

# MAGLUMI 2019-nCoV IgM/IgG

**Cat. # 130219018M**

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*For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.*

**For in vitro diagnostic use**

**For Emergency Use Authorization Only**

**For Prescription Use only**

## INTENDED USE

The MAGLUMI 2019-nCoV IgM/IgG is an *in vitro* chemiluminescence immunoassay intended for the qualitative detection and differentiation of immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies to SARS-CoV-2 in human serum and serum in separating gel tubes (SST) using the MAGLUMI 2000 series fully-automated chemiluminescence immunoassay analyzer. The MAGLUMI 2019-nCoV IgM/IgG is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The MAGLUMI 2019-nCoV IgM/IgG should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity testing.

Results are for the detection and differentiation of SARS CoV-2 antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the MAGLUMI 2019-nCoV IgM/IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the MAGLUMI 2019-nCoV IgM/IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The MAGLUMI 2019-nCoV IgM/IgG is only for use under the Food and Drug Administration's Emergency Use Authorization.

## SUMMARY AND EXPLANATION OF THE TEST

The novel coronavirus (2019-nCoV) causes an epidemic of acute respiratory syndrome in humans<sup>1</sup> and belongs to the genus *Betacoronavirus*. The virus has an envelope; viral particles are round or oval, often polymorphic, and the diameter is 60 - 140nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45)<sup>2</sup>.

2019-nCoV is mainly transmitted through respiratory droplets and can also be transmitted through direct contact. The symptoms of infection seen so far are mainly patients with pneumonia infected by the novel coronavirus<sup>2</sup>.

Research has shown that IgM and IgG antiviral antibodies can be detected in serum samples from a patient<sup>3</sup>. After human infection with 2019-nCoV, its antigen stimulates the immune system to produce an immune response, and corresponding antibodies appear in the blood after several days.

The kit should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status. The test is used as an aid to identify patients with antibodies to SARS-CoV-2 indicating recent or past infection.

The World Health Organization announced the interim name of the novel coronavirus as 2019-nCoV on January 7, 2020; The International Committee on Taxonomy of Viruses (ICTV) announced Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) as the official name of the virus on February 11, 2020. On the same day, the Director General of the World Health Organization (WHO) Tedros Adhanom Ghebreyesus announced that the name for the disease associated with infected with SARS-CoV-2 would be officially named "COVID-19," short for coronavirus disease 2019.

## PRINCIPLE OF THE TEST

The MAGLUMI 2019-nCoV IgM/IgG is a capture chemiluminescence immunoassay for IgM and an indirect chemiluminescence immunoassay for IgG. There are two cassettes that are run separately one for the detection of IgG antibodies to SARS-CoV-2 and another for the detection of IgM antibodies to SARS-CoV-2 from barcoded patient samples. After both cassettes have been run individually, one report with results for both IgM and IgG detection is generated by the system.

#### MAGLUMI 2019-nCoV IgM/IgG – Cassette for IgM Detection

The sample (serum in standard sampling tubes or tubes containing separating gel (SST)), buffer, and magnetic microbeads coated with anti-human IgM monoclonal antibody are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field, the supernatant is decanted, and a wash cycle is performed. Then, the 2019-nCoV recombinant antigen, expressing the full-length spike and nucleocapsid proteins, labeled with ABEI is added and incubated to form complexes. After precipitation in a magnetic field, the supernatant is decanted and another wash cycle is performed. Subsequently, the Starter Buffer is added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is proportional to the concentration of IgM present in the sample. The test is performed with the MAGLUMI 2000 series fully automated chemiluminescence immunoassay analyzer.

#### MAGLUMI 2019-nCoV IgM/IgG – Cassette for IgG Detection

The sample (serum in standard sampling tubes or tubes containing separating gel (SST)), buffer and magnetic microbeads coated with 2019-nCoV recombinant antigen, expressing the full-length spike and nucleocapsid proteins, are mixed thoroughly and incubated, forming immune-complexes. After precipitation in a magnetic field, the supernatant is decanted, and a wash cycle is performed. Then, the anti-human IgG antibody labeled with ABEI is added and incubated to form complexes. After precipitation in a magnetic field, the supernatant is decanted and another wash cycle is performed. Subsequently, the Starter Buffer is added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is proportional to the concentration of IgG presented in the sample. The test is performed with the MAGLUMI 2000 series fully automated chemiluminescence immunoassay analyzer.

**KIT COMPONENTS** – One kit contains two cassettes, one for SARS-CoV-2 IgG detection and another for SARS-CoV-2 IgM detection. The components for IgG and IgM detection with the MAGLUMI 2019-nCoV IgM/IgG are provided below and can be ordered under Catalog # 130219018M.

Cassette	Components	Contents	100 tests
For SARS CoV-2 IgG antibodies	<b>Magnetic Microbeads</b>	Magnetic microbeads coated with 2019-nCoV recombinant antigen, PBS buffer and BSA, NaN <sub>3</sub> (<0.1%)	2.5 mL
	<b>Calibrator Low</b>	2019-nCoV IgG, PBS buffer and BSA, NaN <sub>3</sub> (<0.1%)	1.0 mL
	<b>Calibrator High</b>	2019-nCoV IgG, PBS buffer and BSA, NaN <sub>3</sub> (<0.1%)	1.0 mL
	<b>Buffer</b>	NaCl and BSA, NaN <sub>3</sub> (<0.1%).	23.5 mL
	<b>ABEI Label</b>	Anti-human IgG antibody labeled with ABEI, Tris-HCl buffer, Mouse IgG, Goat IgG, and BSA, NaN <sub>3</sub> (<0.1%)	23.5 mL
	<b>Diluent</b>	PBS buffer and BSA, NaN <sub>3</sub> (<0.1%)	23.5 mL
	<b>Negative Control</b>	PBS buffer, containing BSA, NaN <sub>3</sub> (<0.1%)	1.0 mL
	<b>Positive Control</b>	2019-nCoV IgG, PBS buffer, containing BSA and NaN <sub>3</sub> (<0.1%).	1.0 mL
For SARS-CoV-2 IgM antibodies	<b>Magnetic Microbeads</b>	Magnetic microbeads coated with anti-human IgM monoclonal antibody, PBS buffer and BSA, NaN <sub>3</sub> (<0.1%).	2.5 mL
	<b>Calibrator Low</b>	2019-nCoV IgM, PBS buffer and BSA, NaN <sub>3</sub> (<0.1%).	1.0 mL
	<b>Calibrator High</b>	2019-nCoV IgM, PBS buffer, and BSA, NaN <sub>3</sub> (<0.1%).	1.0 mL
	<b>Buffer</b>	PBS buffer, Goat anti-Human IgG, Goat anti-Human IgA Mouse IgG, Goat IgG and BSA, NaN <sub>3</sub> (<0.1%).	23.5 mL
	<b>ABEI Label</b>	2019-nCoV recombinant antigen labeled with ABEI, Tris-HCl buffer, Mouse IgG, Goat IgG, and BSA, NaN <sub>3</sub> (<0.1%).	23.5 mL
	<b>Diluent</b>	PBS buffer, Goat anti-Human IgG, Goat anti-Human IgA Mouse IgG, Goat IgG and BSA, NaN <sub>3</sub> (<0.1%).	23.5 mL
	<b>Negative Control</b>	PBS buffer, containing BSA, NaN <sub>3</sub> (<0.1%).	1.0 mL
	<b>Positive Control</b>	2019-nCoV IgM, PBS buffer, containing BSA and NaN <sub>3</sub> (<0.1%).	1.0 mL
All reagents are provided ready-to-use.			

#### Components Required but Not Included in the MAGLUMI 2019-nCoV IgM/IgG Test Kit :

Component	Catalog number	Contents	Quantity/Volume
Reaction Module	630003	polypropylene	64/box

Starter Buffer	130299004M	Catalyst in 1.5% NaOH, 0.18% H2O2	230 mLx1
Wash Concentrate	130299005M	Tris-HCl buffer solution	714 mLx1
Light Check	130299006M	ABEI (N-(4-Aminobutyl)-N-ethylisoluminol ), BSA	2mLx5

Instrument
MAGLUMI 2000 series fully-automated chemiluminescence immunoassay analyzer

Please order all above from Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE) or our authorized representative.

## CALIBRATION

Traceability: This method has been standardized against the SNIBE internal reference substance.

Testing of assay specific calibrators allows the RLU values to adjust the assigned master curve. Results are determined automatically by the system via a calibration curve, which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent Radio Frequency Identification (RFID) CHIP.

Recalibration is recommended if any of the following conditions occurs:

- After each exchange of lots (Reagent or Starter Buffer).
- Every week and/or each time a new reagent kit is used.
- After instrument service is required.
- If controls lie outside the expected range.

## QUALITY CONTROL

Follow government regulations or accreditation requirements for quality control frequency.

Quality controls (positive and negative controls) are only applicable with MAGLUMI system.

For details about entering quality control values, refer to the operating instructions of MAGLUMI 2000 series fully-auto chemiluminescence immunoassay analyzer.

To monitor system performance, quality control materials (positive and negative) are required. Treat all quality control with the same level of care as patient samples. A satisfactory level of performance is achieved when analyte values obtained are within the acceptable pre-established ranges. If the quality control results fall outside the pre-established ranges of less than 0.7 AU/mL for negative controls and 2.8-5.2 AU/mL for positive controls, measurement of the quality control should be repeated. If the quality control results still falls outside the pre-established range, do not report results and take the following actions:

- Verify that the quality control materials (positive and negative) are not expired.
- Verify that the analyzer required maintenance was performed.
- Verify that the assay was performed according to the instruction for use.
- Rerun the assay with new quality control samples (positive and negative).
- If necessary, contact your local technical support provider or distributor for assistance.

## SPECIMEN COLLECTION AND PREPARATION- WARNINGS AND PRECAUTIONS

- Serum in standard sampling tubes or tubes containing separating gel is the recommended sample matrix. The sample volume required for a single determination is 10 µL.
- Samples may be infectious so heat inactivation of the samples at 56°C for 30 minutes should be performed before testing, or according to the requirements of state and local governments<sup>2</sup>.
- Ensure that complete clot formation in specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time.
- If the specimen is centrifuged before complete clotting, the presence of fibrin may cause erroneous results. Samples must be free of fibrin and other particulate substances.
- Grossly hemolyzed specimens or specimens containing particulate matter or exhibiting obvious microbial contamination should not be used. All specimens should be inspected for bubbles and bubbles removed before analysis for optimal results.
- All samples (patient specimens and controls) should be tested within 3 hours of placing them on board the MAGLUMI System. Refer to the SNIBE service for more detailed discussion of onboard sample storage constraints. (website : [https://www.snibe.com/zh\\_en/en\\_index.aspx](https://www.snibe.com/zh_en/en_index.aspx))

- Specimens removed from the separator gel, cells, or clot may be stored for 3 days at 2-8°C. If longer storage is required, the specimens should be kept at -20°C or colder<sup>4</sup>.
- Avoid more than three freeze and thaw cycles. Frozen specimens must be mixed thoroughly after thawing by low speed vortex or by gently inverting.
- For optimal results, specimens should be free of fibrin, red blood cells, or other particulate matter. Such specimens may give inconsistent results and must be transferred to a centrifuge tube and centrifuged at  $\geq 10,000\text{RCF}$  (Relative Centrifugal Force) for 10 minutes. Transfer clarified specimens to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.
- Before shipping specimens, it is recommended that specimens be removed from the separator, red blood cells, or clot. When shipped, specimens should be packaged and labeled in compliance with applicable state, federal and international regulations covering the transport of clinical specimens and infectious substances. Specimens should be shipped frozen.

## **WARNING AND PRECAUTIONS FOR USERS**

- IVD** For *In Vitro Diagnostic Use*.
- For Emergency Use Authorization Only
  - For Prescription Use only
  - This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA and meet requirements to perform moderate or high complexity tests.
  - This test has been authorized only for the presence of IgG or IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens.
  - This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
  - Follow the package insert carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

### **Safety Precautions**

- CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the 29 CFR 1910.1030 Occupational exposure to bloodborne pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
- All samples, biological reagents, and materials used in the assay should be considered potentially able to transmit infectious agents. They should therefore be disposed of in accordance with the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.
- This product contains Sodium azide. Dispose of contents and container must be in accordance with all local, regional and national regulations.
- Refer to safety data sheets, which are available on request.

### **Handling Precautions**

- Do not use reagent kits beyond the expiration date.
- Do not interchange reagent components from different reagents or lots.
- Prior to loading the Reagent Kit on the system for the first time, the Reagent Kit requires mixing to re-suspend magnetic microbeads that have settled during shipment. For magnetic microbeads mixing instructions, refer to the Preparation of the Reagent section of this package insert.
- To avoid contamination, wear clean gloves when operating with a reagent kit and sample.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.
- To avoid evaporation of the liquid in the opened reagent kits in a refrigerator, it is recommended that the opened reagent kits be sealed with reagent seals contained within the packaging. The reagent seals are "single use," and if more seals are needed, please contact Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE) or our authorized representative. For detailed discussion of handling precautions during system operation, refer to the SNIBE service information (website : [https://www.snibe.com/zh\\_en/en\\_index.aspx](https://www.snibe.com/zh_en/en_index.aspx))

## **STORAGE AND STABILITY**

- Store at 2-8°C. Do not freeze.
- Keep upright for storage to facilitate later proper resuspension of magnetic microbeads.
- Keep away from sunlight.

<b>Stability of the reagent</b>	
unopened at 2-8°C	until the stated expiration date
opened at 2-8°C	6 weeks
onboard	4 weeks

- To ensure the best kit performance, it is recommended to place opened kits in the refrigerator after the end of the intraday test work.

## TEST PROCEDURE

### Preparation of the Reagent

- Take the reagent kit out of the box and inspect 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 distributor immediately. Then, tear off the kit sealing film carefully.
- Open the reagent area door; hold the reagent handle to get the RFID label close to the RFID reader (for about 2 seconds); the buzzer will beep; one beep sound indicates successful sensing.
- Keeping the reagent straight insert to the bottom along the blank reagent track.
- Observe whether the reagent information is displayed successfully in the software interface, otherwise repeat the above steps.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended and homogenous prior to use.

### Assay Calibration

- Click <**Calibration**> or <**Batch Calibration**> button to execute the calibration operation; for specific information on ordering calibrations, refer to the Calibration Section of the Operating Instructions.
- Execute recalibration according to the calibration interval required in this package insert.

### Quality Control

- In order to avoid manually error in entry of QC information, the provided barcode labels of quality control (positive and negative)) in the kit should be attached to the test tubes.
- If users do not use the provided barcode labels for positive and negative controls contained within the packaging, then quality controls (positive and negative) should be ordered manually.
- For specific information on ordering quality controls (positive and negative), refer to the Quality Control Section of the Operating Instructions.

### Sample Testing

- Carefully transfer serum samples with each minimum volume of 160 $\mu$ L into sample tubes.
- Load sample tubes to sample racks and start testing.
- Order the samples in the Sample Area of the software and click the <**Start**> button to execute testing. For specific information on ordering patient specimens, refer to the Sample Ordering Section of the Operating Instructions.
- Samples from the same patient must be loaded in separate cassettes due to the design of the cleared instrument, MAGLUMII™ series fully-automated chemiluminescence immunoassay analyzer and a single report results for both IgM and IgG SARS-CoV-2 antibodies will be generated per patient.

To ensure proper test performance, strictly adhere to the operating instructions of MAGLUMII™ series fully-auto chemiluminescence immunoassay analyzer.

## LIMITATIONS

- This test is suitable only for investigating single samples, not for pooled samples.
- The product can only be used with MAGLUMII™ series fully-auto chemiluminescence immunoassay analyzer.
- The MAGLUMI 2019-nCoV IgM/IgG has not been evaluated for specimens other than human serum.
- Bacterial contamination or repeated freeze-thaw cycles may affect the test results.
- Assay results should be utilized in conjunction with other clinical and laboratory methods to assist the clinician in making individual patient decisions.
- Assay results should not be used to diagnose or exclude acute COVID-19. Direct viral nucleic acid detection or antigen detection methods should be performed if acute infection is suspected.
  - Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
  - A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody detected by the test.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- SARS-CoV-2 IgM and IgG antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 8 days.
- If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- HAMA antibodies in test samples may cause interference in immunoassays at concentrations greater than 30ng/mL.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.

- Not for the screening of donated blood.

### **Conditions of Authorization for the Laboratory**

The MAGLUMI 2019-nCoV IgM/IgG Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Authorized laboratories using the MAGLUMI 2019-nCoV IgM/IgG must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories<sup>a</sup> using the MAGLUMI 2019-nCoV IgM/IgG will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories will use the MAGLUMI 2019-nCoV IgM/IgG as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the product are not permitted.
- Authorized laboratories that receive the MAGLUMI 2019-nCoV IgM/IgG will notify the relevant public health authorities of their intent to run the assay prior to initiating testing.
- Authorized laboratories using the MAGLUMI 2019-nCoV IgM/IgG will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the MAGLUMI 2019-nCoV IgM/IgG and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH EUA [Reporting@fda.hhs.gov](mailto:Reporting@fda.hhs.gov)) and to Snibe Co. Ltd ([pgshugart@carolinachemistries.com](mailto:pgshugart@carolinachemistries.com)) and MAGLUMI Technical Support ([http://www.snibe.com/zh\\_en/en\\_services.aspx?id=66](http://www.snibe.com/zh_en/en_services.aspx?id=66)) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of the assay of which they become aware.
- All laboratory personnel using the MAGLUMI 2019-nCoV IgM/IgG must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the MAGLUMI 2019-nCoV IgM/IgG Combo Test Kit in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the the MAGLUMI 2019-nCoV IgM/IgG.
- Snibe Co. Ltd., authorized distributors, and authorized laboratories using the MAGLUMI 2019-nCoV IgM/IgG will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

<sup>a</sup> The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate and high complexity tests" as "authorized laboratories".

## **RESULTS**

### **Calculation of Results**

The analyzer automatically calculates the numerical output in each sample by means of a calibration curve which is generated by a two-point calibration master curve procedure. The results are expressed in absorbance unit AU/mL. The results are reported to the end user as "Reactive" and "Non-Reactive". No AU/mL numerical values are reported to the end user. For further information please refer to the operating instructions of MAGLUMI series fully-automated chemiluminescence immunoassay analyzer.

### **Interpretation of Results**

- Non-reactive: A result less than 1.00 AU/mL (<1.00 AU/mL) is considered to be non-reactive.
- Reactive: A result greater than or equal to 1.00 AU/mL (≥1.00 AU/mL) is considered to be reactive.

Analyte	Results	Interpretation	Description*
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<b>SARS-CoV-2 IgG</b>	<1.00 AU/mL	SARS-CoV-2 IgG Non-Reactive	IgG antibodies against SARS-CoV-2 are not detected
	≥1.00 AU/mL	SARS-CoV-2 IgG Reactive	IgG antibodies against SARS-CoV-2 are detected
<b>SARS-CoV-2 IgM</b>	<1.00 AU/mL	SARS-CoV-2 IgM Non-Reactive	IgM antibodies against SARS-CoV-2 are not detected
	≥1.00 AU/mL	SARS-CoV-2 IgM Reactive	IgM antibodies against SARS-CoV-2 are detected

\*If external controls are outside the pre-established ranges do not report results and test the sample again.

## PERFORMANCE CHARACTERISTICS

### Precision

Precision of the MAGLUMI 2019-nCoV IgM/IgG assay was determined as described in the CLSI EP5-A3.2. Controls and three human serum pools containing different levels of analyte were assayed in duplicate at three sites over 5 days, with three runs per day, and one lot of reagent for each run. The results are summarized in the following table:

Analyte	Sample	Mean Value (AU/mL)	N	Repeatability		Between-Lot		Between-Day		Between-Site		Reproducibility	
				SD (AU/mL)	%CV	SD (AU/mL)	%CV	SD (AU/mL)	%CV	SD (AU/mL)	%CV	SD (AU/mL)	%CV
IgG	NQC	0.293	90	0.024	NA	0.005	NA	0.008	NA	0.023	NA	0.035	NA
	PQC	3.915	90	0.199	5.08	0.069	1.76	0.032	0.82	0.265	6.77	0.340	8.68
	S1	0.491	90	0.043	NA	0.015	NA	0.004	NA	0.013	NA	0.047	NA
	S2	3.486	90	0.212	6.08	0.060	1.72	0.050	1.43	0.071	2.04	0.237	6.80
	S3	9.807	90	0.159	1.62	0.122	1.24	0.082	0.84	0.639	6.52	0.675	6.88
IgM	NQC	0.293	90	0.020	NA	0.006	NA	0.007	NA	0.007	NA	0.023	NA
	PQC	3.920	90	0.167	4.26	0.046	1.17	0.062	1.58	0.284	7.24	0.339	8.65
	S1	0.492	90	0.033	NA	0.016	NA	0.009	NA	0.012	NA	0.040	NA
	S2	1.797	90	0.037	2.06	0.018	1.00	0.053	2.95	0.088	4.90	0.111	6.18
	S3	3.411	90	0.076	2.23	0.000	0.00	0.049	1.44	0.226	6.63	0.244	7.15

**Potentially Interfering Substances** The effect of potential interference substances of the performance of the MAGLUMI 2019-nCoV IgM/IgG assay was evaluated using one negative serum sample and one positive serum sample spiked with whether SARS-CoV-2 IgG or SARS-CoV-2 IgM antibodies. Both cassettes (for IgM and IgG) were tested separately according to the instructions for use. No interference was observed up to the concentrations included in the table below:

Potential Interferent		Highest Concentration of Potential Interferent tested with no Interferent Effect
Endogenous	Bilirubin	40 mg/dL
	Triglycerides	1000 mg/dL
	Hemoglobin	2000 mg/dL
	Rheumatoid Factor	1500 IU/mL
	Anti-Mitochondrial	1:64(titer)
	HAMA	30 ng/mL
Exogenous	Total IgG	1600 mg/dL
	Total IgM	280 mg/dL
	Interferon $\alpha$	1500 U/mL
	Ribavirin	90 mg/dL
	Oseltamivir	1.0 mg/dL
	Levofloxacin	1.776 mg/dL
	Azithromycin	1.201 mg/dL
	Ceftriaxone sodium	81.03 mg/dL
	Meropenem	80.15 mg/dL
	Tobramycin	2.4 mg/dL
	Diphenhydramine	4.5 mg/dL
	Oxymetazoline	2.5 mg/dL
	Sodium chloride	45 mg/dL
	Beclomethasone	2.5 mg/dL
	Dexamethasone	18 mg/dL
	Triamcinolone acetonide	5.5 mg/dL
	Budesonide	3.2 mg/dL
	Mometasone	2.5 mg/dL
	Fluticasone propionate	2.5 mg/dL

### Cross-Reactivity

The cross-reactivity of the MAGLUMI 2019-nCoV IgM/IgG was evaluated by testing SARS-CoV-2 seronegative serum samples from patients with antibodies to various viruses and other possible cross-reactants. The cassette used for IgM detection was tested with the potential cross-reactants separately from the cassette for IgG detection following the instructions for use. No false positive results were observed. The results of the potential interference study are listed in the following table:

Condition	Number of Samples Containing Potential Cross-Reactants	Number of False Positive Results	
		SARS-CoV-2 IgM	SARS-CoV-2 IgG
Influenza A virus antibodies	17	0	0
Influenza B virus antibodies	19	0	0
Parainfluenza virus antibodies	23	0	0
Respiratory syncytial virus antibodies	7	0	0
Adenovirus antibodies	9	0	0
EBV NA IgG	10	0	0
EBV VCA IgG	4	0	0
EBV VCA IgM	6	0	0
Measles virus	2	0	0
CMV IgG	6	0	0
CMV IgM	2	0	0
Varicella zoster virus antibodies	2	0	0
<i>M. pneumonia</i> IgG	3	0	0
<i>M. pneumonia</i> IgM	4	0	0
<i>Chlamydia pneumoniae</i> IgG	3	0	0
<i>Chlamydia pneumoniae</i> IgM	3	0	0
<i>Monilia albicans</i>	1	0	0
Antinuclear Antibodies (ANA)	6	0	0
anti-HCV (IgG and IgM)	5	0	0
anti-HBV (IgG and IgM)	5	0	0
anti-HIV (IgG and IgM)	16	0	0
Total	159	0	0

## CLINICAL PERFORMANCE

A total of 490 subjects were enrolled to evaluate the MAGLUMI 2019-nCoV IgM/IgG test clinical performance. Among the 490 serum samples collected, 264 were from SARS-CoV-2 PCR-confirmed positive subjects while 226 were from SARS-CoV-2 PCR-confirmed negative subjects. All samples collected were tested using the MAGLUMI 2019-nCoV IgM/IgG test. The negative percent agreement (NPA) and the positive percent agreement (PPA) were calculated. Out of the 226 PCR negative subjects 3 tested positive with the MAGLUMI 2019-nCoV IgM/IgG (2 false positive for IgG and 1 for IgM), so the NPA is 98.67% (95% CI: 96.17% - 99.55%)

The following tables describe the PPA calculations, by time of sampling days post symptom onset, for IgG and IgM separately as well as combined.

### MAGLUMI 2019-nCoV IgM/IgG – SARS-CoV-2 IgG PPA (Stratified by Days Post-Symptom Onset)

		PCR Comparator
--	--	----------------

Days Post Symptom	PCR Total Positive	IgG Positive Results	IgG PPA	95% Confidence Interval (CI)
≤7	16	5	31.25%	14.16% - 55.60%
8-14	106	96	90.57%	83.50% - 94.80%
≥15	142	142	100.00%	97.37% - 100.00%
Total	264	243	92.05%	88.15% - 94.74%

#### MAGLUMI 2019-nCoV IgM/IgG - SARS-CoV-2 IgM PPA (Stratified by Days Post-Symptom Onset)

Days Post Symptom Onset	PCR Total Positive	PCR Comparator		
		IgM Positive Results	IgM PPA	95% CI
≤7	16	7	43.75%	23.10% - 66.82%
8-14	106	83	78.30%	69.54% - 85.08%
≥15	142	110	77.46%	69.92% - 83.56%
Total	264	200	75.76%	70.24% - 80.53%

#### MAGLUMI 2019-nCoV IgM/IgG – SARS-CoV-2 IgM and IgG Combined PPA (Stratified by Days Post-Symptom Onset)

Days Post Symptom Onset	PCR Total Positive	PCR Comparator		
		IgG/IgM combined Positive Results	IgG/IgM Combined PPA	95% CI
≤7	16	7	43.75%	23.10% - 66.82%
8-14	106	99	93.40%	86.99% - 96.76%
≥15	142	142	100%	97.37% - 100.00%
Total	264	248	93.94%	90.38% - 96.24%

#### SYMBOLS EXPLANATIONS

	Consult instructions for use		Manufacturer
2°C → 8°C	Temperature limit (Store at 2-8°C)		Use-by date
	Contains sufficient for <n> tests		Keep away from sunlight
	This way up		Kit components
	<i>In vitro</i> diagnostic medical device		Batch code
	Catalogue number		



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# **Maglumi 2000 Immunoassay Analyzer**

## **Operating Instructions**



Dear users! Thank you for using our **MAGLUMI®** 2000 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.



## Intellectual Property Statement

Shenzhen New Industries Biomedical Engineering Co., Ltd owns the intellectual properties to this product and copyright of this instruction.

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**Biolumi**, **Biossays**, **MAGLUMI**, **Preaccu** and  are the registered trademarks or trademarks owned by Snibe in China and other countries.

## Information about the Product

**Device Name:** Maglumi 2000 Immunoassay Analyzer

**Intended Use:** The Maglumi 2000 Immunoassay system is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens. The Maglumi 2000 Immunoassay system's assay application utilizes chemiluminescents technology for clinical use.

The Maglumi 2000 Immunoassay system is intended for prescription use.

REF	Device Name	Catalogue Number
	Maglumi 2000 Immunoassay Analyzer	23020006

## Information of operating instructions

**Issued Date:** 2020-07

**Version:** 1.4

**Applicable Scope of Software:** above2.14.8.8

## Company Contact

**Manufacturer:** Shenzhen New Industries Biomedical Engineering Co., Ltd.

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# TABLE OF CONTENTS

INTELLECTUAL PROPERTY STATEMENT .....	5
INFORMATION ABOUT THE PRODUCT.....	5
INFORMATION OF OPERATING INSTRUCTIONS .....	5
COMPANY CONTACT .....	5
<b>NOTES.....</b>	<b>1</b>
PURPOSE .....	2
SAFETY NOTE .....	2
OPERATION NOTES.....	6
OTHER NOTES .....	9
WARNING SYMBOLS.....	10
OTHER SYMBOLS .....	12
<b>1 ABOUT THIS INSTRUCTIONS.....</b>	<b>1</b>
1.1 TEXT CONVENTIONS .....	1
1.2 BUTTON .....	1
1.3 WORD.....	2
1.4 GLOSSARY .....	2
<b>2 MEASURING PRINCIPLE.....</b>	<b>1</b>
2.1 ASSAY PROCEDURE .....	1
2.2 MEASURING PRINCIPLE.....	2
2.3 CALIBRATION .....	3
<b>3 SYSTEM DESCRIPTION.....</b>	<b>1</b>
3.1 SYSTEM STRUCTURE.....	1
3.2 ANALYZER .....	2
3.2.1 Sample Area.....	3
3.2.2 Reagent Area .....	4
3.2.3 Barcode Reader and RFID Reader.....	5
3.2.3.1 Barcode Reader .....	5
3.2.3.2 RFID Reader .....	7
3.2.4 Pipettor.....	7
3.2.5 Stacker .....	8
3.2.6 Incubator .....	9
3.2.7 Incubator Loader and Washer Loader .....	10
3.2.8 Washer .....	10
3.2.9 Pusher.....	11
3.2.10 Back Transport.....	11
3.2.11 Chamber .....	12
3.2.12 Pump System .....	12
3.2.13 Starter.....	13
3.2.14 System Liquid.....	13
3.2.15 Cuvette Waste Bag Bin and Waste Liquid .....	13
3.3 COMPUTER SYSTEM .....	15
3.3.1 Computer System Components.....	15
3.3.2 Basic Operations in Software Interface .....	15
3.3.2.1 Using the Touch monitor Mouse and Keyboard.....	15
3.3.2.2 Software Components.....	16
3.4 TESTING PERFORMANCE .....	19
3.4.1 Batch Assay Repeatability.....	19
3.4.2 Linear Correlation .....	19
3.4.3 Carryover Rate.....	19
3.4.4 Stability.....	19
<b>4 INSTALLATION AND STARTUP .....</b>	<b>1</b>

<b>4.1 ANALYZER TRANSPORTATION AND STORAGE REQUIREMENTS .....</b>	<b>1</b>
4.1.1 Transportation Requirements .....	1
4.1.2 Storage Requirements.....	1
<b>4.2 INSTALLATION REQUIREMENTS .....</b>	<b>1</b>
4.2.1 Installation Environment Requirements.....	1
4.2.2 Power Requirements.....	1
4.2.3 Space Requirements.....	2
4.2.4 Temperature and Humidity Requirements.....	2
<b>4.3 UNPACKING INSPECTION .....</b>	<b>2</b>
4.3.1 Unpacking Procedure .....	2
4.3.2 Analyzer Transportation and Fastening.....	2
<b>4.4 ANALYZER INSTALLATION .....</b>	<b>3</b>
4.4.1 System Circuit Connection.....	3
4.4.2 System Liquid Tank and Waste Liquid Tank Connection .....	3
4.4.3 Starter Connection .....	4
4.4.4 Waster Bag Placement .....	4
4.4.5 Cuvettes Loading .....	5
<b>4.5 POWER-ON AND SYSTEM STARTUP .....</b>	<b>5</b>
4.5.1 Starting the Analyzer .....	5
4.5.2 Starting the PC System and Operating Software .....	5
4.5.3 Performing System Test.....	6
<b>5 DAILY OPERATING PROCESS.....</b>	<b>1</b>
5.1 DAILY OPERATING PROCESS.....	1
5.2 TEST PREPARATION .....	2
5.2.1 Check before Starting .....	2
5.2.2 Power-on and Login the Software .....	2
5.2.3 Check Consumables.....	3
5.2.4 Confirm Device Status .....	3
5.2.5 Confirm Test Condition.....	5
5.2.6 Prepare Reagent .....	5
5.3 TEST ANALYSIS.....	6
5.3.1 Assay Calibration .....	6
5.3.2 Control Registration .....	8
5.3.3 Sample Registration.....	10
5.3.4 Start Test .....	11
5.3.5 Additional Samples and Assays .....	11
5.4 TEST RESULTS .....	11
5.5 END OF ANALYSIS .....	12
5.5.1 Shutdown .....	12
5.5.2 Operation after Shutdown.....	12
<b>6 [SYSTEM] MENU .....</b>	<b>1</b>
6.1 [SYSTEM] MENU INTRODUCTION .....	1
6.2 <INFO> .....	1
6.3 <MODE>.....	2
6.4 <ONLINE>.....	4
6.5 <USER> .....	5
6.6 <LANGUAGE> .....	6
6.7 <MAINTENANCE>.....	7
6.8 <WASH PIPE> .....	9
<b>7 [DEFINITION] MENU .....</b>	<b>1</b>
7.1 [DEFINITION] MENU INTRODUCTION .....	1
7.2 <TEST> .....	1
7.2.1 <Auto Dil.> .....	4
7.2.2 <Format> .....	5

7.2.3 <Qualit. Lbl>.....	5
7.2.4 <Reflex> .....	6
7.2.5 <Master Curve> .....	7
7.3 <CONTROL> .....	8
7.4 <GROUP>.....	11
7.5 <PROFILE>.....	12
7.6 <DILUTER> .....	13
7.7 <SENDER> .....	15
7.8 <RESULT DEFINE> .....	16
<b>8 [PROCESS] MENU.....</b>	<b>1</b>
8.1 [PROCESS] MENU INTRODUCTION .....	1
8.2 <INITIALIZE>.....	2
8.3 <INIT W. CLEAR>.....	2
8.4 <RESTART> .....	3
8.5 <RETURN ASY>.....	3
8.6 <LOW LEVEL>.....	4
8.7 <PROTOCOL> .....	4
8.8 <WARNING Opt.> .....	5
<b>9 [SYSTEM TEST] MENU .....</b>	<b>1</b>
9.1 [SYSTEM TEST] MENU.....	1
9.2 LOAD LIGHT CHECK.....	2
9.3 ADD LIGHT CHECK .....	3
<b>10 [REAGENTS] MENU .....</b>	<b>1</b>
10.1 [REAGENT] INTERFACE.....	1
10.2 REAGENT AREA .....	2
10.3 REAGENT DATA.....	4
10.3.1 Calibrators .....	5
10.3.2 Tolerances .....	5
10.3.3 Remaining Tests.....	6
10.4 CALIBRATION .....	6
10.4.1 <Calibrate> .....	7
10.4.2 <View> .....	7
10.4.2.1 <Calculate Curve>.....	9
10.4.2.2 <Print> .....	9
10.4.2.3<Calibrate History> .....	9
10.4.2.4 <Change Calibrator> .....	10
10.5 REAGENT CALIBRATION AND VALIDATION.....	10
10.6 <BATCH CALIBRATION> .....	11
10.7 <REAGENT INVENTORY> .....	11
10.8 <OK> .....	12
<b>11 [PATIENTS] MENU.....</b>	<b>1</b>
11.1 [PATIENTS] MENU INTRODUCTION.....	1
11.2 [PATIENTS] MENU .....	2
11.2.1 Rack Station .....	2
11.2.2 Sample Info.....	3
11.2.3 Assay Selection .....	5
11.2.4 Profile Selection.....	6
11.2.5 Loading .....	6
11.2.5.1 <Work List> and <Edit>.....	7
11.2.5.2 <STAT>.....	7
11.2.5.3 <Control>.....	8
11.2.5.4 <Std/LC> .....	8
11.2.5.5 <Dilute> .....	9
11.6 <Save> .....	9

<b>12 [REPORT] MENU .....</b>	<b>1</b>
12.1 [REPORT] MENU INTRODUCTION.....	1
12.2 <JOURNAL>.....	2
12.2.1<Sort> .....	2
12.2.2 <Today Rpt.>.....	3
12.2.3 <Recalculate> .....	4
12.2.4 <Online> .....	4
12.2.5 <Edit>.....	5
12.2.6 <Delete> .....	7
12.2.7 <Valid>.....	7
12.2.8 <Print> .....	8
12.2.9 <Remeasure>.....	9
12.3 <VALID>.....	9
12.4 <CALIBRATOR> .....	11
12.5 <CONTROL> .....	12
12.6 <SYSTEM TEST> .....	12
12.7 <REPORT> .....	14
12.7.1 <Import>.....	14
12.7.2 <Search> .....	16
12.7.3 <QC> .....	17
12.7.4 <Dictionary> .....	18
12.7.5 <Setting>.....	19
12.7.6 <Return> .....	21
<b>13 STATUS DISPLAY AND HANDLING.....</b>	<b>1</b>
13.1 STATUS DISPLAY.....	1
13.1.1 Consumables .....	1
13.1.1.1 Cuvettes.....	2
13.1.1.2 System Liquid.....	2
13.1.1.3 Starter Reagents .....	3
13.1.2 Temperature and Voltage.....	3
13.1.3 WASTE .....	4
13.1.3.1 Waste Liquid.....	4
13.1.3.2 Waste Cuvettes.....	4
13.2 HANDLING CONSUMABLES .....	5
13.2.1 Placing Cuvette .....	5
13.2.2 Adding System Liquid .....	5
13.2.3 Change Starter Reagents .....	6
13.2.4 Waste Cuvettes.....	7
13.2.5 Waste Liquid .....	7
<b>14 REAGENT LOADING.....</b>	<b>1</b>
14.1 REAGENT STRUCTURE.....	1
14.2 REAGENT LOADING .....	1
14.2.1 Prepare the Reagent.....	1
14.2.2 Loading the Reagent.....	2
14.2.3 Remove the reagent .....	3
14.3 PROPERLY STORE THE REAGENT.....	3
<b>15 SAMPLE LOADING.....</b>	<b>1</b>
15.1 SAMPLE RACK .....	1
15.1.1 Structure of Sample Rack .....	1
15.1.2 Type of Sample Rack.....	2
15.2 SAMPLE LOADING .....	3
15.2.1 Prepare the Sample .....	3
15.2.2 Sample Rack Loading .....	4
15.2.3 Remove the Sample Rack .....	5

15.3 Maintenance of Sample Rack .....	5
<b>16 LIS INTERFACE.....</b>	<b>1</b>
16.1 DESCRIPTION OF ONLINE MODE .....	1
16.1.1 Enable Online Mode .....	1
16.1.2 Setting Parameters of Online Mode .....	1
16.1.3 Methods of Sending Results .....	3
16.2 INSTRUCTION ON CONTROL CODES .....	4
16.3 INSTRUCTION ON BASIC COMMUNICATION FORMAT.....	4
16.4 INSTRUCTION ON DELIMITERS .....	4
16.5 INSTRUCTION ON TYPE OF MESSAGE .....	4
16.5.1 Message head record (H) .....	5
16.5.2 Patient Info Record (P) .....	5
16.5.3 Assays Record (O) .....	6
16.5.4 Result Record (R) .....	7
16.5.5 Info Required Record (Q).....	7
16.5.6 Message End Record (L) .....	8
16.6 EXAMPLE .....	8
16.6.1 Enquiring Assay.....	8
16.6.2 Returning Assays .....	9
16.6.3 Sending Assay Results.....	10
<b>17 SYSTEM MAINTENANCE .....</b>	<b>1</b>
17.1 DAILY MAINTENANCE .....	1
17.2 WEEKLY MAINTENANCE.....	1
17.3 MONTHLY MAINTENANCE .....	1
17.4 ETENDED SHUNTDOWN-SYSTEM IDLE 5 DAYS OR MORE .....	2
<b>18 TROUBLESHOOTING AND DIAGNOSTICS.....</b>	<b>1</b>
18.1 MANAGE OF SYSTEM INFO AND ERROR MESSAGES .....	1
18.2 EMERGENCY STOP .....	3
18.3 COMMON PROBLEMS.....	5
18.4 ERROR MESSAGE AND SOLUTION.....	10
<b>APPENDIX A ADJUST NEEDLES .....</b>	<b>1</b>
A.1 PREPARATION BEFORE ADJUSTING .....	1
A.2 NEEDLES ADJUST PROGRAM.....	4
A.3 REFERENTIAL POSITION ADJUST .....	5
A.3.1 Left Referential Position Adjust.....	5
A.3.2 Right Referential Position Adjust .....	6
A.4 LEFT PIPETTING POSITION ADJUST .....	7
A.4.1 Left Needle Adjust on Left Pipetting Position .....	7
A.4.2 Right Needle Adjust on Left Pipetting Position .....	10
A.5 INCUBATOR PIPETTING POSITION ADJUST.....	12
A.5.1 Left Incubator Pipetting Position Adjust .....	13
A.5.2 Right Incubator Pipetting Position Adjust .....	15
A.6 RIGHT PIPETTING POSITION ADJUST .....	17
A.6.1 Left Needle Adjust on Right Pipetting Position .....	18
A.6.2 Right Needle Adjust on Right Pipetting Position .....	21
A.7 WASHING POSITION ADJUST .....	24
A.7.1 Left Washing Position Adjust .....	24
A.7.2 Right Washing Position Adjust .....	25
A.8 ADJUST OF NEEDLE POSITION IN SAMPLE AREA.....	26
A.8.1 Adjust of Left Position in Sample Area .....	27
A.8.2 Adjust of Right Position in Sample Area.....	30
A.9 ADJUST OF NEEDLE POSITION IN REAGENT AREA .....	33
A.9.1 Adjust of Left Needle in Reagent Area .....	34

A.9.2 Adjust of Right Needle in Reagent Area .....	39
A.10 CUVETTE HIGH-LEVEL ADJUST.....	44
A.10.1 Left Cuvette High-level Adjust.....	45
A.10.2 Right Cuvette High-level Adjust.....	46
A.11 ADJUST OF START POSITION OF REAGENTS .....	47
A.11.1 Adjust of Left Start Position of Reagents .....	47
A.11.2 Adjust of Right Start Position of Reagents .....	50
<b>APPENDIX B SOFTWARE UPGRADE .....</b>	<b>1</b>
B.1 SOFTWARE UPGRADE .....	1
B.1.1 Installing the Software Installer of New Version .....	1
B.1.2 Installing the Service Pack .....	6
B.2 PROGRAM UPGRADE OF MAIN CONTROL CIRCUIT BOARDS .....	6
B.2.1 Upgrade the Program of 08-E00-COP Circuit Board.....	6
B.2.2 Upgrade and Burning of the Programs of No. 01~07 Circuit Boards.....	7

# **Notes**

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

**Read the operating instructions before you start using the analyzer.**

## Purpose

Maglumi 2000 Immunoassay Analyzer and reagents are strictly restricted to professional in vitro diagnosis (IVD) use.

The operating instructions are intended for the Maglumi 2000 Immunoassay Analyzer. This instruction mainly helps users to understand the principle structure, operation, maintenance and troubleshooting of the Maglumi 2000 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, Incubator 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) This product is an in vitro diagnostic medical device used for quantitative assay of metabolites in various endocrine hormones, tumor markers, virus antibodies in human blood and urine. The analysis results should be used with clinical symptoms or other experimental results for clinical judgment.
- 2) Operating instructions are subject to change without prior notice. Users can consult customer representatives according to the actual situation.
- 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 squash the drainage pipe. Otherwise, waste liquid will overflow from other parts due to poor drainage. In severe cases, it will cause damage to the analyzer.
- 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  $\pm 0.5^{\circ}\text{C}$  of the set value, with a deviation no more than  $1.0^{\circ}\text{C}$ .
  - 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 procedures 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 2000 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 2000 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

Observe the following precautions to ensure transportation safety and correct operation of the analyzer.

### 1. Transportation Safety Information

The person in charge of transportation should transport goods according to the information provided on the packing. Correctly pack the analyzer as the company's requirements before transportation.

Wood packing dimensions:

Maglumi 2000
Length: 150 cm
Width: 94 cm
Height: 110.2 cm

### 2. Rated Input Information

- Input voltage: a.c.100 V-240 V
- Frequency: 50 Hz/60 Hz
- Input power: 500 VA, well grounded (neutral to ground: < 2 V)

### 3. Input and Output Connection Terminals

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



### 4. Switches

Main Switch  
Submain Switch



### 5. Requirements for Storage and Operation Environments

- Storage conditions: temperature: -20°C~55°C; relative humidity: ≤ 93%;
- Operation conditions: temperature: 10°C~30°C; relative humidity: ≤ 70%, air-conditioner recommended; atmospheric pressure: 85 kPa~106 kPa.

## 6. Analyzer Dimensions and Weight

Maglumi 2000
Front length: 135 cm
Width: 64 cm
Height: 87 cm
Working height: 130 cm
Weight: 158 kg

### Warning symbols

#### Warning infection

This sign is located in all area of the machine involving risk of biological infection to remind the people around. It is on  
The frontage of the waste container  
The frontage of the waste tank  
The right side of the sample area  
The up side of the reagent area



#### 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 tray of the starter



#### Warning danger

This sign is located in the area where it is easy to get hurt to remind the safty. It is on  
Below the hinge in the middle of the main support  
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 in The frontage of the pipetting arm



Do not actuate  
during operation

**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 positive side of the handle on the cover



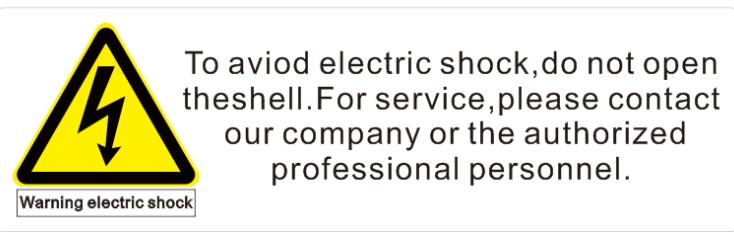
#### **Warning hands pinching**

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 incubator stacker



#### **Warning for 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



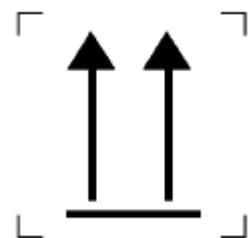
### **Other symbols**

Symbols	Description
	<b>Manufactured</b>
	<b>Catalogue Number</b>
	<b>In Vitro diagnostic medical device</b>
	<b>Serial Number</b>

**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**

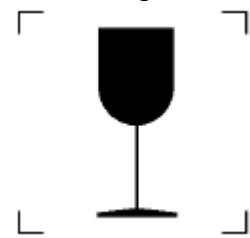
This sign is to remind keeping the package from rain during transport. It is on  
The frontage of the package

The frontage of the wooden box

**Fragile**

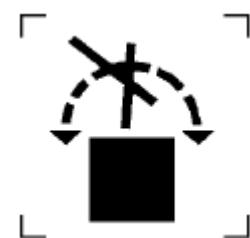
This sign is to remind fragile subject inside, moving carefully. It is on  
The frontage of the package

The frontage of the wooden box

**Rolling is forbided**

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



## **Notes**

---

# 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, **[Definition]** menu, **[Sender]** interface and **[Sender Input]** dialog.
- Button names are boldfaced and put in **<>**. For example, **<OK>** and **<Add>** button.
- User input is boldfaced and appears in **" "**. For example, **[Sample Pipetting Volume] "2" [ $\mu$ l]**.

## 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 Word

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

### 1.4 Glossary

Glossary	Description
<b>Analyzer</b>	The instrument, but not PC, printer and connection cables
<b>Back Transport</b>	In second pipetting step, transfers cuvettes to proper positions in the incubator
<b>Barcode Reader</b>	Assembly to read the sample barcode
<b>BGW</b>	Background Wash, test to check quality of analyzer washing
<b>Chamber</b>	Assembly for measurement
<b>Cuvette</b>	Every cuvette has six cavities plastic module, in which immunometrical reaction can take place
<b>CV%</b>	Coefficient of variation, shows dispersion rate of measurements
<b>Incubator</b>	Assembly in which cuvettes are incubated and pipetted
<b>LC-le</b>	Light check of left pipettor is used to test accuracy of pump volume and stability of the analyzer.
<b>LC-ri</b>	Light check of right pipettor is used to test accuracy of pump volume and stability of the analyzer.
<b>Light Check</b>	Consumable provided as lyophilized material.
<b>Loader</b>	Including incubator loader and washer loader.
<b>Pipettor</b>	Left and right pipetting needles are used for pipetting samples and reagents
<b>Pump system</b>	For high-precision pipetting, washing and starter injection
<b>Pusher</b>	Exchanges cuvettes between washer and chamber.
<b>Reader</b>	Including Barcode reader and RFID reader
<b>Reagent Area</b>	Loading area for reagent
<b>RFID</b>	Radio Frequency Identification Devices, micro-chip present on reagent to allow recognition and data storage
<b>RLU</b>	Relative Light Unit (signal measurement unit)
<b>Samples</b>	Anything that can be introduced by operator into sample area racks, including patient samples, controls and external calibrators
<b>Samples Area</b>	Loading area for samples
<b>Samples Rack</b>	12 positions module to host sample tubes
<b>Stacker</b>	Assembly to store cuvettes
<b>Starter Reagents</b>	Reagents dispensed during the reading to generate chemiluminescent signal
<b>System Liquid</b>	Solution (to be diluted 1:13 in purified water) to wash pipetting needles and magnetic microbeads after reaction.
<b>Washer</b>	For washing unreacted material in cuvettes.
<b>Waste Bag</b>	Container for used cuvettes.

# 2 Measuring Principle

## 2.1 Assay Procedure

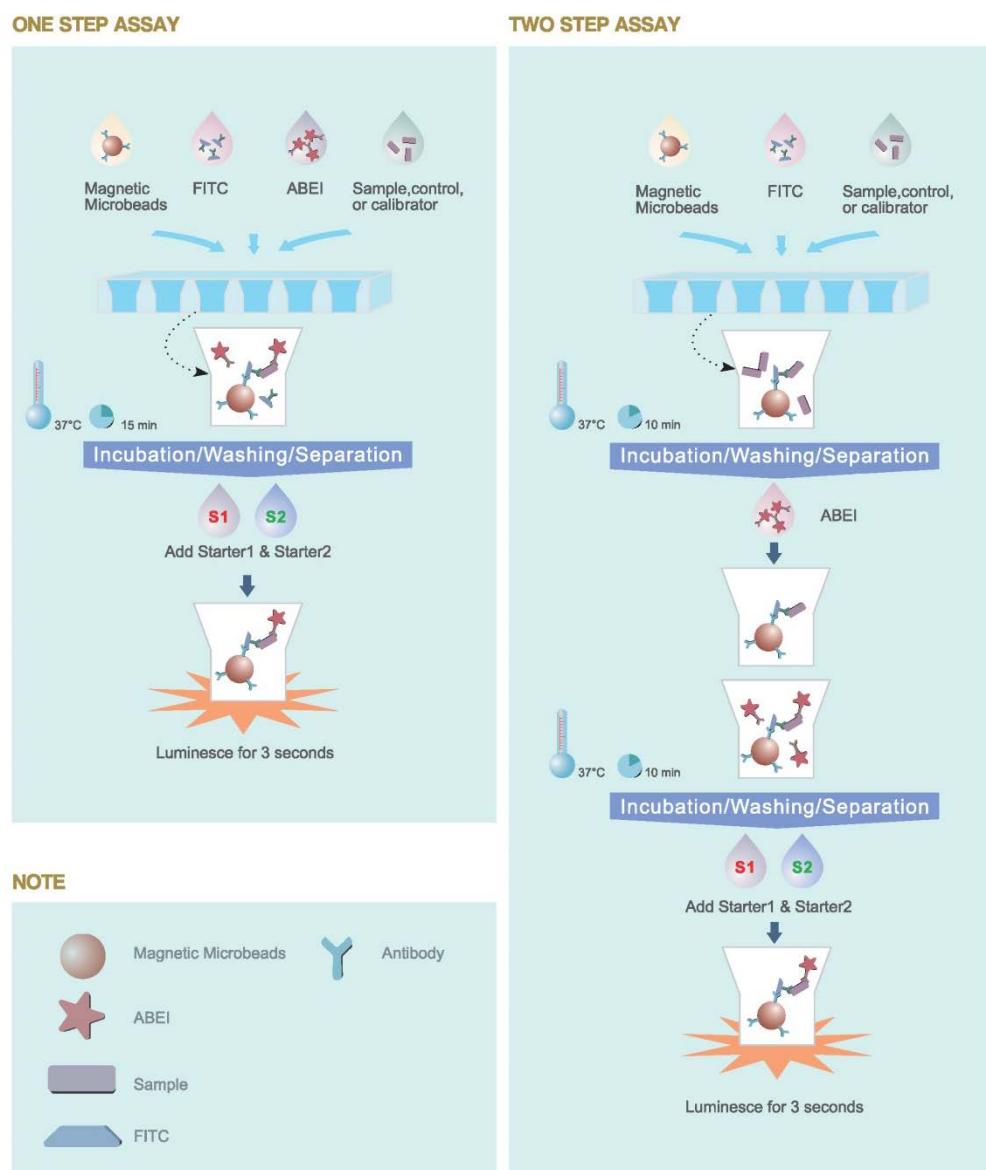


Figure 2.1-1 Assay Procedure

### **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.

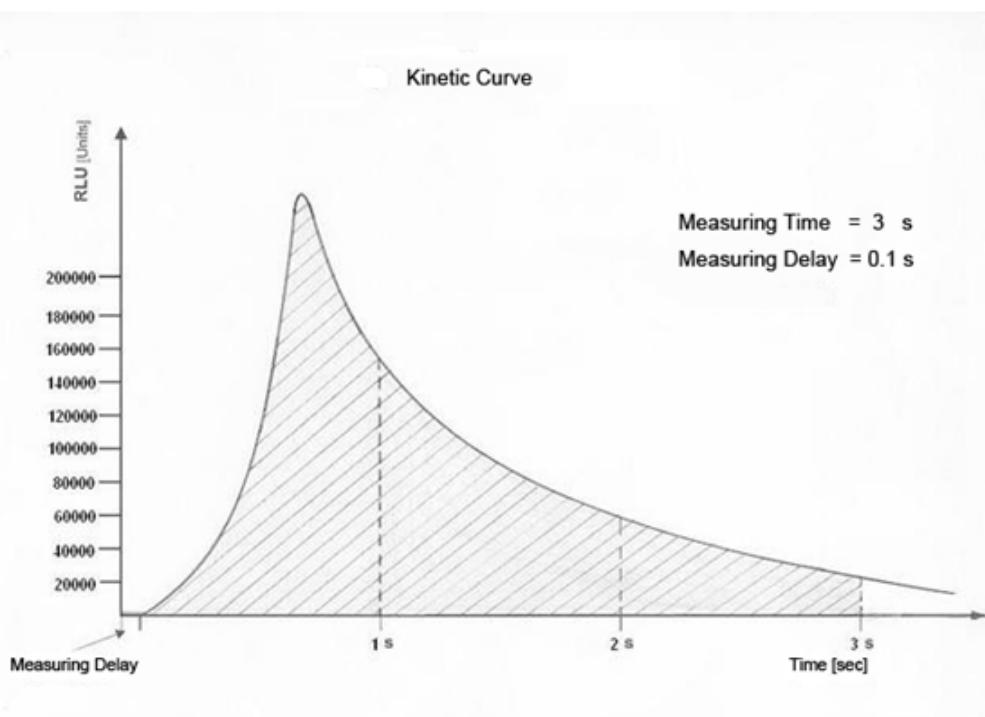


Figure 2.2-1 Kinetics Curve

## 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 curve and recalculate the RLU and concentration.
- The recalculated curve is a valid working curve.

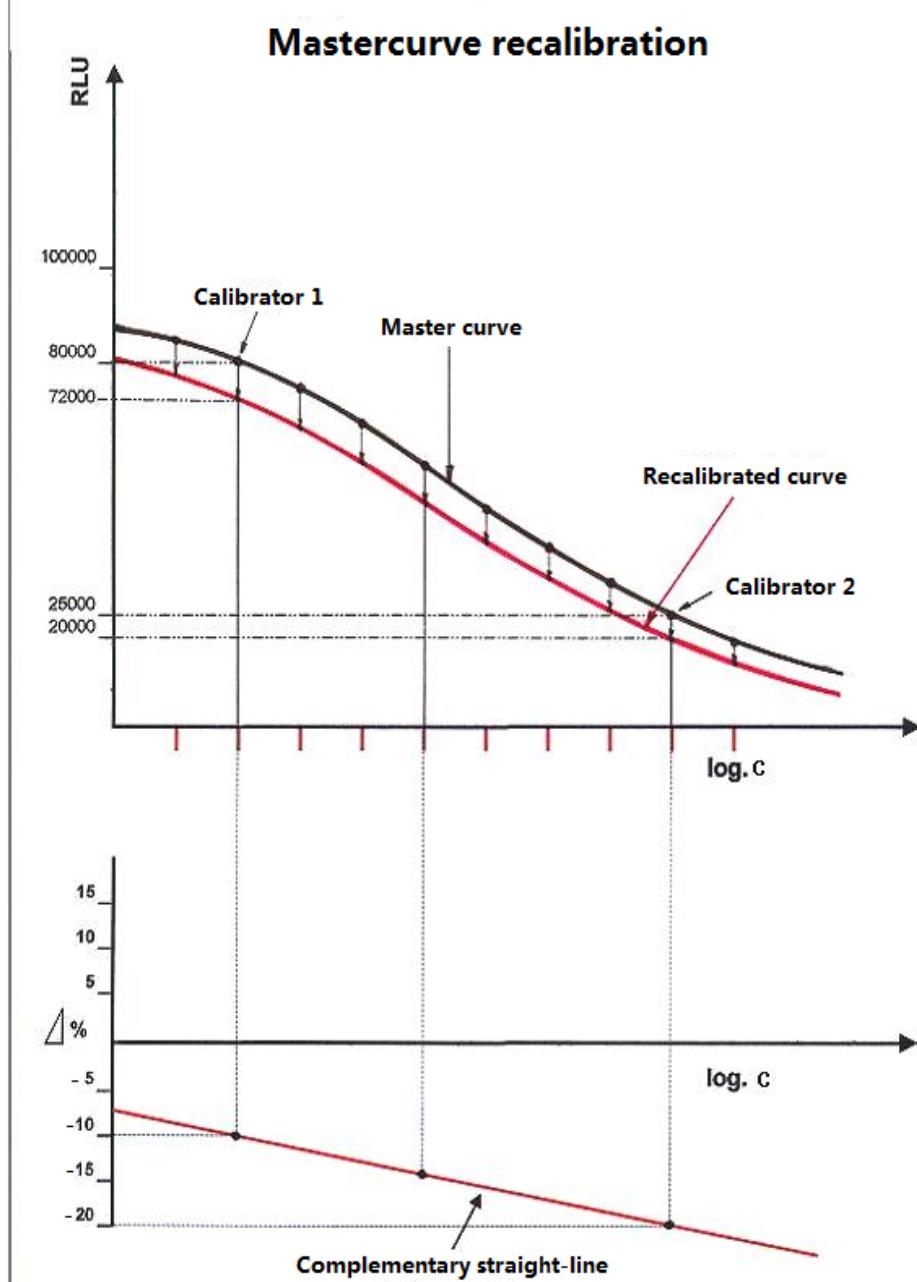


Figure 2.3-1 Calibration Principle



# 3 System Description

Maglumi 2000 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, system liquid module, 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, incubator loader heating module, back transport pipetting area heating module, reagent cooling module and photomultiplier cooling module.
- The mechanical transmission module comprises cuvette loader, stacker, reagent shaker, incubator, incubator loader, washer loader, washer transport, washer lift, back transport, pusher, chamber transport, chamber lift and 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 Analyzer

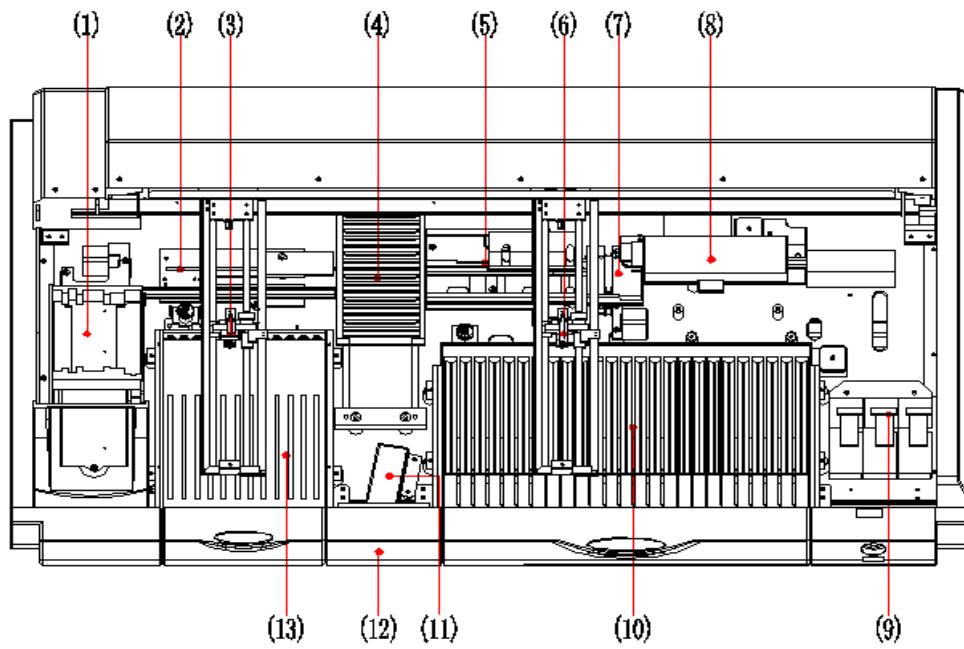


Figure 3.2-1 Maglumi 2000 System Components

- |                  |                    |                     |                  |
|------------------|--------------------|---------------------|------------------|
| (1) Stacker      | (2) Loader         | (3) Left pipettor   | (4) Incubator    |
| (5) Washer       | (6) Right pipettor | (7) Pusher          | (8) Chamber      |
| (9) Pump unit    | (10) Reagent area  | (11) Barcode reader | (12) RFID reader |
| (13) Sample area |                    |                     |                  |

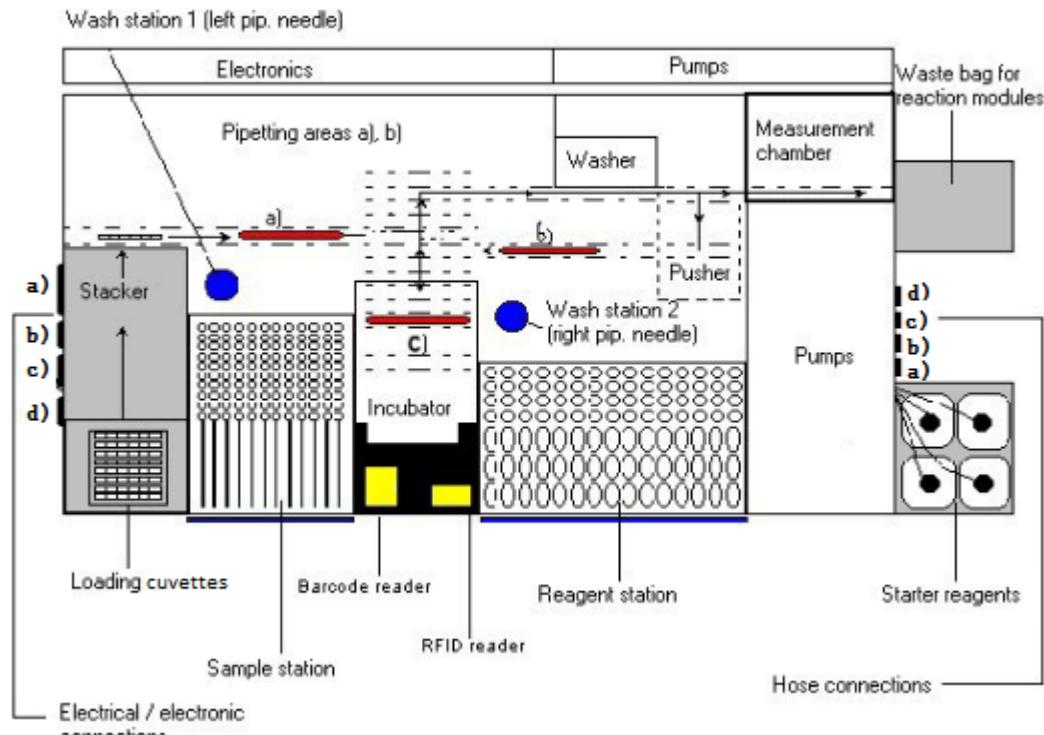


Figure 3.2-2 Schematic Diagram of the Components (view from above without cover and pipetting units).

Pipetting area:

- a) First step pipetting
- b) Second step pipetting
- c) Third step pipetting

Hose connection:

- a) System liquid (pipetting system)
- b) System liquid (washer)
- c) Waste liquid 1
- d) Waste liquid 2

Power connector/data cable connector:

- a) Serial port
- b) Power connector
- c) Main power switch
- d) Subman power switch

#### 3.2.1 Sample Area

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

There are 12 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 3.2-3 12 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.

### 3 System Description

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.

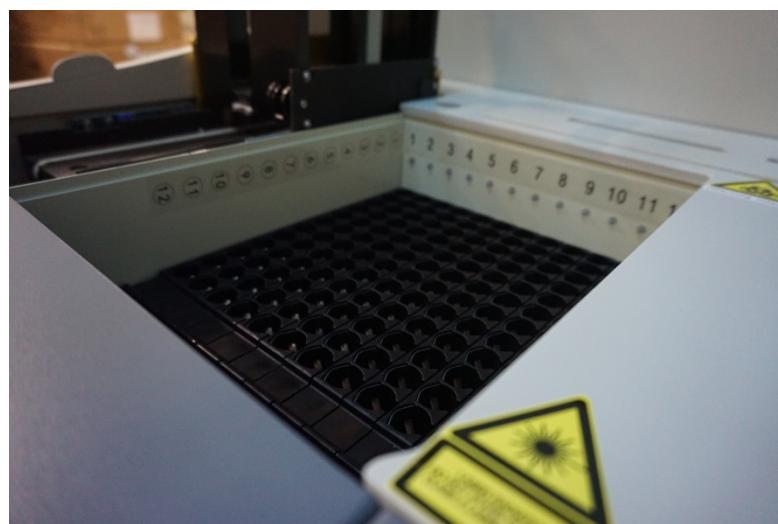


Figure 3.2-4 12 Sample Tracks in the Sample Area

#### 3.2.2 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 **[Reagents]** interface. Because the reagent needs to be kept at a low temperature, only open the reagent door temporarily for loading reagents.

The reagent area has 15 reagent tracks. The reagent is covered by a piece of holed (reserved for pipetting) organic glass.

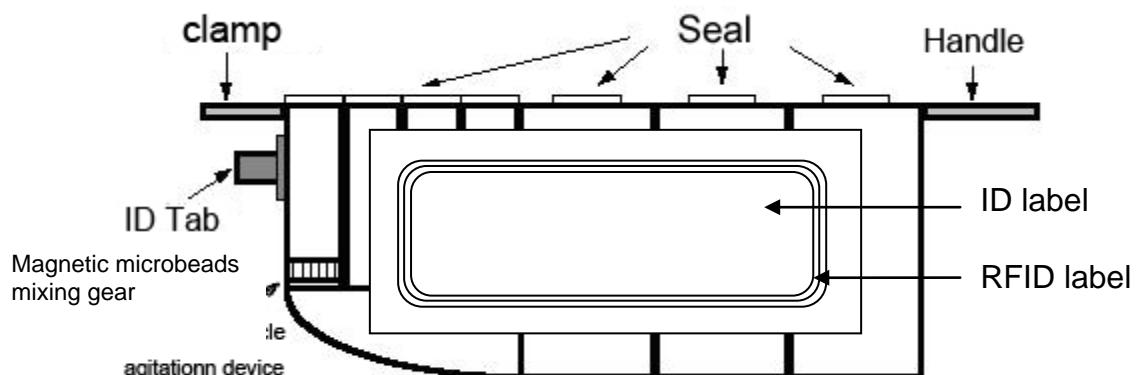


Figure 3.2-5.Reagent Structure

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 3.2-6 15 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 integral 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.

### **3.2.3 Barcode Reader and RFID Reader**

#### **3.2.3.1 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**.

### 3 System Description

Table 3.2-7 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 /EAN128	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
Code UPCA/UPCE	8	Mandatory	0.3 -0.8	N/A	0.33	10
Code EAN 8/13	8 or 13	Mandatory	0.3 -0.8	N/A	0.33	10
Code93	1-25	Mandatory	0.3 -0.8	N/A	0.33	10
Code2/5 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 Code2/5 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 2000 Service]** software.

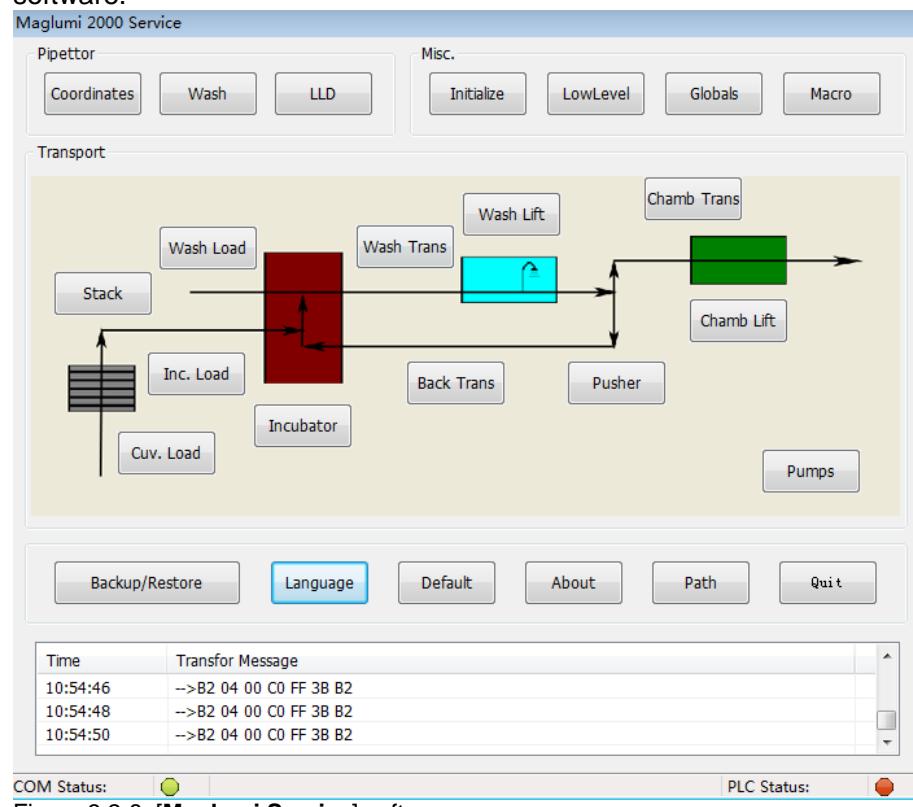


Figure 3.2-8 **[Maglumi Service]** software

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

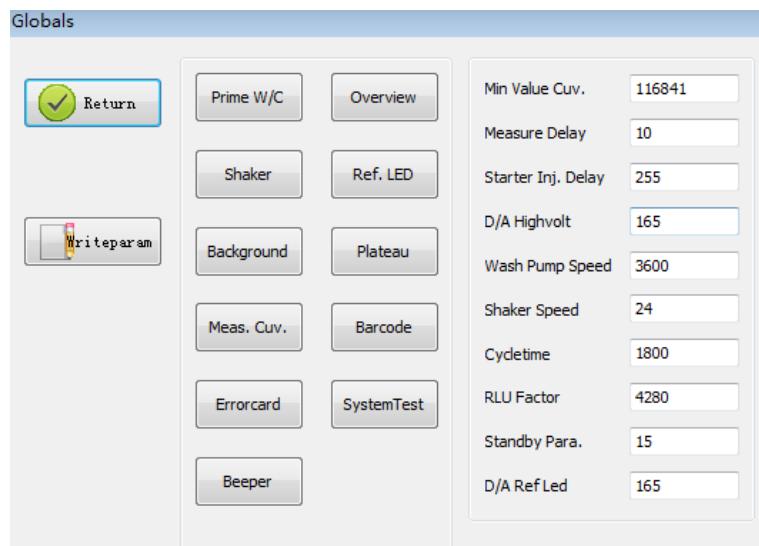


Figure 3.2-9 [Globals] dialog.

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

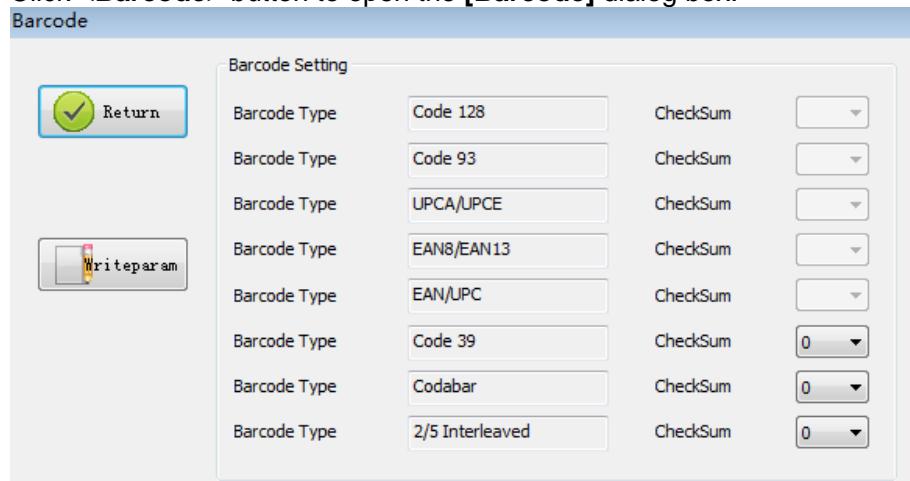


Figure 3.2-10 [Barcode] dialog

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

### 3.2.3.2 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.

### 3.2.4 Pipettor

Left and right pipetting needles are used for pipetting samples and reagents, respectively.

### **3 System Description**

---

Left pipettor is used for pipetting samples, control and calibrators. This pipetting needle is washed in washing hole 1 (See Figure 3.2-2).

Right pipettor is used for pipetting reagents. This pipetting needle is washed in washing hole 2 (See Figure 3.2-2).

The pipetting unit is automatically positioned in the pipetting area by the software.



Figure 3.2-11 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 left pipetting unit immediately moves to the left washing hole and washes the pipetting needle. The second pipetting unit completes the pipetting procedure independently. The software notifies the user of clots detected and adds a mark (D) to this sample in **[Test Result]**.

### **3.2.5 Stacker**

A stacker has 7 layers and each layer can store 14 cuvette bars, providing a maximum processing capacity of 120 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 stacker. When the number of cuvette bars on a layer of the stacker reaches 14, the stacker automatically lifts a layer and continues to load cuvettes till the seventh layer.



#### **NOTE**

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

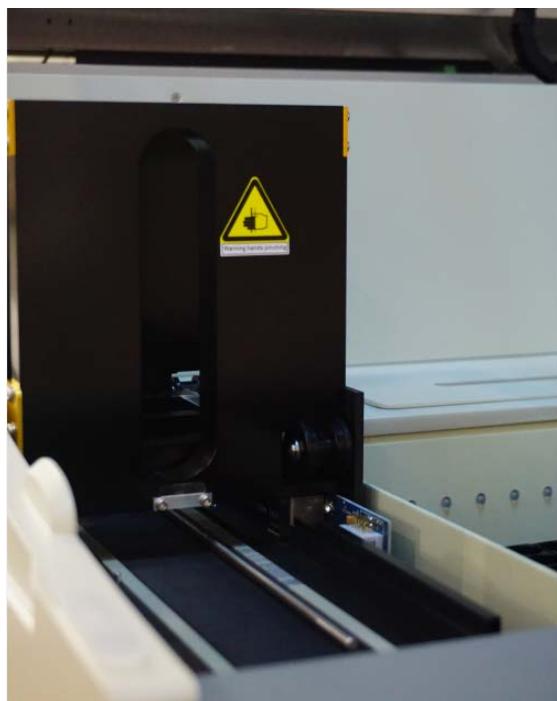


Figure 3.2-12 Cuvette Loading Area

### 3.2.6 Incubator



Figure 3.2-13 Incubator

According to test requirements, cuvettes loaded with samples and reagents are incubated at  $36.8^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  in the incubator. The incubator can incubate 16 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)

#### 3.2.7 Incubator Loader and Washer Loader

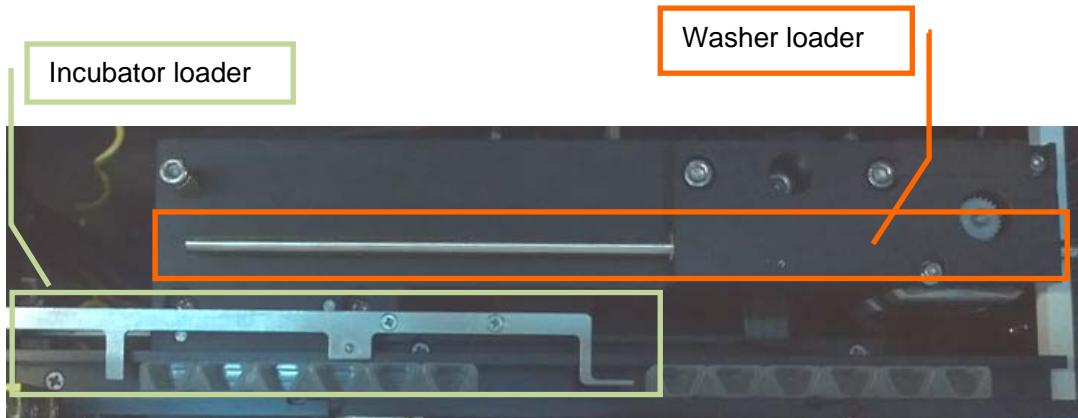


Figure 3.2-14 Incubator Loader and Washer Loader

##### **Incubator loader**

The incubator loader transfers cuvettes in the stacker to the left pipetting area and pushes them to blank positions in the incubator after pipetting.

##### **Washer loader**

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

#### 3.2.8 Washer



Figure 3.2-15 Washer

Magnetic microbeads are washed in the washer with waste liquid pumped away. Three independently controlled washing pumps connected 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.

### **3.2.9 Pusher**

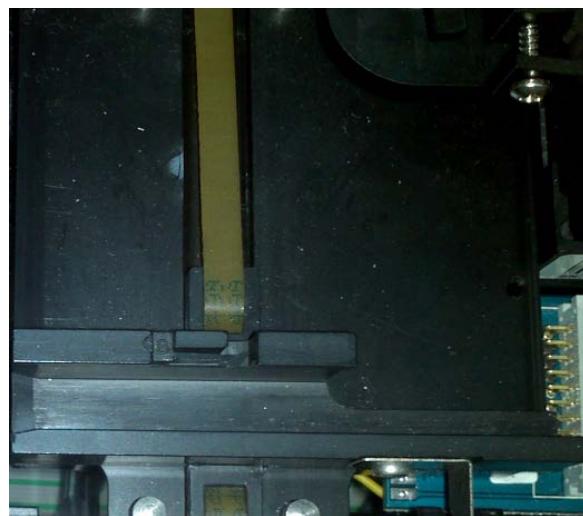


Figure 3.2-16 Pusher

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

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

### **3.2.10 Back Transport**



Figure 3.2-17 Back Transport

The back transport is used for second pipetting of cuvettes.

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

#### **3.2.11 Chamber**

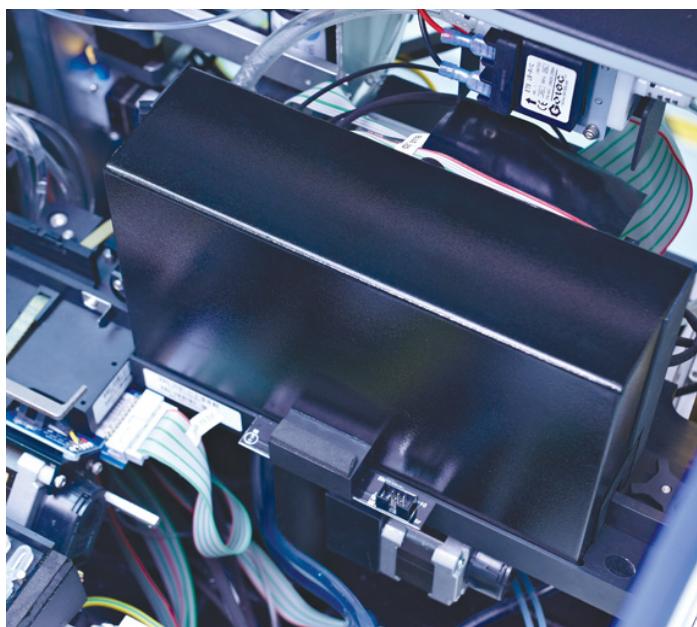


Figure 3.2-18 Chamber

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 microbeadss are resuspended. The geneated 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.

#### **3.2.12 Pump System**

Maglumi 2000 Immunoassay Analyzer offers a range of independently operating pump systems for high-precision pipetting, washing and starter injection, including:

- Two plunger pumps for pipetting units.
- Waste liquid pump for two washing holes of the pipetting unit.
- Vacuum pump for washing pipetting needles.
- 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.

### 3.2.13 Starter

Starter reagents containers are located on the right of 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 3.2-19 Starter Reagents Container



---

**CAUTION**

Do not spill starter in this area!

---

### 3.2.14 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.

### 3.2.15 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.

---

### **3 System Description**

---

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 3.2-20 Cuvette Waste Bag Bin

#### **2. Waste Liquid**

Two waste liquid pipes are connected to Waste liquid 1 and 2 outlets on the right of the analyzer.

- Waste liquid 1 comes from washer and liquid in cuvettes, containing magnetic microbeads, starter, patient samples and laboratory reagents.
- Waste liquid 2 comes from the pipetting needles washing, mainly composed of system liquid.

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)

### **3.3 Computer System**

#### **3.3.1 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 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 ≥ 1 GB, three RS-232 serial ports, USB port.
- Touch monitor: windows, curves and test data of Maglumi 2000 Immunoassay Analyzer operating software are displayed on the monitor.
- Keyboard: for operation control and data input of Maglumi 2000 Immunoassay Analyzer.
- Mouse: for software operation.
- Printer: for printing test data and charts.

#### **3.3.2 Basic Operations in Software Interface**

##### **3.3.2.1 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 System Description

#### 3.3.2.2 Software Components



Figure 3.3-1 Software Interface

The software has 5 different levels of windows:

**1. Menu Bar:** displays different menu. It has 9 menu buttons.



Figure 3.3-2 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.
<Patients>	It shows the information of samples.
<Reagents>	It shows the information of reagents.
<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, sample senders.
<System>	It displays system parameters as well as selection of operating modes.
<Report>	It is for managing results.
<Home>	Return to the home.

**2. Interface:** displays function interface in different menu, including [Home] interface, [Patients] interface, [Reagents] interface and submenu interface.



Figure 3.3-3 [Home] Interface

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



Figure 3.3-4 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.

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



Figure 3.3-5 [System] Submenu

## 5. Dialog

A dialog box can open one or more sub-dialog boxes.

There are two different types of dialog boxes.

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

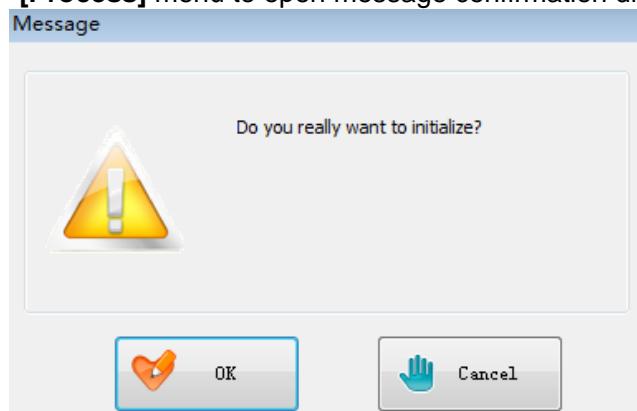


Figure 3.3-6 Message Dialog

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

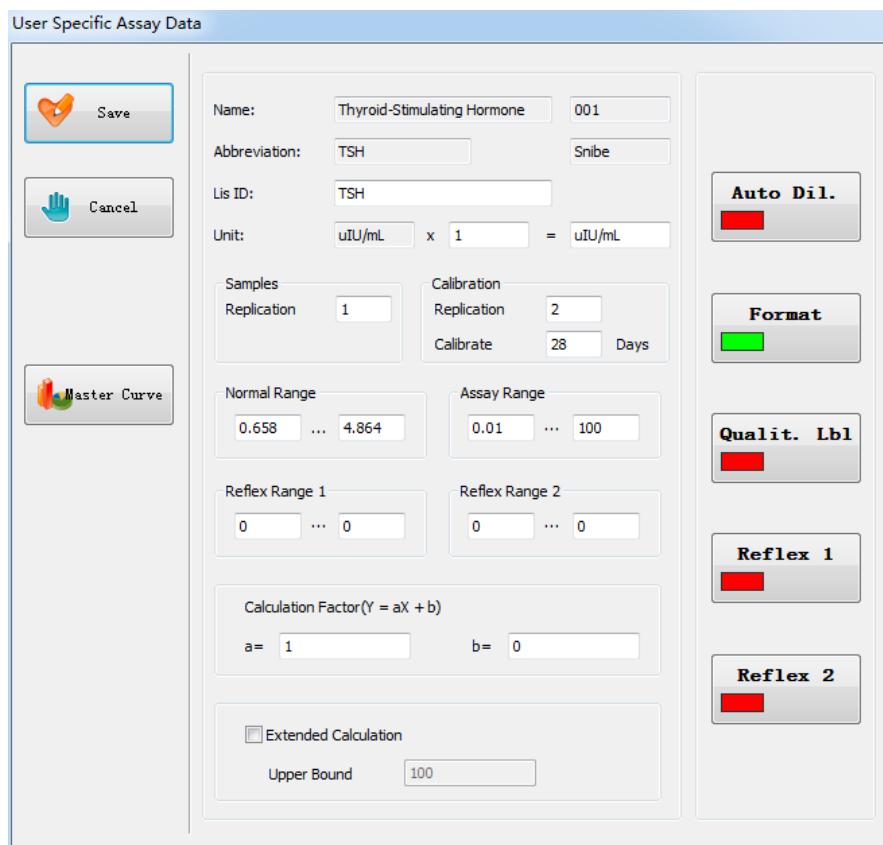


Figure 3.3-6 [User Specific Assay Data] Dialog

## 3.4 Testing Performance

### 3.4.1 Batch Assay Repeatability

Assay repeatability in a batch ( $CV\%$ )  $\leq 8\%$ .

### 3.4.2 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.

### 3.4.3 Carryover Rate

The Carryover rate should be equal to or less than  $10^{-5}$ .

### 3.4.4 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  $\pm 10\%$ .

**3.5 Accessories Required But Not Provided**

Catalogue Number	Name
630003	Reaction Modules
21060625	Waste Bag
130299005M	Wash Concentrate
130299007M	System Tubing Cleaning Solution
130299004M	Starter 1+2
130299006M	Light Check

# 4 Installation and Startup

This chapter describes how to install and start Maglumi 2000 Immunoassay 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 158 kg.
- When the analyzer is working properly, the highest volume at 1 m distance is 40 db.
- Atmospheric pressure: 85 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: 500 VA
- Circuit breaker specifications: F6AL250V (power filter), F3AL250V, F5AL250V, F10AL250V, F15AL250V (control circuit board)

- 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: 135 cm x 64 cm x 87 cm
- Analyzer weight: 158 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. Two installation holes can be installed with metal handles on the two sides of the analyzer. When it is necessary to move the analyzer, install the handles;
- 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.

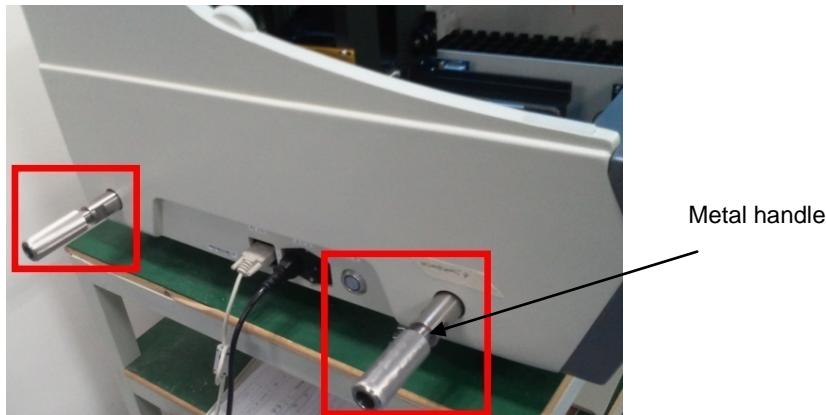


Figure 4.3-1 Metal Handle

## 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 on the left side of analyzer.
- 2) Connect the analyzer's power cable to the power supply port on the left side 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 ports "System liquid 1" and "System liquid 2" on the right of the analyzer.
- 4) Connect two hoses from the waste liquid tank to ports "Waste liquid 1" and "Waste liquid 2" on the right of the analyzer.
- 5) Connect the level sensor cable from the system liquid tank to the port "System Liquid Sensor" on the right of the analyzer.
- 6) Connect the level sensor cable from the waste liquid tank to the port "Waste Liquid Sensor" on the right of the analyzer.

### 4.4.3 Starter Connection

The starters reagent storage box housing is located on the right of 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 on the right of the analyzer.
- 4) Connect the level sensor cable to the reagent bottle marked starter 2 and "S2" port on the right of the analyzer.
- 5) Close the protective cover of the reagent storage box.

### 4.4.4 Waster Bag Placement

The waste bag bin is located on the right of the analyzer chamber.

- 1) Open the protective cover of the waste bag bin.
- 2) Place a waste bag.
- 3) Close the protective cover of the waste bag 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 six 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 stacker.
- 4) When the conveyor stops, place the next set of cuvettes.
- 5) Repeat the above steps until the stacker is full (maximum capacity: 120 cuvettes).

### 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 on the left 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 2000 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**.

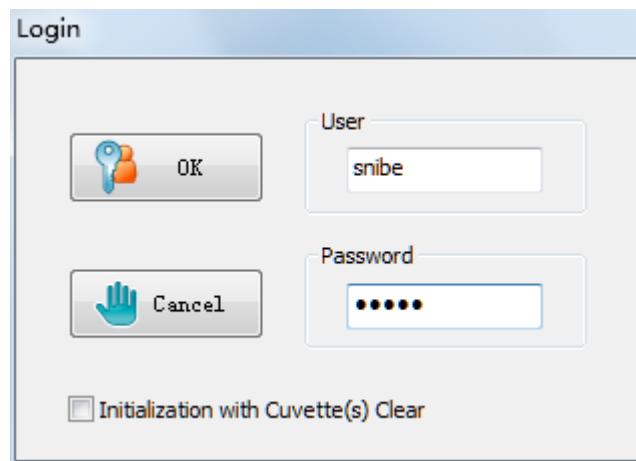


Figure 4.5-1 [Login] Dialog

- 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
	LC-ri	0

- 2) After the prime test is complete, perform the background test and left and right 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
	LC-ri	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 <b>[Login]</b> dialog .
4. Check consumables	Confirm the system liquid, starter 1, starter 2 and cuvettes are enough to complete the test. System liquid must be prepared and standing 6 hours prior to use.
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 $(36.8\pm0.5)^\circ\text{C}$ after it gets stable, with a fluctuation range within $\pm 1^\circ\text{C}$ . 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”.

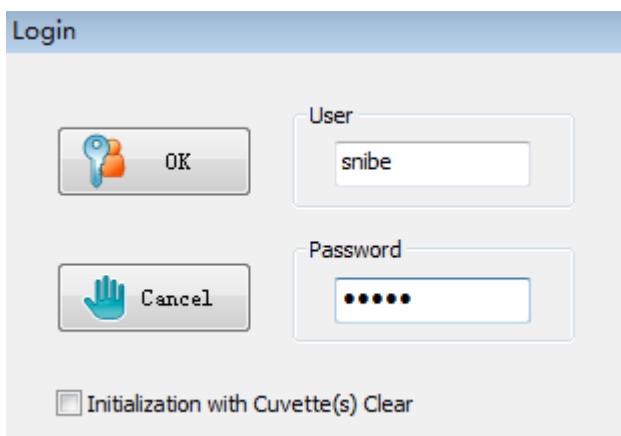


Figure 5.2-1 [Login] Dialog

### 5.2.3 Check Consumables

- 1) Check whether tubes for system liquid, starter 1 and starter 2 are connected properly and the liquid volume is enough; System liquid must be prepared and standing 6 hours prior to use;
- 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  $(36.8 \pm 0.5)^\circ\text{C}$  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  $(36.8 \pm 0.5)^\circ\text{C}$ . 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 Channel 11 or 12 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, or after any analyzer component is replaced.

## 5 Daily Operating Process

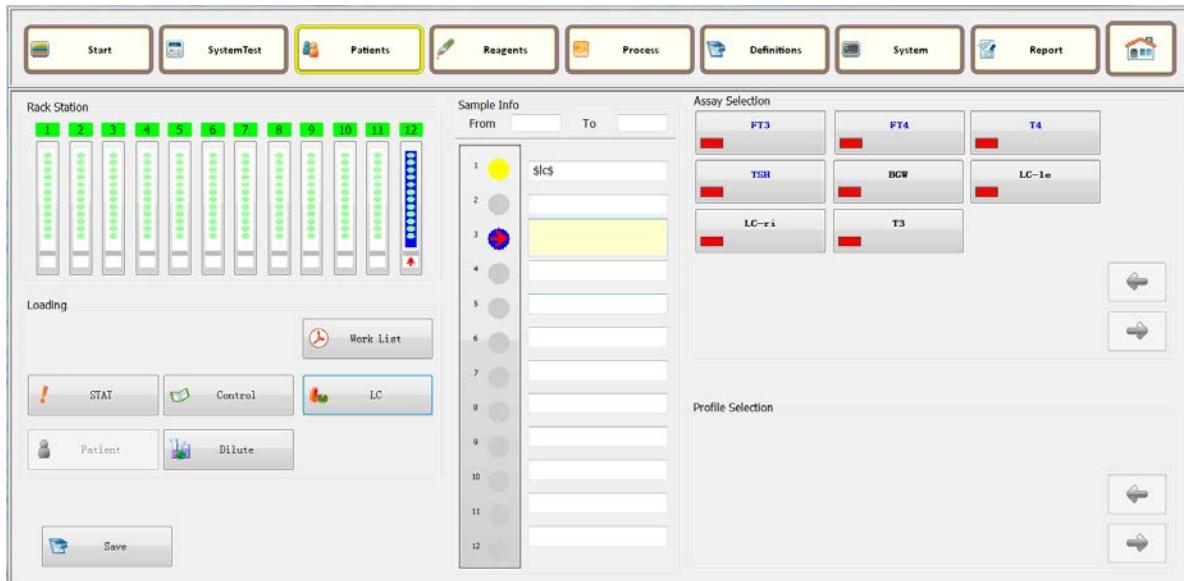


Figure 5.2-2 [Patients] interface

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

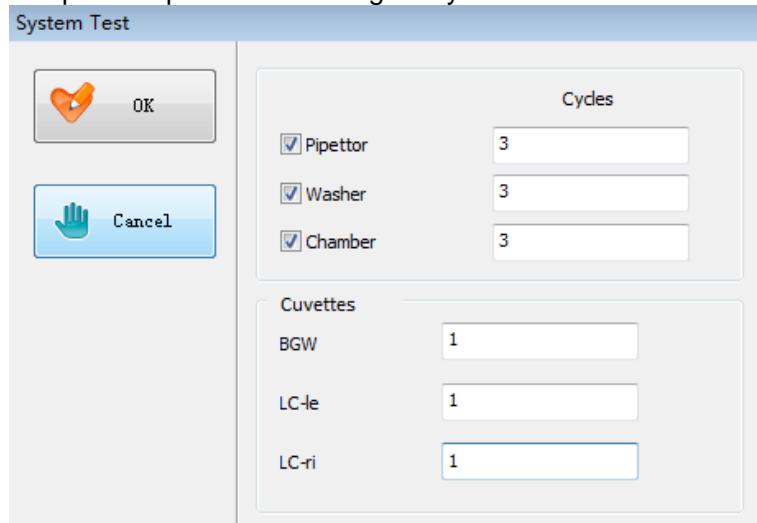


Figure 5.2-3 [System Test] Dialog

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

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.

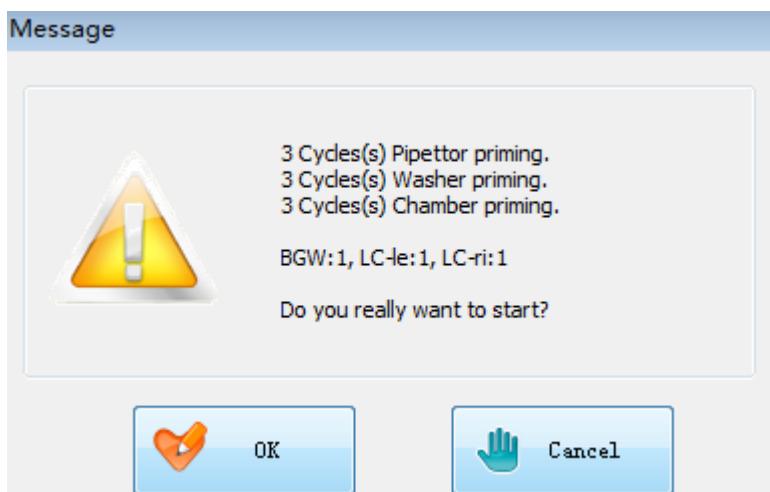


Figure 5.2-4 Confirmation Dialog

- 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 200-1200. See Chapter 9 for details.
  - LC: The reference range of LC results is 400000-650000., CV ≤ 3%. difference between LC(ri) and LC(le) ≤ 5%. 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 abnormality, 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 <Definition> 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 <Definition> 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 <Definition> 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.

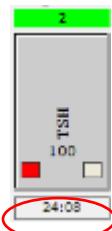
The reagents of different kits cannot be mixed, or else the reliability of the test results might be affected.

### **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.



---

#### **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 **<Reagents>** button in the menu bar or in the **[Home]** interface, or open the reagent area door to enter **[Reagents]** interface.

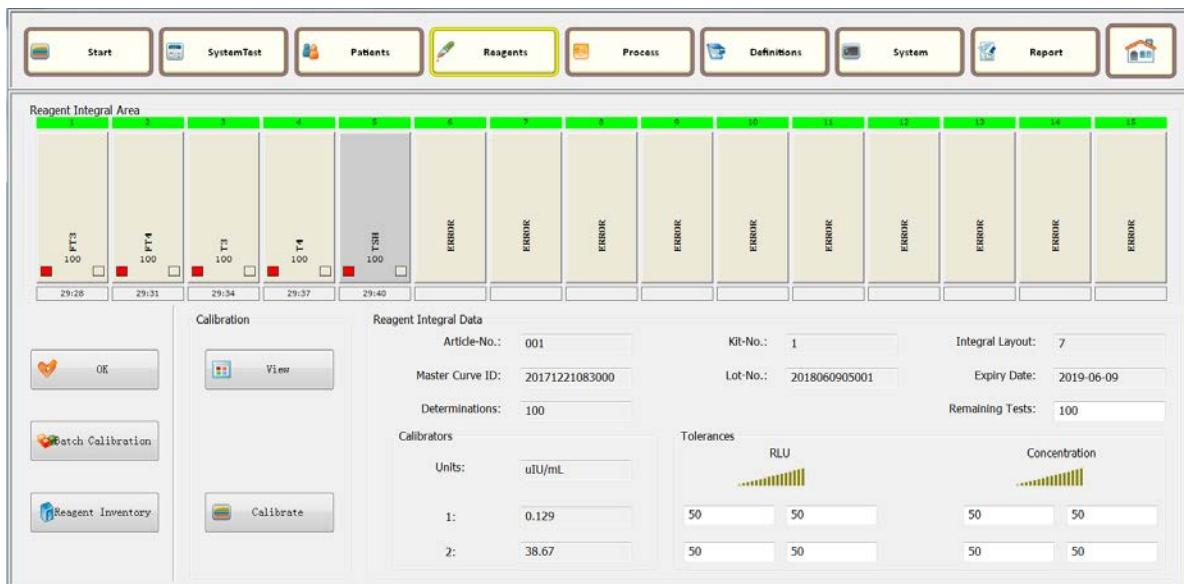


Figure 5.3-1 [Reagents] Interface

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.

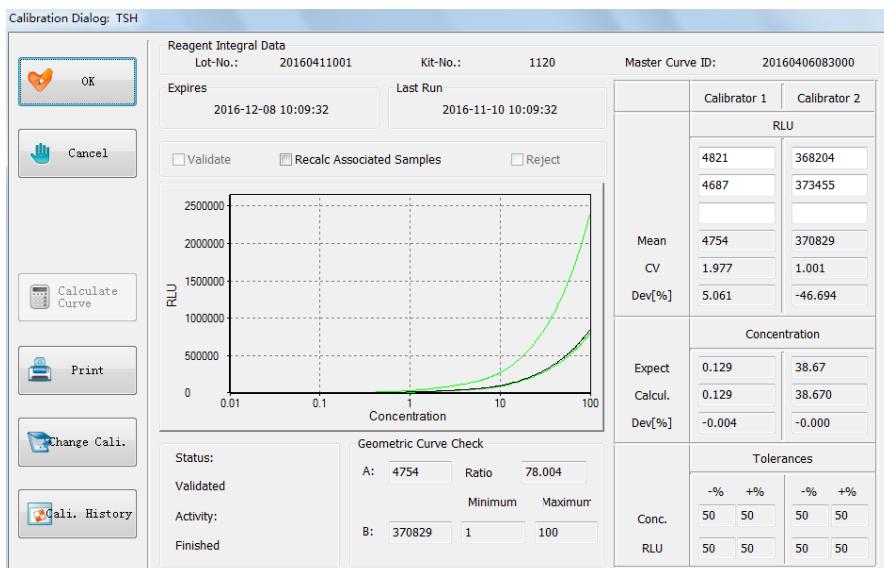


Figure 5.3-2 [Calibration Dialog]

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 <Definition> button in the menu bar, then click <Control> button in [Definition] menu to set up controls .

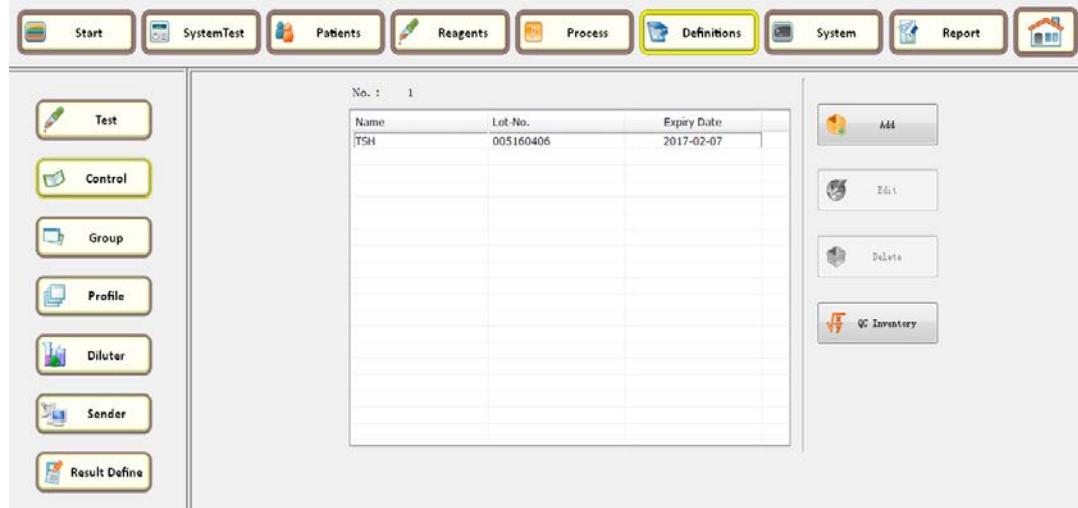


Figure 5.3-3 [Control] interface

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

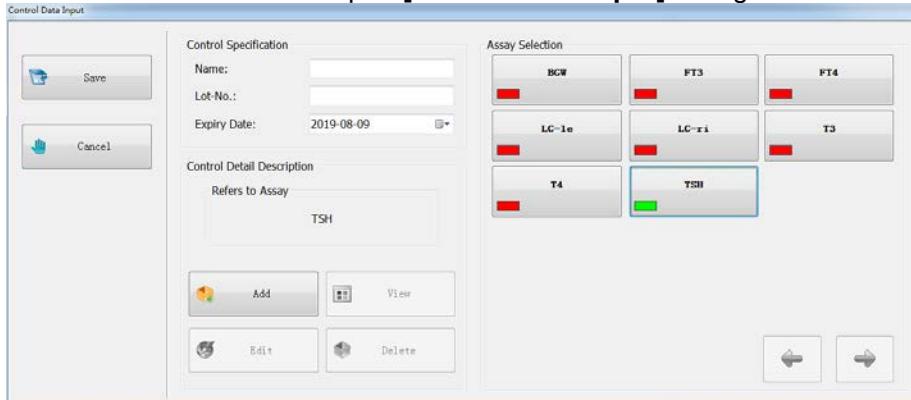


Figure 5.3-4 [Control Data Input] Dialog

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.

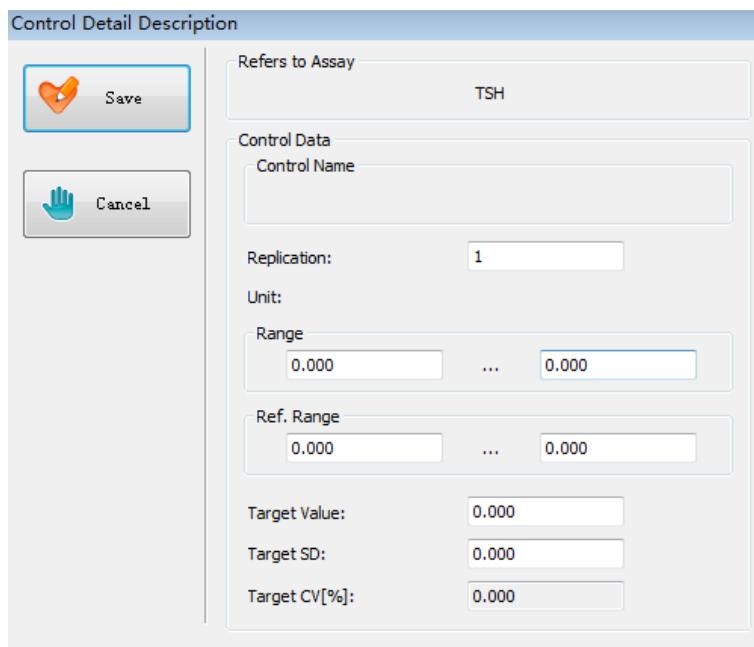


Figure 5.3-5 [Control Detail Description] Dialog

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 [Sample] 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 “Start in Next Run” and click <Save> button to complete QC assay registration.

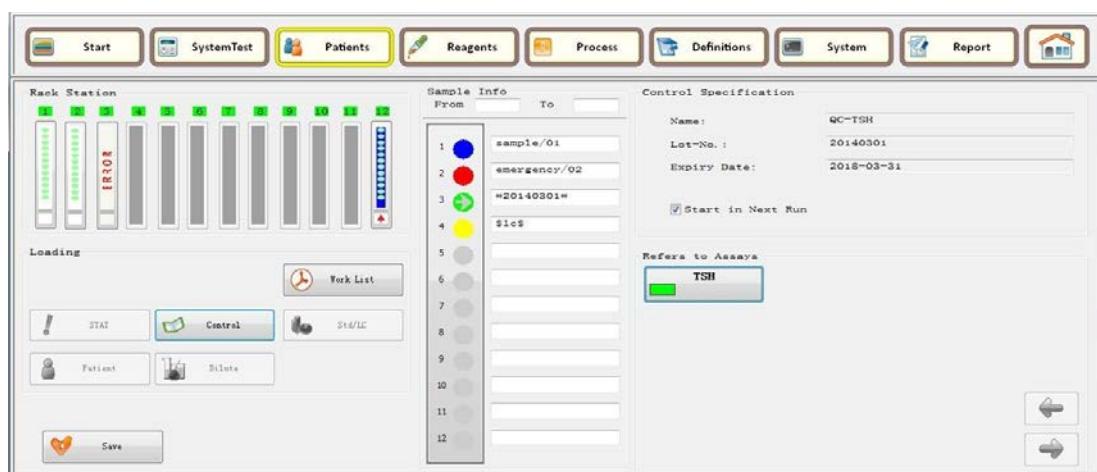


Figure 5.3-6 [Patients] Interface

**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) Sibne recommends that the test results shall not be modified in any manner, and shall not be liable for any consequences arising there from.

Click **<Patients>** button in the menu bar or in the **[Home]** interface, or open the sample area door to enter **[Sample]** 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 **[Sample]** interface.

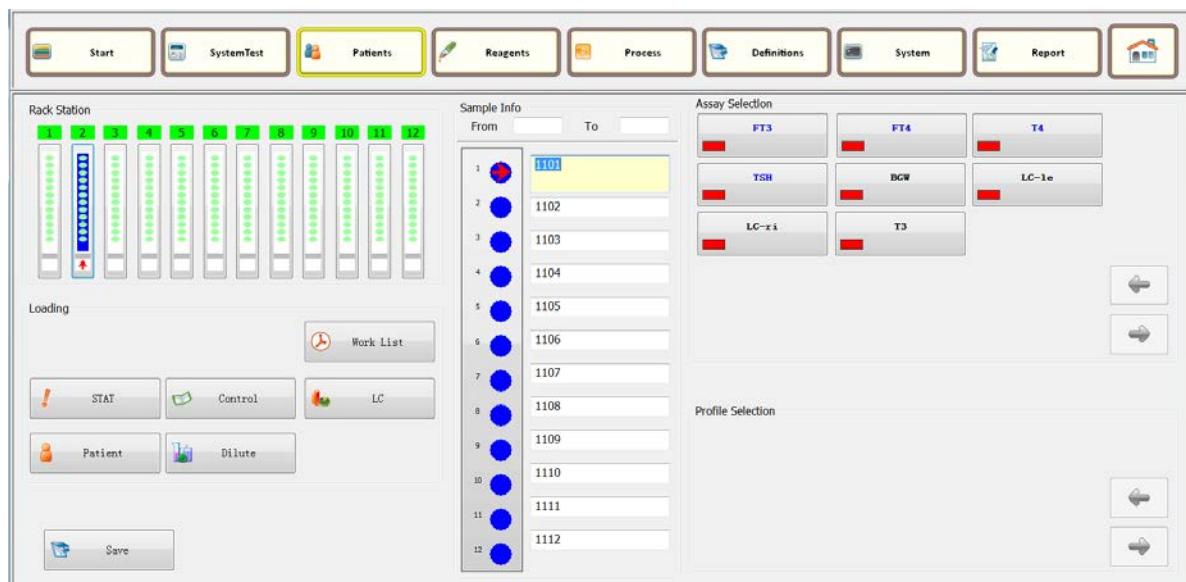


Figure 5.3-7 **[Patient]** Interface

Select the needed assay in the **Assay Selection** (green represents selected), 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 [Sample] 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

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.

The screenshot shows the 'Journal' interface of the Maglumi 2000 software. The top menu bar includes buttons for Start, SystemTest, Patients, Reagents, Process, Definitions, System, Report, and Home. On the left, there is a vertical toolbar with buttons for Journal, Valid, Calibrator, Control, SystemTest, QC, and Report. The main window displays a table of test results with the following columns: SampleID, Assay, Dil., RLU, CV(%), Concentration, and Flag. The table contains 15 records. At the bottom of the table are buttons for Recalc, Online, Edit, Delete, Valid, Print, and Remove.

SampleID	Assay	Dil.	RLU	CV(%)	Concentration	Flag
sample/01	TSH		405832	0.0	34.81 uIU/mL	C;>:R
emergency/02	TSH		7586	0.0	0.521 uIU/mL	*:C:S
#20140301#	TSH		48592	0.0	3.604 uIU/mL	C
1	TSH		2800365	0.0	100.0 uIU/mL	C;>:>
2	TSH		52023	0.0	3.933 uIU/mL	C
3	TSH		244856	0.0	20.53 uIU/mL	C;>
4	TSH		324369	0.0	27.43 uIU/mL	C;>
5	TSH		9816	0.0	0.691 uIU/mL	C
6	TSH		81745	0.0	6.941 uIU/mL	C;>
7	TSH		959654	0.0	93.26 uIU/mL	C;>
8	TSH		14248	0.0	1.004 uIU/mL	C
9	TSH		6414	0.0	0.423 uIU/mL	C
10	TSH		3674	0.0	0.150 uIU/mL	C;<
11	TSH		2047856	0.0	100.0 uIU/mL	C;>:>
12	TSH		844759	0.0	79.49 uIU/mL	C;>

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.

### **5.5 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 Shutdown**

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.
<Mode>	Select running mode and edit sample mode.
<Online>	Used for setting software parameters for connecting to hospital Lis server.
<User>	Set or modify username, login password and user rights.
<Language>	Switch the interface languages of PC software.
<Maintenance>	Set up maintenance reminder, pipe washing, display maintenance procedure and calculate reagent consumption.
<Wash Pipe>	Using system tubing cleaning solution for performing tubing cleaning operation.

## 6.2 <Info>

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

## **6 [System] Menu**

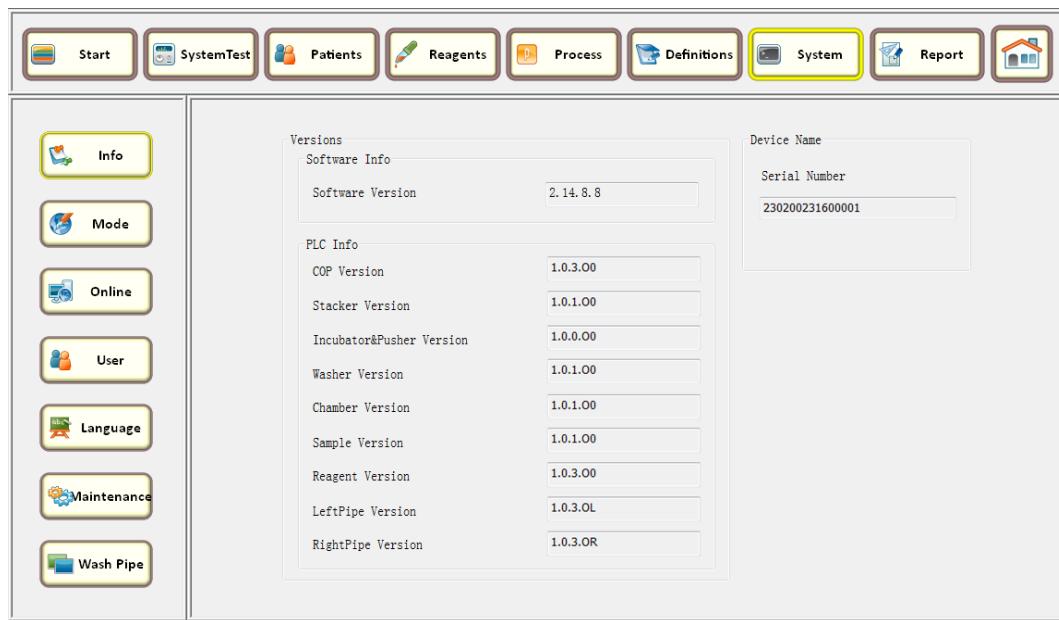


Figure 6.2-1 [**Info**] Interface

[**Info**] interface contains the following information:

### **1. Software Info**

Software Version: Version information of software.

### **2. PLC Info**

COP Version:	Version information of COP.
Stacker Version:	Version information of stacker.
Incubator & Pusher Version:	Version information of incubator and pusher.
Washer Version:	Version information of washer.
Chamber Version:	Version information of chamber.
Sample Version:	Version information of sample area.
Reagent Version:	Version information of reagent area.
Left Pipe Version:	Version information of left pipetting needle.
Right Pipe Version:	Version information of right pipetting needle.

### **3. Device Name**

Serial Number: Serial number of device.

## **6.3 <Mode>**

This software provides multiple sample editing modes and running modes. Users can set according to the actual situation.

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



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.

## **6 [System] Menu**

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

### **6.4 <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**> button in **[System]** menu to open **[Online]** interface.

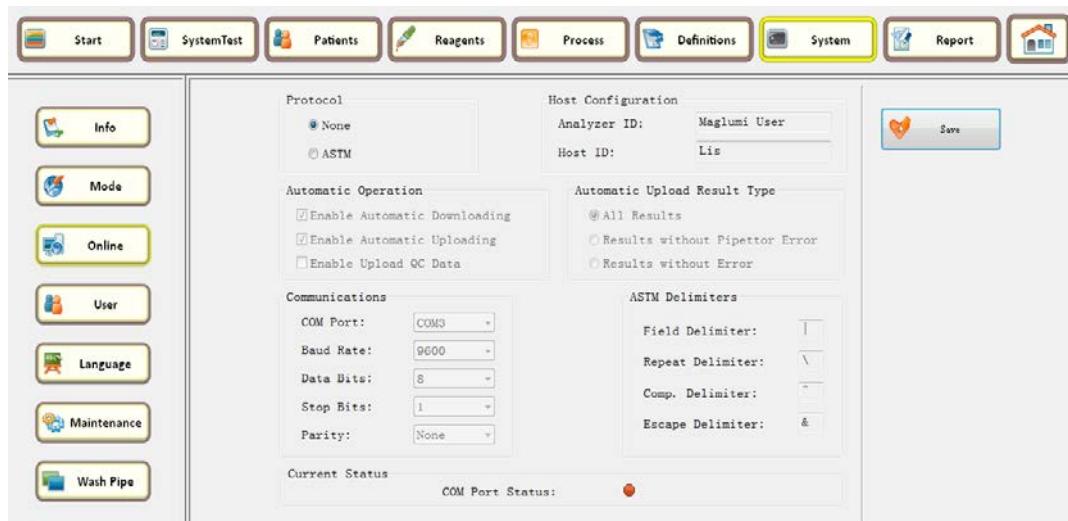


Figure 6.4-1 **[Online]** Interface

**[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.

### 6.5 <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> button in [System] menu to open [User] interface.

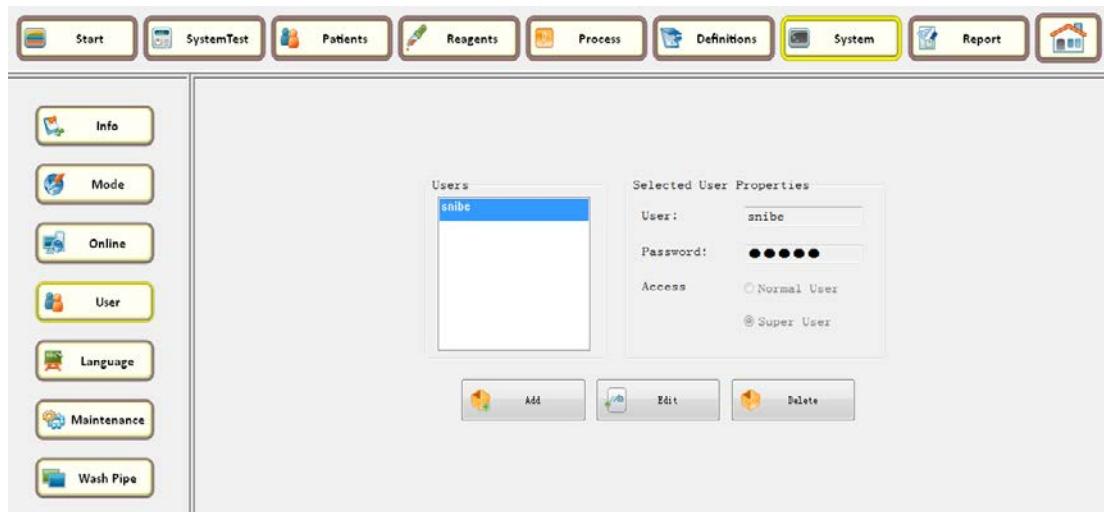


Figure 6.5-1 [User] Interface

[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.

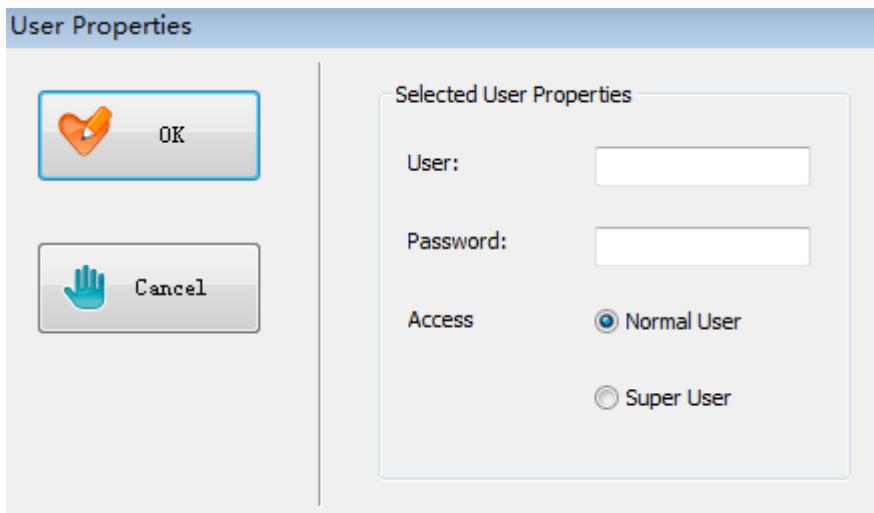


Figure 6.5-2 **[User Properties]** Dialog

- **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.

## **6.6 <Language>**

This software supports 9 interface languages, including Simplified Chinese, English, French, German, Italian, Portuguese, Russian, Spanish and Turkish.

Click **<Language>** button in **[System]** menu to open **[Language]** interface. Click corresponding language button to change to that language.



Figure 6.6-1 [Language] Interface

## 6.7 <Maintenance>

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



Figure 6.7-1 [Maintenance] Interface

[Maintenance] interface contains the following information:

### 1. Maintenance Reminder

- Autoreminders: Daily Maintenance  
When starting the software for the first time every day, you will be reminded of daily maintenance.
- Autoreminders: Weekly Maintenance  
When starting the software for the first time every Monday, you will be reminded of weekly maintenance.
- Autoreminders: Monthly Maintenance  
When starting the software for the first time on the 1<sup>st</sup> day of each month, you will be reminded of monthly maintenance.

Check the desired maintenance item, and click <Save> button to complete maintenance reminder setting.

### 2. Maintenance

- <Priming for All>: Execute priming and cleaning actions.

## **6 [System] Menu**

- **<Daily Maintenance>**: Display daily maintenance procedure.
- **<Monthly Maintenance>**: Display monthly maintenance procedure.
- **<Weekly Maintenance>**: Display weekly maintenance procedure.

Click **< Priming for All>** to complete automatic priming and cleaning.

Click **<Daily Maintenance>**, **<Weekly Maintenance>** or **<Monthly Maintenance>** to open **[Maintain Info Dialog]**, where maintenance procedures can be viewed.

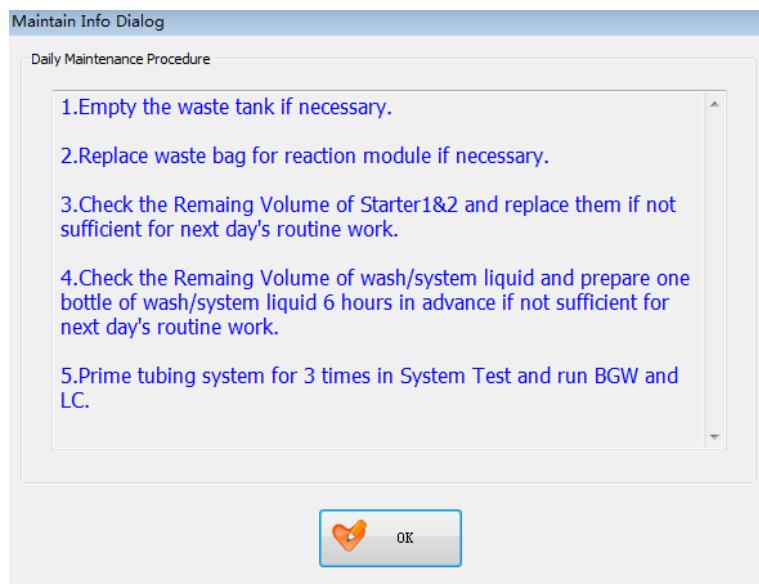


Figure 6.7-2 [Maintain Info Dialog]

### **3. Statistics**

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

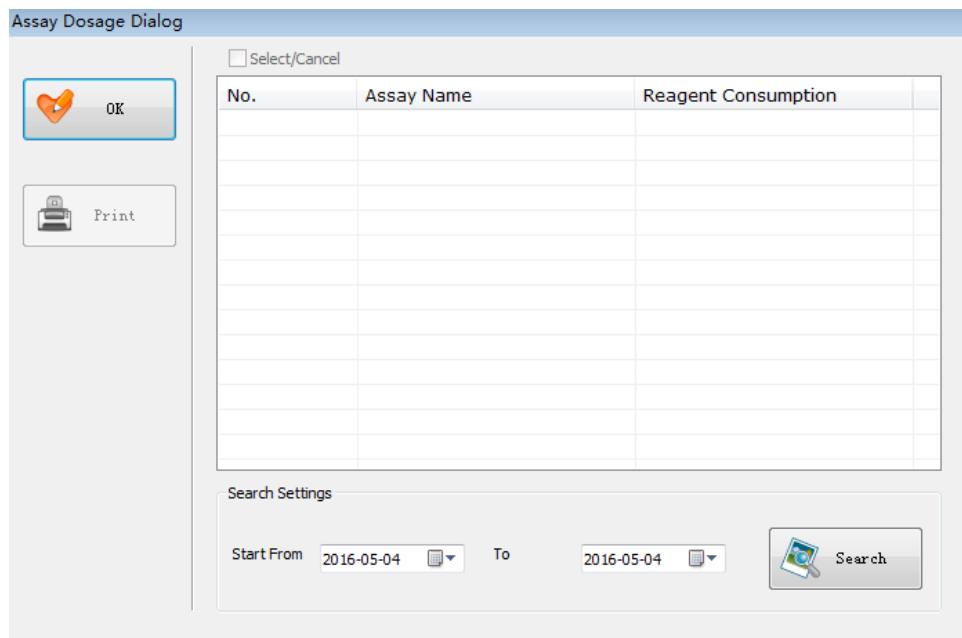


Figure 6.7-3 [Assay Dosage Dialog]

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.

## 6.8 <Wash pipe>

This system can wash system tubing to reduce blockage caused by residues in tubing system, which can affect the reliability of the test results. Meanwhile, it enhances the maintenance performance of analyzer. The cleaning process contains cleaning of pipetting needle, washer waste liquid tube and chamber waste liquid tube.

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

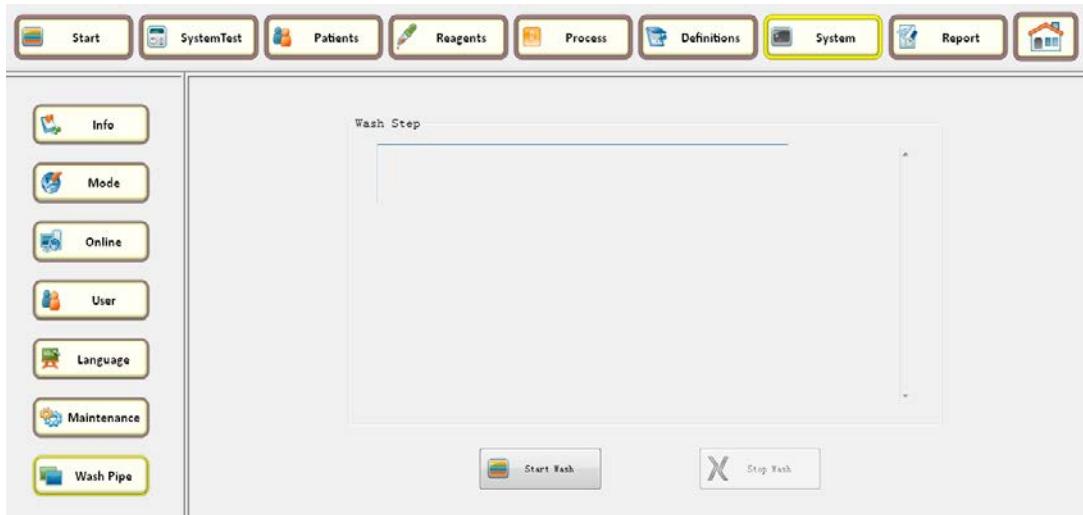


Figure 6.8-1 **[Wash Pipe]** Interface

According to the instruction of System Tubing Cleaning Solution, load System Tubing Cleaning Solution (insert the kit filled with System Tubing Cleaning 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 System Tubing Cleaning Solution for relevant details.



### NOTE

Do not abort wash during the cleaning process.



# 7 [Definition] Menu

## 7.1 [Definition] 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 [Definition] menu. Normally, parameters can be used by all assays after input once.

Click <Definition> button in the main bar to enter [Definition] menu. The function buttons described as follow:



Figure 7.1-1 [Definition] 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
<Sender>	Define the sender
<Result Definition>	Define settings to display, edit and print results.

## 7.2 <Test>

Click <Test> in [Definition] menu to enter [Test] interface.

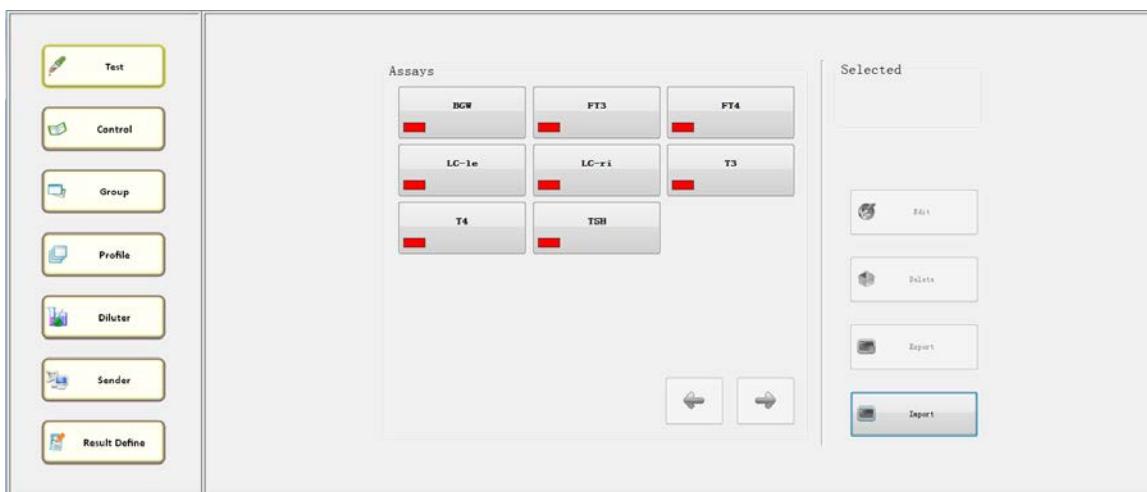


Figure 7.2-1 [Test] Interface

- 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**.

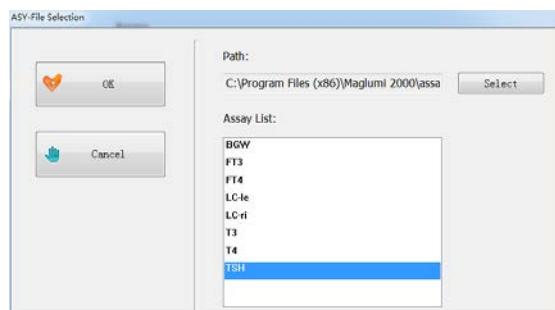


Figure 7.2-2 [ASY-File Selection] Dialog

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.

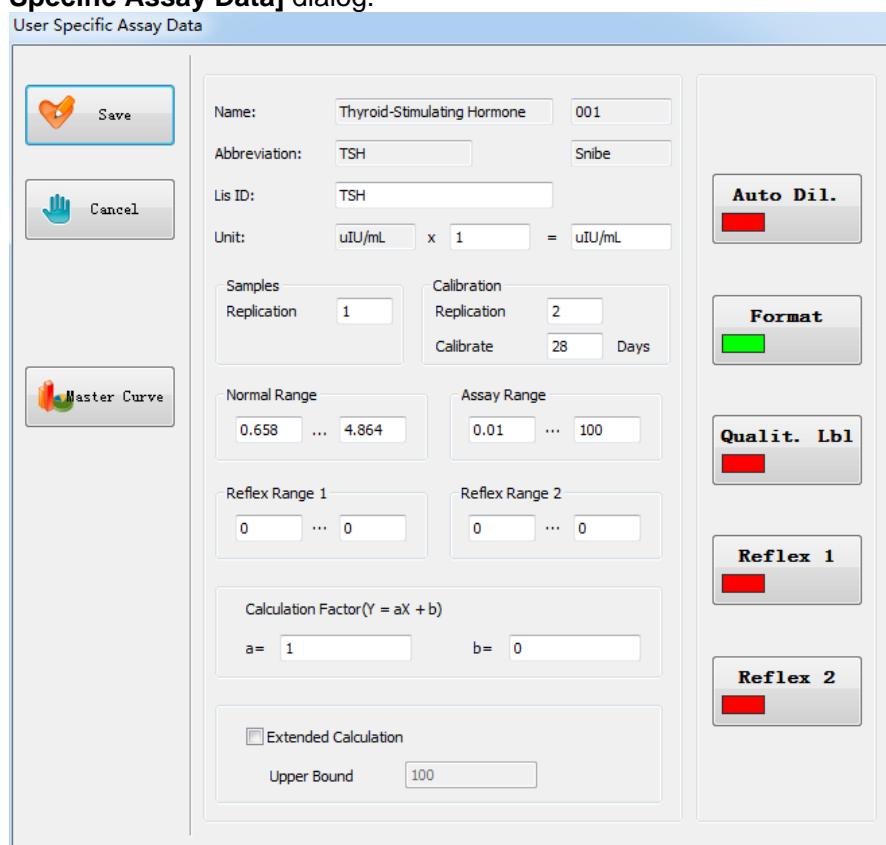


Figure 7.2-3 [User Specific Assay Data] dialog

Field	Description
<b>Name</b>	Assay name, article-No.;
<b>Abbreviation</b>	Abbreviation of the assay's English name and company's English name;
<b>Lis ID</b>	Signal channel used to communicate with LIS system
<b>Unit</b>	Measurement unit. When different measurement units are required, adjacent fields can be input with conversion factors and results;
<b>Sample replication</b>	Definition of sample retest times (range 1-3)
<b>Calibration replication</b>	Definition of calibration retest times (range 1-3);
<b>Calibrate</b>	Definition of valid days of calibration;
<b>Normal range</b>	Different countries and labs can set their own normal reference range. In <b>[Journal]</b> , there is “<” or “>” flag when the range is exceeded;
<b>Assay range</b>	The reagent manufacturer determines its assay range, but it can be modified downward by users. In <b>[Journal]</b> , there is “<<” or “>>” flag when the range is exceeded;
<b>Reflex range</b>	Can be modified by users; when the test results of this assay are within the reflex range, reflex shall be made again;
<b>Calculation factor (Y=ax+b)</b>	Calculate the results according to the calculation factors “a” and “b”, which are input by users.
<b>Extended calculation</b>	Calculate the results exceeding the linear range; the upper bound of extended calculation can be set.



**NOTE**

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.

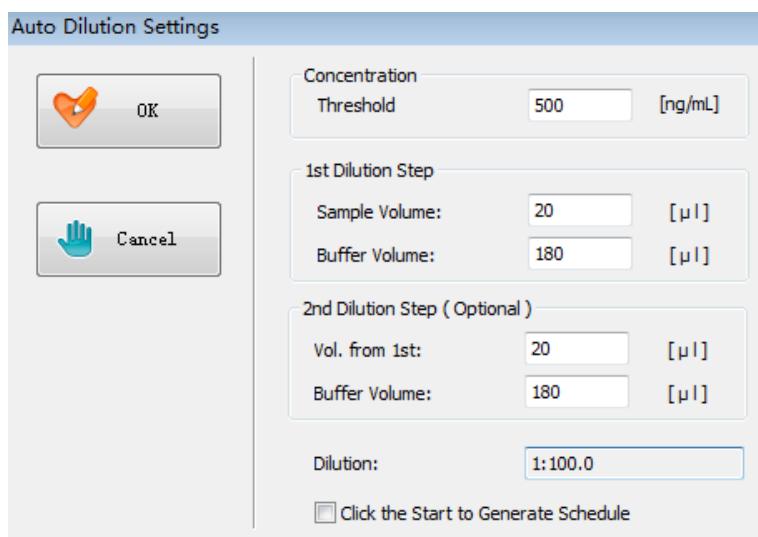


Figure 7.2-4 [Auto Dilution Settings] dialog

**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 sent automatically 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.

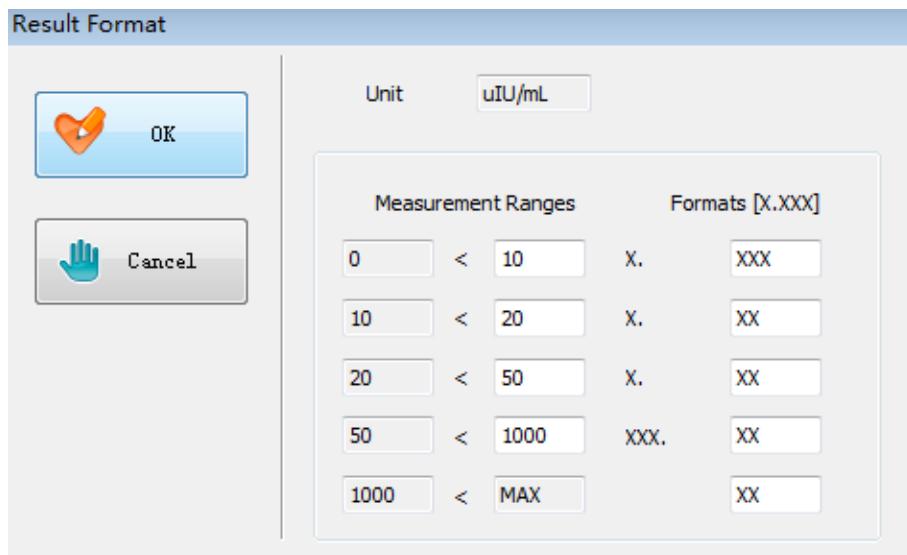


Figure 7.2-5 [Result Format] Dialog

**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.xx" means one integer and two decimals of the measurements in [Journal].

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.

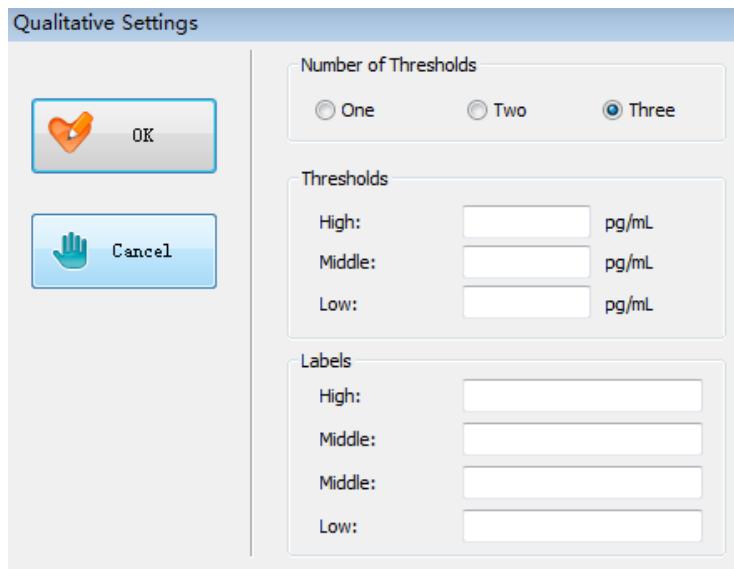


Figure 7.2-6 [Qualitative Settings] Dialog

- 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.

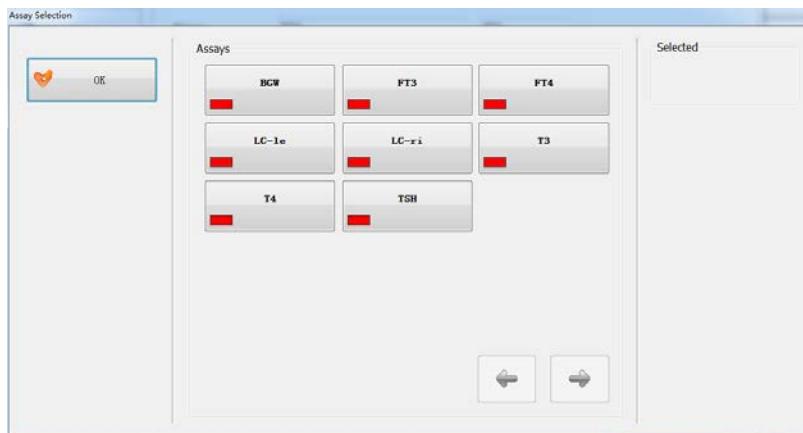


Figure 7.2-7 [Assay Selection] Dialog

In **Assays** field, 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 change 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.

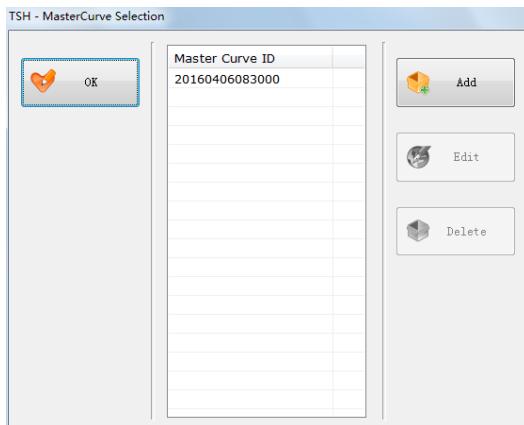


Figure 7.2-8 [Master Curve Selection] Dialog

- 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.

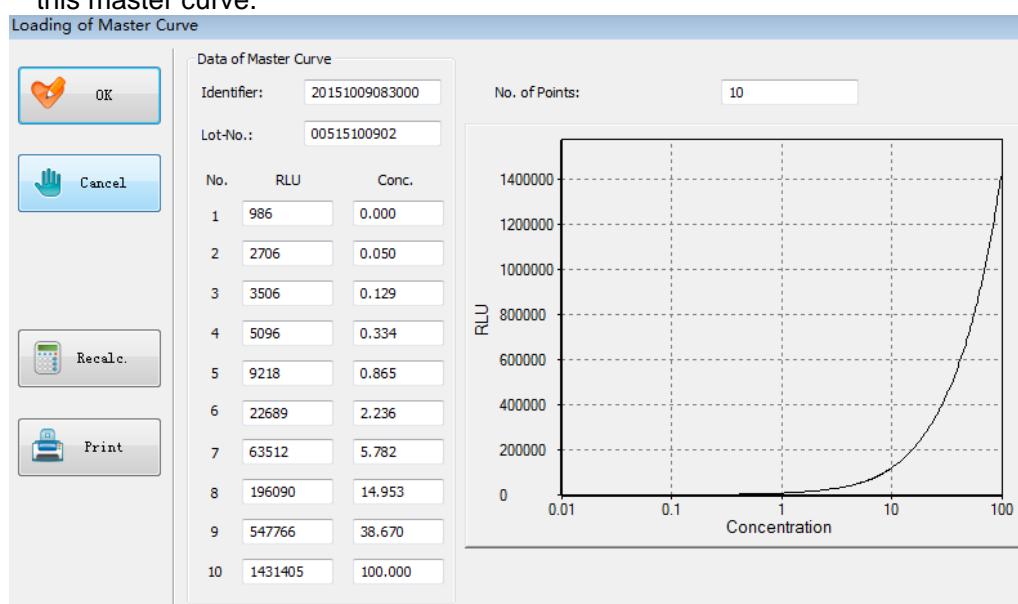


Figure 7.2-9 [Loading of Master Curve] Dialog

- 1. 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;
- Number of Points: number of thresholds of master curve;
- RLU: display RLU value;
- Conc.: display corresponding concentration;

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

**3. <Print>:** Print master curve and data.

Click <**OK**> button, **[message]** dialog appear to prompt whether you want to save the modified master curve.

Click <**OK**> button to confirm master curve setting.

Click <**Cancel**> button to cancel master curve setting.

### **7.3 <Control>**

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

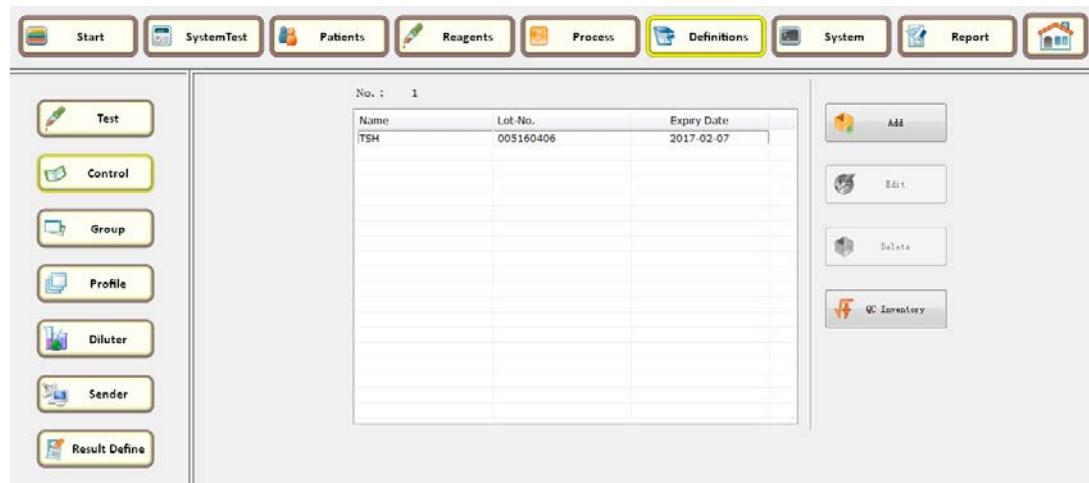


Figure 7.3-1 **[Control]** Interface

**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.

**3. <Delete>:** Delete existing control.

- Select the control to be deleted and click <**Delete**> button.

**4. <QC Inventory >:** Conduct overall browse for all controls.

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

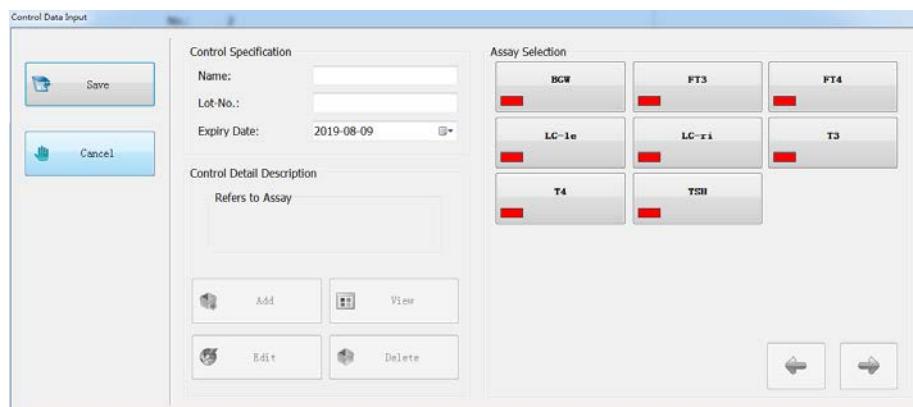


Figure7.3-2 [Control Data Input] dialog

**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.
- **<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.

Control Detail Description

 Save

 Cancel

Refers to Assay: TSH

Control Data  
Control Name:

Replication: 1

Unit:

Range  
0.000 ... 0.000

Ref. Range  
0.000 ... 0.000

Target Value: 0.000

Target SD: 0.000

Target CV[%]: 0.000

Figure 7.3-3 [Control Detail Description] Dialog

**Refers to Assay:** display the selected assay which associated with this QC product;

**Control Data**

- Control Name: quality control name;
- Replication: times of replication, upper limit 99.;
- Range: upper bound and lower bound 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 [Control Detail Description] dialog.

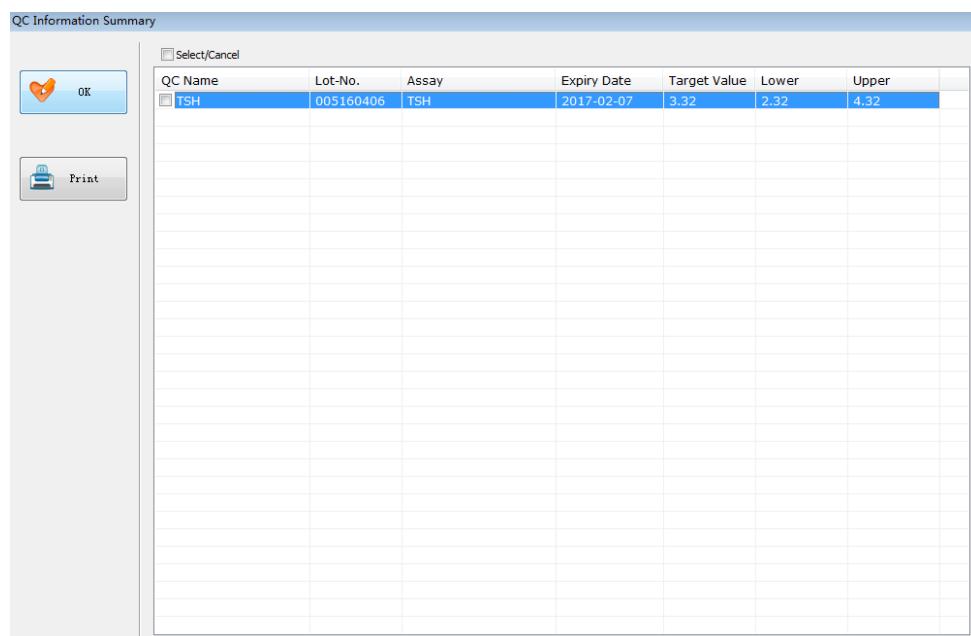


Figure 7.3-4 [QC Information Summary] dialog

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 [Patients] interface (one group contains 15 assays at most) for faster sample registration. Click <Group> button in [Definitions] menu to open [Group] interface.

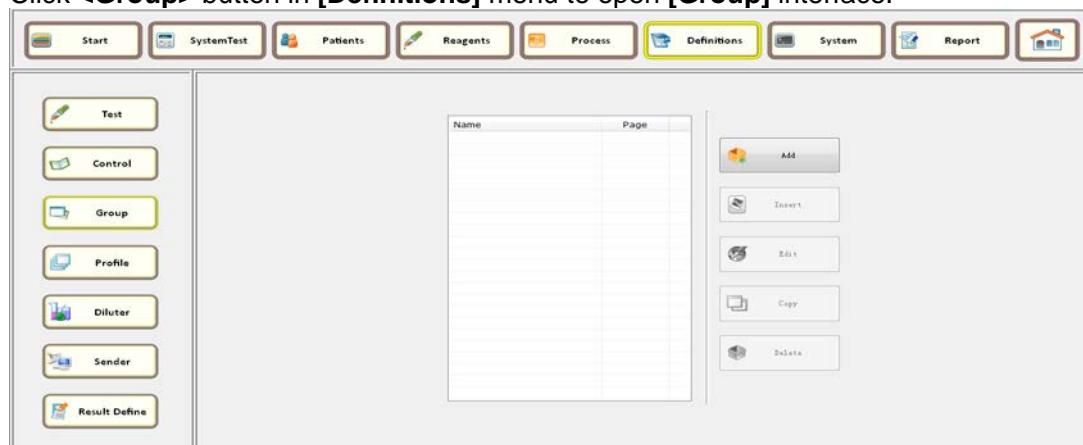


Figure 7.4-1 [Group] interface

**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.

**5. <Delete>**: delete an existing group;

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

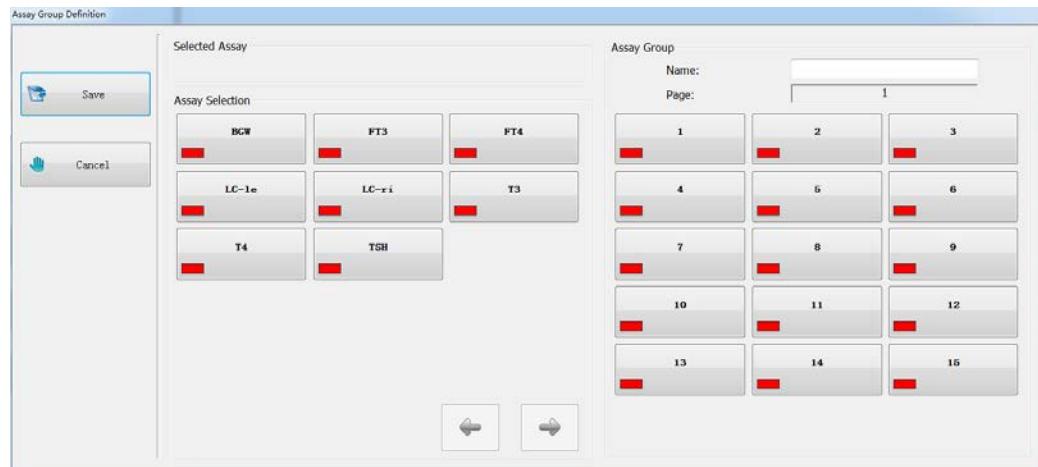


Figure 7.4-2 **[Assay Group Definition]** dialog

**Selected assay**: displays the name of the selected assay;

**Assay selection**: displays the assay list provided by Snibe;

**Assay Group**: displays 15 positions in consecutive numbers, each of which represents an optional assay;

- Name: group name, where you can input alphanumeric characters;
- 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.

## **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 **[Definition]** 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. When selected, the small window of the assay will turn from red to green;

**Profile Name:** Input alphanumeric characters as profile name;

**Profile Assay:** List the assays contained in this profile.

Click <OK> button to save the profile setting.

Click <Cancel> button to cancel the profile setting.

## 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.

## 7 [Definition] Menu



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** field, 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 a assay in **Assay Selection** field, the acquiescent dilutions defined by Snibe displays in the **Dilution Selection** field. Select a dilution ratio in **Dilution Selection** field, then click any button in **Selected Dilutions** field, the dilution ratio added to the selected assay. If user need more dilution ratio, follow the steps:

1. Select a assay in **Assay Selection** field;
2. Click any button in **Selected Dilutions** field;
3. Click <Edit> button to open **[Dilution Specification]** dialog

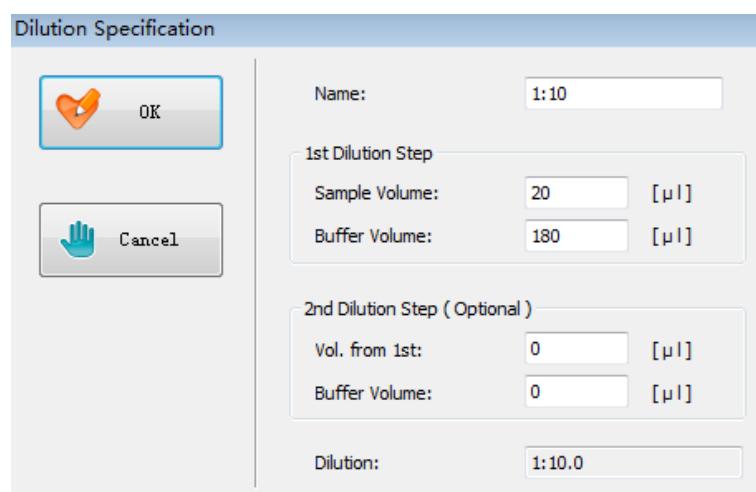


Figure 7.6-2 [Dilution Specification] Dialog

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 <Sender>

Users can create a sender list to differentiate the sources of patient samples. Samples can be assigned to a sender in the <Patient> button on [Patients] interface and the sender info is included in the journal.

Click <Sender> button in [Definition] menu to open [Sender] interface.

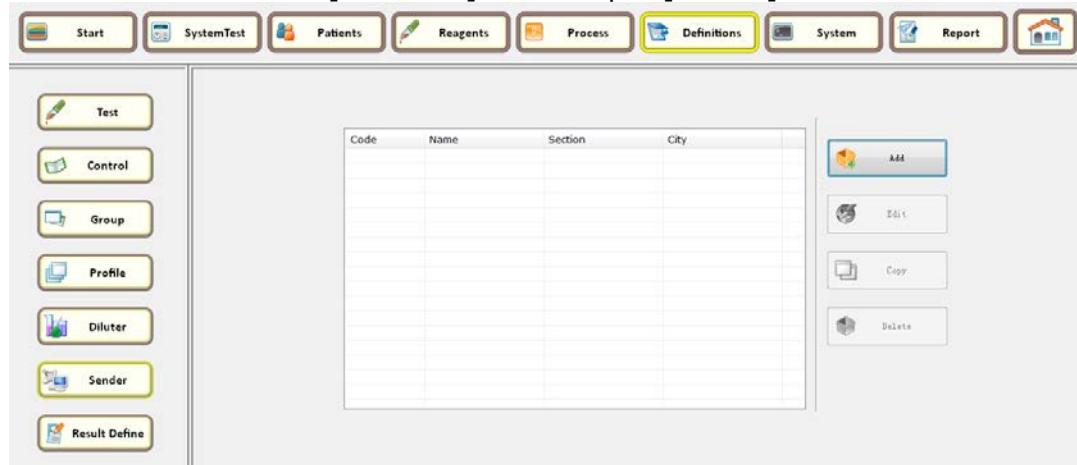


Figure 7.7-1 [Sender] Interface

1. **<Add>:** add a new sender;
  - Click <Add> button to open [Sender Input] dialog to define a new sender.
2. **<Edit>:** edit an existing sender;
  - Select a sender in [Sender] interface, and click <Edit> button to open [Sender Input] dialog.
3. **<Copy>:** copy an existing sender;
  - Select a sender in [Sender] interface, and click <Copy> button to open [Sender Input] dialog, where the sender information is copied. You can also modify the sender's info and save as a new sender.
4. **<Delete>:** delete an existing sender;
  - Select a sender in [Sender] interface, click <Delete> and <OK> button to delete the sender from the sender list.

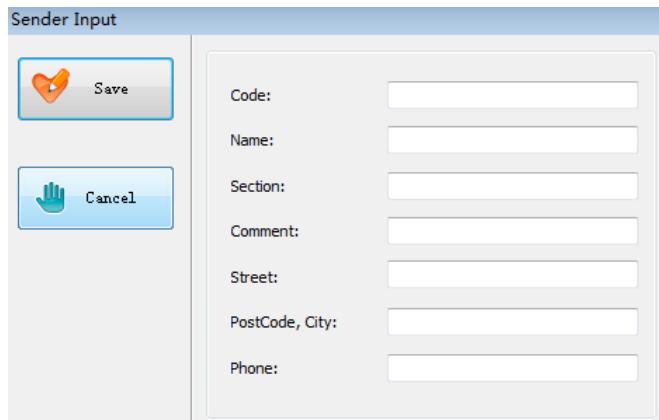


Figure 7.7-2 [Sender Input] Dialog

**Code:** Code of the sender;

**Name:** Name of the sender;

**Section:** Section of the sender;

**Comment:** You can add brief comments;

**Street:** Street of the sender;

**Postcode, City:** Postcode and city of the sender;

**Phone:** Phone number of the sender.

Click <Save> button to save the sender info setting.

Click <Cancel> button to cancel the sender info setting.

## 7.8 <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 [Definition] menu to open [Result define] interface.

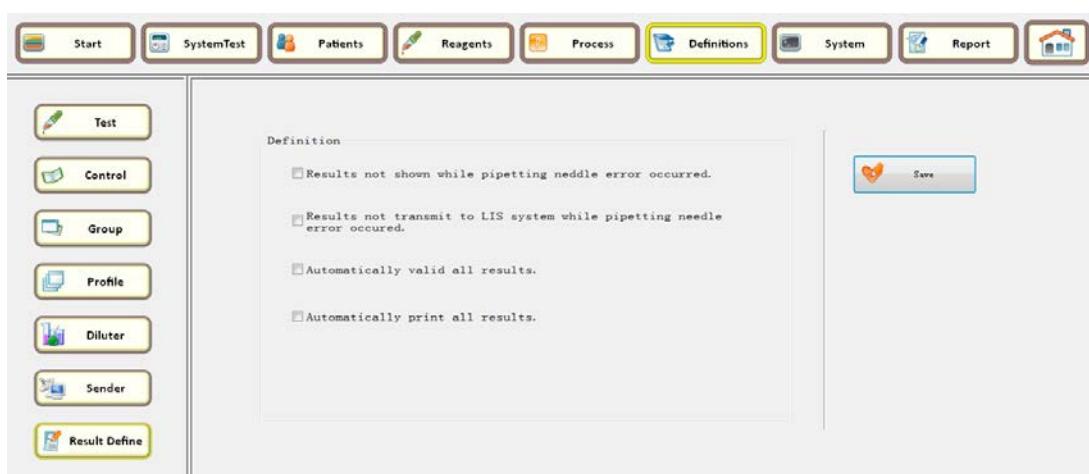


Figure 7.8-1 [Result Define] Interface

### 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.

**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.
<Low Level>	Send command to control specific components of PLC
<Protocol>	Record the intraday communication between PC and PLC
<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.

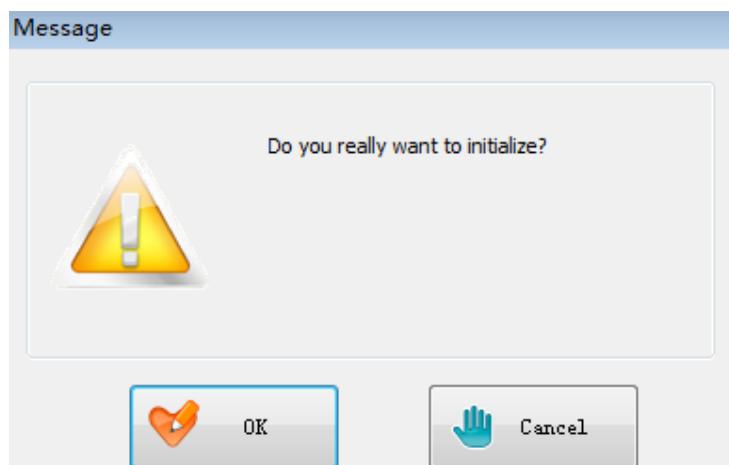


Figure 8.2-1 [Message] Dialog for Initialization

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.

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.

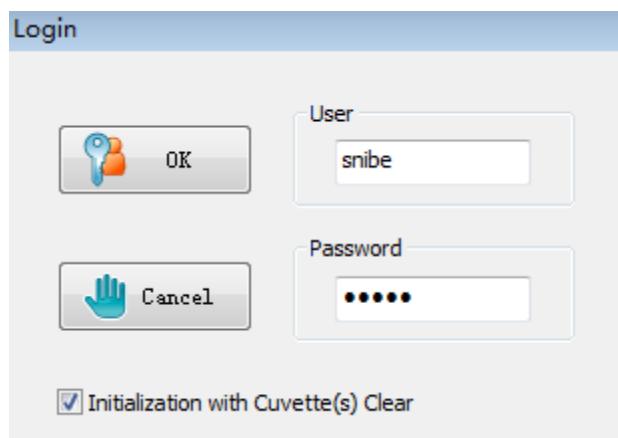


Figure 8.3-1 [Login] Dialog

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

#### 8.4 <Restart>

In the assay process, if the analyzer crashes due to some irresistible reason but PC software is not closed. To avoid users reediting tests, the uncompleted assays can be restarted after clicking <Restart> in [Process] menu. It is convenient for operation.

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

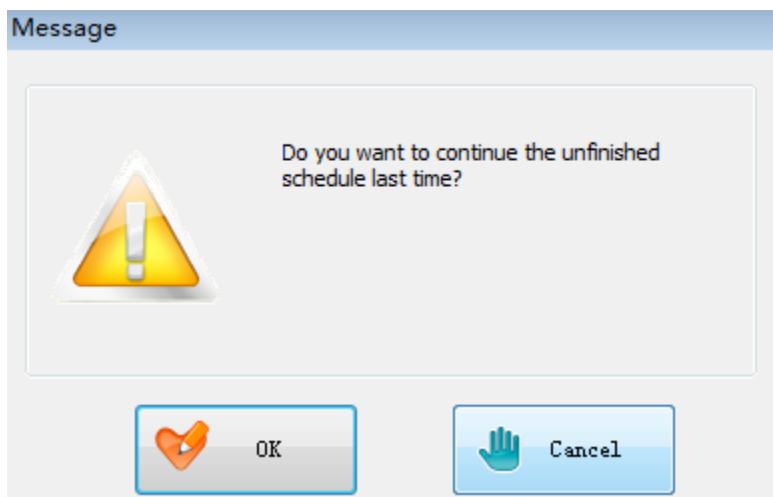


Figure 8.4-1 [Message] Dialog for Restart

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 PLC 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.

## **8 [Process] Menu**

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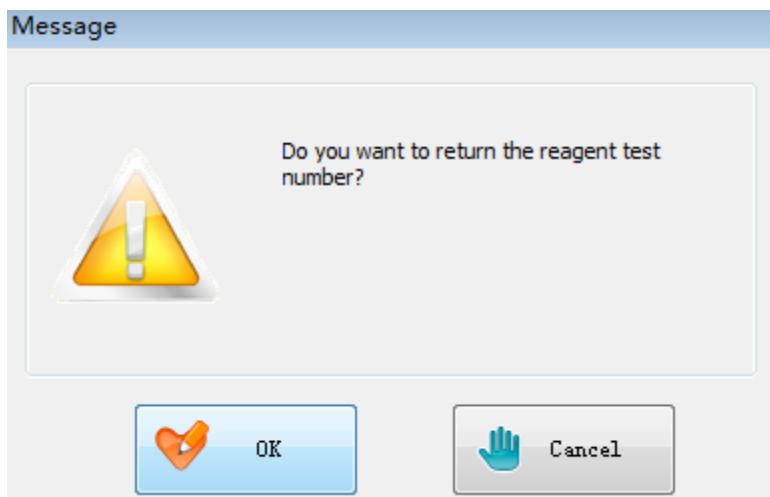


Figure 8.5-1 **[Message]** dialog for Return Assay

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 completed.

Click **<Cancel>** button to cancel the operation.

## **8.6 <Low Level>**

**<Low Level>** function is used to control specific components of PLC. Input PC and PLC communication protocol codes in **Command** bar, click **<Send>** button to make the corresponding components of the analyzer complete corresponding actions.

Click **<Low Level>** in **[Process]** menu to open **[Low Level]** interface.

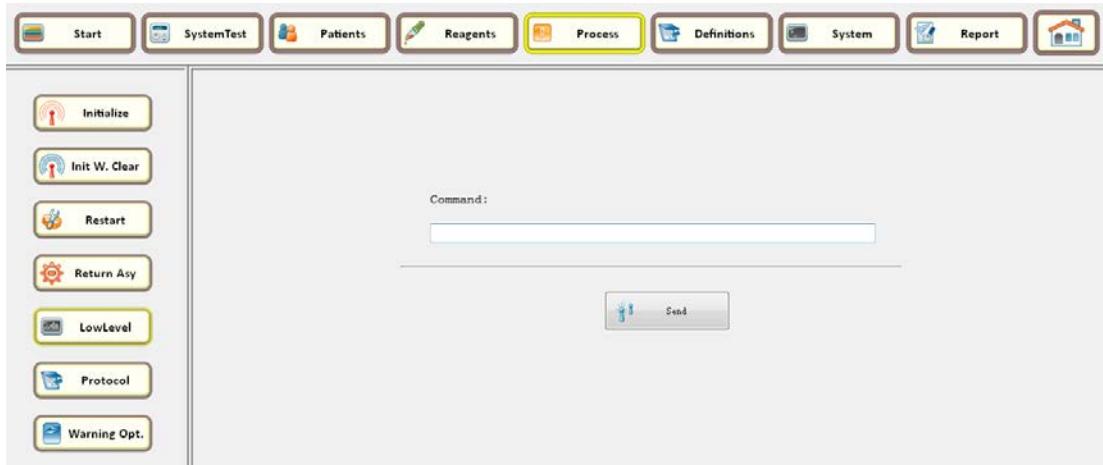


Figure 8.6-1 **[Low Level]** Interface

For example, input 02 01 51 04 04 in **Command** bar and click **<Send>**, the 4<sup>th</sup> incubator of the analyzer will be aligned to the incubator loader. This button is intended for service engineers.

## **8.7 <Protocol>**

**<Protocol>** function is used to record the intraday communication between PC and PLC.

Click **<Protocol>** in **[Process]** menu to open **[Protocol]** interface.

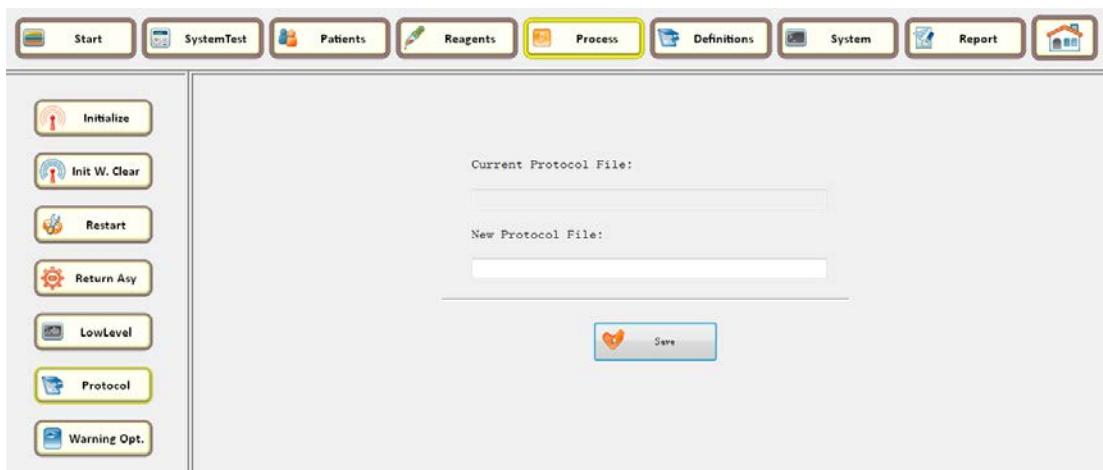


Figure 8.7-1 [Protocol] Interface

Input file name and extension “.txt”, “.xls” or “.doc” in **New Protocol File** bar and click **<Save>**, the intraday communication between PC and PLC will be recorded in the installation directory: Maglumi 2000\protocol.

## 8.8 <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.

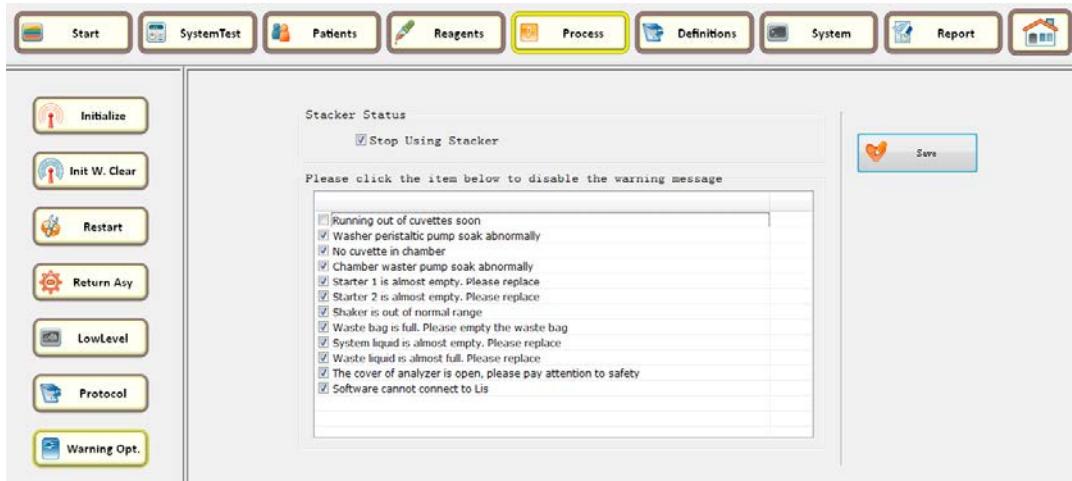


Figure 8.8-1 [Warning Opt.] interface

### 1. Stacker Status

- Stop Using Stacker

### 2. 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;

## **8 [Process] Menu**

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- The cover of analyzer is open, please pay attention to safety;
- Software cannot connect to LIS.

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. All system test must be performed before the analyzer starts an assay. Click [System Test] button in the menu bar to enter [System test] dialog.

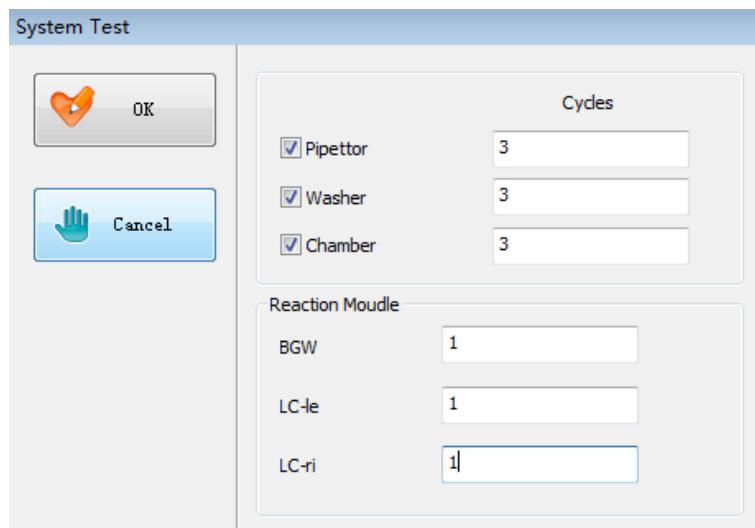


Figure 9.1-1 [System Test] Dialog

[System Test] dialog contains:

- **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.
  - **BGW:** Input cuvette BGW cycles (default: 1).
  - **LC-le/ri:** Input LC cycles. Use left pipetting needle to pipette light check liquid (default: 1).
- BGW and LC must be performed after any starter is replaced.

The requirement of of system test results is:

- 1) BGW: RLU is 200-1200, CV ≤ 10%;
- 2) LC: RLU is 400000-650000, CV ≤ 3%;
- 3) For two-needles modes: mean difference between LC(ri) and LC(le) ≤ 5%.

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.

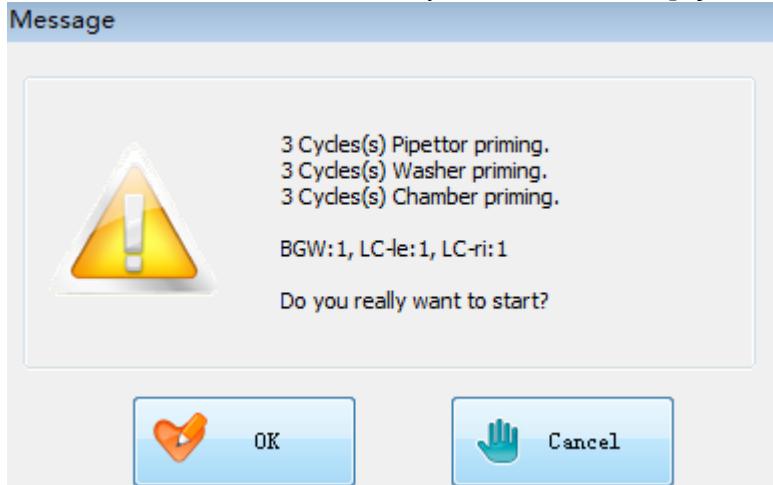


Figure 9.1-2 [Message] Dialog for System Test



### NOTE

When selecting LC-le / LC-ri, the rack carrying the LC liquid must be placed on Track 11 or 12 on the right in the sample area!

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.

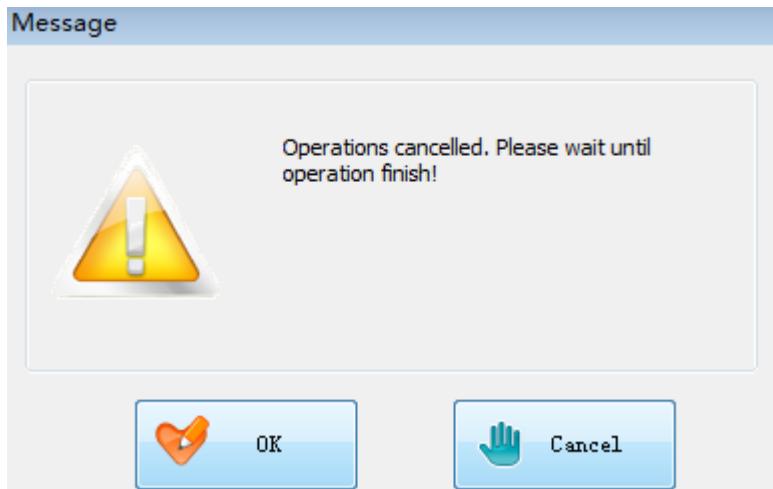


Figure 9.1-3 [Message] Dialog for Operations Canceled

## 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 channel 11 or 12 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 channel 11 or 12 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 <Std/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 system test results is:

- 1) LC: RLU is 400000-650000, CV ≤ 3%;
  - 2) For two-needles modes: mean difference between LC(ri) and LC(le) ≤ 5%.
- Please refer to the LC Reagent Manual of the specific expected value.

### 9.3 Add Light Check

Light Check is obtained by re-dissolution of lyophilized product in certain purified water. It can be used for LC in system test.

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. Use a pipettor to inject 2ml of purified water into the Light Check bottle for re-dissolution.
4. Shake carefully (avoid foam generation) to ensure that lyophilized product adherent to the bottle cap is also completely dissolved.
5. Prior to use, the Light Check solution must be placed still for at least 5min. Light Check test should be performed at room temperature.
6. 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 channel 11 or 12 in the sample area of the analyzer.



Figure 9.3-1 Insert the Light Check Bottle to the Sample Rack

#### **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 [Reagents] Menu

## 10.1 [Reagent] interface

Users can open the [Reagents] menu in the following 3 ways:

- Click <Reagents> on the menu bar;
- Open the reagent area door;
- Click the **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 five colors:

- 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.

Click <Reagent> button in the menu bar to enter [Reagents] interface.

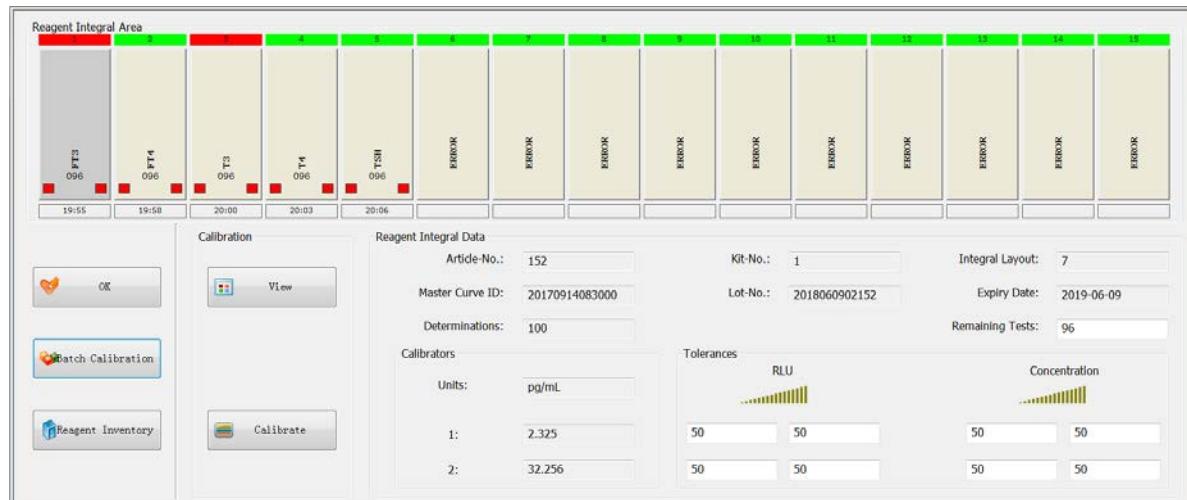


Figure 10.2-2 [Reagents] Interface

- Reagent Area**
- Reagent Data**
- Calibration**
- Reagent Operations**

- Shows the status and name of the reagent.
- Shows the relevant data of the reagent kit.
- View the calculate curve of the reagent. Start calibrate.
- Exit [Reagents] interface. Perform batch calibration.

## 10.2 Reagent Area

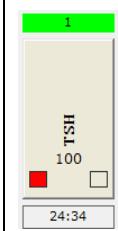
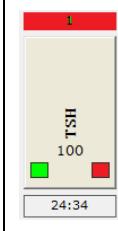
**Reagent Area** shows the status and name of the reagent in the reagent area, the magnetic microbeads mixing time, etc.

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



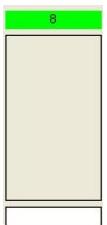
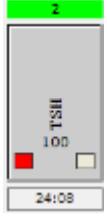
### NOTE

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

## 2. Reagent loading conditions

There are four types of reagent loading conditions.

Table 10.2-2 Reagent loading Conditions

	No reagent inserted into this channel.
	The reagent has been recognized by the system; the reagent is located in No. 2 track of reagent area; 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 track of reagent area; 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 10.2-4 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. 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.

Reagent Integral Data

Article-No.:	001	Kit-No.:	1120	Integral Layout:	7
Master Curve ID:	20160406083000	Lot-No.:	20160411001	Expiry Date:	2017-04-16
Determinations:	100	Remaining Tests: 47			
Calibrators		Tolerances			
Units: uIU/mL		RLU		Concentration	
1:	0.129	50	50	50	50
2:	38.67	50	50	50	50

Figure 10.3-1 Reagent Data

Field	Description
<b>Article-No.</b>	Used for assay search in the system.
<b>Kit-No.</b>	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.
<b>Layout</b>	The number of reagent bottles contained in the reagent.
<b>Master Curve ID</b>	The identification number of the master curve that the reagent uses.
<b>Lot-No.</b>	The lot number of the reagent.
<b>Expiry Dte</b>	The date of expiration (Year; Month; Day).
<b>Determinations</b>	The total number of tests with the reagent.
<b>Remaining Tests</b>	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.

Calibrators

Units:	uIU/mL
1:	0.129
2:	38.67

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.

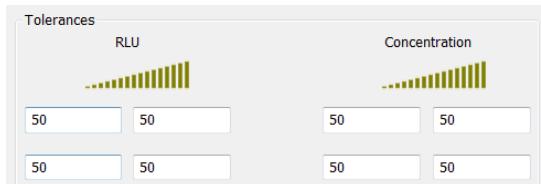


Figure 10.3-3 Reagent Tolerances

### **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.

A screenshot of a software interface titled "Reagent Integral Data". It contains several input fields: Article-No.: 001, Kit-No.: 1121, Integral Layout: 7, Master Curve ID: 2016040608300, Lot-No.: 20160517001, Expiry Date: 2017-03-20, Determinations: 100, and Remaining Tests: 100. The "Remaining Tests" field is highlighted with a red border.

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 "\*\*\*\*".

A screenshot of a software interface showing the "Remaining Tests:" label followed by a two-line input field. The top line contains the number "98" and the bottom line also contains "98". The entire input field is highlighted with a green background.

Figure 10.3-5 Double input

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

A screenshot of a software interface showing the "Remaining Tests:" label followed by a single-line input field containing the number "98". The input field has a light gray background.

Figure 10.3-6 Input correctly

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

A screenshot of a software interface showing the "Remaining Tests:" label followed by a single-line input field containing the text "<ERROR>". The input field has a red background.

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 10.4-1 Calibration

### 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;

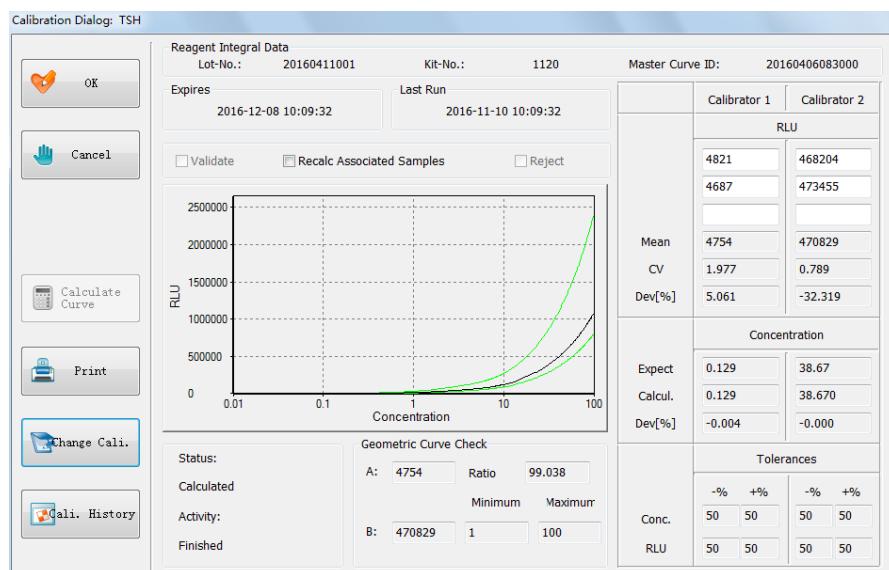


Figure 10.4-2 [**Calibration Dialog**]

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

#### 1. 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

	Calibrator 1	Calibrator 2
RLU		
	4821	468204
	4687	473455
Mean	4754	470829
CV	1.977	0.789
Dev[%]	5.061	-32.319
Concentration		
Expect	0.129	38.67
Calcul.	0.129	38.670
Dev[%]	-0.004	-0.000
Tolerances		
Conc.	-% 50 +% 50	-% 50 +% 50
RLU	50 50	50 50

Figure 10.4-3 Info of Working Curve

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

Status:	Validated
Activity:	Finished

Figure 10.4-4 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).

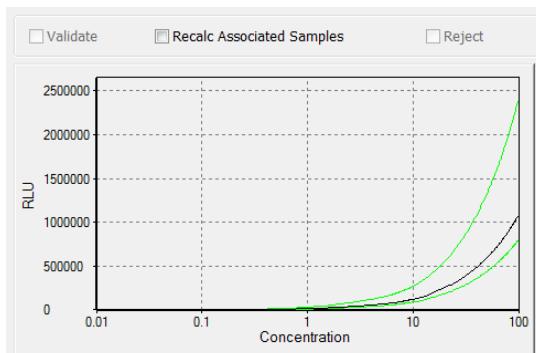


Figure 10.4-5 Calculate Curve

- 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 all information related to the reagent and the calibration 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.

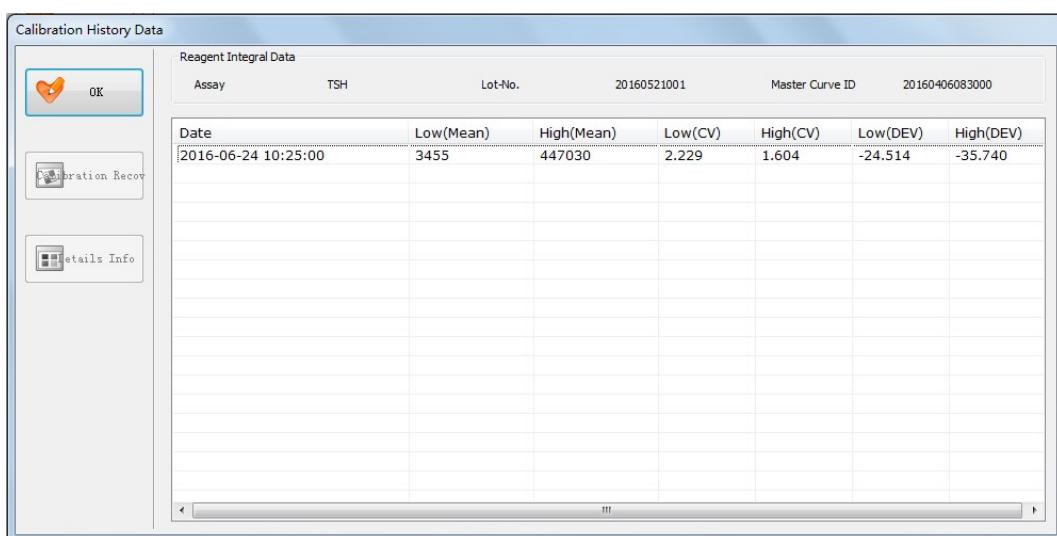


Figure 10.4-6 [**Calibration History Data**] Dialog

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.

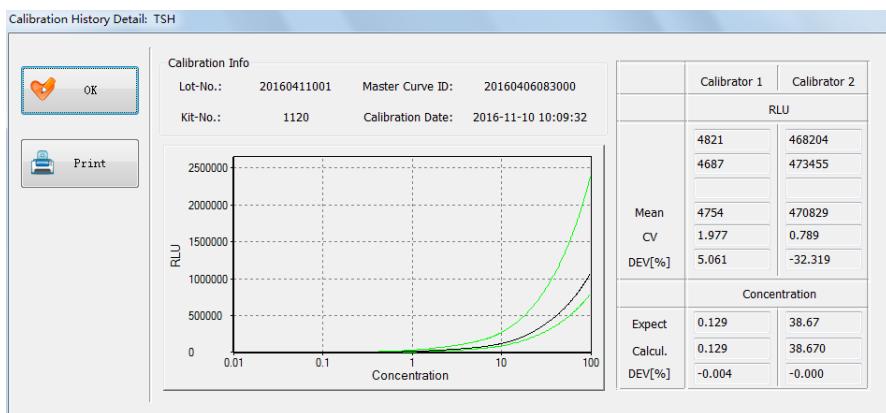


Figure 10.4-7 [Calibration History Detail] Dialog

Click <Print> in [Calibration History Detail] dialog to print all information related to the reagent and the calibration 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 <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) Select the reagent for calibration; click <Calibrate> 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 **Ratio or Dev(%)** shown in green → The measured value is within the allowable range; the measured result is valid.
- The **Ratio or Dev(%)** 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. Select **Reject** and click **<OK>** to reject it, and then 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.

Position	Assay Name	Lot-No.	Master Curve ID	Kit-No.	Calibration Validity Period
1	FT3	2018060902152	20170914083000	1	
2	FT4	2018060901004	20180131090000	1	
3	T3	2018060903151	20171115083000	1	
4	T4	2018060904002	20171123083000	1	
5	TSH	2018060905001	20171221083000	1	
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

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



### NOTE

A reagent not validated is shown in gray; recalibration can be performed only after validation.

## 10.7 <Reagent Inventory>

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

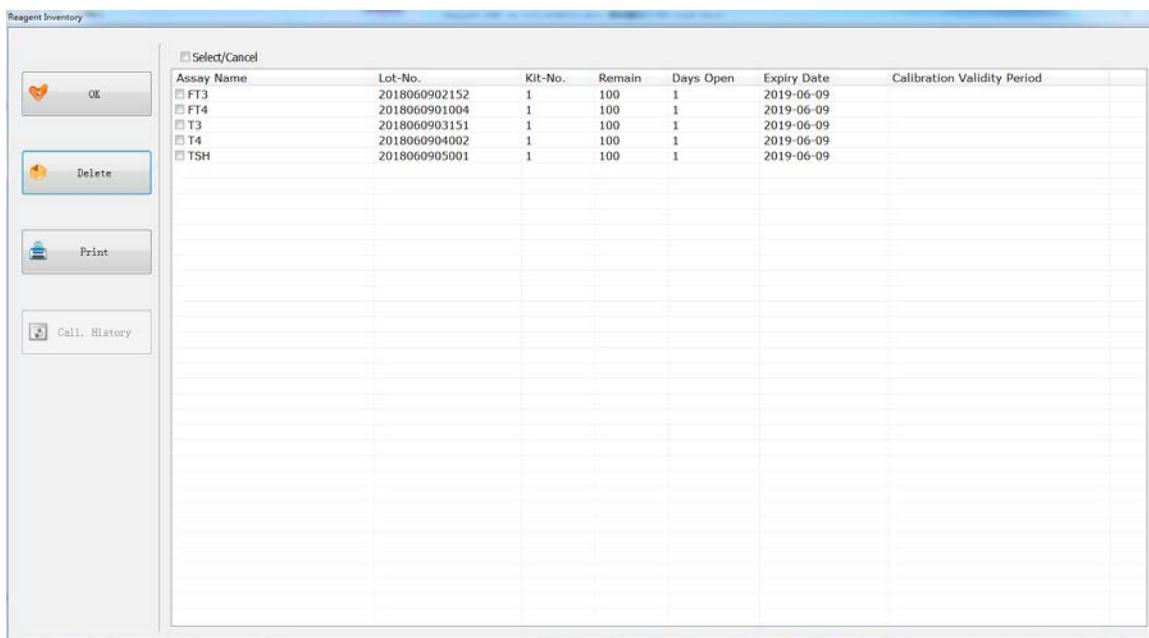


Figure 10.7-1 [Reagent Inventory] Dialog

- 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.

### 10.8 <OK>

Click <OK> button, software will exit [Reagents] interface and go back to [Home] interface.

# 11 [Patients] Menu

## 11.1 [Patients] Menu Introduction

The **[Patients]** menu can be opened in the following 3 ways:

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

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 two colors:

- Red: Indicates the rack at this position is not recognized by the system.
- Green: Indicates the rack at this position is recognized by the system.

### 11.2 [Patients] Menu

[Patients] interface is divided into the following areas:



Figure 11.2-1 [Patients] Interface

#### Rack Station

#### Loading

Shows the rack loading condition.

Definition of test type, such as STAT, Control, Dilution Selection or LC.

Shows the sample number.

Allows users to select assays for different samples.

Allows users to quickly select a required profile.

<Save> Exit [Patients] interface

In the Assay Selection area, the BGW, LC-1e and LC-ri are for system test, please see Chapter 9 System Test.

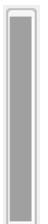
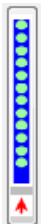
#### 11.2.1 Rack Station

This area contains 12 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.

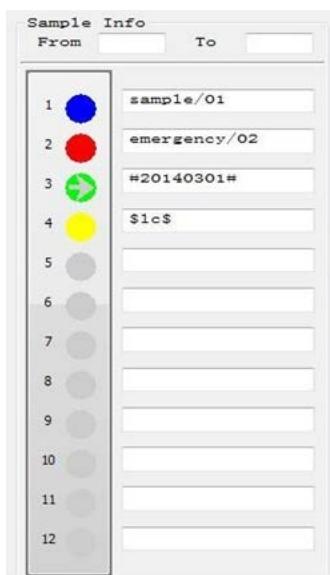


Figure 11.2-2 Rack Station

This area contains 12 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



Slot	Sample ID
1	sample/01
2	emergency/02
3	#20140301#
4	\$1c\$
5	
6	
7	
8	
9	
10	
11	
12	

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.

1	sample/01	Blue: Patient sample
2	emergency/02	Red: STAT sample
3	#20140401#	Green: Control (#)
4	\$1c\$	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:

8	sample08
9	sample09

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 "\*\*\*\*\*".

8	sample08
9	*****

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.

8	sample08
9	*****

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.

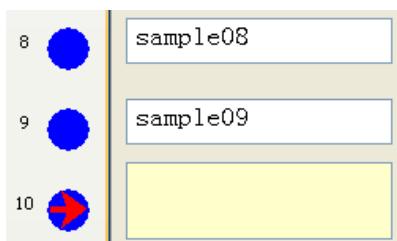


Figure 11.2-7 Input successfully

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 ().

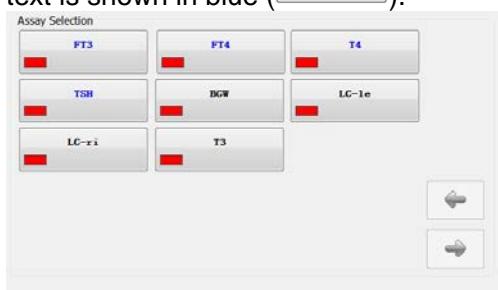


Figure 11.2-9 Assay Selection

#### 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)

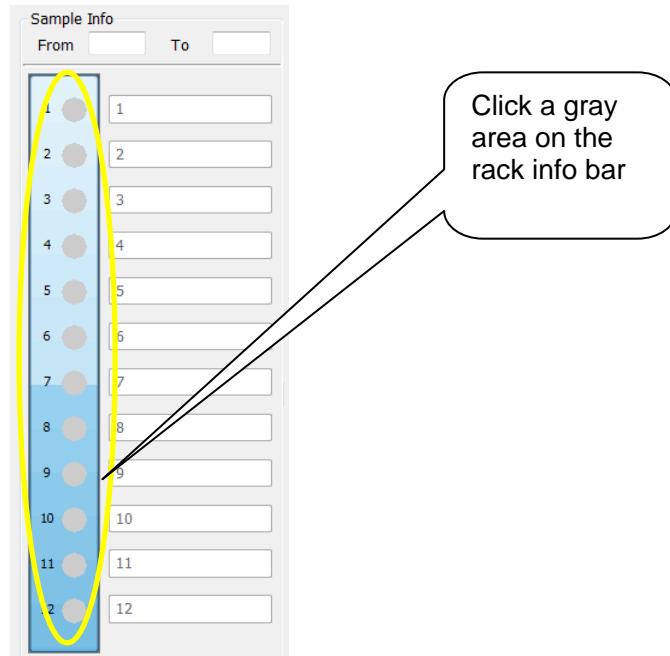


Figure 11.2-10 Sample rack information

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.

### 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.



Figure 11.2-11 [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:

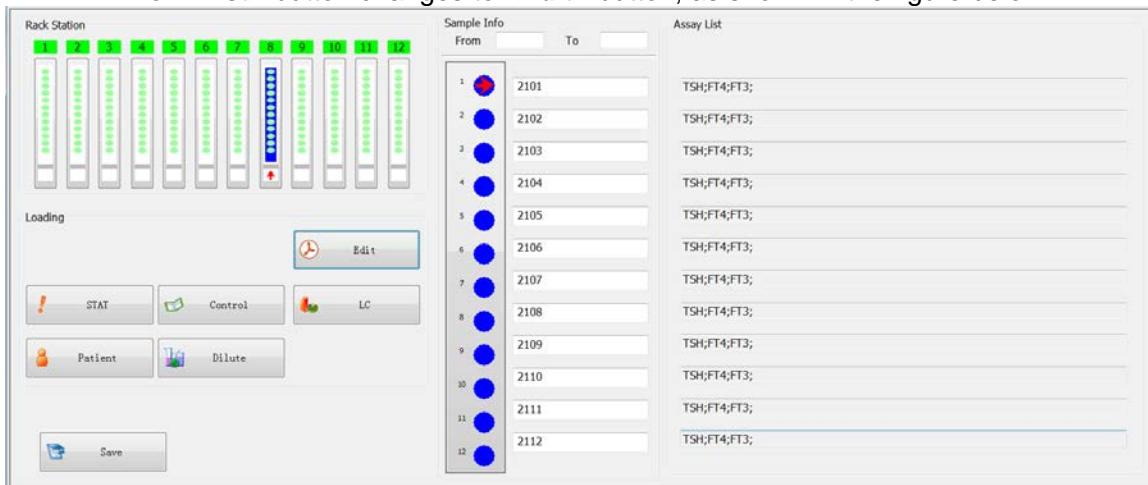


Figure 11.2-13 [Patient] Interface with Assay List

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



Figure 11.2-14 [Patient] 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.

## 11 [Patients] Menu

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.

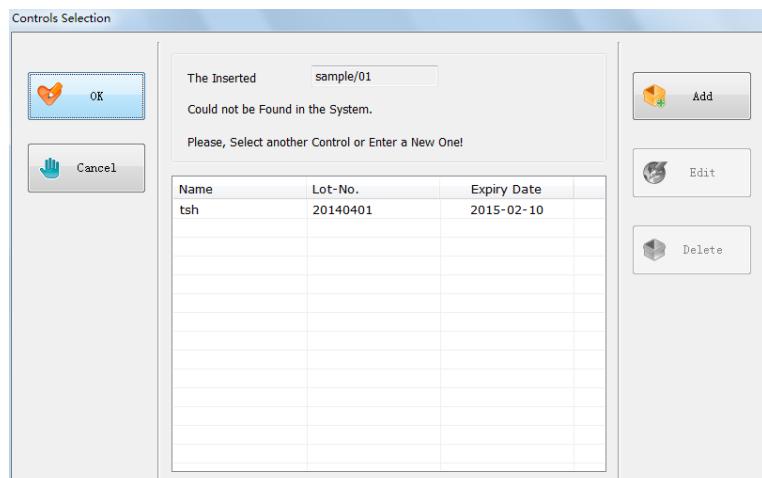


Figure11.2-15 **[Control Selection]** Dialog

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).

Press **[Start in Next Run]** (marked with ✓) to activate the Assay button under **Refers to Assays** a selected assay is shown in green window. Press the Assay button again to cancel the selection, and the window color will change to red. Then press <Start> in the menu bar to begin the control test.

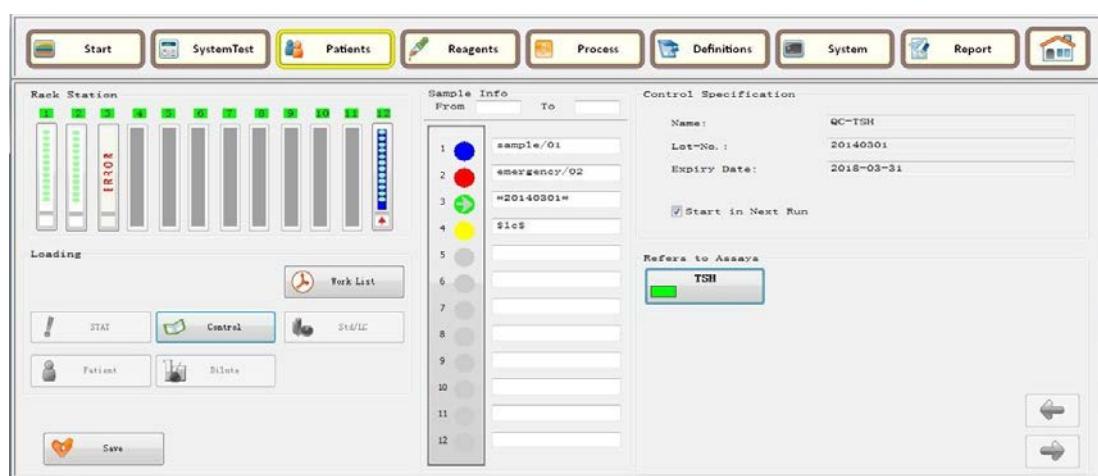


Figure 11.2-16 Select Start in Next Run

### 11.2.5.4 <Std/LC>

Click <Std/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).

Press the corresponding 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 [Patients] interface.

#### 11.6 <Save>

Click <**Save**> to save the registered sample info and exit [Patient] 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.

The screenshot shows the Maglumi 2000 Journal interface. At the top, there is a toolbar with various icons: Start, SystemTest, Patients, Reagents, Process, Definitions, System, Report (which is highlighted), and Home. Below the toolbar, there is a search bar labeled "Sort Criterion: Chronological" and a "Search Key:" input field. To the right of the search bar are buttons for "Records.:" (set to 15), "Sort", and "Today Rpt.". The main area is a grid table with columns: SampleID, Assay, Dil., RLU, CV(%), Concentration, and Flag. The table contains 15 rows of data. Row 12 is currently selected. At the bottom of the table are buttons for Recalc., Undo, Edit, Delete, Valid, Print, and Remove.

SampleID	Assay	Dil.	RLU	CV(%)	Concentration	Flag
sample/01	TSH	405832	0.0	34.81	uIU/mL	C;>R
emergency/02	TSH	7586	0.0	0.521	uIU/mL	*;C;S
#20140301#	TSH	48592	0.0	3.604	uIU/mL	C
1	TSH	2800365	0.0	100.0	uIU/mL	C;>>>
2	TSH	52023	0.0	3.933	uIU/mL	C
3	TSH	244856	0.0	20.53	uIU/mL	C;>
4	TSH	324569	0.0	27.43	uIU/mL	C;>
5	TSH	9816	0.0	0.691	uIU/mL	C
6	TSH	81745	0.0	6.941	uIU/mL	C;>
7	TSH	969654	0.0	93.26	uIU/mL	C;>
8	TSH	14248	0.0	1.004	uIU/mL	C
9	TSH	6414	0.0	0.423	uIU/mL	C
10	TSH	3674	0.0	0.150	uIU/mL	C;<
11	TSH	2047856	0.0	100.0	uIU/mL	C;>>>
12	TSH	844759	0.0	79.49	uIU/mL	C;>

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:

<b>Sample ID</b>	(\$) is marked before and after Calibration or System Test; (#) is marked before and after QC Name.
<b>Assay</b>	English abbreviation of an assay
<b>Dil.</b>	Dilution ratio for diluting the sample
<b>RLU and CV (%)</b>	Shows the experimental status of the sample and the RLU value and CV (%).
<b>Concentration</b>	Test result expressed in concentration unit.
<b>Flag</b>	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.

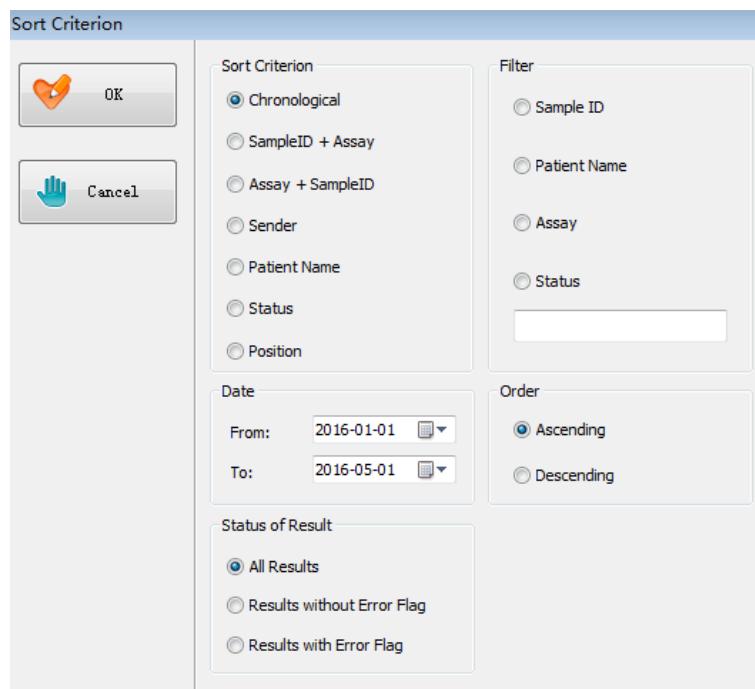


Figure 12.2-2 [Sort Criterion] Dialog

<b>Chronological</b>	Shows journals satisfying the search criteria according to the time of journals.
<b>Sample ID + Assay</b>	First shows the journals according to the first sort criterion: Sample ID; then sorts the journals by assay name (in alphabetical order).
<b>Assay + Sample ID</b>	First shows the journals by assay name (in alphabetical order) according to the first sort criterion; then sorts the journals by Sample ID.
<b>Sender</b>	Sorts the journals by sample sender.
<b>Patient Name</b>	Sorts the journals satisfying the search criteria by patient name of sample.
<b>Status</b>	Sorts the journals satisfying the search criteria by experimental status, such as Placed, To Do, Active, Done, and Failed.
<b>Position</b>	Sorts the journals satisfying the search criteria by the position of sample in the sample area (from left to right, from 1 to 12).
<b>Filter</b>	Set the filter criteria, including Sample ID, Patient Name, Assay and Status. Enter the expected keyword to show the journals satisfying the filter criteria.
<b>Order</b>	Function selection, showing the journals satisfying the search criteria by Ascending or Descending.
<b>Date</b>	Select the expected range of search date.
<b>Status of Result</b>	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.

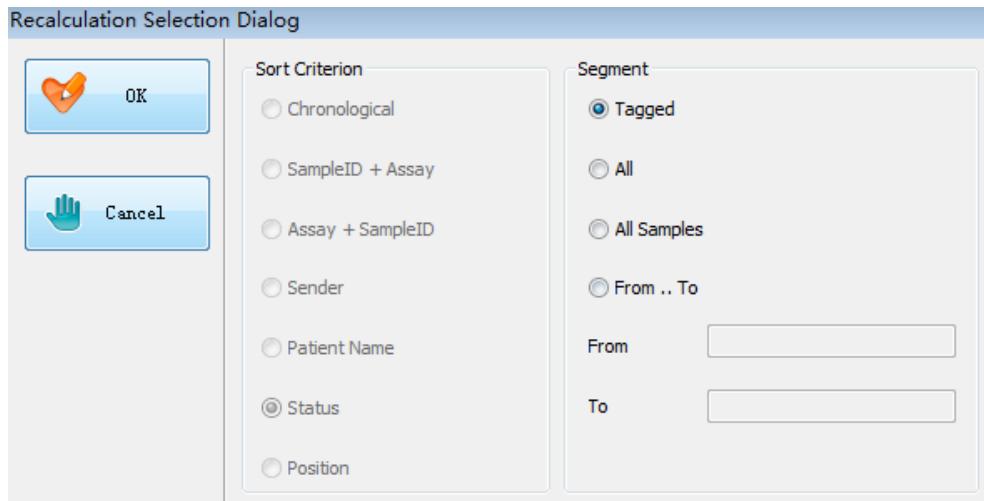


Figure 12.2-3 [Recalculation Selection Dialog]

- |                    |  |
|--------------------|--|
| <b>Tagged</b>      | The tagged journals on [Journal] interface will be recalculated  |
| <b>All</b>         | All journals on [Journal] interface will be recalculated.  |
| <b>All Samples</b> | The sample journals on [Journal] interface will be recalculated.   |
| <b>From...To</b>   | Allows range selection, where users can enter the start and the end of a range. Journals within this range will be recalculated. |

Click <OK> to recalculate journals satisfying the selection criteria.  
Click <Cancel> to cancelrecalculation.

### 12.2.4 <Online>

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

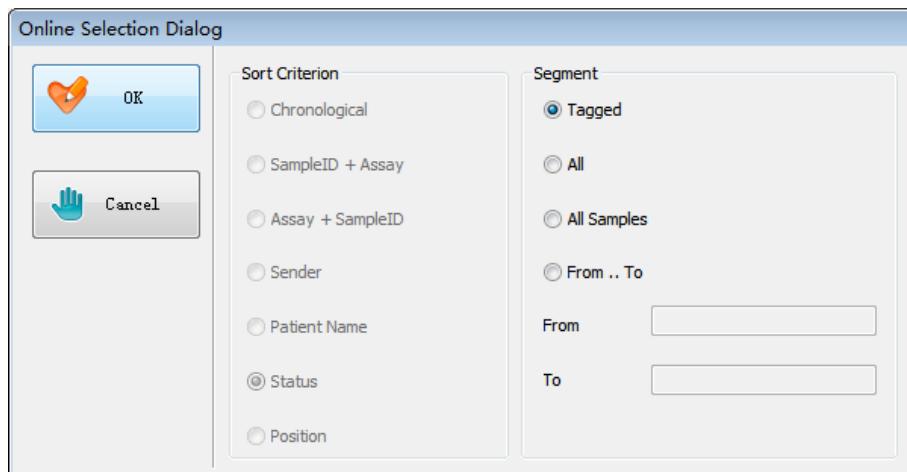


Figure 12.2.4 [Online Selection Dialog]

**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.

**From...To**

Allows range selection, where users can enter the start and the end of a range. Journals within this range 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:** Shows patient info associated with the journal

Name	Name of the patient
Date of Birth	Birthday of the patient.
Sex	Sex of the patient.
Sender	Name of the organization or individual sending the sample.

**Sample:** Records 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 Date	Time when the sample is registered.

**Result:** Shows details of results

RLU	RLU value of the journal
Mean RLU	Mean RLU value of several tubes.
CV%	Variation coefficient of RLU of several tubes.
Conc.	Concentration value of the journal.
Mean Conc.	Mean concentration value of several tubes.
CV%	Variation coefficient of concentration value of several tubes.
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.

**Reagent Data** Shows the reagent data of the assay, including Kit-No., Lot-No. and Master Curve ID.

**Flags** Shows 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 field.

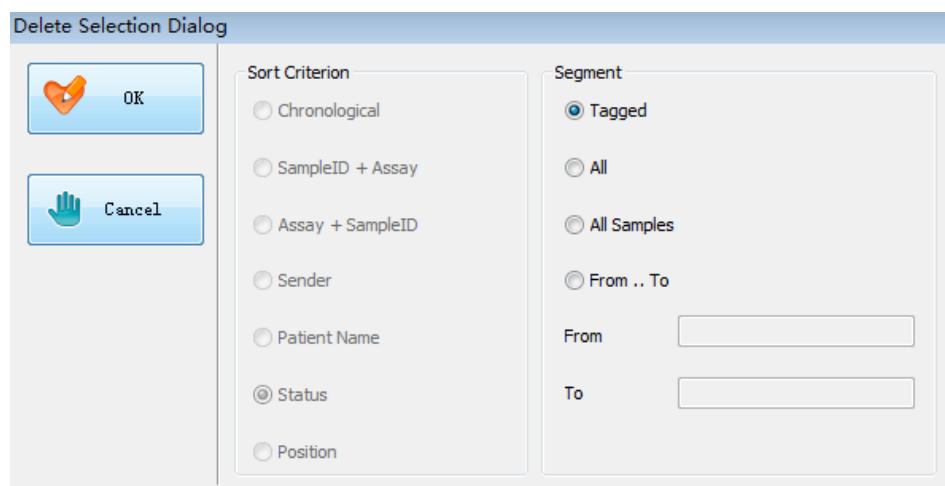


Figure 12.2-6 [Delete Selection Dialog]

- |                    |   |
|--------------------|---|
| <b>Tagged</b>      | The tagged journals on [Journal] interface will be deleted.   |
| <b>All</b>         | All journals on [Journal] interface will be deleted.  |
| <b>All Samples</b> | The sample journals on [Journal] interface will be deleted.   |
| <b>From...To</b>   | Allows range selection, where users can enter the start and the end of a range. Journals within this range 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 field.

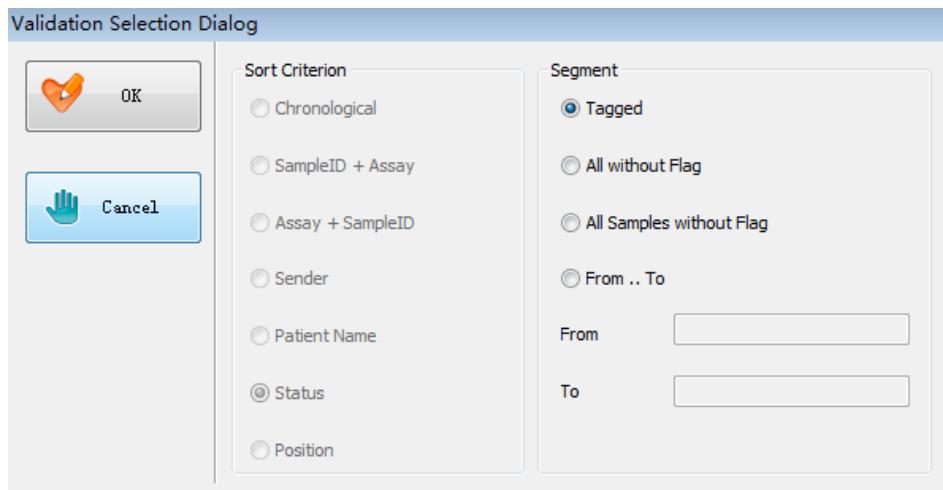


Figure 12.2-7 [Validation Selection Dialog]

- 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.
- From...To** Allows range selection, where users can enter the start and the end of a range. Journals within this range 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** field.

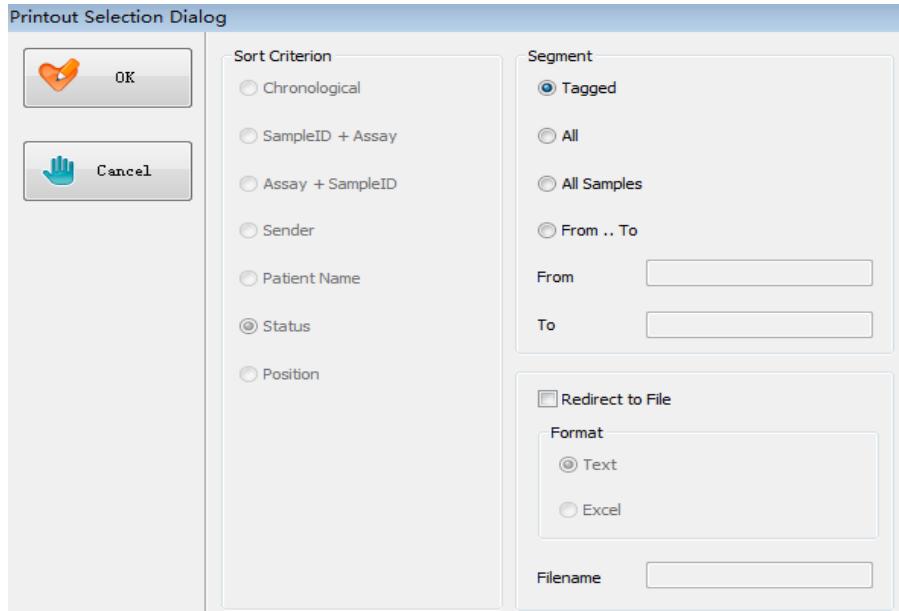


Figure 12.2-8 [Printout Selection Dialog]

- 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.

**From...To** Allows range selection, where users can enter the start and the end of a range. Journals within this range will be printed.

Click <OK> 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 remeasured in the **Segment** area.

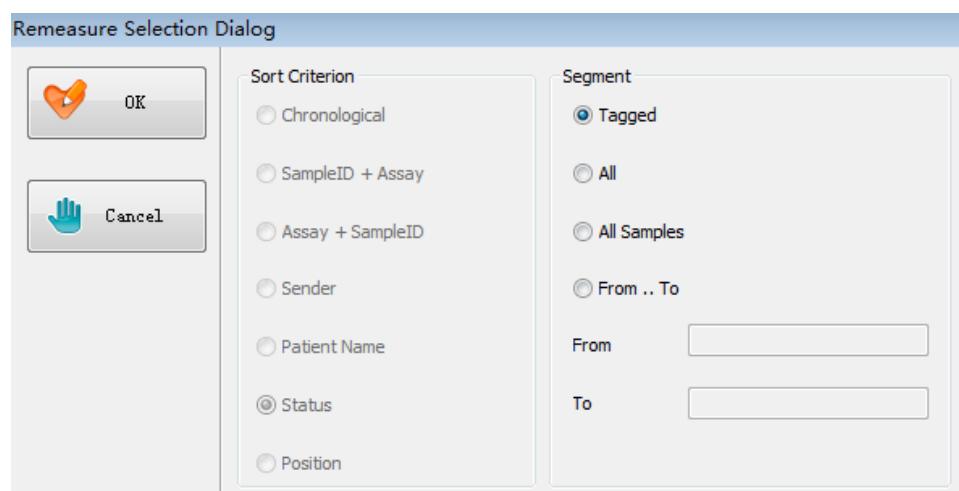


Figure 12.2-9 [Remeasure Selection Dialog]

**Tagged** The tagged journals on [Journal] interface will be remeasured.

**All** All journals on [Journal] interface will be remeasured.

**All Samples** The sample journals on [Journal] interface will be remeasured.

**From...To** Allows range selection, where users can enter the start and the end of a range. Journals within this range will be remeasured.

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.

## 12 [Report] Menu

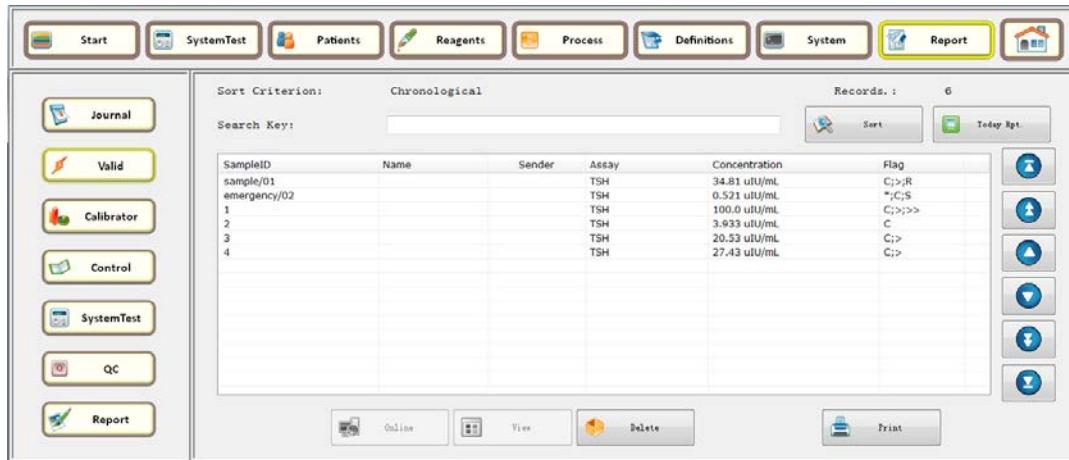


Figure 12.3-1 [Valid] Interface

[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

Last Name:	152.	Conc.:	2.164	uIU/mL	Reagent
First Name:	TSH	Qualit. Label:	21913	Kit-No.:	13284
Birthday:		RLU:		Lot-No.:	005150806
Sex:		Date/Time.:	2015-12-09 20:00:31	Master Curve	20150806083
Patient ID:					

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

**Patient:** Shows patient info associated with the valid result.

- |               |  |
|---------------|--|
| Last Name     | Last name of the patient                     |
| First Name    | First name of the patient                    |
| Date of Birth | Birthday of the patient.                     |
| Sex           | Sex of the patient.                          |
| Patient ID    | Identification number of the patient sample. |

**Sender:** Shows details of the sending organization.

Name	Name of the sending organization.
Code	Identification number of the sending organization.
Section	Section of the sending organization.
City	City where the sending organization is located.
Street	Street where the sending organization is located.
Phone No.	Phone number of the sending organization.

**Sample:** Shows the sample info.

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

**Result:** 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.
Reagent	Shows the reagent data of the assay, including Kit-No., Lot-No. and Master Curve ID.
<b>Flags:</b>	Shows the identifier of result status. (See section 12.1.5)
<b>Assay Range:</b>	Shows the assay range of the journal, and judges whether the journal is within the Assay Range.
<b>Normal Range:</b>	Shows the normal range of the journal, and judges whether the journal 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.

SampleID	Assay	Dil.	RLU	CV(%)	Concentration	Flag
\$TSH\$1	TSH		3455	2.3	0.146	<
\$TSH\$2	TSH		447030	1.6	19.13	>

Figure 12.4-1 [Calibrator] Interface

## 12 [Report] Menu

[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.

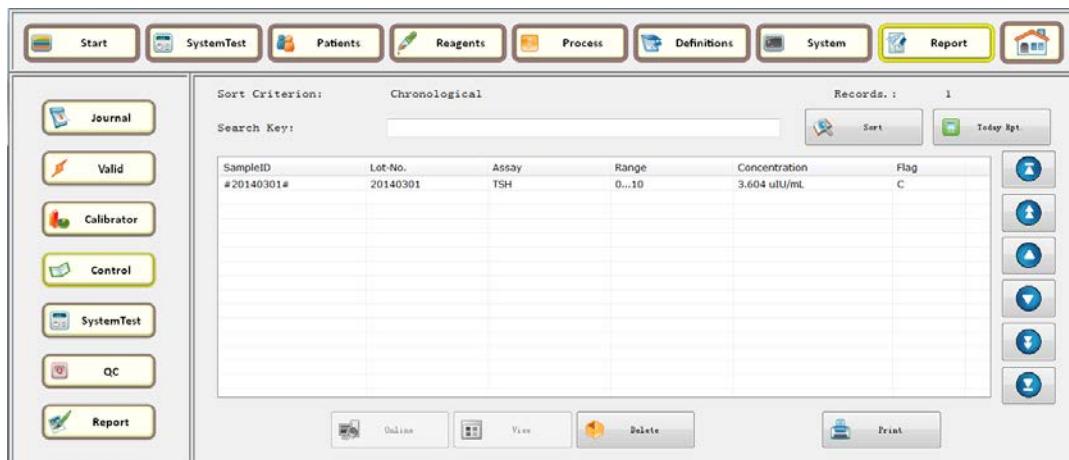


Figure 12.5-1 [Control] Interface

[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.

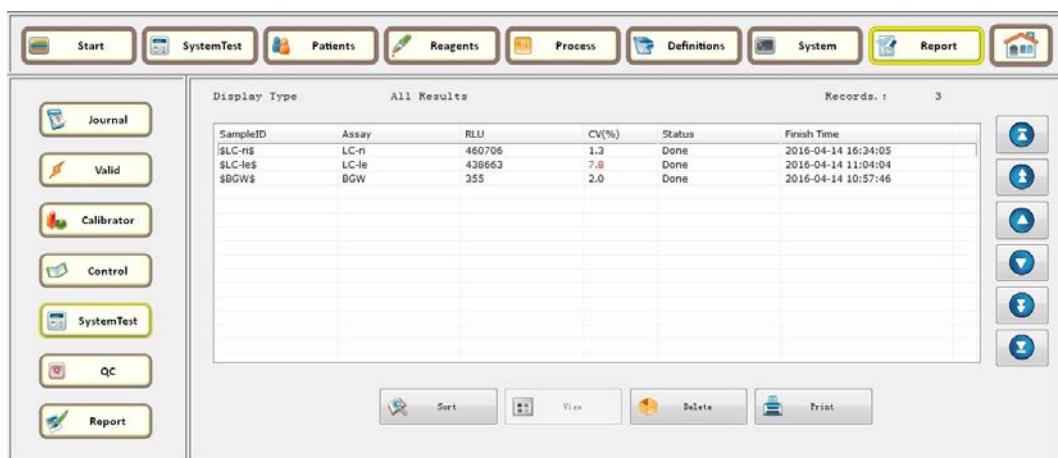


Figure 12.6-1 [System Test] Interface

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

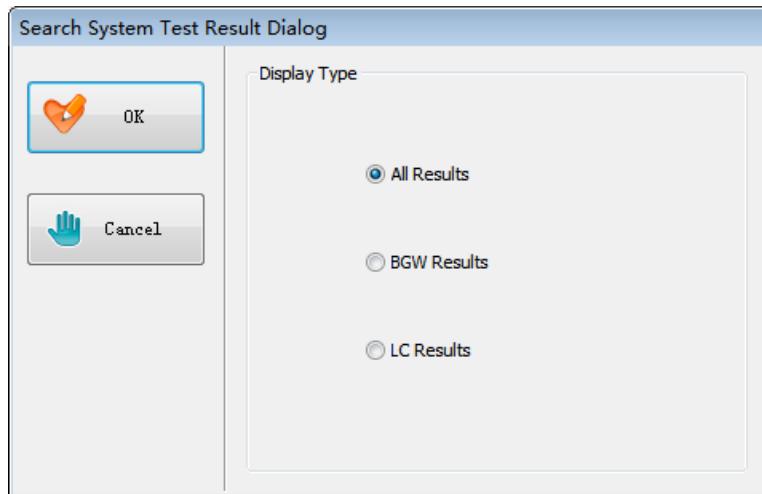


Figure 12.6-2 [Search System Test Result Dialog]

**<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 Maglumi 2000 Service software.

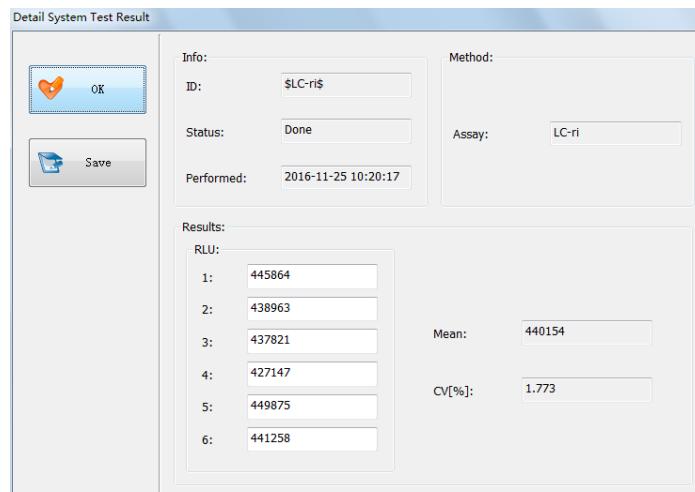


Figure 12.6-3 [Detailed System Test Result] Dialog

**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;

**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.

Sample ID	Name	Patient ID
2	Pa:	
1	Pa:	

Assay	Result
TSH	1.4
T4	82
FT4	11.9
T3	1.69
FT3	2.21

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]**.

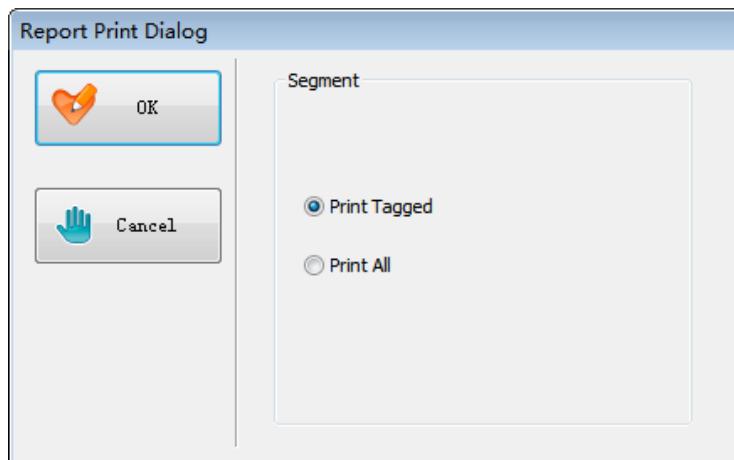


Figure 12.7-4 [Report Print Dialog]

**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.

A screenshot of a search dialog window. On the left, there is a "Search Condition" panel with fields for Patient No., Dept. No., Doctor, From (date: 2010-02-02), To (date: 2016-06-06), Patient Name, and Sample ID. Below these are three buttons: "Search" (with a magnifying glass icon), "Preview" (with a document icon), and "Print" (with a printer icon). On the right, there are two tables. The top table shows a list of samples with columns: Sample ID (23, 24, 25, 26, 27, 28, 29), Name (empty), Patient ID (Pa:), Sex (empty), and Age (-1Y/0). The bottom table shows assay details with columns: Assay Name (empty), Abbr (empty), Value (empty), Unit (empty), and Range (empty).

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; |

### 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; select the Year of QC, Month of QC, QC Assay and QC Materials; the trend of control result change will be shown in the form of curve in the middle of the dialog box. The QC test time and the corresponding test result will be shown at the lower left corner; the assessment result will be shown at the lower right corner.

Data about control result come from validated control result in [Journal] dialog box. Info about QC materials is defined in [QC Definition] dialog box under the [Definitions] menu.

- |          |  |
|----------|--|
| <Save>   | Save input data.   |
| <Add>    | Add a control result for the QC material selected;   |
| <Delete> | Select a control result to be deleted; click <Delete> to finish deleting the control result. |
| <Print>  | Print the control result and curve.  |

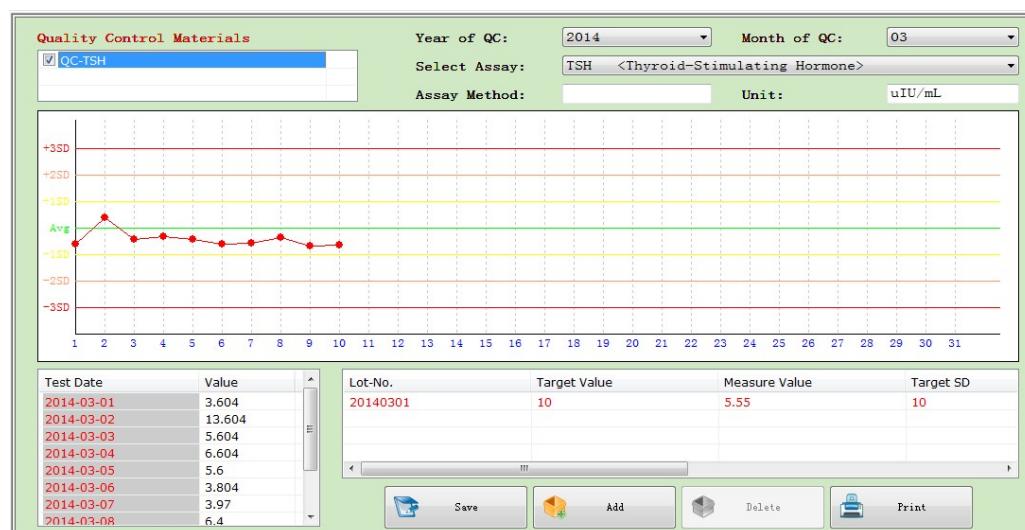


Figure 1 2.7-6 [QC] Dialog

### 12.7.4 <Dictionary>

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

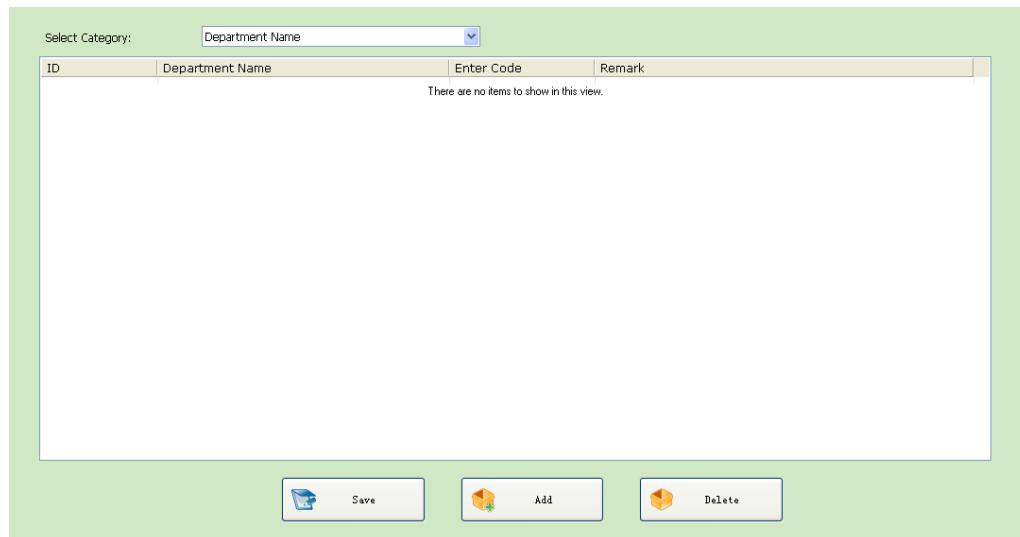


Figure 12.7-7 [**Dictionary**] Dialog

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.

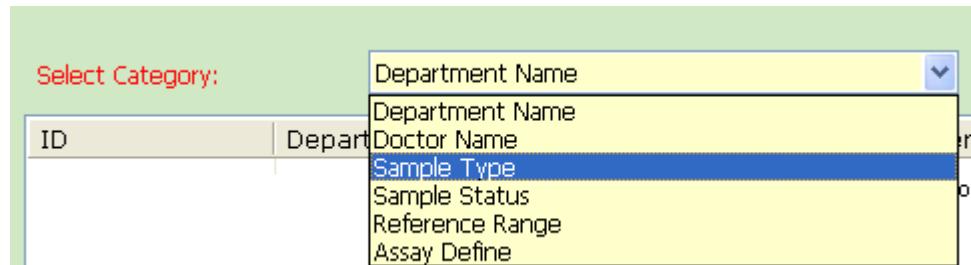


Figure 12.6-8 [**Select Category**] Drop-down Menu

- <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.

ID	Age Range	Lower Bound	Upper Bound	Remark
1	Adult Male	0.658	4.864	

Fi

gure 12.7-9 [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", after entry, 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 12.7-10 [Setting] Dialog

<b>Paper Size</b>	Set the size of paper used in the printer; options include A4 Paper, B5 Paper, and User-defined Paper.
<b>Paper Width, Paper High</b>	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).
<b>Upper, Bottom, Left and Right Margins</b>	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).
<b>Print Mode</b>	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.
<b>Change Pages</b>	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.
<b>Tester</b>	If Print is selected, the tester name will be printed on the report. If Not Print is selected, the tester name will not appear on the report printed or previewed; in such case, the report to be sent can be confirmed by manual signature.
<b>Verifier</b>	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.
<b>Re-print Tag</b>	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.
<b>Diagnosis</b>	If Print is selected, diagnosis will appear at the header of the report printed or previewed; otherwise it will not appear on the report.
<b>Histogram</b>	For a test report containing any histogram, users can select to

<b>Location</b>	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.
<b>Report Title</b>	Words describing the report content, such as "Biochemical Test Report" and "Immunoquantitation Report"; the title is shown after the Name of Hospital.
<b>Remark</b>	Detailed content after <b>[Remark]</b> in the report; for example, "This report is responsible only for this sample"
<b>Remark Font and Font Size</b>	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.
<b>Name of Hospital</b>	Name of the user organization, for example, "XX People's Hospital", which will be displayed at the title of report.
<b>Row Space of Details</b>	Row space of assay details in the report (unit: mm).
<b>Details Font and Font Size</b>	Font and font size of assay details to be printed.
<b>Title Font and Font Size</b>	Font and font size of the title of report to be printed.
<b>Header Font and Font Size</b>	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.
<b>Content Font and Font Size</b>	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

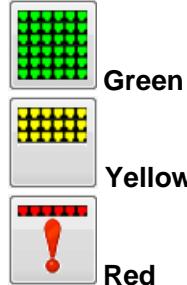
Software interface at the bottom of the status bar has three buttons to display the status

information of the analyzer. They are **<Reservoir>** button (  ) , **<Temp/Volt>** button (  ) , **<Waste>** button (  ) .

### 13.1.1 Consumables

**<Reservoir>** button is used to show whether there are sufficient cuvettes, system liquid and starter 1+2.

The status of **<Reservoir>** button means:



All consumables are sufficient.

One or more consumables are not sufficient.

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

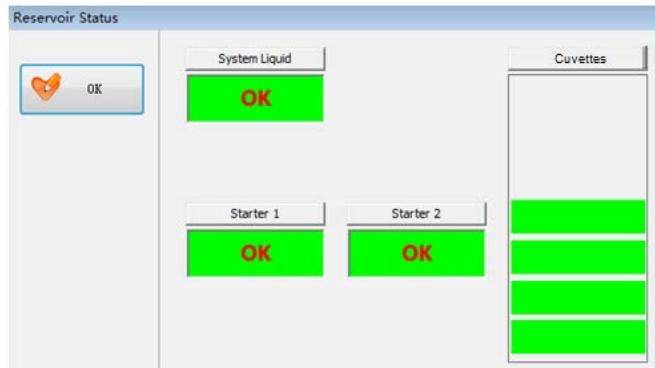


Figure 13.1-2 [Reservoir Status] Dialog

### 13.1.1.1 Cuvettes

Layer graph is used to represent the number of cuvettes in the stacker.



#### WARNING

Please confirm that there are sufficient cuvettes in the stacker before running the analyzer! When there are less than 4 cuvettes bars in the stacker, the analyzer will report an error and shut down.

Green	Number of cuvettes bars > 17.
Yellow	4 ≤ Number of cuvettes bars ≤ 17. At this moment, a warning prompt " <b>Running out of cuvettes soon!</b> " will appear, and an alarm sound will be given.
Red	Number of cuvettes bars < 4. At this moment, a warning prompt " <b>Run out of cuvettes!</b> " 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) System liquid must be prepared and standing 6 hours prior to use. 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



Volume of starter 1+2 ≥ 20%.

Volume of starter 1+2 < 20%.

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.

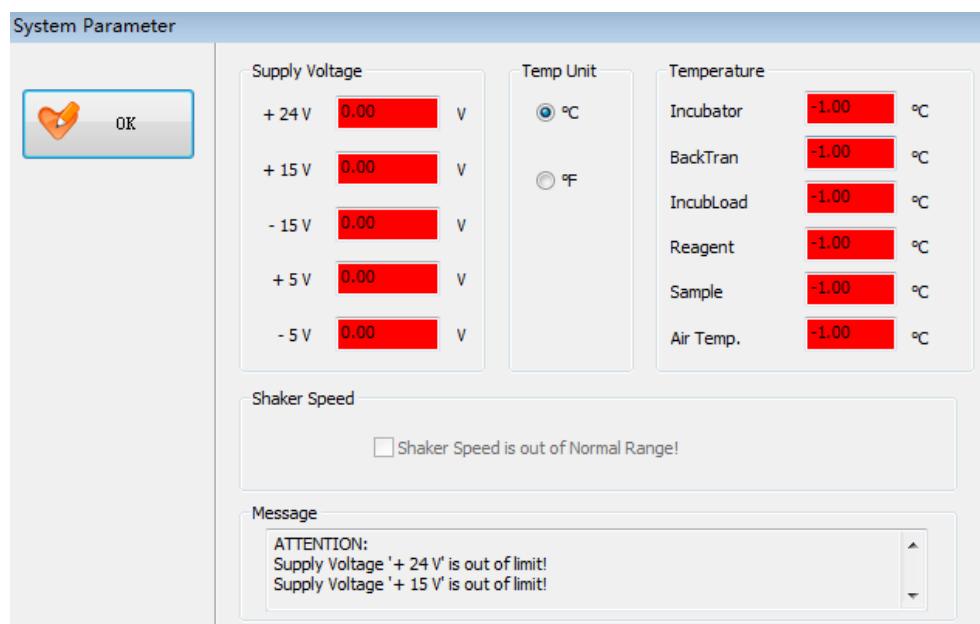


Figure 13.1-3 [System Parameter] Dialog

### 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.

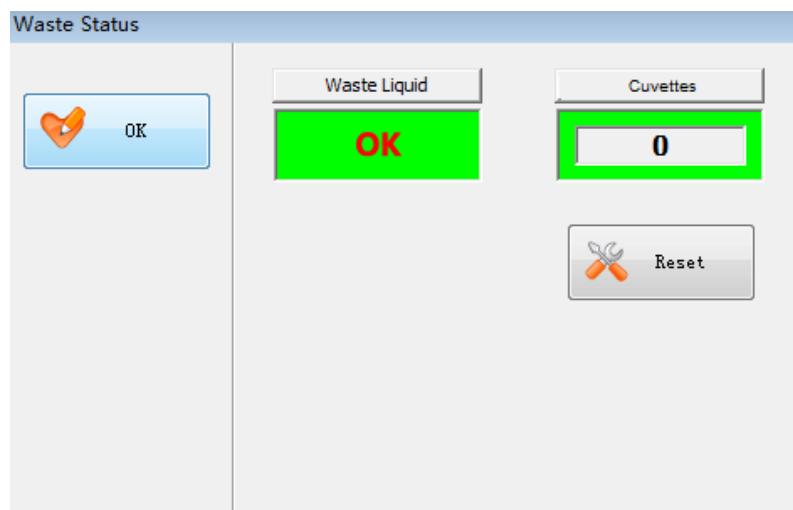


Figure 13.1-4 [Waste Status] Dialog

#### 13.1.3.1 Waste Liquid

Different volume of waste liquid show by following icon



Volume of liquid in the waste liquid tank $\leq$  80%.



Volume of liquid in the waste liquid tank reaches 80-90%.



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**  $60 \leq$  Number of waste cuvettes bars  $<$  80.

**Red** Number of waste cuvettes bars  $\geq$  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 stacker component need initialize).

### 13.2.1 Placing Cuvette

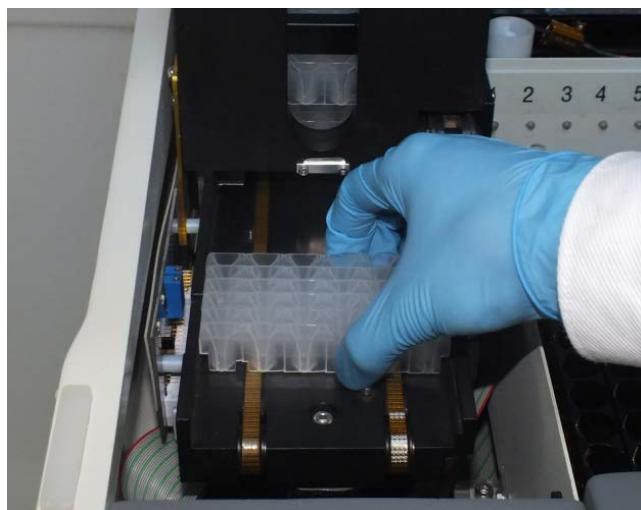


Figure 13.2-1 Placing Cuvette

#### 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 into the stacker.
4. When the conveyor belt stops, users can continue adding cuvettes.
5. Repeat the above steps until the stacker becomes full; the stacker can hold 110 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 stacker should be emptied once a week to ensure cleanliness 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 (2) 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 on the right side of the analyzer. 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. Fill the hoses: Select **<System Test>** on the menu bar, and select chamber in the **[System Test]** dialog. Enter (3) in corresponding cycles, and click **<OK>** to start priming.

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

6. Background test: Select <System Test> on the menu bar. Change (1) preset in the BGW, Lc-le and Lc-ri area 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 two waste liquid ports used for waste liquid are positioned on the right side of the analyzer, which are marked "Waste Liquid"  and

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:

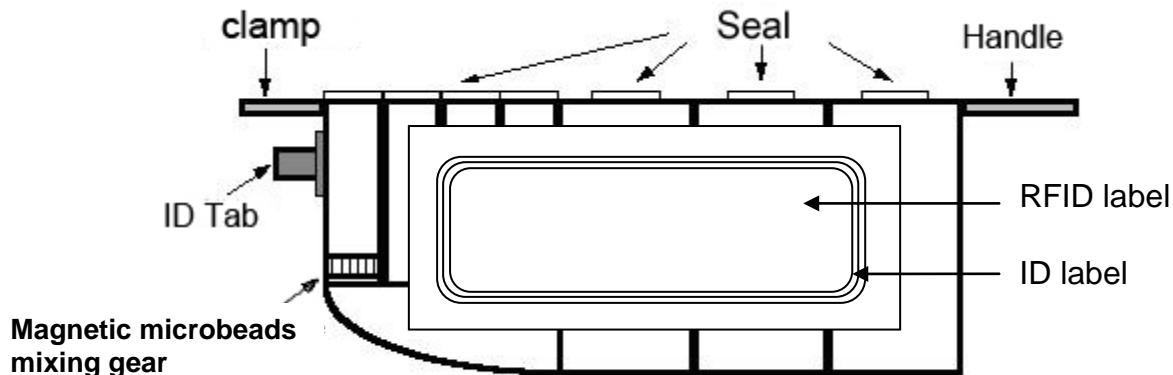


Figure 14.1-1 Reagent Structure

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 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 integral 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 **[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 **[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 **[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. 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**

5. 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.

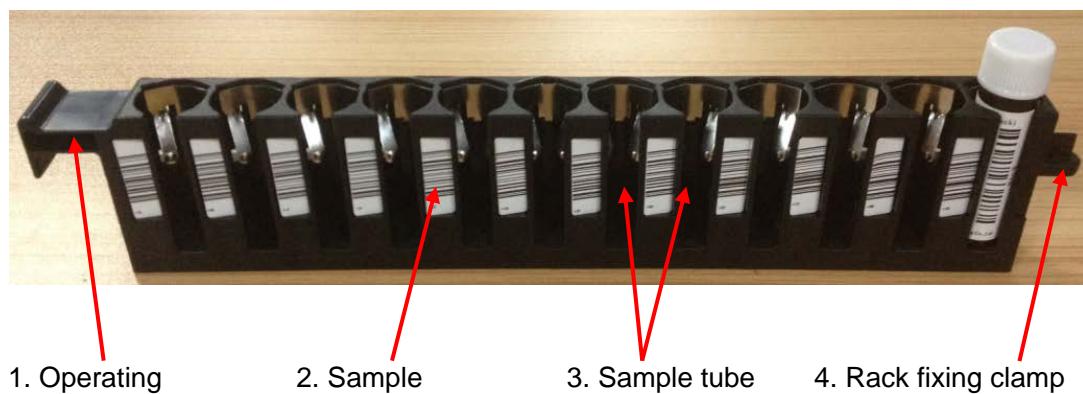


# 15 Sample Loading

## 15.1 Sample Rack

The sample rack specified for the analyzer has 12 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



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 [Patients] interface.

## 15 Sample Loading

---



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.

Sample Info	
From	To
1	12345001
2	12345002
3	
4	
5	12345005
6	12345006
7	12345007
8	12345008
9	12345009
10	12345010
11	12345011
12	12345012

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 " Left/Right Needle can not detect Liquid!, retest should be performed.

The following conditions must be satisfied before measuring sample:

1. Samples include: serum, plasma, urine, cerebrospinal fluid, etc.;
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 rightward so that it can be read by the barcode reader.



Figure 15.2-1 Sample Tubes with Barcode

### NOTE



- 1) Do not revolve a sample tube with barcode in the sample rack to avoid damaging the barcode.
  - 2) After a sample tube is read by the barcode successfully or has been edited manually, it cannot be pulled out and inserted to other slot.
- 

Like 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!
- 

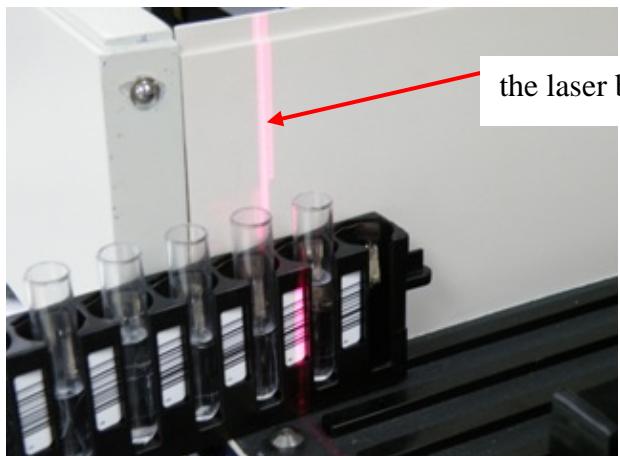


Figure 15.2-2 Barcode Scanning

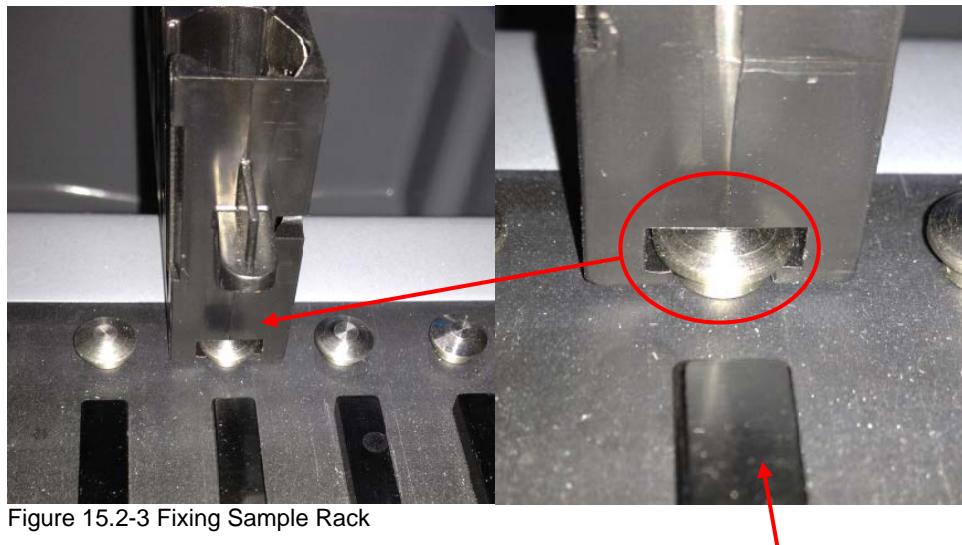


Figure 15.2-3 Fixing Sample Rack

### 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.

## **15 Sample Loading**

---

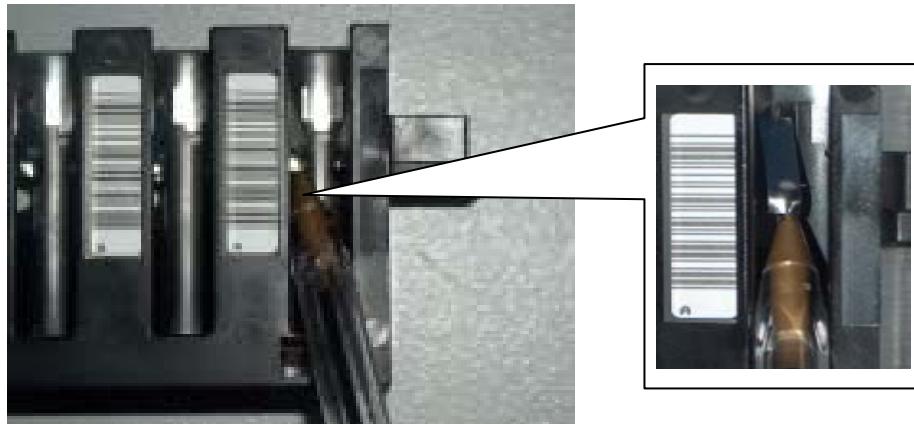


Figure 15.3-1 Adjust the Metal Dome Inside the Slot

# 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 2000 Immunoassay Analyzer operates under different modes. In order to activate the online mode, the user must set up the operating mode first.

Click **<Mode>** button in **[System]** menu to open **[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>** button in **[System]** menu to open **[Online]** interface to set the parameters related to 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

**Current Status**

COM Port Status      Display the status of the COM Port currently used.

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.

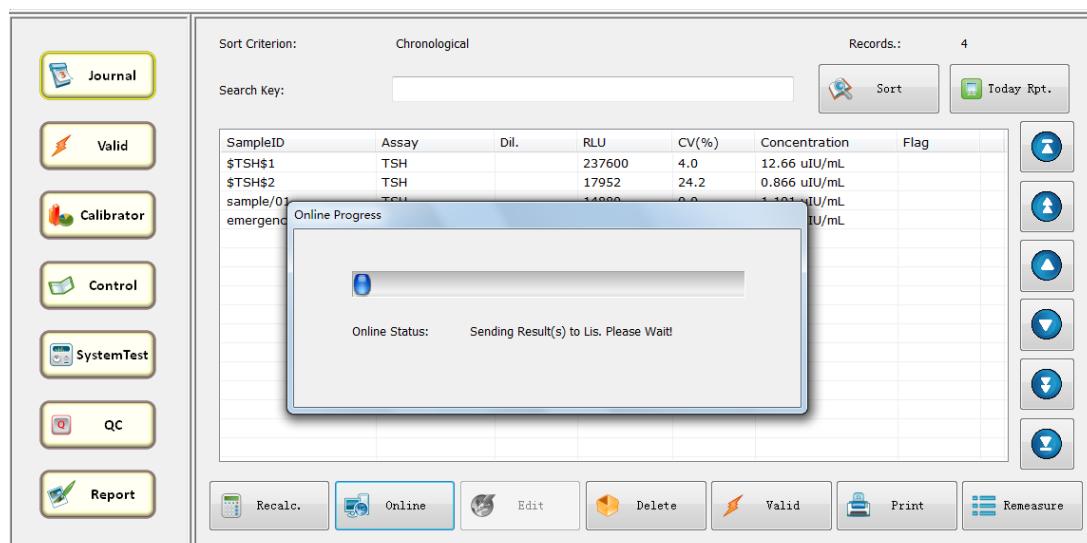


Figure 16.1-3 [Valid] Interface

#### 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.

#### 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 |0.658 to 4.864|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	0.658 to 4.864	30	No
7	10.1.7	Result flag	L,H,N	1	No
13	10.1.13	Test finish time	YYYYMMDDH HMMSS	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 2000||||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 2000||||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 2000||||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 2000||||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 2000||||Lis||P|E1394-97|20100326<CR>
P|1<CR>
O|1|1234567||^\TSH<CR>
R|1|^\TSH|4.3|\muIU/mL|0.658 to 4.864|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 2000||||Lis||P|E1394-97|20100326<CR>
P|1<CR>
O|1|1234567||^\TSH<CR>
R|1|^\TSH|4.3|\muIU/mL|0.658 to 4.864|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. System liquid must be prepared 6 hours prior to use;
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 200-1200, CV ≤ 10%;
  - 2) LC: RLU is 400000-650000, CV ≤ 3%;
  - 3) For two-needles modes: mean difference between LC(ri) and LC(le) ≤ 5%. Please refer to the LC Reagent Manual of the specific expected value.

#### **17.4 Extended Shutdown-System Idle 5 Days or More**

If users don't use the analyzer for 5 or more days, 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].

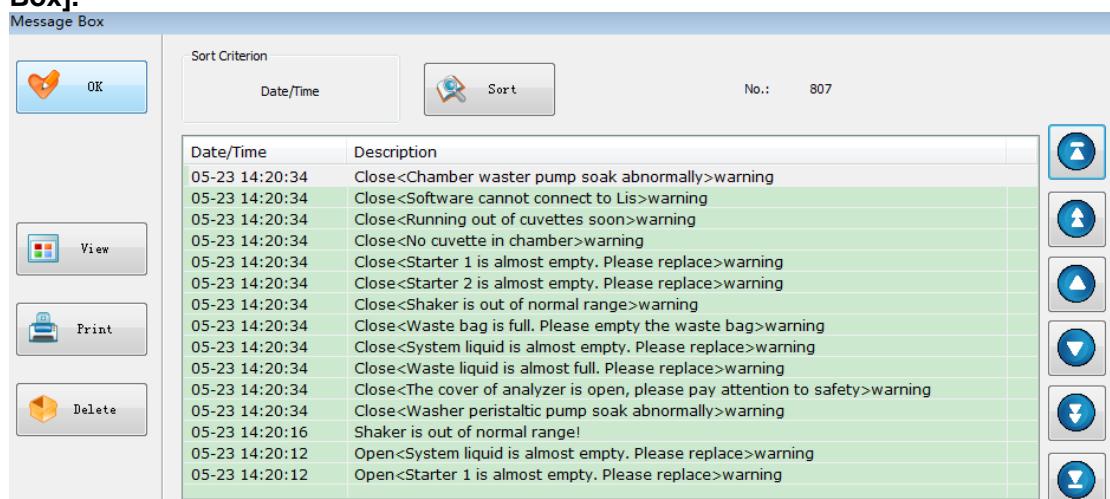


Figure 18.1-1 [Message Box] Dialog for Error Message

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.

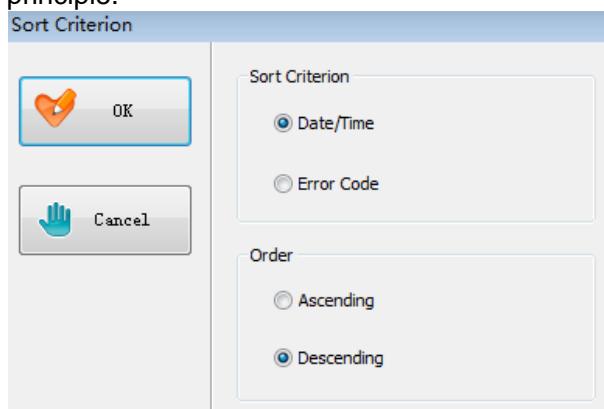


Figure 18.1-2 [Sort Criterion] Dialog  
Sort criterion of error:

- **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.

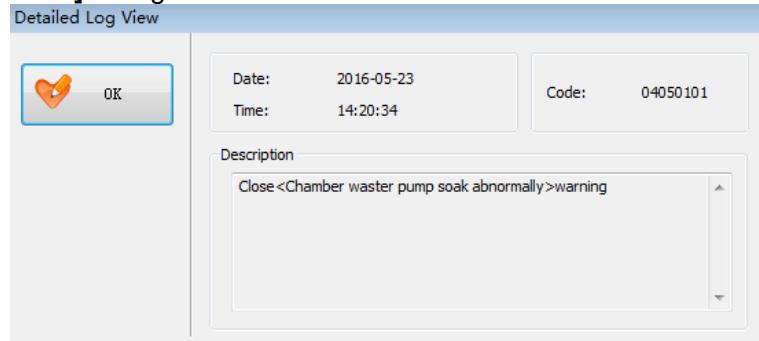


Figure 18.1-3 [Detailed log View] Dialog

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.

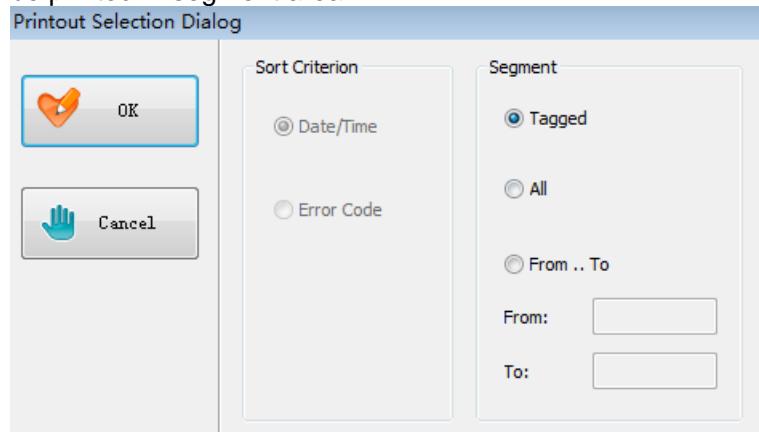


Figure 18.1-4 [Printout Selection Dialog]

**Segment::**

- **Tagged:** The selected errors will be printed;
- **All:** All errors will be printed;
- **From.. To:** Range selection, enter start and end ranges of selected condition. Errors within this range 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.

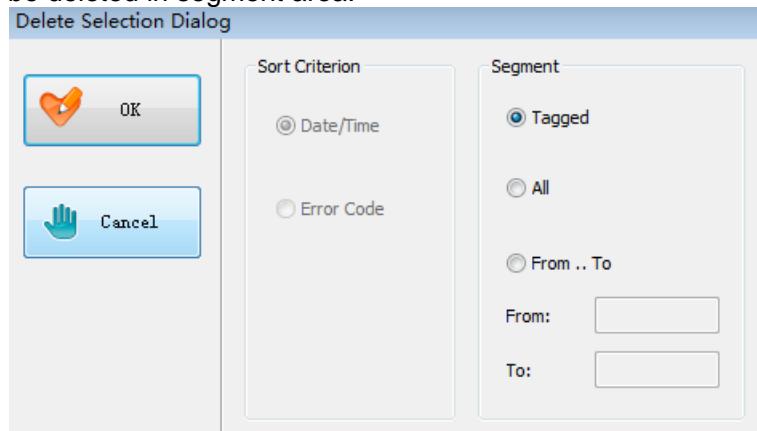


Figure 18.1-5 [Delete Selection Dialog]

#### **Segment::**

- **Tagged:** The selected errors will be printed;
- **All:** All errors will be printed;
- **From.. To:** Range selection, enter start and end ranges of selected condition. Errors within this range 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.

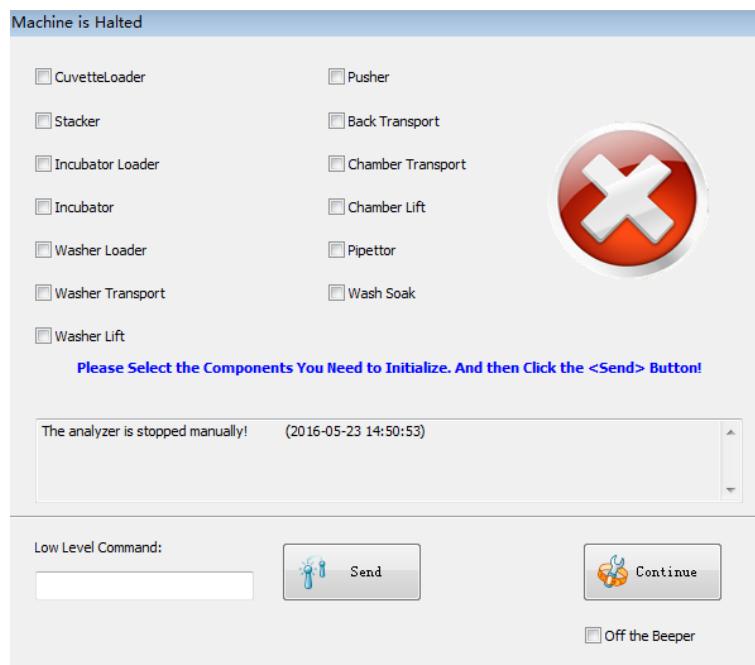


Figure 18.2-1 [Machine is Halted] Dialog

<b>Cuvette Loader</b>	The conveyor that transports the cuvette to the stacker.
<b>Stacker</b>	The stacker holding cuvettes.
<b>Incubator Loader</b>	The loader that transports the cuvette from the stacker to left pipetting position and the incubator.
<b>Incubator</b>	Incubator.
<b>Washer Loader</b>	The loader that transports the cuvette from the incubator to the washer.
<b>Washer Transport</b>	The rack that moves the cuvette in the washer.
<b>Washer Lift</b>	The washing component with injecting needle and aspirating needle for washing the cuvette.
<b>Pusher</b>	The mechanism for transporting the cuvette to the back transport or the chamber.
<b>Back Transport</b>	The mechanism for transporting the cuvette to the right pipetting area.
<b>Chamber Transport</b>	The component that moves the cuvette in the chamber.
<b>Chamber Lift</b>	The mechanism with sprayer and probe in the chamber for injecting starter reagents.
<b>Pipettor</b>	The mechanism for finishing sample and reagent pipetting.
<b>Wash Soak</b>	The peristaltic pump that is connected to washer aspirating needle for extracting liquid in cuvette.
<b>Low-Level Command</b>	The command for controlling motion of singular component.
<b>&lt;Send&gt;</b>	Used for sending Low-Level commands.
<b>&lt;Continue&gt;</b>	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
<b>Abnormal System Test Results: CV and/or RLU out of range</b>	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 $>2\mu\text{s}/\text{cm}$ or not	Clean the wash tank following monthly maintence, apply distilled water with conductivity $<2\mu\text{s}/\text{cm}$ ; 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 dection 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 whlie 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 maintence	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
<b>High CV of light check</b>	Water quality	Check the distilled water conductivity $>2\mu\text{s}/\text{cm}$ or not	Apply distilled water conductivity $<2\mu\text{s}/\text{cm}$
	Abnormal cordination of pipett needle	Check Cordination	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 juction; 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 dection 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 maintence	Check tubing system, if there are dirty or aging	Use Tube cleaning solution to clean tubing system

Problems	Possible Reasons	Self-Check	Solution
<b>Test results with high CV</b>	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 maintence, 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 juction; 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 pipett 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 pipett 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 serum 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 2 $\mu$ s/cm or not.	Clean the System Liquid Tank, dilute system liquid by pure water(<2 $\mu$ s/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
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Problems	Possible Reasons	Self-Check	Solution
Low RLU on sample (even 0)	LLD function abnormal; 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 linear range	None	Dilute
	Wash Concentration expired; storage, the dilute ratio or water improper	Check the Wash Concentration and tank contaminated or not. Check the <i>specific conductance</i> of pure water less than 2 $\mu$ s/cm or not.	Clean the System Liquid Tank, dilute system liquid by pure water(<2 $\mu$ s/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
01010001	Cuvette loader not initialized!	the beeper beeps ,the dialog box <b>[Error Message]</b> is displayed, but the machine is not halted.	The analyzer should be initialized before use, or a belt is broken.	1. Visually inspect whether the belt is broken or dropped. 2. When it returns to normal, select “ <b>Cuvette Loader</b> ” in the dialog box <b>[Machine is Halted]</b> , and then click <Send> and <Continue>.
01020004	Running out of cuvettes soon!	The beeper beeps, the dialog box <b>[Error Message]</b> is displayed, but the machine is not halted.	The stacker is empty or the layer sensor detects no signal.	Please place the cuvette again.
01020005	Run out of cuvettes!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted.	The stacker is empty or the layer sensor detects no signal.	1. Confirm whether the stacker is empty, if so, place cuvettes, otherwise check whether the layer sensor is effective. 2. When it returns to normal, select “ <b>Cuvette Loader</b> ” in the dialog box <b>[Machine is Halted]</b> , and then click <Send> and <Continue>.

Incubator Loader				
Message code	Message Implication	Alarm Method	Cause	Recovery Method
01030001	Incubator loader can not move forward!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	The incubator loader cannot move as a result of mechanical failure, the incubator position is not aligned or the sensor of the incubator loader fails	1. Select “Incubator Loader” or Incubator in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
01030002	Incubator loader can not move back!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	The incubator loader cannot move as a result of mechanical failure, or the sensor of the incubator loader fails.	1. Select “Incubator Loader” in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
01030003	Incubator loader not initialized!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	The incubator loader cannot move as a result of mechanical failure or the machine isn't initialized before operating	1. Select “Incubator Loader” or in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 2. If the problem continues, ask technical staff to inspect mechanical parts and the sensor.
01030004	No cuvette available!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted.	Before the incubator loader loads, it detects there is no cuvette at the outlet.	Check whether there is cuvette in front of the loader and whether the cuvette detection sensor is correctly positioned.
01030005	No cuvette transported!!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	This error will occur in case loading is carried out before the error “there is no cuvette on the incubator loader rail” is solved.	Input cuvette.

Washer Loader				
Message Code	Message Implication	Alarm Method	Cause	Recovery Method
01040001	Washer loader can not move forward!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed 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 incubator loader fails.	1. Select "Washer Loader" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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.
01040002	Washer loader can not move back!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed 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 <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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.
01040003	Washer loader not initialized!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	The machine must be initialized before operating or the washer loader sensor fails.	1. Select "Washer Loader" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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 Loader				
Message Code	Message Implication	Alarm Method	Cause	Recovery Method
02010001	Incubator not initialized!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	A kind of barrier (such as incubator loader) prevents it for moving or the initial position sensor fails..	1. Select "Incubator" or simultaneously select <b>Incubator Loader</b> or <b>Washer Loader</b> in <b>[Machine is Halted]</b> 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.
02010002	Incubator regulation front!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	A kind of barrier (such as incubator loader) prevents it for moving.	1. Select "Incubator" or simultaneously select <b>Incubator Loader</b> or <b>Washer Loader</b> in <b>[Machine is Halted]</b> 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.
02010003	Incubator regulation back!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	A kind of barrier (such as incubator loader) prevents it for moving.	1. Select "Incubator" or simultaneously select <b>Incubator Loader</b> or <b>Washer Loader</b> in <b>[Machine is Halted]</b> 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.
02010004	Incubator can not move front!	The beeper beeps, the dialog box <b>[Machine is Halted]x</b> is displayed and the machine is halted	A kind of barrier (such as incubator loader) prevents it for moving or the encoder fails.	1. Select "Incubator" or simultaneously select <b>Incubator Loader</b> or <b>Washer Loader</b> in <b>[Machine is Halted]</b> 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.
02010005	Incubator can not move back!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	A kind of barrier (such as incubator loader) prevents it for moving or the encoder fails.	1. Select "Incubator" or simultaneously select <b>Incubator Loader</b> or <b>Washer Loader</b> in <b>[Machine is Halted]</b> 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 <b>[Machine is Halted]</b> is displayed 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!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed 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.	<ol style="list-style-type: none"> <li>1. Select “<b>Washer Transport</b>” in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b>.</li> <li>2. If the problem continues, please contact technical service staff to inspect mechanical parts and circuits.</li> </ol>

Washer Lift				
Message Code	Message Implication	Alarm Method	Cause	Recovery Method
03020001	Wash lift not initialized!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	Initial position sensor fails or the friction is large.	Select "Washer Lift" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> .
03020002	Wash lift regulation up!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted.	The friction is large or there is a kind of obstruction.	1. Select "Washer Lift" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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 <b>[Machine is Halted]</b> is displayed and the machine is halted	The friction is large or there is a kind of obstruction.	1. Select "Washer Lift" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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 <b>[Machine is Halted]</b> is displayed and the machine is halted	The friction is large, or it may be caused by encoder failure.	1. Select "Washer Lift" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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 <b>[Machine is Halted]</b> is displayed 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 <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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
02020001	Pusher not initialized!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed 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 <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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.
02020002	Pusher regulation front!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	Pusher block moves slowly. It may be obstructed when it moves.	1. Select "Pusher" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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.
02020003	Pusher regulation back!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed and the machine is halted	Pusher moves slowly. It may be obstructed when it moves.	1. Select "Pusher" in <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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.
02020004	Pusher can not move front!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed 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 <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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.
02020005	Pusher can not move back!	The beeper beeps, the dialog box <b>[Machine is Halted]</b> is displayed 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 <b>[Machine is Halted]</b> dialog box, and then click <b>&lt;Send&gt;</b> and <b>&lt;Continue&gt;</b> . 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.

Back Transport				
Message Code	Message Implication	Alarm Method	Cause	Recovery Method
03030001	Backtransport not initialized!	The beeper beeps, the dialog box [Machine is Halted] is displayed 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 transpor" 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] is displayed 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 transpor" 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] is displayed 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 transpor" 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] is displayed 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] is displayed 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] is displayed 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] is displayed 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 Halted] is displayed and the machine is halted	Downward 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).
04020004	Chamber lift can not move up!	The beeper beeps, the dialog box [Machine is Halted] is displayed 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] is displayed 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	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.

			may be due to failure of encoder.	
04020006	No cuvette in chamber!	The beeper beeps, the dialog box [Error Message] is displayed, 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] is displayed and the machine is halted	It may be because liquid overflow in the chamber resulted in deviation of chamber transport.	Contact technical service staff.

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] is displayed, 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] is displayed, 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] is displayed 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] is displayed 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] is displayed 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] is displayed and the machine is halted		

04040001	Starter 2 inject abnormally. Please shut down the analyzer and check carefully!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted		
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<b>Pipetting Needle System</b>				
<b>Message Code</b>	<b>Message Implication</b>	<b>Alarm Method</b>	<b>Cause</b>	<b>Recovery Method</b>
09010001	Left Needle X direction not initialized!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on X direction is too large.	Contact technical service staff.
09010002	Left Needle can not move left!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on X direction is too large.	Contact technical service staff.
09010003	Left Needle move can not move right!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on X direction is too large.	Contact technical service staff.
09010011	Left Needle Y direction not initialized!	The beeper beeps, the dialog box [Error Message] is displayed, but the machine is not halted.	Resistance on Y direction is too large.	Contact technical service staff.
09010012	Left Needle can not move forward!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on Y direction is too large.	Contact technical service staff.
09010013	Left Needle can not move back!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on Y direction is too large.	Contact technical service staff.
09010021	Left Needle Z direction not initialized!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Operating resistance is too large or it is stuck by debris.	Shut down the analyzer, and manually lift Z-axis to check if it can be lifted. If it still doesn't work, contact technical staff.
09010022	Left Needle can not move up!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Operating resistance is too large or it is stuck by debris.	Shut down the analyzer, and manually lift Z-axis to check if it can be lifted. If it still doesn't work, contact technical staff.
09010023	Left Needle can not move down!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Operating resistance is too large or it is stuck by debris.	Shut down the analyzer, and manually lift Z-axis to check if it can be lifted. If it still doesn't work, contact technical staff.

09010031	Left Needle Inject Pump not initialized!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted		1. Re-initialize the left pipettor; 2. If it cannot be restored or any other fault occurs, please contact technical staff.
09010041	Left Needle can not detect Liquid!	The beeper beeps, the dialog box [ <b>Error Message</b> ] is displayed, but the machine is not halted.		If it cannot be restored or any other fault occurs, please contact technical staff.
09010051	Left Needle detect blood clot.	The beeper beeps, the dialog box [ <b>Error Message</b> ] is displayed, but the machine is not halted.		If it cannot be restored or any other fault occurs, please contact technical staff.
0A010001	Right Needle X direction not initialized!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on X direction is too large.	Contact technical service staff.
0A010002	Right Needle can not move left!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on X direction is too large.	Contact technical service staff.
0A010003	Right Needle move can not move right!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on X direction is too large.	Contact technical service staff.
0A010011	Right Needle Y direction not initialized!	The beeper beeps, the dialog box [ <b>Error Message</b> ] is displayed, but the machine is not halted.	Resistance on Y direction is too large.	Contact technical service staff.
0A010012	Right Needle can not move forward!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on Y direction is too large.	Contact technical service staff.
0A010013	Right Needle can not move back!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Resistance on Y direction is too large.	Contact technical service staff.
0A010021	Right Needle Z direction not initialized!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Operating resistance is too large or it is stuck by debris.	Shut down the analyzer, and manually lift Z-axis to check if it can be lifted. If it still doesn't work, contact technical staff.
0A010022	Right Needle can not move up!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Operating resistance is too large or it is stuck by debris.	Shut down the analyzer, and manually lift Z-axis to check if it can be lifted. If it still doesn't work, contact technical staff.
0A010023	Right Needle can not move down!!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted	Operating resistance is too large or it is stuck by debris.	Shut down the analyzer, and manually lift Z-axis to check if it can be lifted. If it still doesn't work, contact technical staff.

## **18 Troubleshooting and Diagnostics**

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OA010031	Right Needle Inject Pump not initialized!	The beeper beeps, the dialog box [Machine is Halted] is displayed and the machine is halted		1. Re-initialize the left pipettor; 2. If it cannot be restored or any other fault occurs, please contact technical staff.
OA010041	Right Needle can not detect Liquid!	The beeper beeps, the dialog box [ <b>Error Message</b> ] is displayed, but the machine is not halted.		If it cannot be restored or any other fault occurs, please contact technical staff.

# Appendix A Adjust Needles

After the analyzer and the software are installed, the plane position and maximum limit of the left and right pipetting needles shall be calibrated at first.

## A.1 Preparation before Adjusting

Take 2 cuvette bars and fill 100 $\mu$ L water into the positions 1 and 6 of each bar. Place the two cuvette bars onto the first front cuvette position of the left pipetting area and the right pipetting area respectively.

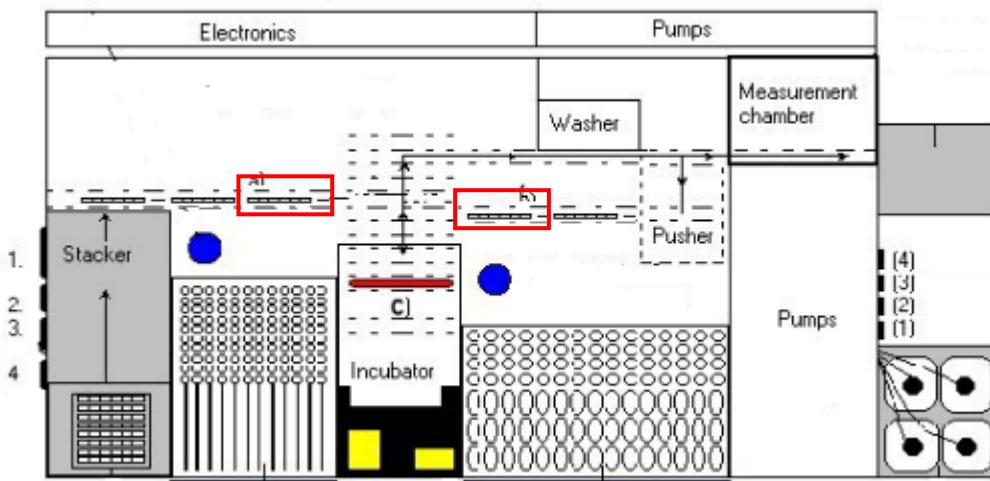


Figure A.1-1 2 cuvette bars place position

Five tubes filled with 100 $\mu$ L of water should be respectively placed at the position 1 and 10 of track1, position 1 and 10 of track11, position 10 of track12.

Take an empty, clean and dry reagent integral and fill 300 $\mu$ L water into its first hole (for magnetic microbeads), fill 300 $\mu$ L water into the second hole (for low calibrator), fill 300 $\mu$ L water into the fourth hole (for displacing reagent), fill 1300 $\mu$ L water into the seventh hole (for buffer), and insert the reagent integral 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 2000 Service]** software.

## Appendix A Needles Adjust

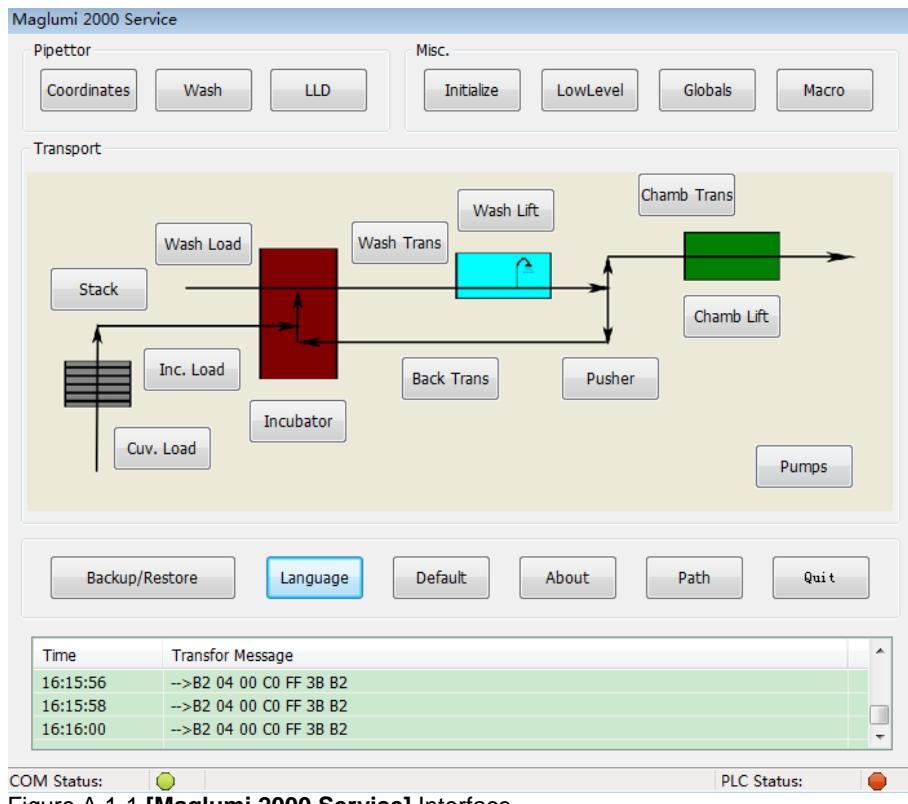


Figure A.1-1 [Maglumi 2000 Service] Interface

1. Click <Initialize> button to initialize the components on the working plane.
2. Click <Incubator> button to display the [Incubator] dialog. Select Inload and click <Return> to return to the [Maglumi 2000 Service] interface.

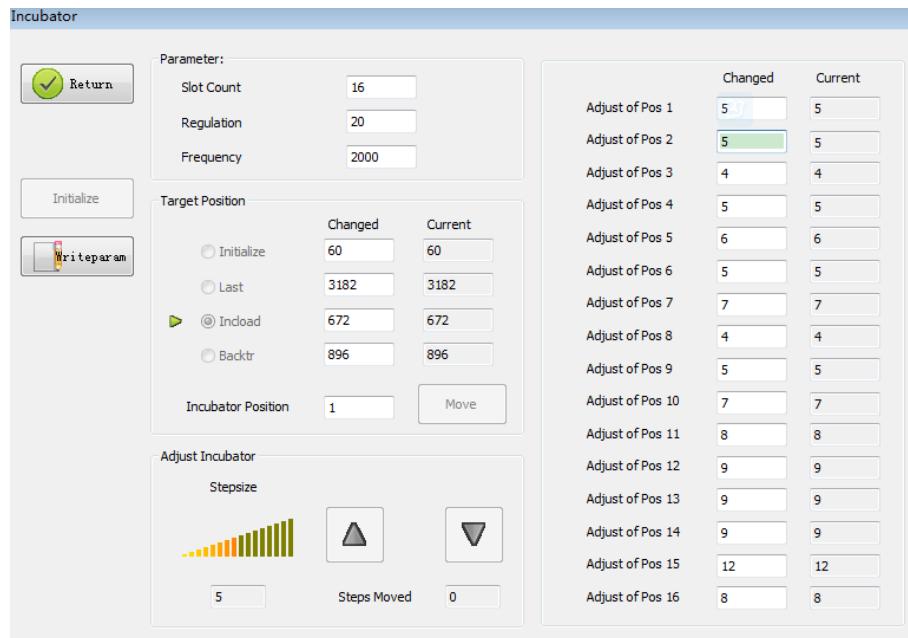


Figure A.1-2 [Incubator] Dialog

3. Click <Inc. Loader> button to display the [Incubator Loader] dialog.

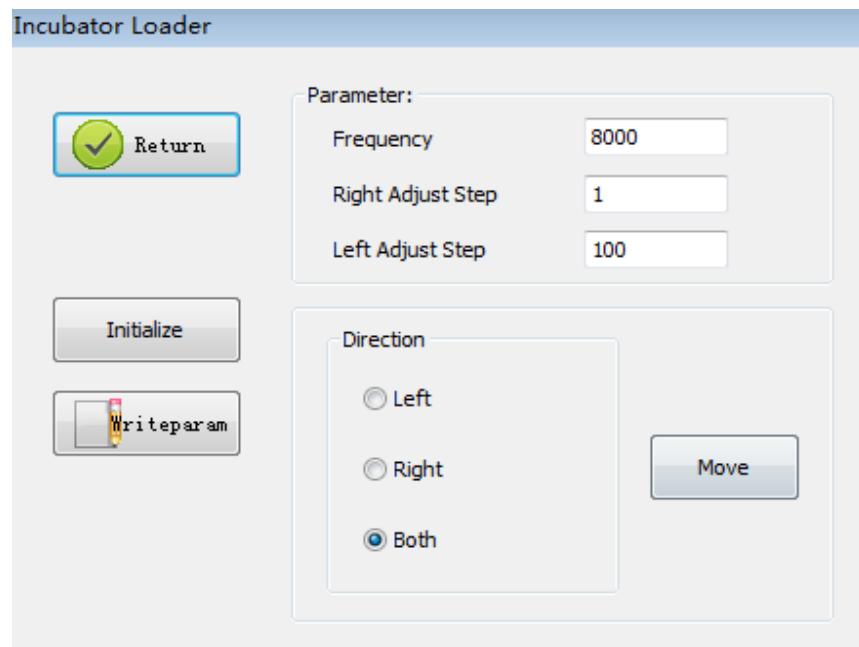


Figure A.1-3 [Incubator Loader] Dialog

4. Click <Move> button to convey a cuvette bar to the left pipetting position and convey another cuvette bar to the pipetting position of the incubator.
5. Click <Return> to return to the [Maglumi 2000 Service] interface.
6. Click <Back Trans> button to open the [Back Transport] dialog.

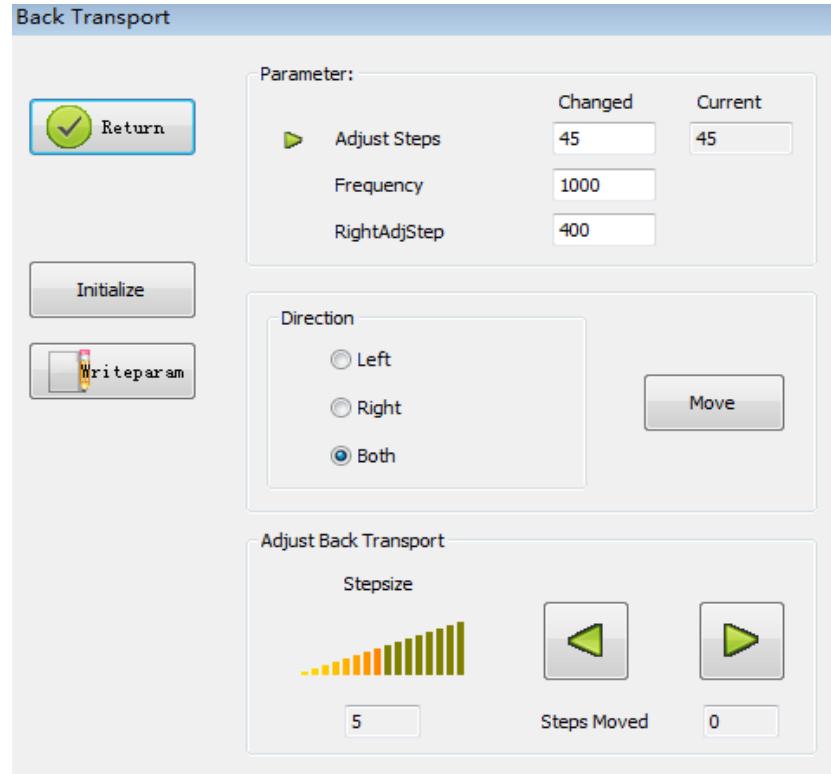


Figure A.1-4 [Back Transport] Dialog

7. Click <Move> button to convey a cuvette bar to the right pipetting position. Click <Return> to return to the [Maglumi 2000 Service] interface.

## A.2 Needles Adjust Program

Click <Coordinates> button on the upper left corner of the [Maglumi 2000 Service] interface to open [Needles Adjust] dialog.

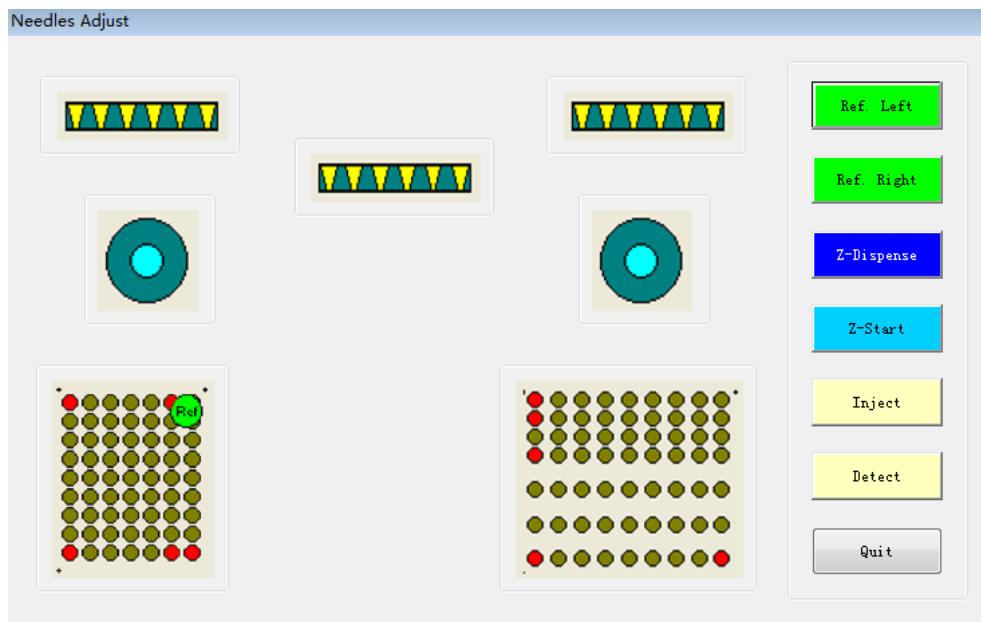


Figure A.2-1 [Needles Adjust] Dialog

Table A.2-2 Shortcut keys for Needles Adjust

Name	Icon	Keyboard shortcut keys
Moves leftwards on X-axis	X-axis fine tuning	←
Moves rightwards on X-axis	X-axis fine tuning	→
Moves forwards on Y-axis	Y-axis fine tuning	↑
Moves backwards on Y-axis	Y-axis fine tuning	↓
Moves upwards on Z-axis	Z-axis fine tuning	Page Up
Moves downwards on Z-axis	Z-axis fine tuning	Page Down
Moves to the middle between the current position and the maximum limit on Z-axis	Shift  Z-Max	Shift on Keyboard + button <Z-Max>

Remark: the directions in the table are based on facing to the analyzer

### A.3 Referential Position Adjust



Figure A.3-1 Referential position adjust tool

#### A.3.1 Left Referential Position Adjust

Click <Ref. Left> button in [Needles Adjust] interface to display [Ref. Left Adjust] dialog.

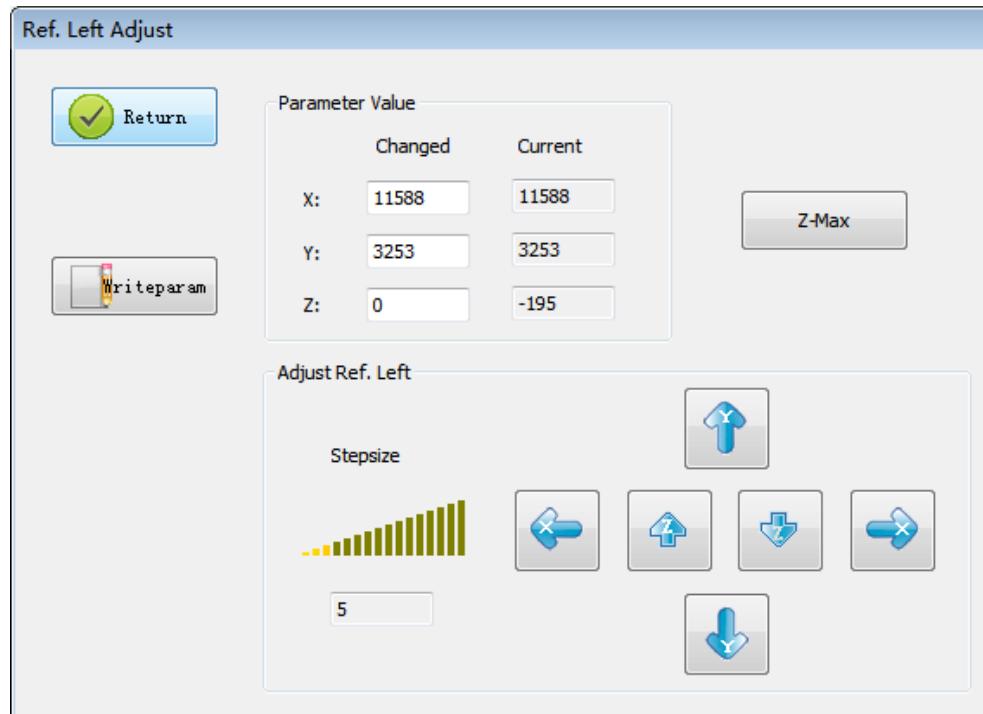


Figure A.3-2 [Ref.Left Adjust] dialog

In **Adjust Ref. Left** area, set the **Stepsize** by changing the number of selected bars. First use a large stepsize to move the pipetting needle to nearby **the top of referential position adjust tool**, and then use a small stepsize 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, and click <**Return**> to exit this interface.

#### Requirements:

- 1) In the top view, the needle point is at the central white point of the referential

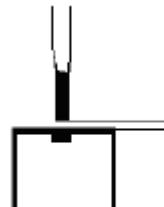
position adjust tool;

Adjust tool



Top view

- 2) In the side view, the needle point is 0.5mm above the central white point of the referential position adjust tool;



Side view

### A.3.2 Right Referential Position Adjust

Click <Ref. Right> button in [Needles Adjust] interface to display [Ref. Right Adjust] dialog.

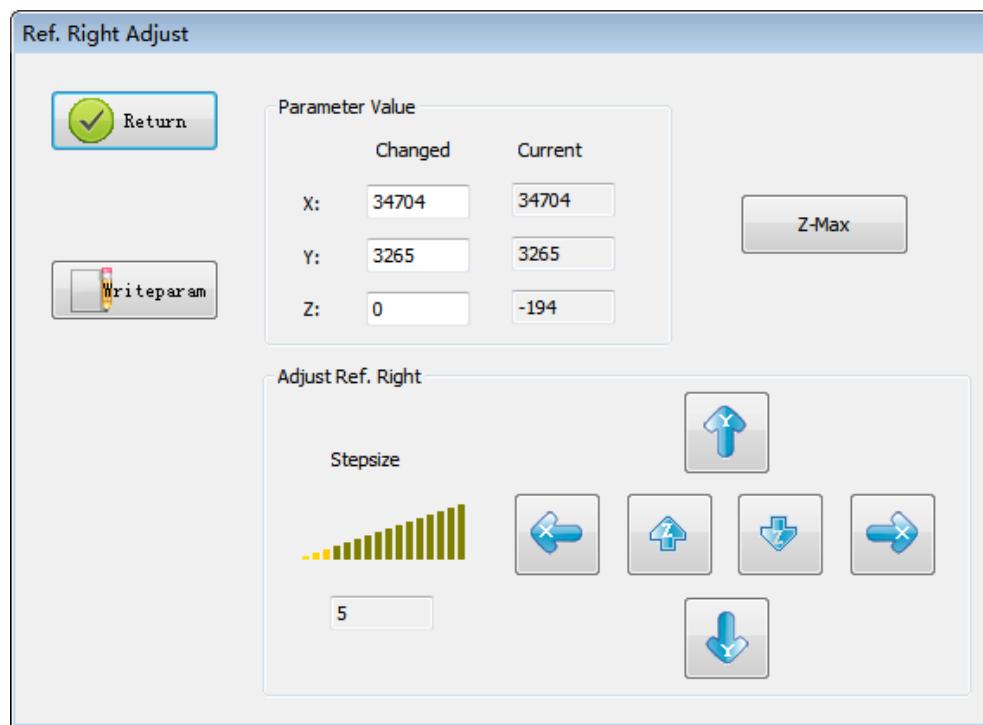
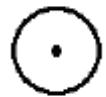


Figure A.3-3 [Ref.Right Adjust] Dialog

In **Adjust Right Ref.** area, set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby **the top of referential position adjust tool**, 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, and click <**Return**> to exit this interface.

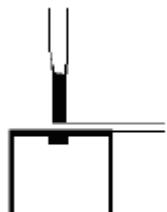
**Requirements:**

- 1) In the top view, the needle point is at the central white point of the referential position adjust tool;  
Adjust tool



Top view

- 2) In the side view, the needle point is 0.5mm above the central white point of the referential position adjust tool;



Side view

#### A.4 Left Pipetting Position Adjust

Click icon on the left of [Needles Adjust] interface to display [Left Pipetting Position Adjust] dialog.

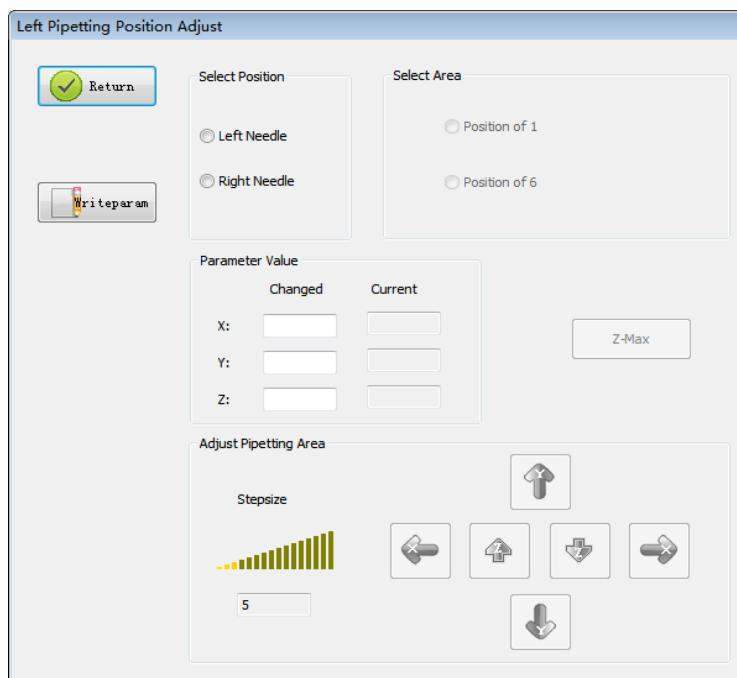


Figure A.4-1 [Left Pipetting Position Adjust] Dialog

##### A.4.1 Left Needle Adjust on Left Pipetting Position

Select Left Needle in **Select Position** area.

1. Select Position of 1 in **Select Area**:

## Appendix A Needles Adjust

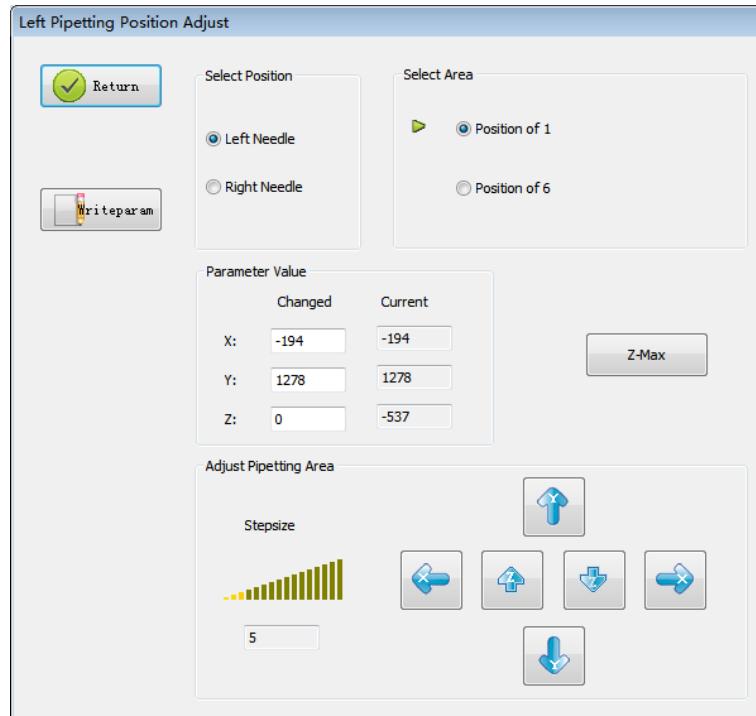
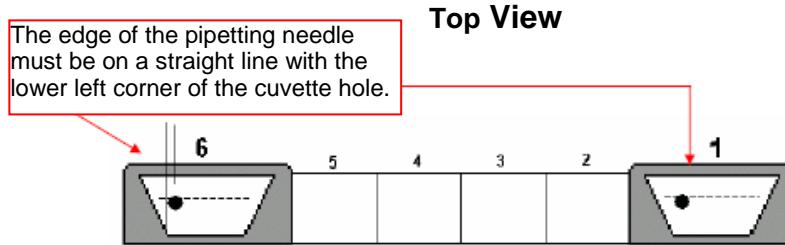


Figure A.4-2 [Left Pipetting Position Adjust] Dialog (Left Needle, Position of 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

2. Select Position of 6 in **Select Area**:

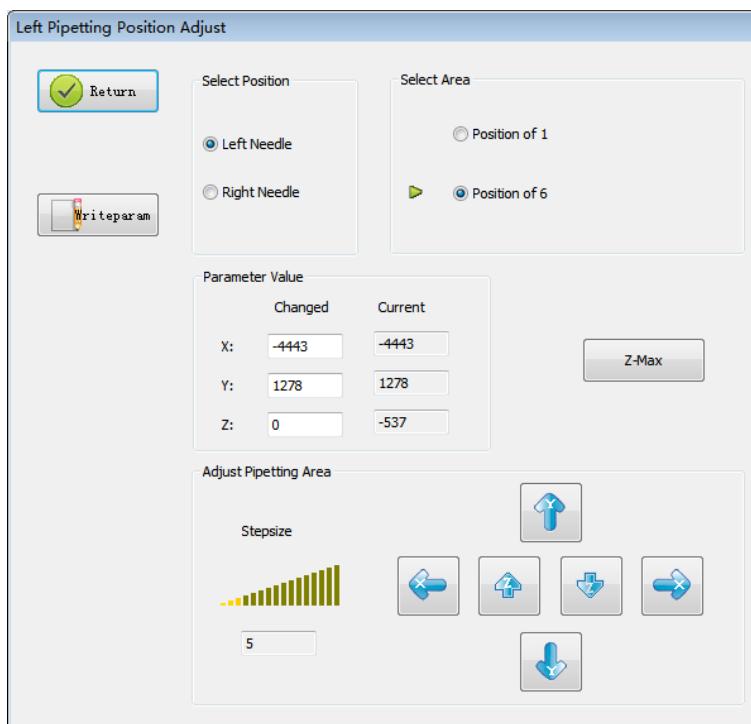


Figure A.4-3 [Left Pipetting Position Adjust] Dialog (Left Needle, Position of 6)

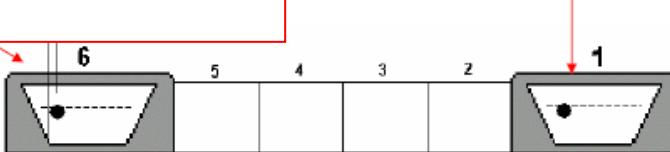
Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the sixth cuvette, and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

**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.

The edge of the pipetting needle  
must be on a straight line with  
the lower left corner of the cuvette hole.

**Top View**



- 2) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### A.4.2 Right Needle Adjust on Left Pipetting Position

Select right needle in **Select Position** area.

#### 1. Select Position of 1 in **Select Area**:

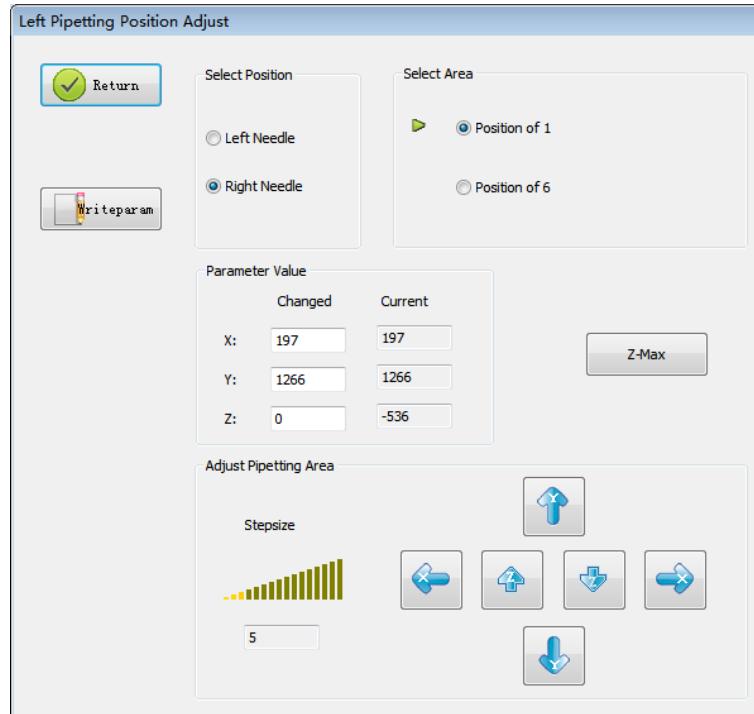
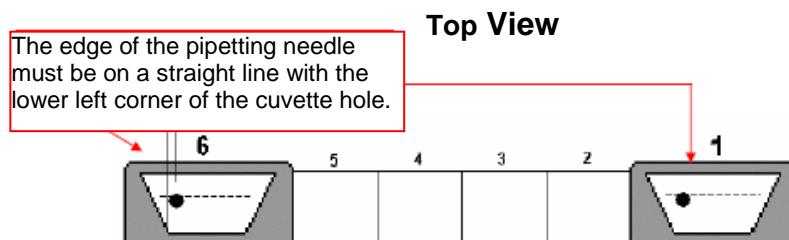


Figure A.4-4 [Left Pipetting Position Adjust] Dialog (Right Needle, Position of 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

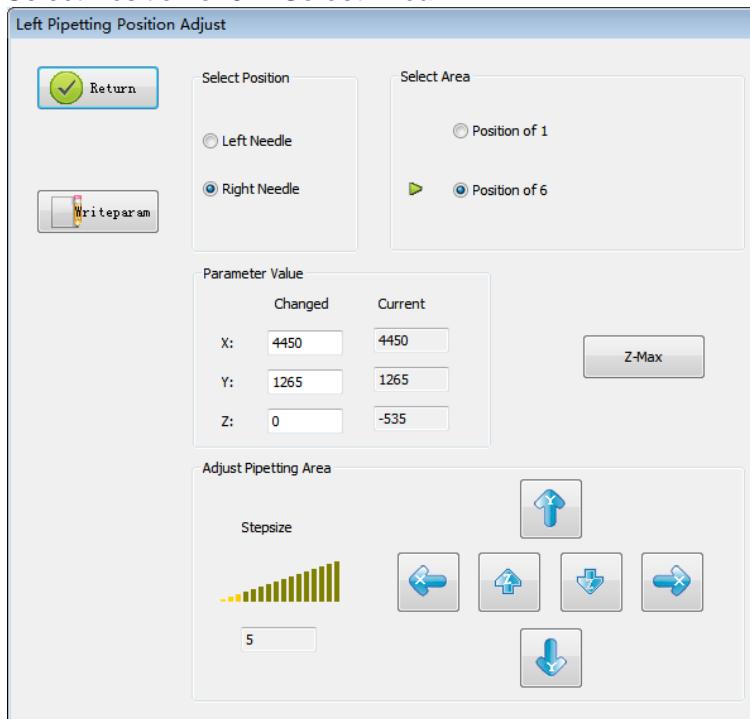
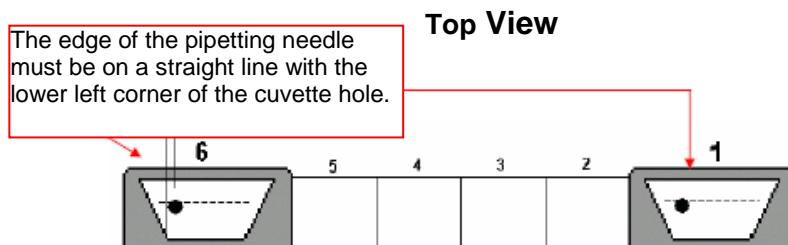
2. Select Position of 6 in **Select Area**:

Figure A.4-5 [Left Pipetting Position Adjust] Dialog (Right Needle, Position of 6)

Move the pipetting needle to nearby the sixth cuvette, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

When right needle adjustment is finished, click <Return> button to return to the **[Needles Adjust]** dialog.

## A.5 Incubator Pipetting Position Adjust

Click  icon in the middle of the [Needles Adjust] dialog to enter [Incubator Position Adjust] dialog .

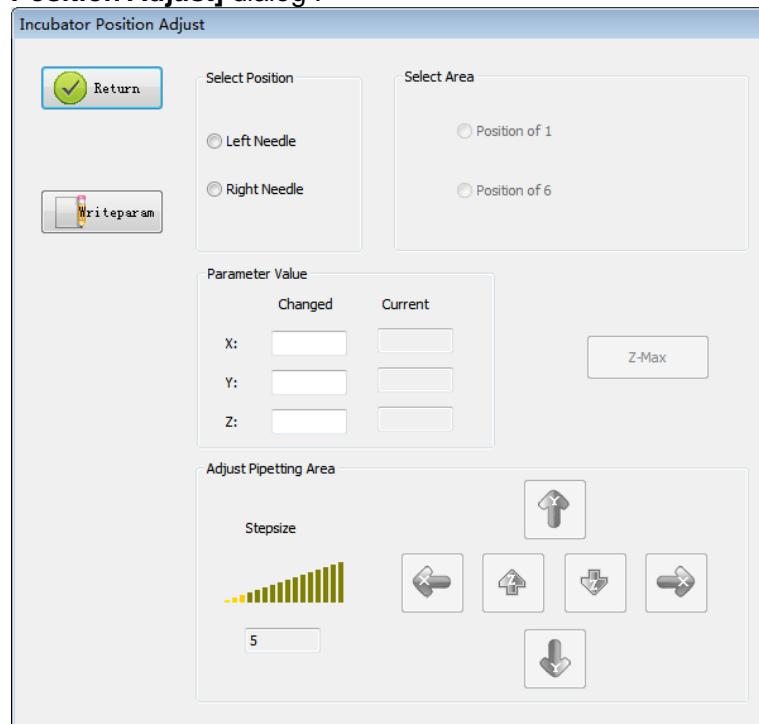


Figure A.5-1 [Incubator Position Adjust] Dialog

### A.5.1 Left Incubator Pipetting Position Adjust

Select left needle in **Select Position** area.

1. Select Position of 1 in **Select Area**:

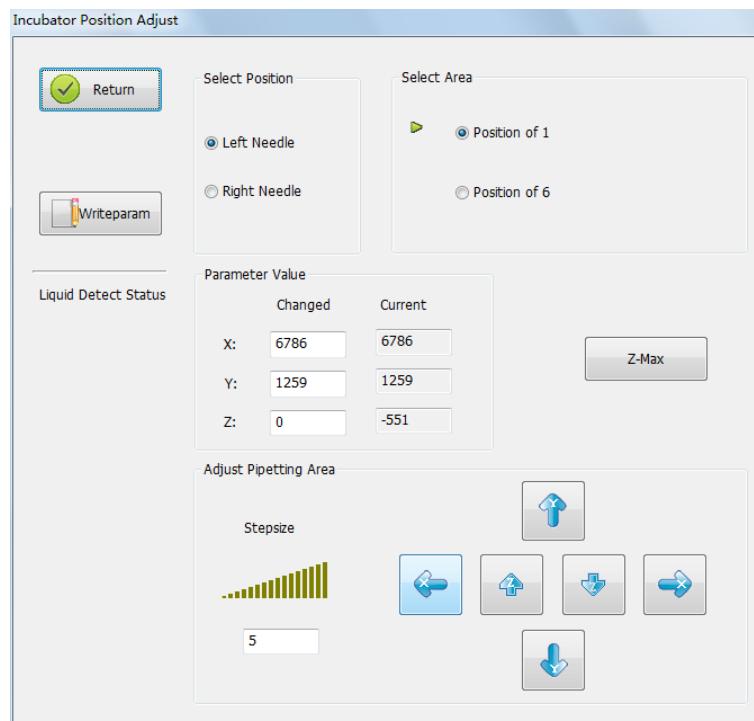
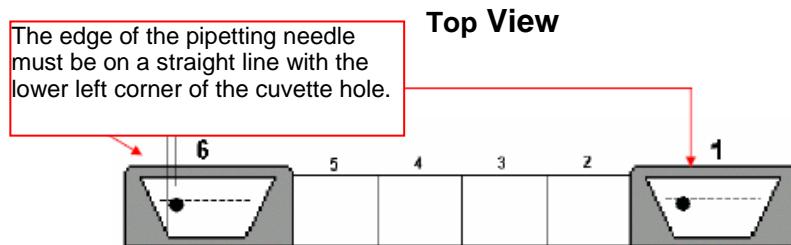


Figure A.5-2 [Incubator Position Adjust] Dialog (Left Needle, Position of 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### 2. Select Position of 6 in **Select Area**:

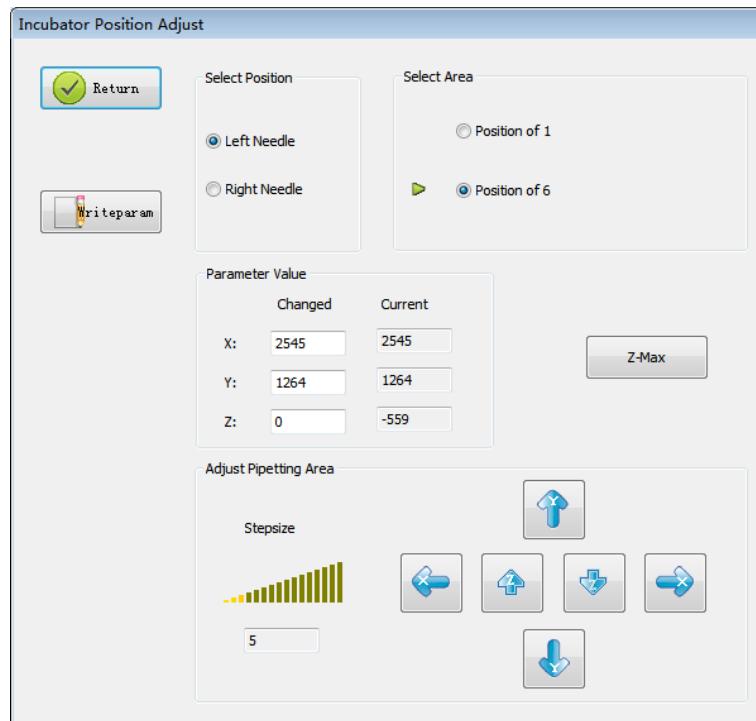
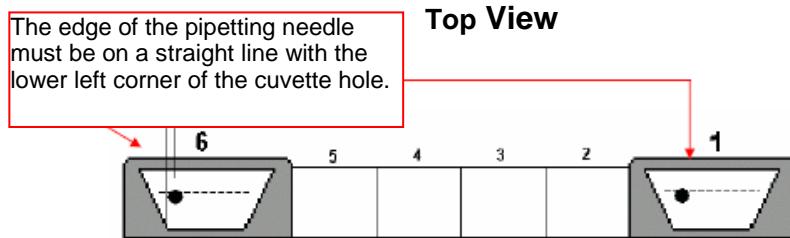


Figure A.5-3 [Incubator Position Adjust] Dialog (Left Needle, Position of 6)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the sixth cuvette, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### A.5.2 Right Incubator Pipetting Position Adjust

Select right needle in **Select Position** area.

1. Select Position of 1 in **Select Area**:

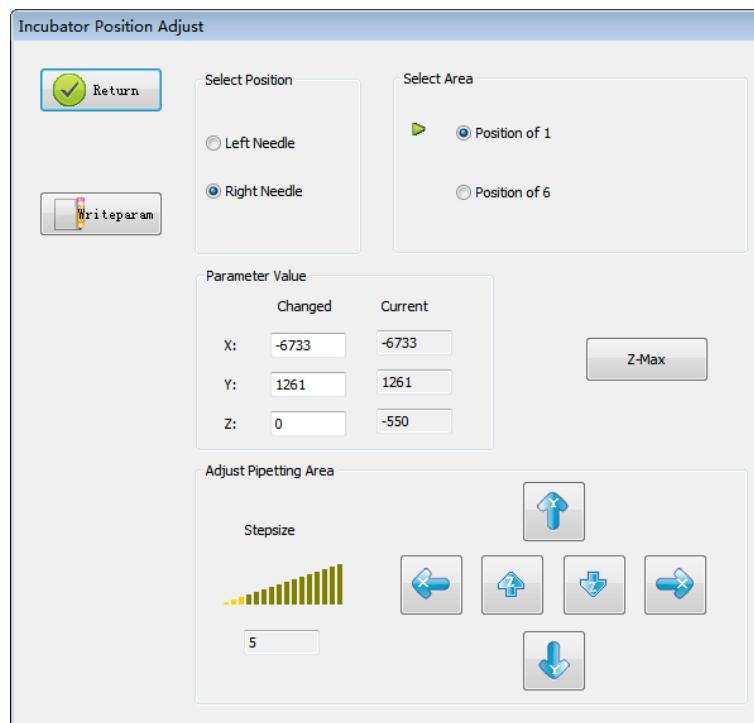
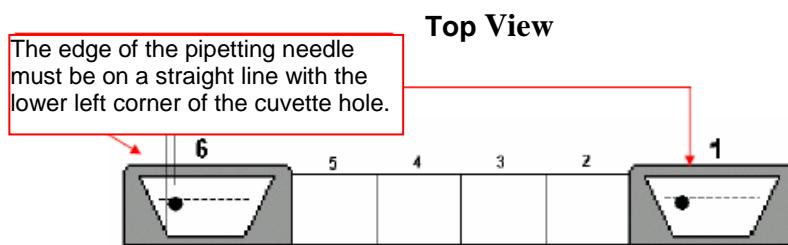


Figure A.5-4 [Incubator Position Adjust] Dialog (Right Needle, Position of 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## Appendix A Needles Adjust

### 2. Select Position of 6 in **Select Area**:

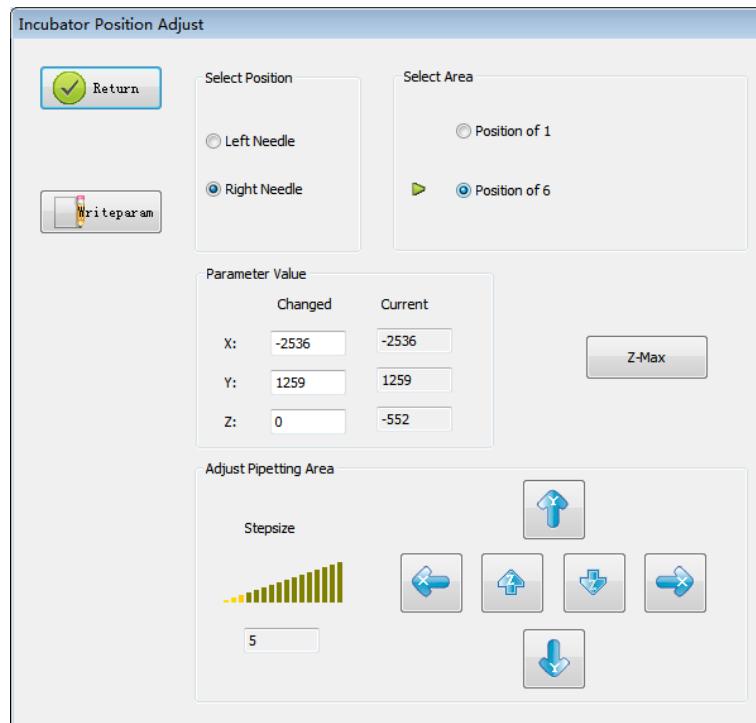
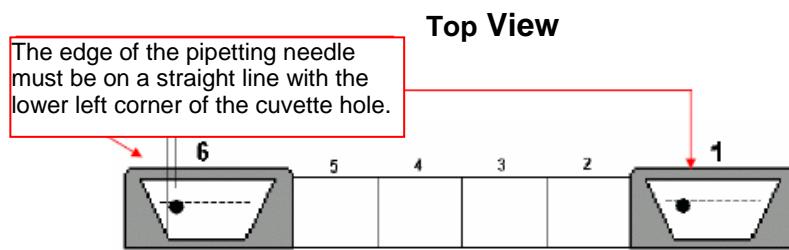


Figure A.5-5 [Incubator Position Adjust] Dialog (Right Needle, Position of 6)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the sixth cuvette, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## A.6 Right Pipetting Position Adjust

Click  icon on the right of the [Needles Adjust] dialog to enter [Right Pipetting Position Adjust] dialog.

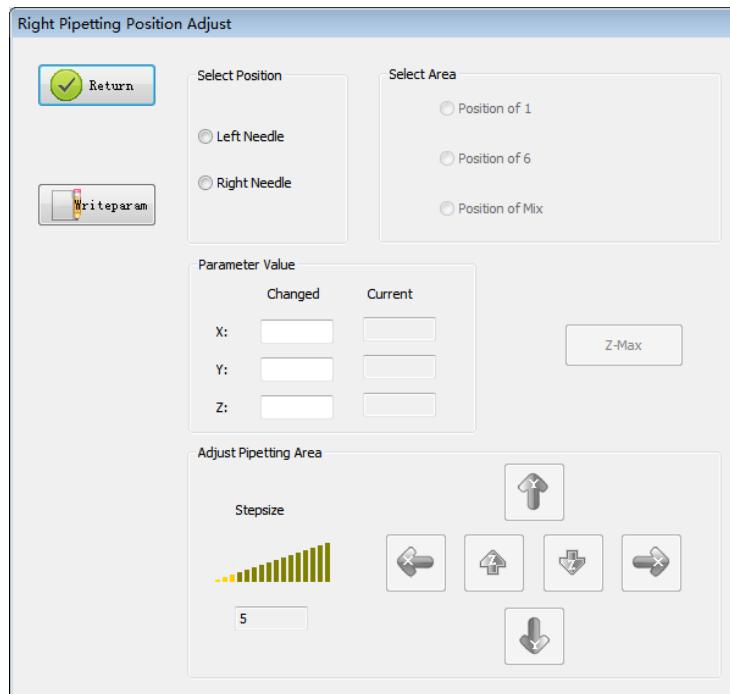


Figure A.6-1 [Right Pipetting Position Adjust] Dialog

### A.6.1 Left Needle Adjust on Right Pipetting Position

Select left needle in **Select Position** area.

#### 1. Select Position of 1 in **Select Area**:

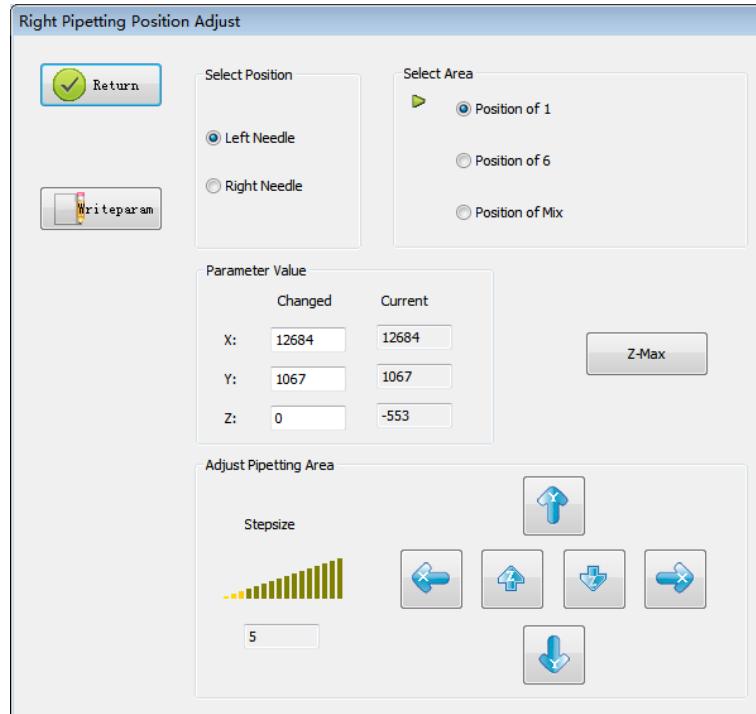


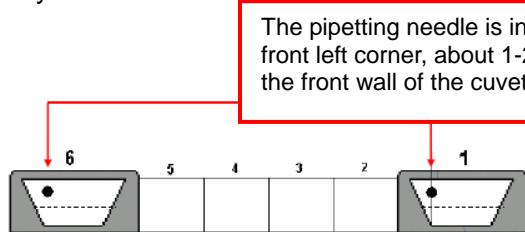
Figure A.6-2 [Left Pipetting Position Adjust] Dialog (Left Needle, Position of 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette, 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 in the center of the front left corner, about 1-2mm away from the front wall of the cuvette:



##### 2) Maximum Limit:

Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

2. Select Position of 6 in **Select Area**:

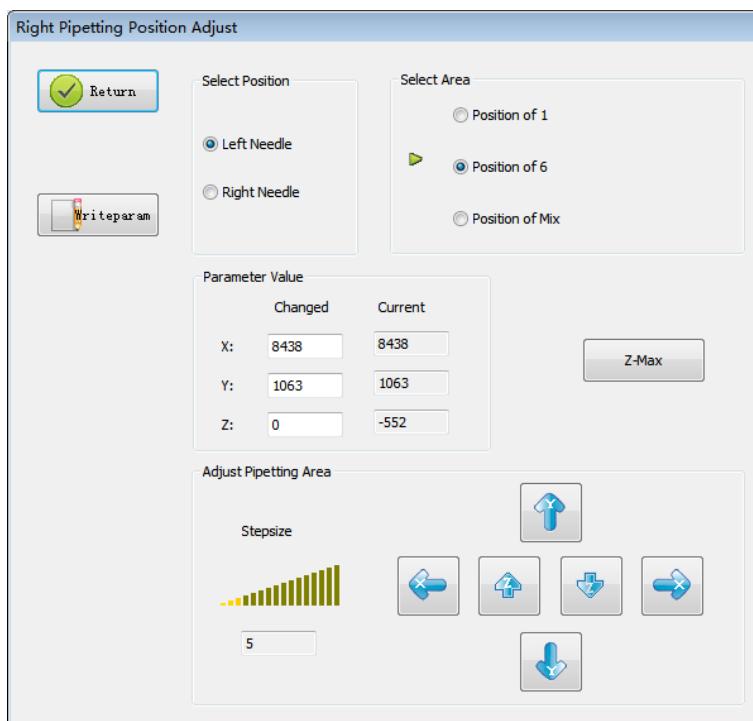


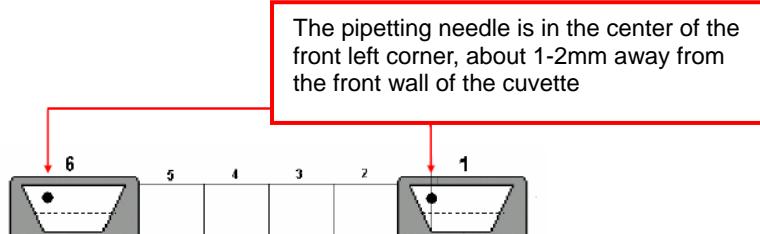
Figure A.6-3 [Left Pipetting Position Adjust] Dialog (Left Needle, Position of 6)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the sixth cuvette, 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 in the center of the front left corner, about 1-2mm away from the front wall of the cuvette;



2) Maximum Limit:

Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### 3. Select Position of Mix in **Select Area**:

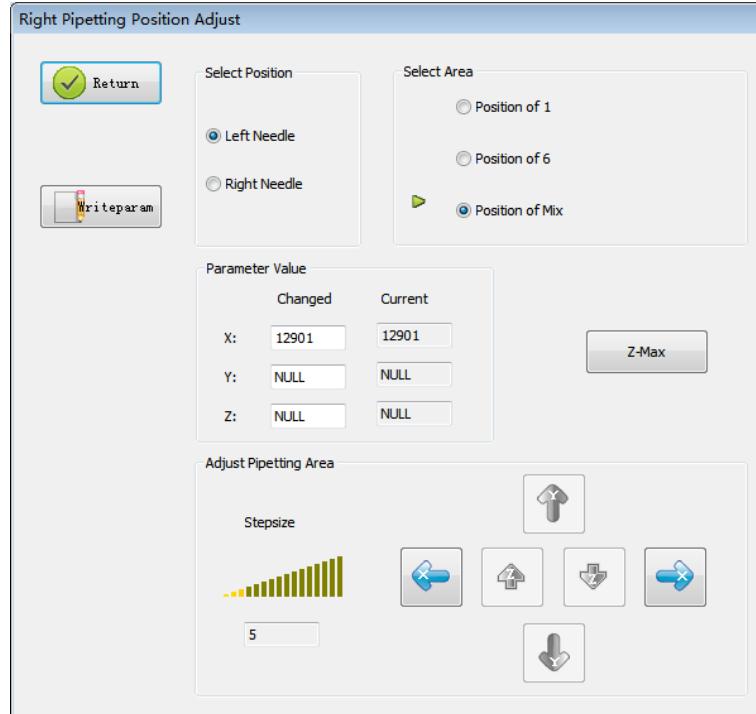
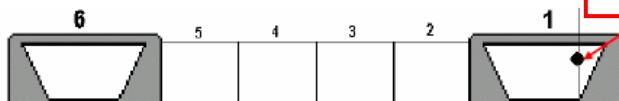


Figure A.6-4 [Left Pipetting Position Adjust] Dialog (Left Needle, Position of Mix)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette on the X-axis, and then use a small step size to fine-tune the needle position on the X-axis until it meets requirements described below.

#### Requirements:

The pipetting needle is in the center of the front right corner of the cuvette.



### A.6.2 Right Needle Adjust on Right Pipetting Position

Select right needle in **Select Position** area.

#### 1. Select Position of 1 in **Select Area**:

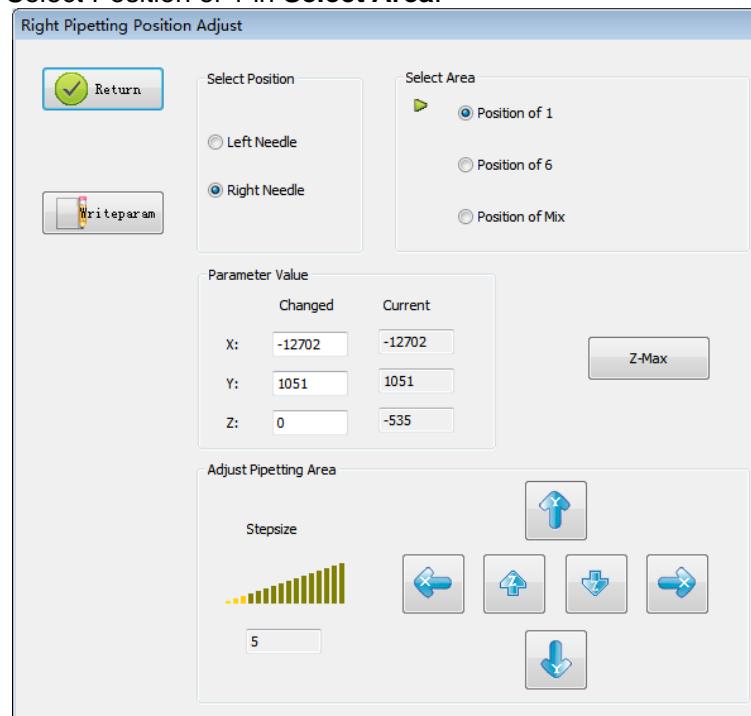


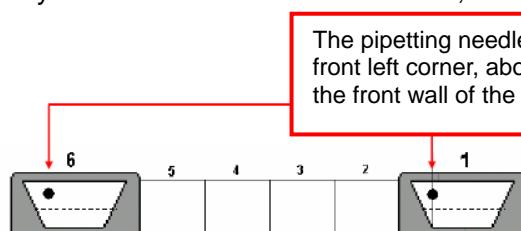
Figure A.6-5 [Right Pipetting Position Adjust] Dialog (Right Needle, Position of 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette, 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 in the center of the front left corner, about 1-2mm away from the front wall of the cuvette;



##### 2) Maximum Limit:

Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## Appendix A Needles Adjust

### 2. Select Position of 6 in **Select Area**:

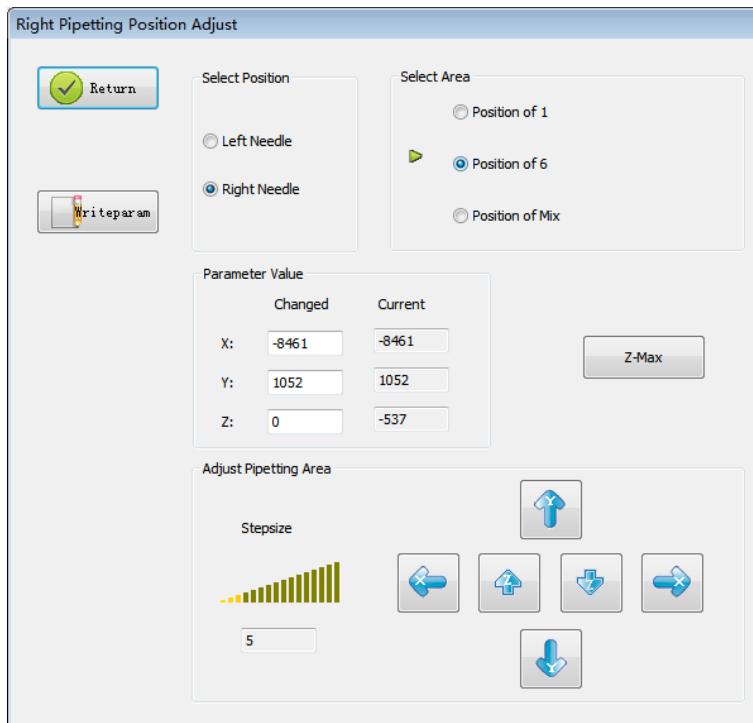
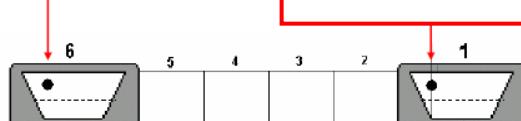


Figure A.6-6 [Right Pipetting Position Adjust] Dialog (Right Needle, Position of 6)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the sixth cuvette, 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 in the center of the front left corner, about 1-2mm away from the front wall of the cuvette;



- 2) Maximum Limit:  
Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

3. Select Position of Mix in **Select Area**:

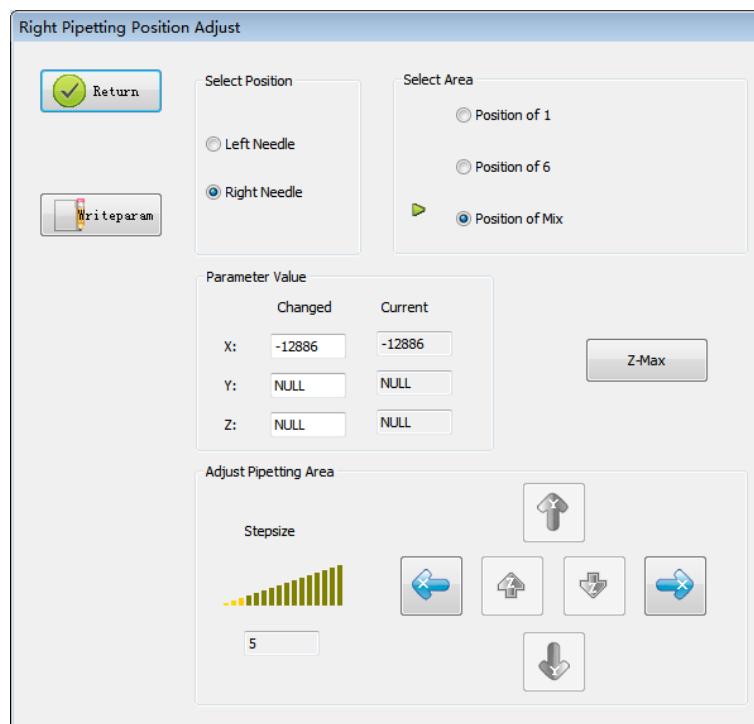
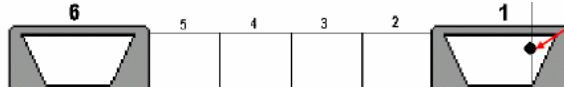


Figure A.6-4 [Right Pipetting Position Adjust] Dialog (Right Needle, Position of Mix)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette on the X-axis, and then use a small step size to fine-tune the needle position on the X-axis until it meets requirements described below.

**Requirements:**

The pipetting needle is in the center of the front right corner of the cuvette.



The pipetting needle is in  
the center of the front right  
corner of the cuvette.

### A.7 Washing Position Adjust

#### A.7.1 Left Washing Position Adjust

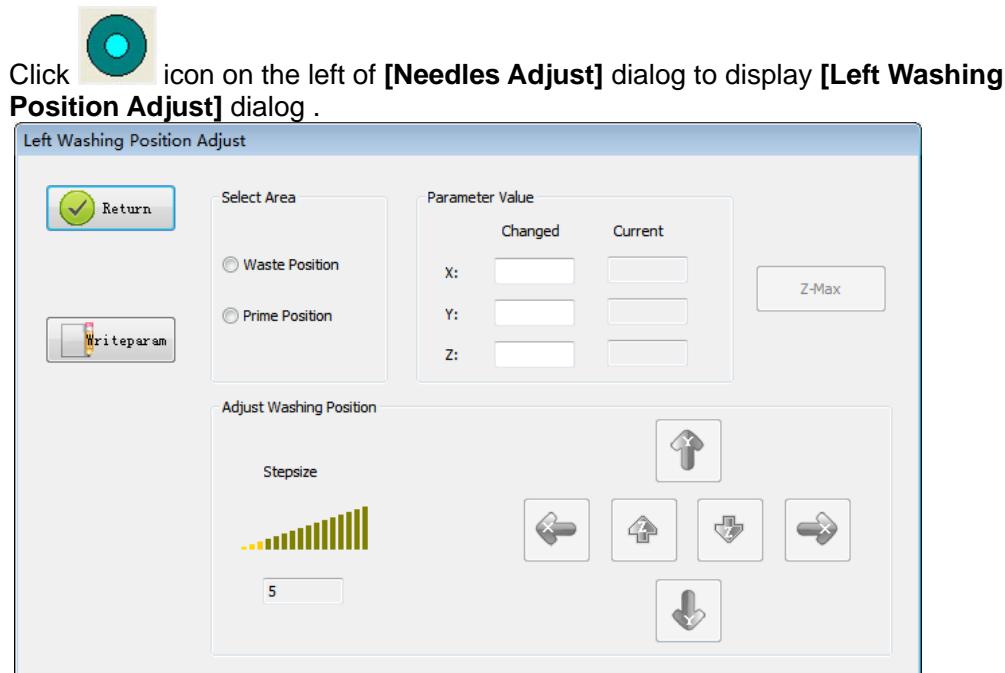
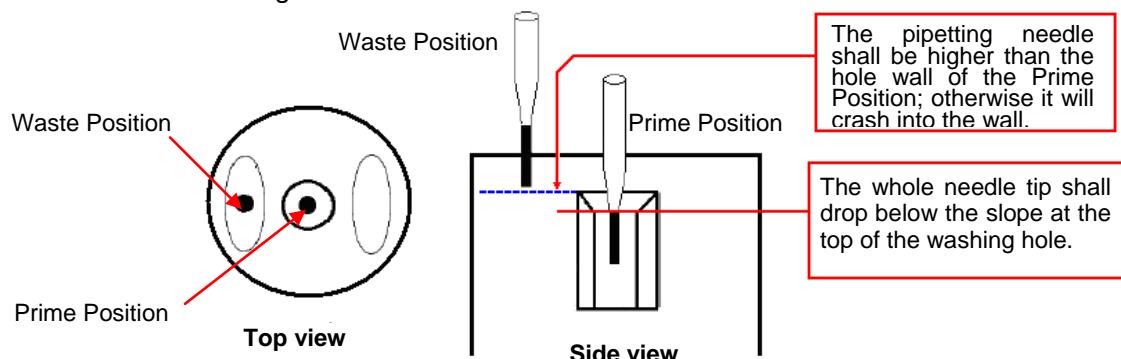


Figure A.7-1 [Left Washing Position Adjust] Dialog

Select Waste Position or Prime Position in **Select Area**. Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby left 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, and click <Return> to exit this dialog.

#### Requirements:

- 1) At Waste Position, the pipetting needle shall be adjusted to the center of the oval washing hole, and the needle must be higher than the hole wall of the Prime Position; otherwise the pipetting needle will crash into the wall when it moves from the Waste Position to the Prime Position;
- 2) At Prime Position, the pipetting needle shall be adjusted to the center of the round washing hole. The whole needle tip shall drop below the slope at the top of the washing hole.



When adjustment is finished, click <Return> to exit this dialog.

### A.7.2 Right Washing Position Adjust

Click  icon on the right of [Needles Adjust] dialog to display [Right Washing Position Adjust] dialog .

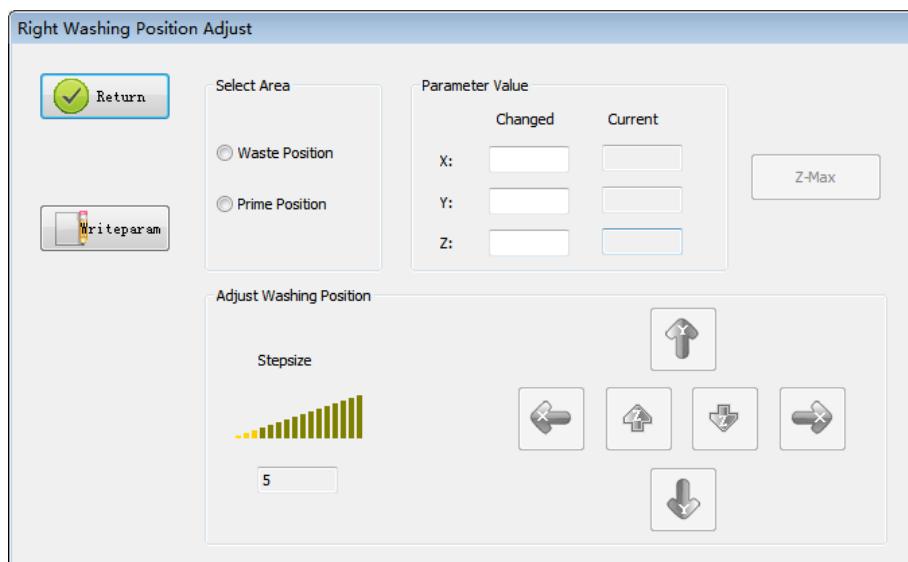
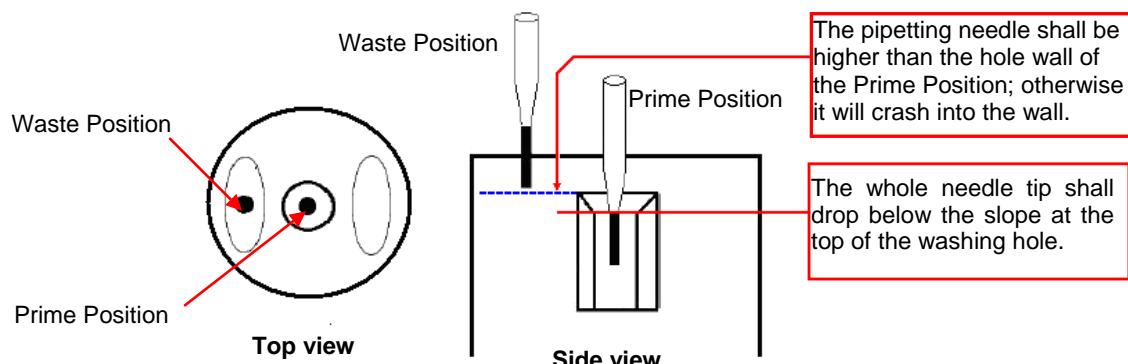


Figure A.7-2 [Right Washing Position Adjust] Dialog

Select Waste Position or Prime Position in **Select Area**. Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle downwards to nearby the right 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, and click <**Return**> to exit this dialog .

#### Requirements:

- 1) At Waste Position, the pipetting needle shall be adjusted to the center of the oval washing hole, and the needle must be higher than the hole wall of the Prime Position; otherwise the pipetting needle will crash into the wall when it moves from the Waste Position to the Prime Position;
- 2) At Prime Position, the pipetting needle shall be adjusted to the center of the round washing hole. The whole needle tip shall drop below the slope at the top of the washing hole.



When adjustment is finished, click <**Return**> to exit this dialog.

### A.8 Adjust of Needle Position in Sample Area

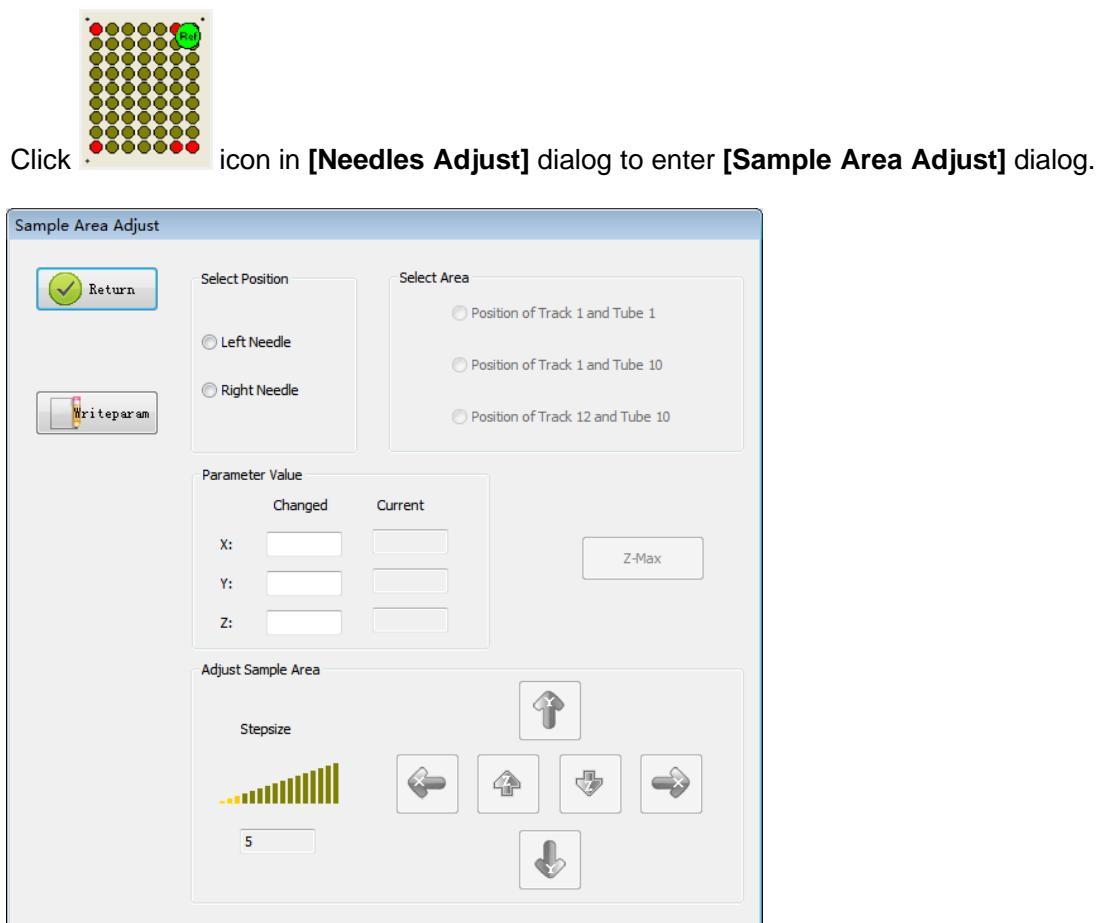


Figure A.8-1 **[Sample Area Adjust]** Dialog

### A.8.1 Adjust of Left Position in Sample Area

Select the left needle in **Select Position**.

1. Select Position of Track 1 and Tube 1 in **Select Area**:

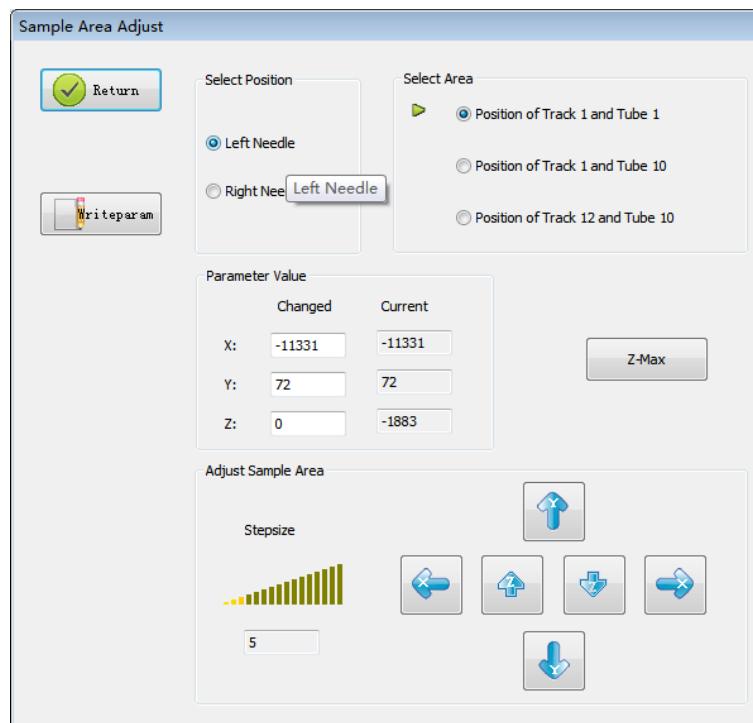


Figure A.8-2 [Sample Area Adjust] Dialog (Left Needle, Position of Track 1 and Tube1)

Set the stepsize by changing the number of selected bars. First use a large stepsize to move the pipetting needle to nearby the position of Track 1 and Tube1, and then use a small stepsize to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

#### Requirements:

- 1) Fill 100 $\mu$ L 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## Appendix A Needles Adjust

2. Select Position of Track 1 and Tube 10 in **Select Area**:



Figure A.8-3 [Sample Area Adjust] Dialog (Left Needle, Position of Track 1 and Tube 10)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 10, 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 100 $\mu$ L 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 Tube 10;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

3. Select Position of Track 12 and Tube 10 in **Select Area**:

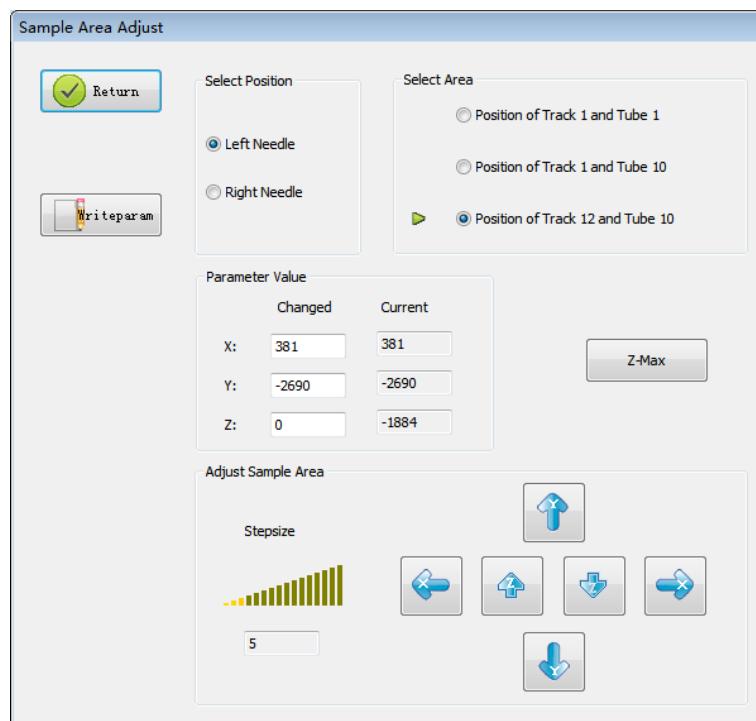


Figure A.8-4 [Sample Area Adjust] Dialog (Left Needle, Position of Track 12 and Tube10)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 12 and Tube 10, 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 100 $\mu$ L water into the tube in advance;
- 2) Position on the top view: Move the needle to the center of tube located in the position of Track 12 and Tube 10;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### A.8.2 Adjust of Right Position in Sample Area

Select the right needle in **Select Position**.

1. Select Position of Track 11 and Tube 1 in **Select Area**:

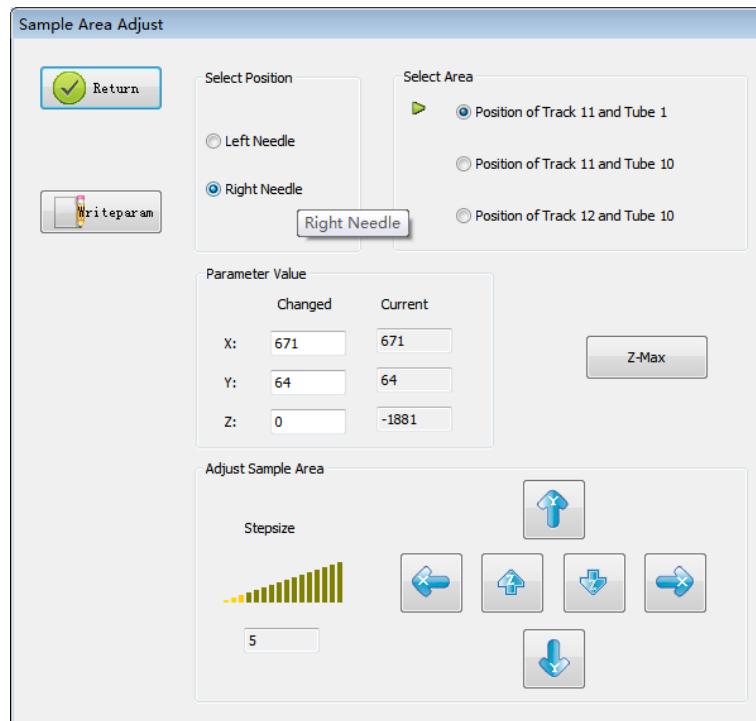


Figure A.8-5 [Sample Area Adjust] Dialog (Right Needle, Position of Track 11 and Tube 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 11 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 100 $\mu$ L 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 11 and Tube 1;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

2. Select Position of Track 11 and Tube 10 **Select Area:**

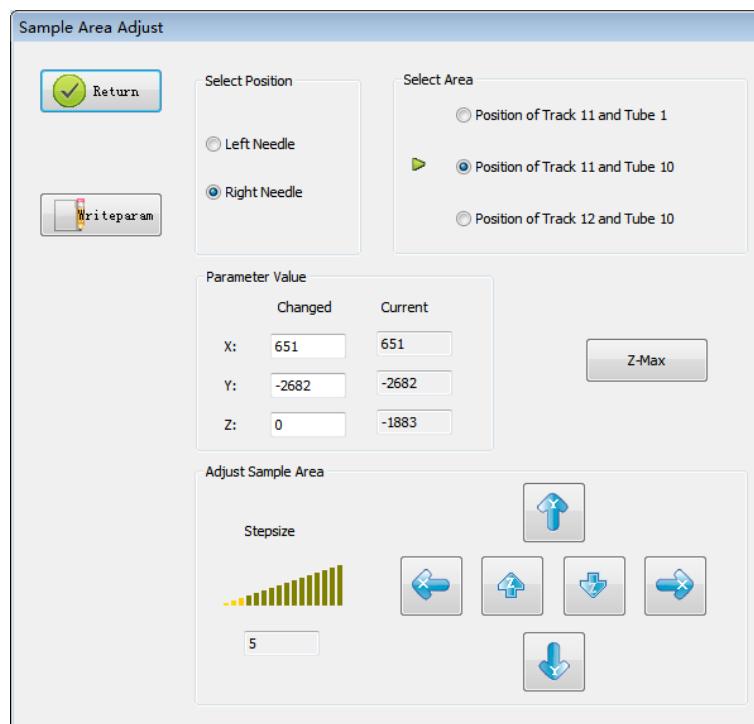


Figure A.8-6 [Sample Area Adjust] Dialog (Right Needle, Position of Track 11 and Tube10)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 11 and Tube 10, 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 100 $\mu$ L 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 11 and Tube 10;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### 3. Select Position of Track 12 and Tube 10 in **Select Area**:



Figure A.8-7 [Sample Area Adjust] Dialog (Right Needle, Position of Track 12 and Tube10)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 12 and Tube 10, 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 100 $\mu$ L 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 12 and Tube 10;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### A.9 Adjust of Needle Position in Reagent Area

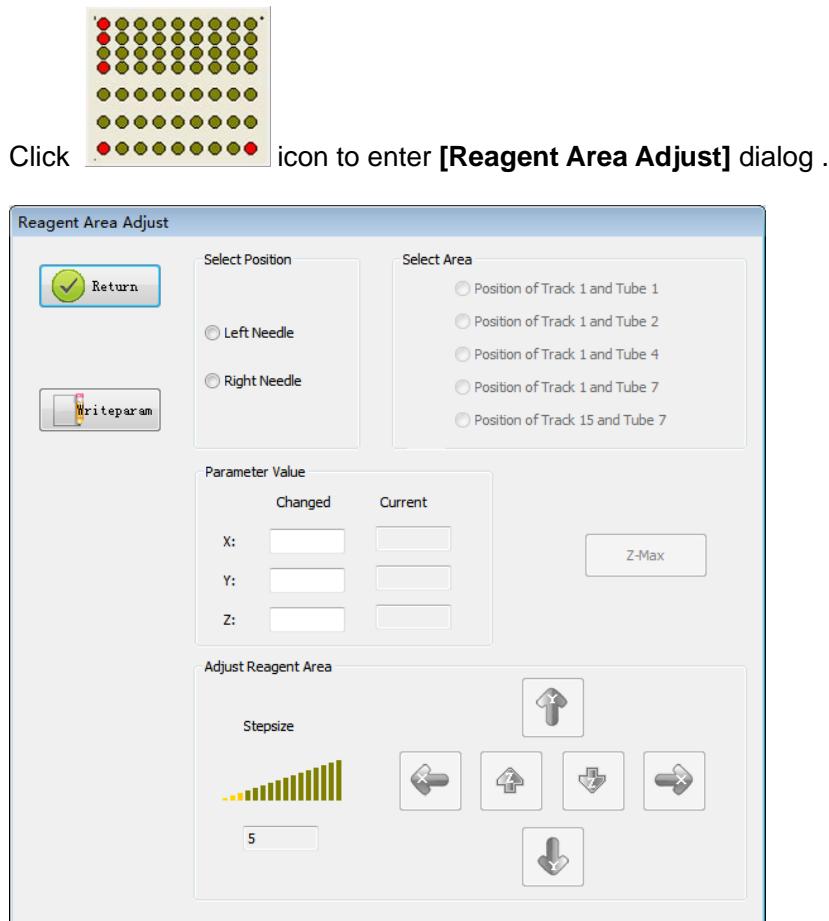


Figure A.9-1 [Reagent Area Adjust] Dialog

### A.9.1 Adjust of Left Needle in Reagent Area

Select the left needle in **Select Position**

1. Select Position of Track 1 and Tube 1 in **Select Area**:

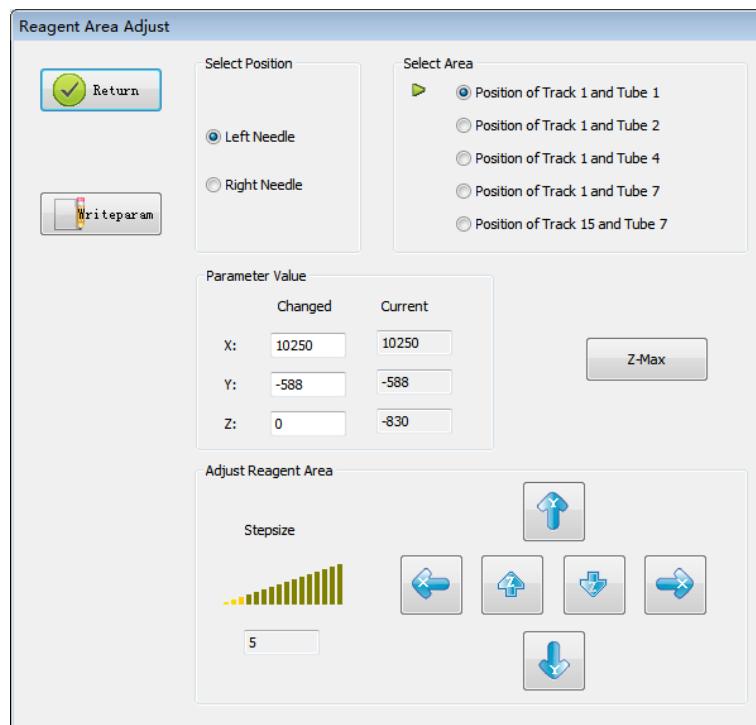


Figure A.9-2 [Reagent Area Adjust] Dialog (Left Needle, Position of Track 1 and Tube 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 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 300 $\mu$ L water into the first tube of the integral in advance;
- 2) Position on the top view: Move the needle to the center of the silicone sealing film of the first tube in the first tube located in the position of Track 1 and Tube 1;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

2. Select Position of Track 1 and Tube 2 in **Select Area**:

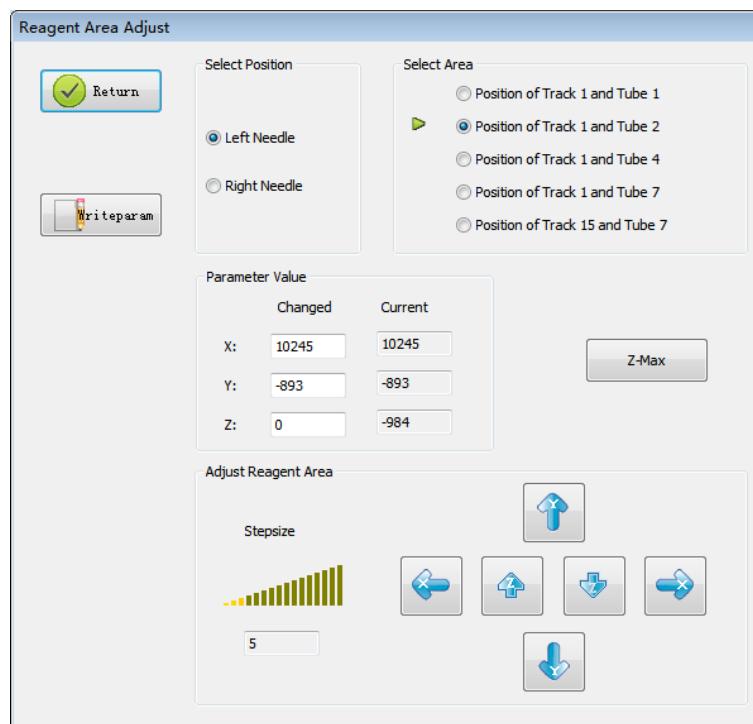


Figure A.9-3 [Reagent Area Adjust] Dialog (Left Needle, Position of Track 1 and Tube 2)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 2, 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 300 $\mu$ L water into the second tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the silicone sealing film of the second tube in the first tube;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## Appendix A Needles Adjust

3. Select Position of Track 1 and Tube 4 in **Select Area**:

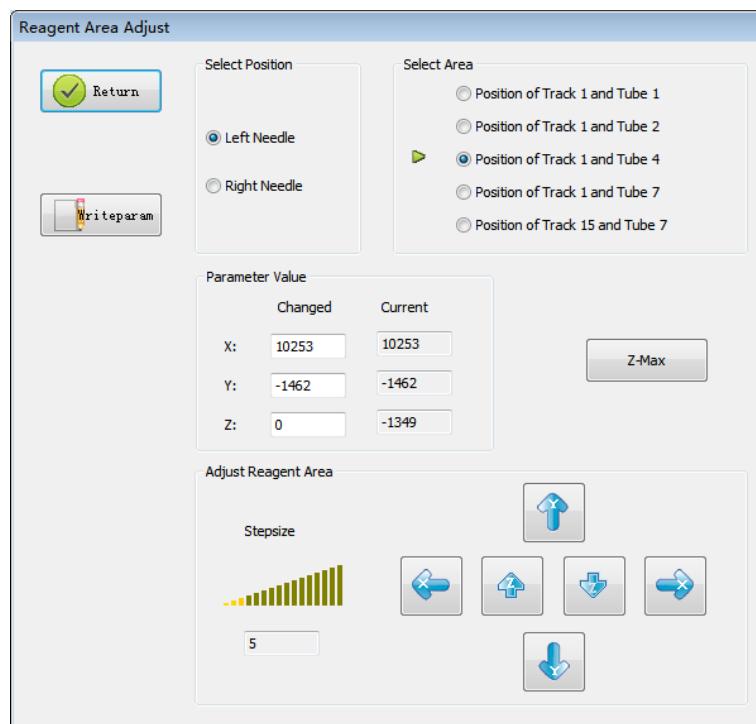


Figure A.9-4 [Reagent Area Adjust] Dialog (Left Needle, Position of Track 1 and Tube 4)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 4, 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 300 $\mu$ L water into the fourth tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the seal located in the position of Track 1 and Tube 4;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

4. Select Position of Track 1 and Tube 7 in **Select Area**:

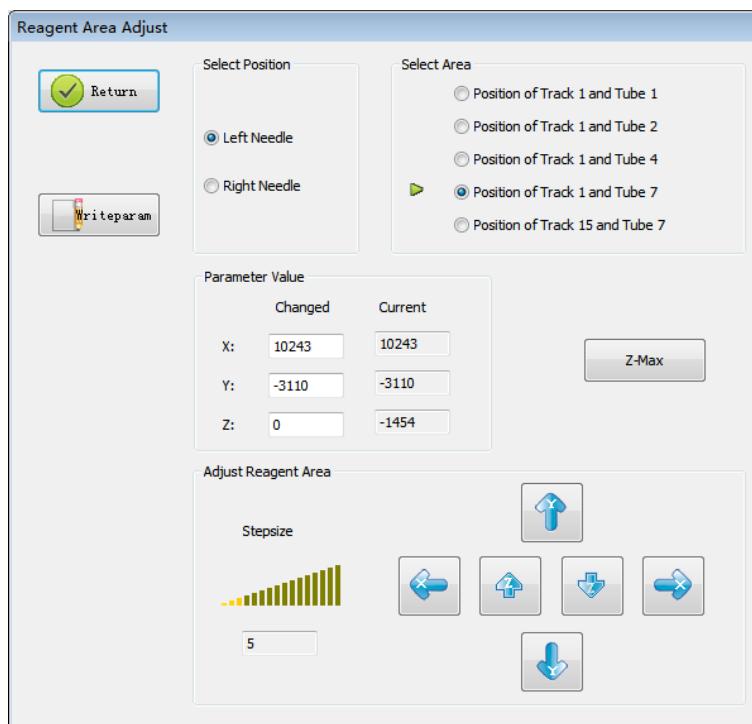


Figure A.9-5 [Reagent Area Adjust] Dialog (Left Needle, Position of Track 1 and Tube 7)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 7, 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 1300 $\mu$ L water into the seventh tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the seal located in the position of Track 1 and Tube 7;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## Appendix A Needles Adjust

5. Insert the reagent into the Track 15 of reagent area. Select Position of Track 15 and Tube 7 in **Select Area**:

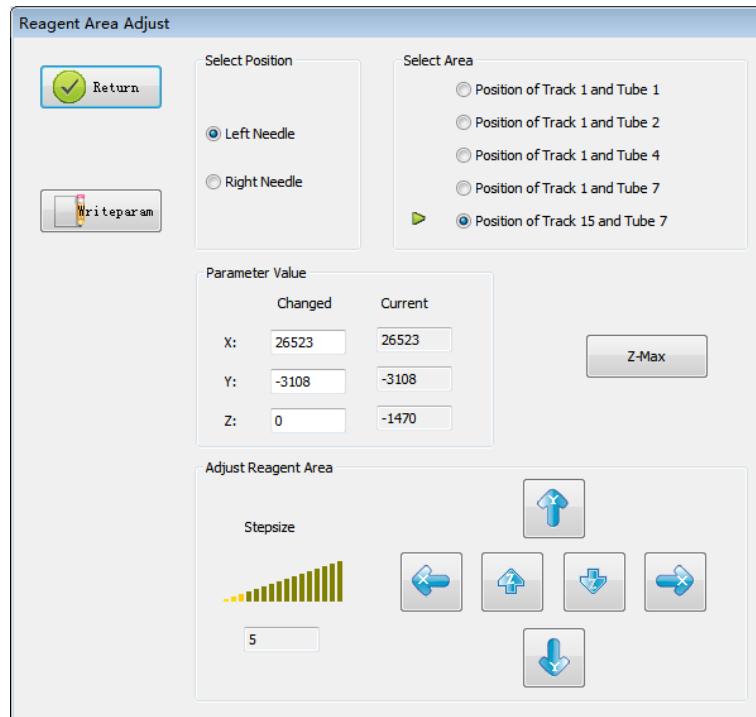


Figure A.9-6 [Reagent Area Adjust] Dialog (Left Needle, Position of Track 15 and Tube7)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 15 and Tube 7, 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 1300 $\mu$ L water into the seventh tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the seal located in the position of Track 15 and Tube 7;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

After needle adjustment is finished, insert the reagent into Track 1 of reagent area.

### A.9.2 Adjust of Right Needle in Reagent Area

Select the right needle in **Select Position**.

1. Select Position of Track 1 and Tube 1 in **Select Area**:



Figure A.9-7 [Reagent Area Adjust] Dialog (Right Needle, Position of Track 1 and Tube 1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 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 300 $\mu$ L water into the first tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the seal located in the position of Track 1 and Tube 1;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## Appendix A Needles Adjust

### 2. Select t Position of Track 1 and Tube 2 in **Select Area**:

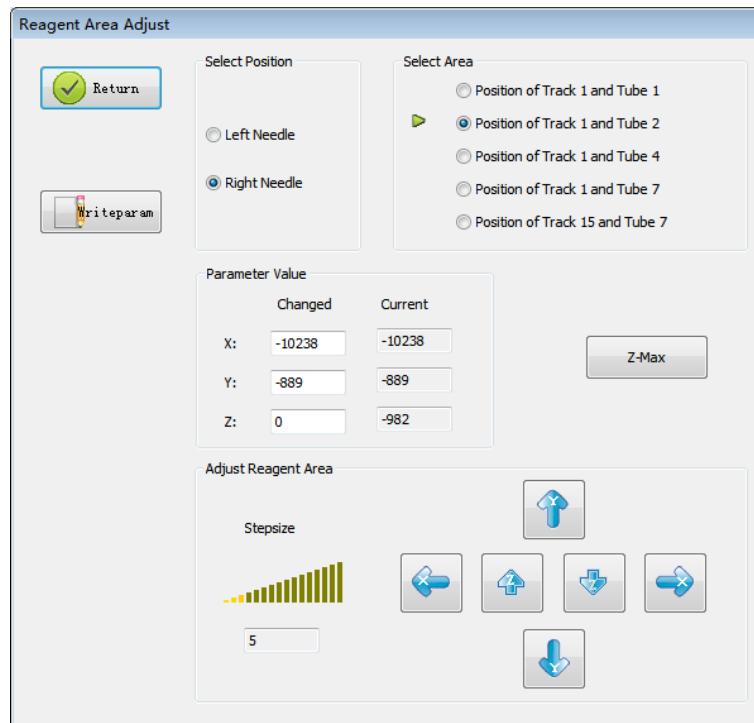


Figure A.9-8 [Reagent Area Adjust] Dialog (Right Needle, Position of Track 1 and Tube 2)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 2, 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 300 $\mu$ L water into the second tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the seal located in the position of Track 1 and Tube 2;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

3. Select Position of Track 1 and Tube 4 in **Select Area**:

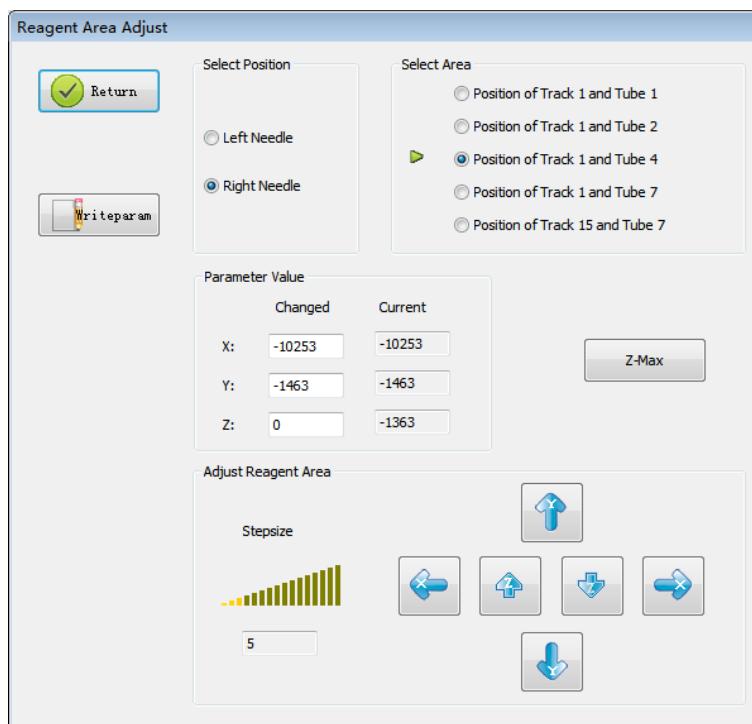


Figure A.9-9 [Reagent Area Adjust] Dialog (Right Needle, Position of Track 1 and Tube 4)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 4, 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 300 $\mu$ L water into the fourth tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the seal located in the position of Track 1 and Tube 4;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### 4. Select Position of Track 1 and Tube 7 in **Select Area**:

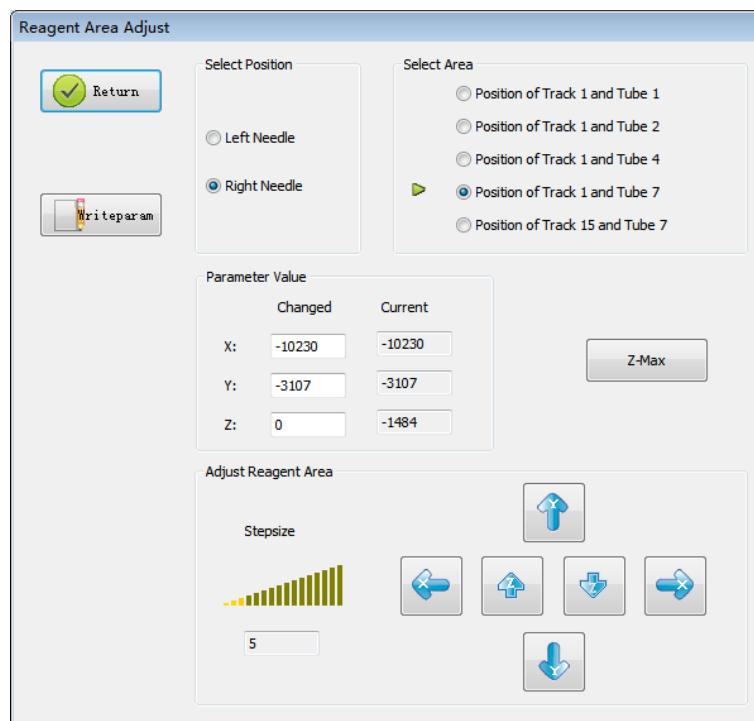


Figure A.9-10 [Reagent Area Adjust] Dialog (Right Needle, Position of Track 1 and Tube 7)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 7, 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 1300 $\mu$ L water into the seventh tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the seal located in the position of Track 1 and Tube 7;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

5. Insert the reagent into Track 15 of reagent area. Select Position of Track 15 and Tube 7 in **Select Area**:

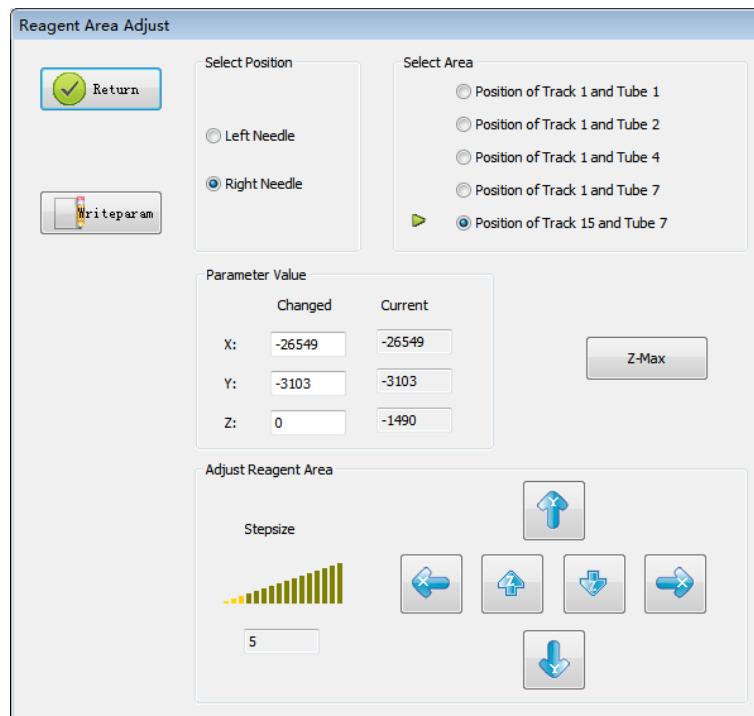


Figure A.9-11 [Reagent Area Adjust] Dialog (Right Needle, Position of Track 15 and Tube7)

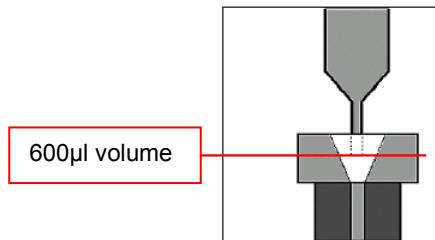
Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 15 and Tube 7 and then use a small step size to fine-tune the horizontal position and vertical height until the needle position meets requirements described below.

#### Requirements:

- 1) Fill 1300 $\mu$ L water into the seventh tube of the reagent in advance;
- 2) Position on the top view: Move the needle to the center of the seal located in position of Track 15 and Tube 7;
- 3) Maximum Limit: Click UP/DOWN arrows to adjust the pipetting needle until the needle tip touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### A.10 Cuvette High-level Adjust

Take a cuvette bar, fill 600 $\mu$ L water into the first cuvette, and place it into the left pipetting position.



Click <Z-Dispense> button to display [Z-Dispense Adjust] dialog.

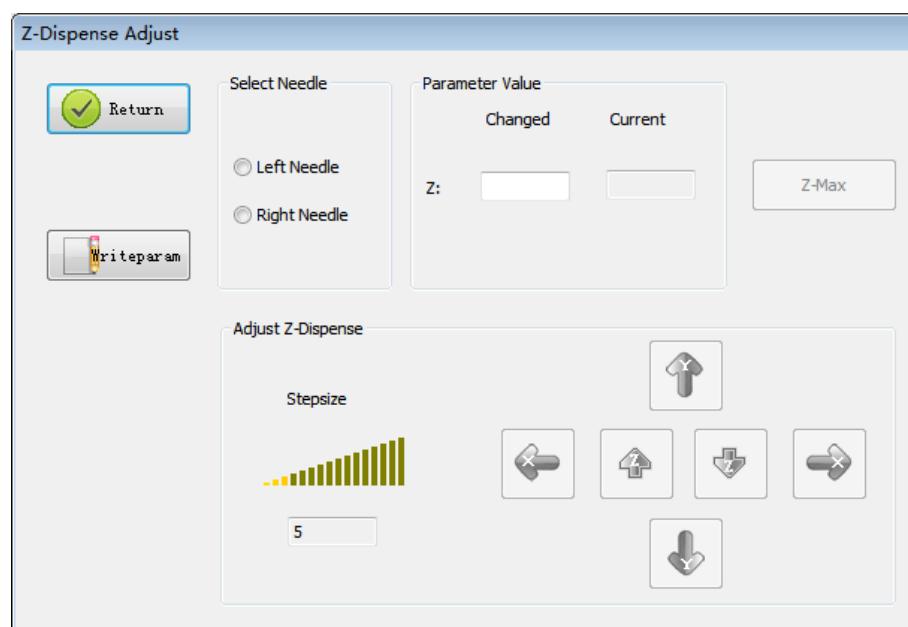
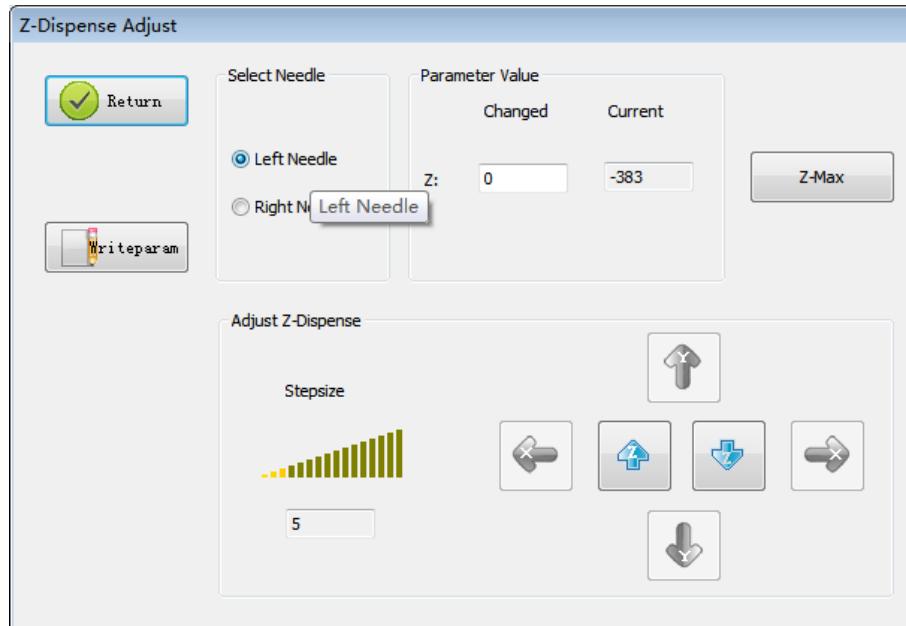


Figure A.10-1 [Z-Dispense Adjust] Dialog

### A.10.1 Left Cuvette High-level Adjust

Select left needle in **Select Needle** area:



FigureA.10-2 [Z-Dispense Adjust] Dialog (Left Needle)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette on the left pipetting position, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

### A.10.2 Right Cuvette High-level Adjust

Select right needle in **Select Needle** area:

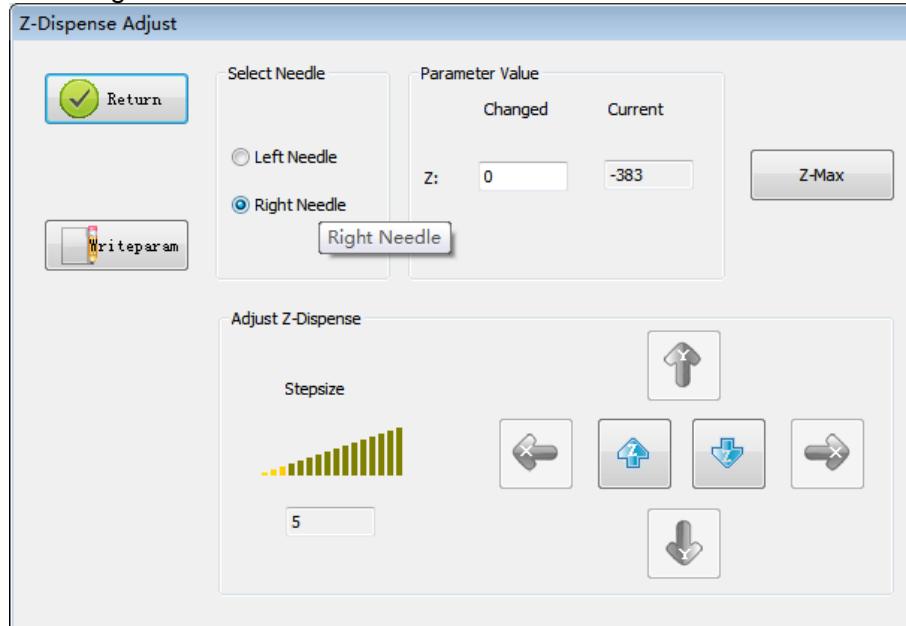


Figure A.10-3 [Z-Dispense Adjust] Dialog (Right Needle)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the first cuvette on the right pipetting position, 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 touch the liquid surface. Click <Writeparam> when the level detection indicator light is on.

## A.11 Adjust of Start Position of Reagents

Click <Z-Start> button to display [Z-Start Adjust] dialog.

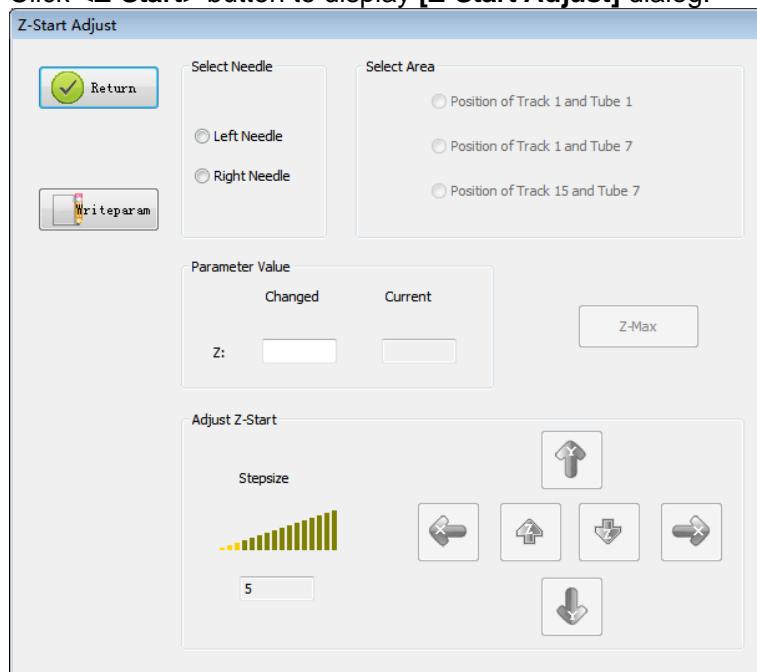


Figure A.11-1 [Z-Start Adjust] Dialog

### A.11.1 Adjust of Left Start Position of Reagents

Insert the reagent into the first reagent position.

Select left needle in **needle selection** area.

1. Select Position of Track 1 and Tube 1 in **Select Area**:

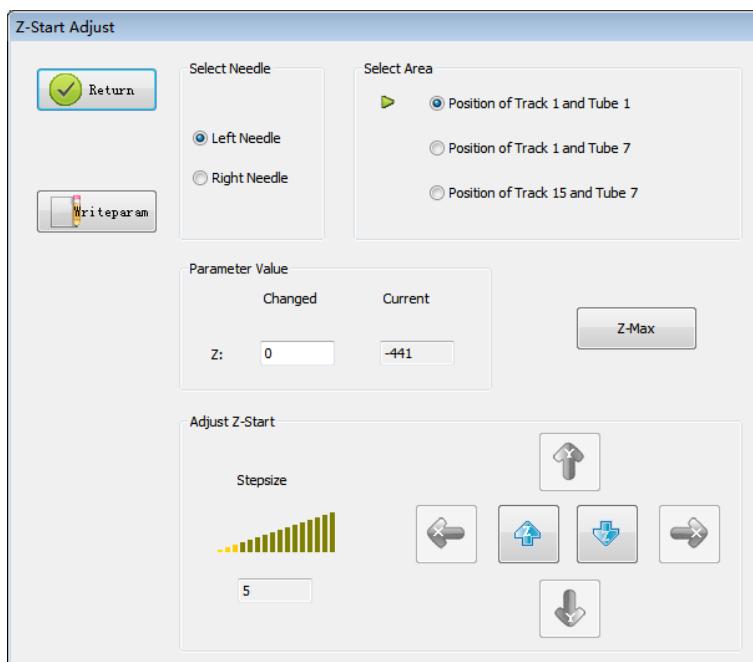


Figure A.11-2 [Z-Start Adjust] Dialog (Left Needle, Position of Track 1 and Tube1)

## Appendix A Needles Adjust

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the seal located in the Position of Track 1 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:

2/3 of Teflon-coated part of the pipetting needle tip is exactly below the seal located in the Position of Track 1 and Tube 1 of the reagent. Click **<Writeparam>** after adjusting is finished.

2. Select Position of Track 1 and Tube 7 in **Select Area**:

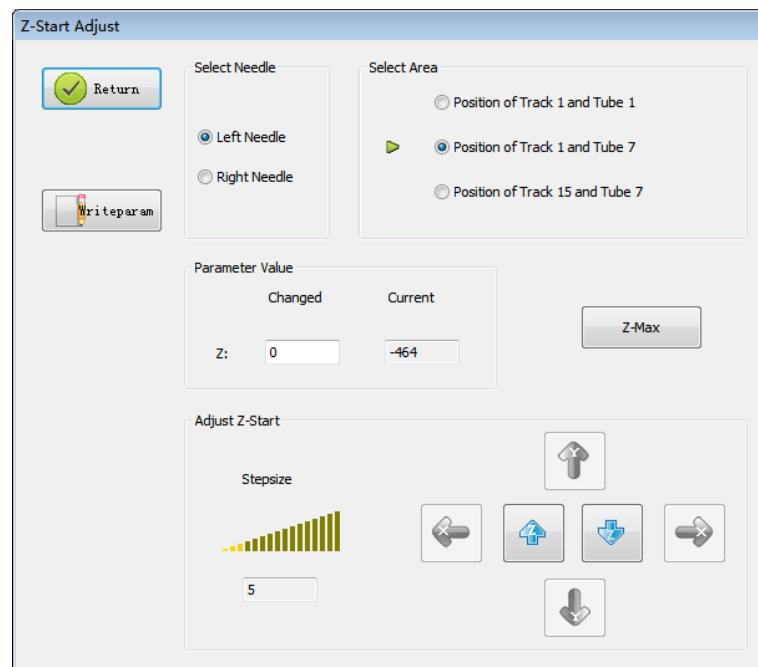


Figure A.11-3 [Z-Start Adjust] Dialog (Left Needle, Position of Track 1 and Tube 7)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 1 and Tube 7, 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:

2/3 of Teflon-coated part of the pipetting needle tip is exactly below the seal located in the position of Track 1 and Tube 7 of the reagent. Click **<Writeparam>** after adjusting is finished.

3. Insert the reagent into Track 15 of reagent area. Select Position of Track 15 and Tube 7 in **Select Area**:

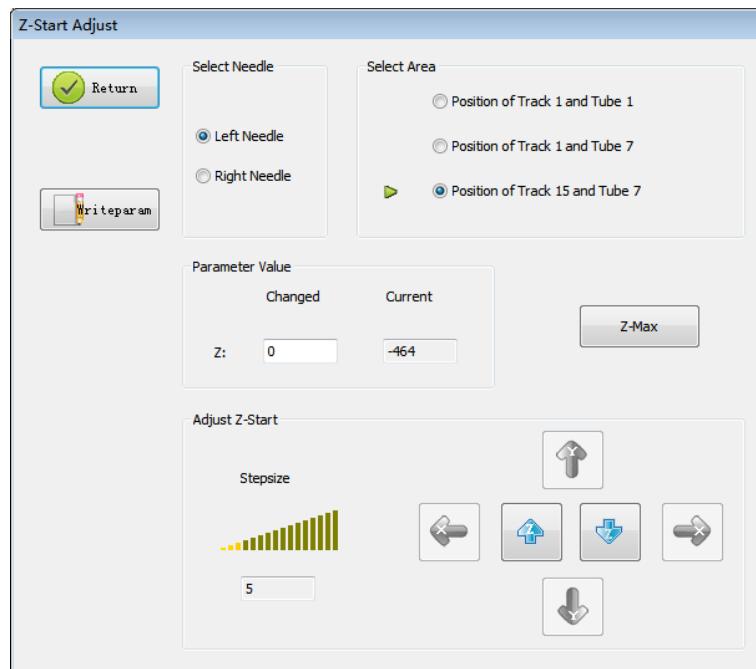


Figure A.11-4 [Z-Start Adjust] Dialog (Left Needle, Position of Track 15 and Tube 7)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the position of Track 15 and Tube 7, 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:**

2/3 of Teflon-coated part of the pipetting needle tip is exactly below the seal located in the position of Track 15 and Tube 7 of the reagent. Click **<Writeparam>** after adjusting is finished.

### A.11.2 Adjust of Right Start Position of Reagents

Insert the reagent into the first reagent position.

Select right needle in **Select Needle** area.

1. Select Position of Track 1 and Tube 1 in **Select Area**:

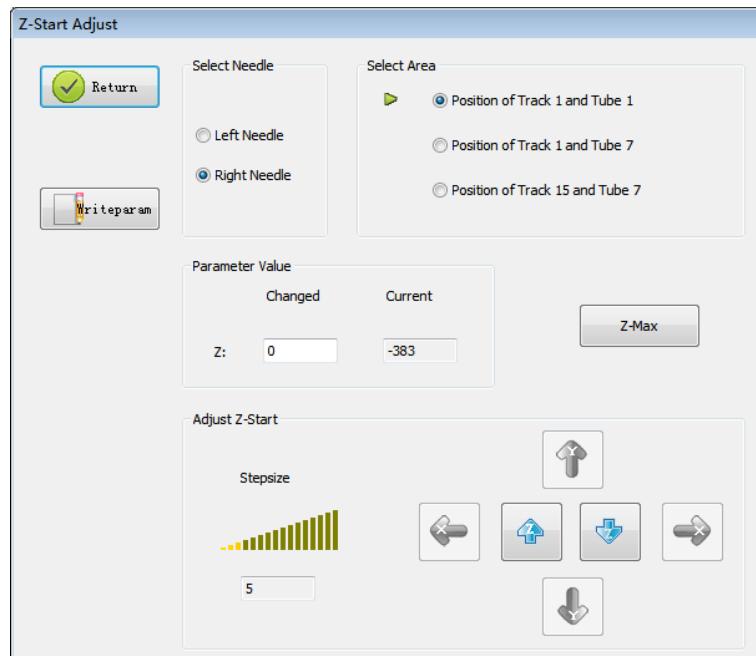


Figure A.11-5 [Z-Start Adjust] Dialog (Right Needle, Position of Track 1 and Tube1)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby seal located in the position of Track 1 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:

2/3 of Teflon-coated part of the pipetting needle tip is exactly below the seal located in the position of Track 1 and Tube 1 of the reagent. Click <Writeparam> after adjusting is finished.

2. Select Position of Track 1 and Tube 7 in **Select Area**:

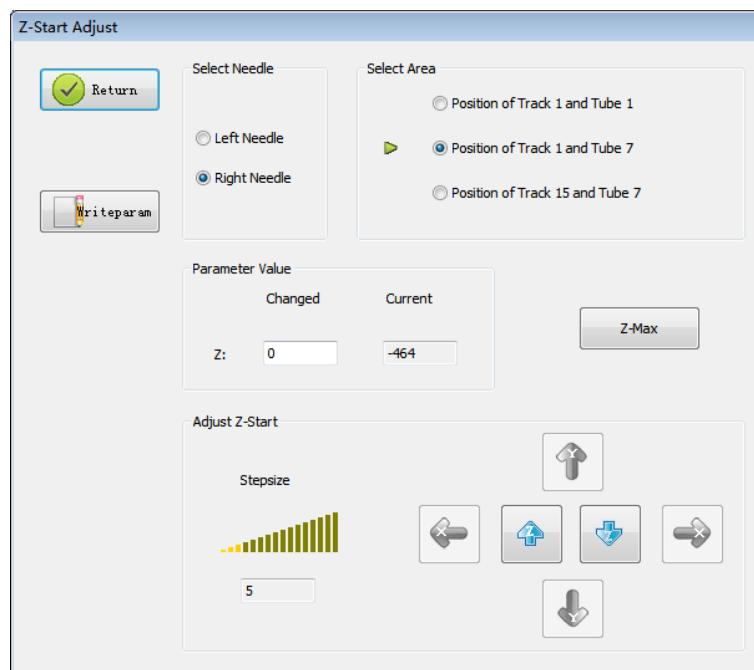


Figure A.11-6 [Z-Start Adjust] Dialog (Right Needle, Position of Track 1 and Tube 7)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the seal located in the position of Track 1 and Tube 7, 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:**

2/3 of Teflon-coated part of the pipetting needle tip is exactly below the seal located in the position of Track 1 and Tube 7 of the reagent. Click <Writeparam> after adjusting is finished.

## Appendix A Needles Adjust

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3. Insert the reagent into Track 15 of reagent area. Select Position of Track 15 and Tube 7 in **Select Area**:

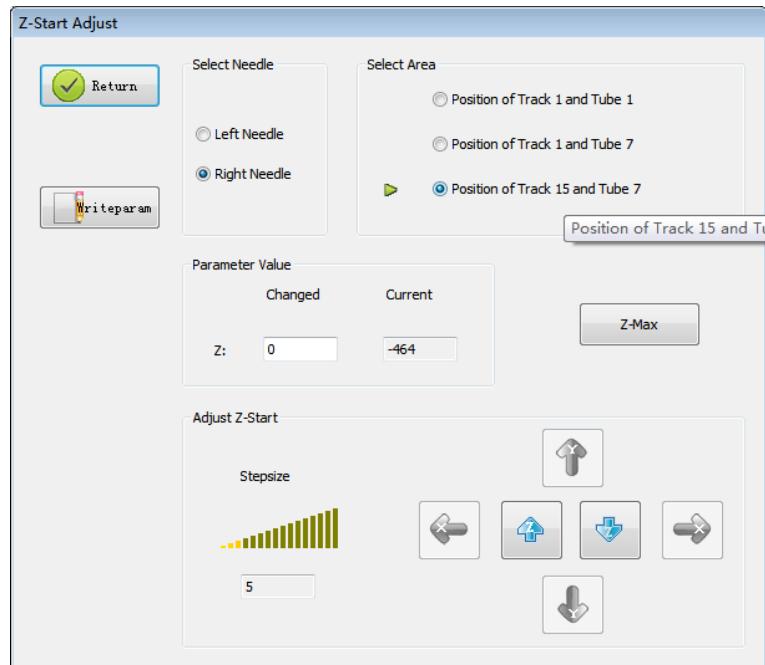


Figure A.11-7 [Z-Start Adjust] Dialog (Right Needle, Position of Track 15 and Tube 7)

Set the step size by changing the number of selected bars. First use a large step size to move the pipetting needle to nearby the seal located in the position of Track 15 and Tube 7, 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:

2/3 of Teflon-coated part of the pipetting needle tip is exactly below the seal located in the position of Track 15 and Tube 7 of the reagent. Click <Writeparam> after adjusting is finished.

# **Appendix B Software Upgrade**

## **B.1 Software Upgrade**

In order to continuously improve the operating software for Maglumi 2000, 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.

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### **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.

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### **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 2000 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

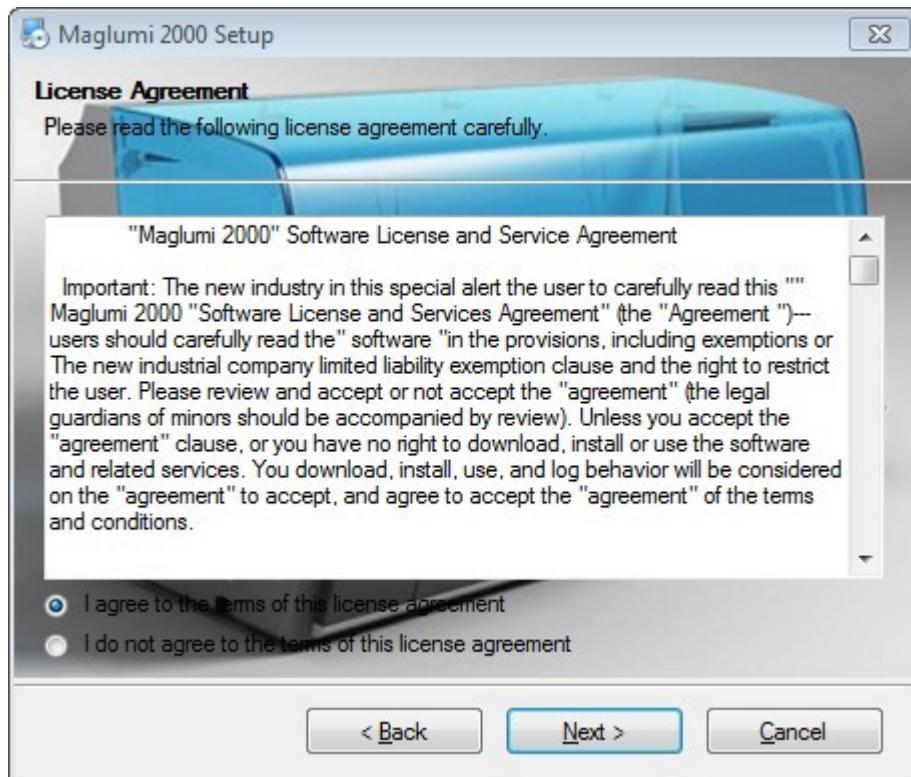


Figure B.1-2 Step 2



Figure B.1-3 Step 3

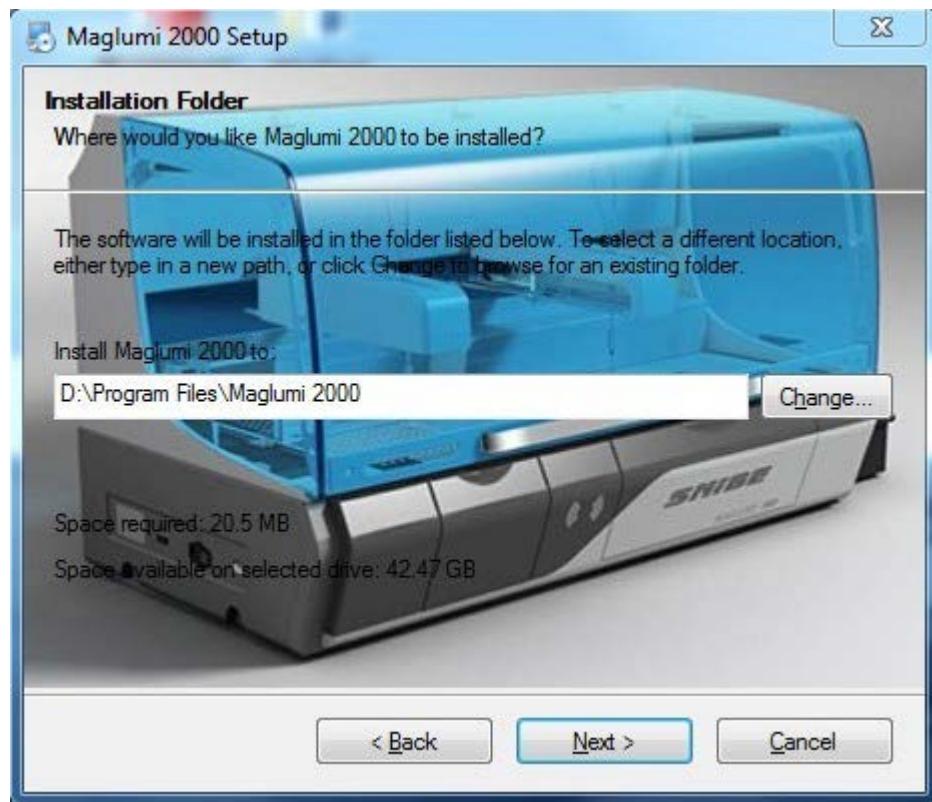


Figure B.1-4 Step 4

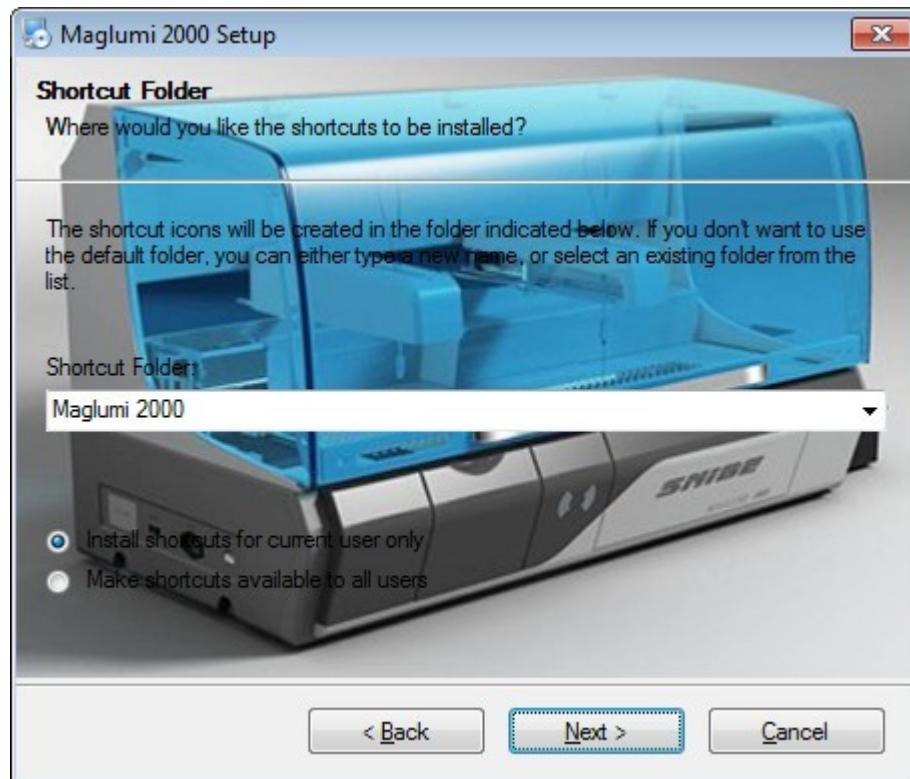


Figure B.1-5 Step 5



Figure B.1-6 Step 6

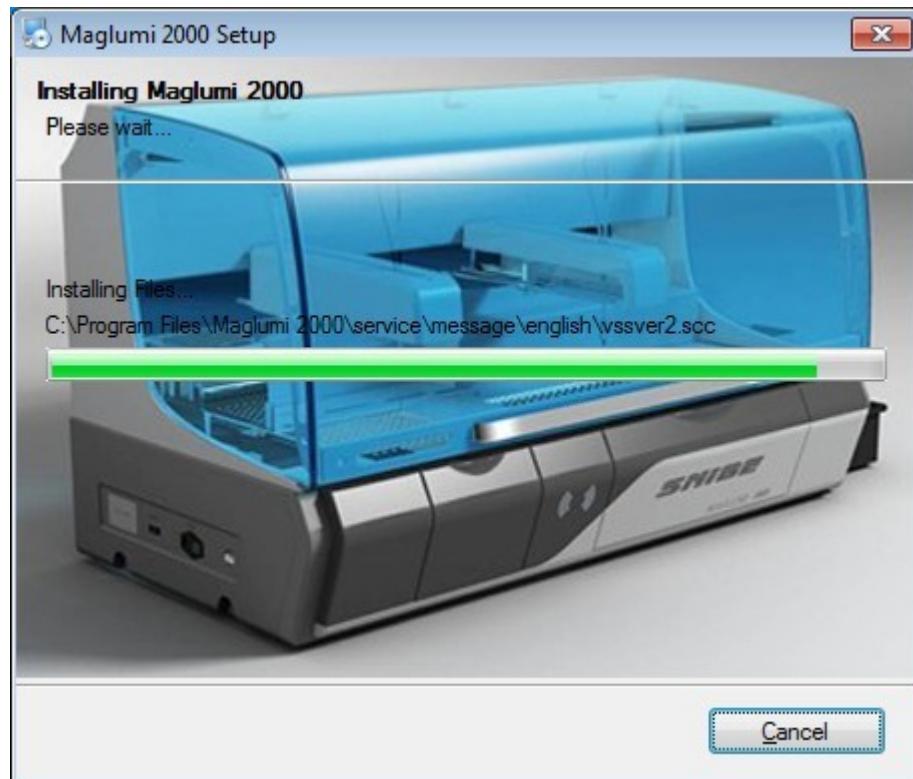


Figure B.1-7 Step 7



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 2000 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 8 main control circuit boards that can be upgraded, which control the corresponding components. Their codes and names are listed below:

- 01-E00-Stacker
- 02-E00-Incubator Pusher
- 03-E00-Washer
- 04-E00-Chamber
- 05-E00-Sample Area
- 06-E00-Reagent Area
- 07-E01-Pipettor
- 08-E00-COP

Program upgrade of 8 main control circuit boards is carried out by two case below:

- 1) Upgrade the program of 08-E00-COP circuit board;
- 2) Upgrade the programs of No. 01~07 circuit boards.

### **B.2.1 Upgrade the Program of 08-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 08-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 08-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.2-1 Parameter Settings of FlashDownload

Step	Option	Content	Meaning
1	Device	LPC2214	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

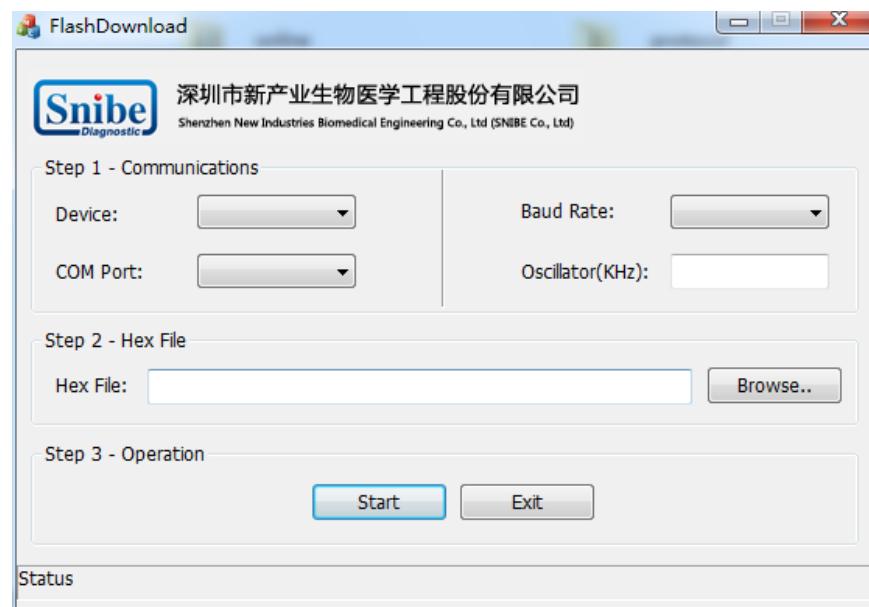


Figure B.2-2 Program Upgrade Process for 08-E00-COP Main Control Circuit Board

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 08-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.



Figure B.2-3 Restore the two Jumper Caps

## B.2.2 Upgrade and Burning of the Programs of No. 01~07 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. 01~07 circuit boards in the

## **Appendix B Software Upgrade**

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analyzer. The program download cable and the connection method are shown in the figures below;



Figure B.2-4 Program Download Cable for No. 01~07 Main Control Circuit Boards

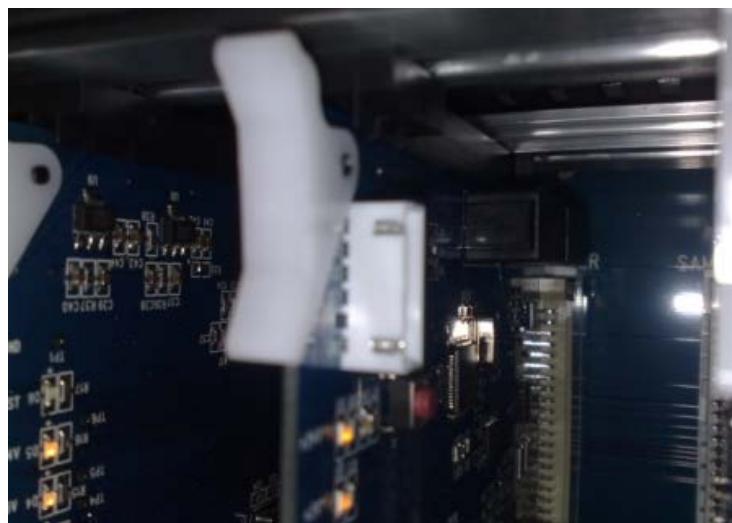


Figure B.2-5 Program Download Connection Ports of Main Control Circuit Boards

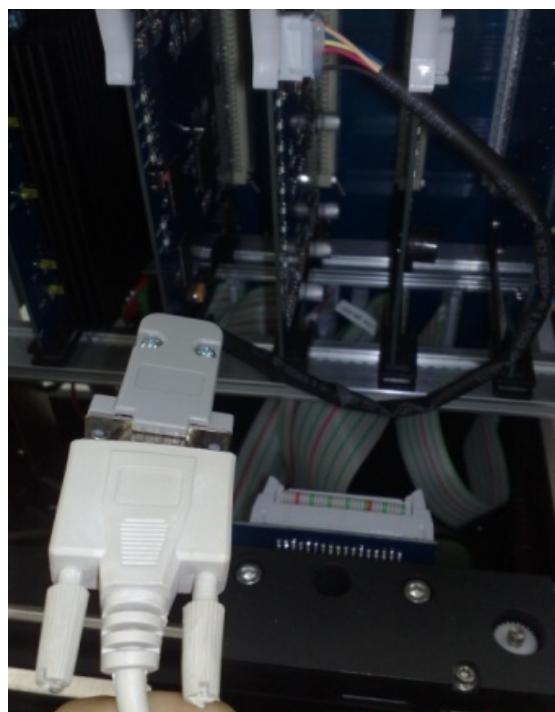


Figure B.2-6 Program Download Connection Method for Main Control Circuit Boards

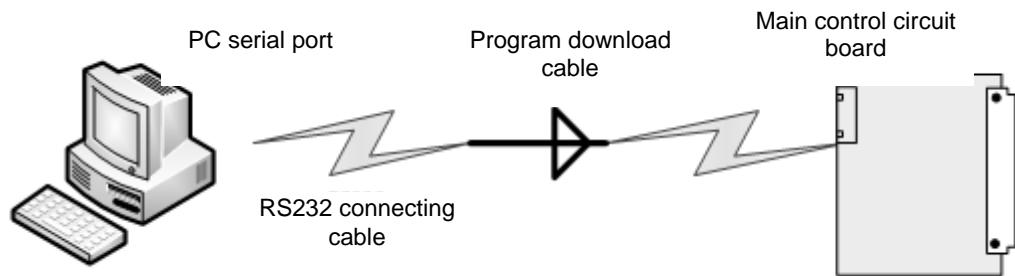


Figure B.2-7 Diagram of Connection Method

- After cable connection, start the computer and the analyzer. Run **FlashDownload.exe** on the computer; then select options as follows:

Table B.2-8 Parameter Settings of FlashDownload

Step	Option	Content	Meaning
1	Device	LPC2132 (01-06) LPC2368 (07)	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 7 main control circuit boards have 8 different files; each file name corresponds to a circuit board name, where 07-E01-Pipettor corresponds to two files, which are provided by Snibe.

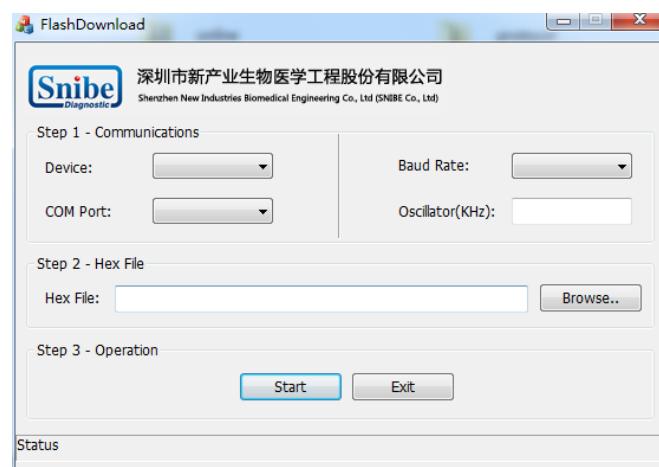


Figure B.2-9 Program Upgrade Process for No. 01-07 Main Control Circuit Boards

- After selecting the above options, click the <Start> button; after successful burning, **Status** will display finished;
- When the writing process is finished, exit the **FlashDownload.exe** program.
- 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.

- 2) The 07-E01-Pipettor circuit board corresponds to 2 program files, one file for the left pipettor and the corresponding program download connector, and the other file for the right pipettor and the corresponding program download connector.

Left pipettor program  
download connector

Right pipettor program  
download connector

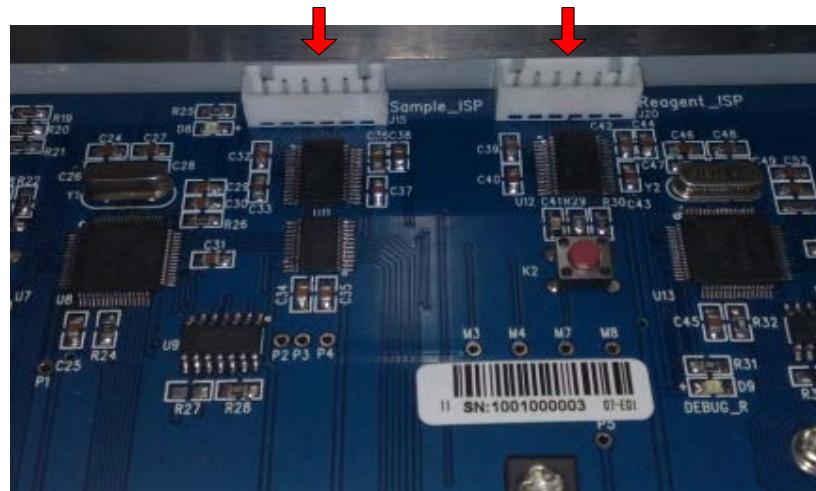


Figure B.2-10 Download Connector of 07-E01-Pipettor Circuit Board



### WARNING

- 1)For the 05-E00-Sample Area main control circuit board, during upgrading program, it is needed to pull off the two **Jumper Caps** on the board; otherwise, program burning cannot be carried out or the circuit board may get damaged.
- 2)After program upgraded, you should push the two Jumper Caps back to the circuit board, Otherwise the barcode data reading function will not work properly.

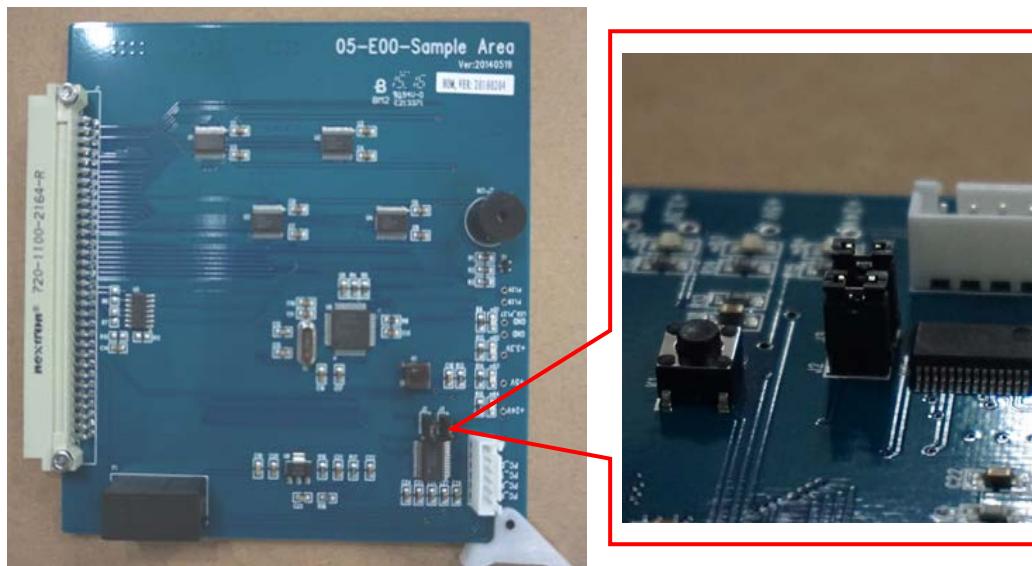


Figure B.2-11 Jumper of 05-E00-Sample Area Main Control Circuit Board