BS-1000M&BS-1100M Chemistry Analyzer

Operator’s Manual

For this Operator’s Manual, the issue date is 2024-03.

Intellectual Property Statement

Responsibility on the Manufacturer Party

Contents of this manual are subject to change without prior notice.

All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

⚠ WARNING

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

⚠ NOTE

This equipment must be operated by skilled/trained clinical professionals.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Customer service department

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057,P.R.China
Website:	www.mindray.com
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680

Preface

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Please read this manual thoroughly before using the product. This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact us.

Observance of this manual is a prerequisite for proper performance and correct operation, and it ensures patient's and operator's safety. All graphics including screens and printouts in this manual are for illustration purpose only and must not be used for any other purposes. The screens and printouts on the product should prevail.

Letter M in "M#" appearing in this manual and on the software stands for module, which means configured analyzer. The product can be operated via both mouse and touchscreen. This manual describes operating instructions based on the use of touchscreen.

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1 Safety Information

In this chapter

1 Safety Information

This chapter provides you with safety symbols used in this manual and their meanings, summarizes the safety hazards and operating precautions that should be considered seriously when the instrument is being operated, and lists the labels and silkscreen that have been applied to the instrument and their indications.

Safety Symbols

Symbol	Description
	Caution, risk of danger
	Warning
	Note
	Biohazard

1.1 Summary of Hazards

Introduction

Observe the following safety precautions when using the product. Ignoring any of these safety precautions may lead to personal injury or equipment damage.

WARNING

If the product is used in a manner not specified by our company, the protection provided by the product may be impaired.

Electric Shock Hazards

Observe the following instructions to prevent electric shock.

WARNING

When the MAIN POWER is turned on, users other than the servicing personnel authorized by our company must not open the rear cover or side cover.

Spillage of reagent or sample on the product may cause equipment failure and even electric shock. Do not place sample and reagent on the panel of the analyzer. In case of spillage, switch off the power immediately, remove the spillage and contact our Customer Service Department or your local distributor.

Moving Parts Hazards

Observe the following instructions to prevent personal injury caused by moving parts.

WARNING

When the system is in operation, do not touch such moving parts as sample/reagent probe, gripper, reagent carousel, cuvette loader, aspirate station and rack loading area.

Do not put your finger or hand into any open part when the system is in operation.

Photometer Lamp Hazards

Observe the following instructions to prevent personal injury caused by Photometer Lamp.

WARNING

- Light sent by the photometer lamp may hurt your eyes. Do not remove the lamp when the system is in operation or standby.
- "f you want to replace the photometer lamp, perform the Replace Lamp procedure on the Semi-Auto Maintenance window. Do not touch the lamp before the countdown is finished, or you may get burned.

Laser Beam Hazards

Observe the following instructions to prevent personal injury caused by laser beam.

WARNING

Light sent by the bar code reader may hurt your eyes. Do not stare into the laser beam radiated from the bar code reader when the system is in operation.

Sample, Calibrator and Control Hazards

Observe the following instructions to protect against the biohazardous infection by samples, calibrators and control samples.

BIOHAZARD

- Inappropriately handling samples, controls and calibrators may lead to biohazardous infection. Do not touch samples, mixtures or waste with your bare hands. Wear gloves and lab coat and, if necessary, goggles and a mask.
- In case your skin contacts the samples, control or calibrator, follow the standard laboratory safety procedure and consult a doctor.

Reagent and Wash Solution/Detergent Hazards

Observe the following instructions to protect against the biohazardous infection by reagents and wash solution.

WARNING

Reagents and concentrated wash solution/detergent are corrosive to human skins. Exercise caution when using reagents and concentrated wash solution. In case your skin or clothes contact them, wash them off with soap and clean water. If reagents or wash solution/detergent spills into your eyes, rinse them with water and consult an oculist.

Waste Hazards

Observe the following instructions to prevent environmental pollution and personal injury caused by waste.

BIOHAZARD

Some substances contained in reagent, control, wash solution/detergent and waste are subject to regulations of contamination and disposal. Dispose of the waste in accordance with your local or national rule for biohazard waste disposal and consult the manufacturer or distributor of the reagents for details.

Solid wastes such as reagent bottles and reaction cuvettes are subject to contamination regulations, and should be disposed of in accordance with your local or national rule for waste disposal.

Wear gloves and lab coat and, if necessary, goggles and a mask.

Handle the waste tank cap, waste tube, waste sensor and waste tank carefully to avoid spilling the waste.

System Disposal Hazards

Observe the following instructions to dispose of the waste analyzer.

WARNING

Materials of the analyzer are subject to contamination regulations. Dispose of a waste analyzer in accordance with your local or national rule for waste disposal.

Fire and Explosion Hazards

Observe the following instructions to prevent fire and explosion.

WARNING

Ethanol is flammable substance. Please exercise caution while using ethanol around the instrument in order to prevent fire and explosion.

Removal of Analyzer from Use for Repair or Disposal

To minimize or eliminate the hazards involved in repair, transportation, and disposal process, please observe the following instruction.

WARNING

When the analyzer is not in use, for example, in repair, transportation or disposal process, please clean and sterilize the parts (sample probe, reagent probe, etc.) or surfaces that may cause biohazdards and remind the person who handles the device of the related hazards.

Software and Cybersecurity

WARNING

Data should be transmitted in a closed network or virtual isolated network environment. The laboratory is responsible for the security of the virtual isolated network environment.

Make sure that the network authorization information (such as user information and password) is secure and not obtained by unauthorized persons.

Please use Microsoft firewall and kill the virus regularly.

Notification of Adverse Events

NOTE

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

1.2 Precautions on use

Introduction

To use the product safely and efficiently, pay attention to the following operating precautions.

Intended Use

WARNING

The instrument is an automated chemistry analyzer for in vitro diagnostic use in clinical laboratories and designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine and cerebrospinal fluid samples. Please consult us before you use the instrument for other purposes.

When drawing a clinical conclusion, please also refer to patients' clinical symptoms and other test results.

Environment Precautions

CAUTION

Evaluate the electromagnetic environment prior to operating the system.

Please install and operate the system in an environment specified by this manual. Installing and operating the system in other environment may lead to unreliable results and even equipment damage.

To relocate the system, please contact our Customer Service Department or your local distributor.

Installation Precautions

NOTE

The safety of any system incorporating the equipment is the responsibility of the assembler of the system.

Electromagnetic Noise Precautions

CAUTION

The IVD MEDICAL EQUIPMENT complies with the emission and immunity requirements described in this part of IEC 61326.

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

The electromagnetic environment should be evaluated prior to operation of the device.

Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

CAUTION

It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

The calculation formula to determine the separation distance between an IVD MEDICAL EQUIPMENT and a mobile phone is given by $d = 6/E \cdot \sqrt{P}$, where d is the minimum separation distance in metres, P is the maximum power in watts, and E is the immunity test level in V/m.

Operating Precautions

⚠ CAUTION

- Take the clinical symptoms or other test results of the patient into considerations when making a diagnosis based on the measuring results produced by the system.
- Operate the system strictly as instructed by this manual. Inappropriate use of the system may lead to unreliable test results or even equipment damage or personal injury.
- Do not open the shielding cover when the system is in operation; otherwise starting analysis is not permitted.
- When using the system for the first time, first run calibrations, and then QC tests to make sure the system is in proper state.
- Be sure to run QC tests every time when you use the system, otherwise the result may be unreliable.
- Do not uncover the reagent carousel when the system is in operation. Keep the reagent carousel cover closed. Please close the front door before the auto loader when the system is in operation.
- The operation unit is a personal computer with the operating software installed. Installing other software or hardware on the computer may interfere with the system operation. Do not run other software when the system is working.
- Computer virus may destroy the operating software or test data. Do not use the computer for other purposes or connect it to the Internet. If the computer is infected by virus, please install anti-virus software to check for and clear virus.
- Do not touch the display, mouse or keyboard with wet hands or hands with chemicals.
- Do not place the MAIN POWER to ON again within 10 seconds since placing it to OFF; otherwise the system may enter the protection status. If it does so, place the MAIN POWER to OFF and place it to ON again.
- Do not start measurement after starting up the system until incubation is finished and the status becomes Standby.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Maintenance and Servicing Precautions

CAUTION

- Maintain the system strictly as instructed by this manual. Inappropriate maintenance may lead to unreliable results, equipment damage or personal injury.
- To wipe off dust from the system surface, use a soft, clean and wet (not too wet) cloth soaked with soap water rather than organic solvents such as ethanol. After cleaning, wipe the surface and dry with dry cloth.
- Switch off all the powers and disconnect the power plug before cleaning. Take necessary measures to prevent liquid ingression, otherwise equipment damage or personal injury may be caused.
- Replacement of such major parts as sample/reagent probe and syringe assembly must be followed by a calibration.
- If the system fails and needs servicing, contact our Customer Service Department or your local distributor. The system may need to be stopped or transported during servicing, which will probably cause biohazards, electric shock hazards and moving part hazards. Exercise caution when preparing the system for servicing.
- Replacement of the photometer lamp should be done when the system power has been switched off for at least 5 minutes.

Test Parameter Configuration Precautions

CAUTION

- To define such parameters as sample volume, reagent volume and wavelength, follow the instructions in this manual and the Instructions for Use of reagents.

ISE Module Precautions

CAUTION

- If the ISE module is configured, to prevent the electrodes from being damaged during system shutdown, if you want to turn off the power of the analyzer for a long time, store the electrodes before shutdown.
- When storing electrodes, prevent them from being exposed to high temperature (over 30 °C) for a long time. If possible, store the samples in a 2-8 °C refrigerator.
- Clean the ISE module regularly to prevent tube clogging or affecting electrode performance.

Sample Precautions

⚠ CAUTION

- Use samples that are completely free of insoluble substances like fibrin or suspended matter; otherwise the sample probe may be blocked. During ISE urine analysis, centrifuge the sample to remove interference from the formed substances, and then dilute the sample as required.
- Medicines, anticoagulants or preservative in the samples may lead to unreliable results.
- Hemolysis, icterus or lipemia in the samples may lead to unreliable test results; running SI test, therefore, is recommended.
- Store the samples properly. Improper storage may change the compositions of samples and lead to unreliable results.
- Sample volatilization may lead to unreliable results. Do not leave the sample open for a long period.
- The system has a specific requirement on the sample volume. Refer to this manual for proper sample volume.
- Load samples to correct positions on the sample rack before the analysis begins; otherwise reliable results may not be obtained.

Reagent, Calibrator and Control Precautions

⚠ CAUTION

- Use proper reagents, calibrators and controls on the system.
- Select appropriate reagents according to the performance characteristics of the system. Consult the reagent suppliers, our company or our authorized distributor for details, if you are not sure about your reagent choice.
- Store and use the reagents, calibrators and controls strictly as instructed by the suppliers; otherwise, reliable results or best performance of the system may not be obtained. Improper storage of reagents, calibrators and controls may lead to unreliable results and bad performance of the system even in validity period.
- Perform calibration after changing the reagents, otherwise reliable results may not be obtained.
- Contamination caused by carryover among reagents may lead to unreliable test results. Consult the reagent suppliers for details.
- Do not use expired reagent, control or calibrator.
- Note: For reagent expiration date, see the label on the reagent bottle or the label on the reagent box. Use the reagent within its expiration date.

Rack Feeder System Precautions

BIOHAZARD

Do not take away the sample rack from track feeder system during test running to prevent skin damage or infection due to contact with the moving parts.

CAUTION

Do not push sample rack in the lane during test running. Beware of pinching.

Data Archiving Precautions

NOTE

The system automatically stores the data to the built-in hard disk. Data loss, however, is still possible due to mis-deletion or physical damage of the hard disk. You are recommended to regularly archive the data to such medium as CDs.

To avoid data loss caused by unexpected power failure, a UPS (uninterrupted power supply) is recommended.

External Equipment Precautions

WARNING

For operating instructions and precautions of the computer and printer, please refer to their operation manuals.

External equipment connected to the analogue and digital interfaces must be complied with relevant safety and EMC standards (e.g., IEC 60950 Safety of Information Technology Equipment Standard and CISPR 22 EMC of Information Technology Equipment Standard (CLASS B)). Any person, who connects additional equipment to the signal input or output ports and configures an IVD system, is responsible for ensuring that the system works normally and complies with the safety and EMC requirements. If you have any questions, consult the technical services department of your local representative.

Tube and Liquid Container Precautions

WARNING

When the tube or the part that contain liquid become aged or damaged, please stop its use immediately and contact our customer service department or your local distributor to check and replace it.

Shielding Cover

⚠ WARNING

Check if the shielding cover is properly supported every day. When it is closed by hand, the shielding cover should be closed stably without automatic opening. Please check the shielding cover daily, in case it falls off suddenly.

Cleaning and Decontamination

⚠ CAUTION

Appropriate decontamination should be carried out in accordance with laboratory safety regulations if reagent, sample or other liquids are spilled onto the equipment. In case of large-amount liquid ingression, please contact our customer service department or the local distributor.

No decontamination or cleaning agents can be used which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it. Strong acid or alkaline solutions are forbidden to clean the equipment.

If there is any doubt about the compatibility of the decontamination or cleaning agents with parts of the equipment or with material contained in it, please contact our customer service department or the local distributor.

⚠ CAUTION

Recommended detergent: water and 75% ethanol.

Prohibited detergent: materials that may corrode metals, for example, 3% hydrogen peroxide.

The user shall perform regular cleaning to the cover of the analyzer. Use the specified materials to clean the equipment only. For any damage to the instrument or other accidents caused by using materials other than specified, Mindray will not provide any warranty.

Mindray does not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.

Disinfection may damage the system to some extent. It is recommended to perform disinfection only when necessary according to your laboratory protocol.

Do not use any cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it.

If you accidentally spill hazardous material (for example, samples and reagents) on the instrument, clean and disinfect the instrument. Recommended detergents and disinfectants include water and 75% ethanol. Do not use materials that may corrode metals (for example, 3% hydrogen peroxide). Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

1.3 Instrument Labels and Silkscreen

Introduction

The following non-warning and warning labels and silkscreen are used on the product for system identification and operating instruction.

For the label marked with  , please consult the related documentations in order to find out the nature of the potential HAZARDS and any actions which have to be taken to avoid them.

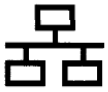
Check the labels regularly for cleanliness and integrity. If any of the labels becomes vague or peels off, contact our Customer Service Department or your local distributor for replacement.

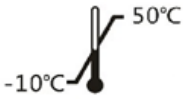
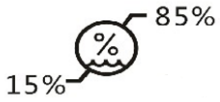
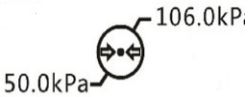
The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows.

Geometric shape	Meaning	Safety color	Contrast color	Graphical symbol color
	Prohibition	Red	White	Black
	Mandatory	Blue	White	White
	Warning	Yellow	Black	Black
	Warning	Yellow	Black	Black

1.3.1 Labels and Silkscreens

Symbol	Meaning
	Serial Number
	Date of Manufacture
	Manufacturer
	Authorized Representative in the European Community

Symbol	Meaning
	The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.
	In Vitro diagnostic medical device
	Biological risks
	Caution
	Laser radiation
	“ON” (Power)
	“OFF” (Power)
	Computer Network
	Protective conductor terminal
	Risk of electric shock
	Alternating current
	Standby When press this button, PC is powered on.

Symbol	Meaning
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Unique device identifier

1.3.1.1 Rack Indicator

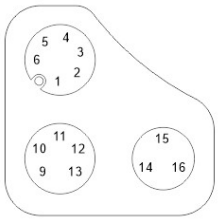
This label located on the sample loading door indicates the ID and status of each rack channel.

1.3.1.2 Syringe

This symbol located below the syringes indicates the sample syringes and reagent syringes..

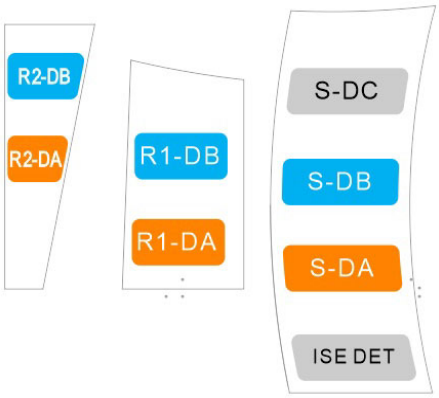
1.3.1.3 Wash tubes

This symbol located near the cuvette wash station indicates the wash tubes.



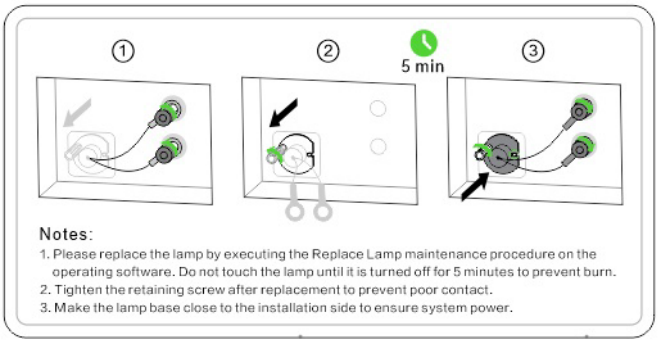
1.3.1.4 Sample Probe Detergent and DA/DB Detergent

This symbol located near the wash well of sample probe indicates sample probe detergent(DC), alkaline detergent(DB), acid detergent(DA) and ISE detergent(ISE DET).



1.3.1.5 Replacement of Lamp

This symbol located on rear shell indicates the replacement process of lamp.



1.3.1.6 Power Supply

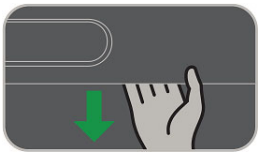
This label located close to power socket indicating rated voltage, alternating current and frequency.

1.3.1.7 Deionized water

This label located on the deionized water tank.

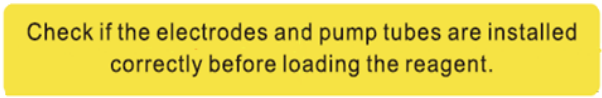
1.3.1.8 ISE replacement window

This label located on the ISE replacement position.



1.3.1.9 ISE Reagent Compartment Indicator

This symbol located below the ISE reagent compartment reminds the user to load the reagent pack according to the correct procedures.

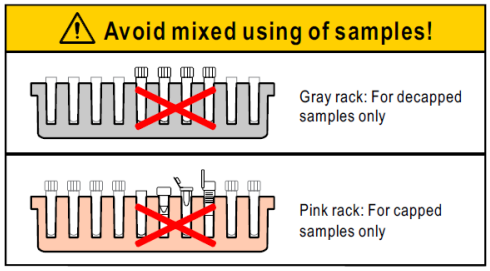


1.3.1.10 UV Radiation

This symbol located on the UV lamp holder below the ISE reagent compartment.

1.3.1.11 Avoid mixed using of samples

This symbol located on the This label is located on the lower-right corner of the analyzer panel.



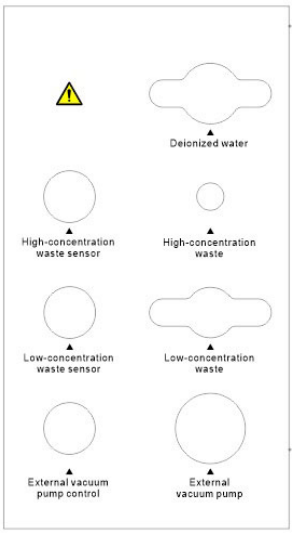
1.3.1.12 Waste

This label located on the high concentration tank.

1.3.1.13 Interfaces for fluid connection

This label located on the fluid connection interfaces indicates the connection of fluid tubing.

The fluidic interfaces for maximum configuration are shown as follows:



1.3.1.14 Warning Labels

1.3.1.15 Biohazard Warning

This label indicating the risk of biohazardous infection is located in the following positions:

- Sample probe wash well
- High-concentration waste outlet
- High-concentration waste tank
- Front and back sides of the waste container

1.3.1.16 Moving Parts Warning

This symbol and text indicating the hazardous moving parts is located in the following positions:

- Reagent probes
- Reagent mixers
- Sample probe

This symbol and text indicating the hazardous moving parts is located near rack loading area:

1.3.1.17 Shielding Cover Warning

This symbol and text located outside the shielding cover and next to the handle reminds you of keeping the shielding cover closed while the system is running tests to prevent injury caused by probes, mixers and various liquids.

1.3.1.18 Risk of Electrical Shock

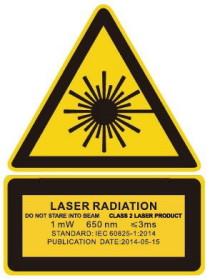
This symbol is located near the power socket indicating the risk of electrical shock.

1.3.1.19 Risk of Electrical Shock

The label located on the cables of circulating water heater indicating the risk of electrical shock.

1.3.1.20 Laser warning

This symbol and text located near the sample bar code reader and reagent bar code reader reminds you of not staring into the laser beam.



1.3.1.21 Photometer lamp warning

This symbol and text located near the lamp reminds you of not touching the lamp before it gets cool.

1.3.1.22 Probe collision warning

This symbol and text located on the lower left corner of the reagent carousel remind you of not opening the carousel cover to prevent from damaging the sample probe.

1.3.1.23 Handle with caution

The combination of arm and extension presents a potential pinch hazard at all points/ positions where the arm and extension can come into contact. The arm has a wide range of motion both up/down and side to side -- consider potential pinch points that may cause personal injury.

1.4 Abbreviations

The following abbreviations are used

Abbreviations	Definition
CV	Coefficient of Variation
Detergent C	Probe Cleanser
dBA	Decibel weighted against the A-frequency response curve. This curve approximate the audible range of the human ear.
EMC	ElectroMagnetic Compatibility
EN	European standard
i.e.	Id est-that is to say
IEC	International Electrical Commission
IVD	In Vitro Diagnostic
LIS	Laboratory Information System
QC	Quality Control
RH	Relative Humidity
SD	Standard Deviation
STAT	Short Turn-Around Time
μL	Microliter. 1ml= 1000μL

2 System Description

In this chapter

2 System Description

2.1 Installation Requirements and Procedure

2.1.1 Installation Requirements

CAUTION

Install the instrument in a place meeting the requirements presented in this section; otherwise, it will not perform as promised.

Mindray authorized personnel are required to install, verify, upgrade and modify the analyzer software.

2.1.1.1 Installation Environment

- The system is for indoor use only.
- The bearing platform (or ground) should be level (with gradient less than 1/200).
- The bearing platform (or ground) should be able to support at least 450 kg.
- The installation site should be well ventilated.
- The installation site should be free of dust.
- The installation side should not be in direct sun.
- The installation site should be kept away from a heat or draft source.
- The installation site should be free of corrosive gas and flammable gas.
- The bearing platform (of ground) should be free of vibration.
- The installation site should be kept away from large noise and power supply interference.
- Keep the system away from brush-type motors and electrical contact device that is frequently switched on and off.
- Do not use such devices as mobile phones and radio transmitter near the system.
- The system should be installed in a place with altitude height between -400 to 4000 meters. If it is higher than 2000 m, an external vacuum pump should be configured. If an ISE module is configured, its operating altitude should be -400-2000 m.

2.1.1.2 Power supply

- Connect the system to a power supply meeting the requirements specified in this manual. For more information, refer to "2.5.1.10 External vacuum pump" (2-34).
- The system is provided with a three-wire power cord, which has good grounding performance.
- The system should be connected to a properly-grounded power socket.

WARNING

Make sure the power junction box is grounded correctly. Improper grounding may lead to electric shock or equipment damage. Check if the power junction box outputs voltage meeting the specified requirements and has a proper fuse installed.

WARNING

Do not plug the power cord of the analyzing unit in the same power strip with the power cords of the operation unit, output unit or other devices.

2.1.1.3 Temperature and humidity

- Ambient Temperature: 15-30°C.
- Humidity: 35%RH-85%RH, without condensation.

CAUTION

Operating the system in an environment other than the specified may lead to unreliable test results. If the temperature or relative humidity does not meet the above-mentioned requirements, use air-conditioning equipment.

The refrigerated reagent compartment is at a low temperature. When both the ambient temperature and the humidity are at a relatively high level (though within the specified range), natural condensation can cause condensate water to be produced on the surface of the reagent compartment or the reagent bottles. In this case, use air-conditioning equipment.

2.1.1.4 Drainage

- The supplied water must meet the following requirement: its resistivity must be no less than 1MΩ.cm@25°C (conductivity no larger than 1μS/cm@25°C).

BIOHAZARD

The supplied water must meet the requirements; otherwise, insufficiently purified water may result in misleading test results.

The temperature of supplied water must meet the requirements of water supply; otherwise, too low or too high temperature may affect the stability of the test results.

- Flow: no less than 42L/H for continuous flow, and 2L/M for transient peak flow.
- Temperature: The temperature of supplied water is within 10°C-30°C.
- If you use water supply equipment, make sure that the water supply pressure is within 100kPa-392kPa and the length of the inlet tubing is no longer than 10m.
- Make sure that the outlet is no less than 50mm wide and no greater than 100mm high, and the length of the waste tubing does not exceed 5 meters. When using the high-concentration waste tank provided with the instrument, ensure the tube is no longer than 2m.

BIOHAZARD

Dispose of the waste liquid according to the local regulations.

After installing the instrument, connect it with the fluidic components as instructed in the figure below.

BIOHAZARD

Wear gloves, mask, lab coat and goggles.

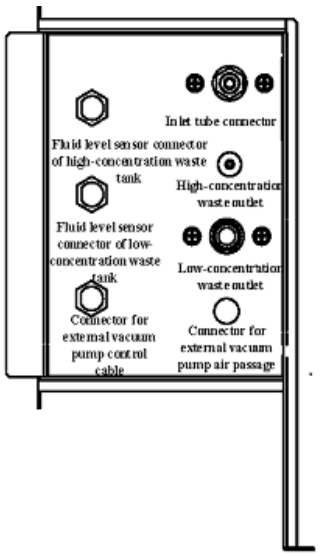
CAUTION

When connecting the tubes, exercise caution to avoid folding or pressing them.

When checking the drain tubes, wear the gloves and lab coat, if necessary, goggles and mask. Keep distance from the tube to avoid injury due to the liquid's splashing or spilling.

When sewer is used to discharge the liquid waste, seal the drain after the outlet of the tube is put into it so as to avoid overflowing of the foam produced by the liquid waste.

Figure 2.1 Fluidic connection diagram



Inlet and outlet of fluidic system (Back, look inside the instrument)

2.1.1.5 Space and accessibility requirements

Install the instrument according to the clearance requirements as shown in the figure below.

WARNING

Do not place the instrument at the place difficult to cut off the power supply.

Figure 2.2 System clearances

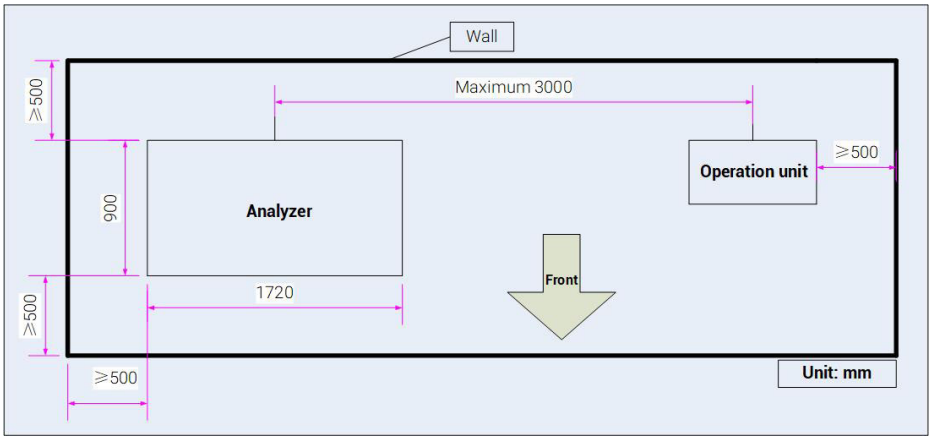


Table 2.1 Recommended computer configuration

WARNING

When reinstalling or upgrading the Windows operating system, please first contact the Customer Service Department or your local distributor for correct software version since operating system is subject to change.

Item	Description
CPU	CPU Frequency 2.8GHz or superior performance
Random access memory (RAM)	At least 4GB
Hard drive	At least 500GB
Network card and Sound card	Dual network cards and one sound card with speaker are required. Compatible with 100BASE-T standards
Hardware interfaces	RS232 serial port, Ethernet interface(2 pcs), Parallel interface/USB Serial port: Compatible with RS232 standards
Operating system	The operating system installed on the computer must be an activated Microsoft Windows 10.
Application software	Except for the operating system, other application software must not be installed or reserved on the computer.
Monitor	23 inches or above (16:9)
Automatic synchronization with Internet time server	Disable the Automatically synchronize with an Internet time server option.
Automatic updates	Turn off the automatic updates.

2.1.1.6 Recommended printer configuration

You are suggested to choose one of the following printers for use with the computer:

- Ink jet printer
- Laser printer

2.1.2 Installation Procedure

⚠ WARNING

The system should be unpacked and installed only by technicians of or authorized by our company.

The system should be unpacked and installed by technicians of or authorized by our company. Before the technicians arrive, prepare a proper site to install the system.

2.1.2.1 Before installation

When you receive the package, check it carefully. If you find any signs of mishandling or damage, file a claim immediately with our Customer Service Department or your local distributor.

After opening the package, check the delivered goods against the packing list, and then visually check the system appearance. If you find anything missing or damaged, alert our Customer Service Department or your local distributor immediately.

2.1.2.2 System relocation

If you want to relocate your system, contact our Customer Service Department or your local distributor.

2.2 Hardware Structure

2.2.1 System Overview

The chemistry analyzer consists of the analyzing unit (analyzing module and optional modules, including ISE module, display arm, external vacuum pump, decapping module, water supply module, drainage module, water quality detection module, and handheld bar code reader), operation unit (computer system), output unit (optional: printer), accessories (power cord), and consumables (reaction cuvette, Na\K\Cl\ reference electrode).

The analyzing unit, determines various clinical tests in samples and displays the test results. It is composed of the following components:

- Sample handling system
- Reagent handling system
- Reaction system
- Cuvette wash station
- Photometric system
- Mixer assembly
- ISE

The **sample handling system** constitutes the rack feeder, built-in sample bar code reader and sample racks.

The **operation unit**, a computer configured with the operating software, a display (or touchscreen display, optional), and a built-in sample barcode reader, controls the analyzing unit to finish tests and produce test results.

The **output unit** is a printer used to print test results and other data.

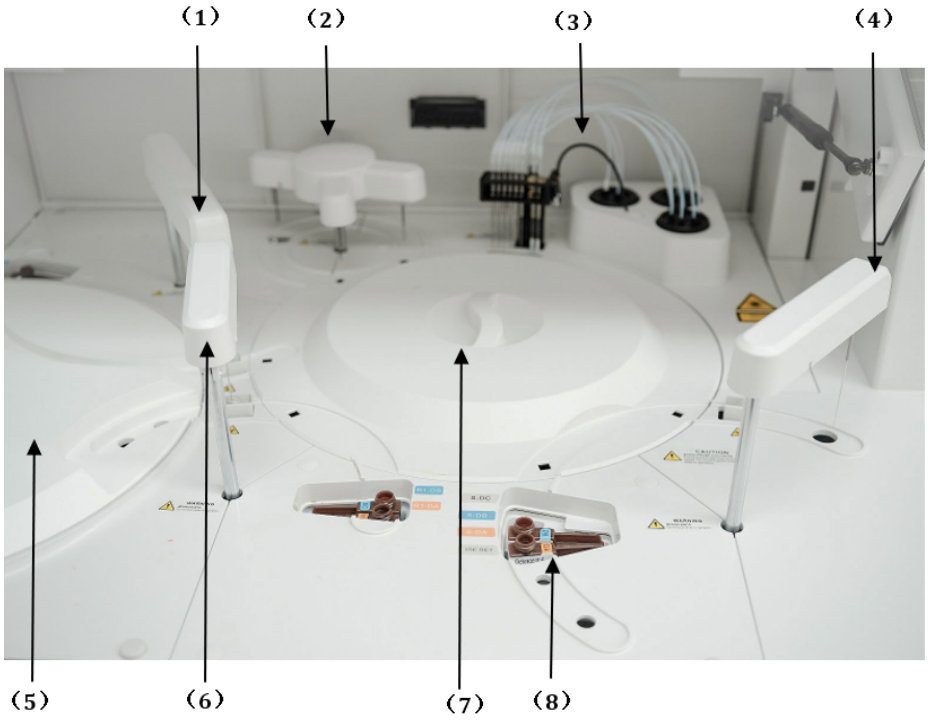
The **accessories and consumables** are components that are required for sample processing and should be replenished regularly, including cuvettes.

Figure 2.3 System overview

① Analyzing unit ② Computer and Display

③ Printer

Figure 2.4 Vertical view



① Reagent Probe 2 ② Mixer

③ Wash Station ④ Sample probe

⑤ Reagent carousel ⑥ Reagent Probe 1

⑦ Reaction carousel ⑧ Sample probe wash well

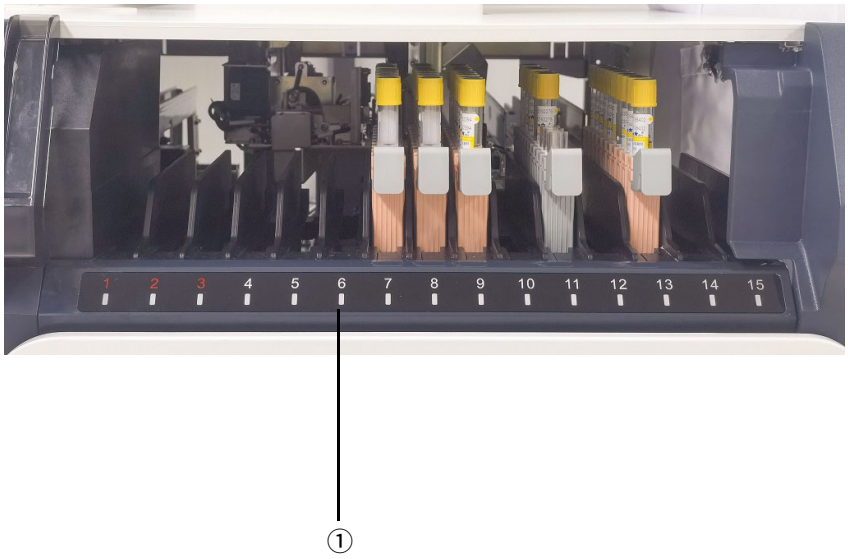
2.2.2 Sample Handling System

The sample handling system is responsible for storing racks to be tested, retrieving the racks when tests are complete, storing the racks that have finished sample aspirating, and preparing the racks for rerunning.

The sample delivery module consists of:

- Sample rack lanes
- Rack transportation mechanism
- Bar code reader
- Racks

Figure 2.5 Sample rack lanes



① Lane indicators

Sample rack lanes

Sample rack lanes are used to hold the sample rack for test and rerun. There are 15 sample rack lanes in total, and 3 internal buffer lanes. It can accommodate up to 18 racks, and 10 sample positions are available on each rack. The racks are marked as 1 to 15 from left to right and No. 1 to No.3 are for STAT test by default.

Lane indicators

The status of the button includes:

- On (blue): test is complete.
- On (orange): abnormal sample lane, sample rack or sample.
- Flickering (blue): testing or awaiting test after feeding in racks.
- Off: stop or no feed-in mission.

2.2.2.1 Sample racks

There are two colors of racks, distinguished by different colors. The racks are described as follows:

- Routine sample rack: Grey, with rack ID beginning with N
- Decapping sample rack: Pink, with rack ID beginning with M

⚠ CAUTION

Do not disinfect the racks at high temperature (over 80°C) or by using strong acid or alkaline; otherwise, the racks may be damaged.

Sample containers

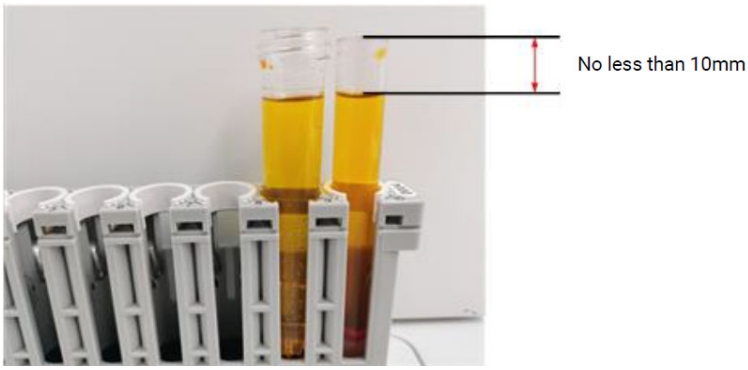
Sample containers used on racks include:

- Microtube: Φ14×25mm, 0.5ml (Beckman); Φ14×25mm, 2ml (Beckman); Φ12×37mm, 2ml (Hitachi).
- Blood collecting tube or plastic tube: Φ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13×75 mm, Φ13×95 mm, Φ13×100 mm, Φ16×75mm, and Φ16×100mm.

Sample tubes varying in specification requires different minimum sample volumes. Each sample tube must contain the minimum amount of sample; otherwise, correct aspirating cannot be ensured. The minimum sample volume is the sum of the sample volume for analysis (sum of defined sample volume for test and the excessive aspiration 5μL) and the dead volume of the sample container.

NOTE

The highest liquid level of blood collecting tube or plastic tubes (Φ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13×75 mm, Φ13×95 mm, Φ13×100 mm, Φ16×75 mm, Φ16×100 mm) shall be no less than 10 mm away from the top of the tube to prevent the sample from being sprayed, which may contaminate the analyzer.



NOTE

If the tested sample is whole blood, the whole blood sample must be held in the sample tube. Whole blood samples cannot be analyzed with microtubes.

To ensure accurate whole blood analysis, make sure that the blood cell height of the whole blood sample is at least 10 mm.

The table below shows the dead volume of each type of sample container.

Table 2.2 Specification and dead volume of sample containers

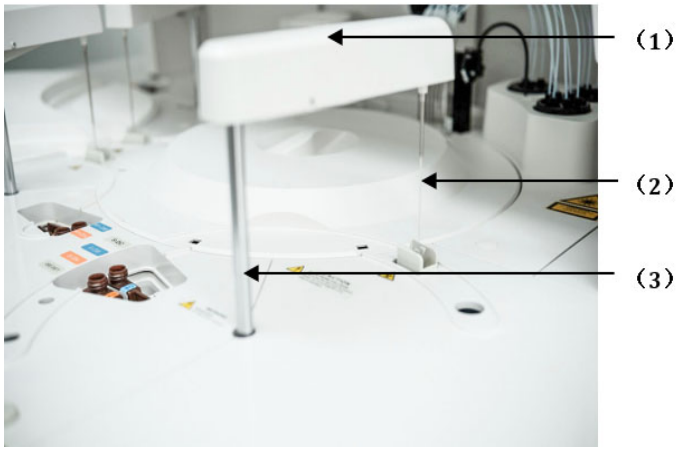
Sample Container	Specification	Dead Volume
Sample cup 0.5 mL-L	Φ14×25mm, 0.5ml (Beckman)	50μL
Sample cup 2 mL-L	Φ14×25mm, 2ml (Beckman)	150μL
Sample cup 2 mL-H	Φ12×37mm, 2ml (Hitachi)	100μL

Sample Container	Specification	Dead Volume
Primary tube/Plastic tube	Φ12×68.5 mm	8mm higher than the unacceptable sample level
	Φ12×99 mm	
	Φ12.7×75 mm	
	Φ12.7×100 mm	
	Φ13×75mm	
	Φ13×95 mm	
	Φ13×100 mm	
	Φ16×75mm	
	Φ16×100mm	

Sample dispenser assembly

The sample dispenser assembly located on the lower right corner of the reagent carousel is composed of the sample probe, probe arm, probe rotor, syringe, wash well and related tubing. It aspirates the specified amount of sample from a sample tube and then dispenses it into a cuvette for reaction and analysis:

Figure 2.6 Sample dispenser assembly



① Sample arm ② Sample probe

③ Sample probe rotor

Sample probe

The analyzer contains an independent sample probe. The sample volume to be aspirated by the sample probe varies with the chemistry type:

- Biochemical tests: 1μL-25μL, with increment of 0.1μL.
- ISE tests: 70ul (serum, plasma), 140ul (urine).

The sample probe is capable not only of aspirating sample but also of the following functions:

- Clog detection: checks the sample probe for blockage. When detecting blockage, the system produces a warning and prompts you with the next step.
- Horizontal obstruct detection: detects obstacles in the horizontal direction. When the sample probe collides with an obstacle in the horizontal direction, the auto guard system is started to prevent the sample probe from being damaged.
- Vertical obstruct detection: detects obstacles in the vertical direction. When the sample probe collides with an obstacle in the vertical direction, the auto guard system is started to prevent the sample probe from being damaged.
- Bubble detection: detects air bubbles in sample. When bubble exists, the system will give an alarm to avoid inaccurate dispensing.
- Level detection and tracking: detects the sample level and determines the depth of lowering down into the sample based on the specified aspirate volume.

⚠ WARNING

When the system is in operation, do not place any part of your body or any obstacle in the route where the sample probe arm moves; otherwise, personal injury or equipment damage may be caused.

Sample probe washing

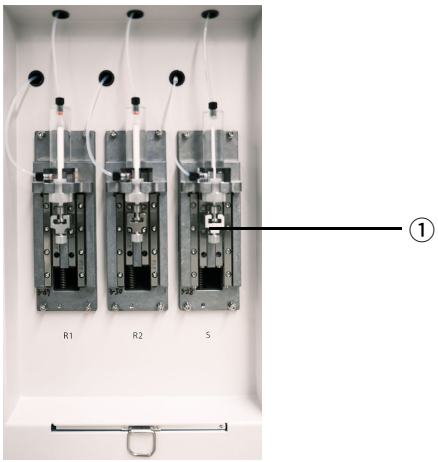
The sample probe is cleaned in its wash well with preheated water spraying its interior and exterior from an oblique direction.

Sample probe detergent (DC), alkaline detergent (DB) and acid detergent (DA) are used to special wash sample probes.

Sample syringe

The sample syringes are located behind the left door of the analyzer. When you open the left door, you will see three syringes. The syringe on the right is intended for sample aspirating and dispensing.

Figure 2.7 Sample syringe



① Sample syringe

2.2.3 Reagent Handling System

The reagent handling system is used to hold reagents and provides them for reacting with samples. It is used to provide reagents, and send reagent to aspirate position for reaction with samples within cuvette. The optical measurement reaction system analyzes test parameters of reaction liquid. It consists of the following assemblies:

- Reagent carousel assembly
- Reagent bar code reader
- Reagent dispenser assembly
- Reagent bottle

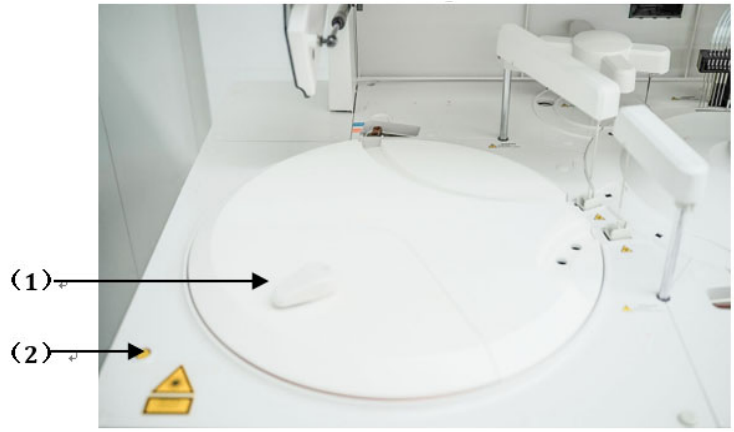
2.2.3.1 Reagent carousel assembly

The reagent carousel is a turntable located on left side of the analyzer panel. It holds reagent bottles and carries each of them to the reagent aspirate position for aspirating.

Reagent carousel contains 109 reagent positions and is composed of inner ring and outer ring. There are 48 positions in the inner ring and 61 positions in the outer ring. Both inner ring and outer ring support R0/R1/R2/R3/R4 reagents and reagent bar code scanning. The reagent carousel is able to hold reagent 20 ml and 62 ml bottles.

The reagent carousel provides a refrigerating environment which is constant within 2-8°C for 24 hours a day. The reagents stored in such environment can be kept stable with little volatilization. The reagent carousel cover must be installed when the reagent compartment is used for refrigeration.

Figure 2.8 Reagent Carousel



① Reagent carousel ② Reagent carousel control button

The reagent carousel cover consists of two parts. Open the front part of reagent carousel cover to load or change reagents.

⚠ CAUTION

Every day before analysis, remove the plug on the reagent carousel in order to prevent mechanical reset failure and bending reagent probe. After finishing the tests every day, insert the plugs on the reagent carousel.

Ensure that the reagent carousel is closed while the system is analysing. Opening the reagent carousel cover during analysing will abort the analysis and invalidate the tests that are running.

If reagent is sprayed on the position numbers of the reagent carousel, clean it immediately with ethanol-dipped gauze.

Reagent carousel control button

The reagent load button located on the lower-left corner of the carousel is used to rotate the reagent carousel. Press and hold the button to rotate the corresponding reagent carousel counterclockwise. when the button is released, the carousel stops rotating.

The control button is available only when the reagent carousel cover is open. The control button is inactive when the carousel cover is closed.

2.2.3.2 Reagent bar code reader

The reagent bar code reader located on the lower-right inside the reagent carousel consists of the following components:

- Reagent bar code reader
- Bar code label
- Hardware and software to control bar code scanning

When the reagent carousel cover is closed after reagent bottles are loaded, the system scans automatically all reagent positions to read reagent information and then displays it on the screen.

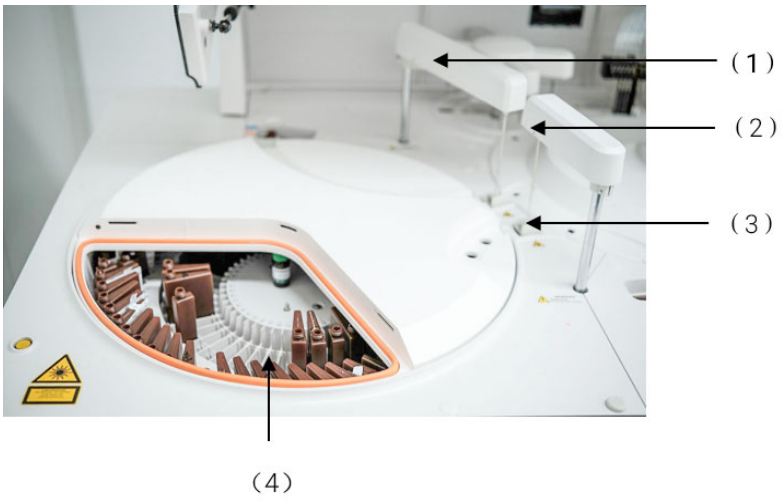
⚠ WARNING

The light radiated from the reagent bar code reader may hurt your eyes. Do not stare into the beam coming from the reagent bar code reader.

2.2.3.3 Reagent dispenser assembly

The reagent dispenser assembly located on the right side of the reagent carousel consists of the reagent probe, probe arm, probe rotor, syringes and related tubing. It aspirates the specified amount of reagent from a reagent bottle and then dispenses it into a cuvette for reaction and analysis.

Figure 2.9 Reagent dispenser assembly



① Reagent Probe 2 ② Reagent Probe 1

③ Wash Station ④ Reagent Carousel

2.2.3.4 Reagent probe

The system has two reagent probes: R1 probe and R2 probe. The two probes aspirate reagent within the following range:

- R1: 10μL-200μL, with increment of 0.5μL
- R2: 10μL-200μL, with increment of 0.5μL

The reagent probes are capable not only of aspirating reagent but also of the following functions:

- Horizontal obstruct detection: detects obstacles in the horizontal direction. When the reagent probe collides with an obstacle in the horizontal direction, the auto guard system is started to prevent the reagent probe from being damaged.
- Vertical obstruct detection: detects obstacles in the vertical direction. When the reagent probe collides with an obstacle in the vertical direction, the auto guard system is started to prevent the reagent probe from being damaged.
- Bubble detection: detects air bubbles in reagent. When bubble exists, the system will give an alarm to avoid inaccurate dispensing.
- Level detection: detects the reagent level inside reagent bottle.
- Bubble auto removing: during the reagent inventory check, if bubbles are detected in the reagent bottle, the system will automatically remove the bubbles from the reagent bottle. If the bubbles remain in the reagent bottle for several times, the system will give an alarm.

⚠ WARNING

When the system is in operation, do not place any part of your body or any obstacle in the route where the reagent probe arm moves; otherwise, personal injury or equipment damage may be caused.

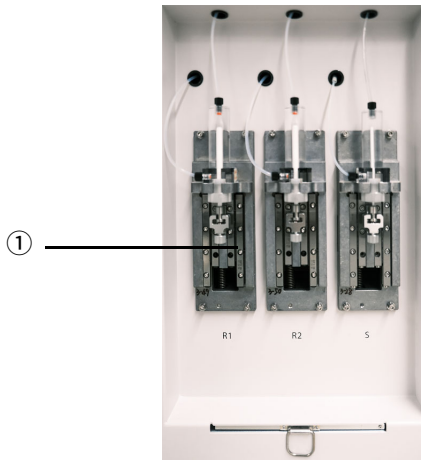
Reagent probe washing

Reagent Probes are cleaned in the wash well with preheated water spraying the interior and exterior from an oblique direction.

Reagent syringe

The reagent syringe is located behind the right door of the analyzer. When you open the right door, you will see three syringes. The two syringes on the left are related to probes R1 and R2.

Figure 2.10 Reagent syringe



① Reagent syringe

2.2.3.5 Reagent bottle

The reagent carousel is compatible with 20ml and 62ml reagent bottles. Only one reagent bottle can be held in each reagent position.

Table 2.3 Specification and dead volume of reagent bottle

Reagent Bottle Type	Dead Volume
20ml	2ml
62ml	3.5ml

2.2.4 Reaction system

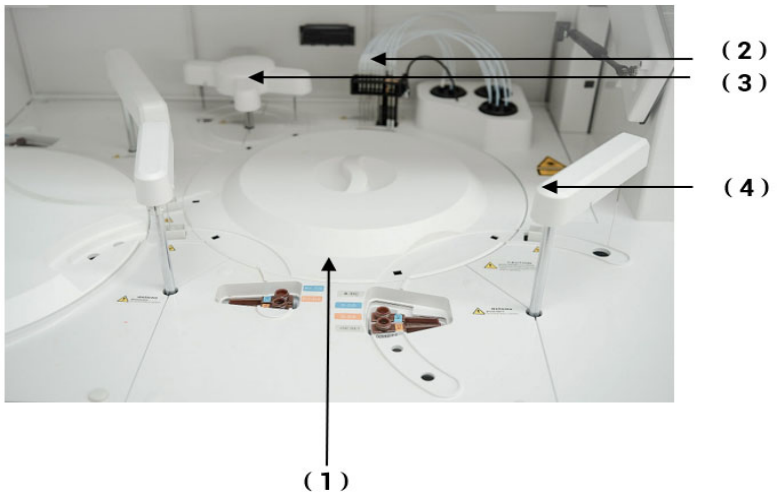
The reaction system is composed of the reaction carousel and cuvettes. It holds reaction cuvettes and provides an appropriate and steady environment for reaction mixture, which is transmitted to the photometric position for signal detecting and absorbance calculation.

2.2.4.1 Reaction carousel

The reaction carousel is a two-ring turntable located in the middle of the analyzer panel and provides 206 positions for cuvettes. It holds reaction cuvettes and transmits each of them to the photometric position for signal detecting and absorbance calculation.

The reaction carousel is capable of temperature control and provides a constant environment at 37±0.3°C with fluctuation of ±0.1°C.

Figure 2.11 Reagent carousel



① Reaction Carousel ② Cuvette wash station

③ Mixer ④ Sample probe

2.2.4.2 Reaction cuvette

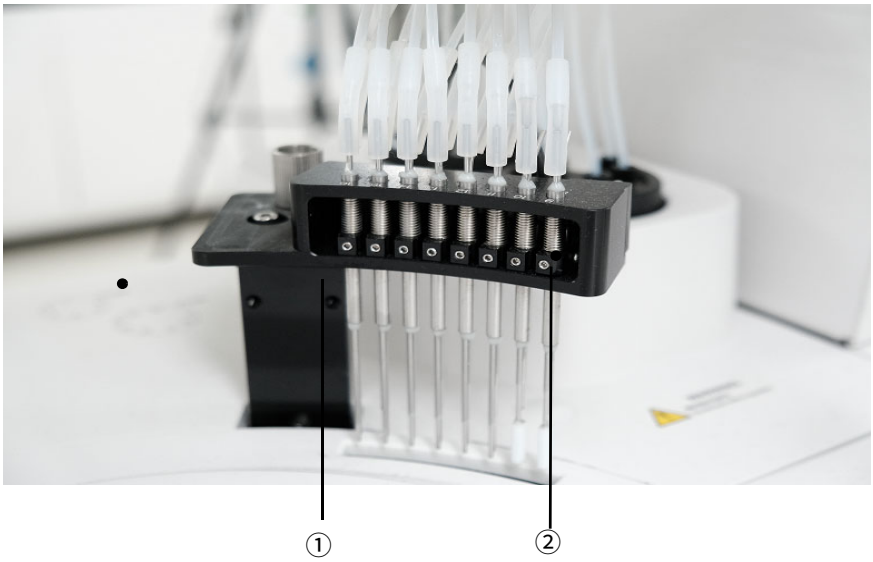
The glass cuvettes are reusable and used to hold reaction mixture for photometric measuring. The light path length of the cuvette is 5mm, and its inside dimension is 5mm (length)*4mm (depth)*29mm (height). The total volume of reaction mixture should be within 80μl-280 μl.

When finishing a test, the system washes and dries the cuvette automatically for later use.

2.2.5 Cuvette wash station

The system provides auto wash function, through which the cuvettes on the reaction carousel are washed via eight-phase wash probes of the wash station when a test is finished. The cuvette wash station consists of the wash probes, elevating motor and related tubing. The wash probes driven by the elevating motor to go up and down during each wash phase dispense and aspirate wash solution in the cuvette to perform washing and drying.

Figure 2.12 System overview



① 1-6 phase wash probe ② 7-8 phase wash probe

The cuvette wash station cleans the cuvettes with wash solution and Deionized water, which are divided as follows:

- Phase 1 and 2: the cuvette is washed with diluted wash solution
- Phase 3 to 6: the cuvette is rinsed with deionized water
- Phase 7 and 8: the cuvette is dried and wiped

The cuvette is washed and rinsed with preheated diluted wash solution and deionized water in phase 1 to 6. After the washing, the waste fluid is discharged in two flows: high-concentration waste and low-concentration waste. The system is capable of detecting the waste fluid level and produces an alarm when detecting excessive waste.

2.2.6 Photometric System

The photometric system located inside of the analyzer measures the absorbance of the reaction mixture in the cuvette. The photometric system, composed of the photometer assembly and the signal detection assembly, measures the light transmitted through the reaction mixture and then converts the light change signal into electrical signal, which reflects the change of the light intensity.

The photometer assembly, which consists of the light source, colorimetric component and optical component, provides sufficient monochromatic light and reliable colorimetric structure.

The signal detection assembly consists of the AD conversion component and the AD signal collection component. It converts the monochromatic light transmitted through the reaction mixture into an electrical signal, which is amplified and output as photometric data and then sent to the corresponding control unit for absorbance calculating.

The table below shows the main technical parameters of the photometric system.

Table 2.4 Specifications of photometric system

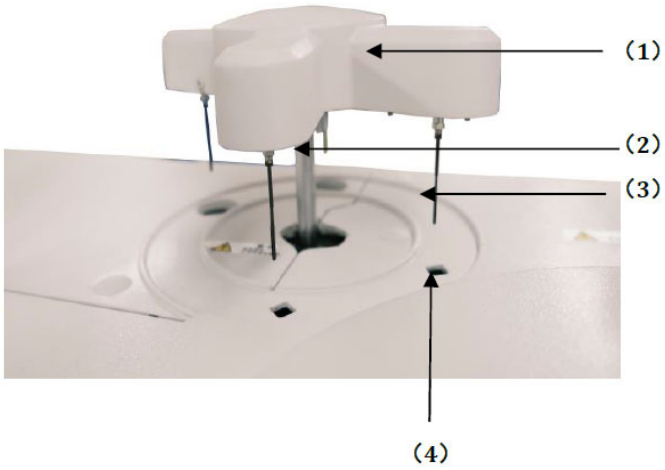
Name	Value
Light source	Tungsten-halogen lamp, 12V/20W
Lamp service life	2000 hours
Colorimetric component	Reaction cuvette
Light transmission component	Holographic concave flat-field gratings
Light transmission mode	Reversed optics
Signal detector	Photodiode array
Signal detector Measuring wavelength	16 wavelengths: 340nm,380nm,412nm,450nm,480nm,505nm,546nm,570nm,605nm,630nm,660nm,700nm,740nm,770nm,800nm and 850nm
Wavelength accuracy	±2nm
Measurement range	0-3.5A
Full width at half maximum (FWHM)	⩽ 10nm
Absorbance resolution	0.0001A

2.2.7 Mixer Assembly

The mixer assembly located at the upper-left corner of the reaction carousel consists of a mixer drive assembly with four mixers, which stir the sample and reagent respectively and are washed with deionized water.

Mixer Assembly

Figure 2.13 Mixer Assembly



① Mixer arm ② Mixer rotor

③ Mixer ④ Mixer wash well

2.2.8 Operation unit

The operation unit is a computer configured with chemiluminescence analyzer operating software. It consists of the monitor, computer, keyboard, hand-held bar code reader and mouse.

2.2.9 Output Unit

The output unit is a printer used to print test results and other data. The system supports two types of printer, which include inkjet printer and laser printer.

Printer is an optional module and not provided when the system is sold. If you want to buy our printer, please contact our customer service department. If you want to buy a printer of other manufacturers, please choose one meeting the requirements.

2.2.10 Accessories and Consumables

Accessories and consumables are replenishable components required to run tests and should be checked regularly for refilling and replacement.

⚠ CAUTION

Use the accessories, power cords and consumables manufactured or recommended by our company in order to achieve the promised system performance and safety. If needed, contact our customer service department or your local distributor.

For more information about consumables, refer to "11.1.2 Consumables" (11-3).

2.2.11 Modular System

The Chemiluminescence Immunoassay Analyzer CL-2600i or CL-2800i can be used in combination with the Chemistry Analyzer BS-1000M or BS-1100M.

2.3 Optional Modules

2.3.1 Introduction

Optional modules are not provided as standard configuration accompanying the instrument when it is delivered. They can be configured according to your requirements. The following modules are supplied:

- Printer
- ISE module
- Water supply module
- Drainage module
- External Vacuum Pump
- Water quality detection module
- Handheld bar code reader
- Displayer Arm
- Decapping module

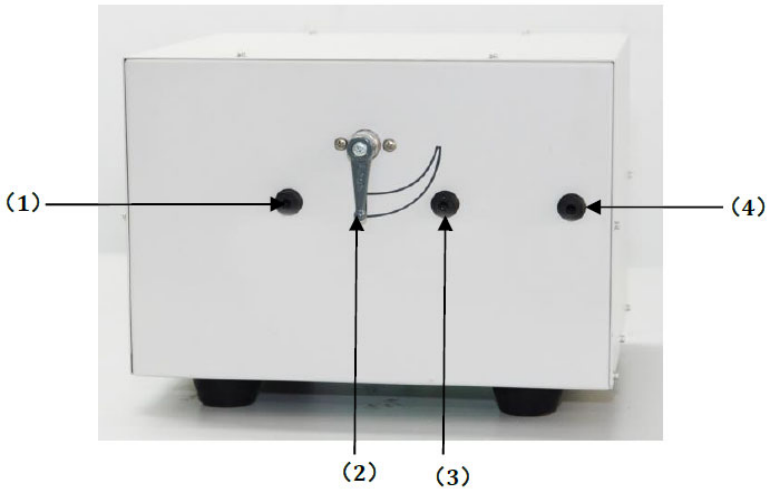
2.3.2 ISE module

The Ion-Selective Electrode (ISE) module consists of the sampling and measuring channel, syringe, heat stabilizer, degassing unit and waste discharger, used in combination with Na+ electrode, K+ electrode, Cl- electrode, reference electrode to measures the concentration of Na, K and Cl in serum, plasma and diluted urine. The sample volume for serum and plasma is 70μl. The sample volume of the diluted urine is 140μl. The theory of measurement is direct ion-selective electrode method.

2.3.3 Water supply module

The water supply module provides deionized water for the chemistry analyzer. When water is required during the measuring process, the water supply module turns on the internal inlet valve and transmits water while driven by the pneumatic pump; when water is not needed, the water supply module turns off the internal inlet valve and cuts off the power supply of the pneumatic pressure pump to stop supplying water.

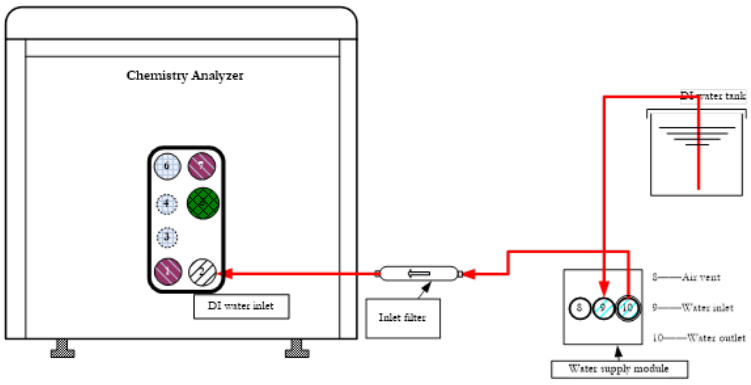
Figure 2.14 Water supply module



① Air vent ② Ball valve

③ Inlet ④ Outlet

Figure 2.15 Connecting instrument with water supply module



Make sure that there is sufficient space between the water supply module and the wall so that it is convenient to connect or disconnect the power cord. Sufficient deionized water should be prepared in the water tank when using the water supply module. Make sure the water supply module is powered on before running. The module should be powered off if not used for a long time.

If there is something wrong with the water supply module, please consult our customer service department or your local distributor.

2.3.4 Drainage Module

The drainage module increases the pressure of waste liquids, which will be discharged more easily. When the outlet tubing of the analyzer exceeds 5m or the sewer is higher than 1.2m, a drainage module is required. Make sure that there is sufficient space between the drainage module and the wall so that it is convenient to connect or disconnect the power cord.

The drainage module collects and discharges to the waste buffer the low-concentration waste liquids from the outlet on rear panel of the analyzer. When the liquid level sensor detects that specified amount of waste liquids have been collected in the waste buffer, the waste pump of the drainage module starts running, discharging the waste to the sewer.

If there is something wrong with the drainage module, please consult our customer service department or your local distributor.

Figure 2.16 Drainage module

① Low-concentration waste 1 ② Low-concentration waste 2

③ Low-concentration waste sensor ④ Outlet

2.3.5 External Vacuum Pump

When operated in a place with the altitude above 2,000m, the system may be degraded in its liquid aspirating performance due to the decreased atmospheric pressure. In this situation, an external vacuum pump is required to assist the system with liquid aspiration.

Make sure that there is sufficient space between the external vacuum pump and the wall (no less than 0.5m in front and back and no less 0.2m on left and right) so that it is convenient to install or operate the module. Before using the vacuum pump, connect the gas connector and control interface with the counterpart connectors on the rear panel of the analyzer; connect the vacuum pump to a properly-grounded power socket with the three-wire power cord. The external vacuum pump will be controlled by the analyzer when powered on and requires no manual operations.

When finishing all tests everyday, you are recommended to power off the external vacuum pump. Before starting the tests every day, please make sure the external vacuum pump is powered on.

The pointer of the pressure gauge is deviated from the 0 point when the vacuum pump works normally. If the pointer stops at the 0 point while the vacuum pump is running, there must be something wrong with the vacuum pump. Consult our customer service department or your local distributor.

The external vacuum pump should be installed and adjusted only by the technicians of or authorized by our company.

2.3.6 Water Quality Detection Module

Water quality detection module is used to detect if the water quality meets the requirement.

2.3.7 Displayer Arm

It is used to hold the displayer, wireless keyboard and mouse and handheld barcode reader.

2.3.8 Handheld Barcode Reader

It is used to scan the barcode of the samples, reagents, calibrators and controls.

2.3.9 Decapping module

The decapping module is composed of decapping delivery unit, decapping upper gripper, decapping lower gripper, waste cap disposal unit, waste cap container and auxiliary mechanism. The decapping module automatically removes the caps of capped sample tubes on the sample racks through sample information obtained from the sample detection module, identifies the position of the barcode on the sample tube and aligns the barcode with the scanning slot of the barcode reader. The removed caps are transported to the waste cap container, which needs to be emptied manually when filled with caps. Composed of the waste cap container and disinfection mechanism, the waste container unit collects the discarded caps and disinfects them by ultraviolet light.

Sample information detection module

This module consists of a vision camera and a barcode reader. The vision camera can identify sample information, including sample container type and sample height. The barcode reader can detect the sample barcode.

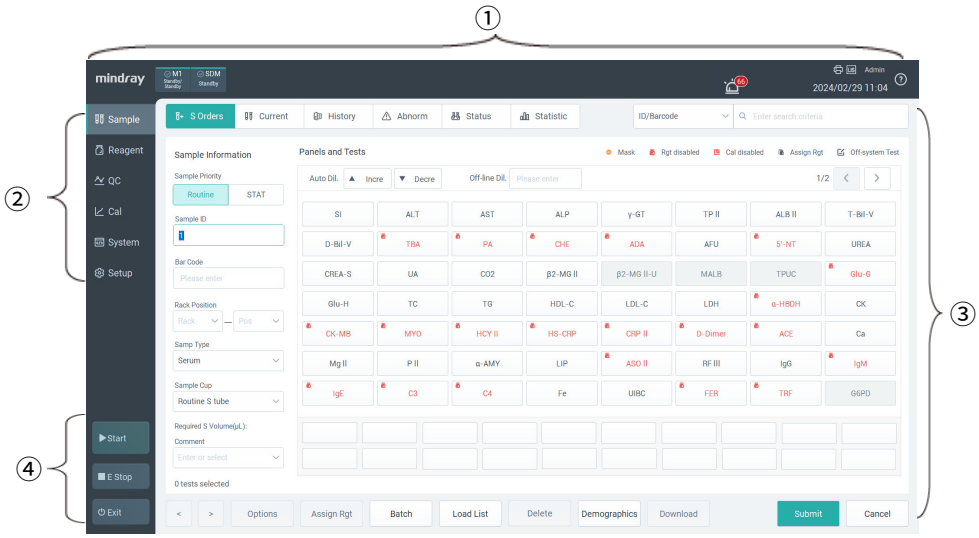
2.3.10 Other Optional Modules

For more information about other optional modules, contact our customer service department or your local distributor.

2.4 Software Description

2.4.1 Main Screen

Figure 2.17 Main screen



① Status display area ② Function buttons area

③ Function window ④ Shortcut buttons area

2.4.1.1 Status display area

The status display area shows the status of the entire system, including: test status, system date/time, LIS connection, printer, login user and module status.

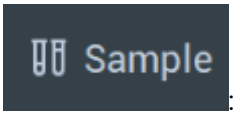
Table 2.5 Status display area

Status Indicator	Description
Remaining time	The status display area shows the status of the entire system, including biochemistry/ISE test status, system date/time, LIS connection, printer, login user and module status.
Date and time	This indicator appears on the lower right corner of the main screen. It indicates the system date and time.
	**LIS status** This indicator appears on the right corner of the main screen. The following information is indicated: • If red icon appears, the LIS host is not connected. • If green icon appears, the LIS host is connected successfully.

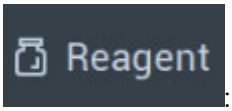
Status Indicator	Description
	**Printer status** This indicator appears on the right corner of the main screen. It indicates the status of the printer: available and printing. • If the icon appears in grey, the printer is not performing print tasks or unconnected. • If the icon appears in green  , the printer is connected.
Login user	This indicator appears on the left of the status display area. It indicates the user who logs in the system.
Module status	This icon shows configured analyzer and its status. Click this icon to display the **System Status** screen, on which the detailed status of the analyzer and sample delivery module are provided. The module status includes: • Error – red: An error occurs. The relevant analyzing unit icon appears in red. • Warning – yellow: A warning occurs. The relevant analyzing unit icon appears in yellow. • Normal: The system is running normally.
	Click this icon to view warnings and prompts.
	Click this icon to open the online help.

2.4.1.2 Function buttons area

The function buttons area contains the following buttons used to access various function windows of the system:

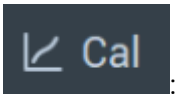


: used to order sample tests and control samples, and view samples and tests, sample results and rack status.

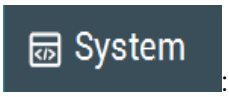


: used to load reagents, view reagent and consumable statuses and inventory check.

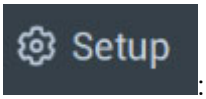
: used to define/edit controls and rules, request QC tests and recall QC results and summary.



: Calibration: Used to define calibrators, request calibration tests and view calibration results and data.



: used to perform maintenance, view system statuses and view edit log and error log.



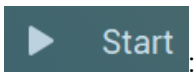
: used to set up test and system parameters.

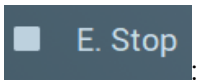
2.4.1.3 Function window

The function window contains options, buttons and other controls used to perform various functions of the system.

2.4.1.4 Shortcut icons area

The shortcut icons area contains the following icons used to quickly access certain function window or perform an operation:

- 

: Start icon. Select it to display the **Start Conditions** window, on which you are allowed to start new analysis or resume early testing.
- 

: Emergency stop icon. Select it to stop all tests and other actions. To restore the system into Standby status, execute the **Home** command.
- 

: exit the system.
- 
: Online help icon. Select it to display the online help of the current window, where you will find description of parameters and operations.

2.4.2 Using a Mouse

2.4.2.1 Move

The mouse is presented on the screen in the form of pointer. Place the mouse on a flat platform, and then move it to make the pointer lap over the object that you want to select or edit.

2.4.2.2 Select

Move the mouse to make the pointer lap over the object that you want to select or edit, and then press the left mouse button and release it quickly. Pressing the left mouse button is functionally equivalent to touching the screen.

2.4.2.3 Double-click

Move the mouse to make the pointer lap over the object that you want to select or edit, and then quickly press the left mouse button twice and release it. Pressing the left mouse button twice is functionally equivalent to touching the screen twice.

2.4.2.4 Drag

Dragging is used to move the slider on a screen in order to choose a scale. Move the mouse to make it stop over the slider, press and hold the left mouse button, move the mouse left and right to adjust the slider to the desired scale.

2.4.2.5 Using a mouse in conjunction with a keyboard

Some lists on the screen allow you to select more than one object at one time, and you can achieve this by using a mouse in conjunction with a keyboard. When selected, the objects will be highlighted for easy identification.

Perform the following operations to select more than one object:

- To select discontinuous objects, press the left mouse button to select the first object, press and hold the **Ctrl** key, use the mouse to select other desired objects, and then release the **Ctrl** key.
- To select continuous objects, press the left mouse button to select the first object, press and hold the **Shift** key, use the mouse to select the last object, and then release the **Shift** key.

2.4.3 Using a Touchscreen

The system supports a touchscreen, by using which you are allowed to perform various operations of measurement. The touchscreen can be operated in the following ways:

2.4.3.1 Move

Put your finger above the mouse pointer, and then move your finger to make the pointer stop at the object that you want to select or edit.

2.4.3.2 Select

Move your finger to make the pointer lap over the object that you want to select or edit, touch the screen and then release it quickly. Touching the screen is functionally equivalent to pressing the left mouse button.

2.4.3.3 Double-click

Move your finger to make the pointer lap over the object that you want to select or edit, quickly touch the screen twice and then release it. Quickly touching the screen twice is functionally equivalent to pressing the left mouse button twice.

2.4.3.4 Drag

Dragging is used to move the slider on a screen in order to choose a scale. Move the mouse pointer to make it stop over the slider, press and hold the screen, and then move the pointer left and right to adjust the slider to the desired scale.

2.4.3.5 Using a touchscreen in conjunction with a keyboard

Some lists on the screen allow you to select more than one object at one time, and you can achieve this by using a touchscreen in conjunction with a keyboard. When selected, the objects will be highlighted for easy identification.

Perform the following operations to select more than one object:

- To select discontinuous objects, touch the screen to select the first object, press and hold the **Ctrl** key, touch the screen again to select other desired objects, and then release the **Ctrl** key.
- To select continuous objects, touch the screen to select the first object, press and hold the **Shift** key, touch the screen again to select the last object you desire, and then release the **Shift** key.

2.4.4 Using Online Help

The system provides you with help information about the screens. If you do not understand a parameter or an operation on a screen, you can go to the online help for relevant information.

2.4.4.1 Accessing the online help

Access the online help from the following screens:

- Select the  icon on the upper right corner to display the help topic related to the current screen.

2.4.4.2 Viewing other information

To view other information in the online help,

1. Select the  icon on the upper right corner of the main screen.
2. Select the following tabs to view relevant information:
   - **Contents**: to navigate through all topics of the online help.
   - **Index**: to view topics related to the input keywords.
   - **Search**: to view topics containing the input keywords.
   - **Bookmarks**: to view your favorite topics.
3. Read the help topics. Move the scroll bar on the right side of the help window to view more information.
4. Select  to close the help window.

2.5 System Specifications

2.5.1 Technical specifications

2.5.1.1 Throughput and reaction type

Table 2.6 Throughput and reaction type

Parameter	Description
Throughput for biochemical tests	1000 tests/hour for single-/double-reagent tests
Throughput for ISE tests (including K, Na, Cl)	Serum/plasma: 100 samples/hour, 300 tests/hour Urine: 60 samples/hour, 180 tests/hour
Maximum number of tests run simultaneously	Maximum 66 tests, including 60 biochemistries, 3 ISE chemistries and 3 SI chemistries.
Principles of analysis	Colorimetry, turbidity, and ion-selective electrode method
Reaction types	Endpoint, fixed-time, and Kinetic
Reagent mode	Supporting single-/double-/triple-/quadruple-reagent tests
Wavelength	Supporting single/double-wavelength mode

2.5.1.2 Sample handling system

Table 2.7 Specifications of the sample handling system

Parameter	Description
Composition	Composed of rack lanes, track transfer device, sample barcode reader and racks.
Sample lanes	Used to load and unload sample racks.
Sample rack	10 sample positions are available on each rack.
Sample capacity	Each rack provides 10 sample positions, and maximum of 18 racks can be accommodated in the lanes. Therefore, up to 180 samples can be held simultaneously.
Sample Container	Support micro tube, primary tube or plastic tube.
Sample Load	Racks can be loaded or unloaded conveniently, and batch load/unload is supported. Samples and tests can be added during analysis. Priority of emergency samples and auto rerun are supported.
Sample volume for biochemical tests	1μL-25μL, with 0.1μL increment
Sample volume for ISE tests	70μl (serum, plasma), 140μl (diluted urine)

Parameter	Description
Bar Code Scanning	The bar code reader is provided together with the instrument and used to scan bar code of racks and samples. The rack bar code is defined by the manufacturer, and the sample bar code can be set up by users.
Sample probe	One sample probe featuring level detection, horizontal/vertical obstruct detection, empty aspiration alarm, probe clogging alarm, and volume tracking. Interior and exterior wash is supported.
Sample probe washing	The sample probe is cleaned in its wash well with water spraying its interior and exterior.
Rerunning mode	Supporting auto dilution and rerunning of samples, and manual rerun.
Decapping speed (When decapping module configured)	For 100 mm capped sample tubes, uncapping peak speed should be no less than 300 tubes/hour
Capacity of waste cap container (When decapping module configured)	≥ 200 tube cap

2.5.1.3 Reagent handling system

Table 2.8 Specifications of the reagent handling system

Parameter	Description
Reagent Carousel	109 positions in total. The reagent carousel provides a refrigerating environment which is constant within 2°C-8°C for 24 hours a day.
Reagent volume	R1/R2:10μL-200μL, with increment of 0.5μL Concentrated reagent: The original volume of reagent and the total volume of the diluent are consistent with the R1/R dispensing range.
Reagent probe	2 reagent probes available: R1 and R2. The 2 probes feature level detection, horizontal/vertical obstruct detection, bubble detection, bubble auto removing.
Reagent probe washing	The two reagent probes are cleaned in the wash well with water spraying its interior and exterior.

2.5.1.4 Mixer system

Table 2.9 Specifications of the sampling system

Description	Description
Mixer assembly	One mixer drive board with four mixers, supporting mixer washing.

Description	Description
Mixer washing	Clean with deionized water.

2.5.1.5 Reaction system

Table 2.10 Specifications of the reaction system

Parameter	Description
Reaction carousel	206 positions in total
Reaction temperature	37°C±0.3°Cwith a fluctuation no more than ±0.1°C
Reaction cuvette	Reusable glass cuvettes 5mm×4mm×29mm (length × depth × height), light path length of 5mm, and volume of 580μL.
Reaction mixture volume	80μL-280μL
Cuvette washing	Washed automatically by the dual-layer wash station in 8 phases.

2.5.1.6 Photometric system

Table 2.11 Specifications of the reaction system

Parameter	Description
Light transmission mode	Holographic concave flat-field gratings
Light source	12V/20W tungsten-halogen lamp
Measuring wavelength	16 wavelengths: 340nm,380nm,412nm,450nm,480nm,505nm,546nm,570nm,605nm,630nm,660nm,700nm,740nm,770nm,800nm and 850nm
Measuring wavelength	18 seconds
Absorbance resolution	0.0001A

2.5.1.7 Water consumption

Average water consumption≤35 L/h.

2.5.1.8 Water supply module

Table 2.12 Specifications of water supply module

Parameter	Description
Power supply	100V-240V~, 50Hz/60Hz
Voltage fluctuation	±10%
Rated input power	50VA
Flow	0.6LPM

Parameter	Description
Tube length and connecting method	4*6mm PU tubes Connecting the water tank and the analyzer, <10m IN and the water tank, <5m OUT2 and the waste outlet,<10m
Weight	9.7kg (±1)
Size(length*width* height)	321.8mm×303.5mm×241.2mm (±5mm)
Maintenance requirement	No need to perform the maintenance procedure

2.5.1.9 Drainage module

Table 2.13 Specifications of drainage module

Parameter	Description
Power supply	100V-240V~, 50Hz/60Hz
Voltage fluctuation	±10%
Rated input power	50VA
Flow	1LPM
Tube length and connecting method	12*18 mm braided tubes Connecting the analyzer and IN1/IN2, <5m OUT and the discharge outlet,<10m
Weight	12.kg (±1)
Size(length*width* height)	436.5mm×312.8mm×287.7mm (±5mm)
Maintenance requirement	No need to perform the maintenance procedure

2.5.1.10 External vacuum pump

Table 2.14 Specifications of external vacuum pump

Parameter	Description
Power supply	110V: 110V/115V~, 60Hz 220V: 220V-240V~, 50Hz 220V/230V~, 60Hz
Voltage fluctuation	±10%
Frequency fluctuation	500VA
No-load flow	100LPM (50Hz)/110LPM (60Hz)
Air tube	PU tube, 7*10 mm, less than 3m
Weight	29.7kg±1.2kg
Size(length*width* height)	478mm×425mm×466mm
Maintenance requirement	Clean the dust screen monthly according to the operation guide

2.5.2 Power Supply Requirements

Table 2.15 Power supply requirements

Parameter	Description
Power	110V: 110V/115V~, 60Hz 220V: 220V-240V~, 50Hz 220V/230V~, 60Hz
Voltage fluctuation	±10%
Frequency fluctuation	±1Hz
Rated power consumption	System power: 2000 VA; Drainage module: 50 VA Water supply module: 50 VA External vacuum pump module: 500 VA
Power cord	Use the power cord in the accessory kit.
Network cable	Standard gigabit network cable, TX twisted pair, RX twisted pair

2.5.3 Environmental Requirements

2.5.3.1 Operating environment

- Temperature: 15°C-30°C
- Humidity: 35%RH-85%RH, without condensation
- Altitude height: -400m-4000m (106kPa-61.6kPa). (If it is higher than 2000 m, an external vacuum pump should be configured. If an ISE module is configured, its operating altitude should be -400-2000 m.)

2.5.3.2 Storage and transportation environment

- Temperature:0°C-40°C
- Humidity: 30%RH-85%RH, without condensation
- Atmospheric Pressure: 106kPa-50kPa

2.5.4 Dimensions and Weight

2.5.4.1 Analyzer:

- Dimension: 1720mm(width)×900mm(depth)×1230mm(height)
- Weight≤450kg

2.5.5 Input device

- Keyboard
- Mouse
- Bar code reader
- RMS (communicating through network interface)
- LIS: HL7 and ASTM1394 (communicating through the network interface or serial port)

2.5.6 Output device

- Printer
- Displayer
- RMS (communicating through network interface)
- LIS: HL7 and ASTM1394 (communicating through the network interface or serial port)

2.5.7 Noise Level

Table 2.16 Noise Level

Parameter	Description
Noise Level	⩽ 65dBA

2.5.8 Communication Interface

Table 2.17 Communication interface

Communication interface	Description
R232 interface	• Used for communication between the LIS and the operation unit • Used for connecting the operation unit with a printer
Network interface of analyzing unit	• Used for connecting the operation unit with a printer • Used for connecting the operation unit with an external storage device • Used for connecting the operation unit with a handheld bar code reader
USB interface	• Used for connecting the operation unit with a printer • Used for connecting the operation unit with an external storage device
VGA and DVI interface	• Used for connecting the operation unit and the displayer.

2.5.9 Safety Classification

Table 2.18 Safety classification

Parameter	Description
Overvoltage type	Class II
Pollution degree	2
Device type	Fixed device
Work type	Continuous
Degree of ingress protection	Common device

2.5.10 Performance Indexes

2.5.10.1 Stray Light

Absorbance should be no less than 4.9.

2.5.10.2 Absorbance Linearity Range

The maximum absorbance with relative bias within ±5% should be no less than 3.5.

2.5.10.3 Absorbance Accuracy

The absorbance accuracy meets the requirements in Table 2.18

Table 2.19 Absorbance accuracy

Parameter	Description
0.5	±0.025
1.0	±0.07

2.5.10.4 Absorbance Stability

Absorbance change should not be greater than 0.01.

2.5.10.5 Absorbance Repeatability

Expressed by coefficient of variation (CV), which should not be greater than 1.0%.

2.5.10.6 Temperature accuracy and fluctuation

The temperature accuracy of the constant temperature chamber is within 37°C±0.3°C and the temperature fluctuation range is not greater than±0.1°C.

2.5.10.7 Sample Carryover Rate

The sample carryover rate should not be greater than 0.05%.

2.5.10.8 Sampling Accuracy and Repeatability

The accuracy and repeatability of sampling shall meet the requirements in "Table 2.20 Sampling Accuracy and Repeatability"

Table 2.20 Sampling Accuracy and Repeatability

Parameter	Volume (ML)	Allowable Error	Coefficient of Variation
Sample dispensing	1	±5%	⩽2%
	5	±5%	⩽2%
	25	±3%	⩽1%
Reagent probe Dispensing	10	±5%	⩽2%
	200	±2%	⩽1%

2.5.10.9 Carryover Rate of ISE Module

The carryover of ISE module should meet the requirements in "Table 2.21 Performance Requirements of ISE Module".

2.5.10.10 Stability of ISE Module

The stability of the ISE module should meet the requirements in "Table 2.21 Performance Requirements of ISE Module" .

2.5.10.11 Accuracy of ISE Module

The accuracy of the ISE module should meet the requirements in "Table 2.21 Performance Requirements of ISE Module".

2.5.10.12 Precision of ISE Module

The precision of the ISE module should meet the requirements in "Table 2.21 Performance Requirements of ISE Module".

2.5.10.13 Linearity of ISE Module

The linearity of the ISE module should meet the requirements in "Table 2.21 Performance Requirements of ISE Module".

Table 2.21 Performance Requirements of ISE Module

Parameter	Carryover (△§)	Stability(△D)	Accuracy	Precision (CV)	Linearity （D）		
					Interval （mmol/L）	Deviation	Related Coefficient （r）
K+	⩽ 1.5%	⩽ 2.0%	No greater than ±3.0%	⩽ 1.5%	1.5 ～ 7.5	⩽ 3.0%	⩾ 0.995
Na+	⩽ 1.5%	⩽ 2.0%	No greater than ±3.0%	⩽ 1.0%	100.0 ～ 180.0	⩽ 3.0%	⩾ 0.995
Cl-	⩽ 1.5%	⩽ 2.0%	No greater than ±3.0%	⩽ 1.5%	80.0 ～ 160.0	⩽ 3.0%	⩾ 0.995

2.5.10.14 Within-run precision of clinical chemistries

The coefficient of variation (CV) shall meet the requirements in ″Table 2.22 Within-Run Precision of Clinical Chemistries″.

Table 2.22 Within-Run Precision of Clinical Chemistries

Test	Concentration range	Coefficient of Variation
ALT (Alanine aminotransferase)	30 U/L ～50 U/L	CV⩽5%
UREA (Urea)	7.0 mmol/L ～11.0 mmol/L	CV⩽2.5%
TP (Total protein)	50.0 g/L ～70.0 g/L	CV⩽2.5%

2.5.10.15 Limitations

Table 2.23 Within-Run Precision of Clinical Chemistries

Test	Concentration range
Limitations	ascorbic acid
	hemoglobin
	lipemia
	bilirubin

2.5.11 Contraindication

None

2.5.12 EMC Requirements

This IVD medical equipment complies with the emission and immunity requirements described in IEC 61326-1/EN 61326-1 and IEC 61326-2-6 /EN 61326-2-6. For EMISSIONS and IMMUNITY specific requirements, see the two tables below:

Table 2.24 GUIDANCE AND MINDRAY DECLARATION- ELECTROMAGNETIC EMISSIONS

GUIDANCE AND MINDRAY DECLARATION- ELECTROMAGNETIC EMISSIONS	
The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.	
EMISSION TEST	**COMPLIANCE**
RF emissions CISPR 11	Group 1 Class A
RF emissions CISPR 11	
Harmonic Emissions IEC 61000-3-2	N/A
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	

Table 2.25 GUIDANCE AND MINDRAY DECLARATION- ELECTROMAGNETIC IMMUNITY

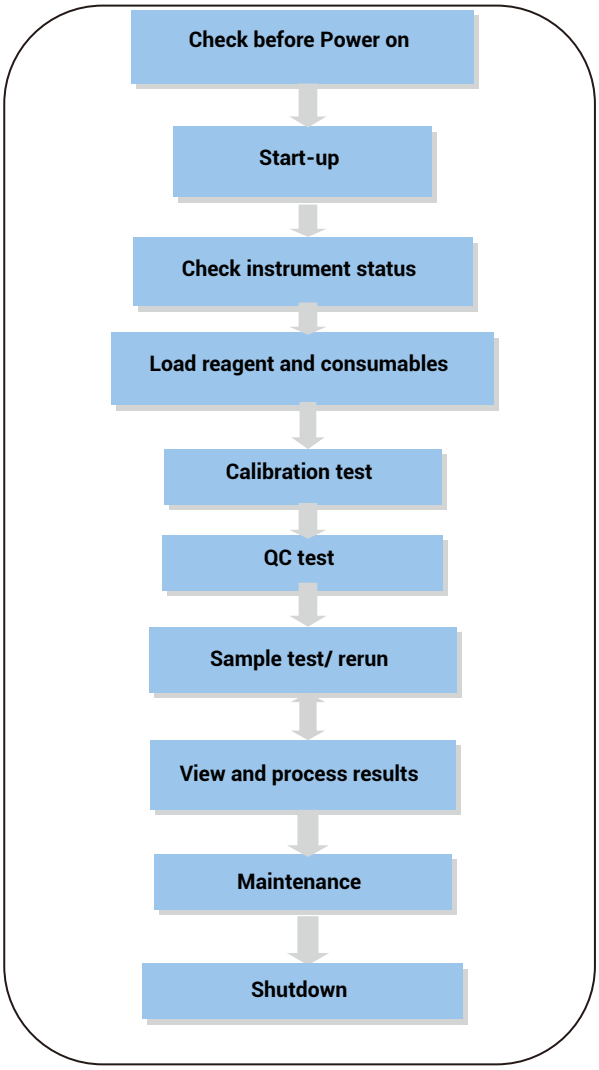
GUIDANCE AND MINDRAY DECLARATION- ELECTROMAGNETIC IMMUNITY			
The system is intended for use in the electromagnetic environment specified below.The customer or the user of system should assure that it is used in such an environment.			
IMMUNITY TEST	**BASIC STANDARD**	**TEST VALUE**	**PERFORMANCE CRITERION**

GUIDANCE AND MINDRAY DECLARATION- ELECTROMAGNETIC IMMUNITY			
Electrostatic Discharge (ESD)	IEC 61000-4-2	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	B B
Electromagnetic field	IEC 61000-4-3	3 V/m (80 MHz to 6 GHz)	A
Electrical fast Transient / burst	IEC 61000-4-4	± 1 kV (5 kHz or 100 kHz)	B
Surge	IEC 61000-4-5	± 0,5 kV line-to-line ± 1 kV line-to-ground	B B
Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
Voltage dips, Short interruptions and voltage variation on power supply input voltage	IEC 61000-4-11	0 % during 0,5 cycles 0 % during 1 cycle 70 % during 25/30 cycles 0 % during 250/300 cycles	B B C C
Power frequency magnetic field	IEC 61000-4-8	3 A/m (50 Hz, 60 Hz)	A
NOTE: "25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test". Performance criterion: A.The equipment shall continue to operate as intended during and after the test. B.The equipment shall continue to operate as intended after the test. C.LOSS OF FUNCTION is allowed, provided the function is self-recoverable or can be restored by the operation of the controls.			

3 General Operating Procedure

In this chapter

3.1 General Operating Procedure



3.2 Check before Powering On

3.2.1 Checking Water Supply

1 Check the deionized water tank or other water reservoirs, and make sure that water can be supplied continuously.

2 Check if the connections between the water supply, water supply module, and analyzer are correct and tight, and the length of the inlet tubing does not exceed 10m.

3 Check if the water tubes are free of twists and leaks.

3.2.2 Checking Power Supply

1 Check if the power supply is available and can provide correct voltage.

2 Check the power cords of the analyzer, operation unit and printer and make sure they are well connected to the power sockets.

3.2.3 Checking Printing Paper

Check if sufficient printing paper is prepared in the printer. If not, refill the printing paper.

3.2.4 Check Waste Tank Connection

The waste fluid of the system is discharged in two flows: high-concentration waste and low-concentration waste. The former is drained through the waste tank and then disposed according to relevant regulations, or drained to the sewer after treatment; the latter can be directly drained to the sewer after treatment.

BIOHAZARD

- While checking the waste tanks and tubing, wear gloves, lab coat, goggles and a mask. Keep a safe distance away from the tubing and waste tank in case the liquid splashes or spatters.
- Dispose of liquid waste according to your local laws and regulations.

NOTE

- High-concentration waste output: 2.2L/H.

1 Check if the high-concentration waste tank has been emptied. If not, empty it.

2 Check if the low-concentration waste tubing is not bent and the sewer opening is lower than the waste outlet of the system.

3.2.5 Checking Probes, Mixers and Syringes

The probe is easy to be polluted or damaged. Check it carefully for dirt and bend before powering on the system.

The sample probes, reagent probes and mixers are easy to be polluted or damaged. Check them carefully for dirt and bend before powering on the system.

1 Check the sample probes for dirt and bend.
   - If they are polluted, clean them.
   - If they are bent, replace them.

2 Check the reagent probes for dirt and bend.
   - If they are polluted, clean them.
   - If they are bent, replace them.

CAUTION

- Every day before analysis, remove the plugs on the reagent carousel in order to prevent mechanical reset failure and bending the probe.

3 Check the sample mixers for dirt and bend.
   - If they are polluted, clean them.
   - If they are bent or scratched, replace them.

4 Check the reagent mixers for dirt and bend.
   - If they are polluted, clean them.
   - If they are bent or scratched, replace them.

5 Check the syringes for leak.

3.2.6 Checking Rack Feeder System

Check the rack lanes to ensure they are normal.

1 Check the rack lanes for racks and dirt.

3.2.7 Checking CD80 Detergent and Probe Detergents

Insufficient wash solutions or probe detergents may terminate the measurements. Check the wash solution according to the following steps:

1 Check the alkaline and acid wash solutions placed on the reagent carousel. If necessary, fill more or replace them.

2 Check the DA, DB, DC probe detergent on the panel.

3 Open the front door of the analyzer and check the CD80 detergent. If necessary, fill more or replace the wash solution.

3.3 Powering on

3.3.1 Turning On Modules

Turn on the water supply switch and ensure that the water supply pressure is within 100kPa~392kPa. If the pressure does not meet the requirements, use an external water supply module. Turn on the water supply module. If an external vacuum pump is required, turn on the external vacuum pump.

3.3.2 Powering On the System

After correctly connecting the system to the power sockets, switch on the power in the sequence presented below:

1 Turn on the power supply of analyzer.

- Toggle the switch toward | to turn it on.
- Toggle the switch toward ○ to turn it off.

2 Turn on the printer.

3 Turn on the monitor of the operation unit.

4 Turn on the display monitor of the computer installed with the Data Management Software.

5 Turn on the computer of operation unit.

6 Turn on the computer installed with the Data Management Software.

3.3.3 Starting the Operating Software

1 When the operation unit (computer) is turned on, the operating software will run automatically.

2 Enter the username and password in the **Login** window, and then select **OK**.

NOTE

- The default username and password for administrator is Admin. Please note that the password is case sensitive. You are recommended to change the password when logging on the system for the first time in order to prevent others from abusing the privileges of the administrator.
- If an operator forgets his password, he may ask the administrator to log on the system and delete the username and then redefine a username; or he may contact our customer service department or your local distributor. If the administrator forgets his password, contact our customer service department or your local distributor.

3 When the startup check is passed, the main screen shows. The startup procedure is finished.

The system will display prompt message when detecting unsatisfied environment during the startup process. Please take actions according to the instructions in the message box.

CAUTION

- To ensure accurate test results, do not start measurement until the system status turns to Standby and the system has been turned on for about 20 minutes, so that the reaction temperature gets steady.

3.4 Checking System Status

After the startup procedure is finished, check the system status, such as the status of the consumables, analyzer status, alarm status, reagent/calibration status, maintenance status and subsystem status. If the status is not satisfied for measurement, troubleshoot and maintain the system as instructed by "12 Alarms and Troubleshooting" (12-1) and "11 Maintenance" (11-1).

3.4.1 Printer Status

Check the printer status indication in the system status area of the main screen:

- If the  icon appears in green, the printer is connected normally.
- If the icon  appears in red, the printer is not normally connected.

3.4.2 LIS Status

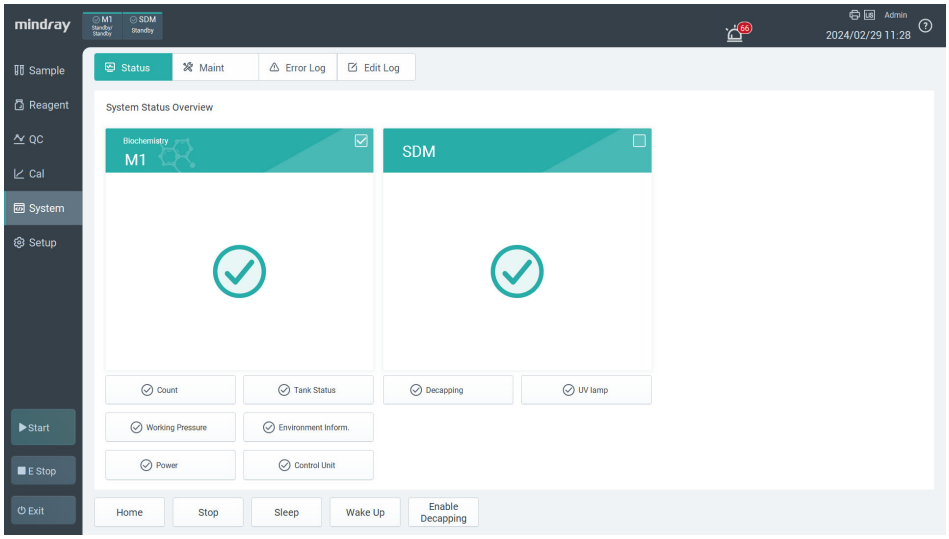
Check the LIS status indication in the system status area of the main screen:

- If the Icon appears in green , the LIS host is connected and online.
- If the icon appears in red, the LIS host is offline.

3.4.3 Checking Analyzer Status

1 Click the module status icon at the top of the screen. The **System Status** screen is displayed.

Figure 3.1 "System Status" screen



The screen shows the system status and alarm status of the sample delivery module and analyzing unit.

- SDM: indicates system status of the sample delivery module.

Status	Description
Standby	The sample delivery module is standby and waiting for delivery of racks.
Running	The sample delivery module is delivering racks.
Stopped	The sample delivery module fails, or the  button is pressed.
Restore	The sample delivery module is being restored.

- M1: shows status of biochemical system and ISE module, measurement time left, and countdown for sample load or reagent load.
- Alarm status: shows status of the analyzer, sample delivery module, and rack transfer lanes. Alarm levels are indicated by different colors, red for error and yellow for warning.

2 If you want to restore an analyzer, select **Home**.

3 If you want to put an analyzer to sleep, select **Sleep**.

4 If you want to wake up an analyzer, select **Wake up**.

5 If you want to stop an analyzer, select **Stop**.

6 To enable the decapping function, select **Enable Decapping**.

3.4.4 Checking Alarm Status

3.4.4.1 View Alarm List and Prompt List

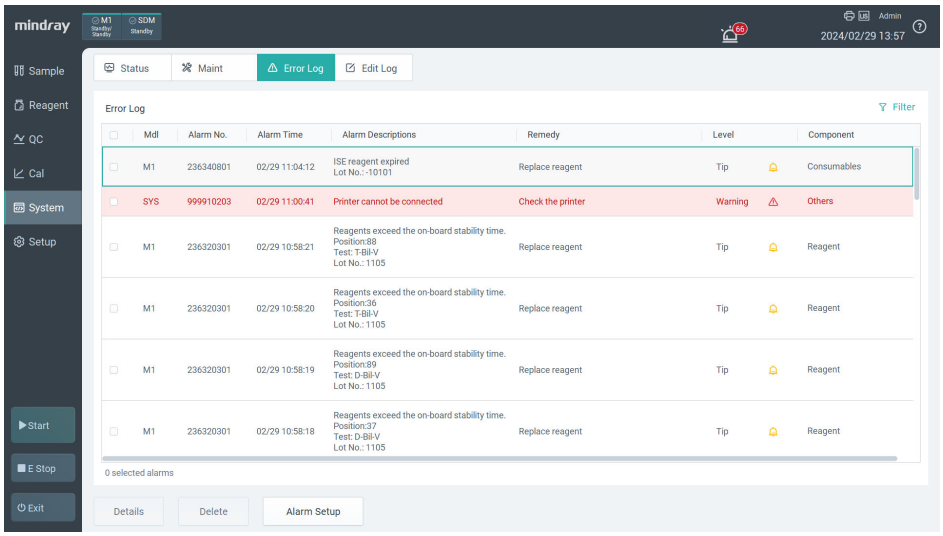
Click 

, and the warning list and prompt list pops up.

3.4.4.2 View Error log

1. Select **System**.
2. Select **Error Log**.
3. Select Error Details.
4. Troubleshoot according to the recommended method.

Figure 3.2 Error Log screen



3.4.5 Checking Maintenance Status

When the system is started up, it is necessary to check the maintenance status. If a maintenance procedure is expired, perform it immediately to make sure that the system will run normally. When a maintenance procedure is expired, the following buttons and options will be indicated by corresponding color:

- Maintenance tab
- Maintenance procedure

1. Select **System** > **Maintenance** > **Maintenance Procedures**.
2. Check if the maintenance procedures tabs appear in yellow. If they do, it indicates that at least one maintenance procedure is expired.
3. Select **Perform Manually** or **Auto Perform** to find the expired maintenance procedure, and then perform the maintenance.
4. Repeat steps 2 and 3 until the maintenance frequency tabs and maintenance procedures are displayed in normal color.

3.4.6 Checking Subsystems

The subsystem status indicates the current working status of each subsystem and hardware component, which includes temperature, power supply, hydropneumatic subsystem, and control modules. When there is problem,  is displayed.

3.4.6.1 Checking Subsystems

1. Select **System** > **System Status**.
2. Select subsystem status tab.

3 Check the subsystem status. When abnormity occurs, troubleshoot errors with the following methods:

- If the cycle count of a component reaches certain limit and an alarm occurs, replace the component or contact out customer service department or your local distributor for replacement of the component.
- If a component's temperature is beyond the valid range or abnormal and an alarm occurs (indicating the overheat protection system works normally), exit the operating software and switch off the analyzer power. After that, switch on the analyzer power again and run the operating software. If the error remains, contact out customer service department or your local distributor for replacement of the component.
- If a component's voltage is beyond the valid range or abnormal and an alarm occurs, exit the operating software and switch off the analyzer power. After that, switch on the analyzer power again and run the operating software. If the error remains, contact out customer service department or your local distributor for replacement of the component.
- If a Hydropneumatic container is beyond the valid range or abnormal and an alarm occurs, exit the operating software and switch off the analyzer power. After that, switch on the analyzer power again and run the operating software. If the error remains, contact out customer service department or your local distributor for replacement of the component.
- If a smart module is abnormal and an alarm occurs, exit the operating software and switch off the analyzer power. After that, switch on the analyzer power again and run the operating software. If the error remains, contact out customer service department or your local distributor for replacement of the component.

3.4.6.2 Description of subsystem status

Status summary

The status summary provides a high-level summary of the status of the system temperatures, power supply, Hydropneumatic, and control modules.

Cycle count

The cycle count provides an approximation of a component's usage, which can be useful for estimating the maintenance frequencies or anticipating component failure.

Ambient information

The actual temperature and valid range of the dispersion carousel, reagent carousel, reaction carousel, instrument interior are displayed.

Power supply

Status for the power supply module shows:

- The actual voltage and valid range for the main board, carousel drive board, probe drive board, and reagent refrigeration board.
- The actual voltage and valid range for the radiator.
- The working status of the fans and mixers.

Hydropneumatic containers

Status for the Hydropneumatic subsystem shows:

- Working status of various tanks
- The actual air pressure and valid range for air pressure equipment

Control Unit

Control Unit status monitors the working status of each smart module, which includes probes, carousels, etc.

3.4.7 Check Reagent/Consumable Status

3.4.7.1 View Via Reagent Overview

Before start testing every day, check the reagents and concumables, etc. If necessary, replenish them.

1 Select **Reagents** > **Overview**.

The displayed information for the reagent includes Test Name, tests available, reagents available, reagent position.

The reagent has the following three statuses:

- Sufficient: No color is marked for the background.
- Low inventory: The background is orange.
- Exhausted: The background is red.

The Consumable has the following three statuses:

- Sufficient: blueish green
- Insufficient for inventory alarm limit: orange.
- Exhausted: red.

When abnormal information exists for the reagent, it is flagged. Click the flag and an air bubble pops up to display the abnormal information.

The abnormal information includes:

- Reagent prompt: Masked reagent
- Reagent warning: Disabled reagent
- Calibration prompt: calibration extension, edited calibration factor, recalculated calibration result, calibration timeout, calibration overridden.
- Calibration warning: Calibration failure, calibration expired, calibration required and calibration unfinished.
- Reagent Expiration: reagent expired.

Intelligent Sort is enabled by default. When it is enabled, the order is sorted as follows:

Reagent exhausted => Insufficient for inventory alarm limit => Sufficient.

3.4.7.2 View Via Reagent List

Select **Reagent** > **R List** > **Reagent/ Consumable**.

3.4.7.3 View Via Reagent Carousel

1 Select **Reagent** > **Carousel**. View reagent information of each position.

The consumable status is as follows:

Table 3.1 Consumable status

Color	Graphic indication	Meaning	actions
Red		exhausted	Load consumable
Orange		Below inventory alarm limit	Refill
Blueish green		Sufficient	No action needed

2 Refer to "3.5 Preparing Reagents and Consumables" (3-11).

3.5 Preparing Reagents and Consumables

After confirming the system status and performing the daily checks, prepare the reagents and consumables for measurement. Tests without reagents loaded can be requested but will not be included in measurements. Loading reagents is allowed when the system status is Standby, Incubation or Sleep. In Running status, you should request reagent load before loading reagents. After assigning reagent positions, print out the reagent list and then manually load reagents according to it. When all reagents are loaded, the system will check the reagent inventory during measurement and then display it on the R List screen. You are recommended to perform inventory check manually after loading reagents; otherwise, the tests left will not be displayed on the R List screen.

If the instrument has set open channels when leaving the factory, the open reagent channels can be used to hold reagents of Mindray or of other manufacturers, and the remaining positions are closed channels and can only hold Mindray reagents. If you want to change the number of open channels, contact our customer service department or your local distributor.

WARNING

- The probe tip is sharp and may cause puncture wounds. To prevent injury, exercise caution when working around the probes.

BIOHAZARD	• Wear gloves and lab coat, if necessary, goggles. • Do not touch the reagent directly with your body; otherwise, skin wound or inflammation may be caused.
CAUTION	• Do not drop liquid on reagent carousel control button to prevent damaging the button.
NOTE	• Prepare sufficient reagent to avoid test interruption due to reagent running out.

3.5.1 Loading Biochemical Reagents

The system supports manual and auto load of biochemical reagents. Each test can have more than one bottle of reagent loaded, and reagents of the same test can be loaded to the same carousel. If your system is not equipped with a reagent bar code reader, you need to enter the reagent information manually when loading reagents; if a reagent bar code reader is configured, the system will scan all reagents automatically and read reagent information from the bar code.

All reagent types of a multi-reagent-type test must be loaded simultaneously to inner ring or outer ring of the reagent carousel. When one or more reagents of a multi-reagent test are not loaded, the "!" sign will appear near the test's reagent types that have been loaded.

Open reagents can be loaded manually or via bar code scanning, while closed reagents can only be loaded via bar code scanning. For more information about loading bar-coded reagents, refer to "5.2.3Reagent Bar Code Setup" (5-6).

NOTE	• Before loading biochemistry reagent, ensure that there are no air bubbles inside the reagent bottle so as to avoid inaccurate test results.

Manual load

When loading reagents manually, you need to enter the reagent information, which is the only information source of the loaded reagents. You are allowed to input reagent information before, during or after loading reagents to the reagent carousel. If loaded reagents are bar-coded, the reagent information cannot be edited; otherwise, all reagent information except for position, test and reagent type can be edited.

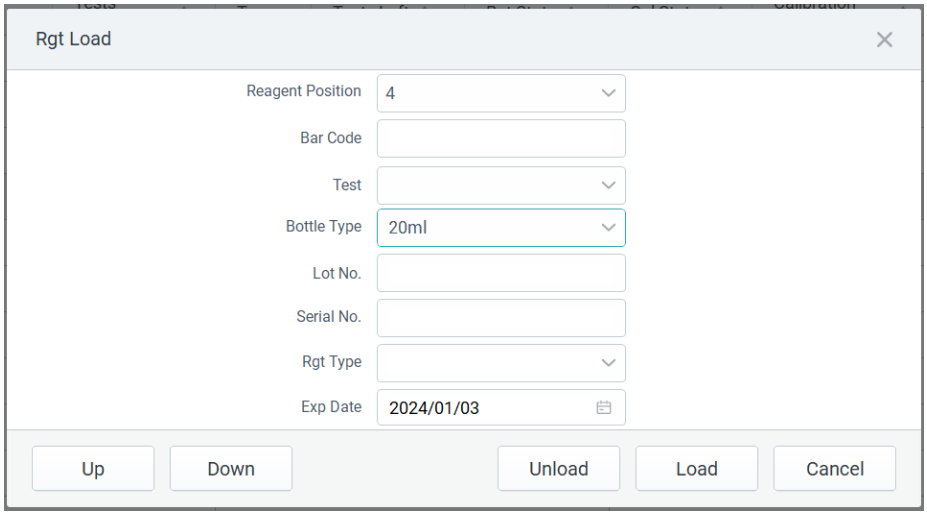
1 Check the system status and operate accordingly.
   - Standby, Incubation or Sleep: Proceed to the next step.
   - Running: Select **Reagent** > **R List**. Select **Rgt Stop** to request reagent load. When the countdown for reagent load becomes 0 and the system status is Reagent Load, a message box pops up. Select **OK**, and then proceed to the next step.

2 Select **Reagent** > **R List** > **Reagent**.

3 Choose a position to which you want to load a reagent.

4 Select **Load**. The **Load Reagent** window is displayed.

Figure 3.3 Load reagent



5 Enter the following reagent information.
- Bar code
- Test name
- Reagent type (required)
- Lot number
- Serial number
- Bottle type (required)
- Expiration date

6 Select **Load** to save the input information.

7 Select **UP** or **Down** to load reagents for other tests.

8 Remove the reagent carousel cover.

The reagent with damaged puncture membrane cannot be used.

9 Remove the reagent carousel cover.

CAUTION

- If the system is running tests, after requesting reagent load, do not remove the reagent carousel cover until the countdown for reagent load is 0, the system status is Reagent Load, and the popup message is confirmed; otherwise, the tests currently run will be invalidated.

10 Load reagents according to the reagent load list to position.

11 Restore the reagent carousel cover.

3.5.1.1 Auto load

Auto load is to load bar-coded reagents to the reagent carousel, which are identified by bar code scanning.

The closed reagents can only be loaded through bar code scanning.

1 Check the system status and operate accordingly.
- Standby or Reagent Load: proceed to next step.
- Running: Select **Reagent** > **Overview/R List**. Select **Reagent Stop** to request reagent load. When the countdown for reagent load becomes 0 and the system status is Reagent Load, a message box pops up. Select **OK**, and then proceed to the next step.

2 Remove the reagent carousel cover.

CAUTION	• When removing the film from the reagent bottle, wear clean gloves to avoid contaminating the bottle opening. • Do not use the damaged reagent kit. Do not invert the opened reagent kit.

3 Place reagent in an idle position of the reagent carousel and open the reagent cap.

4 Remove the reagent carousel cover.

CAUTION	• If the system is running tests, after requesting reagent load, do not remove the reagent carousel cover until the countdown for reagent load is 0, the system status is Reagent Load, and the popup message is confirmed; otherwise, the tests currently run will be invalidated.

5 Load reagents according to the reagent load list to position.

6 Restore the reagent carousel cover.

The system scans all reagent positions automatically and read following reagent information from the bar code:

- Test
- Expiration date
- Lot number
- Bottle No.
- Bottle type

If test name is "Invalid bar code", it means bar code analysis error, bar code type error and bar code data error. Please load reagent with correct bar code.

3.5.2 Loading CD80 Detergent

CD80 detergent, a kind of alkaline concentrated wash solution, is used to clean reaction cuvettes and can only be loaded manually. The lot number, serial number, expiration date, volume, alarm limit and other information of the loaded wash solution must be entered.

1 Select **Reagent** > **R List** > **Consumable**.

2 If CD80 is not sufficient for the current day, load CD80 detergent.

3 Open the front door of the analyzer.

4 Load CD80 detergent. And then lay down the CD80 aspirate tube assembly. When the system detects that CD80 aspirate assembly is placed in the tank, select **Inventory reset**, the volume refreshes to 100%.

Figure 3.4 Position for CD80 detergent

5 Close the front door of the analyzer.

6 Select **Load Consumable**.

7 Enter the following information:

- Volume %
- Serial number
- Expiration date
- Lot number

8 Select **Load**.

3.5.3 Loading reagent probe wash solutions

Reagent probe wash solution including CD80 alkaline concentrated wash solution and acid wash solution poured into a reagent bottle are used to clean the reagent probes, sample probes, sample mixers, reagent mixers, and reaction cuvettes in a special wash procedure. It can only be loaded manually.

You are recommended to check the reagent probe wash solution every day to ensure its efficiency.

NOTE

- Before loading wash solutions, ensure that there are no air bubbles inside the reagent bottle so as to avoid affecting washing effects.

1 Check the system status and operate accordingly.

- Standby, Incubation or Sleep: Proceed to the next step.
- Running: Select **Reagent** > **R List** > **Consumable** Select **Reagent Stop** to request reagent load. When the countdown for reagent load becomes 0 and the system status is Reagent Load, a message box pops up. Select **OK**, and then proceed to the next step.

2 Select **Reagent** > **R List** > **Consumable**.

3 Select DA/DB/Physiological saline you want to load.

4 Select **Load**. The Load Consumable window is displayed.

5 Remove the reagent carousel cover.

6 Place in the designated positions.

7 Restore the reagent carousel cover.

If a reagent bar code reader has been configured, the system will scan the reagent carousel automatically and refresh the displayed reagent information.

8 Enter the following information:

- Volume (100% by default)
- Serial number
- Expiration date
- Lot number
- Bottle type

9 Select **Load**.

NOTE

- Before loading wash solutions, ensure that there are no air bubbles inside the reagent bottle so as to avoid affecting washing effects.

1 Check the system status and operate accordingly.

- Standby, Incubation or Sleep: Proceed to the next step.

2 Select **Reagent** > **R List** > **Consumable**.

3 Select **DA/DB/DC** of sample probe on the panel.

4 Select **Load**.

5 Place CD80 detergent in the DB position, acid wash solution in the DA position and Probe Cleanser in the DC position .

6 Enter the following information:

- Volume (100% by default)
- Serial number
- Expiration date
- Lot number

7 Select **Load**.

3.5.4 Loading Sample Probe Wash Solutions

Sample probe wash solutions including CD80 detergent, acid wash solution and detergent cleanser poured into a reagent bottle, are used to clean the sample probes, sample mixers, reagent mixers, and reaction cuvettes in a special wash procedure. It can only be loaded manually. When the sample probe wash solution is expired or exhausted, the system will give an alarm, which will not influence the analysis. Fill more sample probe wash solution.

You are recommended to check and replace the sample probe wash solution every day to ensure its sufficiency.

NOTE

- Before loading wash solutions, ensure that there are no air bubbles inside the reagent bottle so as to avoid affecting washing effects.

1 Check the system status and operate accordingly.

- Standby, Incubation or Sleep: Proceed to the next step.

2 Select **Reagent** > **R List** > **Consumable**.

3 Select **DA/DB/DC** of sample probe on the panel.

4 Select **Load**.

5 Place CD80 detergent in the DB position, acid wash solution in the DA position and Probe Cleanser in the DC position .

6 Enter the following information:

- Volume (100% by default)
- Serial number
- Expiration date
- Lot number

7 Select **Load**.

3.5.5 Loading Physiological Saline

Physiological saline is used to run sample blanks, reagent blanks and calibrations, and dilute samples, and it can only be loaded manually. The bottle type and volume of the loaded saline must be entered. Physiological saline used for running sample blanks and diluting samples should be loaded to the position 61W on the reagent carousel.

Loading physiological saline to reagent carousel

1 Check the system status and operate accordingly.

- Standby: Proceed to the next step.
- Running: Select **Reagent** > **R List** > **Consumable**. Select **Reagent Stop** to request reagent load. When the countdown for reagent load becomes 0 and the system status is Reagent Load, a message box pops up. Select **OK**, and then proceed to the next step.
- Incubation: Proceed to the next step.
- Sleep: Proceed to the next step.

2 Select **Reagent** > **R List** > **Consumable**

3 Select Physiological Saline in No.61 position that you want to load.

4 Select Load .

5 Remove the reagent carousel cover.

NOTE

- When pulling out the quick joint on the cap of the wash buffer tank, please pull it upright and gently. When it is not upright, please do not pull it out forcibly; otherwise the joint may be scratched or damaged.

6 Place the physiological saline in position 61W.

7 Restore the reagent carousel cover.

If a reagent bar code reader has been configured, the system will scan the reagent carousel automatically and refresh the displayed reagent information.

8 Enter the following information of physiological saline for sample blanks and sample dilution:

- Volume(100 % be default)
- Bottle type

9 Select **Load**.

3.6 Calibration

Running calibration is to calculate calibration factors for sample result calculation. Generally, calibration is recommended when one of the following conditions occurs:

- A new test is configured.
- QC alarms are given while the reagent, calibrator and control sample are within the expiration date.
- Reagent lot or bottle is changed.
- The calibration factors of a test are expired.
- The ISE electrodes are adjusted or the ISE module is maintained.
- The calibration rules are changed, such as calibration method, replicates, concentration and calibrator.
- The test parameters are changed, such as primary wavelength, secondary wavelength, blank time, reaction time, reagent volume (R1/R2/R3/R4), sample volume, sample dilution parameters, reaction type, reaction direction, sample blank and result unit.
- The lamp, syringe or sample probe is replaced.

If any of the following test parameters are changed, a calibration is required:

- Primary wavelength
- Secondary wavelength
- Blank time
- Reaction time
- Reagent volume(R1/R2/R3/R4)
- Standard sample volume, diluting sample volume and diluent volume
- Reaction type
- Sample type
- Reaction direction
- Sample blank and result unit
- Twin test

For more information about calibration setup, refer to "6.3Calibration Setup" (6-6).

3.6.1 Requesting Calibrations

Calibrations can be requested only when calibration information has been set up and calibrators are not expired.

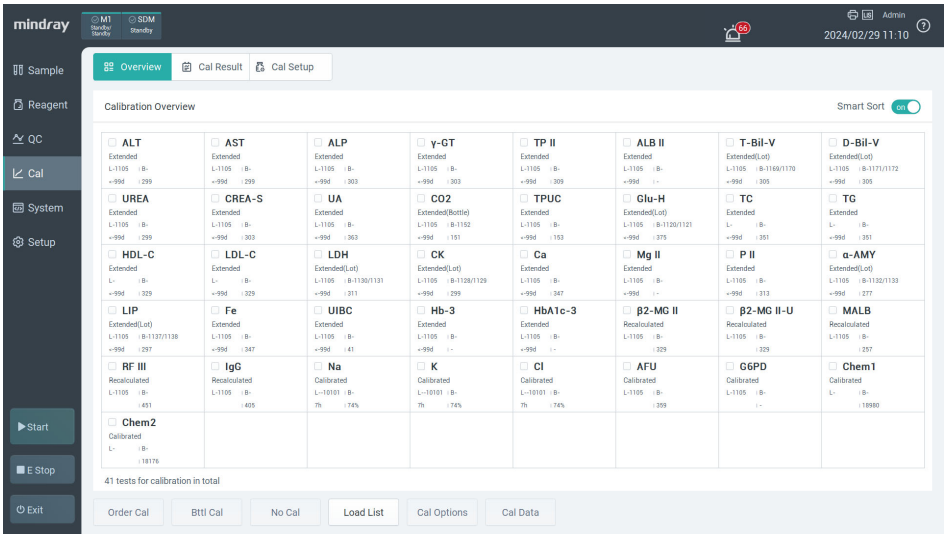
3.6.1.1 Calibration request via Cal Overview screen

When one of the above-mentioned conditions is happened, request a calibration according to the steps stated below.

Before requesting a calibration, make sure that the calibrator has been loaded to correct position.

1 Select **Cal** > **Overview**.

Figure 3.5 Calibration Overview



2 Select the test that needs calibration.

3 Select **Order Cal**.

4 Select Calibration **Options**.

- By bottle
- By lot

5 Select **OK**.

6 If you want to abort the calibration requests, select **No Cal**.

Calibration tests can be canceled only when they have not been started or are interrupted.

3.6.1.2 Calibration request via reagent list screen

When calibration status of a test is Cal Required, Cal Failed or Cal Time Out, the system will give an alarm. Perform the following steps to request a calibration based on the calibration status:

1 Select **Reagent** > **R List** > **Reagent**.

2 Choose the test you want to request calibration.

3 Select **Order Cal**.

4 Select Calibration Options.

- By bottle
- By lot

5 Select **OK**.

6 If you want to abort the calibration requests, select **No Cal**.

Calibration tests can be canceled only when they have not been started or are interrupted.

3.6.2 Cancel calibration request

When the calibration test is requested but it does not start, you can cancel the calibration request by selecting **No Cal**. If the calibration test has started but the rack carrying calibrator has not entered rack transfer unit or if the calibration has been invalidated (e.g. the analyzer is stopped by error.), you are allowed to cancel the calibration test. The calibration status is restored to the most recent status before the calibration test is requested.

3.6.3 Loading Calibrator

BIOHAZARD	• Inappropriate handling of calibrators may lead to biohazardous infection. Do not touch the calibrators directly with your hands. Wear gloves and lab coat, if necessary, goggles. In case your skin contacts the calibrators, follow standard laboratory safety procedure and consult a doctor.

CAUTION	• Do not use expired calibrators; otherwise, unreliable test results may be caused.

1 Select **Cal** > **Overview**.

2 Select **Load List**.

The calibrator list shows all requested tests as well as calibrators, positions, concentration, lot number and expiration date. You can click the header of the column of test and position to sort.

3 Load calibrators according to the calibrator list. load calibrators to an rack, and then put the rack into the rack supply unit.

Ensure that calibrators are loaded to the correct positions.

3.6.4 Running Calibrations

NOTE	• Do not start measurement after starting up the system until the status becomes Standby.

After requesting calibrations and load calibrators to the sample rack you can start the calibration test.

Put the rack in the sample rack lanes, the system starts analysis automatically.

3.7 Quality Control

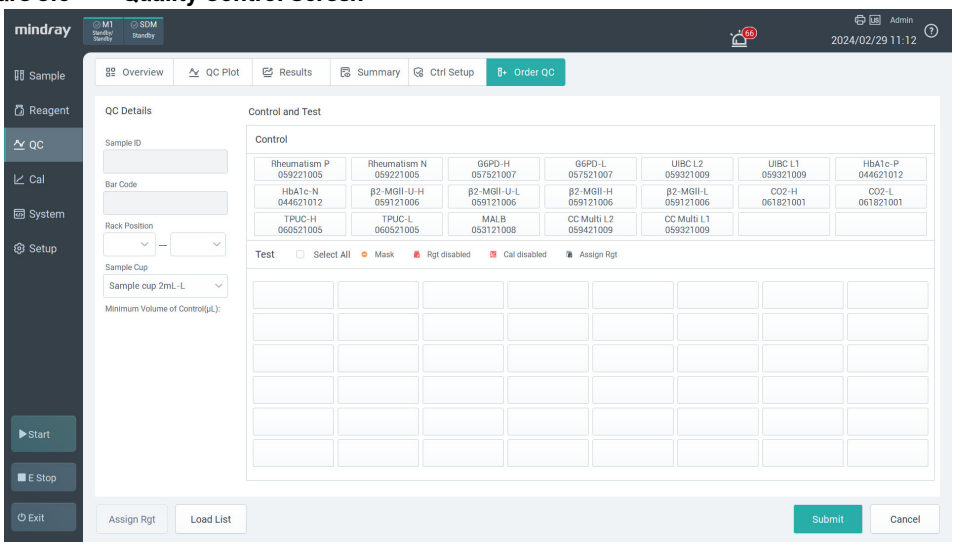
QC results are tools used to monitor the system performance. To check if the system is running normally and steadily, you are recommended to run control samples everyday. The system provides two modes to run control samples, auto and manual. New tests can be added no matter in which status the control samples are. The control orders can be edited when the control status is ordered rather than In Progress.

3.7.1 Requesting Control Test

QC runs are requested by ordering control samples. You are allowed to choose a control, control position and sample cup type as well as tests and panels for measurement. At least one test must be selected for control ordering.

1 Select **QC** > **Order QC**.

Figure 3.6 Quality Control Screen



2 Select a control.

3 Input sample ID and Rack ID and Position.

4 Choose a sample cup type to be used by the selected control.

5 Choose desired tests and panels in the test list.

If the tests included in a panel are set up for QC parameters, they will not be ordered for quality control.

6 If you want to perform QC on certain reagent, select **Assign Rgt**.

Select a reagent and click **OK** on the popup window.

7 Select **Submit**.

3.7.2 Loading Control Samples

BIOHAZARD

- Inappropriate handling of control samples may lead to biohazardous infection. Do not touch the control samples directly with your hands. Wear gloves and lab coat, if necessary, goggles. In case your skin contacts the control samples, follow standard laboratory safety procedure and consult a doctor.

CAUTION

- Do not use expired control samples; otherwise, unreliable test results may be caused.

1 Select **QC** > **Ctrl Setup**.

The control list shows all requested controls and tests, including the following information:

- Sample ID or control name
- Bar code or lot number
- Position
- Sample cup type
- Control volume

The test list shows the following information:

- Test name
- Concentration
- SD
- Unit

2 Load control samples according to the list.

If running control with rack, load controls to a rack, and then put the rack in the rack supply unit. Ensure that controls are loaded to the correct positions.

3.7.3 Running Control Samples

NOTE

- Do not start measurement after starting up the system until the status becomes Standby.

After ordering and load the control samples, you can start the QC test. Put the rack in the sample rack lanes, the system starts analysis automatically.

3.7.4 Auto QC

Controls can be run automatically based on specified samples and calibration. When auto QC is enabled, the system will automatically run all tests of the selected controls once the conditions are met.

For more information about auto quality control, refer to "7.4 Auto Quality Control" (7-12).

1 Select **QC** > **Ctrl Setup**.

2 Select **QC Setup**.

3 Set Auto Request Daily QC: QC Interval (Hour).

4 Set up the conditions for auto quality control:

- Number of samples
- QC after calibration

For more information about auto QC setup, refer to "7.4 Auto Quality Control" (7-12).

5 Select **OK**.

When conditions for auto quality control on racks are satisfied, a message pops up, reminding you to order controls for the relevant tests.

3.8 Ordering routine samples

This section describes how to order and run routine samples.

3.8.1 Routine Sample Orders

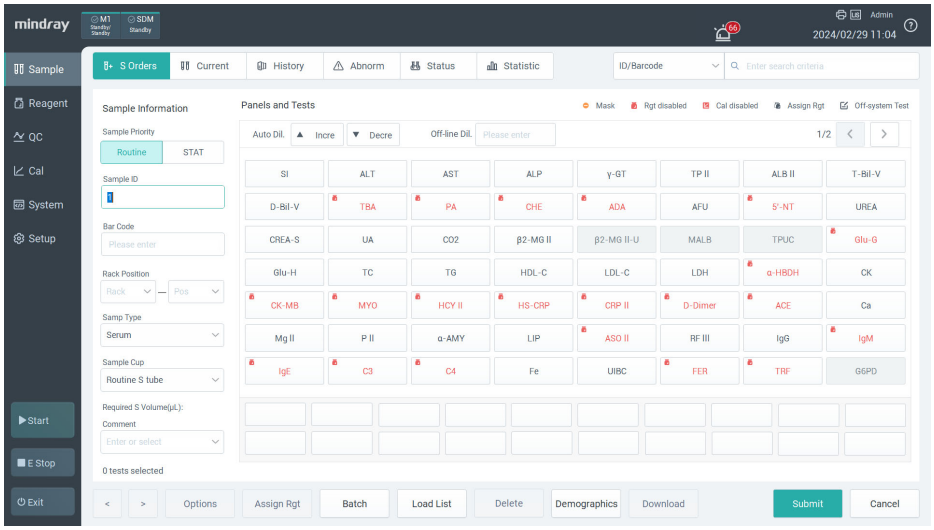
You are allowed to order samples one by one or in batch. Batch order is not allowed when the sample status is In Progress, Incomplete, Rerun or Complete. If the sample status is Ordered, the new order information will overwrite the previous order information.

3.8.1.1 Requesting a sample/batch

1 Select **Sample** > **S Orders**, then select **Routine**.

2 Select **Routine** or **STAT**

Figure 3.7 Sample orders screen



3 Enter the sample ID and barcode.

4 Enter the sample position.

5 Select a sample type from the **Sample Type** pull-down list.

The options include serum, plasma, urine, CSF and other.

6 Select **Sample Cup**.

7 Enter comments.

8 If you want to auto-dilute sample, select Increased or decreased. If you want to manual-dilute the sample, input the Offline Dilution factor.

9 Choose desired tests and panels.

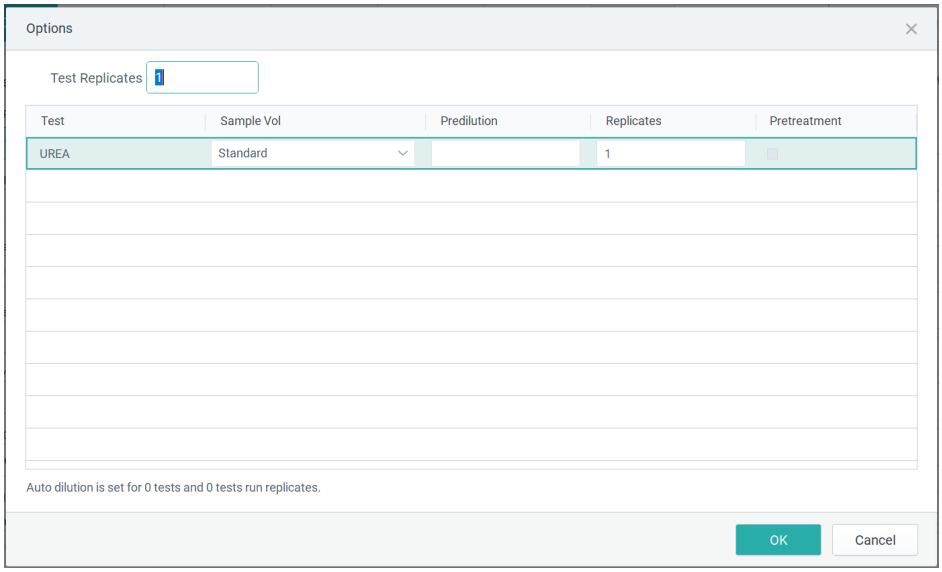
10 Tests in various statuses are indicated by symbols and color.

Table 3.2 Description of test statuses

Symbol or Color	Test	Description
	Masked test	The test is masked. It can be requested but cannot be run.
	Reagent Unavailable	Reagent is not loaded or inventory is 0.
	Calibration Unavailable	The current calibration status does not satisfy test conditions.
Test name in black 	Test Available	The test can be requested for analysis.
Test name in blueish green 	Test selected	The test is selected.

11 Select **Options**.

Figure 3.8 "Options" window



12 Enter **Replicates**. The input range is 1-90.

13 If you want to run a test with different parameters, enter the values in the test option area:

- **Sample Vol**: sample volume required to run the test. The sample volume is the same as that defined for the test. If increased and decreased volumes are defined for the test, Increased and Decreased are available here for selection.
- **Replicates**: number of times that the test is to be run.
- **Predilution**: ratio at which samples containing the test will be prediluted before being analyzed. When standard, increased and decreased sample volume parameters are defined, the product between the maximum dilution factor of the three and the auto dilution factor must not be greater than 134.
- **Sample Blank**: set up sample blank for tests.
- **Pretreatment**: set if pretreatment is needed.

14 Select **OK**.

15 Select **Assign Rgt** to assign reagent for the sample test.

16 Select **Submit**.

- If you want to batch order the samples, select **Batch Order** and input **Number of samples** and **End Sample ID** and then click **Submit**.

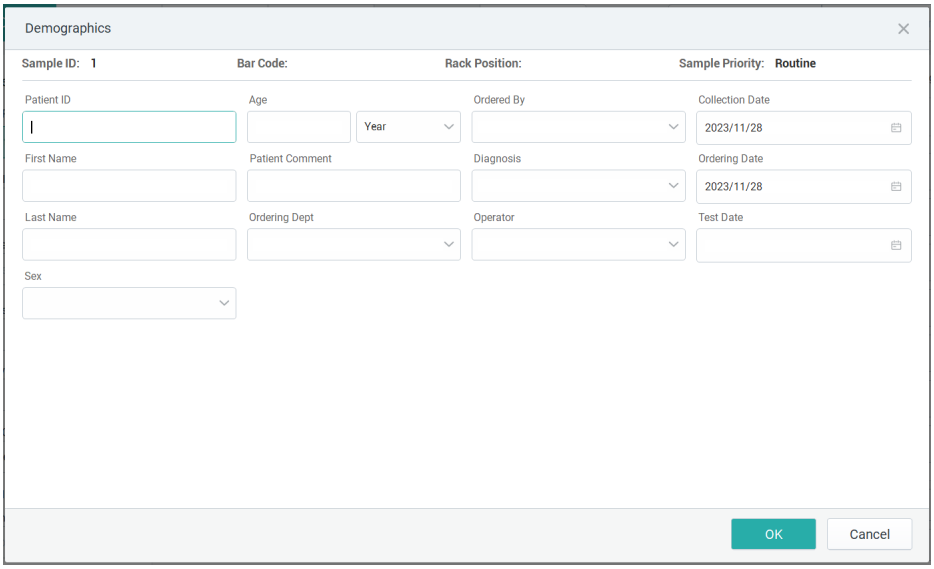
3.8.1.2 Editing patient information

You can enter the patient information at any time. When sample analysis is finished, you can view and edit the sample information on the **Current** and **History** screens.

1 Access the **Demographics** window.

- Select **Sample** > **S orders**, enter the sample ID in the **ID** field, and then select **Demog**.
- Select **Sample** > **Current** or **History**, choose desired sample, and select **Demog**.

Figure 3.9 Demographics window



2 To change the priority of the sample, select Routine under sample priority.

3 Enter the patient information.

4 Select **Submit** to save your input.

5 To edit demographics of other patients, select < > .

6 Select ✕ to close the window.

3.8.1.3 Editing and confirming order information

If the ordered sample is not in progress, you are allowed to edit the order information and add more tests. Samples that are being analyzed, rerun, incomplete or complete must not be edited. New tests can be added to samples of any status.

1 Select **Sample** > **S Orders**.

2 Enter the sample ID/barcode or other information to search for sample.

The order information of the sample is displayed.

3 Edit the following information:

- STAT property
- Sample type
- Comment
- Tests
- Panels
- Sample options and test options

4 Confirm the order information.

5 Select **Submit**.

6 You can select **Delete Order** to delete sample order.

3.8.2 Loading Routine Samples

BIOHAZARD	• Inappropriate handling of samples may lead to biohazardous infection. Do not touch the samples directly with your hands. Wear gloves and lab coat, if necessary, goggles and a mask. In case your skin contacts the samples, follow standard laboratory safety procedure and consult a doctor.

NOTE	• Before loading samples, ensure that the sample cups are free of air bubble so as to avoid inaccurate results.

CAUTION	• Do not use expired samples; otherwise, unreliable test results may be caused. • Prepare the sample according to the procedure recommended by the tube manufacturer. For collection and preparation of samples, please see the reagent instructions. Use clean tubes, microcups and other disposable materials specified by the manufacturer. Do not reuse disposables. When using vacuum collection tube for sample collection, make sure that the cap of the vacuum collection tube is clean.

1 Select **Sample** > **S Orders** > **Load List**.

The sample list shows all ordered samples and tests, including the following information:

- Order date and time
- Sample ID
- Sample bar code or control lot number
- Position
- Patient name
- Test

2 Select **Print**.

Samples are printed out.

3 Load samples according to the printed list.

Load samples to a rack based on the ordering mode, and then put the rack into the rack lane.

3.8.3 Running Routine Samples

Put the rack in the sample rack lanes, the system starts analysis automatically.

3.9 Ordering STAT Samples

STAT sample order allows emergent samples to be ordered and analyzed with high priority. STAT order is used to run emergent samples with higher priority than routine samples.

The system supports two sample analysis modes for racks: rack ID mode and bar code mode, and any one of them can be chosen. For sample ordering in the three modes, refer to "8.2 Sample Ordering and Processing" (8-6).

3.9.1 Ordering STAT Samples

3.9.1.1 Ordering single STAT Sample

1 Select **Sample** > **S Orders**.

2 Select STAT under sample priority.

3 Enter the sample ID and barcode.

Sample ID is composed of numbers, or letters and numbers. Up to 10 digits can be entered. The first sample on each day is numbered as 1. Duplicate sample IDs are not allowed before the next time the samples are released.

4 Enter the sample position.

- If ordering samples with rack, input the rack ID and position number based on the analysis mode.

5 Select a sample type from the **Sample Type** pull-down list.

6 Select **Sample Cup**.

7 Enter sample comment or select one in the **Comment** field.

8 Choose desired tests and panels.

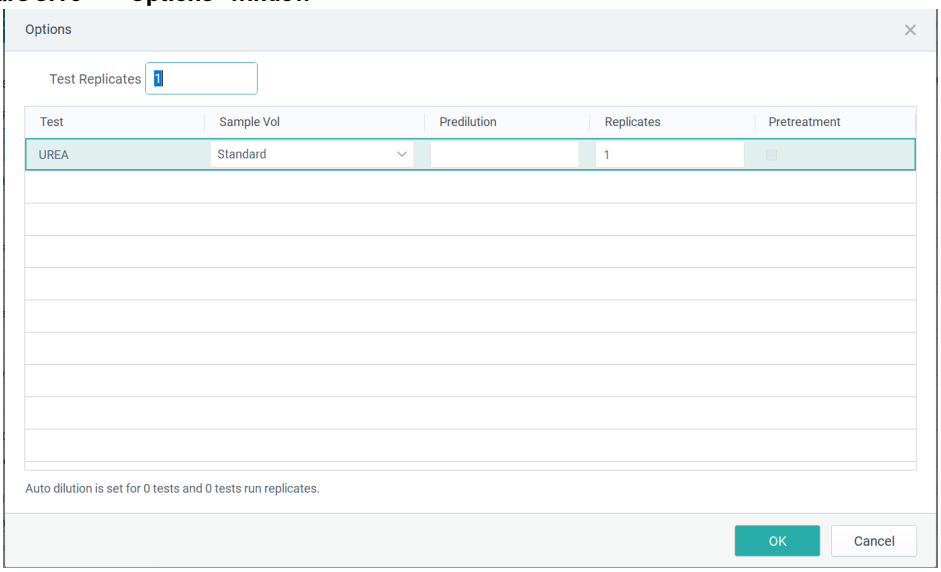
Tests in various statuses are indicated by symbols and color.

Table 3.3 Description of test statuses

Symbol or Color	Test	Description
	Masked test	The test is masked. It can be requested but cannot be run.
	Reagent Unavailable	Reagent is not loaded or inventory is 0.
	Calibration Unavailable	The current calibration status does not satisfy test conditions.
Test name in black 	Test Available	The test can be requested for analysis.
Test name in blueish green 	Test selected	The test is selected.

9 Select **Options**.

Figure 3.10 "Options" window



10 Enter **Replicates**. The input range is 1-90.

11 If you want to run a test with different parameters, enter the values in the test option area:

- **Sample Vol**: sample volume required to run the test. The sample volume is the same as that defined for the test. If increased and decreased volumes are defined for the test, Increased and Decreased are available here for selection.
- **Replicates**: number of times that the test is to be run.
- **Predilution**: ratio at which samples containing the test will be prediluted before being analyzed. When standard, increased and decreased sample volume parameters are defined, the product between the maximum dilution factor of the three and the auto dilution factor must not be greater than 134.
- **Sample Blank**: set up sample blank for tests.
- **Pretreatment**: set if pretreatment is needed.

12 Select **OK**.

13 Select **Assign Rgt** to assign reagent for the sample test.

14 Select **Submit**.

- If you want to batch order the samples, select **Batch Order** and input **Number of samples** and **End Sample ID** and then click **Submit**.

3.9.2 Loading STAT Samples

BIOHAZARD	• Inappropriate handling of samples may lead to biohazardous infection. Do not touch the samples directly with your hands. Wear gloves and lab coat, if necessary, goggles and a mask. In case your skin contacts the samples, follow standard laboratory safety procedure and consult a doctor.

NOTE	• Before loading samples, ensure that the sample cups are free of air bubble so as to avoid inaccurate results.

CAUTION

- Do not use expired samples; otherwise, unreliable test results may be caused.
- Prepare the sample according to the procedure recommended by the tube manufacturer. For collection and preparation of samples, please see the reagent instructions. Use clean tubes, microcups and other disposable materials specified by the manufacturer. Do not reuse disposables. When using vacuum collection tube for sample collection, make sure that the cap of the vacuum collection tube is clean.

3.9.2.1 Loading common STAT samples

1 Select **Sample** > **S Orders**.

2 Select **Load List**.

The sample list shows all ordered samples and tests, including the following information:

- Order date and time
- Sample ID
- Bar code
- Position
- Patient name
- Test

3 Load samples according to the printed list.

- Load samples to a red rack based on the ordering mode. Place the sample rack into the rack lane.

3.9.3 Start Analysis

NOTE

- Do not start measurement after starting up the system until the status becomes Standby.

After ordering and loading the samples, you can start the analysis. To view sample results, refer to 8.8 Results Recall (8-22). Put the rack in the sample rack lanes, the system starts analysis automatically.

3.10 Test Status and Emergency Stop

During the analysis, you can check reagent inventory on the **Reagent Overview** screen, view test status of calibrators, controls, routine and emergent samples on the **Sample** – **Rack Status** screens, and view reagent carousel status on the **reagent carousel** screen.

3.10.1 Checking Reagent/Consumable Status

Please refer to "3.4.7 Check Reagent/Consumable Status" (3-10).

3.10.2 Viewing Status of Racks

The **Rack Status** screen shows the status of the rack storage unit and buffer unit.

Follow this procedure to view rack status:

1 Select **Sample** > **Status**.

Figure 3.11 Rack status

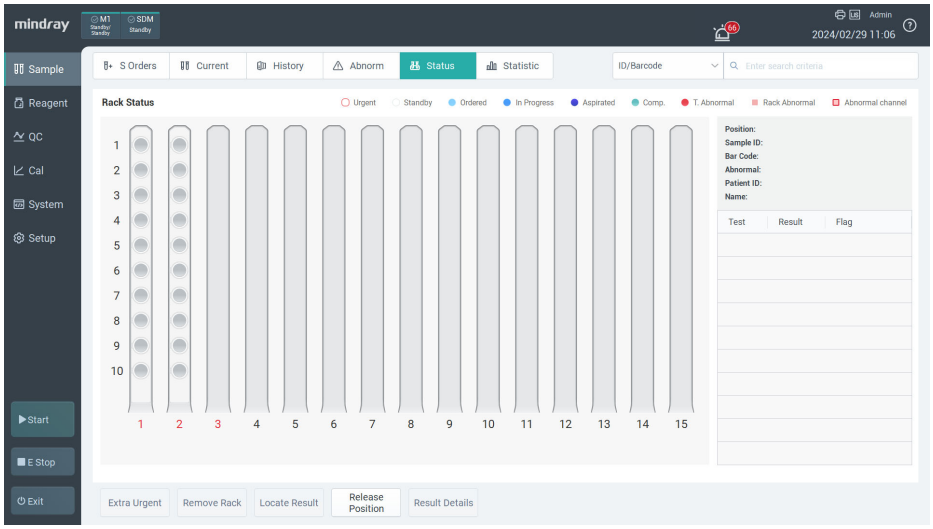


Table 3.4 Sample status on rack

Icon	Color	Sample status	Description
	Red circle	Extra Urgent	Extra urgent sample
	White background	idle	No sample in this position
	Light blue	ordered	The sample is ordered but not measured.
	Sky blue	Aspirated	Sample dispensing has been finished.
	Dark blue	Running	Running test
	green	Complete	All tests of the sample are finished with results calculated.
	red	Test abnormal	Test is incomplete or test is abnormal.
	Red square	Rack abnormal	The rack is duplicate, the rack type cannot be identified, the rack type conflicts with the rack bar code, or the rack bar code scanning fails.
	red square with red frame	Channel abnormal	The rack channel status is abnormal.

2 Select a rack and view the detailed information on the right side of the screen.

3 Choose the following buttons as needed:

- **Remove rack**: Select the rack and click this button to retrieve it.
- **Locate Result**: Locate the result to certain position on the rack.

3.10.2.1 Searching sample

1 Select **Sample** > **Status**.

2 Choose search conditions.

3.10.2.2 Retrieving designated rack

On rack status screen, you can retrieve designated rack to rack storage unit.

1 Select a rack in the buffer area or search a rack through sample ID or Bar code.

2 Click **Remove Rack**.

3.10.3 Reagent Stop

Reagent Stop means to pause dispensing reagent during the test, and then load and unload reagent on the reagent carousel. When Reagent Stop is selected, the countdown for loading reagent is displayed in the status prompt area at the top of the screen. When the started tests finish dispensing reagent, the system status changes to Reagent Load, and you are allowed to load and unload reagent.

To cancel the reagent stop and resume the test, select  or No Load button.

3.10.4 Emergency Stop

The system allows emergently stopping the analyzer. Emergency stop will terminate all measurements and all tests on the analyzer that are not finished yet will be invalidated. Do not use emergency stop unless it is really needed, for example, system failure. Emergency stop can be performed in any system status.

Select the  icon and then select **OK**; or, click the module status icon at the top of the screen to access the **System Status** screen and then select **Stop**. All unfinished actions are cancelled, all pumps and valves are turned off, and the analyzer enters the Stopped status.

To restore system failure, access the **System Status** screen and then select **Home**. To resume the analysis, select the  icon.

3.11 Home the System

The Home command is used to initialize the analyzer, and to recover them from failures, making all components return to the home positions. When the Home command is executed, the system status changes to Standby.

Make sure that the racks on the track are cleared before restoring the system.

1 Select system overview icon or **System** > **System Status**.

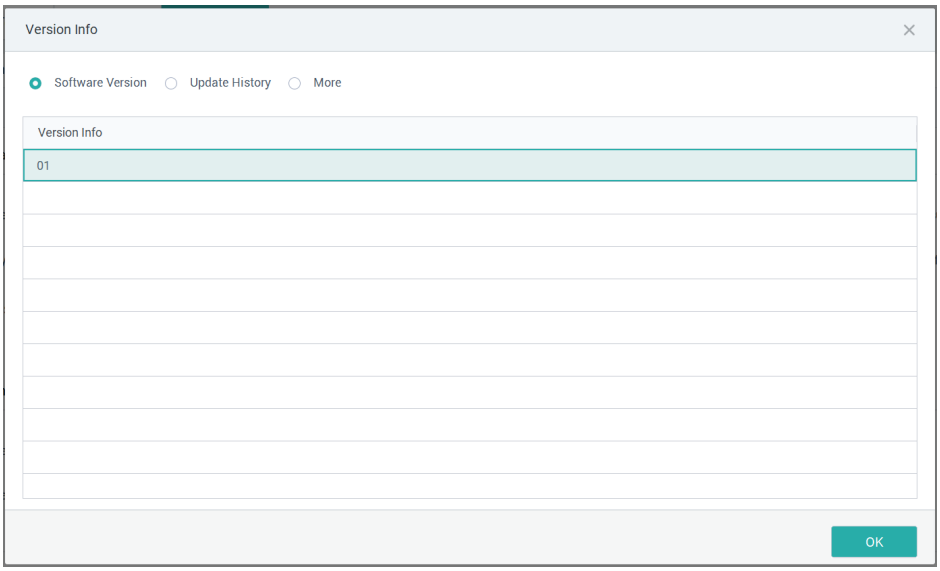
2 Select t **Home**.

3.12 View Software Version

1 Click the upper right corner and click **About**.

2 View the version number and upgrade record.

Figure 3.12 Software version



3.13 View Video Guidance

1 Click the question mark “?”on the upper right corner and click **Video Guidance**.
2 Select **Import** to import video guidance.
3 Select the video you want to watch and play it.

3.14 Daily Maintenance

After finishing all tests every day, you are required to perform the daily maintenance procedures and those maintenance procedures indicated in yellow.

Daily maintenance procedures include:

- Check DI Water Connection
- Check Waste Connection
- Check Probes/Mixers/Wash Wells
- Check Sample/reagent Syringe
- Check inventory of CD80
- Check Sample Probe Wash Solution
- Special Wash Probes/Mixers
- Clean ISE Tubes
- Ultrasonic Cleaning of Sample Tube

For more information, refer to "11.4 Daily Maintenance" (11-11).

3.15 Shutdown and Log Off

Since the system executes maintenance in periodical manner, which is controlled by the software, you are recommended not to power off the computer and the instrument after finishing tests every day.

3.15.1 Log Off

You can log off the operating software and use a new user name and password to log on it.

1. Make sure that the system is in "Standby" status.
2. Select **Exit** on the left of the main screen and select **Log Off**.
3. Select **OK**.
4. Log on again or use a new name and password to log on.

3.15.2 Shut Down

1. Make sure that the system is in "Standby" status.
2. Select **Exit** on the left of the main screen and select **Shut Down**. The Windows operating system will quit automatically.
3. Switch off the power in the following order:
   - Printer
   - Monitor display of the operation unit
   - Analyzer power switch
   - Monitor display of the computer installed with the Data Management Software (optional) or LIS (optional)
   - Water supply module (optional)
   - Drainage module (optional)
   - External vacuum pump (optional)

When the analyzer power is switched off, the refrigeration system is not running; please take out the reagents and place them in a refrigerator. If you are going to store the system for over 7 days, switch off the main power. Take out the reagents and store them that require refrigeration in a refrigerator.

3.16 Check after Powering Off

1. Check the analyzer panel for stains and wipe them off with clean gauze.
2. Check the high-concentration waste tank. Clear it if necessary.
3. Check the lane for racks. If any, take out the racks and store them properly.
4. Take out racks from the lanes and store them properly.

4 Setup

In this chapter

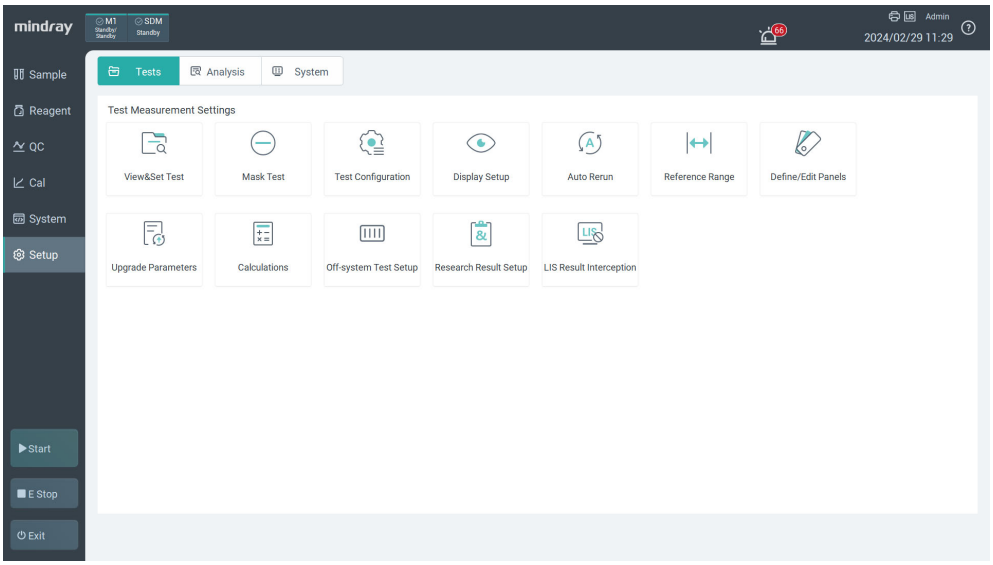
4 Setup

4.1 Test Setup

4.1.1 Introduction

The system supports both closed-reagent and open-reagent tests. Definition, modification, and deletion of user-defined tests are valid for the entire system. Closed-reagent tests can only be run with the reagents provided by our company, and must not be edited for parameters other than print name, result unit, decimal places, error detection limits, and slope/offset. If you are not going to use certain closed-reagent tests, you are allowed to mask them, and if needed some day, unmask them. The **Tests** screen is as shown below:

Figure 4.1 Tests screen



Definition and setup of user-defined tests will be described in detail in the following sections.

4.1.2 Import Tests

The system supports specified and default tests to be imported from an external file, and open-reagent tests to be exported to an external storage device.

When tests are imported, they are enabled by default if set up correctly. If the number of open-reagent tests imported exceeds the maximum limit, the excessive open-reagent tests will be disabled.

Only users with sufficient permission are allowed to import or export tests. Importing and exporting tests can be performed only when the system status is Standby, Incubation, Stop and Sleep.

If an imported closed-reagent test is no longer needed, it can be deleted with the **Delete** button on the **Tests** screen

Import default list of tests

Closed-reagent tests can be imported from an .item file. They include biochemical tests, ISE tests, SI and special calculations, as well as carryover pairs, reagent type, biochemistry calibration settings, unit conversion rules, processing parameters, error detection limits, carryover settings and slope and offset.

Only the print name, result unit, decimal places, error detection limits, and slope/offset can be modified and deleted, while the others can only be browsed.

1 Select **Setup** > **Tests** > **Test view and Setup**.
2 Select **Import**.
3 Select **Load Default**.
All tests contained in the default parameter form are displayed in the **Available Tests** list.
4 Select **Import**.
All imported tests are enabled by default and can be used for measurement. If the result unit is changed, the corresponding test must be recalibrated.
5 Select **OK**.

Import Specified Tests

Open-reagent tests can be imported from a .dat file. The open-reagent tests include biochemical tests, as well as the processing parameters, error detection limits, slop and offset, and sample type.

CAUTION

- While importing tests, do not power off the analyzing unit or exit the operating software.

1 Select **Setup** > **Tests** > **Test view and Setup**.
2 Select **Import**.
3 Select **Open File**.
4 Locate the path of the parameter form, and then select a .dat file.
5 Select **Open**.
6 Select **Import**.
7 Select **OK**.

4.1.3 Open Tests Setup

Defining a test

1 Select **Setup** > **Tests**.
2 Select **Define**.
3 Enter the test, number, test name, print name and select decimal and unit of the result.
4 Set up the analysis parameters, check parameters and calibration parameters.
5 Select **Submit**.

Editing open tests

You are allowed to edit user-defined tests if:

- You have sufficient permissions, and
- The analyzer on which the tests are configured are not running tests.

Editing user-defined tests is similar to defining a test. Refer to other sections in this chapter for details.

Viewing open tests

You are allowed to view the following information in any system status:

- Processing parameters
- Error detection limits
- Slope and offset
- Reference/Critical range
- Carryover

Perform the following steps to view tests you have defined:

1 Select Setup > Tests.

2 Choose a test from the test list.

3 Select **View** and **Edit** to view the processing parameters, error detection limits, reflex testing, and qualitative result flags.

Refer to "4.1.10 Check Parameters" (4-14), "4.1.11 Calibration Parameters" (4-20) and "4.1.13 Editing Closed Tests" (4-22) for parameter settings.

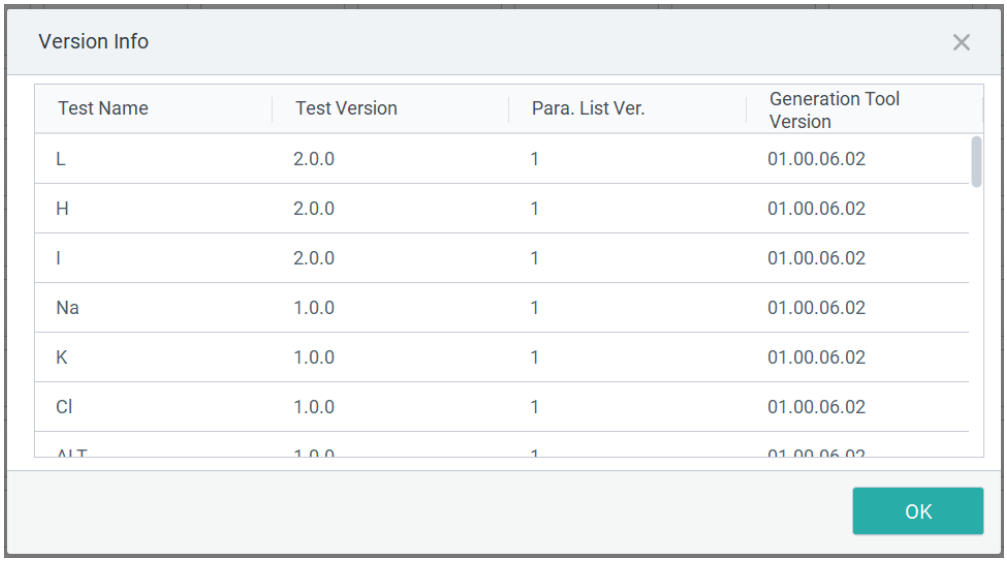
4.1.4 Version Information

The system allows viewing of generation tool version and file version of closed-reagent tests that have been imported.

1 Select **Setup** > **Test Setup** > **Test view and Setup**.

2 Select **Version Info**.

Figure 4.2 Version info window



4.1.5 Deleting Tests

Make sure that you have sufficient permission to delete a test.

1 Remove the reagent from the reagent carousel.

2 Select **Setup** > **Tests** > **Test view and Setup**.

3 Select the test in the test list.

4 Check if the following conditions are satisfied:

- The system is not running tests.
- The selected test is not requested or run for samples, calibrators and controls.

- The corresponding reagent has been unloaded from the reagent carousel.

5 Select **Delete**.

All test results, data and parameters related to the test are cleared.

4.1.6 Slope/Offset Adjustment

The slope and offset are calculation factors that are used to compensate the test results of a test when the QC result of the test is slightly deviating.

When the measurement is finished, the system adjusts the test result with the following equation:

y=kx+b

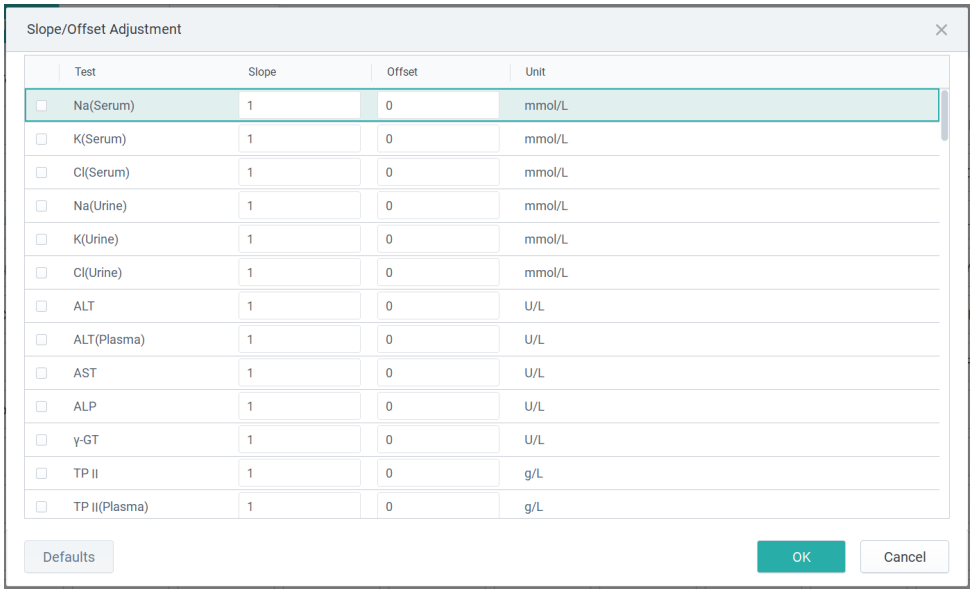
Where, x is the test result before adjustment, y is the result after adjustment, k is the slope, and b is the offset.

Before setting up the calculating factors, make sure that you have sufficient permissions and the system is not running tests.

1 Select **Setup** > **Tests** > **Test view and Setup**.

2 Select **Slope/Offset**.

Figure 4.3 Slope/Offset Adjustment window



3 Choose a test.

4 Double click the **Slope** field and then input the slope.

Positive, negative and decimal numbers (-99999999~99999999) can be entered. The maximum input length is 8 digits.

5 Double click the **Offset** field and then input the offset.

Positive, negative and decimal numbers (-99999999~99999999) can be entered. The maximum input length is 8 digits.

6 Repeat step 3 to 5 to set up the slope and offset for other tests.

7 Select **OK** to save your input information.

8 To restore the factory settings of slope and offset, select **Defaults**.

4.1.7 Test Configuration

The Test Configuration function is used to enable/disable tests that have been defined correctly and customize their display order on the **Sample**, **STAT Sample Order** and **Quality Control** screens. When disabled, tests will no longer appear on the **Sample**, **Reagent list**, **Quality Control**, **Define/Edit Panels**, **Special Calculations**, **Current Result** and **History Result** screens. Only the enabled tests can be requested for measurements and recalled on results screens.

4.1.7.1 Enabling Tests

All tests other than ISE tests and SI can be enabled or disabled. The closed-reagent tests are enabled by default after being imported from a test file; while the open-reagent tests will be enabled only if the parameters are set up correctly. The SI is always enabled and cannot be disabled. If an ISE module is configured, the ISE tests will always be enabled.

To enable tests, perform the following steps:

1 Select **Setup** > **Tests** > **Test Configuration**.

2 Select the test(s) you want to configure.

Configured tests are selected by default and unconfigured ones are not.

3 Select **OK**.

4.1.7.2 Disabling Tests

Some tests that will not be used for the moment can be disabled, and will no longer appear on request screens. ISE tests and SI are always available and cannot be disabled. Results of disabled tests cannot be recalled until the tests are enabled again.

A test can be disabled only if:

- It is not an ISE test.
- It is not SI.
- It has no reagent position.
- It has no calibrator position and has not been requested for calibration.
- It has no control position.
- It is not contained in samples and controls that are in ordered, Incomplete or Rerun status.

When one of a twin tests is deconfigured, the other twin is deconfigured automatically.

Perform the following procedure to disable tests:

1 Select **Setup** > **Tests** > **Test Configuration**.

2 Deselect the tests that you desire to deconfigure.

3 Select **OK**.

4.1.8 Masking/Unmasking Tests

The test masking function is used when a test needs to be disabled temporarily due to abnormal result or reagent exhaustion. Masked tests are flagged with ⛔ and can be requested but cannot be run until they are unmasked. Tests on reagent carousel inner ring or outer ring can be masked or unmasked simultaneously.

4.1.8.1 Masking/Unmasking Tests

1 Select **Setup** > **Tests**.

2 Select Mask/Unmask Test.

3 Choose mask type.

- Test mask: once masked, the sample analysis, QC and calibration cannot be performed for this test. The test which is not started yet will be invalidated and flagged as Mask.
- Sample mask: once masked, the sample analysis is unavailable, but the QC and calibration can be performed. The sample analysis which is not started yet will be invalidated and flagged as Mask.

4 Select the tests you want to mask and click **OK**.

5 To unmask tests, select them again and then select **OK**.

6 Select **Return**.

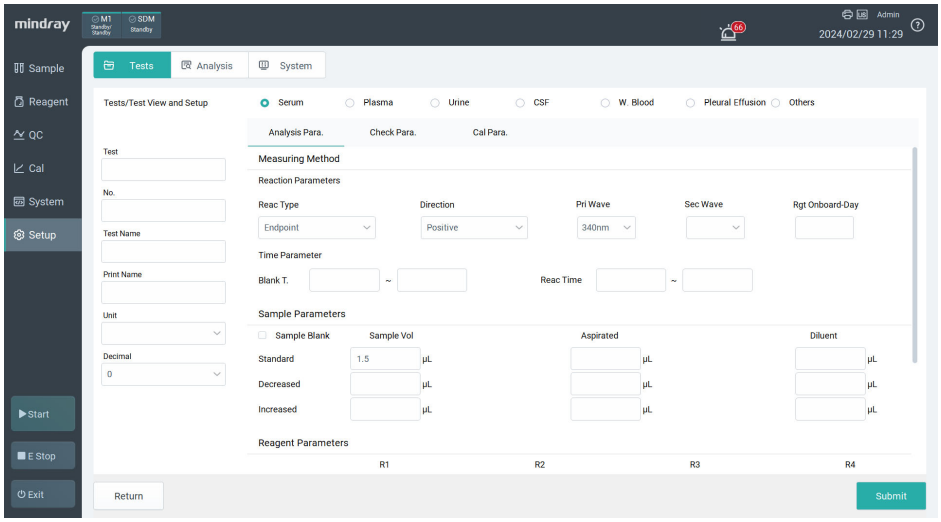
4.1.9 Analysis Parameters

This section introduces the analysis parameters for the tests.

1 Select **Setup** > **Tests** > **Test view and Setup**.

2 Select **View**.

Figure 4.4 Analysis window



Test

Test name is the only identity of a test and must not be duplicate. A test name can be composed of up to 10 characters, and is not case sensitive.

No.

No. is the only ID of a test, which is imported from parameter chart and must not be modified.

Sample type

Sample type refers to the samples to which the test is applicable. The options include serum, plasma, urine, CSF and other. The options available in the Sample Type pull-down list are those supported by the test, and the default is the default sample type.

The system allows definition of test parameters for more than one sample type, including the processing parameters and error detection limits. Sample types of a closed-reagent test are imported through the test list; and sample types of an open-reagent test can be defined by the user.

During definition of open-reagent tests, the parameters should be firstly defined for serum sample, and then for other sample types. Such tests will be calibrated with serum sample parameters by default.

Test name

This field is the complete form of test name. It can be composed of up to 36 characters. The input is not case sensitive. The Test field can be left blank or duplicate.

Print Name

Print name is displayed on patient reports representing a test. It can be composed of up to 15 characters. The print name can be edited and duplicate. When this field is left blank, the short form of the test name will appear on reports.

A test is only represented by its print name on patient reports and appears on other reports in the form of short name.

Unit

Changing the result units of both closed-reagent and open-reagent tests are allowed.

- For closed-reagent tests, only the unit options provided by the manufacturer can be selected. When the result unit is changed, the system will automatically refresh the finished sample results, calibrator concentrations, control concentrations, reference ranges and offsets in light of the conversion rate between units.
- For open-reagent tests, the result unit is blank by default. After changing the unit, you are required to update calibrator concentrations, control concentrations and standard deviations (SDs), reference ranges and offsets. Those test results calculated with the old unit will remain unchanged.

Run calibration again after changing the result unit of open-reagent test.

Decimal

Decimal specifies the number of decimal places for test results. The decimal is allowed to be edited for both open and closed reagent tests. The number of decimal places is 0 for open test and same as that defined in the database for closed test.

Up to 3 decimal places can be set up and respectively correspond to 0, 0.1, 0.01 and 0.001.

Reaction Type

Reaction type is a measurement theory based on which tests are run for samples and then calculated. The system supports three reaction types, which are Endpoint, Fixed-time and Kinetic.

Table 4.1 Reaction types

Reaction type	Description
Endpoint	Qualitative analysis is performed based on the absorption spectrum and absorbed light intensity of the reactant when the reaction becomes equilibrious.
Fixed-time	For this reaction type, the reaction velocity is directly proportional to the substrate concentration. As the substrate is consumed continuously, the reaction velocity is decreasing gradually, and so is the absorbance change rate. It will take a long time for such reaction to become equilibrium, and the reaction can get steady only after a delay.
Kinetic	Kinetic, also called continuous monitoring method, is used to continuously measure the multiple change points of a reactant or substrate's concentration which varies with the enzymatic reaction, thus calculating the initial velocity of the enzymatic reaction and then the enzyme activity. This reaction type is mainly used for measurement of enzyme activity.

Reaction Direction

Reaction direction refers to the change trend of absorbance during the reaction process, and includes two options:

- Positive: indicates increasing absorbance with time.
- Negative: indicates decreasing absorbance with time.

Primary Wavelength

The primary wavelength is chosen based on the light absorption features of the reactant and used to measure the absorbed light intensity.

Options for primary wavelength include 340nm, 380nm, 412nm, 450nm, 480nm,505nm,546nm,570nm,605nm,630nm,660nm,700nm,740nm,770nm,800nm and 850nm.

Secondary Wavelength

The secondary wavelength is used to correct the absorbance measured at the primary wavelength and eliminate the influence of noise, such as light flash and drift, and scratches on cuvettes, etc. The two wavelengths cannot be equal.

Options for secondary wavelength include blank, 340nm, 380nm,412nm, 450nm, 480nm,505nm,546nm,570nm,605nm,630nm,660nm,700nm,740nm,770nm,800nm and 850nm.

On-board Stability Time (days)

The On-board Stability Time refers to the number of days that the reagent can be kept valid since uncapped at the first time.

The input range must be within 1-999 days. The default is blank.

Blank Time and Reaction Time

Blank time refers to the period between dispensing of the second reactant (reagent or sample) in reversed order and of the last reactant (reagent or sample).

For endpoint analysis, the reaction time refers to the time span from the start point of the reaction to the end point; for fixed-time and Kinetic analysis, it refers to the period from reaction equilibrium to the end of monitoring.

The blank time and reaction time are counted in measuring points.

Suppose the blank time range is N-P and the reaction time range is L-M. The start point is the first measuring point after dispensing of R1.

Table 4.2 Blank time and reaction time input ranges for endpoint analysis

Endpoint	Blank Time	Reaction Time
When the blank absorbance is read before the reaction begins,		
Single-reagent	$2 \leqslant Nx \leqslant N \leqslant P \leqslant Px \leqslant 3$	$5 \leqslant Lx \leqslant L \leqslant M \leqslant Mx \leqslant 33$
Double-reagent	$5 \leqslant Nx \leqslant N \leqslant P \leqslant Px \leqslant 16$	$18 \leqslant Lx \leqslant L \leqslant M \leqslant Mx \leqslant 33$
Triple-reagent	$18 \leqslant Nx \leqslant N \leqslant P \leqslant Px \leqslant 36$	$41 \leqslant Lx \leqslant L \leqslant M \leqslant Mx \leqslant 69$
Quadruple-reagent	$41 \leqslant Nx \leqslant N \leqslant P \leqslant Px \leqslant 52$	$54 \leqslant Lx \leqslant L \leqslant M \leqslant Mx \leqslant 69$
When the blank absorbance is read after the reaction begins,		
Single-reagent	$5 \leqslant Nx \leqslant N \leqslant P \leqslant Px$	$P \leqslant Px<L \leqslant M \leqslant Mx \leqslant 33$
Double-reagent	$18 \leqslant Nx \leqslant N \leqslant P \leqslant Px$	$P \leqslant Px<L \leqslant M \leqslant Mx \leqslant 33$
Triple-reagent	$41 \leqslant Nx \leqslant N \leqslant P \leqslant Px$	$P \leqslant Px<L \leqslant M \leqslant Mx \leqslant 69$
Quadruple-reagent	$54 \leqslant Nx \leqslant N \leqslant P \leqslant Px$	$P \leqslant Px<L \leqslant M \leqslant Mx \leqslant 69$
When the blank absorbance is not subtracted,		
Single-reagent	Nx=N=P=Px=0	$5 \leqslant Lx \leqslant L<M \leqslant Mx \leqslant 33$
Double-reagent	Nx=N=P=Px=0	$18 \leqslant Lx \leqslant L<M \leqslant Mx \leqslant 33$
Triple-reagent	Nx=N=P=Px=0	$41 \leqslant Lx \leqslant L<M \leqslant Mx \leqslant 69$
Quadruple-reagent	Nx=N=P=Px=0	$54 \leqslant Lx \leqslant L<M \leqslant Mx \leqslant 69$

Table 4.3 Blank time and reaction time input ranges for fixed-time and Kinetic analysis

Fixed-time and Kinetic	Blank Time	Reaction Time
When the blank absorbance is read before the reaction begins,		
Single-reagent	$2 \leqslant N<P \leqslant 3$	$5 \leqslant L<M \leqslant 33$
Double-reagent	$5 \leqslant N<P \leqslant 16$	$18 \leqslant L<M \leqslant 33$
Triple-reagent	$18 \leqslant N<P \leqslant 36$	$41 \leqslant L<M \leqslant 69$
Quadruple-reagent	$41 \leqslant N<P \leqslant 52$	$54 \leqslant L<M \leqslant 69$
When the blank absorbance is not subtracted,		
Single-reagent	N=P=0	$5 \leqslant L<M \leqslant 33$
Double-reagent	N=P=0	$18 \leqslant L<M \leqslant 33$
Triple-reagent	N=P=0	$41 \leqslant L<M \leqslant 69$
Quadruple-reagent	N=P=0	$54 \leqslant L<M \leqslant 69$

The blank time and reaction time are almost the same for both fixed-time and Kinetic analysis, except that M-L≥2 is required for Kinetic analysis, that is, the reaction time should include at least 3 measuring points.

Sample Volume, Standard, Aspirated, Diluent, Increased, and Decreased

Sample volume is the standard sample amount, which should be dispensed in a normal test. It ranges from 1μL to 25μL with an increment of 0.1μL. The default is 1.5μL. A maximum of one decimal is allowed.

Aspirated volume refers to the amount of sample used for dilution at the specified ratio. It ranges from 1μL to 25μL with an increment of 0.1μL. The default is blank. A maximum of one decimal is allowed.

Diluent volume refers to the amount of diluent used for sample dilution. It ranges from 75μL to 200μL with an increment of 0.5μL. The default is blank. A maximum of one decimal is allowed.

NOTE

- If aspirated volume for dilution and diluent volume are defined, ensure the total sum of them is within 100μL-245μL; otherwise, the settings cannot be saved.
- The diluent volume for standard, increased and decreased analysis can be defined in the same way.

Decreased sample volume indicates the sample amount required for a decrement test. It ranges from 1μL to 25μL with an increment of 0.1μL. The default is blank. A maximum of one decimal is allowed.

Increased sample volume indicates the sample amount required for an increment test. It ranges from 1.5μL to 25μL with an increment of 0.1μL. The default is blank. A maximum of one decimal is allowed.

NOTE

- If aspirated volume for dilution and diluent volume are defined, standard, decreased and increased analysis will be performed with diluted sampled; otherwise, it will be done based on standard, decreased or increased sample volume.

Sample Blank

Sample blank is similar to sample analysis except for use of equivalent amount of physiological saline. Sample blank is used for removal of non-chromogenesis reaction, such as influence of sample interference (Hemolysis, icterus and lipemia) on absorbance readings.

Mark the **Sample Blank** checkbox with a tick. The test will be sample blanked before the reaction begins; the **Sample Blank** checkbox on the **Options** and **Rerun** windows will be selected automatically and cannot be modified.

Reagent Volume and Diluent

Reagent volume specifies the reagent amount, which should be dispensed for measurement. The system allows the dispensing of four reagents:

- R1: 80μL-200μL for normal reagent, 10μL-200μL for concentrated reagent, with an increment of 0.5μL. The default is 120μL.
- R2-R4: 10μL-200μL, with an increment of 0.5μL. The default is blank.

The second, third and fourth reagents are allowed only when the reagent(s) prior to them are configured. For example, R2 can be set up with the prerequisite of R1; R3 with R1and R2; R4 with R1, R2 and R3. If one of R2, R3 and R4 is removed, the remaining reagents behind it will also be removed and appear in grey.

Diluent volume refers to the amount of diluent used for reagent dilution. It ranges from 10μL to 200μL with an increment of 0.5μL. The default is blank. If aspirated reagent volume for dilution and diluent volume are defined, ensure the total sum of R1 and diluent is within 80μL~200μL and that of R2/R3/R4 and diluent is within 10μL~200μL.

The combined volume of all reagents, reagent diluent and sample must be within 80μL and 280μL. If your input does not satisfy the requirements of reaction mixture volume, the system will display an error message. Check the sample volume and reagent volumes you have entered, and change them if necessary.

Sample Pretreatment

Enable the sample pretreatment function to pretreat patient samples with pretreatment reagent for the test. Sample pretreatment includes common pretreatment and blood cell pretreatment.

Pretreatment tests cannot be set with predilution factor. Setting pretreatment parameters for the twin of a former test is not allowed.

- Common Pretreatment

Select this option to pretreat the samples other than whole blood samples. Probe aspirates the sample from the top of the sample tube and then the sample is pretreated with pretreatment reagent.

- Blood Cell Pretreatment

Select this option to pretreat the whole blood samples. Probe aspirates the sample from the bottom of the sample tube and then the sample is pretreatment with pretreatment reagent.

Calibrator Pretreatment

When this option is enabled, the calibrators of the test will be pretreated with the pretreatment reagent during calibration test according to the set pretreat sample volume and pretreatment reagent volume. If a multi-point pretreatment solution is adopted, the calibrator must be pretreated with pretreatment reagent with the sample volume and diluent volume set for calibration dilution.

Control Pretreatment

When this option is enabled, the controls of the test will be pretreated with the pretreatment reagent during QC test according to the set pretreat sample volume and pretreatment reagent volume.

Pretreat sample volume

Enter the pretreat sample volume within 1 μL - 25 μL, with an increment of 0.1 μL. The default is blank.

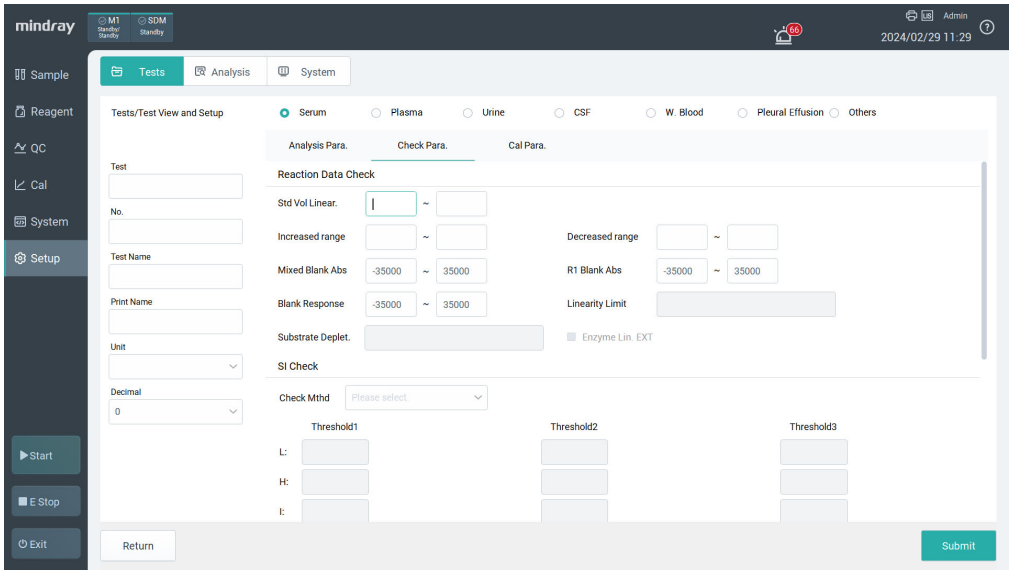
Pretreatment reagent volume

Enter the pretreatment reagent volume within 75 μL - 200 μL, with an increment of 0.5 μL. The default is blank.

The sum of pretreat sample volume and pretreatment reagent volume must be within 100 μL - 245 μL.

4.1.10 Check Parameters

Figure 4.5 Check parameters window



Linearity Range

The linearity range indicates the measurable range of the system, during which the test result is linear to the response R. Determine the linearity range according to the reagent package insert. The high limit can be any number greater than or equal to 0, and the low limit is lower than or equal to the high limit.

The system compares the calculated sample concentration with the linearity range. When the high limit is exceeded, the > sign will appear near the result; when the low limit is exceeded, the < sign will appear.

The input range for standard/increased/decreased linearity Range is -99999-999999. The default is blank, which means not performing this check.

Linearity Limit

The linearity range indicates the measurable range of the system, during which the test result is linear to the response R. Determine the linearity range according to the reagent package insert. The high limit can be any number greater than or equal to 0, and the low limit is lower than or equal to the high limit.

The system compares the calculated sample concentration with the linearity range. When the high limit is exceeded, the > sign will appear near the result; when the low limit is exceeded, the < sign will appear.

The input range for standard/increased/decreased linearity Range is -99999-999999. The default is blank, which means not performing this check.

Substrate Depletion

The Substrate Depletion option is only applicable to Kinetic and fixed-time analysis. It can be obtained through the following formula:

Substrate depletion limit = Input substrate depletion limit + K(L1-Lb)

Where,

- L1: refers to the absorbance of primary wavelength measured at the first measuring point when sample is dispensed and stirred in sample analysis.
- Lb: refers to the absorbance of primary wavelength measured at the first measuring point when sample is dispensed and stirred in a reagent blank test or calibration with 0-concentration calibrator.
- K: correction factor of liquid volume

Results will not be adjusted when L1-Lb≤0 or the measurement is not a reagent blank or 0-concentration calibration. Substrate depletion is not applicable for calibrations.

We deem that substrate depletion occurs if the primary wavelength absorbance of the first measuring point is greater than the substrate depletion limit in ascending reactions or lower than the substrate depletion limit in descending reactions. When substrate depletion occurs, the system will flag the test result with "BOE" in the patient report.

The substrate depletion limit can be any number within -35,000-35,000. The default is blank, which means not performing this check.

Enzyme Linearity Extension

If this option is selected, when the number of measuring points without substrate depletion is N=0 or N=1 within the linearity range, the enzyme linearity range extension function is enabled. If the result can be calculated within the lag time, the result is displayed and marked with "EXP" and "NLN." If the number (N) of valid measuring points within the lag time is less than two, the system shall not display the results but flag ENC (no calculation interval) and give an alarm. If this option is not selected, when the number of measuring points within the linearity range without substrate depletion is N=0 or N=1, the result will not be displayed, and the flag "NLN" will be given.

R1 Blank Absorbance Range

The R1 Blank Abs indicates the allowable range of the maximum absorbance in the previous period prior to sample dispensing. The input range must be within -35,000-35,000, and the low limit lower than the high limit.

If the maximum absorbance in the previous period prior to sample dispensing is beyond the set range, the system will flag the test result with "RBK".

The default is blank, which means not performing this check.

Mixed Blank Absorbance Range

The Mixed Blank Abs indicates the allowable range of the absorbance measured at the end point of a zero-concentration calibrator reaction or a reagent blank reaction. The input range must be within -35,000-35,000, and the low limit lower than the high limit.

If the absorbance measured at the reaction end point is beyond the set range, the system will flag the test result with "MBK".

The default is blank, which means not performing this check.

Blank Response

The Blank Response specifies the allowable range of the response in a zero-concentration calibrator analysis or a reagent blank test. The input range can be any number within -35,000-35,000, and the low limit lower than the high limit.

If the response is beyond the set range, the system will flag the test result with "BLK".

The default is blank, which means not performing this check.

Twin Test

Twin Test is associated with the current test, and the two tests are run with the same reagent. Results of two twin tests are calculated in the same test.

The test whose result will be firstly calculated should be defined prior to the associated test. Volume of the shared reagent and sample volume must be the same for the two tests. Only the two tests that have had no reagents loaded can be configured as twins.

Prozone Check

Prozone check can be performed in two ways: Antigen addition and rate check. Antigen addition is determined by two formulas: Formular 1 and Formular 2. Rate check is based on both rate check formula 1 and formula 2.

Prozone check is applicable to Kinetic, fixed-time and endpoint measurements. When the conditions for triggering an alarm are met, the system shall flag the test result with "PRO" for prozone check error, "BOE" for Kinetic analysis, and give an alarm.

Formula 1 for antigen addition:

PC1≤Aq2-k×Aq1≤PC2

Where,

Aq1 is the absorbance of the Q1 measuring point, and Aq2 is the absorbance of the Q2 measuring point. Q1 and Q2 are the number of the measuring point on the reaction curve.

Single reagent test k=(VR1+VS)/(VR1+VR3+VS)

Double reagent test k=(VR1+VS+VR2)/(VR1+VS+VR2+VR3)

VR1, VR2 and VR3 are the volumes of the R1, R2 and R3 reagent, and VS is the actual volume of sample dispensed. If reagent is concentrated, then VR1, VR2 and VR3 are the sum of reagent volume and diluent volume.

Formula 1 of rate check method:

$$PC = \frac{\frac{A_{q4} - A_{q3}}{q4 - q3}}{\frac{A_{q2} - A_{q1}}{q2 - q1}}$$

Where,

Aq1 ~ Q4 are the absorbance of measuring point Q1, Q2, Q3 and Q4. Where Q1, Q2, Q3 and Q4 are the number of the measuring point on the reaction curve.

Formula 2:

1) Aq6- Aq5≥V3 at Q5≠Q6

2) Q5= Q6: Same point, Aq5≥V3

Where,

Aq5 is the absorbance of the Q5 measuring point, and Aq6 is the absorbance of the Q6 measuring point. Q5 and Q6 are the number of the measuring point on the reaction curve.

Prozone check parameters for rate check:

[Q1] [Q2] [V1] [Y/N] [Q3] [Q4] [V2] [Y/N]

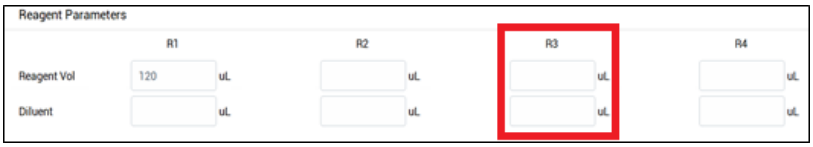
[Q5] [Q6] [V3] [Y/N] [PC1] [PC2] [Y/N] [A/O]

Prozone check parameters for antigen addition:

[Q1] [Q2]

[Q5] [Q6] [V3] [Y/N] [PC1] [PC2] [Y/N] [A/O]

For both single-reagent and double-reagent tests, set up the reagent volume of antigen addition of R3: Reagent volume for R3 and diluent volume for R3.



Factor	Description	Value Range
1st entry field (Q1)	Measuring point on reaction curve	Single and double reagent test of rate check: 2 ⩽ Q1, Q 2, Q 3, Q 4, Q 5, Q 6 ⩽ 33 Antigen addition and rate check R3,R4 reagent test 2 ⩽ Q 1, Q 2, Q 3, Q 4, Q 5, and Q 6 ⩽ 69. Q1 ≠ Q2, Q 3 ≠ Q 4 are required and Q 5= Q 6 are allowed. At least one of Q1, Q2, Q 5 and Q 6 is greater than or equal to 41.
2nd entry field (Q2)	Measuring point on reaction curve	Single and double reagent test of rate check: 2 ⩽ Q1, Q 2, Q 3, Q 4, Q 5, Q 6 ⩽ 33 Antigen addition and rate check R3, R4 reagent test 2 ⩽ Q 1, Q 2, Q 3, Q 4, Q 5, and Q 6 ⩽ 69. Q1 ≠ Q2, Q 3 ≠ Q 4 are required and Q 5= Q 6 are allowed. At least one of Q1, Q2, Q 5 and Q 6 is greater than or equal to 41.
3rd entry field (V1)	Aq2- Aq1 threshold	[-35000，35000]
4th entry field(Y/ N)	Y indicates that condition Aq2- Aq1< V1 is met. N indicates that condition Aq2- Aq1 ⩾ V1 is met. If the conditions are met, the system will not perform prozone check.	Y、N

5th entry field (Q3)	Measuring point on reaction curve	Single and double reagent test of rate check: 2 ⩽ Q1, Q 2, Q 3, Q 4, Q 5, Q 6 ⩽ 33 Antigen addition and rate check R3,R4 reagent test 2 ⩽ Q 1, Q 2, Q 3, Q 4, Q 5, and Q 6 ⩽ 69. Q1 ≠ Q2, Q 3 ≠ Q 4 are required and Q 5= Q 6 are allowed. At least one of Q1, Q2, Q 5 and Q 6 is greater than or equal to 41.
6th entry field (Q4)	Measuring point on reaction curve	Single and double reagent test of rate check: 2 ⩽ Q1, Q 2, Q 3, Q 4, Q 5, Q 6 ⩽ 33 Antigen addition and rate check R3,R4 reagent test 2 ⩽ Q 1, Q 2, Q 3, Q 4, Q 5, and Q 6 ⩽ 69. Q1 ≠ Q2, Q 3 ≠ Q 4 are required and Q 5= Q 6 are allowed. At least one of Q1, Q2, Q 5 and Q 6 is greater than or equal to 41.
7th entry field (V2)	Aq4- Aq3 threshold	[-35000，35000]
8th entry field(Y/ N)	Y indicates condition Aq4- Aq3< V2 is met. N indicates that condition Aq4- Aq3 ⩾ V2 is met. If the conditions are met, the system will not perform prozone check.	Y、N
9th entry field (Q5)	Measuring point on reaction curve	Single and double reagent test of rate check: 2 ⩽ Q1, Q 2, Q 3, Q 4, Q 5, Q 6 ⩽ 33 Antigen addition and rate check R3,R4 reagent test 2 ⩽ Q 1, Q 2, Q 3, Q 4, Q 5, and Q 6 ⩽ 69. Q1 ≠ Q2, Q 3 ≠ Q 4 are required and Q 5= Q 6 are allowed. At least one of Q1, Q2, Q 5 and Q 6 is greater than or equal to 41.

10th entry field (Q6)	Measuring point on reaction curve	Single and double reagent test of rate check: 2 ⩽ Q1, Q 2, Q 3, Q 4, Q 5, Q 6 ⩽ 33 Antigen addition and rate check R3,R4 reagent test 2 ⩽ Q 1, Q 2, Q 3, Q 4, Q 5, and Q 6 ⩽ 69. Q1 ≠ Q2, Q 3 ≠ Q 4 are required and Q 5= Q 6 are allowed. At least one of Q1, Q2, Q 5 and Q 6 is greater than or equal to 41.
11th entry field (V3)	Threshold of formula 2	[-35000，35000]
12th entry field(Y/N)	Define the range to trigger judgment formula 2. Y indicates that the value of formula 2 is within the defined range, and N indicates that the value of formula 2 is outside the defined range.	Y、N
13th entry field (PC1)	Lower threshold of formula 1. PC1<PC2 is required.	[-35000，35000]
14th entry field (PC2)	Upper threshold of formula 1. PC1<PC2 is required.	[-35000，35000]
15th entry field(Y/N)	Defines the range of formula 1 to trigger judgment. Y means the value of PC is within the range of formula 1; N means the value of PC is outside the range of formula 1.	Y、N
16th entry field(A/O)	This sets the logical triggering relationship between formula 1 and formula 2. If A is selected, when both formula 1 and formula 2 are satisfied, the logic relation is triggered ("and" logic). If O is selected, either formula 1 or formula 2 triggers the logic relation ("Or" logic).	A、O

Serum Index Check

Serum index refers to the degree of hemolysis, icterus and lipemia in serum samples.

1. Select appropriate test methods as needed: "Blank," "Semi-quantitative" and "Qualitative ." "Blank" indicates that the serum index check is disabled.
2. Set the alarm threshold for each test : An alarm will be triggered when the L/H/I test result is greater than the threshold.
3. Three levels of alarm thresholds can be set. Threshold 1 must be set, otherwise the alarm function will be disabled. Thresholds 2 and 3 can be null.

4.1.11 Calibration Parameters

This section is to introduce the settings of calibration parameters.

Setting up Calibration Rules

You should set up the calibration rules after defining a calibrator and determining concentrations for it. You are allowed to set up or edit the calibration rules, replicates, K factor and auto calibration only when the system is not running any tests.

1. Select Setup> Tests
2. Choose a calibration method in the Math Model field.

   The options include:

   - K factor
   - Two-point linear
   - Multi-point linear
   - Logit-Log 4P
   - Logit-Log 5P
   - Exponential 5P
   - Polynomial 5P
   - Parabola
   - Spline
   - Logit-Log 3P
   - Polyline
3. If you choose K Factor, type in the K factor in the Factor field.

   This field is activated only when the one-point linear math model is chosen. When the K factor is determined, the calibration results will be calculated with the equation Y=K*X. Where, Y is the calibration result, K is the factor, and X is the response.
4. Choose the number of replicates.

   The input range is 1-5, and the default is 1.

Calibration Check

The system checks the calibration results against the set detection limit. If the set limit is exceeded, the system will give an alarm and add a flag to the calibration result report. Set the parameters as follows and select **Submit**. Select Undo to undo the settings that have not been submitted. Select **Return** to the upper-level screen.

Table 4.4 Calibration Check

Acceptance Criteria	Description
Calibration time (hour)	The validity period indicates the number of days that the calibration factors can be used. If the validity period is exceeded, the system will give an alarm. The input range must be within 1-9999 hours. The default is blank.
Lot Calibration Expiration(Day)	Calibration factors can be used within the specified period. If the set limit is exceeded, the system will give an alarm.
Slope difference	The slope difference is applicable to linear calibration only. It is the K factor (slope) difference between two adjacent calibrations. The system will give the flag "FAC" and an alarm when the slope difference is exceeded. Type in the percentage within 0-100. The default is blank, which means not performing this check.
Standard deviation (SD)	The standard deviation is used for multi-point linear and non-linear calibrations. The system will give the flag "CSD" and an alarm when the SD value is exceeded. The input range must be within 0-999. The default is blank, which means not performing this check.
Determination coefficient	The determination coefficient is used for multi-point linear and non-linear calibrations. It is the fit degree of the calibration curve. The system will give the flag "DET" and an alarm when the calibration fit degree is exceeded. The input range must be within 0-1. The default is blank, which means not performing this check.
Repeatability	The repeatability means the difference of the maximum and minimum response of each calibrator within valid test times exceeds the threshold. If the calculated calibrator response difference is greater than the set absolute and relative threshold, the system will give the flag "DUP" and an alarm. • The input range of absolute threshold must be within 0-35,000. • The input range of relative threshold ABS.x% must be within 0-500. The default is blank, which means not performing this check.

Sensitivity	The sensitivity is ratio between the response difference and concentration difference of the two calibrators with the maximum and minimum concentration. The system will give the flag "SEN" and an alarm when the sensitivity exceeds the defined threshold. • The input range must be within 0-99,999. • The default is blank, which means not performing this check.
Calibration Reminder	When the auto calibration conditions are satisfied, the system will remind you through the calibration status, prompt message and color indication. • If you choose the Bottle Changed option, the system will display a message indicating calibration is required when you use a different bottle of reagents. • If you choose the Lot Changed option, the system will display a message indicating calibration is required when you use reagents of a different lot. • If you choose the Cal Time option, the system will remind you in 30 minutes before the calibration is timed out and display the test name and calibration status with yellow.

4.1.12 Upgrade Parameters

After connecting to the remote download platform, you are allowed to upgrade chemistries by downloading them remotely. Check that the remote download function has been enabled on the **System Setup-Remote Download Setup** window and the corresponding region has been selected.

1. Select **Setup** > **Chemistries** > **Version Upgrade**.
2. Select **Check for updates**.
3. The system automatically downloads the parameter list.
4. Select the new parameter table to be upgraded.
5. Click **Update**.
6. The Import screen is displayed and the new parameter table is opened by default.
7. Choose chemistries to import.
8. Click OK.

4.1.13 Editing Closed Tests

You are allowed to edit closed-reagent tests if:

- You have sufficient permissions, and
- The system is not running tests.

After importing closed-reagent tests, you are enabled to set up the following parameters:

- Print name
- Result unit
- Decimal
- Increased and decreased sample volumes and dilution parameters
- Sample blank
- Linearity range
- Linearity limit
- Auto rerun
- Substrate depletion limit
- R1 blank absorbance
- Mixed blank absorbance
- Blank response
- Reagent on-board stability time
- Twin test
- Reagent alarm limit
- Prozone check

Refer to "4.1.9 Analysis Parameters" (4-8), "4.1.10 Check Parameters" (4-14) and "4.1.11 Calibration Parameters" (4-20) for parameter settings.

4.1.14 Reagent Management Mode

1 Select **Setup** > **Tests** > **Management Mode**.

2 Select **Manage by test/lot/bottle**.

Calibration by bottle can be selected only when Manage by Bottle is selected.

4.1.15 Carryover Setup

The Carryover Setup option is used to set up the carryover relations between open-reagent tests, between samples and between cuvettes. The system will insert a cleaning to reagent probes and cuvettes based on the carryover settings. The closed-reagent tests have been set up by the manufacturer and cannot be viewed or edited, while the open-reagent tests need to be set up on the Carryover window. The setup option is only applied to biochemical tests, rather than SI, ISE test, special calculation, and panel.

When carryover settings are performed for a twin test, the other twin will update synchronously.

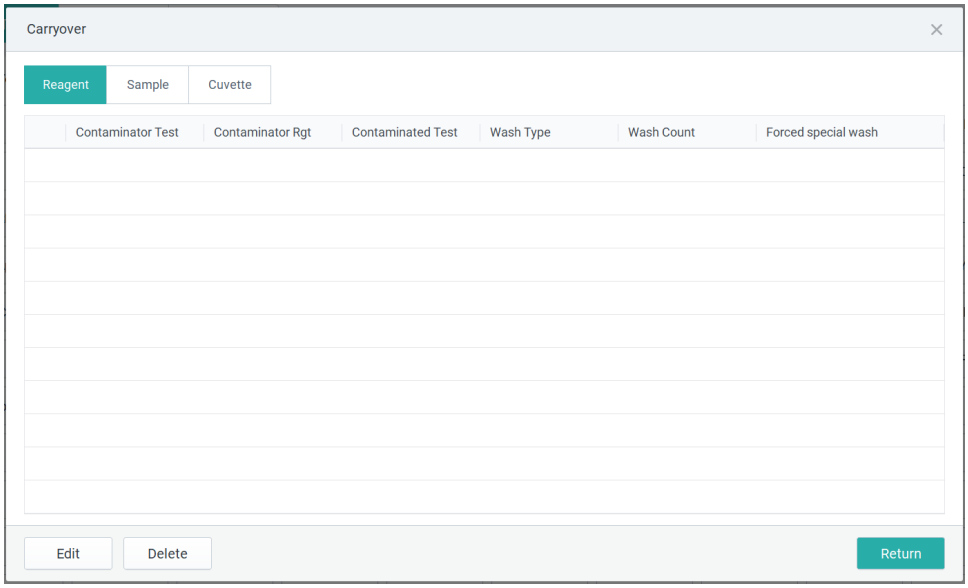
Carryover setup can only be performed by users with sufficient permissions when the system status is not Running.

Defining/Editing Reagent Carryover

1 Select **Setup** > **Tests**.

2 Select a test and select **Carryover**.

Figure 4.6 Carryover window



3 Select **Edit** and **Reagent Carryover**.

4 Choose one or all contaminator tests that may contaminate other tests.

"ALL" means all tests may contaminate others.

5 Choose one contaminator reagent type that may contaminate other tests.

The options include R0, R1, R2, R3 and R4.

6 Choose one or all contaminated tests in the Contaminated list.

"ALL" means all tests may be contaminated. All (the entire contaminator) to All (the contaminated) is not permitted to set up. If the Contaminator is DB/DA, then the wash type cannot be same as it. E.g. If the contaminator is DB, then the wash type must be DA. DA is short for detergent acid and DB for detergent base.

7 Choose a wash type.

The options include alkaline wash(DB), acid wash(DA) , DC wash and routine wash.

8 Define the **wash cycle**.

9 Select if **Compulsory Special Wash** is needed. If selected, the designated wash cycles must be completed, then the tests are allowed.

10 Select **OK**.

The defined carryover pair appears in the Carryover Pairs list.

Defining/Editing Sample Carryover

1 Select **Setup** > **Tests**.

2 Select a test and select **Carryover**.

3 Select **Edit** and **Sample Carryover**.

4 Choose a Contaminator sample type that may contaminate other sample types.

The options include serum, plasma, urine, CSF and other.

5 Choose a Contaminated sample type.

The options include serum, plasma, urine, CSF and other.

6 Choose one contaminated test in the Contaminated list.

7 Choose a wash type.

The options include alkaline special wash, acid special wash and routine wash. If the Contaminator is DB/DA, then the wash type cannot be same as it. E.g. If the contaminator is DB, then the wash type must be DA.

8 Define the wash cycle.

9 Select if **Compulsory Special Wash** is needed.

10 Select **OK**.

Defining/Editing Cuvette Carryover

1 Select **Setup** > **Tests**.

2 Select a test and select **Carryover**.

3 Select **Edit** and **Cuvette Carryover**.

4 Choose one or all contaminator tests that may contaminate other tests.

"ALL" means all tests may contaminate others.

5 Choose one or all contaminated tests in the Contaminated list.

"ALL" means all tests may be contaminated. All (the entire contaminator) to All (the contaminated) is not permitted to set up. If the Contaminator is DB/DA, then the wash type cannot be same as it. E.g. If the contaminator is DB, then the wash type must be DA.

6 Choose a wash type.

The options include alkaline wash(DB), acid wash(DA) , DC wash and routine wash.

7 Define the wash cycle.

8 Select if **Compulsory Special Wash** is needed.

9 Select **OK**.

Removing a Carryover Pair

1 Select **Setup** > **Tests**.

2 Select **Carryover**.

3 Choose desired carryover pair.

4 Select **Delete**.

5 Select **OK** to confirm the deletion.

4.1.16 Panel

A couple of tests combined together for certain clinical purposes can constitute a panel, such as liver function, kidney function, etc. Panels can help fast ordering of samples.

Panels can be composed of biochemical tests and ISE tests. Only users with sufficient permissions are allowed to define, modify and delete panels.

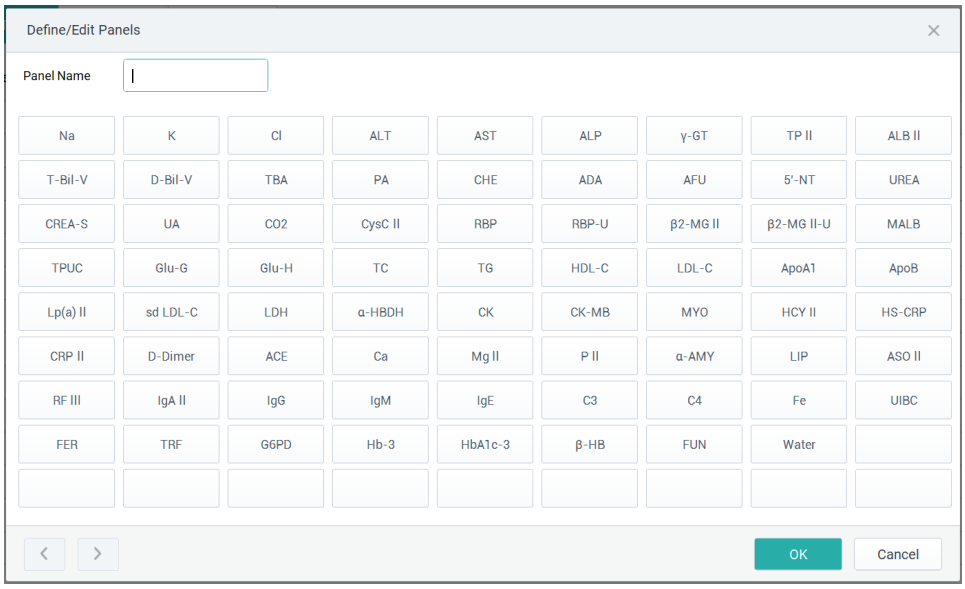
4.1.16.1 Defining/Editing a panel

1 Select **Setup** > **Tests**.

2 Select **Panels**.

3 Select **New**.

Figure 4.7 Panel



4 Type in the panel name.

5 Choose panel types.

- Sample: indicates that the panel can be used for sample analysis.
- QC: indicates that the panel can be used for quality control.

At least one panel type must be selected. A panel can be applied to both sample and control analysis.

6 Choose tests for the panel.

At least one biochemistry should be selected. The three ISE tests (Na, K and Cl) can be selected alone.

7 To remove a test, click it again.

8 Select **OK**.

9 Select < or > to define or edit other panels.

4.1.16.2 Defining the default panel

The system allows a maximum of one default panel to be defined. When a bar-coded sample has no relevant ordering information on the LIS host or has not been ordered manually, it can be analyzed with the default panel. The default panel is only applicable to routine and emergent samples, and often used for a tremendous number of samples that are analyzed with the same tests. The default panel is often used at nighttime or weekends to avoid complicated test requisition.

Only a sample panel rather than control panel can be set as the default.

1 Select **Setup** > **Tests**.

2 Select **Panels**.

3 Select a panel.

4 Mark the **Default** checkbox in the same row as the selected panel.

4.1.16.3 Adjusting Display Order of Panels

Display order of panels on the **Sample** and **Quality Control** screens can be adjusted manually for convenient test requisition.

1 Select **Setup** > **Tests**.

2 Select **Panels**.

3 Select **Up** to move the current panel to the previous position, or select **Down** to move it to the next position.

4 Select **OK** to save the settings.

4.1.16.4 Deleting Panels

Panels can be deleted by users with sufficient permissions while the system status is not Running. When a panel is removed, the tests contained in it will still remain and can constitute panels with other tests.

1 Select **Setup** > **Tests**.

2 Select **Panels**.

3 Choose panels to delete.

4 Select **Delete**.

4.1.17 Special Calculations

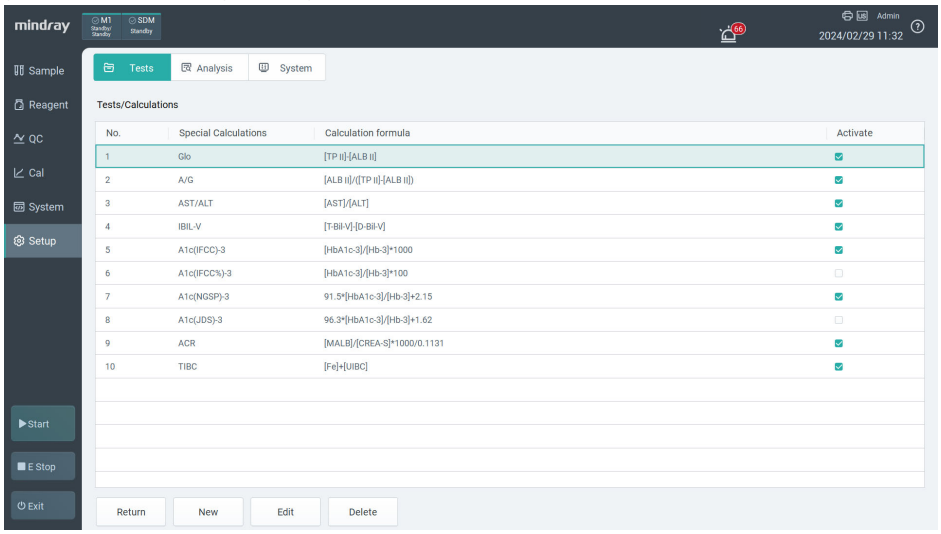
Calculation of certain tests can derive new tests of clinical purposes, such as A/G(ALB/(TP-ALB)), I-BIL (T-Bil - D-Bil), etc.

A calculation is composed of tests, calculation operators and algorithm. Only users with sufficient permissions are allowed to define, modify and delete calculations.

For the print order of calculations, refer to "4.3.10 Print Setup" (4-46)

4.1.17.1 Defining/Editing a Calculation

Figure 4.8 Defining/Editing a Calculation



1 Select **Setup** > **Tests**.

2 Select **Calculations**.

3 Select **New**. Or select **Edit** to modify the calculations.

4 Type in the calculation's short name in the **Test** field.

5 Choose a sample type to which the calculation will be applied.

6 Type in the calculation's full name in the **Test** field.

7 Type in the print name of the calculation to appear on patient reports.

8 Choose a result unit from the **Unit** pull-down list.

9 Choose a result precision, that is, the number of decimal places.

The options include:

- 0
- 0.1
- 0.01
- 0.001

10 Select **Flag**.

When this option is selected, if the result of certain test included in the calculation is beyond the linearity range, the system will flag the calculation with "CalcE."

11 Edit the calculation formula:

- Choose tests in the **Tests** list. The tests are then displayed in the **Formula** field.
- Choose numbers and operators in the **Mathematical Symbols** area to constitute the calculation formula along with the tests.
- To remove a test, number or operator, move the cursor behind them and select **BS**.
- To clear the entire formula, select **AC**.

12 Select **OK** to save the settings.

Enabling/Disabling Calculations

When a special calculation is defined, it is enabled by default and will be calculated for sample analysis. If a calculation is disabled, it will not be calculated for sample measurements. Before enabling or disabling a calculation, make sure that the system status is not Running.

Perform the following steps to enable or disable calculations:

1 Select **Setup** > **Tests**.

2 Select **Calculations**.

- The calculation list shows all calculations and formulas.
- When the **Enable** checkbox is marked, it indicates that the calculation will be included for result calculating.
- When the **Enable** checkbox is not marked, it indicates that the calculation will not be included for result calculating.

3 To activate a calculation, mark the **Enable** checkbox.

4 To inactivate a calculation, deselect the **Enable** checkbox.

4.1.17.2 Deleting User-Defined Calculations

Calculations can be deleted by users with sufficient permissions while the system status is not Running. Only user-defined calculations rather than closed calculations can be deleted.

1 Select **Setup** > **Tests**.

2 Select **Calculations**.

3 Choose calculations to delete.

4 Select **Delete**.

4.1.18 Display Settings

It is used to set up unit, decimal, print name, result optimization, test order, etc.

4.1.18.1 Customizing test display order

1 Select **Setup** > **Tests** > **Display**.

2 Select a test.

3 Use the following buttons to adjust the test's display order:

- **Home**: to move the test to the first position.
- **Up**: to move the test to the previous position.
- **Down**: to move the test to the next position.
- **End**: to move the test to the last position.

4 Select **OK**.

The test list on the request screens are refreshed automatically.

5 Select **Return**.

4.1.18.2 Flag Qualitative Result

When the analyzer is in the status of standby, incubation, hibernation or stop, you can flag the result of the tests qualitatively and the results will be represented by a qualitative flag

1 Select **Setup** > **Tests** > **Display**.

2 Select the desired test.

3 Select **Flag Qualitative Results**.

4 Select **Flag Qualitative Results** and enter the qualitative range and flag.

For instance, type in "10" in the first edit box of the **Range** field, and then enter "+" in the **Flag** field of the same row. If the test result (L1) contained in a sample is less than or equal to 10, the "+" sign will be added to the result in the patient report. Type in "20" in the second edit box below the **Range** icon and "+-" in the second edit box below the **Flag** icon. If the test result (L2) is greater than 10 and less than or equal to 20, the result will be flagged with the "+-" sign. The cycle continues. If the result is greater than L5, the six flag will appear on the patient report.

5 You can also **Semi-quantitative**.

6 Select **OK** to save the settings

4.1.19 Reference/Critical Range Setup

The system allows the setup of reference range, critical range, and custom range, as well as rerun type and priority for each test.

- Reference range indicates the allowable concentration range of a normal sample.
- Critical range is the allowable result range from the perspective of clinical diagnosis.
- Custom range is the allowable result range defined by the user.

If a result is greater than the high limit of the reference range, "^" will appear near the result; if a result is less than the low limit of the reference range, "v" will appear near the result. If a result is greater than the high limit of the critical range, "^!" will appear near the result; if a result is less than the low limit of the critical range, "v!" will appear near the result.

Tests can be rerun with specified rerun type and priority based on its measurement range, which is imported from the parameter file.

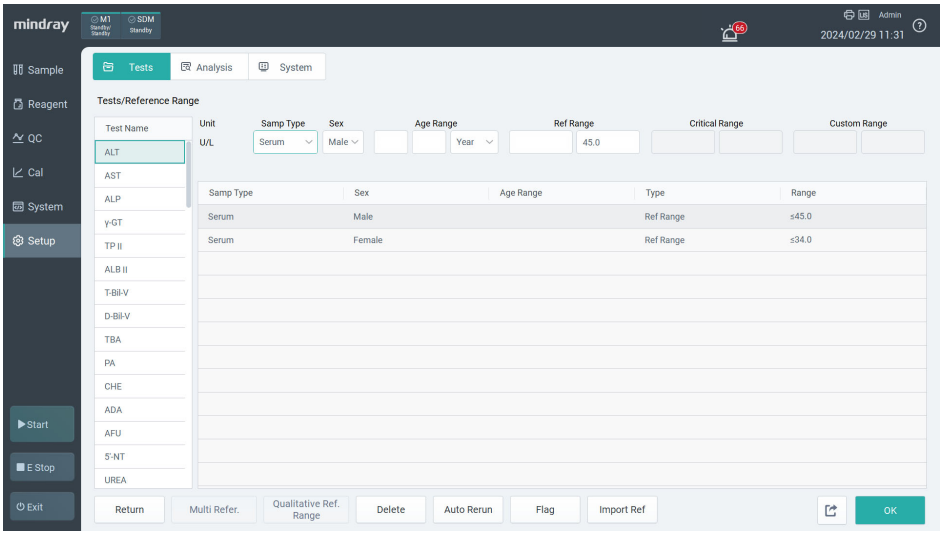
Prior to defining the reference/critical range, ensure that you have sufficient permissions and the system status is not Running.

4.1.19.1 Defining/Editing reference/critical range/Custom range

For each test, reference range, critical range and custom range, as well as rerun type and priority can be set according to sample type, sex and age.

1 Select **Setup** > **Tests** > **Reference Range**.

Figure 4.9 Reference/Critical Range Setup window



2 Choose a test from the **Tests** list.

3 Choose a sample type for the reference and critical range.

4 Choose patient sex for the reference and critical range.

5 Enter the age range in the **Age Range** field.

- Enter the age low limit in the first edit box.
- Enter the age high limit in the second edit box.
- Choose an age unit from year, month, day and hour.

6 Enter the reference range.

- Enter the reference range low limit in the first edit box.
- Enter the reference range high limit in the second edit box.
- The maximum input length is 8 digits.

7 Enter the critical range.

- Enter the critical range low limit in the first edit box.
- Enter the critical range high limit in the second edit box.
- The maximum input length is 8 digits

8 Enter the custom range.

- Enter the custom range low limit in the first edit box.
- Enter the custom range high limit in the second edit box.
- The maximum input length is 8 digits.

9 Select **OK**.

To abort the input information, select **Cancel**.

4.1.19.2 Setting up multi-line reference range

The multi-line reference range setup function allows multiple special reference ranges to be set besides the measurement range. Tests with multi-line reference ranges cannot be rerun automatically or flagged for abnormal results.

1 Select **Setup** > **Tests** > **Reference Range**.
2 Choose a test from the **Test** list.
3 Choose a sample type for the multi-line reference range.
4 Choose patient sex for the multi-line reference range.
5 Enter the age range in the **Age Range** field.
6 Select **Multi-line Ref Range**.
7 Enter the interval, Reference Range Upper Limit and Reference Range Lower Limit.
8 Select **OK**.

4.1.19.3 Deleting a reference/critical range/user defined range

1 Select **Setup** > **Tests** > **Reference Range**.
2 Choose the test name, sample type, sex and age range.
3 Choose a reference/critical range you want to remove.
4 Select **Delete**.
5 Select **Delete Selected Record** or **Delete All Records**.
6 Select **OK**.

4.1.19.4 Import reference range

1 Select **Setup** > **Tests** > **Reference Range**.
2 Click **Import Ref Range**.
3 Select Open File. Select a file in format of rf and click Open.
4 Choose tests from the list. You are allowed to select all tests.
5 Select **OK**.

4.1.19.5 Export reference range

1 Select **Setup** > **Tests** > **Reference Range**.
2 Click  .
3 Choose tests from the list. You are allowed to select all tests.
4 Select export path.
5 Select **OK**.

4.1.19.6 Out of Range Result Flag

Define flags and color for results less than or greater than the reference range, as well as color for results less than or greater than the critical range.

1 Select **Setup** > **Tests** > **Reference Range**.
2 Select **Out of Range Result Flag**.
3 Set the flag and color.

The flags can be composed of numbers, letters and symbols for no more than 10 digits. The default flags for reference range are "^" and "v". If a result is greater than the high limit, "^" will appear near the result; if a result is less than the low limit, "v" will appear near the result.

If test results are beyond the critical range, they will appear in the defined color.

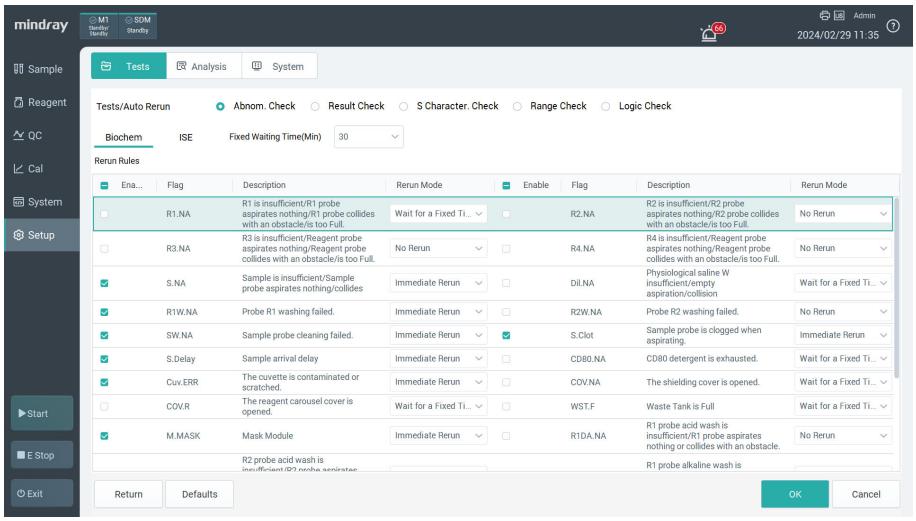
4.1.20 Auto Rerun Setup

The system provides a couple of conditions for auto rerun. When selected conditions are satisfied, tests for which auto rerun has been enabled will be rerun automatically with the specified sample volume type.

4.1.20.1 Auto Rerun Setup-Abnormal Alarm Check

1 Select **Setup** > **Tests** > **Auto Rerun** or select **Setup** > **Tests** > **Reference Range** > **Auto Rerun Setup**.

Figure 4.10 Auto rerun>Abnormal Alarm Check



2 Select **Abnormal Alarm Check**.

3 Define the rerun type for each alarm flag.

The rerun type includes:

- Immediate rerun: After conditions are met, the test is rerun immediately. If the rerun fails, the test is invalidated.
- Immediate retrieval: Once the rack to be rerun reaches the buffer unit, it is retrieved.
- Wait for a fixed time: Count the time when the sample rack returns to the buffer unit, and try every 6s to see if the test conditions are satisfied. If yes, rerun the sample. If the conditions are not satisfied, wait in the buffer unit and try according to the period. If the requirement is not met after the defined waiting time is reached, the test is invalidated. Set the fixed waiting time here.
- No rerun: Rerun is not executed.

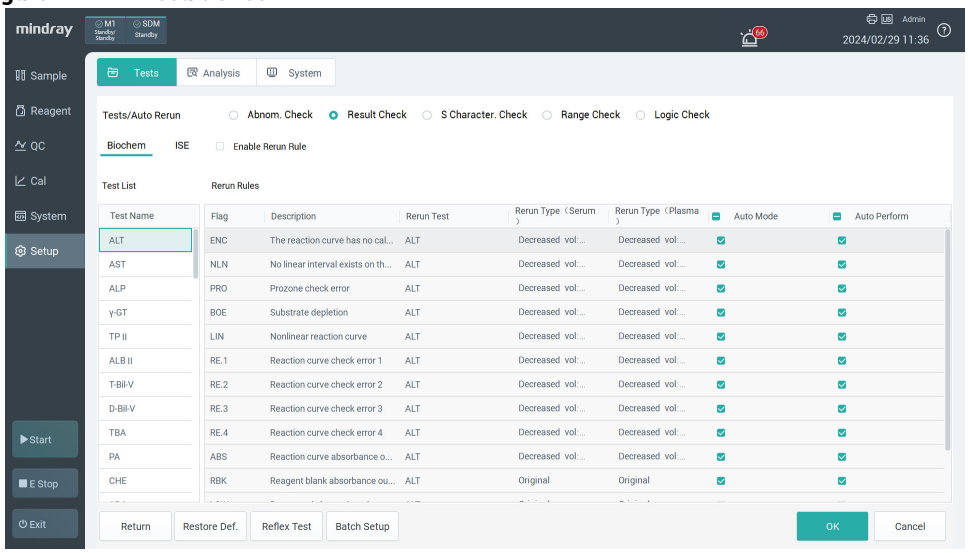
4 Select **Enable**. You can select Enable at the header to enable all rerun rules.

5 Select **OK**.

You can select **Restore Defaults** to restore the settings to the defaults.

4.1.20.2 Auto Rerun Setup-Result Check-Batch Setup

Figure 4.11 Result Check



1 Select **Setup** > **Tests** > **Auto Rerun** or select **Setup** > **Tests** > **Reference Range** > **Auto Rerun Setup**.

2 Select **Result Alarm Check**. Select a test and set the rerun rule and rerun type for each result flag.

3 Select **Reflex Test** to set the test which will be rerun with the current test.

4 Select **Auto Mode** or **Auto Perform**.

- Auto Mode: When the rerun conditions are satisfied, the rerun is requested automatically.
- Auto Perform: When the rerun conditions are satisfied, the sample will be rerun.

You can select the auto request and auto execution at the header to apply to all results flags.

5 Select **OK**.

6 Select **Enable Rerun Rules**.

4.1.20.3 Auto Rerun Setup-Sample characteristic Check-Batch Setup

It is used to allows you to rerun samples with lipemia, hemolysis or icterus.

1 Select **Setup** > **Tests** > **Auto Rerun** or select **Setup** > **Tests** > **Reference Range** > **Auto Rerun Setup**.

2 Select **Sample Characteristic Check**. Select a test and set the rerun rule and rerun module for each result flag.

3 Select **Auto Order** or **Auto Execute**.

- Auto Request: When the rerun conditions are satisfied, the rerun is requested automatically.
- Auto Execution: When the rerun conditions are satisfied, the sample will be rerun.

You can select the auto request and auto execution at the header to apply to all results flags.

4 Select **OK**.

5 Select **Enable Rerun Rules**.

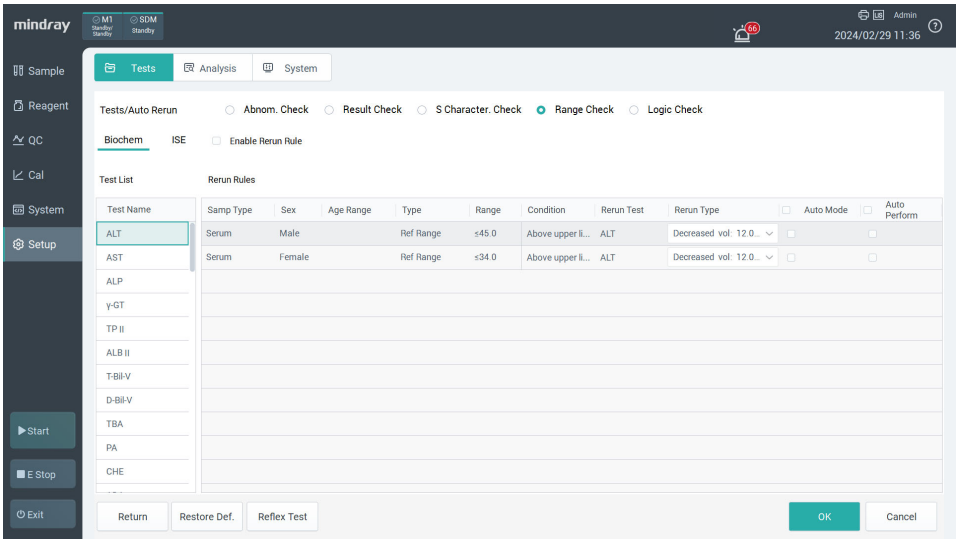
4.1.20.4 Auto Rerun Setup-Range Check

It is used to set the rerun rules when results exceed the defined reference range, critical range or user-defined range.

1 Select **Setup** > **Tests** > **Auto Rerun** or select **Setup** > **Tests** > **Reference Range** > **Auto Rerun Setup**.

2 Select **Range Check**.

Figure 4.12 Auto rerun-Reference Range Check



3 Select a test.

4 Set the rerun type and rerun module.

5 Select Reflex Test to choose a test to run together.

- Auto Mode: When the rerun conditions are satisfied, the rerun is requested automatically.
- Auto Perform: When the rerun conditions are satisfied, the sample will be rerun.

You can select the auto request and auto execution at the header to apply to all results flags.

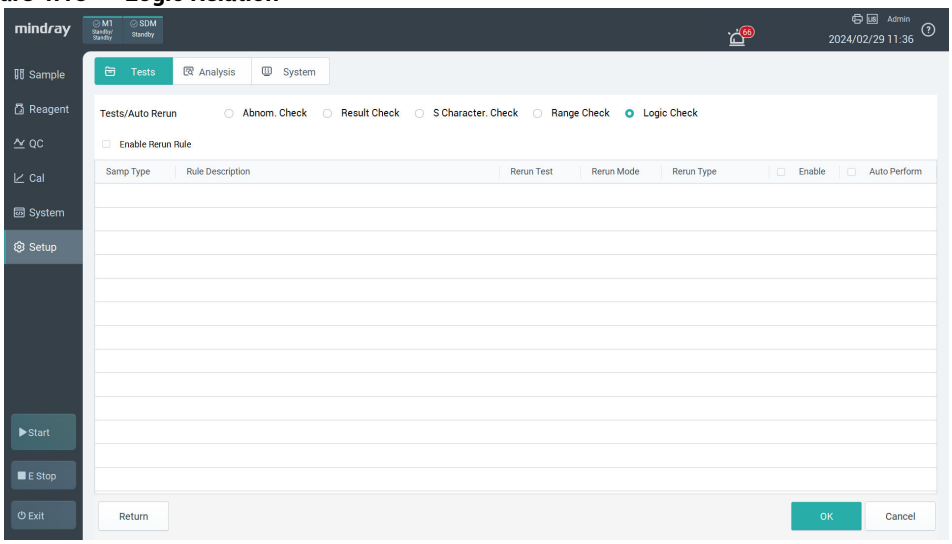
6 Select **OK**.

7 Select **Enable Rerun Rules**.

4.1.20.5 Auto Rerun Setup-Logic Relation Check

In clinical application, the results of different tests will be compared in certain way. The comparison result should meet the logic requirement (e.g. the total bilirubin TBil should not be smaller than the direct bilirubin DBil). Therefore, you can set the auto rerun rules according to the logic relationship.

Figure 4.13 Logic Relation



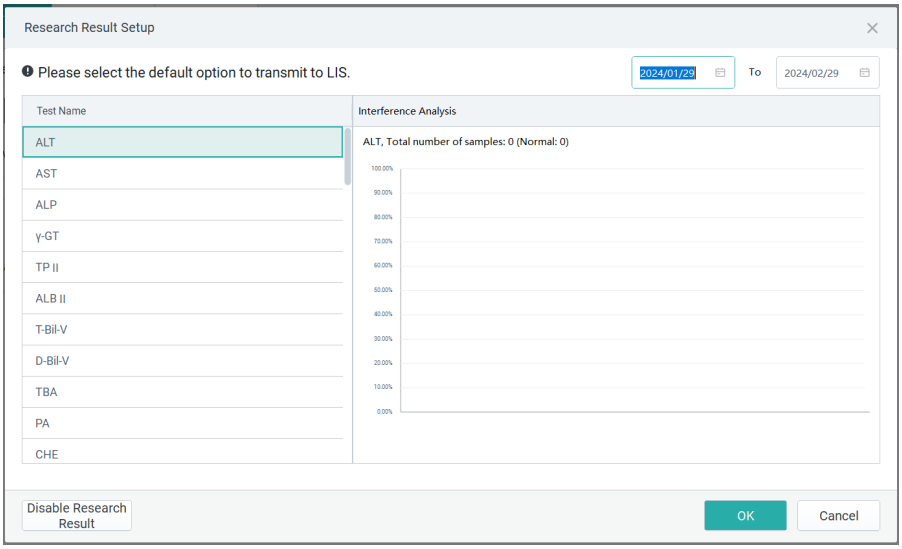
1 Select **Setup** > **Tests** > **Auto Rerun**. Or choose **Setup** > **Tests** > **Range Setup** > **Auto Rerun**.
2 Select logical relation check.
3 Select **New**.
4 Select a sample type.
5 Select operator and test to edit the rules.
6 Select **OK**.
7 On the Logic Relationship Setup screen, set the rerun mode, rerun type, enable/disable and execute status.
8 Select **OK**.

4.1.21 Research Result Setup

This window is used to recall interference analysis of tests and to disable research results.

1 Select **Setup** > **Tests** > **Research Result Setup**.

Figure 4.14 Research Result Setup



2 Choose a test in the list. The right part shows the number and percentage of interference samples for each test.

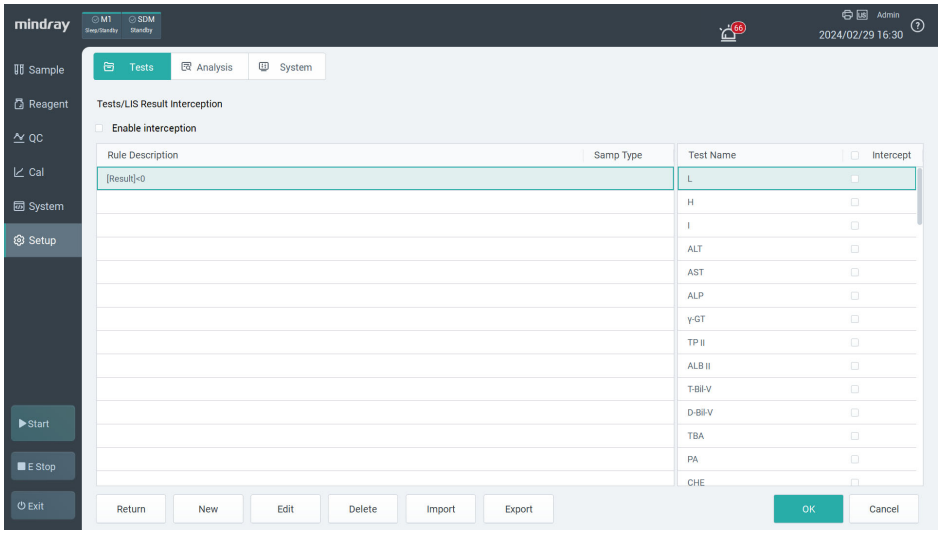
3 Click Disable Research to disable research results. The test will not generate the research results that optimized interference samples.

4.1.22 LIS Result Interception

This window is used to set whether to enable LIS result interception and define interception rules. When the intercept function is enabled, the intercepted sample results will not be sent to the LIS. Only Administrators and above can modify interception rules.

1 Select **Setup** > **Tests** > **LIS Result Interception**.

Figure 4.15 Research Result Setup



2 Click Enable Interception. When the intercept function is enabled, the intercepted sample results will not be sent to LIS.

3 Select the checkbox on the right of a test to enable the rule for the test.

4.1.22.1 Adding Interception Rules

1. Select **Setup** > **Tests** > **LIS Result Interception** > **New**.
2. Select the sample type to which the interception rule applies in pull-down list.
3. Select the corresponding result flag in pull-down list and click Add to automatically generate the interception formula.

   Or edit formula directly. The supported relationship operators include: >, <, =, <>, Contains, Excludes, AND, OR.

   Interception rules support interception of result values and result flags.

- Result flag interception formula: For example, [result flag] Contains {PRO}
  - [result flag]: Rule variable, enclosed by []
  - Contains: Operator (The result flag interception formula only supports Contains and Excludes.)
  - {PRO}: Variable content, enclosed by { }
- Result value interception formula: For example, [result value] <0
  - [result value]: Rule variable, enclosed by []
  - <: Operator
  - 0: value
- Relationship operators can be used between formulas to support more complex interception scenarios.

4. Select **OK**.

4.1.22.2 Editing Interception Rules

1. Select **Setup** > **Tests** > **LIS Result Interception**.
2. Select the interception rule to be edited and click **Edit**.
3. Select **OK**.

4.1.22.3 Deleting Interception Rules

1. Select **Setup** > **Tests** > **LIS Result Interception**.
2. Select the interception rule to be deleted and click **Delete**.
3. Select **OK**.

4.1.22.4 Importing Interception Rules

1. Select **Setup** > **Tests** > **LIS Result Interception**.
2. Click **Import** to import interception rules from the file.
3. Select **OK**.

4.1.22.5 Exporting Interception Rules

1. Select **Setup** > **Tests** > **LIS Result Interception**.
2. Click **Export** to export interception rules in .csv format.
3. Select **OK**.

4.2 Sample Analysis Setup

4.2.1 Sample Order Settings

1 Select **Setup** > **Analysis** > **Sample Order Settings**.

2 Select the following parameters.

Default sample type

The system supports a couple of sample types: Serum, plasma, urine, CSF, whole blood and other. The default is serum. When the default sample type is set up, it will be selected by default for ordering samples on the sample order screen.

Default sample cup type

The system supports the standard sample cup, 0.5 mL micro cup and 2 mL micro cup. The default is the standard sample cup. When the default sample cup type is set up, it will be selected by default for ordering samples on the sample orders screen.

Sample Expiration Date

Sample Expiration Date refers to the time interval that a patient sample is first loaded to the sample rack and then expired. When it is set, the system will allow analysis but will check the valid period of the sample when the sample is tested. If Sample Expiration Date is not set, the default is long-term validity.

The input range is 1-99, which can be hour or day. The default is day.

Sample Analysis Mode

Supports two sample analysis modes: rack ID mode and bar code mode. Routine samples and STAT samples share the same analysis mode.

Before changing the analysis mode, make sure that the system status is Standby or Stopped.

Default STAT Sample ID

Set the default ID for STAT samples. The system default is 9001.

3 Select **OK**.

4.2.2 Rack Supply and Retrieval Settings

1 Select **Setup** > **Analysis** > **Rack Supply and Retrieval Settings**.

2 Select **Priority for Outpatients**. The outpatient samples will be handled first.

3 Set **Reserved STAT Grids**.

4 Set **Priority Retrieval Area**.

5 Set **Retrieve Abnormal sample**.

6 Set **Clear rack status of the retrieval area automatically**.

7 Select **OK**.

4.2.3 SI Index Settings

1 Select **Setup** > **Analysis Setup** > **SI Index Setup**.

2 Select the following options.

Auto Serum Index

When the auto serum index function is enabled, the SI tests will be requested automatically for serum or plasma samples or samples downloaded from the LIS. The system will measure the concentration of hemolysis, icterus and lipemia contained in the samples. If qualitative result flag is enabled on the serum index screen, the system will flag the test result on the patient report.

Serum index is only used to check the integrity of a sample and not to make a diagnosis.

Smart Serum Index

When smart serum index is enabled and serum and plasma samples are ordered on the sample screen or when samples are downloaded from the LIS host, smart request of SI test without lowering analyzing speed will be enabled. The system determines whether to request serum index based on the test parameters and reduces the consumption of physiological saline, thereby increasing the throughput of SI tests.

3 Select **OK**.

4.2.4 Auto Release Sample

When a sample is analyzed, the position cannot be used for ordering new sample until it is released.

Auto Release of Samples

1 Select **Setup** > **Analysis** > **Auto Release Sample**.

2 Select auto release time of patient samples in the **Auto Release Time** field.

The options include 0-23, and the default is 0.

3 Enter the **Shift Transition** Interval.

The input range is any integer within 0-24. The default is 2h. If a sample is being tested during the transition period, it will not be released.

4 Select **OK**.

When the time is reached, the system will automatically release all samples of the current day when system status is standby or Stopped.

4.2.5 Inventory Alarm Limit Settings

When the reagent/consumable inventory is below the alarm limit, the system will give an alarm.

1 Select **Setup** > **Analysis** > **Inventory Alarm Limit Settings**.

2 Select reagent/consumable.

3 Enter **Inventory Alarm Limit**.

4 Select **OK**.

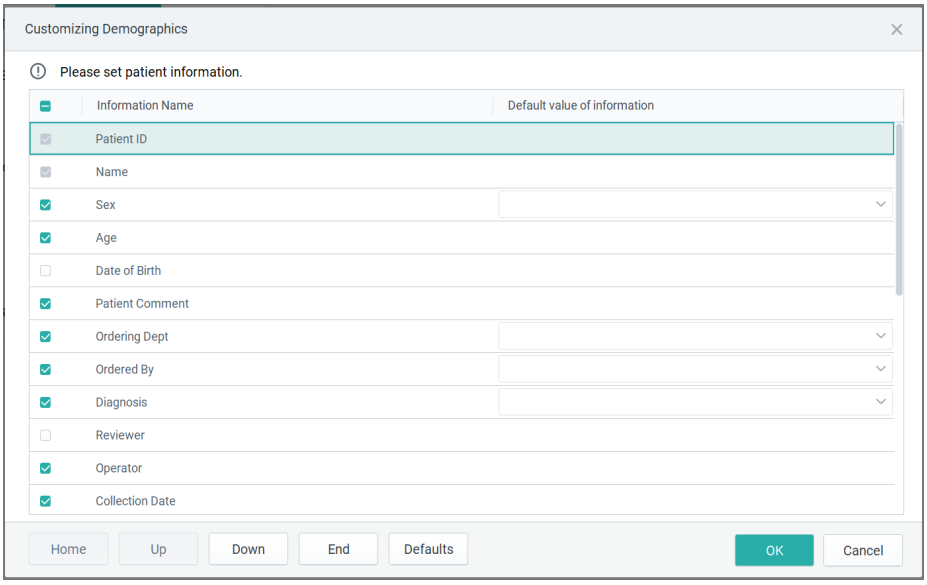
4.2.6 Customizing Patient Demographics

You can specify patient demographics to be displayed, its default and its display order through the **Patient Demographics** screen.

4.2.6.1 Customizing Patient Demographics

1 Select **Setup** > **Analysis** > **Patient Demographics**.

Figure 4.16 Patient Demographics window



2 Select the desired information and you can select at the header to select all.

3 Select **Up**, **Down**, **Home** and **End** button to adjust the displayed order of patient demographics.

4 Select **OK** to save the settings or select **Cancel** to restore the previous settings.

5 Select **Restore Default** to restore to default settings.

4.2.7 Auto Backup

You can export sample data to external storage device.

1 Select **Setup** > **Analysis** > **Auto Backup**.

2 Select **Auto backup to external storage device**.

3 Select **OK**.

4.2.8 Sample Position Traceability Settings

This function is to facilitate the search of samples whose tests are completed.

1 Select **Setup** > **Analysis** > **Sample traceability settings**.

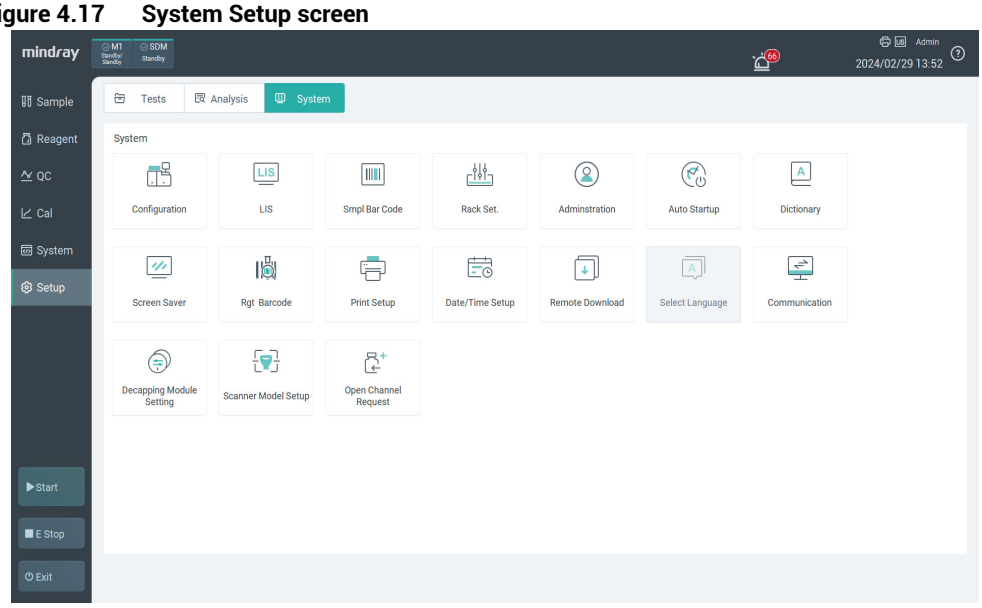
2 Select **Display Sample Traceability**.

3 Select **OK**.

4.3 System Setup

This section summarizes the setup options on the **System Setup** screen as shown in the figure below.

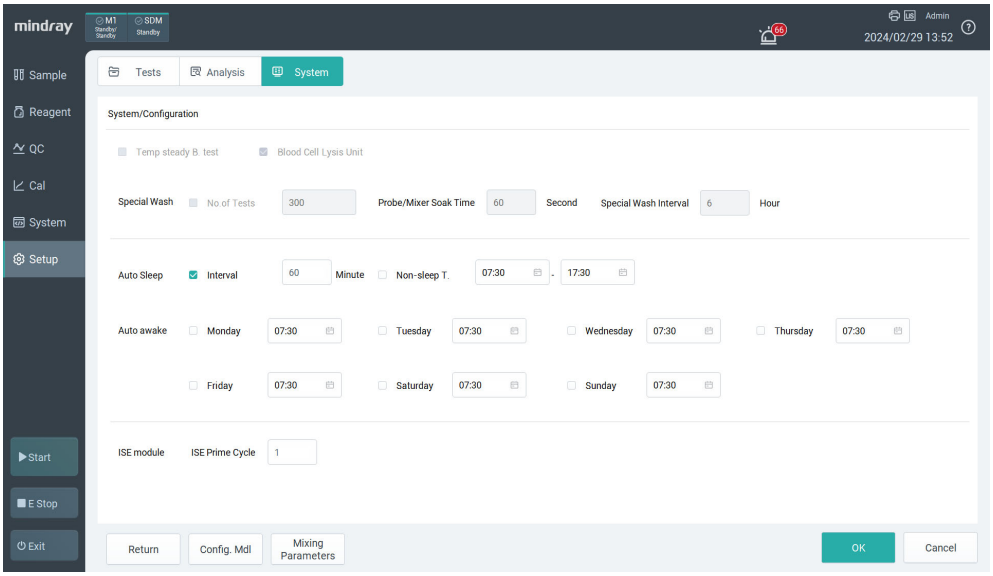
Figure 4.17 System Setup screen



4.3.1 Instrument Setup Options

1 Select **Setup** > **System** > **Instrument Setup**.

Figure 4.18 Instrument Configuration window



Start Analysis When Temperature is Steady

The analyzer temperature can be monitored before analysis begins.

- When the **Start after Temperature Steady** checkbox is selected, the system will check before analysis begins if the temperature of the reaction carousel is normal. If the temperature is normal, you are allowed to start analysis; if the temperature is abnormal, a message will appear indicating analysis is forbidden in current condition.
- When the **Start after Temperature Steady** checkbox is not selected, the system will still check before analysis begins if the temperature of the reaction carousel is normal. If the temperature is normal, you are allowed to start analysis; if the temperature is abnormal, the system will prompt you that the results may be influenced if you continue to start analysis. You may continue or abort the analysis.

Blood Cell Lysis Unit

You can select the blood cell lysis module (for HbA1c analysis).

Special Wash

Select this option to perform the special wash of sample probe during analysis. After this option is selected, input the number of tests when the special wash of sample probe is performed. The default is 300 tests.You can input the probe/mixer soak time and the default is 60 seconds. You can also input the special wash interval and the default is 6 hours.

Auto Sleep

Select sleep interval. The default is 60 minutes. You are allowed to enable/disable auto sleep and set up the time interval for auto sleep. Select "No Sleep" and set the time range.

Auto Awake

The Auto Awake option allows you to set up the auto awake date and time within one week. Choose the weekday for auto awake, and then set up the auto awake time.

You are allowed to wake up the system any time within the week (from Monday to Sunday). When the week and time is reached, the system will be woken up automatically if it is sleeping.

ISE prime cycle

Set the prime cycles. The default is 1. For details of ISE primes setup, refer to "9.8 ISE Prime Cycle Setup" (9-12).

Optional Modules

Select this button to configure optional modules, including ISE module and water quality detection module.

4.3.2 LIS Settings

Refer to "10.2 LIS Communication" (10-2).

4.3.3 User Administration

Users can be defined, deleted or modified. The system allows up to 100 users to be defined and belonged to two user groups: administrator and operator. Administrators are allowed to assign permissions for operators.

NOTE

The default username and password for administrator is Admin. Please note that the password is case sensitive. You are recommended to change the password when logging on the system for the first time in order to prevent others from abusing the privileges of the administrator.

If an operator forgets his password, he may ask the administrator to log on the system and delete the username and then redefine a username; or he may contact our customer service department or your local distributor. If the administrator forgets his password, contact our customer service department or your local distributor.

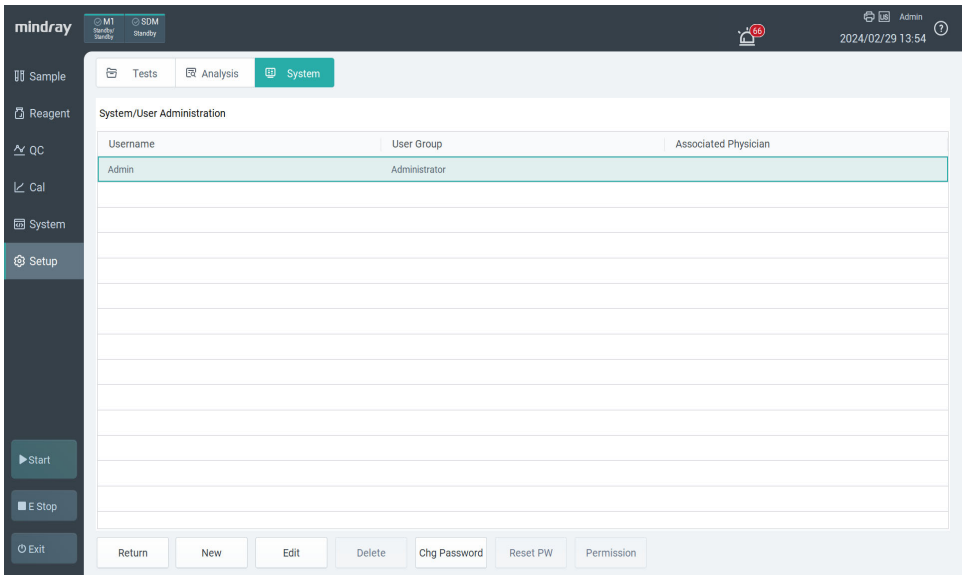
4.3.3.1 Defining a User

Only administrators are allowed to define users. Up to 100 users are allowed, including administrators. You should enter the username, password, confirm password and user group when defining a user.

1 Select **Setup** > **System** > **User Administration**.

2 Select **New**.

Figure 4.19 User and Password window



3 Enter the username.

4 Enter the password.

A maximum of 20 characters can be entered.

5 Enter the password again in the **Confirm** field.

6 Choose a user group in the **User Group** pull-down list.

The options include:

- Administrator
- Operator

7 Select a doctor from **Associated Doctor** pull-down list.

When the user and the associated doctor have been set up, the default tester in the patient demographics is the associated doctor of the current login user.

8 Select **OK**. The defined user appears in the user list.

4.3.3.2 Modifying a User

Only administrators are allowed to edit the user group of themselves and other users. Username and password can only be modified by the user himself rather than anyone else.

1 Select **Setup** > **System** > **User Administration**.

2 Choose a user to edit in the user list.

3 Select **Modify**.

4 Choose a user group in the **User Group** pull-down list.

The options include:

- Administrator
- Operator

5 Choose a doctor associated with the current login user.
6 Select **OK**.

4.3.3.3 Deleting a User

The username that has been used to log on the system currently cannot be deleted. Only the administrators are allowed to delete users.

1 Select **Setup** > **System** > **User Administration**.
2 Choose a username in the user list.
3 Select **Delete**.
4 Select **OK**.

4.3.3.4 Resetting Password

1 Select **Setup** > **System** > **User Administration**.
2 Select current log-on user.
3 Select Reset Password. Enter the old password and reset a new one.
4 Select **OK**.

4.3.4 Auto Startup Settings

It is used to set the date and time when the analyzer will be started automatically.

1 Select **Setup** > **System** > **Auto Startup Settings**.
2 Set the date and time for auto startup.
3 Select **OK**.

4.3.5 Screen Saver Settings

1 Select **Setup** > **System** > **Screen Saver Settings**.
2 Set the time when the software displays screen saver.
3 Select **OK**.

4.3.6 Dictionary Setup

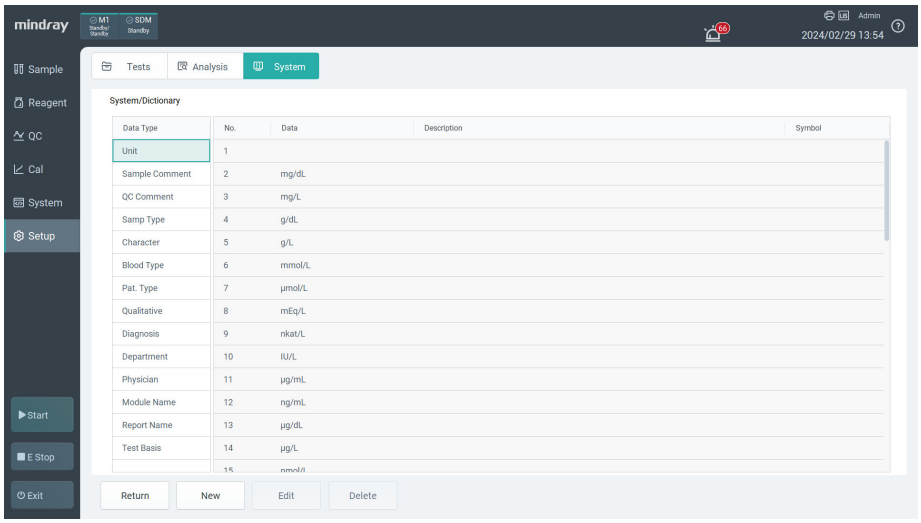
The Dictionary option is provided for setting up and managing frequent data information. Sample comment can be entered manually or selected from the **Comment** pull-down list on the **Sample** screen, **Levey-Jennings** screen, and (QC) **Results** screen.

Data options can be defined, edited or deleted in any system status. The default data options cannot be deleted or edited.

4.3.6.1 Defining, Editing and Deleting Data Option

1 Select **Setup** > **System** > **Dictionary**.

Figure 4.20 Dictionary window



2 Choose desired dictionary in the **Data** list.

To add a data option:

- Select **New**.
- Input the data name in the **Data** field.
- Input the symbolic character for the data.
- Input the data description.
- Select **OK**.

To modify a data option:

- Select desired data option in the data list.
- Modify the data name in the **Data** field.
- Input the symbolic character and data description.
- Select **OK**.

To delete a data option:

- Select desired data option in the data list.
- Select **Delete**.

3 Select **Return**.

4.3.7 Sample Rack Settings

Set the number of calibration racks, QC racks and rerun racks.

1 Select **Setup** > **System** > **Sample Rack Settings**.

2 Set the number of racks.

3 Select **OK**.

4.3.8 Sample Bar Code Setup

Refer to "8.1.2 Sample Bar Code Setup" (8-5).

4.3.9 Reagent Barcode Setup

Please refer to "5.2 Reagent Bar Code Reader" (5-5).

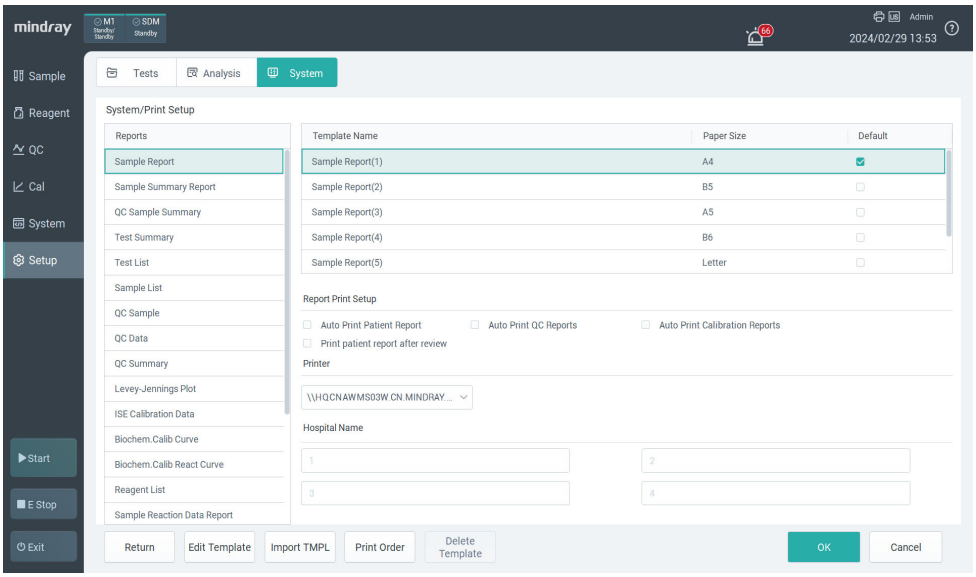
4.3.10 Print Setup

Results and data can be printed out with the specified template through the printer. You are allowed not only to set up the printer type and auto print, but also define the print order of tests.

4.3.10.1 General Print Setup Options

1 Select **Setup** > **System** > **Print Setup**.

Figure 4.21 Print setup screen



2 Select a report type from the report list on the left of the window.

3 Select a template from the template list.

4 Set up auto print options:

- Auto print patient reports
- Auto print QC reports
- Auto print calibration reports
- Print patient report after review

5 Choose a default printer to print reports.

6 Select **OK**.

4.3.10.2 Setting Up Default Template

1 Select **Setup** > **System** > **Print Setup**.

2 Select a report type from the **Report** list on the left of the window.

3 Select a template from the template list.

4 Select **Set Defaults** to set the selected template in the template list as the default one.

4.3.10.3 Deleting Template

1 Select **Setup** > **System** > **Print Setup**.

2 Select a report type from the **Report** list on the left of the window.

3 Select a template from the template list.

4 Select **Delete**.

The selected template cannot be deleted if it is the default one or the print task exists.

4.3.10.4 Importing Template

1 Select **Setup** > **System** > **Print Setup**.

2 Select **Import TMPL**.

4.3.10.5 Editing Template

1 Select **Setup** > **System** > **Print Setup**.

2 Select a report type from the **Report** list on the left of the window.

3 Select a template from the template list.

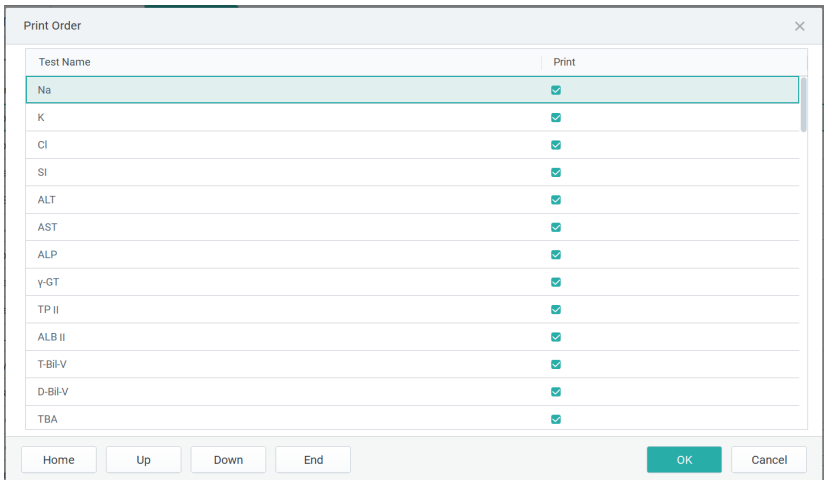
4 Select **Edit**.

4.3.10.6 Defining Test Print Order

1 Select **Setup** > **System** > **Print Setup**.

2 Select **Print Order**.

Figure 4.22 Print Order window



3 Use the following buttons to adjust the test print order:

- **Home**: to move the test to the first position.
- **Up**: to move the test to the previous position.
- **Down**: to move the test to the next position.
- **End**: to move the test to the last position.

4 Set up result print mode.

- To print results on patient report, select the corresponding **Print** checkbox.
- To forbid printing results on patient report, deselect the corresponding **Print** checkbox or leave it unselected.

5 Select **OK** to save your settings.

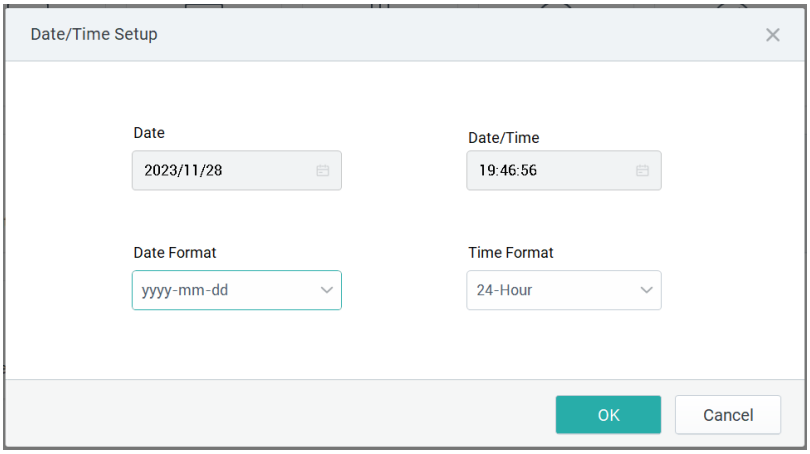
4.3.11 Date and Time

The Date and Time option allows you to set the current date and time, select the date/time formats to be displayed on software screens and printed reports, and restore default date and time formats.

When adjusted, the date and time will influence the time left of reagents and calibration, shelf life of samples, and run length of two-control evaluation. The date and time cannot be edited when the system status is Running. Modification of the date and time will not affect samples on the Current screen or QC evaluation and Twin-Plot chart. Follow this procedure to change system date and time:

1 Select **Setup** > **System** > **Date/Time**.

Figure 4.23 Date/Time window



2 Choose a date format from the **Date Format** pull-down list.
- yyyy-mm-dd: e.g. 2010-07-28
- dd-mm-yyyy: e.g. 28-07-2010
- mm-dd-yyyy: e.g. 07-28-2010

3 Choose a time format from the **Time Format** pull-down list.
- 24-hour: e.g. 14:33:27
- 12-hour: e.g. 02:33:27

4 Select **OK** to save your input information.

4.3.12 Select Language

1 Select **Setup** > **System** > **Select Language**.

2 Select a language.

4.3.13 Remote Download Settings

1 Select **Setup** > **System** > **Remote Download Settings**

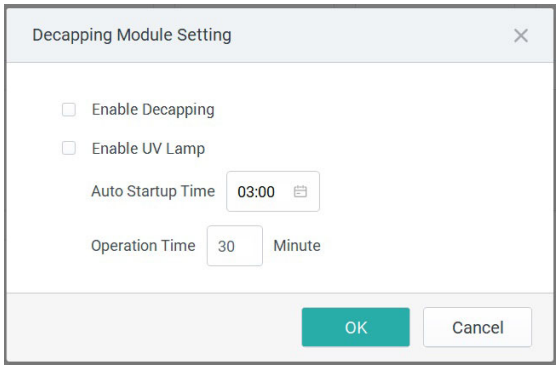
2 Select the options according to your requirements.

3 Select **OK**.

4.3.14 Decapping Module Setting

1 Select **Setup** > **System** > **Decapping Module Setting**

Figure 4.24 Decapping Module window



2 Select **Enable Decapping** or **Enable UV Lamp**.

3 Set **Aoto Startup Time**.

4 Select **OK**.

4.3.15 Scanner Model Setup

1 Select **Setup** > **System** > **Scanner Model Setup**.

2 Select the model of the scanner.

3 Select **OK**.

4.3.16 Open Channel Request

When users need to add open channels or switch the instrument type to be opened or closed, this function requires service personnel to finish requesting on the operating software and obtain authorization from the headquarter.

1 Select the instrument type to be requested and the number of open channels to be added. The number of open channels can be added only. Options for adding open channels include 5, 10, 15, and 20.

2 The service engineer click **Generate Request File** to display the directory selection dialog box. Click **OK** to generate a request file in the directory.

3 After being authorized by the headquarter, the service engineer selects **Import Authorization File** to import the authorization file and finish the request process.

5 Reagents &Consumables

In this chapter

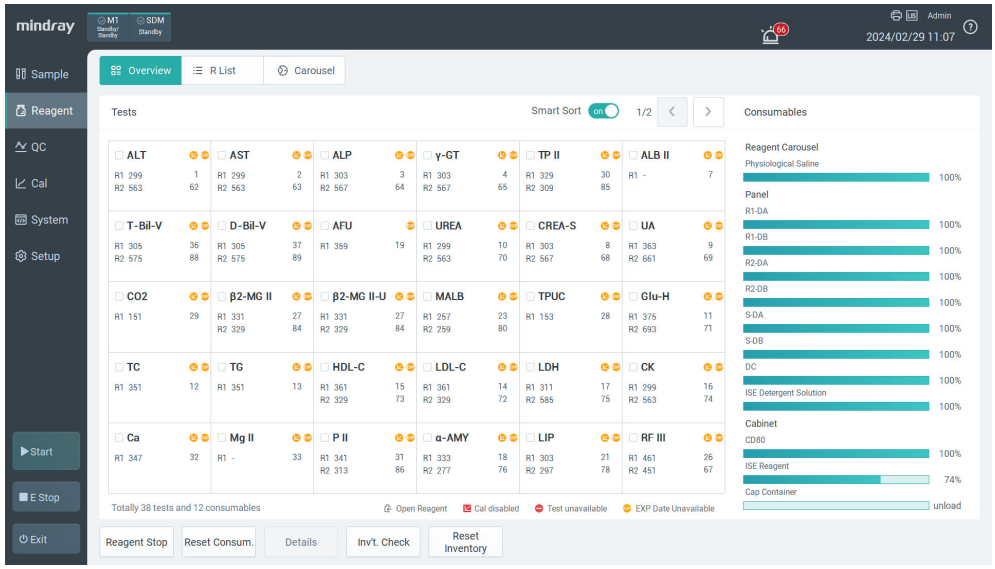
5.1 View Reagents/Consumables

You can view reagent/consumable status via reagent overview/reagent list/ consumable status screen.

5.1.1 Reagent Overview

Select **Reagent** in the function button area of the main screen. The **Reagent Overview** screen is displayed.

Figure 5.1 Reagent overview Window



The screen displays reagent information of all on-board tests, including: test name, reagents available, and test requirements.

The reagents are displayed in three statuses.

- Sufficient: The background colour of the test is not marked.
- Low inventory: The background of the test is marked orange.
- Used up: The background of the test is marked red.

The consumables are displayed in three statuses.

- Sufficient: turquoise.
- Below Inventory Alarm Limit: orange.
- Used up: red.

When a test has abnormal information, abnormal icon will be marked. Select the icon on the test card to display the details of the abnormal information in a bubble. Abnormal information includes prompts and warnings.

- Reagent prompt: Reagent mask
- Reagent warning: Reagent disabled
- Calibration prompts: Calibration extended, calibration edited, calibration recalculated, calibration about to expire, and calibration overridden.
- Calibration warnings: Calibration failed, calibration expired, calibration required, or calibration not completed.
- Reagent Expiration Prompt: expired.

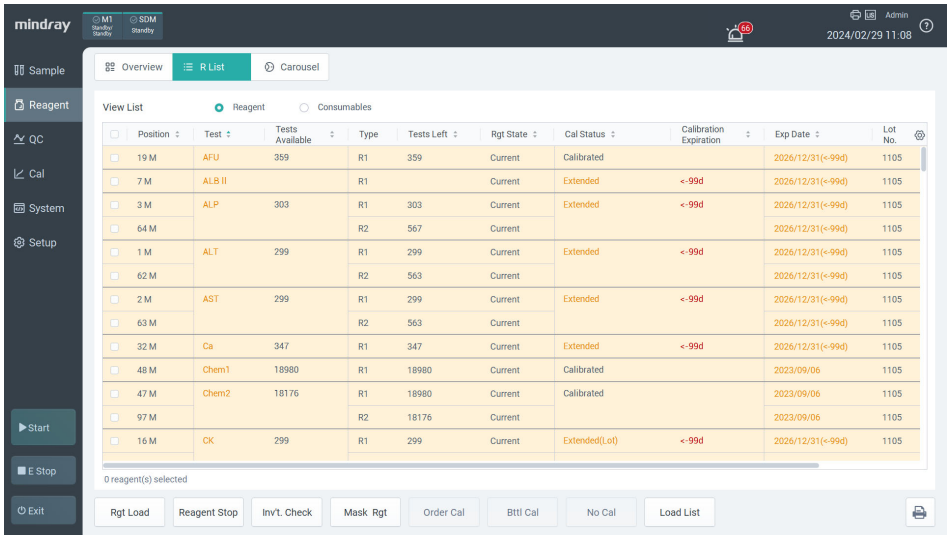
Smart sorting is enabled by default, and it is sorted in the following order:

Reagent used up => below inventory alarm limit => sufficient.

5.1.2 Reagent List

Select **Reagent** in the function button area of the main screen and then select **R List**.

Figure 5.2 Reagent List screen



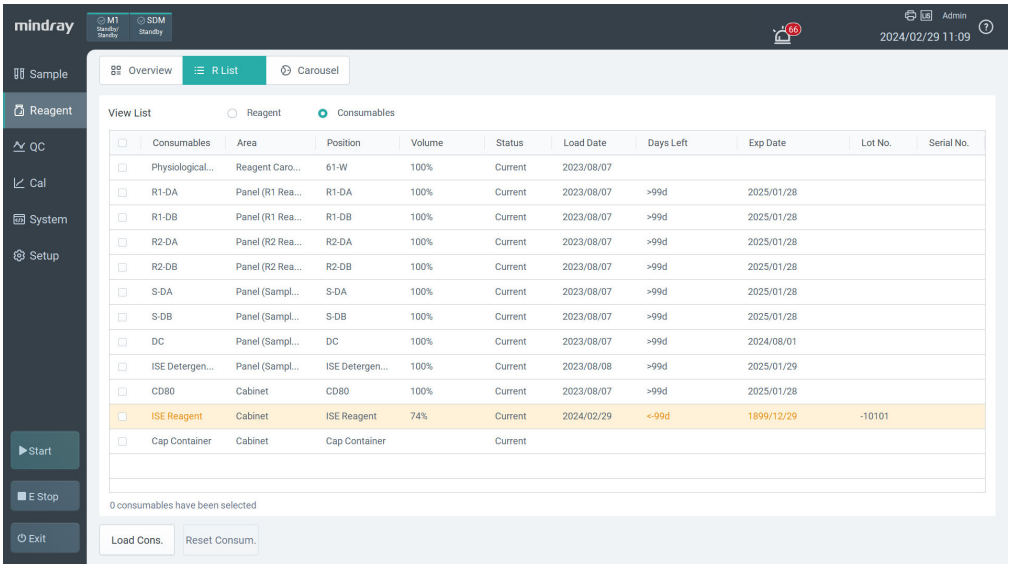
The screen shows all configured biochemistry reagents, including the following information:

- Position: position of the reagent on the reagent carousel.
- Test: name of the test.
- Reagent type: reagent type of a multi-reagent test. It includes R1, R2, R3 and R4.
- Tests left: It refers to the remaining tests of each reagent bottle.
- Reagent status: including current, standby, disabled, masked and exhausted.
- Days left: the difference of reagent expiration date and current date and the on-board stability time, whichever the less. When a negative value is displayed, it indicates that the reagent is expired and should be replaced immediately.
- Lot number: lot number of the reagent. It can be input manually during reagent load.
- Serial number: serial number of reagent bottle.
- Calibration status: calibration status of the test, including, Cal Required, Requested, Calibrated, Cal Failed, Cal Time Out, Cal Time Extended, Calculated, Edited, Cal Overridden and N/A.
- Time left: the time left when the calibration factors are expired. It will be displayed only when the calibration status is Calibrated, Cal Time Out or Cal Time Extended. When the time left is less than 30 minutes, the system displays a message indicating calibration time out; when the calibration time is exceeded, the calibration factors can no longer be used, and you are allowed to recalibrate the test or extend the calibration time.
- Load date: the loading date of the reagent.

5.1.3 Consumable List

Select **Reagent** > **R List** > **Consumables**.

Figure 5.3 Consumables List screen



The screen displays all consumables information, load date, volume, status, days left, and expiration date.

The screen is divided into two areas. The upper list displays consumable name, area, inventory, load date, days left, expiration date, lot number, and serial number. The function buttons area at the bottom is used to perform various operations.

5.1.4 Reagent Carousel

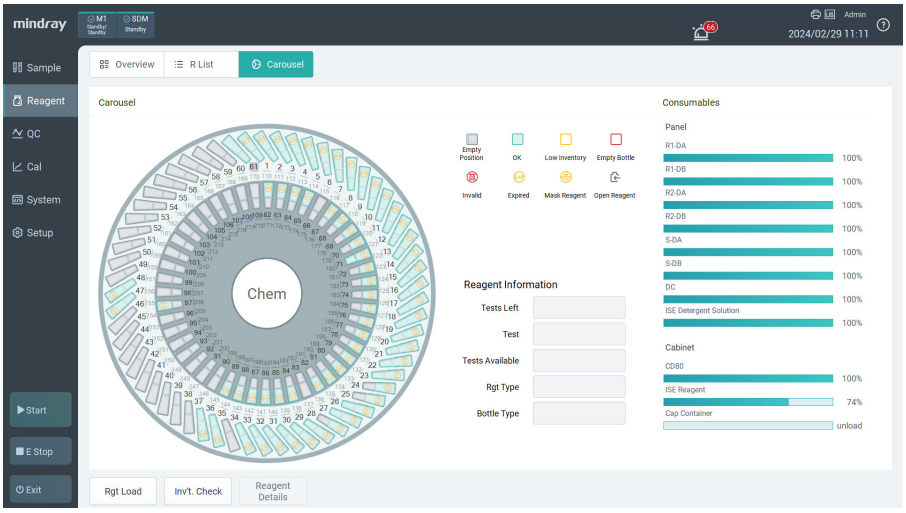
Select **Reagent** > **Carousel**. The screen displays the reagent status of each position of the reagent carousel and the status of the consumables with the legend.

The status of each reagent position of the reagent carousel is displayed on the screen.

When a certain reagent position is selected, the reagent information, including the tests left, test name, the reagent type and bottle type, is displayed on the right side of the reagent carousel.

In the meantime, consumables on both the panel and the cabinet can be viewed through the carousel screen.

Figure 5.4 Reagent Carousel



5.2 Reagent Bar Code Reader

The reagent bar code reader obtains reagent information from the bar code label. When bar-coded reagents are loaded to the reagent carousel, the system will make a full scan and obtain reagent information from the bar code labels.

5.2.1 Reagent Bar Code Specifications

The reagent bar code reader is compatible with various application environments. The code128 is selected by default with total bar code length of 13 digits. Users are allowed to set up the symbology and bar code compositions for open reagents. Open reagents are identified based on the symbology and bar code compositions defined by the user; while closed reagents are identified based on those defined by the manufacturer.

Table 5.1 Reagent bar code specifications

Name	Description
Symbology	Codabar, ITF, Code128, Code39, UPC/ EAN, and Code93
Minimum bar code density	0.25mm
Length	13-30 digits
Format and content	User-defined
Maximum width	55mm (within the flat area of the reagent bottle's back)
Minimum height	12mm
Maximum inclination angle	±5°
Print quality	No less than Class C according to the ANSI MH10.8M Print Quality Specification.
Width and narrowness	2.5:1
Print paper	Coated paper or matte paper. Printing bar code on common paper may result in vague bar code or degraded bar code label. You are not suggested to print bar code on common print paper.
Characters	Meaningful characters, such as numbers (0~9) and upper-case letters (A~Z). You are recommended to print the check digit in order to check that a bar code is read accurately.

5.2.2 Information Contained in a Reagent Bar Code

The system will obtain the following information from a reagent bar code:

- Test number
- Test name
- Reagent type
- Bottle type
- Lot number
- Serial number
- Expiration date (YYMM)

The reagent information obtained from a bar code label cannot be modified.

5.2.3 Reagent Bar Code Setup

It is necessary to set up the reagent bar code symbologies, check digit and bar code information before using the reagent bar code scanning. Only open-reagent bar code needs to be set up.

1. Select **Setup** > **System**.
2. Choose Reagent Bar Code.
3. Select the Analyze Bar Code of Open Reagent checkbox to enable obtaining reagent information from bar code.
4. Choose a bar code symbology and set up the check digit status.

   The following symbologies are provided:

   - Codabar
   - Interleaved 2 of 5
   - Code128
   - Code39
   - UPC/EAN
   - Code93

   Code 128, Code 93 and UPC/EAN requires a check digit by default, and other symbologies are not compulsive. The Code 128 is selected by default and cannot be modified.

⚠ CAUTION

You are recommended to enable the check function for all symbologies in order to prevent misreading of bar code.

5. Define the total length of reagent bar code.
   - Type in the total length of the reagent bar code in the Total field. The input range is 13-30 digits. The Interleaved 2 of 5 only supports bar code of even number length.
   - Type in the start digit of the reagent bar code in the Start Digit field.
   - Type in the end digit of the reagent bar code in the End Digit field.
6. Determine reagent bar code compositions.
   - Type in the number of digits for reagent information in the Digits field.
   - Type in the start digit of the reagent information in the Start Digit field.
   - Type in the end digit of the reagent information in the End Digit field.

Table 5.2 Reagent bar code compositions

Reagent Information	Number of Digits
Test number	0-4 digits
Test name	0-10 digits
Reagent type	1 digit ("1" stands for R1, "2" for R2, "3" for R3, and "4" for R4)
Serial number	0-5 digits
Bottle type	1-3 digits
Lot number	0-18 digits
Expiration date	0, 4, 6 or 8 digits

7 Select OK.

5.2.4 Loading Bar-Coded Reagents

Both open reagents and closed reagents can be loaded through bar code scanning.

When loading bar-coded reagents, put them on the reagent carousel. The system will scan all reagent positions automatically and obtain reagent information from the bar code label. The information obtained from a reagent bar code can only be viewed and cannot be edited.

The bar code scanning is only applied to biochemical reagents.

Refer to "3.5.1 Loading Biochemical Reagents" (3-12) for details.

5.3 Customizing Reagent Display

You are allowed to customize the reagent information on the reagent list screen.

1. Select **Reagent** > **R List** > **Reagent**.
2. Select the icon on the right.
3. Select checkbox of reagent information to display it on the reagent screen, deselect checkbox to cancel the display.
4. Click Up, Down, Home and End to adjust the display order of reagent information on the reagent list screen.
5. You can select **Restore Defaults** to restore the settings.

5.4 Sorting Reagents

Reagents on the reagent list screen can be sorted by name, position, days left and calibration time left, and a V-shape symbol appears to the right of the sort criteria. Prior to loading reagents or running calibrations, sort the reagents to display the desired ones in the front.

5.4.1 Smart Sort on Reagent Overview Screen

Reagent smart sort is enabled by default.

The rules of smart sort are as follows:

Reagent used up => below inventory alarm limit => sufficient

5.4.2 Sorting Reagents on Reagent List Screen

1 Select **Reagent** > **R List** > **Reagent.**

2 Choose a sorting criterion, and then click on the corresponding list head to rearrange the reagents.

To view or load reagents, choose the following standards:

- Reagent carousel
- Reagent position
- Test name
- Reagents available
- Days left

To view calibration status or run calibrations, choose the following standard:

- Calibration time left
- Calibration status

5.5 Masking/Unmasking Reagent

1. Select **Reagent** > **R List**.
2. Select a reagent you want to mask.
3. Select **Mask**.
4. Select Mask Sample or Mask Test.
   - Mask Sample: The masked reagent cannot be used for sample analysis.
   - Mask Reagent: The masked reagent cannot be used for sample, QC and calibration test.

To unmask the reagent, select it and then select Unmask. The masked reagent is displayed with icon  .

5.6 Reagent Inventory Alarm Limits Setup

5.6.1 Introduction

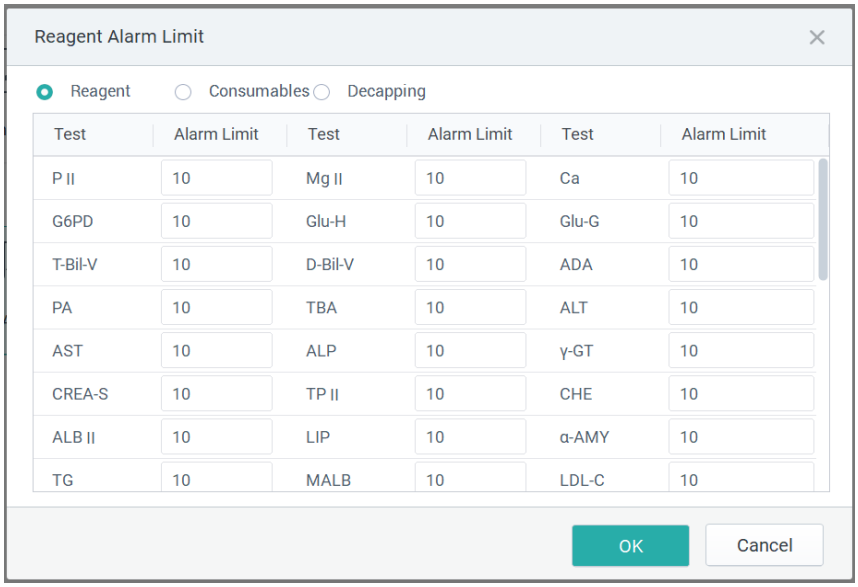
The system provides options to set up inventory alarm limit for reagents/consumables. When inventory is lower than the alarm limits during or before the analysis, the system will give an alarm and mark the consumable name in yellow on the Reagent List and Consumable List screen. When inventory is lower than the daily consumption limit during or before the analysis, the system will mark the consumable name in purple on the Reagent List and Consumable List screen.

5.6.2 Setting Up Inventory Alarm Limits

1 Select **Setup** > **Analysis** > **Inventory Limit Setup**.

2 Set up inventory alarm limit and daily consumption limit.

Figure 5.5 Inventory Limit Setup Screen



3 Select **OK**.

5.7 Printing Reagent Information

When viewing reagent/calibration information or the reagent carousel status, you are allowed to print, by test or by position, all reagents or those with remaining tests less than the alarm limit or equal to 0, or all reagent information. You are also allowed to print the entire special reagent list.

5.7.1 Printing Reagent Requirements

1 Select **Reagent** > **Overview**, or select **Reagent** > **R List.**

2 Select **Requirement Calculation**.

3 Select print button  .

4 Select **OK**.

5.7.2 Printing Reagent list and Reagent Use Record

1 Select **Reagent** > **R List**.

2 Click the print button  .

3 Select **Reagent list** or **Reagent Use Record**.

4 Select **OK**.

5.8 On-line Load of Reagents

The on-line load of reagents is performed while the system is running tests. Before starting an on-line load, request for reagent load, do not load reagents until all started tests are finished for reagent dispensing. If the system is running calibrations, STAT samples or diluted samples, you are not allowed to start loading reagents unless all tests finish reagents dispensing.

You are allowed to load consumables during test running. Perform loading according to indication light status.

WARNING	• The probe tip is sharp and may cause puncture wounds. To prevent injury, exercise caution when working around the probes.

BIOHAZARD	• Wear gloves and lab coat, if necessary, goggles. • Do not touch the reagent directly with your body; otherwise, skin wound or inflammation may be caused.

5.8.1 On-line Load of Reagents

1 Select **Reagent** > **R List**.

2 Select **Reagent**.

3 Select **Reagent Stop** to request for reagent load.

Rack transfer is stopped automatically, the system status area shows a countdown for reagent load, and a message box will be displayed when the countdown is finished.

CAUTION	• Do not open the reagent carousel cover before the countdown is finished; otherwise, the tests currently run will be invalidated.

4 To load non-bar-coded reagents, select **OK** and then **Load**, and remove the reagent carousel cover; to load bar-coded reagents, just remove the reagent carousel cover.

5 Load reagent to positions available.

6 Restore the reagent carousel cover， and the system resumes testing automatically.

- For load of non-bar-coded reagents, enter the reagent bar code on the **Load Reagent** window.
- For load of bar-coded reagents, the system scans all reagent positions automatically and read reagent information from the bar code.

5.9 Off-line Load of Reagents

5.9.1 Introduction

The off-line load of reagents is performed while the system is not running any tests. You are allowed to directly place the reagents on the reagent carousel or in the designated positions.

WARNING	• The probe tip is sharp and may cause puncture wounds. To prevent injury, exercise caution when working around the probes.

BIOHAZARD	• Wear gloves and lab coat, if necessary, goggles. • Do not touch the reagent directly with your body; otherwise, skin wound or inflammation may be caused.

5.9.2 Off-line Load of Reagents

1 Remove the reagent carousel cover.

2 Load reagents.

3 Restore the reagent carousel cover.

- For load of non-bar-coded reagents, enter the reagent information on the **Load Reagent** window.
- For load of bar-coded reagents, the system scans all reagent positions automatically and read reagent information from the bar code.

5.10 On-line Replacement of Reagents

When a reagent is insufficient or exhausted or going to be expired while the system is running tests, you should request for reagent stop and replace the reagent immediately to ensure that the following measurements will be done smoothly.

You are allowed to replace consumables during test running. Perform replacement according to indication light status.

Refer to "5.8 On-line Load of Reagents" (5-13).

5.11 Unloading Reagents

5.11.1 Introduction

If some tests will not be used, you are allowed to clear the test parameters and unload the relevant reagents. To re-assign reagent positions, you can unload the reagents and relocate them. The **Unload** option is used to remove reagents.

When a test is requested for quality control, sample analysis or calibration, all reagents of the test still can be unloaded.

When a reagent is unloaded, all relevant information and its position are cleared. The reagents that are being used for analysis cannot be unloaded.

5.11.2 Unloading Reagents

1. Make sure that the reagents to be unloaded is not being used for analysis.
2. Select **Reagent** > **R List**.
3. Select **Reagent** and the position to unload reagent.
4. Select **Load**.
5. Select **Unload**.
6. Remove the reagent carousel cover.
7. Take out the reagent from the reagent carousel.
8. Restore the reagent carousel cover.

6 Calibration

In this chapter

6 Calibration

6.1 Overview

In a calibration, the system measures the response of the calibrator with given concentration, and then calculates the factors in the concentration-response equation. In this way, a math equation about concentration and response is determined. The concentration of a patient sample can be calculated based on the math equation and the measured sample response.

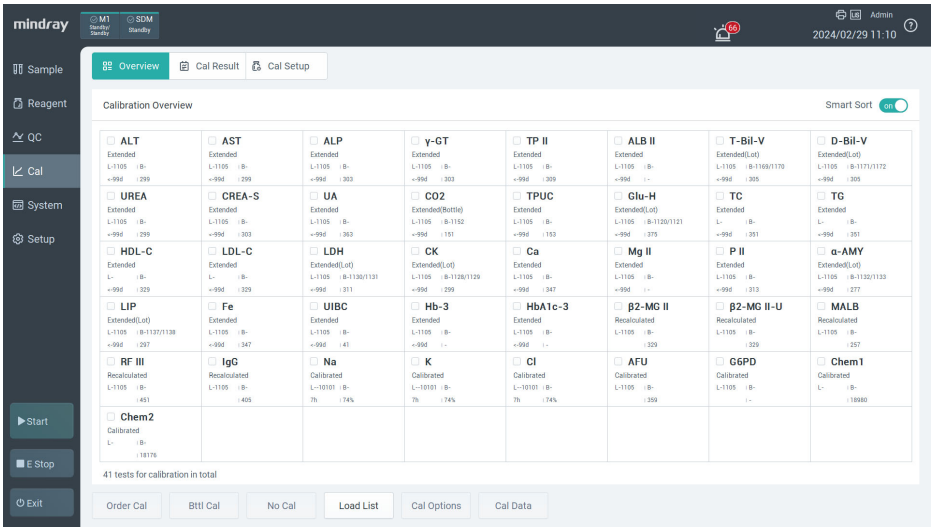
When the calibration status is abnormal, the system will give an alarm and display the calibration status with specific color. The system allows multiple concentrations of a calibrator for multi-point calibration. The calibration factors can be adjusted through a reagent blank test. When you set up the auto calibration conditions, the system will automatically remind you of calibrating tests. Expired calibration factors can be used again by extending the calibration time. You are allowed to override a failed calibration and obtain results based on the failed calibration factors. Current calibration factors can be rejected and the latest valid ones are used to calculate sample results.

6.2 View Calibration Status and Alarm

6.2.1 View Calibration Status Via Calibration Overview

On the **Overview** screen, the tests are indicated with various texts and colors for different calibration status. Tests in Cal Required, Cal Failed or Cal Time Out status can be requested but will not be run.

Figure 6.1 Calibration Overview



Smart Sort is enabled by default for calibration statuses. The sorting rules are as follows:

Calibration Failed - > Cal Time Out - > Cal Required - > Requested - > In Progress - > Overridden- > Extended - > Calculated.

6.2.2 View Calibration Status Via Reagent List

Check the tests' calibration status frequently and take relevant actions according to the following table.

On the reagent list screen, the calibration status of each test is indicated by text and different colors. Tests in Cal Required, Cal Failed or Cal Timed Out status can be requested but will not be run.

Table 6.1 Calibration Status

Calibration status	Description	Severity	Color
Cal Required	Indicates that the test needs to be calibrated. This status appears when the test is not calibrated or auto calibration conditions are satisfied; or calibration information has been modified, such as calibrator and concentration, or result unit.	Serious	Red

Calibration status	Description	Severity	Color
Requested	Indicates that the test has been requested for calibration or the calibration test is running.	Normal	No color indication
Calibrated	Indicates that the test has been calibrated and has not exceeded the calibration period.	Normal	No color indication
Cal Failed	Indicates that the test has finished but cannot calculate the final result; or the calculated result exceeds the acceptance limits; or calibration is requested but test is invalidated during calibration.	Serious	Red
Cal Time Out	Appears when the test exceeds the calibration period.	Serious	Red
Cal Time Extended	Indicates that the calibration period has been extended and the current calibration factors can be used without time limit.	WARNING	Yellow

6.3 Calibration Setup

Perform calibration settings in the following order:

- Define/Edit a calibrator
- Input calibration master curve information
- Set up calibrator position
- Set up Calibration rule

You are allowed to add, edit and delete calibrators only when the system status is not Running.

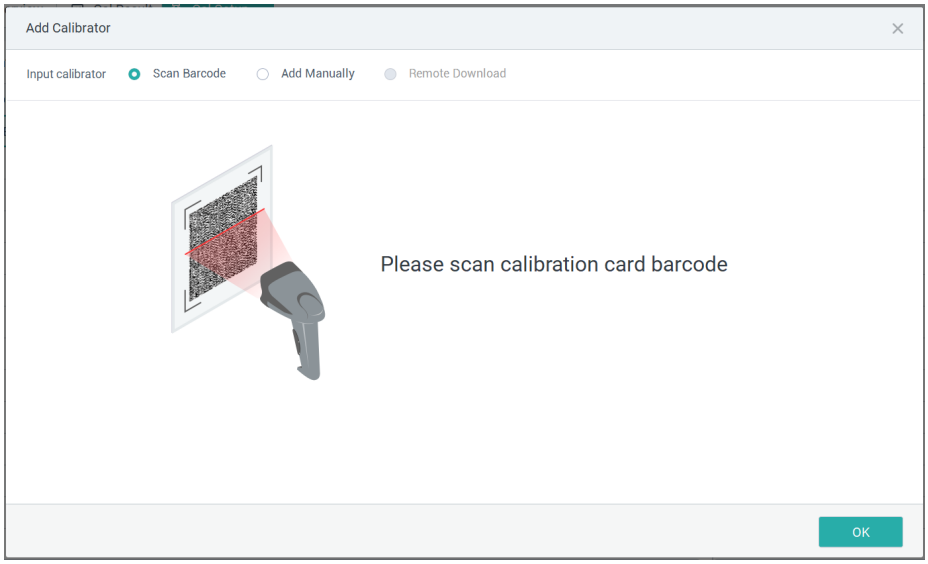
6.3.1 Define a Calibrator

The system allows the definition of up to 99 calibrators. You are required to input the name and position for each defined calibrator.

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.

2 Select **New**.

Figure 6.2 Calibrator Definition window



3 Select **Scan Barcode** or **Add Manually**. The calibrator information can be imported automatically through scanning barcode.

4 If you select manual, enter the expiration date of the calibrator. The default is the current day in the next year.

5 Calibrators beyond the expiration date cannot be used.

6 Enter the lot number.

The input range is 0-18 and accepts numbers and letters. Calibrators with the same name must not have the same lot number.

7 Select **Number of Concentrations** and then select **tests**.

8 Select **Submit**.

6.3.2 Remote Download Calibrators

Download calibrator information through the remote download function.

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.

2 Select **New**.

3 The Calibrator Setup window is displayed.
4 Select **Remote Download**.
5 Enter the lot number.
6 Select Search. The screen shows a set of calibrators with the entered lot number.
7 Select calibrators to be imported and select Import.

6.3.3 Edit a Calibrator

You are allowed to edit calibrators only when the system is not running any tests. It is used for reagent blank measurement and cannot be edited or deleted. WATER can be also placed on any position on a rack, and the WATER on a rack can be modified or deleted.

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.
2 Choose a calibrator to edit.
3 Edit the following calibrator information in the popup dialog box.
- Calibrator name
- Expiration date
- Lot number
- Rack number and positon
- Barcode
- Concentration

4 Select **Submit** to save your input information.

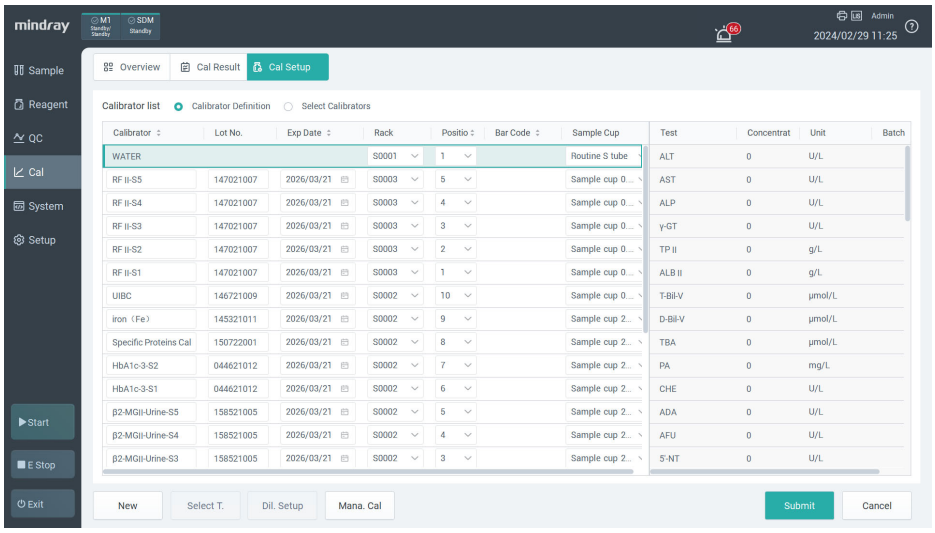
6.3.4 Setting up Calibrator Concentrations

You are required to set up calibrator concentrations for each test after defining the calibrator. A calibrator should be defined with the same concentration for a test on each analyzer. Only the calibrator with positions assigned and concentrations determined can be used for ordering. You are allowed to change the calibrator concentrations when the system is not running any tests.

The default calibrator WATER has concentration of 0 for all tests. It has no lot number and expiration date and must not be edited or removed.

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.
2 Choose a calibrator.
3 Set up the rack number and position for the calibrator.

Figure 6.3 Calibrator concentration setup screen



4 Choose tests in the right list to which the calibrator is applicable, and then select the corresponding **Concentration** column and type in the calibrator concentration for it.

The concentration must be above 0.

5 Select **OK** to save your input information.

A message box pops up indicating that parameters are changed and calibration is required.

6.3.5 Selection of Calibrators

1 Select **Cal** > **Cal Setup** > **Select Calibrators**.

2 Choose a test in the left list. Choose a calibrator on the right of the list.

3 Select **OK**.

6.3.6 Setting up Calibration Rules

After setting up calibrator and concentration, you need to set up the calibration rules for the test. You are allowed to set up or modify the calibration rules, replicates, K factor and auto calibration conditions only when the system is not running any tests.

1 Select **Setup** > **Tests**.

2 Select **View&Set Test**.

3 Select **New** or select a test and select **View** and **Edit**

4 Select Calibration Parameters > Calibration Rules.

The options include:

- K factor
- Two-point linear
- multi-point linear
- Logistic-Log 4P
- Logistic-Log 5P
- Exponential 5P
- Polynomial 5P
- Parabola

- Spline
- Logistic-Log 3P
- Polygon

5 If K factor is selected, enter the factor.

This field is activated only when the one-point linear calibration rule is selected. When the K factor is input, the calibration results will be calculated with Y=K*X. Where, Y is calibration result, K is factor, and X is response.

6 Select replicates from the Replicates pull-down list.

The options include 1-5, and the default is 1.

7 Select **Submit** to save the settings.

6.3.7 Calibrator Management

Deleting a Calibrator

You are allowed to remove the calibrators other than WATER. If a calibrator is configured on more than one analyzer, only that on the selected analyzer will be deleted. When a calibrator is deleted, all calibration settings and its position are cleared, and it cannot be used for ordering. The stored test results of the calibrator can be recalled according to the test name. only calibrators that are not requested or run can be deleted.

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.

2 Select **Manage Cal**.

3 Choose a calibrator you want to remove.

4 Select **Delete**. The selected calibrator is deleted.

Activate or Deactivate Calibrator

The newly imported calibrators are activated by default. When the old lot of calibrators is not used up, a new lot of calibrators are entered in advance, and the old lot of calibrators can be used again by activating them. You are allowed not to display the disabled or used-up calibrators on the calibrator setup screen.

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.

2 Select **Manage Cal**.

3 Select a calibrator from the calibrator list.

4 Select **Activate** or **Deactivate**.

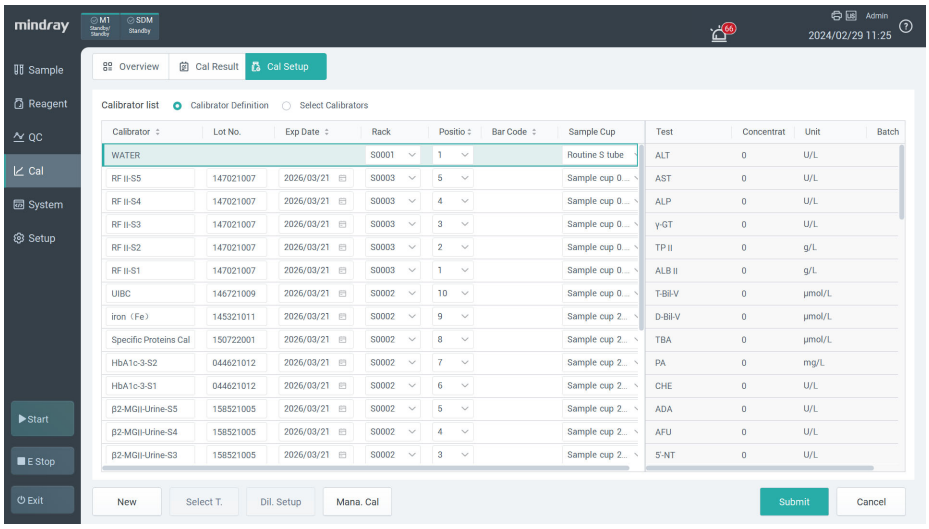
5 Select **OK**.

6.3.8 Assign Calibrator Position

Once the calibrator information is input, you are allowed to assign calibrator position only when the system status is Standby or Stopped. You are allowed to modify and release calibrator position.

1 Select **Cal** > **Cal Setup**.

Figure 6.4 Calibrator Definition window



You can sort the calibrators through Calibrator, Lot No. or Rack.

2 Assign rack ID and position for the calibrator.

3 Select **Submit**.

6.3.9 Calibrator Management

You are allowed to delete calibrators only when the system status is Standby or Stopped. When a calibrator is deleted, all calibration settings and its position are cleared, and it cannot be used for requesting calibration. The stored test results of the calibrator can be recalled according to the test name. only calibrators that are not requested or run can be deleted.

6.3.9.1 Delete Calibrator

1 Select **Cal** > **Cal Setup** > **Mana. Cal**.

2 Choose the calibrator to be deleted.

3 Select **Delete**.

4 Select **OK**.

The selected calibrator will be deleted.

6.4 Calibrator Dilution Setup

6.4.1 Introduction

The system supports calibrator dilution and allows one calibrator to have 9 concentrations for the same test. You are only required to enter the final concentration of the diluted calibrator and the diluted calibrator volume aspirated by the sample probe during calibration. The system will automatically calculate the diluent volume and the sample volume for diluting. When you set up the dilution factors for a test, its original calibrator concentration will be removed.

You are allowed to edit or delete the calibrator dilution factors when the system is not running any tests.

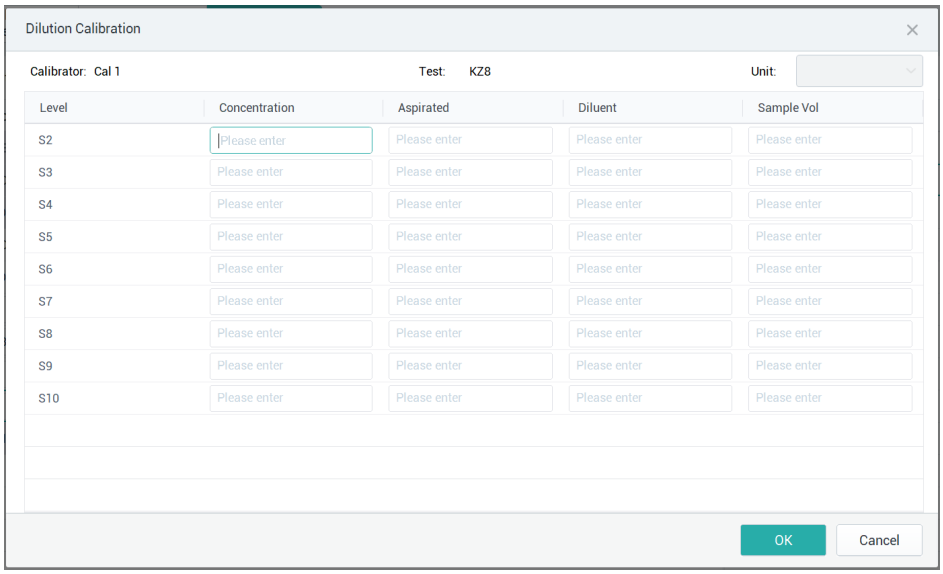
6.4.2 Setting up Calibrator Dilution Factors

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.

2 Choose a calibrator and a test.

3 Select **Dil. Setup**.

Figure 6.5 Calibrator Dilution Setup window



4 Enter the final concentration of the diluted calibrator in the **Conc** field.

5 Enter the calibrator volume used for diluting in the **Neat Vol** field.

The input must be an integer multiple of 0.1 within 1.5μL-25μL. This field can be left blank.

6 Enter the diluent volume used for diluting in the **Diluent Vol** field.

The input must be an integer multiple of 0.5 within 75μL-200μL. This field can be left blank.

NOTE

If the tested sample is whole blood, the whole blood sample must be held in the sample tube. Whole blood samples cannot be analyzed with microtubes.

To ensure accurate whole blood analysis, make sure that the blood cell height of the whole blood sample is at least 10 mm.

7 Enter the calibrator volume dispensed by the sample probe during calibration in the **Aspirated Vol** field.

The input must be an integer multiple of 0.1 within 1.5μL-25μL. This field is required.

8 Select **OK**.

6.4.3 Editing Calibrator Dilution Factors

1 Select **Cal** > **Cal Setup**> **Calibrator Definition**.

2 Choose a calibrator and a test.

3 Select **Dil. Setup**.

4 Change the concentration, sample volume, neat sample volume and diluent volume.

NOTE

If the neat sample volume and diluent volume are defined, ensure that the sum of the two volumes is within 100μL-280μL.

The two volumes must be defined or left blank simultaneously.

5 Select **OK**.

6.5 Reagent Blank

In a reagent blank test, the reagents react with the physiological saline or a calibrator with concentration of 0, and then the blank absorbance is calculated. When a reagent is uncapped for a long period, the reagent absorbance may be changed. At this time, you are allowed to run a reagent blank instead of calibration to calculate the reagent blank absorbance, which will be used to adjust the calibration factors of the reagent in order to ensure reliable sample results.

The reagent blank is allowed only in the following calibration status: Calibrated which means the calibration is successfully performed. Reagent blank is applied to Biochemical tests only.

If the reagent blank results, including the mixed blank absorbance and blank response, are within the acceptance range, the system will update the calibration factors and the remaining calibration time based on the results. If the results exceed the acceptant limits, the system will give an alarm and remind you to rerun the reagent blank. The **Biochemistry Calibration** screen shows the calculated reagent blank response, absorbance and run date.

6.5.1 Mixed Blank Absorbance and Blank Response

When defining a test, you need to set up the mixed blank absorbance and blank response to check the reagent blank results.

The mixed blank absorbance indicates the allowable range of the absorbance measured at the end point of a zero-concentration calibrator reaction or a reagent blank reaction. If the absorbance measured at the reaction end point is beyond the set range, the system will flag the test result.

The blank response specifies the allowable range of the response in a zero-concentration calibrator analysis or a reagent blank test. If the response is beyond the set range, the system will flag the test result.

1. Select **Setup** > **Tests**.
2. Choose a biochemical test, or enter the test name in the **Test Name** field.
3. Select **View**.
4. Select **Check Parameters** and then select **Edit**.
5. Enter the mixed blank absorbance range in the **Mixed Blank Abs** field.
6. Enter the blank response range in the **Blank Response** field.
7. Select **Submit**.

6.5.2 Requesting a Reagent Blank

Please note that reagent blank can only be run in following conditions:

- Tests with all calibration math models rather than two-point linear and K factor must have the 0-concentration calibrator set up.
- K factor tests must have calibrators set up.

The reagent blank is allowed only in Calibrated calibration status.

1. Select **Reagent** > **R List**, and select **Reagent**.
2. Check if the desired tests' calibration status is Calibrated.
3. Choose the tests.
4. Select **Order Cal**.
5. Choose **Rgt Blk**.
6. Select **OK**.

7 Put the rack in the sample rack lanes, the system starts analysis automatically.

6.5.3 Recalling Reagent Blank Results

If the reagent blank results are within the acceptance limit range, they will be used to update the current calibration parameters. You are allowed to recall the reagent blank response, absorbance and run date on the Biochemistry Calibration screen. Calibration curve of reagent blank cannot be recalled.

Recalling reagent blank response

1 Select **Reagent** > **Calibration Result**.
2 Choose a test.
3 Select **Cal Data**.
The calibration results and reagent blank results of the test are displayed in the result list.
4 Choose a calibration result.
5 Select **Cal Curve** or select **Trend**, select the data tab, and then highlight a calibration data record.
6 Select **Reac Curve**.
The response value current displayed is the updated reagent blank response.
7 Select the reaction data table to view the reagent blank reaction data.
8 Choose the following buttons as needed:
- **Print** : to print the current reaction curve or data.

Recalling reagent blank trends

1 Select **Calibration** > **Cal Result**.
2 Choose a test.
3 Select **Cal Data**.
The calibration results and reagent blank results of the test are displayed in the result list.
4 Choose a calibration result.
5 Select **Trend**.
6 Choose a trend type you want to recall.
The options include:
- R1 blank absorbance
- Mixed blank absorbance
- Response of WATER
- Calibrator response
- K factor (for linear calibrations only)

7 Select icon and select the calibration time range.
8 Select **OK**.
The graphical trend of the selected test within the specific period is displayed.
9 Select or to zoom in or out the trend plot.
10 Select **Return**.

6.6 Auto Calibration Reminder

Based on the auto calibration conditions, the system can determine tests that need to be calibrated and remind you through calibration status and color indication. Auto calibration conditions include:

- Calibration factors' validity period
- Reagent lot changed
- Reagent bottle changed

For open tests, when the lot number or serial number of R1, R2, R3 or R4 is changed, calibration is required. If no lot number or serial number is set for open reagents, the tests will not be calibrated automatically even though the conditions are met. When the calibration time is exceeded, the system will remind you of running calibrations.

For closed tests, calibration will be run automatically when reagent lot number is changed.

6.6.1 Auto Calibration Reminder

1. Select **Setup** > **Tests** > **View&Set Test**.
2. Select a test.
3. Select **View**. Select **Calibration Parameters** and then select **Edit**.
4. Choose auto calibration conditions:
   - Bottle changed: The system will remind you to run a calibration when you use a different bottle of reagents.
   - Lot changed: The system will remind you to run a calibration when you use reagents of a different lot.
   - Calibration time: The system will remind you in 30 minutes before the calibration is timed out and display the test's calibration status with yellow.
5. Select **Submit**.

When the auto calibration conditions are satisfied, the system will remind you through the calibration status, prompt message and alarm color.

- If you choose the Calibration Time option, the system will remind you in 30 min before the calibration is timed out and mark the test name with yellow.
- If you choose the option of Lot Changed, the system will prompt you to run a calibration if you use reagent of a different lot.
- If you choose Bottle Changed and use a reagent without the current calibration factors, the system will prompt you to run a calibration for it.

6.6.2 Removing Auto Calibration Reminder

To disable the auto calibration reminder, perform the following steps:

1. Deselect all auto calibration conditions on the Calibration Parameters window.
2. Select **Submit**.

6.7 Extending Calibration Time

6.7.1 Introduction

Calibration factors that exceed the calibration period cannot be used for result calculation. The calibration status becomes Cal Time Out and the test can no longer be run. The system will display a warning message in 30 minutes before the calibration is timed out, and you are allowed to recalibrate the test or extend its calibration time. If you are certain that the calibration factors are correct and valid, you may prolong their validity period by using the calibration time extension function. A calibration time can be extended only if the current calibration of the test is timed out or calibrated. The results calculated based on extended calibration factors will be flagged with “EXT”.

6.7.2 Extending Calibration Time

1. Select **Cal** > **Overview**.
2. Choose a test you want to extend.
3. Select **Extend**.
4. Select **OK**. The calibration factors of the selected test can be used without time limit.

6.7.3 Removing an Extended Status

Calibration extension is not absolutely definite. Recalibrate the test to remove the extended status.

6.8 Calibration Test

For requesting calibration and perform calibration, please refer to "3.6 Calibration" (3-18).

6.9 Calibration Rerun

After calibration has been requested and started, if the calibration test is abnormal, or the calibration test is found abnormal or incomplete on the calibration overview screen.

1. Select test in abnormal calibration status on the calibration overview screen or reagent list screen.
2. Select **Rerun Cal Request**.
3. Prepare calibrators at concentration levels which abnormal calibration occurs.
4. Put the rack into sample rack lanes. The system starts analysis automatically.

6.10 Individual Bottle Calibration

6.10.1 Introduction

The property of some reagent bottles of the same lot may change, so the reagent bottle can be calibrated individually. After calibration, its calibration parameters cannot be applicable to other reagent bottles and it also cannot acquire the calibration parameters from others.

6.10.2 Set up individual bottle calibration

1. Select **Cal** > **Overview**.
2. Select the to-be-calibrated reagent on the calibration overview screen.
3. Select **Order Cal**.
4. Select **Calibration by bottle**.
5. Select **OK**.

   If you want to cancel individual bottle calibration, just cancel ticking **Calibration by bottle** and the calibration status of the reagent returns to that of the reagents of same lot.

6.11 Recalling Calibration Results

On the **Calibration Result** screen, you are enabled to recall the current and stored calibration factors of a test. The **Current** calibration factors are obtained in the recent calibration and are being used for result calculation. You are allowed to recall the calibration data and calibration trends during the specified period, and archive or print the calibration results.

6.11.1 Recalling Calibration Result

1 Select **Cal** > **Cal Result**. Select **Current** or **History**.

The screen shows all the calibrations requested on the day, including the following information:

- Test name
- Result flag
- Calibration status
- Calibration date and time
- Reagent Lot No.
- Reagent Serial No.
- Math model

2 You can click the filter icon to search for results within a certain period.

The calibration results of the selected test are displayed in the result list. Click the header of Test or calibration date/time to sort the calibration results by the test or calibration date/time.

6.11.2 Archiving Calibration Results

The system allows you to archive all searched calibration results to a storage device, such as U disk, floppy disk, etc. Archived calibration results are displayed in the same format as on the software screen. The archiving file is of.csv format and named by date and time.

1 Select **Cal** > **Cal Result**.

2 Search for desired calibration results.

3 Select Archive button .

4 Confirm the archiving path and file name.

5 Select **OK**.

6.11.3 Recalling Calibration Curve and Data

The system allows you to view the detailed calibration information such as test name, reagent information, math model, calibration status, calibration date/time and calibrator's concentration level.

1 Select **Cal** > **Cal Result**.

2 Search for desired calibration results.

3 Select a test you want to view the calibration data.

4 Select **Cal Data**. The calibration curve and data are displayed.

5 Select **Return**.

6.11.4 Calibration Trends

Calibration graphical trends summarize a test's calibrations during a period of time and reflect the trends of the calibrations. Calibration graphical trends show the trends of each calibrator of the test.

Follow this procedure to observe calibration trends:

1 Select **Cal** > **Cal Result**.

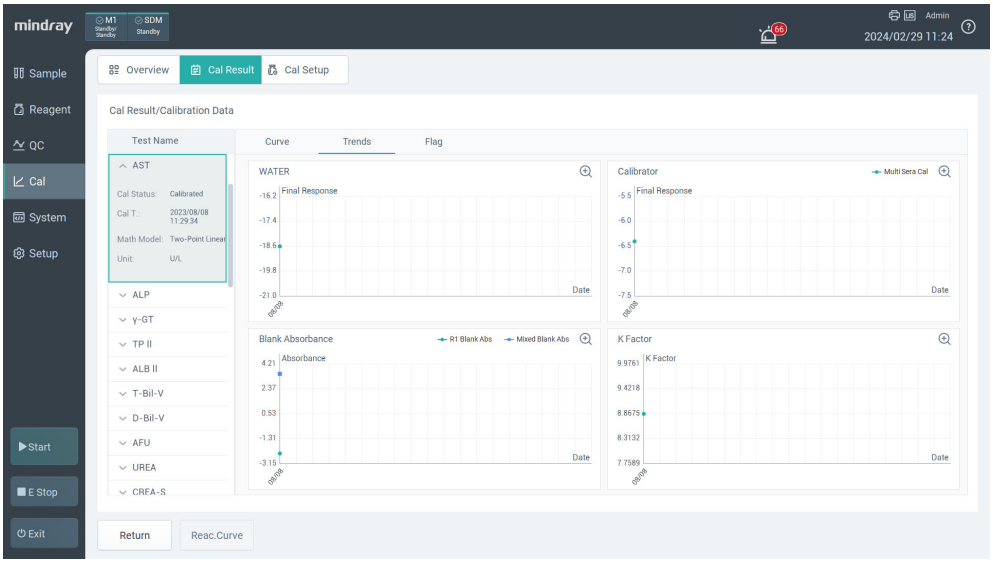
2 Choose a test.

3 Select **Calibration Data**.

The calibration results and reagent blank results of the test are displayed in the result list.

4 Select **Trend**.

Figure 6.6 Calibration Trends



5 Click  icon and select the calibration time range.

6 Select **OK**.

The graphical trend of the selected test within the specific period is displayed. You can view the calibration data on the right side of the screen.

7 Click  or  to zoom in or out the trend plot.

8 Select **Return**.

6.12 Calibration Override

The Calibration Override option allows the system to override a failed calibration and calculate results based on the failed calibration factors. Calibration override is only applied to failed calibrations. Results that are obtained based on failed calibration factors will be flagged with "OVE".

NOTE

Before overriding a calibration, make sure that the calibration factors are within the acceptance limits of your laboratory. The magnitude of the error should be totally under the control of your laboratory. Use of overridden calibration factors may lead to unreliable results and influence the clinical diagnosis. Think twice before overriding a failed calibration.

6.12.1 Overriding a Calibration

1. Select **Cal** > **Overview**.
2. Choose a test you want to override. Select **Cal Options**.
3. Select **Override**.
4. Select **OK**. The failed calibration factors of the selected test can be used for result calculation.

6.12.2 Removing Cal Overridden Status

Recalibrate the test to remove its Cal Overridden status.

6.13 Reject

If the current calibration fails but sample analysis needs to be performed immediately, you may use the Reject function to reject the current calibration factors, and use the latest valid ones for calculating sample results, which will be flagged with "CALJ". Calibration factors of status other than Requested and Cal Required can be rejected. Rejected calibration factors cannot be rejected again.

6.13.1 Rejecting a Calibration

1. Select **Cal** > **Overview**.
2. Choose a test you want to reject. Select **Cal Options**.
3. Select **Reject**.
4. Select **OK**. Calibration factors of the selected test are rejected.

6.13.2 Removing Reject Status

Recalibrate the test to remove its Reject status.

7 Quality Control

In this chapter

7 Quality Control

This chapter describes applications of quality control, which include:

- Daily and monthly QC procedure
- QC alarm indications
- QC result flags
- Control status
- QC evaluation
- Auto QC
- Control results recall

7.1 Overview

7.1.1 Introduction

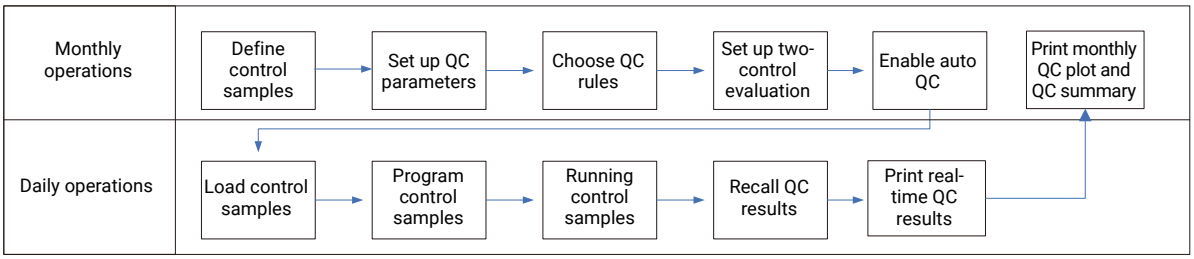
A QC run may require more than one control sample. You are recommended to use two control samples, one with normal values (within the reference range) and the other with abnormal values (beyond the reference range).

To ensure the system performance, run control samples every time after you perform a calibration, or change the reagent lot, or maintain and troubleshoot the instrument.

7.1.2 Quality Control Operating Procedure

After you define a control, test and QC rules, there is no need to edit them frequently, and you are only required to run control samples every day to make sure that the system works well. Run control samples according to the following procedure:

Figure 7.1 Quality control operating procedure



7.1.3 QC Alarms

The system provides the real-time monitoring of quality controls, and check if the QC results are under control when a QC run is finished. If the results exceed the reference range, the system will give an audible alarm and shows an alarm message indicating the test name, control name and control rules. For instance, “Test:, control:, 1-3s out of control!”. In this situation, you should stop the analysis and find the causes of the failure, and resume the analysis after solving the problem.

7.1.4 QC Result Flags

When a QC result fails, the system will give an audible alarm and show alarm message to remind you of the failure. Moreover, the following flags will appear for failed results in the **Flag** column of the QC reports.

- 1_{3s}
- 1_{2s}
- R_{4s}
- 2_{2s}
- 4_{1s}
- 10_{x}

The system checks the failed QC results for system error or random error and then flag them accordingly. A “#” sign indicates a systematic error, and an asterisk “*” indicates a random error. For more information about QC result flags, refer to "12.4 Data alarms" (12-6).

7.1.5 Control Status

When you choose a control on the **Quality Control** screen, the current status of the control is displayed in the **Status** field. It is necessary to understand the control statuses. The table below shows the various statuses of control samples.

Table 7.1 Descriptions of control status

Control Status	Description
N/A	Indicates that the control is not ordered for analysis.
Requested	Indicates that the control sample has been ordered but not analyzed yet.
In Progress	Indicates that the control sample is being analyzed.
Incomplete	Indicates that all tests of the control sample have been finished but one or more of them have no results.
Complete	Indicates that all tests of the control sample have been finished with results.

7.2 QC Evaluation

7.2.1 Introduction

The system provides the Westgard rules for evaluating QC results of the tests, and give alarms and flags when the obtained QC results are beyond the reference range. Since every test may have one or more control samples, the QC results can be evaluated with different rules accordingly. Those controls that are not included in any lots will be evaluated as single controls.

7.2.2 Evaluation of Single Control

The Westgard rules for evaluation of single controls are listed in the table below:

Table 7.2 Westgard rules for single controls

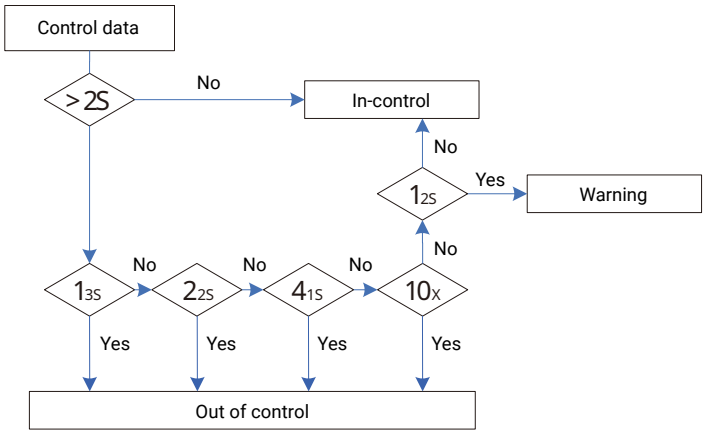
Rules	Description	Flag	Error Type
1_{2s}	One result is between ±2 and ±3 standard deviations from the assigned mean concentration.	N/A	N/A
1_{3s}	One result is greater than ±3 standard deviations from the assigned mean concentration.	1_{3s}	*(1)
2_{2s}	Two continuous results are greater than +2 or -2 standard deviations from the assigned mean concentration, e.g. (Xn, Xn-1)	2_{2s}	#(2)
4_{1s}	Four continuous results are greater than +1 or -1 standard deviation from the assigned mean concentration, e.g. (Xn, Xn-1, Xn-2, Xn-3)	4_{1s}	#
10_{x}	Ten results being compared are on the same side, e.g. (Xn, Xn-1, Xn-2, Xn-3...Xn-9)	10_{x}	#

(1) An asterisk “*” indicates a random error, which requires no special action but must not be ignored.

(2) A “#” symbol indicates a systematic error, which requires special consideration.

The evaluation procedure of single controls is shown in the figure below:

Figure 7.2 Evaluation procedure of single controls



7.2.3 Two-Control Evaluation

7.2.3.1 Two-control evaluation rules

In every QC run, two results are obtained: Xn and Yn, which are used to define a point on the Twin-plot chart. In this way, a complete twin-plot chart is drawn based on all the QC results and used for detecting systematic errors and random errors.

The Westgard rules for two-control evaluation are listed in the table below:

Table 7.3 Two-control evaluation rules

Rules	Description	Flag	Error Type
1_{2s}	One result is between ±2 and ±3 standard deviations from the assigned mean concentration.	N/A	N/A
1_{3s}	One result is greater than ±3 standard deviations from the assigned mean concentration.	1_{3s}	*(1)
2_{2SA}	Two results (Xn, Yn) of a run are simultaneously greater than +2 or -2 standard deviations from the assigned mean.	2_{2s}	#(2)
R_{4s}	One result of a run is greater than +2 standard deviations from the assigned mean and the other greater than -2SDs.	R_{4s}	*
2_{2SW}	Two continuous results of a control are greater than +2 or -2 standard deviations from the assigned mean concentration, e.g. (Xn, Xn-1), (Yn, Yn-1).	2_{2s}	#
4_{1SA}	Results of two continuous runs are greater than +1 or -1 standard deviation from the assigned mean, e.g. (Xn, Yn, Xn-1, Yn-1).	4_{1s}	#

Rules	Description	Flag	Error Type
4_{1SW}	Four continuous results of a control are greater than +1 or -1 standard deviations from the assigned mean concentration, e.g. (Xn, Xn-1, Xn-2, Xn-3), (Yn, Yn-1, Yn-2, Yn-3).	4_{1s}	#
10_{XA}	Results of five continuous runs (10 results) compared are on the same side, e.g. (Xn, Yn, Xn-1, Yn-1, Xn-2, Yn-2, Xn-3, Yn-3, Xn-4, Yn-4).	10_x	#
10_{XW}	Ten continuous results (10 results) of a control are on the same side, e.g. (Xn, Xn-1, Xn-2, Xn-3...Xn-9), (Yn, Yn-1, Yn-2, Yn-3...Yn-9).	10_x	#

(1) An asterisk "*" indicates a random error, which requires no special action but must not be ignored.

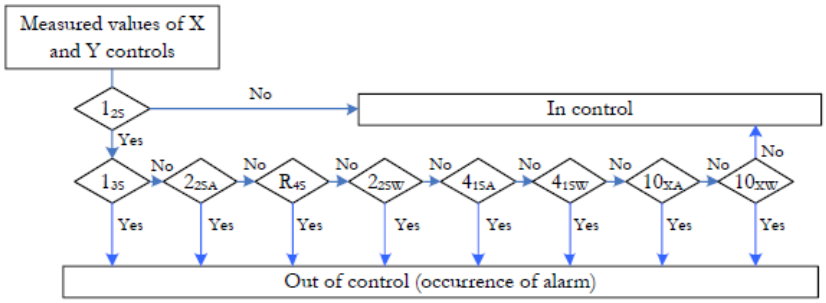
(2) A "#" symbol indicates a systematic error, which requires special consideration.

The systematic errors in two-control evaluation correspond to those in single-control evaluation as follows:

- $2_{2SA}\backslash 2_{2SW}$ corresponding to 2_{2s}.
- $4_{1SA}\backslash 4_{1SW}$ corresponding to 4_{1s}.
- $10_{XA}\backslash 10_{XW}$ corresponding to 10_x.

The procedure of two-control evaluation is shown in the figure below:

Figure 7.3 Two-control evaluation workflow



7.3 QC Setup

7.3.1 Introduction

Perform QC settings in the following order:

- Define/Edit a control
- Select tests
- Set up control concentration parameters (when calibrator is manually set up)
- Assign control position
- Setting up QC rules

7.3.2 Defining/Editing a Control

Control can be set up manually or imported and the system automatically analyzes information from the bar code, such as lot number, expiration date and reference value. It is allowed to scan control bar code only by hand-held bar code reader.

The system allows the definition of up to 99 controls. Adding or editing controls is allowed only when the system status is Incubation, Standby or Stopped.

7.3.2.1 Importing Control

1 Select **QC** > **Ctrl Setup**.

2 Select **Import Control**.

3 Scan bar code with hand-held bar code reader.

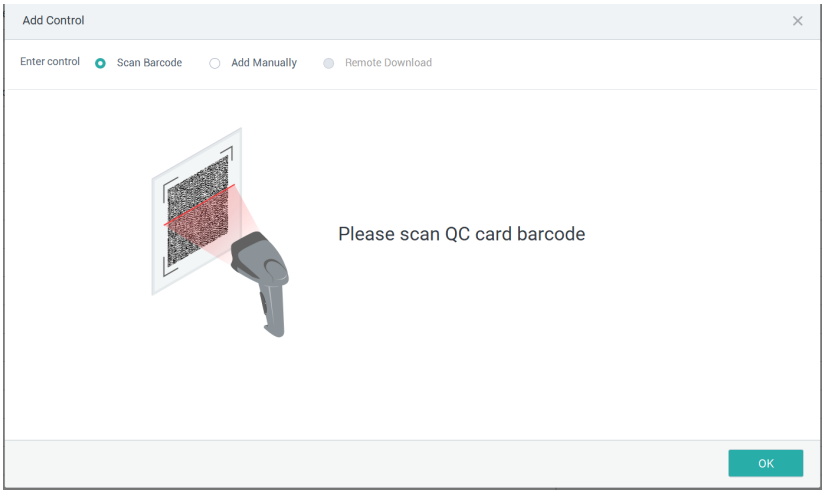
Control information analyzed from the bar code will automatically be shown on the screen, and cannot be modified.

7.3.2.2 Set up Control Manually

1 Select **QC** > **Ctrl Setup**.

2 Select **Add Control** > **Add Manually**.

Figure 7.4 "Define Control" window



3 Type in the control name.

4 Enter the control number.

5 Enter the lot number.

The lot number can be composed of characters or numbers. The combination of control name and lot number must not be duplicate.

6 Select a sample type from the **Sample Type** pull-down list.

7 Select expiration date for the control.

8 Select tests for the control.

When the expiration date is exceeded, the control can still be requested and analyzed, while the system flags the test result with "!" in the **Flag** column to remind you of replacing the expired control.

9 Select **Submit** to save your input information.

7.3.3 Selection of Tests

After defining a control, you need to select tests for which the control will be used. When selecting tests, make sure that the system status is Incubation, Standby, Stopped or Sleep, and the control status is not ordered or Incomplete.

1 Select **QC** > **Ctrl Setup**.

2 Choose a control in the left list.

3 Select **Tests Selection**.

4 Choose tests for the control.

5 To choose all tests in the list, select **Select All**.

6 To deselect the tests, select **Clear**.

7 Select **OK**.

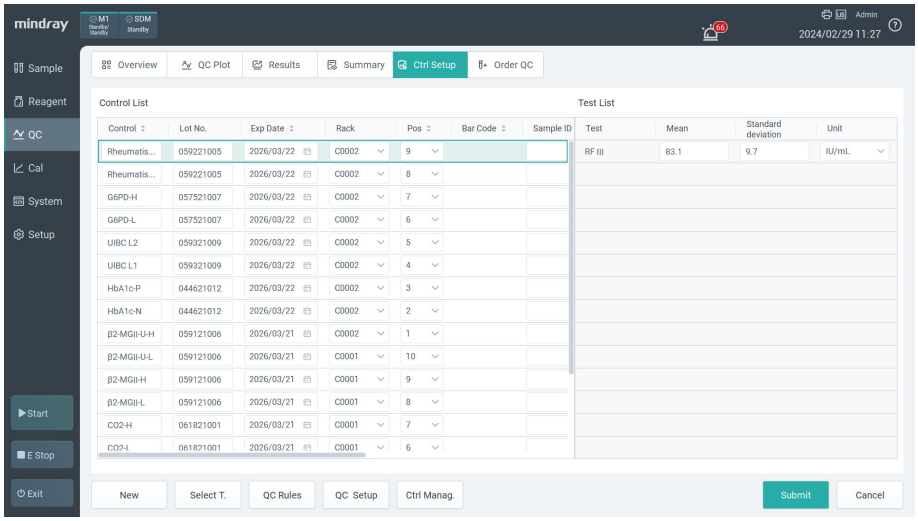
7.3.4 Setting Up Control Position and Concentrations

You are required to set up the average concentrations and SDs of a control for each test after defining the control and choosing tests. Only the control with positions assigned and concentrations determined can be used for ordering.

To run quality control for special calibrations, you must define the mean value and SD; otherwise, no control results will be calculated. If the sub tests of a special calculation have no mean value and SD, QC evaluation will not be done and QC plot cannot be recalled.

1 Select **QC** > **Ctrl Setup**.

Figure 7.5 Control Setup screen



You can sort the controls by control, lot No and Exp Date.

2 Choose a control in the left list.

The tests configured for the control are displayed in the right list.

3 Enter Rack No., Position, Barcode and Sample ID.

4 Select the **Mean** column of a test and type in the average concentration for it.

The concentration must be above 0 with no more than 8 digits.

5 Select the **SD** column of a test and type in the standard deviation for it.

The SD must be above 0 with no more than 8 digits.

6 Select **OK**.

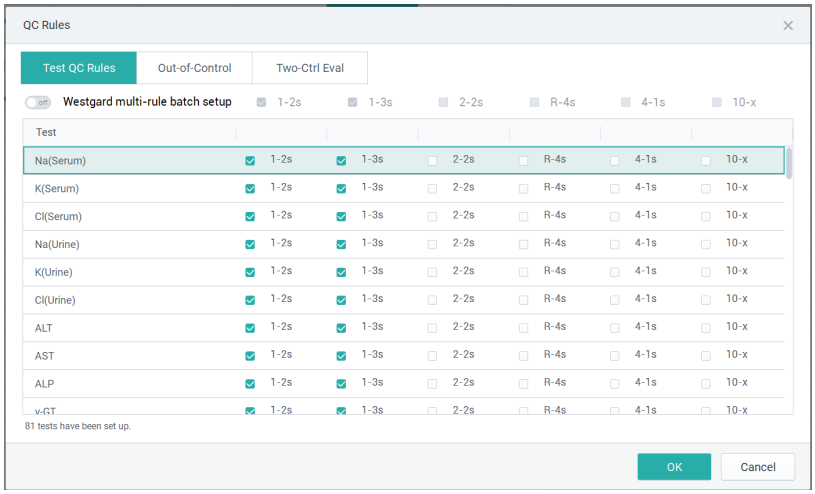
7.3.5 Setting Up QC Rules

You should set up the control rules after defining a control and determining concentrations for it. The controls without QC rule can still be ordered and analyzed but will not be monitored for error detection. You are allowed to change the QC rules when the system is not running any tests.

1 Select **QC** > **Ctrl Setup**.

2 Select **QC Rules**.The **QC Rules Setup** window is displayed.

Figure 7.6 QC Rules Setup window



3 Choose a test you want to define.

4 Choose rules in the Westgard multi-rule setup menu.

You can enable the Westgard multi-rule batch setup switch 

for batch setup.

5 Set up out-of-control warning rules.

6 If you assign a couple of controls for the test, you are allowed to enable the Two-Control Evaluation option.

Those controls that are not included in the two-control evaluation will be evaluated according to the evaluation rules for single controls.

7 Select **OK** to save the settings.

8 Repeat step 3 to 8 to set up quality control rules for other tests.

9 Select the icon  to close the window.

7.3.6 Control Management

7.3.6.1 Deleting a Control

You are allowed to delete controls when the system is not running any tests. When a control is deleted, the control information, concentration parameters and QC results as well as the control position are cleared. If the deleted control is included in the two-control evaluation, the relevant two-control evaluation will be disabled. Those controls ordered for analysis cannot be deleted.

1 Select **QC** > **Ctrl Setup** > **QC Setup**.

2 Choose a control in the list.

3 Select **Delete**.

7.3.6.2 Enabling and Disabling Control

1 Select **QC** > **Ctrl Setup** > **Ctrl Manag**.

2 Choose control(s) in the list.

3 Select **Enable** or Deselect **Enable**.

If you want to disuse certain control, deselect it then this control will not be displayed in the list of controls on the screen.

7.3.7 QC Setup

1 Select **QC** > **Ctrl Setup**.

2 Click **QC Setup**.

3 Set up the interval for auto requesting of daily control.

4 Set up auto QC. The options include:

- QC interval: Set up the number of samples
- QC after calibration

5 Set up **Inherit QC precision**.

Inherit QC precision: If this option is selected, the CV value of the control in the previous lot will still be used when new controls are imported via barcode or file. If this option is disabled, the CV value of the newly imported control will use that imported from QC target value list.

6 Set up **QC Batch Time Limit(Hour)**.

Interval for requesting two batches of QC. The default is 4 hours.

7 Select **OK**.

7.4 Auto Quality Control

7.4.1 Introduction

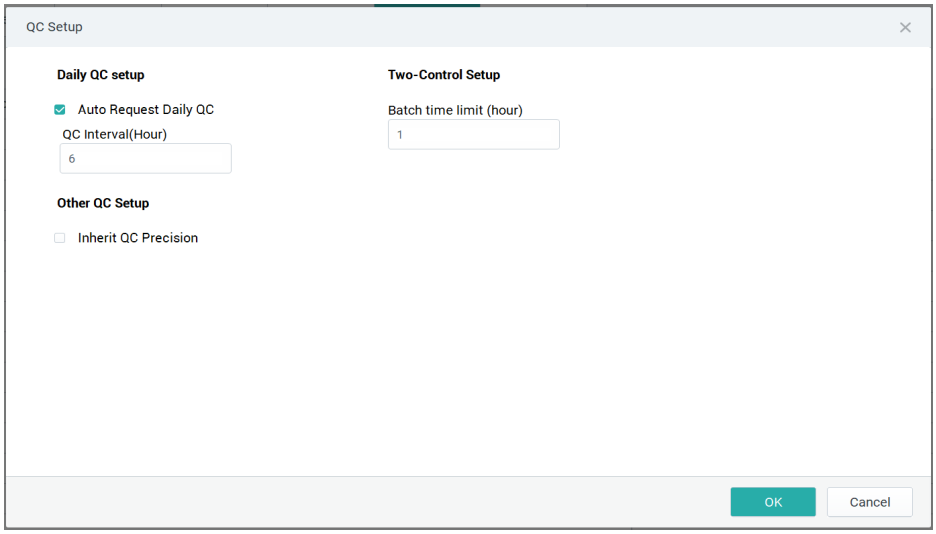
The system provides the auto quality control function. When the conditions for auto quality control are satisfied, a message will pop up reminding you to order controls. The control samples automatically run can be selected on the **QC Rule** window.

7.4.2 Auto QC Setup

1 Select **QC** > **Ctrl Setup**.

2 Select **QC Setup**.

Figure 7.7 QC Parameters window



3 Set up the conditions for auto request quality control:

- QC Interval: set the auto QC interval between two requests.

4 Select **OK**.

7.4.3 Auto Quality Control

When the conditions for auto quality control on racks are satisfied, a message will pop up reminding you to order controls. Order controls according to "3.7 Quality Control" (3-20). Load the controls on the control rack and put the rack into rack supply unit.

7.4.4 Removing Auto QC Status

To remove an auto QC status, deselect the **Auto Request Daily QC** option.

7.5 Recalling Control Results

The Recalling Control Results option allows you to view control sample results, L-J chart, twin-plot chart, analysis data and data summary.

Patient demographics and rerunning are not applicable to controls.

Sample information and rerunning are not applicable to controls.

7.5.1 QC Overview

You can view the QC status on the **QC** - > **Overview** screen.

Display rules of QC status:

- QC out of control: Red background
- QC warning: Orange background
- In-control: White background

The QC status of each level is determined by the last test point at the level.

The screen is displayed via smart sort. Smart sorting rule is QC out of control - QC warning - QC normal - QC not performed.

Click the test card to link to the L-J chart of the test.

A dot indicates the number of QC replicates on the current day, and one dot represents one replicate and a maximum of 5 replicates can be displayed. If more than 5 replicates occur, the last 5 replicates are displayed. If there is no QC test, no dot will be displayed. The color of the dot indicates the QC status:

- Green: Under control
- Yellow: QC warning
- Red: QC out of control

7.5.2 Control Sample Results

1. Select **Sample** > **Current** or **History**.
   - The **Current** screen displays all incomplete patient samples and control samples, as well as those ordered on the current day.
   - The **History** screen displays all patient samples and control samples ordered before the current day.
2. Choose a result recall mode:
   - View Samples
   - View Tests
3. Click filter icon to filter the QC results. Enter the date range and select QC from sample type.
4. When recalling results by sample, choose a control in the left list. The right list displays all results of the control. When recalling results by test, choose a test in the left list. The right list displays all results of the test.
5. Select **Details** to view result flags, alarm information, reaction curve and data. Select **Return** to return to previous screen.
6. Choose the following buttons as needed:
   - **Delete**: to delete the QC results of the selected QC test.
   - **Print** : to print control results.

- **Host** : to transmit the selected control results to the LIS host.

7.5.2.1 Viewing control reaction data

1. Search for desired control results on the **Current** or **History** screen.
2. Choose a test in the result list.
3. Select Result **Details.**
4. Select **Return**.

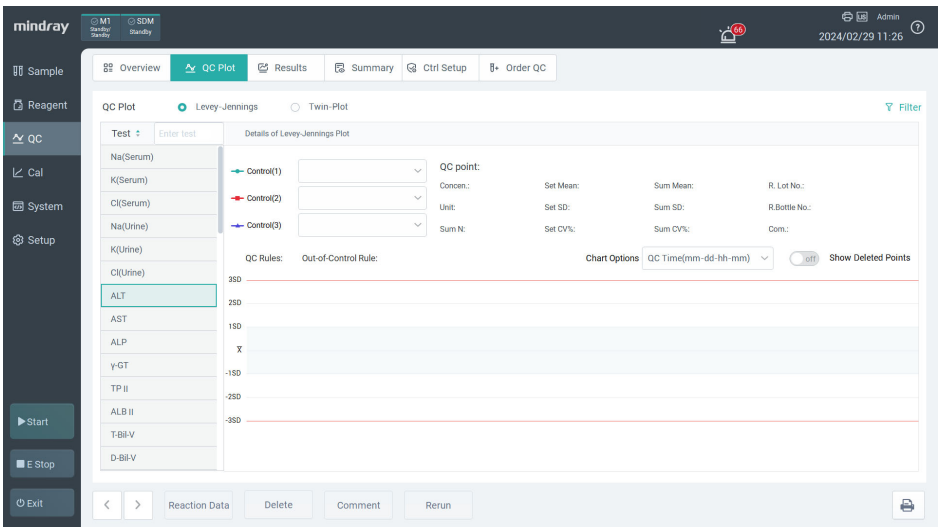
7.5.3 Recalling L-J Chart

A Levey-Jennings (L-J) chart, drawn based on the QC date (X) and test results (Y), shows the QC result trend of a test during the specified period. The graphical trends of up to three controls can be displayed on one L-J chart and distinguished with different colors. The query date must not be longer than 1 year.

7.5.3.1 Recalling L-J Chart

1. Select **QC** > **QC Plot** > **Levey-Jennings**.
2. Choose a test to recall.
3. Click filter icon and select date range.
4. Choose controls you desire to view. Up to 3 controls can be selected.

Figure 7.8 Levey-Jennings screen



5. Choose the following buttons as needed:
   - : to view the L-J chart of the previous test.
   - : to view the L-J chart of the next test.
   - **Delete**: to delete the selected point on the L-J chart. If you want to display the removed points on the L-J chart, mark the **Show Deleted** checkbox.
   - **Print** : to print the current L-J chart.
   - **Comment**: to add, modify and delete comments of a QC point.

7.5.3.2 Adding/Modifying comments

1 Select **QC** > **QC Plot** > **Levey-Jennings**.

2 Select a test, QC date and controls.

3 Choose a QC point on the chart.

4 Select **Comment**, and then choose a comment for the QC point.

QC comment can be defined on the **Dictionary** window.

5 Select **OK**.

Select the QC point on the chart. The comments of this QC point are displayed in the **Comment** area at the upper-right corner of the screen.

To delete the comments of a QC point, select the QC point on the chart, clear the comments, and then select **OK**.

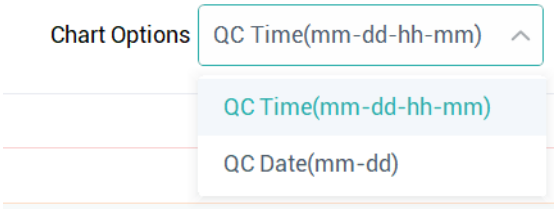
7.5.3.3 Selecting chart option

The L-J chart can be drawn by QC date or QC time. Either of the two options can be selected to display the L-J chart, in which the X coordinate is displayed by date or time. The default standard is QC time.

1 Select **QC** > **QC Plot** > **Levey-Jennings**.

2 Select **Chart**.

Figure 7.9 Chart Options window



3 Choose an option to draw the L-J chart:

- QC Time: The X coordinate of the L-J chart is displayed in the format of "YYMMDDHHMMSS".
- QC Date: The X coordinate of the L-J chart is displayed in the format of "MMDD".

4 Select **OK**. The L-J chart is refreshed automatically and displayed in the selected format.

7.5.4 Recalling Twin-Plot Chart

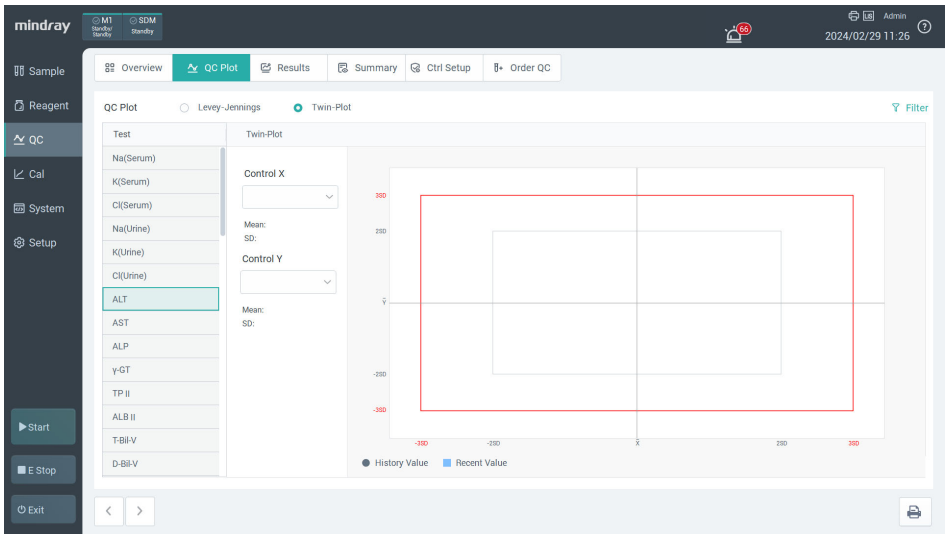
A twin-plot chart, drawn based on the results of control X and control Y in the same run, is used to detect systematic errors and random errors. It shows the recent 10 QC results of a test and excludes those that have been deleted.

1 Select **QC** > **QC Plot** > **Twin-Plot**.

2 Choose a test to recall.

The twin-plot chart area displays the recent 10 results of control X and control Y for the test.

Figure 7.10 Twin-Plot screen



3 Choose the following buttons as needed:

- : to view the twin-plot chart of the previous test.
- : to view the twin-plot chart of the next test.
- : to print the current twin-plot chart.

7.5.5 Recalling QC Data

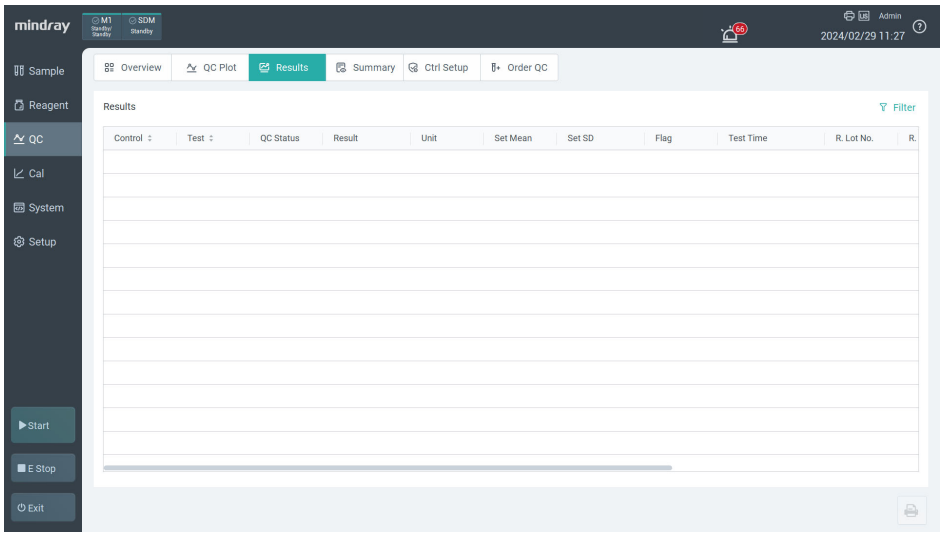
QC data includes QC results, and the set mean and standard deviation, and can be recalled by control name, test name and QC date.

1 Select **QC** > **Results**.

2 Click Filter button to search the results according to time, test and control.

The result list shows all results of the control for the test during the specified period, as well as the set means and standard deviations.

Figure 7.11 Results screen



7.5.5.1 Archive QC Data

The system allows archiving of QC results to a storage device. The file format is CSV and the default file name is QCData.csv. which cannot be edited.

Perform the following steps to archive QC results and data:

1 Search for desired QC results on the **Results** screen.

2 Select **Archive**  .

3 Select **OK**.

7.5.6 Recalling QC Summary

The **QC Summary** reports the measurements of a control for the selected test during the specified period. It presents you the means, standard deviations and coefficients of variation in this period, and compares them with the set mean and SD, enabling you to check if the system is working normally.

1 Select **QC** > **Summary**.

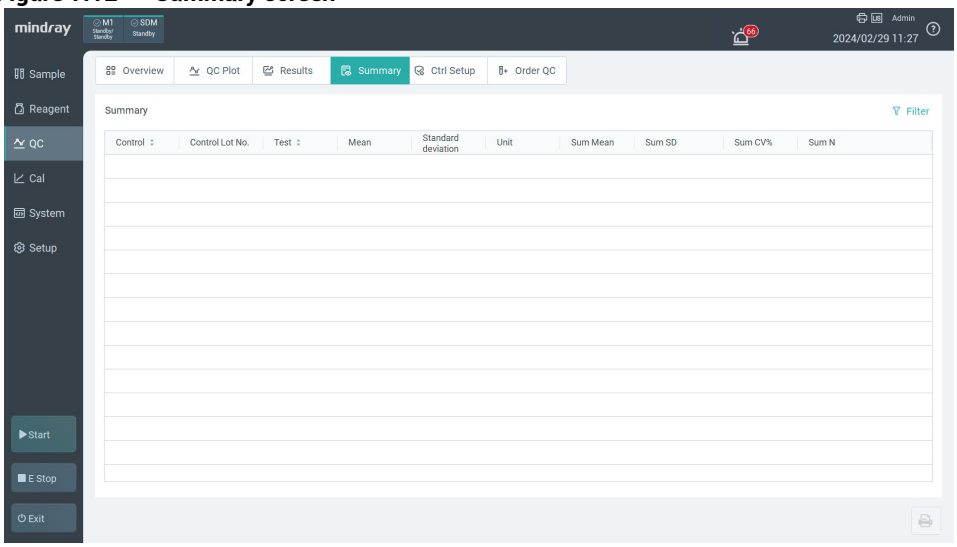
2 Click Filter button to search the results according to time, test and control.

The result list shows all results of the control for the test during the specified period, as well as the set means and standard deviations.

3 Select **OK**.

The result summary of the control for the test is displayed on the screen.

Figure 7.12 Summary screen



4 To print the QC summary report, select **Print**  .

8 Sample Ordering and Processing

In this chapter

8.1 Sample Bar Code

The sample bar code system consists of the sample rack bar code system and sample tube bar code system. The bar code on sample racks is scanned by the bar code reader in the rack feeder system to obtain rack type and rack ID. Sample tube bar code is applied to sample tubes on sample rack. By scanning sample bar code on sample tubes, sample information can be obtained. The bar code reader in the rack feeder system is standard configuration. When bar-coded samples are loaded to sample rack, the system will make a full scan and locate samples through the bar code.

Sample rack bar code

Sample rack bar code has been applied on racks when the racks leave the factory. When sample rack bar code label is damaged and cannot be read normally, it should be replaced immediately.

Table 8.1 Sample rack bar code specifications

Name	Description
Bar code	The bar code consists of 5 characters: XXXXX. The first character indicates rack type, and the remaining characters indicate rack ID. For example, N0001 refers to No.1 normal sample rack. Letter N means normal sample rack; letter E means emergent sample rack, letter C means control sample rack, letter S means calibrator rack, and letter R means rerun sample rack. M means maintenance rack.
Application requirements	Sample rack bar code label should be applied on the front side of rack, facing the sample bar code reader and level to the top of rack. Make sure that the rack ID label is oriented towards the heading direction of rack.

Sample racks can be identified through both bar code and rack ID. The rack ID label is located in the front of rack.

Sample tube bar code specifications

The sample tube bar code reader is in compliance with the Clinical and Laboratory Standards Institute (CLSI) and compatible with various application environments.

Table 8.2 Sample tube bar code specifications

Name	Description
Symbology	Codabar, ITF, Code128, Code39, UPC/EAN, and Code93
Minimum bar code density	0.19mm-0.5mm (7.5mil~19.7mil)
Length	3-27 digits
Format and content	User-defined
Maximum width	55mm
Minimum height	10mm
Maximum inclination angle	±5º
Print quality	No less than Class C according to the *ANSI MH10.8M Print Quality Specification*.
Width and narrowness	2.5-3.0:1

Name	Description
Print paper	Coated paper or matte paper. Printing bar code on common paper may result in vague bar code or degraded bar code label. You are not suggested to print bar code on common print paper.
Characters	Meaningful characters, such as numbers (0-9) and upper-case letters (A-Z). You are recommended to print the check digit in order to check that a bar code is read accurately.

Information contained in a sample tube bar code

The system will obtain the following information from the LIS host based on sample tube bar code:

- Sample category
- Test date/time
- Sample ID
- Sample type
- Panel No.

8.1.1 Sample tube barcode applying requirements

Properly place the sample container with the bar code label facing the scanning slot on the sample rack.

- The bar code label should face the gap on the rack.
- Take the 100 mm high tube as an example. The distance between the lower edge of the barcode (blank not counted) and the bottom of the tube is greater than 20 mm, and the distance between the upper edge of the barcode (blank not counted) and the top of the tube is greater than 17 mm.
- For tubes of other heights, make sure the distance between the lower edge of the barcode (blank not counted) and the tube bottom is greater than 20 mm.
- Stick the barcode label to the tube vertically at an angle of no more than five degrees.

Figure 8.1 Barcode applying requirements

8.1.2 Sample Bar Code Setup

Before performing the setup procedure, check if your system is equipped with a sample bar code reader. If needed, contact our customer service department or your local distributor.

Perform the following steps to set up sample bar code:

1 Select **Setup** > **System** > **Sample Bar Code**.

2 Choose a bar code symbology and set up the check digit status.

The following symbologies are provided:

- Codabar
- Interleaved 2 of 5
- Code128
- Code39
- UPC/EAN
- Code93

Code 128, Code 93 and UPC/EAN requires a check digit by default, and other symbologies are not compulsive. The Code 128 is selected by default and cannot be modified.

CAUTION

- You are recommended to enable the check function for all symbologies in order to prevent misreading of bar code.

---

3 Select **OK** to save the settings.

8.2 Sample Ordering and Processing

Except for analysis of routine samples, you often need to add samples or tests to the order or rerun an abnormal sample. Samples can be diluted manually or pre-diluted automatically before being analyzed.

8.2.1 Adding Samples

BIOHAZARD	• Inappropriate handling of samples may lead to biohazardous infection. Do not touch the samples directly with your hands. Wear gloves and lab coat, if necessary, goggles. In case your skin contacts the samples, follow standard laboratory safety procedure and consult a doctor.

CAUTION	• Do not use expired samples; otherwise, unreliable test results may be caused.

8.2.1.1 Adding samples to rack

New samples can be added at any time in the rack ID mode. Make sure that the added samples are loaded to the assigned racks and positions.

Before adding samples in the bar code mode, ensure that the sample bar code scanning and LIS bidirectional communication functions have been enabled, and the bar code on the sample cups has been applied correctly.

1 Order new samples according to "3.8.1 Routine Sample Orders" (3-22).
2 Check that the sample order information is correct.
3 Load added samples to a new sample rack and put the rack into the lane. The system starts analysis automatically.

8.2.2 Adding/Modifying Tests

No matter in which status a sample is, new tests can be added, and dilution factors and replicates can be defined for them. For samples that are ordered but not analyzed yet, editing the sample information, patient demographics and tests is allowed; for samples in the status of In Progress, Rerun, Incomplete or Complete, the sample information and tests must not be edited, while patient demographics can be edited and new tests can be added.

1 Select **Sample** > **S Orders**.
2 Type in sample ID, bar code, Position, name or patient ID and then press Enter to search for desired sample.
   The ordering information of the sample is displayed on the screen.
3 Deselect tests you won't run, and then select tests you desire to run.
4 Deselect panels you won't run, and then select panels you desire to run.
5 Choose tests and panels to add to the sample.
6 Select **Submit**.

8.2.3 Rerunning samples

Finished samples can be rerun in manual or auto mode. Only tests that have been finished can be rerun. If a test is run for more than one replicate, it cannot be rerun only when all replicates are finished. Manual rerun is performed on the **Abnormal Results** screen, **Current** screen and **History** screen; auto rerun is performed when a result is beyond the set range.

8.2.3.1 Manual rerun on Current or History screen

1 Select **Sample** > **Current** or **History**.

2 Choose the **View Samples** option.

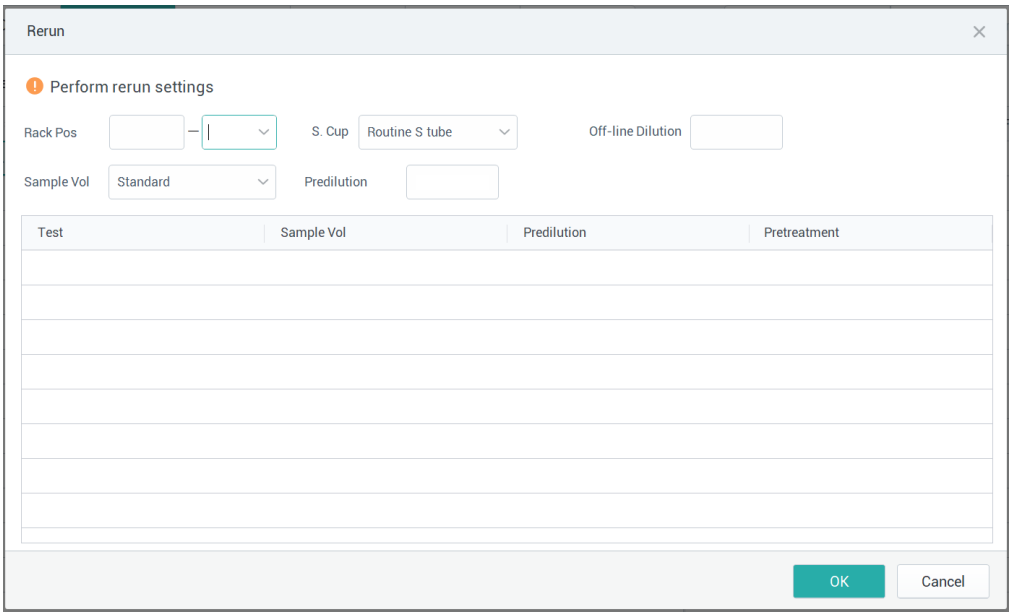
3 Search for desired sample results.

4 Check the **Flag** column for flags indicating abnormalities.

5 Choose results you desire to rerun.

6 Select **Rerun**.

Figure 8.2 Rerun window



7 Change the rack ID and position number.

NOTE

- In rack ID mode, samples can be rerun in the original positions or on a rerun rack; in bar code mode, they can be rerun in any idle positions of a sample rack. To assign positions in bar code mode, only the original or idle positions can be selected.

8 Select a sample volume type to rerun the sample.

The sample volume is the same as that defined for the test. If increased and decreased volumes are defined for the test, Increased and Decreased are available here for selection.

9 Enable or disable sample blank for the sample.

Only when the Set Sample Blank Individually checkbox is selected on the **Setup** > **Analysis** > **Sample Ordering Setup screen**, the Sample Blank option will appear. If you need the settings, contact our customer service department or your local distributor.

10 Choose a sample tube type. The options include micro and standard.

11 Enter the off-line dilution factor.

The input range is 2-9999, and the default is blank.

12 Enter the predilution factor.

The input range is 4-134, and the default is blank.

13 If you want to run a test with different sample volume, replicates and predilution factor, enter the values in the test option area:

- Sample Vol: sample volume required to run the test. The sample volume is the same as that defined for the test. If increased and decreased volumes are defined for the test, Increased and Decreased are available here for selection.
- Predilution: ratio at which samples containing the test will be prediluted before being analyzed. When standard, increased and decreased sample volume parameters are defined, the product between the maximum dilution factor of the three and the auto dilution factor must not be greater than 134.
- Sample Blank: set up sample blank for tests.

14 Select **OK**.

15 Put the original sample rack to the lane.

16 The system starts analysis automatically.

8.2.3.2 Batch rerun on Current or History screen

When recalling results by test on the **Current** or **History** screen, you are allowed to rerun multiple samples of a test that are Complete or Incomplete.

1 Select **Sample** > **Current** or **History**.

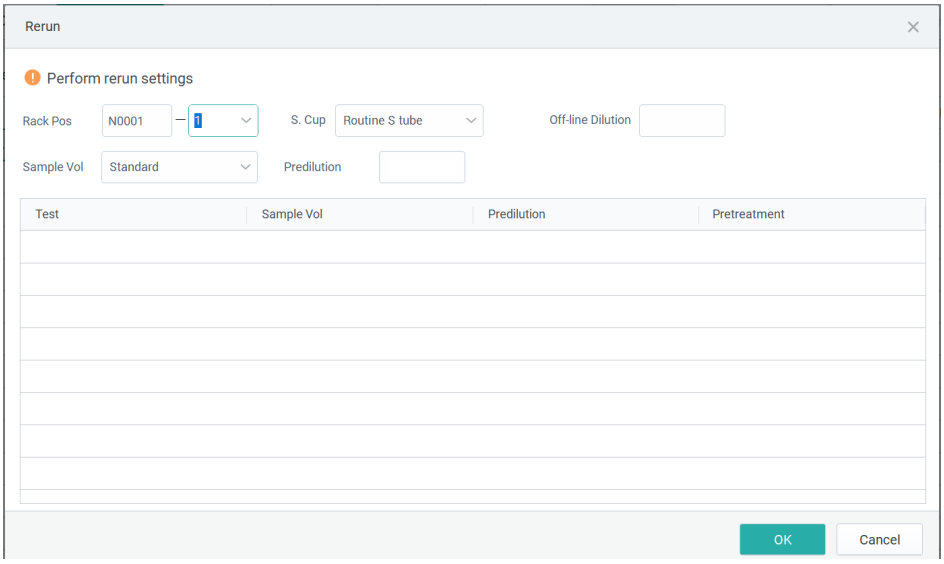
2 Choose the **View Tests** option.

3 Search for desired sample results.

4 Choose a test and samples you desire to rerun.

5 Select **Rerun**.

Figure 8.3 Rerun window



The window shows the selected test and samples, as well as sample ID, bar code, sample volume in previous test, predilution factor, off-line dilution factor, and sample blank.

6 Enable or disable sample blank for the test.

7 Modify the sample volume, predilution factor, off-line dilution factor and sample blank for each sample.
   - Predilution factor: The input range is 4-134, and the default is blank.
   - Off-line dilution factor: The input range is 2-9999, and the default is blank.
   - Sample blank: set up sample blank for samples.
8 Select **OK**.
9 Load the samples.
   - Put the original routine or STAT sample rack to the sample rack lanes.
10 Select **OK** to start the analysis.

8.2.3.3 Rerun on Abnormal Sample screen

1 Select **Sample** > **Abnormal Results**.
2 Select the sample you want to rerun.
3 Choose **Rerun**.

8.2.3.4 Rerun when meeting auto rerun conditions

The auto rerun function can be also enabled on the **Auto rerun Setup** window. Once the auto rerun is enabled, the system will check if the rerun conditions are met, and if they are, will rerun the sample.

1 Select **Setup** > **Tests** > **Auto Rerun** or select **Setup** > **Tests** > **Reference Range** > **Auto Rerun Setup**.
2 Set up auto rerun rules, rerun type and reflex tests.
   The system will rerun the sample if the rerun conditions are met.
3 Select **OK** to save the settings.
4 Select **Return**.

8.2.4 Ordering Samples with Increased or Decreased Volume

In common tests, tests are run with standard sample volume. Owing to the specificity of certain sample, the result may be high or low. To ensure accurate results, the system allows the processing of samples with increased or decreased volume. When a sample is analyzed with standard volume and a result is beyond the reference range or deemed abnormal, you are allowed to rerun the corresponding test manually with the increased or decreased sample volume.

1 Select **Setup** > **Tests** > **View&Set Test**.
2 Choose a test.
3 Select **View** then select **Edit**.
4 Type in the decreased and increased sample volume.
5 Select **OK**.
6 Select **Return**.
7 Select **Sample** > **S Orders**.
8 Enter the following information:
   - ID
   - Sample position (rack ID and position number)
   - STAT status
   - Sample type
   - Comment

- Tests and panels

9 Set the test options:
- Sample volume
- Sample cup
- Number of replicates
- Off-line dilution factor
- Predilution factor
- Sample blank

10 Select **Submit**.

11 The system starts analysis automatically.

8.2.5 Ordering Diluted Samples

Due to patient specificity, certain results of a sample may be relatively high. In this condition, you are allowed to rerun the corresponding tests by manually or automatically diluting the sample at certain ratio for some or all of the tests. When a sample is analyzed and a result is beyond the reference range or deemed abnormal, you are allowed to rerun the corresponding test manually with the sample diluted.

You are allowed to set the sample dilution factors when defining a test or requesting the test for sample analysis. When you set both the off-line dilution factor and predilution factor when requesting a test, the result will be multiplied automatically by the two dilution factors.

If the replicates and predilution factor are set for both the sample and the test, the test will be run based on its own settings instead of those of the sample.

Perform the following steps to run diluted samples.

1 Select **Sample** > **S Orders**.

2 Enter the following information:
- ID
- Sample position
- STAT status
- Sample type
- Comment
- Tests and panels

3 Set the test options:
- Sample cup
- Number of Replicates
- Off-line dilution factor
- Predilution factor
- Sample blank

4 Select **OK**.

5 The system starts analysis automatically.

8.2.6 Sample Analysis Mode

Sample ordering through rack supports two modes: rack ID mode, and bar code mode, and only one of the two modes can be used simultaneously.

8.2.6.1 Rack ID mode

In rack ID mode, the system aligns sample order information with the loaded samples according to the input rack ID and position number, and then analyzes the samples.

When loading samples to racks, make sure the rack ID and position number of the actually-loaded samples is the same with the input one. Racks can be put in any order into the lanes because the system can identify samples through the rack ID and sample position.

Perform the following steps to order single or multiple samples.

Ordering a single sample:

1. Select **Sample** > **S Orders**.
2. Enter the rack ID and position number.
3. Enter the following information:
   - STAT or Routine
   - Sample type
   - Bar code
   - Comment
   - Tests and panels
4. Select **OK**.
5. Repeat steps 2 to 4 to order more samples.
6. Load samples to the assigned positions of the assigned racks.
7. Load samples to the assigned positions of the assigned racks and put racks into the lane.
8. The system starts analysis automatically.

   When system status turns to running from standby, sample request and starting test are successful.
9. To add samples during analysis, repeat steps 2 to 8.

Batch ordering:

1. Select **Sample** > **S Orders**.
2. Enter the rack ID and position number of the first sample.
3. Enter the following information:
   - STAT status
   - Sample type
   - Bar code
   - Remark
   - Tests and panels
4. Select **Batch**, enter the position number of the last sample, and then select **OK**.
5. Load samples to the assigned positions of the assigned racks.
6. Put the racks into the lane.
7. The system starts analysis automatically.

   When system status turns to running from standby, sample request and starting test are successful.
8. To add samples during analysis, repeat steps 2 to 7.

8.2.6.2 Bar code mode

Prior to choosing the bar code mode, ensure that the sample bar code scanning and LIS bidirectional communication functions have been enabled on your system. The system scans bar code on sample cups, obtains sample order information from the LIS host, and then finishes sample ordering and processing automatically.

Perform the following steps to analyze samples in bar code mode:

1. Load bar-coded samples to racks.
2. Put the racks into the lanes.
3. The system starts analysis automatically. The system starts scanning the sample bar code, obtaining relevant order information from the LIS host, and then analyzing the samples.

   When system status turns to running from standby, sample request and starting test are successful.

8.2.7 Sample Blank

Sample blank is similar to sample analysis except for use of equivalent amount of physiological saline. Sample blank is used for removal of non-chromogenesis reaction, such as influence of sample interference (Hemolysis, icterus and lipemia) on absorbance readings.

Running a sample blank

1. Select **Setup** > **Tests** > **View&Set Test**.
2. Choose a test.
3. Select **View** and then **Edit**.
4. Mark the **Sample Blank** checkbox with a tick on Analysis parameters screen.
5. Select **Submit**.
6. Select **Return**.

   The system will run a sample blank when running calibrators, controls and samples for the test.

Recalling sample blank results

1. Select **Sample** > **Current** or **History**.
2. Search for desired sample results.
3. Choose a sample and then a test you desire to recall.
4. Select **Details**.
5. Enable **Sample Blank** Switch.
6. Choose the **Reaction Data** tab to view the reaction data.
7. To print the reaction curve or reaction data, select **Print**.
8. Select **Return**.

8.2.8 Sample Management

Before ordering samples, it is necessary to understand the sample tubes, sample bar code and sample volume of the system, as well as how to load and unload samples.

CAUTION

- Prepare the sample according to the procedure recommended by the tube manufacturer. For collection and preparation of samples, please see the reagent Instructions for Use. Use clean tubes, microcups and other disposable materials specified by the manufacturer. Do not reuse disposables.
- When using vacuum collection tube for sample collection, make sure that the cap of the vacuum collection tube is clean.

8.2.8.1 Sample cup types

The sample rack supports blood collecting tube, centrifugal tube, plastic tube and Microtube, which are available in the following specifications:

- Microtube: Φ14×25mm, 0.5ml (Beckman); Φ14×25mm, 2mL (Beckman); Φ12×37mm, 2mL (Hitachi).
- Blood collecting tube or plastic tube: Φ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13×75 mm, Φ13×95 mm, Φ13×100 mm, Φ16×75mm, and Φ16×100mm.

8.2.8.2 Sample volume

The amount of sample required for a common measurement is 1.5-25μL, with an increment of 0.1μL. Analysis with insufficient samples may lead to inaccurate results.

If a sample is exhausted during the analysis, the system will automatically invalidate all incomplete test of the sample. Before running samples, make sure that they are sufficient in volume for analysis.

8.2.8.3 Loading samples to rack

BIOHAZARD

- Wear gloves and lab coat, if necessary, goggles.

1. Check if the sample inside the sample tube is sufficient for analysis and the bar code label is applied correctly.
2. Load sample tubes to the racks according to the applied analysis mode.
   - Rack ID mode: load samples to the assigned positions of assigned racks.
   - Bar code mode: load bar-coded samples randomly to racks.
3. Check the system status.
   - If the system status is Standby, proceed to the next step.
   - If the system status is Incubation, wait until the system gets steady, and then proceed to the next step.
4. Check if the sample track and the probe have stopped moving.
5. Put the racks into the lanes according to the applied analysis mode.
   - Rack ID mode and bar code mode: put the racks randomly into the lanes.

8.2.8.4 Unloading samples from rack

When the rack lanes are full, take out the racks immediately to prevent rack damage, and then take out sample tubes from the racks.

8.2.9 Delete Sample Orders

The Delete Samples function is used to delete ordered samples that have not been analyzed. One or more samples can be cleared at one time. When samples are cleared, the sample information will be removed completely; the sample ID, position and bar code can be used for ordering other samples. The action of clearing samples will be recorded in the edit logs.

1. Select **Sample** > **S Orders**.
2. Enter the sample ID/bar code, position, patient name or patient ID to inquire the samples.
3. Select **Delete Order**.
4. Select **OK**.

The selected samples are cleared along with their ordering information.

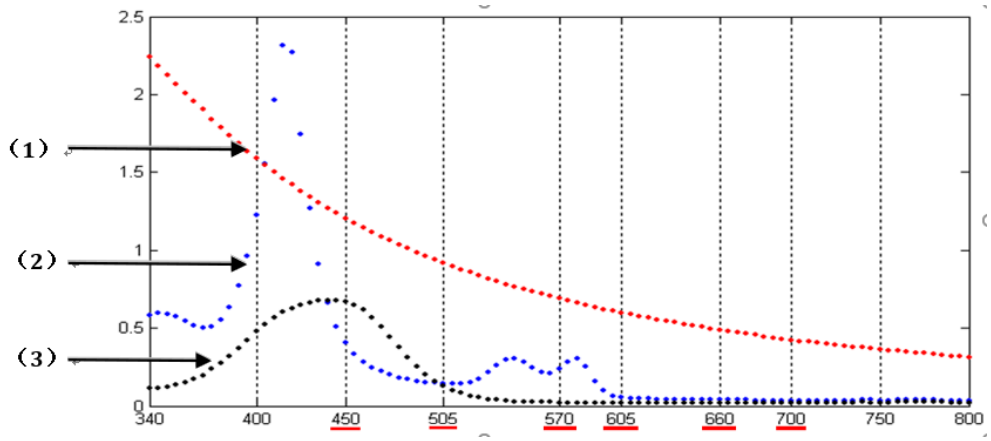
8.3 Serum Index

Serum index is the degree of hemolysis, icterus and lipemia contained in serum sample. They are usually seen in serums and can influence the test results in physical or chemical way.

The serum index function is used to analyze the interferents in samples, helping clinical professionals to evaluate the test results.

8.3.1 Theory of Serum Index

Figure 8.4 Figure 8.4 Absorption spectrum of interferents in serum samples



The figure above shows the absorption spectrum of interferents in serum samples. (1) refers to lipemia, (2) refers to hemolysis, and (3) refers to icterus.

The three interferents are selective to wavelength and have complex absorption spectrums. They cannot be removed completely by means of double-wavelength measurements. The serum index option can be used to analyze the interferents contained in samples, helping clinical professionals to evaluate the test results, determining if the sample is usable or if a sample blank test is needed.

Serum index test is single-reagent endpoint measurement, in which serum sample of 10μL and physiological saline of 200μL are used. Six wavelengths are chosen to determine the serum index. The equations of serum index are as follows:

- Lipemia: primary wavelength of 660, secondary wavelength of 700.
  $A_L = A_{660} - A_{700}$, lipemia index: $L = 1/C \times A_L$
- Hemolysis: primary wavelength of 570, secondary wavelength of 605.
  $A_H = A_{570} - A_{605}$, hemolysis index: $H = 1/A \times (A_H - B \times A_L)$
- Icterus: primary wavelength of 450, secondary wavelength of 505.
  $A_I = A_{450} - A_{505}$, icterus index: $I = 1/D \times [A_I - E \times (A_H - B \times A_L) - F \times A_L]$

Where,

- B and F: determined by the absorption spectrum of lipemia and not adjustable.
- E: determined by the absorption spectrum of hemolysis and not adjustable.
- C: determined by single lipemia, and not adjustable.
- A: determined by single hemolysis, and not adjustable.

8.3.2 Serum Index Setup

The serum index includes lipemia (L), hemolysis (H) and icterus (I), and has the common name of SI. The test name, sample volume and reagent volume of SI are defined by the manufacturer and cannot be modified by users. The SI test cannot be deleted. You are allowed to define the print names and qualitative result flags for the test.

Defining print name

1. Select **Setup** > **Tests** > **View&Set Test**.
2. Choose the **SI** test.
3. Select **View** and then **Edit**.
4. Type in the **print name** of **lipemia** in the Print Name of the Lipemia area. Up to 15 characters can be entered.

   The lipemia index will appear as the print name on patient reports and as "SI" on other reports.
5. Repeat step 4 to define print names for hemolysis and icterus.
6. Select **Submit**.

Defining qualitative result flags

The Qualitative Analysis option, when enabled, analyzes every sample for the detection of lipemia, hemolysis and icterus and calculates the numeric values of the index. If the volume of the interferents contained in a sample is beyond the set range, a flag will be added to the patient report.

The system allows 6 ranges and flags for each interferent.

1. Select **Setup** > **Tests** > **Display Setup**.
2. Choose the L, H or I of **SI** test.
3. Select **Flag Qualitative Results** and mark **Use Qualitative Result**.
4. The **Range** and **Flag** fields below are activated for editing.
5. Type in the detection range in the first edit box of the **Range** field, and then enter a flag in the first edit box of the **Flag** field.
6. For instance, type in 10" in the first edit box of the **Range** field in the **Lipemia** area, and then enter "+" in the Flag field of the same row. If the lipemia volume (L1) contained in a sample is less than or equal to 10, the "+" sign will be added to the result in the patient report. Type in "20" in the second edit box below the **Range** icon and "+-" in the second edit box below the **Flag** icon. If the lipemia volume (L2) is greater than 10 and less than or equal to 20, the result will be flagged with the "+-" sign. The cycle continues. If the result is greater than L5, the six flag will appear on the patient report.
7. Repeat step 4-5 to define ranges and flags for hemolysis and icterus.
8. Select **OK**.

8.3.3 Auto Serum Index

When the Auto Serum Index function is enabled, the system will select the SI test automatically for serum or plasma samples. The SI test will also be requested automatically when you order routine samples manually or by using the LIS host, or order STAT samples, or order routine samples with the default panels.

When ordering samples with auto serum index, you are required to select at least one test other than SI.

1. Select **Setup** > **Analysis** > **SI Settings**.

2 Mark the **Auto Serum Index** checkbox with a tick.

3 Select **OK**.

8.3.4 Running SI Test

The SI test is only applicable to serum and plasma samples (routine and STAT) rather than controls and calibrators.

To run the SI test, choose the SI test while ordering samples. It will be analyzed along with other tests.

8.4 Release Sample Position

8.4.1 Introduction

When a sample is analyzed, the position cannot be used for ordering new sample until it is released. Sample positions can be released automatically at specified time every day. When the set time is reached,

- If the system is shut down, the sample positions in the status of Complete will be released next time when the system is started up.
- If the system is not running any tests, the sample positions in the status of Complete will be released.
- If the system status is Running, the sample positions in the status of Complete will be released when the system status becomes Standby or Failure at the first time.

When a sample is released, its results and ordering information can be still recalled.

8.4.2 Auto Release of Samples

When a sample is analyzed, the position cannot be used for ordering new sample until it is released.

1 Select **Setup** > **Analysis** > **Auto Release Sample**.

2 Select auto release time of patient samples in the **Auto Release Time** field.

3 Enter the **Shift Transition Interval**.

4 Select **OK**.

When the time is reached, the system will automatically release all samples of the current day when system status is standby or Stopped.

8.5 Sample and Test Lists

8.5.1 Introduction

The List option allows you to view, inquire and print all unfinished samples, and assign positions for unpositioned samples.

8.5.2 Sample List and Test List

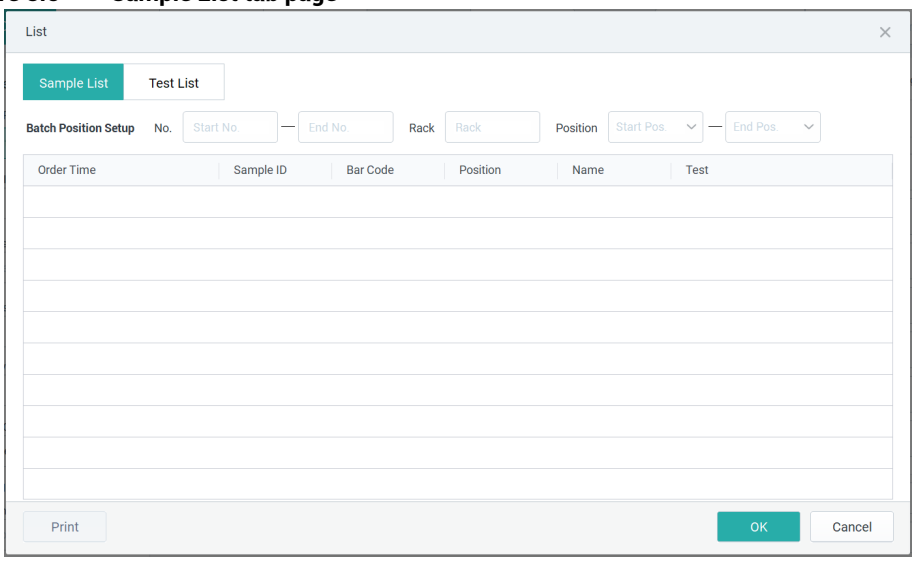
8.5.2.1 Viewing ordered samples

The sample list shows all samples that have been ordered but not analyzed yet. Samples can be inquired by order date, sample status, ID, or bar code.

1 Select **Sample** > **S Orders**.

2 Select **List**.

Figure 8.5 Sample List tab page



3 Select **Sample List** or **Test List**.

4 Set the position for unpositioned samples.

Please first look for the samples without positon then set the positon for them. The positions are assigned automatically according to the start position and the sequence of sample ID.

8.6 Optimizing Result Display

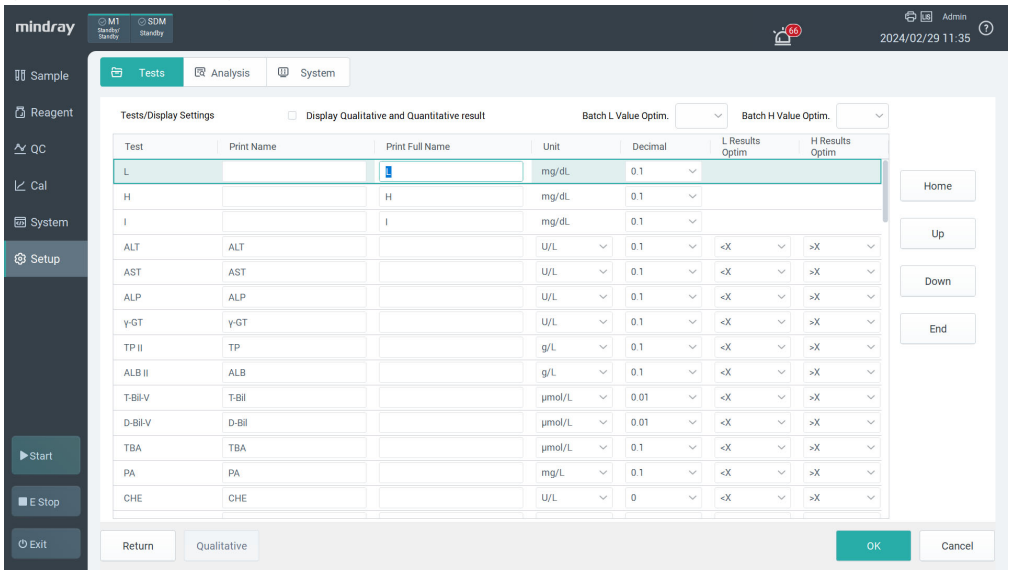
Due to low sensitivity of certain reagents, samples with low concentration may have 0 or negative results, or cannot be represented accurately by results out of linearity range. To express sample concentration accurately, the system provides the Optimize Result Display option to customize such results. When less than the low limit of linearity range, results will show as "< Low limit of linearity range"; when greater than the high limit of linearity range, they will show as "> High limit of linearity range".

Result optimizing will not affect storage, transmission and archiving of results. Only users who have the permissions of system setup are allowed to optimize result display.

8.6.1 Optimizing Result Display

1 Select **Setup** > **Tests** > **Display Settings**.

Figure 8.6 "Display setup" window



2 Find desired test, and mark Optimize low results and Optimize high results.

Click the checkbox again to deselect it.

- Select **Optimize Low results**. When a result is less than the low limit of linearity range or concentration of the lowest-concentration calibrator, it will show as "< X", or " X".
- Select **Optimize high results**. When a result is greater than the high limit of linearity range or concentration of the highest-concentration calibrator, it will show as "> X", or "X".
- Select batch low value optimization and batch high value optimization to optimize the high value and low value results of all tests. Batch optimization can be cleared by selecting the blank value in the drop-down list.

3 Select **OK**.

8.7 Results Recall

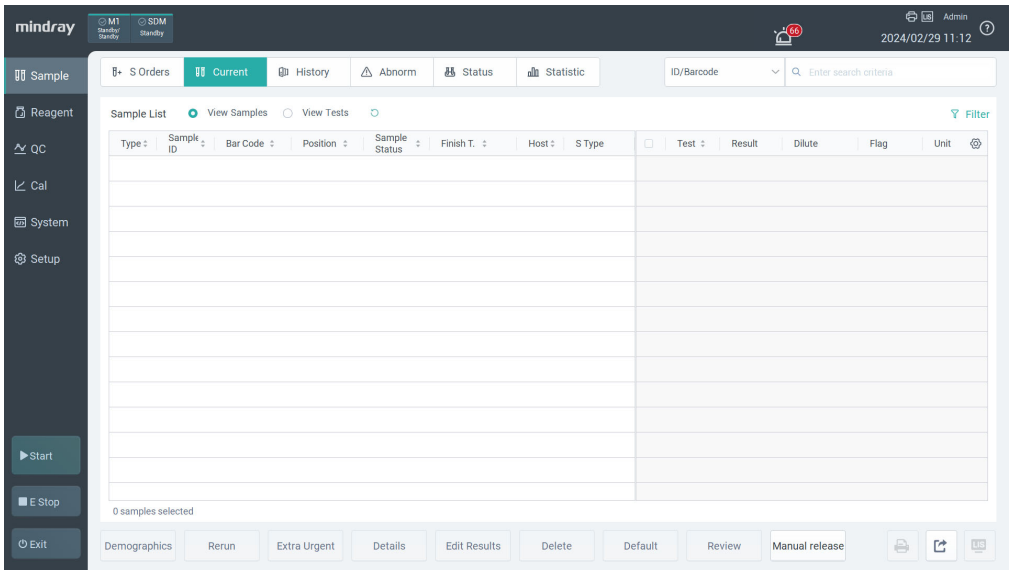
The Results Recall option allows routine samples, STAT samples and controls to be recalled and handled on the **Current** or **History** screen. The **Current** includes those that are ordered and analyzed on the current day; the **History** Results are those ordered and analyzed before the current day. All results can be recalled by sample or by test.

8.7.1 Displaying Current Results

1 Select **Sample** > **Current** or **History.**

The screen shows all samples and controls that are ordered and analyzed on the current day. When certain test of a control sample or patient sample triggers a data alarm, the sample will appear in yellow.

Figure 8.7 Current screen



The sample type includes R, E and C. R stands for routine sample, E for STAT sample, and C for control. The Host column indicates the transmission status of the sample. Y means that the sample has been sent to the LIS host, and N means the opposite. The Print column indicates the print status of the sample. Y means that the sample has been printed, and N means the opposite.

Samples displayed in the sample list can be sorted by the type, ID, status, position, completion time, order date/time, host and print and review fields.

2 Choose a result recall mode:

- View samples
- View tests

3 When recalling results by sample, choose a sample in the left list. The right list displays all results of the sample. When recalling results by test, choose a test in the left list. The right list displays all results of the test.

4 Select **Details** to view Flags, alarms, reaction data, result trace, plots and data list. Click **Return**.

5 Choose the following buttons as needed:

- **Extra Urgent**: to run the sample with top priority.
- **Delete**: to delete sample results.
- **Details**: to view the reaction curve and data of the selected test.

- **Rerun**: to rerun a finished sample.
- **Manual Release**: to release the select sample(s).
- **Edit**: to edit results
- **Demog**: to view patient demographics of the sample.
- **Review**: to review the test results.
- **Print** : to print sample results.
- **Host** : to transmit the selected sample results to the LIS host.
- **Export** : to export results.

8.7.2 Recalling Current Results

Current results can be inquired by sample information and patient demographics, along with the current date. Whichever status the system is, only one condition is required for inquiring desired results.

1 Select **Sample** > **Current** or **History**.

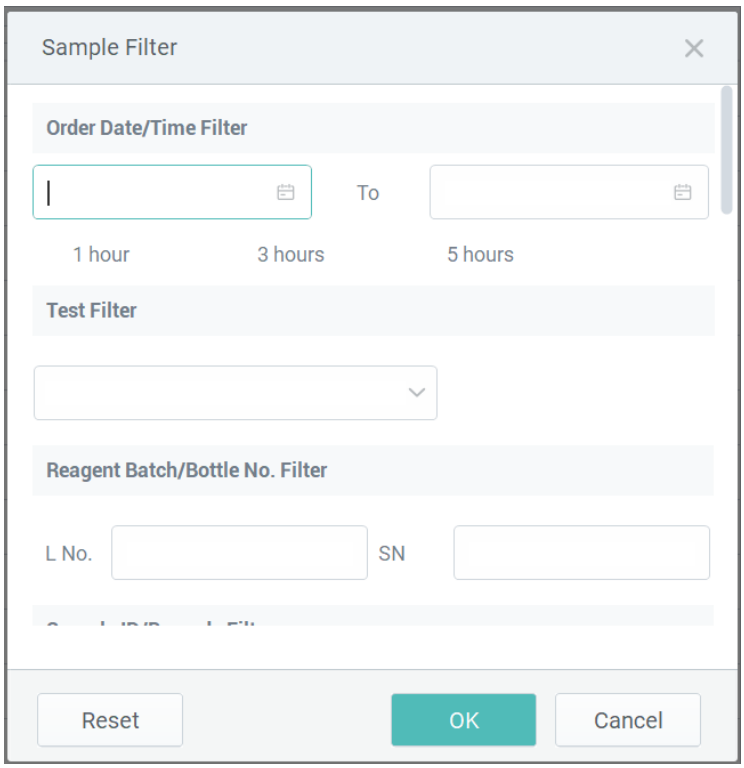
2 Enter the sample ID, bar code, position, patient name or patient ID to search for samples. The system supports fuzzy query.

The retrieved sample information is automatically displayed on the screen.

3 Select **OK**. The samples matching the condition are displayed on the screen.

4 Select a function button to perform relevant operations.

Figure 8.8 Recall results window



8.7.2.1 Search sample via Date/Status/Sample ID

1 Select **Sample** > **Current** or **Result**.

2 Select **Filter** button on the upper right of the screen.

3 Enter Search Conditions.

- Select the order date range from the pull-down list.
- The options include yesterday, within 1h, 3h and 5h.
- Enter the single sample ID or ID range in the ID/bar code field.

4 Select STAT, routine or control in the Sample Type field.

5 Select **OK**. Click Reset to clear the filter condition before confirmation.

The searched results are automatically displayed on the screen. Click of Search Conditions to clear the search conditions and display all sample results.

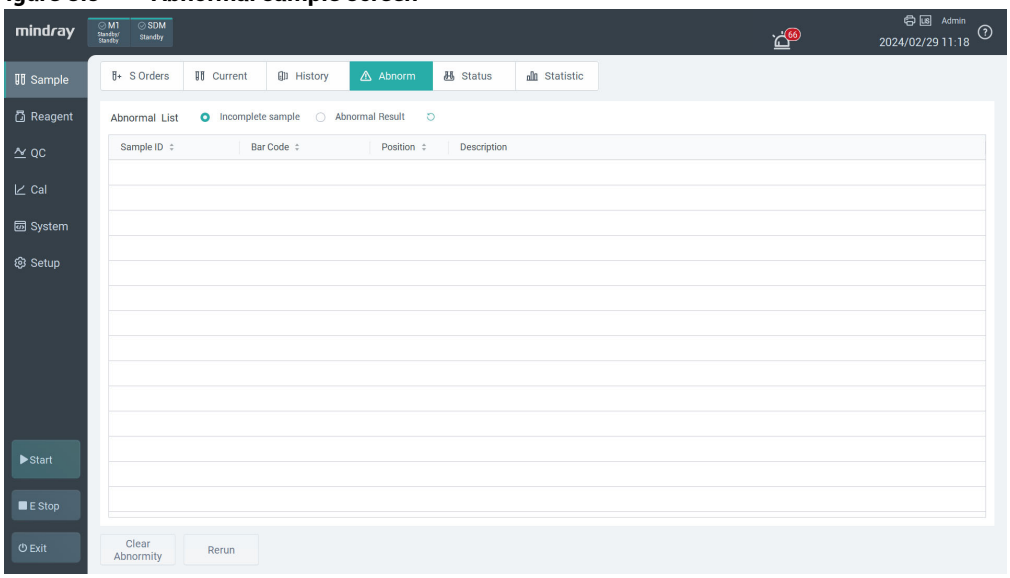
8.7.3 Viewing Abnormal Sample

When the tests of a sample has been completed, but no test result is produced, the sample and its tests will be displayed on the abnormal sample screen.

1 Select **Sample** > **Abnormal Results**.

Sample ID, bar code, position, test, error flag and rerun status of the abnormal sample are displayed in the list.

Figure 8.9 Abnormal sample screen



2 Choose the following buttons as needed:

- **Rerun**: Select this button to rerun the abnormal sample.
- **Result Details**: View result details.

8.7.4 Review Sample Results

Only when the sample status is complete, can the sample results be reviewed.

1 Select **Sample** > **Current** or **History**.

2 Choose the **View Sample** option.

3 Choose a sample or more samples in the sample list.

4 Select **Review**.

The review status in the sample list turns from N to Y.

8.7.5 Viewing/Editing Patient Demographics

Patient demographics can be viewed or edited in any system status.

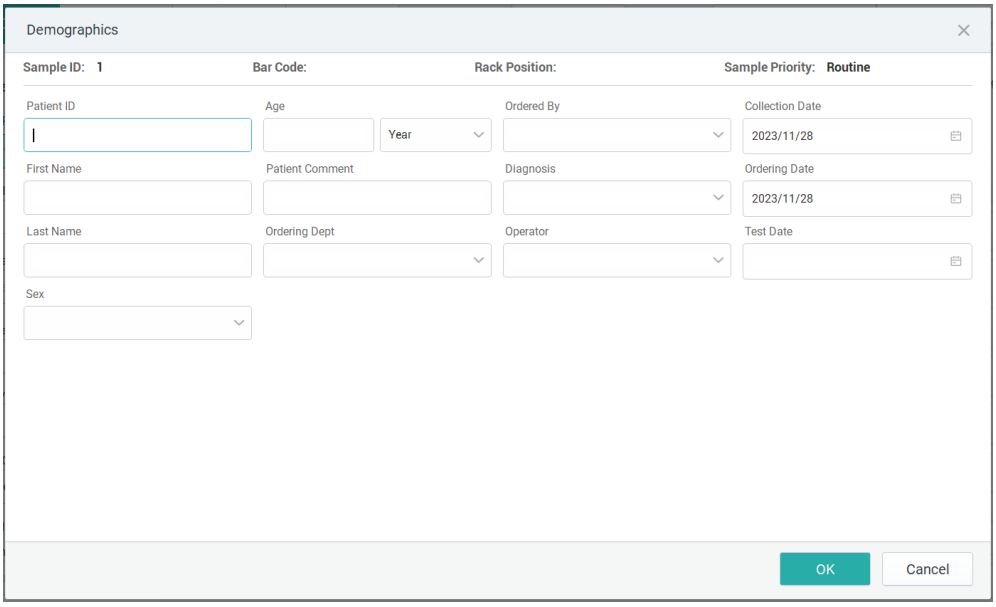
1 Select **Sample** > **Current** or **History**.

2 View the results by samples.

3 Choose desired sample in the sample list. Move the scroll bar on the right of the list to view more samples.

4 Select **Demog**.

Figure 8.10 Demographics window



5 Enter patient information.

6 Select **OK**.

8.7.6 Reaction Data

On the reaction data screen, you can view information of samples and controls, such as test information, results information, calibrator and reagent information.

1 Search for desired sample results on the **Current** or **History** screen.

2 Choose a result recall mode:

- View sample
- View test

3 Choose a test or sample in the result list.

4 Select **Result Details**. The **Reaction Data** screen is displayed.

8.7.7 Transmitting Results to LIS Host

Sample results and QC results can be sent to the LIS host in any system status if the LIS host is connected correctly. The Host option allows the transmission of single or multiple samples, or all samples to the LIS host.

1 Search for desired sample results on the **Current Result** or **History Result** screen.

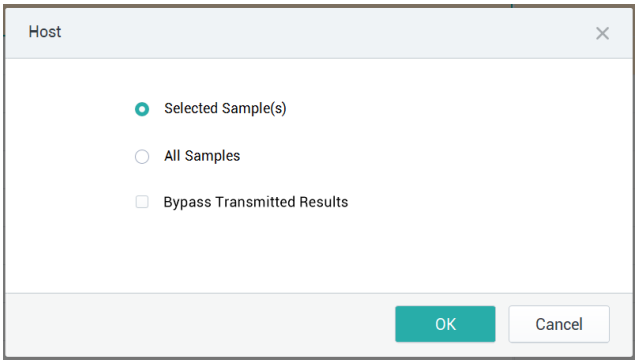
2 View the results by samples.

3 To transmit single or multiple sample results, select them in the left list. To transmit all sample results, do not select.

4 Select **Host** 

.

Figure 8.11 Transmit Results window



5 Select the sample range you want to transmit:

- selected sample(s)
- all samples

6 If you transmit all samples, you are allowed to skip those that are already transmitted to the LIS host. Mark the **Bypass Transmitted Result(s)** checkbox.

7 Select **OK**.

8.7.8 Printing Results

Samples can be printed manually on the **Current** and **History** screens. The system allows multiple samples to be printed on one report or one sample on one report. Before printing the recalled results, you should select a report template on the **System Setup** screen.

The Print option allows single or multiple samples, EQA (External Quality Sample) or all samples to be printed out.

8.7.8.1 Print by Sample

The print by sample option allows you to print the test results of one or more samples when results are recalled by sample.

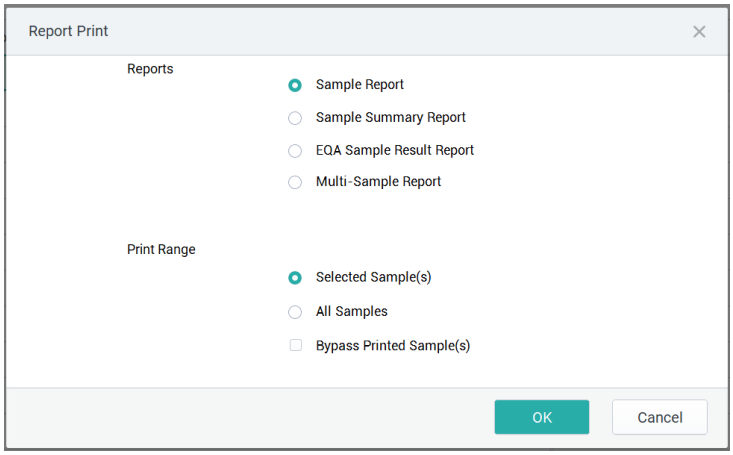
1 Search for desired samples on the **Current Result** or **History Result** screen.

2 Choose the **View Sample** option.

3 To print single or multiple samples, select them in the sample list.

4 Select 
.

Figure 8.12 Print window



5 Select **Sample Report**.

6 Set the print range:

- Selected Sample(s)
- All Samples

7 If you print all samples, you are allowed to skip those that are already printed out. Mark the **Bypass Printed Sample(s)** checkbox.

8 Select **OK**.

8.7.9 Editing Results

The Edit Results option allows editing of results that slightly exceed the reference range or the linearity range but will not lead to mis-diagnosis of patients, or of results that are all on the high side or low side. This option is used for sample results only, exclusive of control results. Results of special calculations cannot be edited while results of off-system test can be edited. Edited results will be flagged for distinguishing from others.

⚠ CAUTION	• Edit Results function gives doctors with freedom to modify the results, and therefore, must be used with cautions. Only users that have sufficient permissions are allowed to edit results.

1 Select **Sample** > **Current** or **History**.

2 Choose a result recall mode:

- View samples
- View tests

3 Enter the sample ID, bar code, position, patient name or patient ID to search for samples. The system supports fuzzy query.

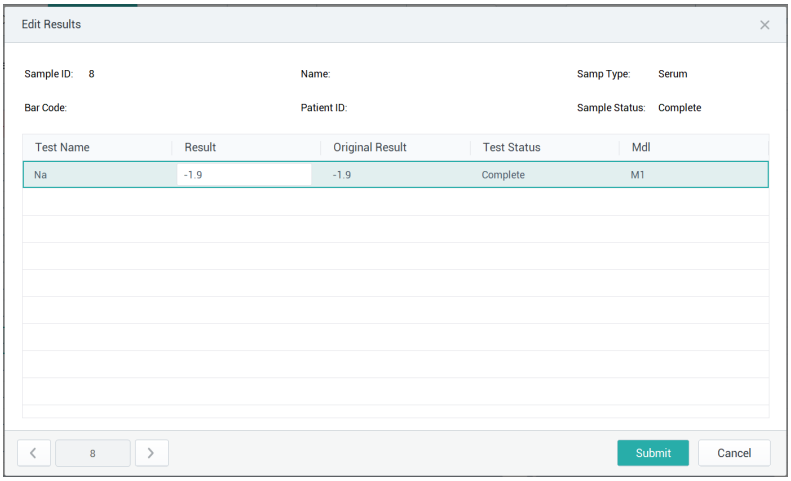
The retrieved sample information is automatically displayed on the screen.

4 Choose a sample or test in the left list.

5 Select **Edit Results**.

The screen shows the sample or test and all measured results.

Figure 8.13 Edit Results window (Current results)



6 Choose a result to edit, and then input result in the **Result** column.
- For normal runs, only Complete tests can be edited.
- For reruns, only the default result can be edited.

7 Repeat step 7 to edit other results.

8 Select **OK** to save your editing.

8.7.10 Deleting Results

The system has a limited storage capacity and can store a maximum of 50,000 samples. The results with the earliest date will be overridden when the capacity is exceeded. The system allows deleting of routine samples, emergent samples and controls, while they are sent to the LIS host or printed out. When the system status is Running, samples in the status of Running cannot be deleted; when the system status is but Running, samples in any status can be removed. Deleted results cannot be restored. Make sure that you have archived them by sending them to the LIS host or printed out or in other ways.

Before deleting a result, check if you have sufficient permissions. Only users that have sufficient permissions are allowed to delete results. The deleting operation will be automatically recorded in event logs.

1 Select **Sample** > **Current** or **History**.

2 Choose a result recall mode:
- View samples
- View tests

3 Enter the sample ID, bar code, position, patient name or patient ID to search for samples. The system supports fuzzy query.

The retrieved sample information is automatically displayed on the screen.

4 Choose a sample or test in the left list.

5 Select **Delete**.

6 Select **OK**.

8.7.11 Customizing Result Display

The Customize Result Display option allows tailoring of sample and result display options on the Current and History screens. When recalling results by sample, the sample list and result list can be customized. When recalling results by test, only the result list can be tailored.

1 Select **Sample** > **Current** or **History**.

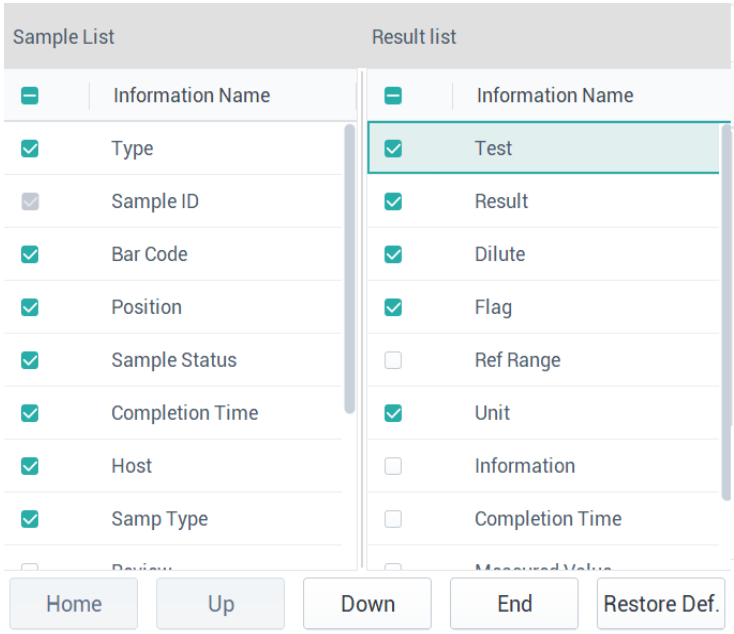
2 Choose a result recall mode:

- View samples
- View tests

3 Select .

4 Select the fields you want to display on the screen.

Figure 8.14 Customize Result Display window



5 If recalling results by sample,

- Choose desired header names in the **Sample List Setup** area and screens where they are going to be displayed. Use the **Up** and **Down** buttons to adjust the display order of the header names.
- To forbid display of a header name in the sample list, deselect the corresponding checkbox. Please note that the Type option for the **History** screen cannot be forbidden.
- Choose desired header names and screen in the **Result List Setup** area. Use the **Up** and **Down** buttons to adjust the display order of the header names.
- To forbid display of a header name in the result list, deselect the corresponding checkbox.

6 If recalling results by test,

Choose desired header names and screen in the **Result List Setup** area. Use the **Up** and **Down** buttons to adjust the display order of the header names.

To forbid display of a header name in the result list, deselect the corresponding checkbox.

8.7.12 Recalculating Results

The Recalculate Results option is used to recalculate current sample results with the latest valid calibration factors of relevant test. This option is often used when test result cannot be calculated due to incomplete or failed calibration.

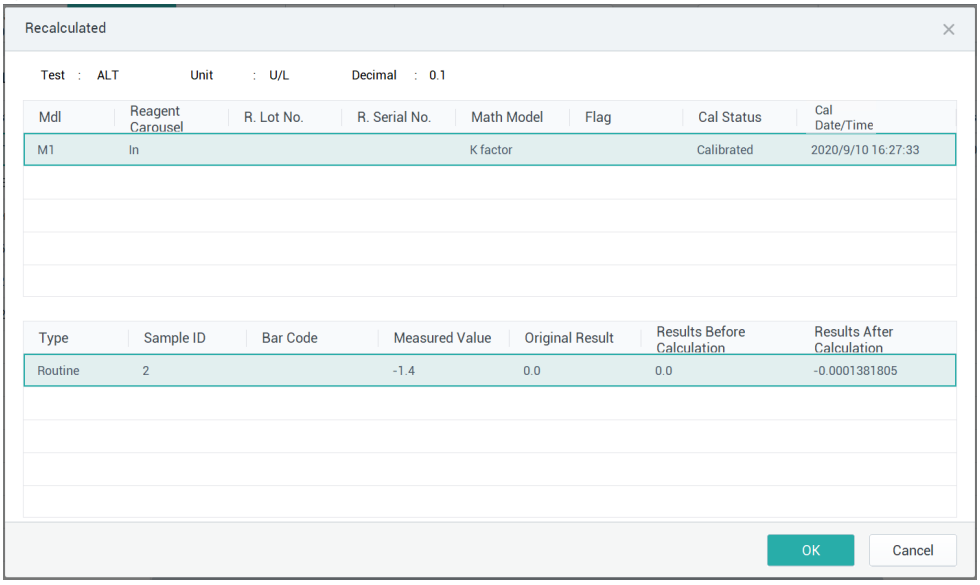
Recalculate Results is only applicable to biochemistries. Result of samples in In Progress status cannot be recalculated. The recalculation will be automatically recorded in event logs.

1 Select **Sample** > **Current Result**.

2 Select a test.

3 Select Recalculate Results.

Figure 8.15 Recalculate Results window



Results of the selected test for the specified samples are recalculated automatically with the latest calibration factors and then displayed in the list at the bottom.

4 Select **OK**.

8.7.13 Compensating Results

The Compensate Results option is used to recalculate multiple results of certain tests through the linear formula Y=K*X+B with specified slope K and offset B.

A calculation will be recalculated automatically once its constituent tests are compensated. Only users that have sufficient permissions are allowed to compensate results. The compensation will be automatically recorded in event logs.

1 Select **Sample** > **Current** or **History**.

2 Choose **View Test**.

3 Choose the test that you want to compensate in the left list.

4 Select Compensate Results.

All results of the test are displayed in the list at the bottom

5 Select desired tests to compensate.

6 Input the slope K and offset B.

7 Select **OK**.

The system recalculates all results of the test with the specified slope and offset. The final results are displayed in the list of the window..

8.7.14 Archiving Results

The system allows archiving of sample results to a storage device. The file format is CSV and the default file name is SampleResultYYYYMMDD.csv.

Perform the following steps to archive sample results and data:

The system allows archiving of sample results to a storage device. The file format is CSV and the default file name is SampleResultYYYYMMDD.csv. which cannot be edited.

Perform the following steps to archive sample results and data:

1 Search for desired sample results on the **Current Result** or **History Result** screen.

NOTE	• It may take a long time to archive a large amount of results. You are recommended not to archive results over one week each time.

2 Select **Archive**  .

3 Select **OK**.

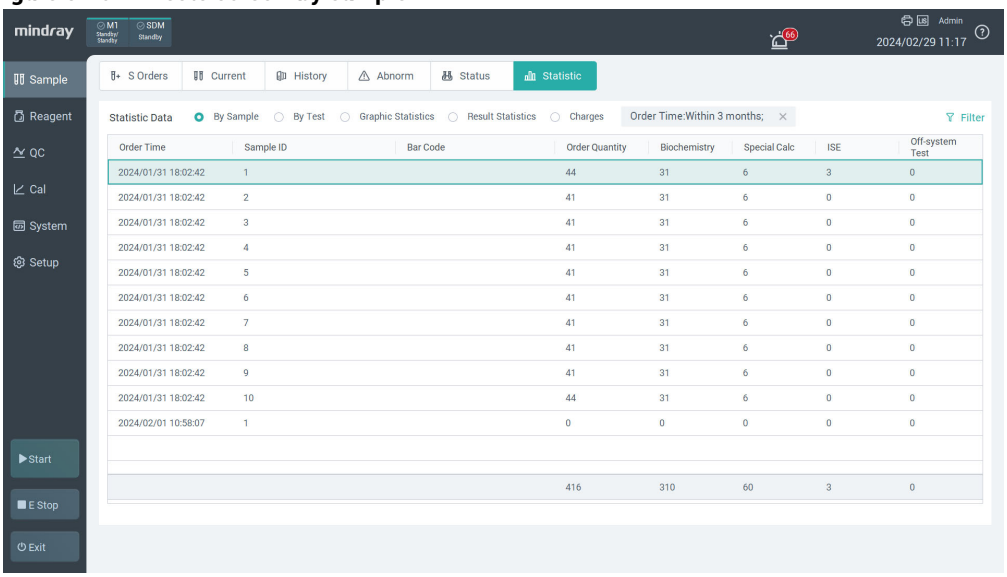
8.8 Test Statistics

On the Tests screen, you can view test requests and reagent application for each test during a period, and you can view sample requests and the quantity of their tests as well. Calibration test and QC test are not included in the statistics.

1 Select **Sample** > **Statistics**.

2 Select **By Sample** or **By Test**.

Figure 8.16 Tests screen-by sample



- By Sample: To view all requested samples and the quantity of their requested tests.
- By Test: To view test requisitions and reagent volume for the tests.

3 Select **Filter** to select the date range.

4 Select **OK**.

All samples or tests requested during the period are displayed in the middle list of the **Tests** screen.

8.9 Result Statistics

Result statistics option can summarize the total tests and the distribution trend of its results, and provide the test data and graph. Calibration and control test are not included in the statistics.

1 Select **Sample** > **Statistics**.

2 Select the **Statistic Graph** or **Statistic Data** tab.

3 Click **Filter** to select the date range.

The relevant statistic results are displayed on the screen:

Figure 8.17 Result statistics screen -statistic graph

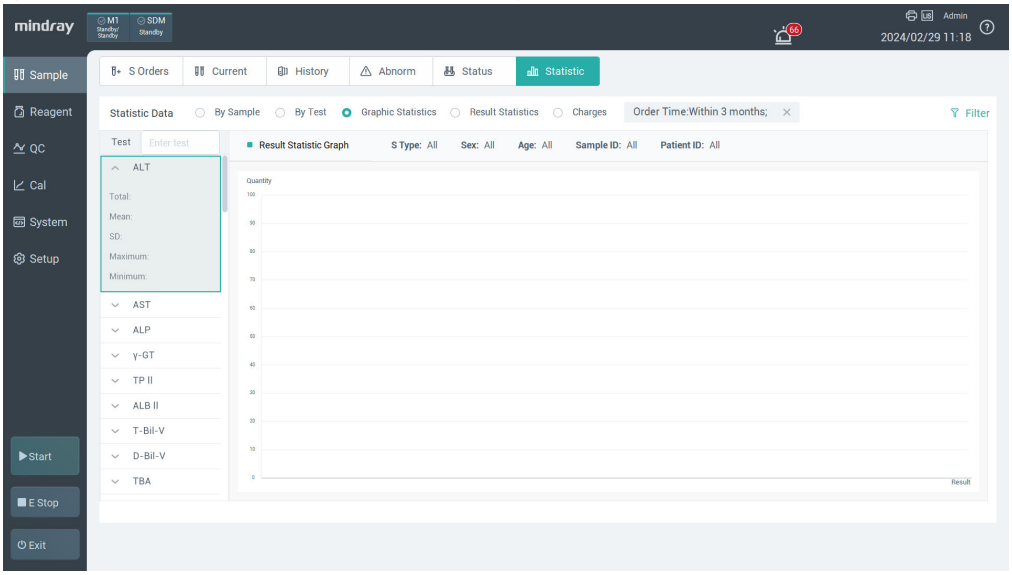
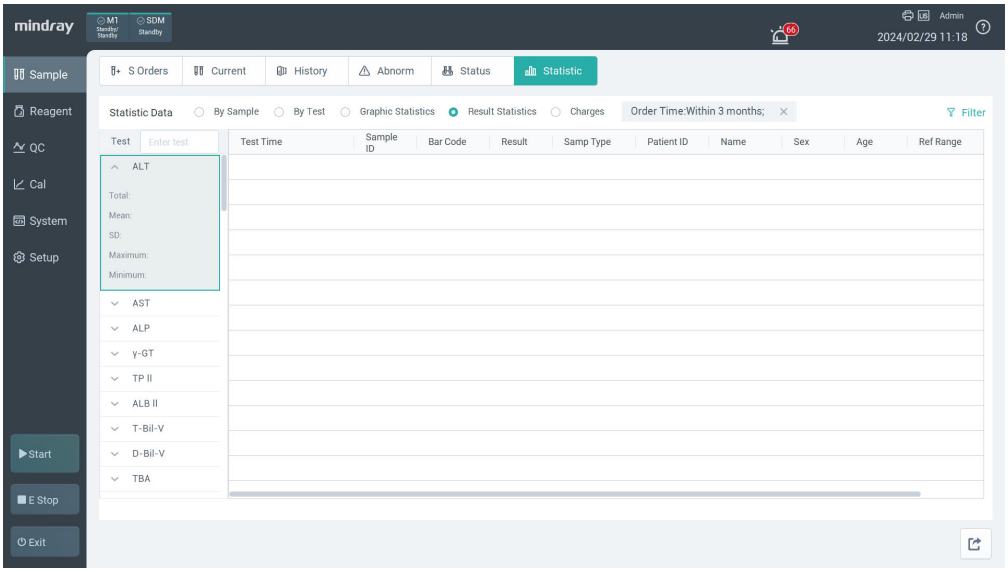


Figure 8.18 Result statistics screen -statistic data



4 Click **OK**.

The relevant statistic results are displayed on the screen.

5 Select  to print out the statistic graph and statistic data.

8.10 Charge Statistics

On Charge statistics screen, you can view the charge information in a period of time.

8.10.1 Charge Setup

1. Select **Sample** > **Statistics**.
2. Select **Charge**.
3. Select **Charge setup**.
4. Set the charge for each test.
5. Select **OK**.

8.10.2 Search Charges

1. Select **Result** > **Statistics**.
2. Select **Charge**.
3. Click **Filter** to select the date range.
4. Select **OK**.

The number of tests and charges for each patient and the total quantity of tests and the sum of charges are displayed on the screen.

9 Use of ISE Module

In this chapter

9.1 Precautions on Use

9.1.1 Introduction

Read the following precautions thoroughly prior to using the ISE module.

9.1.2 Precautions on Use

Sample rack bar code has been applied on racks when the racks leave the factory. When sample rack bar code label is damaged and cannot be read normally, it should be replaced immediately.

Operator Precautions

⚠ WARNING

The system should be unpacked and installed only by technicians of or authorized by our company.

Driver parts precautions

⚠ WARNING

Exercise caution while using the ISE module. Prevent your hair, legs or other parts of your body from being hurt by the driver parts.

Serum sample biohazards

☣ BIOHAZARD

The serum samples remaining in the electrodes may contain a great number of viruses. Wear gloves to prevent infection while operating around the electrodes. If the sample contacts skin, wash it immediately with soap and water.

Contact with the waste tube of ISE waste liquid may lead to infection. Follow the standard laboratory specifications. Wear gloves and mask when handling ISE waste and ISE waste tube.

Electrode precautions

⚠ CAUTION

Before installing the electrodes, visually check whether the liquid inside the electrodes is free of bubbles and whether the black sealing rubber ring is lost.

The service life of is 10,000 samples, nine months on-board for Na+, K+, and reference electrodes or 10,000 samples, six months on-board for CL- electrode or until the expiration date on the electrode package, whichever occurs first.

If electrodes are stored in refrigerated environment, allow them to equilibrate in room temperature for a period of time before use.

Calibration precautions

CAUTION

Calibrate the ISE chemistries before starting the measurement. If the result of a chemistry is based on the calibration factors of another chemistry, it may not be accurate enough.

After changing electrodes or other consumables, calibration is performed automatically. The validity period of ISE calibration is 8 hours.

ISE reagent pack biohazards

BIOHAZARD

The ISE reagent pack contain waste including serum. In case your skin contacts it, wash them off with soap and water. In case the waste spill into your eyes, rinse them with water and consult an oculist. If you swallow them by mistake, see a doctor.

CAUTION

Please use the reagent specified by our company for analysis. Using unspecified reagent may result in erroneous test results, damage the hydropneumatic system, and even reduce the life span of electrodes.

Before using ISE reagent, check if it is within the validity period.

Please place the reagent properly. Incorrect placement may affect test results or result in leaks and module damage.

ISE detergent biohazards

BIOHAZARD

The ISE detergent is sodium hypochlorite. Use the ISE detergent carefully to prevent it from contacting your skins or eyes. If your skins or eyes contact the ISE detergent, rinse them off with fresh water and consult a doctor.

Do not use the uncapped detergent that is beyond the validity period; otherwise, the cleaning effect may be affected and the accuracy of the test results may be affected.

9.2 Principles of Measurement

The ISE unit measures the concentration of Na+, K+ and Cl- ions contained in serum and urine samples with the ion-selective electrode method. The relation between the electromotive force of ion-selective electrodes and the ion concentration is expressed in a Nernst formula. Serum is tested without dilution while urine should be diluted manually before test at the ratio of 1:9.

A single measurement of the ISE unit is conducted in the following order:

- Drainage: The calibrator in the ISE pipe is drained
- Sample analysis: The sample probe dispenses the sample (70μL for serum sample, 140μL for diluted urine) into the sample injection port of the ISE module and then the sample is absorbed into the flow cell for measurement. When the measurement is finished, the waste is drained from it.
- Cleaning pipework: 100μL calibrator A is dispensed into the ISE module for cleaning the ISE flow cell.
- Single point calibration: 80μL calibrator is dispensed into the ISE module to perform single point calibration. The table below lists the measurement range of the ISE module:

Table 9.1 Measurement range of ISE module

Name	Serum	Urine
Na+	100-200mmol/L	10-500mmol/L
K+	1-8mmol/L	5-200mmol/L
Cl-	50-150mmol/L	15-400mmol/L

Sample racks can be identified through both bar code and rack ID. The rack ID label is located in the front of rack.

9.3 ISE Test Parameters

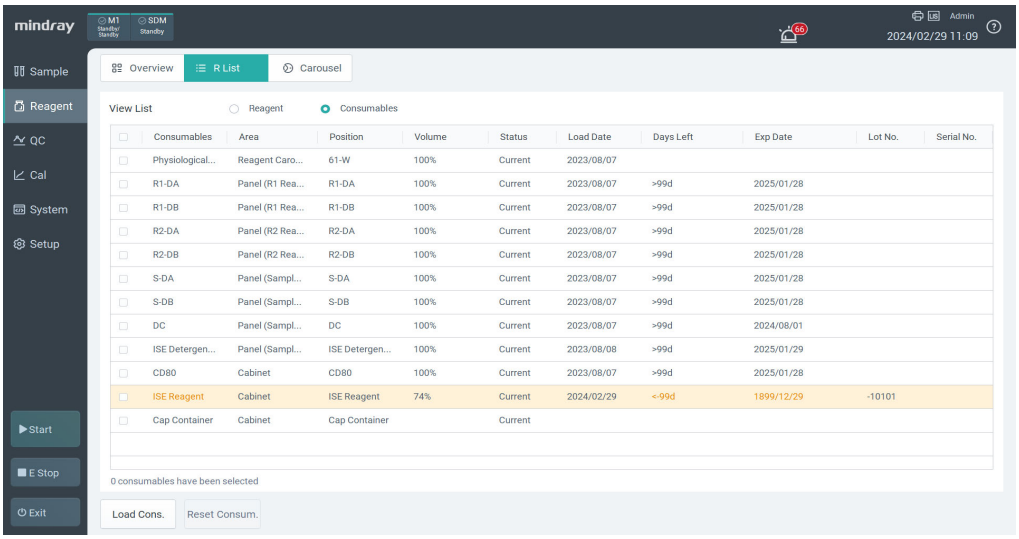
9.3.1 Introduction

The ISE module measures the concentration of K+, Na+ and Cl- ions contained in human body fluid by means of electrodes, helping diagnosis of electrolyte disturbance, body fluid equilibrium, and other relevant diseases.

The ISE tests are applicable to serum and urine, and the default sample type is serum. If the sample is of a type other than serum and urine, it will be analyzed with the test parameters for serum.

ISE chemistry parameters can be viewed but cannot be modified and reconfigured.

Figure 9.1 Define/Edit ISE tests window



9.3.2 Viewing ISE Test Parameters

The ISE test parameters are opened to all users for viewing in any system status.

1 Select **Setup** > **Tests** > **View&Set Test**.
2 Choose the **ISE** test.
3 Select **Define**.
4 View the parameters
5 Select **Rerun** to close the window.

9.3.3 Defining Print Name

The ISE tests are only represented by their print names on patient reports and appear on other reports in the form of short name, i.e. Na, K, Cl. The print names can be defined and modified, and if left blank, will be replaced by the short names on patient reports.

1 Select **Setup** > **Tests** > **View&Set Test**.
2 Choose the **ISE** test.
3 Select **View** and **Edit**.
4 Choose a sample type from the Sample Type pull-down list.
5 The options include:
   - Serum
   - Urine

6 Enter the print names for Na, K and Cl in the **Print Name** field.

7 Select **Submit**.

8 Select **Return**.

9.3.4 Introduction to ISE Test Parameters

ISE chemistry parameters and measurement range are displayed on the Define/Edit ISE chemistries screen. ISE chemistry has two test mode: serum and urine. For urine, it has to be diluted manually before test.

In the following table, U stands for urine and S for serum.

Table 9.2 ISE chemistry parameters(cannot be edited)

Parameter/Chemistry	K+	Na+	Cl-
Unit (S)	mmol/L	mmol/L	mmol/L
Unit (U)	mmol/L	mmol/L	mmol/L
Decimal (S)	0.01	0.1	0.1
Decimal (U)	0	0	0
Measurement Range (S)	1.00-8.00	100.0-200.0	50.0-150.0
Measurement Range (U)	5-200	10-500	15-400

Unit

The unit of K, Na and Cl is mmol/L which can be viewed but cannot be edited.

Decimal

The decimal of the result can be viewed but cannot be edited.

Measurement Range

The measurement range can be viewed but cannot be edited.

9.4 Preparing ISE Reagents for Measurement

9.4.1 Introduction

When the ISE module is removed from the system, the ISE and wash solution that have been loaded will be cleared automatically. Install and replace ISE reagents as instructed below.

9.4.2 Prepare ISE Reagent Pack

The ISE reagent pack is used to clean the tubes and electrodes, calibrate and prime them daily and can only be loaded manually.

1. Check the system status and perform reagent package replacement when the system status is Standby. Unloading reagent package when the ISE module is in working status (running or maintenance) will cause the module to stop.
2. Use scissors to cut off the sealed and waterproof plastic bags of the reagent pack. Remove the rubber plug at the reagent interface before loading the reagent pack. Install the white plastic handle on the front housing of the reagent pack.

9.4.3 Replace ISE Reagent Pack

1. Check the system status and perform reagent pack replacement when the system status is Standby. Unloading reagent package when the ISE module is in working status (running or maintenance) will cause the module to stop.
2. Pull out the old reagent pack. When removing the reagent pack, do not pull the connector of the old reagent package downward. Apply the rubber plug immediately to prevent waste from spilling. After the reagent pack is taken out of the instrument, the reagent compartment indicator will continue to flash, and a prompt will be displayed on the software screen.
3. Insert the new reagent pack into the reagent compartment. After the installation is correct, the reagent compartment indicator will stop flashing, and a prompt will pop up on the software screen.
4. When the reagent loading procedure is complete, a window will pop up. The reagent loading process includes auto calibration.

9.4.4 Preparing ISE Cleaning Solution

ISE cleaning solution is used to clean the electrodes and can only be loaded manually.

1. Check the system status and operate accordingly.
2. Place ISE cleaning solution in the ISE DET position on the panel.

9.4.5 Loading ISE Cleaning Solution

Replacing cleaning solution can be performed when the ISE module status is Standby or Running. If the system status is Standby, you are allowed to directly replace the wash solution in the same way as it is loaded. If its status is Running, you are allowed to replace the ordered sample after finishing the current analysis. If the calibration is in process, the replacement can only start after the whole calibration is finished.

1. Check the system status and operate accordingly.
   - Standby, Incubation or Sleep: Proceed to the next step.
2. Unload ISE cleaning solution in the ISE DET position on the panel.

3 Place new ISE cleaning solution in the position.

9.5 Calibration and Results Recall

9.5.1 Introduction

Current calibration factors and all intermediate data are provided on the ISE Calibration screen. Calibration results can be printed out or archived to an external storage device. The Trend option is provided to enable you to view the calibration trends of ISE chemistries during a period of time. When the calibration factors are expired, the Extend Calibration Time can help prolonging their validity period for measurement.

9.5.2 Calibration Status and Alarm

On the Calibration Status screen, the tests are indicated with various texts and colors for different calibration status. Tests in Cal Required, Cal Failed or Cal Time Out status can be requested but will not be run.

Check the tests' calibration status frequently and take relevant actions according to the following table.

Table 9.3 ISE calibration status

Calibration Status	Description	Severity	Color
Cal Required	Indicates that the test needs to be calibrated. This status appears when the test is not calibrated or the ISE reagent/electrode is replaced.	Serious	Red
Requested	Indicates that the test has been requested for calibration but not finished yet.	Normal	No color indication
Calibrated	Indicates that the test has been calibrated successfully and has not exceeded the calibration time.	Normal	No color indication
Cal Failed	Indicates that the test has calibration factors calculated but they exceed the acceptance limits, or has no calibration factors calculated.	Serious	Red
Cal Time Out	Appears when the test exceeds the calibration period or the reagent of different serial number and lot number is used. Appears when the test exceeds the calibration time.	Serious	Red
Cal Time Extended	Indicates that the calibration period has been extended and the current calibration factors can be used without time limit.	Warning	Yellow

9.5.3 Requesting a Calibration

ISE chemistries, which include Na, K and Cl, are calibrated without being divided into ISE serum and ISE urine.

1 Select **Cal** > **Overview**.
2 Choose an analyzer or All to run calibration.
3 Choose **ISE Serum** or **ISE Urine**, or choose both of them.
4 Select **Cal**.
5 To cancel the calibration requisition, select **No Cal** .
Only calibrations in Requested status can be cancelled.

9.5.4 Starting Analysis

1 Select **Cal** > **Overview**.
2 Select **Load List** .
3 The calibrator list shows all requested ISE tests as well as calibrators, positions, concentration, lot number and expiration date.
4 load calibrators to the relevant rack according to the calibrator list.
5 The analyzer starts analysis automatically.

9.5.5 Results Recall

The calibration data and trends of ISE tests are provided on the ISE Calibration screen. The system allows you to recall the current ISE calibration factors and results of recent 540 calibrations. If a calibration result is abnormal, a flag will be added on patient reports and on the ISE Calibration screen.

For more information about result flags, refer to "12.4 Data alarms" (12-6).

9.5.5.1 Recalling calibration results

1 Select **Cal** > **Cal Result**.
2 Select Filter button and input date range.
3 Select **OK**.

The calibration results of the test are displayed in the result list.

9.5.5.2 Recalling calibration data

All intermediate data during the ISE calibration can be recalled through the ISE Calibration Data window.

1 Search for desired calibration results on the Calibration Result screen.
2 Select **Cal Data**.
3 Choose an ISE test in the result list.

9.5.5.3 Recalling calibration trends

1 Search for desired calibration results on the Cal Result screen.
2 Select **Cal Data**.
3 Select **Trends**. The Calibration Trends window is displayed.
4 Select Filter button and input date range.
5 Choose the Tabular Trend tab to view the trend data.

9.5.5.4 Printing ISE calibration results

Both the current and early calibration factors of ISE tests can be printed.

1 Select **Calibration** > **Cal Result**.

2 Search for desired calibration results.

3 Select Print button.

9.6 Quality Control and Results Recall

9.6.1 Quality Control and Results Recall

Control samples can be defined, run and recalled for the ISE chemistries in the same way as for biochemistries. The ISE chemistries include Na, K and Cl.

Observing QC reaction curve and data is not applicable to ISE chemistry.

For the operating procedure of quality control, refer to "3.7 Quality Control" (3-20).

For details of QC evaluation and results recall, refer to "7 Quality Control" (7-1).

9.7 Sample Ordering and Results Recall

9.7.1 Sample Ordering and Results Recall

The ISE chemistries, like biochemistries, can be also used for analyzing routine samples, emergent samples, added samples and reruns, and requested along with the biochemistries. They are requested in the form of Na, K and Cl, and applicable to serum, plasma, urine, CSF and other sample types. The four sample types other than urine are programmed with the serum parameters, while urine sample is with the urine parameters.

Nevertheless, the ISE chemistries are slightly different from biochemistries for that they do not support the measurement with increased or decreased or prediluted samples, and have no reaction curve and data.

For the operating procedure of sample analysis, refer to "3.8 Ordering routine samples" (3-22).

ISE test results have no reaction curves and can be recalled in the same way as other tests. Refer to "8 Sample Ordering and Processing" (8-1) for details.

9.8 ISE Prime Cycle Setup

9.8.0.1 Introduction

Each time a ISE reagent packet is detected during startup, the ISE module performs priming. Ensure that the tubing is filled with liquid. The number of reagent prime cycles can be set up on the System Setup screen.

Only administrators are allowed to define or modify the prime cycles.

9.8.0.2 Defining ISE Prime Cycles

1 Select **Setup** > **System Setup** > **Configration**.

2 Enter the prime cycle of ISE Prime Cycle edit box.

The input range is 1~9, and the default is 1.

3 Select **OK**.

9.9 Troubleshooting ISE Module

9.9.1 Troubleshooting ISE Module

The failures occurring on the ISE module may be related to the sample probe unit, rack feeder unit, Hydropneumatic unit, ISE module, reagent inventory, reference electrode and communication.

For troubleshooting of the ISE module, refer to "12 Alarms and Troubleshooting" (12-1).

9.10 Daily Maintenance

To ensure the ISE module's life span and measurement performance, maintain it regularly as instructed in this manual. The system provides scheduled maintenance and maintenance instructions, in which the latter contains all of the scheduled maintenance procedures and some maintenance instructions that can be performed independently.

The table below is a summary of the scheduled maintenance procedures and maintenance instructions for the ISE module.

Table 9.4 Table 9.4 Scheduled maintenance and instructions for ISE module

Schedule	Maintenance Procedures
Daily	Clean ISE tubes
Monthly	ISE tube special wash
As required	ISE initialization
	Replace ISE electrodes

For more information about ISE module maintenance, refer to "11 Maintenance" (11-1).

10 LIS

In this chapter

10.1 Overview

The chapter provides detailed description of the LIS.

Laboratory Information System (LIS) is an external host computer connected with the analyzer through a fixed interface. The LIS is used to download sample order information to the analyzer and receives results sent from the analyzer.

You should set up the communication parameters and results transmission methods prior to using the LIS host.

Check that your analyzer is equipped with a LIS. If needed, contact our customer service department or your local distributor.

10.2 LIS Communication

10.2.1 Introduction

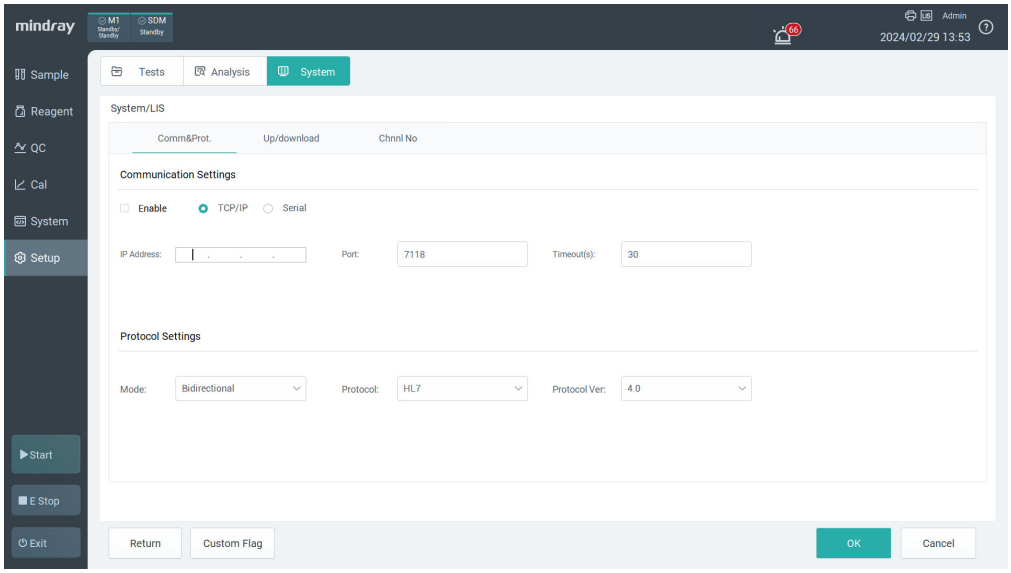
To download sample order information from or sent results to the host, you need to set up the test code used for identification of tests on both the LIS host and the analyzer, which, otherwise, cannot identify the tests simultaneously.

10.2.2 LIS Communication Parameters

1 Select **Setup** > **System**.

2 Select LIS. The Host Communication Parameters window shows.

Figure 10.1 Host communication Parameters window



3 Set up the following parameters:

Table 10.1 Host communication parameters

Parameter	Description
Transport	Choose a transport mode from the **Transport Mode** pull-down list. The options include Serial and TCP/IP. The default is Serial.

Parameter	Description
IP address	Enter the IP address of the LIS host. The connection between the analyzer and the LIS host is based on the network, i.e. TCP/IP protocol.
Port	Enter the interface number of the LIS host.
Timeout	Enter the timeout limit for querying the LIS host. The input range is 30s-60s, and the default is 30s. If the timeout limit is exceeded when you attempt to download sample orders from, or send results to, or connect the analyzer with the LIS host, the system will give an alarm indicating communication timed out.
Serial communication parameters	If you choose Serial as the transport mode, set up the following parameters: Serial port: The default is COM1. Data bits: 7 or 8. The default is 8. Stop bits: 1 or 2. The default is 1. Parity: None, Odd, or Even. The default is None. Baud rate: 300, 1200, 2400, 4800, 9600, or 19200. The default is 9600.
Mode	Choose a data transmission mode for the analyzer and LIS host. The available options are Unidirectional and Bidirectional. Unidirectional: You are only allowed to send results and patient demographics to the host rather than downloading sample orders from it. Bidirectional: You are allowed to send results and patient demographics to the host and downloading sample orders from it.
Protocol	Choose a protocol for connection between the analyzer and the LIS host from the **Protocol** pull-down list. The options include HL7 and ASTM 1394.
Version	LIS protocol version. When version 2.0 is selected, LIS Flag Custom is enabled. You can set which flags are sent to LIS.

4 Set up upload and download parameters:

Parameter	Description
Send Complete Samples	When the checkbox is selected, the system will automatically send results to the LIS host after a sample changes from *In Progress* to *Complete*. This function is only applicable to samples analyzed on the current day rather than those analyzed before.
Send Incomplete Samples	When the checkbox is selected, the system will automatically send results to the LIS host after a sample changes from *In Progress* to *Incomplete*. This function is only applicable to samples analyzed on the current day rather than those analyzed before.

Parameter	Description
Send Actual Results and Rerun Results:	When the checkbox is selected, all actual results and rerun results of each test will be sent to the LIS. If this option is not selected, only the default result will be sent.
Bypass Results Beyond Linearity Upper Limit	When the checkbox is selected, those results that are beyond the linearity upper limit will not be sent to the LIS. If this option is not selected, they will be sent.
Bypass Results Beyond Linearity Lower Limit	When the checkbox is selected, those results that are beyond the linearity lower limit will not be sent to the LIS. If this option is not selected, they will be sent.
Send the QC result as that of routine sample	When the checkbox is selected, the system will send the QC test results as those of routine samples when QC sample is ordered as a routine sample.
Resend result after SI Check	Sample results are sent to LIS after SI check is performed for the sample.
STAT Sample Setting	includes Sample and Test. Selecting sample means when all the test results of the sample are completed, the results will be sent to LIS. Selecting Test means when the result of a test is produced, its result will be sent to LIS.
Routine Sample Setting	includes Sample and Test. Selecting sample means when all the test results of the sample are completed, the results will be sent to LIS. Selecting Test means once its test is completed, the result is sent to LIS.

Table 10.2 Downloading Settings

Parameter	Description
Rerun Finished Tests When Downloaded:	When the checkbox is selected, tests that have been finished will be rerun if downloaded again. If this option is not selected, they will be neglected.
Auto Number Scanned Samples:	The system automatically numbers the samples which have been scanned.
Fuzzy match sample type	If this option is selected, system matches the sample type after sample information is downloaded from LIS. If the downloaded information contains sample type, then this sample type is used. If not, the sample type is other.
Merge Samples by Sample ID	If sample information downloaded from LIS includes both bar code and sample ID, but matching sample in the analyzer cannot be found through barcode, then sample ID is used to find the sample. When the barcode of the found sample is blank if merge samples by sample ID is selected, then the sample information downloaded from LIS will be merged with that of the found sample. if “merge samples by sample ID” is not selected, then a new sample is established with the bar code of the obtained sample and a blank sample ID.

Send barcode failed to read	Disabled by default. When it is selected, enter the barcode that failed to read. The barcode length is within 3-27digits.
Ignore Alarms for Unknown Tests	When the checkbox is selected, the system will not give an alarm if the samples downloaded from the LIS host contain unknown tests without identification code. If this option is not selected, an alarm will be given indicating sample order failure.

5 Select **OK** to save your input information.

10.2.3 Defining Channel Code

Tests are identified by channel number on the analyzer and LIS host. Make sure that the channel numbers assigned to tests on the analyzer are consistent with those on the LIS host; otherwise, correct information transfer cannot be done.

1 Select **Setup** > **System** > **LIS Settings**.

2 Select **Channel No**.

3 View **Channel No**. List.

The list shows test abbreviation and channel number. The left column provides all tests that have been defined and set up correctly; the right column shows the code for identifying a test on the LIS host.

4 Click on the **Channel No.** and **Dilution Channel No.** column of a test, and then type in a code for it.

5 Repeat step 4 to define a code for other tests.

6 Select **OK**.

10.2.4 Requesting Samples with LIS Host

Sample ordering information can be sent by or downloaded from the LIS host, and then the measured results are sent to it manually or in real-time mode.

10.2.5 Requesting Functions

Samples can be downloaded manually or automatically from the LIS host. If the system status is Standby, you are allowed to download samples manually from LIS.

Sample orders downloaded from the LIS host can be edited. When orders are downloaded for samples that are in Ordered status, the requested tests in the orders will be used to overwrite the original tests; if the samples are in a status other than ordered, the requested tests will be added to the original ones.

10.2.5.1 Sending sample orders from LIS

Sending bar-coded samples:

1 When samples are sent from the LIS host to the analyzer, select **Sample** > **S Orders**.

2 Select **Order List** to view the received samples.

3 On the **Sample Orders** screen, type in the sample bar code, and then confirm the order information.

4 Select **OK**.

5 Load the samples to idle positions of rack.

6 Put the rack on the rack lanes and the system start analysis automatically.

10.2.5.2 Obtaining samples automatically

When the system status is Standby or Sample Load, put the rack on the rack lanes and the system start analysis automatically. The system will automatically scan the samples and then query the LIS host to download relevant order information. After matching the downloaded order information with the samples, the system will start the analysis.

The obtained sample order information includes:

- Patient demographics: patient name and sex.
- Requested tests: sample bar code, sample ID, sample type, test code.

10.2.5.3 Downloading samples manually

Downloading bar-coded samples:

1 Select **Sample** > **S Orders**.

2 Select **Download**.

3 Choose one of the following options:

- All ordered samples: to download all samples ordered on the current day.
- Latest samples: to download samples that are ordered on the current day but have not been downloaded.
- Samples with the following IDs: to download samples with the specified order date and ID. Enter the sample IDs or ID range to download.
- Sample with the following bar code: to download the sample with the specified bar code. Enter the bar code of the desired sample.

4 Select **OK**.

5 Confirm the sample information and selected tests/panels on the **Sample List** screen.

6 Load the samples to idle positions of rack.

7 Put the rack on the rack lanes and the system start analysis automatically.

10.3 Result Transmission

Sample results and QC results can be sent manually or in real-time mode to the LIS host for reviewing and storage. When a sample is analyzed with its all tests finished, the system can automatically send the test results to the LIS host; also, you are allowed to search for desired results and then manually send them to LIS.

Patient demographics, sample results and QC results can be sent to the LIS host.

10.3.1 Result Transmission Setup

When all tests of a sample are finished and at least one of them has calculated a result, the result can be sent to the LIS host automatically. The results of all replicates of a sample or test will be sent to the LIS host.

1 Select **Setup**> **System**.

2 Select LIS. The Host Communication Parameters window shows.

3 Mark the Send Complete Samples or Send Incomplete Samples checkbox with a tick.

A sample will be sent to the LIS host automatically when it changes from *In Progress* to *Complete* or *Incomplete*. If you won't send results, deselect the checkbox.

4 Select **OK**.

10.3.2 Manually Sending Results to LIS Host

1 Select **Sample** > **Current** or **History**.

2 Search for control results or sample results to transmit.

3 Select desired samples in the sample list.

4 Select

.

5 Select the sample range you want to transmit:

- Selected sample(s)
- All samples

6 If you transmit all results, you are allowed to skip those that are already transmitted to the LIS host. Mark the **Bypass Transmitted Results** checkbox.

7 Select **OK**.

11 Maintenance

In this chapter

11.1 Overview

11.1.1 Introduction

Maintenance of the system should be performed regularly by trained personnel to ensure reliable performance and reduce unnecessary service calls. Even you are only an operator, it is important for you to read this chapter. Your thorough understanding will help you obtain the best performance of the system.

The system provides maintenance commands and scheduled maintenance procedures. The Scheduled Maintenance Log feature allows you to understand what maintenance is needed, when it is performed and who performed the procedure. It is capable of reminding you of the maintenance that is due and keeping track of what is happened during a maintenance procedure.

In the case of maintenance that is beyond your capability or not covered in this chapter, contact our customer service department or your local distributor.

⚠ WARNING	• Do not perform any maintenance procedures that are not described in this chapter; otherwise, equipment damage or personal injury may be caused. • Do not touch the components other than those specified in this chapter. • Performing unauthorized maintenance procedures can damage the instrument and cause personal injury, or invalidate the applicable warranty provisions in the service contract. • After performing maintenance, make a verification to ensure that the system runs normally. • Do not spill water or reagent on mechanical or electrical components of the system. • If the system is to be stored for a long time (over 1 week) or transported, contact our customer service department or your local distributor to perform necessary maintenance in order to ensure the system's optimal performance in following use.
☣ BIOHAZARD	• Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

11.1.2 Consumables

Please use the consumables manufactured or recommended by our company in order to achieve the promised system performance. If needed, contact our customer service department or your local distributor.

Table 11.1 Component information

Component Name	Position	Remarks
Tungsten-halogen lamp 12 V 20 W lamp	Lamp housing	Replace the parts regularly. Replace the lamp when it has been used for 2000 hours or the system prompts that the lamp intensity is insufficient. It is recommended that each lamp has been used for no more than 6 months.
Reagent probe assembly	Reagent probe arm	Replace parts from time to time. Replace it when it is damaged or bent.
Sample probe assembly	Sample probe arm	Replace parts from time to time. Replace it when it is damaged or bent.
Mixer	Mixer arm	Replace parts from time to time. Replace it when it is damaged or bent.
Water inlet filter	Water supply to the analyzer	Replaced every 6 months
CD80 detergent	/	Consumables
Detergent A acid wash solution	/	Consumables
Detergent B alkaline wash solution	/	Consumables
ISE cleaning solution	ISE module (Optional)	Consumables
ISE detergent	ISE module (Optional)	Consumables
Na cleaning solution	ISE module (Optional)	Consumables
Na electrode (Sodium electrode)	ISE module (Optional)	Consumables
K electrode (Potassium electrode)	ISE module (Optional)	Consumables
Cl electrode (Chlorine electrode)	ISE module (Optional)	Consumables
Ref electrode (Reference electrode)	ISE module (Optional)	Consumables

11.1.3 Tools Required for Maintenance

The following tools will be used for maintenance of the system.

11.1.3.1 Accompanying Tools

Table 11.2 Accompanying Tools

Item	Applicable Maintenance
Cross-head screwdriver φ3.3×100	Cleaning dispersion aspirate probes
Cross-head screwdriver φ4.7×100	Installing probes and lamps
Flathead screwdriver φ4.7×100	Install/remove the probe and install the tube clamp
CD80 Detergent	Special Wash
Detergent A acid wash solution	Special Wash
Detergent B alkaline wash solution	Special Wash
Detergent C probe detergent cleanser	Special Wash
Needle, 0.25+/-0.01 mm*125 mm round head	Unclogging
Unclogging device for reagent probe	Unclogging reagent probe
Unclogging device for sample probe	Unclogging sample probe

11.1.3.2 Tools Prepared by User

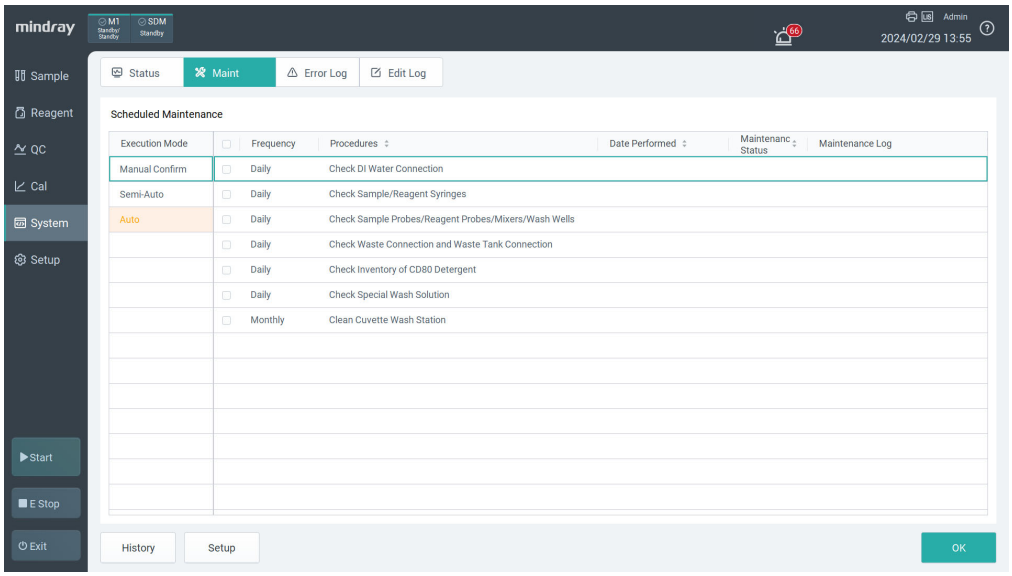
Table 11.3 Tools Prepared by User

Item	Applicable Maintenance
Clean gauze	Check the syringe, wipe the rotor, probe/mixer exterior
Cotton swabs	Clean wash wells and sample compartments
Vacuum cleaner	Clean fans and dust screens
Hair brush	Clean dust screens
Tweezers	Removing/Installing Probe and Syringe Washer
Screw syringe	Unclogging the sample probe and reagent probe
Tube brush or ultrasound cleaner	Clean Filter Core
Beaker	Unclogging
Ethanol	Clean the photometer lens, probes, mixers and wash station.
Fiber-free gloves	Clean and replace cuvettes
Large water container	Clean DI Water Tank
On-screen keyboard wash solution	Clean the touch screen and keyboard
Sample cup	Clean ISE Electrodes
Pipette	Clean ISE tubes and drain outlet

11.2 Maintenance Screen Overview

The screen contains maintenance frequency tabs, maintenance procedures, scroll bar, and function buttons. Select a tab to view the maintenance procedures to be performed in the period. Choose a maintenance procedure, and then select function buttons to access windows to execute an operation.

1 Select **System** > **Maintenance**.



Manual Confirmation List

Displays all manual maintenance procedures that are provided. When each maintenance procedure is finished, select the checkbox in front of each maintenance and select **OK**.

Auto Execution List

Displays all auto maintenance procedures. Auto execution function has been set for all the procedures on this screen. Select the checkbox and click Execute to start the maintenance procedure manually.

Fields and buttons on the screen are introduced as follows.

Execution Mode

Displays how the maintenance procedure is performed. Perform the check manually and click **OK** to record the maintenance log. When performing procedures semi-automatically, you should follow the software prompts to complete the maintenance. The maintenance is performed according to the set period and startup time.

Manual Confirmation

When this option is selected, the maintenance procedures that need to be completed manually are displayed.

Auto Perform

When this option is selected, the maintenance procedures automatically performed by the system will be displayed.

Semi-Auto Perform

When this option is selected, the maintenance procedures automatically performed by the system together with manual operations will be displayed.

Maintenance procedures

Displays all preset and user-defined maintenance procedures of the current frequency.

Operator

Displays the operator of the maintenance procedure, that is, the user ID currently logging on the system.

Date performed

Displays the last time the maintenance procedure is performed. After performing maintenance operations, choose a maintenance procedure and click **OK**. The date is refreshed as the current date. The system will recount down the maintenance period from the current time.

Maintenance Status

The maintenance status is Successful or Failed.

Maintenance Log

Abnormalities or other important events that occur during maintenance are recorded in logs.

Maintenance Setup

The Maintenance Setup option is used to set up maintenance frequencies based on the actual conditions of the system. Select Maintenance Setup on the maintenance screen to open the maintenance setup screen.

To define a maintenance period:

1 Choose a maintenance procedures in the Available Procedures list. Move the scroll bar to view more maintenance items.

2 Choose a maintenance frequency.

3 Click **OK**.

Maintenance History

This option is used to recall all performance records of a maintenance procedure, including the date, status, and operator.

1 Click **Maintenance History** on the **Scheduled Maintenance** screen.

2 Select  to export history record.

3 Select  to print history record

4 Select **Maintenance Data** to view maintenance data.

11.3 Scheduled maintenance

11.3.1 Introduction

Scheduled maintenance procedures are determined by use of the components and frequency of performance, and should be performed regularly by trained personnel to ensure reliable performance and reduce unnecessary service calls. Read this section carefully prior to doing the maintenance.

The Customize feature allows definition of maintenance procedures and configuration of manufacturer-/user-defined maintenance procedures for each maintenance frequency. The Electronic Maintenance Log is provided enabling you to record comments and other important information of maintenance.

Most of the scheduled maintenance procedures are performed by executing maintenance instructions, while the remaining part by manual operations. Perform the maintenance strictly as instructed in this manual.

11.3.2 Maintenance Schedule

The scheduled maintenance procedures are divided into the following periods:

- Daily: 1 day
- Weekly: 8 days
- Monthly: 31 days
- Six-month: 181 days
- Other (As-needed/As-required)

The maintenance frequency is counted down from the date of performing. When the countdown becomes 0, the corresponding maintenance procedure is highlighted in yellow. To determine that a due maintenance procedure is due, check if the following items are displayed in yellow background:

- **Maintenance** button
- **Scheduled Maintenance** tab
- Maintenance frequency tab
- Maintenance procedure

The maintenance information will not be lost when the operating software version is upgraded. When new version software is installed to remove the system failure or fix the system, the maintenance counter returns to 0 and restarts a countdown.

11.3.3 Maintenance Log List

Refer to the following table for scheduled maintenance procedures you are supposed to perform. Please copy it every month and place a check mark in relevant day column every time after you performing maintenance.

Table 11.4 Maintenance Log List 1

Maintenance Log Sheet

Year Month

Daily Maintenance		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Check DI Water Inlet Connection																															
2	Check Waste Connection																															
3	Check Probes/Mixers/ Wash Wells																															
4	Check Sample/ Reagent Syringe																															
5	Check Inventory of CD80 Detergent																															
6	Check Sample Probe Wash Solution																															
7	Special Wash Probes/ Mixers																															
8	Clean ISE Tubes																															
9	Ultrasonic Cleaning of Sample Tube																															
Weekly Maintenance		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
1	Clean Probes/Mixers																															
2	Weekly Special Wash and Cuvette Check																															
3	Special Ultrasonic Cleaning of Sample Tube																															
Monthly Maintenance		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
1	Clean Cuvette Wash Station																															
2	ISE Tube Special Wash																															
3	Clean Wash Wells																															
4	ISE Sample Cup Wash																															

Table 11.5 Maintenance Log List 2

Maintenance Log Sheet 2																															
																										Year			Month		
Six-Month Maintenance		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Replace Circulating Water Filter																														
2	Clean DI Water Tank																														
3	Replace Water Inlet Filter																														
When Appropriate Maintenance		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Replace ISE electrodes																														
2	Replace Lamp																														
3	Replace Cuvettes																														
4	Cuvette Check																														
5	Photometer Check																														
6	Service Life Query of Wearing Parts																														
7	ISE Module Shutdown																														
8	Enable ISE Module																														
9	ISE Initialization																														

11.4 Daily Maintenance

11.4.1 Check DI Water Inlet Connection

If the deionized water is not connected properly, the water supply may be insufficient or water leakage may occur, causing measurement failure.

Purpose

Check the deionized water connection to make sure the water supply is normal.

When to do

You are recommended to perform this procedure every day before starting analysis.

Analyzer Status

Make sure that the system status is Stopped, Incubation or Standby.

Precautions:

- Wear gloves and lab coat, and if necessary, goggles.

How to do

1. Check if the water inlet on the rear panel of the analyzer is well connected to the water supply tube.
2. Check if the water tank or other water containers have sufficient deionized water.
3. Check that the tubes are not bent or folded or leaking.
4. Check if the water supply module is powered on.
5. Select **System** > **Maint**, and select **Manual Confirm**.
6. Select the check deionized water connection procedure and select **OK**.
7. The current maintenance time and status are updated after maintenance.

11.4.2 Check Waste Connection

Improper connection of the waste tube or failure to empty the high-concentration waste tank in time will result in waste overflow, environmental contamination and cross infection, and even damage the instrument. Therefore, it is necessary to check the waste connection frequently.

Purpose

Check the waste tube connection and the high-concentration waste tank to avoid overflow.

When to do

You are recommended to perform this procedure every day before starting analysis.

Analyzer Status

Make sure that the system is Stopped, or the system status is Incubation or Standby.

Precautions:

	• Wear gloves and lab coat, and if necessary, goggles. • Keep a distance from the check object in case the waste is sprayed. • Dispose of the waste in accordance with your local or national guidelines for biohazard waste disposal.

How to do

1. Check if the waste drainage system is normal, make sure that the waste tubes are not bent, the waste is drained smoothly, and the high-/low-concentration waste is handled properly. (Refer to local regulations for waste disposal methods.)
2. Make sure the waste tube is clear and not bent or folded. Otherwise, the waste may overflow from the analyzer panel due to poor drainage, which may cause damage to the analyzer.
3. If leak remains after performing the above-stated steps, contact our customer service department or your local distributor.
4. Empty the high-concentration waste tank.

   High-concentration waste output: 2.2L/H.
5. Select **System** > **Maint**, and select **Manual Confirm**.
6. Select the check waste connection maintenance procedure on the maintenance list, and select **OK**.
7. The current maintenance time and status are updated after maintenance.

11.4.3 Check Probes/Mixers/Wash Wells

Abnormal sample probes, reagent probes or mixers may influence the measurement performance and result in inaccurate results. Prior to measurements everyday, check the sample probes and reagent probes for stains and crystals, check if mixers are working abnormally, and check if wash wells have a normal water flow. If the above-mentioned abnormities exist, clean or adjust them immediately.

Purpose

Check the sample probes and reagent probes for water dripping, stains and liquid flow abnormities. Check if mixers work normally. Check if the water flows out of the wash well normally.

When to do

You are recommended to perform this procedure every day before starting analysis.

Analyzer Status

Make sure that the system status is Standby.

Precautions:

	• Wear gloves and lab coat, and if necessary, goggles.

	• Exercise caution to avoid being hurt by the probes or bending of the sample probes, reagent probes or mixers. Do not approach sample probes, reagent probes, mixers or other moving parts.

How to do

1 Open the upper shielding cover and back cover of the analyzer.
2 Select **System** > **Maint**, and then select **Manual Confirm**.
3 Choose the Check Probes/Mixers/Wash Wells procedure.
4 Select Execute to enter probe interior/exterior wash well maintenance command screen.
5 Select **System** > **Maint**, and then select **Manual Confirm**.
6 Choose the Check Probes/Mixers/Wash Wells procedure.
7 This system updates the current maintenance time and status after maintenance.

11.4.4 Check Sample/Reagent Syringe

The sample syringe and reagent syringe are precise devices used to aspirate/dispense small amounts of sample and reagent. If the syringe leaks, the aspirated and dispensed volume may be inaccurate or even damaged. Prior to measurements everyday, check the sample syringe and reagent syringe for leak.

Purpose

Check the sample syringe and reagent syringe for leak and air bubbles.

When to do

You are recommended to perform this procedure every day before starting analysis.

Materials required

Clean gauze

Analyzer Status

Make sure that the system status is Incubation or Standby.

How to do

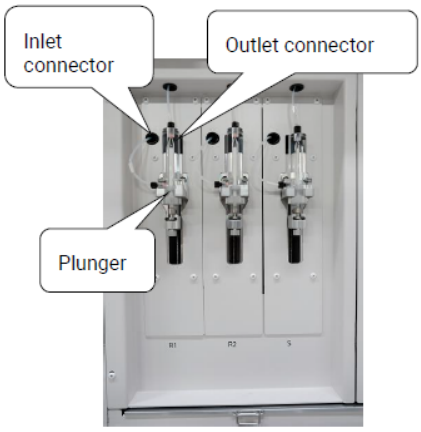
BIOHAZARD

- Wear gloves and lab coat, and if necessary, goggles.

Procedure

1 Open the front door of the analyzer. You will see three syringes on the right of the analyzer.

Figure 11.1 Syringes



2 Use dry gauze to wipe the connector at the inlet and outlet of the syringe, and then check if the gauze is moistened.

If leak occurs, tighten the connector on the inlet and outlet of the syringe.

3 Check the syringe interior for air bubbles.
4 Check the plunger at the bottom of the syringe for leak.
5 Use dry gauze to wipe the plunger and check if the gauze is moistened.
If leak occurs, contact the service engineer to replace the syringe.
6 Close the front door of the analyzer.
7 Select **System** > **Maint**, and then select **Manual Confirm**.
8 Select the check sample/reagent syringe maintenance procedure.
9 Select **OK** to refresh the current date as the performance date.

11.4.5 Check Inventory of CD80 Detergent

If CD80 detergent is insufficient, the system may not be able to run tests continuously. Prior to measurements everyday, check the inventory of CD80 detergent, and replace it when it is insufficient.

Purpose

To check the inventory of CD80 detergent, and prevent them from being insufficient.

When to do

You are recommended to perform this procedure every day before starting analysis.

Analyzer Status

Make sure that the system is powered off, or the system status is Incubation or Standby.

Precautions

⚠ WARNING	• CD80 detergent may hurt your skin. Wear gloves and goggles while checking the CD80 detergent. If your hands or clothes contact them, wash them with soap and water. In case of eye contact, flush with plenty of water immediately and consult an ophthalmologist.

How to do

1 Open the front door of the analyzer and check the inventory of CD80 detergent. If the volume is insufficient, replace the wash solution.
2 Close the front door of the analyzer.
3 Select **System** > **Maint**, and then select **Manual Confirm**.
4 Choose the Check CD80 detergent maintenance procedure on the maintenance list, and then select **OK**.
5 The current maintenance time and status are updated after maintenance.

11.4.6 Check Sample Probe Wash Solution

If the sample probe/reagent carousel wash solution is insufficient, sample probe/reagent probe clog and carryover may occur.

Purpose

To check the sample probe/reagent carousel wash solution volume in case the tests cannot be continued due to insufficient wash solution.

When to do

You are recommended to perform this procedure every day before starting analysis.

Analyzer Status

The system is powered off, or the system status is Incubation or Standby.

Precautions

CAUTION	• To ensure the wash effect, you are recommended to update the sample probe/ reagent carousel wash solution every day to avoid probe clogging and serious cross contamination.

Procedure

1. Remove the sample probe wash solution and the detergent from the DB, DA, DC position next to the sample probe wash well, and then check their volume.
2. Take out the wash solution from position DA and DB of the reagent carousel and check the inventory.
3. If the volume is insufficient, fill more or replace it. To ensure the wash effect, replace the wash solution.
4. Select **System** > **Maint**, and then select **Manual Confirm**.
5. Select Check Sample Probe Wash Solution on the maintenance list, and select OK.
6. The current maintenance time and status are updated after maintenance.

11.4.7 Special Wash Probes/Mixers

Purpose

Avoid accumulation of contaminants on the sample probe, reagent probe and mixers, and avoid carryover.

When to do

Perform the procedure before or after finishing analysis every day.

Materials required

Concentrated wash solution

Analyzer Status

Make sure that the system status is Standby or Sleep.

Procedure

Special wash probes/mixers can be set to Auto Perform or Manual Perform.

Manual operation steps

1. Select **System** > **Maint**, and select **Auto Perform**.
2. Select Probe/Mixer Special Wash and select Execute.
3. Make sure the inventory of probe detergent on the desk panel is greater than 2%, and the inventory of CD80 in the cabinet is greater than 2%.
4. Select **OK**. When Start is selected, the maintenance procedure starts and the maintenance countdown is displayed on the screen.

Auto Operation Procedure

Same as the Auto Maintenance Setup in " Maintenance Setup" (11-7).

11.4.8 Clean ISE Tubes

Clean the ISE tubes with ISE cleaning solution to remove the stains inside of them.

Purpose

To remove the stains inside the tubes and prevent them from accumulating.

When to do

Perform the procedure before or after finishing analysis every day. For customers with large samples, it is recommended to wash them once every 50 samples.

Materials required

ISE cleaning solution

Analyzer Status

Make sure that the ISE module status is Standby.

This procedure can be performed automatically or manually.

Manual operation steps

1. Select **System** > **Maint**, and then select **Auto Perform**.
2. Select Clean ISE Tubes and then select Execute.
3. Make sure the ISE cleaning solution is sufficient on the desk panel. If you are using a sample tube to load ISE cleaning solution, make sure the inventory is no less than 300μl.
4. Select **Execute** and then **OK** to start the procedure.
5. When the maintenance procedure is finished, the current maintenance time and status are refreshed automatically.

Auto Operation Procedure

Same as the Auto Maintenance Setup in " Maintenance Setup" (11-7).

11.4.9 Ultrasonic Cleaning of Sample Tube

The sample probe is cleaned in its wash well by using preheated water to clean its interior and exterior with ultrasound.

Purpose

Use ultrasound to clean the sample probe.

When to do

Perform the procedure before or after finishing analysis every day.

Materials required

Ultrasound wash well

Analyzer Status

Make sure that the ISE module status is Standby.

This procedure can be performed automatically or manually.

Manual operation steps

1. Select **System** > **Maint**, and then select **Auto Perform**.
2. Select Ultrasonic Cleaning of Sample Tube and then select Execute.
3. The status is displayed in the middle of the status bar on the main screen. Sample probe ultrasonic cleaning: In maintenance, click **Cancel** and click **OK** to stop the maintenance.
4. Select **Execute** and then **OK** to start the procedure.
5. When the maintenance procedure is finished, the current maintenance time and status are refreshed automatically.

Auto Operation Procedure

Same as the Auto Maintenance Setup in " Maintenance Setup" (11-7).

11.5 Weekly Maintenance

11.5.1 Clean Probes/Mixers

The exterior of the sample probes, reagent probes and mixers is easy to get dirty, which may cause carryover between samples or reagent and result in incorrect test results.

Purpose

To clean the exterior of the sample probes, reagent probes and mixers to prevent carryover.

When to do

You are recommended to perform this procedure weekly.

Materials required

Clean gauze (two pieces), ethanol, deionized water

Analyzer Status

Make sure that the system status is Incubation or Standby.

Precautions

	• Exercise caution to avoid scratching your hand. Exercise caution while working around the sample probe. If it is bent or damaged, replace it immediately; otherwise, unreliable results may be obtained.
	• Wear gloves and lab coat, and if necessary, goggles.

Procedure

1. Select **System** > **Maint**, and then select **Semi Auto Perform**.
2. Choose the Clean Probes /Mixers maintenance procedure.
3. Select **Execute**.
4. After the probes/mixers finish moving, open the upper shielding cover and back cover of the analyzer.
5. Use clean gauze moistened with ethanol to clean the exterior of the sample probe, probe reagent and mixer until the surface is clean and free of dirt. When wiping the probes and mixer, do not push or pull them horizontally to avoid bending the probes or mixer.
6. Use clean gauze moistened with deionized water to clean the exterior of the sample probe, probe reagent and mixer to clear the ethanol on the surface.
7. Select **Continue**. The system starts cleaning the mixer exterior.
8. Select **Done**. The system resets automatically.
9. The software automatically updates the current maintenance time and status.
10. Close the upper shielding cover and back cover of the analyzer.

11.5.2 Weekly Special Wash and Cuvette Check

Special wash is used to clean the sample probes, reagent probes, mixers, cuvettes and wash station with wash solution, in order to reduce carryover and prevent waste from remaining in the waste tubes. After washing, the system checks the energy of cuvettes and photometer, and verifies the working status of cuvettes, attenuation of lamp radiation, and stability of the lamp.

Purpose

To eliminate carryover among sample probes, reagent probes, mixers, cuvettes and wash station, in order to prevent waste from remaining in the waste tubes. Check the photometer energy and cuvette status after the wash.

When to do

You are recommended to perform this procedure every week or when the system is going to be idle for a long time.

Materials required

CD80, acid wash solution, alkaline wash solution and probe detergent produced by our company.

Analyzer Status

Make sure that the system status is Standby or Sleep.

Procedure

Weekly special wash and cuvette check can be performed automatically or manually.

Manual operation steps

1. Open the upper shielding cover of the analyzer.
2. Fill wash solution in DB/DA/DC on the desk panel. The inventory of S-DA and S-DB wash solution on the desk panel is greater than 5%, and that of S-DC wash solution on the desk panel is greater than 35%. The inventory of panel R1/R2-DA wash solution is greater than 30% and that of panel R1/R2-DB is greater than 50%. The CD80 inventory in the cabinet is greater than 5%.
3. Select **System** > **Maint**, select **Auto Perform**, select the weekly special wash and cuvette check procedure, and then select **Execute**.
4. After maintenance, select the maintenance data button on the Maintenance History window to view cuvette check results.
5. Close the upper shielding cover of the analyzer.

Auto Operation Procedure

Same as the Auto Maintenance Setup in " Maintenance Setup" (11-7).

11.5.3 Special Ultrasonic Cleaning of Sample Tube

The sample probe is cleaned in its wash well by using preheated water to clean its interior and exterior with ultrasound.

Purpose

Use ultrasound to clean the sample probe.

When to do

Perform the procedure before or after finishing analysis every week.

Materials required

Ultrasound wash well

Analyzer Status

Make sure that the ISE module status is Standby.

This procedure can be performed automatically or manually.

Manual operation steps

1. Select **System** > **Maint**, and then select **Auto Perform**.
2. Select Special Ultrasonic Cleaning of Sample Tube and then select Execute.
3. The status is displayed in the middle of the status bar on the main screen. Sample probe ultrasonic cleaning: In maintenance, click **Cancel** and click **OK** to stop the maintenance.
4. Select **Execute** and then **OK** to start the procedure.
5. When the maintenance procedure is finished, the current maintenance time and status are refreshed automatically.

Auto Operation Procedure

Same as the Auto Maintenance Setup in " Maintenance Setup" (11-7).

11.6 Monthly Maintenance

11.6.1 Clean Cuvette Wash Station

Clean the cuvette wash station regularly to prevent waste from accumulating on it.

Purpose

To remove the waste and dust from the five wash wells (reagent probes, sample probe, sample mixer and reagent mixer).

When to do

You are recommended to perform this procedure every month.

Materials required

Gauze, ethanol, deionized water, waste container (large beaker)

Analyzer Status

Make sure that the system status is Standby.

Precautions

- Wear gloves and lab coat, and if necessary, goggles during the maintenance process.
- Dispose of the used gauze in accordance with your local or national guidelines for biohazard waste disposal.

Procedure

1. Open the upper protective shield of the analyzer.
2. Remove the cuvette wash station and use ethanol-moistened gauze to wipe the wash probes and wipe blocks.
3. Use gauze moistened with deionized water to clear the ethanol on the wash probes.
4. Restore the wash station.
5. Select **System** > **Maint**, and then select **Manual Confirm**.
6. Select Clean Cuvette Wash Station.
7. Select **OK**.
8. Close the upper shielding cover and back cover of the analyzer.

11.6.2 ISE Tube Special Wash

Use ISE detergent to clean the ISE tubes to remove the protein and lipid from them and the electrodes, and ensure the electrodes work properly.

Purpose

To remove the stains inside the tubes and prevent them from accumulating.

When to do

Monthly

Materials required

ISE cleaning solution

Analyzer Status

Make sure that the ISE module status is Standby.

Precautions

BIOHAZARD	• Wear gloves and lab coat, if necessary, goggles. • Do not spill liquid on the analyzer. Liquid ingression may cause equipment damage.
CAUTION	• Please use consumables recommended by our company. Use of other consumables may degrade the system performance.

Procedure

1. Select **System** > **Maint**, and then select **Semi Auto Perform**.
2. Select ISE Tube Special Wash.
3. Remove the ISE cleaning solution from the ISE cleaning solution position on the panel.
4. Fill a 2 ml sample cup with at least 300ul ISE detergent, and then load it to the ISE cleaning solution position on the panel.
5. Remove the ISE detergent from the ISE cleaning solution position on the panel.
6. Place the ISE cleaning solution back on the panel.
7. Select **Done**.
8. The current date and time and status of the maintenance are refreshed automatically.

11.6.3 Clean Wash Wells

When the instrument is used for a long time, the waste and dust may accumulate in the wash well and block the wash well. It is recommended to clean the wash wells every month to keep them clean and unblocked.

Purpose

To remove the waste and dust from the five wash wells (reagent probe, sample probe, sample mixer and reagent mixer).

When to do

You are recommended to perform this procedure every month.

Materials required

Cotton swabs and sodium hypochlorite (NaClO)

Analyzer Status

Make sure that the system status is Standby.

Precautions

BIOHAZARD	• Wear gloves and lab coat, if necessary, goggles.

Procedure

1. Select **System** > **Maint**, and then select **Semi Auto Perform**.
2. Select **Clean Wash Wells**.
3. Select **Execute**.
4. After the probes/mixers finish moving, open the upper shielding cover and back cover of the analyzer.

5 Use clean cotton swabs moistened with NaClO to clean the wash wells, and then use clean cotton swabs to clear the residual NaClO solution.

6 Select **Continue**. The system starts cleaning the sample probe, reagent probe, and mixer exterior.

7 Observe if the water flow of the sample probe wash well, R1 probe wash well, R2 probe wash well, sample mixer wash well and the reagent mixer wash well is normal. If not, contact the service engineer.

8 Select **Done**. The system resets automatically.

9 The software automatically updates the current maintenance time and status.

10 Close the upper shielding cover and back cover of the analyzer.

11.6.4 ISE Sample Cup Wash

When the analyzer is used for a long time, waste and dust, as well as sample fibrin, may accumulate in the ISE sample cup and block it. You are recommended to clean the sample cuvettes every month to keep them clean and unblocked.

Purpose

To remove the waste and dust from the ISE sample cup and remove the fibrin to prevent clogging.

When to do

You are recommended to perform this procedure every month.

Materials required

Cotton swabs, ISE detergent or ethanol

Analyzer Status

Make sure that the system status is Standby.

Precautions

- Wear gloves and lab coat, if necessary, goggles.

Procedure

1 Use clean cotton swab soaked with ethanol or ISE detergent to wipe the interior of the sample cup until it is clean.

2 Use clean cotton swabs moistened with deionized water and wipe the interior of the sample aspirate port and the overflow port until the interior of the sample cup is clean.

3 Perform ISE calibration after washing the sample cuvette.

11.7 Six-Month Maintenance

11.7.1 Replace Circulating Water Filter

The filter may be blocked after being used for a long time. Replace the filter core every 6 months to ensure good filtering effects.

Purpose

To replace the filter core and ensure good filtering effects.

When to do

You are recommended to perform this procedure every 6 months.

Materials required

New filter core

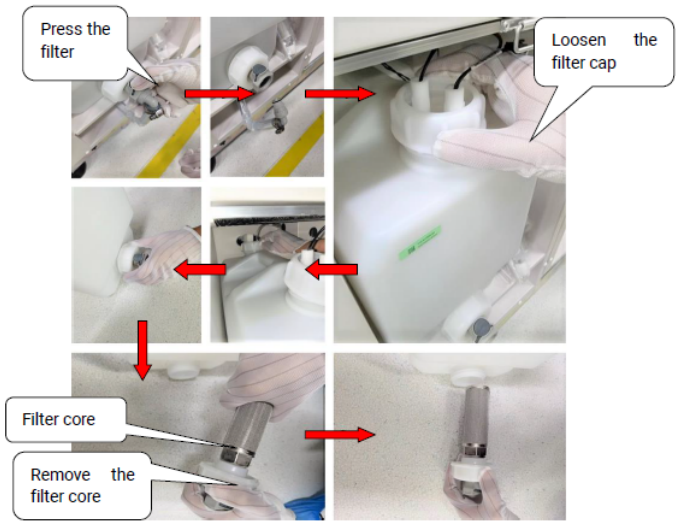
System status

Make sure that the system status is Standby.

How to do

1. Select **System** > **Maint**, and then select **Semi Auto**.
2. Choose Replace Circulating Water Filter. Select **Execute**.
3. Open the left front door of the analyzer.
4. Refer to the following figure. Disconnect the CPC connector of the deionized water tank, loosen the cap of the return tube, and then pull out the deionized water tank assembly.
5. Take out the tubes on the back of the tank and place them in a clean container.
6. Drain the deionized water tank, unscrew the cap on the bottom of the tank, and pay attention not to drop the sealing ring.

Figure 11.2 Remove deionized water filter



7. Remove the filter from the cap and install a new one. Install the water tank cap back to the bottom of the water tank.
8. Reinsert the water tank return tube and level floater into the water tank.
9. Connect deionized water tank CPC connector and sensor cable.
10. Close the left front door of the analyzer.
11. Select Continue. The system starts priming the tubes with deionized water.

12 When the replacement is complete, select **Done**.

13 The maintenance is completed. The corresponding current maintenance time and status are refreshed.

11.7.2 Clean DI Water Tank

If the deionized water tank is used for a long time, stains may accumulate and affect the cleaning effect.

Purpose

Clean the deionized water tank regularly to ensure the cleaning effect.

When to do

You are recommended to clean the deionized water tank once every six months.

Materials required

Water container

Analyzer Status

Make sure that the system status is Standby or Shutdown.

Precautions

BIOHAZARD

- Wear gloves and lab coat, if necessary, goggles.

Procedure

1 Select **System** > **Maint**, and then select **Semi Auto**.

2 Choose the Clean DI Water Tank, and then select **Execute**. A dialog box pops up. Select **Continue**.

3 Open the front door of the analyzer as shown in the figure below.

Figure 11.3 Deionized water tank

4 Unplug the quick connector from the outlet of the water tank, and pull the water tank forward with both hands to expose the opening above the front end of the water tank.

5 Use a water container to hold the water tank connector, and insert another normally open quick connector to the water tank connector. The water will flow out through the quick connector and wait for the water tank to empty before proceeding to the next step. You can also place a hard object against the outlet joint of the water tank to drain the water or take out the water tank and then pour out the water from the upper opening. This method is applicable when the water volume in the water tank is small.

6 Remove the tube from the inlet of the water tank, remove the floater signal cable from the right side panel, pull out the water tank completely, and then remove the floater. The steps of the water tank are shown in the figure below.

Figure 11.4 Figure 11.6 Removing DI water tank

7 Use DI water to wash the water tank several times.

8 Insert the floater into the opening of the water tank, install the water tank back, and insert the reflux tube in a proper position before the water tank is pushed into the analyzer. Connect the floater signal cable and the water outlet tube in front of the water tank according to the label on the vertical plate on the right side of the water tank.

9 Select **Continue**. The system starts priming the tubes with deionized water. When the procedure is completed, the maintenance is finished.

10 Restore the container and close the front door of the analyzer.

If you perform this procedure while the system is shut down, install the water tank and restart the system. After initialization, the system status changes to preheat. On the Scheduled Maintenance window, select Clean DI Water Tank and select Execute. Prime the DI water tube to remove the air from it.

11 The maintenance is completed. The corresponding current maintenance time and status are refreshed.

11.7.3 Replace Water Inlet Filter

When the water inlet filter is used for a long period, it may be blocked, influencing the filtering effects. Replace the water inlet filter every 6 months.

Purpose

To replace the filter core and ensure good filtering effects.

When to do

You are recommended to perform this procedure every 6 months.

Materials required

New water inlet filter

System status

Make sure that the system is powered off, or the system status is Standby or Sleep.

How to do

1. Select **System** > **Maint**, and then select **Semi Auto**.
2. Choose Replace Water Inlet Filter. Select **Execute**. Click **Continue** in the displayed dialog box.
3. Turn off the power switch of the water supply module or water unit.
4. Prepare a new water inlet filter with connectors on its two ends.
5. Turn on the ball valve on the water supply module to release the remaining pressure. When the pressure gauge indicates 0, turn off the ball value.
6. Press the tubing release button to remove the tubing from two ends of the old filter assembly.
7. Wash the tubing and insert them into the new filter. Make sure that the filter is installed in the same direction as the water flow.
8. Power on the water supply module, turn on the ball valve on it and wait for 5 minutes. When you see the water supply module is supplying water continuously which signifies the normal working of the module, turn off its ball valve. Ensure that the pressure gauge on the water supply module is about 0.25MPa.
9. When the replacement is complete, select **Done**.

11.8 When Appropriate Maintenance

11.8.1 Replace ISE electrodes

Due to the limited life span of the electrodes, when the number of tests reaches 10,000, the reference electrode has been used for nine months, or the system gives the alarm that the voltage of the reference electrode is out of range, the electrodes should be replaced to ensure the test performance. It will take about 10 minutes to perform this procedure.

Purpose

To replace the ISE electrodes to ensure the optimal measurement performance.

When to do

Replace the electrodes in the following conditions:

- when 10,000 ISE tests are performed, or the electrodes is used for 9 months (6 months for Cl electrode) .
- when Electrode slope exceeds lower limit of allowable range.

Materials required

ISE electrode

Analyzer Status

Make sure that the ISE module status is Standby.

Precautions

WARNING	• After finishing this procedure, calibrate the ISE module before starting measurements.
BIOHAZARD	• Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Select **System** > **Maint**, and select **Semi-Auto Perform**.
2. Select Replace ISE Electrodes and select **Execute**. The maintenance window pops up. Select **Continue**.
3. Choose electrodes to be replaced and enter the lot number. Click Replace, and then click **OK**.
4. Select **Continue**.
5. Open the right front door of the analyzer and ISE maintenance window.
6. Open the front cover of the ISE module and loosen the ISE electrode locking mechanism.
7. Remove the old electrodes and install the new ones in the correct order. From left to right: K electrode, Na electrode, Cl electrode and Ref electrode.
8. Tighten the ISE electrode locking mechanism.
9. Close the front cover of the ISE module, the ISE maintenance window and the right front door of the analyzer.
10. Select **Continue**. The ISE module performs calibration automatically.
11. Select **Done**.
12. The software automatically updates the current maintenance time and status.

11.8.2 Replace Lamp

An aged lamp will has its energy decreased and influence the measurement accuracy. Failed lamp will make measurements impossible. To ensure the optimal performance of the system, replace the lamp regularly. Every time after you replacing the lamp, if the light intensity is insufficient, replace the lamp immediately.

Purpose

To ensure that the lamp works normally.

When to do

You are recommended to perform this procedure in following conditions: in every 6 months, or in every 2000 hours, or the alarm indicating unsteady lamp happens frequently, or when you find that the lamp does not satisfy the requirements after performing the Photometer Check.

Materials required

New lamp, Philips-head screwdriver, cotton or antistatic gloves

System status

Make sure that the system status is Standby or Failure.

Precautions

CAUTION	• Too hot lamp may burn you. Do not replace the lamp until it gets cool. • Please use consumables recommended by our company. Use of other consumables may degrade the system performance. • Do not touch the light entrance on the lamp housing or the lens in front of the lamp. In case the light entrance is dirty, use cotton swabs moistened with absolute ethanol to clean it.

How to do

1 Select **System** > **Maint**, and then select **Semi Auto**.

2 Choose Replace Lamp. Select **Execute**.

3 Make sure that the lamp has cooled down for 5 minutes, and then select Continue.

4 Remove the lamp replacement door on the back of the analyzer.

5 Wear a pair of cotton or antistatic gloves, loosen the nuts on the cable terminals, and then remove the O-ring connectors from the terminals.

6 Loosen the retaining screw on the left side of the lamp.

7 Remove the lamp from the lamp housing.

8 Hold the new lamp on its handle with its slot facing the reaction carousel and insert the lamp into the lamp housing. Make sure that the slot on the lamp base is aligned to the counterparts on the lamp housing.

CAUTION	• After inserting the lamp into the lamp housing and tightening the retaining screws, check if there is space between the lamp base and the lamp housing. If there is, reinstall the lamp according to step 6 to 8.

9 Install the retaining screw, O-ring connectors, cable terminal nuts and lamp replacement door in the reversed order.

10 Select **Continue**.

11 When the lamp is incubated, select Done.

After replacing the lamp, perform Cuvette Check immediately. For more information, refer to "11.8.4 Cuvette Check" (11-30), otherwise, system operation may be affected.

11.8.3 Replace Cuvettes

If a cuvette is contaminated by serum or other stains, scratches or cracks occur, the absorbance accuracy will be affected. It is necessary to check the reaction cuvettes. If they are abnormal, replace them immediately. It will take about half a minute to replace a cuvette.

Purpose

Make sure the cuvettes are normal and not contaminated, scratched or broken.

When to do

Replace the cuvettes in time when:

- Abnormal cuvette is found after cuvette check.
- The cuvettes are still unusable after washing.
- Scratches or cracks are found on the optical surface of the cuvette.

Materials required

Fiber-free gloves, dry cloth or gauze, reaction cuvettes, and concentrated wash solution manufactured by the company

System status

Make sure that the system status is Standby.

Precautions

CAUTION	• Please use consumables recommended by our company. Use of other consumables may degrade the system performance. • Exercise caution to avoid scratching the reaction cuvettes. Do not touch the optical surface of the reaction cuvettes. If the optical surface is contaminated, the absorbance data may be inaccurate. • While installing the reaction cuvettes, make sure that the optical surface is radially along the reaction carousel. • Wear gloves free of fiber and powder to avoid polluting the optical surface of the reaction cuvettes.
WARNING	• If a cuvette cannot be removed from the reaction carousel, first remove the 1-2 cuvettes to the right of the cuvette to be taken out. Use a blade to remove the spring plate of the cuvette. Finally, take out the cuvette with your hand or tweezers. • In case of large-scale maintenance such as overflow, contact our Customer Service Department or your local distributor.
BIOHAZARD	• Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1 Select **System** > **Maint**, and then select **Semi Auto**.
2 Choose Replace Cuvettes. Select **Execute**.
3 Gently remove the reaction carousel cover.
4 Enter the cuvette number.
5 The input range is 1~ 206. Only one position number can be entered each time.
6 Select **Continue**. Rotate the cuvette to the groove in the front of the analyzer.
7 Use your forefinger and thumb to take out cuvettes in radial direction of the reaction carousel, and then search for corresponding positions according to the silkscreen.
8 Load the cuvettes into the reaction carousel, and press the cuvettes until they stop moving forward.
9 Repeat step 5~9 to replace all reaction cuvettes.
10 Select **Exit**.
11 This interface updates the current maintenance time and status.
12 Restore the reaction carousel cover.

Suggestion: Perform the Cuvette Check procedure to check if the new cuvettes meet the requirements. For more information, refer to "11.8.4 Cuvette Check".

11.8.4 Cuvette Check

If the reaction cuvettes are used for a long time, proteins or debris may remain on their surfaces, which may affect the light transmittance of the cuvettes. In addition, if the interior or exterior of the cuvette is contaminated or there are scratches or cracks on the cuvette, the transmittance or uniformity of the cuvette will be affected, and the accuracy and stability of the absorbance test results will be affected. Check the use status of the cuvettes.

Purpose

To check if the cuvettes are contaminated and the transmittance is decreased in order to avoid affecting test results.

When to do

You are recommended to perform this procedure after replacing or cleaning the reaction cuvettes.

Analyzer Status

Before performing the maintenance, make sure that the system has been powered on for over 20 minutes and the system status is Standby. Check if all cuvette positions have cuvettes. If not, load cuvettes.

Precautions

⚠ CAUTION	• To ensure the photometer's performance, replace or handle the reaction cuvettes as soon as they are judged to be dirty. After replacement, perform Cuvette Check again. • Since residual substances inside the cuvettes may affect the cuvette check results, you are recommended to perform the Cuvette Check after finishing the Special Wash procedure.

Procedure

1. Select **System** > **Maint**, and then select **Semi Auto Perform**.
2. Select Cuvette Check on the Scheduled Maintenance window, and select Execute and then OK. The Cuvette Check window pops up.
3. Select cuvettes to be tested: Select all cuvettes, or select 3 cuvettes in the specified position.
4. After selecting cuvettes, select Start to start cuvette check. To stop the check, select Stop.
5. When finishing the check, the system refreshes the cuvette status based on the check results.
6. The screen shows all cuvette positions with dirty cuvettes indicated by colors.
   - No flag: The cuvette is normal.
   - Red: Incorrect homogeneity
   - Orange: Contamination error
   - Yellow: Consistency error
7. Check the cuvette status and record the cuvettes indicated in yellow. Clean or replace the cuvettes.

8 Select All, that is, select all cuvettes at the same time. Select Blank or Uniformity to view the latest test results of 206 cuvettes at all wavelengths.

Cuvette Water blank absorbance description:

- If the value is less than 3700, it indicates that the energy of the optical system does not meet test requirements.
- If the value is greater than 19500: it indicates that the energy of the optical system is too strong.

9 After cuvette check, select **Exit**.

10 This system updates the current maintenance time and status.

11.8.5 Photometer Check

Decreased light intensity and stability of the lamp will directly influence the accuracy and repeatability of the results. Check the lamp regularly, or if necessary, replace it. The Photometer Check procedure provides detection of too strong or too weak light intensity. The photometer status will be provided through an alarm message or prompt message.

Purpose

To check the light intensity by measuring absorbance of 5 cuvettes and help you determine whether to replace the lamp.

When to do

You are recommended to perform this procedure as required or after replacing the lamp.

Materials required

Gauze, ethanol, deionized water, waste container (large beaker)

Analyzer Status

Make sure that the system status is Standby.

Precautions

- Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

Procedure

1 Select **System** > **Maint**, and then select **Semi Auto Perform**.

2 Select **Photometer Check**. Select **Execute**.

3 Make sure that the lamp has been turned on for over 10 minutes. Select Continue, and click Start on the displayed screen. When finishing the check, the system will automatically refresh the test data and photometer status based on the check results. To stop the analysis, select Stop.

4 If an alarm occurs during measurement, perform the following operations:

- If the prompt indicates the lamp is not turned on, check if the lamp is turned on. If it is not, execute the Home command. If the lamp is turned on, contact our Customer Service Department or local distributor.
- If the alarm indicates light intensity too strong, contact our Customer Service Department or local distributor.
- If the alarm indicates light intensity too weak, replace the lamp. For more information, refer to ""11.8.2 Replace Lamp" (11-27)."

5 View the test results and select the following buttons to perform relevant functions.
   - Save: Select this button to save the photometer check results.
   - Return: Select this button to close the window.

6 Select **Done**.

7 The software automatically updates the current maintenance time and status.

11.8.6 Service Life Query of Wearing Parts

If the wearing parts are replaced, re-set the life count of the wearing parts.

Purpose

Check the service life of the wearing parts and prepare for replacement.

When to do

Replace the wearing parts or check as required.

Materials required

None

Analyzer Status

Non-running status.

Procedure

1 Select **System** > **Maint**, and then select **Semi Auto Perform**.

2 Select the Service Life Query of Wearing Parts.

3 Select Execute. A dialog box pops up. Select OK.

4 Select **Clear** to set the using time to 0.

5 If the parameters on the parameter setup window are modified, select Save to save the usage of the wearing parts.

6 Select **Exit**. The current maintenance time and status are refreshed automatically.

11.8.7 ISE Module Shutdown

When the ISE module is powered off for a long time, the liquid in the tubes of the module may get dry, which may block the tubes and electrode channels. Then it is required to empty the tubes. Temporarily store unused electrodes and reagent to ensure stable performance.

Purpose

Perform ISE module shutdown, unload the reagent pack, electrodes and pumps.

When to do

If the ISE has not been used for a long time (powered off for over 3 days), the ISE module shall be shut down and the software provides the ISE unloading function.

Materials required

ISE cleaning solution

Analyzer Status

Make sure that the system status is Standby.

Precautions

BIOHAZARD	• Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

CAUTION	• After the maintenance, the electrodes shall be sealed and stored in a 2-8 °C refrigerator to avoid volatilization. • Do not lose the black sealing rubber ring. • Put on the rubber plug immediately after leaving the reagent pack to prevent leakage and volatilization. • When the ISE module is shut down successfully, the ISE module will be disabled automatically. The ISE module can only be enabled again through the maintenance procedure of Enable ISE Module.

Procedure

1. Select **System** > **Maint**, and then select **Semi Auto Perform**.
2. Select **ISE Module Shutdown**. Select **OK**. When the maintenance window pops up, select **Start** and proceed to Preparation before ISE shutdown.
3. Select **Continue**, and start Tube empty on the displayed screen. Wait for the countdown of tube empty.
4. Click **Continue**. Follow the instructions on the screen to unload the electrodes, reagent pack and pump tubes.
5. Select **Done**.
6. The software automatically updates the current maintenance time and status.

11.8.8 Enable ISE Module

If you want to use the ISE module again after finishing shutdown procedure, please enable the ISE module, reinstall the pump tubes, reagent pack and electrodes, and follow the operation instructions to perform maintenance to the electrodes.

Purpose

Enable the ISE module again and maintain the electrodes.

When to do

You are recommended to perform this procedure when you want to use the ISE module again after finishing ISE module shutdown procedure.

Materials required

ISE electrodes, reagent pack and Na cleaning solution

Analyzer Status

Make sure that the system status is Standby.

Precautions

BIOHAZARD	• Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

CAUTION	• After the Enable ISE Module procedure is finished, ISE module is enabled automatically. • After finishing this procedure, calibrate the ISE module before starting analysis.

Procedure

1. Select **System** > **Maint**, and then select **Semi Auto Perform**.
2. Select Enable ISE module. Select **OK**.
3. Enter the serial number of Na/K/Cl/Ref electrodes and click Start to start the installation procedure of reagent pack and electrodes.
4. Install the electrodes and reagent pack according to the instructions in the pop-up window, and wait until the countdown for loading the reagent pack ends.
5. Select **Continue**, and execute ISE Initialization and wait until the countdown ends.
6. Select **Continue**. Place Na cleaning solution on the No.1 sample position of the #1 channel of SDM as instructed by the pop-up window. Click Continue to clean the electrodes.
7. Select **Done**.
8. The software automatically updates the current maintenance time and status.

11.8.9 ISE Initialization

Purpose

Restore the failure. If the ISE tubes are not full, prime them through initialization. The maintenance will take about 1 minute.

When to do

You are recommended to perform this procedure as required.

Materials required

None

Analyzer Status

Make sure that the system status is Standby or Sleep.

Procedure

Special wash probes/mixers can be set to Auto Perform or Manual Perform.

Manual operation steps

1. Select **System** > **Maint**, and select **Auto Perform**.
2. Select ISE Initialization and select **Execute**.
3. Select **Execute** and select **OK**.
4. Select **Done**.
5. The software automatically updates the current maintenance time and status.

Auto Operation Procedure

Same as the Auto Maintenance Setup in " Maintenance Setup" (11-7).

12 Alarms and Troubleshooting

In this chapter

12 Alarms and Troubleshooting

The following pages describe how to view and edit error logs and edit logs, and how to locate failure and determine relevant corrective actions. Read this chapter thoroughly to achieve the best performance of the instrument.

12.1 Classification of Logs

12.1.1 Introduction

The logs provided by the system are divided into:

- Error log
- Edit log

12.1.2 Edit Logs

Edit logs record all deletions and part of editing actions performed by the user.

The delete logs record all deleting actions other than the error deletion. The edit logs include editing of sample results and calibration factors.

12.2 Viewing and Handling Logs

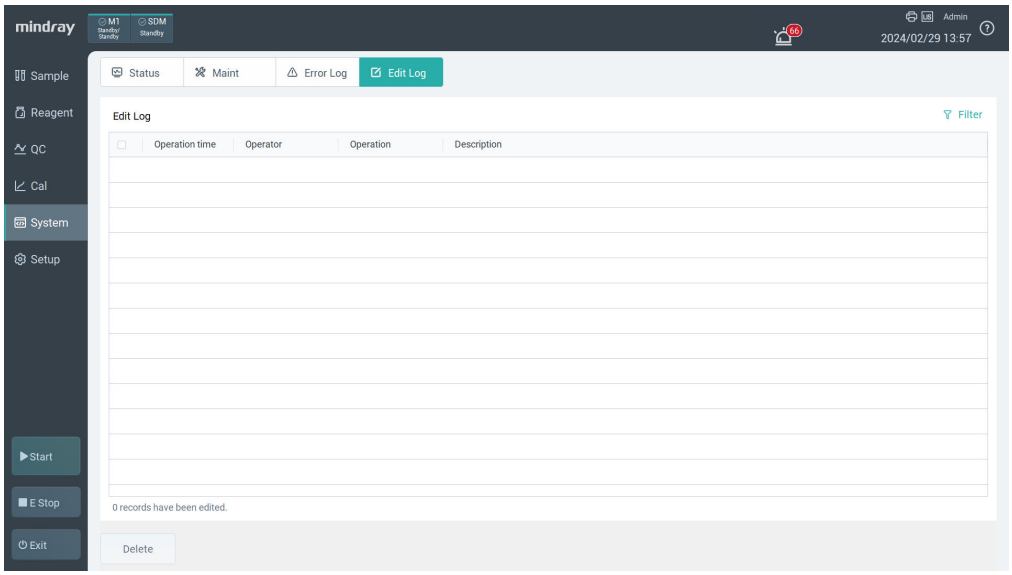
All error logs and edit logs can be recalled, searched, refreshed, deleted and printed.

12.2.1 Description of Edit Log Screen

Select **System** > **Edit Log**. The **Edit Log** screen is displayed and shows all editing actions occurring on the current day. On the **Edit Log** screen, you are allowed to view and handle all deleting/editing actions that occur within the latest 1 year.

You can click **delete** to delete the edit log.

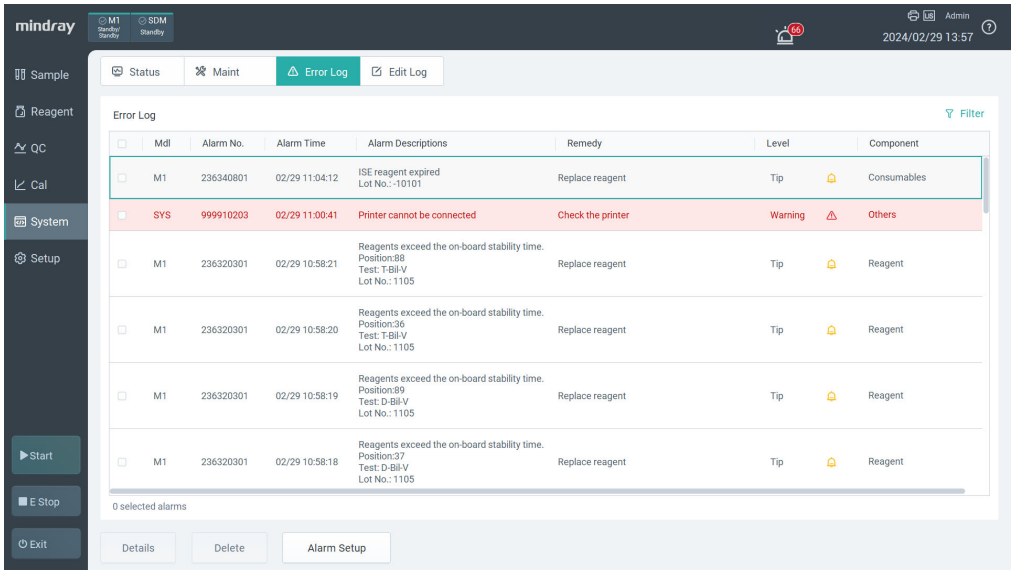
Figure 12.1 Edit Log screen



12.2.2 Description of Error Log Screen

Select **System- Error Log** in the function buttons area of the main screen. The **Error Log** screen is displayed by default and shows all errors occurring on the current day. On the **Error Log** screen, you are allowed to view and handle all errors that occur within the latest 6 months.

Figure 12.2 Error Log screen



Every error log contains the alarm number, date/time, alarm description (by processing method), level and component.

When audible and visual alarm is enabled, after an alarm is given, the alarm light will flash with the color you have set.

Choose the following buttons as needed:

- **Filter** : to search for error logs by date, alarm number, module, or level.
- **Delete**: to remove specified error logs on the screen.
- **Alarm Setup**: to set audio and visual alarm.
- **One-click clear**: to clear the selected errors.

12.2.3 Audio and Visual Alarm Setup

1. Select **System** > **Error Log**.
2. Click **Alarm Setup**.
3. Enable audible and visual alarms. Then select Enable Audible Alarm and/or Enable Light Alarm.
4. Set the number of sound repetitions.
5. Select **Defaults** to restore the factory settings. Click **OK**.

12.3 Error Troubleshooting

12.3.1 Introduction

When an error occurs, it will be indicated in many ways. The following pages describe how to troubleshoot errors and help you determine solutions to such errors.

Generally, troubleshooting is divided into the following steps:

- An error occurs and is indicated in various ways.
- Check the error logs and component status.
- Identify the error and determine relevant solutions.
- Implement the solutions.
- Check and evaluate the implementation of the solutions.

12.3.2 Error Indications

Errors may occur on hardware, software and the entire system. When an error occurs, it will be indicated in many ways to help identify it and determine the possible causes and solutions. Errors can be indicated by alarm tone, alarm message, color, alarm message box, result flag and error log, through which you will obtain detailed information about errors and find the relevant solutions.

12.3.2.1 Alarm tone

When an error occurs, the buzzer gives alarm tone reminding you to notice the error and take corrective actions. Alarm tone can be adjusted manually or silenced.

Perform the following steps to adjust the alarm tone:

1. Select **System** > **Error Log** > **Alarm Setup**.
2. Select **Enable Audio and Visual Alarm**.
3. Select **Enable Sound Alarm** and Adjust the alarm tone in the **Alarm Volume** field.
4. Test the alarm tone until it is suitable.
5. To silence the alarm tone, deselect **Enable Sound Alarm**.
6. Set the Repeat times of alarm sound.
7. Select **OK** to save the adjustment.

12.3.2.2 Alarm message

When an error occurs, the system gives an alarm and displays the alarm message in the prompt message area.

12.3.2.3 Color highlight

An error will be indicated by highlighting relevant buttons and screen texts with different colors. Yellow indicates a warning, and red indicates a serious warning or error.

- **Reagent** button
- **System** button
- **Error Log** button

Select a button to access relevant function page, check for abnormities and take corrective actions. When the problem is solved, the alarm indication disappears.

12.3.2.4 Alarm message box

An error can also be shown in an alarm message box, which contains the date/time, event ID, time(s) and help icon.

Errors that are indicated through an alarm message box are divided into the following types:

- Common error: including those that are indicated by warning the user, and by invalidating tests, reagents and samples. When such error occurs, the alarm message box shows with the title bar highlighted in yellow.
- Serious error: including those except for the common error. When such error occurs, the alarm message box shows with the title bar highlighted in red, and you are only allowed to reboot or exit the system.

When an alarm message box appears, select the **Alarm** button to view the new error logs, analyze the possible causes and determine relevant corrective actions.

12.3.2.5 Flag

Flag is also called data alarm. When calibration error or failure, or sample result error occurs due to the sample, reagent or system failure, a flag will appear near the corresponding calibration result or sample results.

12.3.2.6 Error log

All alarms are recorded in the error logs. By recalling the error logs you are enabled to master the current status of the system and troubleshoot errors.

12.4 Data alarms

12.4.1 Introduction

Data alarm is a result flag indicating that an error or abnormity occurs to a result. By identifying results flags can evaluate if the results are reliable and acceptable. Data alarm is not necessarily an error but will definitely influence the result and should be considered carefully.

The system provides monitoring of test results. When calibration error or failure, or sample result error occurs due to the sample, reagent or system failure, a flag will appear near the corresponding calibration result or sample results. The following pages summary the result flags of the system.

12.4.2 Result Flags

Table 12.1 Result Flags

Flag	Description	Causes	Corrective Actions
<	Exceeds linearity range low	Sample or control result exceeds the low limit of the linearity range.	Take no actions, or rerun the test for confirmation.
>	Exceeds linearity range high	Sample or control result exceeds the high limit of the linearity range.	Rerun the test with diluted sample.
<Def	Exceeds user-defined range low	The concentration is lower than the lower limit of the user-defined range. No actions are required.	No actions are required.

Flag	Description	Causes	Corrective Actions
>Def	Exceeds user-defined range high	The concentration exceeds the high limit of the user-defined range. No actions are required.	No actions are required.
↑	Exceeds reference range high	The result exceeds the high limit of the reference range.	No actions are required.
↑!	Exceeds critical range high	The result exceeds the high limit of the critical range.	No actions are required.
↓	Exceeds reference range low	The result exceeds the low limit of the reference range.	No actions are required.
↓!	Exceeds critical range low	The result exceeds the low limit of the critical range.	No actions are required.
10_{-x}	10_x	Results of five runs (10 results), or 10 continuous results of a control are on the same side.	Check if the reagent is qualified, control sample is normal, and the instrument is working correctly.
1-2s	12S	The current QC result is between ±2 and ±3 standard deviations from the assigned mean concentration.	No actions are required.
1-3s	13s	The current QC result is greater than ±3 standard deviations from the assigned mean concentration.	Check if the reagent is qualified, control sample is normal, and the instrument is working correctly.
2-2s	22s	Results of two controls in the same run or two continuous results of a control are on the same side and greater than ±2 standard deviations from the assigned mean concentration.	Check if the reagent is qualified, control sample is normal, and the instrument is working correctly.
4-1s	41s	Results of two runs (4 results), or 4 continuous results of a control are on the same side and greater than ±1 standard deviation from the assigned mean concentration.	Check if the reagent is qualified, control sample is normal, and the instrument is working correctly.
ABS	Absorbance out of range	The absorbance of primary and secondary wavelength used for calculating results is greater than 3.5 A.	Check the sample for impurities or interferents. Check the reagent placement and reagent quality. Check if the cuvettes are clean. Check if the photometric system is normal.
BIAS	Cl bias out of range	The Cl electrode is dirty. The Cl electrode is degenerated.	1. Clean the electrode repeatedly and then recalibrate. 2. Replace the Cl electrode.

Flag	Description	Causes	Corrective Actions
BLK	Blank response out of range	Reagent goes wrong; reagent is placed in the wrong position; reagent dispensing is insufficient; air bubbles exist in cuvette; light drifts. Cuvette overflow	Check if the cuvette is not overflowed, the position of reagent is correct, the volume of reagent is sufficient (without air bubbles), the test parameters are reasonable, and the light drifts. If yes, replace the reagent and then rerun the test.
BOE	Substrate depletion	Substrate depletion occurs due to too high sample concentration.	Dilute and rerun.
BRRW	Factors reset to default	Use the default calibration factors to calculate sample and QC results	Recalibrate
CalcE	Sub test is out of linearity range	Sample and control results of special calculation are beyond the linearity range.	Manually dilute the sample or use increased or decreased volume method to rerun the test.
CALE	Recalculate results	Use the edited calibration curve to calculate results.	No actions are required.
CAL.EXP	Calibration check failed: Calibration factors or calibrators are expired	Calibration factors or calibrators are expired. Please change and recalibrate	Change and recalibrate.
CAL.EXT	The calibration result is delayed.	The calibration result is delayed.	Take no actions, or recalibrate.
CAL.NA	Test not calibrated	Chemistry is not calibrated. Please calibrate and rerun.	Rerun after calibration.
CALF	Calibration status is not satisfied.	The reagent is not calibrated or calibration failed.	Request and run the calibration.
CALR	Recalculate results	Use the recalculated calibration curve to calculate results.	No actions are required.
CALJ	The calibration factors are rejected.	Use sample and control result gained by the rejected calibration factor	No actions are required.
CALT	The calibration factors are time out.	The calibration factors are time out.	Recalibrate.
CarOvr	Potential carryover	Potential carryover	Rerun.
CCP.ERR	Instrument error: Reaction carousel	Reaction carousel error	Contact our customer service department.
CD80.NA	CD80 detergent is exhausted.	CD80 detergent is exhausted.	Please add and rerun.
CO2.ERR	Ambient CO2 concentration out of range	Ambient CO2 concentration out of range	Please turn on the indoor ventilation device.

Flag	Description	Causes	Corrective Actions
COV	Calibration curve not convergent	For nonlinear calibration, a satisfying base cannot be calculated and no calibration curve is drawn.	Check that the reagent and calibrator are normal, and then recalibrate. If the error remains, contact our customer service department.
COV.NA	The shielding cover is opened.	The shielding cover is opened.	Rerun the test after closing the shielding cover.
COV.R	Reagent carousel cover is opened.	Reagent carousel cover is opened.	Rerun the test after closing the reagent carousel cover.
CSD	Calibration curve SD out of range	The calculated standard deviation of the calibration curve exceeds the specified limit.	Check if the parameters are reasonable, reagent and calibrators are normal, and then recalibrate.
Cuv.ERR	The cuvette is contaminated or scratched.	Cuvettes are contaminated or scratched. Perform weekly special wash.	Perform weekly special wash.
CVTM	No cuvette tray loaded or no cuvettes.	1. No cuvette is loaded. 2. Gripper error.	1. Load the cuvette. 2. Home the system and run the test again. If the error remains, contact our customer service department or your local distributor.
CW.ERR	Instrument error: Cuvette wash	The cuvette wash assembly goes wrong. Contact our customer service department.	Contact our customer service department.
DEL	Deleted QC result	The QC result has been deleted.	No actions are required.
DET	Calibration curve determination coefficient out of range	The calculated fit of the calibration curve exceeds the specified limit.	Check if the parameters are reasonable, reagent and calibrators are normal, and then recalibrate.
Dil.NA	Physiological saline W insufficient/Empty aspiration/Collision	Physiological saline W is insufficient or contains air bubbles, causing empty aspiration or collision.	Check the adding and then rerun the test.
DUP	Calibration repeatability error	CV is larger than the repeatability index obtained from the reagent bar code.	Check if the acceptance limit is reasonable, troubleshoot the error, and then recalibrate.
EDT	Edited result	The result has been edited.	No actions are required.
ERR	The results are invalidated due to instrument failure.	Invalidate the analyzer due to component failure or emergency stop.	Perform troubleshooting based on specific alarms.
ENC	No calculation interval for reaction curve	Sample concentration is too high; Substrate depletion occurs; Please	Dilute and rerun.

Flag	Description	Causes	Corrective Actions
EXP	Enzyme linearity extension stars for the test	The sample concentration is too high. The enzyme linearity extension calculation starts.	No actions are required.
FAC	Calibration slope difference out of range	Only applicable for linear calibration. It refers to the difference between current k and last k in slope. It exceeds the specified limit.	Check if the parameters are reasonable, reagent and calibrators are normal, and then recalibrate.
FAN.ERR	Refrigeration Module Cold End Fan failure	Refrigeration Module Cold End Fan failure	Contact our customer service department or your local distributor.
H. In	Slight hemolysis interference	Slight hemolysis interference found in serum index test	No actions are required.
H.+	Obvious hemolysis interference; positive interference	The serum index test found that the sample had significant hemolysis interference and the result was positively interfered.	Positive interference. Please check the sample.
H.-	Obvious hemolysis interference; negative interference	The serum index test found that the sample had significant hemolysis interference and the result was negatively interfered.	Negative interference. Please check the sample.
H	Obvious hemolysis interference	Hemolysis is found in serum index test	Please check the sample.
H. Out	Serious hemolysis interference	Serum index test found that the sample had serious hemolysis interference	Please check the sample.
HI	Hemolysis and icterus exist simultaneously	Hemolysis and icterus are detected simultaneously	Please check the sample.
ICA	The response is normal, but results cannot be calculated.	Result cannot be calculated due to no valid calibration factors.	Result cannot be calculated due to no valid calibration factors. Rerun it after calibration.
ISE.ERR	Instrument error: ISE module	The ISE assembly goes wrong.	Please contact our customer service department.
ISET.ERR	Instrument failure: ISE cooling fan	The ISE fan assembly goes wrong.	Please contact our customer service department.
ISER.Exp	ISE reagent expired	ISE reagent is expired. Please check and replace it in time.	Check and replace it in time.
ISE.NA	ISE sample diluent dispensing deviation is too large	ISE sample diluent dispensing deviation is too large	Check the electrode installation. Perform ISE wash and then rerun the test.
ISEC.ERR	ISE communication error	ISE communication error.	Restore the analyzing unit.

Flag	Description	Causes	Corrective Actions
ISEC.NA	ISE communication timeout	ISE communication timeout	No actions are required.
ISER.ERR	ISE reagent pack status abnormal	ISE reagent pack status is abnormal.	Replace with a new reagent pack and rerun the test.
I. In	Slight icterus interference	Serum index indicates that the sample has slight icterus.	No actions are required.
I.+	Obviously interfered by icterus.result positive interference	Serum index test shows that the sample has obvious icterus interference.	Result Positive interference. Please check the sample.
I.-	The measurement is obviously interfered by icterus and the result is negative.	Serum index test shows that the sample has obvious icterus interference.	Result Negative interference. Please check the sample.
I	Obvious icterus interference	Serum index test shows that the sample has obvious icterus interference.	Please check the sample.
I. Out	Severe icterus interference	Serum index test shows that the sample has severe icterus interference.	Please check the sample.
IW.ERR	Instrument error: Probe interior wash syringe	The interior wash syringe assembly goes wrong.	Contact our customer service.
L!	Water blank fluctuation out of range	1. Overflow 2. The lamp has been replaced incorrectly. 3. Cuvette check is not performed after cuvette maintenance. 4. The lamp cable is not connected properly. 5. The retaining screw of the lamp has not been tightened. 6. Cuvette wash solution is insufficient. 7. Lamp is aging. 8. Photometer error	Check if the cuvettes are overflowing. Check if the Replace Lamp command is executed when the lamp is replaced. Check if the cable connectors and retaining screws are tightened. Check if the wash solution inside the cuvette is no less than half of the wash solution. If the reaction curve fluctuates irregularly, replace the lamp. If the error remains, contact our customer service department.
LACK.ERR	Instrument error: Front track	The front track of the instrument goes wrong.	Please contact our customer service department.
LH	Lipemia and hemolysis interference	Lipemia and hemolysis co-exist. Please check.	Lipemia and hemolysis co-exist. Please check.
LI	Lipemia and hemolysis interference	Lipemia and icterus co-exist. Please check.	Lipemia and icterus co-exist. Please check.
LHI	Lipemia, hemolysis and icterus interference	Lipemia, hemolysis and icterus interference	Lipemia, hemolysis and icterus co-exist. Please check.

Flag	Description	Causes	Corrective Actions
LHI.NA	Serum index test is not completed or abnormal.	The serum index test is still under way and no action is required.	No actions are required
LIN	Linearity limit out of range	Sample concentration is too high. The measuring points for result calculation are nonlinear or the substrate depletion limit is not specified or unreasonable. The lamp is aging.	Check the reaction curve and the substrate depletion limit. Rerun the test with diluted sample. If the error occurs for multiple chemistries simultaneously, if the reaction curve fluctuates irregularly, replace the lamp.
LOW	Response less than that of the lowest-level calibrator	The sample concentration is lower than the sensitivity indicated on the reagent pack, making response less than that of the lowest-concentration calibrator.	For ascending calibration curve, rerun the test with normal or increased volume; for descending calibration curve, rerun the test with diluted sample.
L. In	Slight lipemia	Slight lipemia is found in the serum index test.	No actions are required
L.+	Lipemia is interfered obviously . Positive interference.	Slight lipemia is found in the serum index test.	Positive interference. Please check the sample.
L.-	Lipemia is interfered obviously. Negative interference	Slight lipemia is found in the serum index test.	Negative interference. Please check the sample.
L	Obvious lipemia interference	Lipemia is found in serum index test	Please check the sample.
L. Out	Severe lipemia interference	Serum index test shows that the sample has serious lipemia interference.	Please check the sample.
LH	Lipemia and hemolysis interference	Serum index test found that the sample had lipemia and hemolysis at the same time.	Please check the sample.
LI	Lipemia or icterus	Serum index test shows that the sample is interfered by lipemia and icterus at the same time.	Please check the sample.
LHI	Lipemia, hemolysis and icterus interference	Serum index test shows that the sample is interfered by lipemia, hemolysis and icterus at the same time.	Please check the sample.
LHI.NA	Serum index test is not finished or abnormal.	The serum index test is still in progress.	No actions are required.

Flag	Description	Causes	Corrective Actions
MBK	Mixed blank absorbance out of range	The reagent goes wrong. Cuvettes are not clean. Cuvettes are overflowed; reagent addition is not sufficient.	Check if the cuvette is clear and not overflowed, the reagent is sufficient without air bubbles, and the test parameters are reasonable. If yes, replace the reagent and then rerun the test.
MASK	The test is masked. The test is not allowed.	The test is masked.	Unmask the test and run its test.
MON	Calibration curve is not monotonic.	The calibration data and calibration curve are not monotonic.	Check if the calibrator is defined and placed correctly, and then recalibrate.
NLN	No linear interval	The high-concentration sample leads to less than 3 valid measuring points within the reaction time of rate check measurements.	Rerun the test with diluted sample.
NOID	Instrument error: Software error	Instrument software error. Sample ID is lost.	If the error remains, contact our customer service department.
OVE	Calibration factor overridden	Use the sample and control result gained by the overridden calibration factor	Take no actions, or recalibrate.
Overflow!	Cuvette overflow	1.Weekly special wash solution and optical unit check are not performed on time. 2.Overflow	Check if the cuvettes are overflowing. If not, execute the weekly special wash and optical unit check commands. If the error remains, contact our customer service department.
PRO	Prozone check error	Antigen excess occurs due to too high sample concentration.	Replace and rerun
QC.EXP	Control is expired	Control is expired	No actions are required.
R	Rerun result	Retest the finished test	No actions are required.
R-4S	R4S	One result of a run is greater than +2 standard deviations from the assigned mean and the other greater than -2SDs.	Check if the reagent is qualified, control sample is normal, and the instrument is working correctly.
RACK.NA	No sample is detected on the rack.	No sample is detected on the rack.	Place the right sample.
RBK	R1 blank absorbance out of range	The absorbance of primary and secondary wavelengths of the test is not within [-35000 or 35000] at the 1-4 measuring point. The reagent goes wrong. Cuvettes are not clean. Cuvettes are overflowed; reagent addition is not sufficient.	Check if the cuvette is clear and not overflowed, the reagent is sufficient without air bubbles, and the test parameters are reasonable. If yes, replace the reagent and then rerun the test.

Flag	Description	Causes	Corrective Actions
R. Exp	Reagent expired	Reagent expired	Please check the reagent and replace it in time.
R1.NA	R1 reagent insufficient/ aspiration empty/ collision/too Full.	R1 reagent insufficient/ aspiration empty/collision/ too Full. Please check.	Please check the corresponding reagent volume.
R1DA.NA	Acid wash for Probe R1 is insufficient. Reagent probe aspirates nothing or collides.	Acid wash for Probe R1 is insufficient. Reagent probe aspirates nothing or collides.	Please check the corresponding acid wash volume.
R1DB.NA	Probe R1 alkaline wash is insufficient. Probe R1 aspirates nothing or collides. Please check.	Probe R1 alkaline wash is insufficient. Probe R1 aspirates nothing or collides. Please check.	Please check the corresponding alkaline wash volume.
R1W.NA	Probe R1 reagent washing failed.	Probe R1 reagent washing failed.	Please rerun
R1W.ERR	Instrument error: Probe R1 washing failed.	Probe R1 washing failed.	Perform the test again after resetting.
R2.NA	R2 reagent insufficient/ aspiration empty/ collision/over Full.	R2 reagent insufficient/ aspiration empty/collision/ over Full. Please check.	Please check the corresponding reagent volume.
R2DA.NA	Acid wash for R2 probe is insufficient. R2 probe aspirates nothing or collides.	Acid wash for R2 probe is insufficient. R2 probe aspirates nothing or collides.	Please check the corresponding Acid wash volume.
R2DB.NA	Alkaline wash for R2 probe is insufficient or R2 reagent probe aspirates nothing or collides. Please check.	Alkaline wash for R2 probe is insufficient or R2 reagent probe aspirates nothing or collides. Please check.	Please check the corresponding Alkaline wash volume.
R2W.NA	Probe R2 reagent Wash failed.	Probe R2 reagent Wash failed.	Please rerun.
R2W.ERR	Instrument error: Probe R2 washing	Probe R2 cleaning failed.	Perform the test again after resetting.
R3.NA	R3 Reagent is insufficient. Reagent probe aspirates nothing/collides with an obstacle. R3 is too Full.	R3 Reagent is insufficient. Reagent probe aspirates nothing/collides with an obstacle. R3 is too Full.	Please check the corresponding reagent volume.
R4.NA	R4 Reagent is insufficient. Reagent probe aspirates nothing/collides with an obstacle. R4 is too Full.	R4 Reagent is insufficient. Reagent probe aspirates nothing/collides with an obstacle. R4 is too Full.	Please check the corresponding reagent volume.
R1.ERR	Instrument error: Probe R1	Probe R1 goes wrong.	Contact our customer service department.

Flag	Description	Causes	Corrective Actions
R2.ERR	Instrument error: Probe R2	Probe R2 goes wrong.	Contact our customer service department.
RM.ERR	Instrument error: Reagent mixing	Reaction curve is abnormal.	Check and rerun.
RT.ERR	Instrument error: Reagent refrigeration	The reagent refrigeration assembly goes wrong.	Contact our customer service department.
RE	Reaction curve abnormal		
REE	Compensated Result	Proceed	No actions are required.
RCE	Result cannot be calculated	The absorbance data for calculation is incomplete, or the dividend is 0.	Rerun the test. If the error remains, contact our customer service department.
REC	Recalculate the sample results manually.	The sample result is calculated manually with the latest calibration factors.	No actions are required.
RG!	Reagent blank error	Fluctuation of reagent blank exceeds 0.2Abs in ten consecutive tests.	1.Check if the cuvettes are overflowed 2.Check whether the temperature and humidity of the test environment are too high. 3.Check if reagent is expired or contains air bubbles.
RM.ERR	Instrument error: reagent mixing	The mixer assembly of instrument reagent goes wrong.	Contact our service engineer
RP.ERR	Instrument error: reagent carousel	The reagent carousel assembly goes wrong.	Contact our service engineer
RRN	Sample concentration is higher than that of the highest-level calibrator	The sample concentration exceeds the high limit of the calibrator concentration.	Rerun the test with diluted sample.
S.ERR	Sample probe movement error	The sample probe assembly goes wrong.	Contact our customer service department or your local distributor.
S.CarOvr	The sample may be contaminated by the previous test.	The sample may be contaminated by the previous test.	Check if the wash solution is sufficient.
S.Clot	Sample probe is clogged when aspirating sample.	Sample probe is clogged when aspirating sample.	Check if the sample probe is clogged.
SDA.NA	Sample probe acid wash is insufficient. Sample probe aspirates nothing or collides.	Sample probe acid wash is insufficient. Sample probe aspirates nothing or collides.	Check corresponding acid wash.

Flag	Description	Causes	Corrective Actions
SDB.NA	Sample probe alkaline wash is insufficient. Sample probe aspirates nothing or collides.	Sample probe alkaline wash is insufficient. Sample probe aspirates nothing or collides.	Check corresponding alkaline wash.
SDC.NA	Insufficient sample probe detergent/ sample probe aspirates nothing or collision	Insufficient sample probe detergent/sample probe aspirates nothing or collision	Check detergent cleanser.
SEN	Calibration sensitivity out of range	The difference of final response of the maximum and minimum concentration calibrators exceeds the specified limit.	Check if the parameters are reasonable, reagent and calibrators are normal, and then recalibrate.
SEQ.ERR	Sample loading order is not satisfied	Dispensing order is not satisfied	Check the sample loading order and then rerun.
S.Exp	Sample expired	Sample expired	Prepare new sample.
SLP	The correction factor is set for the test.	The correction factor is set for the test.	No actions are required.
SLP.M	The correction factor is set for the test.	The correction factor is set for the test.	No actions are required.
STATUS.ERR	Instrument status is not satisfied	Instrument status is not satisfied	Contact our service engineer
S.NA	Sample is insufficient/ aspirated nothing/ collision	Sample is insufficient/ aspirated nothing/collision	Check sample
S.Delay	Sample is delayed to reach its place.	Because sample is delayed to reach the sampling position, the test is invalidated.	Rerun the invalidated test.
SDM.ERR	SDM error	SDM error	Home the system. If the error remains, contact our customer service department or your local distributor.
SM.ERR	Instrument error: Mixing sample	The sample mixer assembly goes wrong.	Please contact our customer service department.
SW.NA	Sample probe cleaning failed.	Sample probe cleaning failed.	Please rerun
SW.ERR	Instrument error: Sample probe washing	Sample probe cleaning failed.	Please contact our customer service department.
SYS.ERR	Instrument error: Instrument does not work normally	Instrument does not work normally	Contact our customer service department or your local distributor.

Flag	Description	Causes	Corrective Actions
TD	Photoelectric measurement is time out.	Photoelectric measurement is time out.	1. Rerun the operating software. 2. Restart the analyzing unit. 3. If the error remains, contact our customer service department.
T.ERR	Instrument error: Temperature control system	Instrument error: Temperature control system	Contact our customer service department or your local distributor.
TEST.CANCEL	Test cancelled/out manually retrieval	Test cancelled/out manually retrieval	Rerun the test.
TEST.UNABLE	Test unavailable	Test unavailable	Check and rerun.
TRACK.ERR	Track failure	Track failure	Check and rerun.
TUBE.NA	Sample tube abnormal	Sample tube abnormal	Check and rerun.
VAC.ERR	Instrument error: Cuvette wash error	Cuvette wash is abnormal.	Please contact our customer service department.
W.ERR	Instrument error: Fluidic unit error	Fluidic unit error	Contact our service engineer
WST.F	Waste tank is full.	Waste tank is full.	Empty or replace the waste tank.
WST.ERR	Waste drainage system abnormal.	Waste drainage system abnormal.	Contact our customer service department or your local distributor.

12.5 Troubleshooting Procedure

When the analyzer is running, some problems may occur. When the analyzer detects these problems, it will give an audible and visual alarm to remind you of the problem. You can see the current problem on the software screen. Meanwhile, you can clear the alarm through the prompt on the software screen. When the problem is solved, the analyzer will go back to normal. If the troubleshooting measures provided by the analyzer cannot solve your problem, please give feedback to Mindray customer service department in time.

12.5.1 Error Alerts and View

The analyzer provides alerts in multiple ways. For abnormal situations that require immediate intervention, the instrument will remind the user through audible and visual alarms. When the consumables of the cabinet need to be replenished, the consumables indicator of the instrument will prompt the user to add the consumables. If the error is not serious and does not need immediate handling you can see the alarm message on the software screen, and then choose your handling method according to the software prompts and actual conditions.

The analyzer classifies alarms into three levels, and different levels of alarms will be indicated in different ways.

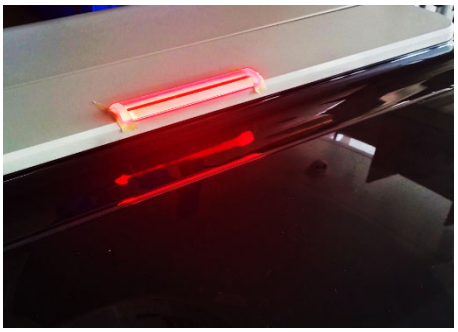
12.5.1.1 Alarm level

The analyzer classifies alarms into three categories: Severe alarm, warning alarm and prompt alarm.

- For alarms that cause stop or are about to cause stop, you need to handle them immediately.
- Warning alarms are alarms that may pause the analysis, or stop the system if not handled properly, and affect the TAT time of the sample. You should also handle them as soon as possible after a warning alarm occurs.
- For prompt-level alarms, generally you need not to take actions, which has little impact on the test. If you are beside the analyzer, you can check the prompt messages on the software screen.

12.5.1.2 Analyzer status indicator

The status indicators above the shielding cover indicate the status of the analyzer with different colors. When you are far away from the analyzer, you can determine whether the analyzer is working or not according to the color of the analyzer status indicator. When the analyzer is in the sleep or shutdown status, all the analyzer status indicators are not on.



There are three colors when the analyzer status indicator is working. Different colors indicate different statuses of the analyzer.

Red:

When the status indicator of the analyzer is red, the analyzer may have a serious error, which triggers a serious alarm that the analyzer has stopped or is about to stop. Check the instrument as soon as possible to check for errors.

Yellow:

When the status indicator of the analyzer is yellow, the analyzer triggers a warning alarm. Problems will not lead to the stop of the analyzer, but may affect the current test, for example, the reagent of a test is used up or consumables are used up. If the analyzer status indicator is yellow, you should also go to the analyzer as soon as possible to avoid delaying the completion of tests and report output.

Blue:

When the status indicator of the analyzer is blue, the analyzer is in normal working status and does not require much intervention. If you are in front of the analyzer, tap the alarm button on the analyzer screen to access the alarm screen. On the Alarm screen, you can see the abnormal information of the analyzer.

12.5.2 Software Screen Prompt

When detecting an abnormity, the analyzer will remind you in the following two ways:

12.5.2.1 Display of severe alarms

When the analyzer is in serious failure and may stop. An alarm box pops up on the software screen. You can view the error information in the pop-up alarm box and determine the solution according to the prompt.

In the pop-up window, if you are prompted to recover the failure, you can select a failed module and then click the "**Home**" button to start the process.

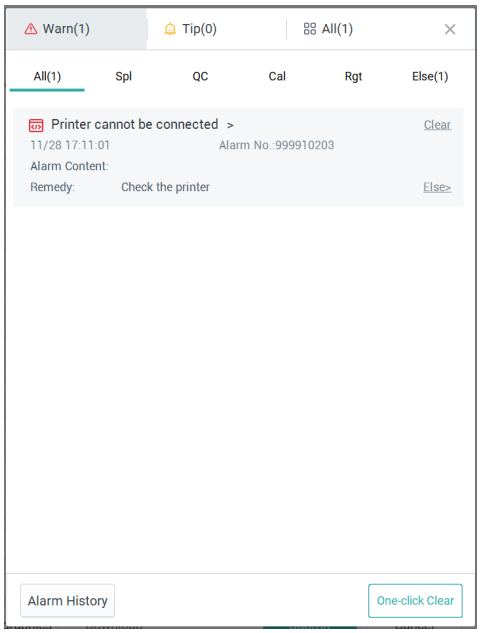
If you have closed the error dialog box but need to check the error information or the solutions, click the analyzer status icon in the upper left corner of the software screen or the system icon in the middle left corner of the software.

In this window, you can view the alarms that have not been recovered, select a faulty module and click the "**Home**" button to recover the failure.

12.5.2.2 Display of warning and prompt alarms

There is an icon in the upper right corner of the screen.

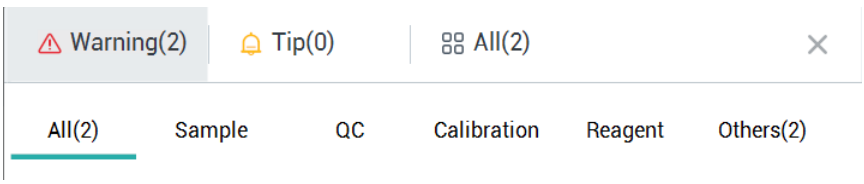
You can click the icon to enter the screen for warning and prompt alarms.



On the warning and prompt alarm screens, all warning errors are displayed by default.

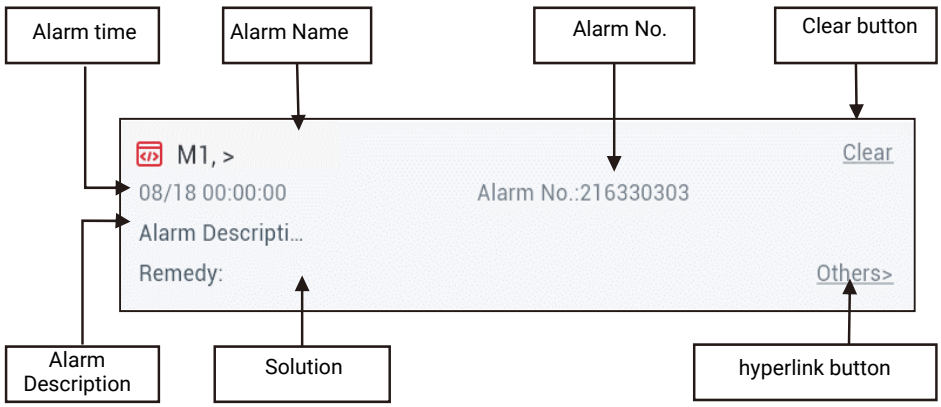
You can also view the prompts by clicking the "Prompt" tab.

On the warning and prompt screens, you are also allowed to view the errors of the corresponding categories through the "Sample," "QC," "Calibration" and "reagent" tabs.



12.5.3 Troubleshooting

You can see cards with error messages in the pop-up window for severe alarms and warning and prompt alarms.



The alarm card contains the following information:

- Alarm Name
- Alarm time
- Alarm No.
- Alarm Description
- Solution
- Clear button: If you do not care about the alarm or you can confirm that the alarm is resolved, click the **Clear** button. When the button is clicked, the screen will display and delete the corresponding alarms.
- Hyperlink button: You can click this button to enter other screens related to this alarm. After entering the corresponding screen, you can perform relevant software operations to solve the problem.

You can try to solve the problem according to the prompt on the alarm card.

See the table for the causes and solutions of common errors.

If the error still remains, contact our customer service department or your local distributor.

To contact Mindray customer service personnel, prepare the following information:

- Account/User ID
- Analyzer SN
- Module Type and SN
- Software version
- Alarm and Alarm Code

If test results are involved, you should also provide the following information:

- Reagent Ref No., Lot No., and Expiration Date
- Recent calibration results
- Latest QC results
- Abnormal test results and test-related information (If specific tests are involved).

12.5.4 Clear Errors

Errors can be cleared automatically by the instrument or manually by the user.

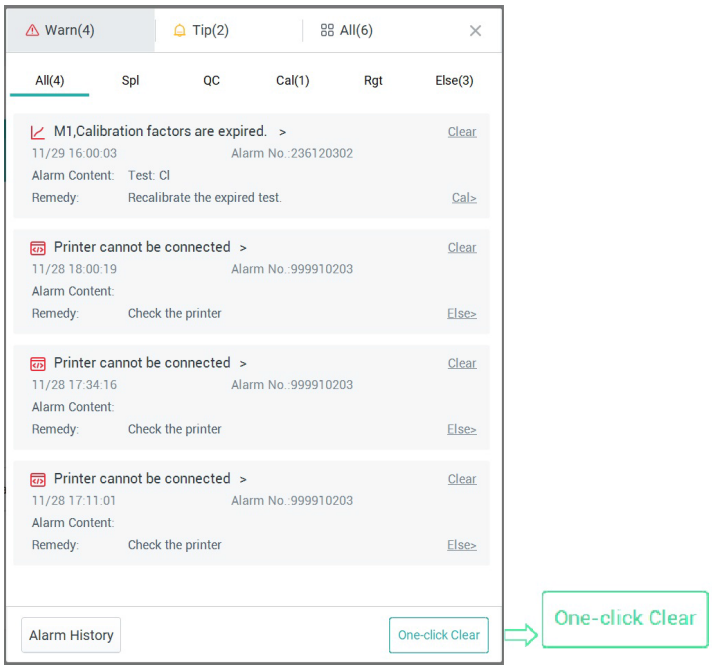
12.5.4.1 Auto Clear

If the analyzer detects that the previous alarms or condition no longer meets the alarm conditions, the corresponding alarm will be cleared automatically. Clearing alarms in such cases is the active operation of the analyzer. For example, if an alarm indicates that a reagent has been used up, the analyzer will clear the alarm after detecting that the reagent has been added.

12.5.4.2 Manual Clear

Some alarms are used to record abnormal conditions that have occurred and may not be cleared automatically. In this case, the corresponding alarm can also be cleared manually.

On the warning and prompt screens, if you know all alarms and you do not need to pay attention to them, you can click the **one-click clear** button on the lower right corner of the warning and prompt screens. After you click this button, the software clears the alarms on the corresponding alarm screen and clears the corresponding alarm count.



Note that the above alarm clearing function is only used to clear the prompt information on the alarm screen. If you do not actively clear the alarms on the screen, no extra impact will be incurred.

12.6 Error Messages and Corrective Actions

12.6.1 No Alarm Troubleshooting

The following table lists conditions that may affect the startup of the analyzer. If the analyzer cannot be turned on or is not connected or offline without any alarm, it is recommended to perform the following checks. If the problem is not solved through all measures, please contact technical support.

Cause Description	Corrective Actions
Instrument is not powered on.	Connect the power cord to the socket or the air switch.

The instrument switch is turned off.	Switch on the main switch and module switch to the ON position.
Network cable is not connected.	Connect the computer network cable to the network interface on the back of the SDM.
Network cable connection error	Possible cause: Incorrectly plug the communication network cable into the LIS communication port. Adjust the network cable connection.
The instrument is set to offline/ disconnected status.	Turn off the computer software and power switch of the module, wait for 10 seconds, and turn on the module power in turn, and then run the operating software again.

12.6.2 Troubleshooting Alarms

If there is an alarm error, follow the prompt dialog box displayed on the screen or click the icon  on the upper right corner of the main screen to find out the solution. You can also click the **>** next to the title of the error alarm to go to the error log screen and view the solution and details. The error details include the detailed error causes and solutions.

If the problem is not solved through all measures, please contact the Customer Survice.

13 Operation Theories

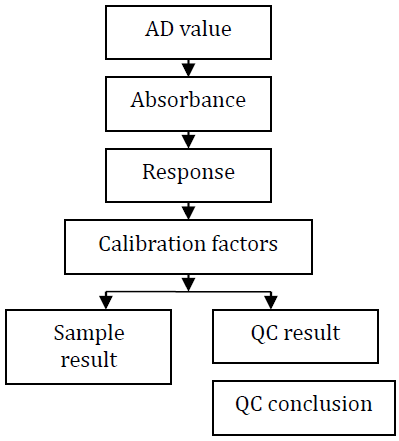
In this chapter

13.1 Overview

The system is a fully automated computer-controlled clinical chemistry analyzer allowing the random selection of tests. It is capable of running a variety of tests based on the operation theories and measurement principles.

The system performs measurement and generates the test results in the following procedure:

Figure 13.1 Measurement workflow



The system measures the light intensity through photoelectric conversion, linear amplification and AD conversion, and then calculates the reaction mixture's absorbance and the absorbance change rate, that is, the response, based on which the calibration factors are obtained. The system performance is evaluated according to the test results of the control samples. If the system is working normally, you may start the analysis of patient samples and the system will calculate the sample results with the calibration factors.

13.2 Principles of Measurement

13.2.1 Introduction

The system performs measurement with the following principles:

- Endpoint
- Fixed-time
- Kinetic

In the description of the following sections, N and P indicate the blank read time range, L and M indicate the reaction read time range. In double-wavelength measurements, absorbance A is the absorbance difference between the primary and secondary wavelengths; in single-wavelength measurements, absorbance A is the absorbance measured at the primary wavelength.

13.3 Endpoint Measurements

13.3.1 Introduction

In endpoint measurements, the reaction reaches equilibrium after a period of time. Since the equilibrium constant is quite high, it can be considered that all substrates (analytes) have changed into products, and the absorbance of the reactant will not change any more. The absorbance change is directly proportional to the analytes' concentration. The endpoint method, also called equilibrium method, is most ideal for measurements.

The endpoint reaction is insensitive to minor changes in such conditions as the enzyme volume, pH value and temperature, provided the changes are not significant enough to affect the reaction time.

13.3.2 Calculation of Reaction Absorbance

Set up the reaction time range by understanding the following instructions:

- If L=M, that is, [M] and [M] are entered for the reaction time range, one measuring point will be used for absorbance calculation, and the reaction absorbance will be the absorbance measured at point M, i.e. Ai=AM.
- If L=M-1, that is, [M-1] and [M] are entered for the reaction time range, two measuring points will be used for absorbance calculation, and the reaction absorbance will be the average of the absorbance measured at the two points, i.e. Ai= $\frac{A_M + A_{M-1}}{2}$.
- If L=M-2, that is, [M-2] and [M] are entered for the reaction time range, three measuring points will be used for absorbance calculation, and the reaction absorbance will be the mediate absorbance measured at the three points, while the maximum and minimum absorbance is removed.
- If M>L+2, the reaction absorbance will be the average of the remaining absorbance when the maximum and minimum absorbance is removed.

13.3.3 Calculation of Blank Absorbance

The blank absorbance Ab is calculated in the same way as the reaction absorbance Ai.

When N=P=0, the blank absorbance Ab will not be calculated.

13.3.4 Calculation of K Factor

The system provides four K factors for result calculation, which are expressed through the following equations:

- $k1 = \frac{V_{R1}}{V_{R1} + V_S}$
- $k2 = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$
- $k3 = \frac{V_{R1} + V_S + V_{R2}}{V_{R1} + V_S + V_{R2} + V_{R3}}$
- $k4 = \frac{V_{R1} + V_S + V_{R2} + V_{R3}}{V_{R1} + V_S + V_{R2} + V_{R3} + V_{R4}}$

Where, VR1, VR2, VR3 and VR4 are the volumes of R1, R2, R3 and R4; Vs is the actual volume of sample dispensed for reaction.

The response in endpoint measurements is calculated as follows: $R = Ai - k \times A_b$

k is the calculation factor and varies with the test parameters.

Table 13.1 Calculation of response for endpoint measurements

Endpoint	Blank Time	Reaction Time	K
When the blank absorbance is read before the reaction begins,			
Single-reagent	2 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 3	5 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 33	K1
Double-reagent	5 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 16	18 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 33	K2
Triple-reagent	18 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 36	41 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 69	K3
Quadruple-reagent	41 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 52	54 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 69	K4
When the blank absorbance is read after the reaction begins,			
Single-reagent	5 ⩽ Nx ⩽ N ⩽ P ⩽ Px	P ⩽ Px<L ⩽ M ⩽ Mx ⩽ 33	1
Double-reagent	18 ⩽ Nx ⩽ N ⩽ P ⩽ Px	P ⩽ Px<L ⩽ M ⩽ Mx ⩽ 33	1
Triple-reagent	41 ⩽ Nx ⩽ N ⩽ P ⩽ Px	P ⩽ Px<L ⩽ M ⩽ Mx ⩽ 69	1
Quadruple-reagent	54 ⩽ Nx ⩽ N ⩽ P ⩽ Px	P ⩽ Px<L ⩽ M ⩽ Mx ⩽ 69	1
When the blank absorbance is not subtracted,			
Single-reagent	Nx=N=P=Px=0	5 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 33	0
Double-reagent	Nx=N=P=Px=0	18 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 33	0
Triple-reagent	Nx=N=P=Px=0	41 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 69	0
Quadruple-reagent	Nx=N=P=Px=0	54 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 69	0

13.3.5 Sample Blanked Response

Sample blank is used for removal of non-chromogenesis reaction, such as influence of sample interference (Hemolysis, icterus and lipemia) on absorbance readings. The sample blank reaction curve is almost a straight line with slope of 0 during the reaction period, and therefore means nothing for fixed-time and Kinetic analysis.

In single-reagent endpoint measurements, the response of the sample blank test is Rsb = Ai-k×Ab, and the sample blanked response is $R' = R - R_{sb}$.

13.4 Fixed-time Measurements

13.4.1 Introduction

In fixed-time measurements, namely, rate measurements, the reaction velocity (v) is directly proportional to the substrate concentration [S] within a specific period, that is, v=k[S]. As the substrate is consumed continuously, the reaction velocity is decreasing gradually, and so is the absorbance change rate. It takes a long time for the reaction to reach equilibrium. Theoretically, the absorbance reading can be taken at any time. The reaction, however, can become steady only after a lag because it is complicated at the beginning and there are miscellaneous reactions due to complex serum compositions.

For any rate measurements, the substrate concentration [S] at a given point t since the reaction begins is obtained through the following formula: $[S] = [S_0] \times e^{-kt}$

Where,

- S_0: the initial substrate concentration
- e: base of the natural log
- k: velocity constant

The change of substrate concentration Δ[S] over a fixed time interval, t_1 to t_2, is related to $[S_0]$ by the following equation: $[S_0] = \frac{-\Delta[S]}{e^{-kt_1} - e^{-kt_2}}$

That is, the change in substrate concentration is directly proportional to its initial concentration within a fixed time interval. This is the common feature of rate measurements. Within this interval, the absorbance change is directly proportional to the analytes concentration. The fixed-time reaction is also called, rate reaction, first-order Kinetic reaction and two-point Kinetic reaction.

It is available in single-interval and double-interval according to the input mode of measuring points. In the double-interval reaction, the sample blank, which is the absorbance change at two points within the incubation time, is subtracted from the reaction absorbance.

The fixed-time measurements allow the check of substrate depletion at the two measuring points. When detecting substrate depletion, the system will flag the test result with "BOE" and give an alarm.

13.4.2 Calculation of Response

The response in fixed-time measurements is calculated as follows:

$$R = 60 * \left(\frac{A_M - A_L}{t_M - t_L} - k \cdot \frac{A_P - A_N}{t_P - t_N}\right)$$

k is the calculation factor and varies with the test parameters.

Table 13.2 Calculation of response for fixed-time measurements

Fixed-time	Blank Time	Reaction Time	K Factor
When the blank absorbance is read before the reaction begins,			
Single-reagent	2 ⩽ N<P ⩽ 3	5 ⩽ L<M ⩽ 33	K1
Double-reagent	5 ⩽ N<P ⩽ 16	18 ⩽ L<M ⩽ 33	K2
Triple-reagent	18 ⩽ N<P ⩽ 36	41 ⩽ L<M ⩽ 69	K3
Quadruple-reagent	41 ⩽ N<P ⩽ 52	54 ⩽ L<M ⩽ 69	K4
When the blank absorbance is not subtracted,			
Single-reagent	N=P=0	5 ⩽ L<M ⩽ 33	0
Double-reagent	N=P=0	18 ⩽ L<M ⩽ 33	0
Triple-reagent	N=P=0	41 ⩽ L<M ⩽ 69	0
Quadruple-reagent	N=P=0	54 ⩽ L<M ⩽ 69	0

13.5 Kinetic Measurements

13.5.1 Introduction

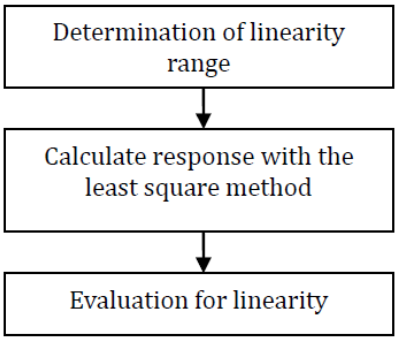
In Kinetic measurements, namely, zero-order Kinetic measurements or continuous-monitoring measurements, the reaction velocity is not related to substrate concentration and remains constant during the reaction process. As a result, the analytes absorbance changes evenly at a given wavelength, and the change rate (A/min) is directly proportional to the activity or concentration of the analytes. The Kinetic method is usually used to measure enzyme activity.

In fact, it is impossible for the substrate concentration to be absolutely high, and the reaction will be no longer a zero-order reaction when the substrate is consumed to certain degree. Therefore, the reaction type only stands within certain reaction period. In addition, the reaction can become steady only after a period of time, because the reaction is complicated at the beginning and there are miscellaneous reactions due to complex serum compositions.

In Kinetic reaction, the concentration or activity is obtained according to the absorbance change among specified measuring points.

13.5.2 Data Calculation in Kinetic Measurements

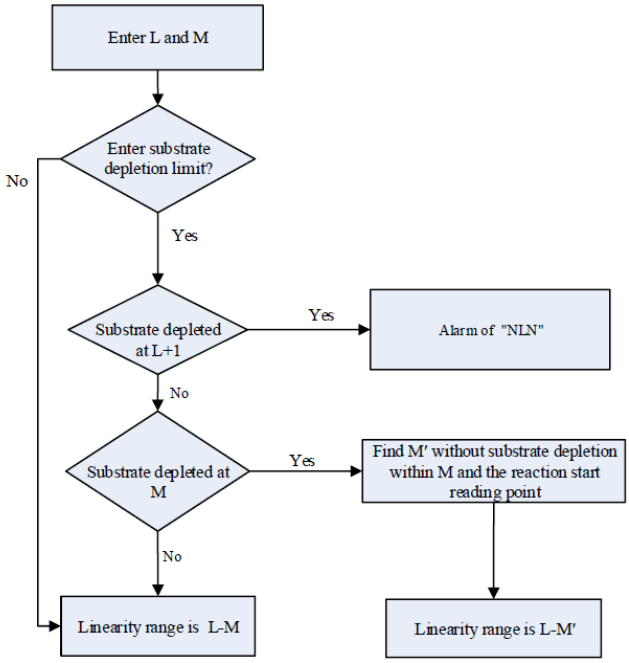
Figure 13.2 Data calculation flow of Kinetic measurements



13.5.3 Determination of Linearity Range

The absorbance linearity range is determined based on the substrate depletion limit, and checked within the reaction time rather than the blank time.

Figure 13.3 Determination of linearity range for Kinetic measurements



The number (N) of measuring points within the substrate depletion limit is monitored for different operations:

- If N≥3, the linearity range includes all measuring points from the reaction start point to the substrate depletion limit;
- If N=2, the system will give the flag "NLN" while using two measuring points for calculating the response.
- If N=0 or 1, when Enzyme Linear Extension option is selected on the chemistry parameter screen, enzyme linear extension will be enabled and the system gives the flag "NLN"; when Enzyme Linear Extension option is not selected on the chemistry parameter screen, enzyme linear extension will not be enabled and the system gives the flag "NLN" too.

13.5.4 Calculation of Response

Absorbance change rate ⊿ALM' within the reaction time

The response⊿ALM' within L-M' is calculated with the least square method.

$$\Delta A_{LM'} = 60 * \frac{\sum_{i=L}^{M'} (T_i - \overline{T}) \cdot (A_i - \overline{A})}{\sum_{i=L}^{M'} (T_i - \overline{T})^2}$$

Where,

- L: start point of the linearity range
- M': end point of the linearity range
- Ai: absorbance measured at measuring point i
- $\overline{A}$: average absorbance within L-M'
- Ti: actual measuring time (second) at measuring point i
- $\overline{T}$: average measuring time within L-M

If there are less than two measuring points without substrate depletion within the reaction time, the system will calculate the absorbance change rate by extending the enzyme linearity range.

Absorbance change rate ?ANP within the blank time

The absorbance change rate ?ANP within the blank time is calculated with the same equation as ⊿ALM'.

If N=P=0, the absorbance change rate within the blank time is 0.

Calculation of Response

The response in Kinetic measurements is calculated as follows:

$$R = \Delta A_{LM} - K \cdot \Delta A_{NP}$$

k is the calculation factor and varies with the test parameters.

Table 13.3 Calculation of response for Kinetic measurements

Fixed-time	Blank Time	Reaction Time	K
When the blank absorbance is read before the reaction begins,			
Single-reagent	2 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 3	5 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 33	K1
Double-reagent	5 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 16	18 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 33	K2
Triple-reagent	18 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 36	41 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 69	K3
Quadruple-reagent	41 ⩽ Nx ⩽ N ⩽ P ⩽ Px ⩽ 52	54 ⩽ Lx ⩽ L ⩽ M ⩽ Mx ⩽ 69	K4
When the blank absorbance is not subtracted,			
Single-reagent	Nx=N=P=Px=0	5 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 33	0
Double-reagent	Nx=N=P=Px=0	18 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 33	0
Triple-reagent	Nx=N=P=Px=0	41 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 69	0
Quadruple-reagent	Nx=N=P=Px=0	54 ⩽ Lx ⩽ L<M ⩽ Mx ⩽ 69	0

Note: M-L≥2 indicates that at least 3 measuring points should be included within the reaction time.

13.5.5 Evaluation for Linearity

$$\text{Linearity} = \frac{|\Delta A_f - \Delta A_b|}{|\Delta A_{u,v}|} \times 100 < LinearityLimit$$

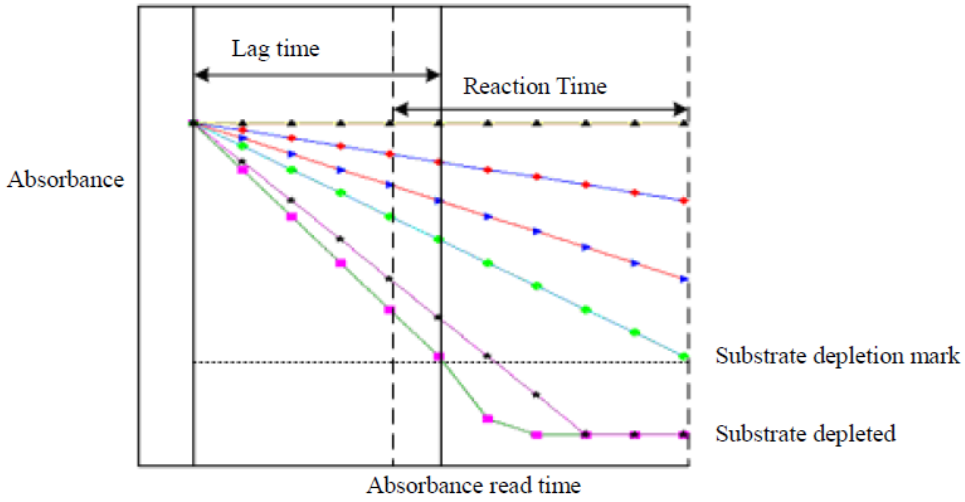
Where, ΔA_f, ΔA_b, and $\Delta A_{u,v}$ are the absorbance change rates in the front part, back part and at all measuring points of the reaction. These three values are calculated based on the number of measuring points within the linearity range.

- When N>8, ΔA_f is the absorbance change rate of the first 6 measuring points, ΔA_b of the last 6 measuring points, and $\Delta A_{u,v}$ of all measuring points.
- When 4≤N≤8, ΔA_f is the absorbance change rate of the first 3 measuring points, ΔA_b of the last 3 measuring points, and $\Delta A_{u,v}$ of all measuring points.
- When N≤3, the system will not check the test results for linearity.
- When $|\Delta A_f - \Delta A_b| \leqslant 60$ or $|\Delta A_{u,v}| \leqslant 60$ (unit: A/10000/minute), the system will not check the test results for linearity.

The system will compare the calculated linearity with that defined for the test, and will flag the test result with "LIN" and given an alarm if the configured linearity is exceeded.

13.5.6 Enzyme Linearity Range Extension

Figure 13.4 Reaction curve with extended enzyme linearity range



In high-activity enzyme measurements, the substrate may be depleted quickly and the reaction curve will appear obviously nonlinear (as a smooth curve). If the measurement is performed based on the general procedure, the system will flag the test result with "NLN" (no linearity interval), reminding the user to rerun the test after diluting the sample. This will more or less bring troubles to the user.

Extending enzyme linearity range:

Suppose the reaction start time is t1 and the reaction time is tL-tM, then t1-tL is the lag time.

If the number (N) of valid measuring points within tL-tM is less than 2 and too few to calculate the response, the sample response can be obtained by extending the enzyme linearity range.

Calculation of ⊿Amax:

The linearity range t1-tL' without substrate depletion is found within the lag time t1-tL.

If the number (N) of valid measuring points within tL-tM is less than 2, the system will not calculate the response but flag the test result with "ENC" (no calculation interval) and give an alarm; or the system calculates the reaction rate ⊿A=60*(Ai+1-Ai)/(ti+1-ti), i=1, 2…L' with the lag time t1-tL'. The maximum ⊿A is taken as the response of the sample. Therefore, the enzyme linearity range is extended via the lag time. The results calculated by extending the enzyme linearity range will be flagged with "EXP".

13.6 Calibration Math Model and Factors

The system provides linear and non-linear math models. The former is used for Colorimetry tests and the later for turbidity tests.

In this section,

- R: calibrator response
- C: calibrator concentration (or internal converting concentration in non-linear calibrations)
- K, R_0, a, b, c and d: calibration factors

Single-point linear calibration

The single-point linear calibration is also called the K factor method. Calculation formula: $C=K\times(R-R_0)$

Where, K is the user-defined K factor, R0 is the reagent blank response of the first calibrator. If the test is not reagent blanked, R0=0.

Please note that the R and R0 must be divided by 10,000.

Two-point linear calibration

Calculation formula: $C=K\times(R-R_0)$

The formula contains two factors, K and R0, where $K=\frac{C_2-C_1}{R_2-R_1}$, and $R_0=R_1-\frac{C_1}{K}$.

The calibration math model requires two calibrators. C1 and C2 are the concentrations of calibrator 1 and 2; R1 and R2 are the responses of calibrator 1 and 2.

Multi-point linear calibration

Calculation formula: $C=K\times(R-R_0)$

The formula contains two factors, K and R0. The calibration math model requires n(n≥3) calibrators. Ci is the concentration of calibrator i. Ri is the response of calibrator i. K and R0 can be calculated with the least square method:

$$K=\frac{\sum_{i=1}^{n}CiRi-(\sum_{i=1}^{n}Ci)(\sum_{i=1}^{n}Ri)/n}{\sum_{i=1}^{n}Ri^2-(\sum_{i=1}^{n}Ri)^2/n}$$

$$R_{0i}=\frac{C_{i-1}R_i-C_iR_{i-1}}{C_{i-1}-C_i}$$

13.6.1 Non-Linear Calibrations

Logit-Log 4P

Calculation formula: $$R = R_0 + K\frac{1}{1+\exp[-(a+b\ln C)]}$$

The formula contains four factors, which are R0, K, a and b.

The calibration math model requires at least four calibrators. The four factors can be calculated with the L-M method.

This calibration type is applied to the tests which have a calibration curve with the response reversely proportional to the concentration.

Logit-Log 5P

Calculation formula: $$R = R_0 + K\frac{1}{1+\exp[-(a+b\ln C+cC)]}$$

The formula contains five factors, which are R0, K, a, b and c. The calibration math model requires at least five calibrators, and calculates the five factors with the L-M method.

This math model has the same application with the Logit-Log 4P except for a higher fitting.

Exponential 5P

Calculation formula: $R = R_0 + K\exp[a\ln C + b(\ln C)^2 + c(\ln C)^3]$

The formula contains five factors, which are R0, K, a, b and c. The calibration math model requires at least five calibrators, and calculates the five factors with the L-M method.

This calibration type is applied to the tests which have a calibration curve with the response directly proportional to the concentration.

Polynomial 5P

Calculation formula: $$\ln C = a + b(\frac{R-R_0}{100}) + c(\frac{R-R_0}{100})^2 + d(\frac{R-R_0}{100})^3$$

The formula contains five factors, which are R0, a, b, c and d. The calibration math model requires at least five calibrators. The response (R) of the first calibrator (with internal converting concentration of 0) is R0, which is given.

Suppose, y=ln C and $x = \frac{R-R_0}{100}$.

Then, $y = a + bx + cx^2 + dx^3$ can be calculated with the least square method for polynomial expressions.

Parabola

Calculation formula: $R = aC^2 + bC + R_0$

The formula contains three factors, which are a, b and R0. The calibration math model requires at least three calibrators. The three factors can be calculated with the least square method.

Spline

Calculation formula: $R = R_{0i} + a_i(C-C_i) + b_i(C-C_i)^2 + c_i(C-C_i)^3$

The calibration math model requires 2-9 calibrators. Suppose the number of calibrators is n, then the calculation formula contains 4(n-1) factors, which are R_{0i}, a_i , b_i and c_i. Due to the subsection fitting, this math model has be best fit curves than other math models.

Logistic-Log3P

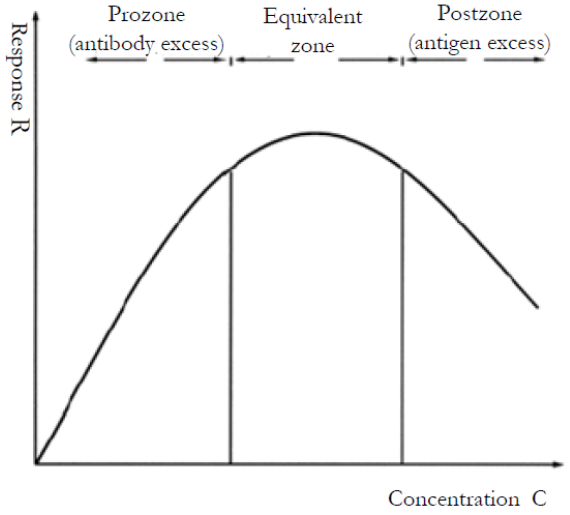
Calculation formula: $$R = R_0 + K\frac{1}{1+aC}$$

The formula contains three factors, which are R0, K and a. At least 3 calibrators (including blank solution) shall be provided. Use L-M method to solve the parameters R_0, K and a.

13.7 Prozone Check

13.7.1 Introduction

Figure 13.5 Reaction curve of antigen and antibody



In the reaction of antigen and antibody, the amount of generated insoluble compound is closely related to the proportion of antigen and antibody. The maximum amount of compound will be generated at a proper proportion of antigen and antibody, at this point least light is passed and the greatest absorbance is obtained. For other proportions, the amount of insoluble compound will decrease with more light passed and lower absorbance calculated. Therefore, samples with quite different concentrations may generate the equivalent amount of insoluble antigen/antibody compound, and can have the same test results without a Prozone check. The Prozone check, therefore, is necessary for antigen-antibody reactions.

The Prozone limit is the allowable maximum or minimum PC when antigen excess does not happen.

The Prozone check factors include:

- PCM (Prozone check limit), q1, q2, q3 and q4.
- Absorbance low limit: **ABS**

The Prozone check can be performed in two ways: rate check and antigen addition, which are described in detail in the following sections.

13.7.2 Antigen Addition Method

Antigen excess can be detected by further addition of antigen. When enough antibodies are provided, the antigen reacts with them in reaction medium and forms into stable compound particles, thus producing dispersed light, which increases dynamically with compound amount increased and reaction time extended (antibody excess). If the antibody keeps excess in specified period, it will continue to react with further added antigen, and the reaction will increase accordingly. If the antigen is excessive before further addition, the reaction will decrease. The antigen addition method is applicable to both single-/double-reagent chemistries.

Enter the Prozone check factors as follows:

- PCM (Prozone check limit), q1 and q2.
- If the absorbance low limit ABS appears in grey, that is q3=q4=0, it cannot be set up.
- 74≥q2≥46, 44≥q1≥Reaction end point.

If one of PCM, q1 and q2 is not input, the system will not check the antigen.

- Sample PC=Aq2-k×Aq1.
  - k is the calculation factor.
  - For single-reagent chemistries: k=(VR1+VS)/(VR1+2VS).
  - For double-reagent chemistries: k=(VR1+VS+VR2)/(VR1+2VS+VR2).
  - The system will flag the test result with "PRO" (Prozone check abnormal) and give an alarm if PC<PCM in positive reactions or PC>PCM in negative reactions.

13.7.3 Reaction Rate Method

The rate check is based on the condition that the antibody excess reaction rather than the antigen excess reaction can reach equilibrium within the same specified period. Enter the Prozone check factors as follows:

- PCM (Prozone check limit), q1, q2, q3 and q4.
- Absorbance low limit: ABS
- Sample PC: $PC = \frac{\frac{A_{q4} - A_{q3}}{q4 - q3}}{\frac{A_{q2} - A_{q1}}{q2 - q1}}$.

  If PC>PCM, the system will flag the test result with "PRO" and give an alarm.

Enter the measuring points as follows:

- Single-reagent chemistries: 5≤q1<q2<q3<q4≤33, "5" is the first measuring point after the sample is dispensed and stirred.
- Double-reagent chemistries: 16≤q1<q2<q3<q4≤33. "16" is the first measuring point after R2 is dispensed and stirred.
- Triple-reagent chemistries: 46≤q1<q2<q3<q4≤74. "46" is the first measuring point after R3 is dispensed and stirred.
- Quadruple-reagent chemistries: 57≤q1<q2<q3<q4≤74. "57" is the first measuring point after R4 is dispensed and stirred.

If one of PCM, q1, q2, q3 and q4 is not input, the system will not check the reaction rate. Prozone check will be disabled if:

- (Reaction end point absorbance - Reaction start point absorbance) <ABS
- The sample response is not within the calibrator response range for sample and control analysis of non-linear chemistries.

Vocabulary

Absorbance

The difference between the amount of light entering a solution (incident light) and the amount of light passing through the solution (transmitted light) without being absorbed, to determine the concentration of the substance in the solution.

Analyzer

The analyzer, determines various clinical tests in samples and displays the test results. It consists of the sample handling system, reagent handling system, reaction system, cuvette wash station, photometric system, and mixer assembly.

Auto rerun

When a result is beyond the defined range or satisfies the defined conditions, the test will be run again.

Auto serum index

When the Auto Serum Index function is enabled, the system will select the SI test automatically for serum or plasma samples. The SI test will also be requested automatically when you order routine samples manually or by using the LIS host, or order STAT samples, or order routine samples with the default panels.

Bar code reader

Fixed laser beam scanner. It scans the bar code label on sample tubes to identify samples and match the obtained ordering information with the scanned samples.

Batch order

Batch order is to order a group of samples with identical ordering information, with the exception of the sample ID.

Blank time

Blank time refers to the period between dispensing of the second reactant (reagent or sample) in reversed order and of the last reactant (reagent or sample).

Bottle type

Volume of the reagent bottle.

Calibration curve

A calibration curve reflects the mathematical relation between calibrator concentration and response. It is drawn based on the obtained response and the multiple values between the minimum and maximum concentrations of the calibrator.

Calibration factor

Calibration factor is obtained based on the equation of calibrator concentration (known) and response (calibration math model).

Calibration math model

Calibration math model is used to calculate calibration factors and create calibration curves. It includes single-point K factor, two-point linear, multi-point linear, Logit-Log4P, Logit-Log5P, Exponential5P, Polynomial5P, Parabola and Spline.

Calibration trend

Calibration trend summarizes a test's calibrations during a period of time and reflect the trends of the calibrations.

Carryover

Carryover is the interference of certain substance contained in a reagent. It can influence measurement of another test or the reaction of other mixture, resulting in inaccurate results.

Closed-reagent test

Closed-reagent test is run by using the reagents provided by the analyzer manufacturer. Closed-reagent tests cannot be modified or deleted.

Concentrated wash solution

Concentrated wash solution is used to clean the sample probe and used in daily clean.

Critical range

An allowable result range from the perspective of clinical diagnosis. If the test result is beyond the critical range, the patient may need immediate treatment. You may enable the auto rerun function for a test, which will be rerun automatically once the test result is beyond the critical range.

Current results

Current results include those that are in Incomplete status until the current system time and those ordered and analyzed on the current day.

Database

A collection of data arranged for quick search and retrieval.

Decreased

Decreased indicates the sample volume required for analysis and can be defined on the **Define/Edit** Tests window.

Diluent

Liquid used to dilute other liquids.

Dilution factor

User-defined dilution ratio, to be multiplied with sample result to obtain the final result.

Download

To obtain sample ordering information from the LIS host and match it with the scanned samples. The system supports real-time and manual downloading of sample ordering information.

Flag

Flag is a manufacturer-defined symbol, which appears on patient reports or result list when a result is beyond the user-defined reference range or exceeds the defined limits.

History results

Stored results are those ordered and analyzed before the current day.

Initialization

Initialization is a series of operations automatically performed by the system during the startup procedure. It includes parameters check, reset, testing, cleaning and priming.

ISE

ISE is the abbreviation of Ion Selective Electrode. It consists of the Na electrode, K electrode, Cl electrode, and reference electrode. The ISE module measures the concentration of Na, K and Cl in serum, plasma and diluted urine.

LIS

LIS stands for Laboratory Information System. It is a host computer and communicates with the analyzer through the internet interface.

L-J chart

A Levey-Jennings (L-J) chart, drawn based on the QC date (X) and test results (Y), shows the QC result trend of a test during the specified period. The graphical trends of up to 3 controls can be displayed on one L-J chart and distinguished with different colors.

Lot number

Lot number is assigned to controls, calibrators or wash solutions of the same lot for identifying manufacture date, quality, expiration date and other related information.

Mask/Unmask tests

Used when a test needs to be disabled temporarily due to abnormal result or reagent exhaustion. The masked test will have a  symbol appearing on its upper-left corner, and will still be displayed on the **Sample**, **Quality Control** and **Reagent/Calibration** screens but not run for sample analysis. Masked tests cannot be requested until they are unmasked.

Multi-sample report

Containing the results of multiple samples, and can be printed out on the **Current** and **History** screens.

Off-line dilution

Prior to analysis, samples are diluted manually based on specific ratio.

Offset

Offset is a value added or subtracted to compensate a result. It is often used along with the slop in the equation y=kx+b, in which k is the slope and b is the offset.

Online help

Online help provides you with help information about the screens. If you do not understand a parameter or an operation on a screen, you can go to the online help for relevant information. Access the online help from the following screens:

- Select the  icon on the upper right corner to display the help topic related to the current screen.

Operation unit

Operation unit is a computer installed with operating software to control the operation of the analyzer and process the data.

Output unit

A printer used to print test results and other data.

Panel

Consists of a couple of tests combined together for certain clinical purposes, such as liver function, kidney function, etc. Panels can help fast ordering of samples.

Patient demographics

Patient demographics contain information related to the patient and sample, such as patient name, age, gender, collection date/time, etc.

Physiological saline

0.9% sodium chloride solution, used for reagent blank and sample dilution.

The photon counting module detects light intensity of the liquid to be measured, and calculates the analyte concentration by calibration curve.

Predilution

Prior to analysis, samples are diluted automatically based on the defined dilution factor.

Primary wavelength

The primary wavelength is chosen based on the light absorption features of the reactant and used to measure the absorbed light intensity. Options for primary wavelength include: 340nm, 380nm, 412nm, 450nm, 505nm, 546nm, 570nm, 605nm, 660nm, 700nm, 740nm, 800nm, and 850nm.

Prime

Prime is an action to replace the reagents in tubing of the ISE module. A prime is required to replace the reagents in tubing with new ones during the startup procedure or when a reagent is changed.

Print name

Print name appears on a patient report representing a test, and if left blank, will be replaced by the short name of the test.

Prozone check

Prozone check is intended to checking samples with quite different concentrations, which may generate the equivalent amount of insoluble antigen/antibody compound and can have the same test results. The Prozone check can be performed in two ways: rate check and antigen addition.

Pull-down list

A control of the software screen or window. Select the down-triangle button on the right of a pull-down list to show multiple options.

QC panel

Used for analysis of control samples.

QC rule

A set of rules to evaluate if the QC results are under control and the analyzing system is stable. Examples of QC rule are 1-2s, 1-3s, etc.

QC summary

Contains the mean values and standard deviations of controls analyzed within the specified period, as well as the set mean and SD value. The obtained results are compared with the set values to judge if the system is working normally.

Qualitative analysis

Qualitative analysis is used to analyze every sample for the detection of lipemia, hemolysis and icterus and calculate the numeric values of the index. If the volume of the interferents contained in a sample is beyond the set range, a flag will be added to the patient report.

Rack supply unit

This unit is used to load racks to be tested. The system delivers the racks automatically from this unit to the rack transfer unit when analysis starts. This unit can accommodate up to 30 racks, and 10 sample positions are available on each rack, indicating that at most 300 samples can be accepted at one time. Users are allowed to add new samples without stopping the analysis.

Random error

An alarm of quality control monitoring. A random error may occur when the lowest and highest values of QC results respectively exceed -2SD/-3SD and +2SD/+3SD.

Reaction carousel

Reaction carousel is a turntable, and used to hold reaction cuvettes and transmit each of them to the photometric position for signal detecting and absorbance calculation.

Reaction cuvette

Reaction cuvette is a carrier in which reagents and samples react with each other and then carried to the photoelectric position for signal detecting and RLU calculation.

Reagent carousel

The reagent carousel is located on left side of the analyzer panel. It holds reagent bottles and carries each of them to the reagent aspirate position for aspirating.

Reagent inventory alarm limit

Alarm limit of reagents and wash solutions. When the reagent inventory is lower than the alarm limits during or before the analysis, the system will give an alarm and display the reagent or wash solution name in yellow on the **Reagent/ Calibration** screen.

Reagent probe

The reagent probe aspirates the specified amount of reagent from a reagent bottle and then dispenses it into a cuvette for reaction and analysis. There is one reagent probe, with up to 3 reagent components can be added for one step method, 4 components for two step method.

Reference range

Reference range is a user-defined range consisting of low limit and high limit. When a result is beyond the reference range, a flag will appear near the result.

Release

Positions on single rack, or multiple racks, or positions on all racks can be released simultaneously. When a sample is released, its results and ordering information can be still recalled. and the released position can be used for ordering of new samples.

Replicates

Number of times to run a test, to ensure accurate results.

Sample blank

Sample blank is similar to sample analysis except for use of equivalent amount of physiological saline. Sample blank is used for removal of non-chromogenesis reaction, such as influence of sample interference (Hemolysis, icterus and lipemia) on absorbance readings.

Sample comments

Remarks for some special samples, such as, ** sample has hemolysis; ** sample needs to be analyzed immediately, etc.

Sample delivery module

The sample delivery module is responsible for storing racks to be tested, retrieving the racks when tests are complete, and preparing the racks for repeated analysis.

Sample panel

Used for analysis of patient samples.

Sample probe

The sample probe aspirates the specified amount of sample from a sample tube and then dispenses it into a cuvette for reaction and analysis.

Sample probe wash solution

Used to clean the sample probe and located in special wash position of the analyzer's front panel.

Sample rack

There are two types of racks, distinguished by different colors. The racks are described as follows:

- Routine sample rack: Gray, with rack ID beginning with N
- Decapping sample rack: Pink, with rack ID beginning with M

Sample type

Type of sample. The sample type options include serum, plasma, urine, amnio fluid and other.

Screen

Screen is a part of the software interface. It is rectangular and contains various controls, such as edit box, function button, etc.

Serial number

Sequence number of the reagent bottle.

Slope

Multiplied with the test result to make it consistent with that obtained on other instruments. It is often used along with the offset in the equation y=kx+b, in which k is the slope and b is the offset.

Special calculation

Special calculation is derived from calculation of certain tests and has specific clinical purposes, such as A/G, TBil-DBil, etc.

Standard deviation (SD)

Standard deviation is the mean of deviations from the mean value. It is an index to judge the measurement accuracy under specific conditions. In this manual, SD refers to the standard deviation of control concentration.

Standby

Standby is one of the system statuses. When the system status is Standby, it indicates that all tests are finished and all actions of the system have stopped.

STAT

STAT means emergent, including common STAT and quick STAT order. STAT sample order allows emergent samples to be ordered and analyzed with high priority. Common STAT order is used in daytime to run emergent samples with higher priority than routine samples. Quick STAT order is mainly used in nighttime and weekends to order emergent samples quickly with higher priority than routine samples.

Symbology

Symbology is a set of rules for encoding and decoding information contained in a bar code label. The system provides a couple of symbologies, such as Codabar, ITF, code128, code39, UPC/EAN, and Code93.

Systematic error

An alarm of quality control monitoring. A systematic error may occur when both the lowest value and highest value of a QC result are on the same side.

Test configuration

Test configuration is applicable to all tests and used to enable or disable tests that have been defined correctly.

Transmit

Transmit is an action sending specified sample results or QC results to the LIS host.

Twin-Plot chart

A twin-plot chart, drawn based on the results of control X and control Y in the same run, is used to detect systematic errors and random errors. It shows the recent 10 QC results of a test and excludes those that have been deleted.

Two-control evaluation

In two-control evaluation, two results are obtained: Xn and Yn, which are used to define a point on the Twin-plot chart. In this way, a complete twin-plot chart is drawn based on all the QC results and used for detecting systematic errors and random errors.

Unpositioned samples

Samples without positions assigned or with positions not assigned successfully, including those:

- downloaded from the LIS host and not positioned yet.
- that are in Incomplete status when their positions are assigned for new samples.
- that are incomplete when their positions are released.

Westgard rule

Westgard rule is used for monitoring of quality control. In the Westgard rule, single rules such as 12S, 13S, 22S and 41S are combined to evaluate results of single or multiple controls.

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Electronic Interface

Table .1 Electronic interface

Description	Network interface
Interface Standard	The interface standard of RJ45 is met.
Interface Specifications	The communication rate is 100 Mbps
Interface Purpose	The host receives and executes instructions from the PC through this interface, and returns the execution results to the PC through this interface.

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