanical transmission module comprises cuvette loader, reagent shaker, incubator, sample loader, washer loader, washer transport, washer lift, back transport, pusher, chamber transport, chamber lift and two-joint pipettor.
- The optical path detection module is composed of a chamber module, photomultiplier module and main control circuit.
- The circuit control module consists of a power module, main control board, wire harness and a variety of sensors and motors. The computer is an optional accessory.

3.2 Specification of instrument

Table 3.2-1 Instrument Specifications

Item		Specification
Basic feature	Test speed	180 tests/hour, the first result takes 17 minutes 24-Hour standby
	Sample area	Capable of containing 40 samples Capable of containing 144 samples
	Reagent area	9 channels 1. The kit integrated calibrator, which is easy to load 2. RFID reagent label stores all reagent information, which can be directly read from the RFID
	Test modes	Random mode, batch mode, and STAT mode
	Sample type	Serum, plasma, whole blood, and urine
	Bar code type	Supports five bar codes of Code128, Code39、Code93, Codabar, 2/5 Interleaved
	Sample identification method	Barcode edit and manual edit
	QC	Batch QC, monthly QC
	Test features	1. Continuous loading, STAT first 2. Auto dilution or selecting dilution rate 3. Joint project inspection can be started within a preset range 4. Sample information is automatically obtained after connecting to the LIS system 5. Two-point calibration master curve adjustment 6. A stable calibration time of up to 4 weeks
	Analysis method	Competition method, sandwich method, capture method, indirect method
	Cuvette load amount	40 strips of cuvettes
	Sample probe	Liquid level detection, clot detection, anticollision, tracking with measurement
	Reagent probe	Liquid level detection, anticollision, tracking with measurement
	Incubator	13 strips of cuvettes can be incubated at the same time (78 samples) Temperature: 36.8°C±0.5°C
	Washer	1. It applies highly magnetic permanent magnets, three sets of washing needles (four sets for Maglumi 4000 Plus), which are spill proof. 2. Fast and effective magnetic microbead separation
	Chamber	1. Applies a photomultiplier with high sensitivity and low noise. 2. Possesses reaction detection functionality and is spill proof. 3. Single photon counting technology
External interface	Printer	Supports various mainstream printers
	LIS system	Supports LIS system for bi-directional communication through ASTM protocol

	Operating system	Supports Windows XP, Windows 7, and Windows 10
Working environment	Temperature	10°C ~ 30°C
	Relative humidity	≤ 70%
	Atmospheric pressure	85.0kPa-106.0kPa
	Others	Keep away from electromagnetic sources that can cause interference with the device
Storage environment	Temperature	-20°C ~ 55°C
	Relative humidity	≤ 93%
	Atmospheric pressure	50.0kPa-106.0kPa
	Others	Room free of strong sunlight, corrosive gases and with good ventilation
Safety classification	Anti-electric shock grade	Type I
	Overvoltage type	Type II
	Pollution grade	Grade 2
Whole machine	Outline dimension Length (left to right) * width (front to back) * height and weight	102 cm * 72 cm * 56 cm, 73 kg
	External packing size Length (left to right) * width (front to back) * height	102 cm * 80 cm * 78.4 cm
	Power supply	100 ~ 240 Vac, 50/60 Hz
	Power consumption (VA)	630 VA

3.3 Analyzer

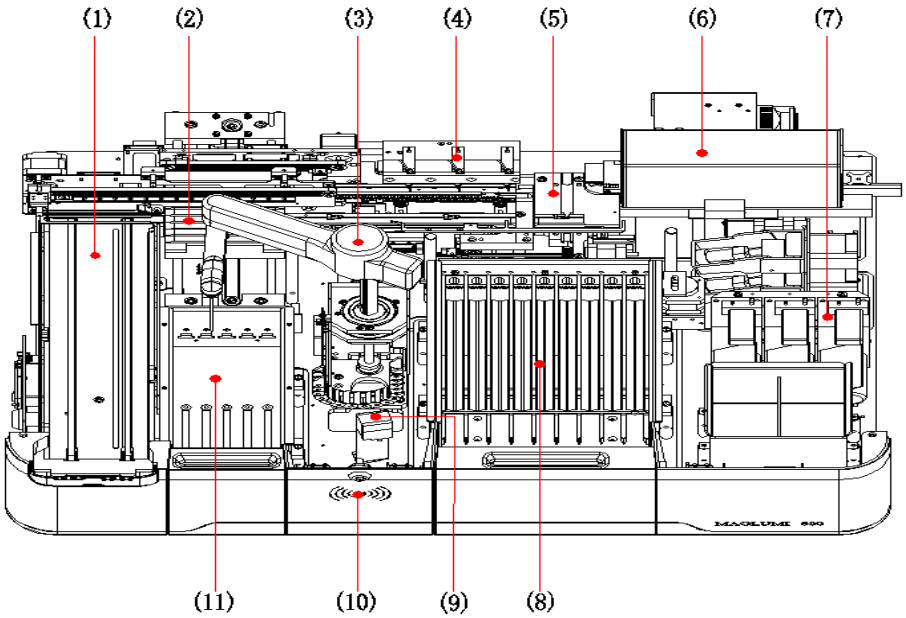


Figure 3.3-1 Maglumi 800 System Components

(1) Cuvette loader
(2) Incubator
(3) Two-joint pipettor
(4) Washer
(5) Pusher
(6) Chamber
(7) Pump unit
(8) Reagent area
(9) Barcode reader
(10) RFID reader
(11) Sample area

3.3.1 Sample Area

Open the sample area door and run the operating software to automatically log in to the **[Pat&Rea]- Patients** interface.

There are 5 rack tracks in the sample area, and each rack rear panel corresponds to an LED.

- Green LED on: There is no rack or rack use is complete.
- Orange LED on: The rack is in use.

CAUTION

When the orange LED is on, do not remove the rack.

1. Loading samples

Ensure that sample tubes are placed upright in the rack.

NOTE

When labels with barcodes are used on sample tubes, ensure that barcodes face the right to the opening of the rack.

Figure 3.3-2 8 Sample Slots in the Rack

2. Loading sample rack

The rack has a handle on the user side and a bolt for mechanical locking on the analyzer side. Hold the rack handle and slide the rack into the track till the stopper position, accompanied by a "click". When the rack is correctly inserted, the software automatically detects and displays it on the display.

When the rack is correctly inserted, the operating software automatically detects and displays it on the display. If barcodes are used, ID information of samples is automatically displayed in the editable input box in **Sample Info** of **[Patients]** interface. Other sample information can be called through a remote computer or manually input.

If there is no barcode, you can enter sample information manually in the input box.

NOTE

Use only the rack provided by our company. Using other racks may cause damage to the analyzer.

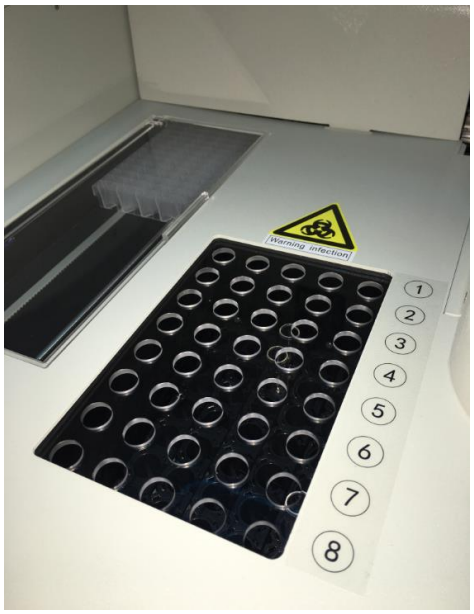


Figure 3.3-3 5 Sample Tracks in the Sample Area

3.3.2 Reagent Area

The reagent area is accessible from the front cover. Open the reagent area door or run the operating software to automatically call the **[Pat&Rea]]**-**Reagents** interface. Because the reagent needs to be kept at a low temperature between 5-15°C, only open the reagent door temporarily for loading reagents.

The reagent area has 9 reagent tracks. The reagent is covered by a piece of holed (reserved for pipetting) organic glass.

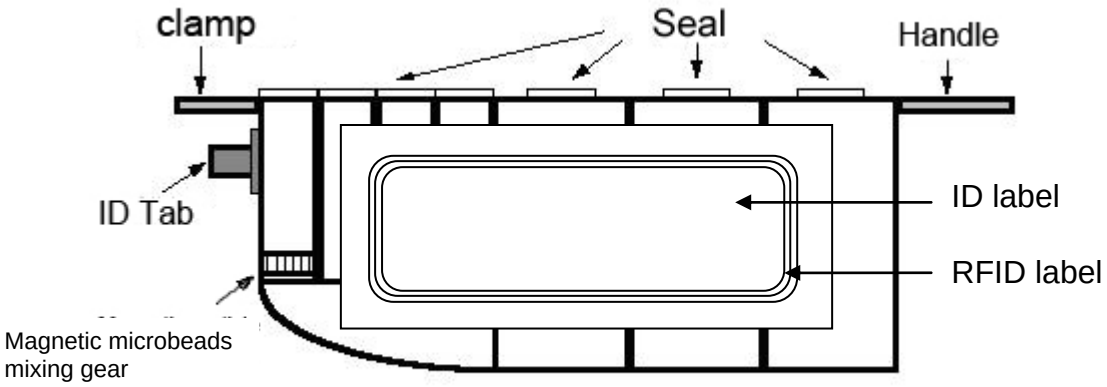


Figure3.3-4.Reagent Structure

Each reagent provides space a maximum of 7 positions. The first position of each kit is for magnetic microbeads. After the analyzer starts, it keeps the magnetic microbeads in the evenly mixing state through the action of a shaker spline.

An RFID tag is attached to one side of the reagent and the RFID data can be read by the RFID reader. The reagent has a handle at the end and a clip in the front for fastening the reagent.

Figure 3.3-5 Reagent Tracks in the Reagent Area

Loading reagent

Remove the seal on the reagent. Hold the reagent handle and put the RFID tag near to the RFID reader. If reading is correct, the buzzer beeps. Insert the reagent to the selected track till the stopper position. When the reagent kit is correctly inserted, the software automatically detects and displays it on the display. Before the test, keep the reagent in the track for at least 30 minutes so that the magnetic microbeads are mixed evenly and get suspended.

NOTE

Read related information provided by the manufacturer before using reagents.

3.3.3 Barcode Reader and RFID Reader

3.3.3.1 Barcode Reader

WARNING

A barcode reader emits laser beams that are harmful to eyes. Therefore, do not look into the barcode reader.

The barcode reader is located between the sample area and reagent area. When you open the sample area door, the barcode reader starts up automatically.

After a sample rack is inserted, barcode labels of the rack and sample tubes are automatically read. The inserted rack is displayed in **[Patients]** interface, and sample information is displayed in **Sample Info**.

Table 3.3-6 Printing Requirements for Sample Tube Barcodes

Supported Coding type	Data Length Range (characters)	Parity	Barcode Width (mm)	Barcode Height	Recommended Width (mm)	Recommended Height (mm)
Code128	1-25	Mandatory	0.3 -0.8	N/A	0.33	10
Code39	1-25	Optional	0.3 -0.8	N/A	0.33	10
Codabar	1-2	Optional	0.3 -0.8	N/A	0.33	10
Code93	1-25	Mandatory	0.3 -0.8	N/A	0.33	10
2/5 Interleaved	2-24	Optional	0.3 -0.8	N/A	0.33	10
Blank area at both sides shall be at least 7 times the width of the barcode						

When the coding type is Code39, Codabar or 2/5 Interleaved, the barcode reader does not check parity during data reading and processes parity as common bits, which may cause inconsistency between read information and encoded information. If you print a barcode with parity for the above three coding types, the following system settings can be used to avoid information misreading.

1. Click **Maglumi Service** icon on the desktop to open **[Maglumi Service]** software.

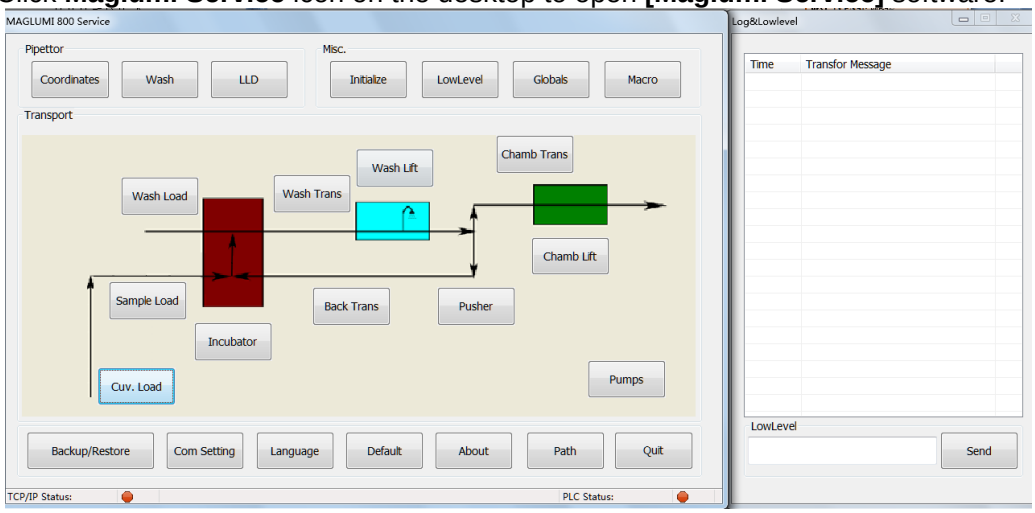


Figure 3.3-7 [**Maglumi Service**] software

2. Click **<Globals>** button to open the **[Globals]** dialog.

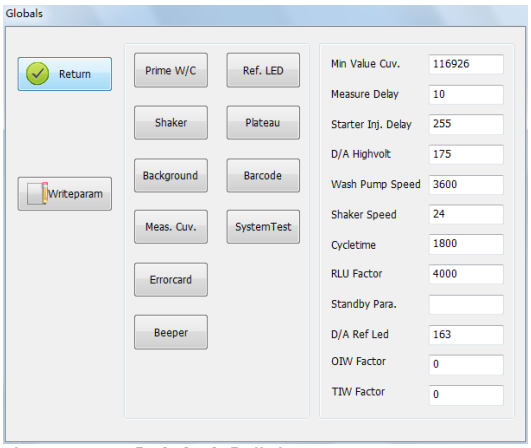


Figure 3.3-8 **[Globals]** dialog.

3. Click **<Barcode>** button to open the **[Barcode]** dialog box.

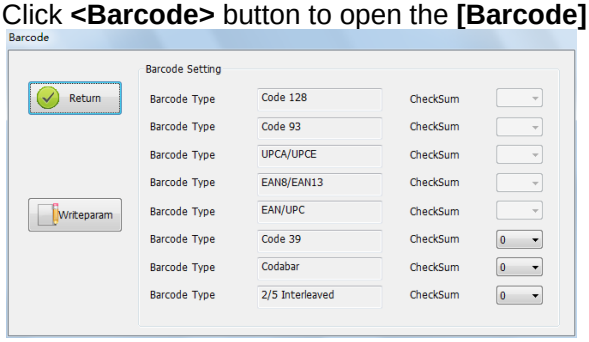


Figure 3.3-9 **[Barcode]** dialog

4. Change the **CheckSum** of the related coding type to **1**.

3.3.3.2 RFID Reader

The RFID reader uses wireless technology to read RFID data from the kit. Its operating band is 13.553~13.567 MHz, within the fundamental frequency of ISM analyzer.

Place the RFID side of the reagent within 30 mm of the reader. If the buzzer beeps once, means that the data is successfully read. Then, insert the reagent into a reagent track. The **[Reagents]** interface displays information about this reagent.

NOTE

When multiple reagents need to be loaded, repeat the above operating procedure for loading one by one.

3.3.4 Two-joint Pipettor

The same pipetting needle is used for pipetting samples and reagents. The pipetting unit is automatically positioned in the pipetting area by the software.

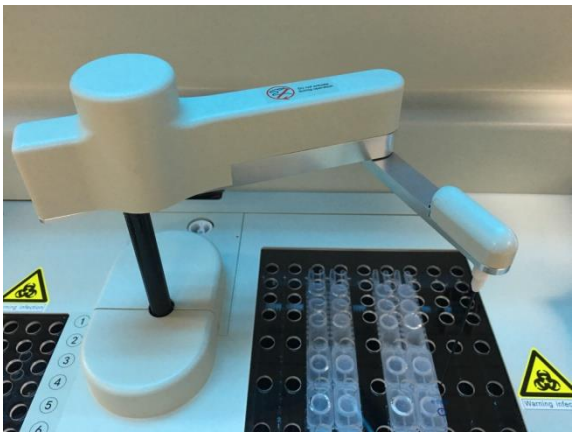


Figure 3.3-10 Pipetting Needle

NOTE

To ensure correct pipetting operation, liquid surface in sample tubes must be free of bubbles.

Clot detection function

The pipetting needle can detect clots in samples. When a clot is detected or pipetted, the pipetting unit immediately moves to the washing hole and washes the pipetting needle, at the same time the software notifies the user of clots detected and adds a mark (D) to this sample in **[Journal]**.

3.3.5 Cuvette loader

Cuvette loader is used for adding and storing cuvettes.

Loading cuvettes

The cuvette loading area is located on the left of the analyzer.
Place 8 cuvette bars each time. After the photoelectric sensor detects the cuvettes, horizontal conveyor automatically transfers the cuvettes to the top of the cuvette loader.

NOTE

The cuvette loader should be emptied once a month to ensure its cleanliness!

Figure 3.3-11 Cuvette Loader

3.3.6 Incubator

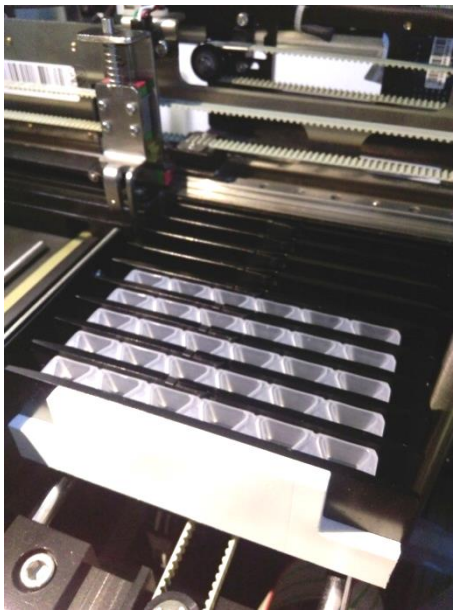


Figure 3.3-12 Incubator

According to test requirements, cuvettes loaded with samples and reagents are incubated at 36.8°C ± 0.5°C in the incubator. The incubator can incubate 13 cuvettes each time, and the incubation time is controlled by software.

If the temperature is abnormal, the  icon automatically appears on the display. (See Chapter 13)

3.3.7 Sample Loader and Washer Loader

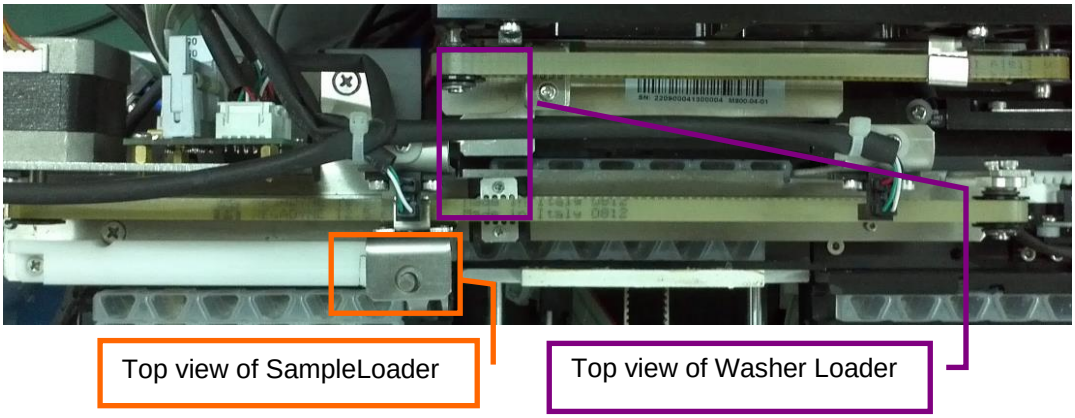


Figure 3.3-13 Sample Loader and Washer Loader

Sample loader
The sample loader transfers cuvettes in the cuvette loader to the pipetting area.

Washer loader
The washer loader transfers cuvettes from the incubator to the washer after cuvette incubation completes.

3.3.8 Washer

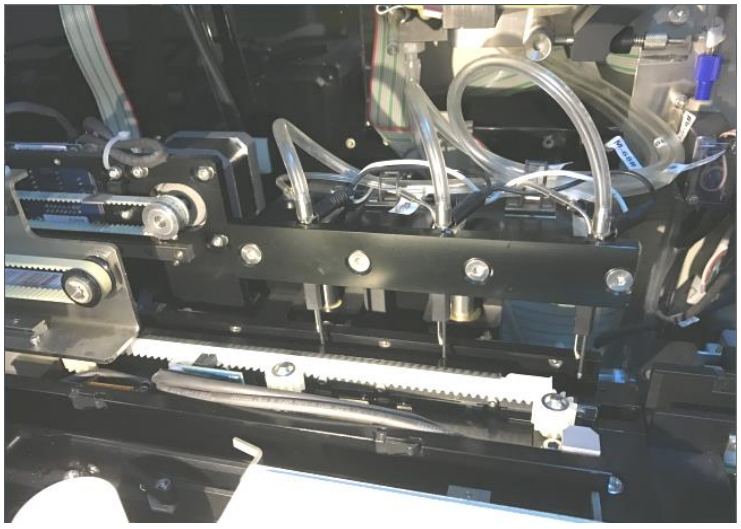


Figure 3.3-14 Washer

Magnetic microbeads are washed in the washer with waste liquid pumped away. Three independently controlled washing pumps connected with three injecting needles pump system liquid. Fastened to the washer lift, 3 aspirating needles are connected to a wash soak (peristaltic pump) for draining waste liquid from cuvettes.
The washer lift has the 4 positions:

- Initial position: At this position, waste liquid needles are fully elevated to a position where cuvettes can move freely.
- Injection position: At this position, the center of wash needle outlet and the top edge of cuvette should at the same height.
- Pipetting position: At this position, waste liquid needles touch the bottom of cuvettes.
- Washing position: At this position, the washer lift is slightly above transport track.

3.3.9 Pusher

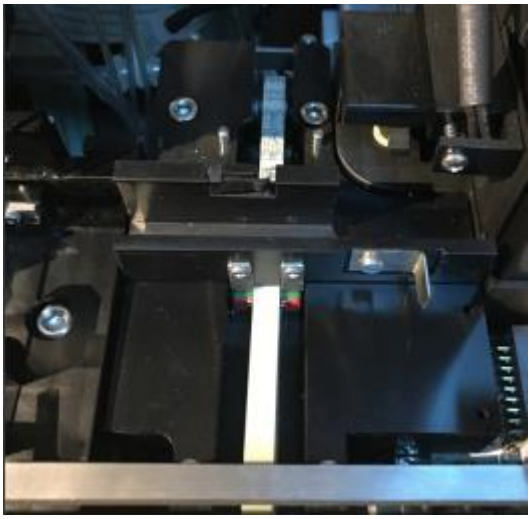


Figure 3.3-15 Pusher

After being washed by the washer, cuvettes are transferred to the pusher.

- Scenario 1: cuvettes are transferred to the pipetting area for second-step pipetting, incubation, washing and measurement.
- Scenario 2: cuvettes are transferred to the chamber for measurement

3.3.10 Back Transport

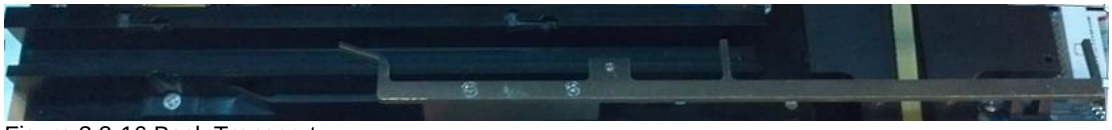


Figure 3.3-16 Back Transport

The back transport is used for second pipetting of cuvettes.

- Scenario 1: cuvettes are transferred from the pusher to the pipetting area.
- Scenario 2: After cuvettes are pipetted in the pipetting area, the back transport transfers cuvettes to proper positions in the incubator.

3.3.11 Chamber

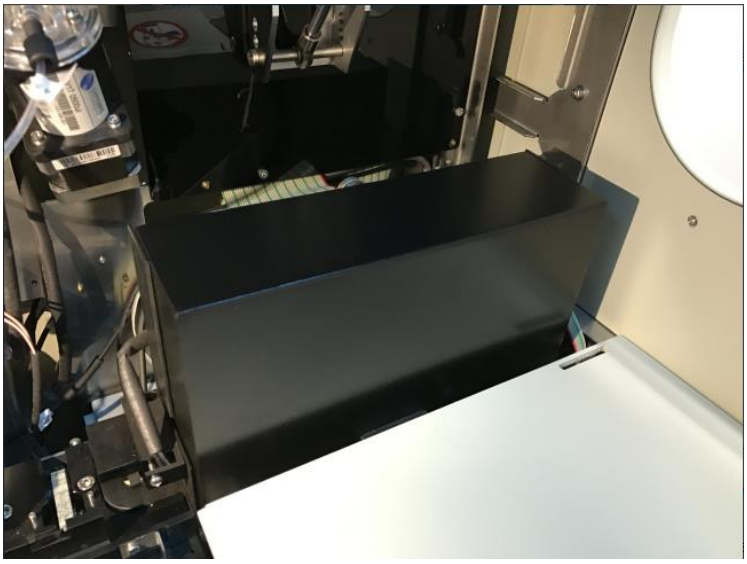


Figure 3.3-17 Chamber

After going through the washer, samples are sent to the sealed dark chamber for measurement. Starter 1 and Starter 2 are injected successively at certain angles into cuvettes to through two independently controlled starter pumps ensure that the magnetic microbeads are resuspended. The generated optical signals are accurately measured through the photomultiplier.

After each measurement, the waste liquid is drained. After being measured, the cuvette is transferred to the waste bag.

3.3.12 Pump System

Maglumi 800 fully-auto chemiluminescence immunoassay analyzer offers a range of independently operating pump systems for high-precision pipetting, washing and starter injection, including:

- Plunger pumps for pipetting units.
- Waste liquid pump for the washing hole of the pipetting unit.
- Vacuum pump for washing pipetting needle.
- Pump for the washer.
- Starter pump for the chamber.
- Wash soak for draining waste liquid from the washer.
- Waste liquid pump for the chamber.

NOTE

Pump maintenance must be carried out by professionals or according to the instructions.

3.3.13 Starter

Starter containers are located inside the analyzer. S1 and S2 are marked to indicate Starter 1 and Starter 2, respectively. Starter status is detected by a liquid level detector in the starter container. After starter supplement or replacement, you need to click **<SystemTest>** in the menu bar to prime the tubing system to ensure that the tubing system is filled with starter.

Starter tubing system pressure: -0.5~0.1 bar

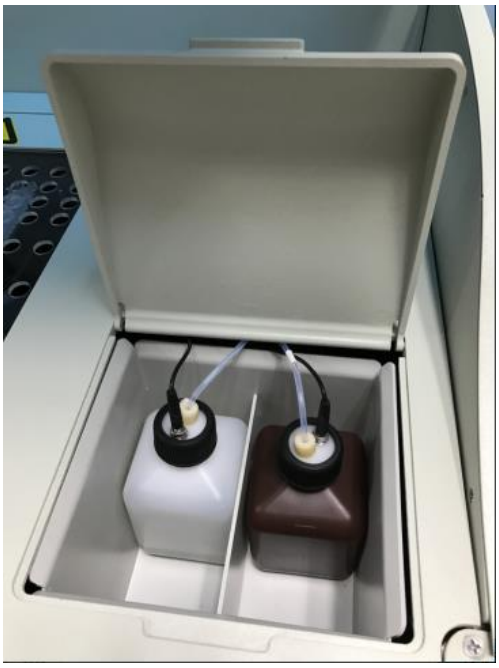


Figure 3.3-18 Starter Reagents Container inside the Analyzer

CAUTION

Do not spill starter in this area!

3.3.14 System Liquid

System liquid is used to wash pipetting needles and magnetic microbeads after reaction.

The system liquid container has a liquid level detector for detecting remaining liquid amount. After supplement or replacement of system liquid, you need to click **<SystemTest>** in the menu bar to fill up the tubing system.

System liquid inlet pressure:-0.5~0.5 bar

The ports are connected to the analyzer using a coupling head. Press the metal clip to release and remove the pipe.

3.3.15 Cuvette Waste Bag Bin and Waste Liquid

1.Cuvette Waste Bag Bin

Located on the right of the analyzer, the cuvette waste bag bin is next to the chamber. Put a waste bag in the waste bag bin to collect waste cuvettes.

CAUTION

It is essential to correctly place a waste bag under the cuvette outlet. Otherwise, the waste bag edge will block cuvettes and cause interruption of operation.

When the waste bag is full, users must take it out of the waste container and seal it with a cover.

NOTE

During assays, cuvettes may come into contact with potentially infectious materials. Therefore, it is necessary to properly dispose of waste bags.

Figure 3.3-19 Waste Cuvette Container

2. Waste Liquid

Waste liquid pipes are located on the right of the analyzer.

- Waste liquid comes from magnetic microbeads, starter, system liquid, washer and liquid in cuvettes (patient samples and laboratory reagents).

Waste liquid outlet pressure: -0.5~0.1 bar.

WARNING

Biological waste must be disposed of in accordance with related laboratory regulations.
Do wear protective gloves!

Waste bag and waste bin status is displayed by **<Waste Status>** icon.(See Chapter 13).

3.4 Computer System

3.4.1 Computer System Components

A computer system is installed with operating software to control system operation and data processing. It is composed of a computer, 19-inch LCD touch monitor, keyboard, mouse and printer.

- Computer: installed with Windows operating system, specific application software and database.
- Minimum configuration: CPU frequency ≥ 2.0 GHz, hard disk ≥ 320 GB, memory ≥ 2GB, three RS-232 serial ports, USB port, etc.
- Touch monitor: windows, curves and test data of Maglumi 800 fully-auto chemiluminescence immunoassay analyzer operating software are displayed on the monitor.
- Keyboard: for operation control and data input of Maglumi 800 fully-auto chemiluminescence immunoassay analyzer.
- Mouse: for software operation.
- Printer: for printing test data and charts.

3.4.2 Basic Operations in Software Interface

3.4.2.1 Using the Touch monitor Mouse and Keyboard

The software is easy to use with a touch screen, mouse and keyboard.

Touch monitor operation

Touch the monitor with a finger or a touch pen to realize the same functions of the mouse.

- Touch a button to activate the related function.
- Touch an option or control zone to activate the corresponding function.
- Touch an input box and use the keyboard to input content at the cursor.

Mouse operation

Commonly used mouse functions can be executed.

- Click to select a function or option.
- Double-click to open the selected file.
- Drag the mouse to select an area or range

Keyboard operation

Enter letters, words and numbers using the keyboard.

In the dialog box, repeatedly press **<Tab>** key till the desired option is selected and press the **<Enter>** key to confirm. Press **<Del>** key to delete the selected document.

3.4.2.2 Software Components

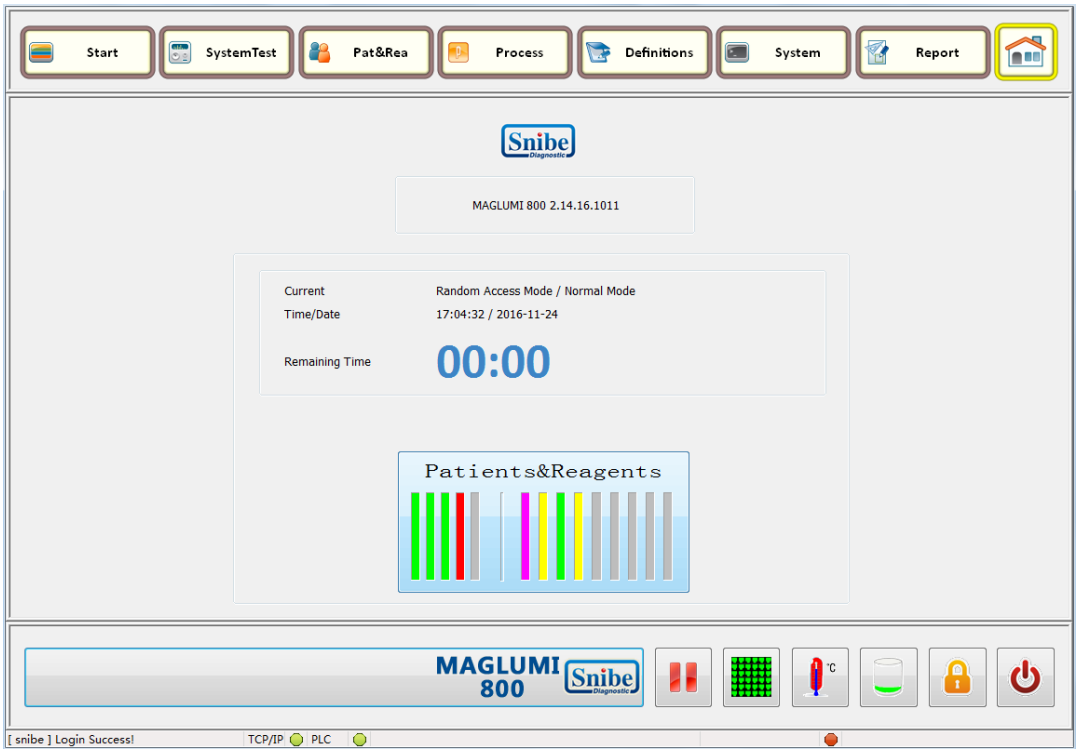


Figure 3.4-1 Software Interface

The software has 5 different levels of windows:

1. Menu Bar: displays different menu. It has 8 menu buttons.

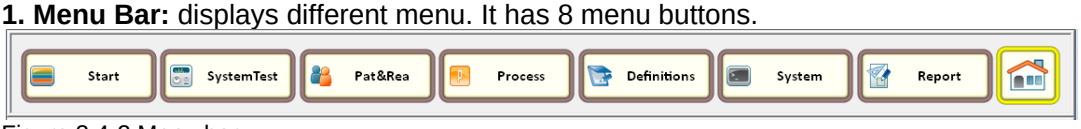


Figure 3.4-2 Menu bar

Button	Description
<Start>	It is for starting measuring samples or controls.
<System Test>	It is for entering system test functions e.g. flush tube system and carry out internal test measurements.
<Pat&Rea>	Enter [**Pat&Rea**] interface, carry out samples registration and calibration, etc.
<Process>	It is for entering process functions e.g. automatic clearance of the cuvettes.
<Definitions>	It is for users to set assays, controls, dilutions, assay groups and assay profiles.
<System>	It displays system information, system setting and maintenance, etc.
<Report>	It is for managing results.
<Home>	Return to the home.

2. Interface: displays function interface in different menu, including **[Home]** interface, **[Pat&Rea]** interface and submenu interface.

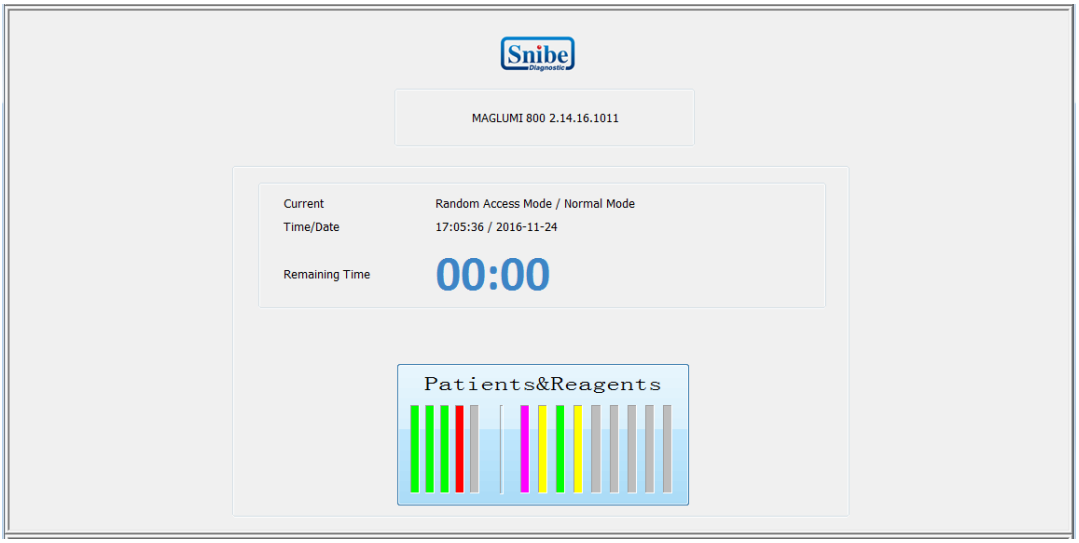


Figure 3.4-3 **[Home]** Interface

3. Status Bar: display analyzer status and relogin or exit the software.

Figure 3.4-4**Status Bar**

Icon	Button	Description
	< Message Box>	It is used for showing the actual system and error messages.
	<Pause Measure>	It is for emergency stop of the analyzer.
	<Reservoir Status>	It indicates the status of the system liquid, starter reagents and cuvettes.
	<System Parameter>	It indicates the supply voltage and temperature.
	<Waste Status>	It indicates the status of waste liquid and waste cuvette.
	<Relogin>	It is used for relogin the software.
	<Close Software>	It is used for exiting the software.

The following information is displayed at the bottom of the status bar:

- Current logged-in users and logging status. Logging status includes: Login Success, Logout Success, Incorrect Password, Invalid Username;
- COM Status indicator; the indicator light is green when COM is opened successfully and red when COM cannot be opened.

- PLC Status indicator; the indicator light is green when PLC is connected successfully and red when PLC is connected unsuccessfully.

4. Submenu: click the **<Process>**, **<Definitions>**, **<System>** or **<Report>** button on the menu bar, on the left display its submenu buttons.

Figure 3.4-5 **[System]** Submenu

5. Dialog

A dialog box can open one or more sub-dialog boxes.
There are two different types of dialog boxes.

a) Clicking submenu button triggers a dialog. For example, click **<Initialize>** button in **[Process]** menu to open message confirmation dialog.

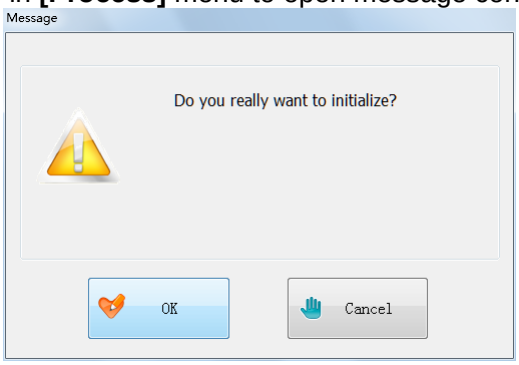


Figure 3.4-6 Message Dialog

b) Clicking a button in submenu interface triggers a dialog. For example, click **<Edit>** button in **[Test]** interface to open **[User Specific Assay Data]** dialog.

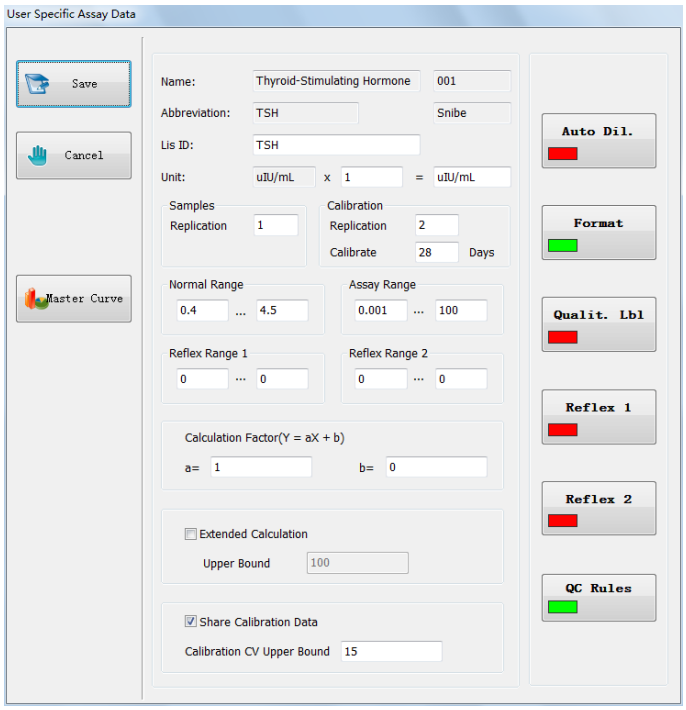


Figure 3.4-7 **[User Specific Assay Data]** Dialog

3.5 Testing Performance

3.5.1 Batch Assay Repeatability

Assay repeatability in a batch (CV%) ≤ 8%.

3.5.2 Linear Correlation

In the concentration range of two or more orders of magnitude, the linear correlation coefficient should be equal or more than 0.99.

3.5.3 Carryover Rate

The Carryover rate should be equal to or less than10^{-5}.

3.5.4 Stability

Differences between the test results in the 4th and 8th hours after the analyzer runs stably and those in the initial stable running status are within ±10%.

4 Installation and Startup

This chapter describes how to install and start Maglumi 800 analyzer. Basic analyzer installation is implemented by engineers trained and authorized by Snibe.
Users can install and use the system according to the installation procedure.

NOTE

1) To ensure user safety, installation and commissioning of analyzer can only be implemented by professionals trained and authorized by Snibe.
2) Analyzer must run under the operating conditions specified in the instructions.

4.1 Analyzer Transportation and Storage Requirements

4.1.1 Transportation Requirements

- The analyzer must be transported in the upright direction and cannot be tilted.
- Analyzer must be free of moisture, water, violent vibration and extrusion during transportation, and handled gently during loading and unloading.

4.1.2 Storage Requirements

- The analyzer should be stored in a well-ventilated indoor environment without chemicals, corrosive gases or strong sunlight.
- The temperature should be -20°C~55°C and relative humidity ≤ 93%.

4.2 Installation Requirements

4.2.1 Installation Environment Requirements

- For indoor installation and use only. The installation environment should be well-ventilated and free of dust, mechanical vibration, loud noise and power interference.
- The table should be flat and able to withstand a minimum weight of 73 kg.
- When the analyzer is working properly, the highest volume at 1 m distance is 40 db.
- Atmospheric pressure: 86 kPa~106 kPa.
- No corrosive or flammable gases.

4.2.2 Power Requirements

- Voltage: a.c.100 V-240 V, frequency: 50 Hz/60 Hz.
- Rated power: 630 VA
- Circuit breaker specifications: F3AL250V, F5AL250V, F6AL250V (power filter)
- The analyzer requires a well grounded electrical outlet to provide desired power.

4.2.3 Space Requirements

To ensure space required for repair and maintenance, analyzer installation must meet the following requirements:

- Analyzer dimensions: length x width x height: 102cm × 72cm × 56cm
- Analyzer weight: 73 kg
- The distance between the analyzer rear and the wall cannot be less than 50 cm.
- The distance between left and right sides of the analyzer and the wall cannot be less than 50 cm.
- The distance between the analyzer front and other analyzer cannot be less than 100 cm
- The power outlet should be located in a place with enough space to facilitate connecting and disconnecting the power cable. Do not place the analyzer in a place where it is difficult to operate the disconnecting device.

4.2.4 Temperature and Humidity Requirements

- Ambient temperature: 10°C~30°C, air-conditioner recommended;
- Relative humidity: ≤ 70%

4.3 Unpacking Inspection

4.3.1 Unpacking Procedure

After arrival of the analyzer, carefully check analyzer packing. If there is damage, contact with Snibe or your local dealer. If there is no external damage, unpack the analyzer under the following procedure:

1) The packing case must be placed upright to the arrow direction.
2) Open the accessory box and main box, and check inside items according to the packing list. If there is any item missing, contact with Snibe or your local dealer.
3) Carefully check the appearance of the analyzer. If it is damaged, immediately contact with Snibe or your local dealer.

4.3.2 Analyzer Transportation and Fastening

- The analyzer can be directly moved in a short distance and stable manner.
- The analyzer should be kept in an upright position all the time during transportation.
- Minimize vibration during transportation. After transportation, check and commission the analyzer before use.
- Adjust foot height to ensure analyzer levelness when fastening the analyzer.

4.4 Analyzer Installation

4.4.1 System Circuit Connection

Computer connection:

1) Connect the monitor, keyboard and mouse to the related ports on the rear of the computer case.
2) Connect the connection cable of the monitor touch screen to the USB port on the rear of the computer case.
3) Connect power cables of the computer case and monitor to the related ports.
4) Connect an RS232 cable to the COM1 serial port on the rear of the computer case.

Analyzer connection:

1) Connect the other end of the RS232 cable to the RS232 port next to the power supply port of analyzer.
2) Connect the analyzer's power cable to the power supply port of analyzer.
3) Connect all power cable to electrical outlet.

4.4.2 System Liquid Tank and Waste Liquid Tank Connection

Connection ports for the system liquid tank and waste liquid tank are on the right of the analyzer. System liquid preparation should follow the corresponding instructions for use.

Figure 4.4-1 System Liquid and Waste Liquid connection ports

Use a coupling head to connect conduits to the analyzer, and press the metal clip to remove the conduits.

1) Install the cover with a system liquid level detector to the tank marked "System liquid".
2) Install the cover with a waste liquid level detector to the tank marked "Waste liquid".
3) Connect two hoses from the system liquid tank to port "System liquid".
4) Connect hoses from the waste liquid tank to the "Waste liquid" port.
5) Connect the level sensor cable from the system liquid tank to the port "System Liquid Sensor".
6) Connect the level sensor cable from the waste liquid tank to the port "Waste Liquid Sensor".

4.4.3 Starter Connection

The starters storage box housing is located inside the analyzer.
Open the protective cover of the starter storage box.

1) Connect the white conduit marked "S1" to the bottle marked starter 1.
2) Connect the white conduit marked "S2" to the bottle marked starter 2.
3) Connect the level sensor cable to the reagent bottle marked starter 1 and "S1" port.

4) Connect the level sensor cable to the reagent bottle marked starter 2 and "S2" port.
5) Close the protective cover of the starters storage box.

4.4.4 Waste Bag Placement

The waste bag for collecting waste cuvettes is nested in the waste cuvette bin; the waste cuvette bin is located on the right of the analyzer.

1) Open the protective cover of the waste cuvette bin.
2) Place a waste bag.
3) Close the protective cover of the waste cuvette bin.

CAUTION

Waste bag must be properly installed to ensure that the waste bag is under the chamber outlet. Otherwise, the waste bag may block cuvettes from the chamber, causing analyzer error reporting and operation interruption.

4.4.5 Cuvettes Loading

Each cuvettes has 6 reaction holes used as sample reaction and result assay reactors.
Cuvettes loading procedure:

1) Open a bag of cuvettes and take out a set (4 to 8) of cuvettes.
2) Place the cuvettes on the conveyor of the cuvette loader.
3) The conveyor automatically moves and transfers the cuvettes to the top of the cuvette loader.
4) When the conveyor stops, place the next set of cuvettes.
5) Repeat the above steps until the cuvette loader is full.

4.5 Power-on and System Startup

Before starting the system, ensure that the procedure in section 4.4.1 "System Circuit Connection" has been completed.
Start the system as follows:

1) Start the analyzer.
2) Start the PC system and operating software.
3) Perform system testing.

4.5.1 Starting the Analyzer

Power on the analyzer and turn on the main switch and submain switch of the analyzer.

4.5.2 Starting the PC System and Operating Software

Power on the host and monitor, and wait for the system to start (when the system desktop appears, the system startup is complete).
The Maglumi 800 user software button is generally located on the Windows system desktop.

1) Double-click the **User.exe** on the desktop using a mouse or a touch screen.
2) Enter a correct user name and password to access the Maglumi software system. The default user name and password are **snibe**.

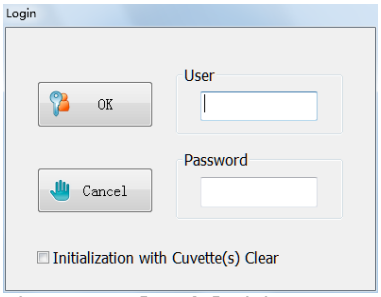


Figure 4.5-1 **[Login]** Dialog

3) After you enter a correct user name and password, the Maglumi software system automatically starts.
4) After the system is connected to the analyzer, the system automatically runs the initialization command to initialize analyzer components.
5) After initialization is complete, the analyzer is ready to work if there are no error messages or pop-up windows.

4.5.3 Performing System Test

When analyzer initialization is complete and there are no error messages or pop-up windows, perform system testing as follows:

1) Perform the component prime test according to the requirements in Table 4.5-2.

Table 4.5-2 System test (round 1)

		Number of Times
Priming	Pipettor	3
	Washer	6
	Chamber	3
Cuvettes	BGW	0
	LC-le	0

2) After the prime test is complete, perform the background test and pipetting needle checks according to the requirements in Table 4.5-3.

Table 4.5-3 System test (round 2)

		Number of Times
Priming	Pipettor	0
	Washer	0
	Chamber	0
Cuvettes	BGW	1
	LC-le	1

The requirement of system test results : details see 9.1.

5 Daily Operating Process

This chapter mainly introduces the basic operating process of this system. After learning the content of this chapter, users are able to use this system to complete basic daily operation.

5.1 Daily Operating Process

Table 5.1-1 Operating process for daily testing

Operating steps	Operation
1. Check before starting (1) Check the power supply (2) Check the analyzer	Confirm the power supply is normal; Make necessary check for the appearance and status of the analyzer.
2. Power-on	Connect the power supply , and turn on the main switch and submain switch of the analyzer .
3. Log in the user software	Input the user name and password in **[Login]** dialog .
4. Check consumables	Confirm the system liquid, starter 1, starter 2 and cuvettes are enough to complete the test.
5. Confirm device status (1) Confirm incubator temperature (2) Confirm system test	Confirm whether incubator temperature is stable. The range of incubator temperature shall be (36.8±0.5)℃ after it gets stable, with a fluctuation range within ± 1℃. Perform system test operation and confirm the tubing is full of system liquid and starter. Confirm whether the measured values of LC test and BGW test are within the allowable range.
6. Confirm test condition (1) Confirm assay (2) Profile/group setting	Confirm assay parameters. Set profile/group according to actual situation.
7. Prepare reagent (1) Confirm the remaining tests of reagent (2) Mixing time of magnetic microbeads	Confirm the remaining reagent tests of each assay is enough to complete the test. Confirm the mixing time of the magnetic microbeads is at least 30 minutes.
8. Assay calibration QC assay registration	Confirm whether the reagent has been calibrated, and perform calibration for the reagent without valid calibration. Perform QC operation for the reagent.
9. Sample registration	Perform conventional sample registration; Perform STAT sample registration;

	Perform dilution sample registration.
10. Test start	Click **<Start>** button to perform test.
11. Test of additional samples	Users can register additional samples during the test. (If the additional samples are STAT samples, STAT sample registration should be performed; if the additional samples are dilution samples, dilution sample registration should be performed); Click **<Start>** button to perform test.
12. Confirm test results	Search, recalculate, delete and print test results.
13. Operation at end of the test Quit operating software	Quit the software.
14. Shutdown	Turn off the main switch and submain switch and disconnect the power supply of the device and the computer.
15. Operation after the test is finished	Take away the reagent from reagent area; Empty the waste tank; Remove the discarded cuvettes.

5.2 Test preparation

Complete the preparation work of conventional sample test via the following steps.

5.2.1 Check before Starting

Before starting, the following checks should be made to ensure the system works properly after starting.

NOTE

Make sure to wear gloves and work clothes to prevent infection. If necessary, wear protective glasses.

1) Check the power supply to confirm it supplies power normally. Check the communication cables and power cables of the analyzer, the computer and the printer to confirm they are connected properly.
2) Check whether the pipetting needle is at the correct position, whether the needle tip has water drop, pollution or bending.

5.2.2 Power-on and Login the Software

1) Connect the power supply , and turn on the main switch and submain switch of the analyzer.
2) Connect the power supplies of computer and printer.
3) After logging in Windows operating system, double click the shortcut icon of the user software on the desktop. After starting, **[login**] dialog will appear on the screen. Enter the user name and password, and click **<OK>** button to enter the user software interface.
4) After the analyzer and all components complete initialization, wait until the incubator temperature gets stable. Then the test can be started.

NOTE

The user name of system administrator is “snibe”. Its initial password is “snibe”.

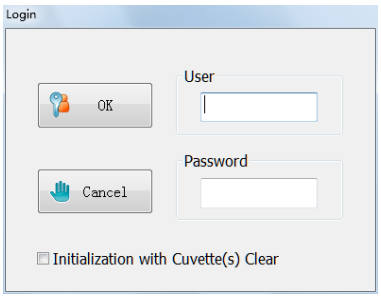


Figure 5.2-1 **[Login]** Dialog

5.2.3 Check Consumables

1) Check whether the system liquid, starter 1, and starter 2 are properly connected and that the liquid volume is sufficient;
2) Check whether there are enough cuvettes to complete the test;
3) Check whether the waste liquid is drained;
4) Check whether the discarded cuvettes are removed.

5.2.4 Confirm Device Status

Confirm whether the device is normal via the following steps:

1. Confirm incubator temperature

Observe the color of button in the status bar. Test can only be started when the color is stable green. If incubator temperature exceeds (36.8±0.5)℃ in the test process, the button turns red, but the analyzer will continue testing.

NOTE

After the analyzer is started, it will take about 30 minutes for the temperature in the incubator to be stable at (36.8±0.5)℃. Therefore, wait for 30 minutes after startup of analyzer to perform sample test.

2. Confirm system test

Put the light check liquid on the rack with its tag facing the code reader, and load it to any position of the sample area. The light check liquid is automatically identified and displayed in yellow color in the **Sample Info** of the software, i.e. lc, as shown below. Light Check inspection should be made once every week, and after any analyzer component is replaced. Do not load light check liquid on the machine when the system isn’t performing light check tests.

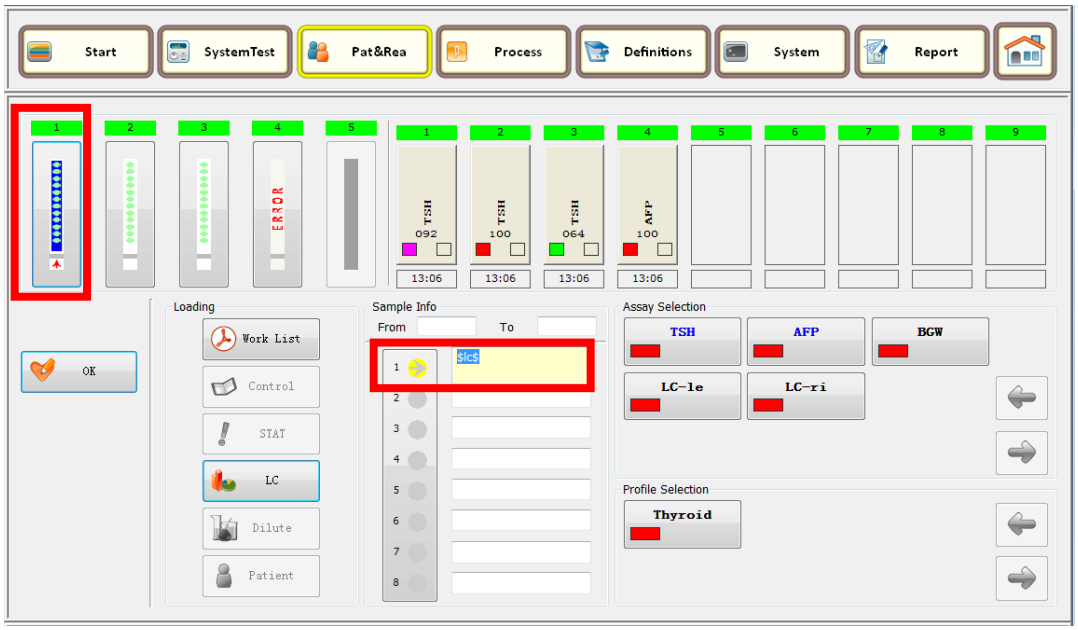


Figure 5.2-2 **[Patients]** interface

Click **<System Test>** button in the menu bar to enter **[System Test]** dialog. Here you can perform parameter setting for system test.

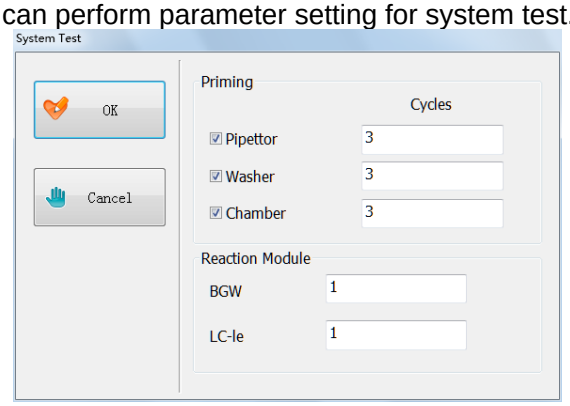


Figure 5.2-3 **[System Test]** Dialog

Input the priming times of the pipettor, the washer and the chamber. Input test times of BGW and LC-le.

Click **<OK>** button, **[Message]** dialog appears to confirm parameter setting, click **<OK>** button again.
Click **<Cancel>** button to cancel system test and exit **[System Test]** dialog.

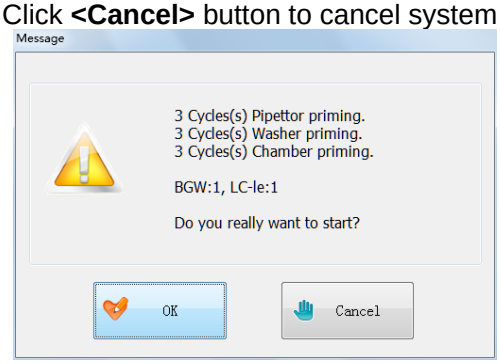


Figure 5.2-4 Confirmation Dialog

- Priming: Ensure the tubing of pipetting needle, washer and chamber is full of liquid. See Chapter 9 for details.
- BGW: The reference range of BGW results is 100-1200. See Chapter 9 for details.

- LC: The reference range of LC results is 450000-650000. , CV ≤ 3%. See Chapter 9 for details.

Please refer to the specific expectations LC reagent instructions.

Test can be conducted only when BGW results and LC results meet the requirements. In case of measurement abnormity, the test results might be not reliable.

5.2.5 Confirm Test Condition

Before performing tests, confirm that the reagent parameters and settings of this assay are correct. Perform the settings of group/profile.

1. Confirm assay parameters

Before using a new reagent, please read the instruction for use of the reagent carefully, and set up or confirm its parameters item by item according to actual requirements.

The set-up steps are as follows:

- Click **<Definitions>** button in the menu bar, then click **<Test>** button.
- Select the assay to be edited, click **<Edit>** button to enter **[User Specific Assay Data]** dialog for test setting.
- Finally, click <**Save**> button to complete test setting.

2. Profile/group setting

In order to facilitate sample registration, the assays can be set with profile/group:
The set-up steps are as follows:

- Click **<Definitions>** button in the menu bar, then click **<Profile>** button to enter **[Profile Definition]** dialog, where you can set the profile according to specific needs.
- Click **<Definitions>** button in the menu bar, then click **<Group>** button to enter **[Assay Group Definition]** dialog, where you can set the group according to specific needs.

5.2.6 Prepare Reagent

Scan reagent in the reagent area. Reagent calibration, QC test and sample test can be started when

- the reagent in the expiry date,
- the remaining test of the reagent is enough to complete the test,
- the shaking time of the magnetic microbeads of the reagent reaches 30 minutes.

1. Notes on use of reagent

CAUTION

Please remove the seals on the reagent kit before using a new reagent,

The preparation, use and storage of the reagent must be in strict accordance with its user manual. Prevent bubbles from forming in the reagent; or else the pipetting accuracy will be affected, hence affecting the test results.
The reagents of different kits cannot be mixed, or else the reliability of the test results might be affected.

2. Confirm remaining tests of reagent

After scanning RFID tag of the reagent in the reagent area and inserting the kit, make sure the remaining number of tests is enough to complete the number of tests needed.

If it is not enough to complete the testing, please insert another reagent in the reagent area.

3. Shaking time of magnetic microbeads
When inserting the kit, the assay name, the remaining tests, the calibration information and the shaking time of magnetic microbeads are displayed in the window corresponding to associated buttons.

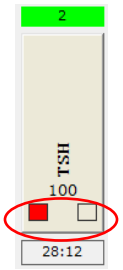


Figure 5.2-5 Reagent button

NOTE

The shaking time of the magnetic microbeads must be 30 minutes; or else the reliability of the test results cannot be ensured!

5.3 Test Analysis

After completing the preparation, the sample test can be performed.

5.3.1 Assay Calibration

Click **<Pat&Rea>** button in the menu bar or in the **[Home]** interface to enter **[Pat&Rea]** interface; select a reagent kit to enter **Reagents** interface.

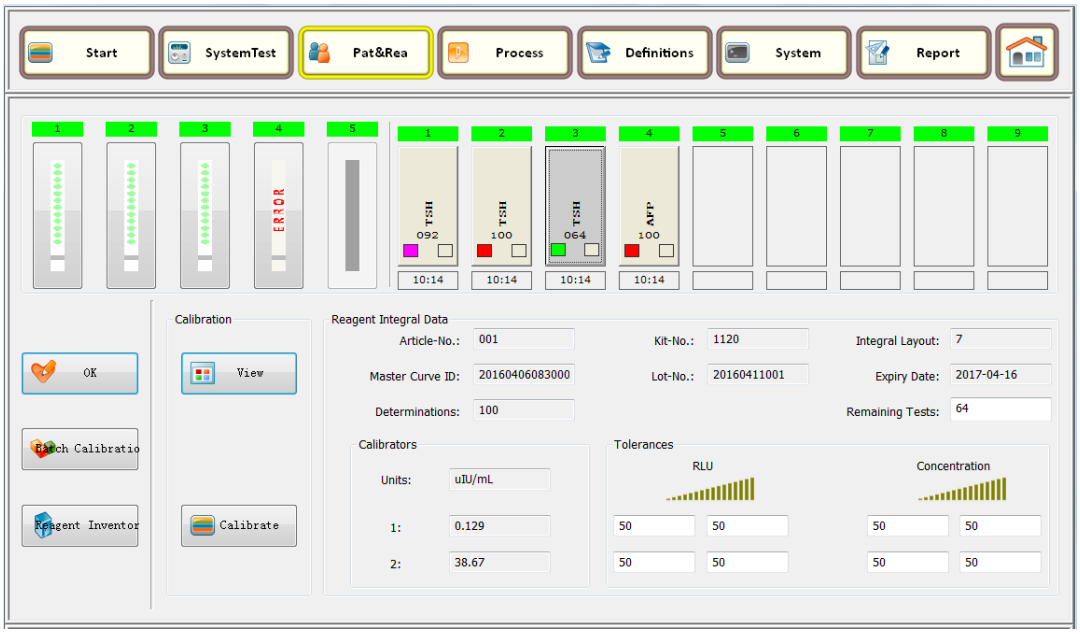


Figure 5.3-1 **[Pat&Rea]** Interface

Confirm whether the reagent used in the test is calibrated and valid. If the reagent is without valid calibration, click **<Calibration>** or **<Batch Calibration>** button to execute calibration operation.

Valid calibration is required for the assay to calculate sample concentration.

After calibration, click **<View>** button to open **[Calibration Dialog]** dialog, where you can view working curve information and accept/reject new working curve.

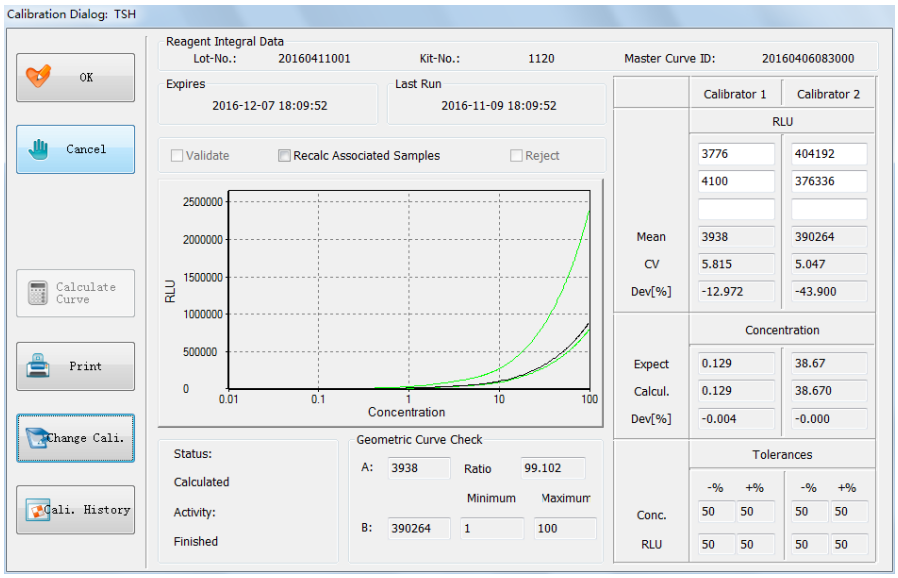


Figure 5.3-2 **[Calibration Dialog]**

Select **Validate** and click **<OK>** button to accept the new calibration data.
Select **Reject** and click **<OK>** button to give up the new calibration data. Click **<Calibration>** or **<Batch Calibration>** button in **Reagents** interface to re-execute calibration operation.

5.3.2 Control Registration

1. Click **<Definitions>** button in the menu bar, then click **<Control>** button in **[Definitions]** menu to set up controls .

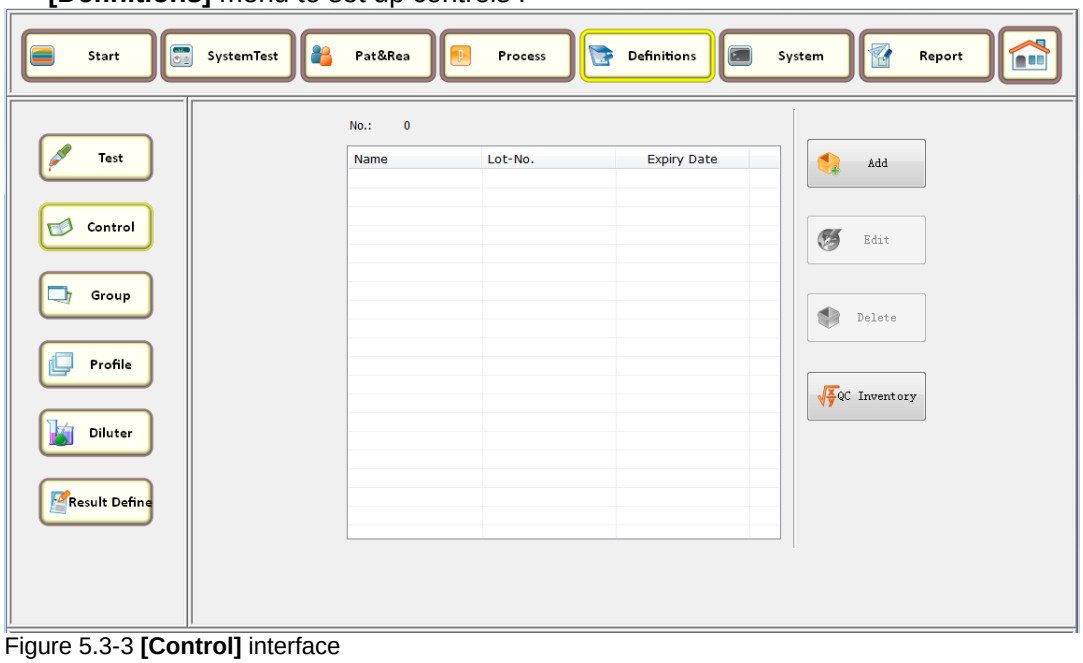


Figure 5.3-3 **[Control]** interface

2. Click **<Add>** button to open **[Control Data Input]** dialog.

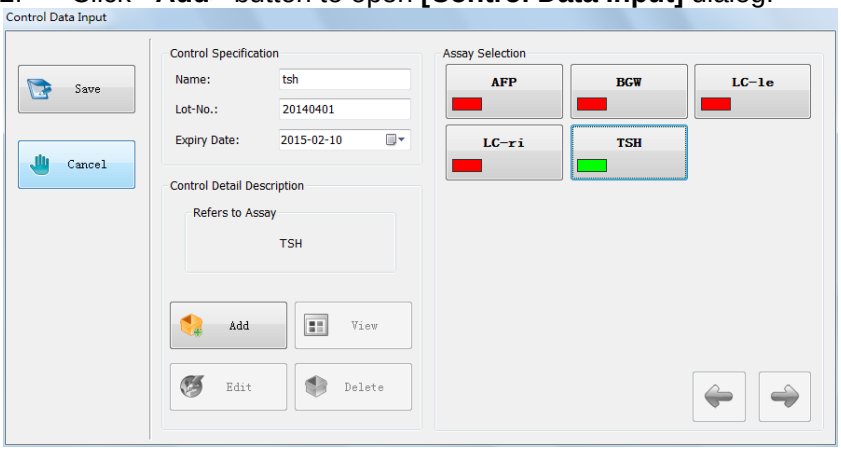


Figure 5.3-4 **[Control Data Input]** Dialog

3. Input the name and lot No. of the Control product, select the assay in need of control test, and click **<Add>** button to open **[Control Detail Description]** dialog.

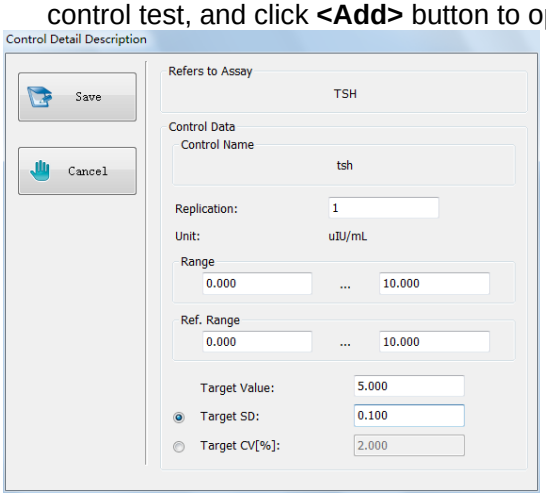


Figure 5.3-5 **[Control Detail Description]** Dialog

4. Input the expected concentration range, target value, target SD and replication times of this assay.
5. Click **<Save>** button, **[Message]** dialog appears to confirm parameter setting, click **<OK>** button to complete the control parameter setting.
6. Enter **[Pat&Rea]** interface. Properly load the rack with the control product, select the position of the control, and click **<Control>** button in the loading information area to open **[Controls Selection]** dialog, select the control information which has been set up, click **<OK>** button, and select the QC assay to complete QC assay registration.

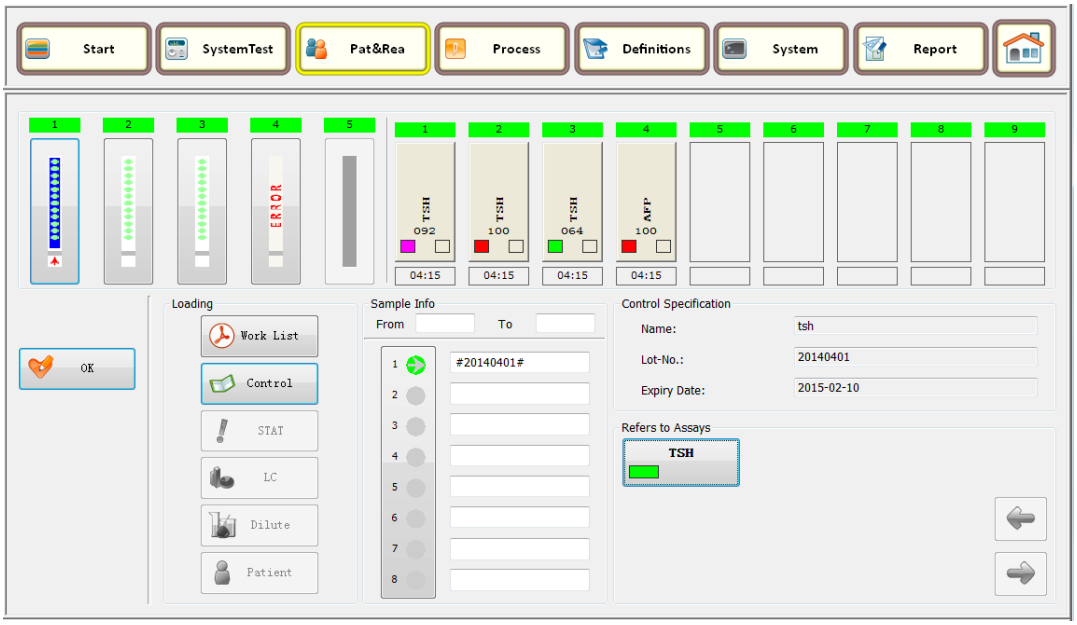


Figure 5.3-6 **[Pat&Rea]** Interface

NOTE

Sample test can be conducted only when the control test results of the reagent meet the requirements; or else the reliability of the sample test results cannot be ensured!

5.3.3 Sample Registration

NOTE

1) The samples with hemolysis, lipemia and icterus will affect the test results;
2) Ensure the sample is exclusive of clot; or else the pipetting needle will be blocked, which seriously affects the test results;
3) Some substances in the sample, such as drug, anticoagulant and preservative, will interfere with the test results;
4) Do not leave the sample open for a long time; or else the sample will volatilize, which affects the test results;
5) Improper parameter setting will affect the test results;
6) Snibe recommends that the test results shall not be modified in any manner, and shall not be liable for any consequences arising there from.

Click **<Pat&Rea>** button in the menu bar or in the **[Home]** interface, or open the sample area door to enter **[Pat&Rea]** interface. Users can perform sample registration and view rack status.

Put the sample on the rack with its barcode facing the code reader, and load it to the samples area. The sample is automatically identified in the **[Pat&Rea]** interface.

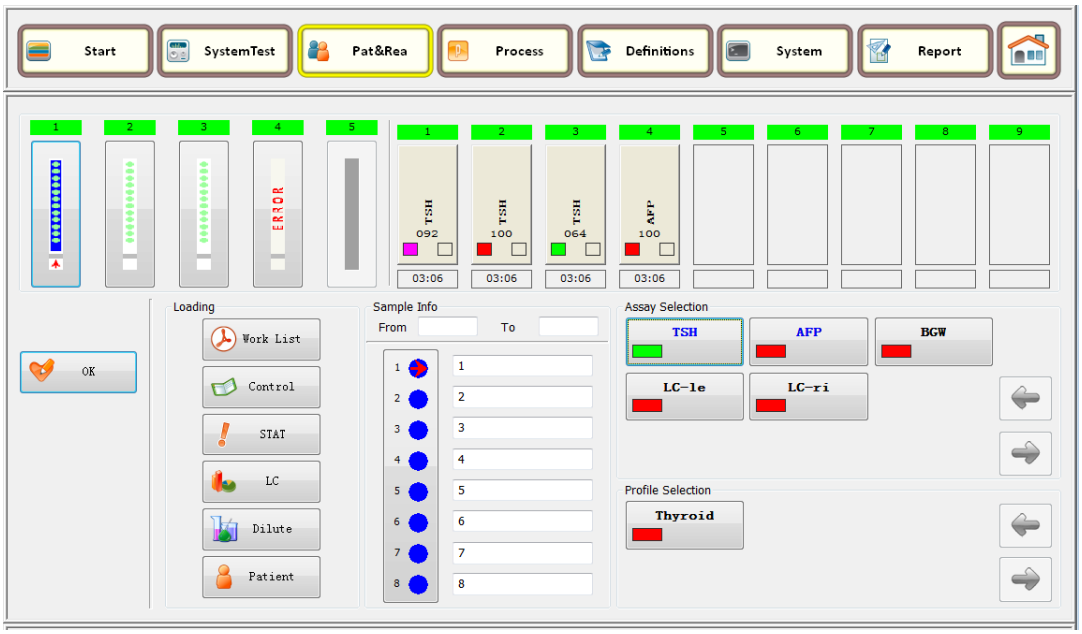


Figure 5.3-7 **[Pat&Rea]** Interface

Select the needed assay in the **Assay Selection** area, or select the assay in the **Profile Selection**.

For STAT sample registration, select **<STAT>** button. The currently-registered STAT samples will be prioritized.
For dilute samples, select **<Dilute>** button, and select dilution ratio for the assay need to be diluted.

If the samples of the same rack are given the same assay, the whole rack can be selected so that the assay information can be added at one time for faster sample editing.
LIS application function can be used to obtain the assay info of the sample from the LIS server.
Click **<Save>** button to complete sample registration.

5.3.4 Start Test

After completing sample registration, click **<Start>** button in the menu bar to send the test command, and the analyzer will start test.

5.3.5 Additional Samples and Assays

1. Additional assay for registered samples
If additional assays are required for registered samples in the test process, assay registration should be first performed. In the **Rack Station** of the **[Pat&Rea]** interface, select the samples that need additional assay, select the assay in the Assay Selection area, and click **<Save>** button to complete registration.
After the additional assay is registered, if there is no reagent for this assay in the reagent area, the reagent should be loaded; if there is reagent in the reagent area, click **<Start>** button in the menu bar to complete the continuous loading for the additional assay.

2. Test of additional samples
If additional samples need to be added in the test process, sample registration should be firstly performed (refer to 5.3.3 Sample registration). Use a blank rack for the new

samples. Load the samples properly, select the needed assay in the **Assay Selection** area, and click **<Save>** button to complete sample registration.
For STAT sample registration, select **<STAT>** button. The currently-registered STAT samples will be prioritized.
To dilute samples, select **<Dilute>**button, and select dilution ratio for the assay need to be diluted.
If there is no reagent for this assay in the reagent compartment, the reagent should be loaded in the reagent compartment; if there is reagent in the reagent compartment, click **<Start>** button in the menu bar to complete continuous loading.

5.4 Test Results

5.4.1 Sample Result

After the test, the test results can be searched in **[Report]** function. Processing of test results includes confirmation, printing, etc.
Click **<Report>** in the menu bar, then click **<Journal>** button on the left. Users can view, delete and modify the test results and print the journal.

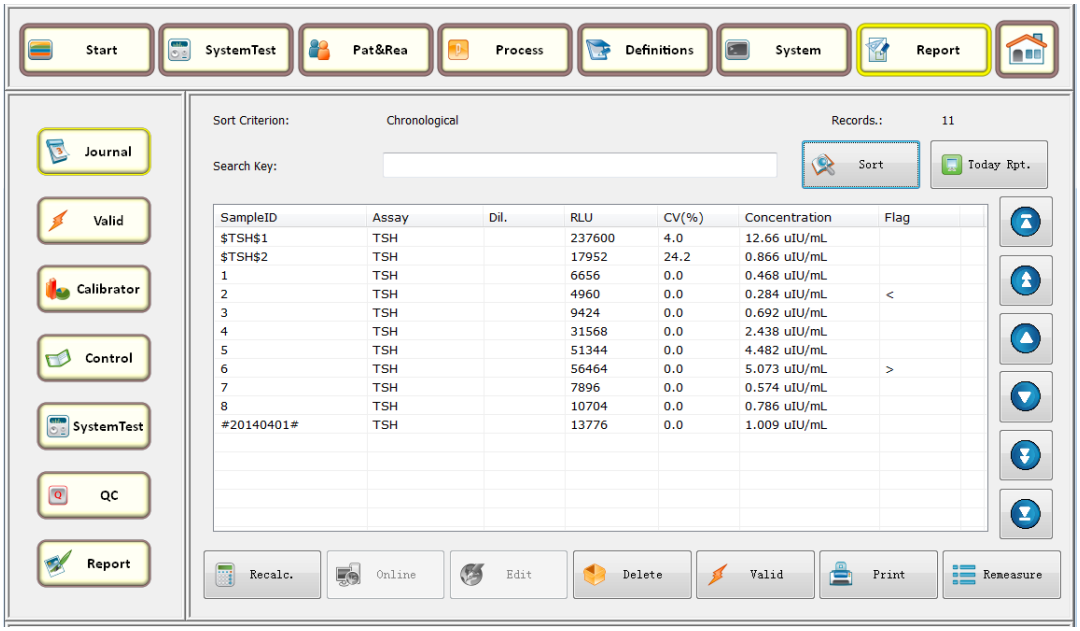


Figure 5.4-1 **[Journal]** Interface

Click **<Sort>** button and input corresponding date to search for historical journal information. You can also enquire journal information of certain ID, and choose to display test results according to the selected sorting criterion.
Click **<Valid>** button to confirm the selected test results according to the selected conditions. The confirmed journal is displayed in **[Valid]** interface.

5.4.2 QC Result and QC Graph

After validating the QC result, click the **[QC]** button in the [View Result] menu to enter the **[QC]** interface. Check the batch QC graph or monthly QC graph for the corresponding result, as shown in the following figure.

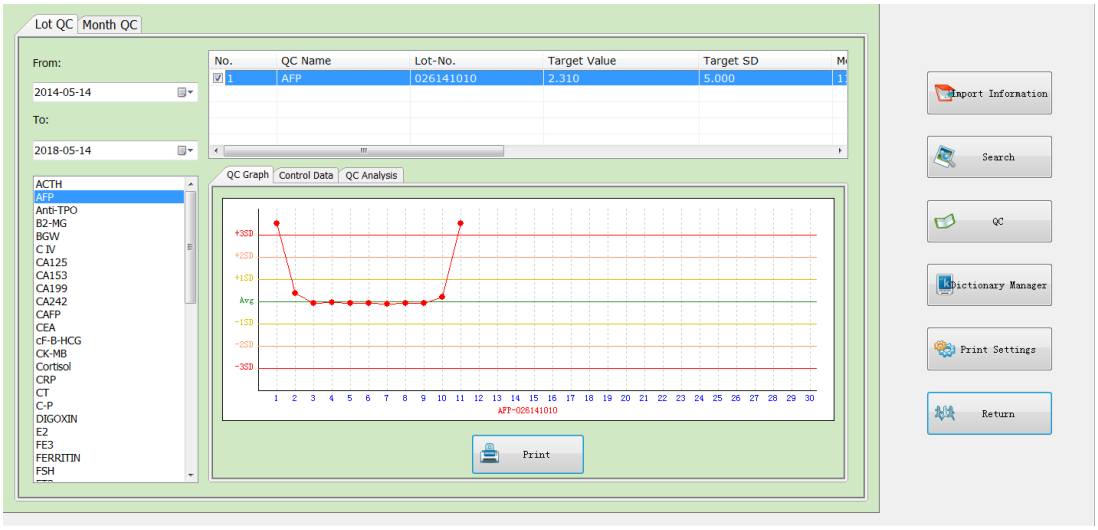


Figure 5.4-2 **[QC]** interface

Select “Batch QC” or “Monthly QC” tab to enter the corresponding interface. The user can select the time (a period of time for batch QC, and a specific month for monthly QC), QC items, and QC lot number to select the corresponding QC result data , and to view the QC graph and QC analysis result generated by the software.

5.5 End of Analysis

When all the tests have been completed, quit the operating software and Windows operating system. Turn off the power supply of all parts.

5.5.1 Shut down

When all the tests have been completed, quit the user software and Windows operating system. Turn off the power of all parts in the following order:

1) Turn off the power of the printer;
2) Turn off the power of the computer;
3) Turn off the power of the submain switch of the device.

NOTE

After the submain switch of the device is turned off, the reagent refrigerating system still works. Shutdown reagent refrigerating system should turn off the main power switch.

5.5.2 Operation after Shutdown

To make preparation for the next test, inspect the following items:

1) Remove the samples in the sample area;
2) Remove the reagents in the reagent area;
3) Empty the waste tank;
4) Empty the discarded cuvettes in the waste bag;
5) Inspect whether the analyzer surface has stains. If so, wipe off the stains with a clean and soft cloth.

6 [System] Menu

6.1 [System] Menu Introduction

Click **<System>** button in the menu bar to enter [**System**] menu, where you can set up a series of functions, as described below:

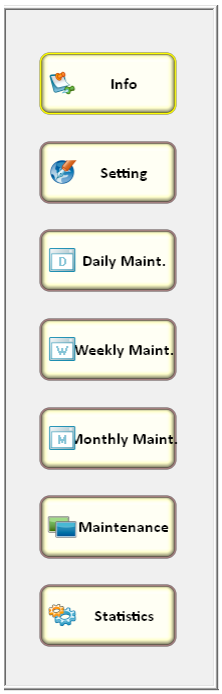


Figure 6.1-1 **[System]** Menu

Button	Functions
<Info>	Display PC software, PLC software version info and analyzer serial number.
<Setting>	Include 4 Tab: Mode, Online, User, Language. In Mode, you can select operation mode and sample editing mode; In Online, you can set up parameters to connect the software to hospital's LIS server; In User, you can set up or modify user name, password and access right; In Language, you can select the interface language for the software.
<Daily Maint.>	Set daily maintenance reminder, and display the operation procedure of daily maintenance.
<Weekly Maint.>	Set weekly maintenance reminder, and display the operation procedure of weekly maintenance.
<Monthly Maint.>	Set monthly maintenance reminder, and display the operation procedure of monthly maintenance.
<Maintenance>	Include one-key cleaning and tubing cleaning
<Statistics>	Make statistics of reagent consumption.

6.2 <Info>

Click **<Info>** button in **[System]** menu to open **[Info]** interface.

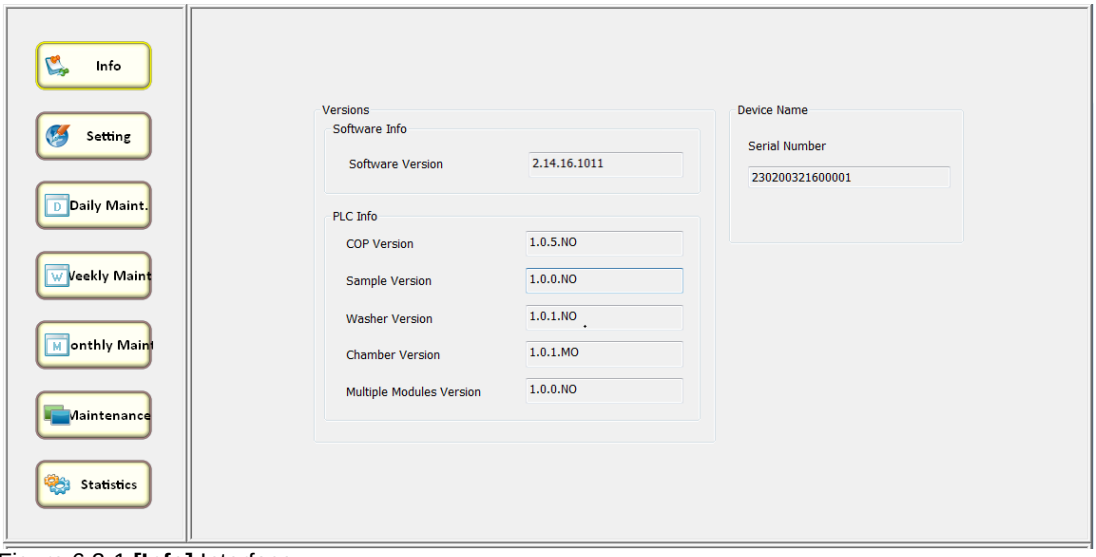


Figure 6.2-1 **[Info]** Interface

[Info] interface contains the following information:

1. Software Info

Software Version: Version information of software.

2. PLC Info

COP Version: Version information of COP.
Sample Version: Version information of pipetting needle and sample area.
Washer Version: Version information of washer.
Chamber Version: Version information of chamber.
Multiple Modules Version: Version information of Multiple Modules.

3. Device Name

Serial Number: Serial number of device.

6.3 <Setting>

Users can set modes, online, user and language in System Setting. .

6.3.1 <Mode>

This software provides multiple sample editing modes and running modes. Users can set according to the actual situation.
Click **"Mode"** tab to enter **[Mode]** interface, as shown in the figure below.

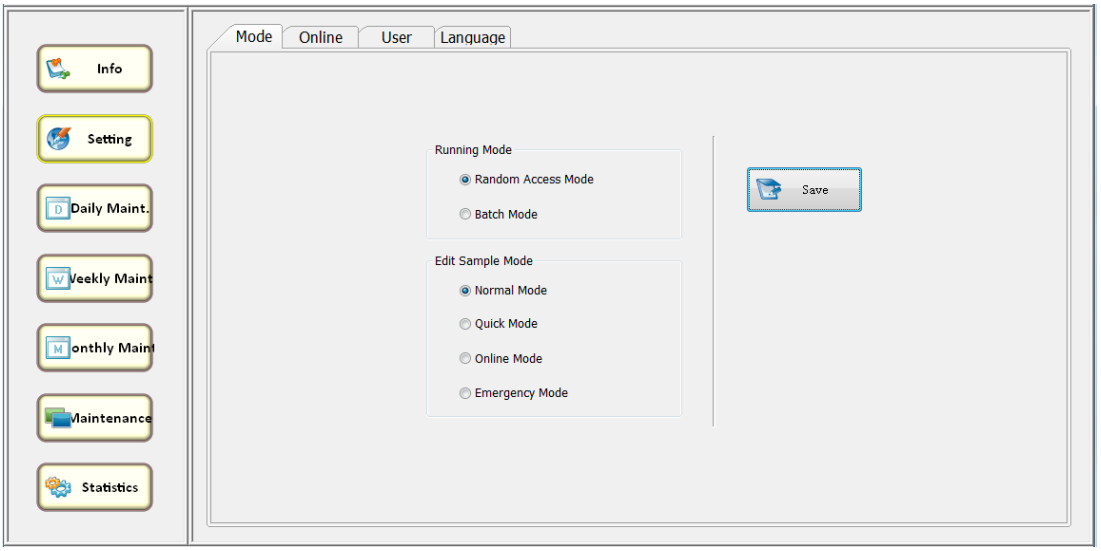


Figure 6.3-1 **[Mode]** Interface

[Mode] interface contains the following information:

1. Running Mode

- Random Access Mode——processing one rack after another, prioritized as follows:
  A.STAT assay;
  B.Assays with automatic reference and automatic dilution;
  C.From left to right racks;
  D.According to incubation time, from the longest to the shortest;
  E.According to assay name abbreviations, from A to Z;
  F.According to positions of sample tubes on racks;
  Advantage: this mode allows removal of a rack after the whole rack is process and re-adding of new samples.
  Disadvantage: processing time is not optimal.

- Batch mode——Processing all samples with optimal time, prioritized as follows:
  A.STAT assay;
  B.Assays with automatic reference and automatic dilution;
  C.According to incubation time, from the longest to the shortest;
  D.According to assay name abbreviations, from A to Z
  E.From left to right racks, from back tubes to front tubes within a rack.
  Advantage: This mode makes full use of cuvettes with the highest efficiency.
  Disadvantage: Unable to process a whole rack so as to add new samples.

2. Edit Sample Mode:

- Normal Mode:
  Barcode reader directly reads the barcode from sample tubes to generate sample ID.
- Quick Mode:

Software directly generates sample ID without reading barcode from sample tubes.

- Online Mode:
  Software reads assay information from LIS server via sample ID, and sends test results to hospital LIS server.
- Emergency Mode:
  When there is an error with the sample area door sensor or barcode reader (after the rack is loaded, the corresponding position of "rack station" in **[Patients]** interface displays "ERROR") and thus "sample info" cannot be edited in the sample loading interface, emergency mode can be enabled. In this mode, users can still edit sample info.

Select required running mode and sample editing mode, click <**Save**> to confirm mode selection.

6.3.2 <Online>

This software provides two-way communication with LIS server in the hospital. It is able to acquire assay information from hospital LIS server via sample ID and send test results to the LIS server.
Click **"Online"** tab to enter **[Online]** interface, as shown in the figure below:

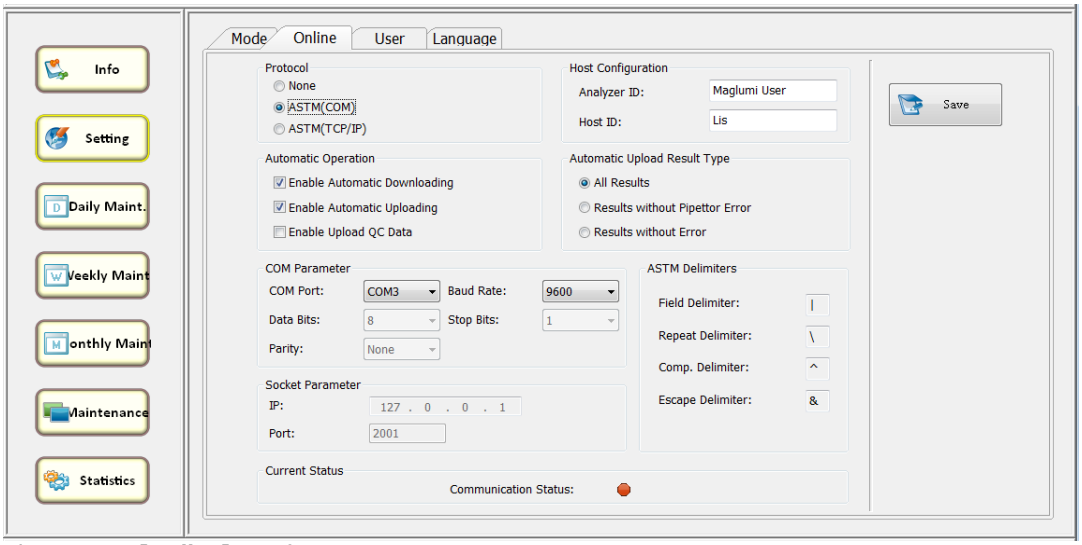


Figure 6.3-2 **[Online]** Interface

[Online] interface contains the following information:

1. Protocol

- None: Not connect to hospital LIS server.
- ASTM: Use ASTM protocol to communicate with hospital LIS server.

2. Host Configuration

- Analyzer ID: Input name of the analyzer that communicates with hospital LIS server.
- Host ID: Input the name of hospital LIS server.

3. Automatic Operation

- Enable Automatic Downloading: Enable the analyzer to automatically acquire the assay info of samples from hospital LIS server.
- Enable Automatic Uploading: Enable the analyzer to automatically upload the test results of samples to hospital LIS server.
- Enable QC Data Uploading: Enable the analyzer to automatically upload the test results of QC to hospital LIS server.

4. Automatic Upload Result Type

- All Results: Enable the analyzer to send all test results to hospital LIS server.
- Results without Pipettor Error: Enable the analyzer to send all the test results without pipettor error to hospital LIS server.
- Results without Error: Enable the analyzer to send all the test results without instrument error to hospital LIS server.

5. Communications

- COM Port: Select the serial number of the COM Port that communicates with hospital's LIS.
- Baud Rate: Select the Baud rate for communicating with hospital's LIS.
- Data Bits: Select the data bits for communicating with the hospital's LIS.
- Stop Bits: Select the stop bits for communicating with the hospital's LIS.
- Parity: Select the parity bits for communicating with the hospital's LIS.

6. ASTM Delimiters

- Field Delimiter: Display the field delimiter for communicates with hospital's LIS.
- Repeat Delimiter: Display the repeat delimiter for communicating with hospital's LIS.
- Comp. Delimiter: Display the component delimiter for communicating with the hospital's LIS.
- Escape Delimiter: Display the escape delimiter stop bits for communicating with the hospital's LIS

7. Current Status

- COM Port Status: Display the status of the currently-used COM port.

Click **<Save>** button to complete the parameter setting for two-way communication between the software and hospital LIS server.

6.3.3 <User>

This software provides a user management system. An authorized system administrator can assign different user rights to different users, as well as add, edit username, password and user rights.

Click **"User"** tab to enter **[User]** interface, as shown in the figure below:

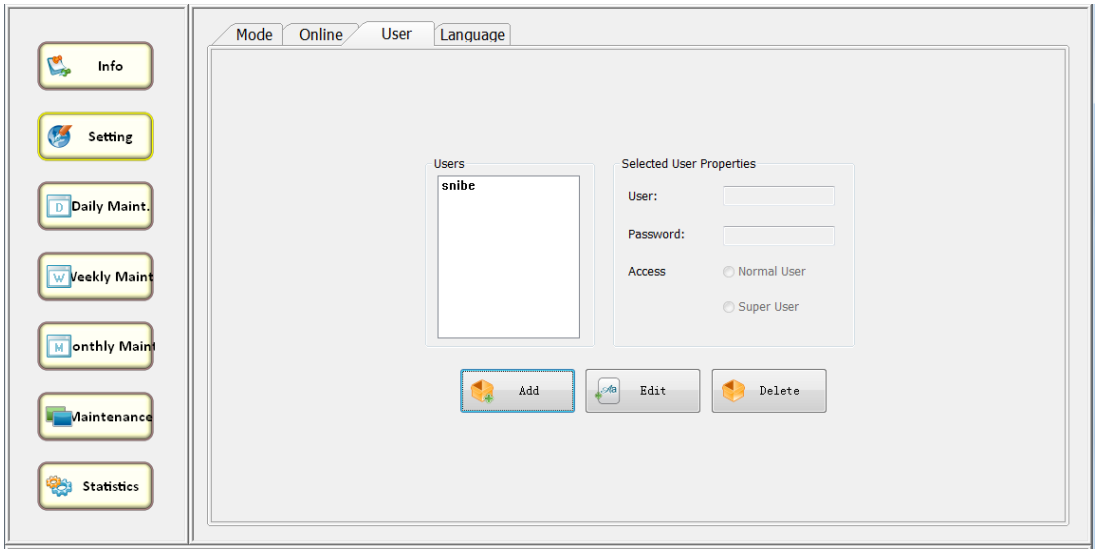


Figure 6.3-3 **[User]** Interface

[User] interface contains the following information:

1.Users: A list displays existing users.
2.Selected User Properties: Display info of the selected user in users list.
3.<Add>: Add new users.
Click **<Add>** to open **[User Properties]** dialog, in which you can input user info.

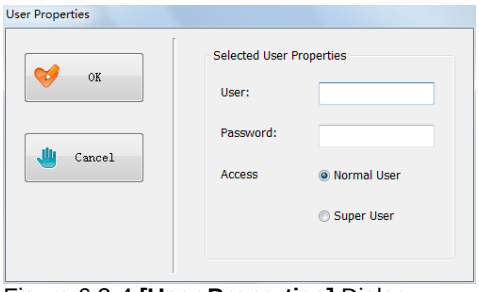


Figure 6.3-4 **[User Properties]** Dialog

- **User:** Input alphanumeric characters.
- **Password:** Input password for the user.
- **Access:** User properties.
  Normal User: can use specified functions;
  Super User: can use all functions of the software.

Click **<OK>** button to complete adding a new user.
Click **<Cancel>** button to cancel adding new user and quit **[User Properties]** dialog.

4.<Edit>: Edit the selected user data (modify username, password and user rights).
Select a user in users list, then click **<Edit>** button to open **[User Properties]** dialog, where you can modify the selected user data.
Click **<OK>** button to complete modifying the selected user data.
Click **<Cancel>** button to cancel modifying the selected user data and quit **[User Properties]** dialog.

5.<Delete >: Delete existing users.
Select a user in **[Users]** list, click **<Delete>** button, and then click **[OK]** button to confirm deletion of this user.

6.3.4 <Language>

This software supports 10 interface languages, including Simplified Chinese, English, French, German, Italian, Portuguese, Romanian, Russian, Spanish and Turkish.

Click **"Language"** tab to enter **[Language]** interface, as shown in the figure below. Click the corresponding language button to change to that language.

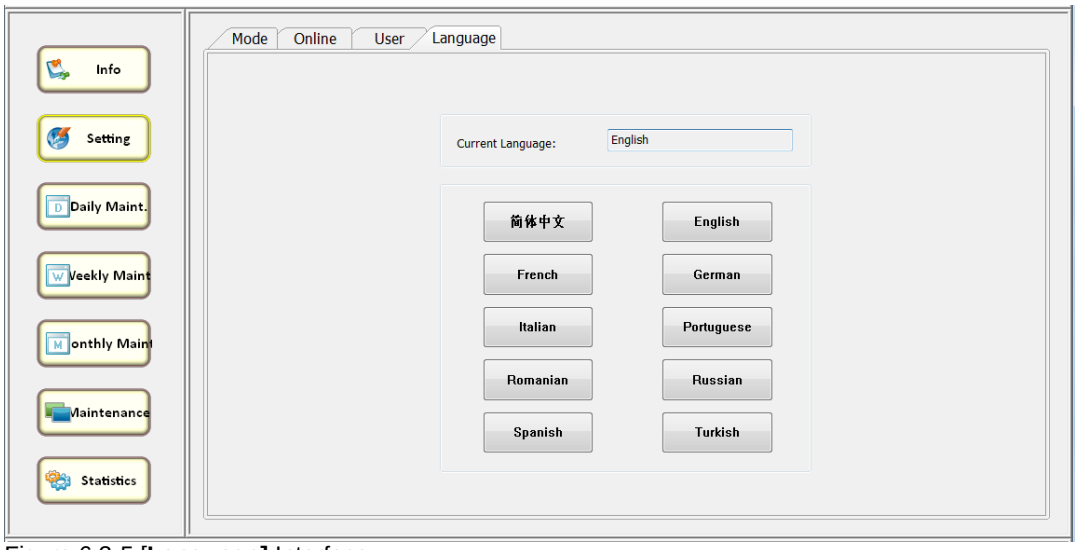


Figure 6.3-5 [**Language**] Interface

6.4 <Daily Maint.>

Click **<Info>** button in **[System]** menu to open **[Daily Maint.]** interface, as shown in the figure below:

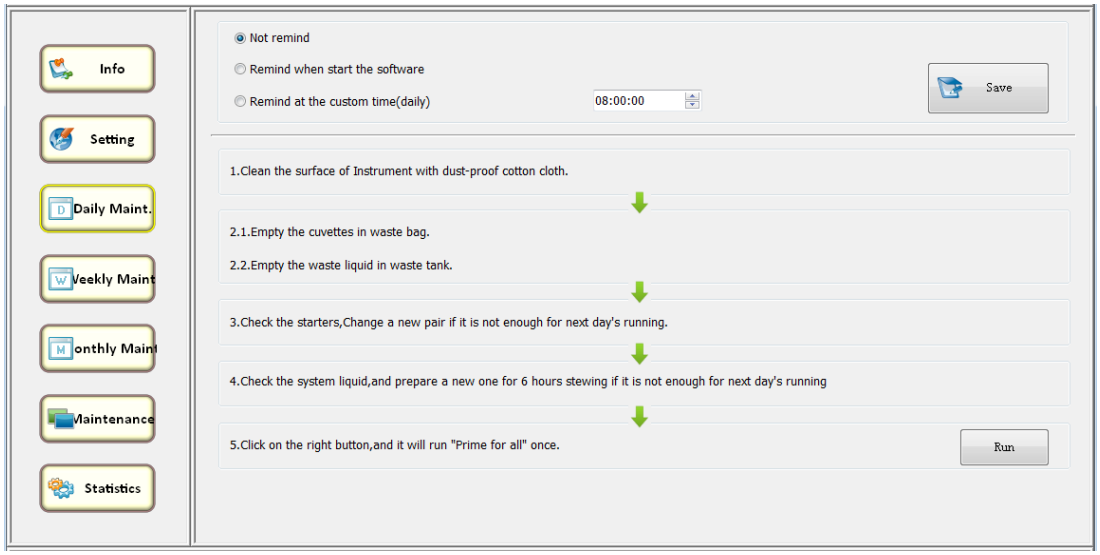


Figure 6.4-1 **[Daily Maint.]** Interface

[Daily Maint.] interface contains the following information:

1. Maintenance Reminder Setting:

Not remind: You will not be reminded of daily maintenance;

Remind when start the software: When starting the software, you will be reminded of daily maintenance;

Remind at the custom time (daily): You will be reminded of daily maintenance at the preset time.

After selecting maintenance reminder occasion and custom time, click **<Save>** button to complete maintenance reminder setting.

2. [Maintenance Steps]

Carry out maintenance according to the maintenance steps shown on the interface. When it is needed to execute one-key cleaning, simply click **<Execute>** button in the

corresponding step. (For detailed steps, see Chapter 17 *System Maintenance* of this manual.)

6.5 <Weekly Maint.>

Click **<Info>** button in **[System]** menu to open **[Weekly Maint.]** interface, as shown in the figure below:

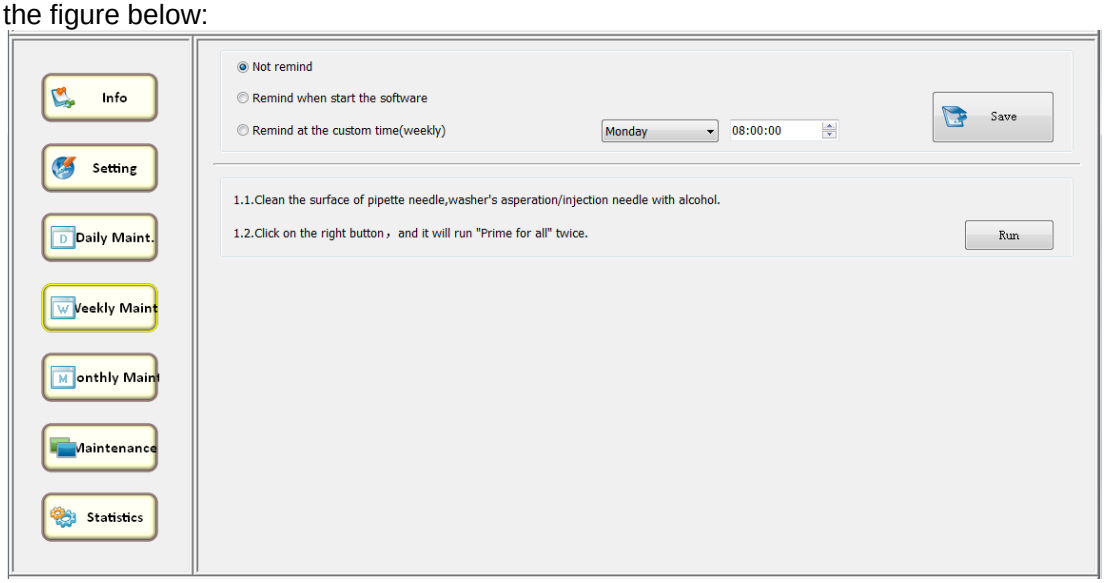


Figure 6.5-1 **[Weekly Maint.]** Interface

[Weekly Maint.] interface contains the following information:

1. Maintenance Reminder Setting:

Not remind: You will not be reminded of weekly maintenance;

Remind when start the software: When starting the software, you will be reminded of weekly maintenance;

Remind at the custom time (weekly): You will be reminded of weekly maintenance at the preset time.

After selecting maintenance reminder occasion and custom time, click **<Save>** button to complete maintenance reminder setting.

2. [Maintenance Steps]

Carry out maintenance according to the maintenance steps shown in the interface. When it is needed to execute one-key cleaning, simply click **<Execute>** button in the corresponding step. (For detailed steps, see Chapter 17 *System Maintenance* of this manual.)

6.6 <Monthly Maint.>

Click **<Info>** button in **[System]** menu to open **[Monthly Maint.]** interface, as shown in the figure below:

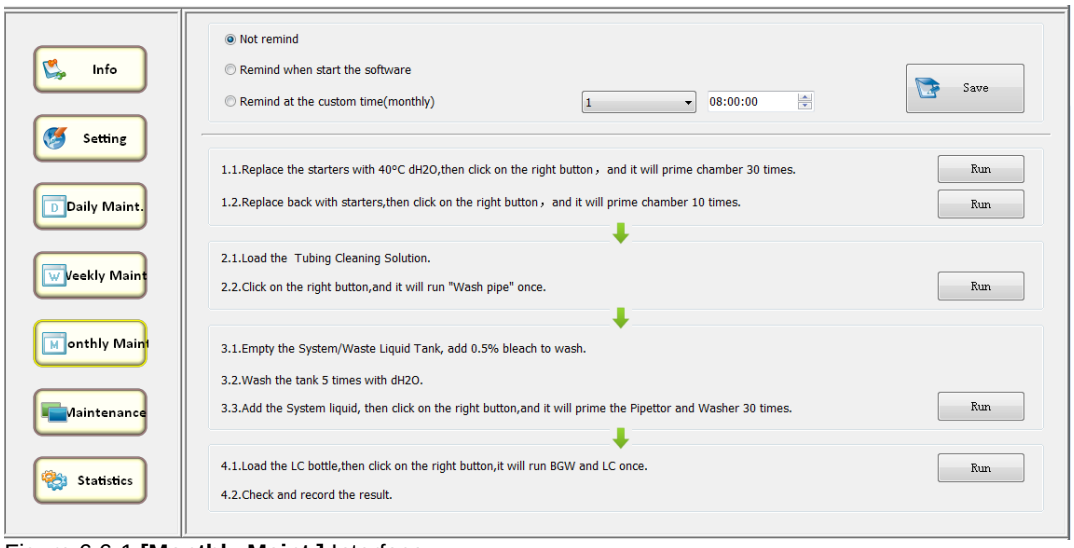


Figure 6.6-1 **[Monthly Maint.]** Interface

[Monthly Maint.] interface contains the following information:

1. Maintenance Reminder Setting:

Not remind: You will not be reminded of monthly maintenance;

Remind when start the software: When starting the software, you will be reminded of monthly maintenance;

Remind at the custom time (monthly): You will be reminded of monthly maintenance at the preset time.

After selecting maintenance reminder occasion and custom time, click **<Save>** button to complete maintenance reminder setting.

2. [Maintenance Steps]

Carry out maintenance according to the maintenance steps shown in the interface. When it is needed to execute perfusion, tubing cleaning, BGW and LC, simply click **<Execute>** button in the corresponding step. (For detailed steps, see Chapter 17 *System Maintenance* of this manual.)

6.7 <Maintenance>

This system provides one-key tubing perfusion and tubing cleaning functions so that users can execute routine tubing maintenance operations.

6.7.1 <Maintenance>

Click **<Maintenance>** tab to enter **[Maintenance]** interface, as shown in the figure below:

Prime for All: Perfuse the pipettor twice; perfuse the washer and the chamber six times, respectively.

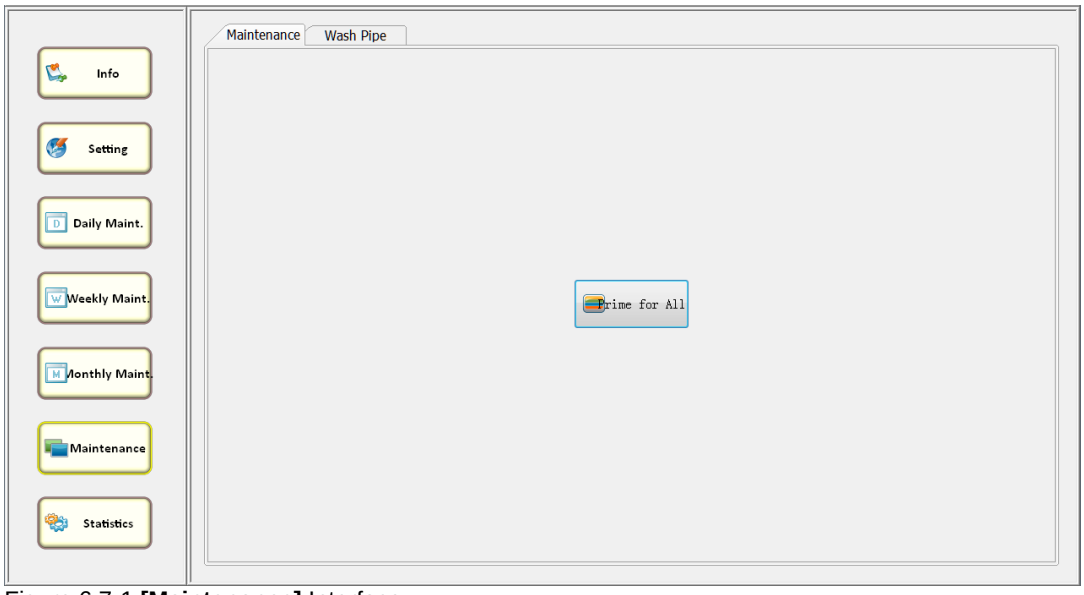


Figure 6.7-1 **[Maintenance]** Interface

6.7.2 <Wash Pipe>

Click **<Wash Pipe>** tab to enter **[Wash Pipe]** interface, as shown in the figure below.

According to the instruction of Maglumi System Tubing Cleaning Solution (hereafter Solution), load the Solution (insert the kit filled with the Solution into the Track 1 of the reagent area) and click **<Start Wash>** button to start tubing washing. The whole cleaning process takes about 40 minutes.

Please refer to the instruction for use of the Solution for details.

NOTE

Do not abort wash during the cleaning process.

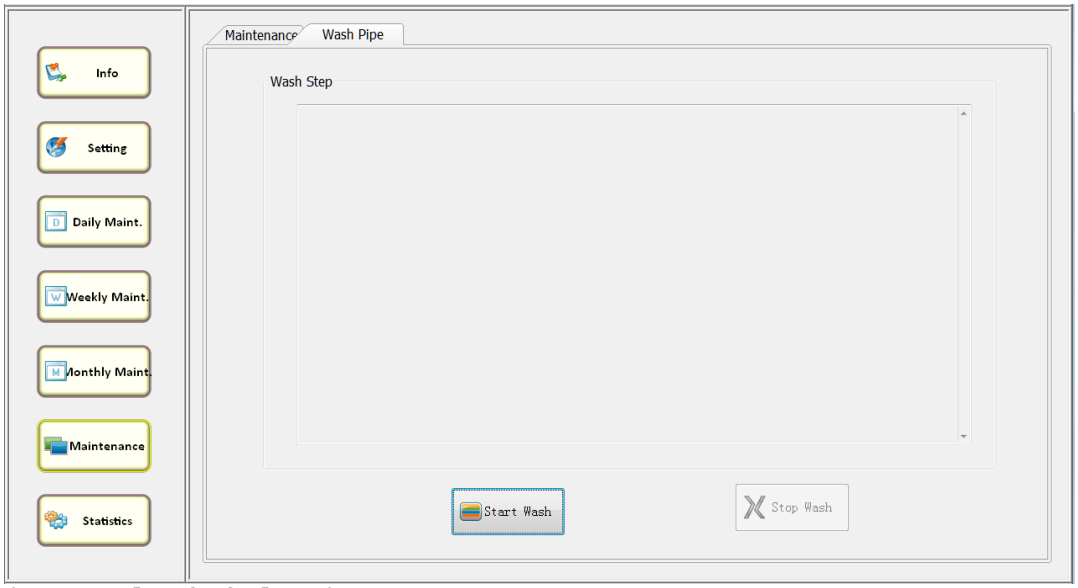


Figure 6.7-2 **[Wash Pipe]** Interface

6.8 Statistics

Click **<Statistics>** button in **[System]** menu to open **[Statistics]** interface, as shown in the figure below:

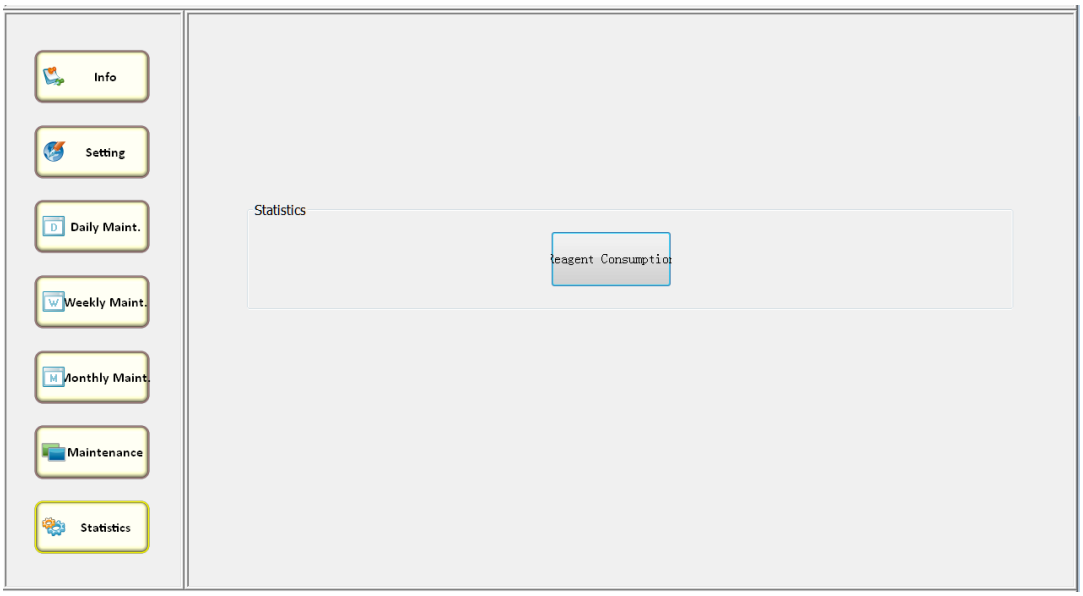


Figure 6.8-1 **[Statistics]** Interface

Click **<Reagent Consumption>** button to open **[Assay Dosage Dialog]**.

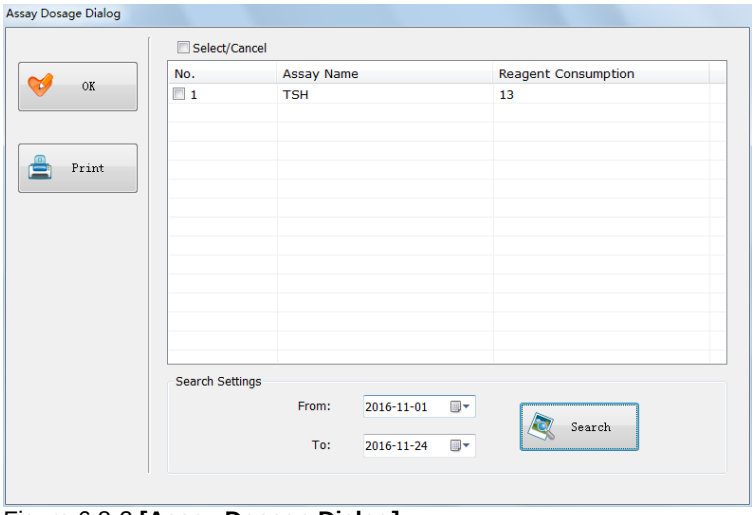


Figure 6.8-2 **[Assay Dosage Dialog]**

In Search Settings, input start time and end time, and then click **<Search>** to display the reagent consumption within the specified time period. Check an assay and click <**Print**> to print consumption info, and click **<Select/Cancel>** to check or cancel all assays.

7 [Definitions] Menu

7.1 [Definitions] Menu Introduction

Basic tests have been set up for this system in the factory. The basic tests can also be modified and redefined by click the function buttons of **[Definitions]** menu. Normally, parameters can be used by all assays after input once.
Click **<Definitions>** button in the main bar to enter **[Definitions]** menu. The function buttons described as follow:

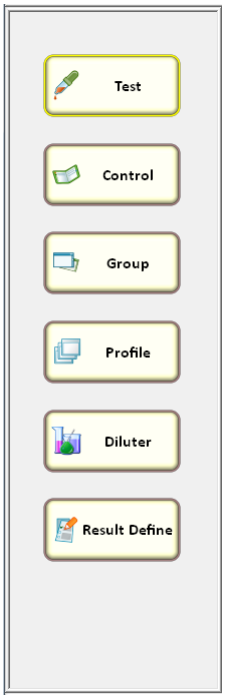


Figure 7.1-1 **[Definitions]** Menu

Button	Functions
<Test>	Set detailed parameters of the assay;
<Control>	Define control
<Group>	Define check group
<Profile>	Define several assays as a profile. When many samples are given the same assays, you can edit profile for collective processing
<Diluter>	Define the assay to be diluted and the dilution ratio
<Result Define>	Define settings to display, edit and print results.

7.2 <Test>

Click <**Test**> in **[Definitions]** menu to enter **[Test]** interface, as shown in the figure below. Click the corresponding button to select the desired assay, and it will be displayed in the **Selected** area.

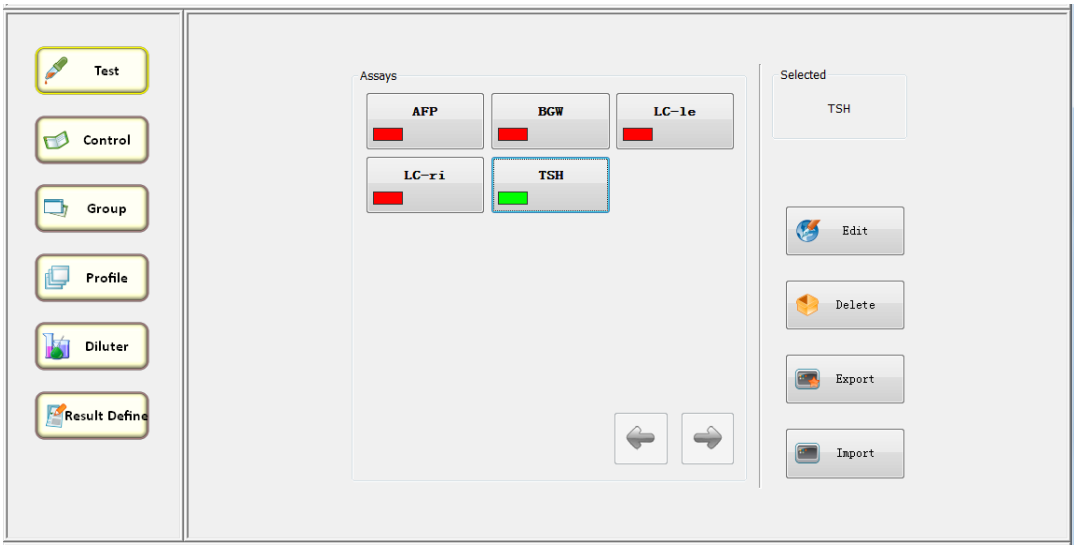


Figure 7.2-1[**Test]** Interface

1. Assay: contains all the assays provided by Snibe.

2. Selected: displays the name of selected assay.

3. <Export>: Export the data file of a selected assay to specified path.
When software must be reinstalled, assay data files can be exported to store the previous data of the selected assay, such as calibration data

4. <Import>: Import assay files from a hard disk or CD-ROM to system database.
Snibe provides the required assay data files. Click **<Import>** button to open **[ASY-File Selection]** dialog. Open the directory of assay files and select the required assay from **Assay List**.

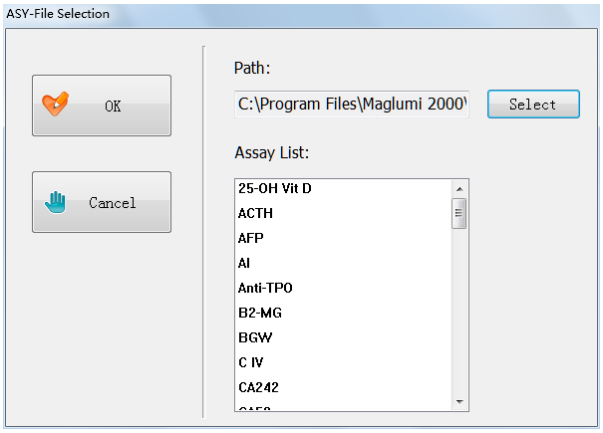


Figure 7.2-2 **[ASY-File Selection]** Dialog

Click **<OK>** button to complete importing parameter file of the selected assay.
Click **<Cancel>** button to cancel importing parameter file of the selected assay.
If this assay already exists, **[Message]** dialog appear to prompt asking if you want to rewrite. Click **<OK>** button to confirm rewriting data of this assay.

After importing an assay file, users must redefine the following options of this assay:

- Control definition;
- Dilution definition;
- Group definition;
- Profile definition.

5. <Delete>: Delete the parameter file of the selected assay.
Select an assay in **Assay** area of **[Test]** interface, click **<Delete>** button to delete the parameters of this assay.

6. <Edit>: Set parameters for the selected assay.
Select an assay in **Assay** area of **[Test]** interface, click <**Edit**> button to open **[User Specific Assay Data]** dialog.

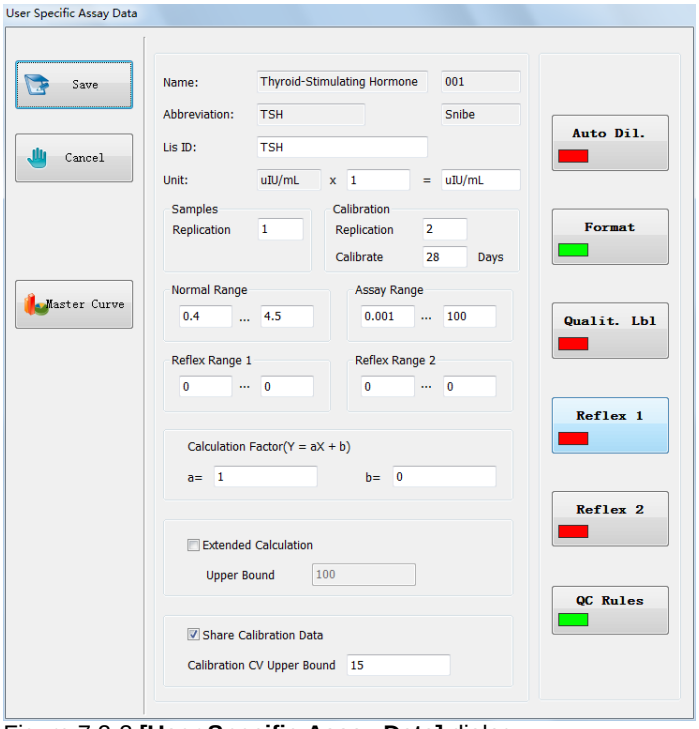


Figure 7.2-3 **[User Specific Assay Data]** dialog

Field	Description
Name	Assay name, article-No.;
Abbreviation	Abbreviation of the assay's English name and company's English name;
Lis ID	Signal channel used to communicate with LIS system
Unit	Measurement unit. When different measurement units are required, adjacent fields can be input with conversion factors and results;
Sample replication	Definition of sample retest times (range 1-3)
Calibration replication	Definition of calibration retest times (range 1-3);
Calibrate	Definition of valid days of calibration;
Normal range	Different countries and labs can set their own normal reference range. In **[Journal]**, there is "<" or ">" flag when the range is exceeded;
Assay range	The reagent manufacturer determines its assay range, but it

	can be modified downward by users. In [**Journal**], there is "<<" or ">>" flag when the range is exceeded;
Reflex range	Can be modified by users; when the test results of this assay are within the reflex range, reflex shall be made again;
Calculation factor (Y=ax+b)	Calculate the results according to the calculation factors "a" and "b", which are input by users.
Extended calculation	Calculate the results exceeding the linear range; the upper bound of extended calculation can be set.
Share Calibration Data	Select whether reagents of the same Lot-No. will share the calibration data.
Calibration CV Upper	Set the CV upper bound in calibration result RLU; a prompt will be given when the upper bound is exceeded.

NOTE

1. BGW, LC-le and Lc-ri are BGW and LC test items and their assay parameters cannot be modified.
2. Only when there is no reagent of the assay in reagent area, the definitions in this dialog can be modified. Otherwise, **<Save>** cannot be clicked, thus the modified parameters of the assay cannot be saved.

7.2.1 <Auto Dil.>

Click **<Auto Dil.>** button in **[User Specific Assay Data]** dialog to open **[Auto Dilution Settings]** dialog.

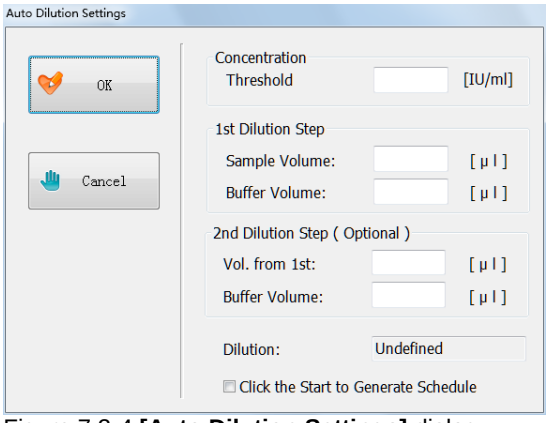


Figure 7.2-4 **[Auto Dilution Settings]** dialog

1. Concentration:

- Threshold: Used to set the initial value for the auto dilution;

2. 1st Dilution Step:

- Sample volume: Used to set the sample volume pipetted for 1st auto dilution step;
- Buffer volume: Used to set the buffer volume pipetted for 1st auto dilution step;

3. 2nd Dilution Step (Optional):

- Vol. from 1st: Used to set the diluted sample volume pipetted for 2nd auto dilution step;
- Buffer volume: Used to set the buffer volume pipetted for 2nd auto dilution step.

4. Dilution: Display the dilution rate of auto dilution

5. Click the start to generate schedule

- Select: If the concentration of test results exceeds auto dilution concentration, registration of diluted sample will be automatically completed, but **<Start>** button should be manually clicked to complete auto dilution test.

- Not select: If the concentration of test results exceeds auto dilution concentration, registration of diluted sample in the Patients area will be automatically completed and schedule command will be sentautomatically to complete auto dilution test.

Click **<OK>** button to complete auto dilution parameter setting.
Click **<Cancel>** button to cancel auto dilution parameter setting.

7.2.2 <Format>

Click **<Format>** button in **[User Specific Assay Data]** dialog to open **[Result Format]** dialog, where you can define number of decimal digits corresponding to measurement ranges.

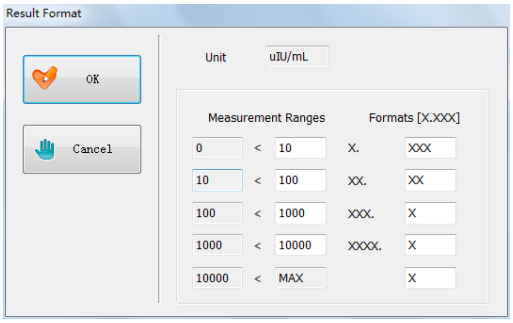


Figure 7.2-5 **[Result Format]** Dialog

1. Unit: Concentration unit

2. Measurement Ranges: Measurement ranges of concentration results;

3. Formats [X.XXX]: Number of decimal digits corresponding to concentration ranges.

- If you input the upper bound of a measurement range, the lower bound of the next higher measurement range will be automatically changed. Result formats can be defined. For example, "**x.xxx**" means a measurement value in **[Journal]** has three decimal places.

Click **<OK>** button to complete format setting.
Click **<Cancel>** button to cancel format setting.

7.2.3 <Qualit. Lbl>

Tags can be defined for measured result to indicate it is within a specific range, and the tags are displayed in **[Journal]** interface for the convenience of result analysis.
Click **<Qualit. Lbl>** button in **[User Specific Assay Data]** dialog to open **[Qualitative Settings]** dialog.

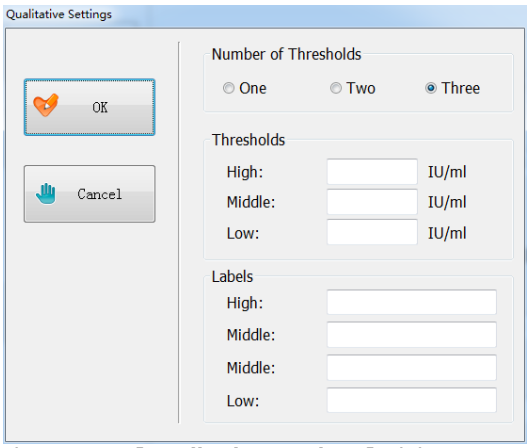


Figure 7.2-6 **[Qualitative Settings]** Dialog

1. Number of thresholds: define the number of threshold concentrations;

2. Thresholds: threshold concentrations;

3. Labels: use alphanumeric, characters or words as labels, such as negative, positive;

Click **<OK>** button to complete qualitative label setting.
Click **<Cancel>** button to cancel qualitative label setting.

7.2.4 <Reflex>

Reflex is to start an associated assay when the test results of the current assay are within the reflex range.

Click **<Reflex 1>** in **[User Specific Assay Data]** dialog to enter **[Assay Selection]** dialog.

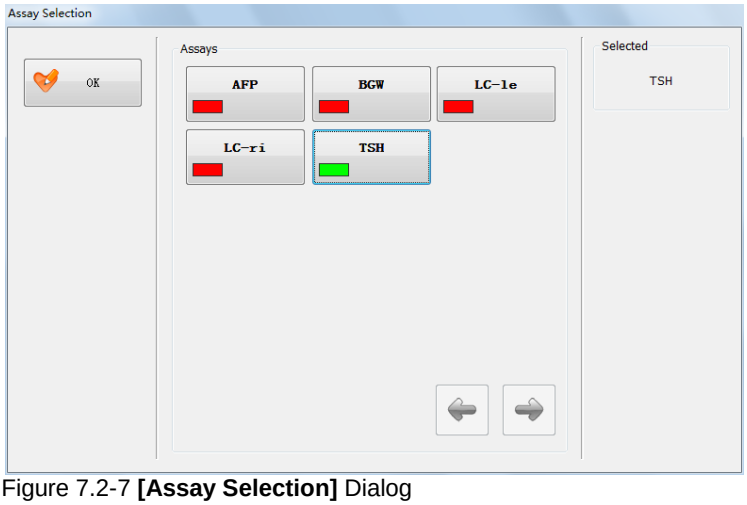


Figure 7.2-7 **[Assay Selection]** Dialog

In **Assays** area, select an assay to be reflexed, click **<OK>** button to save assay information and return to **[User Specific Assay Data]** dialog. **<Reflex 1>** button will change to the name of reflex assay. If you click the reflex assay in **[Assay Selection]** dialog again, it will changes to **<Reflex 1>** and click **<Save>** button to save operation.

<Reflex 2> button has the same function and operation to **<Reflex 1>** button.

7.2.5 <Master Curve>

Master curve is the basis of calibration. The data is determined by Snibe. The master curve of each assay is marked with ID-No. and lot-No..
Click **<Master Curve>** button in **[User Specific Assay Data]** dialog to open **[Master Curve Selection]** dialog, where users can modify master curve data.

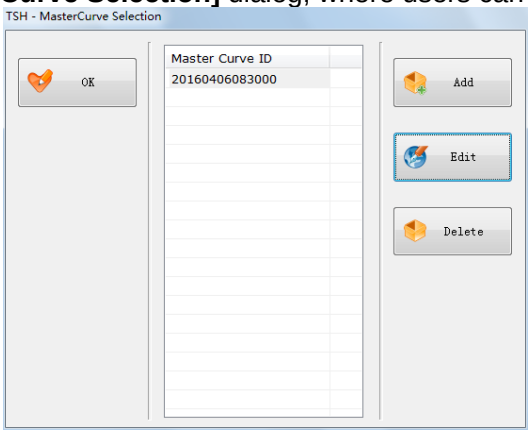


Figure 7.2-8 **[Master Curve Selection]** Dialog

1. Master Curve ID: display the ID-No. of master curve.

2. <Add>: Add new master curve.
- Click **<Add>** button to open **[Loading of Master Curve]** dialog.

3. <Edit>: Edit existing master curve.
- Select one master curve and click **<Edit>** button to open **[Loading of Master Curve]** dialog.

4. <Delete>: Delete master curve.
- Select one master curve, click **<Delete>** button, and click **<OK>** button to delete this master curve.

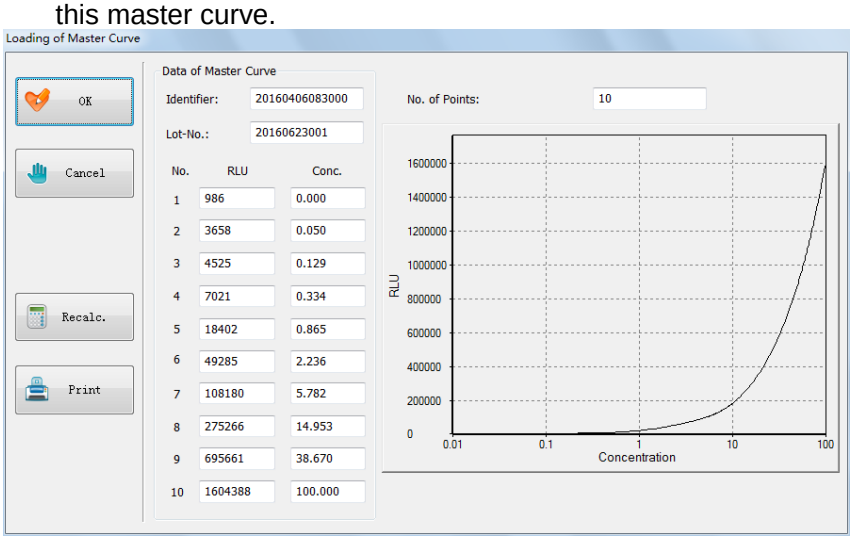


Figure 7.2-9 **[Loading of Master Curve]** Dialog

Data of Master Curve: display the data of master curve, with 10 thresholds at most;
- Identifier: display the ID-No. of master curve;
- **Lot-No.**: display the Lot-No. of master curve;
- **No. of Points:** number of thresholds of master curve;
- **RLU**: display RLU value;
- **Conc.**: display corresponding concentration;

<Recalc.>: After inputting data, click **<Recalc.>** button to refit and display master curve;

<Print>: Print master curve and data.
Click **<OK>** button to confirm master curve setting.
Click **<Cancel>** button to cancel master curve setting.

7.2.6 <QC Rules>

The software supports WestGard multi-rule QC judgment. User can select QC judgment rules for assays as needed. Click **<QC Rules>** button in **[User Specific Assay Data]** dialog to open **[QC Rules]** dialog.

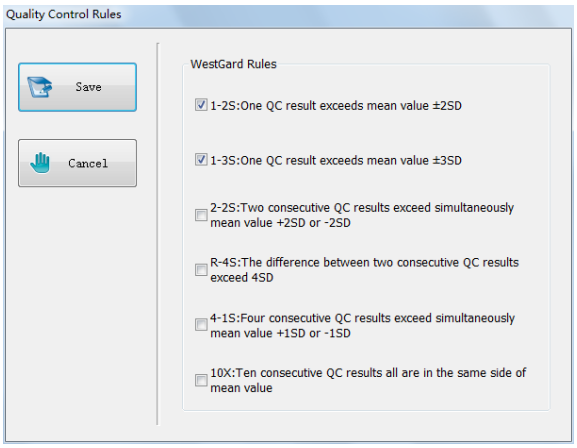


Figure 7.2-10 **[Quality Control Rulers]** Dialog

- 1-2S: One QC result exceeds mean value ±2SD
- 1-3S: One QC result exceeds mean value ±3SD
- 2-2S: Two consecutive QC exceed simultaneously mean value +2SD or -2SD
- R-4S: The difference between two consecutive QC results exceed 4SD
- 4-1S: Four consecutive QC results exceed simultaneously mean value +1SD or -1SD
- 10X: Ten consecutive QC results all are in the same side of mean value

Check the desired quality control rule(s) (1-2S and 1-3S are selected by default).
Click **<Save>** button to complete quality control rule definition.

Click **<Cancel>** button to cancel quality control rule definition.

7.3 <Control>

In order to monitor the reliability of system and reagent, control must be performed.
Click **<Control>** button in **[Definitions]** menu to open **[Control]** interface.

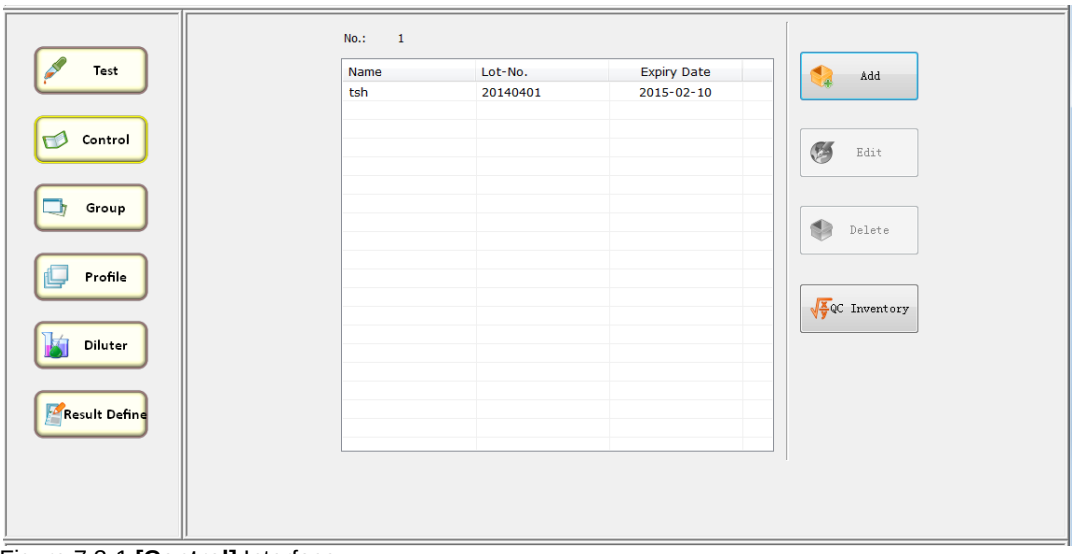


Figure 7.3-1 **[Control]** Interface

1. <Add>: Add new control.

- Click **<Add>** button to open **[Control Data Input]** dialog.

2. <Edit>: Edit existing control.

- Select the control to be edited and click **<Edit>** button to open **[Control Data Input]** dialog, in which the corresponding control data is displayed.

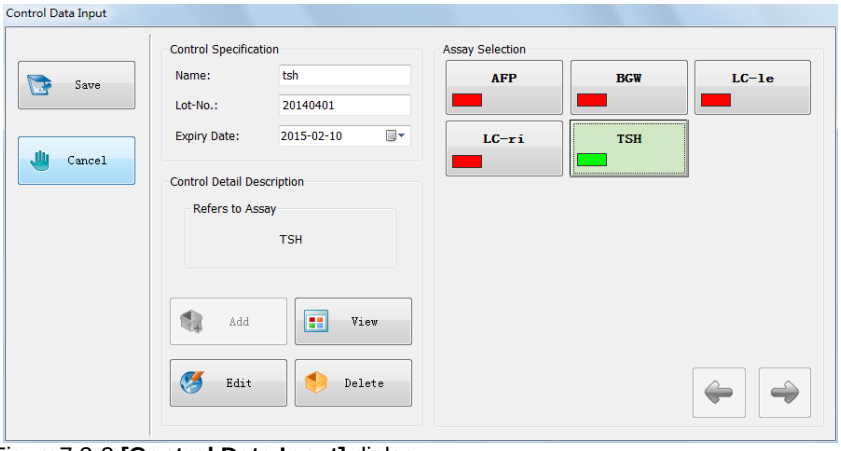


Figure7.3-2 **[Control Data Input]** dialog

1. Control Specification:

- Name: Control name
- Lot-No.: Lot number
- Expiry Date: Date of expiration

2. Assay Selection:

- This area displays all assays. Each control at least corresponds to an assay. Select an assay in **Assay Selection**, then the assay name will display in the **Refers to Assay**.

3. Control Detail Description:

- **Refers to Assay:** display the selected assay which associated with this QC product;
- **<Add>:** Used to input detailed QC data. Click **<Add>** button to open **[Control Detail Description]** dialog.

- **<View>:** Used to browse existing QC data, which cannot be modified. Select a defined assay in **[Assay Selection]** area and click **<View>** button to open **[Control Detail Description]** dialog, in which the corresponding control data are displayed.

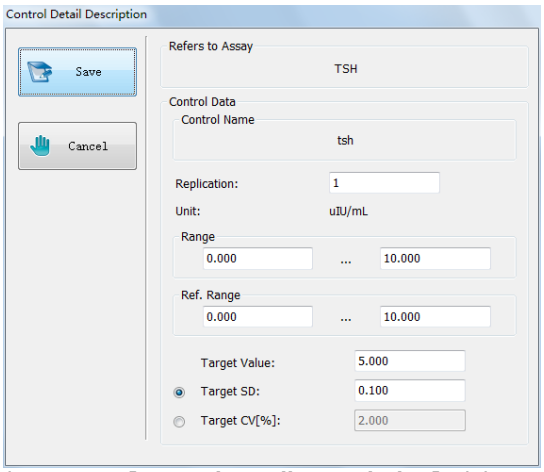


Figure 7.3-3 **[Control Detail Description]** Dialog

Refers to Assay：display the specified QC assay.

Control Data

- Control Name: quality control name;
- Replication: enter the number of QC tests;
- Unit: display the unit of the QC assay;
- Range: upper and lower bounds of the expected concentration of quality control for specified assays;
- Ref. Range: quality control reference range defined by user;
- Target value: mid-value of the range;
- Target SD: uncertainty of target value, reflecting the accuracy of measurement;
- Target CV [%]: coefficient of variation of target value.

Click **<Save>** button to complete the input of control details and quit **[Control Detail Description]** dialog.
Click **<Cancel>** button to cancel the input of control details and quit **[Control Detail Description]** dialog.

- **<Edit>:** Used to edit or browse existing QC data. Select a defined assay in **Assay Selection** area, and then click **<Edit>** button to open **[Control Detail Description]** dialog, where you can edit corresponding control data. After edit and save the QC detail information in **[Control Detail Description]** dialog, the small window of the assay in **Assay Selection** will turn to green.
- **<Delete>:** Used to delete assays associated with the QC products. After selecting a defined assay, click **<Delete>** button, and then click **<OK>** button to confirm deletion. The selected assay is no longer associated with this QC product.

Click **<Save>** button to complete the input of control data and quit **[Control Data Input]** dialog. The new control is added to the control list in **[Control]** interface.
Click **<Cancel>** button to cancel the input of control data and quit **[Control Data Input]** dialog.

3. <Delete>: Delete control.
Select the control to be deleted, and click **<Delete>** button to delete it.

4. <QC Inventory >: It is an overview for all controls.

Click <**QC Inventory**> button to open **[QC Information Summary]** dialog, in which all defined control data are displayed.

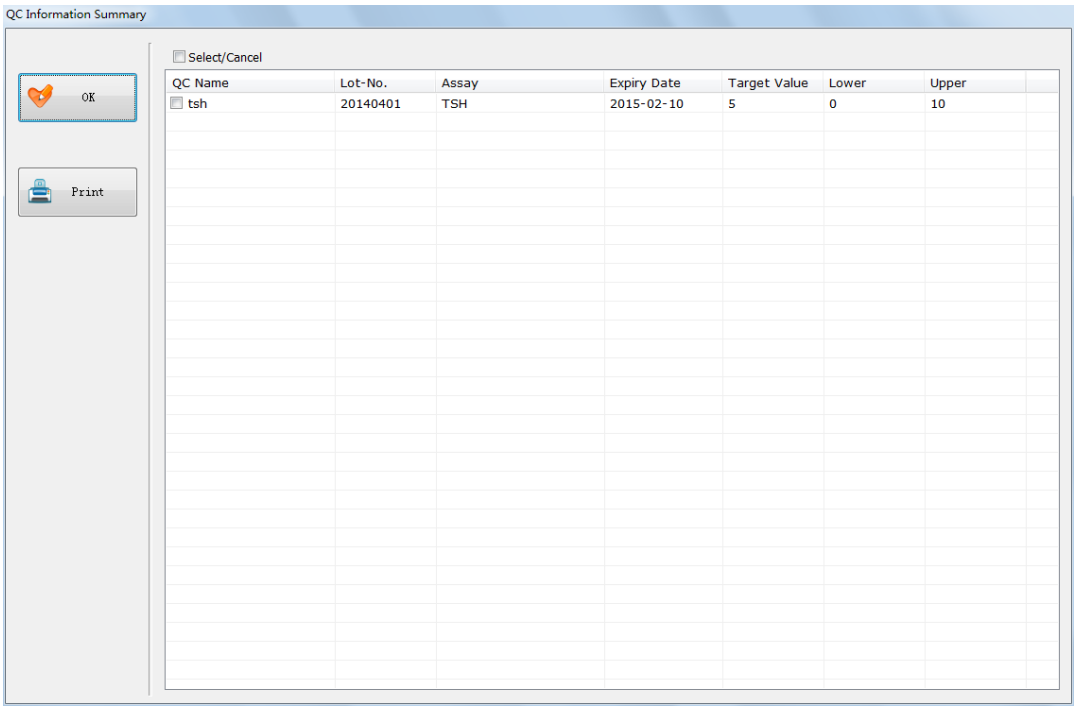


Figure 7.3-4 **[QC Information Summary]** dialog

Select the control to be printed and click **<Print>** button to print control information list. Click **<OK>** button and quit **[QC Information Summary]** dialog.

7.4 <Group>

Users can define groups and these groups are displayed page by page in **[Pat&Rea]** interface (one group contains 9 assays at most) for faster sample registration.
Click **<Group>** button in **[Definitions]** menu to open **[Group]** interface.

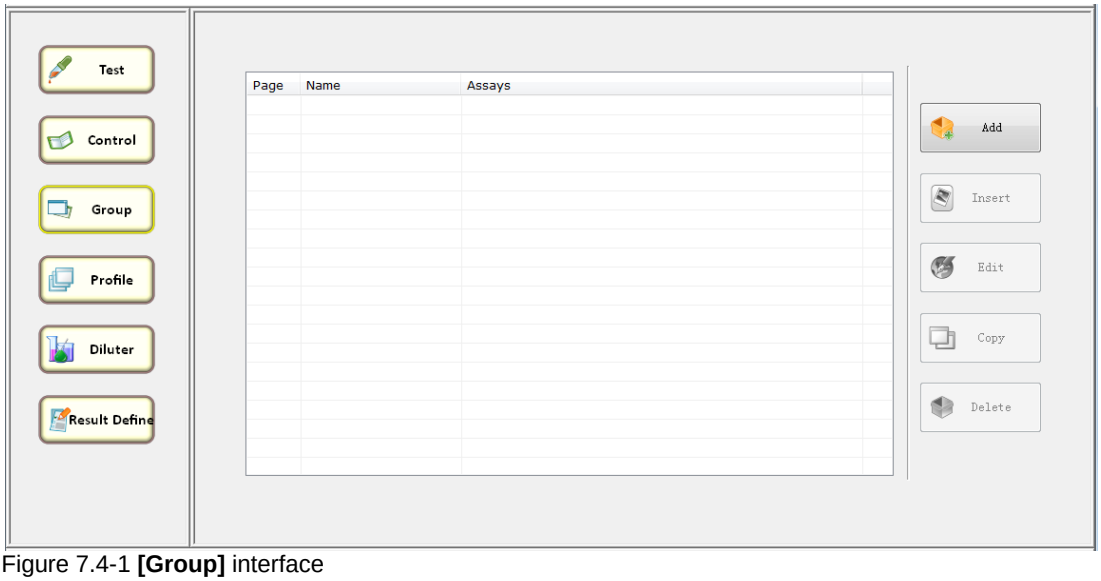


Figure 7.4-1 **[Group]** interface

1. <Add>: add a new group;

- Click **<Add>** button to open **[Assay Group Definition]** dialog.

2. <Insert>: insert a new group;

- Select a group and click **<Insert>** to open **[Assay Group Definition]** where you can add the assay you need and input group name to save as. The new group will insert before the selected group automatically.

3. <Edit>: edit an existing group;

- Select a group to be edited and click **<Edit>** button to open **[Assay Group Definition]** dialog.

4. <Copy>: copy an existing group;

- Select a group and click **<Copy>** to open **[Assay Group Definition]** where the assay information of this group is copied. You can edit the group and input group name to save as a new group.

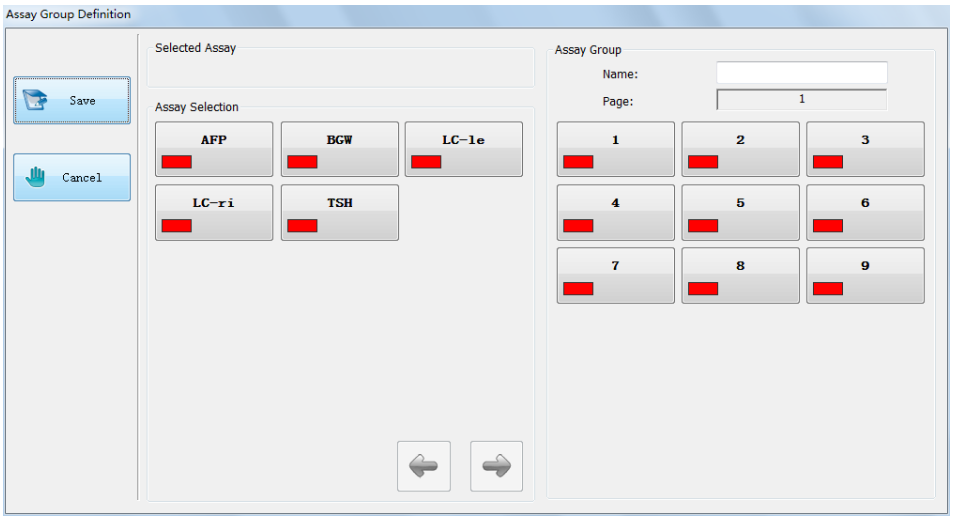


Figure 7.4-2 **[Assay Group Definition]** dialog

Selected assay: displays the name of the selected assay;
Assay selection: displays the assay list provided by Snibe;
Assay Group: displays 9 positions in consecutive numbers, each of which represents an optional assay;

- **Name:** group name, for which you can input text, letters and digits;
- **Page:** serial No. of continuous pages, automatically allocated to groups.

Click **<Save>** button to complete the assay group edit option.
Click **<Cancel>** button to cancel the assay group edit option.

5. <Delete>: delete an existing group;

- Select a group to be deleted and click **<Delete>** button to delete this group.

7.5 <Profile>

Users can use several assays to create a profile, which is displayed in the **Profile Selection** area of **[Patients]** interface. You can use one button to allocate several assays to one sample for faster sample registration.
Click **<Profile>** button in **[Definitions]** menu to open **[Profile]** interface.

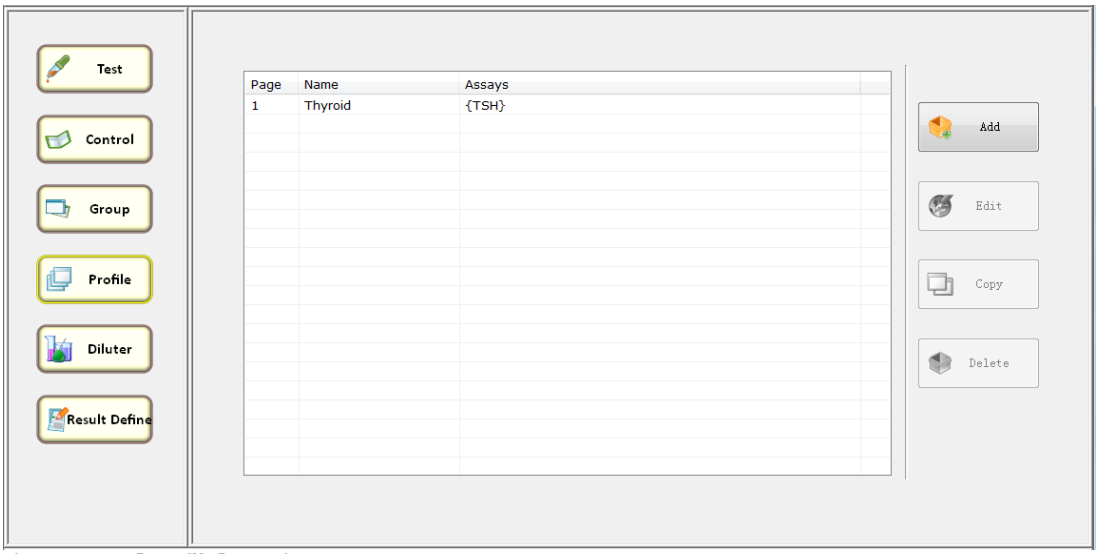


Figure 7.5-1 **[Profile]** Interface

1. <Add>: add a new profile;

- Click **<Add>** button to open **[Profile Definition]** dialog;

2. <Edit>: edit an existing profile;

- Select a profile in **[Profile]** interface and click **<Edit>** button to open **[Profile Definition]** dialog.

3. <Copy>: copy an existing profile;

- Select a profile in **[Profile]** interface and click **<Copy>** button to open **[Profile Definition]** dialog, where the assay information of this profile is copied. You can edit the profile and input profile name to save as a new profile.

4. <Delete>: delete an existing group;

- Select a profile in **[Profile]** interface and click **<Delete>** button to delete this group.

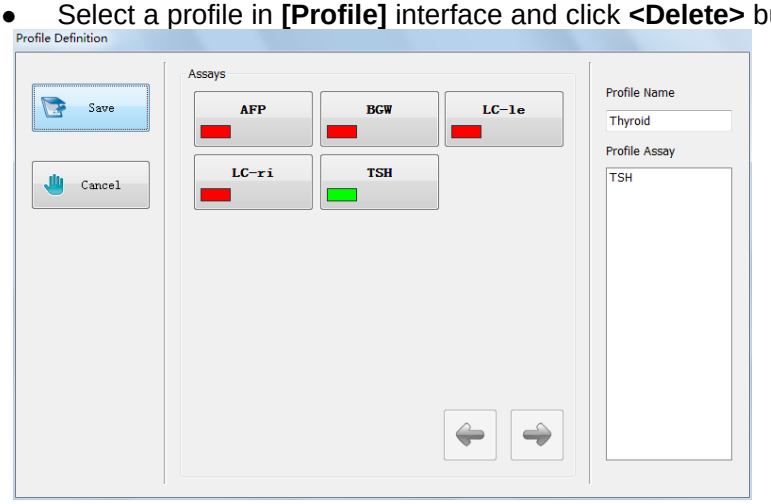


Figure 7.5-2 **[Profile Definition]** dialog

Assays: The assays are provided by Snibe. The assay button turns to green if selected;
Profile Name: Input a profile name; you can input Chinese characters, letters or digits;
Profile Assay: List the assays contained in this profile.

Click **<Save>** button to complete profile editing.
Click **<Cancel>** button to cancel profile editing.

7.6 <Diluter>

Dilution can be defined for a reagent that contains buffer. The system supports up to 9 dilution ratios, which can be customized by users.
Click **<Diluter>** button in **[Definitions]** menu to open **[Diluter]** interface.

Figure 7.6-1 **[Diluter]** interface

1. Assay: The selected assay.

2.Assay Selection: the assays defined by Snibe. When you select an assay in **Assay Selection** area, all buttons of **[Selected Dilutions]** area are activated.

3. Dilution Selection: the dilutions defined by Snibe;

4. Selected Dilutions: dilutions selected by users(maximum is 9).

5. <Edit>: edit dilution parameters.
- Select a dilution and click **<Edit>** button to open **[Dilution Specification]** dialog.

6. <Delete>: delete dilution parameters
- Select a dilution and click **<Delete>** button to delete this dilution setting.

Select an assay in **Assay Selection** area, the dilutions defined by Snibe displays in the **Dilution Selection** area. Select the desired dilution ratio, then click any button in **Selected Dilutions**, the dilution ratio added to the selected assay. If user needs more dilution ratios, follow the steps:
1. Select a assay in **Assay Selection** area;
2. Click any button in **Selected Dilutions** area;
3. Click **<Edit>** button to open **[Dilution Specification]** dialog

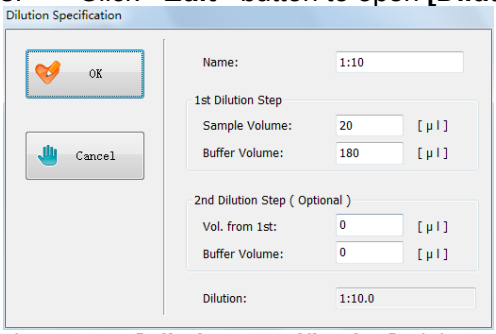


Figure 7.6-2 **[Dilution Specification]** Dialog

Dilution can be performed for the same sample in two steps. Dilution ratio for each step is 50 times at the most (maximum dilution: 1:2500).
Name: the dilution name to be edited;
1st Dilution Step:
- Sample Volume: volume of the sample;
- Buffer Volume: volume of the buffer.

2nd Dilution Step (Optional):
- Vol. from 1st: Volume of the sample pipetted after 1st dilution step;
- Buffer Volume: Volume of the buffer;

Dilutions: Total dilution factors obtained from automatic computation.

NOTE

Pay attention to the pipetted sample volume (total pipetting volume). The maximum volume of pipetting needle is 380 µL. The maximum volume of cuvette is 600µL.

Click **<OK>** button to save the dilution setting.
Click **<Cancel>** button to cancel the dilution setting.

7.7 <Result Define>

Users can define screening conditions for test results to output valid results in order to improve test efficiency. Check the required option, and click **<Save>** button to complete result definition setting.
Click **<Result Define>** button in **[Definitions]** menu to open **[Result define]** interface.

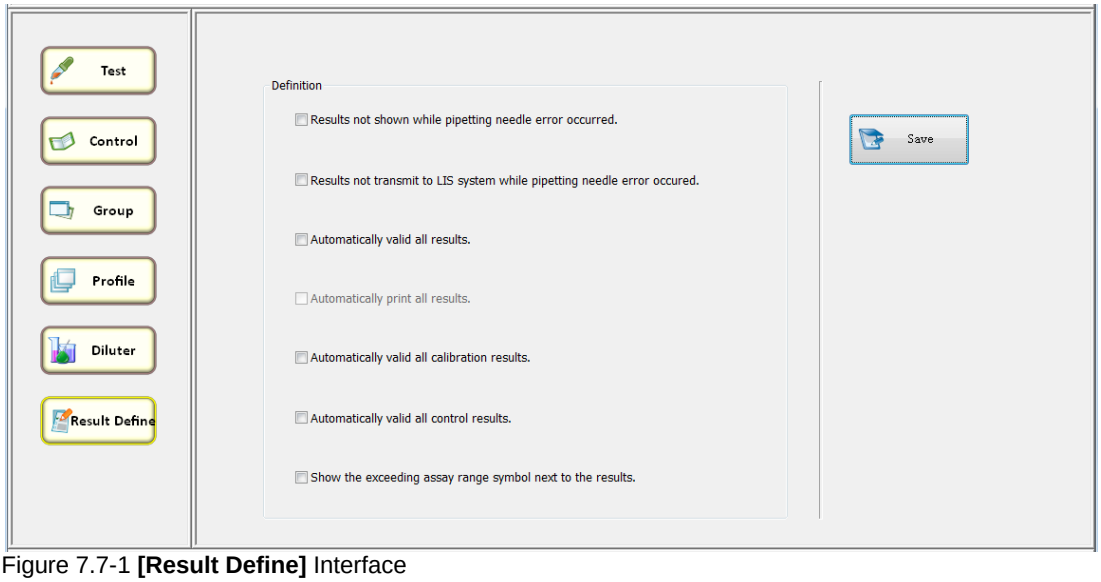


Figure 7.7-1 **[Result Define]** Interface

1. Definition:
- **Results not shown while pipetting needle error occurred:**
  If you check this option, the results with pipetting error flag are displayed as Error;
- **Results not transmitted to LIS system while pipetting needle error occurred:**
  If you check this option, the results with pipetting error flag are not transmitted to LIS system;
- **Automatically valid all results:**
  If you check this option, the test results are automatically validated;
- **Automatically print all results:**

If you check this option, a report for all assays of the sample is automatically generated and printed after all the assay results are obtained.

- **Automatically valid all calibration results:**
  If you check this option, the calibration results are automatically validated.
- **Automatically valid all control results:**
  If you check this option, the control results are automatically validated.
- **Show the exceeding assay range symbol next to the results:**
  If you check this option, marks will be added in front of results beyond the exceeding assay range

2. <Save>: Save the selection

Check the required option and then click **<Save>** to complete setting.

8 [Process] Menu

8.1 [Process] Menu Introduction

Click **<Process>** button in the menu bar to enter **[Process]** menu, where you can set up a series of functions, as described below:

Figure 8.1-1 **[Process]** Menu

Button	Function
< Initialize>	Initialize the analyzer
<Init W. Clear>	Initialization with Cuvette(s) Clear
< Restart>	Restart uncompleted assays
<Return Asy>	Return uncompleted test time.
<Warning Opt.>	Set up the warning message in emergency circumstances.

8.2 <Initialize>

Click **<Initialize>** button in **[Process]** menu to open **[Message]** dialog to confirm the operation.

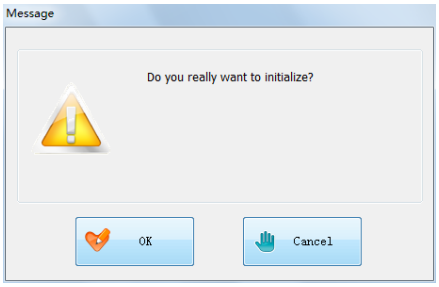


Figure 8.2-1 **[Message]** Dialog for Initialization

Click **<OK>** button to confirm the operation. The analyzer will be initialized. Initialization contains the test of various functions of the analyzer and the reset of its components. After **<Initialize>**, the analyzer is in standby state. Click **<Cancel>** button to cancel initialization of the analyzer.
After powering-off or quit the operating software, initialization is required when you power on the analyzer or login the operating software again. If there are severe problems in analyzer hardware or if the analyzer fails to connect with the operating software, the analyzer needs to be initialized as well.

8.3 <Init W. Clear>

If there has(have) cuvette(s) in the transmission channel when the analyzer is powered off, initialization with cuvette(s) clear is required. The following conditions are required treatment:

- If you have exit out the software, open the software, input the user name and password and select **[Initialization with Cuvette(s) Clear]** in **[Login]** dialog. The analyzer will remove residual cuvette(s) after initialization operation. If **[Initialization with Cuvette(s) Clear]** is not checked, the device will only perform initialization after login to the software.

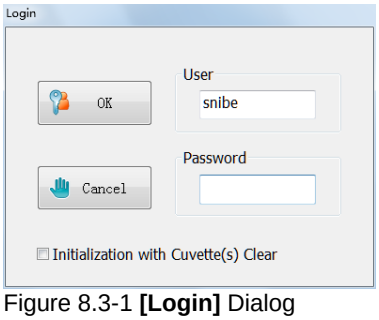


Figure 8.3-1 **[Login]** Dialog

- If you are still running the software, click **<Init W. Clear>** in **[Process]** menu. The analyzer will remove residual cuvette(s) after initialization operation.

8.4 <Restart>

This function is used to avoid users re-editing tests. In the assay process, if the analyzer crashes but PC software is not closed, after the analyzer is turned on again, the uncompleted assays can be restarted by clicking **<Restart>** in **[Process]** menu.
Click **<Restart>** in **[Process]** menu to open **[Message]** dialog to confirm the operation.

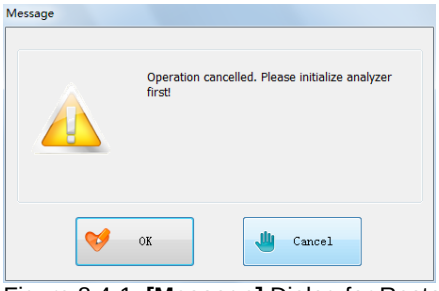


Figure 8.4-1 **[Message]** Dialog for Restart

Click **<OK>** button to confirm the operation. PC regenerates schedule for the unfinished assays edited before the analyzer is turned off and send it to the device to continue the assay.
Click **<Cancel>** button to cancel the operation.

NOTE

If the analyzer stop by some irresistible reason, only when the software didn't close, the **<Restart>** function can be used. If software shut down before the restart, this function is invalid.

8.5 <Return Asy>

After editing samples and assays, click **<Start>**. The software calculates available test times of reagents by deducting the number of edited tests. In the assay process, if the analyzer crashes due to some irresistible reason with pipetting for some reagents not completed, after the analyzer is turned on again, click **<Return Asy>** to recalculate the available test times of the reagents by returning the assays for which reagent pipetting is not completed.
Click **<Return Asy>** in **[Process]** menu to open **[Message]** dialog to confirm the operation.

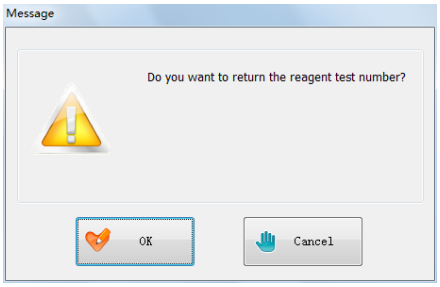


Figure 8.5-1 **[Message]** dialog for Return Assay

Click **<OK>** button to confirm the operation. The software will recalculate the available test times of the reagents by returning the assays for which reagent pipetting is not carried out.
Click **<Cancel>** button to cancel the operation.

8.6 <Warning Opt.>

<Warning Opt.> function is used to ignore the warning message in emergency circumstances. After masking the warning message will not prompt and beep.
Click **<Warning Opt.>** in **[Process]** menu to open **[Warning Opt.]** interface.

Figure 8.6-1 **[Warning Opt.]** Interface

Disable the warning message

- Running out of cuvettes soon;
- Washer peristaltic pump soak abnormally;
- No cuvette in chamber;
- Chamber waster pump soak abnormally;
- Starter 1 is almost empty. Please replace;
- Starter 2 is almost empty. Please replace;
- Shaker is out of normal range;
- Waste bag is full. Please empty the waste bag;
- System liquid is almost empty. Please replace;
- Waste liquid is almost full. Please replace;
- The cover of analyzer is open, please pay attention to safety;
- Software cannot connect to LIS.
- Cuvette loader exit sensor fail.

Click the **<Save>** button to complete the operation, while the status bar **<Message Box>** button will display the operating information.

9 [System Test] Menu

9.1 [System Test] Menu

[System Test] menu is used to wash pipe system of the analyzer. BGW and LC are used to detect pipetting system, washer, chamber and starter. Click **<System Test>** button in the menu bar to enter **[System test]** dialog.

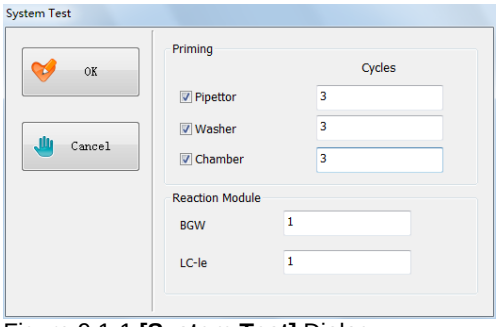


Figure 9.1-1 **[System Test]** Dialog

[System Test] dialog contains:

1. Priming

- **Pipettor:** Set up wash cycles for the pipe, hose and pipetting needle of the pipetting system.
- **Washer:** Set up wash cycles for the wash pump, hose and wash needle of the washer. Users must perform wash before the analyzer runs.
- **Chamber:** Set up wash cycles for the pipe system of the chamber.

2. Reaction Module

[BGW] Input BGW cycles (default: 1).

[LC-le] Input LC cycles of the pipetting needle. Use the pipetting needle to pipette light check liquid (default: 1).

BGW and LC must be performed after any starter is replaced.

The requirement of system test results is:

1) BGW: RLU is 100-1200, CV ≤ 10%;
2) LC: RLU is 450000-650000, CV ≤ 3%;

Please refer to the LC Reagent Manual of the specific expected value.

To perform BGW and LC, the default cycle (1) can be changed according to needs. Meanwhile, the cuvettes of corresponding number should be put in. If BGW or LC is not necessary, the default cycle (1) can be changed to (0). Click **<OK>** button, **[Message]** dialog appears to confirm parameter setting, click **<OK>** button again. Click **<Cancel>** button to cancel system test and exit **[System Test]** dialog.

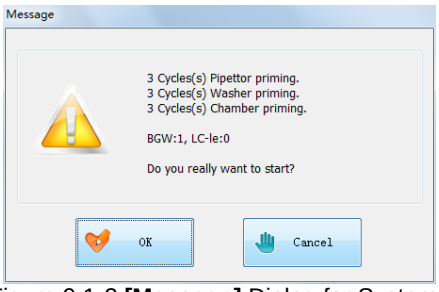


Figure 9.1-2 **[Message]** Dialog for System Test

NOTE

All system tests must be completed before the analyzer starts an assay.

When the analyzer is running an assay, if you want to enter **<System Test>** from the menu bar, a message confirmation dialog appears to prompt that system test can only be performed after end of the assay.

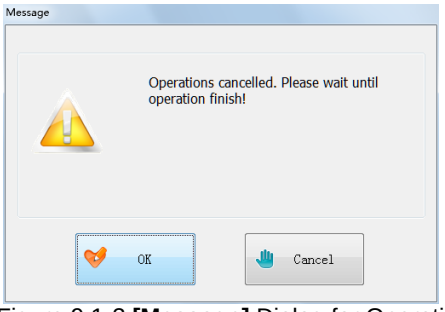


Figure 9.1-3 **[Message]** Dialog for Operations Canceled

9.2 Load Light Check

MAGLUMI Light Check produced by Snibe is used for testing the pipetting needle performance of analyzer. When performing Light Check, put prepared Light Check liquid on the rack with its tag surface facing the code reader and load it to any position in the sample area. The liquid will be automatically identified and displayed in **Sample Info** of the software in yellow, i.e. lc.

Manually run LC sample

If the code reader fails or the tag of Light Check liquid is damaged, manual editing can be made in the software. Put LC liquid on the tube rack and load it to any position in the sample area. Use the mouse or touch the screen to select the position of Light Check liquid in the sample area; Light Check must be defined by pressing **<LC>**, with this position displayed in yellow, i.e. LC. Click **<Save>** to return to the **[Home]** interface, and click **<Start>** to perform LC.

The requirement of LC results is:

LC: RLU is 450000-650000, CV ≤ 3%;

Please refer to the LC Reagent Manual of the specific expected value.

9.3 Add Light Check

LC should be performed under the following three circumstances:

1) Before the instrument starts the first round of test every day;
2) After change the Lot-No. of starter reagents;
3) After maintenance of the instrument.

Opened LC fluid should be stored at 2-8°C till the shelflife specified in the Instruction for use.

Prepare Light Check solution:

1. Take a bottle of Light Check out of the packaging box.
2. Carefully unplug the bottle.
3. Prior to use, the Light Check solution must be placed still for at least 5min. Light Check test should be performed at room temperature.
4. Insert the Light Check bottle (with rubber plug removed) to the sample rack; ensure that the barcode on the bottle directly faces the opening position of the sample rack. Then insert the sample rack into any position in the sample area of the analyzer.

WARNING

Prevent air bubbles from forming, which may affect the Light Check result in system test, and further affecting the reliability of test result obtained by the instrument.

10 [Pat&Rea]-Reagents Menu

10.1 [Pat&Rea]-Reagents Interface

Users can open the **Reagents** interface under **[Pat&Rea]** in the following 3 ways:

- Click **<Pat&Rea>** on the menu bar;
- Open the reagent area door;
- Click the **Patient&Reagents** icon on the **[Home]** interface.

After entering the interface, users can:

1. Load or unload reagents;
2. View/ accept/reject/validate calibrator results and start calibrate.

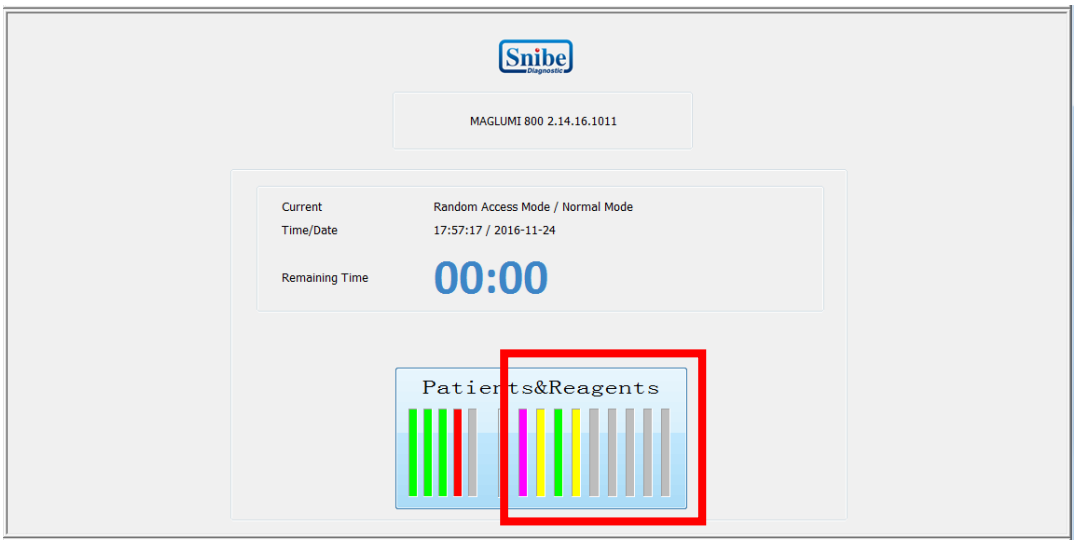


Figure 10.1-1 **[Home]** Interface

On the **[Home]** interface, **Reagents** icon is mainly shown in six colors:

- Gray: No reagent inserted;
- Red: Not recognized by the system;
- Yellow: Recognized by the system, without valid calibration data;
- Green: Recognized by the system, with valid calibration data;
- Purple:Recognized by the system, with expired calibration data;
- Black: Recognized by the system, but with expired reagents.

Enter **[Pat&Rea]**; select a reagent kit to enter **Reagents** interface, which is divided into 4 zones, as shown in the figure below.

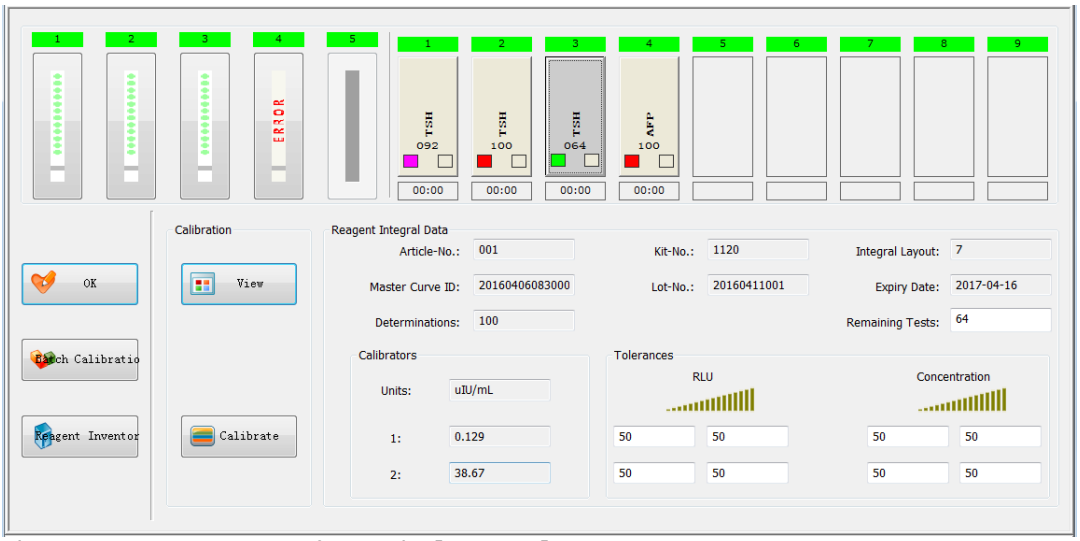


Figure 10.1-2 **Reagents** Interface under **[Pat&Rea]**

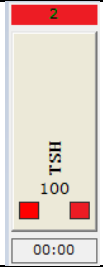
Reagent Area	Shows the status and name of the reagent.
Reagent Data	Shows the relevant data of the reagent kit.
Calibration	View the calculate curve of the reagent. Start calibrate.
Reagent Operations	Exit **[Pat&Rea]** interface. Perform batch calibration.

10.2 Reagent Area

Reagent Area shows the status and name of the reagent in the reagent area, the magnetic microbeads mixing time, etc.
The digits below the assay name indicate the number of tests that can be performed with the reagent. The countdown timer indicates the magnetic microbeads mixing time.

1. Definitions of numbers and colors
Red and green are used to show the state of reagents and give prompts as to when the reagent can be taken out of the reagent area.

Table 10.2-1 States of reagent

	Number 1 means the reagent is located in No. 1 track of reagent area. Green means the reagent is not used, and the kit can be taken out of the reagent area.
	Number 2 means the reagent is located in No. 2 track of reagent area. Red means the reagent is being used, and the kit cannot be taken out of the reagent area.

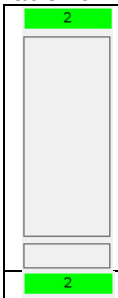
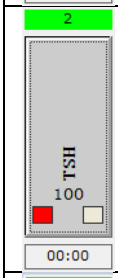
NOTE

Users must pay attention to the usage state of each reagent!

2. Reagent loading conditions

There are four types of reagent loading conditions.

Table 10.2-1 Reagent loading Conditions

	No reagent inserted into this channel.
	The reagent has been recognized by the system; the reagent is located in No. 2 channel; the background color is light gray, indicating the reagent is not selected.
	The reagent has been recognized by the system; the reagent is located in No. 2 channel; the background color is dark gray, indicating the reagent is selected.
	Reagent is available in the channel, but has not been recognized by the system. The reagent needs to be reloaded.

3. Status of calibration

Two small squares with different color display the status of calibration, as shown in Table 10.2 -3.

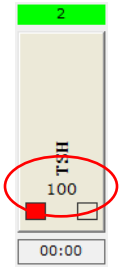


Table 10.2-2 Status of Calibration

Symbol	Definition
(Red) (Gray)	Without valid calibration.
(Red) (Red)	Without valid calibration, calibration in progress.
(Red) (Green)	Without valid calibration, new calibration has been executed but has not been validated.
(Green) (Gray)	With valid calibration (calibration has taken effect).
(Green) (Red)	With valid calibration, the second calibration is in progress.
(Green) (Green)	With valid calibration, and the second calibration has been executed but has not taken effect.
(Purple) (Gray)	The calibration has expired.
(Purple) (Red)	The calibration has expired; the second calibration is in progress.
(Purple) (Green)	The calibration has expired; the second calibration has been executed but has not been validated.
(Black) (Black)	The reagent has expired.

4. Status of time

The countdown timer indicates the magnetic microbeads mixing time, which is 30min by default; when users click **<Start>** before the countdown timer reaches 00:00, the analyzer will give a prompt message indicating that magnetic microbeads are not homogeneously mixed. In such case, users need to click the **<OK>** button to start test.

The magnetic microbeads mixing time will be reset to 30:00 in the following two ways:
1) The magnetic microbeads mixing time will be reset after the analyzer is restarted.
2) The reagent is reloaded after it has been taken out for more than 2min.

5. Order of using reagents

When there are more than one reagent of the same type loaded in the reagent area, such reagents should be used in the following sequence:
1) Priority is given to reagents allowing fewer remaining tests.
2) Use reagents from left to right.

10.3 Reagent Data

Get the electronic tag on the reagent close to the sensing area; the buzzer beep once indicating successful reading of the electronic tag, beep twice indicating reading failed. Insert the reagent into the reagent area; all experimental data will be automatically read by the PC software and displayed in the **Reagent Data** area on **Reagents** interface under **[Pat&Rea]**. If the data are not correctly recognized during reading, the data must be manually input into the editable region according to the tag on the reagent.

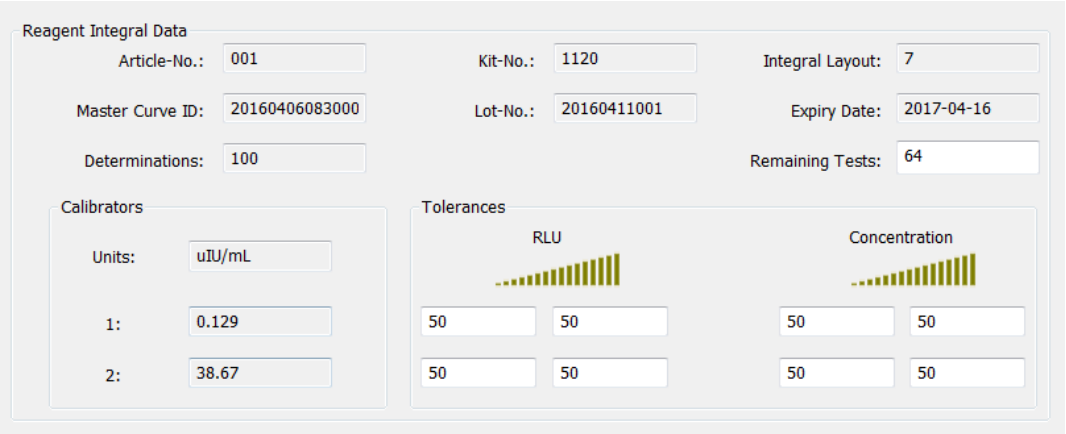


Figure 10.3-1 Reagent Data

Field	Description
Article-No.	Used for assay search in the system.
Kit-No.	The reagent number, used for the system to detect whether the reagent has been placed in and the consumption of the reagent. The amount is calculated and displayed accordingly.
Intergral Layout	The number of reagent bottles contained in the reagent.
Master Curve ID	The identification number of the master curve that the reagent uses.
Lot-No.	The lot number of the reagent.
Expiry Date	The data of expiration (Year; Month; Day).
Determinations	The total number of tests with the reagent.
Remaining Tests	The remaining number of tests with the reagent.

10.3.1 Calibrators

The unit and concentration of Calibrator 1 and Calibrator 2 are shown in this zone.

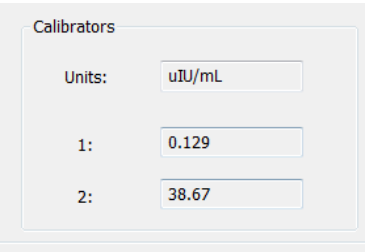


Figure 10.3-2 Reagent Calibrators

10.3.2 Tolerances

The upper and lower deviation limits of RLU value and concentration of calibrator 1 and calibrator 2.

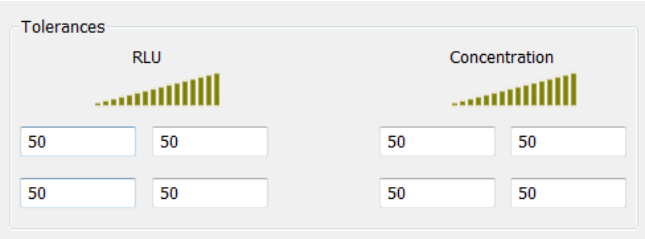


Figure 10.3-3 Reagent Tolerances

10.3.3 Remaining Tests

The Remaining Tests displays the remaining number of tests with the reagent. If the number does not match the actual remaining test, users can be appropriate to modify the remaining number according to the actual situation.
After clicking the Remaining Tests zone, the input space will double in size automatically, allowing users to input relevant info twice.

Figure 10.3-4 Remaining Tests with the Reagent

When entering Remaining Tests, the keyboard will automatically lock to the first row; after inputting the number, press <**Enter>** or **<Tab>** to switch to the second row. Input the same number again, the number input in the first row will automatically change to "***".

Figure 10.3-5 Double input

If the same number is input twice, the following will be shown in the field:

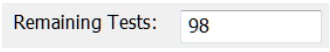


Figure 10.3-6 Input correctly

If different numbers are input, the following will be shown in the field:

Figure 10.3-7 Input error

10.4 Calibration

Calibration is required before use of each reagent. Calibration verifies the compatibility between the reagent and the analyzer and provides more accurate working curves.

Figure 10.4-1Calibration

10.4.1 <Calibrate>

Click **<Calibrate>** to start calibration of the selected reagent (dark gray background). If the system cannot recognize the reagent, this button will be locked by the system.

10.4.2 <View>

Click **<View>** to open **[Calibration Dialog]**, users can:

1) View working curve and calibration result;
2) Modify the calibration result;
3) Print calibration info;
4) View the history calibration;

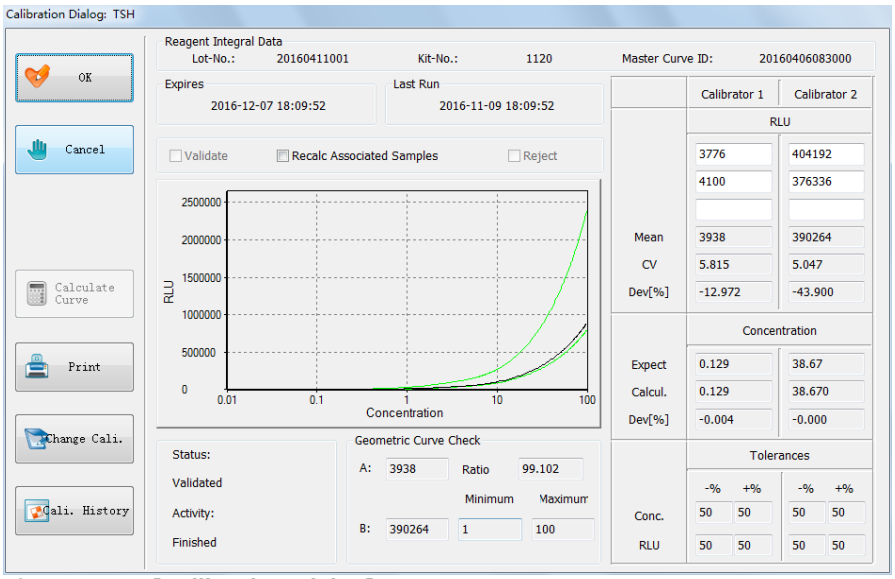


Figure 10.4-2 **[Calibration Dialog]**

Lot-No.	Shows the lot number of the reagent selected.
Kit-No.	Shows the reagent number of the reagent selected.
Master Curve ID	Show the master curve id of the reagent selected.
Expires	Shows the expiry time of the working curve.
Last Run	Shows the time of the last calibration.

1. Geometric Curve Check

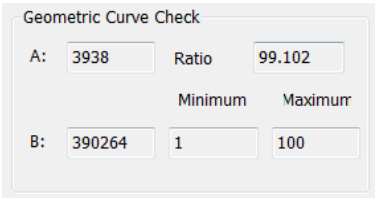


Figure 10.4-3 Geometric Curve Check

Click **<Calculate Curve>** to obtain relevant geometric curve. It can serve as a non-standard additional reference curve to help determine whether the calibration results reliable or not. "Ratio" is obtained by B/A.

2. Info of working curve

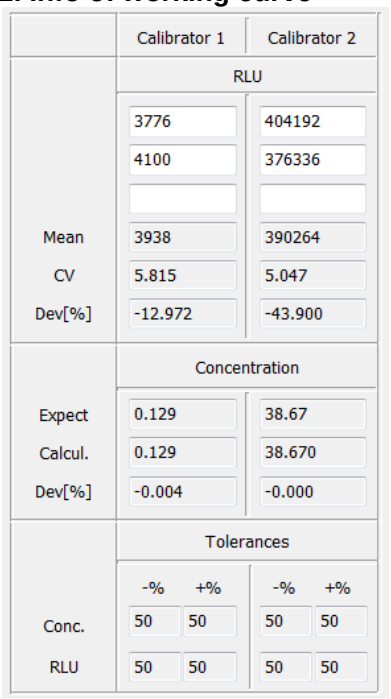


Figure 10.4-4 Info of Working Curve

Calibrator 1
Calibrator 2 Show the test results of two calibrations.

RLU Shows the measured RLU value of calibration; at most three times

Mean The mean of RLU values.

CV The variation coefficient of measured values.

Dev[%] The deviation between mean and factory value (in percentage).

Concentration Shows the measured value of calibration concentration.

Expect Sets the calibration concentration.

Calcul. The concentration value of the last calibration curve or new calibration curve calculated by click **<Calculate Curve>** button.

Dev[%] The percentage of deviation between expected value and actual calibration value.

Tolerances The allowable variation range of measured calibration concentration and RLU value set by the analyzer.

3. Status Info

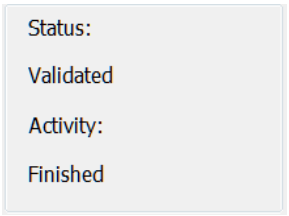


Figure 10.4-5 Status Info

Status: Shows the assessment of calibration result, including:

- No description: no calibration result.
- Not Validated: calibration result has not been validate.
- Validated: calibration result has been validate.
- Calculated: calibration result has been operated **<Calculate Curve>** or **<Change Calibrator>.**

Activity: Shows situation of calibration, including:

- No description: calibration operation has not been done.
- Finished: calibration operation has been done.

10.4.2.1 <Calculate Curve>

If the tolerances are within the acceptable range, click **<Calculate Curve>** to calculate the valid working curve, as shown in Fig. 10.2-11 (tolerances are shown in green).

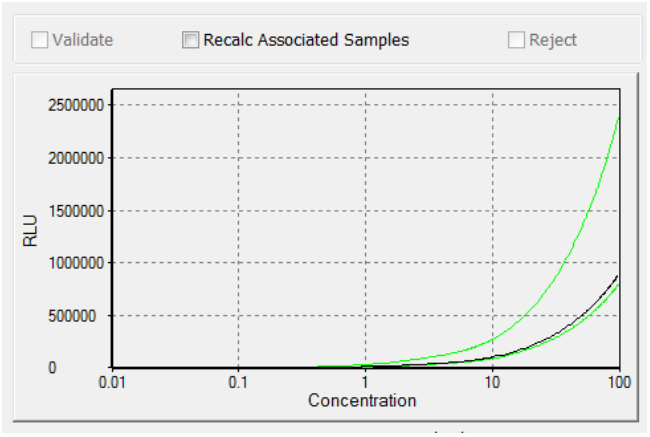


Figure 10.4-6 Calculate Curve

- If the result is acceptable, select **Validate**; the calibrator result will be accepted by the system.
- If the result is not acceptable, select **Reject**; the calibrator result will be rejected by the system.
- If **Recalc Associated Samples** is selected, all sample results of this assay will be recalculated with a new calibration curve (limited to the sample results and quality control results on the current day).

10.4.2.2 <Print>

Users can click **<Print>** to print basic info of the selected kit and the info of working curve.

10.4.2.3 <Calibrate History>

Click **<Calibrate History>** to open the **[Calibration History Data]** dialog, where users can view the calibration history of the reagent selected.

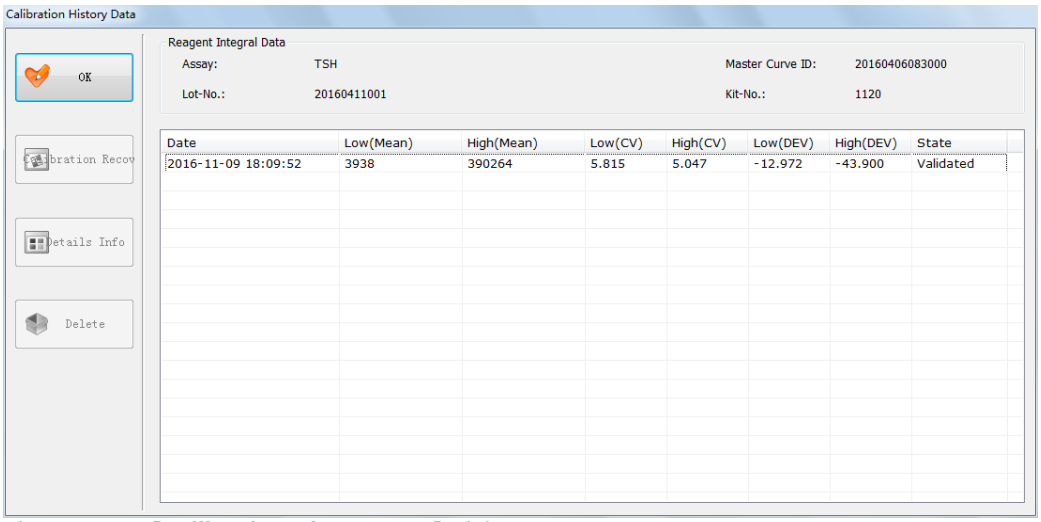


Figure 10.4-7 **[Calibration History Data]** Dialog

Select a record of calibration history; click **<Details Info>** to open the **[Calibration History Detail]** dialog, where users can view details info of this calibration.

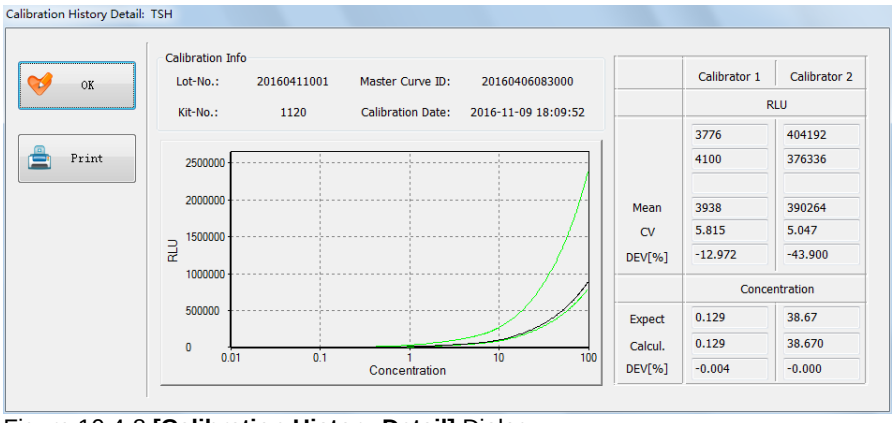


Figure 10.4-8 **[Calibration History Detail]** Dialog

Click **<Print>** in **[Calibration History Detail]** dialog to print basic info of the kit selected and the info of working curve

In the **[Calibration History Data]** dialog, select a record of calibration history, and click **<Calibration Recover>.** The current reagent calibration record will be overwritten by the selected history record. Click **<Delete>** to delete the selected calibration record. Click **<OK>** to exit the dialog box.

10.4.2.4 <Change Calibrator>

After manually changing the calibration info, click **<Change Calibrator>** to complete manual change of the calibration data.

WARNING

Snibe does not recommend users to change calibrator results, and will assume no liability for any consequences arising there from.

Press **<OK>** to exit **[Calibration Dialog].** The data and assessment results saved at the same time.
Press **<Cancel>** to exit **[Calibration Dialog]** without saving data. **<Change Calibrator>** only can be performed after confirm calibration.

10.5 Reagent Calibration and Validation

Follow the following steps after the reagent is correctly inserted into the reagent channel for at least 30min:

1) Enter the **[Reagents]** interface;
2) Click **<Calibrate>** or **<Batch Calibration>** to start calibration;
3) When calibration is finished, select **<View>** to confirm the calibrator result;
4) Now users have two options:
   a. Accept the working curve, or
   b. Reject the working curve.

Users may decide whether or not to accept the calibrator result on their own, or make a judgment according to the following:

- The **Ratio** of Geometric curve check
- RLU **Dev(%)**
- Concentration **Dev(%)**

For example:

- **The Dev(%)** or **CV** shown colorlessly →The measured value is within the allowable range; the measured result is valid.
- The **Dev(%)** or **CV** shown in red→The measured value is beyond the allowable range; the measured result is invalid.

If any of the above results is marked in red, the calibrator result should be deemed invalid. User can check **Reject** and perform recalibration, or directly perform recalibration.
Select **Validate** to accept the calibrator result and validate the working curve.
Select **Recalc Associated Samples** to recalculate all results of associated samples completed on the current working day.
Click **<OK>** button to activate the new working curve. Click **<Print>** to print the calibrator result.

10.6 <Batch Calibration>

Click **<Batch Calibration>** to open **[Batch Calibration]** dialog. Select the reagent for calibration, click **<OK>** to start calibration; click **<Cancel>** to exit the **[Batch Calibration]** dialog box.

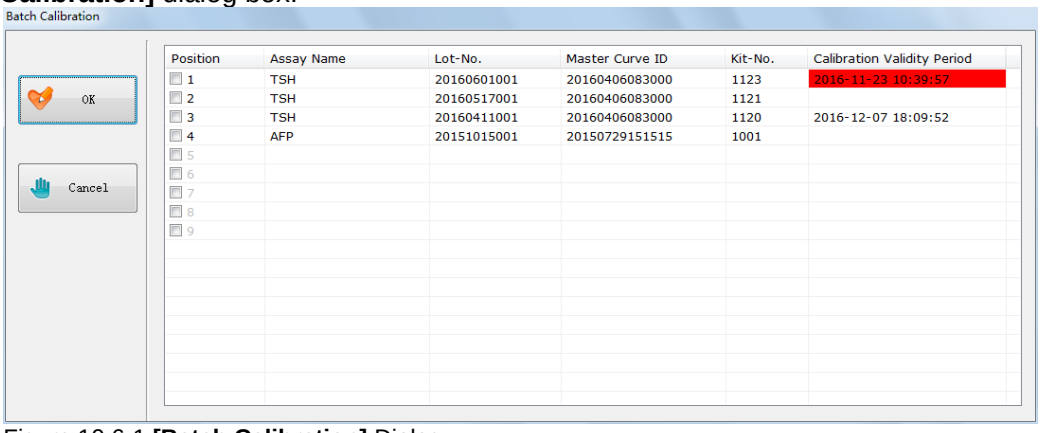


Figure 10.6-1 **[Batch Calibration]** Dialog

NOTE

The “Calibration Validity Period” column of a reagent with calibration expired is shown in red; please perform recalibration.

10.7 <Reagent Inventory>

Click **<Reagent Inventory>** to open **[Reagent Inventory]** dialog. Users can view all reagent inventories having been loaded to this analyzer.

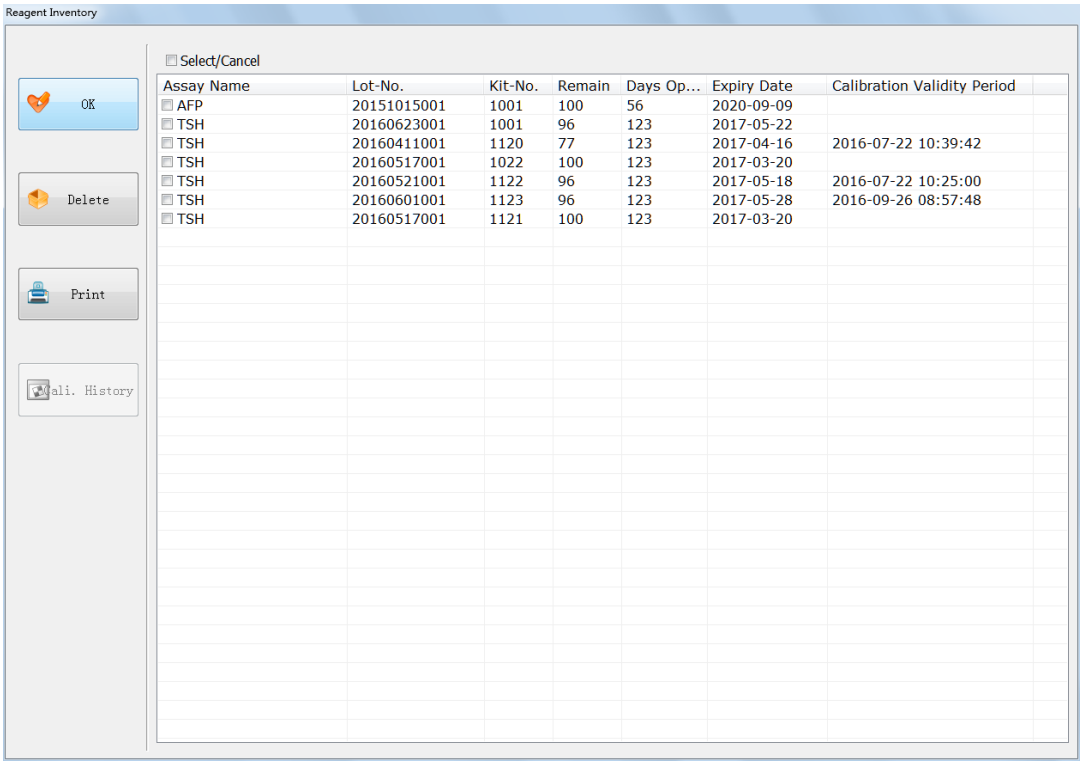


Figure 10.7-1 **[Reagent Inventory]** Dialog

Check an assay name, and click **<Delete>** to delete the reagent info selected.
Check an assay name, and click **<Print>** to print the reagent info selected.
Select any reagent, and click **<Calibrate History>** to open **[Calibration History Data]** dialog. (See 10.4.2.3)
Click **<OK>** to exit the **[Reagent Inventory]** dialog.

11 [Pat&Rea]-Patients Menu

11.1 [Pat&Rea]-Patients Interface Introduction

The **Patients** interface under **[Pat&Rea]** can be opened in the following 3 ways:

- Click **<Pat&Rea>** button in menu bar.
- Open the door of the sample area.
- Click the **Pat&Rea** icon the **[Home]** interface.

After entering the Patients interface, users can:

1) Load the type of test sample, including: Sample, Control, and LC;
2) Select assays for the sample;
3) Define STAT test or Dilution test;
4) Edit sample Information.

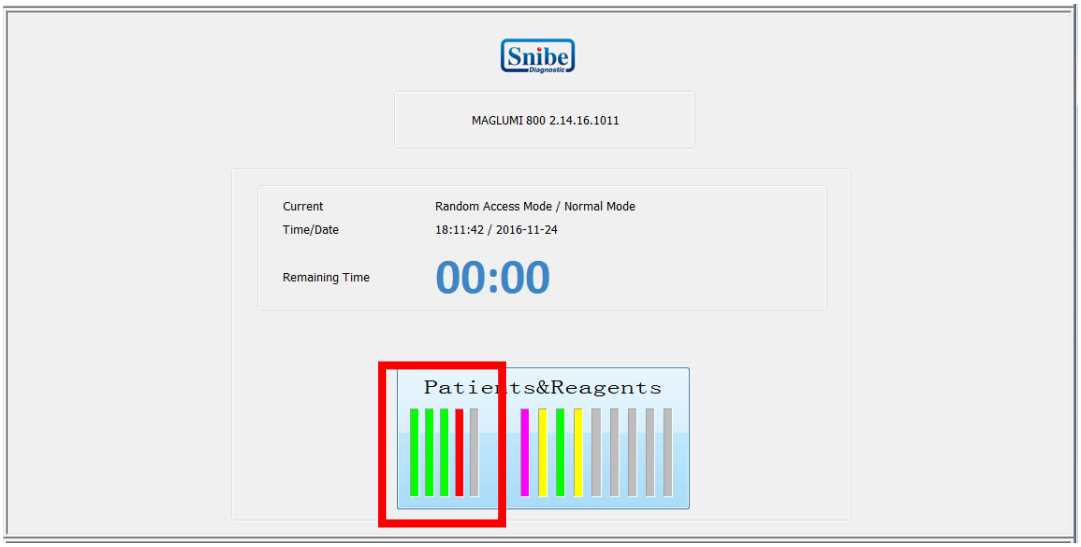


Figure 11.1-1 **[Home]** Interface

The Patients bar graph is shown in three colors:

- Red: the rack at this position is not recognized by the system.
- Green: the rack at this position is recognized by the system.
- Gray: no rack is inserted at this position.

11.2 [Pat&Rea] Menu

[Pat&Rea]-Patients interface is divided into the following areas:

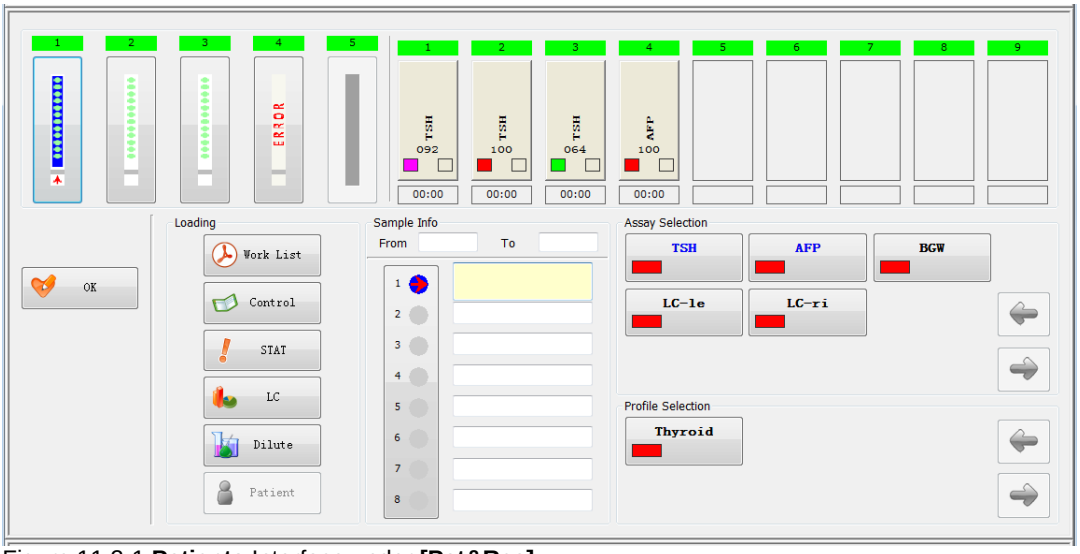


Figure 11.2-1 **Patients** Interface under **[Pat&Rea]**

Rack Station	Shows the rack loading condition.
Loading	Definition of test type, such as STAT, Control, Dilution Selection or LC.
Sample Info	Shows the sample number.
Assay Selection	Allows users to select assays for different samples.
Profile Selection	Allows users to quickly select a required profile.
<OK>	Exit **[Pat&Rea]** interface

In the Assay Selection area, the BGW,LC-ri and LC-le are for system test, please see Chapter 9 System Test.

11.2.1 Rack Station

This area contains 5 sample channels. After a rack is added, relevant sample data will be read by the barcode reader. Each button represents a sample channel. Select a rack number, and press the button; the sample ID will be shown in the **Sample Info** area, and the sample channel is shown in blue.

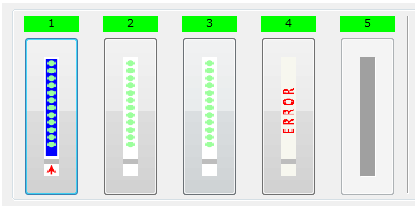
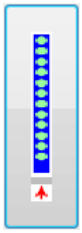
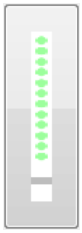


Figure 11.2-2 Rack Station

This area contains 5 sample channels. The meanings of different colors are listed below:

	This icon indicates the sample channel is empty.
	This icon indicates the channel has valid samples and has been selected.
	This icon indicates the channel has valid samples but has not been selected.
	This icon indicates the rack inserted in the channel is not recognized and must be reinserted.

11.2.2 Sample Info

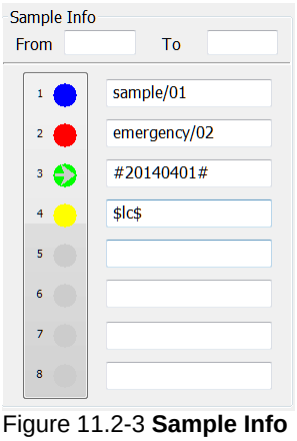
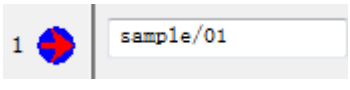
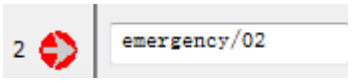
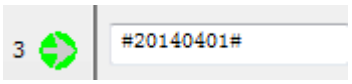
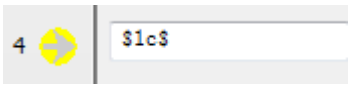


Figure 11.2-3 **Sample Info**

The sample ID is shown in the corresponding position; a selected sample will be marked with a red arrow. Users can select an assay or profile in the **Assay Selection** and **Profile Selection** areas, respectively; the assay or profile selected is shown in green window.
Different colors of sample frame and arrow represent different sample types.

	Blue: Patient sample

	Red: STAT sample
	Green: Control (#)
	Yellow: LC fluid ($) or externally calibrated sample

Input Sample ID

NOTE

If barcode label is not used, the Patient ID should be manually input into the corresponding position. ID shall be input twice: input the ID, then press, **<Enter>** or **<TAB>**to enter the second line, and input the ID again. If the two results are identical to each other, the arrow color will change to green; otherwise to red, in which case, re-input is required.

Use the mouse or touch screen to lock the cursor to the corresponding sample ID input field; input the sample ID, for example, to No. 9 position in the figure below:

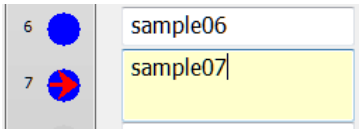


Figure 11.2-4 First input

After first input, use the **<ENTER>** or **<TAB>** key on the keyboard to confirm the input info; the info in the sample edit field will change to "*******".

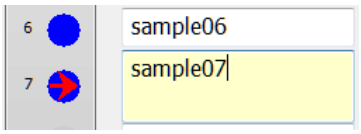


Figure 11.2-5 Finish first input

Then input the same sample ID again; if the input info is identical to that input at the first time, the background of the edit field turns green.

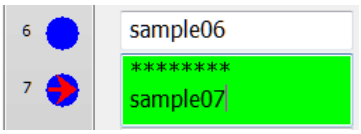


Figure 11.2-6 Second input

Use the **<ENTER>** or **<TAB>** key on the keyboard to confirm the re-input, and move the cursor to the next sample ID input field.

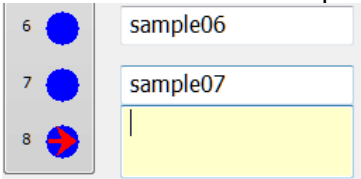


Figure 11.2-7 Input successfully

If the input in the second line is not identical to that in the first line, the background of the edit field turns red, with **<ERROR>** displayed, In such case, input the sample ID again.

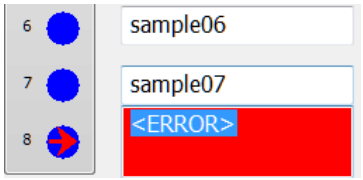


Figure 11.2-8 Input failed

11.2.3 Assay Selection

This area is for assay selection. First select a sample, then select the required assay.
If the reagents for the selected assay are not available in the reagent area, the text on this option is in black (

); if the reagents are available in the reagent area, the text is shown in blue (

). Reagents inserted into the reagent area will be arranged at the top of in the **Assay Selection**.

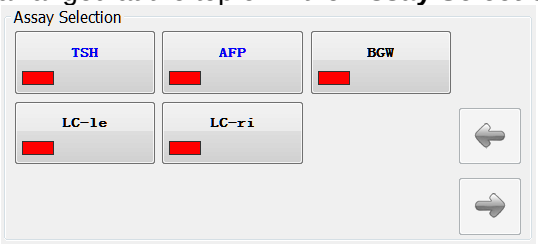


Figure 11.2-9 Assay Selection

How to quickly allocate assays for all samples on the same rack

1. Click a gray area on the rack info bar, as shown in the figure below; after successful selection, the entire rack info bar changes to gray (non-editable state)

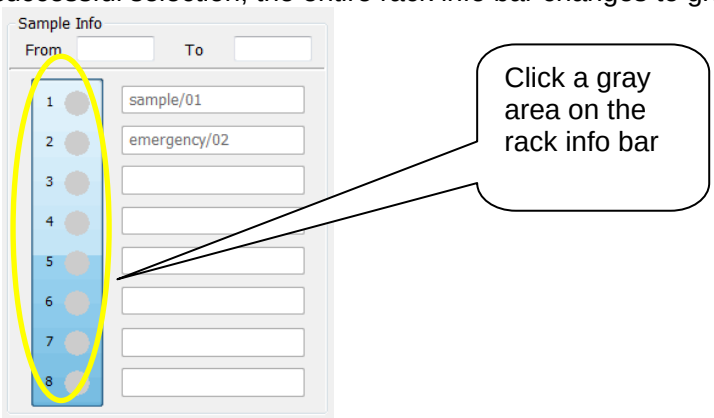


Figure 11.2-10 Sample rack information

2. Select assays in the **Assay Selection** on the right side. (Users can select one or several assays)
3. After completion, click the gray area on the rack info bar so that the rack will return to the editable state. All selected assays will be assigned to all samples on the rack.

11.2.4 Profile Selection

Profile Selection allows users to select a series of assays of the same type. This function can help users to avoid repeated operations during assay selection. For profile settings, please see Section 7.4.
First select a sample, then select a required profile. After a profile is selected, all assays included in this profile will be allocated to the sample.

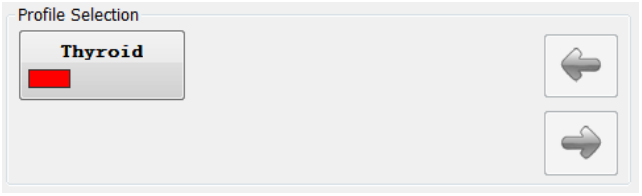


Figure11.2-11 **[Profile]** Selection

11.2.5 Loading

The buttons in **Loading** is used to subdivide the running status of the sample in **[Sample Info]**.

Figure 11.2-12 Loading information

11.2.5.1 <Work List> and <Edit>

Select a rack, then click **<Work List>** to view the assay list of all samples on this rack. **<Work List>** button changes to **<Edit>** button, as shown in the figure below:

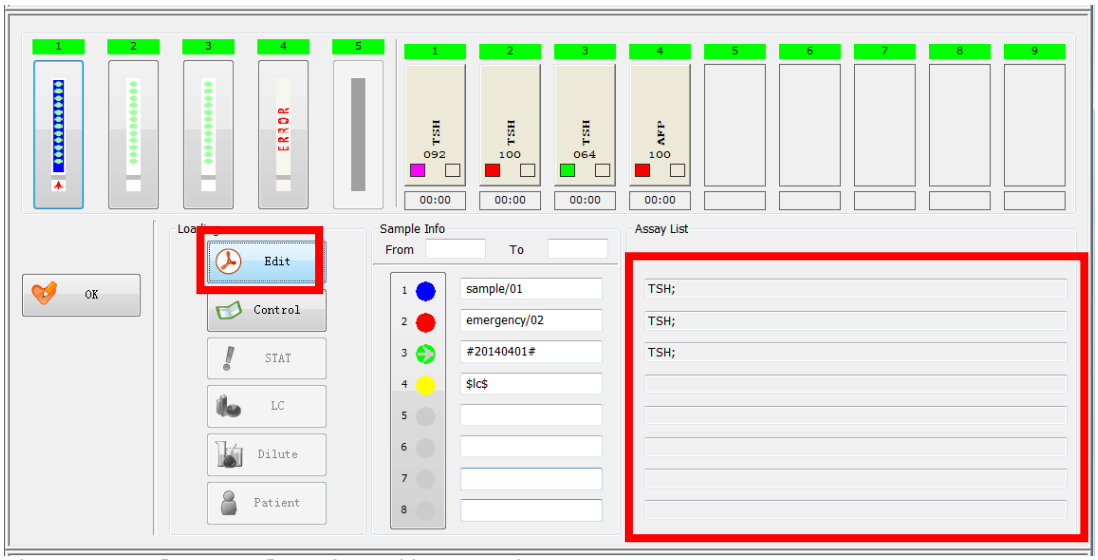


Figure11.2-13 **[Pat&Rea]** Interface with Assay List

Users can click **<Edit>** to return to the previous assay edit mode.

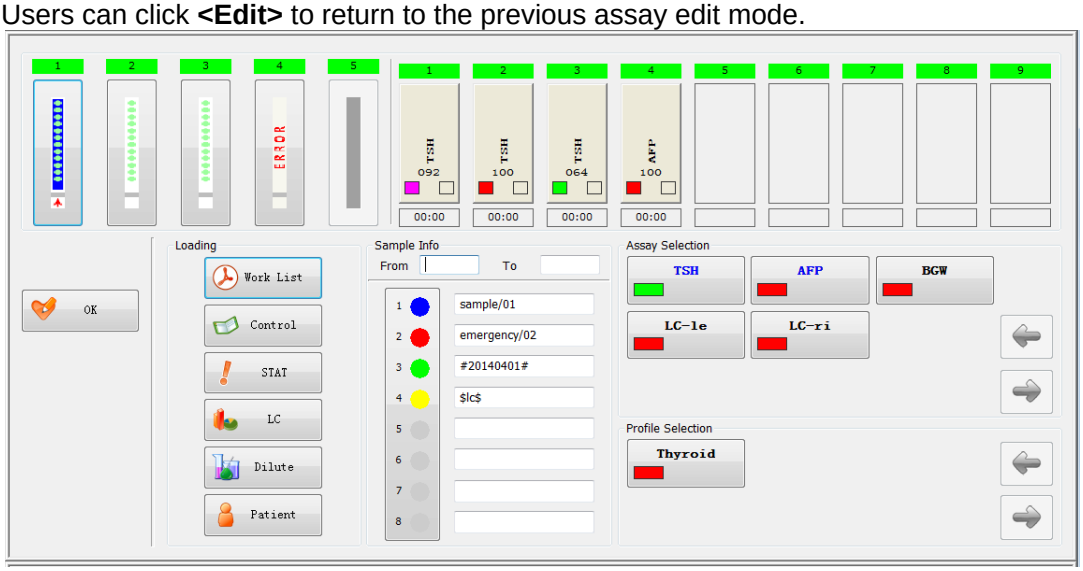


Figure11.2-14 **[Pat&Rea]** Interface with Assay Selection

11.2.5.2 <STAT>

The STAT function is used to obtain the assay result for an emergency sample. The emergency sample has the highest priority.
First select a sample, then click **<STAT>** to define the sample as a STAT sample. Then select assays in the **Assay Selection** on the right side.

11.2.5.3 <Control>

Click **<Control>** to open **[Control Selection]** dialog.

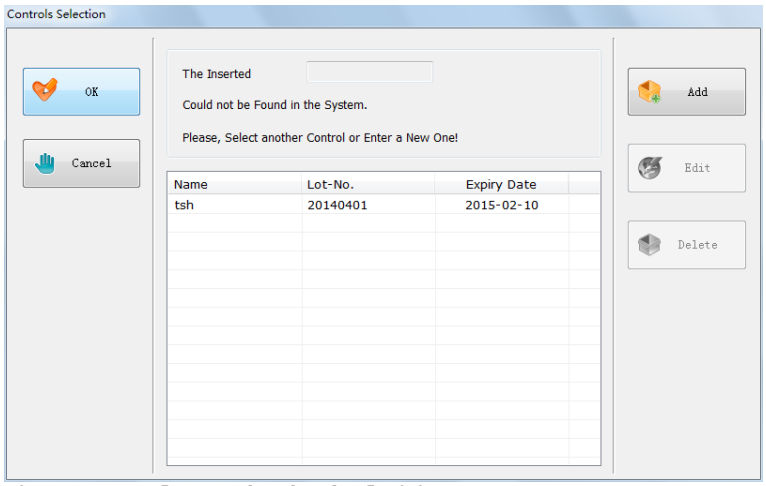


Figure11.2-15 **[Control Selection]** Dialog

After selecting a control material, you can press **<OK>** to exit and return to **[Patient]** interface; if there is no preset control, press **<Add>** to add a new control (see Chapter 7).

In **Sample Info**, # is marked before the selected control name, and this column is marked in green.
Control selected are listed in **Refers to Assays**
Control Cycles is preset by the operator (see Chapter 7).

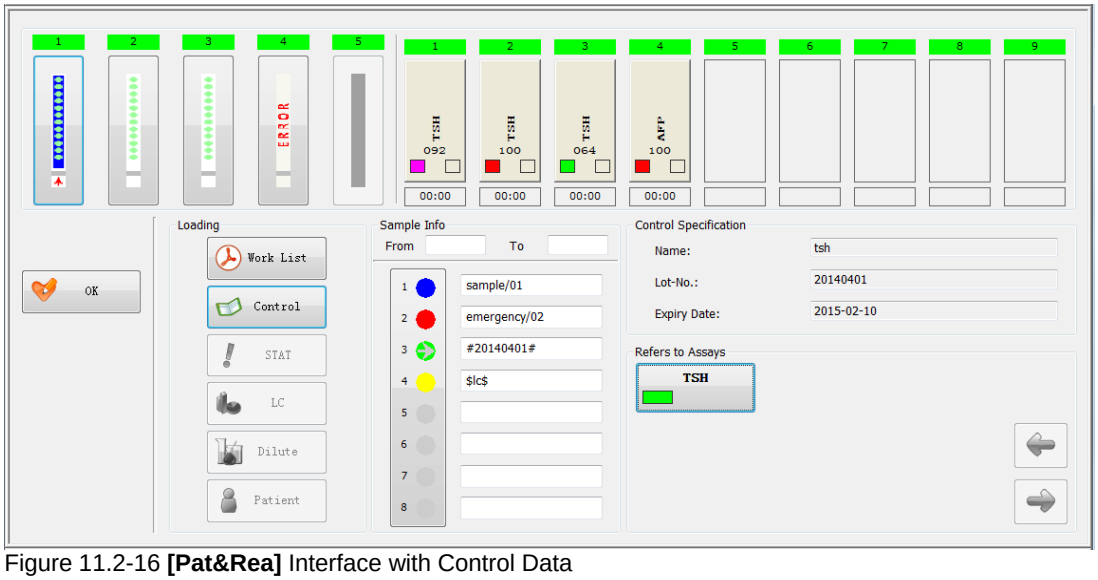


Figure 11.2-16 **[Pat&Rea]** Interface with Control Data

11.2.5.4 <LC>

Click **<LC>** button to perform LC test. $ is marked before the sample name; and this column is shown in yellow. For details on system tests, see Chapter 9.

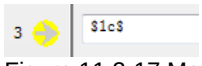


Figure 11.2-17 Manual editing LC number

11.2.5.5 <Dilute>

This function allows users to define the dilution ratio for sample assay.
Click **<Dilute>** button. Press the corresponding button to select an assay to display the Dilution Ratio List (see Chapter 7).

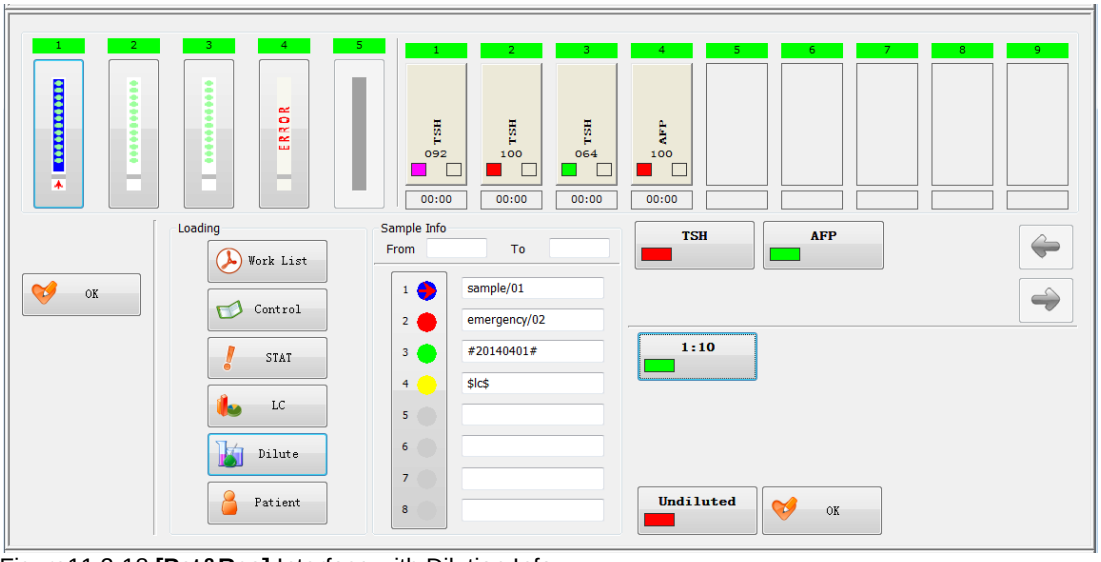


Figure11.2-18 **[Pat&Rea]** Interface with Dilution Info

Press the corresponding preset Dilution Ratio to set a sample and assay dilution ratio. A selected dilution ratio button is shown in green. Press this button again to cancel the selection, and the window color will change to red. If **<Undiluted>** is pressed, users can register an undiluted sample test in registering diluted tests. Press **<OK>** to save settings and return to **Edit Sample** interface.

11.2.5.6 <Patient>

The <**Patient**> function is used for quick input of patient info. Select a sample; click <**Patient**> button in [**Loading**] area to open **[Sample Info]** dialog.

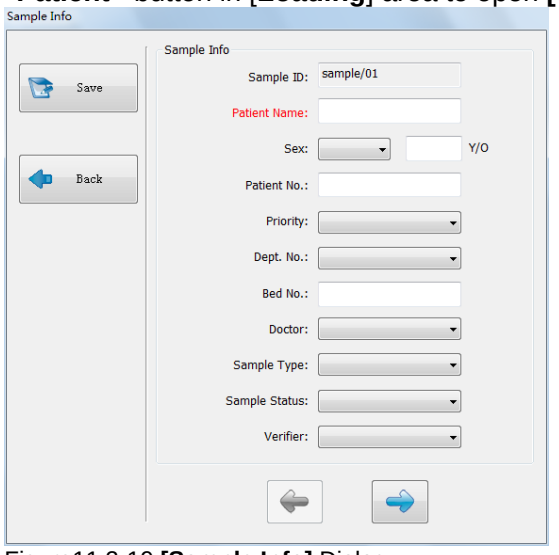


Figure11.2-19 **[Sample Info]** Dialog

Sample ID	Identification number of the sample;
Patient Name	Name of the patient;
Sex	Input the sex and age of the patient;
Patient No.	Outpatient number of the patient in the hospital;

Priority	Include General, Priority, Urgent, and Immediately;
Dept. No.	Department in which the patient sees a doctor;
Bed No.	Hospital bed No. of the patient
Doctor	The patient's doctor;
Sample Type	Type of sample tested;
Sample Status	Status of sample tested;
Verifier	The doctor verifying the journal.

Input corresponding info into **[Sample Info]** dialog; click "Page Up" or "Page Down" to switch to the previous or next sample, and continue info input. Patient info option can be defined in **<Dictionary>** in **[Report]** interface.
After info input, click **<Save>** to save sample info. Sample info saved will be associated with patient info in **[Detailed Sample Result]** dialog and **<Import>** info in **[Report]** interface. Click **<Back>** to exit **[Sample Info]** dialog.

11.2.6 <OK>

Click **<OK>** to save the registered sample info and exit **[Pat&Rea]** interface to **[Home]** interface.

12 [Report] Menu

12.1 [Report] Menu Introduction

Click **<Report>** on the menu bar to open **[Report]** menu. The buttons on the left:

Figure 12.1-1 [**Report**] Menu

Button	Function
<Journal>	display the journals on the then-current day, and search and display historical journals
<Valid>	display the validated journals on the then-current day, and search and display historical valid results
<Calibrator>	display the validated calibrator results on the then-current day, and search and display historical calibrator results
<Control>	display the validated control test results on the then-current day
<System Test>	display all system test results
<QC>	display content related to quality control chart
<Report>	display the assay report and relevant settings

12.2 <Journal>

Click **<Journal>** button on **[Report]** menu to enter **[Journal]** interface.

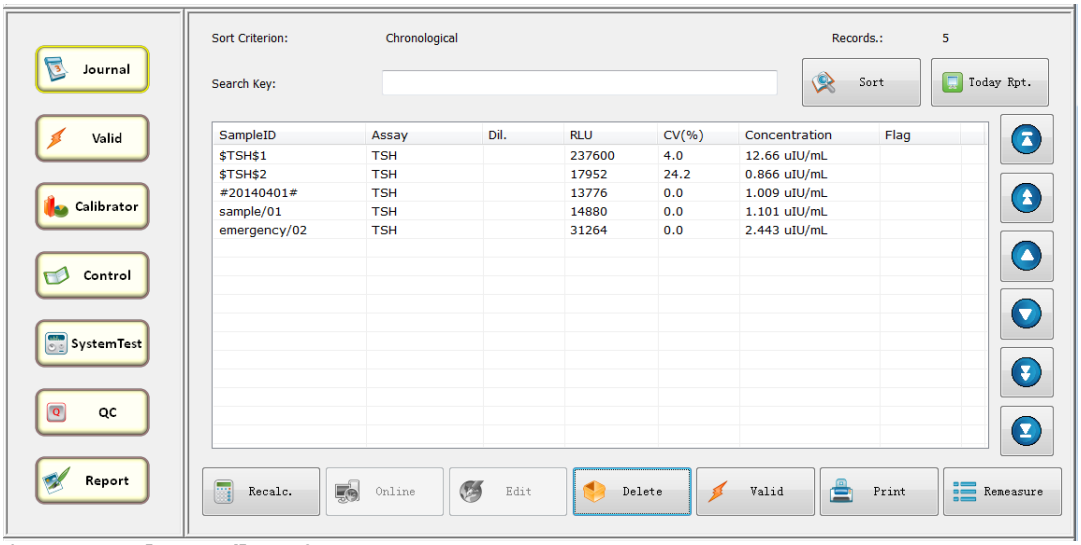


Figure 12.2-1 **[Journal]** Interface

All journals satisfying the current search criteria will be shown on **[Journal]** interface which also supports searching historical journals; the journal on the then-current day is displayed by default.
Journal list includes the information below:

Sample ID	($) is marked before and after Calibration or System Test; (#) is marked before and after QC Name.
Assay	English abbreviation of an assay
Dil.	Dilution ratio for diluting the sample
RLU and CV (%)	Shows the experimental status of the sample and the RLU value and CV (%).
Concentration	Test result expressed in concentration unit.
Flag	Warning sign of the test result; different symbols can be used depending on circumstances.

12.2.1 <Sort>

Click **<Sort>** button to open **[Sort Criterion]** dialog, where users can set the search criteria and search journals satisfying the search criteria.

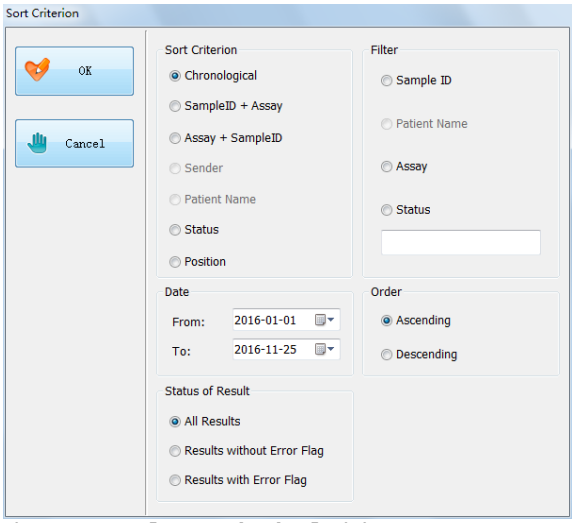


Figure 12.2-2 **[Sort Criterion]** Dialog

Chronological	Shows journals satisfying the search criteria according to the time of journals.
Sample ID + Assay	First shows the journals according to the first sort criterion: Sample ID; then sorts the journals by assay name (in alphabetical order).
Assay + Sample ID	First shows the journals by assay name (in alphabetical order) according to the first sort criterion; then sorts the journals by Sample ID.
Sender	Sorts the journals satisfying search criteria by sample sender (logged-in user).
Patient Name	Sorts the journals satisfying the search criteria by patient name of sample.
Status	Sorts the journals satisfying the search criteria by experimental status, such as Placed, To Do, Active, Done, and Failed.
Position	Sorts the journals satisfying the search criteria by the position of sample in the sample area (from left to right, from 1 to 8).
Filter	Set the filter criteria, including Sample ID, Patient Name, Assay and Status. Enter the expected keyword to show the journals satisfying the filter criteria.
Order	Function selection, showing the journals satisfying the search criteria by Ascending or Descending.
Date	Select the expected range of search date.
Status of Result	Select the expected Status of Result, such as All Results, Results without Error Flag, and Results with Error Flag.

12.2.2 <Today Rpt.>

Click **<Today Rpt.>** in **[Journal]** interface, then shows all journals on the then-current day. It facilitates users' search of all journals on the then-current day.

12.2.3 <Recalculate>

For journals satisfying the selection criteria, the concentration value of the sample will be recalculated according to the working curve confirmed most recently. Click **<Recalculate>** to open **[Recalculation Selection Dialog]**. The **Segment** zone is for specifying journals to be recalculated.

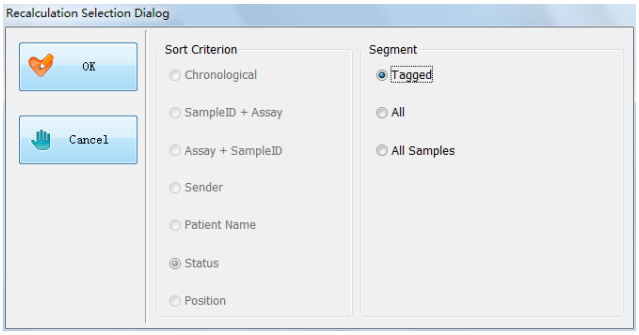


Figure 12.2-3 **[Recalculation Selection Dialog]**

Tagged	The tagged journals on [Journal] interface will be recalculated
All	All journals on [Journal] interface will be recalculated.
All Samples	The sample journals on [Journal] interface will be recalculated.

Click **<OK>** to recalculate journals satisfying the selection criteria.
Click **<Cancel>** to cancel recalculation.

12.2.4 <Online>

Click **<Online>** in **[Journal]** interface to open **[Online Selection Dialog]**. The **Segment** area is for specifying journals to be sent to the LIS.

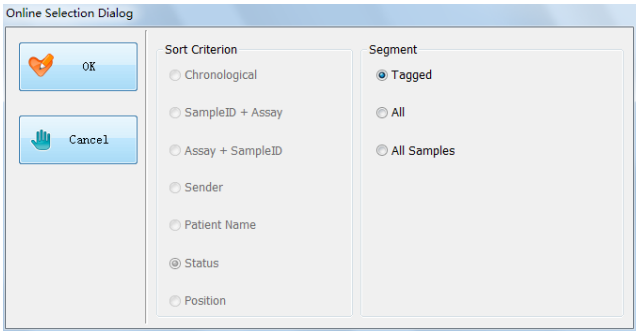


Figure 12.2-4 **[Online Selection Dialog]**

Tagged	The tagged journals on [Journal] interface will be sent to the LIS
All	All journals on [Journal] interface will be sent to the LIS.
All Samples	The sample journals on [Journal] interface will be sent to the LIS.

Click **<OK>** to send journals satisfying the criteria.
Click **<Cancel>** to cancel sending journals.

12.2.5 <Edit>

After selecting a journal on **[Journal]** interface, click **<Edit>** to open **[Detailed Sample Result]** dialog, where details of the tagged journals will be displayed.

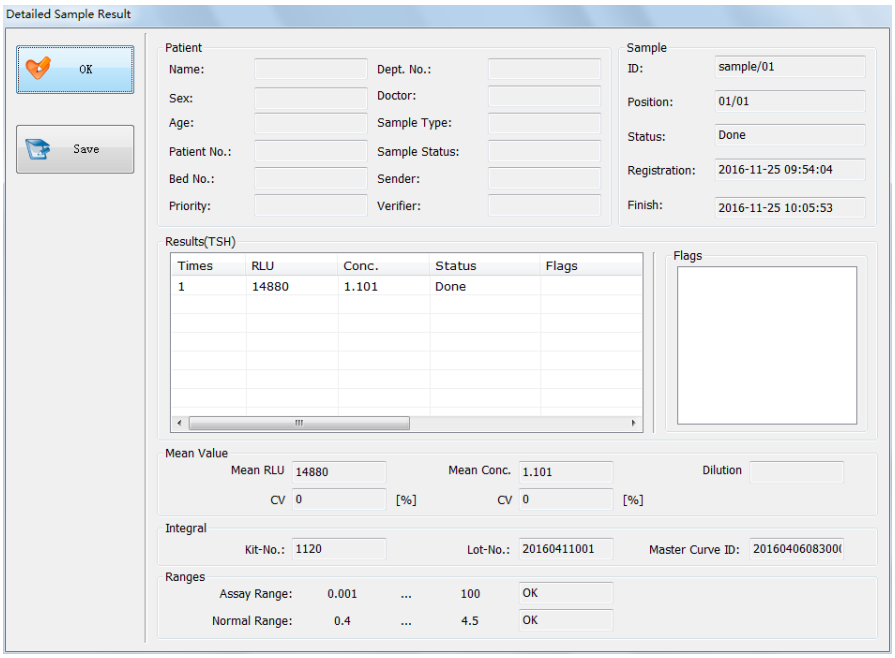


Figure 12.2-5 **[Detailed Sample Result]** Dialog

Patient: Show patient info associated with the journal

Name	Name of the patient
Sex	Sex of the patient.
Age	Age of the patient
Patient No.	Outpatient number of the patient in the hospital.
Bed No.	Hospital bed No. of the patient.
Priority	Priority level of patient sample.
Dept. No.	Department in which the patient sees a doctor.
Doctor	The doctor applying for test.
Sample Type	Type of sample tested.
Sample Status	Status of sample tested.
Sender	The doctor testing the sample.
Verifier	The doctor verifying the journal.

Sample: Record relevant info of the journal on the analyzer

ID	Identification number of the sample.
Position	Position of the rack where the sample is positioned and Position of the sample on the rack.
Status	Assay status of the sample
Registration	Time when the sample is registered.
Finish	Time when the assay journal is completed.

Results: Show details of results

Times	Test times.
RLU	RLU value of the journal.

Conc.	Concentration value of the journal.
Status	Test status of the journal.
Flags	Flag info of the journal.
Finish Time	Time when the assay is completed of the journal.
Big Cycle	Major cycle for assay completion of the journal.
Min Cycle	Minor cycle for assay completion of the journal.

Mean Value: Show the mean value of results.

Mean RLU	Mean RLU value of several tubes of the journal.
CV	Variation coefficient of RLU of several tubes. Unit: [%].
Mean Conc.	Mean concentration value of several tubes of the journal.
CV	Variation coefficient of concentration value of several tubes. Unit: [%].
Dilution	Dilution ratio for diluting the sample.

Ranges: Shows and judges the Assay Range and the Normal Range of the journal

Assay Range	Shows the assay range of the journal, and judges whether the journal is within the Assay Range.
Normal Range	Shows the normal range of the journal, and judges whether the journal is within the Normal Range.

Integral: Show the reagent data of the assay, including Kit-No., Lot-No. and Master Curve ID.

Flags: Show the flag info associated with the journal, including Analyzer Failure, Reagent Expired, Calibration Expired, Above Normal Range, Below Normal Range, Recalculate, Above Assay Range, Below Assay Range, Blood Clot, Pipette Error, Pipette Suction, Above Control Range, and Below Control Range.

List of Warning Symbols：

*	Analyzer failure;
E	The reagent using which the result is obtained has been expired;
C	The working curve using which the result is calculated has been expired;
> / <	The sample journal is beyond the Normal Range;
R	The journal has been recalculated;
>Q and <Q	The quality control result is beyond the set Control Range;
S	The sample or a component of the reagent is not sufficient;
D	The pipette detects blood clots;
N	The pipette impacts against the cuvette, sample rack, bottom of test tube, etc., which causes pipette error;
>>/<<	The journal is above or below the Assay Range

Click **<Save>** to save the modified info.
Click **<OK>** to cancel the modified info.

WARNING

Snibe does not recommend users to change results, and will assume no liability for any consequences arising there from.

12.2.6 <Delete>

Click **<Delete>** in **[Journal]** interface to open **[Delete Selection Dialog]**. Select the journal to be deleted in the **Segment** area.

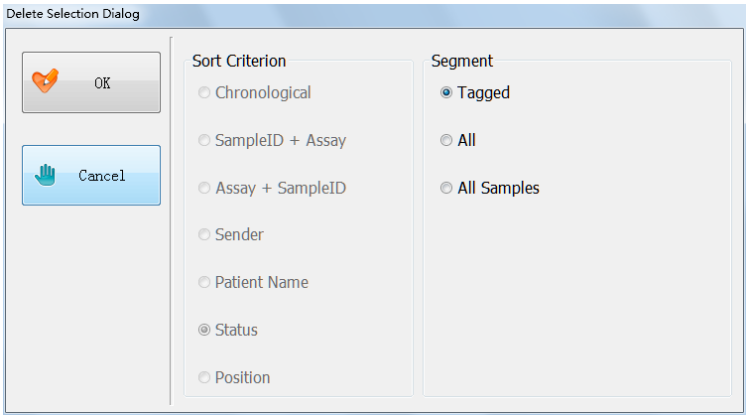


Figure 12.2-6 **[Delete Selection Dialog]**

Tagged	The tagged journals on **[Journal]** interface will be deleted.
All	All journals on **[Journal]** interface will be deleted.
All Samples	The sample journals on **[Journal]** interface will be deleted.

Click **<OK>** to delete the selected journals.
Click **<Cancel>** to cancel deleting the selected journals.

12.2.7 <Valid>

Click **<Valid>** in **[Journal]** interface to open **[Validation Selection Dialog]**. Select the journal to be validated in the **Segment** area.

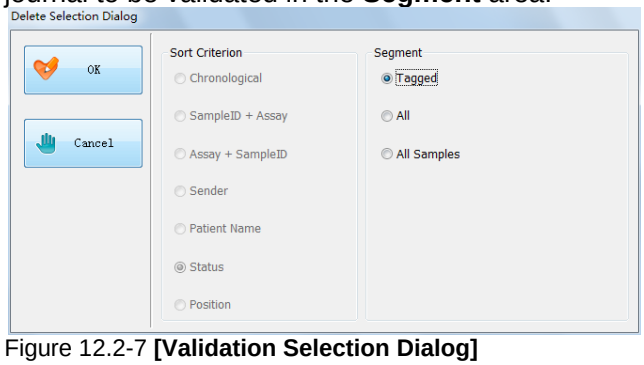


Figure 12.2-7 **[Validation Selection Dialog]**

Tagged	The tagged journals on **[Journal]** interface will be validated
All without Flag	All journals without flag will be validated.
All Samples without Flag	The sample journals without flag will be validated.

Click **<OK>** to validate the selected journals.
Click **<Cancel>** to cancel validating the selected journals.

12.2.8 <Print>

Click **<Print>** in **[Journal]** interface to open **[Printout Selection Dialog]**. Select the journal to be printed in the **Segment** area.

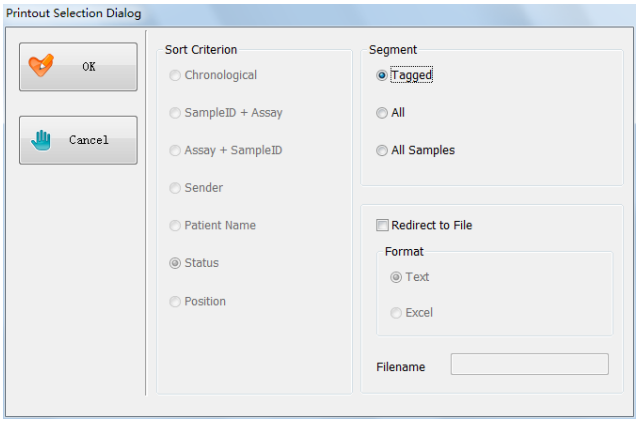


Figure 12.2-8 **[Printout Selection Dialog]**

Tagged	The tagged journals on **[Journal]** interface will be printed
All	All journals on **[Journal]** interface will be printed.
All Samples	The sample journals on **[Journal**] interface will be printed.

Select **Redirect to File** to save a file in Text or Excel format.

Format	Format in which a file is saved, supporting Text and Excel.
File name	Specifies the name of a file.

Click **<OK>** to print the selected journals.
Click **<Cancel>** to abort printing the selected journals.

12.2.9 <Remeasure>

Click **<Remeasure>** in **[Journal]** interface to open **[Review Selection Dialog]**. Select the journal to be re-measured in the **Segment** area.

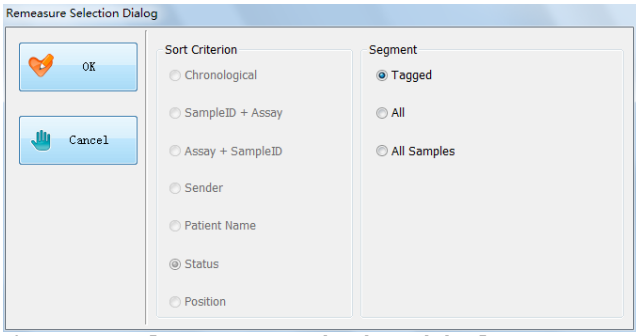


Figure 12.2-9 **[Remeasure Selection Dialog]**

Tagged	The tagged journals on **[Journal]** interface will be re-measured.
All	All journals on **[Journal]** interface will be re-measured.
All Samples	The sample journals on **[Journal]** interface will be re-measured.

Click **<OK>** to remeasure the selected journals.

Click **<Cancel>** to cancel remeasuring the selected journals.

12.3 <Valid>

Click **<Valid>** on **[Report]** menu to open **[Valid]** interface, where validated sample journals satisfying the criteria will be displayed.

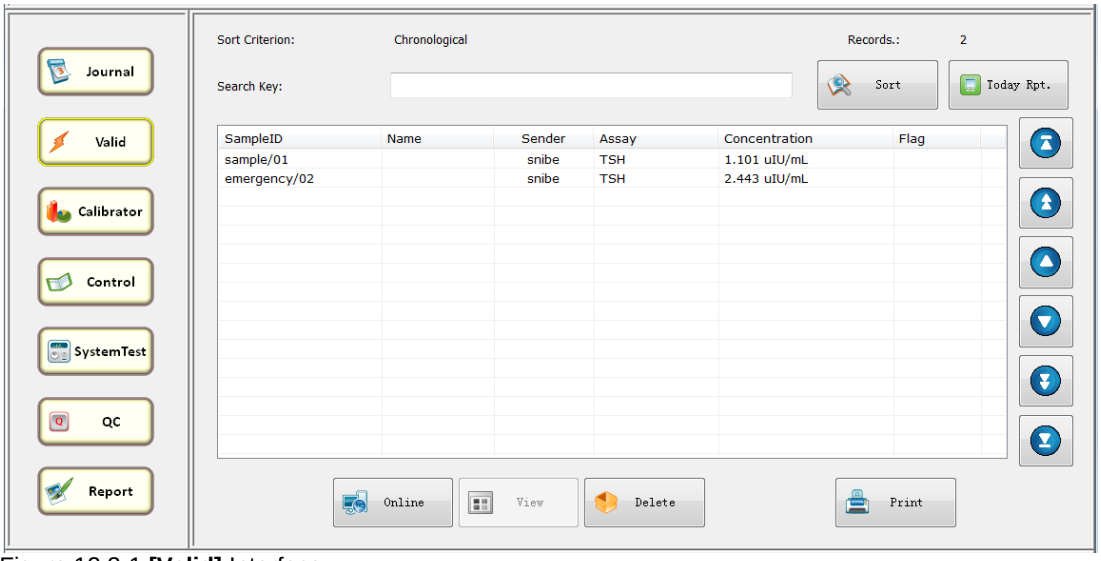


Figure 12.3-1 **[Valid]** Interface

[Valid] interface is similar to **[Journal]** interface, there has **<Sort>**, **<Today Rpt.>**, **<Online>**,<**View**>, **<Delete>** and **<Print>** button.
The functions of **<Sort>**, **<Today Rpt.>**, **<Online>**, **<Delete>** and **<Print>** button are identical to those of **[Journal]** interface. The functions of <**View**> button is to view the detail of the valid result.

Click **<View>** to open **[Detailed Sample Result - Validated]** dialog

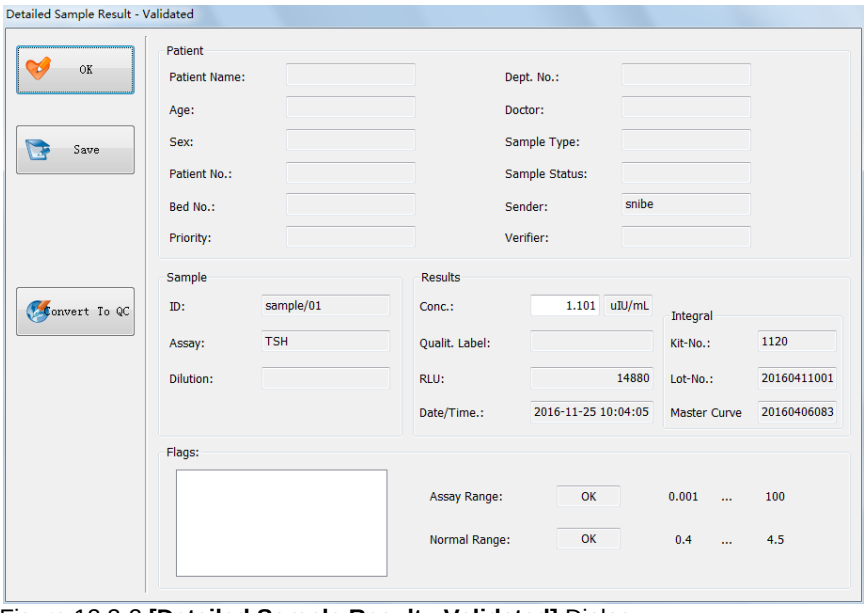


Figure 12.3-2 **[Detailed Sample Result - Validated]** Dialog

Patient: Shows patient info associated with the valid result.

Patient Name	Name of the patient
Age	Age of the patient
Sex	Sex of the patient.
Patient No.	Outpatient number of the patient in the hospital.
Bed No.	Hospital bed No. of the patient.
Priority	Priority level of patient sample.
Dept. No.	Department in which the patient sees a doctor.
Doctor	The doctor applying for test.
Sample Type	Type of sample tested.
Sample Status	Status of sample tested.
Sender	The doctor testing the sample.
Verifier	The doctor verifying the journal.

Sample: Shows the sample info.

ID	Identification number of the sample.
Assay	Assay that the sample undergoes.
Dilution	Dilution ratio for diluting the sample.

Results: Shows relevant data of the result

Conc.	Concentration value of the sample result.
Qualit. Lbl	Qualitative label of the assay, which can be defined in [Reagent Definition].
RLU	RLU value of the sample result.
Date/Time	Time of sample test.

Integral: Shows the reagent data of the assay, including Kit-No., Lot-No. and Master Curve ID.

Flags：	Shows the identifier of result status.（See section 12.1.5）
Assay Range：	Shows the assay range of the result, and whether the result is within the Assay Range.
Normal Range:	Shows the normal range of the result, and whether the result is within the normal Range.

12.4 <Calibrator>

Click **<Calibrator>** button in **[Report]** menu to open **[Calibrator]** interface, where validated calibrator results satisfying the criteria will be displayed.

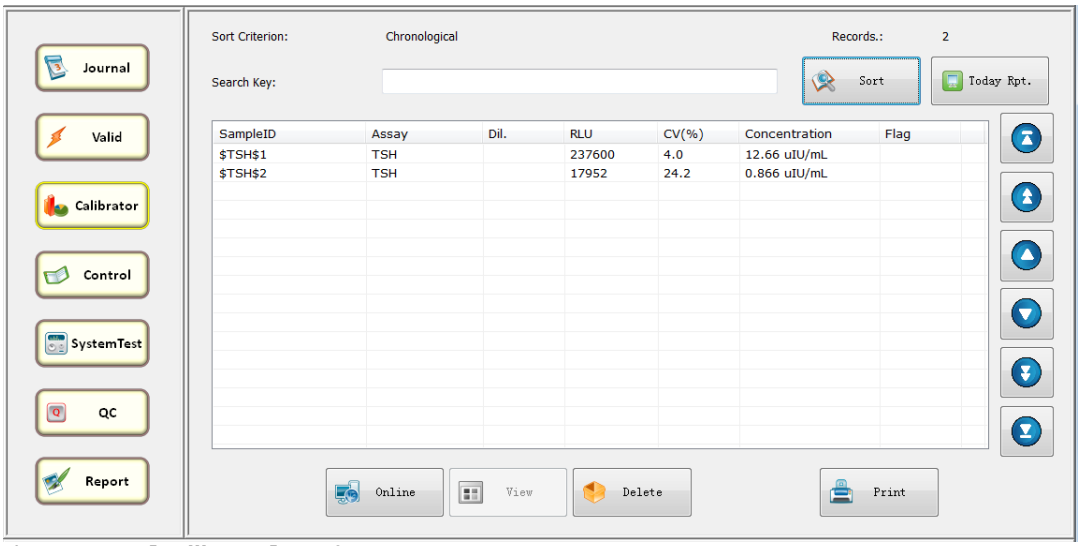


Figure 12.4-1 **[Calibrator]** Interface

[Calibrator] interface is similar to **[Journal]** interface, there has **<Sort>**, **<Today Rpt.>**, **<Online>**,<**View**>, **<Delete>** and **<Print>** button.
The functions of **<Sort>**, **<Today Rpt.>**, **<Online>**, **<Delete>** and **<Print>** button are identical to those of **[Journal]** interface. The function of **<View>** button is identical to this of **[Valid]** interface.

12.5 <Control>

Click **<Control>** button in **[Report]** menu to open **[Control]** interface, where validated control results satisfying the criteria will be displayed.

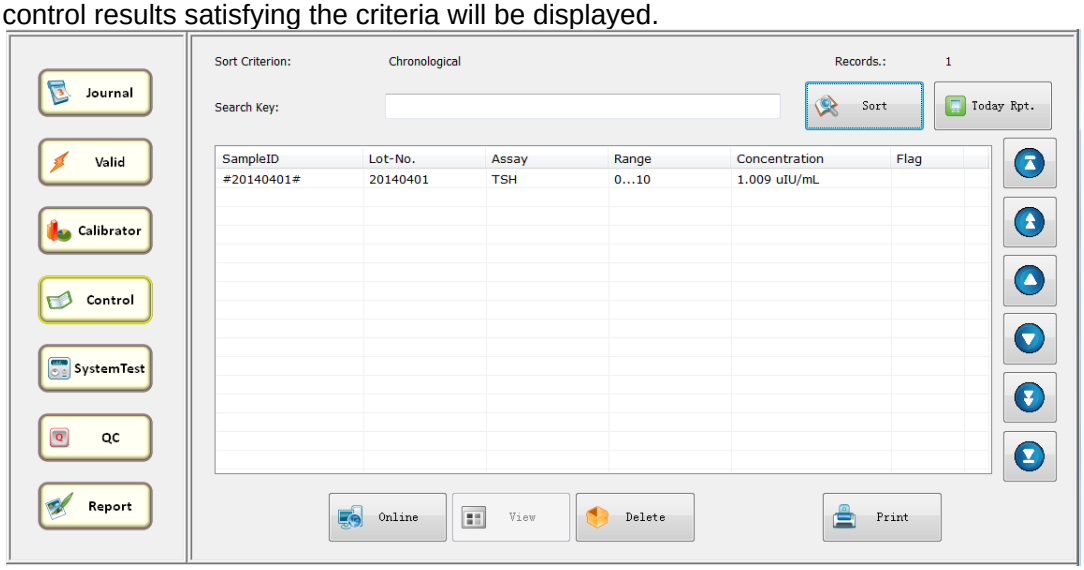


Figure 12.5-1 **[Control]** Interface

[Control] interface is similar to **[Journal]** interface, there has **<Sort>**, **<Today Rpt.>**, **<Online>**,<**View**>, **<Delete>** and **<Print>** button.
The functions of **<Sort>**, **<Today Rpt.>**, **<Online>**, **<Delete>** and **<Print>** button are identical to those of **[Journal]** interface. The function of **<View>** button is identical to this of **[Valid]** interface.

12.6 <System Test>

Click **<System Test>** button in **[Report]** menu to open **[System Test]** interface, where all system test results will be shown.

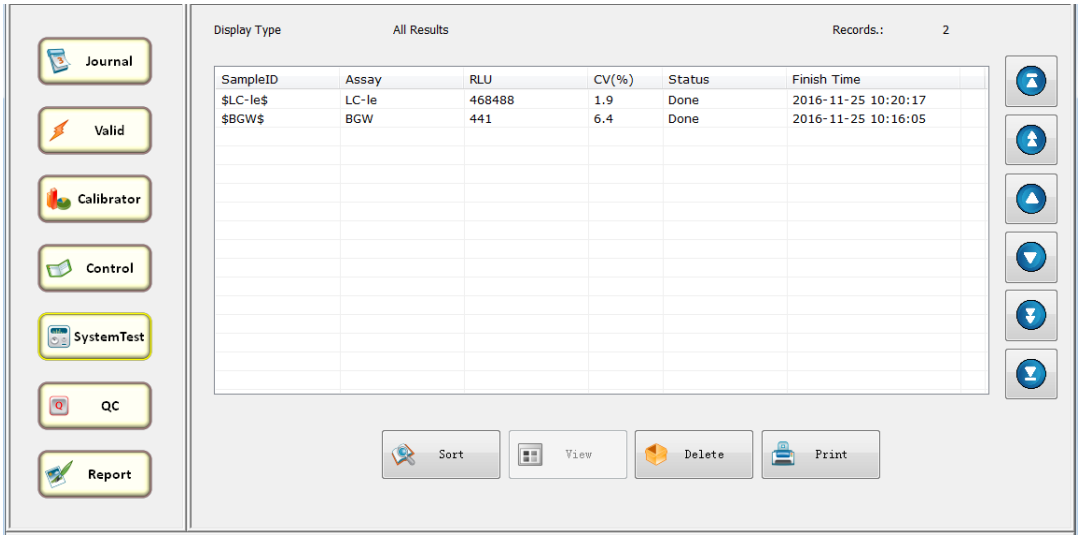


Figure12.6-1 **[System Test]** Interface

<Sort> Click **<Sort>** button to open **[Search System Test Result Dialog]** to select and view the types of system test results shown.

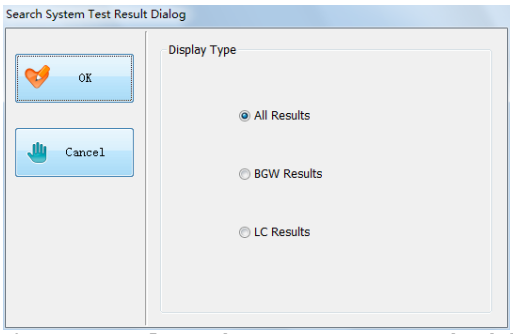


Figure 12.6-2 **[Search System Test Result Dialog]**

<View> Click **<Sort>** button to open **[Detailed System Test Result]** dialog to view details of system test results. If the value exceeds the set value, the numerical value of this result will be shown in red. Set the range of set value in Service software.

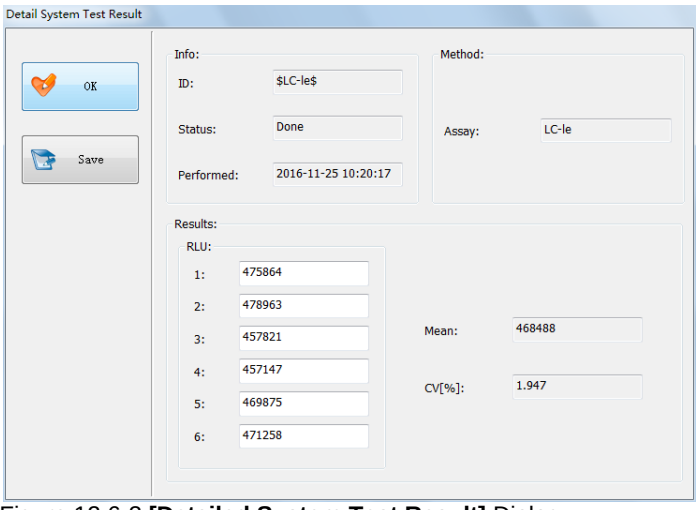


Figure 12.6-3 **[Detailed System Test Result]** Dialog

Info: Details of system test.

ID	Name of system test, before and after which ($) is marked.
Status	Processing status of system test.
Performed	Editing time of system test.

Method: Name of system test

Results: Details of system test result

RLU	Shows the RLU value of each assay in system test.
Mean	Mean value in system test.
CV%	Variation coefficient of six RLU values.

12.7 <Report>

Click **<Report>** button on **[Report]** menu to open **[Report]** interface, where the test report satisfying the criteria will be displayed and users can set the print info and quality control chart for the test report.

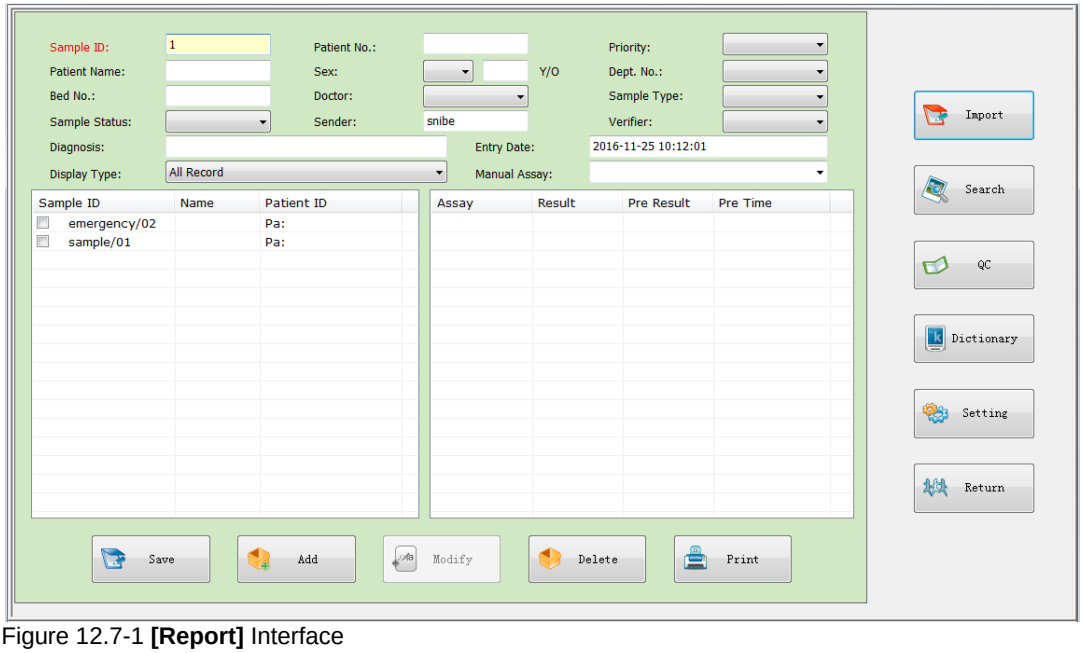


Figure 12.7-1 **[Report]** Interface

12.7.1 <Import>

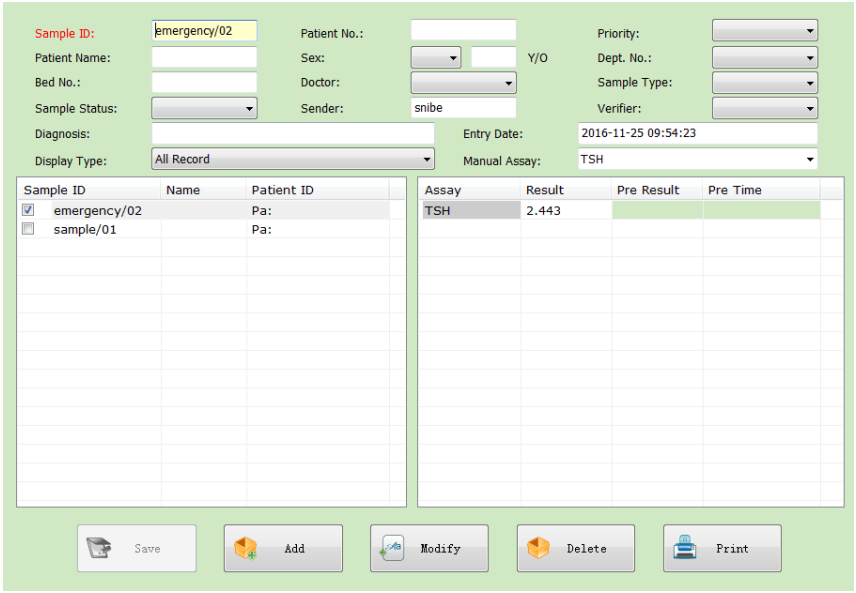


Figure 12.7-2 **[Import]** Dialog

Display Type: Select the type of test report to be displayed, including: Recorded, But not Value; Recorded, And with Value; All Record.

Recorded, But not Value	Test report with patient data imported, but journal not received.
Recorded, And with Value	Test report with patient data imported and journal received.
All Record	Test report of both the above states.

Sample ID	Number of test report, and also the Sample ID in the journal;
Patient No.	Patient number registered in the hospital;
Priority	Options include: Normal, Prioritized, Urgent, and Immediate;
Patient Name	Name of the patient;
Sex	Sex and age of the patient;
Dept. No.	Department where the patient sees a doctor;
Bed No.	Bed number of the patient during hospitalization;
Doctor	Doctor of the patient;
Sample Type	Type of the sample tested;
Sample Status	Status of the sample tested;
Sender	Current user logging into Maglumi software;
Verifier	Doctor verifying the patient journal;
Diagnosis	Diagnosis content of patient test report;
Entry Date	Time when the test report is entered;
Manual Assay	Select assay to add manual results.

Report Entry: Enter the patient sample ID; Pat.-ID, Name and Bed No. in text box, and select the Priority, Sex, Dept. No., Doctor, Sample Type, Sample Status, and Verifier; click **<Save>** to finish info entry for the test report.

The Sample ID in the test report is associated with the Sample ID in the journal. After journal validation in [**Journal**] dialog, result info will be added to the test report with patient info entered; if no test report is available, a test report will be created.

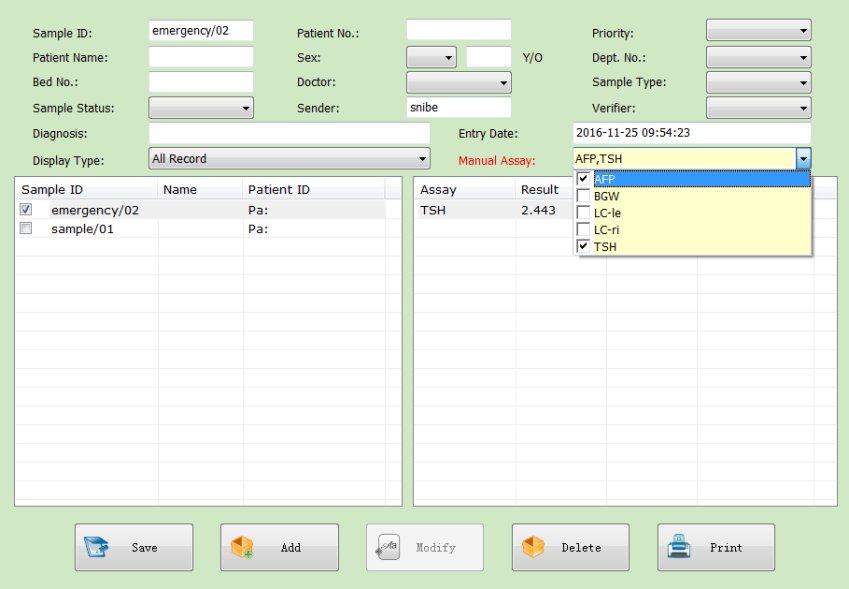


Figure12.7-3 Manually Add Result

Manually Add Result: Click the test report to which the result will be added; click **<Modify>**; select the assay to be added in the "**Manual Assay**" drop-down menu; enter the concentration value for the corresponding assay into the Result text box; click **<Save>** to finish adding the journal.

Modify Result: Select the test report of which the result is to be modified; click **<Modify>**; select the assay to be modified; modify the result value; click **<Save>** to finish modifying the result value.

Modify Patient Data: Select the test report of which the patient data is to be modified; click **<Modify>**; then modify the data item by item according to the actual situation; click **<Save>** to finish modifying the test report data.

Delete Test Report: Select the test report to be deleted; click **<Delete>** to finish deleting the test report.

Print Test Report: Select the test report to be printed; click **<Print>**; select the criteria for printing the test report in **[Report Print Dialog]**.

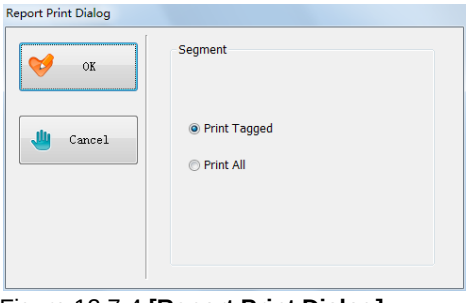


Figure 12.7-4 **[Report Print Dialog]**

Add Diagnosis: To add diagnosis info to the test report, click **<Modify>**, and add relevant diagnosis info under **"Diagnosis"**; click **<Save>** to finish adding diagnosis info to the test report.

12.7.2 <Search>

Search historical test reports according to the set search condition. Click **<Result Search>** to show test reports satisfying the current search criteria. Input the corresponding search condition (Patient No., Dept. No., Doctor, Date Range for Search, Name, Sample ID); click **<Search>** to show test reports satisfying the condition. Click **<Preview>**; the test report selected will be shown in the form of test report sheet. Click **<Print>** to print the test report selected.

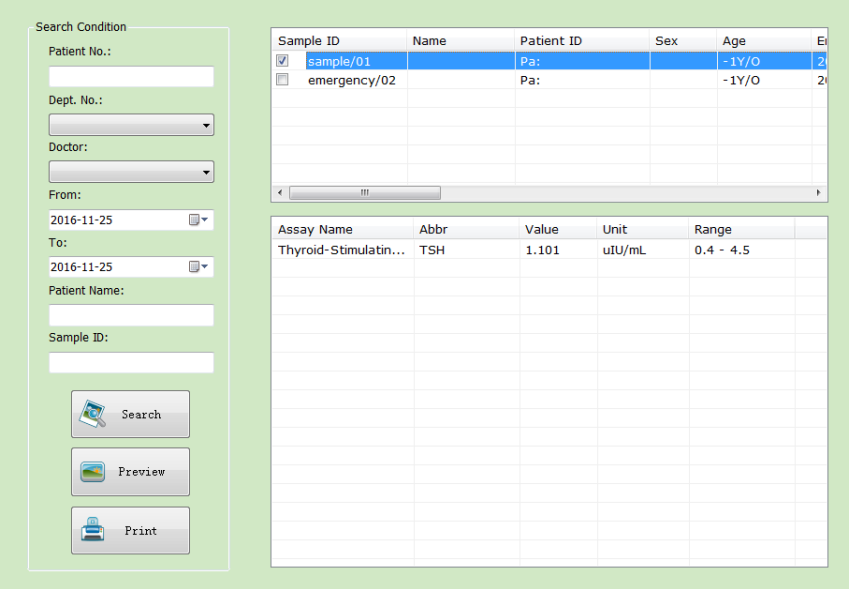


Figure 12.7-5 **[Search]** Dialog

Search Condition: Input the condition for searching historical test reports

Patient No.	Search a specific patient number;
Dept. No.	Search test reports of a department;
Doctor	Search test reports issued by a doctor;
From	Starting date for search;
To	Ending date for search;
Name	Search the test report of a specific patient;
Sample ID	Search the test report of a specific sample ID;

Figure 12.7-6 Preview

12.7.3 <QC>

Quality control is to ensure the reliability of each sample test result. The reliability of test results, including the meaning of two aspects, one is the precision and the repeatability of test results, the laboratory test results every day change is very small, mainly to eliminate or reduce the effects of random error; On the other hand is high accuracy, and the test result is correct, close to the true value, mainly to eliminate or reduce the influence of system error.

Click **<QC>** to show **[QC]** dialog box, where Lot QC chart and monthly QC chart are displayed.

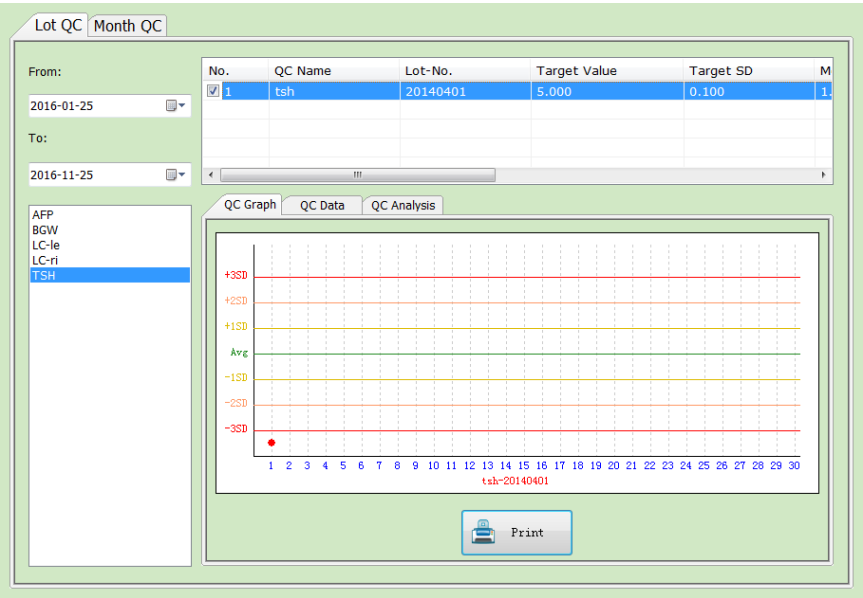


Figure 12.7-7 **[QC]** Dialog

12.7.3.1 Lot QC

Lot QC means analyzing QC data of a lot for a certain assay within a period time, which also supports multi-lot QC analysis. Select "Lot QC" tab to show **[Lot QC]** dialog; after selecting Start Time, Finish Time and QC Assay, QC results of all lots for

this assay will be shown in the Lot QC Result List at the upper right corner of the dialog box. After selecting a QC result, the QC graph, QC data and QC analysis will be shown at the lower right corner.

QC result data are from QC results validated in **[Journal]** dialog. Relevant info of quality control materials is defined in **[QC Definition]** in **[Definition]** menu.

The Lot QC Result List contains the following info:

No.	Serial number of QC result of different QC liquids or same QC liquid in different lots.
QC Name	Name of QC liquid.
Lot-No.	Lot-No. of QC liquid.
Target Value	Target value when the selected QC liquid is used for QC test of the selected assay.
Target SD	Target SD value when the selected QC liquid is used for QC test of the selected assay.
Measure Value	Target value actually measured in QC results of the same Lot-No.
Measure SD	SD value actually measured in QC results of the same Lot-No.
Target CV(%)	Target CV value when the selected QC liquid is used for QC test of the selected assay.
MeasureCV(%)	CV value actually measured in QC results of the same Lot-No.

QC Graph: Display the QC chart of results of the selected Lot-No. Click **<Print>** button to print the lot QC chart and relevant info.

QC Data: Display the latest 30 entries of QC results of the selected Lot-No.

QC Analysis: Display the result of QC analysis on results of the selected Lot-No.

12.7.3.2 Month QC

Monthly QC means analyzing QC data for a certain assay within a month, which also supports multi-lot QC analysis for the same assay. Select "Monthly QC" tab to show **[Monthly QC]** dialog; after selecting Month and Assay, QC results of all lots for this assay in the selected month will be shown in the Monthly QC Result List at the upper right corner of the dialog box. After selecting a QC result, the QC graph, QC data and QC analysis will be shown at the lower right corner.

Structure of the Monthly QC Result List is identical to the Lot QC Result List
The content shown in the QC chart and QC analysis is identical to that in the QC chart and QC analysis in **[Lot QC]** dialog. The latest QC data of each lot every day of the current month will be used.

12.7.4 <Dictionary>

Click **<Dictionary>** to show the **[Dictionary]** dialog.

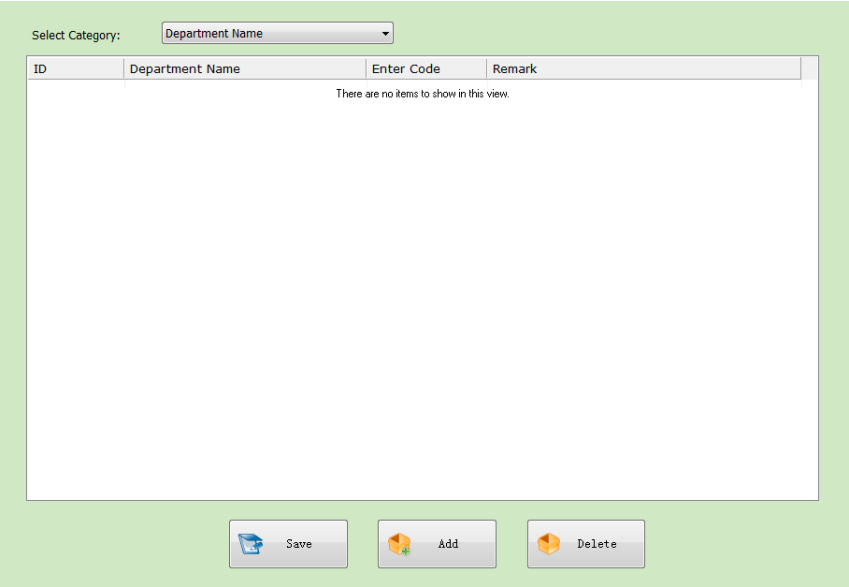


Figure 12.7-8 **[Dictionary]** Dialog

Select an option to be edited from the **Select Category** drop-down box; users can edit the Department Name, Doctor Name, Sample Type, Sample Status, Reference Range, and Assay Definition.

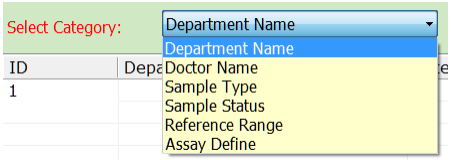


Figure12.7-9 **[Select Category]** Drop-down Menu

<Save> Save the newly entered info;

<Add> Add a new info record;

<Delete> Delete an info record;

Department Name Select **Department Name** from the **"Select Category"** drop-down box; click **<Add>** to show a blank sheet below; input the department name in the corresponding blank space below **"Dept. Name"**; to add **"Enter Code"**, enter the corresponding content below; after entry, click **<Save>** to finish entering the department name.

The method for editing **Doctor Name**, **Sample Type and Sample Status** is the same as that for editing **Department Name**.

Reference Range Click **Reference Range"** in the **Select Category** drop-down box, to edit the normal reference range for the assay. Select the assay for which the reference range is to be edited from **"Assay"** at the upper right corner of the dialog box; then click **<Add>**; click **"Age Range"** to show the Age Category **Range** menu; select the desired age range, such as "Male Adult" and "Female Adult"; enter digits under **[Lower Bound]** and **[Upper Bound]**, respectively; click **<Save>** to finish setting the reference range for the designated age category in the selected assay. To continue adding, please repeat the above operations. To input multiple lines of reference values, please input "**Special Immune Male** " or "**Special Immune Female**" under [**Age Range**]; input "－1" under **[Lower Bound]** and **[Upper Bound]**; then input multi-line reference under

[Remark]; use ";" in English input mode to separate reference values.

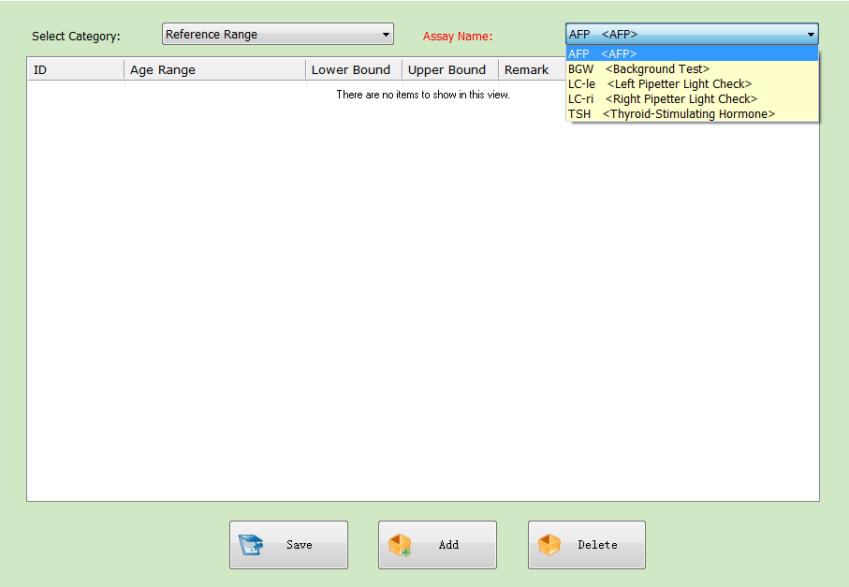


Figure 12.7-10 **[Reference Range]** Drop-down Menu

Assay Define Select **Assay Define** from the **"Select Category"** drop-down box; click **<Add>** to show a blank sheet below; input the "**Assay Abbr"** in the corresponding blank space below **"Assay Abbr", "Printer Order"** and **"Assay Method"**, and click **<Save>** to finish entering the department name.

12.7.5 <Setting>

Click **<Setting>** button to open **[Setting]** dialog, where users can set report sheet and format of report sheet and carry out print setting. Click **<Save>** to save the newly entered info;

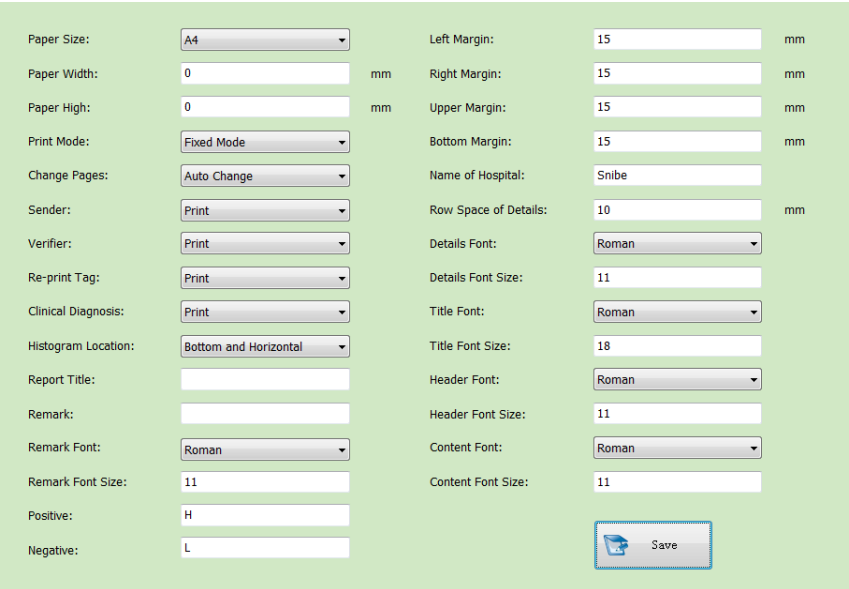


Figure 12.7-11 **[Setting]** Dialog

Paper Size	Set the size of paper used in the printer; options include A4 Paper, B5 Paper, and User-defined Paper.
Paper Width, Paper High	The attributes of Paper Width and Paper High are valid only for user-defined paper. Paper Width and Paper High define the size of the paper used in the printer (unit: mm).
Upper, Bottom, Left and Right Margins	The attributes of Upper, Bottom, Left and Right Margins respectively define the blank region at the upper, bottom, left and right edges of the printer paper selected, i.e., define the non-printing region (unit: mm).
Print Mode	Two print mode options are available: Fixed Mode and Compact Mode. In Fixed Mode, the endnotes of a report are printed above the bottom margin of the paper, regardless of the number of result details. In Compact Mode, the endnotes of a report are printed immediately following the last assay.
Change Pages	Options for changing pages include: Continuous, and Auto Change. Continuous is selected when there is a large number of assays and it is impossible to print all on one page of the defined size, which ignores the size (height) of paper to continuously print all assays. This option usually applies to perforated paper and stylus printers. Auto Change is selected when it is impossible to print all assays on one page, which divides the report into two or more pages for printing. When the assays contain multiple references (i.e., multiple reference ranges, multi-line output required during printing), Auto Change will be ignored automatically.
Sender	If Print is selected, the sender name will be printed on the report. If Not Print is selected, the sender name will not appear on the report printed or previewed; in such case, the report to be sent can be confirmed by manual signature.
Verifier	If Print is selected, the verifier name will be printed on the report. If Not Print is selected, the verifier name will not appear on the report printed or previewed; in such case, the report to be sent can be verified by manual signature.
Re-print Tag	For a report not entered on the then-current day, the [Re-print] tag will be printed at the upper left corner of the report. If Not Print is selected, this tag will not appear on the report printed or previewed.
Diagnosis	If Print is selected, diagnosis will appear at the header of the report printed or previewed; otherwise it will not appear on the report.
Histogram Location	For a test report containing any histogram, users can select to output the histogram on the right side (longitudinal) or bottom side (transverse) of the report; the corresponding options are Right Longitudinal and Bottom Transverse, respectively.
Report Title	Words describing the report content, such as "Biochemical Test Report" and "Immunoquantitation Report"; the title is shown after the Name of Hospital.
Remark	Detailed content after **[Remark]** in the report; for example, "This report is responsible only for this sample"
Remark Font and Font Size	Font and font size of the remark printed; press the arrow key in the Font input box or double click to get the list of fonts currently available in the system; the font size should not be expressed in decimals.
Positive	H is the default flag of positive result.
Negative	L is the default flag of negative result.
Name of Hospital	Name of the user organization, for example, "XX People's Hospital", which will be displayed at the title of report.
Row Space of Details	Row space of assay details in the report (unit: mm).

Details Font and Font Size	Font and font size of assay details to be printed.
Title Font and Font Size	Font and font size of the title of report to be printed.
Header Font and Font Size	Header of report refers to the area above assay details in the report. Font and font size of the header of report to be printed.
Content Font and Font Size	Font and font size of assay details of the header content of report to be printed.

After changing the options under Setting, click **<Save>** to save the changed content of Setting. After saving, the system will update the settings immediately; it is unnecessary to restart the system program.

12.7.6 <Return>

Click **<Return>** to go back to the **[Journal]** interface.

13 Status Display and Handling

13.1 Status Display

Figure 13.1-1 Status Bar

Software interface at the bottom of the status bar has three buttons to display the status information of the analyzer. They are **<Reservoir>** button（  ）, **<Temp/Volt>** button（  ）, **<Waste>** button（  ）.

13.1.1 Consumables

<Reservior> button is used to show whether there are sufficient cuvettes, system liquid and starter 1+2.
The status of **<Reservior>** button means:

 **Green** All consumables are sufficient.

 **Yellow** One or more consumables are not sufficient.

 **Red** One or more consumables are almost used up.

WARNING

In case of an alarm, please check which consumable has run out and replenish it.

Click **<Reservior>** button to open [**Reservoir Status]** dialog, where shows the status of cuvettes , starter reagents and system liquid.

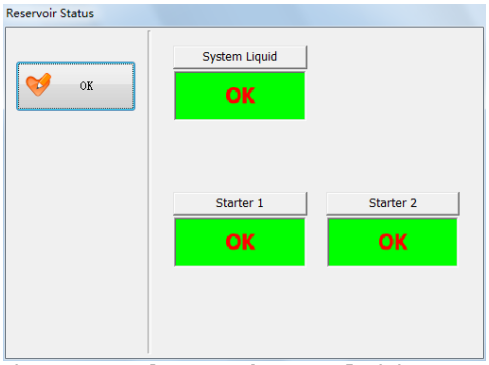


Figure 13.1-2 [**Reservoir Status]** Dialog

13.1.1.1 Cuvette Loader

Pattern and color of consumables are used to represent the number of cuvettes in the cuvette loader.

Green	Number of cuvettes bars > 5.
Yellow	1 ≤ Number of cuvettes bars ≤ 5. At this moment, a warning prompt "**Running out of cuvettes soon!**" will appear, and an alarm sound will be given.
Red	Number of cuvettes bars = 0. At this moment, a warning prompt "**Run out of cuvettes!**" will appear, and an alarm sound will be given. The analyzer will report an error and shut down.

13.1.1.2 System Liquid

Different volume of system liquid show by following icon

OK	Volume of system liquid ≥ 20%.
WARNING	Volume of system liquid < 20%.
EMPTY	System liquid has run out; the analyzer reports an error and shuts down.

WARNING

1) Change the system liquid only when the analyzer has shut down. But users can connect the system liquid tank to another one with the "Continuous Loading Pipe", so that add system liquid during the analyzer working
2) Please store and use the system liquid according to the Instruction Manual provided in its package.

13.1.1.3 Starter Reagents

Different volume of starter reagents show by following icon

OK	Volume of starter 1+2 ≥ 20%.
WARNING	Volume of starter 1+2 < 20%.

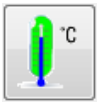
EMPTY	Starter 1+2 has run out; the analyzer reports an error and shuts down.

WARNING

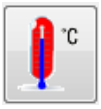
The starter 1+2 can not be exchanged when the analyzer is testing.

13.1.2 Temperature and Voltage

The status of **<Temp/Volt>** button means:



All temperatures and voltages in the analyzer are normal.



One or several temperatures or voltages in the analyzer are beyond the normal

Click **<Temp/Volt>** button to open **[System Parameter]** dialog, which shows the temperature and voltage parameters of the analyzer.

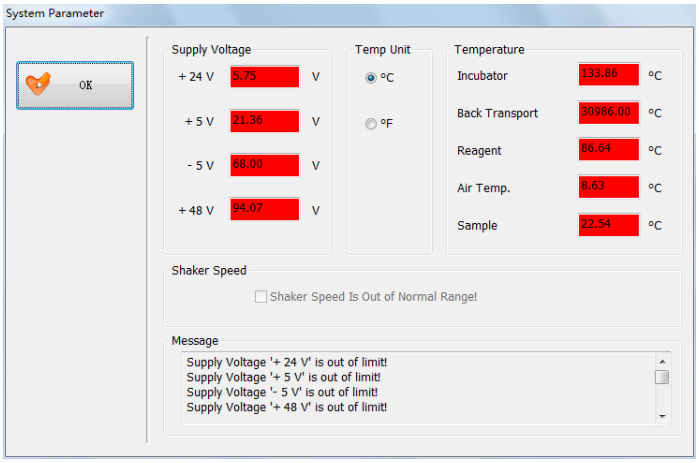


Figure 13.1-3 **[System Parameter]** Dialog

13.1.3 Waste

The status of **<Waste>** button :

The status of all kinds of waste are normal.

One or more kinds of waste is nearly full.

One or more kinds of waste have been full.

Click **<Waste>** button to open **[Waste Status]** dialog, where shows the volume of liquid in the waste liquid tank and the number of waste cuvettes in the waste bag.

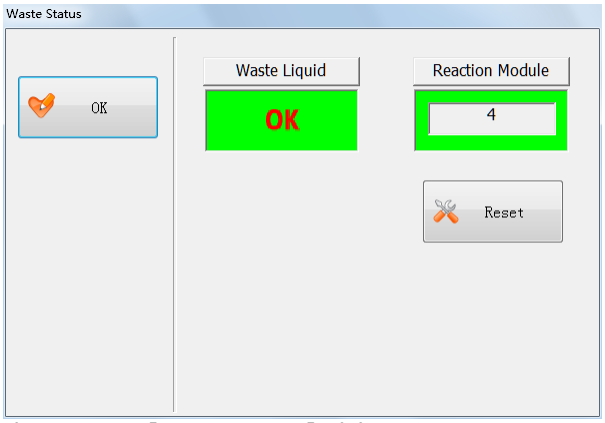


Figure 13.1-4 **[Waste Status]** Dialog

13.1.3.1 Waste Liquid

Different volume of waste liquid show by following icon

OK	Volume of liquid in the waste liquid tank≤ 80%.
WARNING	Volume of liquid in the waste liquid tank reaches 80-90%.
FULL	Volume of liquid in the waste liquid tank reaches 90-100%.

WARNING

When yellow or red appears, the system will display a warning message; in such case, please empty the waste liquid tank.

13.1.3.2 Waste Cuvettes

Green	Number of waste cuvettes bars < 60.
Yellow	60 ≤Number of waste cuvettes bars < 80.
Red	Number of waste cuvettes bars ≥80.

WARNING

When yellow or red appears, the system will display a warning message; in such case, please empty the waste bag.

13.2 Handling Consumables

When consumables are running out or waste is fulling up, the analyzer will report an error and shut down, the software interface will open **[Machine is halted]** dialog at the same time. After replenishing the consumables and clearing away waste, click **<Continue>** button to continue the assay (The cuvette loader component need initialize).

13.2.1 Placing Cuvette

The cuvette loader is located on the left of the analyzer. In case of an alarm or error report, open the flip in front of the analyzer and add cuvettes.

Figure 13.2-1 Placing Cuvette

Operation Steps:

1. Unpack the cuvettes as instructed, and take out a layer of (8) cuvettes bars.
2. Place the cuvettes on the conveyor belt along the proper direction.
3. The conveyor belt will automatically transfer the cuvettes to the top of the cuvette loader.
4. When the conveyor belt stops, users can continue adding cuvettes.
5. Repeat the above steps until the cuvette loader becomes full; the stacker can hold 40 cuvettes bars at most.

Cuvettes can be added at any time when the analyzer is running.

NOTE

1) Pay attention to the remaining number of cuvettes during assay!
2) The cuvette loader should be emptied once a week to ensure cleanness of cuvettes.

13.2.2 Adding System Liquid

System liquid is connected at the right side of the analyzer. **"System liquid"** is used for cleaning pipette, system pipe and magnetic microbeads. The volume of system liquid is detected by the level detector, and shown with the "Warning Light" of **<Consumables>** icon on the main menu. Click <**Consumables>** button to open [**Reservoir Status]** window. The displayed information includes the stock of cuvettes in the stacker, starters and system liquid.

WARNING

Make sure there is sufficient system liquid before and during operation of the analyzer!

The way of add System Liquid in standby:

1. Take the sealing cover with level detector and hose out of the corresponding bottle.
2. Add system liquid, and close the sealing cover.
3. Fill the hoses: Select <System Test> on the menu bar, and select pipettor and washer in the [System Test] dialog. Enter (3) and (6) in corresponding cycles, and click <OK> to start priming.

The way of add System Liquid in testing:

Use the "Continuous Loading Pipe" and another "System Tank" which equips with System Liquid to add system liquid during the test.

13.2.3 Change Starter Reagents

The container of starter is inside the box on the right side of the reagent area. S1 and S2 are marked on the container. The digit "S1" and "S2" represent starter 1 and starter 2, respectively. The reagent bottle is sealed with an openable screw cap. The level of starter can be detected with the level detector fixed to the cap.

WARNING

1) Make sure there is sufficient starter before operation of the analyzer!
2) The starters can not be changed when the analyzer is testing.
3) Please make sure hoses for starters 1 and 2 are connected correctly.

WARNING

1) Never pour out starters, liquid splash is not allowed in this area!
2) Never mix starter 1 and starter 2 manually.
3) Chemical burn risk! Please read the reagent instructions in the package of starter.

Operation steps:

Change starters of the same lot number：

1. Open the starter 1 and take out the connecting hose.
2. Place a new bottle of starter 1 at the corresponding position.
3. Close the screw cap.
4. Replace starter 2 according to the above steps.
5. Different numbers are marked on the connecting hose for starters. Make sure the hoses are connected correctly.
6. Fill the hoses: Select **<System Test>** on the menu bar, and select chamber in the **[System Test]** dialog. Enter (3in corresponding cycles, and click **<OK>** to start priming.

Change starters of different lot number, please do the following additional operations:

7. Background test: Select **<System Test>** on the menu bar. Change (1) Preset BGW to (1), Lc to (0), and press <**OK**> to start the BGW test.

13.2.4 Waste Cuvettes

The waste bag holder for placing waste cuvettes is positioned on the right side of the analyzer, close to the chamber. The software will automatically count the number of waste cuvettes and prompt users.
When the waste bag is full, users can take it out of the holder and seal it with a cover. Replace with a new waste bag and correctly fit in the holder. Click **<Waste>** button in status bar to open **[Waste Status]** dialog, click **<Reset>** button to reset the number of waste cuvettes.

WARNING

1) After replace the waste bag, please reset the number of waste cuvettes. Or the warning message will always remain.
2) Make sure the waste bag is placed properly; otherwise the analyzer may be disrupted as the cuvettes are stuck at the edge of the waste bag when they are pushed out of the chamber.
3) The used cuvettes must be placed in the waste bag since residual substances in the cuvettes may cause contamination. Please dispose of waste cuvettes in accordance with local laws and regulations.

13.2.5 Waste Liquid

The waste liquid port used for waste liquid are positioned on the right side of the analyzer, which are marked "Waste Liquid".

Waste liquid comes from cuvettes, pipetting system and washer during assay, including magnetic microbeads, starters, samples, reagents, and system liquids.

WARNING

1) Please wear gloves for operation!
2) Please dispose of waste liquid in accordance with local laws and regulations.
3) Please clean the waste liquid tank on a regular basis according to the Maintenance Manual.

14 Reagent Loading

14.1 Reagent Structure

All reagent basically have the following structure:

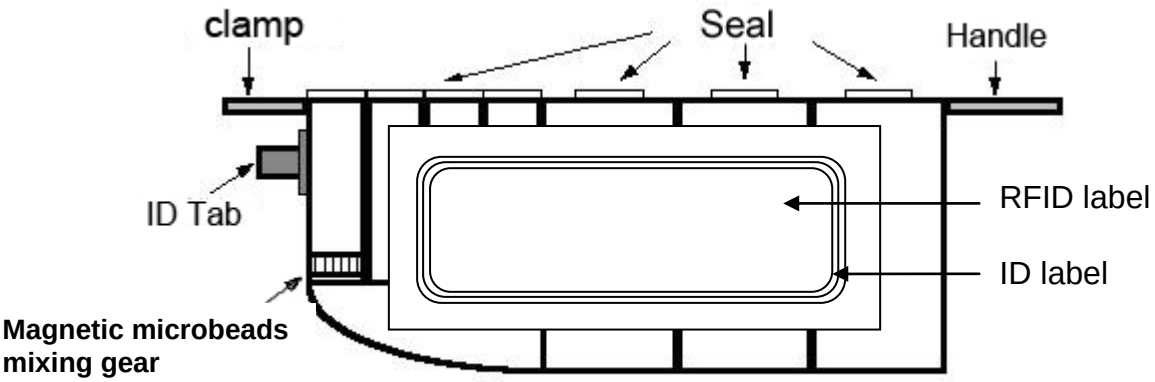


Figure 14.1-1 Reagent Structure

1. Seal is for sealing reagent. The pipetting needle enters the kit from here to absorb reagent;
2. Handle is convenient for users to hold the kit by hand;
3. The RFID label which behind the ID label records the reagent data;
4. The ID label indicates the reagent components, name, expiry date and other info of the kit;
5. The magnetic microbeads mixing gear is used in conjunction with the rocker in the reagent area to mix magnetic microbeads homogeneously;
6. ID Tab is used to block optocoupler when the reagent is inserted to the reagent area so that it can be identified;
7. Clamp is used to fix the reagent inserted to the reagent area.

14.2 Reagent Loading

14.2.1 Prepare the Reagent

Please ensure that the up and down orientations of the reagents are correct when storing; upside-down status is not allowed. Besides, please do not shake the reagent.

1. Take the reagent packaging box out of the refrigerator;
2. Take the reagent kit out of the packaging box;
3. Observe the sealing film and other parts of the reagent kit to see if there is any leakage. In case of leakage, please contact your local agent immediately;
4. Observe each component liquid of the reagent kit to see if air bubbles exist. If yes, please use a pipettor to remove the air bubbles; the reagent kit can be used after confirming that all air bubbles are eliminated;

5. Gently turn the magnetic microbeads mixing gear to make sure it can rotate freely;
6. Carefully tear off the kit sealing film;
7. Clean up liquid on the reagent kit surface to avoid cross infection.

14.2.2 Loading the Reagent

Before inserting the reagent to the reagent area, please make sure the software and the lower computer are working normally.

1. Open the reagent area door; the software will automatically display the **[Pat&Rea]-Reagents** interface;
2. Hold the reagent handle to get the RFID label close to the sensing area (for about 2s); the buzzer will beep; one beep sound indicates successful sensing;
3. Keeping the reagent straight insert to the bottom along the blank reagent track;
4. Relevant reagent data will be read out via computer software; the **[Pat&Rea]-Reagents** interface will show the reagent name, and the corresponding reagent position button will change to dark gray;
5. In case of failure to read data, please repeat the above operations;
6. After finishing reading reagent data, please close the reagent area door and exit the **[Pat&Rea]-Reagents** interface.

Figure 14.2-1 Scanning Reagent

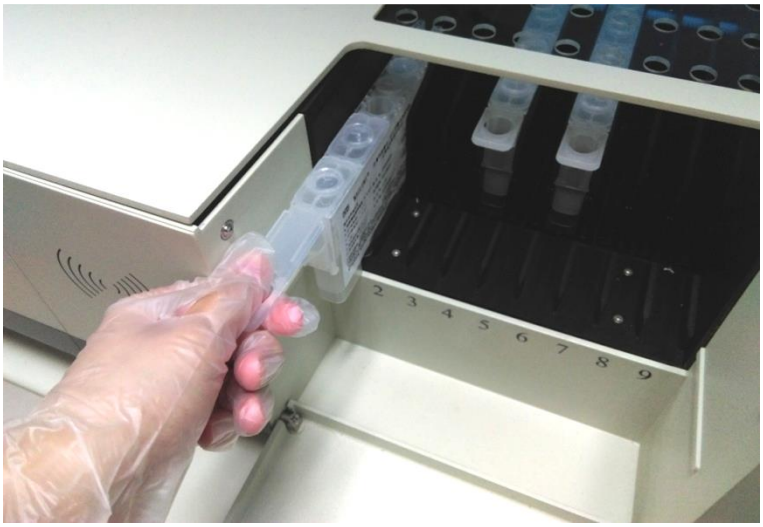


Figure 14.2-2 Inserting Reagent

14.2.3 Remove the reagent

When taking the kit out of the analyzer, users should make sure both the software and the analyzer are running normally, so as to ensure the reagent is removed in normal condition. The reagent should not be removed if there are still some assays in progress or pending for results on the analyzer (corresponding track in **[Pat&Rea]** interface should be shown in red). Otherwise the result will be an error, and may cause damage to the analyzer.

1. Open the reagent area door;
2. Hold the reagent handle to take the kit out of the reagent area;
3. Please ensure that the up and down orientations of the reagent are correct.

If the reagent is empty

4. Please properly dispose of the reagent;

If the reagent is not empty

4. Put the kit and store it in a refrigerator, ensure that the up and down orientations of the reagent are correct.

14.3 Properly Store the Reagent

1. Keep the reagent at 2-8°C with correct up and down orientations ensured;
2. If the reagent is opened, please use additional sealing film to cover each hole of the reagent in order to avoid liquid evaporation.

15 Sample Loading

15.1 Sample Rack

The sample rack specified for the analyzer has 8 sample positions, where sample tubes with or without barcode can be inserted; barcodes of sample tubes can be automatically scanned into the analyzer.

15.1.1 Structure of Sample Rack

1. Operating handle
2. Sample position barcode
3. Sample tube position
4. Rack fixing clamp

Figure 15.1-1 Sample Rack

The structure of sample rack:

1. Operating handle: is used for loading and unloading the sample rack;
2. Sample position barcode: can be used to determine the position of a sample tube;
3. Sample tube position: has a retaining clip inside to fix a sample tube ;
4. Rack fixing clamp: can be used to fix the sample rack and detect the status of sample tube..

The barcodes on the sample rack are used to determine the specific positions of sample tubes. When sample rack is inserted, the barcode detector will scan barcode info on the rack one by one; the position of each sample and other info contained in the barcode will all be displayed on the Sample Info of **[Pat&Rea]-Patients** interface.

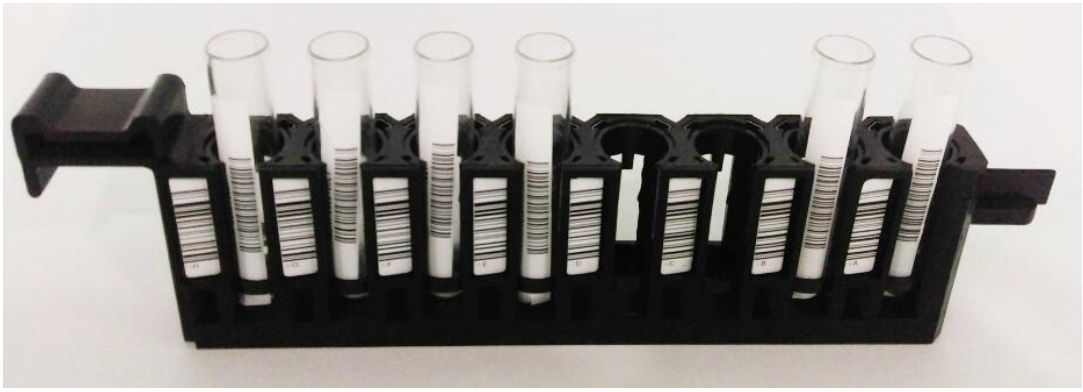


Figure 15.1-2 Sample Tube Barcodes on the Sample Rack

After the sample rack is correctly inserted to the sample reservoir, the sample info will be read.

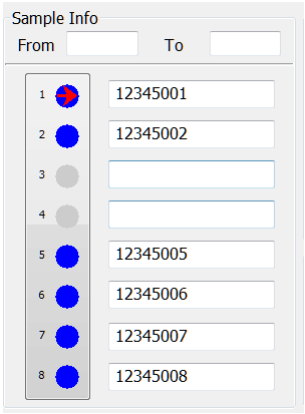


Figure 15.1-3 Sample Position Info

No. 3 & 4 sample tubes have no barcode, therefore cannot be automatically identified. If a sample is not automatically identified, users can manually edit the sample info.

15.1.2 Type of Sample Rack

The analyzer only uses one type of sample rack. Sample tubes with the inner diameter of φ8 mm~φ12 mm and the height of 60 mm~100mm can be used.

15.2 Sample Loading

WARNING

1) Please make sure the sample tube has been uncapped before pipetting; otherwise the sampling needle will get damaged.
2) In order to avoid infection, please wear gloves before operating each sample.

15.2.1 Prepare the Sample

NOTE

In case of lack or absence of sample solution, the analyzer will still show the result; therefore, when the analyzer shows a warning message such as " Needle can not detect Liquid!", retest should be performed.

The following conditions must be satisfied before measuring sample:

1. Samples include: serum, plasma, urine, whole blood;
2. Prepare anticoagulants such as EDTA and heparin;
3. The blood drawing process should be standardized; serum should be separated from blood clots;
4. If the sample contains suspended solids or is turbid, or has blood lipids or RBC fragments, filtering or centrifugation must be performed prior to test;
5. Samples with hemolysis or lipemia, or infected by microorganism, should not be used for test;
6. Please ensure the sample contains no air bubbles prior to measure.

NOTE

To ensure safety, the sample must satisfy relevant requirements and operation conditions to avoid air bubbles and blood clots!

The sample satisfying all conditions can be put in a sample tube to be inserted to the sample rack. The operation steps are described as follows:

1. Test tubes must conform to specification requirements;
2. Carefully insert each sample tube to the sample rack;
3. If barcode scanning will be performed for the sample rack, each barcode should face the opening of sample rack so that it can be read by the barcode reader.

NOTE

1) Do not revolve a sample tube with barcode in the sample rack to avoid damaging the barcode.
2) After inserting the sample rack with sample tubes to the sample area, do not change the position of sample tubes at will; otherwise test results may be in disorder.

Similar to handling of samples, each barcode of Light Check fluid provided by Snibe should face the barcode reader so that it can be read. If a sample tube is not properly inserted to the sample rack, please pull it out and reinsert it.

15.2.2 Sample Rack Loading

Please load the sample rack according to the steps below:

1. Open the door of sample area;
2. Select an empty slot to push in the sample rack;
3. Slowly insert the sample rack so that each barcode can be read effectively;
4. Make sure the sample rack is kept vertical when it is pushed in; push in the rack smoothly until the edge of sample rack is in close contact with the edge of sample area;
5. In case of barcode scanning failure, please reload the sample rack and scan the barcode.

NOTE

1) Before pushing the sample rack into the sample compartment, please make sure both the machine and the software have entered the working status. Otherwise, the sample cannot be read and subsequent operation will be invalid.
2) The barcode reader has laser radiation hazard. Please avoid looking directly at the laser beam!

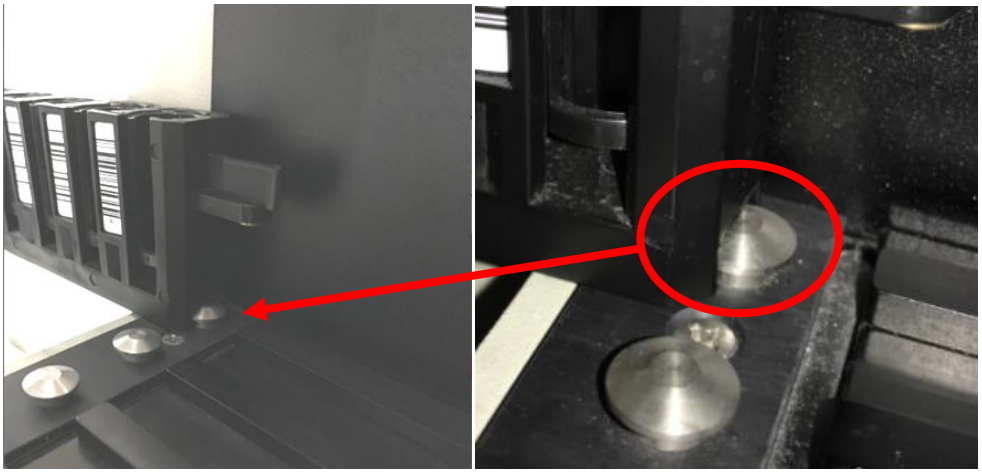


Figure 15.2-1 Fixing Sample Rack

15.2.3 Remove the Sample Rack

Before removing the sample rack, please make sure both the analyzer and the software are running normally. The sample rack to be removed should not be in active status (orange light is on); otherwise, a result error will occur and the analyzer may get damaged.

1. Open the door of sample area;
2. Grasp the rack handle with your thumb and index finger to smoothly pull the sample rack out of the sample area until the sample rack completely leaves the sample area;

If the sample tube is empty

3. Dispose of the sample tube according to relevant regulations;

If the sample tube is not empty and may be used in the future

4. Seal and store the sample properly according to relevant laboratory regulations;

15.3 Maintenance of Sample Rack

The maintenance of sample rack is necessary under the following special circumstances.

1. The rack is in direct contact with any biochemical substance.
2. A sample tube cannot be inserted to the sample rack stably.

In the first case:

1. Transfer all samples on the contaminated sample rack to another clean rack;
2. Soak the contaminated sample rack in 0.1% sodium chloride solution for 15~30min. In order to avoid corrosion of the sample rack, the duration should not exceed 30min;
3. Take out the sample rack; use a clean, dry towel to wipe it dry.

In the second case:

1. Take a ball-point pen; insert its tip below the retainer of metal plate inside the sample rack slot, as shown in Fig. 15.3-1; then, apply gentle force to make the retainer upwarp;
2. Insert a sample tube conforming to specification requirement and check if the problem is fixed;
3. If the sample tube is still loose, please repeat Step 1 and 2 until the tube can be inserted firmly.

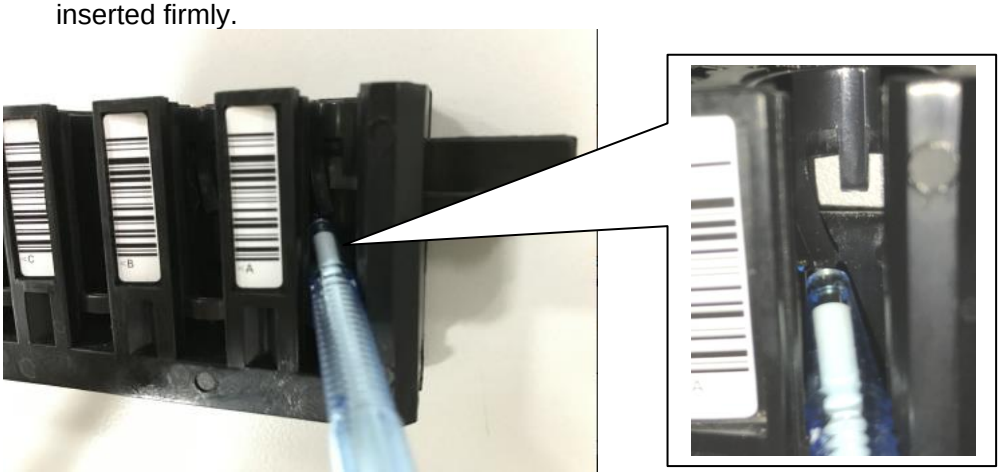


Figure 15.3-1 Adjust the Metal Dome Inside the Slot

16 LIS Interface

16.1 Description of Online Mode

This chapter describes settings of laboratory information system (LIS). Only information related to users is provided. Special settings about LIS connection and details of configuration are not covered in this manual.
LIS is now widely used for management of chemical or microbiological assays in clinical laboratories. As an external software, it forms a part of the central information processing system in clinical institutes.

16.1.1 Enable Online Mode

Maglumi 800 analyzer operates under different modes. In order to activate the online mode, the user must set up the operating mode first.

Click **<System>** button in the main menu to enter **[System]** menu. Click **<Setting>** button to enter **[Setting] i**nterface; select **"Mode"** tab to show **[Mode]** interface.

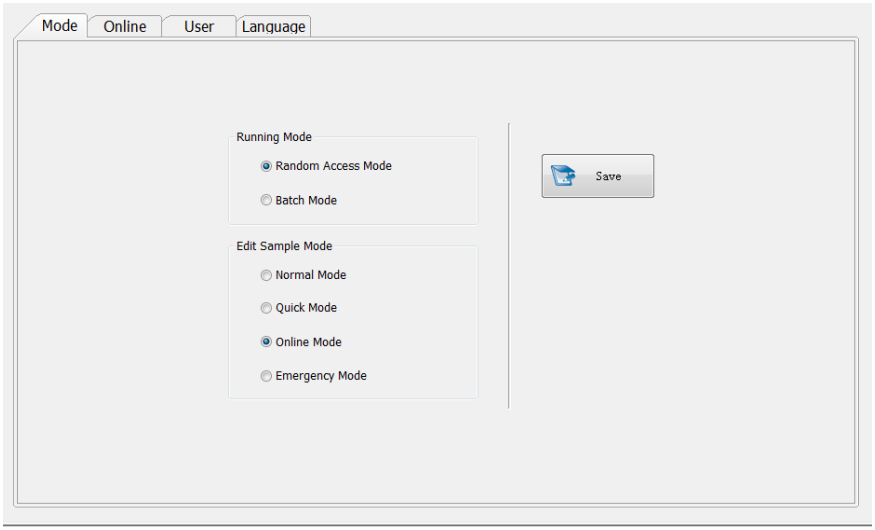


Figure 16.1-1 **[Mode]** Interface

The software cannot connect to **LIS** until the **Online Mode** is selected. After selecting the **Online Mode**, click the **<Save>** button to confirm.

16.1.2 Setting Parameters of Online Mode

Click **"Online"** tab in **[Setting]** interface to enter **[Online]** interface, where you can set the parameters related to LIS.

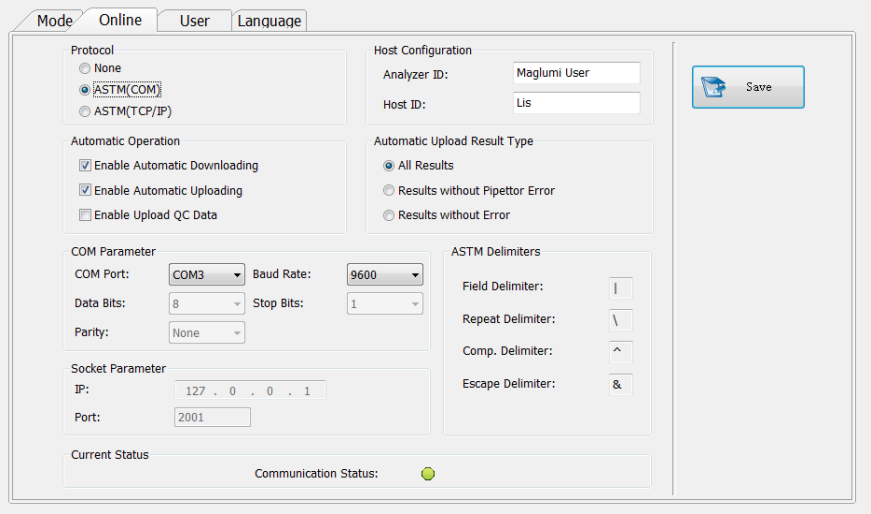


Figure 16.1-2 **[Online]** Interface

The following options are provided in the **[Online]** interface:

1. Protocol

None	Do not connect to hospital's LIS.
ASTM (COM)	Communicate with the hospital's LIS server with ASTM (COM) protocol.
ASTM (TCP/IP)	Communicate with the hospital's LIS server with ASTM (TCP/IP) protocol.

2. Host Configuration

Analyzer ID	Enter the name of the analyzer that communicates with the hospital's LIS.
Host ID	Enter the name of the hospital's LIS.

3. Automatic Operation

Enable Automatic Downloading	Enable the analyzer to automatically download the test information of the sample from hospital's LIS.
Enable Automatic Uploading	Enable the analyzer to automatically upload the results of the sample to hospital's LIS server.
Enable Upload QC Data	Enable the analyzer to automatically upload the results of QC to hospital's LIS server.

4. Automatic Upload Result Type

All Results	Enable the analyzer to upload all test results to hospital's LIS.
Results without Pipettor Error	Enable the analyzer to upload all results without pipettor error to hospital's LIS.
Results without Error	Enable the analyzer to upload all results without any analyzer error to hospital's LIS server.

5. COM Parameter

COM Port	Select the serial number of the COM Port that communicates with hospital's LIS.
Baud Rate	Select the Baud rate for communicating with hospital's

	LIS.
Data Bits	Display the data bits for communicating with the hospital's LIS.
Stop Bits	Display the stop bits for communicating with the hospital's LIS.
Parity	Display the parity bits for communicating with the hospital's LIS

6. Socketet Parameter

IP	Select the IP address for communication with hospital's LIS.
Port	Select the port No. for communication with hospital's LIS.

7. ASTM Delimiters

Field Delimiter	Display the field delimiter for communicates with hospital's LIS.
Repeat Delimiter	Display the repeat delimiter for communicating with hospital's LIS.
Comp. Delimiter	Display the component delimiter for communicating with the hospital's LIS.
Escape Delimiter	Display the escape delimiter stop bits for communicating with the hospital's LIS

8. Current Status

Communication Status	Display the status of current communication.

Click **<Save>** button to save parameters. The software is ready for communicating with **LIS**.

16.1.3 Methods of Sending Results

After sample is tested, the user can send the results to remote host through the following methods:

1. **Manually send validated results**

After the results are validated on analyzer, they can be manually sent to the host in **[Valid]**. Click the **<Valid>** button in **[Report]** menu to enter **[Valid]** interface. Click the **<Online>** button in the **[Valid]** interface to send the validated results to LIS.

2. **Manually send results before validation**

The results are manually sent to and validated on the remote host, instead of validated on the analyzer. Click the **<Journal>** button in **[Report]** menu to enter **[Journal]** interface. Click the **<Online>** button to send the results to LIS before validation.

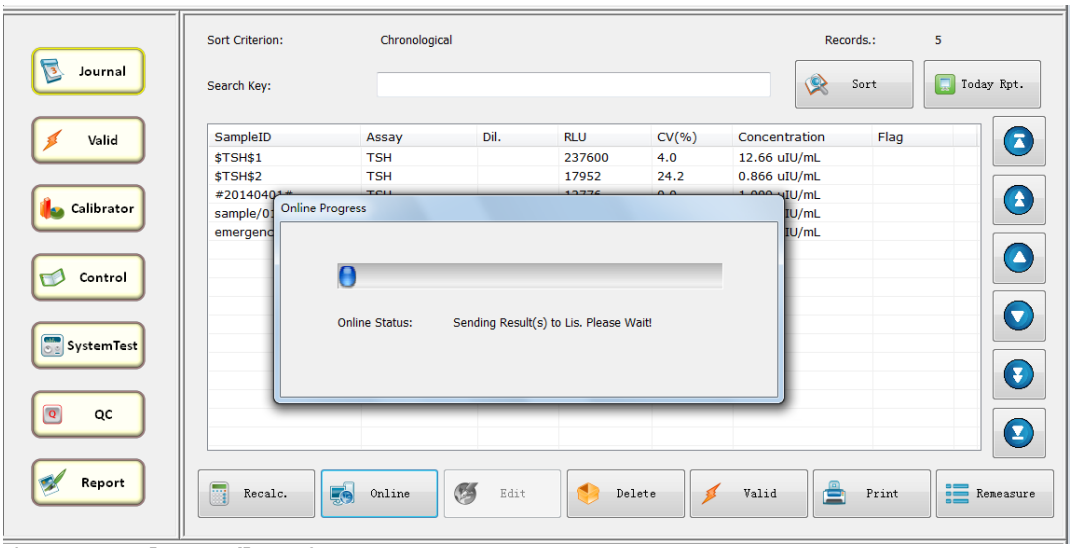


Figure 16.1-3 **[Journal]** Interface

3. **Automatically send results before validation**

The results are automatically sent to and validated on the remote host, instead of validated on the analyzer. When **Enable automatic uploading** is selected, each result obtained in the process of test will be sent to LIS.

If the software fails to send all results to LIS, the user can manually send the results again to LIS.

16.2 Instruction on Control Codes

The software employs ASTM E1394 protocol for communication. All communication information between the software and LIS is stored in the directory \online\log.

Table 16.2-1 Instruction on Control Codes

Character	Meaning	Corresponding ASCII
<ENQ>	Request	0x05
<ACK>	Confirm Response	0x06
<STX>	Start	0x02
<ETX>	End	0x03
<CR>	Home key	0x0D
<EOT>	End Transmission	0x04

16.3 Instruction on Basic Communication Format

Example:
<ENQ><STX>TEXT< ETX ><EOT>

Table 16.3-1 Instruction on Basic Communication Format

Character	Meaning	Corresponding ASCII
<ENQ>	Request	0x05
<STX>	Start	0x02
T	Letter T	0x54
E	Letter E	0x45
X	Letter X	0x58
T	Letter T	0x54
<ETX>	End	0x03
<EOT>	End Transmission	0x04

16.4 Instruction on Delimiters

There are 4 delimiters defined in ASTM E1394, which are used for separating contents of communication. See section 6.4 of E1394 for details. Meaning of each delimiter is shown in the following table:

Table 16.4-1 Instruction on Delimiter

Delimiter	Meaning	Corresponding ASCII
<CR>	Home key	0x0D
|	Field Delimiter	0x7C
\	Repeat Delimiter	0x5C
^	Comp. Delimiter	0x5E
&	Special Delimiter	0x26

16.5 Instruction on Type of Message

Table 16.5-1 Instruction on Type of Message

Message Identifier	Meaning
H	Message head record
P	Patient info record
O	Assay item record
R	Result record
Q	Info required record
L	Message end record

16.5.1 Message head record (H)

Instruction:
Contents in this section are corresponding to section 7 of ASTM E1394.
Message head record is placed in the front of all transmitted records. It is used to describe basic information of some protocols and transmission.

Examples：
H|\^&||PSWD|Maglumi|||||Lis||P|E1394-97|20100323<CR>

Table 16.5-2 Message Head Record

Field	E1394	Name of ASTM Field	Content	Maximum Length	Required or Not
1	7.1.1	Type of message	H	1	Yes
2	7.1.2	Delimiter definition	| \ ^ &	4	Yes
4	7.1.4	Password	PSWD	20	No
5	7.1.5	Name of transmitter	Maglumi	20	Yes
10	7.1.10	Name of receiver	Lis	20	Yes
12	7.1.14	Mode of processing	P	1	Yes
13	7.1.13	Protocol Version No.	E1394-97	10	Yes
14	7.1.14	Date	YYYYMMDD	14	Yes

NOTE

1) There are 14 fields in the protocol, but only the fields required by this software are listed here. Other fields can be added in actual communication process and automatically recognized by the software. If there is blank field, use the delimiter "|" to separate fields as shown in the example.
2) "<CR>" at the end of a message record is required, and this delimiter shall be added to the end of each message record for indicating the end of the record.

16.5.2 Patient Info Record (P)

Instruction:
Contents in this section are corresponding to section 8 of ASTM E1394.
Information of each patient shall be described by this record.

Examples:
P|1||||ABC|||F <CR>

Table 16.5-3 Patient Info Record

Field	E1394	Name of ASTM Field	Content	Maximum Length	Required or Not
1	8.1.1	Type of message	P	1	Yes
2	8.1.2	Serial No.	1	6	Yes
6	8.1.6	Name of Patient	ABC	30	No
9	8.1.9	Sex	M,F,U	1	No

NOTE

1) Only the first and second fields are required. In the software, this record is normally in following format: P|1 <CR>.
2) There are 35 fields in the protocol, but only the fields required by this software are listed here. Other fields can be added in actual communication process and automatically recognized by the software.
3) "<CR>" at the end of a message record is required, and this delimiter shall be added to the end of each message record for indicating the end of the record.

16.5.3 Assays Record (O)

Instruction:
Contents in this section are corresponding to section 9 of ASTM E1394.
Assays of each test shall be described by this record.

Examples:
O|1|1234567||^^^TSH|R<CR>

Table 16.5-4 Assays Record

Field	E1394	Name of ASTM Field	Content	Maximum Length	Required or Not
1	9.1.1	Type of message	O	1	Yes
2	9.1.2	Serial No.	1	6	Yes
3	9.1.3	Sample No.	1234567	22	Yes
5	9.1.5	Assays	^^^TSH	30	Yes
6	9.1.6	Priority	S,R	1	Yes

NOTE

1) "^^^" in the front of the fifth field "Assays" are required, and the following TSH is the project name.
2) In the sixth field "Priority", S means emergency, R means regular. R is used by default.
3) There are 31 fields in the protocol, but only the fields required by this software are listed here. Other fields can be added in actual communication process and automatically recognized by the software.
4) <CR> at the end of a message record is required, and this delimiter shall be added to the end of each message record for indicating the end of the record.

16.5.4 Result Record (R)

Instruction:
Contents in this section are corresponding to section 10 of ASTM E1394.
Each result shall be described by this record.
Examples:
R|1|^^^TSH|4.3|μIU/mL |0.3 to 4.5|N|||||20160326172956<CR>

Table 16.5-5 Result Record

Field	E1394	Name of ASTM Field	Content	Maximum Length	Required or Not
1	10.1.1	Type of message	R	1	Yes
2	10.1.2	Serial No.	1	5	Yes
3	10.1.3	Assay record	^^^TSH	10	Yes
4	10.1.4	Result	4.3	12	No
5	10.1.5	Unit	μIU/mL	10	No
6	10.1.6	Reference range	0.3 to 4.5	30	No
7	10.1.7	Result flag	L,H,N	1	No
13	10.1.13	Test finish time	YYYYMMD DHHMMSS	14	No

NOTE

1) "^^^" in the front of the third field "Assays" are required, and the following TSH is the project name.
2) In the seventh field "Result flag", L means lower than normal, H means higher than normal, and N is normal.
3) There are 14 fields in the protocol, but only the fields required by this software are listed here. Other fields can be added in actual communication process and automatically recognized by the software.
4) <CR> at the end of a message record is required, and this delimiter shall be added to the end of each message record for indicating the end of the record.

16.5.5 Info Required Record (Q)

Instruction:
Contents in this section are corresponding to section 12 of ASTM E1394.
It is used to request information on assays corresponding to the sample.

Examples:
Q|1|^1234567||ALL|||||||O<CR>

Table 16.5-6 ENQ Info Record

Field	E1394	Name of ASTM Field	Content	Maximum Length	Required or Not
1	12.1.1	Type of message	Q	1	Yes
2	12.1.2	Serial No.	1	6	Yes
3	12.1.3	Sample No.	^1234567	22	Yes
5	12.1.5	Assay record	ALL	10	Yes
13	10.1.13	Required info status	O	1	Yes

NOTE

1) "^" in the front of the third field "Sample No." is required, and the following 1234567 is the sample number.
2) There are 13 fields in the protocol, but only the fields required by this software are listed here. Other fields can be added in actual communication process and automatically recognized by the software.
3) <CR> at the end of a message record is required, and this delimiter shall be added to the end of each message record for indicating the end of the record.

16.5.6 Message End Record (L)

Instruction:
Contents in this section are corresponding to section 13 of ASTM E1394.
It is used as the last piece of all transmitted records, indicating completion of transmission.

Examples:
L|1|N<CR>

Table 16.5-7 Message end record

Field	E1394	Name of ASTM Field	Content	Maximum Length	Required or Not
1	13.1.1	Type of message	L	1	Yes
2	13.1.2	Serial No.	1	6	Yes
3	13.1.3	Termination code	N	1	Yes

NOTE

<CR> at the end of a message record is required, and this delimiter shall be added to the end of each message record for indicating the end of the record.

16.6 Example

16.6.1 Enquiring Assay

User inserts a sample rack into the sample area, after the sample barcode is scanned by the analyzer, the software requests for assay info from **LIS** with the following message.

Message Content:

```
--><ENQ>
<--<ACK>
--><STX>
<--<ACK>
-->H|\^&||PSWD|Maglumi 800|||||Lis||P|E1394-97|20100323<CR>
Q|1|^1234567||ALL|||||||O<CR>
L|1|N<CR>
<--<ACK>
--><ETX>
<--<ACK>
--><EOT>
<--<ACK>
```

Table 16.6-1 The Meaning of Characters

Character	Meaning	Corresponding ASCII
-->	Software sending	
<--	Software receiving	
<ENQ>	Request	0x05
<ACK>	Confirm Response	0x06
<STX>	Start	0x02
<ETX>	End	0x03
<CR>	Home key	0x0D
<EOT>	End Transmission	0x04

Therein:

```
H|\^&||PSWD|Maglumi 800|||||Lis||P|E1394-97|20100323<CR>
Q|1|^1234567||ALL|||||||O<CR>
L|1|N<CR>
```

In ASTM E1394 protocol, this message is used to request reagent information corresponding to the sample. In the previous example, the reagent corresponding to the sample 1234567 is requested.

NOTE

1) <ACK> in above example is returned by LIS, and corresponding <ACK> command must be sent in specified position; otherwise this software deems that LIS is disconnected.
2) Upon receiving this content, LIS must return assay info.

16.6.2 Returning Assays

After LIS receives assay request from the software, it must return information on assays.

Message Content:

```
<--<ENQ>
--><ACK>
<--<STX>
--><ACK>
<--H|\^&||PSWD|Maglumi 800|||||Lis||P|E1394-97|20100319<CR>
P|1<CR>
O|1|1234567||^^^TSH|R<CR>
L|1|N<CR>
--><ACK>
<--<ETX>
--><ACK>
<--<EOT>
--><ACK>
```

The meaning of characters is the same to Table 16.6-1.

Therein:

```
H|\^&||PSWD|Maglumi 800|||||Lis||P|E1394-97|20100319<CR>
P|1<CR>
O|1|1234567||^^^TSH|R<CR>
L|1|N<CR>
```

In ASTM E1394 protocol, this message is used by LIS to return information on assays corresponding to the sample.
In the previous example, the LIS returns assays, i.e. reagent TSH for the sample 1234567.

NOTE

<ACK> in above example is returned by LIS, and corresponding <ACK> command must be sent in the position specified; otherwise this software deems that LIS is disconnected.

16.6.3 Sending Assay Results

```
--><ENQ>
<--<ACK>
--><STX>
<--<ACK>
-->H|\^&||PSWD|Maglumi 800|||||Lis||P|E1394-97|20100326<CR>
P|1<CR>
O|1|1234567||^^^TSH<CR>
R|1|^^^TSH|4.3|μIU/mL|0.3 to 4.5|N||||||20100326172956<CR>
L|1|N<CR>
<--<ACK>
--><ETX>
<--<ACK>
--><EOT>
<--<ACK>
```

The meaning of characters is the same to Table 16.6-1.

Therein:

```
H|\^&||PSWD|Maglumi 800|||||Lis||P|E1394-97|20100326<CR>
P|1<CR>
O|1|1234567||^^^TSH<CR>
R|1|^^^TSH|4.3|μIU/mL |0.3 to 4.5|N||||||20100326172956<CR>
L|1|N<CR>
```

In ASTM E1394 protocol, this message is used to send assay results to LIS. In the previous example, the software transmits results of the reagent TSH corresponding to the sample 1234567 to LIS.

NOTE

<ACK> in above example is returned by LIS, and corresponding <ACK> command must be sent in the position specified; otherwise this software deems that LIS is disconnected.

17 System Maintenance

17.1 Daily Maintenance

Materials needed:
Clean waste bag, clean cotton cloth.

Maintenance Process:

1. Use the clean cotton cloth to clean the analyzer surface;
2. Empty the waste bag to remove cuvettes and replace a clean waste bag; empty the waste liquid container;
3. Check the volume of starters; if not enough for use of the next day, please replenish or change it;
4. Check the volume of system liquid; if not enough for use of the next day, prepare a new system liquid to have ready;
5. Perform the "**Priming for All**" function once.

17.2 Weekly Maintenance

Materials needed:
Cotton swabs, alcohol

Maintenance Process:
Use cotton swabs dipped in alcohol to clean the outer walls of pipette needle, washer's injecting needle and aspirating needle; then perform the "**Priming for All**" function twice.

17.3 Monthly Maintenance

Materials needed:
160 ml 84 disinfectant, purified water, System Tubing Cleaning Solution, Light Check Liquid

Maintenance Process:

1. Use 40℃ purified water to replace starters, and perfuse the chamber 30 times; then replace the water with starters, and perfuse the chamber 10 times;
2. Use System Tubing Cleaning Solution to perform the "**Wash Pipe**" function once;
3. Empty the System Liquid Tank and the waste liquid Tank; clean them with 80mL 84 disinfectant + 2L purified water respectively, and empty the tanks; then use purified water (2L each time) to clean the System Liquid Tank five times; last replace the water with System Liquid to perfuse the pipettor and the washer 30 times each;
4. Place the Light Check Liquid at the upper right corner of the sample compartment; perform BGW and LC once; view the results and make records thereof;
5. Requirements on system test results:
   1) BGW: RLU is 100-1200, CV ≤ 10%;
   2) LC: RLU is 450000-650000, CV ≤ 3%;
      Please refer to the LC Reagent Manual of the specific expected value.

17.4 Extended Shuntdown-System Idle 5 Days or More

If users don't use the analyzer for 5 or more day, the following steps should be completed:

1. Replace the Starter 1+2 bottles with the two bottles of purified water.
2. Replace the system liquid tank with a tank of purified water.
3. Click **<System Test>** button in menu bar, select Pipettor, Washer and Chamber, the cycles is 30, 20 and 10 respectively.

When using the analyzer again, the following steps should be completed:

1. Remove the purified water bottles and the purified water tank. Click **<System Test>** button in menu bar, select Pipettor, Washer and Chamber, the cycles is 30, 20 and 10 respectively.
2. Place two bottles of Starter 1+2.
3. Place a tank of system liquid.
4. Click **<System Test>** button in menu bar, select Pipettor, Washer and Chamber, the cycles is 30, 20 and 10 respectively. And system test results must meet the requirements.

18 Troubleshooting and Diagnostics

18.1 Manage of System Info and Error Messages

All system info and error messages are stored in a list of system database. Technical service staff and users are able to obtain summary of all system info from there. This is helpful for understanding the causes and solution of errors.
The current system info and error messages are displayed on the lower left corner of the main menu. By clicking this dialog box, you can obtain the following **[Message Box].**

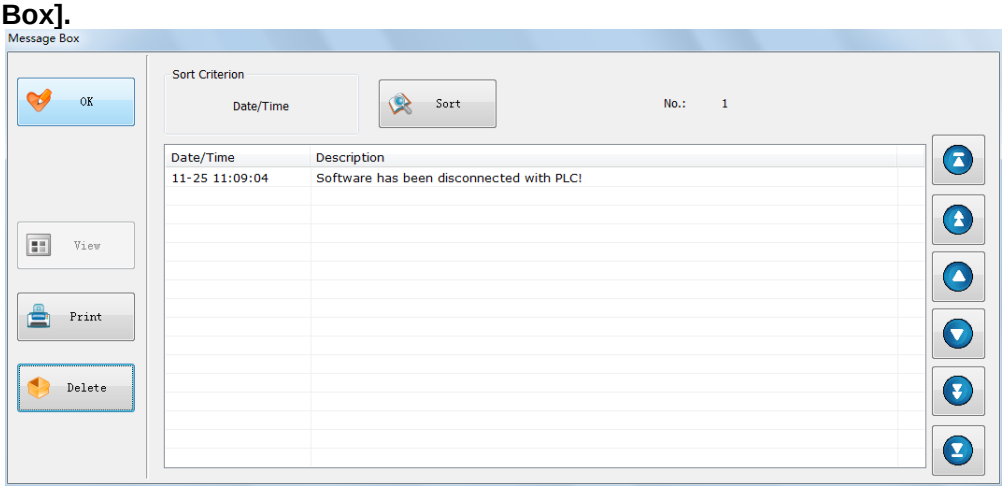


Figure 18.1-1 **[Message Box]** Dialog for Error Message

1. **Each message includes the following information(from left to right):**
   - **Date/Time:** The date and time when the error appears;
   - **Description:** The description of system info and error message.

2. **Sort Criterion:** Display the current sorting order, include date/time, error code.

3. **<Sort>**
   Click the **<Sort>** button to open **[Sort Criterion]** dialog, and select error ordering principle.

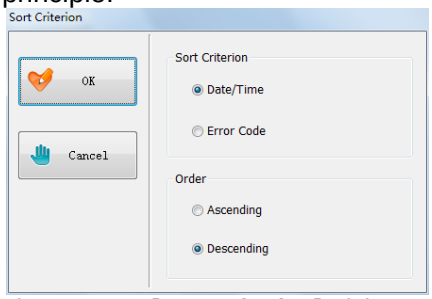


Figure 18.1-2 **[Sort Criterion]** Dialog

Sort criterion of error:
- **Date/Time:** Sort by the date and time when the error appears;
- **Error Code:** Sort by the number of error code;
- **Ascending:** Sort by ascending;
- **Descending:** Sort by descending.

The selected assay is represented by symbol . Click the **<OK>** button to return to the **[Message Box]**, and error will be displayed in the selected order.

4. **No. :** The number of error messages,

5. **<View>**
Select an error and message and click the **<View>** button to enter **[Detailed log View]** dialog which contains additional information.

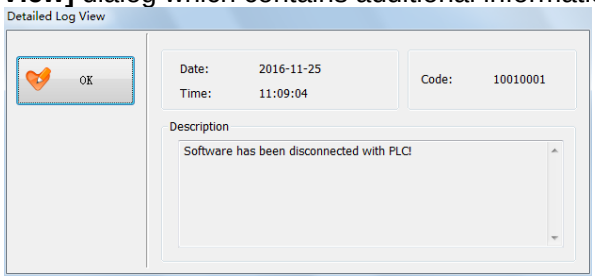


Figure 18.1-3 **[Detailed log View]** Dialog

Click the **<OK>** button to return to the **[Message Box]** dialog.

6. **<Print>**
Click the **<Print>** button to enter **[Printout Selection Dialog]**; select the errors to be printed in segment area.

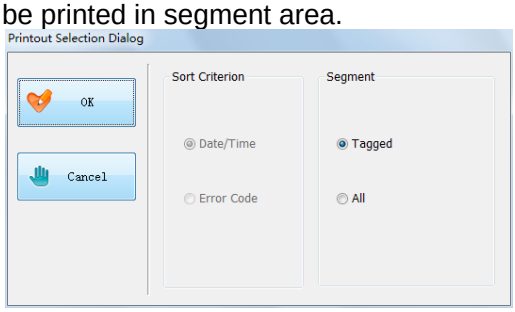


Figure 18.1-4 **[Printout Selection Dialog]**

Segment::
- **Tagged:** The selected errors will be printed;
- **All**: All errors will be printed;

Click the **<OK>** button to return to **[Message Box]** dialog; the errors meeting the selected conditions will be printed.

7. **<Delete>**
Click the **<Delete>** button to enter **[Delete Selection Dialog]**; select the errors to be deleted in segment area.

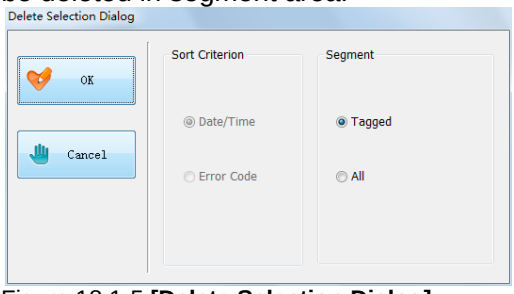


Figure 18.1-5 **[Delete Selection Dialog]**

Segment::
- **Tagged:** The selected errors will be printed;
- **All**: All errors will be printed;

Click the **<OK>** button to return to **[Message Box]** dialog; the errors meeting the selected conditions will be deleted.

18.2 Emergency Stop

1. Automatic halt

When any mechanical failure occurs, the analyzer automatically halts and pops up [Machine is Halted] debugging dialog box. If there is no operation in the software within 10 seconds, the failed component is initialized automatically and the [Machine is Halted] dialog box is closed. If the initialization succeeds, the analyzer will continue to work; if the initialization fails, the analyzer halts again with the [Machine is Halted] dialog opened, and automatic initialization will not be carried out again.

2.Manual halt

When the  button in the menu bar is clicked, the analyzer will suspend work and open the **[Machine is Halted**] dialog.

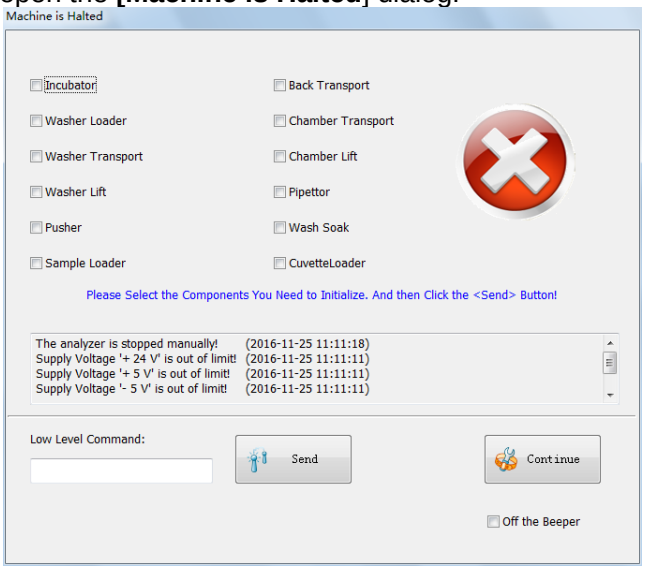


Figure 18.2-1 **[Machine is Halted]** Dialog

Incubator	Incubator.
Washer Loader	The loader that transports the cuvette from the incubator to the washer.
Washer Transport	The rack that moves the cuvette in the washer.
Washer Lift	The washing component with injecting needle and aspirating needle for washing the cuvette.
Pusher	The mechanism transporting the cuvette to the back transport or the chamber.
Sample Loader	The loader transporting the cuvette to the pipetting area from cuvette loader.
Back Transport	The mechanism transporting the cuvette to the right pipetting area.
Chamber Transport	The component that moves the cuvette in the chamber.
Chamber Lift	The mechanism with sprayer and probe in the chamber for injecting starter reagents.
Pipettor	The mechanism for finishing sample and reagent pipetting.
Wash Soak	The peristaltic pump that is connected to washer aspirating needle for extracting liquid in cuvette.
Cuvette Loader	Used for storing cuvettes.

Low-Level Command	The command for controlling motion of singular component.
<Send>	Used for sending Low-Level commands.
<Continue>	Used for sending error recovery command to make the analyzer continue to work after any error occurs.

When a mechanical failure occurs, the analyzer also triggers audio alarm in addition to displaying error message. You can check the option “off the Beeper“ to block audio alarm triggered by a certain error.

18.3 Common Problems

Problems	Possible Reasons	Self-Check	Solution
Abnormal System Test Results: CV and/or RLU out of range	Expired system liquid, poor water quality or improper preparation of system liquid	Check system liquid is too thick, check filth inside the wash tank or check the distilled water conductivity >2μs/cm or not	Clean the wash tank following monthly maintenance, apply distilled water with conductivity <2μs/cm; Make system liquid following the instruction of insert.
	Abnormal injection of washer needle	Check the injection volume of 3 pairs of injection needles, see if there is any tubing tangle, air leakage or whether fixing screws of magnetic valve are loose	Contact technical support
	Abnormal soaking Washer peristaltic pump or blocking in washer needles	Check whether the flow speed of the waste tubes is too low or not	Contact technical support
	Contamination inside Chamber or detection window blurred	Check if there are liquid or crystal inside chamber	Contact technical support
	The abnormal injection of Starter pump	Check the remaining starters, if there is any strange noise while the starter pumps are working, whether the starter tubes are bent or retracted	Contact technical support
	PMT failure	Check BGW result	Contact technical support
	long time using without maintenance	Check tubing system, if there are dirty or aging	Use Tube cleaning solution to clean tubing system
	Expired starters	Check starter expire date, make sure the storing is under desired condition	Change new starters

Problems	Possible Reasons	Self-Check	Solution
High CV of light check	Water quality	Check the distilled water conductivity >2μs/cm or not	Apply distilled water conductivity <2μs/cm
	Abnormal coordination of pipette needle	Check Coordination	Contact technical support
	air leakage within pipetting system	Check if there is drop or bubble at the tip of need after washing；bubbles within pipetting system；leakage or crystal at junction	Check any leakages at junction； Check remaining system liquid； Check wash position of washing； Re-priming after above checkings, Contact technical support if still leakage
	Sample pump，Washer pump or related valve failure	Check warming massage：Initial failed or any liquid leakage or ejection within tubing system	Contact technical support
	Liquid level detection error or suction failure	The results are nearly zero	Contact technical support
	Dirty or damaged pipetting needle	Check if there are crystals on the surface or needle or the Teflon layer damaged	Wipe pipett needle if dirty, Contact technical support to replace if damaged
	Contamination inside Chamber or detection window blurred	Check if there are liquid or crystal inside chamber	Contact technical support
	Abnormal injection of Starter pump	Check the remaining starters, if any strange noise while working, any bent or retracted happened	Contact technical support
	PMT failure	Check BGW result	Contact technical support
	Long time using without maintenance	Check tubing system, if there are dirty or aging	Use Tube cleaning solution to clean tubing system

Problems	Possible Reasons	Self-Check	Solution
Test results with high CV	Expired system liquid, poor water quality or improper preparation of system liquid	Check system liquid is too thick, check filth inside the wash tank or check the distilled water with conductivity >2μs/cm or not	Clean the wash tank following monthly maintenance, apply distilled water with conductivity <2μs/cm; Make system liquid following the instruction of insert.
	Air leakage within pipetting system	Check if there is drop or bubble at the tip of need after washing；bubbles within pipetting system；leakage or crystal at junction	Check any leakages at junction； Check remaining system liquid； Check wash position of washing； Re-priming after above checkings, Contact technical support if still leakage
	Sample pump，Washer pump or related valve failure	Check warming massage：Initial failed or any liquid leakage or ejection within tubing system	Contact technical support
	Liquid level detection error, suction failure on sample or reagent	Check recent results, if there are RLU extremely high or low	Contact technical support
	Dirty or damaged pipetting needle	Check if there are crystals on the surface or needle or the Teflon layer damaged	Wipe pipetting needle if dirty, Contact technical support to replace if damaged
	Abnormal injection of washer needle	Check the injection volume of 3 pairs of injection needles, see if there is any tubing tangle, air leakage or whether fixing screws of magnetic valve are loose	Contact technical support
	Abnormal soaking Washer peristaltic pump or blocking in washer needles	Check whether the flow speed of the waste tubes is too low or not	Contact technical support
	Dirty or damaged washer needle or incorrect washer position not	Check the surface of needles: if there are crystals or the Teflon layer damaged Check if the washer lift injection position too low or suction position too high	Wipe pipetting needle if dirty, Contact technical support
	The Chamber or glass window contaminated	Check if have any crystal or liquid in chamber	Contact technical support
	Starter injection volume inaccuracy	Check the Starter injection volume, Starter pump, and the Starter tube	Contact technical support
	PMT failure	Check the BGW result	Contact technical support

	Long time using without maintenance	Check tubing system, if there are dirty or aging	Use Tube cleaning solution to clean tubing system
	Bubble or others in sample or reagent	Visual inspection	Remove bubble
	Sample centrifuge insufficient	Visual inspection	Centrifuge in a proper condition
	Sample tube loaded in rack improper	Visual inspection	Make the tube touch the bottom of the sample rack

Problems	**Possible Reasons**	**Self-Check**	**Solution**
Cross-Contamination	Probe not clean enough	Check the sample needle position and the contamination outside	Adjust the sample needle position correctly and clean the probe
	Diluter pump, washer pump or valve abnormal	Check the historical alarm information about the peristaltic pump initialization, check the pump damaged or leakage or not	Contact technical support
	Probe contaminated or damaged	Check any crystal or Teflon breakage outside of probe	Clean the probe or ask after-sales to replace it
	Wash Concentration expired; storage, the dilute ratio or water improper	Check the Wash Concentration and tank contaminated or not. Check the *specific conductance* of pure water less than 2μs/cm or not.	Clean the System Liquid Tank, dilute system liquid by pure water(<2μs/cm)
	The volume of the Washer injection abnormal	Check all the Washer injection volume, injection tubes and the tighten of valves	Contact technical support
	Peristaltic pump abnormal or waste needle of Washer stuck	Check the flow speed of liquid in waste tube	Contact technical support
	Needles of Washer contaminated, damaged or in incorrectly position	Check whether the needles in Washer contaminated or damaged; check the position of washer lift	Clean the needles in Washer or contact after-sales
	Chamber or the glass window of chamber lift contaminated	Check if have any crystal or liquid in chamber and chamber lift	Contact technical support
	Sample contaminated during the transport or other analyzer	None	Split sample to test or prior at Maglumi system

Problems	Possible Reasons	Self-Check	Solution
Low RLU on sample （even 0）	Liquid level detection error or suction failure; didn't add any sample or reagent	Check the recent results, especially too high or too low RLU sample	Contact technical support
	Sample insufficient	Visual inspection	Add sample
	Starter pump injection abnormally	Check the Starter injection volume, Starter pump and Starter tubes abnormal or not	Contact technical support
	PMT abnormal	Check the Background in Service	Contact after-sales
	Calibration improper, or not validate the calibration curve	Check the Calibration result abnormal or not	Recalibrate or confirm it
High RLU on sample	Sample concentration exceed assay range	None	Dilute
	Wash Concentration expired; storage, the dilute ratio or water improper	Check the Wash Concentration and tank contaminated or not. Check the *specific conductance* of pure water less than 2μs/cm or not.	Clean the System Liquid Tank, dilute system liquid by pure water(<2μs/cm)
	Washer injection abnormal	Check all the Washer injection volume, injection tubes and the tighten of valves	Contact technical support
	Peristaltic pump abnormal or waste needle of Washer stuck	Check the flow speed of liquid in waste tube	Contact technical support
	Needles of Washer contaminated, damaged or in incorrectly position	Check the needles in Washer contaminated or damaged, and the position of washer lift	Clean the needles or contact after-sales
	Light leakage of chamber	Check the RLU of other samples in same batch abnormal or not	Contact technical support
	PMT abnormal	Check the Background in Service	Contact technical support
	Serum treatment incorrectly	Visual inspection	Centrifuge the sample in proper condition

18.4 Error Message and Solution

Cuvette Loader				
Message code	**Message implication**	**Alarm Method**	**Cause**	**Recovery Method**
05050001	Cuvette loader not initialized!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted.	The analyzer should be initialized before use, or a belt is broken.	Ask technical staff to inspect mechanical parts.
05050002	Running out of cuvettes soon!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted.	The stacker is empty or the layer sensor detects no signal.	Please place the cuvette again.
05050003	Run out of cuvettes!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted.	The stacker is empty or the layer sensor detects no signal.	1. Confirm whether the cuvette loader is empty, if so, place cuvettes, otherwise check whether the layer sensor is effective. 2. When it returns to normal, select "**Cuvette Loader**" in the dialog box **[Machine is Halted]**, and then click **<Send>** and **<Continue>**.
05050004	Cuvette loader exit empty!	The beeper beeps; the dialog box [**Machine is Halted**] pops up and the machine is halted.	There is no cuvette at the cuvette loader exit, or the sensor detects no signal.	1. Confirm whether the cuvette loader is empty, if so, place cuvettes, otherwise check whether the sensor is effective. 2. When it returns to normal, select "**Cuvette Loader**" in the dialog box **[Machine is Halted]**, and then click **<Send>** and **<Continue>**.
05050005	Cuvette loader exit sensor fail!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted.	Cuvette has been moved away, but the cuvette loader exit sensor detects the cuvette.	If the problem continues, ask technical staff to inspect mechanical parts and the sensor.

Sample Loader				
Message code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
05040001	Sample loader can not move to backtransport!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The sample loader cannot move as a result of mechanical failure, the incubator position is not aligned or the sensor of the sample loader fails.	1. Select "**Sample Loader**" or "**Incubator**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
05040002	Sample loader can not move to incubator!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The sample loader cannot move as a result of mechanical failure, or the sensor of the sample loader fails.	1. Select "**Sample Loader**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
05040003	Sample loader not initialized!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The sample loader cannot move as a result of mechanical failure, or it is not initialized before operation of the device.	1. Select "**Sample Loader**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
05040004	Sample loader can not move to cuvette loader!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted.	The sample loader cannot move as a result of mechanical failure, or the sensor of the sample loader fails.	1. Select "**Sample Loader**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
05040005	No cuvette transported!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted.	The cuvettes at the cuvette loader outlet are out of position, or the sensor of the sample loader fails.	1. Arrange the cuvettes in alignment. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.

Washer Loader				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
05030001	Washer loader can not move forward!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The washer loader cannot move as a result of mechanical failure, the incubator position is not aligned or the sensor of the sample loader fails.	1. Select "**Washer Loader**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall remove the main cover of the machine and check whether there is barrier, e.g. The incubator is not aligned and is at a wrong position. Check whether the sensor is effective.
05030002	Washer loader can not move back!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The washer loader cannot move or the washer loader sensor fails as a result of mechanical failure.	1. Select "**Washer Loader**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall remove the main cover of the machine and check whether there is barrier, e.g. Check whether the sensor is effective.
05030003	Washer loader not initialized!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The machine must be initialized before operating or the washer loader sensor fails.	1. Select "**Washer Loader**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall remove the main cover of the machine and check whether there is barrier, e.g. Check whether the sensor is effective.

Incubator				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
05010001	Incubator not initialized!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	A kind of barrier prevents it for moving or the initial position sensor fails..	1. Select ”**Incubator**” or simultaneously select **Sample Loader** or **Washer Loader** in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall inspect the friction of the incubator guide rail, inspect whether each position of the incubator is aligned, and inspect the initial position sensor, etc.
05010002	Incubator regulation front!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	A kind of barrier prevents it for moving.	1. Select ”**Incubator**” or simultaneously select **Sample Loader** or **Washer Loader** in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall inspect the friction of the incubator guide rail, inspect whether each position of the incubator is aligned, etc.
05010003	Incubator regulation back!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	A kind of barrier prevents it for moving.	1. Select ”**Incubator**” or simultaneously select **Sample Loader** or **Washer Loader** in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall inspect the friction of the incubator guide rail, inspect whether each position of the incubator is aligned, etc.
05010004	Incubator can not move front!	The beeper beeps; the dialog box **[Machine is Halted]**x pops up and the machine is halted	A kind of barrier prevents it for moving or the encoder fails.	1. Select ”**Incubator**” or simultaneously select **Sample Loader** or **Washer Loader** in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall inspect the friction of the incubator guide rail, inspect whether each position of the incubator is aligned, and inspect whether the encoder is effective.

05010005	Incubator can not move back!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	A kind of barrier prevents it for moving or the encoder fails.	1. Select ”**Incubator**” or simultaneously select **Sample Loader** or **Washer Loader** in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, technical staff shall inspect the friction of the incubator guide rail, inspect whether each position of the incubator is aligned, and inspect whether the encoder is effective.

Washer Transport				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
03010001	Wash transport not initialized!	The beeper beeps; the dialog box **[Machine is Halted** pops up and the machine is halted	Initial position (sensor) may be incorrectly adjusted.	Contact technical service staff to inspect mechanical parts and circuits.
03010002	Wash transport can not move forward!	The beeper beeps; the dialog box **[Machine is Halted** pops up and the machine is halted	This error may be caused by failure of washer transport sensor. It may be also due to another kind of washing path obstruction such as the width of washing path is incorrectly adjusted or adjusting parameters of washer transport are incorrect.	1. Select “**Washer Transport**” in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please contact technical service staff to inspect mechanical parts and circuits.
03010003	Wash transport can not move forward!	The beeper beeps; the dialog box **[Machine is Halted** pops up and the machine is halted	This error may be caused by failure of washer transport sensor. It may be also due to another kind of washing path obstruction such as the width of washing path is incorrectly adjusted or adjusting parameters of washer transport are incorrect.	1. Select “**Washer Transport**” in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please contact technical service staff to inspect mechanical parts and circuits.

Washer Lift				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
03020001	Wash lift not initialized!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Initial position sensor fails or the friction is large.	Select "**Washer Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**.
03020002	Wash lift regulation up!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted。	The friction is large or there is a kind of obstruction.	1. Select "**Washer Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please contact technical service staff to inspect mechanical parts and circuits.
03020003	Wash lift regulation down!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The friction is large or there is a kind of obstruction.	1. Select "**Washer Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please contact technical service staff to inspect mechanical parts and circuits.
03020004	Wash lift can not move up!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The friction is large, or it may be caused by encoder failure.	1. Select "**Washer Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please contact technical service staff to inspect mechanical parts or encoder.
03020005	Wash lift can not move down!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The friction is large or there is obstruction by a kind of barrier (such as cuvette position in washer transport is incorrect), or it may be caused by encoder failure.	1. Select "**Washer Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please contact technical service staff to inspect mechanical parts or encoder.

Pusher				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
05020001	Pusher not initialized!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Due to a kind of obstruction such as the chamber transport is not initialized or the initial position sensor fails.	1. Select "**Pusher**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, check whether the cuvette is stuck between the washer transport and pusher; if not, please contact technical service staff to inspect mechanical parts.
05020002	Pusher regulation front!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Pusher block moves slowly. It may be obstructed when it moves.	1. Select "**Pusher**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, check whether the cuvette is stuck between the washer transport and pusher; if not, please contact technical service staff to inspect mechanical parts.
05020003	Pusher regulation back!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Pusher moves slowly. It may be obstructed when it moves.	1. Select "**Pusher**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, check whether the cuvette is stuck between the washer transport and pusher; if not, please contact technical service staff to inspect mechanical parts.
05020004	Pusher can not move front!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Due to a kind of obstruction such as chamber transport unit is not initialized or position of slider belt tension clamp (under the baseboard) is incorrect. Or it may be caused by failure of encoder.	1. Select "**Pusher**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, check whether the cuvette is stuck between the washer transport and pusher; if not, please contact technical service staff to inspect mechanical parts.
05020005	Pusher can not move back!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Due to a kind of obstruction such as chamber transport unit is not initialized or position of slider belt tension clamp (under the baseboard) is incorrect. Or it may	1. Select "**Pusher**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, check whether the cuvette is stuck between the washer transport and pusher; if not, please contact technical service staff to inspect mechanical parts.

			be caused by failure of encoder.	

Back Transport				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
03030001	Backtransport not initialized!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Some barriers make the back transport cannot move or sensor fail	1. Check whether there is obstruction, if not, select “Back transport” in [**Machine is Halted**], and click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
03030002	Backtransport can not move left! !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Some barriers make the back transport cannot move or sensor fail	1. Check whether the incubator is aligned, and whether there is an extra cuvette in the tank; if not, select “Back transport” in [**Machine is Halted**], and click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
03030003	Backtransport can not move right!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Some barriers make the back transport cannot move or sensor fail	1. Check whether the incubator is aligned, and whether there is an extra cuvette in the tank; if not, select “Back transport” in [**Machine is Halted**], and click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.

Chamber Transport Component				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
04010001	Chamber transport not initialized!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	This is due to mechanical obstruction (such as there is a cuvette in chamber) or sensor failure.	1. Select "**Chamber Transport**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please check whether the chamber lift height is correct or contact technical staff to inspect mechanical parts and circuits.
04010002	Chamber transport can not move!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	This is due to mechanical obstruction (such as chamber lift height is incorrect) or sensor failure.	1. Select "**Chamber Transport**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please check whether the chamber lift height is correct or contact technical staff to inspect mechanical parts and circuits.

Chamber Lift				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
04020001	Chamber lift not initialized!	The beeper beeps, the dialog box **[Machine is Halted]** pops up and the machine is halted	Chamber lift is obstructed or initial position sensor fails.	1. Select "**Chamber Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, please contact technical service staff to inspect mechanical parts and circuits.
04020002	Chamber lift regulation up!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Upward moving speed of chamber lift is too slow. It may be due to overflow of liquid in chamber or incorrect adjustment of the lift rack .	1. Select "**Chamber Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**. 2. If the problem continues, ask technical staff to remove the chamber cover and inspect if the lift rack is obstructed, e.g. Obstructed cuvette, apparent crystallization (white powder).
04020003	Chamber lift regulation down!	The beeper beeps; the dialog box **[Machine is**	Downward moving speed of chamber lift is too slow. It may be due to	1. Select "**Chamber Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>**.

		Halted] pops up and the machine is halted	overflow of liquid in chamber or incorrect adjustment of the lift rack.	2. If the problem continues, ask technical staff to remove the chamber cover and inspect if the lift rack is obstructed, e.g. Obstructed cuvette, apparent crystallization (white powder).
04020004	Chamber lift can not move up!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The chamber lift is blocked when it moves upwards. It may be because liquid in the chamber once overflowed on test inlet door or rack caused adhesion. Or it may be due to failure of encoder.	1. Select "**Chamber Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>** 2. If the problem continues, ask technical staff to remove the chamber cover and inspect if the chamber inlet rail or lift rack is obstructed, e.g. Obstructed cuvette, apparent crystallization (white powder). It may also because that the balls of lifter dropped out from rail or the reflection sensor (under the test module) is damaged.
04020005	Chamber lift can not move down!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The chamber lift is blocked when it moves downwards. It may be because liquid in the chamber once overflowed on test inlet door or rack caused adhesion, or the cuvette is stucked in chamber transport. Or it may be due to failure of encoder.	1. Select "**Chamber Lift**" in [**Machine is Halted**] dialog box, and then click **<Send>** and **<Continue>** 2. If the problem continues, ask technical staff to remove the chamber cover and check whether there is obstruction on test module lift rail or test module lift transfer rod, e.g. Obstructed cuvette, apparent crystallization (white powder). It may also because that the balls of lifter dropped out from rail or the reflection sensor is damaged.
04020006	No cuvette in chamber!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted.	The problem is caused by incorrect setting of minimum light intensity on global parameter interface of the service software	Contact technical staff to inspect photomultiplier or blue light; if there is no problem, adjust the minimum value cuvette.
04020007	Cuvette not moved out from chamber!	The beeper beeps; the dialog box **[Machine is Halted]** pops	It may be because liquid overflow in the chamber resulted in deviation of	Contact technical service staff.

		up and the machine is halted	chamber transport.	

All kinds of Pump				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
03070001	Washer peristaltic pump soak abnormally!	The beeper beeps; the dialog box [Error Message] pops up, but the machine is not halted.	It may be because the clamp is too loose or too tight.	Manually twist the knurled nut that presses the spring; if it still doesn't work, please contact technical staff.
04050001	Chamber waste Pump can not aspirate!	The beeper beeps; the dialog box [Error Message] pops up, but the machine is not halted.	The waste liquid pipe is blocked or the waste liquid pump is broken.	Contact technical service staff.
03040001	Washer Injector_1 inject abnormally. Please shut down the analyzer and check carefully!	The beeper beeps; the dialog box [Machine is Halted] pops up and the machine is halted	The system liquid pipe is stuck by any other component or the pump is broken.	Check whether the system liquid pipe is stuck; if not, please contact technical staff.
03050001	Washer Injector_2 inject abnormally. Please shut down the analyzer and check carefully!	The beeper beeps; the dialog box [Machine is Halted] pops up and the machine is halted	The system liquid pipe is stuck by any other component or the pump is broken.	Check whether the system liquid pipe is stuck; if not, please contact technical staff.
03060001	Washer Injector_3 inject abnormally. Please shut down the analyzer and check carefully!	The beeper beeps; the dialog box [Machine is Halted] pops up and the machine is halted	The system liquid pipe is stuck by any other component or the pump is broken.	Check whether the system liquid pipe is stuck; if not, please contact technical staff.
04030001	Starter 1 inject abnormally. Please shut down the analyzer and check carefully!	The beeper beeps; the dialog box [Machine is Halted] pops up and the machine is halted		
04040001	Starter 2 inject abnormally. Please shut down the analyzer and	The beeper beeps; the dialog box [Machine is Halted] pops up and the		

	check carefully!	machine is halted		

Pipetting Needle System				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
02010001	The outer track of SampleArm can not be initialized !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Initial-position optocoupler of outer track cannot be detected	1. Reinitialize the Sample Arm. 2. Check if the Initial-position optocoupler of outer track of Sample Arm is loosened from the optocoupler connecting cable. 3. Contact maintenance staff.
02010002	The outer of SampleArm can not be moved clockwise !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The outer track encoder judges no change in position during movement	1. Check if there is any object impeding the movement of pipetting needle in the horizontal direction. 2. Reinitialize the Sample Arm. 3. Contact maintenance staff.
02010003	The outer of SampleArm can not be moved counter-clockwise !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The outer track encoder judges no change in position during movement	1. Check if there is any object impeding the movement of pipetting needle in the horizontal direction. 2. Reinitialize the Sample Arm. 3. Contact maintenance staff.
02010011	The inner track of SampleArm can not be initialized !	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted	Initial-position optocoupler of inner track cannot be detected	1. Reinitialize the Sample Arm. 2. Check if the Initial-position optocoupler of inner track of Sample Arm is loosened from the optocoupler connecting cable. 3. Contact maintenance staff.
02010012	The inner of SampleArm can not be moved clockwise !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	The inner track encoder judges no change in position during movement	1. Check if there is any object impeding the movement of pipetting needle in the horizontal direction. 2. Reinitialize the Sample Arm. 3. If it cannot be restored or any other fault occurs, please contact maintenance staff.
02010013	The inner of SampleArm can not be moved counter-	The beeper beeps; the dialog box **[Machine is Halted]** pops up	The inner track encoder judges no change in	1. Check if there is any object impeding the movement of pipetting needle in the horizontal direction.

	clockwise !	and the machine is halted	position during movement	2. Reinitialize the Sample Arm. 3. Contact maintenance staff.
02010021	SampleArm can not be initialized on vertical !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Running resistance is too high or the Sample Arm is stuck by foreign objects	Power off the device; lift the Sample Arm by hand to see if it can be lifted. If the problem still exists, please contact technical service staff.
02010022	SampleArm can not be moved down !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Running resistance is too high or the Sample Arm is stuck by foreign objects	Power off the device; lift the Sample Arm by hand to see if it can be lifted. If the problem still exists, please contact technical service staff.
02010023	SampleArm can not be moved up !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted	Running resistance is too high or the Sample Arm is stuck by foreign objects	Power off the device; lift the Z axis by hand to see if it can be lifted. If the problem still exists, please contact technical service staff.
02010031	The Inject pump of SampleArm can not be initialized !	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted		1. Reinitialize the Sample Arm. 2. If it cannot be restored or any other fault occurs, please contact maintenance staff.
02010041	SampleArm can not detect liquid. Sample ID: %s, Assay: %s!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		If it cannot be restored or any other fault occurs, please contact maintenance staff.
02010051	SampleArm detect blood clot. Sample ID: %s, Assay: %s!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		If it cannot be restored or any other fault occurs, please contact maintenance staff.
02010052	SampleArm detect bubbles. Sample ID: %s, Assay: %s!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		If it cannot be restored or any other fault occurs, please contact maintenance staff.

Other				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
00000001	The analyzer is stopped manually!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted		In the dialog box **[Machine is Halted]**, click **<Continue>**.
00060001	System liquid is almost empty. Please replace!	The beeper beeps; the dialog box [**Error Message]** pops up, but the machine is not halted		Please carry out replenishment according to system liquid replenishing steps.
00060002	System liquid is empty. Please replace it immediately!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted		Please carry out replenishment according to system liquid replenishing steps.
00090001	Waste liquid is almost full. Please replace!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please empty the waste liquid tank.
00090002	Waste liquid is full. Please replace it immediately!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please empty the waste liquid tank.
00070001	Starter 1 is almost empty. Please replace!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please carry out replacement according to starter replacing steps.
00070002	Starter 1 is empty. Please replace it immediately!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted		Please carry out replacement according to starter replacing steps.
00070003	Starter 2 is almost empty. Please replace!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please carry out replacement according to starter replacing steps.
00070004	Starter 2 is empty. Please replace it immediately!	The beeper beeps; the dialog box **[Machine is Halted]** pops up and the machine is halted		Please carry out replacement according to starter replacing steps.
00050001	Shaker is out of normal range!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please contact technical staff.
00130001	Waste cuvette is full. Please empty the waste bag!	The beeper beeps; the dialog box [**Error Message]** pops up, but the machine is not halted		Please empty waste cuvette.

COP				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
08010001	The cover of analyzer is open, please pay attention to safety!	The computer beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Close the cover of analyzer.
08010002	The cover lock of the analyzer failed to lock properly!	The computer beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Lock the cover lock of the analyzer again.
08010003	The cover lock of the analyzer failed to open properly!	The computer beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Open the cover lock of the analyzer again.
08020010	COP lost connection with Module SampleArm!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please contact technical staff.
08020011	COP lost connection with Module Washer!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please contact technical staff.
08020012	COP lost connection with Module Chamber!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please contact technical staff.
08020013	COP lost connection with Module Multiple Module!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please contact technical staff.

Online				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
15010001	Online COM port is not work!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please contact technical staff.
15010002	Software cannot connect to Lis!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted		Please contact technical staff.

System				
Message Code	**Message Implication**	**Alarm Method**	**Cause**	**Recovery Method**
16010001	Software has been disconnected with PLC!	The beeper beeps; the dialog box **[Error Message]** pops up, but the machine is not halted	The device is not powered on, or network port/serial port between PC and device is not connected.	Check whether the device is powered on, or whether network port/serial port between PC and device is connected. In case of failure to recover, please contact technical staff.

Appendix A Adjust Needles

After the analyzer and the software are installed, the plane position and maximum limit of the pipetting needles shall be calibrated at first.

A.1 Preparation before Adjusting

Take 2 cuvette bars and fill 100μL water into the positions 1 and 6 of each bar. Place the two cuvette bars onto the first cuvette position of the incubator area and the previous position of the right pipetting area respectively.

Three tubes filled with 100μL of water should be respectively placed at the position 1 and 8 of track1, position 1 and 10 of track11, position 8 of track 5

Take an empty, clean and dry reagent kit and fill 300μL water into its first hole (for magnetic microbeads), fill 300μL water into the second hole (for low calibrator), fill 300μL water into the fourth hole (for displacing reagent), fill 1300μL water into the seventh hole (for buffer), and insert the reagent kit into the first reagent position of the reagent area.
Turn on the main switch and the submain switch of the analyzer, and start the computer.

Click **Maglumi Service** icon on desktop and enter password to open **[Maglumi 800 Service]** software.

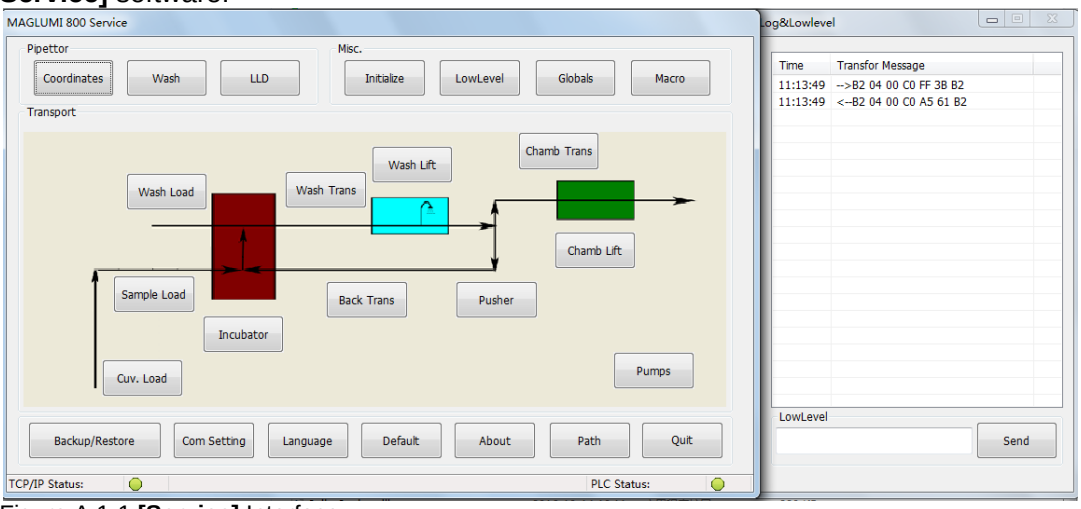


Figure A.1-1 **[Service]** Interface

1. Click **<Initialize>** button to initialize the components on the working plane.
2. Click **<Incubator>** button to display the **[Incubator]** dialog. Select **Back Transport** in **Target Position** and click **<Return>** to return to the **[Service]** interface.

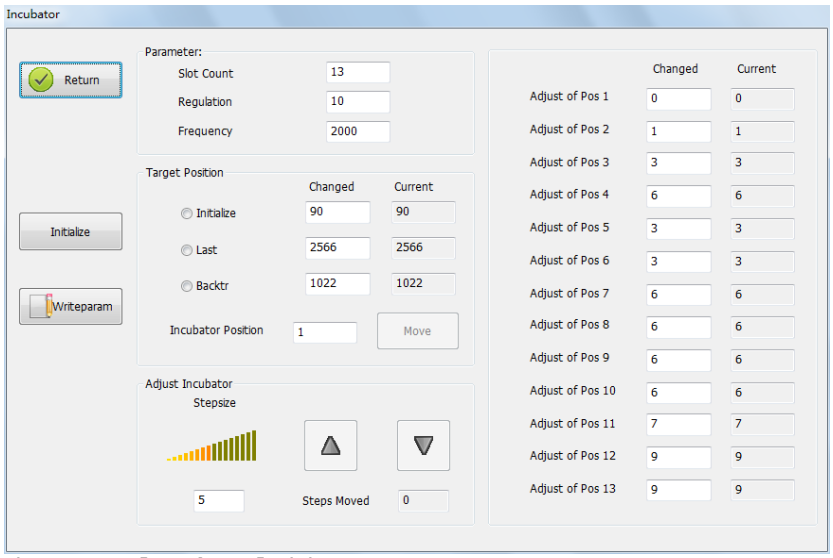


Figure A.1-2 **[Incubator]** Dialog

3. Click **<Sample Load>** button on **Service** interface to open the **[Sample Loader]** dialog.

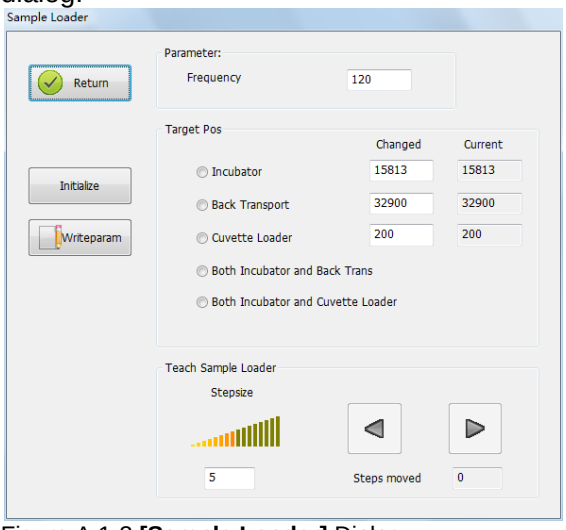


Figure A.1-3 **[Sample Loader]** Dialog

4. Select **Both Incubator and Back Trans** in **Target Position** to convey a cuvette bar to the first-step pipetting position.

5. Click **<Return>** to return to the **[Service]** interface.

A.2 Needles Adjust Program

Click **<Coordinates>** button on the upper left corner of the **[Service]** interface to open **[Needles Adjust]** dialog.

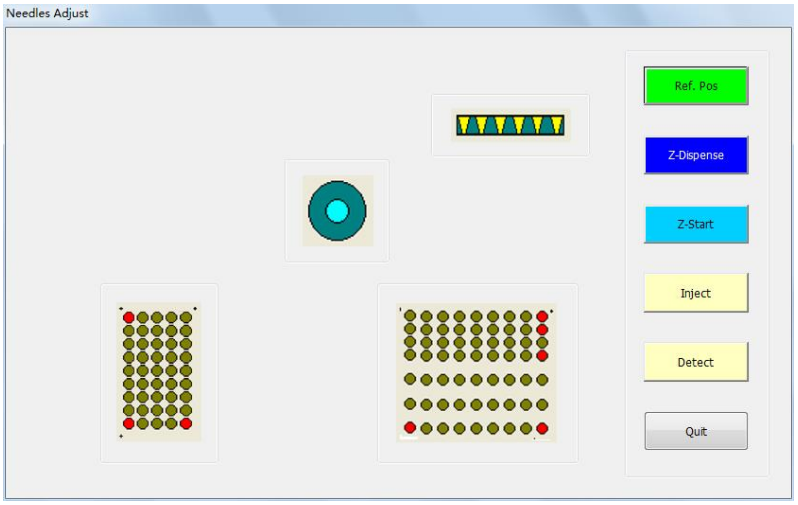


Figure A.2-1 **[Needles Adjust]** Dialog

Table A.2-1 Shortcut keys for Needles Adjust

Name	Icon	Keyboard shortcut keys
Outer arm moves clockwise	Outer arm fine tuning 	←
Outer arm moves counter-clockwise	Outer arm fine tuning 	→
Inner arm moves clockwise	Inner arm fine tuning 	↑
Inner arm moves counter-clockwise	Inner arm fine tuning 	↓
Moves upwards vertically	Vertical fine tuning 	Page Up
Moves downwards vertically	Vertical fine tuning 	Page Down
Moves to the middle between the current position and the maximum limit on Z-axis		Shift on Keyboard + button **<Z-Max>**

Remark: the directions in the table are based on facing to the analyzer

A.3 Reference Position Adjust

Click **<Ref. Pos>** button in **[Needles Adjust]** interface to display **[Ref. Adjust]** dialog.

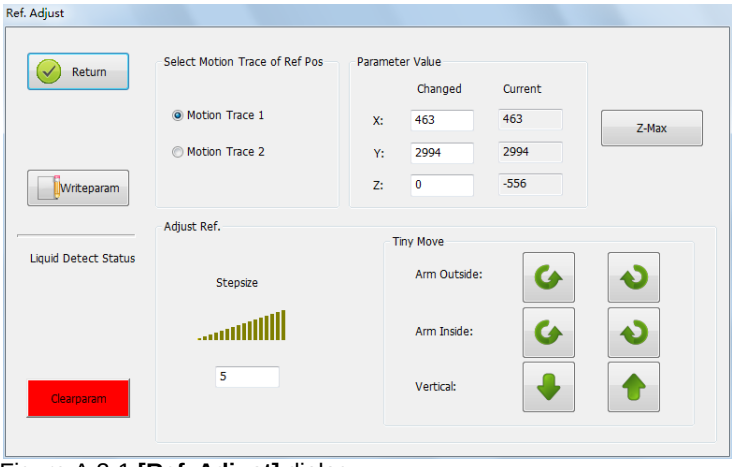


Figure A.3-1 **[Ref. Adjust]** dialog

Select **Motion Trace 1** in **Select Motion Trace of Ref. Pos** area. In **Adjust Ref.** area, set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to horizontally move the pipetting needle to nearby the **Ref. Pos**, and then use a small step size to adjust the horizontal position and vertical height until the needle position meets requirements described below.

Requirements:

1. The needle tip is located at the central red point of **Ref. Pos**;

2. The needle tip is 0.5mm above the central red point of **Ref. Pos**.

After adjustment, click **<Writeparam>** to save the position parameters. Adjust **Motion Trace 2** with the same method.

Click **<Return>** to exit the interface.

1. Make sure the same reference position is used for calibrating Motion Trace 1 and Motion Trace 2 of the pipetting needle!

2. Positional relationship between the two horizontal arms of Motion Trace 1: The outer arm shall be on the left of the inner arm.

3. Positional relationship between the two horizontal arms of Motion Trace 2: The outer arm shall be on the right of the inner arm.

4. For needle adjustment at all other positions (except the motion trace here), make sure that the outer arm is on the left of the inner arm

The needle tip shall be located at the central red point of **Ref. Pos**; the needle tip shall be located 0.5mm above the central red point of **Ref. Pos**.

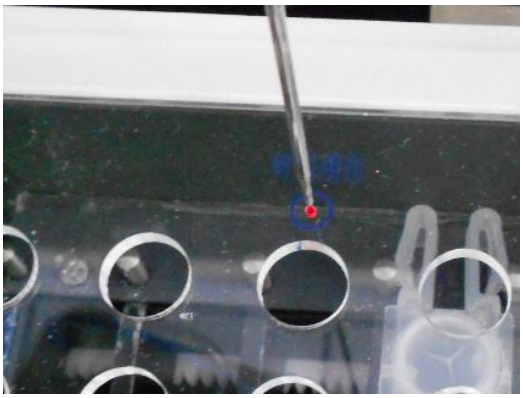


Figure A.3-2 Reference Position

A.4 Pipetting Position Adjust

Click  icon on the upper right of **[Needles Adjust]** interface to open **[Right Pipetting Position Adjust]** dialog.

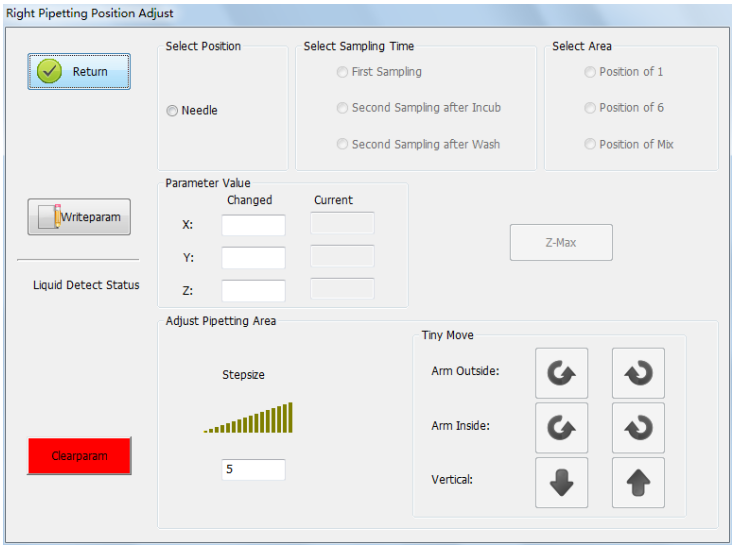


Figure A.4-1 **[Right Pipetting Position Adjust]** Dialog

A.4.1 First Sampling Position Adjust

Select **First Sampling** in **Select Sampling Time** area. Select **Position of 1** in **Select Area**:

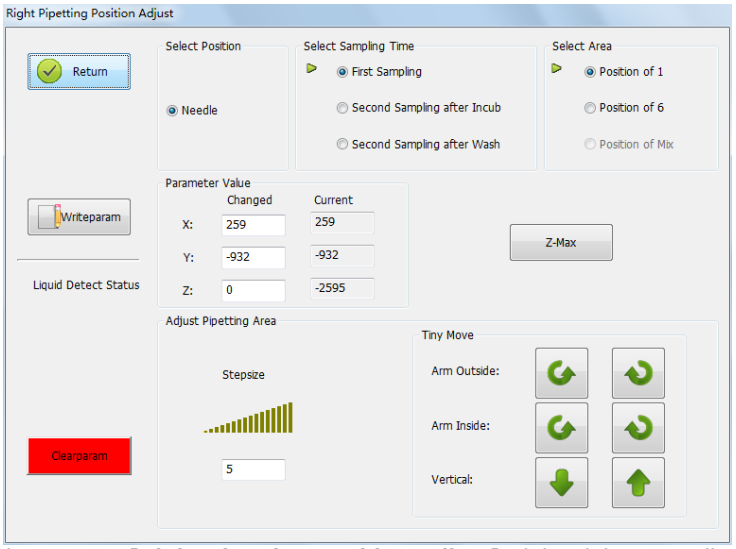
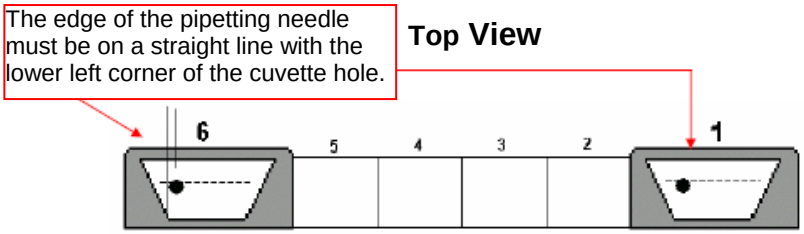


Figure A.4-2 **[Right Pipetting Position Adjust]** Dialog (First Sampling, Position of 1)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the **cuvette Position of 1**, and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

Requirements:

1) On the top view, the edge of the pipetting needle must be on a straight line with the lower left corner of the cuvette hole.



2) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touches the liquid surface. Click **<Writeparam>** when the level detection indicator light is on. Select **Position of 6** in **Select Area**. Adjust the cuvette Position of 6 in First Sampling by the same method.

A.4.2 Second Sampling after Incub Adjust

Select **Second Sampling after Incub** in **Select Sampling Time** area; select **Position of 1** in **Select Area**:

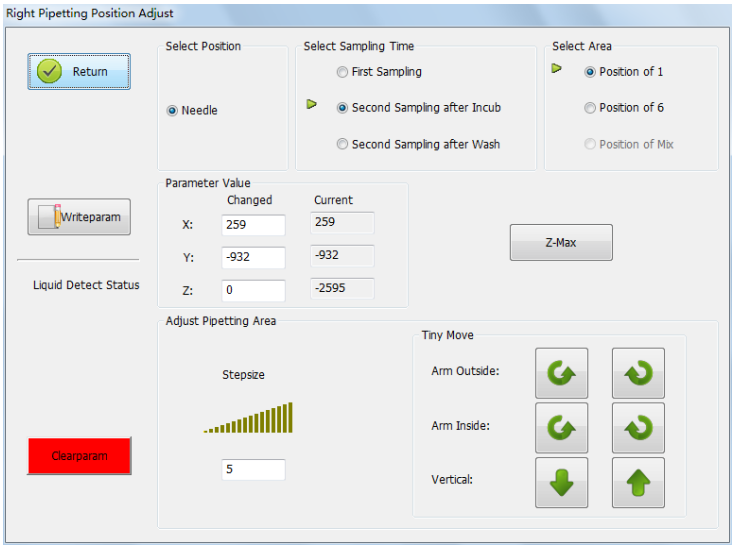
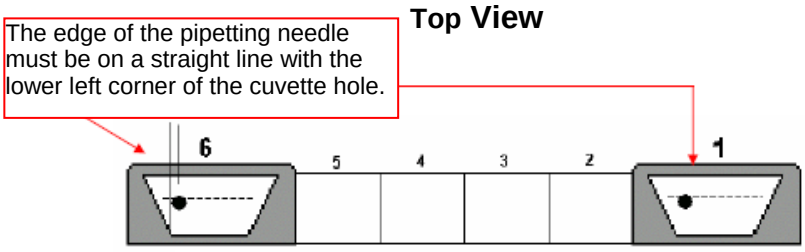


Figure A.4-3 **[Right Pipetting Position Adjust]** Dialog (Second Sampling after Incub, Position of 1)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to mov e the pipetting needle to nearby the **cuvette Position 1**, and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

Requirements:

1) On the top view, the edge of the pipetting needle must be on a straight line with the lower left corner of the cuvette hole.



2) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touches the liquid surface. Click **<Writeparam>** when the level detection indicator light is on. Select **Position of 6** in **Select Area**, and adjust the cuvette Position 6 in Second Sampling after Incub by the same method.

A.4.3 Second Sampling after Wash Adjust

Return to **[Maglumi Service]** interface.

Click **<Incubator>** button to display [Incubator] interface. Select **Backtr** in **Target Position** and click **<Return>** to return to the **[Maglumi Service]** interface.

Click **<Back Transport>** button in **[Maglumi Service]** interface to display **<Back Transport>** interface.

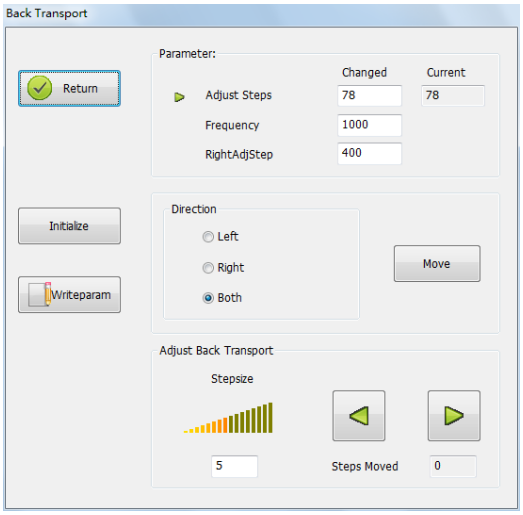


Figure A. 4-4 **[Back Transport]** Interface

Select **Both** in **Direction** area; click **<Move>** button to convey a cuvette bar to the **Second Sampling after Wash** position, and push back a cuvette bar to the first cuvette position of the incubator area.

Click **<Return>** to return to **[Maglumi Service]** interface.

Select **Second Sampling after Wash** in **Select Sampling Time** area in **[Right Pipetting Position Adjust]** interface; select **Position of 1** in **Select Area**:

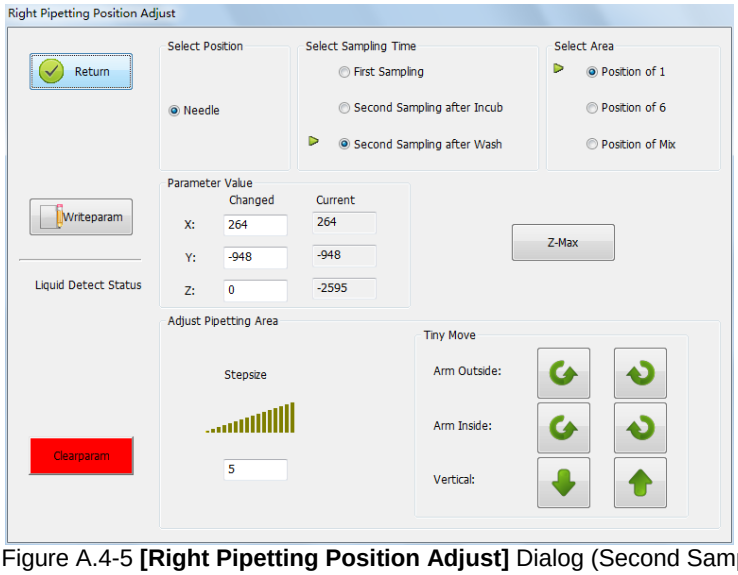


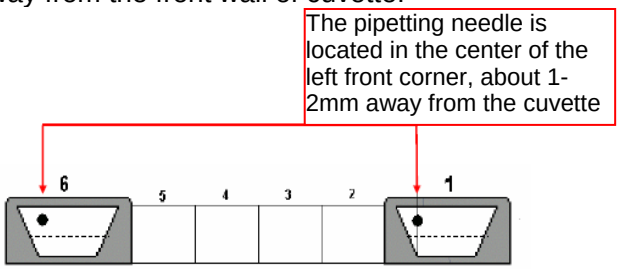
Figure A.4-5 **[Right Pipetting Position Adjust]** Dialog (Second Sampling after Wash, Position of 1)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the

cuvette Position of 1, and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

Requirements:

1) On the top view, the pipetting needle is located in the center of the front corner, about 1-2mm away from the front wall of cuvette.



2) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touches the liquid surface. Click **<Writeparam>** when the level detection indicator light is on. Select **Position of 6** in **Select Area** and adjust the cuvette **Position of 6** in **Second Sampling after Wash** by the same method.

Select **Position of Mix** in **Select Area**:

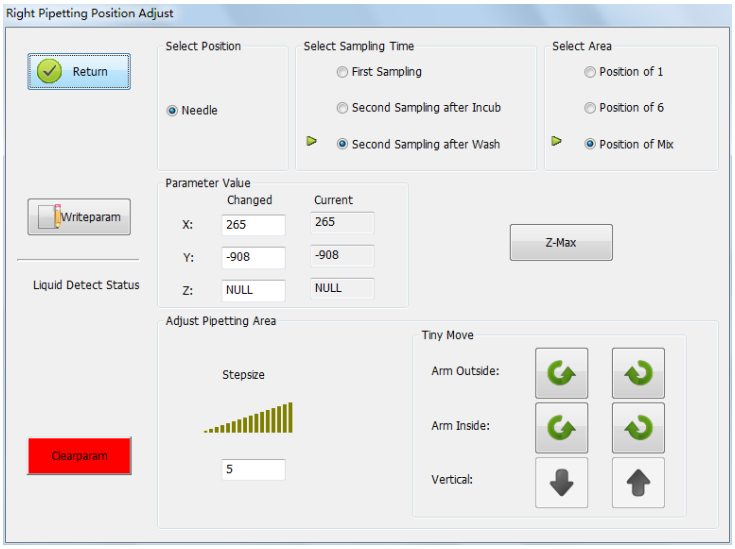
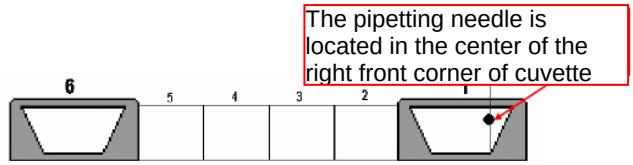


Figure A.4-6 **[Left Pipetting Position Adjust]** Dialog (Second Sampling after Wash, Position of Mix)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the **cuvette Position 1**, and then use a small step size to fine-tune the horizontal position so the needle tip can drop into the cuvette without any obstacle. Then, click **<Z-Max>** button to lower down the pipetting needle to the height of **Position of 1** in **Second Sampling after Wash**. Finally, adjust the horizontal position until the needle position meets requirements described below.

Requirements:
The pipetting needle is located in the center of the front corner of cuvette.



When pipetting position adjustment is finished, click **<Return>** button to return to the **[Needles Adjust]** dialog.

A.5 Washing Position Adjust

Click  icon in **[Needles Adjust]** dialog to display **[Washing Position Adjust]** dialog.

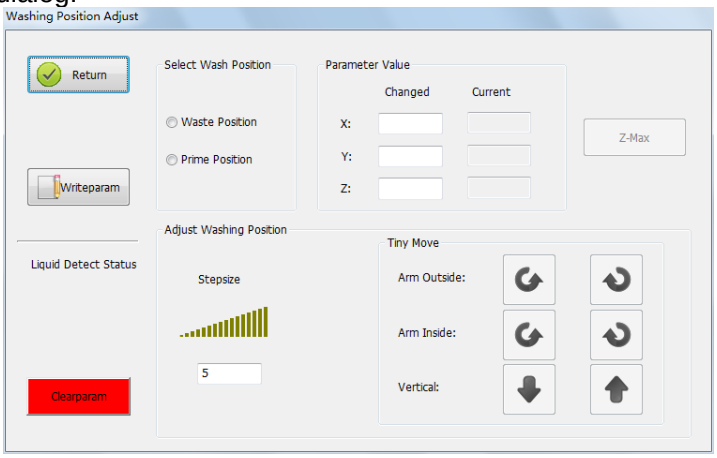


Figure A.5-1 **[Washing Position Adjust]** Dialog

A.5.1 Waste Position

Select **Waste Position** in **Select Wash Position** area:

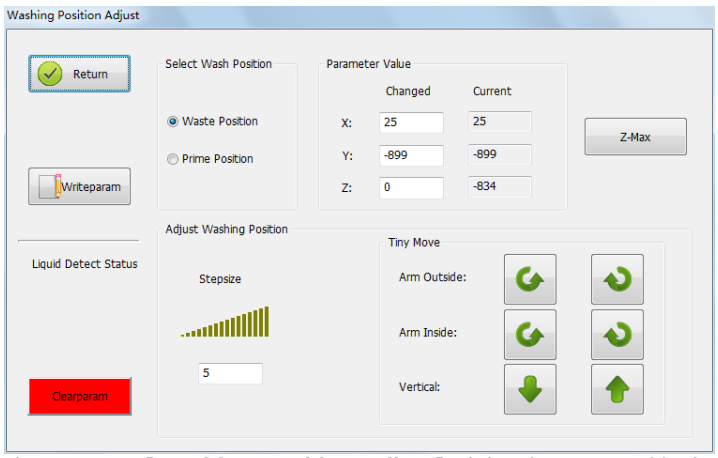


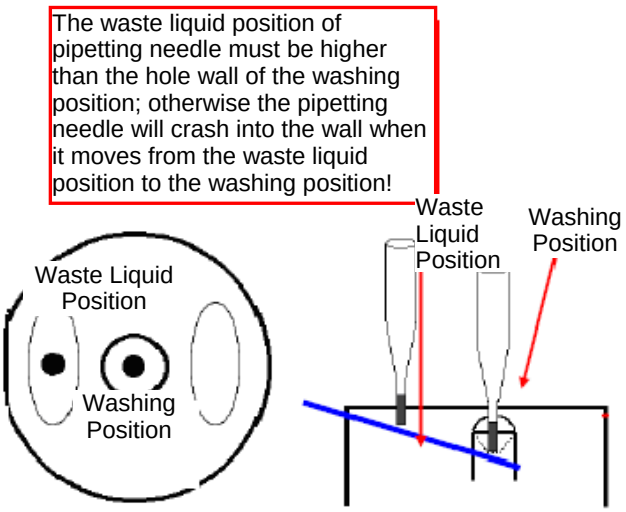
Figure A. 5-2 **[Washing Position Adjust]** Dialog (Waste Position)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the **washing hole**, and then use a small step size to fine-tune the horizontal position and

vertical height until the needle position meets requirements described below. Upon completion, click **<Writeparam>** to save the adjusted position parameters.

Requirements:

The waste liquid position of pipetting needle must be higher than the hole wall of the washing position; otherwise the pipetting needle will crash into the wall when it moves from the waste liquid position to the washing position!



A.5.2 Prime Position

Select **Prime Position** in **Select Wash Position** area:

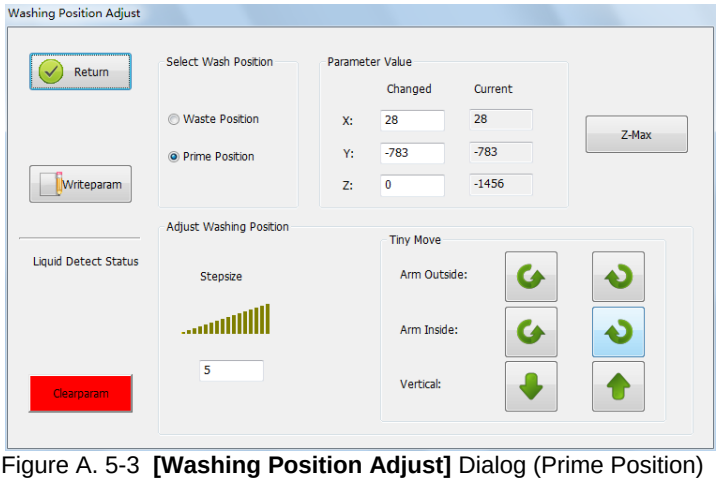
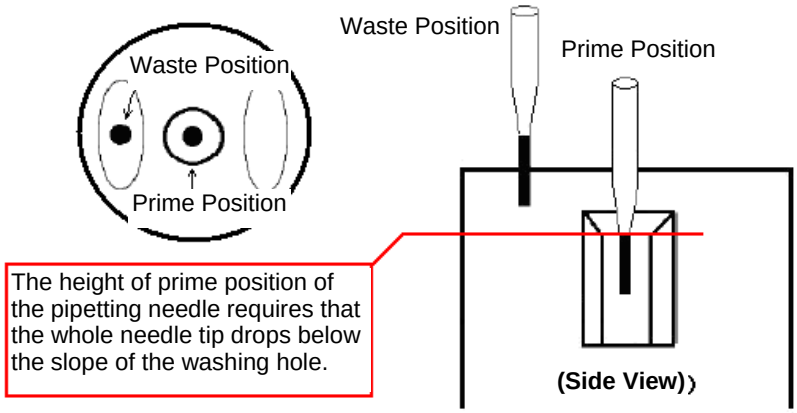


Figure A. 5-3 **[Washing Position Adjust]** Dialog (Prime Position)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the **washing hole**, and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below. Upon completion, click **<Writeparam>** to save the adjusted position parameters.

Requirements:

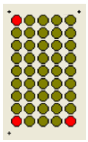
The height of prime position of the pipetting needle requires that the whole needle tip drops below the slope of the washing hole.



When adjustment is finished, click **<Return>** to return to **[Needles Adjust]** dialog.

A.6 Adjust of Needle Position in Sample & Reagent Area

A.6.1 Adjust of Needle Position in Sample Area

Click  icon in **[Needles Adjust]** dialog to enter **[Sample Area Adjust]** dialog. Select **Needle** in **Select Position** area, then select **Position of Track 1 and Tube 1** in **Select Area**.

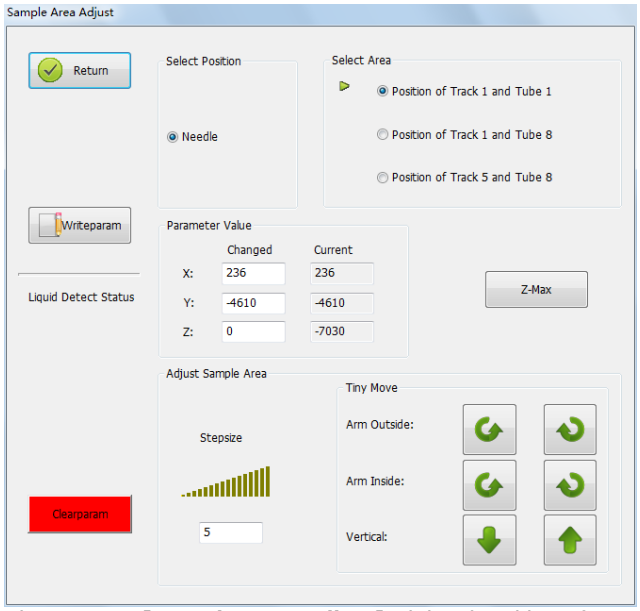


Figure A.6-1 **[Sample Area Adjust]** Dialog (Position of Track 1 and Tube 1)

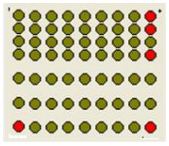
Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the **Position of Track 1 and Tube1**, and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

Requirements:

1) Fill 100μL water into the tube in advance;
2) Position on the top view: Move the needle to the center of the tube located in the Position of Track 1 and Tube1;
3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touches the liquid surface. Click **<Writeparam>** when the level detection indicator light is on.
4) Press and hold Shift on the keyboard, and click <**Z-Max**>; the needle will lower down by half of the difference between Current value and Changed value and gradually approach **Z-Max** to avoid crashing into the bottom of the test tube.

Select **Position of Track 1 and Tube 8** and **Position of Track 5 and Tube 8** respectively in **Select Area,** and adjust the needle at these positions using the same method.

A.6.2 Adjust of Needle Position in Reagent Area

Click  icon in **[Needles Adjust]** dialog to enter **[Reagent Area Adjust]** dialog. Select **Needle** in **Select Position** area, then select **Position of Track 9 and Tube 1** in **Select Reagent Area**:

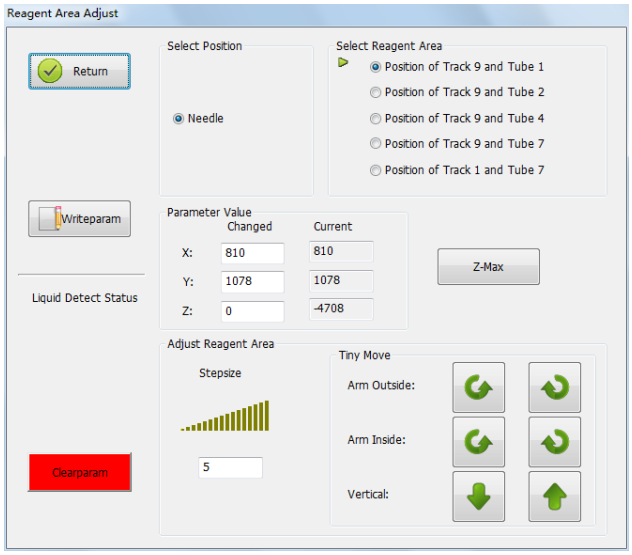


Figure A.6-2 **[Reagent Area Adjust]** Dialog (Position of Track 9 and Tube 1)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the **Position of Track 9 and Tube 1**, and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

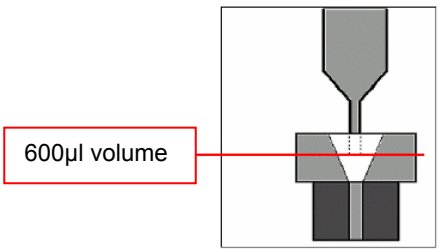
Requirements:

1) Fill 300μL water into the first hole (for magnetic microbeads) of the reagent kit in advance;
   Fill 300μL water into the second hole (for low calibrator) of the reagent kit in advance;
   Fill 300μL water into the fourth hole (for displacing reagent) of the reagent kit in advance;
   Fill 1300μL water into the seventh hole (for FITC) of the reagent kit in advance;
2) Position on the top view: Move the needle to the center of the tube located in the position of Track 9 and Tube 1;
3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touches the liquid surface. Click **<Writeparam>** when the level detection indicator light is on. Click **<Writeparam>** button.
4) Press and hold Shift on the keyboard, and click <**Z-Max**>; the needle will lower down by half of the difference between current value and changed value and gradually approach **Z-Max** to avoid crashing into the bottom of the kit.

Select **Position of Track 9 and Tube 2**, **Position of Track 9 and Tube 4**, **Position of Track 9 and Tube 7** and **Position of Track 1 and Tube 7** respectively in **Select Reagent Area**. Adjust the needle at these positions by the same method.

A.7 Cuvette Z-Dispense Position Adjust

Take a cuvette bar, fill 600μL water into the first cuvette, and place it into the first cuvette position of the incubator area.



1. Click **<Initialize>** in **[Maglumi Service]** interface. Upon completion, click **<Incubator>** to open **[Incubator]** dialog. Select **Backtr** in **Target Position** (Figure A.7-1). Then click **<Return>** button to return to **[Maglumi Service]** interface.

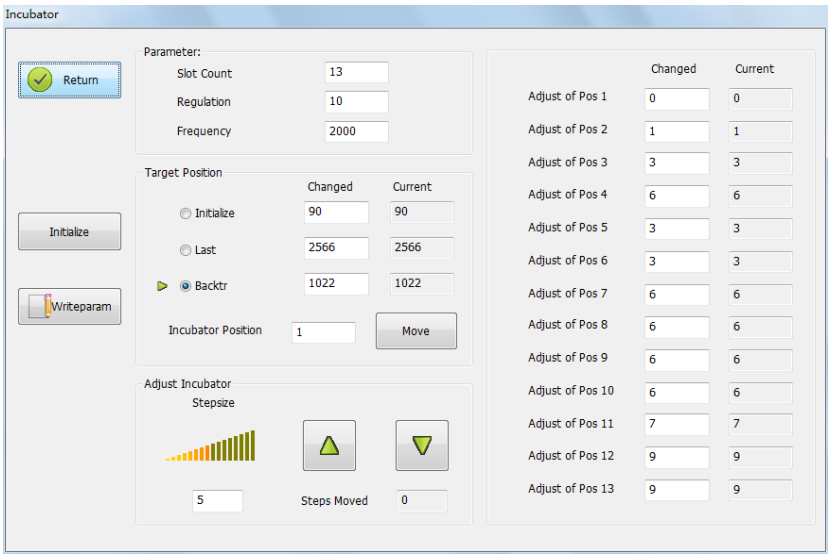


Figure A.7-1 **[Incubator]** Dialog

2. Click **<Sample Loader>** to enter **[Sample Loader]** dialog. Select **Both Incubator and Back Trans** in **Target Position** (Figure A.7-2). Then click **<Return>** button to return to **[Maglumi Service]** interface.

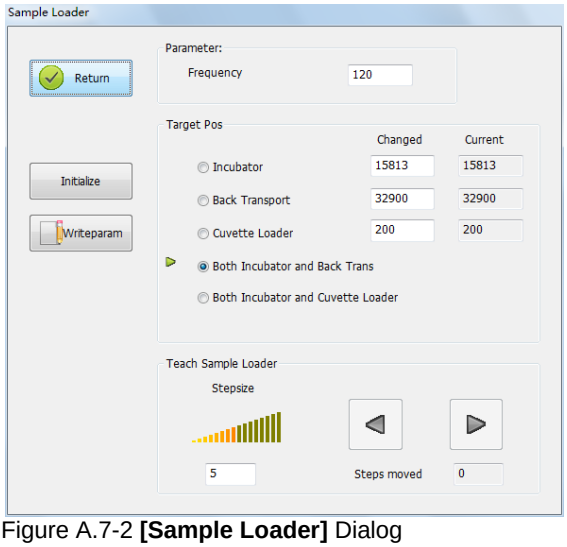


Figure A.7-2 **[Sample Loader]** Dialog

3. Click **<Needles Adjust>** button to enter **[Needles Adjust]** dialog. Click **< Z-Dispense >**button to open **[Z-Dispense Adjust]** dialog. Select **Needle** in **Select Needle** area.

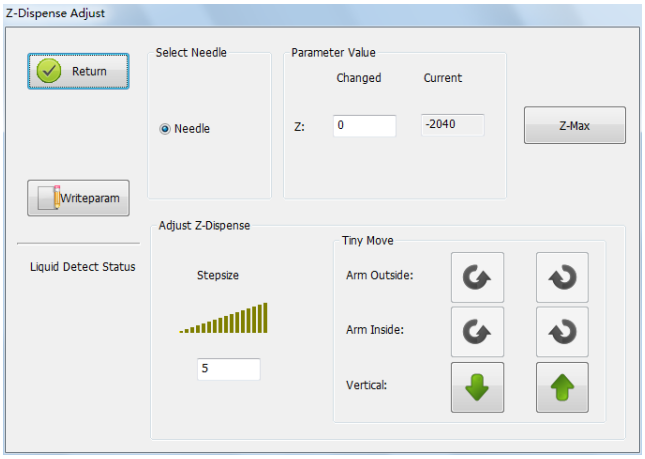
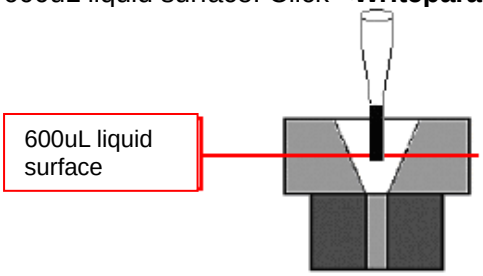


Figure A.7-3 **[Z-Dispense Adjust]** Dialog

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the **cuvette**, and then use a small step size to fine-tune the vertical height until the needle position meets requirements described below.

Requirements:
Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touches the 600uL liquid surface. Click **<Writeparam>** when the level detection indicator light is on.



A.8 Adjust of Z-Start Position of Reagents

Click **<Z-Start>** icon in **[Needles Adjust]** dialog to display **[Z-Start Adjust]** dialog. Select **Needle** in **Select Needle** area, then select **Position of Track 9 and Tube 1** in **Select Area**:

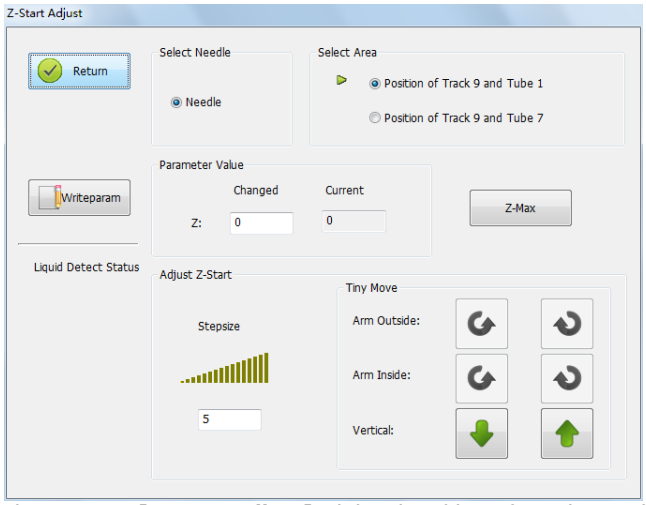


Figure A.8-1 **[Z-Start Adjust]** Dialog (Position of Track 9 and Tube 1)

Set the step size by changing the number of selected bars or manually filling in the step size. First use a large step size to move the pipetting needle to nearby the seal located in the Position of Track 9 and Tube 1, and then use a small step size to fine-tune the vertical height until the needle position meets requirements described below.

Requirements:
2/3 of Teflon-coated part of the pipetting needle tip is exactly below the silicone seal located in the Position of Track 9 and Tube 1 of the reagent. Click **<Writeparam>** after adjusting is finished.

Select **Position of Track 9 and Tube 7** in **Select Area**, and adjust the pipetting needle at this position using the same method.

A.9 Compensate Parameter Adjust

Click **[Detect]** button on the right of **[Needles Adjust]** dialog to enter **[Detect]** dialog.

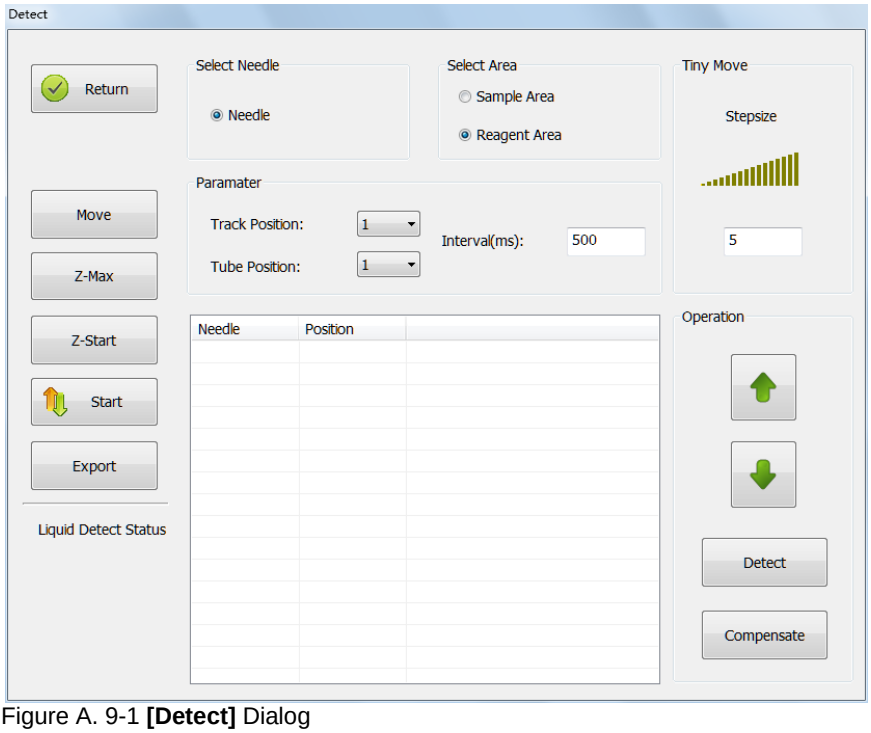


Figure A. 9-1 **[Detect]** Dialog

1. Insert a kit into the first position from left of the reagent area.

2. Select **Reagent Area** in **Select** Area; click **<Move>** button on the left to move the pipetting needle horizontally to the Position of Track 1 and Tube 1 of the reagent area. Set the step size by changing the number of selected bars or manually filling in the step size, and adjust the vertical height to make the needle tip stop above the silicone **seal** of the kit, and observe where the needle point is located in the center of the **seal**.

3. If the needle tip is located in the center of the **seal**, it indicates the compensation is appropriate. Directly click **<Return>** button on the left side to return to the **Needles Adjust** interface.
If the needle tip deviates from the center of the **seal**, it indicates the compensate parameter should be adjusted. Click **<Compensate>** button at the lower right corner to enter **[Pipe Compensate]** dialog.

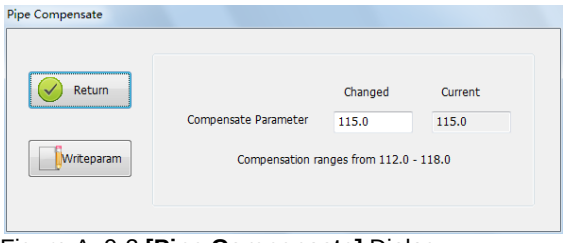


Figure A. 9-2 **[Pipe Compensate]** Dialog

4. Change the Compensate Parameter value, and click **<Writeparam>**; then click **<return>** button to return to **[Detect]** interface. Repeat Steps 2 and 3 until the needle tip is located in the center of the seal.

Appendix B Software Upgrade

B.1 Software Upgrade

In order to continuously improve the operating software for Maglumi 800, upgrade is necessary.
Upgrade can be realized by:
1) Installing the software installer of new version;
2) Installing the service pack.

This section will introduce the general operation process required for upgrade. There will be a special guide for each specific upgrade task.

WARNING

To ensure safety and reliability of the analyzer, software upgrade of the analyzer can be performed only by persons having been trained by our Company or after approval by engineers in our Company.

B.1.1 Installing the Software Installer of New Version

In case of any change of the operating software, the new version of operating software for Maglumi 800 analyzer should be reinstalled.
The new version of operating software will be stored in the upgrade disc. It is suggested to back up the original operating software prior to upgrade.

Upgrade Steps:
1. Back up the original operating software;
2. Uninstall the original operating software;
3. Insert the disc into the computer optical drive; open the disc folder; find the installation file "Maglumi.exe" and run it;
4. Copy the "component" folder in the original operating software having been backed up to the root directory of the new software; otherwise it will be necessary to readjust the analyzer parameters;
5. Restart the computer;
6. Start the analyzer; run **Service.exe**; check and confirm the position of pipette and cuvette transfer module; exit the software after completion;
7. Run **User.exe** to finish software upgrade.

Please see the figures below for the detailed installation steps:

Figure B.1-1 Step 1

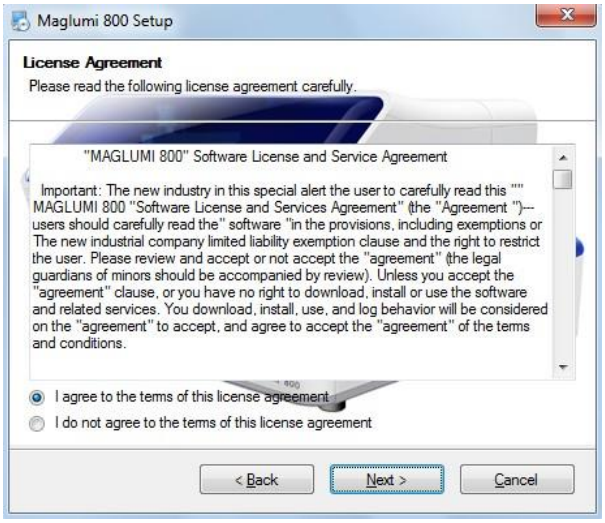


Figure B.1-2 Step 2

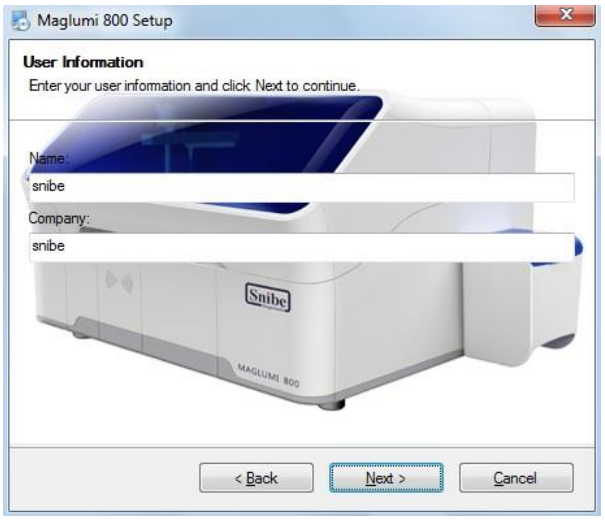


Figure B.1-3 Step 3

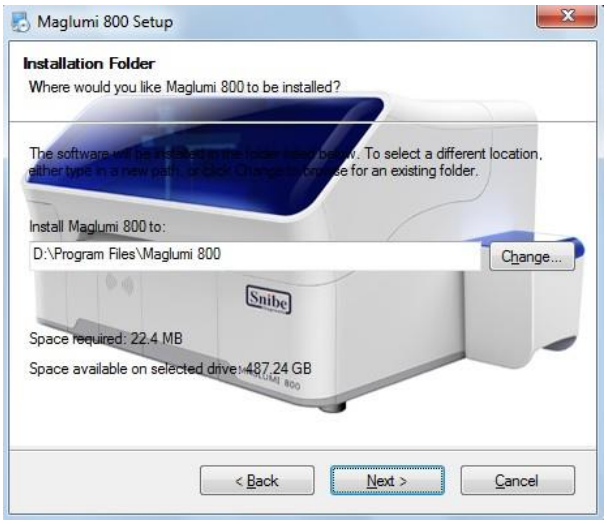


Figure B.1-4 Step 4

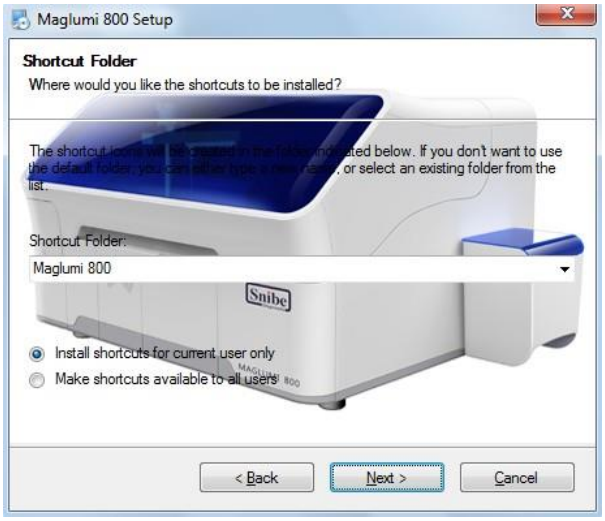


Figure B.1-5 Step 5

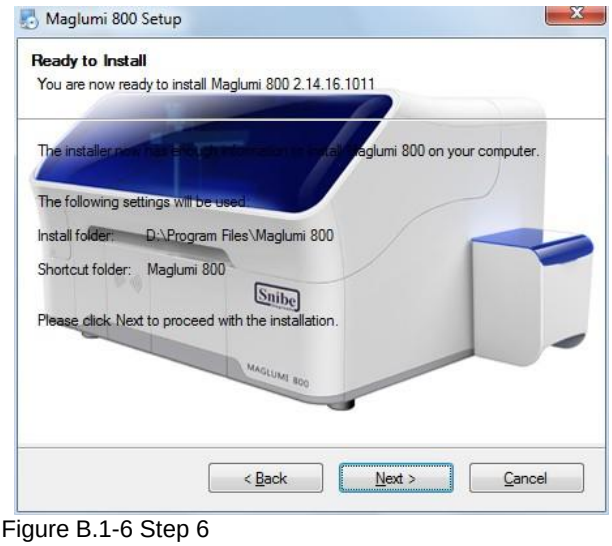


Figure B.1-6 Step 6

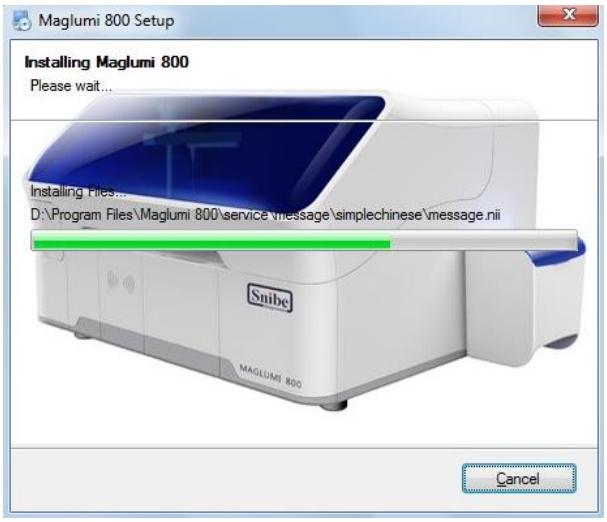


Figure B.1-7 Step 7

Figure B.1-8 Step 8

B.1.2 Installing the Service Pack

For information safety or software compatibility reason, the upgrade patch of operating software for Maglumi 800 may be sent. Upgrade of the operating software can be realized by running the upgrade patch found in the upgrade disc or downloaded online. Refer to the instructions provided in the service pack for details of upgrade method.

B.2 Program Upgrade of Main Control Circuit Boards

Each component of the analyzer has a corresponding control circuit board. A data port for upgrade is available on each control circuit board.

The analyzer has 5 main control circuit boards that can be upgraded, which control the corresponding components. Their codes and names are listed below:

- 01-E00-COP
- 02-E00-Sample Arm
- 03-E00-Washer
- 04-E00- MeasureChamber
- 05-E00- Multiple Modules

Program upgrade of 5 main control circuit boards is carried out by two case below:

1) Upgrade the program of 01-E00-COP circuit board;
2) Upgrade the programs of No. 02~05 circuit boards.

B.2.1 Upgrade the Program of 01-E00-COP Circuit Board

Upgrade Steps:

1. Power off the analyzer prior to upgrade.. Use the RS232 data cable supplied by our Company to connect the COM port on the computer with the RS232 port on the analyzer;
2. Remove the 01-E00-COP circuit board from the analyzer, and put the two **Jumper Caps** at correct position, as shown below which in Red box. Otherwise the program burning cannot be carried out.

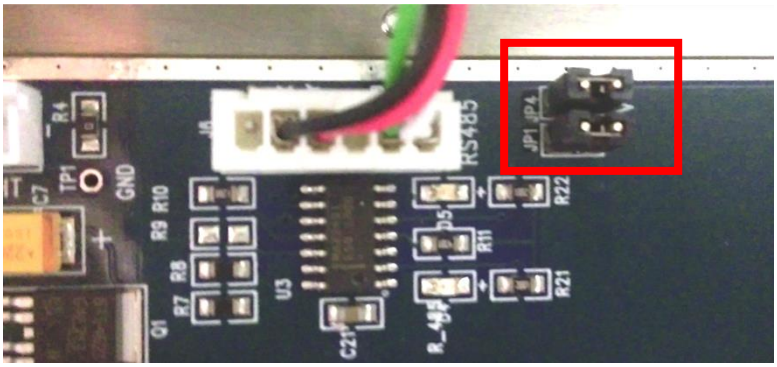


Figure B.2-1 Put the two **Jumper Caps** at correct position

3. Put the 01-E00-COP back into the analyzer. Start the computer and the analyzer. Run **FlashDownload.exe** on the computer; then select options as follows:

Table B.2-2 Parameter Settings of FlashDownload

Step	Option	Content	Meaning
1	Device	LPC2468	Burning chip
2	COM Port	COM1	Communication port
3	Baud Rate	115200	Burning speed
4	Oscillator(KHz)	14318.18	Frequency (fixed)
5	Hex File	hex file	Select the burning file (COP.hex), which is provided by Snibe

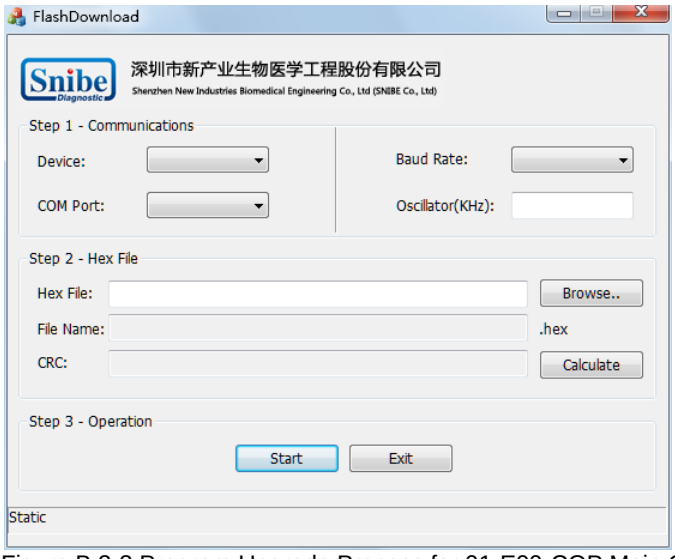


Figure B.2-3 Program Upgrade Process for 01-E00-COP Main Control Circuit Board

4. After selecting the above options, click the **<Start>** button; after successful burning, "Finished" will be displayed at the "Status" position;

5. When the writing process is finished, power off the analyzer and get the 01-E00-COP circuit board out of the analyzer again, and put the two **Jumper Caps** at the position which shown below in Red box. Otherwise the analyzer will not work properly.

B.2.2 Upgrade and Burning of the Programs of No. 02~05 Circuit Boards

Upgrade Steps:

1. Power off the analyzer prior to upgrade. Use the RS232 data cable and program download cable supplied by our Company to connect the COM port on the computer with the program download port on No. 02~05 circuit boards in the analyzer. The program download cable and the connection method are shown in the figures below;

Figure B.2-4 Program Download Cable for No. 02~05 Main Control Circuit Boards

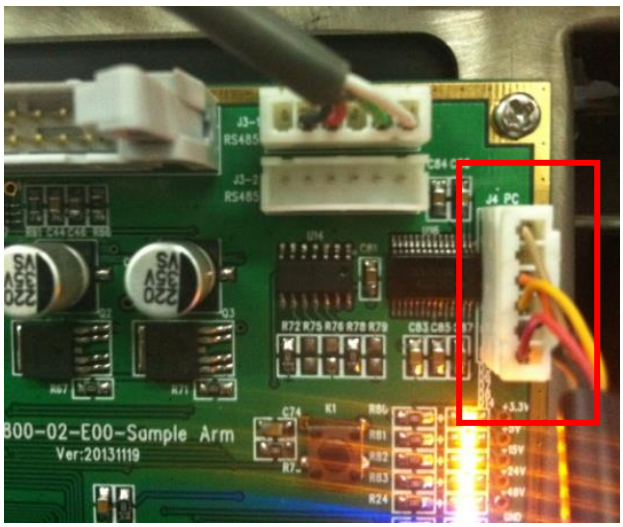


Figure B.2-5 Program Download Connection Port J4 of No. 02 Main Control Circuit Board

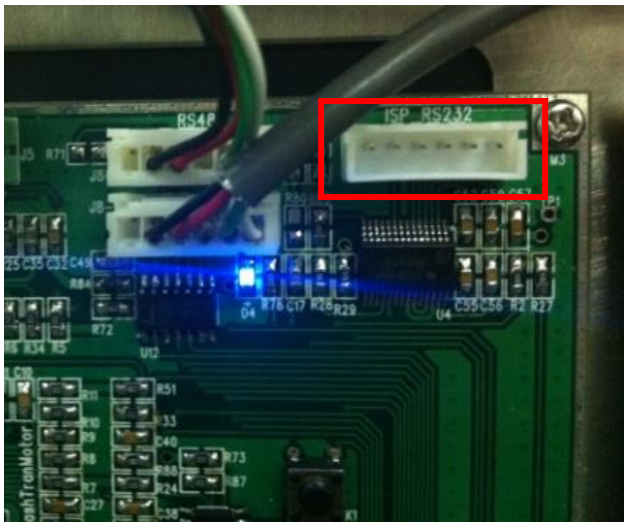


Figure B.2-6 Program Download Connection Port J7 of No. 03 Main Control Circuit Board

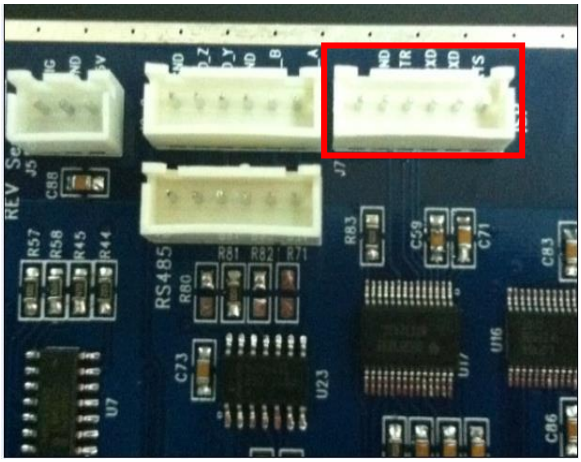


Figure B.2-7 Program Download Connection Port J7 of No. 04 Main Control Circuit Board

Figure B.2-8 Program Download Connection Port J4 of No. 05 Main Control Circuit Board

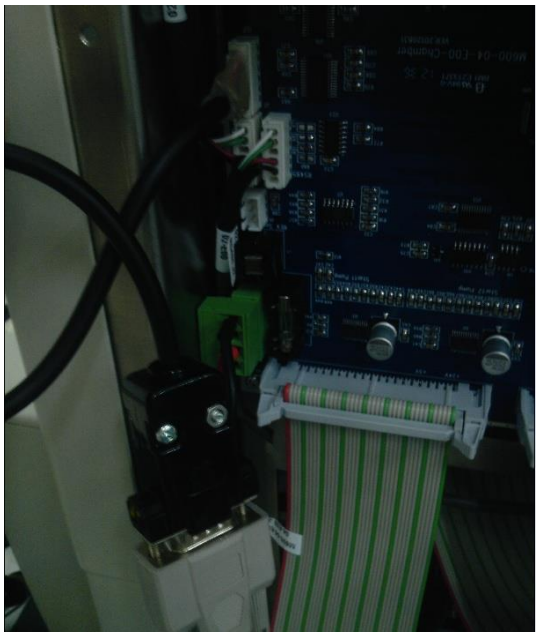


Figure B.2-9 Program Download Connection Method for Main Control Circuit Boards

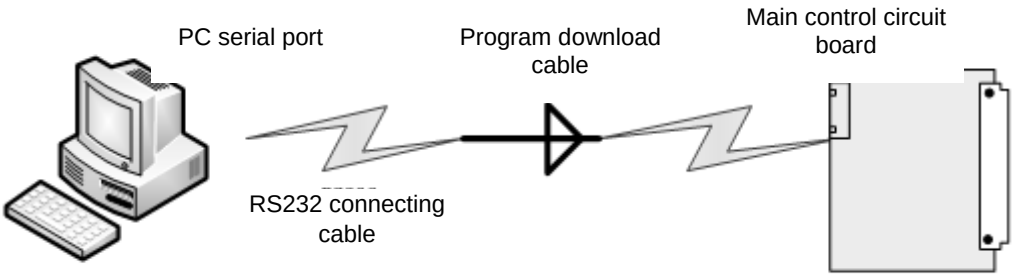


Figure B.2-10Diagram of Connection Method

2. After cable connection, start the computer and the analyzer. Run **FlashDownload.exe** on the computer; then select options as follows:

Table B.2-11 Parameter Settings of FlashDownload

Step	Option	Content	Meaning
1	Device	LPC2387(02) LPC2132(03) LPC2468(05)	Burning chip
2	COM Port	COM1	Communication port
3	Baud Rate	115200	Burning speed
4	Oscillator (KHz)	14318.18	Frequency (fixed)
5	Hex File	hex file	Select the burning file; the above 4main control circuit boards have 4 different files; each file name corresponds to a circuit board name, which are provided by Snibe.

Figure B.2-12 Program Upgrade Process for No. 02-05 Main Control Circuit Boards

3. After selecting the above options, click the **<Start>** button; after successful burning, **Status** will display finished;
4. When the writing process is finished, exit the **FlashDownload.exe** program.
5. Power off the analyzer; remove the program download cable; reconnect the RS232 data cable with the RS232 port on the analyzer; restart the analyzer.

WARNING

During program upgrade, users must follow the principle that hot plugging of the connecting cable is not allowed; the analyzer must be powered off before the connecting cable is plugged, otherwise the main control circuit board will be burnt.