BS-450

Chemistry Analyzer

Operator's Manual

For this Operator's Manual, the issue date is 2024-05.

Publication Information

Publication version	Revision date	Change description
1.0	2016-02	First version
2.0	2016-03	Added syringe maintenance items
3.0	2019-04	Safety standard was upgraded
4.0	2020-11	Deleted the words “up to” before the test speed
5.0	2021-11	Added unique device identifier, and electronic interfaces.
6.0	2022-03	Added contents according to the requirements of *REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU*.
7.0	2022-04	Added the description of glass cuvette configuration.
8.0	2022-06	Modified the laser warning label.
9.0	2023-01	Added the positions of DC, ISE Cleaning Solution, and alkaline wash solution DB on the sample carousel and modified the alkaline wash solution position on the reagent carousel. Modified the maintenance procedure related to the ISE module.
10.0	2023-04	Added description of G6PD twin chemistry.
11.0	2024-01	Updated the figure and text description related to calibration result screen.
12.0	2024-05	Deleted ISE detergent

Intellectual Property Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this Mindray product and this manual. This manual may refer to information protected by copyright or patents and does not convey any license under the patent rights or copyright of Mindray, or of others.

Mindray intends to maintain the contents of this manual as confidential information. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

Release, amendment, reproduction, distribution, rental, adaptation, translation or any other derivative work of this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

mindray , MET , OmniLab , DigiPrince , MINDRAY BeneView, WATO, BeneHeart, are the trademarks, registered or otherwise, of Mindray in China and other countries. All other trademarks that appear in this manual are used only for informational or editorial purposes. They are the property of their respective owners.

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

EC - Representative

EC-Representative:	Shanghai International Holding Corp. GmbH(Europe)
Address:	Eiffestraβe 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

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. Observance of this manual is a prerequisite for proper performance and correct operation, and it ensures patient and operator 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 actual product should prevail.

Intended audience

This manual is intended for medical laboratory professionals to do the following:

- Learn about the system hardware and software.
- Perform daily operating tasks.
- Maintain and troubleshoot the system.

Product introduction

BS-450 is a computer-controlled fully-automated chemistry analyzer, intended for quantitative determination of clinical chemistries in serum, plasma, urine, cerebrospinal fluid (CSF), and other human body fluids. It can fulfill auto dispensing, reaction, colorimetric measurement, process monitoring, and result calculation. It provides measurement of multiple biochemistries and ISE (ion-selective electrode) tests (Na+, K+ and Cl-), with maximum throughput of 626 tests per hour. It is one of the necessary tools for laboratory automation.

Related documents

The following documents are provided for searching information about the instrument:

Operator's Manual

Contains instrument compositions, operating instructions, maintenance and troubleshooting methods. At the beginning of this manual is a table of contents, which provides references of all chapters for searching desired information. At the end of this manual is a glossary and index, which provide term definitions and index to key words.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. It you have any questions, please contact us.

Operation Card

Provides daily operating procedure for quickly guiding you through basic operations of the instrument. It includes pre-startup checks and startup, operations before test, routine test, daily performance and powering off.

Maintenance Card

Provides regular and irregular maintenance of the instrument to help you maintain it so that it can work normally.

📖 For detailed maintenance instructions, see the *Operator's Manual*.

Online help

Contains detailed descriptions of the software screens and parameters. It also covers the Operator's Manual, which enables you to retrieve information related to the software screens and operation tasks.

Conventions

Graphical symbols, formats and abbreviations are used to get better visual effects and readability. To help you understand this manual correctly, this section provides statements of pictures, terms and applicable models used in this manual.

Symbols and formats

The following symbols and formats are used:

Symbol and format	Meaning
	A safety symbol, for alerting you to warnings about safety and system operations.
	Alerts you to biohazards.
•	Item list.
🕮	Reference content or cross reference.
Bold	Headings or important information.
Italic	Key points.
➤	Start of operating procedure.

Picture

All pictures in this manual are for illustration purpose only and must not be used for any other purposes. The pictures of the actual product should prevail.

Online help

The operating software provides a context-sensitive online help, which can help you better understand the screen parameters and perform correct operations. The online help is related to software screens, and it can display information related to menu page, maintenance item, maintenance command, and event log.

You can open the online help window in the following ways:

- Alt+F1: press this shortcut key combination on any screen.
-  : click this icon on the top-right of any screen.
-  : click this button to the left of a maintenance item, a maintenance command, or an event log.

🕮 For more information about online help, see1.4.5 Using online help.

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 silkscreens that have been applied to the instrument and their indications.

Safety symbols

Safety symbols are used in this manual in order to remind you of the instructions necessary to operate the product safely and in accordance with its function and intended use. A safety symbol and text constitutes a warning as shown in the table below:

Symbol	Text	Description
	WARNING	Read the statement following the symbol. The statement is alerting you to an operating hazard that can cause personal injury.
	BIOHAZARD	Read the statement following the symbol. The statement is alerting you to a potentially biohazardous condition.
	CAUTION	Read the statement following the symbol. The statement is alerting you to a possibility of system damage or unreliable results.
	NOTE	Read the statement following the symbol. The statement is alerting you to information that requires your attention.

Summary of hazards

This section lists hazards of the instrument itself. The hazards of specific operation are included in the warning information of each operation task.

Observe the following safety precautions when using the product. Ignoring any of them 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

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 product. 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

WARNING

- Do not touch such moving parts as sample carousel, reagent carousel, reaction carousel, sample probe, reagent probe, mixer, and cuvette wash station, when the system is in operation.
- Exercise caution while using the ISE module. Prevent your hair, legs or other parts of your body from being hurt by the driving parts.
- Do not put your fingers or hands into any open part when the system is in operation.

Photometer lamp hazards

WARNING

- Eye injury could occur from light emission from the photometer lamp. Do not stare into the lamp when the system is in operation.
- If you want to replace the photometer lamp, first switch off the MAIN POWER and then wait at least 5 minutes for the lamp to cool down before touching it. Do not touch the lamp before it cools down, or you may get burned.

Laser beam hazards

WARNING

Light emitted by the bar code reader may cause eye injury. Do not stare into the laser beam radiated from the bar code reader when the system is in operation.

Sample, calibrator and control hazards

 **BIOHAZARD**

- Inappropriately handling samples, controls and calibrators may lead to biohazardous infection. Do not touch samples, controls, calibrators, mixtures, or waste with your bare hands. Wear gloves and lab coat and, if necessary, goggles.
- In case your skin contacts the sample, control or calibrator, follow the standard laboratory safety procedure and consult a doctor.
- The serum samples remaining in the electrodes may contain a great number of viruses. Wear gloves to prevent infection while operating around the electrodes.

Reagent and wash solution hazards

 **WARNING**

Reagents and concentrated wash solution 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 spills into your eyes, rinse them with much water and consult an oculist.

Waste hazards

 **BIOHAZARD**

- Some substances contained in reagent, control, calibrator, concentrated wash solution, 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.
- Wear gloves and lab coat and, if necessary, goggles.

System disposal hazards

 **WARNING**

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

Fire and explosion hazards

 **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

 **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.

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.

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.

Summary of precautions

This section lists precautions to be understood during instrument operation. The precautions of specific operation are included in the warning information of each operation task.

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

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

WARNING

- 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.

NOTE

- 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 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.
- When using the system for the first time, run calibrations and 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.
- The RS-232 port on the analyzing unit is used for connection with the operation unit only. Do not use it for other connections. Use the cables provided by our company or your local distributor for the connection.
- 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 after 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.
- 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.

Chemistry parameter configuration precautions

CAUTION

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

Maintenance and Servicing Precautions

NOTE

Check the safe state of the equipment after repair. Make sure the equipment is safe and then offer it to the customer.

ISE module precautions

CAUTION

To prevent ISE electrodes from being damaged due to water scarcity, if the system, when equipped with an ISE module, will be powered off for a long time, perform the electrode storage maintenance.

Sample precautions

CAUTION

- Use samples that are completely free of insoluble substances like fibrin or suspended matter; otherwise the sample probe may be clogged. 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 a serum index 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 carousel 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.

ISE calibration precautions

BIOHAZARD

The calibrators contain preservatives. In case your skin contacts calibrators, wash them off with soap and water. In case the calibrators spill into your eyes, rinse them with water and consult an oculist. If you swallow them by mistake, see a doctor.

CAUTION

Use the calibrators specified by our company. Use of other reagents or calibrators may result in unreliable results, or damage the Hydropneumatic system, or even shorten the electrodes life span.

Prior to using the calibrators, check if they are within the expiration date.

Place them correctly; otherwise, it may cause unreliable results, or leak, or module damage.

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 the data loss caused by unexpected power failure, 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 authorized and 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.

Labels and silkscreen

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

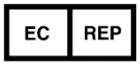
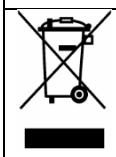
For the label marked with  , please consult the related documentations in order to find out the nature of the potential HAZARDS and any actions which have to be taken to avoid them.

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

Labels and Silkscreen

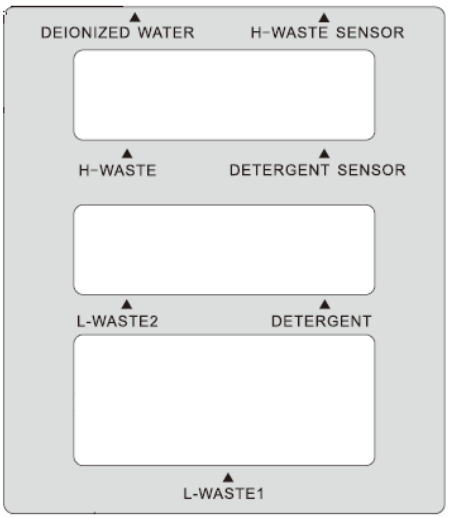
Symbol	Meaning
	Serial Number
	Date of Manufacture
	Manufacturer
	CE marking
	Unique device Identifier
	Authorized Representative in the European Community
	The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated 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.

Symbol	Meaning
IVD	In Vitro diagnostic medical device
	Biological risks
	Caution
	Caution: hot surface
	Caution: Laser radiation
	"ON" (Power)
	"OFF" (Power)
	"ON" for a part of equipment
	"OFF" for a part of equipment
	Serial interface
	Computer Network
	Protective conductor terminal
	Alternating current

Non-warning labels and silkscreen

Interfaces for fluid connection

This symbol located on the right panel of the analyzer indicates the connection of fluid tubing.



ISE Reagent Pack

This symbol and text is located under the ISE reagent compartment. Please check if the electrodes and pump tubes are installed correctly before loading the ISE Reagent Pack.

Service Label

Located on the panel. Scan the QR barcode to contact Customer Service.

Warning labels

Biohazard warning

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

- Sample probe
- Waste outlet
- Waste tank

Moving parts warning

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

- Sample probe and reagent probe

- Mixer
- Wash station

Laser warning

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

Photometer lamp warning

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

Probe collision warning

This symbol and text located near the sample carousel, reagent carousel and reaction carousel reminds you of not opening the cover to prevent from damaging the probe.

Upper cover

This symbol and text located on the transparent upper cover reminds you of not wipe the upper cover with ethanol or other organic solutions.

ISE module

This symbol and text is located on the left side panel of the analyzer. Please turn off the main power before opening the small door.

Risk of Electrical Shock

This symbol and text located on the power supply shield, reminds you of not touching or removing the power supply shield while the power is on.

Risk of Chemical Hazards

This symbol and text is located on the diluted wash solution tank. Take cautions to avoid the chemical hazards of the wash solution.

Liquid level floater

This symbol and text is located near the liquid level floater of the DI water tank and the wash solution tank, Please do not take out the liquid level floater during test.

Table of contents

1 System description

This chapter describes the system from the installation, hardware, software and specifications perspectives, including:

- Installation requirements and methods of the instrument
- Hardware components
- Introduction of software screens
- Technical specifications

1.1 Installation requirements and procedure

1.1.1 Installation requirements

CAUTION

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

Installation environment

The following environment requirements must be satisfied:

- 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 220Kg weight.
- 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 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 -400-2000 m.

Power supply

The following power supply requirements must be satisfied:

- Connect the system to a power supply meeting the requirements specified in this manual.

For more information on power supply, see 1.5.5requirements on page 1-36.

- Use the three-wire power cord provided with the system, which has good grounding performance.
- Connect the system to a properly-grounded power socket.
- Configure the grounding voltage correctly.

WARNING

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

Temperature and humidity

The following temperature and humidity requirements must be satisfied:

- Ambient temperature: 15°C-30°C
- Relative humidity: 35%-85%, 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.

Water supply and drainage

The supplied water must meet the requirements of CLSI type II, with resistance more than 1MΩ.CM. and silicate lower than 0.1 mg/L.

CAUTION

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

Flow: ≥42L/H for average flow, and 2L/M for transient peak flow.

If you use water-purifying equipment, make sure that the water supply pressure is within 95kPa-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.

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.

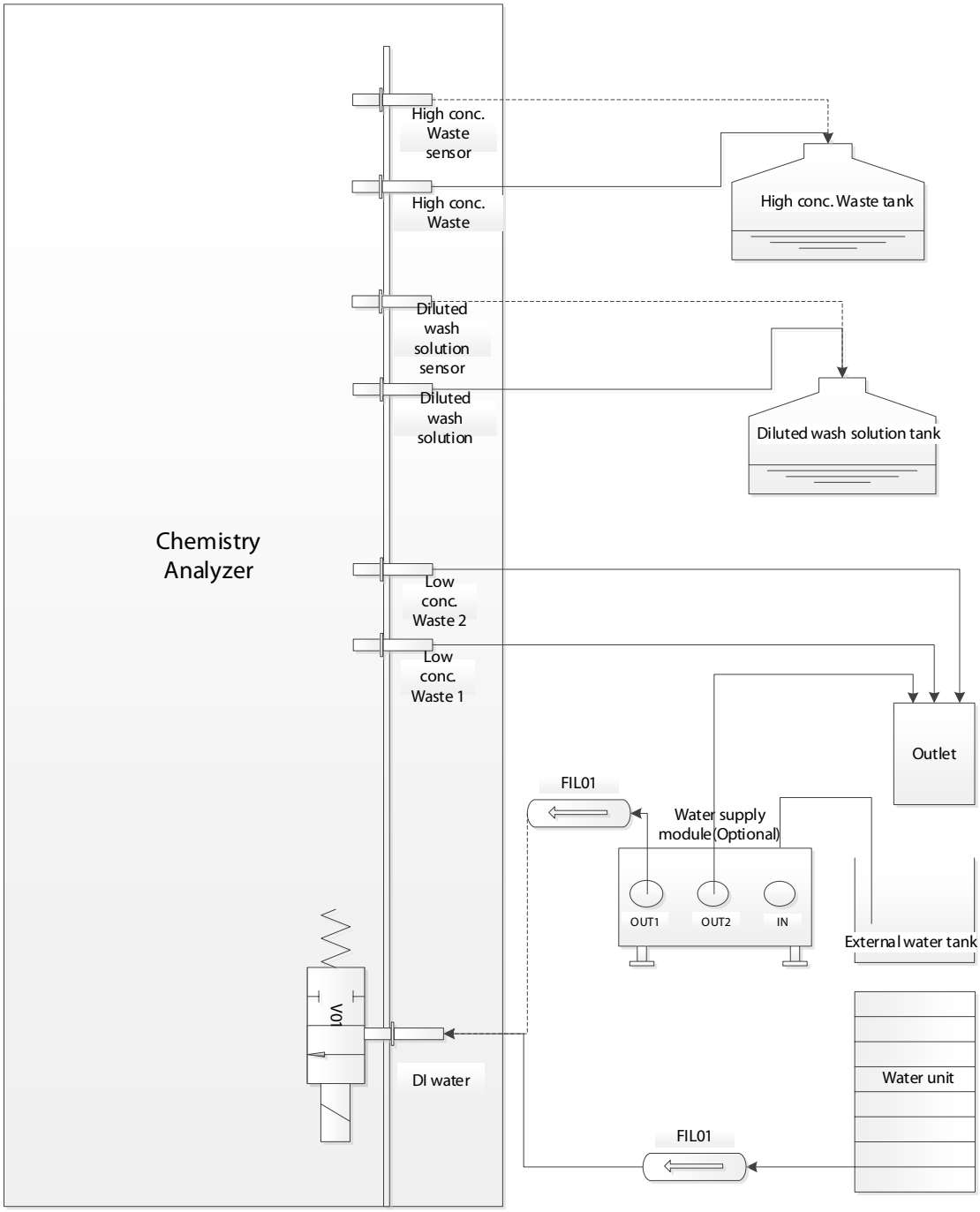
BIOHAZARD

Wear gloves and lab coat, if necessary, goggles.

CAUTION

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

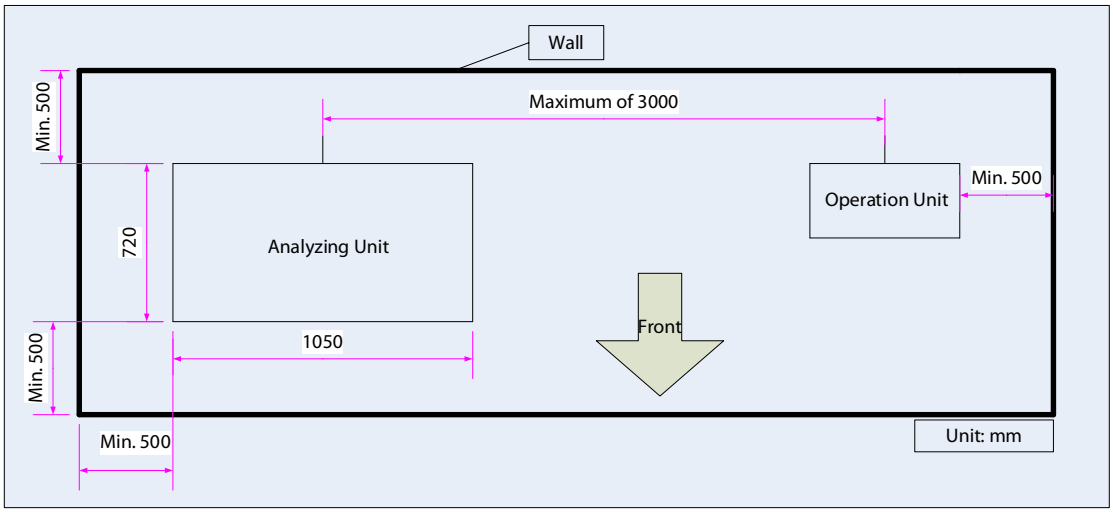
Figure 1.1 Fluidic connection diagram



Space and accessibility requirements

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

Figure 1.2 System clearances



Recommended computer configuration

Table 1.1 Recommended computer configuration

Item	Description
CPU	At least 2.6GHz or above
Random access memory (RAM)	At least 2GB or above
Network adapter	The computer is connected to the chemistry analyzer through a network adapter. If you are going to connect the computer with the LIS or Internet, you should prepare another network adapter (Intel gigabit network adapter)
Serial port	The computer should provide an RS232 serial port, which is used to connect it with the chemistry analyzer.
Parallel port or USB interface	Used for connecting the operation unit with a printer or an external storage device.
Network interface	Used for communication between the analyzing unit and the operation unit, or between the LIS and the operation unit.
Hard disk defragment	At least 160GB or above for hard disk. Install the operating system in the C drive and the operating software of the instrument in the D drive. Make sure that the C drive is over 30G and D drives over 100G, and the disk file system is of NTFS format. Deselect the two options at the bottom of the disk properties window: "Compress drive to save disk space" and "Allow Indexing Service to index this disk for fast file searching".
Operating system	The operating system installed on the computer must be an activated or free version Microsoft Windows 8(64 bit).
Application software	Except for the operating system, other application software must not be installed or reserved on the computer. If an anti-virus application has been installed, then remove the automatic scheduled scanning and add the operating software and BSLOG to the trust list.
Screen saver and system standby	Turn off the screen saver and BS Special Power Policy power scheme, and then disable the hibernation option.
Screen display properties	Set the screen resolution as 1280*1024 pixels and color quality as Highest (32 bit).
Automatic synchronization with Internet time server	Disable the Automatically synchronize with an Internet time server option.
Automatic updates	Turn off the automatic updates.

Item	Description
Auto awake and shutdown setup	If you are going to use the auto awake/shutdown function, perform necessary settings for BIOS and network adapters while referring to their operation manuals.
Sound card and speaker	The system must be configured with sound card and speaker.

Recommended printer configuration

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

- Ink jet printer
- Laser printer (black and white)
- Stylus printer

1.1.2 Installation Procedure

WARNING

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

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

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.

System relocation

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

1.2 Hardware components

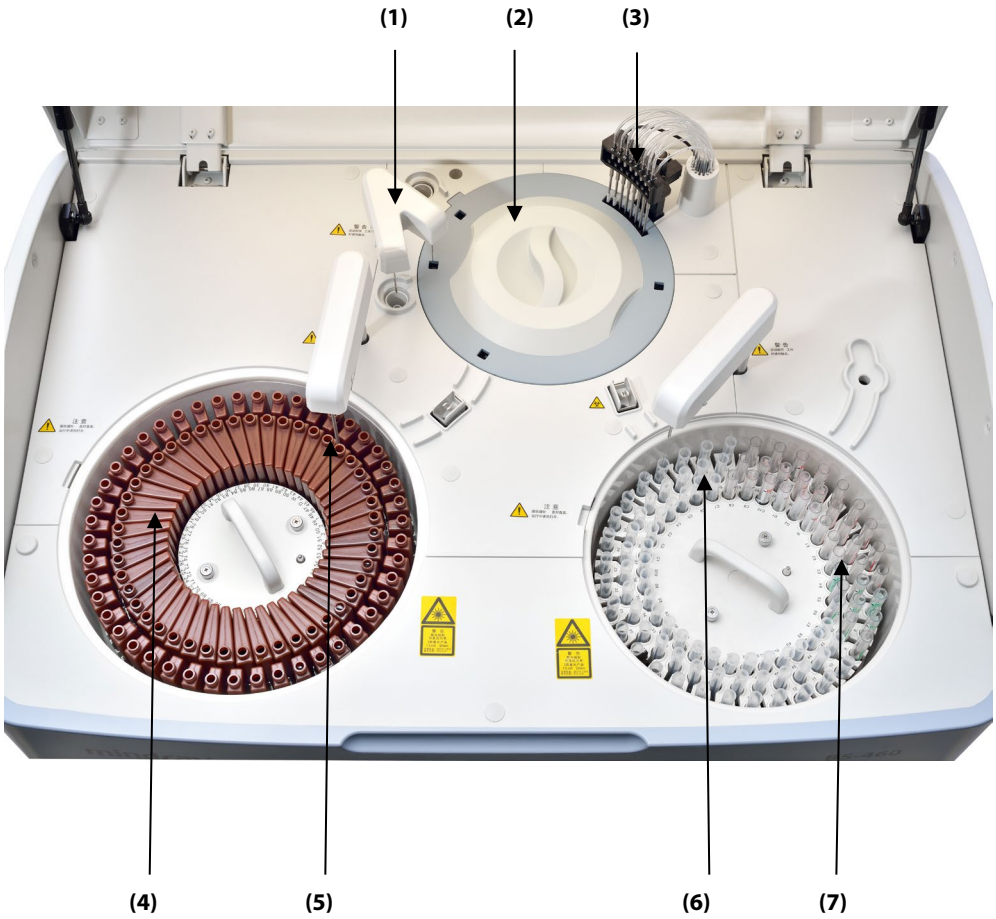
1.2.1 Overview

The BS-450 consists of the following components:

- Analyzing unit (analyzer)
- Operation unit (computer)
- Output unit (printer)
- Accessories and consumables

Figure 1.3 Chemistry analyzer

Figure 1.4 Layout



(1)Mixers
(2)Reaction carousel
(3)Wash station
(4)Reagent carousel
(5)Reagent probe
(6)Sample probe
(7)Sample carousel

Analyzing unit

The analyzer, determines various clinical chemistries in samples and generates test results. It is composed of the following components:

- Sample handling system
- Reagent handling system
- Mixer assembly
- Reaction system
- Cuvette wash station
- Photometric system
- ISE unit (optional)

Operation unit

A computer with the operating software installed to perform test requisition, measurement, reaction process monitoring, result calculation, and input, storing and query of test data.

Output unit

A printer for printing out test results and other data.

Accessories and consumables

Includes cuvette, lamp, concentrated wash solution (CD80), and other accessories and consumables required by test.

1.2.2 Sample handling system

The sample handling system holds samples and provides them for analysis. It consists of the following assemblies:

- Sample carousel assembly
- Built-in bar code reader (optional)
- Dispenser assembly
- Sample tube

Sample carousel assembly

The sample carousel is a turnable disk located on the right side of the analyzer panel. It holds sample tubes and carries each of them to the aspirate position for aspirating.

Figure 1.5 Sample carousel assembly

(1) Sample carousel

Carousel positions

The sample carousel includes the outer ring, middle ring and inner ring. The three rings provides the following positions:

- STAT position: 11 in total, E1~E11(69~79).
- Calibrator position:10 in total, S1~S10(80~89).
- Control position:9 in total, C1~C9(90~98).

The following fixed positions are provided for:

- ISE for ISE Cleaning Solution (100)
- DC for Probe Cleanser (99)
- DB for alkaline wash solution (101)
- W for physiological saline (102)

NOTE

The refrigeration unit is powered independently from the analyzing unit, and it is operational once the MAIN POWER is put to the ON position.

One current sample carousel and nine virtual sample carousel are supported.

To remove the sample carousel,

- Loosen the two retaining screws on the sample carousel.
- Grab the handle and pull the sample carousel upward to remove it from the rotor.

To install the sample carousel,

- Align the positioning pins on the sample carousel to the counterparts on base.
- Set the sample carousel and tighten the two retaining screws on the carousel.

Sample containers

Sample containers are used to hold sample.

Different sample tubes require different minimum sample volumes. Each sample tube must contain the amount of sample 8mm higher than the unreachable sample level; otherwise, correct aspirating cannot be ensured.

Table 1.2 Specification of sample containers

Sample Container	Specification
Microtube	Φ14×25 mm, 0.5 mL
	Φ14×25 mm, 2 mL
	Φ12×37 mm, 2 mL
Primary 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

For the tests of the whole blood(centrifuged),onlyΦ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13×75 mm, Φ13×95 mm, Φ13×100 mm anticoagulation tubes can be used. The sample height in the tube should be no higher than 55mm and the blood cell level should be no lower than 10mm. Microcups are not allowed. To ensure the clinical performance and avoid the system alarm, EDTA anticoagulation tubes are recommended.

Loading/Unloading sample tube

WARNING

Before installing or removing a sample tube, make sure that the sample carousel and the probe have stopped.

Do not use sample tubes other than the specified ones.

BIOHAZARD

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

To load a sample tube, insert it into the tube holder until the tube bottom contacts the groove of the tube rack.

To unload a sample tube, grab it and pull it upwards to remove from the tube holder.

Built-in bar code reader (optional)

The bar code reader is provided for optional configuration. It is used to scan the bar code on sample tube.

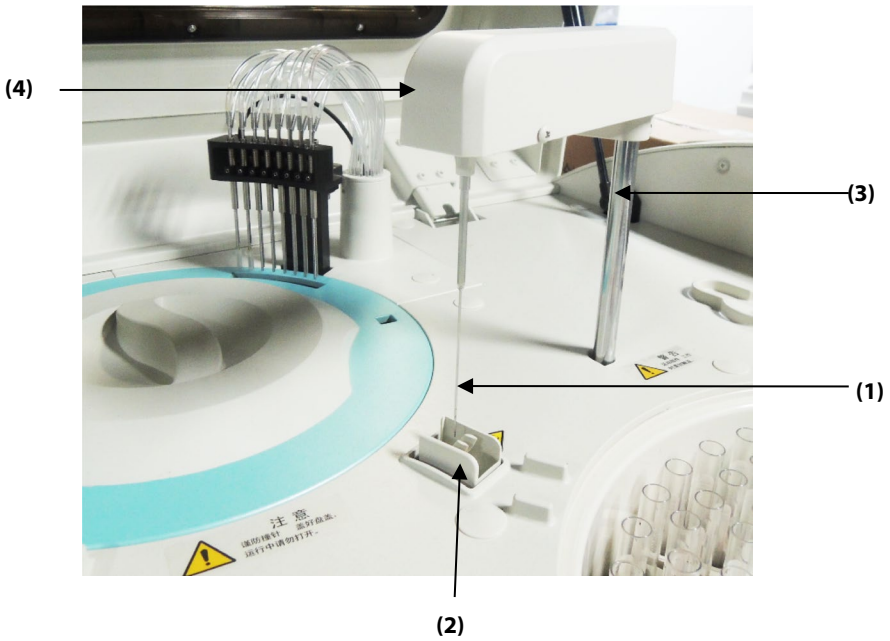
WARNING

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

Sample Dispenser assembly

The dispenser assembly located above the sample carousel is composed of the sample probe, sample probe arm, probe rotor, syringe, wash well, and related fluidic tubes. It aspirates the specified amount of sample from a sample tube and then dispenses it into a cuvette for reaction.

Figure 1.6 Sample Dispenser assembly



(1)Sample probe (2)Wash well
(3) Probe rotor (4) Probe arm

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

One sample probe is available to add sample with the following volume range:

- Biochemistry: 1.5-45 µL, with increment of 0.1 µL.
- ISE test: 70 µL for serum and plasma, and 140 µL for diluted urine.
- Sample dilution:the predilution factor is 3~134.

Besides adding sample and reagent, the probe has the following functions:

- **Clog detection(Optional)**: 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.

- **Level detection and tracking**: detects the sample level and determines the depth of lowering down into the sample based on the specified aspirate volume.
- **Empty aspiration alarm**: When the sample probe aspirates nothing or aspirates insufficient sample due to sample insufficiency or air bubble, the system will give an alarm.

Blood cell membrane breaking module

It is used to break the blood cell membrane for whole blood test. It is composed of sample probe, wash well and related circuits.

Sample syringe

When the front right door of the analyzer is opened, you will see the sample syringe as shown below:

Figure 1.7 Sample syringe

1. Sample syringe

Sample probe washing

The sample probe is cleaned in its wash well with water widely flushing its interior and exterior.

1.2.3 Reagent handling system

The reagent handling system is used to hold reagents and provides them for reacting with samples. It consists of the following assemblies:

- Reagent carousel assembly
- Reagent bar code reader(Optional)
- Reagent dispenser assembly
- Reagent bottle

Reagent carousel assembly

The reagent carousel assembly consists of a reagent carousel (including a cover) and a refrigeration unit.

The reagent carousel holds reagent bottles and carries the defined reagent bottle to the aspirate position for aspirating reagent.

The refrigeration unit keeps reagents in a low-temperature environment to keep them stable and minimize volatilization.

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

Reagent positions: There are 92 bottle positions on the reagent carousel. DB is for alkaline wash solution and W is for deionized water or physiological saline.

NOTE

The refrigeration unit has a power supply independent of that of the analyzing unit. The refrigeration unit is operational once the MAIN POWER is turned to the ON position.

Figure 1.8 Reagent carousel

1. Reagent carousel **(1)**

CAUTION

Note: Every day before analysis, remove the plug on the reagent carousel in order to prevent mechanical reset failure and bending reagent probe. Restore the plugs after finishing tests of the day.

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

One virtual reagent carousel (92 positions) is allowed. You'll be reminded to change the reagent carousel on which all reagent aspiration is finished.

To remove the reagent carousel,

- Loosen the two retaining screws on the reagent carousel.
- Grab the handle and pull the reagent carousel upward to remove it from the rotor.

To install the reagent carousel,

- Align the positioning pins on the reagent carousel to the counterparts on base.
- Set the reagent carousel and tighten the two retaining screws on the carousel.

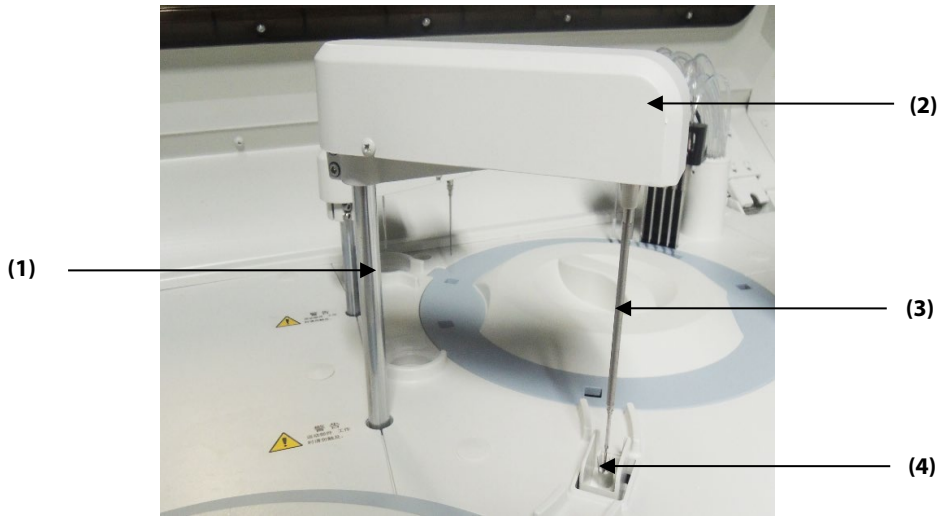
Reagent bar code reader(Optional)

The reagent bar code reader is an optional module and used to obtain reagent information through reading a reagent bar code. For more information, refer to 1.3.4Built-in Reagent Bar Code Reader (page 1-20).

Reagent dispenser assembly

The sample dispenser assembly located on the upper right 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 1.9 Reagent dispenser assembly



1. Probe rotor
2. Reagent probe arm
3. Reagent probe
4. Probe wash well

Reagent probe

- The system has one reagent probe. Reagent volume: 10μL ~200μL with 0.5μL increment.
- Concentrated reagent is supported with dilution ratio at 19(concentrated reagent):1(DI water)~ 1 (concentrated reagent):19(DI water).

The reagent probe is 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.
- **Level detection and tracking:** detects the reagent level and determines the depth of lowering down into the reagent based on the specified aspirate volume.
- **Empty aspiration alarm:** When the reagent probe cannot aspirate or aspirate insufficient reagent due to reagent insufficiency or air bubble, 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

The reagent probe is cleaned in its wash well with water spraying its interior and exterior from two opposite directions.

Reagent syringe

When the left door of the analyzer is opened, you will see the reagent syringes as shown below.

Figure 1.10 Reagent syringe

1. Reagent syringe

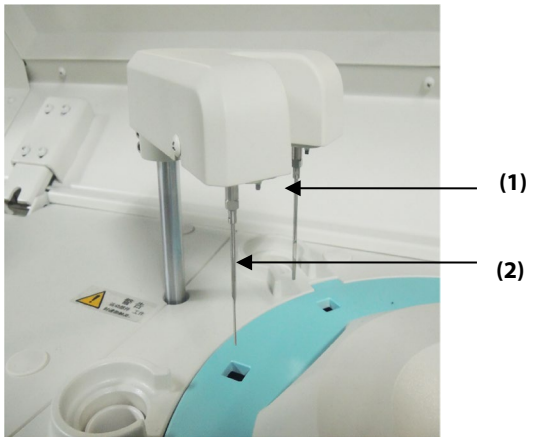
Reagent bottle

40 ml and 20ml reagent bottle.

1.2.4 Mixer assembly

The mixer assembly, located on the lower-left side of the reaction carousel, is composed of the mixer, mixer arm, and drive assembly. It stirs the reaction liquid in cuvettes once sample and reagent are added.

Figure 1.11 Mixer assembly



(1) Sample mixer (2)Reagent mixer

When stirring is finished, the mixer moves automatically to the wash well for cleaning.

1.2.5 Reaction system

The reaction system consists of the reaction carousel, cuvettes and drive assembly. It holds the reaction cuvettes and carries them to the specified position for washing, adding reagent and sample, mixing, reaction, and absorbance measuring.

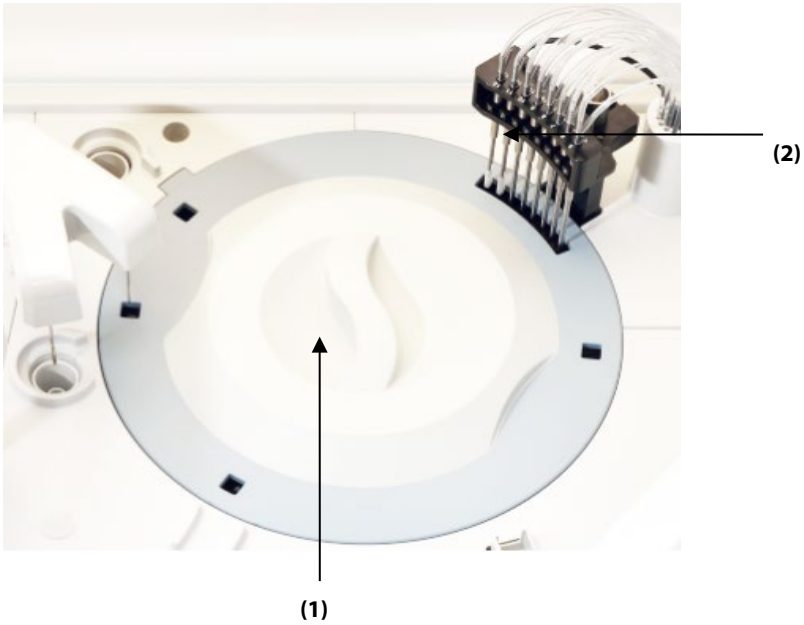
Reaction carousel

The reaction carousel rotates counter-clockwise, carrying the specified cuvette to reagent dispensing position, sample dispensing position, mixing position and then washing position successively.

The reaction carousel is circular and can hold 93 semi-permanent plastic cuvettes or glass cuvettes.

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

Figure 1.12 Reaction carousel



(1)Reaction carousel (2) Cuvette wash station

Reaction cuvette

The plastic cuvette or glass cuvette is provided by the factory. The light path length of the cuvette is 5mm±0.03mm, and its inside dimension is 5mm (length)*4mm (depth)*29mm (height).

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

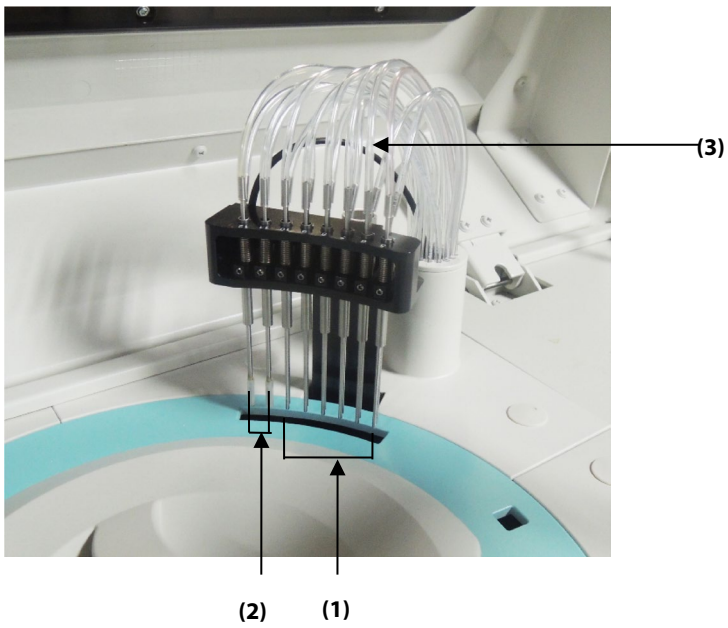
1.2.6 Cuvette wash station

The cuvette wash station cleans the cuvettes with wash solution and Deionized water in eight phases, 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.

Figure 1.13 Cuvette wash station



(1) Phase1-6 wash probes
(2) Phase 7-8 wipe blocks
(3) Wash tubes

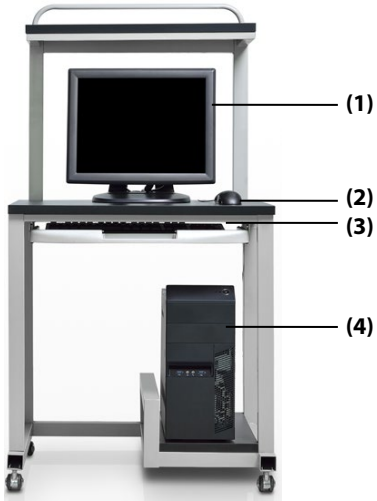
1.2.7 Photometric system

The photometric system located inside the analyzing unit measures absorbance of the reaction mixture in cuvettes. It comprises the light source, lens, and other components.

1.2.8 Operation unit

The operation unit is a computer configured with the operating software. It consists of the monitor, computer, keyboard, and mouse.

Figure 1.14 Operation unit



(1) Display monitor
(2) Mouse
(3) Keyboard
(4) Computer

📖 For more information on the operation unit, see its operation manual.

1.2.9 Output unit

The output unit is a printer used to print out test results and other data. The system supports three types of printer: inkjet printer, laser printer (black and white) and stylus printer.

Figure 1.15 Output unit

(1) Printer

You should purchase an appropriate printer compatible with the analyzer.

📖 For more information on the printer, see its operation manual.

1.2.10 Accessories and consumables

Accessories are necessary components for the instrument to perform sample analysis, and they should be replaced regularly. Consumables are replenishable materials to be replaced after each use, or vulnerable materials that should be replaced on a regular basis.

⚠ 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.

Please use the accessories and consumables manufactured or recommended by our company in order to achieve the promised system performance. The Accessories and consumables list is subject to change; if needed, contact our customer service department or your local distributor.

Table 1.3 Accessories and consumables

No.	Part Name	Remarks
1	Cross screw driver 102*100	Accessory
2	Needle .0.25+/-0.01mm*125mm round head	Accessory
3	Kleohn 14271 Teflonwasher,14271washer	Accessory
4	Valve Washer,10-32,18011Telfon washer	Accessory
5	Water tank	Accessory
6	20ml reagent bottle brown	Accessory
7	40ml reagent bottle brown	Accessory
8	Reagent bottle label	Accessory
9	BS200 white cap of reagent bottle	Accessory
10	BS200 red cap of reagent bottle	Accessory
11	Parameter list	Accessory
12	Accessory kit bar code	Accessory
13	PVC Braided Tube 12mm*18mm semi- transparent	Accessory
14	Plastic cuvette (with surface processed)	Accessory
15	Serial port cable	Accessory
16	Tube. Precision soft PU(Polyether)tube 4mm*6mm transparent	Accessory
17	Clamp 12-20mm width 9mm 304 Stainless steel	Accessory

No.	Part Name	Remarks
18	Operating Software Installation CD	Accessory
19	Plug	Accessory
20	Mixer wrench	Accessory
21	ISE Cleaning Solution	Consumable
22	Na Cleaning Solution	Consumable
23	MR Na electrode	Consumable
24	MR K electrode	Consumable
25	MR Cl electrode	Consumable
26	MR Ref electrode	Consumable
27	ISE Reagent Pack	Consumable
28	Urine Diluent (50ml)	Consumable
29	ISE Accessory Kit	Consumable
30	CD80(international 6 bottles)	Consumable
31	CD80(international 2 bottles)	Consumable
32	Plastic cuvette or glass cuvette (international, 100pcs)	Consumable
33	Three-core power cord international standard 10A 250V 1.6m	Consumable
34	Power cord US standard 1.5M15A	Consumable
35	Power cord US standard 2.5M16A	Consumable
36	Power cord UK standard	Consumable
37	Power cord Europe standard (International)	Consumable
38	Power cord Brazil 250V 10A 3M	Consumable
39	Power cord Brazil 250V 16A 2.5M	Consumable
40	1.8m Power cord India H05VV-F3X1.5mmVolex	Consumable
41	Power cord Australia V-75 3×1.0 PVC	Consumable
42	Water supply module kit(International)	Consumable

1.3 Optional modules

1.3.1 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:

- ISE module
- Built-in sample bar code reader
- Built-in reagent bar code reader
- Water supply module

1.3.2 ISE Module

The ISE (Ion Selective Electrode) unit consists of the ISE module, the pump module and the reagent module, used in combination with Na, K, Cl, and reference electrodes to measure the concentration of Na+, K+ and Cl^- ions in serum, plasma and diluted urine.

The sample volume for measuring serum and plasma is 70μl; the sample volume for measuring diluted urine is 140μl. The theory of measurement is direct ion-selective electrode method.

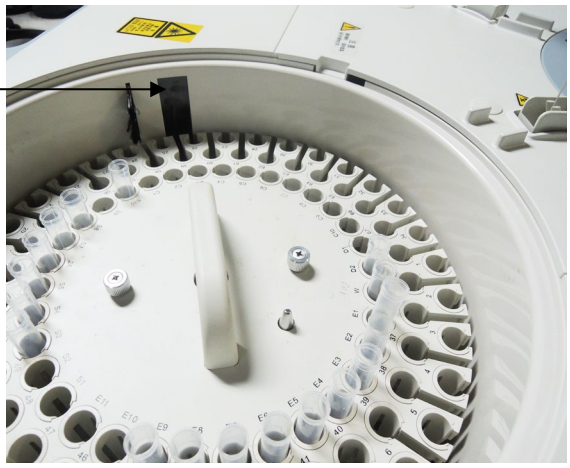
1.3.3 Built-in Sample Bar Code Reader

The sample bar code reader is located on the left inside the sample carousel. The outer ring and middle ring of the sample carousel support bar code scanning. The sample bar code reader assembly consists of the following components:

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

When sample tubes are loaded to the sample carousel, the system scans the bar code label on the sample tubes to read the sample information and then display it on the screen.

Figure 1.16 Sample bar code scanning window



1. Sample bar code scanning window

WARNING

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

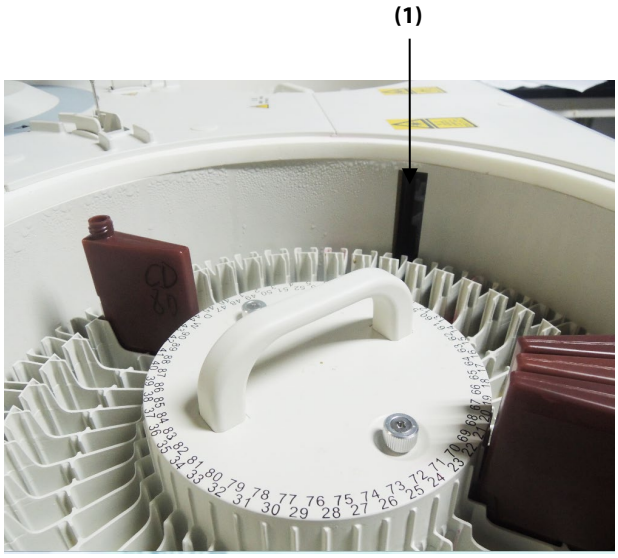
1.3.4 Built-in Reagent Bar Code Reader

The reagent bar code reader located on the 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, select **End Load F2**, the system scans all reagents positions to reader reagent information and then displays it on the screen.

Figure 1.17 Reagent bar code scanning window



1. Reagent bar code scanning window

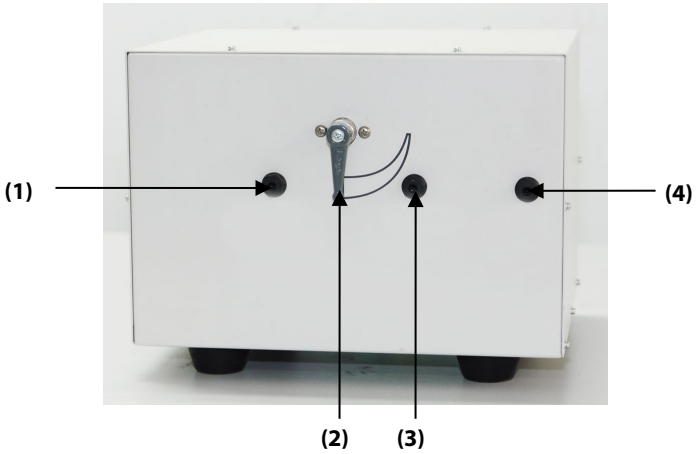
WARNING

The light emitted by the reagent bar code reader may cause eye injury. Do not stare into the laser beam coming from the reagent bar code reader.

1.3.5 Water Supply Module

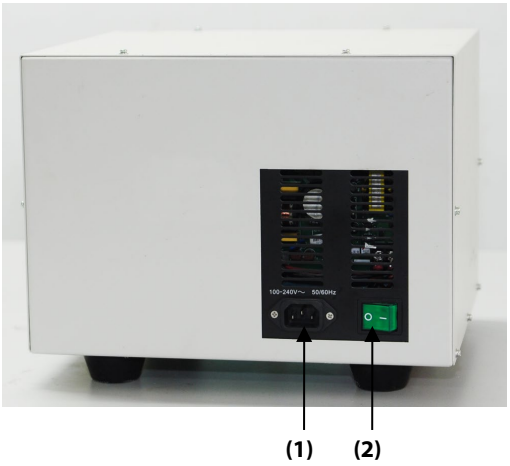
The water supply module provides deionized water for the chemistry analyzer. When water is required during the measuring process, the water supply module turns on the internal inlet valve and transmits water while driven by the pneumatic pump; when water is not needed, the water supply module turns off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

Figure 1.18 Front view of water supply module



1. Air vent
2. Ball valve
3. Inlet
4. Outlet

Figure 1.19 Rear view of water supply module



1. Power jack 2. Power switch

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

1.3.6 Probe clog detection module

Probe clog detection module is used to detect if the sample probe is clogged. If it is clogged, the software will give an alarm.

1.3.7 Other Optional Modules

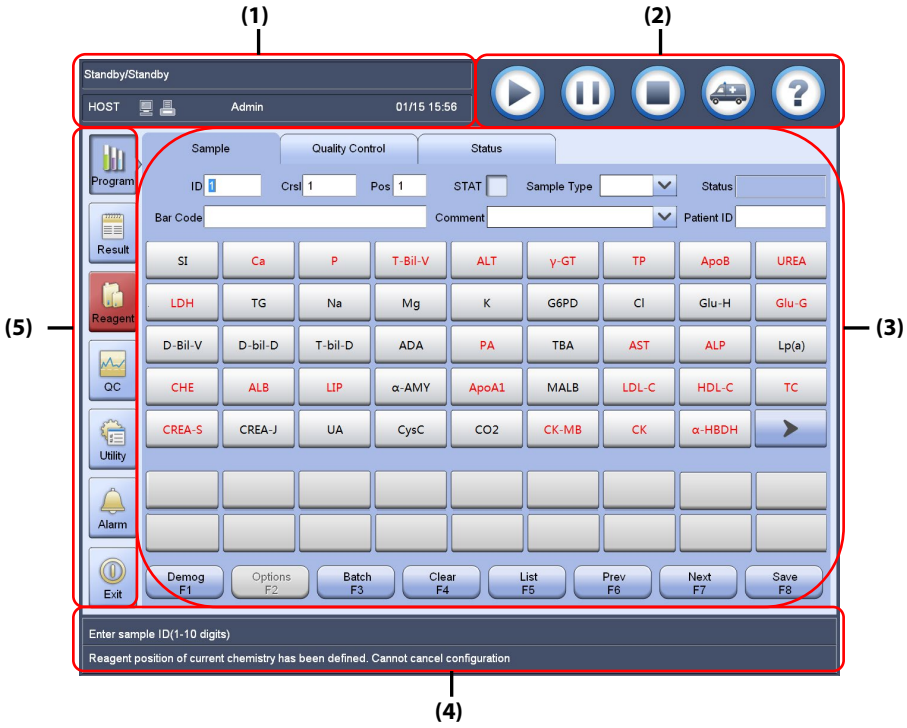
For more information about other optional modules, contact our customer service department or your local distributor.

1.4 Software description

1.4.1 Screen areas

The software screen is divided into the following areas:

Figure 1.20 Screen areas



(1) Status display area
(2) Shortcut icons area
(3) Function window
(4) Prompt message area
(5) Function buttons area

Status display area

The status display area shows the system status, including: biochemistry/ISE system status, test time left, countdown for pausing, LIS connection, printer, login user, and system date/time.

If not especially stated, "non-test status" in this manual refers to Incubation, Standby and Stopped; while "test status" refers to other statuses.

Table 1.4 Status display area

Status indicator	Description
Biochemistry/ISE	This indicator appears on the left of the status display area. If an ISE module is installed, the ISE status appears. The status of the biochemistry system includes: Initialize, Incubation, Standby, Running, Pause, Stopped, Maintenance, and Shutdown. The status of the ISE module includes: Initialize, Standby, Running, Stopped, Maintenance, and Shutdown.
Test time left	This indicator appears in the middle of the status display area. It indicates the minutes left that the analysis will be finished.
Countdown for pausing	This indicator appears on the right of the status display area. It indicates the minutes left that the dispensing of sample or reagent will be stopped.

Status indicator	Description
HOST	**LIS connection status** This indicator appears on the left of the status display area. The following information is indicated: If the  icon appears in blue, the LIS host is connected and online. If the  icon appears in grey, the LIS host is offline.
	**Printer connection status** This indicator appears on the left of the status display area. It indicates the status of the printer: not printing and printing. If the icon appears in grey  , the printer is not printing or unconnected. If the icon appears in blue  , the printer is printing.
Login user	This indicator appears in the middle of the status display area. It indicates the user who logs in the system.
Date and time	This indicator appears on the right of the status display area. It indicates the system date and time.

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 testing.
-  : Pause icon. Select it to stop dispensing of sample and reagent. Then you are allowed to load new samples or reagents on the sample/reagent carousel. To resume the test, select  .
-  : Emergency stop icon. Select it to stop all tests and other actions. To restore the system into Standby status, execute the **Home** command.
-  : STAT icon. Select it to display the **STAT Sample Program** window, on which you are enabled to program emergency samples quickly.
-  : Online help icon. Select it to display the online help of the current window, where you can find description of parameters and operations.

Function window

It displays the page or window related to the selected function button or shortcut icon. It is used to perform system operations.

Prompt message area

The prompt message area contains two lines, the upper line displaying operation prompts for screen controls and the lower line displaying error messages.

Function buttons area

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

- 

: used to program patient samples and control samples, and view sample carousel status.
- 

: used to recall test results of patient samples and controls and view the result statistics and test statistics.
- 

: used to set reagents, define/edit calibrators, request calibrations, recall calibration results, and view reagent carousel status.
- 

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

: used to execute instrument commands, set up chemistry and system parameters, perform system maintenance, and view component status.
- 

: used to recall and handle error logs and editing logs.
- 

: used to log off or shut down the system.

1.4.2 Screen elements

Page

A page appears when a tab is selected. The figure below is an example of page:

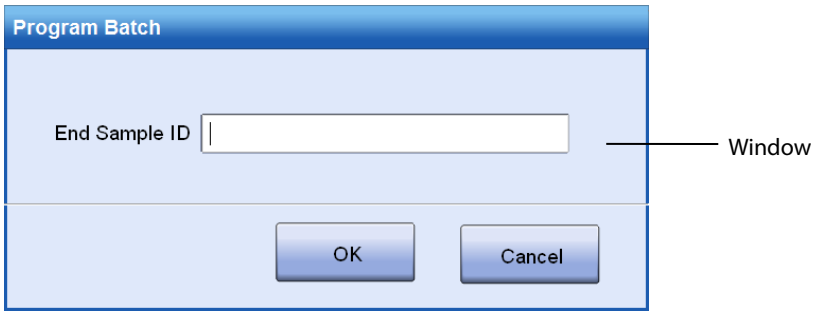
Figure 1.21 Example of page

Window

A window has visible boundaries, which consists of title bar, content area and buttons.

The figure below is an example of window:

Figure 1.22 Example of window

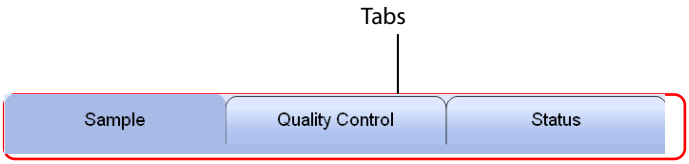


Tab

Click a tab to access the working page that it indexes.

The figure below is an example of tab:

Figure 1.23 Example of tab

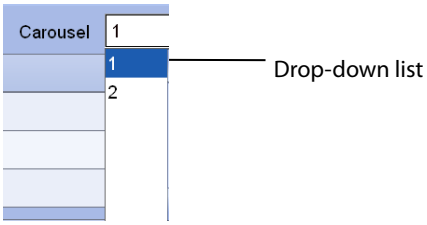


Drop-down list

Click  to display a list and choose desired item in the list.

The figure below is an example of drop-down list:

Figure 1.24 Example of drop-down list

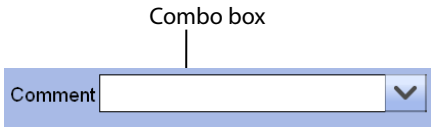


Combo box

A combo box includes a field and a drop-down list, in which you can manually input characters or select an option.

The figure below is an example of combo box:

Figure 1.25 Example of combo box

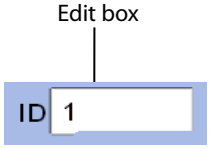


Edit box

An edit box is a field in which you can input characters manually.

The figure below is an example of edit box:

Figure 1.26 Example of edit box

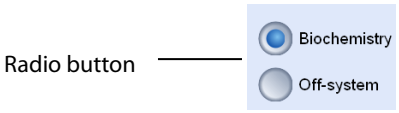


Radio button

A radio button is a circle with text beside. It indicates a set of choices from which only one can be selected.

The figure below is an example of radio button:

Figure 1.27 Example of radio button

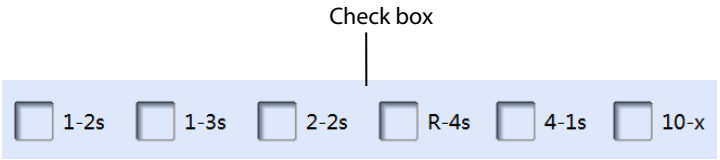


Check box

A check box is a square box with text beside. It indicates a set of choices from which one or more can be selected.

The figure below is an example of check box:

Figure 1.28 Example of check box



Button

A button is used to open a window or to execute a defined function.

The figure below is an example of button:

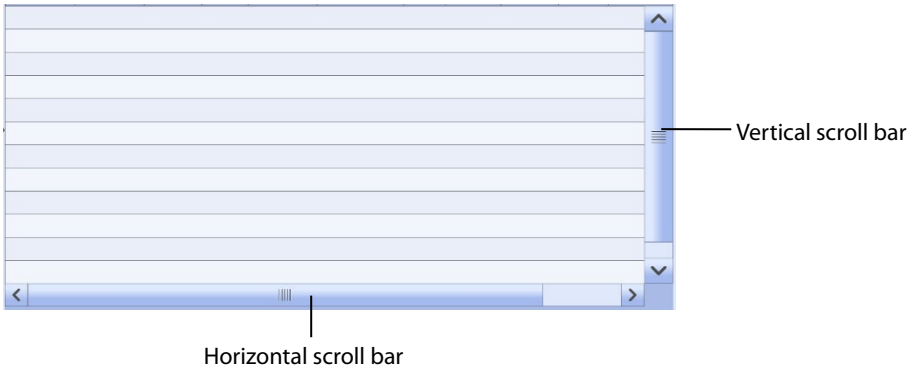
Figure 1.29 Example of button

Scroll bar

A scroll bar is used to display the hidden contents when they are too many to be shown on one screen. A vertical scroll bar moves the screen up and down, and a horizontal scroll bar moves the screen left and right.

The figure below is an example of scroll bar:

Figure 1.30 Example of scroll bar

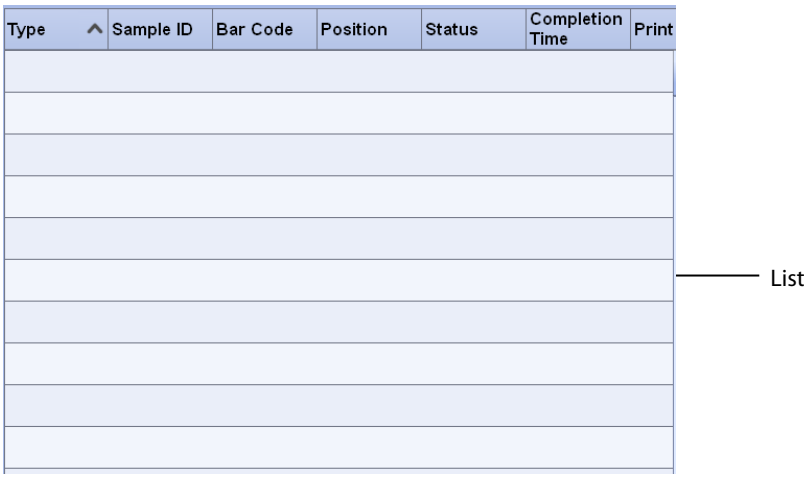


List

A list holds multiple chemistries or panels, or contains texts or charts in the form of table.

The figure below is an example of list:

Figure 1.31 Example of list

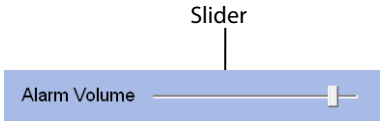


Slider

A slider is used to select a scale continuously. Click and hold the slider and drag it to the desired scale.

The figure below is an example of slider:

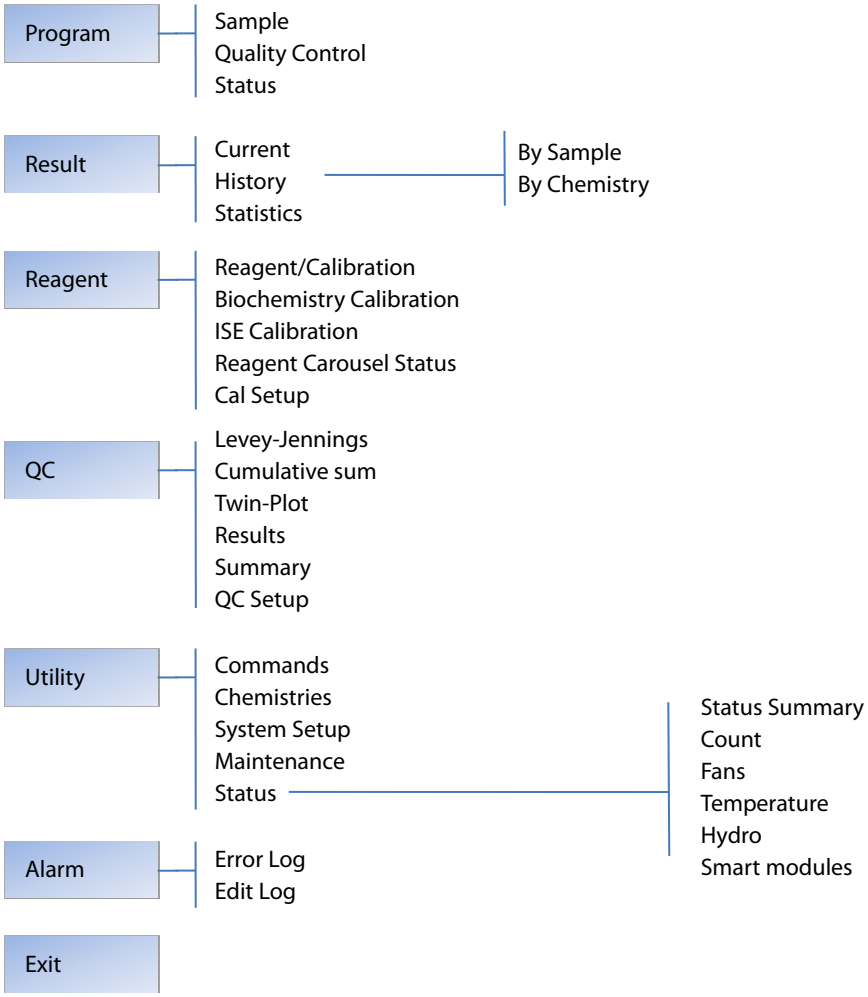
Figure 1.32 Example of slider



1.4.3 Software hierarchy

The figure below shows the menu structure of the operating software. By clicking a function button, or a shortcut icon can access the relevant window.

Figure 1.33 Software hierarchy



1.4.4 Using the mouse

The mouse can be used to move, click, double-click, and drag an object. It can be also used to select an option when combined with the keyboard.

Move

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

Click

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.

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.

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.

Using the 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.

1.4.5 Using online help

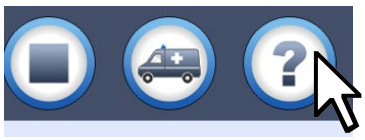
The online help provides you information related to the software screens. If you want to understand a parameter or an operation on a screen, you can go to the online help for relevant information.

Accessing the online help

Access the online help in any of the following ways:

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

Figure 1.34 Accessing the online help from the main screen

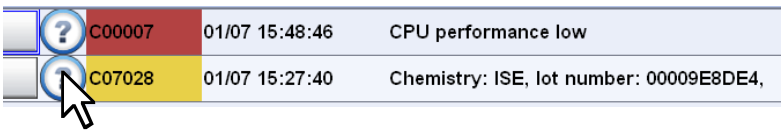


- Select the  icon in front of each maintenance command or regular maintenance item to display the relevant operating instructions.

Figure 1.35 Accessing the online help from the Maintenance window

- Select the  icon in front of each error log to display the corresponding topic.

Figure 1.36 Accessing the online help from the Error Log screen



- Select the  icon on a warning message window to display the corresponding descriptions and solutions.
- Select the  icon on an error message window to display the corresponding descriptions and solutions.
- Press the shortcut key combination **Alt+F1** to display the topic related to the current page or window.

Viewing other information

To view other information in the online help, perform the following steps:

1 Select the  icon on the upper right corner of the main screen, or press the shortcut key combination **Alt+F1**.

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.
- **Favourites**: 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.

1.5 System specifications

This section provides technical specifications of the system. Understand them to use the system correctly.

1.5.1 Analyzing unit

The technical specifications and performance parameters of the analyzing unit are shown in the following tables.

Throughput and reaction type

Table 1.5 Specifications of throughput and reaction type

Parameter	Description
Throughput for biochemistries	420 tests/hour for single-/double-reagent chemistries
Throughput for ISE tests (including K, Na, Cl)	Serum/plasma: 312 tests/hour Urine: 156 tests/hour
Biochemistries and ISE chemistries	626 tests/hour
Throughput for HbA1c tests	80 tests/hour
Maximum number of tests run simultaneously	96 tests, which include 90 biochemistries, 3 ISE chemistries and 3 serum index chemistries.
Principles of analysis	Colorimetry, turbidity, and ISE method
Reaction types	Endpoint, fixed-time, and Kinetic
Reagent mode	Supporting single-/double-/triple-/quadruple-reagent tests
Wavelength	Supporting single/double-wavelength mode

Sample handling system

Table 1.6 Specifications of the sample handling system

Parameter	Description
Sample carousel	One carousel, including three rings. Each provides 34 positions, 102 positions in total.
Sample volume for routine chemistry	1.5 µL - 45 µL, with increment of 0.1 µL

Parameter	Description
Sample volume for ISE chemistry	Serum/Plasma: 70μL; diluted urine: 140 μL
Auto sample dilution	Dilution factor: 3-134
Sample Probe	One sample probe available, featuring level detection, horizontal/vertical obstruct detection, clog detection, empty aspiration alarm and level tracking.
Sample probe washing	The sample probe is cleaned in its wash well with water widely flushing its interior and exterior
Emergent samples	Emergent samples can be inserted at any time with highest priority.
Rerunning mode	Supporting auto dilution, standard volume, increment, decrement, decrement dilution, increment dilution.

Reagent handling system

Parameter	Description
Reagent carousel	Reagent carousel provides 92 positions of which DB is used for wash solution and W for physiological saline water.
Reagent volume	10μl~200μl with increment of 0.5μl.
Concentrated reagent	Concentrated reagent is supported with dilution ratio at 19(concentrated reagent):1(DI water)~ 1 (concentrated reagent):19(DI water).
Reagent probe	One reagent probe, featuring level detection, horizontal/vertical obstruct detection, empty aspiration alarm and level tracking.
Reagent probe washing	The reagent probe is cleaned in its wash well with water spraying its interior and exterior.

Mixer assembly

Parameter	Description
Mixer assembly	Composed of mixer, probe arm and probe rotor
Mixer	Two mixers available, one sample mixer and one reagent mixer

Reaction system

Table 1.7 Specifications of the reaction system

Parameter	Description
Reaction carouse	93 positions available
Reaction temperature	37 ℃
Reaction cuvette	Plastic cuvette or glass cuvette. 5mm×4mm×29mm (length × depth × height), light path length of 5mm±0.03mm
Reaction mixture volume	Plastic cuvette: 90μl-300μl Glass cuvette: 100μl-300μl

Photometric system

Table 1.8 Specifications of the photometric system

Parameter	Description
Light transmission mode	Holographic concave flat-field gratings
Light source	12V/20W tungsten-halogen lamp
Measuring wavelength	12 wavelengths: 340nm, 380nm, 412nm, 450nm, 505nm, 546nm, 570nm, 605nm, 660nm, 700nm, 740nm and 800nm
Measuring period	8.55 seconds

Cuvette wash station

Table 1.9 Specifications of the cuvette wash station

Parameter	Description
Cuvette wash	8-phase wash
Preheating	Cuvette washing fluid and wash solution preheating
Cuvette wash station	Vertical anti-bumping

Average water consumption

≤ 20 L/H

Water supply module

Table 1.10 Specifications of water supply module

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

1.5.2 Main Performance Indices

Stray light

Absorbance shall be no less than 4.9.

Absorbance Linearity Range

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

Absorbance Accuracy

The absorbance accuracy shall meet the requirements in Table 1.11.

Table 1.11 Absorbance Accuracy

Absorbance Value	Absorbance Accuracy
0.5	±0.025
1. 0	±0.07

Absorbance Stability

Absorbance change should not be greater than 0.01.

Absorbance Repeatability

Expressed by coefficient of variation (CV value), which should not be greater than 1%.

Accuracy and fluctuation of reaction carousel temperature

The temperature should be 37℃, the accuracy of the temperature should not be greater than ±0.3℃, and the fluctuation should not be greater than ±0.1℃.

Sample Carryover

Sample carryover rate of should not be greater than 0.05%

Dispensing Accuracy and Repeatability

The dispensing accuracy and repeatability shall meet the requirements of Table 1.12, where the dispensing repeatability is expressed by coefficient of variation.

Table 1.12 Dispensing Accuracy and Repeatability

Category	Volume μL	Allowable Error	Coefficient of Variation
Sample probe	1.5	±5%	≤2%
	5	±5%	≤2%
	45	±3%	≤1%
Reagent probe	10	±5%	≤2%
	200	±2%	≤1%

Carryover Rate of ISE Module

The carryover rate of ISE module should meet the requirements in Table 1.13.

Stability of ISE Module

The stability of the ISE module should meet the requirements in Table 1.13.

Accuracy of ISE Module

The accuracy of the ISE module should meet the requirements in Table 1.13.

Precision of ISE Module

The precision of the ISE module should meet the requirements in Table 1.13.

Linearity of ISE Module

The linearity of the ISE module should meet the requirements in Table 1.13.

Table 1.13 Performance Requirements Of ISE Module

Parameter	Carryover(△§)	Stability(△D)	Accuracy(B)	Precision(CV)	Linearity(D)
K+	≤1.5%	≤2.0%	≤3.0%	≤1.5%	≤3.0%
Na+	≤1.5%	≤2.0%	≤3.0%	≤1.0%	≤3.0%
Cl-	≤1.5%	≤2.0%	≤3.0%	≤1.5%	≤3.0%

1.5.3 Contraindication

None.

1.5.4 Bar code specifications

Sample bar code specifications

Table 1.14 Sample bar code specifications

Name	Description
Symbology	Codabar, ITF, Code128, Code39, UPC/EAN, and Code93
Minimum bar code density	0.19mm~0.5mm
Length	3-27 digits
Format and content	User-defined
Maximum width	55mm
Minimum height	10mm
Maximum inclination angle	±5°
Print quality	No less than Class C according to the *ANSI MH10.8M Print Quality Specification*.
Width and narrowness	2.5-3.0:1
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.

Reagent bar code specifications

Table 1.15 Reagent bar code specifications

Name	Description
Symbology	Codabar, ITF, Code128, Code39, UPC/EAN, and Code93
Minimum bar code density	0.25mm-0.5mm
Length	13-30 digits
Format and content	User-defined
Maximum width	44mm
Minimum height	12mm
Maximum inclination angle	Less than 5°

Name	Description
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.

1.5.5 Power supply requirements

Choose proper power supply according to the following requirements:

Table 1.16 Power supply requirements

Power supply	100-240V ~ 50/60Hz
Rated power consumption	≤1000VA
Voltage fluctuation	±10%
Frequency fluctuation	±1Hz

1.5.6 Environment requirements

Operate and store the instrument in compliance with the following environment requirements:

Operating environment

- Temperature: 15 - 30 °C
- Relative humidity: 35% - 85%, without condensation
- Altitude height: -400 m - 2000 m (80 kPa - 106 kPa)

Storage environment

- Temperature: 0 - 40 °C
- Relative humidity: 30% - 85%, without condensation
- Altitude height: 50 kPa - 106 kPa

1.5.7 Dimensions and weight

- Dimension: ≤ 1050 mm (length) × 720 mm (depth) × 1150 mm (height)
- Weight: ≤ 200 Kg

1.5.8 Noise and fuse

Table 1.17 Noise and fuse

Noise	≤ 65 dBA
Fuse	For 110V: 250V 10A For 220V: 250V 10A

1.5.9 Input device

- Keyboard (prepared by user)
- Mouse (prepared by user)

- Display monitor (prepared by user)
- Bar code reader
- LIS: HL7 and ASTM1394 (communicating through serial port or net port of the TCP/IP interface of static IP address)

1.5.10 Output device

- Printer (prepared by user)
- Display monitor (prepared by user)
- LIS HL7 and ASTM1394 (communicating through serial port or net port of the TCP/IP interface of static IP address)

1.5.11 Communication interfaces

The analyzing unit, operation unit, output unit (printer), LIS, and external storage device, can be connected through the following interfaces. Connect them correctly according to the descriptions below:

Table 1.18 Communication interfaces

RS232 serial port	Used for communication between the analyzing unit and the operation unit Used for communication between the LIS and the operation unit Used for connecting the operation unit with a printer
Network interface	Used for communication between the analyzing unit and the operation unit Used for communication between the LIS and the operation unit
Parallel port or USB interface	Used for connecting the operation unit with a printer Used for connecting the operation unit with an external storage device

1.5.12 Safety classification

Table 1.19 Safety classification

Overvoltage type	Class II
Pollution degree	2
Device type	Fixed device
Work type	Continuous
Degree of IP(Ingress Protection)	Common device ,IPX0 (no protection against liquids)

1.5.13 EMC requirements

The IVD device complies with the EMC standard 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 1.20 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.	
EMISSIONS TEST	COMPLIANCE

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS	
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 1.21 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
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.			

2 Daily operating procedure

This chapter describes a typical daily operating procedure of the instrument. For instructions of more operations, see other chapters in this book.

All operations described in this chapter are based on complete configuration of the instrument. If you do not have certain optional module, please neglect the relevant steps or operate in another way provided .

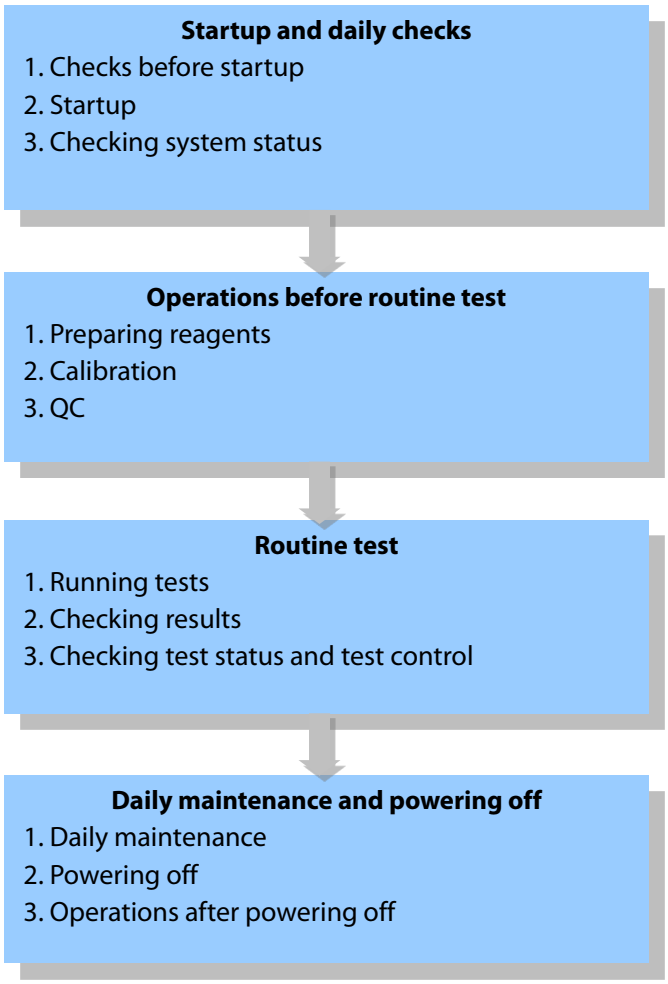
🕮 To understand the detailed information of software screens, see the *Online Help*.

2.1 Daily operating procedure

The daily operation of the instrument includes: startup and daily checks, operations before routine test, routine test, daily maintenance and powering off.

The following is a typical daily operating procedure:

Figure 2.1 Daily operating procedure



2.2 Startup and daily checks

Startup and daily checks can be done in following steps:

- Checks before startup
- Startup
- Checking instrument status

2.2.1 Checks before startup

Perform the following checks before starting up the instrument:

Table 2.1 Checks before startup

Check items	Checking methods
Water supply	Check the deionized water tank or other water reservoirs, and make sure that water can be supplied continuously.
	If you use a water unit, check if it has been powered on.

Check items	Checking methods
	Check if the connections between the water supply and the analyzer are correct and tight.
	Check if the water tubes are free of twists and leaks.
Power supply	Check if the power supply is available and can provide correct voltage.
	Check the connections among the analyzing unit, operation unit and printer. Make sure the connections are correct and secure. Check the power cords and make sure they are well connected to the power sockets.
Printing paper	Check if sufficient printing paper is prepared in the printer. If not, refill the printing paper.
Waste connection	Check if the high-concentration waste tank has been emptied. If not, empty it. High-concentration waste output: about 1 L/H
	Check if the low-concentration waste tank has been emptied. If not, empty it.
	Check if the low-concentration waste tube is not bent and the sewer opening is lower than the waste outlet of the system.
Probe and mixer	Check the sample probe and reagent probe for dirt and bend. If it is polluted, clean it. If it is bent, replace it.
	Check the sample mixer and reagent mixer for dirt and bend. If it is polluted, clean it. If it is bent, replace it.
Diluted and probe wash solution	Check the probe wash solution on the sample/reagent carousel. If necessary, fill more or replace the wash solution.
	Check the diluted wash solution. If necessary, fill more or replace the wash solution.

2.2.2 Startup

The instrument can be started manually or automatically. For manual startup, you need to switch on the power supply manually; for auto startup, you should set up the weekday and time for the instrument to start up automatically.

Manual startup

You need to switch on the power supply and log on the operating software. When the instrument is powered on, the operating software runs automatically and requires you to enter the username and password.

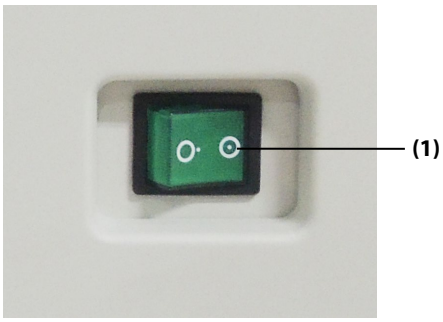
To switch on the power supply

1 Turn on the main power switch on the left panel.

Place the switch to the | position to turn it on. Place the switch to the ○ position to turn it off.

2 Turn on the analyzing unit power switch on the left panel.

Figure 2.2 Analyzing unit power switch



(1) Analyzing unit power switch

Place the switch to the ⊙ position to turn it on. Place the switch to the ○ position to turn it off.

3 Turn on the printer.

4 Turn on the monitor and computer of the operation unit.

To start the operating software

NOTE

If virtual reagent carousel is used, please make sure that the loaded one is the NO.1 reagent carousel before starting the operating software each time.

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**.

3 Select Quick login to skip the initialization procedure if you do not want to perform this procedure.

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.

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 light source and reaction temperature gets steady.

Auto startup

You should specify the weekday and time for auto startup. When the set time is reached, the system will start up automatically if it is off.

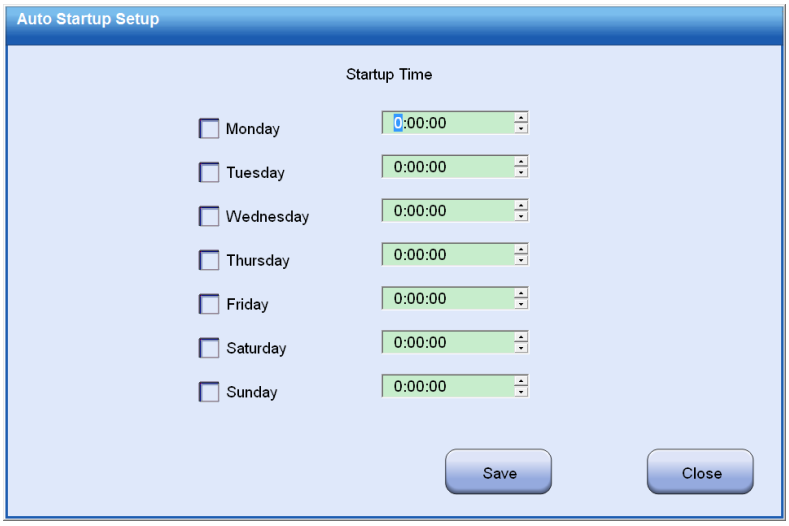
To set up auto startup timer

1 Select **Utility > System Setup**, and click **Instrument F1**.

2 Select **Sleep/Awake**.

3 Select **Auto Startup Setup**.

Figure 2.3 Auto Startup Setup window



4 Specify the weekday and time for auto startup.

Any time within a week (from Monday to Sunday) can be defined for the system to start up automatically.

5 Select **Save**.

6 Select **Close**.

NOTE

After setting up the auto startup time, ensure that the operation unit and the analyzer are connected to power supply; otherwise, they cannot be started up automatically.

To start the operating software

1 When the set time is reached, the instrument starts up automatically, and the operating software starts running.

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

2.2.3 Checking system status

After the startup procedure is finished, check the system status, such as system status, alarm status, reagent/calibration status, maintenance status and sub system status.

If the status is not satisfied for measurement, troubleshoot and maintain the system as instructed by 11 Maintenance on page 11-1 and 12 Alarms and troubleshooting on page 12-1.

Checking system status

Check the system status, print status, ISE module status, and LIS connection status, according to the table below:

Table 2.2 System status

Status name	Status	Meaning	Action
System status	Initialize	The system is performing the startup procedure.	Wait until the initialization is complete.
	Incubation	The lamp has been turned on and is stabilizing.	Wait until the lamp incubation is complete.

Status name	Status	Meaning	Action
	Standby	The system is started and can perform tests.	You can start tests.
	Stopped	The system experiences a failure during startup.	Select **Utility > Command > Home** to initialize the system.
Printer status	Grey icon 	The printer is connected normally and in standby status.	You can start printing reports.
ISE module status	Initialize	The ISE module is performing the startup procedure.	Wait until the initialization is complete.
	Standby	The ISE module is started and can perform tests.	You can start tests.
	Stopped	The ISE module experiences a failure during startup.	Select **Utility > Command > Home** to initialize the system.
LIS connection status	Blue icon 	The LIS is connected normally.	You can download sample programs from the LIS, or send test results to it.
	Grey icon 	LIS is not connected.	Select **Utility > System Setup**, click **Host F5**, set up the LIS communication status, and then click **Connect**.

Checking alarm status

Check for alarms during the startup procedure and take corrective actions.

To check alarm status

1. Check the **Alarm** button on the left of the main screen.
2. If the button is normal, it means that no alarm occurs. Neglect the following steps.
3. If the button appears in yellow, it indicates that a warning occurs.
4. If the button appears in red, it indicates that an error occurs, or both warning and error occur.
5. Select the **Alarm** button. The **Error Log** screen is displayed.

Figure 2.4 Error Log screen

6 Select the help button in front of the new alarm messages to view relevant descriptions and solutions.

7 Take actions according to the recommended solutions.

Checking reagent/calibration status

Check the reagent and calibration status, and determine if the reagent volume is sufficient and if chemistry calibration fails or is required.

To check reagent/calibration status

1 Check the **Reagent** button on the left of the main screen.

- If it appears in yellow, it indicates that a warning occurs.
- If it appears in red, it indicates that an error occurs, or both warning and error occur.

2 Select the **Reagent** button. The **Reagent/Calibration** screen is displayed.

Figure 2.5 Reagent/Calibration screen

3 View the reagent status. When a reagent is insufficient or exhausted, the corresponding chemistry name and chemistries left will be indicated as follows:

- Yellow: indicates that the reagent is insufficient or expired, and the analysis will continue. Refill or replace the reagent.
- Red: indicates that the reagent is exhausted or at least one reagent type is not loaded, and the analysis is stopped. Refill or replace the reagent.

4 View the calibration status. When the calibration is succeeded or failed, the **Cal Status** column of the chemistry shows the calibration status in corresponding color.

- Yellow: indicates that the calibration factors of the chemistry have been calculated, or extended, edited or overridden.
- Red: indicates that the calibration of the chemistry fails or expired, or the chemistry needs to be calibrated.

5 Check the calibration time left. If it will be expired, perform calibration immediately.

For more information about calibration, refer to 2.3.2Calibration on page 2-18.

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:

- **Utility** button on the left of the main screen
- **Maintenance** tab
- **Maintenance** button
- **Scheduled Maintenance** tab
- Maintenance frequency tab
- Maintenance procedure

To check maintenance status

1. Check the **Utility** button on the left of the main screen. If it appears in yellow, it indicates that a maintenance procedure is expired.
2. Select **Utility > Maintenance > Maintenance**.
3. Check if the **Scheduled Maintenance** tab and maintenance frequency tabs appear in yellow. If they do, it indicates that at least one maintenance procedure is expired.
4. Select the maintenance frequency tab appearing in yellow, find the expired maintenance procedure, and then perform the maintenance.

   For more information of maintenance, see 11 Maintenance on page 11-1.
5. Repeat steps 3 and 4 until the maintenance frequency tabs and maintenance procedures are displayed in normal color.

Checking subsystem status

The subsystem status indicates the current working status of each subsystem and hardware component, which includes the status summary, cycle count, temperature, fans, Hydropneumatic subsystem, and control modules.

Description of subsystem status

Status summary

The status summary provides a high-level status summary of the system temperatures, Hydropneumatic, fans, smart modules, and middle-layer unit.

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.

Temperatures

The actual temperature and valid range of the deionized water, cuvette washing fluid and wash solution are displayed.

Fans

The actual status of the reagent refrigeration fans is displayed.

Hydropneumatic subsystem

Status for the Hydropneumatic subsystem shows: working status of various tanks.

Smart modules

Smart module status monitors the working status of each smart module, which includes probes, mixers, carousels, cuvette wash station, ISE unit, etc.

Checking subsystem status

Check the actual value of each component against the reference range and check if the status is normal. Abnormal value or status will be indicated in red.

Follow this procedure to check the subsystem status:

1. Select **Utility > Status**.
2. Choose a subsystem tab.
3. Check the subsystem status. When abnormity occurs, troubleshoot errors with the following methods:

Table 2.3 Troubleshooting errors of the subsystems

Subsystem status	Abnormal phenomena	Corrective actions
Count	If the cycle count of a component reaches certain limit and an alarm occurs, the count appears in red.	Replace the component or contact out customer service department or your local distributor for replacement of the component.
Temperature	If a component's temperature is beyond the valid range or abnormal and an alarm occurs, the measured value appears in red.	1. Exit the operating software and switch off the analyzing unit power. After that, switch on the analyzing unit power again and run the operating software. 2. If the error remains, contact out customer service department or your local distributor for replacement of the component.
Fans	If the status of a fan is abnormal, the measured value appears in red.	
Hydropneumatics	If a Hydropneumatic component is beyond the valid range or abnormal and an alarm occurs, the status appears in red.	
Smart modules	If a smart module is abnormal and an alarm occurs, the status appears in red.	

2.3 Operations before routine test

Before starting routine test, you must prepare the biochemical reagents, ISE reagent and other special reagents, to ensure that tests be performed normally. To ensure steady test performance of the system, you are suggested to perform calibration and QC tests regularly.

2.3.1 Preparing reagents

Reagent types

After checking the system status, you need to prepare the following reagents used in routine test:

- Biochemical reagent
- ISE reagent pack
- Diluted wash solution
- Probe wash solution
- ISE wash solution
- Physiological saline
- Pretreatment reagent

You can load all these reagents in *Standby* or *Incubation* status.

Reagent channel

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

Safety information

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.

Loading biochemical reagents

The system supports manual and auto load of biochemical reagents. If your system is not equipped with a bar code reader, you need to enter the reagent information manually when loading reagents; if a bar code reader is configured, the system will scan all reagents automatically and read reagent information from the bar code. Open reagents can be loaded manually or via bar code scanning, while closed reagents can only be loaded via bar code scanning.

Chemistries without reagents loaded can be requested but will not be included in measurements. Each chemistry can have more than one bottle of reagent loaded; however the reagent of same chemistry must be loaded on the same reagent carousel.

If an exclamation mark (!) appears near a reagent type, it indicates that one or more reagent types of the chemistry have not been loaded yet.

NOTE

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

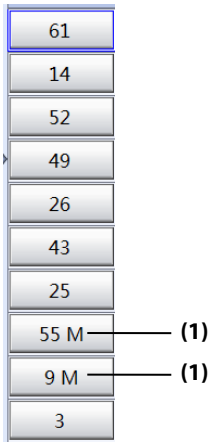
If a chemistry is set with sample pretreatment, ensure that the chemistry reagent and the pretreatment reagent are loaded to the same reagent carousel; otherwise, the chemistry cannot be run.

Manual load

When loading reagents manually, you need to enter the reagent information, which is the only information source of the loaded reagents. If loaded reagents are bar-coded, the reagent information cannot be edited; otherwise, all reagent information except for position, chemistry and reagent type can be edited.

Manually loaded reagents have the letter “M” (Manual) appearing near them.

Figure 2.6 Flag for manually loaded reagents



(1) Flag "M" for manually loaded reagents

Manual load of biochemical reagents includes two steps:

- Setting up reagent information
- Loading reagents

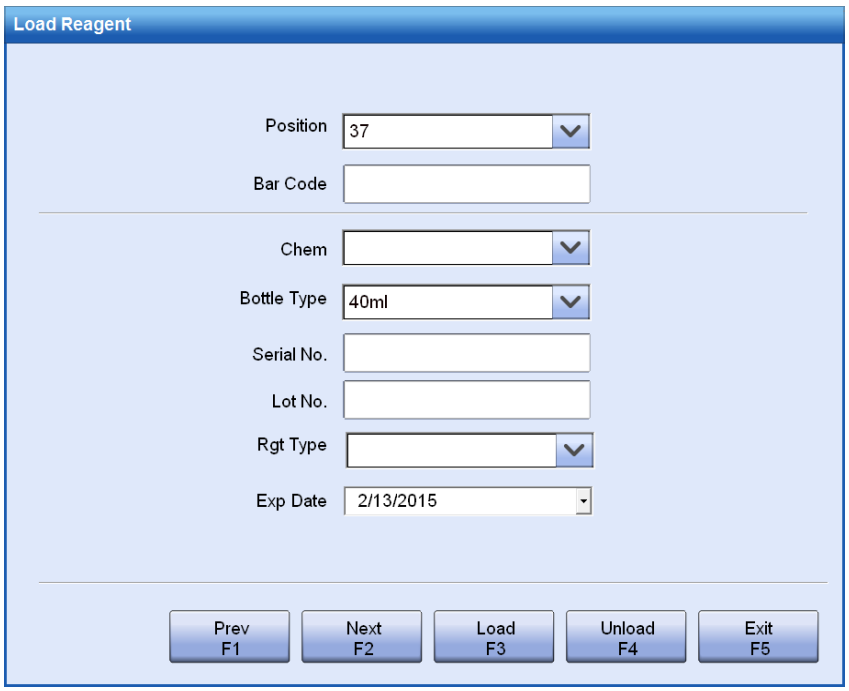
To set up reagent information

1 Select **Reagent > Reagent/Calibration**, or select **Reagent > Reagent Carousel Status**.

2 Select a reagent carousel from the **Reagent Carousel** drop-down list.

3 Choose a position to which you want to load a reagent, and then select **Load F1**. The **Load Reagent** window is displayed.

Figure 2.7 Load reagent window



4 Enter the following reagent information:

- Bar code
- Chemistry name
- Reagent type
- Lot number
- Serial number
- Bottle type
- Expiration date

5 Select **Load F3** to save the input information.

6 Select **Prev F1** and **Next F2** to load reagents for other chemistries, and then repeat steps 4-6.

7 Select **Print F7** to print out the biochemical reagent list.

To load reagents

1 Remove the reagent carousel cover.

CAUTION

If the system is running tests, wait until the system status becomes *Reagent load* before removing the reagent carousel cover. Otherwise, probe collision or other error may occur.

2 Load reagents to the set positions according to the reagent load list, and then uncap the reagent bottles.

3 Restore the reagent carousel cover.

4 Select **End Load F2**.

5 Select **Inventory F3** to check the volume of the loaded reagents and refresh the number of tests left on the screen.

For more information on reagent inventory check, see 3.1.7 Checking and auto refreshing reagent inventory on page 3-4.

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 be loaded only through bar code scanning.

To load bar-coded reagents

1 Remove the sample/reagent carousel cover.

CAUTION

If the system is running tests, wait until the system status becomes *Reagent load* before removing the reagent carousel cover. Otherwise, probe collision or other error may occur.

2 Place the reagents in idle positions of the reagent carousel and then uncap the reagent bottles.

3 Restore the reagent carousel cover.

4 Select **End Load F2.**

The system scans all reagent positions and read the reagent information from the bar code.

Loading ISE reagent pack

The ISE Reagent Pack comprises calibrator A, calibrator B, waste container, and volume detection chip. Before running ISE tests, load the reagent pack, perform fluidic prime and calibration.

To prepare ISE Reagent Pack

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.

To load 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.

NOTE

Make sure the electrodes and pump tubes of the ISE module are installed before loading the reagent pack. If the reagent pack is loaded when the electrodes are not installed, liquid overflow from the electrodes may cause damage to the analyzer.
During the loading process, the ISE module will be primed and calibrated automatically. Do not take out the reagent pack.

Loading ISE Cleaning Solution

ISE Cleaning Solution is used to wash the electrodes. Follow this procedure to load ISE wash solution:

1 Open the sample carousel cover.

2 Put the ISE Cleaning Solution in positionISE (No.100) on inner ring of the sample/reagent carousel.

Loading diluted wash solution

Diluted wash solution is diluted at the ratio 1:10 or 1:50 from CD80 alkaline concentrated wash solution. It is used to clean the reaction cuvettes and the mixer.

For plastic cuvettes, the dilution ratio is 1:10 while for glass cuvette, it is 1:50.

A tank of diluted wash solution is 15L and can be used for analysis for 7~8 days on condition that 840 tests are performed every day. Please check and refill the diluted wash solution according to the consumption and tank volume.

Load the diluted wash solution in following steps:

- Preparing diluted wash solution
- Loading diluted wash solution

CAUTION

Use the concentrated wash solution specified by our company. Using other wash solutions may cause inaccurate test result.

To prepare diluted wash solution

1 Pour the concentrated wash solution (1L) into the diluted wash solution tank.

2 Add deionized water to the diluted wash solution tank until it reaches the scale of 11L.

3 Install the tank cover, and shake the tank slightly to mix the liquid completely.

To load diluted wash solution

1 Select **Reagent > Reagent/Calibration**.

2 Select **Diluted W Sol**.

3 Click **Load F1** to display the **Reagent Load** window.

4 Input the following information:

- Volume
- Serial number

- Lot number
- Expiration date
- Alarm limit

5 Click **Load F3**, and then click **Exit F5** to close the window.

6 Connect the diluted wash solution tank to the corresponding interface on the analyzer.

Loading sample probe wash solution

Sample probe wash solution is used to clean the sample probe, and can only be loaded manually. When the sample probe wash solution is expired or exhausted, 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 solution, ensure that there are no air bubbles inside the test tube so as to avoid affecting washing effects..

1 Check the system status and operate accordingly.

- Standby: Proceed to the next step.
- Running: Select the  button on the upper-right corner of the main screen to stop sample aspirating and dispensing. When the countdown for sample stop becomes 0 and the system status is Sample Load, proceed to the next step.

2 Remove the sample carousel cover;

3 Place alkaline wash solution in position DB of the sample carousel and probe cleanser (if configureed) in position DC of the sample carousel.

4 Restore the sample carousel cover.

Loading reagent probe wash solution

Reagent probe wash solution can only be loaded manually. The volume, lot number, serial number, expiration date, bottle type and other information of the loaded wash solution must be entered.

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

NOTE

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

1 Select **Reagent > Reagent/Calibration**, and select **R Wash Solution DB**.

2 Or select **Reagent > Reagent Carousel Status**, and then click position DB.

3 Select **Load F1**. The **Load Reagent** window is displayed.

4 Remove the reagent carousel cover.

4 Place the alkaline wash solution in position DB (No.92) of the reagent carousel.

5 Restore the reagent carousel cover.

6 Enter the following information:

- Volume (%)
- Serial number
- Expiration date
- Lot number
- Bottle type (required)
- Reagent alarm limit

9 Select **Load F3**.

10 Select **Exit F5** to close the window.

11 Select **End Load F2**.

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 W on the reagent carousel; and that for running reagent blanks and calibrations should be loaded manually to the position W on the sample carousel.

Loading physiological saline on the sample carousel

1 Check the system status and operate accordingly.

- Standby: Proceed to the next step.
- Running: Select the  button on the upper-right corner of the main screen to stop sample aspirating and dispensing. When the countdown for sample stop becomes 0 and the system status is Sample Load, proceed to the next step.

2 Remove the sample carousel cover.

3 Place physiological saline in position W(position 102) of the sample carousel.

4 Restore the sample carousel cover.

Loading physiological saline on the reagent carousel

1 Check the system status and operate accordingly.

- Standby: Proceed to the next step.
- Running: Select **Reagent-Reagent/Calibration**. Select **Load F1** to stop reagent aspirating and dispensing. Meanwhile **Load F1** becomes **No load F1**. If you want to abort load, select **No load F1**. When the countdown for reagent stop 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.

2 Select **Reagent > Reagent/Calibration** Or select **Reagent > Reagent Carousel Status**.

3 Select **Saline W** in the lower reagent list.

4 Select **Load F1**. The **Load Reagent** window is displayed.

5 Remove the reagent carousel cover.

CAUTION

If the system is running tests, after requesting reagent stop, do not remove the reagent carousel cover until the countdown for reagent stop is 0, the system status is Reagent Load, and the popup message is confirmed; otherwise, Probe collision or other error may occur.

6 Place the physiological saline for sample blanks and sample dilution in position W (No.91) of the outer ring of the reagent carousel.

7 Restore the reagent carousel cover.

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

- Volume %
- Bottle type
- Reagent alarm limit

9 Select **Load F3**.

10 Select **Exit F5** to close the window.

11 Select **End Load F2**.

Loading pretreatment reagent

Pretreatment reagent is used to pretreat whole blood samples. For auto loading pretreatment reagent, please stick the bar code in the reagent box on the pretreatment reagent bottle first and place it on the reagent carousel for scanning. Follow this procedure to load pretreatment reagent:

1 Select **Reagent > Reagent/Calibration** Or select **Reagent > Reagent Carousel Status**.

NOTE

Make sure that it is on the same carousel as the chemistry reagent set with sample pretreatment; otherwise, the chemistry cannot be run.

2 Select a reagent carousel from the **Reagent Carousel** drop-down list.

3 Choose a position to which you want to load a reagent, and then select **Load F1**. The **Load Reagent** window is displayed.

4 Enter the following reagent information:

- Bar code
- Chemistry name
- Reagent type(R0)
- Lot number
- Serial number
- Bottle type
- Expiration date

5 Select **Load F3** to save the input information.

6 Select **Prev F1** and **Next F2** to load other pretreatment reagent, and then repeat steps 4-6.

7 Remove the reagent carousel cover.

CAUTION

If the system is running tests, wait until the system status becomes *Reagent load* before removing the reagent carousel cover. Otherwise, probe collision or other error may occur.

8 Load the pretreatment reagent to the set positions and uncap the reagent bottles.

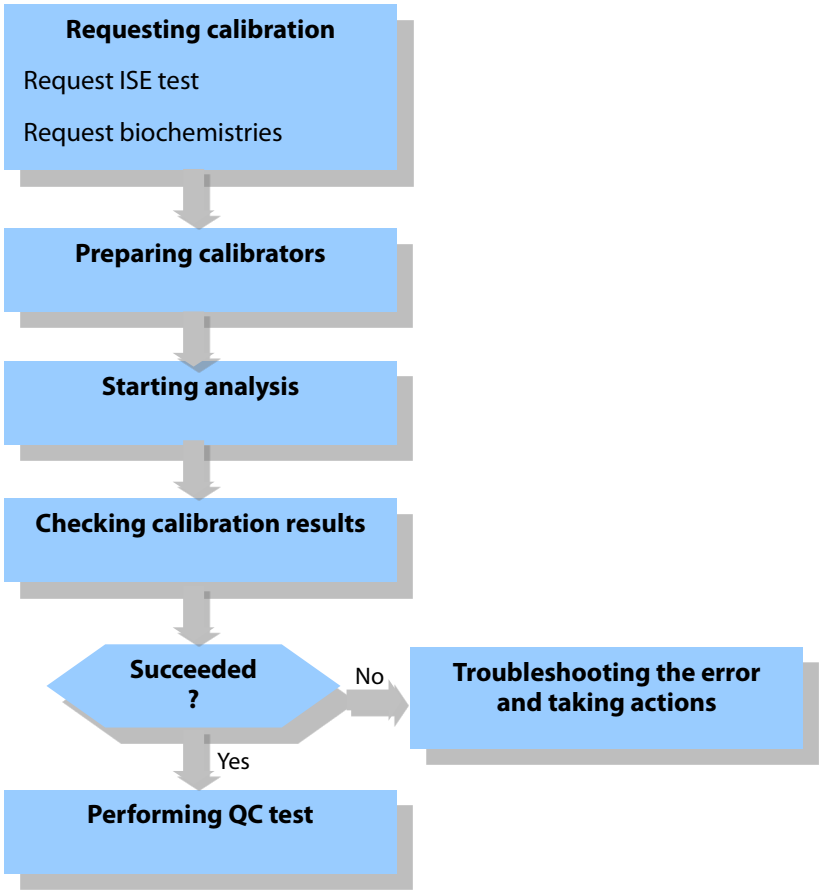
9 Restore the reagent carousel cover.

10 Select **End Load F2**.

2.3.2 Calibration

Calibration is performed to obtain calibration factors for calculate sample test results. The calibration test procedure is as shown below:

Figure 2.8 Calibration test procedure



Requesting calibration

Calibration request includes ISE test and biochemistries.

CAUTION

Check the ISE calibration status before starting tests. If the status does not meet the requirement, perform calibration for ISE serum chemistries and urine chemistries. If the results of a chemistry are calculated based on the calibration factors of another chemistry, the accuracy and precision of the test may be affected. After cleaning ISE tubes, special washing ISE tubes and changing electrodes or other consumables, perform a calibration. You are recommended to perform calibration at least once every day to ensure accurate results.

To request ISE calibration

1 Select **Reagent > Reagent/Calibration**.

Figure 2.9 ISE Reagent/Calibration screen

2 Select **ISE**.

3 Click **Calibrate F5**.

To request biochemistry calibration

1 Select **Reagent > Reagent/Calibration**.

2 Select a reagent carousel from the **Reagent Carousel** drop-down list.

3 Select the down-arrow button on the right side of the screen to display the biochemistry reagent/calibration screen.

Figure 2.10 Biochemistry Reagent/Calibration screen

4 Select chemistries you want to calibrate.

Select the up-/down-arrow buttons to select more chemistries.

5 Select **Cal F5**.

6 Select **Calibration**, and select **OK**.

7 If you want to abort the calibration requests, select **No Cal F6**.

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

Preparing calibrators

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.

To prepare calibrators

1 Select **Reagent > Reagent/Calibration**.

2 Select a reagent carousel from the **Reagent Carousel** drop-down list.

3 Select the down-arrow button on the right side of the screen to display the biochemistry reagent/calibration screen.

4 Select **Load List F4**.

The calibrator list shows all requested chemistries as well as calibrators, positions, concentration, lot number and expiration date.

5 Select **Print F7**, and select **Close F8**.

6 Load calibrators to the sample carousel according to the calibrator list.

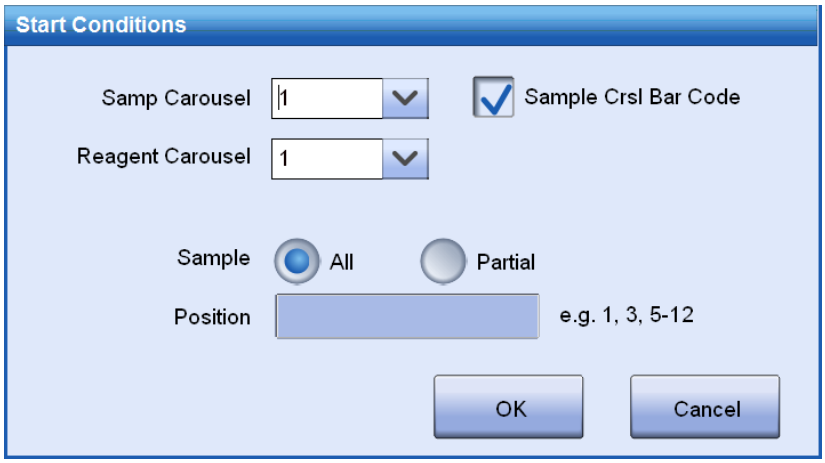
Starting analysis

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

To start calibration test

1 Select  on upper right corner of the main screen. The **Start Conditions** window is displayed.

Figure 2.11 Start Conditions window



2 Select a sample carousel to which the calibrators are loaded.

3 Select a reagent carousel to which the reagents are loaded.

4 Select **OK** to start analysis.

Checking calibration results

After the calibration test is complete, check the test results and calibration status. If you see any abnormity, troubleshoot the error immediately.

To check calibration results

1 Select **Reagent** > **Biochemistry Calibration** or **Reagent** > **ISE Calibration**.

2 Check for result flags in the result list.

If you see result flags, troubleshoot the error according to 12.4.1 Data alarms and corrective actions on page 12-9.

3 Check if the **Cal Status** column appears in red. If it is, it means the calibration fails or calibration is required. Perform calibration immediately.

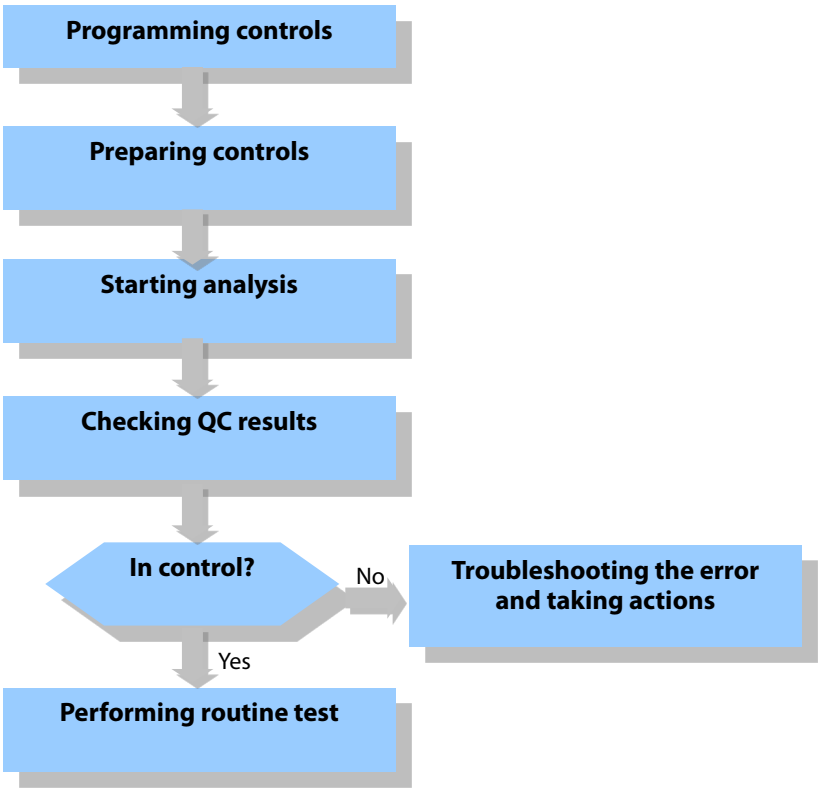
4 After taking actions, you can start the QC test.

2.3.3 QC

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 every day.

The QC test procedure is as shown below:

Figure 2.12 QC test procedure



Programming controls

Before routine test, biochemistries, ISE test, calculations, and panels should be run with control samples. Prior to programming controls, make sure that the QC parameters have been set correctly; otherwise, the chemistries cannot be requested.

To program controls

1 Select **Program** > **Quality Control**.

Figure 2.13 Quality Control screen

2 Select a control from the **Control** drop-down list.

3 Select a position from the **Pos** drop-down list.

The options include all positions defined for the control. The default is the position on the first defined sample carousel in ascending numerical order.

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

5 Choose desired chemistries and panels in the chemistry list.

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

6 If you want to run the QC test by the reagent lot number of the chemistry:

a. First select **Options F2**.

b. Then select reagent lot number for the chemistry.

c. Select **Save**.

7 Select **Save F8**

8 To program other controls, select **Prev F4** or **Next F5**, and then repeat steps 3-7.

Preparing controls

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.

To prepare controls

1 Select **Program** > **Sample**.

2 Select **List F5**.

The sample list shows all programmed patient samples, control samples and chemistries.

3 Select **Print F7**.

Samples and controls are printed out separately.

4 Select **Exit F8**.

5 Load control samples to the sample carousel according to the printed list.

Starting analysis

After programming and load the control samples, you can start the QC test.

To start QC test

1 Select  on upper right corner of the main screen. The **Start Conditions** window is displayed.

2 Select a sample carousel to which the control samples are loaded.

3 Select a reagent carousel to which the reagents are loaded.

4 Select **OK** to start analysis.

Checking QC results

After the QC test is complete, check if the test results are within the normal range and the data points on the QC chart are normal. If you see any abnormity, troubleshoot the error immediately.

To check QC results

1. Select **Result > Current**, and click the **By Sample** option button.
2. Check for result flags in the result list.

   If you see result flags, troubleshoot the error according to 12.4.1 Data alarms and corrective actions on page 12-9.
3. Select **QC > Levey-Jennings**, **Cumulative sum** or **Twin-Plot**, and check if the data points on the charts are normal.
4. After taking actions, you can start the routine test.

2.4 Routine test

Routine test includes the following operations:

- Programming and processing samples
- Checking test results
- Checking test status and performing test control

2.4.1 Programming and processing samples

Analysis of routine and STAT samples are described in this section supposing no LIS or bar code reader is configured. STAT sample is to be run at higher priority than routine sample.

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.

NOTE

Before loading sample, ensure that there are no air bubbles inside the sample cup so as to avoid inaccurate test results.

To program routine and STAT samples

1. Select **Program > Sample**.

Figure 2.14 Sample screen

2 Input the sample information, including: sample ID, carousel No. and position, STAT property, sample type, comment, and patient ID.

3 Select chemistries and panels to be run.

4 To input patient information, click **Demog F1**.

5 To set number of replicates and dilution factors, click **Options F2**.

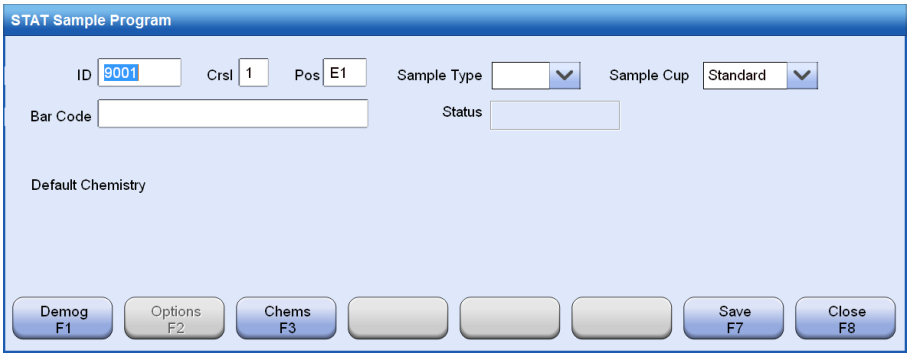
6 Click **Save F8**.

7 To program more samples, repeat steps 2-6.

To quickly program STAT samples

1 Select  on upper right corner of the main screen. The **STAT Sample Program** window is displayed.

Figure 2.15 STAT Sample Program window



2 Input the sample information, including: sample ID, carousel No. and position, sample type, and sample cup.

3 Confirm the default chemistries.

4 To select more chemistries, perform the following steps:

a. Click **Chems F3**.

b. Select chemistries and panels to be run for the samples.

c. Click **Save F7**.

5 To input patient information, click **Demog F1**.

6 To set number of replicates and dilution factors, click **Options F2**.

7 Click **Save F7**.

8 To program more samples, repeat steps 2-7.

9 Click **Close F8** to close the window.

To prepare samples

1 Select **Program** > **Sample**.

2 Select **List F5**.

The sample list shows all programmed samples, controls and chemistries.

3 Select **Print F7**.

Samples and controls are printed out separately.

4 Select **Exit F8**.

5 Load samples to the sample carousel according to the printed list.

To start sample analysis

1 Select  on upper right corner of the main screen. The **Start Conditions** window is displayed.

2 Select a sample carousel to which the samples are loaded.

3 Select a reagent carousel to which the reagents are loaded.

4 Select a patient sample range: All or Partial. When you select Partial, you should specify a sample position range for analysis.

5 Select **OK**.

Other sample test methods

Besides the manual programming of single sample described above, the system supports other test methods.

Batch programming

With this function, you can program multiple samples at one time. For batch-programmed samples, all program information such as sample information, chemistries and patient demographics other than position, ID and bar code are the same.

📖 For details about batch programming, see 6.2.3 Batch programming on page 6-6.

Adding samples

You can add routine sample and STAT sample at any time.

📖 For details about adding samples, see 6.2.4 Adding samples on page 6-6.

Adding chemistries

You can add chemistries to samples of any status. Whether to change the program information will be determined based upon the sample status.

For details about adding chemistries, see 6.2.5 Adding/Modifying chemistries on page 6-7.

Rerunning samples

The system supports manual rerun and auto rerun. Manual rerun can be performed through the **List** window and the **Current** or **History** screen. Auto rerun is based on the set critical range of the ISE test and the rerun conditions of biochemistries. When the conditions are met, the relevant chemistries will be rerun automatically.

For details about rerunning samples, see 6.2.6 Rerunning samples on page 6-7.

Programming bar-coded samples with LIS

If the instrument is connected with LIS and bar code reader, you can program samples without manually inputting the program information.

For details about programming bar-coded samples with LIS, see 6.2.1 Processing samples with LIS on page 6-3.

2.4.2 Checking test results

After the sample analysis is complete, you can check the test results on the **Result > Current** screen. The test results beyond the set reference range will be flagged and indicated in yellow. After checking the results, you can print them on reports.

To check test results

1. Select **Result > Current > By Sample**.
2. Select the desired sample in the left list. The test results of this sample are displayed in the right list.
3. Check for flags in the result list.
4. If you see result flags, troubleshoot the error according to 12.4.1 Data alarms and corrective actions on page 12-9.
5. Take corrective actions.

To print test results

1. Select **Result > Current > By Sample**.
2. Select the desired sample in the left list.
3. Click Print F7.
4. Select **Print Sample Report**.
5. Select the print range: **Selected Sample(s)** or **All Sample(s)**.
6. To neglect the samples that have been printed, select the **Bypass Printed Sample(s)** check box.
7. Click **OK**.

2.4.3 Checking test status and performing test control

During the analysis, you can check reagent inventory on the **Reagent/Calibration** screen, and view test status of calibrators, controls, routine and emergent samples on the **Program > Status** screen. View the reagent carousel status through **Reagent > Reagent Carousel Status** screen**.** If needed, you can pause or stop analysis, or change the sample carousel and reagent carousel, during test.

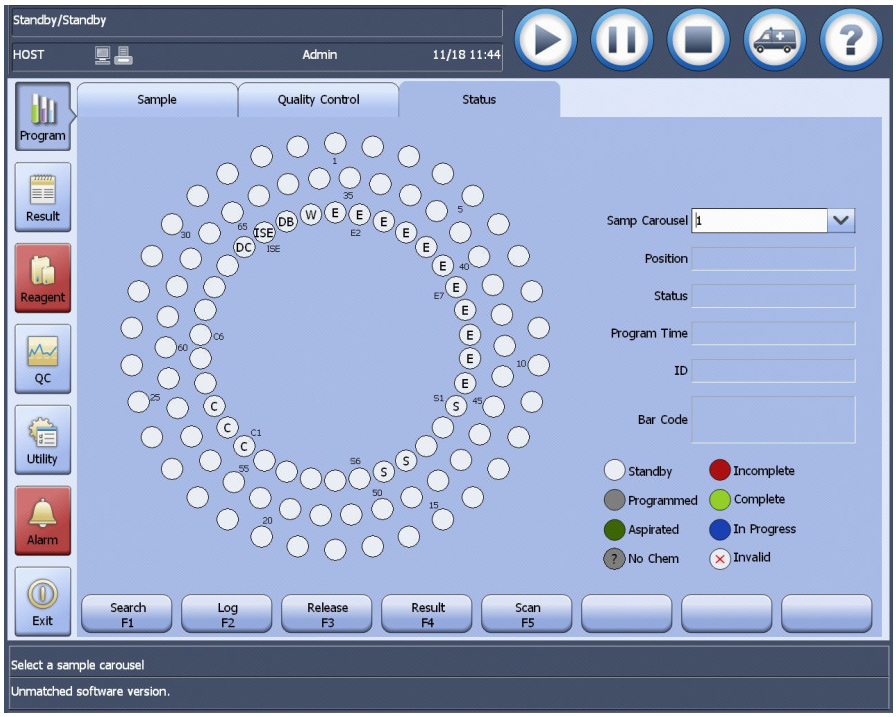
Checking sample carousel status

On the **Program > Status** screen, you can check the test status of each sample position.

To check sample carousel status

1 Select **Program** > **Status**.

Figure 2.16 Status screen



2 View the status of calibrators, controls and samples on the sample carousel graph.

Refer to the explanations of various sample statuses on the lower-right corner of the screen.

3 To view the detailed information of certain sample, select the sample position on the sample carousel graph.

The detailed information of the selected sample position is displayed on the right side of the screen.

4 Choose the following buttons as needed:

- **Search F1**: used to search for desired calibrator, control or patient sample.
- **Log F2**: used to recall controls and patient samples which are not complete due to some reasons within the recent 24 hours.
- **Release F3**: used to release the specified or all positions on the current sample carousel.
- **Result F4**: used to display the **Current Results** screen, on which you can recall all controls and patient samples that are programmed and analyzed since the system is started up.
- **Scan F5**: used to scan the specified position or all positions on the selected sample carousel.

Checking reagent carousel status

On the **Reagent** > **Reagent Carousel Status** screen, you can check the reagent volume and view the detailed information of each reagent.

To check reagent carousel status

1 Select **Reagent** > **Reagent Carousel Status**.

2 Select a reagent carousel from the **Carousel** drop-down list.

Figure 2.17 Reagent carousel status

3 Check the reagent volume status according to the explanation in the middle of the carousel graph. If a reagent is insufficient or exhausted, replace it immediately.

For instructions of loading reagent in *Running* status, see 3.1.3Loading biochemistry reagents or pretreatment reagent in Running status on page 3-3.

4 To view the detailed information of certain reagent, select the reagent position on the reagent carousel graph.

The detailed information of the selected reagent position is displayed on the right side of the screen.

5 Select the following buttons to perform respective operations:

- **Load F1**: select this button to load the reagent.
- **End Load F2**: If a bar code reader is configured and the reagents have been loaded, select this button to scan the reagent carousel; if the function of auto refreshing reagent inventory has been enabled, the reagents with inventory 0 can be refreshed as available when **End Load F2** is selected.
- **Inventory F3:** select this button to check reagent inventory.

Switching carousels

Switching carousels means changing sample carousel and reagent carousel during measurement, so that the samples and reagents on them can be tested.

Switching sample carousel

The system supports 10 virtual sample carousels, on all of which samples can be programmed in order to improve the test efficiency.

After samples on multiple sample carousels are programmed, if those on the current sample carousel are about to finish sample dispensing during test process, the screen shows the countdown for sample loading and the **Start Conditions** window pops up. Select desired sample carousel, load samples to it, and then select **OK** to resume the test.

Switching reagent carousel

The system supports 2 virtual reagent carousels, on both of which biochemistry reagents, wash solution and physiological saline can be loaded. However, reagents of the same chemistry must be loaded on the same carousel, and only the chemistries on the same carousel can be tested in every batch of tests.

To run chemistries on the other reagent carousel, click  to display the **Start Conditions** window. Select the other reagent carousel, load reagents to it, and then select **OK** to resume the test.

Pause

"Pause" means to stop addition of sample and reagent temporarily during test process, so that you can load/unload sample and reagent on the carousel. After you click  , when the started tests finish sample/reagent dispensing, the system enters the *Pause* status. Then you can start loading/unloading sample and reagent.

To cancel pausing and resume the test, select  .

Emergency stop

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

Select the  icon on upper right corner of the screen, and then select **OK**. All unfinished actions of the system are cancelled, all pumps and valves are turned off, and the system enters the *Stopped* status.

To restore system failure, select **Utility > Commands**, and then select **Home**. To resume the analysis, select the  icon.

2.5 Daily maintenance and powering off

After finishing the test tasks of the day, you should perform the following operations:

- Daily maintenance
- Powering off
- Operations after powering off

2.5.1 Daily maintenance

Perform the daily maintenance procedures and those maintenance procedures indicated in yellow.

Daily maintenance procedures include:

- Check probe/mixer/wash well
- Check DI water tank and tube connection
- Check diluted wash solution tank
- Check waste connection
- Check sample syringe and reagent syringe
- Check probe wash solution
- Special wash probes/mixers
- Clean ISE tubes

📖 For detailed information of daily maintenance, see 11.5Daily Maintenance on page 11-12.

2.5.2 Powering off

If you have set the auto startup timer, ignore the following powering off procedure.

To power off the system

1. Make sure that the system is in *Standby* status.
2. Select **Exit > Shut Down** on the left of the main screen. The Windows operating system will quit automatically.
3. Switch off the power in the following order:
   - Printer
   - Monitor display of the operation unit
   - Analyzing unit power switch

   When the analyzing unit power is switched off, the refrigeration system is still running. If you are going to store the system for over 7 days, switch off the main power.

NOTE

If the ISE tubes have not been cleaned before shutdown, perform this procedure when you switch off the analyzer.

When the analyzing unit power is switched off, the refrigeration system is still running. If you are going to store the system for over 7 days, switch off the main power.

2.5.3 Operations after powering off

Perform the following operations after powering off the system:

1. Remove the sample/reagent carousel cover, and then remove the calibrators, controls and patient samples.
2. Check the analyzer panel for stains and wipe them off with clean gauze if any.
3. Check the high-concentration waste tank and the low-concentration waste tank. Clear them if necessary.

3 Reagent

This chapter describes reagent and calibration operations related to ISE and biochemistry tests.

3.1 Biochemistry reagent

3.1.1 Biochemistry reagent/calibration screen

Select **Reagent > Reagent/Calibration**. Click the down-arrow button on the right side of the screen to display the biochemistry reagent/calibration screen.

Figure 3.1 Biochemistry reagent/calibration screen

All set biochemistry reagents are displayed. The reagent name is indicated by different colors according to the reagent volume and loading status.

- Yellow: indicates that the reagent is insufficient or expired.
- Red: indicates that the reagent is exhausted or at least one reagent type is not loaded.

3.1.2 Sorting reagents

Reagents on the biochemistry reagent/calibration screen can be sorted by name, position, chemistries left, days left, calibration time left, and calibration status, and a V-type 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.

To sort reagents

1. Select **Reagent > Reagent/Calibration**.
2. Select a reagent carousel from the **Reagent Carousel** drop-down list.
3. Select the down-arrow button on the right side of the screen to display the biochemistry reagent/calibration screen.
4. Choose a sorting criterion, and then click on the corresponding list head to rearrange the reagents.

   a. To view or load reagents, choose the following standards:
   - Reagent position
   - Chemistry name
   - Chemistries left
   - Tests left

- Days left

b. To view calibration status or run calibrations, choose the following standard:

- Calibration time left
- Calibration status

3.1.3 Loading biochemistry reagents or pretreatment reagent in Running status

If the screen prompts that a biochemistry reagent has been used up or is less than the alarm limit, replace it immediately.

The methods of loading reagent in Running status are similar with in Standby and Incubation status, except that you need to pause the sample and reagent addition before the operation.

To load biochemistry reagents in Running status

1. Click **Load F1**.
2. When the system status changes to Rgt Load, start replacing reagents in the same way as initial loading.

   For the methods of loading biochemistry reagents, see 2.3.1Preparing reagents on page2-10.

3.1.4 Unloading biochemistry reagents or pretreatment reagent

If some chemistries will not be used, you are allowed to clear the chemistry parameters and unload the relevant reagents or pretreatment reagent. When a chemistry is requested for quality control, sample analysis or calibration, all reagents of the chemistry 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.

The following procedure is only applicable to unloading the reagents without bar code; for those reagents with barcode, when the reagents are taken away from the reagent carousel, they are unloaded automatically.

To unload biochemistry reagents or pretreatment reagent

1. Select **Reagent > Reagent/Calibration**, and select the up and down arrow buttons to display the biochemical regent/calibration screen.
2. Or select **Reagent > Reagent Carousel Status**.
3. Select the desired reagent or pretreatment reagent.
4. Select **Load F1**, and then **Unload F4**.
5. Remove the reagent carousel cover, take out the reagent or pretreatment reagent, and restore the cover.
6. Select **Exit F5** to close the window.
7. Select **End Load F2**.

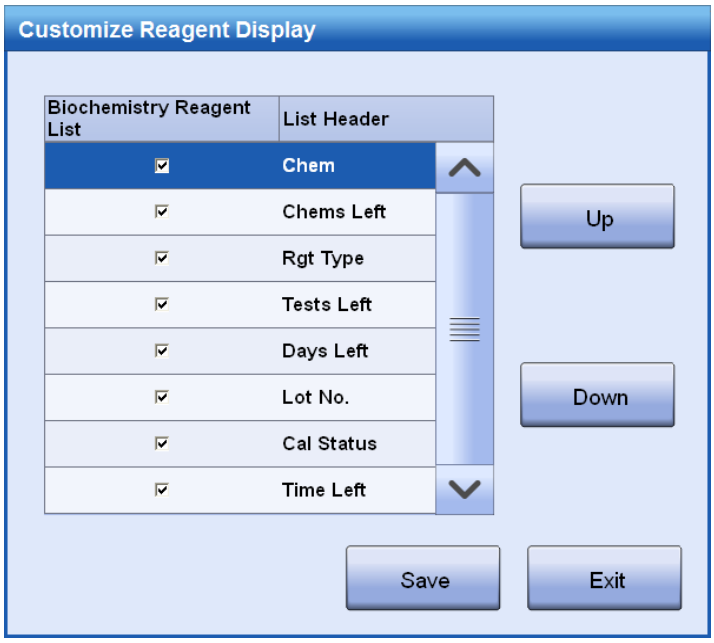
3.1.5 Customizing reagent display

The reagent information on the biochemistry reagent/calibration screen can be tailored and displayed in desired order.

To customize reagent display

1. Select **Utility > System Setup**.
2. Click **Instrument F1**, and select **Customize Reagent Display**.

Figure 3.2 Customize Reagent Display window



3 To display a header on the reagent/calibration screen, select the check box on the left.

4 To cancel displaying a header, deselect the corresponding check box.

5 Select **Up** and **Down** to adjust the display order of the reagent information.

6 Select **Save** to save the settings.

7 Select **Exit** to close the window.

3.1.6 Setting up reagent alarm limit

The system provides the function of reagent alarm limit setup. When a reagent is less than the set alarm limit, the reagent name and the number of chemistries left on the biochemistry reagent/calibration screen will be indicated in yellow. You should replace the reagent immediately.

To set up reagent alarm limit

1 Select **Utility** > **Chemistries**.

2 Select the chemistry that you want to set reagent alarm limit.

3 Select **Define F1**. Select down arrow to get to the second page.

4 Type in the reagent alarm limit.

Enter an integer within 1-100. The default is 10.

5 Select **Save F7**.

6 Select **Close F8**.

3.1.7 Checking and auto refreshing reagent inventory

The system provides the manual and auto check of inventory of biochemical reagents. During the test, the system automatically checks the reagent inventory and displays it on the **Reagent/Calibration** screen. After the reagents are loaded, it is necessary to perform the inventory check in order to ensure that sufficient reagents are available for analysis.

When reagent has been loaded and **End Load** button is selected, you can configure whether to automatically refresh the reagent with 0 inventory as available for test.

Checking reagent inventory

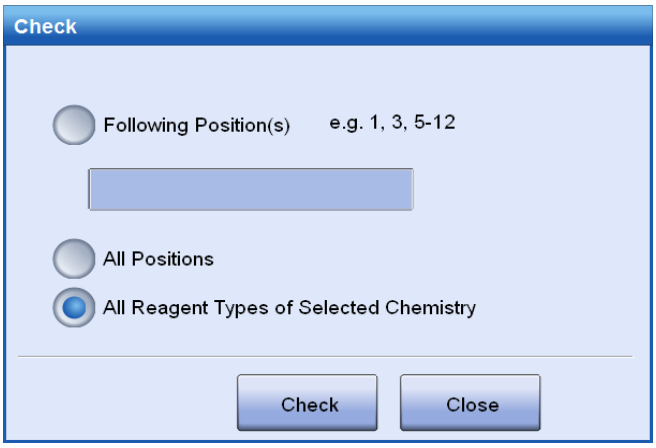
Reagent inventory check is allowed only when the biochemistry system status is Incubation or Standby, and the ISE system is Standby or Stopped or unconfigured.

Checking reagent inventory

1 Select **Reagent > Reagent/Calibration**, or select **Reagent > Reagent Carousel Status**.

2 Select **Inventory F3**.

Figure 3.3 Check window



3 Choose reagent positions:

- Following position(s): check the reagents on specified positions. Enter reagent positions and separate them with a comma. Enter single reagent positions like 1, 2, 3, or position range like 2-15, 20-25.
- All positions: check all reagent positions of the reagent carousel.
- All reagents of selected chemistry: check the inventory of all reagent types of the selected chemistry.

4 Select **Check**.

- The reagent carousel graph refreshes the reagent status automatically.
- The **Reagent/Calibration** screen refreshes the **Tests Left** of the selected chemistry, **Chems Left**, and the **Volume** of the selected wash solution.

Canceling reagent inventory check

To cancel reagent inventory check, select **Close** on the **Check** window, and then select **No Invent. F3** on the **Reagent/Calibration** screen, or on the **Reagent Carousel Status** screen.

Auto refreshing reagent inventory

1 Select **Utility > System Setup**.

2 Select **Instrument F1**, and then select **Reagent/Calibration Setup**.

3 Select the option **Auto Refresh Reagent Inventory**, which is unselected by default.

4 Click **Save**.

5 Click **Exit** to close the window.

3.2 Special reagent

3.2.1 Special reagent/calibration screen

Select **Reagent > Reagent/Calibration**. The special reagent/calibration is displayed by default.

Figure 3.4 ISE reagent/calibration screen

The special reagent/calibration screen is divided into three areas:

- ISE test calibration information area
- Special reagent list
- Function buttons area

When a reagent is insufficient or exhausted, the reagent name will be indicated as follows:

- Yellow: indicates that the reagent is insufficient or expired.
- Red: indicates that the reagent is exhausted and the volume is 0.

3.2.2 Loading special reagents in Running status

The special reagents used by the system include: ISE reagent, diluted wash solution, probe wash solution and physiological saline. If the software indicates that any of them has been used up or is less than the alarm limit, replace them immediately.

The methods of loading reagent in Running status are similar with in Standby and Incubation status, except that you need to pause the sample and reagent addition before the operation.

To load special reagents in Running status

1 Click **Load F1**.

2 When the system status changes to Reagent load , start replacing reagents in the same way as initial loading.

For the methods of loading special reagents, see 2.3.1Preparing reagents on page2-10.

3 After finishing replacement, click  to resume the previous test or to start new test.

NOTE

Do not replace ISE reagent when you request tests of ISE chemistries; otherwise, tests may be invalidated. For the replacement of ISE reagent, pleaser refer to 2.3.1 Preparing reagents (2-10).

3.2.3 Unloading special reagents

The system allows you to unload probe wash solution and physiological saline. Diluted wash solution cannot be unloaded, and do not unload ISE reagents when the system is in the Initialization, Running and Maintenance status.

To unload special reagents

1. Select **Reagent > Reagent/Calibration**.
2. Select the special reagent you want to unload.
3. Click **Load F1**.
4. Click **Unload F3**.
5. Click **Exit F5**.

   To ensure that the routine test can go smoothly, load the special reagent immediately after unloading.

3.2.4 Printing special reagent/calibration list

To print special reagent/calibration list

1. Select **Reagent > Reagent/Calibration**.
2. Click **Print F7**.

4 Calibration

This chapter provides calibration setup, calibration status, and calibration result recall of ISE test and biochemistry.

4.1 Biochemistry calibration

This section describes calibration setup, calibration status and alarm, reagent blank test, calibration result recall of biochemistry.

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.

4.1.1 Calibration setup

Perform calibration settings in the following order:

- Define a calibrator
- Import a calibrator
- Set up calibrator concentrations
- Calibrator dilution setup
- Set up calibration rules
- Set up calibrator acceptance limits
- Auto calibration

If you change the calibration model, number of replicates, calibrator concentration, and calibrators, you must run calibration test again.

You are allowed to remove the calibrators other than WATER.

Defining a calibrator

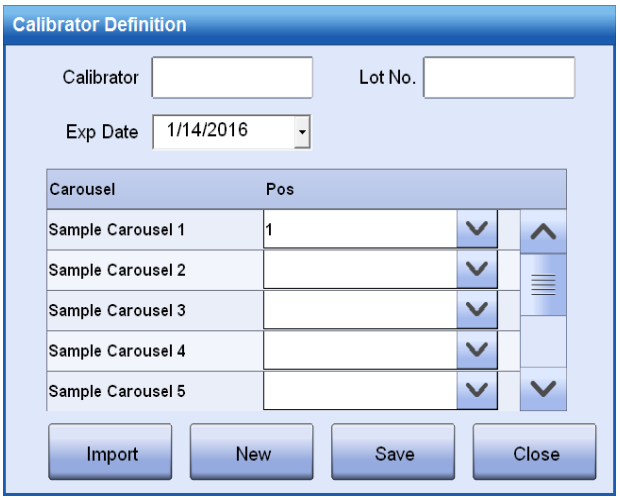
The system allows the definition of up to 99 calibrators. You are allowed to add, edit and delete calibrators only when the system status is not Running.

To define a calibrator

1 Select **Reagent > Cal Setup**.

2 Select **Define F1**.

Figure 4.1 Calibrator Definition window



3 Enter the calibrator name, lot number and expiration date.

4 Assign positions for the calibrator.

You are allowed to assign one position of each sample carousel for the calibrator.

NOTE

Calibrators of a chemistry must be placed and analyzed on the same sample carousel.

5 Select **Save** to save your input information.

6 To define more calibrators, click **New** and then repeat step 3 to 5.

7 Select **Close** to exit the window.

8 To edit a calibrator, select it, click **Edit F2**, and then change the settings as the steps above.

Importing a calibrator

Calibrator parameters such as calibrator name, lot number, expiration date, concentration of each chemistry and dilution parameter can be imported.

To import a calibrator

1 Select **Reagent** > **Cal Setup**.

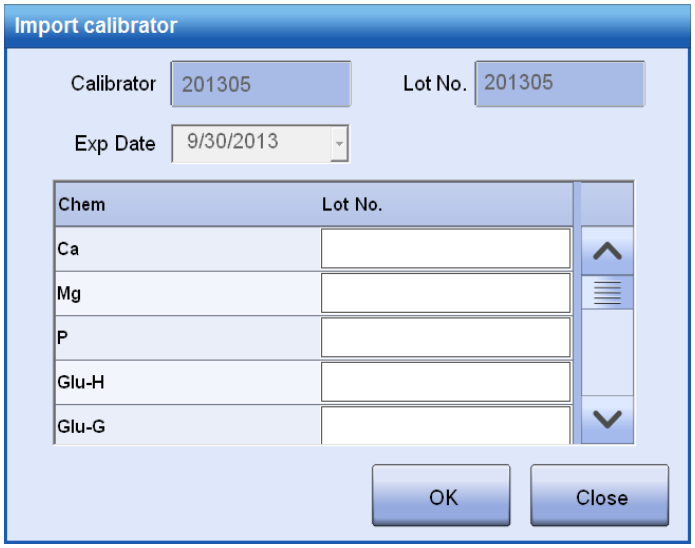
2 Select **Define F1**.

3 Select **Import** and insert USB drive.

4 Select the path of .cif file.

Only .cif file can be imported; each .cif file stores information for one calibrator and each time only one calibrator can be imported. When the system reads the calibrator information, the following window is displayed:

Figure 4.2 Calibrator Definition window



5 Enter the lot number, select **OK**, and then select **Close**.

6 Assign position for the calibrator.

7 Select **Save** and then **Close**.

Setting up calibrator concentrations

You are required to set up calibrator concentrations for each chemistry after defining the calibrator. Only the calibrator with positions assigned and concentrations determined can be used for programming. The default calibrator WATER has concentration of 0 for all chemistries. It has no lot number and expiration date and must not be edited or removed.

You are allowed to change the calibrator concentrations when the system is not running any tests.

To set up calibrator concentrations

1 Select **Reagent > Cal Setup**.

2 Choose a calibrator in the left list.

The chemistries configured for the calibrator are displayed in the right list.

3 Click **Chems F3** to choose chemistries to which the calibrator is applicable.

4 Select the corresponding **Conc** column and type in the calibrator concentration for it.

The concentration must be above 0.

5 Select the **Unit** from the drop-down list.

6 Select **Save F8** to save your input information.

A message box pops up indicating that parameters are changed and calibration is required.

Setting up calibrator dilution factors

The system supports calibrator dilution and allows one calibrator to have 9 concentrations for the same chemistry.

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 chemistry, 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.

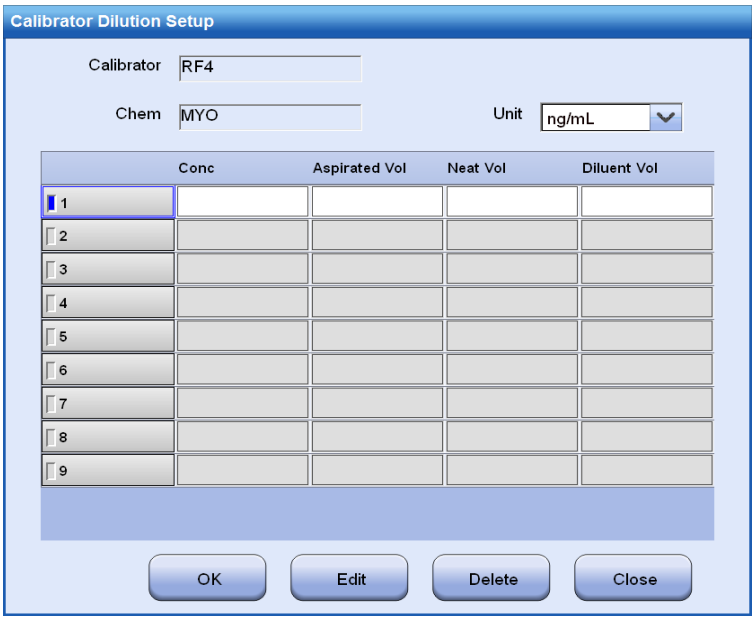
To set up calibrator dilution factors

1 Select **Reagent > Cal Setup**.

2 Choose the desired calibrator and chemistry.

3 Select **Dilute F5**.

Figure 4.3 Calibrator Dilution Setup window



4 Set up the unit, concentration, aspirated volume, neat sample volume, and diluent volume.

5 Select **Save**.

6 To edit the dilution factors, select the number button on the left, click **Edit,** and change the settings.

7 To delete the dilution factors, select the number button on the left and click **Delete**.

8 Select **Close** to exit the window.

Setting up calibration rules

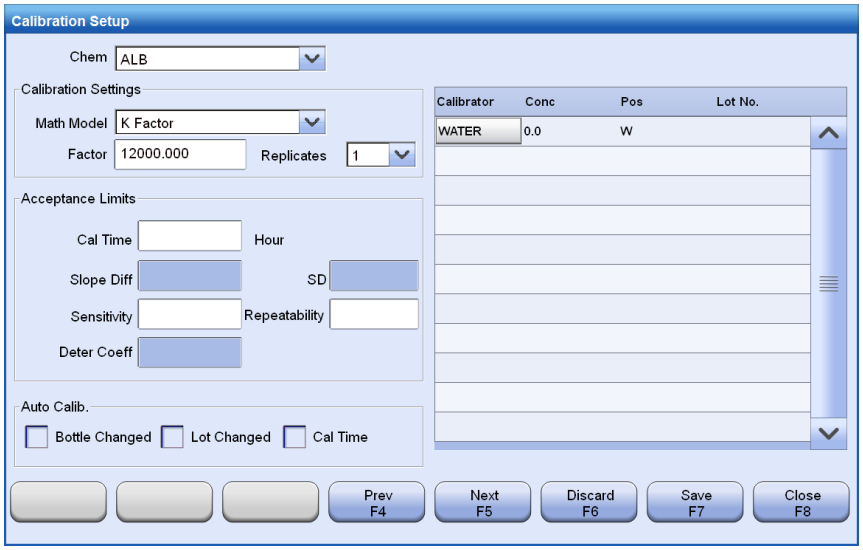
You should set up the calibration rules after defining a calibrator and determining concentrations for it. You are allowed to set up or edit the calibration rules, replicates, K factor and auto calibration only when the system is not running any tests.

To set up calibration rules

1 Select **Reagent > Cal Setup**.

2 Select **Rules F4**.

Figure 4.4 Calibration Setup window



3 Choose a chemistry from the **Chem** drop-down list.

4 Set the calibration method, K factor and number of replicates.

5 Choose calibrators in the right list for the chemistry.

The correspondence between the number of calibrators and calibration math model is shown in the table below.

Table 4.1 Correspondence between number of calibrators and calibration math model

Calibration Math Model	Number of Calibrators
K Factor	N=0 or 1
Two-point linear	N=2
Multi-point linear	2< N≤10
Logit-Log 4P	4≤N≤10
Logit-Log 5P	5≤N≤10
Exponential 5P	5≤N≤10
Polynomial 5P	5≤N≤10
Parabola	3≤N≤10
Spline	3≤N≤10

Calibration Math Model	Number of Calibrators
LOG3P	3≤N≤10
Line	2≤N≤10

6 Select **Save F7** to save your input information.

7 Select **Close F8** to close the window.

Setting up calibrator acceptance limits

The calibration results are compared with the determined acceptance limits. If the calibration results exceed the acceptance limits, the system will give an alarm and flag the results on calibration reports.

To set up calibrator acceptance limits

1 Select **Reagent > Cal Setup**.

2 Select **Rules F4**.

3 Enter the following acceptance limits in the **Acceptance Limits** area.

- Calibration time
- Slope difference
- Standard deviation (SD)
- Sensitivity
- Repeatability
- Determination coefficient

4 Select **Save F7** to save your input information.

5 Select **Close F8** to close the window.

Auto calibration

Based on the auto calibration conditions, the system can determine chemistries that need to be calibrated and remind you through calibration status and color indication.

Setting up auto calibration

1 Select **Reagent > Cal Setup**.

2 Select **Rules F4**.

3 Choose a chemistry from the **Chem** drop-down list.

4 Choose auto calibration conditions:

- Bottle changed
- Lot changed

Unavailable for closed chemistries, of which calibration will be run automatically when reagent lot number is changed.

- Calibration time

NOTE

If the **Manage Reagents by Lot** option on the **System Setup** screen is enabled, **Bottle Changed** and **Lot Changed** will not appear. When a different reagent lot is used, the system will request and run calibration automatically.

5 Select **Save F7**.

Auto calibration reminding

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 chemistry name and calibration status with yellow.

Removing auto calibration

1. Select **Reagent > Cal Setup**.
2. Select **Rules F4**.
3. Choose a chemistry from the **Chem** drop-down list.
4. Deselect all auto calibration conditions.
5. Select **Save F7**.
6. Select **Close F8** to close the window.

Deleting a calibrator

You are allowed to remove the calibrators other than WATER. When a calibrator is deleted, all calibration settings and its position are cleared, and it cannot be used for programming. The stored test results of the calibrator can be recalled according to the chemistry name. only calibrators that are not requested or run can be deleted.

To delete a calibrator

1. Select **Reagent > Cal Setup**.
2. Choose a calibrator you want to remove.
3. Select **Delete F6**.
4. Select **OK**. The selected calibrator is deleted.

4.1.2 Calibration status and alarm

On the **Reagent/Calibration** screen, the chemistries are indicated with various texts and colors for different calibration status. Chemistries in Cal Required, Cal Failed or Cal Time Out status can be requested but will not be run.

Check the chemistries' calibration status frequently and take relevant actions according to the following table.

Table 4.2 Calibration status

Calibration Status	Description	Severity	Color
Cal Required	Indicates that the chemistry needs to be calibrated. This status appears when the chemistry is not calibrated and auto calibration conditions are satisfied; or calibration information or chemistry parameters are modified.	Serious	Red

Calibration Status	Description	Severity	Color
Requested	Indicates that the chemistry has been requested for calibration but the test has not begun.	Normal	No color indication
Calibrated	Indicates that the chemistry 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 without results due to test error.	Serious	Red
Cal Time Out	Appears when the chemistry 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
Calculated	Indicates that the calibration factors of the chemistry have been recalculated.	Warning	Yellow
Edited	Indicates that the calibration factors of the chemistry have been edited.	Warning	Yellow
Cal Overridden	Indicates that the test results of the chemistry are based on a failed calibration, and flagged accordingly.	Warning	Yellow
N/A	Indicates the reagent has no calibration status.	Normal	No color indication

4.1.3 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 Calibrated status, which means the calibration is successfully performed.

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.

Setting up mixed blank absorbance and blank response

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.

To set up mixed blank absorbance and blank response

1. Select **Utility > Chemistries**.
2. Choose a biochemical chemistry, or enter the chemistry name in the **Chemistry Name** field.
3. Select **Define F1**.

4 Enter the mixed blank absorbance range in the **Mixed Blank Abs** field.

5 Enter the blank response range in the **Blank Response** field.

6 Select **Save F7**.

Running reagent blank test

Please note that reagent blank can only be run in following conditions:

- Chemistries with all calibration math models rather than two-point linear and K factor must have the 0-concentration calibrator set up.
- K factor chemistries must have calibrators set up.

The reagent blank is allowed only in Calibrated calibration status.

Running reagent blank test

1 Select **Reagent > Reagent/Calibration**,

2 Select a reagent carousel from the drop-down list of **Reagent Carousel**.

3 Select the up and down arrow buttons to display the biochemical reagent/calibration screen.

4 Check if the desired chemistries' calibration status is Calibrated.

5 Choose the chemistries.

6 Select **Cal F5**.

7 Choose **Rgt Blk**, and select **OK**.

8 Select the  icon to start the analysis.

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.

To recall reagent blank response

1 Select **Reagent > Biochemistry Calibration**.

2 Choose the desired calibration result.

3 Select **Reac Curve F3**.

Figure 4.5 Reagent blank reaction curve

The response value current displayed is the updated reagent blank response.

4 Select the reaction data table to view the reagent blank reaction data.

5 Choose the following buttons as needed:

- **Prev F4**: to view reaction curve and data of the previous calibration test.
- **Next F5**: to view reaction curve and data of the next calibration test.
- **Print F7**: to print the current reaction curve or data.

6 Select **Close F8**.

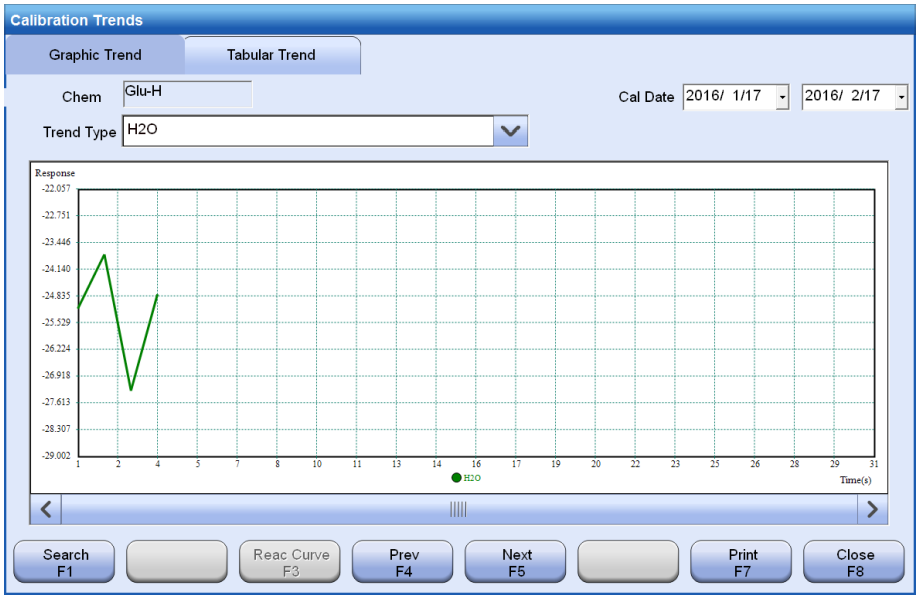
To recall reagent blank trends

1 Select **Reagent > Biochemistry Calibration**.

2 Choose the desired calibration result.

3 Select **Trend F6**.

Figure 4.6 Graphic Trend tab page



4 Choose a trend type you want to recall.

The options include:

- R1 blank absorbance
- Mixed blank absorbance
- Calibrator response
- K factor (for linear calibrations only)

5 Select the calibration time range.

6 Select **Search F1**.

The graphical trend of the selected chemistry within the specific period is displayed.

7 Select the **Tabular Trend** tab to view the trend data.

8 Choose the following buttons as needed:

- **Prev F4**: to view the calibration trends and data of the previous chemistry.
- **Next F5**: to view the calibration trends and data of the next chemistry.
- **Print F7**: to print the current graphic trend or data.

9 Select **Close F8** to close the window.

4.1.4 Recalling calibration results

This chapter describes the following operations related to calibration result of biochemistry.

- Recalling history calibration results
- Observing calibration curve
- Recalculating calibration factors
- Observing calibration reaction curve
- Editing calibration factors
- Archiving calibration results
- Observing calibration trends
- Extending calibration time
- Overriding calibration
- Rejecting calibration

Recalling history calibration results

1 Select **Reagent > Biochemistry Calibration**.

2 Choose the **History** option button.

3 Choose a chemistry from the **Chem** drop-down list.

4 Select the date range in the **Cal Date** field.

5 Select **Search F1**.

The calibration factors used within the specified period are displayed on the screen.

6 Choose the following buttons as needed:

- **Cal Curve F2**
- **Reac Curve F3**
- **Edit F4**
- **Archive F5**
- **Trend F6**
- **Print F7**

Observing calibration curve

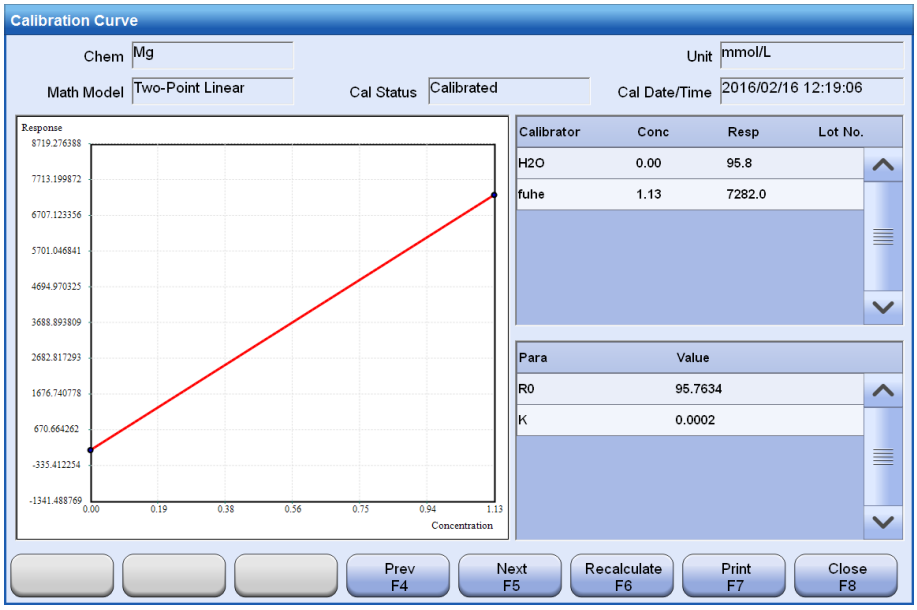
A calibration curve reflects the mathematical relation between calibrator concentration and response. It is drawn based on the obtained response and the multiple values between the minimum and maximum concentrations of the calibrator. The calibration curve is a straight line in linear calibrations and a curve in nonlinear calibrations.

K-factor, edited or reagent-blanked calibration factors have no calibration curve to recall.

To observe calibration curve

1. Search for desired calibration results on the **Biochemistry Calibration** screen.
2. Choose a chemistry in the result list.
3. Select **Cal Curve F2**. The **Calibration Curve** window is displayed.

Figure 4.7 Calibration Curve window



4. Choose the following buttons as needed:
   - **Prev F4**: to view the calibration curve of the previous chemistry.
   - **Next F5**: to view the calibration curve of the next chemistry.
   - **Recalculate F6**: to recalculate the calibration factors based on the specified math model.
   - **Print F7**: to print the current calibration curve.
5. Select **Close F8** to close the window.

Recalculating calibration factors

Calibration results in Calibrated, Cal Failed, Cal Time Out, Extended, or Overridden status can be recalculated based on the existing factors, a new math model and calibrators. The flag "CALR" indicating that the calibration result is recalculated will appear on the **Biochemistry Calibration** screen.

Recalculating calibration factors is not applicable to K factor calibrations. Calibration factors that have been recalculated cannot be calculated again.

Recalculation can be performed only when the parameter type of the chemistry to be recalculated is the same as the currently used one.

To recalculate calibration factors

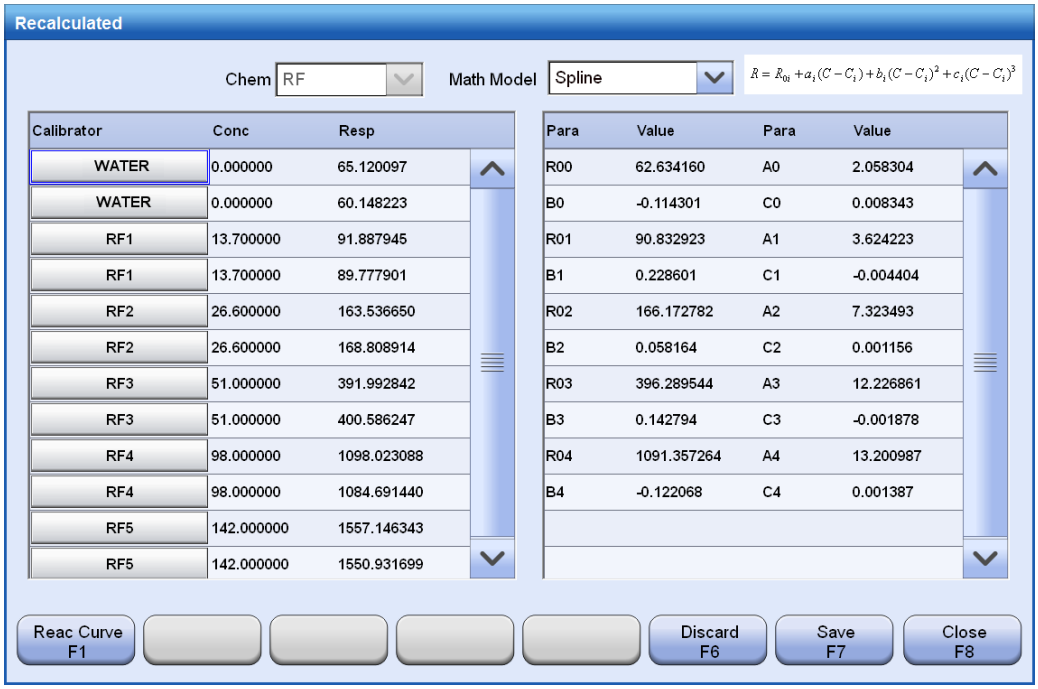
1. Select **Reagent > Biochemistry Calibration**.
2. Search for desired calibration results to recalculate.

3 Choose a chemistry in the result list.

4 Select **Cal Curve F2**.

5 Select **Recalculate F6**. The **Recalculate** window shows.

Figure 4.8 Recalculate window



6 Choose a math model from the **Math Model** drop-down list.

The corresponding calculation formula is displayed in the text box to the right of the **Math Model** field.

7 Choose calibrators to recalculate in the left list. Move the scroll bar to view more calibrators.

Choose the correct number of calibrators corresponding to the math model.

8 Select **Save F7**.

The system will recalculate the calibration factors with the selected math model and calibrators.

- If the recalculation is succeeded, the new calibration factors will be displayed on the **Biochemistry Calibration** screen with the calibration status shown as Recalculated, and "CALR" will appear in the corresponding **Flag** column.
- If the recalculation fails, the system will show a message box indicating the old calibration factors will remain to be used.

9 Select **Close F8** to close the window.

Observing calibration reaction curve

A calibration reaction curve reflects the relationship of the absorbance measured at the primary wavelength, secondary wavelength and primary-secondary wavelength. It is drawn based on the absorbance of the calibrator-reagent mixture measured within the reaction period.

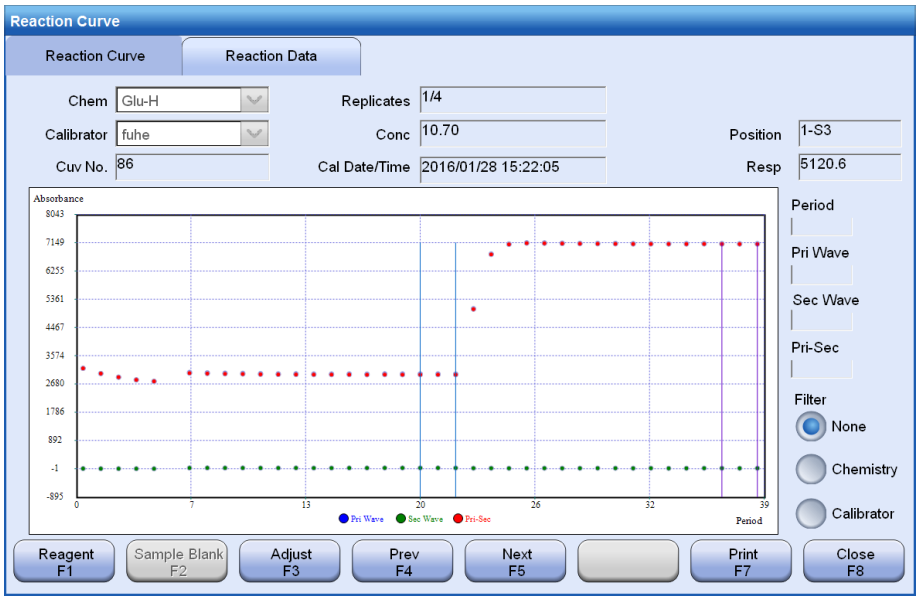
To observe calibration reaction curve

1 Search for desired calibration results on the **Biochemistry Calibration** screen.

2 Choose a chemistry in the result list.

3 Select **Reac Curve F3**. The **Reaction Curve** window is displayed.

Figure 4.9 Reaction Curve window



4 Select a point on the curve. Relevant measuring period and absorbance are displayed on the right of the window.

5 Select a filter condition from the following options:

- None: observe reaction curve and data in the default mode.
- Chemistry: observe reaction curve of the results for the selected test.
- Calibrator: observe reaction curve of the results for the selected calibrator.

6 Choose the **Reaction Data** tab to view the reaction data.

7 Choose the following buttons as needed:

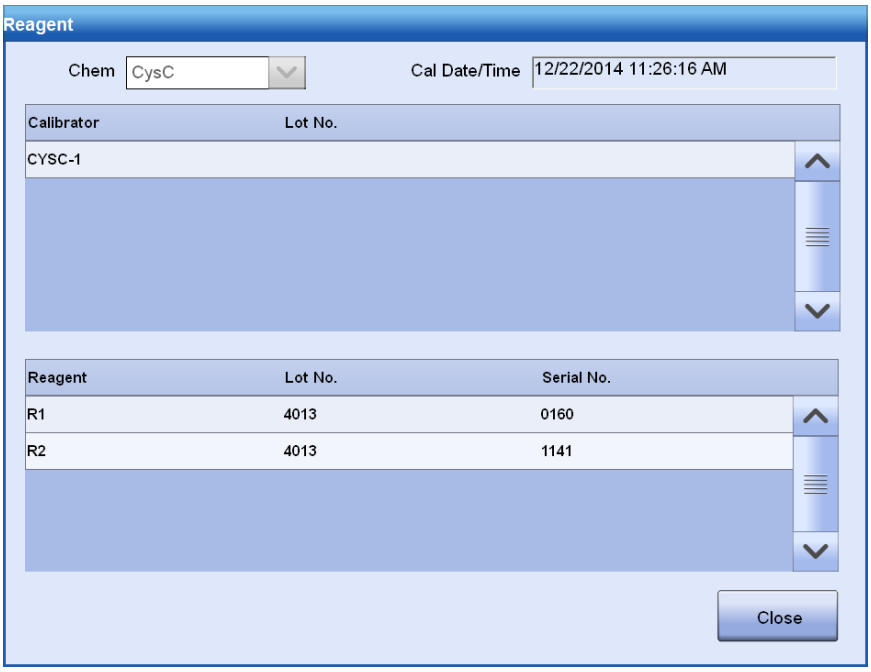
- **Reagent F1:** to view the calibrators and reagents used in calibration, and reagents for reagent blank test.
- **Sample Blank F2**: to view the sample blank reaction curve and reaction data of the calibrator.
- **Adjust F3**: to adjust the absorbance display range of current reaction curve.
- **Prev F4**: to view reaction curve and data of the previous calibration test.
- **Next F5**: to view reaction curve and data of the next calibration test.
- **Print F7**: to print the current reaction curve or data.

8 Select **Close F8** to close the window.

To view reagent information

1 Select **Reagent F1** on the **Reaction Curve** window.

Figure 4.10 Reagent window



The window shows the calibrators and reagents used in calibration, and reagents for reagent blank test.

2 Select **Close** to exit the window.

Editing calibration factors

If the calibration factors of linear calibration are higher or lower than the expected values or than those obtained on other instruments, you are allowed to edit them to keep them consistent with the expected ones or those on other instruments. The flag "CALE" will appear for results calculated based on edited calibration factors, and the calibration curve and reaction curve of edited calibration factors cannot be recalled.

Prior to editing calibration factors, ensure that you have sufficient permissions and the system status is not Running.

Editing can be performed only when the parameter type of the chemistry to be edited is the same as the currently used one.

To edit calibration factors

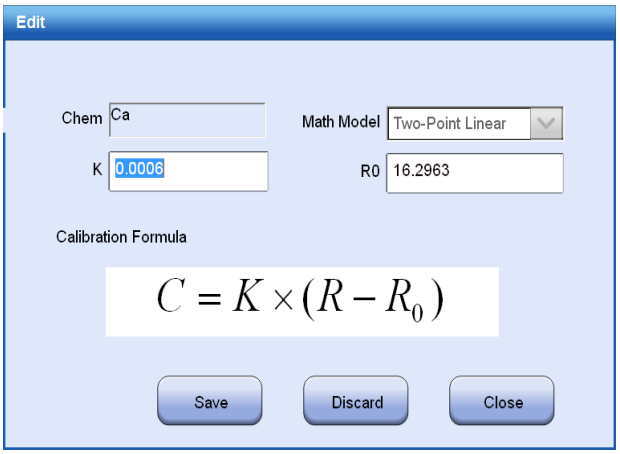
1 Select **Reagent > Biochemistry Calibration**.

2 Search for desired calibration results to edit.

3 Choose a desired chemistry.

4 Select **Edit F4**. The **Edit** window shows.

Figure 4.11 Edit window



5 Type in slope K and offset R_0.

6 Select **Save**.

The system will refresh the calibration results and curves with the input slope and offset, and take the edited calibration factors as the defaults.

7 Select **Close** to exit the window.

Archiving calibration results

The system allows you to archive all searched calibration results to a storage device, such as U disk. Archived calibration results are displayed in the same format as on the software screen. The archived content includes: chemistry name, flag, calibration status, R0, K factor, calibration coefficients A/B/C/D, and calibration time. The archiving file is of .csv format and named by date and time.

To archive calibration results

1 Select **Reagent > Biochemistry Calibration**.

2 Search for desired calibration results.

3 Select **Archive F5**.

4 Confirm the archiving path and file name.

5 Select **OK**.

Observing calibration trends

Calibration graphical trends summarize a chemistry's calibrations during a period of time and reflect the trends of the calibrations. The calibration graphical trends show the chemistry's R1 blank absorbance, mixed blank absorbance and calibrator response.

R1 blank absorbance and mixed blank absorbance are available only for chemistries with 0-concentration calibrators. The K factor trends can be recalled for linear chemistries.

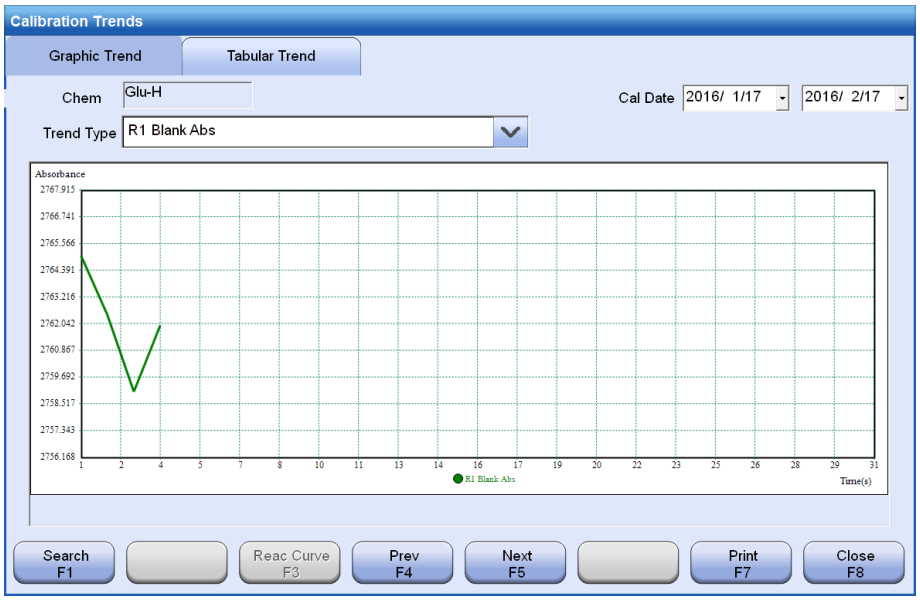
To observe calibration trends

1 Search for desired calibration results on the **Biochemistry Calibration** screen.

2 Choose a chemistry in the result list.

3 Select **Trend F6**. The **Calibration Trends** window is displayed.

Figure 4.12 Calibration Trends window



4 Choose a trend type you want to recall.

The options include:

- R1 blank absorbance
- Mixed blank absorbance
- Calibrator response
- K factor (for linear calibrations only)

5 Select the date range in the **Cal Date** field.

6 Select **Search F1**.

The trend within the specified period is displayed on the screen.

7 Choose the **Tabular Trend** tab to view the trend data.

Figure 4.13 Tabular Trend window

8 Choose the following buttons as needed:

- **Reac Curve F3**: to view the reaction curve and data of the selected calibrator.
- **Prev F4**: to view the calibration trends and data of the previous chemistry among the selected results.

- **Next F5**: to view the calibration trends and data of the next chemistry among the selected results.
- **Print F7**: to print the current graphic trend or data.

9 Select **Close F8** to close the window.

Extending calibration time

Calibration factors that exceed the calibration period cannot be used for result calculation. The calibration status becomes Cal Time Out and the chemistry 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 chemistry 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 chemistry is timed out or succeeded. The results calculated based on extended calibration factors will be flagged with "EXT".

To extend calibration time

1 Select **Reagent > Reagent/Calibration**.

2 Select a reagent carousel from the drop-down list of **Reagent Carousel**;

3 Select the up and down arrow buttons to display the biochemical reagent/calibration screen.

4 Choose a chemistry you want to extend.

5 Select **Cal Options F8**.

6 Select **Extend Calibration Time** from the **Calibration Options** window.

7 Select **OK**. The calibration factors of the selected chemistry can be used without time limit.

To remove an extended status

Calibration extension is not absolutely definite. Recalibrate the chemistry to remove the extended status.

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".

CAUTION

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 doctor's diagnosis. Think twice before overriding a failed calibration.

To override a calibration

1 Select **Reagent > Reagent/Calibration**.

2 Choose a chemistry you want to override.

3 Select **Cal Options F8**.

4 Select **Calibration Override** from the **Calibration Options** window.

5 Select **OK**. The failed calibration factors of the selected chemistry can be used for result calculation.

Removing Cal Overridden status

Recalibrate the chemistry to remove its Cal Overridden status.

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.

Rejecting a calibration

1. Select **Reagent > Reagent/Calibration**.
2. Choose a chemistry you want to reject.
3. Select **Cal Options F8**.
4. Select **Reject** from the **Calibration Options** window.
5. Select **OK**. Calibration factors of the selected chemistry are rejected.

Removing Reject status

Recalibrate the chemistry to remove its Reject status.

4.2 ISE calibration

This section describes the calibration setup, calibration status, and calibration result recall of ISE test.

4.2.1 Calibration setup

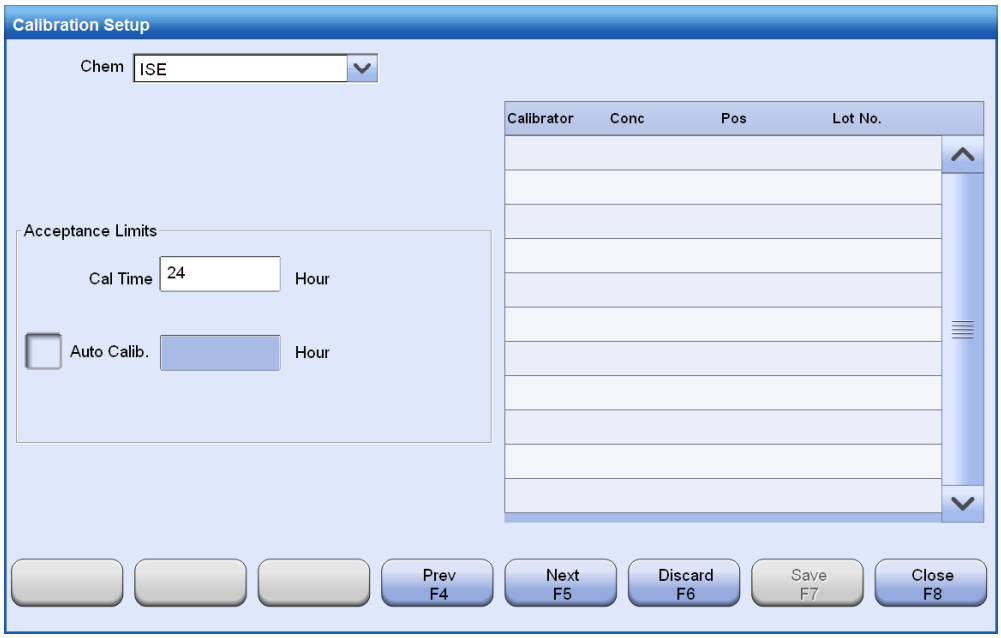
You are allowed to set up the calibration time and auto calibration of ISE test.

When a calibrator is expired, it will be indicated in yellow and cannot be used for calibration. When the auto calibration interval is reached, the system reminds you to perform ISE calibration.

To set up ISE calibration options

1. Select **Reagent > Setup**, and then select **Rules F4**.
2. Select **ISE** from the **Chemistry** pull-down list.

Figure 4.14 ISE calibration setup window



3 Enter the calibration time in the **Cal Time** field.

The input range is 1-8, and the default is 8 hours.

4 Select the **Auto Calibration** check box and enter the auto calibration time.

The range is 1-24 hour; the default is blank.

5 Select **Save F7** to save the settings.

6 Select **Close F8** to close the window.

4.2.2 Calibration status and alarm

On the **Reagent/Calibration** screen, the chemistries are indicated with various texts and colors for different calibration status. Chemistries in Cal Required, Cal Failed or Cal Time Out status can be requested but will not be run.

Check the chemistries' calibration status frequently and take relevant actions according to the following table.

Table 4.3 ISE calibration status

Calibration Status	Description	Severity	Color
Cal Required	Indicates that the chemistry needs to be calibrated. This status appears when the chemistry is not calibrated or the ISE reagent/electrode is replaced.	Serious	Red
Requested	Indicates that the chemistry has been requested for calibration but not finished yet.	Normal	No color indication
Calibrated	Indicates that the chemistry has been calibrated successfully and has not exceeded the calibration time.	Normal	No color indication

Calibration Status	Description	Severity	Color
Cal Failed	Indicates that the chemistry has calibration factors calculated but they exceed the acceptance limits, or has no calibration factors calculated.	Serious	Red
Cal Time Out	Appears when the chemistry exceeds the calibration period or the reagent of different serial number and lot number is used. Appears when the chemistry exceeds the calibration time.	Serious	Red
N/A	Indicates that the reagent is not loaded.	Normal	No color indication

4.2.3 Results recall

You can recall history calibration result and calibration trend, archive calibration result, and extend the calibration time.

Recalling history calibration results

To recall history calibration results

1. Select **Reagent > ISE Calibration**.
2. Select the **History** option button, and then select date range that the ISE test is calibrated.
3. Select **Search F1**.

   The ISE calibration results are displayed in the result list.
4. To print the calibration report, select **Print F7**.

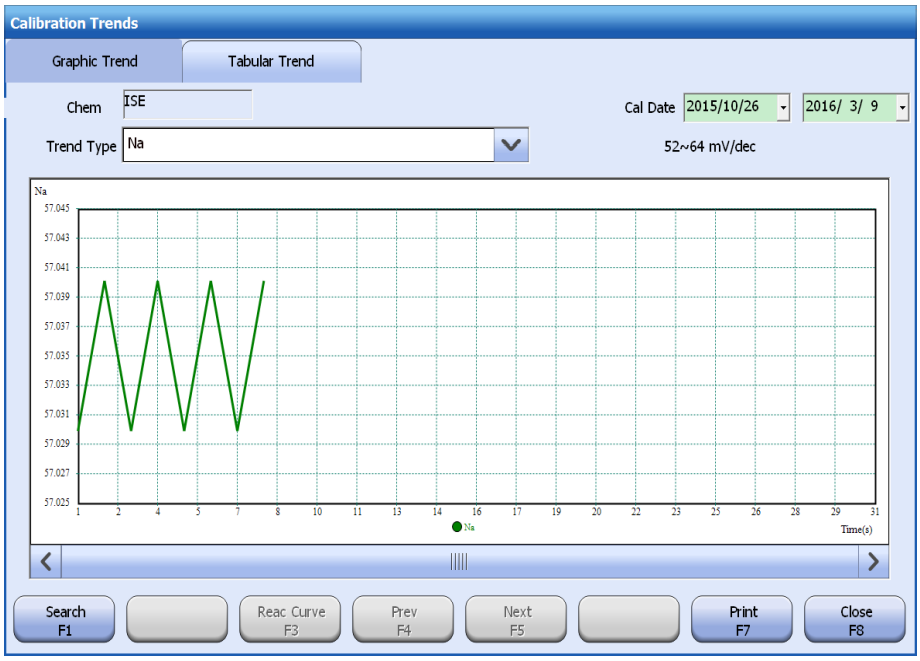
Recalling calibration trends

To recall calibration trends

1. Select **Reagent > ISE Calibration**.
2. Search for desired calibration results.
3. Select **Trend F6**. The **Calibration Trends** window is displayed.
4. Choose desired trend type and calibration date range, and then select **Search F1**.

   The ISE trend within the specified time period is displayed on the screen. The trend type options will not include Reference Electrode when trends of ISE Urine are being recalled.

Figure 4.15 Calibration Trends window



5 Choose the **Tabular Trend** tab to view the trend data.

6 To print the current graphic trend or data, select **Print F7**.

7 Select **Close F8** to close the window.

Archiving ISE calibration results

Both the current and early calibration factors of ISE chemistries can be archived. The archiving file is of .csv format and named by the date and time the results are archived.

To archive ISE calibration results

1 Select **Reagent > ISE Calibration**.

2 Search for desired calibration results.

3 Select **Archive F5**.

4 Confirm the archiving path and file name.

5 Select **OK**.

5 Quality Control

This chapter describes QC setup and QC result processing.

5.1 Overview

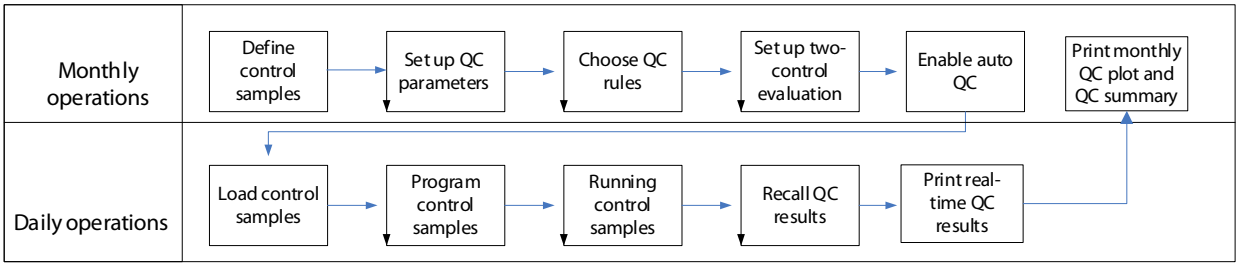
QC test is performed on samples provided with known concentration range of various analytes by authority divisions or reagent suppliers. By comparing with the given range, the test results obtained on this instrument can be used to judge if the instrument is in normal status and the sample results are reliable.

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.

5.1.1 QC procedure

After you define a chemistry, control, 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 5.1 QC procedure



5.1.2 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
- 2-2s
- 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, see 12.4Data alarms on page 12-8.

5.1.3 Control status

When you choose a control on the **Program > Quality Control** screen, the current status of the control is displayed in the **Sample Status** field. It is necessary to understand the control statuses. The table below shows the various statuses of control samples.

Table 5.1 Descriptions of control status

Control Status	Description
N/A	Indicates that the control is not programmed for analysis.
Requested	Indicates that the control sample has been programmed but not analyzed yet.
In Progress	Indicates that the control sample is being analyzed.

Control Status	Description
Incomplete	Indicates that all chemistries of the control sample have been finished but one or more of them have no results.
Complete	Indicates that all chemistries of the control sample have been finished with results.

5.2 QC setup

Perform QC settings in the following order:

- Define a control
- Set up control concentrations
- Set up QC rules
- Auto QC

You can delete controls while the system is in non-test status.

5.2.1 Defining/Editing a control

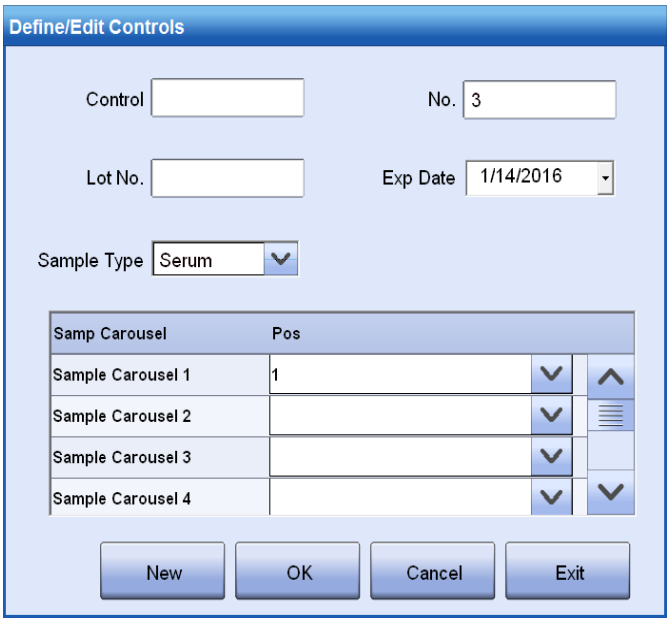
The system allows the definition of up to 99 controls. You are required to enter the control name and sample type. The combination of control name and lot number must not be duplicate and should be unique. If a control has no lot number, you are not allowed to define another control with the same name.

To define/edit a control

1 Select **QC > QC Setup**.

2 Select **Define F1**.

Figure 5.2 Define/Edit Controls window



3 Set up the control name, No., lot number, expiration date, and sample type.

4 Assign positions for the control.

You are allowed to assign one position of each sample carousel for the control.

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

6 To define more controls, select **New** and repeat step 3 to 5.

7 Select **Exit** to exit the window.

5.2.2 Setting up control concentrations

After defining a control, you must set the applicable chemistries and concentration parameters. Only when both control position and concentration are specified can QC test be requested and run.

To set up control concentrations

1 Select **QC > QC Setup**.

2 Choose a control in the left list.

3 Select **Chems F2** and choose chemistries for the control.

4 Select the **Mean** column of a chemistry and type in the average concentration for it.

5 Select the **SD** column of a chemistry and type in the standard deviation for it.

6 Select a unit from the drop-down list.

The options include all units set for the chemistry. This field is uneditable for open-reagent chemistry.

7 Select **Save F8** to save your input information.

5.2.3 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 programmed and analyzed but will not be monitored for error detection.

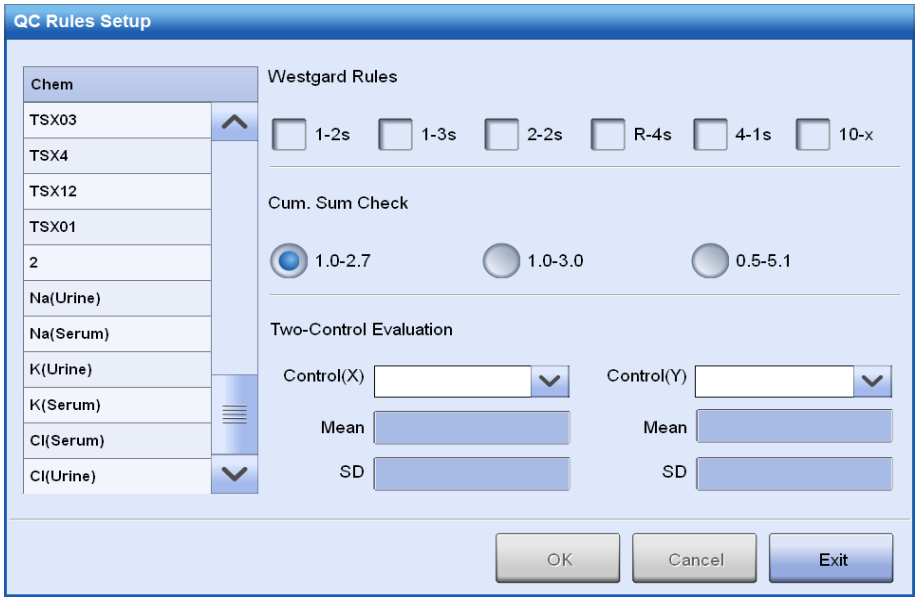
You are allowed to change the QC rules when the system is not running any tests.

To set up QC rules

1 Select **QC > QC Setup**.

2 Select **Rules F3**. The **QC Rules Setup** window is displayed.

Figure 5.3 QC Rules Setup window



3 Choose a chemistry from the **Chem** list.

4 Choose QC rules in the **Westgard Rules** area.

5 Select the control limit from cumulative sum.

6 If you assign a couple of controls for the chemistry, you are allowed to enable the Two-Control Evaluation option.

Those controls not contained in the two-control evaluation will be monitored according the Westgard rules.

7 Select the first control in the **Control (X)** field.

8 Select the second control in the **Control (Y)** field.

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

10 Select **Exit** to exit the window.

5.2.4 Auto QC

The system provides the auto quality control function. The conditions for auto quality control include:

- Number of samples: indicates the number of patient samples. After the given number of samples is finished, the system will run the selected control(s) automatically.
- When calibrated: The system will automatically run the chemistry for the selected control(s) every time when the chemistry is calibrated. Auto QC is not applicable to non-measurement calibrations, such as recalculation and editing.

When the control samples automatically run are selected, all chemistries configured for the control samples will be run.

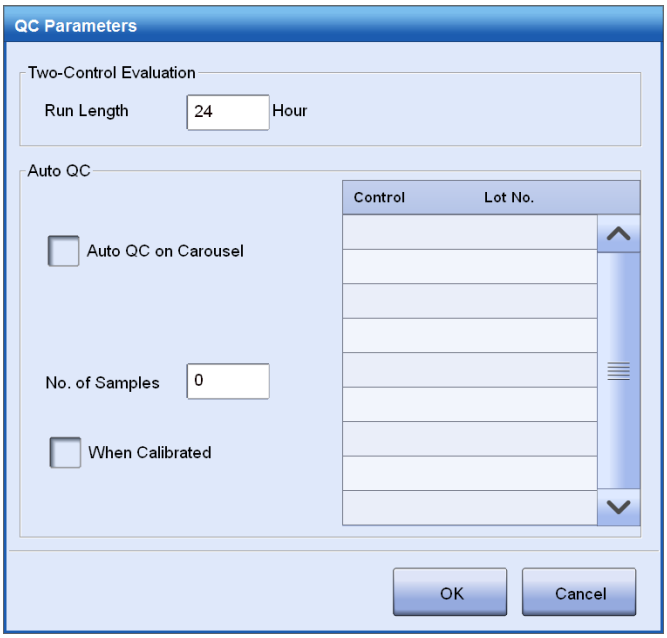
To set up and run auto QC

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Choose **QC Evaluation**.

Figure 5.4 QC Parameters window



4 Select **Auto QC on carousel**.

5 Set up the conditions for auto quality control:

- **Number of Samples**: enter the number of samples for auto QC run. The input range is 10-500, 0 means auto QC is disabled.
- **When Calibrated**: select the checkbox to allow the system to run controls when a chemistry is calibrated.

6 Choose controls to be run automatically.

One or more controls can be selected.

7 Select **OK**.

During test, the system will insert QC runs automatically once the conditions are met.

To remove auto QC status

To remove an auto QC status, clear the auto QC settings on the **QC Parameters** window.

5.2.5 Deleting a control

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 programmed for analysis cannot be deleted.

To delete a control

1 Select **QC > QC Setup**.

2 Choose a control in the left list.

3 Select **Delete F6**.

5.3 Recalling control results

The Recalling Control Results option allows you to view control sample results, L-J chart, cumulative sum, twin-plot chart, analysis data and data summary.

5.3.1 Result > History screen

The **History** screen is used to recall results of patient sample and control sample that are programmed and analyzed before the current day. You can observe QC reaction curve and print QC results.

To recall history QC results

1 Select **Result > History**.

2 Choose a result recall mode:

- By sample
- By chemistry

3 When recalling results by sample, choose a control in the left list. The right list displays all results of the control.

4 When recalling results by chemistry, choose a chemistry in the left list. The right list displays all results of the chemistry.

5 Choose the following buttons as needed:

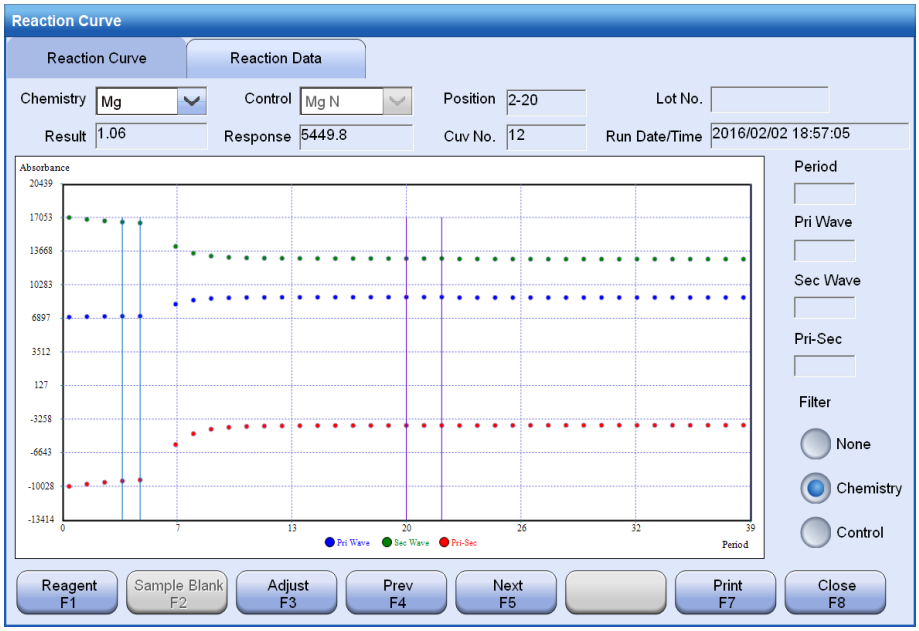
- **Search F1**: to recall control results.
- **Options F2**: to delete or archive control samples.
- **Reac Curve F4**: to view reaction curve of the selected QC test.
- **Print F7**: to print control results.
- **Host F8**: to transmit the selected control results to the LIS host.

To view control reaction curve

1 Choose the desired chemistry on the **History Results** screen..

2 Select **Reac Curve F4**. The **Reaction Curve** window is displayed.

Figure 5.5 Reaction Curve screen



3 Choose the **Reaction Data** tab to view the reaction data.

4 Choose the following buttons as needed:

- **Sample Blank F2**: to view the sample blank reaction curve and reaction data of the selected control.
- **Adjust F3**: to adjust the absorbance display range of current reaction curve.
- **Prev F4**: to view the reaction curve and data of the previous test.
- **Next F5**: to view the reaction curve and data of the next test.
- **Print F7**: to print the current reaction curve or data.

5 Select **Close F8** to close the window.

To print control results

1 Select the desired control result on the **History** screen.

2 Select **Print F7**.

3 Select **Print Sample Report**.

4 Choose the print range:

- Selected Sample(s)
- All Sample(s)

5 If you print all samples, you are allowed to skip those that are already printed out. Mark the **Bypass Printed Sample(s)** checkbox.

6 Select **OK**.

5.3.2 QC > Levey-Jennings screen

The **Levey-Jennings** (L-J) screen provides the functions of recalling L-J chart and filling comments.

A Levey-Jennings (L-J) chart, drawn based on the QC date (X) and test results (Y), shows the QC result trend of a chemistry 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. Each page can display 31 QC points. The query date must not be longer than 1 year.

To recall L-J chart

1 Select **QC** > **Levey-Jennings**.

2 Click **Chart F3** to set the drawing mode of the L-J chart.

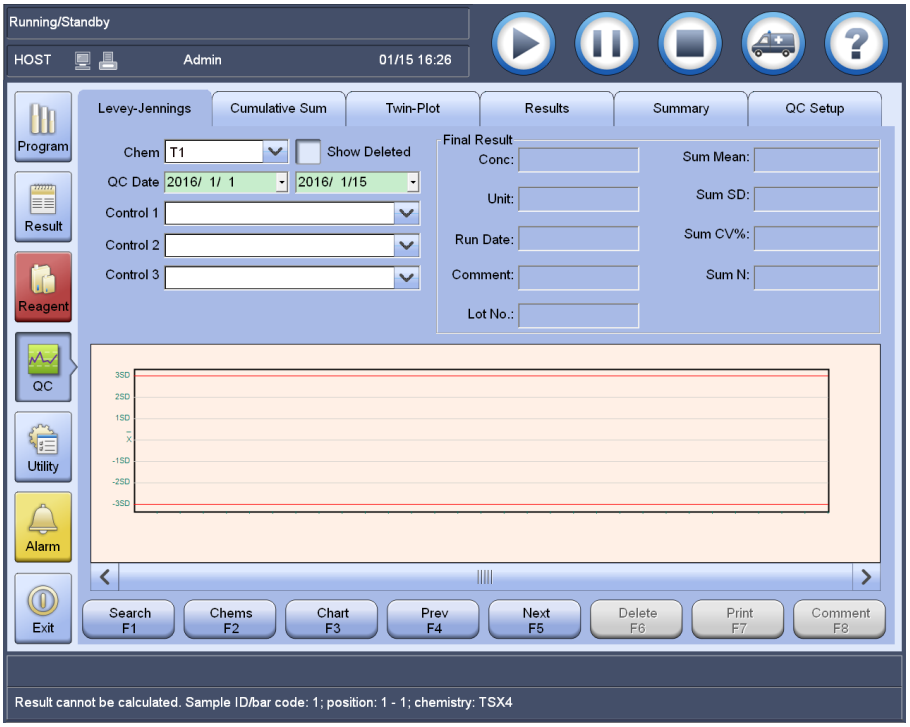
3 Choose a chemistry to recall in the **Chem** drop-down list, or select **Chems F2** and then choose a chemistry.

4 Select the date range in the **QC Date** field.

5 Choose controls you desire to view. Up to 3 controls can be selected.

6 Select **Search F1**. The L-J chart area shows the QC result trends of the selected chemistry during the specified period.

Figure 5.6 Levey-Jennings screen



7 Choose the following buttons as needed:

- **Prev F4**: to view the L-J chart of the previous chemistry.
- **Next F5**: to view the L-J chart of the next chemistry.
- **Delete F6**: 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 F7**: to print the current L-J chart.
- **Comment F8**: to add, modify and delete comments of a QC point.

To add/modify comments

1 Choose a QC point on the L-J chart.

2 Select **Comment F8**, and then input comments for the QC point.

3 Select **OK**.

4 To delete the comments of a QC point, perform the following steps:

a. Select the QC point on the chart.

b. Click Comment F8.

c. Clear the comments.

d. Click **OK**.

5.3.3 Recalling cumulative sum chart

1 Select **QC > Cumulative sum**.

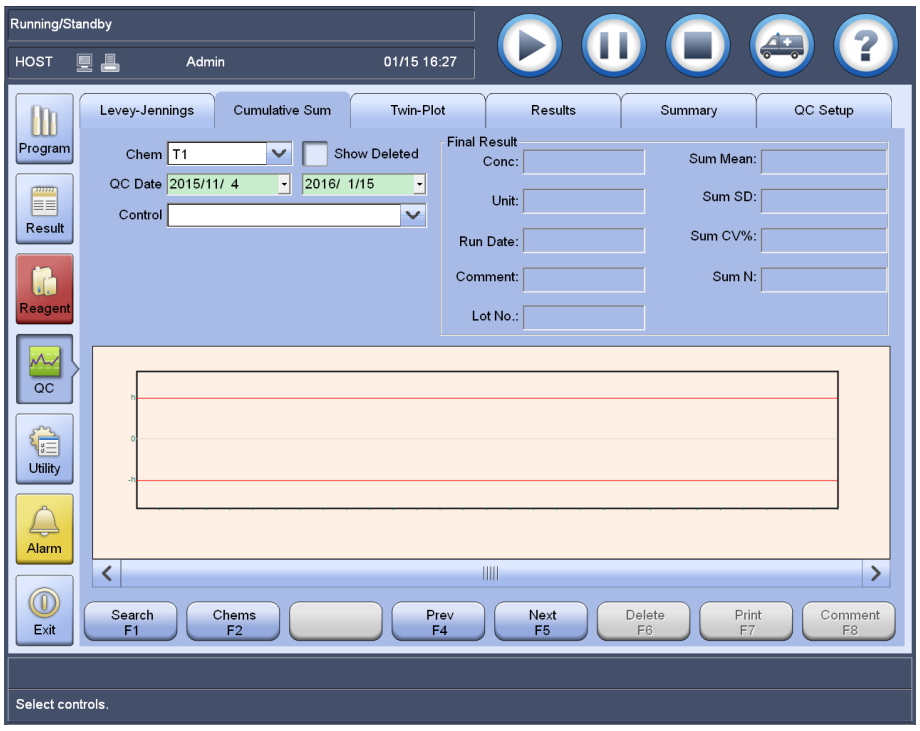
2 Choose a chemistry to recall in the **Chem** drop-down list, or select **Chems F2** and then choose a chemistry.

3 Select the date range in the **QC Date** field.

4 Choose controls you desire to view.

5 Select **Search F1**. The Cumulative sum chart area shows the QC result trends of the selected chemistry during the specified period.

Figure 5.7 Cumulative sum screen



6 Choose the following buttons as needed:

- **Prev F4**: to view the cumulative sum chart of the previous chemistry.
- **Next F5**: to view the cumulative sum chart of the next chemistry.
- **Delete F6**: to delete the selected point on the cumulative sum chart If you want to display the removed points on the cumulative sum chart, mark the **Show Deleted** checkbox.
- **Print F7**: to print the current cumulative sum chart.
- **Comment F8**: to add, modify and delete comments of a QC point.

To add/modify comments

1 Choose a QC point on the cumulative sum chart.

2 Select **Comment F8**, and then input comments for the QC point.

3 Select **OK**.

4 To delete the comments of a QC point, perform the following steps:

- Select the QC point on the chart.
- Click **Comment F8**.
- Clear the comments.
- Click **OK**.

5.3.4 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 chemistry and excludes those that have been deleted.

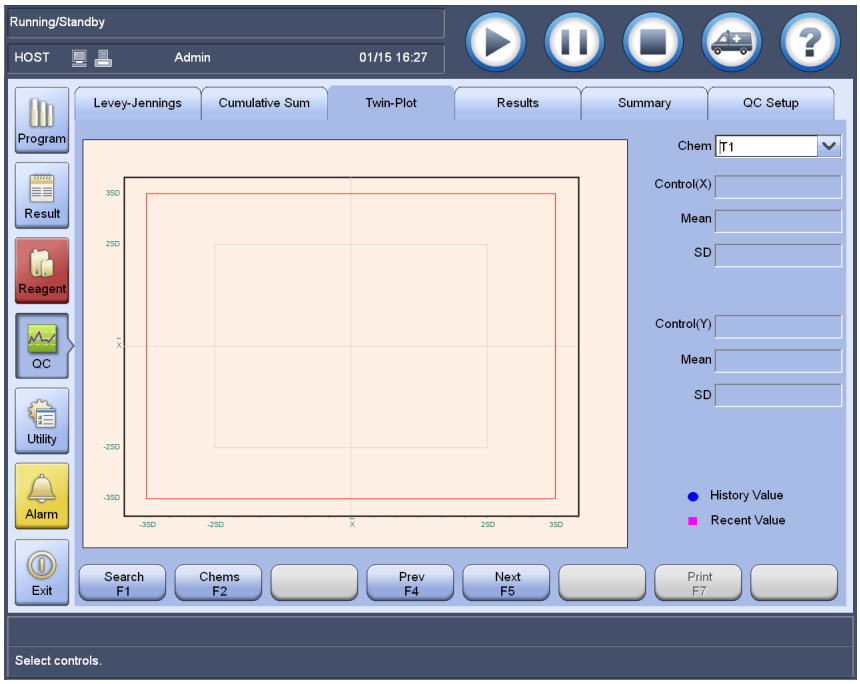
To recall Twin-Plot chart

1 Select **QC > Twin-Plot**.

2 Choose a chemistry to recall in the **Chem** drop-down list, or select **Chems F2** and then choose a chemistry.

3 Select **Search F1**. The twin-plot chart area displays the recent 10 results of control X and control Y for the chemistry.

Figure 5.8 Twin-Plot screen



4 Choose the following buttons as needed:

- **Prev F4**: to view the twin-plot chart of the previous chemistry.
- **Next F5**: to view the twin-plot chart of the next chemistry.
- **Print F7**: to print the current twin-plot chart.

5.3.5 QC Results screen

The **QC > Results** screen provides the functions of recalling QC data, viewing reaction curve and archiving QC data.

QC data includes QC results, and the set mean and standard deviation, and can be recalled based on control name, chemistry name and run date.

To recall QC data

1 Select **QC** > **Results**.

2 Select **Chems F2**.

3 Choose a chemistry to recall, and then select **OK**.

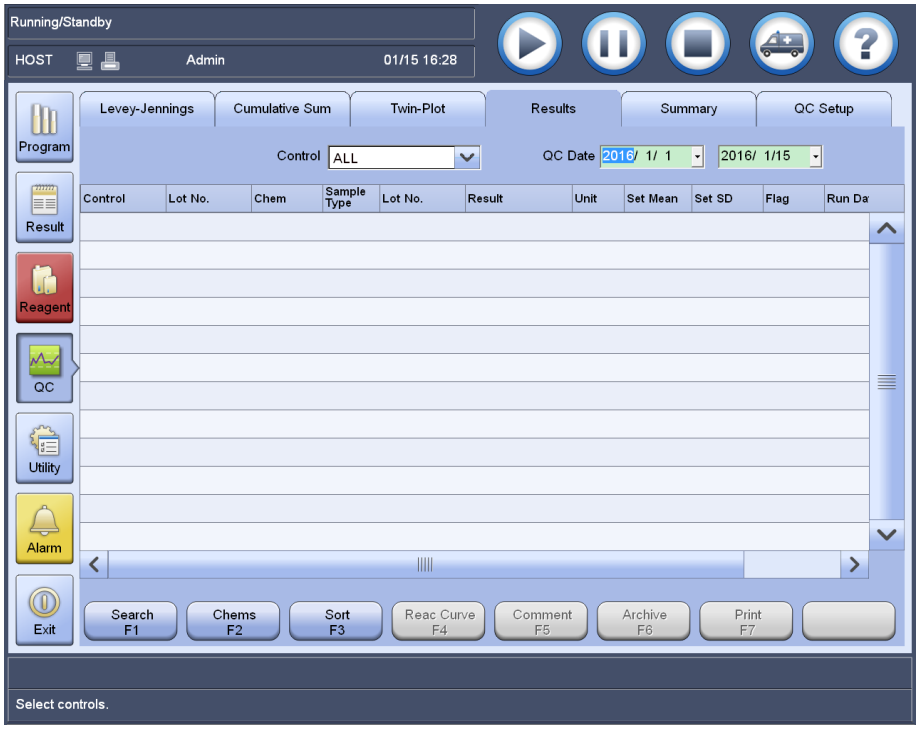
4 Select the date range in the **QC Date** field.

5 Choose a control in the **Control** drop-down list.

6 Select **Search F1**.

The result list shows all results of the control for the chemistry during the specified period, as well as the set means and standard deviations.

Figure 5.9 Results screen



7 Choose the following buttons as needed:

- **Sort F3**: to sequence the QC results by control or chemistry.
- **Reac Curve F4**: to view the reaction curve and data of the selected QC result.
- **Comment F5**: to add comments to the selected QC result.
- **Archive F6**: to archive the currently displayed QC results to an external storage device.
- **Print F7**: to print the QC results currently displayed in the result list.

To sort QC results

1 Search for desired QC results on the **Results** screen.

2 Select **Sort F3**.

3 Select a sorting criterion.

- Control: control number + chemistry + run date/time
- Chemistry: chemistry order + control + run date/time

4 Select **OK**.

The QC results on the **Results** screen are rearranged ascending based on the selected criterion.

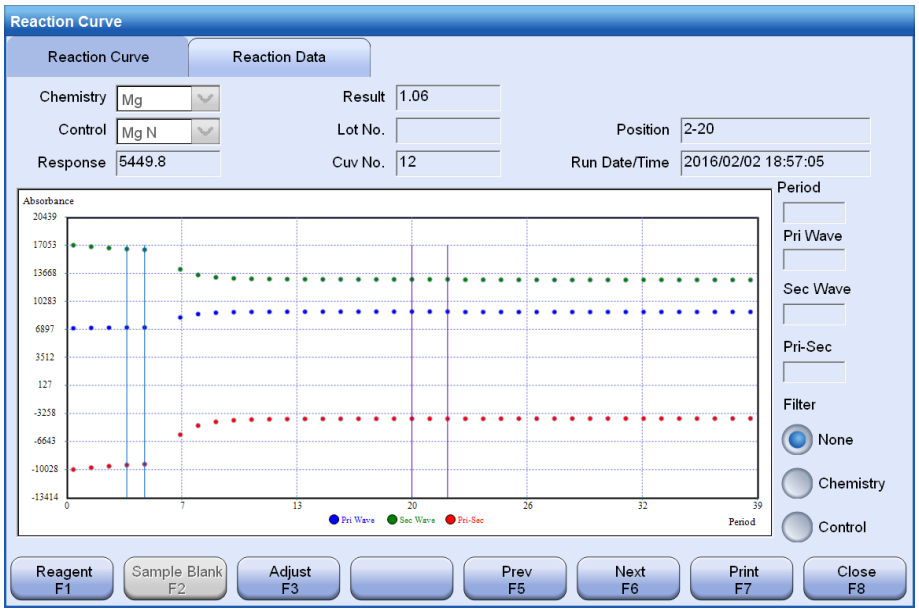
To view control reaction curve

1 Search for desired QC results on the **Results** screen.

2 Choose a QC result to recall.

3 Select **Reac Curve F4**. The **Reaction Curve** window is displayed.

Figure 5.10 Control reaction curve



4 Select a point on the curve. Relevant measuring period and absorbance are displayed on the right of the window.

5 Select a filter condition from the following options:

- None: observe reaction curve and data in the default mode.
- Chemistry: observe reaction curve of the results for the selected test.
- Control: observe reaction curve of the results for the selected control.

6 Select the **Reaction Data** tab to view the reaction data.

7 Choose the following buttons as needed:

- **Reagent F1:** to view the reagents used for quality control, calibrators and reagents used in calibration, and reagents for reagent blank test.
- **Sample Blank F2**: to view the sample blank reaction curve and reaction data of the selected control.
- **Adjust F3**: to adjust the absorbance display range of current reaction curve.
- **Prev F5**: to view the reaction curve and data of the previous QC test.
- **Next F6**: to view the reaction curve and data of the next QC test.
- **Print F7**: to print the current reaction curve or data.

8 Select **Close F8** to close the window.

To add QC comments

1 Search for desired QC results on the **Results** screen.

2 Choose a QC result in the result list.

3 Select **Comment F5**.

4 Type in comments for the selected QC result.

Up to 100 characters can be entered.

5 Select **OK**.

To archive QC data

1 Search for desired QC results on the **Results** screen.

2 Select **Archive F6**.

3 Select **OK**.

5.3.6 Recalling QC Summary

The QC summary reports the measurements of a control for the selected chemistry 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.

To recall QC summary

1 Select **QC** > **Summary**.

2 Select **Chems F2**.

3 Choose a chemistry to recall, and then select **OK**.

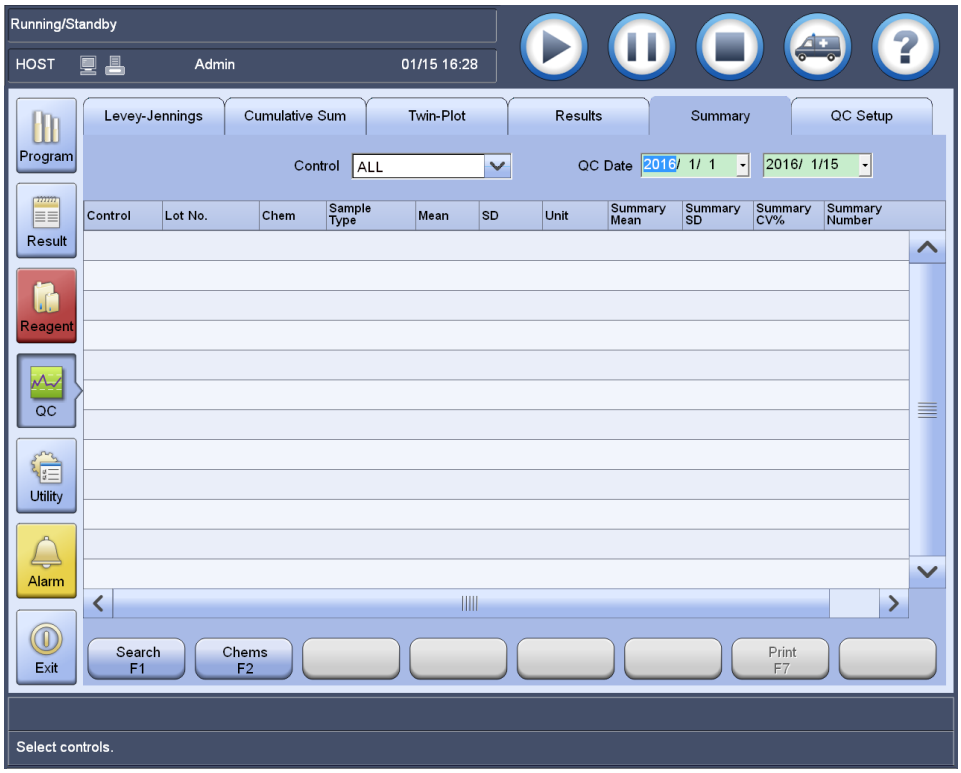
4 Select the date range in the **QC Date** field.

5 Choose a control in the **Control** drop-down list.

6 Select **Search F1**.

The result summary of the control for the chemistry is displayed on the screen.

Figure 5.11 Summary screen



7 To print the QC summary report, select **Print F7**.

6 Sample Programming

This chapter describes operations related to sample analysis.

6.1 Sample management

Before programming samples, it is necessary to understand the sample containers 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.

Sample container types

The sample carousel supports blood collecting tube, centrifugal tube, plastic tube and Microtube, which are available in the following specifications:

- Microtube: Φ14×25 mm, 0.5 mL (Beckman); Φ14×25 mm, 2 mL (Beckman); Φ12×37 mm, 2 mL (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.

For the tests of the whole blood(centrifuged),onlyΦ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13×75 mm, Φ13×95 mm, Φ13×100 mm anticoagulation tubes can be used. The sample height in the tube should be no higher than 55mm and the blood cell level should be no lower than 10mm. Microcups are not allowed. To ensure the clinical performance and avoid the system alarm, EDTA anticoagulation tubes are recommended.

Sample volume

The amount of sample required for a common measurement is 1.5-45 µL, with an increment of 0.1 µL. Analysis with insufficient samples may lead to inaccurate results.

If a sample is exhausted during the analysis, the system will automatically invalidate all incomplete chemistry of the sample. Before running samples, make sure that they are sufficient in volume for analysis.

Loading samples

BIOHAZARD

Wear gloves and lab coat, if necessary, goggles.

To load samples

1. Check if the sample inside the sample tube is sufficient for analysis and the bar code label is applied correctly.
2. Check the system status.
   - If the system status is Running, select  to request for sample stop.
   - If the system status is Standby or Incubation proceed to the next step.
3. Check if the sample carousel and the sample probe have stopped moving.
4. To load samples, remove the sample carousel cover.
5. Insert the sample tube into the tube holder until the tube bottom contacts the groove of the tube rack.
6. Repeat step 5 to load more samples.

7 Close the sample carousel cover.

Unloading samples

BIOHAZARD

Wear gloves and lab coat, if necessary, goggles.

To unload samples

1 Check if the sample carousel and the sample probe have stopped moving.

2 If the system status is Running, select  to request for sample stop.

3 Remove the sample carousel cover.

4 Grab the sample tube and pull it upward to remove it from the tube holder.

5 Repeat step 4 to unload more samples.

6 Close the sample carousel cover.

6.2 Sample programming and processing

Except for routine sample test, the system also provides the following test functions:

- Processing samples with LIS
- Processing bar-coded samples
- Batching programming
- Adding samples
- Adding/Modifying tests
- Rerunning samples
- Running sample blank
- Processing whole blood test

6.2.1 Processing samples with LIS

When connected with LIS, the system allows automatically obtaining and manually downloading sample programs.

NOTE

Please check the ISE module calibration status before starting tests to make sure it has been calibrated successfully.

Obtaining samples automatically

When the system status is Standby or Pause, load the samples to the sample carousel, and then select  . The system will automatically scan the samples and then query the LIS host to download relevant program information. After matching the downloaded program information with the samples, the system will start the analysis.

Downloading sample programs manually

Both bar-coded and non-bar-coded samples can be downloaded from LIS. Bar-coded samples can be programmed and analyzed automatically, while non-bar-coded samples need to be positioned before analysis.

To download bar-coded samples

1. Select **Program** > **Sample**, select **List F5** and then **Download F7**.
2. Choose one of the following options:
   - All programmed samples: to download all samples programmed on the current day.
   - Latest samples: to download samples that are programmed on the current day but have not been downloaded.
   - Samples with the following IDs: to download samples with the specified program 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.
3. Select **OK**.
4. Confirm the sample information and selected chemistries/panels on the **Sample List** screen.
5. Load the samples to idle positions of the sample carousel.
6. Select the  icon, set the test conditions, select the **Sample Crsl Bar Code** check box, and then click **OK** to start analysis.

To download non-bar-coded samples

1. After downloading samples from LIS, select **List F5**.
2. Select **Unpositioned F2**,and select **Assign**.
3. Select the date the desired samples are programmed.
4. Type in the single sample ID or ID range in the **ID** field.
5. Choose a sample carousel on which you will place the sample.
6. Enter the sample position.

   The options include all available positions of the selected sample carousel.
   - To assign position for single sample, input the position number in the first edit box.
   - To assign positions for multiple samples, enter the start position number in the first edit box, and then the end position number in the second edit box. The system will assign positions for the samples ascending according to the sample ID.
7. Select **OK**.
8. Load the samples to the assigned positions on the sample carousel.
9. Select the  icon, set the test conditions, and then click **OK** to start analysis.

6.2.2 Processing bar-coded samples

Bar-coded samples can be processed with or without LIS.

📖 For processing samples with LIS, see 6.2.1Processing samples with LIS on page 6-3.

If your system is not connected with a LIS host, you can program bar-coded samples with the default panel or program them manually one by one or by batch. This section describes two methods of manually programming samples without LIS.

📖 For sample analysis with default panel, see 7.7.5Setting up and running default panel on page 7-28.

Before processing bar-coded samples, check if the following conditions are satisfied:

- The sample bar code reader has been configured.
- The **Sample Crsl Bar Code** check box on the **Sample Bar Code** window is selected.
- The system status is Standby or Pause.

To process bar-coded samples without LIS -- Method 1

1. Program samples manually according to "2.4.1Programming and processing samples" (Page2-24).
2. Place the bar-coded samples sequentially on the sample carousel.
3. Select the  icon on the upper-right corner of the main screen.
4. Select a sample carousel to which the samples are loaded.
5. Select the **Sample Crsl Bar Code** check box.
6. Specify the sample range: All or Partial. When you select Partial, you should specify a sample position range for analysis.
7. Select **OK**.

   The system scans the samples on the sample carousel to match the program information, and then starts analysis.

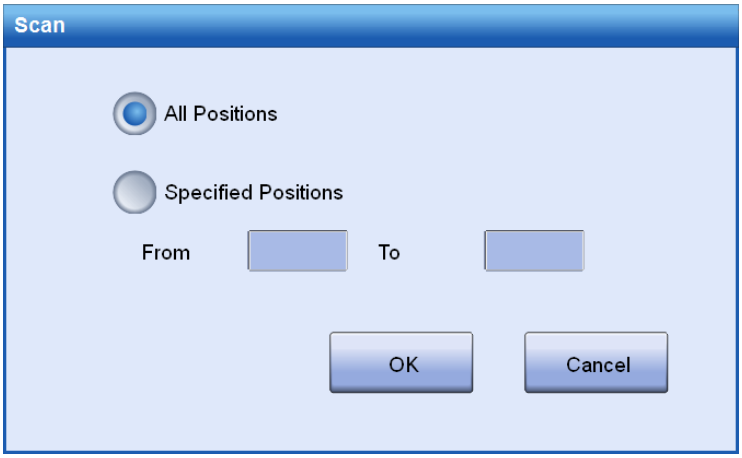
To process bar-coded samples without LIS -- Method 2

1. Program samples manually according to "2.4.1Programming and processing samples" (Page2-24).
2. Place bar-coded samples sequentially on the sample carousel.

   If the auto numbering feature is enabled, the system will automatically number the samples according to the order in which they have been placed. The start number will be the next available one since the last sample is programmed.

   For auto numbering of bar-coded samples, see 8.5 Bar code setup on page 8-18.
3. Select **Program** > **Status**.
4. Select **Scan F5**. The **Scan** window is displayed.

Figure 6.1 Scan window



5. Choose the scanning range.

   - All positions: to scan all positions on the sample carousel.
   - Specified positions: to scan the specified positions on the sample carousel. Input the start and end scanning positions.

6 Select **OK**.

7 Select the icon, set the test conditions, and then click **OK** to start analysis.

6.2.3 Batch programming

For batch-programmed samples, all program information such as sample information, chemistries and patient demographics other than position, ID and bar code are the same.

To batch program samples

1 Select **Program > Sample**.

2 Enter the sample ID of the first sample.

3 Enter the start position to place the samples.

4 Set the sample information, including: STAT property, sample type, comment, and patient ID.

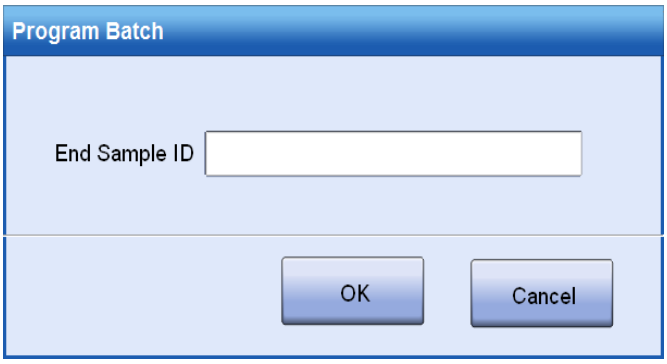
5 Choose desired chemistries.

6 To set patient demographics, select **Demog F1**.

7 To set replicates and dilution factors**,** select **Options F2**.

8 Select **Batch F3**.

Figure 6.2 Program Batch window



8 Enter the sample ID of the last sample.

9 Select **OK**.

10 Select the icon, set the test conditions, and then click **OK** to start analysis.

6.2.4 Adding samples

You can add routine samples and STAT samples at any time, and test them in the same way as routine test. You can also add and analyze calibrators and controls in the same way.

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.

To add samples in Running status

1 Add samples according to "2.4.1Programming and processing samples" (Page2-24).

2 Select the  icon on the upper-right corner of the main screen.

3 When the system status becomes Pause, place the added samples on the assigned positions of the sample carousel, and then select  .

- If the samples are on the current sample carousel, click **OK** to start the test.
- Otherwise, you should specify the sample carousel and position to start the analysis.

To add samples in other system statuses

1 Add samples according to "2.4.1Programming and processing samples" (Page2-24).

2 Place the added samples on the assigned positions of the sample carousel.

3 Select the  icon, set the test conditions, and then click **OK** to start analysis.

6.2.5 Adding/Modifying chemistries

No matter in which status a sample is, chemistries can be added or removed.

To add/modify chemistries

1 Select **Program** > **Sample**.

2 Type in the sample ID and press **Enter**.

The programming information of the sample is displayed on the screen.

3 Deselect chemistries you won't run, and then select chemistries you desire to run.

4 Deselect panels you won't run, and then select panels you desire to run.

5 Select **Save F8**.

- If the system is running tests, it will analyze the added chemistries and panels automatically.
- If the system is in Standby status, select the  icon, set the test conditions, and then click **OK** to start analysis.

6.2.6 Rerunning samples

The system provides the manual rerun and auto rerun functions, for rerunning samples that have abnormal results or have results beyond the set linearity range or critical range.

Perform manual rerun on the following screens:

- **Program** > **Sample** > **List** window: rerun single or batch samples

- **Result** > **Current** or **History** screen: rerun by sample or by chemistry

Perform auto rerun on the following screens:

- **Utility** > **Chemistries** > **Reference/Critical Range** window: rerun ISE test
- **Utility** > **System Setup** > **Auto Rerun Setup** screen: rerun biochemistry

Manual rerun on List window

The **List** > **Rerun** window allows you to manually rerun single or multiple samples that are in Complete, Incomplete, Rerun or In Progress status.

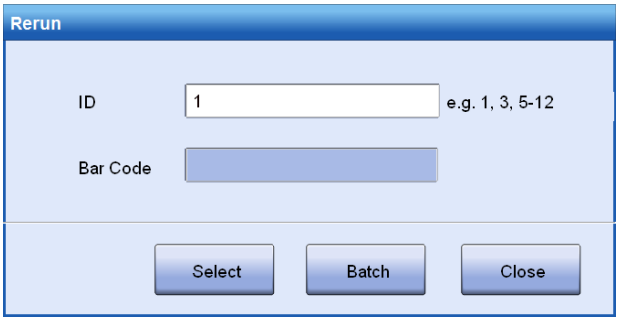
When rerunning samples, you are allowed to edit the sample cup type, sample position, STAT feature and chemistries. If a chemistry is finished, it can be rerun with edited sample volume, replicates and predilution factor. Sample ID, bar code, sample type and collection time of rerunning samples must not be edited.

To rerun single sample

1 Select **Program** > **Sample**, and select **List F5**.

2 Select **Rerun F4**.

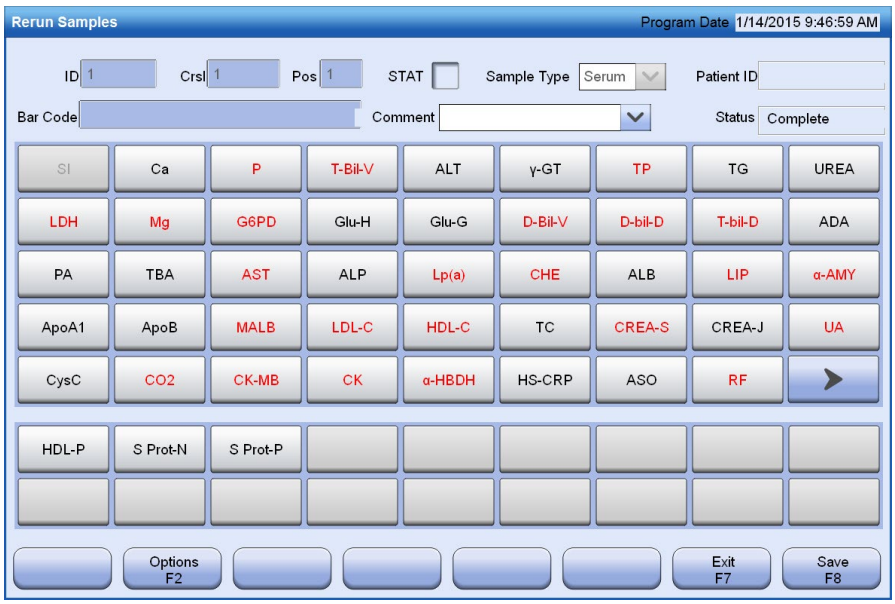
Figure 6.3 Rerun window



3 Type in the ID or bar code of the sample you desire to rerun or enter the barcode of the sample.

4 Click **Select**.

Figure 6.4 Rerun Samples window



5 Edit the following information:

- Position: change the carousel number and position of the sample.
- STAT: select or deselect the **STAT** checkbox.

- Comment: choose or enter a sample comment.
- Chemistry and panel: change chemistries and panels.
- Options: edit the number of replicates and predilution factors for the sample or for a chemistry, and then modify the sample cup type.

6 Select **Save F8**.

7 Select **Exit F7**.

8 After confirming all rerun information, load samples to the assigned positions, and select  to start the analysis.

- If the sample is on the current sample carousel, it is analyzed automatically.
- Otherwise, you should specify the sample carousel and position to start the analysis.

To rerun batch samples

1 Select **Program > Sample**, and select **List F5**.

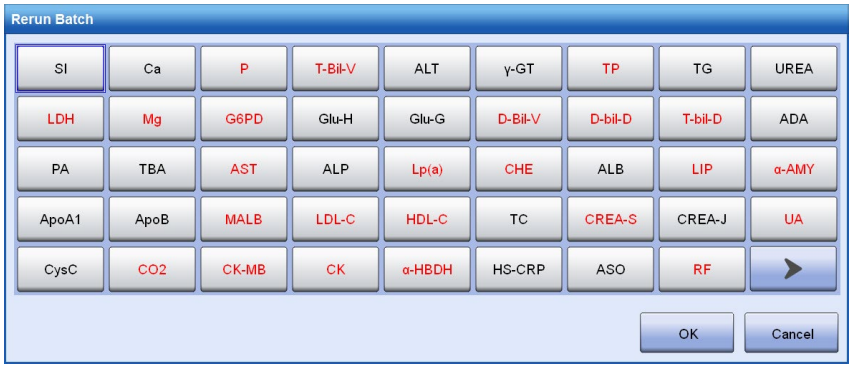
2 Select **Rerun F4**.

3 Type in the sample ID or range you desire to rerun.

Separate single samples with comma, e.g. 5, 7, 9; and connect multiple continuous samples with a dash, e.g. 1-3.

4 Select **Batch**.

Figure 6.5 Rerun Batch window



5 Choose chemistries for rerunning the samples.

The list includes all chemistries that have been enabled and configured. The selected chemistries will be requested for rerunning the samples.

6 Select **OK**.

7 After confirming all rerun information, load samples to the assigned positions, and select  to start the analysis.

- If the samples are on the current sample carousel, they are analyzed automatically.
- Otherwise, you should specify the sample carousel and position to start the analysis.

Manual rerun on Current or History screen

With the **Rerun F5** button on the Current or History screen, you can rerun samples in Complete or Incomplete status that have finished tests. You can rerun multiple chemistries by sample or rerun multiple samples by chemistry.

To rerun chemistries by sample

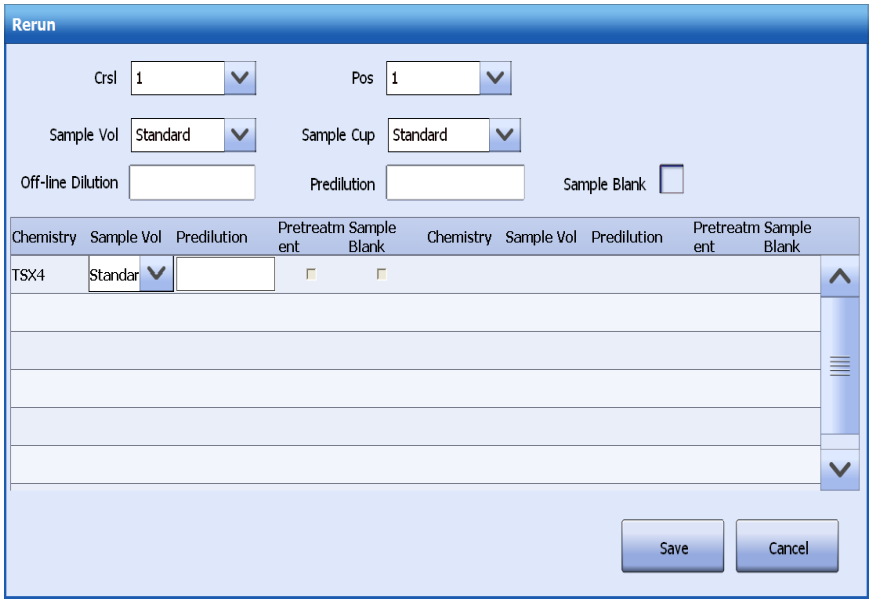
1 Select **Result > Current** or **History**, and choose the **By Sample** option.

2 Search for desired sample results.

3 Select the sample and chemistries you desire to rerun.

4 Select **Rerun F5**.

Figure 6.6 Rerun window



5 Modify the following sample information for all chemistries:

- Carousel No. and position
- Sample volume
- Sample cup
- Off-line dilution factor
- Predilution factor
- Sample blank

6 Modify the following information for single chemistry:

- Sample volume
- Predilution factor
- Sample blank
- Pretreatment

7 Select **Save**.

8 Load samples to the assigned positions, and select  to start the analysis.

- If the sample is on the current sample carousel, it is analyzed automatically.
- Otherwise, you should specify the sample carousel and position to start the analysis.

To rerun samples by chemistry

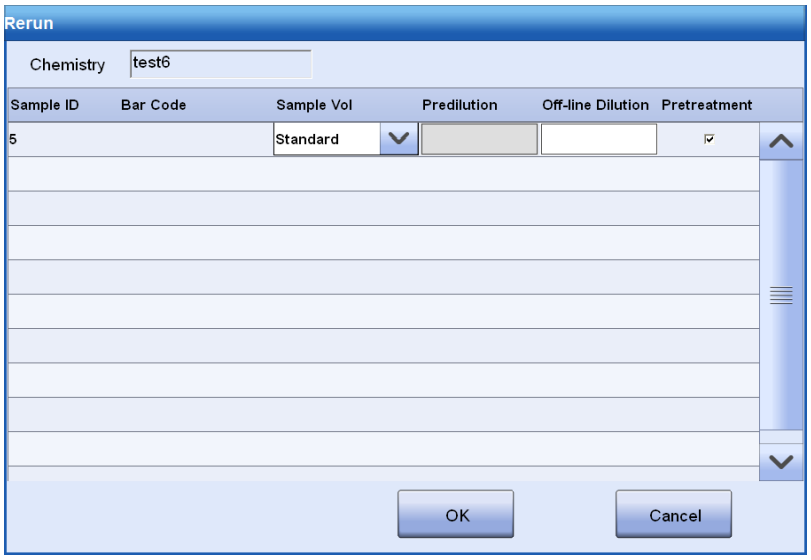
1 Select **Result > Current Results** or **History Results**, and choose the **By Chemistry** option.

2 Search for desired sample results.

3 Choose the chemistry and samples you desire to rerun.

4 Select **Rerun F5**.

Figure 6.7 Rerun window



5 To run sample blank for all samples, select the **Sample Blank** check box.

6 Modify the following information for single sample:

- Sample volume
- Predilution factor
- Off-line dilution factor
- Sample blank
- Pretreatment

7 Select **OK**.

8 Load samples to the original positions, and select  to start the analysis.

- If the samples are on the current sample carousel, they will be analyzed automatically.
- Otherwise, you should specify the sample carousel and position to start the analysis.

Auto rerun of ISE chemistry based on critical range

The auto rerun function can be enabled on the **Reference/Critical Range** window. Once the auto rerun is enabled, the system will check if the ISE result is beyond the critical range, and if it is, will rerun the sample.

To auto rerun ISE test

1 Select **Utility > Chemistries**, and select **Ref Range F4**.

2 Select ISE from the **Chemistry** drop-down list.

3 Set up the critical range as well as sample type, patient gender and age range.

4 Mark the **Auto Rerun** checkbox with a tick.

5 Select **Save F7** to save the settings.

6 Select **Exit F8** to close the window.

The system will rerun samples if the ISE test result is beyond the critical range.

NOTE

Make sure there is sufficient sample and at least 90µl sample for ISE serum analysis.

Rerunning biochemistries when meeting auto rerun conditions

The auto rerun function can be also enabled on the Define/Edit Chemistries 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.

To enable auto rerun and set up error detection parameters

1. Select **Utility > Chemistries**.
2. Choose a chemistry, and select **Define F1**.
3. Mark the **Auto Rerun** checkbox with a tick.
4. Select the down-arrow button to show the error detection parameters setup page.
5. Set up the following parameters:
   - Linearity range (for standard, decreased and increased volumes)
   - Linearity limit
   - Substrate depletion limit
   - Mixed blank absorbance
   - R1 blank absorbance
   - Blank response
   - Prozone check parameters (Q1-Q4, PC, ABS)
6. Select **Save F7** to save the settings.
7. Select **Close F8** to close the window.

To set up critical range

1. Select **Utility > Chemistries**, and select **Ref Range F4**.
2. Select the desired biochemistry from the **Chemistry** drop-down list.
3. Set up the critical range as well as sample type, patient gender and age range.
4. Select **Save F7** to save the settings.
5. Select **Exit F8** to close the window.

To set up the auto rerun conditions

1. Select **Utility > System Setup**.
2. Click the arrow buttons to display the auto rerun setup screen.
3. Select the check box in front of desired conditions, and choose a sample volume for rerun from the drop-down list.
4. Click Save F8.

   The system will rerun samples with the set volume type if the test result satisfies the conditions

Recalling rerun results

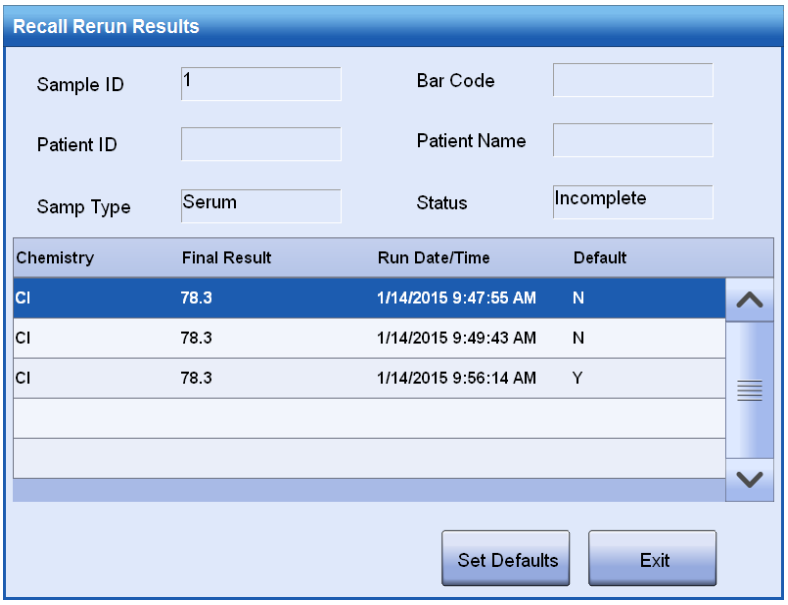
The rerun results of a sample are presented on the **Recall Rerun Results** window, through which you are allowed to recall all rerun results. You can set the result of any rerun as the default of a chemistry.

To recall rerun results

1. Select **Result** > **Current** or **History**.
2. Search for desired sample results.
3. Choose a sample and then a chemistry you desire to recall.
4. Select **Options F2**, and select **Recall Rerun Results**. The **Recall Rerun Results** window is displayed.

   The window shows the sample information and all reruns results of the chemistry.

Figure 6.8 Recall Rerun Results window



5. The latest rerun result is the default one. To change the default result, choose a result, and then select **Set Defaults**.

   The **Default** column of the result shows **Y**, which stands for Yes.
6. Select **Exit** to exit the window.

6.2.7 Sample blank

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

To run sample blank

1. Select **Utility** > **Chemistries**.
2. Choose a chemistry.
3. Select **Define F1**.
4. Mark the **Sample Blank** checkbox with a tick.
5. Select **Save F7**.
6. Select **Close F8**.

   The system will run a sample blank when running calibrators, controls and samples for the chemistry.

To recall sample blank reaction curve

1. Select **Result > Current** or **History**.
2. Search for desired sample results.
3. Choose a sample and then a chemistry you desire to recall.
4. Select **Reac Curve F4**.
5. Select **Sample Blank F2**.

Figure 6.9 Sample blank reaction curve

6. Choose the **Reaction Data** tab to view the reaction data.
7. To print the reaction curve or reaction data, select **Print F7**.
8. Select **Close F8** to close the window.

6.2.8 Whole Blood Test

The system supports whole blood test by pretreating patient sample, control and calibrator before test. Chemistries run with whole blood are similar with other routine biochemistries in parameter setup, calibration setup and reagent loading, except that pretreatment reagent should be set and loaded.

For pretreatment setup, see 7.2.3Error detection limits on page 7-12.

For instructions of loading pretreatment reagent, see reagent on page 2-17.

For the test of whole blood(centrifuged)sample, the parameters can be set up on the chemistry parameter screen or on the chemistry options window and rerun window. On the chemistry parameter screen, once sample pretreatment is selected, all the tests of this chemistry will perform pretreatment. You can enable or disable pretreatment on the chemistry options window or rerun window so that manually pretreated sample can be tested.

Preparing sample

Put the centrifuged whole blood sample(2000rpm,5min) into the sample positions.

NOTE

For the tests with blood cell pretreatment, please prepare the centrifuged whole blood sample. For the centrifuged whole blood sample,onlyΦ12×68.5 mm, Φ12×99 mm, Φ12.7×75 mm, Φ12.7×100 mm, Φ13×75 mm, Φ13×95 mm, Φ13×100 mm anticoagulation tubes can be used. The sample height in the tube should be no higher than 55mm and the blood cell level should be no lower than 10mm. Microcups are not allowed. To ensure the clinical performance and avoid the system alarm, EDTA anticoagulation tubes are recommended.

If manual pretreatment is required due to abnormal test results, please deselect the pretreatment option on the chemistry options window and the rerun window.

Follow the steps below to perform whole blood sample tests:

1. Select **Utility > Chemistries**.
2. Select a chemistry**.**
3. Select **Define F1.**
4. Select **Sample pretreatment** and common pretreatment or blood cell treatment.
5. Enter **Pretreat sample Vol** and **Pretreat reagent vol.**
6. Select **Save F7.**
7. Select **Exit F8.**

   Check if the reagent and pretreatment reagent have been loaded and the reagent has been calibrated.
8. Select **Program > Sample**.
9. Enter the following sample information:

   - ID
   - Position
   - STAT
   - Sample type(Other)
   - Comment
   - Chemistry and panel
10. Select chemistry options:

    - Sample volume
    - Sample cup
    - Replicates
    - Off-line dilution
    - Predilution
    - Sample blank
    - Pretreatment
11. Select **Save F8.**
12. Click  .

6.3 Extended functions

This section describes other functions related to sample analysis.

6.3.1 Clearing samples

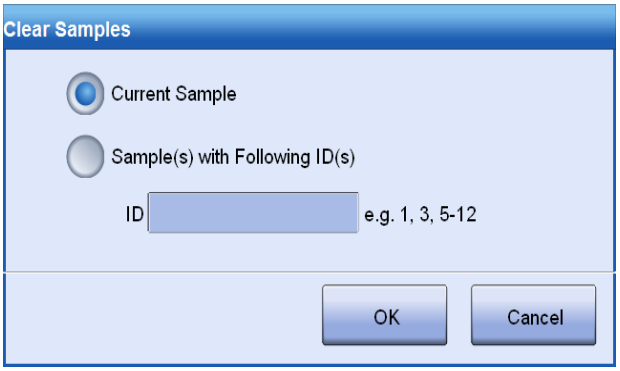
The Clear Samples function is used to delete programmed samples that have not been analyzed. One or more samples can be cleared at one time. When samples are cleared, the sample information will be removed completely; the sample ID, position and bar code can be used for programming other samples. The action of clearing samples will be recorded in the edit logs.

To clear samples

1 Select **Program** > **Sample**.

2 Select **Clear F4**. The **Clear Samples** window appears.

Figure 6.10 Clear Samples window



3 Select samples you desire to clear.

- Current sample: type in the sample ID on the **Sample** screen.
- Sample(s) with following ID(s): type in the sample ID range in the **Sample ID** field. Single sample ID and sample range are acceptable.

4 Select **OK**.

The selected samples are cleared along with their programming information.

6.3.2 Sample and chemistry lists

The List option allows you to view, inquire and print all unfinished samples, and assign positions for unpositioned samples. You are also allowed to view the requested chemistries' calibration status, reagent status, tests left, and number of requests.

The **List** window includes two tab pages: **Sample List** and **Chemistry List**.

Sample list

The sample list shows all patient and controls samples that have been programmed but not analyzed yet. On the **Sample List** screen, you can search samples, assign position for unpositioned samples, download program information from LIS, rerun tests, and print the sample list.

📖 For assigning position for unpositioned samples, see 6.3.3 Viewing unpositioned samples on page 6-18.

📖 For downloading program information from LIS, see 6.2.1 Processing samples with LIS on page 6-3.

📖 For manual rerun, see Manual rerun on List window on page 6-8.

To view programmed samples

1 Select **Program** > **Sample**.

2 Select **List F5**.

Figure 6.11 Sample List tab page

3 Move the scroll bar to view more samples.

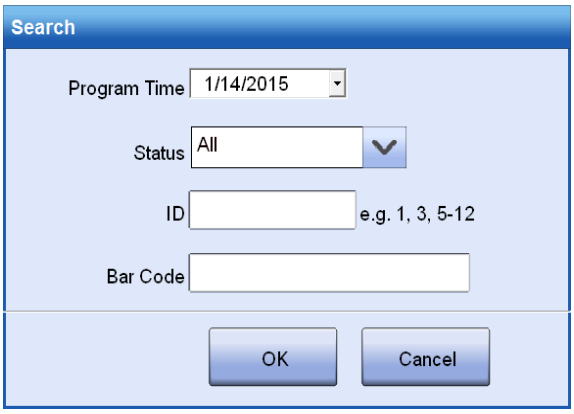
4 To print the sample list, select **Print F7**.

5 Select **Exit F8** to close the window.

To inquire samples by program date, sample status or ID

1 Select **Search F1** on the **Sample List** tab page.

Figure 6.12 Search window



2 Enter the conditions:

- Select the program date of samples you desire to inquire; and/or
- Select a sample status, which is available in All, Programmed, In Progress, Incomplete, Complete, and Rerun; and/or
- Type in the single sample ID or ID range in the **Sample ID** field.

3 Select **OK**. All samples that satisfy the conditions are displayed on the screen.

To inquire a bar-coded sample

1 Select **Search F1** on the **Sample List** tab page.

2 Type in the sample bar code you desire to inquire.

3 Select **OK**. The corresponding sample is displayed on the screen.

Chemistry list

The chemistry list shows the summary of chemistries that are requested on the current day or requested before but not finished yet. On the **Chemistry List** screen, you can download program information from LIS and rerun tests.

📖 For downloading program information from LIS, see 6.2.1 Processing samples with LIS on page 6-3.

📖 For manual rerun, see Manual rerun on List window on page 6-8.

To view chemistry list

1 Select **Program** > **Sample**.

2 Select **List F5**.

3 Select the **Chemistry List** tab.

Figure 6.13 Chemistry List tab page

4 Move the scroll bar to view more chemistries.

5 To print the chemistry list, select **Print F7**.

6 Select **Exit F8** to close the window.

6.3.3 Viewing unpositioned samples

Unpositioned samples are those:

- downloaded from the LIS host and not positioned yet. Such samples cannot be programmed for analysis until they have positions assigned. If your system is equipped with a sample bar code reader, the samples can be analyzed immediately without assigning positions for them.
- those are in Incomplete status when their positions are used for programming new samples.
- those are incomplete when their positions are released.

Once positioned, the samples will be removed from the unpositioned samples list.

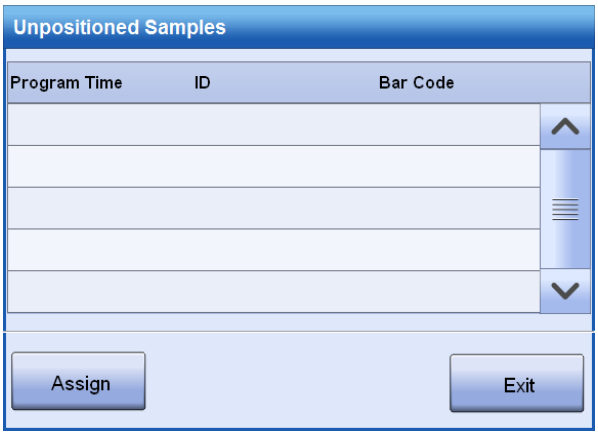
To view unpositioned samples

1 Select **Program** > **Sample**.

2 Select **List F5**.

3 Select **Unpositioned F2**.

Figure 6.14 Unpositioned Samples window

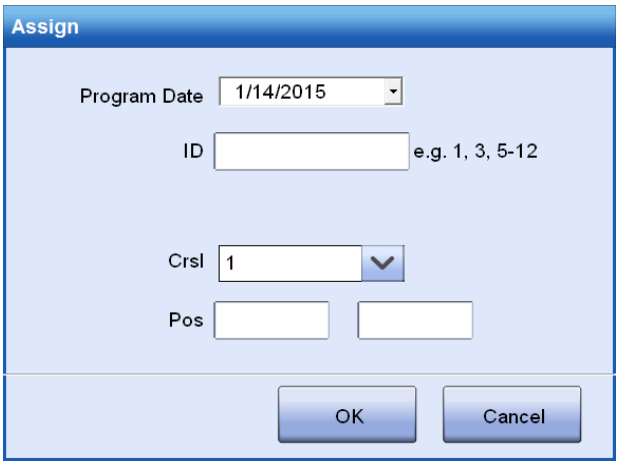


4 Move the scroll bar to view more samples.

To assign positions and perform test

1 Select **Assign** on the **Unpositioned Samples** window.

Figure 6.15 Assign positions



2 Select the program date of sample(s) to assign position.

3 Type in the sample ID or range in the **ID** field.

4 Choose a sample carousel on which you will place the sample.

5 Enter the positions in the **Pos** field.

- To assign position for single sample, input the position number in the first edit box.
- To assign positions for multiple samples, enter the start position number in the first edit box, and then the end position number in the second edit box. The system will assign positions for the samples ascending according to the sample ID.

6 Select **OK**.

7 Select the  icon, set the test conditions, and then click **OK** to start analysis.

6.3.4 Releasing sample position

When a sample is analyzed, the position cannot be used for programming new sample until it is released. The system provides the function of manual and auto releasing samples.

The **Program > Status** screen provides the Release Sample Position function, which allows you to release the selected position or all positions on the current sample carousel that are not running any tests. Only patient samples rather than controls, calibrators, ISE wash solution and physiological saline can be released.

Sample positions can be released automatically at specified time every day.

When a sample is released, its results and programming information can be still recalled.

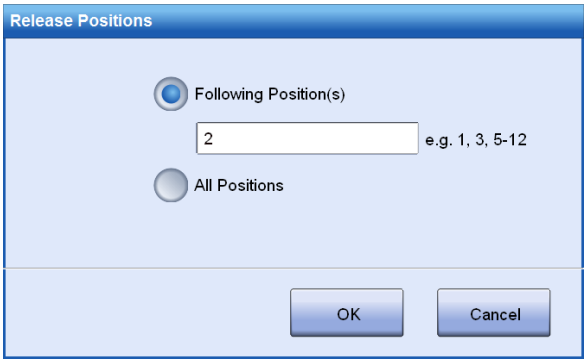
To manually release sample positions

1 Select **Program > Status**.

2 Choose a sample carousel to release samples.

3 Select **Release F3**.

Figure 6.16 Release Positions window



4 Choose the sample range:

- Following position(s): type in single sample position or position range in the edit box.
- All positions: to release all positions of the selected sample carousel.

5 Select **OK**.

To automatically release samples

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Auto Release Sample**.

4 Select the auto release time of patient samples in the **Auto Release Time** field.

Select an integer between 00 and 23. The default is 00.

5 Select **OK**.

When the time is reached, the system will release automatically all sample positions in the status of Complete.

6.3.5 View sample logs

The **Sample Logs** screen provides the controls and patient samples that are not complete within the recent 24 hours due to certain reasons. You are to rerun the samples or take other actions for the controls and samples.

To view sample logs

1 Select **Program** > **Status**.

2 Select **Log F2**.

Figure 6.17 Sample Logs window

3 To print the sample logs, select **Print F7**.

4 Select **Exit F8** to close the window.

6.3.6 Customizing sample information

The system provides the Cust. Sample Info. option for specifying sample information to be displayed on the **Sample** screen.

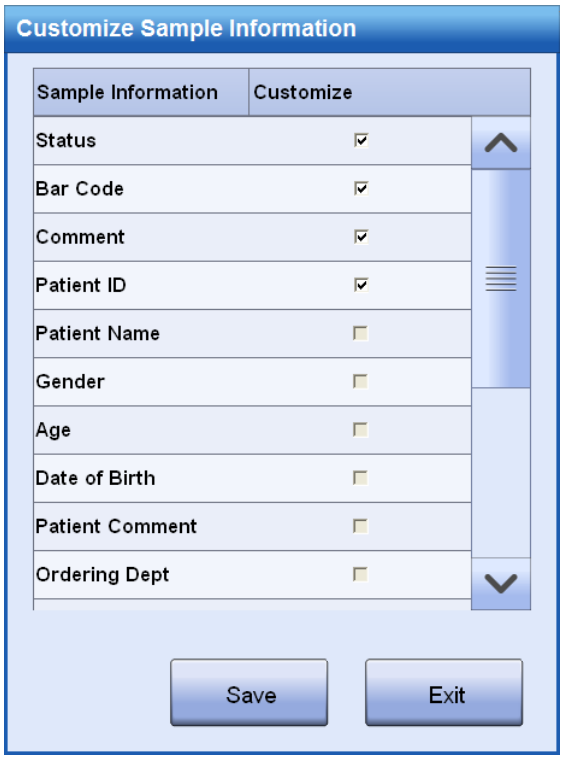
To customize sample information

1 Select **Utility** > **System Setup**.

2 Select **Instrument F1**.

3 Select **Cust. Sample Info**.

Figure 6.18 Customize Sample Information window



4 Find desired sample information and mark the corresponding **Customize** checkbox.

Click the checkbox again to deselect it.

5 Select **Save**.

6 Select **Exit** to close the window.

6.3.7 Customizing patient demographics

You can specify patient demographics to be displayed, its default and its display order on the **Patient Demographics** screen.

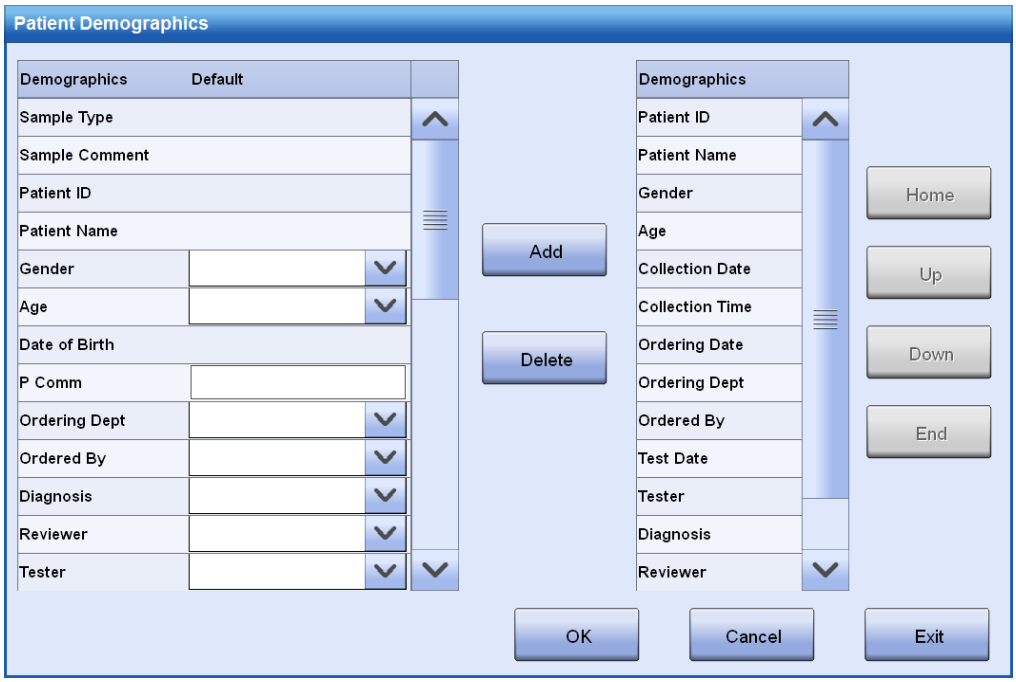
To customize patient demographics

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Patient Demographics**.

Figure 6.19 Patient Demographics



4 Select the desired information and the default value and then click **Add**.

5 Select the desired information and click **Delete** to delete it from the demographics list.

6 Select **Up**, **Down**, **Home** and **End** button to adjust the displayed order of patient demographics.

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

8 Select **Exit** to close the window.

6.3.8 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.

Table 6.1 Optimizing result display

When test result..	Displayed as...
Less than the low limit of linearity range	< Low limit of linearity range
greater than the high limit of linearity range	> High limit of linearity range
less than concentration of the lowest-concentration calibrator	< Concentration of the lowest-concentration calibrator
greater than concentration of the highest-concentration calibrator	> Concentration of the highest-concentration calibrator
less than both the low limit of linearity range and concentration of the lowest-concentration calibrator	< Maximum of the two values
greater than the high limit of linearity range and concentration of the highest-concentration calibrator	> Minimum of the two values

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.

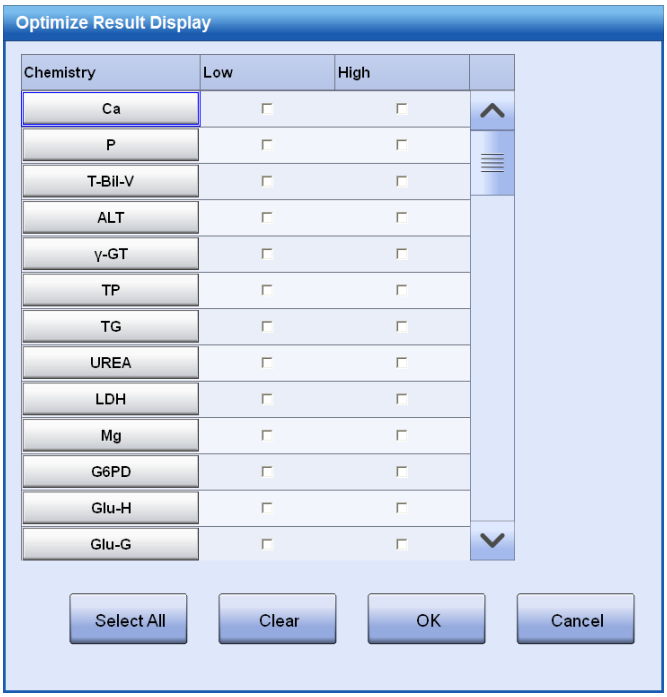
To optimize result display

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Optimize Result Display**.

Figure 6.20 Optimize Result Display window



4 Find desired chemistry, and mark the corresponding **Low** and **High** checkboxes.

5 To optimize result display of all chemistries, select **Select All**.

6 To cancel all settings, select **Clear**.

7 Select **Save**.

8 Select **Cancel** to close the window.

6.4 Results Recall

The Results Recall option allows routine samples, STAT samples and controls to be recalled and handled on the **Current Results** or **History Results** screen. The Current Results include those that are programmed and analyzed on the current day; the History Results are those programmed and analyzed before the current day. All results can be recalled by sample or by chemistry.

Except the **Recalculate** option for current results, other operations are applicable to both current and history results.

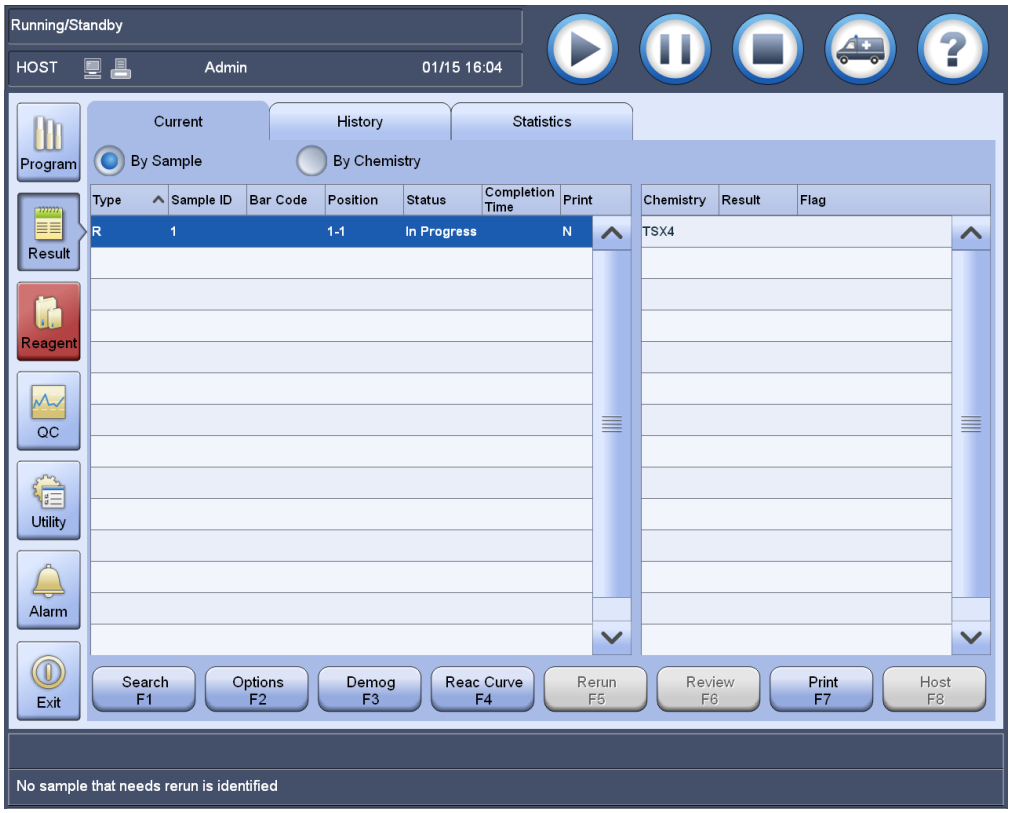
6.4.1 Viewing current results

The **Current** screen shows all samples and controls that are programmed and analyzed on the current day. You can search current results by sample information and patient demographics, and can sort samples by sample category, sample ID, status, position, completion time, program date/time, host, print and review statuses.

To view current results

1 Select **Result > Current**.

Figure 6.21 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.
- When certain test of a control sample or patient sample triggers a data alarm, the sample will appear in yellow.

2 Choose a result recall mode:

- By sample
- By chemistry

3 When recalling results by sample, choose a sample in the left list. The right list displays all results of the sample.

4 When recalling results by chemistry, choose a chemistry in the left list. The right list displays all results of the chemistry.

5 Choose the following buttons as needed:

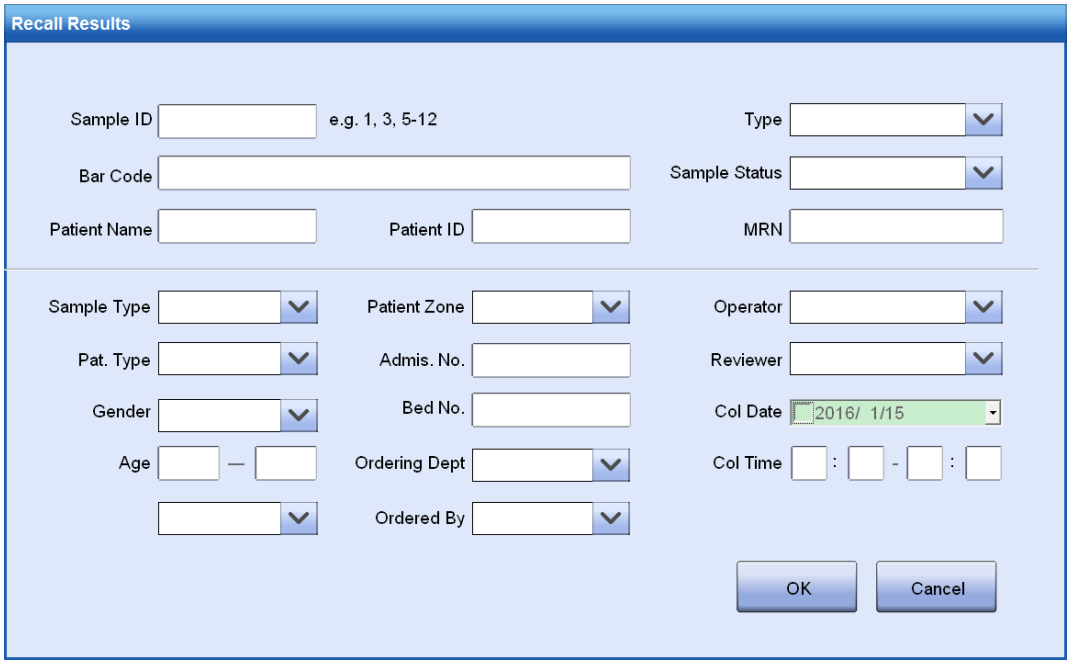
- **Search F1**: to inquire sample results.
- **Options F2**: to delete, edit and print samples, recall rerun results, customize result display options, recalculate results, compensate results, archive results, and observe result trend.
- **Demog F3**: to view patient demographics of the sample.
- **Reac Curve F4**: to view the reaction curve and data of the selected test.
- **Rerun F5**: to rerun a finished sample.
- **Review F6** to review the sample result.
- **Print F7**: to print sample results.
- **Host F8**: to transmit the selected sample results to the LIS host.

To recall current results

1 Select **Result > Current**.

2 Select **Search F1**.

Figure 6.22 Recall results window



3 Enter one or more search conditions.

4 Select **OK**. The samples matching the condition are displayed on the screen.

5 Select a function button to perform relevant operations.

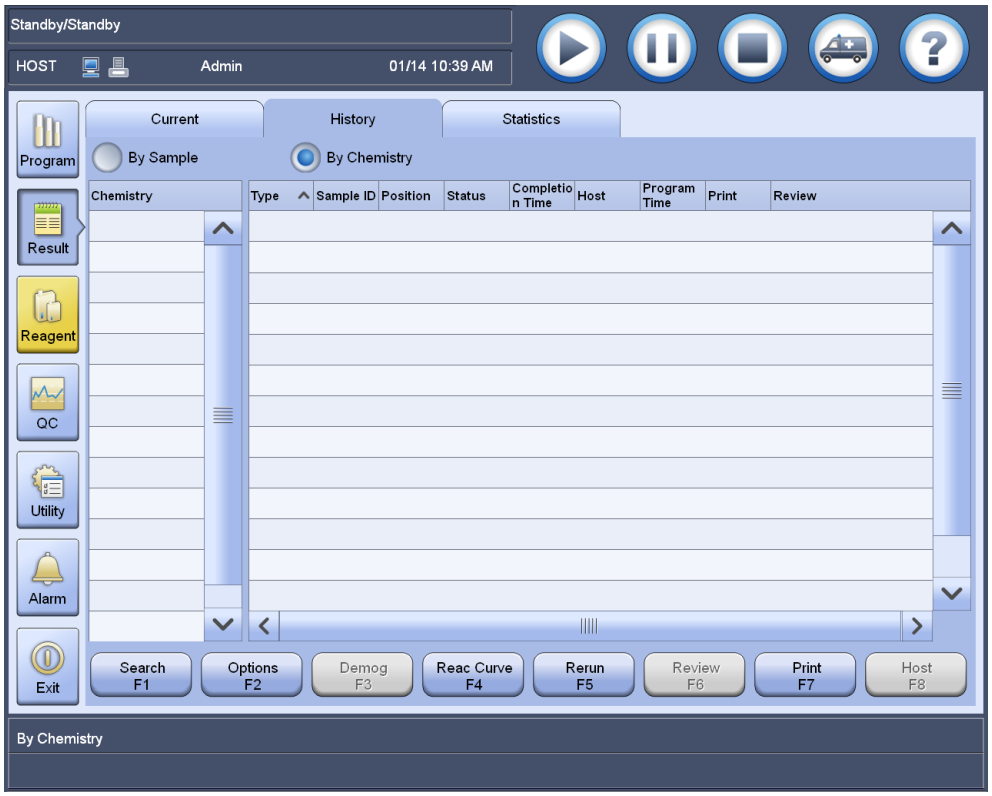
6.4.2 Viewing history results

The **History** screen shows all samples and controls that are programmed and analyzed before the current day. You can search history samples by sample type, patient name, patient ID, sample ID or sample bar code, along with the program date. To quickly search for desired results from the tremendous amount of data, you are recommended to enter both the program date and any of the conditions.

To view history results

1 Select **Result > History**.

Figure 6.23 History Results 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.

2 Choose a result recall mode:

- By sample
- By chemistry

3 Select **Search F1** to search for desired results.

4 When recalling results by sample, choose a sample in the left list. The right list displays all results of the sample.

5 When recalling results by chemistry, choose a chemistry in the left list. The right list displays all results of the chemistry.

6 Choose the following buttons as needed:

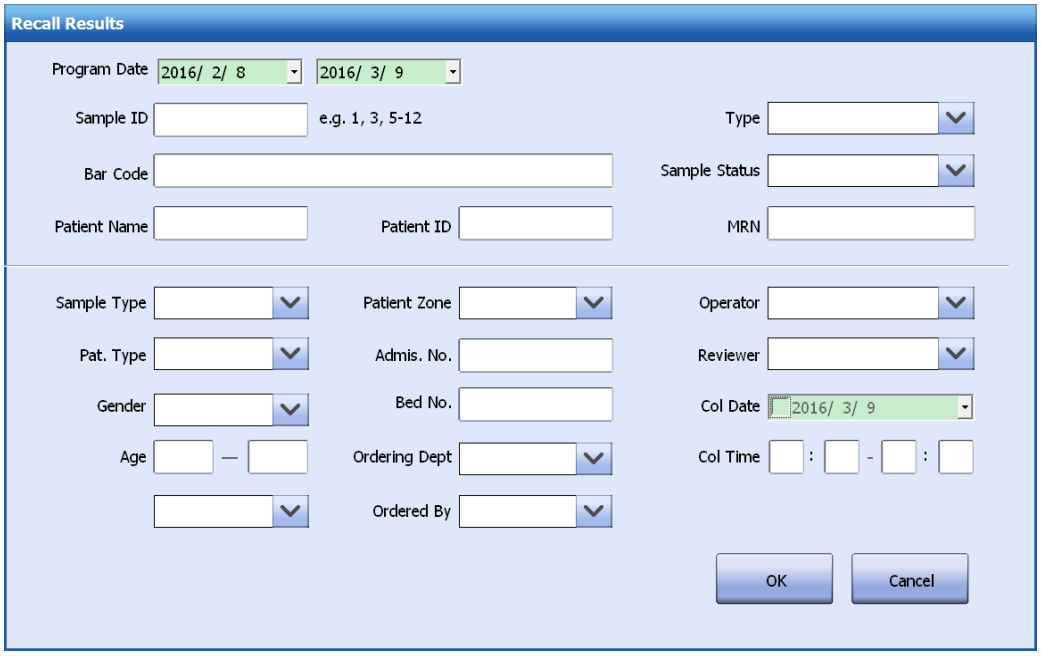
- **Options F2**: to delete, edit and print samples, recall rerun results, customize result display options, compensate results, archive results, and observe result trend.
- **Demog F3**: to view patient demographics of the sample.
- **Reac Curve F4**: to view the reaction curve and data of the selected test.
- **Rerun F5**: to rerun a finished sample.
- **Review F6** to review the sample results.
- **Print F7**: to print sample results.
- **Host F8**: to transmit the selected sample results to the LIS host.

To recall history results

1 Select **Result > History Results**.

2 Select **Search F1**.

Figure 6.24 Recall Results window



3 Select the program date range you want to recall. Select the start date in the first box and the end date in the second box.

4 Enter one or more search conditions.

5 Select **OK**. The samples matching the condition are displayed on the screen.

6 Select a function button to perform relevant operations.

6.4.3 Reviewing sample results

Only when the sample status is complete, can the sample results be reviewed.

To review sample results

1 Select **Result > Current** or **History**.

2 Choose the **By Sample** option.

3 Choose a sample or more samples in the sample list.

4 Select **Review F6**.

The review status in the sample list turns from N to Y.

5 Select **No Review** to cancel the review operation.

6.4.4 Viewing/Editing patient demographics

Patient demographics can be viewed or edited in any system status.

To view/edit patient demographics

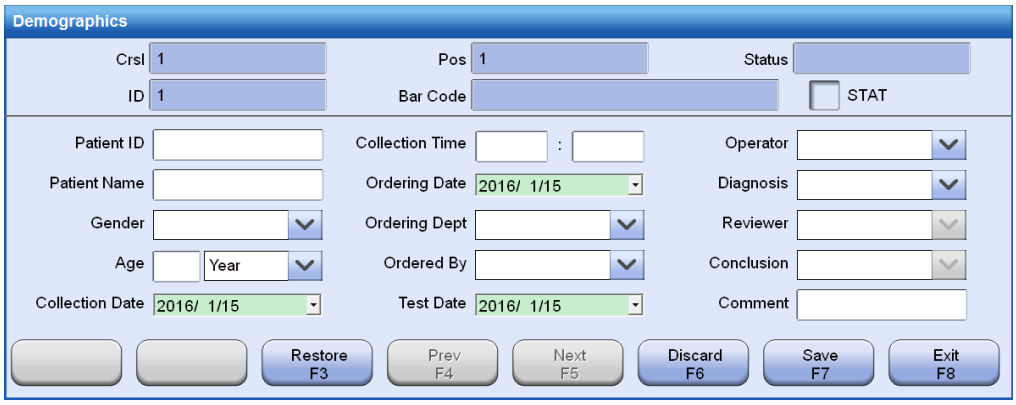
1 Select **Result > Current** or **History**.

2 Choose the **By Sample** option.

3 Choose a sample in the sample list.

4 Select **Demog F3**.

Figure 6.25 Demographics window



Patient demographics can be customized. For more information, see 6.3.7Customizing patient demographics on page 6-22.

5 Edit the related patient information:

6 Select **Save F7** to save your input.

7 To obtain the default values, select **Restore F3**.

8 Select **Exit F8** to close the window.

6.4.5 Viewing reaction curve

A reaction curve reflects the relationship of the absorbance measured at the primary wavelength, secondary wavelength and primary-secondary wavelength. It is drawn based on the absorbance of the sample-reagent mixture measured within the reaction period.

Observing reaction curve and data is not applicable to ISE chemistry, off-system chemistry, and special calculation.

Viewing reaction curve

1 Search for desired samples on the **Current** or **History** screen.

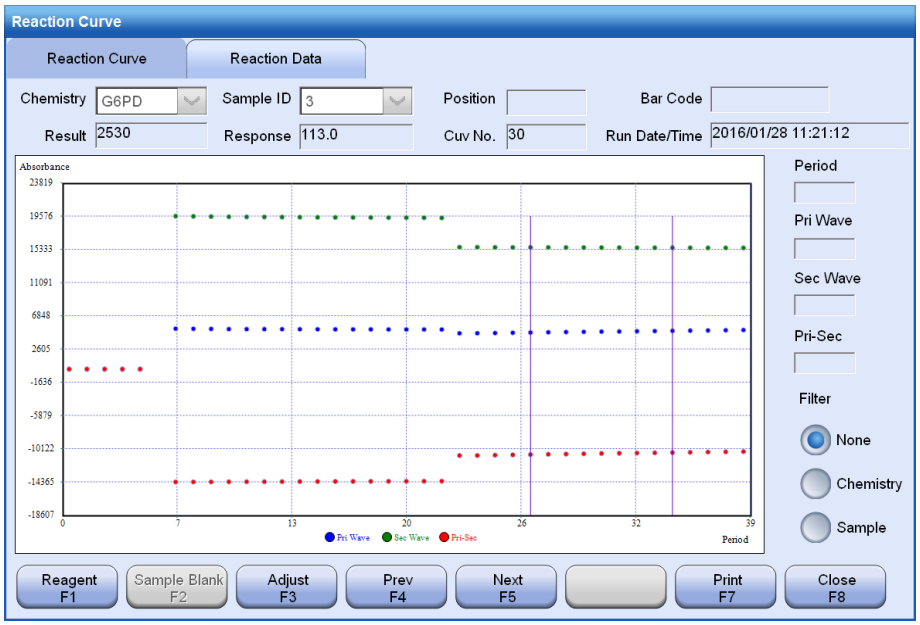
2 Choose a result recall mode:

- By sample
- By chemistry

3 Choose desired result in the result list.

4 Select **Reac Curve F4**. The **Reaction Curve** window is displayed.

Figure 6.26 Sample reaction curve



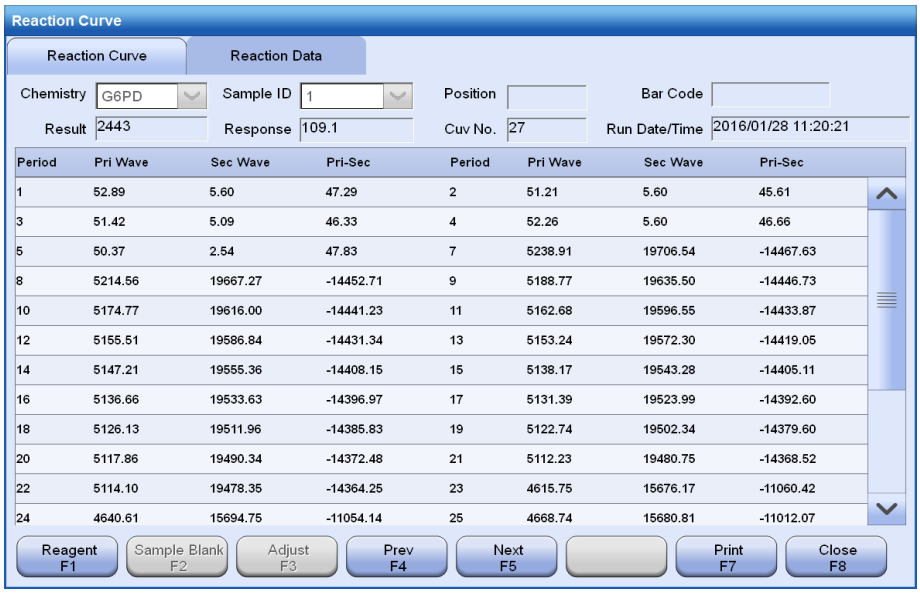
5 Select a point on the curve. Relevant measuring period and absorbance are displayed on the right of the window.

6 Select a filter condition from the following options:

- None: observe reaction curve and data in the default mode.
- Chemistry: observe reaction curve of the results for the selected test.
- Sample: observe reaction curve of the results for the selected sample.

7 Choose the **Reaction Data** tab to view the reaction data.

Figure 6.27 Sample reaction data



Period	Pri Wave	Sec Wave	Pri-Sec	Period	Pri Wave	Sec Wave	Pri-Sec
1	52.89	5.60	47.29	2	51.21	5.60	45.61
3	51.42	5.09	46.33	4	52.26	5.60	46.66
5	50.37	2.54	47.83	7	5238.91	19706.54	-14467.63
8	5214.56	19667.27	-14452.71	9	5188.77	19635.50	-14446.73
10	5174.77	19616.00	-14441.23	11	5162.68	19596.55	-14433.87
12	5155.51	19586.84	-14431.34	13	5153.24	19572.30	-14419.05
14	5147.21	19555.36	-14408.15	15	5138.17	19543.28	-14405.11
16	5136.66	19533.63	-14396.97	17	5131.39	19523.99	-14392.60
18	5126.13	19511.96	-14385.83	19	5122.74	19502.34	-14379.60
20	5117.86	19490.34	-14372.48	21	5112.23	19480.75	-14368.52
22	5114.10	19478.35	-14364.25	23	4615.75	15676.17	-11060.42
24	4640.61	15694.75	-11054.14	25	4668.74	15680.81	-11012.07

8 Choose the following buttons as needed:

- **Reagent F1:** to view the reagents used for sample analysis, calibrators and reagents used in calibration, and reagents for reagent blank test.
- **Sample Blank F2**: to view the sample blank reaction curve and reaction data of the selected sample.
- **Adjust F3**: to adjust the absorbance display range of current reaction curve. Refer to the following page for details.

- **Prev F4**: to view the reaction curve and data of the previous test.
- **Next F5**: to view the reaction curve and data of the next test.
- **Print F7**: to print the current reaction curve or data.

9 Select **Close F8** to close the window.

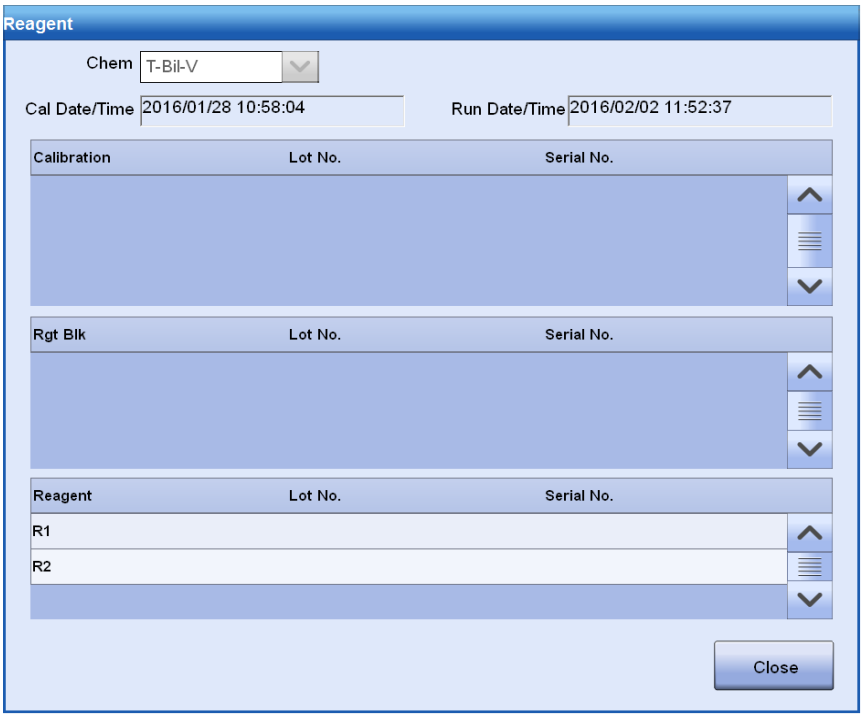
Viewing reagent information

On the reaction curve window, you are allowed to view the reagents in sample measurement, the calibrators and reagents used in calibration, and reagents for reagent blank test.

To view reagent information

1 Select **Reagent F1** on the **Reaction Curve** window.

Figure 6.28 Reagent window



The window shows the calibration date and time; sample measurement date and time; calibrators, reagents for reagent blank test; and reagents for sample analysis.

2 Select **Close** to exit the window.

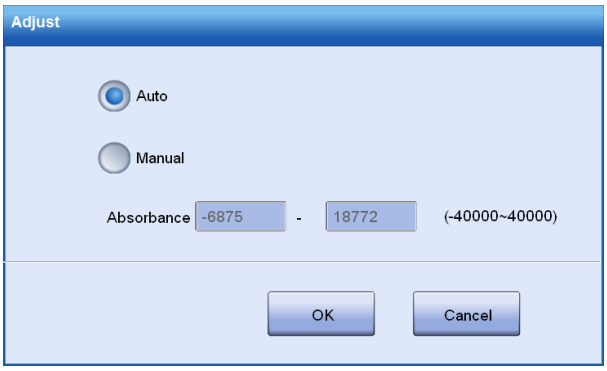
Adjusting display range

The maximum absorbance display range of reaction curve can be adjusted automatically or manually. The adjustment is only applicable to the currently-displayed curve, which will restore the default display when opened next time.

To adjust display range

1 Select **Adjust F3** on the **Reaction Curve** window.

Figure 6.29 Adjust window



2 Choose an adjustment mode:

- Auto: The system automatically determines the display range of X axis (measuring period) and Y axis (absorbance) according to the reaction data.
- Manual: The system displays the reaction curve according to the specified absorbance range. Input the absorbance range (-40000-40000).

3 Select **OK**. The current reaction curve is refreshed accordingly.

6.4.6 Sending 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.

To send results to LIS host

1 Search for desired samples on the **Current** or **History** screen.

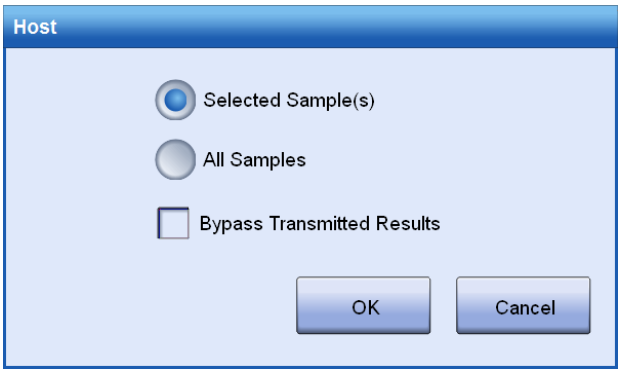
2 Choose the **By Sample** option.

3 To transmit single or multiple samples, select them in the sample list.

4 To transmit all samples, do not select any samples.

5 Select **Host F8**.

Figure 6.30 Transmit Results window



6 Select the sample range you want to transmit:

- Selected sample(s)
- All samples

7 If you transmit all samples, you are allowed to skip those results that are already transmitted to the LIS host. Mark the **Bypass Transmitted Results** checkbox.

8 Select **OK**.

6.4.7 Printing results

Samples can be printed manually on the **Current Results** and **History Results** 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, or all samples to be printed out.

Printing results by sample

You can print test results of one or more samples when they are recalled by sample.

To print results by sample

1 Search for desired samples on the **Current** or **History** screen.

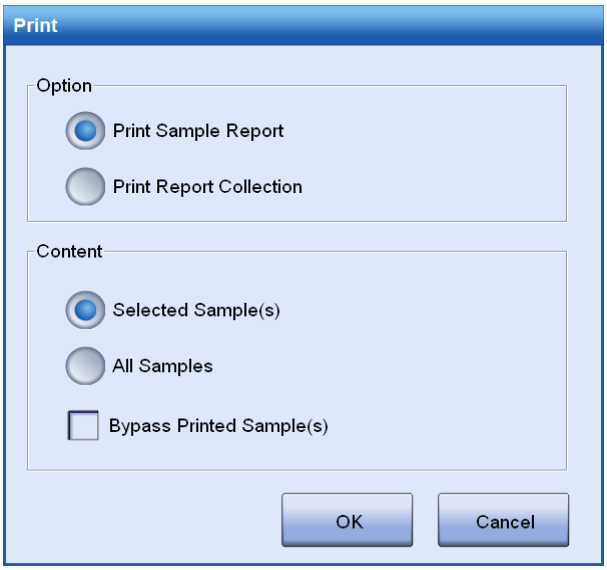
2 Choose the **By Sample** option.

3 To print single or multiple samples, select them in the sample list.

4 To print all samples, do not select any samples.

5 Select **Print F7**.

Figure 6.31 Print window



6 Select **Print Sample Report**.

7 Choose the print range:

- Selected Sample(s)
- All Sample(s)

8 If you print all samples, you are allowed to skip those that are already printed out. Mark the **Bypass Printed Sample(s)** checkbox.

9 Select **OK**.

Printing results by chemistry

You can print test results of one or more chemistries when they are recalled by chemistries.

To print results by chemistry

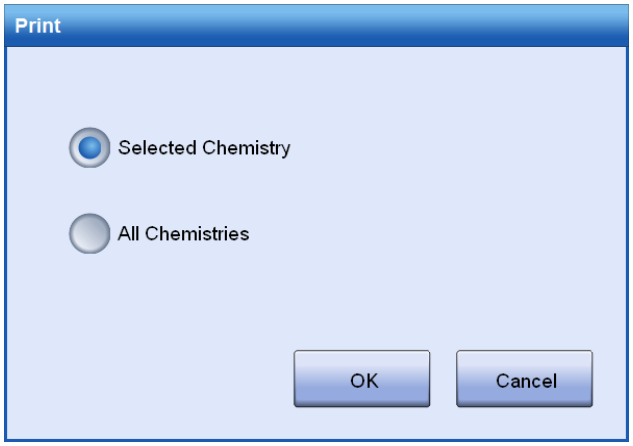
1 Search for desired samples on the **Current** or **History** screen.

2 Choose the **By Chemistry** option.

3 To print single chemistry in the chemistry list, select it; to print all chemistries, there is no need to select them.

4 Select **Print F7**.

Figure 6.32 Print window



5 Choose the print range:

- Selected chemistry
- All chemistries

6 Select **OK**.

6.4.8 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 chemistry can be edited. Edited results will be flagged for distinguishing from others.

Only the samples that have been analyzed and have results can be edited. For those tests that are run for over one time, result of each run can be edited. For rerun tests, only the default result can be edited.

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.

To edit results

1 Select **Result > Current** or **History**.

2 Choose a result recall mode:

- By sample
- By chemistry

3 Select **Search F1** to search for desired results.

4 Choose a sample or chemistry in the sample list which includes the off-system chemistries as well.

5 Select **Options F2**, and select **Edit Results**.

The screen shows the samples or chemistry and all measured results.

Figure 6.33 Edit Results window – By sample (Current results)

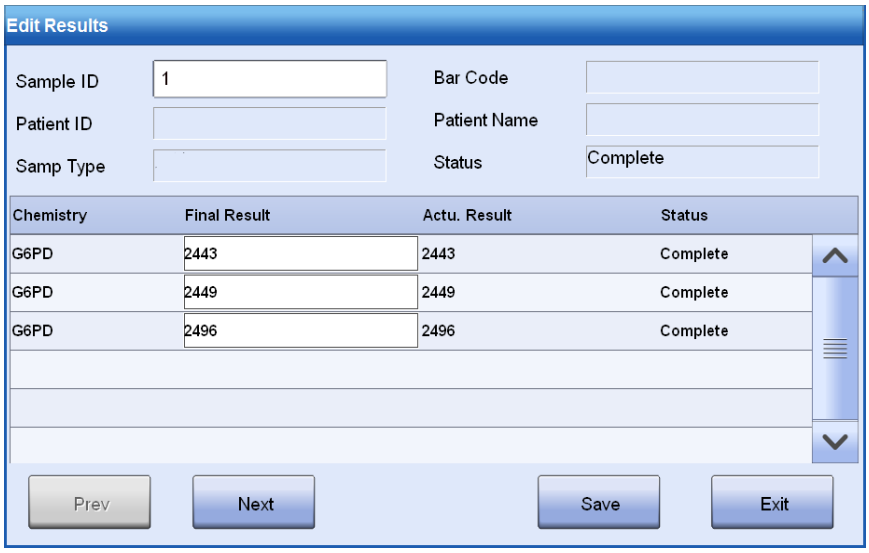


Figure 6.34 Edit Results window – By sample(History results)

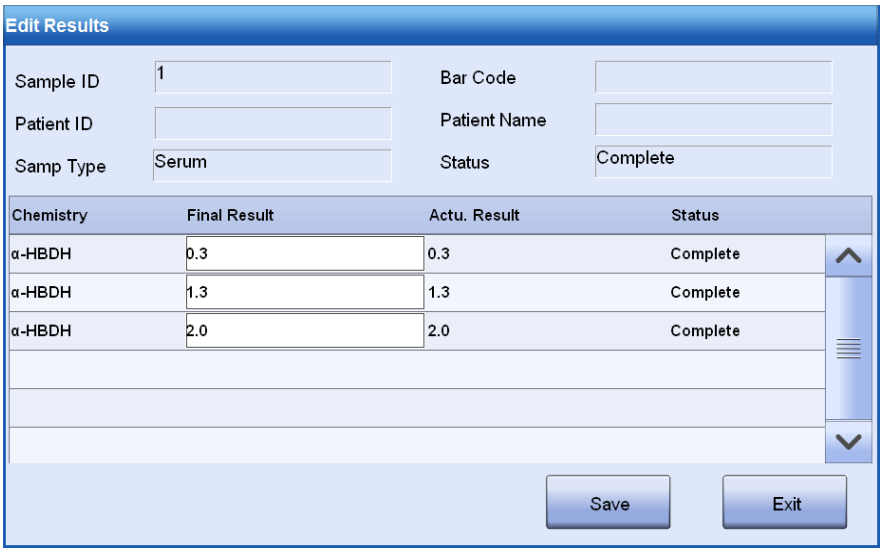


Figure 6.35 Edit Results window – By chemistry

6 Choose a chemistry to edit, and then input result in the **Final Result** column.

- For normal runs, only Complete chemistries can be edited.
- For reruns, only the default result can be edited.

7 Select **Save** to save your editing.

8 Select **Exit** to close the window.

6.4.9 Deleting results

The system has a limited storage capacity, and when it is exceeded, the results with the earliest date will be overridden. 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.

To delete results

1 Select **Result > Current** or **History**.

2 Choose a result recall mode:

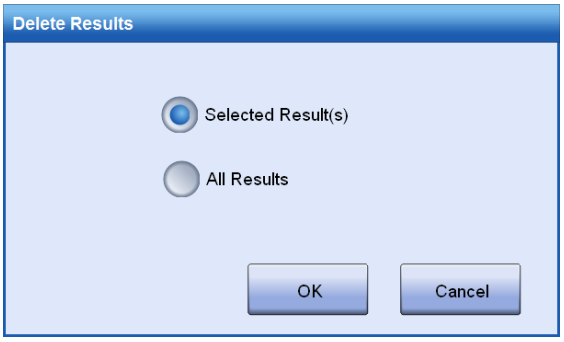
- By sample
- By chemistry

3 Select **Search F1** to search for desired results.

4 When recalling results by sample, choose samples in the sample list. When recalling results by chemistry, choose a chemistry in the left list.

5 Select **Options F2**, and select **Delete Results**.

Figure 6.36 Delete Results window



6 Choose the sample range:

- Selected result(s): to delete the results of the selected samples or chemistries.
- All results: to delete all results on the screen.

7 Select **OK**.

6.4.10 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 chemistry, only the result list can be tailored.

To customize result display

1 Select **Result > Current** or **History**.

2 Choose a result recall mode:

- By sample

- By chemistry

3 Select **Options F2**, and select **Customize Result Display**.

Figure 6.37 Customize Result Display window – By sample

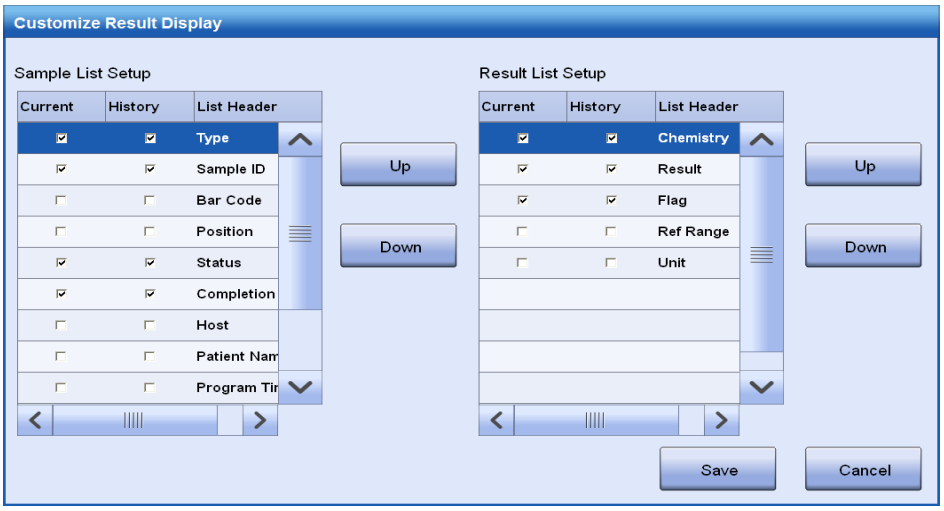
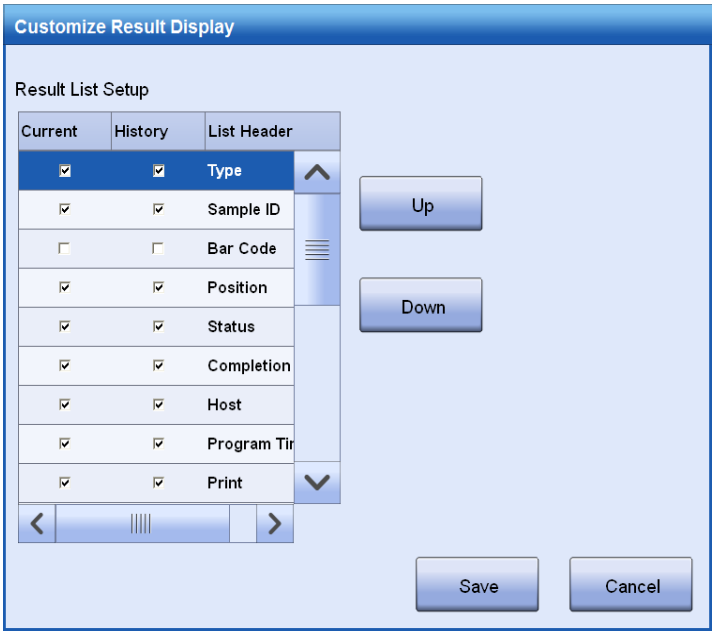


Figure 6.38 Customize Result Display window – By chemistry



4 If recalling results by sample,

a. To forbid display of a header name in the sample list, deselect the corresponding checkbox.

b. 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.

c. Choose desired header names 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.

5 If recalling results by chemistry,

a. To forbid display of a header name in the result list, deselect the corresponding checkbox.

b. Choose desired header names in the **Result List Setup** area. Use the **Up** and **Down** buttons to adjust the display order of the header names.

6 Select **Save** to save the settings and close the window.

6.4.11 Recalculating results

The Recalculate Results option is used to recalculate current sample results with the latest valid calibration factors of relevant chemistry. This option is often used when test result cannot be calculated due to incomplete or failed calibration.

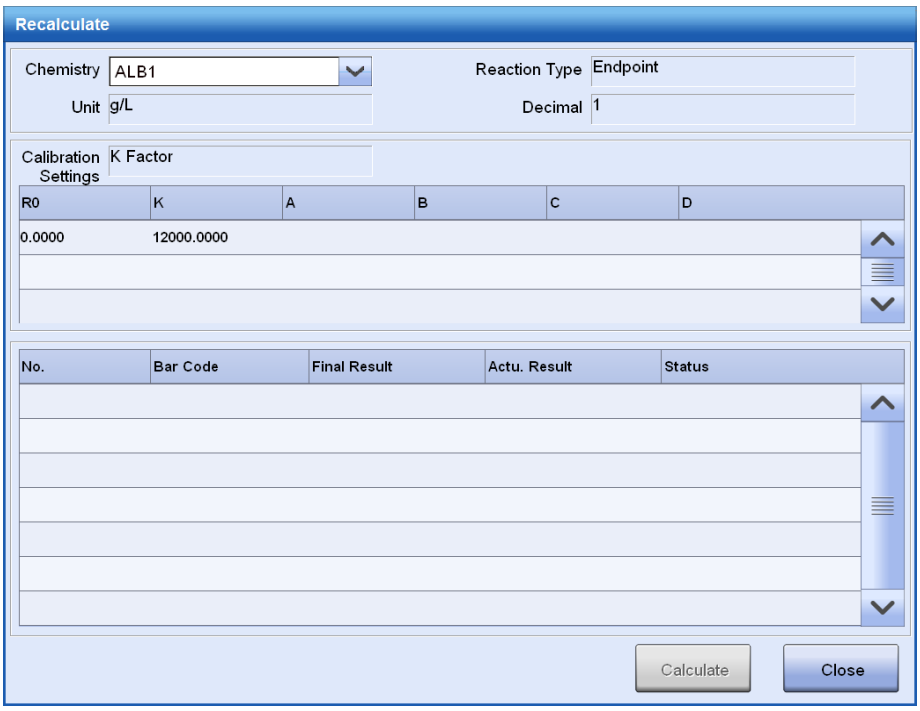
Recalculate Results is only applicable to biochemistries. Result of samples in In Progress status cannot be recalculated. The recalculation will be automatically recorded in event logs.

To recalculate results

1 Select **Result > Current**.

2 Select **Options F2**, and select **Recalculate**.

Figure 6.39 Recalculate window



3 Choose a chemistry from the **Chem** drop-down list.

4 Select **Calculate**.

Results of the selected chemistry for the specified samples are recalculated automatically with the latest calibration factors and then displayed in the list at the bottom.

5 Select **Close** to exit the window.

6.4.12 Compensating results

The Compensate Results option is used to recalculate multiple results of certain biochemistry through the linear formula Y=K*X+B with specified slope K and offset B.

Compensate Results is invalid for ISE chemistry, special calculations and off-system chemistries. A calculation will be recalculated automatically once its constituent chemistries are compensated. Only users that have sufficient permissions are allowed to compensate results. The compensation will be automatically recorded in event logs.

To compensate results

1 Select **Result > Current** or **History**.

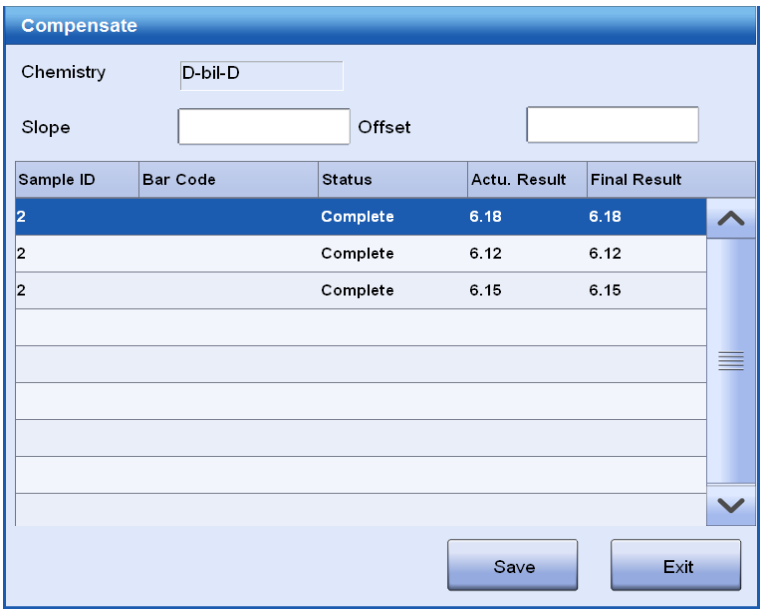
2 Choose the **By Chemistry** option.

3 Choose the chemistry that you want to compensate in the left list.

4 Select **Options F2**, and select **Compensate Results**.

All results of the chemistry are displayed in the list at the bottom.

Figure 6.40 Compensate window



5 Input the slope K and offset B.

6 Select **Save**.

The system recalculates all results of the chemistry with the specified slope and offset. The final results are displayed in the list of the window.

7 Select **Exit** to close the window.

6.4.13 Recalling result trend

Result trend allows you to observe the result trend of the selected chemistry.

To recall result trend

1 Select **Result** > **Current** or **History**.

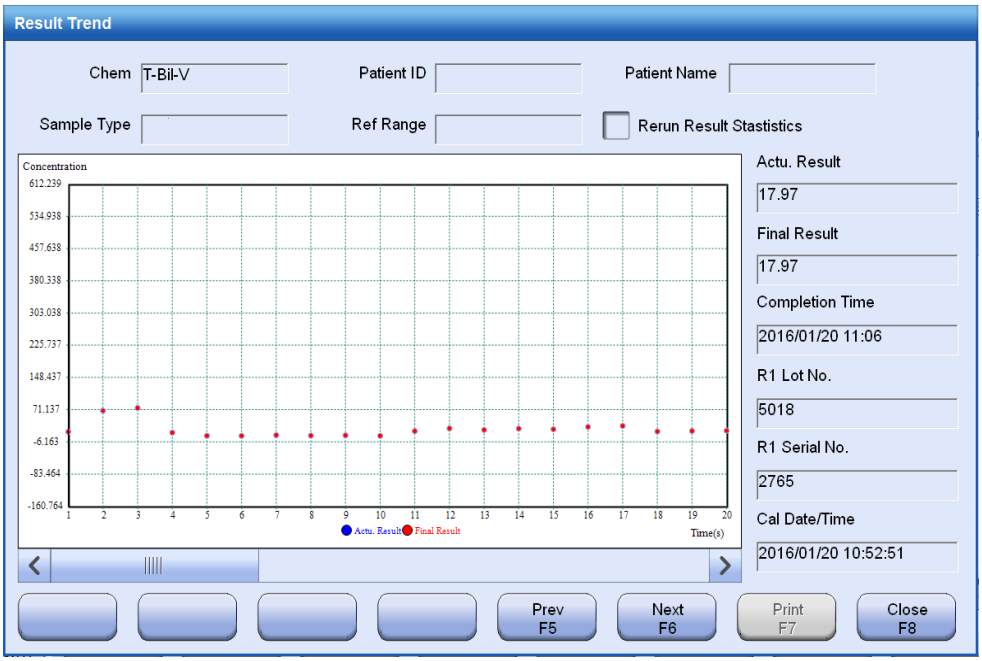
2 Choose the result recall mode - By chemistry.

3 Select **Search F1** to search for desired results.

4 Choose a chemistry in the left list.

5 Select **Options F2**, and select **Recall Result Trend**.

Figure 6.41 Result Trend window



6 Move the cursor to certain point on the graphic trend. The actual result, final result, completion time, reagent lot number, serial number, and calibration time are displayed on the right of the window.

7 To show all results of repeated analysis or rerun tests, select the **Include Replicate Results** checkbox.

8 To observe result trend of other sample tests, select **Prev F1** or **Next F2**.

9 Select **Exit F8** to close the window.

6.4.14 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. which cannot be edited.

To archive sample results and data

1 Search for desired sample results on the **Current** or **History** 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 **Options F2**.

3 Select **Archive**.

4 Select **OK**.

6.5 Test statistics

On the Tests screen, you can view test requests and reagent application for each chemistry during a period, and you can sample requests and the quantity of its chemistries as well. Calibration test and QC test are not included in the statistics.

To view test statistics

1 Select **Result > Statistics > Tests**.

2 Select **By Sample** or **By Test**.

Figure 6.42 Tests screen - By sample

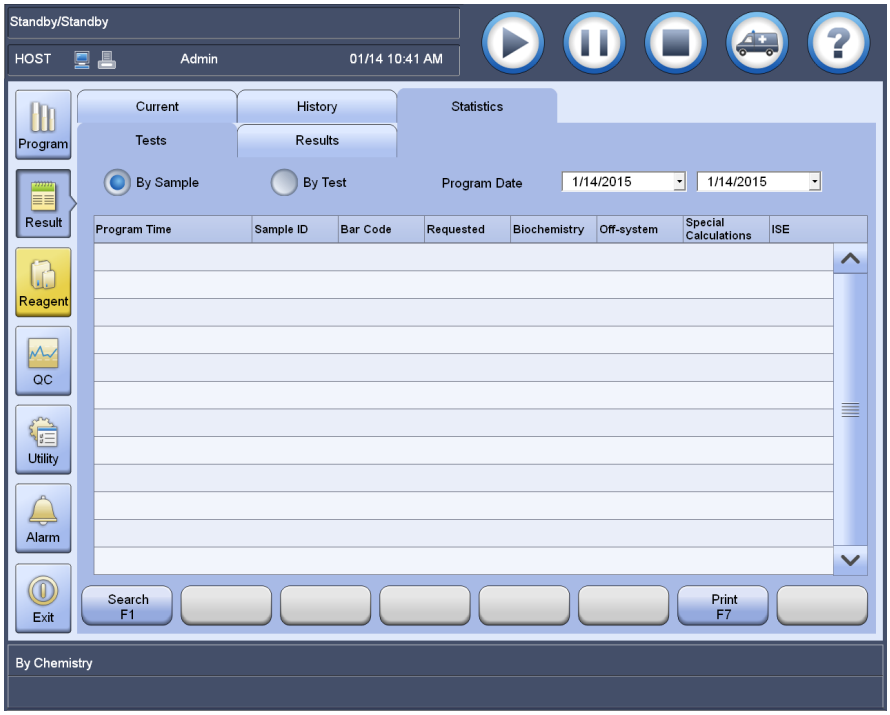
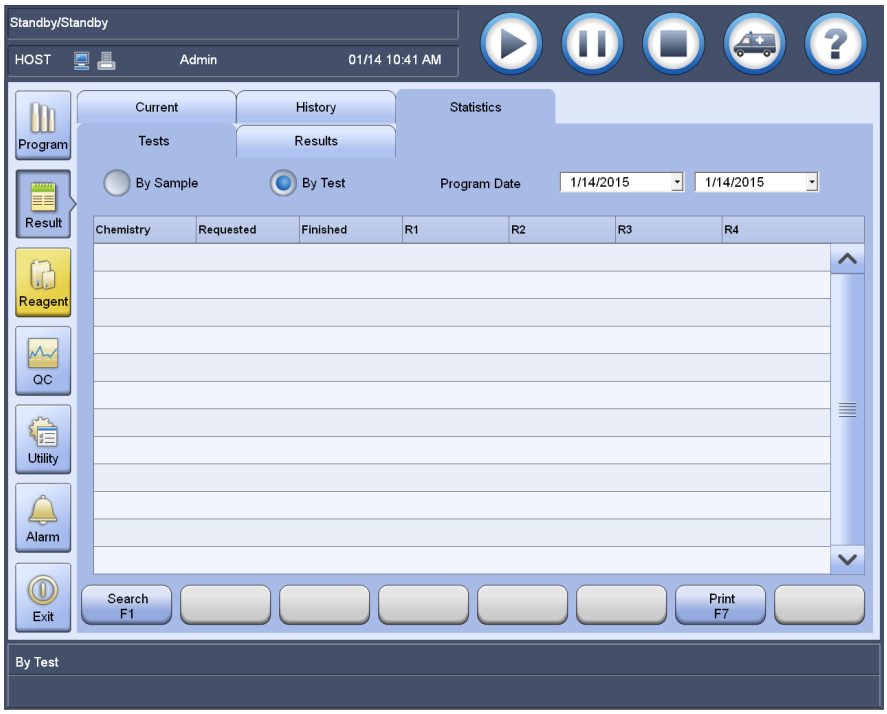


Figure 6.43 Tests screen - By test



- By Sample: To view all requested samples and the quantity of its requested chemistries.
- By Test: To view test requisitions and reagent volume for the chemistries.

3 Select or enter the start date and end date in the **Date** field. the start date cannot be later than the end date.

4 Select **Search F1**.

All samples or tests requested during the period are displayed in the middle list of the **Tests** screen.

5 Select **Print** to print out the currently displayed statistic information of measurements.

6.6 Result statistics

Result statistics option can summarize the total chemistries and the distribution trend of its results and provide the test data and graph. Calibration and control tests are not included in the statistics.

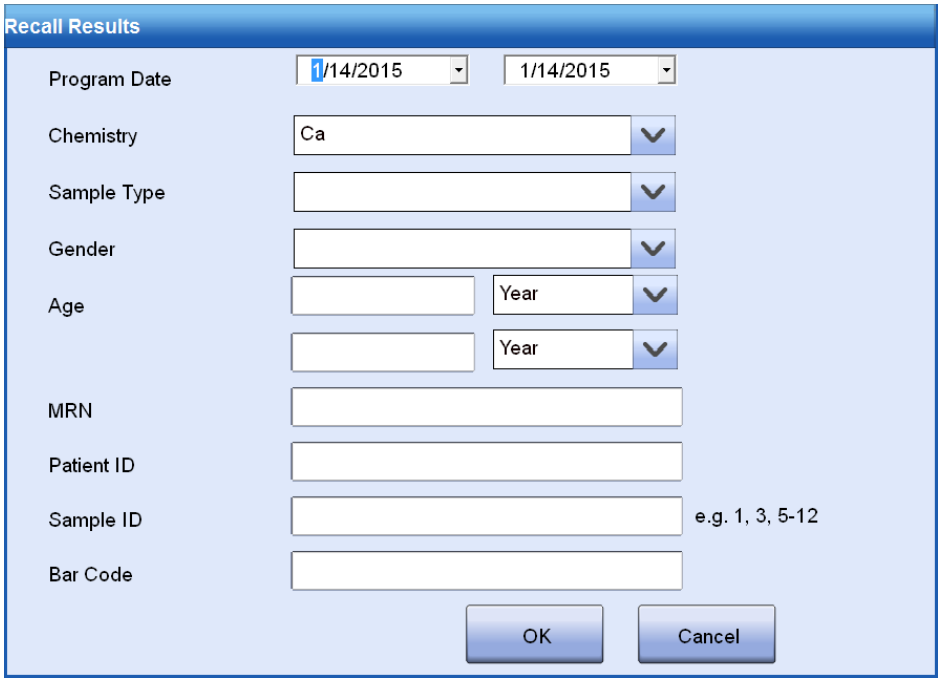
1 Select **Result > Statistics**.

2 Select the **Results**.

3 Select **Statistic Graph** or **Statistic Data**.

4 Click **Search F1**. The **Recall results** box pops up.

Figure 6.44 Recall results window



5 Input one or more search conditions.

6 Click **OK**.

The statistic results matching the search conditions are displayed.

Figure 6.45 Result statistics screen -statistic graph

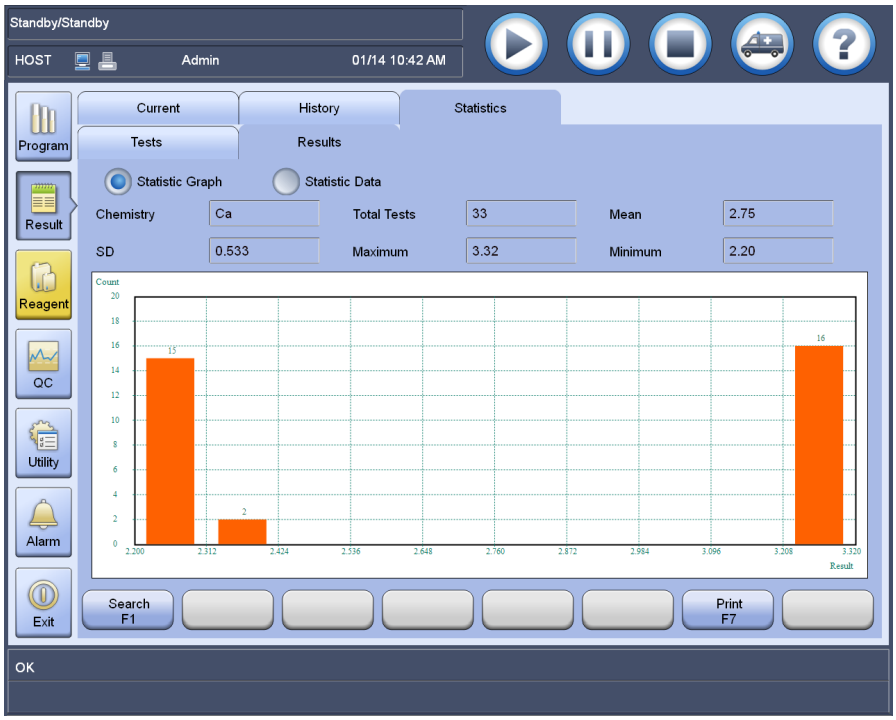
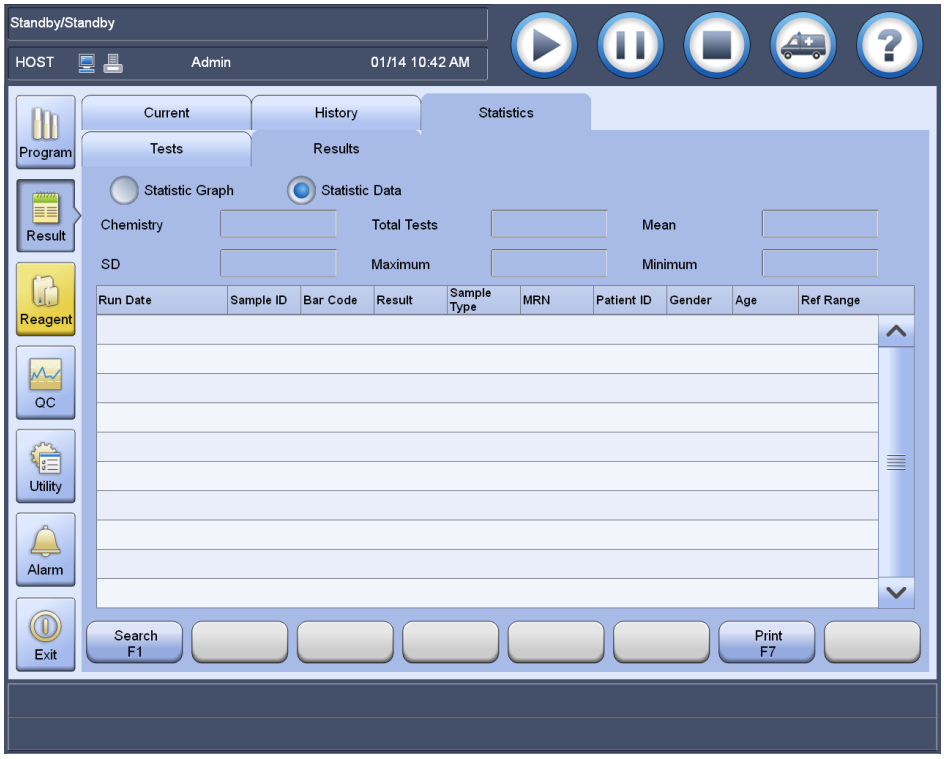


Figure 6.46 Result statistics screen -statistic data



7 Select **Print F7** to print out the statistic graph and statistic data.

7 Chemistry

This chapter describes the setup methods of closed-/open-reagent chemistries and special chemistries, as well as the extended chemistry functions.

7.1 Importing/Exporting chemistries

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

A maximum of 300 open-/closed-reagent chemistries can be imported. When chemistries are imported, they are enabled by default if set up correctly. If the number of open-reagent chemistries imported exceeds the maximum limit, the excessive open-reagent chemistries will be disabled.

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

CAUTION

While importing chemistries, do not switch off the analyzing unit main power or exit the operating software.

If an imported chemistry is no longer needed, it can be deleted with the **Delete F2** button on the **Chemistries** screen.

7.1.1 Importing default chemistry list

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

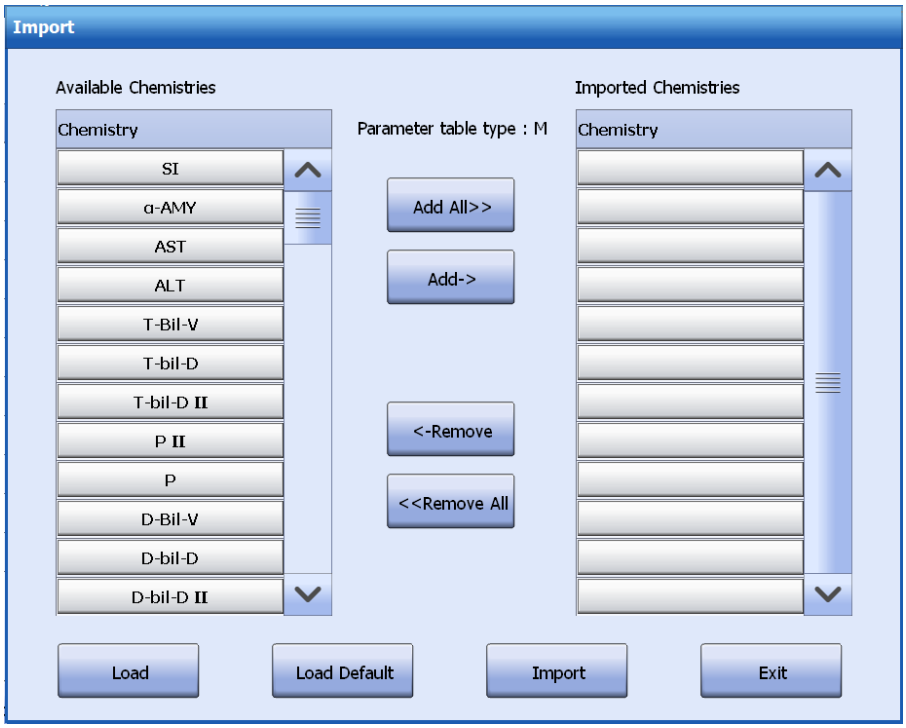
Only the full name, print name, result unit, decimal places, and error detection limits can be edited, while others can only be browsed.

The letter "M" is shown to remind that the parameter table for reagents with ml package is imported. If the parameter table for reagents with number of test package is imported, the letter "T" will be displayed.

To import default chemistry list

1. Select **Utility > Chemistries**, select **Config F3**.
2. Select **Options**, and then select **Import**.

Figure 7.1 Import window



3 Select **Load Default**.

All chemistries contained in the default parameter form are displayed in the **Available Chemistries** list.

4 Use the following buttons to import desired chemistries:

- **Add All>>**: add all chemistries in the **Available Chemistries** list to the **Imported Chemistries** list.
- **Add ->**: add the selected chemistries in the **Available Chemistries** list to the **Imported Chemistries** list.
- **<-Remove**: remove the selected chemistries from the **Imported Chemistries** list.
- **<<Remove All**: remove all chemistries from the **Imported Chemistries** list.

5 Select **Import**.

All imported chemistries are enabled by default and can be used for measurement. If the result unit is changed, the corresponding chemistry must be recalibrated.

6 Select **Exit**.

7.1.2 Importing specified chemistry list

Open-reagent chemistries can be imported from a .csv file. The open-reagent chemistries include biochemistries, as well as the processing parameters, error detection limits, slope and offset.

To import specified chemistry list

1 Select **Utility > Chemistries**, select **Config F3**, and then **Options**.

2 Select **Import**.

3 Select **Load**.

4 Locate the path of the parameter form, select a .csv file, and then select **Open**.

All chemistries contained in the parameter form are displayed in the **Available Chemistries** list.

5 Use the following buttons to import desired chemistries:

- **Add All>>**: add all chemistries in the **Available Chemistries** list to the **Imported Chemistries** list.
- **Add ->**: add the selected chemistries in the **Available Chemistries** list to the **Imported Chemistries** list.
- **<-Remove**: remove the selected chemistries from the **Imported Chemistries** list.
- **<<Remove All**: remove all chemistries from the **Imported Chemistries** list.

6 Select **Import**.

All imported chemistries with correct parameters are enabled by default and can be used for measurement. If you change any of the following parameters of an imported chemistry, recalibrate the chemistry:

- Reaction type
- Primary wavelength
- Secondary wavelength
- Reaction direction
- Reaction time
- Blank time
- Result unit
- Standard sample volume, diluting sample volume and diluent volume
- Reagent volume
- Sample blank
- Twin chemistries
- Pretreatment parameters

7 Select **Exit**.

7.1.3 Exporting chemistries

Open-reagent chemistries, as well as the processing parameters, error detection limits and slope and offset, can be exported to a storage device.

To export chemistries

1 Select **Utility > Chemistries**, select **Config F3** and then **Options**.

2 Select **Export**.

Figure 7.2 Export window

3 Use the following buttons to export desired chemistries:

- **Add All>>**: add all chemistries in the **Available Chemistries** list to the **Exported Chemistries** list.
- **Add ->**: add the selected chemistries in the **Available Chemistries** list to the **Exported Chemistries** list.
- **<-Remove**: remove the selected chemistries from the **Exported Chemistries** list.
- **<<Remove All**: remove all chemistries from the **Exported Chemistries** list.

4 Select **Export**.

5 Select the path to export and input the file name.

The default file name is composed of the current date and time, such as 20140827_0951. The file format is .csv.

6 Select **Save**.

7 Select **Exit**.

7.2 Biochemistry setup

This section describes the setup of open-reagent chemistry and closed-reagent chemistry.

7.2.1 User-defined chemistry setup

User-defined chemistry, also called open-reagent chemistry, can be defined, edited and deleted. Only when the system status is Standby, Incubation or Stopped, can be operations be done.

Defining a chemistry

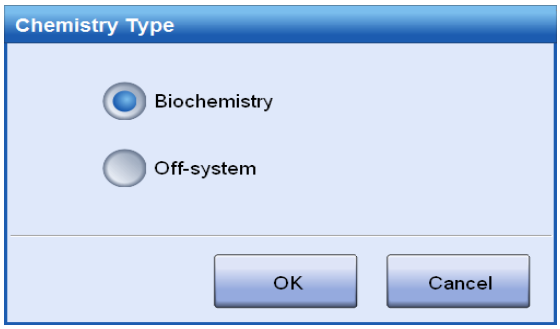
Up to 200 chemistries can be defined.

To define a chemistry

1 Select **Utility > Chemistries**.

2 Choose a blank frame in the chemistry list, and select **Define F1**.

Figure 7.3 Chemistry Type window



Biochemistry is selected by default.

3 Select **OK**.

4 Set the processing parameters and error detection limits of the chemistry.

For more information on setup of processing parameters and error detection limits, see 7.2.2Processing parameters on page 7-7 and 7.2.3Error detection limits on page 7-12.

5 Select **Save F7** to save your input information.

6 Select **Close F8** to exit the window.

7 To set up the reference range, select **Ref Range F4**.

8 To set up slope and offset, select **Slop/Offset F5**.

Editing user-defined chemistry

You are allowed to edit user-defined chemistries if:

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

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

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

- Primary wavelength
- Secondary wavelength
- Blank time
- Reaction time
- Reagent volume
- Standard sample volume, diluting sample volume and diluent volume
- Reaction type
- Reaction direction
- Sample blank and result unit
- Twin chemistries
- Pretreatment parameters

Deleting a user-defined chemistry

Make sure that you have sufficient permission to delete a chemistry you have defined. When a chemistry is deleted, all relevant test results, data and parameters are cleared.

To delete a user-defined chemistry

1 Remove the reagent from the reagent carousel.

2 Select **Utility > Chemistries**.

3 Select the chemistry in the chemistry list.

4 Check if the following conditions are satisfied:

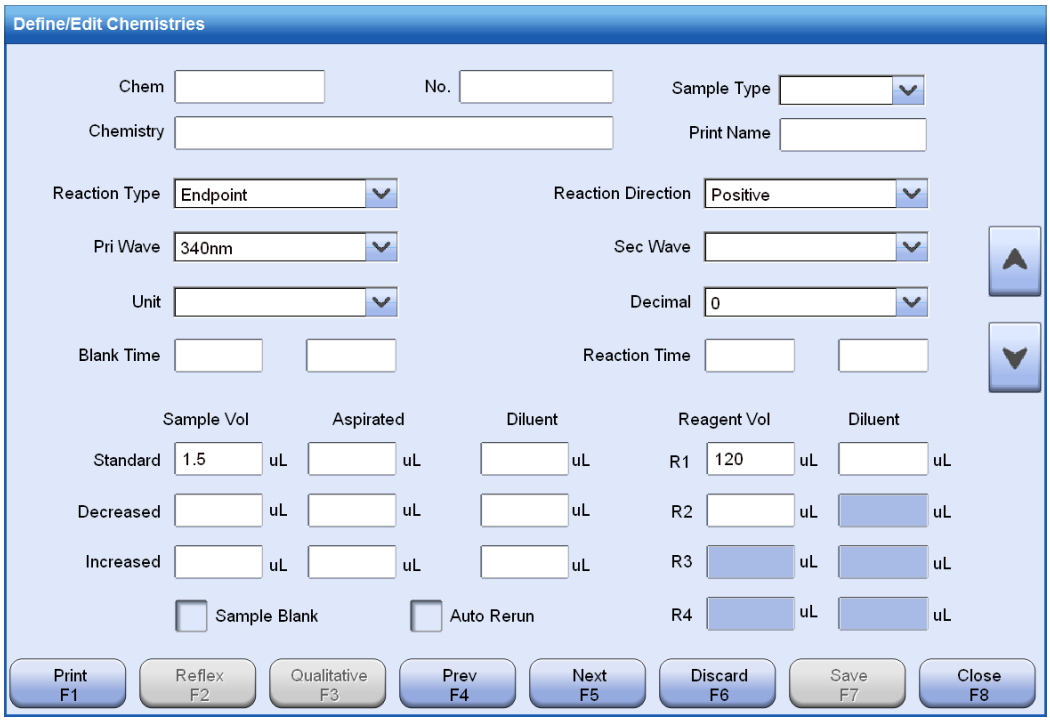
- The selected chemistry is not requested or run for samples, calibrators and controls.
- The selected chemistry is disabled.
- The corresponding reagent has been unloaded from the reagent carousel.

5 Select **Delete F2**.

7.2.2 Processing parameters

This section describes the setup of processing parameters. The processing parameters setup window is as shown below:

Figure 7.4 Processing parameters setup window



Chem

Chemistry name is the only identity of a chemistry and must not be duplicate. A chemistry name can be composed of up to 10 characters.

No.

No. is a unique number for chemistry. It can be left blank but must not be duplicate. Chemistry number is composed of numbers, and it ranges from 1-400 for open-reagent chemistries.

Sample type

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

The system allows definition of chemistry parameters for more than one sample type, including the processing parameters and error detection limits. During definition of chemistries, the parameters should be firstly defined for serum sample, and then other sample types. Such chemistries will be calibrated with serum sample parameters by default.

Chemistry

Chemistry is the complete form of chemistry name. It can be composed of up to 50 characters. The input is not case sensitive. The **Chemistry** field can be left blank or duplicate.

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

Print Name

Print name is displayed on patient reports representing a chemistry. 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 chemistry name will appear on reports. A chemistry is represented by its short name on all reports other than patient reports.

Reaction Type

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

Table 7.1 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, 405nm, 450nm, 510nm, 546nm, 578nm, 630nm, and 670nm.

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, 405nm, 450nm, 510nm, 546nm, 578nm, 630nm, and 670nm.

Unit

Changing the result units of the chemistries are allowed.

- For closed-reagent chemistries, 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 chemistries, 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.

Decimal

Decimal specifies the number of decimal places for test results. The decimal is allowed to be edited. Up to 3 decimal places can be set up and respectively correspond to 0, 0.1, 0.01 and 0.001.

Incubation Time, Blank Time and Reaction Time

Incubation time refers to the period between sample addition and R2 addition. It is applicable to double-reagent chemistry.

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.

Incubation time, blank time and reaction time are counted in measuring points. Suppose the incubation time is F, the blank time range is N-P and the reaction time range is L-M.

For single-reagent chemistry, 0 point is the measuring point at which sample is added; for double-reagent chemistry, 0 point is the measuring point at which R2 is added.

Table 7.2 Input range of incubation time, blank time and reaction time for endpoint analysis

Endpoint	Blank time	Reaction time	K
When the blank absorbance is read before the reaction begins,			
Single-reagent	1≤N≤P≤5	7≤L≤M≤39	K1
Double-reagent	7≤N≤P≤22	23≤L≤M≤39	K2
Triple-reagent	23≤N≤P≤47	53≤L≤M≤86	K3
Quadruple-reagent	53≤N≤P≤68	69≤L≤M≤86	K4
When the blank absorbance is read after the reaction begins,			
Single-reagent	7≤N≤P	P<L≤M≤39	1
Double-reagent	23≤N≤P	P<L≤M≤39	1
Triple-reagent	53≤N≤P	P<L≤M≤86	1
Quadruple-reagent	69≤N≤P	P<L≤M≤86	1
When the blank absorbance is not subtracted,			
Single-reagent	N=P=0	7≤L≤M≤39	0
Double-reagent	N=P=0	23≤L≤M≤39	0
Triple-reagent	N=P=0	53≤L≤M≤86	0
Quadruple-reagent	N=P=0	69≤L≤M≤86	0

Table 7.3 Input range of incubation time, blank time and reaction time for fixed-time

Fixed-time and Kinetic	Blank Time	Reaction Time	K
When the blank absorbance is read before the reaction begins,			
Single-reagent	1≤N<P≤5	7≤L<M≤39	K1
Double-reagent	7≤N<P≤22	23≤L<M≤39	K2
Triple-reagent	23≤N<P≤47	53≤L<M≤86	K3
Quadruple-reagent	53≤N<P≤68	69≤L<M≤86	K4
When the blank absorbance is not subtracted,			
Single-reagent	N=P=0	7≤L<M≤39	0
Double-reagent	N=P=0	23≤L<M≤39	0
Triple-reagent	N=P=0	53≤L<M≤86	0
Quadruple-reagent	N=P=0	69≤L<M≤86	0

Table 7.4 Input range of incubation time, blank time and reaction time for Kinetic analysis

Fixed-time and Kinetic	Blank Time	Reaction Time	K
When the blank absorbance is read before the reaction begins,			
Single-reagent	1≤N<P≤5	7≤L<M≤39	K1
Double-reagent	7≤N<P≤22	23≤L<M≤39	K2
Triple-reagent	23≤N<P≤47	53≤L<M≤86	K3
Quadruple-reagent	53≤N<P≤68	69≤L<M≤86	K4
When the blank absorbance is not subtracted,			
Single-reagent	N=P=0	7≤L<M≤39	0
Double-reagent	N=P=0	23≤L<M≤39	0
Triple-reagent	N=P=0	53≤L<M≤86	0
Quadruple-reagent	N=P=0	69≤L<M≤86	0

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 1.5 µL to 45µL with an increment of 0.1 µL. The default is 1.5 µL. 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 1.5 µL to 45 µL with an increment of 0.1 µL. 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 75 µL to 200 µL with an increment of 0.5 µL. 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 125μL - 295 μL; 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 1.5 μL to 45μL with an increment of 0.1 μL. 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 1.5 μL to 45μL with an increment of 0.1 μL. The default is blank. A maximum of one decimal is allowed.

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 blank is only effective for single-reagent endpoint chemistries.

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

Auto Rerun

The Auto Rerun option is used to rerun the chemistries when the auto rerun conditions are satisfied.

Mark the **Auto Rerun** checkbox means enabling the auto rerun option.

For more information about auto rerun, see 6.2.6Rerunning samples on page 6-7.

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,R2,R3 and R4.

Reagent	Reagent volume	Diluent volume	Reagent volume+ Diluent volume
Non-concentrated reagent			
R1~R4	10μl~200μl, with an increment of 0.5μl	N/A	10μl~200μl
Concentrated reagent			
R1	10μl~200μl, with an increment of 0.5μl	10μl~200μl,with an increment of 0.5μl	100μl~200μl
R2	10μl~200μl, with an increment of 0.5μl	10μl~200μl,with an increment of 0.5μl	10μl~200μl
R3	10μl~200μl, with an increment of 0.5μl	10μl~200μl,with an increment of 0.5μl	10μl~200μl
R4	10μl~200μl, with an increment of 0.5μl	10μl~200μl,with an increment of 0.5μl	10μl~200μl

- 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. The combined volume of all reagents, reagent diluent and sample must be within 100μl and 300μl. If your input does not satisfy the requirements of reaction mixture volume, the system will display an error message. Check the sample volume, reagent diluent and reagent volumes you have entered, and change them if necessary.

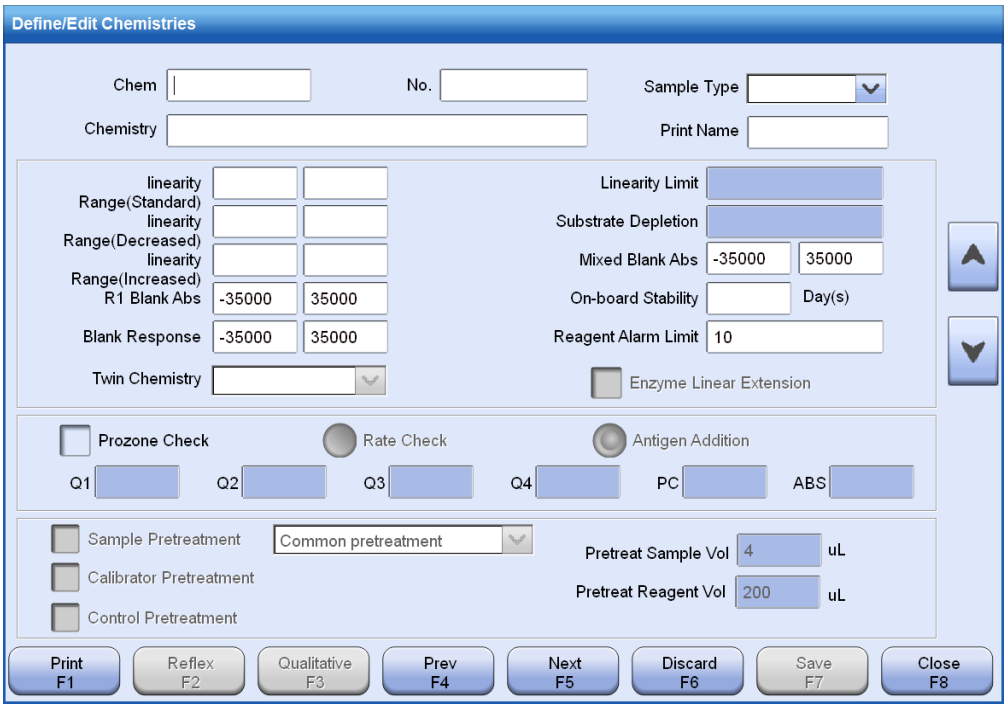
NOTE

The combined volume of all reagents and sample must be within 100 µL and 300 µL.

7.2.3 Error detection limits

This section describes the setup of error detection limits. The error detection limits setup window is as shown below:

Figure 7.5 Error detection limits setup 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 linearity range for standard, increased and decreased sample volume test should be set separately. The input should be no more than 12 digits, and the default is blank.

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 default is blank, which means not performing this check.

Linearity Limit

Linearity limit is only applicable to Kinetic analysis, in which the absorbance change is linear to the reaction time. If the reagent undergoes substrate depletion, or the photometer fluctuates, or the reaction mixture is not stirred evenly, the test results may be unreliable. Therefore, the linearity of the measuring period is calculated and then compared with the set linearity limit.

If the reaction data within the linearity range does not satisfy the linearity limit, the system will flag the test result with "LIN" on the patient report.

The linearity limit can be any number between 0 and 1 with a maximum of 2 decimals. 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 -35000-35000. The default is blank, which means not performing this check.

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 -35000-35000, 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 -35000-35000; the field can be left blank.

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 -35000-35000, 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 -35000-35000; the field can be left blank.

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 -35000-35000, 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 -35000-35000; the field can be left blank.

On-board Stability

It 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.

Twin Chemistry

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

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

📖 For more information about twin chemistries, see 7.5Twin chemistr on page 7-23.

Reagent Alarm Limit

Set up the reagent alarm limit for the chemistry. The input range is 1-100, and the default is 10. It can be left blank. When the number of chemistries left is lower than the limit, an alarm will occur; if no alarm limit is defined, the system will not give an alarm.

Only when sample type is Serum can reagent alarm limit be defined.

Enzyme Linear Extension

Linearity limit is only applicable to Kinetic analysis. Select this option to enable enzyme linear extension function.

📖 For more details of enzyme linear extension, see 13.5.6 on page 13-8.

Prozone Check

The Prozone check can be performed by means of rate check.

You are required to set up the following six parameters for the rate check method, which are Q1, Q2, Q3, Q4, PC and ABS. The unit is the same as the reaction time and blank time.

Enter the six parameters as follows:

- Single-reagent chemistries: 7≤q1<q2<q3<q4≤39. "7" is the first measuring point after the sample is dispensed and stirred.
- Double-reagent chemistries: 23≤q1<q2<q3<q4≤39. "23" is the first measuring point after R2 is dispensed and stirred.
- Triple-reagent chemistries: 53≤q1<q2<q3<q4≤86. "53" is the first measuring point after R3 is dispensed and stirred.
- Quadruple-reagent chemistries: 69≤q1<q2<q3<q4≤86. "69" is the first measuring point after R4 is dispensed and stirred.
- PC: a number between -99999999 and 99999999, with four decimals.
- ABS: any integer between -99999999 and 99999999.

Pretreatment

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

Only when the **Pretreatment** checkbox is selected, common pretreatment, blood cell pretreatment, pretreatment of calibrator and control can be enabled, and the pretreat sample volume and pretreatment reagent volume can be set.

Pretreatment chemistries cannot be set with predilution factor. To set pretreatment parameters for either of twin chemistries, remove the twin relation prior to the settings. Setting pretreatment parameters for the twin of a latter chemistry is not allowed.

Common Pretreatment

Select this option to pretreat the samples other than whole blood samples.

Blood Cell Pretreatment

Select this option to pretreat the whole blood samples.

Calibrator Pretreatment

When this option is enabled, the calibrators of the chemistry will be pretreated with the pretreatment reagent during calibration test according to the set calibrator volume and diluent volume.

Control Pretreatment

When this option is enabled, the controls of the chemistry 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 1.5 µL - 45 µL, with an increment of 0.1 µL. The default is 4 µL.

Pretreatment reagent volume

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

The sum of pretreat sample volume and pretreatment reagent volume must be within 110 µL - 245 µL.

7.2.4 Using qualitative result

When the analyzer is in the status of standby, incubation, or stopped, you can flag the result of the chemistries qualitatively and the results will be represented by a qualitative flag.

To use qualitative result

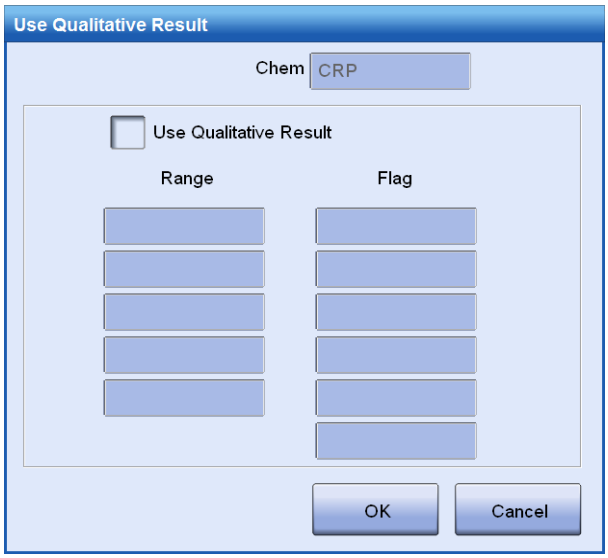
1 Select **Utility > Chemistries**.

2 Select the desired chemistry.

3 Select **Define F1**.

4 Select **Qualitative F3**.

Figure 7.6 Qualitative result window



5 Select **Use Qualitative Result**.

6 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 chemistry 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 chemistry 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.

7 Select **OK** to save the setup.

7.2.5 Slope and offset adjustment

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

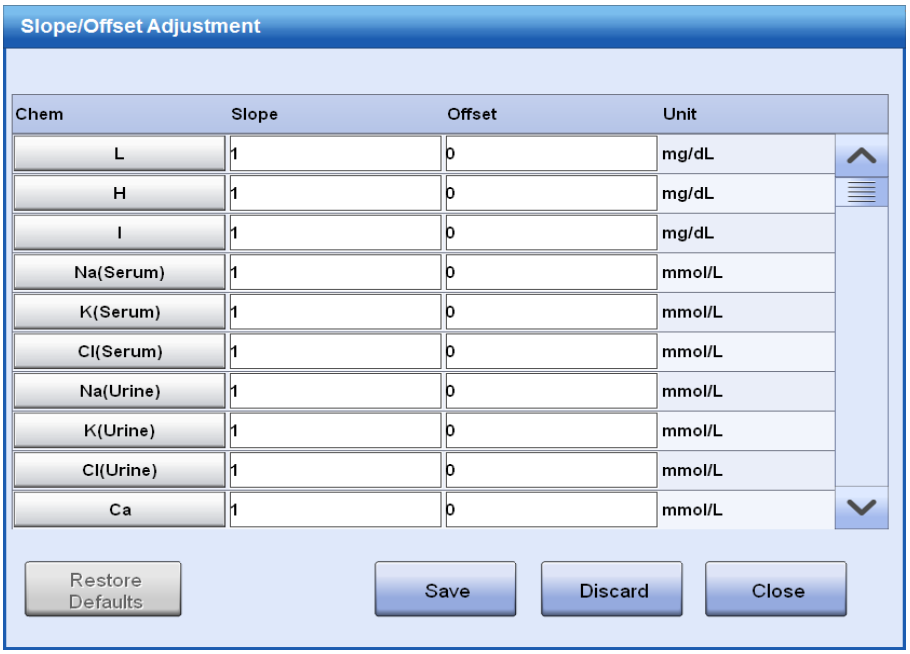
Before setting up the calculating factors, make sure that you have sufficient permissions and the system is not running tests.

To set up slope and offset

1 Select **Utility > Chemistries**.

2 Select **Slope/Offset F5**.

Figure 7.7 Slope/Offset Adjustment window



3 Choose a chemistry.

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

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

6 Select **Save** to save your input information.

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

8 Select **Close** the exit the window.

7.2.6 Reference/Critical range setup

The system allows the setup of reference/critical ranges for each chemistry.

- Reference range indicates the allowable concentration range of a normal sample.
- Critical range is the allowable result range from the perspective of clinical diagnosis.

If the calculated sample concentration is beyond the defined reference range or critical range, the following flags will be given:

Table 7.5 Flags for test result beyond reference range and critical range

Condition	Flag
Greater than the high limit of the reference range	^

Condition	Flag
Less than the low limit of the reference range	v
Greater than the high limit of the critical range	^!
Less than the low limit of the critical range	v!

The system provides auto rerun of ISE test. When ISE test result is beyond the set critical range, the ISE test will be rerun automatically.

Prior to defining the reference/critical range, ensure that you have sufficient permissions and the system status is not Running.

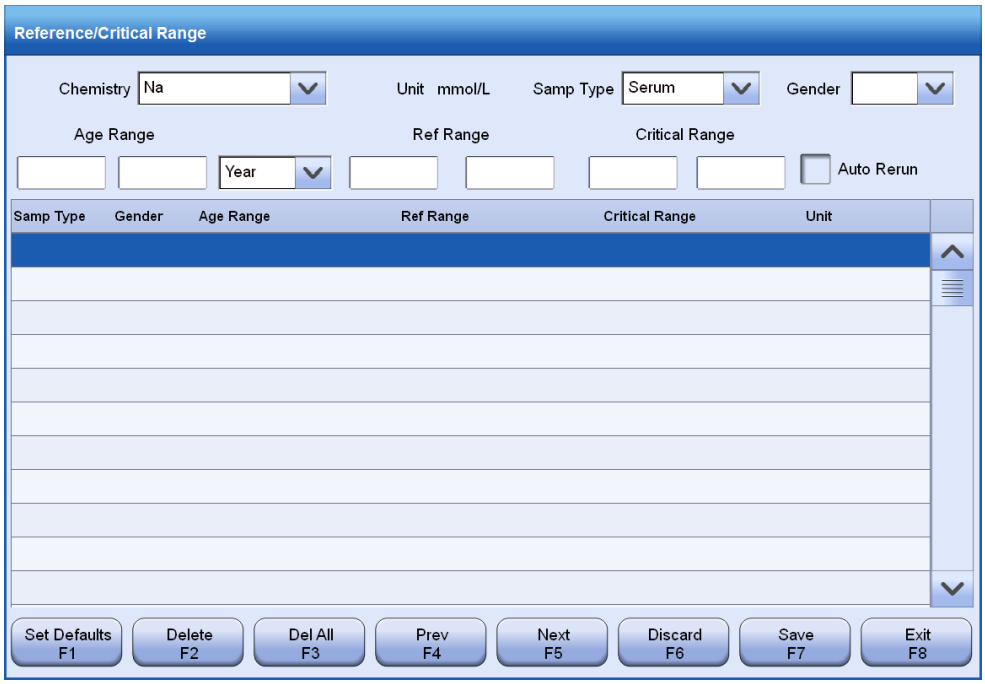
Defining/Editing reference/critical range

To define/edit reference/critical range

1 Select **Utility > Chemistries**.

2 Select **Ref Range F4**.

Figure 7.8 Reference/Critical Range Setup window



3 Choose a chemistry from the **Chemistry** drop-down list.

4 Set the applicable sample type, patient gender and age range.

5 Set the reference range and critical range.

6 To rerun the ISE chemistry when its test result is beyond the critical range, mark the **Auto Rerun** check box with a tick.

For more information about auto rerun, see 6.2.6 Rerunning samples on page 6-7.

7 Select **Save F7**. The reference/critical range are displayed in the middle list.

8 Select **Prev F4** or **Next F5** to set up reference/critical range for more chemistries.

9 Select **Exit F8** to close the window.

Setting up default reference/critical range

You are allowed to select a default reference/critical range for a sample type and gender. The default range appears in red. Only one default reference/critical range is allowed for the same sample type and gender of each chemistry.

To set up default reference/critical range

1. Select **Utility > Chemistries**.
2. Select **Ref Range F4**.
3. Choose the chemistry, sample type, gender and age range.
4. Choose a reference/critical range in the middle list.
5. Select **Set Defaults F1**.

   The selected reference/critical range is set as the default of the chemistry. The system will check the test result, and if necessary, flag and rerun the chemistry.
6. Select **Exit F8** to close the window.

Deleting a reference/critical range

You are allowed to delete the set reference range and critical range.

1. Select **Utility > Chemistries**.
2. Select **Ref Range F4**.
3. Choose the chemistry name, sample type, gender and age range.
4. Choose a reference/critical range you want to remove.
5. Select **Delete F2**, and then select **OK**.
6. To clear all ranges of the chemistry, select **Del All F3**, and then select **OK**.
7. Select **Exit F8** to close the window.

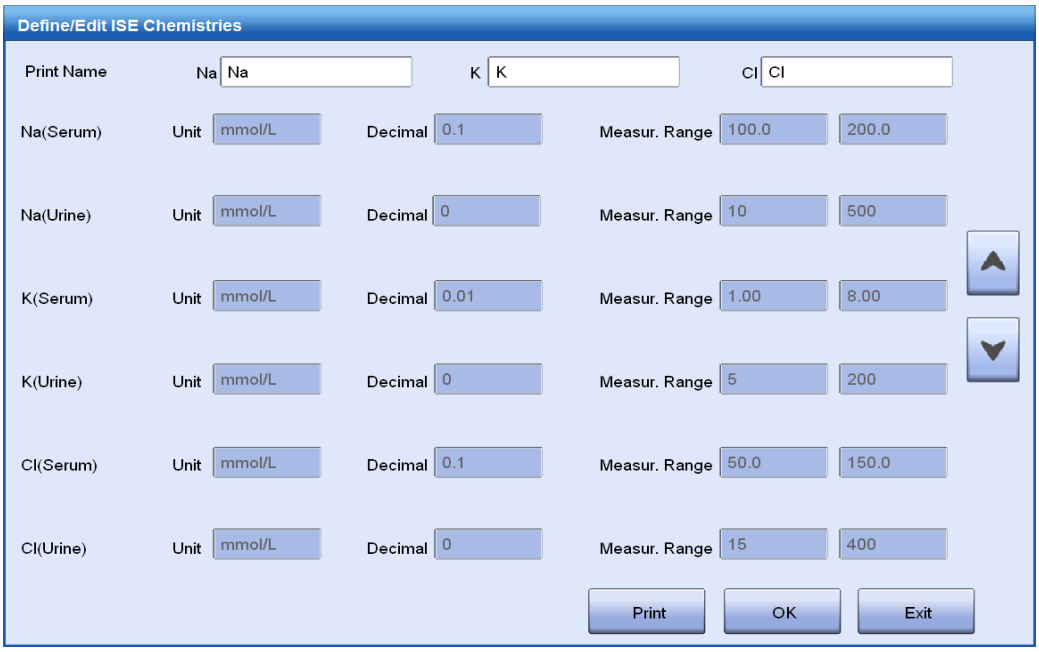
7.3 ISE chemistry setup

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 chemistries 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 chemistry parameters for serum.

ISE chemistry parameters can be viewed but cannot be modified and reconfigured. ISE test results can be expressed by qualitative flags.

Figure 7.9 Define/Edit ISE Chemistries window



7.3.2 Viewing ISE chemistry parameters

The ISE chemistry parameters are open to all users for viewing in any system status.

1 Select **Utility > Chemistries**.

2 Choose the **ISE** box.

3 Select **Define F1**.

4 View the parameters.

5 Click **Exit** to close the window.

7.3.3 Description of ISE chemistry 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 7.6 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

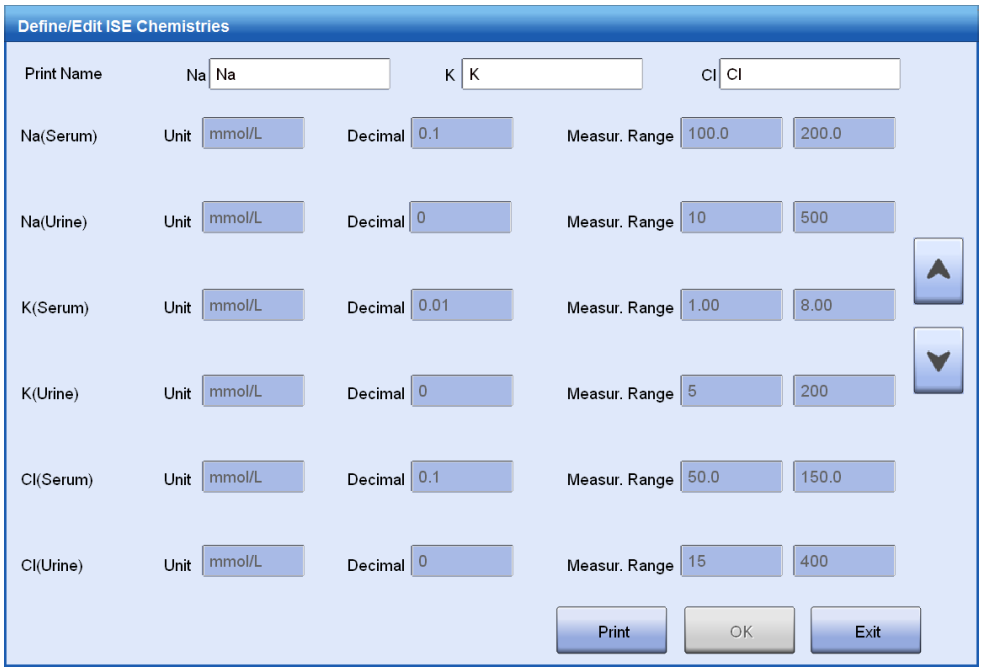
The measurement range can be viewed but cannot be edited.

7.3.4 Using ISE qualitative result

To use ISE qualitative result

1. Select **Utility > Chemistries**.
2. Choose the **ISE** box, select **Define F1**, and then click the down arrow button.

Figure 7.10 Define/Edit ISE Chemistries window



3. Select **Use Qualitative Result** under Na.
4. Enter the qualitative range and flag.

   For instance, type in "10" in the first edit box of the **Range** field under Na, and then enter "+" in the **Flag** field of the same row. If the Na concentration (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 Na concentration (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. Repeat steps 5-6 to flag the qualitative result for K and Cl.
6. Click **OK** to save the setup.
7. Select **Exit** to close the window.

7.4 Chemistry configuration

The Chemistry Configuration function is used to enable/disable chemistries that have been defined correctly and customize their display order on the **Sample**, **STAT Sample Program** and **Quality Control** screens.

7.4.1 Enabling chemistries

Only the enabled chemistries can be requested for measurements and recalled on results screens. The closed-reagent chemistries are enabled by default after being imported from a chemistry file; while the open-reagent chemistries will be enabled only if the parameters are set up correctly. If an ISE module is configured, the ISE chemistries will always be enabled.

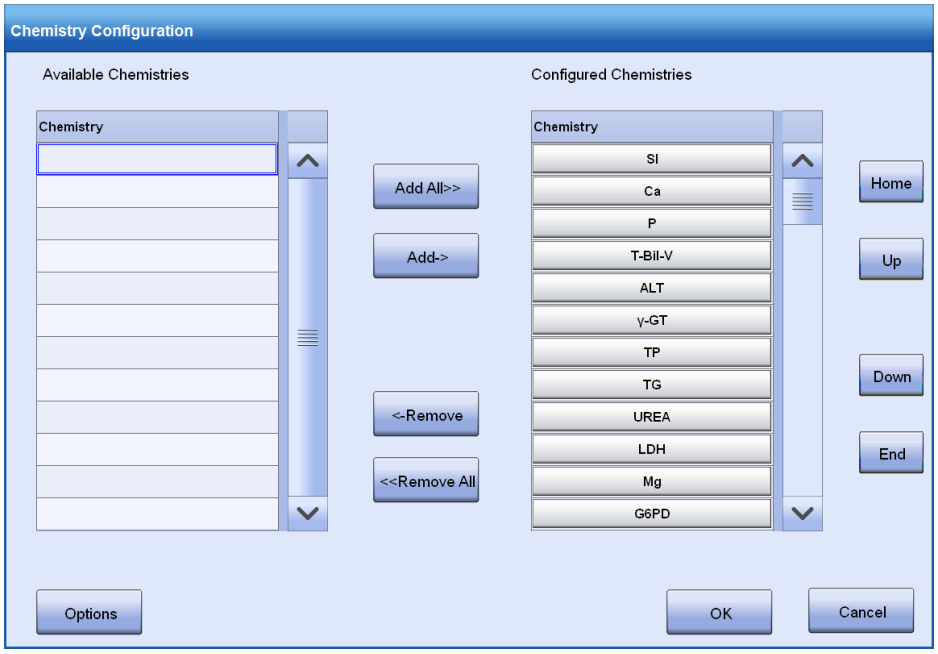
The system allows up to 200 chemistries to be enabled. The number of open-reagent chemistries can be adjusted according to the practical situations in your laboratory.

To enable chemistries

1 Select **Utility > Chemistries**.

2 Select **Config F3**.

Figure 7.11 Chemistry Configuration window



3 Choose one or more chemistries in the **Available Chemistries** list.

4 Select **Add->**.

The selected chemistries are enabled and appear in the **Configured Chemistries** list.

5 To enable all available chemistries, select **Add All>>**.

All chemistries in the **Available Chemistries** list are enabled and displayed in the **Configured Chemistries** list.

6 Select **OK**.

7.4.2 Disabling chemistries

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

A chemistry can be disabled only if:

- It is not an ISE chemistry.
- 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 Programmed, Incomplete or Rerun status.

To disable chemistries

1. Select **Utility** > **Chemistries**.
2. Select **Config F3**.
3. Choose a chemistry in the **Configured Chemistries** list.
4. Select **<-Remove**.

   The selected chemistry is disabled and removed from the **Configured Chemistries** list.
5. To disable all chemistries, select **<<Remove All**.

   All chemistries in the **Configured Chemistries** list that meet the requirements are disabled. The disabled open-reagent chemistries are indicated in red.

   If one of the chemistries does not satisfy the requirements, the operation will be aborted and all the chemistries cannot be disabled.
6. Select **OK**.

7.4.3 Customizing chemistry display order

Chemistries can be customized to match the test order of your laboratory and will be refreshed on the request screens.

Chemistries on the **Chemistry Configuration** window are displayed alphabetically. In case an ISE module is configured, Na, K and Cl will appear on the first three positions after SI in the **Configured Chemistries** list. In the **Available Chemistries** and **Configured Chemistries** lists, click the **Chemistry** or **Module** header line to sort the chemistries by name or by module.

To customize chemistry display order

1. Select **Utility** > **Chemistries**.
2. Select **Config F3**.
3. Choose a chemistry in the **Configured Chemistries** list.
4. Use the following buttons to adjust the chemistry's display order:

   - **Home**: to move the chemistry to the first position.
   - **Up**: to move the chemistry to the previous position.
   - **Down**: to move the chemistry to the next position.
   - **End**: to move the chemistry to the last position.
5. Select **OK**.

   The chemistry list on the request screens are refreshed automatically.

7.4.4 Adjusting test order of chemistries

Test order of configured biochemistries can be adjusted manually. During sample analysis, the chemistries are run in the order of ISE chemistries, SI, and then biochemistries. If multiple biochemistries are requested, they will be run in the default order. If the test order is adjusted manually, the biochemistries will be run in the updated order.

Only users with corresponding permission are allowed to adjust the test order of biochemistries.

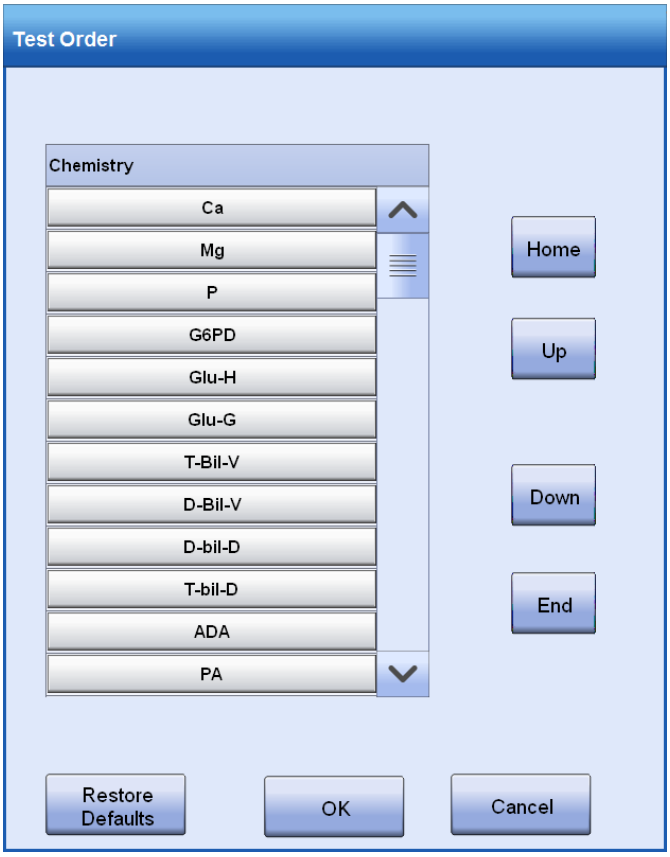
To adjust test order of chemistries

1. Select **Utility** > **Chemistries**.

2 Select **Config F3**.

3 Select **Options**, and then select **Test Order**.

Figure 7.12 Test Order window



4 Choose a chemistry in the **Configured Chemistries** list.

5 Use the following buttons to adjust the chemistry's test order:

- **Home**: to move the chemistry to the first position.
- **Up**: to move the chemistry to the previous position.
- **Down**: to move the chemistry to the next position.
- **End**: to move the chemistry to the last position.

6 Select **OK**.

7 To restore the default test order, select **Restore Defaults**.

7.5 Twin chemistry

Twin chemistries are run and calculated based on the same reagent. Results of the two twin chemistries are calculated through the same test. Take the reagent HBA1C as an example. It can be used for running two chemistries in the same test. The chemistry HB is measured during the former reaction period, while the chemistry HbA1c measured during the latter one. Finally, HbA1C (%) can be calculated based on results of the two chemistries.

Similar to normal chemistries, twin chemistries can be run only when the following settings are finished:

- defining chemistries
- assigning reagent position
- setting up calibrator and calibration rule
- setting up control and QC rule

7.5.1 Chemistry definition

Twin chemistries can be defined in the same way as normal chemistries. The following parameters, however, must be set up differently for two twin chemistries:

- Sample type
- Normal sample volume, increased sample volume, and decreased sample volume
- Volume of the same reagent type
- Prozone check

For setup of chemistry parameters, see 7.2 Biochemistry setup on page 7-5.

A chemistry that has been set as the twin of another chemistry must not have another twin. When twin chemistries are defined, both chemistries must be calibrated.

7.5.2 Removing twin relation

To remove the twin relation between two chemistries, cancel the selection of a twin chemistry. Only when reagents of the two chemistries are unloaded can the twin relation between them be removed.

7.5.3 Reagent setup

Twin chemistries are run with the same reagent in the same position. The reagent can be loaded manually or through bar code scanning.

Manual load

You are only required to manually set up reagents for one of the twin chemistries. The reagent of the same type for the other twin chemistry will be automatically set up with the same position.

Automatic load

Place the bar-coded reagents of twin chemistries on the reagent carousel, the system will scan the reagent bar code and automatically assign the same position for the same reagent of the twin chemistries.

If reagent loading fails for either of the twin chemistries, both chemistries cannot be run.

For details of reagent loading, see 2.3.1reagents on page 2-10.

7.5.4 Setting up and requesting calibration

Calibration setup

The calibrator, number of replicates and auto calibration conditions must be the same for two twin chemistries.

📖 For calibration settings, see 4.1.1 Calibration setup on page 4-2.

Requesting calibration

Twin chemistries can be requested for calibration in the same way as normal chemistries. When either of the twin chemistries is requested, the other twin will be requested automatically, and finally both chemistries will be calibrated. You are allowed to recall the calibration results, calibration curves and reaction curves of the two chemistries.

7.5.5 Setting up and requesting quality control

QC setup

Twin chemistries must be defined with the same control, and the QC setup of twin chemistries is the same as that of normal chemistries.

For QC settings, see 5.2 QC setup on page 5-3.

Programming controls

Twin chemistries can be requested for quality control in the same way as normal chemistries. For reagents other than G6PD, when one of the twin chemistries is requested, the other twin will be requested automatically. The QC tests of G6PD twin chemistries are performed separately. You are allowed to recall the QC results and QC reaction curves of the two chemistries.

7.5.6 Sample programming and processing

Twin chemistries can be requested for sample analysis in the same way as normal chemistries. When either of the twin chemistries is requested, the other twin will be requested automatically, and finally both chemistries will be run for sample analysis. You are allowed to recall the sample results and sample reaction curves of the two chemistries.

7.6 Special Calculations

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

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

7.6.1 Defining/Editing a calculation

Importing and defining calculations is supported. The system allows a maximum of 50 calculations to be defined.

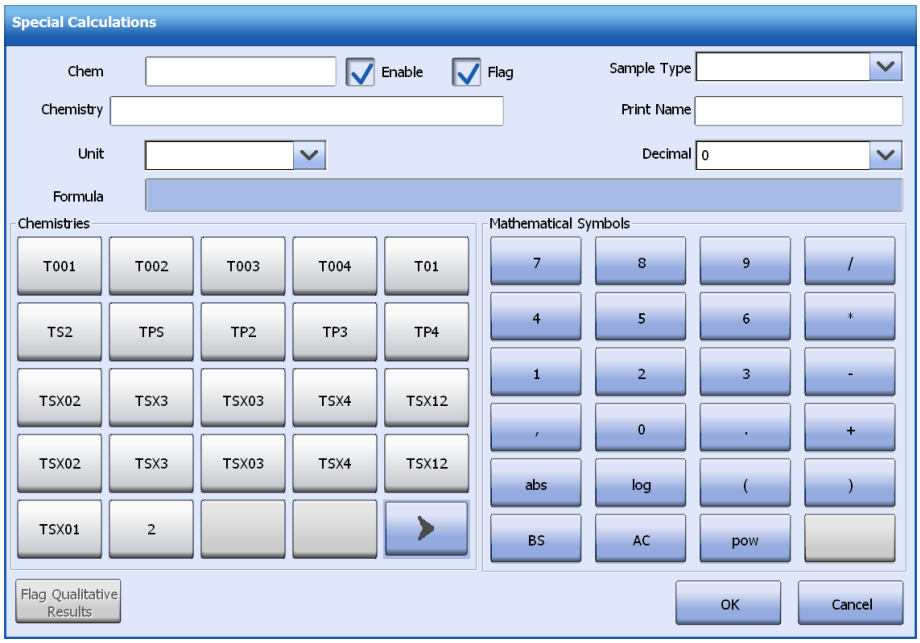
For importing methods of closed calculations, see 7.1.1 Importing default chemistry list on Page 7-2.

To define/edit a calculation

1 Select **Utility > Chemistries**.

2 Select **Calculations F6**, and then elect **Define F1**.

Figure 7.13 Special Calculations window



3 Input the following information:

- Abbreviation name and full name
- Sample type
- Print name

- Result unit and decimal place

4 If you are going to use the calculation for analysis, mark the **Enable** checkbox. Select **Flag** to flag the calculations.

5 Edit the calculation formula:

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

6 Select **Flag qualitative results** if you want to flag the qualitative results.

For more information on using qualitative results, see 7.2.4 Using qualitative result on page 7-15.

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

8 Select **Exit** to exit the window.

7.6.2 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.

To enable/disable calculations

1 Select **Utility > Chemistries**.

2 Select **Calculations F6**.

Figure 7.14 Special Calculations window

3 To activate a calculation, mark the **Enable** checkbox.

4 To inactivate a calculation, deselect the **Enable** checkbox.

7.6.3 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.

To delete user-defined calculations

1 Select **Utility > Chemistries**.

2 Select **Calculations F6**.

3 Choose calculations to delete.

4 Select **Delete F2**.

7.6.4 Running calculations

Calculations will not be run for calibration, but for quality control and sample analysis along with other chemistries.

If a chemistry contained in a calculation is run for more than one replicates, the final result of the chemistry will be used to calculate the result of the special calculation.

7.7 Panels

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

Panels can be composed of biochemistries and ISE chemistries. The system allows a maximum of 100 panels to be defined. Only users with sufficient permissions are allowed to define, modify and delete panels.

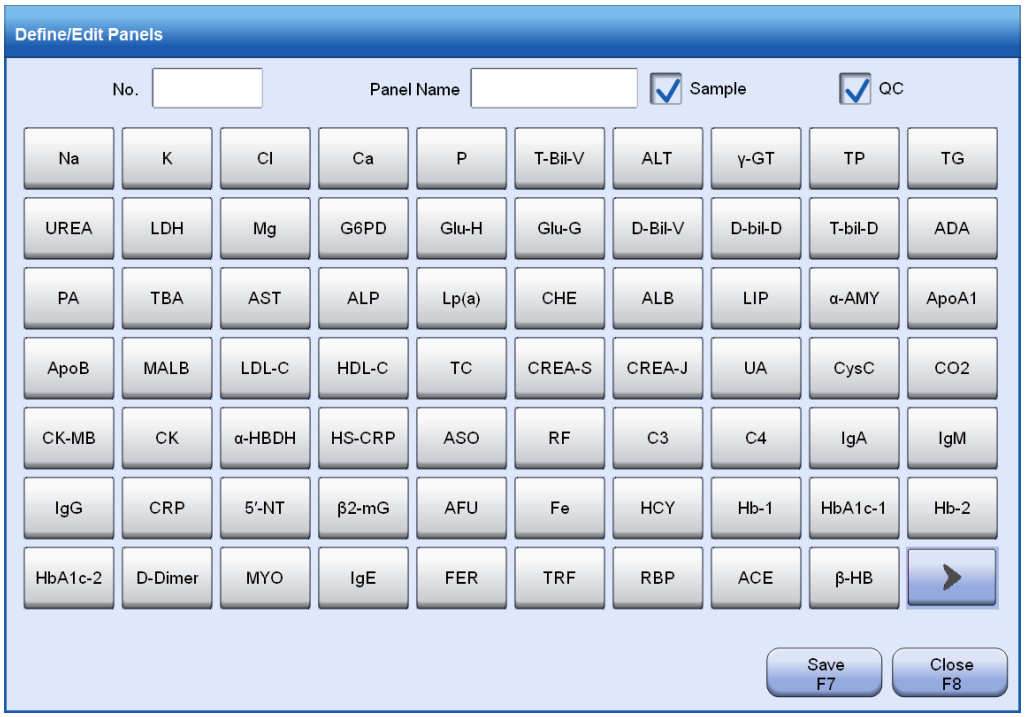
7.7.1 Defining/Editing a panel

To define/edit a panel

1 Select **Utility > Chemistries**.

2 Select **Panels F7**, and then select **Define F1**.

Figure 7.15 Define/Edit Panels window



3 Type in the panel number and name.

4 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.

5 Choose chemistries for the panel.

At least one biochemistry should be selected.

6 Select **Save F7**.

7 Select **Close F8** to close the window.

7.7.2 Adjusting display order of panels

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

To adjust display order of panels

1 Select **Utility > Chemistries**.

2 Select **Panels F7**.

3 Select the panel you want to move.

4 Select **Up F3** to move the current panel to the previous position, or select **Down F4** to move it to the next position.

5 Select **Save F7** to save the settings.

7.7.3 Deleting panels

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

To delete panels

1 Select **Utility > Chemistries**.

2 Select **Panels F7**.

3 Choose panels to delete.

4 Select **Delete F2**.

7.7.4 Running panels

Panels will not be run for calibration, but for sample and control analysis along with other chemistries.

7.7.5 Setting up and running default panel

The system allows a maximum of one default panel to be defined. When a bar-coded sample has no relevant programming information on the LIS host or has not been programmed 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 amount of samples that are analyzed with the same chemistries.

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

To define the default panel

1 Select **Utility > Chemistries**, and then select **Panels F7**.

2 Choose the desired panel in the panel list.

3 Mark the **Default** check box in the same row as the selected panel.

4 Select **Close F8** to close the window.

To running the default panel for patient sample

1 Load bar-coded samples to the sample carousel.

2 Select the  icon on the upper-right corner of the main screen.

3 Select a sample carousel to which the samples are loaded.

4 Select **OK**.

7.8 Off-system chemistry

All the chemistries that are not run by the analyzer are referred to as the off-system chemistries. You can manually enter the off-system chemistry results into the system to print out them in the patient report.

There are two types of off-system test: qualitative and quantitative.

- Qualitative chemistries: No numeric results are obtained but the flags you defined on the system. Reference value can be set for the qualitative chemistries
- Quantitative chemistries: Numeric results and defined flags are displayed and printed. Reference range can be set for the quantitative chemistries

7.8.1 Defining/Editing off-system chemistry

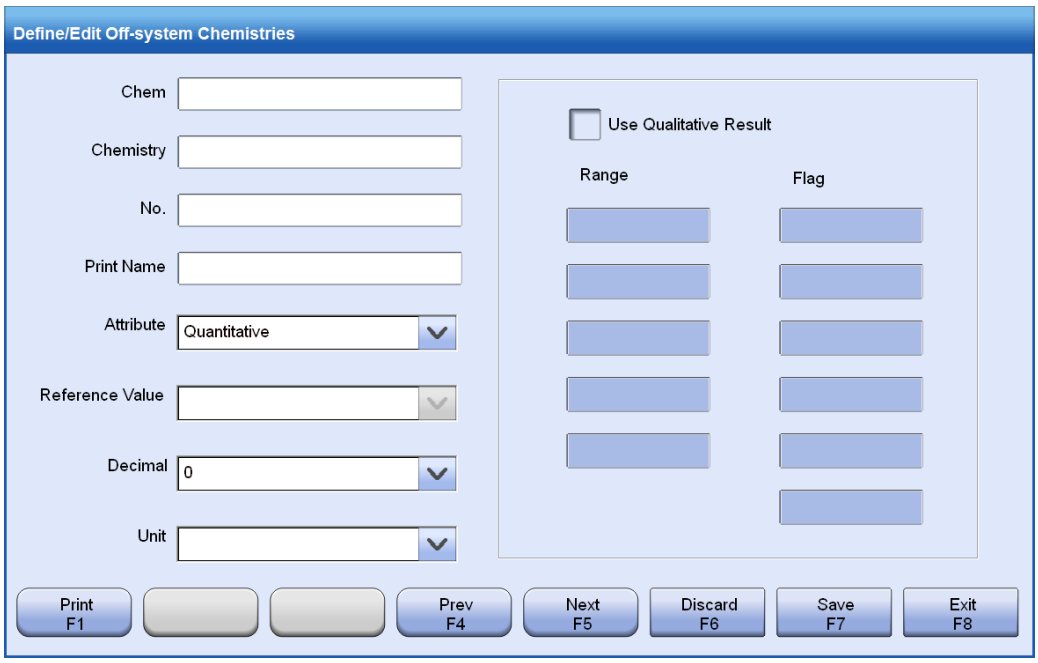
To define/edit off-system chemistry

1 Select **Utility** > **Chemistries**.

2 Select a blank chemistry box, and select **Define F1**.

3 Select **Off-system**, and select **OK**.

Figure 7.16 Define/Edit chemistries



4 Enter the following chemistry parameters:

- Abbreviation name and full name

- ID number
- Print name
- Attribute and reference value
- Result unit and decimal place

5 To set up result flags for quantitative result, perform the following steps:

a. Select the **Use Qualitative Result** check box.

b. 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 chemistry 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 chemistry 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.

6 Select **Save F7**.

7 Select **Exit F8**.

7.8.2 Running off-system chemistry

After the off-system chemistries are programmed, you can edit their results on the **Result** screen. The results of the off-system chemistries can be edited in any status of the sample.

To run off-system chemistry

1 Program off-system chemistries on the **Program > Sample** screen.

For more information on sample programming, see 2.4.1Programming and processing samples on page 2-24.

2 Select **Result > Current**.

3 Select the desired sample in the sample list.

4 Select **Option F2**, and select **Edit Results**.

5 Select the requested off-system chemistries, and input the results.

6 Click **Save**.

7.8.3 Deleting off-system chemistry

When the system status is not running, the off-system chemistries can be deleted.

To delete off-system chemistry

1 Select **Utility > Chemistries**.

2 Select the off-system chemistry you want to delete.

3 Select **Delete F2**.

7.9 Carryover setup

The Carryover Setup option is used to set up the carryover relations between open-reagent chemistries and between cuvettes. The system will insert a cleaning to reagent probe and cuvettes based on the carryover settings. The closed-reagent chemistries have been set up by the manufacturer and cannot be viewed or edited, while the open-reagent chemistries need to be set up on the **Carryover** window.

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

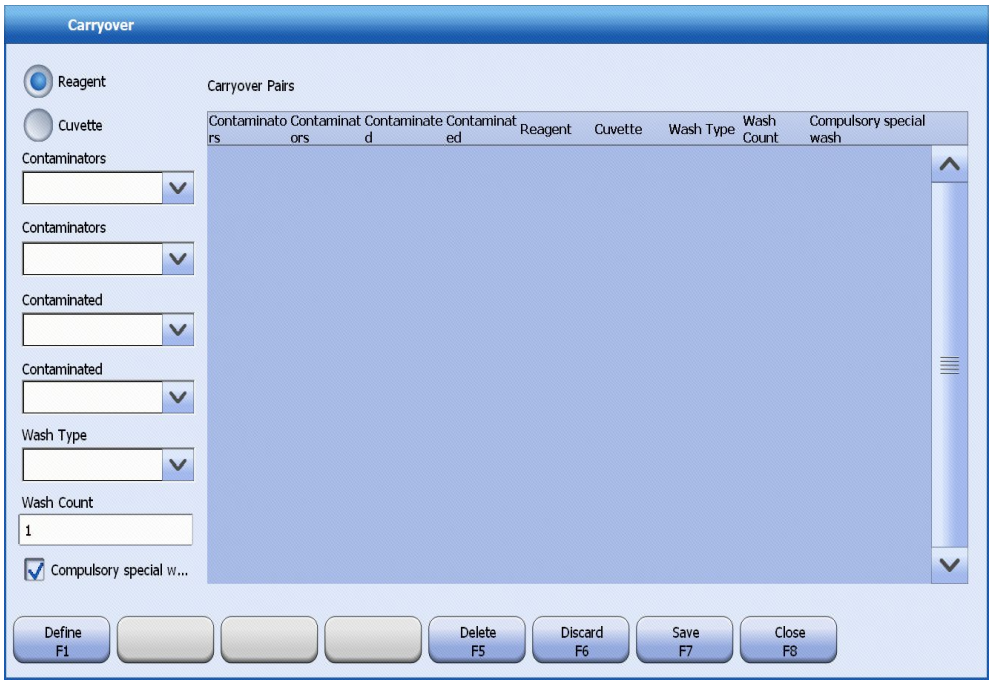
Carryover setup can only be performed by users with sufficient permissions when the system status is not Running.

7.9.1 Defining/Editing carryover pair

To define/edit carryover pair

1 Select **Utility > Chemistries**, and select **Carryover F8**.

Figure 7.17 Carryover window



2 Choose the carryover type:

- Reagent
- Cuvette

3 Choose one or all contaminator chemistries that may contaminate other chemistries.

"ALL" means all chemistries may contaminate others.

4 Choose one or all contaminated chemistries in the **Contaminated** list.

"ALL" means all chemistries may be contaminated. All (the entire contaminator) to All (the contaminated) is not permitted to set up.

5 Choose contaminator reagent that may contaminate other reagent.

6 Choose the contaminated reagent.

7 Choose a wash type.

The options include special wash and routine wash.

8 Define the wash cycle.

Only when either of the contaminator or contaminated is ALL, you are enabled to define wash cycle (1-5).

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

10 Select **Save F7**.

The defined carryover pair appears in the **Carryover Pairs** list. To abort the carryover settings, select **Discard F6**.

11 Select **Define F1** and follow the above steps to set up other carryover pairs.

12 Select **Close F8** to close the window.

7.9.2 Removing a carryover pair

To remove a carryover pair

1 Select **Utility > Chemistries**, and select **Carryover F8**.

2 Choose desired carryover pair.

3 Select **Delete F5**.

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

5 Select **Close F8** to close the window.

7.10 Masking/Unmasking chemistries

The chemistry masking function is used when a chemistry needs to be disabled temporarily due to abnormal result or reagent exhaustion. Masked chemistries can be requested but cannot be run until they are unmasked.

In any system status chemistries can be masked or unmasked. Any users are allowed to mask or unmask chemistries.

If a sample contains masked chemistries, it will enter the Incomplete status when finished; if chemistries are unmasked while the sample status is Programmed, the they will be run along with other chemistries; if chemistries are unmasked while the sample is being analyzed, they will be added automatically to the analysis; if chemistries are unmasked after the sample is analyzed, they will be run automatically when analysis begins next time.

To mask/unmask chemistries

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Mask/Unmask Chem**.

4 Choose chemistries to mask, select **OK**.

The marked chemistry will have a  symbol appearing on its upper-left corner, and will still be displayed on the **Sample**, **Quality Control** and **Reagent/Calibration** screens.

5 To unmask chemistries, select them and then select **OK**.

6 Select **Exit** to close the window.

7.11 Reflex

The Reflex option allows related chemistries to be requested and run automatically when the deciding biochemistry's result is within specified range. Each biochemistry may embrace multiple reflex conditions, and each condition may contain a maximum of 20 related chemistries.

Reflex conditions and related chemistries are open for observation, but only users with corresponding permission are allowed to set, modify or delete reflex relation.

7.11.1 Setting up reflex relation

Before using the reflex function, it must be enabled with reflex conditions and related chemistries configured. Please note that the chemistries in a reflex condition must have existed. When the system status is running, the reflex function cannot be set up.

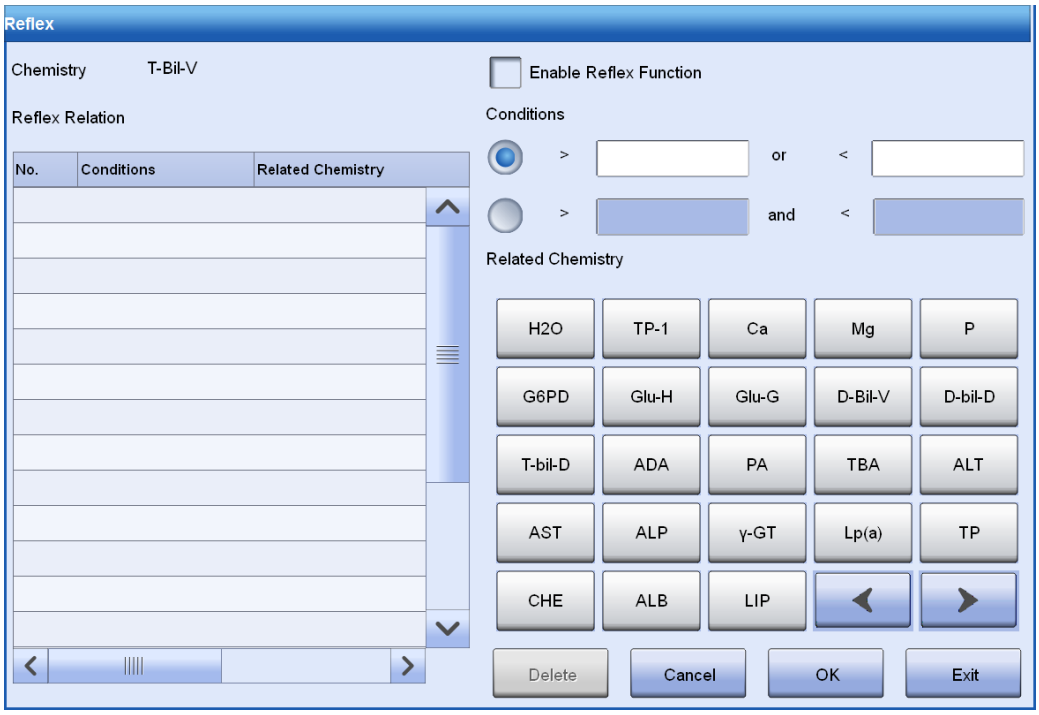
To set up reflex relation

1 Select **Utility > Chemistries**.

2 Choose a chemistry for which you desire to configure reflex settings, and then select **Define F1**.

3 Select **Reflex F2**.

Figure 7.18 Reflex window



4 Mark the **Enable Reflex Function** checkbox to activate this option.

5 Set up reflex conditions.

Two conditions are available: "or" and "and":

- or: When the test result (concentration) is greater than certain value OR less than certain value, the related chemistries will be requested and run automatically.
- and: When the test result (concentration) is greater than certain value AND less than certain value, the related chemistries will be requested and run automatically.

Select an option and input the concentration range.

6 Choose related chemistries in the chemistry list.

The options include all configured biochemistries.

7 Select **OK**.

The defined reflex relation is shown in the left list.

8 Select **Exit** to close the window.

7.11.2 Editing reflex relation

Only users with corresponding permission are allowed to edit reflex relation.

To edit reflex relation

1 Select the desired reflex relation on the **Reflex** window.

2 Modify the condition and related chemistries.

3 Select **OK**.

4 Select **Exit** to close the window.

7.11.3 Deleting reflex relation

Only users with corresponding permission are allowed to delete reflex relation. If a chemistry is deleted, the corresponding reflex relation to which it is related will be removed automatically.

To delete reflex relation

1 Select the desired reflex relation on the **Reflex** window.

2 Select **Delete**.

3 Select **OK**.

4 Select **Exit** to close the window.

7.11.4 Measurement and result recall

Chemistries with reflex settings are run in the same way as routine biochemistries. When the test result meets the set condition, the related chemistries will be requested and run automatically while those that have been requested for the sample will be excluded. To view the results, select **Result > Current** or **History**.

8 Utility

This chapter provides descriptions of system commands, system setup, instrument setup, print setup, bar code setup, LIS setup, and user setup.

8.1 System commands

The system provides two commands: Home and Stop Print, which are respectively used to restore the system into standby status and stop the printing.

8.1.1 Home

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

To home the system

1. Select **Utility > Commands**.
2. Select **Home**.

8.1.2 Stop print

The Stop Print command will stop all print requests in the print queue and prevent them from being sent to the printer. This feature is used for stopping print requests of many pages, such as error logs, QC reports, multi-sample reports, etc. The print tasks that are Printing, Deleted, Canceling or Canceled in the print task window will not be deleted.

To stop printing

1. Select **Utility > Commands**.
2. Select **Stop Print**. All print requests in the print queue will be removed.

8.1.3 Waking up the System

1. Select **Utility > Commands**.
2. Select **Wake Up**.
3. The system is waking up, and the system status becomes Standby.

8.2 System setup

This section describes the setup options on the **System Setup** screen, which includes the following pages:

- Sample test setup page
- Auto rerun setup page

Click the arrow buttons on the right to switch between the two pages.

Select **Utility > System Setup** to display the following screen:

Figure 8.1 System Setup screen

8.2.2 Sample test setup page

The following setup options are provided on the sample test setup page.

Default sample type

The system supports a couple of sample types, which include serum, plasma, urine, cerebrospinal fluid samples (CSF) and other. The default is serum. When the default sample type is set up, it will be selected by default for programmed samples on the **Sample** screen.

Default sample cup type

The system supports the standard sample cup and Microtube. The default is the standard sample cup. When the default sample cup type is set up, it will be selected by default for programmed samples on the **Sample** screen.

Valid period of samples

Valid period of samples refers to the time interval that a patient sample is first loaded to the sample carousel and then expired. When the valid period of samples is set up, only samples within this period are allowed for analysis. If the valid period is not set up, the samples are valid all the time.

The valid period ranges from 1 to 99 in hour or day. The default is day.

Valid period is applicable to patient samples rather than calibrators and controls. Once the collection time is entered, the system will calculate the valid period from the time when the sample is collected; otherwise, the time when the sample is programmed will be used for calculating the valid period.

Special wash sample probe

After going through a large number of tests, the sample probe may get clogged. To prevent this from happening, enable the sample probe special wash function to execute additional cleaning procedure for the sample probe during measurement in order to avoid clogging. Enter the number of tests in the **Number of Tests** field. The input range is 100-10000, and the default is 400. When the number of tests is finished, the system will clean the sample probe with wash solution in an additional cleaning procedure.

Reaction temperature monitoring

The reaction temperature can be monitored before analysis begins.

- When the **Start Analysis When Temperature is Steady** checkbox is selected, the system will check before analysis begins if the reaction temperature is normal. If the temperature is normal, you are allowed to select  to start analysis; otherwise, a message will appear indicating analysis is forbidden in current condition.
- When the **Start Analysis When Temperature is Steady** checkbox is not selected, the system will still check before analysis begins if the reaction temperature is normal and within 37±2.0°C. If the temperature is normal, you are allowed to select  to start analysis; otherwise, the system will remind you that the results may be influenced if you continue to start analysis. You may continue or abort the analysis.

Auto serum index

When the auto serum index function is enabled, the SI chemistry on the Sample screen will be selected by default for programmed serum or plasma samples, and the system will measure the degree of Hemolysis, icterus and lipemia contained in these samples. If the Qualitative Analysis checkbox on the Auto Serum Index window is marked, the system will display qualitative flags of serum index on patient reports.

Serum index is only used to evaluate the integrity of samples rather than making a diagnosis for patients.

Alarm when reagent exhausted

Each chemistry can have more than one bottle of reagent loaded. You can set up alarms for the case that the reagent is running out.

Select the **Alarm when reagent exhausted** option. When the reagent is exhausted, the system will give an alarm. If the option is not selected, the system will not give an alarm.

Manage reagents by lot

This option is used to monitor the calibration status and time of each reagent lot, supports reagent lot calibration, and displays calibration results of each reagent lot.

When this option is enabled, special attentions should be paid for the following operations:

- Loading reagents: You are required to input the lot number when loading reagents manually. The lot number of bar-coded reagents cannot be left blank; otherwise, reagent load will fail.
- Viewing calibration status and requesting calibration: You can view calibration status and time of each reagent lot, and request calibration accordingly.
- Recalling calibration results: You can recall calibration results of each reagent lot on the **Biochemistry Calibration** screen.
- Auto calibration: Auto calibration by reagent bottle or lot is forbidden. When a different reagent lot is used, the system will request and run calibration automatically. Reagent lots with valid calibration factors will not be calibrated again when used for measurement.

Result display settings

This option is used to set up 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.

Click the relevant color setup button, choose desired color, and then select **OK**. The system will display flags in the **Flag** column of the **Current Results** and **History Results** screens and on patient reports if the test result is less than or greater than the reference range. 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 set color.

Reagent alarm limit

Reagent alarm limit is only applicable to ISE reagent. The input range is 1-50, and the default is 5. If the inventory alarm limit is set up, the system will give an alarm and mark the reagent with colors when the reagent inventory is less than the alarm limit.

Alarm Sound volume

This option is to adjust the volume of alarm tone and beep. Alarm tone is the sound of a system alarm and beep is given when mis-input or mis-operation occurs. Volume of both sounds can be adjusted manually according to the practical conditions of the environment. Drag the slider in the **Alarm Volume** and **Beep Volume** fields horizontally. The scale is ascending from left to right. When the slider is moved to the leftmost position, the alarm buzzer is silenced.

Since the Windows 8 does not support alarming through buzzer, you should install an audio card on your computer in order to ensure the alarm and beep sound can be adjusted and given.

ISE prime cycle

Set up the ISE prime cycle. The input range is 1-9, and the default is 1.

While the analyzer is started up and new reagent pack is identified, the ISE module will prime automatically to replace the reagents inside of it with fresh reagents.

Only administrators are allowed to define or modify the startup prime times.

8.2.3 Auto rerun setup

The system provides a couple of conditions for auto rerun. When selected conditions are satisfied, chemistries for which auto rerun has been enabled will be rerun automatically with the specified sample volume type.

Only users who have the permissions of system setup are allowed to set up auto rerun conditions.

Above Critical High

Select a rerun mode from the drop-down list. It means that the system will rerun the tests with the selected mode when the test result exceeds the critical range high limit.

Unselection means this item will not be checked.

Below Critical Low

Select a rerun mode from the drop-down list. It means that the system will rerun the tests with the selected mode when the test result is lower than the critical range low limit.

Unselection means this item will not be checked.

Above Linearity High

Select a rerun mode from the drop-down list. It means that the system will rerun the tests with the selected mode when the test result exceeds the linearity high limit.

Unselection means this item will not be checked.

Below Linearity Low

Select a rerun mode from the drop-down list. It means that the system will rerun the tests with the selected mode when the test result is lower than the linearity low limit.

Unselection means this item will not be checked.

Above Highest Calib.

Select a rerun mode from the drop-down list. When selected, it means the analyzer will rerun the sample with the selected mode automatically if its response is beyond that of the highest-concentration calibrator.

Unselection means this item will not be checked.

Below Lowest Calib.

Select a rerun mode from the drop-down list. When selected, it means the analyzer will rerun the sample with the selected mode automatically if its response is beyond that of the lowest-concentration calibrator.

Unselection means this item will not be checked.

Substrate Depletion

Select a rerun mode from the drop-down list. When selected, it means the analyzer will rerun the tests with the selected mode automatically if the substrate ran out during running.

Unselection means this item will not be checked.

Prozone Check Error

Select a rerun mode from the drop-down list. It means that the system will rerun the tests with the selected mode when prozone occurs during reaction process.

Unselection means this item will not be checked.

Nonlinear

Select a rerun mode from the drop-down list. If the calculated linearity is greater than the defined linearity limit, the system will rerun the tests with the selected mode.

Unselection means this item will not be checked.

No Linear Interval

Select a rerun mode from the drop-down list. It means that the system will rerun the tests with the selected mode when the number of measuring points within substrate limit is less than or equal to 3. This option applies to Kinetic method only.

Unselection means this item will not be checked.

No Calculation Interval

Select a rerun mode from the drop-down list. If the number of measuring points within linearity range is less than 2 during high-activity enzyme measurement, the linearity range will be expanded. If the number of measuring points is less than 2 even when the lag time is included, the system will rerun the tests with the selected mode. This option applies to Kinetic method only.

Unselection means this item will not be checked.

8.3 Instrument setup

On the **Instrument Setup** window, you are allowed to perform the following settings.

8.3.1 Sleep/Awake

Sleep/Awake feature includes the Auto Sleep Setup, Auto Startup Setup and Auto Awake Setup options.

The Auto Sleep Setup option is used to set up the time interval of auto sleep time of the system. After the sleep time interval is set up, a countdown will begin from the moment that the system status becomes Standby. When the time interval is elapsed, the system will begin sleeping. Except for the auto sleep setting, the system can be woken up by means of the wake up command.

The Auto Startup Setup and Auto Awake Setup options allow you to define date and time of starting up or waking up the system. When the time is reached, the system will be started up or woken automatically no matter if it is off or sleeping.

Auto Sleep Setup

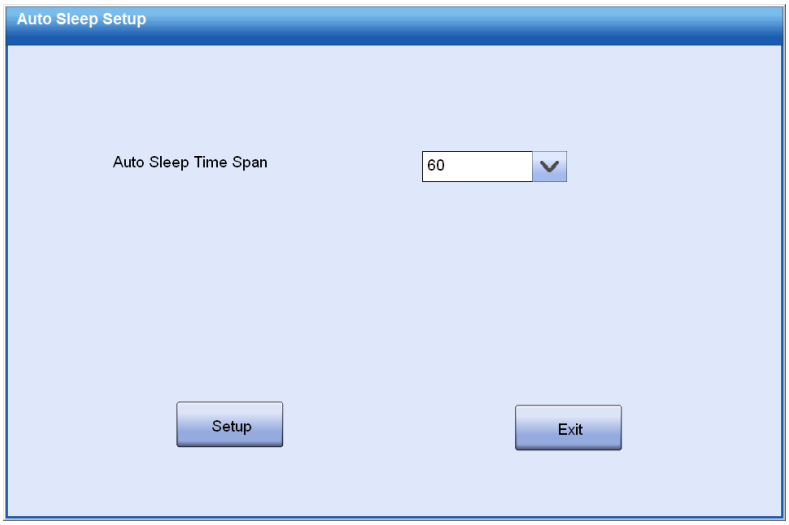
1 Select **Utility** - **System Setup**.

2 Select **Instrument F1**.

3 Select **1 Sleep/Awake**.

4 Select **1 Auto Sleep Setup**.

Figure 8.2 Auto Sleep Setup window



5 Type in the time interval for auto sleep.

The options include N/A, 30, 60, 90, 120, 150, 180,210,240,270 and 300 and the default is 60 minutes. N/A means the auto sleep timer is disabled

NOTE

If auto sleep is not enabled, some components, such as lamp, may get aged quickly and degraded in performance. You are recommended to enable this option.

6 Select **Save**.

When the interval is elapsed, the system will starts to sleep and the system status becomes Sleep.

7 Select **Exit**.

Auto Startup Setup

NOTE

After setting up the auto startup time, ensure that the operation unit and the analyzer are connected to power supply; otherwise, they cannot be started up automatically.

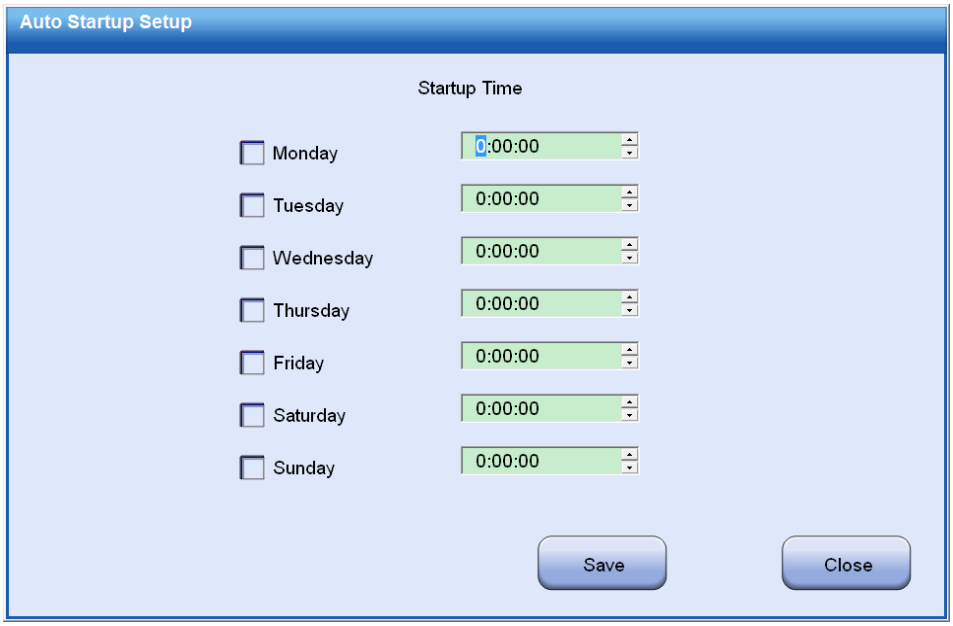
1 Select **Utility** - **System Setup**.

2 Select **Instrument F1**.

3 Select **1 Sleep/Awake**.

4 Select **2 Auto Startup Setup**.

Figure 8.3 Auto Startup Setup



5 Choose the weekday for auto startup, and then set up the specific time.

Any time within a week(from Monday to Sunday) can be defined for the system to start up automatically.

6 Select **Save**.

When the date and time is reached, the system will be started up automatically if it is off.

7 Select **Close**.

Auto Awake Setup

NOTE

After setting up the auto awake time, ensure that the operation unit and the analyzing unit are connected to power supply; otherwise, they cannot be woken up automatically.

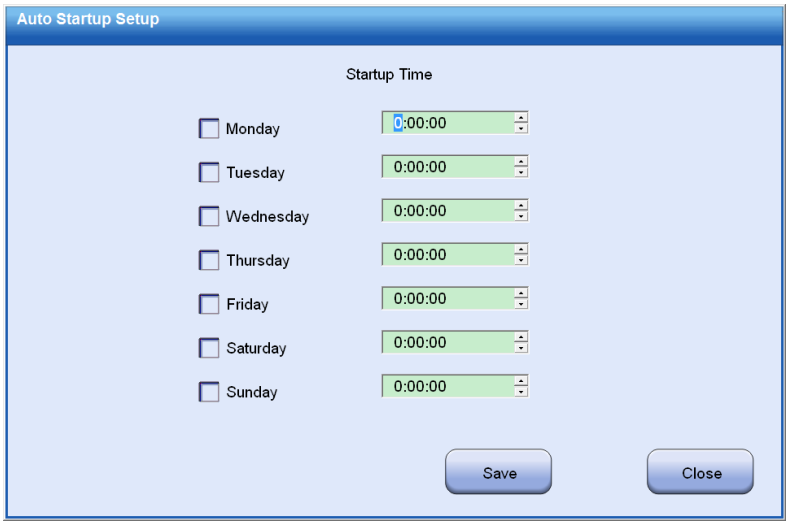
1 Select **Utility** - **System Setup**.

2 Select **Instrument F1**.

3 Select **1 Sleep/Awake**.

4 Select **2 Auto Awake Setup**.

Figure 8.4 Auto Awake Setup



5 Choose the weekday for auto startup, and then set up the specific time.

Any time within a week (from Monday to Sunday) can be defined for the system to wake up automatically.

6 Select **Save**.

When the date and time is reached, the system will be woken up automatically if it is sleeping.

7 Select **Exit**..

8.3.2 Masking/Unmasking Chemistries

The Masking/Unmasking Chemistries option is used to disable chemistries, which will still be displayed on the **Sample**, **Quality Control** and **Reagent/Calibration** screens. Masked chemistries can be requested but will not be run for sample analysis.

For details of chemistry masking/unmasking, see 7.10Masking/Unmasking chemistries on page 7-32.

8.3.3 Dictionary setup

The Dictionary option is provided for setting up and managing frequent data information, such as: result unit, sample type, sample comment, and QC comment. Sample comment can be entered manually or selected from the **Comment** drop-down list on the **Sample** screen, **Levey-Jennings** screen, and (QC) **Results** screen.

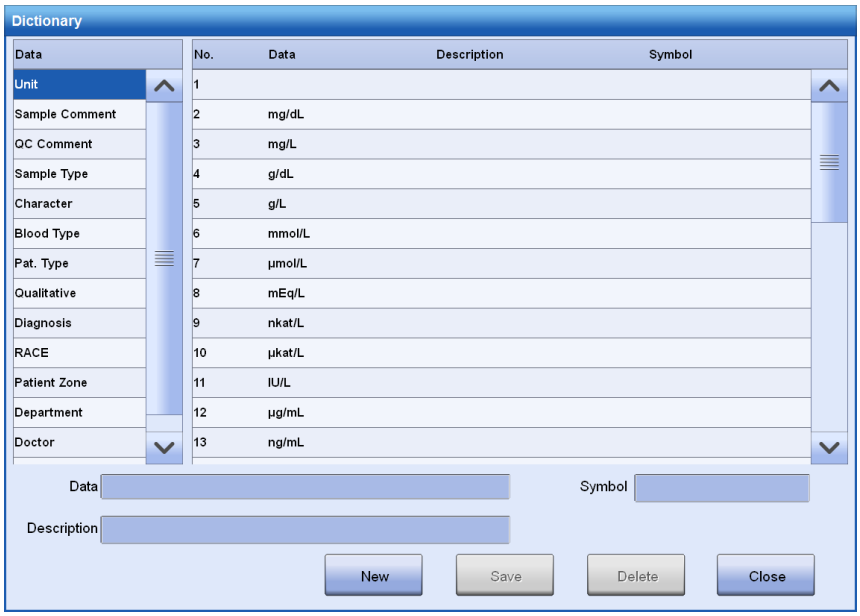
Data options can be defined, edited or deleted in any system status. The default data options cannot be deleted or edited.

To define, edit and delete data options

1 Select **Utility > System Setup**, and select **Instrument F1**.

2 Select **Dictionary**.

Figure 8.5 Dictionary window



3 Choose desired dictionary in the Data list.

4 To add a data option:

a. Select **New**.
b. Input the data description in the **Data** field.
c. Select **Save**.

5 To modify a data option:

a. Select desired data option in the data list.
b. Modify the data description in the **Data** field.
c. Select **Save**.

6 To delete a data option:

a. Select desired data option in the data list.
b. Select **Delete**.

7 Select **Close**.

8.3.4 System communication options

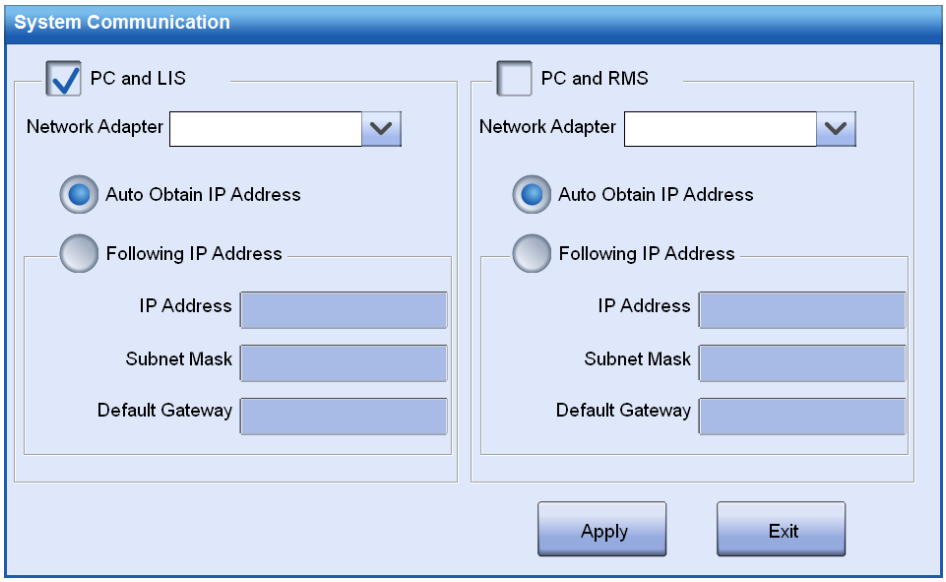
The Com Setup option is used to set up the IP address for connections between the PC and LIS/RMS

To set up communication parameters

1 Select **Utility > System Setup**, and select **Instrument F1**.

2 Select **Com Setup**. The **System Communication** window is displayed.

Figure 8.6 System communication setup



3 Select **PC and LIS** (selected by default) and **PC and RMS**.

4 Choose a network connection in the **Network Adaptor** area.

5 Set up the connection between operation unit and LIS/RMS.

- Auto Obtain IP Address(selected by default)
- Or set using **Following IP Address**: type in the **IP Address**, **Subnet Mask** and **Default Gateway** for connecting the operation unit PC with the LIS host and RMS.

6 Select **Apply**.

A dialog box pops up: Check the network cable connection prior to applying new settings. Please check the connection of the network cable and then click **OK** to save the settings.

7 Select **Exit** to close the window.

8.3.5 Selecting language

The operating software is displayed by default in the same language as the current operating software. You are allowed to change the language of the operating software.

Select **System Setup** > **Instrument F1** > **5 Language**, and then choose a language from the options. Select **OK** to save the settings. The language you select will take effect only when you reboot the operating software.

8.3.6 Software upgrading

Software Upgrade is used to upgrade the operating software and ISE module software. When software versions is upgraded, the original data, including those in the database and saved in files, will not be destroyed and can be compatible with the new versions.

To upgrade the software

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Version Upgrade**.

4 Insert the U disk containing the software into the USB interface of the computer.

5 Select **OK**, and then operate according to the screen prompts.

8.3.7 Viewing software versions

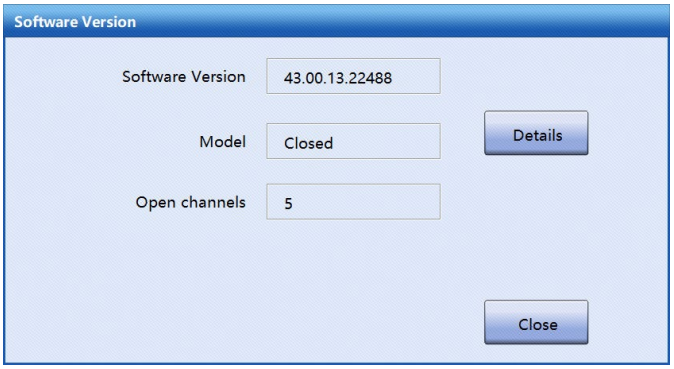
You are allowed to view the version number of the operating software and control software in any system status.

To view the software version

1 Select **Utility > System Setup**, and select **Instrument F1**.

2 Select **Version Info**.

Figure 8.7 Software Version window



3 View the version number of the operating software, model, and number of open channels.

4 To view the version numbers of the smart module software, select **Details**.

5 Move the scroll bar to view more versions.

6 Select **OK**.

8.3.8 Setting up system 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.

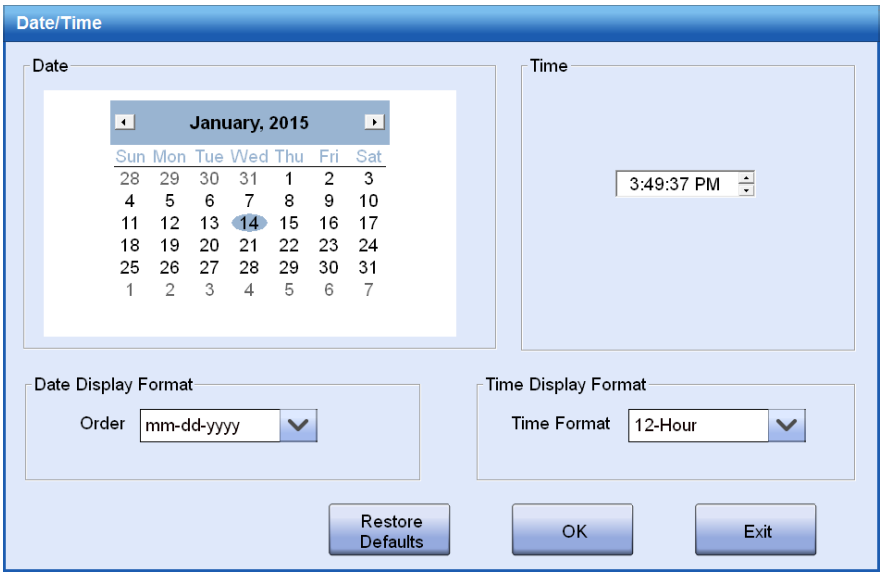
When adjusted, the date and time will influence the time left of reagents and calibration, shelf life of samples, and run length of two-control evaluation. The date and time cannot be edited when the system status is Running. Modification of the date and time will not affect samples on the Current Results screen or QC evaluation and Twin-Plot chart.

To set up the system date and time

1 Select **Utility > System Setup**, and select **Instrument F1**.

2 Select **Date/Time**.

Figure 8.8 Date/Time window



3 Set the current date and time.

4 Choose a date format from the **Order** drop-down list.

- yyyy-mm-dd: e.g. 2014-08-27
- dd-mm-yyyy: e.g. 27-08-2014
- mm-dd-yyyy: e.g. 08-27-2014

5 Choose a time format from the **Time Format** drop-down list.

- 24-hour: e.g. 14:33:27
- 12-hour: e.g. 02:33:27

6 To restore the date and time defaults, select **Restore Defaults**.

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

8 Select **Exit** to close the window.

8.3.9 Setting up QC run length and auto QC

By choosing the QC Evaluation, you are allowed to set up the QC run length and auto QC conditions.

📖 For setup of QC run, see Setting up QC rules on page 5-4.

📖 For auto QC setup, see 5.2.4 Auto QC on page 5-5.

8.3.10 Auto release of samples

The system allows setting of daily release time of samples. When the set time is reached, samples that are currently in Complete status will be released automatically.

📖 For more information on auto releasing samples, see 6.3.4Releasing sample position6-20 on page 6-20.

8.3.11 Voice tone setup

This option is used to customize the alarm sound and beep sound.

The Voice Tone Setup option provides voice tone choices for system failures or user's mis-input or mis-operation. You are allowed to import audio files from an external storage device and set them as voice tone.

To import audio files

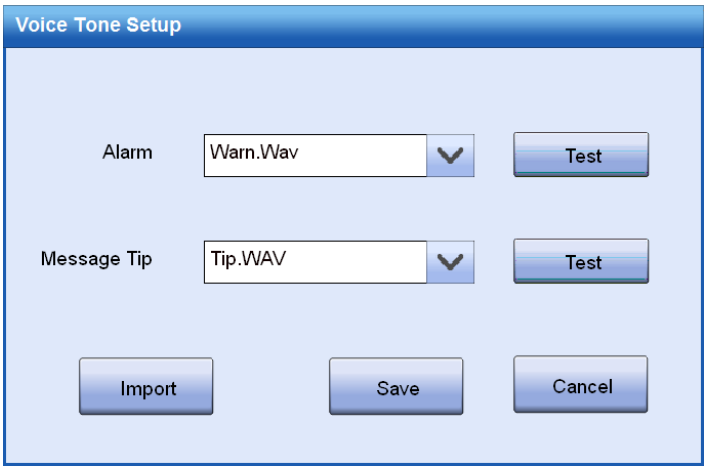
1. Select **Utility > System Setup**, and select **Instrument F1**.
2. Select **Voice Tone Setup**.
3. Select **Import**.
4. Select the path and one or more favorite audio files.
5. Select **Open**.

   The imported audio files are displayed in the **Alarm** and **Message Tip** drop-down lists.

To set up voice tone

1. Select **Utility > System Setup**, and select **Instrument F1**.
2. Select **Voice Tone Setup**.

Figure 8.9 Voice Tone Setup window



3. Choose a voice tone from the drop-down list, and then select the corresponding **Test** button to test the voice effect until the proper one is found.
4. Select **Save** to save the settings.

8.3.12 Optimizing result display

This option is used to set up display mode of sample results that are beyond the linearity range.

For more information on optimizing result display, see 6.3.8Optimizing result display on page 6-23

8.3.13 Customizing sample information

Customizing sample information allows you to specify sample information to be displayed on the **Sample** screen.

For more information on customizing sample information, see 6.3.6Customizing sample information on page 6-21.

8.3.14 Customizing patient demographics

You can specify patient demographics to be displayed, its default and its display order on the **Patient Demographics** screen.

For more information on customizing patient demographics, see 6.3.7Customizing patient demographics on page 6-22.

8.3.15 Reagent/Calibration setup

Via **Reagent/Calibration** option on instrument setup screen, you can configure whether to automatically refresh the reagent with 0 inventory as available for test, when reagent has been loaded and **End Load F2** button is selected.

For more information on auto refreshing reagent volume, see 3.1.7 Checking and auto refreshing reagent inventory on page 3-4.

8.3.16 Customizing reagent display

This option is used to set up reagent information displayed on the biochemistry reagent/calibration screen.

For more information on customizing reagent display, see 3.1.5Customizing reagent display on page 3-3.

8.4 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, default printer and printed hospital name, import print report, but also define the print order of chemistries, edit print template and preview print template.

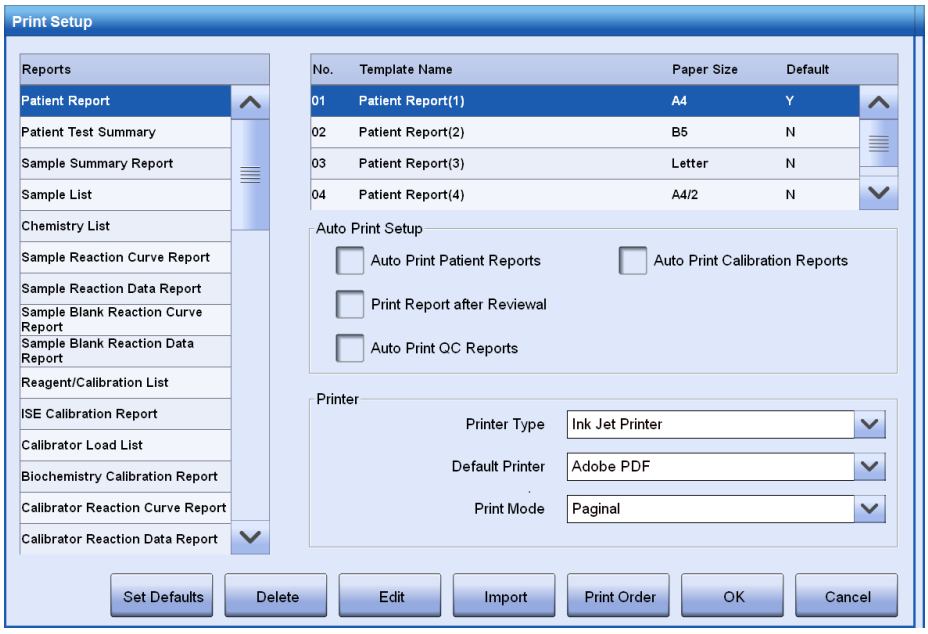
8.4.1 General print setup options

You can enable auto printing of patient report, calibration report and QC report, and specify a printer and print mode.

To perform general print setup

1 Select **Utility > System Setup**, and select **Print F3**.

Figure 8.10 Print setup screen



2 Enable the following auto print functions:

- Auto print patient reports
- Print after reviewal
- Auto print QC reports
- Auto print calibration reports

3 Choose a printer type.

The system supports three types of printer, which include laser printer, inkjet printer and stylus printer.

4 Choose a default printer to print reports.

5 Choose a print mode between Paginal and Serial.

- Paginal: applied to non-stylus printer. Report contents are printed on multiple pieces of paper by page.
- Serial: applied to stylus printer. Report contents are printed continuously without distinguishing pages.

6 Select **OK**.

8.4.2 Editing print template

To edit print template

1 Select **Utility > System Setup**, and select **Print F3**.

2 Select a report type from the **Report** list on the left of the window.

3 Select a template from the template list.

4 Click **Edit** to open the template modifying software. You can edit the report templates as needed.

For details of the template modifying software, see 9 Template modifying software on page 9-1.

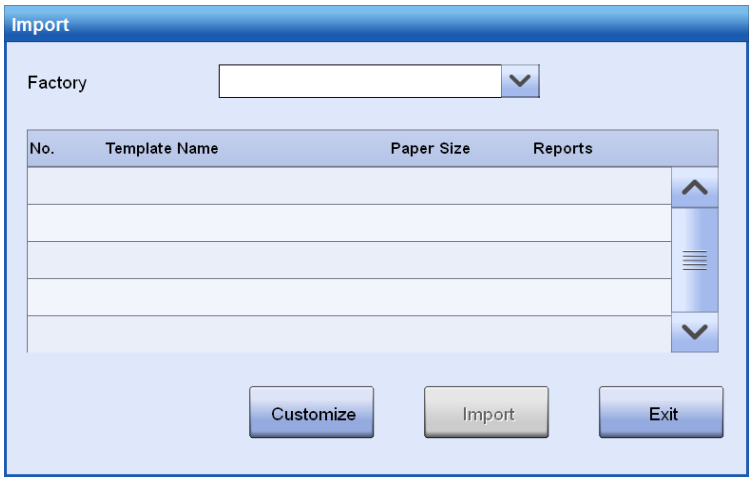
8.4.3 Importing print template

To import print template

1 Select **Utility > System Setup**, and select **Print F3**.

2 Click **Import** to import the print template.

Figure 8.11 Import print template window



3 Select a report type from the **Factory** drop-down list.

4 Select one or more templates in the template list to be imported, and click **Import.**

The selected template(s) can be imported.

5 Click **Customize** to import the template you edited from a tmplt file.

The legal directory should be a portable storage device. The templates can be imported in batch.

6 Click **Import**

The imported templates will be displayed in the template list.

7 Click **Exit** to exit the window.

8.4.4 Setting up default template

To set up default template

1 Select **Utility > System Setup**, and select **Print F3**.

2 Select a report type from the **Report** list on the left of the window.

3 Select a template from the template list.

4 Click **Set Defaults** to set the selected template in the template list as the default one.

8.4.5 Deleting a template

To delete a template

1 Select **Utility > System Setup**, and select **Print F3**.

2 Select a report type from the **Report** list on the left of the window.

3 Select a template from the template list.

4 Click **Delete** to delete the selected template.

If it is the default one or it has the print duty, it cannot be deleted.

8.4.6 Defining chemistry print order

To define chemistry print order

1 Select **Utility > System Setup**, and select **Print F3**.

2 Select **Print Order**.

Figure 8.12 Print Order window

3 Use the following buttons to adjust the chemistry print order:

- **Home**: to move the chemistry to the first position.

- **Up**: to move the chemistry to the previous position.
- **Down**: to move the chemistry to the next position.
- **End**: to move the chemistry 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.

6 To restore the factory settings, select **Restore Defaults**.

8.5 Bar code setup

On the **Bar Code Setup** window, you can set up sample and reagent bar code parameters. Only when a bar code reader is installed, can the settings be performed.

To perform sample bar code setup

1 Select **Utility > System Setup**, and select **Bar Code F4**.

2 Choose **Sample Bar Code**.

3 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.

4 Set up sample bar code applications.

- Enable/Disable sample carousel bar code

When this option is selected, the system scans the entire sample carousel to locate samples at the beginning of test.

- Enable or disable auto numbering of bar-coded samples

When this option is enabled, the system will automatically number the bar-coded samples during bar code scanning. The start number will be the next available one since the last sample is programmed. The default start number for every day is 1.

- Extract sample information

When this option is selected, the system will automatically extract the sample information according to the barcode.

Only when LIS communication mode is unidirectional, can the option be enabled.

- Define STAT sample positions on sample carousel

Input the start and end positions within the range of 1~79 and E1~E11. The set positions will be indicated by E (Emergent) on the sample carousel status screen. Samples placed in the specified STAT positions will be taken automatically as emergent samples.

The **Sample Crsl Bar Code** and **Auto Number Scanned Samples** options are selected by default.

5 Select **OK** to save the setup.

6 Select **Format**

7 Define the bar code digits.

The system can scan a sample bar code of fixed length or within 3-27 digits. The Interleaved 2 of 5 only supports bar code of even number length and the digits of the barcode must be defined.

- To use a fixed-length bar code,

Mark the **Fixed Digits** checkbox of relevant symbology.

Type in the number of digits in the edit box to the right of the **Fixed Digits** field.

- To use a sample bar code within 3-27 digits, you have no need to define the fixed digits.

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

To perform reagent bar code setup

1 Select **Utility > System Setup**, and select **Bar Code F4**.

2 Choose **Reagent Bar Code**.

3 Select or deselect **Analyze barcode of open reagent**.

- If Reagent barcode system is configured, the option **Analyze barcode of open reagent** is not selected by default
- When **Analyze barcode of open reagent** is selected, once the barcode of the open reagent is identified, its information is analyzed according to its setup.
- While loading the reagent manually, you can enter the barcode of the open reagent on the condition that **Analyze barcode of open reagent** is not selected.

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 **T** 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 **S** field.
- Type in the end digit of the reagent bar code in the **E** 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 **S** field.
- Type in the end digit of the reagent information in the **E** field.

Table 8.1 Reagent bar code compositions

Reagent Information	Number of Digits
Chemistry number	0-4 digits
Chemistry name	0-10 digits
Reagent type	1 digit ("1" stands for R1 and "2" stands for R2)
Serial number	0-5 digits
Bottle type	1-3 digits(one digit is recommended; "1" stands for Mindray 20ml inner or outer ring reagent bottle; "2" for mindray old 40ml inner ring bottle; "3" for new 40ml inner ring bottle;)
Lot number	0-18 digits
Expiration date	0, 4, 6 or 8 digits (4 digits: yymm; 6 digits: yyyymm; 8 digits: yyyymmdd)

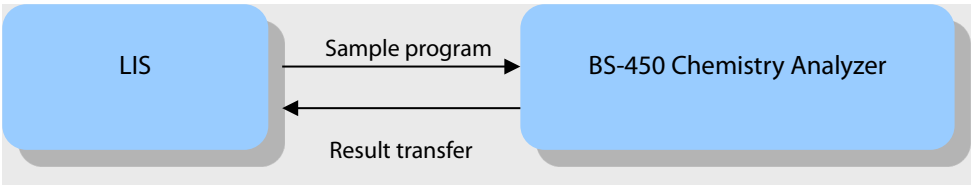
7 Select **OK**.

8.6 LIS setup

8.6.1 Introduction

The BS-450 is connected with LIS (Laboratory Information System) through a fixed interface, to download sample program information, send test results after test, review and print the test results.

Figure 8.13 Connection between the BS-450 and LIS



The host communication parameters, such as transmission mode, IP address and port, should be set up prior to use of the LIS host. To download sample program information from or sent results to the host, you need to set up the chemistry code used for identification of chemistries on both the LIS host and the analyzer, which, otherwise, cannot identify the chemistries simultaneously.

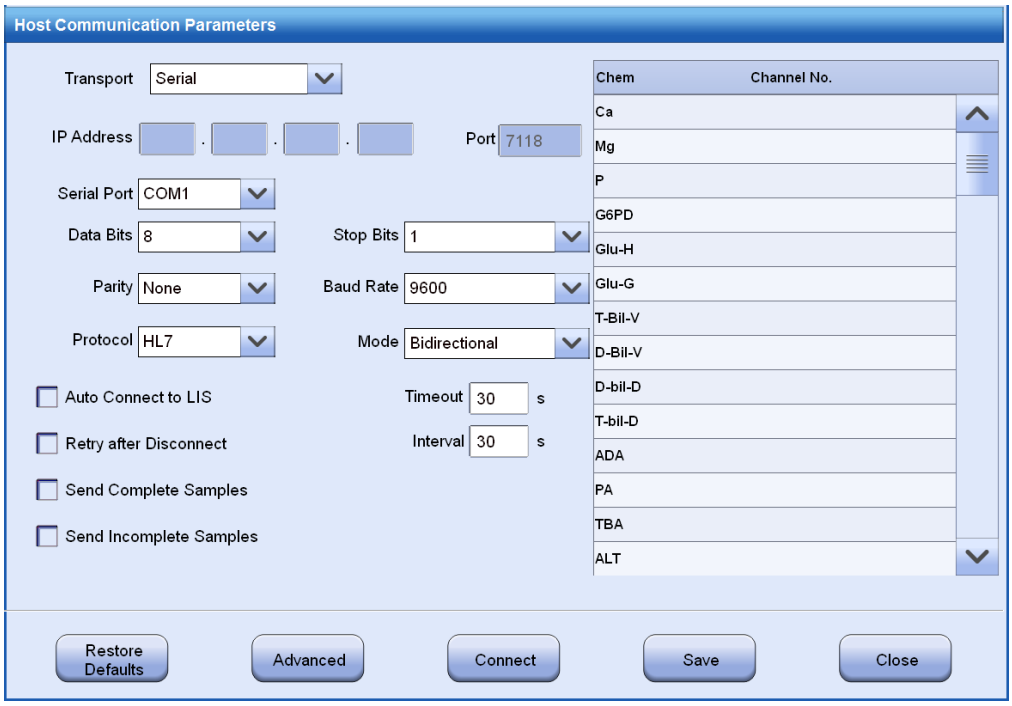
8.6.2 Setting up host communication parameters

To set up host communication parameters

1 Select **Utility** > **System Setup**.

2 Select **Host F5**. The **Host Communication Parameters** window shows.

Figure 8.14 Host communication Parameters window



3 Set up the following parameters:

Table 8.2 Host communication parameters

Parameter	Description
Transport	Choose a transport mode from the **Transport Mode** drop-down list. The options include Serial and TCP/IP. The default is Serial.
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.
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.
Protocol	Choose a protocol for connection between the analyzer and the LIS host from the **Protocol** drop-down list. The options include HL7 and ASTM 1394.
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 programs from it. Bidirectional: You are allowed to send results and patient demographics to the host and downloading sample programs from it.

Parameter	Description
Timeout	Enter the time out limit for querying the LIS host. The input range is 30s-60s, and the default is 30s. If the time out limit is exceeded when you attempt to download sample programs from, or send results to, or connect the analyzer with the LIS host, the system will give an alarm indicating communication timed out.
Auto Connect to LIS	When the checkbox is selected, the system will connect to the LIS host automatically when started up.
Retry after Disconnection	When the checkbox is selected, the system will try to reconnect the LIS host for every set interval once the connection is interrupted.
Interval	Input the time interval for which the system will try to reconnect the LIS host for every set interval once the connection is interrupted. The default is 30 seconds.
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.
Advanced options	Select **Advanced**. The **Advanced** window appears, providing the following options: **Send Programmed Samples**: When the checkbox is selected, the system will automatically send the program information to the LIS host once a single or batch routine and STAT samples are programmed. **Rerun Finished Chemistries When Downloaded**: When the checkbox is selected, chemistries that have been finished will be rerun if downloaded again. If this option is not selected, they will be neglected. **Send Actual Results and Rerun Results**: When the checkbox is selected, all actual results and rerun results of each chemistry will be sent to the LIS. If this option is not selected, only the default result will be sent. **Bypass Results Beyond Linearity Range**: When the checkbox is selected, those results that are beyond the linearity range will not be sent to the LIS. If this option is not selected, they will be sent. **Ignore Alarms for Unknown Chemistries**: When the checkbox is selected, the system will not give an alarm if the samples downloaded from the LIS host contain unknown chemistries without identification code. If this option is not selected, an alarm will be given indicating sample programming failure.

4 Select **Save** to save your input information.

5 Select **Connect** to connect the analyzer with the LIS host.

8.6.3 Defining channel number of chemistries

Chemistries are identified by channel number on the analyzer and LIS host. Make sure that the channel numbers assigned to chemistries on the analyzer are consistent with those on the LIS host; otherwise, correct information transfer cannot be done.

To define channel number of chemistries

1 Select **Utility > System Setup**.

2 Select **Host F5**. The **Host Communication Parameters** window shows.

3 View the chemistry channel number list on the right of the window.

The screen shows the chemistries and code in two columns. The left column provides all chemistries that have been defined and set up correctly; the right column shows the code for identifying a chemistry on the LIS host.

4 Click on the **Channel No.** column of a chemistry, and then type in a code for it.

5 Repeat step 4 to define a code for other chemistries.

6 Select **Save**.

8.7 User and Password Setup

Users can be defined, deleted or modified on the **User and Password** window. 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.

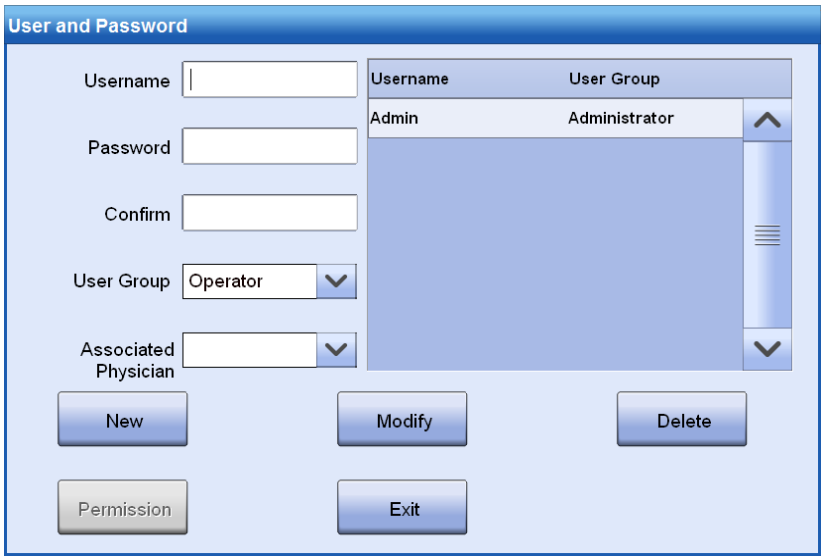
8.7.1 Defining a user

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.

To define a user

1 Select **Utility > System Setup**, and select **User F6**.

Figure 8.15 User and Password window



2 Enter the username.

3 Enter the password.

A maximum of 20 characters can be entered.

4 Enter the password again in the **Confirm** field.

5 Choose a user group in the **User Group** drop-down list.

The options include:

- Administrator
- Operator

6 Select a doctor from **Associated Physician** drop-down list.

When the user and the associated physician have been set up, the default operator in the patient demographics is the associated physician of the current login user.

7 Select **New**. The defined user appears in the user list.

8 Select **Exit** to close the window.

8.7.2 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.

To modify a user

1 Select **Utility > System Setup**, and select **User F6**.

2 Choose a user to edit in the user list.

3 Enter the new username.

4 Enter the new password.

5 Enter the new password again in the **Confirm Password** field.

6 Choose a user group in the **User Group** drop-down list.

The options include:

- Administrator
- Operator

7 Select **Modify**.

8 Select **Exit** to close the window.

8.7.3 Assigning/Modifying permissions

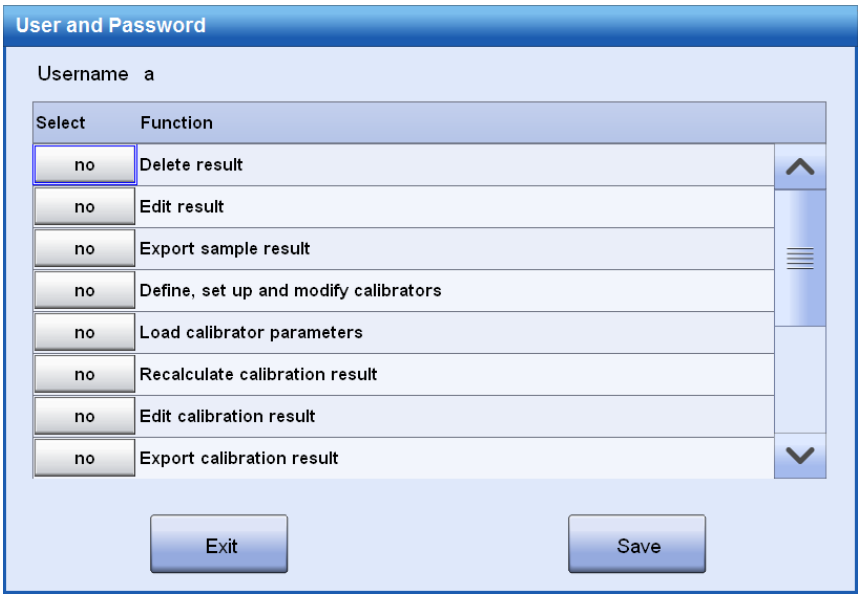
Permissions are assigned to user groups, which include administrator and operator. Administrators are allowed to use, assign and modify all permissions that are assigned for operators; while operators are only allowed to use common functions, such as assigning reagent position; programming samples, controls and calibrators; recalling sample/QC/calibration results; and those assigned by the administrators.

To assign/modify permissions

1 Select **Utility > System Setup**, and select **User F6**.

2 Choose a user you desire to set up permissions in the user list, and then select **Permission**.

Figure 8.16 Permission assignment



3 Assign permissions for the selected user.

- To assign new permissions, select the box in front of the relevant operation. The select button changes to Yes.
- To cancel permissions, deselect the box in front of the relevant operation. The select button changes to No.

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

5 Select **Exit** to close the window.

8.7.4 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.

To delete a user

1 Select **Utility > System Setup**, and select **User F6**.

2 Choose a username in the user list.

3 Select **Delete**.

4 Select **OK**.

5 Select **Exit** to close the window.

9 Template modifying software

The Template Modifying Software is affiliated with the Operating Software and used to create or edit print templates, which illustrate the contents and format of patient reports.

The Template Modifying Software can be started separately or together with the Operating Software. To start the Template Modifying Software, select the **Edit** button on the **Print** page of the operating software.

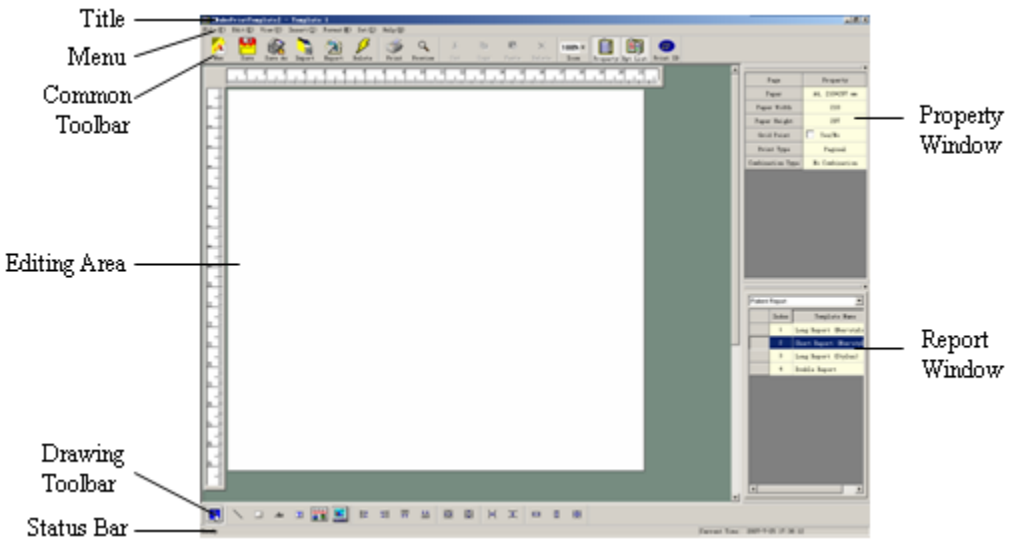
The following sections introduce the Template Modifying Software by menus and toolbars.

9.1 Main screen

9.1.1 Main screen

The following figure shows the main screen of the Template Modifying Software.

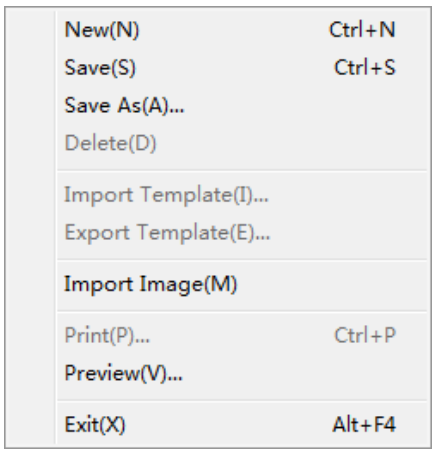
Figure 9.1 Main screen



9.1.2 File (F)

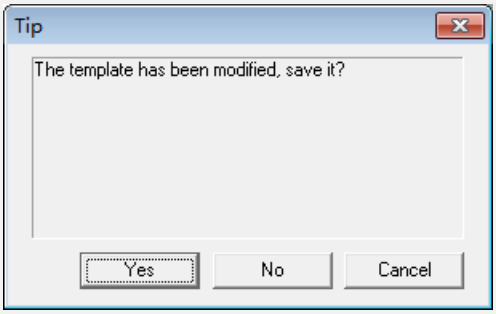
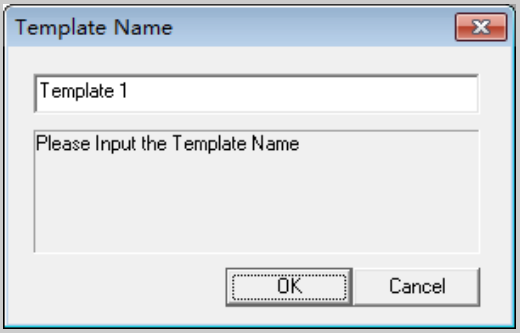
The **File** menu is used to create, save, import/export and print out the templates. Select **File** on upper-left corner of the main screen. The **File** menu is displayed.

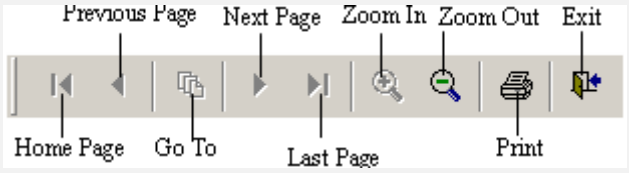
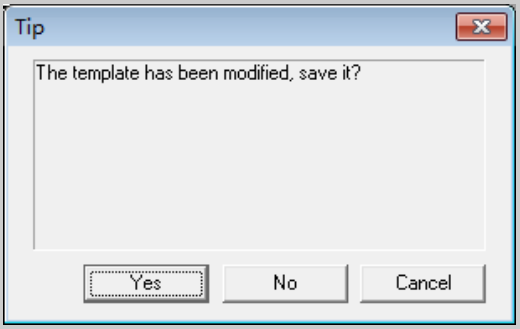
Figure 9.2 File menu



The following table explains the menu in detail.

Table 9.1 Options of the File menu

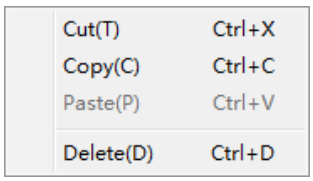
Option	Description
New	Select **New** to create a template. The type of the template is determined by the report that is currently selected on the report window. You can also use the shortcut key Ctrl+N instead. After changing the currently-displayed template, select **New** to display the following dialog box.  Select **Yes** to save the changes and create a template. Select **No** to cancel the changes and create a template. Select **Cancel** to abort creating and return to the previous screen.
Save	Select **Save** to save the newly-created template or the changes to a template. You can also use the shortcut key Ctrl+S instead. To save a new template, you should define the template name:  Enter the name in the edit box. Select **OK** to save the template and add the name to the template list on the report window. Select **Cancel** to abort saving and return to the previous screen. If a template with the same name already exists, a dialog box pops up. Select **Yes** to overwrite the template. Select **No** to cancel saving and return to the previous screen.
Save As	Save the current template with another name. If a template with the same name already exists, a dialog box appears to ask for your confirmation.
Delete	Delete a template. Not available.
Import Template	Import a template. Not available.
Export Template	Export a template. Not available.

Option	Description
Import Image	Import BMP, GIF, JPEG, PNG, TIFF, and EMF images from a storage device to the picture folder.
Print	Print the current template. Not available.
Preview	Select this option to view the template exactly as it will be printed out. The main screen will be hidden when you preview a template. The tool bar on the **Preview** window is as follows.  If the template has more than one page, and are available. : Go to the first page. : Go to the previous page. : Go to the specified page. : Go to the next page. : Go to the last page. : Select to expand the template view among 25%, 50%, 75% and 100%. The default is 100%. : Select to shrink the template view. : Print out the template. It is equivalent to the **Print** option in the **File** menu. : Select to exit the preview window and return to the template.
Exit	Select this option to close the Template Modifying Software. You can use the shortcut key Alt+F4 instead. If the template is changed, the following dialog box pops up.  Select **Yes** to save the changes and exit the software. Select **No** to exit the software without saving the changes. Select **Cancel** to abort exiting and return to the previous screen.

9.1.3 Edit (E)

The **Edit** menu provides the functions like cut, copy, paste and delete. Select **Edit** on the menu bar of the main screen. The **Edit** menu is displayed.

Figure 9.3 Edit menu



NOTE

The control(s) you have cut or copied can only be pasted on the current Template Modifying Software rather than another one or other software.

The following table explains the menu in detail.

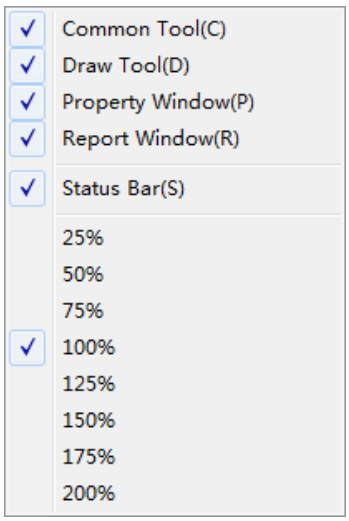
Table 9.2 Options of the Edit menu

Option	Description
Cut	Select this option to copy and delete single or multiple controls. You can use the shortcut key Ctrl+X instead. This option is available only when a control(s) is selected.
Copy	Select this option to copy single or multiple controls. You can use the shortcut key Ctrl+C instead. This option is available only when a control(s) is selected.
Paste	Select this option to paste the controls that are previously cut or copied at the same place as where the controls are from. You can use the shortcut key Ctrl+P instead. This option is available only when a control(s) is cut or copied.
Delete	Select this option to delete single or multiple controls You can use the shortcut key Ctrl+D instead. This option is available only when a control(s) is selected.

9.1.4 View (V)

The ***View*** menu is used to enable or disable the toolbars and to set up the displaying proportion. Select **View** on the menu bar of the main screen. The **View** menu is displayed.

Figure 9.4 View menu



The following table explains the menu in detail.

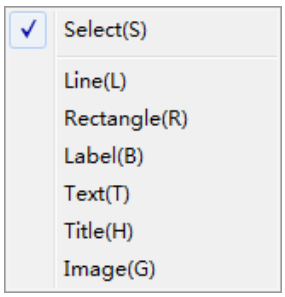
Table 9.3 Options of the View menu

Option	Description
Common Tool	Enable or disable the common toolbar.
Draw Tool	Enable or disable the draw toolbar.
Property Window	Enable or disable the property window.
Report Window	Enable or disable the report window.
Status Bar	Enable or disable the status bar.
25%-200%	Select a proportion to display the template. The default is 100%. **NOTE** You are recommended to select 100% when saving a template.

9.1.5 Insert (I)

The **Insert** menu is used to create controls in the editing page. Select **Insert** on the menu bar of the main screen. The **Insert** menu is displayed.

Figure 9.5 Insert menu



Only one option on the **Insert** menu can be selected simultaneously.

Table 9.4 Options of the Insert menu

Option	Description
Select	Select this option to change the mouse pointer to a . When the mouse pointer changes to a , you can select single or multiple controls in the editing area. **NOTE** Selecting a control while holding the Ctrl key copies the control.
Line	Select this option to insert a line in the editing area. The mouse pointer changes into a +. Click once in the editing area and drag the mouse to draw a line.
Rectangle	Select this option to insert a rectangle in the editing area. The mouse pointer changes into a +. Click once in the editing area and drag the mouse to draw a rectangle.
Label	Select this option to insert a label in the editing area. The mouse pointer changes into a +. Click once in the editing area and drag the mouse to draw a label. Label is a type of text control and the contents on a label will not change when printed.
Text	Select this option to insert a text control in the editing area. The mouse pointer changes into a +. Click once in the editing area and drag the mouse to create a text. The contents in a text control will be replaced by the actual test data when printed.
Title	Select this option to insert a title in the editing area. The mouse pointer changes into a +. Click once in the editing area and drag the mouse to create a title. Title is a type of text control. The "%s" will be replaced by a hospital name when printed. Please note "%s" is added by user and not produced automatically.
Image	Select this option to insert an image in the editing area. The mouse pointer changes into a +. Click once in the editing area and drag the mouse to create an image. The image on the template is for illustration only and will be replaced by corresponding curve graph when printed.

9.1.6 Format (M)

The **Format** menu is used to arrange the controls on a template. Select **Format** on the menu bar of the main screen. The **Format** menu is displayed.

Figure 9.6 Format menu

The following table explains the menu in detail.

Table 9.5 Options of the Format menu

Option	Description
Left	Align the specified controls with the left of the lastly-selected control.
Right	Align the specified controls with the right of the lastly-selected control.
Top	Align the specified controls with the top side of the lastly-selected control.
Bottom	Align the specified controls with the bottom side of the lastly-selected control.
Center H	Align one or multiple controls to the horizontal center of current template.
Center V	Align one or multiple controls to the vertical center of current template.
Even Space H	Arrange three or more controls with same space horizontally.
Even Space V	Arrange three or more controls with same space vertically.
Same Width	Adjust the specified controls to the same width as the lastly-selected control.
Same Height	Adjust the specified controls to the same height as the lastly-selected control.
Same Size	Adjust the specified controls to the same width and height as the lastly-selected control.

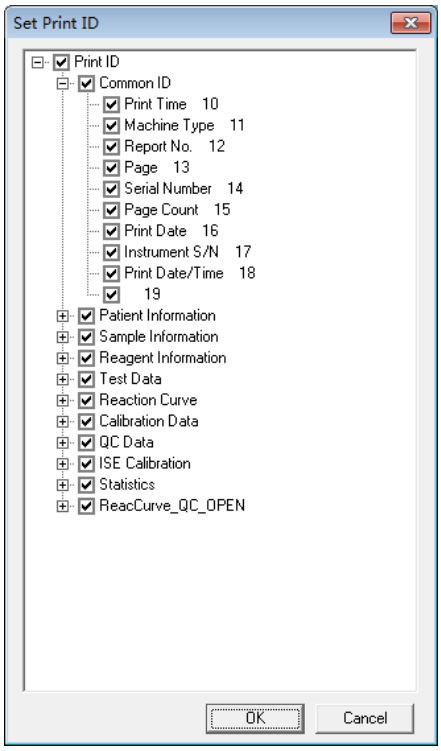
9.1.7 Set(S)

The ***Set*** menu only includes an option, **Print ID**. See the figure below.

Figure 9.7 Set menu

Select **Print ID.** The **Set Print ID** dialog box is displayed. You can enable or disable the print fields and view the corresponding ID of each field.

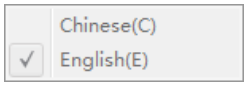
Figure 9.8 Set Print ID window



9.1.8 Language (L)

Select **Language** on the menu bar of the main screen. The **Language** menu is displayed.

Figure 9.9 Language menu



The following table explains the menu in detail.

Table 9.6 Options of the Language menu

Option	Description
Chinese	Switch the screen language to Chinese. Not available.
English	Switch the screen language to English. Not available.

9.1.9 Help (H)

Select **Help** on the menu bar of the main screen. The **Help** menu is displayed.

Figure 9.10 Help menu

The following table explains the menu in detail.

Table 9.7 Options of the Help menu

Option	Description
Version	Select this option to view the version information of the template modifying software.

9.2 Common tools

The common toolbar provides the shortcut buttons that enables you to perform an operation quickly.

Figure 9.11 Common toolbar

The following table shows the correspondence between the shortcut buttons and menu options.

Table 9.8 Common tools

Button	Menu Option	Button	Menu Option
New	File/New	Cut	Edit/Cut
Save	File/Save (not enabled)	Copy	Edit/Copy
Save As	File/Save As	Paste	Edit/Paste
Import	File/Import	Delete	Edit/Delete
Export	File/Export	Zoom	View/25%-200%
Delete	File/Delete	Property	View/Property Window
Print	File/Print	Rpt List	View/Report Window
Preview	File/Preview	Print ID	Set/Print ID

9.3 Draw tools

The draw toolbar provides the shortcut buttons that enables you to create and draw controls quickly.

Figure 9.12 Draw tool bar

The following table shows the correspondence between the shortcut buttons and menu options.

Table 9.9 Draw tools

Button	Menu Option	Button	Menu Option
	Insert/Select		Format/Top
	Insert/Line		Format/Bottom
	Insert/Rectangle		Format/Center H
	Insert/Label		Format/Center V
	Insert/Text		Format/Even Space H
	Insert/Title		Format/Even Space V

Button	Menu Option	Button	Menu Option
	Insert/Image		Format/Same Width
	Format/Left		Format/Same Height
	Format/Right		Format/Same Size

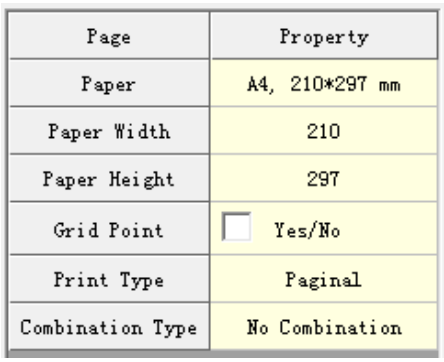
9.4 Property window

The property window enables you to view and edit the properties of the selected control. If no control is selected in the window, the properties of the current template are displayed.

9.4.1 Page

When no control is selected, the property window shows the properties of the current template, such as paper, print type, etc.

Figure 9.13 Page property area



Page	Property
Paper	A4, 210*297 mm
Paper Width	210
Paper Height	297
Grid Point	Yes/No
Print Type	Paginal
Combination Type	No Combination

The following table explains the template properties in detail.

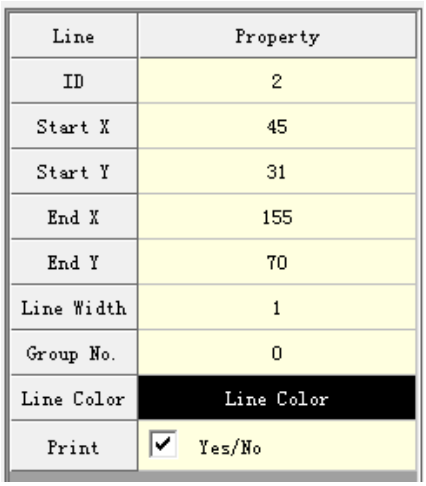
Table 9.10 Page properties

Parameter	Description
Paper	Define the paper type of the template. There are 9 common types available. If the paper width and height you defined are beyond the specified range, **Custom** is displayed in the **Paper** field.
Paper Width	Define the width of the template.
Paper Height	Define the height of the template.
Grid Point	Enable or disable grid points on the template.
Print Type	Includes Paginal and Serial. Not available.
Combination Type	Whether to print two reports on one piece of paper. Merging reports is now not permitted. Not available.

9.4.2 Line

When a line control is selected, the property window shows the properties of the line.

Figure 9.14 Line property area



The following table explains the line properties in detail.

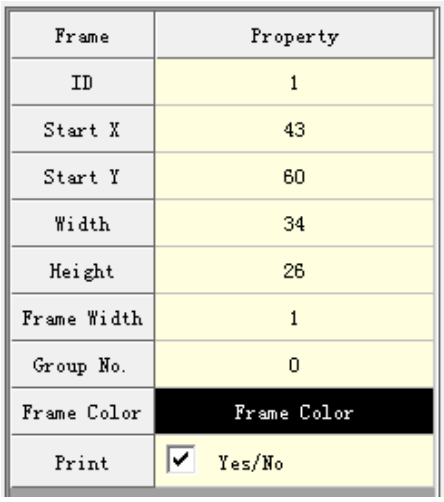
Table 9.11 Line properties

Parameter	Description
ID	Print ID of the line. The ID is 2.
Start X	Set the X-coordinate value of the start point. **NOTE** The control coordinate originates from the upper-left corner of the editing area, from which the X axis (positive) is extended horizontally to the right and the Y axis (positive) vertically to the bottom. The unit is mm.
Start Y	Set the Y-coordinate value of the start point.
End X	Set the X-coordinate value of the end point.
End Y	Set the Y-coordinate value of the end point.
Line Width	Set the width of the line. The unit is mm.
Group No.	A group gathers multiple controls that will be used frequently on the template. e.g. a line of controls constitutes a group. The group No. is 0 if not defined.
Line Color	Set the color of the line.
Print	Enable or disable printing the line on actual reports.

9.4.3 Rectangle

When a rectangle control is selected, the property window shows the properties of the rectangle.

Figure 9.15 Rectangle property area



The following table explains the rectangle properties in detail.

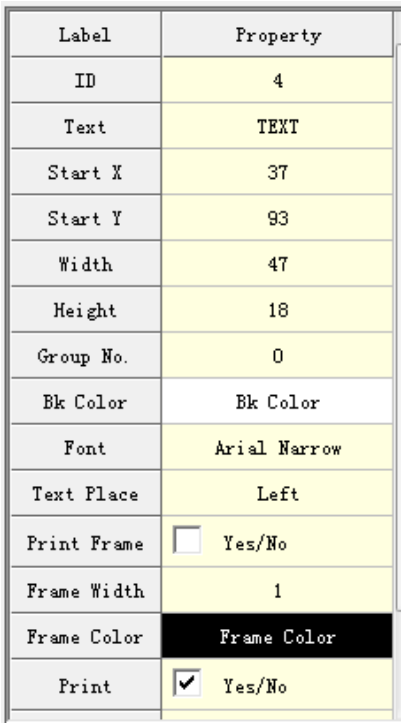
Table 9.12 Rectangle properties

Parameter	Description
ID	Print ID of the line. The ID is 1.
Start X	Set the X-coordinate value of the start point (upper-left corner).
Start Y	Set the Y-coordinate value of the start point (upper-left corner).
Width	Set the width of the rectangle.
Height	Set the height of the rectangle.
Frame Width	Set the frame width of the rectangle.
Group No.	A group gathers multiple controls that will be used frequently on the template. e.g. a line of controls constitutes a group. The group No. is 0 if not defined.
Frame Color	Set the color of the frame.
Print	Enable or disable printing the rectangle on actual reports.

9.4.4 Label

When a label control is selected, the property window shows the properties of the label.

Figure 9.16 Label property area



The following table explains the label properties in detail.

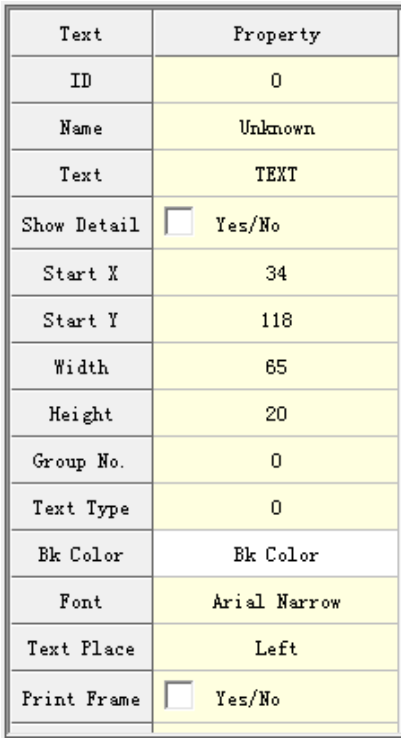
Table 9.13 Label properties

Parameter	Description
ID	Print ID of the label. The ID is 4.
Text	Set the text on the label. It will be printed unchanged on actual reports.
Start X	Set the X-coordinate value of the start point (upper-left corner).
Start Y	Set the Y-coordinate value of the start point.
Width	Set the width of the label.
Height	Set the height of the label.
Group No.	A group gathers multiple controls that will be used frequently on the template. e.g. a line of controls constitutes a group. The group No. is 0 if not defined.
Bk Color	Set the background color of the label.
Font	Set the font of the label text.
Text Place	Set the aligning mode of label text. It includes Left, Center and Right.
Print Frame	Enable and disable printing frame.
Frame Width	Set the width of the label frame.
Frame Color	Set the color of the label frame.
Print	Enable or disable printing the label on actual reports.
Text ID	Set text ID for the control. When it is edited, the template is refreshed.
Replace text	Choose whether to use the defined text ID to replace the text of the control.

9.4.5 Text

When a text control is selected, the property window shows the properties of the text.

Figure 9.17 Text property area



The following table explains the text properties in detail.

Table 9.14 Text properties

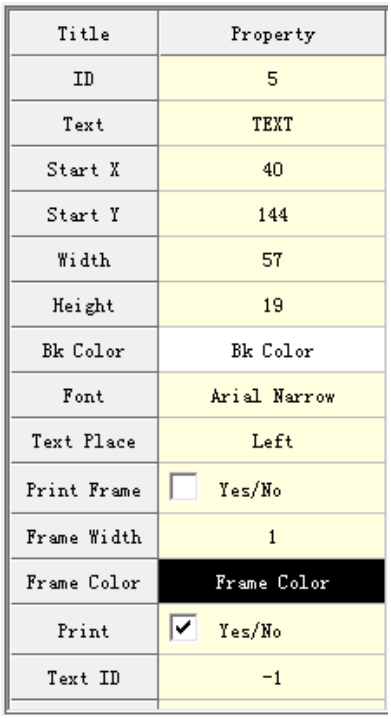
Parameter	Description
ID	Print ID of the text. The default is 0 and means unknown ID. Print ID indicates the meaning of the text. Correct printout can be ensured only when print ID is set properly.
Name	Set the contents to be displayed on the text control. It varies from different IDs.
Text	Set the contents displayed on the text control. It will be replaced by actual data when printed.
Show Detail	Enable or disable printing the control in group.
Start X	Set the X-coordinate value of the start point (upper-left corner).
Start Y	Set the Y-coordinate value of the start point.
Width	Set the width of the text.
Height	Set the height of the text.
Group No.	A group gathers multiple controls that will be used frequently on the template. e.g. a line of controls constitutes a group. The group No. is 0 if not defined.
Text Type	Reserved parameter. The default is 0.
Bk Color	Set the background color of the text.
Font	Set the font of the text.
Text Place	Set the aligning mode of the text. It includes Left, Center and Right.

Parameter	Description
Print Frame	Enable and disable printing frame.
Frame Width	Set the width of the text frame.
Frame Color	Set the color of the label frame.
Print	Enable or disable printing the text on actual reports.

9.4.6 Title

When a title control is selected, the property window shows the properties of the title.

Figure 9.18 Title property area



The following table explains the title properties in detail.

Table 9.15 Title properties

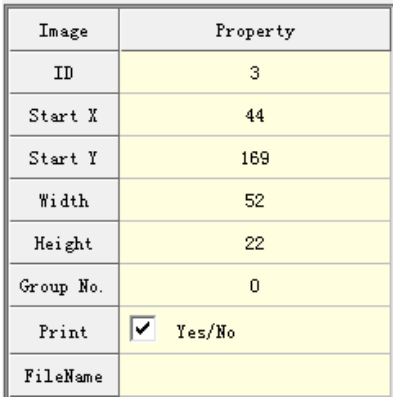
Parameter	Description
ID	Print ID of the title. The ID is 5.
Text	Set the contents to be displayed on the title. "%s" will be replaced by a hospital name and can be displayed in any place of the title.
Start X	Set the X-coordinate value of the start point (upper-left corner).
Start Y	Set the Y-coordinate value of the start point.
Width	Set the width of the title.
Height	Set the height of the title.
Bk Color	Set the background color of the title.
Font	Set the font of the title text.

Parameter	Description
Text Place	Set the aligning mode of title text. It includes Left, Center and Right.
Print Frame	Enable and disable printing frame.
Frame Width	Set the width of the title frame.
Frame Color	Set the color of the title frame.
Print	Enable or disable printing the title on actual reports.
Text ID	Set text ID for the control. When it is edited, the template is refreshed.
Replace text	Choose whether to use the defined text ID to replace the text of the control.

9.4.7 Image

When an image control is selected, the property window shows the properties of the image.

Figure 9.19 Image property area



The following table explains the image properties in detail.

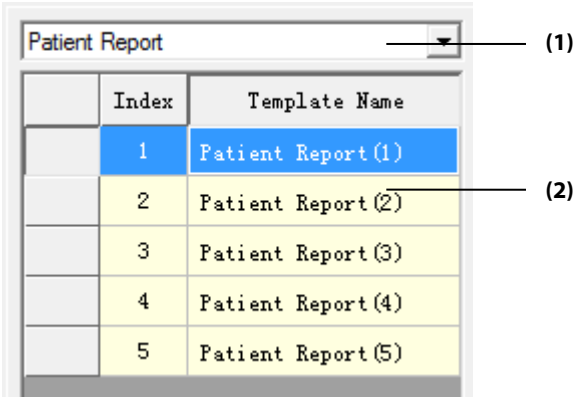
Table 9.16 Image properties

Parameter	Description
ID	Print ID of the image. The ID is 3.
Start X	Set the X-coordinate value of the start point (upper-left corner).
Start Y	Set the Y-coordinate value of the start point.
Width	Set the width of the image.
Height	Set the height of the image.
Group No.	A group gathers multiple controls that will be used frequently on the template. e.g. a line of controls constitutes a group. The group No. is 0 if not defined.
Print	Enable or disable printing the image on actual reports.
File Name	Name of image file. Specify it in the picture folder and draw it on the image control.

9.5 Report window

The report window locates on the lower-right corner of the main screen and shows all the templates of a selected report type.

Figure 9.20 Report window



(1) Report type

(2) Template list

10 Diagnostics

This chapter provides test descriptions, test procedures, test results and corrective actions for diagnosis in Sample and Reagent systems.

10.1 Overview

Diagnostics consist of a series of tests and actions, which are used for troubleshooting errors. These tests and actions are made to detect failures, but cannot be used to confirm one specific failure. Users should make a judgment by integrating the information of diagnosis and warnings with the failure characteristics. Diagnostic tests available in two function modules are described in the table below.

Table 10.1 Categories of diagnostics

Function Module	Description
Sample System	Diagnostic tests here are used to detect failures of components in Sample system.
Reagent System	Diagnostic tests here are used to detect failures of components in Reagent system.
Sensor Diagnosis	Diagnostic tests here are used to detect failures of the sensors.

10.2 Diagnosis of Sample System

10.2.1 Introduction

The Sample System is responsible for delivering samples to the system for analysis. Tests include:

- Sample Probe Clog Detection
- Sample Probe Level Sense Test

10.2.2 Sample Probe Clog Detection

Test description

This test can help you find if the Sample Probe Clog Detection function works normally. Related data or text will be displayed after testing, which can be used to confirm the results.

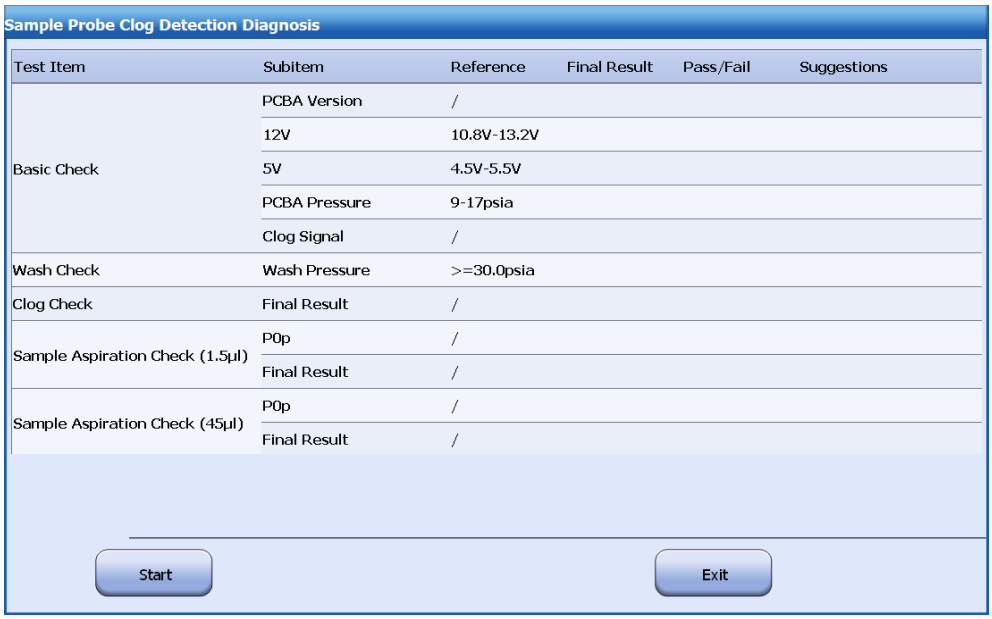
Use this test when one of the following alarms is given:

- Clog detection board communication error.
- The sample probe is clogged while the sample is deemed OK.
- The sample probe is clogged during cleaning.
- Clog detection board working mode setting error.

Test procedure

1. Select **Utility > Maintenance > Diagnostics**.
2. Select **Sample System** tab.
3. Select **Sample Probe Clog Detection**.
4. Load one sample tube of water onto Position 1 on sample carousel, and click **Next** to open the **Sample Probe Clog Detection Diagnosis** window.

Figure 10.1 Sample Probe Clog Detection Diagnosis window



5 Click **Start**.

The system starts to run each test for sample probe clog detection. Tests include:

- Basic Check
- Wash Check
- Clog Check
- Sample Aspiration Check (1.5μL)
- Sample Aspiration Check (45μL)

6 When tests are complete, the tested voltage and the level sense test data are displayed on the screen.

7 Click **Exit** to close the window.

Test results

The testing result of each subitem is displayed on the screen. Judge if the result meets the requirements by comparing with the corresponding reference value. “PASS” in the PASS/FAIL column indicates the test is normal, while “FAIL” indicates the test fails and it should be corrected based on the suggestions provided.

Corrective action

Table 10.2 Sample system obstruction detection reference range and corrective action

Test Type	Test Item	Reference Range	Corrective Action
Basic Check	Version of Clog Detection Board	/	Contact our customer service department or your local distributor.
	12V	10.8V-13.2V	
	5V	4.5V-5.5.V	
	Pressure of Clog Detection Board	9psia-17psia	
	Clog Signal	OK/Error/”/”	
Wash Check	Wash Pressure	≥30 psia	
Clog Check	Final Result	OK/Error/”/”	
	P0p	/	

Test Type	Test Item	Reference Range	Corrective Action
Sample Aspiration Check (1.5μL)	Final Result	OK/Error/"/"	
Sample Aspiration Check (45μL)	P0p	/	
	Final Result	OK/Error/"/"	

10.2.3 Sample Probe Level Sense Test

Test description

The Level Sense Test is used to diagnose the level detection performance of the sample system and gives related data that helps you locate the causes of an error.

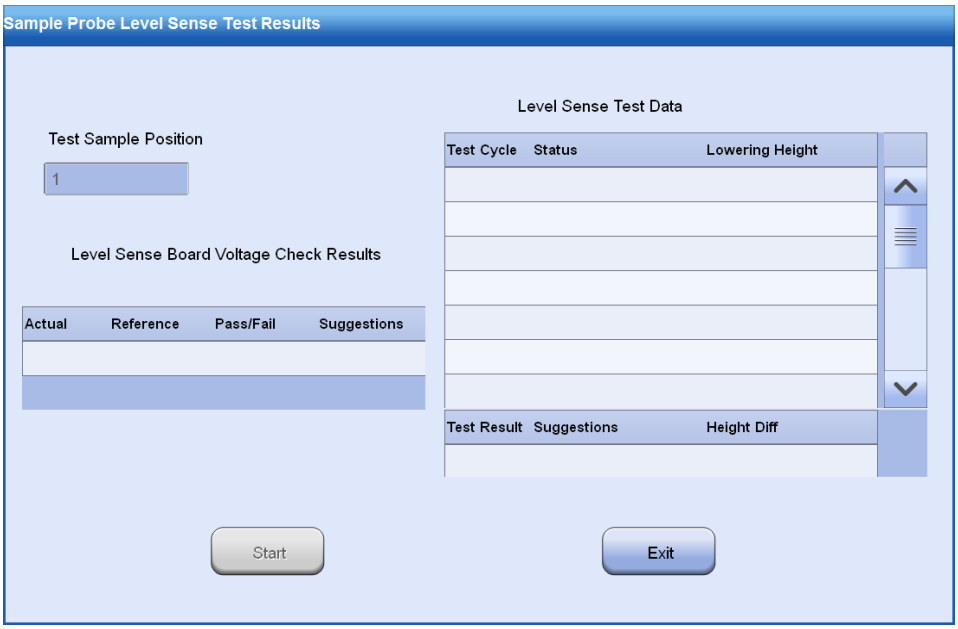
Use this test when one of the following conditions happens:

- An alarm message appears indicating that the sample probe contacts no liquid in the aspiration positions (include sample carousel, reaction carousel and concentrated wash position) and the analysis is stopped.
- An alarm message appears indicating that the sample probe aspirates nothing in the aspiration positions and the analysis is stopped, and has confirmed that the failure is not caused by probe clog.
- An alarm message appears indicating that the sample probe contacts no liquid during dispensing samples into reaction carousel and the analysis is stopped, and has confirmed that the failure is not caused by neither reagent bubbles nor reagent probe level sensing.
- An alarm message appears indicating that problems related with level sensing occur during dispensing samples in ISE module, and has confirmed it is not the problems of ISE module itself.
- An alarm message appears indicating that the sample probe contacts no liquid during liquid dispensing (also called water testing), and the analysis is stopped.
- An alarm message appears indicating that the sample probe contacts no liquid in the wash well and the analysis is stopped, and has confirmed that it is not a hydropneumatic failure.

Test procedure

1. Select **Utility > Maintenance > Diagnostics**.
2. Select **Sample System** tab.
3. Select **Sample Probe Level Sense Test**.
4. Place a tube with its 2/3 full of water in test position, and click **Next** to open the **Sample Probe Level Sense Test Results** window.

Figure 10.2 Sample Probe Level Sense Test Results window



The default test position is position 1 on the sample carousel. To change the test position, click **Change Pos** and enter a new number within the range from 1 to 102, and then click **Next**.

5 Click **Start**.

The system will start to check the level sense board voltage of the sample probe, and continuously detect level in the test position for 20 times.

6 When tests complete, the tested voltage and the level sense test data will be displayed on the screen.

7 Click **Exit** to close the window.

Test results

The results shown are described below:

Level Sense Board Voltage Check Results

If the Actual value falls in the Reference range, the result is PASS, indicating the voltage of the level detection board is normal; otherwise, the result is FAIL, indicating the voltage is abnormal. You should correct it based on the suggestions provided.

Level Sense Test Data

The system will continuously check the lowering height of the sample probe for 20 times, to judge if the lowering position is the vertical extreme position. If it is, abnormity exists. If the extreme difference of 20 lowering heights is greater than 1mm, then the result should be considered as abnormal, indicating that there are problems with connections of sample probe and Printed Circuit Board Assembly (PCBA), PCBA power, output voltage for level sense detection, or connections of level sense board and probe/mixer conversion board, and vice versa. You should correct it based on the suggestions provided.

Corrective action

If the operating voltage of the level detection board is beyond the reference range of 2.8V-4.8V, contact our customer service department or your local distributor.

If the result of the level detection performance is abnormal, contact our customer service department or your local distributor.

10.3 Diagnosis of Reagent System

10.3.1 Reagent Probe Level Sense Test

Test description

The Level Sense Test is used to diagnose the level detection performance of the reagent probe and gives related data that helps you locate the causes of an error.

Use this test when one of the following conditions happens:

- An alarm message appears indicating that the reagent probe contacts no liquid on the reagent carousel, and the analysis is stopped.
- An alarm message appears indicating that reagent probe aspirates nothing in the aspiration position and the analysis is stopped.
- An alarm message appears indicating that the reagent probe contacts no liquid during dispensing reagents and the analysis is stopped, and has confirmed that it is not caused by reagent bubbles.
- An alarm message appears indicating that the reagent probe contacts no liquid in the wash well and the analysis is stopped, and has confirmed that it is not a hydropneumatic failure.

Test procedure

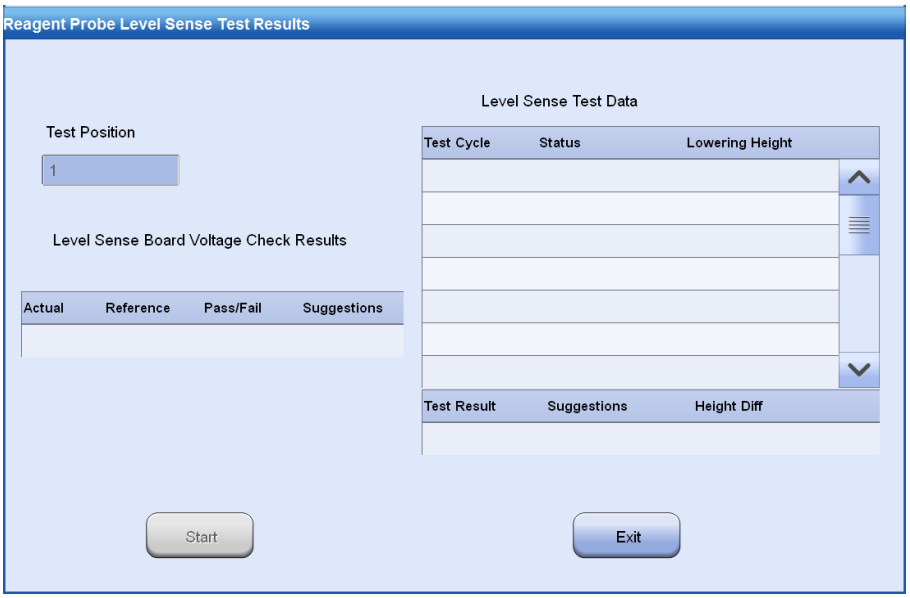
1 Select **Utility> Maintenance>Diagnostics**.

2 Select **Reagent System** tab.

3 Select **Reagent Probe Level Sense Test**.

4 Place a bottle with its 2/3 full of water in position 1 of the reagent carousel, and click **Next** to open **Reagent Probe Level Sense Test Results** window.

Figure 10.3 Reagent Probe Level Sense Test Results window



The default test position is position 1 on reagent carousel. To change the test position, click **Change Pos** and enter a new number within the range from 1 to 92, and then click **Next**.

5 Click **Start**.

The system starts to check the level sense board voltage for reagent probe, and continuously detects level in the test position for 20 times.

6 When tests complete, the tested voltage and the level sense test data are displayed on the screen.

7 Click **Exit** to close the window.

Test results

The results shown are described below:

Level Sense Board Voltage Check Results

If the Actual value falls in the Reference range, the result is PASS, indicating the voltage of the level detection board is normal; otherwise, the result is FAIL, indicating the voltage is abnormal. You should correct it based on the suggestions provided.

Level Sense Test Data

The system will continuously check the lowering height of reagent probe for 20 times, to judge if the lowering position is the vertical extreme position. If it is, abnormity exists. If the difference of 20 lowering heights is greater than 1mm, then the result should be considered as abnormal, indicating that there are problems with connections of reagent probe and PCBA, PCBA power, output voltage for level sense detection, or connections of level sense board and probe/mixer conversion board, and vice versa. You should correct it based on the suggestions provided.

Corrective action

If the operating voltage of the level detection board is beyond the reference range of 2.8V-4.8V, contact our customer service department or your local distributor.

If the result of the level detection performance is abnormal, contact our customer service department or your local distributor.

10.4 Sensor Diagnosis

10.4.1 Introduction

Sensor diagnosis provides diagnosis results of the sensors of the analyzer to help locate the failure cause of the related parts.

10.4.2 Sensor Diagnosis

Use this test when one of the following conditions happens:

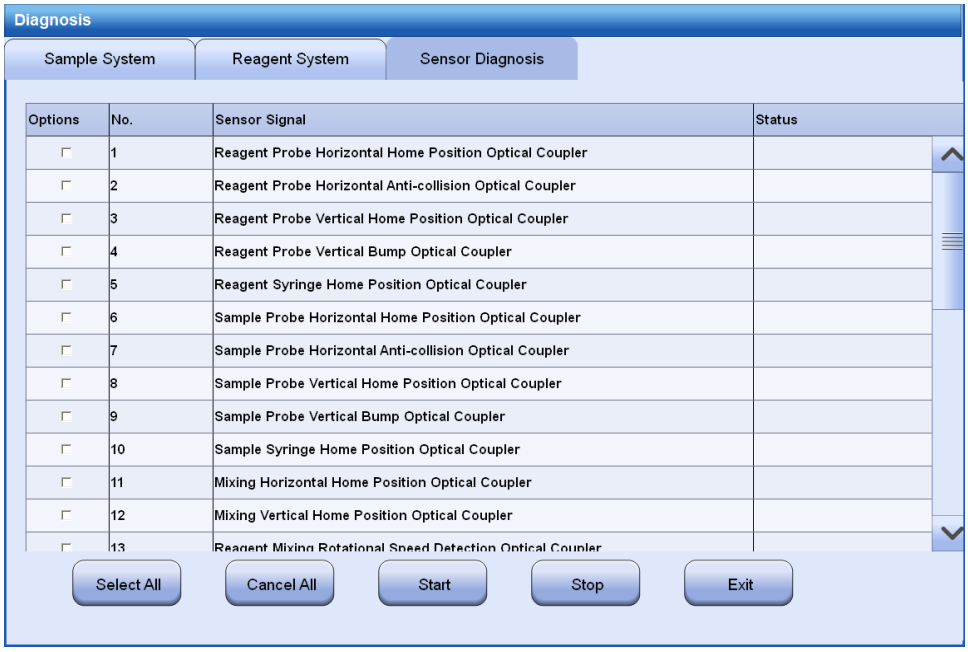
- Reaction carousel loses steps or positioning failed.
- Wash station loses steps or fails to find the mechanical zero position.
- Sample carousel loses steps or positioning failed.
- Sample probe loses steps in horizontal or vertical movement or fails to find the mechanical zero position.
- Sample syringe loses steps or fails to find the mechanical zero position.
- Reagent carousel loses steps or positioning failed.
- Reagent probe loses steps in horizontal or vertical movement or fails to find the mechanical zero position.
- Reagent syringe loses steps or fails to find the mechanical zero position.
- Sample mixer, reagent mixer fails to find the mechanical zero position.
- Interior wash syringe fails to find the mechanical zero position.
- Phase 1-2 wash syringe fails to find the mechanical zero position.

Test procedure

1 Select **Utility> Maintenance> Diagnostics**.

2 Select **Sensor Diagnosis** tab.

Figure 10.4 Sensor diagnosis window



3 Select the optical couplers to be diagnosed.

Click **Select All** or **Cancel All** to select the sensors.

4 Select **Start** to inquire the status of the sensors.

To stop the test, select **Stop**.

5 Click **Exit** to close the window.

Test result

Sensor high level signal is indicated by “unblocked “while low level signal is indicated by “blocked”.

Corrective action

Perform the operations: block or unblock the sensors and perform the diagnosis test. Observe if the sensor signal is changed accordingly with your operations. If the displayed status is changed accordingly, it means the sensor works normally; If the displayed status is not changed with your operations, it means the sensor is abnormal and please contact our customer service department

11 Maintenance

This chapter provides you with maintenance of the instrument, including frequently-used maintenance commands and scheduled maintenance procedures. The purpose, time, system status, precautions and steps of each maintenance procedure are described here.

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 Biochemistry Maintenance, ISE Maintenance and Scheduled Maintenance are provided. The Biochemistry Maintenance and ISE Maintenance features provide a list of the maintenance procedures that can be performed to optimize the system performance. 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.

The maintenance frequencies stated in this manual are based on working for 2 hours a day, that is 2*420=840 tests/day, and 2*420*25=21,000 tests/month.

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 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 Spare Parts and Consumables

Please use the spare parts and 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 Spare parts

Part	Maintenance item	Remarks
Lamp	Replace lamp	Replaced when it is used for 2000hours or six months.
Cuvette	Replace cuvette	Replaced every three months
Filter core	Replace filter core	Replaced every three months
Inlet filter	Replace inlet filter	Replaced every six months

Part	Maintenance item	Remarks
Sample probe	Replace sample probe	Replaced when it is damaged or bent.
Reagent probe	Replace probe	Replaced when it is damaged or bent.
MR Na electrode	Replace ISE electrode	Replaced when needed.
MR K electrode	Replace ISE electrode	Replaced when needed.
MR Cl electrode	Replace ISE electrode	Replaced when needed.
MR Ref electrode	Replace ISE electrode	Replaced when needed.
ISE Cleaning Solution	Clean ISE tubes	Used when cleaning ISE tubes per day.
Na Cleaning Solution	Na electrode slope adjustment	Used when needed.

11.1.3 Tools to be Prepared by User

The following tools will be used for maintenance of the system and should be prepared by the user.

Table 11.2 Tools to be prepared by user

Item	Applicable Maintenance
Tube brush, ultrasound cleaner	Cleaning the filter core
Clean gauze	Cleaning the syringes, rotors, probes/mixers
Cotton swabs	Cleaning the wash well, sample compartment, etc.
Suction cleaner	Cleaning the fans and dust screens
Hair brush	Cleaning the dust screen
Tweezers	Removing/Installing probes and syringe washers
Tube brush or ultrasound cleaner	Cleaning the filter core
Beaker	Cleaning the needle and unclogging device
Ethanol	Cleaning the photometer lens, probes, mixers and wash station
NaClO (0.5% sodium hypochlorite solution)	Cleaning the wash wells
Fiber-free gloves	Replacing reaction cuvettes etc.
Large water container	Cleaning the deionized water tank
Screen and keyboard wash solution	Cleaning the screen and keyboard

11.2 Biochemistry Maintenance

11.2.1 Introduction

The Biochemistry Maintenance feature provides maintenance instructions for the biochemistry system. The following three types of maintenance are available.

11.2.2 Biochemistry Maintenance Screen Overview

Select **Utility** - **Maintenance** - **Maintenance** - **Biochemistry Maintenance**. The screen shows the biochemistry maintenance commands that are frequently used.

Figure 11.1 Biochemistry Maintenance screen

Maintenance procedures

Provides frequently-used maintenance commands of the biochemistry system. Select a maintenance command button to start the maintenance procedure.

Online help

Online help information is provided for each biochemistry maintenance command. Select the icon to the left of a maintenance command to show relevant instructions.

Exit

Select this button to close the **Maintenance** window.

11.3 ISE Maintenance

11.3.1 Introduction

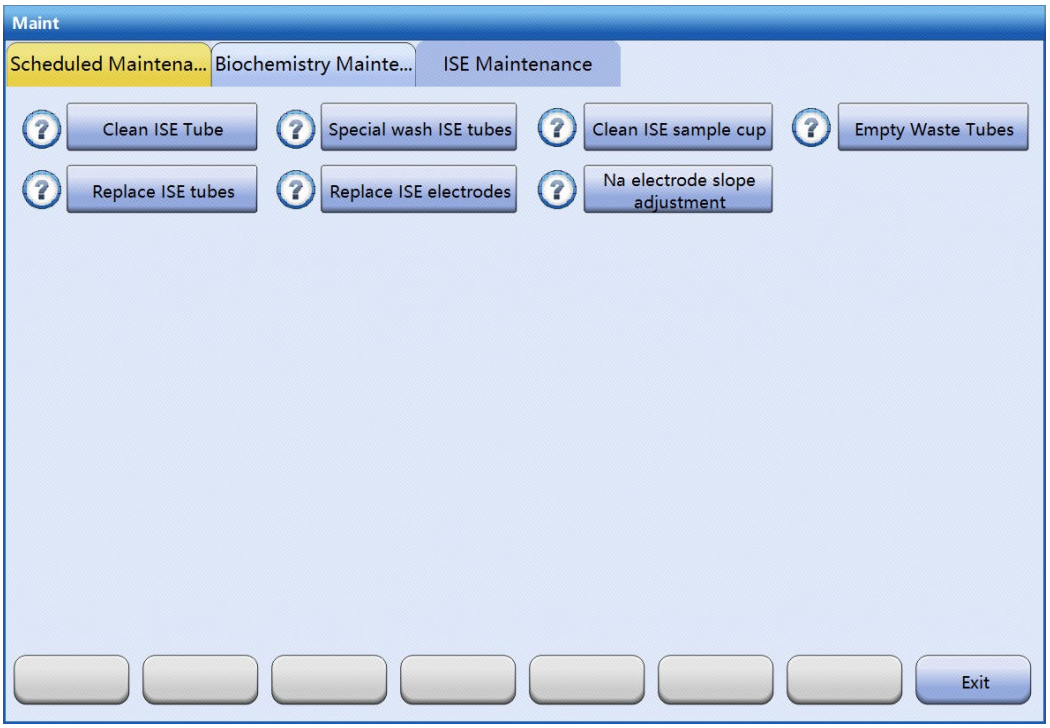
The ISE Maintenance feature provides maintenance commands for the ISE module.

The ISE maintenance is described in detail in the following pages.

11.3.2 ISE Maintenance Screen Overview

Select **Utility** - **Maintenance** - **Maintenance** - **ISE Maintenance**. The screen shows the ISE maintenance commands that are frequently used. Operate according to the screen prompts.

Figure 11.2 ISE Maintenance screen



Maintenance procedures

Provides frequently-used maintenance commands of the ISE module. Select a maintenance command button to start the maintenance procedure.

Online help

Online help information is provided for each ISE maintenance command. Select the icon to the left of a maintenance command to show relevant instructions.

Exit

Select this button to close the **Maintenance** window.

11.4 Scheduled Maintenance Log

11.4.1 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.

11.4.2 Maintenance Schedule

The scheduled maintenance procedures are divided into the following periods:

- Daily: 1 day
- Weekly: 8 days

- Two-week: 15 days(No maintenance item for this model)
- Monthly: 31 days
- Three-month: 91 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:

- **Utility** button on the main screen
- **Maintenance** tab
- **Maintenance** button
- **Scheduled Maintenance** tab
- Maintenance frequency tab
- Maintenance procedure

11.4.3 Scheduled Maintenance Procedures

Maintenance procedures vary from different maintenance frequencies. The maintenance procedures described in this chapter are based on a complete configuration of the system. If some modules are not equipped on your system, you have no need to perform relevant maintenance.

Perform the scheduled maintenance according to the instruction in this chapter. Run calibration or quality control after performing the maintenance.

11.4.4 Maintenance Log Sheet

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 11.3 Maintenance Log Sheet

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 Probes/Mixers/Wash Wells																															
2	Check Sample/Reagent Syringe																															
3	Check Deionized Water Connection																															
4	Check Waste Tube Connection																															
5	Check Diluted Wash Solution																															
6	Check Sample/Reagent Probe Wash Solution																															
7	Clean ISE Tube																															
8	Special Wash Probes/Mixers																															
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 Sample/Reagent probe Exterior																															
2	Clean Mixers																															
3	Special Wash																															
4	Cuvette Check																															
5	Photometer Check																															
Two-week 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	Special wash ISE tubes																															
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 Wash Wells																															
2	Clean Cuvette Wash Station and Tubes																															
3	Clean Dust Screens																															
4	Clean ISE sample cup																															
Three-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	Clean DI Water Tank																															
2	Replace Filter Core																															
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 Lamp																															
2	Replace Water Supply Filter																															
As-Required/As-Needed 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 Analyzer Panels																															

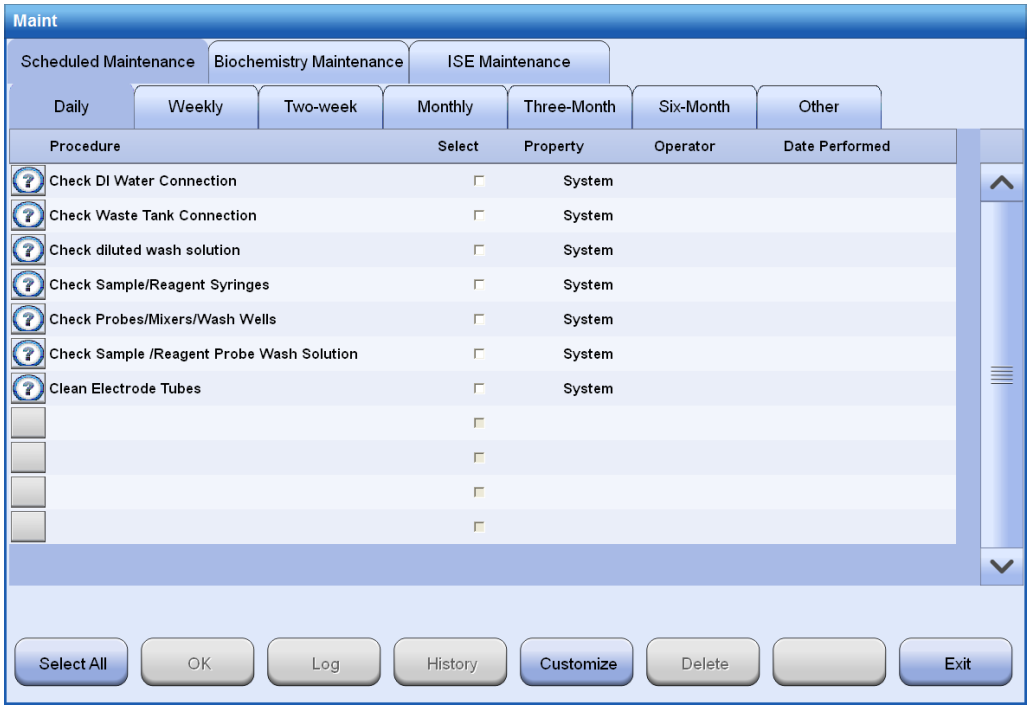
Maintenance Log Sheet

		Year																																	
		Month																																		
2	Bar Code Maintenance																																		
3	Clean Sample Compartment																																		
4	Clean Reagent Compartment																																		
5	Clean Sample Probe Interior																																		
6	Clean Reagent Probe Interior																																		
7	Replace Sample Probe																																		
8	Replace Reagent Probe																																		
9	Replace sample mixer																																		
10	Replace reagent mixer																																		
11	Special Wash Probes																																		
12	Replace Cuvettes																																		
13	Empty Waste Tubes																																		
14	Replace ISE Electrodes																																		
15	Na electrode slope adjustment																																		
16	Remove air bubbles in sample syringe																																		
17	Remove air bubbles in reagent syringe																																		
18	Replace sample syringe																																		
19	Replace reagent syringe																																		

11.4.5 Scheduled Maintenance Screen Overview

The **Scheduled Maintenance** 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.

Figure 11.3 Scheduled Maintenance screen



Fields and buttons on the screen are introduced as follows.

Maintenance procedures

Shows the preset and user-defined maintenance procedures for the current maintenance frequency.

Select field

Choose a maintenance procedure and click on the corresponding **Select** checkbox. A tick appears in the middle of the checkbox, which indicates the maintenance procedure is chosen. Select the function buttons at the bottom of the screen to access a window or execute an operation. To deselect a maintenance procedure, click on the **Select** checkbox again. The tick inside the checkbox disappears, which indicates the maintenance procedure is deselected.

Property field

Shows how the maintenance procedure is defined. The Property includes two options: System and User. System indicates that the maintenance procedure is defined by the manufacturer and cannot be configured; User indicates that the maintenance is defined by user and can be configured for each maintenance frequency.

Operator field

Shows who performs the maintenance procedure, that is, the user ID currently logging on the system.

Date Performed field

Shows the date confirmed by the operator on which the maintenance was performed. After performing a maintenance procedure, mark the **Select** checkbox and select **OK**. The date is refreshed and displayed as the current date. The system will restart the countdown of the maintenance frequency from the current date.

Scroll bar

If all maintenance procedures of a period are not shown on the current screen, move the scroll bar view more maintenance procedures.

Select All button

This function allows selection of all maintenance procedures currently available on the screen. When the **Select All** button is selected, a tick appears in all **Select** checkboxes to the right of the maintenance procedures. Choose the following buttons as needed:

- **OK**: allows the reviewal of the selected maintenance procedure and entering of the date performed.
- **Log**: allows recording of comments and other important information of maintenance.
- **History**: provides a stored history record of maintenance performance with date and operator for the procedure selected.

OK button

This function allows the reviewal of the selected maintenance procedure and entering of the date performed. When the approving a maintenance procedure, the date of performance will be displayed as the current date.

Log button

The electronic maintenance log function allows the recording of comments and other important information of maintenance. Choose one or more maintenance procedures, and then select the **Log** button. The **Maintenance Log** window shows. Input logs for the procedure selected, and then select **OK**. Your input information will be applied to the selected maintenance procedure.

History button

This feature provides a stored history record of maintenance performance with date and operator for the procedure selected. You are allowed to edit or delete a maintenance record. Please note that only one maintenance procedure can be recalled for history performance at one time.

1 Choose a maintenance procedure on the **Scheduled Maintenance** screen.

2 Select **History**. The **Maintenance Log** window is displayed.

3 View all performance records of the selected maintenance procedure.

4 To edit a maintenance record:

- Mark the checkbox of the desired maintenance record.
- Select Edit.
- Modify the maintenance record.
- Select OK.

Only one maintenance record can be edited at one time.

5 To delete maintenance records:

- Mark the checkbox of one or more desired maintenance records.
- Select Delete.
- Select OK. The selected maintenance records are removed.

6 To print maintenance log:

- Mark the checkbox of one or more desired maintenance records.
- Select **Print**.

7 Select **Close** to exit the window.

Customize button

The Customize function allows definition of new maintenance procedures and configuration of manufactured-/user-defined maintenance procedures. User-defined maintenance procedures can be deleted.

Select **Customize** on the **Scheduled Maintenance** screen. The **Customize Maintenance Procedure** window is displayed.

To define a maintenance procedure:

- Select **New**.
- Enter the name of the new maintenance procedure.
- Select **OK**. The maintenance procedure is displayed in the **Available Procedures** list.
- Use **>>** and **<<** to configure or cancel user-defined maintenance procedures. The property of a user-defined maintenance procedure is User.
- Select **OK** to save the configuration, or select **Cancel** to abort it.

To configure a maintenance procedure:

- Choose a maintenance frequency in the **Frequency** pull-down list.
- Choose a maintenance procedure in the **Available Procedures** list. Move the vertical scroll bar to view more maintenance procedures.
- Select **>>**. The selected maintenance procedure appears in the **Enabled Procedures** list, and the relevant maintenance schedule screen will be refreshed automatically.

To remove a maintenance procedure:

- Choose a maintenance procedure in the **Enabled Procedures** list.
- Select **<<**. The selected maintenance procedure is removed from the **Enabled Procedures** list and appears in the **Available Procedures** list. The relevant maintenance schedule screen will be refreshed automatically.
- Select **OK** to save the configuration, or select **Cancel** to abort it.

Delete button

The system allows deleting of maintenance procedures that will no longer be used. Only user-defined rather than manufacturer-defined maintenance procedures can be deleted.

1 Choose a maintenance procedure on the **Scheduled Maintenance** screen.

2 Select **Delete**.

3 Select **OK**. The selected maintenance procedure is deleted. The **Available Procedures** list on the **Customize Maintenance Procedure** window is refreshed automatically.

Close

Select this button to close the **Maintenance** window.

11.5 Daily Maintenance

11.5.1 Check Sample Probe / Reagent Probe/Mixers/Wash Wells

Abnormal sample probe, reagent probe, wash wells or mixers may influence the measurement performance and result in inaccurate results. Prior to measurements every day, check the sample probe and reagent probe for stains and crystals, and check if the mixers cannot rotate normally or are lifted and the water flow in the wash wells is abnormal. If the above-mentioned abnormities exist, clean or adjust the probes and mixers immediately.

Purpose

To check the sample probe and reagent probe for water dripping, stains and liquid flow abnormities, and check if the mixers can rotate normally and the water flow in the wash wells is abnormal.

When to do

You are recommended to do this maintenance procedure every day before starting the analysis.

System status

Make sure that the system status is Standby.

Precautions

Warning

The probes and mixers are sharp and vulnerable. To prevent injury and equipment damage, exercise caution when working around the probes and mixers. Keep away from the probes and mixers to avoid collision with them.

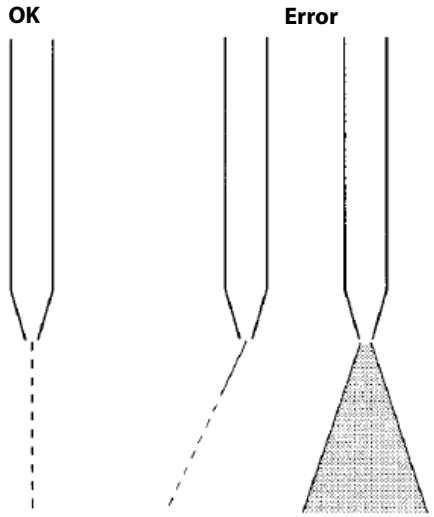
BIOHAZARD

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

How to do

1. Open the protective shield of the analyzer.
2. Select **Utility> Maintenance > Maintenance >Biochemistry Maintenance**.
3. Select **Clean Probes/Mixers/Wash Wells**.
4. Check the exterior of the probes/mixers for stains. If stains exist, perform the Clean Sample/Reagent Probe Exterior or Clean Mixers procedure.
5. Select **Continue** to clean the reagent probe and sample probe interiors.
6. Check the liquid flow of the sample probe and reagent probe. If the liquid flow is sprayed out or does not come out vertically, the probe may be clogged. Perform the Special Wash Probes procedure,, and then check them again. If the abnormity remains, perform the Clean Sample Probe Interior or Clean Reagent Probe Interior procedure. If the abnormity still remains, perform the Replace Sample Probe or Replace Reagent Probes procedure, or contact a service engineer. If the liquid flow is not continuous or the sound produced by broken bubbles is heard, there must be air bubbles in the tube. Please perform **Clean Probes Interior** to prime the probe interior and discharge the air bubbles.

Figure 11.4 Normal and abnormal liquid flows of sample probe and reagent probe



7 Select **Second Wash**. The probe interior wash can be performed again.

8 Select **Continue**.

9 Observe the water flow of the probe/mixer wash wells, and check if the water reaches to about 5mm of the probe/mixer from the tip. If it does, proceed to the next step; otherwise, contact a service engineer.

10 Select **Continue**.

11 Select **Done**.

12 Restore the protective shield.

11.5.2 Check Sample/Reagent Syringe

The sample syringe and reagent syringes are precise devices used to aspirate/dispense small amount of sample and reagent. If the syringes leak, they cannot aspirate/dispense the correct amount of sample or reagent, and may even be damaged. Prior to measurements every day, check the sample/reagent syringes for leak.

Purpose

To check the sample/reagent syringes for leak.

When to do

You are recommended to do this maintenance procedure every day before starting the analysis.

Materials required

Clean gauze

System status

Make sure that the system status is Incubation or Standby.

Precautions

BIOHAZARD

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

How to do

1 Open the front door of the analyzer. You will see the syringe on the two side of the water tank.

2 Use dry gauze to wipe the syringe plunger and the connector, and then check if the gauze is moistened.

- If it is not, proceed to the next step.
- If it is, tighten the syringe.

3 Close the front door of the analyzer.

11.5.3 Check Deionized Water Connection

If the deionized water tubes are not connected properly, deionized water cannot be supplied normally or leak may be caused, influencing the measurements.

Purpose

To check the DI water connection to ensure normal supply of DI water.

When to do

You are recommended to do this maintenance procedure every day before starting the analysis.

System status

Make sure that the system is powered off, or the system status is Incubation or Standby.

How to do

1 Check that the water tank or other water containers have sufficient deionized water.

2 Check that the tubes are not bent or folded or leaking.

3 Check that the water supply module is powered on.

11.5.4 Check Waste and Waste Tank

If the waste tube is not connected properly or the high-concentration waste tank is full, overflow may be caused, resulted in environmental contamination or cross contamination, or even damaging the equipment. It is necessary to regularly check the waste tube connection and the high-concentration waste tank.

Purpose

To check the waste tube connection and the high-concentration waste tank to prevent overflow.

When to do

You are recommended to do this maintenance procedure every day before starting the analysis.

System status

Make sure that the system is powered off, or the system status is Incubation or Standby.

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

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 works well, and make sure that the waste tube is not bent or folded and the high-/low-concentration waste is drained properly.

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

High-concentration waste output: 1L/H, low-concentration waste output: no more than 19L/H, and water consumption: no more than 20L/H.

3 If leak remains after performing the above-stated steps, contact our customer service department or your local distributor.

11.5.5 Check Diluted Wash Solution

Insufficient concentrated wash solution may terminate the measurements. Prior to measurements every day, check the concentrated wash solution volume, and fill more, if necessary.

A full tank of diluted wash solution is 15L and can be used for 8 days for plastic cuvettes on condition that 840tests are done every day. Please check and refill the diluted wash solution according to the consumption and tank volume.

For preparation of diluted wash solution, please refer to Loading diluted wash solution on page 2-14.

Purpose

To check the concentrated wash solution volume to prevent measurements from being terminated.

When to do

You are recommended to do this maintenance procedure every day before starting the analysis.

System status

Make sure that the system status is Incubation or Standby.

Precautions

Warning

Diluted wash solution is corrosive to human skins. Wear gloves and goggles while checking the concentrated wash solution. In case your hand or clothes contact the wash solution, wash them off with soap and water. If the wash solution spills into your eyes, rinse them with water and consult an oculist.

How to do

1 Open the front door of the analyzer and check the concentration wash solution. If necessary, fill more or replace the wash solution.

2 Close the front door of the analyzer.

11.5.6 Check Probe Wash Solution

Insufficient probe wash solution (CD80 alkaline concentrated wash solution) may cause probe clogging and cross contamination. You are recommended to check and replace the probe wash solution every day to ensure its sufficiency.

Three special washes will be conducted for the sample probe when every batch of tests is finished, and about 270μl wash solution is consumed for each wash. The concentrated wash solution for the reagent probe is about 600μl for each wash. It is recommended to prepare 1.5ml concentrated wash solution for sample probe and 5ml for reagent probe every day.

Purpose

To check the sample probe and reagent probe wash solution volume to prevent measurements from being terminated.

When to do

You are recommended to do this maintenance procedure every day before starting the analysis.

System status

Make sure that the system is powered off, or the system status is Incubation or Standby.

Precautions

CAUTION

You are recommended to replace the sample probe and reagent probe wash solution every day in order to prevent probe clogging and cross contamination.

While the system is running tests, do not try to fill probe wash solution until the system status becomes Standby.

How to do

1. Check the volume of the probe wash solution on the sample carousel position DB and reagent carousel position DB.
2. If necessary, fill more or replace the wash solution.

11.5.7 Special Wash Probes/Mixers

After a high-protein sample is tested, residues may exist on the sample probe and mixer, causing sample probe/reagent probe clogging and carryover. Special wash of probes and mixers can effectively reduce the residues and remove the contamination.

Purpose

To 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.

System status

Make sure that the status of both the biochemistry system and ISE module is Standby.

Precautions

BIOHAZARD

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

The wash solution may hurt your eyes and skins. Exercise caution while using the wash solution. If your eyes contact the wash solution, rinse them off with fresh water and consult a doctor.

CAUTION

Please use consumables recommended by our company. Use of other consumables may degrade the system performance.

How to do

1. Select **Utility > Maintenance> Maintenance> Biochemistry Maintenance**.
2. Choose **Special Wash Probes/Mixers**. The maintenance guide window shows.
3. Please confirm that at least 1 ml DC is loaded to the position DC on the sample carousel.
4. Enter the soaking time in the edit box.
5. Select **Continue**. The system starts the procedure.
6. Select **Done**.

11.5.8 Clean ISE Tubes

When the ISE module finishes a great number of measurements, the proteins and lipid obtained in samples may remain on surfaces of the electrodes, influencing their measurement performance. You should clean the electrodes regularly to ensure system performance. It will take about 2 minutes to perform this procedure.

Purpose

To remove the proteins and lipid remaining on the electrode surfaces.

When to do

You are recommended to perform this procedure after finishing all ISE tests of the day, or before shutting down the system, or 50 samples are analyzed.

Materials required

ISE Cleaning Solution, 2 ml sample tube

System status

Make sure that the status of both the biochemistry system and ISE module is Standby.

Precautions

BIOHAZARD

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

The wash solution may hurt your eyes and skins. Exercise caution while using the wash solution. If your eyes contact the wash solution, rinse them off with fresh water and consult a doctor.

CAUTION

Please use consumables recommended by our company. Use of other consumables may degrade the system performance.

Note

After finishing this procedure, calibrate the ISE module before starting measurements. Do not take out the reagent pack during maintenance.

How to do

1. Select **Utility > Maintenance> Maintenance> ISE Maintenance**.
2. Choose **Clean ISE Tubes**. The maintenance guide window shows. Check if the reagent pack is loaded to the analyzer. If yes, select **Continue**.
3. Open the upper cover of the analyzer.
4. Fill a 2ml sample tube with at least 300µl ISE Cleaning Solution, and then load it to position ISE on the sample carousel.
5. Select **Continue**. The system starts the procedure.
6. Select **Done**.

11.6 Weekly Maintenance

11.6.1 Clean Sample/Reagent Probe Exterior

The sample probe and reagent probe are often dirty on their surfaces, causing carryover between samples or reagents and resulting in inaccurate results. You are recommended to perform this procedure every week.

Purpose

To clean the exterior of the sample probe and reagent probe to prevent cross contamination.

When to do

This procedure should be performed on weekly basis.

Materials required

2 pieces of clean gauze, ethanol, deionized water, tweezers

System status

Make sure that the system status is not Running.

Precautions

Warning

The probe tip is sharp and may cause puncture wounds. To prevent injury, exercise caution when working around the probes. If the probe is bent or damaged, replace it immediately; otherwise, unreliable results may be obtained.

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Switch off the analyzing unit power.
2. Rotate the probe arm to move the probe to a position convenient for cleaning, and then use gauze soaked with ethanol to gently wipe the probe exterior. Clean the probe tip until it becomes clear without stain.

   Do not pull the probe horizontally to prevent probe damage.
3. Use gauze moistened with deionized water to clear the ethanol on the probe.
4. After finishing the cleaning, turn on the analyzing unit power switch.
5. Select **Utility> Commands >Home** to reset the probe.

11.6.2 Clean Mixers

The mixers are often dirty on their surfaces, causing carryover between samples or reagents and resulting in inaccurate results. You are recommended to perform this procedure every week.

Purpose

To clean the sample mixer and reagent mixer to prevent cross contamination.

When to do

This procedure should be performed on weekly bases.

Materials required

2 pieces of clean gauze, ethanol, deionized water, tweezers

System status

Make sure that the system status is not Running.

Precautions

Warning

Exercise caution while working around the mixer. If it is bent or damaged, replace it immediately; otherwise, unreliable results may be obtained.

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Switch off the analyzing unit power.
2. Rotate the mixer arm to move the mixer to a position convenient for cleaning, and then use gauze soaked with ethanol to gently wipe the mixer exterior until it becomes clear without stain.

   Do not pull the mixer horizontally to prevent damage.
3. Use gauze moistened with deionized water to clear the ethanol on the mixer.
4. After finishing the cleaning, turn on the analyzing unit power switch.
5. Select **Utility> Commands >Home** to reset the mixer.

11.6.3 Special Wash

Special wash is to clean the sample probe, reagent probe, mixers, reaction cuvettes and wash station by using the concentrated wash solution, with the aim of eliminating carryover and preventing waste from leaving in the waste tubes. It will take about 30 minutes to perform this procedure.

Purpose

To eliminate cross contamination among the sample probe, reagent probe, mixers, cuvettes and wash station, and prevent waste from leaving in the waste tubes.

When to do

You are recommended to perform this procedure on weekly basis or when the equipment is to be stored for a long time.

Materials required

Concentrated wash solution manufactured by our company

System status

Make sure that the system status is Standby.

How to do

1. Open the upper protective shield of the analyzer.
2. Place more than 30ml concentrated wash solution in position DB of the reagent carousel, and place more than 5ml concentrated wash solution in position DB on the sample carousel.
3. Select **Utility > Maintenance >Maintenance >Biochemistry Maintenance**.
4. Choose **Special Wash**.
5. Confirm if cuvette check is needed after the special wash. If it is, mark the checkbox in front of **Perform Cuvette Check**.
6. Select **Continue** to continue, or select **Exit** to abort the special wash.

7 The system starts cleaning the sample probe, reagent probe, mixers, cuvettes and wash station. To terminate the clean process, select **Stop**.

8 Perform the cuvette check procedure. Refer to 11.6.4 Cuvette Check (page 11-20) for details.

9 Select **Done**.

10 Restore the upper protective shield of the analyzer.

11.6.4 Cuvette Check

After being used for a long time, the reaction cuvettes may have proteins or other stains left inside of them that are difficult to remove and will influence the light transmittance of the cuvettes. If the cuvettes are polluted or scratched or damaged, the light transmittance will be affected, threatening the accuracy and stability of the results. Check the reaction cuvettes regularly to avoid unwanted results. It will take about 20 minutes to perform this procedure.

Purpose

To check if the reaction cuvettes are polluted and the light transmittance is decreased in order to prevent unreliable test results.

When to do

You are recommended to perform this procedure on weekly basis or after performing special wash or after replacing the reaction cuvettes.

System status

Prior to performing the maintenance, make sure that the system has been power on for over 10 minutes and the system status is Standby. Check if the reaction carousel has a cuvette for each position. If not, load cuvettes.

Precautions

NOTE

When a cuvette is deemed dirty, clean or replace it immediately, and then perform the cuvette check again.

Stains inside cuvettes will influence the photometric measurement. You are recommended to perform the Cuvette Check after finishing the Special Wash procedure.

How to do

1 Select **Utility>Maintenance>Maintenance >Biochemistry Maintenance**.

2 Choose **Cuvette Check**.

3 Make sure that the lamp has been turned on for over 10 minutes. Select **Continue** and then select **Start**. When finishing the check, the system refreshes the cuvette status based on the check results. Record the cuvettes highlighted in yellow and please replace the cuvettes highlighted in yellow. To abort the cuvette check, select **Stop**.

The screen shows all cuvettes and highlights the dirty cuvettes with special color:

- No color indication: normal cuvette
- Yellow: dirty cuvette

4 Select **Result**. The **Cuvette Check Results** window appears and shows the latest check result of the 93 cuvettes at all wavelengths.

5 Choose a cuvette in the result list. The **Cuvette Status** window pops up.

Choose the following buttons as needed:

- |<: to view the first cuvette.
- <: to view the previous cuvette.
- >: to view the next cuvette.
- >|: to view the last cuvette.
- **Print**: to print the results currently displayed on the screen.
- **Exit**: to close the **Cuvette Status** window.

6 Select **Exit** to close the **Cuvette Check** window.

11.6.5 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 on weekly basis or after replacing the lamp.

System status

Prior to performing the maintenance, make sure that the system has been power on for over 10 minutes and the system status is Standby.

Precautions

NOTE

Before checking the lamp, perform the Cuvette Check procedure and replace or clean the dirty cuvettes; otherwise, the photometer check results are unreliable.

To ensure the photometer's measurement performance, replace the lamp in the case of weak light intensity.

How to do

1 Select **Utility> Maintenance>Maintenance> Biochemistry Maintenance**.

2 Choose **Photometer Check**. The following window appears.

3 Make sure that the lamp has been turned on for over 10 minutes. Select **Continue** and then select **Start**. When finishing the check, the system displays the results and refreshes the photometer status. To abort the photometer check, select **Stop**.

On the left of the screen shows the absorbance at each wavelength in the current photometer check; on the right of the screen shows that of the previous photometer check. By checking the results of the previous and current photometer check, you may understand the status of the lamp.

4 If an alarm occurs during the check, operate as follows:

- If the alarm indicates the lamp is off, check if the lamp has been turn on. If not, execute the Home command; if yes, contact our customer service department or your local distributor.
- If the alarm indicates light intensity too strong, contact our customer service department or your local distributor.
- If the alarm indicates light intensity weak, replace the lamp. For more information, refer to 11.10.1 Replace Lamp (page 11-28).

5 Choose the following buttons as needed:

- Print: to print the photometer check results currently available on the screen.
- Exit: to close the window.

6 Select **Done** to close the **Photometer Check** window.

11.7 Two-week Maintenance

11.7.1 Special Wash ISE Tubes

Purpose

Use probe cleanser to clean the ISE tubes to remove the protein and lipid from them and the electrodes, and ensure the electrodes work properly.

When to do

This procedure should be performed every two weeks.

System status

Make sure that the status of both the biochemistry system and ISE module is Standby.

Precautions

BIOHAZARD

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

The wash solution may hurt your eyes and skins. Exercise caution while using the wash solution. If your eyes contact the wash solution, rinse them off with fresh water and consult a doctor.

CAUTION

Please use consumables recommended by our company. Use of other consumables may degrade the system performance.

Note

After finishing this procedure, calibrate the ISE module before starting measurements.

How to do

1 Make sure that the system status is Incubation or Standby.

2 Select **Utility>Maintenance >Maintenance> ISE Maintenance**.

3 Choose **Special Wash ISE Tubes**.

4 Place at least 1 ml probe cleanser in the DC position of the sample carousel.

5 Select **Continue**. The system starts the procedure.

6 Select **Done**.

11.8 Monthly Maintenance

11.8.1 Clean Wash Wells

When the system is used for a long time, waste and dust may accumulate in the wash wells and block them. Clean the wash wells every month to keep them clean and smooth.

Purpose

To remove the waste and dust from the wash wells (of reagent probe, sample probe, sample mixer and reagent mixer).

When to do

This procedure should be performed on monthly basis.

Materials required

Cotton swabs and sodium hypochlorite solution (NaClO, with 0.5% chlorite)

System status

Make sure that the system status is not Running.

Precautions

 **BIOHAZARD**

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Switch off the analyzing unit power.
2. Open the upper protective shield of the analyzer.
3. Rotate the same probe, reagent probe and mixers to keep them away from the wash wells.
4. Use clean cotton swabs moistened with NaClO to clean the wash wells.
5. After finishing the cleaning, turn on the analyzing unit power switch.
6. Select **Utility > Commands > Home** to reset the probes and mixers, check if the wash wells have a normal water flow.

11.8.2 Clean Wash Station and Tubes

Clean the wash station and tubes regularly to prevent waste from accumulating on it.

Purpose

To clean the cuvette wash station and tubes in order to avoid waste buildup and cross contamination.

When to do

This procedure should be performed on monthly basis.

Materials required

Gauze, ethanol, deionized water, waste container (large beaker)

System status

Make sure that the system status is Standby

Precautions

 **BIOHAZARD**

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.

How to do

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 **Utility > Maintenance > Maintenance > Biochemistry Maintenance**.
6. Choose **Prime Wash Station**. The maintenance guide window shows. Select **Continue**.
7. Enter the wash cycle (1~100). The default is 10.
8. Select **Continue**.
9. When the cleaning and priming are finished, select **Done**.
10. Restore the upper protective shield of the analyzer.

11.8.3 Clean Dust Screens of the Analyzer

Dust may accumulate on the dust screens when the instrument is used for a long time, influencing the ventilation and heat elimination effects. It is necessary to clean the dust screens regularly.

Purpose

To clean the dust screens to ensure good ventilation.

When to do

This procedure should be performed on monthly basis.

Materials required

Suction cleaner, hair brush and fresh water

System status

Make sure that the analyzer main power is off.

Precautions

NOTE

Use a suction cleaner to clean the dust screens while keeping them uninstalled, or use a hair brush and fresh water to clean the dust screens after removing them from the analyzer.

Do not reinstall the dust screens until they are dry completely.

Install the dust screens correctly to avoid gaps.

To clean the dust screens by knocking them at solid ground, find an appropriate place, and then carefully knock them at the ground.

How to do

1. Switch off the analyzer's main power.
2. Open the front door of the analyzer and remove the dust screens by lifting in the middle and pushing outwards.
3. Use the suction cleaner, or hair brush and fresh water to clean the dust screens, and then dry them in air.

4 Reinstall the dust screens when they are dry.

5 Close the front door of the analyzer.

6 Power on the analyzer and run the operating software.

7 Make sure that the system status is Incubation or Standby.

11.8.4 Clean ISE Sample Cup

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 and ethanol

System status

Make sure that the status of both the biochemistry system and ISE module is Standby.

How to do

1 Make sure that the system status is Incubation or Standby.
2 Select **Utility >Maintenance > Maintenance > ISE Maintenance**.
3 Choose the **Clean ISE Sample CUP** option.
4 Open the upper cover of the analyzer.
5 Select **Continue**.
6 Use clean cotton swab soaked with ethanol to wipe the interior of the sample cup until it is clean; then use clean cotton swabs soaked 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.
7 Select **Done**.

11.9 Three-Month Maintenance

11.9.1 Clean DI Water Tank

Stains will remain in the deionized water tank when it is used for a long time and may influence the cleaning effects of the system.

Purpose

To clean the deionized water tank to ensure good cleaning performance of the system.

When to do

You are recommended to perform this procedure every 3 months.

Materials required

Water container

System status

Make sure that the system status is Standby

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Select **Utility > Maintenance> Maintenance > Biochemistry Maintenance**.
2. Choose **Clean Filter/Water Tank**, and then select **Continue**.
3. Open the front door of the analyzer. You will see the deionized water tank as shown in the figure below.
4. Remove the quick connector from the outlet of the water tank, and then pull the water tank outwards for a little to expose its opening.
5. Put a water container below the outlet of the DI water tank; insert another normally open quick connector into the outlet to drain water into the water container. When the DI water tank is emptied, proceed to the next step. Or you may close the outlet with a solid plug, take out the water tank completely, and then empty it by inclining it. Choose this method if there is little water inside the DI water tank.
6. Remove the tubes from the inlet of the water tank and pull out the water tank completely. Take out the level floater and hang it in place.. Perform this step according to the figure below.

Figure 11.5 Remove deionized water tank

7 Clean the water tank repeatedly with deionized water until there are no visible impurities in the tank.

8 Insert the floater into the connector on rear panel of the water tank, connect the backflow tube to the water tank, connect the floater signal cable and water supply tube to the water tank according to the labels on it, and then place the water tank in the cabinet of the analyzer.

9 Select **Continue**. The system automatically primes the deionized water tubes.

10 Take away the water container and close the front door of the analyzer.

If you perform this procedure while the instrument is off, install the water tank and start it up until the system status becomes Incubation. Perform **Clean Filter/Water Tank** to remove air from the fluidic tubes by priming deionized water.

11 Select **Utility> Maintenance> Maintenance**, and then select **Three-Month**.

12 Select **Clean DI Water Tank** procedure of corresponding module.

13 Select **OK**.

11.9.2 Replace Filter Core

The filter may be blocked after being used for a long time. Replace the filter core every 3 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 3 months.

Materials required

New filter core

System status

Make sure that the system status is Standby.

How to do

1 Select **Utility >Maintenance> Maintenance> Biochemistry Maintenance**.

2 Choose **Clean Filter/Water Tank**, and then select **Continue**.

3 Open the right front door of the analyzer.

4 Check if the filter core becomes rusty or there is unremovable stains on it. If so, change it. If not, clean the filter core by referring Clean Filter Core procedure. Install back the filter core into the filter and restore the analyzer.

5 Take out the tubes on the back of the container and place them in a clean container.

6 Drain the deionized water tank water, unscrew the cap on the bottom of the water tank, and pay attention not to drop the sealing ring.

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 quick connector.

10 Close the right front door of the analyzer.

11 Select **Utility >Maintenance> Maintenance**, and then select **Three-Month**.

12 Select **Replace Filter Core** procedure of corresponding module.

13 Select **OK**.

11.10 Six-Month Maintenance

11.10.1 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. It will take about 10 minutes to perform this procedure.

Purpose

To ensure that the lamp works normally.

When to do

You are recommended to perform this procedure every 6 months or when you find that the lamp does not satisfy the requirements after performing the Photometer Check.

Materials required

New lamp

System status

Make sure that the system status is Standby or Stopped.

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 **Utility > Maintenance > Maintenance > Biochemistry Maintenance**.
2. Choose **Replace Lamp**. The maintenance guide window pops up. Select **Continue**.
3. Make sure that the lamp has cooled down for 5 minutes, and then select **Continue**.
4. Remove the cover plate of the lamp.
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.

   CAUTION

   Do not hold the lamp by its bulb to prevent contamination and damage.
8. Install the retaining screw, O-ring connectors, cable terminal nuts and lamp cover plate in the reversed order.
9. Select **Continue**.

10 When the lamp is incubated, select **Done**.

Perform the Photometer Check procedure to ensure the system power is normal. For more information, refer to 11.6.5 Photometer Check (page 11-21).

11 Select **Utility** - **Commands**, and then select **Home** to put the instrument into the Standby status.

12 Execute the **Photometer Check** maintenance command to check the lamp.

11.10.2 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 water inlet filter to ensure the 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 Incubation or Standby.

How to do

1 Check that the system is powered off, or the system status is Incubation or Standby.

2 Turn off the power switch of the water supply module or water unit.

3 Prepare a new water inlet filter with connectors on its two ends.

4 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.

5 Press the tubing release button to remove the tubing from two ends of the old filter assembly.

6 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.

7 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.

11.11 As-Needed/As-Required Maintenance

11.11.1 Clean Analyzer Panels

The analyzer and computer are often accessed and easily get dirty. To keep a good operating environment and minimize the biohazards, clean the components that are often accessed, such as analyzer panel, carousel cover, screen, keyboard, etc.

Purpose

To clean the analyzer panels, carousel covers, screen and keyboard.

When to do

Perform this procedure when dust or other stains are found on the components.

Materials required

Clean gauze, screen wash solution, and deionized water

System status

Make sure that the system status is not Running.

Precautions

Warning

Do not spill liquid on the analyzer. Liquid ingression may cause equipment damage.

BIOHAZARD

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.

How to do

1. Make sure that the system is not running tests, and then open the protective shield.
2. Use clean gauze moistened with ethanol to clean the analyzer panels and carousel covers.
3. Use wash solution to clean the screen and keyboard.
4. Restore the protective shield.

11.11.2 Clean Sample Compartment

When samples are sprayed into the sample compartment, or dusts accumulate inside the compartment, clean them immediately in order to minimize the risks of cross contamination.

Purpose

To clean the sample carousel assembly to ensure clear operating environment and eliminate the risks of cross contamination.

When to do

Perform this procedure when samples are spilled into the sample compartment or dust is found inside of it.

Materials required

Clean gauze, deionized water, ethanol, and cotton swabs

System status

Make sure that the system is not running any tests

Precautions

Warning

Do not spill water or ethanol into the sample compartment to prevent equipment damage.

BIOHAZARD

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.

How to do

1. Make sure that the system is not running any tests.
2. Remove the sample carousel cover and sample carousel, and then store them properly.
3. Use clean gauze soaked with deionized water or ethanol to clean the interior of the sample compartment. If necessary, you can use gauze moistened with neutral wash solution.
4. Use clean gauze soaked with deionized water or ethanol to clean the sample carousel, and then use cotton swabs dipped with ethanol to clean the sample positions.
5. Install the sample carousel and the carousel cover.

11.11.3 Clean Reagent Compartment

When reagents are sprayed into the reagent compartment, or dusts accumulate inside the compartment, clean them immediately in order to minimize the risks of cross contamination.

Purpose

To clean the reagent carousel assembly to ensure clear operating environment and eliminate the risks of cross contamination.

When to do

Perform this procedure when reagents are spilled into the reagent compartment or dust is found inside of it.

Materials required

Clean gauze, deionized water, ethanol, and cotton swabs

System status

Make sure that the system is not running any tests.

Precautions

Warning

Do not spill water or ethanol into the reagent compartment to prevent equipment damage.

BIOHAZARD

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.

How to do

1. Make sure that the system is not running any tests.
2. Remove the reagent carousel cover and reagent carousel, and then store them properly.
3. Use clean gauze soaked with deionized water or ethanol to clean the interior of the reagent compartment. If necessary, you can use gauze moistened with neutral wash solution.
4. Use clean gauze soaked with deionized water or ethanol to clean the reagent carousel, and then use cotton swabs dipped with ethanol to clean the reagent positions.
5. Install the reagent carousel and the carousel cover.

11.11.4 Clean Sample Probe Interior

The sample probe, once blocked, cannot aspirate or dispense sample correctly. When you find that the sample probe is clogged and cannot aspirate or dispense sample, or when the sample probe is detected with abnormal liquid flow through the Check

Probes/Mixers maintenance, perform this procedure to solve the problems.

Purpose

To clean the interior of the sample probe and avoid clogging.

When to do

Perform this procedure when you find that the sample probe is clogged and cannot aspirate or dispense sample, or when the sample probe is detected with abnormal liquid flow through the Check Probes/Mixers maintenance.

Materials required

Unclogging device (needle), small Philips-head screwdriver, beaker, tweezers, deionized water, and thread syringe

System status

Make sure that the system status is not running any tests.

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Recall the maintenance logs and check if the sample probe has been removed and reinstalled for 3 times. If it has, prepare a new washer and moisten it with deionized water. Store the washer properly to avoid being lost.
2. Switch off the analyzing unit power.
3. Loosen the screws on the arm cover and remove the cover from the arm base.
4. Press the circuit board with one hand and unplug the tube connector with the other hand,.
5. Remove the retaining screw from the sample probe and take out the spring.
6. While holding the connector on the sample probe with one hand, unscrew the tube connector counterclockwise with the other hand until the tube connector is disconnected. Remove the tube from the sample probe.

   Exercise caution to prevent the washer from dropping out. If the washer drops out, store it in a clear place for later installation. To replace the washer, take it out from the tube connector.

7 Remove the sample probe.

8 Insert the needle into the probe to unclog the block inside.

If the probe cannot be unclogged with the needle, replace the sample probe.

9 Insert the sample probe downwards into the hole on the probe arm while aligning the screw hole on the probe plate to the rod inside the arm.

10 To replace the washer, remove the old one from the tube connector and install the new one. Connect the tube connector to the sample probe and then tighten it.

11 Fix the earthing wire of the sample probe to the earthing terminal inside the arm; connect the probe connector to the liquid level detection board.

12 Sleeve the spring on the rod and tighten the retaining screw. Pay attention to the spring direction and make the thread opening face downwards.

13 Pinch the sample probe by the part near the probe arm. Push the sample probe upwards and then release it to check if the spring works well.

- If it does, proceed to the next step.
- If not, check if the spring is clamped or fixed too tightly.

14 Switch on the analyzing unit power, and then check if the No.D2 LED indicator on the circuit board inside the probe arm is lit.

- If it is, the liquid level detection system is normal.
- If not, the liquid level detection system is abnormal. Contact our customer service department or your local distributor.

15 Install the probe arm cover properly until you hear a click, and then tighten the screws on it.

16 Pinch the sample probe by the part near the probe arm. Push the sample probe upwards and then release it to check if the spring works well.

- If it does, proceed to the next step.
- It not, it indicates that the arm cover is not installed correctly. Reinstall the arm cover and check the spring until it can move freely.

17 Execute the **Home** maintenance command or the **Home** system command. Check if the water flow coming out of the sample probe is continuous and in the same direction as the probe. If it is not, perform the Check Probes/Mixers procedure to troubleshoot the problems.

18 Select **Utility > Commands**, and then select **Home** to put the instrument into the Standby status.

11.11.5 Clean Reagent Probe Interior

The reagent probe, once blocked, cannot aspirate or dispense reagent correctly. It is necessary to clean the reagent probe interior at times.

Purpose

To clean the interior of the reagent probe and avoid clogging.

When to do

Perform this procedure when you find that a reagent probe is clogged and cannot aspirate or dispense sample, or when a reagent probe is detected with abnormal liquid flow through the Check Probes/Mixers maintenance.

Materials required

Unclogging device (or needle),, small Philips-head screwdriver, beaker, tweezers, deionized water, and thread syringe

System status

Make sure that the system status is not running any tests.

Precautions

 **BIOHAZARD**

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Recall the maintenance logs and check if the reagent probe has been removed and reinstalled for 3 times. If it has, prepare a new washer and moisten it with deionized water. Store the washer properly to avoid being lost.
2. Switch off the analyzing unit power.
3. Clean the reagent probe by referring to step 3 to 18 in 11.11.4 Clean Sample Probe Interior.
4. Select **Utility** - **Commands**, and then select **Home** to put the instrument into the Standby status.

11.11.6 Remove Air Bubbles in Sample Syringe

Purpose

To remove the air bubbles possibly existing inside the tubes and clean/prime the probes, mixers and wash wells. It will take about 20 seconds to perform this procedure.

When to do

Perform this procedure when you find air bubbles inside the sample syringe.

Materials required

Concentrated wash solution

System status

Make sure that the system status is Standby.

Precautions

 **BIOHAZARD**

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Switch off the analyzing unit power, and open the front door of the analyzer.
2. Loosen counterclockwise the four retaining screws on top of the syringe, and then remove the screws and the fixing blocks.
3. Loosen counterclockwise the retaining screw at the bottom of the syringe and then remove it.
4. Hold the T piece with one hand and the syringe connector with the other hand. Loosen the syringe counterclockwise and then remove the washer.
5. Soak the syringe connector in the deionized water beaker, pull the plunger head to aspirate half syringe of deionized water, and then push the plunger head to remove the air. Repeat this pull-push operation until the air bubbles are removed from the syringe. Fill the syringe with half cylinder of deionized water to prevent new bubbles.

6 Put the washer in the T piece. Hold the T piece with one hand and the syringe connector with the other hand, and then screw the T piece clockwise.

7 Install the syringe on the bracket.

8 Install the fixing blocks and 4 retaining screws while having the retaining screws not tightened.

9 Align the plunger head to the retaining screw at the bottom of the syringe, and then tighten clockwise the retaining screw.

10 Pinch the plunger guide cap to adjust the syringe height. For the sample syringe, make the syringe head over the upper fixing block for 7.5 scales; for the reagent syringes, make the syringe head over the upper fixing block for 15 scales.

11 Tighten the four retaining screws on the fixing blocks.

12 Turn on the analyzing unit power switch.

13 Perform the **Home** maintenance procedure. Check the new syringe for leak and bubbles, and if there is, perform the Check Sample/Reagent Syringes procedure.

14 Close the front door of the analyzer.

11.11.7 Remove Air Bubbles in Reagent Syringe

Purpose

To remove the air bubbles possibly existing inside the tubes and clean/prime the probes, mixers and wash wells. It will take about 20 seconds to perform this procedure.

When to do

Perform this procedure when you find air bubbles inside the reagent syringe.

Materials required

Concentrated wash solution

System status

Make sure that the system status is Standby.

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1 Switch off the analyzing unit power, and open the front door of the analyzer.

2 Remove the air bubbles in reagent syringe by referring to step 2 to 14 in 11.11.6 Remove Air Bubbles in Sample Syringe (page 11-34).

11.11.8 Replace Sample Syringe

The sample syringe has a limited life span, and when due, may have leak or other phenomena causing inaccurate aspirating/dispensing and resulting in unreliable results.

Purpose

To replace the syringe plunger assembly to ensure optimal measuring performance.

When to do

Perform this procedure when the syringe is used for 100,000 times.

Materials required

Deionized water, beaker, and syringe plunger assembly

System status

Make sure that the system status is Standby.

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Prepare a new syringe plunger assembly and washer, put the plunger head in the deionized water beaker to remove air from the syringe, and then moisten the washer in the deionized water.
2. Switch off the analyzing unit power.
3. Open the front door of the analyzer. You will see two syringes, reagent syringe to the left of the water tank and sample syringe to the right.
4. Loosen counterclockwise the four retaining screws on top of the syringe, and then remove the screws and the fixing blocks.
5. Loosen counterclockwise the retaining screw at the bottom of the syringe and then remove it.
6. Hold the T piece with one hand and the syringe connector with the other hand. Loosen the syringe counterclockwise and then remove the washer.
7. Loosen the plunger guide cap counterclockwise, hold the plunger head and pull it slightly to remove the plunger assembly from the syringe.
8. Insert the plunger head of the new plunger assembly into the bottom of the syringe, and then tighten the retaining screw to fix the plunger head.
9. Soak the new syringe connector in the deionized water beaker, pull the plunger head to aspirate half syringe of deionized water, and then push the plunger head to remove the air.
10. If there is no washer inside the T piece, put the new washer in the T piece. Hold the T piece with one hand and the syringe connector with the other hand, and then screw the T piece clockwise.
11. Install the syringe on the bracket.
12. Install the fixing blocks and 4 retaining screws while having the retaining screws not tightened.
13. Align the plunger head to the retaining screw at the bottom of the syringe, and then tighten clockwise the retaining screw.
14. Pinch the plunger guide cap to adjust the syringe height. For the sample syringe, make the syringe head over the upper fixing block for 7.5 scales; for the reagent syringes, make the syringe head over the upper fixing block for 15 scales.
15. Tighten the four retaining screws on the fixing blocks.
16. Turn on the analyzing unit power switch.

17 Perform the **Home** maintenance procedure. Check if the new syringe has leak. If it does, perform the Check Sample/Reagent Syringes procedure to check the syringe.

18 Close the front door of the analyzer.

11.11.9 Replace Reagent Syringe

The reagent syringe has a limited life span, and when due, may have leak or other phenomena causing inaccurate aspirating/dispensing and resulting in unreliable results.

Purpose

To replace the syringe plunger assembly to ensure optimal measuring performance.

When to do

Perform this procedure when the syringe is used for 300,000 times.

Materials required

Deionized water, beaker, and syringe plunger assembly

System status

Make sure that the system status is Standby.

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1 Prepare a new syringe plunger assembly and washer, put the plunger head in the deionized water beaker to remove air from the syringe, and then moisten the washer in the deionized water.

2 Switch off the analyzing unit power.

3 Replace the reagent syringe by referring to step 3 to 18 in 11.11.8 Replace Sample Syringe (page11-35).

11.11.10 Replace Sample Probe

Replace the sample probe when it is damaged and cannot be repaired, or blocked seriously, or bent.

Purpose

To replace the sample probe.

When to do

Perform this procedure when the sample probe is damaged and cannot be repaired due to the following causes, such as serious blockage, or bending.

Materials required

Small slot-head screwdriver, small Philips-head screwdriver, tweezers, and new sample probe

System status

Make sure that the system status is not running any tests.

Precautions

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, and if necessary, goggles during the maintenance process.

How to do

1. Prepare the new sample probe. Recall the maintenance logs and check if the sample probe has been removed and reinstalled for 3 times. If it has, prepare a new washer and moisten it with deionized water. Store the washer properly to avoid being lost.
2. Switch off the analyzing unit power.
3. Loosen the screws on the arm cover and remove the cover from the arm base.
4. Press the circuit board with one hand and unplug the tube connector with the other hand.
5. Remove the retaining screw from the sample probe and take out the spring.
6. While holding the connector on the sample probe with one hand, unscrew the tube connector counterclockwise with the other hand until the tube connector is disconnected. Remove the tube from the sample probe.

   Exercise caution to prevent the washer from dropping out. If the washer drops out, store it in a clear place for later installation. To replace the washer, take it out from the tube connector.
7. Remove the sample probe.
8. Insert the sample probe downwards into the hole on the probe arm while aligning the screw hole on the probe plate to the rod inside the arm.
9. To replace the washer, remove the old one from the tube connector and install the new one. Connect the tube connector to the sample probe and then tighten it.
10. Fix the earthing wire of the sample probe to the earthing terminal inside the arm; connect the probe connector to the liquid level detection board.
11. Sleeve the spring on the rod and tighten the retaining screw. Pay attention to the spring direction and make the thread opening face downwards.
12. Pinch the sample probe by the part near the probe arm. Push the sample probe upwards and then release it to check if the spring works well.
    - If it does, proceed to the next step.
    - If not, check if the spring is clamped or fixed too tightly.
13. Switch on the analyzing unit power, and then check if the No.D2 LED indicator on the circuit board inside the probe arm is lit.
    - If it is, the liquid level detection system is normal.
    - If not, the liquid level detection system is abnormal. Contact our customer service department or your local distributor.
14. Install the probe arm cover properly until you hear a click, and then tighten the screws on it.
15. Execute the **Home** maintenance command or the **Home** system command. Check if the water flow coming out of the sample probe is continuous and in the same direction as the probe. If it is not, perform the Check Probes/Mixers procedure to troubleshoot the problems.

16 Select **Utility > Commands**, and then select **Home** to put the instrument into the Standby status.

11.11.11 Replace Reagent Probe

Replace the reagent probes when they are damaged and cannot be repaired, or blocked seriously, or bent.

Purpose

To replace the reagent probes.

Materials required

Small slot-head screwdriver, small Philips-head screwdriver, tweezers, and new reagent probe

System status

Make sure that the system status is not running any tests.

Precautions

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, and if necessary, goggles during the maintenance process.

How to do

1 Prepare the new reagent probe. Recall the maintenance logs and check if the reagent probe has been removed and reinstalled for 3 times. If it has, prepare a new washer and moisten it with deionized water. Store the washer properly to avoid being lost.

2 Switch off the analyzing unit power.

3 Replace the reagent probe by referring to step 3 to 15 in 11.11.10 Replace Sample Probe (page 11-37).

4 Select **Utility > Commands**, and then select **Home** to put the instrument into the Standby status.

11.11.12 Replace Sample Mixer

Replace the sample mixer when they are bent or damaged and cannot be repaired.

Purpose

Replace the sample mixer.

When to do

Perform this procedure when the sample mixer are damaged and cannot be repaired.

Materials required

Ethanol, clean gauze, new mixer, mixer wrench

System status

Make sure that the system status is not running any tests.

Precautions

Warning

The mixer tips are sharp and may cause puncture wounds. To prevent injury, exercise caution when working around the mixers.

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Switch off the analyzing unit power.
2. Gently pull the sample mixer to its highest point and rotate it to a position convenient to operate.
3. Use one mixer wrench to hold the mixer by the flat area, use the other mixer wrench to hold the lock nut, unscrew the lock nut counterclockwise to loosen the mixer, and then pull the mixer downwards to remove it and remove the lock nut.

   CAUTION

   When trying to pull out the mixer, concentrate your force in the direction of the axis on the mixer arm. Biased force may damage the mixer and/or the axis.
4. Align the new mixer to the bigger hole of the retaining nut and gently screw it into the nut until the end of the mixer is in line with the smaller hole of the nut.
5. Pinch the mixer by the flat part and align the hole of the nut to the axis on the mixer and push the nut onto the mixer until it reaches the end of the mixer. Use one mixer wrench to hold the mixer by the flat area, use the other mixer wrench to hold the lock nut, and then screw the lock nut clockwise to tighten the mixer.

   CAUTION

   When trying to push the mixer into the arm, concentrate your force in the direction of the axis on the mixer arm. Biased force may damage the mixer and/or the axis.

   Ensure the mixer is all the way pushed to the end.

   When tightening the lock nut with the mixer wrench, use even force to prevent bending the mixer rotor.
6. After replacing the bar, visually check whether the mixer is vertical to the bar arm.
   - If not, remove the mixer and reinstall it.
   - If so, proceed to the next step.
7. Pull the mixer arm to its highest point and rotate it back to a position above its wash well.
8. Turn on the analyzing unit power switch.
9. Select **Utility > Command;** Perform the **Home** maintenance procedure.

11.11.13 Replace Reagent Mixer

Replace the reagent mixer when they are bent or damaged and cannot be repaired.

Purpose

Replace the reagent mixer.

When to do

Perform this procedure when the reagent mixer are damaged and cannot be repaired.

Materials required

Ethanol, clean gauze, new reagent mixer, mixer wrench

System status

Make sure that the system status is not running any tests.

Precautions

Warning

The mixer tips are sharp and may cause puncture wounds. To prevent injury, exercise caution when working around the mixers.

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Switch off the analyzing unit power.
2. Replace the reagent mixer by referring to step 2 to 9 in 11.11.13 Replace Reagent Mixer (page 11-40).
3. Select **Utility > Command > Home.**

11.11.14 Replace Cuvette

The reaction cuvettes, if contaminated by serum or other stains, or scratched or damaged, will result in inaccurate photometric measurement. Check the reaction cuvettes regularly, and if necessary, replace them immediately. It is recommended to change the cuvettes every three months. It will take about half a minute to replace a cuvette.

Purpose

To ensure that the cuvettes are normal and not contaminated, scratched or damaged.

When to do

Replacing cuvettes is performed as needed or as required. Replace a cuvette if,

- it is detected abnormal through the Cuvette Check procedure; or
- scratches or cracks are found on the optical surface of the cuvette.

Materials required

Fiber-free gloves, dry cloth or gauze, and reaction cuvettes

System status

Make sure that the system status is Standby or Stopped.

Precautions

Warning

While installing the reaction cuvettes, exercise caution to avoid scratching them. Do not touch the optical surface of the reaction cuvettes. If the optical surface is polluted, the obtained absorbance may be inaccurate.

While installing the reaction cuvettes, make sure that the optical surface is confronted with the outside of the reaction carousel.

Wear gloves free of fibre and powder to avoid polluting the optical surface of the reaction cuvettes.

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

CAUTION

Please use consumables recommended by our company. Use of other consumables may degrade the system performance.

NOTE

If a cuvette cannot be removed from the reaction carousel, use a knife to remove the metal plate next to it, and then use your hands or tweezers to take out the cuvette.

When serious problems occur such as overflow and require the reaction cuvettes to be maintained, contact our customer service department or your local distributor.

How to do

1. Select **Utility > Maintenance >Maintenance >Biochemistry Maintenance**.
2. Choose **Replace Cuvette**.
3. Select **Continue**.
4. Remove the reaction carousel cover.
5. Type in the position number of the cuvette you want to replace.

   The input range is 1-93. Only one position number can be entered each time.
6. Select **Replace**.
7. Wear a pair of gloves and remove the specified cuvette by pulling it outwards.
8. Install the provided or cleaned cuvette to the reaction carousel and make sure that the cuvette bottom can no longer proceed.
9. Restore the reaction carousel cover.
10. Select **Done**. The system resets mechanically.
11. Perform the Cuvette Check procedure to check if the new cuvettes meet the requirements.

    For more information, refer to 11.6.4 Cuvette Check (page 11-20).

11.11.15 Special Wash Probes

Purpose

To eliminate cross contamination among the sample probe and reagent probe, and prevent waste from leaving in the waste tubes.

When to do

Perform this procedure when the probes are clogged or the carryover result exceeds the limit.

Materials required

Concentrated wash solution

System status

Make sure that the system status is Standby.

How to do

1. Open the upper protective shield of the analyzer.
2. Place more than 30ml concentrated wash solution in position DB of the reagent carousel, and place more than 3ml concentrated wash solution in position DB on the sample carousel.
3. Select **Utility > Maintenance> Maintenance > Biochemistry Maintenance**.
4. Choose **Special Wash Probes**.
5. Select Special Wash Reagent Probe and Special Wash Sample Probe, and then select **Continue**.
6. Set the wash times for sample probe (1-30) and for reagent probe (1-100).
7. Set the sample probe wash solution volume as 45µl or 90µl.
8. Select **Continue**.

   The system resets and then cleans the two probes.
9. When the cleaning is finished, select **Done**.
10. Restore the upper protective shield of the analyzer.

11.11.16 Bar Code Maintenance

This maintenance procedure is used to clean the sample and reagent bar code scanning windows in order to avoid influencing bar code scanning.

Purpose

To clean the glass of the sample and reagent bar code scanning windows in order to avoid influencing bar code scanning.

When to do

This maintenance should be performed if the glass of the sample or reagent bar code scanning window is contaminated and causes bar code scanning failure.

Materials required

Clean gauze, deionized water, ethanol, and cotton swabs

System status

Make sure that the system is not running any tests.

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

CAUTION

Exercise caution not to spray water or ethanol or other liquids on the glass of the bar code scanning window.

How to do

1. Remove the sample/reagent carousel covers and the carousels.
2. Use clean gauze to clean the bar code reader window inside the sample compartment and reagent compartment. If necessary, you can use gauze soaked with ethanol or deionized water. Make sure that there is no trace or dust left on the glass.
3. Install the carousels and carousel covers.

11.11.17 Empty Waste Tubes

If the analyzer is powered off for a long time and the electrodes and reagent pack are stored, remove the reagent pack first. Before removing reagent pack and electrode, emptying waste tubes is needed.

When to do

Perform this procedure when the ISE module is powered off for a long time (for over three days) or the electrodes and reagent pack are stored away from the system, or when the tube is blocked by protein.

System status

Make sure that the ISE module system is Standby or Failure.

Precautions

NOTE

After removing and storing the electrodes, please remove the reagent pack in time to avoid overflow.

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

How to do

1. Select **Utility > Maintenance> Maintenance > ISE Maintenance**.
2. Choose **Empty Waste Tubes**.
3. When the procedure is finished, select **Done**.

To store electrodes and reagent pack, perform the following operations after emptying the tubes:
1) Take out the reagent pack and apply the rubber plug immediately to prevent leakage and volatilization.
2) Open the ISE maintenance window.
3) Open the front cover of the ISE module and loosen the ISE electrode locking mechanism;
4) Remove and seal the electrodes. Store them in a 2-8 °C refrigerator to avoid volatilization.

11.11.18 Replace ISE Electrodes

ISE electrodes are consumables and have a limited life span. When used for a long period or after measuring a large number of samples, the ISE electrodes may have their performance degraded and should be replaced immediately. 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

System status

Make sure that the status of the analyzer is Standby and the ISE module status is Standby or Failure.

Precautions

BIOHAZARD

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

NOTE

After performing this procedure, recalibrate the ISE electrodes prior to starting analysis.

How to do

1. Select **Utility > Maintenance> Maintenance >ISE Maintenance**.
2. Choose **Replace ISE Electrodes**.
3. Enter the SN of the new electrode. Select **OK**.
4. Select **Continue**.
5. Open window at the right side to replace the electrode.
6. Unscrew the compressing knob to remove all electrodes.
7. Replace the old electrode and then screw the knob.
8. Select **Continue**.

   NOTE

   The new electrode can be calibrated successfully only after being primed for multiple times.
9. Select **Done**.

11.11.19 Na Electrode Slope Adjustment

When the Na electrode has been used or has been removed from the instrument for a long period, you are allowed to adjust the slope of the Na electrode through this maintenance procedure.

Purpose

To adjust the electrode slope.

Materials required

Na cleaning solution

When to do

Perform this procedure when the slope is lower than the reference range.

System status

Make sure that the ISE module status is Standby .

Precautions

 **BIOHAZARD**

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

How to do

1. Select **Utility > Maintenance> Maintenance > ISE Maintenance**.
2. Choose **Na Electrode Slope Adjustment**.
3. Load at least 300µl Na cleaning solution to the 2 ml sample tube, and place it in the position C7 of the sample carousel. Select **Continue**.
4. Wait till the procedure completes.
5. Select **Done**.

 **NOTE**

After performing this procedure, recalibrate the ISE electrodes prior to starting analysis.

12 Alarms and troubleshooting

This chapter describes 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

The logs provided by the system are divided into:

- Error log
- Edit log

12.1.1 Error logs

Error logs record all types of failures occurring on the system components. The table below shows all failures divided by component:

Table 12.1 Classification of failure based on component

No.	Failure by component	No.	Failure by component
1	Operating system	13	Reagent mixer unit
2	System communication	14	Reaction carousel unit
3	Database	15	Sample carousel unit
4	Result calculation	16	Reagent carousel unit
5	Sample bar code	17	Wash station
6	Reagent bar code	18	Temperature unit
7	Host communication	19	ISE unit
8	Command execution	20	Light source
9	Sample probe unit	21	Cuvette wash station
10	Probe R1 unit	22	Reagent refrigeration unit
11	Reagent probe unit	23	Other
12	Sample mixer unit	24	Home process

Error code

Each error has a unit code used for identification and locating probable causes and solutions. An error code consists of 6 letters and numbers, such as "C01001", in which "C" indicates that the error occurs on the operation unit, "01" is the error description of instrument connection, and "001" is the serial number of the error. Therefore, "C01001" is described as "the first error of instrument connection on the operation unit".

The following tables provide a summary of error codes for the operation unit and analyzing unit.

Table 12.2 Error code of the operation unit

Error Code	Description
C	Indicates that the error occurs on the operation unit.

Error Code	Description
00-99	Indicates the specific component on which the error occurs. 00-Operating system 01- System communication 02-Database 03-Result calculation 04-Sample bar code 05-Reagent bar code 06-LIS host communication 07-Other
000-999	Serial number of the error.

Table 12.3 Error code of the analyzing unit

Error Code	Description
A	Indicates that the error occurs on the analyzing unit.
00-99	Indicates the specific component on which the error occurs. 00-Command execution 01-Sample probe unit 02-Probe R1 unit 03-Reagent probe unit 04-Sample mixer 05-Reagent mixer 06-Reaction carousel unit 07-Sample carousel unit (including sample bar code module) 09-Reagent carousel unit (including reagent bar code module) 11-Wash unit 12-Temperature unit 14-Reagent refrigeration unit 15-Other 21-Probe interior wash unit 22-Home process or ISE unit
000-999	Serial number of the error.

Help

Every error log is provided with online help information. Select the  icon in front of an error log. The descriptions, possible causes and solutions of the error are displayed.

12.1.2 Edit logs

Edit logs record all deletions and part of editing actions performed by the user.

- The deleting logs record all deleting actions other than the error deletion.
- The editing 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 Error Log screen

Select **Alarm** 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.

Figure 12.1 Error Log screen

Every error log contains the event ID, date/time, error description (by processing method), event class (by subsystem) and symptom.

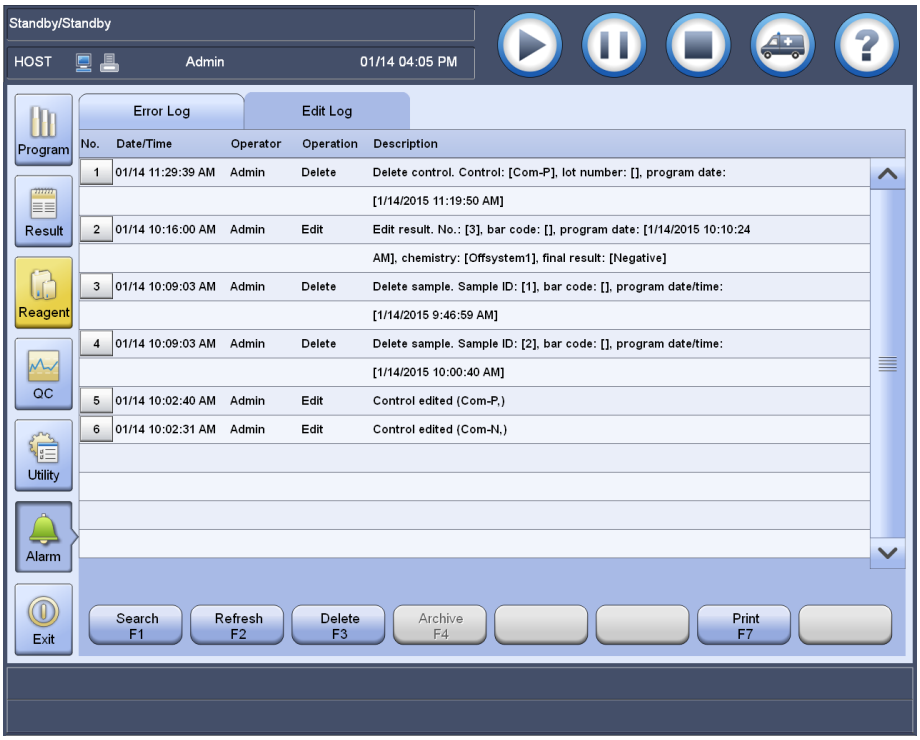
Choose the following buttons as needed:

- **Search F1**: to search for error logs by date, event ID, symptom, or event class.
- **Refresh F2**: to refresh the error logs based on the current search conditions.
- **Delete F3**: to remove specified error logs on the screen.
- **Print F7**: to print all error logs currently displayed on the screen.

12.2.2 Description of Edit Log screen

Select **Alarm > Edit Log**. The **Edit Log** screen is displayed and shows all editing actions occurring on the current day.

Figure 12.2 Edit Log screen



Every edit log contains the serial number, date/time, operator, event type and description.

Choose the following buttons as needed:

- **Search F1**: to search for edit logs based on the occurring date.
- **Refresh F2**: to refresh the edit logs based on the current search conditions.
- **Delete F3**: to remove specified edit logs on the screen.
- **Print F7**: to print all edit logs currently displayed on the screen.

12.2.3 Recalling logs

Error logs and edit logs can be recalled by all users in any system status. Error logs can be recalled by date, event ID, symptom and event class, while edit logs can only be recalled by occurring date.

Perform the following steps to recall desired event logs:

1 Select **Alarm > Error Log** or **Edit Log**.

2 Select **Search F1**.

3 Enter one or more of the following conditions:

- Date
- Event ID (available for error logs only)
- Symptom (available for error logs only)
- Event class (available for error logs only)

4 Select **OK**. The event logs satisfying the conditions are displayed on the screen.

5 Choose the following buttons as needed:

- **Refresh F2**: to refresh the logs based on the current search conditions.
- **Delete F3**: to remove specified logs on the screen.
- **Print F7**: to print all logs currently displayed on the screen.

12.2.4 Refreshing Logs

To refresh the event logs, perform the following procedure:

1. Select **Alarm** > **Error Log** or **Edit Log**.
2. Select **Refresh F2**.
3. The system refreshes the logs based on the previous search conditions.
   - New error logs are displayed chronologically and highlighted by different colors. Yellow indicates a warning, and red indicates a serious error.
   - New edit logs are displayed chronologically on the front-most of the log list.
4. Choose the following buttons as needed:
   - **Delete F3**: to remove specified logs on the screen.
   - **Print F7**: to print all logs currently displayed on the screen.

12.2.5 Clearing logs

Since the system has a limited storage capacity, you should clear and manage the event logs regularly to ensure that the most-recent and important logs are kept. Only users with sufficient permissions are allowed to delete event logs.

📖 For more information about user permissions, refer to 8.7.3 Assigning/Modifying permissions on page 8-24.

Perform the following steps to clear event logs:

1. Select **Alarm** > **Error Log** or **Edit Log**.
2. Select event logs you desire to delete.
3. Select **Delete F3**.
4. Select **OK**. To abort the deleting, select **Cancel**.

   When you confirm the deleting, the system removes the selected event logs from the screen.

12.2.6 Printing logs

After searching for desired logs on the **Error Log** or **Edit Log** screen, select **Print F7**. The event logs currently displayed are printed out in the same format as shown on the screen.

Printing logs will take a long time and requires a great number of papers. Think twice before printing logs.

To terminate the printing, select **Utility** > **Commands** > **Stop Print**.

12.3 Error Troubleshooting

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.

12.3.1 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.

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 **Utility > System Setup**.
2. Adjust the alarm tone in the **Alarm Volume** field.
3. Test the alarm tone until it is satisfied.
4. To silence the alarm tone, drag the slider to the leftmost position of the scale.
5. Select **Save F8** to save the adjustment.

Alarm message

When an error occurs, the system gives an alarm and displays the alarm message in the second line of the prompt message area.

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
- **Utility** button
- **Alarm** 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.

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.

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.

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.

12.3.2 Identifying errors

To identify errors, understand the error indication thoroughly, check the error logs and system status, and then determine relevant solutions.

The table below shows the error types that may occur on the system. Find relevant corrective actions according to the description.

Table 12.4 Error types

Error Type	Description
Instrument failure and error	Instrument failure and error may be detected on all subsystems and processed in different ways. Such errors are shown in the Error messages and corrective actions table, and can be identified through the event ID.
Data alarm	Data alarm is a flag indicating biochemistry or ISE chemistry result error. The flags are included in the Result flags table, and can be identified through the flag symbol.

12.4 Data alarms

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 biochemistry results and ISE chemistry 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.

12.4.1 Data alarms and corrective actions

Table 12.5 Data alarms and corrective actions

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
<	Result related	Exceeds linearity range low	The result exceeds the low limit of the linearity range.	Take no actions, or rerun the test for confirmation.
<	ISE result related	Exceeds measurement range low	Sample or control result exceeds the low limit of the measurement range.	Take no actions, or rerun the test for confirmation.
>	Result related	Exceeds linearity range high	The result exceeds the high limit of the linearity range.	Rerun the test with sample diluted or decreased.
>	ISE result related	Exceeds measurement range high	Sample or control result exceeds the high limit of the measurement range.	Rerun the test with sample diluted or decreased.
▲	Result related	Sample volume is Increased one	Sample volume is Increased one	No actions are required.
▼	Result related	Sample volume is decreased one	Sample volume is decreased one	No actions are required.
^	Result related	Exceeds reference range high	The result exceeds the high limit of the reference range.	No actions are required.
^!	Result related	Exceeds critical range high	The result exceeds the high limit of the critical range.	No actions are required.
v	Result related	Exceeds reference range low	The result exceeds the low limit of the reference range.	No actions are required.
v!	Result related	Exceeds critical range low	The result exceeds the low limit of the critical range.	No actions are required.
10-x	Result related	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	Result related	1-2s	The current QC result is between ±2 and ±3 standard deviations from the assigned mean concentration.	No actions are required.
1-3s	Result related	1-3s	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.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
2-2s	Result related	2-2s	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	Result related	4-1s	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	Result related	Absorbance out of range	The absorbance of primary or secondary wavelength used for calculating results is greater than 3.4A.	Check the sample for foreign matters or interferents; check if the reagent is qualified and placed in the correct position; check the cuvette is clean; check if the photometric system is working normally.
BLK	Calibration related	Blank response out of range	The reagent goes wrong; insufficient reagent is dispensed; the cuvette contains air bubbles; the light drifts; or the cuvette is overflowed.	Check if the cuvette is not overflowed, the reagent is sufficient without air bubbles, the light does not drift and the chemistry parameters are reasonable. If yes, replace the reagent and then rerun the test.
BOE	Result related	Substrate depletion	The sample concentration is too high, and substrate depletion occurs during fixed-time measurements.	Check the reaction curve and the substrate depletion limit. Rerun the test with diluted sample.
CALCE	Result related	Chemistries of the special calculation exceeding the linear range.	Chemistries of the special calculation exceeding the linear range.	Check if the sample contains foreign matters such as clot and if sample probe is clogged. Check if the reagent is expired. If there are no above mentioned problem, please rerun the test or run the HbA1c test by manually pretreating the sample
CALE	Result related	Edited calibration factor	The calibration factors are edited.	No actions are required.
CALF	Result related	Calibration failed.(for biochemistries)	The calibration fails.	Recalibrate.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
CALF	Result related	No fluid in tubing	1. Waste pump tube is aging, blocked, or broken; 2. Sample injection port and fluidic path are blocked or leaking. 3. Air bubble detector failed.	1. Replace the reagent pack with a new one 2. Perform purge B to remove bubbles 3. /4. Replace the pump tube 5. Clean the sample injection port and reinstall electrodes. 6. Replace the bubble detector.
				1. Place sufficient ISE wash solution. 2. Replace the pump tube 3. Clean the sample injection port and reinstall electrodes. 4. Replace the bubble detector.
CALF	Calibration related	No fluid in tubing	1. Waste pump tube is aging, blocked, or broken; 2. Sample injection port and fluidic path are blocked or leaking. 3. Air bubble detector failed.	1. Replace the reagent pack with a new one 2. Perform purge B to remove bubbles 3. /4. Replace the pump tube 5. Clean the sample injection port and reinstall electrodes. 6. Replace the bubble detector.
				1. Place sufficient ISE wash solution. 2. Replace the pump tube 3. Clean the sample injection port and reinstall electrodes. 4. Replace the bubble detector.
CALJ	Calibration related	Rejected calibration factor	The calibration factors are rejected.	No actions are required.
CALM	Result related	Air in segment	1. Waste pump tube is aging, blocked, or broken; 2. Sample injection port and fluidic path are blocked or leaking. 3. Air bubble detector failed.	1. Replace the pump tube 2. Clean the sample injection port and reinstall electrodes. 3. Replace the bubble detector.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
CALM	Calibration related	Air in segment	1. Waste pump tube is aging, blocked, or broken; 2. Sample injection port and fluidic path are blocked or leaking. 3. Air bubble detector failed.	1. Replace the pump tube 2. Clean the sample injection port and reinstall electrodes. 3. Replace the bubble detector.
CALR	Result related	Recalculated calibration factor	The calibration factors are recalculated.	No actions are required.
COV	Calibration related	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.
CSD	Calibration related	Calibration curve standard deviation out of range	The calculated standard deviation of the calibration curve exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.
DEL	Calibration related	Deleted QC result	The QC result has been deleted.	No actions are required.
DET	Calibration related	Calibration determination coefficient out of range	The calculated determination coefficient of the calibration curve exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.
DEP	Calibration related	Saving calibration result error	1. ISE communication cable failure. 2. Communication interface or pins failure 3. Main control board of the ISE module goes wrong. 4. Software error.	1. Replace the ISE communication cable. 2. Replace the interface or pins. 3. Replace the main control board of the ISE module. 4. Upgrade the operating software or reinstall it.
DTGL	Result related	Insufficient probe wash solution	The probe wash solution is insufficient during measurement.	Fill more probe wash solution.
DUP	Calibration related	Calibration repeatability error	The difference between the maximum and minimum response of the calibrator exceeds the specified limit.	Check if the acceptance limit is reasonable, troubleshoot the error, and then recalibrate.
EDT	Result related	Edited result	The result has been edited.	No actions are required.
EDT	Calibration related	Edited calibration factor	The calibration factors have been edited.	No actions are required.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
ENC	Result related	No calculation interval	The sample concentration is too high, and substrate depletion occurs within the lag time of rate check measurements.	Check the reaction curve and the substrate depletion limit. Rerun the test with diluted sample.
EXP	Result related	Enzyme linearity range extension	The high-concentration sample leads to substrate depletion during the reaction time, and the result is calculated by using measuring points within the lag time.	Rerun the test with diluted sample.
EXT	Result related	Extended calibration factor	The result is obtained by extending the calibration time.	Take no actions, or recalibrate.
FAC	Calibration related	Calibration slope difference out of range	The slope difference is applicable to linear calibration only and refers to the K factor (slope) difference between two adjacent calibrations. It exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.
ICA	Result related	The response is normal, but results cannot be calculated.	The chemistry has not been calibrated.	Rerun it after calibration.
ISEC.ERR	Result related	ISE unit cannot be connected.	1. ISE module power supply goes wrong. 2. ISE Communication cable goes wrong. 3. Communication interface or pins go wrong. 4. Main control board of the ISE module goes wrong.	1. Turn off the analyzing unit power and reswitch it on. If the error occurs for continuous three times, please contact our customer service or your local distributor. 2. Replace the ISE module power supply board. 3. Replace the communication cable. 4. Replace the interface or pins. 5. Replace the main control board of the ISE module.
ISEC.ERR	Result related	ISE communication error	ISE is time out for 3 consecutive times.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
ISEC.NA	Result related	ISE timeout	Module instruction communication or execution is time out.	Home the system.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
ISEE.ERR	Result related	Electrode response voltage too low	1. The electrode is degenerated. 2. Liquid in the electrode does not touch the electrode lead. 3. Reference electrode failed.	1. Speical wash ISE tubes, adjust Na electrode slope and then try again. 2. Replace the electrode filled with insufficient liquid. 3. Replace the reference electrode.
ISEE.Exp	Result related	ISE electrode using time exceeds the allowable limit. Electrode: Na/K/Cl/Ref	ISE electrode using time exceeds the allowable limit.	Replace the failed electrode.
ISEE.Exp	Result related	ISE electrode test number exceeds the allowable limit. Electrode: Na/K/Cl/Ref	ISE electrode test number exceeds the allowable limit.	Replace the failed electrode.
ISEE.NA	Result related	Electrode response voltage too low	1. The electrode is degenerated. 2. Liquid in the electrode does not touch the electrode lead. 3. Reference electrode failed.	1. Speical wash ISE tubes, adjust Na electrode slope and then try again. 2. Replace the electrode filled with insufficient liquid. 3. Replace the reference electrode.
ISER.ERR	Result related	Reagent pack reader error	1. RFID card reader electrical interface is in poor contact. 2. RFID card reader goes wrong. 3. ISE main control board goes wrong.	1. Replug the RFID communication cable. 2. Replace the RFID card reader assembly. 3. Replace the ISE main control board.
ISER.ERR	Result related	Reagent pack registration failure	RFID card is damaged.	1. Remove and insert the reagent pack. 2. Replace the reagent pack with a new one.
ISER.ERR	Result related	Reagent pack not registered	1. Reagent pack is not registered. 2. RFID card is damaged.	1. Remove and insert the reagent pack. 2. Replace the reagent pack with a new one.
ISER.ERR	Result related	Reagent pack status is abnormal. Reagent pack is removed when the system is in the initialization, testing or maintenance status.	Reagent pack is removed when the system is in the initialization, testing or maintenance status.	Load the reagent pack.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
ISER.ERR	Result related	ISE reagent purge A contains air.	1. Calibrator tube A is not filled. 2. A pump tube is incorrectly installed. 3. Tubes are clogged.	1. Remove and insert the reagent pack when the system status is Standby or Stopped. 2. Check pump tubes. 3. Empty waste tubes.
ISER.Exp	Result related	ISE reagent expired	ISE reagent is expired.	Replace the reagent pack with a new one.
ISER.Exp	Result related	ISE reagent is used beyond the on-board stability time.	ISE reagent is used beyond the on-board stability time.	Replace the reagent pack with a new one.
ISER.NA	Result related	ISE reagent exhausted	ISE reagent is exhausted.	1. Remove and insert the reagent pack when the system status is Standby or Stopped. 2. Replace the reagent pack with a new one.
ISER.NA	Result related	ISE reagent purge A contains air.	1. Calibrator tube A is not filled. 2. A pump tube is incorrectly installed. 3. Tubes are clogged.	1. Remove and insert the reagent pack when the system status is Standby or Stopped. 2. Check pump tubes. 3. Empty waste tubes.
ISES. ERR	Result related	Liquid level is detected before ISE dispensing.	1. Sample cup interior is contaminated. 2. W pump tube is reversly installed and ISE sample cup overflow occurs. 3. Tube is clogged. Sample cup overflow occurs. 4. Sample cup dispensing position is too close to the cup wall.	1. Clean ISE sample cup. 2. Check if tubes are properly connected. 3. Check if tubes are clogged and if waste tubes are emptied. 4. Contact our customer service department or your local distributor to readjust the sample probe's dispensing position.
ISES. ERR	Result related	ISE sample contains air bubbles.	1. Peristaltic pump tubes are wrongly installed. 2. Electrode is not properly sealed or tubes are contaminated. 3. Bubble detector goes wrong. 4. Sample is insufficient or contains air bubbles. 5. Sample probe alignment position is incorrect.	1. Check if the peristaltic pump tubes are correctly installed. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened to clean the ISE tubes. 3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Check if sample is sufficient. 5. Readjust the position of the sample probe.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
ISES. ERR	Result related	ISE sample insufficient	1. Sample is insufficient. 2. Electrode is not properly sealed. 3. Bubble detector goes wrong. 4. Sample probe alignment position is incorrect.	1. Check if sample is sufficient. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened. 3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Readjust the position of the sample probe.
ISES. ERR	Result related	ISE sample excessive	1. Peristaltic pump tubes are aging. 2. Tubes are clogged.	1. Recalibrate ISE electrode. 2. Check and empty the waste tubes.
ISES.NA	Result related	Liquid level is detected before ISE dispensing.	1. Sample cup interior is contaminated. 2. W pump tube is reversly installed and ISE sample cup overflow occurs. 3. Tube is clogged. Sample cup overflow occurs. 4. Sample cup dispensing position is too close to the cup wall.	1. Clean ISE sample cup. 2. Check if tubes are properly connected. 3. Check if tubes are clogged and if waste tubes are emptied. 4. Contact our customer service department or your local distributor to readjust the sample probe's dispensing position.
ISES.NA	Result related	ISE sample contains air bubbles.	1. Peristaltic pump tubes are wrongly installed. 2. Electrode is not properly sealed or tubes are contaminated. 3. Bubble detector goes wrong. 4. Sample is insufficient or contains air bubbles. 5. Sample probe alignment position is incorrect.	1. Check if the peristaltic pump tubes are correctly installed. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened to clean the ISE tubes. 3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Check if sample is sufficient. 5. Readjust the position of the sample probe.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
ISES.NA	Result related	ISE sample insufficient	1. Sample is insufficient. 2. Electrode is not properly sealed. 3. Bubble detector goes wrong. 4. Sample probe alignment position is incorrect.	1. Check if sample is sufficient. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened. 3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Readjust the position of the sample probe.
ISES.NA	Result related	ISE sample excessive	1. Peristaltic pump tubes are aging. 2. Tubes are clogged.	1. Recalibrate ISE electrode. 2. Check and empty the waste tubes.
L!	Result related	Water blank fluctuation is out of range.	1. The cuvette is overflowing. 2. The lamp has been replaced incorrectly. 3. Cuvette check is not performed after maintenance. 4. The cable connectors are not tightened. 5. The retaining screw is not tightened. 6. Cleaning liquid inside the cuvette is little. 7. The lamp is aged. 8. The photometer goes wrong.	1. Check if the cuvette is overflowing. 2. Check if the **Replace Lamp** command is executed during lamp replacement. 3. Check if the cable connectors and retaining screw of the lamp have been tightened. 4. Check if the cleaning liquid inside the cuvette is no less than half of the cuvette. 5. Check if the reaction curve fluctuates irregularly. If yes, replace the lamp. 6. If the error remains, contact our customer service department.
LIN	Result related	Non-linear	The measuring points for result calculation are nonlinear, because the sample concentration is too high, or the substrate depletion limit is not specified or unreasonable. The lamp is aged.	Check the reaction curve and the substrate depletion limit. Rerun the test with diluted sample. If the alarm occurs for more than one chemistry, and the reaction curve fluctuates irregularly, replace the lamp.
LOW	Result related	Response less than that of the minimum-concentration 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 standard or increased sample volume; for descending calibration curve, rerun the test with diluted sample.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
MBK	Calibration related	Mixed blank absorbance out of range	The reagent goes wrong; the cuvette is not clear; the reaction cuvette is overflowed; or insufficient reagent is dispensed.	Check if the cuvette is clear and not overflowed, the reagent is sufficient without air bubbles, and the chemistry parameters are reasonable. If yes, replace the reagent and then rerun the test.
MON	Calibration related	Calibration curve not monotonic	The calibration data and calibration curve are not monotonic.	Check if the calibrator is defined and placed correctly, and then recalibrate.
NLN	Result related	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.
NOIS	Result related	Electrode voltage noise	1. Electrode failure. 2. Environment interference. 3. ISE main control board failure. 4. Salt buildup around electrodes or tubes due to fluidic leaks.	1. Replace the electrode. 2. Relocate the instrument. 3. Replace the main control board of the ISE module. 4. Clean the tubes and electrodes.
NOIS	Calibration related	Electrode voltage noise	1. Electrode failure. 2. Environment interference. 3. ISE main control board failure. 4. Salt buildup around electrodes or tubes due to fluidic leaks.	1. Replace the electrode. 2. Relocate the instrument. 3. Replace the main control board of the ISE module. 4. Clean the tubes and electrodes.
OVE	Result related	Overridden calibration factor	The result is obtained by overriding a failed calibration.	Take no actions, or recalibrate.
PUGA	Result related	Air in calibrator A	1. Calibrator A is exhausted. 2. Bubbles exist in calibrator tube A 3. Pump tube A is aging, blocked, or broken. 4. Waste pump tube is aging, blocked, or broken; 5. Sample injection port and fluidic path are blocked or leaking. 6. Air bubble detector failed.	1. Replace the reagent pack with a new one 2. Perform purge B to remove bubbles 3. /4. Replace the pump tube 5. Clean the sample injection port and reinstall electrodes. 6. Replace the bubble detector.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
PUGA	Calibration related	Air in calibrator A	1. Calibrator A is exhausted. 2. Bubbles exist in calibrator tube A 3. Pump tube A is aging, blocked, or broken. 4. Waste pump tube is aging, blocked, or broken; 5. Sample injection port and fluidic path are blocked or leaking. 6. Air bubble detector failed.	1. Replace the reagent pack with a new one 2. Perform purge B to remove bubbles 3. /4. Replace the pump tube 5. Clean the sample injection port and reinstall electrodes. 6. Replace the bubble detector.
PUGB	Result related	Air in calibrator B	1. Calibrator B is exhausted. 2. Bubbles exist in calibrator tube B 3. Pump tube A is aging, blocked, or broken. 4. Waste pump tube is aging, blocked, or broken; 5. Sample injection port and fluidic path are blocked or leaking. 6. Air bubble detector failed.	1. Replace the reagent pack with a new one 2. Perform purge B to remove bubbles 3. /4. Replace the pump tube 5. Clean the sample injection port and reinstall electrodes. 6. Replace the bubble detector.
PUGB	Calibration related	Air in calibrator B	1. Calibrator B is exhausted. 2. Bubbles exist in calibrator tube B 3. Pump tube A is aging, blocked, or broken. 4. Waste pump tube is aging, blocked, or broken; 5. Sample injection port and fluidic path are blocked or leaking. 6. Air bubble detector failed.	1. Replace the reagent pack with a new one 2. Perform purge B to remove bubbles 3. /4. Replace the pump tube 5. Clean the sample injection port and reinstall electrodes. 6. Replace the bubble detector.
PRO	Result related	Prozone check error	Antibody excess occurs due to too high sample concentration.	Check the reaction curve and the prozone check parameters. Rerun the test with diluted sample.
R	Result related	Rerun result	The result is obtained by rerunning the test.	No actions are required.
R4S	Result related	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.
RBK	Result related	R1 blank absorbance out of range	The reagent goes wrong; the cuvette is not clear; the reaction cuvette is overflowed; or insufficient reagent is dispensed.	Check if the cuvette is clear and not overflowed, the reagent is sufficient without air bubbles, and the chemistry parameters are reasonable. If yes, replace the reagent and then rerun the test.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
RCE	Result related	Response calculation error	Absorbance data for calculation is incomplete, or the dividend is 0.	Rerun the test. If the error remains, contact our customer service department.
REC	Result related	Recalculated result	The sample result is recalculated manually with the latest calibration factors.	/
REE	Result related	The sample result is compensated.	The sample result is compensated.	/
RESP	Result related	ISE response check code error Command format or execution error	1. ISE communication cable failure. 2. Communication interface or pins failure 3. Main control board of the ISE module goes wrong. 4. Software error.	1. Replace the ISE communication cable 2. Replace the interface or pins. 3. Replace the main control board of the ISE module. 4. Upgrade the operating software or reinstall it.
RESP	Calibration related	ISE response check code error Command format or execution error	1. ISE communication cable failure. 2. Communication interface or pins failure 3. Main control board of the ISE module goes wrong. 4. Software error.	1. Replace the ISE communication cable. 2. Replace the interface or pins. 3. Replace the main control board of the ISE module. 4. Upgrade the operating software or reinstall it
RGTE	Result related	Expired reagent	The result is based on an expired reagent.	Replace the reagent.
RGTL	Result related	Insufficient reagent	The result is based on insufficient reagent.	Replace the reagent.
RGTL	Calibration related	Insufficient reagent	The calibration result is based on insufficient reagent.	Replace the reagent.
RRN	Result related	Response greater than that of the maximum-concentration calibrator	The sample concentration exceeds the high limit of the calibrator concentration.	Rerun the test with diluted sample.
SEN	Calibration related	Calibration sensitivity error	The difference of final response of the maximum and minimum concentration calibrators exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.
SJAM	Result related	Sample probe is clogged	Probe clogging is detected during sampling or the sample probe is clogged during sampling.	Sample treatment.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
SLDR	Calibration related	Electrode slope drift	1. Electrode or reagent pack fails. 2. Electrode is unsteady. 3. New reagent pack is unsteady. 4. Reference electrode has been used for over 66 months. 5. ISE main control board failure. 6. Ambient temperature fluctuates drastically	1. Replace the problematic electrode and reagent pack. 2. New electrode will become steady after 15 minutes since installed. 3. Run a couple of calibrations after installing new reagent pack. 4. Replace the reference electrode. 5. Replace the ISE main control board. 6. Control the ambient temperature to make the fluctuation within +/-4℃.
SLEX	Calibration related	Slope out of range	1. Electrode is not installed correctly. 2. Calibrator expired. 3. Electrode degenerated 4. Bubbles in reference electrode 5. Reference electrode has been used for a long time 6. Electrodes interfered. 7. Module or tubing temperature above 32℃.	1. Reinstall the electrode 2. Replace the calibrator. 3. Replace the problematic electrode and rerun. 4. Remove the electrode and clap on it to eliminate bubbles. Reinstall the electrode and run calibration. 5. Replace reference electrode and rerun. 6. Troubleshoot the electrodes by replacing them in different groups. 7. Monitor temperature, if too high, relocate equipment.
SLP	Result related	Corrected result	The result is adjusted with calculation factors.	No actions are required.
SLP	Result related	The results are produced when the calibration factors instead of the default ones are configured for the second time calibration.	Calibration factors instead of the default ones are configured for the second time calibration.	No actions are required.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
SMPA	Result related	Air in sample	1. Sample is insufficient or contains many bubbles after dispensing. 2. No or insufficient sample has been dispensed into the sample injection port. 3. The electrodes are not properly installed, causing leakage. 4. The waste pump tube is aging or broken.	1. Increase the sample volume. At least 90µl sample should be prepared. 2. Electrode is not installed correctly. Reinstall it. 3. Check the waste tube, and if necessary, replace it.
SMPE	Result related	Expired sample	The sample is expired.	Replace the sample.
SMPL	Result related	Insufficient sample	The sample is insufficient during analysis.	Refill the sample.
SMPL	Calibration related	Insufficient sample	The sample is insufficient during analysis.	Refill the sample.
VDRF	Result related	Electrode voltage drift	1. Electrode or reagent pack fails. 2. Electrode is unsteady. 3. New reagent pack is unsteady. 4. Reference electrode has been used for over 66 months. 5. ISE main control board failure. 6. Ambient temperature fluctuates drastically.	1. Replace the problematic electrode and reagent pack. 2. New electrode will become steady after 15 minutes since installed. 3. Run a couple of calibrations after installing new reagent pack. 4. Replace the reference electrode. 5. Replace the ISE main control board. 6. Control the ambient temperature to make the fluctuation within +/-4℃
VOUT	Result related	Electrode Voltage Overflow	1. Electrode or reagent pack fails. 2. Electrode is unsteady. 3. New reagent pack is unsteady. 4. Reference electrode has been used for over 66 months. 5. ISE main control board failure.	1. Replace the problematic electrode and reagent pack. 2. New electrode will become steady after 15 minutes since installed. 3. Run a couple of calibrations after installing new reagent pack. 4. Replace the reference electrode. 5. Replace the ISE main control board.

Flag	Alarm Type	Description	Probable Causes	Corrective Actions
VOUT	Calibration related	Electrode Voltage Overflow	1. Electrode or reagent pack fails. 2. Electrode is unsteady. 3. New reagent pack is unsteady. 4. Reference electrode has been used for over 66 months. 5. ISE main control board failure.	1. Replace the problematic electrode and reagent pack. 2. New electrode will become steady after 15 minutes since installed. 3. Run a couple of calibrations after installing new reagent pack. 4. Replace the reference electrode. 5. Replace the ISE main control board.
T1	Result related	Reaction disk temperature error	1. The ambient temperature is out of range. 2. The temperature sensor goes wrong. (component error and cable error) 3. The temperature protection switch goes wrong. (component error and cable error) 4. The heater goes wrong. (component error and cable error) 5. PCB error 6. Parameters are lost. 7. Electromagnetic interference exists.	1. Check if the error is accidental. 2. If not, contact our customer service department.
TD	Result related	The photoelectric measurement period is out of range	1.Software error	1. Rerun the operating software. 2. Re-switch on the analyzing unit. 3. If the error remains, contact our customer service department or your local distributor.

12.5 Error Messages and Corrective Actions

Table 12.6 Error messages and corrective actions

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A00006	Instruction error	Error	Equipment configuration cannot be read or saved Error:	/	E2PROM read/write error	Switch off the analyzing unit power and switch on it again. Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.
A01006	Sample probe unit	Error	Sample probe vertical movement error Position: Error: Or Sample probe horizontal movement error Position: Error: Or Sample syringe movement error. Position: Error:	/	Sample probe vertical movement error 1. Sensor status error: The sample probe assembly is probably forced to move vertically. 2. Failed to find the zero position: The sample probe assembly is probably jammed. 3. Collision occurs during operation other than aspirating: The sample probe collides with other object. 4. Collision error: The collision remains. 5. Moving vertically is not allowed in current position: The sample probe moves vertically in an unknown position. 6. Losing step in vertical direction. Sample probe is probably clogged. Sample probe horizontal movement error	Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					1. Sensor status error: The sample probe assembly is probably forced to move horizontally. 2. Failed to find the zero position: The sample probe assembly is obstructed when rotating. 3. Collision occurs during horizontal movement: The sample probe assembly is obstructed when rotating. 4. Moving horizontally is not allowed in current position: The sample probe assembly is probably forced to move vertically. 5. Losing steps in horizontal direction. Sample probe is probably clogged. Sample syringe movement error. 1. Sensor status error: The syringe assembly is probably forced to move. 2. Failed to find the zero position: The syringe assembly is probably jammed. 3. Syringe loses steps when passing the zero position. Syringe assembly is probably jammed.	
A01007	Sample probe unit	Warning	Sample probe collides with an obstacle when aspirating Sample position: Sample ID/bar code: Specific position:	/	1. Collision occurs during aspirating: The sample probe collides with other object.	1. Collision occurs during aspirating: Remove the obstacle, and then recover failure by performing the Home maintenance procedure.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A01021	Sample probe unit	Error	Clog detection board communication error.	/	Clog detection board communication error.	Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A01022	Sample probe unit	Warning	Sample syringe aspirates too much Sample ID/bar code: Position:	/	The aspirate volume is beyond the range of the syringe.	Define the aspirate volume correctly.
A01023	Sample probe unit	Warning	Sample syringe dispenses too much Cuvette No.: Sample ID/bar code: Chemistry:	/	The dispense volume is beyond the range of the syringe.	Define the dispense volume correctly.
A01024	Sample probe unit	Warning	Insufficient sample Sample position: Sample ID/bar code: or Sample probe level detection failed.	/	There is no sample or insufficient sample on the designated position.	1. Check if the sample is sufficient, and then try again. 2. If the error remains, contact our customer service department or your local distributor.
A01027	Sample probe unit	Error	Sample is insufficient or contains air bubbles Position: Sample ID/bar code: or Sample probe level detection failed Position: Sample ID/bar code:	/	There is no sample or insufficient sample on the designated position.	1. Check if the sample is sufficient, and then try again. 2. If the error remains, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A01028	Sample probe unit	Error	Sample probe fails to detect liquid level during cleaning	/	There is no deionized water, or the deionized water is not supplied normally.	1. Check if the water supply is normal. 2. Recover the failure for 3 times. If the error remains, contact our Customer Service Department or your local distributor.
A01029	Sample probe unit	Warning	Sample contains fibrins and clots Position: Sample ID/bar code: or Sample probe clog detection failed. Position: Sample ID/bar code:	/	1. The sample contains clots, or is too thick. 2. The sample probe is clogged.	1. Check that the sample is preprocessed correctly; or check if the sample contains foreign matters such as clot. If it does, change the sample. 2. Clean the sample probe with wash solution. If the problem remains, remove the sample probe and unclog it, and then continue with the measurement.
A01030	Sample probe unit	Error	Sample probe is clogged during cleaning Sample ID/bar code: Position: or Sample probe clog detection failed. Sample ID/bar code: Position:	/	The sample probe is clogged.	1. Clean the sample probe with wash solution. Remove the sample probe and unclog it. 2. If the problem remains, contact the manufacturer.
A01033	Sample probe unit	Warning	Sample probe fails to detect liquid level on reaction carousel when dispensing. Cuvette No.: Sample ID/bar code: Chemistry:	/	There is no reagent or insufficient reagent in the reaction cuvette.	1. Check if R1 volume is sufficient and the reagent bottle is free of air bubbles, and then try again. 2. If the problem remains, contact the manufacturer.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			or Sample probe level detection failed. Cuvette No.: Sample ID/bar code: Chemistry:			
A01036	Sample probe unit	Error	Sample probe level detection board communication error	/	Level detection board communication error	Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A01037	Sample probe unit	Error	Sample probe level detection board self-calibrating failed	/	1. The sample probe is not installed correctly or goes wrong. 2. Level detection board communication error	1. Check if the sample is installed correctly or damaged. 2. Recover the failure. If your attempt fails, contact our customer service department or your local distributor.
A01038	Sample probe unit	Error	Sample probe interior wash is abnormal.	/	When washing the probe, the washing pressure is too low.	1. Check if the sample probe is well installed or damaged. 2. Recover the failure. If your attempt fails, contact our customer service department or your local distributor.
A02006	Reagent probe unit	Error	Reagent probe vertical movement error Position: Error: Or	/	Probe R2 vertical movement error 1. Sensor status error: The Reagent probe assembly is probably forced to move vertically. 2. Failed to find the zero position: The Reagent probe assembly is probably jammed. 3. Collision occurs during operation other than aspirating:	Switch off the analyzing unit power and switch on it again. Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			Reagent probe horizontal movement error Position: Error: Or Reagent syringe movement error Position: Error:		The Reagent probe collides with other object. 4. Collision error: The collision remains. 5. Moving vertically is not allowed in current position: The Reagent probe moves vertically in an unknown position. 6. Losing steps in vertical direction. Reagent probe assembly is probably clogged. Reagent probe horizontal movement error 1. Sensor status error: The Reagent probe assembly is probably forced to move horizontally. 2. Failed to find the zero position: The Reagent probe assembly is obstructed when rotating. 3. Collision occurs during horizontal movement: The probe R1 assembly is obstructed when rotating. 4. Moving horizontally is not allowed in current position: The Reagent probe assembly is probably forced to move vertically. 5. Losing steps in horizontal direction. Reagent probe assembly is probably clogged. Reagent syringe movement error. 1. Sensor status error: The syringe assembly is probably forced to move.	

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					2. Failed to find the zero position: The syringe assembly is probably jammed. 3. Syringe loses steps when passing the zero position. Syringe assembly is probably jammed.	
A02007	Reagent probe unit	Warning	Reagent probe collides with an obstacle when aspirating Reagent position: Specific position:	/	1. Collision occurs during aspirating: The Reagent probe collides with other object.	1. Collision occurs during aspirating: Remove the obstacle and then recover the failure.
A02023	Reagent probe unit	Warning	Insufficient reagent Chemistry: Position: Or Reagent probe level detection failed. Chemistry: Position:	/	There is no reagent or insufficient reagent on the designated position.	1. Check if the reagent is sufficient, and then try again. 2. If the error remains, contact our customer service department or your local distributor.
A02026	Reagent probe unit	Error	Reagent probe fails to detect liquid level during cleaning.	/	There is no deionized water, or the deionized water is not supplied normally.	1. Check if the water supply is normal. 2. If the error remains, contact our customer service department or your local distributor.
A02027	Reagent probe unit	Warning	Water residues exist in the cuvette	/	Water residues exist in the cuvette	Recover failure by performing the Home maintenance procedure. If the error remains, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A02030	Reagent probe unit	Error	Reagent probe level detection board communication error	/	Level detection board communication error	Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A02031	Reagent probe unit	Error	Reagent probe level detection board self-calibrating failed	/	Level detection board communication error	1. Check if the reagent probe is installed correctly and intact. 2. Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A02032	Reagent probe unit	Warning	Reagent is insufficient or contains air bubbles Chemistry: Position:	/	1. Air bubbles exist in the reagent bottle. 2. The reagent bottle does not meet the requirements.	1. Check if the reagent bottle contains air bubbles, and then try again. 2. Check if the reagent bottle meets the requirements. 3. If the error remains, contact our customer service department or your local distributor.
A02033	Reagent probe unit	Warning	Insufficient reagent is dispensed or air bubbles exist. Reagent probe level detection failed	/	The R2 reagent is insufficient, or air bubbles exist in the reagent bottle.	1.Check if the reagent is sufficient and the reagent bottle contains air bubbles, and then try again. 2. If the error remains, contact our customer service department or your local distributor.
A04006	Reagent mixer unit	Error	Mixer vertical movement error Or Mixer horizontal movement error	/	Mixer vertical movement error 1. Sensor status error The reagent mixer assembly is probably forced to move vertically. 2. Failed to find the zero position The reagent mixer assembly is probably jammed.	Switch off the analyzing unit power and switch on it again. Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					3. Moving vertically is not allowed in current position The reagent mixer moves vertically in an unknown position. 4. Losing steps vertically when passing zero position. Mixer assembly is probably jammed. Mixer horizontal movement error 1. Sensor status error The reagent mixer assembly is probably forced to move vertically. 2. Failed to find the zero position The reagent mixer assembly is obstructed when rotating. 3. Moving horizontally is not allowed in current position The Mixer moves vertically in an unknown position. 4. Losing steps horizontally when passing zero position. Mixer assembly is probably jammed.	
A04007	Mixer unit	Error	Sample mixer rotation error	/	The mixer is obstructed by other object or interfered by the reaction cuvette.	Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.
A04008	Mixer unit	Error	Reagent mixer rotation error	/	The mixer is obstructed by other object or interfered by the reaction cuvette.	Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A04009	Mixer unit	Error	Sample and reagent mixer rotation speed is abnormal.	/	The mixer is obstructed by other object or interfered by the reaction cuvette.	Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.
A05016	Reagent mixer unit	Error	Reagent mixer rotation error Rotation speed: Position:	/	The mixer is obstructed by other object or interfered by the reaction cuvette.	Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.
A06006	Reaction carousel unit	Error	Reaction carousel movement error Error:	/	Reaction carousel movement error 1. Failed to find the home position The reaction carousel is obstructed or blocked. 2. The coder missed steps The reaction carousel is obstructed or blocked. 3. The reaction carousel missed steps when moving to the home position. The reaction carousel is obstructed or blocked.	Switch off the analyzing unit power and switch on it again. Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.
A07006	Sample carousel unit	Error	Sample carousel movement error Error:	/	Sample carousel movement error 1. Failed to find the home position The sample carousel is obstructed or blocked. 2. The coder missed steps The sample carousel is obstructed or blocked. 3. The sample carousel missed steps when moving to the home position.	Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					The sample carousel is obstructed or blocked.	
A07009	Sample carousel unit	Error	Sample bar code reader error	/	The sample bar coder reader goes wrong due to system failure.	Recover the failure. If the error still remains, contact our Customer Service Department or your local distributor.
A07010	Sample carousel unit	Warning	Sample bar code error Position:	/	Sample bar coder reader does not work normally due to communication error.	Try again. If your attempt fails, contact our customer service department or your local distributor.
A07011	Sample carousel unit	Error	Sample bar code sending buffer is full	/	Sample bar coder sending buffer is full due to communication error.	Recover the failure or reboot the analyzing unit.
A09006	Reagent carousel unit	Error	Reagent carousel movement error Error:	/	Reagent carousel movement error 1. Failed to find the zero position The reagent carousel is obstructed or blocked. 2. The coder missed steps The reagent carousel is obstructed or blocked. 3. The reagent carousel missed steps when moving to the home position. The reagent carousel is obstructed or blocked.	Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A09011	Reagent carousel unit	Error	Reagent bar code reader does not work normally	/	The reagent bar coder reader goes wrong due to system failure.	Recover the failure. If the error still remains, contact our Customer Service Department or your local distributor.
A09012	Reagent carousel unit	Warning	Reagent bar code error Position:	/	Reagent bar coder sending buffer is full due to communication error.	Try again. If your attempt fails, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A09014	Reagent carousel unit	Error	Reagent bar code sending buffer is full Position:	/	Reagent bar coder reader does not work normally due to communication error.	Recover the failure or reboot the analyzing unit.
A11005	Wash station	Error	Wash station movement error Error:	/	Wash station movement error 1. Sensor status error The wash station assembly is probably forced to move. 2. Failed to find the home position The wash station assembly is obstructed by other object. 3. The wash station collides with an obstacle when moving. The wash station collides with other object, or the wash probes then collide with the reaction carousel.	Switch off the analyzing unit power and switch on it again. Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.
A11012	Wash station	Warning	Water supplying is too slow	/	1. The water unit goes wrong. 2. The water supply valve goes wrong. 3. The low-level floater of the water tank goes wrong. 4. The water supply tube is bent. 5. The outlet filter of the water supply tube is clogged.	1. Check the water unit. 2. Check if the water supply tube is smooth. 3. Check if the water level inside the water tank is low (at the scale of 5L). 4. Check if the error is accidental. 5. If the error is not accidental, contact our customer service department or your local distributor.
A11013	Wash station	Error	Water tank is empty	/	1. The water unit goes wrong. 2. The water supply valve goes wrong. 3. The low-level floater of the water tank goes wrong. 4. The water supply tube is bent. 5. The outlet filter of the water supply tube is clogged.	1. Check the water unit. 2. Check if the water supply tube is smooth. 3. Check if the water level inside the water tank is low (at the scale of 5L). 4. Check if the error is accidental.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						5. If the error is not accidental, contact our customer service department or your local distributor.
A11015	Wash station	Error	Insufficient diluted wash solution	/	1. The diluted wash solution is nearly exhausted. 2. The low-level floater of the diluted wash solution tank goes wrong.	1. Check the floater of the diluted wash solution tank. 2.. Check if the error is accidental. 3. If the error is not accidental, contact our customer service department or your local distributor.
A11019	Wash station	Error	Low concentration waste collector is full	/	1. The low-concentration waste drain tube is bent. 2. The low-concentration waste discharge outlet is too high.	1. Check if the error is accidental. 2. If the error is not accidental, contact our customer service department or your local distributor.
A11020	Wash station	Error	High concentration waste tank is full	/	1. The high concentration waste tank is full 2. The floater of the high concentration waste tank goes wrong.	1. Check the high-concentration waste tank. If it is full, replace the waste tank, close the full tank and dispose of the waste properly. 2. Check if the error is accidental. 3. If the error is not accidental, contact our customer service department or your local distributor.
A11028	Wash station	Error	Water tank floater logic error	/	1. Water tank high level and low level floater go wrong	1. Check if the error is accidental. 2. If the error is not accidental, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A11034	Wash station	Error	Cuvette wash syringe movement error. Error:	/	Cuvette wash syringe movement error. 1) Sensor status is incorrect. The syringe assembly is probably forced to move. 2) Mechanical home position is not found. The syringe assembly is probably jammed. 3) Syringe loses steps when passing the zero position. The syringe assembly is probably jammed.	Recover failure by performing the Home maintenance procedure. If this message appears for 3 times, contact our customer service department or your local distributor.
A12005	Temperature unit	Warning	Reaction carousel temperature is out of range TDISP temperature: TS01: TS02: TS03:(Adjusted temperature ΔT for 3 Pt1000 sensors)	T1	1. The ambient temperature is out of range. 2. The temperature sensor goes wrong. (component error and cable error) 3. The temperature protection switch goes wrong. (component error and cable error) 4. The heater goes wrong. (component error and cable error) 5. PCB error 6. Parameters are lost. 7. Electromagnetic interference exists.	1. Check if the error is accidental. 2. If the error is not accidental, contact our customer service department or your local distributor.
A12006	Temperature unit	Warning	Temperature of wash solution for cleaning cuvettes is out of range Temperature:	/	1. The ambient temperature is out of range. 2. The temperature sensor goes wrong. (component error and cable error) 3. The temperature protection switch goes wrong. (component error and cable error) 4. The heater goes wrong. (component error and cable error) 5. PCB error 6. Parameters are lost. 7. Electromagnetic interference exists.	1. Check the temperature of the deionized water for cleaning the whole unit. 2. Check if the water supply is normal and has the temperature between 15°C-30°C. 3. Check if the error is accidental. 4. If the error is not accidental, contact our customer service department or your local distributor.
A12007	Temperature unit	Warning	Temperature of deionized water for cleaning cuvettes is out of range	/	1. The ambient temperature is out of range. 2. The temperature sensor goes wrong. (component error and cable error)	1. Check the temperature of the deionized water for cleaning the whole unit.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			Temperature:		3. The temperature protection switch goes wrong. (component error and cable error) 4. The heater goes wrong. (component error and cable error) 5. PCB error 6. Parameters are lost. 7. Electromagnetic interference exists.	2. Check if the water supply is normal and has the temperature between 15°C-30°C. 3. Check if the error is accidental. 4. If the error is not accidental, contact our customer service department or your local distributor.
A14011	Reagent refrigeration unit	Warning	Reagent refrigerating fan is abnormal	/	1. The fan is blocked. 2. The fan is damaged. 3. The power supply goes wrong.	1. Check if the error is accidental. 2. If the error is not accidental, contact our customer service department or your local distributor.
A22001	ISE unit	Error	Slope out of range, electrode:	SLEX	1. Electrode installation incorrect. 2. Calibrator expired. 3. Electrode degenerated. 4. Bubbles in reference electrode. 5. Reference electrode has been used for a long time. 6. Electrodes interfered. 7. Module or tubing temperature above 32℃.	1. Reinstall the electrode. 2. Replace the calibrator. 3. Replace the problematic electrode and rerun. 4. Remove the electrode and clap on it to eliminate bubbles. Reinstall the electrode and run calibration. 5. Replace reference electrode and rerun. 6. Troubleshoot the electrodes by replacing them in different groups. 7. Monitor temperature, if too high, relocate equipment.
A22002	ISE unit	Error	Air in sample. Position:	SMPA	1. Sample is insufficient or contain much bubbles after dispensing. 2. No or insufficient sample has been dispensed into the sample injection port. 3. Liquid leakage due to that the electrodes are not properly installed. 4. The waste pump tube is aging or broken.	1.&2. Increase the sample volume. At least 90µl sample should be prepared. 3. Electrode is not installed correctly. Reinstall it. 4. Check the waste tube, and if necessary, replace it.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22004	ISE unit	Error	ISE unit cannot be connected.	/	1. ISE power supply failure. 2. ISE communication cable failure. 3. Communication interface or pins failure. 4. ISE main control board failure.	1. Replace the 24V power supply board. 2. Replace the ISE communication cable. 3. Replace the interface or pins. 4. Replace the ISE main control board.
A22005	ISE unit	Error	ISE unit response error	/	1. ISE communication cable failure. 2. Communication interface or pins failure. 3. ISE main control board failure. 4. Software failure.	1. Replace the ISE communication cable. 2. Replace the interface or pins. 3. Replace the ISE main control board. 4. Upgrade the operating software or reinstall it.
A22006	ISE unit	Error	Purge A and B failed.	/	1. Leaks exist due to improperly-installed electrode or missing O ring. 2. Sample injection port or electrode inside is clogged. 3. Calibrator is exhausted. 4. Prime combinations are not enough. 5. Pump tube is aging, blocked, or broken. 6. Calibrator cannot be dispensed normally due to clogged reagent pack tube.	1. Reinstall the electrode and check for O ring. 2. Use warm water to clean and unclog the sample injection port with fresh water and unclog the electrode tube. Check the reference electrode for crystallized salt. 3. Replace the reagent pack. 4. Increase the prime cycle. 5. Replace the pump tube. 6. Unclog the reagent pack tube with warm water.
A22007	ISE unit	Warning	ISE reagent is going to be exhausted.	/	Calibrator is exhausted.	Replace the reagent pack with a new one.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22008	ISE unit	Error	Voltage overflow, electrode:	VOUT	1. Electrode or reagent pack failed. 2. Electrode is unsteady. 3. New reagent pack is unsteady. 4. Reference electrode has been used for over 6 months. 5. ISE main control board failure.	1. Replace the problematic electrode and reagent pack. 2. New electrode will become steady after 15 minutes since installed. 3. Run a couple of calibrations after installing new reagent pack. 4. Replace the reference electrode. 5. Replace the ISE main control board.
A22009	ISE unit	Error	Electrode slope drift. (during calibration) Or Electrode voltage drift. (during sample analysis) Electrode:	VDRF/ SLDR	1. Electrode or reagent pack failed. 2. Electrode is unsteady. 3. New reagent pack is unsteady. 4. Reference electrode has been used for over 6 months. 5. ISE main control board failure. 6. Ambient temperature fluctuates drastically.	1. Replace the problematic electrode and reagent pack. 2. New electrode will become steady after 15 minutes since installed. 3. Run a couple of calibrations after installing new reagent pack. 4. Replace the reference electrode. 5. Replace the ISE main control board. 6. Control the ambient temperature to make the fluctuation within +/-4℃.
A22010	ISE unit	Error	Voltage noise, electrode:	NOIS	1. Electrode failure. 2. Environment interference. 3. ISE main control board failure. 4. Salt buildup around electrodes or tubes due to fluidic leaks.	1. Replace the electrode. 2. Relocate the instrument. 3. Replace the ISE main control board. 4. Clean the tubes and electrodes.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22011	ISE unit	Error	Air in calibrator B	PUGB	1. Calibrator B is exhausted. 2. Bubbles exist in calibrator tube B. 3. Pump tube B is aging, blocked, or broken. 4. Waste pump tube B is aging, blocked, or broken. 5. Sample injection port and fluidic path are blocked or leaking. 6. Air bubble detector fails.	1. Replace the reagent pack with a new one. 2. Perform purge B to remove bubbles. 3.&4. Replace the pump tube. 5. Clean the sample injection port and reinstall electrodes. 6. Replace the air bubble detector.
A22012	ISE unit	Error	Air in calibrator A	PUGA	1. Calibrator A is exhausted. 2. Bubbles exist in calibrator tube A. 3. Pump tube B is aging, blocked, or broken. 4. Waste pump tube B is aging, blocked, or broken. 5. Sample injection port and fluidic path are blocked or leaking. 6. Air bubble detector fails.	1. Replace the reagent pack with a new one. 2. Perform purge A to remove bubbles. 3.&4. Replace the pump tube. 5. Clean the sample injection port and reinstall electrodes. 6. Replace the air bubble detector.
A22013	ISE unit	Error	ISE pump calibrating failed!	/	1. Pump tube is aging. 2. Sample probe aspiration/dispensing failure.	1. Replace the pump tube. 2. Replace the sample probe.
A22014	ISE unit	Error	Air bubble detector failure	/	1. Air bubble detector board is eroded due to the leaks at the joint of sample injection port and bubble detector. 2. Air bubble detector fails.	Replace the bubble detector.
A22015	ISE unit	Error	Reagent pack chip reading error. Load the reagent pack again.	/	1. Reagent pack is not installed. 2. Reagent pack wand fails.	1. Install reagent pack. 2. Replace the wand.
A22016	ISE unit	Error	Reagent pack chip writing error.	/	1. Reagent pack is not installed. 3. Reagent pack wand fails.	1. Install reagent pack. 3. Replace the wand.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22017	ISE unit	Error	Air in ISE wash solution	/	1. ISE wash solution is insufficient. 2. Waste pump tube B is aging, blocked, or broken. 3. Sample injection port and fluidic path are blocked or leaking. 4. Air bubble detector fails.	1. Place sufficient ISE wash solution. 2. Replace the pump tube. 3. Clean the sample injection port and reinstall electrodes. 4. Replace the air bubble detector.
A22018	ISE unit	Error	No fluid in tubing	CALF	1. Waste pump tube B is aging, blocked, or broken. 2. Sample injection port and fluidic path are blocked or leaking. 3. Air bubble detector fails.	1. Place sufficient ISE wash solution. 2. Replace the pump tube. 3. Clean the sample injection port and reinstall electrodes. 4. Replace the air bubble detector.
A22019	ISE unit	Error	Saving calibration result error	DEP	1. ISE communication cable failure. 2. Communication interface or pins failure. 3. ISE main control board failure. 4. Software failure.	1. Replace the ISE communication cable. 2. Replace the interface or pins. 3. Replace the ISE main control board. 4. Upgrade the operating software or reinstall it.
A22021	ISE unit	Error	Command format or execution error	RESP	1. ISE communication cable failure. 2. Communication interface or pins failure. 3. ISE main control board failure. 4. Software failure.	1. Replace the ISE communication cable. 2. Replace the interface or pins. 3. Replace the ISE main control board. 5. Upgrade the operating software or reinstall it.
A22022	ISE unit	Error	No fluid in tubing	/	1. Waste pump tube B is aging, blocked, or broken. 2. Sample injection port and fluidic path are blocked or leaking. 3. Air bubble detector fails.	1. Place sufficient ISE wash solution. 2. Replace the pump tube. 3. Clean the sample injection port and reinstall electrodes. 4. Replace the air bubble detector.
A22023	ISE unit	Error	No reagent module has been loaded.	/	1. Reagent pack is not installed. 2. Reagent pack wand fails.	1. Install reagent pack. 2. Replace the wand.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22024	ISE unit	Error	ISE response check code error	RESP	1. The communication wire between ISE and the middle-layer unit goes wrong. 2. Communication interface or pin error. 3.Main control board does not function. 4.Software error	1.Replace the communication wire 2.Change the interface or the pin. 3.Change the main control board. 4.Upgrade the software or reinstall the software.
A22025	/	Error	Equipment cannot be connected Unit:	/	1. The serial port wire is not connected 2. The power supply of the analyzer is off.	1. Check the connection of the serial port wire. 2. Remove and replug in the serial port wire. 3. Check whether the power supply of the analyzer is on. 4. Perform the Home procedure. 5. Reboot the PC and the analyzer. 6. If the error still remains for continuous three times after the above procedures have been performed, please contact our customer service or your local distributor.
A22026	/	Error	Configuring key parameters failed. Unit: %s	/	Key parameters are not configured	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
A22027	/	Error	Fluidic prime failed.	/	Fluidic is not primed.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22028	/	Error	Downloading key parameters failed. Unit:	/	1.Downloading key parameters failed. 2. Reading the parameters from E2ROM failed. 3.Configuring the parameters of the smart module failed.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
A22029	/	Error	Collecting dark current failed.	/	Collecting dark current failed.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
A22032	/	Error	Floater status error: Floater:	/	1. Low level floater status of the water tank is empty. 2. The low level floater status of the diluted wash solution container is empty. 3. The floater status of the low concentration waste container is full. 4. The status of the high concentration waste container is full.	1. Check the water unit and the water supply tubes. 2. Check the floater status of the water tank, diluted wash solution container, , low concentration waste container and external the high concentration waste container 3. Check if the error is accidental. 4. If the error is not accidental, contact our customer service department or your local distributor.
A22034	/	Error	Resetting auto wash syringe failed.	/	Resetting auto wash syringe failed.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
A22036	/	Error	Initializing sample bar code reader failed.	/	Sample bar code reader failed due to system error.	1. Recover failure by performing the Home maintenance procedure.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						2. If this error remains contact our customer service department or your local distributor.
A22037	/	Error	Initializing reagent bar code reader failed.	/	Reagent bar code reader failed due to system error.	1. Recover failure by performing the Home maintenance procedure. 2. If this error remains contact our customer service department or your local distributor.
A22038	/	Error	Scanning reagent bar code failed.	/	Scanning reagent bar code failed.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
A22039	/	Error	Unmatched software version.	/	1.Version inquiry instruction failed. 2. The version information of the control software does not match the one stored in the operating software.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
A22040	/	Error	ISE response timeout	/	ISE calculating test result is time out.	1. Recover failure by performing the Home maintenance procedure or check ISE pump. 2.If pump check failed, clean the tubes and check again. 3. Change the pump tube. 4. If this error remains contact our customer service .department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22041	/	Error	Sample probe cleaning failed	/	Sample probe collides at the wash well or no liquid level is detected during cleaning.	1.If the sample probe is bent, replace it. 2. If this error remains contact our customer service department or your local distributor.
A22050	ISE unit	Error	ISE unit cannot be connected.	ISEC.ERR	1. ISE module power supply goes wrong. 2. ISE Communication cable goes wrong. 3. Communication interface or pins go wrong. 4. Main control board of the ISE module goes wrong.	1. Turn off the analyzing unit power and reswitch it on. If the error occurs for continuous three times, please contact our customer service or your local distributor. 2. Replace the ISE module power supply board. 3. Replace the communication cable. 4. Replace the interface or pins. 5. Replace the main control board of the ISE module.
A22051	ISE unit	Warning	ISE timeout	ISEC.NA	Module instruction communication or execution is time out.	Home the system.
A22052	ISE unit	Error	ISE communication error	ISEC.ERR	ISE is time out for 3 consecutive times.	1. Turn off the analyzing unit power and reswitch it on. 2. If the error occurs for continuous three times, please contact our customer service or your local distributor.
A22053	ISE unit	Error	Reagent pack reader error	ISER.ERR	1. RFID card reader electrical interface is in poor contact. 2. RFID card reader goes wrong. 3. ISE main control board goes wrong.	1. Replug the RFID communication cable. 2. Replace the RFID card reader assembly. 3. Replace the ISE main control board.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22054	ISE unit	Error	Reagent pack registration failure	ISER.ERR	RFID card is damaged.	1. Remove and insert the reagent pack. 2. Replace the reagent pack with a new one.
A22055	ISE unit	Error	Reagent pack not registered	ISER.ERR	1. Reagent pack is not registered. 2. RFID card is damaged.	1. Remove and insert the reagent pack. 2. Replace the reagent pack with a new one.
A22056	ISE unit	Error	Reagent pack status is abnormal. Reagent pack is removed when the system is in the initialization, testing or maintenance status.	ISER.ERR	Reagent pack is removed when the system is in the initialization, testing or maintenance status.	Load the reagent pack.
A22057	ISE unit	Warning	Electrode response voltage too low	ISEE.NA	1. The electrode is degenerated. 2. Liquid in the electrode does not touch the electrode lead. 3. Reference electrode failed.	1. Speical wash ISE tubes, adjust Na electrode slope and then try again. 2. Replace the electrode filled with insufficient liquid. 3. Replace the reference electrode.
A22058	ISE unit	Error	Electrode response voltage too low	ISEE.ERR	1. The electrode is degenerated. 2. Liquid in the electrode does not touch the electrode lead. 3. Reference electrode failed.	1. Speical wash ISE tubes, adjust Na electrode slope and then try again. 2. Replace the electrode filled with insufficient liquid. 3. Replace the reference electrode.
A22059	ISE unit	Warning	Liquid level is detected before ISE dispensing.	ISES.NA	1. Sample cup interior is contaminated. 2. W pump tube is reversly installed and ISE sample cup overflow occurs.	1. Clean ISE sample cup. 2. Check if tubes are properly connected. 3. Check if tubes are clogged and if waste tubes are emptied.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					3. Tube is clogged. Sample cup overflow occurs. 4. Sample cup dispensing position is too close to the cup wall.	4. Contact our customer service department or your local distributor to readjust the sample probe's dispensing position.
A22060	ISE unit	Error	Liquid level is detected before ISE dispensing.	ISES. ERR	1. Sample cup interior is contaminated. 2. W pump tube is reversly installed and ISE sample cup overflow occurs. 3. Tube is clogged. Sample cup overflow occurs. 4. Sample cup dispensing position is too close to the cup wall.	1. Clean ISE sample cup. 2. Check if tubes are properly connected. 3. Check if tubes are clogged and if waste tubes are emptied. 4. Contact our customer service department or your local distributor to readjust the sample probe's dispensing position.
A22061	ISE unit	Warning	ISE sample contains air bubbles.	ISES.NA	1. Peristaltic pump tubes are wrongly installed. 2. Electrode is not properly sealed or tubes are contaminated. 3. Bubble detector goes wrong. 4. Sample is insufficient or contains air bubbles. 5. Sample probe alignment position is incorrect.	1. Check if the peristaltic pump tubes are correctly installed. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened to clean the ISE tubes. 3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Check if sample is sufficient. 5. Readjust the position of the sample probe.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22062	ISE unit	Error	ISE sample contains air bubbles.	ISES. ERR	1. Peristaltic pump tubes are wrongly installed. 2. Electrode is not properly sealed or tubes are contaminated. 3. Bubble detector goes wrong. 4. Sample is insufficient or contains air bubbles. 5. Sample probe alignment position is incorrect.	1. Check if the peristaltic pump tubes are correctly installed. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened to clean the ISE tubes. 3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Check if sample is sufficient. 5. Readjust the position of the sample probe.
A22063	ISE unit	Warning	ISE sample insufficient	ISES.NA	1. Sample is insufficient. 2. Electrode is not properly sealed. 3. Bubble detector goes wrong. 4. Sample probe alignment position is incorrect.	1. Check if sample is sufficient. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened. 3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Readjust the position of the sample probe.
A22064	ISE unit	Error	ISE sample insufficient	ISES. ERR	1. Sample is insufficient. 2. Electrode is not properly sealed. 3. Bubble detector goes wrong. 4. Sample probe alignment position is incorrect.	1. Check if sample is sufficient. 2. Check if the black washer on the side of the electrode is missing, and if the locking knob is tightened.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						3. Check whether the calibrator tubes A and B are filled and then calibrate three times. If the bubble detector calibration fails after several times, replace it. 4. Readjust the position of the sample probe.
A22065	ISE unit	Warning	ISE sample excessive	ISES.NA	1. Peristaltic pump tubes are aging. 2. Tubes are clogged.	1. Recalibrate ISE electrode. 2. Check and empty the waste tubes.
A22066	ISE unit	Error	ISE sample excessive	ISES. ERR	1. Peristaltic pump tubes are aging. 2. Tubes are clogged.	1. Recalibrate ISE electrode. 2. Check and empty the waste tubes.
A22067	ISE unit	Warning	ISE reagent purge A contains air.	ISER.NA	1. Calibrator tube A is not filled. 2. A pump tube is incorrectly installed. 3. Tubes are clogged.	1. Remove and insert the reagent pack when the system status is Standby or Stopped. 2. Check pump tubes. 3. Empty waste tubes.
A22068	ISE unit	Error	ISE reagent purge A contains air.	ISER.ERR	1. Calibrator tube A is not filled. 2. A pump tube is incorrectly installed. 3. Tubes are clogged.	1. Remove and insert the reagent pack when the system status is Standby or Stopped. 2. Check pump tubes. 3. Empty waste tubes.
A22069	ISE unit	Warning	ISE electrode using time exceeds the allowable limit. Electrode: Na/K/Cl/Ref	ISEE.Exp	ISE electrode using time exceeds the allowable limit.	Replace the failed electrode.
A22070	ISE unit	Warning	ISE electrode test number exceeds the allowable limit. Electrode: Na/K/Cl/Ref	ISEE.Exp	ISE electrode test number exceeds the allowable limit.	Replace the failed electrode.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22072	ISE unit	Warning	ISE reagent expired	ISER.Exp	ISE reagent is expired.	Replace the reagent pack with a new one.
A22073	ISE unit	Warning	ISE reagent is used beyond the on-board stability time.	ISER.Exp	ISE reagent is used beyond the on-board stability time.	Replace the reagent pack with a new one.
A22074	ISE unit	Warning	ISE reagent insufficient	/	The remaing volume of ISE reagent is insufficient.	Replace the electrode with a new one.
A22075	ISE unit	Error	ISE reagent exhausted	ISER.NA	ISE reagent is exhausted.	1. Remove and insert the reagent pack when the system status is Standby or Stopped. 2. Replace the reagent pack with a new one.
A22076	ISE unit	Warning	ISE calibration and air bubble detector calibration failed.	/	1. Calibrator tubes A and B are not filled. 2. Bubble detector goes wrong,	1. Remove and insert the reagent pack when the system status is Standby or Stopped. 2. After filling the calibrator tubes A and B, check if the electrodes of the peristaltic pump are correctly installed. If three continuous calibrations fail, contact our customer service department or your local distributor.
A22077	ISE unit	Warning	ISE calibration failed. Peristaltic pump calibration goes wrong. Pump No.: A/B/W	/	1. Calibrator tubes A and B are not filled. 2. Peristaltic pump tubes are aging.	1. Remove and insert the reagent pack while the system status is Standby or Stopped, and perform multiple calibrations. 2. Replace the pump tubes.
A22078	ISE unit	Warning	ISE calibration failed. Tube contamination calibration goes wrong. Chemistry: K/Na/Cl	/	ISE electrode tubes are contaminated.	Special wash ISE tubes, adjust slope for Na electrode and then try again.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A22079	ISE unit	Warning	ISE calibration failed. Electrode slope is unstable. Chemistry: K/Na/Cl	/	1. The electrode is unsteady. 2. The electrode is degenerated.	1. Special wash ISE tubes, adjust slope for Na electrode and then try again. 2. Initialize electrode priming and then recalibrate. 3. Replace the failed electrode.
A22080	ISE unit	Warning	ISE calibration failed. Electrode slope is out of reference range. Chemistry: K/Na/Cl	/	1. The electrode is degenerated. 2. The electrode is unsteady.	1. Special wash ISE tubes, adjust slope for Na electrode and then try again. 2. Initialize electrode priming and then recalibrate. 3. Replace the failed electrode.
A22081	ISE unit	Warning	ISE calibration failed. Electrode response voltage is too low.	/	1. The electrode is degenerated. 2. The electrode is unsteady. 3. Reference electrode failed,	1. Special wash ISE tubes, adjust slope for Na electrode and then try again. 2. Replace the electrode with insufficient liquid inside. 3. Replace the reference electrode.
A22083	ISE unit	Error	The ISE program version does not match.		The ISE program version and the operating software version do not match.	Upgrade the ISE program.
A22084	ISE unit	Warning	Electrode voltage noise	ISEE.NA	Electromagnetic interference exists.	If the error occurs continuously, power off and reboot the instrument, or contact our Customer Service Department or your local distributor.
C00007	Operating system	Warning	CPU performance low	/	The CPU is too busy.	Reboot the computer and operating software. If this message appears for 3 times, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C00011	Operating system	Warning	The last abnormal exit may cause carryover not handled. Execute the Special Wash maintenance command before starting analysis to ensure accurate results.	/	The operating software is abnormal, or the instrument power is cut off unexpectedly.	Restart the operating software, and execute the Special Wash maintenance command before starting analysis.
C00012	Operating system	Warning	Sound card failure	/	No sound card is installed. Sound card failure. Incorrect sound card driver.	Reinstall the sound card or the sound card driver.
C01001	Instrument connection	Error	Equipment cannot be connected	/	The serial cable is not connected; or the analyzing unit power is switched off.	Check the serial port connection. Replug the cable. Check if the analyzing unit is powered on. Start the initialization again. Restart the computer and analyzing unit. If three continuous attempts are failed, contact our customer service department or your local distributor.
C02001	Database	Error	Database initialing failed	/	The database file is damaged or lost.	Reboot the computer and analyzing unit. If three continuous attempts are failed, contact our customer service department or your local distributor.
C02002	Database	Error	Database upgrade failed	/	The database file is damaged or lost.	Reboot the computer and analyzing unit. If three continuous attempts are failed, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C02004	Database	Warning	Database backup failed	/	The database file is damaged or lost.	Reboot the computer and analyzing unit. If three continuous attempts are failed, contact our customer service department or your local distributor.
C02005	Database	Warning	Reading/Writing database failed	/	The database does not work normally.	Reboot the computer and analyzing unit. If three continuous attempts are failed, contact our customer service department or your local distributor.
C03001	Result calculation	Warning	Result cannot be calculated Sample ID/bar code: Position: Chemistry:	RCE	Absorbance data for calculation is incomplete, or the dividend is 0.	Rerun the test. If the error remains, contact our customer service department or your local distributor.
C03002	Result calculation	Warning	Absorbance out of range Sample ID/bar code: Position: Chemistry:	ABS	1. Probe R1 dispenses insufficient reagent, or air bubbles exist in the reagent. 2. The reagent is placed in an incorrect position or is abnormal. 3. The sample concentration is too high, resulting in great response. 4. The absorbance data used for calculation is incomplete (due to photoelectric data loss), or the error of division by zero occurs.	1. Observe the reaction curve. If the absorbance of R1 is too high, check the reagent for air bubbles and the syringe for leaking. 2. Check if the reagent has been placed in the correct position. 3. Rerun the test after dilution. 4. Contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C03003	Result calculation	Warning	R1 blank absorbance out of range Sample ID/bar code: Position: Chemistry:	RBK	The reagent goes wrong; the cuvette is not clear; the reaction cuvette is overflowed; or insufficient reagent is dispensed.	Check if the reagent is sufficient without air bubbles and the chemistry parameters are reasonable. If yes, replace the reagent and then rerun the test. Check if the cuvette is normal. If the error remains, contact our customer service department or your local distributor.
C03004	Result calculation	Warning	Substrate depletion Sample ID/bar code: Position: Chemistry:	BOE	The sample concentration is too high, and substrate depletion occurs during fixed-time measurements.	Check the reaction curve and the substrate depletion limit. Rerun the test with diluted sample.
C03005	Result calculation	Warning	Result cannot be calculated Sample ID/bar code: Position: Chemistry:	ENC	The sample concentration is too high, and substrate depletion occurs within the lag time of rate check measurements.	Check the reaction curve and the substrate depletion limit. Rerun the test with diluted sample.
C03006	Result calculation	Warning	Linearity limit out of range Sample ID/bar code: Position: Chemistry:	LIN	The measuring points for result calculation are nonlinear, because the sample concentration is too high, or the substrate depletion limit is not specified or unreasonable.	Check the reaction curve and the substrate depletion limit. Rerun the test with diluted sample.
C03007	Result calculation	Warning	Prozone check error Sample ID/bar code: Position: Chemistry:	PRO	Antibody excess occurs due to too high sample concentration.	Check the reaction curve and the prozone check parameters. Rerun the test with diluted sample.
C03008	Result calculation	Warning	Sample concentration is higher than that of the highest-level calibrator Sample ID/bar code:	RRN	The sample concentration exceeds the high limit of the calibrator concentration.	Rerun the test with diluted sample.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			Position: Chemistry:			
C03009	Result calculation	Warning	Mixed blank absorbance out of range Chemistry:	MBK	The reagent goes wrong; the cuvette is not clear; the reaction cuvette is overflowed; or insufficient reagent is dispensed.	Check if the reagent is sufficient without air bubbles and the chemistry parameters are reasonable. Check if the cuvette is normal. Replace the reagent and then rerun the test. If the error remains, contact our customer service department or your local distributor.
C03010	Result calculation	Warning	Blank response out of range Chemistry:	BLK	The reagent goes wrong; insufficient reagent is dispensed; the cuvette contains air bubbles; the light drifts; or the cuvette is overflowed.	Check if the reagent is sufficient without air bubbles and the chemistry parameters are reasonable. Check if the cuvette is normal. Replace the reagent and then rerun the test. If the error remains, contact our customer service department or your local distributor.
C03011	Result calculation	Warning	Calibration repeatability exceeds limit. Chem:	DUP	The difference between the maximum and minimum response of the calibrator exceeds the specified limit.	Check if the acceptance limit is reasonable, troubleshoot the error, and then recalibrate.
C03012	Result calculation	Warning	Calibration sensitivity exceeds limit. Chem:	SEN	The difference of final response of the maximum and minimum concentration calibrators exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.
C03013	Result calculation	Warning	Calibration curve SD exceeds limit, Chem:	CSD	The calculated standard deviation of the calibration curve exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C03014	Result calculation	Warning	Calibration determination coefficient exceeds limit, Chem:	DET	The calculated determination coefficient of the calibration curve exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.
C03015	Result calculation	Warning	Calibration slope difference out of range. Chem:	FAC	The slope difference is applicable to linear calibration only and refers to the K factor (slope) difference between two adjacent calibrations. It exceeds the specified limit.	Check if the acceptance limit is reasonable and the reagent and calibrator are normal, and then recalibrate.
C03016	Result calculation	Warning	Calibration curve is not monotonic, Chem:	MON	The calibration data and calibration curve are not monotonic.	Check if the calibrator is defined and placed correctly, and then recalibrate.
C03017	Result calculation	Warning	Calibration curve is not convergent, Chem:	COV	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 or your local distributor.
C03018	Result calculation	Warning	Chemistry: Control: 1-2s warning	1-2s	The QC result is between ±2 and ±3 standard deviations from the assigned mean concentration.	No actions are required.
C03019	Result calculation	Warning	Chemistry: Control: 1-3s out of control	1-3s	The QC result is greater than ±3 standard deviations from the assigned mean concentration.	Check if the reagent is qualified and control is normal. If the error remains, contact our customer service department or your local distributor.
C03020	Result calculation	Warning	Chemistry: Control: 2-2s out of control	2-2s	Results of two controls or two results of one control within a run are simultaneously greater than +2 or -2 standard deviations from the assigned mean.	Check if the reagent is qualified and control is normal. If the error remains, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C03021	Result calculation	Warning	Chemistry: Control: R-4s out of control	R-4s	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 and control is normal. If the error remains, contact our customer service department or your local distributor.
C03022	Result calculation	Warning	Chemistry: Control: 4-1s out of control	4-1s	Results of two runs in two-control evaluation or four continuous results of a control are greater than +1 or -1 standard deviation from the assigned mean concentration.	Check if the reagent is qualified and control is normal. If the error remains, contact our customer service department or your local distributor.
C03023	Result calculation	Warning	Chemistry: Control: 10-x out of control	10-x	Results of five runs in two-control evaluation or ten continuous results of a control that are being compared are on the same side.	Check if the reagent is qualified and control is normal. If the error remains, contact our customer service department or your local distributor.
C03024	Result calculation	Error	Biochemistry test period time out. Cannot continue	/	1. Software error 2. Operating system error	Rerun the test. Reboot the operating software, analyzing unit and computer. If the error remains, contact our customer service department or your local distributor.
C03026	Result calculation	Warning	Photoelectric data is lost	/	Communication error.	If the error persists, contact our customer service department or your local distributor.
C03027	Result calculation	Warning	Chemistry: Control: 1.0-2.7 out of control	2.7s	Multiple QC data and threshold values or cumulative sum exceed ±2.7SD.	Check if the reagent is qualified and control is normal. If the error remains, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C03028	Result calculation	Warning	Chemistry: Control: 1.0-3.0 out of control	3.0s	Multiple QC data and threshold values or cumulative sum exceed ±3.0SD.	Check if the reagent is qualified and control is normal. If the error remains, contact our customer service department or your local distributor.
C03029	Result calculation	Warning	Chemistry: Control: 0.5-5.1 out of control	5.1s	Multiple QC data and threshold values or cumulative sum exceed ±5.1SD.	Check if the reagent is qualified and control is normal. If the error remains, contact our customer service department or your local distributor.
C03030	Result calculation	Error	Photoelectric measurement period is out of range Sample ID/bar code: Position: Chemistry:	/	1. Software error	1. Rerun the operating software. 2. Reboot the operation unit. 3. If the error remains, contact our customer service department or your local distributor.
C03031	Result calculation	Error	Multiple consecutive photoelectric measurements are time out Sample ID/bar code: Position: Chemistry:	/	1. Software error	1. Rerun the operating software. 2. Reboot the operation unit. 3. If the error remains, contact our customer service department or your local distributor.
C04001	Sample bar code	Warning	Duplicate sample bar code. Sample ID/bar code: Position 1: Position 2:	/	Duplicate bar code is used.	Replace the duplicate sample bar code label.
C04002	Sample bar code	Warning	Bar code has no corresponding programming. Sample ID/bar code:	/	The sample of the bar code has not been programmed.	Program the sample of the bar code.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			Position:			
C04006	Sample bar code	Warning	Sample is expired Sample ID/bar code: Position:	/	The sample is loaded after its shelf life is exceeded.	The sample is expired. Replace the sample and program it again. Reject the expired sample. If the sample shelf life is too short, change it to a reasonable one.
C04008	Sample bar code	Warning	Sample bar code too long. Position:	/	The bar code length is greater than the maximum value of 27 digits.	Redefine the bar code with no more than 27 digits.
C04009	Sample bar code	Warning	Sample bar code is less than 3 digits. position:	/	The sample bar code is too short, less than the minimum range of 3 digits.	Reprint the bar code and ensure it is no less than 3 digits.
C04012	Sample bar code	Warning	Sample bar code analysis error Sample bar code: Position:	/	Barcode information does not conform with the barcode format	Reset the barcode format or reprint the barcode and scan it.
C05001	Reagent bar code	Warning	Duplicate reagent bar code Reagent: Position 1: Position 2:	/	Incorrect reagent or reagent bar code is being used, or an invalid reagent bar code is being used. Bar code is aligned with reagents, and cannot be used again for new reagent when a reagent is exhausted.	Reprint the reagent bar code, or replace the reagent bottle with an invalid bar code.
C05002	Reagent bar code	Warning	Reagent bar code information error. Position:	/	Incorrect reagent bar code is being used, or reagent bar code is not configured reasonably. The reagent bar code contains incomplete or incorrect reagent information, such as expiration date, reagent volume, etc.	Print the new reagent bar code with correct settings and check the bar code against the settings. Replace the reagent bottle, or contact the reagent supplier.
C05003	Reagent bar code	Warning	Reagent bar code analysis error Position:	/	Incorrect reagent bar code is being used, or reagent bar code settings are incorrect. The system fails to extract reagent information from the bar code.	Check the reagent bar code settings, or reprint the reagent bar code against the settings. Contact the reagent supplier.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C05006	Reagent bar code	Error	Wash solution position on reagent carousel is occupied by another reagent Position:	/	Reagent rather than wash solution is placed in the fixed wash solution position (D) on reagent carousel.	Reposition the reagent, or remove it from the fixed reagent position.
C05008	Reagent bar code	Error	Physiological saline position on reagent carousel is occupied by another reagent Position:	/	Reagent rather than physiological saline is placed in the fixed physiological saline position (W) on reagent carousel.	Reposition the reagent, or remove it from the fixed wash solution position.
C06001	Host communication	Error	LIS initialization error	/	Host file is damaged or does not exist.	Reinstall the operating software.
C06002	Host communication	Error	LIS communication parameter error	/	Host parameters error	Re-set or modify the host communication parameters.
C06003	Host communication	Error	LIS communication error	/	Communication error	If the error occurs accidentally, send or receive the instruction again. If the error still remains, contact our customer service department or your local distributor.
C06004	Host communication	Error	LIS host cannot be connected	/	Abnormal network connection or the LIS host is not started.	Check LIS connection and network cable. Check if LIS host and LIS station can start normally.
C06005	Host communication	Warning	Sending sample results failed. Sample ID/bar code: Position:	/	Communication error	If the error occurs accidentally, send or receive the instruction again. If the error still remains, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C06006	Host communication	Warning	Sending sample information failed. Sample ID/bar code: Position:	/	Communication error	If the error occurs accidentally, send or receive the instruction again. If the error still remains, contact our customer service department or your local distributor.
C06007	Host communication	Warning	Inquiring sample information failed. Sample ID/bar code: Position:	/	LIS host failure.	If the error occurs accidentally, neglect it. If the error occurs frequently, contact the manufacturer of LIS or contact our customer service department or your local distributor.
C06008	Host communication	Warning	Downloading sample failed. Sample ID/bar code: Position:	/	Incorrect channel settings or insufficient or redundant chemistries on the LIS host.	Check and re-set the chemistry correspondence between the operating software and the LIS host.
C07003	Light source	Error	Light intensity is too weak	/	1. The lamp is not installed correctly. 2. The cuvette is contaminated. 3. The lamp is aging. 4. The wash station dispenses liquid incorrectly. 5. The photoelectric collection board goes wrong.	1. Check if the lamp is installed correctly. 2. Perform the diluted wash procedure and then the lamp check procedure. 3. Replace the lamp. 4. Check if the wash station dispenses liquid with correct volume to reaction cuvettes. 5. If your attempt fails, contact our customer service department or your local distributor.
C07004	Light source	Warning	Cuvette blank out of range Cuvette No.:	/	1. The cuvette is contaminated. 2. The lamp is aging. 3. The lamp is not installed correctly. 4. The wash station dispenses liquid incorrectly.	1. Open the reaction carousel and check if the lamp is turned on. If it is not, rerun the operating software.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					5. The photoelectric collection board goes wrong.	2. Check if the lamp is installed correctly. 3. Perform the diluted wash procedure and then the cuvette check procedure. 4. Replace or clean the failed cuvette. 5. Replace the lamp. 6. Check if the wash station dispenses liquid with correct volume to reaction cuvettes. 7. If your attempt fails, contact our customer service department or your local distributor.
C07005	Light source	Error	Lamp is not turned on	/	1. The lamp is damaged. 2. The lamp cable is not connected properly. 3. The power board of the lamp is not connected properly. 4. The power supply of the analyzing unit is disconnected. 5. The photoelectric collection board goes wrong.	1. Open the reaction carousel and check if the lamp is turned on. If it is not, rerun the operating software. 2. Check if the lamp cable is tightened. 3. Replace the lamp. 4. If your attempt fails, contact our customer service department or your local distributor.
C07006	Light source	Error	Light intensity is too strong	/	1. A cuvette position has no cuvette installed. 2. The circuit gain is too high and beyond the measurement range.	1. Check if all cuvette positions have cuvettes installed. 2. Contact our customer service department or your local distributor to adjust the gain.
C07007	Light source	Error	Dark current is too high Channel: AD:	/	1. The circuit gain is too high and beyond the measurement range. 2. The photoelectric collection board goes wrong.	If three continuous attempts are failed, contact our customer service department or your local distributor.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C07008	Light source	Warning	Lamp has exceeded its life span. Replace it immediately.	/	1. The lamp has been used for over 2000 hours. 2. The lamp has been replaced incorrectly.	1. Replace the lamp. 2. Perform the **Replace Lamp** maintenance procedure again.
C07009	Light source	Error	Water blank out of range (10X)	L!	1. The cuvette wash station is overflowing. 2. The lamp has been replaced incorrectly. 3. Cuvette check is not performed after maintenance. 4. The cable connectors are not tightened. 5. The retaining screw is not tightened. 6. The wash station dispenses insufficient fluid. 7. The lamp is aged. 8. The photometer goes wrong.	1. Check if the cuvette is overflowing. 2. Check if the **Replace Lamp** command is executed during lamp replacement. 3. Check if the **Cuvette Check** command is executed after maintenance. 4. Check if the cleaning liquid inside the cuvette is no less than half of the cuvette. 5. Check if the cable connectors and retaining screw of the lamp have been tightened. 6. Check if the reaction curve fluctuates irregularly. If yes, replace the lamp. 7. If the error remains, contact our customer service department.
C07010	Light source	Error	Reagent blank abnormal (10X)	RG!	1. The cuvette wash station is overflowing. 2. The reagent is abnormal. 3. The cuvette is dirty.	1. Remove the cuvette and check if the cuvette is overflowing. Dry the cuvette. 2. If the alarm occurs to just one reagent, request the test again. 3. Perform the special wash procedure.
C07012	Other error of operation unit	Warning	Storage device error. Cannot import data	/	No U disk is inserted. No file is found in the U disk, or file error, or file is damaged. The U disk is locked or damaged.	Check if a U disk is inserted or full. Check if the storage device is damaged.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
C07013	Other error of operation unit	Warning	Storage device error. Cannot export data	/	No U disk is inserted. Insufficient disk space. The U disk is locked or damaged.	Check if a U disk is inserted or full. Check if the storage device is damaged.
C07014	Other error of operation unit	Warning	Reagent exhausted Chemistry: Position:	/	All reagents of the reagent type for the chemistry are less than the minimum limit. All reagents of the type are too little to be detected.	Refill or replace the reagent.
C07016	Other error of operation unit	Warning	Insufficient wash solution Position:	/	Insufficient wash solution on the reagent carousel.	Refill the wash solution on the reagent carousel.
C07017	Other error of operation unit	Warning	Wash solution is exhausted Position:	/	The wash solution on the reagent carousel is exhausted.	Refill the wash solution on the reagent carousel.
C07022	Other error of operation unit	Warning	Less than X tests are left in biochemistry reagent. Chemistry:	/	All reagents of the reagent type for the chemistry are less than the minimum limit. All reagents of the type are too little to be detected.	Refill or replace the reagent.
C07023	Other error of operation unit	Warning	Chemistry: %s, 30 minutes left for next calibration.	/	The calibration factors will be expired.	Recalibrate the chemistries.
C07027	Other error of operation unit	Warning	Calibrator %s has been expired	/	The calibrator is expired.	Replace the calibrator.
C07028	Other error of operation unit	Warning	Chemistry: %s, lot No.: %s, position: %s, has been expired	/	The reagent is expired.	Replace the reagent.
C07029	Other error of operation unit	Warning	Chemistry: %s, lot No.: %s, position: %s, has exceeded the on-board stability time	/	The on-board stability time of the reagent pack is too long.	Replace the reagent.
C07034	Other error of operation unit	Warning	Insufficient physiological saline	/	Insufficient physiological saline.	Refill the physiological saline on the reagent carousel.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			Position:			
C07035	Other error of operation unit	Warning	Physiological saline is exhausted Position:	/	Physiological saline is exhausted.	Refill the physiological saline on the reagent carousel.
C07036	Other	Warning	Chemistry: %s. Calibration factors are expired	/	The calibration factors have been expired.	Recalibrate the chemistry.
C07037	Other	Warning	Reagent bottle number of %s chemistry is changed. Please recalibrate	/	Serial number of the reagent is changed.	Recalibrate the chemistry.
C07038	Other	Warning	Reagent lot number of %s chemistry is changed. Please recalibrate	/	Lot number of the reagent is changed.	Recalibrate the chemistry.
C07039	Other	Warning	Calibration factors of %s chemistry are expired. Recalibrate	/	The calibration factors are expired.	Recalibrate the chemistry.
C07040	Other	Warning	Reagent exhausted Chemistry:	/	1. The reagent is running out. 2. The reagent is too little to be detected.	Refill or replace the reagent.
C07041	Other	Error	ISE reagent is less than %s	/	ISE reagent inventory is below the alarm limit	Check the inventory. If the reagent is insufficient, load the reagent.
C07042	Other	Warning	%s, lot number: %s, position: %s, has been expired	/	One or more special reagents have been expired.	Replace them with new reagents.

13 Operation theories

This chapter gives brief introduction of the operation theories of the instrument, which include:

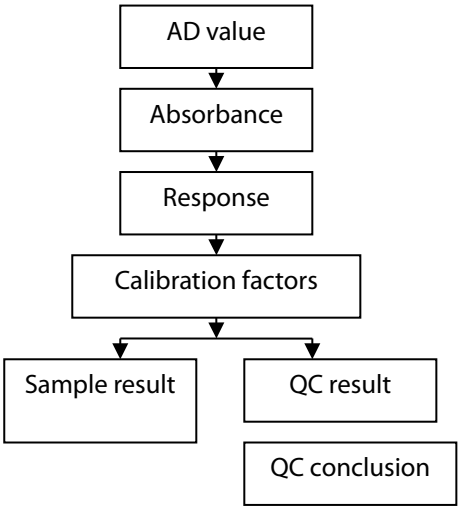
- Principles of biochemistry measurement
- Calibration math model and calculation of factors
- QC determination methods
- Prozone check
- Principles of ISE measurement

13.1 Overview

The system is a fully automated computer-controlled clinical chemistry analyzer allowing the random selection of chemistries. It is capable of running a variety of chemistries 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. $A_i=A_M$.
- 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 A_b is calculated in the same way as the reaction absorbance Ai.

When N=P=0, the blank absorbance A_b 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, V_{R1}, V_{R2}, V_{R3} and V_{R4} are the volumes of R1, R2, R3 and R4; V_s is the actual volume of sample dispensed for reaction.

13.3.5 Calculation of Response

The response in endpoint measurements is calculated as follows:

$$R = A_i - k \cdot A_b$$

k is the calculation factor and varies with the chemistry parameters.

Table 13.1 Calculation of response for endpoint measurements

Endpoint	Blank Time	Reaction Time	K Factor
When the blank absorbance is read before the reaction begins,			
Single-reagent	1≤N≤P≤5	7≤L≤M≤39	K1
Double-reagent	7≤N≤P≤22	23≤L≤M≤39	K2

Endpoint	Blank Time	Reaction Time	K Factor
Triple-reagent	23≤N≤P≤47	53≤L≤M≤86	K3
Quadruple-reagent	53≤N≤P≤68	69≤L≤M≤86	K4
When the blank absorbance is read after the reaction begins,			
Single-reagent	7≤N≤P	P<L≤M≤39	1
Double-reagent	23≤N≤P	P<L≤M≤39	1
Triple-reagent	53≤N≤P	P<L≤M≤86	1
Quadruple-reagent	69≤N≤P	P<L≤M≤86	1
When the blank absorbance is not subtracted,			
Single-reagent	N=P=0	7≤L≤M≤39	0
Double-reagent	N=P=0	23≤L≤M≤39	0
Triple-reagent	N=P=0	53≤L≤M≤86	0
Quadruple-reagent	N=P=0	69≤L≤M≤86	0

13.3.6 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 $Rsb = A_i - k \cdot A_b$, 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 can, however, 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:

$$R = 60 * (\frac{A_M - A_L}{t_M - t_L} - k \cdot \frac{A_P - A_N}{t_P - t_N})$$

k is the calculation factor and varies with the chemistry 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	1≤N<P≤5	7≤L<M≤39	K1
Double-reagent	7≤N<P≤22	23≤L<M≤39	K2
Triple-reagent	23≤N<P≤47	53≤L<M≤86	K3
Quadruple-reagent	53≤N<P≤68	69≤L<M≤86	K4
When the blank absorbance is not subtracted,			
Single-reagent	N=P=0	7≤L<M≤39	0
Double-reagent	N=P=0	23≤L<M≤39	0
Triple-reagent	N=P=0	53≤L<M≤86	0
Quadruple-reagent	N=P=0	69≤L<M≤86	0

13.5 Kinetic Measurements

13.5.1 Introduction

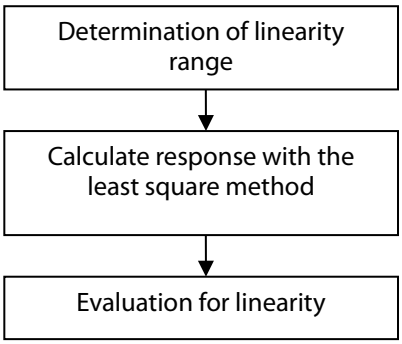
In Kinetic measurements, namely, zero-order Kinetic measurements or continuous-monitoring measurements, the reaction velocity is not related to substrate concentration and remains constant during the reaction process. As a result, the analytes absorbance changes evenly at a given wavelength, and the change rate (ΔA/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

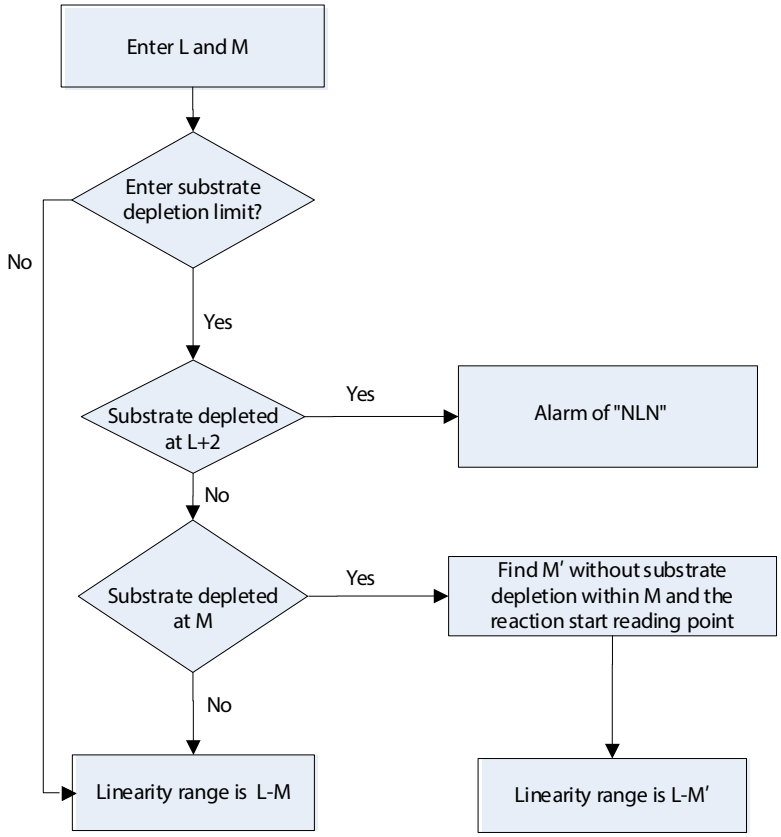
Figure 13.2 Data calculation flow of Kinetic measurements



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 $\Delta A_{LM'}$ 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 ΔA_{NP} within the blank time is calculated with the same equation as $\Delta A_{LM'}$.

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 chemistry parameters.

Table 13.3 Calculation of response for Kinetic measurements

Kinetic	Blank Time	Reaction Time	K
When the blank absorbance is read before the reaction begins,			
Single-reagent	1≤N<P≤5	7≤L<M≤39	K1
Double-reagent	7≤N<P≤22	23≤L<M≤39	K2
Triple-reagent	23≤N<P≤47	53≤L<M≤86	K3
Quadruple-reagent	53≤N<P≤68	69≤L<M≤86	K4
When the blank absorbance is not subtracted,			
Single-reagent	N=P=0	7≤L<M≤39	0
Double-reagent	N=P=0	23≤L<M≤39	0
Triple-reagent	N=P=0	53≤L<M≤86	0
Quadruple-reagent	N=P=0	69≤L<M≤86	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

$$\text{Linearity}=\frac{\left|\Delta A_f-\Delta A_b\right|}{\left|\Delta A_{u,v}\right|}\times 100 < Linearity\ Limit$$

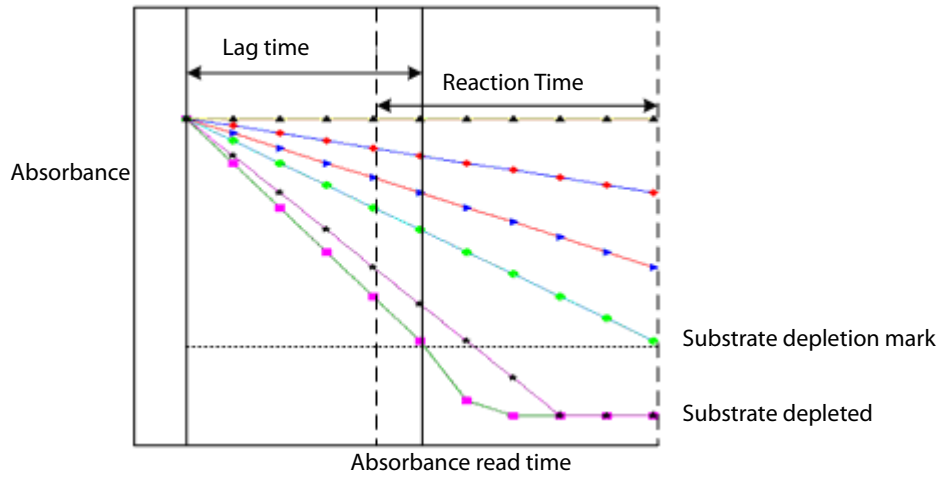
Where, ΔA_f, ΔA_b and $\Delta A_{u,v}$ are the absorbance change rates in the front part, back part and at all measuring points of the reaction. These three values are calculated based on the number of measuring points within the linearity range.

- 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 $4 \le N \le 8$, 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$\le$3, the system will not check the test results for linearity.
- When $\left|\Delta A_f-\Delta A_b\right| \le 60$ or $\left|\Delta A_{u,v}\right| \le 60$ (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 chemistry, 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" and "NLN".

13.6 Calibration Math Model and Factors

The system provides linear and non-linear math models. The former is used for Colorimetry chemistries and the later for turbidity chemistries.

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

13.6.1 Linear Calibrations

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, R_0 is the reagent blank response of the first calibrator. If the chemistry is not reagent blanked, R_0=0.

Two-point linear calibration

Calculation formula: $C = K \times (R - R_0)$

The formula contains two factors, K and R_0, 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. C_1 and C_2 are the concentrations of calibrator 1 and 2; R_1 and R_2 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 R_0. 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 R_0 can be calculated with the least square method:

$$K = \frac{\sum_{i=1}^{n} CiRi - (\sum_{i=1}^{n} Ci)(\sum_{i=1}^{n} Ri)/n}{\sum_{i=1}^{n} Ri^2 - (\sum_{i=1}^{n} Ri)^2/n}$$

$$R_0 = (\sum_{i=1}^{n} Ri)/n - \frac{(\sum_{i=1}^{n} Ci)/n}{K}$$

13.6.2 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 R_0, 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 chemistries 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 R_0, 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 R_0, 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 chemistries 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 R_0, 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 R_0, 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 R_0. 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 3-10 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.

Logit–Log 3P

Calculation formula: $$R = R_0 + K\frac{1}{1+aC}$$

The calibration math model requires 3-10 calibrators. Use L-M method to calculate R_0, K and a.

Line

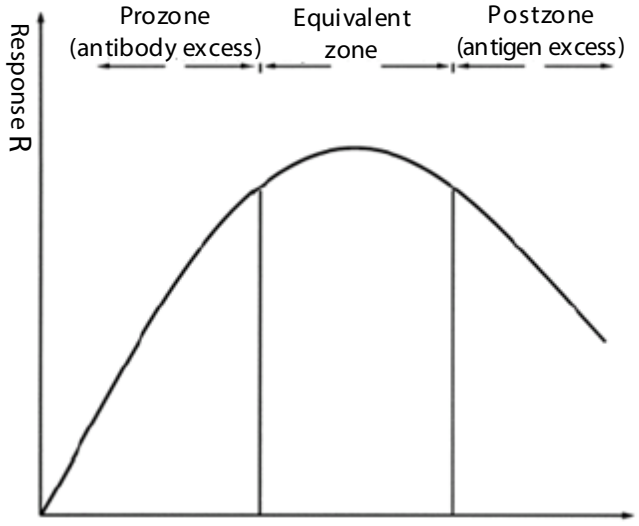
Calculation formula: $$C = K_i \times (R - R_{0i})$$

The calibration math model requires 2-10 calibrators. Suppose the number of calibrators is n, then the calculation formula contains 2(n-1) factors, which are K_i, R_{0i} (i=2…,n).

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:

- PC_M (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:

- PC_M (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.
- 86≥q2≥53, 52≥q1≥Reaction end point.

If one of PC_M, q1 and q2 is not input, the system will not check the antigen.

- Sample PC=A_{q2}-k×A_{q1}.
  - 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<PC_M in positive reactions or PC>PC_M 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:

- PC_M (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>$PC_M$, the system will flag the test result with "PRO" and give an alarm.

Enter the measuring points as follows:

- Single-reagent chemistries: 7≤q1 <q2< q3< q4≤39, "7" is the first measuring point after the sample is dispensed and stirred.
- Double-reagent chemistries: 23≤q1 <q2< q3< q4≤39. "23" is the first measuring point after R2 is dispensed and stirred.
- Triple-reagent chemistries: 53≤q1 <q2< q3< q4≤86. "53" is the first measuring point after R3 is dispensed and stirred.
- Quadruple-reagent chemistries: 69≤q1 <q2< q3< q4≤86. "69" is the first measuring point after R4 is dispensed and stirred.

If one of PC_M, 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.

13.8 Principles of ISE 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 with buffer solution 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 (70 μL for serum sample,140 μL 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: 100 μL calibrator A is dispensed into the ISE module for cleaning the ISE flow cell.
- Single point calibration: 80 μL calibrator is dispensed into the ISE module to perform single point calibration.

Glossary

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.

Analyzing unit

The analyzing unit, the analyzer, determines various clinical chemistries in samples and displays the test results. It consists of the sample/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 chemistry will be run again.

Bar code reader

Fixed laser beam scanner. It scans the bar code label on sample tube and reagent bottle to identify the sample and reagent.

Batch program

Batch program is to program a group of samples with identical programming 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 chemistry'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 chemistry or the reaction of other mixture, resulting in inaccurate results.

Chemistry configuration

Chemistry configuration is applicable to all chemistries other than ISE chemistry and SI, and used to enable or disable chemistries that have been defined correctly.

Closed-reagent chemistry

Closed-reagent chemistry is run by using the reagents provided by the analyzer manufacturer. Closed-reagent chemistries cannot be modified or deleted.

Concentrated wash solution

CD80 alkaline concentrated wash solution, used to clean the reaction cuvettes during 8 phases.

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 chemistry, 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 programmed and analyzed on the current day.

Cuvette wash station

The cuvette wash station consists of the wash probes, elevating motor and related tubing, and is used to clean the reaction cuvettes with the four wash probes when a test is finished.

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 Chemistries** 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 programming information from the LIS host and match it with the scanned samples. The system supports real-time and manual downloading of sample programming information.

Endpoint

The endpoint method, also called equilibrium method, is most ideal for measurements. 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.

Fixed-time

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].

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.

High-concentration waste

High-concentration waste is produced during the phase 1 cuvette wash. It can be drained to the provided high-concentration waste tank and then disposed of according to your local or national regulations.

History results

Stored results are those programmed and analyzed before the current day.

Increased

Increased indicates the sample volume required for analysis and can be defined on the **Define/Edit Chemistries** window.

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.

Inventory check

Used to check the remaining volume of the biochemistry reagents, sample probe wash solution and reagent probe wash solution and refresh the tests left and wash solution volume on the **Reagent/Calibration** screen.

ISE

ISE is the abbreviation of Ion Selective Electrode. It consists of the ISE module, pump module and reagent module, and is used to measure the concentration of Na, K and Cl ions in serum, plasma and diluted urine.

K factor

K factor is manually input for single-point linear calibration formula $C = K \times (R - R_0)$ and used to calculate results.

Lamp

Lamp is located on the photometer assembly and used to measure the absorbance of mixture in a reaction cuvette. It should be replaced regularly.

Linearity

Degree of linearity for a reaction curve or calibration curve. Reaction curve linearity is available in fixed-time measurements, while calibration curve linearity specifies the allowable concentration range for result calculation.

LIS

LIS stands for Laboratory Information System. It is a host computer and communicates with chemistry analyzers 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 chemistry 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.

Low-concentration waste

Low-concentration waste is produced during phase 2-4 cuvette wash and probe/mixer cleaning. It can be drained to the provided low-concentration waste tank or the sewer of your laboratory.

Mask/Unmask chemistries

Used when a chemistry needs to be disabled temporarily due to abnormal result or reagent exhaustion. The masked chemistry 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 chemistries cannot be requested until they are unmasked.

Mixer

The system provides one mixer for stirring the mixture inside a reaction cuvette when sample and R2 are respectively dispensed.

Multi-sample report

Containing the results of multiple samples, and can be printed out on the **Current Results** and **History Results** 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 slope in the equation y=kx+b, in which k is the slope and b is the offset.

Off-system chemistry

All the chemistries that are not run by the analyzer are referred to as the off-system chemistries.

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.
- Select the  button in front of each maintenance instruction or item to display the relevant operating instructions.
- Select the  button in front of each error log to display the corresponding topic.
- Click the  button on a warning message window to display the corresponding descriptions and solutions.
- Press the shortcut combination key Alt+F1 to display the topics related to the current screen or window.

Open-reagent chemistry

Open-reagent chemistry, an opposite of the closed-reagent chemistry, can be measured by using the reagents provided by other manufacturers. It can be user-defined, edited and deleted.

Operation unit

The operation unit, a computer configured with the operating software, controls the analyzing unit to finish tests and produce test results.

Output unit

A printer used to print out test results and other data.

Panel

Consists of a couple of chemistries combined together for certain clinical purposes, such as liver function, kidney function, etc. Panels can help fast programming 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.

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: 340 nm, 405 nm, 450 nm, 510 nm, 546 nm, 578 nm, 630 nm, and 670 nm.

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 chemistry, and if left blank, will be replaced by the short name of the chemistry.

Probe

The probe aspirates the specified amount of sample and reagent and then dispenses it into a cuvette for reaction and analysis.

Probe wash solution

CD80 alkaline concentrated wash solution. It is placed in position DB of the sample/reagent carousel, and used for special cleaning the probe, in order to prevent cross contamination.

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 rate check method is supported.

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.

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 curve

A reaction curve reflects the relationship of the absorbance measured at the primary wavelength, secondary wavelength and primary-secondary wavelength. It is drawn based on the absorbance of the sample-reagent mixture measured within the reaction period. The system provides 4 types of reaction curves: calibration reaction curve, QC reaction curve, sample blank reaction curve, and sample reaction curve.

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 response calculation.

Reaction direction

Reaction direction refers to the change trend of absorbance during the reaction process. It includes positive and negative.

Reaction time

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.

Reagent blank

In the reagent blank test, the reagents react with the physiological saline, and the blank absorbance is calculated to correct the calibration factors. Only the reagents that are in Calibrated status can be requested for reagent blank.

Reagent carryover

Cross contamination between the reagent probe and the mixers. When the number of tests between the contaminating chemistry and the contaminated is less than or equal to the defined number (N), and no concentrated wash is inserted between the two chemistries, it indicates that the reagents underlie the risk of carryover.

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.

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

Used to clear the specified sample position or all positions on the current sample carousel. When a sample is released, its results and programming information can be still recalled. The released position can be used for programming of new samples.

Replicates

Number of times to run a test, to ensure accurate results.

Result statistics

Result statistics option can summarize the total chemistries and the distribution trend of its results and provide the test data and graph.

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/Reagent carousel

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

Sample comments

Remarks for some special samples, such as, ** sample has hemolysis; ** sample needs to be analyzed immediately, etc.

Sample log

Contains the controls and patient samples that are not complete within the recent 24 hours due to certain reasons. Based on the sample log you are allowed to rerun the samples or take other actions for the controls and samples.

Sample panel

Used for analysis of patient samples.

Sample type

Type of sample. The sample type options include serum, plasma, urine, CSF and other.

Page

Page is a part of the software interface. It is rectangular and contains various controls, such as edit box, function button, etc.

Secondary wavelength

The secondary wavelength is used to remove the interference in primary wavelength values and eliminate the influence of noise, such as light flash and drift, and scratches on cuvettes, etc. It cannot be the same as the primary wavelength.

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 chemistries and has specific clinical purposes, such as A/G, TBil-DBil, etc.

Special wash

Special wash is to clean the probe, mixer and reaction cuvettes by using the probe wash solution, with the aim of eliminating carryover and preventing waste from leaving in the waste tubes.

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 program. STAT sample program allows emergent samples to be programmed and analyzed with high priority. Common STAT program is used in daytime to run emergent samples with higher priority than routine samples. Quick STAT program is mainly used in nighttime and weekends to program emergent samples quickly with higher priority than routine and common STAT 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.

Transmit

Transmit is an action sending specified sample results or QC results to the LIS host.

Twin chemistries

Twin chemistries are run with the same reagents and calculated through the same test. For two twin chemistries, the sample volume, volume of shared reagent, calibration replicates, and auto calibration conditions should be the same. When either of the two chemistries is requested for calibration, quality control or sample analysis, the other chemistry will be automatically requested, and finally results of both chemistries will be calculated.

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 chemistry 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.

Wash solution

All wash solution used by the instrument is CD80 alkaline concentrated wash solution. It is used to clean the probe, mixer and reaction cuvettes.

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.

Test statistics

On the Tests screen, you can view test requests and reagent application for each chemistry during a period, and sample requests and the quantity of its chemistries.

Index

Q

R

S

T

U

W

Electronic interface

Description	Serial interface
Interface Standard	RS232 standard communication serial interface. The RXD and TXD signal level meets the RS232 interface standard.
Interface Specifications	The baud rate is 115200bps.
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.
Intended User	Operator and service personnel

Bibliography

1. Burtis C.A., Ashwood E.R. and Bruns D.E. Tietz Fundamentals of Clinical Chemistry. 6th Ed. Saunders/Elseviser, St. Louis, Missouri, 2008, 63-262.

2. Burtis C.A., Ashwood E.R. and Bruns D.E. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 5th Ed., Saunders/Elseviser, St. Louis, Missouri, 2012, 7-59.

3. Gauglitz G. and Vo-Dinh T. Handbook of Spectroscopy. WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim, 2003, 37-162.

4. Gottschalk P.G. and Dunn J.R. The five-parameter logistic: A characterization and comparison with the four-parameter logistic. Analytical Biochemistry, 2005; 343: 54–65.

5. Levey S. and Jennings E.R. The use of control charts in the clinical laboratory. Am J Clin Pathol, 1950; 20: 1059-1066.

6. Madsen K., Nielsen H.B. and Tingleff O. Methods for Non-Linear Least Squares Problems. 2nd Ed., Informatics and Mathematical Modelling, Technical University of Denmark, Lyngby, Denmark, 2004.

7. Westgard J.O. and Barry P.L. Cost-Effective Quality Control: Managing the quality and productivity of analytical processes. AACC Press, Washington DC, 1986.

8. Westgard J.O., Barry P.L., Hunt M.R. and Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem 1981; 27: 493-501.

P/N:046-008998-00(12.0)