BS-240
Chemistry Analyzer

Operator’s Manual

For this Operator's Manual, the issue date is 2016-03.

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- 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.

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- 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.

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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-240 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 up to 400 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.

Terms

The analyzer has one probe for adding sample and reagent. If not specifically stated, it is referred to as "probe". For emphasis purpose in software operations, "sample probe" is used for adding sample, and "reagent probe" is used for adding reagent.

The analyzer has one carousel for holding sample and reagent. If not specifically stated, it is referred to as "sample/reagent carousel". For emphasis purpose in software operations, "sample carousel" is used for sample, and "reagent carousel " is used for reagent.

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.

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/reagent carousel, reaction carousel, 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 10 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 that may cause biohazards(probe, mixer, etc.) and remind the person who handles the device of the related hazards.

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.

Electromagnetic noise precautions

CAUTION

Electromagnetic noise may interfere with operations of the system. Do not install devices generating excessive electromagnetic noise around the system. Do not use such devices as radio transmitters in the room housing the system. Do not use other CRT displays around the system.

Do not use other medical instruments around the system that may generate electromagnetic noise to interfere with their operations.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. mobile phones or radio transmitters), as these may interfere with the proper operation.

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

This device has been designed and tested to CISPR 11 Class A, and in a domestic environment may cause radio interference, in which case, you may need to take measures to mitigate the interference.

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 it will perform as intended.

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.

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.

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.
- 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 sample blank 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.
- Prepare sufficient sample volume before analysis.
- 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.

ISE wash solution biohazards

BIOHAZARD

The ISE wash solution is sodium hypochlorite. Use the ISE wash solution carefully to prevent it from contacting your skins or eyes. If your skins or eyes contact the ISE wash solution, rinse them off with fresh water and consult a doctor.

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.

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.

Non-warning labels and silkscreen

Serial number

This symbol, contained in the product label which is attached to the rear cover of the system, indicates the production serial number of the product.

Date of manufacture

This symbol, contained in the product label which is attached to the rear cover of the system, indicates the manufacture date of the product.

In vitro diagnostic equipment

This symbol, contained in the product label which is attached to the rear cover of the system, indicates that the product is in vitro diagnostic equipment.

European community representative

This symbol, contained in the product label which is attached to the rear cover of the system, indicates the name and address of the authorized representative in the European Community.

WEEE label

The following definition of the WEEE label applies to EU member states only.

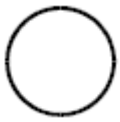
The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.

Main power switch: ON

This symbol located on the main power switch indicates that the system power is on when the switch is toggled rightwards to expose this symbol and ON character and the green light is lightened.

Main power switch: OFF

This symbol located on the main power switch indicates that the system power is off when the switch is toggled leftwards to expose this symbol and OFF character and the green light is extinguished. All components including the reagent refrigeration system will be stopped.

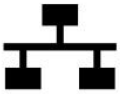


Analyzer power switch

This symbol located on the analyzer power switch indicates that the analyzer power is on when the switch is on the dotted-circle portion and off when it is on the blank-circle portion.

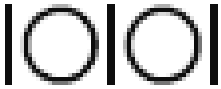
Network interface

This symbol located on the network interface indicates the connection between the analyzer and the operation unit.



Serial port

This symbol located on the serial port indicates the connection between the analyzer and the operation unit.

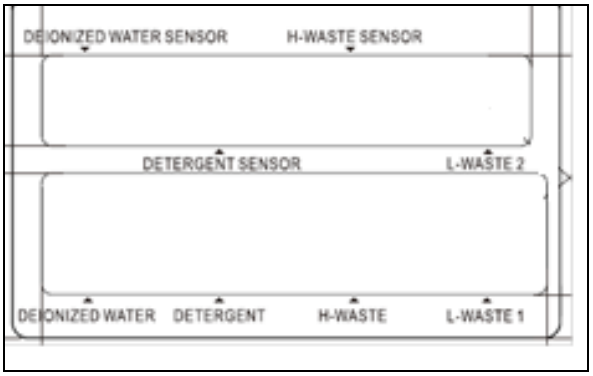


Electrical ground

This symbol indicates an electrical ground.

Interfaces for fluid connection

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



Warning labels

Biohazard warning

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

- Probe
- Waste outlet
- Waste tank

Moving parts warning

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

- 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/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 located on the left side panel of the analyzer. Please turn off the main power before opening the small door.

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.

Cuvette replacement window

This symbol and text is located on the cuvette replacement window.

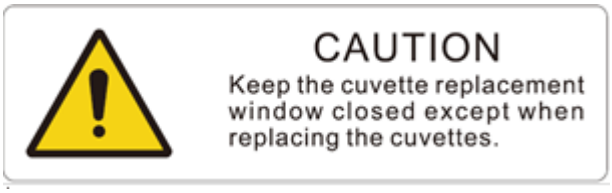


Table of contents

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 should be level (with gradient less than 1/200).
- The bearing platform should be able to support at least 130Kg 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 1.4.2Power supply requirements on page 1-29.

- 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.

The high-/low-concentration waste produced during cuvette wash are drained separately. The high-concentration waste is discharged to the provided 10 L waste tank, and the low-concentration waste is discharged to the provided 15 L waste tank or to a drain outlet.

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.

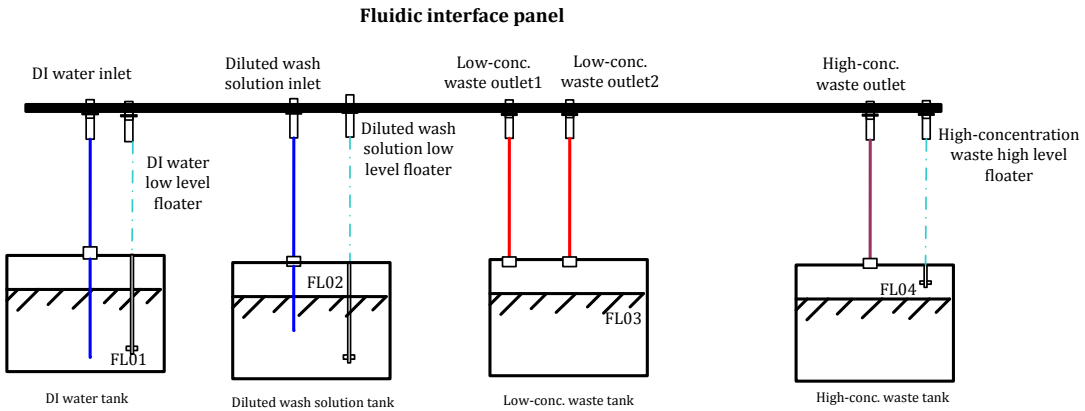
BIOHAZARD

Wear gloves and lab coat, if necessary, goggles.

CAUTION

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

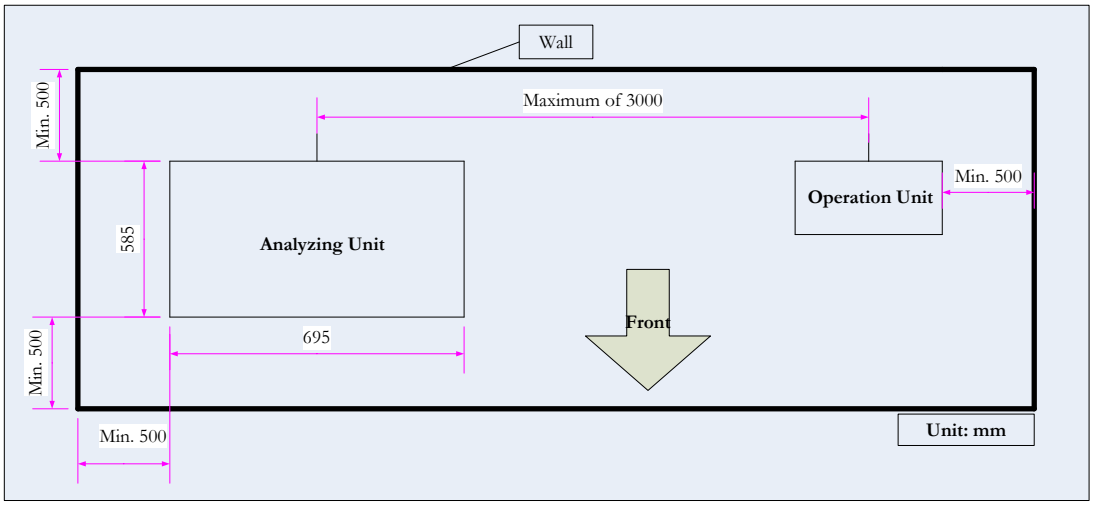
Figure 1.1 Fluidic connection diagram



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 P4 2.6GHz or above
Random access memory (RAM)	At least 2GB or above for each RAM
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.
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.

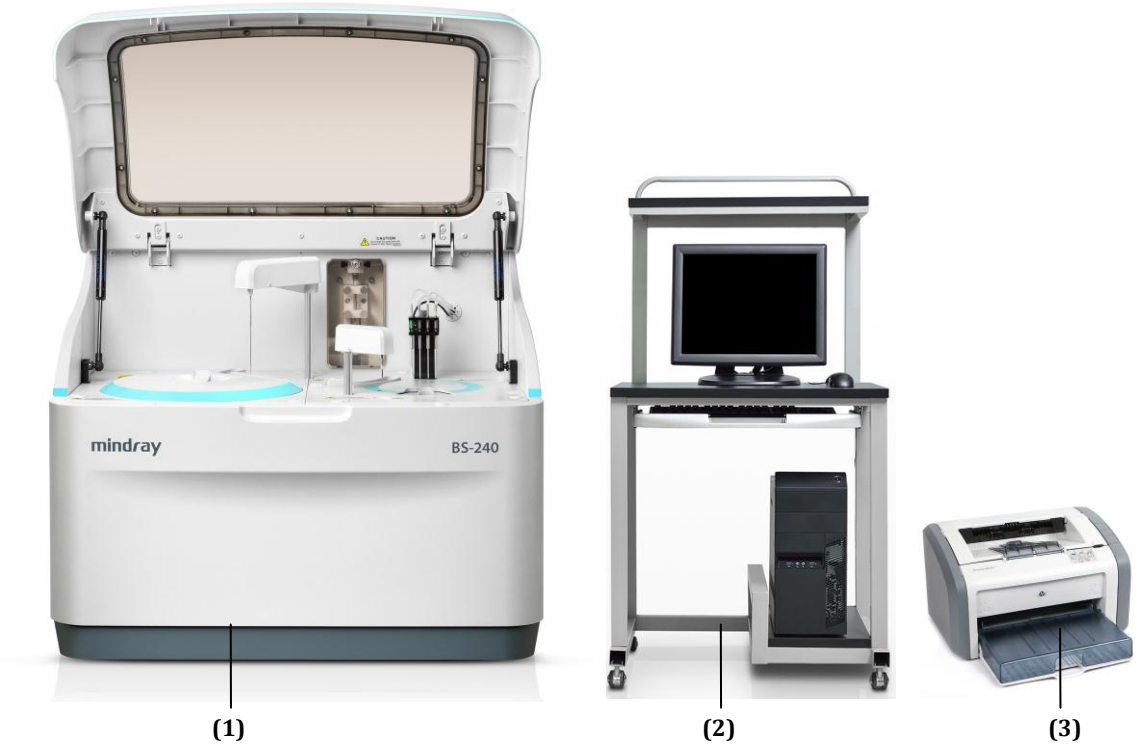
1.2 Hardware components

1.2.1 Overview

The analyzer consists of the following components:

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

Figure 1.3 BS-240 chemistry analyzer



(1) Analyzing unit
(2) Operation unit
(3) Output unit

Analyzing unit

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

- Sample/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/Reagent handling system

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

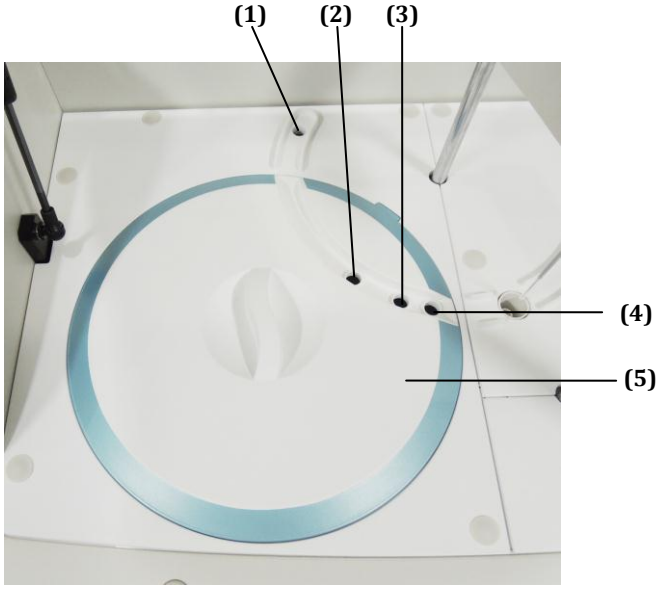
- Sample/Reagent carousel assembly

- Built-in bar code reader (optional)
- Dispenser assembly
- Probe wash assembly

Sample/Reagent carousel assembly

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

Figure 1.4 Sample/Reagent carousel assembly



(1) ISE sample injection port
(2) Aspirate port on inner ring
(3) Aspirate port on middle ring
(4) Aspirate port on outer ring
(5) Sample/Reagent carousel

Carousel positions

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

- Outer ring: No.1-40, can hold 40 samples.
- Middle ring: No.1-40, can hold forty 20 mL reagent bottles, or 40 sample tubes with adapter.
- Inner ring: No.41-80, can hold forty 20 mL reagent bottles, or forty 40 mL reagent bottles after merged with the middle ring.

The following fixed positions are provided for special reagents:

- W for physiological saline
- D for probe wash solution
- D1 for ISE wash solution
- User-defined position for pretreatment reagent

Reagent refrigeration

The sample/reagent carousel provides a refrigerating environment which is constant within 2°C-12°C for 24 hours a day. The reagents stored in such environment can be kept stable with little volatilization.

CAUTION

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

Ensure that the sample/reagent carousel is closed while the system is running tests. Opening the carousel cover during test could result in probe collision or other failures.

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.

Installing/Removing the sample/reagent carousel

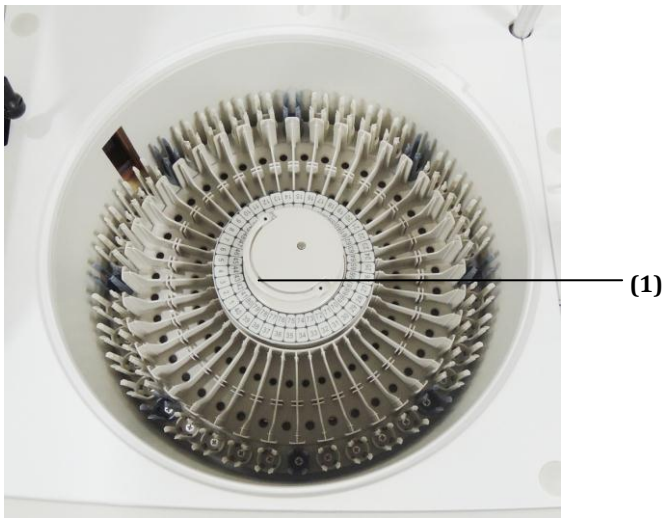
WARNING

Before installing or removing the sample/reagent carousel, make sure that the analyzer is in standby status or is shut down, and the sample/reagent carousel has stopped.

BIOHAZARD

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

Figure 1.5 Sample/Reagent carousel



(1) Handle

Installing the sample/reagent carousel

1. Lift the handle to make it vertical.
2. Align the hole on the hand wheel to the pin on the rotor, and then gently lay the sample/reagent carousel.
3. Move the handle back to the horizontal position to secure the carousel to the rotor.

Removing the sample/reagent carousel

1. Lift the handle to make it vertical.
2. Hold the handle or the hand wheel to take out the sample/reagent carousel.

CAUTION

Make sure the carousel cover is closed; otherwise the refrigeration performance could be degraded and the probe could be damaged.

Before system operation, make sure that the carousel cover is closed properly; otherwise the probe could be damaged.

The sample/reagent compartment and the carousel could be contaminated during measurement. If sample or reagent spills in the compartment or on the carousel, switch off the analyzing unit power, and wipe them with cloth soaked with water or disinfector.

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	Φ 14×25 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.

Reagent bottles

20mL and 40mL reagent bottles are used.

Loading/Unloading sample tube

WARNING

Before installing or removing a sample tube, make sure that the sample/reagent 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.

Loading/Unloading reagent bottle

WARNING

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

Do not use reagent bottles other than the specified.

Some reagents may hurt human skins. Exercise caution when using the reagents. In case your skin or clothes contact them, wash them off with clean water. In case the reagents spill into your eyes, rinse them with much water and consult an oculist.

To load a reagent bottle, insert it into the bottle holder until the bottle bottom contacts the groove of the holder.

To remove a reagent bottle, grab it and pull it upwards to remove from the bottle holder.

Built-in bar code reader (optional)

The bar code reader is provided for optional configuration. It is located on the upper-left corner of the sample/reagent carousel, and used to scan the bar code on sample tube and reagent bottle.

Figure 1.6 Bar code scanning window

(1) 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 bar code reader.

The table below lists the specifications of the bar code reader:

Table 1.3 Specifications of the bar code reader

Symbology	Codabar, ITF, Code128, Code39, UPC/EAN, and Code93
Minimum bar code density	0.19 mm - 0.50 mm
Length	Sample bar code: 3-27 digits Reagent bar code: 13-30 digits
Format and content	User-defined
Maximum width	55mm

Minimum height	Sample bar code: 10 mm Reagent bar code: 12 mm
Maximum inclination angle	±5°
Print quality	No less than Class C according to the *ANSI MH10.8M Print Quality Specification*.
Width and narrowness	Sample bar code: (2.5-3.0):1 Reagent bar code: 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.

Dispenser assembly

The dispenser assembly located at the upper-right corner of the sample/reagent carousel is composed of the probe, probe arm, probe rotor, syringe, wash well, and related fluidic path. It aspirates the specified amount of sample and reagent from a sample tube and a reagent bottle and then dispenses them into a cuvette for reaction.

Figure 1.7 Dispenser assembly

(1) Probe arm
(2) Probe rotor
(3) Probe wash well
(4) Probe

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.

Probe

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

- Biochemistry: 2-45 µL, with increment of 0.1 µL.
- ISE test: 70 µL for serum and plasma, and 140 µL for diluted urine.
- Reagent: 10-250 µL, with increment of 0.5 µL.

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

- **Vertical obstruct detection:** Detects obstacles in the vertical direction. When the probe collides with an obstacle in the vertical direction, the auto guard system is started to prevent the probe from being damaged.
- **Level detection and tracking:** Detects the liquid level in sample tube and reagent bottle and determines the depth of lowering down into the liquid based on the specified aspirate volume.

Probe wash assembly

The probe wash assembly consists of the wash well and related fluidic path. It is responsible for cleaning the probe interior and exterior after the probe adds sample or reagent.

1.2.3 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 1.8 Mixer assembly

(1) Mixer rotor
(2) Mixer wash well
(3) Mixer
(4) Mixer arm

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

1.2.4 Reaction system

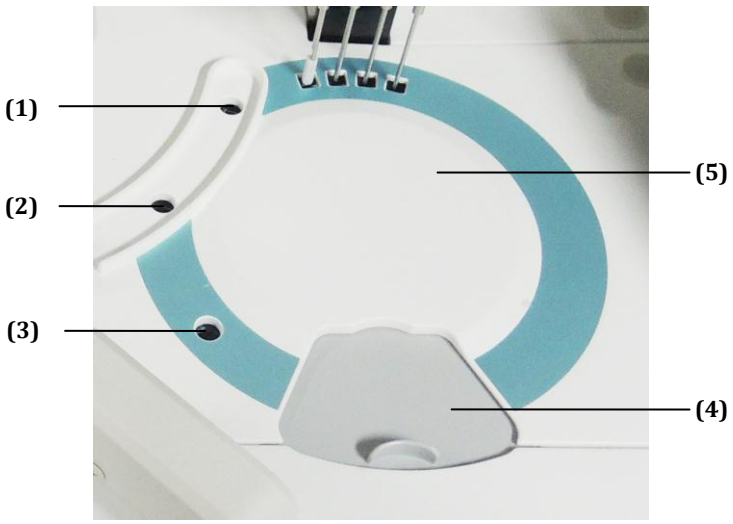
The reaction system consists of the reaction carousel, cuvettes and drive assembly. It holds the reaction cuvettes and carries them to the specified position for washing, adding reagent and sample, mixing, reaction, and absorbance measuring.

Reaction carousel

The reaction carousel is a single-ring turntable, which can hold 8 cuvette segments. Each cuvette segment includes 5 cuvettes.

The reaction carousel is heated by means of air bath to provide a constant environment at 37±0.3°C with fluctuation of ±0.1°C.

Figure 1.9 Reaction carousel



(1) R1 dispense position
(2) Sample and R2 dispense position
(3) Mixing position
(4) Cuvette replacement window
(5) Reaction carousel

Reaction cuvette

Plastic reaction cuvette segments are used. Each segment includes 5 cuvettes (5 mm × 5 mm). The light path length of the cuvette is 5 mm, and the internal dimension is 5 mm (length) × 5 mm (depth) × 29.5 mm (height).

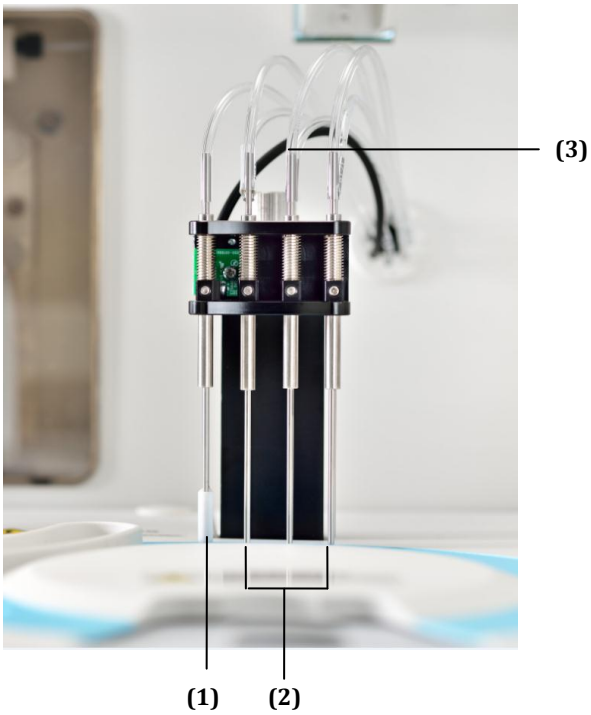
The cuvettes used on the BS-240 can be washed automatically and should be replaced every 3 months.

1.2.5 Cuvette wash station

The BS-240 provides the 8-phase cuvette auto wash function, through which the cuvettes are washed twice via four wash probes when a test is finished.

The cuvette wash station consists of the wash probes, elevating motor and related fluidic path. The wash probes driven by the elevating motor to go up and down during each wash phase dispense and aspirate wash solution in the cuvettes to finish washing.

Figure 1.10 Cuvette wash station



(1) Phase-4 wipe block
(2) Phase 1-3 wash probes
(3) Wash tubes

The cuvette wash station performs 8-phase wash on cuvettes by using diluted CD80 wash solution and deionized water, so that the cuvettes can be contamination free and dry during the test process.

After wash, the liquid waste is discharged in two flows: high-concentration waste and low-concentration waste. The system provides level detection of high-concentration waste. When the high-concentration waste exceeds the specified volume, the system gives an alarm to reminds you to empty the high-concentration waste tank.

📖 For drainage requirements of high-/low-concentration waste, see Water supply and drainage on page 1-3.

1.2.6 Photometric system

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

1.2.7 ISE unit (optional)

WARNING

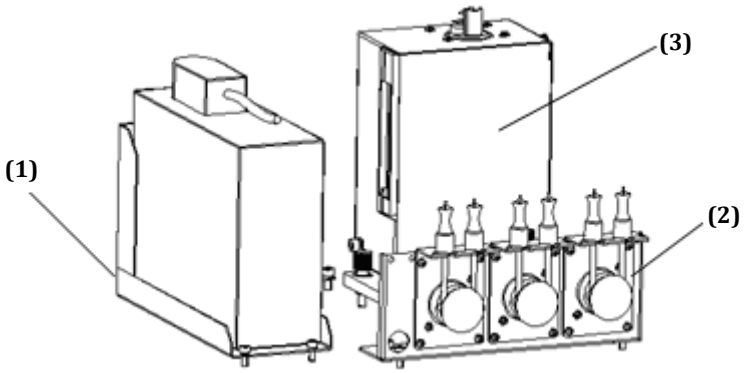
The ISE unit must be operated by skilled/trained doctors, nurses or clinical professionals.

Exercise caution while using the ISE unit Prevent your hair, legs or other parts of your body from being hurt by the driving parts.

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

If not specifically noted, "ISE module" represents the ISE unit.

Figure 1.11 ISE system



(1) Reagent module (2) Pump module
(3) ISE module

In ISE test, 70 μL serum or plasma, or 140 μL diluted urine (diluted at the ratio of 1:10) is required.

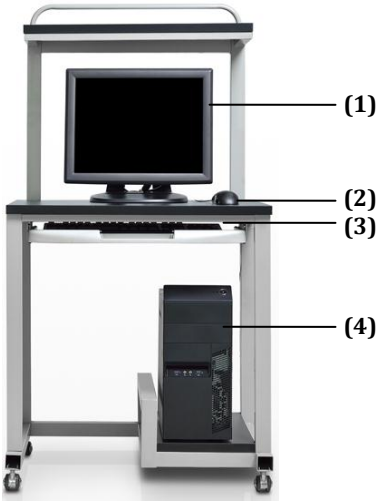
The following components are comprised in the ISE unit:

- ISE module: includes the spacer, Na, K, Cl, and reference electrodes.
- Reagent module: includes the calibrator A, calibrator B, waste container, and chip for measuring reagent volume.
- Pump module: includes the calibrator A pump, calibrator B pump and waste pump.

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 1.12 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 1.13 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.

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 1.4 Accessories and consumables

No	Part Name	Remark
1	Needle .0.25+/-0.01mm*125mm round head	Accessory
2	Valve Washer,10-32,18011Telfon washer	Accessory
3	20ml reagent bottle brown	Accessory
4	40ml reagent bottle brown	Accessory
5	20ml reagent bottle	Accessory
6	Reagent bottle label	Accessory
7	BS200 white cap of reagent bottle	Accessory
8	BS200 red cap of reagent bottle	Accessory
9	Accessory kit bar code	Accessory
10	Parameter list	Accessory
11	Cross screwdriver 102*100	Accessory
12	Serial port cable	Accessory
13	Cuvette (Surface processed)	Accessory
14	10L water tank	Accessory
15	Water tank	Accessory
16	Filter	Accessory
17	Tube Φ9.525XΦ15.875 PVC 55~60 degree	Accessory
18	BA24 Operating Software Installation CD	Accessory
19	Plug	Accessory
20	Cable strap CHS-3X100mm Nylon	Accessory
21	Mixer wrench	Accessory
22	Tube.3.2*6.4mm TPU(Polyether)tube	Accessory
23	Reference electrode	Consumable
24	K electrode	Consumable

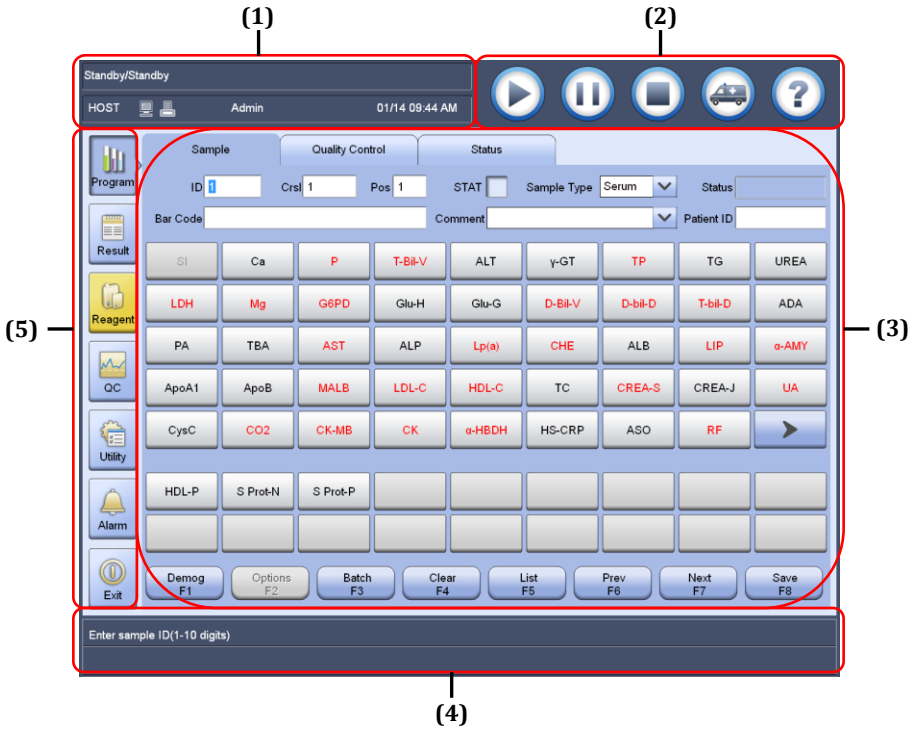
No	Part Name	Remark
25	Na electrode	Consumable
26	Spacer	Consumable
27	ISE wash solution	Consumable
28	Urine diluent	Consumable
29	MEDICA control (Level 3)	Consumable
30	Urine diluent (125ml)	Consumable
31	ISE reagent pack	Consumable
32	ISE Cl electrode (Turkey)	Consumable
33	ISE reference electrode (Turkey)	Consumable
34	ISE K electrode(Turkey)	Consumable
35	ISE Na electrode (Turkey)	Consumable
36	ISE spacer (Turkey)	Consumable
37	ISE wash solution (Turkey)	Consumable
38	ISE urine diluent(Turkey)	Consumable
39	MEDICA control Level 3(Turkey)	Consumable
40	ISE reagent pack (Turkey)	Consumable
41	ISE reagent pack (5425)with package	Consumable
42	Cl electrode 5207	Consumable
43	ISE Accessory kit with package	Consumable
44	ISE Accessory kit (OEM with package)	Consumable
45	CD80(international 6 bottles)	Consumable
46	CD80(international 1L*1 bottle)	Consumable
47	Plastic cuvette (8 pcs)	Consumable
48	Three-core power cord international standard 10A 250V 1.6m	Consumable
49	Power cord Europe standard (International)	Consumable
50	Power cord US standard 1.5M15A	Consumable
51	Power cord UK standard	Consumable
52	1.8mPower cord India H05VV-F3X1.5mmVolex	Consumable
53	Power cord Australia V-75 3×1.0 PVC	Consumable
54	Power cord Brazil 250V 10A 3M	Consumable
55	Sample tube adapter(5pcs)	Consumable

1.3 Software description

1.3.1 Screen areas

The software screen is divided into the following areas:

Figure 1.14 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 1.5 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, Sample load, Reagent load, cuvette load, inventory check, restore 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.
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.

1.3.2 Screen elements

Page

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

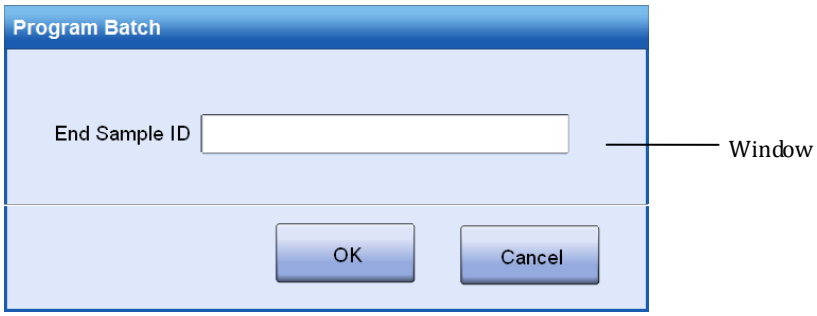
Figure 1.15 Example of page

Window

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

The figure below is an example of window:

Figure 1.16 Example of window

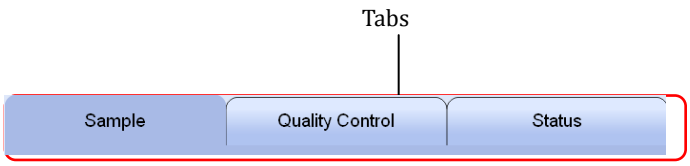


Tab

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

The figure below is an example of tab:

Figure 1.17 Example of tab

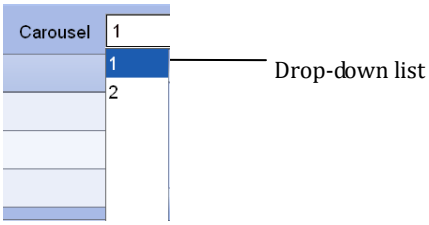


Drop-down list

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

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

Figure 1.18 Example of drop-down list

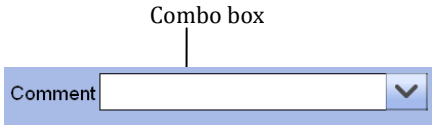


Combo box

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 1.19 Example of combo box

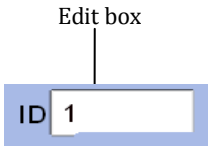


Edit box

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

The figure below is an example of edit box:

Figure 1.20 Example of edit box

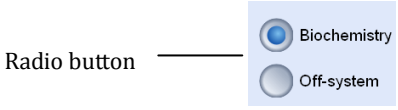


Radio button

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 1.21 Example of radio button

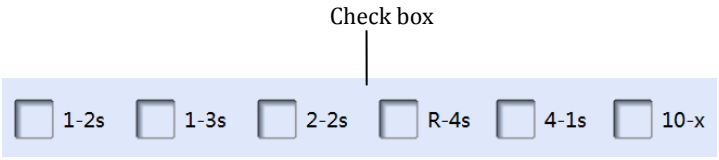


Check box

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 1.22 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:

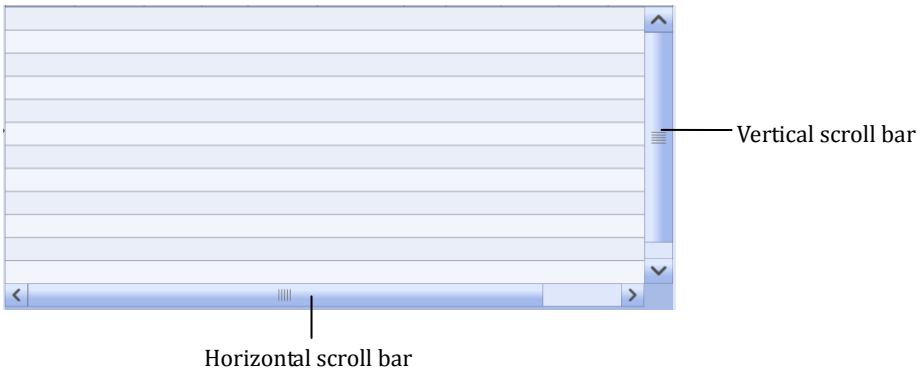
Figure 1.23 Example of button

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 1.24 Example of scroll bar

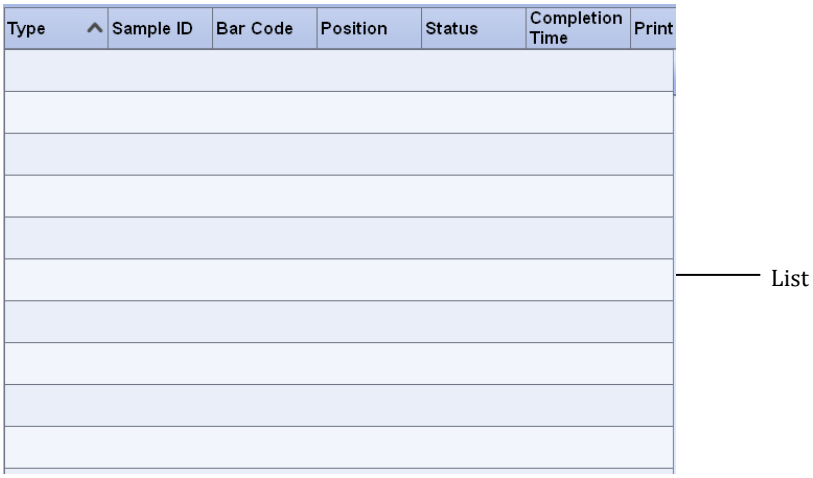


List

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 1.25 Example of list

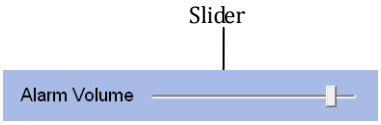


Slider

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:

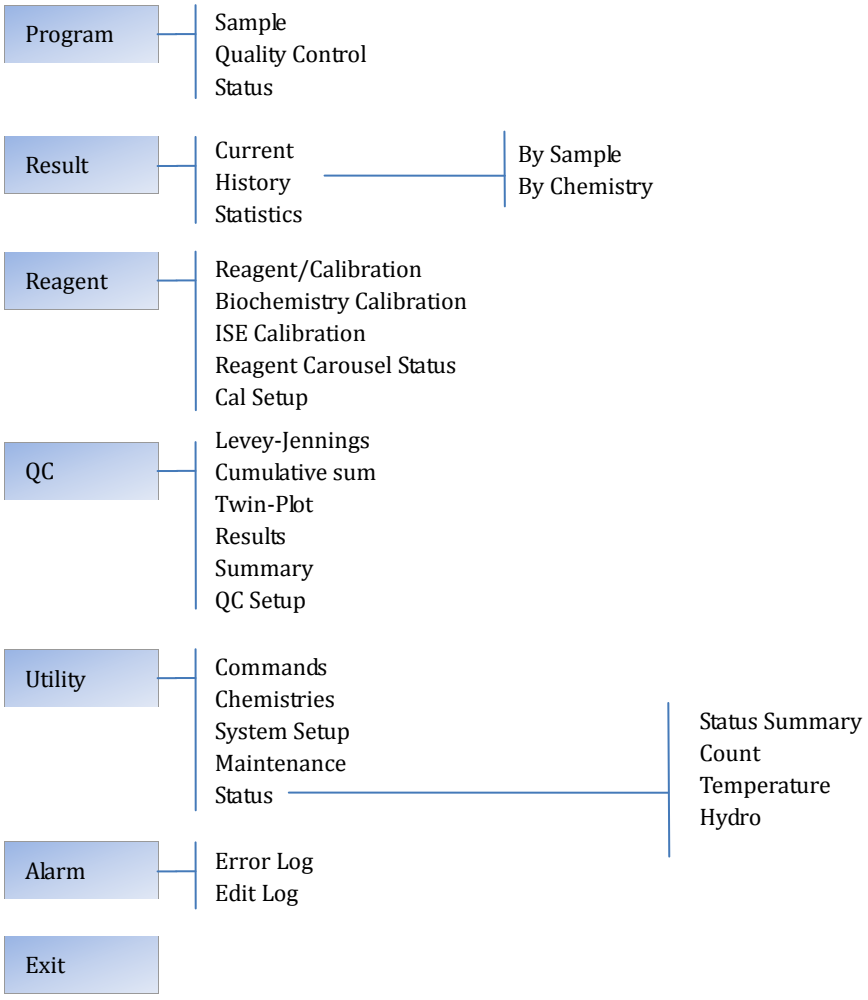
Figure 1.26 Example of slider



1.3.3 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 1.27 Software hierarchy



1.3.4 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.

1.3.5 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 1.28 Accessing the online help from the main screen

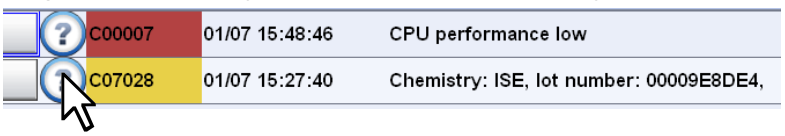
- Select the  icon in front of each maintenance command or regular maintenance item to display the relevant operating instructions.

  Figure 1.29 Accessing the online help from the Maintenance window

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

  Figure 1.30 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.

1.4 System specifications

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

1.4.1 Analyzing unit

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

Throughput and reaction type

Table 1.6 Specifications of throughput and reaction type

Throughput for biochemistries	Up to 200 tests/hour for single-reagent chemistries
Throughput for ISE tests (including K, Na, Cl)	Serum/plasma: 100 samples/hour and 300 tests/hour Diluted urine: 66 samples/hour and 198 tests/hour
Biochemistries and ISE chemistries	Up to 400 tests/hour
Maximum number of tests run simultaneously	Without ISE module: up to 80 With ISE module: up to 83
Principles of analysis	Colorimetry, turbidity, and ISE method
Reaction types	Endpoint, fixed-time, and Kinetic
Reagent mode	Supporting single-/double-reagent tests
Wavelength	Supporting single/double-wavelength mode

Sample/Reagent handling system

Table 1.7 Specifications of the sample/reagent handling system

Sample/Reagent carousel	Includes outer ring, middle ring and inner ring, with 120 positions. • Outer ring: 40 sample positions • Middle ring: 40 positions for sample or reagent • Inner ring: 40 reagent positions The middle and inner rings can be merged for holding 40 mL reagent bottle. 24 hour continuous refrigeration at 2-12 °C.
Sample volume for routine chemistry	2 μL - 45 μL, with increment of 0.1 μL
Sample volume for ISE chemistry	Serum/Plasma: 70μL; diluted urine: 140 μL
Reagent volume	10 μL - 250 μL, with increment of 0.5 μL
Probe	One probe for adding sample and reagent, featuring level detection, vertical obstruct detection, and level tracking.
Probe washing	The probe is cleaned in its wash well with water spraying 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.

Mixer assembly

- One mixer to mix the reaction liquid after sample and R2 are added.
- Cleaned externally with deionized water.

Reaction system

Table 1.8 Specifications of the reaction system

Reaction carousel	40 positions available
Reaction temperature	37 °C ± 0.3 °C
Heating mode	Air bath
Reaction cuvette	Plastic cuvette segment, each including 5 cuvettes. 5 mm × 5 mm × 29.5 mm (length × depth × height), light path length 5 mm reusable cuvette
Reaction mixture volume	100 μL - 360 μL

Cuvette wash station

Table 1.9 Specifications of the cuvette wash station

Cuvette wash	8-phase wash through 4 wash probes.
Preheating	Supporting cuvette wash with preheated deionized water and wash solution
Wash station	Featuring vertical obstruct detection

Photometric system

Table 1.10 Specifications of the photometric system

Light source	12V/20W tungsten-halogen lamp, 2000 hours life span
Colorimetric component	Reaction cuvette
Light-splitting mode	Filter wheel forward optics
Detector	Photodiode
Measuring wavelength	8 wavelengths: 340nm, 405nm, 450nm, 510nm, 546nm, 578nm, 630nm, and 670nm
Absorbance measurement range	0 - 4.0 A
Measuring period	18 seconds
Reaction volume	100 μL - 360 μL

Average water consumption

≤ 5 L/H

1.4.2 Power supply requirements

Choose proper power supply according to the following requirements:

Table 1.11 Power supply requirements

Power supply	110V: 110V/115V~, 60Hz 220V: 220V-240V~, 50Hz 220V/230V~, 60Hz
Rated power consumption	≤1000VA
Voltage fluctuation	±10%
Frequency fluctuation	±1Hz

1.4.3 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

1.4.4 Dimensions and weight

- Dimension: ≤ 695 mm (length) × 585 mm (depth) × 600 mm (height)
- Weight: ≤ 130 Kg

1.4.5 Noise and fuse

Table 1.12 Noise and fuse

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

1.4.6 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)

1.4.7 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)

1.4.8 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 1.13 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

1.4.9 Safety classification

Table 1.14 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)

1.4.10 EMC requirements

This equipment complies with the emission and immunity requirements described in EN61326-1:2013/IEC61326-1:2012 and EN61326-2-6:2013/IEC61326-2-6:2012.

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 .

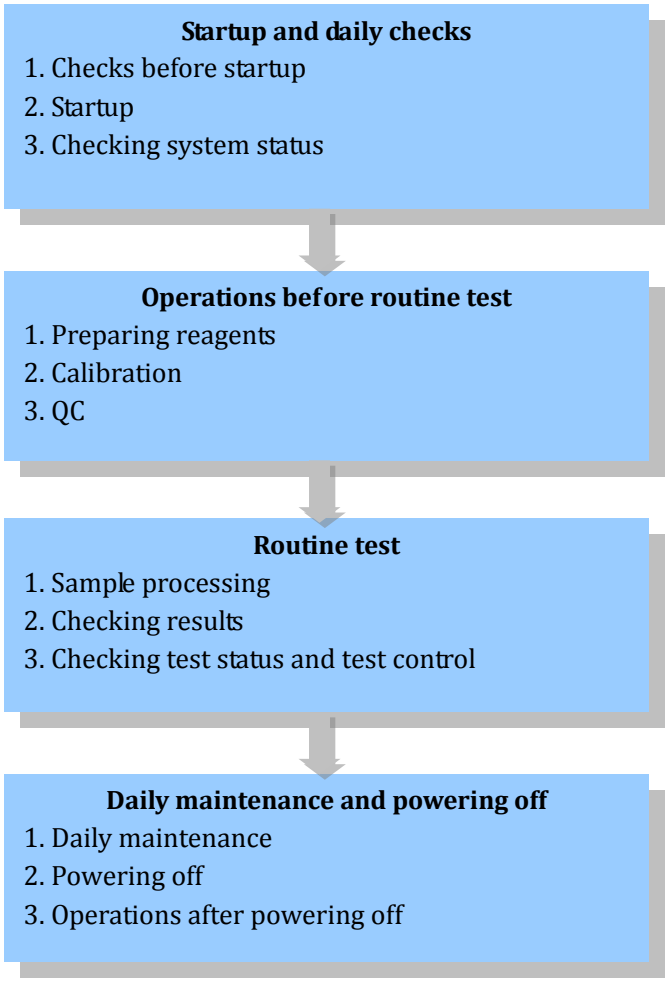
🕮 To understand the detailed information of software screens, see the *Online Help*.

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	Comment

Water supply	Check the deionized water tank or other water reservoirs, and make sure that water can be supplied continuously.	Ensure that the top of the deionized water tank is lower than the operating platform of the analyzer.
	If you use a water unit, check if it has been powered on.	
	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 volume: 0.4 L/H.	Ensure that the top of the waste tank is lower than the operating platform of the analyzer, to prevent waste from flowing back. Ensure that the waste tubes are above the waste tank and smooth without bending or twisting. Otherwise, the waste may overflow the analyzer panels to damage the analyzer.
	Check if the low-concentration waste tank has been emptied. If not, empty it. Low-concentration waste volume 4.42 L/H.	
	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 probe for dirt and bend. • If it is polluted, clean it. • If it is bent, replace it.	
	Check the 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.	Insufficient diluted wash solution or probe wash solution could terminate the measurements.
	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.

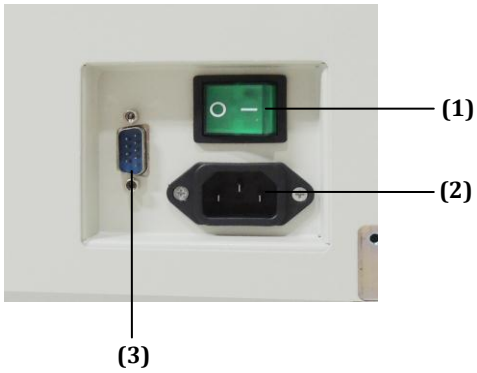
Manual startup

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 rear panel.

Figure 2.2 Main power switch of the analyzer

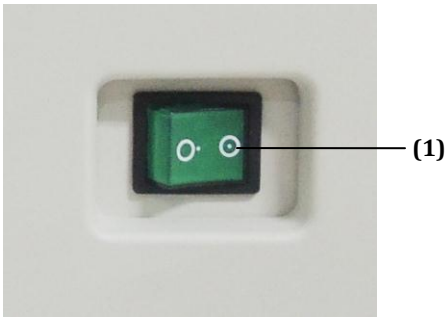


(1) Main power switch (2) Power socket
(3) Serial port

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 2.3 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**.

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.

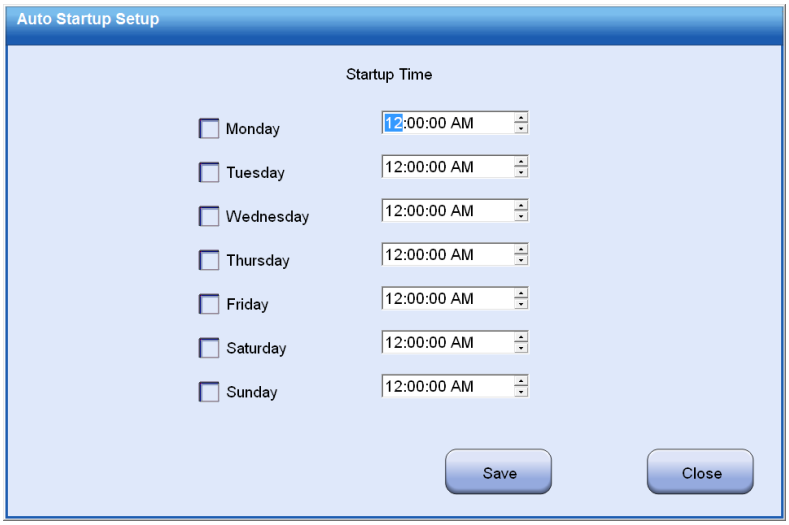
To set up auto startup timer

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

2 Select **Auto Startup Setup**.

3 Select **Auto Startup Setup**.

Figure 2.4 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 10 Maintenance on page 10-1 and 11 Alarms and troubleshooting on page 11-1.

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.
	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 2.5 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 2.6 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 2.3.2Calibrationon page 2-16.

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 10 Maintenance on page 10-1.
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 and Hydropneumatic subsystem.

Description of subsystem status

Status summary

The status summary provides a high-level status summary of the system temperatures and Hydropneumatic system.

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 reaction carousel, cuvette cleaning fluid, cuvette wash solution and reagent preheating temperature are displayed.

Hydropneumatic subsystem

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

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.
Hydropneumatics	If a Hydropneumatic component is beyond the valid range or 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.

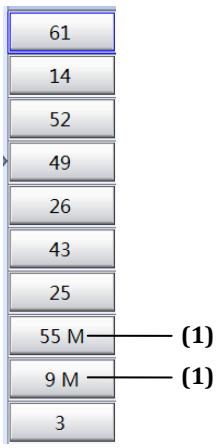
If a chemistry is set with sample pretreatment, ensure that the chemistry reagent and the pretreatment reagent are loaded to the same reagent carousel; otherwise, the chemistry cannot be run.

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 2.7 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

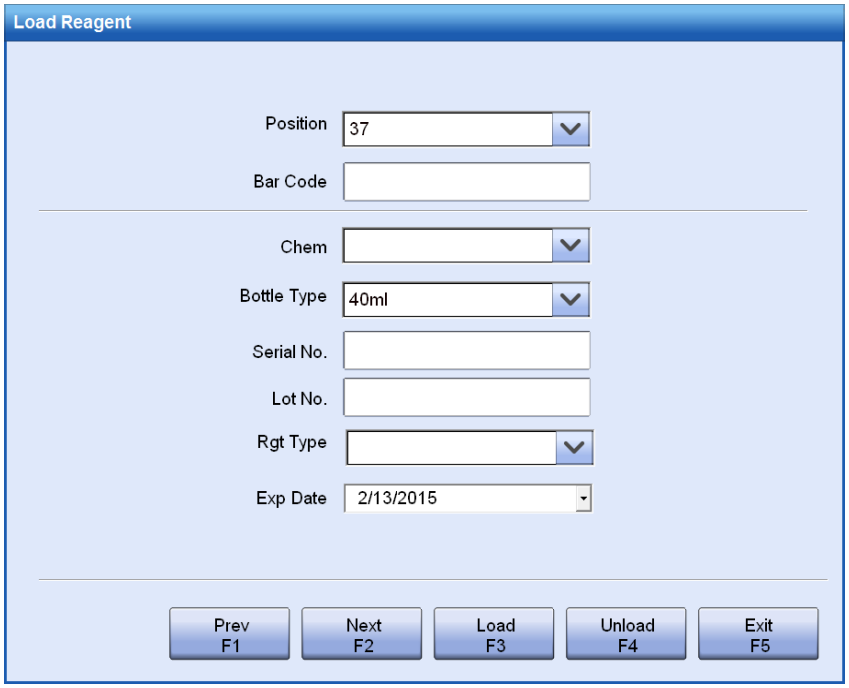
To set up reagent information

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 2.8 Load reagent window



4 Enter the following reagent information:

- Bar code
- Chemistry name
- Reagent type(R1/R2)
- 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 4-5.

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

To load reagents

1 Remove the sample/reagent carousel cover.

CAUTION

If the system is running tests, click and wait until the system status becomes *Pause* 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 sample/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 3.2.7 Checking and auto refreshing reagent inventory on page 3-6.

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, click and wait until the system status becomes *Pause* 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 sample/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 load ISE reagent pack

1 Select **Reagent > Reagent/Calibration > ISE Reagent**, and select **Load F1**.

2 Remove the red caps from the reagent pack and push the wand above the top of reagent pack.

3 Make sure that the three pipe adapters at the bottom of the wand are opposite to those on the top of reagent pack, and then push down the wand. The wand will only fit one way.

4 Once the wand is connected to the reagent pack, place the reagent pack in the mounting position.

NOTE

When installing ISE reagent pack, do not twist, press and squeeze the pipes of the ISE Module otherwise the ISE pipes may be clogged.

To perform fluidic prime and calibration

1. On the **Rgt Load** window, enter the purge times in the **Purge A/B** field. The input can be any integer within 1-50 and the default is 30.
2. Click **Prime**.
3. When Purge A/B is complete, select **OK** to perform calibration.

Loading ISE wash solution

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

1. Open the ISE wash solution loading window:
   a. Select **Reagent > Reagent/Calibration**.
   b. Select **ISE Wash Solution** in the special reagent list.
   c. Click **Load F1**.
   Or
   a. Select **Reagent > Reagent Carousel Status**.
   b. Click position 38#.
   c. Click **Load F1**.
2. Input the following reagent information:
   - Serial number
   - Lot number
   - Volume
   - Expiration date
   - Alarm limit
3. Click **Load F3** to save the input information.
4. Remove the sample/reagent carousel cover.
5. Put the ISE wash solution in position 38# on the sample/reagent carousel.
6. Restore the sample/reagent carousel cover.
7. Click **End Load F2**.

Loading diluted wash solution

Diluted wash solution is diluted at the ratio 1:9 from CD80 alkaline concentrated wash solution. It is used to clean the reaction cuvettes and the mixer.

A tank of diluted wash solution is 10L and can be used for analysis for 5 days on condition that 200 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 is full.
3. Install the tank cover, and shake the tank slightly to mix the liquid completely.

To load diluted wash solution

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

Loading probe wash solution

Probe wash solution, also called probe special wash solution, is CD80 and used for cleaning the probe. You should check it every day to ensure that it is sufficient for routine test.

To prepare probe wash solution

1. Find a 20 mL reagent bottle.
2. Fill the reagent bottle with CD80 concentrated wash solution.

To load probe wash solution

1. Select **Reagent > Reagent/Calibration**, and select **Wash D(39#)**.
2. Or select **Reagent > Reagent Carousel Status**, and then click position D.
3. Click **Load F1** to display the **Reagent Load** window.
4. Input the following information:
   - Serial number
   - Lot number
   - Volume
   - Expiration date
   - Alarm limit
5. Click **Load F3**, and then click **Exit F5** to close the window.
6. Remove the sample/reagent carousel cover.
7. Put the probe wash solution in position D (No.39) on inner ring of the sample/reagent carousel.

   NOTE

   Before loading wash solution, ensure that there are no air bubbles inside the reagent bottle so as to avoid affecting washing effects.
8. Restore the sample/reagent carousel cover.
9. Click **End Load F2**.

Loading physiological saline

Physiological saline is used for sample dilution, sample blank test, reagent blank test, and calibration test. Follow this procedure to load physiological saline.

To prepare physiological saline

1. Find a 20 mL reagent bottle.
2. Fill the reagent bottle with physiological saline.

To load physiological saline

1. Select **Reagent > Reagent/Calibration**, and select **Saline D**.
2. Or select **Reagent > Reagent Carousel Status**, and then click position W.
3. Click **Load F1** to display the **Reagent Load** window.
4. Input the following information:
   - Volume
   - Alarm limit
5. Click **Load F3**, and then click **Exit F5** to close the window.
6. Remove the sample/reagent carousel cover.
7. Put the physiological saline in position W (No.40) on inner ring of the sample/reagent carousel.
8. Restore the sample/reagent carousel cover.
9. Click **End Load F2**.

Loading pretreatment reagent

Pretreatment reagent is used to pretreat whole blood samples. Follow this procedure to load pretreatment reagent:

1. Select **Reagent > Reagent/Calibration**, and click **Load F1** to display the **Load Reagent** window.
2. Or select **Reagent > Reagent Carousel Status**, click the position on the reagent carousel graph to load the pretreatment reagent, and select **Load F1**.

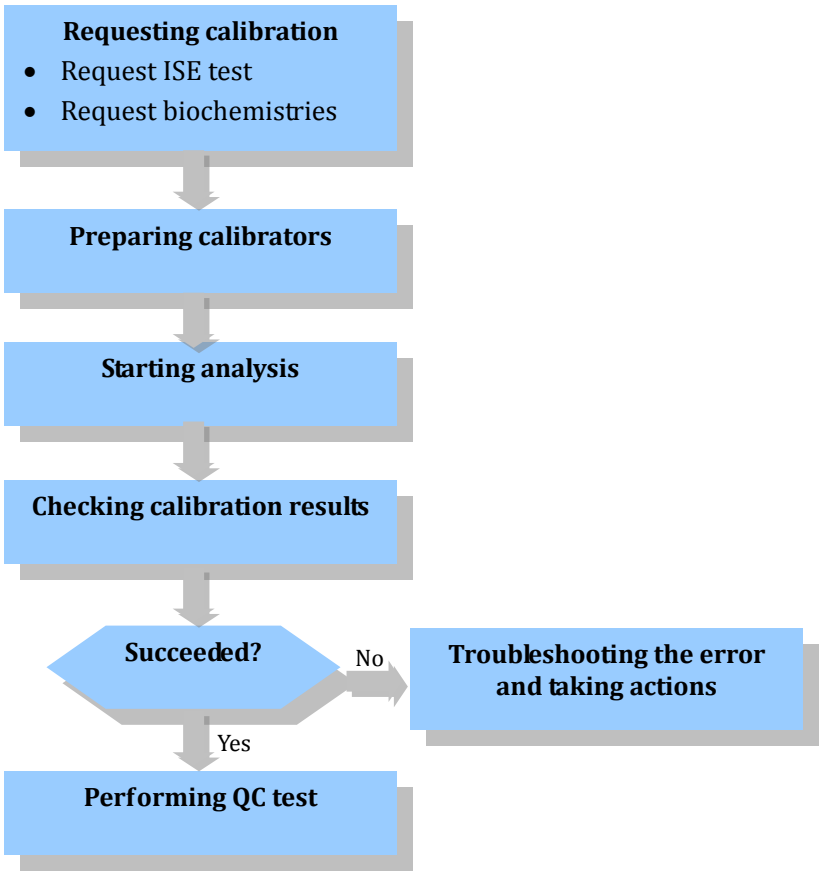
   NOTE

   Pretreatment reagent can be only loaded on one reagent carousel. Make sure that it is on the same carousel as the chemistry reagent set with sample pretreatment; otherwise, the chemistry cannot be run.
3. Enter the following information:
   - Bar code
   - Chemistry
   - Bottle type
   - Lot number
   - Serial number
   - Reagent type(R0)
   - Expiration date
4. Select **Load F3**, and select **Exit F5** to close the window.
5. Remove the sample/reagent carousel cover.
6. Place the pretreatment reagent in the set position of the sample/reagent carousel.
7. Restore the sample/reagent carousel cover.
8. 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 2.9 Calibration test procedure



Requesting calibration

Calibration request includes ISE test and biochemistries.

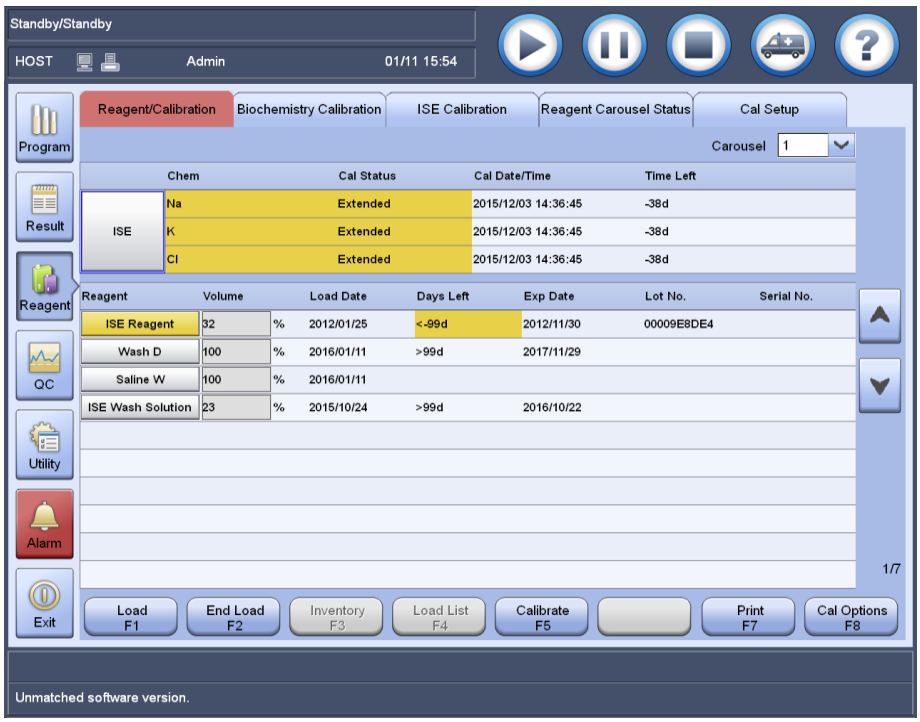
CAUTION

After 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 2.10 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 2.11 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.

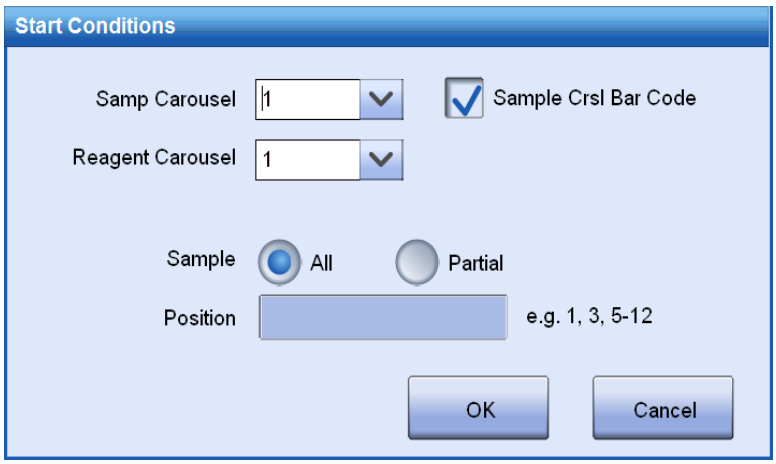
Starting analysis

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 2.12 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 11.4.1 Data alarms and corrective actions on page 11-9.

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.

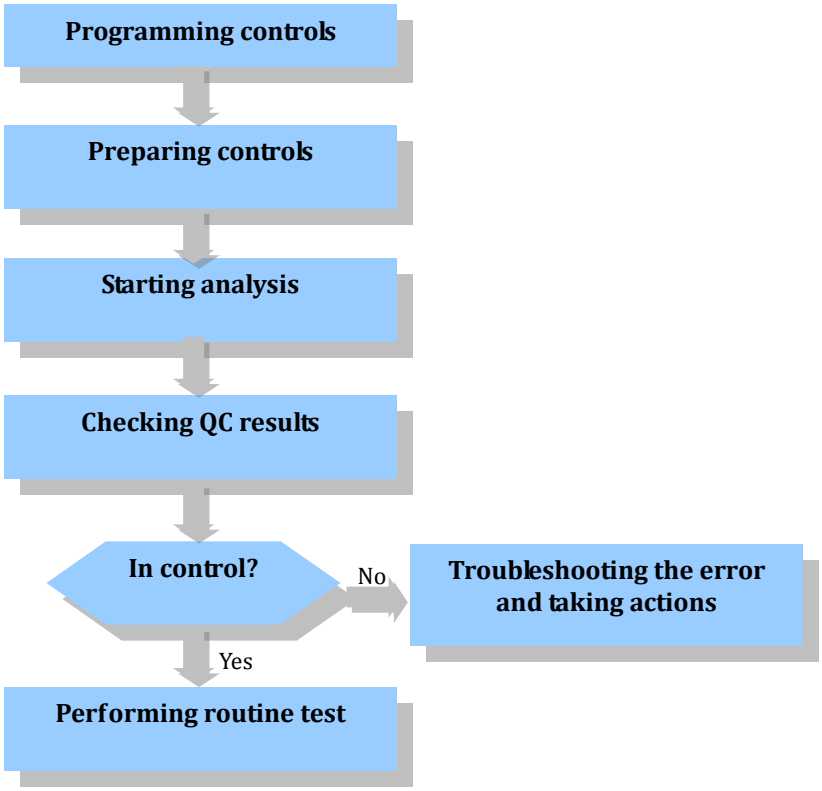
4 After taking actions, you can start the QC test.

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 2.13 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 2.14 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 11.4.1 Data alarms and corrective actions on page 11-9.
3. Select **QC > Levey-Jennings** 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 2.15 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**.

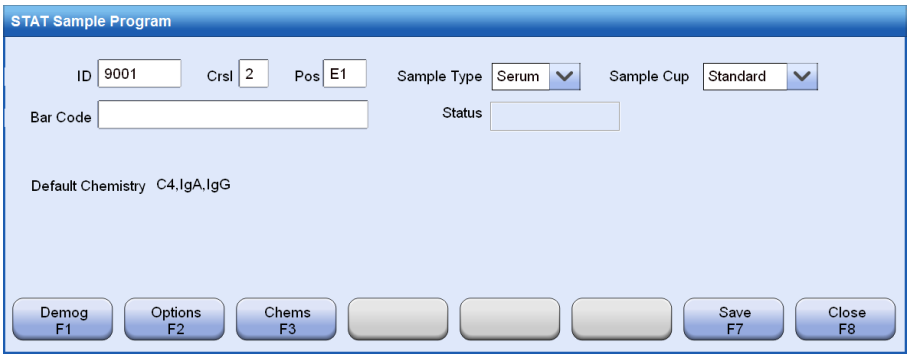
6 Click **Save F8**.

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 2.16 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 6-5.

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.

Whole blood sample test

The system supports whole blood test.

📖 For details about whole blood sample test, see 6.2.8Whole Blood Test on page 6-13.

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 11.4.1 Data alarms and corrective actions on page 11-9.
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.

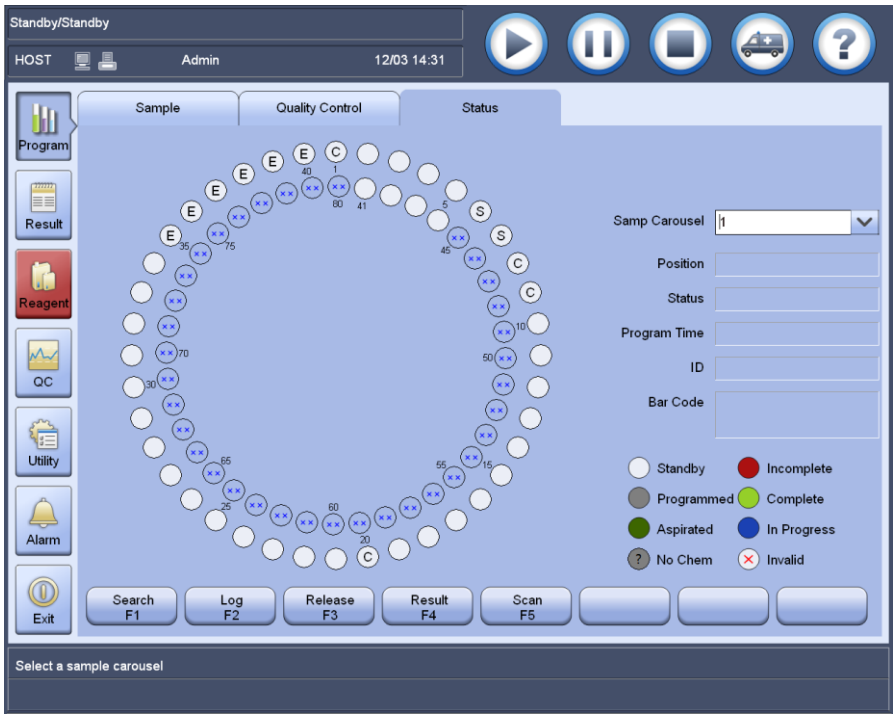
Checking sample carousel status

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 2.17 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

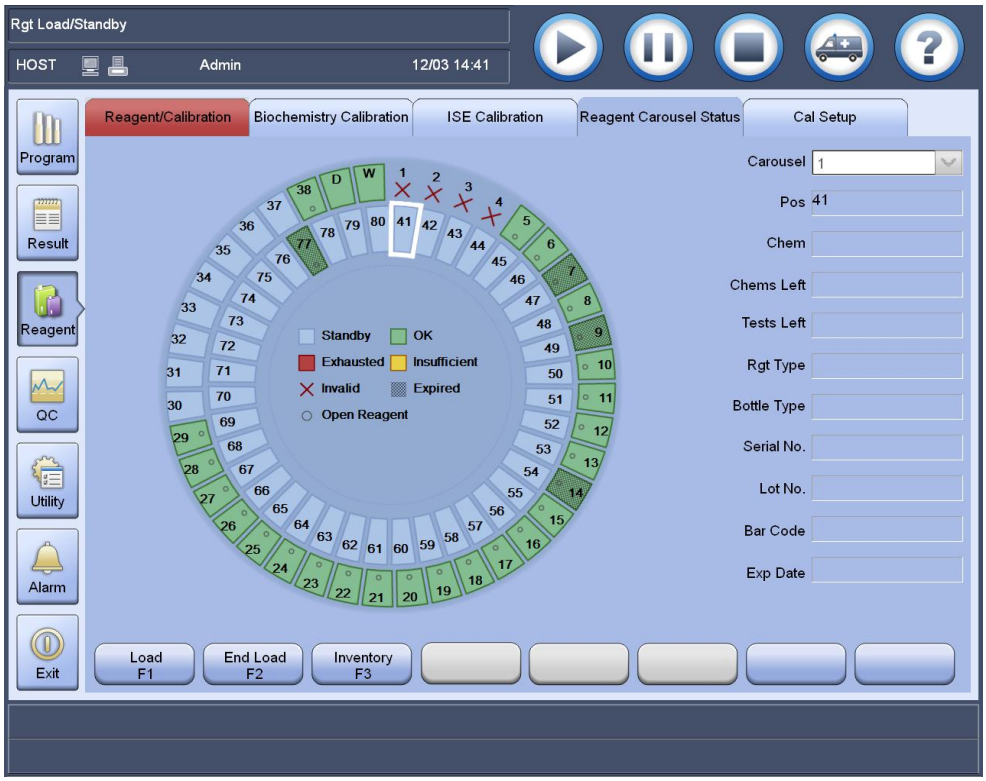
On the **Reagent > Reagent Carousel Status** screen, you can check the reagent volume and view the detailed information of each reagent.

To check reagent carousel status

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

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

Figure 2.18 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 3.2.3Loading biochemistry reagents in Running status on page 3-4.

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 and tube connection
- Check waste connection
- Check probe wash solution
- Clean electrode tubes

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

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

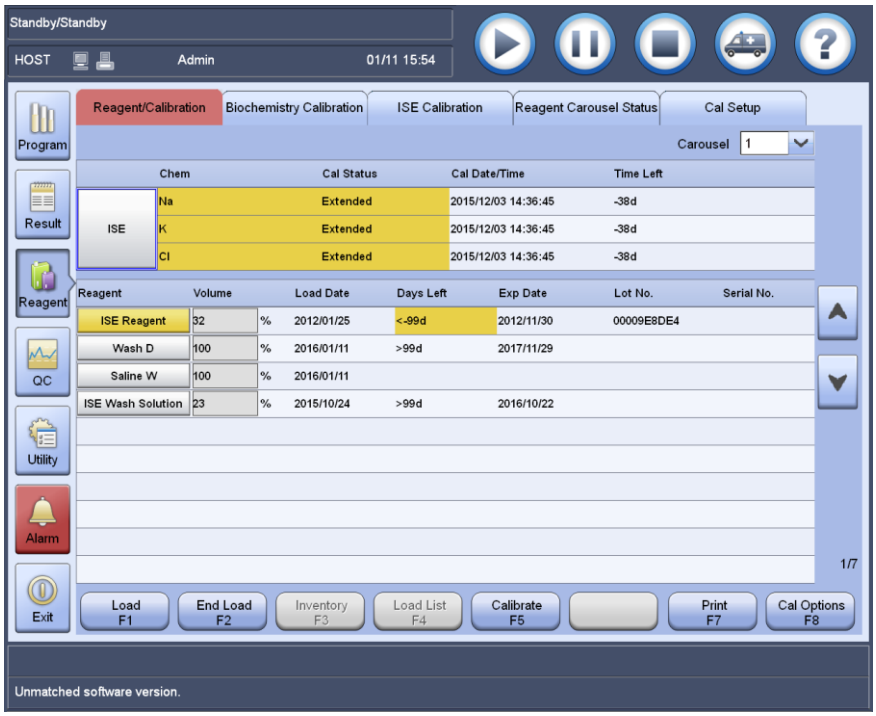
This chapter describes reagent and calibration operations related to ISE and biochemistry tests.

3.1 Special reagent

3.1.1 ISE reagent/calibration screen

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

Figure 3.1 ISE reagent/calibration screen



The ISE 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.

3.1.2 Loading special reagents in Running status

The special reagents used by the system include: ISE reagent, diluted wash solution, probe wash solution, physiological saline and ISE wash solution. 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 Rgt Load, start replacing reagents in the same way as initial loading.

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

3 After finishing replacement, the system automatically resumes the previous test or to start new test.

3.1.3 Unloading special reagents

The system allows you to unload the ISE reagent, probe wash solution, physiological saline, ISE wash solution.

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.

3.1.4 Printing ISE reagent/calibration list

The ISE calibration information and special reagent information on the ISE reagent/calibration screen can be printed on a report.

To print ISE reagent/calibration list

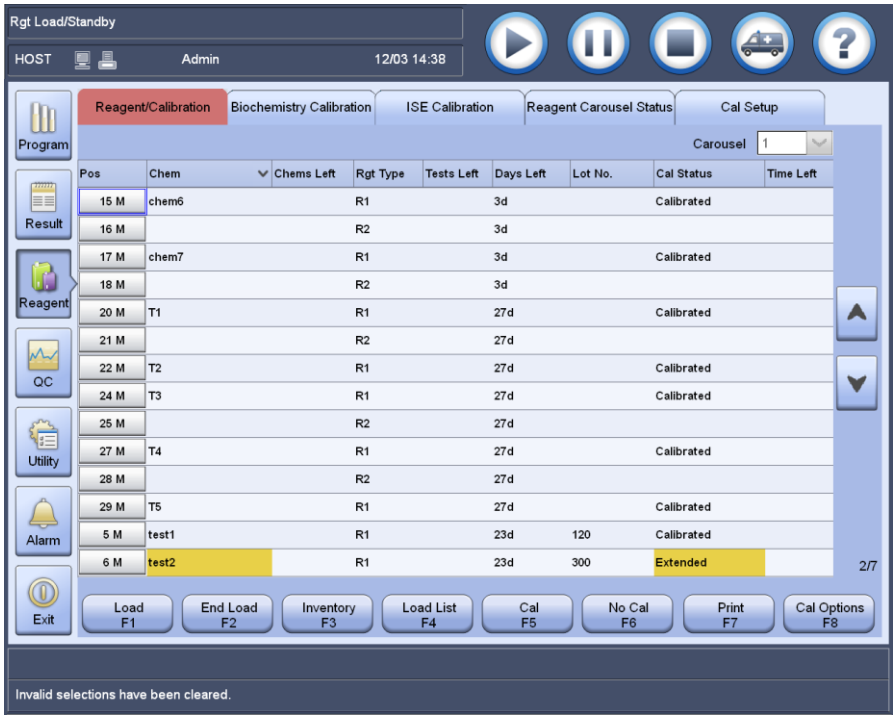
1. Select **Reagent > Reagent/Calibration**.
2. Click **Print F7**.

3.2 Biochemistry reagent

3.2.1 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 3.2 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.

3.2.2 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

3.2.3 Loading biochemistry reagents 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 2.3.1reagents on page 2-10
3. After finishing replacement, the system automatically resumes the previous test or to start new test.

3.2.4 Unloading biochemistry reagents

If some chemistries will not be used, you are allowed to clear the chemistry parameters and unload the relevant reagents. 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

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.
4. Select **Load F1**, and then **Unload F4**.
5. Remove the sample/reagent carousel cover, take out the reagent , and restore the cover.
6. Select **Exit F5** to close the window.
7. Select **End Load F2**.

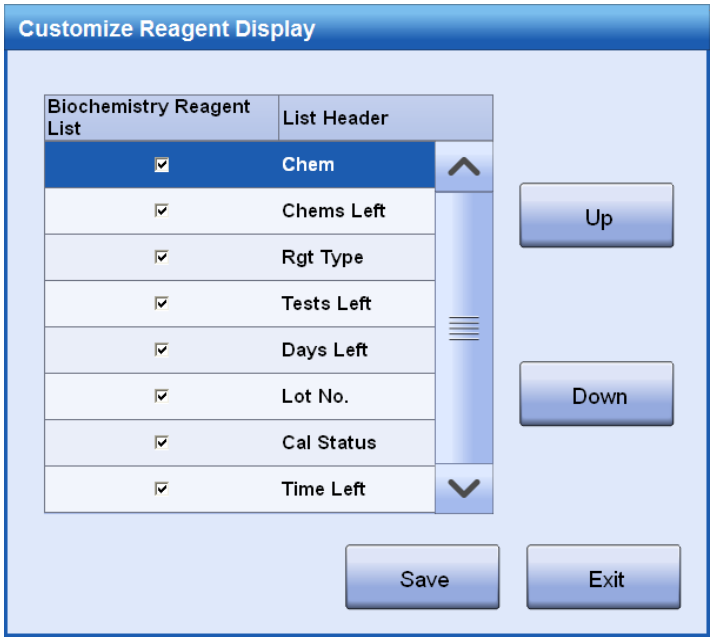
3.2.5 Customizing reagent display

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 3.3 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.

3.2.6 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**.

3.2.7 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.

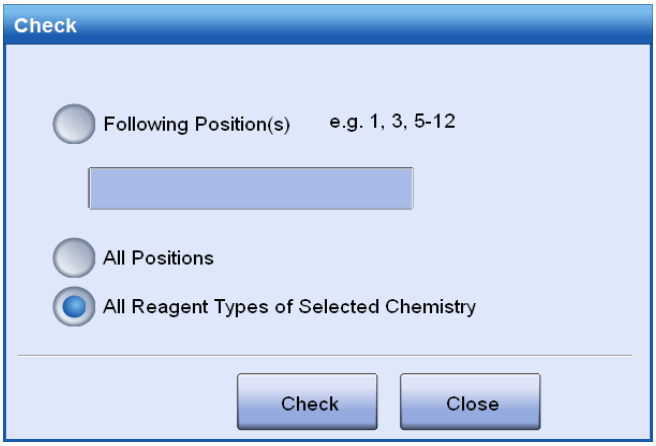
Checking reagent inventory

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 3.4 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.

4 Calibration

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

4.1 ISE calibration

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

4.1.1 Calibration setup

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

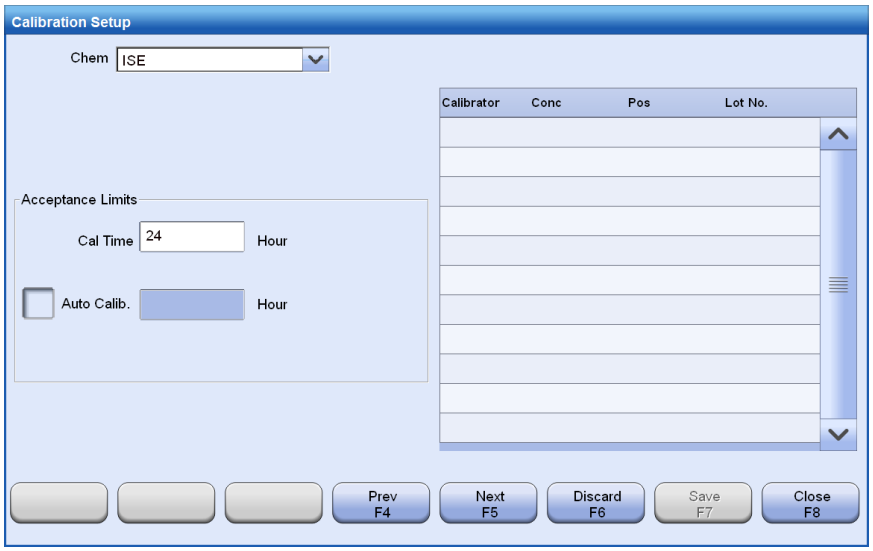
When a calibrator is expired, it will be indicated in yellow and cannot be used for calibration. When the auto calibration interval is reached, the system reminds you to perform ISE calibration.

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 4.1 ISE calibration setup window



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

The input range is 1-9999, and the default is 8 hours. If the field is left blank, it indicates that the calibration factors can be always used.

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.

4.1.2 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 4.1 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
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
Cal Time Extended	Indicates that the calibration period has been extended and the current calibration factors can be used without time limit.	Warning	Yellow
N/A	Indicates that the reagent is not loaded.	Normal	No color indication

4.1.3 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

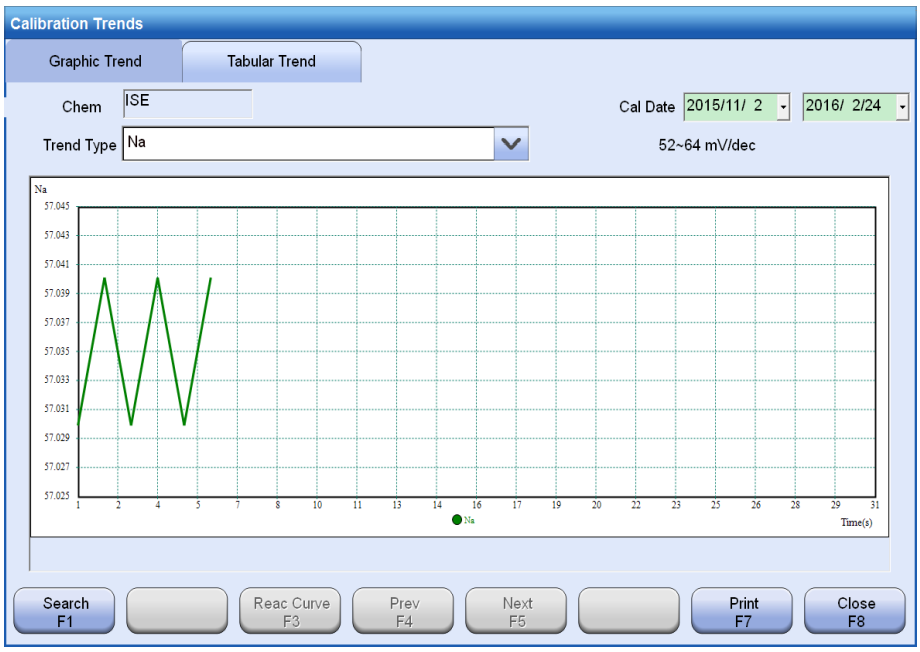
1. Select **Reagent > ISE Calibration**.
2. Select the **History** option button, and then select date range that the ISE test is calibrated.
3. Select **Search F1**.
   The ISE calibration results are displayed in the result list.
4. To print the calibration report, select **Print F7**.

Recalling calibration trends

To recall calibration trends

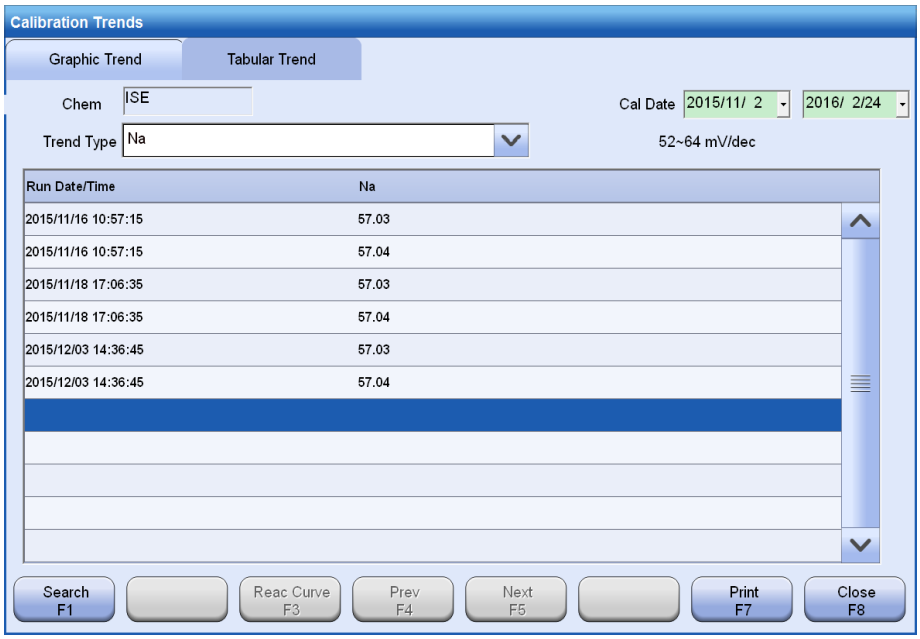
1. Select **Reagent > ISE Calibration**.
2. Search for desired calibration results.
3. Select **Trend F6**. The **Calibration Trends** window is displayed.
4. Choose desired trend type and calibration date range, and then select **Search F1**.
   The ISE trend within the specified time period is displayed on the screen. The trend type options will not include Reference Electrode when trends of ISE Urine are being recalled.

Figure 4.2 Calibration Trends window



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

Figure 4.3 Tabular Trend window



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**.

Extending ISE calibration time

When ISE calibration factors exceed the validity period, they cannot be used for measurement, and the calibration status changes to Cal Time Out. 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.

To extend ISE calibration time

1 Select **Reagent > Reagent/Calibration**.
2 Choose the ISE chemistry.
3 Select **Cal Options F8**.
4 Select **Extend Calibration Time** from the **Calibration Options** window.
5 Select **OK**. The calibration factors of the ISE chemistry can be used without time limit.
6 To remove the extended status, recalibrate the ISE chemistry.

4.2 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.

4.2.1 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

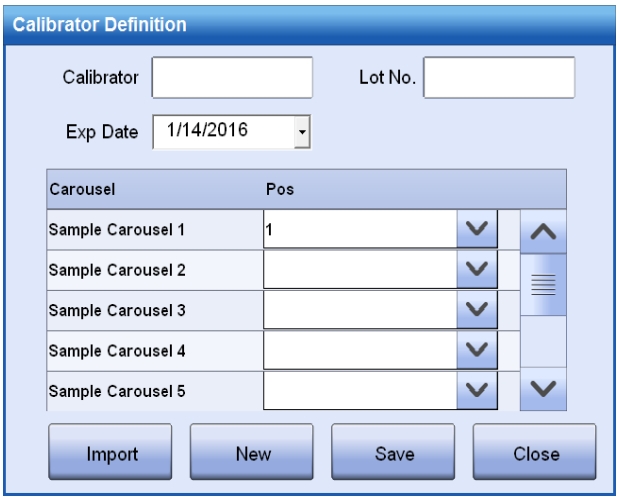
The system allows the definition of up to 99 calibrators. You are allowed to add, edit and delete calibrators only when the system status is not Running.

To define a calibrator

1 Select **Reagent > Cal Setup**.

2 Select **Define F1**.

Figure 4.4 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 7.

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**.

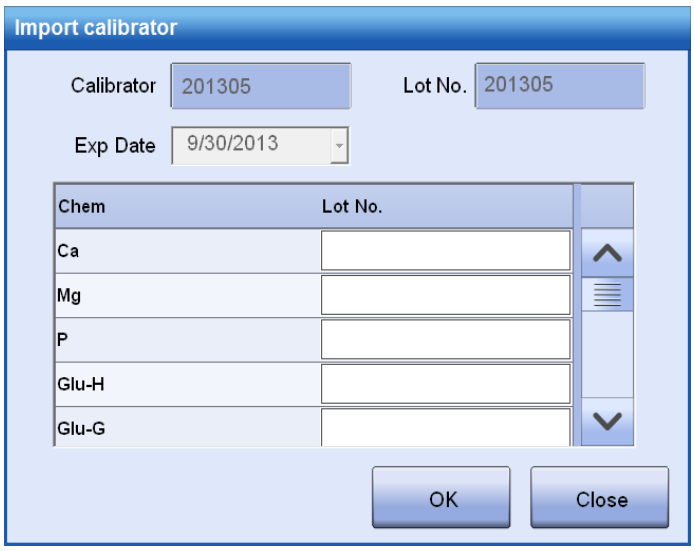
2 Select **Define F1**.

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 4.5 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.

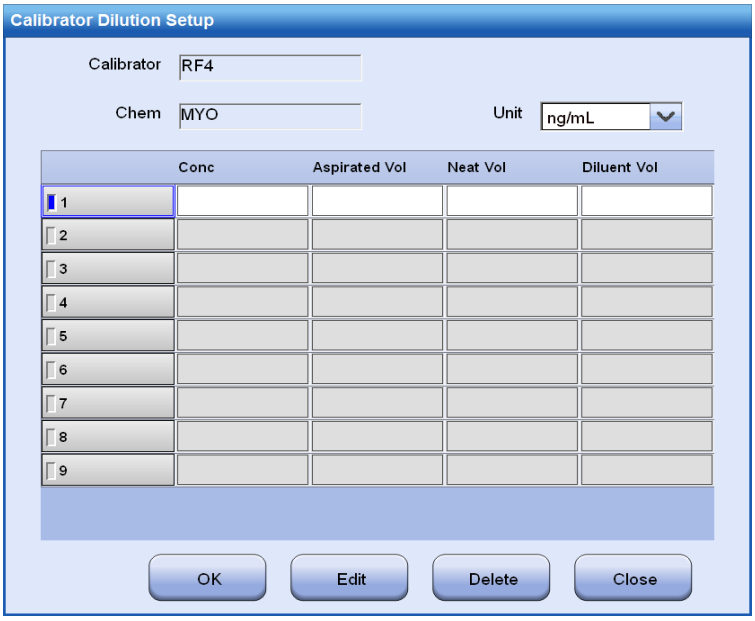
To set up calibrator dilution factors

1 Select **Reagent > Cal Setup**.

2 Choose the desired calibrator and chemistry.

3 Select **Dilute F5**.

Figure 4.6 Calibrator Dilution Setup window



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

- The input of aspirated volume and neat sample volume must be an integer multiple of 0.1 within 2 µL - 45 µL. The aspirated volume is required.
- The input of diluent volume must be an integer multiple of 0.5 within 100 µL - 250 µL. This field can be left blank.
- If the neat sample volume and diluent volume are defined, ensure that the sum of the two volumes is within 125 µL - 295 µL.

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

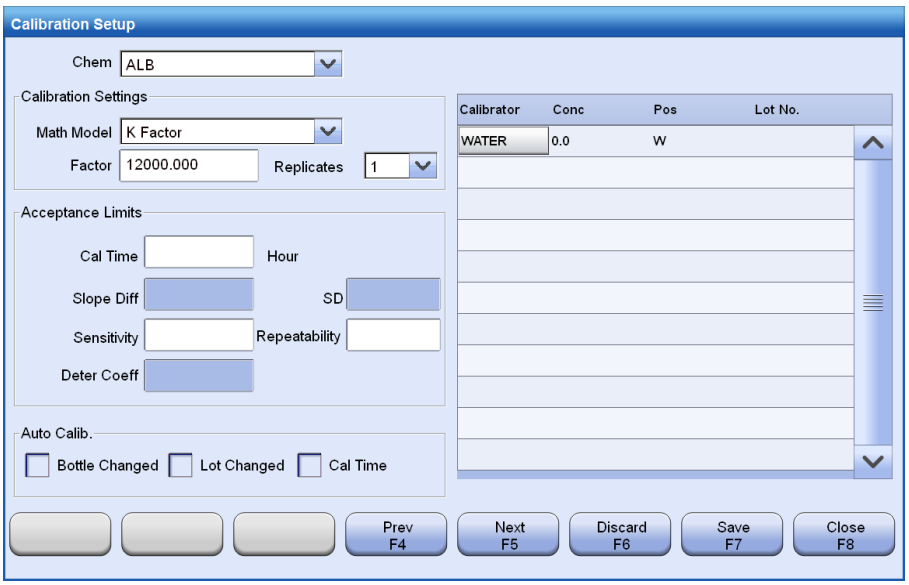
You should set up the calibration rules after defining a calibrator and determining concentrations for it. You are allowed to set up or edit the calibration rules, replicates, K factor and auto calibration only when the system is not running any tests.

To set up calibration rules

1 Select **Reagent > Cal Setup**.

2 Select **Rules F4**.

Figure 4.7 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 4.2 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

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.

4.2.2 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 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
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

4.2.3 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.

   Both the low and high limits must be an integer within -40000-40000. The default is -40000-40000, and it can be left blank.
5. Enter the blank response range in the **Blank Response** field.

   Both the low and high limits must be an integer within -40000-40000. The default is -40000-40000, and can be left blank.
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.

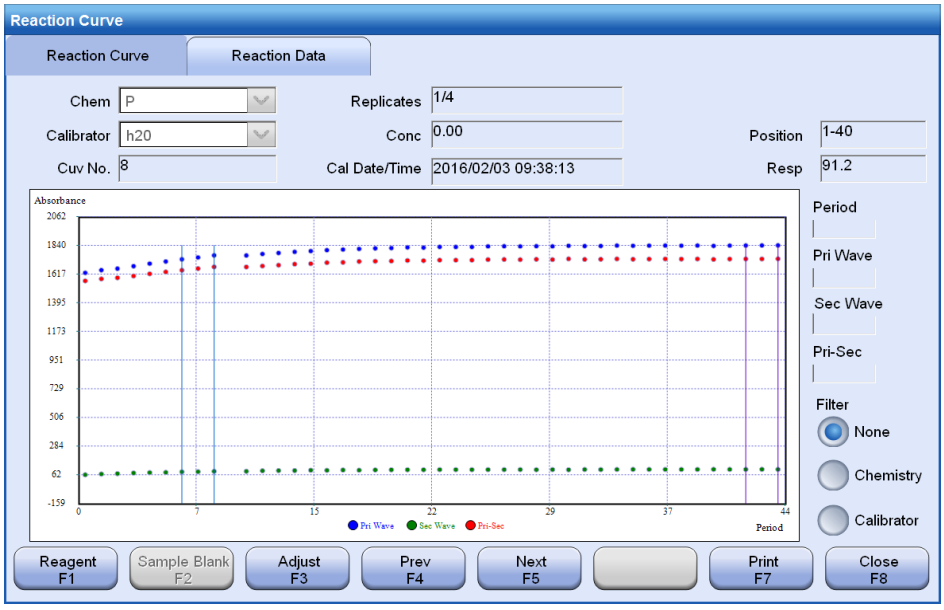
To recall reagent blank response

1 Select **Reagent > Biochemistry Calibration**.

2 Choose the desired calibration result.

3 Select **Reac Curve F3**.

Figure 4.8 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.

Figure 4.9 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**.

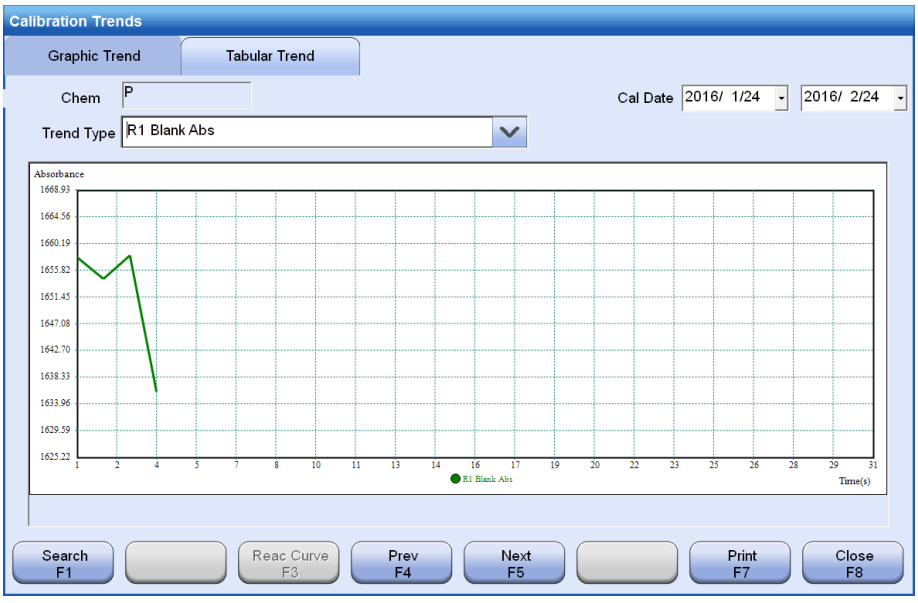
To recall reagent blank trends

1 Select **Reagent > Biochemistry Calibration**.

2 Choose the desired calibration result.

3 Select **Trend F6**.

Figure 4.10 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.

Figure 4.11 Tabular Trend tab page

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.

4.2.4 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.

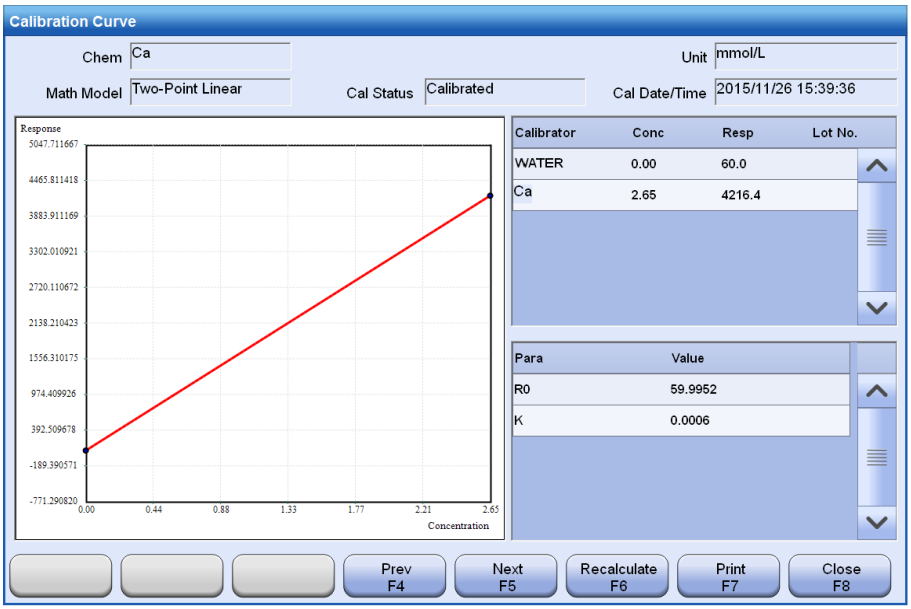
To observe calibration curve

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 4.12 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

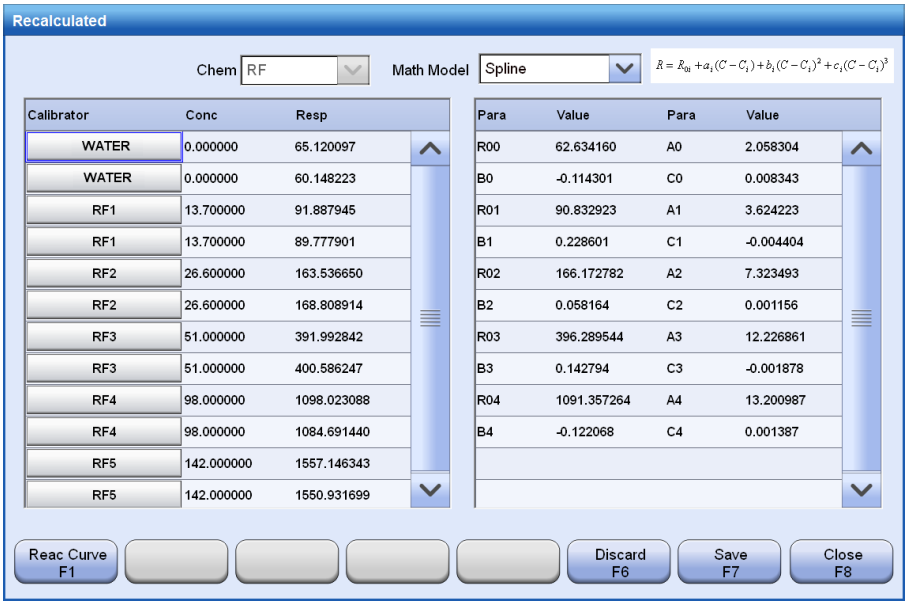
Calibration results in Calibrated, Cal Failed, Cal Time Out, Extended, or Overridden status can be recalculated based on the existing factors, a new math model and calibrators. The flag "CALR" indicating that the calibration result is recalculated will appear on the **Biochemistry Calibration** screen.

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

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 4.13 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. To view the reaction curve of the selected calibrator, select **Reac Curve F1**.
10. Select **Close F8** to close the window.

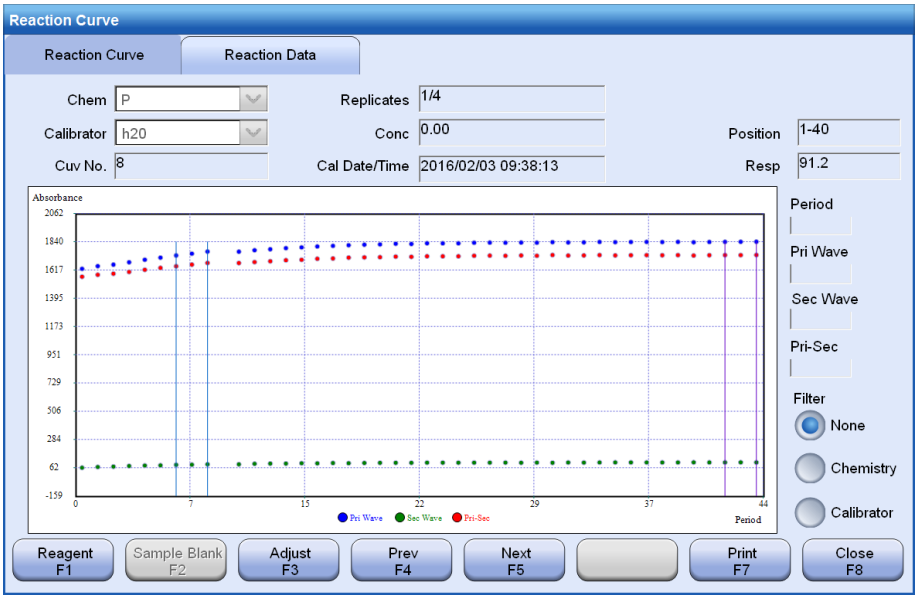
Observing calibration reaction curve

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 4.14 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.

Figure 4.15 Reaction Data tab page

7 Choose the following buttons as needed:

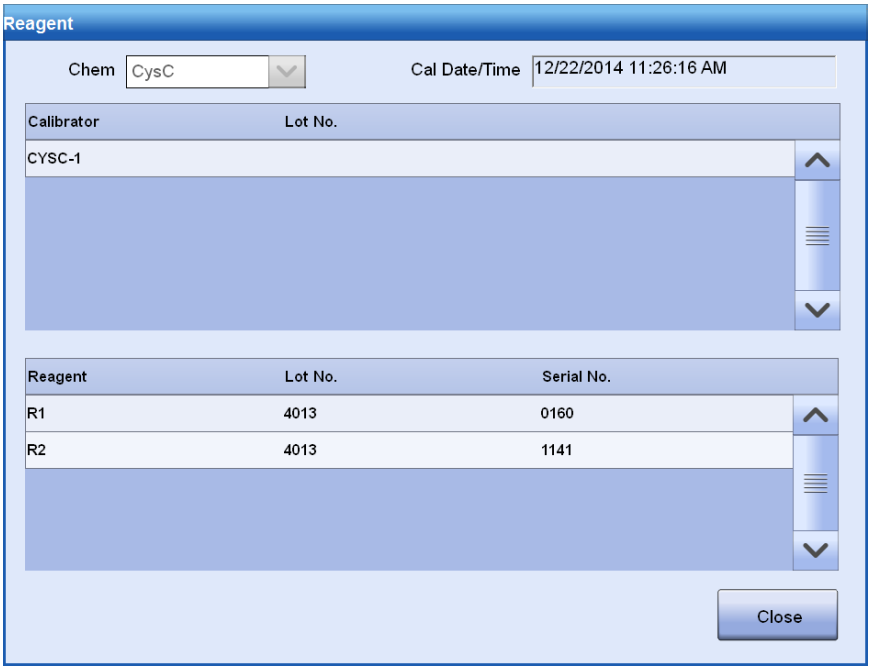
- **Reagent F1:** to view the calibrators and reagents used in calibration, and reagents for reagent blank test.
- **Sample Blank F2**: to view the sample blank reaction curve and reaction data of the calibrator.
- **Adjust F3**: to adjust the absorbance display range of current reaction curve.
- **Prev 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 4.16 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.

To edit calibration factors

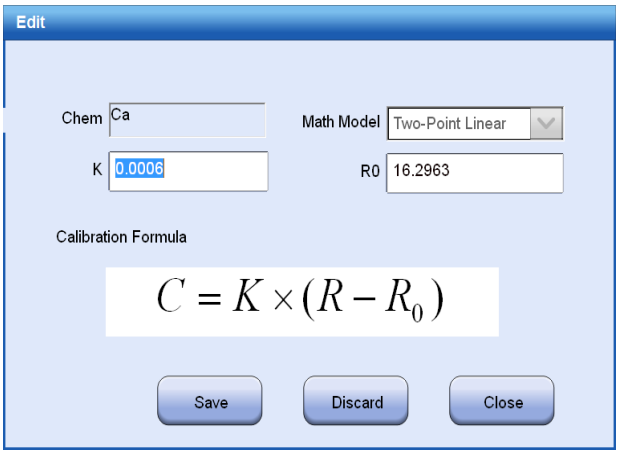
1 Select **Reagent > Biochemistry Calibration**.

2 Search for desired calibration results to edit.

3 Choose a desired chemistry.

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

Figure 4.17 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.

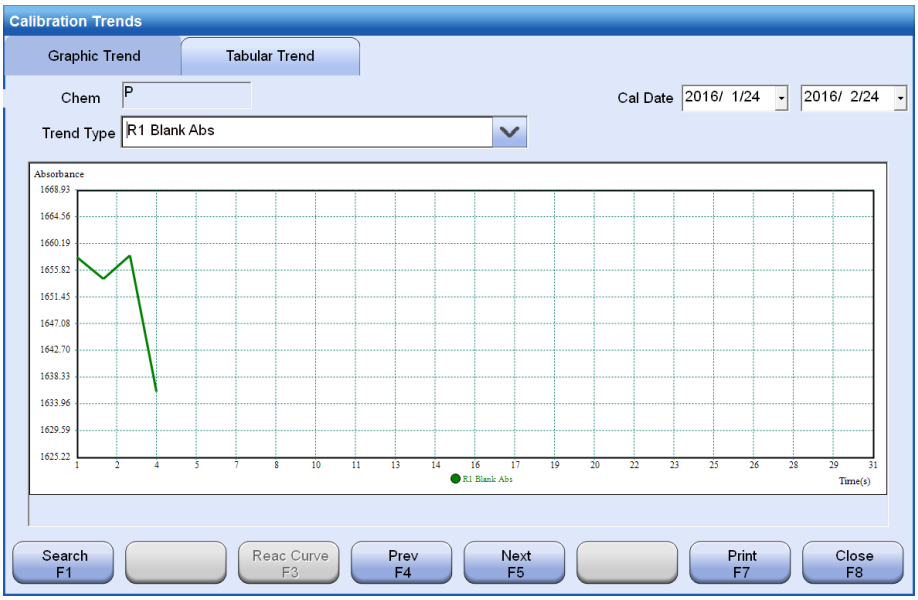
To observe calibration trends

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 4.18 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 4.19 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.

5 QC

This chapter describes QC setup and QC result processing.

5.1 Overview

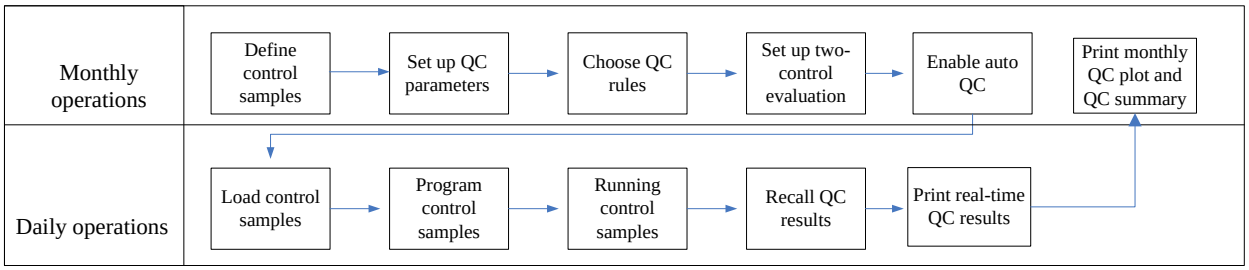
QC test is performed on samples provided with known concentration range of various analytes by authority divisions or reagent suppliers. By comparing with the given range, the test results obtained on this instrument can be used to judge if the instrument is in normal status and the sample results are 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 11.4Data alarms on page 11-7.

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.

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

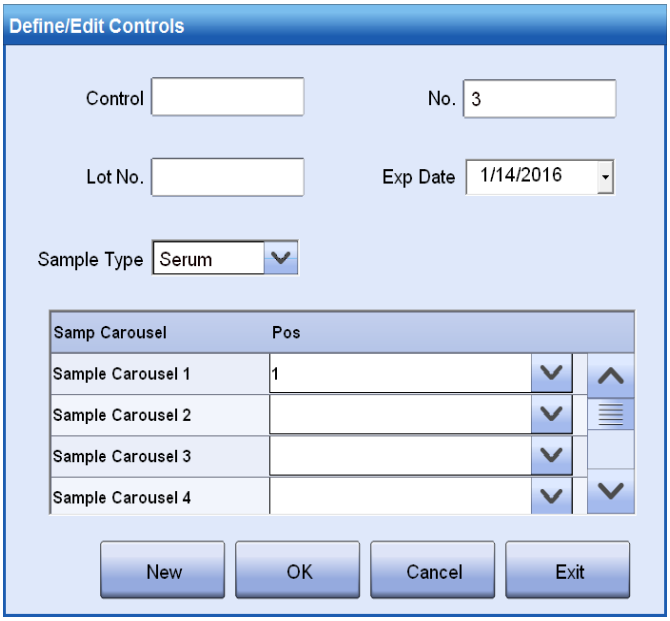
The system allows the definition of up to 99 controls. You are required to enter the control name and sample type. The combination of control name and lot number must not be duplicate and should be unique. If a control has no lot number, you are not allowed to define another control with the same name.

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

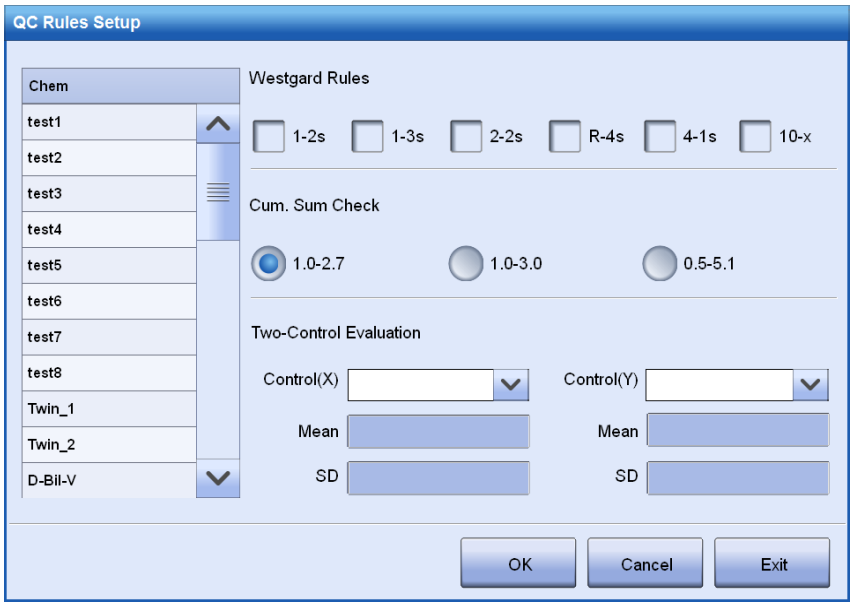
You should set up the control rules after defining a control and determining concentrations for it. The controls without QC rule can still be programmed and analyzed but will not be monitored for error detection.

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.

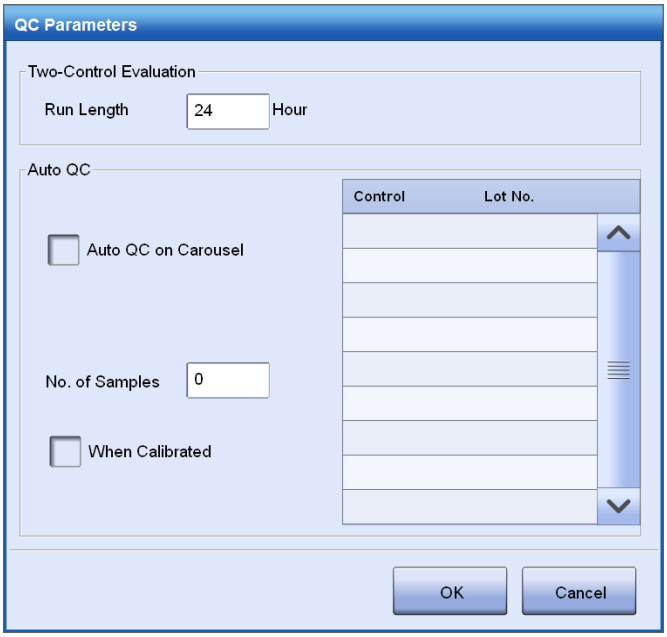
To set up and run auto QC

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Choose **9 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:

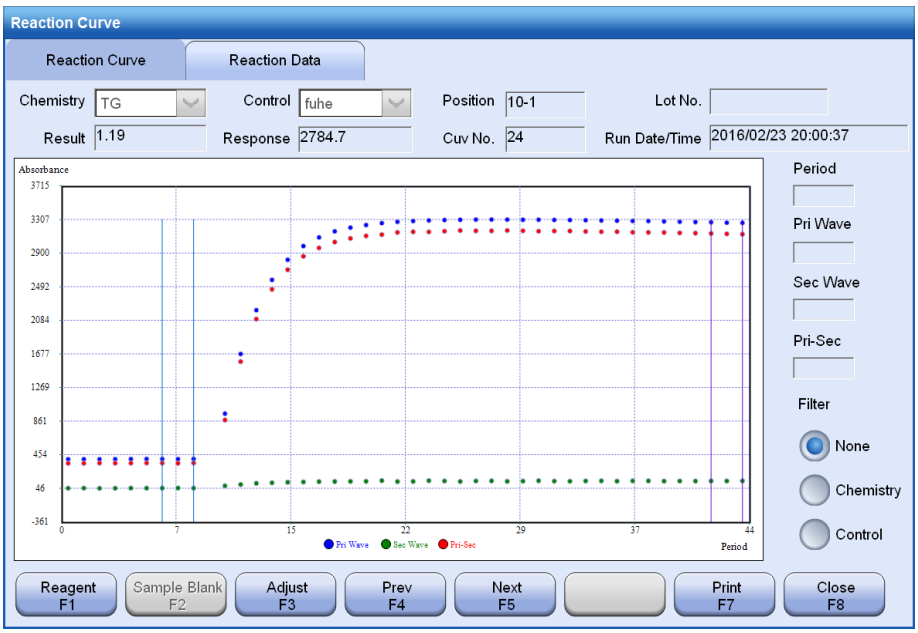
- **Search F1**: to recall control results.
- **Options F2**: to delete or archive control samples.
- **Reac Curve F4**: to view reaction curve of the selected QC test.
- **Print F7**: to print control results.
- **Host F8**: to transmit the selected control results to the LIS host.

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.

Figure 5.6 Reaction Data screen

Period	Pri Wave	Sec Wave	Pri-Sec	Period	Pri Wave	Sec Wave	Pri-Sec
1	399.52	48.10	351.43	2	400.23	49.30	350.93
3	400.05	46.38	353.67	4	400.76	48.10	352.66
5	402.17	49.13	353.04	6	403.23	48.79	354.44
7	402.87	49.47	353.40	8	401.64	50.33	351.31
9	403.76	49.13	354.63	11	953.06	76.98	876.08
12	1677.41	93.19	1584.22	13	2208.41	107.86	2100.55
14	2575.92	114.43	2461.49	15	2820.23	121.18	2699.05
16	2985.97	123.95	2862.02	17	3091.77	128.11	2963.66
18	3164.87	129.67	3035.21	19	3210.30	131.40	3078.90
20	3241.53	132.09	3109.44	21	3265.03	140.07	3124.96
22	3280.73	128.80	3151.93	23	3290.07	130.88	3159.19
24	3297.45	139.38	3158.07	25	3301.88	135.56	3166.32

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 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.

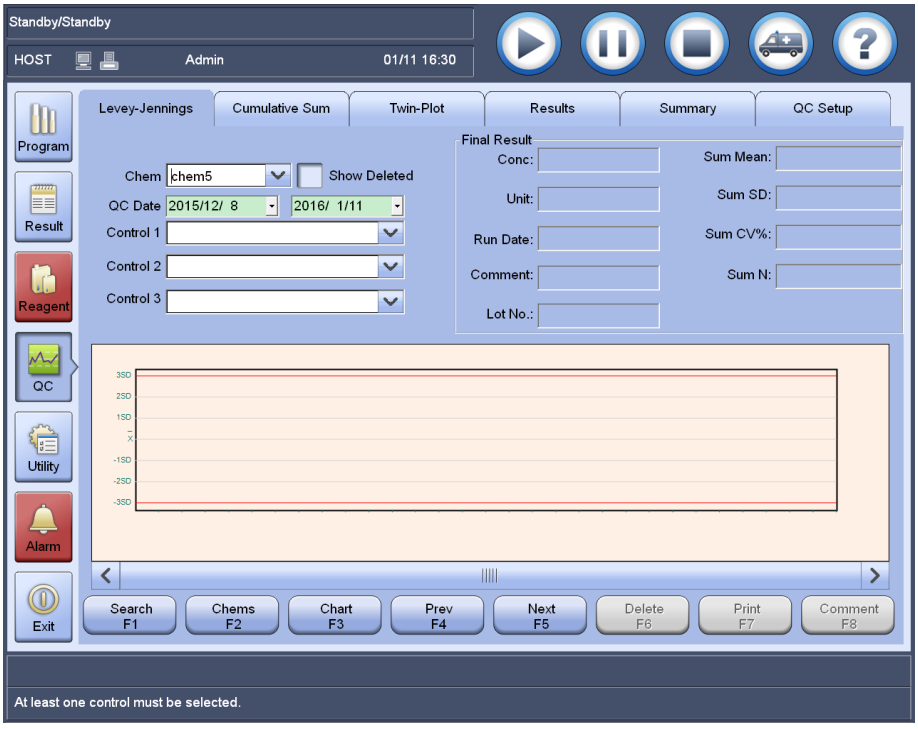
3 Choose a chemistry to recall in the **Chem** drop-down list, or select **Chems F2** and then choose a chemistry.

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 5.7 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**.

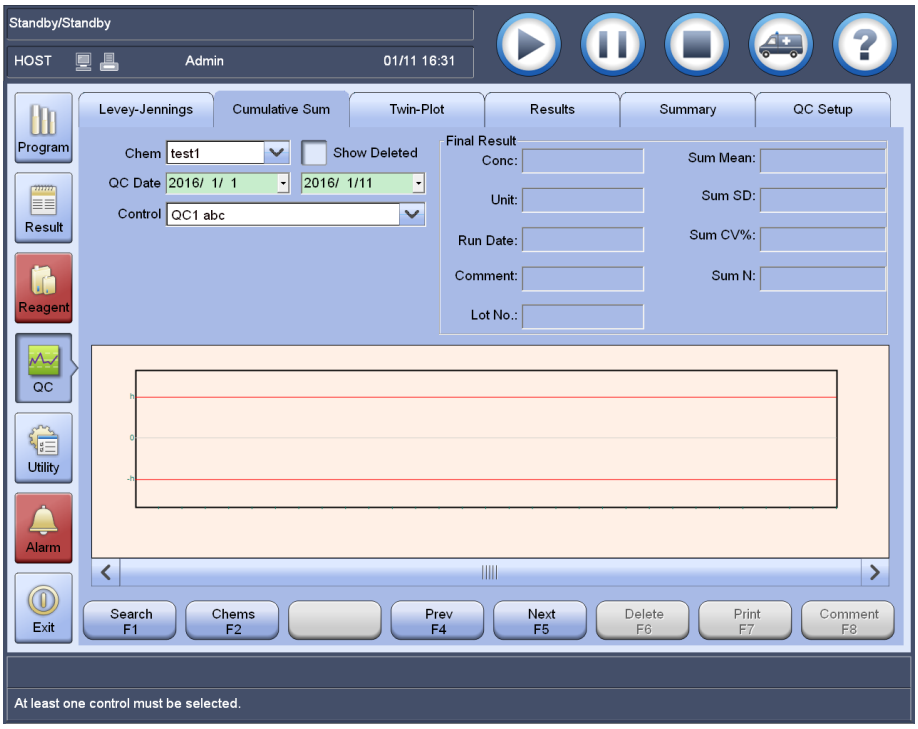
2 Choose a chemistry to recall in the **Chem** drop-down list, or select **Chems F2** and then choose a chemistry.

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 5.8 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

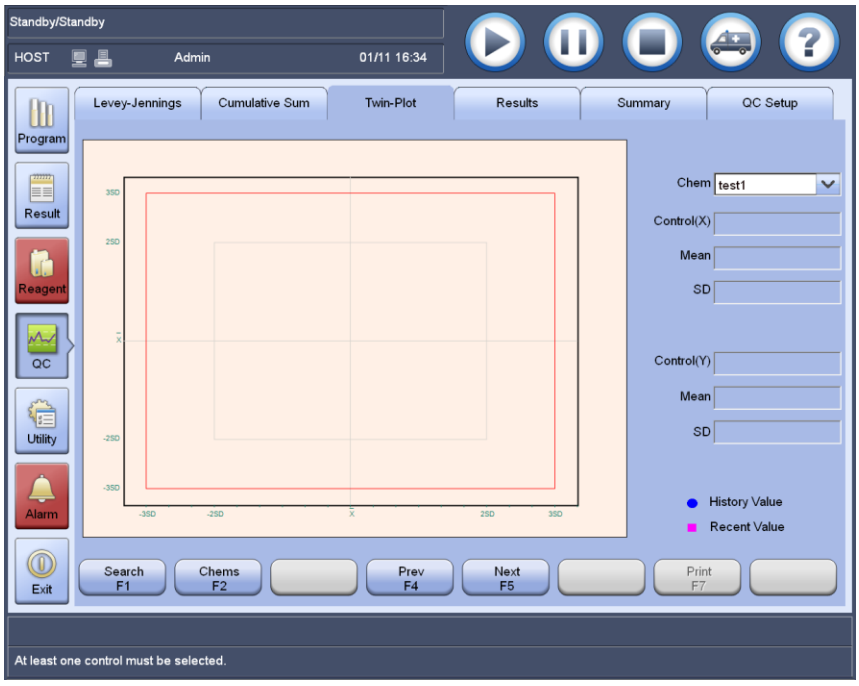
5.3.4 Recalling Twin-Plot chart

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 5.9 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**.

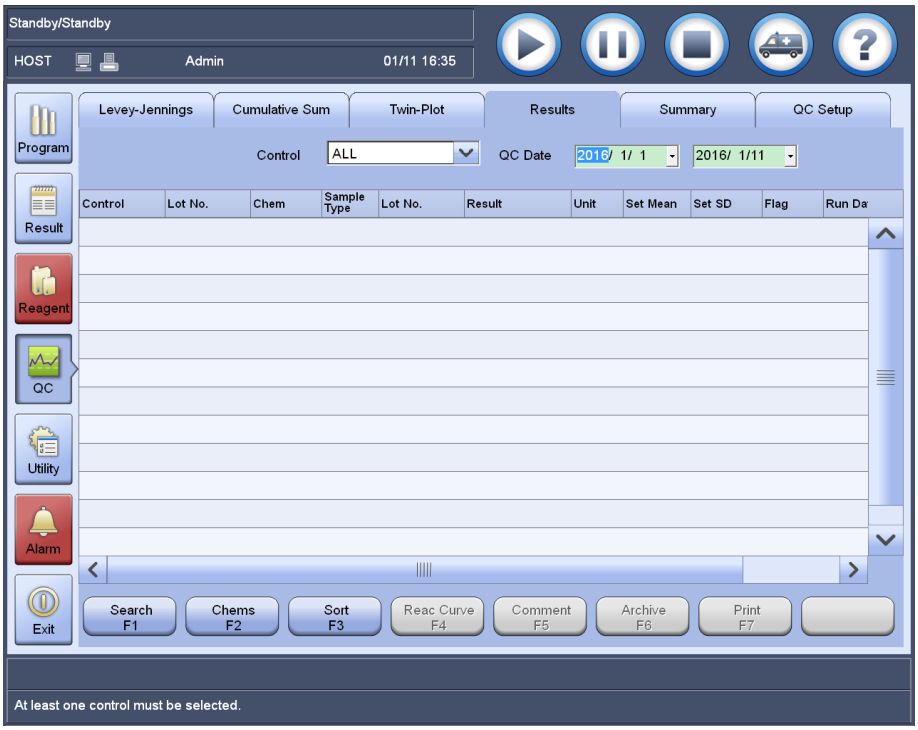
4 Select the date range in the **QC Date** field.

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 5.10 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 5.11 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.

Figure 5.12 Control 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**.

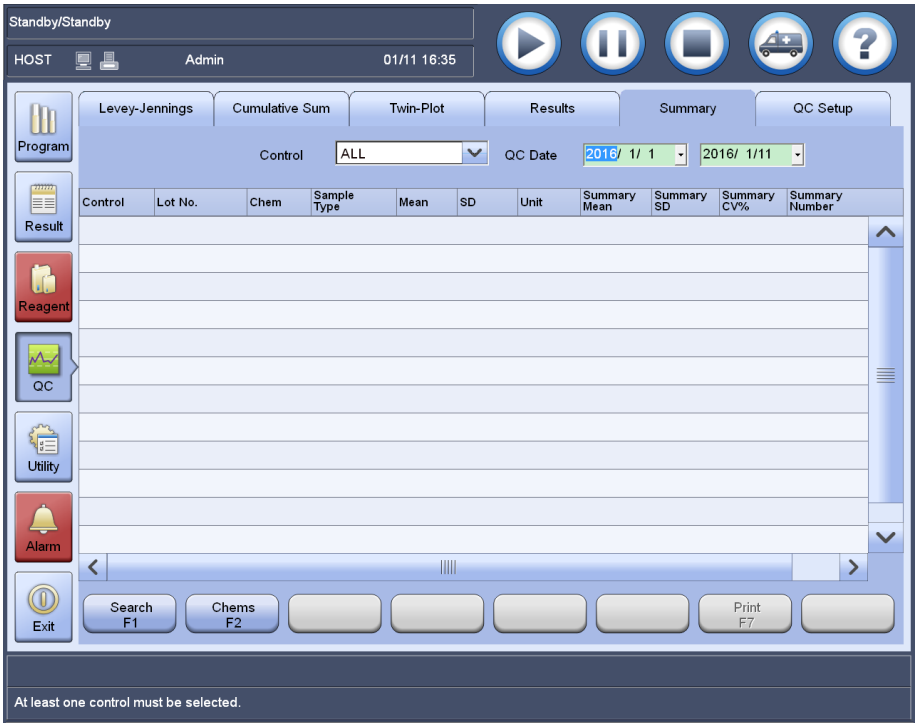
4 Select the date range in the **QC Date** field.

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 5.13 Summary screen



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

6 Program

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.

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 2-45 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. Restore the sample carousel.

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. Restore the sample carousel.

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.

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 7-26.

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" (Page 2-23).

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" (Page 2-23).

2 Place bar-coded samples sequentially on the sample carousel.

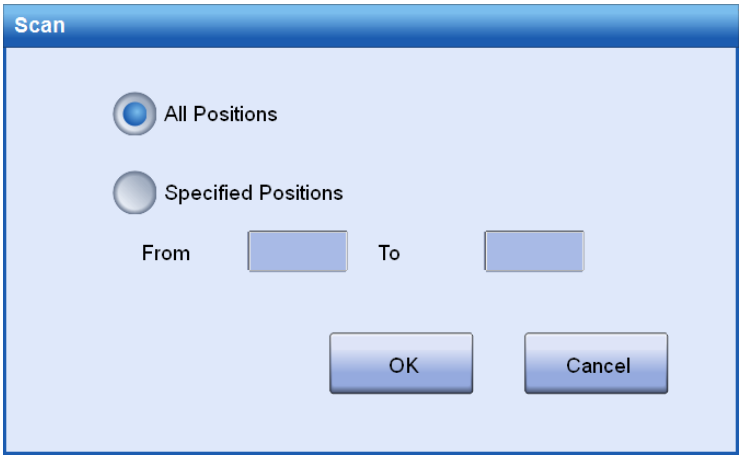
If the auto numbering feature is enabled, the system will automatically number the samples according to the order in which they have been placed. The start number will be the next available one since the last sample is programmed.

For auto numbering of bar-coded samples, see 8.5 Bar code setup on page 8-16.

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.

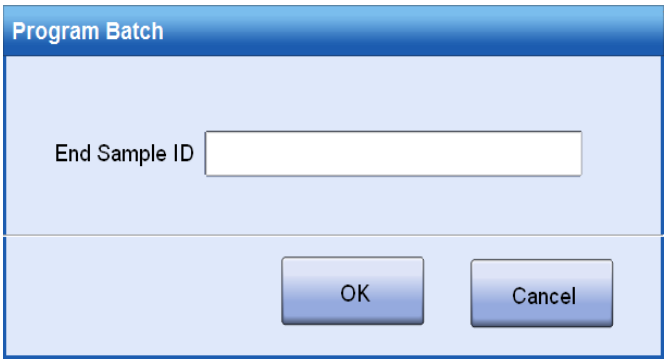
5 Choose desired chemistries.

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 (page 2-23).

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 (page 2-23).

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

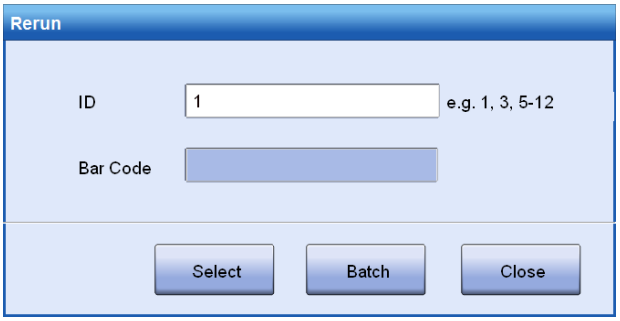
The **List** > **Rerun** window allows you to manually rerun single or multiple samples that are in Complete, Incomplete, Rerun or In Progress status.

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**.

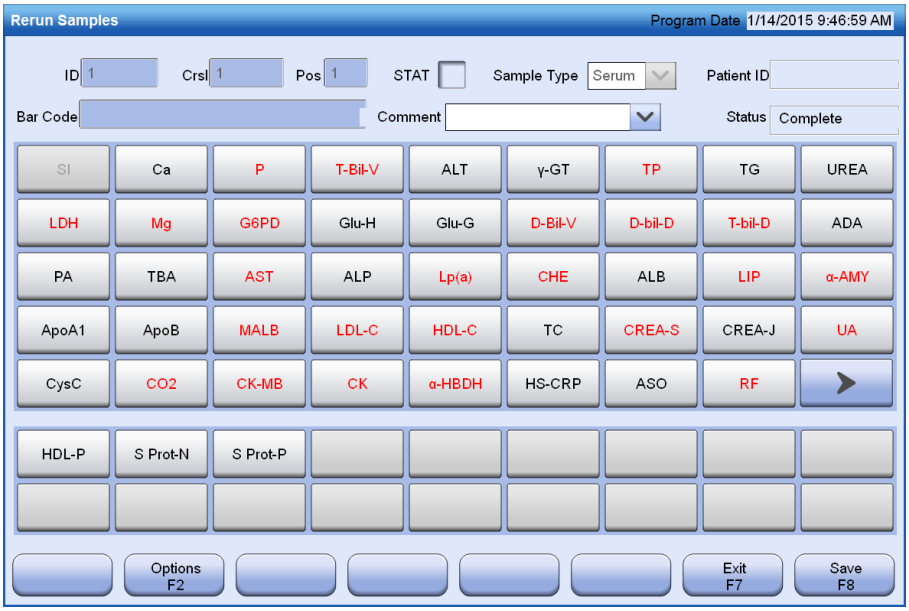
Figure 6.3 Rerun window



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**.

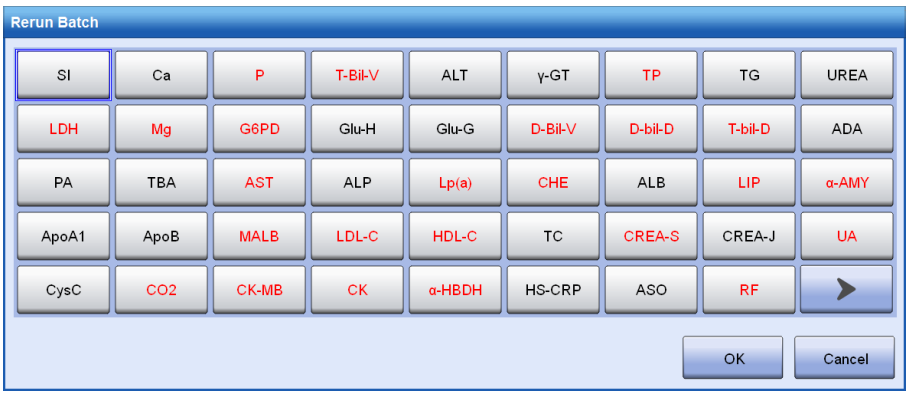
2 Select **Rerun F4**.

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

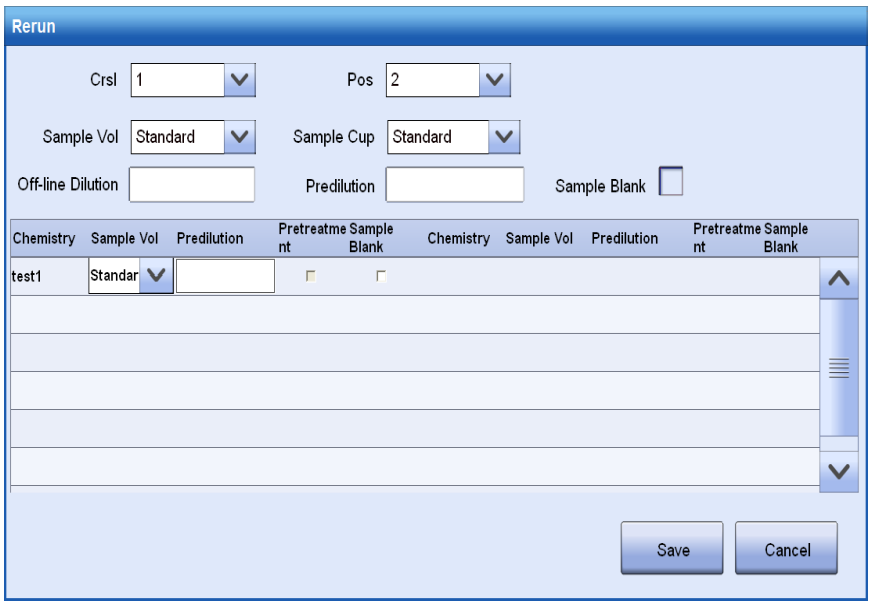
1 Select **Result > Current** or **History**, and choose the **By Sample** option.

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 (2-45)
- Sample cup
- Off-line dilution factor (2-9999)
- Predilution factor (4-126)
- Sample blank

6 Modify the following information for single chemistry:
- Sample volume (2-45)
- Predilution factor (4-126)
- 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

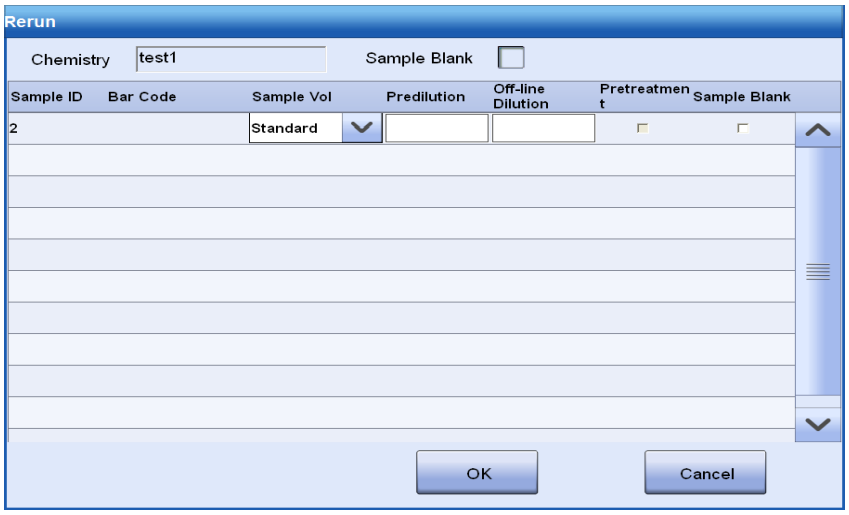
1 Select **Result > Current Results** or **History Results**, and choose the **By Chemistry** option.

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 (2-45)
- Predilution factor (4-126
- Off-line dilution factor (2-9999)
- 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

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**.

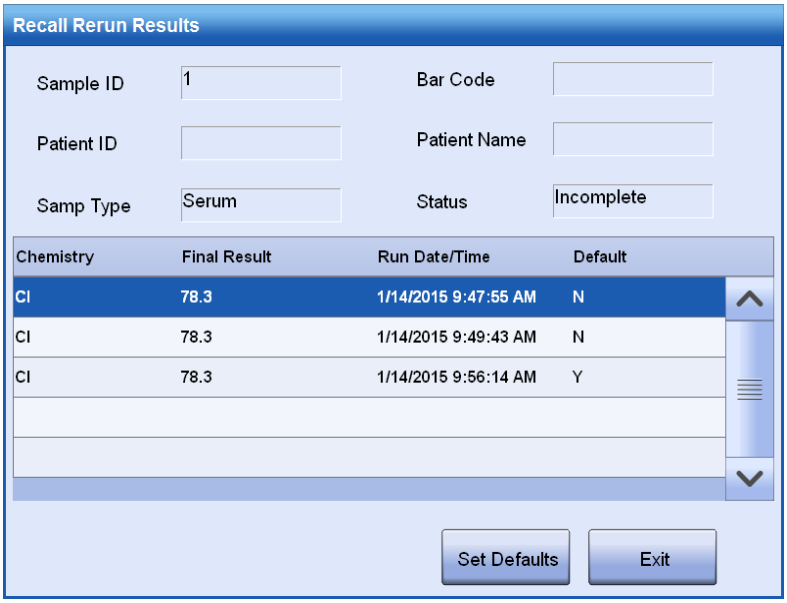
2 Search for desired sample results.

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. 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**.

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 7-10.

For instructions of loading pretreatment reagent, see Loading pretreatment reagent on page 2-16.

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

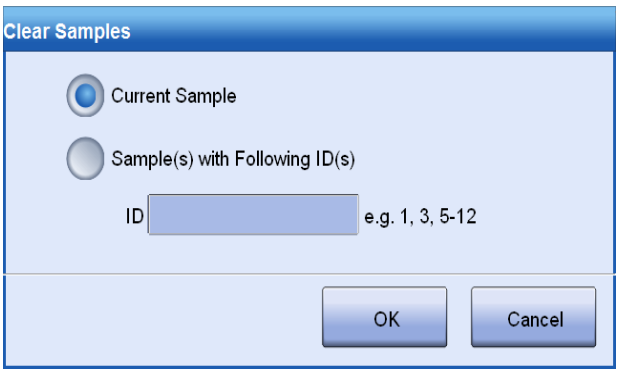
The Clear Samples function is used to delete programmed samples that have not been analyzed. One or more samples can be cleared at one time. When samples are cleared, the sample information will be removed completely; the sample ID, position and bar code can be used for programming other samples. The 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 6.9 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 6-17.

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 6-7.

To view programmed samples

1 Select **Program > Sample**.

2 Select **List F5**.

Figure 6.10 Sample List tab page

3 Move the scroll bar to view more samples.

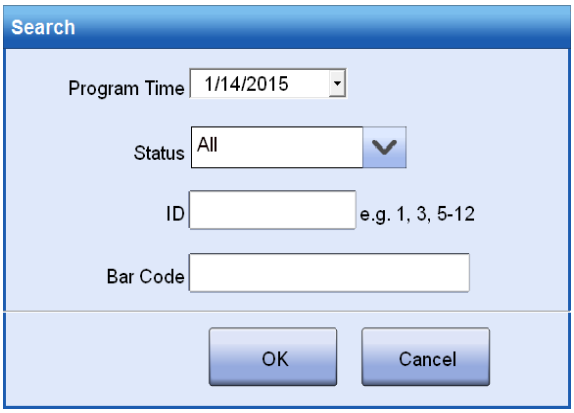
4 To print the sample list, select **Print F7**.

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 6.11 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 6-7.

To view chemistry list

1 Select **Program > Sample**.

2 Select **List F5**.

3 Select the **Chemistry List** tab.

Figure 6.12 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**.

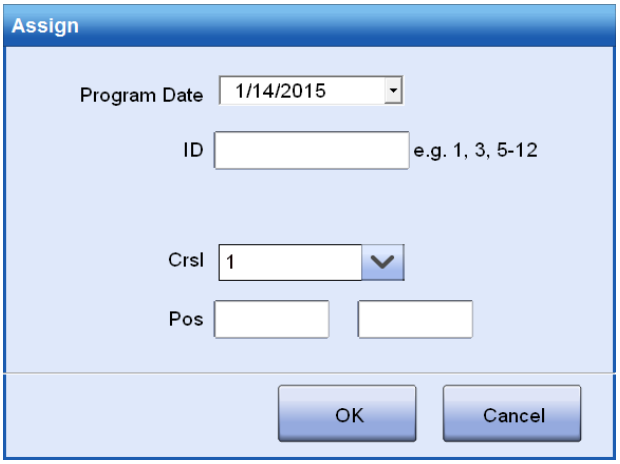
Figure 6.13 Unpositioned Samples window

4 Move the scroll bar to view more samples.

To assign positions and perform test

1 Select **Assign** on the **Unpositioned Samples** window.

Figure 6.14 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.

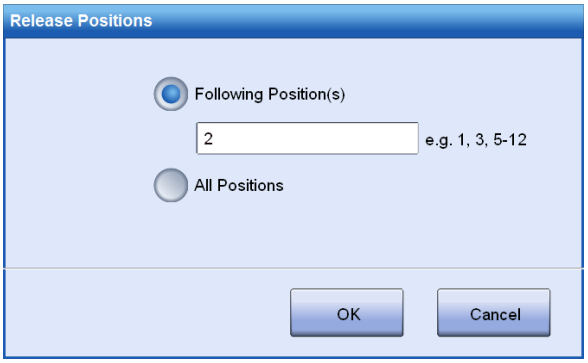
To manually release sample positions

1 Select **Program > Status**.

2 Choose a sample carousel to release samples.

3 Select **Release F3**.

Figure 6.15 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 6.16 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.

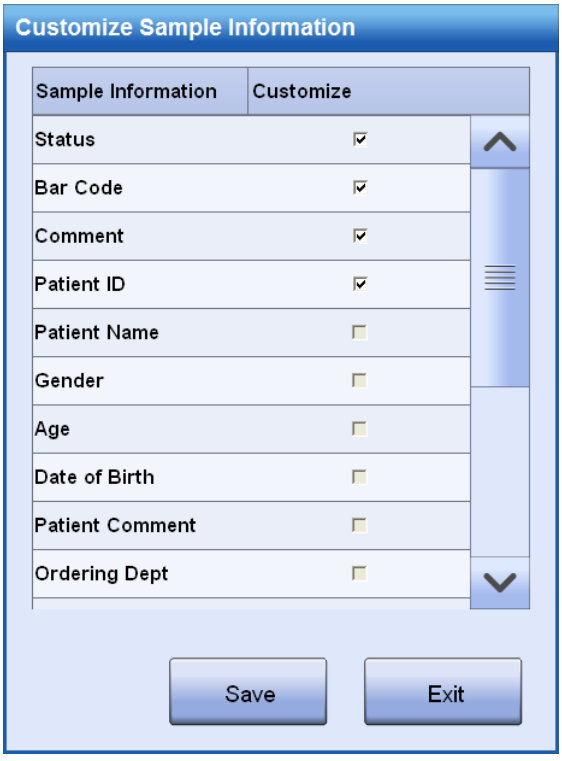
To customize sample information

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Cust. Sample Info**.

Figure 6.17 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.

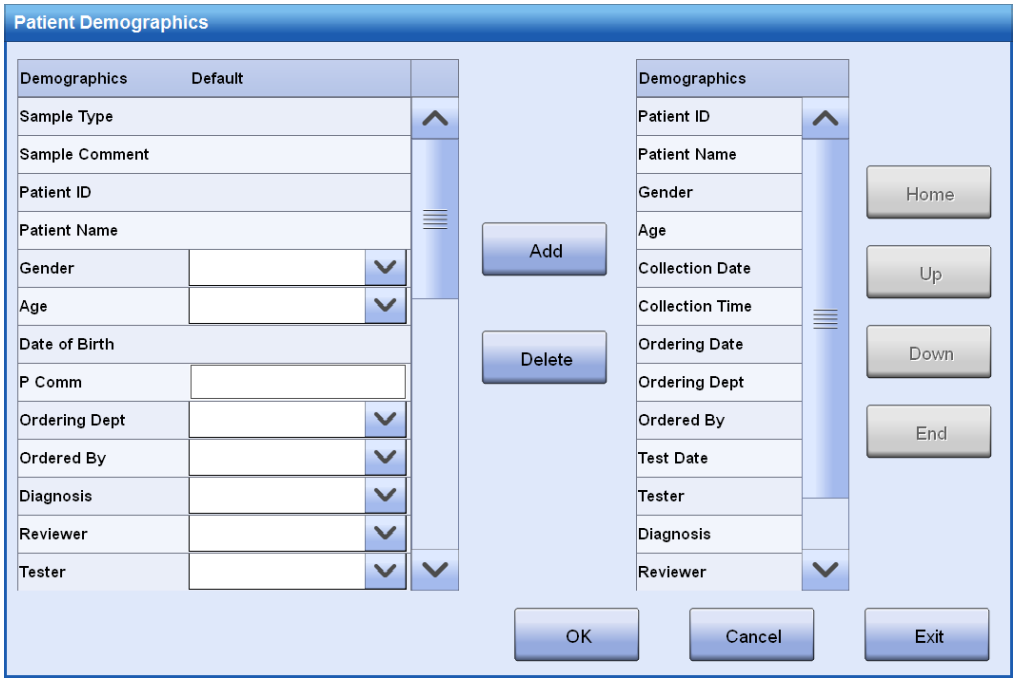
To customize patient demographics

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Patient Demographics**.

Figure 6.18 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.

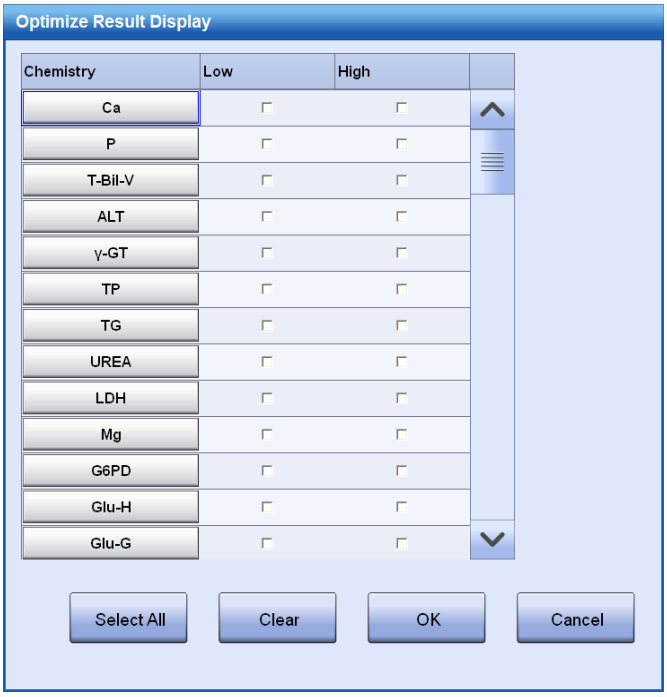
To optimize result display

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Optimize Result Display**.

Figure 6.19 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.

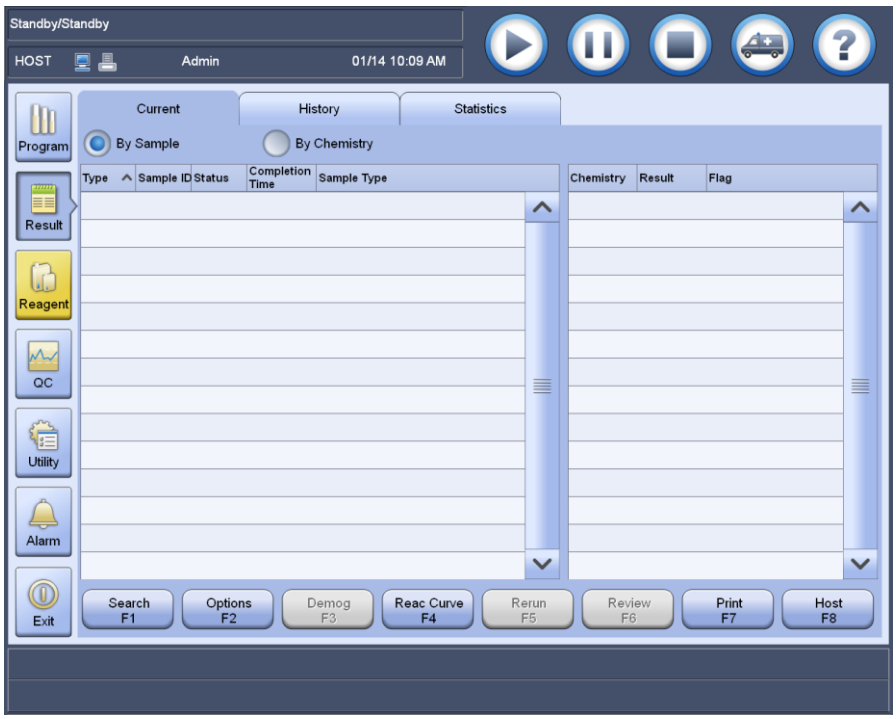
6.4.1 Viewing current results

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 6.20 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:

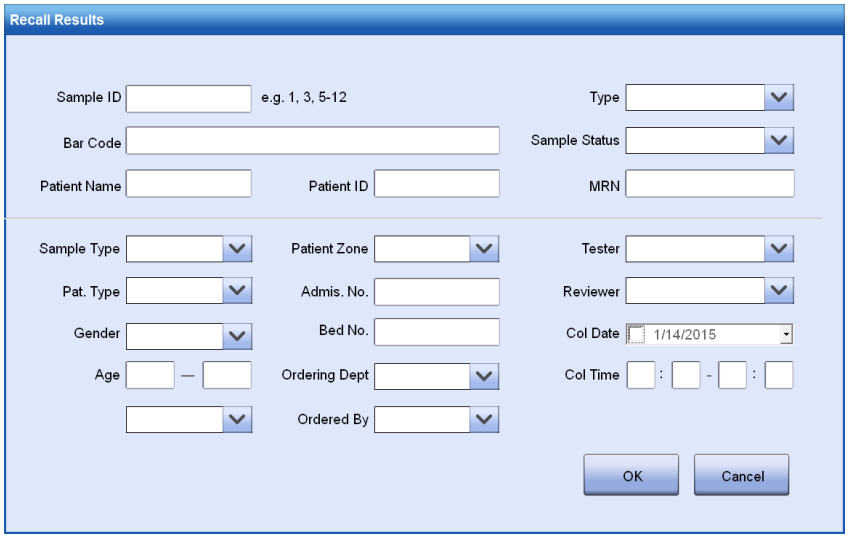
- **Search F1**: to inquire sample results.
- **Options F2**: to delete, edit and print samples, recall rerun results, customize result display options, recalculate results, compensate results, archive results, and observe result trend.
- **Demog F3**: to view patient demographics of the sample.
- **Reac 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 6.21 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.

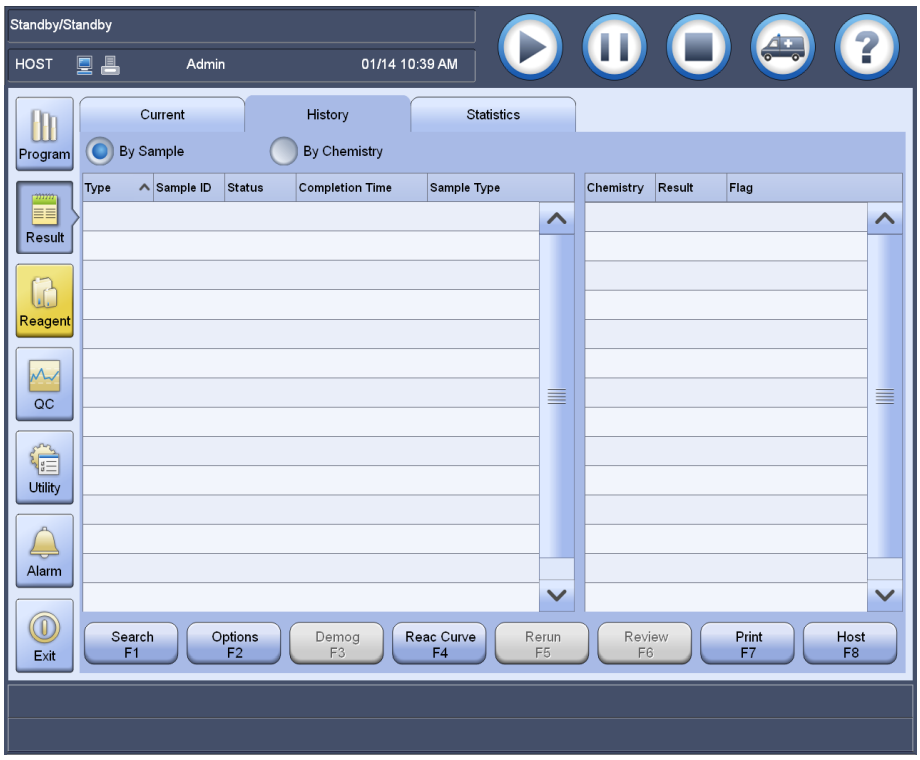
6.4.2 Viewing history results

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 6.22 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:

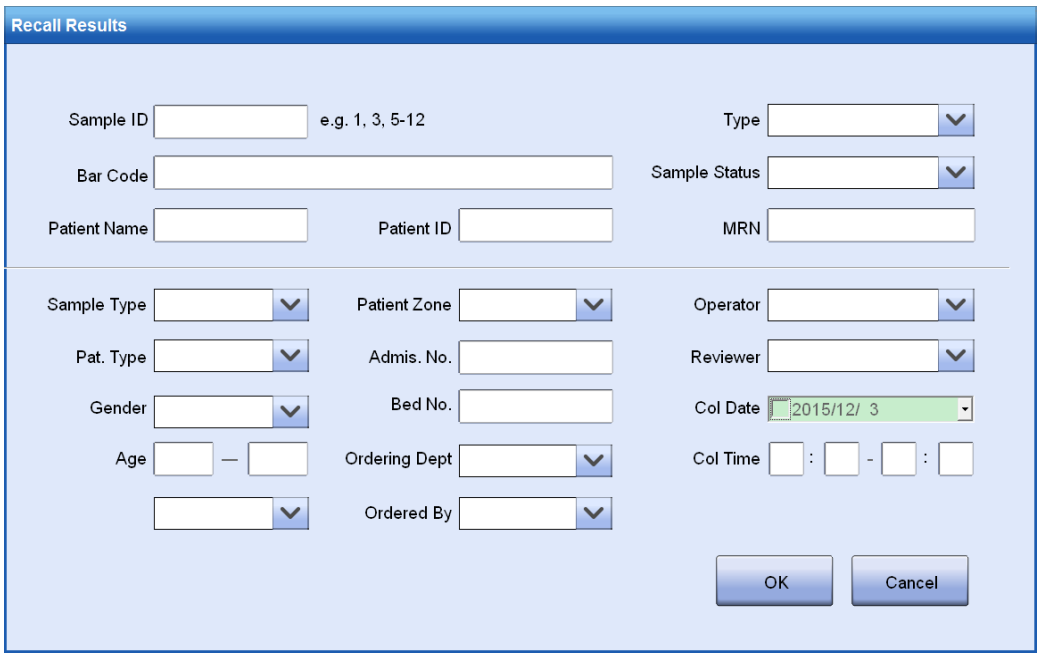
- **Options F2**: to delete, edit and print samples, recall rerun results, customize result display options, compensate results, archive results, and observe result trend.
- **Demog F3**: to view patient demographics of the sample.
- **Reac Curve F4**: to view the reaction curve and data of the selected 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 6.23 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

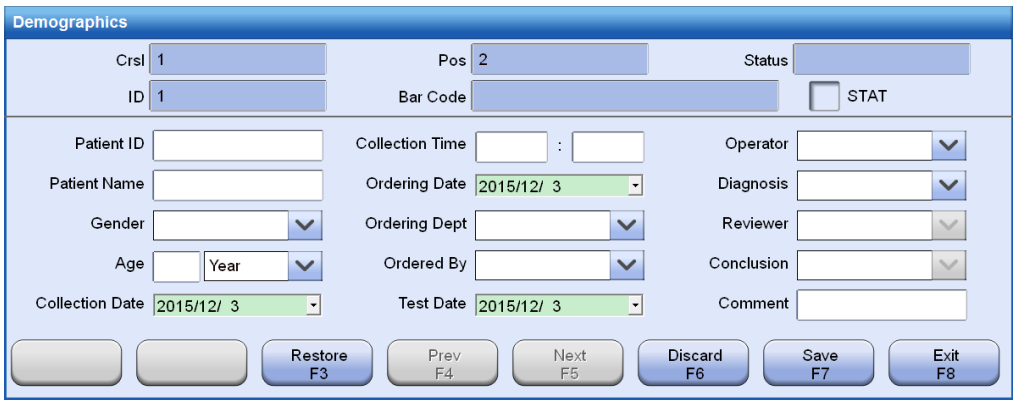
1 Select **Result > Current** or **History**.

2 Choose the **By Sample** option.

3 Choose a sample in the sample list.

4 Select **Demog F3**.

Figure 6.24 Demographics window



Patient demographics can be customized. For more information, see 6.3.7Customizing patient demographics on page 6-21.

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.

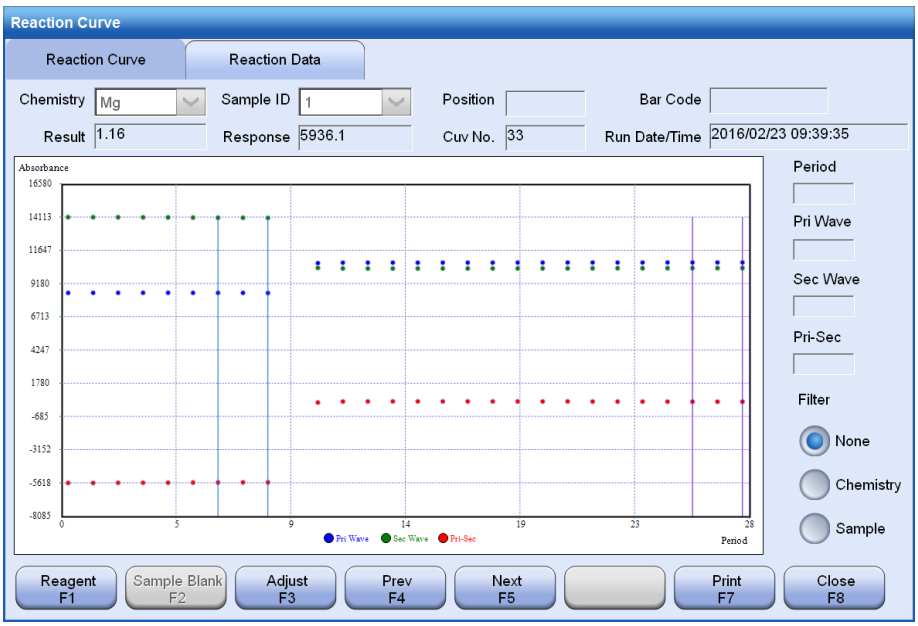
2 Choose a result recall mode:

- By sample
- By chemistry

3 Choose desired result in the result list.

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

Figure 6.25 Sample reaction curve



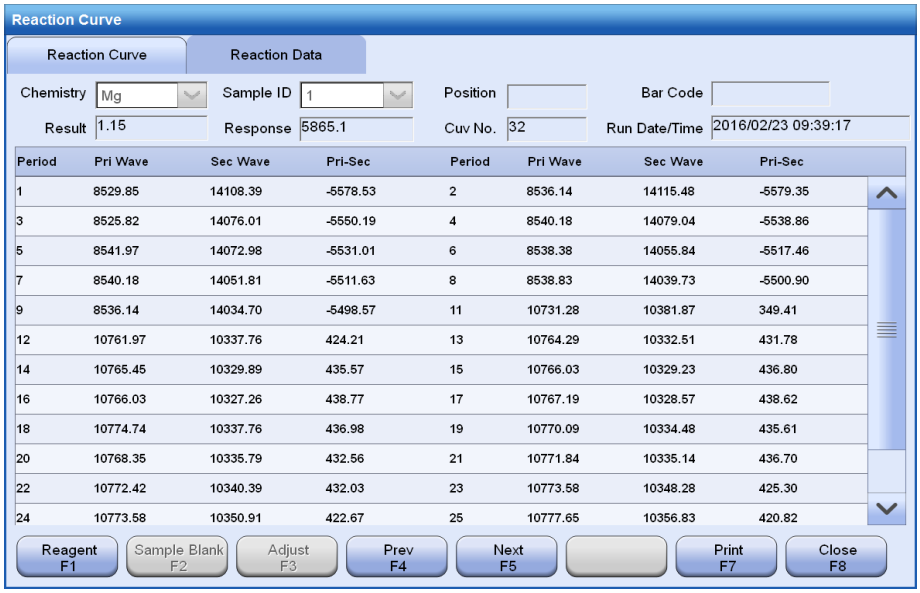
5 Select a point on the curve. Relevant measuring period and absorbance are displayed on the right of the window.

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 6.26 Sample reaction data



Period	Pri Wave	Sec Wave	Pri-Sec	Period	Pri Wave	Sec Wave	Pri-Sec
1	8529.85	14108.39	-5578.53	2	8536.14	14115.48	-5579.35
3	8525.82	14076.01	-5550.19	4	8540.18	14079.04	-5538.86
5	8541.97	14072.98	-5531.01	6	8538.38	14055.84	-5517.46
7	8540.18	14051.81	-5511.63	8	8538.83	14039.73	-5500.90
9	8536.14	14034.70	-5498.57	11	10731.28	10381.87	349.41
12	10761.97	10337.76	424.21	13	10764.29	10332.51	431.78
14	10765.45	10329.89	435.57	15	10766.03	10329.23	436.80
16	10766.03	10327.26	438.77	17	10767.19	10328.57	438.62
18	10774.74	10337.76	436.98	19	10770.09	10334.48	435.61
20	10768.35	10335.79	432.56	21	10771.84	10335.14	436.70
22	10772.42	10340.39	432.03	23	10773.58	10348.28	425.30
24	10773.58	10350.91	422.67	25	10777.65	10356.83	420.82

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.

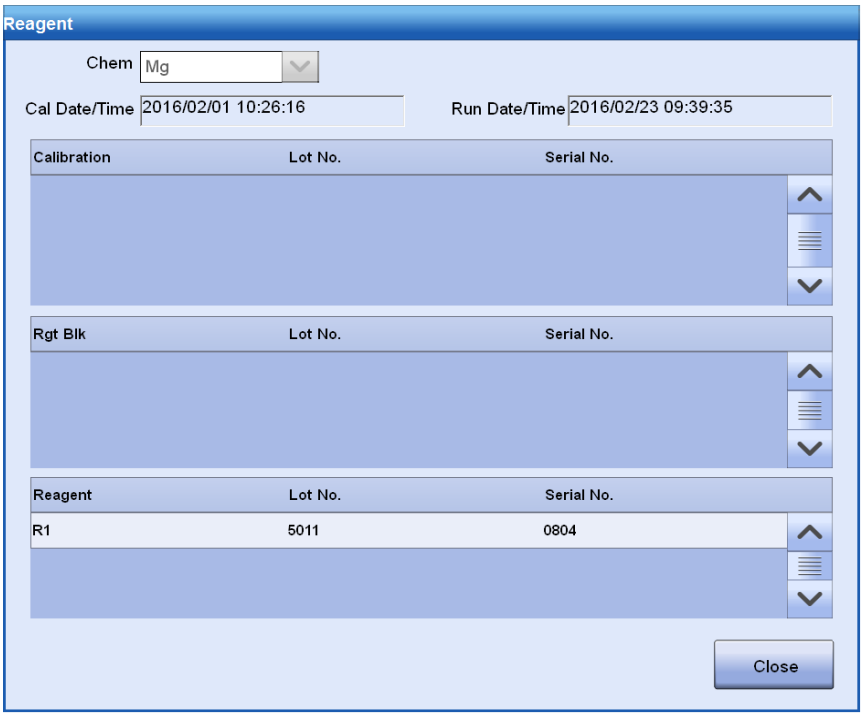
Viewing reagent information

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 6.27 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.

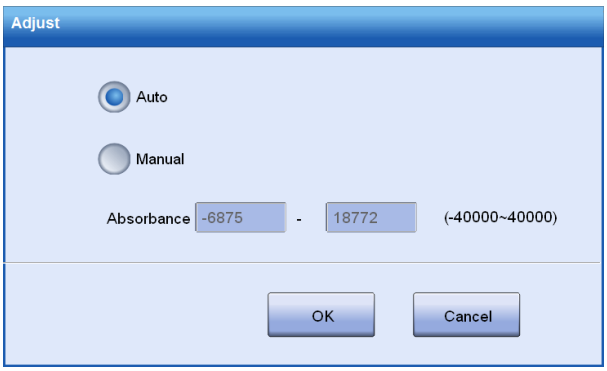
Adjusting display range

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 6.28 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.

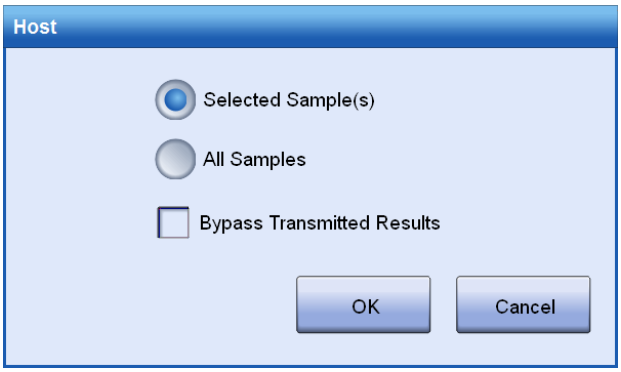
2 Choose the **By Sample** option.

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 6.29 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.

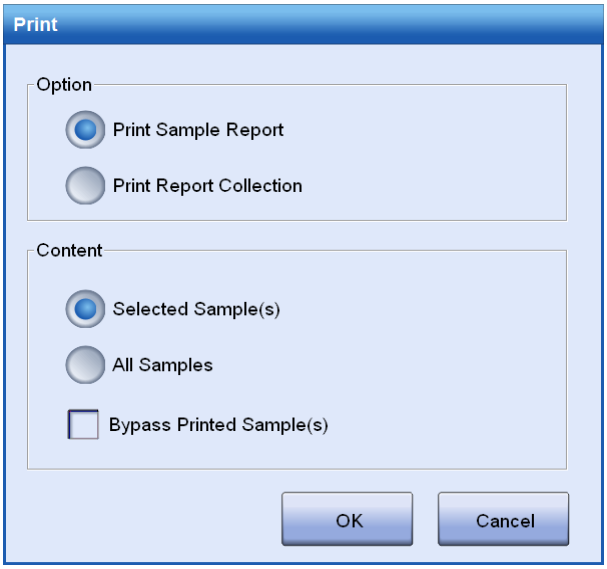
Printing results by sample

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 6.30 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

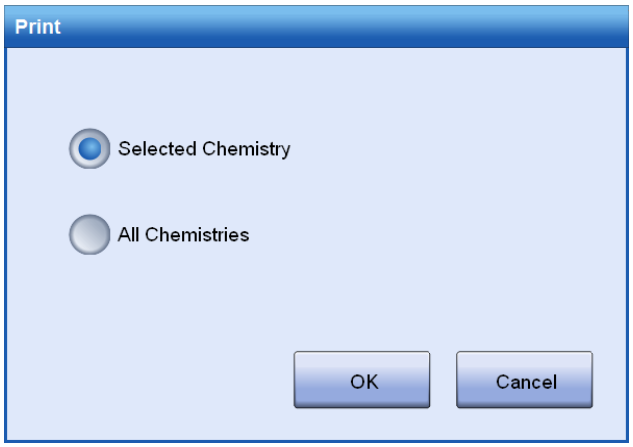
You can print test results of one or more chemistries when they are recalled by chemistries.

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 6.31 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 6.32 Edit Results window – By sample (Current results)

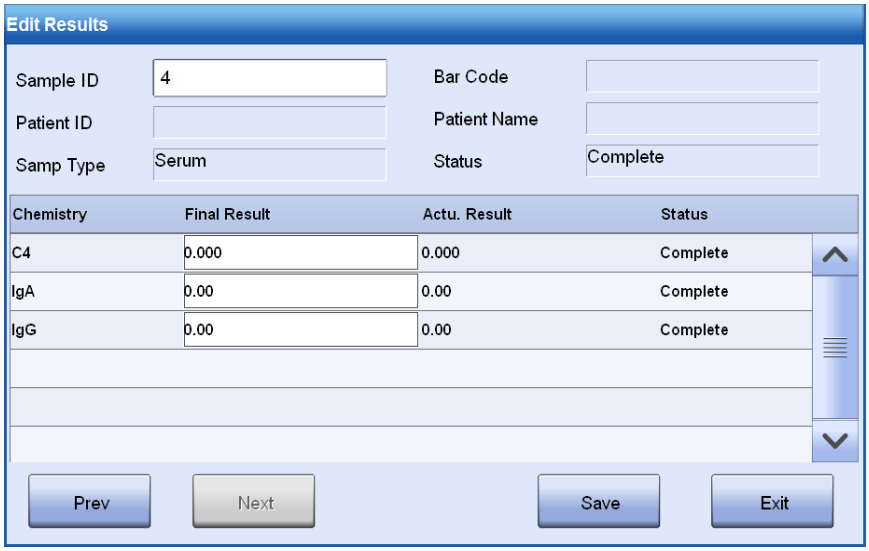


Figure 6.33 Edit Results window – By sample(History results)

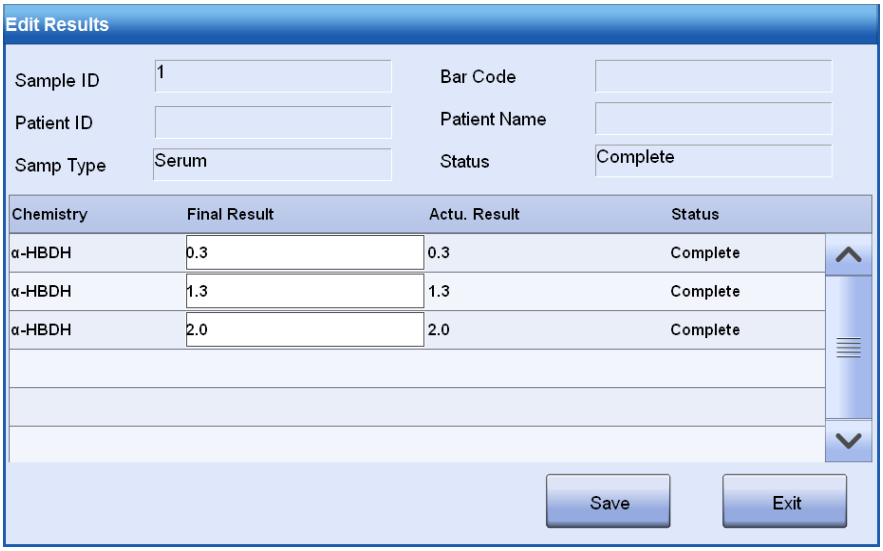


Figure 6.34 Edit Results window – By chemistry

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:

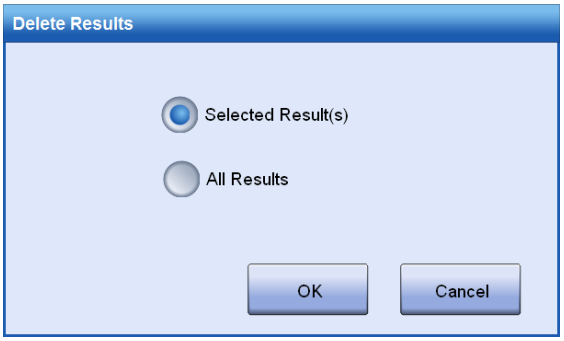
- By sample
- By chemistry

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 6.35 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 6.36 Customize Result Display window – By sample

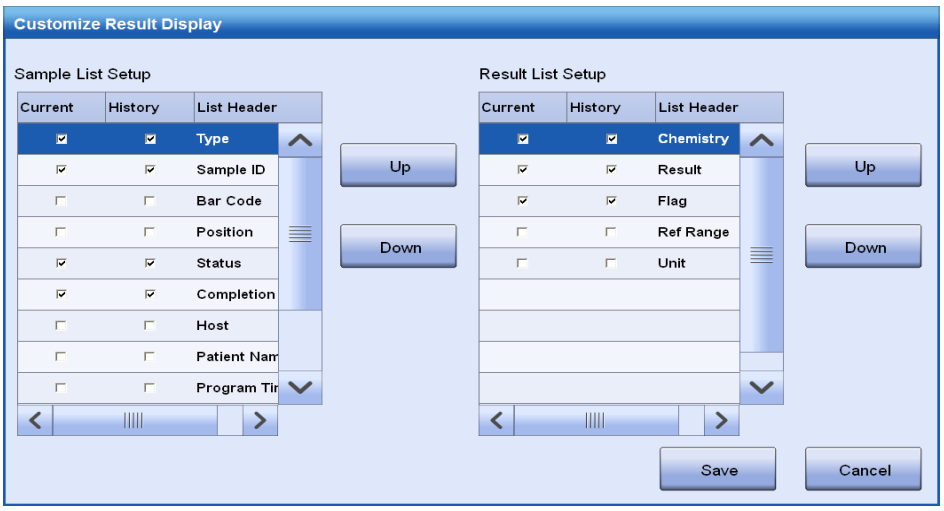
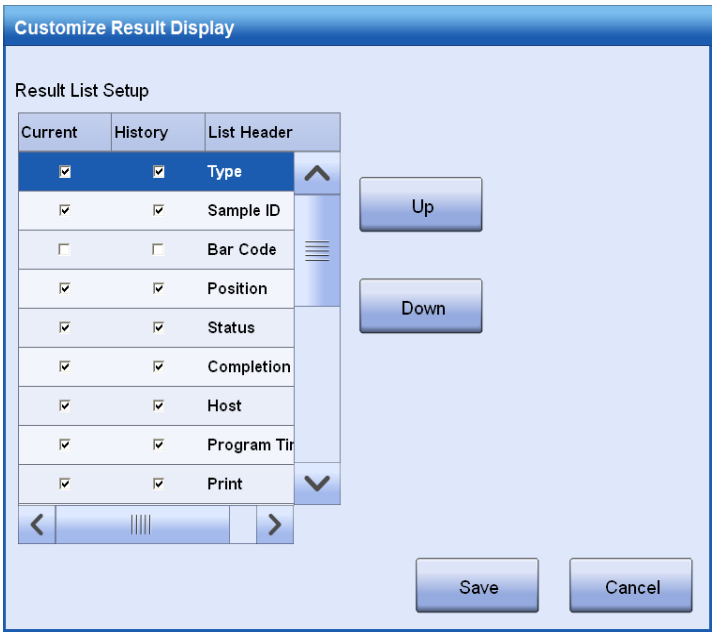


Figure 6.37 Customize Result Display window – By chemistry



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.

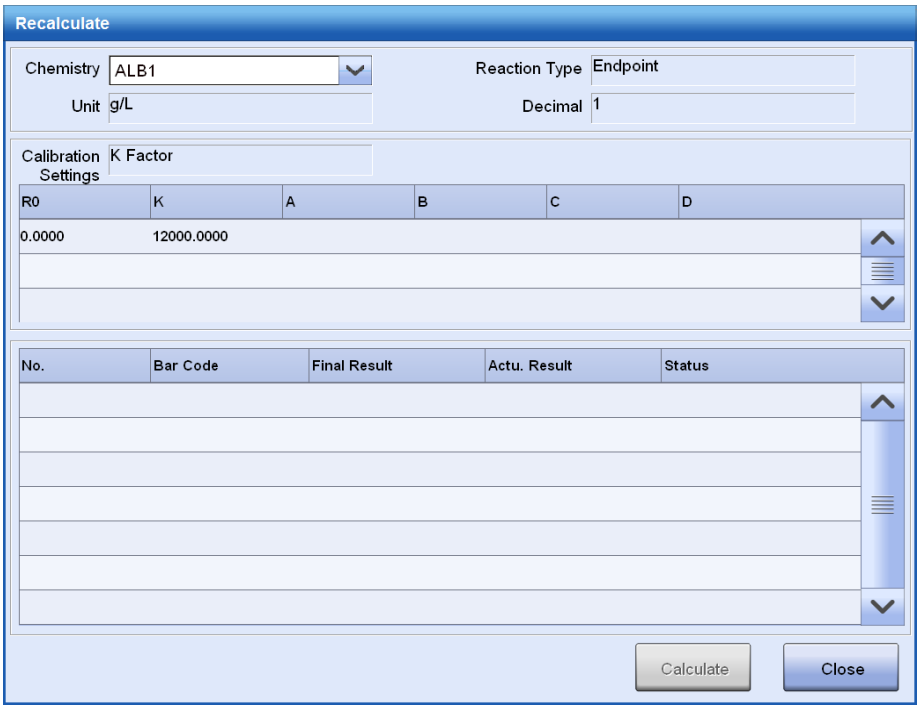
Recalculate Results is only applicable to biochemistries. Result of samples in In Progress status cannot be recalculated. The recalculation will be automatically recorded in event logs.

To recalculate results

1 Select **Result > Current**.

2 Select **Options F2**, and select **Recalculate**.

Figure 6.38 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

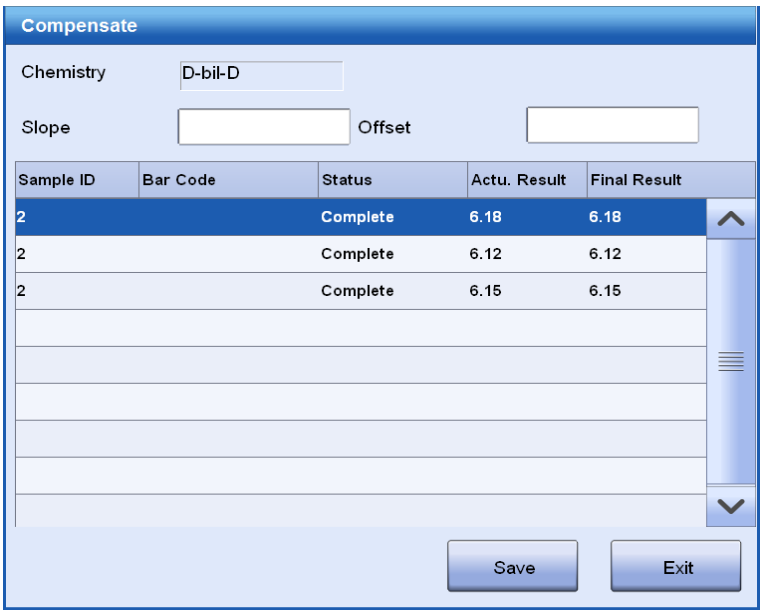
1 Select **Result > Current** or **History**.

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 6.39 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**.

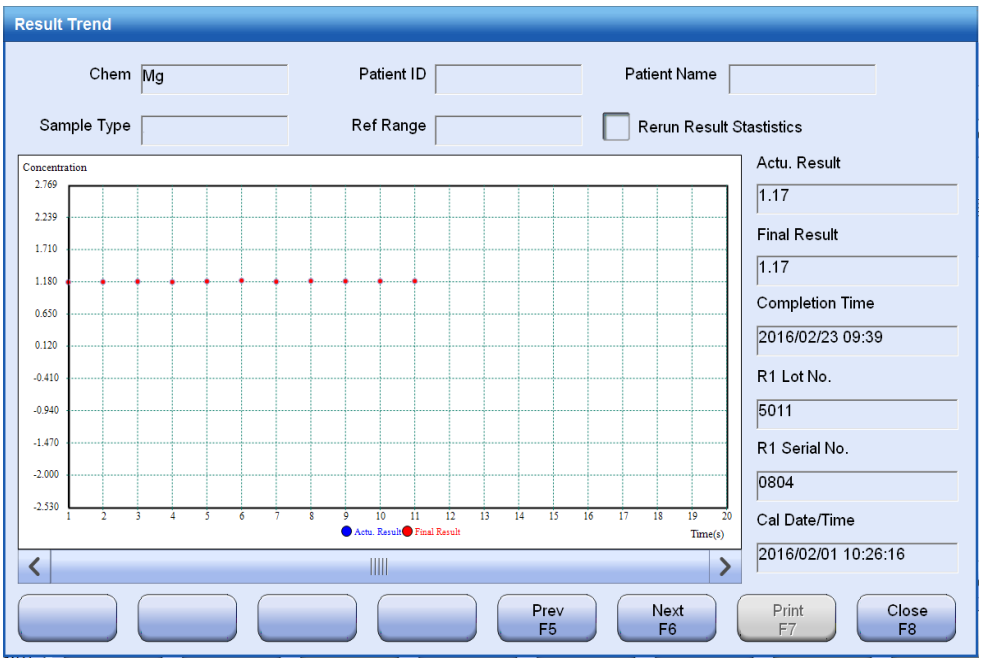
2 Choose the result recall mode - By chemistry.

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 6.40 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 6.41 Tests screen - By sample

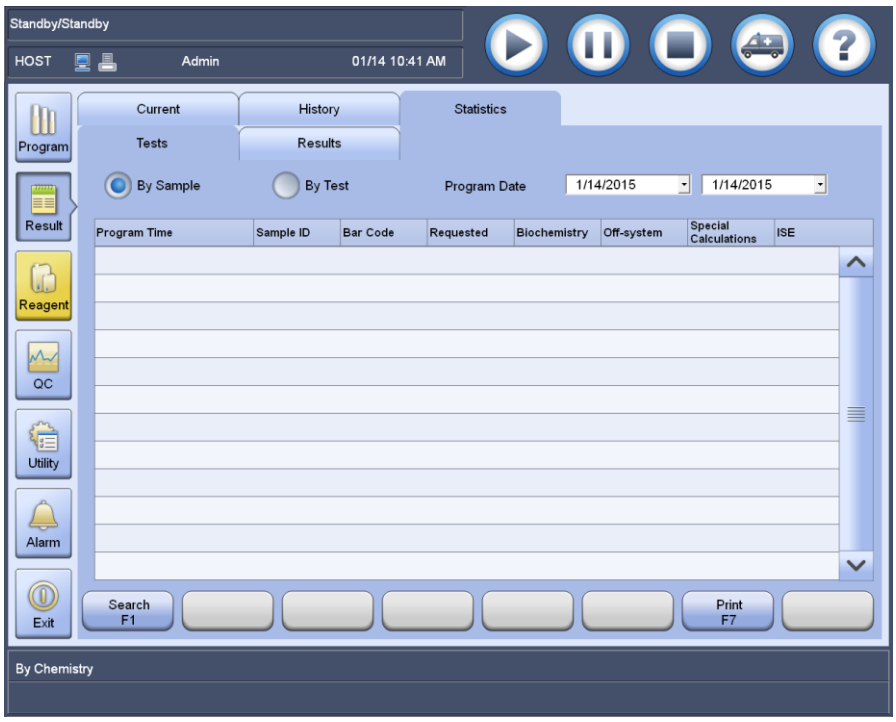
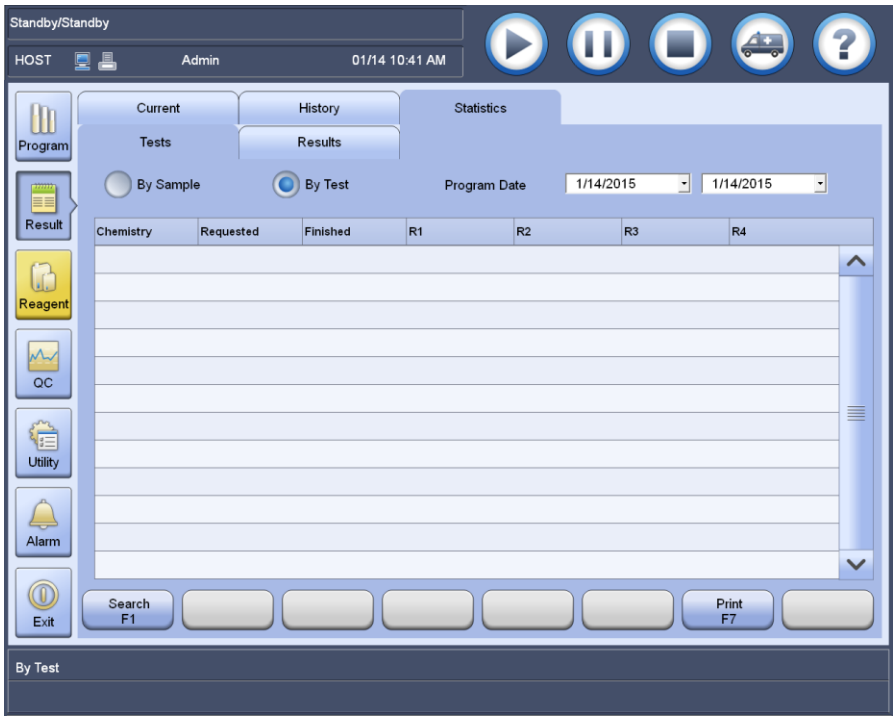


Figure 6.42 Tests screen - By test



- 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.

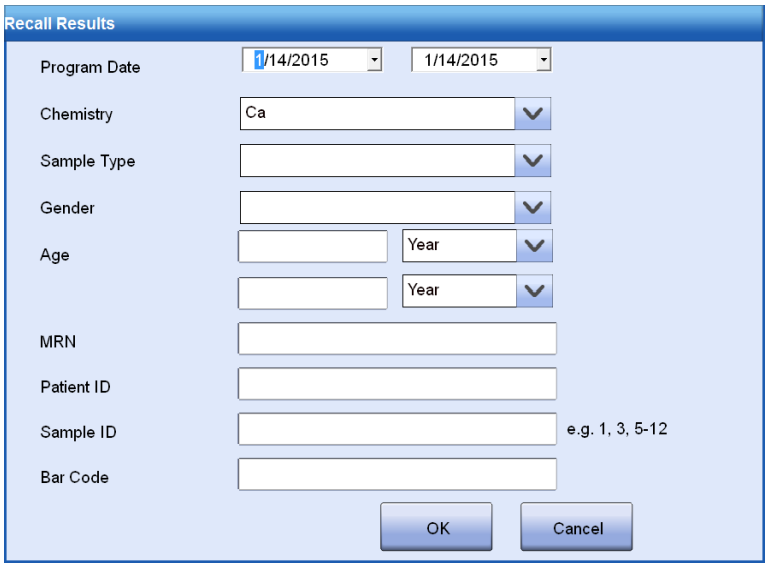
1 Select **Result > Statistics**.

2 Select the **Results**.

3 Select **Statistic Graph** or **Statistic Data**.

4 Click **Search F1**. The **Recall results** box pops up.

Figure 6.43 Recall results window



5 Input one or more search conditions.

6 Click **OK**.

The statistic results matching the search conditions are displayed.

Figure 6.44 Result statistics screen -statistic graph

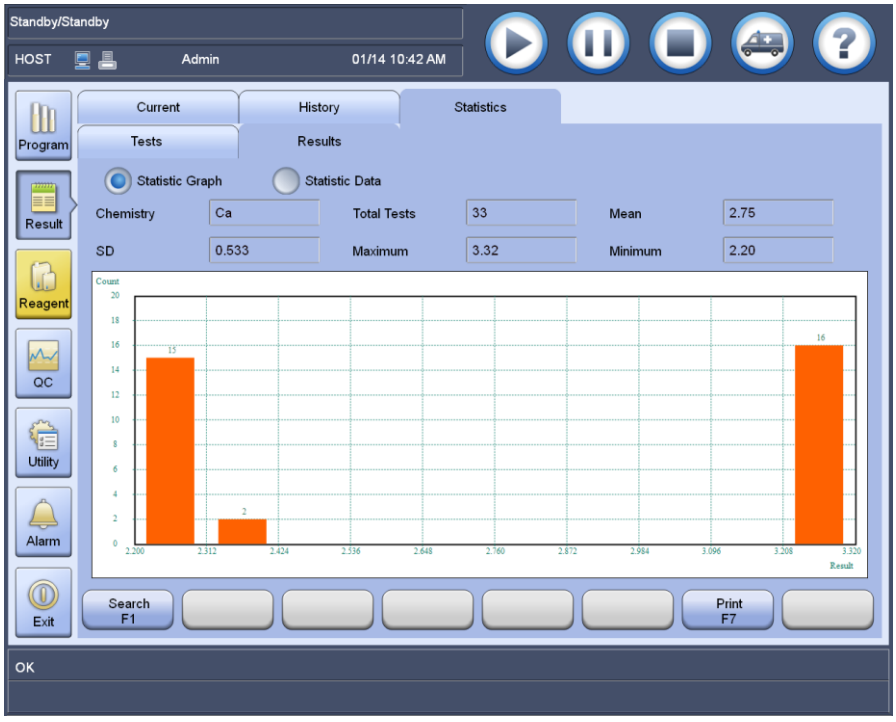
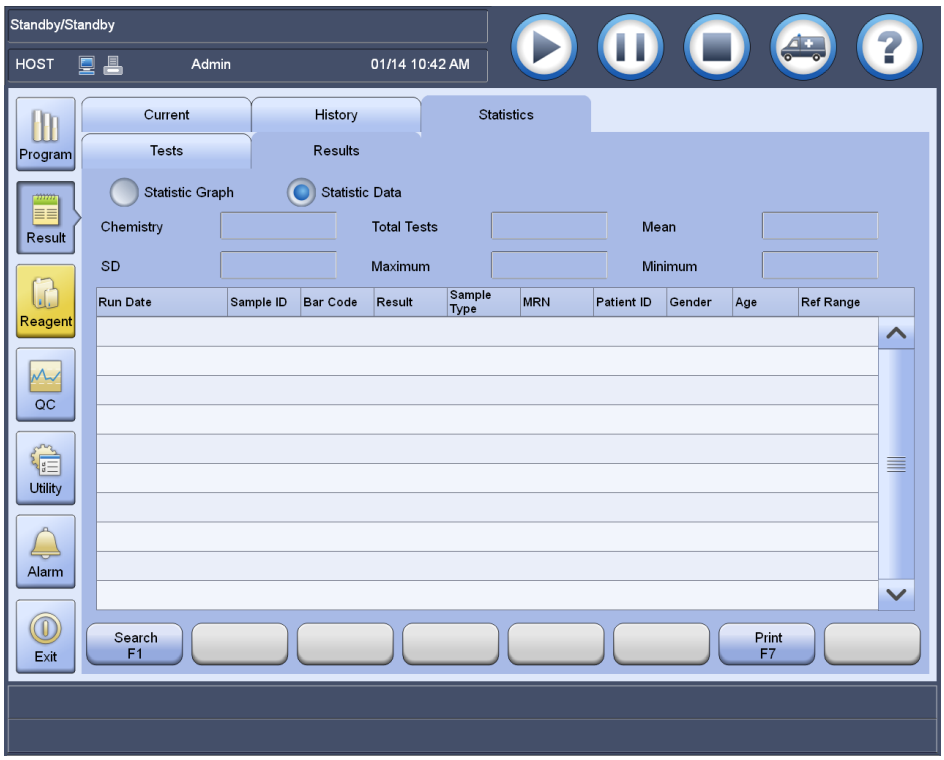


Figure 6.45 Result statistics screen -statistic data



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.

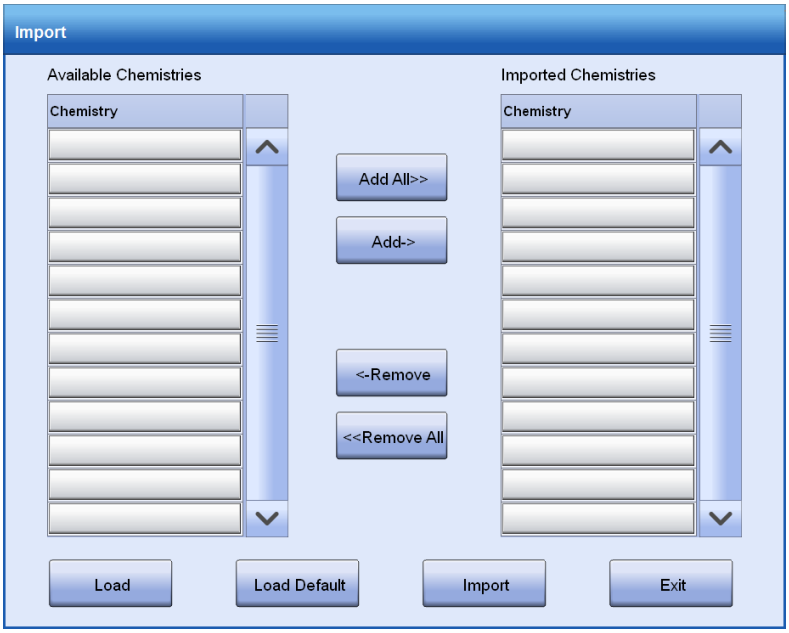
Only the full name, print name, result unit, decimal places, and error detection limits can be edited, while others can only be browsed.

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 (R1 and R2)
- Sample blank

- Twin chemistries
- Pretreatment parameters

7 Select **Exit**.

7.1.3 Exporting chemistries

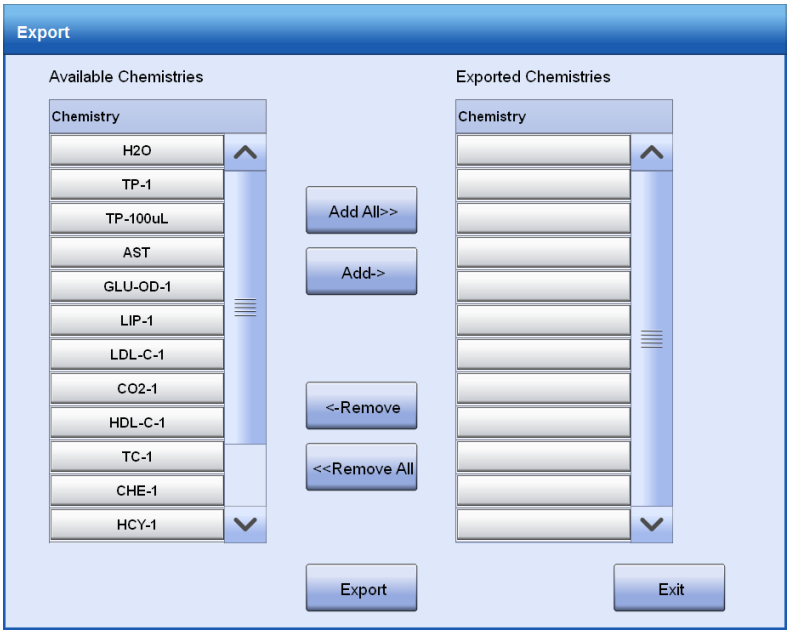
Open-reagent chemistries, as well as the processing parameters, error detection limits and slope and offset, can be exported to a storage device.

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

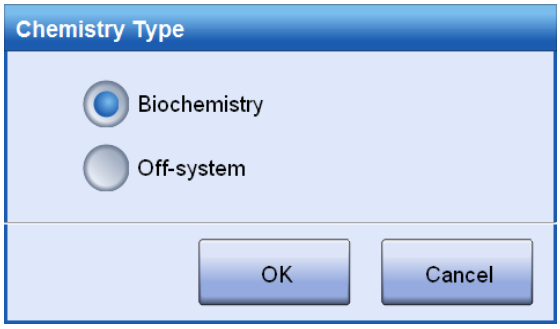
Up to 200 chemistries can be defined.

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 7-6 and 7.2.3Error detection limits on page 7-10.

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 (R1/R2)
- 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.

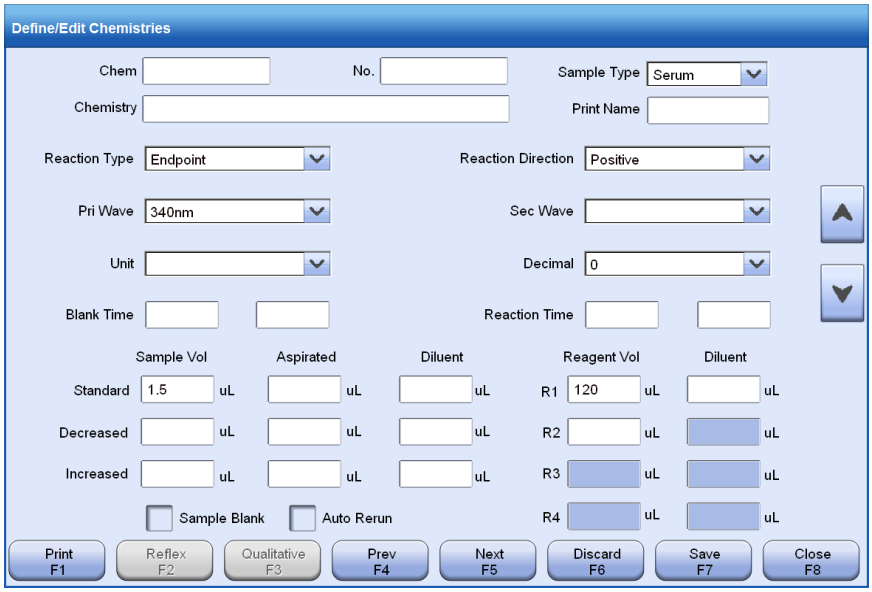
To delete a user-defined chemistry

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	Incubation time	Blank time	Reaction time	K
When the blank absorbance is read before the reaction begins,				
Single-reagent	/	-9≤N≤P≤-1	1≤L≤M≤68	K1
Double-reagent	0≤F≤34	-F≤N≤P≤-1	1≤L≤M≤34	K2
When the blank absorbance is read after the reaction begins,				
Single-reagent	/	1≤N≤P	P<L≤M≤68	1
Double-reagent	0≤F≤34	1≤N≤P	P<L≤M≤34	1
When the blank absorbance is not subtracted,				

Single-reagent	N/A	N and P are blank.	1＜L≤M≤68	0
Double-reagent	0≤F≤34	N and P are blank.	1＜L≤M≤34	0

Table 7.3 Input range of incubation time, blank time and reaction time for fixed-time and Kinetic analysis

Fixed-time and Kinetic	Incubation time	Blank time	Reaction time	K
When the blank absorbance is read before the reaction begins,				
Single-reagent	N/A	-9≤N≤P≤-1	1≤L≤M≤68	K1
Double-reagent	0≤F≤34	-F≤N≤P≤-1	1≤L≤M≤34	K2
When the blank absorbance is not subtracted,				
Single-reagent	N/A	N and P are blank.	1≤L≤M≤68	0
Double-reagent	0≤F≤34	N and P are blank.	1≤L≤M≤34	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 2 μL to 45μL with an increment of 0.1 μL. The default is 2 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 2 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 100 μL to 250 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 2 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 2 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

Reagent volume specifies the reagent amount, which should be dispensed for measurement.

- R1: 100 µL to 250 µL with an increment of 0.5 µL.
- R2: 10 µL to 250 µL with an increment of 0.5 µL.

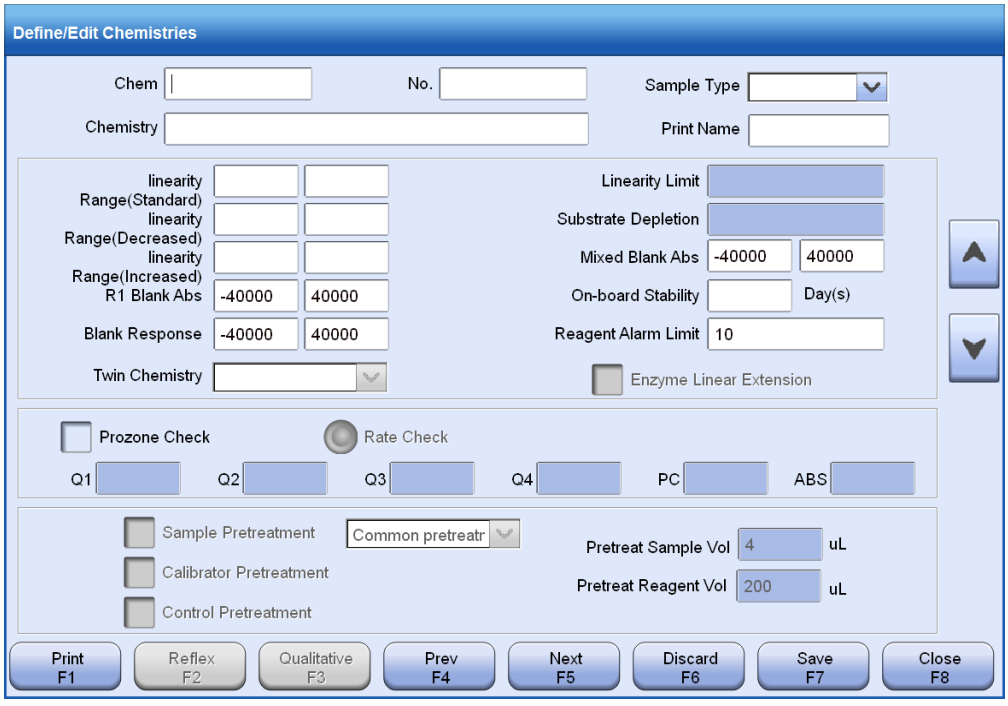
NOTE

The combined volume of all reagents and sample must be within 100 µL and 360 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 -40000-40000. 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 -40000-40000, 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 -40000-40000; 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 -40000-40000, 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 -40000-40000; 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 -40000-40000, 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 -40000-40000; 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 7-22.

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 Enzyme linearity range extension on page 12-7.

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: $1 \le q1 < q2 < q3 < q4 \le 68$, "1" is the first measuring point after the sample is dispensed and stirred.
- Double-reagent chemistries: $1 \le q1 < q2 < q3 < q4 \le 34$, "1" is the first measuring point after R2 is dispensed and stirred.
- PC: any integer between -99999999 and 99999999.
- ABS: any integer between -99999999 and 99999999.

Pretreatment

Enable the pretreatment function to pretreat patient samples with pretreatment reagent for the chemistry.

Only when the **Sample Pretreatment** checkbox is selected, common pretreatment and blood cell treatment can be enabled, and the pretreat sample volume and pretreatment reagent volume can be set.

Common pretreatment: Probe aspirates the sample from the top of the sample tube and then the sample is pretreated with pretreatment reagent.

Blood cell pretreatment: Probe aspirates the sample from the bottom of the sample tube and then the sample is pretreatment with pretreatment reagent.

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.

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 2 μL - 45 μL, with an increment of 0.1 μL. The default is 4 μL. For blood cell pretreatment, the pretreat sample volume is 2μl~10μl,.

Pretreatment reagent volume

Enter the pretreatment reagent volume within 100 μL - 250 μL, with an increment of 0.5 μL. The default is 200 μL. For blood cell pretreatment, the pretreat reagent volume is 100μl~200μl.

The sum of pretreat sample volume and pretreatment reagent volume must be within 125 μL - 295 μL.

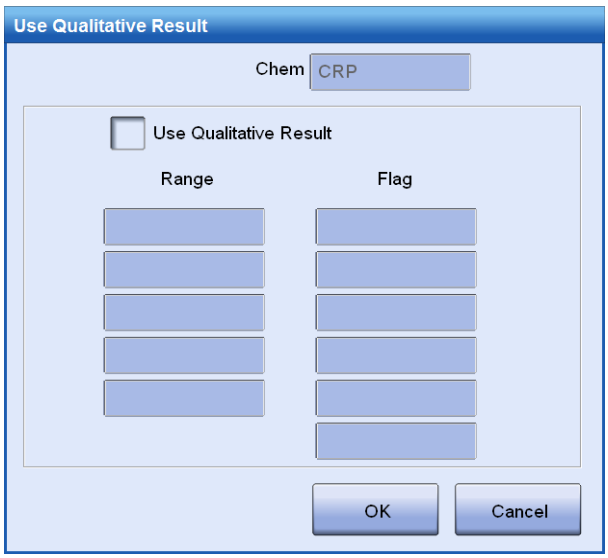
7.2.4 Using qualitative result

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.

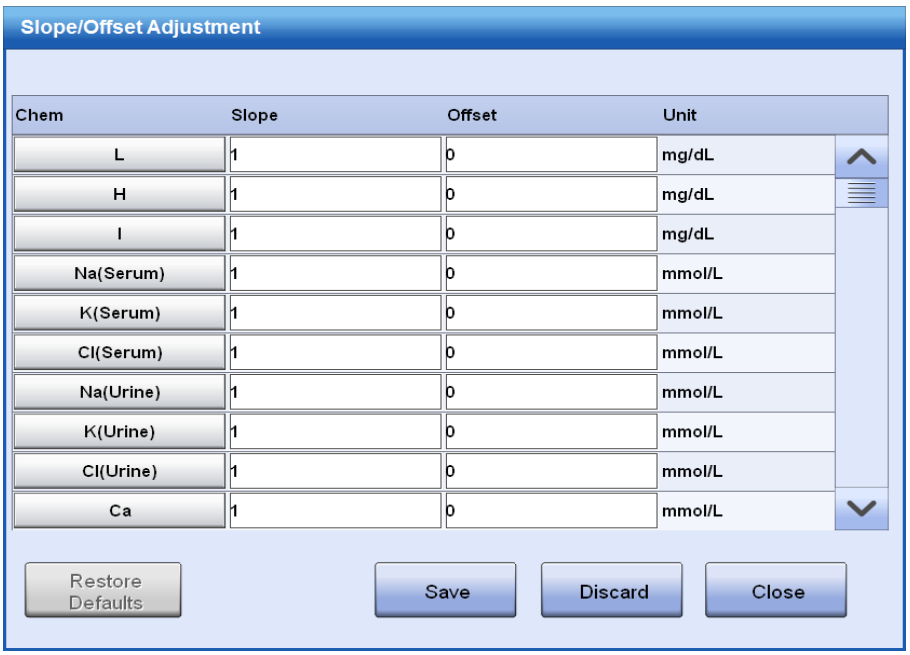
Before setting up the calculating factors, make sure that you have sufficient permissions and the system is not running tests.

To set up slope and offset

1 Select **Utility > Chemistries**.

2 Select **Slope/OffsetF5**.

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 7.4 Flags for test result beyond reference range and critical range

Condition	Flag
Greater than the high limit of the reference range	^
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.

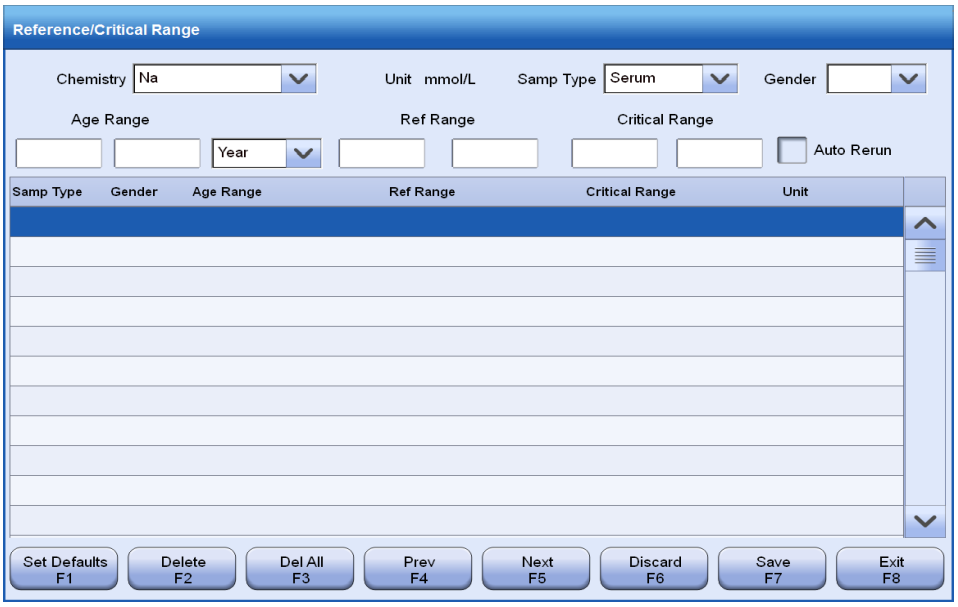
Defining/Editing reference/critical range

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 6.2.6Rerunning 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.

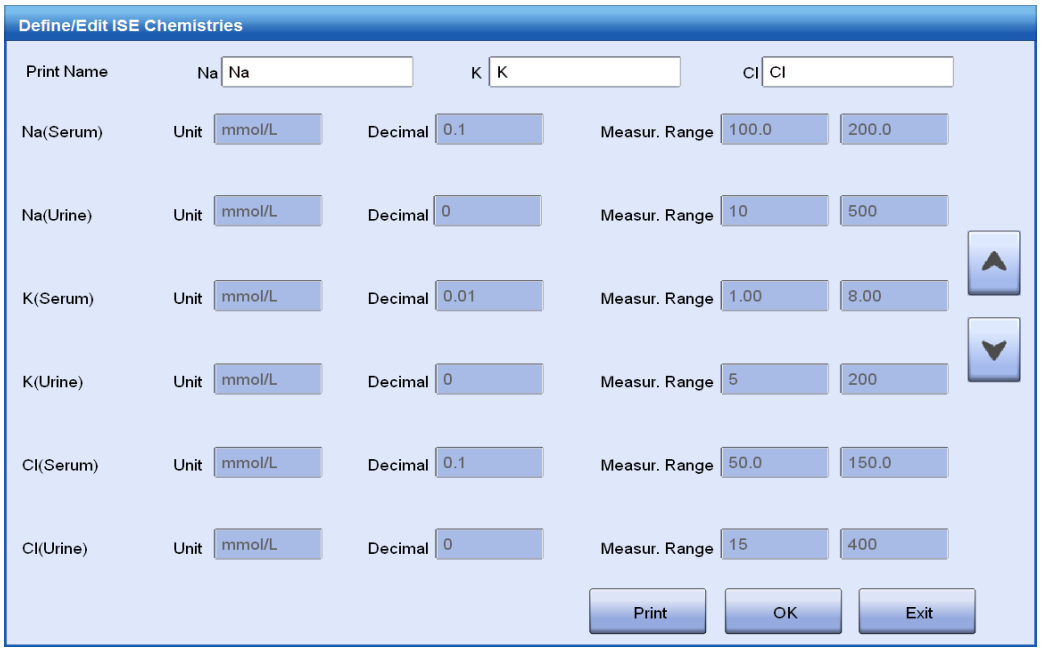
7.3 ISE chemistry setup

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 7.5 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.

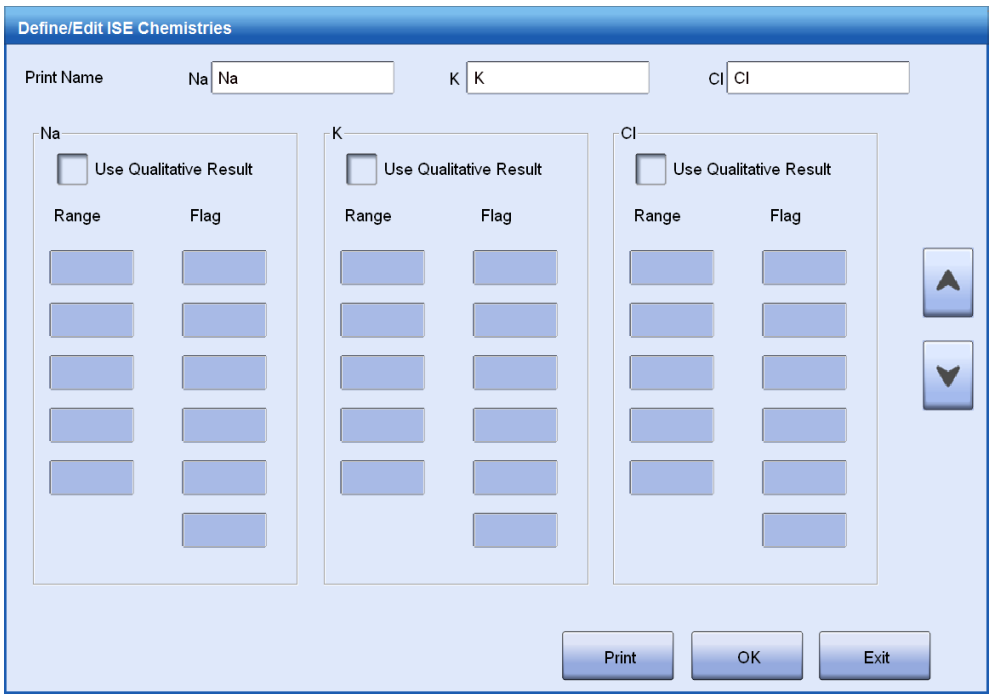
7.3.4 Using ISE qualitative result

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.

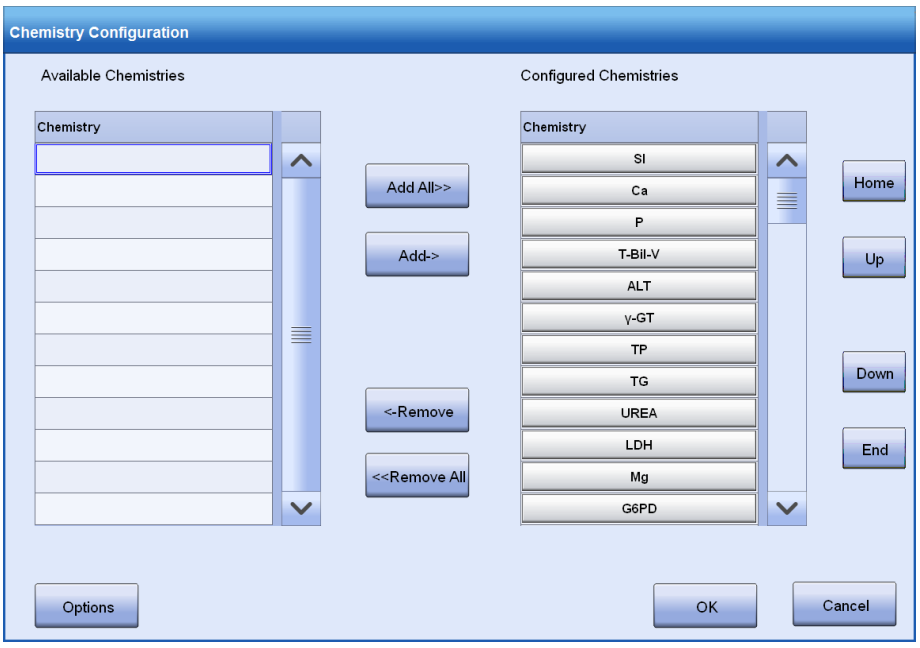
The system allows up to 200 chemistries to be enabled. The number of open-reagent chemistries can be adjusted according to the practical situations in your laboratory.

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 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.

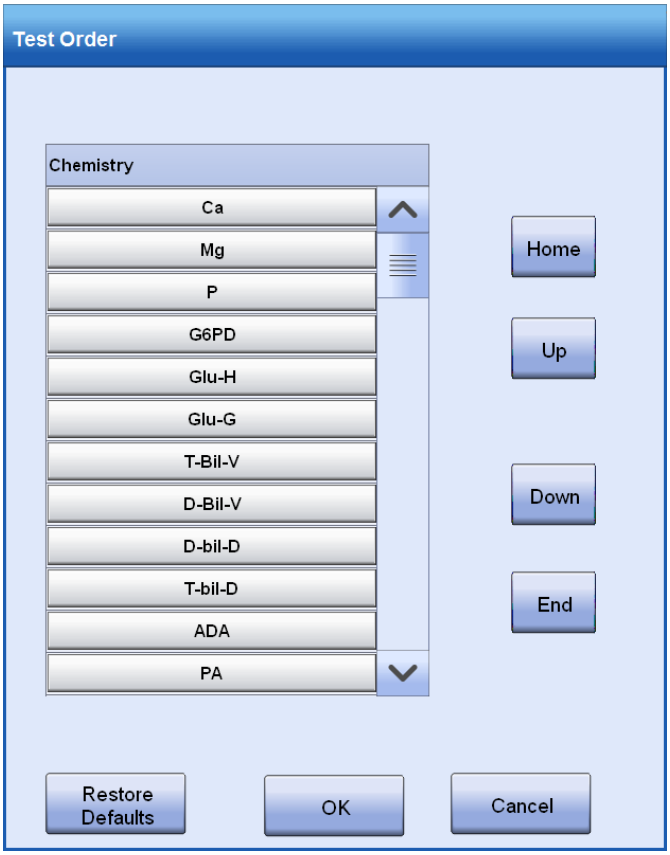
To adjust test order of chemistries

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 7-4.

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 4.2.1 Calibration setup on page 4-5.

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. When either of the twin chemistries is requested, the other twin will be requested automatically, and finally both chemistries will be run for quality control. 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

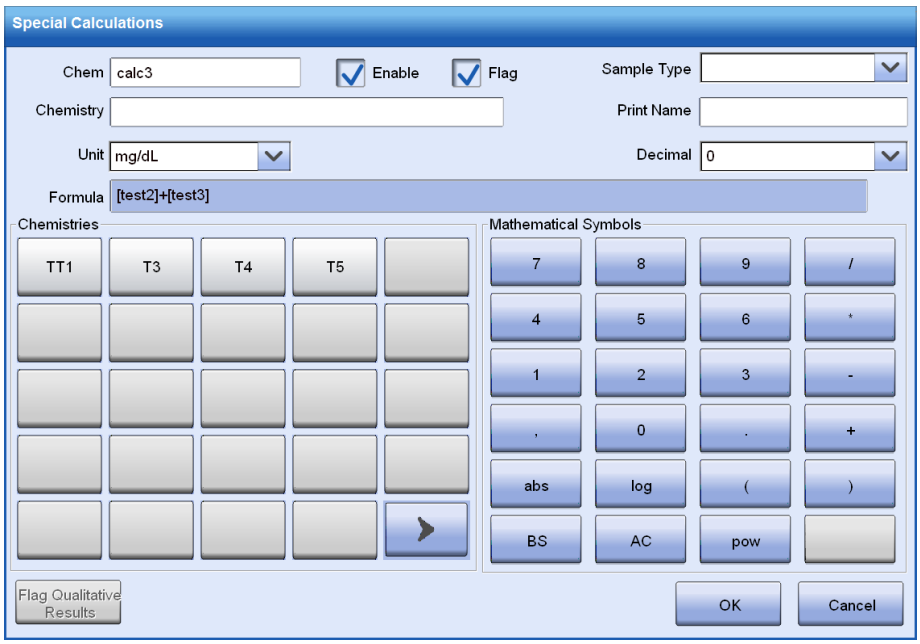
Importing and defining calculations is supported. The system allows a maximum of 50 calculations to be defined.

📖 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 result of the calculation.

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 7-13.

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**.

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.

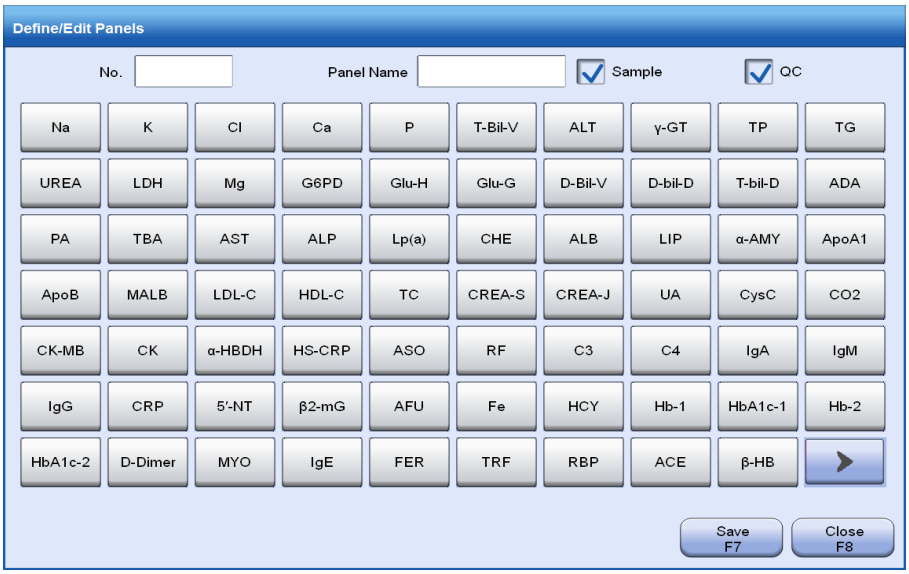
Panels can be composed of biochemistries and ISE chemistries. The system allows a maximum of 100 panels to be defined. Only users with sufficient permissions are allowed to define, modify and delete panels.

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 7.14 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

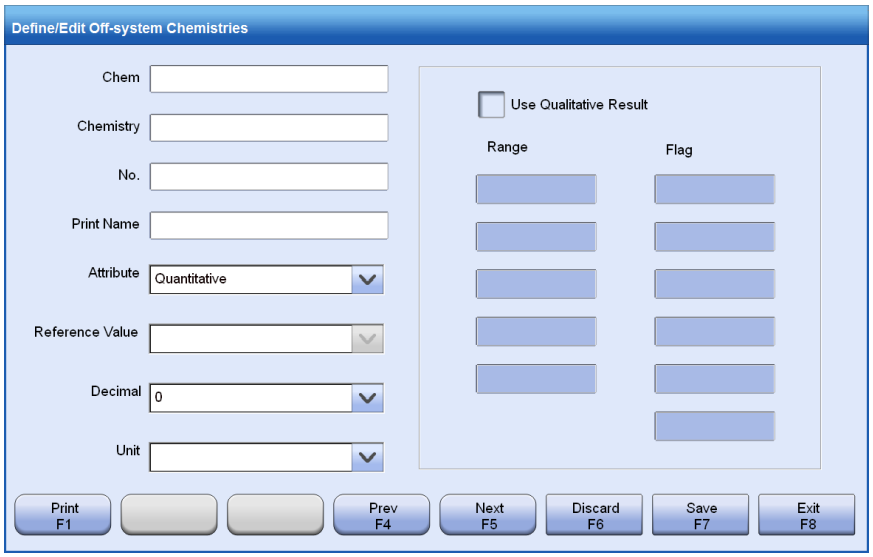
To define/edit off-system chemistry

1 Select **Utility > Chemistries**.

2 Select a blank chemistry box, and select **Define F1**.

3 Select **Off-system**, and select **OK**.

Figure 7.15 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 2.4.1samples on page 2-23.

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.

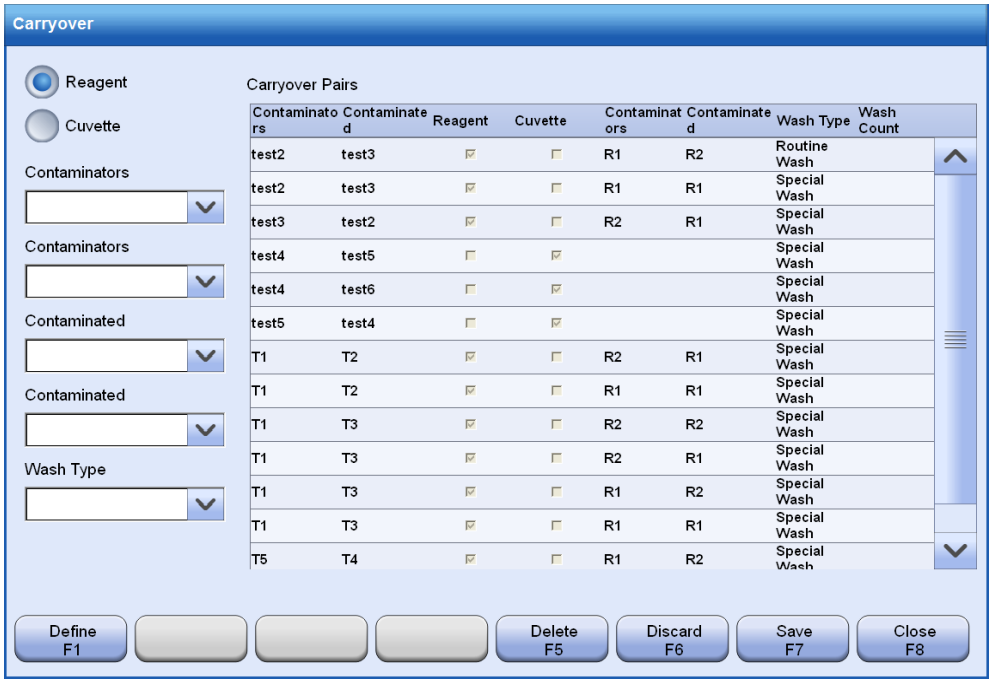
Carryover setup can only be performed by users with sufficient permissions when the system status is not Running.

7.9.1 Defining/Editing carryover pair

To define/edit carryover pair

1 Select **Utility > Chemistries**, and select **Carryover F8**.

Figure 7.16 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 **Save F7**.

The defined carryover pair appears in the **Carryover Pairs** list. To abort the carryover settings, select **Discard F6**.

10 Select **Define F1** and follow the above steps to set up other carryover pairs.

11 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.

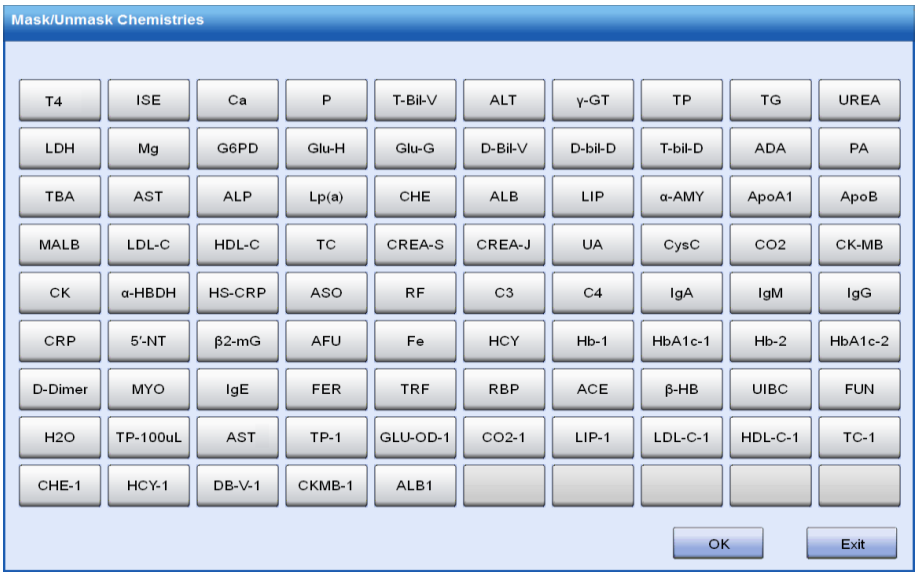
To mask/unmask chemistries

1 Select **Utility > System Setup**.

2 Select **Instrument F1**.

3 Select **Mask/Unmask Chem**.

Figure 7.17 Mask/Unmask Chemistries window



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.

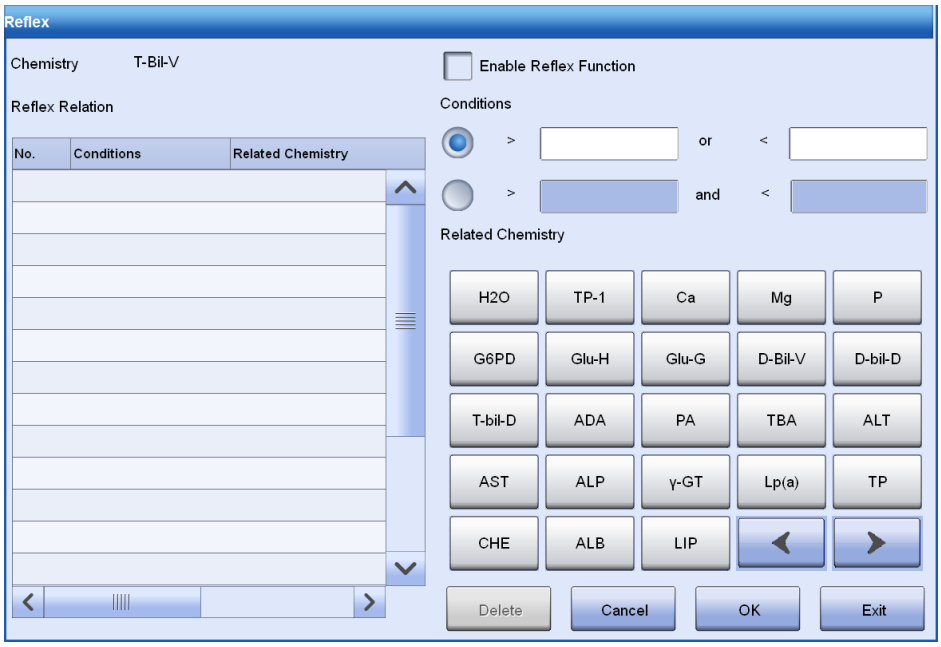
To set up reflex relation

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.

8.2 System setup

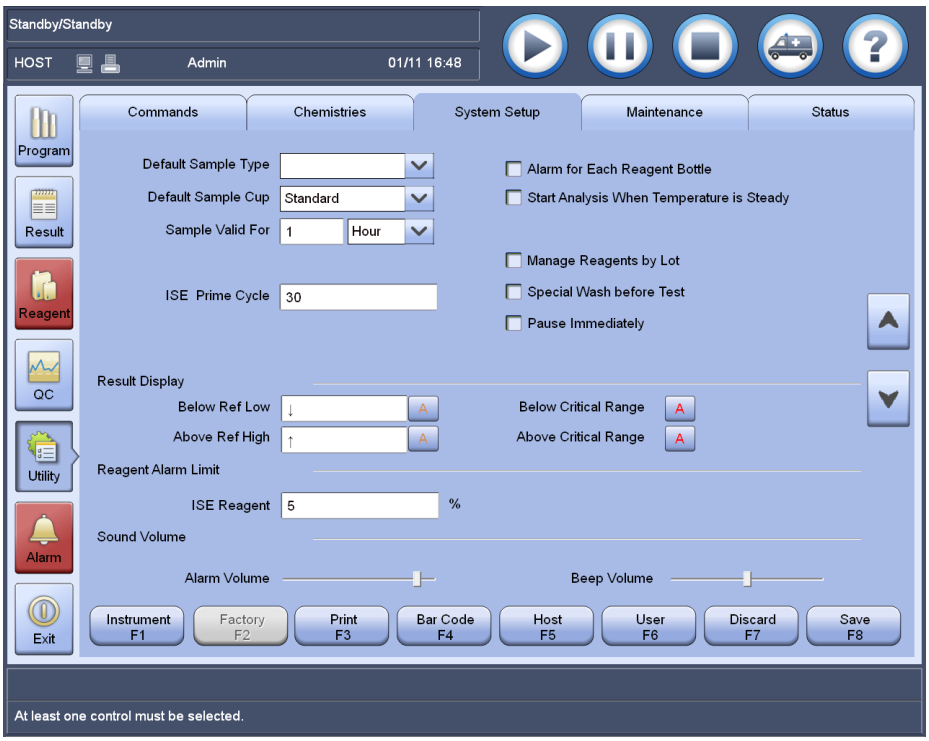
This section describes the setup options on the **System Setup** screen, which includes the following pages:

- 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.

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.

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.

Special wash before test

Select this option to execute a special wash with wash solution for the sample probe, reagent probes and mixers before a batch of tests. If it is unselected, no special wash will be performed before a batch of tests.

Pause immediately

Select this option to pause the analyzer immediately after one test period about 18s once the Pause button on the right corner of the main screen is clicked.

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 1-50, and the default is 30.

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 Auto startup setup

The Auto Startup Setup option allows you to define date and time of starting up the system.

The system allows you to choose a weekday and specific time that the system will be started up automatically. When the time is reached, the system will be started up if it is off.

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.

For details of Auto startup setup, see Auto startup on page 2-5.

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 7-30.

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.

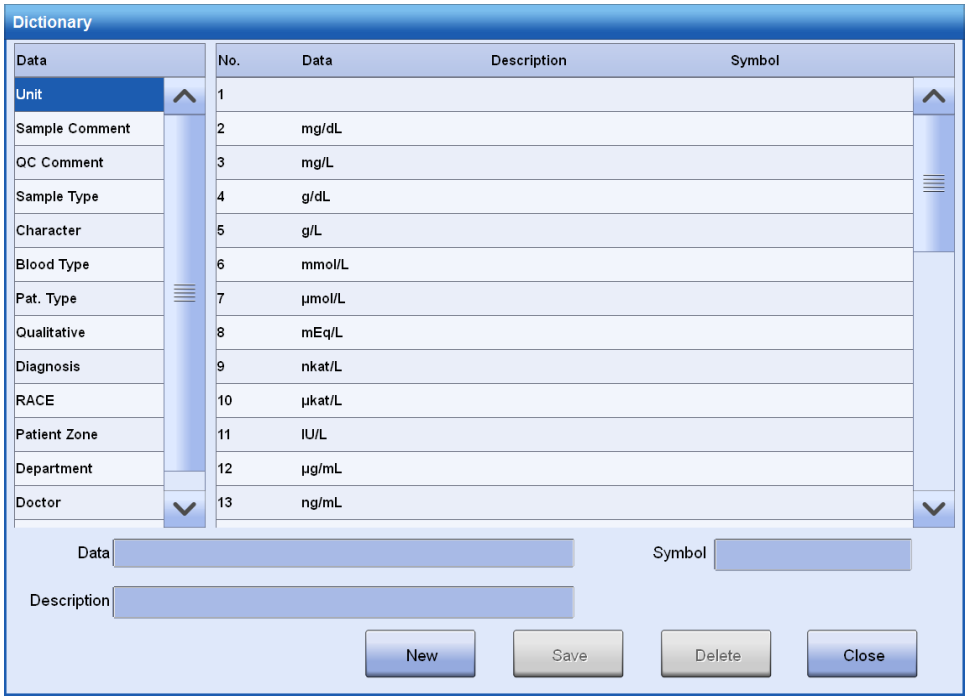
Data options can be defined, edited or deleted in any system status. The default data options cannot be deleted or edited.

To define, edit and delete data options

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

2 Select **Dictionary**.

Figure 8.2 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

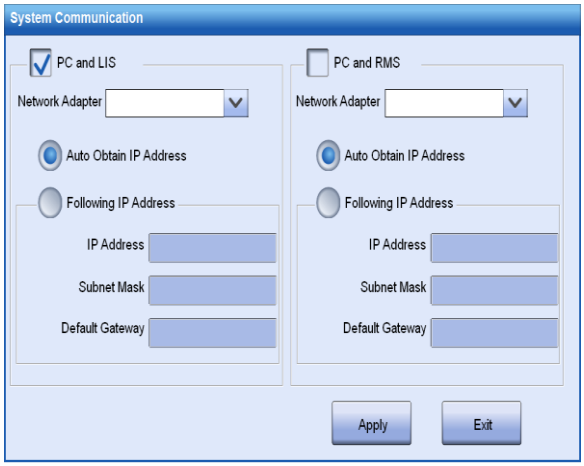
The Com Setup option is used to set up the IP address for connections between the PC and LIS/RMS

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 8.3 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 following options: Chinese, English, Turkish, Russian, French, Portuguese, Italian, Spanish, and Polish. 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.

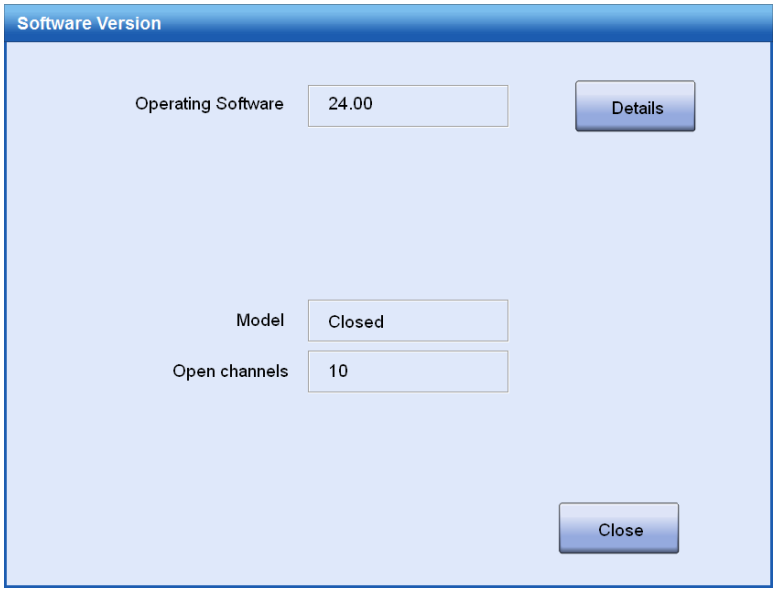
8.3.7 Viewing software versions

You are allowed to view the version number of the operating software and control software in any system status.

To view the software version

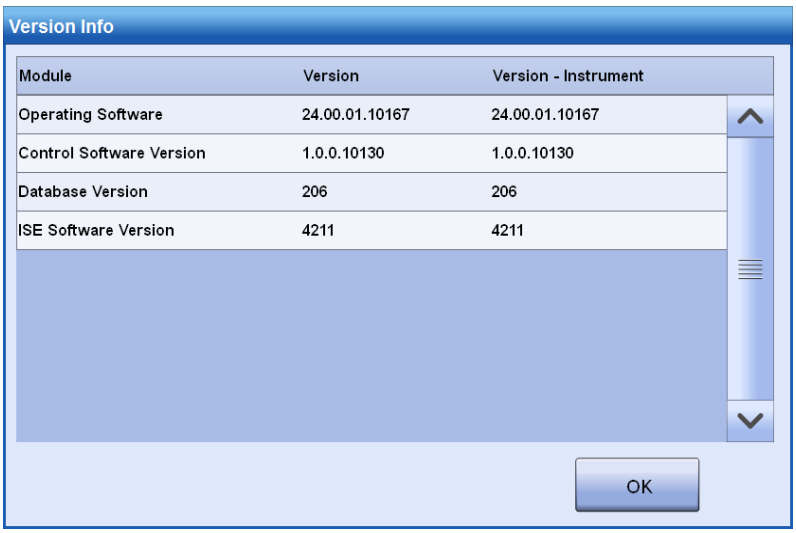
1. Select **Utility > System Setup**, and select **Instrument F1**.
2. Select **Version Info**.

Figure 8.4 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**.

Figure 8.5 Smart module software version window



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.

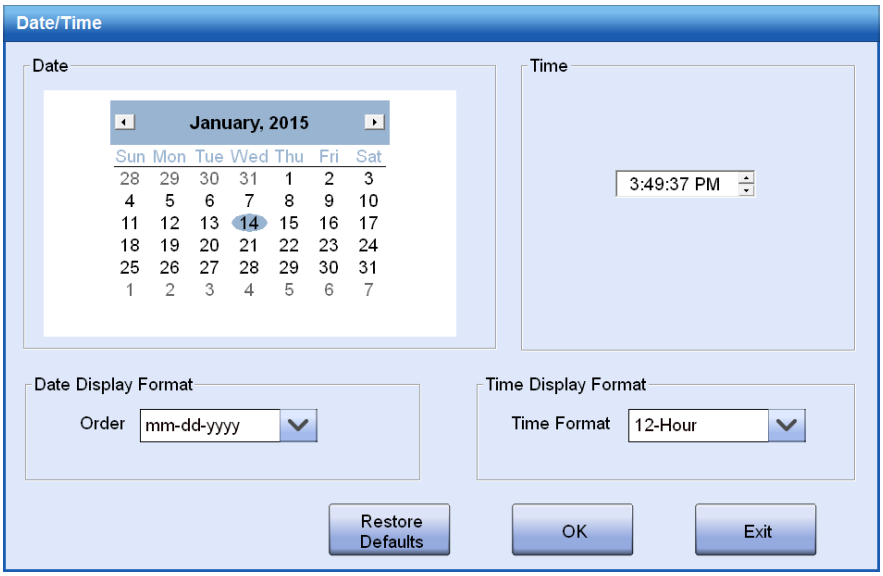
When adjusted, the date and time will influence the time left of reagents and calibration, shelf life of samples, and run length of two-control evaluation. The date and time cannot be edited when the system status is Running. Modification of the date and time will not affect samples on the Current Results 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 8.6 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 run on page 12-11.

📖 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 position on page 6-18.

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**.

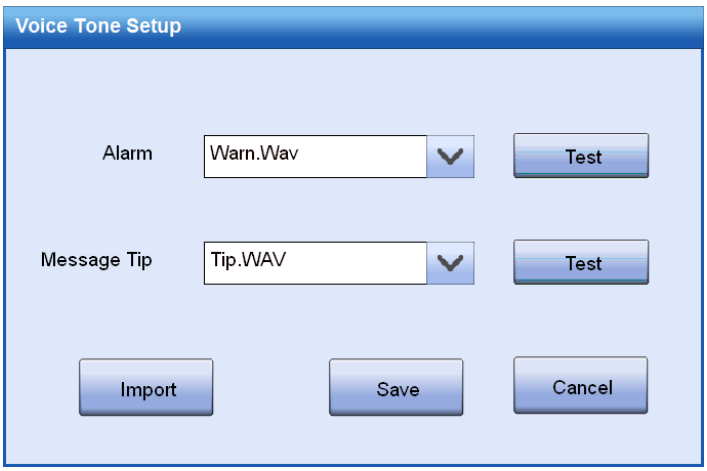
The imported audio files are displayed in the **Alarm** and **Message Tip** drop-down lists.

To set up voice tone

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

2 Select **Voice Tone Setup**.

Figure 8.7 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 6.3.8display on page 6-21.

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 6.3.6information on page6-20.

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 6.3.7demographics on page 6-21.

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 3.2.7 Checking and auto refreshing reagent inventory on page 3-6.

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 3.2.5Customizing reagent display on page 3-5.

8.3.17 Customizing sample position

On the middle ring of the sample/reagent carousel, 40 sample tubes can be placed with adapters. Before placing sample tubes on the middle ring, you should specify the sample position range so that the samples can be identified correctly.

To customize sample position

1. Select **Utility > System Setup**, and select **Instrument F1**.
2. Select **Customize Sample Position**.
3. Specify the sample position range (40-80).

   For example: When 50 is input, it means that the positions from No.1 on the outer ring to No.50 on the middle ring are used to hold samples.
4. Select **Save**.
5. Select **Exit**.

After customizing sample positions, the positions on the sample carousel and reagent carousel are indicated as follows:

- The set positions of the inner ring on the **Program > Status** screen are indicated in white, which means available for sample.
- The positions indicated with two crosses"××"on the sample carousel graph can be only used for reagents.
- The positions indicated with a red cross "  " on the **Reagent > Reagent Carousel Status** screen means unavailable for reagents.

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.

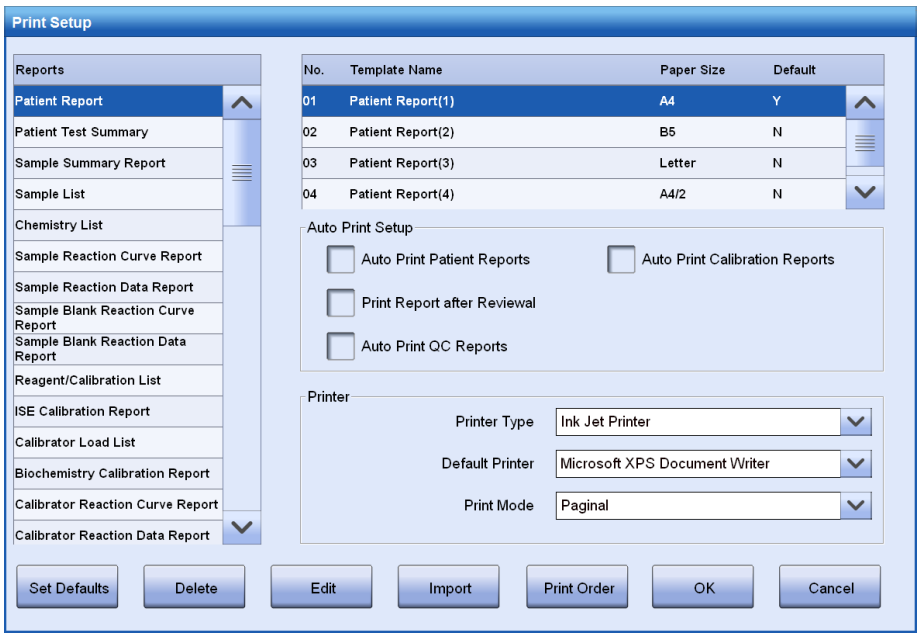
8.4.1 General print setup options

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 8.8 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.

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.

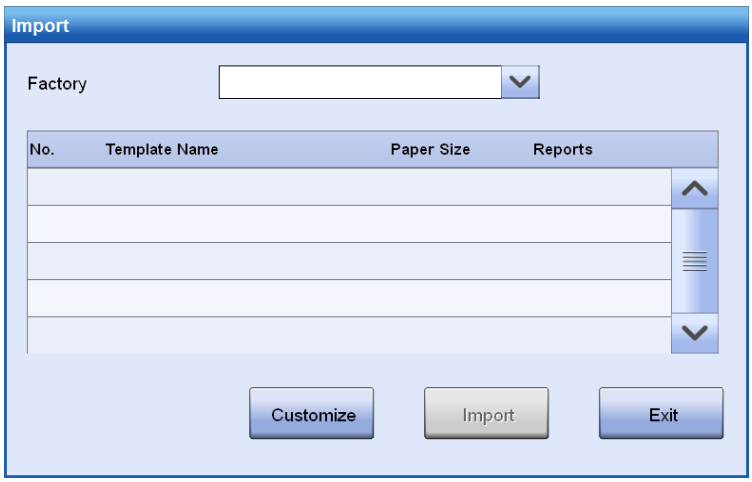
8.4.3 Importing print template

To import print template

1 Select **Utility > System Setup**, and select **Print F3**.

2 Click **Import** to import the print template.

Figure 8.9 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.

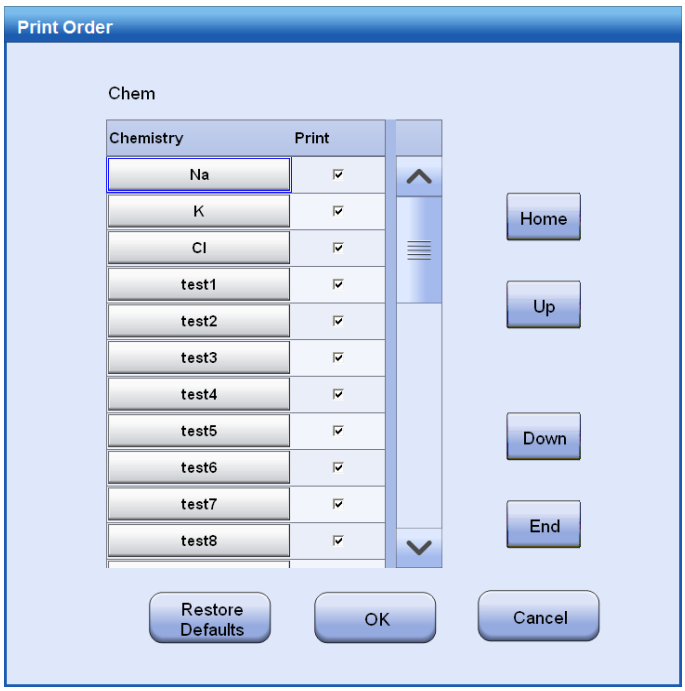
8.4.6 Defining chemistry print order

To define chemistry print order

1 Select **Utility > System Setup**, and select **Print F3**.

2 Select **Print Order**.

Figure 8.10 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 1~40. If the sample positions on the middle ring are customized, these positions can be set as STAT positions. 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
Lot number	0-18 digits
Expiration date	0, 4, 6 or 8 digits (4 digits: yymm; 6 digits: yyyymm; 8 digits: yyyymmdd)

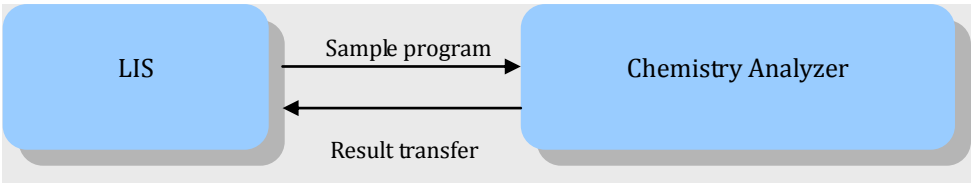
7 Select **OK**.

8.6 LIS setup

8.6.1 Introduction

The BS-240 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 8.11 Connection between the analyzer 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 8.12 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.
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.

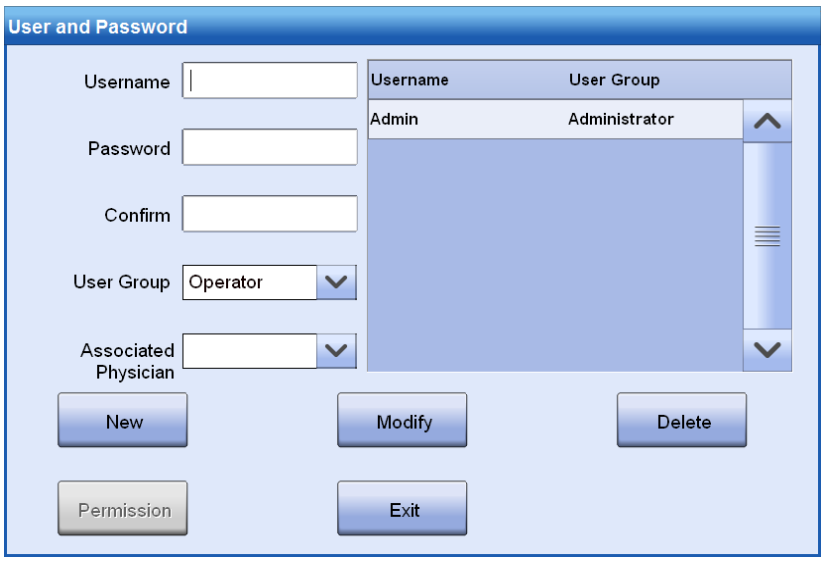
8.7.1 Defining a user

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 8.13 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 tester 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

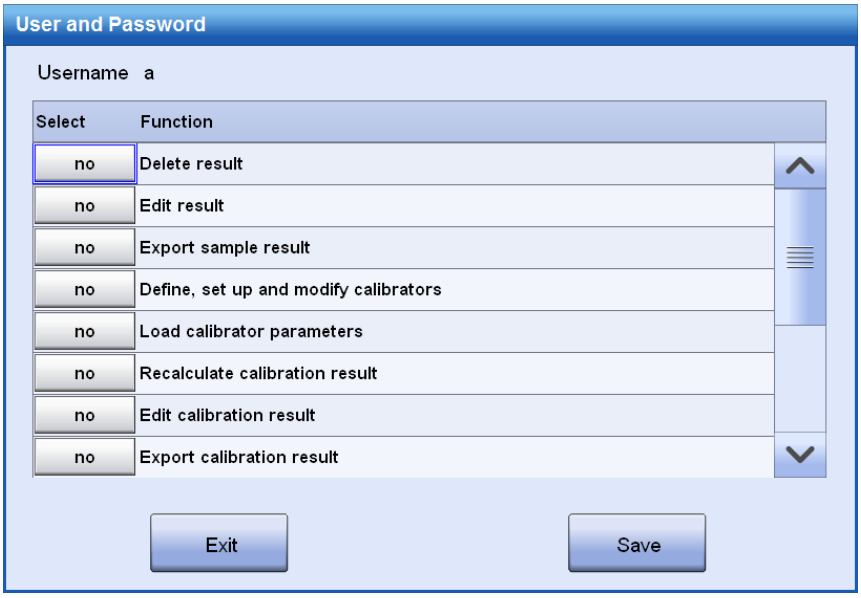
Permissions are assigned to user groups, which include administrator and operator. Administrators are allowed to use, assign and modify all permissions that are assigned for operators; while operators are only allowed to use common functions, such as assigning reagent position; programming samples, controls 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 setup permissions in the user list, and then select **Permission**.

Figure 8.14 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.

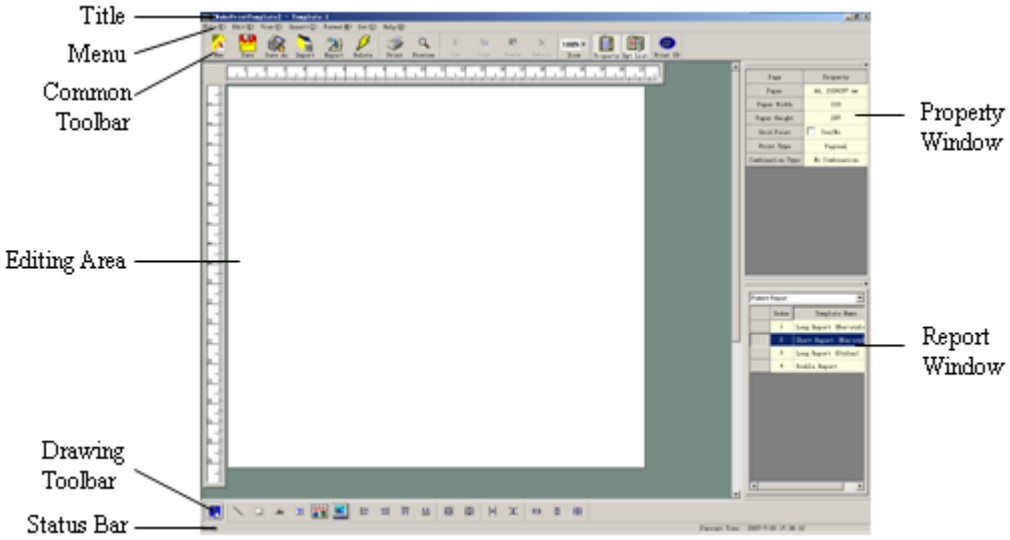
The Template Modifying Software can be started separately or together with the Operating Software. To start the Template Modifying Software, select the **Edit** button on the **Print** page of the operating software.

The following sections introduce the Template Modifying Software by menus and toolbars.

9.1 Main screen

9.1.1 Main screen

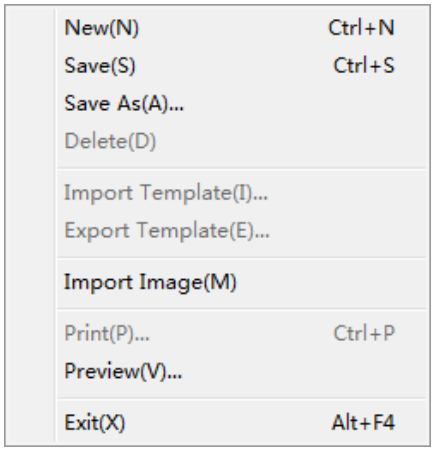
The following figure shows the main screen of the Template Modifying Software Main screen



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 9.1 File menu



The following table explains the menu in detail.

Table 9.1 Options of the File menu

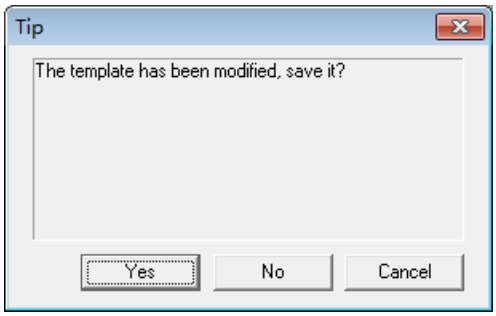
Option	Description

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.



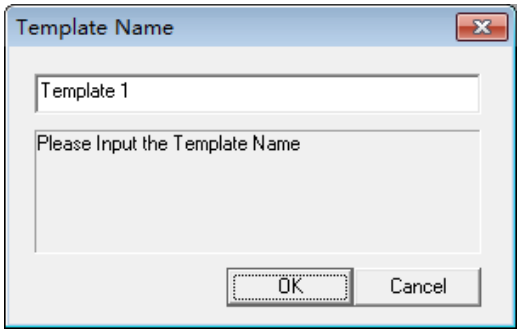
- Select **Yes** to save the changes and create a template.
- Select **No** to cancel the changes and create a template.
- Select **Cancel** to abort creating and return to the previous screen.

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.

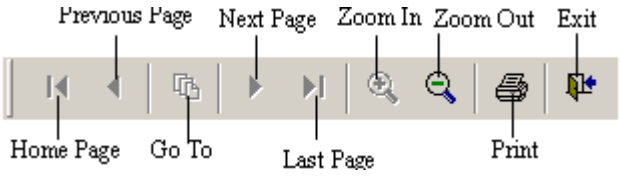
Import Image

Import BMP, GIF, JPEG, PNG, TIFF, and EMF images from a storage device to the picture folder.

Print

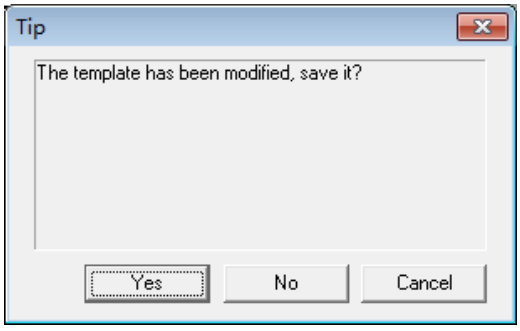
Print the current template. Not available.

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.

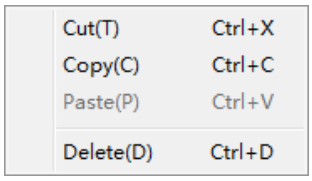


- Select **Yes** to save the changes and exit the software.
- Select **No** to exit the software without saving the changes.
- Select **Cancel** to abort exiting and return to the previous screen.

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 9.2 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.

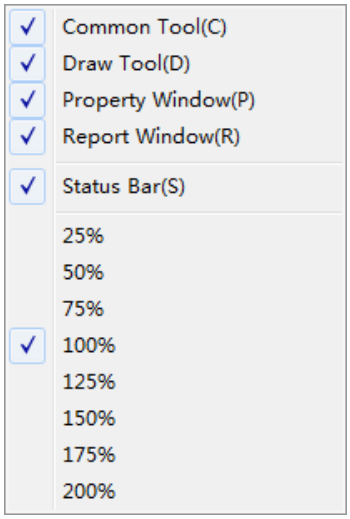
Table 9.2 Options of the Edit menu

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 9.3 View menu



The following table explains the menu in detail.

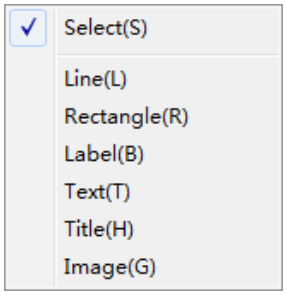
Table 9.3 Options of the View menu

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 9.4 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 9.5 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.

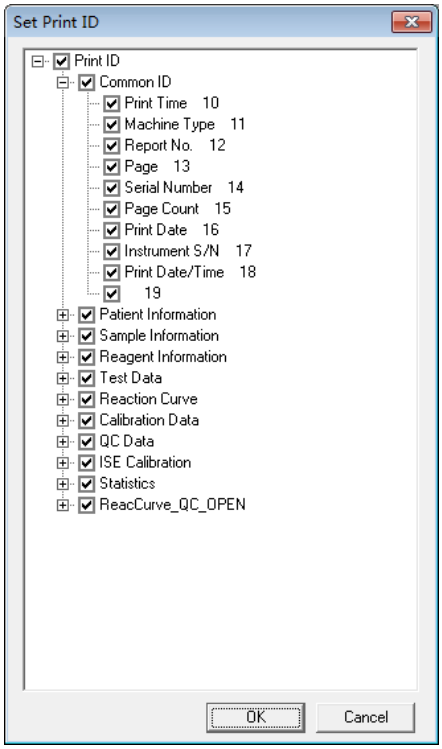
9.1.7 Set(S)

The ***Set*** menu only includes an option, **Print ID**. See the figure below.

Figure 9.6 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.

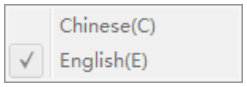
Figure 9.7 Set Print ID window



9.1.8 Language (L)

Select **Language** on the menu bar of the main screen. The **Language** menu is displayed.

Figure 9.8 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 9.9 Help menu

The following table explains the menu in detail.

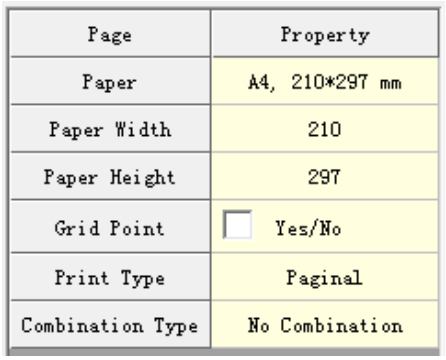
Table 9.7 Options of the Help menu

Option	Description
Version	Select this option to view the version information of the template modifying software.

9.1.10 Page

When no control is selected, the property window shows the properties of the current template, such as paper, print type, etc.

Figure 9.10 Page property area



The following table explains the template properties in detail.

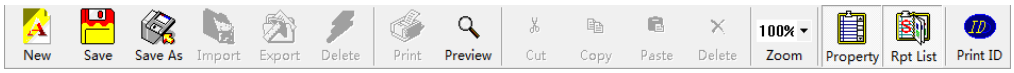
Table 9.8 Page properties

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.

9.2 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 9.9 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 9.10 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

	Insert/Image		Format/Same Width
	Format/Left		Format/Same Height
	Format/Right		Format/Same Size

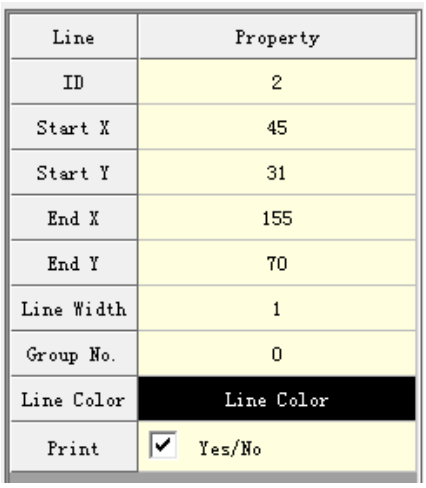
9.4 Property window

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 Line

When a line control is selected, the property window shows the properties of the line.

Figure 9.13 Line property area



The following table explains the line properties in detail.

Table 9.11 Line properties

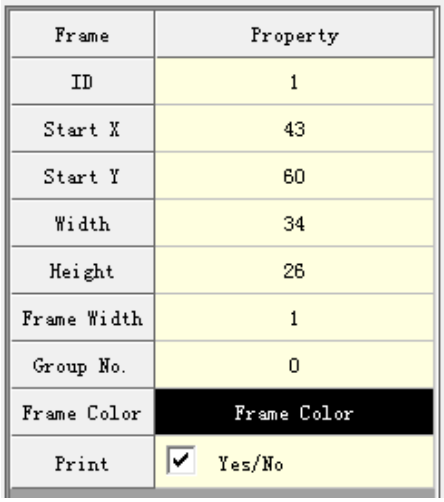
Parameter	Description
ID	Print ID of the line. The ID is 2.
Start X	Set the X-coordinate value of the start point. **NOTE** The control coordinate originates from the upper-left corner of the editing area, from which the X axis (positive) is extended horizontally to the right and the Y axis (positive) 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.

9.4.2 Rectangle

When a rectangle control is selected, the property window shows the properties of the rectangle.

Figure 9.14 Rectangle property area



The following table explains the rectangle properties in detail.

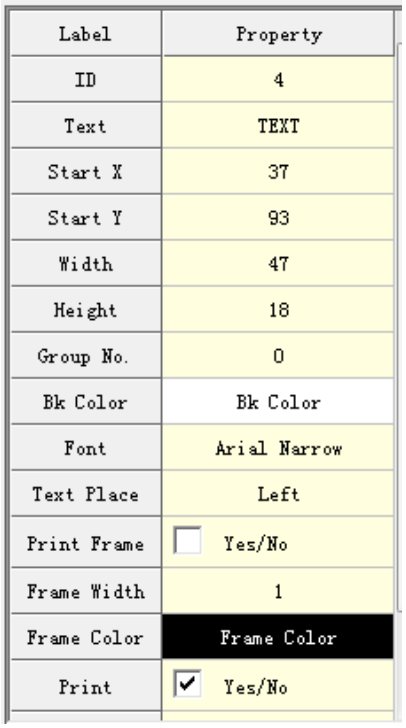
Table 9.12 Rectangle properties

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.

9.4.3 Label

When a label control is selected, the property window shows the properties of the label.

Figure 9.15 Label property area



The following table explains the label properties in detail.

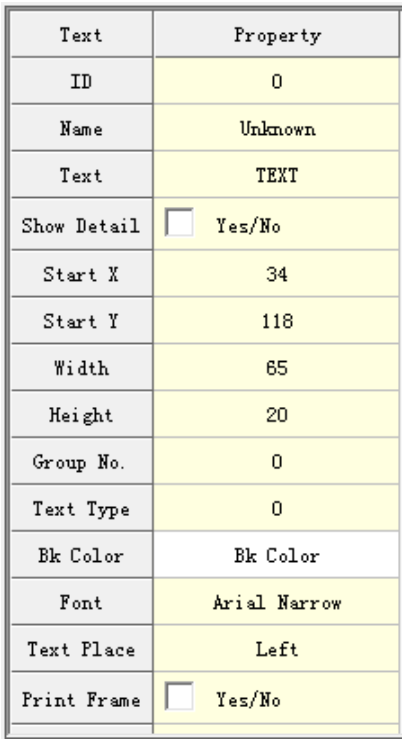
Table 9.13 Label properties

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.

9.4.4 Text

When a text control is selected, the property window shows the properties of the text.

Figure 9.16 Text property area



Text	Property
ID	0
Name	Unknown
Text	TEXT
Show Detail	Yes/No
Start X	34
Start Y	118
Width	65
Height	20
Group No.	0
Text Type	0
Bk Color	Bk Color
Font	Arial Narrow
Text Place	Left
Print Frame	Yes/No

The following table explains the text properties in detail.

Table 9.14 Text properties

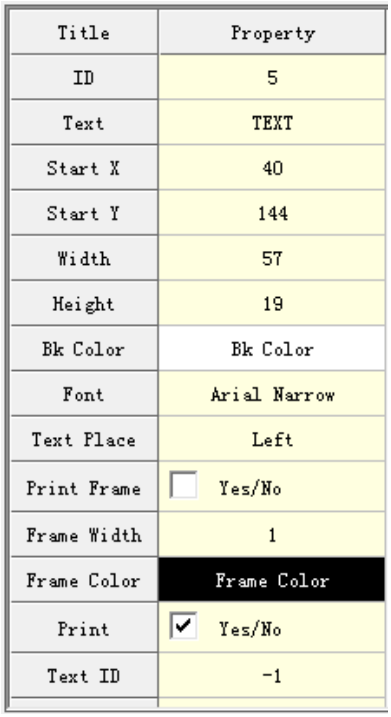
Parameter	Description
ID	Print ID of the text. The default is 0 and means unknown ID. Print ID indicates the meaning of the text. Correct printout can be ensured only when print ID is set properly.
Name	Set the contents to be displayed on the text control. It varies from different IDs.
Text	Set the contents 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.

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.

9.4.5 Title

When a title control is selected, the property window shows the properties of the title.

Figure 9.17 Title property area



The following table explains the title properties in detail.

Table 9.15 Title properties

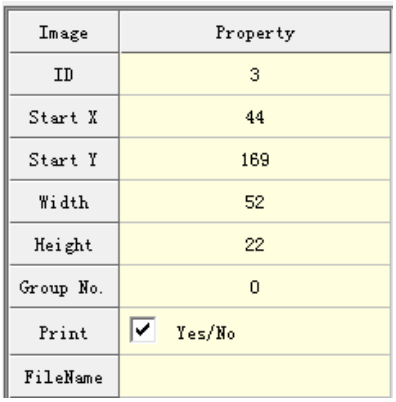
Parameter	Description
ID	Print ID of the title. The ID is 5.
Text	Set the contents to be displayed on the title. "%s" will be replaced by a hospital name and can be displayed in any place of the title.
Start X	Set the X-coordinate value of the start point (upper-left corner).
Start Y	Set the Y-coordinate 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.
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.

9.4.6 Image

When an image control is selected, the property window shows the properties of the image.

Figure 9.18 Image property area



The following table explains the image properties in detail.

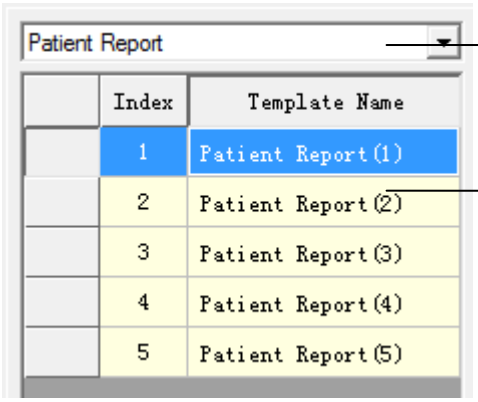
Table 9.16 Image properties

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 9.19 Report window



(1) Report type (2) Template list

10 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.

10.1 Overview

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.

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.

Maintenance frequency

The maintenance frequencies stated in this manual are based on 300 tests/day, and 300×25=7,500 tests/month.

10.1.1 Safety information

WARNING

- Maintain the system strictly as instructed by this manual. Inappropriate maintenance may lead to unreliable results, equipment damage or personal injury.
- 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.
- Do not spill water or reagent on mechanical or electrical components of the system.
- Shut down and turn off analyzer and disconnect the power plug before cleaning. Take necessary measures to prevent water ingression, otherwise equipment damage or personal injury may be caused.
- Replacement of the photometer lamp should be done when the system power has been switched off for at least 10 minutes.
- If the system fails and needs servicing, contact our Customer Service Department or your local distributor. The system may need to be stopped or transported during servicing, which will probably cause biohazards, electric shock hazards and moving part hazards. Exercise caution when prepare the system for servicing.

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

CAUTION

- To wipe off dust from the system surface, use a soft, clean and moistened cloth soaked with soap water rather than organic solvents such as ethanol. After cleaning, wipe the surface dry with dry cloth.
- Replacement of major parts as photometer lamp, probe and mixer must be followed by re-calibration.
- After performing maintenance, make verification to ensure that the system runs normally.
- 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.

10.1.2 Tools and Spare Parts

Please use the accessories and spare parts 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.

Accessories

- Cross screwdriver (φ4.7×100): for install and removing the probe
- Round-head needle, 0.25+/-0.01mm×125mm: for unclogging the probe

Spare parts

Table 10.1 Spare parts

Part name	Related maintenance	Comment
Lamp	Replacing lamp	Regularly-replaced part. Replace it when it serves for over 2000 hours or in every 6 months.
Syringe	Replacing syringe	Replace it when it serves for over 100,000 times.
Reaction cuvette	Replacing cuvette	Consumable. Replace it when needed.
Probe	Replacing probe	Regularly-replaced part. Replace it when needed.
ISE electrode	Replacing ISE electrode	Regularly-replaced part. Replace it when needed.
Electrode case	Storing ISE electrode	Use it when store the ISE electrodes.
ISE wash solution	Cleaning electrode tubes	Consumable. Use it when cleaning the electrode tubes every day.

Tools to be prepared by user

Before maintenance, prepare the following tools:

Table 10.2 Tools to be prepared by user

Item	Applicable maintenance
Clean gauze	Checking syringe; cleaning rotors, probe/mixer exterior and cuvette wash station
Cotton swabs	Cleaning wash well and sample/reagent compartment
Suction cleaner	Cleaning fans and dust screens
Hair brush	Cleaning dust screen
Tweezers	Removing/Installing probe and syringe washer
Thread syringe	Unclogging the probe
Tube brush or ultrasound cleaner	Cleaning filter core
Beaker	Unclogging and cleaning the probe
Ethanol	Cleaning the photometer lens, probe, mixer and wash station
NaClO (0.5% sodium hypochlorite solution)	Cleaning wash wells
Fiber-free gloves	Cleaning and replacing reaction cuvettes
Large water container	Cleaning deionized water tank
Screen and keyboard wash solution	Cleaning screen and keyboard
Sample tube	Cleaning ISE electrodes

10.1.3 Concepts

The **Maint** window includes the following tab pages:

- **Scheduled Maintenance**: Provides maintenance reminding and maintenance record tracking.
- **Biochemistry Maintenance**: Provides maintenance commands of the biochemistry system, which can be performed through the screen wizards.
- **ISE Maintenance**: Provides maintenance commands of the ISE module, which can be performed through the screen wizards.

The scheduled maintenance items can be performed manually or automatically through a wizard. The biochemistry and ISE maintenance commands can be executed by specified frequency or according to the instrument condition.

Scheduled maintenance item

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. The maintenance item can be performed manually, or by executing one or more maintenance commands.

The scheduled maintenance item list provides the functions of maintenance confirmation, auto maintenance reminding, filling maintenance logs, recalling maintenance history, and customizing maintenance items.

Maintenance confirmation

After maintenance confirmation, the system updates the **Date Performed** of relevant maintenance item as the current date, and uses it to calculate the next maintenance time.

Auto maintenance reminding

When a maintenance procedure is expired, the system displays the following buttons and options in yellow. You should perform relevant maintenance immediately.

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

Filling maintenance logs

Recording the abnormal conditions and other information about the maintenance.

Recalling maintenance history

Viewing all execution records of each maintenance item, including date, log and operator. Each maintenance record can be edited or deleted.

Customizing maintenance item

Defining and customizing maintenance items according to the actual use. You are allowed to add and delete self-defined maintenance items.

Biochemistry maintenance command

Maintenance item of the biochemistry system, which can be performed through wizard. The commands may be included in certain scheduled maintenance procedure, or may be executed independently when needed.

ISE maintenance command

Maintenance item of the ISE module, which can be performed through wizard. The commands may be included in certain scheduled maintenance procedure, or may be executed independently when needed.

10.1.4 Maintenance period

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

The maintenance information will not be lost when the operating software version is upgraded. When new version software is installed to remove the system failure or fix the system, the maintenance counter returns to 0 and restarts a countdown.

10.1.5 Maintenance execution methods

Follow these steps to perform scheduled maintenance and maintenance commands.

To perform scheduled maintenance

1. Determine the maintenance items you are going to perform.
   - Check for maintenance items indicated in yellow on the **Scheduled Maintenance** tab page.
   - Determine maintenance items according to using conditions of the system components.
   - Select **Utility > Status > Count**, check the use count of each component, and determine maintenance items.
2. Find the maintenance items in this chapter and perform the described steps.
3. After maintenance, select **Utility > Maintenance > Maintenance > Scheduled Maintenance**, and then click the relevant frequency tab.
4. Select the corresponding **Select** check box and click **OK**. The system updates the current date as the date performed.
5. Click **Log** to record comments and other important information of the maintenance, and then click **OK**.

To execute biochemistry maintenance command

1. Select **Utility > Maintenance > Maintenance > Biochemistry Maintenance**.
2. Click the maintenance command you are going to execute.
3. Perform the maintenance according to the wizard.

To execute ISE maintenance command

1. Select **Utility > Maintenance > Maintenance > ISE Maintenance**.
2. Click the maintenance command you are going to execute.
3. Perform the maintenance according to the wizard.

10.1.6 Extended operations of maintenance item

You can view execution records of each maintenance item, customize and delete self-defined maintenance items.

Viewing maintenance history

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.

To view maintenance history

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:
   a. Mark the checkbox of the desired maintenance record.
   b. Select **Edit**.
   c. Modify the maintenance record.
   d. Select **OK**.
   Only one maintenance record can be edited at one time.
5. To delete maintenance records:
   a. Mark the checkbox of one or more desired maintenance records.
   b. Select **Delete**.
   c. Select **OK**. The selected maintenance records are removed.
6. Select **Close** to exit the window.

Customizing maintenance item

Based on the actual use condition of the instrument, you can define and delete maintenance items.

To access the Customize Maintenance Procedure window

Select **Customize** on the **Scheduled Maintenance** screen. You can add, define and delete maintenance items for the selected frequency.

To define a maintenance procedure

1. Select **New**.
2. Enter the name of the new maintenance procedure.
3. Select **OK**. The maintenance procedure is displayed in the **Available Procedures** list.
4. Use **>>** and **<<** to configure or cancel user-defined maintenance procedures. The property of a user-defined maintenance procedure is User.
5. Select **OK** to save the configuration, or select **Cancel** to abort it.

To configure a maintenance procedure

1. Choose a maintenance frequency in the **Frequency** drop-down list.
2. Choose a maintenance procedure in the **Available Procedures** list. Move the vertical scroll bar to view more maintenance procedures.
3. 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

1. Choose a maintenance procedure in the **Enabled Procedures** list.
2. 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.
3. Select **OK** to save the configuration, or select **Cancel** to abort it.

Deleting self-defined maintenance procedure

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.

To delete self-defined maintenance procedure

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.

10.2 Scheduled maintenance and maintenance commands

This section provides a summary of all scheduled maintenance items, biochemistry and ISE maintenance commands. Execute them when needed.

10.2.1 Scheduled maintenance

The following table lists all scheduled maintenance items and their execution frequency.

CAUTION

"Cleaning ISE waste tube" is not provided on the software. To avoid clogged waste tube after long-term use, when you see alarm “No fluid in tube” or “Air in calibrator A” or “Air in calibrator B”, and check that the waste tube is clogged, perform this maintenance item.

Table 10.3 Scheduled maintenance items

Frequency	Maintenance item
Daily	Check probe/mixer/wash well
	Check DI water tank and tube connection
	Check diluted wash solution tank and tube connection
	Check waste connection
	Check probe wash solution
	Check sample/reagent syringe
	Clean electrode tubes

Frequency	Maintenance item
Weekly	Clean probe exterior
	Clean mixer
	Special wash
	Cuvette check
	Photometer check
Monthly	Clean wash wells
	Clean wash station
	Clean sample injection port
	Pump calibration
	Air bubble detector calibration
3-month	Clean DI water tank
	Clean diluted wash solution tank
6-month	Replace lamp
As-needed/As-required	Clean analyzer panels
	Bar code maintenance
	Clean sample/reagent compartment
	Clean probe interior
	Clean rotors
	Replace probe
	Replace mixer
	Special wash probe
	Replace cuvette
	Replace ISE electrode
	Store electrodes
	Remove reagent pack
	Replace syringe
	Remove air bubbles in syringe
	Clean ISE waste tube

10.2.2 Biochemistry maintenance commands

The following table lists all maintenance commands of the biochemistry system, as well as their usage and execution time. You can execute them according to the descriptions in this chapter or through the wizard on the software.

Table 10.4 Biochemistry maintenance commands

Biochemistry maintenance command	Usage	Execution time
Home	Reset the probe, mixer and wash station, and clean the probe and mixer.	• Check probe/mixer/wash well • Clean probe interior • Replace probe • Replace mixer • Clean wash wells • Special wash probe
Clean probe/mixer/wash wells	Reset the probe and mixer mechanically to return them to the wash position.	Check probe/mixer/wash well
Clean probes interior	Remove air bubbles possibly existing in the tubes, and clean the probe and wash well.	After maintenance of probe and wash wells
Special wash	Use concentrated wash solution to clean the probe, mixer, cuvettes, and wash station.	Special wash
Special wash probes	Use concentrated wash solution to clean the probe in order to eliminate cross contamination.	Special wash probe
Circulate wash cuvettes	Clean the reaction cuvettes circularly, to check the auto wash effects, and to check if the injection, aspiration, cuvette residue, and waste discharge are normal.	Used by service engineers to check cuvette wash
Clean probes/mixers exterior	Remove air bubbles possibly existing in the tubes, and clean the probe and wash well.	After maintenance of probe and wash wells
Prime wash station	Prime the wash station and tubes to remove air bubbles.	Clean wash station
Cuvette check	Check for dirty cuvettes by running water blank.	• Cuvette check • Special wash
Photometer check	Check the light intensity by measuring the average absorbance of 5 cuvettes at 340 nm.	• Photometer check • Replace lamp
Replace lamp	Replace the lamp.	Replace lamp
Replace cuvettes	Replace cuvettes.	Replace cuvette

10.2.3 ISE maintenance commands

The following table lists all maintenance commands of the ISE module, as well as their usage and execution time. You can execute them according to the descriptions in this chapter or through the wizard on the software.

Table 10.5 ISE maintenance commands

ISE maintenance command	Usage	Execution time
Two-point calibration	Calibrate the ISE module with calibrators A and B.	When needed

ISE maintenance command	Usage	Execution time
Clean electrode tubes	Clean the electrode tubes with ISE wash solution to remove the materials on the electrode surface.	Clean electrode tubes
Pump calibration	Calibrate the peristaltic pump to ensure accurate test result.	Pump calibration
Maintenance	Discharge the calibrator from the electrode inside before electrode replacement.	When needed Or automatically executed during "Clean sample injection port" and "Replace electrode"
Air bubble detector calibration	Calibrate the air bubble detector to ensure good sensitivity.	Air bubble detector calibration
Purge A	Dispense 100 µL calibrator A to the inside of the electrodes through the sample injection port.	When needed Or automatically executed during " Clean sample injection port", "Replace electrode" and "Unload reagent pack"
Purge B	Dispense 100 µL calibrator B to the inside of the electrodes through the sample injection port.	When needed Or automatically executed during " Clean sample injection port", "Replace electrode" and "Unload reagent pack"
Replace electrode	Replace the ISE electrodes.	Replace electrode
Replace tubes of pump and calibrator	Replace the aging tubes of the peristaltic pump and calibrator.	Used by service engineers to replace the tubes of pump and calibrator
Unload reagent pack	Remove the reagent pack and empty the tubes.	Remove reagent pack
Program check	View the software version of the ISE module.	When needed
Air bubble detector calibration result	View the result of air bubble detector calibration.	After performance of "Air bubble detector calibration"
Pump calibration result	View the result of pump calibration.	After performance of "Pump calibration"
Write dallas chip	Write information on the Dallas chip.	When needed
Read dallas chip	Read the information on the Dallas chip.	When needed
Store Electrodes	Remove the electrodes and store them	When needed
Clean Sample Injection Port	Clean the sample injection port	When needed

10.3 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 10.6 Maintenance log sheet

Maintenance log sheet																																		
																												Month			Year				
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 probe/mixer/wash well																																	
2	Check DI water tank and tube connection																																	
3	Check diluted wash solution tank and tube connection																																	
4	Check waste connection																																	
5	Check probe wash solution																																	
6	Clean electrode tubes																																	
7	Check sample/reagent syringe																																	
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 probe exterior																																	
2	Clean mixer																																	
3	Special wash																																	
4	Cuvette check																																	
5	Photometer check																																	
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 wash station																																	
3	Clean sample injection port																																	
4	Pump calibration																																	
5	Air bubble detector calibration																																	
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	Clean diluted wash solution tank																																	
3	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																																	
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																																	
2	Bar code maintenance																																	
3	Clean sample/reagent compartment																																	

Maintenance log sheet																												Month			Year		
4	Clean probe interior																																
5	Clean rotors																																
6	Replace probe																																
7	Replace mixer																																
8	Special wash probe																																
9	Replace cuvette																																
10	Replace ISE electrode																																
11	Store electrodes																																
12	Remove reagent pack																																
13	Clean ISE waste tube																																
14	Replace syringe																																
15	Remove air bubbles in syringe																																

10.4 Daily maintenance

10.4.1 Checking probe/mixer/wash well

Abnormal probe, wash well or mixer may influence the measurement performance and lead to inaccurate results. Prior to measurements every day, check the probe and mixer for stains and crystals, and check if the water flow in the wash wells is abnormal. If the above-mentioned abnormities exist, clean or adjust the probe and mixer immediately.

Purpose

To check the probe for water dripping, stains and liquid flow abnormities, and check if the mixer 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 probe and mixer are sharp and vulnerable. To prevent injury and equipment damage, exercise caution when working around the probe and mixer. Keep away from the probe and mixer to avoid collision with them.

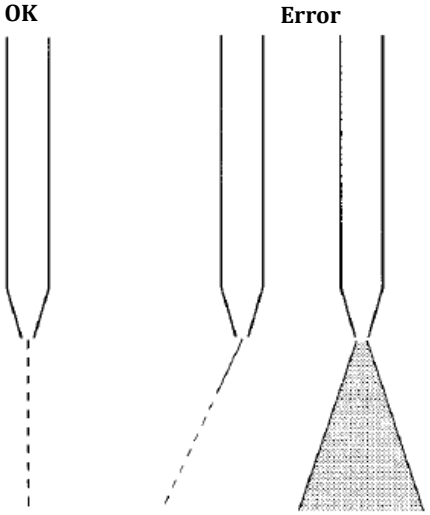
BIOHAZARD

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 probe and mixer for stains. If stains exist, perform the "Cleaning probe exterior" and "Cleaning the mixer" procedures.
5. Select **Continue** to clean the probe interior.
6. Check the liquid flow of the probe.
   - If the liquid flow is sprayed out or does not come out vertically, the probe may be clogged. Perform the "Special wash probe" procedure, and then check it again.
   - If the abnormity remains, perform the "Cleaning probe interior" procedure.
   - If the abnormity still remains, perform the "Replacing the probe" procedure, or contact a service engineer.

Figure 10.1 Normal and abnormal liquid flows of the 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 5 mm of the probe/mixer from the tip.

10 If the water flow is abnormal, contact a service engineer.

11 Select **Continue** and **Done**.

12 Restore the protective shield.

10.4.2 Checking DI water tank and tube connection

If the deionized water tank is empty or the tubes are not connected properly, the deionized water cannot be supplied normally or leak may be caused, influencing the measurements. Perform this check every day.

Purpose

To check the deionized water tank and the tube 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.

10.4.3 Checking diluted wash solution tank and tube connection

If the diluted wash solution tank is empty or the tubes are not connected properly, tests cannot be performed. Perform this check every day.

Purpose

To check the diluted wash solution tank and the tube connection to ensure normal supply of diluted wash solution.

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 diluted wash solution tank has sufficient wash solution.

2 If the wash solution is insufficient, fill more.

10.4.4 Checking waste connection and waste tank connection

If the waste tube is not connected properly or the high-/low-concentration waste tanks are 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-/low-concentration waste tanks.

Refer to the following waste amount when checking the waste tanks:

- high-concentration waste0.4 L/H, low-concentration waste no more than 4.2 L/H.

Purpose

To check the waste tube connection and the high-/low-concentration waste tanks 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 the high-/low-concentration waste tubes, and ensure that they are not leaking or bent.

2 Check if the high-/low-concentration waste tanks are full. If yes, empty them.

10.4.5 Checking 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 probe when every batch of tests is finished, and about 295 μL wash solution is consumed each time. The amount of concentrated wash solution for weekly cleaning of reaction cuvettes is 15 mL.

Purpose

To check the sample 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 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/reagent carousel position D.
2. If necessary, fill more or replace the wash solution. To ensure wash effects, you are recommended to replace it.

10.4.6 Cleaning electrode tubes

When the ISE module finishes a great number of measurements, the proteins and lipid contained in samples may remain on surfaces of the electrodes, influencing their measurement performance. You should clean the electrodes regularly to ensure system performance.

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 wash solution, 20 mL or 40 mL reagent bottle

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 performing this procedure, recalibrate the ISE electrodes prior to starting analysis.

How to do

1 Select **Utility > Maintenance > Maintenance > ISE Maintenance**.

2 Choose **Clean Electrode Tubes**. The maintenance guide window shows.

3 Open the upper protective shield of the analyzer.

4 Fill a reagent bottle with at least 2.5 mL ISE wash solution, and then load it to ISE wash solution position (Position 38#) on the sample/reagent carousel.

5 Select **Continue**. The system starts cleaning the ISE electrode tubes.

6 Select **Done**.

After finishing the maintenance, run ISE calibration.

For more information on ISE calibration, see Requesting calibration on page 2-17.

10.4.7 Checking Sample/Reagent Syringe

The sample syringe /reagent syringe is precise devices used to aspirate/dispense small amount of sample and reagent. If the syringe leaks, it cannot aspirate/dispense the correct amount of sample or reagent, and may even be damaged. Prior to measurements every day, check the sample/reagent syringe for leak.

Purpose

To check the sample/reagent syringe for leak and air bubbles.

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 upper shield. You will see one syringe.
2. Check the T piece assembly and plunger guide cap for leak.
3. Use dry gauze to wipe the T piece, and then check if the gauze is moistened.
    - If it is not, proceed to the next step.
    - If it is, tighten the T piece.
    - Check the T piece and plunger guide cap again. If the leak remains, check if the washer inside the syringe connector is intact.
    - If the washer is damaged, replace it with a new one; otherwise, replace the syringe.
4. Check the syringe interior for air bubbles. If yes, remove the air bubbles.
5. Check if the retaining screws at the bottom of the syringe are tightened.
    - If not, tighten them and proceed to the next step.
    - If yes, proceed to the next step.

10.5 Weekly maintenance

10.5.1 Cleaning probe exterior

The probe is often dirty on its surface, 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 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. Pull the probe arm to the highest point and then rotate it to move the probe to a position convenient for cleaning.
3. Use gauze soaked with ethanol to gently wipe the probe exterior. Clean the probe tip until it becomes clear without stain.

4 Use gauze moistened with deionized water to clear the ethanol on the probe.

CAUTION

Do not pull the probe horizontally to prevent probe damage.

5 After finishing the cleaning, close the shielding cover, and turn on the analyzing unit power switch.

6 Select **Utility > Commands > Home** to reset the system.

10.5.2 Clean the mixer

The mixer is often dirty on its surface, causing carryover between samples or reagents and resulting in inaccurate results. You are recommended to perform this procedure every week.

Purpose

To clean the 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

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

CAUTION

Exercise caution while working around the mixer. If it is bent or damaged, replace it immediately; otherwise, unreliable results may be obtained.

How to do

1 Switch off the analyzing unit power.

2 Pull the mixer arm to the highest point and then rotate it to move the mixer to a position convenient for cleaning.

3 Use gauze soaked with ethanol to gently wipe the mixer exterior until it becomes clear without stain.

4 Use gauze moistened with deionized water to clear the ethanol on the mixer.

CAUTION

Do not pull the mixer horizontally to prevent damage.

5 After finishing the cleaning, close the shielding cover, and turn on the analyzing unit power switch.

6 Select **Utility > Commands > Home** to reset the system.

10.5.3 Special Wash

Special wash is to clean the probe, mixer, 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.

Purpose

To eliminate cross contamination among the probe, mixer, 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 20 mL concentrated wash solution in position D(Position 39) of the reagent carousel.
3. Select **Utility > Maintenance > Maintenance > Biochemistry Maintenance**, and select the **Special Wash** check box.
4. To perform cuvette check after the special wash, mark the check box in front of **Perform Cuvette Check**.
5. Select **Continue**. The system starts cleaning the probe, mixer, cuvettes, and wash station.

After the cleaning, the system performs cuvette check automatically.

10.5.4 Cuvette check

If the uniformity of a cuvette becomes poor due to contaminated interior or exterior, and the transmittance decreases, accurate test results may not be obtained. Check the reaction cuvettes regularly, and if necessary, replace them.

Purpose

To check for dirty cuvettes by measuring the water blank of each cuvette.

When to do

- Every week
- Any time
- After performing special wash
- After replacing or cleaning the cuvettes

System status

Prior to performing the maintenance, make sure that the system has been power on for over 5 minutes and the system status is Standby.

Precautions

NOTE

When a cuvette is deemed dirty, clean or replace it immediately, and then perform the cuvette check again.

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 5 minutes. Select **Continue** and then select **Start**.

When finishing the check, the system refreshes the cuvette status based on the check results and highlights the dirty cuvettes in yellow.

4 Record the cuvettes highlighted in yellow and replace them.

5 Select **Result**. The **Cuvette Check Results** window appears and shows the latest check results at all wavelengths.

6 To view the test result and current status of certain cuvette, click the cuvette No. in the result list. The **Cuvette Status** window pops up.

7 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.

8 Select **Exit** to close the **Cuvette Check** window.

10.5.5 Photometer check

If the lamp is aging, the light amount will go beyond measurement range of the photometer, and correct measurement will not be done due to too much noise. You should check the lamp regularly.

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**.
3. Select **Continue** and then select **Start**.
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 on replacing lamp, refer to 10.8.1 Replacing lamp on page 10-26.
5. When the test is finished, check the test results.

   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.
6. Check the results of the previous and current photometer check to understand the lamp status.
7. Choose the following buttons as needed:
   - **Print**: to print the photometer check results currently available on the screen.
   - **Exit**: to close the window.
8. Select **Done** to close the **Photometer Check** window.

10.6 Three-month maintenance

10.6.1 Cleaning 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.

How to do

1 Remove the quick connector from the outlet of the water tank.
2 Clean the water tank repeatedly with deionized water.
3 Connect the outlet tube of the water tank.

10.6.2 Cleaning diluted wash solution tank

Stains will remain in the diluted wash solution tank when it is used for a long time and may influence the cleaning effects of the system.

Purpose

To clean the diluted wash solution 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

How to do

1 Remove the quick connector from the outlet of the diluted wash solution tank.
2 Clean the diluted wash solution tank repeatedly with deionized water.
3 Connect the outlet tube of the diluted wash solution tank.

10.7 Monthly maintenance

10.7.1 Cleaning 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 the probe and 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. Rotate the probe and mixer to keep them away from the wash wells.
3. Use clean cotton swabs moistened with NaClO to clean the wash wells.
4. After finishing the cleaning, turn on the analyzing unit power switch.
5. Select **Utility > Commands > Home** or execute the **Clean Probes/Mixers/Wash Wells** command, and check if the wash wells have a normal water flow.

10.7.2 Cleaning wash station and tubes

Clean the wash station regularly to prevent waste from accumulating on it.

Purpose

To clean the cuvette wash station 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. Remove the cuvette wash station and use ethanol-moistened gauze to wipe the wash probes and wipe block.
2. Use gauze moistened with deionized water to clear the ethanol on the wash probes.
3. Restore the wash station.
4. Select **Utility > Maintenance > Maintenance > Biochemistry Maintenance**.
5. Choose **Prime Wash Station** The maintenance guide window shows. Select **Continue**.
6. Enter the wash cycle (1~100). Select **Continue**.
7. When the cleaning and priming are finished, select **Done**.
8. Select **Utility > Commands**, and then select **Home** to put the instrument into the Standby status.

10.7.3 Cleaning sample injection port

When the ISE module is used for a period, stains may build up in the sample injection port and influence the measurement performance. Clean the sample injection port regularly to keep it clear.

Purpose

To remove the stains accumulating in the sample injection port.

When to do

You are recommended to perform this procedure every month.

Materials required

Deionized water, cotton swabs, and ethanol

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

System status

Make sure that the status of the ISE module is Standby or Stopped.

How to do

1. Select **Utility > Maintenance > Maintenance > ISE Maintenance**, and choose the **Clean Sample Injection Port** option.
2. Select **Continue**.
3. Use clean cotton swab soaked with ethanol to wipe the sample injection port (interior of the sample injection cup of the ISE module) until it is clean.
4. Use a clean cotton swab soaked with DI water to wipe the interior and periphery of the sample injection port.
5. Select **Done**.
6. Select **Purge A** and **Purge B** to prime the ISE module, each for 3 times.
7. Restore the cover of the ISE module.

10.7.4 Pump calibration

The peristaltic pump may get aging when used for a long time. It is necessary to calibrate it regularly.

Purpose

To calibrate the peristaltic pump to ensure accurate test result.

When to do

This procedure should be performed on monthly basis.

Materials required

Deionized water, sample tube

System status

Make sure that the status of the biochemistry system and the ISE module 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 > ISE Maintenance**.
2. Choose **Pump Calibration**.
3. Fill the sample tube with at least 1000 μL deionized water and then place it in No.40 position of the sample carousel.
4. Select **Start**.

   When the calibration is complete, the calibration results are displayed on the screen.
5. Select **Done**.
6. To view the detailed results, select **Pump Calibration Result**. The detailed results are displayed in the data list.

10.7.5 Air bubble detector calibration

The air bubble detector may get aging when used for a long time. It is necessary to calibrate it regularly.

Purpose

To calibrate the air bubble detector to ensure accurate test result.

When to do

This procedure should be performed on monthly basis.

System status

Make sure that the status of the biochemistry system and the ISE module 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 > ISE Maintenance**.
2. Choose **Air Bubble Detector Calibration**.
3. Select **Start**.

   When the calibration is complete, the calibration results are displayed on the screen.
4. Select **Done**.
5. To view the detailed results, select **Air Bubble Detector Calibration Result**. The detailed results are displayed in the data list.

10.8 Six-month maintenance

10.8.1 Replacing lamp

An aged lamp will has its energy decreased and influence the measurement accuracy. Failed lamp will make measurements impossible. To ensure the optimal performance of the system, replace the lamp regularly.

Every time after you replacing the lamp, if the light intensity is insufficient, replace the lamp immediately.

Purpose

To ensure that the lamp works normally.

When to do

You are recommended to perform this procedure 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 10 minutes, and then select **Continue**.
4. Remove the cover plate of the lamp.
5. 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 new lamp, and the retaining screw, O-ring connectors, cable terminal nuts and lamp cover plate in the reversed order.
9. Select **Done**.

   Perform the Photometer Check procedure to ensure the system power is normal.

   For more information, refer to 10.5.5 Photometer check (page 10-21).

10.9 As-needed/As-required maintenance

10.9.1 Cleaning 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

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.

CAUTION

Do not spill liquid on the analyzer. Liquid ingression may cause equipment damage.

How to do

1 Use clean gauze moistened with ethanol to clean the analyzer panels and carousel covers.

2 Use wash solution to clean the screen and keyboard.

10.9.2 Cleaning sample/reagent compartment

When sample or reagent is sprayed into the compartment, or dusts accumulate inside the compartment, clean them immediately in order to minimize the risks of cross contamination.

Purpose

To clean the sample/reagent carousel assembly to ensure clear operating environment and eliminate the risks of cross contamination.

When to do

Perform this procedure when sample or reagent is spilled into the 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

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.

CAUTION

Do not spill water or ethanol into the sample compartment to prevent equipment damage.

How to do

1. Remove the sample/reagent carousel cover and the carousel, and then store them properly.
2. Use clean gauze soaked with deionized water or ethanol to clean the interior of the compartment. If necessary, use gauze moistened with neutral wash solution.
3. Use clean gauze soaked with deionized water or ethanol to clean the carousel, and then use cotton swabs dipped with ethanol to clean the sample and reagent positions.
4. Install the sample/reagent carousel and the carousel cover.

10.9.3 Cleaning probe interior

The probe, once blocked, cannot aspirate or dispense sample and reagent correctly. Clean the probe interior regularly to ensure normal test performance of the instrument.

Purpose

To clean the interior of the probe and avoid clogging.

When to do

Perform this procedure when you find that the probe is clogged and cannot aspirate or dispense sample and reagent, or when the probe is detected with abnormal liquid flow during the "Checking probe/mixer/wash well" maintenance.

Materials required

Unclogging device (or needle), small slot-head screwdriver, 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

To remove the probe

1. Recall the maintenance logs and check if the probe has been removed and reinstalled for 3 times. If it has, replace the washer with a new one.

   a. Prepare a new washer.

   b. 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 Use a small screwdriver to remove the retaining screw from the probe and take out the spring.

6 While holding the connector on the probe with one hand, unscrew the tube connector counterclockwise with the other hand until the tube connector is disconnected. Remove the tube from the 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 To replace the washer, remove it.

8 Remove the sample probe.

To clean the probe

1 Connect the unclogging device to the probe.

2 Fill the syringe with deionized water and then connect it to the unclogging device.

3 Put the probe inside the beaker while keeping the probe tip not contacting the beaker.

4 Push the syringe to rinse the interior of the probe. Repeat this step for 10 times.

5 If the syringe plunger leaks and the probe cannot be unclogged due to serious blockage, replace the probe.

6 Check if continuous water flow comes out of the probe in the same direction with the probe. If it does, it indicates the cleaning procedure is finished successfully.

7 If water flow is still abnormal after unclogging, replace the probe with a new one.

8 Remove the unclogging device.

To install the probe

1 Insert the probe downwards into the hole on the probe arm while aligning the screw hole on the probe plate to the rod inside the arm.

2 If you have removed the old washer from the tube connector, install a new one.

3 Connect the tube connector to the probe and then tighten it.

4 Fix the earthing wire of the probe to the earthing terminal inside the arm; connect the probe connector to the liquid level detection board.

5 Sleeve the spring on the rod and tighten the retaining screw.

Pay attention to the spring direction and make the thread opening face downwards.

6 Pinch the probe by the part near the probe arm. Push the probe upwards and then release it to check if the spring works well.

6 If the spring cannot restore, check if it is clamped or fixed too tightly.

To check the probe

1 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.

2 If it is not, the liquid level detection system is abnormal. Contact our customer service department or your local distributor.

3 Install the probe arm cover properly, and then tighten the screws on it.

4 Pinch the probe by the part near the probe arm. Push the probe upwards and then release it to check if the spring works well.

5 If the spring cannot restore, it indicates that the arm cover is not installed correctly. Reinstall the arm cover and check the spring until it can move freely.

6 Execute the **Home** maintenance command or the **Home** system command. Check if the water flow coming out of the probe is continuous and in the same direction as the probe.

7 If it is not, perform the "Checking probe/mixer/wash well" procedure to troubleshoot the problems.

10.9.4 Cleaning rotor

Clean the rotor of the probe and mixer to eliminate noise and fraying.

Purpose

Clean the rotor of the probe and mixer to minimize noise and fraying due to movement in order to extend the service life.

When to do

This procedure should be performed when there are dirty substances or dust on the rotors.

Materials required

Clean gauze

System status

Make sure that the system status is Standby.

Precautions

Warning

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

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 Switch off the analyzing unit power.

2 Pull the probe/mixer arm to the highest point, and then rotate the arm to move the probe/mixer to a position convenient to operate.

3 Wipe the rotor with clean gauze.

4 After finishing the cleaning, turn on the analyzing unit power switch.

5 Select **Utility > Commands > Home** to reset the probe and mixer.

10.9.5 Replacing the probe

Replace the probe when it is damaged and cannot be repaired, or blocked seriously, or bent.

Purpose

To replace the probe.

When to do

Perform this procedure when the 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 probe

System status

Make sure that the system 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

To remove the old probe

Remove the old probe.

For more information on removing probe, see 10.9.3 Cleaning probe interior on page 10-29.

To install the new probe

Install the new probe.

For more information on installing probe, see 10.9.3 Cleaning probe interior on page 10-29.

To check the new probe

Check the new probe.

For more information on checking probe, see 10.9.3 Cleaning probe interior on page 10-29.

10.9.6 Replacing the mixer

Replace the mixer when it is bent or damaged and cannot be repaired.

Purpose

Replace the mixer.

When to do

Perform this procedure when the mixer is damaged and cannot be repaired.

Materials required

Ethanol, clean gauze, new mixer

System status

Make sure that the system is not running any tests.

Precautions

Warning

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

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

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.
- Ensure the mixer is all the way pushed to the end.

How to do

Replacing the mixer includes the following steps:

- Removing the mixer
- Installing and checking the mixer

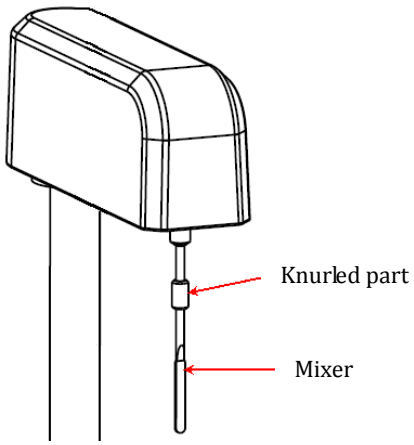
To remove the mixer

1 Switch off the analyzing unit power.

2 Gently pull the mixer to its highest point and rotate it to a position convenient to operate.

3 Pinch the mixer by the knurled part with one hand and unscrew (counterclockwise) the retaining nut with the other hand until the mixer loosened.

Figure 10.2 Mixer

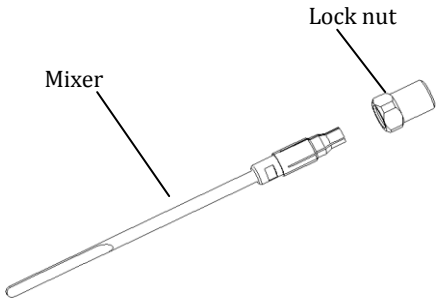


4 Pull the bar downward to remove it and remove the nut.

To install and check the new mixer

1 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.

Figure 10.3 Mixer and lock nut



2 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.
3 Screw the lock nut clockwise to tighten the mixer.
4 Visually check whether the mixer is vertical to the bar arm.
5 If it is not, remove the mixer and reinstall it.
6 Pull the mixer arm to its highest point and rotate it back to a position above its wash well.
7 Turn on the analyzing unit power switch.
8 Select **Utility > Commands**, and execute the **Home** command.

10.9.7 Removing Air Bubbles in Syringe

Purpose

To remove the air bubbles possibly existing inside the syringe tubes.

When to do

Perform this procedure when you find air bubbles inside the sample syringe.

Materials required

Deionized water, 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.

How to do

1 Switch off the analyzing unit power, and open the upper shield 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 to make the syringe head over the upper fixing block for 7.5 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 Syringe procedure.

10.9.8 Replacing Syringe

The 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 upper shield of the analyzer. You will see one syringe.

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 to make the syringe head over the upper fixing block for 7.5 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 Syringe procedure to check the syringe.

10.9.9 Replacing 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 replace the cuvette every three months.

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.
- It is overflowing.
- Scratches or cracks are found on the optical surface of the cuvette.
- Every three months

Materials required

Fiber-free gloves, dry cloth or gauze, and reaction cuvettes

System status

Make sure that the system status is Standby .

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.

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.

How to do

1. Select **Utility > Maintenance > Maintenance > Biochemistry Maintenance**.
2. Choose **Replace Cuvette**.
3. Open the cuvette replacement cover.
4. Select **Continue**.
5. Type in the position number of the cuvette you want to replace.
6. Find the specified cuvette position, grab the cuvette segment with your thumb and forefinger, and then take it out.
7. Install a new cuvette segment on the positioning pins, and then press it with the retaining screw.
8. Close the cuvette replacement cover.
9. Select **Done**.

10.9.10 Special wash probe

Purpose

To eliminate cross contamination of the probe, and prevent waste from leaving in the waste tubes.

When to do

Perform this procedure when the probe is clogged or the carryover result exceeds the limit.

Materials required

Concentrated wash solution manufactured by our company, or sodium hypochlorite solution (NaClO, with 0.5% chlorite)

System status

Make sure that the system status is Standby

How to do

1 Place more than 20 mL concentrated wash solution in position D of the reagent carousel.

2 Select **Utility > Maintenance > Maintenance > Biochemistry Maintenance**.

3 Choose **Special Wash Probe**.

4 Set replicates and wash volume, and then select **Continue**.

6 When the cleaning is finished, select **Done**.

10.9.11 Bar code maintenance

This maintenance procedure is used to clean the bar code scanning windows in order to avoid influencing bar code scanning.

Purpose

To clean the glass of the 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 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 cover and the carousel.

2 Use clean gauze to clean the bar code scanning window inside the compartment.

3 If necessary, use gauze soaked with ethanol or deionized water. Make sure that there is no trace or dust left on the glass.

4 Install the carousel and the carousel cover.

10.9.12 Replacing ISE electrode

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.

Purpose

To replace the ISE electrodes to ensure the optimal measurement performance.

When to do

- Reference electrode: Every 6 months

- Other electrodes:
  - When 10,000 ISE tests are performed.
  - When the ISE electrodes are used for 6 months since installation.
  - When calibration fails or quality control is abnormal as the result of degraded electrode performance.

Materials required

Reference electrode, ISE electrode

System status

Make sure that the status of the ISE module is Standby or Stopped

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

To remove the electrodes

1. Select **Utility > Maintenance > Maintenance > ISE Maintenance**.
2. Choose **Replace Electrode**.
3. Select desired electrodes, and enter the lot number and expiration date.
4. Select **Add** and then select **OK**.
5. Select **Continue**.
6. Open the ISE side door and remove the cover of the shielding box.
7. Open the electrode case, take out the electrode, remove the tapes around its inside, and then use clean tissue to wipe it.

   NOTE

   Take out the insert from the reference electrode, and ensure no crystallized salt exists in and around it. If needed, clean the electrode with warm water.

   Make sure the red ball of the reference electrode floats on the internal fluid. Make sure the O rings of all electrodes remain intact.
8. Remove all electrodes from the ISE module.

To install the new electrodes

1. To install a new reference electrode:

   a. Place the reference electrode at the bottom of the ISE module and make the rear part of the electrode contact closely with the internal wall of the ISE module.

   b. Loosen the compressor and ensure the electrodes are fixed tightly.
2. Install other electrodes in the order of Cl, K, Na, and spacer from bottom to top.
3. If the O ring is lost, install a new one.

   There are two more O rings in each electrode case.
4. Check if the electrode positions are correct:

- The Na, K and Cl electrodes are of the same size and shape. Ensure that the electrodes are inserted in the correct order.
- If one of the electrodes cannot be easily pushed into the housing, check the electrode first and then repeat the installation process.
- Check if the 5 electrodes are relatively on the same straight line; otherwise, liquid cannot flow through the electrode tubes smoothly.

5 Select **Continue**. The system primes the tubes with calibrators A and B.

6 Select **Done**.

7 Restore the cover of the shielding box and close the side door of the ISE module.

8 Run ISE calibration.

NOTE

The new electrode can be calibrated successfully only after certain time period.

9 If the calibration fails, perform the following operations:

- Run ISE calibration for multiple times so that the electrodes can get steady quickly.
- Or, drip little serum sample in the electrode channel, and leave it for 10-30 minutes, and then run calibration again.

10.9.13 Removing reagent pack

When powering off the analyzer for a long time, or storing the electrodes, or replacing the electrode tubes, remove the reagent pack first.

When to do

Perform this maintenance procedure when powering off the analyzer for a long time (over 3 days), or storing the electrodes, or replacing the electrode tubes.

System status

Make sure that the status of the ISE module is Standby or Stopped

How to do

1 Select **Utility > Maintenance > Maintenance > ISE Maintenance**, and choose **Remove Reagent Pack**.

2 Remove the tube of pump A and then reinstall the tube by switching the connectors of the tube.

3 Handle pump B in the same way.

4 Select **Continue**.

The system executes purge A and B each for 30 times.

5 Restore the reversed pump tubes.

6 Install the three red caps on the tube connectors of the reagent pack, and keep the reagent pack at room temperature away from sunshine.

7 Select **Done**.

10.9.14 Storing electrodes

Before the analyzer is powered off for a long time or after the reagent pack is removed, the ISE electrodes cannot be moistened by regular prime, and may be damaged due to lack of water. It is necessary to store the electrodes properly before powering off the analyzer for a long period.

Purpose

To store the electrodes separately to prevent them from being damaged due to lack of water while the analyzer is powered off.

Materials required

Electrode cases and tapes

When to do

Perform this procedure when the analyzer is going to be powered off for over 3 days. If it will be powered off for no more than 3 days, prime the ISE electrodes to protect them from being damaged.

System status

Make sure that the status of the ISE module is Standby or Stopped

Precautions

 **BIOHAZARD**

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

 **NOTE**

Make sure that the storage temperature is below 40˚C.

How to do

1. Remove the reagent pack according to 10.9.13 Removing reagent pack on page 10-40.
2. Open the ISE side door and remove the cover of the shielding box.
3. Remove all electrodes from the ISE module.
4. To save the reference electrode:

   a. Put back the insert to the cell of the reference electrode and prevent the crystallized salt from clogging the cell.

   b. Store the electrode in an electrode case at the room temperature in a sun-shielding place.
5. To save the Na, K and Cl electrodes:

   a. Take out a little calibrator A from the reagent pack, inject it into the cell of the electrode and seal it with tape. Make sure proper amount of calibrator is injected into the cell of the electrode.

   b. Store the capped electrodes in an electrode case at the room temperature in a sun-shielding place.
6. Restore the cover of the shielding box and close the side door of the ISE module.

10.9.15 Cleaning ISE waste tube

Samples containing insoluble substance like fibrin may accumulate in the ISE wand waste outlet after extended usage and clog the waste tube.

Purpose

Clean the waste tube of ISE module to prevent the sediment inside from clogging the tube.

When to do

When the alarm "No fluid in tube" or "Air in calibrator A" or "Air in calibrator B" occurs and the waste tube is clogged.

Materials required

Unclogging tool for the ISE waste tube, bleaching agent(Dilution Ratio 1:1) or 50% sodium hypochlorite, and deionized water

System status

Make sure that the system is not running test.

Precautions

BIOHAZARD

Wear gloves and lab coat, and if necessary, goggles during the maintenance process.

Note

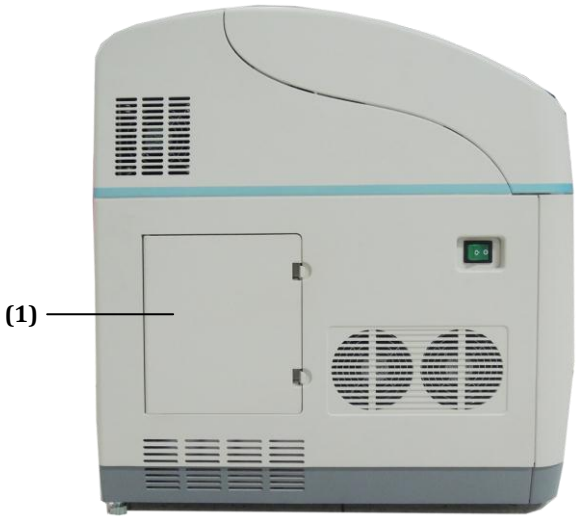
Excessive bleach and DI water flushed into the ISE reagent pack waste bag may cause waste bag over expansion and clog the Cal A & Cal B reagent flow.

Do not spill liquid on the analyzer. Liquid ingression may cause equipment damage.

How to do

1 Ensure the analyzer is in *Standby* status. Open the ISE cover on the left panel.

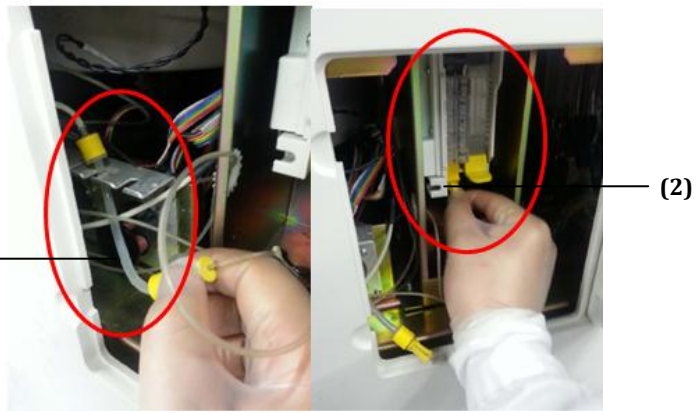
Figure 10.4 Open the ISE cover



(1) ISE module cover

2 Remove the electrode housing cover. Remove the waste tube fitting from the bottom of the right angle adapter. Remove waste peri-pump tube from the pump bracket. Refer to pictures below.

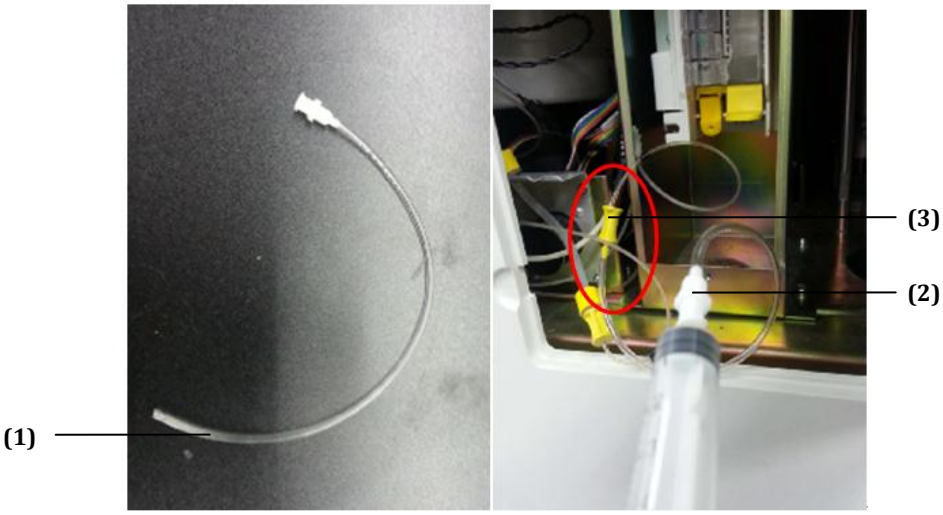
Figure 10.5 Removing the right angle adapter and waste pump



(1) Waste pump tube (2) Right angle adapter

3 Connect the waste tube fitting to a syringe and unclogging tool with 5 mL of undiluted household bleach. Refer to pictures below.

Figure 10.6 Connect the unclogging tool and the right angle adapter



(1) and (2) Unclogging tool (3) Tube fitting for right angle adaptor

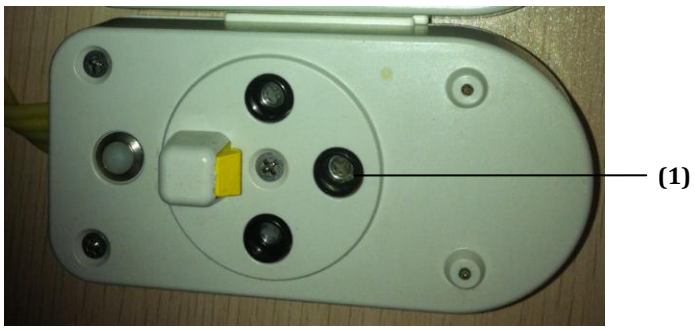
4 Press the wand release button to remove the wand from the current in use ISE reagent pack and keep it in a save place. Engage the wand to an old used-up reagent pack.

5 Inject bleach into the ISE waste tube and soak the tube for 5 minutes. Discharge the waste into the reagent pack.

6 If the bleach cannot be injected into the ISE pack, remove the wand and push down to open the waste valve manually with a sharp object, and then inject again.

- If bleach can go through this time, the waste bag was clogged and cannot be used.
- If bleach still cannot be injected, replacing the ISE wand is recommended.

Figure 10.7 Waste valve



(1) Waste valve

7 Repeat steps 5-6, and clean the tubes with the syringe by aspirating 5 mL deionized water.

8 Remove the wand from the old use-up pack and re-install it back to the current in use ISE pack. Re-install the waste tube fitting back to the ISE electrode housing right angle adaptor and waste peri-pump tube back to the pump bracket. Re-install the housing cover.

9 Calibrate ISE pump to ensure it passes, all reagents and waste flow are normal.

10 Calibrate all electrodes and run QC test to ensure they all pass within their given range.

11 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.

11.1 Classification of logs

The logs provided by the system are divided into:

- Error log
- Edit log

11.1.1 Error logs

Error logs record all types of failures occurring on the system components. 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 11.1 Error code of the operation unit

Error Code	Description
C	Indicates that the error occurs on the operation unit.
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 11.2 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 • 01/02-Probe unit • 05-Mixer • 06-Reaction carousel unit • 07-Sample /reagent carousel unit • 11-Wash unit • 12-Temperature unit • 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.

11.1.2 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.

11.2 Viewing and handling logs

All error logs and edit logs can be recalled, searched, refreshed, deleted and printed.

11.2.1 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 11.1 Error Log screen

Every error log contains the event ID, date/time, error description (by processing method), event class (by subsystem) and symptom.

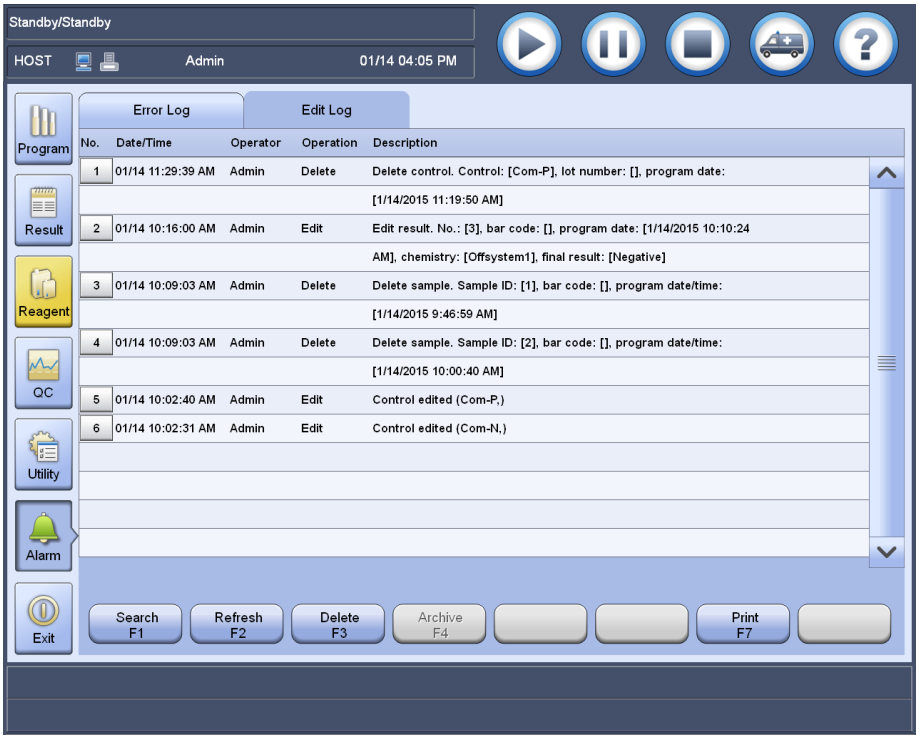
Choose the following buttons as needed:

- **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.

11.2.2 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 11.2 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.

11.2.3 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.

11.2.4 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.

11.2.5 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 8.7.3permissions on page 8-23.

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.

11.2.6 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**.

11.3 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.

11.3.1 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.

11.3.2 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 11.3 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.

11.4 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.

11.4.1 Data alarms and corrective actions

Table 11.4 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.
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.
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.

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.
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.
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.

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.
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.

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.
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.	/
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.
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˚C.
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˚C.	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.
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 90 μl 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.
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.

11.5 Error Messages and Corrective Actions

Table 11.5 Error messages and corrective actions

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A00006	Middle layer unit	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.
A00007	Middle layer unit	Error	Instruction execution error	/	Instrument instructions cannot be executed.	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:	/	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	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
					position: The sample probe moves vertically in an unknown position. Sample probe horizontal movement error 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. 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.	
			Or Sample syringe movement error. Position: Error:			
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
A01024	Sample probe unit	Warning	Insufficient sample 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.
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.
A01033	Sample probe unit	Warning	Sample probe fails to detect liquid level on reaction carousel when dispensing. Cuvette No.: Sample ID/bar code: Chemistry: or Sample probe level detection failed. 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.
A01039	Probe unit	Error	Instruction execution error	/	Instrument instructions cannot be executed.	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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						distributor.
A02007	Probe unit	Warning	Probe R2 collides with an obstacle when aspirating Reagent position: Specific position:	/	1. Collision occurs during aspirating: The probe R2 collides with other object.	1. Collision occurs during aspirating: Remove the obstacle and then recover the failure.
A02023	Probe unit	Warning	Insufficient reagent Or Probe R2 level detection failed.	/	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.
A02025	Probe unit	Warning	Probe dispenses insufficient reagent	/	1. The probe aspirates nothing.	1. Check if the reagent satisfies the requirement and is sufficient in volume, and then try again. 2. Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A02027	Probe unit	Warning	Water residues exist in the cuvette or Probe level detection failed	/	DI water residual exists in cuvette.	Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A05006	Mixer unit	Error	Mixer vertical movement error Mixer horizontal movement error	/	1.Sensor status error. the assembly is probably forced to move vertically. 2.Failed to find the zero position. The mixer assembly is probably jammed 3.Vertical movement is not allowed in current horizontal position. The reagent mixer moves vertically in an unknown position.	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 assembly is probably forced to move vertically. 2. Failed to find the zero position The mixer assembly is obstructed when rotating 3. Horizontal movement is not allowed in current vertical position.	
A05007	Mixer unit	Error	Instruction execution error	/	Instrument instructions cannot be executed.	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.
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.
A06007	Reaction carousel unit	Error	Filter wheel movement error	/	1. Instrument instructions cannot be executed. 2. Filter wheel motor error 3. The home position sensor of Filter wheel is abnormal.	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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						distributor.
A06008	Reaction carousel unit	Error	Instruction execution error	/	Instrument instructions cannot be executed.	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/reagent 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. The sample carousel is obstructed or blocked.	Recover the failure. If this message appears for 3 times, contact our customer service department or your local distributor.
A07009	Sample/reagent 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/reagent 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/reagent 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.
A09011	Sample/reagent	Error	Reagent bar code	/	The reagent bar coder reader goes wrong	Recover the failure. If the error still

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
	carouse unit		reader does not work normally		due to system failure.	remains, contact our Customer Service Department or your local distributor.
A09012	Sample/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.
A09014	Sample/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.
A11013	Wash station	Error	Water tank is empty	/	1. The water tank is empty. 2. The low-level floater of the water tank goes wrong.	1. Check if the water level inside the water tank is low. 2. Check if the error is accidental. 3. 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 low-level floater of the diluted wash solution tank goes wrong.	1. Check the floater of the diluted wash solution tank.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					2. The diluted wash solution tank is empty.	2.Fill the diluted wash solution tank. 3. Check if the error is accidental. 4. 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.
A11034	Wash station	Error	Cuvette wash syringe movement error.	/	1.Sensor status error. The syringe assembly is probably forced to move.2.Failed to find the mechanical zero position. The syringe 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.
A11038	Wash station	Error	Instruction execution error	/	Instruction execution 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.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
A12005	Temperature unit	Warning	Reaction carousel temperature is out of range	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. Temperature control fan error. 6 PCB error 7. Parameters are lost. 8. 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) 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.	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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					7. Electromagnetic interference exists.	department or your local distributor.
A12010	Temperature unit	Warning	Reagent preheating temperature is out of range.	/	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.
A21001	Probe Interior Wash Unit	Error	Probe interior wash syringe movement error. Error:	/	1.Sensor status error. The syringe assembly is probably forced to move.2.Failed to find the mechanical zero position. The syringe 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.
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°C.	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,

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						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 90 μl sample should be prepared. 3. Electrode is not installed correctly. Reinstall it. 4. Check the waste tube, and if necessary, replace it.
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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						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.
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.
A22011	ISE unit	Error	Air in calibrator B	PUGB	1. Calibrator B is exhausted.	1. Replace the reagent pack with a

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					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.	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	Reading reagent pack chip error	/	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. Unload the reagent pack and load it again.	/	1. Reagent pack is not installed. 3. Reagent pack wand fails.	1. Install reagent pack. 3. Replace the wand.
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	1. Place sufficient ISE wash solution. 2. Replace the pump tube. 3. Clean the sample injection port

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					blocked or leaking. 4. Air bubble detector fails.	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.
A22024	ISE unit	Error	ISE response check code error	RESP	1. The communication wire between ISE and the middle-layer unit goes wrong.	1.Replace the communication wire 2.Change the interface or the pin.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					2. Communication interface or pin error. 3.Main control board does not function. 4.Software error	3.Change the main control board. 4.Upgrade the software or reinstall the software.
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.
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. 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.
C00007	Operating system	Error	CPU performance low	/	The CPU is too busy.	Reboot the computer and operating software. If this message appears for 3 times, contact our customer

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						service department or your local distributor.
C00011	Operating system	Error	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.
C00013	Operating system	Error	The cuvette status may not be refreshed due to the last abnormal exit of the system. To ensure the correct test results, please check the cuvettes and replace them.	/	The operating software is not exited normally due to some reasons.(BS-230)	Take out and check the standby cuvettes. If they are used, replace them. When you are uncertain if they are used, replace them.
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	/	The database file is damaged or lost.	Reboot the computer and analyzing unit. If three continuous attempts

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			failed			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.
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),	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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
					or the error of division by zero occurs.	distributor.
C03003	Result calculation	Warning	R1 blank absorbance out of range	RBK	The reagent goes wrong; the cuvette is not clear; the reaction cuvette is overflowed; or insufficient reagent is dispensed. (BS-240) The reagent goes wrong; or insufficient reagent is dispensed.(BS-230)	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	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
			the highest-level calibrator Sample ID/bar code: 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. (BS-240) The reagent goes wrong; insufficient reagent is dispensed; the cuvette contains air bubbles; the light drifts;(BS-230)	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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						calibrator are normal, and then recalibrate.
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.
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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						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: Position:	/	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
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.
C05006	Reagent bar code	Error	Wash solution position on reagent carousel is occupied	/	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.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			by another 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.
C05010	Reagent bar code	Error	The pretreatment reagent position is occupied by other reagent. Position:	/	Reagent rather than pretreatment reagent is placed in the pretreatment reagent position on reagent carousel.	Reposition the reagent, or remove it from the pretreatment reagent position.
C05011	Reagent bar code	Error	The ISE wash solution position is occupied by another reagent.	/	Reagent rather than ISE wash solution is placed in the pretreatment reagent position on reagent carousel.	Reposition the reagent, or remove it from the ISE 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

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
						department or your local distributor.
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	/	1. The cuvette is contaminated.	1. Open the reaction carousel and check if the lamp is turned on. If it

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			range Cuvette No.:		2. The lamp is aging. 3. The lamp is not installed correctly. 4. The wash station dispenses liquid incorrectly. 5. The photoelectric collection board goes wrong.	is not, rerun the operating software. 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.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
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.
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.	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.
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.
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:	/	All reagents of the reagent type for the chemistry are less than the minimum limit.	Refill or replace the reagent.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			Position:		All reagents of the type are too little to be detected.	
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 Position:	/	Insufficient physiological saline.	Refill the physiological saline on the reagent carousel.
C07035	Other error of	Warning	Physiological saline is	/	Physiological saline is exhausted.	Refill the physiological saline on the

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
	operation unit		exhausted Position:			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.
C07043	Other	Warning	Pretreatment reagent is exhausted. Position:	/	The pretreatment reagent is running out.	Add more pretreatment reagent
C07044	Other	Warning	Pretreatment reagent is insufficient. Position:	/	The pretreatment reagent is insufficient.	Add more pretreatment reagent
C07045	Other	Warning	ISE wash solution is	/	ISE wash solution is exhausted.	Add the ISE wash solution.

Event ID	Component	Event class	Error Message and Event Log	Flag	Probable Causes	Corrective Actions
			exhausted.			
C07046	Other	Warning	ISE wash solution is insufficient.	/	ISE wash solution is insufficient.	Add the ISE wash solution.

12 Operation theories

This chapter gives brief introduction of the operation theories of the instrument, which include:

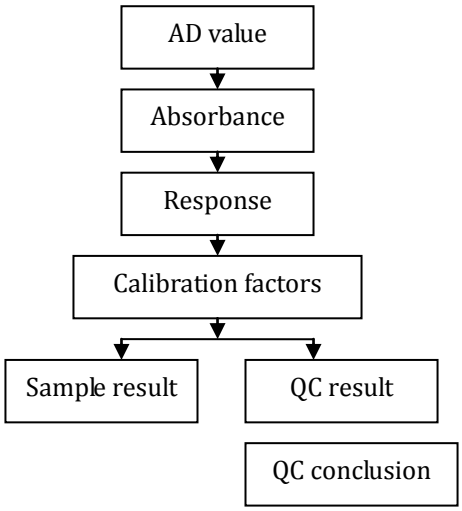
- Principles of biochemistry measurement
- Calibration math model and calculation of factors
- QC determination methods
- Prozone check
- Principles of ISE measurement

12.1 Overview

The system is a fully automated computer-controlled clinical chemistry analyzer allowing 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 12.1 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.

12.2 Principles of measurement

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, and F indicates the incubation time. 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.

12.2.1 Endpoint 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. 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

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.

Calculation of blank absorbance

The blank absorbance A_b is calculated in the same way as the reaction absorbance Ai.

When N and P are not specified, the blank absorbance A_b will not be calculated.

Calculation of K factor

The system provides four K factors for result calculation, which are expressed through the following equations:

- $k1 = \frac{V_{R1}}{V_{R1} + V_S}$
- $k2 = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$

Where, V_{R1} and V_{R2} are the volumes of R1 and R2; V_s is the actual sample volume dispensed for reaction.

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.

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 $R' = R - R_{Sb}$.

12.2.2 Fixed-time measurements

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 (Tl-Tm). 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.

12.2.3 Calculation of Response

The response in fixed-time measurements is calculated as follows:

$$R = 60 * \left(\frac{A_M - A_L}{t_M - t_L} - k \cdot \frac{A_P - A_N}{t_P - t_N}\right)$$

k is the calculation factor and varies with the chemistry parameters.

12.2.4 Kinetic measurements

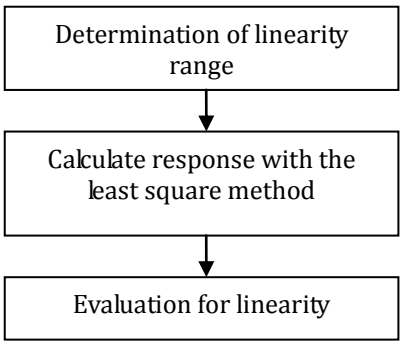
In Kinetic measurements, namely, zero-order Kinetic measurements or continuous-monitoring measurements, the reaction velocity is not related to substrate concentration and remains constant during the reaction process. As a result, the analytes absorbance changes evenly at a given wavelength, and the 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.

Data calculation in Kinetic measurements

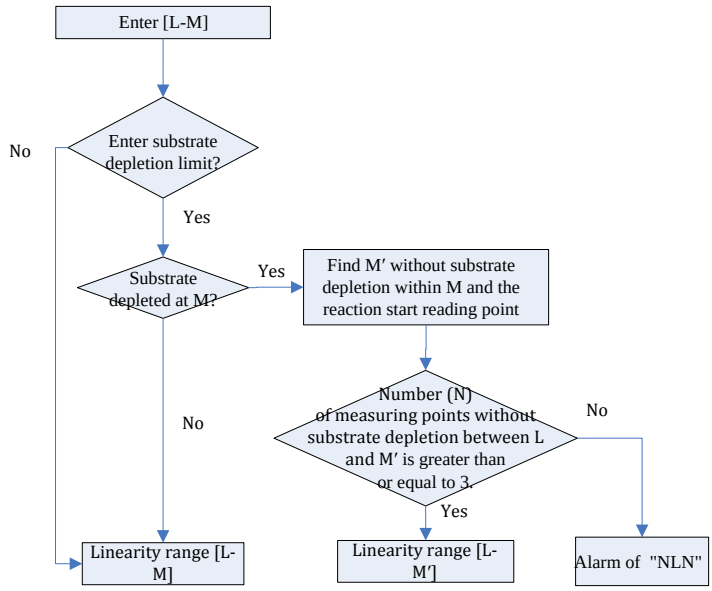
Figure 12.2 Data calculation flow of Kinetic measurements



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 12.3 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.

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 rangeM': 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 rang.

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.

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.

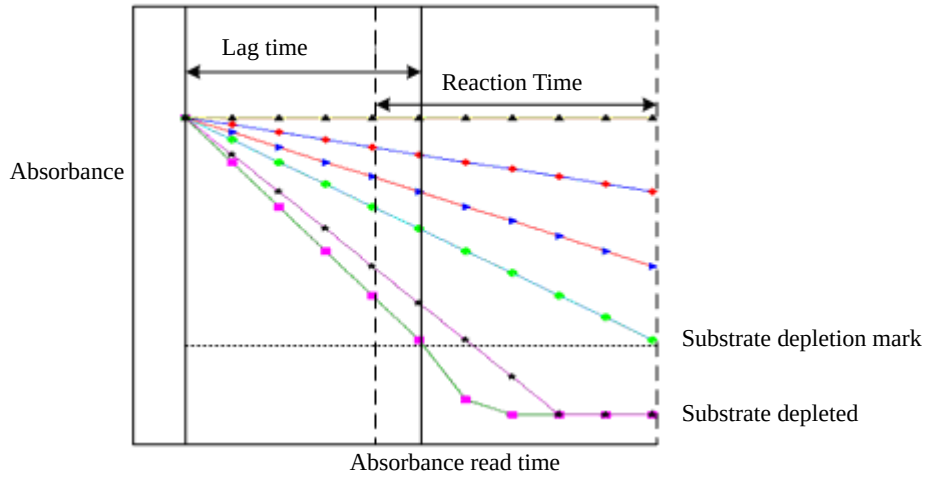
- When N>8, ΔA_f is the absorbance change rate of the first 6 measuring points, ΔA_b of the last 6 measuring points, and $\Delta A_{u,v}$ of all measuring points.

- 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≤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.

Enzyme linearity range extension

Figure 12.4 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".

12.3 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

12.3.1 Linear calibrations

Single-point linear calibration

The single-point linear calibration is also called the K factormethod. 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.

Please note that the R and R_0 must be divided by 10,000.

Two-point linear calibration

Calculation formula: $C = K \times (R - R_0)$

The formula contains two factors, K and 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:

$$K = \frac{\sum_{i=1}^{n} CiRi - (\sum_{i=1}^{n} Ci)(\sum_{i=1}^{n} Ri)/n}{\sum_{i=1}^{n} Ri^2 - (\sum_{i=1}^{n} Ri)^2/n}$$

$$R_0 = (\sum_{i=1}^{n} Ri)/n - \frac{(\sum_{i=1}^{n} Ci)/n}{K}$$

12.3.2 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 2-9 calibrators. Suppose the number of calibrators is n, then the calculation formula contains 4(n-1) factors, which are R_{0i}, a_i, b_i, and c_i. Due to the subsection fitting, this math model has be best fit curves than other math models.

12.4 QC evaluation

The system provides the Westgard rules for evaluating QC results of the chemistries, and give alarms and flags when the obtained QC results are beyond the reference range. Since every chemistry may have one or more control samples, the QC results can be evaluated with different rules accordingly. Those controls that are not included in any lots will be evaluated as single controls.

12.4.1 Evaluation of single controls

The Westgard rules for evaluation of single controls are listed in the table below:

Table 12.1 Westgard rules for single controls

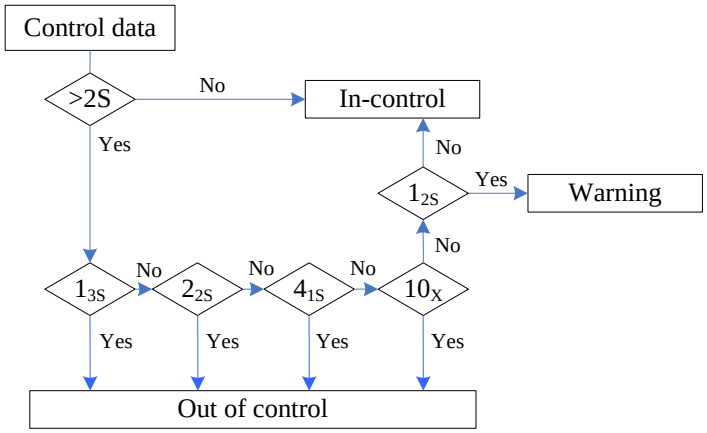
Rules	Description	Flag	Error Type
1-2s	One result is between ±2 and ±3 standard deviations from the assigned mean concentration.	N/A	N/A
1-3s	One result is greater than ±3 standard deviations from the assigned mean concentration.	1-3s	*(1)
2-2s	Two continuous results are greater than +2 or -2 standard deviations from the assigned mean concentration, e.g. (Xn, Xn-1)	2-2s	#(2)
4-1s	Four continuous results are greater than +1 or -1 standard deviation from the assigned mean concentration, e.g. (Xn, Xn-1, Xn-2, Xn-3)	4-1s	#
10-x	Ten results being compared are on the same side, e.g. (Xn, Xn-1, Xn-2, Xn-3..Xn-9)	10-x	#

(1) An asterisk "*" indicates a random error, which requires no special action but must not be ignored.

(2) A "#" symbol indicates a systematic error, which requires special consideration.

The evaluation procedure of single controls is shown in the figure below:

Figure 12.5 Evaluation procedure of single controls



12.4.2 Two-control evaluation

Setting up QC run

A QC run is based on two control samples: C1 and C2, and at most one QC run is performed for each chemistry. The system allows the definition of QC run interval on the **System Setup** screen. The maximum QC run interval is 24 hours.

To set up QC run

1. Select **Utility** > **System Setup**.
2. Select **Instrument F1**.
3. Choose **9 QC Evaluation**.
4. Type in the QC run length in the **Run Length** field.
   Enter an integer between 1 and 24. The default is 24.
5. Select **OK**.

Two-control evaluation rules

In every QC run, two results are obtained: Xn and Yn, which are used to define a point on the Twin-plot chart. In this way, a complete twin-plot chart is drawn based on all the QC results and used for detecting systematic errors and random errors.

The Westgard rules for two-control evaluation are listed in the table below:

Table 12.2 Two-control evaluation rules

Rules	Description	Flag	Error Type
1-2s	One result is between ±2 and ±3 standard deviations from the assigned mean concentration.	N/A	N/A
1-3s	One result is greater than ±3 standard deviations from the assigned mean concentration.	1-3s	*(1)
2-2SA	Two results (Xn, Yn) of a run are simultaneously greater than +2 or -2 standard deviations from the assigned mean.	2-2s	#(2)

R-4s	One result of a run is greater than +2 standard deviations from the assigned mean and the other greater than -2SDs.	R-4s	*
2-2SW	Two continuous results of a control are greater than +2 or -2 standard deviations from the assigned mean concentration, e.g. (Xn, Xn-1), (Yn, Yn-1).	2-2s	#
4-1SA	Results of two continuous runs are greater than +1 or -1 standard deviation from the assigned mean, e.g. (Xn, Yn, Xn-1, Yn-1).	4-1s	#
4-1SW	Four continuous results of a control are greater than +1 or -1 standard deviations from the assigned mean concentration, e.g. (Xn, Xn-1, Xn-2, Xn-3), (Yn, Yn-1, Yn-2, Yn-3).	4-1s	#
10-XA	Results of five continuous runs (10 results) compared are on the same side, e.g. (Xn, Yn, Xn-1, Yn-1, Xn-2, Yn-2, Xn-3, Yn-3, Xn-4, Yn-4).	10-x	#
10-XW	Ten continuous results (10 results) of a control are on the same side, e.g. (Xn, Xn-1, Xn-2, Xn-3..Xn-9), (Yn, Yn-1, Yn-2, Yn-3..Yn-9).	10-x	#

(1) An asterisk "*" indicates a random error, which requires no special action but must not be ignored.

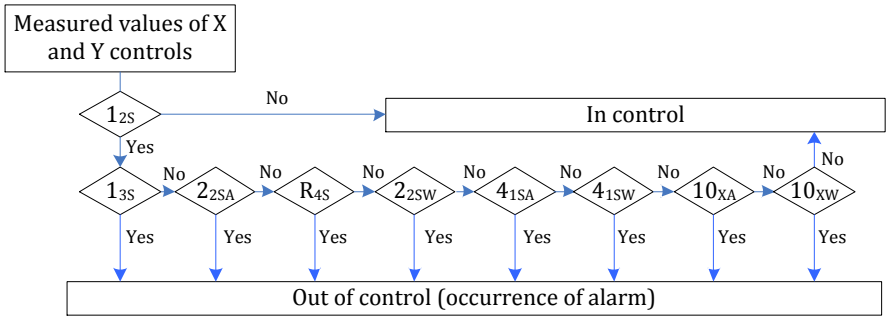
(2) A "#" symbol indicates a systematic error, which requires special consideration.

The random errors in two-control evaluation correspond to those in single-control evaluation as follows:

- $2_{2SA}\backslash 2_{2SW}$ corresponding to 2_{2s}.
- $4_{1SA}\backslash 4_{1SW}$ corresponding to 4_{1s}.
- $10_{XA}\backslash 10_{XW}$ corresponding to 10_{x}.

The procedure of two-control evaluation is shown in the figure below:

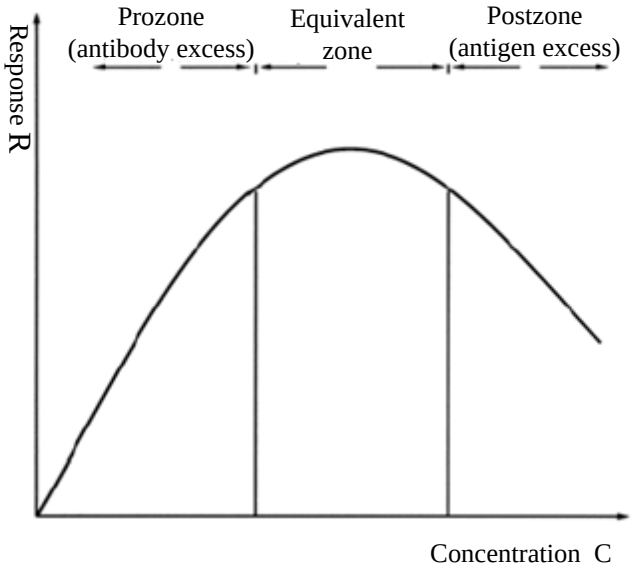
Figure 12.6 Two-control evaluation workflow



12.5 Prozone Check

12.5.1 Introduction

Figure 12.7 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 system supports the rate check method.

12.5.2 Rate check method

The rate check method 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: 1≤q1<q2<q3<q4≤68, "1" is the first measuring point after the sample is dispensed and stirred.
- Double-reagent chemistries: 1≤q1<q2<q3<q4≤34. "1" is the first measuring point after R2 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.

12.6 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 ash solution

CD80 alkaline concentrated wash solution. It is placed in position D 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.

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