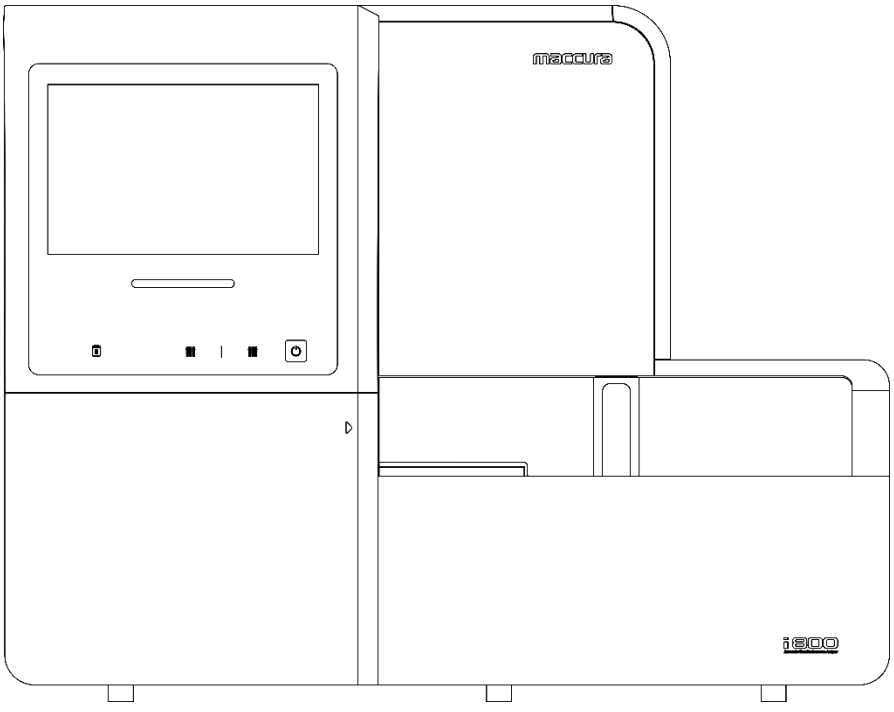
maccura

i800

Automatic Chemiluminescence Analyzer
User Manual



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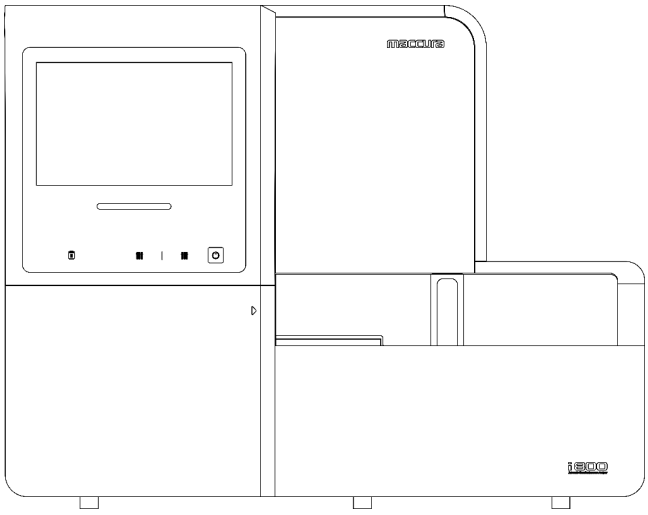

Automatic Chemiluminescence Analyzer User Manual

Read this manual before use and keep it handy
■ Carefully read and correctly understand the safety instructions before using the Analyzer.
■ Keep the Manual in an accessible place for reference.

Manufacturer: Maccura Medical Instrument Co., Ltd.

Revision History

Version	Date	Change Description
Initial release	2022-12-08	Initial release

Product Registration

Product name: Automatic Chemiluminescence Analyzer
Models: i 800, i 820, i 6000, i 8000, i 9000
Registrant/ Manufacturer: Maccura Medical Instrument Co., Ltd.
Address: Building 4, 8#, 2nd Anhe Road, Hi-tech Zone, 611731 Chengdu, PEOPLE’ S REPUBLIC OF CHINA
Tel: +86 400 602 8007 +86 28 8173 1888
After sales service provider: Maccura Medical Instrument Co., Ltd. or authorized dealer(s)

Declaration

Please carefully read and understand these statements about this Manual:

- The manual is subject to change without notice.
- The manual is owned by Maccura Medical Instrument Co., Ltd. (the "Company"). No part of this manual may be copied or reproduced or disclosed to any third party in any form or by many means without written consent of the Company.
- In no event will the Company be liable for direct or indirect damages or damages arising of any use of the product not specified in the manual.
- Failure to use the system equipment as specified in the Manual may cause damage to the protection provided by the equipment.

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Preface

Thank you for purchasing the Automatic Chemiluminescence Analyzer (the "Analyzer") of Maccura Medical Instrument Co., Ltd. (the "Company").

Use the Analyzer under the guidance of a specially trained technician. Use it for clinical examination under the guidance of a physician or clinical laboratory technician.
Incorrect use of samples, reagents or consumables on the Analyzer may lead to inaccurate results or hazards to the Analyzer or operator.
Read through the Manual before using the Analyzer.
Keep the Manual in an accessible place for reference at any time.

Product Assurance

Despite the limited description in the Manual, use of the Analyzer as instructed in the Manual can guarantee the normal use of the instrument.

Warranty coverage

For any failure caused by defects in manufacturing, the Company will provide repair services free of charge. During the service, some substitutes may be used or the parts to be repaired may be replaced.

Region

Within the country/region where the product is sold.

Disclaimers

The following is not covered under the warranty even within the warranty period:

- Failures resulting in the use of the product not in the applicable environment as specified in the manual.
- Failures resulting in the use of the product not at the specified power supply, voltage or frequency, and those caused due to power exception.
- Failures resulting in circuit corrosion and degradation due to highly corrosive gases in the air.
- Failures resulting in the use of hardware, software or auxiliaries not provided by the Company.
- Failures resulting in the use of the product according to a method not specified in the manual or incorrect use of the product, and those caused due to repair by a party other than the Company.
- Failures resulting in the maintenance by a party other than the maintenance company designated by the Company.
- Failures resulting in the move or transportation of the installed product with a method not authorized by the Company
- Failures resulting in unauthorized disassembly or alternation of the product.
- Failures resulting in fires, earthquakes, wind damages, floods, lightning strokes, crimes, violence, terrorist acts, radioactive contaminations, wars, hazardous substances and other acts of God
- Failures occurred to scrapped Analyzers or the Analyzers sub-purchased without the written consent of the Company.

Manual rights

The manual is subject to change without notice.

Storage and Shipping Conditions

Storage Conditions

The packed Analyzer should be stored in a well ventilated environment free of corrosive gases under-20°C to +55°C with the relative humidity not exceeding 90%.

Transportation Conditions

Special packaging box designated by the Company should be used to pack the instrument during transportation. Shipping without packaging is prohibited. During shipping, the packaging box must be fastened to the transportation facility as instructed on the package. Tilting or collision is prohibited. The product should be protected from damp and sun. Rain exposure is strictly prohibited.

How to Get Help

If you have any questions when installing or using this Analyzer, please contact the Company or authorized dealer(s). The contact information is as follows:

- Company website: www.maccura.com
- Contact information:
  Tel.: +86 400 602 8007
  +86 28 8173 1888
  E-mail: maccura@maccura.com

Please prepare the following materials:

- The SN of the Analyzer (on the nameplate of the Analyzer at backplate).
- Problem description.
- Methods and operating steps you've taken to try to resolve the problem.
- Contact information such as your phone number and E-mail address.

Installation, Moving and After-sales Service

Installation and Moving

- The user may not try to install this Analyzer by themselves. To ensure the safe

and normal use of the Analyzer, the service department of the Company or authorized dealer(s) will provide you with installation services.

- The responsibility of the user is to prepare the hardware and corresponding working environment required for the installation of the Analyzer.
- If you need to move the Analyzer after purchase, please contact the service department of the Company or authorized dealer(s) to avoid possible faults of the instrument.

After-sales Service

- Contact the service department of the Company or authorized dealer(s) for matters related to after-sales service and maintenance contracts.
- The items that can be maintained by the user are limited to the scope described in this manual. Before maintenance, understand the contents in detail. Don't try to maintenance projects outside of the manual, or Analyzer will be dangerous, and may cause personal injury.
- In case of aging or damage of the warning and identification labels, please contact the service department of the Company or authorized dealer(s) for replacement.
- Prepare maintenance contract, inspection service contract, etc., and negotiate with the service department of the Company or authorized dealer(s) for services after the warranty period.

User Training

The Company provides training services on how to use the Analyzer. For more information, please consult the service department of the Company.

Manufacture Date and Service Life

The production date is shown on the Analyzer nameplate, and the service life is 10 years

The service life of the Analyzer is determined by the aging test and risk management. User should maintain and repair the product as required in the Manual in use.

Notice for Safe and Effective Use

The warnings are listed in this Manual below. The protective articles mentioned below include medical gloves, goggles, protective clothing and masks.
For ensure safety, please carefully read, understand and follow the safety instructions before using the Analyzer. If not, the company is not liable for any damage or injury caused.

Description of Identifiers

Pay attention to and observe all warning labels in the Manual or affixed to this product. Do not cover or remove these labels.

- Identifiers in the Manual

The following Identifiers are used in the Manual, and their meanings are as follows:

Identifiers	Meaning
	Warning sign, indicates a potentially dangerous situation that requires great attention. If not avoided, system function will be affected, or death or serious injury may be caused.
	Caution sign, prompts the user to operate according to the description under the symbol. Otherwise, product fault or damage may occur, or the test results may be affected.
	Precautions sign, indicates a potential hazard and prompts the operator to pay appropriate attention and operate as instructed under the symbol. Otherwise, minor damage may be caused, system performance may be degraded, and system operation may be impeded.
	Prompts the operator to follow the instructions under the symbol, or biological infection may be caused.
	Indicates a hazardous condition that could result in death or serious injury in the vicinity of this sign. Please refer to the Manual to ensure proper use.

- Labels in the Analyzer System

The following labels may be found on the Analyzer system, reagent packages, calibrators, controls, and other supporting accessories. The labels on the Analyzer should be inspected, cleaned and maintained constantly to ensure they can be easily read within a safe distance. If the label is aged or damaged, please contact the service department of the Company or authorized dealer(s) for replacement.

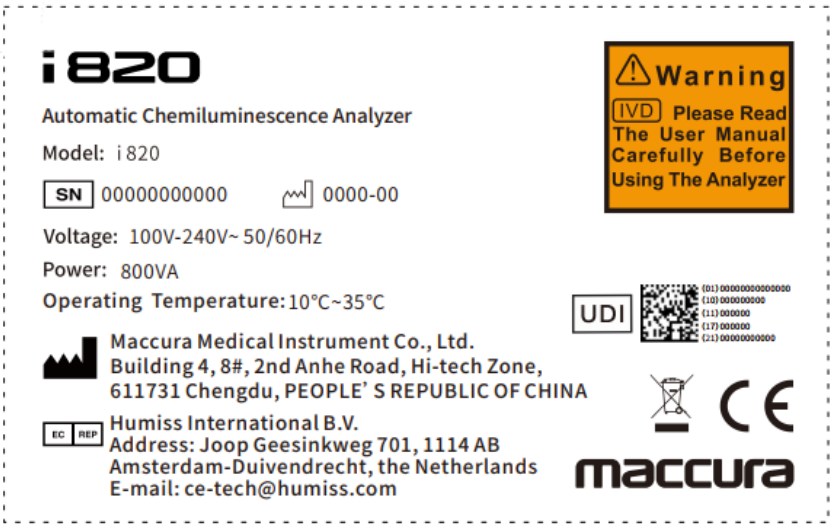
Label	Meaning
	**Warning - Biohazard** It indicates a potential biohazard in the vicinity of this sign. Relevant laboratory safety procedures must be followed.
	**Warning - High Voltage danger** It indicates the presence of a high-voltage part in the vicinity of this symbol. Contact may cause an electric shock, so connection must be reliable.
	**Warning - Hand Pinching** It indicates that there is a risk of pinching hand if you extend your hand into an area in the vicinity of this sign.
	**Warning - Do not open this area when the Analyzer is running.** It indicates a potential hazard if the cover is opened while the Analyzer is running.
	**No pressing** Do not press or place items to avoid damage.
	**Alarm Sign** It indicates that the area adjacent to this sign is in danger of causing death or serious injury. Please refer to the Manual to ensure proper use.
	**Nameplate** of the Analyzer
	Unique Device Identification
	Caution
	AC power
	Grounding protection
	Manufacturer
	Date of production
	Refer to user manual
	Serial number

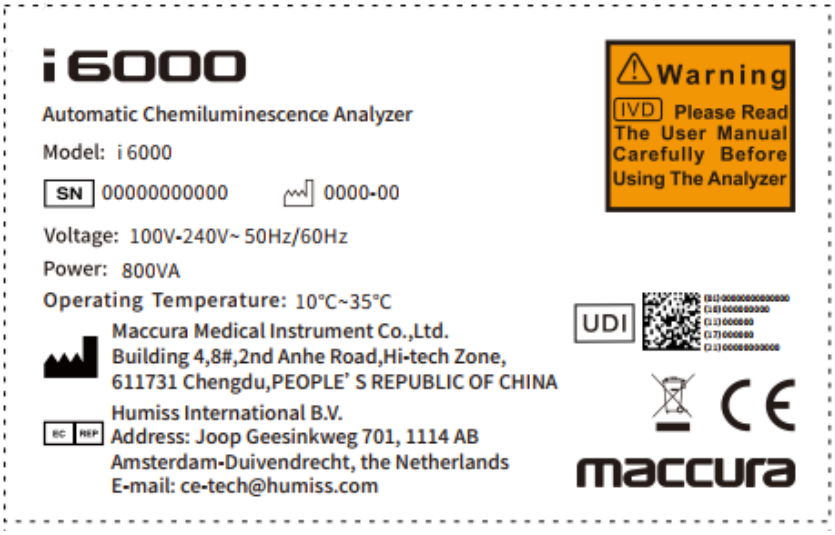
IVD	In vitro diagnostic use only
	Use-by date
	Upward
	Fragile
	Keep away from rain
	Keep away from sunlight
	Stacking limit by number
REF	Catalog number
EC REP	Authorized representative in the European Community
	Do not discard it carelessly, hand it over to appropriate facilities

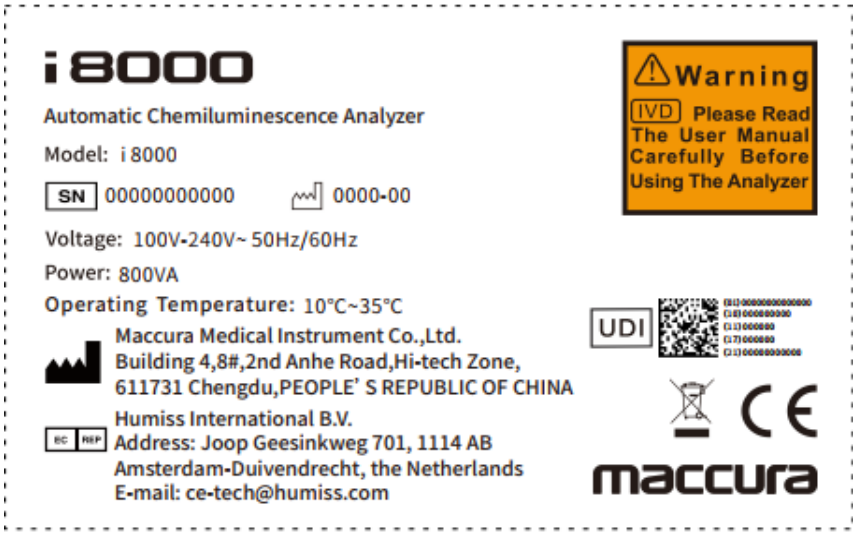
- Nameplate

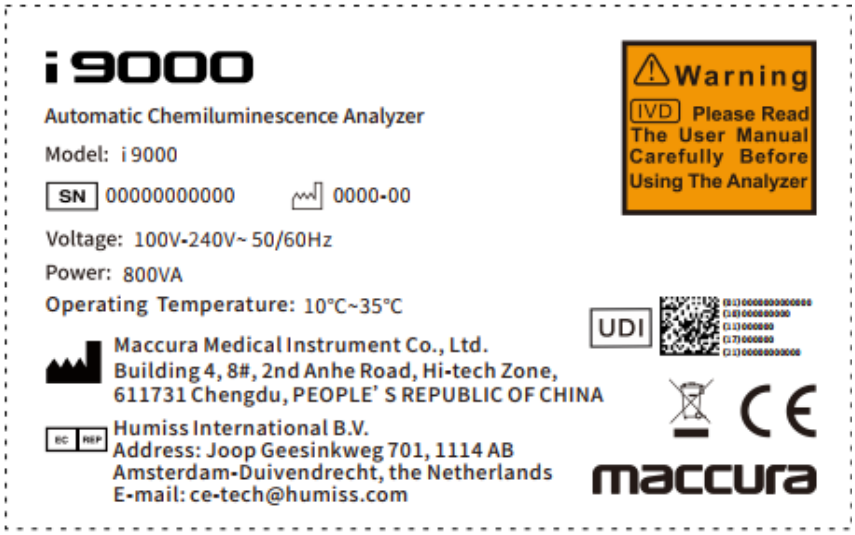
The model, registration information, SN and other information are displayed o on the nameplate of the Analyzer at backplate.




i820
Automatic Chemiluminescence Analyzer
Model: i820
SN 00000000000
0000-00
Voltage: 100V-240V~ 50/60Hz
Power: 800VA
Operating Temperature: 10°C~35°C
Maccura Medical Instrument Co., Ltd.
Building 4, 8#, 2nd Anhe Road, Hi-tech Zone,
611731 Chengdu, PEOPLE' S REPUBLIC OF CHINA
EC REP
Humiss International B.V.
Address: Joop Geesinkweg 701, 1114 AB
Amsterdam-Duivendrecht, the Netherlands
E-mail: ce-tech@humiss.com
Warning
IVD Please Read The User Manual Carefully Before Using The Analyzer
UDI
maccura


i6000
Automatic Chemiluminescence Analyzer
Model: i6000
SN 00000000000
0000-00
Voltage: 100V-240V~ 50Hz/60Hz
Power: 800VA
Operating Temperature: 10°C~35°C
Maccura Medical Instrument Co.,Ltd.
Building 4,8#,2nd Anhe Road,Hi-tech Zone,
611731 Chengdu,PEOPLE' S REPUBLIC OF CHINA
EC REP
Humiss International B.V.
Address: Joop Geesinkweg 701, 1114 AB
Amsterdam-Duivendrecht, the Netherlands
E-mail: ce-tech@humiss.com
Warning
IVD Please Read The User Manual Carefully Before Using The Analyzer
UDI
maccura





Warning Identifiers

Fire Prevention

⚠	■ The product should be installed by a person approved by the Company, as required in the Manual. ■ In case of a system failure, power supply of the Analyzer must be disconnected before any repair services. ■ Don't use any combustible or inflammable or explosive solid, gas or liquid near the Analyzer, or explosion may be caused. ■ Don't place any high-temperature and heating objects on the Analyzer surface.

Electric Shock Prevention

	■ Don't remove any casing, cover or panel of the Analyzer. ■ Don't remove the cover of the power module, as some components exist in the power module under high pressure, which may cause electric shock. ■ Do not switch the power supply during the maintenance of the Analyzer; otherwise it may cause personal injury or Analyzer damage. ■ In the situation of long-time power cut, switch off the circuit breaker distributed by the laboratory to the Analyzer circuit, in order to ensure all power sources can be cut off. ■ If any liquid spills onto the Analyzer, disconnect the Analyzer from the power supply network immediately before wiping off the liquid. If the liquid enters the Analyzer, please report this situation to the service department of the Company or authorized dealer(s) before re-starting the instrument.

Infection Prevention

	■ Dispose all samples, sample racks, reagents, waste liquids, wastes, as well as the wastes after maintenance as potential sources of infection, and follow the comprehensive protective measures stipulated in the local or national or regional regulations, in order to prevent infection caused by direct contact. ■ If the user has his/her skin contact with the source of infection, mediately flush the contact site with large quantity of water and seek medical help when necessary. ■ If the system on accident on pollutants, wipe them away immediately and disinfect the contact site. Wipe supplies should be handled as potential sources of infection. ■ If the source of infection sticks to the appliances, wear protective gear to clean and disinfect them immediately. ■ If accidental swallowing the source of infection, seek medical help immediately.

Water Leakage Prevention

Caution

- To prevent water leaks, please ensure that the water supply and drainage hoses are installed in accordance with local regulations by personnel authorized by the Company only.
- Continuous attention should be paid to abnormal sound, liquid leakage or other abnormal conditions during use.
- If water leaks, take appropriate safety measures and contact the service department of the Company or authorized dealer(s).

Sample Processing

Sample Collection and Storage

Precautions

- Please refer to the instructions for use of the reagents for information about sample collection and storage. Improper sample storage may cause changes of the analytes in the sample.

Samples for Analysis

Precautions

- Clotting of the sample may block the filling needle and adversely affect the analysis results.
- The presence of chemicals (medicine, anticoagulant and antiseptic, etc.) in the sample could seriously affect the test results.
- High viscous sample may disrupt sample testing and affect the data reliability.
- Samples with microbial contamination, fibrous protein, cells or other particles, severe lipid blood, and severe hemolysis will affect the test results. Please refer to the reagent instructions for specific information.
- Do not mix samples for use.

Sample Preprocessing

Precautions

- Use only designated clean blood collection tubes and sample tubes (cups).
- Serum and plasma samples should be fully centrifuged to separate the blood cells and thus reducing the risks of disturbances. Before analysis, confirm that the sample is free of suspended substances, such as fibrin.
- Confirm that the anticoagulant or blood collection tube with a barrier and the sample tube are compatible with the test reagent.
- When using a blood collection tube that has been added with separating agent, confirm that the collected serum is sufficient to avoid separating agent contamination or filling needle blocking.
- Confirm that the sample volume is sufficient to guarantee sampling correctness.
- Before analysis, prevent sample evaporation or contamination.
- Confirm that there is no bubble in the sample.
- Analyzers i 800, i 820, i 6000, i 8000 and i 9000 models support auto dilution of samples. When using the Analyzer, for the retest on sample that exceeds the linear upper limit, you can select manual dilution on the operation interface and input the dilution ratio, and the Analyzer will test the manually diluted sample detect the manfully diluted sample and multiply the results with the dilution ratio. For information about the sample dilution ratio, refer to the relevant reagent instructions.

Handling Reagents, Wash buffers, Substrate Solutions, Calibrators and Controls



- Related to the storage (before and after unpacking), disposal and use of auxiliary reagent reagents, wash buffers, substrate solutions, calibrators and controls, please follow their respective instructions.
- Please ensure no bubbles when adding them to the reagent bottle. If bubbles form in the reagent bottle, measurement may be inaccurate due to insufficient sample aspiration.
- Follow all applicable warnings or suggestions regarding the carry-over between analytical items. If one reagent is contaminated by another during the analysis, it may affect the results. The actual interference effect depends on the reagent. Please contact the reagent manufacturer or dealer for detailed information. For the information on how to

	check the interference information, please contact the service department of our company or authorized dealer(s). ■ Reagents, calibrators, controls, waste, etc., have potential biological infectious risks, and some reagents and substrate solutions are strong acid or alkali, avoid contact with bare hands or clothing. The operation should comply with the laboratory safety operation regulations. Be sure to wear appropriate protective articles or comply with other protective requirements of the laboratory.

Disposal of Waste Liquids

	■ Special treatment may be required before the cleaning of certain waste liquid and mixture. For applicable methods about disposing of waste liquid, refer to the local and national rules and rules of other authorities. ■ For the disposal of waste liquids, hospitals should be equipped with the waste-discharge system for disposing of waste liquid, or the waste liquid may be disposed of by a designated treatment institution. ■ Waste liquids containing infectious pathogens must be disposed of according to relevant laws and regulations under the guidance of the personnel responsible for the management of infectious medical wastes.

Disposal of Wastes

	■ Special treatment may be required before the cleaning of certain solid waste and mixture. For applicable methods about disposing of solid waste, refer to the local and national rules and rules of other authorities. ■ All used cuvettes should be disposed as infectious waste. These materials should be properly disposed of according to relevant laws and regulations. ■ Waste samples, reagents and consumables should be disposed in accordance with the national biohazard safety guidelines or regulations, or in accordance with the relevant environmental protection regulations of the country of sale. ■ Users are responsible for the disposal, storage or discard of the used samples in accordance with predetermined

	standards. Therefore, it is recommended to extract and store some samples in advance to avoid accidental sample loss caused by errors in operation or other reasons.

Removal of Contaminants on the Panel

	■ Clean up the contaminants on the Analyzer surface in time, and dispose the items used in the cleaning as medical wastes.

Precautions for Manual Operation

Sample Reading Error Caused by Manual Registration

Precautions

- If a wrong position is entered for a sample during its manual registration, the obtained measurement result is that of another sample.
- Place the sample in the sample rack according to the procedure specified in this Manual, and confirm that the placed sample matches the set information.

Control Reading Error Caused by Manual Registration

Precautions

- An input error during the manual registration of controls will lead to incorrect QC results due to the use of non-compliant control.
- Therefore, when manually register a control, please enter its information according to the procedures specified in this Manual.

Starting Analysis

Precautions

- Confirm no one is performing maintenance, and operate the software to start analysis. If the Analyzer starts analysis during maintenance, the parts or tools used in maintenance may touch the operating mechanism and cause damage to the Analyzer.

Operation of the Analyzer

Precautions

- Operate and maintain the Analyzer according to the steps described in this Manual. Incorrect operation may lead to incorrect results or system failure.
- Confirm that the power supply, operating environment and grounding of the Analyzer meet the requirements, in order to ensure that the instrument works normally and safely.
- Be sure to wear protective appliances to avoid contamination by the infectious substances before using, inspecting or maintaining the Analyzer. Be sure to follow the specific regulation or user manual if there is any.
- Ensure the quality of purified water comply with regulations.
- Check the sample for foreign matters (dust, fibrous protein, etc.).
- Pay special attention when placing calibrators, controls, and samples on the Analyzer for testing. Incorrect placement will lead to incorrect analysis results.
- An inclined reagent bottle may lead to incorrect results or damage the filling needle.
- Check to confirm that all items to be tested have passed the calibration and that the calibration has not expired.
- When checking the stability of the reagent and the operation of the Analyzer, test the controls to ensure accurate control. Ensure that the results of the controls meet the requirements, and check the QC data before testing the patients' samples.
- Don't open the cover of the Analyzer's test module or the cover of the working chamber, or the test results may be inaccurate.
- Don't touch any part of the Analyzer while it is running.
- Check the sample number and sample ID after the analysis results are transmitted to the host to ensure all data are transmitted correctly.
- In case of any leak at the Analyzer, the leaking liquid is bio-infectious.
- Check whether there is any abnormality prompt in the analytical results.
- Check the analysis results obtained, as well as the test results of the contrast samples obtained before and after the analysis results are obtained to confirm that whether these results are normal.
- Clean the filling needle and the injection/aspirating needle in the magnetic separation system regularly to ensure that the surface is free from dirt; otherwise it will lead to failure of the Analyzer or inaccurate results.
- Don't use expired samples, reagents or other relevant liquids, or it may lead to analysis error or inaccurate results.
- Wear protective gloves when operating the filling needle or any other sharp

parts to avoid personal injury.

- Don't leave the samples, calibrators or controls in the air for a long time, otherwise they will be concentrated due to evaporation, and cannot be analyzed accurately, resulting in inaccurate results.
- Don't re-add reagents, or cross contamination may occur, resulting in inaccurate results.
- Pipeline filling is required before analysis each day, otherwise the analysis results will be inaccurate.
- Exposure to sample rack, cuvette bracket, sample mechanism, reagent dispensing mechanism, cleaning mechanism, or other mechanisms may result in infection or injury.
- Ensure that the Analyzer is in standby state before maintenance.
- The surface of all components of the Analyzer is potentially bio-infectious and safety precautions should be taken during operation and maintenance.
- Replace the vulnerable parts in time; otherwise it will lead to inaccurate results.
- Be sure to wear protective equipment and follow the procedures specified in this Manual during maintenance and inspection.
- When the Analyzer is running, switch to STAT mode and put in or take out the samples. Withdraw the rack to a safe and accessible place in the rack tray before putting in or taking out samples.
- In the event of an alarm at the sample arm or sample rack, the samples cannot be put in or taken out even under STAT mode.

Computer Security

Data Backup

Precautions

- If the Analyzer malfunctions or is operated incorrectly, it is unable to view or use the analysis results and parameters. For safety reasons, it is recommended that you regularly back up the measurement results and parameters.

Computer Operation

Precautions

- Long-time looking at the LCD screen in the same posture will aggravate the fatigue of your body and eyes. For your health, please rest for 10~15min after watching the LCD screen continuously for one hour. Ensure less than 6 hours of continuous looking at the LCD screen every day.

Computer Virus Protection

Precautions

- Once a computer is infected with a virus, the virus may spread to other computers through communication or storage media.
- Don't use programs or storage media with suspected viruses.
- Before using a portable storage medium, use an antivirus program to check it for viruses.
- The computer hardware should be used exclusively for running the system software, and should not be connected to the network without instructions from the Company to avoid software virus attack.
- Your computer may have been attacked by a computer virus if programs or data suddenly corrupted or something unexpected appear during operation or on the screen.
- A computer virus is a malicious program that infiltrates a computer and causes data anomalies or corruption.
- Programs designed to protect against computer viruses are called antivirus programs.
- Possible causes of virus attack: downloading of a program with a virus during communication.

Precautions for Control Unit Operation

Precautions

- If the control unit is suddenly powered off in the process of accessing a hard disk or other portable media, the data/software stored in it may be damaged. Refer to the relevant section of the Manual for the proper way to power off the control unit.
- Don't install other programs into the control unit or change the settings of the unit.
- Don't remove the portable medium when its indicator is on; otherwise the instrument or the portable medium will be damaged.
- Don't put magnetic objects close to the display; otherwise they may be damaged.

Component Replacement and Routine Maintenance

Precautions

- Before maintenance, ensure that the moving parts have stopped running. Otherwise, mechanical injury may be caused to the operator.
- To ensure the system performance, replace the components according to the instructions, and maintain and inspect the system periodically.
- After key parts (such as the filling needle) are replaced, calibration may be required. After parts replacement or major maintenance, it is strongly recommended to implement control analysis. If any deviation is observed, recalibrate the system.
- Develop a maintenance plan for the Analyzer and follow the plan. Please refer to Chapter 6 User Services for details of our recommended maintenance plan. Failure to maintain the system according to these guidelines cannot guarantee the performance and operation safety of the system.
- Only the engineer approved by the Company has the right to replace the Analyzer's components.
- Don't modify the Analyzer or use parts that are not specified; otherwise hazards may be caused.
- The Analyzer must be maintained with the parts provided by the Company. If you have any question, please contact the service department of the Company or authorized dealer(s).
- This Manual is not a maintenance manual and only provides the measures to be taken by the operator in case of failure alarm of the Analyzer.
- Avoid using organic solvents other than maintenance solvent.

Other Warnings

⚠ Warning

- The system can only be operated by professional inspectors, physicians or laboratory operators trained by the Company or the authorized dealers.
- If the hospital or institution that is responsible for the Analyzer fails to provide a good maintenance plan, it may result in failure of the Analyzer and may endanger human health.
- Ensure that the Analyzer is used under the operating conditions specified in the instruction manual. If the operating conditions are beyond the specifications, the Analyzer may not operate normally, the measurement results are not reliable, and the Analyzer components may be damaged and

personal safety may be harmed.

- The Analyzer should be used with a good grounded condition.
- It should be confirmed that the voltage meets the requirements.
- Don't place the instrument close to any interference source of electromagnetic wave; otherwise it will cause interference to the instrument, inaccurate results, or even instrument failure.
- Don't move the Analyzer without authorization. If needed, please contact the service department or the Company or authorized dealer(s).
- The reagent is irritative to eyes, skin and mucosa. The operator should abide by the laboratory's operating safety regulations and wear personal protective appliances for contacting reagent-related articles.
- Reagents, waste liquids, waste samples, etc. should be disposed in line with the relevant local and national regulations on the disposal of these materials and other relevant biological infectious materials.
- Please pay close attention when using the filling needle, as it is thin and the calibrator, control and sample it carries are potentially biologically infectious.
- Packages of the waste calibrators and controls should be disposed in line with the relevant local and national regulations on the disposal of reagents, wastes and other relevant biological infectious materials.
- Only engineers and operators approved by the Company can carry out operation and maintenance, otherwise harmful radiation emission may be caused.

Other Attentions

Precautions

- This Analyzer is used for clinical screening. When making judgments based on the analysis results, the physician should also take into account the clinical examination results or other test results.
- Before using the Analyzer every day, check the reagent allowance and estimate whether it is enough for the sample use of the day. In case of any shortage, prepare the reagent in advance in time.
- Unpacking or installation by personnel not authorized or trained the Company may cause damage to the Analyzer, so do not unpack or install the instrument without the presence of authorized personnel.
- After a sample is analyzed, the sample number will be automatically incremented by +1. Therefore, as long as the samples on the worksheet are registered in order, there is no need to open the manual specimen numbers during the test.
- To ensure the reliability and stability of the Analyzer, be sure to execute the

shutdown procedure after the analysis.

- Please check the installation, connection and remaining paper of the printer before executing the report printout.
- The user should use the controls and calibrators designated by the Company and store them in strict accordance with the storage environment designated in the user manuals.
- Incorrect maintenance may cause damage to the Analyzer. The operator should carry out the maintenance in strict accordance with the Manual.
- In case of problems not specified in the Manual, please contact the service department of the Company or authorized dealer(s) for assigning professionals to give maintenance suggestions.

Not all unexpected situations can be predicted and the hazard warning signs in this Manual and on the instrument cannot cover all possible situations, so only following the given instructions is far from enough for operation. Please be alert and apply common sense while operating the instrument.

Our Authorized Representative in the EU

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CE

Disposal of the Analyzer

- Contact the service department of the Company or authorized dealer(s) for safe procedures for disposing the Analyzer.
- The Analyzer should be disposed in strict accordance with the local regulations.

Vigilance

- If any serious incident has occurred in relation to this product, please contact the manufacturer and report to the local competent authority.



Chapter 1
System Introduction

1.1 Overview

The Analyzer is a type of in vitro diagnostic equipment and constitutes a closed system with its relevant reagents for determining the concentration of various substances in the sample. This chapter describes the reaction principle, working principle, application scope and hardware composition of the system.
Based on different sample dilution times, the Analyzer is divided into five models: i 800, i 820, i 6000, i 8000, and i 9000.

Model	Speed	Division basis
i 800	Up to 200 tests/h	With in-machine sample dilution function, the maximum dilution factor: 6400 times
i 820	Up to 200 tests/h	With in-machine sample dilution function, the maximum dilution factor: 3200 times
i 6000	Up to 200 tests/h	With in-machine sample dilution function, the maximum dilution factor: 2000 times
i 8000	Up to 200 tests/h	With in-machine sample dilution function, the maximum dilution factor: 1600 times
i 9000	Up to 200 tests/h	With in-machine sample dilution function, the maximum dilution factor: 1000 times

Precautions

This Analyzer is used for clinical screening. When making judgments based on the analysis results, the physician should also take into account the clinical examination results or other test results.

1.2 Reaction Principle

The Analyzer adopts the direct chemiluminescence immunoassay principle to test clinical serum/plasma/whole blood/urine and other samples. The chemiluminescence reagent used is acridinium ester (AE). Through heterogeneous reaction, the magnetic separation of magnetic particles can achieve the separation of immune complex from other substances that are not involved in the reaction.

Based on the different immunoreaction mode, it can be classified into sandwich method, competitive method, and capture method.

Sandwich method
Based on the test object, sandwich method can be classified into double-antibody

sandwich method and double-antigen sandwich method.

The basic principle of double-antibody sandwich method is that the specific antibody connected to the solid state magnetic particle and the AE-marked specific antibody combine with two different epitopes on the test antigen, to form the "antibody-antigen-antibody" immune complex. Magnetic particles are absorbed by the magnetic field, and the immune complex aggregates directionally. Then, other substances that are not involved in the reaction can be removed through washing. After the substrate is added, chemiluminescence reaction occurs to the AE on the immune complex and the substrate. The chemiluminescence signal can be measured with the instrument, and the chemiluminescence signal value is directly proportional to the concentration of the test antigen in the sample.

The basic principle of double-antigen sandwich method is as follows: the specific antigen connected to the solid state magnetic particle and the AE-marked specific antibody combine with two different sites on the test antibody, to form the "antigen-antibody-antigen" immune complex. Magnetic particles are absorbed by the magnetic field, and the immune complex aggregates directionally. Then, other substances that are not involved in the reaction can be removed through washing. After the substrate is added, chemiluminescence reaction occurs to the AE on the immune complex and the substrate. The chemiluminescence signal can be measured with the instrument, and the chemiluminescence signal value is directly proportional to the concentration of the test antibody in the sample.

Competitive method

Based on the test object, competitive method can be classified into double-antigen competitive method and double-antibody competitive method.

Double-antigen competitive method is used for the test on antigen, and its basic principle is as follows: the AE-marked antigen and the test antigen in the sample compete to combine with the antibody connected to the solid state magnetic particle, to form the "AE-antigen-antibody" and the "sample antigen-antibody" immune complexes. Magnetic particles are absorbed by the magnetic field, and the two types of immune complexes aggregate directionally. Then, other substances that are not involved in the reaction can be removed through washing. After the substrate is added, chemiluminescence reaction occurs to the AE on the "AE-antigen-antibody" immune complex and the substrate. The chemiluminescence signal can be measured with the instrument, and the chemiluminescence signal value is inversely proportional to the concentration of the test antigen in the sample.

Double-antibody competitive method is used for the test on antibody, and its basic principle is as follows: the AE-marked antibody and the test antibody in the sample compete to combine with the antigen connected to the solid state magnetic particle, to form the "AE-antibody-antigen" and the "sample antibody-antigen"

immune complexes. Magnetic particles are absorbed by the magnetic field, and the two types of immune complexes aggregate directionally. Then, other substances that are not involved in the reaction can be removed through washing. After the substrate is added, chemiluminescence reaction occurs to the AE on the "AE-antibody-antigen" immune complex and the substrate. The chemiluminescence signal can be measured with the instrument, and the chemiluminescence signal value is inversely proportional to the concentration of the test antibody in the sample.

Capture method

Capture method can be classified into capture method and reverse capture method (indirect method).

For both of them, the basic principle is as follows: the secondary antibody captures the antibody, and form the "secondary antibody-antibody-antigen" immune complex with the antigen. The difference is that, for capture method, the secondary antibody connects to the solid state magnetic particle, and the antigen connects to the AE; while for indirect method, the antigen connects to the solid state magnetic particle, and the secondary antibody connects to the AE. Magnetic particles are absorbed by the magnetic field, and the immune complex aggregates directionally. Then, other substances that are not involved in the reaction can be removed through washing. After the substrate is added, chemiluminescence reaction occurs to the AE on the immune complex and the substrate. The chemiluminescence signal can be measured with the instrument, and the chemiluminescence signal value is directly proportional to the concentration of the test antibody in the sample

1.3 Working Principle

Analyzer Principle

The Automatic Chemiluminescence Analyzer adopts the controller area network (CAN) bus technology to automatically implement the entire process of chemiluminescence immunoassay reaction based on magnetic particles.

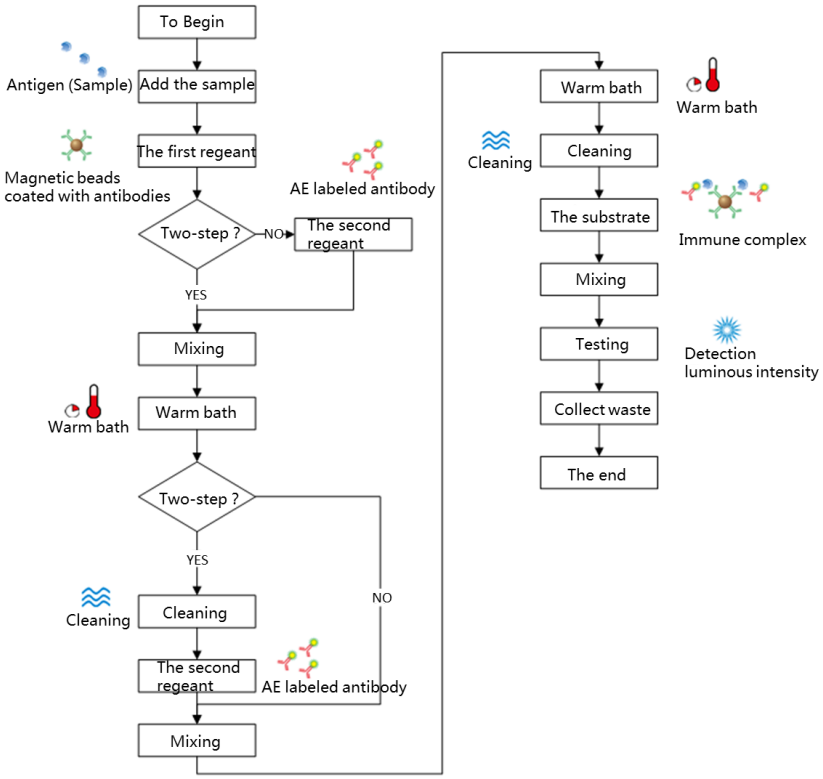
Actuator

By integrating precision fluid operation unit, temperature control unit, result test unit and auto operation and transfer unit, the Analyzer realizes the fully automated process from sample filling, reagent filling, reaction liquid incubation reaction, reaction liquid filling washing, and reaction result test and analysis.

The Automated Chemiluminescence Analyzer supports both one-step and two-step approaches.

Analysis Process

Taking sandwich ELISA as an example, the analysis procedure is as shown in the following figure:



1.4 Scope of Application

The product is based on the principle of direct chemiluminescence and is used in conjunction with reagents, calibrators, controls and other accessories from Maccura Biotechnology Co.,Ltd for qualitative and/or quantitative analysis of analytes in serum/plasma/whole blood/urine/other samples, including clinical immunization items, is only suitable for in vitro diagnosis.

1.5 Hardware System

- Structures

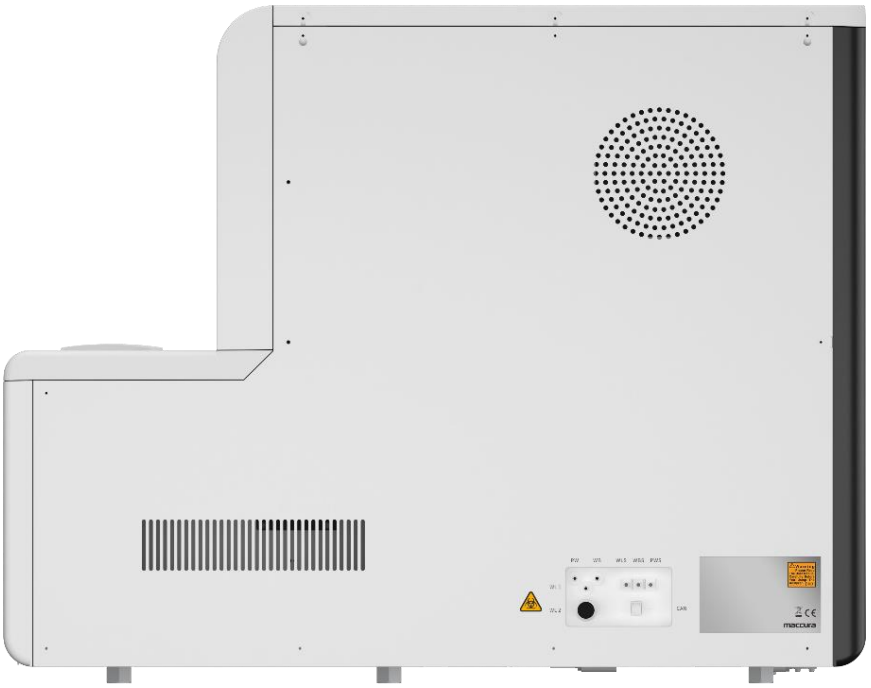
The product mainly consists of the filling system, sampling system, cuvette transfer system, reaction system, cuvette bracket system, reagent storage system, magnetic separation system, test system, transfer system, pipeline system, IPC and software (release version V1).

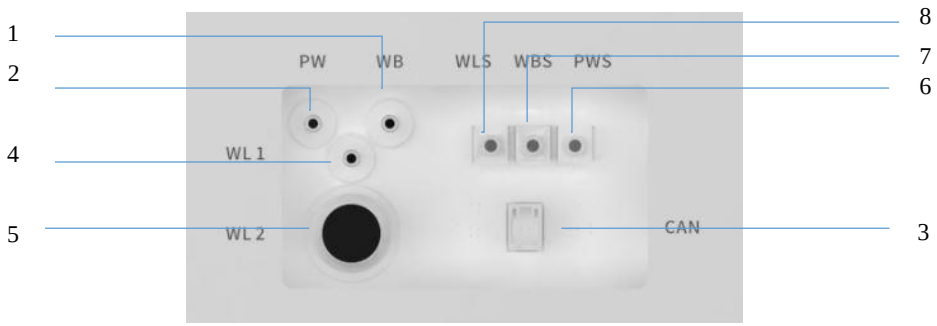
- Front View of the Analyzer



SN	Name	Function Description
1	Analyzer status indicator	Displays the current state of the Analyzer. Green: normal; Red: stop; Yellow: alarm.
2	Waste container status indicator	Light in green: removed; Off: normal.
3	Cuvette indicator	Light in green: removed; Off: normal.
4	Computer switch button	Switch button for the computer inside the Analyzer

- Rear View of the Analyzer





SN	Name	Function Description
1	Wash buffer port	Used to connect to the Wash buffer pipe.
2	Purified water port	Used to connect to the purified water pipe.
3	CAN port	Used for communication with external dilution.
4	Waste liquid port 1	Used to connect to slim waste liquid pipe A
5	Waste liquid port 2	Used to connect to thick waste liquid pipe B
6	Purified water sensor port	Used to connect to the purified water container sensor.
7	Wash buffer sensor port	Used to connect to the Wash buffer container sensor.
8	Waste liquid sensor port	Used to connect to the waste liquid container sensor.

- Left View of the Analyzer





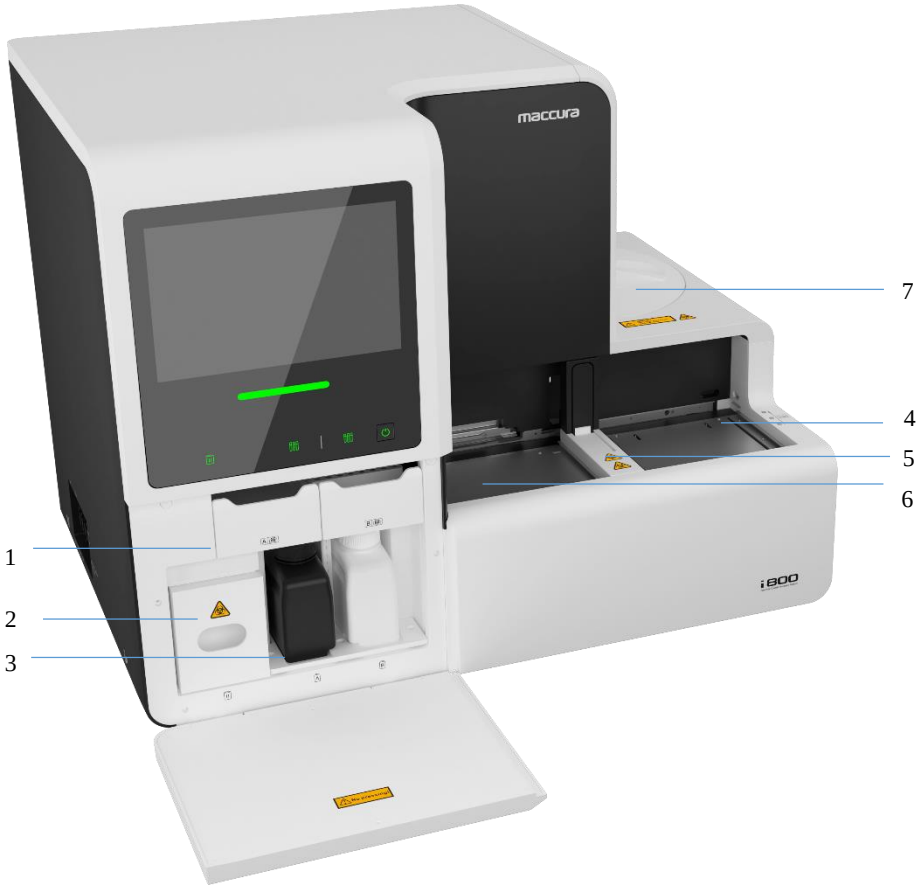
SN	Name	Function Description
1	Power switch	A switch used to control the power supply to the Analyzer.
2	Power cable port	Provides a port for power cable connection.
3	LAN interface	Used for communication with the Analyzer computer.
4	RS232	For serial communication
5	USB1-USB4	To connect external USB devices
6	Fuse	To protect circuit security

- Right View of the Analyzer



SN	Name	Function Description
1	Lifting position	To prompt that the device should be moved here
2	Do not move here	To prompt that the device should not be moved here
3	Air inlet Dust filter	Dustproofing at the bottom

- Details of the Analyzer



SN	Name	Function Description
1	Position for adding cuvette	Used to add the cuvette.
2	Solid waste container	Used to collect the cuvettes after test.
3	Substrate module	Used to store substrate.
4	Sampling channel	The position where test samples are placed.
5	STAT position	Used to place 1 STAT sample
6	Rack withdrawing channel	Used to place tested samples
7	Reagent compartment	Used to store reagent for test.

1.6 Software Operation Interface

1.6.1 Login Interface

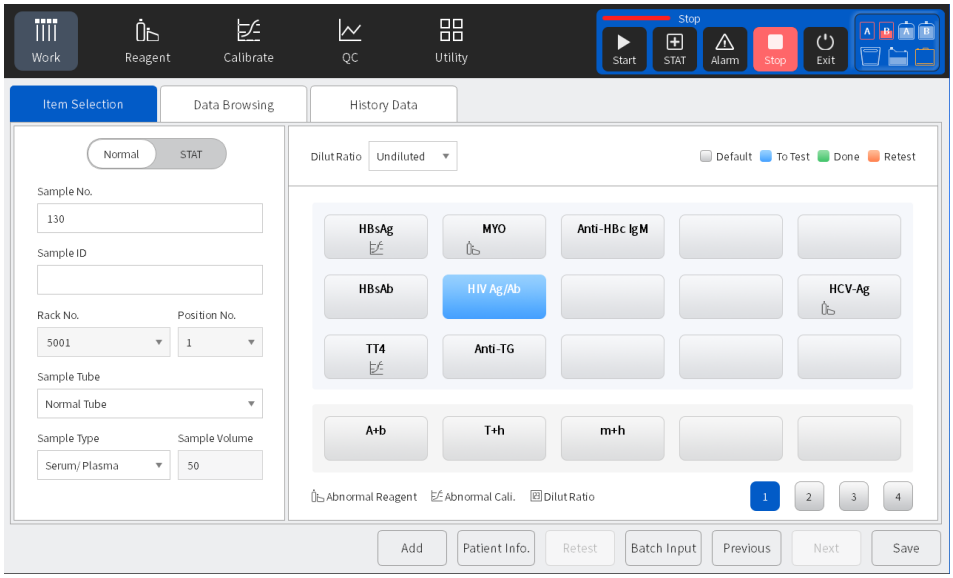
After startup, the Analyzer will automatically run the user software, and the login interface will be displayed after startup. You can log in after entering the username and password.

Note: Use the default username and password when you log in for the first time. Please change the username and password in time after you successfully log in.

Click "" on the left of "Login" to exit the software.

1.6.2 Interface Layout

After successful login, the interface layout can be displayed, as shown in the figure.



Interface Layout

Title Bar

The interface displays the running status of the Analyzer, menu, submenus, view area, current login username, system date and time.

Running Status Area

For convenient operation, shortcut buttons are set on the upper right side of the screen, including startup, STAT, alarm, stop and exit.

General menu	Function Key	Purpose
Start	OK	To start sample test
	Automatic Retest	To enable or disable the automatic retest function
	Host communication	To enable or disable the communication function
	Item Mask	To disable the items
	Cancel	Exit the menu
STAT		To start STAT sample test
Alarm		View the alarm information
	Cancel	Exit the menu
Stop		The Analyzer stops all actions and enters the shutdown state.
Exit	Exit the program	Shut down the program
	Switch user	Change account login

Function Menu Area

The area includes Menu and Submenus. Menu includes five functional menus: "Work", "Reagent", "Calibration", "QC", and "Utility". Each menu has many submenus. For example, the work menu with submenus includes "Test Selection" and "Data Review", and "History Data".

Function menu

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
Work	Item Selection		<Sample item input>
		Add	Switch to the new sample interface
		Patient Info.	Enter information, such as name and age
		Retest	Set the rack number and position number for manual retest
		Batch Input	Enter multiple samples with the same parameters and test items in lots
		Previous	View information about the previous sample
		Next	View information about the next sample
		Save	Save the selection information for the current sample
	Data Browsing		< View sample information and sample-related project information >
		Screen	Search for samples by setting filter criteria
		Item Browsing	View the detailed project information of the selected sample

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
		Select All	Select all on the sample list
		Delete	Deletes the selected sample information
		Review	Review/Cancel the selected samples
		Print	Print or export the selected samples with a printer
		Transmit	Manually send test results to the reporting system
		Export	Export the sample test results to the computer hard drive
	History Data	Query	Search for samples by setting search criteria
		Select All	Select all on the sample list
		Review	Review/Cancel the selected samples
		Print	Print or export the selected samples with a printer
		Transmit	Manually send test results to the reporting system
		Export	Export the sample test results to the computer hard drive
Reagent	Reagent Status		< Display reagent tray, reagent status, substrate remaining volume, Wash buffer remaining volume, residual number of cuvettes and waste container status >

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
		Renew Reagents	Load or unload reagents and diluents in the running, sample injection or stop states
		Substrate Fill	Perform substrate filling on the replaced substrate
		Rotate Reagent Tray	Rotate the reagent tray to find the reagent position to operate
		Reagent Scanning	Scan all reagents and diluents in the reagent storage system and update reagent and diluent information
		Mag. Bead Mix	Rotate the reagent tray and perform magnetic bead mixing maintenance
		Priority Use	If there are the same reagents, choose the one with the priority use.
	Reagent Info.		< View reagent details >
		Renew Reagents	Load or unload reagents and diluents in the running, sample injection or stop states
		Substrate Fill	Perform substrate filling on the replaced substrate
		Rotate Reagent Tray	Rotate the reagent tray to find the

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
			reagent position to operate
		Reagent Scanning	Scan all reagents and diluents in the reagent storage system and update reagent and diluent information
		Mag. Bead Mix	Rotate the reagent tray and perform magnetic bead mixing maintenance
		Priority Use	If there are the same reagents, choose the one with the priority use.
	Consumable Info.		< View details of all consumables of the module >
Calibrate	Calibration Status		< View calibration information for all in-machine items >
		Calibration Results	View the current calibration results for the selected items
		Instr. Coeff.	Input calibration factors
		Select	When the barcode of the calibration product is damaged, manually select the item for calibration
	Calibration History		View the calibration information of the selected item for the last 50 times
	Calibration Setting		< Set calibrators for calibration >

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
		Scan	Scan the barcode of the calibrator and record the calibrator information
		Delete	Delete the scanned barcode information
QC	QC status		< View QC information of module project >
		Default QC	Set the default QC item information
		Backup Vial QC	Select the QC items to be used for the backup vial
		Select	Select or cancel the QC item information
	Levey-Jennings Graph		Display the information of all controls of the selected items, the latest 500 QC records of the selected items, and the Levey-Jennings QC chart
		QC chart	Display the QC chart for the selected item
		Detail	View the detailed information about the test result
		Print	Print QC chart and data
		OOC Trtm	Edit out-of-control reasons and corrective measures
		TGT VAL SD	Update the set target value and

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
			standard deviation to the current cumulative target value and standard deviation
		Calculate	Select by default. If it is deselected, it will not be included in the QC data statistics and will not be displayed in the QC chart
	Twin-Plot Graph		Display the previous 500 groups of joint QC records and Twin-Plot graph of the selected item within the set time
		Detail	View the detailed information about the test result
		Print	Print QC chart and data
		OOC Trtm	Edit out-of-control reasons and corrective measures
		Calculate	Select by default. If it is deselected, it will not be included in the QC data statistics and will not be displayed in the QC chart
	QC Setting		< Add or remove information related to controls >
		Manual	Input the information of controls manually

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
		Scan	Scan the barcode of controls
		Download	Download the information of controls from the Internet
		Modify	Modify control information
		Delete	Delete a QC item
		OOC Rule	Select the out-of-control rule of the items
		Edit	Edit and select the target value and standard deviation of the controls
		Save	Save the changed target values and standard deviations
Utility	Item		< Project parameter information >
		Para DL	Get parameter information of items
		Delete	Delete parameter information of items
		Alternative Unit	Add alternative units
		Save	Save current changes
		REF Range	Reference interval setting of items
	Maint.		< View, set and perform maintenance items of the Analyzer>
		Instrument Maintenance	Run the maintenance program of the Analyzer

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
		Maintenance Log	Display the maintenance status
		Alarm Info.	Display the alarm information
		Temperature Check	Temperature display in each area
	System		< General settings, such as mode setting, display setting, and user setting >
		Automatic Startup Setting	Set the automatic daily startup time
		Alarm Setting	Set the alarm value
		User Management	Set the username, password, and operating authorization
		Profile Setting	Set the group items
		Item Position	Assign keys to test items
		Calculation Item	Set calculation items
		Calibration Mask	Set the item to be calibrated and shielded
		Print Setting	Set the print content of the report form
		Communication Settings	Communication settings
		Maintenance Settings	Set multiple maintenance items into groups
		Language Setting	Select the operating software language
		Automatic Maintenance Setting	Set regular maintenance

Menu	Submenu	Function Key/Input Box	Meaning or Purpose
		Remote Assistance	Set network assistance parameters
		Version Information	Display software version
		Help Documentation	Display help documents
		Sample Scanning	Turn on and off the sample barcode scanning switch
		Ext Dilution Module	Turn on and off the external dilution module switch
		Fast Mode	Turn on and off the quick mode switch
		Enable Review	Enable and disable the audit button function
		Enable WLB	Open and close the waste liquid container connection
		Standby Maintenance INR	Set the automatic maintenance interval of the Analyzer

Viewport

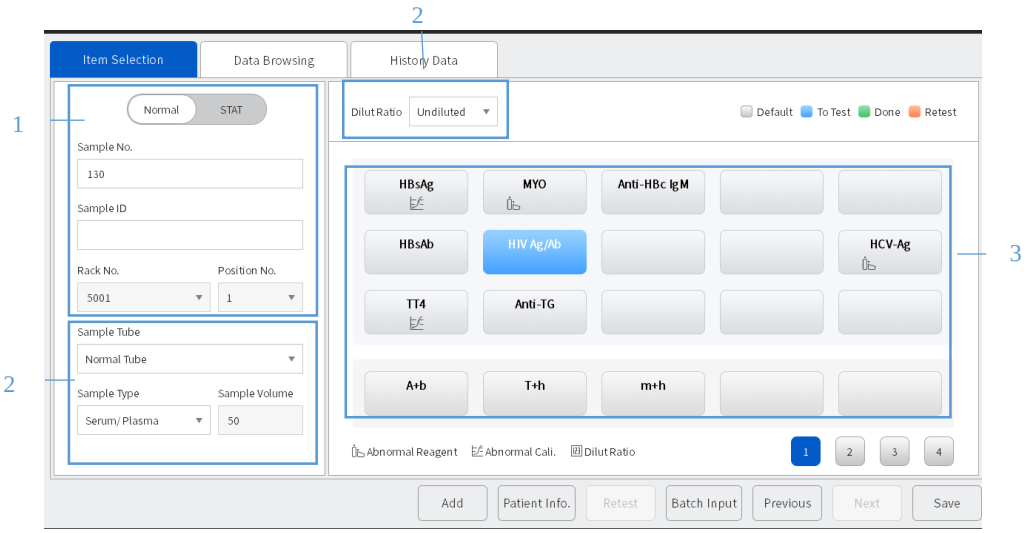
This area displays information corresponding to the selected submenu in the form of a dialog box.

1.6.3 Work Interface

Upon successful login, the "Work" interface is displayed by default. By clicking an icon on this interface, you can access the corresponding function interface.

■ Item Selection

On this interface, you can manually add or delete general or STAT samples, set test item or combination item and set the sample tube type and dilution ration, as shown in the figure.



Item Selection

1 Sample Area

Normal: Select this item as a general sample to input the test item

STAT: Select this item as a STAT sample to input the test item

Sample No: Input the sample number; range: 1 to 999999999999. After the sample number is saved, the number of the next sample will automatically increase by one (N+1)

Sample ID: Scan or input the sample barcode; up to 25-digit 1D barcode is supported

Rack No.: Set the rack number where the sample are

Position No.: Set the sample position number.

2 Sample test conditions

Sample Type : Serum/Plasma/Whole blood/Urine/Other

Sample Tube: General sample tube, micro sample tube

Dilut Ratio: Select the dilution ratio of the item to be diluted.

Sample Volume: Statistics of the sampling amount of all items of the current sample.

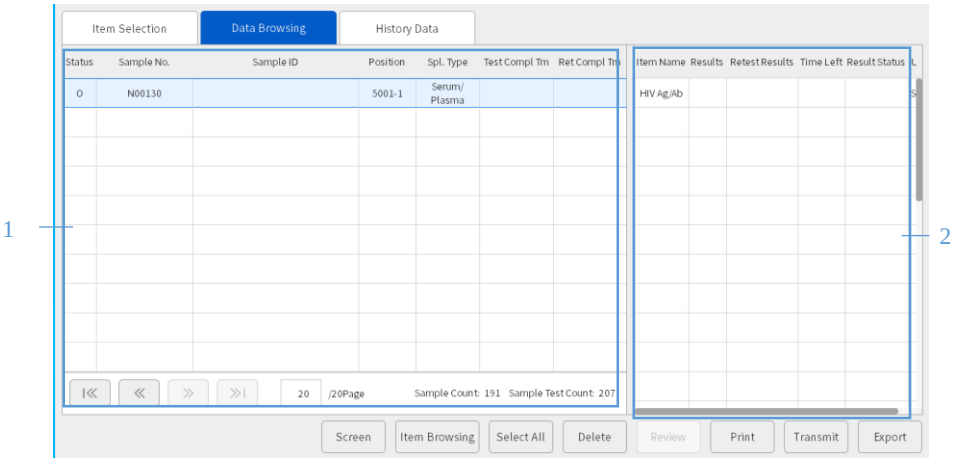
3 Item selection

Icons for selecting item viewports are described as follows:

Icon	Description
	No item
	Items to be tested
	Tested items
	Items to be retested
	When the item will be diluted, the dilution ratio is shown below the item
	When the item reagent is abnormal, it will be displayed below the item.
	When the item calibration is abnormal, it will be displayed below the item.

■ Data Browsing

This interface displays the sample items and results, as shown in the figure.



Data Browsing

1 Sample List

Sample status:

Displayed Content	Description
H	Processing and transmission completed
P	Processing
O	Waiting for processing
Nothing	Test completed

Sample No: Display the sample number

Sample ID: Display the sample barcode

Note: When sample scanning is closed, the Sample No is displayed. When sample scanning is open, the Sample ID is displayed.

Position: Display the position of the sample during test.

Test Compl Tm: The end time of test.

Retest Compl Tm: The end time of retest.

2. Result List

This area displays all result information of the currently selected sample, including " Item Name", "Results", "Retest Results", "Time Left", "Status Result" and "Unit".

Note: The system displays only the last retest result.

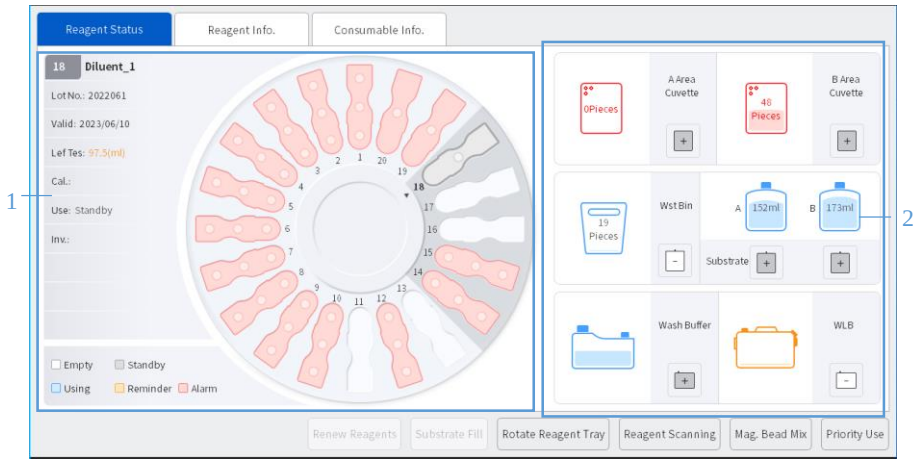
■ History Data

Display the information about all test results for history samples.

1.6.4 Reagent Interface

On this interface, you can view reagents, consumables and their details, and use function keys to manage the reagents and consumables.

■ Reagent Status



Reagent Status

1 Reagent Compartment Status

Display the reagent position and status in the reagent compartment and select the reagent position to view the detailed information of the reagent at this position.

2 Consumables Status

Display the status of cuvettes, solid waste, substrates, Wash buffer and waste liquid containers.

Cuvettes in area A and area B: Add the cuvette and show the vacancy and available position of the cuvette for details.

Empty the waste container: When the Analyzer is in standby or running state, empty the waste container.

Add the substrate: Add substrates A and B.

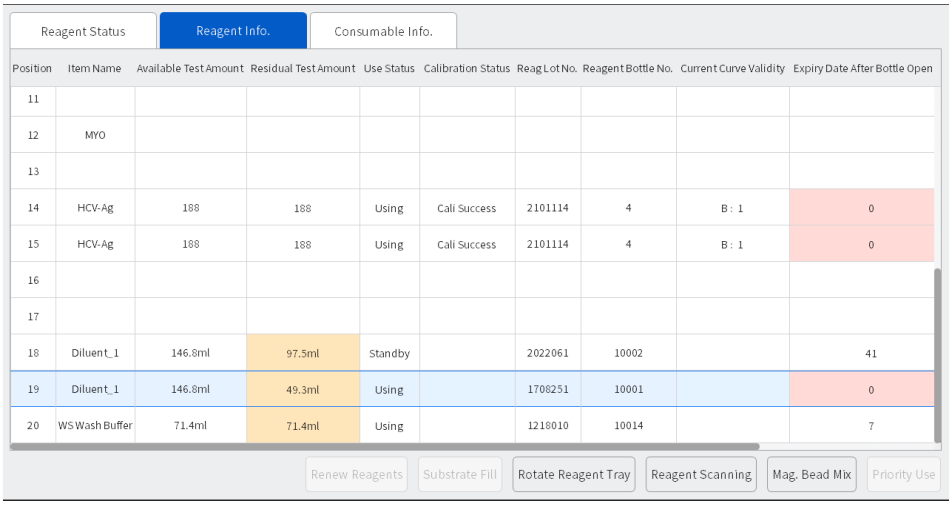
Add Wash buffer: Add the Wash buffer.

Empty the waste liquid container: When the Analyzer is in standby or running state, empty the waste liquid container.

■ Reagent Info.

In this interface, the user can view the information of each bottle of reagent, including item name, available test amount, residual test amount, etc., as shown in

the figure.



Reagent info.

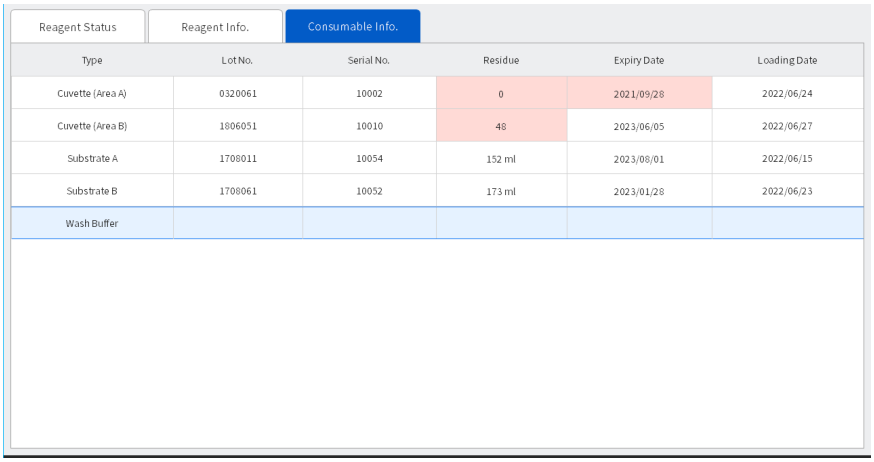
Reagent Information List

Detailed information of each reagent position in the current Reagent compartment is displayed. The meanings of each column are as follows:

Title	Description
Position	Display the reagent tray position of the current reagent bottle.
Item Name	Display the item name
Available Test Amount	Display the times of tests that can be used for sample reagent test
Residual Test Amount	Display the times of tests for loaded reagent of the current item
Use Status	Display the usage status of the current reagent
Calibration Status	Display the calibration status of the current reagent
Reagent Lot No.	Display the lot number of the current reagent
Reagent Bottle No.	Display the bottle number of the current reagent
Current Curve Validity	Display the remaining valid days of the current calibration curve
Expiry Date After Bottle Open	Display the number of available days left after the current reagent is opened
Expiry Date Of Reagent	Display the number of days remaining valid for the current reagent
Loading Time	Display the first scanning time of the current reagent

■ Consumable Info.

In this interface, the user can view the information of all consumables that the Analyzer has scanned the barcode, as shown in the figure.



Consumable Info.

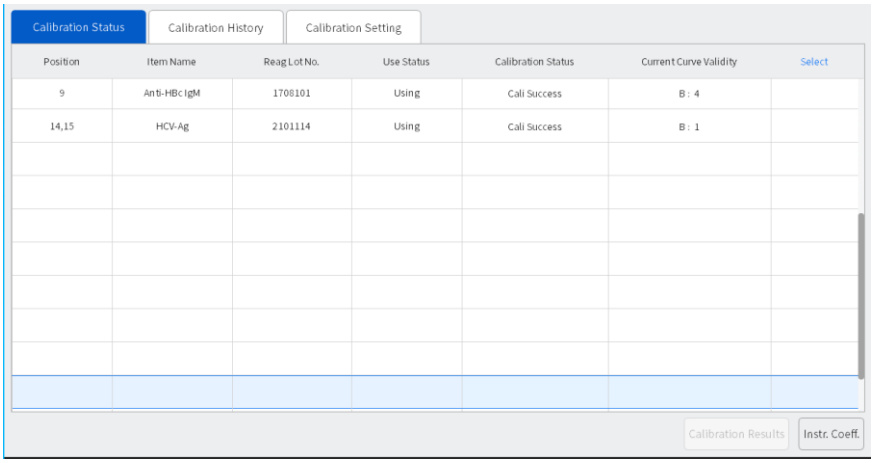
Consumables List

Title	Description
Type	Display types of consumables
Lot No.	Display the lot number of consumables
Serial No.	Display the unique number of substrates and Wash buffers
Residue	Display the remaining consumables
Expiry Date	Expiration date of consumables
Loading Date	On-machine time of consumables loading

1.6.5 Calibration Interface

■ Calibration Status

Click "Calibration" in the function menu to display the calibration overview interface as shown in the figure.

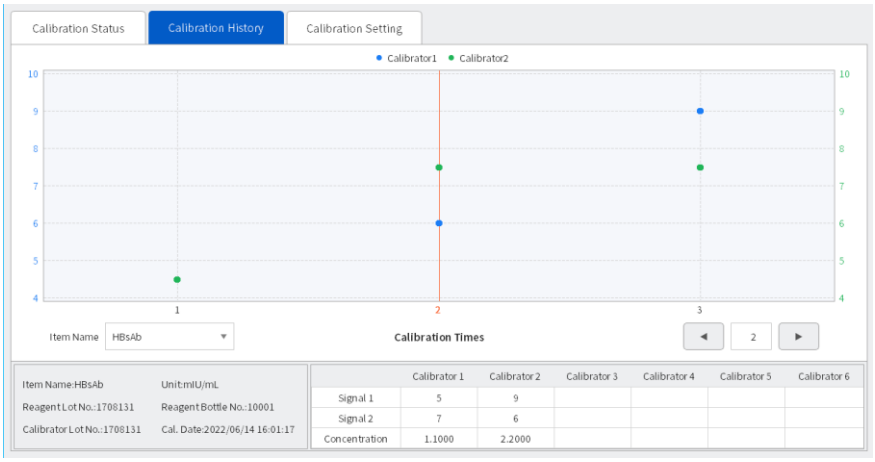


Calibration Status

Title	Description
Position	Display the reagent tray position of the current reagent bottle
Item Name	Display the item name
Reagent lot No.	Display the lot number of the bottle
Use Status	Being used, Standby
Calibration Status	Calibrating, Not Calibrate, Calibration Success, and Calibration Failure
Current curve Validity	Display the number of days remaining valid for calibration of the bottle/lot
Select	Select a bottle of reagent for calibration

■ Calibration History

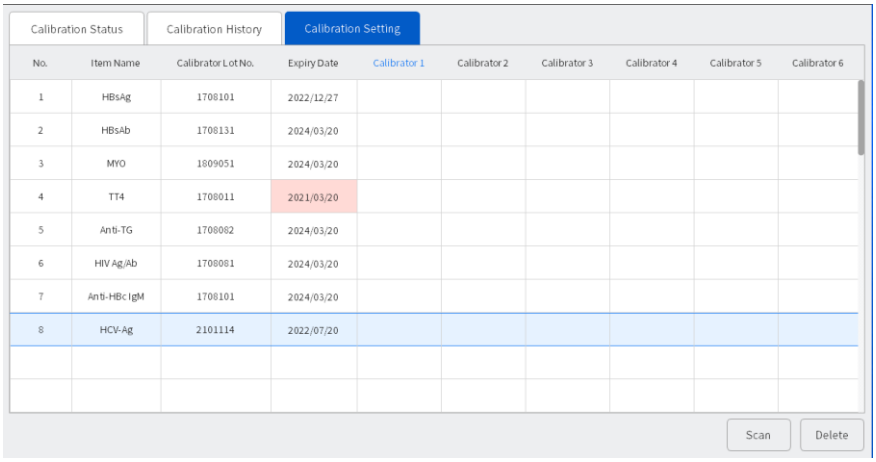
View the calibration information of the selected item for the last 50 times.



Calibration History

■ Calibration Setting

Use a handheld scanner to scan the calibrator barcode, set the position of the calibrator on the calibration rack, etc. The calibration setting interface is shown in the figure.



Calibration setting

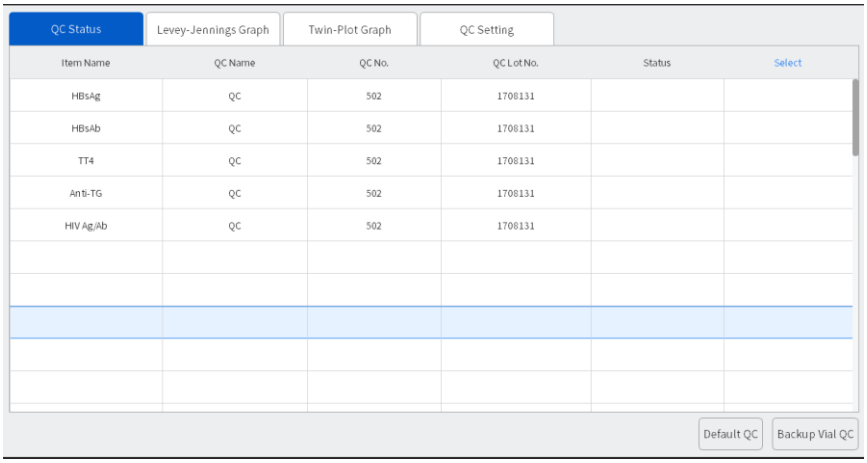
Title	Description
No.	Display the serials number
Item Name	Display the scanned calibration item name.
Calibrator Lot No.	Display the scanned calibration lot number.
Expiry Date	Display the scanned calibrator expiration date
Calibrator	Allocate positions for level calibrators (for details, refer to Chapter 4 Calibration)

1.6.6 QC Interface

Click "QC" in the function menu to enter the QC interface.

■ QC Status

Click "QC" and the system will enter the "QC Status" menu by default, as shown in the figure.

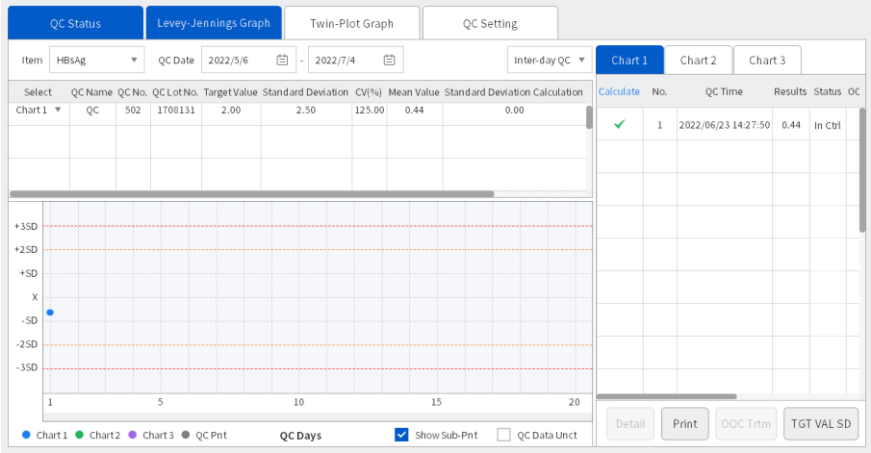


QC Status

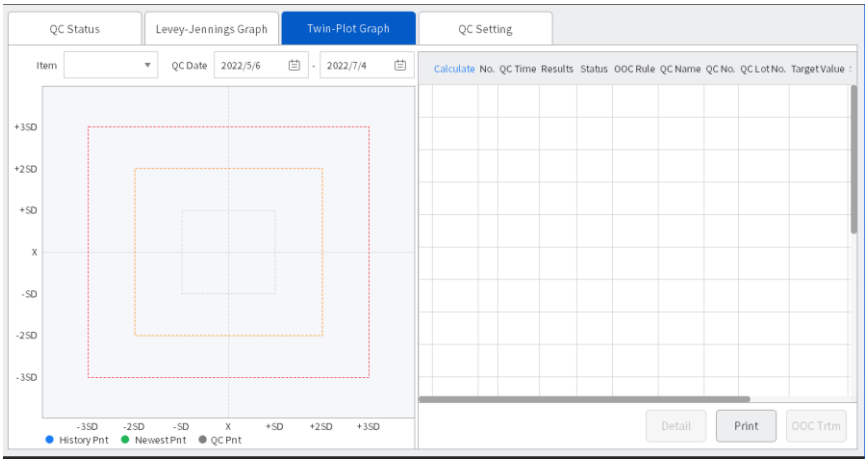
The QC status interface will display the" Item Name ", "QC Name", "QC No.", "QC Lot No.", "Select" and "Status".

■ "Levey-Jennings Graph" or "Twin-Plot Graph"

It displays information such as "Item", "QC Name", "QC Lot No.", "QC Time", " Target Value", "Standard Deviation", " No.", " Mean Value ", "Standard Deviation Calculation ", "CV(%)", etc.



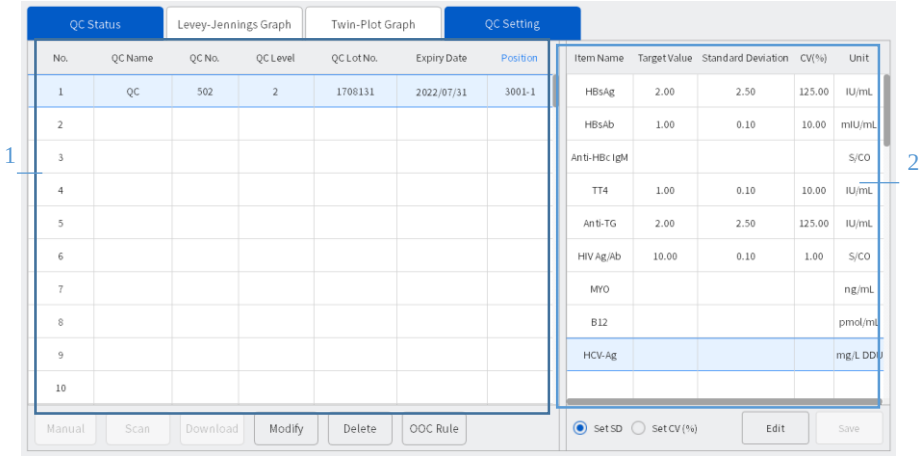
Levey-Jennings graph



Twin-Plot graph

■ QC Setting

This interface displays the control and the corresponding control item. Users can manually add, scan, input, and download the related information of the control on this interface. On this interface, users can add or delete the current controls as required. As shown in the figure.



QC Setting

1 Control List

The list displays the "No.", "QC Name", "QC No.", "QC Lot No.", "Expiry Date", and "Position".

2 Details about a selected control

It is the information list of controls, including "Item Name", "Target Value", " Standard Deviation", "CV(%)" and "Unit".

1.6.7 Utility Interface

Click the "Utility" button on the menu to switch to the "Utility" interface. Three

modules included in the "Utility" interface are "Item", "Maint." and "System".

Item

The system enters the menu "Item", as shown in Fig. 1.6.7-1.

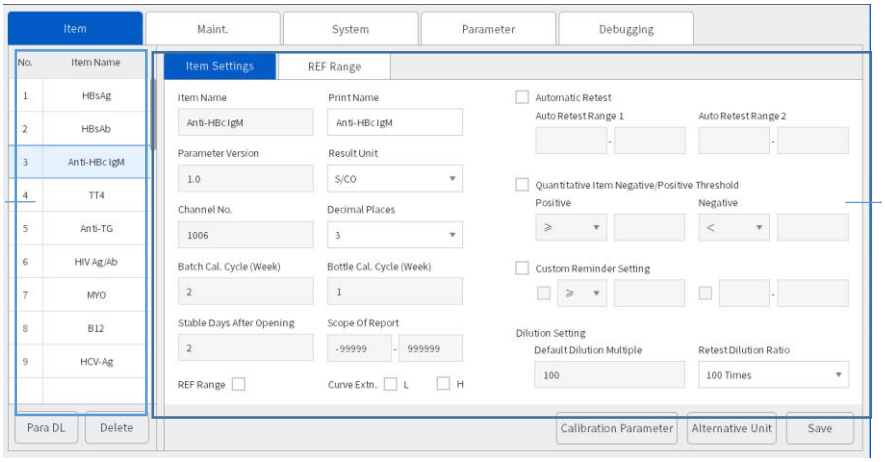


Fig. 1.6.7-1

1 Item Display List

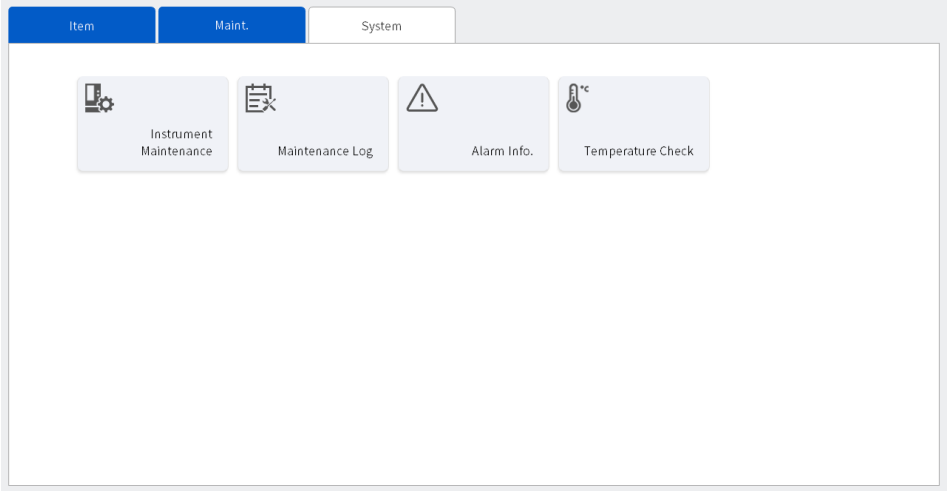
The number and name of items are displayed on the interface. "No." indicates the series number when the item is loaded, and "Item Name" cannot be changed.

2 Item Parameters

This area displays detailed parameters of an item, including " Item Name ", "Channel No.", "Parameter Version", "Result Unit", "Print Name", "Stable Days After Opening", "Bottle Cal. Cycle(Week)", "Batch Cal. Cycle(Week)", "Scope Of Report", "REF Range", "Curve Extn.", "Automatic Retest", "Quantitative Item Negative/Positive Threshold", "Custom Reminder Setting" , "Dilution Setting" and etc.

Maint.

Click "Maint." to access the "Maint." menu, as shown in figure.



Maint.

Instrument Maintenance

Display the on/off maintenance settings, auto maintenance and so on the interface.

Maintenance Log

Display the maintenance log on the interface.

Alarm Info.

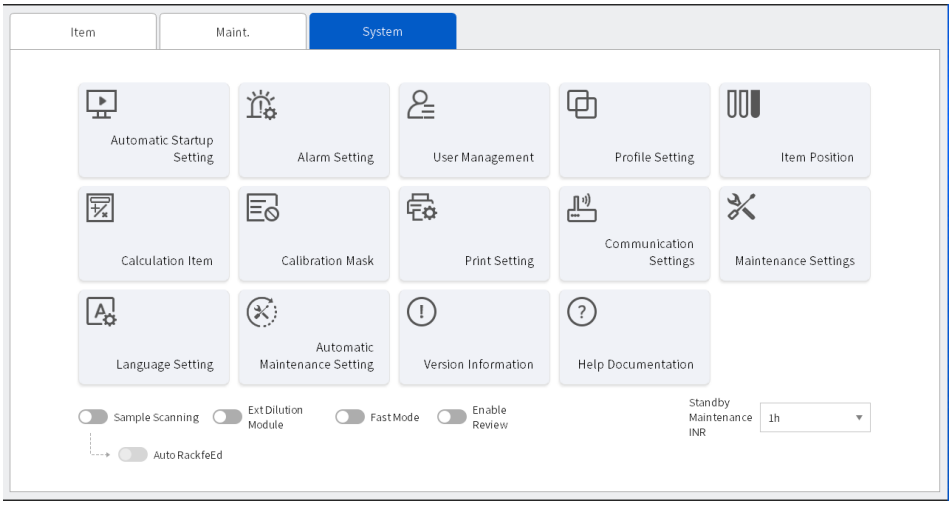
Display the alarm information generated by the Analyzer to facilitate fault locating.

Temperature Check

Display the temperature of parts of the Analyzer on the interface.

System

This interface displays information related to system settings. Through relevant function keys, you can implement functions including "Automatic Startup Setting", "Alarm Setting", "User Management", "Profile Setting", "Item Position", "Calculation Item", "Calibration Mask", "Print Setting", "Communication Settings", "Maintenance Settings", "Language Setting", "Version Information", "Help documentation", and so on. As shown in the figure.



System



Chapter 2 System Installation

2.1 Overview

In order to ensure the transportation process from collision, the Analyzer was properly packed before delivery through inspection. After the goods arrive, check whether the packing is in good condition carefully first. In case of any damage, inform the Company or the service department of the authorized distributor immediately.

The Analyzer must be installed by professionally trained personnel. Before installing the hardware, the user should carefully read and understand the requirements and operating steps in this User Manual to ensure that the following space, power, environment, and EMC requirements are met.

The user should cooperate with the engineer in meeting the relevant installation requirements in the Manual to ensure the normal operation and service life of the Analyzer.

Warning

- Do not unpack or install the Analyzer without the presence of the personnel authorized by the company. Unpacking or installation by personnel not authorized or trained by the company may cause damage to the Analyzer.
- If the Analyzer is not used for a long time, a package procedure should be performed to empty the Analyzer and clean it with deionized water. The storage conditions of the Analyzer should meet the relevant storage requirements.

2.2 Space Requirements

To meet the requirements for maintenance space of the Analyzer, and to make sure sufficient heat dissipation and avoid squeezing the pipeline of the Analyzer, the installation position of the Analyzer should meet the following requirements:

- The desktop should be level.
- The desktop should be strong enough to bear the weight of the instrument (load capacity: ≥ 200 kg/ m^2).
- There should be no perceptible vibration.
- The reserved space of the left and right doors and walls of the Analyzer should be ≥50cm;
- The reserved space of the back plate and wall of the Analyzer should be≥ 15cm;
- Ensure that there is enough space for pure water container, Wash buffer container, waste liquid container, etc. on the operating table and under the

Analyzer, and connect the waste liquid direct outlet if necessary.

- Do not place the Analyzer in a position where the switch is hard to disconnect.

Precautions

- Analyzer: 850 x 618 x 675 (W x D x H, in mm), with a net weight of 99.5kg.

2.3 Power Supply Requirements

In order to ensure that the Analyzer runs in a safe and stable power environment, the following requirements should be noted:

Power supply Voltage	Frequency	Power	Fuse Specifications
100V-240V~	50/60Hz	800VA	F6.3AL250VP F32VDC 25A F32VDC 10A

- Ensure that the power supply voltage meets the requirements listed in the table above.
- The power switch should be in the "OFF" position when all connections are made.
- No other interfering electronic devices are connected to the same circuit.
- The power supply is controlled by a wall-mounted switch or time relay. A temporary power outage may cause damage to analysis templates and computer memory.
- Do not extend the conductor without protection; otherwise, the secure connection will be interrupted.
- To add/remove parts to/from this system, disconnect the power connecting wires before connecting or disconnecting these connected power connection wires.

Warning

- The Analyzer should be used with a good grounded condition.
- The fuse of the specified specification should be adopted for the Analyzer.
- If the power grid in the environment where the Analyzer is used is unstable or there is an abnormal power outage, it is recommended that the user use a backup power supply such as a voltage stabilizer or an uninterruptible power supply (UPS).

2.4 Environmental Requirements

The Analyzer must be used in the following environments:

	Normal Working Environment
Temperature	10℃ ~ 35℃
Relative humidity	30% ~ 70%
Atmospheric pressure	64.0kPa ~ 106.0kPa

- The installation and use environment of the instrument should be as clean as possible and free of dust, mechanical vibration, large noise and power interference.
- Do not have the instrument close to a source of high electromagnetic interference, lest it may interfere with the normal operation of the Analyzer.
- Do not put the Analyzer near the brush motor, scintillation fluorescent lamp, and electrical contact equipment often used.
- The Analyzer should be kept away from direct sunlight or placed near heat sources.
- The Analyzer should be kept well-ventilated.
- Clear air and good ventilation.
- Protect from direct sunlight.
- Air-condition the environment if the room temperature and relative humidity are not suitable.
- Do not install the Analyzer in an environment with large temperature fluctuation
- Place in a good grounding environment, and do not use in places where electrical interference, dust and acidic volatile gases are likely to occur.



- Do not use the Analyzer in flammable and explosive environments, so as to avoid danger.
- Do not move the Analyzer without authorization. If needed, please contact the service department or the company or authorized dealer(s).

2.5 Electromagnetic Compatibility (EMC) Requirements

The Analyzer should be used in a good EMC environment and users should pay attention to the following matters:

- Keep the Analyzer away from high electromagnetic radiation facilities, such as the dental beds, pacers, and welding equipment.
- Keep the Analyzer away from high-power equipment that starts frequently, such as the refrigerators and centrifuges.
- Keep the Analyzer away from equipment that will produce electromagnetic and strong magnetic interference (such as radiological equipment, centrifuges, electric discharge machine, mobile phone, transceiver, cordless phone, etc.).
- Do not connect too many devices to the power strip for the Analyzer.
- During a test, do not plug in or out other devices that are connected to the same power strip as the Analyzer.
- Make sure that the Analyzer power socket is reliably grounded. Do not use non-standard power cable.

2.6 Analyzer Connection Requirements

The personnel authorized by the company should complete the following connections when installing the Analyzer:

2.6.1 Power System Requirements and Analyzer Connection

- Use the power cord with factory standard configuration
- There is a switchboard within 5m from the Analyzer.
- There is a separate grounding terminal (the ground resistance is less than 10Ω or meets the hospital-class grounding requirements).
- Nothing can be placed on the connected cables, whether temporarily, permanently or intermittently. Cables must not cross pedestrian paths.
- Cables should not be looped or knotted, or coiled with wires from other electronic equipment in close proximity.
- The power switch should be in the OFF position when all connections are made.
- No other interfering electronic devices are connected to the circuit.
- Avoid using extended sockets and connecting terminal blocks.
- The power supply is controlled by a wall-mounted switch or time relay.

Temporary power outages may cause damage to analysis templates and computer memory.

- Do not extend the conductor without protection; otherwise, the secure connection will be interrupted.
- To add/remove parts to/from this system, disconnect the power connecting wires before connecting or disconnecting these connected power connection wires.

2.6.2 Water Supply and Drainage Requirements and Pipeline Connection

Warning

- Reagents, waste liquids, waste samples, etc. should be disposed in line with the relevant local and national regulations on the disposal of these materials and other relevant biological infectious materials.
- The reagent is irritative to eyes, skin and mucosa. The operator should abide by the laboratory's operating safety regulations and wear personal protective appliances for contacting reagent-related articles.
- Do not place reagents or other liquids above the Analyzer.

2.7 Software Operating Environment Requirements

2.7.1 Operating Environment Configuration

- CPU: dual-core or above
- RAM: 4G or higher
- Hard disk: 100GB or above
- Graphics card: Integrated graphics card or discrete graphics card
- Operating system: Windows 10 and operating system of higher versions

2.7.2 System Environment

- Data interface
  TCP/IP transmission, mySQL data storage.
- User access control:
  Identity authentication by user name and password; users are classified into L1, L2, and L3 users. L1 users have common operator rights, L2 users have lab administrator rights, and L3 users have engineer rights. Only with the engineer rights can the Analyzer be set or adjusted for use.

- Security software
  Antivirus software needs to be installed to perform necessary virus protection and system vulnerability patching. If necessary, system software, support software, application software, and security software should be updated through local storage media or network updates by after-sales engineers when necessary.

- Sleep management
  Set the computer sleep and standby options to never sleep

- Firewall
  The firewall provided by windows is enabled by default. Meanwhile, security policies are set to allow the software to exchange data through the firewall.

Precautions

- Copy the installation package to the hard disk of the internal computer, double-click the installation package on the hard disk, and install the software as prompted.



Chapter 3 Daily Operation

3.1 Overview

This chapter introduces the daily operation process of the Analyzer, including startup, sample analysis and shutdown.

3.2 Work Procedure

The working procedure can be classified into that for test sample, calibrator and control. The working procedure varies slightly with the test object.

- Sample Working Procedure

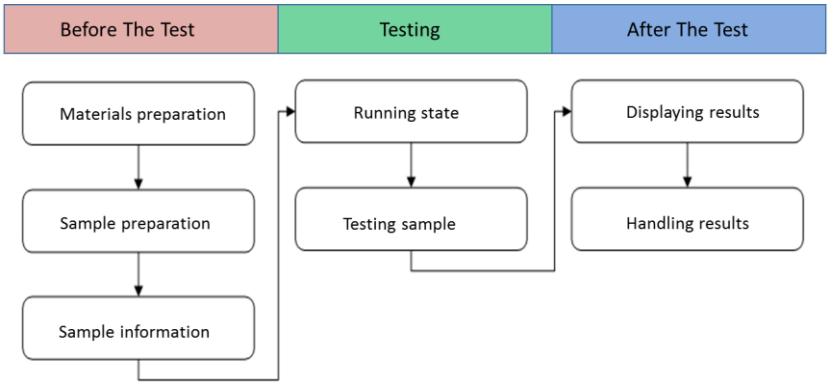


Fig. 3.2.1-1

- Calibrator Working Procedure

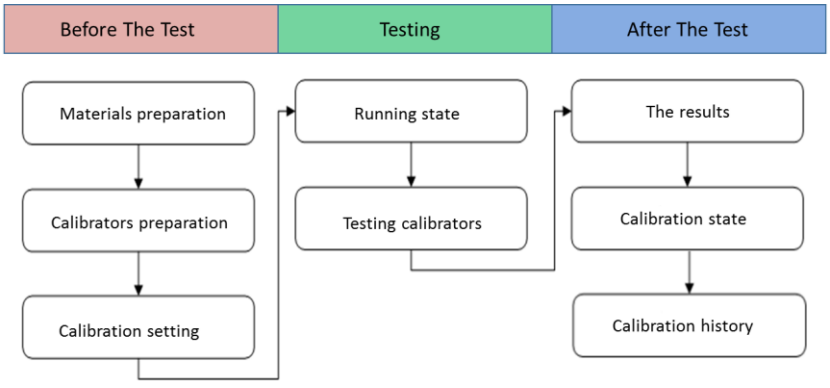


Fig. 3.2.2-1

- Control Working Procedure

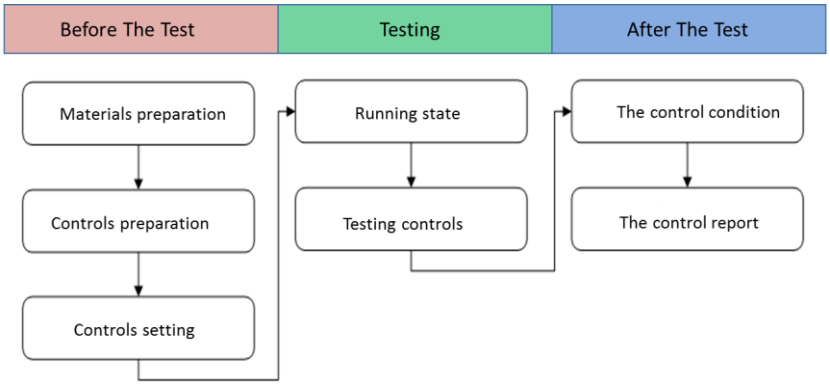


Fig. 3.2.3-1

Before powering on the Analyzer, the following checks should be made to ensure normal operation of the system.

- Power Supply

Check whether the external power supply works properly.

- Water Supply

Check whether the external water supply equipment works properly and whether the water quality meets the requirements.

Note: For the use of water purifier, refer to the water purifier instructions.

- Cuvette

Ensure that the cuvettes are sufficient for the operation and sample testing of the Analyzer.

- Inspection of Solid Waste Container and Waste Liquid Container

Ensure that there is enough space for solid waste/liquid waste containers to meet the operation and sample testing demands of the Analyzer.

- Wash Buffer

Ensure that the wash buffer is sufficient for the operation and sample testing of the Analyzer.

- Substrate

Ensure that the substrates are sufficient for the operation and sample testing of the Analyzer.

	The sample, calibrator, control, waste liquid, etc. are potentially bio-infectious. During operation, be sure to comply with safe operation requirements of the lab and wear proper personal protective equipment.

Warning

Reagents, waste liquids, waste samples, etc. should be disposed of in line with the relevant local and national regulations on the disposal of these materials and other relevant biological infectious materials.

3.3 Startup

Make preparations before startup, turn on the power switch of the Analyzer, and the Analyzer will start and the software will run automatically.

- The switch of the Analyzer is usually in the normally open state to supply power for the refrigeration of the reagent compartment.
- After the switch of the Analyzer is turned on, the Analyzer enters the initialization, and the login window is displayed. The Analyzer enters the standby state after the startup maintenance (Please refer to Chapter 6 about User Services for startup maintenance) is completed.

Precautions

If the Analyzer fails to start up, alarm will be generated. Troubleshoot based on the alarm information. If the problem cannot be solved, please contact the service department of the company or the authorized distributor.

3.4 Checking and Preparing Reagents

The Analyzer identifies reagents through RFID, and the reagent can be placed in any position in the reagent compartment. Each time the reagent compartment is closed, the Analyzer will automatically scan and read the reagent RFID information.

3.4.1 Checking Reagent Amount and Reagent Status

- Check the remaining amount of reagent loaded by the Analyzer, and add the kits with insufficient remaining volume in time.
- Check the calibration status of loaded reagents.
- Check the use status of the loaded reagents. If the kit with abnormal status is used for test, the system will give an alarm and mark it in the test result. It is suggested to replace the kit.
- When the remaining volume of the diluent kit in the reagent compartment is insufficient or there is no diluent, the Analyzer will ignore the diluent-related item and give an alarm during the measurement of the diluent-related items.

3.4.2 Loading & Unloading Reagents

Reagents are loaded and unloaded manually.

Loading reagents

- Standby state of the Analyzer: Open the reagent compartment, click "Rotate Reagent Tray" of the software, put the kit into the reagent position and close the reagent compartment, and the Analyzer will automatically scan the reagent and read the reagent information. After the reagent scanning is completed, please check the reagent information in the software to confirm that the loading is successful.
- Running status of the Analyzer: During the operation of the Analyzer, apply for and load reagents through the button "Renew Reagents". In the Reagent Status /Reagent Info. interface of the software, click "Renew Reagents", and the Analyzer will pop up a dialog box asking whether to confirm the application for reagent replacement. Then, click "Yes (Y)", and the software interface will display "Running - applying". When the reagents can be replaced, the software interface will display "Running - successful application". At this time, the Reagent compartment will be opened first, and the kit will be put into the reagent position by pressing "Rotate Reagent Tray", and the Reagent compartment will be closed. Then, the Analyzer will automatically scan the reagent and read the reagent information. After the reagent scanning is completed, please check the reagent information in the software to confirm that the loading is successful.

Unloading reagent

- Standby state of the Analyzer: When the Analyzer is in the standby state, open the reagent compartment, remove the kit to be unloaded and close the reagent compartment with the button "Rotate Reagent Tray", and the Analyzer will automatically confirm the reagent information. Then, the Analyzer will automatically confirm the reagent information.
- Running status of the Analyzer: During the operation of the Analyzer, apply for and unload reagents through the button "Renew Reagents". In the reagent overview/reagent information interface of the software, click "Renew Reagents", and the Analyzer will pop up a dialog box asking whether to confirm the application for reagent replacement. Then, click "Yes (Y)", and the software interface will display "Running - applying". When the reagents can be replaced, the software interface will display "Running - successful application". At this time, the reagent compartment will be opened first, and the kit will be put into the reagent position by pressing "Rotate the reagent compartment". Then, the corresponding reagent kit will be taken out, the

chamber will be closed, and the Analyzer will automatically scan the reagent and read the reagent information. After the reagent scanning is completed, please check the reagent information in the software to confirm that the unloading is successful.

Precautions

The reagent compartment cannot be opened during the operation of the Analyzer. If you click "Renew Reagents", you can open the reagent compartment only after the status of the Analyzer shows that the application is successful.

To turn the reagent tray, click on the " Rotate reagent tray" button in the software after opening the reagent compartment.

3.5 Checking Consumable Status

■ Checking Consumable Status

Consumables include cuvettes, wash buffer and substrate. You can view the status and refill each consumable on the interface. See Fig. 3.5.1-1:

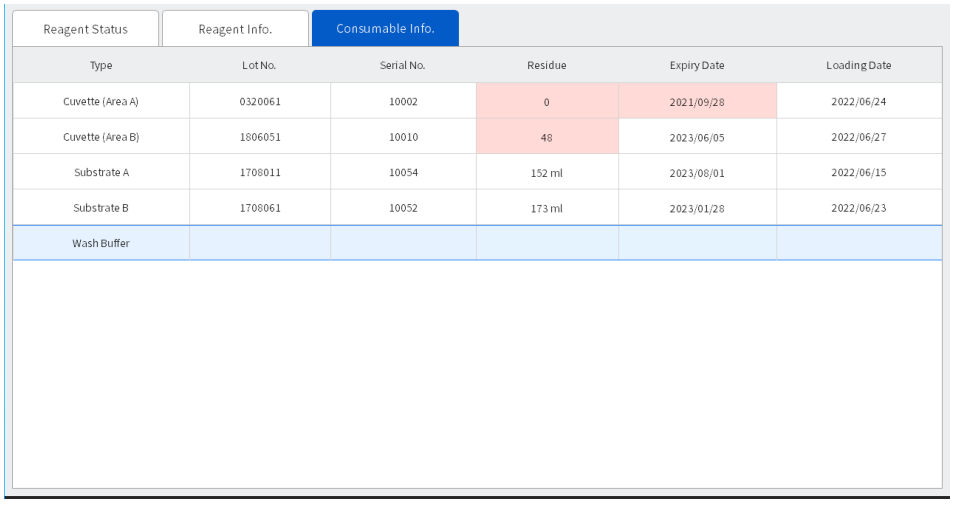


Fig. 3.5.1-1

■ Replacing Consumables

In the "Reagent Status" interface, click on the "  " key to enter the corresponding consumable information, and the Analyzer will automatically analyze the consumable type, lot No., expiry date, etc. Put the consumables in the

correct position after entering the information.

3.6 Calibration and Control

Before sample analysis, item calibration and control measurements need to be performed to guarantee reliable analysis results. For details, refer to Chapter 4 Calibration and Chapter 5 Control.

3.7 Preparing Samples

3.7.1 Sample Tube

Sample tubes that can be used with this product are as follows:

Diameter: 13 mm or 16 mm; length: 75 mm or 100 mm.

Cuvette (standard cuvette and micro-cuvette)



Use of non-standard sample tubes may affect the Analyzer operation and sample test, and even lead to Analyzer failure.

3.7.2 Barcode

The barcode label is attached to the outer side of the sample tube. The lower end of barcode should be at least 7 mm away from the bottom of the tube.

3.7.3 Sample Rack

4 kinds of sample racks are provided, namely gray, white, black and pink, with specific purposes. The Analyzer identifies the sample rack through the sample rack barcode.

Color	Sample Rack Name	Sample Rack Purpose
	Grey sample rack	Routine sample analysis
	White sample rack	Control analysis
	Black sample rack	Reagent calibration
	Pink sample rack	Sample retest and analysis

3.7.4 Placing Sample Tube to Sample Rack

Requirements for correct placement of sample tubes into sample racks are as follows.

1. Place each sample in the appropriate sample rack.

The sample rack is numbered. Please put the sample in the sample rack with the corresponding number.



Correct insert the sample tube into the sample rack. Incorrect placement of sample tube may damage the Analyzer hardware.

2. Check each opening of the sample rack and make sure the barcode is center aligned.



Do not rotate sample tubes with barcode labels which have been placed in the sample rack. Otherwise, the barcodes may be polluted or damaged, resulting in reading errors. Use only the sample rack provided together with the Analyzer.

3.7.5 Preparing for Installation of Sample Rack on the Analyzer

The manufacturer provides multiple sample racks. Up to 5 sample racks can be placed simultaneously.



Note that sample racks should be placed in place.

3.8 Item Selection

3.8.1 Sample Number and Sample ID

The valid field of sample identification depends on the type of sample (STAT, or general) and the mode used (sample scanning is enabled, or sample scanning is

disabled).

When sample scanning is disabled, you need to manually enter the sample number and test item. When sample scanning is enabled, the added item can be directly read through the scanned barcode.

3.8.2 Item Selection

Each page has 20 buttons. In the "Utility" menu, set the items corresponding to the buttons. Up to 4 groups can be set. One group at a time is displayed on the "Item Position" screen. Click on the button to select items. See Fig. 3.8.2-1:

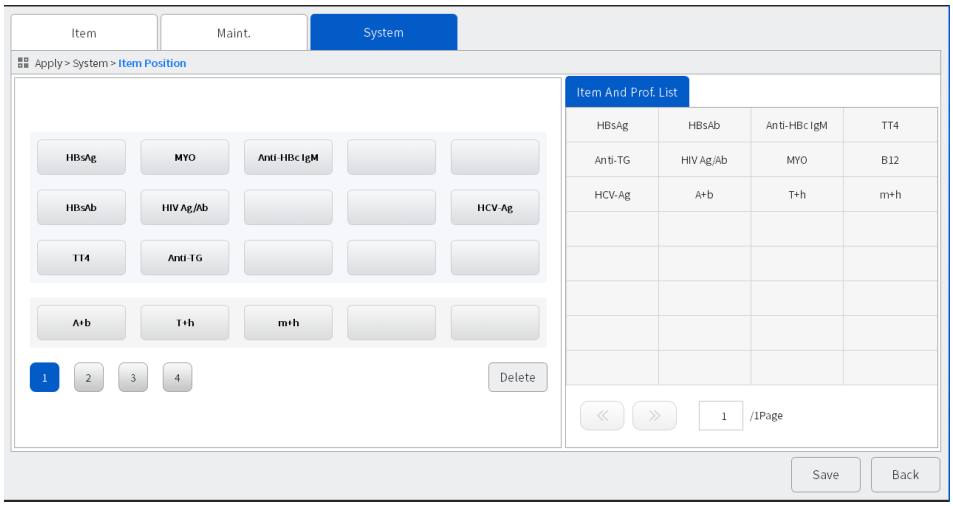


Fig. 3.8.2-1

3.8.3 Function Buttons

Add: Add the test information of a sample.

Patient info: Enter patient-related information, including age, gender, department, etc., as shown in Fig. 3.8.3-1.

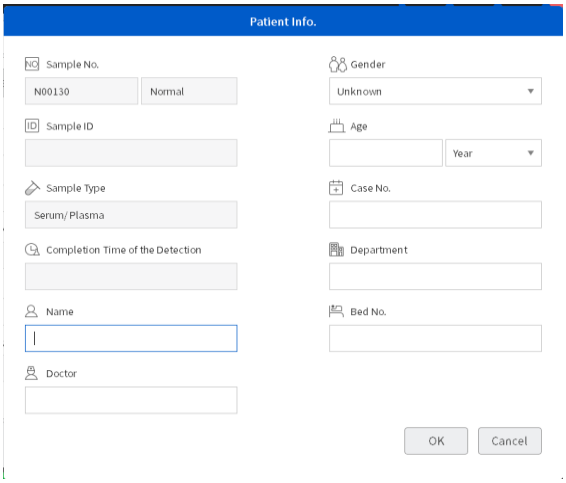


Fig. 3.8.3-1

Retest: When the sample needs to be retested, allocate a sample rack for the sample, as shown in Fig. 3.8.3-2.

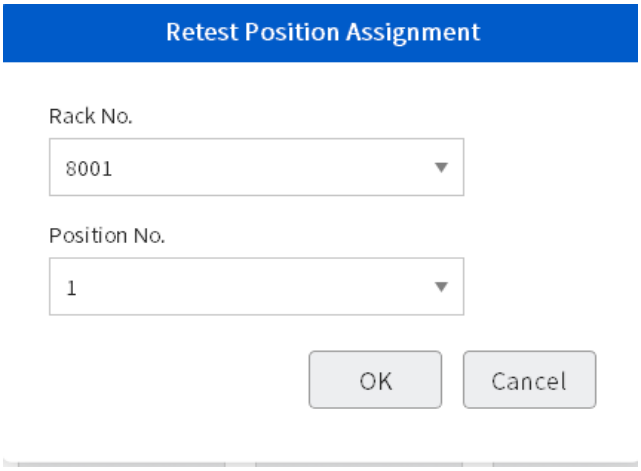


Fig. 3.8.3-2

Batch Input: Enter multiple samples of the same item in a batch, as shown in Fig. 3.8.3-3.

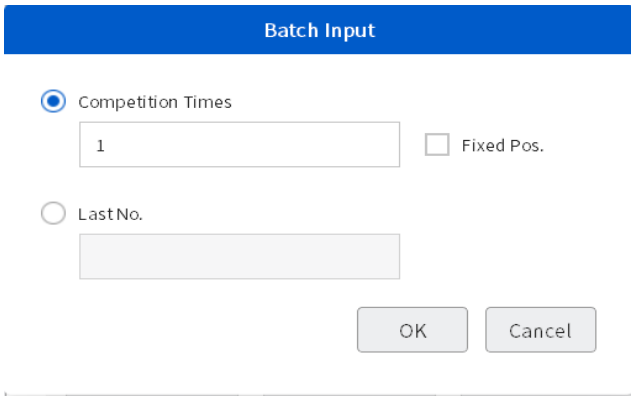


Fig. 3.8.3-3

Last No.: Enter the last sample No.

Completion Times: Enter the number of repetitions in the text box (the maximum number of repetitions is 100)

3.9 Starting Analysis

Open the "Start" menu in the "General Menu" on the right side of the interface, as shown in Fig. 3.9-1.

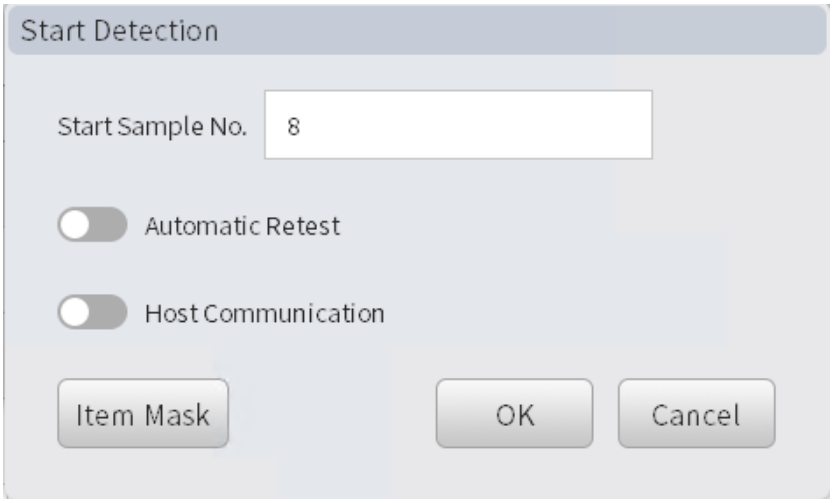


Fig. 3.9-1.

Set the sample test conditions in the start interface, and click on the " Start" button to run the applied calibration, control and samples.

Host Communication: Connect the host communication test results and output the test results according to the communication settings.

Automatic Retest: Enable the automatic retest function, and the Analyzer will judge whether the sample is retested according to the set automatic retest conditions.

Item Mask: Suspend the use of items loaded on the Analyzer.

Cancel: Exit.

Precautions

- After the automatic retest is enabled, the system will determine whether to retest after the sample is tested. If the sample rack is not taken away, the Analyzer will automatically rescan the sample tube for automatic retest.

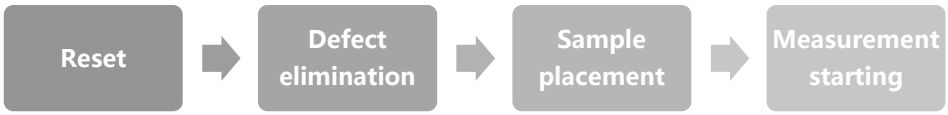
3.10 Inserting STAT

In the process of automatic sample loading, if STAT samples need to be inserted, operate as follows:

1. First click on the "STAT" button to pop up the STAT compartment;
2. Place the sample in the STAT compartment, and click "OK" in the STAT interface to start the STAT mode.

3.11 Troubleshooting of Instrument Breakdown during Automatic Sample Loading

During automatic sample loading, the Analyzer will stop measuring in case of shutdown fault.
After shutdown, resume the measurement according to the following steps:



3.12 Sample Results View

The system will save all test data for browsing and querying.

The undeleted test data is displayed in "Work" → "Data Browsing"; history data can be queried conditionally in the "History Data" button.

3.12.1 Data Browsing

In this interface, you can view the sample items and result information, and edit the sample information and print the report through the function keys, as shown in Fig. 3.12.1-1.

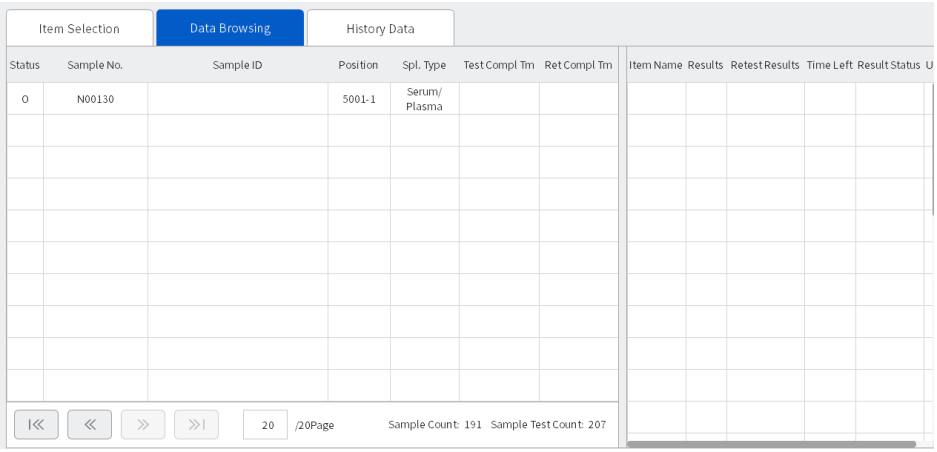


Fig. 3.12.1-1

3.12.2 Function Keys

Screen: Screen or reset the sample information of the current sample database.

Item Browsing: Browse the details of the selected sample, as shown in Fig. 3.12.2-1.

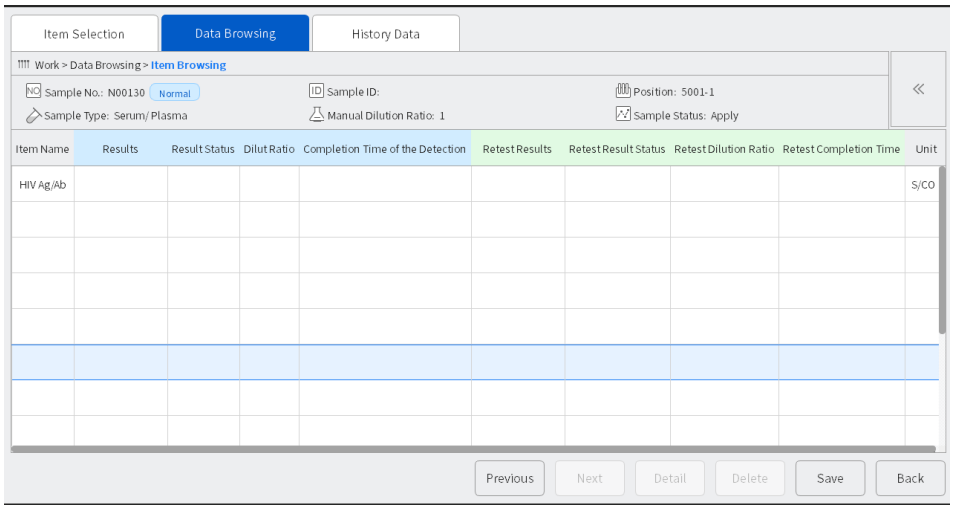


Fig. 3.12.2-1

Select All: Select all sample information in the interface

Delete: Delete the selected sample information

Review: Review the samples that have been tested. Only the reviewed samples can be printed and cannot be modified

Print: Select to print

Transmit: Transmit the selected sample information manually

Export: Export the sample data to the computer hard disk

3.13 Shutdown Maintenance

Perform shutdown maintenance procedures before daily shutdown. (For details about shutdown maintenance, refer to Chapter 6 List of User Service)

3.14 Shutdown Procedure

Enter "Exit" from the general menu on the right. If the Analyzer is on, it is recommended to perform shutdown maintenance once after analysis every day or after continuous operation for 24h.
If the Analyzer needs to be shut down for a long time, please contact the Service Department of our company or authorized dealer.

	■ Samples, calibrators, controls, waste liquid, etc. and the areas exposed to these substances have potential biological infectious hazards. During operation, please observe the laboratory safety operation regulations and wear personal protective equipment.

Precautions

■ To ensure the reliability and stability of the Analyzer's results, please follow the steps below to perform the shutdown procedure.

The shutdown process is as follows:



Precautions

■ Empty solid waste in a timely manner and properly dispose of waste liquid.



Chapter 4
Calibration

4.1 Overview

The purpose of calibration of test items is to ensure the accuracy of analysis results.

4.2 Calibration Frequency

The accuracy of the analysis results can be guaranteed within a certain period of time after the test items have been calibrated, but the test items still need to be recalibrated in the following cases.

- Before use after not being used for a long time;
- After the main components are replaced;
- When there is a systematic deviation in the control data through observation and it still cannot be corrected after repeated confirmation.

4.3 Calibration Mode

4.3.1 Calibration Preparation

Please confirm the following conditions before calibration:

- The residual amount of calibrator and reagent is enough to complete this calibration. In case of insufficient calibrators and reagents during calibration, recalibrate the Analyzer;



- Calibrators are as potentially biological infectious as samples. During operation, please observe the laboratory safety operation regulations and wear personal protective equipment.



- Because the filling needle is thin, the calibrator, control and sample carried by it have potential biological infectivity. Please pay attention during operation.
- Packages of the waste calibrators and controls should be disposed in line with the relevant local and national regulations on the disposal of reagents, wastes and other relevant biological infectious materials.

Precautions

- Only login users with administrator rights can perform calibration.
- The user should use the calibrator designated by the company and store it in strict accordance with the storage environment designated in the user manuals of calibrator and reagent.

4.3.2 Calibration

4.3.2.1 Manual Calibration

Follow these steps for manual calibration:

1. Check whether there is a failure prompt at present and eliminate the failure first if any;

a) If the status light of the Analyzer is not on or in other colors, there may be a failure;

b) If the status light of the Analyzer is green, calibration test can be conducted.

2. Assign the calibrator to the corresponding sample rack: [Calibration] - [Calibration Setting] - Assign the corresponding rack number - [Save]

3. Select the item to be calibrated: Select the item to be calibrated [Calibration] - [Status] - [Select]

4. Prepare the calibrator according to the user manual of reagent, and put the calibrator in the corresponding position of the set sample rack

5. Put the sample rack into the sample loading place of the Analyzer

6. Click [Start], and the Analyzer will automatically run the calibration measurement process

7. After the analysis, the obtained calibration results will be displayed in the calibration status interface.

Precautions

- If the calibration result does not conform to the specification, there will be corresponding prompt information and re-calibration will be required.

4.3.2.2 Automatic Calibration

Follow the following steps for automatic calibration:

1. Check whether there is a failure prompt at present and eliminate the failure first if any;

a) If the status light of the Analyzer is not on or in other colors, there may be a failure.

b) If the status light of the Analyzer is green, calibration test can be conducted.

2. Select the item to be calibrated: Select the item to be calibrated [Calibration]

- [Status] - [Select]

3. Confirm the Analyzer is in standby state.

4. Prepare the calibrator according to the user manual of reagent, and put the calibrator in the corresponding position of the set sample rack

5. Put the sample rack into the sample loading place of the Analyzer

6. Click [Start], and the Analyzer will automatically run the calibration measurement process

7. After the analysis, the obtained calibration results will be displayed in the calibration status interface.

Precautions

- If the calibration result does not conform to the specification, there will be corresponding prompt information and re-calibration will be required.

4.4 Calibration Setting

4.4.1 Inputting Calibrators

There are two input methods for calibrator information.

First, for the items with calibrators in the kit, when the Analyzer successfully scans the reagent RFID barcode, it will automatically download the calibrator information, including the name, lot No., expiry date, concentration, etc. of the calibrator.

Second, for the items without calibrators in the kit, there is a corresponding two-dimensional barcode in the calibrator kit. Click "Scan" in the calibration setting interface as shown in Fig. 4.4.1-1, and the calibrator information can be downloaded by scanning the two-dimensional barcode.

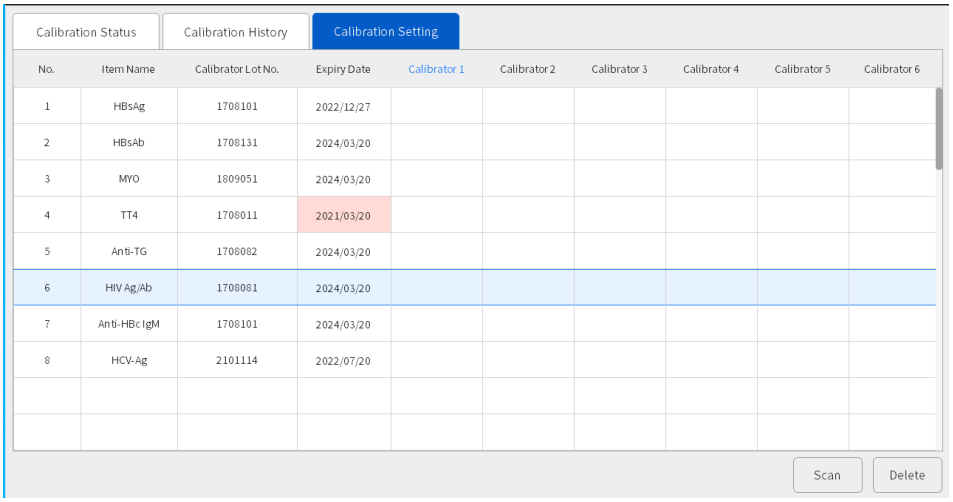


Fig. 4.4.1-1

4.4.2 Calibrator Position

After entering calibration information, you can set the position of calibrator in the "Calibration Setting" interface. Click the blue square under "Calibrator", select the rack No. and location No., and click "Save" after modification.

Precautions

- Calibrators of the same item must be placed on the same sample rack continuously in the specified order.
- Different items may have different calibration cycles. Please operate according to the calibration requirements in the corresponding item kit instructions. If the calibration fails, please contact the Service Department of the company or authorized dealer.

4.5 Implementing Calibration

4.5.1 Selecting Calibration Item

The system can identify the 1D barcode on the calibrator and match it with the corresponding reagent to implement auto calibration. If the calibrator is placed onto the sample rack and put into the Analyzer directly for auto calibration, the reagent currently being used will be used for calibration by default. If the standby reagent is selected for calibration, only the standby reagent will be calibrated. If both the current bottle and standby bottle of the same batch are selected at the same time, both bottles of reagents will be calibrated simultaneously.
When the barcode of the calibrator is damaged or missing, the automatic calibration function cannot be used. You need to select the corresponding item in the "Calibration Status" interface, and set the position of the corresponding calibrator in the "Calibration Setting" interface, and then save it, as shown in Fig. 4.5.1-1.

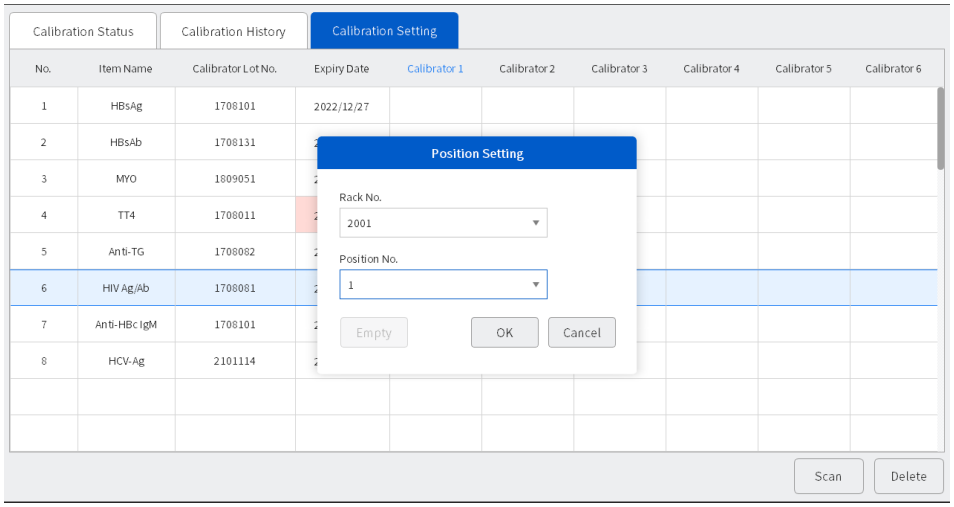


Fig. 4.5.1-1

4.5.2 Placing Calibrators

After selecting calibration items, prepare the corresponding calibrator, place it on the corresponding sample rack, and put it into the Analyzer.

4.5.3 Starting Calibration

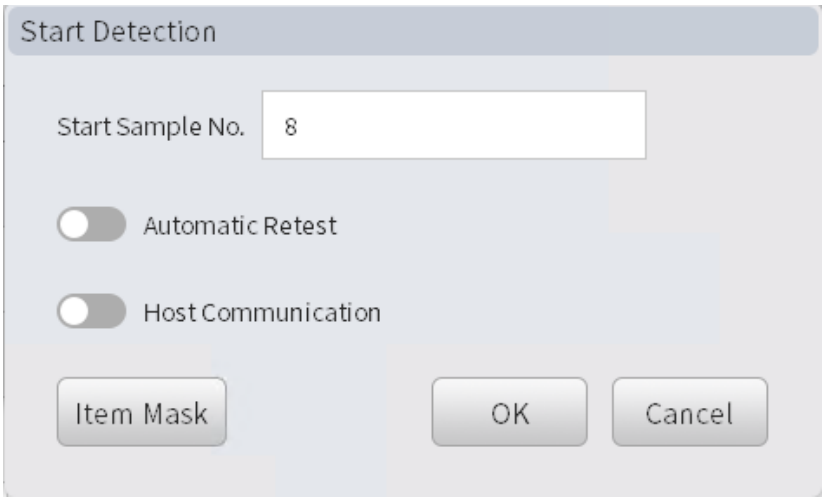


Fig. 4.5.3-1

If the Analyzer is in operation, it can conduct automatic calibration after the sample rack is put in; if the Analyzer is in sample injection stop and standby state, click the "Start" button to start running the test.

The calibrator can be performed simultaneously with the routine sample.

4.6 Calibration Result

Calibration history: View nearly 50 pieces of calibration history information of an item, as shown in Fig. 4.6-1.
In the calibration history chart, the signal values of the two-concentration calibrators will be displayed separately. L1 represents level 1, L2 represents level 2. Click certain calibration, and the corresponding information of the calibration will be displayed on the top of the chart.

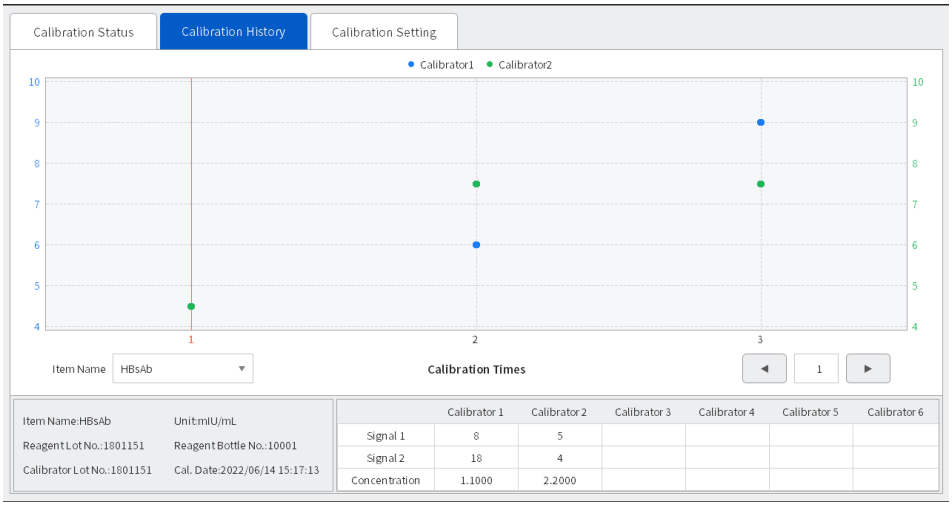
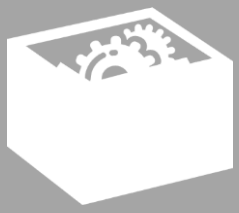


Fig. 4.6-1

Calibration result: View the relevant information of the current calibration curve. The current working curve of the selected reagent bottle will be displayed in the chart.



Chapter 5
Quality Control

5.1 Overview

In order to monitor the performance of the Analyzer in the process of use, it is necessary to carry out the QC regularly, and the laboratory should formulate a set of standardized QC operation process and strictly implement it.
After the Analyzer is calibrated or the main components are replaced, the additional QC is required.

Precautions

- Only specified controls can be used, and they should be stored and used in strict accordance with the requirements of the user manual of control.

5.2 Control Analysis

Control can be implemented by sampling mode supported by the Analyzer.

Follow the steps below for control analysis.
1. Check whether there is a failure prompt at present and eliminate the failure first if any;
a) If the status light of the Analyzer is not on or in other colors, there may be a failure;
b) If the status light of the Analyzer is green, control test can be conducted.
2. Input the control information into the Analyzer manually or by scanning.
3. Assign the controls to the corresponding sample rack: [QC] - [QC Setting] - Assign the corresponding rack No. - [Save]
4. Select the item to be controlled: Select the item to be controlled [QC] - [QC Status] - [Select]
5. Prepare the control according to the content of the user manual of control, and put the control in the corresponding position of the set sample rack
6. Put the sample rack into the sample loading place of the Analyzer
7. Click [Start], and the Analyzer will automatically run the QC measurement process
8. After the analysis, the obtained calibration results will be displayed in the QC status interface.

5.3 Control Setting

Users can set the controls in the QC module, select the QC items, view the QC

results and other operation, as shown in Fig. 5.4-1.

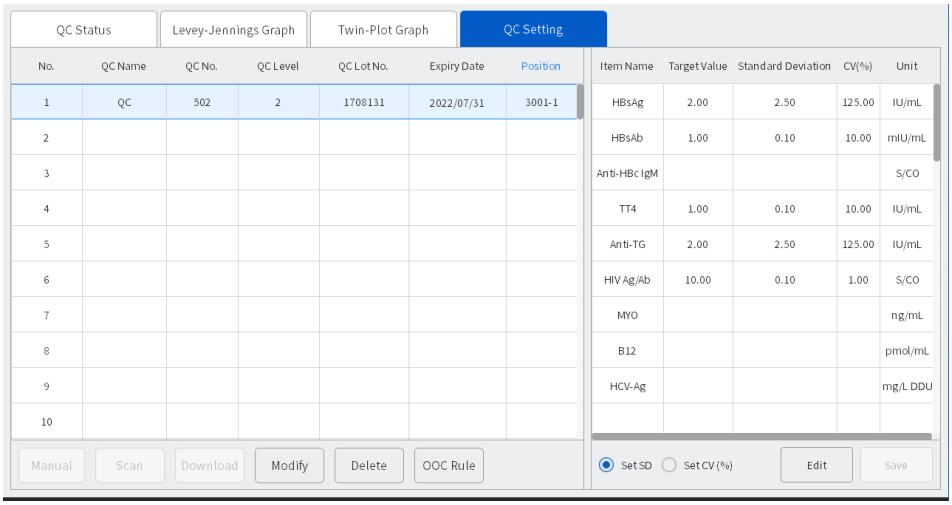


Fig. 5.3-1

5.3.1 Adding Controls

Matching controls: Download control information through barcode scanning or downloading from the network.

Third-party controls: Users can add control information by themselves, click the "Manual" button at the bottom, and add corresponding control information in the dialog box, as shown in Fig. 5.3.1-1.

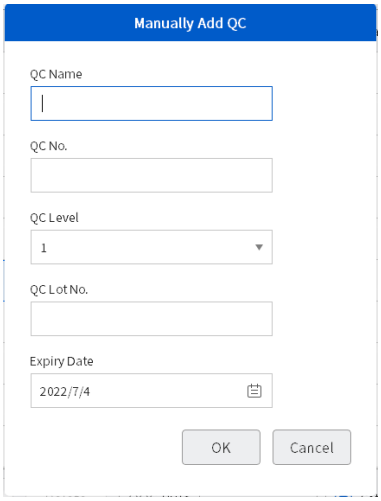


Fig. 5.3.1-1

5.3.2 Setting Target Value and Standard Deviation

Controls with barcode: Download the target value and standard deviation of control through barcode or network.

Controls without barcode: Select the control to be set in the left list and click "Edit", as shown in Fig. 5.3.2-1. Click "Save" after editing.

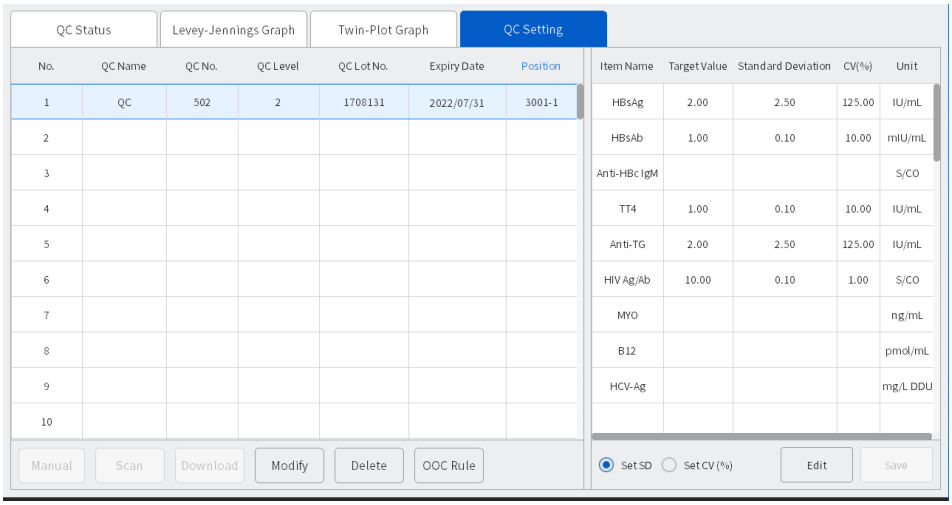


Fig. 5.3.2-1

5.3.3 Control Position

As shown in Fig. 5.4.2-1, in the QC setting interface, click the blue block in the "Position" column to select the available QC positions.

5.4 Implementing QC

5.4.1 Selecting QC Items

In the "QC Status" interface, select the item to be tested for QC, click in the "Select" column, and click again to cancel the selection, as shown in Fig. 5.4.1-1.

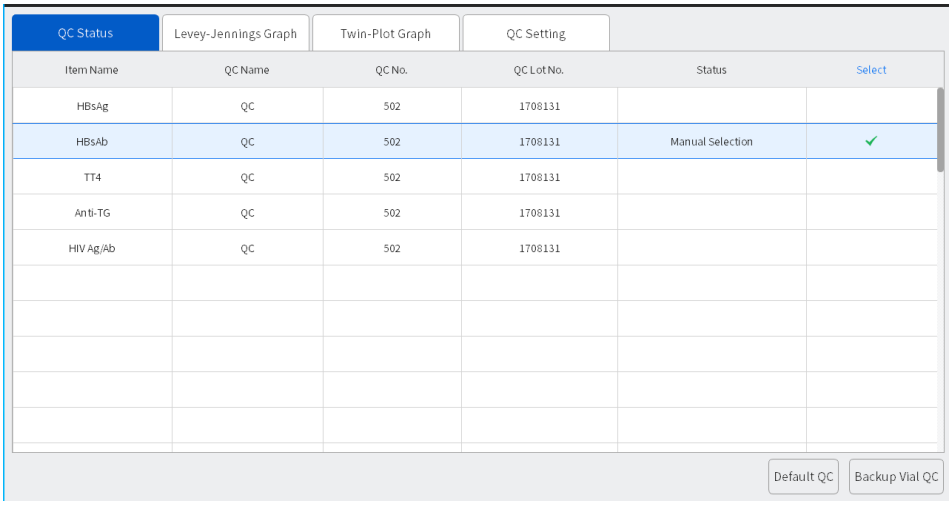


Fig. 5.4.1-1

Precautions

- If the QC items are the same each time, the default QC can be set, as shown in Fig. 5.4.1-2.

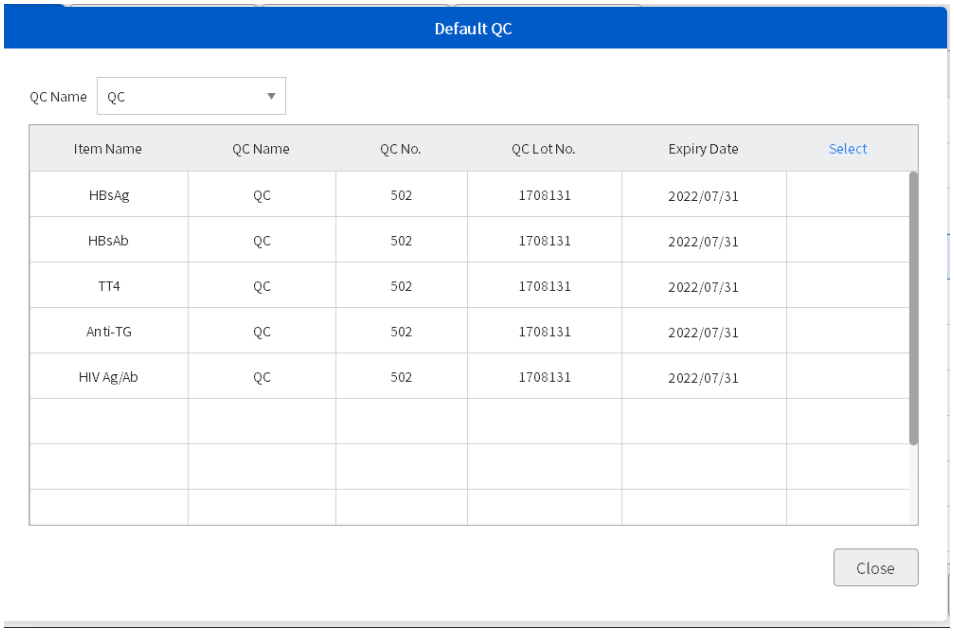


Fig. 5.4.1-2

For the same item, if multiple bottles of reagents are placed, except for the current bottle, the standby bottles can also be used to test the same control. In the "Default QC" interface, select the corresponding standby bottle of reagent, as shown in Fig. 5.4.1-3.

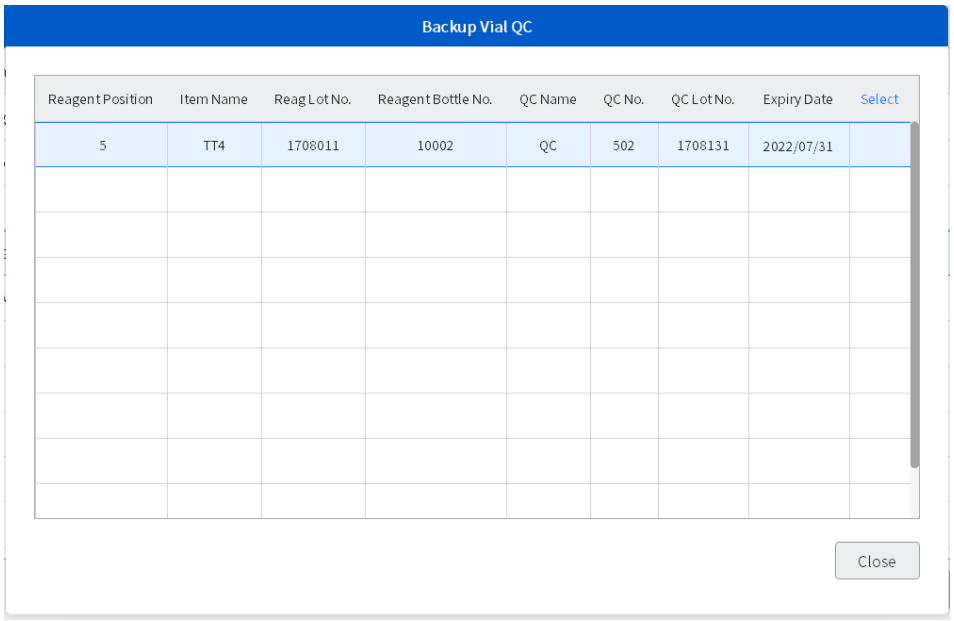


Fig. 5.4.1-3

5.4.2 Placing Controls

After selecting the QC items, prepare the corresponding controls, place them on the sample rack, and then put the rack into the Analyzer.

5.4.3 Starting QC

If the Analyzer is in operation, it automatically starts sampling; if it is in sample injection stop and standby state, click the "Start" button to start testing, and the QC can be carried out at the same time as routine samples.

5.5 QC Result

The "Levey-Jennings Graph" or "Twin-Plot Graph" interface displays information such as "Item Name", "QC Name", "QC Lot No.", "QC Time", " Target Value", "Standard Deviation", " No.", " Mean Value", " Standard Deviation Calculation" , " CV(%)", etc., as shown in Fig. 5.5-1 and 5.5-2. Each item provides the function of viewing the corresponding chart.

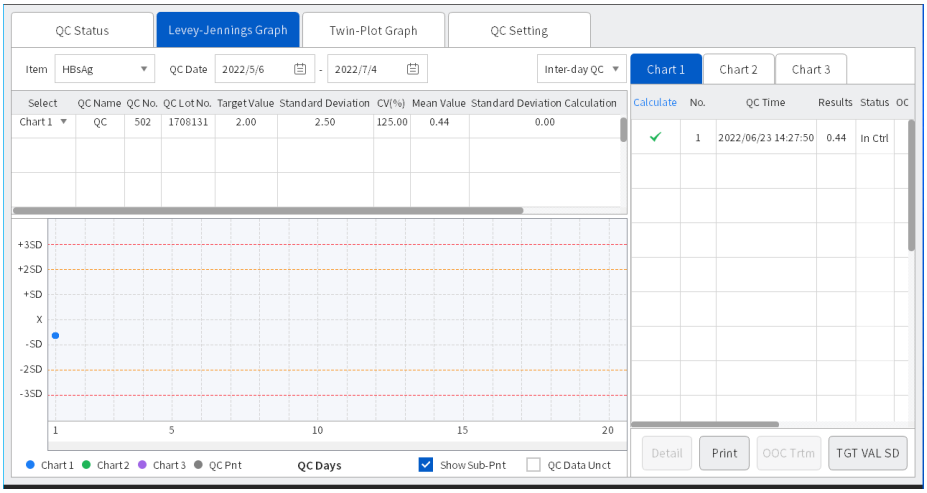


Fig. 5.5-1·

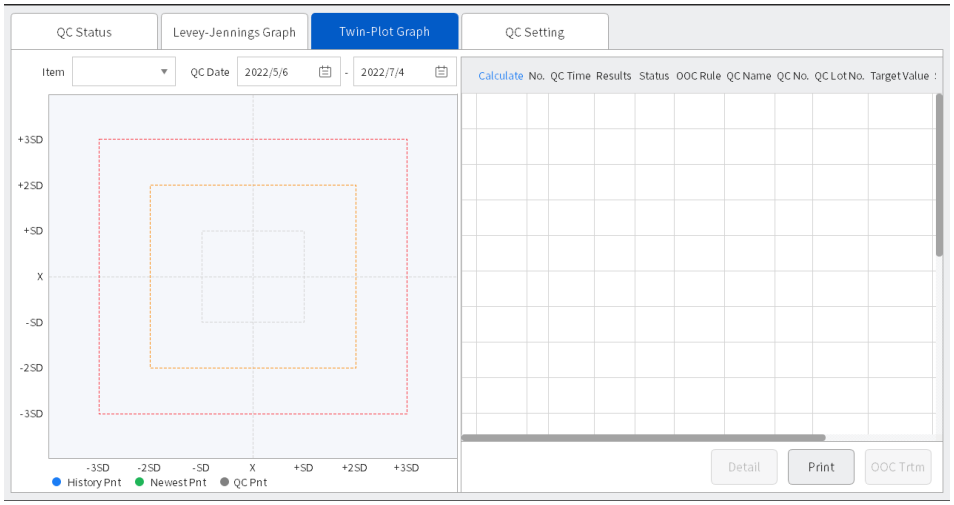
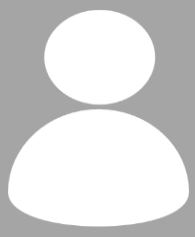

QC Status
Levey-Jennings Graph
Twin-Plot Graph
QC Setting
Item
QC Date
2022/5/6
2022/7/4
Calculate
No.
QC Time
Results
Status
OOC Rule
QC Name
QC No.
QC Lot No.
Target Value
+3SD
+2SD
+SD
X
-SD
-2SD
-3SD
History Pnt
Newest Pnt
QC Pnt
Detail
Print
OOC Trtm

Fig. 5.5-2



Chapter 6
User Service

6.1 Overview

In order to ensure the accurate and effective operation of the Analyzer, operators should carry out daily maintenance in accordance with the requirements of this chapter. The Analyzer has a variety of maintenance functions, which are convenient for operators to maintain.



- The surface of all components of the Analyzer is potentially biological infectious and safety precautions should be taken during operation and maintenance.
- During the operation, if samples or controls fall on the surface of the Analyzer, they can be wiped with disinfectant alcohol. Safety measures should be taken in the cleaning process, and the laboratory safety operation code should be strictly followed.

Precautions

- Incorrect maintenance may cause damage to the Analyzer. The operator should carry out the maintenance in strict accordance with the Manual.
- In case of problems not specified in the user manual, please contact the Service Department of our company or the authorized dealer, and our company will designate professionals to give maintenance suggestions.
- The Analyzer must be maintained with the parts provided by the company. If you have any questions, please contact the Service Department of our company or authorized dealer.

6.2 Preventive Maintenance

In order to maintain the normal performance of the Analyzer, preventive maintenance should be carried out regularly. Maintenance items are as follows:

6.2.1 Check

Find out abnormalities at the initial stage

- Daily inspection (before and after operation)
- Periodical inspection

6.2.2 Scheduled Maintenance

Maintain equipment performance

- Replacement or repair of aging parts

6.2.3 Spare parts storage

For use in case of failure

- Ensure adequate inventory of spare parts

6.2.4 Environmental Improvement and Control

Take measures to maintain performance in the following aspects:

- Temperature and humidity
- Water quality
- Dust and gas

6.3 Analyzer Maintenance

- Manual maintenance: Maintenance operations carried out by the users step by step according to this chapter.
- System maintenance: Maintenance operations automatically carried out by the Analyzer after the relevant buttons on the "Maint." interface are clicked.

Precautions

- The routine maintenance personnel of the Analyzer must be trained by the company before maintenance.

6.3.1 Safety Instructions for Maintenance and Troubleshooting

To safely maintain the Analyzer and ensure good performance, make sure to observe the following precautions.

Warning

- In the context of this user manual, each heading is marked where attention is required.

6.3.2 Infection/Injury Caused by Contacting an Analyzer System

Warning

Contact with the magnetic separation system, test system and sampling system may cause injury or infection.

- Before manual maintenance or inspection, be sure to wear protective equipment and operate according to the procedures specified in the user

manual.

- Wash with water immediately, disinfect the part, and consult a doctor in case that your body is exposed to the sample, reagent or other solutions.

Scope of application: 6.3.6 Maintenance Interval Management in System Maintenance.



- Contact with the sampling system may cause injury or infection.

Scope of application: Analyzer maintenance.

6.3.3 Direct contact with reagents can cause burns to the skin



Direct contact with substrates A and B, Wash buffer, etc. may cause skin burns.

- When moving the cleaning solution, be sure to wear protective equipment and follow the special instructions specified on the reagent package label.
- In case of any problem about the compatibility between the Wash buffer and the instrument parts, or about the substances included, consult the Company or an authorized dealer.

Scope of application: Washing the flow path with Wash buffer.

6.3.4 Contact with samples can cause infection



Contact with sample solution may cause infection.

- Before manual maintenance, be sure to wear protective equipment.
- When samples contact with the skin, immediately wash with water and disinfect the contact site, and seek medical help.
- When samples are found to be attached to the Analyzer parts, immediately wear protective equipment and then remove the samples and disinfect the contact site.

Scope of application: Pump tube replacement.

Warning

Fire and scald prevention. Ethanol/isopropanol is a combustible substance, which can cause fire.

- Do not approach open flames when using these liquids for maintenance. Otherwise, it may cause fire.

Scope of application: Cleaning the outer surface of the filling needle and the liquid injection/aspiration probe of the magnetic separation system.

Precautions

Improper disposal of waste liquid or other waste can cause pollution.

The waste contains samples (such as serum), therefore is very likely to be infectious. They must be disposed of as instructed by relevant authorities of infectious medical waste management based on applicable laws and regulations. Besides, concentrated water contains high concentration of reaction mixture, and should be disposed of as infectious waste.

- For details about substances subject to the management under laws and regulations included in reagents, calibrators or controls, consult your reagent supplier. Also, please abide by the device drainage regulations.

Scope of application: Cleaning of waste liquid outlet and waste container.

Precautions

Improper disposal of infectious waste

- Waste and cuvette must be disposed of as infectious medical waste. They must be disposed of as instructed by relevant authorities of infectious medical waste management by referring to the device safe control procedure.

Scope of application: Disposing of used cuvettes and waste liquid.

6.3.5 Maintenance Preparation

The following necessary items should be prepared before maintenance.

Item	Purpose

Cleaning gauze	For cleaning
Lint-free cotton swab	For cleaning
Disinfectant ethanol	For wiping
Protective equipment	Required for maintenance
WS Wash buffer	For cleaning

Note: Do not use cleaning agents or disinfectants that react chemically with the materials contained in the equipment; if you have any questions, please consult our company.

6.3.6 Maintenance Conditions and Frequencies

Status of the Analyzer during maintenance



- When cleaning the Analyzer's system or replacing parts, the procedures specified in this user manual should be followed. Turn off the power supply of the Analyzer before replacing parts.
- During the maintenance that is allowed to be performed with the Analyzer energized, make sure its upper cover is closed. When the front cover needs to be opened, make sure to not contact any other parts except the target part.

Maintenance interval management

After the maintenance interval is set, you can monitor the maintenance time on the screen.

If any maintenance item exceeds the actual maintenance time limit, the message about timeout of maintenance may be displayed in yellow or red.

Maintenance frequency

The maintenance frequency is determined according to the equipment running 4 hours a day and 25 days a month. Please refer to the following table to perform regular maintenance.

SN	Item	Daily	*As Required	Weekly	Monthly	Quarterly	Every Six Months	Annually
1	Filling needle	○	○	○				
2	Liquid injection/aspiration needle of magnetic separation system	○	○	○				
3	Device surface	○						
4	Cooling fan						○	
5	Dust filter at the bottom of Analyzer					○		

Note: Remove the blockage when the filling needle and pipeline may be blocked.

Regularly Replacing Parts

Certain parts need to be replaced regularly for preventive maintenance. The replacement cycle is determined based on the assumption that the device runs for 4 hours a day, 25 days a month. Please determine your own replacement cycle according to actual circumstances. At the time of purchase, provide the Company

or an authorized dealer with the relevant part number for replacement.

SN	Item	Daily	As Required	Weekly	Monthly	Quarterly	Every Six Months	Annually
1	Filling needle							○

Maintenance of the Spare Parts Inventory

Spare parts for maintenance should be prepared for Analyzer repair. At the time of purchase, consult the Company or an authorized dealer.

Precautions for Continuous Operation

In order to detect STAT samples at night, please be sure to manage the time cycle of each maintenance item if the Analyzer has been working continuously (without shutdown) for more than 24 hours. The maintenance table and protective equipment should be prepared for manual maintenance. The maintenance cycle and periodic replacement time are estimated based on 4 hours of work per day, and the frequency can be reset according to the actual operation time.

Operation precautions after long-time shutdown

If the Analyzer is shut down for three days or more, clean the pipeline and drain the Analyzer's pipeline; the performance should be checked and confirmed before startup. For details, please consult the Service Department of our company or authorized dealer.

6.3.7 Maintenance Item List

SN	Maintenance Item	Maintenance Frequency	Maintenance Type
1	Startup maintenance	Daily	System maintenance
2	Shutdown maintenance	Daily	System maintenance

3	Instrument resetting	As demanded	System maintenance
4	Reagent scanning	As demanded	System maintenance
5	Magnetic beads mixing	As demanded	System maintenance
6	Pipeline filling	As demanded	System maintenance
7	Substrate filling	As demanded	System maintenance
8	Pipeline washing	As demanded	System maintenance
9	Magnetic separation filling	As demanded	System maintenance
10	Magnetic separation pipeline washing	As demanded	System maintenance
11	Substrate pipeline washing	As demanded	System maintenance
12	Cuvette removal	As demanded	System maintenance
13	Cuvette removal (complete machine)	As demanded	System maintenance
14	Weekly maintenance	Weekly	System maintenance
15	Monthly maintenance	Monthly	System maintenance
16	Soaking and washing needle	As demanded	System maintenance
17	Test end maintenance	As demanded	System maintenance
18	Automatic shutdown	As demanded	System maintenance

Startup/ Shutdown Maintenance of Flow Path

Contamination of the flow path on the inner wall of the filling needle may cause inaccurate measurement results or blockage.

Conduct startup maintenance and flow path filling before the start of work every day.

As required, conduct weekly maintenance to clean the flow path of the Analyzer, and manually switch the pure water pipeline before weekly maintenance.

Filling needle

Contamination of the inner and outer surfaces of the filling needle may cause inaccurate measurement results or blockage.

Warning

- The external surface of the filling needle and the procedure for removing blockage are described below. In case of an alarm of filling needle blockage which persists after automatic cleaning, the blockage must be removed manually.

Soaking the surface of filling needle

Immersion of the filling needle surface should be carried out after the test every day.

1. Confirm that the Analyzer is in standby state, and put the WS Wash buffer into the reagent compartment.

2. Perform shutdown maintenance.

3. When needed, maintenance can be carried out at any time, and immersion and probe cleaning are used as the maintenance items.

Cooling fan

The cooling fan is located at the back of the Analyzer. After a long time of use, a large amount of dust will accumulate on the fan, causing the temperature control of the Analyzer to be abnormal. Clean the cooling fan every six months.

1. Disconnect the operating power switch of the Analyzer.

2. Clean the dust on each fan of the Analyzer with a vacuum cleaner.

Dust filter at the bottom of Analyzer

The dust filter is located at the bottom of the Analyzer. After long use, a large amount of dust will accumulate, resulting in abnormal temperature control of the Analyzer. Clean the dust filter quarterly.

1 . Disconnect the operating power switch of the Analyzer.

2．Take out the dust filter, clean it with water, dry it in the air, and then put it back into the Analyzer.

Fuse and Overheat Protection Device

As a protector for short circuit and overcurrent, the power supply of the Analyzer is equipped with 3 kinds of fuses: F6.3AL250VP (023706.3MXP), F32VDC 10A (0287010, 10A), F32VDC 25A (0287025. PXCN); please contact the Service Department of our company or authorized dealer if the Analyzer cannot work normally due to overcurrent or short circuit.

The heating and cooling parts of the Analyzer are equipped with temperature sensors and temperature protection switches. In order to ensure their normal functions, the Service Department of the company or authorized dealer will conduct regular inspections.



Chapter 7
Troubleshooting

7.1 Overview

This chapter introduces the possible failure of the Analyzer in use and provides the corresponding treatment methods.

Precautions

- This user manual is not a maintenance manual, but only provides the emergency measures to be taken by the operator in case of failure alarm of the Analyzer.

7.2 Fault Information and Handling

During the use of the Analyzer, if abnormal conditions are detected, the Analyzer's status indicator will turn yellow (warning) or red (shutdown).
The "Alarm" column in the general menu bar on the right will flash continuously.
After clicking the "Alarm" option in the general menu bar on the right, the current alarm content of the Analyzer will be displayed.
For general warning information, the alarm can be eliminated after browsing the alarm content and closing the alarm information interface.
If the alarm cannot be eliminated by the above measures, refer to the handling methods in the following table:

Faulty Module	Fault Description	Solution
System-level failure	Abnormal startup and shutdown of instrument	1. Restart user software; 2. If this problem persists, please contact Maccura's customer service or the distributor in the area.
	Abnormal fan operation	1. Please pull out the dust filter to check whether there are foreign bodies and remove them; 2. Please contact Maccura's customer service center or a local distributor.
	Abnormal ambient temperature inside the machine	1. Check whether the room temperature is within 10℃-35℃; if so, please perform step 2; 2. Please contact Maccura's customer service center or a local

		distributor.
	Abnormal instrument communication	1. Please exit user software and turn off the power of the Analyzer; 2. Please turn on the power supply of the Analyzer and user software; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Software exception	1. Restart the software; 2. Please contact the Service Department of our company or authorized dealer if it still fails after three repetitions.
	Failure to establish connection with LIS	1. Check whether the serial port cable connection and serial port parameter settings are correct. If both are correct, please go to step 2; 2. If this problem persists, please contact Maccura's customer service or the distributor in the area.
CAN communication failure	Command parameter error	1. Please exit user software and turn off the power of the Analyzer; 2. Please turn on the power supply of the Analyzer and user software; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Task execution failure	1. Please exit user software and turn off the power of the Analyzer; 2. Please turn on the power supply of the Analyzer and user software; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Command timeout	1. Please exit user software and turn off the power of the Analyzer; 2. Please turn on the power supply of the Analyzer and user software; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.

	Flash initialization failure	1. Please exit user software and turn off the power of the Analyzer; 2. Please turn on the power supply of the Analyzer and user software; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
Filling system failure	Reset failure	After the test of the added sample is completed, the instrument turns to standby or shutdown state and performs the following actions: 1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal operation	After the instrument is switched to standby or shutdown state, perform the following steps: 1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If you fail three times, please contact Maccura's customer service or local distributor.
	Failure to take sample/reagent	After the instrument is switched to standby or shutdown state, perform the following steps: 1. Please check whether the corresponding sample size/kit reagent amount is sufficient. If the sample size/kit reagent amount is insufficient, please replace the sample/reagent. If the residual kit/ sample is sufficient, please perform the following steps: 2. Check whether the

		corresponding sample has abnormalities such as clots; 3. If reagent/diluent test fails, open the reagent compartment cover, select the reagent position without kit, and gently pull the reagent tray to see if the reagent tray is loose. If it is loose, please contact Maccura's customer service or local distributor.
Reagent storage module failure	Reset failure	After the test of the added sample is completed, the instrument turns to standby or shutdown state and performs the following actions: 1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal operation	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Reagent compartment cover opened	1. Close the Reagent compartment cover.
	Failure to read reagent information	1. Place the kit again, and replace the kit if it fails again, and perform step 2 if it fails again; 2. Restart user software; 3. Please contact Maccura's customer service or local distributor if the restart fails.
	Abnormal temperature	1. Please contact the Service Department of our company or

	control	authorized dealer.
Reaction module failure	Abnormal temperature control	1. Please contact the Service Department of our company or authorized dealer.
Sampling module failure	Reset failure	After the test of the added sample is completed, the instrument turns to standby or shutdown state and performs the following actions: 1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Operation timeout	1. Execute the instrument reset. If the reset fails, please go to step 2; 2. Restart software and reset the instrument; 3. Please contact the Service Department of our company or authorized dealer if it still fails after three repetitions.
	Failure to detect the sample rack	1. Please put in the sample rack before entering the rack; 2. If the above scheme fails, please reset the instrument before entering the rack; 3. If this problem persists, please contact Maccura's customer service or local distributor.
	Sample rack detected	1. Please take away the sample rack on the conveyor belt before entering the rack; 2. If the above scheme fails, please reset the instrument; 3. If this problem persists, please contact Maccura's customer service or local distributor.
	Scanner configuration	1. Perform instrument reset; If the instrument reset fails, please

	failure	perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Sample loading system full of racks	1. Please take away the sample rack in the rack withdrawing position; 2. If the above scheme fails, please reset the instrument; 3. If this problem persists, please contact Maccura's customer service or local distributor.
	Scanning failure	1. Check whether the barcode of the sample rack number is correct and free of dirt and damage; 2. Reset the instrument; carry out the test before the instrument is successfully reset; 3. Please contact Maccura's customer service or local distributor.
Test module failure	Reset failure	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal operation of mixing motor of test system	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal temperature control	1. Please contact the Service Department of our company or authorized dealer.
Magnetic separation	Reset failure	1. Perform instrument reset; If the

module failure		instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal operation	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal operation of mixing motor of magnetic separation system	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal temperature control	1. Please contact the Service Department of our company or authorized dealer.
Cuvette transfer module failure	Reset failure	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal operation	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.

	Abnormal cuvette taking	1. Check whether there is a cuvette at the cuvette taking position 2. Perform instrument reset; if the instrument reset fails, please perform step 2; 3. Restart user software and reset the instrument; 4. If the problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal cuvette placement	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
Transfer system failure	Reset failure of transfer system	After the test of the added sample is completed, the instrument turns to standby or shutdown state and performs the following actions: 1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Transfer system movement timeout	1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
	Abnormal mixing of transfer system	After the test of the added sample is completed, the instrument turns to standby or shutdown state and performs the following actions:

		1. Perform instrument reset; If the instrument reset fails, please perform step 2; 2. Restart user software and reset the instrument; 3. If this problem persists, please contact Maccura's customer service center or the distributor in the area.
Driving system failure	Driving chip temperature out of limit	1. Restart user software; 2. If this problem persists, please contact Maccura's customer service or the distributor in the area.
	Short circuit between motor phase B and power supply	1. Restart user software; 2. If this problem persists, please contact Maccura's customer service or the distributor in the area.
	Short circuit between motor phase A and power supply	1. Restart user software; 2. If this problem persists, please contact Maccura's customer service or the distributor in the area.

7.3 Handling before Stop of the Analyzer

Take the following measures before the stop of the Analyzer due to maintenance or transportation:

(1) If the Analyzer is shut down for three days or more, please clean the pipeline; properly dispose of and empty the waste liquid in the waste liquid container and the solid waste in the waste container. The performance should be checked and confirmed before startup. For details, please consult our customer service center.

(2) Before transportation, take away the test tube rack on the sample feeding unit, the substrate container in front of the Analyzer, and the reagent kit inside the reagent compartment.

(3) Keep the Analyzer upright during all handling and transportation.

(4) Prevent vibration during carrying, check and adjust the Analyzer after carrying to make sure that it is normal before using.



Appendixes

Performance Indicators

Specification	Description
Entire system performance	Instrument type: fully automatic, random tube-type analysis Working principle: acridinium ester chemiluminescence technology Test throughput: i 800/i 820/i 6000/i 8000/i 9000: 200 tests/hour First result report time: less than 14 minutes Intra assay CV for clinical projects: intra assay CV of alpha fetoprotein (AFP) ≤ 5.0%. Analyzer stability: The relative deviation of the test results of alpha fetoprotein (AFP) at the fourth hour and the eighth hour after the Analyzer enters stable operation from the test result when the Analyzer first enters stable operation does not exceed ±10%. Linear correlation: For alpha fetoprotein (AFP), with no less than 3 orders of magnitude covered by the concentration range, the linear correlation coefficient (r) ≥ 0.99.
Sampling system	The instrument can accommodate 5 sample racks in single sample loading, and can realize continuous sample loading. 1 STAT position Supporting automatic sample review
Filling system	Sampling range: 5μL~100μL Sampling precision: When V≤10μL, the error will not exceed ±10%, CV≤3%; when 10μL<V≤50μL , the error will not exceed ±10%, CV≤2%; when V>50μL, the error will not exceed ±5%, CV≤1% Carry-over rate: $\leq 2\times10^{-7}$ Filling needle: supports features such as liquid level detection, block detection, amount-based tracking, and anti-collision detection, etc. Sample type: serum/plasma/whole blood/urine/other samples
Reagent storage	Number of reagent positions: 20 Reagent compartment refrigeration: 2℃~8℃

system	Reagent mixing: real-time online mixing
Reaction system	Cuvettes: box-type cuvettes, each box of 8*13, a total of 104, a total of 2 boxes, and the remaining number of cuvettes displayed in real time. Reaction temperature: The temperature accuracy should be within 37℃± 0.5℃, and the fluctuation should not exceed 0.5℃. Mixing of reaction solution: non-contact mixing Magnetic separation: quadruple magnetic separation technology
Test system	Instrument noise: The instrument noise should not exceed 150RLU. Linear range of luminescence value: linear correlation coefficient (r) ≥0.99 in the range of not less than 3 luminescence value orders of magnitude. Repeatability of luminescence value: The coefficient of variation (CV) should not exceed 3.0%. Stability of luminescence value: The change of luminescence value should not exceed ±5.0% by using the luminescence reagent method.
System function	Computer system: Supporting Windows 10 and higher Chinese and English operating systems Remote diagnosis: Yes, through the network failure diagnosis system Automatic startup/shutdown function: Yes, users define the time.
Environmental requirements	Temperature: 10 ℃~35 ℃; relative humidity: 30%~70%; atmospheric pressure: 64kPa~106kPa. Power supply: voltage 100V-240V~, frequency 50/60Hz, power 800VA Waste liquid treatment method: direct discharge and waste liquid container discharge Water consumption: ≤7L/h When the ambient noise is less than 40dB, the operating noise of the instrument is greater than 70dB (excluding occasional noise and failure alarm sound).

Overall Size and Weight

Overall size: 850mm wide, 618mm deep, 675mm high
Net weight: about 99.5kg

List of Parts

	i 800	i 820	i 6000	i 8000	i 9000
Power cable EU 2 pin plug (CEE 7/7)(piece)	1	1	1	1	1
Power cable UK 3 pin plug (BS 1363)(piece)	1	1	1	1	1
Power cable USA 3 pin plug (NEMA 5-15P)(piece)	1	1	1	1	1
Network cable(piece)	1	1	1	1	1
Barcode reader (piece)	Optional	Optional	Optional	Optional	Optional
Barcode reader rack (piece)	Optional	Optional	Optional	Optional	Optional
Sample rack (set)	1	1	1	1	1
Purified water container (piece)	1	1	1	1	1
Wash buffer container (piece)	1	1	1	1	1
Liquid container (piece)	1	1	1	1	1
Purified water bottle A(piece)	1	1	1	1	1
Purified water bottle B (piece)	1	1	1	1	1
Waste liquid container (piece) (Optional)	1	1	1	1	1
DC fuse 10A (piece)	2	2	2	2	2
DC fuse 25A (piece)	2	2	2	2	2
AC fuse 6.3A (piece)	4	4	4	4	4

Float switch for waste liquid container (set) (Optional)	1	1	1	1	1
Float switch for purified water container (set)	1	1	1	1	1
Float switch for Wash buffer container (set)	1	1	1	1	1
TPU pipe (piece)	1	1	1	1	1
PVC resin hose (piece)	1	1	1	1	1
Sample storage pipe (bag)	1	1	1	1	1
Chemiluminescence Analyzer Reaction Cuvettes (bag)	4	4	4	4	4
Online filter(s)	2	2	2	2	2

EMC Instructions

Description

According to the electromagnetic compatibility test, the product complies with the requirements of *IEC 61326-1/ EN 61326-1 Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements - Part 1: General Requirements* and *IEC 61326-2-6/ EN 61326-2-6 Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements - Part 2-6: Particular Requirements - In Vitro Diagnostic (IVD) Medical Equipment*.

The following requirements should be strictly observed during use; otherwise, it may cause electromagnetic interference to other equipment or reduce the anti-electromagnetic interference ability of the Analyzer, or even cause loss of the basic performance.

The equipment is designed and tested according to Group I Class A equipment in CISPR 11. In the home environment, the equipment may cause radio interference, thus preventive measures should be taken. It is recommended to evaluate electromagnetic environment before using the device.

Description about that portable and mobile RF communication equipment may affect medical electrical equipment: As portable and mobile RF communication

equipment may affect the normal operation of the Analyzer, a certain spatial distance should be kept between portable and mobile RF communication equipment and the Analyzer. Specific requirements are shown in Table 4.
Warning 1: Except for energy converters and cables sold by manufacturer of the equipment or system as the spare parts of internal components, using unprescribed accessories, energy converters and cables may lead to transmission increase or immunity decrease of the equipment or system.
Warning 2: The equipment or system should not be placed near or stacked up with other equipment. If you have to do so, please observe and confirm its normal operation under existing configuration.
Warning 3: It is forbidden to use the equipment beside any source of intense radiation, or it may interfere with normal operation of the equipment.

Performance criteria statement: The product meets the following performance criteria:

Table 1 Instructions and Manufacturer's Statement - Electromagnetic Emission

<table>
<tr><th colspan="3">Instructions and Manufacturer's Statement - Electromagnetic Emission</th></tr>
<tr><td colspan="3">The product is expected to be used under the electromagnetic environment specified below, and the buyer or user should ensure it is used under this kind of electromagnetic environment.</td></tr>
<tr><th>Emission Test</th><th>Conformance</th><th>Electromagnetic Environment - Guidelines</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Automatic Chemiluminescence Analyzer only uses radio frequency energy for its internal functions. Therefore, its radio-frequency emission is very low and the possibility of interference on electric devices is quite small.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The Automatic Chemiluminescence Analyzer is applicable to non-domestic facilities and all facilities not directly connected with the public low-voltage power network for domestic residences.</td></tr>
<tr><td>Harmonic emission IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/ flickering emission IEC 61000-3-3</td><td>Conforming</td></tr>
</table>

Table 2 Instructions and Manufacturer's Statement - Electromagnetic Immunity

Instructions and Manufacturer's Statement - Electromagnetic Immunity			
The product is expected to be used under the electromagnetic environment specified below, and the buyer or user should ensure it is used under this kind of electromagnetic environment.			
Immunity Test	**IEC 61326 Guidelines of Test Level**	**Conforming Level**	**Electromagnetic Environment - Guidelines**
Electrostatic discharge IEC 61000-4-2	±2kV、±4kV Contact discharge ±2kV、±4kV、±8kV air discharge	±2kV and ±4kV contact discharge ±2kV, ±4kV and ±8kV air discharge	The ground should be made of wood, concrete, or ceramic tile. If the ground is cover by synthetic materials, the relative humidity should be at least 30%.
Pulse group IEC 61000-4-4	±1kV to power cable	±1kV to power cable	The network power supply should have the quality for usage in a typical business or hospital environment.
Surge IEC 61000-4-5	±1kV line to line ±2kV line to ground	±1kV line to line ±2kV line to ground	The network power supply should have the quality for usage in a typical business or hospital environment.

Voltage dip Voltage interruption IEC 61000-4-11	0%U_T, lasting for 1 cycle (On U_T, 100% voltage dip) 40%U_T, lasting for 5 cycles (On U_T, 60% voltage dip) 70%U_T, lasting for 25 cycles (On U_T, 30% voltage dip) 0%, lasting for 250 cycles (On U_T, 100% voltage interruption)	0%U_T, lasting for 1 cycle (On U_T, 100% voltage dip) 40%U_T, lasting for 5 cycles (On U_T, 60% voltage dip) 70%U_T, lasting for 25 cycles (On U_T, 30% voltage dip) 0%, lasting for 250 cycles (On U_T, 100% voltage interruption)	The network power supply should have the quality for usage in typical business or hospital environment. If users of the Automatic Chemiluminescence Analyzer need to operate continuously during power interruption, it is recommended that the Automatic Chemiluminescence Analyzer use uninterruptible power supply or battery power supply.
Rated power frequency magnetic fields (50/60Hz) IEC 61000-4-8	3A/m	3A/m	If abnormal operation occurs, it is necessary to keep the Analyzer away from the power frequency magnetic field or install magnetic shielding at the site. The power frequency magnetic field in the intended installation site should be measured and it should be lower than the coincidence level.
Note: UT is the AC supply voltage before the test level is applied. 50Hz corresponds to 5 cycles, 25 cycles and 250 cycles and 60Hz corresponds to 6 cycles, 30 cycles and 300 cycles.			

Table 3 Instructions and Manufacturer's Statement - Electromagnetic Immunity

Instructions and Manufacturer's Statement - Electromagnetic Immunity			
The product is expected to be used under the electromagnetic environment specified below, and the buyer or user should ensure it is used under this kind of electromagnetic environment.			
Immunity Test	**IEC 61326 Test Level**	**Conforming Level**	**Electromagnetic Environment - Guidelines**
RF conduction IEC 61000-4-6	3V (effective value) 150 kHz ~ 80 MHz	3V (effective value)	Portable and mobile RF communication equipment should not be closer to any part of the Automatic Chemiluminescence Analyzer than the recommended isolation distance, including cables. The formula corresponding to the transmitter frequency should be used for the calculation of this distance. Recommended isolation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d=2.3\sqrt{P}$ 800 MHz ~ 2.7 GHz Wherein: P: maximum output rated power of the transmitter provided by the manufacturer, in watt (W); d - recommended isolation distance, in meter (m). Field strength of fixed RF transmitter is determined according to the survey[a] on the electromagnetic field, which should be under the coincidence level in every frequency range[b]. Interference may appear around the equipment marked with the symbol below.
Radiated electromagnetic field IEC 61000-4-3	3 V/m 80 MHz ~ 2.0 GHz 3V/m 1.4 GHz-2 GHz 1V/m 2.0 GHz-2.7 GHz	3 V/m 80 MHz ~ 2.0 GHz 3V/m 1.4 GHz-2 GHz 1V/m 2.0 GHz-2.7 GHz	

Note 1: A formula for a higher frequency band should be adopted at the 80MHz and 800MHz frequency points.

Note 2: These instructions might not be applicable for all situations.

Electromagnetic transmission is affected by the absorption and reflection of buildings, objects, and human bodies.

a. The field strength of fixed transmitters, such as base station of wireless (cell/cordless) phone and ground mobile radio, amateur radio, AM & FM radio and TV broadcasting, can not be accurately predicted theoretically. Survey on electromagnetic fields should be considered so as to evaluate the electromagnetic environment of the stationary type radio frequency transmitter. If the measured field strength of the place where the product is located is higher than the above radio frequency coincidence level, then the product should be observed to verify its normal operation. In case of any observation of abnormal performance, it is necessary to take supplementary measures such as readjusting the direction or location of the product.

When b is within the entire frequency scope of 150KHz~80MHz, the field strength should be below 3V/m.

Table 4 Recommended Isolation Distance between Portable and Mobile Radio Frequency (RF) Communication Devices and the Product

Recommended Isolation Distance between Portable and Mobile Radio Frequency (RF) Communication Devices and the Product			
The product is expected to be used under the radio frequency radiated disturbance controlled electromagnetic environment. According to the maximum output power of the communication equipment, the buyer or user of the product can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication devices and this product.			
Maximum output Rated output power W	Isolation distances corresponding to different transmitter frequencies /m		
	150 KHz ~ 80 MHz $d=1.2\sqrt{P}$	80 MHz ~ 800 MHz $d=1.2\sqrt{P}$	800 MHz ~ 2.0 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the maximum rated power of the transmitter not listed in the above table, the recommended isolation distance d, in meter (m), can be determined by the formula corresponding to the transmitter frequency column, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W). Note 1: A formula for a higher frequency band should be adopted at the 80MHz and 800MHz frequency points. Note 2: These instructions might not be applicable for all situations. Electromagnetic transmission is affected by absorption and reflection of buildings, objects and human bodies.			

Instructions and Risk Warnings about Electromagnetic Compatibility

According to the electromagnetic compatibility test, the product complies with the requirements of *IEC 61326-1/ EN 61326-1 Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements - Part 1: General Requirements* and *IEC 61326-2-6/ EN 61326-2-6 Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements - Part 2-6: Particular Requirements - In*

Vitro Diagnostic (IVD) Medical Equipment.

The following requirements should be strictly observed during use; otherwise, it may cause electromagnetic interference to other equipment or reduce the anti-electromagnetic interference ability of the Automatic Chemiluminescence Analyzer, or even cause loss of the basic performance.

This product is the Class A equipment of Engineering Medical Group 1 as stipulated in CISPR 11, and is not expected to be directly connected to the public power grid; device not permanently installed; not life support equipment.

Description about that portable and mobile RF communication equipment may affect medical electrical equipment: As portable and mobile RF communication equipment may affect the normal operation of the product, a certain spatial distance should be kept between portable and mobile RF communication equipment and the Automatic Chemiluminescence Analyzer. Specific requirements are shown in Table 4.

The equipment power cable is 2.9 meters long, without a shielding layer, and the network cable is 2.5 meters long, with a shielding layer. If the connecting line is faulty, contact our company for repair or replacement; otherwise it may cause excessive electromagnetic interference. In case of any failure of the equipment, please contact our company in time, and do not repair or replace the components without permission; otherwise it may cause excessive electromagnetic interference.

Warning: Except for energy converters and cables sold by manufacturer of the equipment or system as the spare parts of internal components, using unprescribed accessories, energy converters and cables may lead to transmission increase or immunity decrease of the equipment or system.

Warning: The equipment or system should not be placed near or stacked up with other equipment. If you have to do so, please observe and confirm its normal operation under existing configuration.

This product is a professional IVD equipment, and the following precautionary warnings should be paid attention to:

a) Emission and immunity requirements specified in Table 1 to Table 4 should be met.

b) The equipment is designed and tested according to Class A equipment in CISPR 11. In home environment, the equipment may cause radio interference, thus preventive measures should be taken.

c) It is recommended to evaluate electromagnetic environment before using the device.

d) It is forbidden to use this device beside any source of intense radiation (such as unshielded RF source), or it may interfere with the normal operation of this device.

Basic performance: The product works normally, and the coefficient of variation (CV) of alpha fetoprotein (AFP) test results should not exceed 5.0%.

Test method: Use alpha fetoprotein (AFP) calibrator and kit to test the corresponding normal value control or fresh patient sample on the Analyzer, repeat the test for 20 times, and calculate the coefficient of variation (CV, %) of the test results, which should meet the requirements of basic performance.

Working mode: Set software in the test mode to repeatedly measure the control of alpha fetoprotein (AFP).

Note: Pure water should be used to replace samples and reagents in radiation emission and conduction emission tests.