



Automated Immunoassay System

HISCL-5000

Instructions for Use

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Other changes:

Clarification to text

The following sections from the previous version were removed:

- 2.10 Computer viruses
- 2.11 Other software

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Chapter 1 Introduction

Thank you for purchasing the Automated Immunoassay System HISCL-5000.
Read and understand the contents of this manual before operating the product.
Keep the manual near the instrument for future reference.

- The instrument details and screens that are shown in this manual are provided as examples. These may differ from the actual instrument.
- Sysmex reserves the right to improve this product whenever necessary. Product specifications and appearance are subject to change without notice for the purpose of improvement. For this reason, some descriptions in this manual may differ from the actual product specifications.
- Never use substitute parts or modify the product. This is dangerous.
- Decisions that the doctor makes based on analysis results should be part of an overall diagnosis that includes clinical symptoms and the results of other examinations.
- Follow the instructions in this manual when operating the product. Sysmex cannot guarantee accurate analysis results if the instructions are not followed. Sysmex cannot guarantee the operation of the instrument if it or any related programs are not used as instructed.

Contact Addresses



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Ordering of Supplies and Replacement Parts

If you need to order supplies or replacement parts, please contact your local Sysmex representative.

Service and Maintenance

Please contact the Service Department of your local Sysmex representative.

1.1 Intended use

The HISCL-5000 is for in vitro diagnostic use in clinical laboratories. Only the samples specified in the package insert for each reagent can be analyzed. Any other use is outside of the specified scope. Use only the reagents, detergents, and supplies indicated in this manual. The intended use includes observance of the specified cycles for cleaning and maintenance.

1.2 Overview of the instrument

The HISCL-5000 is a fully automated immunoassay system that can quantitatively or qualitatively analyze samples for minute traces of protein, hormones, and other substances.

By simply placing the samples and reagents in the instrument, quantitative or qualitative analysis of the sample for infection, hormones, tumor markers, and other substances takes place completely and automatically based on the chemiluminescent enzyme immunoassay method as the principle of measurement.

Samples are mixed with reagents and heated to cause an immunoreaction followed by an enzymatic reaction.

Samples are quickly and automatically analyzed for minute traces of protein, hormones, and other substances with high sensitivity and accuracy using the chemiluminescent enzyme immunoassay method, which counts photons (photon counting) emitted during the enzymatic reaction.

Up to 200 samples can be analyzed in 1 hour, with a reaction time^{*1} per analysis of about 17 minutes. Analysis can be interrupted for an urgent sample.

The most recent 100,000 samples of analysis data can be saved. The data can be displayed or printed. Sampling is possible from sample cups or sample tubes.

Analysis using sample barcodes is also supported.

IC tag support prevents incorrect reagent placement and enables control of the expiration date and number of tests to prevent erroneous analysis results.

Analysis results are managed on the IPU^{*2}. The touch panel display that connects to the IPU can be used to check data and send operation commands to the instrument.

*1 Time from sample aspiration to data display

*2 This manual refers to the Information Processing Unit as the "IPU".

1.3 Manuals

1.3.1 List of manuals

The manuals indicated below are provided with the HISCL-5000.

The manuals are provided as printed documents with the product; however, manuals with the same content are also available for viewing on the IPU. For the procedure for viewing the on-screen manuals, see Chapter 4.

(►P.80 "Chapter 4: 4.2 Viewing the on-screen manuals")

- Instructions for Use (this manual)

This manual explains how to operate the instrument, focusing on routine work.

- Administrator's Guide

This manual explains operations performed by the administrator, such as configuring instrument settings.

1.3.2 Structure of this manual

This manual consists of the following chapters:

Chapter	Description
Chapter 1: Introduction	Provides an overview of this manual and the instrument.
Chapter 2: Safety information	Indicates safety rules to be observed for safe use of the instrument, and explains the meaning of the safety symbols that appear on the instrument.
Chapter 3: Before using the instrument	Provides information you should know before using the instrument, including preparations for installation of the instrument and an overview of optional devices.
Chapter 4: Starting up/Shutting down the instrument	Explains the procedures for starting up and shutting down the instrument.
Chapter 5: Preparations for analysis and tasks after analysis	Explains the preparations that are required for analysis, replenishment of supplies, and tasks that must be performed after analysis is finished.
Chapter 6: Creating a standard curve	Explains how to create standard curves.
Chapter 7: Performing QC analysis	Explains the regular control tasks that must be performed to ensure reliability of analytical results.
Chapter 8: Performing sample analysis	Explains how to analyze samples.
Chapter 9: Operations during analysis	Explains the tasks that the operator must perform during analysis.
Chapter 10: Checking analysis results	Explains how to check analysis results.
Chapter 11: Instrument maintenance/ Replacing supply parts	Provides an overview of maintenance, and explains the procedures for performing maintenance tasks and replacing supplies.
Chapter 12: Troubleshooting	Explains the instrument errors that may occur and how to resolve the errors.
Chapter 13: Technical information	Provides technical information such as specifications and principles.

1.3.3 Points to note about this manual

- Unauthorized reproduction of the contents of this manual in whole or in part is prohibited.
- Any names that appear in this manual, such as patient names or doctor names, are not related in any way to actual people.
- Instrument details and screens appearing in this manual may differ from the actual instrument due to instrument specification changes or updates.
- The screens that appear in this manual are examples. Depending on the type of instrument you are using, some screens may be different.
- The following abbreviations are used in this manual:

Product name	Abbreviation
HISCL Washing Solution	HISCL washing
HISCL Line Washing Solution	Line washing
HISCL Line Washing Solution Concentrated	Concentrated line washing
HISCL Probe Washing Solution	Probe washing
HISCL Diluent	Sample diluent
HISCL Cuvette L	Cuvette
HISCL DISPOSABLE TIP	Tip
HISCL Washing Solution HISCL Line Washing Solution HISCL Line Washing Solution Concentrated HISCL Probe Washing Solution	Detergent*

* Only when HISCL Washing Solution, HISCL Line Washing Solution, HISCL Line Washing Solution Concentrated, and HISCL Probe Washing Solution are indicated as a group.

1.4 Symbols used in this manual

This manual uses symbols to alert the user to important information regarding safety and operation, including infection risks, warnings, precautions, and useful information. Failure to observe this cautionary information may impair the safety features incorporated into the instrument.



Risk of infection

Indicates a risk of infection by pathogens or other infectious materials.



Warning!

Indicates a risk of death or serious injury to the operator, or serious damage to physical property.



Caution!

Indicates a risk of injury to the operator, incorrect output results, or damage to physical property.



Caution, Hot

Indicates a potential risk of burns or other physical damage in the event of incorrect operation or failure to observe the content.



Information

Indicates information users should know to maintain performance and prevent damage to the instrument.



Note:

Indicates useful information regarding the use of the instrument.

1.5 Trademarks

- Sysmex and HISCL are registered trademarks of Sysmex Corporation.
- Windows is a registered trademark of Microsoft Corporation.
- ActiveReports for .NET is copyrighted material owned by Data Dynamics, Ltd., and is used based on a licensing agreement.
- Linux is a registered trademark or trademark of Linus Torvalds in the U.S.A. and other countries.
- Other company names and product names are trademarks or registered trademarks of their respective companies.

The fact that a trademark is not explicitly indicated in this manual does not authorize its use.

The TM and ® symbols are not used in this manual.

1.6 Warranty

All Sysmex instruments are warranted against defective material or workmanship for a period of 1 year, commencing on the date of installation on the customer's premises. This warranty does not cover any defects, malfunctioning, or damages due to:

- Accident, neglect, or willful misuse of the product.
- Failure to use, operate, service, or maintain the product in accordance with the applicable Sysmex Instructions for Use.
- Failure to use the proper reagents and supplies specified for the product.



Information

If the customer moves the instrument or operates it in a different location, the warranty is invalidated. Contact your local Sysmex representative if you need to move the instrument.

Chapter 2 Safety information

This chapter explains safety information that must be observed in order to use the product safely. Read and understand the contents of this chapter before using the product.

2.1 General information



Warning!

- Use only the specified accessories and supplies.
- Do not mix reagents together.
- Periodically run the quality control procedure.
- Do not step or stand on sampler or instrument covers.
There is a risk of injury and instrument damage.
- Keep your fingers, clothing, and hair away from the instrument while it is in operation.
Danger of injury if fingers, clothing, or hair become caught in the instrument.
- Do not spill blood, reagents, or other liquids into the instrument. Take care not to drop staples, paper clips, or other metal objects into the instrument.
This may cause short-circuiting and smoke.
- Never touch electrical circuitry inside a cover.
Danger of electrical shock, especially if the hand is wet.
- Do not damage the power cable, place heavy objects on it, or forcibly pull on it.
There is a risk of fire and electrical shock due to short-circuiting or wire breakage.
- If using an extension power cable with the power cable, locate in a place where the connection between the cables will not come into contact with water.
There is a risk of short-circuiting, electrical shock, and fire.
- Do not use more than 1 extension power cable with the power cable. Do not bundle or tie the power cable and extension power cable together.
There is a risk of fire due to heat generation.
- Use only a Sysmex-specified power cable and extension power cable. Do not use a Sysmex-specified power cable or extension power cable with any other products.
- In the event that an abnormal odor or smoke is produced, immediately turn off the power and unplug the power cable from the power outlet. Contact your Sysmex service representative. Continuing to use the instrument may result in fire, electrical shock, and injury.



Caution!

- Do not reuse supplies that have already been used.
Correct analysis results may not be obtained.
- When handling a rack or sample tube, take care not to accidentally knock or bump the rack or sample tube and cause a sample to spill.
- Do not lean against the instrument.
The force applied to the instrument may cause it to tip over or otherwise become damaged.
- The instrument is equipped with a barcode reader. The LED irradiation class is 1. The emission intensity is low, however, do not look directly at or condense the light.



cTÜVus mark indicates that the equipment is tested and certified to comply with the electrical and fire safety regulations controlled by the US and Canadian governments. Those tests were conducted thoroughly by TÜV Rheinland that is accredited as a Nationally Recognized Testing Laboratory (NRTL) by OSHA (The Occupational Safety and Health Administration) in the United States, and by SCC (Standards Council of Canada) in Canada.

2.2 Installation



Warning!

- Your local Sysmex representative will handle the unpacking, installation, and confirmation of initial operation of the instrument.
- Never connect the analyzer to other than a 200 to 240 V AC power outlet. Never connect the pneumatic unit to other than a 220 to 240 V AC or a 100 to 117 V AC power outlet.
The equipment must be grounded.
There is a risk of fire and electrical shock.
- Always switch off the power before connecting optional devices and peripheral devices.
There is a risk of electrical shock and failure.



Caution!

- The instrument is designed for indoor use only.
- Install the instrument in a location where it will not come into contact with water.
- Install in a location where the instrument will not be subject to the effects of high temperature, humidity, dust or direct sunlight.
- Do not subject the instrument to intense shock or vibration.
- Install in a location with good ventilation.
- Do not install the instrument near equipment that generates electrical interference, such as a radio or centrifugal separator.
- Do not use this instrument in any operating environment which has electroconductive or flammable gases, including oxygen, hydrogen, and anesthesia.
- Install the waste tank in a position lower than the bottom of the analyzer.
- Do not place the reagents anywhere other than in their set position.
- Storage conditions for the instrument are as follows:
Ambient temperature: -10 to 60°C
Relative humidity: 20 to 95% (no condensation)

2.3 Electromagnetic compatibility (EMC)

The instrument complies with the following IEC (EN) standards:

- IEC61326-2-6:2005 (EN61326-2-6:2006): Electrical equipment for measurement, control and laboratory use - EMC requirements
- EMI (Electromagnetic Interference): For this standard the requirements of class A are fulfilled.
- EMS (Electromagnetic Susceptibility): For this standard the minimum requirements with regards to immunity are fulfilled.
- This instrument has been designed and tested to CISPR11 Class A/Group 1. This means that this instrument is not intended to generate and/or use radio-frequency energy in the form of electromagnetic radiation, inductive, and/or capacitive coupling during operation. This also means that the instrument is suitable for use in all facilities except for the following:
 - Domestic facilities
 - Facilities directly connected to a low voltage power supply network which supplies to buildings used for domestic purposes

Use in a domestic environment may cause radio interference, which may require you to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operation of the instrument. Do not use this instrument in close proximity to sources of strong electromagnetic radiation (such as unshielded intentional radio sources), as these may interfere with the proper operation.

The instrument is equipped with RFID for the control of reagent information.

- Complies with ISO/IEC15693, ISO/IEC18000-3 (Mode 1).

The instrument includes an RFID(Radio-Frequency Identification Device) module.

- RFID device: TR3-C202-A0-8
- Intended use: This RFID module is an electromagnetic induction type non-contact IC can read and write RFID tag data.
- Frequency band: 13.56 MHz
- Maximum radio-frequency power: 74.8 dBuV/m at 10 m(QP)

This instrument complies with following countries.

- Indonesia

This instrument is certified by SDPPI.

30112/SDPPI/2013 4377



Caution!

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

RFID statement required by Taiwan NCC.

依據 低功率電波輻射性電機管理辦法

第十二條 經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條 低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前項合法通信，指依電信法規定作業之無線電信。

低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

2.4 Avoiding infection



Risk of infection

- Always wear protective gloves, mask, eye protection, and a lab coat when performing any task on the instrument, including inspection, maintenance, preparation, and post processing. When finished, wash your hands with a disinfectant.
There is a risk of infection by pathogens and other contaminants.
- Be sure to connect the instrument waste fluid to a waste container in your facility (a container that has an insertion nipple for the waste tube or other means of fixing the waste tube so that there is no risk of waste fluid splattering) or a dedicated waste tank.
When connected to a waste container in your facility, periodically verify that the waste tube is securely connected and there is no risk of waste fluid splattering.
- Never touch waste, or parts that have come in contact with waste, with your bare hands.
If you inadvertently come in contact with potentially infectious materials or surfaces, wash immediately with copious amounts of water and follow your laboratory's prescribed cleaning and decontamination procedures.
- Exercise full caution when handling samples and quality control materials. In the event that infectious material enters the eyes or an open wound, wash with copious amounts of water and seek immediate medical attention.

2.5 Handling of reagents and quality control materials

Reagent



Warning!

- Avoid direct contact with reagents.
Reagents can cause irritation of the eyes, skin, and mucous membranes.
- Should you inadvertently come in contact with a reagent, wash immediately with copious amounts of water.
- If a reagent enters your eye, wash immediately with copious amounts of water and seek immediate medical attention.
- If a reagent is accidentally swallowed, vomit or induce vomiting by drinking copious amounts of warm, salty water and seek immediate medical attention.
- Always wear protective gloves, mask, eye protection, and a lab coat when handling samples and reagents. When finished, wash your hands with a disinfectant.
There is a risk of infection by pathogens and other contaminants.
- See the package insert and the label on the reagent container for instructions on reagent handling.
- The reagent expiration date and shelf life after opening are indicated on the reagent box and package insert.



Information

- Do not allow reagents to come in contact with dust, dirt or bacteria.
- Do not use a reagent that has expired.
- Handle reagents carefully so that they do not foam. If there is foam, wait for the foam to disappear before use.
- Do not spill reagents. If spilled, wipe up the spillage using a damp cloth.

Quality control materials



Caution!

Do not inject or ingest.



Information

- Follow the instructions on the package insert.
- Do not allow control materials to come in contact with dust, dirt or bacteria.
- Do not use a control material that has expired.
- Handle control materials carefully so that they do not foam. If there is foam, wait for the foam to disappear before use.
- Do not spill control materials. If spilled, wipe up the spillage using a damp cloth.
- Do not use data from different lots of a control material as data on the same plot.

2.6 Maintenance



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when performing service and maintenance work. When finished, wash your hands with a disinfectant.
There is a risk of infection by pathogens and other infectious materials.



Information

When performing maintenance, use only the tools that are particularly provided for the work.

2.7 Disposal of waste fluid, waste materials, and the instrument



Warning!

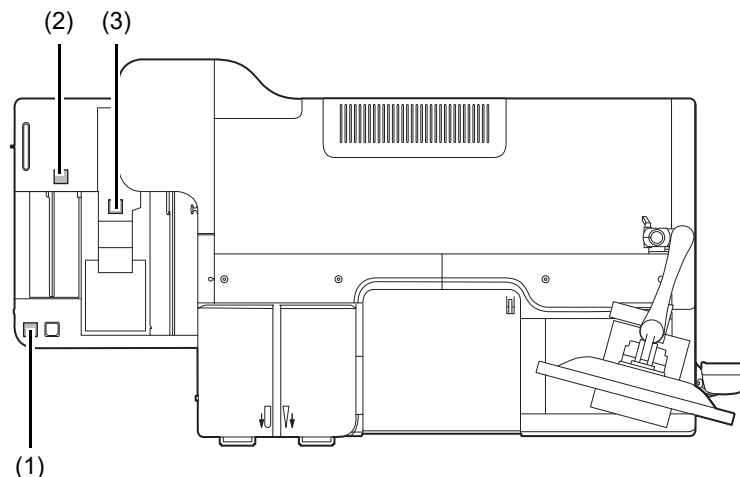
Dispose of waste fluids, supplies, and the instrument as biological waste, infectious waste, and/or industrial waste, in accordance with local laws and regulations.



This symbol is affixed by the requirement by Article 14. (4) of the WEEE Directive (2012/19/EU), and indicates the waste end-of-life equipment should not be disposed as unsorted municipal waste and such equipment shall be collected separately.

2.8 Instrument warning labels

Top of instrument



(1) Main unit



Risk of infection

- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
 - Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
- There is a risk of infection by pathogens and other contaminants.

(2) Sampler cover



Warning!

When placing the sample rack in the sampler, take care that your hand does not become caught between the cover and rack.

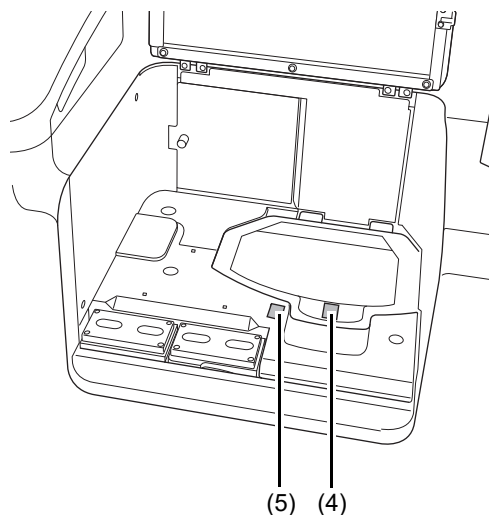
(3) Urgent sample holder cover



Caution!

The drive unit is visible when the urgent sample holder cover is open. The drive unit is locked when the cover is open, but take care not to insert your hand in the opening. There is a risk of injury.

Inside of operation cover



(4) Access cover of reagent holder A



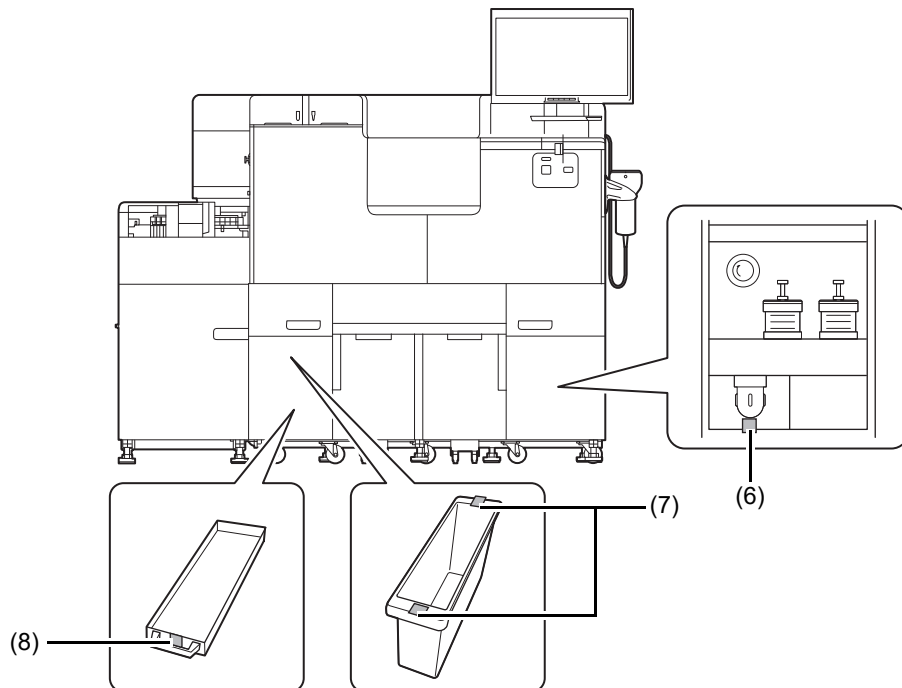
Caution!

The drive unit is visible when the access cover of reagent holder A is open. The drive unit is locked when the cover is open, but take care not to insert your hand in the opening. There is a risk of injury.

(5) Reagent holder A/reagent holder B/continuous unit

**Risk of infection**

- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
 - Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
- There is a risk of infection by pathogens and other contaminants.

Front of the instrument

(6) Trap chamber

**Risk of infection**

- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
 - Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
- There is a risk of infection by pathogens and other contaminants.

(7) Waste box



Risk of infection

- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
 - Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
- There is a risk of infection by pathogens and other contaminants.

(8) Waste box tray

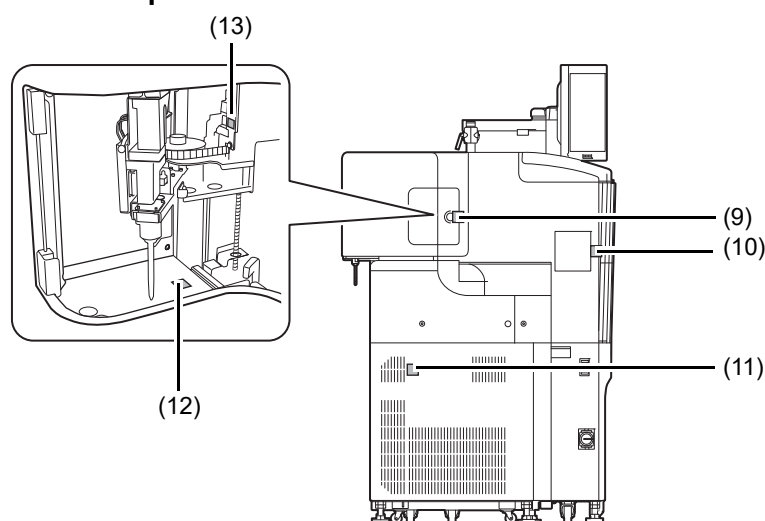


Risk of infection

- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
 - Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
- There is a risk of infection by pathogens and other contaminants.

Left side of instrument

Inside of sample arm cover



(9) Sample arm cover

**Warning!**

Do not release the lock while the instrument is in operation. An emergency stop will occur.

**Caution!**

Do not close the cover with the lock fitting down. The fitting may hit and damage the main unit.

(10) Tip jam maintenance cover

**Warning!**

- Do not open the tip jam maintenance cover for any purpose other than to remove jammed tips.
- If the cover is opened during analysis or other operation, operation will stop.
- Before opening the tip jam maintenance cover, turn off the power of the instrument.
There is a risk of electrical shock.
- Do not touch the drive unit. Make sure your hands are free of static electricity before you touch the instrument.
There is a risk of injury or malfunction.

(11) Air intake and exhaust outlet

**Warning!**

Do not block the air intake or exhaust outlet.
This may cause failure.

(12) Inside of sample arm cover

**Risk of infection**

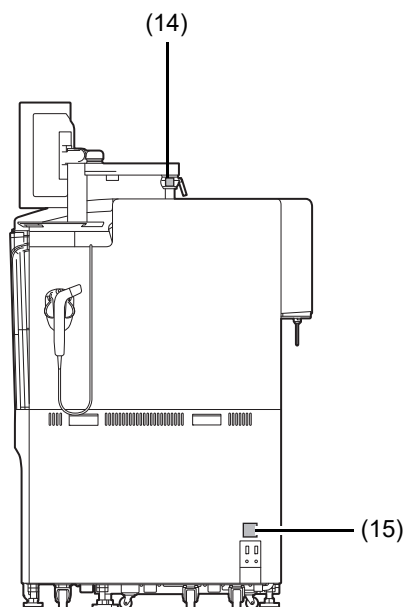
- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
- Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
There is a risk of infection by pathogens and other contaminants.

(13) Sample arm drive motor

**Caution, Hot**

The area near the sample arm drive motor becomes very hot. Do not touch.
There is a risk of burns.

Right side of the instrument



(14) Monitor arm



Caution!

When the fixing screw has been loosened for vertical adjustment of the monitor arm or other reason, always support the monitor arm with your hand. After adjusting the position, be sure to tighten the fixing screw.

There is a risk of monitor arm and display falling and causing injury or damage to the cover.

(15) Waste fluid drain nipple

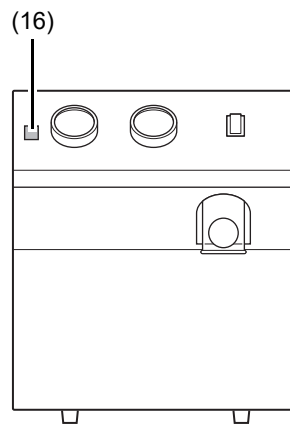


Risk of infection

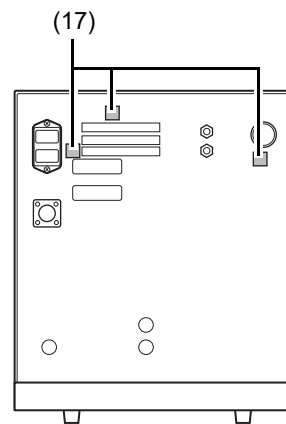
- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
 - Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
- There is a risk of infection by pathogens and other contaminants.

Pneumatic unit

Front



Back



(16) Pneumatic unit

**Risk of infection**

- There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.
- Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials. There is a risk of infection by pathogens and other contaminants.

(17) Back of pneumatic unit

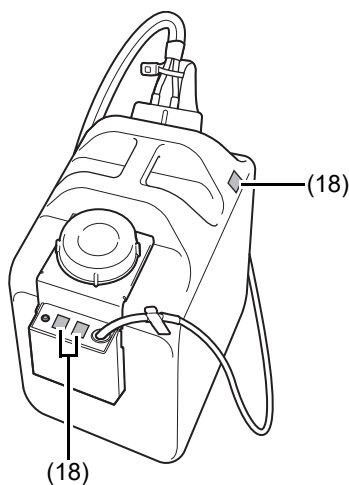
**Warning!**

- Always unplug the power cable before performing inspection. There is a risk of electrical shock.
- When replacing the fuse, be sure to replace it with a fuse of the specified type and rating. There is a risk of smoke emission and fire.

**Caution!**

Do not block the exhaust outlet.
There is a risk of failure.

Waste tank (optional)



(18) Waste tank (optional)



Risk of infection

- Handle the waste tank and its contents assuming that there is a risk of infection from pathogens.
 - Do not handle the waste tank without wearing protective gloves, mask, eye protection, lab coat and other protective equipment.
 - Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant.
- Discard the waste appropriately keeping in mind that it is medical waste and infectious waste.



Warning!

Be careful not to remove the waste tank (optional) level sensor while in use (while the LED is blinking).
Accidentally removing the level sensor may cause interruption of analysis or operation.

2.9 Operators



Information

- Operators with limited or no experience using the instrument must receive guidance and assistance from an experienced operator.
- In the event of an instrument failure, the administrator of the instrument should follow the instructions in the manual to resolve the problem. For repairs beyond the scope of the manual, contact your local Sysmex representative.

2.10 Cybersecurity



Warning!

Please note the following points to ensure cybersecurity.

- Install the device in a locked and access-controlled area.
- For external connection terminals that will not be used, please consider installing physical protections.
- Properly manage account information such as user IDs and passwords, and conduct periodic reviews.
- Do not share your user account information with another party.
- Do not use this device to browse Internet websites or use other online services, unless specified by Sysmex.
- Use a dedicated line or VPN to connect to an external network, and do not connect directly to the Internet.
- Do not connect the device to a wireless network unless authorized by Sysmex.
- Do not use the device for purposes other than its intended purpose.
- Do not make any changes to the settings that are not described in this manual.
- If you are using external media such as USB storage devices, please make sure that they are not infected with a virus.
- If you notice any suspicious behavior that may indicate a virus, please contact your authorized local Sysmex representative.
- Do not install any software on this device, except for software approved by Sysmex.
- In case of problems with this device due to the use of unauthorized software, the product warranty will be void.

Use the antivirus software to periodically check for viruses.

- (1) Use antivirus software designed for your operation system to periodically check for viruses.
- (2) Disable the antivirus software during instrument software operation as it may adversely affect instrument operation.

Chapter 3 Before using the instrument

This chapter provides information you should know before using the instrument.

3.1 Installation preparations

Your local Sysmex representative will handle installation of the HISCL-5000, as well as moving of the HISCL-5000 in the event that you move to a different location. Please prepare for installation as described below:

- Ensure that there is ample space for installation with consideration given to safety.
- Note the weight of the instrument, and make sure that the floor and equipment on which the instrument is to be installed can withstand the weight.
- Make sure that the instrument power cable is in a position where it can easily reach the power supply.
(The power cable is 2.5 m long.)
- Immediately after the instrument is delivered, check the condition of its packaging.



Information

If the packaging has been damaged in any way, immediately contact your local Sysmex representative.

- Keep the instrument in its packaging in a dry place until you are ready for installation. Do not tip the instrument over on its side or invert it.

3.1.1 Contents of package

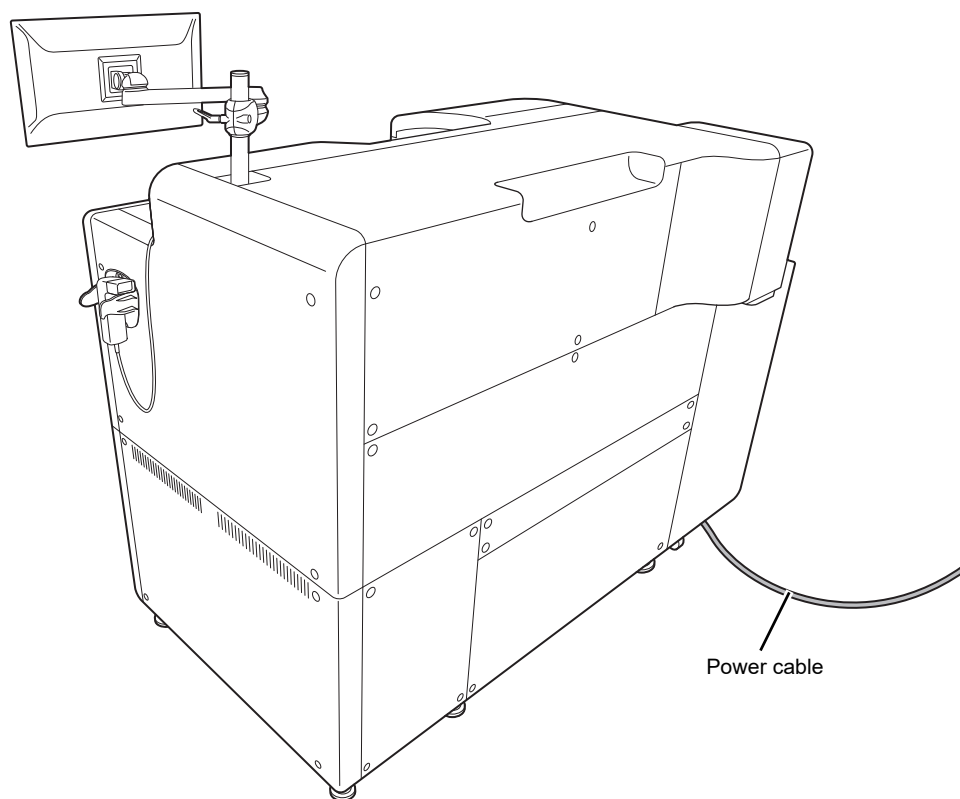
The contents of the HISCL-5000 package are as follows:

- Analyzer (main unit)
- Analyzer (sampler)
- Pneumatic unit (PU-13)
- IPU (Information Processing Unit)
- Touch panel

3.1.2 Plugging in the power cable

To ensure safety, connection of the power cable to the instrument is performed by your local Sysmex representative.

Insert the plug of the power cable on the back of the instrument into the power outlet.



Caution!

- Install the instrument in a location where it will not come into contact with water.
 - Use a plug with the proper shape, voltage, and capacity.
(►P.371 "Chapter 13: 13.1 Performance/specifications")
- There is a risk of failure, electrical shock, fire, and other hazards if the wrong type is used.

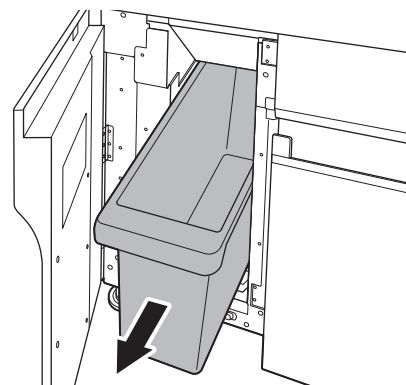
3.1.3 Preparing the waste unit

Used tips and cuvettes are discarded into the waste box of the waste unit.
Follow the steps below to prepare the waste unit.

1 Prepare a new waste bag.

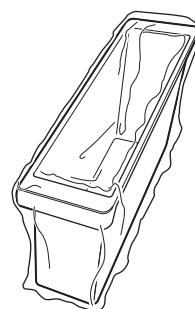
2 Remove the waste box.

Open the waste unit cover at the bottom left of the front of the instrument, and take out the waste box.



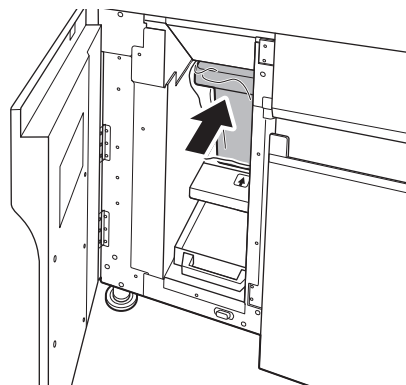
3 Line the waste box with the new waste bag.

Fold the top edge of the waste bag over the edges of the waste box and push the waste bag all the way down into the waste box.



4 Insert the waste box into the waste unit.

Firmly press in all the way.



5 Close the waste unit cover.

3.2 Connecting peripheral devices and optional devices

If peripheral devices or optional devices will be used, connect each device to the IPU or analyzer with the corresponding connection cable.



Information

See the computer's manual for the port locations and other details.
For more information, contact your local Sysmex representative.

3.2.1 Peripheral devices

Peripheral devices can be connected to expand the system.

Device	Description	Connection to instrument
Conveyor system	Connects to the analyzer for aspiration of samples from the conveyor line.	Can be connected using the serial port on the analyzer.
Host computer	Connects to the IPU for communication of analysis orders and analysis results.	Can be connected using the IPU's LAN port or serial port.
Printer	Prints analysis results and other data.	For compatible printers and other details, consult your local Sysmex representative.
Caresphere (network service)	Connects to the IPU for communication of QC data, error logs, and other information, and enables remote control of the IPU screen.	Can be connected to the IPU's LAN port. For details, contact your local Sysmex representative.
LU-10	Dilutes the HISCL concentrated line washing and supplies the solution to the analyzer.	Can be connected to the IPU's LAN port.

3.2.2 Optional devices

Optional devices can be connected to expand the system.

Device	Description	Connection to instrument
Waste tank	Connects to the analyzer. Used reagents, samples, and detergents are discarded into this tank.	For details, contact your local Sysmex representative.
Indicator light	Connects to the analyzer and shows the instrument operation status.	For details, contact your local Sysmex representative.

3.3 User groups

The HISCL-5000 has the following types of user privileges:

User privilege	Description
Operator	Can perform analysis operations.
Data administrator	Can perform analysis operations and data operations.
Analyzer administrator	Can perform analysis operations, data operations, and user operations.

The following user IDs are pre-registered in the HISCL-5000:

User ID	Description
admin	For users with analyzer administrator privileges. Use this user ID for initial operation.

The password for the admin account is indicated in the initial passwords list.

User privileges

		Operator	Data administrator	Analyzer administrator
Analysis operations	Analysis operations	✓	✓	✓
	Display patient information	✓	✓	✓
Data operations	Validation	—	✓	✓
	Edit/delete saved sample data	—	✓	✓
	Change analysis conditions (settings)	—	✓	✓
User operations	User registration	—	—	✓
	Modify user information	Self only	Self only	✓
	Change password	Self only	Self only	✓

For information on user registration, see the "Administrator's Guide".

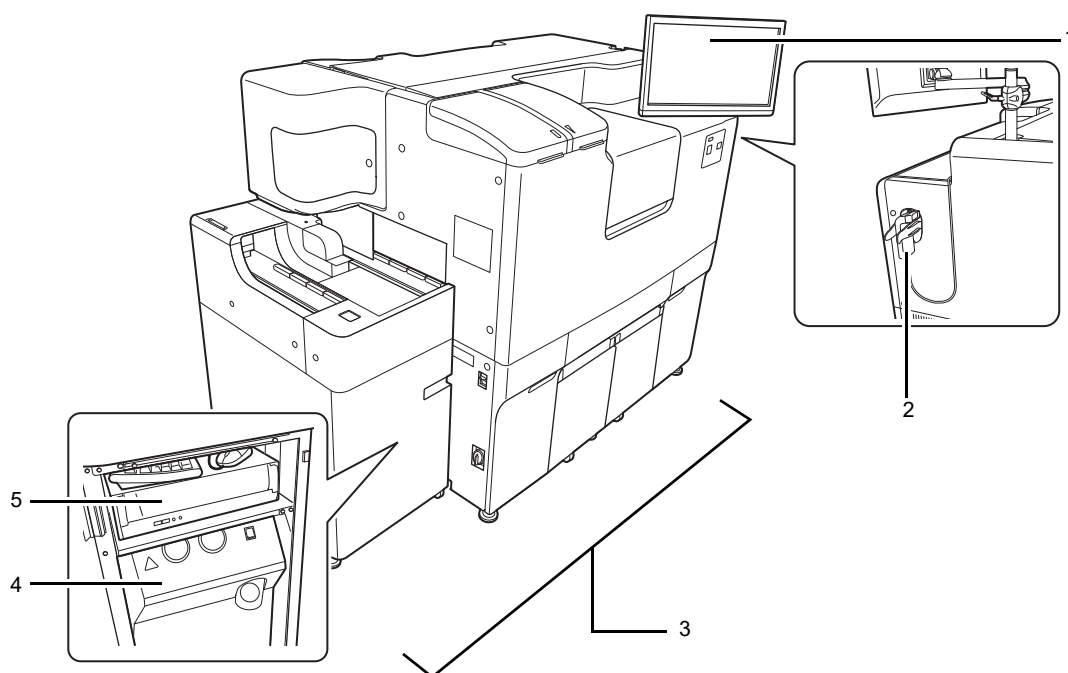
(► Administrator's Guide, "Chapter 2: 2.2 Editing user information")

3.4 Instrument parts and functions

A brief description of the appearance and the basic operation of each component of the HISCL-5000 are given below.

3.4.1 System components

The main components of the HISCL-5000 system are described below.



- 1 Operation screen (touch panel)
Display. Supports touch operation.



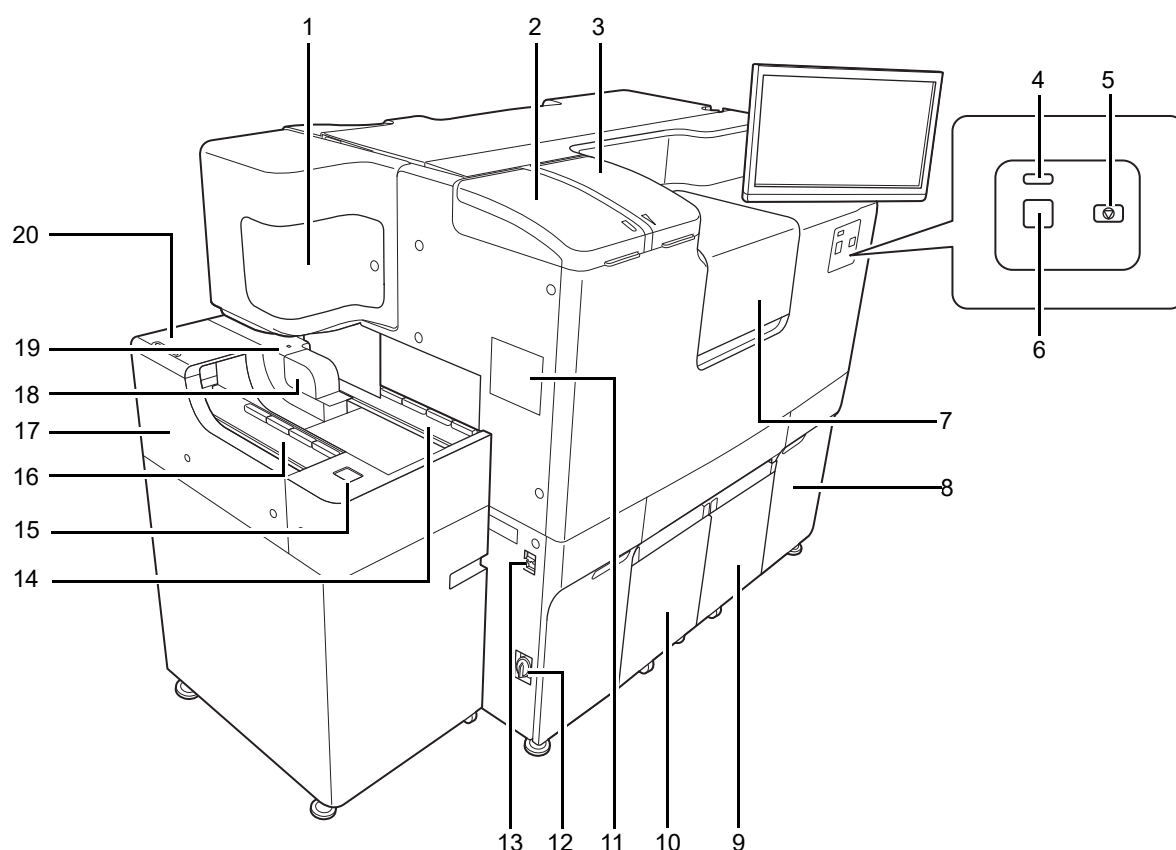
Caution!

Depending on the position of the touch panel display arm, caution may be required to avoid hitting your head when performing maintenance.

- 2 Handheld barcode reader
Scans barcode labels on supplies, reagents, and detergents.
- 3 Analyzer
Analyzes samples. Interrupt analysis function is also possible.
Includes a sampler that automatically feeds samples to the analyzer.
For the units of the analyzer, see the following.
(►P.43 "Units of the analyzer")
- 4 Pneumatic unit
Supplies compressed air to the analyzer.
- 5 IPU (Information Processing Unit)
Analyzes and saves data acquired from the analyzer.
Operated by touch panel display. Can also be operated by mouse and keyboard.
The operation of the analyzer program is based on Windows.
For information on how to perform basic operations, see the manual or Help for the operating system.

3.4.2 Instrument part description

Outside or front of the instrument



- 1 **Sample arm cover**
Open to wipe the sample nozzle and replace supplies.
- 2 **Cuvette feeder**
Cuvettes loaded in this feeder are automatically fed into the instrument.
- 3 **Tip feeder**
Tips loaded in this feeder are automatically fed into the instrument.
- 4 **Instrument status LED**
Shows the status of the instrument.
For LED and instrument statuses, see the following.
(►P.44 "3.4.3.1 Status indicated by the status LED [in front of instrument]")
- 5 **Emergency stop button**
Hold down at least 1 second to immediately stop operation of the instrument.
- 6 **Start button**
Same as the [Start] on the IPU screen toolbar.
Press this button to feed in a rack.

- 7 Operation cover
Open to place R1-R3 and R4/R5 reagents.

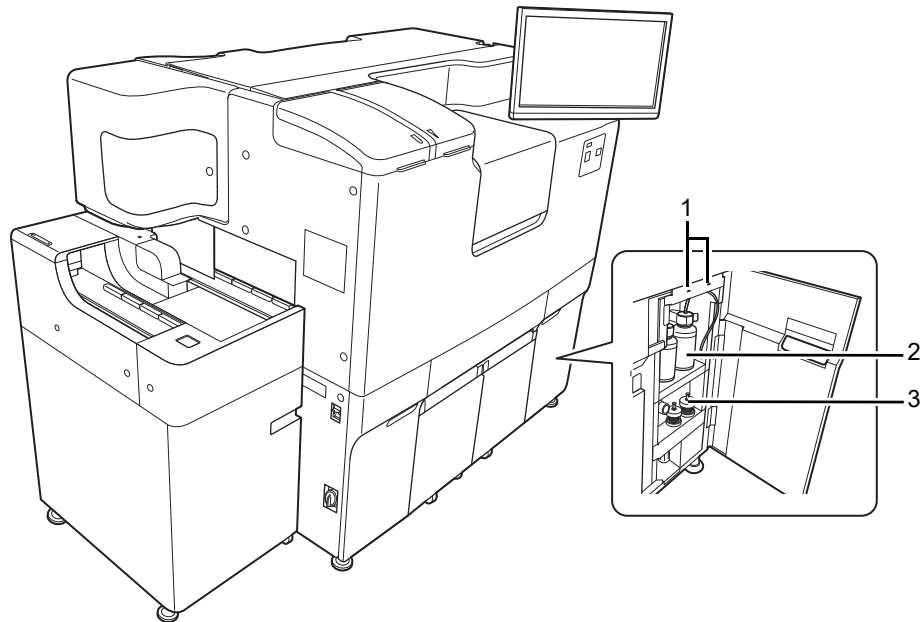


Information

Never leave the operation cover open unnecessarily, even when the instrument is in the READY state.

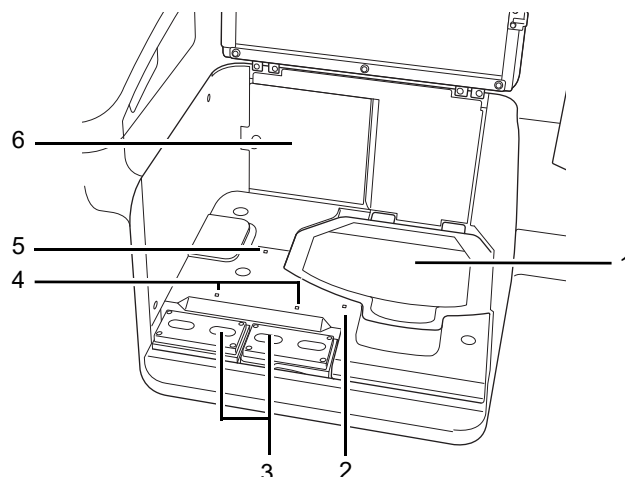
- 8 Probe washing holder/pressure regulator
Open to place probe washing or adjust the air pressure.
- 9 Line washing/concentrated line washing holder
Holds the line washing/concentrated line washing.
- 10 HISCL washing holder
Holds the HISCL washing.
- 11 Tip jam maintenance cover
Open to remove jammed tips.
- 12 Power breaker switch
Breaks the power line to the instrument.
Use if there is an abnormal odor or smoke.
To turn the power on/off normally, use the power switch.
- 13 Power switch
Turns the power on and off.
- 14 Sample rack removal area
After all samples in a rack have been aspirated in the sampler, the rack is stacked here. A maximum of 20 racks can be stacked.
- 15 Start button
Same as the [Start] on the IPU screen toolbar.
Press this button to feed in a rack.
- 16 Sample rack feeder
A sample rack in which samples have been placed is placed here. A maximum of 20 racks can be placed.
- 17 Sampler
Automatically conveys samples placed in the sample rack to the aspiration position.
- 18 Urgent sample holder
To analyze an urgent sample, open the cover and place the sample in this holder.
- 19 Urgent sample holder status LED
This indicates whether the urgent sample holder cover can be opened.
For LED and urgent sample holder cover statuses, see the following.
(►P.44 "3.4.3.2 Status indicated by the reagent holder A cover status LED [R1-R3]/urgent sample holder status LED [STAT]/continuous unit status LED")
- 20 Sampler cover
A sample rack placed in the sample rack feeder passes through this unit and is carried to the analyzer.
When a rack jams, open this cover to remove the rack.

Inside of the probe washing holder/pressure regulator



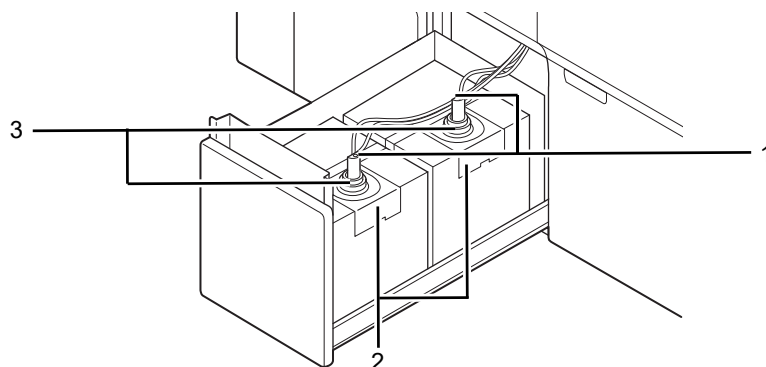
- 1 **Probe washing holder status LED**
Displays the status of the probe washing.
For LED and instrument statuses, see the following.
(►P.45 "3.4.3.4 Status indicated by the line washing status LED [LINE1], [LINE2]/concentrated line washing status LED [CONC1], [CONC2]/probe washing status LED [(L)], [(R)]/HISCL washing status LED [WASH1], [WASH2]")
- 2 **Probe washing bottle holder**
Holds the probe washing.
- 3 **Pressure regulator**
Adjusts the air pressure supplied from the pneumatic unit.

Inside of the operation cover



- 1 **Cover of the reagent holder A**
Open to place an R1-R3 reagent bottle before analysis.
- 2 **Reagent holder A status LED**
Indicates whether the cover of reagent holder A can be opened.
For LED and cover statuses, see the following.
(►P.44 "3.4.3.2 Status indicated by the reagent holder A cover status LED [R1-R3]/urgent sample holder status LED [STAT]/continuous unit status LED")
- 3 **Covers of the reagent holder B**
Open to place R4/R5 reagent bottle. 2 covers, left and right. The side not in use can be opened while analysis is in progress. The left side is labeled "L" and the right side is labeled "R".
- 4 **R4/R5 reagent status LED (L,R)**
Indicates whether the R4/R5 reagent is placed properly, whether it is in use, and other information.
For LED and reagent statuses, see the following.
(►P.45 "3.4.3.3 Status indicated by the R4/R5 reagent status LED [R4/R5 (L)], [R4/R5 (R)]")
- 5 **Continuous unit status LED**
Indicates whether the continuous unit cover can be opened.
For LED and cover statuses, see the following.
(►P.44 "3.4.3.2 Status indicated by the reagent holder A cover status LED [R1-R3]/urgent sample holder status LED [STAT]/continuous unit status LED")
- 6 **Continuous unit cover**
When there is an open position in reagent holder A, a reagent can be replaced even while analysis is in progress (continuous loading). Open to perform continuous loading.

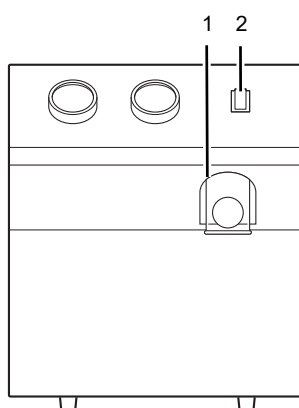
Inside of line washing holder/concentrated line washing/HISCL washing holder



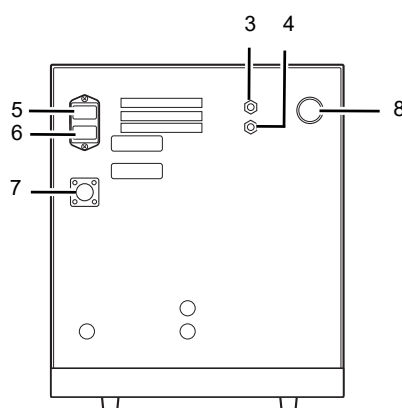
- 1 Line washing holder/concentrated line washing/HISCL washing holder status LED
Displays the status of the line washing/concentrated line washing/HISCL washing.
For LED and line washing/concentrated line washing/HISCL washing statuses, see the following.
(►P.45 "3.4.3.4 Status indicated by the line washing status LED [LINE1], [LINE2]/concentrated line washing status LED [CONC1], [CONC2]/probe washing status LED [(L)], [(R)]/HISCL washing status LED [WASH1], [WASH2]")
- 2 Fixing metal
Fix the dispensing set on the reagent.
- 3 Dispensing set
Dispenses reagent.

Pneumatic unit

Front



Back



- 1 Trap chamber
Prevents reagents etc. from flowing into the Pneumatic Unit during an instrument failure.
- 2 Power switch
Turns the power ON and OFF.
- 3 Main Unit pipe connection nipple (for positive pressure)
Used to connect the positive pressure pipe to the Main Unit.

- 4 Main Unit pipe connection nipple (for negative pressure)
Used to connect the negative pressure pipe to the Main Unit.
- 5 Fuse cap holder
Fuses are attached here.
Use the fuse of the specified type and rating.

Specification	Part code	Description	Type
117 VAC	266-7650-9	Fuse 313005 (250 V 5 A)	Time Lag
220-240 VAC	AY579418	Fuse 02183.15MXP (250 V 3.15 A)	Time Lag



Warning!

The power must be turned off and the power cable unplugged before fuses will be replaced. This is necessary to avoid the risk of electrical shock.

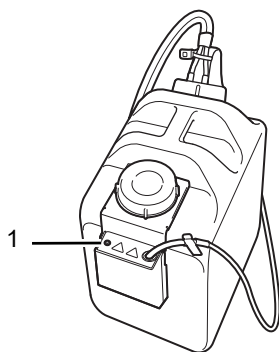


Caution!

Use a fuse of the specified type and rating.
Smoke or fire may result.

- 6 Inlet
Insert the power cord.
- 7 Main Unit wiring connector
Connects the control output connector from the Main Unit.
- 8 Positive pressure relief valve
Adjusts positive pressure supplied to the Main Unit.

Waste tank (optional)



- 1 Waste tank status LED
Displays the status of the waste tank (optional).
For LED and waste tank (optional) statuses, see the following.
(►P.46 "3.4.3.5 Status indicated by the waste tank status LED [1], [2]")

Units of the analyzer

The analyzer consists of the following units:

Name	Description
Sampler	Automatically conveys samples placed in the sample rack to the aspiration position.
Urgent sample holder	When you have an urgent sample, place the sample in this holder to have it conveyed to the aspiration position.
Cuvette feeder	Lines up and feeds cuvettes.
Tip feeder	Lines up and feeds tips.
Reagent holder A	Holds the R1-R3 reagent bottles and sample diluent.
Reagent holder B	Holds R4/R5 reagent.
Continuous unit	When R1 - R3 reagent is placed here, the reagent is conveyed to an empty position in reagent holder A. The reagent in reagent holder A is removed from here.
R1 reagent arm	Dispenses R1 reagent. The catcher moves and mixes the cuvettes.
Sample dispenser	Mixes the sample, R1 reagent, and sample diluent.
Sample arm	Dispenses samples using the tips.
R2 reagent arm	Dispenses R2 reagent.
1st B/F separation unit	Performs B/F separation of the reaction liquid in the cuvettes.
R3 reagent arm	Dispenses R3 reagent.
2nd B/F separation unit	Performs B/F separation of the reaction liquid in the cuvettes.
R4/R5 reagent arm	Dispenses R4/R5 reagent.
Reaction unit	Heats the reaction liquid in the cuvettes.
Detector	Cuvettes containing reaction liquid are introduced into the photodetection unit and measured to determine the luminescence of the reaction liquid.
Tip/cuvette waste unit	Used tips and cuvettes are discarded into this unit.



Information

When the PC is turned off and the system is in reagent refrigeration mode, adding reagent from the continuous unit and removal are not possible.

3.4.3 LED display status

The instrument status LED display indicates the status of the instrument and whether the units can be accessed.

The instrument status for each LED color and pattern display is described below.

3.4.3.1 Status indicated by the status LED [in front of instrument]

Display		Status
Color	Pattern	
Green	Lit	The instrument is in ready mode. Analysis can be started with the analysis start button.
	Blinking	Analysis is in progress or the instrument is in some other operation.
Blue	Lit	The instrument is in reagent refrigeration mode.
Orange	Lit	An error that allows continued operation has occurred, and analysis is in progress after verification.
	Blinking	An error that allows continued operation has occurred during analysis.
Red	Lit	An error that does not allow continued operation has occurred.
	Blinking	An error that allows continued analysis operation has occurred, and the error has not been checked.
None	Off	Indicates that the power is off.

3.4.3.2 Status indicated by the reagent holder A cover status LED [R1-R3]/urgent sample holder status LED [STAT]/continuous unit status LED

Display		Status
Color	Pattern	
Green	Lit	Can be accessed.
	Blinking	Cannot be accessed.

3.4.3.3 Status indicated by the R4/R5 reagent status LED [R4/R5 (L)], [R4/R5 (R)]

Display		Status
Color	Pattern	
Green	Lit	The reagent is loaded but is not in use.
	Blinking	The reagent is loaded and is in use.
Orange	Lit	The reagent is low and is not in use.
	Blinking	The reagent is low and is in use.
Red	Lit	The reagent has run out or an error has occurred. The reagent is not in use.
	Blinking	The reagent has run out or an error has occurred. The reagent is in use.
None	Off	The reagent has not been placed in the holder.

3.4.3.4 Status indicated by the line washing status LED [LINE1], [LINE2]/ concentrated line washing status LED [CONC1], [CONC2]/probe washing status LED [(L)], [(R)]/HISCL washing status LED [WASH1], [WASH2]

Display		Status
Color	Pattern	
Green	Lit	The detergent is loaded but is not in use.
	Blinking	The detergent is loaded and is in use.
Orange	Lit	The detergent has expired and is not in use.
	Blinking	The detergent has expired and is in use.
Red	Lit	The detergent has run out or an error has occurred, and the detergent is not in use.
	Blinking	The detergent has run out or an error has occurred, and the detergent is in use.

3.4.3.5 Status indicated by the waste tank status LED [1], [2]

Display		Status
Color	Pattern	
Green	Lit	The waste tank (optional) is empty and is not in use.
	Blinking	The waste tank (optional) is empty and is in use.
Red	Lit	The waste tank (optional) is full or an error has occurred. The waste tank is not in use.
	Blinking	The waste tank (optional) is full or an error has occurred. The waste tank is in use.
None	Off	The waste tank (optional) is set to "not used".

3.4.3.6 Status indicated by the indicator light (optional)

Display		Status
Color	Pattern	
Green	Lit	The instrument is in ready mode.
Orange	Lit	Indicates that an error that allows continued analysis operation has occurred, and the error has been checked.
Red	Lit	An error that does not allow continued operation has occurred.
	Blinking	An error that allows continued analysis operation has occurred, and the error has not been checked.
None	Off	Indicates that the instrument is in reagent refrigeration mode or the power is off.

3.4.4 Access control during operation

The covers on the analyzer are locked and cannot be opened in the states mentioned below:

Cover	Instrument status
Urgent sample holder cover	During instrument initialization During urgent sample analysis operation
Cover of reagent holder A	During instrument initialization During analysis operation During reagent replacement During automatic R1-R3 reagent replacement When analyzer power is OFF
Continuous unit cover	During instrument initialization During automatic R1-R3 reagent replacement

3.4.5 Operation modes

The analyzer has the 3 operation modes as mentioned below:

Operation mode	Description
Active mode	The analyzer is ready, communication with the IPU has been established, and all functions including analysis can be executed.
Standby mode	The analyzer is waiting to communicate with the IPU. The reagent holder cooling function and the reaction unit and detector heating functions are operating. The analyzer enters this mode when: • The analyzer power is switched from "off" to "on" in other than reagent refrigeration mode. • An error occurs in communication with the IPU in active mode.
Reagentrefrigeration mode	The cooling function of the reagent holder is operating and the analyzer is waiting to communicate with the IPU. The analyzer enters this mode when reagent refrigeration is executed during shutdown.

3.4.6 Alarm sounds

Audible alarms indicate various operation states and errors.

The types of alarm sounds are stated below:

Cause	Alarm sound (pattern)
Instrument status changes/Analysis starts	Selected sound (single sound)
Operation rejected	Selected sound (single sound)
Error	Selected sound (continuous)
Warning error	Selected sound (single sound)
Notice	Selected sound (single sound)
Urgent sample analysis/sampler ends	Selected sound (single sound)
Analysis ends	Selected sound (single sound)



Note:

With the exception of alarm sounds for specific errors, alarm sound and pattern settings can be changed.

To configure the settings, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 2: 2.15 Setting alarm sounds")

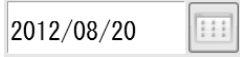
3.4.7 IPU screens

IPU screens and basic operations are explained below.

3.4.7.1 Common screen elements

Several buttons and other elements are common to screens of the HISCL-5000.

These are described below:

Button	Function
 	Touch to move the list display 1 page left or right.
 	Touch to move the selection or cursor in the list left or right.
 	Touch to move the list display 1 page up or down.
 	Touch to move the selection or cursor in the list up or down.
 	Touch to move the selection or cursor in the list to the 1st line or last line.
	Touch to display a software keyboard or numeric keys for entry of characters and numbers. 
	Touch to display a calendar that allows any date to be selected.
	Touch to display a software keyboard or comment edit dialog box for editing of comments. For the comment edit dialog box, see the following. (►P.58 "3.4.8 Edit comment dialog box")

3.4.7.2 IPU screen

The IPU screen is explained below.



Toolbar

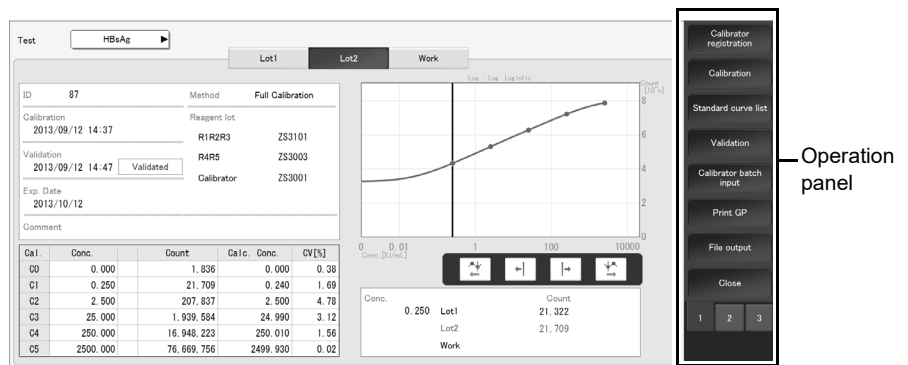
The toolbar provides shortcuts to the main functions.
For details, see the following.
(► **P.50** "3.4.7.3 Toolbar")

View

Area for performing various processes and operations.
The displayed contents vary depending on the function that is executed.
The main menu screen appears initially.
(► **P.56** "3.4.7.6 Main menu screen")

Operation panel

When a button on the toolbar or in the view is touched, the operation panel appears on the right side of the view.



Operation buttons related to the view contents appear in this area.
For details, see the following.
(► **P.51** "3.4.7.4 Operation panel")

System area

Displays the status of the IPU and the instrument.
For details, see the following.
(► **P.52** "3.4.7.5 System area")

3.4.7.3 Toolbar

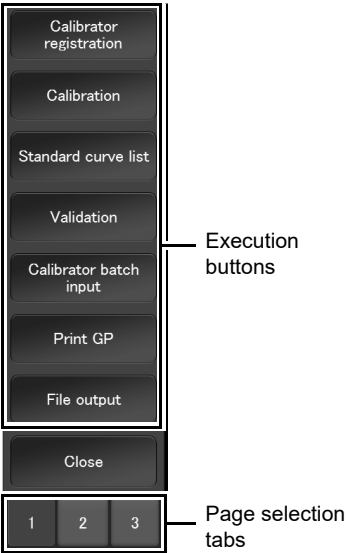
Shortcuts to the main functions appear on the toolbar.



[Menu]	Touch to display the main menu screen. The main functions, including display of screens, can be executed from this screen. For details, see the following. (▶P.56 "3.4.7.6 Main menu screen")
[Portal]	Touch to display the [Portal] screen. The contents of the notice board and standard curve expiration dates can be checked on this screen. For details, see Chapters 5 and 6. (▶P.101 "Chapter 5: 5.1.5 Using the bulletin board") (▶P.135 "Chapter 6: 6.2 Checking the expiration date of the standard curve")
[Set Up]	Touch to display the [Set Up] screen. Supplies and reagent levels can be checked on this screen. For details, see Chapter 5. (▶P.87 "Chapter 5: 5.1 Checking the analysis preparation status")
[STD]	Touch to display the [Standard Curve] screen. A standard curve that has been created can be checked on this screen. For details, see Chapter 6. (▶P.133 "Chapter 6: 6.1 Standard Curve screen")
[QC]	Touch to display the [Quality control] screen. QC analysis results can be checked on this screen. For details, see Chapter 7. (▶P.153 "Chapter 7: 7.1 Quality control screen")
[Order Regist]	Touch to display the [Order registration] screen. Analysis orders can be entered on this screen. For details, see Chapter 8. (▶P.180 "Chapter 8: 8.1.1 Order registration screen")
[Progress]	Touch to display the [Progress] screen. The analysis end time and time remaining for the completion of analysis can be checked on this screen. For details, see Chapter 9. (▶P.205 "Chapter 9: 9.1 Checking analysis end time")
[Joblist]	Touch to display the [Joblist] screen. The list of analysis results can be viewed on this screen. For details, see Chapter 10. (▶P.220 "Chapter 10: 10.1.1 Job list screen")
[Browser]	Touch to display the [Browser] screen. Details of analysis results can be checked on this screen. For details, see Chapter 10. (▶P.226 "Chapter 10: 10.2.1 Browser screen")
[Maintenance]	Touch to display the [Maintenance] screen. HISCL-5000 maintenance tasks can be performed on this screen. For details, see Chapter 11. (▶P.256 "Chapter 11: 11.1.1 Maintenance screen")
[Wake Up]	Touch to switch the analyzer from reagent refrigeration mode to the READY state.
[Shutdown]	Touch to shut down the analyzer.
[STAT]	Touch to display the [Order registration] screen to interrupt analysis for an urgent sample. The analysis order for an urgent sample can be entered on this screen. For details, see Chapter 8. (▶P.183 "Chapter 8: 8.1.3 Registering an urgent sample order")
[Sampling Stop]	Touch to pause the current analysis operation.
[Start]	Touch to start analysis.

3.4.7.4 Operation panel

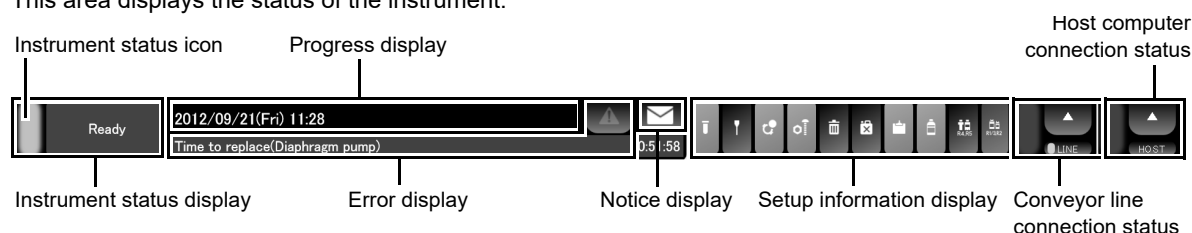
The operation panel contains execution buttons, [Close], and page selection tabs.



Execution buttons	The execution buttons execute the functions of each screen, and are different on each screen. The layout and content displayed can be edited in the [Settings] dialog box. To configure the settings, see the "Administrator's Guide". (► Administrator's Guide, "Chapter 2: 2.7 Configuring operation panel settings")
[Close]	Touch to return to the previously displayed screen. When the main menu screen appears, the screen does not change.
Page selection tabs	Changes the displayed execution buttons. The maximum number of tabs is 3.

3.4.7.5 System area

This area displays the status of the instrument.



● Instrument status display

Instrument status icon	Displays the status of the instrument by an icon. The colors and patterns of the instrument status icon, and instrument statuses, are as follows.
Green	The instrument is in the READY state. Analysis operation is possible even if the instrument status text is not [Ready].
Blinking green	Analysis is in progress or the instrument is in some other operation.
Blue	The instrument is in reagent refrigeration mode.
Orange	An error indicating continued analysis operation has occurred, the error has been checked, and the instrument is in the READY state.
Blinking orange	An error indicating continued operation has occurred during analysis.
Red	An error that does not allow continued operation has occurred.
Blinking red	An error indicating continued analysis operation has occurred, and the error has not been checked.
Gray	The instrument is in a state that does not allow analysis.
Instrument nickname	Displays the nickname of the instrument. The nickname can be changed in the settings. To configure the settings, see the "Administrator's Guide". (►Administrator's Guide, "Chapter 2: 2.16 Setting the nickname of the instrument")
Instrument status text	Displays the status of the instrument by text.
[Initial]	Indicates that mechanical unit is initializing after the power is turned on, or the reagents are being scanned.
[Start Up]	Indicates the instrument is waiting for the temperature and other conditions to stabilize after initialization.
[Ready]	Indicates the instrument can start analyzing immediately without waiting for the temperature or other conditions to stabilize, e.g. before analysis starts (after completion of startup) and after analysis ends.
[Reserve]	Indicates that the instrument will execute analysis without entering the READY state because analysis start was executed in advance during startup.
[Analyzing]	Indicates that analysis is in progress after analysis start was executed.
[Stop]	Indicates that the instrument is waiting for analysis to end after an error occurred and analysis was stopped.
[Pause]	Indicates that analysis has been paused.
[Run]	Indicates that mechanical units or fluid units are in operation but analysis is not being performed, such as during initialization or test operation.

[Reagent Refrigeration]	Indicates that the instrument is in reagent refrigeration mode. For instrument operation modes, see the following. (► P.47 "3.4.5 Operation modes")
[Error]	Indicates that an operating error or other error has occurred.
[Standby]	Indicates that the instrument is in standby mode.
[Not Connected]	Indicates that a communication error occurred, or that the IPU was started before the analyzer was started.

● Progress display

Progress text	Displays instrument operation progress by text. If there is no progress to be displayed, it will display the current date and time.
Progress display	Displays a progress bar allowing progress to be checked.

● Error display

Error text	When an error occurs in the instrument, a text description of the error appears. For details, see Chapter 12. (► P.297 "Chapter 12: 12.4.1 Displaying an error")
Show error list button	Touch to display the [Error List] dialog box. For details, see Chapter 12. (► P.297 "Chapter 12: 12.4.1 Displaying an error")

● Notice display

Notice button	Touch to display the [Notice List] dialog box. For details, see Chapter 12. (► P.298 "Chapter 12: 12.4.2 Displaying a notice")
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● Setup information display

Displays the statuses of supplies and reagents by an icon.

Touch an icon to display the [Set Up] screen.

The icon colors indicate the following states:

Gray: Ready

Orange: Warning

Red: Error

Display	Description	Display	Description
	Cuvettes		Waste box
	Tips		R4/R5 reagent
	Membrane filter replacement/ Sample nozzle cleaning		Probe washing
	Maintenance parts		HISCL washing Line washing Concentrated line washing
	Waste tank*		R1-R3 reagent

* The waste tank is an option. When the waste tank (optional) is not used, the icon appears in black.

● Host computer connection status

Displays the status of the connection with the host computer by an icon.

Touch the icon to display the connection settings screen.

Display		Status
Color	Pattern	
Green	Lit	Connected
Red	Lit	Connection error
No icon		No Connection

● Conveyor line connection status

Displays the status of the connection with the conveyor line by an icon.

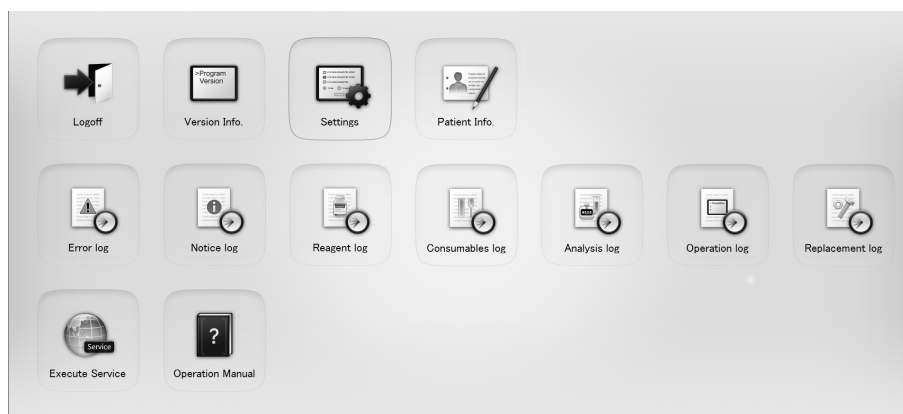
Touch the icon to display the connection settings screen.

Display		Status
Color	Pattern	
Green	Lit	Connected
Red	Lit	Connection error
Gray	—	No Connection
		Conveyor line priority

* Conveyor line connection is an option.

3.4.7.6 Main menu screen

The main menu screen is the initial screen that appears on the IPU. The main functions, including display of screens, are executed from this screen.



[Logoff]	Touch to display a confirmation dialog box. Touch [OK] to close the dialog box and execute logoff.
[Version Info.]	Touch to display the [Version Info.] dialog box. Displays the version of the IPU and analyzer. For details, see Chapter 13. (▶P.372 "Chapter 13: 13.3 Program version")
[Settings]	Touch to display the [Settings] dialog box. Basic instrument settings can be configured on this screen. For details, see the following. (▶P.68 "3.10.1 Displaying the settings dialog box")
[Patient Info.]	Touch to display the [Patient info.] screen. This shows registered patient information. For details, see the "Administrator's Guide": (▶Administrator's Guide, "Chapter 7: 7.1 Checking patient information")
[Error log]	Touch to display the [Error log] screen. A log of error information appears. For details, see the "Administrator's Guide": (▶Administrator's Guide, "Chapter 8: 8.1 Viewing the error log")
[Notice log]	Touch to display the [Notice log] screen. A log of notice information appears. For details, see the "Administrator's Guide": (▶Administrator's Guide, "Chapter 8: 8.2 Viewing the notice log")
[Reagent log]	Touch to display the [Reagent log] screen. A log showing reagent replacement information appears. For details, see the "Administrator's Guide": (▶Administrator's Guide, "Chapter 8: 8.3 Viewing the reagent log")
[Consumables log]	Touch to display the [Consumable log] screen. A log related to supplies appears. For details, see the "Administrator's Guide": (▶Administrator's Guide, "Chapter 8: 8.4 Viewing the consumables log")
[Analysis log]	Touch to display the [Analysis log] screen. Monthly analysis counts appear. For details, see the "Administrator's Guide": (▶Administrator's Guide, "Chapter 8: 8.5 Viewing the analysis log")

[Operation log]	Touch to display the [Operation log] screen. A log of sample number modifications, recalculations, and other data revisions appears. For details, see the "Administrator's Guide": (► Administrator's Guide, "Chapter 8: 8.6 Viewing the operation log")
[Replacement log]	Touch to display the [Part Replacement log] screen. A log related to part replacement appears. For details, see the "Administrator's Guide": (► Administrator's Guide, "Chapter 8: 8.7 Viewing the replacement log")
[Execute Service]	When Caresphere is enabled, touch to display the [Execute Service] dialog box. You can execute the Caresphere function.
[Operation Manual]	Touch to display the [Operation Manual] screen. The contents of the operation manual can be viewed. For details, see Chapter 4. (► P.80 "Chapter 4: 4.2 Viewing the on-screen manuals")

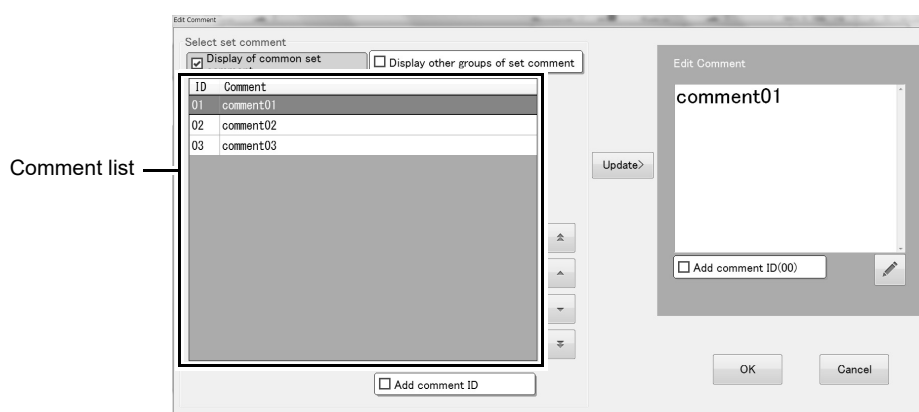
3.4.8 Edit comment dialog box

Comments can be added to samples on the screens for each function, including the order registration, QC, analysis results, and maintenance screens.

Touch the  button to display the edit comment dialog box.

For details, see the following.

(►P.48 "3.4.7.1 Common screen elements")



[Select set comment]	When preset comments are set, you can select a preset comment from the comment list.
[Display of common set comment]	Select the checkbox to display preset comments that are common to all screens in the comment list.
[Display other groups of set comment]	Select the checkbox to display preset comments set for other screens in the comment list.
Comment list	Preset comments that can be used appear in this list.
[Add comment ID]	Select the checkbox to add the ID number of the selected preset comment to the beginning of the comment in [Edit Comment].
[Update]	Touch to display the comment selected in the comment list in [Edit Comment].
[Edit Comment]	Use this to edit a comment that you want to display on the screens of the functions.
[Add comment ID (00)]	Select the checkbox to add the ID number [00] to the beginning of [Edit Comment].
[OK]	Touch to have the comment in [Edit Comment] displayed in [Comment] on each screen.
[Cancel]	Touch to close the edit comment dialog box without saving the edited comment.

3.5 List of supplies

Supplies used in the HISCL-5000 are shown below. For details, contact your local Sysmex representative.

Part code	Product name	Model name	Capacity
06451419	HISCL DISPOSABLE TIP	NDT-400A * ¹	500 pieces x 10 bags
CP815570	HISCL Cuvette L	HCL-400A * ²	500 pieces x 10 bags

*1 Includes 6 membrane filters.

*2 Includes 9 waste bags.

3.6 Reagents

3.6.1 Reagents used for analysis

Reagents used in the HISCL-5000 are shown below:

Type	Name	Description
Reagents specific for the tests	R1 reagent R2 reagent R3 reagent	Reagents used in specific tests. Place in reagent holder A.
Substrate	R4 reagent R5 reagent	Reagent used in all tests. Place in reagent holder B.
Detergent	Probe washing	Used to clean the reagent probe. 2 bottles can be placed simultaneously.
	Line washing Concentrated line washing	Used to clean the nozzles. 2 boxes can be placed simultaneously.
	HISCL washing	Performs B/F separation. 2 boxes can be placed simultaneously.
HISCL diluent	Sample diluent	Used for dilution analysis. Place in reagent holder A.



Information

- For information on R1-R5 reagents and sample diluent, see the package insert for each reagent.
- For reagent holders A and B, see the following.
(► **P.37** "3.4.2 Instrument part description")

3.6.2 Symbols

The symbols below are used on reagent containers and outer boxes.



Caution!

Important information on handling reagents is provided on reagent containers, outer boxes, and package inserts. Understand the information before use.



In vitro diagnostic medical device



Keep away from sunlight



Manufacturer



Use no hooks



Consult instructions for use



This way up



Temperature limitation



Keep dry



Biological risks



Stacking limit by number



Use by



Fragile; handle with care



Batch code



Corrugated recycles



Catalogue number



Do not reuse



Concentrated reagent

CONT

Contents

CUVETTE

Cuvette

TRASH BAG

Trash bag

FILTER

Filter

TIP

Tip

The design of some symbols may vary on the actual product.

3.7 List of supply parts

Supply parts used in the HISCL-5000 are shown below:

Some supply parts may not be available for additional purchase, or the order unit quantity may differ from the quantity supplied with this instrument. For details, contact your local Sysmex representative.

No.	Part code	Name	Count	Use
1	BB119136	HISCL-5000 Instructions for Use	1	Instructions for Use
2	CC510799	HISCL-5000 Administrator's Guide	1	Manual for administrators.
3	BZ046508	Cassette_ASSY No. 39	6	5-sample rack
4	BF346882	Adapter No. 276	5	Adapter for sample tubes with an outer diameter of 16 mm (Black)
5	CW036661	Adapter No. 352	100	Adapter for sample tubes with an outer diameter of 13 mm (White)
6	CY749662	Adapter No. 418	100	Adapter for sample tubes with an outer diameter of 13 mm (Brown)
7	AP809810	Adapter No. 268	3	6-sample adapter (White)
8	CC604680	Adapter No. 279	3	6-sample adapter (Green)
9	AF580778	Adapter No. 280	3	6-sample adapter (Yellow)
10	CM746202	Holder_Assy No. 636	1	AC cable disconnection prevention plate
11	92380928	Power Cord No. 15 Assembly	1	Pneumatic unit power cable 2 m
12	BU182928	Wiring cord_Assy No. 5152	1	Pneumatic unit connection cable 1.3 m
13	AY921939	Sensor_Assy No. 91	1	4 tube set with sensors for HISCL washing/line washing level monitoring.
14	CD739981	Barcode Reader_Assy No. 29	1	Handheld barcode reader
15	AY350381	Filter_Assy No. 24	1	Membrane filter holder
16	36333305	Aspiration_Fixing_Metal No. 423	4	Support plate for HISCL washing/line washing/concentrated line washing level monitoring sensors
17	AC797007	Power Cable_Assy No. 7717	1	Analyzer power cable 3 m
18	46231221	Cap Opener No. 2	1	Cap opener for HISCL washing/line washing/concentrated line washing container
19	CX960451	Barcode reader stand 11-0360	1	Barcode reader stand + Installation screws M3 x 20 (x2) + Spacer (x2)
20	BR795472	Barcode labels (1-60)	3	Sample rack barcode labels (NW7)
21	26651060	Fuse ST4-6.3A-N1 (100 V Specifications/250 V 6.3 A, Time Lag)	2	Pneumatic unit fuse (for replacement)
22	CS133341	Tweezers TSP-37	1	Tweezers

No.	Part code	Name	Count	Use
23	26594365	LAN cable NSED-PC-S-MP4P-2SB568B/AB	1	Analyzer - IPU connection cable 2 m
24	24192187	EMI core ESD-SR-250	1	Ferrite core
25	44250554	Tube 3.4 x 1.8 5 m	1	Tube (spare)
26	44253387	Tube 6 x 4 5 m	1	Tube (spare)
27	BF966029	Tube Silicone 6 x 10_#9E55 20 m	2	Drain tube
28	44264865	Reagent tube PHARMED_BPT_1/8 in x 1/4 in 500 mm	1	Reagent tube
29	44253405	Tube 9 x 6 50 mm	1	For prevention of HISCL washing/line washing/concentrated line washing tube disconnection
30	CN054796	Jig_Assy No. 30	1	For opening of R1-R3 reagent
31	46230101	Hopper jam removal pole	1	For maintenance of the tip feeder and cuvette feeder.
32	BY697776	Cable CBL-203B-5M	1	Touch panel USB cable
33	CF050939	Cable SMP-050	1	Touch panel audio cable
34	CE690429	Cable KC-DVI-5K	1	Touch panel display cable
35	AU908259	Bottle_Assy No. 26	2	For sample nozzle cleaning
36	AH040633	Jig No. 990	1	For release of reagent holder A cover lock
37	BR797092	Jig No. 1040	1	Jig for adjustment of sampler
38	CQ008123	Jig No. 1217	1	Jig for adjustment of sample aspiration position
39	34850651	Hex Socket Bolt M6 x 14	5	For coupling of main unit and sampler
40	34841188	Washer built-in screw M5 x 16	3	For coupling of main unit and sampler
41	34841094	Washer built-in screw M4 x 10	4	For cover Assy No. 188 installation (x2) For cover Assy No. 202 installation (x2)
42	26571535	Power Cord TA-6P(A)+TA-5(A) H05VV-F	1	Pneumatic unit power cable
43	AY579418	Fuse 02183.15MXP (220 - 240 V Specifications/ 250 V 3.15 A, Time Lag)	2	Pneumatic unit fuse (for replacement)
44	AD143915	Label No. 1848	3	Sample rack barcode labels (CODE39)
45	BW569956	Holder_Assy No. 292	1	Tray for storing and carrying 5-sample racks
46	AE538288	CDR_Assy No. 118	1	Program CD (CDR2HI5X)

3.8 List of maintenance parts

Parts that require replacement after a certain number of uses or a certain interval of use are listed below.

When it is time to replace a part, contact your local Sysmex representative.

The operation guideline counts for part replacement are shown below:

Part name	Replacement guideline count	Part name	Replacement guideline count
Membrane filter	1,000 operations	2nd BF mixing catcher C	90,000 operations
Sample syringe	300,000 operations	2nd BF mixing catcher D	
R1 reagent probe	90,000 operations	WTKV of R5 reagent line	500,000 operations
R2 reagent probe		Lubricator (R1/3)	60,000 operations
R3 reagent probe		Lubricator (R2)	
1st BF separation unit nozzle A		1st BF wait port	100,000 operations
1st BF separation unit nozzle B		1st BF holder A	
1st BF separation unit nozzle C		1st BF holder B	
1st BF separation unit nozzle D		1st BF holder C	
2nd BF separation unit nozzle A		1st BF holder D	
2nd BF separation unit nozzle B		2nd BF wait port	
2nd BF separation unit nozzle C		2nd BF holder A	
2nd BF separation unit nozzle D		2nd BF holder B	
R5 syringe	270,000 operations	2nd BF holder C	
R1 mixing catcher	90,000 operations	2nd BF holder D	
R2 mixing catcher		R45 holder	300,000 operations
R3 mixing catcher		PW supply DP	
R45 mixing catcher		R1/3 drive gear	60,000 operations
1st BF mixing catcher A		R2 drive gear	
1st BF mixing catcher B		Pneumatic unit (Piston pump)	Every 5 years
1st BF mixing catcher C		Bellows (for -0.053)	Every 3 years
1st BF mixing catcher D		Bellows (for -0.033)	
2nd BF mixing catcher A		Air dryer	Every year
2nd BF mixing catcher B		PHARMED for fluid pinching	

3.9 Overall flow of operation

This section explains the basic procedures for operation, from startup to shutdown.

The general steps for operating the HISCL-5000 are described below.

Once you understand the overall flow, see the detailed explanation of each step in the respective sections.

1 Check the cable connections and then turn on the power of the analyzer.

(▶P.75 "Chapter 4: 4.1 Starting up the instrument")

2 Check the state of the reagents, tips, cuvettes, disposal bags, and waste tank (optional).

(▶P.87 "Chapter 5: 5.1 Checking the analysis preparation status")

3 Make sure that the standard curve is correctly set before starting analysis.

(▶P.146 "Chapter 6: 6.6.1 Checking a standard curve")

4 Perform quality control to maintain the reliability of analysis data.

(▶P.153 "Chapter 7: Performing QC analysis")

5 Prepare the samples and place them in the instrument.

(▶P.197 "Chapter 8: 8.2.1 Performing analysis from the sampler")

6 Register an analysis order.

(▶P.179 "Chapter 8: 8.1 Registering an order")

7 Start analysis.

8 Check the progress of the analysis and the time remaining until completion.

(▶P.205 "Chapter 9: 9.1 Checking analysis end time")

9 Check, validate, and report the analysis results.

(▶P.219 "Chapter 10: Checking analysis results")

10 Shut down the analyzer and IPU.

(▶P.83 "Chapter 4: 4.4 Shutting down the instrument")

3.9.1 Flow of standard curve creation

This section explains the flow of standard curve creation.

For details, see Chapter 6.

(► **P.133** "Chapter 6: Creating a standard curve")

The standard curve is used to calculate the concentration and cutoff index from the measured count value (the luminous intensity of the sample).

A standard curve can be created by analyzing a calibrator.

In the following situations, create a new standard curve:

- When performing analysis for the first time.
- When the lot of the reagent kit (R1-R3 reagent) changes.
- When a QC error occurs, or the data varies significantly on the QC chart.
- The probe has been replaced or its position has been adjusted.
- When it is otherwise necessary due to the state of the instrument, reagents, analysis results, or period of use*.

* For the term of validity of the standard curve, see the package insert for each reagent.



Caution!

Do not use a calibrator that has expired.

Correct analysis results may not be obtained.

1 Check the standard curve.

Check the standard curve on the [Standard Curve] screen of the IPU.

2 Register calibrator information.

3 Register a standard curve order.

4 Analyze the calibrator.

5 Validate the standard curve.

3.9.2 Flow of QC analysis

This section explains the flow of QC analysis.

For details, see Chapter 7.

(►P.153 "Chapter 7: Performing QC analysis")

Quality control must be performed to maintain the reliability of analysis data.

The HISCL-5000 analyzes control serum and other standard samples (control materials), and statistically manages the results.

Always run a QC check before starting the day's analysis work to ensure that there are no abnormalities.

1 Register a QC order.

2 Start QC analysis.

3 Check the QC plot data.

3.9.3 Flow of sample analysis

This section explains the flow of sample analysis.

For details, see Chapter 8.

(►P.179 "Chapter 8: Performing sample analysis")

1 Register an analysis order.

2 Load a sample rack in which samples have been placed in the sampler.

3 Start analysis.

4 Check the analysis results.

3.10 Basic instrument settings

This section explains the basic instrument settings that are configured in order to perform analysis. The settings are configured in the [Settings] dialog box of the IPU.



Note:

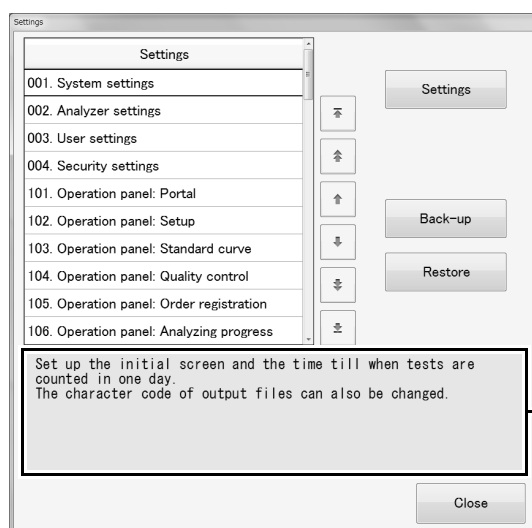
The settings can only be changed if you are logged on with administrator privileges. The settings cannot be changed if you are logged on as an operator. For settings configured by the administrator, see the "Administrator's Guide".

3.10.1 Displaying the settings dialog box

The procedure for displaying the [Settings] dialog box, and the settings in the dialog box, are explained below. Follow the steps below to display the [Settings] dialog box.

1 Touch [Menu] - [Settings] on the toolbar.

The [Settings] dialog box appears.



Setting item display

[Settings] dialog box

2 Check the setting items.

The following items are displayed in the dialog box:

[Settings]	Displays the list of the tests. Select settings from the list.
Setting item display	Displays the detailed settings of each setting item. The contents of the screen vary depending on the settings.
[Settings]	Touch to display the dialog box that lets you edit the selected setting item.
[Back-up]	Touch to save all current settings to a specified file.
[Restore]	Touch to restore the settings in the specified backup file.
[Close]	Touch to close the dialog box.

3.10.2 Startup and shutdown settings

Basic settings for startup and shutdown are described below:

Setting	Description
Wake-up settings	Sets the auto wake-up time and time cycle. Auto wake-up takes place automatically at a specified time every day, or only on a specified day of the week, or only at the beginning of the month (or end of month). When the set day is specified as a non-work day on the calendar, auto shutdown will take place on the next work day (if every day is specified, auto shutdown does not take place on non-work days). For details, see Chapter 11. (► P.259 "Chapter 11: 11.2.2.1 Setting auto wake-up")
Shut-down settings	Sets the auto shutdown time and time cycle. Auto shutdown takes place automatically at a specified time every day, or only on a specified day of the week, or only at the beginning of the month (or end of month). When the set day is specified as a non-work day on the calendar, auto shutdown will take place on the next work day (if every day is specified, auto shutdown does not take place on non-work days). For details, see Chapter 11. (► P.260 "Chapter 11: 11.2.2.2 Setting auto shutdown")
User settings	Registers and deletes users of the instrument. Items set are the logon name, operator name, operator information, user type and user icon. A maximum of 20 users can be registered, including the 2 preset users.
Back-up settings	Specifies the save location of the backup file that is automatically generated at shutdown and when settings are changed.

To configure the settings, see the "Administrator's Guide".

(► Administrator's Guide, "Chapter 2: 2.2 Editing user information", **P.6-5** "Chapter 6: 6.4 Configuring settings for auto backup at shutdown")

3.10.3 Standard curve settings

Basic settings for standard curves are described below:

Setting	Description
Standard curve validation	Sets whether the standard curve is automatically validated, and whether the standard curve is automatically corrected.
Calibrator registration	Registers the lot information when a new calibrator is created. Sets the product code, lot number, expiration date, concentration, priority specification, and other information.

When setting calibrator information, make sure the values are the intended values. Incorrect values may prevent correct analysis results from being obtained.

To configure the settings, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 3: Using Standard Curve Functions")

3.10.4 QC settings

Basic settings for QC are described below:

Setting	Description
QC material registration	Registers samples used in QC analysis. A maximum of 30 QC names, and tests for each QC sample, can be set. A maximum of 3 types of lot information (lot number, expiration date, and sample number) can be registered, and the lot to be used preferentially can be specified. For each sample lot, you can specify whether the lot is displayed in the QC chart of the [Quality control] screen.
QC chart settings	Sets the layout of the QC chart on the [Quality control] screen. You can set the tab names on the screen and assign charts to the tabs. The lot chart sorting order can be set for each QC sample. In addition, you can set whether a chart is displayed for the lot.
QC limit settings	Sets a target/limit (upper and lower limits for determining whether data is normal) for each QC chart.

To configure the settings, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 4: Using Quality Control Functions")

3.10.5 Analysis method settings

Basic analysis method settings are described below:

Setting	Description
Rack start settings	Sets whether analysis starts when a sample rack is loaded in the sampler.
6-sample-rack settings	Registers the rack ID when a 6-sample adapter is attached to a rack to change it to a 6-sample rack. When a rack is specified as a 6-sample rack, the sample barcode is not scanned.
Error handling settings	Specifies what the instrument does when an error occurs.
Barcode settings	Specify whether or not sample barcodes/rack barcodes are scanned by the ID barcode reader, and specify the barcode standard that is used. The number of characters expressed by the sample barcode, and the effective part of the sample barcode that is used as the sample number, can also be specified. When NW-7 is specified for the rack barcode standard, the start/stop character can be specified.

To configure the settings, see Chapter 8.

(► **P.188** "Chapter 8: 8.1.7 Registering a default order for a rack")

3.10.6 Analysis order settings

Basic settings for analysis orders are described below:

Setting	Description
Test settings	For the tests used on the instrument, a maximum of 50 tests can be selected from the 100 tests that are available in the system.
Test info settings	For each test, a screen display name, host computer transmission ID, and other information can be set.
Retest settings	Sets whether a retest order is automatically created, and if created, sets criteria values for the concentration and other results that determine whether a retest order is created.
Auto rack order settings	Sets whether the corresponding order is automatically used if the sample rack ID or sample number matches the rack ID or sample number registered in the retest list or default order for the rack in the IPU.
Auto STAT order settings	You can set whether the corresponding order is automatically used if a sample number registered for urgent sample analysis matches the sample number registered in the retest list in the IPU.
STAT default order settings	Registers a default order for urgent samples (STAT). The tests, dilution ratio, and analysis count are set for a sample.
Test set settings	Registers a test set that allows multiple tests to be specified simultaneously. A maximum of 10 test sets can be registered. Register a display name and the tests. The dilution ratio and analysis count of the initial order are applied.
Rack settings	Registers a default order for a rack ID. There are 4 types of racks: QC rack: Registers a default QC order. Calibration rack: Registers a default standard curve order. A QC order can also be registered. Default order rack: Registers a default regular sample analysis order. You can also specify whether sample barcodes are scanned for each rack ID. Host supplement rack: Changes the dilution ratio and analysis count in an order specified from the host.

To configure the settings, see the "Administrator's Guide".

(► Administrator's Guide, "Chapter 5: Using Order Registration Functions")

3.10.7 Analysis result settings

Basic settings for analysis results are described below:

Setting	Description
Order display settings	For over-range analysis results, select the text that is output to the [Joblist] screen and printer. The text that is output to the host computer depends on the settings. For information on the settings, contact your local Sysmex representative. The background color of positive results can also be set. For details, see Chapter 10. (►P.240 "Chapter 10: 10.5.1 Setting the display of positive results")
Auto validate settings	Sets whether analysis results are automatically validated when all results of a sample have been obtained. When auto validation is performed, conditions for auto validation can be set for each sample type.
Auto output settings	Sets whether automatically validated analysis results are automatically sent to the host computer or automatically printed in report format. When automatically sent or printed, the sample type must be specified.
Auto printing for check	Sets whether or not analysis results are automatically printed for review. When printed automatically, the conditions for auto printing must be set for each sample type. For details, see Chapter 10. (►P.241 "Chapter 10: 10.5.2 Automatically printing abnormal values")
Joblist layout settings	Sets the tab names on the [Joblist] screen and the information displayed on each tab. Also sets whether past data and deleted data are displayed.
Joblist display settings	Sets the display conditions for the [Joblist] screen. Sets the conditions of display for each display condition name and display condition. Displayed analysis results can also be sorted. Ascending or descending are set for 3 sort keys.

Exercise full caution when changing settings related to the displayed content of analysis results, such as criteria values for qualitative classifications, display ranges, and data display formats. Otherwise there is a possibility that the intended display content will not appear.

To configure the settings, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 6: 6.3 Setting conditions for automatic output of analysis results (host output and printing)")

Chapter 4 Starting up/Shutting down the instrument

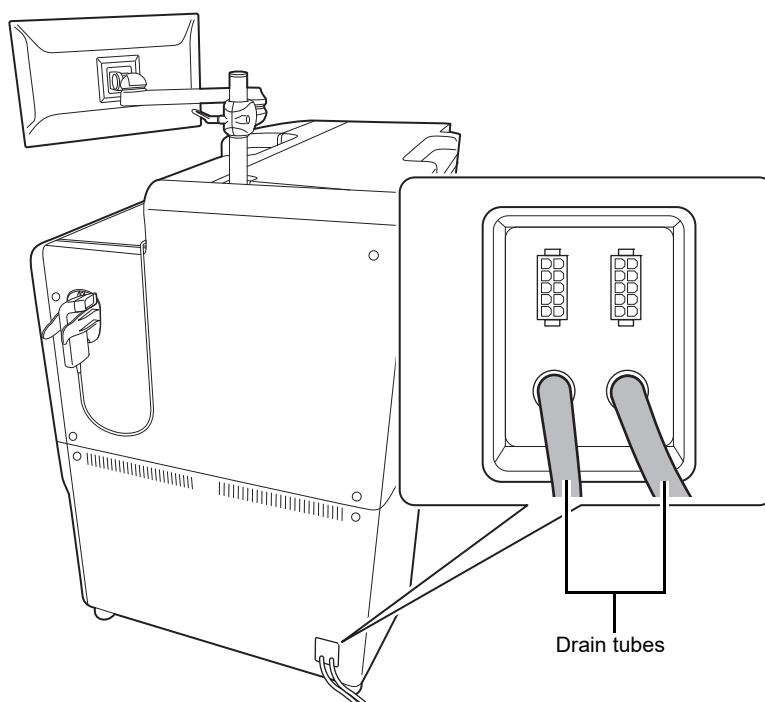
This chapter explains how to start up and shut down the instrument.

4.1 Starting up the instrument

4.1.1 Checking the instrument before startup

Before turning on the power, check the following:

- Are there any externally connected tubes bent or disconnected from the instrument?
- Are the drain tubes on the right side of the instrument connected?



Caution!

- Do not disconnect or reconnect the drain tubes while the power is on or the instrument is starting up.
There is a risk of waste fluid splashing.
- Do not reverse the connections to WASTE1 and WASTE2.
- Connect the drain tubes to the appropriate drain system or drain outlets.

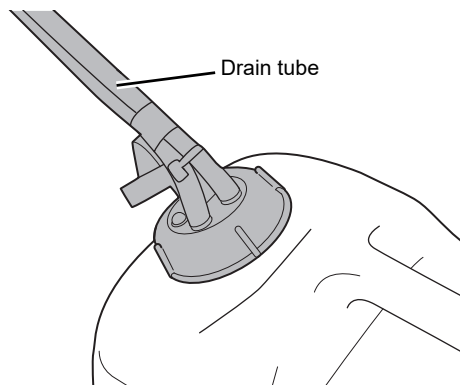
- Are the power cables of the analyzer, IPU, and pneumatic unit firmly plugged into their power outlets?
(►P.32 "Chapter 3: 3.1.2 Plugging in the power cable")



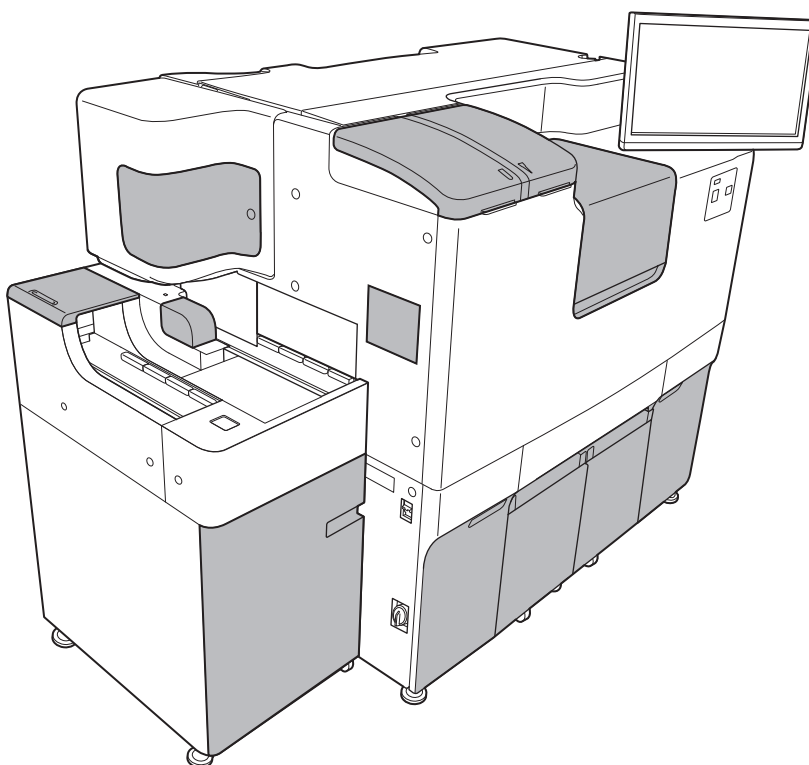
Caution!

Before connecting power cables, always turn off the main unit power.
There is a risk of electrical shock.

- Are the communication cables that link other devices to the IPU connected?
(► **P.34** "Chapter 3: 3.2 Connecting peripheral devices and optional devices")
- Is the drain tube for the waste tank (optional) or waste fluid treatment line connected?
e.g. Waste tank (optional) drain tube



- Are all instrument covers closed?



- Is sufficient reagent at hand for the number of samples to be processed?
(► **P.59** "Chapter 3: 3.6 Reagents")
- Does a sample rack remain in the instrument?
- Is any fluid leaking from the instrument?
- Has fluid collected in the trap chamber?
(► **P.272** "Chapter 11: 11.3.6 Emptying the trap chamber")

4.1.2 Starting up the instrument

- **If the analyzer and IPU are both powered off**

Follow the steps below to turn on the power of the HISCL-5000.

1 Turn on the power of the analyzer.

The analyzer starts up.

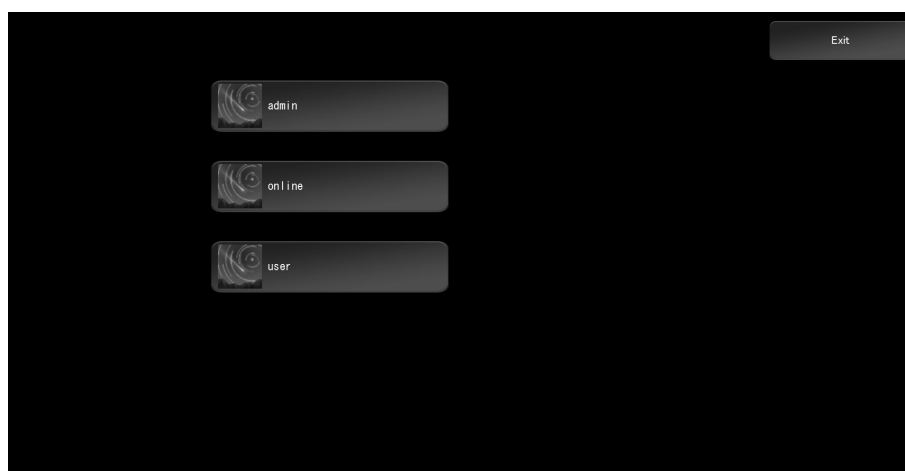
For the location of the power switch, see Chapter 3.

(►P.37 "Chapter 3: 3.4.2 Instrument part description")

2 Turn on the power of the touch panel display.

The IPU starts and the Select Logon User screen appears.

It will take time for the IPU to start.



Select Logon User screen

- **When the analyzer is in reagent refrigeration mode and the IPU is powered off**

When the start button on the analyzer is pressed, the computer and IPU start.

The Select Logon User screen appears.

For the location of the start button, see Chapter 3.

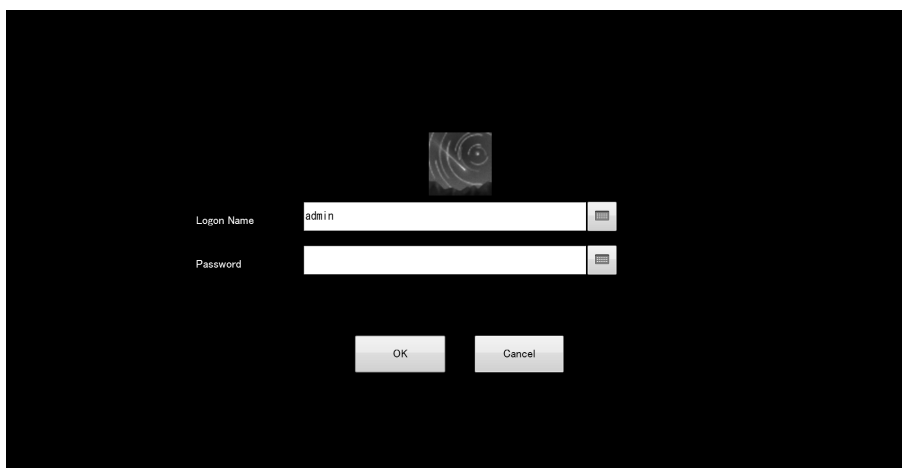
(►P.37 "Chapter 3: 3.4.2 Instrument part description")

4.1.3 Logging on

When the Select Logon User screen appears on the IPU, follow the steps below to log on.

1 Select the user name.

The following dialog box appears.



2 Enter the password.

3 Touch [OK].

The dialog box closes. The instrument enters the startup state and startup processing starts. [Start Up] appears in the instrument status display of the IPU screen.

**Note:**

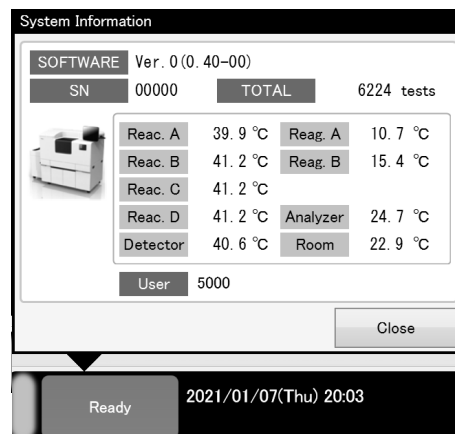
Ask the administrator of the instrument for the user name and password.

4.1.4 Checking the status of the instrument

Follow the steps below to check the status of the instrument.

1 Touch the instrument status display on the IPU screen.

The dialog box on the right appears.



2 Check the status of the instrument.

If the temperature does not stabilize, the relevant part will be indicated by a red background. For details, see Chapter 12.

(►P.292 "Chapter 12: 12.3.1 Problems at startup")

The following items are displayed in the dialog box:

[SOFTWARE]	The current software version of the IPU is displayed.
[SN]	The serial number of the instrument is displayed.
[TOTAL]	The instrument's total test count is displayed.
[Reac.A]	The temperature of reaction unit A is displayed.
[Reac.B]	The temperature of reaction unit B is displayed.
[Reac.C]	The temperature of reaction unit C is displayed.
[Reac.D]	The temperature of reaction unit D is displayed.
[Detector]	The temperature of the detector is displayed.
[Reag.A]	The temperature of the reagent set A is displayed.
[Reag.B]	The temperature of the reagent set B is displayed.
[Analyzer]	The temperature inside the instrument is displayed.
[Room]	The temperature outside the instrument is displayed.
[User]	The logon name is displayed.

3 Touch [Close].

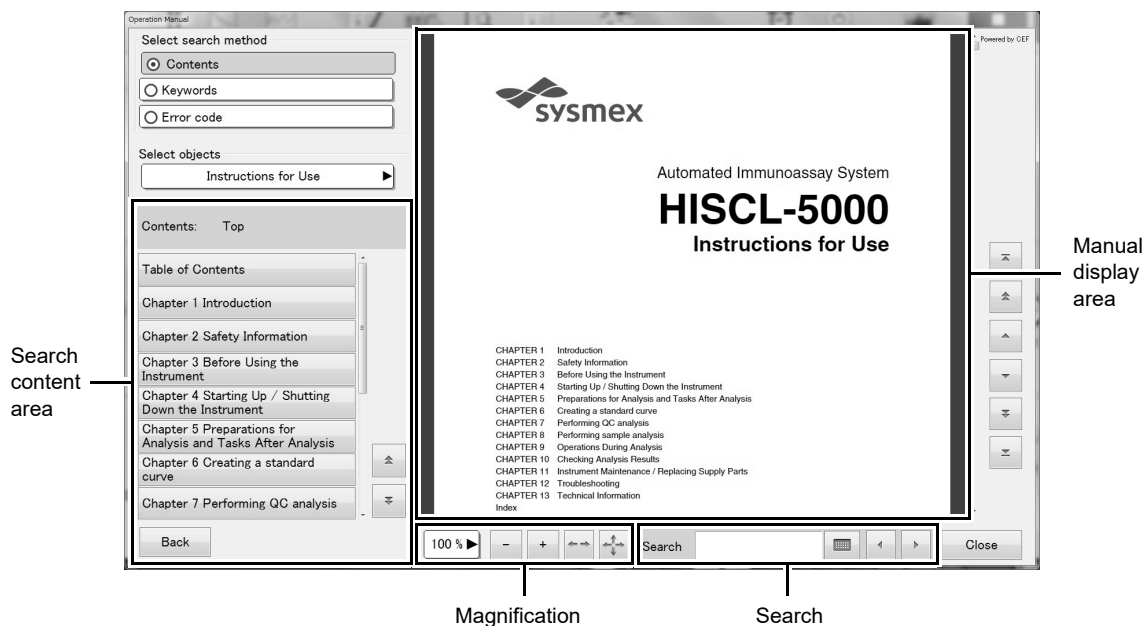
The dialog box closes.

4.2 Viewing the on-screen manuals

To enable quick access to necessary information, the instrument manuals are available for viewing on the IPU. Follow the steps below to view a manual.

1 Touch [Menu] - [Operation Manual] on the toolbar.

The following screen appears.



2 View the manual.

The following items are displayed in the dialog box:

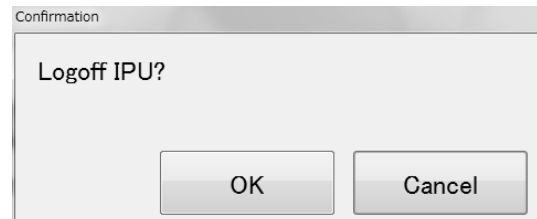
[Select search method]	
[Contents]	Select to display the table of contents of the manual in the search content area.
[Keywords]	Select to show the keyword list in the search content area. Touch a keyword to show the corresponding section in the manual display area.
[Error code]	Select to display the error code entry box in the search content area. Enter an error code, and then touch one of the topics that are found to display the corresponding section in the manual display area.
[Select objects]	Select a manual. Select from [Instructions for Use], [Administrator's Guide], or [License Information]. The selected manual appears in the manual display area.
Search content area	The search content of the method selected in [Select search method] appears.
[Enter Keywords]	This only appears when [Keywords] is selected in [Select search method]. Touch to show the keyword entry field. Enter a keyword in the entry field to search for that keyword.
[Back]	The contents that appear vary depending on the selected search method. When [Contents] is selected, touch to show the contents of the next higher level. When [Keywords] is selected and the keyword entry field does not appear, touch to show the keywords of the next higher level. When [Keywords] is selected and the keyword entry field appears, touch to hide the keyword entry field and to show the previous search state. When [Error code] is selected, touch to cancel the search state and show all error codes.
Magnification	Select the display magnification.
[+]	Touch to increase the magnification in the order [25%], [50%], [75%], [100%], [125%], [150%].
[-]	Touch to decrease the magnification in the order [150%], [125%], [100%], [75%], [50%], [25%].
	Touch to fit the width of the manual to the screen.
	Touch to fit the full view of the manual to the screen.
Search	Enter the text you want to find and search the selected manual.
Manual display area	Displays the manual.
[Close]	Touch to close the screen.

4.3 Logging off

Follow the steps below to log off.

1 Touch [Menu] - [Logoff] on the toolbar.

The dialog box on the right appears.



2 Touch [OK].

The current user is logged off from the IPU.

After logoff, the logon dialog box appears.

(► **P.78** "4.1.3 Logging on")

4.4 Shutting down the instrument

This section explains how to shut down the HISCL-5000.

4.4.1 Checking the instrument before shutdown

Before shutting down the instrument, check the following:

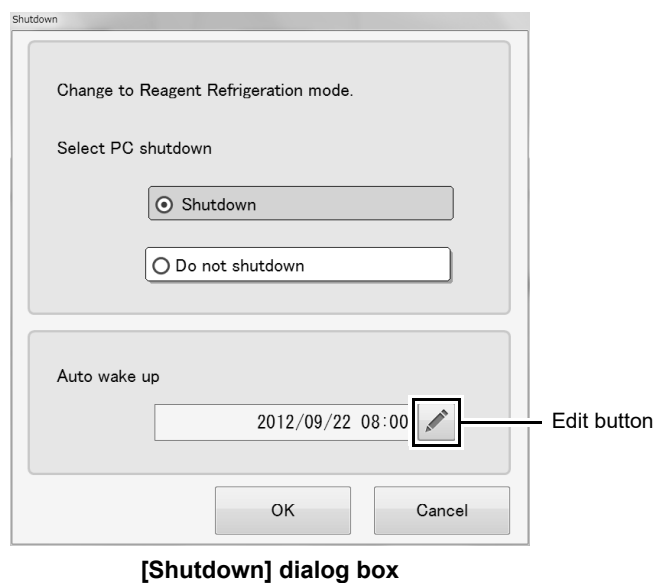
- Are there any remaining analysis orders?
If orders remain, make sure that analysis is completed and then delete unrequired orders.
For details, see Chapter 8.
(►P.185 "Chapter 8: 8.1.4 Deleting an order")
- Do any errors or notices remain?
If an error or notice remains, check the error or notice and take appropriate action.
For details, see Chapter 12.
(►P.297 "Chapter 12: 12.4 Handling an error")

4.4.2 Shutting down the instrument

To maintain the state of the instrument, always execute shutdown before turning off the power.
Follow the steps below to shut down the overall instrument.

1 Touch [Shutdown] on the toolbar.

The [Shutdown] dialog box appears.



2 Touch [Shutdown] in [Select PC shutdown].



Note:

- If you wish to check analysis results on the IPU, shut down only the analyzer.
To shut down only the analyzer, select [Do not shutdown] in [Select PC shutdown] in the [Shutdown] dialog box, and touch [OK]. Automatic backup of data and automatic washing of the analyzer start. The analyzer enters reagent refrigeration mode and the IPU does not shut down.
- To shut down the IPU when you have finished work after shutting down the analyzer, select [Shutdown] in [Select PC shutdown] in the [Shutdown] dialog box, and touch [OK]. IPU shutdown starts.

3 Touch [OK].

Shutdown starts.

Automatic backup of data and automatic washing of the analyzer start.

Only the cooling function (reagent refrigeration mode) of the reagent holder operates on the analyzer, and the computer shuts down. For information on reagent refrigeration mode, see Chapter 3.

(►P.47 "Chapter 3: 3.4.5 Operation modes")



Information

- Automatic washing starts when shutdown is executed. Do not turn off the instrument power until automatic washing finishes.
- In some cases, shutdown may take about 15 minutes.
- If you will not use the instrument for 2 weeks or longer, contact your local Sysmex representative.
- Before turning off the instrument power, take out all reagents from reagent holders A and B, and keep in a refrigerator.

4.5 Starting up and shutting down at specified times

You can have the instrument automatically wake up and shut down at times specified on the [Maintenance] screen. For details, see Chapter 11.

(► **P.259** "Chapter 11: 11.2.2 Configuring auto wake-up and shutdown settings")



Note:

To configure auto wake-up and shutdown settings for multiple days, see Chapter 11.

(► **P.261** "Chapter 11: 11.2.3 Creating a maintenance plan")

4.5.1 Starting up at a specified time

Before shutting down the instrument, check the next auto wake-up time.

Follow the steps below to set the next auto wake-up time.

1 Touch [Shutdown] on the toolbar.

The [Shutdown] dialog box appears.

For details on the [Shutdown] dialog box, see the following.

(► **P.83** "4.4.2 Shutting down the instrument")

2 Make sure that [Select PC shutdown] is set to [Shutdown], and check the auto wake-up time setting.

3 To change the auto wake-up time, touch the edit button.

The dialog box on the right appears.

Next wake up setting

Date
2012/09/22

Hour
3

Minute
44

OK Cancel

4 Set the date and time.

5 Touch [OK].

The dialog box closes, and the auto wake-up time changes.

6 Touch [OK].

Shutdown starts.

Automatic backup of data and automatic washing of the analyzer start.

The analyzer enters reagent refrigeration mode and the computer shuts down.

When the specified time arrives, auto wake-up will take place.



Note:

When using auto wake-up, do not turn off the power of the instrument.

4.5.2 Shutting down at a specified time

When auto shutdown is set, the [Shutdown] dialog box appears when the specified time arrives and shutdown takes place automatically. Shutdown also takes place if you touch [OK] in the [Shutdown] dialog box.

To set the auto shutdown time, see Chapter 11.

(►P.260 "Chapter 11: 11.2.2.2 Setting auto shutdown")

If analysis is in progress at the specified time, shutdown cannot be executed. After analysis has been completed, execute shutdown manually.

(►P.83 "4.4 Shutting down the instrument")



Note:

To stop shutdown, touch [Cancel] in the [Shutdown] dialog box. To shut down manually afterward, see the following.

(►P.83 "4.4 Shutting down the instrument")

Chapter 5 Preparations for analysis and tasks after analysis

This chapter explains the preparations that are required for analysis, replenishment of supplies, and tasks that must be performed after analysis is finished.

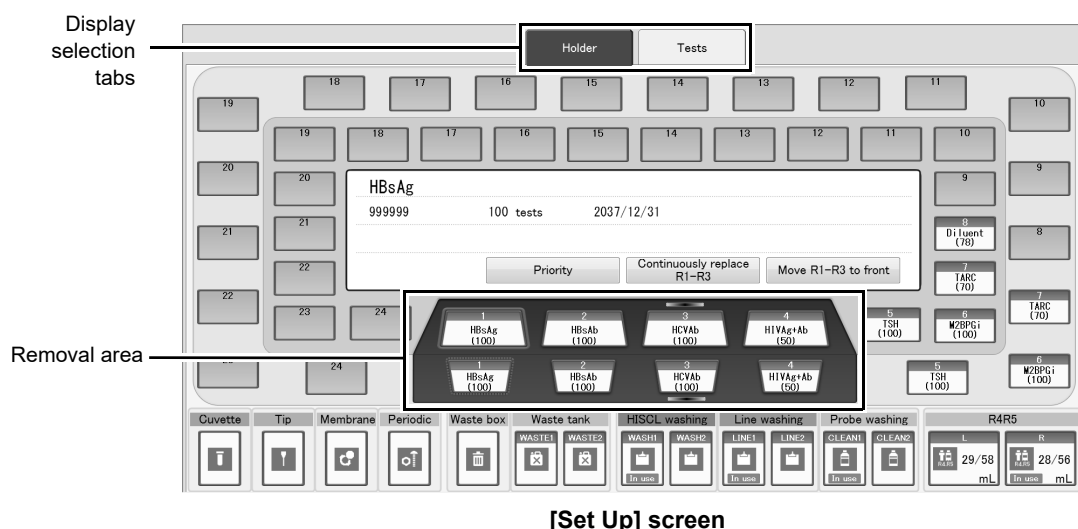
5.1 Checking the analysis preparation status

Before starting analysis, check the status of analysis preparations. Check supplies and reagent levels. Replenish sufficient quantity of supplies and reagents for the day's analysis work.

The [Set Up] screen can be used to check the level of supplies and reagents, and perform replenishment.

Check the status of the instrument on this screen before analysis, and make preparations so that the instrument is ready for analysis.

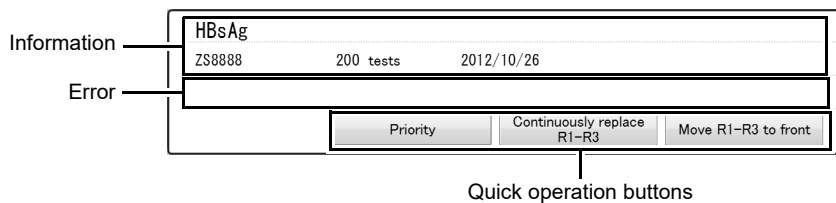
Touch [Set Up] on the toolbar to display the following screen.



[Set Up] screen

Tabs	The tabs are used to change the contents of the [Set Up] screen that are displayed.
[Holder]	Touch to change the reagent status display to icon format.
Removal area	Displays the status of R1 - R3 reagent that can be removed from the cover of reagent holder A by an icon.
[Tests]	Touch to change the reagent status display to list format.
[Cuvette]	Displays the remaining volume of cuvettes by an icon.
[Tip]	Displays the remaining volume of tips by an icon.
[Membrane]	Displays the status of membrane filter replacement/sample nozzle cleaning by an icon.
[Periodic]	Displays the status of maintenance parts by an icon.
[Waste box]	Displays the status of the waste box by an icon.
[Waste tank]	Displays the status of the waste tank (optional) by an icon.

When an icon on the [Holder] tab is touched, detailed information appears in the center of the [Set Up] screen.



Information	Displays detailed information on the status of the selected icon.
Error	Displays errors that might have occurred in relation to the selected icon.
Quick operation buttons	Displays actions that can be taken in relation to the selected icon. The contents that appear depend on the selected icon.
[Move R1-R3 to front]	Touch to move the selected R1 - R3 reagent from the cover of reagent holder A to the removal area.
[Continuously replace R1-R3]	Touch to display a dialog box that allows replacement of multiple R1-R3 reagents.
[Priority]	Touch to set the selected reagent, detergent, or waste tank (optional) for priority use.
[Cancel priority]	Touch to cancel the priority use setting of the selected reagent, detergent, or waste tank (optional).
[Reset waste box]	Touch to reset the waste count (theoretical value) of the waste box.
[Input data]	Touch to enter information on the selected icon.

5.1.1 Checking remaining supply amounts

This section explains the status of the supplies that appear on the [Set Up] screen.
Remaining amounts of tips and cuvettes are indicated as described below:

Display	Description
White	A sufficient quantity is loaded. Analysis can be performed.
Orange	Running low. Refill as soon as possible. Analysis can be performed. To replenish tips and cuvettes, see the following. (► P.103 "5.2.1 Replenishing cuvettes", P.105 "5.2.2 Replenishing tips")
Red	None left. Replenish immediately. To replenish tips and cuvettes, see the following. (► P.103 "5.2.1 Replenishing cuvettes", P.105 "5.2.2 Replenishing tips") If a sufficient amount of tips or cuvettes are loaded in the feeder, use the provided hopper jam removal pole to stir the tips or cuvettes in the feeder and clear the jam. (► P.306 "Chapter 12: 12.4.6 Removing a tip or cuvette feeder jam")

5.1.2 Checking maintenance items

This section explains the status of the maintenance items that appear on the [Set Up] screen.

5.1.2.1 Status of membrane filter replacement/sample nozzle cleaning

The status of membrane filter replacement/sample nozzle cleaning is indicated as described below:

Display	Description
White	There are no problems with membrane filter replacement/sample nozzle cleaning. Analysis can be performed.
Orange	The replacement count for membrane filter replacement/sample nozzle cleaning is finished. Execute membrane filter replacement/sample nozzle cleaning immediately. To replace the membrane filter and clean the sample nozzle, see Chapter 11. (► P.266 "Chapter 11: 11.3.4 Replacing the membrane filter", P.270 "Chapter 11: 11.3.5 Cleaning the sample nozzle")

5.1.2.2 Status of maintenance parts

The status of the maintenance parts are indicated as described below:

Display	Description
White	There are no problems with maintenance parts. Analysis can be performed.
Orange	There are maintenance parts such as the probe that have exceeded the count for replacement. Check the operation counts of the maintenance parts and replace those that require replacement. To check the operation count, see Chapter 11. (► P.282 "Chapter 11: 11.4.6 Checking the operation count of each system unit")

5.1.2.3 Status of the waste box

Used tips and cuvettes are discarded into the waste box.

The status of the waste box is indicated as described below:

Display	Description
White	The waste box has sufficient free space. Analysis can be performed.
Orange	The waste box is almost full. Replace the waste box as soon as possible. For the procedure for replacing the waste bag, see the following: (► P.127 "5.6.1 Disposing of waste in the waste box")
Red	The waste box is full or is not in place. Check the waste bag. For the procedure for replacing the waste bag, see the following: (► P.127 "5.6.1 Disposing of waste in the waste box")



Note:

The level at which waste box almost full is detected can be set to any desired value.
To configure the setting, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 2: 2.8 Configuring reagent remaining volume control settings and standard curve expiration control settings")

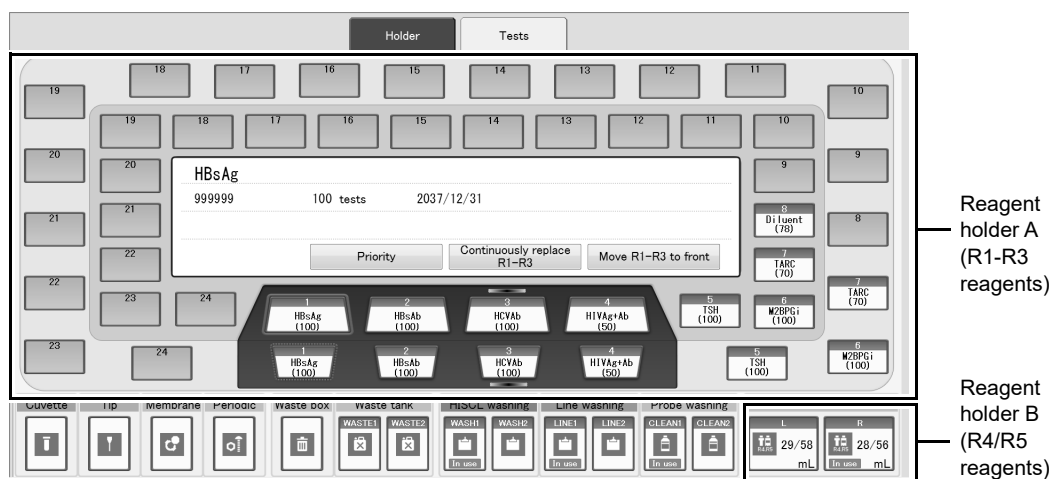
5.1.2.4 Statuses of the waste tank (optional)

2 waste tanks (optional) can be placed simultaneously. The statuses of the waste boxes (optional) are indicated as described below:

Display	Description
White	The waste tank (optional) has sufficient free space or is not in use. Analysis can be performed.
Red	The waste tank (optional) is full or is not in place. If a waste tank (optional) is full, dispose of the waste fluid and then put the tank properly back in position. For the procedure for replacing the waste tank (optional), see the following. (► P.130 "5.6.2 Disposing of waste fluid")
In use	Appears on the tank that is in use.

5.1.3 Checking reagent levels

Display the status of the reagents by an icon on the [Holder] tab.



Reagent holder A (R1-R3 reagents)

Displays the status of the R1-R3 reagents and sample diluent by an icon. Also, it shows the level of each reagent. The reagent marked by ( :Green) is preferentially used for analysis.

[HISCL washing]

Displays the status of the HISCL washing by an icon.

[Line washing]/[LU-10]

Displays the status of the line washing by an icon. When the LU-10 is connected, an icon shows the status of the LU-10.

[Probe washing]

Displays the status of the probe washing by an icon.

Reagent holder B (R4/R5 reagents)

Displays the status of the R4/R5 reagents by an icon. Also, it shows the level of each reagent.



Information

When there is a high initial washing count at the time of turning on the instrument, consumption of R4/R5 reagent for washing increases and it may not be possible to perform the specified number of tests.

5.1.3.1 Status of R1-R3 reagents

The status of the R1-R3 reagents are indicated as described below:

Display	Description
White	The reagent is properly placed and a sufficient quantity remains.
Orange	The reagent is running low. To replace an R1-R3 reagent, see the following. (►P.108 "5.3.1 Replenishing an R1-R3 reagent")
Red	The reagent cannot be used due to one of the following errors: • None remains. • Reagent has expired. • Reagent not recognized. • The other reagent of the pair is not in place. To replace an R1-R3 reagent, see the following. (►P.108 "5.3.1 Replenishing an R1-R3 reagent")
Gray	Reagent is not in place.
Mark ( :Yellow)	Reagent warnings that may appear are as follows: • No validated standard curve for the reagent lot. • The R4/R5 reagent lot number of the standard curve does not match the R4/R5 reagent lot number currently in use. • Reagent approaching expiry. For the procedure for replenishing R1-R3 reagent, see the following: (►P.108 "5.3.1 Replenishing an R1-R3 reagent")



Note:

You can set the level at which low reagent is detected, and the time at which reagent approaching expiry is detected.

To configure the setting, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 2: 2.8 Configuring reagent remaining volume control settings and standard curve expiration control settings")

5.1.3.2 Status of R4/R5 reagents

2 sets of R4/R5 reagents can be placed simultaneously. The status of the R4/R5 reagents are indicated as described below:

Display	Description
White	The reagent is properly placed and a sufficient quantity remains.
Orange	Running low. - The total volume of R4 reagent or R5 reagent (the total remaining volume of the reagents that are set in the holder positions [L] and [R]) is below the setting. - None remains (before switching of reagent is finished). When the reagent runs out, the other R4/R5 reagent will be used automatically. To replenish R4/R5 reagent, see the following. (► P.113 "5.3.3 Replenishing R4/R5 reagent")
Red	The reagent cannot be used due to one of the following errors: - None remains (after switching of reagent is finished). - Reagent has expired. - Reagent not recognized. - The lot of R4 is different from the lot of R5. - The other reagent of the pair is not in place. To replenish R4/R5 reagent, see the following. (► P.113 "5.3.3 Replenishing R4/R5 reagent")
Gray	Reagent is not in place.
In use	Appears on the reagent that is in use.



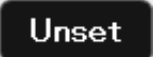
Note:

The level at which low reagent is detected can be set to any desired value.
To configure the setting, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 2: 2.8 Configuring reagent remaining volume control settings and standard curve expiration control settings")

5.1.3.3 Status of probe washing

2 containers of probe washing can be placed simultaneously.

The status of the probe washing is indicated as described below:

Display	Description
White	The probe washing is properly placed and a sufficient quantity remains.
Orange	The probe washing that is in use is running low. When this runs out, the other probe washing will be used automatically. For the procedure for replenishing probe washing, see the following. (► P.118 "5.3.5 Replenishing probe washing")
Red	The probe washing cannot be used because it has run out. Immediately replace the probe washing for which the error occurred. For the procedure for replenishing probe washing, see the following. (► P.118 "5.3.5 Replenishing probe washing")
	Appears on the probe washing that is in use.
	The probe washing is not in place. Immediately place the probe washing for which the error occurred.
	The probe washing cannot be used because it has expired. Immediately replace the probe washing for which the error occurred. For the procedure for replenishing probe washing, see the following. (► P.118 "5.3.5 Replenishing probe washing")

5.1.3.4 Status of line washing/HISCL washing

2 containers of line washing/HISCL washing both can be placed simultaneously.

The status of the line washing/HISCL washing is indicated as described below:

Display	Description
White	Line washing/HISCL washing are placed properly and sufficient quantities remain.
Orange	The line washing/HISCL washing currently in use is running low. When this runs out, the other line washing/HISCL washing will be automatically used. To replenish line washing/HISCL washing, see the following. (►P.115 "5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")
Red	One of the following errors has occurred in relation to the line washing/HISCL washing: • None remains. • Not placed properly. Immediately replace the line washing/HISCL washing for which the error occurred. To replenish line washing/HISCL washing, see the following. (►P.115 "5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")
	Appears on the line washing/HISCL washing that is in use.
	Line washing or HISCL washing has expired. Immediately replace the line washing/HISCL washing for which the error occurred. To replenish line washing/HISCL washing, see the following. (►P.115 "5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")



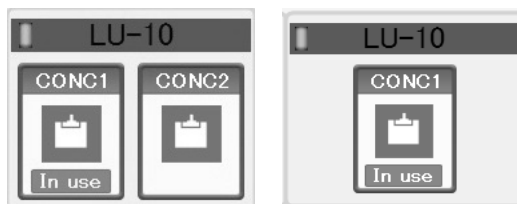
Note:

If  appears, follow steps 2 to 11 below.

(►P.115 "5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")

5.1.3.5 LU-10/concentrated line washing status

When the LU-10 is connected, the status of the LU-10 and concentrated line washing is shown instead of the status of the line washing.



[Set Up] screen (LU-10 connection)

The LU-10 connection status is indicated as described below:

Display	Description
Green	LU-10 status is normal.
Red	LU-10 unable to supply reagent. Check the LU-10.
Gray	Connection to LU-10 not established. Check the LAN cable and the LU-10.



Note:

If you are using LU-10, operation can also be performed when only 1 concentrated line washing has been connected. If you want to change the operation method, contact your local Sysmex representative.

The status of the concentrated line washing is indicated as described below:

Display	Description
White	A sufficient quantity is loaded.
Orange	Running low. Replenish soon.
Red	Out of solution, cannot be used. Replenish immediately.
In use	Indicates that the solution is to be aspirated.
Expired	Expired. Replenish immediately.
Tank	No line washing in supply tank. If the LU-10 instrument status is green, wait briefly. If the LU-10 instrument status is red or gray, check the LU-10.



Note:

- If  appears, replace the concentrated line washing by the appropriate procedure.
- HISCL-5000 Instructions for Use (► **P.115** "5.3.4 Replenishing line washing/concentrated line washing/HISCL washing", steps 2 to 11)
 - LU-10 Instructions for Use (► LU-10 Instructions for Use, "Chapter 6: 6.3 Replacing the reagent", steps 2 to 7)

5.1.3.6 R1-R3 reagent test count list

When the [Tests] tab is displayed, the test counts of R1-R3 reagent are listed on the left side of the [Set Up] screen.

Display filter

Parameter test count list

Test count list for each bottle

Display filter	Filters the contents of the R1-R3 reagent test count list.
[All]	Select to show the test counts of all reagents in the instrument.
[Residual insufficient]/ [Residual little]/ [No curve lot]/ [Unusable bottle]	Displays only the test counts of reagents that are selected.
Parameter test count list	
[Reagent]	Displays the reagent test name.
[Plan]	Displays the number of tests scheduled for each parameter on the present day. To set the scheduled number of tests for the present day, see the "Administrator's Guide". (►Administrator's Guide, "Chapter 2: 2.9 Setting the number of scheduled tests for each reagent")
[Done]	Displays the number of tests run on the present day till now.
[Diff]	Displays the number that results from subtracting the number of tests scheduled for the present day from the remaining volume of placed reagent.
[Remain]	Displays the total remaining volume of the placed R1-R3 reagent and sample diluent.
[Status]	Displays the status of the reagent. If correctly placed, nothing will appear.
[No curve]	No standard curve for the R1-R3 reagent lot number.
[R4R5 curve]	No standard curve for the R4/R5 reagent lot number.
[R1]/[R2]/[R3]/ [Diluent]	Error detected in the reagent.
[Expired]	The reagent has expired.
[Empty]	The reagent has run out.
[No reagent]	Reagent is not in place.
[No pair]	The other reagent of the pair is not in place.

Test count list for each bottle

[Lot]	Displays the lot number of the reagent.
[Priority]	The marked reagent is preferentially used for analysis.
[Remain]	Displays the reagent remaining volume in each bottle.
[Expiry date]	Displays the expiration date of the reagent.
[R1]	Displays the reagent bottle holder number on the inner side of reagent holder A.
[R2]	Displays the reagent bottle holder number on the outer side of reagent holder A.

**Note:**

- When a warning is issued for a reagent, such as less reagent remaining than the specified number, the item is highlighted in orange.
- If a test has multiple R1-R3 reagents set, the reagents are listed and used in the following order:
 1. Specified for priority use.
 2. Same lot number as reagent specified for priority use.
 3. Has a validated standard curve.
 4. Reagent expiration date is nearer.
 5. Less reagent remaining.
 6. In order of placement position.
- The expiration date, use by date, or shelf life after opening is displayed, whichever will arrive first.

5.1.3.7 Common reagent test count list

When the [Tests] tab is displayed, the common reagent test count list (R4/R5 reagent, line washing, concentrated line washing, probe washing, HISCL washing) appears on the right side of the [Set Up] screen.

The screenshot shows the 'Tests' tab in the HISCL-5000 interface. The main table on the left lists various reagents with their respective counts and status. A smaller table on the right, titled 'Common reagent test count list', provides detailed information for specific reagents (R4/R5, Probe, Line, HISCL), including their status, lot number, priority, and expiration date. A label points to this right-hand table.

Common reagent test count list

[Reagent]	Displays the reagent type.
[Status]	Displays the status of the reagent. If correctly placed, nothing will appear.
[Low]	The reagent is running low.
[Empty]	The reagent has run out.
[No pair]	The other reagent of the pair is not in place.
[Expired]	The reagent has expired.
[Unset]	The reagent is not in place.
[Lot]	Displays the lot number of the reagent.
[Priority]	The marked reagent is preferentially used for analysis.
[Expiry date]	Displays the expiration date of the reagent.



Note:

The expiration date, use by date, or shelf life after opening is displayed, whichever will arrive first.

5.1.4 Checking the standard curve

[Standard curve list] can be touched on the [Set Up] screen to display the expiration date of the standard curve. When the expiration date draws near, create the standard curve again.

For details, see Chapter 6.

(►P.133"Chapter 6: Creating a standard curve")

5.1.5 Using the bulletin board

This section explains how to use the bulletin board on the [Portal] screen.

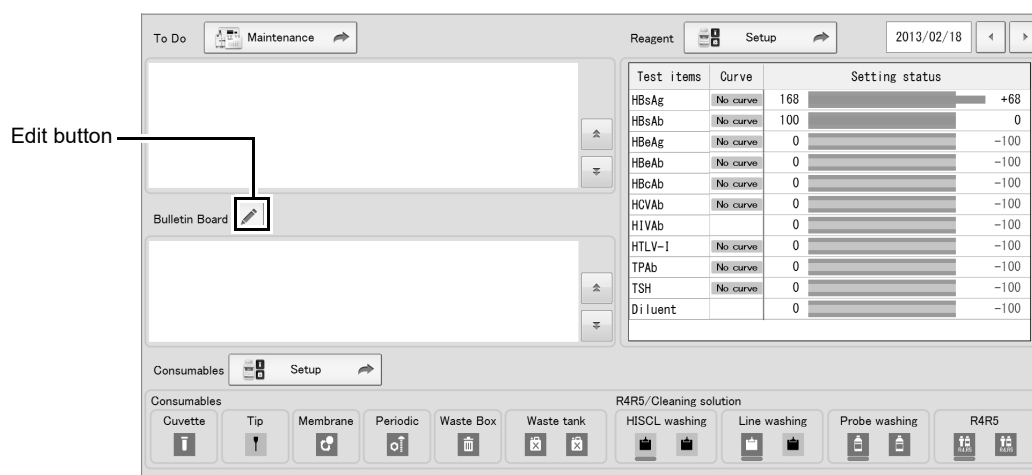
The bulletin board shows messages and other information for the laboratory personnel. The information shown on the bulletin board can be changed, added, or deleted.

The bulletin board can only be edited by users with maintenance permission.

Follow the steps below to view and enter comments on the bulletin board.

1 Touch [Portal] on the toolbar.

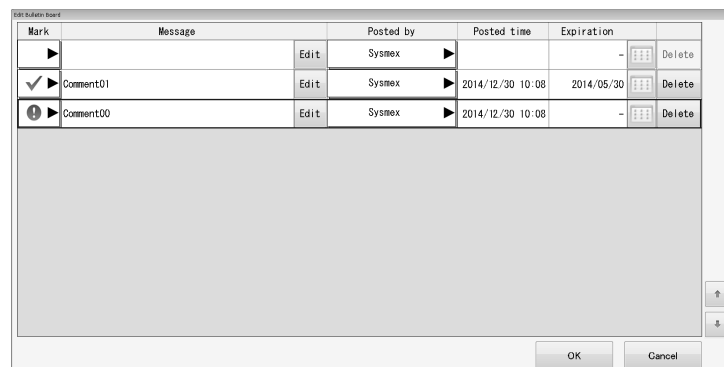
The following screen appears.



[To Do]	Displays the contents of the [Maintenance] screen of the selected day.
[Maintenance]	Touch to display the [Maintenance] screen.
[Bulletin Board]	Displays the bulletin board created.
[Consumables]	Displays the statuses of the supplies.
[Setup]	Touch to display the [Set Up] screen.
[Reagent]	Displays the statuses of the reagents.
[Setup]	Touch to display the [Set Up] screen.

2 Touch the [Bulletin Board] edit button.

The following dialog box appears.



3 Leave a message on the bulletin board.

The following items are displayed in the dialog box:

[Mark]	The mark that indicates bulletin board content can be selected.
[Message]	Touch the [Edit] button to edit the message.
[Posted by]	The person who is posting the message can be selected.
[Posted time]	Displays the date and time the message was posted.
[Exp.]	The expiration date of the message can be selected.
[Delete]	Touch to delete a message from the bulletin board.

4 Touch [OK].

The dialog box closes.

5.2 Replenishing supplies

When a supply starts to run low, the status of the supply is highlighted by an orange background.

Replenish the supply.

For supply status displays, see the following.

(► **P.89** "5.1.1 Checking remaining supply amounts")

5.2.1 Replenishing cuvettes

When the cuvettes run low, replenish with new cuvettes.



Information

- Use only Sysmex-specified cuvettes.
- Be careful not to spill the cuvettes during replenishment.
- When replenishing cuvettes, do not handle with your bare hands.
- Do not replenish with previously used cuvettes.
- After replenishing the cuvettes, be sure to close the cover.
- As a guideline, when the amount used is an average of 10 tests or less per day, replenish the amount used per week each week.

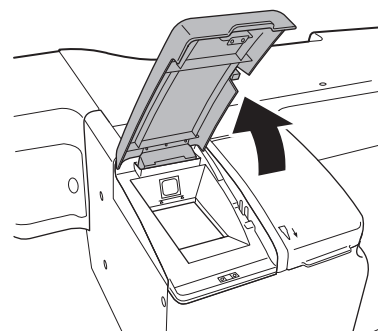
Follow the steps below to replenish the cuvettes.

1 Prepare new cuvettes.

2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

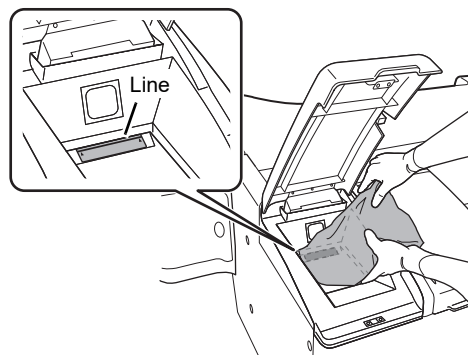
3 Open the cover of the cuvette feeder at the upper left of the front of the instrument.



Information

- Take care not to confuse the cuvette feeder with the tip feeder.
- The feeder cover stops at a position of about 60 degrees. Take care not to open the cover excessively.

4 Replenish the cuvettes in the feeder.



Caution!

When replenishing, fill to a level that is below the line.

5 Close the cuvette feeder cover.



Caution!

Exercise caution not to get your fingers caught when closing the cuvette feeder cover. There is a risk of injury.

6 Make sure that the cuvette status icon is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.



Information

If the number of prepared new cuvettes exceeds the number that can be replenished in the feeder, store the excess cuvettes in a manner that does not allow contact with dust or dirt.



Note:

For information on the supply replenishment log, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 8: 8.4 Viewing the consumables log")

5.2.2 Replenishing tips

When the tips run low, replenish with new tips.



Information

- Use only Sysmex-specified tips.
- Be careful not to spill the tips during replenishment.
- When replenishing tips, do not handle with your bare hands.
- Do not replenish with previously used tips.
- After replenishing the tips, be sure to close the cover.

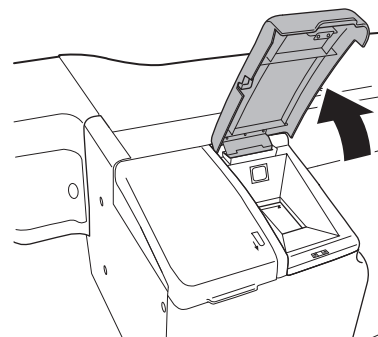
Follow the steps below to replenish the tips.

1 Prepare new tips.

2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

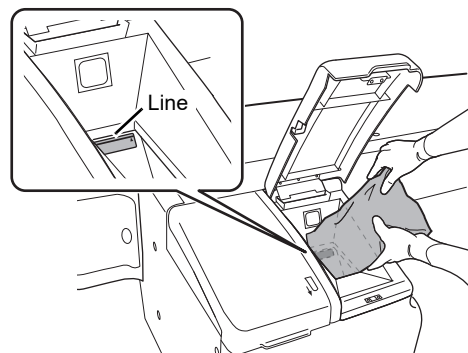
3 Open the cover of the tip feeder at the upper left of the front of the instrument.



Information

- Take care not to confuse the tip feeder with the cuvette feeder.
- The feeder cover stops at a position of about 60 degrees. Take care not to open the cover excessively.

4 Replenish the tips in the feeder.



Caution!

When replenishing, fill to a level that is below the line.

5 Close the tip feeder cover.



Caution!

Exercise caution not to get your fingers caught when closing the tip feeder cover. There is a risk of injury.

6 Make sure that the tip status icon is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.



Information

If the number of prepared new tips exceeds the number that can be replenished in the feeder, store the excess tips in a manner that does not allow contact with dust or dirt.



Note:

For information on the supply replenishment log, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 8: 8.4 Viewing the consumables log")

5.3 Replenishing reagents

When a reagent or detergent starts to run low, the status of the reagent or detergent is shown in orange on the [Set Up] screen.

Replenish the R1-R3 reagent, R4/R5 reagent, or detergent.

For reagent status displays, see the following.

(► **P.92** "5.1.3 Checking reagent levels")

If a reagent IC tag scan error occurs, see Chapter 12.

(► **P.300** "Chapter 12: 12.4.3 Recovering from a reagent IC tag scan error")



Warning!

- Dispose of waste fluids, supplies, and the instrument as biological waste, infectious waste, and/or industrial waste, in accordance with local laws and regulations.
- Keep your fingers, clothing, and hair away from the instrument while it is in operation.
Danger of injury if fingers, clothing, or hair become caught in the instrument.
- Do not insert your hand into any openings.
There is a risk of injury.
- Do not insert your hand into the area under the cover of the continuous unit.
There is a risk of injury.

5.3.1 Replenishing an R1-R3 reagent

This section explains how to replenish R1-R3 reagents.

To replenish R1-R3 reagent during analysis, see Chapter 9.

(►P.208 "Chapter 9: 9.2.2 Replenishing an R1-R3 reagent")



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to replenish an R1-R3 reagent.

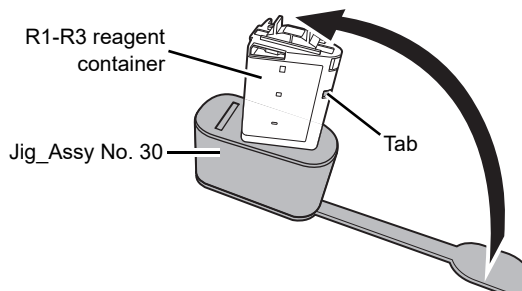
1 Follow the instructions on the package insert to prepare the new R1-R3 reagent.



Warning!

- To open the R1-R3 reagent for the first time, use Jig_Assy No. 30 that is supplied with the instrument. Opening the reagent without the jig may result in injury.
- Place the Jig_Assy No. 30 in a horizontal position when opening the reagent.

- (1) Place the R1-R3 reagent container in Jig_Assy No. 30 and cover the top of the container with the black rubber of the jig.



- (2) Press down on the rubber to depress the tab on the front of the container, and push the outer case completely down.



2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

3 Touch the status icon of the used reagent.

4 Touch [Move R1-R3 to front] on the operation panel.

5 Open the operation cover on the analyzer.



Caution!

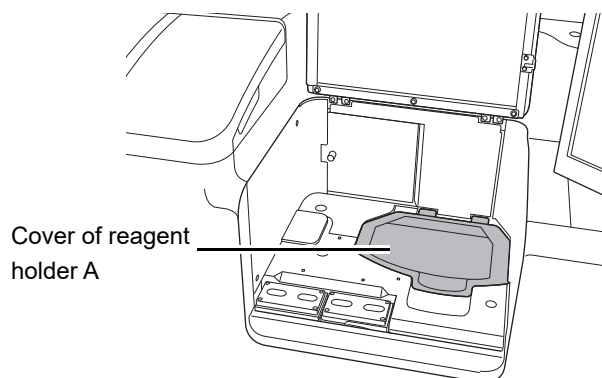
Be careful not to hit your head on the operation cover when it is open.



Information

When opening and closing the operation cover, exercise caution to make sure your fingers are not pinched by the cover.

6 Open the cover of reagent holder A.



7 Remove the used R1-R3 reagent.

8 Place the new R1-R3 reagent in reagent holder A.



Information

- When placing a reagent, do not press down forcefully. This may cause failure.
- Make sure that the reagent is placed securely in its position.
- Do not move the cover of reagent holder A or B while analysis is in progress. Analysis may be interrupted if the instrument detects that the covers are not closed properly.
- When placing a reagent on the reagent table, place gently to avoid foaming and splashing.
- If the magnetic particles in the R2 reagent have settled to the bottom of the container, remove the R2 container and mix by hand, taking care not to create any air bubbles. Visually confirm that the magnetic particles have dispersed. Do not shake vigorously or tip the container over.

9 Close the cover of reagent holder A.

10 Close the operation cover.

11 Make sure that the status of the replaced R1-R3 reagent is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.

12 Dispose of the used reagent container appropriately.

5.3.2 Replacing R1-R3 reagents continuously

This section explains how to replace R1-R3 reagents continuously.

To replenish R1-R3 reagent during analysis, see Chapter 9.

(►P.208 "Chapter 9: 9.2.2 Replenishing an R1-R3 reagent")



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials. There is a risk of infection by pathogens and other contaminants.

Follow the steps below to replace R1-R3 reagents continuously.

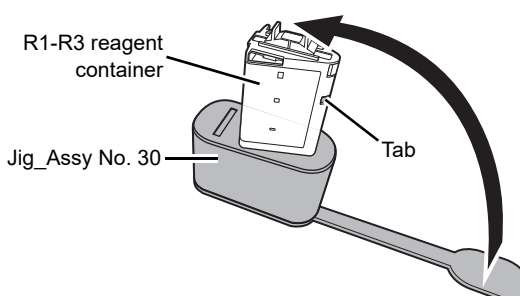
1 Follow the instructions on the package insert to prepare the new R1-R3 reagent.



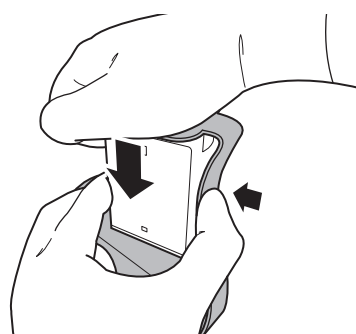
Warning!

- To open the R1-R3 reagent for the first time, use Jig_Assy No. 30 that is supplied with the instrument. Opening the reagent without the jig may result in injury.
- Place the Jig_Assy No. 30 in a horizontal position when opening the reagent.

- (1) Place the R1-R3 reagent container in Jig_Assy No. 30 and cover the top of the container with the black rubber of the jig.



- (2) Press down on the rubber to depress the tab on the front of the container, and push the outer case completely down.



2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

3 Touch [Continuously replace R1-R3] on the operation panel.

The dialog box appears.

4 Open the operation cover on the analyzer.**Caution!**

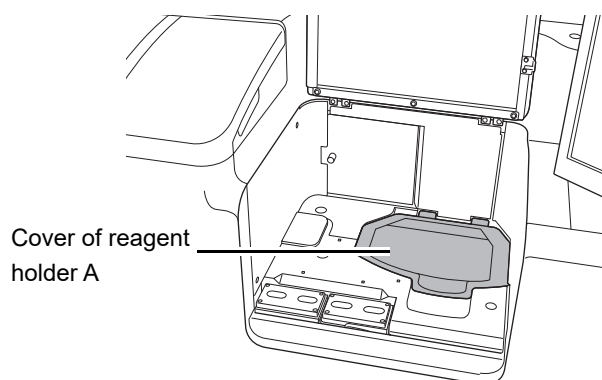
Be careful not to hit your head on the operation cover when it is open.

**Information**

When opening and closing the operation cover, exercise caution to make sure your fingers are not pinched by the cover.

5 Touch [Next] while checking the [Set Up] screen.

Move the reagents that you want to replace to the removal area.

6 Open the cover of reagent holder A.

7 Remove the used R1-R3 reagent.

8 Place the new R1-R3 reagent in reagent holder A.



Information

- When placing a reagent, do not press down forcefully. This may cause failure.
- Make sure that the reagent is placed securely in its position.
- Do not move the cover of reagent holder A or B while analysis is in progress. Analysis may be interrupted if the instrument detects that the covers are not closed properly.
- When placing a reagent on the reagent table, place gently to avoid foaming and splashing.
- If the magnetic particles in the R2 reagent have settled to the bottom of the container, remove the R2 container and mix by hand, taking care not to create any air bubbles. Visually confirm that the magnetic particles have dispersed. Do not shake vigorously or tip the container over.

9 Close the cover of reagent holder A.

The reagents in the removal area are moved automatically. If you want to replace reagents continuously, repeat steps 5 to 9.

10 Close the operation cover.

11 Touch [Finished].

12 Make sure that the status of the replaced R1-R3 reagent is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.

13 Dispose of the used reagent container appropriately.

5.3.3 Replenishing R4/R5 reagent

This section explains how to replenish R4/R5 reagents.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to replace R4/R5 reagent.

1 Follow the instructions on the package insert to prepare the new R4/R5 reagent.

2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

3 Open the operation cover on the analyzer.



Caution!

Be careful not to hit your head on the operation cover when it is open.



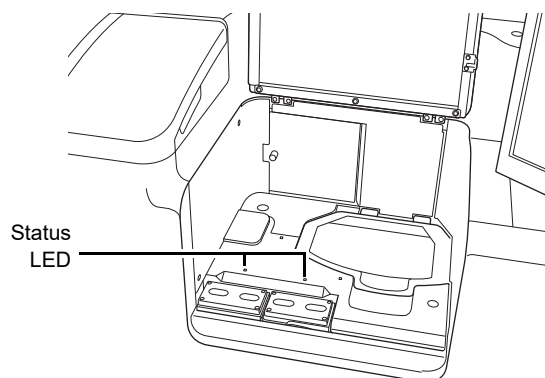
Information

When opening and closing the operation cover, exercise caution to make sure your fingers are not pinched by the cover.

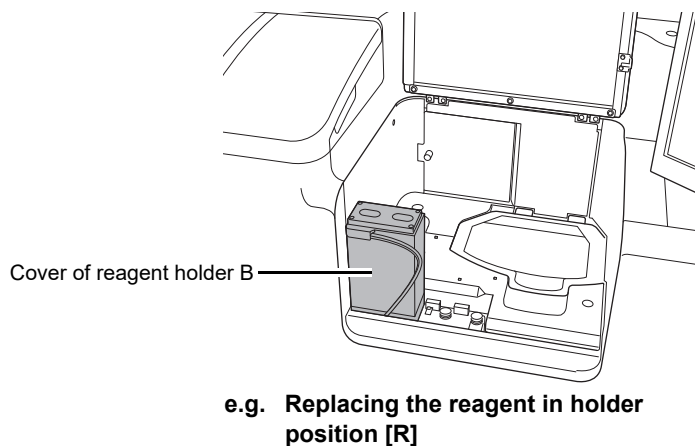
4 Make sure the status LED of the used R4/R5 reagent is red.

For the status LED of the R4/R5 reagent, see Chapter 3.

(►P.45 "Chapter 3: 3.4.3.3 Status indicated by the R4/R5 reagent status LED [R4/R5 (L)], [R4/R5 (R)]")



- 5 Lift the reagent holder B cover of the used R4/R5 reagent, and place on the neighboring cover as shown.**



Information

While analysis is in progress, do not open the cover on reagent holder B that is in use (while the LED is blinking). Analysis may be interrupted if the instrument detects that the covers are not closed properly.

- 6 Remove the used reagent container and place the new container.**



Caution!

Place R4 reagent first.
Otherwise, R4 reagent may mix in with R5 reagent.

- 7 Replace the reagent holder B cover.**

The reagent IC tag is scanned automatically.

- 8 Close the operation cover.**

- 9 Make sure that the status of the replaced R4/R5 reagent is white on the [Set Up] screen.**

An interval of time is required for the status to be updated on the screen.

- 10 Dispose of the used reagent container appropriately.**

5.3.4 Replenishing line washing/concentrated line washing/HISCL washing

This section explains how to replenish line washing/concentrated line washing/HISCL washing.

If the LU-10 is connected, replace the concentrated line washing as explained in the "LU-10 Instructions for Use". (►LU-10 Instructions for Use, "Chapter 6: 6.3 Replacing the reagent")

Make sure that the status icon of the concentrated line washing is white on the [Set Up] screen.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.



Information

- Use only Sysmex-specified line washing/concentrated line washing/HISCL washing.
- After replacing the line washing/concentrated line washing/HISCL washing container, firmly tighten the cap so that solution does not spill.
- When replacing the line washing/concentrated line washing/HISCL washing, take care that fragments of cardboard do not get into the container.
- When replacing line washing/concentrated line washing/HISCL washing, take care that the line washing/concentrated line washing/HISCL washing holder does not move.
- Take care not to misconnect the line washing, concentrated line washing, and HISCL washing tubes.
- If the level sensor is pulled out of the container at an angle when replacing the line washing/concentrated line washing/HISCL washing, malfunctioning may result. The level sensor must be pulled straight out of the container mouth. After pulling the level sensor out, do not tilt the sensor sideways or upside down. This may cause malfunctioning after replacement.
- Make sure that the connections to WASH1 and WASH2 are not reversed.
- Make sure that the connections to LINE1 and LINE2 are not reversed.
- Make sure that the connections to CONC1 and CONC2 are not reversed.

Follow the steps below to replenish line washing/concentrated line washing/HISCL washing.

1 Prepare new line washing/concentrated line washing/HISCL washing.

2 Touch [Set Up] on the toolbar.

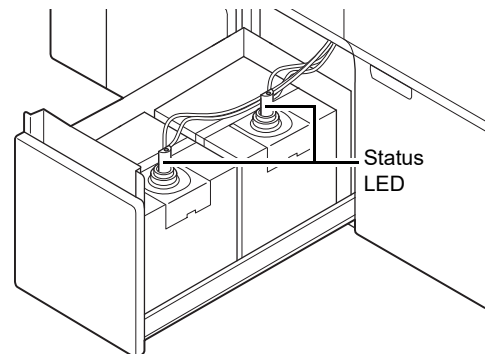
The [Set Up] screen appears.

3 Pull out the line washing/concentrated line washing/HISCL washing holder.

4 Make sure the status LED of the used line washing/concentrated line washing/HISCL washing is red.

For the status LEDs of the line washing/concentrated line washing/HISCL washing, see Chapter 3.

(►P.45 "Chapter 3: 3.4.3.4 Status indicated by the line washing status LED [LINE1], [LINE2]/concentrated line washing status LED [CONC1], [CONC2]/probe washing status LED [(L)], [(R)]/HISCL washing status LED [WASH1], [WASH2]")



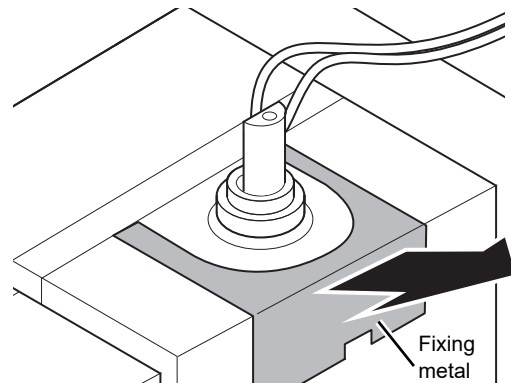
Caution!

During analysis or operation, do not remove the level sensor while in use (while the LED is blinking). Accidentally removing the level sensor may cause interruption of analysis or operation.

5 Open the new box of line washing/concentrated line washing/HISCL washing.

To open the box, follow the instructions on the box.

6 Remove the fixing metal from the used line washing/concentrated line washing/HISCL washing.



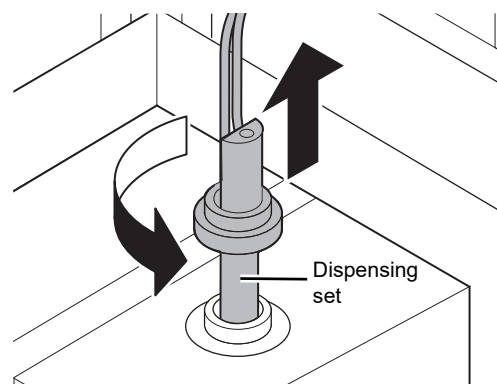
7 Attach the fixing metal to the new line washing/concentrated line washing/HISCL washing.

Firmly press in all the way.

8 Remove the cap from the new line washing/concentrated line washing/HISCL washing.

9 Remove the dispensing set from the used line washing/concentrated line washing/HISCL washing.

Turn the dispensing set counterclockwise to detach it, and pull straight out.



10 Firmly attach the dispensing set to the new line washing/concentrated line washing/HISCL washing.**Note:**

Orange labels are affixed to the line washing sensor and container. Brown labels are affixed to the concentrated line washing sensor and container. Blue labels are affixed to the HISCL washing sensor and container. Connect the tubes so that the colors match. This prevents wrong connection.

11 Replace the container in the holder with the new container.

12 Scan the barcode (GS1-128) on the box with the handheld barcode reader.

13 Return the line washing/concentrated line washing/HISCL washing holder to its original position.

Firmly press in all the way.

14 Make sure that the line washing/concentrated line washing/HISCL washing status icons are white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.

15 Dispose used line washing/concentrated line washing/HISCL washing container appropriately.

5.3.5 Replenishing probe washing

When the probe washing runs low, replenish with new probe washing.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials. There is a risk of infection by pathogens and other contaminants.



Caution!

The temporary placement tray is not a work platform. Do not attach or remove the reagent cap with the probe washing placed on the temporary placement tray. There is a risk of fluid splashing.



Information

- Use only Sysmex-specified probe washing.
- After replacing the probe washing container, firmly tighten the cap so that probe washing does not spill.
- Do not pull on the probe washing tube.

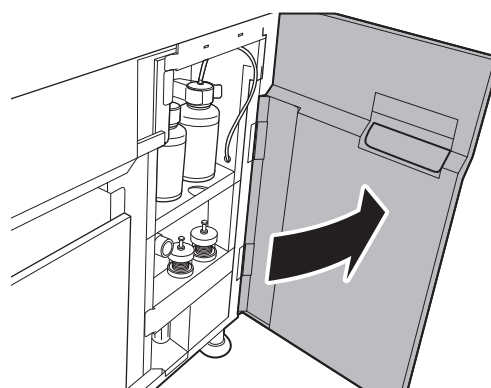
Follow the steps below to replenish the probe washing.

1 Prepare the new probe washing.

2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

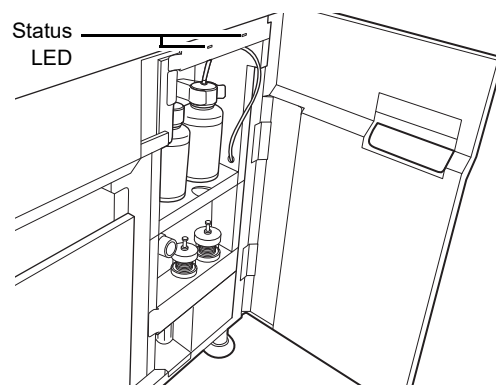
3 Open the probe washing holder/pressure regulator cover at the bottom right of the front of the instrument.



4 Make sure the status LED of the used probe washing is red.

For the status LED of the probe washing, see Chapter 3.

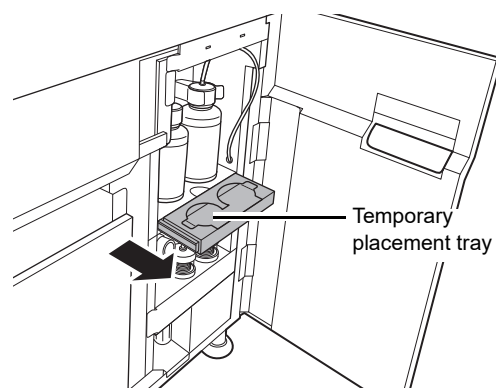
(►P.45 "Chapter 3: 3.4.3.4 Status indicated by the line washing status LED [LINE1], [LINE2]/concentrated line washing status LED [CONC1], [CONC2]/probe washing status LED [(L)], [(R)]/HISCL washing status LED [WASH1], [WASH2]")



Information

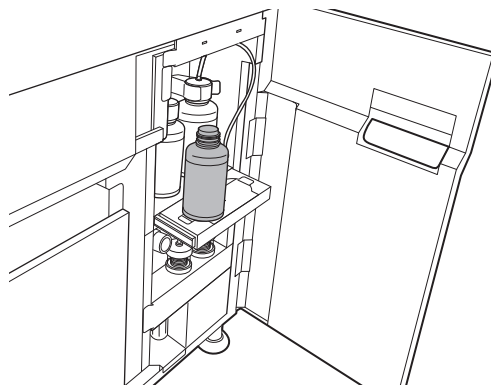
During analysis or operation, do not remove the level sensor while in use (while the LED is blinking). Accidentally removing the level sensor may cause interruption of analysis or operation.

5 Pull out the temporary placement tray.



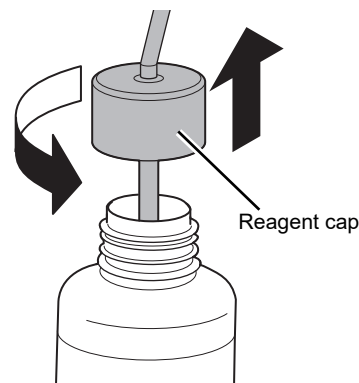
6 Remove the cap from the new probe washing.

7 Place the new probe washing on the temporary placement tray.



8 Remove the used probe washing from the holder and remove the reagent cap.

Turn the reagent cap counterclockwise to detach it, and pull straight out.



9 Attach the reagent cap firmly on the new probe washing.

10 Place the new probe washing in the holder.

A confirmation dialog box appears.

11 Touch [OK].

12 Push the temporary placement tray back in.

13 Close the probe washing holder/pressure regulator cover.

14 Dispose used probe washing container appropriately.

15 Scan the barcode (GS1-128) on the box with the handheld barcode reader.

16 Make sure that the probe washing status icon is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.

5.4 Setting a reagent for priority use

When there are more than one of the same type of reagent, detergent, or waste tank (optional), you can select their priority order.

If a reagent priority setting is not specified, the order of use is the reagent with the nearer expiration date, then the reagent with the lower level, then the reagent with the lower set reagent holder number.

For automatic standard curve correction (lots are not distinguished for R4/R5), see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 3: 3.2 Correcting the standard curve")

5.4.1 Selecting the reagent, detergent, or waste tank (optional) to be given priority

You can select which reagent, detergent, or waste tank (optional) is given priority.

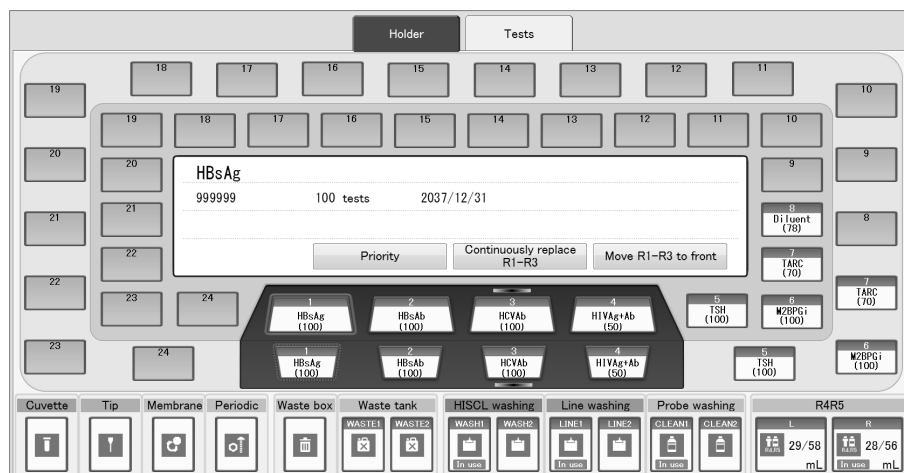
Follow the steps below to set priority use.

1 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

2 Touch the reagent, detergent, or waste tank (optional) for which you want to set priority use.

Detailed information appears in the center of the screen.



3 Touch [Priority] on the operation panel.

The selected reagent, detergent, or waste tank (optional) is set for priority use.

The mark that appears when priority use is set is indicated below.

R1-R3 reagent	The mark ( :Green) appears in the status of the reagent that has been given priority.
R4/R5 reagent Detergent Waste tank	The In use mark appears in the status of the R4/R5 reagent, detergent, or waste tank (optional) that has been given priority.

5.4.2 Canceling priority use of a reagent, detergent, or waste tank (optional)

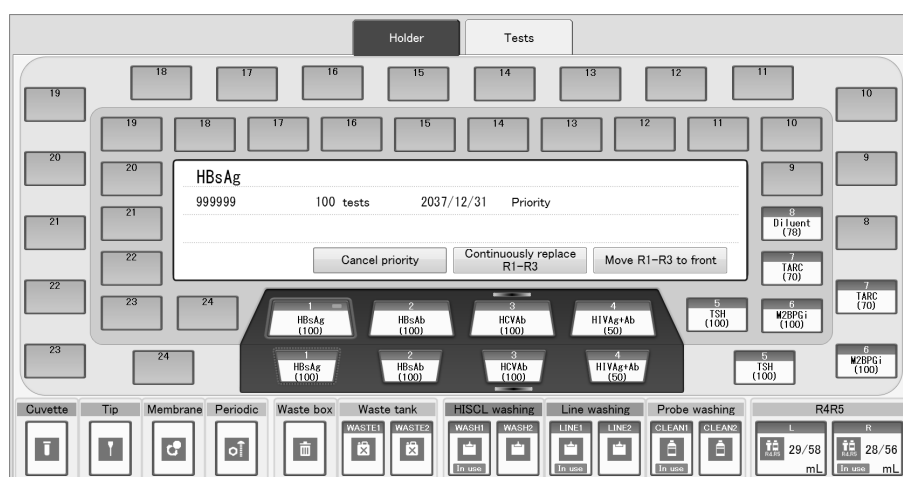
You can cancel priority use of a reagent, detergent, or waste tank (optional).
Follow the steps below to cancel priority use.

1 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

2 Touch the reagent, detergent, or waste tank (optional) for which you want to cancel priority use.

Detailed information appears in the center of the screen.



3 Touch [Cancel priority] on the operation panel.

Priority use of the selected reagent, detergent, or waste tank (optional) is canceled.

The screen is updated and the mark ( / **In use**) is removed from the reagent, detergent, or waste tank (optional) for which priority use was canceled.

This step can also be performed by touching [Cancel priority] in the center of the screen.

5.5 Preparing the sample

This section explains how to prepare the sample for analysis.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat while preparing blood samples. When finished, wash your hands with a disinfectant.

If your skin or clothing comes into contact with a sample, pathogenic or other infection may occur.



Information

- The actual sample volume required is the total sample volume required for each test plus the dead volume.
- Use a suitable sample tube type as indicated in the package insert for each reagent test.
- If the specified sample tube is not used or the sample volume is not sufficient, air or blood cells may be aspirated and correct analysis results may not be obtained.
- The maximum sample volume that can be aspirated is 30 μ L.
- Make sure sample tubes are inserted all the way into the rack (to the bottom of the rack).
- The optional sample tube adaptor that is appropriate for the sample tube may vary depending on the thickness of the sample barcode label used.
- When using your own rack/sample barcode labels, make sure that there are margins of at least 5 mm at both ends of the barcode.
- When placing the sample in the rack, insert slowly so that foaming and splashing do not occur.
- If a sample tube is filled too high, the sample may spill during sampler operation.



Note:

For information on the nature of the samples and how the samples are collected, see the package insert provided with each reagent.

5.5.1 Types of samples that can be analyzed

Prepare properly pre-treated serum or plasma as samples for analysis.

The pre-treatment method varies by test.

For details, see the package insert for each reagent.

5.5.2 Usable sample tubes and sample cups

Usable sample tubes and dead volume

Sample tube	Dead volume
Diameter (outer) 13 to 16 mm	The depth of the serum (plasma) components must be at least 5 mm from the surface.
Height 75 to 100 mm	

Usable sample cups and dead volume

Sample cup	Dead volume
Conical 4 mL	0.15 mL

If a sample is dispensed at an angle into a sample cup, aspiration problems such as a short sample may result. After loading the sample rack in the sampler, make sure that the fluid surface is level. If the fluid surface is not level, tap the sample cup with your finger or otherwise make it level.



Caution!

To use conical 4 mL sample cups, the 6-sample adapter must be used.

5.5.3 Supported racks

Only Sysmex 5-sample racks can be used.

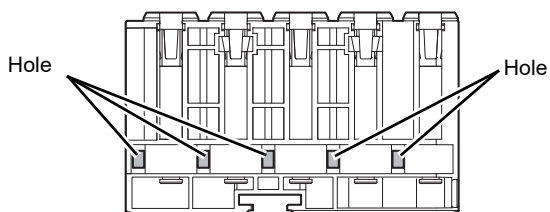
Attach the special holder to the rack as needed depending on the diameter of the sample tube.

To use conical 4 mL sample cups, the 6-sample adapter must be attached to the sample rack.

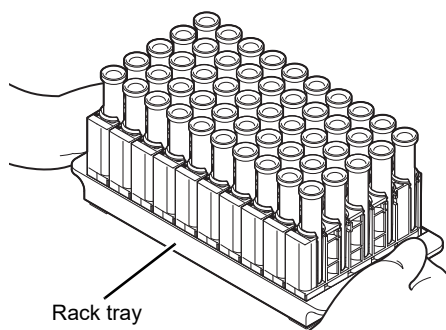


Caution!

- Do not cover the 5 holes on the side of the rack.
There is a risk of instrument malfunctioning.



- When using a rack tray, take care not to accidentally knock or bump the tray and cause a sample to spill.
- When carrying samples in a rack tray, hold both ends of the tray and carry slowly to avoid foaming and splashing.



5.5.4 Affixing a barcode label

When using a rack barcode or sample barcode, the barcode label must be affixed in the correct position and the sample tube must be correctly placed in the rack so that the sample barcode is visible.

To prevent reporting of incorrect data due to sample misplacement or input mistakes, it is recommended that sample barcodes are used.



Caution!

Follow the rules below when affixing barcode labels.

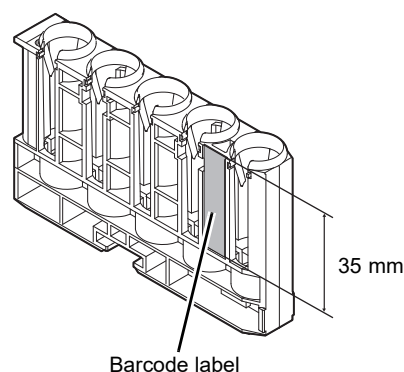
Otherwise misreading of barcodes and wrong aspiration of samples may occur.

- Affix the barcode so that the bars are horizontal.
- Affix in the correct position.
- Do not affix multiple labels.
- The label surface must not be wrinkled.
- Do not use barcode labels that easily peel off.

5.5.4.1 Affixing a rack barcode label

Before loading the rack in the sampler, affix the rack barcode label between the 1st and 2nd sample tubes as shown at right.

Align the label so that its top edge is aligned with the top edge of the rack.



Warning!

When using a rack barcode, use a check digit whenever possible. If a check digit is not used, the potential for misreading the barcode increases.

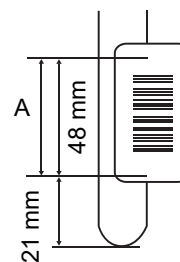


Note:

When using the supplied rack barcode labels, set to "NW-7" and "Modulus 16" or "CODE39" and "Modulus 43".

5.5.4.2 Affixing a sample barcode label

Affix the label so that the barcode is within range A.



Warning!

When using a sample barcode, use a check digit whenever possible.
If a check digit is not used, the potential for incorrect reading of a barcode increases.

5.6 Tasks after analysis

When analysis is finished, check the status of the waste box and waste tank (optional). Dispose of the waste in the waste box, replace the waste tank (optional), and perform post analysis maintenance.

5.6.1 Disposing of waste in the waste box

When the waste box is almost full, the status icon of the waste box is highlighted by an orange background.
Replace the waste bag in the waste box.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.



Warning!

Dispose of used supplies as biological waste and infectious waste in accordance with local laws and regulations.

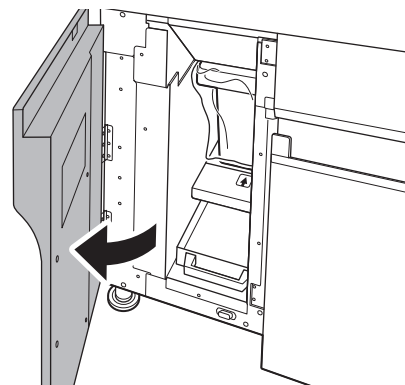
Follow the steps below to dispose of used cuvettes and tips.

1 Prepare a new waste bag.

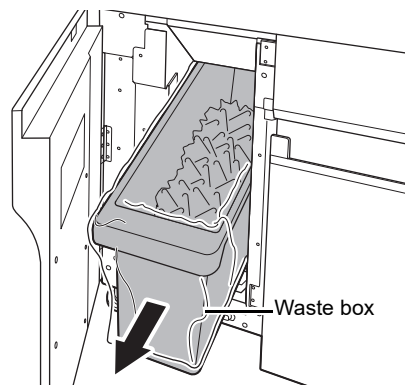
2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

3 Open the waste unit cover at the bottom left of the front of the instrument.



4 Pull out the waste box.



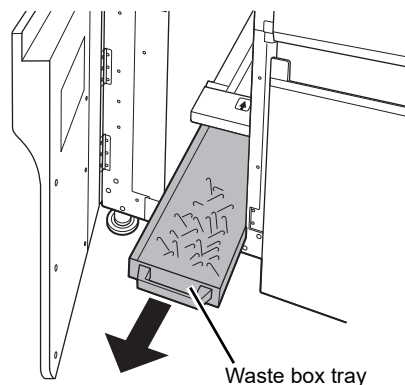
Information

Pulling the waste box out while analysis is in progress will stop analysis.

However, because the instrument continues with the analysis that is in progress, the cuvettes and tips used for this analysis are discarded. The discarded cuvettes collect on the tray under the waste bag, so dispose the waste of the tray as well.

5 Pull out the waste box tray and check if there is waste.

If there is waste in the tray, dispose of it together with the waste in the waste box.



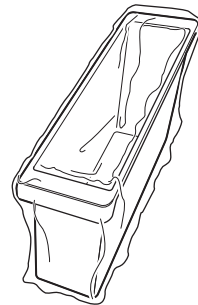
6 Remove the waste bag.



7 Dispose of the bag appropriately.

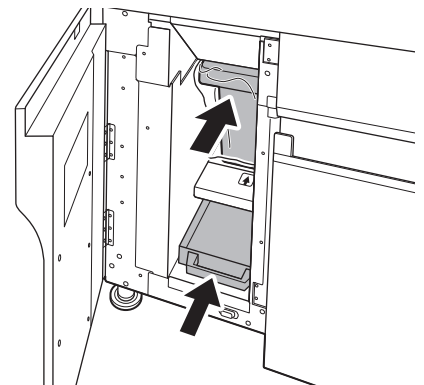
8 Line the waste box with the new waste bag.

Fold the top edge of the waste bag over the edges of the waste box and push the waste bag all the way down into the waste box.



9 Insert the waste box and waste box tray into the waste unit.

Firmly press in all the way.



10 Close the waste unit cover.

11 Touch [Reset waste box] on the operation panel.

12 Make sure that the waste box status icon is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.

5.6.2 Disposing of waste fluid

When the waste tank (optional) becomes full, the waste tank status LED lights red.



Risk of infection

- Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.
There is a risk of infection by pathogens and other contaminants.
- Before replacing the waste tank (optional), always make sure the waste tank status LED is not blinking. If the waste tank (optional) is replaced when the waste tank status LED is blinking, waste fluid may spurt from the waste fluid tube adapter when it is removed and cause a risk of infection from pathogens and other contaminants.



Warning!

Dispose of waste fluid as biological waste and infectious waste in accordance with local laws and regulations.

Follow the steps below to replace and change the waste tank (optional).

1 Prepare an empty waste tank (optional).

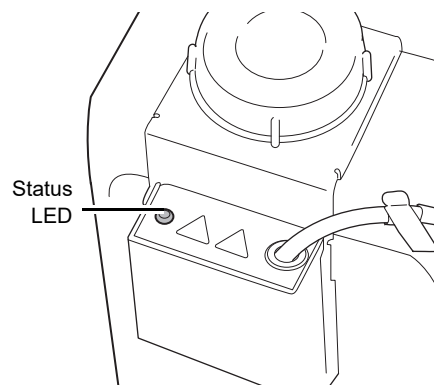
2 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

3 Make sure the status LED of the used waste tank is red.

For the status LED of the waste tank (optional), see Chapter 3.

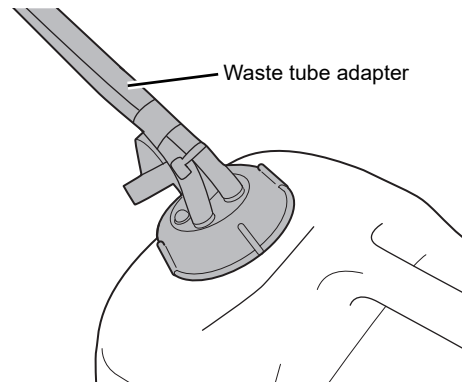
(►P.46 "Chapter 3: 3.4.3.5 Status indicated by the waste tank status LED [1], [2]")



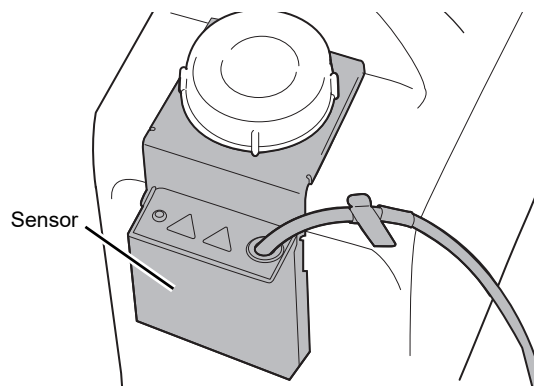
Caution!

During analysis or operation, do not remove the level sensor while in use (while the LED is blinking). Accidentally removing the level sensor may cause interruption of analysis or operation.

4 Remove the waste tube adapter from the used waste tank (optional) and attach it to the empty tank.



5 Remove the sensor from the used waste tank (optional) and attach it to the empty tank.



Caution!

- When attaching the sensor attachment plate to the waste tank (optional), secure with the waste tank (optional) cap so that there is no gap between the attachment plate and the side of the waste tank (optional).
- When attaching the sensor to the attachment plate during waste tank (optional) replacement, insert the sensor firmly into the attachment plate so that there is no gap between the sensor and the attachment plate.

6 Dispose of the waste fluid in the used waste tank (optional) appropriately.

7 Make sure that the waste tank (optional) status icon is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.

5.6.3 Cleaning the instrument

Perform regular cleaning of the instrument. For details, see Chapter 11.

(► **P.263** "Chapter 11: 11.3 Maintaining the instrument")

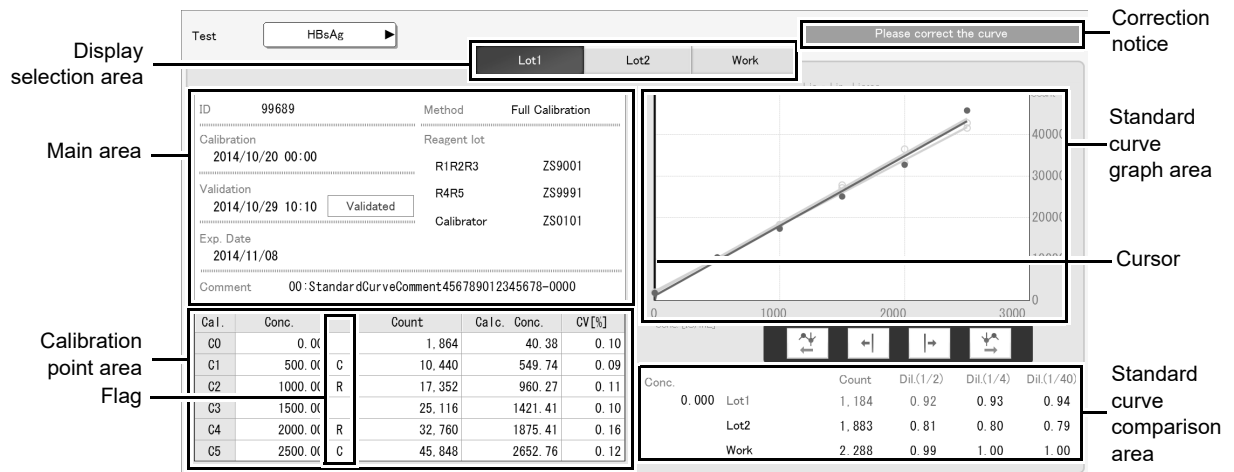
Chapter 6 Creating a standard curve

This chapter explains how to create a standard curve.

6.1 Standard Curve screen

You can check a standard curve that you have created on the [Standard Curve] screen.

Touch [STD] on the toolbar to display the [Standard Curve] screen.



[Standard Curve] screen

[Test]	Select the test.
Display selection area	Select the standard curve data. Multiple standard curves can be selected to overlay and compare the curves.
[Lot1]/[Lot2]	Standard curves used for analysis. These are stored by validating the standard curve analysis results. 2 standard curves for a different reagent lots can be analyzed and stored.
[Work]	Area for work data. Standard curve analysis results are temporarily stored in this area.
Correction notice	A message is displayed here when the standard curve must be corrected.
Main area	Displays the base data of the standard curve.
[ID]	Displays the standard curve ID.
[Calibration]	Displays the date and time the standard curve was created. [Error]: There is an error. [Information]: There is a notice. Touch to display the dialog box with details.
[Validation]	Displays the date and time the standard curve was validated and the validation status. [Validated]: The results have been validated. [Not Validate]: The results have not been validated.

[Exp. Date]	Displays the expiration date of the standard curve. If expired, [Expired] appears.
[Method]	Displays the method by which the standard curve was created. [Full Calibration]: Created by full calibration [Point replace]: Created by specified point replacement analysis [Correct]: Created by correction using R5 reagent [Manual]: Created by manual correction
[Reagent lot]	Displays the lot numbers of the [R1R2R3] reagents, [R4R5] reagents, and [Calibrator] used to create the standard curve.
[Comment]	Displays comments regarding the standard curve.
Standard curve graph area	Displays a graph of the standard curve. The vertical axis shows the [Count] and the horizontal axis shows the [Conc.] (concentration). Move the cursor on the graph to display the correspondence between the [Conc.] and [Count].
Cursor	Use the buttons to move the cursor left and right.
 (Light blue)	Graph of the selected lot.
 (Gray)	Graph of the lot that is not selected.
	Displayed when standard curve data is created (qualitative parameters only).
Calibration point area	Displays the analysis results for each calibrator. If a [Please check the standard curve data] error occurs, the result of the abnormal point will appear in white on a red background.
[Cal.]	Displays the reagent name of the calibrator.
[Conc.]	Displays the concentration of the calibrator.
Flag	Displays the method used to acquire count values. No flag: Data acquired by analysis. [R]: Data replaced by specified point replacement analysis. [M]: Data entered by manual revision. [C]: Data corrected by R5 reagent correction.
[Count]	Displays the average value of the calibrator analysis data.
[Calc. Conc.]	Displays the concentration of the calibrator calculated using the standard curve.
[CV[%]]	Displays the coefficient of variation of the count value of the calibrator.
Standard curve comparison area	Displays the comparison data of the standard curve. The selected lot name, count value, and dilution ratio appear in light blue.
[Conc.]	Displays the concentration of the selected lot.
[Count]	Displays the count values.
[Dil.]	Displays the dilution correction ratio. Not shown when dilution correction is not performed for the test.

6.2 Checking the expiration date of the standard curve

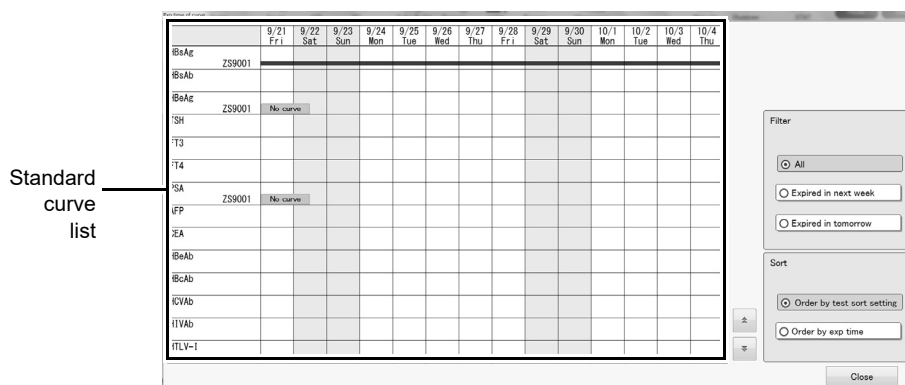
This section explains how to check the expiration date of a standard curve on the [Set Up] screen. Follow the steps below to check the expiration date of a standard curve.

1 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

2 Touch [Standard curve list] on the operation panel.

The following dialog box appears.



3 Check the expiration date of the standard curve.

The following items are displayed in the dialog box:

Standard curve list	Displays a list of the standard curves.
Test	Displays the tests.
Lot number	The lot numbers of reagents R1-R3 appear.
[No curve]	Appears when there is no standard curve. Validate the standard curve or create a new standard curve.
[Work area]	Standard curve in the [Work] tab. The standard curve must be validated.
[Expiration date]	Indicates the expiration date of the standard curve.
[Filter]	The displayed items can be filtered. Select from [All], [Expired in next week], or [Expired in tomorrow].
[Sort]	The displayed items can be sorted. Select from [Order by test sort setting] or [Order by exp time].
[Close]	Touch to close the dialog box.



Note:

If the standard curve is validated at a later time, recalculation takes place automatically.

6.3 Registering a calibrator

This section explains how to register a calibrator for creating a standard curve. There are 2 methods for registering calibrators: registering calibrators one at a time in a sequence, and registering all calibrators at once.

6.3.1 Registering calibrators one at a time

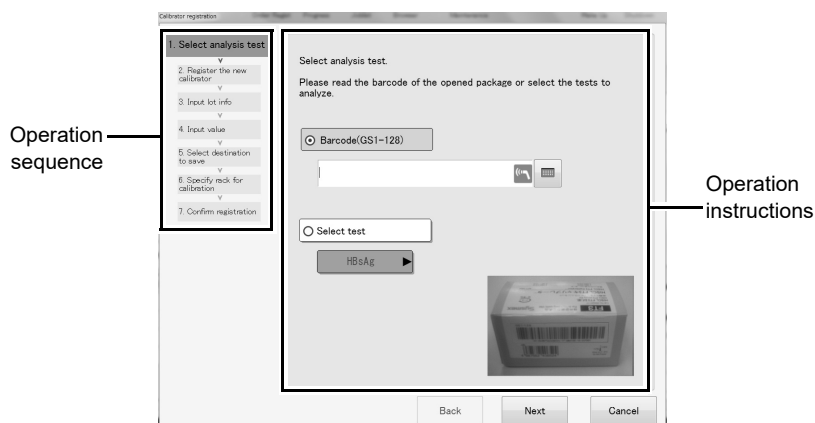
Follow the steps below to register calibrators one at a time.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

2 Touch [Calibrator registration] on the operation panel.

The following dialog box appears.



3 Follow the instructions in the dialog box, and touch [Next].

The following items are displayed in the dialog box:

[Next]/[Back]	Touch to move forward to the next operation sequence or backward to the previous operation sequence.
[Cancel]	This cancels your settings and closes the dialog box.

1. Select analysis test

Select the tests for the calibrator being registered.

The following items are displayed in the dialog box:

[Barcode (GS1-128)]	Select this when you have the calibrator box. The barcode on the box can be read with the handheld barcode reader.
[Select test]	Select this when you do not have the calibrator box. Tests can be selected.

2. Register the new calibrator

Select the tests you want to register from the test list.

[2. Register the new calibrator] may appear when you are registering a new calibrator.

**Note:**

If the test you want to register does not appear in the test list, contact your local Sysmex representative.

3. Input lot info

Enter the lot number and expiration date.

If the calibrator barcode was read in [1. Select analysis test], the [Lot] and [Exp. Date] appear automatically.

The following items are displayed in the dialog box:

[Test]	Displays the selected tests.
[Lot]	Enter the lot of the calibrator.
[Exp. Date]	Enter the expiration date of the calibrator. If the expiration date is not indicated on the calibrator, enter the last day of the month the calibrator expires.

4. Input value

Enter the displayed values of the calibrator being registered.

The displayed values are indicated on the manual included in the calibrator box.

Only items for which the calibrator concentrations vary are shown.

The following items are displayed in the dialog box:

[Barcode (GS1-128)]	Select to read the barcode on the manual with the handheld barcode reader. After reading the barcode, you will automatically move to the next operation sequence. To check the entered values, touch [Back] in [5. Select destination to save].
[Display value input]	Select to enter the displayed values indicated on the manual, following the steps below 1) Select the sample to be registered. 2) Touch [Edit]. 3) Enter the displayed value and touch [Next]. Repeat these steps until all displayed values of the sample are entered.

5. Select destination to save

Select the location where the new lot of the calibrator will be saved.

The following items are displayed in the dialog box:

[Destination]	Select to specify the location where the new lot will be saved.
[Calibration rack]	Lots used with a standard curve rack are indicated by a checkmark.
[Lot]	Displays the lot of the registered calibrator.
[Exp. Date]	Displays the expiration date of the registered calibrator.

**Caution!**

If a calibrator has already been registered in the selected [Destination] location, that calibrator will be overwritten. Once overwritten, the information of that calibrator cannot be restored.

6. Specify rack for calibration

Specify the lot to be used with the standard curve rack.

The following items are displayed in the dialog box:

[Calibration rack]	Select to specify the lot used with the standard curve rack.
[Lot]	Displays the lot of the registered calibrator.
[Exp. Date]	Displays the expiration date of the registered calibrator.
[Use registered lot]	Touch to select the currently registered lot.

7. Confirm registration

Check the information set in steps 1 to 6.

4 Touch [Finished].

The dialog box closes and the entered calibrator is registered.

6.3.2 Registering a batch of calibrators

Follow the steps below to register all calibrators at once.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

3 Select [402. Calibrator batch input] and touch [Settings].

The following dialog box appears.

Test	Calibrator Code
HBsAg	FT4
HBsAb	PSA
HBeAg	AFP
HBeAb	CEA
HBcAb	CA125
HCVAb	CA19-9
HTLV-I	TM
TPAb	TAT
TSH	PIC
FT3	tPAI-C
FRN	Insulin
HIVAg+Ab	ProGRP
HCVGr1	HCVGr2
NTproBNP	CK19F
TnT	TARC
ANP	MZBPGi
SP-A	

Priority	Lot	Exp. Date
✓	ZS3004	2015/05/22

Buttons: New, Edit, Delete, OK, Cancel

4 Select the test for which you want to register a calibrator, and touch [New].

The following dialog box appears.

Lot barcode(Package GS1-128)

Lot No.

Exp. Date: 2015/06/01

Concentration barcode(manual)

Calibration rack

Cal.	Display value
C0	0.000
C1	0.250
C2	2.500
C3	25.000
C4	250.000
C5	2500.000

[U/mL]

Buttons: Confirm, Edit, OK, Cancel



Note:

You can also select a lot and touch [Edit] to edit the information of that lot.

5 Set the displayed items.

The following items are displayed in the dialog box:

[Lot barcode(Package GS1-128)]	Select this when you have the calibrator box. The barcode on the calibrator box can be read with the handheld barcode reader.
[Confirm]	Touch to set the lot number and expiration date that were read from the barcode.
[Lot No.]	Enter the lot number of the calibrator.
[Calibration rack]	Select this checkbox to change the lot to the lot of analysis using the standard curve rack.
[Exp. Date]	Enter the expiration date of the calibrator. If the expiration date is not indicated on the calibrator, enter the last day of the month the calibrator expires.
[Concentration barcode(manual)]	Read the barcode on the manual included in the calibrator box.
[Confirm]	Touch to set the concentration that was read from the barcode.
[Cal.]	The calibrator is displayed.
[Display value]	The displayed values appear.
[Edit]	Select [Cal.] and then touch this to enter the displayed values indicated on the manual, following the steps below 1)Select the sample to be registered. 2)Touch [Edit]. 3)Enter the displayed value and touch [Next]. Repeat these steps until all displayed values of the sample are entered.

6 Touch [OK].

The calibrators are all registered.

6.4 Registering a standard curve order

Before a standard curve order can be registered, input of the reagent information into the instrument must be completed and the reagent information must appear on the [Set Up] screen. Registration of the calibrator must also be completed.

6.4.1 Using a standard curve rack to register a standard curve order

When a standard curve rack is used, the order is automatically registered when analysis starts.

For the procedure for setting the standard curve rack, see Chapter 8.

(►P.188 "Chapter 8: 8.1.7 Registering a default order for a rack")

When there are 6 calibrators, analysis can be performed by the following methods:

- Attach the 6-sample adapter to a rack and analyze using that rack.

To start standard curve analysis, see the following.

(►P.144 "6.5 Performing standard curve analysis")

6.4.2 Registering a standard curve order without using a standard curve rack

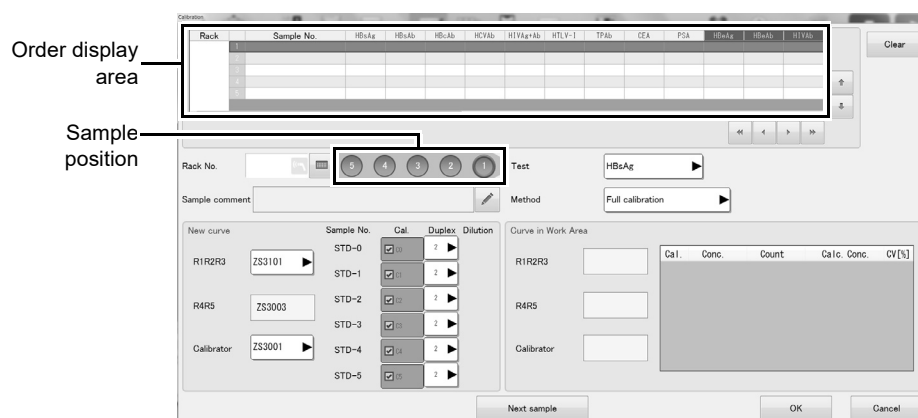
This section explains how to register an order without using a standard curve rack. Follow the steps below to register an order.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Calibration] on the operation panel.

The following screen appears.



3 Populate the displayed fields.

The following items are displayed in the dialog box:

Order display area	Displays the contents of the order entered for each rack number. When an order has not been completed, the sample position number appears in yellow. Specify tests and complete the order.
[Clear]	Touch to delete the entered order.
[Rack No.]	Enter the rack number. This can also be scanned using the handheld barcode reader.
Sample position	Select the position where the sample is placed.
[Test]	Select the test.
[Sample comment]	A sample comment can be entered.
[Method]	Select the calibration method.
[Full calibration]	Analyze all calibrators.
[Point replace]	Analyze by specified point replacement.
[New curve]	Displays the new standard curve order.
[R1R2R3]*	Select the R1-R3 reagent lot to be used. The "No curve" icon appears on lot numbers that do not have a standard curve.
[R4R5]	Displays the R4/R5 reagent lot being used.

[Calibrator]	Select the lot number of the calibrator used for analysis.
[Sample No.]	Displays the sample number.
[Cal.]	Select the calibrator number. Orders are not created for calibrators that do not have a checkmark.
[Duplex]	Select the test count.
[Dilution]	Select the calibrator test count used to determine the ratio for dilution correction. To perform dilution correction, contact your local Sysmex representative. Not shown when dilution correction is not performed for the test.
[Curve in Work Area]	Displays reference data on the selected test.
[R1R2R3]	Displays the lot of the R1-R3 reagent in the reference data.
[R4R5]	Displays the lot of the R4/R5 reagent in the reference data.
[Calibrator]	Displays the lot number of the calibrator in the reference data.
[Cal.]	Displays the calibrator number in the reference data.
[Conc.]	Displays the calibrator concentration in the reference data.
[Count]	Displays the average value of the calibrator analysis data in the reference data.
[Calc. Conc.]	Displays the concentration calculation result of the calibrator in the reference data.
[CV[%]]	Displays the coefficient of variation of the count value of the calibrator in the reference data.
[Next sample]	Touch to complete the entered order. The next order can be registered.

* If a [R1R2R3] reagent is not selected, the reagent set for priority use is used.

For reagent priority use, see Chapter 5.

(►P.121 "Chapter 5: 5.4 Setting a reagent for priority use")

4 Touch [OK].

The standard curve order is registered.

A green checkmark appears on registered orders.

Entered orders can also be viewed on the [Joblist] screen.

To start standard curve analysis, see the following.

(►P.144 "6.5 Performing standard curve analysis")



Note:

- "STD-" is added at the beginning of standard curve sample numbers displayed on the [Joblist] screen.
- To edit a registered order, select the order you want to edit on the [Order registration] screen. Touch [Correction] on the operation panel and edit the order.
(►P.180 "Chapter 8: 8.1.1 Order registration screen")

6.5 Performing standard curve analysis

This section explains how to perform standard curve analysis.
Follow the steps below to perform standard curve analysis.

1 Prepare the samples (calibrators).

Follow the instructions on the package insert to prepare each sample (calibrator).

2 Registering an order.

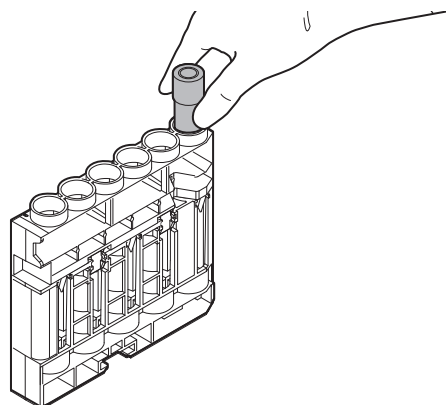
If the order is in the host, it is not necessary to register the order.

For the procedure for registering orders, see the following.

(► **P.142** "6.4.2 Registering a standard curve order without using a standard curve rack")

3 Load the sample cups containing the calibrators in the sample rack.

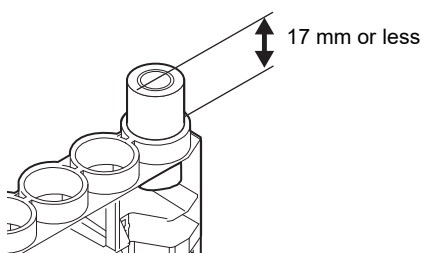
Load the sample cups containing the calibrators as specified in the registered standard curve order. If using a rack with a default order registered for standard curve analysis, load the sample cups in the registered standard curve rack.



Warning!

- When loading sample cups in the sample rack, firmly push all the way in.
- Load the sample cups so that they are no more than 17 mm from the top of the 6-sample adapter.

There is a risk of the rack falling and sample splashing.



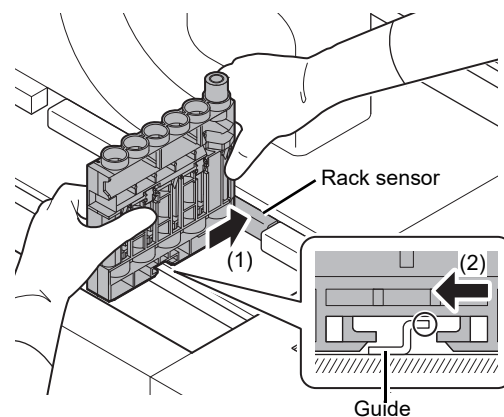
4 Place the sample rack so that the guide on the sampler fits into the notch in the rack.

- (1) Push the sample rack against the rack sensor on the sample rack feeder.
- (2) Place the sample rack so that the guide on the sampler fits into the notch in the sample rack.

The instrument's status LED indicates that the instrument is in operation.

After the instrument initializes, the sample rack is fed in and analysis starts.

The analysis will take about 20 minutes.



Information

- Hold both ends of the sample rack as shown above and load in the sampler.
- If the sample rack is not placed correctly in the sampler, the instrument may malfunction.
- Leaving calibrators at room temperature for a prolonged period may cause the calibrators to deteriorate. Place the calibrators in the sampler immediately before starting analysis.

6.6 Checking and validating a standard curve

This section explains how to check and validate a standard curve.

6.6.1 Checking a standard curve

A standard curve can be checked on the [Standard Curve] screen.
Follow the steps below to check a standard curve.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

2 Display the standard curve that you want to check.

Select the [Test] and [Lot1], [Lot2], or [Work] to display the desired standard curve.

3 Check the validity of the standard curve.

Check the information in the main area, calibration point area, and standard curve graph area to determine the validity of the standard curve.



Information

If the [Conc.] (concentration) and [Calc. Conc.] (calculated values) of the standard curve to be validated deviate significantly, or if the difference between the counts of the calibrators is small, create the standard curve again.

6.6.2 Using (validating) a standard curve for sample analysis

A standard curve is validated by verifying the standard curve analysis results and confirming that there are no problems.

Once validated, a standard curve can be registered for use in analysis.

To validate the standard curve after performing quality control, see the "Administrator's Guide".

(► Administrator's Guide, "Chapter 3: 3.3 QC using the standard curve in the Work Area")

To use auto validation of standard curves, see Chapter 10.

(► **P.245** "Chapter 10: 10.8.1 Automatically validating results")

Follow the procedure below to validate the standard curve analysis results.

Validation cannot be performed if an error appears.

Perform [Standard curve data administration] or re-analyze the standard curve to create a standard curve that does not show an error.

Follow the steps below to validate a standard curve.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

2 Display the standard curve that you want to validate.

Select the [Test], [Lot1], [Lot2], or [Work] to display the desired standard curve.

3 Check the validity of the standard curve.

Check the information in the main area, calibration point area, and standard curve graph area to determine the validity of the standard curve.

4 Touch [Validation] on the operation panel.

The following dialog box appears.

Validation

Select a path to save the curve in. Data will be overwritten.

Save to

Current curve

	Lot1	Lot2
ID	99692	99693
Status	Not Validate	Not Validate
Calibration	2012/08/24 00:03	2012/08/24 00:04
Validation		
Exp. Date		
Method	Full Calibration	Full Calibration
R1R2R3	ZS9001	ZS9002
R4R5	ZS9991	ZS9991
Calibrator	ZS0102	ZS0202
Comment	00:StandardCurveComment456789012345678-0100	00:StandardCurveComment456789012345678-0101

OK Cancel



Information

A standard curve already in the save location will be overwritten. If needed, output the data to a file or otherwise save the data before saving the new standard curve.

5 Select the location where the standard curve will be saved.

Select from [Lot1] or [Lot2] for the save location of the validated standard curve.

6 Touch [OK].

A confirmation dialog box appears.

7 Touch [OK].

The dialog box closes and the standard curve is validated.



Information

A standard curve will be invalidated after it has passed its expiration date. Create the standard curve again.



Note:

- To successively display each standard curve that has not been validated, touch [Search unvalidated curves] repeatedly.
- If the reagent lot of the standard curve to be validated is the same as the reagent lot of a standard curve that has already been saved, the standard curve that is already saved will be invalidated.
- After analysis, the created standard curve is temporarily saved in the [Work] directory. Validating the standard curve registers it in [Lot1] or [Lot2], allowing it to be used for regular analysis.
- If [QC using the standard curve in the Work Area] is enabled for the standard curve validation setting, the standard curve in [Work] is preferentially used for QC analysis only. In this case, if the reagent lot numbers matched, the concentration is calculated even if the standard curve has not been validated.

6.6.3 Not using (invalidating) a standard curve for sample analysis

When a validated standard curve is invalidated, it is not used for analysis.
Follow the steps below to invalidate a standard curve.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

2 Display the standard curve that you want to invalidate.

Select the [Test] and [Lot1], [Lot2], or [Work] to display the desired standard curve.

3 Touch [Invalidate] on the operation panel.

A confirmation dialog box appears.

4 Touch [OK].

The dialog box closes and the standard curve is invalidated.

6.7 Saving standard curve data

The data of a standard curve can be saved. The procedures for saving standard curve data to a file and printing standard curve data are explained below.

6.7.1 Saving to a file

Specified standard curve data can be saved to a file in CSV format.

The average value of the analysis results of all calibrators and the data of all analysis results are output.

Follow the steps below to save a standard curve to a file.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

2 Display the standard curve that you want to save to a file.

Select the [Test] and [Lot1], [Lot2], or [Work] to display the desired standard curve.

3 Touch [File output] on the operation panel.

The dialog box appears.

4 Specify the save folder.

5 Enter the file name.

The file extension is ".csv".



Note:

The default file name is "STD_test display name_R1R2R3 lot number_R4R5 lot number_date created (YYYYMMDD)_time created (HHMMSS).csv".

6 Touch [OK].

The dialog box closes and the CSV file is stored in the specified folder.

6.7.2 Printing

A standard curve can be printed in a specified format.

Print formats are [Print LP] and [Print GP].

The standard curve data, reagent lot number, calibration point data, and graph are printed.



Information

To print, connect a printer

Printing is not possible unless a printer is connected.

Follow the steps below to print a standard curve.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

2 Display the standard curve that you want to print.

Select the [Test] and [Lot1], [Lot2], or [Work] to display the desired standard curve.

3 Touch the print format on the operation panel.

A confirmation dialog box appears. Make sure that a printer is in the READY state.

4 Touch [OK].

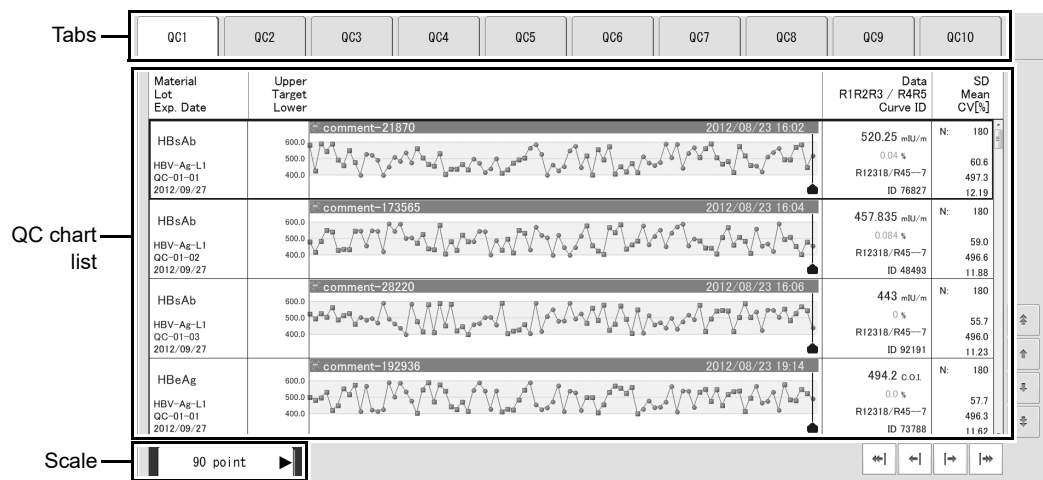
The dialog box closes and printing starts.

Chapter 7 Performing QC analysis

This chapter explains the regular control tasks that are performed to ensure reliability of analytical results. Quality control (QC) is performed to check that analysis results are consistently reliable, and to prevent problems by constantly monitoring the condition of the instruments. QC is implemented by analyzing a control material, such as a control serum. QC analysis results can be displayed in a chronological chart to enable monitoring of day-based or time-based changes.

7.1 Quality control screen

Touch [QC] on the toolbar to display the following screen.



[Quality control] screen

Tabs	The tabs are used to select the QC chart group that is displayed. Up to 11 tabs can be created. (►P.168 "7.5.3 Editing the QC tab")
QC chart list	QC analysis results are sorted in chronological order in the list. For details on the QC chart, see the following. (►P.165 "7.5.1 QC chart screen")
Scale	Changes the display scale of the QC chart.
[Auto]	[Auto] scale automatically sets the scale to 30→60→90→120→150→180 points depending on the number of analysis results.
[30 point]	The data of 30 analysis results are displayed in one QC chart.
[60 point]	The data of 60 analysis results are displayed in one QC chart.
[90 point]	The data of 90 analysis results are displayed in one QC chart.
[180 point]	The data of 180 analysis results are displayed in one QC chart.



Note:

A single chart stores a maximum of 180 analysis results.
If analysis is performed 3 times a day (morning, noon, and night), changes over a 60-day span can be controlled.

7.2 Registering a QC material

To use a new control serum for quality control, the QC material information must be registered. There are 2 methods for registering QC materials: registering QC materials one at a time in a sequence, and registering all QC materials at once.

If administrator privileges are available, the QC materials and the target/limit can be registered as a batch by using the settings file delivered by Caresphere and the barcode of the control product.

(►Administrator's Guide, "Chapter 4: 4.1 Registering a QC material", "Chapter 4: 4.2.1 Setting the target/limit for each control product")

7.2.1 Registering QC materials one at a time

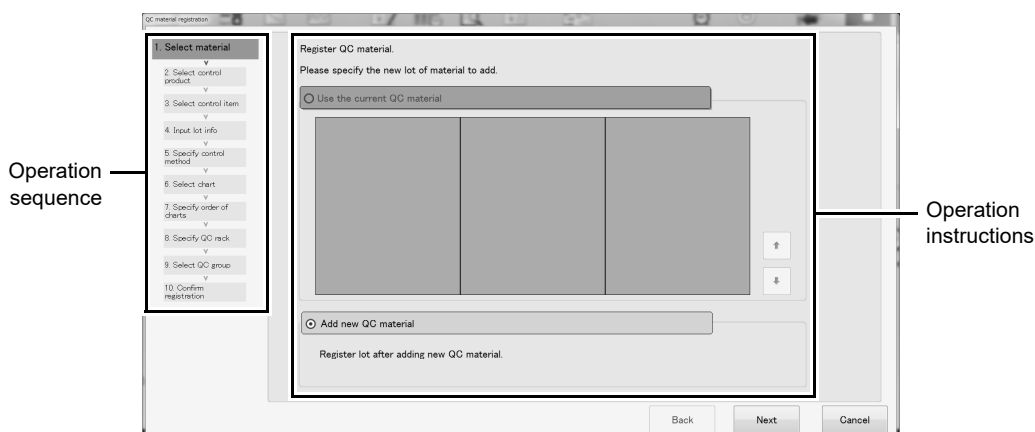
Follow the steps below to register QC materials one at a time.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Touch [QC material registration] on the operation panel.

The following dialog box appears.



3 Follow the instructions in the dialog box, and touch [Next].

The following items are displayed in the dialog box:

[Next]/[Back]	Touch to move forward to the next operation sequence or backward to the previous operation sequence.
[Cancel]	This cancels your settings and closes the dialog box.

1. Select material

Select the QC material to be registered.

The following items are displayed in the dialog box:

[Use the current QC material]	Select this to add a new lot of a QC material that is currently being used.
[Add a new QC material]	Select this to register a new QC material that is not currently being used.

2. Select control product

Select the new QC material to be added.

[2. Select control product] only appears when a new QC material is being added.

The following items are displayed in the dialog box:

[Product]	Select this to use a QC material provided by Sysmex. Select the QC material that you want to register from the QC material list.
[Other than product]	Select this to use a QC material that is not provided by Sysmex. Enter the name of the QC material in [Material name].

**Note:**

When a QC material that is [Other than product] is selected, Caresphere service cannot be provided.

3. Select control item

Select the tests used for QC with the new QC material.

Multiple tests can be selected.

[3. Select control item] only appears when a new QC material is being added.

4. Input lot info

Enter the information of the new QC material lot.

The following items are displayed in the dialog box:

[Sample No. for test]	Enter the sample number used for QC analysis.
[Lot No.]	Enter the lot number of the QC material. Enter the number indicated on the container of each material.
[Exp. Date]	Enter the expiration date of the QC material. If the expiration date is not indicated on the QC material, enter the last day of the month the material expires.
[Registered sample No.]	Displays a list of the sample numbers of currently registered QC materials.
[QC material name]	Displays the names of the registered QC materials.
[Lot]	Displays the lot numbers of registered QC materials.
[Sample No.]	Displays the sample numbers of registered QC materials.

**Note:**

- When [QC(special sample No.)] is enabled in the auto rack order settings, QC analysis can be performed automatically without registering an order.
For information on the auto rack order settings, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings")
- When using Caresphere service, enter the lot number according to the "HISCL Code Table", which can be obtained from the Caresphere site.

5. Specify control method

Specify control method used for the QC material.

The following items are displayed in the dialog box:

[Chart Display]	Specify whether or not the analysis results are shown in the chart on the QC screen.
[Display]	Select to show the analysis results in the chart.
[Not display]	Select if you do not want to show the analysis results in the chart.
[QC emergency supervision]	Specify whether an error notification is generated when an analysis result exceeds the allowed QC data range.
[Supervise]	Select if you want to be notified of errors.
[Not supervise]	Select if you do not want to be notified of errors.

6. Select chart

Select the save location for the new lot of QC material.

The following items are displayed in the dialog box:

[Save]	Select to specify the location where the new lot will be saved.
[QC rack]	Lots used with a QC rack are indicated by a checkmark.
[Chart]	Analysis results that are shown on the QC screen chart are indicated by a checkmark.
[Emergency supervision]	Analysis results for which an error notification is generated when the allowed QC data range is exceeded are indicated by a checkmark.
[Lot]	Displays the lots of registered QC materials.
[Sample No. for test]	Displays the sample numbers of registered QC materials.
[Exp. Date]	Displays the expiration dates of registered QC materials.
[Recent analysis]	Displays the date used in the most recent QC analysis.

**Caution!**

If a QC material has already been registered in the selected [Destination] location, that material will be overwritten. Once overwritten, the information of that QC material cannot be restored. However, if [Export the data to be overwritten.] is selected prior to saving, a backup will be made of the QC data before it is overwritten.

7. Specify order of charts

Specify the order of the QC chart shown on the QC screen.

The following item is displayed in the dialog box.

[Up]/[Down]	Touch to move a selected lot up or down.
--------------------	--

8. Specify QC rack

Specify the lot to be used with the QC rack.

The following items are displayed in the dialog box:

[QC rack]	Select to specify the lot to be used with the QC rack can be specified.
[Chart]	Analysis results that are shown on the QC screen chart are indicated by a checkmark.
[Emergency supervision]	Analysis results for which an error notification is generated when the allowed QC data range is exceeded are indicated by a checkmark.
[Lot]	Displays the lots of registered QC materials.
[Sample No. for test]	Displays the sample numbers of registered QC materials.
[Exp. Date]	Displays the expiration dates of registered QC materials.
[Recent analysis]	Displays the date used in the most recent QC analysis.
[Use registered lot]	Touch to select the currently registered lot.

9. Select QC group

Select a group for which a chart of new QC materials is shown.

Up to 10 groups can be created.

The following items are displayed in the dialog box:

[Registered group]	Select to select an already registered QC group and set QC materials.
[New group]	Select to create a new QC group and set QC materials.

10. Confirm registration

Check the information set in steps 1 to 9.

4 Touch [Complete].

The dialog box closes and the entered QC material is registered.

7.2.2 Registering a batch of QC materials

Follow the steps below to register a batch of QC materials.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

3 Select [404. QC material batch input] and touch [Settings].

The [QC material batch input] dialog box appears.

Material list area

Test selection area

Lot information area

Priority	Chart	Emergency supervision	Lot	Sample No. for test	Exp. Date
	✓	✓	2121212	HBV-Ag-L1	2015/05/30
✓	✓	✓	6666666	HBV-Ag-L1	2015/05/30

[QC material batch input] dialog box

4 Touch [New] in the material list area.

The following dialog box appears.

Control product	Screen display
HISCL M2BPGi Control Level 1	M2BPGi-L1
HISCL M2BPGi Control Level 2	M2BPGi-L2
HISCL SP-A Control Level 1	SP-A-L1
HISCL SP-A Control Level 2	SP-A-L2
HISCL Immuno Multi Control Level 1	ImmunoMulti-L1
HISCL Immuno Multi Control Level 2	ImmunoMulti-L2
Eitest Control set Level 1	Eitest-L1
Eitest Control set Level 2	Eitest-L2
HISCL HIV Ag+Ab Control (Neg 1)	HIV-Neg-1
HISCL HIV Ag+Ab Control (Pos 2)	HIV-Pos-2

☐ Other than product

Material name

Caresphere can not be used except for product.

OK Cancel



Information

You can also select a material and touch [Edit] to edit the information of that material. When the information of a material is edited, the previous information of the material is overwritten without deleting the registered lot information and the QC chart data of the material.

5 Select the materials you want to register.

The following items are displayed in the dialog box. Select the new QC materials to be added.

[Product]	Select this to use a QC material provided by Sysmex. Select the QC material that you want to register from the QC material list.
[Other than product]	Select this to use a QC material that is not provided by Sysmex. Enter the name of the QC material in [Material name].



Note:

When a QC material that is [Other than product] is selected, Caresphere service cannot be provided.

6 Touch [OK].

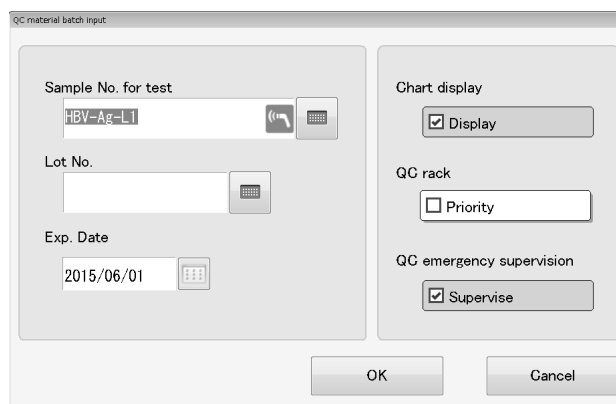
The [QC material batch input] dialog box appears.

7 Touch the tests you want to use in the test selection area.

Select the QC tests that you want to run using the QC material selected in the material list area.

8 Touch [New] in the lot information area.

The following dialog box appears.



The dialog box is titled "QC material batch input". It contains the following fields and controls:

- Sample No. for test:** A text field containing "HBV-Ag-L1" with a touch icon to its right.
- Lot No.:** An empty text field with a touch icon to its right.
- Exp. Date:** A date field showing "2015/06/01" with a calendar icon to its right.
- Chart display:** A checkbox labeled "Display" which is checked.
- QC rack:** A checkbox labeled "Priority" which is unchecked.
- QC emergency supervision:** A checkbox labeled "Supervise" which is checked.
- Buttons:** "OK" and "Cancel" buttons at the bottom right.



Information

You can also select a lot and touch [Edit] to edit the information of that lot.
 When the lot information is edited, the previous lot information is overwritten without deleting the QC chart data of the lot.
 You cannot edit the lot number for material that has been registered in [408. QC lot batch registration].

9 Set the displayed items.

The following items are displayed in the dialog box:

[Sample No. for test]	Set the sample number used for QC analysis.
[Lot No.]	Enter the lot number of the QC material.
[Exp. Date]	Enter the expiration date of the QC material. If the expiration date is not indicated on the QC material, enter the last day of the month the material expires.
[Chart display]	Select this checkbox to display the selected lot in the QC chart.
[QC rack]	Select this checkbox to set this lot as the lot used when the QC rack is used for analysis.
[QC emergency supervision]	Select this checkbox to have an error notification generated when an analysis result exceeds the allowed QC data range



Note:

- When [QC(special sample No.)] is enabled in the auto rack order settings, QC analysis can be performed automatically without registering an order.
For information on the auto rack order settings, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings")
- When using Caresphere service, enter the lot number according to the "HISCL Code Table", which can be obtained from the Caresphere site.

10 Touch [OK].

All QC materials are registered.

7.3 Registering a QC order

This section explains the registration tasks that are necessary to perform QC analysis. After registering the material, register a QC order on the [Order registration] screen.

7.3.1 Using a QC rack to register a QC order

When a QC rack is used, the QC order is automatically registered when analysis starts.

For the procedure for setting the QC rack, see Chapter 8.

(►P.188 "Chapter 8: 8.1.7 Registering a default order for a rack")

To start QC analysis, see the following.

(►P.163 "7.4 Performing QC analysis")

7.3.2 Registering a QC order without using a QC rack

Follow the steps below to register a QC order without using a QC rack.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [QC] on the operation panel.

The following screen appears.

Order display area

Sample position

Order input area

3 Populate the displayed fields.

The following items are displayed in the dialog box:

Order display area	Displays the contents of the order entered for each rack number. When an order has not been completed, the sample position number appears in yellow. Specify tests and complete the order.
[Clear]	Touch to delete the entered order.
[Rack No.]	Enter the rack number. This can also be scanned using the handheld barcode reader.
Sample position	Select the position where the sample is placed.
[Material]	Select the material.
[Lot]	Displays the lot.
[Sample comment]	A sample comment can be entered.
[Sample No.]	Displays the sample number.
Order input area	Enter an analysis order for each sample.
[Test]	Select the test.
[Dilution]	Select the dilution ratio.
[R1R2R3]*	Select the R1-R3 reagent lot to be used.
[Only configured tests]	Select the checkbox to display a list of the parameters registered for the selected [Material].
[Next sample]	Touch to complete the entered order. The next order can be registered.

* If a [R1R2R3] reagent is not selected, the reagent set for priority use is used.

For reagent priority use, see Chapter 5.

(►P.121 "Chapter 5: 5.4 Setting a reagent for priority use")

4 Touch [OK].

The QC order is registered.

A green checkmark appears on registered orders.

Entered orders can also be viewed on the [Joblist] screen.

To start QC analysis, see the following.

(►P.163 "7.4 Performing QC analysis")



Note:

- To edit a registered order, select the order you want to edit on the [Order registration] screen. Touch [Correction] on the operation panel and edit the order.
(►P.180 "Chapter 8: 8.1.1 Order registration screen")
- The analysis order depends on the item sort settings.
For the item sort settings, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 5: 5.4.3 Configuring test sorting settings")

7.4 Performing QC analysis

X-bar control or L-J control can be used on the HISCL-5000 to simultaneously analyze control of 3 lots of QC materials.

A QC error is reported when a QC analysis result exceeds the specified limit.



Warning!

Always run a QC check before starting the day's analysis work to ensure that there are no QC errors.

Follow the steps below to perform QC analysis.

1 Prepare the sample (control).

Follow the instructions on the package insert to prepare each sample (control).

2 Register the order.

If the order is in the host, it is not necessary to register the order.

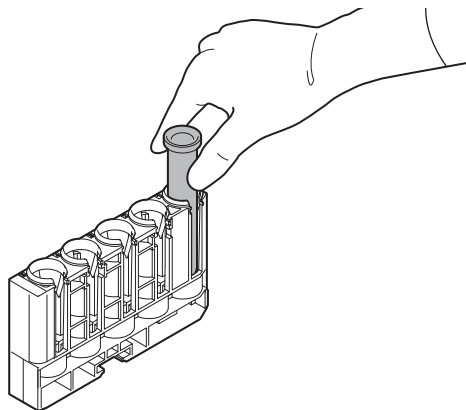
For the procedure for registering orders, see the following.

(►P.161 "7.3 Registering a QC order")

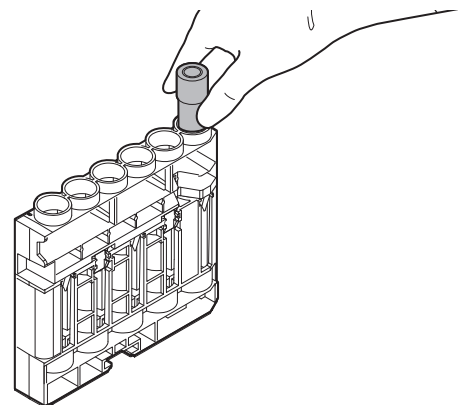
3 Load the sample tubes or sample cups containing the controls in the sample rack.

Load the sample tubes or sample cups containing the controls as specified in the registered QC order.

If using a rack with a default order registered for QC analysis, load the sample cups in the registered QC rack.



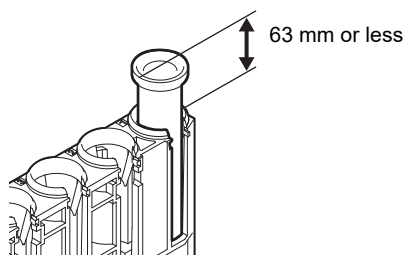
Using the sample tube



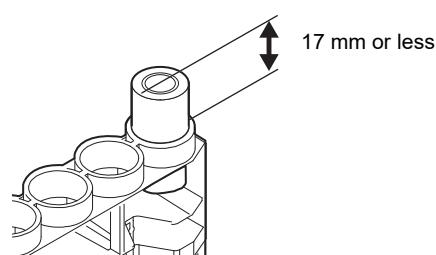
Using the sample cup

Warning!

- When loading sample tubes or sample cups in the sample rack, firmly push all the way in.
 - When using the sample tubes, load so that they are no more than 63 mm from the top of the rack. When using the sample cups, load so that they are no more than 17 mm from the top of the rack.
- There is a risk of the rack falling and sample splashing.



Using the sample tube



Using the sample cup

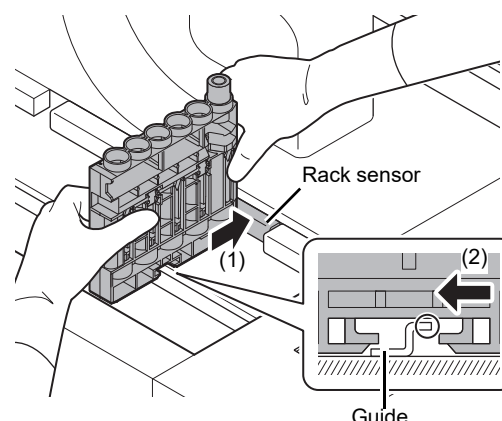
4 Place the sample rack so that the guide on the sampler fits into the notch in the rack.

- (1) Push the sample rack against the rack sensor on the sample rack feeder.
- (2) Place the sample rack so that the guide on the sampler fits into the notch in the sample rack.

The instrument's status LED indicates that the instrument is in operation.

After the instrument initializes, the sample rack is fed in and analysis starts.

The analysis will take about 20 minutes.



Information

- Hold both ends of the sample rack as shown above and load in the sampler.
- If the sample rack is not placed correctly in the sampler, the instrument may malfunction.
- Leaving samples at room temperature for a prolonged period may cause the samples to deteriorate. Place the sample in the sampler immediately before starting analysis.

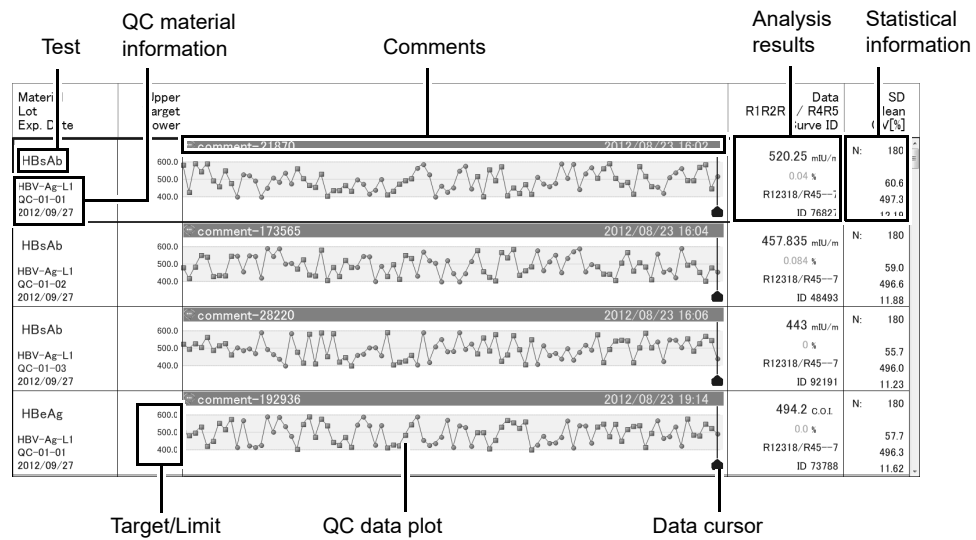
7.5 Checking QC data

This section explains how to check the results of QC analysis.

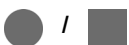
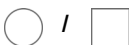
7.5.1 QC chart screen

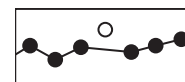
QC analysis results are displayed in chronological order on the QC chart.

The data of the most recent 180 tests appears.



Test	Displays the test. If set not to detect QC errors, [Unsupervised] will appear at the upper right of the test.
QC material information	QC material name Lot number Expiration date QC material name Lot number Expiration date
Target/Limit	Displays the target/limit assigned to the chart.
Upper	Displays the upper limit value.
Target	Displays the target.
Lower	Displays the lower limit value.

QC data plot	Displays the QC analysis results.
	Indicates that the analysis result is a control result and is within the upper and lower limits. The plot alternates between  and  each time the R1-R5 reagent lot changes.
	Indicates that the analysis result is excluded from control. Displayed when the analysis data is excluded from control. As shown at right, a point that is excluded from control is not joined to the line. Even if outside the upper and lower limit range of control, data excluded from control is shown this way. The plot alternates between  and  each time the R1-R5 reagent lot changes. For data excluded from control, see the following. (►P.174 "7.7.1 Including data in QC/excluding data from QC")
X	Indicates that the analysis result is a QC error and exceeds the upper or lower limit.
Comments	Displays a comment added to the data point at the cursor position.
Data cursor	Selects a data point on the chart. The analysis date and time of the data indicated by the cursor is displayed at the upper right.
Analysis results	The QC analysis result indicated by the cursor is displayed.
Concentration	Displays the concentration.
Deviation range	Displays the range of deviation from the target.
Lot number	Displays the lot numbers of R1-R5 that were used for analysis. Displayed in the format XXXX/YYYYY*. * XXXX: Lot number of R1-R3 YYYY: Lot number of R4/R5
Standard curve ID	Displays the ID of the standard curve used for analysis. For information on standard curve IDs, see Chapter 6. (►P.133 "Chapter 6: Creating a standard curve")
Statistical information	Displays statistical information on the data on the chart. If the analysis results are specified in [Select date range], the statistical values for the specified results are displayed. The statistical information does not include data that is excluded from control.
N	Displays the number of analysis results.
SD	Displays the standard deviation (N-1 method) of the concentration.
Mean	Displays the average value of the concentration.
CV	Displays the coefficient of variation of the concentration as a percentage.



520.25 mIU/m — Concentration
0.04 % — Deviation range
R12318/R45—7 — Lot number
ID 76827 — Standard curve ID

N: 180 — N

60.6 — SD

497.3 — Mean

12.19 — CV

7.5.2 Selecting displayed data by date

Data analyzed during a specific period can be selected by specifying a date range; for example, from the beginning to the end of the month.

Follow the steps below to select data.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Touch [Select date range] on the operation panel.

The dialog box on the right appears.

Set the start date and end date.

Enter dates by selecting from the calendar.



3 Touch [OK].

The dialog box closes, and the data of the specified dates appears.



Note:

The data of the specified dates is selected.

With the analysis results selected, perform the next task, such as printing.

7.5.3 Editing the QC tab

The steps for creating, editing, and deleting QC tabs are explained below.

QC charts on a QC tab can also be sorted.

Follow the steps below to edit a tab.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

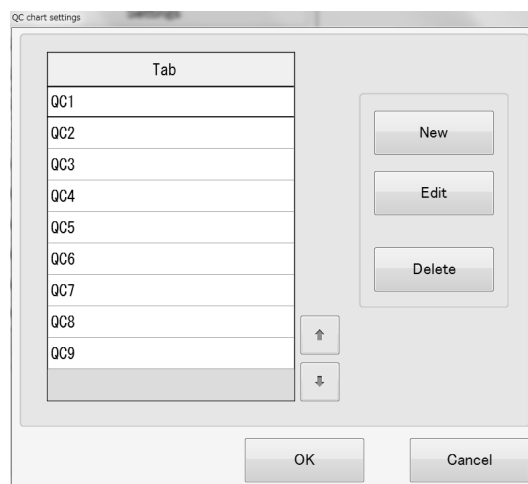
2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

3 Select [406. QC chart settings] and touch [Settings].

The [QC chart settings] dialog box appears.



[QC chart settings] dialog box

4 Populate the displayed fields.

The following items are displayed in the dialog box:

[Tab]	Displays the tab name.
[New]	Touch to create a new QC tab in the dialog box that appears.
[Edit]	Touch to edit the selected QC tab in the dialog box that appears.
[Delete]	Touch to delete the selected tab.

5 Touch [OK].

The dialog box closes, and the set QC tab appears.

7.5.3.1 Creating a new QC tab

Follow the steps below to create a new QC tab.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

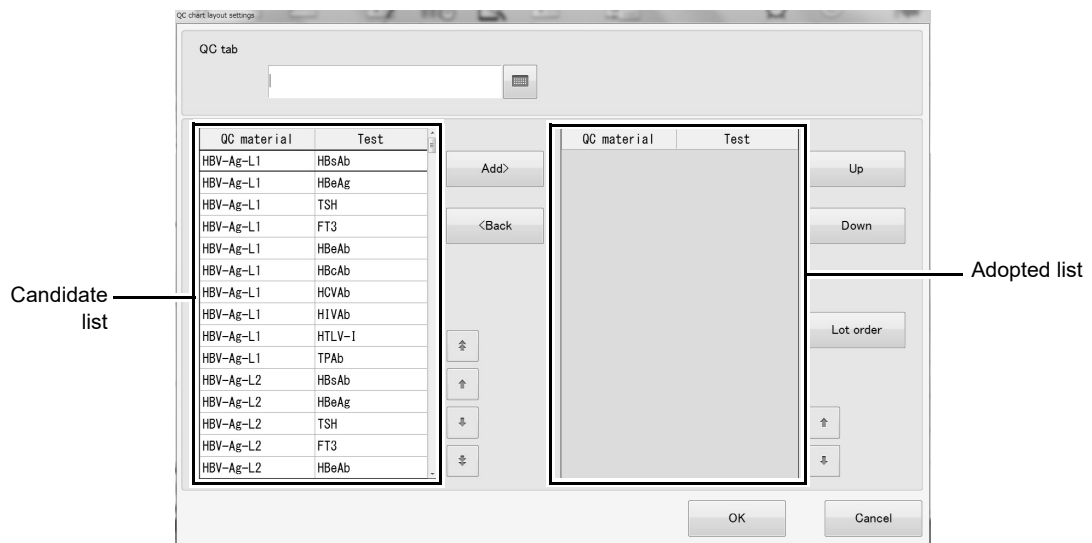
(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

3 Select [406. QC chart settings] and touch [Settings].

The [QC chart settings] dialog box appears.

4 Touch [New].

The [QC chart layout settings] dialog box appears.



[QC chart layout settings] dialog box

5 Populate the displayed fields.

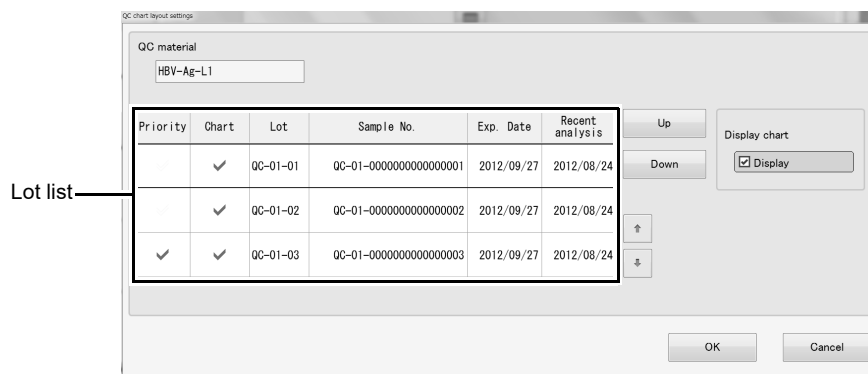
The following items are displayed in the dialog box:

[QC tab]	Enter the tab name.
Candidate list	Displays a list of the QC materials.
Adopted list	Displays the QC materials added from the candidate list.
[Add]	Touch to move the selected material from the candidate list to the adopted list.
[Back]	Touch to move the selected material from the adopted list to the candidate list.
[Up]/[Down]	Touch to move the selected material up or down one line.
[Lot order]	Touch to change the order of the selected materials in the dialog box that appears.

6 Touch [Lot order].

The following dialog box appears.

Specify the order of the lots and the displayed items.



[QC material]	Displays the QC material label.
Lot list	The QC materials are sorted by lot in the list.
[Display chart]	
[Display]	Select the checkbox to display the selected chart in the QC chart list.
[Up]/[Down]	Touch to move the selected chart up or down one line.

7 Touch [OK].

The dialog box closes, and a tab is created with the set QC chart order on the QC screen.

7.5.3.2 Editing a QC tab

Follow the steps below to edit a QC tab.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

3 Select [406. QC chart settings] and touch [Settings].

The [QC chart settings] dialog box appears.

4 Select the tab that you want to change and touch [Edit].

The [QC chart layout settings] dialog box appears.

Follow steps 5 and 6 of the tab creating procedure.

For new creation, see the following.

(►P.169 "7.5.3.1 Creating a new QC tab")

5 Touch [OK].

The dialog box closes, and the QC charts on the QC screen are sorted in the set order.

7.5.3.3 Deleting a QC tab

Follow the steps below to delete a QC tab.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

3 Select [406. QC chart settings] and touch [Settings].

The [QC chart settings] dialog box appears.

4 Select the tab that you want to delete and touch [Delete].

5 Touch [OK].

The dialog box closes and the selected tab is deleted.

7.6 Searching for QC errors

You can search for analysis results in which a QC error occurred.
Follow the steps below to search for QC errors.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Select the chart that you want to search for errors.

3 Touch [QC error search] on the operation panel.

The cursor moves to the error analysis results in the selected chart.



Information

After you have verified that there are no QC errors or that the errors have been cleared, perform sample analysis.



Note:

- Each time you touch [QC error search], the cursor moves to the next QC error.
- If the analysis results of QC analysis are out of scope of control, you can make the settings to temporarily skip the analysis of some specific items. For details, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 5: 5.4.4 Selecting items that are to be temporarily excluded from analysis")

7.7 Editing QC data

The actions below can be performed with respect to an analysis result.

- A result can be excluded from QC.
- A result can be excluded from QC error searches.
- A comment can be entered.

7.7.1 Including data in QC/excluding data from QC

Data that is excluded from QC using the exclude from QC setting is not recognized as abnormal when the data exceeds the upper or lower QC limit, and is displayed in the chart using the QC-excluded plot pattern.

Excluding analysis data from QC also excludes the data from the following functions:

- Statistical calculations (N, Mean, SD, CV)
- Target/Limit auto calculation
- Variable target calculation
- Error search

Follow the steps below to select settings.

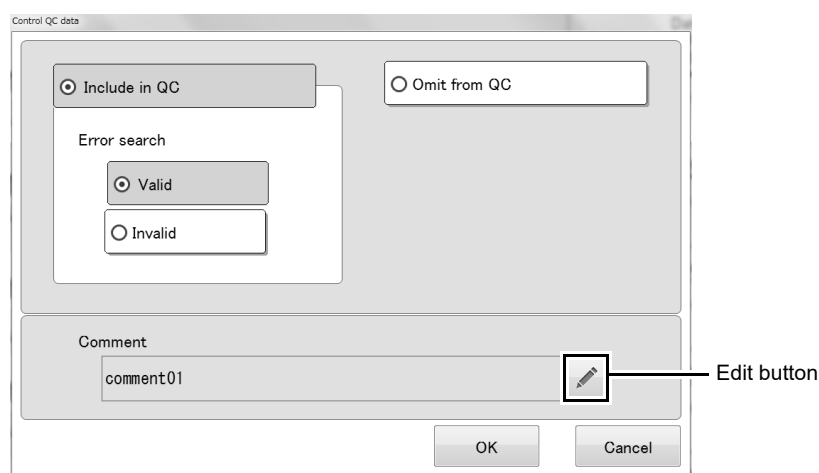
1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Select the analysis results whose QC data control settings you want to change.

3 Touch [QC data administration] on the operation panel.

The [Control QC data] dialog box appears.



[Control QC data] dialog box

4 Select settings.

The following items are displayed in the dialog box:

[Include in QC]	Select to include the data in QC. The data will be included in statistical calculations.
[Error search]	
[Valid]	Select to include in QC error searches.
[Invalid]	Select to exclude from QC error searches.
[Omit from QC]	Select to exclude the data from QC. The data point is plotted on the chart, but is not included in statistical calculations. The data is excluded from QC error searches.
[Comment]	Any comment can be added to analysis data. For information on comments, see the following. (► P.176 "7.7.2 Adding a comment to QC data")

5 Touch [OK].

The dialog box closes, and the screen is updated based on your settings.



Note:

- When an analysis result is excluded from quality control, the plot display changes. Entered comments can be viewed by moving the cursor to the analysis result.
- The QC data control setting applies only to the data point selected by the cursor. Even if multiple results are selected, the QC data control setting is only applied to the result selected by the cursor.

7.7.2 Adding a comment to QC data

Any comment can be added to analysis data. Comments can be entered, edited, and deleted for any type of analysis data, including normal data, abnormal data, and QC-excluded data.

A comment can be viewed by simply moving the data cursor to the analysis result.

Follow the steps below to enter, edit, or delete a comment.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Select the analysis results to which you want to add a comment.

3 Touch [QC data administration] on the operation panel.

The [Control QC data] dialog box appears.

4 Touch the [Comment] edit button.

The software keyboard appears.

5 Enter, edit, or delete the comment.

6 Touch [OK].

The dialog box closes and the comment is added to the selected QC data.

7.7.3 Deleting QC data

Unrequired analysis results can be deleted from the chart. Analysis results that are in the selected state will be deleted.

Follow the steps below to delete QC data.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Select the analysis results that you want to delete.

3 Touch [Delete] on the operation panel.

4 Touch [OK].

The dialog box closes and the selected analysis results are deleted.

7.8 Saving QC data

QC data can be saved. The procedures for saving data to a file and printing data are explained below.

7.8.1 Saving to a file

The control data and analysis data in a specified chart can be saved to a file in CSV format. Analysis results, control material information, statistical data, comments, and other data are output. Only charts that are selected are saved. Follow the steps below to save a QC chart to a file.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Select the chart that you want to save to a file.

3 Touch [File output] on the operation panel.

The dialog box appears.

4 Specify the save folder.

5 Enter the file name.

The file extension is ".csv".

**Note:**

The default file name is "QC_test display name_QC material name_material lot number_date created (YYYYMMDD)_time created (HHMMSS).csv".

6 Touch [OK].

The dialog box closes and the CSV file is stored in the specified folder.

7.8.2 Printing

A QC chart can be printed in a specified format.

Analysis results that meet the automatic output conditions are printed automatically.

To set the auto output conditions, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 6: 6.3 Setting conditions for automatic output of analysis results (host output and printing)")



Information

To print, connect a printer.

Printing is not possible unless a printer is connected.

7.8.2.1 Printing in report format

Report print formats are [Print LP] and [Print GP].

Follow the steps below to print in report format.

1 Touch [QC] on the toolbar.

The [Quality control] screen appears.

2 Select the tab, chart, or QC results that you want to print.

3 Touch the print format on the operation panel.

A confirmation dialog box appears. Make sure that a printer is in the READY state.

4 Touch [OK].

The dialog box closes and printing starts.



Note:

If you have remarks regarding the contents of the report, enter the remarks in "Remarks" on the cover page, and then sign on the "Signature" line to make the report a documentation report.

Chapter 8 Performing sample analysis

This chapter explains how to perform analysis on the HISCL-5000.

8.1 Registering an order

Analysis is performed based on registered analysis orders.

An order consists of a sample number, rack number, test, dilution ratio, and test count.

Registered orders are displayed on the [Joblist] screen.

The following methods can be used to register analysis orders on the HISCL-5000:

- **Manual input**

Entry by test

Batch input using a test set

- **Input of order information from host computer**

Batch query

Real-time query

- **Automatic input of registered default orders**

For the procedure for registering a default order for a rack, see the following.

(▶P.188 "8.1.7 Registering a default order for a rack")



Caution!

If a sample comment or patient comment that exceeds the specified number of characters is received from the host computer, only the specified number of characters are saved and the remaining characters are discarded.



Note:

- To register an order for calibration, see Chapter 6.
(▶P.141 "Chapter 6: 6.4 Registering a standard curve order")
- To register an order for QC analysis, see Chapter 7.
(▶P.161 "Chapter 7: 7.3 Registering a QC order")

8.1.1 Order registration screen

Touch [Order Regist] on the toolbar to display the following screen.

The screenshot shows the [Order registration] screen. It features a table with the following columns: Rack, Sample No., Set, HBsAg, HBsAb, HBeAg, TSH, FT3, FT4, PSA, AFP, CEA, HBsAb, and HBeAb. The table is divided into two sections: 'Order list' (Rack 1/2) and 'Test set' (Rack 2/2). Below the table, there are fields for 'Sample information' (Search, 001, 2012/09/22 14:12:50, 1-1) and 'Patient information' (Name, ID, Address).

[Order registration] screen

Order list	Displays the registered orders.
[Rack]	Displays the rack number.
[Sample No.]	Displays the sample number.
Test set	Displays whether a test set is specified. ✓: A test set has been specified. (Blank): A test set has not been specified. * Not displayed if a test set is not specified. For test set settings, see Chapter 3 or the "Administrator's Guide". (►P.74 "Chapter 3: 3.10.7 Analysis result settings") (►Administrator's Guide, "Chapter 5: 5.3 Editing test sets")
Test	Displays whether the tests are specified. ✓: Specified. (Blank): Not specified. [1/2], [1/4], [1/10], [1/20], [1/40], [1/100], [1/400], [1/1600]: Analyzes at the indicated dilution ratio. [x2]: Analyzes the indicated number of times. * When a test set has been specified, individual tests cannot be specified. To specify individual tests, remove the checkmark for the test set.
[Search]	Select the checkbox to read sample barcodes with the handheld barcode reader and search for a sample number.
Sample information	Displays the sample information.
Patient Information	Displays the patient information that corresponds to the sample.

8.1.2 Registering a sampler order

When the sampler is used, analysis orders for 5 samples in each rack can be entered.

Up to 5 racks of used orders for which analysis has been completed are stored. New orders for 60 racks of samples can be input.

Follow the steps below to register a sampler order.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Sample rack] on the operation panel.

The following dialog box appears.

The screenshot shows the 'Order registration' dialog box. Labels on the left point to the 'Order display area' (a table showing rack and sample data), 'Sample position' (a row of buttons 1-5), 'Test set' (a grid of test selection buttons), and 'Order input area' (the same grid). A label on the right points to 'Patient information' (fields for Patient ID and Sample comment). Buttons at the bottom include 'Next sample', 'OK', and 'Cancel'.

Rack	Sample No.	Set-B1	HBsAg	HBsAb	HBsAg	TSR	FT3	FT4	FT4	AFP	CEA	PSA	TPA
1	001	✓	✓	1/100	1/100	✓							
2	002	✓	✓										
3	003												

3 Populate the displayed fields.

The following items are displayed in the dialog box:

Order display area	Displays the contents of the orders entered for each rack number. When an order has not been completed, the sample position number appears in yellow. Specify tests and complete the order.
[Clear]	Touch to delete the entered order.
[Host]	Touch to query the host computer for the order information and download the corresponding sample number and tests.
[Rack No.]	Enter the rack number. This can also be scanned using the handheld barcode reader.
Sample position	Select the position where the sample is placed.
[Sample No.]	Enter the sample number. This can also be scanned using the handheld barcode reader.
[Patient ID]	Enter the patient ID that corresponds to the sample.
[Sample comment]	A sample comment can be entered.
Patient Information	Displays the information of the patient associated with the ID entered in [Patient ID].
Order input area	Enter an analysis order for each sample.
[Test]	Select the test.

Test set	Specifies a test set. * When a test set has been specified, individual tests cannot be specified. To specify individual tests, remove the checkmark for the test set. * Not displayed if a test set is not specified. For test set settings, see Chapter 3 or the "Administrator's Guide". (►P.74 "Chapter 3: 3.10.7 Analysis result settings") (►Administrator's Guide, "Chapter 5: 5.3 Editing test sets")
[Dilution]	Select the dilution ratio.
[Duplex]	Select the test count.
[Survey sample]	Select the checkbox to specify a survey sample. Correction of the concentration in the analysis result will be turned off.
[Next sample]	Touch to complete the entered order. The next order can be registered.

4 Touch [OK].

The sampler order is registered.

A green checkmark appears on registered orders.

Entered orders can also be viewed on the [Joblist] screen.

To start sample analysis, see the following.

(►P.197 "8.2 Analyzing a sample")



Information

If the order for a rack is still being edited when the rack is fed into the sampler, analysis will not be performed. To analyze using the order, finish registering the order and then replace the rack in the sampler.



Note:

- The dilution ratio and test count set in the default order is used in both test sets and individual tests.
For information on the default order, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 5: Using Order Registration Functions")
- When order query is set and the sample rack ID or sample number are registered in the IPU retest list or default order for the rack, the tests are downloaded automatically.
For details, see Chapter 3.
(►P.73 "Chapter 3: 3.10.6 Analysis order settings")
- To edit a registered order, select the order you want to edit on the [Order registration] screen.
Touch [Correction] on the operation panel and edit the order.
(►P.180 "8.1.1 Order registration screen")
- The analysis order depends on the item sort settings.
For the item sort settings, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 5: 5.4.3 Configuring test sorting settings")

8.1.3 Registering an urgent sample order

An analysis order for an urgent sample can be entered.

An urgent (STAT Assay) sample is analyzed prior to samples in the sampler or conveyor line.

Follow the steps below to register an urgent sample order.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Urgent] on the operation panel.

The [STAT Assay] dialog box appears.

Order input area

Patient Information

Analysis types

[STAT Assay] dialog box

3 Populate the displayed fields.

The following items are displayed in the dialog box:

[Sample No.]	Enter the sample number. This can also be scanned using the handheld barcode reader.
[Patient ID]	Enter the patient ID that corresponds to the sample.
[Sample comment]	A sample comment can be entered.
Patient Information	Displays the information of the patient associated with the ID entered in [Patient ID].
Order input area	Enter an analysis order for each sample.
[Test]	Select the test.
[Dilution]	Select the dilution ratio.
[Duplex]	Select the test count.
[Current order]	Displays the input source of the currently displayed order.
Analysis types	Select the analysis type.
[Host]	Touch to query the host computer for the order.
[Adopt untested or retest]	Touch to use an order that was not analyzed due to an error, or a retest order that was automatically created due to criteria met during the initial test.
[Adopt STAT order]	Touch to use the registered default urgent sample order.
[Clear]	Touch to delete the entered order.

4 Touch [OK].

The urgent sample order is registered.

A green checkmark appears on registered orders.

Entered orders can also be viewed on the [Joblist] screen.

To start urgent sample analysis, see the following.

(► **P.202** "8.3 Analyzing an urgent sample")



Note:

- The dilution ratio and test count set in the default order is used in both test sets and individual tests.
For information on the default order, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 5: Using Order Registration Functions")
- When order query is set and the sample number is registered in the IPU retest list or default order for the rack, the tests are downloaded automatically.
For details, see Chapter 3.
(► **P.73** "Chapter 3: 3.10.6 Analysis order settings")
- To edit a registered order, touch [STAT] on the toolbar and edit the order.
- The analysis order depends on the item sort settings.
For the item sort settings, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 5: 5.4.3 Configuring test sorting settings")

8.1.4 Deleting an order

An entered order can be deleted.

There are 2 methods in deleting orders: by sample and by rack.

8.1.4.1 Deleting by sample

An order for a sample can be deleted.

Follow the steps below to delete an order for a sample.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Select the order that you want to delete.

3 Touch [Delete sample] on the operation panel.

The order is deleted.



Note:

When the cursor is moved to the order in step 2, a pop-up appears. You can also delete the order by touching [Delete sample] in the pop-up.

8.1.4.2 Deleting by rack

All orders of a rack can be deleted.

Follow the steps below to delete the orders of a rack.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Select the rack whose orders you want to delete.

3 Touch [Delete rack] on the operation panel.

The orders are deleted.

To delete additional racks, repeat steps 2 to 3.



Note:

When the cursor is moved to the order in step 2, a pop-up appears. You can also delete the rack orders by touching [Delete rack] in the pop-up.

8.1.5 Using the work list

The work list can be used to register an order based on the sample number.
Follow the steps below to register an order using the work list.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Worklist] on the operation panel.

The following dialog box appears.

Order display area

Order input area

Patient information

3 Populate the displayed fields.

The following items are displayed in the dialog box:

Order display area	Displays the contents of the entered order. When an order has not been completed, the sample position number appears in yellow. Specify tests and complete the order.
[Clear]	Touch to delete the entered order.
[Host]	Touch to query the host computer for the order information and download the corresponding sample number and tests. A query is made for an order that specifies a only sample number without any tests.
[Sample No.]	Displays the sample number.
[Edit]	Select the checkbox to enter a sample number. This can also be scanned using the handheld barcode reader.
[Patient ID]	Enter the patient ID that corresponds to the sample.
[Sample comment]	A sample comment can be entered.
Patient Information	Displays the information of the patient associated with the ID entered in [Patient ID].
Order input area	Enter an analysis order for each sample.
[Test]	Select the test.
[Dilution]	Select the dilution ratio.
[Duplex]	Select the test count.
[Survey sample]	Select the checkbox to specify a survey sample. Correction of the concentration in the analysis result will be turned off.

[Next sample]	Touch to complete the entered order. The next order can be registered.
[Close]	Touch to close the dialog box.

4 Touch [Close].

The entered order is registered.

A green checkmark appears on registered orders.

8.1.6 Host computer query

When a host computer query is used, the order is automatically downloaded from the host computer based on the sample number acquired when the instrument's barcode reader scans the barcode on the sample.

If sample barcodes are not used and the sample has been placed, the rack number and sample position are used to automatically download the order.

In this case, the sample number is sent to the host computer if it has been entered on the [Order registration] screen. If the sample number has not been entered, a blank sample number is sent.

For urgent sample analysis, when the sample barcode is scanned and the sample is placed, the order can be automatically downloaded using the scanned sample number.



Information

- If the order downloaded from the host computer has an error in it, a query error will occur and the order will be discarded.
- If there are retest or default orders for a rack, these orders will be downloaded first.
If there are no retest or default orders for a rack, or retest and default orders for a rack are not configured to be used, the order will be downloaded from the host computer.
- When the patient ID is blank in patient information in an order downloaded from the host computer, an automatically assigned patient ID is registered. To check patient information, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 7: 7.1 Checking patient information")



Note:

- If a scanning error occurs when a sample barcode is scanned, the sample number will automatically be prefixed with "ERR". A query for a sample number beginning with "ERR" is not made to the host computer.
- For host computer query settings, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings")

8.1.7 Registering a default order for a rack

A default analysis order for QC analysis, standard curve analysis, or sample analysis can be registered for a rack number.

When a default analysis order is registered for a rack, just place the rack in the sampler or on the conveyor line and it will be analyzed using the default order.

There is no need to input an order prior to analysis.

This makes it easy to perform daily standard curve and QC analyses.

To register a default order for an urgent sample, see the following.

(►P.195 "8.1.9 Registering a default order for an urgent sample")



Information

To use the default order function, select the use setting for each rack (QC rack, standard curve rack, default order rack, and QC) in the auto rack order settings.

For information on the auto rack order settings, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings")

Follow the steps below to register a default order for a rack.

1 Touch [Menu] - [Settings] on the toolbar.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

2 Select [503. Rack settings] and touch [Settings].

The following dialog box appears.

[Rack]	Displays the registered rack number.
[New]	Touch to register a new rack number.
[Edit]	Touch to edit a registered rack number.
[Delete]	Touch to delete a registered rack number.
[Barcode input]	Select to enable input of rack number by handheld barcode reader.



Information

Duplicate numbers cannot be registered.

3 Touch [New] for the rack you want to register.

The order registration dialog box for the selected rack appears.



Note:

Select the rack that you want to edit and touch [Edit]. The rack order can also be edited.

4 Populate the displayed fields.

The dialog box varies depending on the rack that is selected.

● QC rack

Set orders for QC racks. Up to 50 racks can be registered.

Order display area

Sample position

Order input area

Order display area	Displays the contents of the entered order. When an order has not been completed, the sample position number appears in yellow. Specify tests and complete the order.
[Delete]	Touch to delete the entered order.
[Rack No.]	Enter the rack number. This can also be scanned using the handheld barcode reader.
Sample position	Select the position where the sample is placed.
[Material]	Select the material.
[Lot]	Displays the lot.
[Sample comment]	A sample comment can be entered.
Order input area	Enter an analysis order for each sample.
[Test]	Select the test.
[Dilution]	Select the dilution ratio.
[Next]	Touch to complete the entered order. The next order can be registered.

● Calibration rack

Set orders for calibration racks. Up to 50 racks can be registered.

Orders for calibration and QC can be set.

[Standard curve] tab

Order display area	Displays the contents of the entered order. When an order has not been completed, the sample position number appears in yellow. Specify tests and complete the order.
[Delete]	Touch to delete the entered order.
[Rack No.]	Enter the rack number. This can also be scanned using the handheld barcode reader.
Sample position	Select the sample position.
[Test]	Select the test.
[Calibrator]	Displays the lot of the calibrator.
[Sample comment]	A sample comment can be entered.
Order input area	Enter an analysis order for each sample.
[Sample No.]	Displays the sample number for calibration.
[Cal.]	Select the calibrator number. When a checkmark is removed, an order is not created.
[Duplex]	Select the test count.
[Dilution]	Select the calibrator test count used to determine the ratio for dilution correction. To perform dilution correction, contact your local Sysmex representative. Not shown when dilution correction is not performed for the test.
[Next]	Touch to complete the entered order. The next order can be registered.

[QC] tab

The contents of the screen are the same as for QC rack. (▶P.189 "●QC rack")

● Default order rack

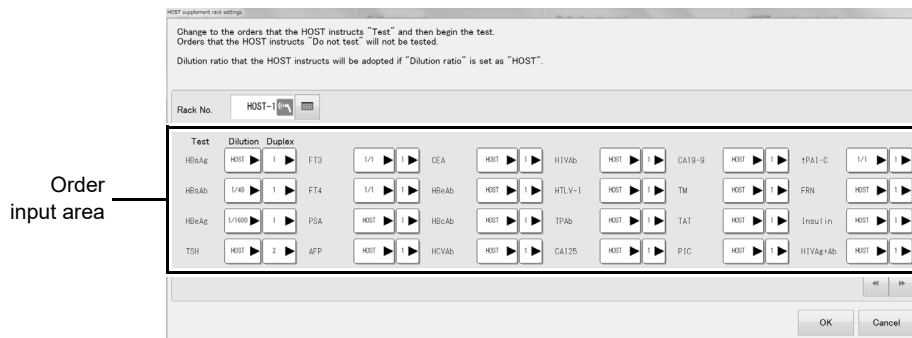
Set orders for racks that are always analyzed by default order. Up to 20 racks can be registered.

[Rack No.]	Enter the rack number. This can also be scanned using the handheld barcode reader.
[Sample comment]	A sample comment can be entered.
Order input area	Enter an analysis order for each sample.
[Test]	Select the test.
[Dilution]	Select the dilution ratio.
[Duplex]	Select the test count.

● Host supplement rack

Set racks for which the dilution ratio and test count of the test specified by the host computer by host real time query can be changed. Up to 20 racks can be registered.

The dilution ratio and test count in the order information received from the host computer can be set.



[Rack No.]	Enter the rack number. This can also be scanned using the handheld barcode reader.
Order input area	Enter an analysis order for each sample.
[Test]	Displays the test.
[Dilution]	Select the dilution ratio.
[Duplex]	Select the test count.

5 Touch [OK].

The dialog box closes.

6 Touch [OK].

The dialog box closes and the default order for a rack is registered.

To start standard curve analysis, see Chapter 6.

(►P.144 "Chapter 6: 6.5 Performing standard curve analysis")

To start QC analysis, see Chapter 7.

(►P.163 "Chapter 7: 7.4 Performing QC analysis")

To start sample analysis, see the following.

(►P.197 "8.2 Analyzing a sample")

8.1.8 Setting a 6-sample rack

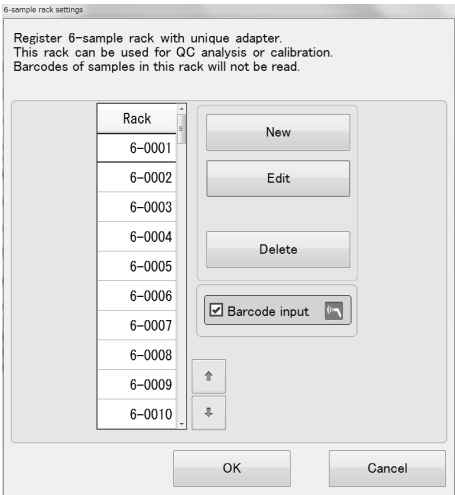
Register a rack on which a 6-sample adapter is to be attached.
Scanning of sample barcodes is not performed.
The 6-sample rack are mainly used for calibration and QC analysis.
Follow the steps below to set a 6-sample rack.

1 Touch [Menu] - [Settings] on the toolbar.

The [Settings] dialog box appears.
(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

2 Select [502. 6-sample-rack settings] and touch [Settings].

The dialog box on the right appears.



[Rack]	Displays the registered rack number.
[New]	Touch to register a new rack number.
[Edit]	Touch to edit a registered rack number.
[Delete]	Touch to delete a registered rack number.
[Barcode input]	Select the checkbox to enable input of rack number by handheld barcode reader.

3 Touch [New].

The dialog box on the right appears.



Information

Even if a 6-sample adapter is attached, a rack that is not registered as a 6-sample rack cannot be used.



Note:

Select the rack that you want to edit and touch [Edit]. The registered rack number can also be edited.

4 Enter the rack number.

Duplicate numbers cannot be registered.

5 Touch [OK].

The dialog box closes and the entered rack number appears in [Rack].

6 Touch [OK].

The dialog box closes and the rack is registered as a 6-sample rack.

8.1.9 Registering a default order for an urgent sample

A default analysis order can be registered for urgent samples.

When a default analysis order is registered, just place an urgent sample in the urgent sample holder and it will be analyzed using the default order.

There is no need to input an order prior to analysis.

If the sample ID is entered in the [STAT Assay] dialog box or if the sample ID is read with a handheld barcode reader before the sample is placed in the urgent sample holder, analysis will take place using the entered sample ID.

If a sample ID is not entered in advance, a sample ID prefixed with "Auto" is automatically assigned.



Information

To use the default order function, select the use STAT default order setting in the auto STAT order settings.

For information on the auto STAT order settings, see the "Administrator's Guide"

(►Administrator's Guide, "Chapter 5: 5.6 Configuring urgent sample order query settings")

Follow the steps below to register a default order for urgent samples.

1 Touch [Menu] - [Settings] on the toolbar.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

2 Select [506. STAT default order settings] and touch [Settings].

The following dialog box appears.

STAT default order settings

Set up STAT default order.
Switch Auto adopt this order/Do not adopt this order in "Auto STAT order settings".
Order can also be manually adopted in STAT order registration.

Test set	Dilution	Duplex
☐ Set-01	☒ TSH	1/1 2
☒ HCVAb	1/1	☐ FT3
☒ HEVAb	1/40	☐ FT4
☒ HIV-1	1/1600	☐ PSA

☐ HCVAb ☐ CA125 ☐ P1C
☐ HEVAb ☐ CA19-9 ☐ HPA1-C
☐ HIV-1 ☐ TNF ☐ PRN
☐ TPAb ☐ TAT ☐ Insulin

OK Cancel

3 Populate the displayed fields.

The following items are displayed in the dialog box:

[Test]	Select the test.
Test set	Specifies a test set. * When a test set has been specified, individual tests cannot be specified. To specify individual tests, remove the checkmark for the test set. * Not displayed if a test set is not specified. For test set settings, see Chapter 3 or the "Administrator's Guide". (►P.74 "Chapter 3: 3.10.7 Analysis result settings") (►Administrator's Guide, "Chapter 5: 5.3 Editing test sets")
[Dilution]	Select the dilution ratio.
[Duplex]	Select the test count.

4 Touch [OK].

The dialog box closes and the default order for urgent sample analysis is registered.

To start urgent sample analysis, see the following.

(►P.202 "8.3 Analyzing an urgent sample")

8.2 Analyzing a sample

This section explains the procedures for analyzing a sample.

8.2.1 Performing analysis from the sampler

Follow the steps below to perform analysis from the sampler.

1 Make sure the instrument is in the READY state.

If analysis is in progress, the rack will be automatically transported to the instrument when placed.

Make sure that the order registration has been completed.

If order registration has not been completed, the order will be registered in the untested/retest list.

For details, see Chapter 9.

(►P.214 "Chapter 9: 9.4.1 Displaying the untested/retest list")

2 Check the connection between the conveyor line and the HISCL-5000.

Make sure that the [LINE] icon in the bottom right corner of the IPU screen is not green.

If the conveyor line is set for priority use, change the priority use setting to the sampler.

For details, see Chapter 9.

(►P.217 "Chapter 9: 9.5 Switching conveyor line and sampler priority")

3 Register the order.

If the order is in the host or a default order is registered for the rack, order registration is not necessary.

Go to the next step.

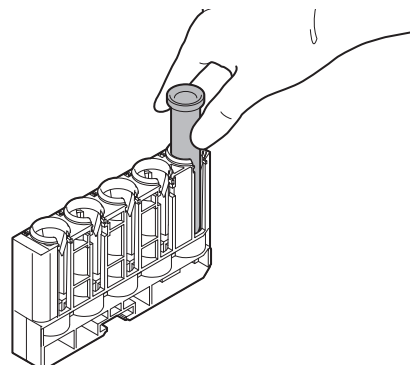
For the procedure for registering orders, see the following.

(►P.181 "8.1.2 Registering a sampler order")

For the procedure for registering a default order for a rack, see the following.

(►P.188 "8.1.7 Registering a default order for a rack")

4 Load the sample tubes or sample cups containing the samples in the sample rack.



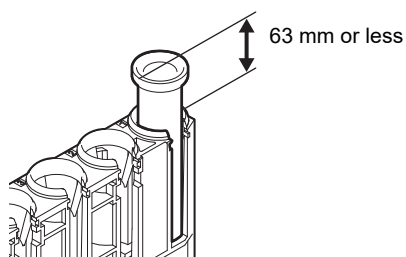
i Information

Leaving samples at room temperature for a prolonged period may cause the samples to deteriorate. Place the sample in the sampler immediately before starting analysis.

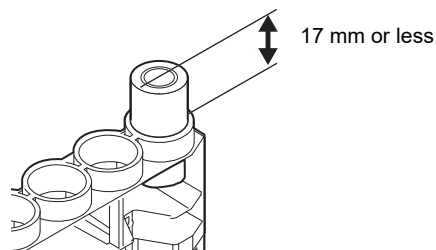
! Warning!

- When loading sample tubes or sample cups in the sample rack, firmly push all the way in.
- When using the sample tubes, load so that they are no more than 63 mm from the top of the rack. When using the sample cups, load so that they are no more than 17 mm from the top of the rack.

There is a risk of the rack falling and sample splashing.



Using the sample tube



Using the sample cup

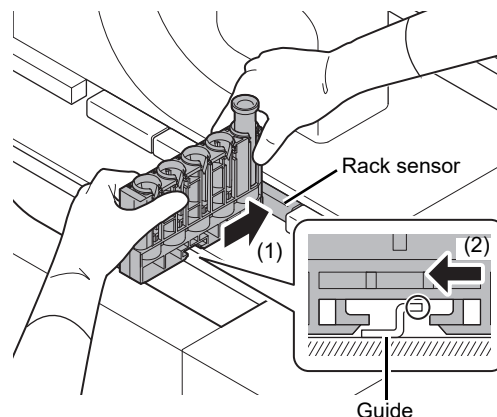
5 Place the sample rack so that the guide on the sampler fits into the notch in the rack.

- (1) Push the sample rack against the rack sensor on the sample rack feeder.
- (2) Place the sample rack so that the guide on the sampler fits into the notch in the sample rack.

The instrument's status LED indicates that the instrument is in operation.

After the instrument initializes, the sample rack is fed in and analysis starts.

The analysis will take about 20 minutes.



Information

- Hold both ends of the sample rack as shown above and load in the sampler.
- If the sample rack is not placed correctly in the sampler, the instrument may malfunction.
- When many tests are performed or the tests are time consuming, the samples may wait longer before being aspirated after they have been placed in the sampler. Make sure that the samples do not deteriorate due to the effects of room temperature or evaporation during this waiting time.
- If the sample number registered on the [Order registration] screen and the sample number read by the instrument barcode reader are not the same, analysis may not be performed (this depends on the settings).
For details, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings")
- Do not move the rack in the analysis lane (the innermost rack) while analysis is in progress. The rack in the analysis lane is monitored to prevent sample mix-ups. If an abnormal condition is detected, sample dispensing is stopped.



Note:

- When 5-sample racks are used, up to 20 racks (100 samples) can be loaded simultaneously.
- To check analysis results, see Chapter 10.
(► **P.219** "Chapter 10: 10.1 Checking the list of analysis results (Job list)")
- For the procedures for registering and deleting orders, see the following.
(► **P.179** "8.1 Registering an order")
- Once the rack number is read after analysis starts and the background of the corresponding order changes to gray, you will not be able to edit the order.
- Additional analysis orders can be registered and racks (samples) can be added while analysis is in progress. Simply place the rack in the sampler and analysis will continue. It is not necessary to touch the [Start].

8.2.2 Performing analysis from the conveyor line

Follow the steps below to perform analysis from the conveyor line.

1 Make sure the instrument is in the READY state.

If analysis is in progress, the rack will be automatically transported to the instrument when placed.

Make sure that registration of the order has been completed.

If order registration has not been completed, the order will be registered in the untested/retest list.

For details, see Chapter 9.

(►P.214 "Chapter 9: 9.4.1 Displaying the untested/retest list")

2 Check the connection between the conveyor line and the HISCL-5000.

Make sure that the [LINE] icon in the bottom right corner of the IPU screen is green.

If the sampler is set for priority use, change the priority use setting to the conveyor line.

For details, see Chapter 9.

(►P.217 "Chapter 9: 9.5 Switching conveyor line and sampler priority")

3 Register an order.

If the order is in the host or a default order is made, order registration is not necessary.

Go to the next step.

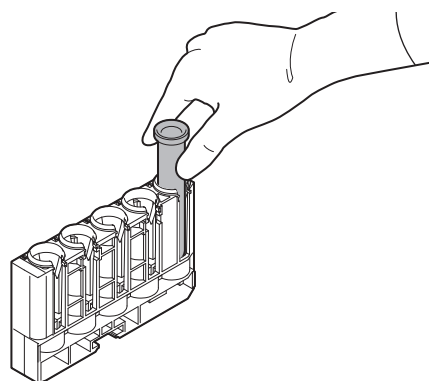
For the procedure for registering orders, see the following.

(►P.181 "8.1.2 Registering a sampler order")

For the procedure for registering a default order for a rack, see the following.

(►P.188 "8.1.7 Registering a default order for a rack")

4 Load the sample tubes or sample cups containing the samples in the sample rack.



5 Place the sample rack on the conveyor line.

The instrument's status LED indicates that the instrument is in operation.

After the instrument initializes, the sample rack is fed in and analysis starts.

If there is a rack in the sampler, the rack in the sampler will be analyzed before the samples on the conveyor line.

**Note:**

- To check analysis results, see Chapter 10.
(► **P.219** "Chapter 10: 10.1 Checking the list of analysis results (Job list)")
- Once the rack number is read after analysis starts and the background of the corresponding order changes to gray, you will not be able to edit the order.
- Additional analysis orders can be registered and racks (samples) can be added while analysis is in progress. While analysis is in progress, it is not necessary to touch the [Start].
- Even after the previously loaded rack is stored, if you register an order and load a rack while analysis is still in progress, the new rack will be analyzed.
- If you wish to analyze samples on the conveyor line first (for example, when samples remain on the conveyor line), you can manually change the order of priority.
For the procedure for changing the order of priority, see Chapter 9.
(► **P.217** "Chapter 9: 9.5 Switching conveyor line and sampler priority")

8.3 Analyzing an urgent sample

To analyze a sample that requires urgent analysis, use the urgent sample holder.

An urgent sample is given priority over regular samples. A sample can be placed in the urgent sample holder.

For usable sample cups, see Chapter 5.

(►P.124 "Chapter 5: 5.5.2 Usable sample tubes and sample cups")

When processing of the urgent sample is finished, the interrupted regular analysis resumes automatically.

Follow the steps below to perform urgent sample analysis.

1 Register an order.

If the order is in the host or a default order is made, order registration is not necessary.

Go to the next step.

For the procedure for registering orders, see the following.

(►P.183 "8.1.3 Registering an urgent sample order")

For the procedure for registering a default order for urgent samples, see the following.

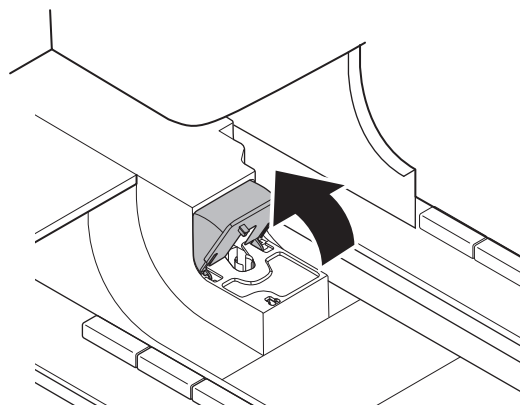
(►P.195 "8.1.9 Registering a default order for an urgent sample")



Note:

- To check analysis results, see Chapter 10.
(►P.219 "Chapter 10: 10.1 Checking the list of analysis results (Job list)")
- For the procedures for registering and deleting orders, see the following.
(►P.179 "8.1 Registering an order")

2 Open the urgent sample holder cover.

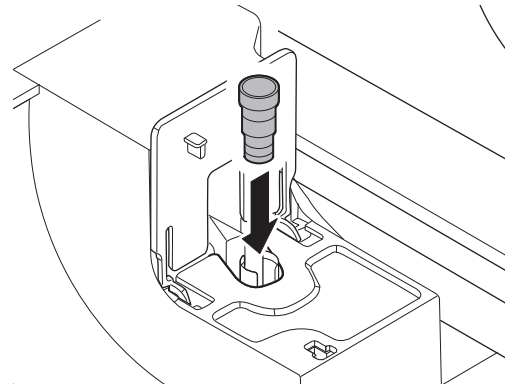


Risk of infection

There is a risk of infection from pathogens and other contaminants if any part or surface of the instrument is touched.

3 Insert the sample into the urgent sample holder.

Insert the sample all the way in.



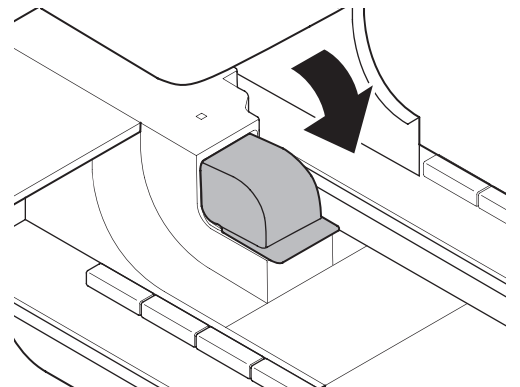
4 Close the urgent sample holder cover.

Analysis of the urgent sample starts.

The cover locks and the urgent sample holder status LED blinks.

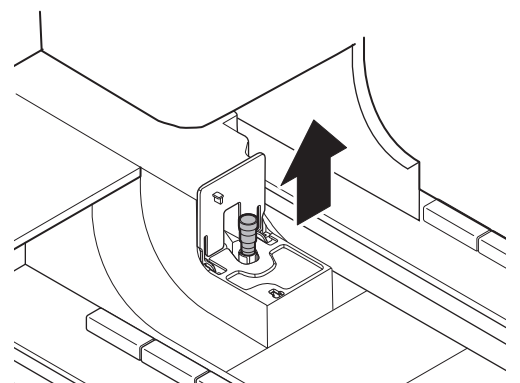
After the sample is aspirated, the urgent sample order is cleared from the [Order registration] screen and the next order can be entered.

When analysis is complete, the cover lock releases and the urgent sample holder status LED lights steadily.



5 Open the urgent sample holder cover.

6 Remove the sample from the urgent sample holder.



7 Close the urgent sample holder cover.



Note:

To check analysis results, see Chapter 10.

(►P.219 "Chapter 10: 10.1 Checking the list of analysis results (Job list)")

Chapter 9 Operations during analysis

This chapter explains the tasks that the operator performs during analysis.

9.1 Checking analysis end time

The analysis end time or time remaining for the completion of a test can be checked.

9.1.1 Checking the end time

Follow the steps below to check the analysis end time.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

For details, see Chapter 10.

(► **P.220** "Chapter 10: 10.1.1 Job list screen")

2 Check the time in [Left].



Note:

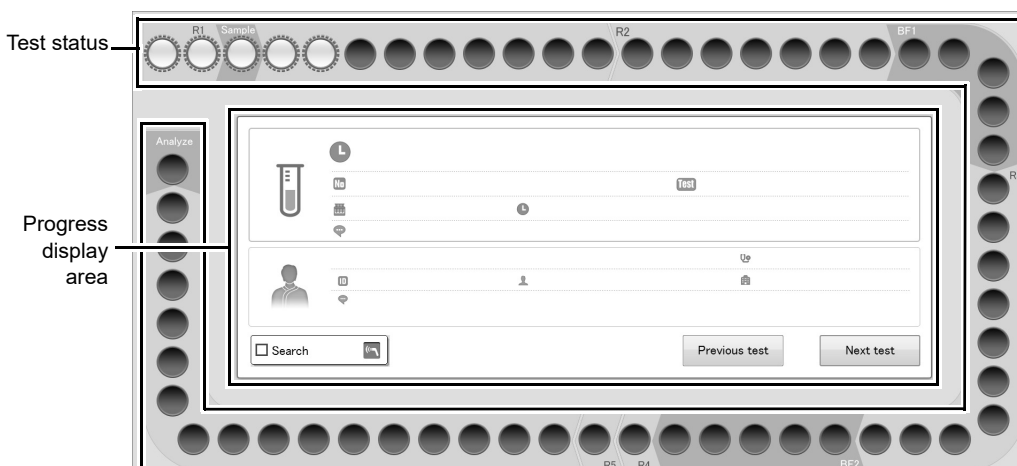
Until the sample is aspirated, the order registration time appears. When sample aspiration finishes, the time is updated to the estimated time that analysis results will be obtained. In some cases this may differ from the time that the instrument actually finishes operation.

9.1.2 Checking the time remaining until the completion of a test

Follow the steps below to check the time remaining until the completion of a test.

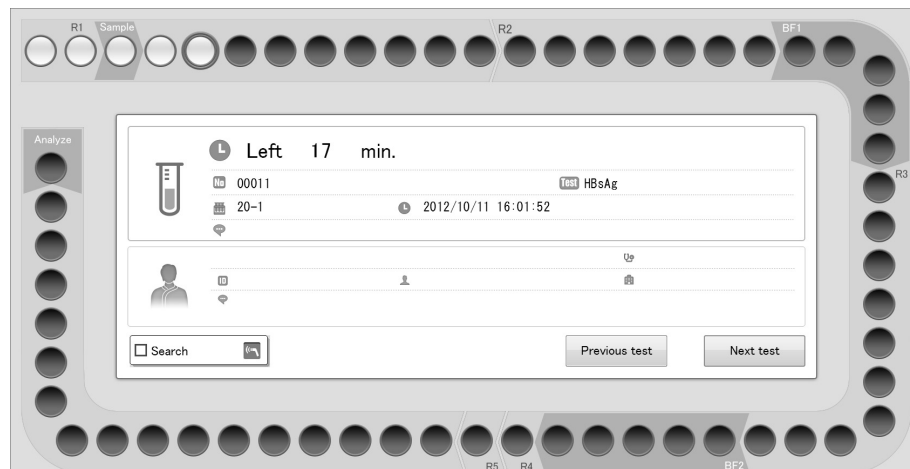
1 Touch [Progress] on the toolbar.

The following screen appears.



Test status	The status of the test is indicated by the background color. Background colors and test status are as follows:
 (Black)	Indicates that there is no test.
 (White)	Indicates that the test is a sampler test. Indicates that analysis is in progress normally.
 (White (striped pattern))	Indicates that the test is a conveyor line test. Indicates that analysis is in progress normally.
 (Red)	Indicates that the test is a sampler test. Indicates that an error has occurred.
 (Red (striped pattern))	Indicates that the test is a conveyor line test. Indicates that an error has occurred.
Progress display area	You can touch the test status to show progress information and check the remaining time. It is also possible to search by specifying a patient name or scanning a sample barcode with the handheld barcode reader.
[Previous test]/[Next test]	Touch to move the selected test one position forward or backward.

2 Select the test (○ mark) whose remaining time you want to check.



Note:

A test that is selected is indicated by a blue frame. A test aspirated from the same sample tube as the selected test is indicated by a dotted blue frame.

9.2 Replenishing supplies and reagents

This section explains how to replenish supplies and reagents during analysis.

9.2.1 Replenishing tips and cuvettes

When the instrument runs out of tips or cuvettes during analysis, an error message appears. Replenish the item that ran out.

To replenish tips and cuvettes, see Chapter 5.

(► **P.103** "Chapter 5: 5.2.1 Replenishing cuvettes")

(► **P.105** "Chapter 5: 5.2.2 Replenishing tips")

9.2.2 Replenishing an R1-R3 reagent

When the instrument runs out of R1-R3 reagent during analysis, an error message appears. Replenish the item that ran out. To replenish an R1-R3 reagent, see Chapter 5.

(► **P.108** "Chapter 5: 5.3.1 Replenishing an R1-R3 reagent")

When R1-R3 reagent runs out, analysis may stop automatically (this depends on the settings). When you have finished replenishing the reagent, touch [Start] on the toolbar to resume analysis.

If there is an open position in reagent holder A, R1-R3 reagent with little reagent remaining can be placed in the continuous unit before analysis, and when reagent runs out during analysis, the reagent can be automatically replenished.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to replenish R1-R3 reagent during analysis.

1 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

2 Check if the reagent to be replenished has an empty position.

If reagent holder A does not have an empty position, remove another reagent from reagent holder A.

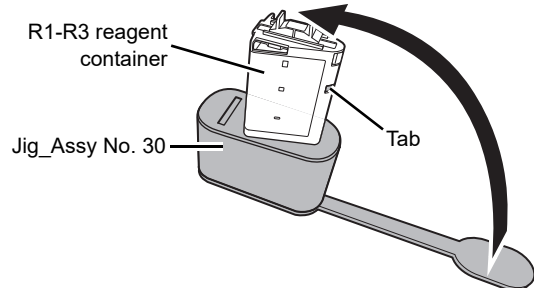
3 Follow the instructions on the package insert to prepare the new R1-R3 reagent.



Warning!

- To open the R1-R3 reagent for the first time, use Jig_Assy No. 30 that is supplied with the instrument. Opening the reagent without the jig may result in injury.
- Place the Jig_Assy No. 30 in a horizontal position when opening the reagent.

- (1) Place the R1-R3 reagent container in Jig_Assy No. 30 and cover the top of the container with the black rubber of the jig.



- (2) Press down on the rubber to depress the tab on the front of the container, and push the outer case completely down.



4 Open the operation cover on the analyzer.



Caution!

Be careful not to hit your head on the operation cover when it is open.



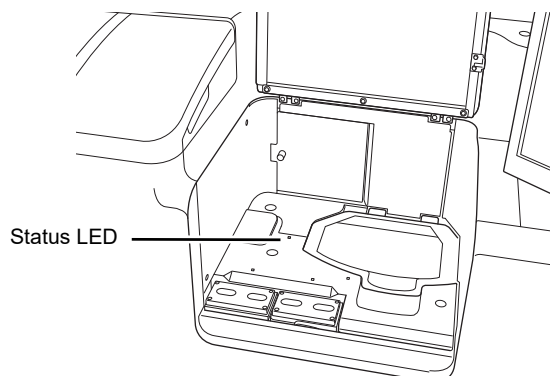
Information

When opening and closing the operation cover, take care not to let your fingers be pinched by the cover.

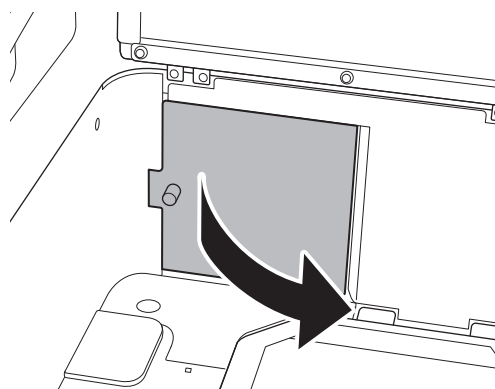
5 Make sure that the continuous unit status LED lights green.

For information on the continuous unit status LED, see Chapter 3.

(►P.44 "Chapter 3: 3.4.3.2 Status indicated by the reagent holder A cover status LED [R1-R3]/ urgent sample holder status LED [STAT]/ continuous unit status LED")

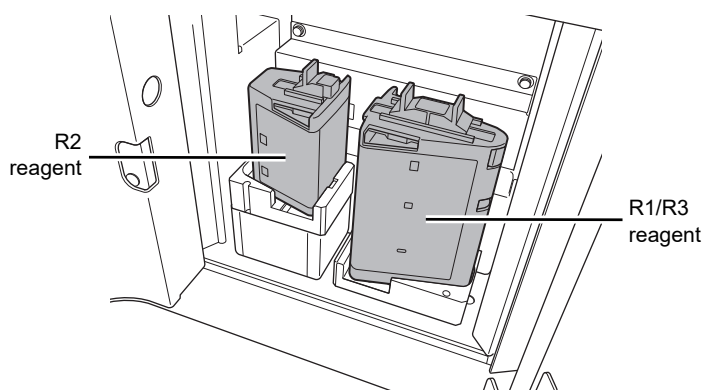


6 Open the cover of the continuous unit.



7 Place the new R1-R3 reagent.

Place R1/R3 reagent in the reagent position on the right. Place R2 reagent in the reagent position on the left.



Information

- When placing a reagent, do not press down forcefully. This may cause failure.
- Make sure that the reagent is placed securely in its position.
- If the magnetic particles in the R2 reagent have settled to the bottom of the container, remove the R2 container and mix by hand, taking care not to create any air bubbles. Visually confirm that the magnetic particles have dispersed. Do not shake vigorously or tip the container over.

8 Close the cover of the continuous unit.

9 Close the operation cover.

The reagent in the continuous unit will automatically be replenished.

10 Take out the used reagent and discard the container appropriately.

For the procedure for removing used reagent, see the following.

(►P.211 "9.2.3 Removing R1-R3 reagent")

9.2.3 Removing R1-R3 reagent

Used R1-R3 reagent can be removed during analysis.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to remove R1-R3 reagent during analysis.

1 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

2 Touch the status icon of the used reagent.

3 Touch [Take R1-R3 out] on the operation panel.

The selected used reagent moves to the continuous unit.

4 Open the operation cover on the analyzer.



Caution!

Be careful not to hit your head on the operation cover when it is open.



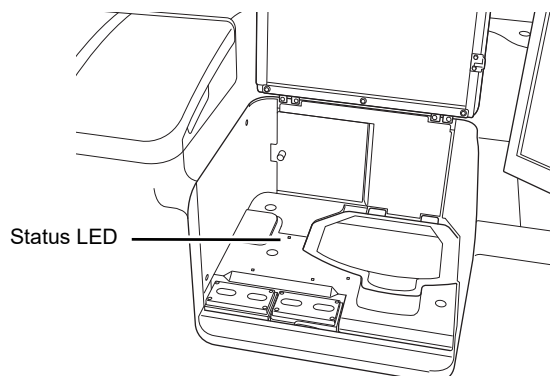
Information

When opening and closing the operation cover, take care not to let your fingers be pinched by the cover.

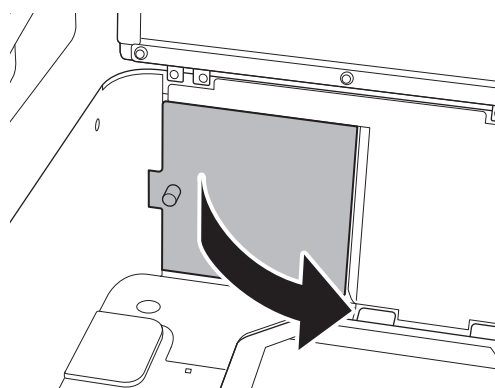
5 Make sure that the continuous unit status LED lights green.

For information on the continuous unit status LED, see Chapter 3.

(►P.44 "Chapter 3: 3.4.3.2 Status indicated by the reagent holder A cover status LED [R1-R3]/ urgent sample holder status LED [STAT]/ continuous unit status LED")



6 Open the cover of the continuous unit.



7 Take out the used reagent and discard the container appropriately.

9.2.4 Replacing R4/R5 reagents

When the instrument runs out of R4/R5 reagent during analysis, an error message appears. Replenish the item that ran out. To replenish R4/R5 reagent, see Chapter 5.

(►P.113 "Chapter 5: 5.3.3 Replenishing R4/R5 reagent")



Information

Do not replace a reagent that is being used for analysis. If you attempt to replace a reagent that is in use, an error message will appear and analysis will stop. Follow the instructions in the message to clear the error. For error messages, see Chapter 12.

(►P.314 "Chapter 12: 12.5 Troubleshooting by error message")

9.2.5 Replenishing line washing/concentrated line washing/HISCL washing

When the instrument runs out of line washing/concentrated line washing/HISCL washing during analysis, an error message appears. Replenish the item that ran out.

To replenish line washing/concentrated line washing/HISCL washing, see Chapter 5.

(►P.115 "Chapter 5: 5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")



Information

Do not replace line washing/concentrated line washing/HISCL washing that is being used for analysis. If you attempt to replace a reagent that is in use, an error message will appear and analysis will stop. Follow the instructions in the message to clear the error. For error messages, see Chapter 12.

(►P.314 "Chapter 12: 12.5 Troubleshooting by error message")

9.2.6 Replenishing probe washing

When the instrument runs out of probe washing during analysis, an error message appears. Replenish the solution. For the procedure for replenishing probe washing, see Chapter 5.

(►P.118 "Chapter 5: 5.3.5 Replenishing probe washing")



Information

Do not replace probe washing that is being used for analysis. If you attempt to replace a reagent that is in use, an error message will appear and analysis will stop. Follow the instructions in the message to clear the error. For error messages, see Chapter 12.

(►P.314 "Chapter 12: 12.5 Troubleshooting by error message")

9.3 Disposing of waste materials and waste fluid

9.3.1 Disposing of tips and cuvettes

When tips and cuvettes are replenished, the old tips and cuvettes must be disposed of. To dispose of tips and cuvettes, see Chapter 5.

(►P.127 "Chapter 5: 5.6.1 Disposing of waste in the waste box")

9.3.2 Replacing the waste tank (optional)

When the waste tank (optional) becomes full, an error message appears. Replace the waste tank (optional). To replace the waste tank (optional), see Chapter 5.

(►P.130 "Chapter 5: 5.6.2 Disposing of waste fluid")

**Note:**

If you have connected the instrument to waste fluid equipment at your facility instead of using the waste tank (optional), waste tank replacement is not necessary.

9.4 Analyzing a sample that could not be analyzed

9.4.1 Displaying the untested/retest list

The untested list shows information on samples for which an order was registered but analysis did not take place due to a sample or reagent aspiration problem, a mechanism problem, or other abnormality.

To set the retest conditions, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 5: 5.2 Configuring retest settings")

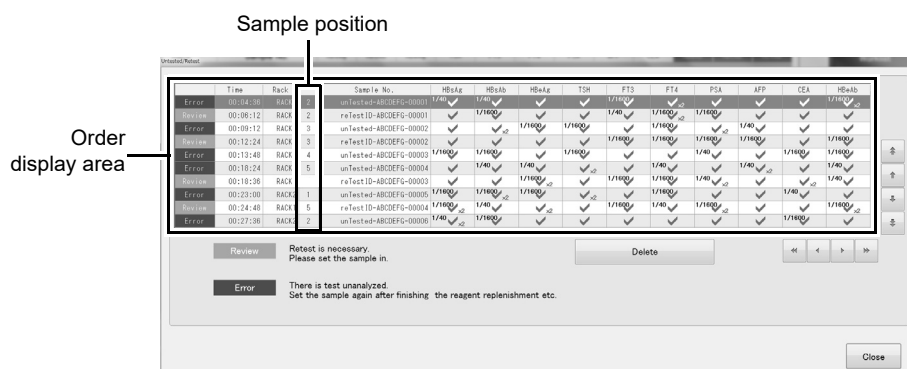
Follow the steps below to check the untested list.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Untested/Retest] on the operation panel.

The [Untested/Retest] dialog box appears.



[Untested/Retest] dialog box

Order display area	Displays untested/retest orders.
[Error]/[Review]	Displays a retest order or untested order.
[Time]	Displays the order registration time.
[Rack]	Displays the rack number of the sample.
Sample position	Displays the sample position.
[Sample No.]	Displays the sample number.

Test	Displays whether the tests are specified. ✓: Specified. (Blank): Not specified. [1/2], [1/4], [1/10], [1/20], [1/40], [1/100], [1/400], [1/1600]: Analyzes at the indicated dilution ratio. [x2]: Analyzes the indicated number of times.
[Delete]	Touch to delete the selected order.
[Close]	Touch to close the dialog box.

9.4.2 Placing only untested samples in a rack and analyzing

Follow the steps below to place only untested samples in a rack and analyze the samples.
For this analysis, sample barcodes are necessary. To set sample barcodes, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 5: 5.1 Configuring barcode settings")



Information

To use untested/retest orders, enable the use of [Untested/Retest] in the auto rack order settings.

For information on the auto rack order settings, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings")

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Untested/Retest] on the operation panel.

The [Untested/Retest] dialog box appears.

3 Check untested samples.

Samples without sample barcodes do not appear in the [Untested/Retest] dialog box. To analyze samples without barcodes, enter the orders manually.

4 Place the untested samples in the rack.

5 Place the rack in the sampler.

The instrument's status LED indicates that the instrument is in operation.
After the instrument initializes, the sample rack is fed in and analysis starts.

9.4.3 Using the initial rack for analysis

Follow the steps below to analyze untested samples using the initial rack that includes tested samples. The samples that have been tested are skipped and only the untested samples are analyzed. For this analysis, sample barcodes are necessary. To set sample barcodes, see the "Administrator's Guide". (►Administrator's Guide, "Chapter 5: 5.1 Configuring barcode settings")



Information

To use untested/retest orders, enable the use of [Untested/Retest] in the auto rack order settings.

For information on the auto rack order settings, see the "Administrator's Guide". (►Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings")

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Untested/Retest] on the operation panel.

The [Untested/Retest] dialog box appears.

3 Check untested samples.

4 Load the previously analyzed rack in the sampler.

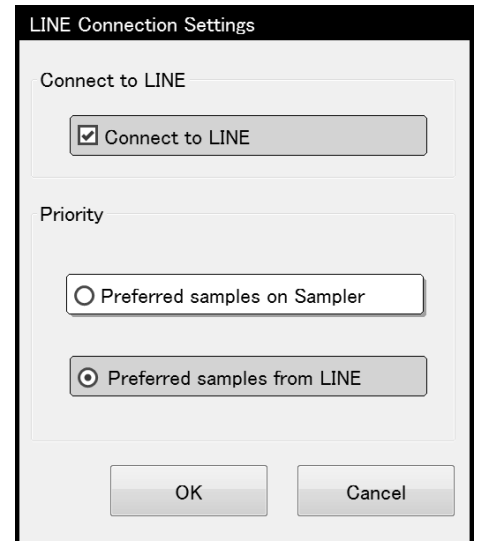
The instrument's status LED indicates that the instrument is in operation. After the instrument initializes, the sample rack is fed in and analysis starts.

9.5 Switching conveyor line and sampler priority

Follow the steps below to switch the priority of the conveyor line and the sampler.

1 Touch [LINE] in the conveyor line connection status on the IPU screen.

The dialog box on the right appears.



The screenshot shows a dialog box titled "LINE Connection Settings". It contains two main sections. The first section, "Connect to LINE", has a checkbox labeled "Connect to LINE" which is checked. The second section, "Priority", has two radio button options: "Preferred samples on Sampler" (which is unselected) and "Preferred samples from LINE" (which is selected). At the bottom of the dialog box are two buttons: "OK" and "Cancel".

2 Select [Preferred samples on Sampler] or [Preferred samples from LINE] for the priority specification.

3 Touch [OK].

The specified setting is given priority.

Chapter 10 Checking analysis results

This chapter explains how to check, display, and validate analysis results.

10.1 Checking the list of analysis results (Job list)

Analysis results can be checked on the [Joblist] screen.

Touch [Joblist] on the toolbar to display the job list screen.

The job list is used to check the progress of analysis jobs while performing work.

A job starts when an order is registered, and ends when the results are reported to a host computer or a printer.

An order is added to the job list when it is registered on the [Order registration] screen. After analysis starts, the status of the job (such as processing, complete, and reported) is displayed to allow you to check progress.

A combined maximum of 100,000 registered orders and analysis results are held in the job list.

For sample analysis, the analysis results of up to 2 analyses of the same sample are displayed as 1 job.

If the same sample is analyzed 2 times, a single concentration is calculated from the standard curve and the average of the 2 assay count values.

However, if an error occurred or the reagent lot changed during 1 of the analyses, the concentration is only calculated from the other assay count value.

For standard curve analysis, the number of displayed analysis results is equal to the analysis count.

If the same sample is analyzed 3 times, 3 results will be displayed, and the [Standard Curve] screen will display the average of the 3 assay count values.

For QC analysis, the job list will display 1 analysis result using L-J control, and 2 results using X-bar control. For X-bar control analysis, the average of the 2 concentration results is displayed on the [Quality control] screen.

10.1.1 Job list screen

Touch [Joblist] on the toolbar to display the [Joblist] screen.



[Joblist] screen

Tabs	The tabs are used to change the contents of the [Joblist] screen that are displayed. For details, see the following. (►P.237 "10.3.3 Changing the tab display")
Job list	Displays registered orders, analysis results, and other information. For details, see the following. (►P.221 "10.1.2 Job list")
Display conditions	Displays display conditions such as the filter, date conditions, and analysis result conditions. The display conditions can be changed by selecting the items below. For details, see the following. (►P.229 "10.3 Displaying specific analysis results")
[Search]	Select the checkbox to read sample numbers with the handheld barcode reader and search for analysis results.
[Expansion]	Select the checkbox to enlarge the text in the job list.
[The lasted data]	Select the checkbox, the latest analysis results are automatically selected each time analysis results are obtained. A range cannot be selected and data cannot be output or edited.
Date condition	Conditions for filtering by analysis date can be selected.
Analysis result conditions	The analysis progress of each job can be selected.
Sample information	Displays the selected sample information. (►P.224 "10.1.3 Sample information")
Patient Information	Displays the patient information associated with the selected sample. For details, see the following. (►P.224 "10.1.4 Patient information")
Detail area	Shows the detailed information of the analysis results associated with the selected sample. For details, see the following. (►P.225 "10.1.5 Display the detail area")

10.1.2 Job list

Job information is shown in the job list.

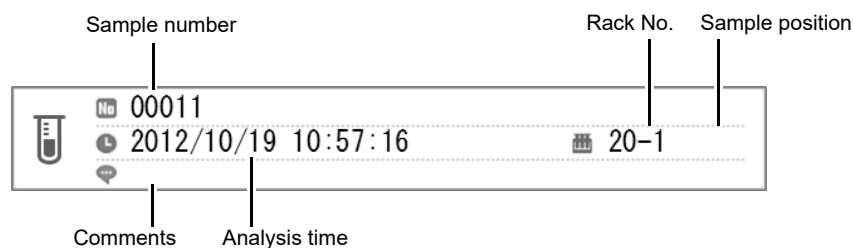
[Progress]	Displays the progress of each job. [Pending]: The analysis order has been registered, but analysis has not yet started. [Processing]: Analysis is in progress. [Error]: An error occurred in part of the analysis results, or the sample number in the registered order does not match the sample barcode. An untested order may have been created. [On Hold]: The analysis results include results for which the concentration cannot be calculated because there is no standard curve. Recalculation is necessary. [Review]: The analysis results include low-reliability results or results that are outside the analysis range, and a retest order has been created. The conditions for creating a retest order can be set. To configure the settings, see the "Administrator's Guide". (►Administrator's Guide, "Chapter 5: 5.2 Configuring retest settings") [Complete]: All analysis results have been obtained. [Validated]: The results have been validated. The results can be reported to the host computer or a printer. [Reported]: The results have been reported to the host computer or a printer. The job is finished.
[Registration date]/ [Registration time]	Displays the date and time the order was registered. This is updated to the time the analysis results are obtained for each sample aspiration. For a real-time query, this displays the date and time the order was specified from the host computer.
[Assay date]/ [Assay time]	Displays the date and time when all results of the tests specified in the order were obtained.
[Left]	Displays the estimated time remaining until all results of the tests specified in the order are obtained.
[Sample No.]	Displays the sample number. In addition to regular sample numbers, the following sample numbers may appear: [ERR]: A sample number for which a sample barcode scan error occurred, or for which an error occurred in the query sample number check. [Auto]: A sample number that was automatically assigned. [STD]: A sample number used in standard curve analysis.
[Patient ID]	Displays the patient ID corresponding to the sample.
[First name]/ [Last name]	Displays the first and last name of the patient corresponding to the sample.
[Rack No.]	Displays the rack number. [STAT] appears when the sample is an urgent sample.
[Rack seq.]	Displays the sequence number of the rack loaded in the instrument. This is blank when the sample is an urgent sample.
[Pos.]	Displays the position of the sample in the rack.

[Type]	Displays the sample type. [Regular]: Regular sample. [QC]: Sample for QC analysis. [Cal]: Sample for calibration.
[Retest]	Displays whether the sample is a retest sample. (Blank): First test. [Retest]: Analysis of a retest order.
[V]	Displays the validation status of the analysis results. [V]: The results have been validated. (Blank): The results have not been validated.
[Report]	Displays the report status of the analysis results. [L]: Not printed by the list printer. [G]: Not printed by the graphic printer. [H]: Not sent to the host computer. (Blank): Host computer output, graphic printer printing, or list printer printing completed.
[Sample No. class]	Indicates how the sample number was input. [M]: Manually entered sample number. Classes are as follows: • Sample number manually entered from software keyboard • Sample number entered by standard curve order • Sample number entered by QC order • Sample number entered by repeat [A]: Sample number automatically assigned by the instrument. Classes are as follows: • ERR number for barcode scan error • Auto number of the default order registered for a rack [B]: Sample number read by the instrument. Classes are as follows: • Sample number entered by handheld barcode reader • Sample number entered by sampler barcode reader • Sample number entered from conveyor line [C]: Sample number specified by host computer.
[Order class]	Indicates how the order was input. [M]: Manually entered order. Classes are as follows: M00: Manually entered order other than the types below. M01: Order entered by repeat M02: Order entered by QC order input or standard curve order input [C]: Order specified by host computer. Classes are as follows: C00: Order acquired by real-time query C01: Order acquired by batch query C02: Order acquired by real-time query with information specified by host supplement rack applied [A]: Automatically created order. Classes are as follows: A00: Untested order A01: Retest order A02: Order specified for QC rack or standard curve rack A03: Order specified for default order rack or urgent sample default order A04: QC order based on special sample number A05: Untest order for a retest order A10: Final analysis result that consolidates untest orders for the initial test A15: Final analysis result that consolidates untest orders for the retest.

[Auto curve]	Indicates whether there were analysis results for which standard curve auto correction was performed.
Analysis results	Displays the results of each test. The concentration, concentration units, concentration mask, flags, and qualitative analysis result (positive/negative) are shown.
Value:	Concentration or cutoff index.
[*]:	Indicates that a warning occurred during analysis, or that the results of duplicate testing of a regular sample have low reliability because one result was abnormal (only the other result was used).
[<]:	The concentration was under the set lower limit for display.
[>]:	The concentration was over the set upper limit for display. In the case of a result that was over the range, this indicates that the concentration exceeded the specified upper limit of the analysis range.
[****.***]:	A test error occurred and analysis results were not obtained. Numerical values cannot be checked.
[----.---]:	Indicates that calculation was not possible. For sample analysis, this indicates that an analytical error occurred, or that analysis of duplex testing is still in progress. For QC analysis, this indicates that an analytical error occurred. For standard curve analysis, this is always displayed. In the case of standard curve analysis, check for errors in the progress display or [Browser] screen. Numerical values cannot be checked.
[+++++.+++]:	The concentration was over the specified upper limit of the analysis range. Numerical values cannot be checked.
[XXXXX.XXX]:	Indicates that the concentration has not been calculated because the reagent lot used for analysis does not have a standard curve. The concentration will be calculated when the standard curve is created and used to execute calculation.
[-]:	Indicates a negative result.
[+-]:	Indicates that the classification is on hold.
[+]:	Indicates a positive result.
[1+]:	Indicates a low-level positive result.
[2+]:	Indicates a medium-level positive result.
[3+]:	Indicates a high-level positive result.

10.1.3 Sample information

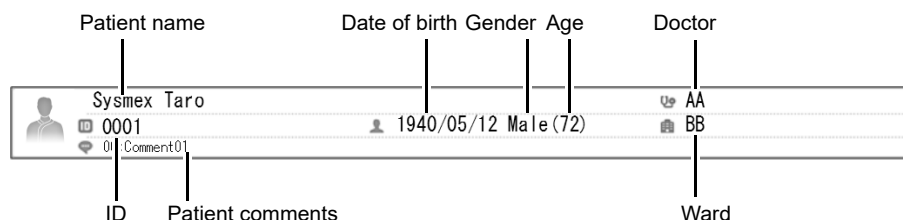
Detailed information on the sample is shown.



Sample number	Displays the sample number.
Rack No.	Displays the rack number.
Sample position	Displays the sample position.
Analysis time	Displays the date and time of analysis.
Comments	Displays comments regarding the sample.

10.1.4 Patient information

Detailed patient information is shown.



Patient name	Displays the patient's name.
ID	Displays the patient ID.
Date of birth	Displays the date of birth.
Gender	Displays the patient's gender.
Age	Displays the patient's age.
Doctor	Displays the name of the doctor.
Ward	Displays the ward name.
Patient comments	Displays comments regarding the patient.

10.1.5 Display the detail area

Displays detailed information of analysis results.

Test	Concentration	Level	Dilution
HBsAb [mIU/mL]	3350.9	IND	1/40
HBsAg [C.O.I.]	1741.6		1/1600
HBsAb [mIU/mL]	1071.1	-	1/40
HBcAb [C.O.I.]	4210.8	IND	1/1
HCVAb [C.O.I.]	1195.8	2	1/1
HIVAg+Ab [C.O.I.]	784.3	3+	1/1
HBsAg [IU/mL]	2784.681		1/1600
HTLV-I [C.O.I.]	2204.5	RE	1/1600
TPAb [C.O.I.]	4564.5	-	1/1600
FT3 [pg/mL]	1504.09	IND	1/40
PSA			

[Test]	Displays tests and the units of the concentration.
[Concentration]	Displays the concentration.
[Level]	Displays the qualitative classification flag of the analysis results.
[Dilution]	Displays the dilution ratio used for analysis.

10.1.6 Data selection

Data in the job list can be selected.

Operations such as validation and printing require analysis results to be selected.

Analysis results are selected from the analysis results shown in the list. Analysis results that are hidden by a display filter cannot be selected.

If you need to select a hidden result, remove the display filter.

For details on display filters, see the following.

(► **P.230** "10.3.2.1 Setting the display conditions (filter)")

The following methods can be used to select data. A maximum of 300 items of data can be selected at once.

Data	Method
Any data	Touch the data in the job list that you want to select. Multiple data items can be selected.
All data	Touch [Select all] on the operation panel.
Latest data	Select [The lasted data] in the display conditions.



Information

When the display condition is [The lasted data], a range cannot be selected.

10.2 Checking details of analysis results (Browser)

The [Browser] screen shows detailed information on analysis results (reagent lot used for analysis, standard curve ID, errors, etc.). A chart showing up to 8 previous analysis results for the same patient ID is displayed, allowing changes in the analysis results to be viewed.

10.2.1 Browser screen

The [Browser] screen lets you view detailed information on the data selected in the job list.

Touch [Browser] on the toolbar to display the [Browser] screen.

The screenshot shows the [Browser] screen with the following components:

- Displayed information:** Tabs for Complete, Validated, and Sample No. (selected). Fields for Sample No. (0), Type (Regular), and Result comment (Comment).
- Analysis results list:** A table with columns: Test, Concentration, Level, Information, Curve ID, R1R2R3, R4R5, Dilution, and Count.

Test	Concentration	Level	Information	Curve ID	R1R2R3	R4R5	Dilution	Count
HBsAg [IU/ml]	1147.444	-		79485	ZS9001	ZS9991	1/1600	13.095
	6512.889	+		79485	ZS9001	ZS9991	1/1600	17.538
	2358.283	-		49476	ZS9001	ZS9991	1/1600	12.121
HBsAb [mIU/ml]	4242.5	-		22026	ZS9001	ZS9991	1/40	13.259
	466.5	3+		22026	ZS9001	ZS9991	1/40	12.599
	567.5	RE		98109	ZS9001	ZS9991	1/40	12.099
HBeAg [O.O.I.]	365.6	1+		88254	ZS9001	ZS9991	1/1600	14.977
	4611.8	+		88254	ZS9001	ZS9991	1/1600	11.997
	6995.4	2+		51447	ZS9001	ZS9991	1/1600	18.046
TSH [uIU/ml]	8022.185	3+		84384	ZS9001	ZS9991	1/40	11.786
- Sample information:** 08/25 06:00:30, RACK38-1, Duplicate test count.
- Patient information:** Patient ID and name field.

[Browser] screen

Displayed information	Indicates whether the analysis result needs review, its validation status, and whether a sample ID error occurred.
[Complete]	Analysis finished without errors.
[Review]	There is a retest order.
[Error]	An error occurred.
[Validated]	The results have been validated.
[Not Validate]	The results have not been validated.
[Sample No.]	Appears when the sample number on the [Order registration] screen does not match the scanned sample barcode. Review is necessary.
[Sample No.]	Displays the sample number.
[Type]	Displays the sample type.
[Result comment]	Displays comments regarding the analysis results.

Analysis results list	A list of the detailed results of each test appears.
[Test]	Displays tests and the units of the concentration.
Duplicate test count	Displays whether the analysis result is the final result, or in the case of duplicate tests, the count of the analysis result. [F]: Final result. [1]: 1st analysis result. [2]: 2nd analysis result.
[Concentration]	Displays the concentration.
[Level]	Displays the qualitative classification flag of the analysis results.
[Information]	If there is an error in the analysis results, error information appears. Touch [More] to check details on the error in the dialog box that appears. For details, see the following. (►P.239 "10.4 Checking the cause of a failed analysis and the remedial action")
[Curve ID]	Displays the ID and method used to create the standard curve used for analysis.
[R1R2R3]	Displays the R1-R3 reagent lots that were used for analysis.
[R4R5]	Displays the R4/R5 reagent lots that were used for analysis.
[Dilution]	Displays the dilution ratio used for analysis.
[Count]	Displays the analysis result count value. If duplicate analysis (2 tests or more) was performed, this shows the method selected for the final analysis results. [mean]: The mean is selected. [1]: The analysis result of the 1st test is selected. [2]: The analysis result of the 2nd test is selected.
Sample information	Displays the sample information. For details, see the following. (►P.224 "10.1.3 Sample information")
Patient Information	Displays the patient information corresponding to the sample. For details, see the following. (►P.224 "10.1.4 Patient information")

**Note:**

To move to the analysis results above or below the displayed results, touch [Previous] or [Next] on the operation panel of the [Browser] screen.

10.2.2 Chart dialog box

Starting from the displayed analysis results, the [Chart] dialog box shows up to 8 of the past analysis results of the same patient ID in chronological order.

Analysis results without numerical data are skipped and do not appear on the chart.

Follow the steps below to display the [Chart] dialog box.

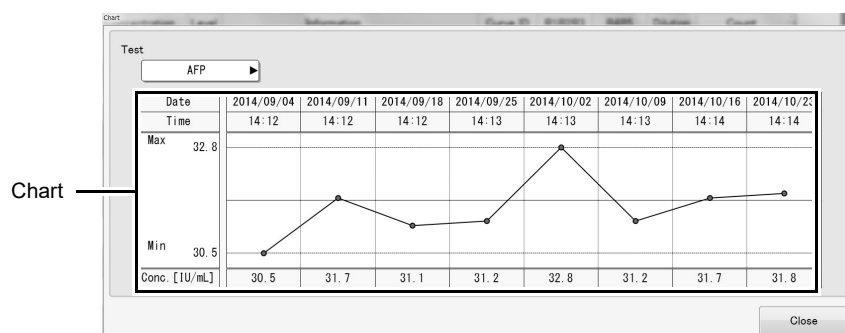
1 Touch [Browser] on the toolbar.

The [Browser] screen appears.

2 Select the analysis results for which you want to display the chart dialog box.

3 Touch [Chart] on the operation panel.

The following dialog box appears.



[Test]	Select the test.
Chart	Displays the chronological changes of the selected test.
[Date]	Displays the analysis date.
[Time]	Displays the analysis time.
[Max]	Displays the maximum value of the analysis results.
[Min]	Displays the minimum value of the analysis results.
[Conc.]	Displays the analysis results and the cutoff index.
[Close]	Touch to close the dialog box.

10.3 Displaying specific analysis results

Analysis results displayed on the [Joblist] screen can be filtered or sorted. The items displayed on the screen and display conditions can be set for each tab.

10.3.1 Changing the display conditions

A display filter can be applied based the analysis date or analysis results.

A sorting condition such as sample number ascending order can be simultaneously specified.

When analysis results are filtered, only analysis results that are displayed can be edited.

10.3.1.1 Selecting displayed data by date

Displayed analysis results can be filtered by date.

Follow the steps below to filter the displayed data by date.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Touch the date condition.

The condition list appears.

The date conditions that can be selected vary depending on the list display settings of the displayed tab.

When the tab is set to display analysis results from [Last 5 days], you can select from [Today], [Last 2 days], [Last 3 days], [Last 4 days], or [Last 5 days].

When the tab is set to display [Specified period] or [Canceled results], you can select a month from the current month to 6 months ago, or a specified period.

3 Select the desired condition.

Only analysis results that meet the specified date condition are displayed.

10.3.1.2 Selecting displayed data by a user specified condition

Displayed analysis results can be filtered by a customer specified condition.
Follow the steps below to select displayed data by user specified condition.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Touch the analysis result conditions.

The list of customer specified conditions appears.
To set a condition, see the following.

(►P.230 "10.3.2 Changing the display condition settings")

3 Select the desired condition.

Only analysis results that meet the specified condition are displayed.
When the selected condition is changed to [No designation], the selection is canceled.

10.3.2 Changing the display condition settings

Display conditions for analysis results shown in the job list can be set. Display conditions can be specified in the filter settings and the sort settings.

10.3.2.1 Setting the display conditions (filter)

Display conditions for analysis results shown in the job list can be set.
Follow the steps below to select analysis result display conditions.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

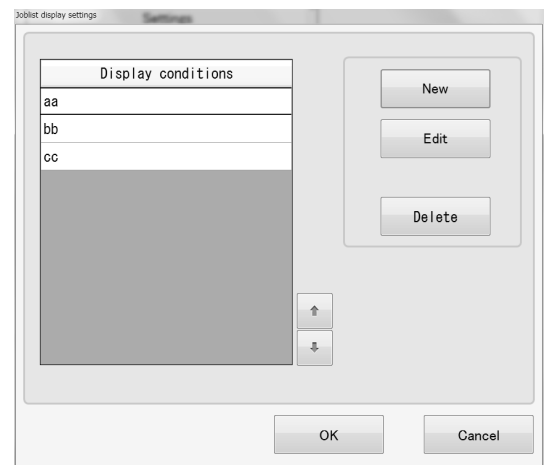
2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

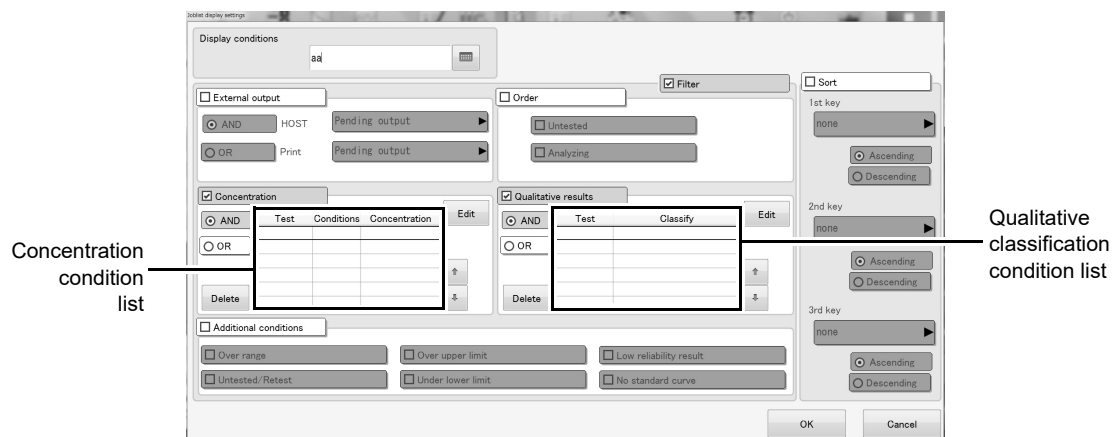
3 Select [702. Joblist display settings] and touch [Settings].

The dialog box on the right appears.



4 Select the [Display conditions] whose settings you want to change and touch [Edit].

The following dialog box appears.



Note:

To create a new display condition, touch [New].

To delete a display condition, select the display condition and touch [Delete].

5 Select the [Filter] checkbox and set the displayed items.

The following items are displayed in the dialog box:

[Display conditions]	The display condition name can be changed.
[Filter]	Select the checkbox to set details for the display condition.
[External output]	Select the checkbox to set details for the [External output] display conditions.
[AND]	Select to display, analysis results that meet all of the set conditions are displayed.
[OR]	Select to display, analysis results that meet any of the set conditions are displayed.
[HOST]	Specify whether reporting of the analysis results to the host computer is pending/done.
[Print]	Specify whether printing of the report format from a printer is pending/done.
[Order]	Select the checkbox to set details for the [Order] display conditions.
[Untested]	Select the checkbox to specify untested orders.
[Analyzing]	Select the checkbox to specify orders being processed.
[Concentration]	Select the checkbox to set details for the [Concentration] display conditions.
[AND]	Select to display, analysis results that meet all of the set conditions are displayed.
[OR]	Select to display, analysis results that meet any of the set conditions are displayed.
Concentration condition list	Displays the concentration conditions of each test.
[Delete]	Touch to delete the selected concentration condition from the concentration condition list.
[Qualitative results]	Select the checkbox to set details for the [Qualitative results] display conditions.
[AND]	Select to display, analysis results that meet all of the set conditions are displayed.
[OR]	Select to display, analysis results that meet any of the set conditions are displayed.
Qualitative condition list	Displays the qualitative conditions of each test.
[Delete]	Touch to delete the selected qualitative classification condition from the qualitative classification condition list.
[Additional conditions]	Select the checkbox to set details for the [Additional conditions] display conditions.
[Over range]	Select the checkbox to specify analysis results that exceed the upper limit of the analysis range.
[Untested/Retest]	Select the checkbox to specify retest orders and the corresponding analysis results.
[Over upper limit]	Select the checkbox to specify analysis results that exceed the upper limit of the display range.
[Under lower limit]	Select the checkbox to specify analysis results that are less than the lower limit of the display range.
[Low reliability result]	Select the checkbox to specify analysis results that have poor reliability.
[No standard curve]	Select the checkbox to specify analysis results that have no standard curve.

6 Set details for conditions.

Details can be set for the concentration conditions and qualitative conditions.

For the setting method, see the following.

(►P.233 "●Detailed concentration display condition settings", P.234 "●Detailed qualitative display condition settings")

7 Touch [OK].

The dialog box closes, and the display condition settings change.

● Detailed concentration display condition settings

Concentration conditions can be set for each test. The set conditions appear in the concentration condition list. Follow the steps below to select detailed concentration display conditions.

1 Select the concentration condition you want to change.

To set a new condition, touch a blank line.

2 Touch [Edit].

The dialog box on the right appears.

3 Populate the displayed fields.

The following items are displayed in the dialog box:

[Test]	Select the test.
[$\geq$]	Select to specify analysis results higher than the entered value.
[$\leq$]	Select to specify analysis results lower than the entered value.

4 Enter the numerical value.

5 Touch [OK].

The dialog box closes and the concentration display conditions change.

● Detailed qualitative display condition settings

Qualitative conditions for each test can be set. The set conditions appear in the qualitative condition list. Follow the steps below to select detailed qualitative display conditions.

1 Select the qualitative condition you want to change.

To set a new condition, touch a blank line.

2 Touch [Edit].

The following dialog box appears.

3 Populate the displayed fields.

The following items are displayed in the dialog box:

[Test]	Select the test.
[Results for each test]	Select to specify the qualitative result for each test.
[Unclassified]	Select the checkbox to specify analysis results that were not qualitatively classified.
[Negative(-)]	Select the checkbox to specify negative results.
[Pending(+/-)]	Select the checkbox to specify pending results.
[Positive(+,1+,2+,3+)]	Select the checkbox to specify positive results. This includes low-level, medium-level, and high level results.
[Results for group]	Select to specify the qualitative result for each group level.
[Group 1(1)]	Select the checkbox to specify group 1 results.
[Group 2(2)]	Select the checkbox to specify group 2 results.
[Unclassified(ND)]	Select the checkbox to specify results with no data.
[Pending(IND)]	Select the checkbox to specify pending results.
[Recommend dilution & retest(RE)]	Select the checkbox to specify results for which retesting with dilution is recommended.

4 Touch [OK].

The dialog box closes and the qualitative display conditions change.

10.3.2.2 Setting the sorting conditions

Conditions for sorting analysis results in the job list can be set. The results that appear after filtering by the filter conditions are sorted.

Follow the steps below to select analysis result sorting conditions.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Touch [Settings] on the operation panel.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

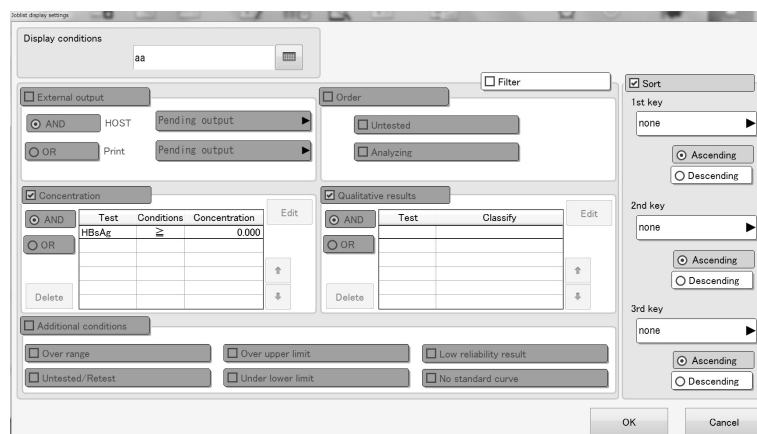
3 Select [702. Joblist display settings] and touch [Settings].

The dialog box on the right appears.



4 Select the [Display conditions] whose settings you want to change and touch [Edit].

The following dialog box appears.



Note:

To create a new display condition, touch [New].

To delete a display condition, select the display condition and touch [Delete].

5 Select the [Sort] checkbox and set the displayed items.

The following items are displayed in the dialog box:

[Display conditions]	The display condition name can be changed.
[Sort]	Select the checkbox to set sort condition details.
[1st key] to [3rd key]	The sorting conditions of each key can be set. The order of priority of conditions is from [1st key]. Touch to display the sorting condition list. Select from [none], [Analyzing progress], [Order registration date], [Order registration time], [Test completion date], [Test completion time], [Sample No.], [Patient ID], [First name], [Last name], [Rack No.], [Rack order], [Test tube's position in rack], [Sample type], [First test/Retest info], [Validation info], [Pending output flag], [Attribute of sample No. input], or [Attribute of order input]. If nothing is selected, the analysis results are sorted by date and time.
[Ascending]	Sorted in the order 0→9/A→Z/past→current. [Analyzing progress] is sorted in the order [Pending]→[Processing]→[Error]*→[On Hold]→[Review]*→[Complete]→[Validated]→[Reported].
[Descending]	Sorted in the order 9→0/Z→A/current→past. [Analyzing progress] is sorted in the order [Reported]→[Validated]→[Complete]→[Review]*→[On Hold]→[Error]*→[Processing]→[Pending].

* [Error] and [Review] analysis results are shown in the order "done", "not done".

6 Touch [OK].

The dialog box closes, and the sorting condition settings change.

7 Touch [OK].

The dialog box closes, and the display condition settings change.

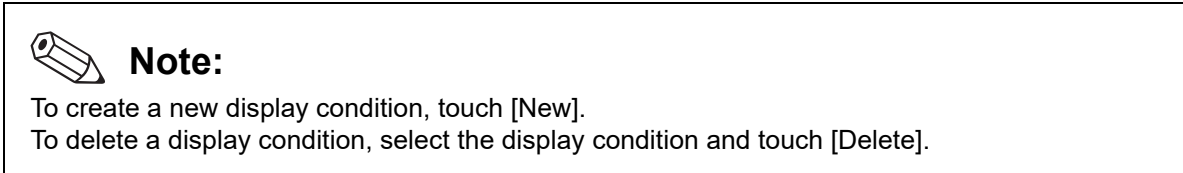
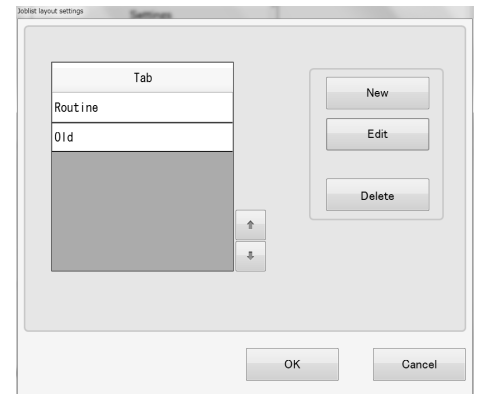
You can change the number of job list lines on each tab and show/hide patient information. The names and display order of the tabs, and the items displayed on each tab and their order of display can also be changed. Follow the steps below to change the display of a tab.

The [Joblist] screen appears.

The [Settings] dialog box appears.

(► **P.68** "Chapter 3: 3.10.1 Displaying the settings dialog box")

The dialog box on the right appears.

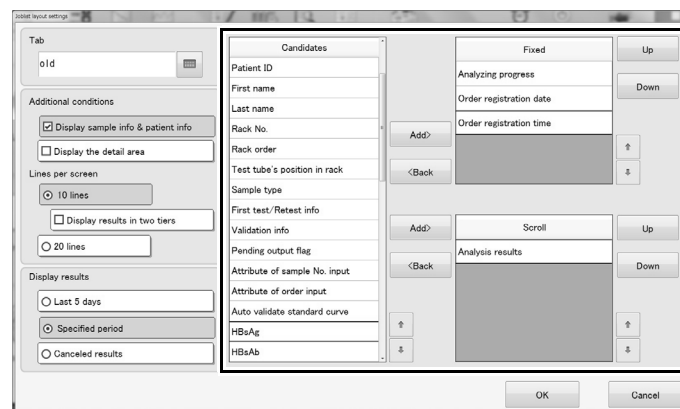


Note:

To create a new display condition, touch [New].

To delete a display condition, select the display condition and touch [Delete].

The following dialog box appears.



Items displayed
on tab

5 Populate the displayed fields.

The following items are displayed in the dialog box:

[Tab]	The tab name can be changed.
[Additional conditions]	
[Display sample info & patient info]	Select the checkbox to display the sample information and patient information.
[Display the detail area]	Select the checkbox to display the detailed information of analysis results.
[Lines per screen]	The number of lines in the job list can be set.
[10 lines]	Select to show 10 lines per screen.
[Display results in two tiers]	Select the checkbox to show analysis results in 2 tiers.
[20 lines]	Select to show 20 lines per screen. This cannot be selected when [Display results in two tiers] is selected.
[Display results]	The analysis results that are displayed can be set.
[Last 5 days]	Select to show only the last 5 day's results, including the current day.
[Specified period]	Select to show only analysis results of the last several months or a specified period.
[Canceled results]	Select to display only deleted data.
Items displayed on tabs	The items displayed on each tab can be set.
[Candidates]	Displays a list of the items that can be displayed on the tab. For details on the items that can be selected, see the following. (►P.220 "10.1.1 Job list screen")
[Fixed]	Set the items that always appear in the job list. Select from [Candidates]. Up to 10 items can be selected.
[Scroll]	Set the items that appear when the job list is scrolled to the right. Select from [Candidates]. Items not selected in [Fixed] can be selected.
[Add]	Touch to add the items selected in [Candidates] to each display list.
[Back]	Touch to remove the selected items from each display list and return them to [Candidates].
[Up]/[Down]	Touch to move the selected item up or down one line. The top or bottom item of the list is displayed at the left or right end of each line.

6 Touch [OK].

The dialog box closes and the tab content changes.

7 Touch [OK].

The dialog box closes, and the display condition settings change.

10.4 Checking the cause of a failed analysis and the remedial action

Details of errors displayed on the [Joblist] screen and the [Browser] screen can be checked.
Follow the steps below to check error details.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results in the list that show an error.

3 Touch [Browser] on the operation panel.

Test	Concentration	Level	Information	Curve ID	R1R2R3	R4R5	Dilution	Count
HBsAg [Error]	F	*****	Sample has not arrived to the charging position(Sampler)	ZS888			1/1	-

4 Touch the [More] icon in [Information].

On the [Joblist] screen, touch [Error] in [Progress].
The dialog box on the right appears.

Error list

Error details display area

Close

5 Select the error in the error list.

Details on the selected error are displayed in the error details display area.

6 Check the error.

To correct the error, see Chapter 12.
(►P.314 "Chapter 12: 12.5 Troubleshooting by error message")

7 Touch [Close].

The dialog box closes.

10.5 Making analysis results easy to view

Analysis results can be made easier to view, such as showing positive results in bold and automatically printing abnormal values.

10.5.1 Setting the display of positive results

The background color of positive analysis results can be selected.



Information

- Displaying analysis results in bold does not affect the output content or content sent to the host.
- Note that when over-range result display is set to [> (Upper limit)], the appearance will be the same as for an analysis value that exceeds the upper display limit.

Follow the steps below to set the background color of positive results.

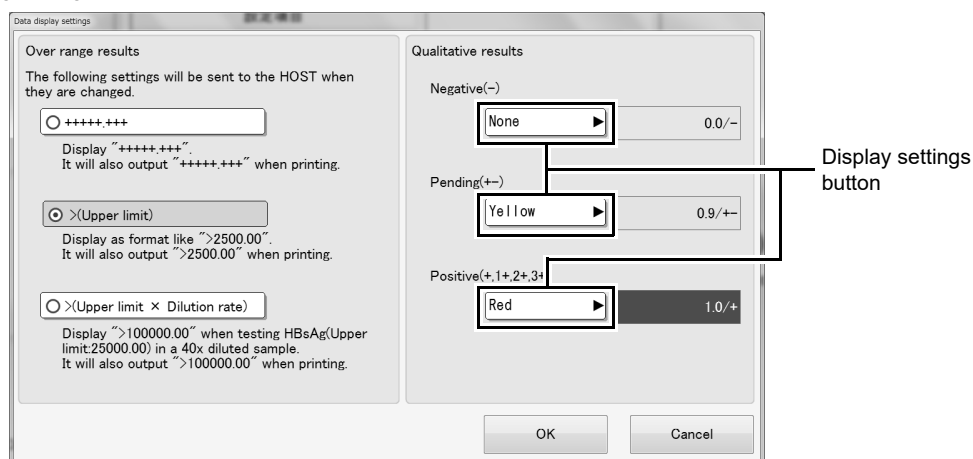
1 Touch [Menu] - [Settings] on the toolbar.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

2 Select [601. Order display settings] and touch [Settings].

The following dialog box appears.



3 Select the [Qualitative results] display setting.

Touch the display settings button and select the background color.

4 Touch [OK].

The dialog box closes and the positive result display setting is updated.

10.5.2 Automatically printing abnormal values

You can specify whether or not abnormal analysis results are automatically printed for review.



Information

When using a filter, note that printing will only apply to analysis results that are displayed.

Follow the steps below to set automatic printing for review.

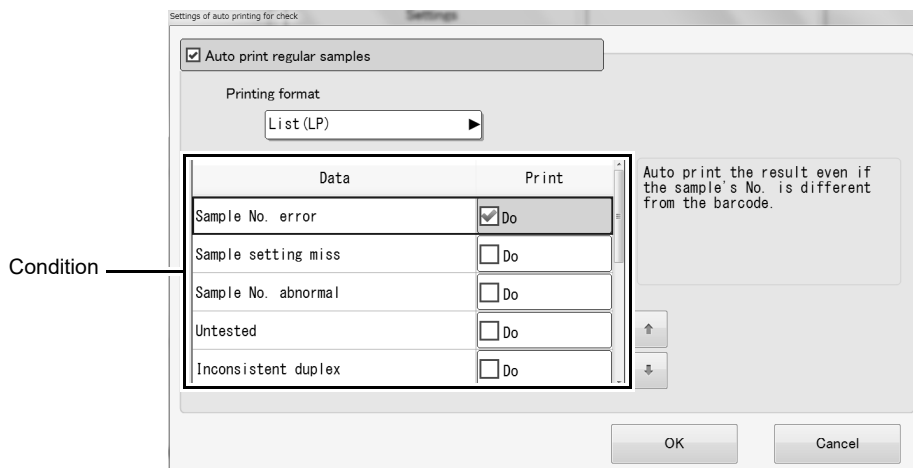
1 Touch [Menu] - [Settings] on the toolbar.

The [Settings] dialog box appears.

(►P.68 "Chapter 3: 3.10.1 Displaying the settings dialog box")

2 Select [604. Auto printing for check] and touch [Settings].

The following dialog box appears.



3 Specify automatic printing settings.

The following items are displayed in the dialog box:

[Auto print regular samples]	Select the checkbox to have analysis results that meet the specified condition automatically printed.
[Printing format]	Select the print format.
Condition	Set the condition for performing auto printing.
[Data]	Displays the type of data.
[Sample No. error]	Prints analysis results of samples whose manually registered sample number does not match the sample barcode.
[Sample setting miss]	Prints analysis results of samples whose sample position does not match the analysis order.

[Sample No. abnormal]	Prints analysis results of samples that are untested due to a sample barcode read error or sample number error in the order from the host.
[Untested]	Prints analysis results that include tests with the analysis result [***] mask or [---] mask (other than calibrator) due to an instrument error.
[Inconsistent duplex]	Prints analysis results that include tests with the analysis result [***] mask due to mismatching results or results outside the allowable gap in duplicate analysis.
[Low reliability result]	Prints analysis results that include tests with the analysis result [*] flag due to an instrument error or the use of a reagent for evaluation.
[No standard curve]	Prints analysis results that include tests whose result was the [XXX] mask because there is no standard curve that can be used to calculate the measured value (concentration).
[Require retest]	With regard to analysis results for which a retest order was issued because the first test met the retest condition (setting), this prints the result of the first test that did not use the retest order.
[Over range]	Prints analysis results that include tests whose result was over the range.
[Over diluted]	Prints analysis results that include tests whose measured value (concentration) for dilution analysis was 0.
[None of the above]	Prints analysis results that do not meet any of the above conditions.
[Print]	
[Do]	Select checkboxes to enable auto printing of the corresponding items.

4 Touch [OK].

The dialog box closes and the auto print for review settings change.

10.6 Searching for analysis results by patient information or sample number

You can search for analysis results by specifying a sample number or patient ID as a keyword. Follow the steps below to search for analysis results.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Touch [Search] on the operation panel.

The following dialog box appears.

3 Enter the search conditions.

The following items are displayed in the dialog box:

[Sample No.]	Search for analysis results based on the entered sample number. A sample number can also be entered by scanning with the handheld barcode reader.
[Patient ID]	Search for analysis results based on the entered patient ID.
[First name]	Search for analysis results based on the entered patient first name.
[Last name]	Search for analysis results based on the entered patient last name.
[Reset condition]	Touch to clear the search conditions.
[Close]	Touch to close the dialog box.

4 Touch [Previous] or [Next].

Data that satisfy all specified conditions are selected in the job list.

[Previous]	Touch to search for analysis results upward from the selected line of the job list.
[Next]	Touch to search for analysis results downward from the selected line of the job list.

5 Touch [Close].

The dialog box closes and search is exited.



Note:

"*" and "?" can be entered as wildcard characters in a search.

"?": Use "?" as a wildcard for 1 character.

e.g. If "99?99" is entered, "99099", "99999" and "99A99" are all selected.

"*": Use "*" as a wildcard for 0 or more characters.

e.g. If you search for "9 * 9", results such as "909", "9119", and "99A99" are selected.

10.7 Retest

When analysis has to be repeated to double-check a positive result or because an error or over-range result occurred, a retest order is created. Retest orders are not created for standard curve analysis, QC analysis, or retest analysis.

The procedures for viewing the retest list and analyzing retest orders are the same as for untested samples. For details, see Chapter 9.

(► **P.214** "Chapter 9: 9.4 Analyzing a sample that could not be analyzed")

There are 2 types of retest orders.

- **Re-dilution analysis:** An order is created with the same tests as the initial analysis, with a different dilution ratio. This type of order is created when the result is over-the range, or when dilution analysis produces a low concentration result.
- **Repeat analysis:** An order is created with the same tests with the same dilution ratio as the initial analysis. This type of order is created when an analysis error occurs, or when specified conditions are met.

Retest orders are added to the untest/retest list. A combined maximum of 300 untest orders and retest orders can be saved in the untest/retest list. Once the number of orders reaches 300, each new orders automatically delete the oldest orders. Alternatively, orders from the previous day are automatically deleted. Retest orders can be used automatically based on the sample number.

10.8 Validating analysis results

Validation is the act of checking analysis results and determining that the results are suitable for external reporting.

Once validated, analysis results can be printed or sent to a host PC.

After results are validated, it is not possible to recalculate for results, change the sample number or patient ID, or edit sample comments and result comments.

If you need to edit any of these items, invalidate the results first.

10.8.1 Automatically validating results

You can have results be automatically validated when analysis finishes (when the results are complete) if their progress meets preset conditions. If the results do not meet the conditions, auto validation does not take place. To set auto validation, see the "Administrator's Guide".

(► Administrator's Guide, "Chapter 6: 6.1 Setting auto validation of analysis results")



Information

If automatic validation does not take place, the progress will not change to [Validated].
Check the analysis results and then validate manually.

10.8.2 Manually validating results

Results that are completed can be validated.

This can be executed when the progress on the [Joblist] screen is [Review] or [Error], or the analysis result review information on the [Browser] screen is [Review] or [Error].

Follow the steps below to validate results manually.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results that you want to validate.

You can also display the desired analysis results on the [Browser] screen and then follow the steps below.



Information

An analysis result whose progress is [Pending] or [Processing] cannot be validated. If such a result is included in a selection of multiple results, only results that have been completed will be validated.

For any results that were not validated, validate after analysis is completed.

3 Touch [Validation] on the operation panel.

A confirmation dialog box appears.

4 Touch [OK].

The dialog box closes, and the progress of the validated analysis result changes to [Validated].

On the [Browser] screen, the validation information changes to [Validated].

10.8.3 Invalidating results

To edit analysis results that have been validated, the results must be invalidated.
Follow the steps below to invalidate analysis results.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results that you want to invalidate.

You can also display the desired analysis results on the [Browser] screen and then follow the steps below.

3 Touch [Invalidate] on the operation panel.

A confirmation dialog box appears.

4 Touch [OK].

The dialog box closes, the progress returns to the state prior to [Validated], and you can edit the results.
On the [Browser] screen, the validation information changes to [Not Validate].



Information

When you report analysis results, the progress changes to [Reported].
Results that have been "Reported" can be invalidated, but the progress will continue to indicate [Reported]. Editing is possible after the results are invalidated.

10.9 Deleting analysis results

Unrequired analysis results can be deleted. Results cannot be deleted until analysis has finished.
When the number of stored samples reaches 100,000, each new analysis result automatically deletes the oldest result.

Follow the steps below to delete analysis results.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results that you want to delete.

You can also display the desired analysis results on the [Browser] screen and then follow the steps below.

3 Touch [Delete] on the operation panel.

A confirmation dialog box appears.

4 Touch [OK].

The dialog box closes and the selected data is deleted.

Deleted data can be checked by creating a [Canceled results] tab from the job list layout settings.

For details, see the following.

(► **P.237** "10.3.3 Changing the tab display")

10.10 Recalculation using a new standard curve

Recalculation can be used to recalculate the concentration using a newly created standard curve. If analysis is performed using a reagent for which a standard curve has not been created, the displayed result will be masked using the no standard curve mask and the concentration will not appear.



Information

- The results of the recalculation will overwrite the existing data. Make a backup or copy of the existing data beforehand as necessary.
- Analysis results that have been validated cannot be recalculated. To recalculate validated results, invalidate the results. To invalidate results, see the following. (►P.247 "10.8.3 Invalidating results")

10.10.1 Automatically recalculating results

When a standard curve is validated, any analysis results that do not have a calculated concentration will be automatically recalculated.

This only applies to uncalculated results of the present day that were analyzed using the same lot as the R1-R5 reagent lot used for the validated standard curve.

The reagent lot used for analysis can be checked on the [Browser] screen.

When a result is recalculated automatically, it is validated and output automatically.

A manually recalculated result is not validated and output automatically.

10.10.2 Manually recalculating results

Follow the steps below to perform manual recalculation.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results that you want to recalculate.

You can also display the desired analysis results on the [Browser] screen and then follow the steps below.

3 Touch [Recalculate] on the operation panel.

The dialog box on the right appears.

Recalculation

Calculate selected data in Joblist or data on Browser screen again.

Test

HBsAg

OK Cancel

4 Specify the test.

To select the test, touch [Test].

5 Touch [OK].

The dialog box closes, the specified analysis results are recalculated, and the calculation results are displayed.



Information

The concentration is calculated using the standard curve that is currently retained.
If an analysis result that does not have a standard curve is recalculated, the result will change to "Uncalculated data (XXXXX.XXX)".



Note:

To recalculate past analysis results, recycle the standard curve. For information on recycling standard curves, see the "Administrator's Guide".
(► Administrator's Guide, "Chapter 3: 3.6 Retrieving standard curves")

10.11 Saving analysis results

Analysis result data can be saved. Data can be saved to a file, printed, and sent to a host computer.

10.11.1 Saving to a file

Only completed results can be saved to a file in CSV format.

Sample numbers, concentrations, and other information are output as a list.

Results from an analysis that is still in progress are not output.

Follow the steps below to save analysis results to a file.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results that you want to save to a file.

You can also display the desired analysis results on the [Browser] screen and then follow the steps below.

3 Touch [File output] on the operation panel.

A confirmation dialog box appears.

4 Touch [OK].

The dialog box appears.

5 Specify the save folder.

6 Enter the file name.

The file extension is ".csv".



Note:

The default file name is "AssayResult_date created (YYYYMMDD)_time created (HHMMSS).csv".

7 Touch [OK].

The dialog box closes and the CSV file is stored in the specified folder.



Note:

When the instrument is shut down, the analysis results of that day are automatically saved to a preset output location. To change the automatic save location, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 6: 6.4 Configuring settings for auto backup at shutdown")

10.11.2 Printing

Analysis results can be printed in a specified format.

Print formats are [Assay sheet print GP], [Assay sheet print LP], [List print GP], [List print LP], [Laboratory print GP], [Laboratory print LP].

Analysis results that meet the automatic output conditions are printed automatically.

To set the auto output conditions, see the "Administrator's Guide".

(► Administrator's Guide, "Chapter 6: 6.3 Setting conditions for automatic output of analysis results (host output and printing)")



Information

To print, connect a printer.

Printing is not possible unless a printer is connected.

Follow the steps below to print analysis results.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results that you want to print.

You can also display the desired analysis results on the [Browser] screen and then follow the steps below.

3 Touch the print format on the operation panel.

A confirmation dialog box appears. Make sure that a printer is in the READY state.

4 Touch [OK].

The dialog box closes and printing starts.



Information

Analysis results that have not been validated will not be printed in the list and form formats.

Validate the results before printing.

10.11.3 Sending to the host computer

Analysis results can be sent to the host computer using a specified communication format.

Analysis results can be output if the progress is [Validated] or if the validation information indicates the results have been validated.

If the conditions for auto output are met, the results will be output to the host computer automatically. To set the auto output conditions, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 6: 6.3 Setting conditions for automatic output of analysis results (host output and printing)")



Information

- Analysis results that have not been validated are not sent to the host computer. Validate the results before sending.
- When analysis results with an automatically assigned patient ID are sent to the host computer, the patient information is not sent. To check patient information, see the "Administrator's Guide".
(►Administrator's Guide, "Chapter 7: 7.1 Checking patient information")

Follow the steps below to send analysis results to the host computer.

1 Touch [Joblist] on the toolbar.

The [Joblist] screen appears.

2 Select the analysis results that you want to send.

You can also display the desired analysis results on the [Browser] screen and then follow the steps below.

3 Touch [Send to HOST] on the operation panel.

A confirmation dialog box appears.

4 Touch [OK].

The dialog box closes, and the results that have been validated among those that are selected are sent.

Chapter 11 Instrument maintenance/Replacing supply parts

This chapter describes the instrument maintenance and inspection tasks, how to replace supply parts, how to collect information about the instrument, and how to perform operation tests.

To ensure that the HISCL-5000 is kept in good working condition, periodic maintenance must be performed.

- Shutdown (probe washing)
(▶**P.83** "Chapter 4: 4.4 Shutting down the instrument")
- Replenish the cuvettes
(▶**P.103** "Chapter 5: 5.2.1 Replenishing cuvettes")
- Replenish the tips
(▶**P.105** "Chapter 5: 5.2.2 Replenishing tips")
- Replenish the R1-R3 reagent
(▶**P.108** "Chapter 5: 5.3.1 Replenishing an R1-R3 reagent")
- Replenish the R4/R5 reagent
(▶**P.113** "Chapter 5: 5.3.3 Replenishing R4/R5 reagent")
- Replenish line washing/concentrated line washing/HISCL washing
(▶**P.115** "Chapter 5: 5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")
- Replenish probe washing
(▶**P.118** "Chapter 5: 5.3.5 Replenishing probe washing")
- Discard used cuvettes and tips
(▶**P.127** "Chapter 5: 5.6.1 Disposing of waste in the waste box")
- Discard the waste fluid in the waste tank (optional)
(▶**P.130** "Chapter 5: 5.6.2 Disposing of waste fluid")
- Clean the surface of the instrument
(▶**P.263** "11.3 Maintaining the instrument")
- Clean the probe washing holder
(▶**P.265** "11.3.3 Cleaning the probe washing holder")
- Replace the membrane filter (every 1,000 operations)
(▶**P.266** "11.3.4 Replacing the membrane filter")
- Clean the sample nozzle
(▶**P.270** "11.3.5 Cleaning the sample nozzle")
- Adjust the pressure
(▶**P.276** "11.4.2 Checking pressure values")
- Check the fluid level and drain the fluid from the trap chamber
(▶**P.272** "11.3.6 Emptying the trap chamber")
- Rack and sample barcode reading check
(▶**P.284** "11.4.7 Racks and samples' barcode reading test")
- Automatic washing of the probe and fluid lines
The instrument performs these tasks automatically before analysis, after analysis, and during shutdown. If needed, this can be done manually from the [User maintenance] dialog box.
For information on the [User maintenance] dialog box, see the following.
(▶**P.258** "11.1.2 User maintenance dialog box")
- Draining condensation
The instrument automatically drains condensation after a fixed time elapses. If needed, this can be done manually from the [User maintenance] dialog box.
For information on the [User maintenance] dialog box, see the following.
(▶**P.258** "11.1.2 User maintenance dialog box")
- R2 reagent mixing
The instrument automatically mixes the reagent after a fixed time elapses. If needed, this can be done manually from the [User maintenance] dialog box.
For information on the [User maintenance] dialog box, see the following.
(▶**P.258** "11.1.2 User maintenance dialog box")

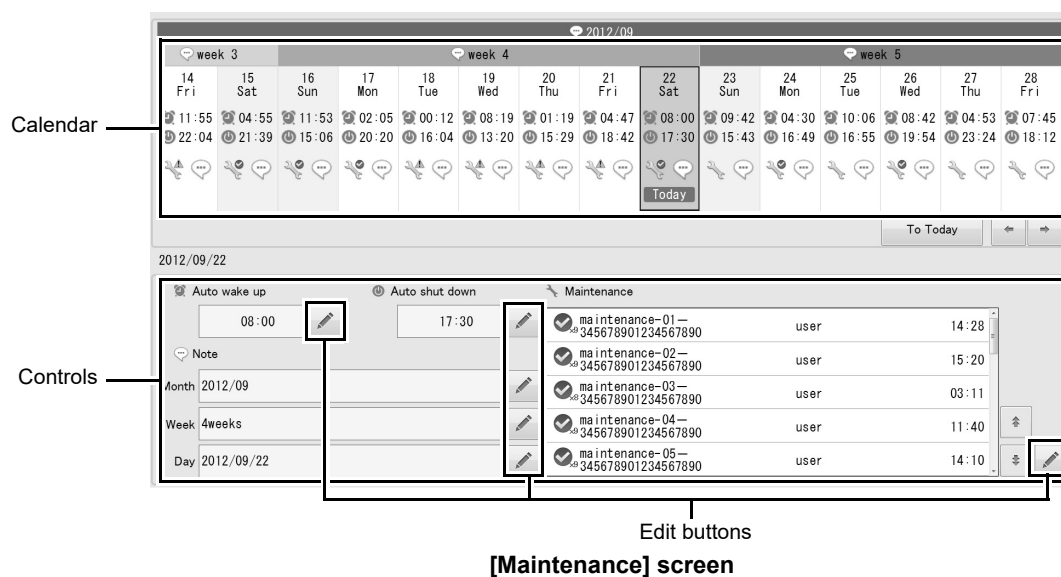
11.1 Screens used for maintenance

Maintenance of the HISCL-5000 can be performed from the [Maintenance] screen and the [User maintenance] dialog box.

11.1.1 Maintenance screen

This is the main screen used for maintenance of the HISCL-5000.

Touch [Maintenance] on the toolbar to display the [Maintenance] screen.



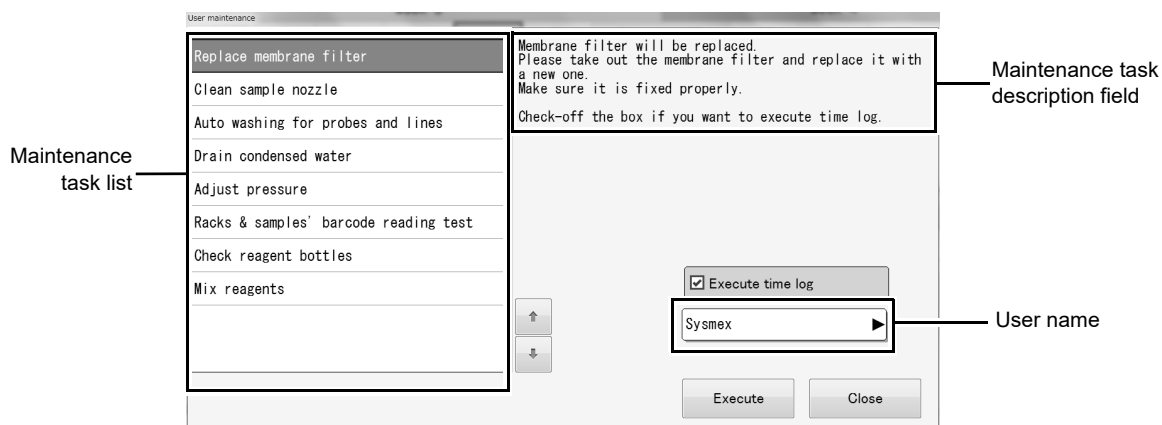
Calendar	The week before and the week after the current day are displayed. The selected date is indicated by a blue frame. Set holidays are grayed out. To set holidays, see the "Administrator's Guide". (► Administrator's Guide, "Chapter 2: 2.13 Setting instrument holidays")
Today	Appears on the current day.
	Displays the set time for auto wake-up.
	Displays the set time for auto shutdown.
	Indicates that maintenance tasks are scheduled, completed, or have not been performed.
	Indicates that there are special instructions.
[To Today]	Touch to select this day.

Controls	Displays the maintenance schedule for the selected date.
[Auto wake up]	Displays the registration status and set time for auto wake-up. Prior to the set time, the settings can be changed and new registration performed. Touch the Edit button to display the registration dialog box. For details, see the following. (► P.259 "11.2.2.1 Setting auto wake-up")
[Auto shut down]	Displays the registration status and set time for auto shutdown. Prior to the set time, the settings can be changed and new registration performed. Touch the Edit button to display the registration dialog box. For details, see the following. (► P.260 "11.2.2.2 Setting auto shutdown")
[Maintenance]	Displays maintenance tasks registered to be performed that day and task information. The  icon, the time the task was performed, and the user name appear on tasks that have been completed. Touch a task to perform maintenance in the dialog box that appears. Touch the Edit button to display the edit maintenance information dialog box for registering maintenance tasks to be performed that day. For details, see the following. (► P.261 "11.2.3 Creating a maintenance plan")
[Note]	Displays special instructions for the selected day/week/month. Touch the Edit button to display the edit comment dialog box. For details, see the following. (► P.262 "11.2.4 Adding special instructions")

11.1.2 User maintenance dialog box

The [User maintenance] dialog box is used to perform specific HISCL-5000 maintenance tasks and to check and test operation.

Touch [User maintenance] on the operation panel on the [Maintenance] screen to display the [User maintenance] dialog box.



[User maintenance] dialog box

Maintenance task list	Displays the maintenance tasks. The maintenance tasks set in the maintenance task settings are shown. To configure the settings, see the "Administrator's Guide". (► Administrator's Guide, "Chapter 2: 2.11 Setting maintenance items that are used")
Maintenance task description field	Displays a description of the selected maintenance task.
[Execute time log]	Select the checkbox to record the maintenance task name, user name, and time the task was performed in the log.
User name	Select the name of the user performing maintenance.
[Execute]	Touch to execute the selected maintenance task.
[Close]	Touch to close the dialog box.

11.2 Support functions for daily maintenance

Maintenance can be performed automatically and comments regarding maintenance can be entered.

11.2.1 Schedule

The maintenance schedule function can be used to manage the schedule for maintenance work (entering the schedule and checking if tasks were performed).

The schedule is managed on the [Maintenance] screen. (► P.256 "11.1.1 Maintenance screen")

11.2.2 Configuring auto wake-up and shutdown settings

Times can be set to have the instrument automatically wake up and shut down.

This saves you the time and effort of manually waking up and shutting down the instrument.



Information

When the instrument wakes up, it mixes the R2 reagent.

11.2.2.1 Setting auto wake-up

Follow the steps below to set auto wake-up.

1 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

2 Touch [Auto wake-up] on the operation panel.

The dialog box on the right appears.

You can also display the dialog box by touching the [Auto wake up] edit button.

3 Configure the settings.

Select the [Set to wake up] checkbox and set the time.

4 Touch [OK].

The dialog box closes and the settings are stored.

11.2.2.2 Setting auto shutdown

Follow the steps below to set auto shutdown.

1 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

2 Touch [Auto shut-down] on the operation panel.

The dialog box on the right appears.

You can also display the dialog box by touching the [Auto shut down] edit button.



3 Configure the settings.

Select the [Set to shutdown] checkbox and set the time.

4 Touch [OK].

The dialog box closes and the settings are stored.

11.2.3 Creating a maintenance plan

Maintenance tasks and cycles can be registered. When establishing a periodic maintenance plan, specify the task cycle, such as "every day" or "end of month".

Follow the steps below to set the cycle.

1 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

2 Touch [Maintenance plan settings] on the operation panel.

The following dialog box appears.

Maintenance list	
Racks & samples' barcode reading test	

Regular maintenance	Cycle
Replace membrane filter	BOM
Clean sample nozzle	BOM
Auto washing for probes and lines	Mon.
Adjust pressure	Daily

Cycle

☐ Daily Except rest days

Weekly

☐ Sun. ☒ Mon. ☐ Tue. ☐ Wed. ☐ Thu. ☐ Fri. ☐ Sat.

Monthly

☐ BOM ☐ EOM

BOM: The first working day of the month.
EOM: The last working day of the month.

3 Register maintenance tasks.

Select the task you want to register from [Maintenance list] and touch [Add].

To delete a task from the registered tasks, touch [Back].

4 Set the cycle.

You can select from every day, every week (selected days of the week), or every month (beginning/end) for the cycle.

5 Touch [OK].

The dialog box closes and the settings are stored.

11.2.4 Adding special instructions

The comments that appear in the special instructions field can be edited.
Follow the steps below to edit a comment.

1 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

2 Touch [Notes(daily)]/[Notes(weekly)]/[Notes(monthly)] on the operation panel.

The edit comment dialog box appears.

You can also display the dialog box by touching the [Note] edit button.

For information on the edit comment dialog box, see Chapter 3.

(►P.58 "Chapter 3: 3.4.8 Edit comment dialog box")

3 Enter, edit, or delete the comment.

4 Touch [OK].

The dialog box closes and the comment is added to the selected maintenance task.

11.3 Maintaining the instrument

Perform regular maintenance of the instrument.

11.3.1 Cleaning the exterior of the instrument

The steps for cleaning the exterior of the instrument are explained below.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to clean the exterior of the instrument.

1 Shut down the instrument.

To shut down the instrument, see Chapter 4.

(►P.83 "Chapter 4: 4.4 Shutting down the instrument")

2 Turn off the power and switch off the power breaker switch.

For the locations of the power breaker switch and power switch, see Chapter 3.

(►P.37 "Chapter 3: 3.4.2 Instrument part description")



Warning!

Always turn off the power and switch off the power breaker switch before cleaning the instrument. There is a risk of electrical shock.

3 Wipe the exterior of the instrument.

Use a cloth moistened with water and neutral detergent to wipe dirt off the exterior of the instrument.



Information

Never use cleaning solutions other than water and neutral detergent.

There is a risk of damage to the surface coating on the instrument.

4 Wipe with a dry cloth.

11.3.2 Cleaning the interior of the instrument

The steps for cleaning the interior of the instrument are explained below.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to clean the interior of the instrument.

1 Shut down the instrument.

To shut down the instrument, see Chapter 4.

(►P.83 "Chapter 4: 4.4 Shutting down the instrument")

2 Turn off the power and switch off the power breaker switch.

For the locations of the power breaker switch and power switch, see Chapter 3.

(►P.37 "Chapter 3: 3.4.2 Instrument part description")



Warning!

Always turn off the power and switch off the power breaker switch before cleaning the instrument. There is a risk of electrical shock.

3 Open the operation cover on the analyzer.



Caution!

Be careful not to hit your head on the operation cover when it is open.



Information

When opening and closing the operation cover, exercise caution to make sure your fingers are not pinched by the cover.

4 Wipe the area around the reagent holders.

Use a cloth moistened with water and neutral detergent to wipe off dirt from the area around the reagent holders. In particular, when the R4/R5 reagent is replaced, drops of reagent fall on the covers of reagent holder B. Wipe off the drops of reagent.



Information

Never use cleaning solutions other than water and neutral detergent. There is a risk of damage to the surface coating on the instrument.

5 Wipe with a dry cloth.

6 Close the operation cover.

11.3.3 Cleaning the probe washing holder

This section explains how to clean the probe washing holder.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.



Caution!

- The probe washing is a strong alkali. Exercise caution when cleaning.
- If solution accidentally comes in contact with the eyes, mouth, or skin, rinse with copious amounts of water and seek medical attention if necessary.
- Contains sodium hypochlorite. Do not mix with an acidic material. Mixing with an acidic material will cause the formation of chlorine gas.

Follow the steps below to clean the probe washing holder.

1 Shut down the instrument.

To shut down the instrument, see Chapter 4.

(►P.83 "Chapter 4: 4.4 Shutting down the instrument")

2 Turn off the power and switch off the power breaker switch.

For the locations of the power breaker switch and power switch, see Chapter 3.

(►P.37 "Chapter 3: 3.4.2 Instrument part description")



Warning!

Always turn off the power and switch off the power breaker switch before cleaning the holder. There is a risk of electrical shock.

3 Open the probe washing holder/pressure regulator cover at the bottom right of the front of the instrument.



Information

When opening and closing the probe washing holder/pressure regulator cover, take care that your fingers are not pinched by the cover.

4 Wipe the area around the probe washing holder/pressure regulator.

Use a cloth moistened with water and neutral detergent to wipe off dirt from the area around the probe washing holder/pressure regulator.



Information

Never use cleaning solutions other than water and neutral detergent.
There is a risk of damage to the surface coating on the instrument.

5 Wipe with a dry cloth.

6 Close the probe washing holder/pressure regulator cover.

11.3.4 Replacing the membrane filter

This section explains the procedure for replacing the membrane filter that wipes off and cleans the tip of the sample nozzle.

Replace the membrane filter if the surface becomes noticeably damaged or dirty, or each time it exceeds an operation count of 1,000.

The membrane filter is provided with the "HISCL DISPOSABLE TIP NDT-400A" supply item.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to replace the membrane filter.

1 Make sure the instrument is in the READY state.

2 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

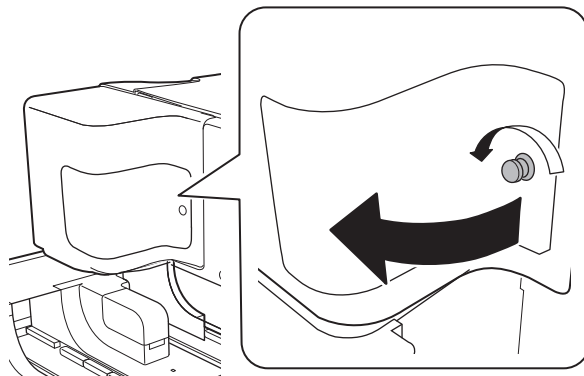
3 Touch [User maintenance] on the operation panel.

4 Touch [Replace membrane filter].

5 Check the user name and touch [Execute].

A dialog box indicating that processing is in progress appears on the IPU screen, and instrument operation is restricted.

6 Turn the lock on the sample arm cover on the left side of the instrument counterclockwise to release, and open the sample arm cover.



Warning!

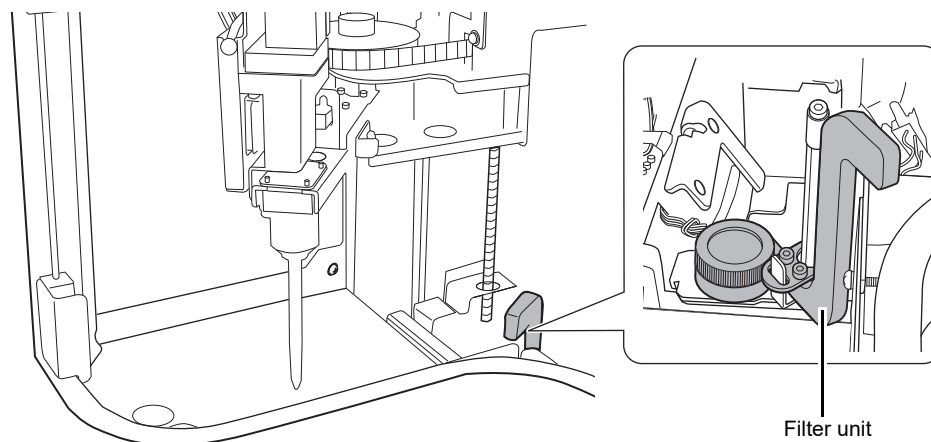
- Do not release the lock while the instrument is in operation. An emergency stop will occur.
- The drive unit is visible when the sample arm cover is opened. The drive unit is locked when the sample arm cover is open, but take care not to insert your hand in the opening. There is a risk of injury.



Information

When opening and closing the sample arm cover, take care that your fingers are not pinched by the cover.

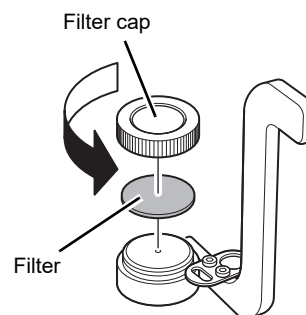
7 Remove the filter unit.



Caution!

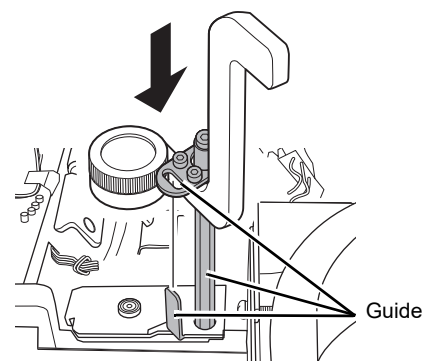
Take care not to drop the filter unit into the instrument.

8 Remove the filter cap by turning it counterclockwise. Dispose of the used filter appropriately.



9 Place a new filter and turn the filter cap clockwise to tighten.

10 Align the filter unit with the guide and replace in its original position.



Caution!

Take care not to drop the filter unit into the instrument.

11 Close the sample arm cover, and turn the lock clockwise to lock the cover.

12 Touch [OK].

The dialog box closes and the instrument can be operated.

11.3.5 Cleaning the sample nozzle

Clean the sample nozzle at the same time you replace the membrane filter.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to clean the sample nozzle.

- 1 Make sure the instrument is in the READY state.**
- 2 Touch [Maintenance] on the toolbar.**
The [Maintenance] screen appears.
- 3 Touch [User maintenance] on the operation panel.**
- 4 Touch [Clean sample nozzle].**
- 5 Check the user name and touch [Execute].**
A confirmation dialog box appears.
- 6 Touch [OK].**
The following dialog box appears.



7 Follow the operation instructions in the dialog box.

To cancel the current task and close the dialog box, touch [Cancel].

The following text appears in the dialog box.

1. Move sample dispensing unit

The sample dispensing unit automatically moves to the work position. When the unit has finished moving, the dialog box automatically changes.

2. Clean nozzle

Open the sample arm cover and clean the sample nozzle.

When you close the sample arm cover after finishing, the dialog box automatically changes.



Warning!

- Do not release the lock while the instrument is in operation. An emergency stop will occur.
- The drive unit is visible when the sample arm cover is opened. The drive unit is locked when the sample arm cover is open, but take care not to insert your hand in the opening. There is a risk of injury.
- When opening and closing the sample arm cover, take care that your fingers are not pinched by the cover.

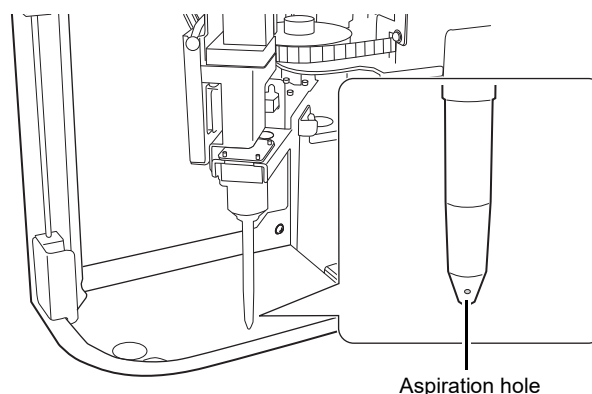


Caution!

After wiping the tip of the sample nozzle, make sure there is no foreign matter in the aspiration hole in the sample nozzle using the bottle_Assy No. 26.

If there is foreign matter, remove by wiping with a cloth or other means.

Otherwise, correct analysis results may not be obtained.



Information

Before using Bottle_ASSY No. 26, add enough 70% or higher ethanol to immerse the entire sponge. If the sponge is dry, add ethanol.

3. Move back sample dispensing unit

The sample dispensing unit automatically moves back to its original position. When the unit has finished moving, the dialog box automatically changes.

4. Finished

8 Touch [Finished].

The dialog box closes and sample nozzle cleaning finishes.

11.3.6 Emptying the trap chamber

Check if fluid has collected in the trap chamber, and empty as needed.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to empty the trap chamber.

1 Shut down the instrument.

To shut down the instrument, see Chapter 4.

(►P.83 "Chapter 4: 4.4 Shutting down the instrument")

2 Turn off the power and switch off the power breaker switch.

For the locations of the power breaker switch and power switch, see Chapter 3.

(►P.37 "Chapter 3: 3.4.2 Instrument part description")

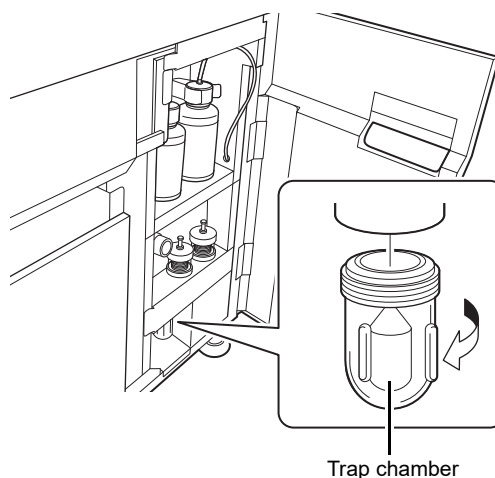


Warning!

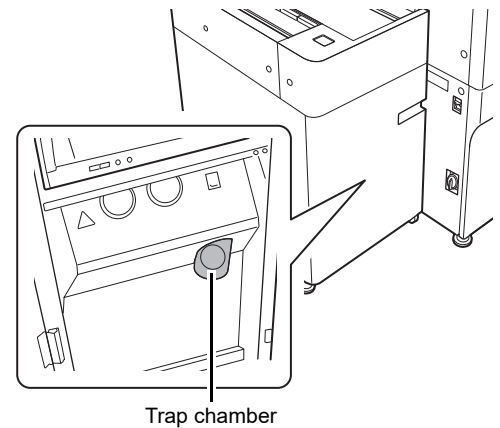
Always turn off the power and switch off the power breaker switch before emptying the chamber. There is a risk of electrical shock.

3 Open the probe washing holder/pressure regulator cover at the bottom right of the front of the instrument.

4 Rotate the trap chamber in the direction shown to remove it.



-
- 5** Dispose of the fluid in the trap chamber appropriately.
-
- 6** Replace the trap chamber and tighten so that there is no air leakage.
-
- 7** Open the cover at the bottom left of the front of the instrument.
-
- 8** Rotate the trap chamber of the pneumatic unit in the direction shown to remove it.
-



-
- 9** Dispose of the fluid in the trap chamber of the pneumatic unit appropriately.
-
- 10** Replace the trap chamber of the pneumatic unit and tighten so that there is no air leakage.
-
- 11** Turn on the instrument power and check the pressure.
(►P.276 "11.4.2 Checking pressure values")
-
- 12** Check if fluid has collected again in the trap chamber.
If needed, repeat steps 3 to 7.
-
- 13** Close the cover at the bottom left of the front of the instrument and the cover of the probe washing holder/pressure regulator.
-

11.4 Inspecting the instrument

Check the pressure, temperature, operation count, and other instrument information, and adjust as needed.

11.4.1 Checking the pressure, temperature, and voltage

The pressure, temperature, voltage, and other information related to the instrument can be checked.
Follow the steps below to check the pressure, temperature, and voltage.

1 Make sure the instrument is in the READY state.

2 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

3 Touch [Analyzer info] on the operation panel.

The following dialog box appears.

Temperature [°C]		Pressure [MPa]		Power supply [V]	
R1R2R3 Reagent part (8.0)	8.4	Pressure 0.250	0.243	24V	23.8
R4R5 Reagent part (15.0)	13.3	Pressure 0.060	0.063	12V	11.8
Incubator A (42.0)	42.0	Vacuum 0.053	0.054	5V	5.1
Incubator B (42.0)	42.2	Vacuum 0.033	0.034		
Incubator C (42.0)	42.0				
Incubator D (42.0)	42.2				
Detector (42.0)	41.8				
		Environment [°C]			
		Analyzer inside (14.0–38.0)		26.6	
		Room air (15.0–35.0)		27.2	
Start pressure check		Stop pressure check		Close	

4 Touch [Start pressure check].

The pneumatic unit starts, and pressure information appears on the screen once a second.

5 Check the instrument information.

Normal values are shown below:

Parameter		Normal value
Temperature	R1R2R3 Reagent part	2.0 to 17.0 °C
	R4R5 Reagent part	13.0 to 17.0 °C
	Incubator A to D	41.5 to 42.5 °C
	Detector	41.0 to 43.0 °C
Pressure	Pressure 0.250 MPa	0.210 to 0.290 MPa
	Pressure 0.060 MPa	0.053 to 0.080 MPa
	Vacuum -0.053 MPa	-0.047 to -0.059 MPa
	Vacuum -0.033 MPa	-0.027 to -0.036 MPa
Power supply	24.0 V	22.8 to 25.2 V
	12.0 V	11.4 to 12.6 V
	5.0 V	4.794 to 5.406 V
Environment	Analyzer inside	14.0 to 38.0 °C
	Room air	15.0 to 35.0 °C

If the temperature or voltage is not normal, contact your local Sysmex representative.

If the pressure is not normal, adjust the pressure.

(► **P.276** "11.4.2 Checking pressure values")

If the environment is not normal, adjust the room temperature by air conditioning or otherwise.

6 Touch [Stop pressure check].

The pneumatic unit stops.

7 Touch [Close].

The dialog box closes.

11.4.2 Checking pressure values

When adjusting a pressure value, check the value in the dialog box as you adjust.
Follow the steps below to check a pressure value.

1 Make sure the instrument is in the READY state.

2 Touch [Maintenance] on the toolbar.

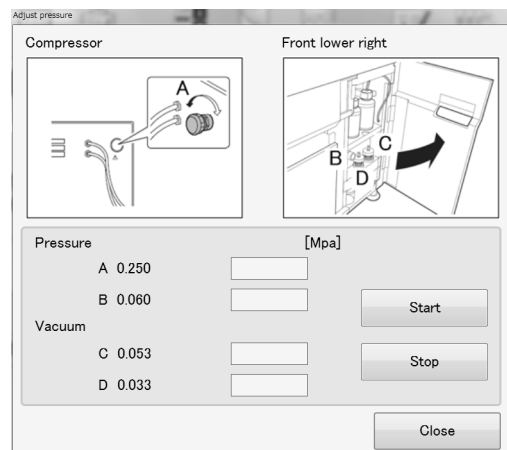
The [Maintenance] screen appears.

3 Touch [User maintenance] on the operation panel.

4 Touch [Adjust pressure].

5 Check the user name and touch [Execute].

The [Adjust pressure] dialog box appears.



[Adjust pressure] dialog box

6 Touch [Start].

The pneumatic unit starts, and pressure information appears on the screen once a second.

7 Check the pressure.

If any pressure values are abnormal, adjust the values while checking them in the dialog box. For the adjustment method, see the following.

(►P.278 "11.4.3 Adjusting the 0.250 MPa pressure", P.280 "11.4.4 Adjusting the 0.060 MPa pressure", P.281 "11.4.5 Adjusting vacuum")

8 Touch [Stop].

The pneumatic unit stops.

9 Touch [Close].

The dialog box closes.

**Note:**

Adjust the pressure values from the pneumatic unit to vacuum: -0.053 MPa and -0.033 MPa, and pressure: 0.250 MPa and 0.060 MPa.

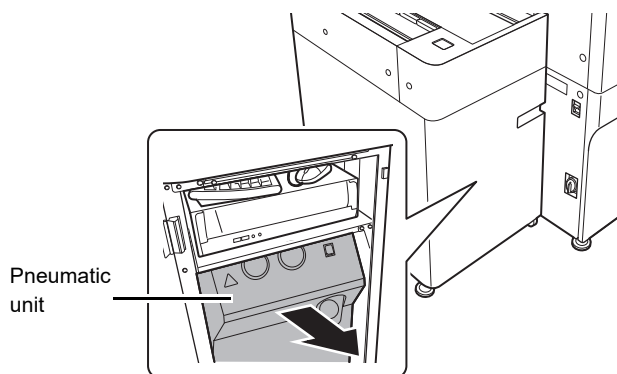
These pressures are constantly monitored by the pressure sensor, and an error message is displayed if an abnormal value is detected.

If an error message indicating a pressure error appears, check for air leaks and cracks in the tubing and tubing connections, and obstructions and bends in the tubing. If no problems are found in the tubing, adjust the air pressures.

11.4.3 Adjusting the 0.250 MPa pressure

The 0.250 MPa pressure is adjusted using the adjustment knob at the back of the pneumatic unit. Follow the steps below to adjust the pressure.

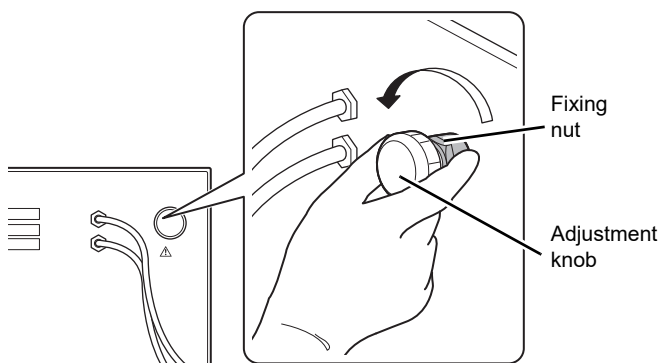
- 1 Open the cover at the bottom left of the front of the instrument and pull out the pneumatic unit.



Caution!

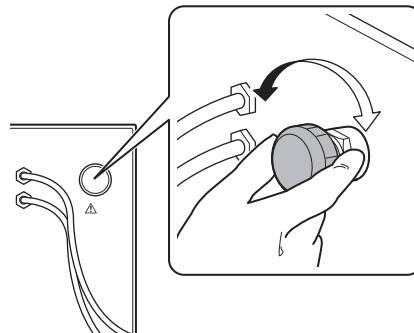
- When pulling out the pneumatic unit, exercise caution to make sure your fingers are not pinched.
- Take care that the pneumatic unit tubing and power cable do not disconnect.

- 2 Loosen the fixing nut on the relief valve adjustment knob on the back of the pneumatic unit.



3 While checking the 0.250 MPa pressure value in the [Adjust pressure] dialog box, turn the adjustment knob to adjust the pressure.

The adjustment range is 0.240 to 0.260 MPa.



Information

To increase the pressure, turn the adjustment knob clockwise. Always adjust the pressure to the required level by increasing the pressure. If the pressure is too high, lower it below the required level and then increase it to the required level.

Otherwise, it may not be possible to accurately adjust the pressure.

4 Tighten the fixing nut, taking care that the adjustment knob does not turn.



Information

If you adjusted the 0.250 MPa pressure, check the 0.060 MPa pressure. If abnormal, adjust the 0.060 MPa pressure. Adjust the pressure using the pressure values on the IPU screen.

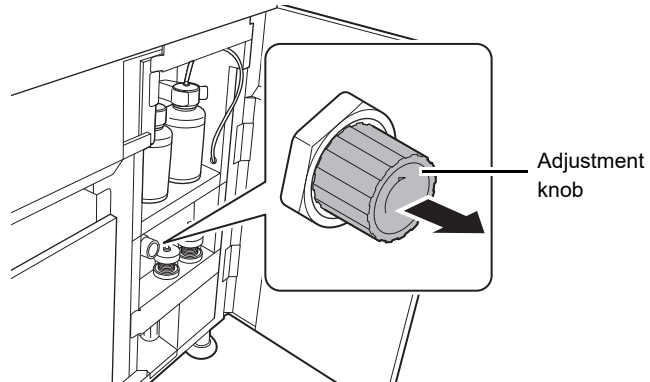
5 Close the lower left cover in front of instrument.

11.4.4 Adjusting the 0.060 MPa pressure

The 0.060 MPa pressure is adjusted using the pressure regulator inside the cover at the lower right of the front of the instrument.

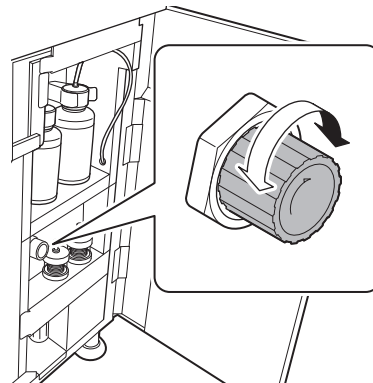
Follow the steps below to adjust the pressure.

- 1 Open the probe washing holder/pressure regulator cover at the bottom right of the front of the instrument.**
- 2 Pull the 0.060 MPa adjustment knob forward to release the lock.**



- 3 While checking the 0.060 MPa pressure value in the [Adjust pressure] dialog box, turn the adjustment knob to adjust the pressure.**

The adjustment range is 0.057 to 0.063 MPa.



Information

To increase the pressure, turn the adjustment knob clockwise. Always adjust the pressure to the required level by increasing the pressure. If the pressure is too high, lower it below the required level and then increase it to the required level.

Otherwise, it may not be possible to accurately adjust the pressure.

- 4 Push the adjustment knob in to lock it, taking care that the knob does not turn.**



Information

If you adjusted the 0.060 MPa pressure, check the 0.250 MPa pressure. If abnormal, adjust the 0.250 MPa pressure. Adjust the pressure using the pressure values on the IPU screen.

- 5 Close the probe washing holder/pressure regulator cover at the bottom right of the front of the instrument.**

11.4.5 Adjusting vacuum

The -0.053 MPa and -0.033 MPa vacuum are adjusted using the pressure regulator inside the cover at the lower right of the front of the instrument.

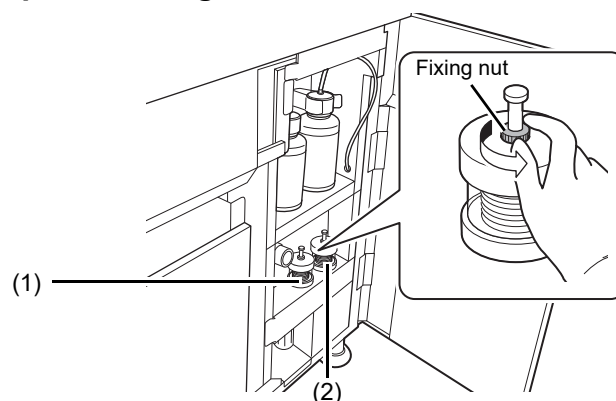
Follow the steps below to adjust these pressures.

1 Open the probe washing holder/pressure regulator cover at the bottom right of the front of the instrument.

2 Loosen the fixing nut on the bellows pressure regulator.

(1) Bellows for -0.033 MPa adjustment

(2) Bellows for -0.053 MPa adjustment



3 While checking the -0.053 MPa or -0.033 MPa pressure values in the [Adjust pressure] dialog box, turn the adjustment knobs to adjust the pressure.

The adjustment ranges are as follows.

(1) -0.033 MPa: -0.031 to -0.035 MPa

(2) -0.053 MPa: -0.051 to -0.055 MPa



Information

To increase the pressure, turn the adjustment knob clockwise. Always adjust the pressure to the required level by increasing the pressure. If the pressure is too high, lower it below the required level and then increase it to the required level.

Otherwise, it may not be possible to accurately adjust the pressure.

4 Tighten the fixing nut, taking care that the adjustment knob does not turn.



Information

After adjusting one of the vacuum, check the other vacuum.

5 Close the probe washing holder/pressure regulator cover at the bottom right of the front of the instrument.

11.4.6 Checking the operation count of each system unit

The operation count of each maintenance part can be checked.

When the operation count nears the replacement guideline count, the status icon of the periodic replacement part appears in orange on the [Set Up] screen. Contact your local Sysmex representative.

Follow the steps below to check the operation counts.

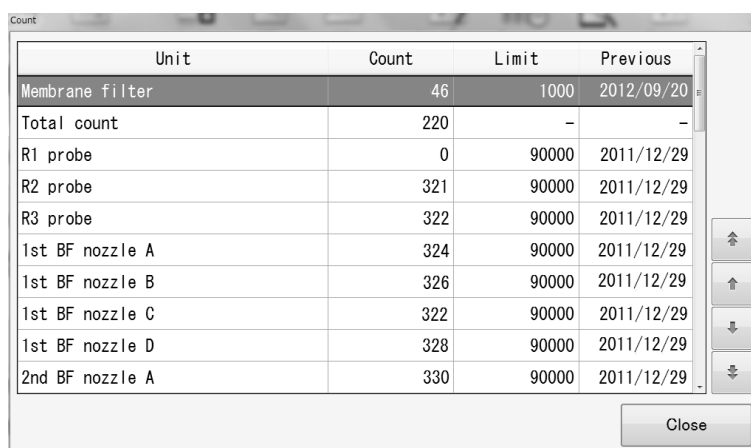
1 Make sure the instrument is in the READY state.

2 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

3 Touch [Movement info] on the operation panel.

The following dialog box appears.



Unit	Count	Limit	Previous
Membrane filter	46	1000	2012/09/20
Total count	220	-	-
R1 probe	0	90000	2011/12/29
R2 probe	321	90000	2011/12/29
R3 probe	322	90000	2011/12/29
1st BF nozzle A	324	90000	2011/12/29
1st BF nozzle B	326	90000	2011/12/29
1st BF nozzle C	322	90000	2011/12/29
1st BF nozzle D	328	90000	2011/12/29
2nd BF nozzle A	330	90000	2011/12/29

4 Check the operation counts.

**Note:**

- When the operation count of the membrane filter exceeds the replacement guideline count, perform membrane filter replacement and sample nozzle cleaning. For details, see the following.
(► **P.266** "11.3.4 Replacing the membrane filter", **P.270** "11.3.5 Cleaning the sample nozzle")
- The operation counts of maintenance parts, guideline counts for part replacement, dates of previous replacement, and other information is shown.
- An operation count that is over the guideline count for replacement is shown in red.
- The total operation count of the instrument can also be checked. A guideline count for replacement is not shown for the total operation count.

5 Touch [Close].

The dialog box closes.

11.4.7 Racks and samples' barcode reading test

Reading tests of rack ID and sample ID (positions 1 to 5) barcodes can be performed.
Follow the steps below to perform a sample ID scanning test.

1 Make sure the instrument is in the READY state.

2 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

3 Touch [User maintenance] on the operation panel.

4 Touch [Racks & samples' barcode reading test].

5 Check the user name and touch [Execute].

6 Touch [OK].

The dialog box on the right appears.

Barcode reading test

Going to test barcode reading.
Please set on the rack and push "Execute" button.

Pos.	Barcode
Rack	
Pos. 1	
Pos. 2	
Pos. 3	
Pos. 4	
Pos. 5	
Check	

Execute

Close

7 Replace the rack in the sampler.

8 Touch [Execute].

The rack ID and sample IDs (positions 1 to 5) scanned with the barcode reader are displayed.



Note:

If a scanning error occurs, "ERRXX" (where XX is the position number) appears.
(e.g. "ERR03" indicates that a scanning error occurred in position 3.)

9 Touch [Close].

The dialog box closes.

11.4.8 Check if there is a problem with the reagent bottles

Follow the steps below to check all reagent bottles placed in the instrument for problems.

1 Make sure the instrument is in the READY state.

2 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

3 Touch [User maintenance] on the operation panel.

4 Touch [Check reagent bottles].

5 Check the user name and touch [Execute].

6 Touch [OK].

All reagent bottles placed in the instrument will be checked.

11.4.9 Mixing R2 reagent

Follow the steps below to mix R2 reagent before analysis.

1 Make sure the instrument is in the READY state.

2 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

3 Touch [User maintenance] on the operation panel.

4 Touch [Mix reagents].

5 Check the user name and touch [Execute].

6 Touch [OK].

R2 reagent will be mixed for about 10 minutes.

11.5 Saving maintenance data

Maintenance data can be saved. This section explains the procedures for saving to a file and printing.

11.5.1 Displaying the maintenance log

The [Maintenance log] screen shows the status of maintenance tasks and special instructions by month. The last 6 months of the maintenance log and the maintenance schedule for the next 3 months can be displayed.

Follow the steps below to display the maintenance log screen.

1 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

2 Touch [Maintenance log] on the operation panel.

The [Maintenance log] screen appears.

[Maintenance log] screen

[Result]	Displays registered maintenance tasks and their status. For details, see the following. (► P.261 "11.2.3 Creating a maintenance plan")
  	Indicates that maintenance tasks are scheduled, completed, or have not been performed.
[Note]	Displays comments registered as special instructions. For details, see the following. (► P.262 "11.2.4 Adding special instructions")
[Print]	Touch to print the maintenance log of the selected month.
[Export]	Touch to export the maintenance log of the selected month to a file in CSV format.
[Close]	Touch to close the screen.

11.5.2 Saving to a file

The maintenance log can be saved to a file in CSV format.
Follow the steps below to save the maintenance log to a file.

1 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

2 Touch [Maintenance log] on the operation panel.

The [Maintenance log] screen appears.

3 Touch [Export].

4 Specify the save folder.

5 Enter the file name.

The file extension is ".csv".

**Note:**

The default file name is "Maintenance_year/month output(YYYYMM)_date created (YYYYMMDD)_time created (HHMMSS).csv".

6 Touch [OK].

The dialog box closes and the CSV file is stored in the specified folder.

11.5.3 Printing

The maintenance log can be printed.



Information

To print, connect a printer.

Printing is not possible unless a printer is connected.

Follow the steps below to print the maintenance log.

1 Touch [Maintenance] on the toolbar.

The [Maintenance] screen appears.

2 Touch [Maintenance log] on the operation panel.

The [Maintenance log] screen appears.

3 Touch [Print].

A confirmation dialog box appears. Make sure that a printer is in the READY state.

4 Touch [OK].

The dialog box closes and printing starts.

Chapter 12 Troubleshooting

This chapter explains the instrument errors that may occur and how to resolve them.

12.1 Introduction

This chapter explains HISCL-5000 errors and how to resolve them.

The main sections are as follows:

- Frequently asked questions
Answers to frequently asked questions.
- Procedures for resolving problems
Information on errors that are not indicated by error messages.
- Procedure for displaying errors
Recent errors can be displayed and checked.
- Procedure for displaying the error log
Errors are stored in the error log.
The error log can be displayed to check information on each error.
- Troubleshooting by error message
Lists the error messages that appear on the screen when problems occur, and how to resolve them.

If a problem cannot be resolved by performing the procedures in this chapter, contact your local Sysmex representative.

12.2 Frequently asked questions

Answers to frequently asked questions about the HISCL-5000 are provided below.

Operation and use

What should I do if there is a power outage?	Remove all reagents, store them in a refrigerator, and then shut down the IPU and instrument. Calibration is not required next time the instrument is started up. For the procedure for removing reagent, see the following. (►P.310 "12.4.8 Releasing the lock on the reagent holder A cover")
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Reagents

Can an expired reagent be used?	An expired reagent cannot be used. Replace with a new reagent.
What should I do if I accidentally invert or tip over and cause mixing of the R2 reagent?	If the reagent is only tipped over for several seconds, there is no problem. Promptly follow the instructions on the package insert and gently shake by hand to mix. The reagent can then be used. If the reagent is inverted for an extended time, avoid using as the quality may be degraded due to the magnetic particles drying or other problems. If the reagent is tipped over and mixed, let sit for 24 hours and then use if there are no air bubbles.
Can a reagent be reused after being temporarily removed?	Reagents are controlled by IC tag, and thus once a reagent is set and calibration is performed, the reagent can be reused as long as it has not expired.
Can a reagent be used if it was accidentally frozen?	If a reagent is frozen, the quality may be affected and correct analysis results may not be obtained. Avoid using a reagent that has been frozen.

Standard curve

When is it necessary to create a standard curve?	A standard curve must always be created when a reagent lot changes or the previous standard curve expires. A standard curve can be changed in other situations as well.
I added a new reagent lot with the old reagent lot still remaining, and I cannot create a standard curve for the new reagent lot.	The standard curve is created with priority given to the old reagent lot. If new and old lots both exist, remove the old reagent lot before creating the standard curve.
If a new standard curve is created using the same lot, what happens to the new standard curve and the old standard curve?	The new standard curve is created in the work area. When the new standard curve is validated, the new standard curve overwrites the lot area where the old standard curve was registered.
If I know the expiration date of a standard curve, can I re-validate it?	The expiration date of a standard curve is 1 month after validation. Create the standard curve again.

Analysis

If the computer goes down during operation, can analysis be continued?	If communication with the IPU is cut off, analysis operation stops and errors occur for all tests that were in progress. Repeat the analysis.
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Time requirement guidelines

How much time is required for startup for a normal routine?	It takes about 12 minutes at normal temperature to enter the READY state from reagent storage mode.
After the analysis start button is pressed, how long does it take until the results appear?	The time from aspiration of the sample until the analysis results are displayed is about 17 minutes, although this varies depending on how many cuvettes remain in the analyzer

Host communication

Communication with the host suddenly broke off.	Make sure the LAN cable is connected properly and check the host communication settings.
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Display

I performed analysis, but the analysis results do not appear anywhere.	Check the display selection settings.
I want to change the item display order.	Change the item display order in the IPU settings.
I want to change the number of digits to the right of the decimal point.	Change the number of decimal digits in the test information in the IPU settings.

12.3 Resolving problems

Solutions to problems that are not displayed in error messages are explained below.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant.

Danger of infection by pathogens or other infectious materials if contaminated by blood or other substances.

12.3.1 Problems at startup

Problem	Cause	Action
Nothing happens when the power is turned on.	- The power breaker switch is off. - The power cable is not properly connected. - The AC outlet does not have power.	- Make sure the power breaker switch is on. - Check if the power cable is correctly connected. - Make sure the AC outlet has power.
Nothing is displayed when the power is turned on and a constant "beep" sound is heard.	A memory problem has occurred.	Turn off the power, wait 1 to 2 minutes, and then turn the power on again.
Nothing appears on the screen.	- The display power is not on. - The power cable is not properly connected. - The input/output cable is not properly connected.	- Make sure the display power is on. - Check if the power cable is correctly connected. - Check if the input/output cable is correctly connected.
Fluid is leaking from the instrument.	- A reagent was spilled. - A tube is not connected properly.	Turn off the power and wipe off the leaked fluid.
The IPU does not enter the READY state when turned on.	- The temperature has not stabilized. - The IPU is not connected to the main unit.	- From the start of instrument wake-up, it takes about 30 minutes until the temperature stabilizes and the READY state is entered. - Check if the LAN cable between the IPU and analyzer is properly connected.

12.3.2 Reagent problems

Problem	Cause	Action
Reagent bottle not recognized	- Failed to read reagent bottle information. - Problem in reagent bottle information.	Correct the reagent and try scanning again, or perform correction. (►P.300 "12.4.3 Recovering from a reagent IC tag scan error")

12.3.3 Standard curve problems

Problem	Cause	Action
The standard curve differs greatly from the previous standard curve.	- The standard curves of other tests also differ greatly. - The R4/R5 reagent has deteriorated. - The standard curve of only one specific test differs greatly. - The calibrator or reagent for the test may have deteriorated. - Incorrect calibrator placement. - Incorrect test information set.	- Change to a new R4/R5 reagent. - Check the calibrator and repeat calibration. - Check if the settings related to the standard curve in the test information are correct.

12.3.4 QC problems

Problem	Cause	Action
Outside the limit range of the target (QC error)	- Both over the upper limit value and less than the lower limit value. - The limit range setting is too narrow. - Mainly over the upper limit value or mainly less than the lower limit value. - Target not redefined. - The limit value was suddenly exceeded. - Short sample or insufficient reagent. - The data gradually shifts and a limit value is exceeded. - The calibrator or a reagent has deteriorated.	- Fluctuations in the data can cause the limit values to be exceeded. Check the limit range settings. - When the reagent lot or control lot changes, the QC data sometimes shifts. Suitable target that accord with the shift must be set. Check the target settings. - Check if there are sufficient volumes of calibrator and reagent, and repeat QC. - Replace the calibrator or reagent and repeat QC.

12.3.5 Problems during analysis operation

Problem	Cause	Action
Analysis does not start	- Order registration has not finished. - The instrument is not ready to analyze. - Out of reagent for the test. - The reagent for the test has expired. - The temperature has not stabilized.	- Check the order registration information on the [Order registration] screen. - If the sample number registered on the [Order registration] screen and the sample number read by the instrument barcode reader are not the same, analysis may not be performed (this depends on the settings). For details, see the "Administrator's Guide": (► Administrator's Guide, "Chapter 5: 5.5 Configuring analysis order settings") - If analysis is started while the instrument is starting up, the analysis is reserved. - Please wait until the analysis in progress is finished. - Replenish the reagent. - Check the current temperature in the instrument information, and use air conditioning if needed to adjust the temperature.
Cannot resume analysis.	- Error recovery processing has not finished. - An analysis in progress in the instrument has not finished.	Complete error recovery processing and then resume analysis. Resume analysis after the test currently in progress has finished.
The analysis results do not appear.	- If "XXXX.X" appears, there is no validated standard curve. - If "++++.+" appears, the results are over the range or over the display limit.	- Create a standard curve and repeat calculation. - Perform dilution analysis.

12.3.6 Shutdown problems

Problem	Cause	Action
Shutdown does not end	Automatic cleaning of the entire instrument is being performed at shutdown.	This cleaning is required to maintain instrument performance. Wait until cleaning finishes. In some cases, shutdown may take about 15 minutes. Do not turn off the instrument power until automatic cleaning finishes.

12.3.7 Host communication problems

Problem	Cause	Action
Cannot communicate with host	• Incorrect IPU settings • Incorrect host settings • The communication cable is not properly connected.	• Check the settings in the IPU [HOST settings] dialog box. • Check the host communication settings. • Check if the cable is connected.

12.3.8 Conveyor line problems

Problem	Cause	Action
Cannot communicate with conveyor line	• Incorrect IPU settings • Incorrect conveyor line settings • The communication cable is not properly connected.	• Check the settings in the IPU [Analyzer settings] dialog box. • Check the communication settings for the conveyor line. • Check if the cable is connected.

12.3.9 LU-10 problems

Problem	Cause	Action
Cannot communicate with LU-10	• Incorrect IPU settings • Incorrect LU-10 settings • The communication cable is not properly connected.	• Check the settings in the IPU [LU-10 settings] dialog box. • Check the LU-10 communication settings. • Check if the cable is connected.
Line washing is not supplied from the LU-10.	Instrument trouble has occurred on the LU-10.	Cancel the LU-10 connection and replace the line washing. (►P.312 "12.4.9 Canceling the LU-10 connection and connecting line washing")

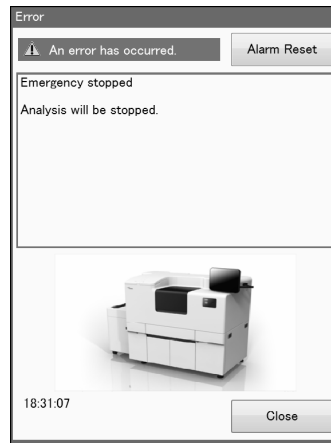
12.3.10 Other problems

Problem	Cause	Action
Cannot communicate with Caresphere	• Incorrect IPU settings • The communication cable is not connected.	• Check the IPU settings. • Check if the cable is connected.
The analysis results do not print.	• Not connected to printer. • Incorrect IPU output settings • Incorrect printer settings.	• Check if a printer is connected. • Check the IPU output settings and printer settings. Results from an analysis that is still in progress cannot be output.
The screen freezes	• The touch panel cable from the display is not properly connected. • Heavy load on the IPU.	• Check if the touch panel cable is correctly connected. • Wait briefly without taking any action.
Error message does not disappear.	• Error recovery processing has not finished. • The error occurred again.	Perform error recovery processing and then press the analysis start button. Check the instrument status again. When the cause of the error is removed, the error message disappears and analysis starts.

12.4 Handling an error

12.4.1 Displaying an error

When an error occurs, the [Error] dialog box appears. Check details on the error (and how to reset).



[Error] dialog box

Touch [Alarm Reset] to stop the alarm.

Even when an [Error] dialog box does not appear, recent errors can be displayed, allowing you to check details on an error (and how to reset).

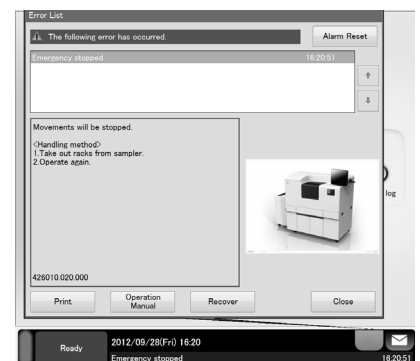
Follow the steps below to display and check an error.

1 Touch the show error list button on the IPU screen.

The [Error List] dialog box appears.

To display the error log, see the "Administrator's Guide".

(►Administrator's Guide, "Chapter 8: 8.1 Viewing the error log")



[Error List] dialog box

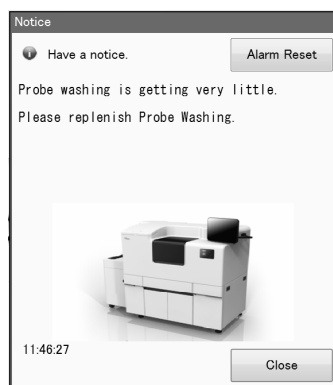
2 Check the error.

The following items are displayed in the dialog box:

[Alarm Reset]	Touch to stop the alarm.
[Print]	Touch to print an error.
[Operation Manual]	Touch to display the Operation Manual dialog box and move to the page that shows the explanation of the error code of the selected error.
[Recover]	Touch to perform error recovery. After error recovery, the error is deleted from the list. Whether or not error recovery can take place depends on the severity of the error and the state of the instrument.
[Close]	Touch to close the dialog box.

12.4.2 Displaying a notice

When a notice event occurs, the [Notice] dialog box appears. The [Notice] dialog box shows an action message indicating the action to be taken, including a brief explanation of what happened together with an image or other supplemental information as needed.



[Notice] dialog box

Touch [Alarm Reset] to stop the alarm.

Even when a [Notice] dialog box does not appear, notices can be displayed and checked.

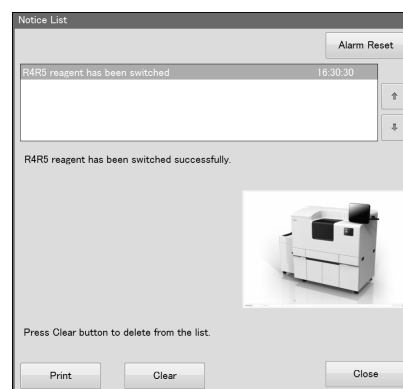
Follow the steps below to display and check a notice.

1 Touch the show notice list button on the IPU screen.

The [Notice List] dialog box appears.

To display the notice log, see the "Administrator's Guide".

(► Administrator's Guide, "Chapter 8: 8.2 Viewing the notice log")



[Notice List] dialog box

2 Check the notice event.

The following items are displayed in the dialog box:

[Alarm Reset]	Touch to stop the alarm.
[Print]	Touch to print a notice.
[Clear]	Touch to clear the event from the list.
[Close]	Touch to close the dialog box.

Displayed notices and instrument statuses are as follows:

Notice	Instrument status
Analyzer wake-up has completed.	Instrument wakeup is finished.
R4/R5 reagent has been switched	Switching of R4/R5 reagent finished normally. Replace the R4/R5 reagent whose status LED is lit red. (►P.113 "Chapter 5: 5.3.3 Replenishing R4/R5 reagent")
Switching of the Probe washing was complete	Switching of the probe washing finished normally. Replace the probe washing whose status LED is lit red. (►P.118 "Chapter 5: 5.3.5 Replenishing probe washing")
The concentrated line washing in use is used up.	The concentrated line washing in use has run out. Replace the concentrated line washing whose status LED is lit red. (►P.115 "Chapter 5: 5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")
Switching of the concentrated LINE washing was complete	Switching of the concentrated line washing finished normally. Replace the concentrated line washing whose status LED is lit red. (►P.115 "Chapter 5: 5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")
Switching of the HISCL washing was complete	Switching of the HISCL washing finished normally. Replace the HISCL washing whose status LED is lit red. (►P.115 "Chapter 5: 5.3.4 Replenishing line washing/concentrated line washing/HISCL washing")
Condensed water drainage has completed.	Draining of condensation from inside reagent holder A is finished.
Analyzer shutdown has completed.	Instrument shutdown is finished. To start the instrument, touch [Wake Up] on the toolbar.
There is a standard curve that is approaching expiry (test name)	There are one or more standard curves that will soon expire. Check the standard curves on the [Portal] screen or the [Standard Curve] screen, and create new standard curves if needed.
There is one or more bottles of reagent remaining in the continuous supply unit.	There are one or more bottles of reagent remaining in the continuous unit. Remove the bottles of reagent from the continuous unit.
The time to conduct inspections of LU-10 maintenance part is coming soon.	Contact our Customer Support Center or branch offices/sales offices. For the timings scheduled for inspection, see the "LU-10 Instructions for Use". (►LU-10 Instructions for Use, "Chapter 6: 6.4.2 Replacing a maintenance part")

12.4.3 Recovering from a reagent IC tag scan error

When the IC tag on an R1-R5 reagent or sample diluent bottle cannot be recognized, enter the reagent information from the reagent barcode.

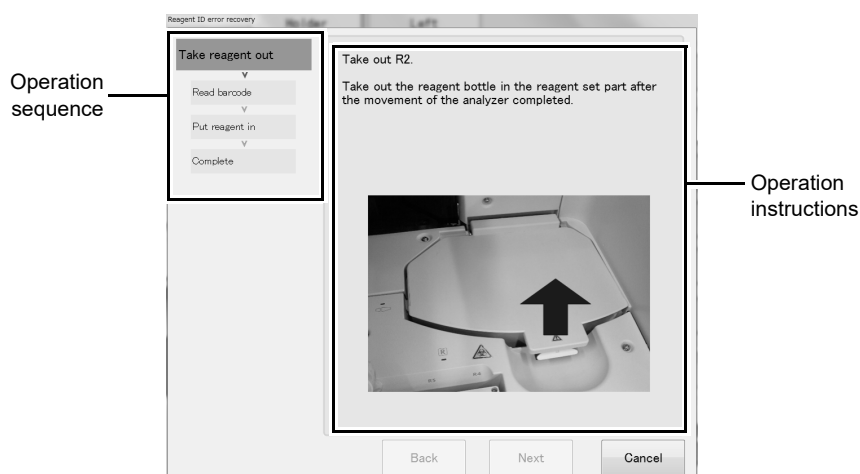
Follow the steps below to recover from a reagent IC tag scan error.

1 Touch [Set Up] on the toolbar.

The [Set Up] screen appears.

2 Touch [Reagent ID error recovery] on the operation panel.

The following dialog box appears.



3 Follow the operation instructions in the dialog box, and touch [Next].

The next operation appears.

Repeat this step until you reach the bottom of the operation sequence and [Finish] appears.

4 Touch [Finish].

The dialog box closes and reagent identification is completed.

12.4.4 Recovering from a standard curve error

If abnormal data that exceeds the allowed range specified in the settings is detected in the standard curve analysis results, an error message will appear. Set the abnormal result to not used, or repeat standard curve analysis using point replacement mode.

(►P.301 "12.4.4.1 Setting the abnormal analysis result to not used")

(►P.302 "12.4.4.2 Repeating standard curve analysis using point replacement mode")

12.4.4.1 Setting the abnormal analysis result to not used

In standard curve analysis, each calibrator is analyzed multiple times and the average is used to create a standard curve. A value with a large deviation width will have a large effect on the average, and thus must be excluded from the calculation of the average.



Information

The standard curve in the Work Area will be overwritten by the changed data. Make a backup or copy of this data beforehand as necessary.

Follow the steps below to perform standard curve data control.

1 Touch [STD] on the toolbar.

The [Standard Curve] screen appears.

For the [Standard Curve] screen, see Chapter 6.

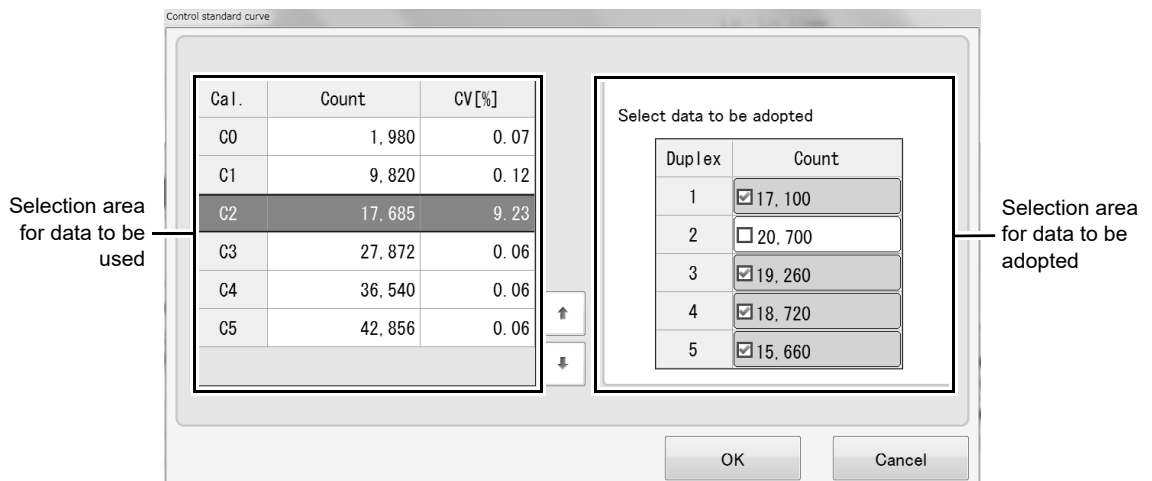
(►P.133 "Chapter 6: 6.1 Standard Curve screen")

2 Display the standard curve for which you want to perform data control.

Select the [Test], [Lot1], [Lot2], or [Work] to display the desired standard curve.

3 Touch [Standard curve data administration] on the operation panel.

The following dialog box appears.



4 Select the calibrator in the table.

The following items are displayed in the dialog box:

Selection area for data to be used	Displays the results of standard curve analysis.
[Cal.]	Displays the name of the sample.
[Count]	Displays the count value.
[CV[%]]	Displays the coefficient of variation for the analysis result for each calibration parameter.
Selection area for data to be adopted	Displays the count values of multiple tests using the selected calibrator.
[Duplex]	Displays the test repetitions.
[Count]	Displays the count values. Select checkboxes to select the results that you want to use for creation of a standard curve.

5 Remove checkmarks from count values that you want to exclude.

6 Touch [OK].

A confirmation dialog box appears.

7 Touch [OK].

The dialog box closes. The standard curve is regenerated and the previous data in the Work Area is overwritten.

To use the modified standard curve for analysis, it must be validated.

To validate, see Chapter 6.

(►P.147 "Chapter 6: 6.6.2 Using (validating) a standard curve for sample analysis")

12.4.4.2 Repeating standard curve analysis using point replacement mode

Analysis can be repeated with the abnormal analysis result point replaced.

Follow the steps below to repeat standard curve analysis using point replacement mode.

1 Touch [Order Regist] on the toolbar.

The [Order registration] screen appears.

2 Touch [Calibration] on the operation panel.

The following screen appears.

Rack

SAMPLE NO.	HBSAg	HBSAb	HBCAb	MVAB	MVLx+AB	MFLY-I	TPAS	CEA	PSA	HBAg	HBSab	MVBAS

Rack No. [] [] [5] [4] [3] [2] [1]

Test: HBSAg

Sample comment: [Full calibration]

Method: Full calibration

New curve

	SAMPLE NO.	Cal.	DUPLEX	DILUTION
RIR2R3	ZS3101	[C1] 2	2	
	STD-0	[C1] 2	2	
R4R5	ZS3003	[C2] 2	2	
	STD-2	[C2] 2	2	
		[C3] 2	2	
	STD-3	[C3] 2	2	
Calibrator	ZS3001	[C4] 2	2	
	STD-4	[C4] 2	2	
		[C5] 2	2	
	STD-5	[C5] 2	2	

Curve In Work Area

	Cal.	Conc.	Count	Calc Conc.	DV[%]
RIR2R3					
R4R5					
Calibrator					

Next sample OK Cancel

3 Touch [Test] and select the analysis parameter for which an error occurred.

4 Touch [Method] and select [Point replace].

5 Register the standard curve order.

For the procedure for registering standard curve orders, see Chapter 6.

(► **P.142** "Chapter 6: 6.4.2 Registering a standard curve order without using a standard curve rack")

6 Touch [OK].

The standard curve order is registered.

A green checkmark appears on registered orders.

Entered orders can also be viewed on the [Joblist] screen.

To start standard curve analysis, see Chapter 6.

(► **P.144** "Chapter 6: 6.5 Performing standard curve analysis")



Note:

- "STD-" is added at the beginning of standard curve sample numbers displayed on the [Joblist] screen.
- To edit a registered order, select the order you want to edit on the [Order registration] screen. Touch [Correction] on the operation panel and edit the order.
(▶ **P.180** "Chapter 8: 8.1.1 Order registration screen")

12.4.5 Removing jammed rack

If a rack jams and an error occurs, remove the jammed rack from the sampler.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials. There is a risk of infection by pathogens and other contaminants.

Follow the steps below to remove the rack from the sampler.

1 Shut down the instrument.

To shut down the instrument, see Chapter 4.

(►P.83 "Chapter 4: 4.4 Shutting down the instrument")

2 Turn off the power and switch off the power breaker switch.

For the locations of the power breaker switch and power switch, see Chapter 3.

(►P.37 "Chapter 3: 3.4.2 Instrument part description")

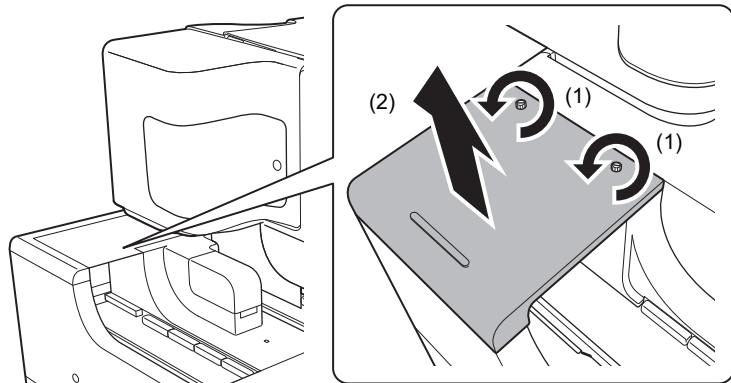


Warning!

Always turn off the power and switch off the power breaker switch before removing a rack jam. There is a risk of electrical shock.

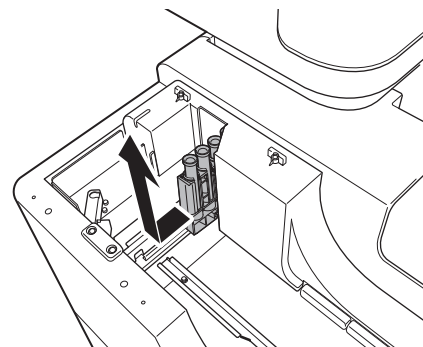
3 Remove the sampler cover.

- (1) Remove the 2 screws counterclockwise.
- (2) Remove the cover.



Warning!

- Do not remove the sampler cover for any purpose other than to remove a jammed rack.
 - If the cover is removed during analysis or other operation, operation will stop.
 - Do not touch the drive unit. Make sure your hands are free of static electricity before you touch the instrument.
- There is a risk of injury or malfunction.

4 Remove the jammed rack.

5 Replace the sampler cover.

6 Start up the instrument.

To start up the instrument, see Chapter 4.

(►P.77 "Chapter 4: 4.1.2 Starting up the instrument")

**Caution!**

Please reregister orders and retest all the samples in the rack where some samples were failed to be dispensed (rack where error happened).

12.4.6 Removing a tip or cuvette feeder jam

If a tip or cuvette jams and an error occurs, use the hopper jam removal pole to remove the jam in the tip or cuvette feeder.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

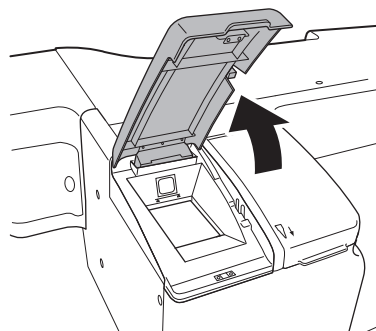


Information

After removing the jam, be sure to close the cover.

Follow the steps below to remove a tip or cuvette feeder jam.

- 1 Open the cover of the tip or cuvette feeder at the upper left of the front of the instrument.**

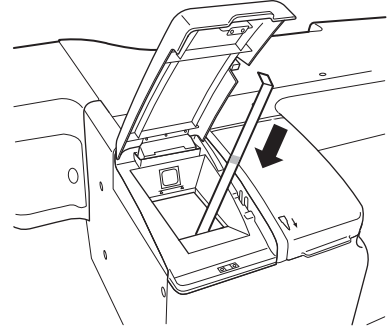


Information

The feeder cover stops at a position of about 60 degrees. Take care not to open the cover excessively.

2 Insert the provided hopper jam removal pole inside the tip or cuvette feeder and stir the tips or cuvettes.

Insert the hopper jam removal pole all the way in, and while viewing the inside, move the pole up and down and side to side to sufficiently stir.



3 Close the tip or cuvette feeder cover.

If a tip jam error does not clear, remove the jammed tip.
(►P.308 "12.4.7 Removing a tip jam")



Caution!

Exercise caution not to get your fingers caught when closing the tip or cuvette feeder cover.
There is a risk of injury.

12.4.7 Removing a tip jam

If tips jam and an error occurs, free the jam in the tip feeder.

(►P.306 "Chapter 12: 12.4.6 Removing a tip or cuvette feeder jam")

If the error does not clear after freeing the tip jam, remove the jammed tip.

Follow the steps below to remove the jammed tip.

1 Shut down the instrument.

To shut down the instrument, see Chapter 4.

(►P.83 "Chapter 4: 4.4 Shutting down the instrument")

2 Turn off the power and switch off the power breaker switch.

For the locations of the power breaker switch and power switch, see Chapter 3.

(►P.37 "Chapter 3: 3.4.2 Instrument part description")

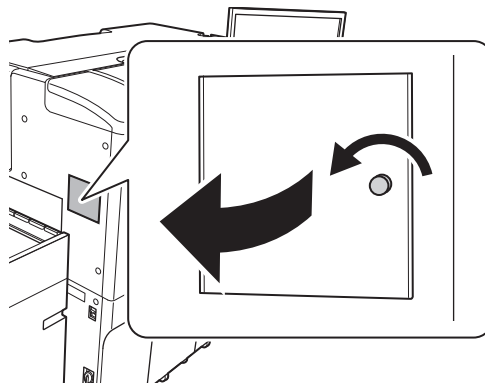


Warning!

Always turn off the power and switch off the power breaker switch before removing a tip jam. There is a risk of electrical shock.

3 Open the tip jam maintenance cover on the left side of the instrument.

Turn the screw counterclockwise to open the door.

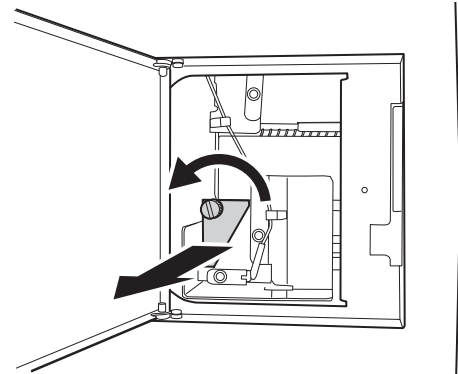


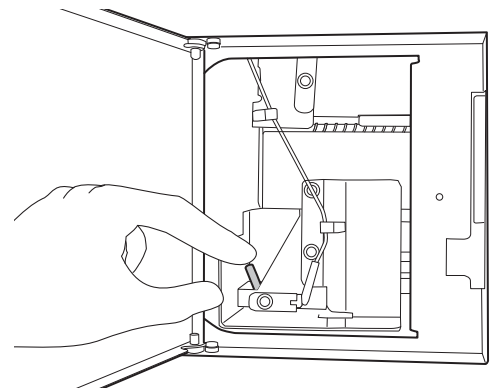
Warning!

- Do not open the tip jam maintenance cover for any purpose other than to remove jammed tips.
- If the cover is opened during analysis or other operation, operation will stop.
- Before opening the tip jam maintenance cover, turn off the power of the instrument. There is a risk of electrical shock.
- Do not touch the drive unit. Make sure your hands are free of static electricity before you touch the instrument. There is a risk of injury or malfunction.

4 Remove the part inside the cover.

Turn the screw counterclockwise to remove the part.



5 Remove the jammed tip with your fingers.**Caution!**

Do not use tweezers to remove a tip jam.
Any damage will cause tips to jam more easily.

6 Replace the part.

7 Close the tip jam maintenance cover.

8 Start up the instrument.

To start up the instrument, see Chapter 4.

(►P.77 "Chapter 4: 4.1.2 Starting up the instrument")

12.4.8 Releasing the lock on the reagent holder A cover

If the power supply to the analyzer is interrupted because the power is turned off or a power failure occurs, the cover of reagent holder A locks.

If you want to remove R1-R3 reagent when power is not supplied to the analyzer, release the lock and then open the cover of reagent holder A.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials.

There is a risk of infection by pathogens and other contaminants.

Follow the steps below to release the lock on the cover of reagent holder A.

1 Open the operation cover on the analyzer.



Caution!

Be careful not to hit your head on the operation cover when it is open.

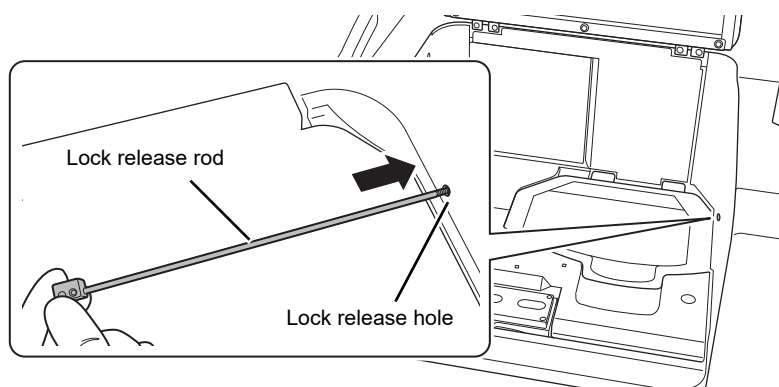


Information

When opening and closing the operation cover, take care not to let your fingers be pinched by the cover.

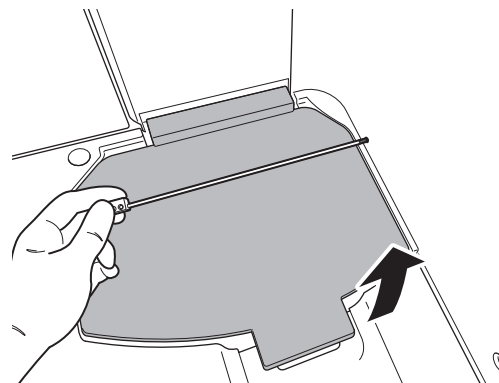
2 Insert the lock release rod into the lock release hole.

Press in all the way.



3 Lift up the cover of reagent holder A.

Lift up the cover with the lock release rod inserted into the lock release hole.



4 Remove the lock release rod from the lock release hole.

If the rod is removed without lifting up the cover of reagent holder A, the cover will lock again.

5 Open the cover of reagent holder A.

6 Remove the R1-R3 reagent.

7 Insert the lock release rod into the lock release hole.

Press in all the way.

8 Close the cover of reagent holder A.

Close the cover with the lock release rod inserted into the lock release hole.

9 Remove the lock release rod from the lock release hole.

The cover of reagent holder A locks. To reopen the cover of reagent holder A, repeat steps 2 to 5.

10 Close the operation cover.

12.4.9 Canceling the LU-10 connection and connecting line washing

If instrument trouble occurs on the LU-10, line washing may not be supplied from the LU-10. You can cancel the LU-10 connection and connect line washing to continue using the analyzer.



Risk of infection

Always wear protective gloves, mask, eye protection, and a lab coat when working. When finished, wash your hands with a disinfectant. Treat as if contaminated with blood or other infectious materials. There is a risk of infection by pathogens and other contaminants.



Caution!

- Only use Sysmex-specified line washing.
- After replacing the line washing container, firmly attach the cap so that solution does not spill.
- When replacing line washing, take care that fragments of cardboard do not get into the container.
- When replacing line washing, take care that the line washing/concentrated line washing holder does not move.
- Take care not to misconnect the line washing and HISCL washing tubes.
- When replacing the line washing, pulling the level sensor out of the container at an angle may cause malfunctioning. The level sensor must be pulled straight out of the container mouth. After pulling the level sensor out, do not tilt the sensor sideways or upside down. This may cause malfunctioning after replacement.

Follow the steps below to cancel the LU-10 connection and connect the line washing.

1 Touch [Menu] - [Settings] on the toolbar.

The [Settings] dialog box appears.

2 Select [607. LU-10 settings] and touch [Settings].

The [LU-10 settings] dialog box appears.

3 Remove the checkmark from [Detergent supply from LU-10].

4 Touch [OK].

The dialog box closes and the LU-10 connection settings change.

5 Touch [Close].

The dialog box closes.

6 Prepare new line washing.

7 Touch [Set Up] on the toolbar.

The [Set Up] screen appears. The concentrated line washing icon changes to the line washing icon.

8 Open the new box of line washing.

To open the box, follow the instructions on the box.

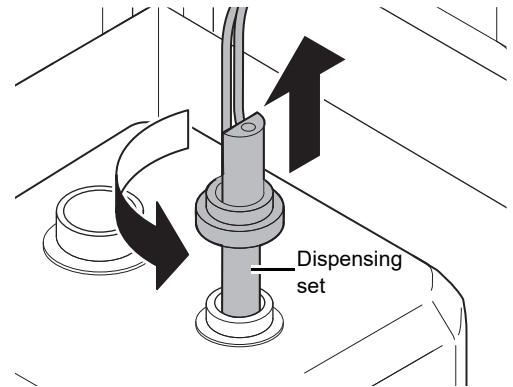
9 Attach the fastening plate to the new line washing.

Firmly press in all the way.

10 Remove the cap from the new line washing.

11 Remove the dispensing set (orange label) from the supply tank.

Turn the dispensing set counterclockwise to detach it, and pull straight out.



12 Firmly attach the dispensing set to the new line washing.**Note:**

Orange labels are affixed to the line washing sensor and container. Connect the tubes so that the colors match. This prevents wrong connection.

13 Scan the barcode (GS1-128) on the box with the handheld barcode reader.

14 Make sure that the status icon of the line washing is white on the [Set Up] screen.

An interval of time is required for the status to be updated on the screen.

12.5 Troubleshooting by error message

This section explains error messages displayed on the HISCL-5000, failures, and remedial actions.

12.5.1 Error message list (in alphabetical order)

Refer to the pages below for the error list and remedial actions.

1st B/F error(279)	321
1st B/F error(280)	321
1st B/F error(281)	321
1st B/F error(282)	321
1st B/F error(283)	321
1st B/F error(285)	321
1st B/F error(303)	321
1st B/F error(304)	321
2nd B/F error(308)	322
2nd B/F error(309)	322
2nd B/F error(310)	322
2nd B/F error(311)	322
2nd B/F error(312)	322
2nd B/F error(314)	322
2nd B/F error(332)	322
2nd B/F error(333)	322
A stationary rack has been moved	340
Abnormal message was received from the HOST computer	348
Air-cooling fan error	342
An unknown sample has arrived at the aspiration position	367
Analysis start temperature has been exceeded (item name)	344
Analysis start temperature not reached (item name)	344
Analyzer communication error	345
Barcode reader initialization error	338
Charging of HISCL washing failed	323
Charging of LINE washing failed	352
Charging of reagent R1 failed[Pos.No - (Reag.)]	325
Charging of reagent R2 failed[Pos.No - (Reag.)]	327
Charging of reagent R3 failed[Pos.No - (Reag.)]	330
Charging of reagent R4 failed	332
Charging of reagent R5 failed	332
Concentrated LINE washing has expired	353
Continuous supply unit error(231)	336
Continuous supply unit error(232)	336
Continuous supply unit error(233)	336
Continuous supply unit error(234)	336
Continuous supply unit error(235)	336
Continuous supply unit error(236)	336
Continuous supply unit error(237)	336
Continuous supply unit error(9)	336
Conveyor line command receiving error	366
Conveyor line communication error	366
Conveyor line communication establishment error	366
Cover of continuous supply unit is open	337
Cover of emergency sample setting unit is opened	338
Cover of reagent set A is opened	362
Cover of reagent set A is unlocked	362
Cover of reagent set B is opened	364
Cover of sampler is opened	338
Cover of sampling arm is opened	357

Cover of sampling arm is unlocked	358
Cover of tip maintenance is opened	350
Cover of tip maintenance is unlocked	350
Cuvette catch miss(1st B/F Catcher)	333
Cuvette catch miss(1st B/F separation unit)	333
Cuvette catch miss(2nd B/F Catcher)	333
Cuvette catch miss(2nd B/F separation unit)	333
Cuvette catch miss(Detector)	333
Cuvette catch miss(R1 reagent arm)	333
Cuvette catch miss(R2 reagent arm)	333
Cuvette catch miss(R3 reagent arm)	333
Cuvette catch miss(R4/R5 reagent arm)	334
Cuvette release miss(1st B/F Catcher)	334
Cuvette release miss(1st B/F separation unit)	334
Cuvette release miss(2nd B/F Catcher)	334
Cuvette release miss(2nd B/F separation unit)	334
Cuvette release miss(Detector)	334
Cuvette release miss(R1 reagent arm)	334
Cuvette release miss(R2 reagent arm)	334
Cuvette release miss(R3 reagent arm)	334
Cuvette release miss(R4/R5 reagent arm)	334
Cuvette supply unit error(457)	335
Cuvette supply unit error(458)	335
Cuvette supply unit error(467)	335
Cuvette supply unit error(468)	335
Cuvette supply unit error(469)	335
Cuvette supply unit error(470)	335
Cuvettes got blocked(462)	332
Cuvettes got blocked(463)	332
Cuvettes got blocked(464)	332
Cuvettes have been used up	333
Cuvettes supply low	333
Dark count value is too high	355
Detector error(337)	355
Detector error(338)	355
Detector error(356)	355
Detector error(357)	355
Detector error(358)	355
Detector error(359)	355
Detector error(360)	355
Detector error(361)	355
Detector PMT error	354
Detector System error(363)	354
Detector temperature error	354
Different rack from what is registered has been set on	340
Diluent is used up(Diluent name)	359
Diluent to be aspirated is insufficient[Pos.No - (Diluent name)]	360
Dilution rate of the order is wrong	347
Discharging of R4/R5 reagent failed	331
Discharging of reagent R4 failed	332
Discharging of reagent R5 failed	332
Drain condensed water failed	342
Drainage failed	347
Emergency stopped	341
Error has been detected in the check of B/F	345
Error occurred in the results of data analysis	343
Expired calibrator has been used in the analysis	348
Expired concentrated line washing has been used in the analysis	353
Expired HISCL washing has been used in the analysis	323
Expired line washing has been used in the analysis	352

Expired probe washing has been used in the analysis	348
Expired QC material has been used in the analysis	348
Failed to read info of the reagent bottle	360
Failed to write info into bottles of R4R5	331
Failed to write info into the reagent bottle	360
Failure to correct standard curve(Reag.)	342
Failure to make standard curve(Reag.)	342
Fluid system error(1st B/F separation nozzle)	345
Fluid system error(2nd B/F separation nozzle)	345
Fluid system error(Overflow)	345
HISCL washing Fluid system error(388)	323
HISCL washing is used up	323
HISCL washing level low	323
HISCL washing replenishment failed	323
HOST computer communication error	341
ID notices of samples from conveyor line are over capacity	366
Internal temperature of the analyzer is high	344
Internal temperature of the analyzer is low	344
LINE washing Fluid system error(387)	352
LINE washing is used up	352
LINE washing level low	352
LINE washing replenishment failed	352
Liquid level of R1 arm is too high[Pos.No - (Reag.)]	325
Liquid level of R2 reagent is too high[Pos.No - (Reag.)]	328
Liquid level of R3 arm is too high[Pos.No - (Reag.)]	330
Long time under power-off condition	343
LU-10 communication error	348
Mixing movement error(1st B/F separation unit)	369
Mixing movement error(2nd B/F separation unit)	369
Mixing movement error(R1 reagent arm)	369
Mixing movement error(R2 reagent arm)	369
Mixing movement error(R3 reagent arm)	369
Mixing movement error(R4/R5 reagent arm)	369
No order to analyze	344
No remaining amount of R4/R5 reagent	331
Out of upper/lower limit of QC(Reag.)	343
Please check the dilution analysis result(Reag.)	343
Please check the standard curve data(Reag.)	342
Power dropped	345
Power off without shutdown	343
Pre-count value is too high	355
Pressure error(-0.033MPa negative pressure)	354
Pressure error(-0.053MPa negative pressure)	354
Pressure error(0.06MPa positive pressure)	354
Pressure error(0.25MPa positive pressure)	354
Probe washing is used up	351
Probe washing level low	351
QC analysis failed	343
R1 reagent arm error (97)	324
R1 reagent arm error (98)	324
R1 reagent arm error (99)	324
R1 reagent arm error (102)	324
R1 reagent arm error (102)[Pos.No - (Reag.)]	324
R1 reagent arm error (106)	324
R1 reagent arm error (107)	324
R1 reagent arm error (108)	324
R1 reagent arm error (110)	324
R1 reagent arm error (116)	324
R1 reagent arm error (117)	324
R1 reagent arm Fluid system error(370)	325

R1 reagent arm Fluid system error(371)	325
R1 reagent bottle error[Pos.No - (Reag.)]	360
R2 reagent arm error(126)	326
R2 reagent arm error(127)	326
R2 reagent arm error(128)	326
R2 reagent arm error(130)	326
R2 reagent arm error(130)[Pos.No - (Reag.)]	326
R2 reagent arm error(133)	326
R2 reagent arm error(134)	326
R2 reagent arm error(135)	326
R2 reagent arm error(136)	326
R2 reagent arm error(138)	327
R2 reagent arm error(145)	326
R2 reagent arm error(146)	326
R2 reagent arm error(151)	326
R2 reagent arm Fluid system error(372)	327
R2 reagent arm Fluid system error(373)	327
R2 reagent bottle error[Pos.No - (Reag.)]	360
R3 reagent arm error(155)	328
R3 reagent arm error(156)	328
R3 reagent arm error(157)	328
R3 reagent arm error(159)	328
R3 reagent arm error(159)[Pos.No - (Reag.)]	328
R3 reagent arm error(162)	329
R3 reagent arm error(163)	328
R3 reagent arm error(164)	328
R3 reagent arm error(165)	328
R3 reagent arm error(167)	329
R3 reagent arm error(168)	329
R3 reagent arm error(174)	328
R3 reagent arm error(175)	328
R3 reagent arm error(180)	328
R3 reagent arm Fluid system error(374)	329
R3 reagent arm Fluid system error(375)	329
R3 reagent bottle error[Pos.No - (Reag.)]	360
R4/R5 reagent arm error(184)	330
R4/R5 reagent arm error(185)	331
R4/R5 reagent arm error(193)	330
R4/R5 reagent arm error(194)	330
R4/R5 reagent arm error(195)	330
Rack failed to move	353
Rack ID reading failed	353
Rack is full	353
Racks with the same ID are entered	340
Reactor error(270)	365
Reactor error(271)	365
Reactor System error(273)	365
Reactor temperature error	365
Reagent addition error	337
Reagent is used up(Reag.)	359
Reagent of the specified lot No. not found(Reag.)	359
Reagent R1 to be aspirated is insufficient[Pos.No - (Reag.)]	359
Reagent R2 to be aspirated is insufficient[Pos.No - (Reag.)]	359
Reagent R3 to be aspirated is insufficient[Pos.No - (Reag.)]	359
Reagent R4R5 being used has been changed.	365
Reagent set A error(212)	362
Reagent set A error(213)	362
Reagent set A error(214)	362
Reagent set A error(215)	362
Reagent set A error(216)	362

Reagent set A error(217)	362
Reagent set A error(218)	362
Reagent set A System error(220)	361
Reagent set A System error(221)	361
Reagent set A temperature error	362
Reagent set B error(251)	364
Reagent set B error(252)	364
Reagent set B error(253)	364
Reagent set B error(254)	364
Reagent set B System error(242)	363
Reagent set B System error(243)	363
Reagent set B System error(259)	364
Reagent set B System error(260)	363
Reagent set B temperature error	363
Received "new sample arrived" notice during sample aspiration	367
Sample aspiration failed(81)	358
Sample aspiration failed(82)	358
Sample dispense unit error(207)	361
Sample dispense unit error(208)	361
Sample has not arrived to the charging position(Conveyor)	367
Sample has not arrived to the charging position(Sampler)	339
Sample ID does not match (Sampler)	339
Sample ID reading failed	339
Sample is insufficient.	358
Sample is not set on	339
Sampler error(404)	337
Sampler error(405)	337
Sampler error(413)	337
Sampler error(414)	337
Sampler error(415)	337
Sampler error(416)	337
Sampler error(417)	337
Sampler error(418)	337
Sampler error(419)	337
Sampler error(420)	337
Sampler error(421)	337
Sampler error(422)	337
Sampler error(423)	337
Sampler error(424)	337
Sampler error(429)	337
Sampler error(430)	337
Sampling arm error (68).	356
Sampling arm error (69).	356
Sampling arm error (70).	356
Sampling arm error (71).	356
Sampling arm error (72).	356
Sampling arm error (73).	356
Sampling arm error (74).	356
Sampling arm error (75).	356
Sampling arm error (76).	356
Sampling arm error (78).	357
Sampling arm error (83).	356
Sampling arm error (84).	357
Service call has been made.	347
Software error(30)	341
Software error(31)	341
Software error(64)	341
Software error(65)	341
System error(63)	340
Temperature exceeded upper the limit during the analysis (item name).	344

Temperature fell below the lower limit during the analysis (item name)	344
Test for which sample analysis is not to be performed are present. (item name)	349
The arrived sample's ID does not match	367
The hard disk has very little free space left.	347
The reagent scanning is cancelled	347
There are samples that have not been analyzed	347
There is a notice of error from LU-10	348
There is a notice of error from the conveyor line	366
There is rack remaining in the sampler	338
Time to replace(1st B/F mixing holder A)	368
Time to replace(1st B/F mixing holder B)	368
Time to replace(1st B/F mixing holder C)	368
Time to replace(1st B/F mixing holder D)	368
Time to replace(1st B/F mixing unit A)	368
Time to replace(1st B/F mixing unit B)	368
Time to replace(1st B/F mixing unit C)	368
Time to replace(1st B/F mixing unit D)	368
Time to replace(1st B/F mixing waiting holder)	368
Time to replace(1st B/F separation nozzle A)	368
Time to replace(1st B/F separation nozzle B)	368
Time to replace(1st B/F separation nozzle C)	368
Time to replace(1st B/F separation nozzle D)	368
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12.5.2 Errors related to 1st B/F separation unit

Error codes/ Error messages	210051	1st B/F error(279)
	218020	1st B/F error(281)
	242422	1st B/F error(283)
	249504	1st B/F error(303)
	249505	1st B/F error(304)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	210052	1st B/F error(280)
	218021	1st B/F error(282)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	243157	1st B/F error(285)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.3 Errors related to 2nd B/F separation unit

Error codes/ Error messages	210053 2nd B/F error(308) 218022 2nd B/F error(310) 242423 2nd B/F error(312) 249508 2nd B/F error(332) 249509 2nd B/F error(333)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	210054 2nd B/F error(309) 218023 2nd B/F error(311)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	243161 2nd B/F error(314)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

12.5.4 Errors related to HISCL washing

Error codes/ Error messages	136157	HISCL washing Fluid system error(388)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	136125	HISCL washing is used up
Probable cause	Out of both HISCL washing. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) Replenish new HISCL washing. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	136120 136153	Charging of HISCL washing failed HISCL washing replenishment failed
Probable cause	Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) Please reset the dispensing set. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	136124	HISCL washing level low
Probable cause	Out of both HISCL washing. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	Replenish new HISCL washing. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	472101	Expired HISCL washing has been used in the analysis
Probable cause	Expired HISCL washing has been used.	
Actions	Replace the HISCL washing.	

12.5.5 Errors related to R1 reagent arm

Error codes/ Error messages	232161 R1 reagent arm error (97) 232162 R1 reagent arm error (98) 232163 R1 reagent arm error (99) 232169 R1 reagent arm error (106) 232170 R1 reagent arm error (107) 232171 R1 reagent arm error (108) 232173 R1 reagent arm error (116) 232174 R1 reagent arm error (117)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	232166 R1 reagent arm error (102) R1 reagent arm error (102)[Pos.No - (Reag.)]
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If there is any problem with the reagent bottle, press the Recover button and take out the bottle. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	232172 R1 reagent arm error (110)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	215350	R1 reagent arm Fluid system error(370)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	215351	R1 reagent arm Fluid system error(371)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.6 Errors related to R1 reagent

Error codes/ Error messages	232168	Charging of reagent R1 failed[Pos.No - (Reag.)]
Probable cause	Insufficient volume of reagent. Mechanical unit out of position, failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Confirm the reagent bottle and re-set it. (Replace the reagent if the bottle has any problem.) 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232167	Liquid level of R1 arm is too high[Pos.No - (Reag.)]
Probable cause	Foam in reagent. Mechanical unit out of position, failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Confirm the reagent bottle and re-set it. (Replace the reagent if the bottle has any problem.) 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.7 Errors related to R2 reagent arm

Error codes/ Error messages	232178 R2 reagent arm error(126) 232179 R2 reagent arm error(127) 232180 R2 reagent arm error(128) 232186 R2 reagent arm error(134) 232187 R2 reagent arm error(135) 232188 R2 reagent arm error(136) 232190 R2 reagent arm error(145) 232191 R2 reagent arm error(146) 232195 R2 reagent arm error(151)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	232182 R2 reagent arm error(130) R2 reagent arm error(130)[Pos.No - (Reag.)]
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If there is any problem with the reagent bottle, press the Recover button and take out the bottle. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	232185 R2 reagent arm error(133)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	232189	R2 reagent arm error(138)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	215352	R2 reagent arm Fluid system error(372)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	215353	R2 reagent arm Fluid system error(373)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.8 Errors related to R2 reagent

Error codes/ Error messages	232184	Charging of reagent R2 failed[Pos.No - (Reag.)]
Probable cause	Insufficient volume of reagent. Mechanical unit out of position, failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Confirm the reagent bottle and re-set it. (Replace the reagent if the bottle has any problem.) 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232183	Liquid level of R2 reagent is too high [Pos.No - (Reag.)]
Probable cause	Foam in reagent. Mechanical unit out of position, failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Confirm the reagent bottle and re-set it. (Replace the reagent if the bottle has any problem.) 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.9 Errors related to R3 reagent arm

Error codes/ Error messages	232196 R3 reagent arm error(155) 232197 R3 reagent arm error(156) 232198 R3 reagent arm error(157) 232204 R3 reagent arm error(163) 232205 R3 reagent arm error(164) 232206 R3 reagent arm error(165) 232209 R3 reagent arm error(174) 232210 R3 reagent arm error(175) 232214 R3 reagent arm error(180)	
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232200	R3 reagent arm error(159) R3 reagent arm error(159)[Pos.No - (Reag.)]
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If there is any problem with the reagent bottle, press the Recover button and take out the bottle. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232203 232208	R3 reagent arm error(162) R3 reagent arm error(168)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232207	R3 reagent arm error(167)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	215354	R3 reagent arm Fluid system error(374)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	215355	R3 reagent arm Fluid system error(375)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.10 Errors related to R3 reagent

Error codes/ Error messages	232202	Charging of reagent R3 failed[Pos.No - (Reag.)]
Probable cause	Insufficient volume of reagent. Mechanical unit out of position, failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Confirm the reagent bottle and re-set it. (Replace the reagent if the bottle has any problem.) 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232201	Liquid level of R3 arm is too high[Pos.No - (Reag.)]
Probable cause	Foam in reagent. Mechanical unit out of position, failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Confirm the reagent bottle and re-set it. (Replace the reagent if the bottle has any problem.) 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.11 Errors related to R4/R5 reagent arm

Error codes/ Error messages	232215 232217 232218 232219	R4/R5 reagent arm error(184) R4/R5 reagent arm error(193) R4/R5 reagent arm error(194) R4/R5 reagent arm error(195)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232216	R4/R5 reagent arm error(185)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.12 Errors related to bottles of R4R5

Error codes/ Error messages	232223	Discharging of R4/R5 reagent failed.
Probable cause	No reagent. Clogged, disconnected, or ruptured tube. Sensor failure. Mechanical unit out of position.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232224	No remaining amount of R4/R5 reagent
Probable cause	Both the sets of the R4/R5 reagent have run out. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) Replenish the R4/R5 reagent. 2) Execute the analysis again.	

Error codes/ Error messages	446304	Failed to write info into bottles of R4R5.
Probable cause	Reagent bottle IC failure. IC reader failure.	
Actions	Press the Recover button to recover the analyzer.	

Error codes/ Error messages	139050	Charging of reagent R4 failed.
Probable cause	No reagent. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) Wait until the analysis is finished. 2) Confirm the reagent bottle. 3) Press the Recover button. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	149110 149112	Discharging of reagent R4 failed. Discharging of reagent R5 failed.
Probable cause	Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	139051	Charging of reagent R5 failed.
Probable cause	No reagent. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) Wait until the analysis is finished. 2) Confirm the reagent bottle. 3) Press the Recover button. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.13 Errors related to cuvettes

Error codes/ Error messages	245302 245303 245304	Cuvettes got blocked(462) Cuvettes got blocked(463) Cuvettes got blocked(464)
Probable cause	Cuvette jam in cuvette feeder. Failure of mechanical unit of cuvette feeder.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	423070	Cuvettes have been used up
Probable cause	Out of cuvettes. Sensor failure. Break in wiring cord.	
Actions	1) Wait until the analysis is finished. 2) Replenish new cuvettes. 3) Press the Recover button. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	423071	Cuvettes supply low
Probable cause	Cuvettes are running low. Sensor failure. Break in wiring cord.	
Actions	Please prepare new cuvettes to replenish.	

12.5.14 Errors related to cuvette catch miss

Error codes/ Error messages	249506 243158 249510 243162 232175 249514	Cuvette catch miss(1st B/F Catcher) Cuvette catch miss(1st B/F separation unit) Cuvette catch miss(2nd B/F Catcher) Cuvette catch miss(2nd B/F separation unit) Cuvette catch miss(R1 reagent arm) Cuvette catch miss(Detector)
Probable cause	Mechanical unit out of position. Cuvette sensor failure. Break in wiring cord.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232192 232211	Cuvette catch miss(R2 reagent arm) Cuvette catch miss(R3 reagent arm)
Probable cause	Mechanical unit out of position. Cuvette sensor failure. Break in wiring cord.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232220	Cuvette catch miss(R4/R5 reagent arm)
Probable cause	Mechanical unit out of position. Cuvette sensor failure. Break in wiring cord.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.15 Errors related to cuvette release miss

Error codes/ Error messages	249507 243159 249511 243163	Cuvette release miss(1st B/F Catcher) Cuvette release miss(1st B/F separation unit) Cuvette release miss(2nd B/F Catcher) Cuvette release miss(2nd B/F separation unit)
Probable cause	Mechanical unit out of position. Cuvette sensor failure. Break in wiring cord.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232176 232193 232212 232221	Cuvette release miss(R1 reagent arm) Cuvette release miss(R2 reagent arm) Cuvette release miss(R3 reagent arm) Cuvette release miss(R4/R5 reagent arm)
Probable cause	Mechanical unit out of position. Cuvette sensor failure. Break in wiring cord.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	249515	Cuvette release miss(Detector)
Probable cause	Mechanical unit out of position. Cuvette sensor failure. Break in wiring cord.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.16 Errors related to cuvette feeder

Error codes/ Error messages	245300 245301	Cuvette supply unit error(457) Cuvette supply unit error(458)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	245305 245306 245307 245308	Cuvette supply unit error(467) Cuvette supply unit error(468) Cuvette supply unit error(469) Cuvette supply unit error(470)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.17 Errors related to continuous unit

Error codes/ Error messages	421572	Continuous supply unit error(9)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	After the movement is finished, please confirm if there is anything that prevents the cover from being locked.	

Error codes/ Error messages	429139 429140 429141 429142 429143	Continuous supply unit error(231) Continuous supply unit error(232) Continuous supply unit error(233) Continuous supply unit error(234) Continuous supply unit error(235)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	429144	Continuous supply unit error(236)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) Wait until the analysis is finished. 2) Confirm if the bottle is in the right place. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	429145	Continuous supply unit error(237)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) Confirm if the bottle is in the right place. 2) Operate again.	

Error codes/ Error messages	429146	Reagent addition error
Probable cause	A reagent bottle is set in the continuous unit with the PC powered off. Sensor failure.	
Actions	Please add the reagents again.	

Error codes/ Error messages	421568	Cover of continuous supply unit is open
Probable cause	The cover is open. Cover sensor failure.	
Actions	1) Close the cover. 2) Wait until the analysis is finished. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.18 Errors related to sampler

Error codes/ Error messages	259100 Sampler error(404) 259101 Sampler error(405) 253010 Sampler error(413) 253000 Sampler error(414) 254200 Sampler error(415) 254201 Sampler error(416) 254202 Sampler error(417) 254203 Sampler error(418) 255500 Sampler error(419) 255501 Sampler error(420) 255502 Sampler error(421) 255503 Sampler error(422) 259108 Sampler error(423) 259109 Sampler error(424) 259106 Sampler error(429) 259107 Sampler error(430)	
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) Take out the racks from the sampler. 2) If any analysis is still running, wait until it is completed. 3) Press the Recover button to recover the analyzer. 4) Please re-register orders of samples in the rack where error happened, and then press the Start button to analyze again.	

Error codes/ Error messages	421574	Cover of sampler is opened
Probable cause	The cover is open. Cover sensor failure.	
Actions	1) Take out the racks from the sampler. 2) Close the cover. 3) Press the Recover button to recover the analyzer. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	259102	There is rack remaining in the sampler
Probable cause	Rack remains under sampler cover. Sensor failure. Break in wiring cord.	
Actions	1) Take out the racks from the sampler. 2) If any analysis is still running, wait until it is completed. 3) Press the Recover button to recover the analyzer. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	446306	Barcode reader initialization error
Probable cause	Barcode reader failure. Break in wiring cord.	
Actions	Press the Recover button to recover the analyzer.	

Error codes/ Error messages	421562	Cover of emergency sample setting unit is opened
Probable cause	The cover is open. Cover sensor failure.	
Actions	1) Close the cover. 2) Take out the racks from the sampler. 3) Press the Recover button to recover the analyzer. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	446310	Sample ID does not match (Sampler)
Probable cause	Sample that arrived at the aspiration position does not match pre-read sample ID. Barcode is dirty.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	446308	Sample ID reading failed
Probable cause	Barcode is dirty. Incorrect barcode settings. Barcode reader failure.	
Actions	Confirm if the sample ID is correct.	

Error codes/ Error messages	429130	Sample is not set on
Probable cause	Sample not inserted in rack. Sensor failure. Break in wiring cord.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	429137	Sample has not arrived to the charging position(Sampler)
Probable cause	Sensor or motor failure. Break in wiring cord. An object is obstructing sampler operation.	
Actions	1) Take out the racks from the sampler. 2) If any analysis is still running, wait until it is completed. 3) Press the Recover button to recover the analyzer. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	259104	A stationary rack has been moved.
Probable cause	Sensor failure. Break in wiring cord. Sampler mechanical unit failure.	
Actions	1) Take out the racks from the sampler. 2) Confirm that the holes on the side of the rack are not covered. 3) If any analysis is still running, wait until it is completed. 4) Press the Recover button to recover the analyzer. 5) Please re-register orders of samples in the rack where error happened, and then press the Start button to analyze again.	

Error codes/ Error messages	446305	Different rack from what is registered has been set on
Probable cause	6-sample adapter attached to rack with ID not registered in 6-sample racks. 6-sample adapter not attached to rack with ID registered in 6-sample racks. Sensor failure. Break in wiring cord.	
Actions	1) Confirm if the rack ID is correct. 2) Confirm the rack settings.	

Error codes/ Error messages	446309	Racks with the same ID are entered
Probable cause	Racks with same ID placed in succession. Barcode is dirty.	
Actions	Confirm if the rack ID is correct.	

12.5.19 Errors related to system

Error codes/ Error messages	431000	System error(63)
Probable cause	Board failure. Thermistor wire break.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	431100 Software error(30) 431101 Software error(31) 611050 Software error(64) 611051 Software error(65)
Probable cause	Program error. Database error.
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.

Error codes/ Error messages	441010 HOST computer communication error
Probable cause	Settings for communication with host computer not configured. Host computer power not on. Cable for communication with host computer not connected.
Actions	1) Confirm the HOST settings. 2) Confirm the HOST computer. 3) Press the Recover button to recover the analyzer.

Error codes/ Error messages	426010 Emergency stopped
Probable cause	Emergency stop button was pressed.
Actions	1) Take out the racks from the sampler. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	459020	Air-cooling fan error
Probable cause	Cooling fan failure. Break in wiring cord.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	479002	Drain condensed water failed.
Probable cause	Clogged solenoid valve. Clogged tube.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Take out the reagent and keep in refrigerator. 3) Turn off the power of the analyzer. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	465030	Failure to make standard curve(Reag.)
Probable cause	No result obtained during standard curve analysis. Result of standard curve analysis not a monotonic increase or monotonic decrease.	
Actions	Please confirm the standard curve on the calibration screen.	

Error codes/ Error messages	465040	Please check the standard curve data(Reag.)
Probable cause	In the standard curve analysis results, data that exceeded the allowed range specified in the settings was detected.	
Actions	Please confirm the standard curve on the calibration screen. From [Standard curve data administration], perform standard curve data calibration or repeat standard curve analysis.	

Error codes/ Error messages	417011	Failure to correct standard curve(Reag.)
Probable cause	A standard curve with the lot number of the R4/R5 reagent in use in standard curve correction was not obtained.	
Actions	For items which R4/R5 reagent lot numbers have not been changed to the ones of the R4/R5 reagent being used in the standard curve screen, or items which results failed to be calculated in the job list screen, please recalibrate and recalculate.	

Error codes/ Error messages	417010	Error occurred in the results of data analysis
Probable cause	Cannot analyze because analysis results were not obtained.	
Actions	Please confirm the analysis results on joblist or browser screen.	

Error codes/ Error messages	417012	Please check the dilution analysis result(Reag.)
Probable cause	The concentration is within the undiluted measurement range.	
Actions	1) Check if the sample has any problem. 2) Confirm the results on joblist. 3) Execute the analysis again, if necessary.	

Error codes/ Error messages	461000	Out of upper/lower limit of QC(Reag.)
Probable cause	Refer to page that explains QC errors.	
Actions	Please confirm the QC data on QC screen.	

Error codes/ Error messages	462000	QC analysis failed
Probable cause	No result obtained during QC analysis.	
Actions	Please confirm the analysis result on joblist, and execute the analysis again.	

Error codes/ Error messages	429136	Power off without shutdown
Probable cause	Power interruption. The power stopped while the instrument was in operation.	
Actions	1) Execute probe cleaning before analyzing. 2) Run quality control and confirm if there is any QC error. The reagent in the analyzer may have deteriorated.	

Error codes/ Error messages	429134	Long time under power-off condition
Probable cause	Left idle with power off for 24 hours or more.	
Actions	1) Execute probe cleaning before analyzing. 2) Change reagent R4/R5. 3) Do not use the reagent in the analyzer. 4) Run quality control and confirm if there is any QC error.	

Error codes/ Error messages	121030	Internal temperature of the analyzer is high
Probable cause	Environmental temperature outside of the allowed range. Sensor failure. Break in wiring cord.	
Actions	1) Lower the temperature of the air conditioner or other air cooler. 2) Wait until the internal temperature of the analyzer becomes steady. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	121031	Internal temperature of the analyzer is low
Probable cause	Environmental temperature outside of the allowed range. Sensor failure. Break in wiring cord.	
Actions	1) Increase the temperature of the air conditioner or other air cooler. 2) Wait until the internal temperature of the analyzer becomes steady. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	121032	Analysis start temperature not reached (item name)
	121034	Temperature fell below the lower limit during the analysis (item name)
Probable cause	Environmental temperature outside allowed range.	
Actions	1) Check the temperature range on the package insert for the reagent. 2) Wait until the analysis is completed. 3) Check the room temperature and execute the analysis again.	

Error codes/ Error messages	121033	Analysis start temperature has been exceeded (item name)
	121035	Temperature exceeded upper the limit during the analysis (item name)
Probable cause	The temperature inside the instrument rises due to analysis. Environmental temperature outside allowed range.	
Actions	1) Check the temperature range on the package insert for the reagent. 2) Wait shortly after the analysis is completed. 3) Execute the analysis again.	

Error codes/ Error messages	481020	No order to analyze
Probable cause	Order not registered. Received "no order" from host computer. Wrong sample ID.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	486050	Analyzer communication error
Probable cause	Cannot communicate with analyzer. Cable for communication with analyzer not connected.	
Actions	1) Take out the racks from the sampler. 2) Wait until the communication with analyzer has recovered. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	451950	Power dropped
Probable cause	Power unit failure. Electrical trouble in facility.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	149300	Fluid system error(Overflow)
Probable cause	-	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	243174 243175	Fluid system error(1st B/F separation nozzle) Fluid system error(2nd B/F separation nozzle)
Probable cause	Problem in a nozzle. (Foreign matter contamination/Deformation.) Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	243177	Error has been detected in the check of B/F.
Probable cause	Problem in a nozzle. (Foreign matter contamination/Deformation.)	
Actions	Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	425070	Waste Box is not set
Probable cause	Waste box not inserted. Sensor failure.	
Actions	Set the waste box onto the analyzer. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	425082	Waste box will get full soon
Probable cause	The quantity of waste in the waste box has reached the specified value. Sensor failure.	
Actions	Please prepare a new waste bag for the replacement.	

Error codes/ Error messages	425080	Waste Box is full
Probable cause	Waste box is full. Sensor failure.	
Actions	1) Take out the waste box. 2) Replace the waste bag. 3) Open the Setup screen. 4) Reset the counts of waste box. 5) Set the waste box onto the analyzer. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	141196	Waste tank is not connected
Probable cause	Waste tank sensor not installed. Sensor failure. Break in wiring cord.	
Actions	1) Connect the waste tank. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	141195	Waste tank is full
Probable cause	Waste tank is full. Sensor failure. Break in wiring cord.	
Actions	Empty the waste tank. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	141000	Drainage failed
Probable cause	Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	429138	There are samples that have not been analyzed
Probable cause	Analysis has remained stopped for a certain time.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	426080	The reagent scanning is cancelled
Probable cause	During reading or writing of R1-R3 reagent information, the R1-R3 information was lost because the emergency stop button was pressed, the waste tank was removed, or otherwise.	
Actions	Press the Recover button to recover the analyzer.	

Error codes/ Error messages	900000	Service call has been made
Probable cause	Service call button was pressed.	
Actions	Please wait a minute for reply from Service Center.	

Error codes/ Error messages	431104	The hard disk has very little free space left.
Probable cause	Less than 30% of total hard disk space is free.	
Actions	Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	481021	Dilution rate of the order is wrong.
Probable cause	In response to a host real-time order query, an order was received with a dilution ratio of other than [1/1] in a test that is not dilutable. In response to a host real-time order query, an order was received with a dilution ratio of other than [1/1], [1/2], [1/4], [1/10], [1/20], [1/40], [1/100], [1/400], or [1/1600].	
Actions	When acquiring an order from the host computer, check the order registered in the host computer.	

Error codes/ Error messages	441001	Abnormal message was received from the HOST computer
Probable cause	Patient first/last name, doctor, ward, sample comment or patient comment over the specified number of characters received from the host computer. Patient first/last name, doctor, ward, sample comment or patient comment including characters that cannot be input received from the host computer.	
Actions	1) Confirm the HOST computer. 2) Press the Recover button.	

Error codes/ Error messages	449001	There is a notice of error from LU-10
Probable cause	Error occurred in concentrated reagent dilution instrument.	
Actions	1) Confirm the status of the LU-10. 2) Press the Recover button.	

Error codes/ Error messages	449002	LU-10 communication error
Probable cause	A communication cable problem or other problem is preventing communication with the concentrated reagent dilution instrument.	
Actions	1) Confirm the LU-10 connection settings. 2) Confirm the status of the LU-10. 3) Press the Recover button.	

Error codes/ Error messages	472102	Expired probe washing has been used in the analysis
Probable cause	Expired probe washing has been used for analysis.	
Actions	Replace the probe washing.	

Error codes/ Error messages	472106	Expired calibrator has been used in the analysis
Probable cause	Expired calibrator has been used in the standard curve analysis.	
Actions	Register a new calibrator.	

Error codes/ Error messages	472107	Expired QC material has been used in the analysis
Probable cause	Expired material was used in the QC analysis.	
Actions	Register a new material.	

Error codes/ Error messages	511020	Test for which sample analysis is not to be performed are present. (item name)
Probable cause	In the test exclusion settings, some of the analysis items cannot be analyzed.	
Actions	If the test exclusion settings are as intended, ignore this error. If the test exclusion settings are not as intended, cancel the test exclusion settings. (► Administrator's Guide, "Chapter 5: 5.4.4 Selecting items that are to be temporarily excluded from analysis")	

12.5.20 Errors related to tips

Error codes/ Error messages	240104 Tips got blocked(484) 240105 Tips got blocked(485) 240106 Tips got blocked(486) 240107 Tips got blocked(487) 240108 Tips got blocked(488)	
Probable cause	Tip jam in tip feeder. Failure of mechanical unit of tip feeder.	
Actions	1) Wait until the analysis is finished. 2) Press the Recover button. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	420000	Tips have been used up
Probable cause	Out of tips. Sensor failure. Break in wiring cord.	
Actions	1) Wait until the analysis is finished. 2) Replenish new tips. 3) Press the Recover button. 4) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	420001	Tips supply low
Probable cause	Tips are running low. Sensor failure. Break in wiring cord.	
Actions	Please prepare new tips to replenish.	

Error codes/ Error messages	240015	Cover of tip maintenance is opened
Probable cause	The cover is open. Cover sensor failure.	
Actions	1) Close the cover. 2) Wait until the analysis is finished. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	421573	Cover of tip maintenance is unlocked
Probable cause	The lock was released. Lock mechanism failure. Lock monitor sensor failure.	
Actions	Please lock the cover. Analysis will stop if the cover is opened during the analysis.	

12.5.21 Errors related to tip feeder

Error codes/ Error messages	240100	Tip supply unit error(477)
	240101	Tip supply unit error(478)
	240102	Tip supply unit error(479)
	240103	Tip supply unit error(480)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	240109 240110	Tip supply unit error(497) Tip supply unit error(498)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	240111	Tip supply unit error(499)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) Wait until the analysis is finished. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.22 Errors related to probe washing

Error codes/ Error messages	136151	Probe washing is used up
Probable cause	Out of both probe washing. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	Please replenish Probe Washing. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	136150	Probe washing level low
Probable cause	Out of both probe washing. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	Please replenish Probe Washing.	

12.5.23 Errors related to line washing

Error codes/ Error messages	136155	LINE washing Fluid system error(387)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	136010	LINE washing is used up
Probable cause	Out of both line washing. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) Replenish new LINE washing. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	136013 136152	Charging of LINE washing failed LINE washing replenishment failed
Probable cause	Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	1) Please reset the dispensing set. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	136123	LINE washing level low
Probable cause	Out of both line washing. Clogged, disconnected, or ruptured tube. Sensor failure.	
Actions	Replenish new LINE washing. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	472100	Expired line washing has been used in the analysis
Probable cause	Expired line washing has been used in the analysis.	
Actions	Replace the line washing.	

Error codes/ Error messages	472105	Expired concentrated line washing has been used in the analysis
Probable cause	Expired concentrated line washing has been used for analysis.	
Actions	Replace the concentrated line washing.	

Error codes/ Error messages	472108	Concentrated LINE washing has expired
Probable cause	The concentrated line washing connected to the LU-10 has expired.	
Actions	Replace the concentrated line washing.	

12.5.24 Errors related to racks

Error codes/ Error messages	446307	Rack ID reading failed
Probable cause	Barcode is dirty. Incorrect barcode settings. Barcode reader failure.	
Actions	Confirm if the rack ID is correct.	

Error codes/ Error messages	259103	Rack is full
Probable cause	Sampler rack removal area full. Sensor failure. Wiring cord failure.	
Actions	Take out the rack. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	259105	Rack failed to move
Probable cause	Sensor failure. Break in wiring cord. Sampler mechanical unit failure.	
Actions	1) Take out the racks from the sampler. 2) Confirm that the holes on the side of the rack are not covered. 3) If any analysis is still running, wait until it is completed. 4) Press the Recover button to recover the analyzer. 5) Please re-register orders of samples in the rack where error happened, and then press the Start button to analyze again.	

12.5.25 Errors related to pressure

Error codes/ Error messages	114201 114200 113301 113300	Pressure error(-0.033MPa negative pressure) Pressure error(-0.053MPa negative pressure) Pressure error(0.06MPa positive pressure) Pressure error(0.25MPa positive pressure)
Probable cause	Clogged, disconnected, or ruptured tube. Pressure adjustment values out of adjustment. Pneumatic unit failure.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.26 Errors related to detector

Error codes/ Error messages	341600	Detector PMT error
Probable cause	PMT failure. Wiring cord failure.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	127933	Detector System error(363)
Probable cause	Board failure. Thermistor wire break.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	121400	Detector temperature error
Probable cause	Environmental temperature outside of the allowed range. Temperature control unit failure. Sensor failure. Break in wiring cord.	
Actions	1) Turn off and on the power of the analyzer. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again. (If the error occurs repeatedly, contact our Customer Support Center or branch offices/sales offices.)	

Error codes/ Error messages	249512 Detector error(337) 249513 Detector error(338) 233003 Detector error(356) 233004 Detector error(357) 233005 Detector error(358) 233008 Detector error(361)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	233006 Detector error(359) 233007 Detector error(360)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	341601 Pre-count value is too high
Probable cause	PMT failure. Dirt in detector. Wrong reagent placed.
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	411040 Dark count value is too high
Probable cause	PMT failure. Failure of filter drive unit in detector.
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.

12.5.27 Errors related to sample arm

Error codes/ Error messages	231119 Sampling arm error (68) 231120 Sampling arm error (69) 231121 Sampling arm error (70) 231122 Sampling arm error (71) 231124 Sampling arm error (73) 231125 Sampling arm error (74) 231126 Sampling arm error (75) 231133 Sampling arm error (83)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	231123 Sampling arm error (72)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	1) If any analysis is still running, wait until it is completed. (If there is any rack left in the sampler, please take it out.) 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	231127 Sampling arm error (76)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.

Error codes/ Error messages	231129	Sampling arm error (78)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Check if the sample has any problem. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	231134	Sampling arm error (84)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	421571	Cover of sampling arm is opened
Probable cause	The cover is open. Cover sensor failure.	
Actions	1) Close the cover. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	421569	Cover of sampling arm is unlocked
Probable cause	Cover lock released. Lock sensor failure.	
Actions	Please lock the cover. Analysis will stop if the cover is opened during the analysis.	

Error codes/ Error messages	231130	Tip abnormality detected during sample aspiration
Probable cause	Tip part error. Sensor failure. Break in wiring cord.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	231131 231132	Sample aspiration failed(81) Sample aspiration failed(82)
Probable cause	Insufficient sample. Foam in sample. Sample arm mechanical unit out of position. Sample arm mechanical unit failure. Sensor failure.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	231128	Sample is insufficient.
Probable cause	Insufficient sample volume.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.28 Errors related to bottles of reagent

Error codes/ Error messages	151000	Reagent is used up(Reag.)
Probable cause	No reagent for displayed parameter.	
Actions	1) Replenish the reagent. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	151001	Reagent of the specified lot No. not found(Reag.)
Probable cause	During standard curve creation or otherwise, applicable reagent of order specifying a lot not placed.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	154301	Diluent is used up(Diluent name)
Probable cause	No sample diluent.	
Actions	1) Replenish the diluent. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	232164 232181 232199	Reagent R1 to be aspirated is insufficient[Pos.No - (Reag.)] Reagent R2 to be aspirated is insufficient[Pos.No - (Reag.)] Reagent R3 to be aspirated is insufficient[Pos.No - (Reag.)]
Probable cause	Insufficient volume of reagent. Reagent arm mechanical unit out of position. Reagent arm mechanical unit failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Replenish the reagent. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	210055 210056 210057	R1 reagent bottle error[Pos.No - (Reag.)] R2 reagent bottle error[Pos.No - (Reag.)] R3 reagent bottle error[Pos.No - (Reag.)]
Probable cause	The cap is stuck on the reagent bottle. Sensor or motor failure. Drive unit failure. An object is obstructing mechanical unit operation.	
Actions	1) Wait until the analyzer stops running. 2) Take out the reagent bottle. 3) Confirm the cover of the reagent bottle.	

Error codes/ Error messages	232165	Diluent to be aspirated is insufficient[Pos.No - (Diluent name)]
Probable cause	Insufficient volume of reagent. Reagent arm mechanical unit out of position. Reagent arm mechanical unit failure. Sensor failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Replenish the diluent. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	446301	Failed to read info of the reagent bottle.
Probable cause	Reagent bottle IC failure. IC reader failure.	
Actions	1) Press the Recover button to recover the analyzer. 2) Correct the reagent info.	

Error codes/ Error messages	446302	Failed to write info into the reagent bottle.
Probable cause	Reagent bottle IC failure. IC reader failure.	
Actions	Press the Recover button to recover the analyzer.	

12.5.29 Errors related to sample dispensing unit

Error codes/ Error messages	249500	Sample dispense unit error(207)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	249501	Sample dispense unit error(208)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.30 Errors related to reagent holder A

Error codes/ Error messages	127930	Reagent set A System error(220)
Probable cause	Board failure. Thermistor wire break.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	446300	Reagent set A System error(221)
Probable cause	Board failure. Thermistor wire break.	
Actions	1) Press the Recover button to recover the analyzer. 2) Correct the reagent info.	

Error codes/ Error messages	125606	Reagent set A temperature error
Probable cause	Environmental temperature outside of the allowed range. Temperature control unit failure. Sensor failure. Break in wiring cord.	
Actions	Please wait a moment until the temperature becomes steady. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	210040 Reagent set A error(212) 210041 Reagent set A error(213) 210042 Reagent set A error(214) 210043 Reagent set A error(215) 210044 Reagent set A error(216) 210045 Reagent set A error(217) 210046 Reagent set A error(218)	
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	421560	Cover of reagent set A is opened
Probable cause	The cover is open. Cover sensor failure.	
Actions	1) Close the cover. 2) Wait until the analysis is finished. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	421567	Cover of reagent set A is unlocked
Probable cause	The lock was released. Lock mechanism failure. Lock monitor sensor failure.	
Actions	Please lock the cover. Analysis will stop if the cover is opened during the analysis.	

12.5.31 Errors related to reagent holder B

Error codes/ Error messages	127931 139053	Reagent set B System error(242) Reagent set B System error(260)
Probable cause	Board failure. Thermistor wire break.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	446303	Reagent set B System error(243)
Probable cause	Board failure. Thermistor wire break.	
Actions	1) Take out the racks from the sampler. 2) Press the Recover button to recover the analyzer. 3) Operate again.	

Error codes/ Error messages	125607	Reagent set B temperature error
Probable cause	Environmental temperature outside of the allowed range. Temperature control unit failure. Sensor failure. Break in wiring cord.	
Actions	Please wait a moment until the temperature becomes steady. (After that, the analysis will automatically start again.)	

Error codes/ Error messages	210047 210048 210049	Reagent set B error(251) Reagent set B error(252) Reagent set B error(253)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	210050	Reagent set B error(254)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	139052	Reagent set B System error(259)
Probable cause	Clogged, disconnected, or ruptured tube. Break in wiring cord. Syringe operation error.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	421561	Cover of reagent set B is opened
Probable cause	The cover is open. Cover sensor failure.	
Actions	Close the cover.	

Error codes/ Error messages	151110	Reagent R4R5 being used has been changed.
Probable cause	Reagent bottle with different ID from reagent bottle in use was placed. Reagent bottle IC failure. IC reader failure.	
Actions	1) Wait until the analysis is finished. 2) Setup the original reagent. (Replace it if there is no reagent remained.) 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.32 Errors related to reactor

Error codes/ Error messages	127932	Reactor System error(273)
Probable cause	Board failure. Thermistor wire break.	
Actions	1) Turn off the power of the analyzer. 2) Take out the racks from the sampler. 3) Take out the reagent and keep in refrigerator. 4) Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	123430	Reactor temperature error
Probable cause	Environmental temperature outside of the allowed range. Temperature control unit failure. Sensor failure. Break in wiring cord.	
Actions	1) Turn off and on the power of the analyzer. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again. (If the error occurs repeatedly, contact our Customer Support Center or branch offices/sales offices.)	

Error codes/ Error messages	249502 249503	Reactor error(270) Reactor error(271)
Probable cause	Sensor or motor failure. Drive unit failure. Break in wiring cord. An object is obstructing mechanical unit operation.	
Actions	Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.33 Errors related to conveyor

Error codes/ Error messages	484122 484123	There is a notice of error from the conveyor line ID notices of samples from conveyor line are over capacity
Probable cause	Error occurred on conveyor line.	
Actions	1) Confirm the status of the conveyor. 2) Confirm the settings of the conveyor. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	484127	Conveyor line command receiving error
Probable cause	Received conveyor group ID notification or conveyor sample ID notification from conveyor line when not in the analyzing state.	
Actions	1) Confirm the status of the conveyor. 2) Confirm the settings of the conveyor. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	484121	Conveyor line communication error
Probable cause	Settings for communication with conveyor line not configured. Conveyor line power not on. Cable for communication with conveyor line not connected.	
Actions	1) Confirm the status of the conveyor. 2) Confirm the settings of the conveyor. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	484130	Conveyor line communication establishment error
Probable cause	Detected command error during (before) reception of power-on command from conveyor line.	
Actions	1) Confirm the status of the conveyor. 2) Confirm the settings of the conveyor. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	484125	An unknown sample has arrived at the aspiration position
Probable cause	Notification of pre-read sample ID not received from conveyor line for sample that arrived at aspiration position.	
Actions	Confirm if the sample ID is correct.	

Error codes/ Error messages	484128	Sample has not arrived to the charging position(Conveyor)
Probable cause	Sample did not arrive due to error on conveyor line or other problem.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	484129	Received "new sample arrived" notice during sample aspiration
Probable cause	Received incorrect notice from conveyor line regarding sample being aspirated.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

Error codes/ Error messages	484126	The arrived sample's ID does not match
Probable cause	Sample that arrived at the aspiration position does not match sample ID pre-read by conveyor line.	
Actions	1) Check if the sample has any problem. 2) Please re-register orders of samples with failed results, and then press the Start button to analyze again.	

12.5.34 Errors related to maintenance parts

Error codes/ Error messages	474010	Time to replace(1st B/F separation nozzle A)
	474011	Time to replace(1st B/F separation nozzle B)
	474012	Time to replace(1st B/F separation nozzle C)
	474013	Time to replace(1st B/F separation nozzle D)
	479307	Time to replace(1st B/F mixing unit A)
	479308	Time to replace(1st B/F mixing unit B)
	479309	Time to replace(1st B/F mixing unit C)
	479310	Time to replace(1st B/F mixing unit D)
	474020	Time to replace(2nd B/F separation nozzle A)
	474021	Time to replace(2nd B/F separation nozzle B)
	474022	Time to replace(2nd B/F separation nozzle C)
	474023	Time to replace(2nd B/F separation nozzle D)
	479316	Time to replace(2nd B/F mixing unit A)
	479317	Time to replace(2nd B/F mixing unit B)
	479318	Time to replace(2nd B/F mixing unit C)
	479319	Time to replace(2nd B/F mixing unit D)
	475000	Time to replace(R1 probe)
	479300	Time to replace(R1 mixing unit)
	475001	Time to replace(R2 probe)
	479301	Time to replace(R2 mixing unit)
	475002	Time to replace(R3 Probe)
	479302	Time to replace(R3 mixing unit)
	479303	Time to replace(R45 mixing unit)
	474000	Time to replace(Sample arm syringe)
	479304	Time to replace(R45 cleaning holder)
	479305	Time to replace(Reagent set A lubricator)
	479306	Time to replace(Reagent set B lubricator)
	479311	Time to replace(1st B/F mixing waiting holder)
	479312	Time to replace(1st B/F mixing holder A)
	479313	Time to replace(1st B/F mixing holder B)
	479314	Time to replace(1st B/F mixing holder C)
	479315	Time to replace(1st B/F mixing holder D)
	479320	Time to replace(2nd B/F mixing waiting holder)
	479321	Time to replace(2nd B/F mixing holder A)
	479322	Time to replace(2nd B/F mixing holder B)
	479323	Time to replace(2nd B/F mixing holder C)
	479324	Time to replace(2nd B/F mixing holder D)
	479325	Time to replace(Diaphragm pump)
	473124	Time to replace(R5 syringe)
	479326	Time to replace(R5WTKV)
	479351	Time to replace(R2 drive gear)
Probable cause	When the operation count exceeds the specified count, it is time for replacement.	
Actions	Contact our Customer Support Center or branch offices/sales offices.	

Error codes/ Error messages	479100	Time to replace(Membrane filter)
Probable cause	When the operation count exceeds the specified count, it is time for replacement.	
Actions	Please replace the filter when the analyzer is in ready state or Reagent refrigeration mode.	

12.5.35 Errors related to mixing unit

Error codes/ Error messages	243160 Mixing movement error(1st B/F separation unit) 243164 Mixing movement error(2nd B/F separation unit) 232177 Mixing movement error(R1 reagent arm) 232194 Mixing movement error(R2 reagent arm) 232213 Mixing movement error(R3 reagent arm) 232222 Mixing movement error(R4/R5 reagent arm)
Probable cause	Mixing motor failure. Break in wiring cord.
Actions	1) If any analysis is still running, wait until it is completed. 2) Press the Recover button to recover the analyzer. 3) Please re-register orders of samples with failed results, and then press the Start button to analyze again.

13.1 Performance/specifications

371/386

Class of protection against electrical shock	Class I equipment
EMC characteristics	Conforms with IEC61326-2-6: 2005
Safety	IEC 61010-1:2001, IEC 61010-1:2010+A1 IEC 61010-2-081:2001+A1, IEC 61010-2-081:2019 IEC 61010-2-101:2002, IEC 61010-2-101:2018
Instrument category (overvoltage category)	Category II
Laser class	Class I (IEC60825-1)



Information

The power receptacle of the analyzer conforms to "NEMA standard L6-20". (2P 20 A grounding, single phase)

13.2 System limits

The analysis range varies by test. See the package insert for each reagent.

For instrument display ranges, see the following.

(► **P.371** "13.1 Performance/specifications")

13.3 Program version

To check the current program version of the IPU, touch [Menu] - [Version Info.] on the toolbar.

The dialog box appears, indicating the version.

13.4 Principle

The basic principle of the HISCL-5000 is described below.

13.4.1 Chemiluminescent enzyme immunoassay

The HISCL-5000 uses chemiluminescent enzyme immunoassay to analyze samples quantitatively or qualitatively for minute traces of protein, hormones, and other substances. Samples are mixed with reagents and heated to cause an immunoreaction followed by an enzymatic reaction. By counting photons (photon counting) emitted during the enzymatic reaction, minute traces of protein, hormones, and other substances in the sample are measured or detected. The HISCL-5000 uses alkaline phosphatase for the enzyme and CDP-Star, which shows a strong emission intensity with chemiluminescent substrates, to achieve high sensitivity.

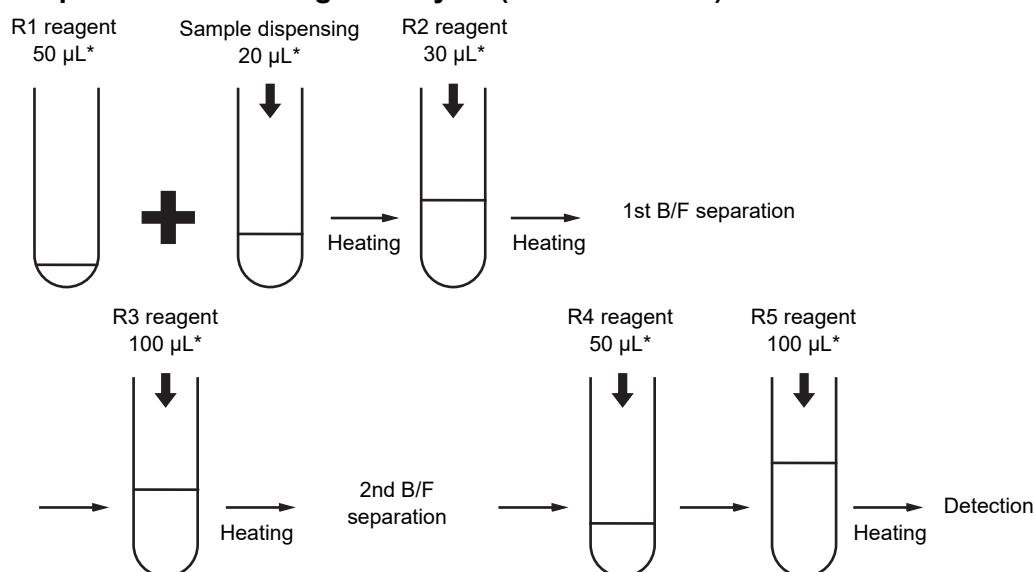
Chemiluminescent enzyme immunoassay methods are described below:

Analysis method	Main tests	Features
2STEP method	HBsAg	1st B/F separation and 2nd B/F separation are performed.
1STEP method	HBsAb	- Does not dispense R3 reagent. 1st B/F separation is not performed; only 2nd B/F separation is performed.
D-1STEP method	FT3, FT4, TSH	1st B/F separation is not performed; only 2nd B/F separation is performed.

Analysis sequence

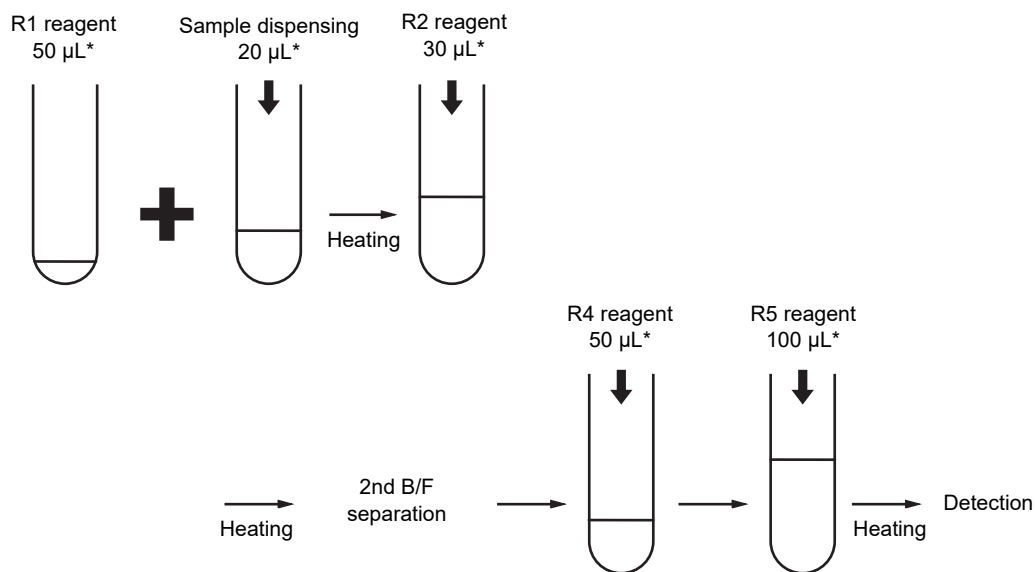
The analysis sequence is described below.

● Sequence of HBs antigen analysis (2STEP method)



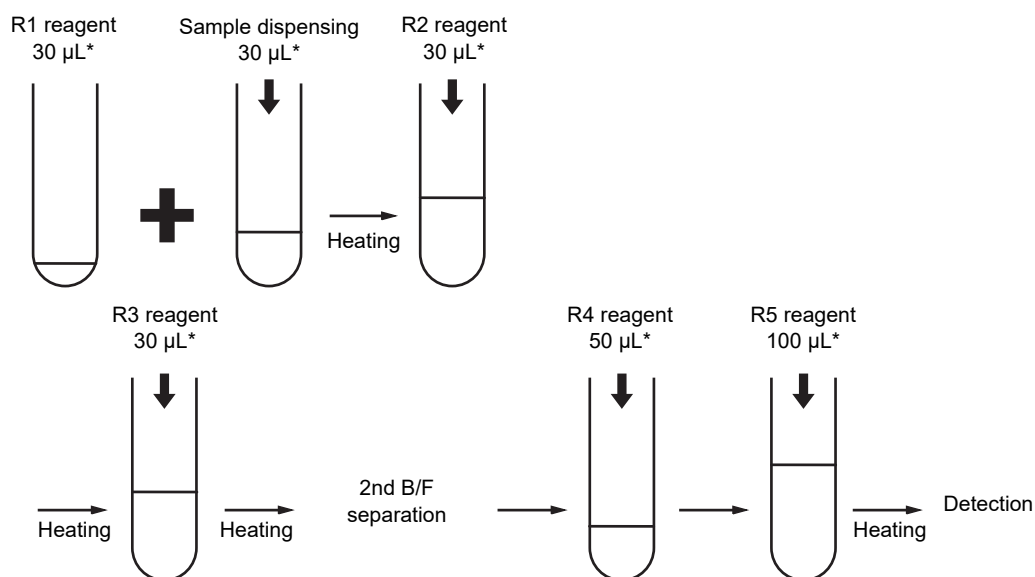
* The R1-R5 reagents and dispensing quantities vary by test.

● Sequence of HBs antibody analysis (1STEP method)



* The R1-R5 reagents and dispensing quantities vary by test.

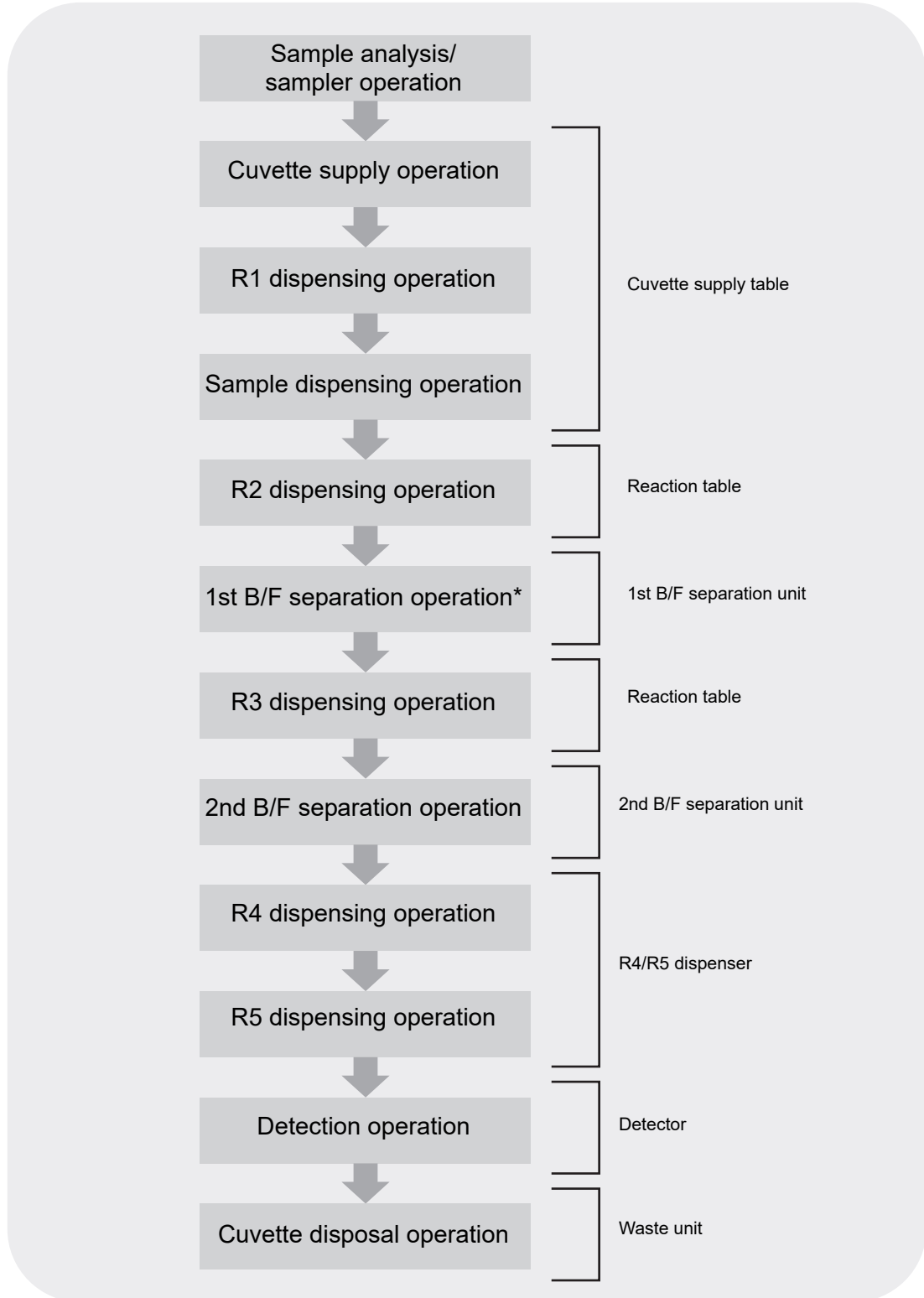
● Sequence of TSH analysis (D-1 STEP method)



* The R1-R5 reagents and dispensing quantities vary by test.

13.4.2 Analysis operation

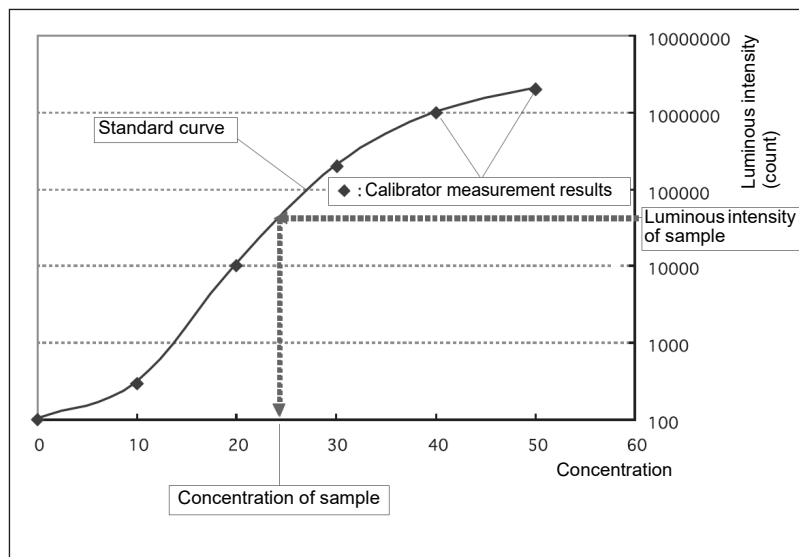
The HISCL-5000 automates the analysis sequence, from dispensing of samples to disposal of cuvettes. The diagram below shows the general steps of the standard analysis sequence.



* Only when the analysis method is the 2STEP method.

13.4.3 Standard curve

The standard curve expresses the relationship between concentration and luminous intensity. This curve is created by interpolation or approximation from the relationship between luminous intensity and concentration obtained by analyzing multiple calibrators (samples of known concentration), each with a different concentration. By creating a standard curve, the concentration of an unknown sample can be calculated from its measured luminous intensity.



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Version 2, June 1991

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