



INSTRUCTIONS FOR USE

Automated Blood Coagulation Analyzer

CA-600 series

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KOBE, JAPAN

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1. Introduction

1.1 Intended Use

The Sysmex® Automated Blood Coagulation Analyzer CA-600 series is a series of compact automated analyzers capable of 5 parameter random analysis for In Vitro Diagnostic use.

The clotting method, chromogenic method and immunoassay method can be selected for analysis. Analysis data can be displayed and printed out together with reaction curves, so you can obtain highly reliable analysis results while checking the reaction process. The instrument also have multiple functions such as order inquiry by ID barcode, analysis result transmission, priority processing of STAT samples, and quality control.

* CA-620: ID barcode reader is optional.

Analysis Parameters and Detection Principles

| Parameter | Test name | Applied |
|---------------------------------------|-----------------|--------------------|
| Prothrombin Time | PT | Clotting Method |
| Activated Partial Thromboplastin Time | APTT | Clotting Method |
| Fibrinogen | Fbg | Clotting Method |
| Thrombin Time | TT | Clotting Method |
| Protein C coagulometric | PCcl | Clotting Method |
| Batroxobin Time | BXT | Clotting Method |
| LA1 Screening | LA1 | Clotting Method |
| LA2 Confirmation | LA2 | Clotting Method |
| Factor Assay | VII, VIII | Clotting Method |
| Antithrombin* | AT | Chromogenic Method |
| Antithrombin III* | AT3 | Chromogenic Method |
| Protein C chromogenic* | BCPC | Chromogenic Method |
| Heparin* | Hep, HepI, HepU | Chromogenic Method |
| D-Dimer* | DDPI, DDi | Immunoassay Method |
| von Willebrand Factor* | vWF, WFa | Immunoassay Method |

(*) CA-660 only

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Ordering of Supplies and Replacement Parts

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

Service and Maintenance

Please contact the Service Department of your local representative.

Training Courses

For further information please contact the representative in your country.

CE-Mark



The IVD system described in this manual is marked with a CE mark which confirms the observance of the essential requirements of the following European directives:

-98/79/EC in-Vitro Diagnostics Directive.

1.2 Explanation of Signs

This manual carries a variety of illustrations to make sure that the product can be used safely and correctly, thus preventing users and others from suffering injuries and damage to property.

The illustrations and meaning are described in the following.

Do understand what they mean before proceeding to the text of the MANUAL.



Risk of Infection

Indicates the presence of a biohazardous material or condition.



Warning!

If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which could result in death or serious injury of operator, or grave property damage.



Caution!

If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation which may result in injury of operator, adverse effect on results, or may cause property damage.



Information

Indicates what we would like you to know to maintain instrument performance and prevent its damage.



Note

Indicates information which will come handy in operating the instrument.

1.3 Protected names

- Sysmex is a registered trademark of SYSMEX CORPORATION.
- CA CLEAN is a trademark of SYSMEX CORPORATION.
- Actin, Berichrom, Dade, INNOVANCE, Innovin, Multifibren, Pathromtin and Thromborel are trademarks of Siemens Healthcare Diagnostics.
- VACUTAINER is a registered trademark of Becton, Dickinson and Company.
- VACUETTE is a registered trademark of C.A. GREINER und Sohne GmbH.
- Other registered trademarks or trademarks referenced are property of their respective owners.

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

1.4 Revision History

| Version | | Revision date | Changes |
|---------|----------|-----------------|------------------|
| Manual | Software | | |
| 1.0 | 00-22 | September, 2011 | Launch Version |
| 1.0 | 00-22 | May, 2012 | Launch Version |
| 1.0 | 00-22 | March, 2013 | Minor Correction |
| 2.0 | 00-27 | April, 2014 | Minor Correction |

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2. Safety Information

Before operating this instrument, carefully read this manual, and strictly follow the instructions given in them.

2.1 Specified Conditions of Use

The CA-600 series is intended solely for In Vitro diagnostic use. The primary sample for analysis is the plasma component of human blood with added anticoagulant (sodium citrate). Any other use is regarded as non-specified. Only reagents and cleaning solutions mentioned in this manual are permitted for use. The specified conditions of use also entail the observance of the cleaning and maintenance procedures described in these instructions.

2.2 General Information



Warning!

- Keep long hair, fingers and clothing away from mechanical parts of the instrument.
- During analysis, do not open the light shield cover and put in hands or fingers.
This could cause injury. When the light shield cover is opened during analysis, the alarm sounds and the operation stops.
- In the event that the instrument emits an abnormal odor or any smoke, turn off its power supply immediately and pull out the power plug from the wall socket.
If the instrument is used continuously in that state, there is a hazard that fire, electrical shock, or injury may result. Contact your local service representative for inspection.
- Take care not to spill blood or reagent, or drop wire staples or paper clips into the instrument.
These might cause short circuit or smoke emission. If such problem should occur, turn off the power supply immediately and pull out the power plug from the wall socket. Then contact your local service representative for inspection.



Warning!

- Do not touch the electric circuits inside the instrument. Especially with wet hands there is a risk of electric shock.
- Never put the power plug in any socket other than that specified. When installing the instrument, be sure to ground it. Otherwise, fire or electrical shock will result.
- Take care not to damage the power cord, put a heavy thing on it, or pull it forcibly. Otherwise, the wire may become shorted or break, causing fire or electrical shock.
- When connecting the instrument to a peripheral (host computer, etc.), be sure to switch off the power supply beforehand. Otherwise, fire or electrical shock may result.
- Use the check-digit as much as possible. If the check-digit cannot be used, the potential of the incorrect reading of the barcode label may be increased.



Caution!

- Read this manual carefully to operate the instrument by the proper method. Keep it securely in a specified location for future reference.
- This instrument must only be operated as instructed in this manual.

2.3 Installation Location



Caution!

- Install in a place which is not subject to water splash.
- Install in a place which is not subject to adverse effects of high temperature, high humidity, dust, direct sunlight, etc.
- Do not give the instrument a strong vibration or impact.
- Install at a place which is well ventilated.
- Avoid installation of the instrument near devices that emit electrical interference, such as a centrifuge.
- Do not install near chemicals storage or in a place where gas is generated.

2.4 Electromagnetic Compatibility (EMC)

This instrument complies to the following IEC (EN) standards:

- IEC61326-2-6:2005 (EN61326-2-6:2006)
Equipment for measurement, control and laboratory use — EMC-Requirements.
- EMI (Electromagnetic Interference)
For this standard the requirements of class B are fulfilled.
- EMS (Electromagnetic Susceptibility)
For this standard the minimum requirements with regards to immunity are fulfilled.

2.5 Avoidance of Infections



Risk of Infection

- In principle, all parts and surfaces of the instrument must be regarded as infectious. Should you inadvertently come in contact with potentially infectious materials or surfaces, immediately rinse skin thoroughly with plenty of water, then follow the antiseptic regulations of your laboratory.
- Use care when handling waste liquid. Never touch waste, or parts having been in contact with waste, with bare hands. If it adheres to the skin or clothing, wash it off using an antiseptic solution.
- Be careful when handling samples or reagents (including Control plasma). Always wear latex or non latex examination gloves; otherwise contamination could result. After completion of work, wash hands with disinfectant to avoid the risk of infection with pathogens etc. If a sample or reagent happens to enter your eye or a cut, wash it off with plenty of water, and immediately visit a physician.
- Always wear latex or non latex examination gloves when performing maintenance work or inspection. Also use the specified tools and parts. After work is over, wash the hands in an antiseptic solution. There is a possibility that those areas of the hand which came in contact with blood could suffer infection.
 - eg.
 - Handling the waste bottle and its contents
 - Handling the trash box
 - Discarding used reaction tubes
 - Cleaning the probe
 - Draining the trap chamber
- When discarding waste liquid, instrument consumables and instrument, take proper steps to dispose of them as medical, infectious and industrial wastes. If they are contaminated with blood, there is a possibility of bacterial infection occurring. Take care not to spill waste liquid that may have collected in the trash box.

**Risk of Infection**

- If the analysis is performed with the trash box removed, the inside of the analyzer will be contaminated since the reaction tube contaminated by blood drops into the analyzer. When the error message is displayed, be sure to set the trash box correctly. When cleaning the inside of the analyzer or disposing of the reaction tube which dropped into the analyzer, be sure to put on the latex or non latex examination gloves.
- The end of the probe is sharp. Handle with sufficient caution. When cleaning the probe, wipe off the sample probe from top to bottom.

2.6 Handling of Reagents



Warning!

- Do not directly touch the reagents. Reagents can cause irritation of the eyes, skin and mucous membranes.
- Should you inadvertently come in contact with reagent, immediately rinse skin thoroughly with water.
- If a reagent should get in your eyes, rinse thoroughly with water and contact your physician immediately.
- If a reagent is accidentally swallowed, vomit or induce vomiting by drinking copious amounts of warm, salty water and contact your physician immediately.
- CA CLEAN™ II is an acidic cleaning agent. It should not come in contact with skin or clothing. If it happens rinse skin or clothing with plenty of water to avoid injury or damage.
- The CA CLEAN™ I detergent contains sodium hypochlorite. If CA CLEAN™ I comes in contact with the instruments surfaces, it will affect the surface finish and there is danger of corrosion. Immediately wipe up CA CLEAN™ I with a damp cloth.
- Extra care should be taken to make sure CA CLEAN™ I is not mixed and used with acidic solutions such as CA CLEAN™ II. Direct mixing of CA CLEAN™ I and an acidic solution will result in the highly hazardous release of poisonous chlorine gas.
- When handling samples or reagents, always wear latex or non-latex gloves.
After completion of work, wash hands with disinfectant to avoid the risk of infection with pathogens etc.

**Caution!**

- Follow directions on reagent labelings.
- Avoid letting the reagent come in contact with dust, dirt or bacteria.
- Reagents must not be used after their expiration date.
- Handle reagents gently to avoid bubbling.
- Take care not to spill reagents.
- Handle and store reagents according to the instructions provided with each reagent.

To maintain the storage stability of the reagents, they should be stored cooled with their lids closed out of the instrument in a refrigerator.

Leaving reagents for long periods with open caps could affect data.

2.7 Maintenance of the Instrument



refer to “2.5 Avoidance of Infections”

**Warning!**

When carrying out inspection and maintenance of the instrument, use only the specified tools and parts.

2.8 Disposal of Materials



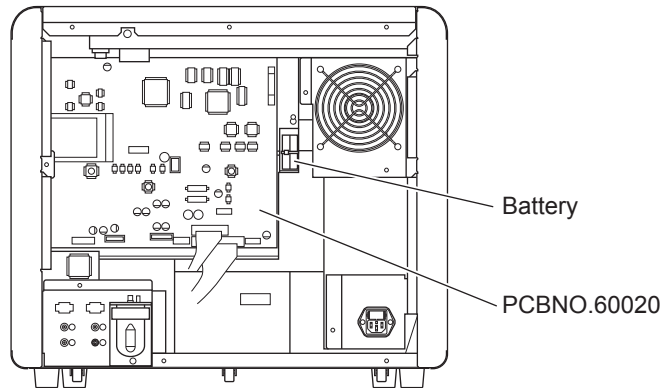
refer to “2.5 Avoidance of Infections”



Warning!

Battery is installed in CA-600 series to store data.
When discarding the instrument, remove the battery.
If the instrument is thrown into fire, it may explode.

* We really appreciate your recycling of the removed battery by collection route.



Waste Disposal



Risk of Infection

After becoming waste at end-of-life, this instrument and its accessories are regarded as infectious. They are therefore exempted from EU directive 2012/19/EU (Waste Electrical and Electronic Equipment Directive) and may not be collected by public recycling to prevent possible risk of infection of personnel working at those recycling facilities.



Warning!

- Do not dispose the instrument, accessories and consumables via public recycling!
- Incineration of contaminated parts is recommended!
- Contact your local Sysmex service representative and receive further instructions for disposal! Follow local legal requirements at all times.



Caution!

Waste effluents from the instrument may contain dangerous substances in it and decision about disposal only has to be made by local water authority.

Decontamination



Warning!

Before decontaminating the instrument, be sure to turn off the power supply and unplug the power cord. This is necessary to avoid the risk of electric shock. When cleaning the instrument, always wear protective gloves and gown. Also, wash hands after decontamination carefully with antiseptic solution first and with soap afterwards. Do not open the instrument for decontamination inside. This is executed only by Service Technician.

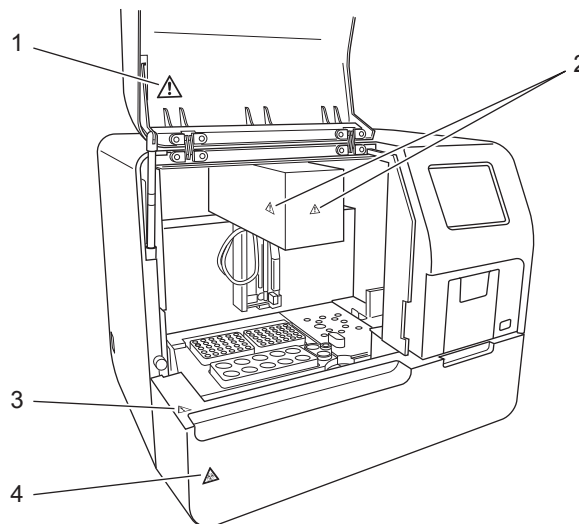




Information


- To ensure decontamination of the instrument outer surfaces, clean the instrument surface at the end of the daily work. This has to be executed in the following three situations;
 - Regularly, at the end of a daily work,
 - Immediately, during contamination with potentially infectious material, and
 - In advance of repair or maintenance by the field technical service representative
- Wipe off the instrument surfaces using a cloth soaked with a suitable decontamination solution. Please use one-way cloths, e.g. made of paper or cellulose. The cloth may be moistened in a way only that no wetness may reach the inside of the instrument.
- The indicated residence time of the decontamination solution shall be observed.
- If required, you may afterwards remove normal contaminations with commercial neutral detergent, in case these could not be removed by the decontaminant.
- As a last step the instrument shall be dried with a dry one-way cloth.


2.9 Markings on the Instrument

Front

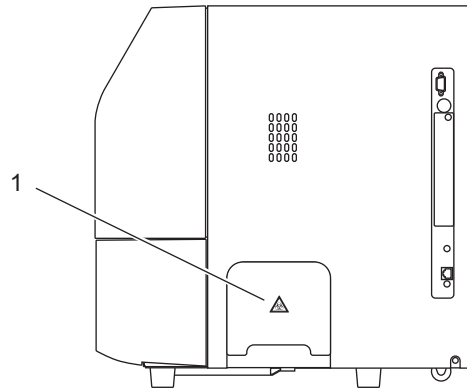



-  **Caution!**
When closing the light shield cover, be sure to hold the handle.
If it is closed by holding other parts, the hand or finger may get pinched or injured.
Be sure to fully open the light shield cover and check that it will not fall down by its own weight.
If the light shield cover falls down, there is a risk of causing injury on the head.
Also, do not place any object on the instrument covers.
-  **Caution!**
When the probe has been lowered, move it until the probe and the catcher lower surface are leveled, and then move the arm.

3.  **Caution!**
Do not apply excessive force to the sampler unit.
It may break.

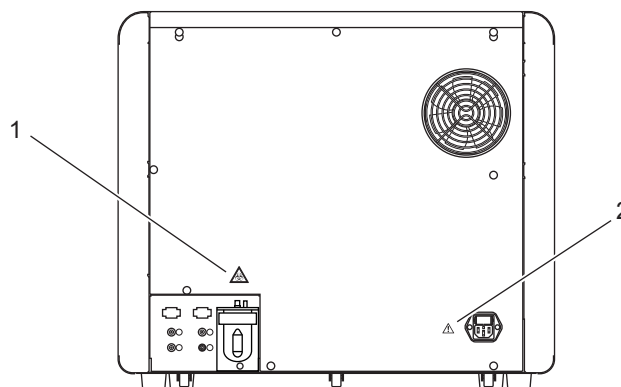
4.  refer to “2.5 Avoidance of Infections”


Left Side





1.  refer to “2.5 Avoidance of Infections”

Rear

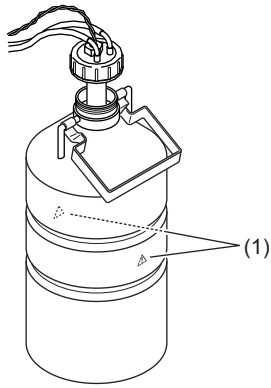


1.  refer to “2.5 Avoidance of Infections”

2.  **Warning!**
 As it is dangerous, be sure to pull out the power cord before inspection.
 To avoid risk of electric shock, disconnect the power cord before replacing the fuse.
 For continued protection against risk of fire, replace only with fuse of the specified type and current ratings.
 Otherwise, fire or electrical shock will result.

 **Warning!**
 Be sure to ground the instrument.
 If grounding is not sufficient, there is a risk of electric shock.

Rinse Bottle (Pale blue)



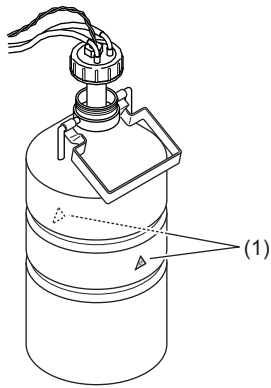
1.



Caution!

Refill the rinse bottle with distilled water only.
When refilling, be careful not to allow dirt to adhere to the float switch, etc.

Waste Bottle (Gray)



1.



refer to “2.5 Avoidance of Infections”

2.10 Personnel



Warning!

This instrument is clinical laboratory equipment for screening.

When making clinical judgment based on analysis results, the doctor must also consider clinical conditions and other inspection results for an overall judgment.



Caution!

- Those who have no or only limited experience in using the instrument are recommended to have guidance or assistance from those with sufficient experience.
- If the instrument has developed a problem by any chance, a person in charge of it should take steps within the range specified in Instructions For Use. As to problems other than those mentioned, contact your local service representative for repair.
- Instrument unpacking, installation, and confirmation of initial operation must be done by your local service representative.

2.11 Storage Condition (Transportation)

- Ambient Temperature: -10°C to +60°C
- Relative humidity: 95% or less
(Non condensing / Keep dry)

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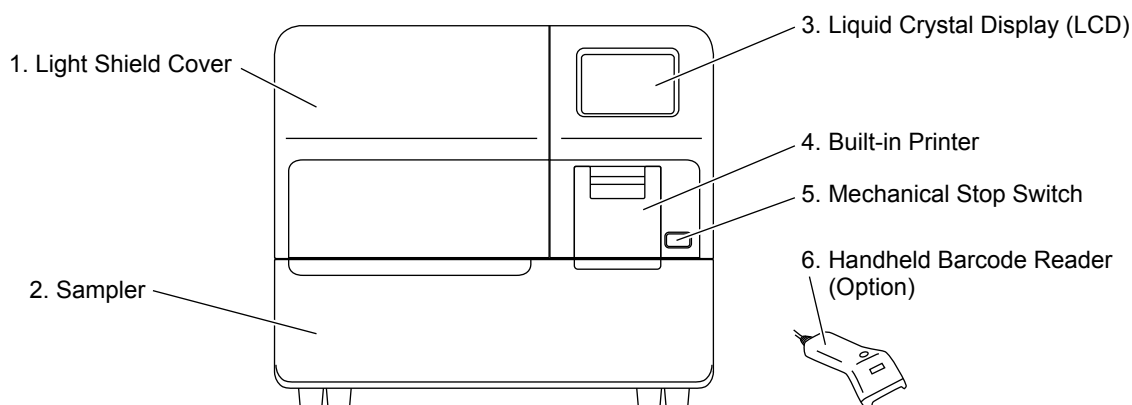
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3. Design and Function

3.1 Overview

Front



1. Light Shield Cover

Prevents photoelectric detection from being affected by scattered light from external sources. Ensure this cover is shut before proceeding to analyze any samples. Analysis cannot be started if this cover remains open.



Warning!

Do not open the Light Shield Cover while analysing. Opening the cover will suspend analysis and beep the alarm. Also, opening the cover and inserting your hand may cause injury.

2. Sampler

The sampler has a load capacity of one sampler rack with 10 sample tubes. The sampler racks are specific for Sysmex instruments. One rack can be set on the sampler at a time.

Pull out the Sampler toward you to load a rack. Once the rack is loaded, the sampler will operate without the need for intervention by the operator.



Note

- The sampler unit is locked while sampling and dispensing. Once the status has become ready to set samples, the sampler lock is released. You can pull out the sampler to set samples on available positions on the rack in use, or to place a next rack to allow continuous analyses.
- The sampler unit can also be pulled out by the STAT sample analysis procedure to allow an analysis of a STAT sample.

3. Liquid Crystal Display (LCD)

Displays analysis results, reaction curves, sample numbers, test conditions, etc.

The LCD functions as a touch-sensitive control panel. The operator can execute various operations and enter settings by lightly touching keys displayed on the LCD.

4. Built-in Printer

Setting conditions, error messages and analysis results are printed out on the thermal paper of the graphic printer. The LCD contrast adjustment knob is located inside the built-in printer.

5. Mechanical Stop Switch

Press this switch to stop the operation of the instrument. It is necessary to reanalyze because the sample being analyzed is discarded.



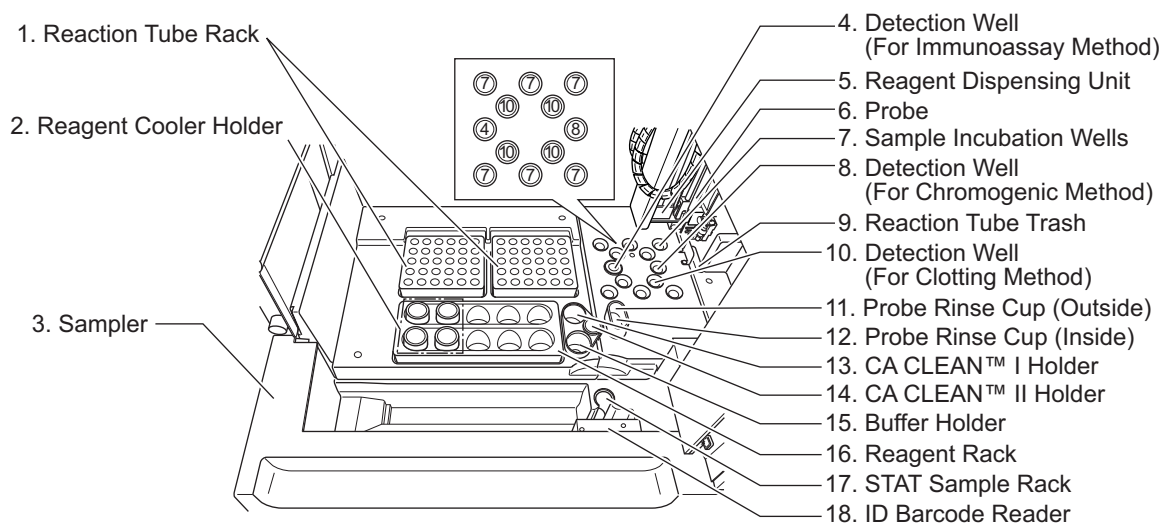
Information

If there is a sample that has been already dispensed, this sample has to be reanalyzed from the start.

6. Hand-held Barcode Reader (Optional)

Sample ID and reagent information can be entered by hand-held barcode reader.

Front Interior (When Opening Light Shield Cover)



1. Reaction Tube Rack
Two reaction tube racks can be set. One rack holds up to 30 reaction tubes (SU-40). The compartments of Reaction Tube Rack are numbered from the right end to the front as 1, 2, 3...60.
2. Reagent Cooler Holders
Can hold up to 4 vials with cooler function.
3. Sampler
Can hold one sample rack.
4. Detection well (For Immunoassay Method: CA-660 only)
Detection well for the immunoassay sample. The number of wells is one. The detector is always kept at $37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$.
5. Reagent Dispensing Unit
A mechanical part to dispense the reagent dispensed by probe to a sample.
6. Probe
This pipette is used to aspirate samples and reagents. It is kept at $37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$.
7. Sample Incubation Wells
Six incubation wells are provided, and these wells are kept at $37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$.
8. Detection Well (For Chromogenic Method: CA-660 only)
Detection well for the chromogenic sample. The number of wells is one. The detector is always kept at $37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$.
9. Reaction Tube Trash
Used reaction tubes are disposed into this trash.
10. Detection Wells (For Clotting Method)
Four scattered light detection wells are provided, and these wells are kept at $37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$.

11. Probe Rinse Cup (Outside)

The outside of the probe is rinsed with the rinse fluid kept in this rinse cup.

12. Probe Rinse Cup (Inside)

The inside of the probe is rinsed in this rinse cup.

13. CA CLEAN™ I Holder

CA CLEAN™ I detergent is set in the vial, whose outer diameter is 22 mm or less, and height is 50 mm or less.



Caution!

Use the provided vials to hold the CA CLEAN™ I detergent. If any vial higher than 50 mm is used, the Probe will be damaged permanently.

14. CA CLEAN™ II Holder

Set CA CLEAN™ II into a 4mL (code No. 424-1160-8) conical container.

15. Buffer Holder

Buffer diluent used for sample dilution is set in the vial, whose outer diameter is 22 mm or less, and height is 50 mm or less.



Caution!

Use the provided vials for the container to keep the Buffer. If any vial higher than 50 mm is used, the Probe will be damaged permanently.

16. Reagent Rack

Reagent vials, whose outer diameter is 22 mm and height is 40 mm, can be set directly. Use sample cups or optional holders to place any vial with other outer diameters.



Caution!

If any vial higher than 40 mm is used, the Probe will be damaged permanently.

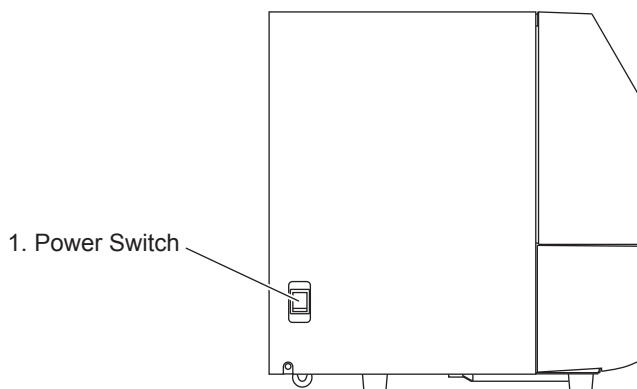
17. STAT Sample Rack

Place a STAT sample collection tube or sample cup here. If a sample collection tube is placed, use optional holders to make the tube diameter fit the rack.

18. ID Barcode Reader (Optional on CA-620)

ID Barcode Reader moves in front of the rack and reads the barcoded label automatically.

Left Side



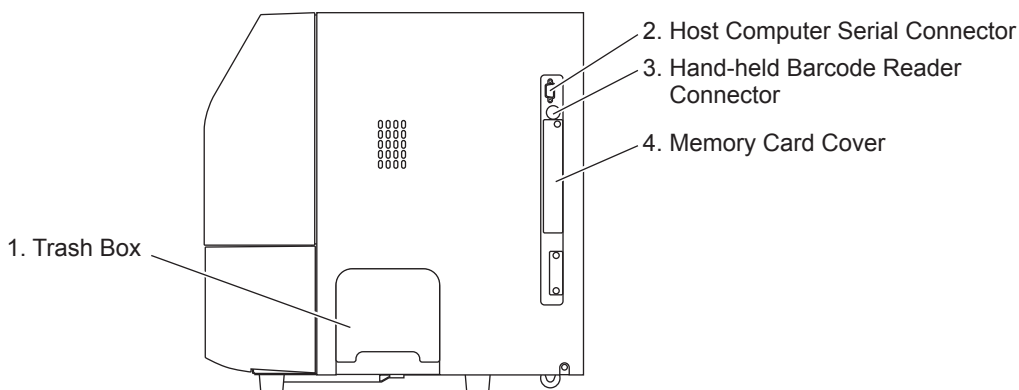
1. Power Switch
Turns the power ON or OFF.



Caution!

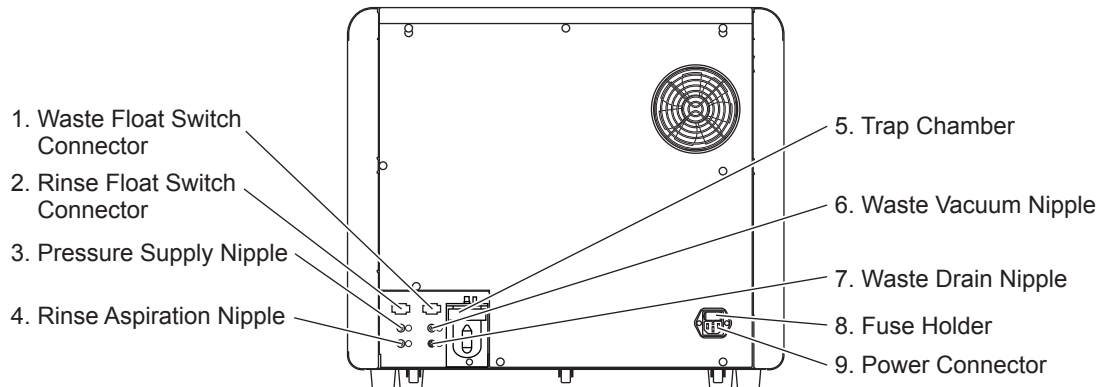
Please allow at least 5 seconds between turning the instrument OFF and back ON, or the fuse may be blown.

Right Side



1. Trash Box
Used for storing used reaction tubes.
2. Host Computer Serial Connector
For connecting to the external host computer.
3. Hand-held Barcode Reader Connector
For connecting to the Hand-held barcode reader.
4. Memory Card Cover
This card has PROM chips to load the CA-600 program into RAM memory. (Intended for your local service representative use only)

Rear



1. Waste Float Switch Connector (“WASTE”)
For connecting the float sensor switch, located on the Waste Bottle, for detecting the waste fluid level.
2. Rinse Float Switch Connector (“RINSE”)
For connecting the float sensor switch, located on the Rinse Bottle, for detecting rinse water level.
3. Pressure Supply Nipple (Colored Black)
To be connected via a tube with the Rinse Bottle.



Information

When the Rinse Bottle is to be opened, disconnect this tubing first to release the pressure accumulated inside the Rinse Bottle. Failing to do this will splash the pressurized rinse fluid.

4. Rinse Aspiration Nipple (Colored Blue)
For aspirating the rinse water from the Rinse Bottle. To be connected via a tube to the Rinse Bottle.



Information

When the Rinse Bottle is to be opened, disconnecting this tubing first will splash the pressurized rinse fluid. Disconnect the black tubing first.

5. Trap Chamber
Prevents the waste fluid from flowing back to affect the vacuum pump, in the event of an abnormality with the instrument.
6. Waste Vacuum Nipple (Colored Green)
To be connected via a tube with the Trap Chamber.
7. Waste Drain Nipple (Colored Red)
For draining waste fluids. Must be connected via a tube to the Waste Bottle.

8. Fuse Holder

Two time-lag type fuses are installed in this Fuse Holder. Replace with the correct type of fuse (supplied).

| Part No. | Description | Fuse Type | Location |
|----------|----------------|-----------|------------|
| BC963426 | Fuse 250V 4.0A | Time Lag | Rear Panel |

**Warning!**


- To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.
- For continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.


9. Power Connector

For connecting the main power supply (via the supplied power cable).

3.2 Operation Flow

| Manual Order Registration | On-Line Order Registration (Manual Inquiry) | On-Line Order Registration (Auto Inquiry) |
|---|--|--|
| Inspection Before Turning On Power | | |
| Turn On Power | | |
| <ul style="list-style-type: none"> • Self Check | | |
| Ready | | |
| Prepare Reagents | | |
| Register Analysis (Manual Registration) | Prepare Samples | Prepare Samples |
| Prepare Samples | Register Analysis Press [HC] key | |
| Press [Start] key | | |
| <ul style="list-style-type: none"> • Execution of Analysis • Completion of Analysis | | |
| Ready | | |
| Turn Off Power | | |
| Operation After Completion of Analysis | | |

:Indicates actions performed by the operator.

:The message "Ready" will appear on the LCD screen, indicating that analysis, setting, data processing and other operations can be executed.

| | | |
|-----------|---------------------------------------|------------|
| 4. | Installation Environment | 4-1 |
| 4.1 | Installation and Relocation | 4-1 |
| 4.2 | Installation Location | 4-1 |
| 4.3 | Basic Instrument Settings | 4-3 |



4. Installation Environment

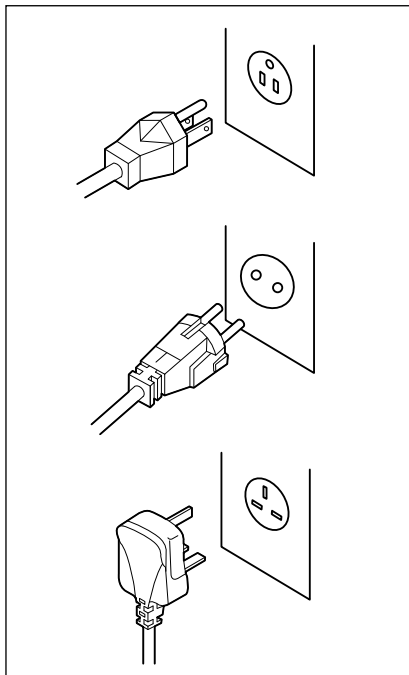
4.1 Installation and Relocation

Installation of the instrument must be conducted by your local service representative. If it is necessary to relocate the instrument, contact your local service representative.

It is to be noted that if problems should develop as a result of relocation conducted by a customer, it will void the warranty even if the instrument is in the warranty period.

4.2 Installation Location

Grounding



The power cord of each instrument uses the 3P plug. When the power supply socket is 3P (with ground) type, simply plug it to the socket. The type of cord and plug supplied depends on the source voltage for the system.



Warning!

Proper use of the appropriate power cord assures adequate grounding for the system. Failure to properly ground the instrument bypasses important safety features and may result in an electric hazard.



Note

The number of power supply sockets required is one.

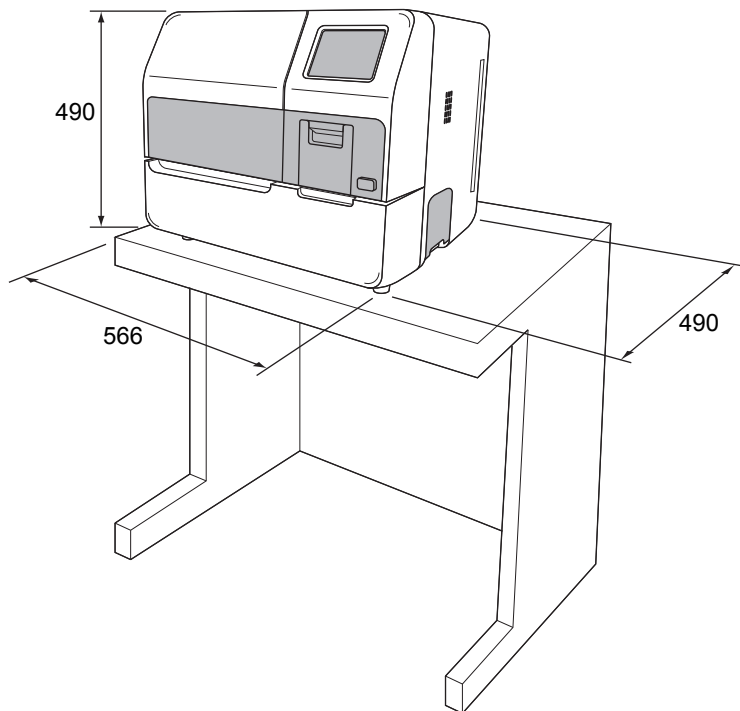
Installation Space

To ensure optional instrument performance properly, install it at an appropriate location.

- Select a place where the power supply is located close.
- Be sure to use the supplied bottles to collect rinse solution and waste.
- Keep a space for maintenance and service. Giving consideration to heat radiation by the instrument, provide at least 50 cm distance from the wall to sides, rear, and top panels.

The dimensions of the instrument are shown below. The power cord is 2.5 m long.

| | Width (mm) | Depth (mm) | Height (mm) | Weight (kg) |
|-----------|------------|------------|-------------|-------------|
| Main unit | 566 | 490 | 490 | Approx. 43 |



Caution!

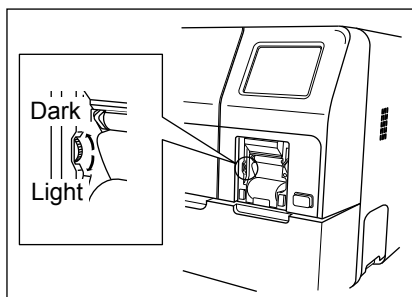
Be sure to place the rinse bottle and waste bottle on the base on which the instrument is set. Do not place them on the instrument. They may cause the instrument to break down or to fail to produce correct results.

Installation Environment

- Use the instrument at an ambient temperature of 15 - 35°C.
- Use it at a relative humidity range of 30 - 85%.
- When the ambient temperature and humidity are not appropriate, control by air conditioning.
- Avoid using the instrument in a place where the temperature can become extremely high or low.
- Avoid using the instrument in a place where it may be frozen.
- Avoid using the instrument where it can be exposed to direct sunlight.
- Select a well-ventilated place.
- Avoid using it at a place close to a transceiver, communication equipment, etc. which may emit high-frequency waves or interfere with radio waves.

4.3 Basic Instrument Settings

Contrast Adjustment for LCD Screen



Remove the printer cover, and adjust LCD screen contrast (shade) using the contrast adjust dial on the left side of the printer.

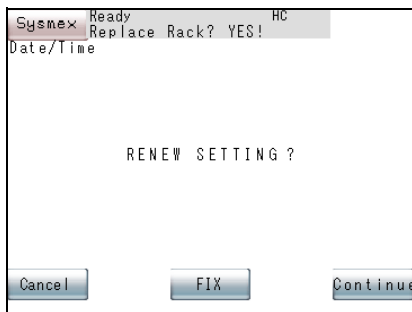
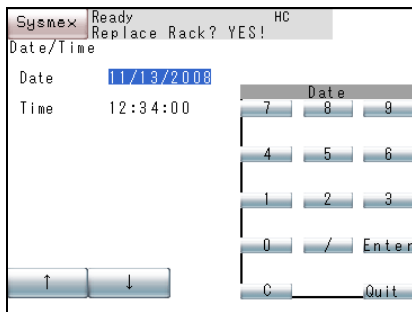
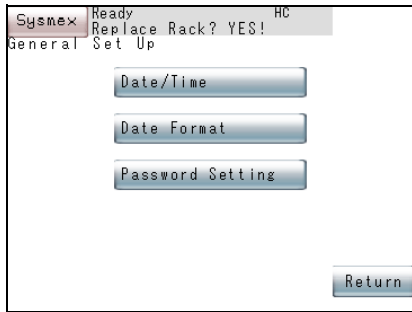
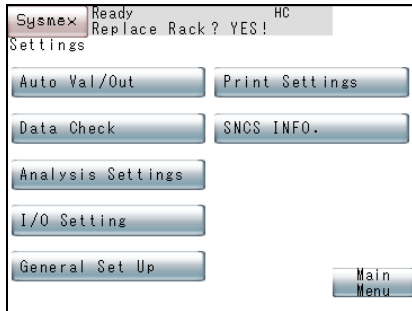
Turning up the dial makes the screen darker and turning down makes it lighter.

Setup of System (Date/Time)

Set date and time.

The instrument has a built-in clock, so there is no need to set the date and time every day. Should the power be turned off, the built-in clock is powered by an internal battery.

1. Press [**Special Menu**] key on the Main Menu screen.
The contents of the Main Menu will change over.
2. Press [**Settings**] key on the Main Menu screen.
The Setting Menu screen will appear.



3. Press **[General Set Up]** key on the Setting Menu screen.

The General Set Up Menu screen will appear.

4. Press **[Date/Time]** key on the General Set Up Menu screen.

The Date/Time Setting screen will display current date and time.

5. Using **[↑]** and **[↓]** keys, move the cursor to select Date or Time.

6. Using the numeric keys, set Date and Time, and press **[Enter]** key.

The parameter in the cursor position is set and the cursor will move to the next parameter.



Information

- When entry is made in the wrong format, the setting is not executed.
- If the number of day or month is a single digit, enter it with a 0 preceding it.
- Enter the time in a 24-hour clock system.

7. When setting is completed, press **[Quit]** key.

The Renew Confirmation screen will appear.

8. Press **[FIX]** key, **[Continue]** key, or **[Cancel]** key.

[FIX] key: Changes to the renewed setting and returns to the General Set Up Menu screen.

[Continue] key: Returns to the Date/Time Setting screen and allows continued operation.

[Cancel] key: Cancels the renewed setting and returns to the General Set Up Menu screen.

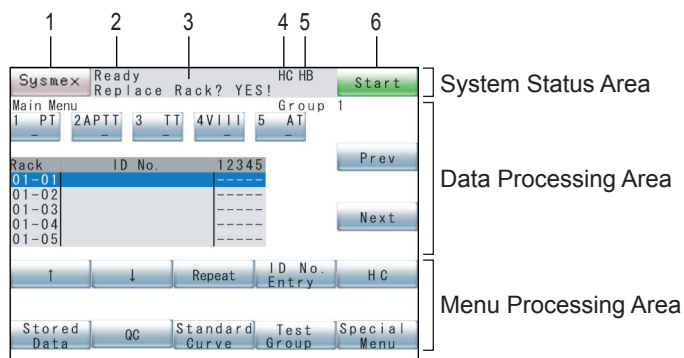
| | | |
|-----------|---|------------|
| 5. | Operation | 5-1 |
| 5.1 | Display Screens and Operation Keys | 5-1 |
| 5.2 | Menu Tree | 5-3 |
| 5.3 | Types of Alarm | 5-5 |
| 5.4 | Inspection before Turning ON the Power | 5-5 |
| 5.5 | Turn ON the Power | 5-7 |
| 5.6 | Prepare Reagents | 5-8 |
| 5.7 | Set Reaction Tubes | 5-14 |
| 5.8 | Confirm Standard Curve | 5-15 |
| 5.9 | Execute Quality Control | 5-16 |
| 5.10 | Prepare Samples | 5-16 |
| 5.11 | Set Sample Nos. | 5-20 |
| 5.12 | Manual Inquiry | 5-23 |
| 5.13 | Automatic Inquiry | 5-23 |
| 5.14 | Start Analysis | 5-25 |
| 5.15 | Automatic Sensitivity Adjustment of the Detector (for CA-660 only) | 5-28 |
| 5.16 | Catcher unit replacing message | 5-29 |
| 5.17 | Trash box monitoring | 5-29 |
| 5.18 | Mixing motor error check | 5-30 |
| 5.19 | Display Analysis Result | 5-31 |
| 5.20 | Interrupt Analysis | 5-32 |
| 5.21 | Add Samples | 5-33 |
| 5.22 | Analyze STAT Sample | 5-34 |
| 5.23 | Emergency Stop | 5-35 |
| 5.24 | Shutdown | 5-37 |



5. Operation

5.1 Display Screens and Operation Keys

The instrument displays all information including the instrument status, analysis results, etc. on the LCD screen. The LCD screen is divided into system status area, data processing area, and menu processing area. Press a key pad, and the function indicated on the key will work.



System Status Area

The System Status Area displays **[Sysmex]** key, error message, analysis status, and the status of externally connected instruments.

1. **[Sysmex]** key

Press this key to display Sysmex menu showing Error List, Temperature, and Paper Feed. When the instrument develops an error, causing the alarm to sound, **[ALARM RESET]** key appears. Press **[Error List]** key to display Error History. Press **[Temperature]** key to display temperatures of various units. Press **[P. FEED]** key to feed printer paper. For Sysmex Menu, refer to “12. Troubleshooting”.

2. Analysis Status

This indicates analysis status with the current instrument. “Ready”, “Analyzing”, “Waiting” will appear.

3. Rack Replacement

This indicates whether the sample rack can be replaced or not.

4. HC (Host Computer)

Indicates the connection status with the host computer.

HC (no background color): Host computer is set to be connected.

HC (green background): Communicating with the host computer.

HC (red background): An error occurred during the communication with the host computer.

5. HB (Hand-held Barcode Reader)

Indicates the connection status with hand-held barcode reader.

HB (no background color): Hand-held barcode reader is set to be connected.

HB (green background): Receiving data by hand-held barcode reader.

HB (red background): An error occurred during the communication with hand-held barcode reader.

6. [Start]/[INTERR] key

Press this key to start/stop the sample analysis.

For STAT sample analysis, [Start STAT] key appears.

Data Processing Area

The data processing area displays analysis progress status, work list, stored data list, reaction curve, quality control data, standard curve data, instrument setup status, etc.

When the power supply is turned on, the work list screen (Main Menu screen) appears.

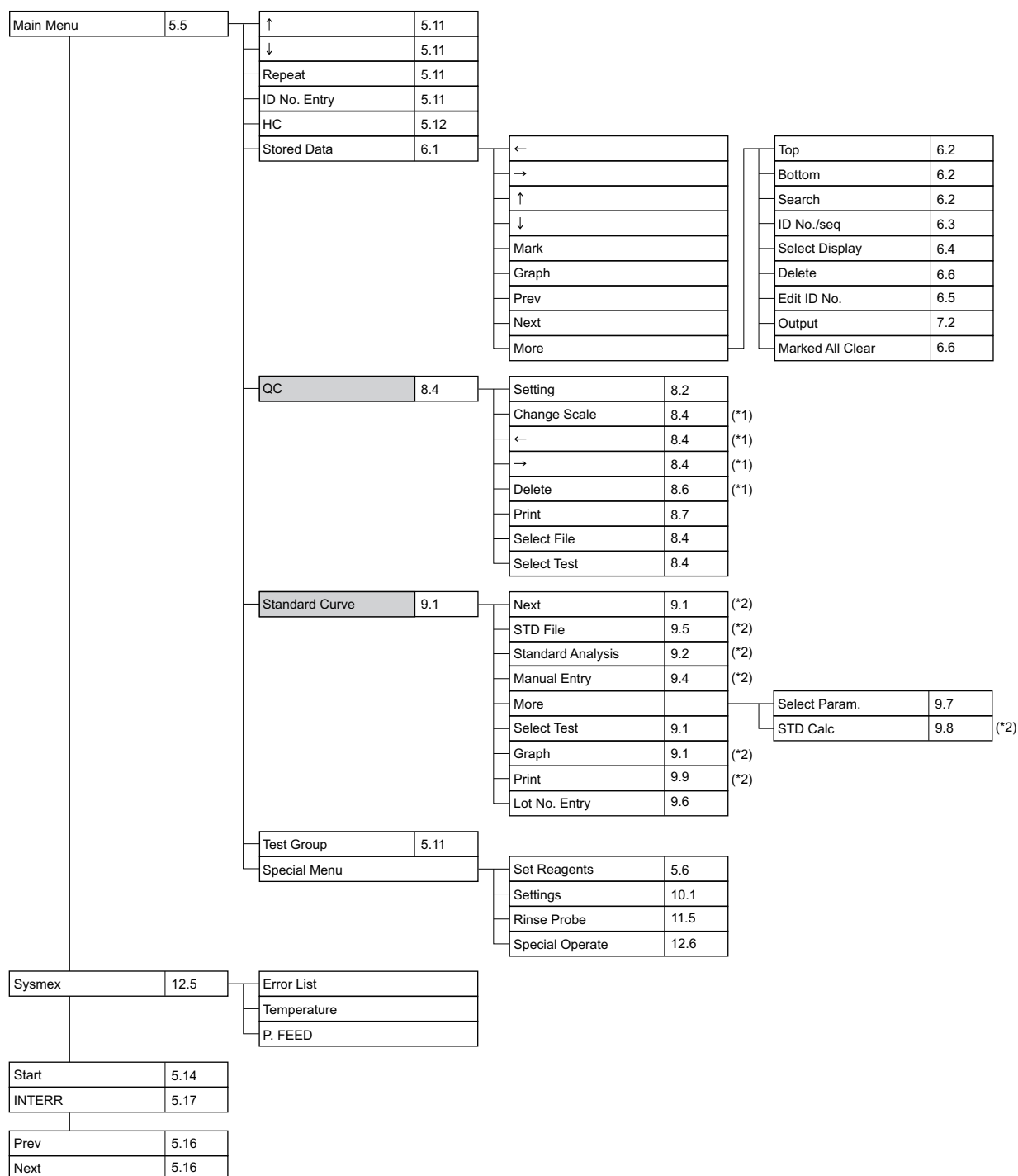
Menu Processing Area

The menu processing area always displays the menu for function selection.

In selecting a menu, touch a key that shows a menu you want to see.

After power supply turn-on, when system check is completed, the Main Menu appears. The Main Menu is the basic menu for selecting functions of this instrument.

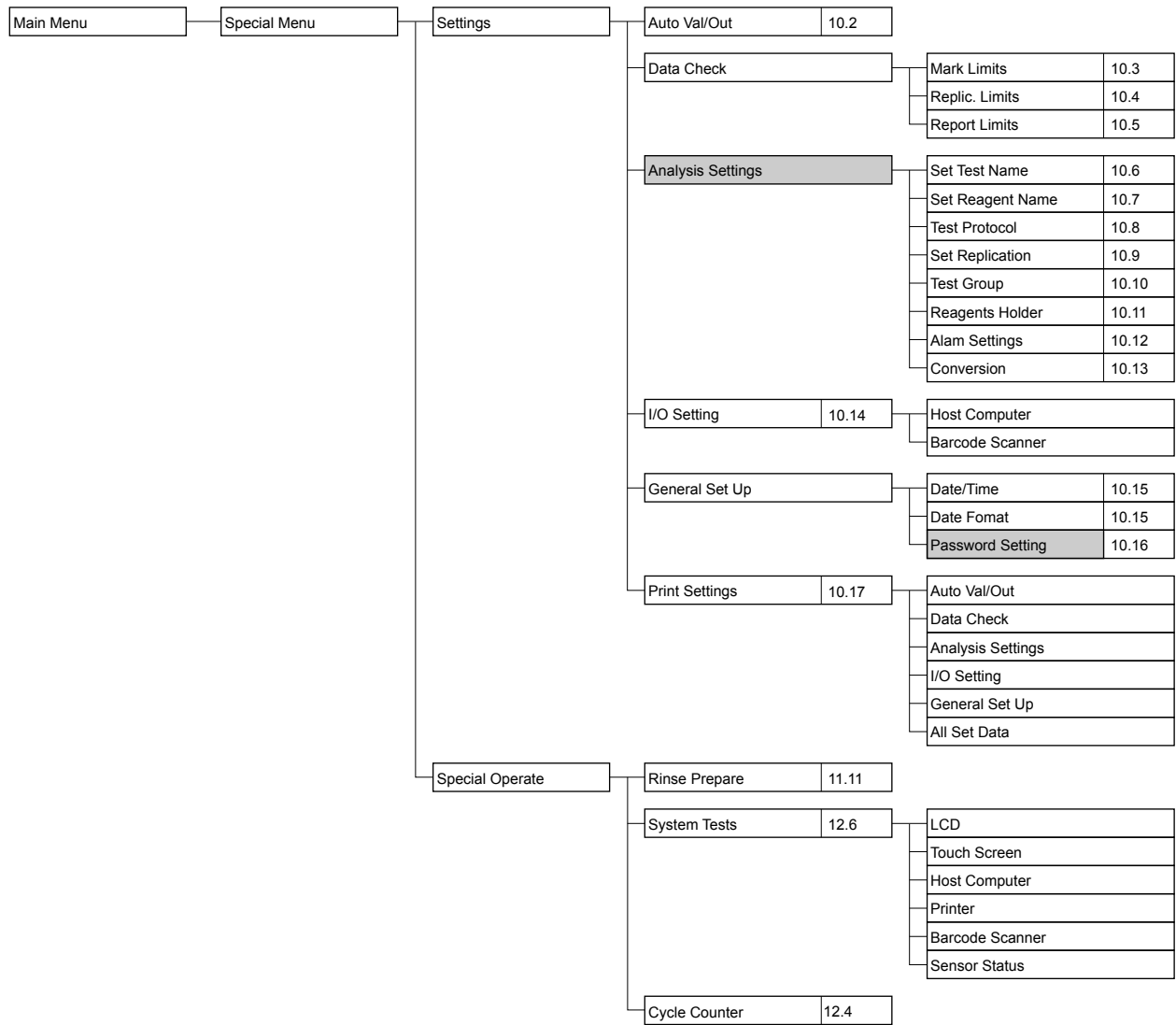
5.2 Menu Tree




■: If set, password has to be entered.

*1: This item is displayed only when QC data is stored.

*2: This item is displayed only when calculation parameter is set.



: If set, password has to be entered.

5.3 Types of Alarm

The instrument alarm emits 4 different sounds:

- Key entry sound (pip)
Sounds about 0.1 sec. when a touch panel key is pressed.
- Rack replacement sound (pip, pip, pip)
Sounds when sampling and dispensing of all set samples are completed and the system becomes ready to add orders or replace racks.
- Analysis completion sound (pip, pip, peep)
Sounds when analysis of all registered samples is completed.
- Instrument error sound (beep)
Sounds when some error has occurred in the instrument.
This sound continues until [ALARM RESET] key is pressed.
While the alarm is sounding, the [ALARM RESET] key is displayed in place of [Sysmex] key.
This sound is emitted also when the sample rack has been lifted after the system ran out of sample tubes or reagents or when they were being replenished.
This alarm sound stops when the [Conf.] key is pressed or when the sample rack is set correctly.

5.4 Inspection before Turning ON the Power

Inspect Rinse Bottle

When the rinse solution level is found low, replenish the rinse bottle with distilled water. As to the procedure for replenishing rinse solution, refer to “11.16 Replenish Rinse Solution”.



Caution!

When analysis is made with the rinse bottle lying flat, there is a possibility that correct analysis result may not be obtained. Make sure the rinse bottle is not lying flat.

Inspect Waste bottle

When waste liquid has collected in the waste bottle, discard the contents. Regarding how to dispose of waste liquid, refer to “11.4 Dispose of Waste”.



Information

When analysis is made with the waste bottle lying flat, waste may flow back into the vacuum pump, causing the pump to fail.
Make sure the waste bottle is not lying flat.

Check Power Cord

Check to see the power cord is securely plugged in the socket.

Check Connection Cord

When the instrument is connected with the host computer and hand-held barcode reader, check to see the connection cord is securely connected.

Check Trash Box

When used reaction tubes remain in the trash box, discard them.
As to discarding, refer to “11.3 Discard Used Reaction Tubes”.

Check Printer Paper

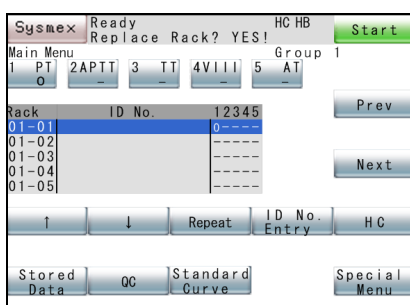
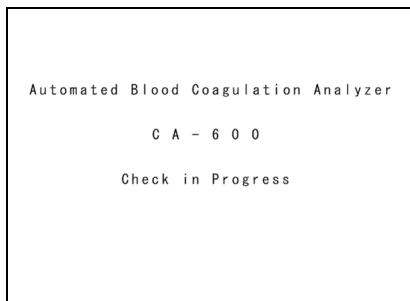
Check to see the Built-in Printer has enough paper to handle the number of samples expected that day.

Check Light Shield Cover

Open the cover and check to see there are no obstacles for analysis.

5.5 Turn ON the Power

Turn ON the Power



1. Turn on the power switch on the left side of the instrument.
The system automatically performs a roughly 10-second self check, and the Main Menu screen will appear.

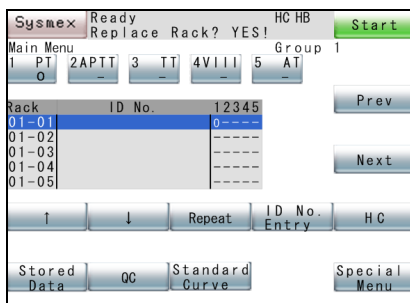
2. When the detector and cooler reach an analysis-permitting temperature, the Main Menu screen displays “Ready”.



Note

- The detector and cooler reach an analysis-permitting temperature in about 5 - 30 minutes after power turn-on.
- When the system is waiting for an analysis-permitting temperature, the message “Not Ready” is displayed and “Start” key is not displayed.

Confirm Automatic Output



If it is necessary to output to the built-in printer or host computer automatically, check the setting of Automatic Transfer/Printout. Refer to “10.2 Setup of Automatic Transfer/Printout”.



Note

[HC] key is displayed only when the system is set for manual inquiry to the host computer. For detail, refer to “5.12 Manual Inquiry”.

5.6 Prepare Reagents

Prepare Reagents

Prepare coagulation reagents needed for analysis, Owren's Veronal Buffer, and rinse solution. Refer to the package insert of each reagent for more information.

| Parameter | Reagent | Consumption per Test |
|-------------------------------------|---|----------------------|
| PT | PT Reagent | 100 µL |
| APTT | APTT Reagent | 50 µL |
| | Calcium Chloride Solution (0.025 mol/L) | 50 µL |
| Fbg | Thrombin Reagent | 50 µL |
| | Owren's Veronal Buffer | 90 µL |
| Fbg MFU | Multifibren® U | 100 µL |
| TT | Test Thrombin Reagent | 100 µL |
| TT TC | Thromboclotin | 100 µL |
| VII Factor Assay (Extrinsic) | PT Reagent | 100 µL |
| | Factor VII Deficient Plasma | 50 µL |
| | Owren's Veronal Buffer | 45 µL |
| VIII Factor Assay (Intrinsic) | APTT Reagent | 50 µL |
| | Calcium Chloride Solution (0.025 mol/L) | 50 µL |
| | Factor VIII Deficient Plasma | 50 µL |
| | Owren's Veronal Buffer | 45 µL |
| PCcl | Protein C Reagent | |
| | Protein C Deficient Plasma | 45 µL |
| | Activator | 50 µL |
| | Reagent APTT | 50 µL |
| | Calcium Chloride Solution (0.025 mol/L) | 50 µL |
| BXT | Batroxobin Reagent | 100 µL |
| LA1 | LA1 Screening Reagent | 100 µL |
| LA2 | LA2 Confirmation Reagent | 100 µL |
| AT3* | Berichrom® Antithrombin III (A) Assay | |
| | REAGENT THR | 125 µL |
| | SUBSTRATE | 33 µL |
| | Owren's Veronal Buffer | 83 µL |
| AT* | INNOVANCE® Antithrombin Assay | |
| | INNOVANCE® Antithrombin REAGENT | 80 µL |
| | INNOVANCE® Antithrombin SUBSTRATE | 80 µL |
| | INNOVANCE® Antithrombin BUFFER | 110 µL |

| Parameter | Reagent | Consumption per Test |
|------------------------|---|----------------------|
| BCPC* | Berichrom [®] Protein C | |
| | Protein C Activator | 125 µL |
| | Substrate Reagent | 30 µL |
| Hep* HepL* HepU* | Berichrom [®] Heparin | |
| | REAGENT AT | 20 µL |
| | REAGENT FX | 125 µL |
| | SUBSTRATE | 40 µL |
| DDPI* | D-Dimer PLUS Assay | |
| | D-Dimer PLUS ACTIVATOR | 25 µL |
| | D-Dimer PLUS REAGENT | 150 µL |
| DDi* | INNOVANCE [®] D-Dimer Assay | |
| | INNOVANCE [®] D-Dimer DILUENT | 12 µL |
| | INNOVANCE [®] D-Dimer SUPPLEMENT | 16 µL |
| | INNOVANCE [®] D-Dimer BUFFER | 80 µL |
| | INNOVANCE [®] D-Dimer REAGENT | 44 µL |
| vWF* | vWF Ag Assay | |
| | BUFFER | 60 µL |
| | REAGENT | 90 µL |
| | Owren's Veronal Buffer | 15 µL |
| WFa* | INNOVANCE [®] VWF Ac Assay | |
| | REAGENT I | 20 µL |
| | REAGENT II | 50 µL |
| | REAGENT III | 20 µL |
| | Owren's Veronal Buffer | 48 µL |

(*) CA-660 only

The amount of Distilled water per test includes the amount used in dilution for each analysis parameter.

When analyzing the parameters that require two reagents, a rinse operation is performed three times in total after dispensing samples and reagents.

Thus the amount used per test is approximately 30 mL. However, the number of rinse operations can be changed. (Refer to “10.8 Test Protocol”.)

CA CLEAN™ I is used after the reagent is dispensed. The amount used for one rinse is the amount of the reagent + 10 µL.



Caution!

- Prepare each reagent taking into consideration the analysis parameters and the number of the samples to be analyzed. Prepare extra volumes as shown below, in addition to the required volumes for analysis:
Each coagulation reagent: Approx. 0.6 mL
Distilled water: Approx. 500 mL
Owren's Veronal Buffer: Approx. 0.9 mL
CA CLEAN™ I: Approx. 0.9 mL
- The amount of reagent used in the initial operation (rinse operation) after analysis starts is as follows:
Distilled water: Approx. 40 mL
CA CLEAN™ I: Approx. 125 µL
Owren's Veronal Buffer: Approx. 200 µL (*)
(*)only when parameters are analyzed for the Chromogenic Method or Immunoassay Method.
- The amount of reagent used for probe rinsing is as follows.
Distilled water: Approx. 150 mL
CA CLEAN™ I: Approx. 125 µL
CA CLEAN™ II: Approx. 250 µL
- When the reagent lot changes and becomes different from the one used to create the standard curve, change the lot number of the reagent information and set the standard curve again.
When setting the standard curve, check the ISI value, normal value of PT and calibrator value of the calibrator, and change those values if necessary.

The amount of extra reagents required vary according to the container used.

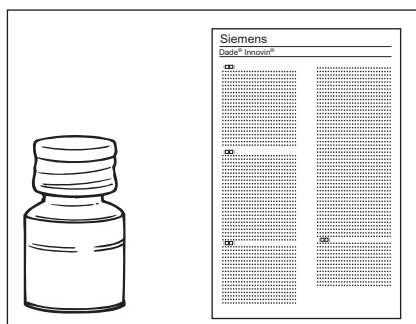
| | |
|---|----------------|
| Sample cup conical (4 mL): | Approx. 0.3 mL |
| Siemens 5 mL vial (GW5): | Approx. 0.8 mL |
| Push Vial PV-10 (22 mm OD × 40 mm high): | Approx. 0.9 mL |
| SLD Vial: | Approx. 0.4 mL |

There may be variation due to differences in fluid viscosity and slight vial to vial variation.



Caution!

- Prepare a sufficient volume of reagent which takes into consideration the minimum sample volume required. When the volume of the reagent is insufficient, sample may not be analyzed accurately.
- Use a Conical 4 mL sample cup (code No.424-1160-8). If a different sample cup is used, the reagent may not be aspirated correctly, which would influence the analysis results.



1. Prepare Reagents.

Prepare reagents as per the document supplied with each reagent.



Caution!

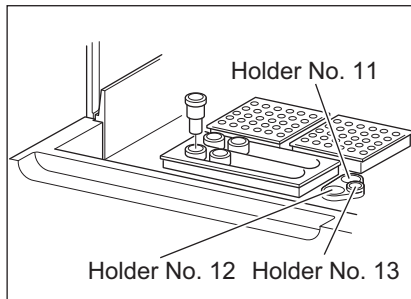
Strictly follow the instructions as given in the package insert supplied with each reagent. Otherwise, you will fail to obtain correct analysis result.

2. Check that the analysis status display is “Ready”, and open the light shield cover.



Warning!

Be sure to fully open the light shield cover and check that it will not fall down by its own weight.
If the light shield cover falls down, there is a risk of causing injury on the head.
Also, do not place any object on the instrument covers.



3. Set the reagents on the rack.

Reagent bottles (each measuring 22 mm OD and 40 mm height), or optional reagent holders and sample cups can be set in the reagent rack. (Refer to “10.19 Reagent Name/Holder List”.)



Caution!

- Always set the reagents at the specified positions to obtain correct results.
- Confirm that reagents contain no bubbles. Otherwise, correct analysis results cannot be obtained.
- Be sure to set CA CLEAN™ I in Holder No. 11 (inner right side: The position of label “I”).
- Be sure to set CA CLEAN™ II in Holder No. 13 (the position of label “II”).
- Be sure to set buffer in Holder No. 12 (the position of label “B”).

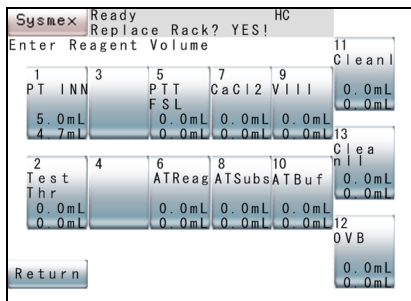
Register Reagent Volume

1. Press **[Special Menu]** key on the Main Menu screen.

The contents of the Main Menu will change over.

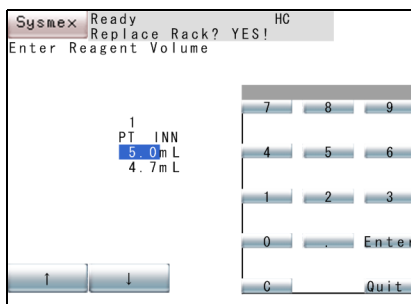
2. Press **[Set Reagents]** key in the Main Menu.

The Reagent Volume screen will display reagent level for each reagent holder.



3. Press the key of the reagent holder to be registered.

The Reagent Volume Entry Screen will display the numeric keys to enter reagent volume.



4. Enter the reagent volume set on the reagent holder and press **[ENTER]** key.

The value entered at the cursor position will be displayed. The second line will automatically display the available reagent volume to be used for the analyses.

By pressing [↑] and [↓] keys, movement can be effected to the preceding or following reagent holder No.



Note

- If the Reagent Volume Monitoring is set to “Valid”, each time the reagent is dispensed, the volume for the test will be subtracted from the entered value.
- Refer to “10.12 Setup of Reagent Volume Monitoring” for the setting procedures.
- Refer to “10.11 Reagent Holder” for confirmation of vial type.

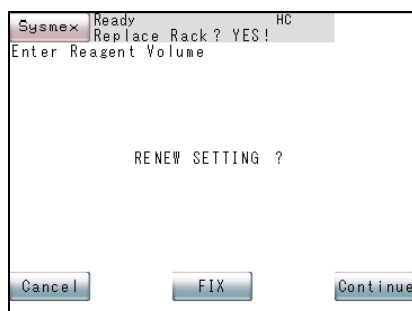
5. Press [**Quit**] key on the numeric keys.

The Reagent Volume Screen will reappear.

Confirm the entered value.

6. Press [**Main Menu**] key on the Reagent Volume screen.

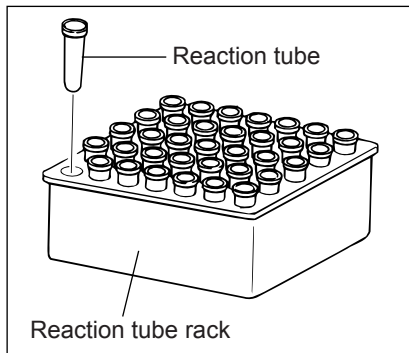
The Renew Check screen is displayed. Press [**Cancel**] key, [**FIX**] key, or [**Continue**] key to return to the Main Menu screen.



Information

The reagent amount which was input is erased when the power is turned OFF.

5.7 Set Reaction Tubes



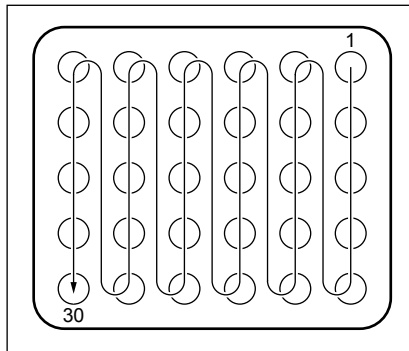
Set the reaction tubes for analysis on the reaction tube rack.

Set the reaction tube rack on the specified location on the analysis table.



Caution!

- When setting reaction tubes on the reaction tube rack, be careful not to drop sweat or the saliva into the reaction tube. This will alter the analysis result.
- Reaction tubes are intended for single use only. If used more than once, rewashed, or recycled, inaccurate measuring results may be obtained due to the effect of possible contamination. Inaccurate results could lead to inappropriate patient diagnosis or treatment.



Information

- Set the reaction tube rack securely to prevent the tubes from unseating and rising; otherwise, the probe might be damaged.
- The reaction tubes are set successively from the first position (top on extreme right-hand column). Therefore, make sure no position is left empty.
- Make ready some extra reaction tubes in addition to the quantity needed for analysis.
- Be sure to use the supplied reaction tubes (SU-40). Reaction tube (SUC-400A) for CS-2000*i* and other reaction tubes manufactured by other companies cannot be used.



Note

A maximum of 30 reaction tubes can be mounted on a reaction tube rack. Since two reaction tube racks can be used, the maximum number of reaction tubes that can be set is 60.

5.8 Confirm Standard Curve

Confirm before performing analysis that the standard curve is correctly set.



Caution!

- Unless the standard curve is properly set, percent activity, concentration, and other calculation parameters cannot be reported.
- If calculation parameters are changed after the plotting of a Standard Curve, data coordination will become impossible. When calculation parameters are changed, always perform standard curve analysis again.

1. Press [**Standard Curve**] key on the Main Menu screen.
The Standard Curve screen will be displayed.
2. Press [**Select Test**] key on the Standard Curve screen.
The Select Test screen will appear.

| Sysmex Ready HC | | Replace Rack? YES! | |
|-----------------|-------|--------------------|------------|
| Standard Curve | | PT | |
| PT% | sec | Cal Date | EXP. |
| 105.0 | 10.5 | PT INN | 12/20/2012 |
| 67.0 | 12.5 | | |
| 44.0 | 15.6 | | |
| 23.0 | 25.8 | 0VB | 12/20/2012 |
| 13.0 | 42.3 | Calibr. | 12/20/2012 |
| 10.0 | 49.6 | | |
| Normal | 0.0 | | |
| ISI | 0.00 | | |
| Next | | STD | Standard |
| | | File | Analysis |
| | | | Manual |
| | | | Entry |
| | | | More |
| Select | Graph | Print | Lot No. |
| Test | | | Entry |
| | | | Main |
| | | | Menu |

| Sysmex Ready HC | | Replace Rack? YES! | |
|-----------------|------|--------------------|--------|
| Standard Curve | | PT | |
| PT T | PT | FS | APTT |
| | | | Fbg |
| | | TT | VIII |
| | | | AT |
| AT3 | HepL | DDi | Cancel |

3. Press the analysis parameter key to be confirmed.
The standard curve data of the parameter selected will appear on the standard curve screen.

| Sysmex Ready HC | | Replace Rack? YES! | |
|-----------------|-------|--------------------|------------|
| Standard Curve | | VIII | |
| VIII% | sec | Cal Date | EXP. |
| 129.0 | 66.7 | VIII | 12/20/2012 |
| 86.0 | 72.1 | PT FSL | 12/20/2012 |
| 43.0 | 82.2 | CaCl2 | 12/20/2012 |
| 21.5 | 92.9 | 0VB | 12/20/2012 |
| 10.7 | 104.0 | Calibr. | 01/31/2013 |
| 0.0 | 0.0 | | |
| STD | | Standard | Manual |
| File | | Analysis | Entry |
| | | | More |
| Select | Graph | Print | Lot No. |
| Test | | | Entry |
| | | | Main |
| | | | Menu |

4. Press [**Graph**] key.
Check the standard curve.
5. Press [**Main Menu**] key.
The standard curve setting program is now completed.

Repeat the above Step-(2 - 3) to confirm the standard curve of each analysis parameter. For detail, refer to “9.2 Standard Curve Analysis”.

5.9 Execute Quality Control

To maintain the reliability of analyzed data, quality control has to be performed.

With the instrument, when QC File No. (QC01 - QC06) is registered for ID No., and QC sample (control plasma, pooled plasma, etc.) is analyzed, then analysis data is kept in the QC File. It is by processing this analysis data with the QC Program that instrument stability that varies from-time-to-time is monitored.

For detail of the QC Program, refer to “8. Quality Control”.

5.10 Prepare Samples

Set sample tubes or dispensed sample cups on the sampler rack.



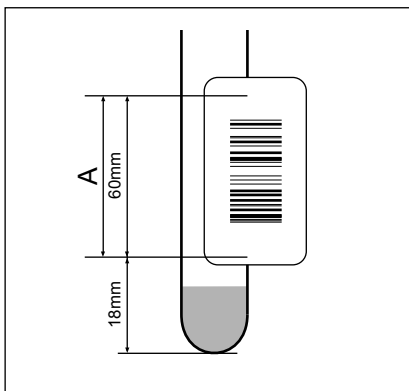
Caution!

If samples are left at room temperature for a long time, they may deteriorate. Set samples to the sampler just before analysis starts.

Also, if the sample volume is insufficient, use new sample tubes to collect blood again.

1. Prepare plasma.


- 1) Add 1 part of 3.8%, 3.2% or 3.13% sodium citrate solution as anticoagulant to 9 parts of venous blood, and mix the contents thoroughly.
- 2) Centrifuge the blood tube directly after blood collection for 15 minutes at 1500 x g to 2500 x g. Please refer to CLSI guideline H21-A5 for further details.
- 3) Affix Barcode Label (Option).
To ensure correct reading of a barcode, a barcode label has to be affixed at the proper position.
- 4) Set, in the supplied sample rack, the centrifuged blood tube itself or the plasma which has been removed and put into another test tube. Insert the test tube securely to the bottom of the rack.
When an optional sample barcode scanner is used, set barcode labels so as to face the scanner.



Warning!

Affix the barcode label so that the bars on the label would become horizontal when the rack is placed on the sampler. If the barcode label is affixed slanted, the potential of the incorrect reading of the barcode label will be increased.

| | |
|---------------|---|
| Anticoagulant | 3.8% sodium citrate solution 3.2% sodium citrate solution 3.13% sodium citrate solution |
| Useable | OD: 10 - 15 mm HT: 65 - 78 mm (Tubes less than 8 mm in ID cannot be used) |

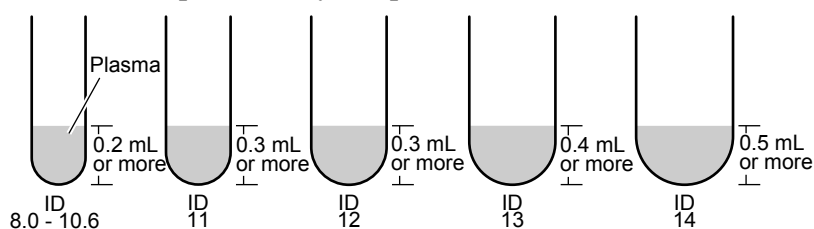


Caution!

Cautions about handling plasma:

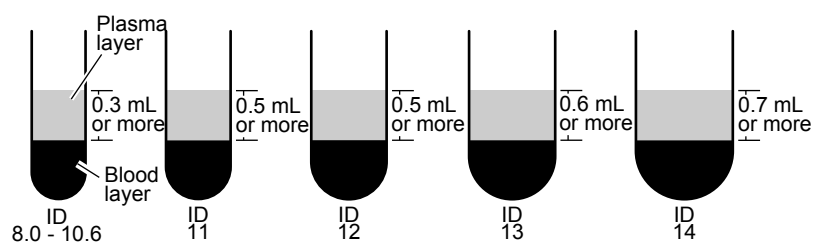
- As its container, use a plastic or silicone-coated glass tube.
- As anticoagulant, use 3.8%, 3.2% or 3.13% sodium citrate solution. When any other anticoagulant than this solution is used, it will cause a white precipitation and lead to incorrect analysis results.
- Mix blood and sodium citrate solution in an accurate ratio of 9 parts to 1 part, respectively. As the mixing ratio varies, coagulation time also varies, occasionally leading to incorrect analysis results.
- Samples must be analyzed within 4 hours of collecting if stored cool.
Those samples that had more than 4 hours pass after collecting and those kept in improper storage condition will not give correct analysis results.

Dead volume of plasma-only sample



Height between tube bottom and plasma surface: Approx. 7 mm

Dead volume of centrifuged sample



Height of plasma layer: Approx. 4.5 mm

| OD x Length | Blood Volume |
|-----------------|--|
| 13 mm x 75 mm | 1.8*, 2.4, 2.7**, 3.0**, 3.5**, 4.5 mL |
| 13.2 mm x 78 mm | 1.8, 2.7, 4.5 mL |
| 12.8 mm x 75 mm | 1.8, 2.7, 3.6 mL |
| 12.7 mm x 75 mm | 1.8, 2.7 mL |

* Does not include VACUTAINER Plus Plastic Citrate Tube 1.8 mL (Becton Dickinson).

** Except for the following tubes with a double wall structure any other tubes with a double wall structure are not applicable:

- VACUTAINER Plus Plastic Citrate Tube, 2.7 mL
- VACUETTE Sandwich Coagulation Tube, 3.0 mL/3.5 mL

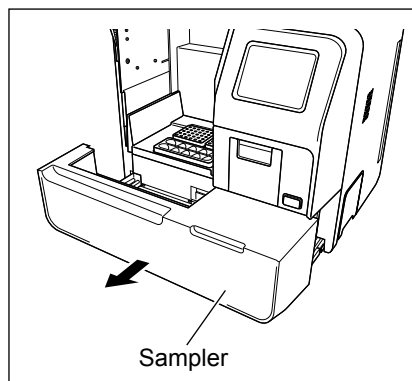


Caution!

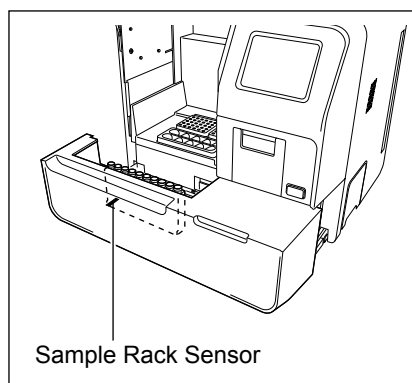
- The blood volumes shown above are the dead volumes. (Prepare an extra volume for the parameter to be analyzed.)
- If there is plasma only in the test tubes and the sample volume is lower than the dead volume, air may get aspirated and/or a “Probe Crash” or “Sampling Error” may occur, preventing correct analysis results from being obtained.
- If there is plasma only in the tubes, it is not recommended to use the following tubes with a double wall structure because their narrow inner diameters and higher bottom positions cause a higher possibility of a short sample error.
 - VACUTAINER Plus Plastic Citrate Tube, 13 mm x 75 mm, 2.7 mL
 - VACUETTE Sandwich Coagulation Tube, 13 mm x 75 mm, 3.0 mL/3.5 mL
- If the sample volume of centrifuged samples is lower than the dead volume, blood cells may get aspirated, preventing correct analysis results from being obtained.

**Caution!**

- When using test tubes with an outside diameter of 15 mm, remove the 13 mm tube adapters from the sample rack beforehand.
When using test tubes with an outside diameter of 10 mm, remove the adapters from the sample rack and mount the optional holder No. 113 (10 mm test tube adapter) beforehand.
- When using sample cups, set the optional holder No. 70 beforehand.
- When using sample cups, avoid setting samples which are low in plasma volume. Such samples will cause the error of "Probe Crash".
For samples, prepare the required volume plus 100 μ L.



2. Pull out the sampler.



3. Set the sample rack in the sampler.

Only one rack (10 samples) can be set.

**Information**

Unless the sample rack is correctly set, instrument failure will result.

Press in the sample rack sensor (lower left) so that the sample rack is level.

5.11 Set Sample Nos.

Set Sample Nos. and Analysis Parameters

With the instrument, all samples are analyzed according to the analysis order.

Analysis information for 10 samples (1 rack filled) can be set at a time.

There are four procedures for setting sample ID Nos. and analysis parameters:

- Manual setting with the numeric keys and analysis parameter keys.
- Receiving sample ID Nos. and analysis parameters collectively from the host computer (Refer to “5.12 Manual Inquiry”).)
- Manually entering sample ID Nos. so that analysis orders will be automatically received from the host computer (Refer to “5.13 Automatic Inquiry”).)
- Using sample ID Nos. that have been read with the optional barcode scanner so that analysis information will be automatically received from the host computer. (Refer to “5.13 Automatic Inquiry”).)



Information

The instrument does not store analysis information. The information is erased when power is turned off.

Setting of Sample ID Nos.

1. Specify the rack to be set on the Main Menu screen.
Press [↑] and [↓] keys to move the cursor to the desired rack position.

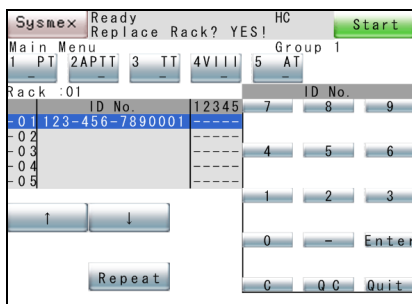
2. Press [ID No. Entry] key.

The numeric keys screen will be displayed.

3. Enter sample ID No. and press [Enter] key.

By pressing [C] key, you can erase one letter entered (back space function).

When entering a sample ID No. for QC, press [QC] key following a numeral between 01 - 06.



**Information**

- When an ID No. is not registered, this instrument automatically assigns it. After power turn-on, it begins with 000000000000001 (15 digits), which is incremented by 1 at a time.
- Analysis results will not be stored in a QC File if a Standard Curve is not set and QC parameters are set as calculation parameters.
- If sample ID is "0", automatic output to the host computer and printout cannot be performed. However, manual output to the host computer and printout can be performed. If the power is turned off, analysis results of sample ID "0" will be deleted from the memory.

**Note**

To completely erase a registered sample ID No., position the cursor over the number and press first **[C]** key then **[Enter]** key.

4. Press **[Quit]** key on the numeric keys.
The screen returns to the Main Menu.

Group Selection

A combination of analysis parameters, selected from three menus, can be set. The analysis parameters that can be set are limited to those in the selected group.

1. Press **[Test Group]** key on the Main Menu.
The Group Setting screen will be displayed.

**Note**

When the cursor is on a rack which has been or is being analyzed, **[Test Group]** key is not displayed if an analysis parameter is already set.

2. Press **[Group]** key.
Select a group from among three groups (**[Group 1]** - **[Group 3]**) by using **[↑]** key, or **[↓]** key. For the group setting program, refer to "10.10 Setup of Test Group".

3. Press **[Return]** key.

The Main Menu will return and the analysis parameter will change to the parameter selected with the group setting program.



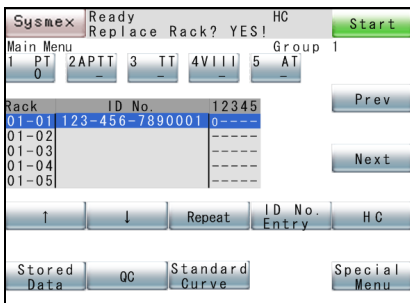
Note

When this **[Test Group]** function is used, the analysis at various dilution ratios can be performed.

Example:

- + Fbg is a parameter that is analyzed with Fbg diluted to 1:20 (a half of the usual concentration).
- - Fbg is a parameter that is analyzed with Fbg diluted to 1:5 (2 times of the usual concentration).

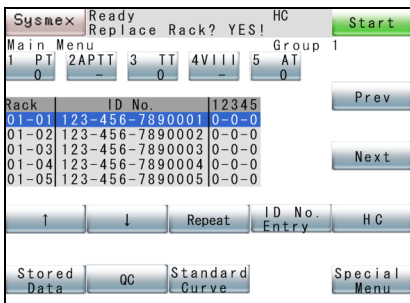
Setting of Analysis Parameters



1. Specify the samples to be set on the Main Menu screen
Press **[↑]** and **[↓]** keys to move the cursor to a sample to be set.
2. Set an analysis parameter by pressing analysis parameter keys.
Each time an analysis parameter key (**[PT]**, **[APTT]**, **[Fbg]**, **[TT]**, **[AT3]**) is pressed, signs “- (Not analyze)” and “O (Analyze)” change alternately.

Repeat

Assigns consecutive sample ID Nos. for one rack (10 samples), with the cursor positioned at the top, and copies analysis parameter setting for all subsequent samples.



1. Using **[↑]** and **[↓]** keys, specify a sample you want to repeat.
2. In the Main Menu screen or ID No. Entry screen, press **[Repeat]** key.



Information

When sample ID No. is “0” or it is for QC or Standard Curve, **[Repeat]** cannot be executed.



Note

Sample ID No. cannot be carried beyond “-”.
For example, the number following 1-99 will be 1-00.

5.12 Manual Inquiry

When the instrument is bidirectionally connected with the host computer, analysis information for one rack (10 samples), based on rack Nos., can be received prior to analysis. For this purpose, the host computer needs to be set in the conditions shown below. For detail, refer to “10.14 Devices to be connected”.

Connection: Connected
 Class: Class B
 Inquiry: Manual

1. Press [HC] key on the Main Menu.

The instrument makes inquiries to the host computer for a specified rack No. and receives analysis information. Each time analysis information is received for one sample, it is displayed on the screen.

2. Analysis information received is confirmed on the screen.

5.13 Automatic Inquiry

The following automatic inquiry process is performed depending on barcode scanner connection status and order entry status.

| Sample ID No. | | With manually entered order | Without manually entered order |
|-------------------------|----------------|---|--|
| Without barcode scanner | | <ul style="list-style-type: none"> • No inquiry to host computer • Analysis with automatically-assigned sample ID No. and manually entered order | <ul style="list-style-type: none"> • No inquiry to host computer • No analysis |
| With barcode scanner | Reading normal | <ul style="list-style-type: none"> • No inquiry to host computer • Analysis with sample ID No. from barcode and manually entered order of barcode | <ul style="list-style-type: none"> • Inquiry made to host computer using sample ID No. from barcode • Analysis with sample ID No. and order from host computer |
| | Reading error | <ul style="list-style-type: none"> • No inquiry to host computer • Analysis with error No. and manually entered order | <ul style="list-style-type: none"> • No inquiry to host computer • No analysis |

Automatic Inquiry (without barcode scanner)

When the instrument is bidirectionally connected with the host computer, the instrument can receive, in advance, analysis information for one rack (10 samples) based on manually entered sample ID Nos.

The host computer must be set in the conditions given below. For detail, refer to “10.14 Devices to be connected”.

Host Computer Status: Connected
 Class: Class B
 Inquiry: Auto

Barcode scanner: Not connected

1. Manually set sample ID Nos.

Refer to “5.11 Set Sample Nos.”.

**Note**

- Should any error occur in reading barcode labels, the sample ID Nos. become “ERR000000001” and increase in sequence. Inquiry is not performed.
- Regarding the rack positions for those ID Nos. that have been manually set, you can make inquiries to the host computer using the manually set ID Nos, without reading barcodes.
- Inquiries are not made for samples with registered analysis parameters.

5.14 Start Analysis

With completion of analysis preparation and registration of analysis information, the instrument is now ready to start analysis.

1. Check the system status display of the instrument.

Make sure that the Main Menu screen displays “Ready”.

**Information**

- Before analysis, confirm that there is sufficient amount of rinse solution in the rinse bottle, the waste bottle will not be filled up during analysis, and the trash box is not filled up with reaction tubes.
- Approx. 125 μ L of CA CLEAN™ I is used for initial cleaning. Before analysis, confirm the remaining amount of CA CLEAN™ I is sufficient.

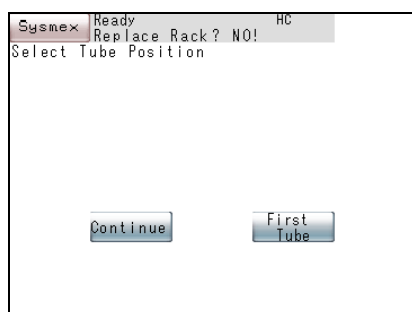
2. Press [**Start**] key.

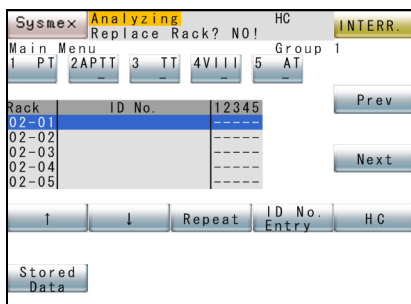
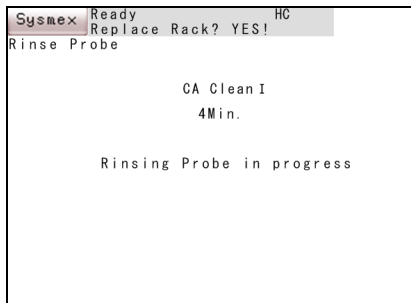
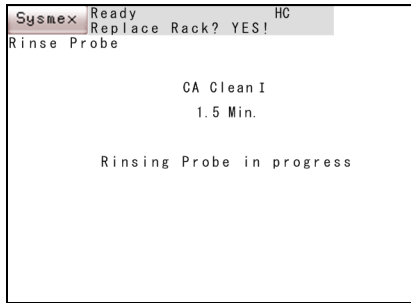
The screen confirming the first tube's initial position will appear.

3. Press [**Continue**] key or [**First Tube**] key.

[Continue] key: Starts with the reaction tube that follows the last used tube in the previous analysis.

[First Tube] key: Starts with the upper extreme-right tube in the right-hand reaction tube rack.





When the analysis is started, the initial rinse probe is started (approx 1.5 minutes) and “Analyzing” is displayed on the screen.

The initial rinse time is approx 4 minutes when the first analysis starts after power-ON or, when analysis starts after each interval of 24 hours.

When the rinse probe is finished, the workload list is displayed and the sample dispensing is started. The cursor position of the workload list moves to the next compartment of the rack.



Information

When you have pressed **[First Tube]** key inadvertently, causing the instrument to stop by error, then Continue information for the reaction tubes is lost. In this case, set the reaction tubes again from the first position, and press **[Start]** key.



Note

- The first time the analysis is started after power switch on, **[Continue]** key is not displayed.
- Automatic sensitivity adjustment of the detector is performed when the first analysis starts after power-ON, or when analysis starts after each interval of 24 hours. (Refer to “5.15 Automatic Sensitivity Adjustment of the Detector (for CA-660 only)”.)

4. When all analyses are over, the alarm sounds “pip, pip, peep”.

If you want to continue analysis, when the message “Replace Rack? No!” changes to “Replace Rack? YES!”, then samples can be set to the next sample rack or the same sample rack. (Refer to “5.21 Add Samples” for sample addition.)

Even during analysis, when the **[INTERR]** key changes to the **[Start]** key, it will be possible to analyze samples in the next rack.



Warning!

During analysis, do not insert hands or fingers, either through the gap in the light shield cover or by opening the cover. This is to avoid the risk of injury. If you open the light shield cover during operation, the alarm will beep and the instrument will stop.

**Caution!**

When the power switch is turned off during operation, the instrument will fail. Make sure the analysis has been completed and the instrument status display is "Ready" before turning off the power switch.

**Information**

During operation, the sampler cannot be pulled out as the lock mechanism is activated to prevent injury and damage to the instrument.

**Note****RESTRICTIONS DURING OPERATION**

- Only **[Stored Data]**, **[↑]**, **[↓]**, **[Repeat]**, **[ID No. Entry]**, **[HC]**, **[Prev]**, **[Next]** in the Main Menu can be used during operation.
- Once registered, analysis information cannot be changed.

5.15 Automatic Sensitivity Adjustment of the Detector (for CA-660 only)

At the start of analysis at either of the times below, sensitivity adjustment of the detector is performed automatically.

- Start of first analysis after power-ON
- Start of analysis after each interval of 24 hours



Note

When Chromogenic Method parameters are included in the parameters selected for group settings, adjustment is performed for the Chromogenic Method detectors. When Immunoassay Method parameters are included, adjustment is performed for the Immunoassay Method detectors.

First, 200 μ L Owen's Veronal Buffer is aspirated and dispensed in the reaction tube. Then, using the buffer, automatic sensitivity adjustment is performed in the detectors for the Chromogenic Method and Immunoassay Method (for CA-660 only) respectively.

If the results of sensitivity adjustment indicate that the detector (LED) must be replaced, then a message will appear prompting the operator to replace the detector. Contact your local service representative.

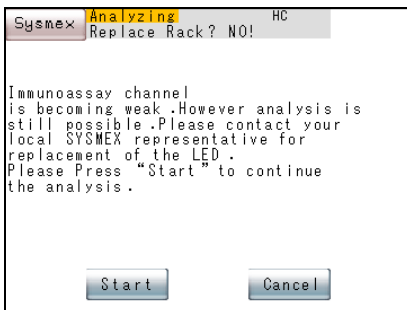
The message varies as shown below according to the detector.

- For the Chromogenic Method detector:
"Chromogenic channel is becoming weak."
- For the Immunoassay Method detector :
"Immunoassay assay channel is becoming weak."
- For both the Immunoassay Method detector and the Chromogenic Method detector:
"Chromogenic and Immunoassay assay channels are becoming weak."



Note

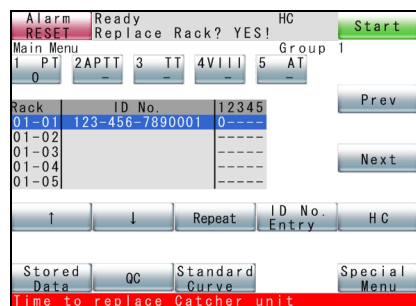
Analysis can still be performed after the replace-detector message has appeared.



Press **[Start]** key to continue with analysis.

To cancel analysis, press **[Cancel]** key.

5.16 Catcher unit replacing message



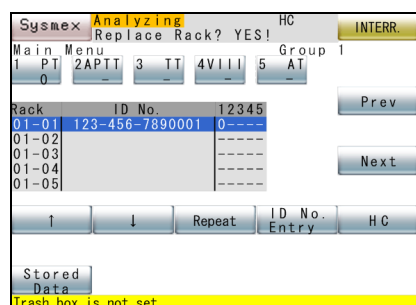
At the start of analysis, if the number of times of analyses reaches 25000, a message prompting to replace the catcher unit appears.



Note

Analysis start process continues even if the message for replacement is displayed.

5.17 Trash box monitoring



At the start of analysis, the trash box is checked. If the trash box is not installed, an error message appears and an alarm sounds. If the trash box is removed during analysis, the same error will occur.



Note

Analysis continues even if such an error occurs.

If such an error occurs, press the **[ALARM RESET]** key. Install the trash box to recover from the error.

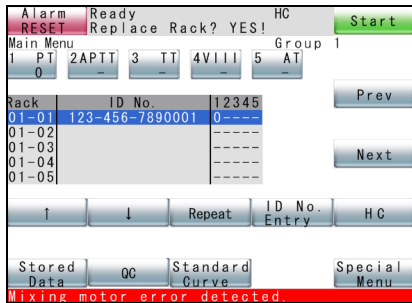


Note

If the trash box is installed, the error message will disappear. The alarm, however, continues sounding until the **[ALARM RESET]** key is pressed.

5.18 Mixing motor error check

At the start of analysis



When the reaction tube is caught, the mixing motor is driven for 0.5 second to check the mixing motor error.

If an error is detected, an error message appears and an alarm sounds. The screen returns to “Ready” without performing the analysis.

Press the **[ALARM RESET]** key to stop the alarm and clear the error message.

During analysis

When an error is detected, analysis is paused and the following processes are performed.

- For samples under analysis, the analysis continues. The analysis results for other samples will be masked as errors.
- New sample dispensing, sample aspiration, reagent aspiration and mixing will not be performed.
- Analysis results of the samples which cannot be mixed are masked as errors.

Press the **[Conf.]** key to stop the alarm, clear the error message, and return to the analyzing screen.

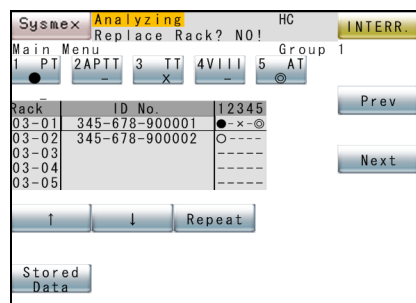
When all the processes during the pause of analysis are finished, the screen to confirm whether or not to continue the unfinished analysis appears.

Press **[Start]** key to continue with analysis.

To cancel analysis, press **[Cancel]** key.

5.19 Display Analysis Result

Analysis Status Display (Main Menu screen)



Analysis status of each sample is displayed on the Main Menu screen.

A sample is distinguishable by ID No. and rack position.

1. Press **[Prev]** key, **[Next]** key, **[↑]** key, or **[↓]** key to search for samples whose analysis status you want to check.
2. Current analysis status of each of the applicable samples is displayed as follows:

Meanings of the analysis status symbols:

- : Analysis is not ordered for the parameter.
- : Analysis is requested.
- ⊙ : Analysis is in progress.
- : Analysis is completed.
- × : Analysis is not completed due to interruption or error.

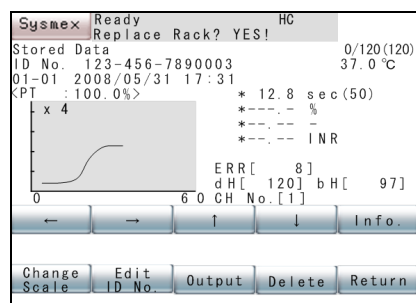
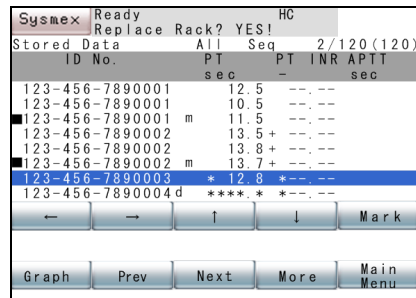
Display and Printout of Sample Data

1. Press **[Stored Data]** key on the Main Menu screen.

Analysis data will be displayed in the list format.

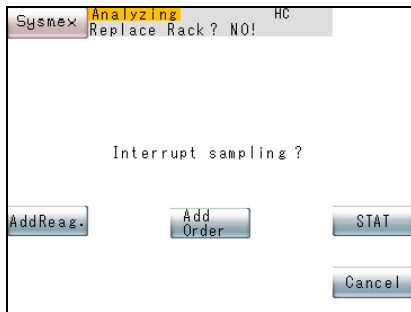
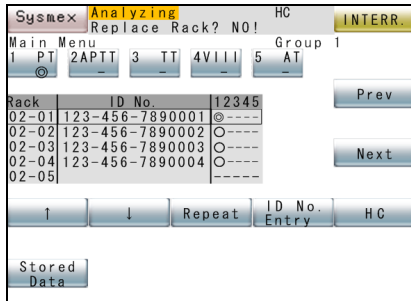
2. To display coagulation curves, press **[Graph]** key.

Move the cursor to the sample whose coagulation curve you wish to display, and press **[Graph]** key.



For detail, refer to “6. Display and Processing of Analysis Results”.

5.20 Interrupt Analysis



The analysis process can be interrupted at any time.

1. Press **[INTERR.]** key.

While analysis is being performed, **[Start]** key at the upper right corner of the screen is replaced by **[INTERR.]** key.

The Interruption Confirmation screen will be displayed.

2. Press **[AddReag.]** key, **[AddOrder]** key, **[STAT]** key, or **[Cancel]** key.

[AddReag.] key: The interruption process starts and no new analysis is performed.

[AddOrder] key: The order addition process starts.

[STAT] key: The process moves to the STAT sample processing. Refer to “5.22 Analyze STAT Sample”.

[Cancel] key: The screen returns to the original one.



Note

While the Interruption Confirmation screen is on, the instrument is performing analysis.

When all analyses are completed with this screen on, the Main Menu screen returns and “Ready” is displayed.

3. During the analysis interruption process, **[Resume]** key is displayed at the upper right corner of the screen.

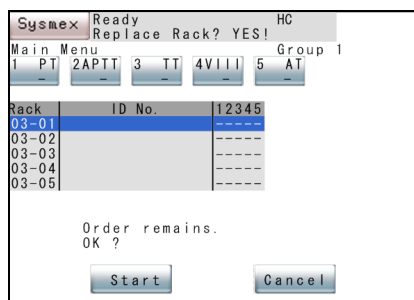
When you want to interrupt analysis, do not press **[Resume]** key.

When **[Resume]** key is pressed:

Analysis restarts.

When **[Resume]** key is not pressed:

When analysis for dispensed samples is completed, and there are still parameters remaining to be analyzed, a screen is displayed to confirm analysis continuation. If reagent is to be added, add it at this time.



4. When you want to interrupt analysis, press **[Cancel]** key.

[Start] key: Analysis restarts.

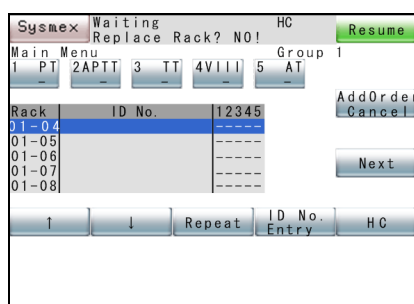
[Cancel] key: Analysis is canceled and the screen returns to the Main Menu.



Note

The samples whose analysis has been canceled have “X” displayed in the Work List.

5.21 Add Samples



1. Press **[INTERR]** key.

The Interruption Confirmation screen will be displayed.

2. Press **[AddOrder]** key on the Interruption Confirmation screen.

Analysis of the new sample will be interrupted, and the Sample Addition screen will be displayed.

3. When the analysis interruption process is completed, “Replace Rack? YES!” is displayed.

Then the sampler can be pulled out.

4. Pull out the sample rack only, without opening the light shield cover, and register the parameters to be added.



Information

- Registered sample ID Nos. and orders cannot be modified.
- Additional orders can only be registered to a position after the final rack position of the registered orders.

5. Register sample ID Nos. and analysis parameters for additional orders.

- When entering sample ID Nos. manually, press **[ID No. Entry]** key, and input sample ID Nos.

Refer to “5.11 Set Sample Nos.”, or “Automatic Inquiry (without barcode scanner)” of “5.13 Automatic Inquiry”.

- Press **[HC]** key to receive sample ID Nos. and analysis parameters from the host computer.

Refer to “5.12 Manual Inquiry”.

This registration process is not required when sample ID Nos. are read using an optional barcode scanner, and analysis parameters are sent automatically from the host computer.

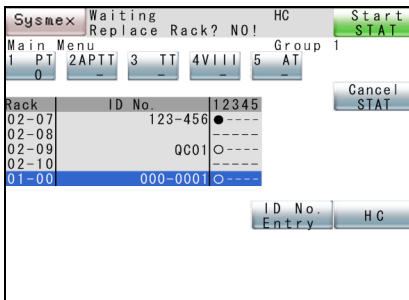
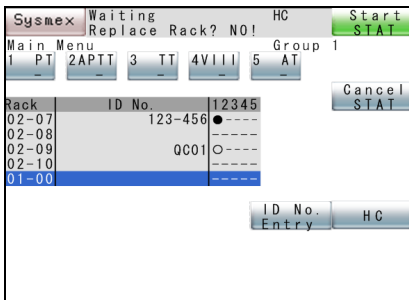


Note

To cancel addition of orders, press [**AddOrderCancel**] key.

6. Press [**Resume**] key.
Analysis restarts.

5.22 Analyze STAT Sample

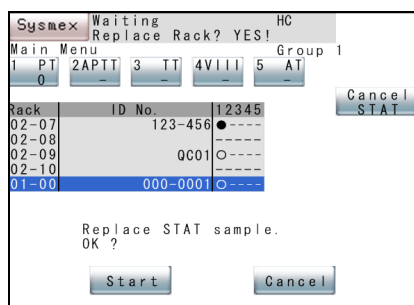


1. Press [**INTERR.**] key.
The Interruption Confirmation screen will come on.
2. Press [**STAT**] key.
Analysis of the new sample will be interrupted.
3. When the analysis interruption process is over, “Replace Rack? YES!” is displayed, and the sampler can now be pulled out.
4. Set a STAT sample in a STAT sample rack.
5. Register ID Nos. and analysis parameters for STAT samples.
When entering sample ID Nos. manually, press [**ID No. Entry**] key, and input sample ID No.
Refer to “5.11 Set Sample Nos.”.
Press [**HC**] key to receive sample ID Nos. and analysis parameters from the host computer.
Refer to “5.12 Manual Inquiry”.




Note


To cancel registration of STAT samples, press [**Cancel STAT**] key.



- Press **[Start STAT]** key.
Analysis of a STAT sample starts.

 **Note**
When **[Start STAT]** key is pressed without pulling out the sampler, the message “Replace STAT Sample. OK?” will appear. Press **[Cancel]** key, and STAT Sample Order Setting screen returns without starting STAT analysis.


- When STAT analysis is completed, analysis of the original rack continues.

 **Note**

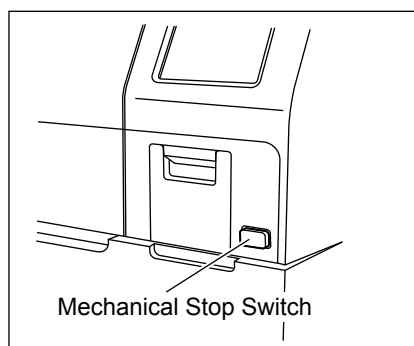
- Rack Nos. 01-00, 02-00, 03-00, and 99-00 of STAT samples are displayed and 99-00 is followed by 01-00.
- While STAT sample is being dispensed, **[INTERR.]** key is not displayed.

5.23 Emergency Stop

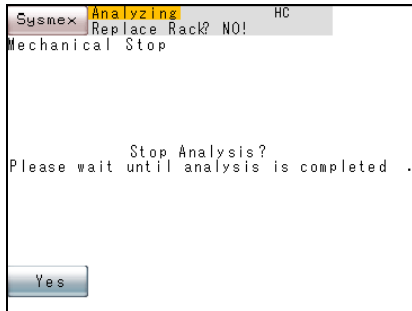
By pressing the Mechanical Stop switch, analysis operation can be stopped immediately.

 **Information**

- Should the instrument need to be shut down in an emergency, such as an unexpected outage of power to the laboratory, immediately turn off the power switch to the instrument.
- Note that the above-mentioned switch differs from the emergency mechanical stop switch on the front of the instrument. When the mechanical stop switch is pressed, the mechanical system comes to a stop but the power supply is not turned off.




- Press the Mechanical Stop switch.
Analysis operation will stop immediately.
- When the Mechanical Stop switch is pressed during photo detection, the screen for confirming whether to stop photo detection comes on.



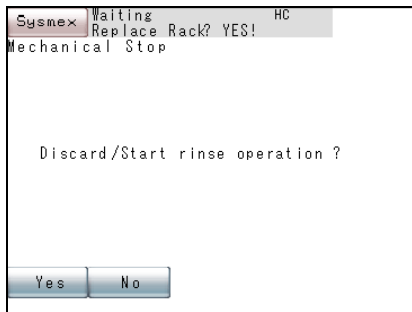
- To stop analysis, press **[Yes]** key.

When the sample tube is not in place at the detector, the following screen comes on:



Caution!

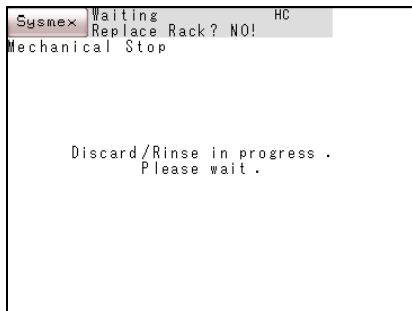
- When photo detection is stopped and discard/rinse operation starts, the sample data being analyzed is discarded. Reanalyze sample data marked with “x” in the Work List.
- If the sampler table is pulled out when the sample probe is lowered in the tube, the sample probe will be permanently damaged.




- To start discard/rinse operation, press **[Yes]** key.

The screen will display the message “Discard/Rinse in progress. Please wait.”.

The discard/rinse operation will be executed.

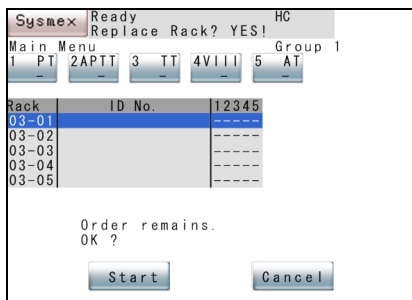


- When rinse operation cannot be performed, press **[No]** key.
- When an unanalyzed order remains, the screen for choosing whether to continue analysis comes on.



Note

Discard/rinse operation cannot be executed when, for example, the sample probe could be damaged by doing so.



- Press **[Start]** key or **[Cancel]** key.

[Start] key: Starts analysis.

[Cancel] key: Interrupts analysis and returns the screen to Main Menu.

5.24 Shutdown

Turn OFF the Power

Confirm that the instrument status is “Ready” before turning off the power switch.

Operation after Analysis Completion

At the conclusion of the day's analyses or after the instrument has been run for at least 24 hours, perform the following daily maintenance:

- 1) Discard the used reaction tubes.
- 2) Dispose of waste fluids.
- 3) Remove dew from the reagent holders.
- 4) Clean the sample probe.

For detail, refer to “11. Maintenance and Supplies Replacement”.



Caution!

If the power is turned off when the rinse bottle or waste bottle are lying flat, the solution may flow back into the instrument.

Before turning off the power switch, confirm that the bottles are not lying flat.

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| | | |
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6. Display and Processing of Analysis Results

The instrument displays analysis results and information that helps interpret analysis results, and outputs them to external devices. This chapter describes the processing of analysis results, including display of stored data and output to external devices.

6.1 List Display/Graphic Display

The instrument can store analysis results of up to 600 samples (3000 tests) and reaction curves. The stored data is kept even when the power switch is turned off and will be displayed unless erased.

1. Press **[Stored Data]** key on the Main Menu screen.

The analysis result will appear in List Display together with Local Menu of Stored Data.

By pressing **[More]** key, Local Menu can be changed-over. When a desired Local Menu is not displayed, press **[More]** key.

| Sysmex | | Ready | HC |
|-------------------|---------|--------------------|------------|
| Stored Data | | Replace Rack? YES! | 2/120(120) |
| ID No. | PT | PT | INR APIT |
| | seg | seg | sec |
| QC01 | 10.6 | --- | --- |
| QC02 | 10.8 | --- | --- |
| 123-456-7890001 | 10.6 | --- | --- |
| 123-456-7890002 | 13.5+ | --- | --- |
| 123-456-7890002 | 13.8+ | --- | --- |
| 123-456-7890002 m | 13.7+ | --- | --- |
| 123-456-7890003 | * 12.8 | *-- | -- |
| 123-456-7890004 d | ****. * | *-- | -- |

← → ↑ ↓ Mark

Graph Prev Next More Main Menu

List Display

When **[Stored Data]** key on the Main Menu is pressed, the Analysis Result screen appears. While the Graphic Display screen is on, press **[Return]** key on Local Menu to view the analysis results.



Note

Using **[Select Display]** and **[ID No./Seq]** keys, you can change a stored data to be displayed and its chronological sequential arrangement. When the power switch is turned off or the display is returned to the Main Menu, however, all stored data return to the previous list in chronological analysis sequence.

The Stored Data List Display screen can display up to 8 samples per screen. When the first List Display screen appears after the power switch is turned on, data of the last 8 samples is displayed. When latest analyses are completed, those sample data are automatically added to the last of the List. The List Display screen is composed of the analysis results, showing 3 data parameters at a time, and the sample information. Use **[←]** and **[→]** keys to switch between pages.

| Sysmex | | Ready | Replace | Rack? | YES! | HC |
|---------------------|------|-------|---------|-------------|------|-----|
| Stored Data | | All | Seq | 2/120 (120) | | |
| ID No. | PT | sec | PT | INR | APTT | sec |
| 0C01 | | 10.6 | | --- | --- | --- |
| 0C02 | | 10.8 | | --- | --- | --- |
| ■ 123-456-7890001 | | 10.6 | | --- | --- | --- |
| 123-456-7890002 | | 13.5+ | | --- | --- | --- |
| 123-456-7890002 | | 13.8+ | | --- | --- | --- |
| ■ 123-456-7890002 m | | 13.7+ | | --- | --- | --- |
| 123-456-7890003 | * | 12.8 | * | --- | --- | --- |
| 123-456-7890004 d | **** | * | --- | --- | --- | --- |

← → ↑ ↓ Mark

Graph Prev Next More Main Menu

Key operation on the List Display screen is as follows:

- [Prev]** key: Scrolls down one display screen (8 samples).
- [↑]** key: Moves the cursor up one sample position.
When the cursor is at the top of the screen, the List scrolls down.
- [↓]** key: Moves the cursor down one sample position.
When the cursor is at the bottom of the screen, the List scrolls up.
- [Next]** key: Scrolls the List up one screen (8 samples).
- [←] [→]** key: Turns over a page (scrolls sideways).
- [Mark]** key: Attaches or deletes marking.

When you press **[Mark]** key on the List Display screen, a mark (■) can be put on an analysis data in the current cursor position. The mark will appear at left side of the data.

When an analysis data is already attached with a mark, pressing **[Mark]** key causes the mark to be deleted.

Analysis Result Screen

When **[Stored Data]** key on the Main Menu screen is pressed, the Analysis Result screen appears first. This screen also appears when you press **[→]** key on the Sample Information screen.

The Analysis Result screen displays the results for calculation parameter and coagulation time that were selected in the test protocol and standard curve parameter setting. Analysis parameters are shown with 3 parameters on each page. **[←]** and **[→]** keys can be used to change parameters.

The following contents are displayed on the Analysis Result screen.

ID No.:

Sample ID Nos. entered by operator, transmitted from host computer, and read by barcode scanner are displayed.

Calculation parameters, coagulation time, Δ OD/min:

The calculation results and coagulation time or Δ OD/min for each parameter are displayed. If the calculation did not take place normally for any parameter, one of the following is displayed.

**** : Analysis data was not obtained due to an error or other cause.

--- : The calculation parameter could not be calculated.

+++ : The calculated value was large and exceeded the number of available display digits.

| Sysmex | | Ready | Replace | Rack? | YES! | HC |
|---------------------|------|-------|---------|-------------|------|-----|
| Stored Data | | All | Seq | 2/120 (120) | | |
| ID No. | PT | sec | PT | INR | APTT | sec |
| 0C01 | | 10.6 | | --- | --- | --- |
| 0C02 | | 10.8 | | --- | --- | --- |
| ■ 123-456-7890001 | | 10.6 | | --- | --- | --- |
| 123-456-7890002 | | 13.5+ | | --- | --- | --- |
| 123-456-7890002 | | 13.8+ | | --- | --- | --- |
| ■ 123-456-7890002 m | | 13.7+ | | --- | --- | --- |
| 123-456-7890003 | * | 12.8 | * | --- | --- | --- |
| 123-456-7890004 d | **** | * | --- | --- | --- | --- |

← → ↑ ↓ Mark

Graph Prev Next More Main Menu

Abnormal Flag:

Abnormal flags displayed on the right or left of an analysis data indicate the following:

- m (on right of ID No.): The data is a mean. The parameter has been calculated from mean data of seconds or Δ OD/min.
- d (on right of ID No.): A dilution ratio other than 100% was used for the data.
- * (on left of data): Some kind of error has occurred, or there is deviation in repeated analysis.
- > (on left of data): A data that exceeds the Upper Report Limits
- < (on left of data): A data that exceeds the Lower Report Limits
- + (on right of data): A data that exceeds the Upper Mark Limits
- (on right of data): A data that exceeds the Lower Mark Limits



Note

Abnormal flags are displayed according to the following priority.

1. *
2. <, >
3. +, -

Sample Information Screen

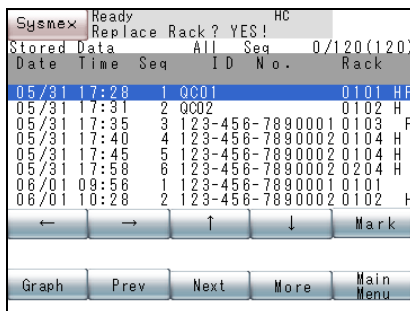
When [←] key is pressed on the first page of the Analysis Result Screen, the Sample Information screen will be displayed.

Contents of Sample Information Screen

- DATE: The date the analysis was conducted.
- TIME: The time the analysis result was obtained.
- SEQ: A sequential sample number counted from power turn-on.
- ID No.: The sample No. entered by operator, transmitted from host computer, or read by barcode scanner.
- RACK: The rack number and tube position number are displayed as follows:

| | Rack No. | Tube Position No. |
|------------------------|----------|-------------------|
| Normal Sample, QC Data | 01 - 99 | 01 - 10 |
| STAT Sample | 01 - 99 | 00 |
| Standard Curve | 00 | 01 - 06 |

- OUT: Data output flag:
 - H: When output to the host computer, the flag disappears.
 - P: When output to the built-in printer, the flag disappears.

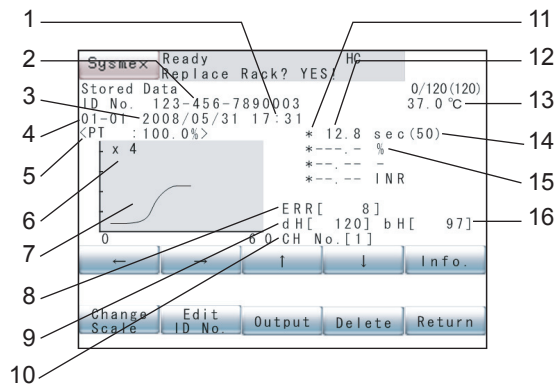


Graphic Display

Using the cursor, specify a sample to be graphically shown on the List Display screen, then press **[Graph]** key on the Local Menu. This enables displaying the coagulation curve of the sample chosen from the stored data.

While Graphic Display is on, press **[↑]** key to display a sample one position above on the List; and press **[↓]** key to display a sample one position below.

By pressing **[←]** and **[→]** keys, a parameter for an identical sample can be shifted to another parameter.



The following contents are displayed on the Graphic Display screen.

1. Analysis Time
Time of day the analysis result was obtained
2. ID No.
Sample ID No. entered by operator, transmitted from host computer, or read by barcode scanner
3. Analysis Date
Date the analysis was conducted
4. Rack No./Tube Position No.
Rack No. and tube position No. where sample was placed:
00 - 99: Rack No. (00 indicates standard curve analysis.)
00 - 10: Tube position No. (00 indicates STAT sample holder.)
5. Analysis Parameter Name/Dilution Ratio
Analysis parameter and dilution ratio of the displayed reaction curve
6. Scale of Scattered Light Intensity
If an enlarged graph is available, an enlarged graph with the scale such as “x4” is displayed when **[Change Scale]** key is pressed.

7. Reaction curve

A graph is plotted with time on the horizontal axis and the scattered light intensity or light absorbance variation on the vertical axis.

Time scale is shown at right end.

When the reaction curve graph area is pressed, the Graphic Enlargement window will be displayed. Refer to “Graphic Enlargement Window” described later.

8. Error code

Error code when an error occurs in analysis result

When there is no error, 0 appears.

9. dH

Increase of scattered light intensity in reaction process

10. CH No.

Detection channel in which analysis was conducted

11. Abnormal Flag

Abnormal flags displayed on the right or left of an analysis data.

12. Coagulation Time or Light Absorbance Variation

Time taken for coagulation or change in light absorbance

13. Analysis Temperature

Temperature of the detector at the start of analysis

14. Coagulation detection point

Coagulation detection point set

It is not displayed in case of analyses by Chromogenic Method and Immunoassay Method.

15. Calculated Parameters

Activity percentage, PT ratio, INR (PT), (Fbg concentration), etc.

16. bH

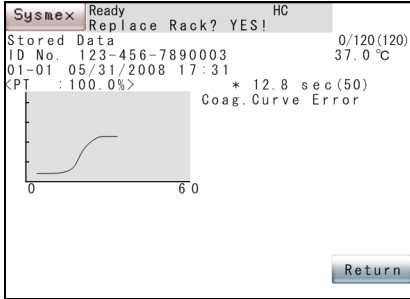
Scattered light intensity at the start of analysis



Note

Reaction curve is not displayed when some error occurred during analysis and no analysis data was obtained. The curve is also not displayed for the mean data of repeated analysis.

Error Detail Window

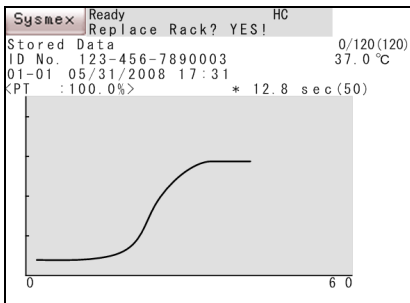


When an analysis error has occurred, its detail can be displayed in the window.

1. Press **[Info.]** key on the Graphic Display screen to display the Error Detail window.
2. Press **[Return]** key of Error Detail Window.

The Error Detail window will be closed.

Graphic Enlargement Window



The reaction curve graph on the Graphic Display screen can be enlarged on the window.

1. Press an area of the reaction curve graph on the Graphic Display screen.

The Graphic Enlargement window will be displayed.

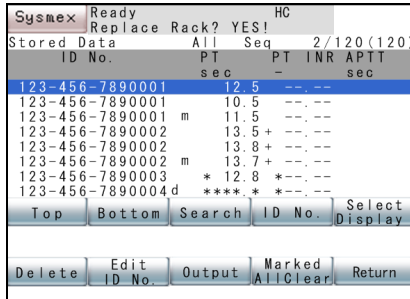
2. Press an area of reaction curve graph on the Graphic Enlargement window.

The Graphic Enlargement window will be closed.

6.2 Search

With this program, a data can be moved to the top data point or the bottom data point in the List Display, and samples that agree with specified conditions can be searched from stored data.

Top Data/Bottom Data



The cursor in the screen can be moved to the top of the list or the end of the list in the List Display.

[Top] key: Displays the top of analysis data at the head of the List.

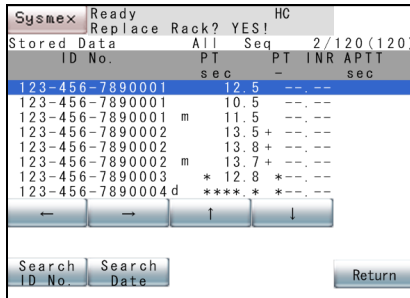
[Bottom] key: Displays the bottom of analysis data at the tail of the List.

Search by ID No.

Analysis data of a specified sample ID No. can be searched from stored data.

1. Press **[Search]** key on the Stored Data List Display screen.
The Local Menu for search will appear.
2. Press **[Search ID No.]** key.

The Search by ID No. screen will appear.

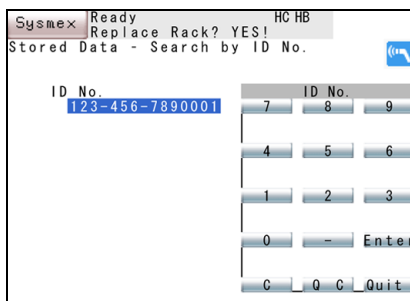


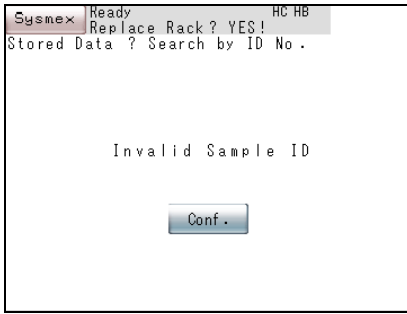
3. Enter sample ID No.

Using the ID No. numeric keys on the Search by ID No. screen, enter a sample ID No. to be searched.

If **[C]** key is pressed when there is no entry, **[QC]** key will change to **[STD]** key.

Sample ID can also be entered by hand-held barcode reader (optional).





Note

- To use the hand-held barcode reader, it is necessary to make the connection setting to “Connected”. When barcodes can be read by hand-held barcode reader, an icon appears on the upper right of the screen.
- When sample ID is entered by hand-held barcode reader, the entered sample ID is checked and if there is an incorrect sample ID, a confirmation message appears. Press the [**Conf.**] key to return to the Search by ID No. screen, where ready for entering.

4. Press [**Enter**] key on the ID No. numeric keys.

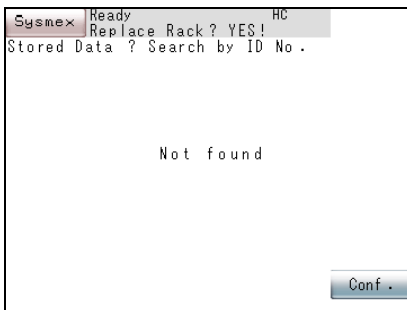
Search by ID No. begins from the sample ID No. in the current cursor position toward the latest sample. To cancel search by ID No., press [**Quit**] key on the ID No. numeric keys.

5. A List is displayed in which analysis data of the sample ID No. entered is listed.

When analysis data of the specified ID No. is found, a list of analysis data the List will indicate the analysis data at the head of the screen. The cursor is on the analysis data corresponding to the ID No.

When analysis data corresponding to an entered ID No. is not found, the Confirmation Message screen will appear.

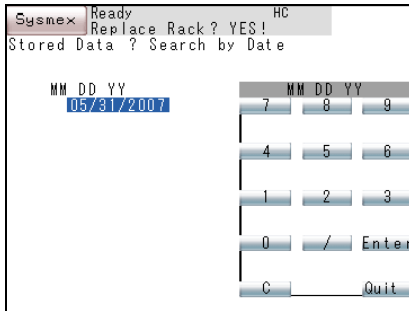
Press [**Conf.**] key to return to the Search by ID No. screen.



Search by Date

The first analysis data of a specified date can be displayed at the head of the screen.

1. Press [**Search**] key on the Stored Data List Display screen.
The Local Menu for search will appear.
2. Press [**Search Date**] key.
The Search by Date screen will appear.



3. Enter Date.

Using the date numeric keys in the Search by Date screen, enter a date by which to search.

4. Press **[Enter]** key on the date numeric keys.

Search by date begins from the sample in the current cursor position toward the latest sample.

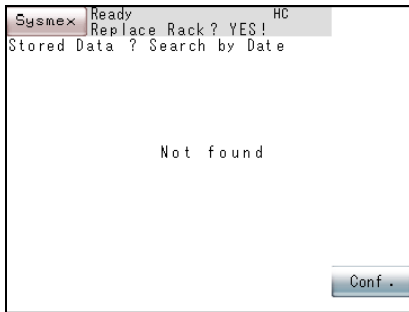
To cancel search by date, press **[Quit]** key on the date numeric keys.

5. A List is displayed in which analysis data of the date entered is listed.

When analysis data of the specified date is found, the a list of analysis data will be displayed. The cursor is on the first analysis data corresponding to the date entered.

When analysis data corresponding to the date entered is not found, the Confirmation Message screen will appear.

Press **[Conf.]** key to return to the Search by Date screen.



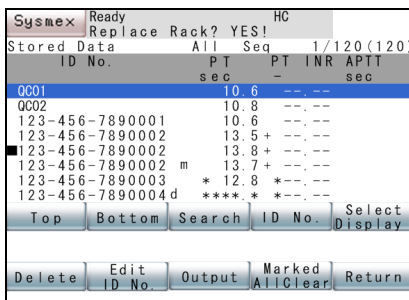
6.3 Sort in Sequence of Sample ID Nos. and Analyses

With this program, stored analysis data can be listed in a specified sequence.

The Stored Data List Display screen displays **[Seq]** key when the data are listed in the sequence of ID No. and **[ID No.]** key when the data are listed in the chronological analysis sequence.

[ID No.] key: The analysis data are listed as rearranged in the sample ID No. sequence.

[Seq] key: The analysis data are listed as rearranged in the chronological analysis sequence.



Note

While analysis is in progress, the program is automatically run in the analysis sequence.

6.4 Select Display

With this program, the type of data to be list-displayed can be selected from all stored data.

All Data

| ID No. | PT | PT INR | APTT |
|-----------------|----|--------|------|
| 123-456-7890001 | | 12.5 | --- |
| 123-456-7890001 | | 10.5 | --- |
| 123-456-7890001 | m | 11.5 | --- |
| 123-456-7890002 | | 13.5 | + |
| 123-456-7890002 | | 13.8 | + |
| 123-456-7890002 | m | 13.7 | + |
| 123-456-7890003 | * | 12.8 | * |
| 123-456-7890004 | d | **** | * |

As the condition for displaying a list, All Data can be specified.

1. Press **[Select Display]** key on the Stored Data List Display screen.
The Local Menu for selecting a display will appear.
2. Press **[All]** key on the Local Menu.

All analysis data stored are displayed in the sequence chosen from ID No. sequence and analysis sequence.

To cancel selection, press **[Cancel]** key. The Stored Data List Display screen will return.

Mean Data

As the condition for displaying a list, Mean Data can be specified.

When there is no sample to be displayed, the screen as shown at the left will appear.

1. Press **[Select Display]** key on the Stored Data List Display screen.
The Local Menu for selecting a display will appear.

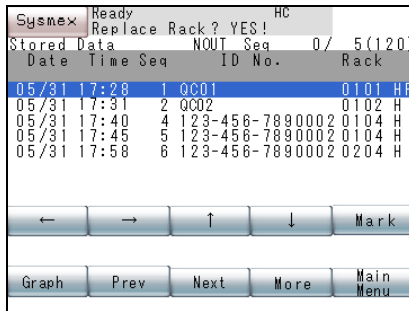
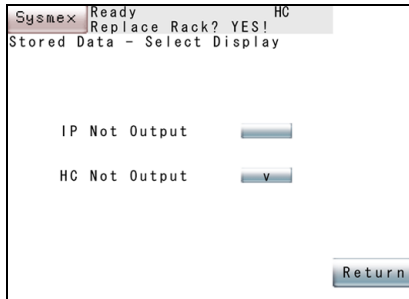
| ID No. | Mean | PT | PT INR | APTT |
|-----------------|------|------|--------|------|
| 123-456-7890001 | m | 11.5 | --- | --- |
| 123-456-7890002 | m | 13.7 | --- | --- |
| 234-567-890003 | m | 12.5 | --- | --- |
| 234-567-890004 | m | 13.5 | --- | --- |
| 234-567-890005 | m | 13.8 | --- | --- |
| 234-567-890006 | m | 13.7 | --- | --- |
| 234-567-890007 | m | 12.8 | --- | --- |

2. Press **[Mean]** on the Local Menu.

From among the stored data, only mean data are displayed in the sequence chosen, either ID No. sequence or analysis sequence.

To cancel selection, press **[Cancel]** key. The Stored Data List Display screen will return.

Not Output



As the condition for displaying a list, the data that have not yet output can be specified.

1. Press **[Select Display]** key on the Stored Data List Display screen.

The Local Menu for selecting a display will appear.

2. Press **[Not Output]** key on the Local Menu.

The Not Output Data Selection screen will be displayed.

To cancel the selection, press **[Return]** key. The Stored Data List Display screen will return.

3. On the Not Output Data Selection screen, press the key to select the Not Output data to display. The selected data is indicated with a “v”.

To cancel the selection, press **[Return]** key. The screen will return to the Stored Data List Display.

The “v” alternately appears or disappears each time the key is pressed.

IP Not Output: Stored analysis data that have not yet output to the built-in printer are displayed in the sequence chosen, either ID No. sequence or analysis sequence.

HC Not Output: Stored analysis data that have not yet output to the host computer are displayed in the sequence chosen, either ID No. sequence or analysis sequence.



Information

When an output was performed with the display condition “Not output data” selected, the output flag will be changed but the data will remain in the “Not output data” display even though the data has been output. In this case, exit from the “Not output data” display by pressing **[Main Menu]** key, or change the display condition, to update the contents of the “Not output data” display.

6.5 Edit ID No.

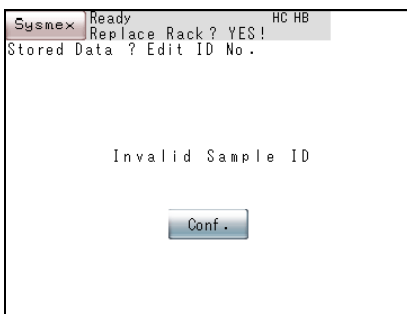
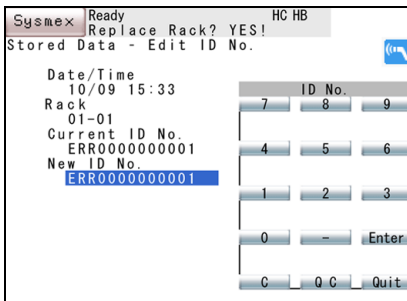
With this program, ID No. of cursor-specified analysis data can be changed.

1. Press **[Stored Data]** key on the Main Menu screen.
2. Press **[↑]** key or **[↓]** key to select data.
3. Press **[More]** key.
4. Press **[Edit ID No.]** key on the Stored Data List Display screen.

The Edit ID No. screen will display Date/Time, Rack position, and sample ID No.

5. Enter a new sample ID No. on the ID No. numeric keys.

Sample ID can also be entered by hand-held barcode reader (optional).



Note

- To use the hand-held barcode reader, it is necessary to make the connection setting to “Connected”. When barcodes can be read by hand-held barcode reader, an icon appears on the upper right of the screen.
- When sample ID is entered by hand-held barcode reader, the entered sample ID is checked and if there is an incorrect sample ID, a confirmation message appears. Press the **[Conf.]** key to return to the Search by ID No. screen, where the input field is cleared and ready for entering.

6. Press **[Enter]** key or **[Quit]** key on the ID No. numeric keys.

[Enter] key: Changes sample ID No. and returns you to the Stored Data List Display screen.

[Quit] key: Cancels editing sample ID No. and returns you to the Stored Data List Display screen.



Caution!

There should be thorough control of sample ID Nos. within the facility, so that when the sample ID No. is changed, the new No. can be used to identify the patient.



Note

When ID No. sequence is chosen instead of analysis sequence, change in sample ID No. will not automatically cause change in arrangement of the samples. By pressing **[Seq]** key and then **[ID No.]** key on the Stored Data List Display screen, the sample arrangement will return to normal.

6.6 Deletion

With this program, Stored Data can be deleted.

Data to delete can be specified on the Local Menus for Current Data, Marked Data, and All Data.



Note

Once deleted, data cannot be restored. Check carefully in advance before deleting data.

Current Data

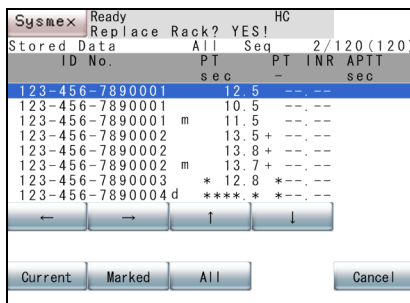
From the analysis data, the data in the current cursor position can be deleted.

1. Press **[Delete]** key on the Stored Data List Display screen.

The Local Menu for deletion will appear.

2. Press **[Current]** key on the Local Menu.

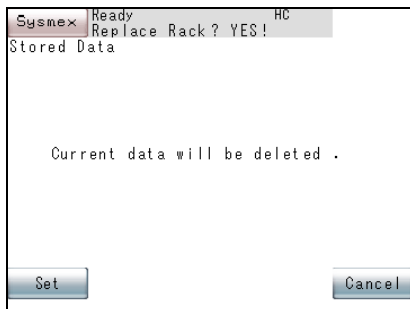
The Deletion Confirmation screen will appear.



3. Press **[Set]** key or **[Cancel]** key on the Deletion Confirmation screen.

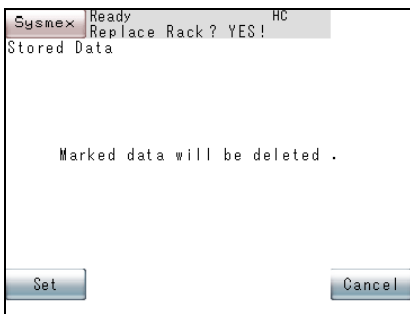
[Set] key: Deletes analysis data in the current cursor position.

[Cancel] key: Cancels deletion and returns you to the Local Menu for deletion.



Marked Data

| ID No. | PT | sec | PT | INR | APTT | sec |
|---------------------|----|------|-----|-----|------|-----|
| QC01 | | 10.6 | --- | --- | | |
| QC02 | | 10.8 | --- | --- | | |
| ■ 123-456-7890001 | | 10.6 | --- | --- | | |
| 123-456-7890002 | | 13.5 | + | --- | | |
| 123-456-7890002 | | 13.8 | + | --- | | |
| ■ 123-456-7890002 m | | 13.7 | + | --- | | |
| 234-567-890001 | | 12.6 | * | --- | | |
| 234-567-890002 d | | **** | * | --- | | |



From the analysis data, the marked data can be deleted.

1. Press **[Mark]** key on the Stored Data List Display screen and make a mark.

When **[Mark]** key is pressed, the analysis data in the current cursor position will be marked (■). If the mark is already there, it will disappear.

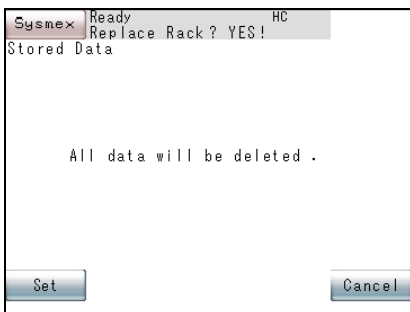
Press **[Marked All Clear]** key to remove all marks.

2. Press **[More]** key.
3. Press **[Delete]** key on the Stored Data List Display screen.
The Local Menu for deletion will appear.
4. Press **[Marked]** key on the Local Menu.
The Deletion Confirmation screen will appear.
5. Press **[Set]** key or **[Cancel]** key on the Deletion Confirmation screen.

[Set] key: Deletes marked analysis data.

[Cancel] key: Cancels deletion and returns you to the Local Menu for deletion.

All Data



All data can be deleted.

1. Press **[Delete]** key on the Stored Data List Display screen.
The Local Menu for deletion will appear.
2. Press **[All]** key on the Local Menu.
The Deletion Confirmation screen will appear.
3. Press **[Set]** key or **[Cancel]** key on the Deletion Confirmation screen.

[Set] key: Deletes all analysis data.

[Cancel] key: Cancels deletion and returns you to the Local Menu for deletion.

| | | |
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| 7.1 | Automatic Printout of Analysis Data | 7-1 |
| 7.2 | Output of Analysis Data | 7-1 |
| 7.3 | Example of Printout | 7-3 |



7. Output

7.1 Automatic Printout of Analysis Data

The instrument can automatically output analysis data to the built-in printer or the host computer. Refer to “10.2 Setup of Automatic Transfer/Printout”.

7.2 Output of Analysis Data

The instrument can output analysis data to the built-in printer or the host computer.

The data to be output to an external device can be specified via Local Menu of Current Data, Marked Data, and All Data. To display this menu, press **[Output]** key on the Stored Data List Display screen.

| ID No. | PT | INR | APTT |
|-----------------|--------|-----|------|
| 123-456-7890001 | 12.5 | -- | -- |
| 123-456-7890001 | 10.5 | -- | -- |
| 123-456-7890001 | m 11.5 | -- | -- |
| 123-456-7890002 | 13.5 | + | -- |
| 123-456-7890002 | 13.8 | + | -- |
| 123-456-7890002 | m 13.7 | + | -- |
| 123-456-7890003 | * 12.8 | * | -- |
| 123-456-7890004 | d **** | * | -- |

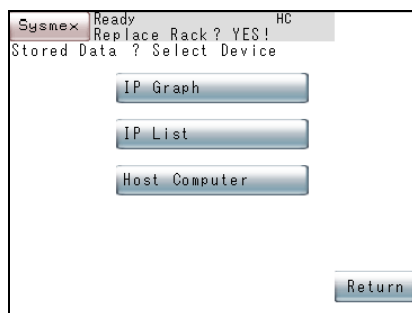
Current Data

The data in the cursor position can be output to the built-in printer or the host computer.

1. Press **[Current]** key on the Local Menu for external output.

The Select Device screen will appear.

2. Select the device on the Select Device screen.



[IP Graph] key: Analysis data (with graph) at the cursor position is output to the built-in printer.

[IP List] key: Analysis data (without graph) at the cursor position is output to the built-in printer.

[Host Computer] key: Analysis data at the cursor position is output to the host computer. (Displayed only when “Connected” is selected.)

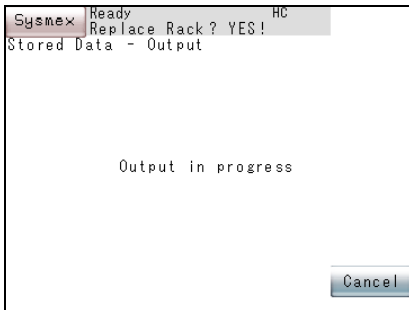
[Return] key: Cancels the device selection and returns the screen to the Local Menu for External Output.



Information

Notice for the setting of **[IP Graph]**.

- If the setting of “Format” in **[Auto Val/Out]** specified from **[Settings]** is “Print + Graph”, data with a graph will be printed out.
- If the setting of that is “Analysis”, analysis data will be printed out. Even in this case, however, if the power is turned off after the analysis, analysis data will not be printed out but data with a graph will be printed out.
- Even in the case of “Print + Graph”, if no reaction curve is drawn, data without a graph will be printed out.
- In the case of “Auto + Graph”, analysis data will be printed out for analysis items with a coagulation curve error.



3. Output of analysis data in the current cursor position begins.

The screen of output in progress will appear.

If **[Cancel]** key is pressed on the screen of output in progress, the output stops and the Select Device screen returns.

Marked Data

The marked data can be output to the built-in printer or the host computer.

1. Press **[Mark]** key on the Stored Data List Display screen to make a mark.

When **[Mark]** key is pressed, the analysis data in the current cursor position will be marked (■). When the mark is already there, it will disappear.

Press **[Marked All Clear]** key to remove all the marks.

2. Press **[More]** key.

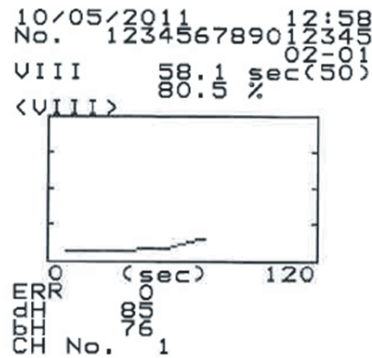
3. Press [**Output**] key on the Stored Data List Display screen.
The Local Menu for external output will appear.
4. Press [**Marked**] key on the Local Menu to display the Select Device screen.
5. Select the device on the Select Device screen.
6. Output of marked analysis data begins.
The screen of output in progress will appear.
If [**Cancel**] key is pressed on the screen of output in progress, the output stops and the Select Device screen returns.

All Data

All data can be output to the built-in printer or the host computer.

1. Press [**All**] key on the Local Menu for external output.
The Select Device screen will appear.
2. Select a device on the Select Device screen.
3. Output of all analysis data begins.
The screen of output in progress will appear.
If [**Cancel**] key is pressed on the screen of output in progress, the output stops and the Select Device screen returns.

7.3 Example of Printout



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| | | |
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| 8. | Quality Control | 8-1 |
| 8.1 | Quality Control Methods | 8-1 |
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8. Quality Control

Quality control is performed to obtain high-reliability data over long periods and also to constantly monitor the status of the instrument to prevent problem in advance.

This instrument analyses control plasma and other standard samples (QC samples) and performs statistical control of the results.



Caution!

Use the QC samples or reagent in accordance with the usage described in each attached instruction.
Perform quality control at least once every 24 hours and check that the instrument operates correctly.

8.1 Quality Control Methods

Two QC Programs are available:

\bar{X} control: Uses an average data of two consecutive analyses made on a QC sample (control plasma or pooled plasma). Because an average is used as control data, this control method suffers virtually no effects of reproducibility during analysis.

L-J control: Uses data of a single analysis on a QC sample. The L-J control is susceptible to effects of reproducibility so that its control range is wider than \bar{X} control.

8.2 QC File Setting

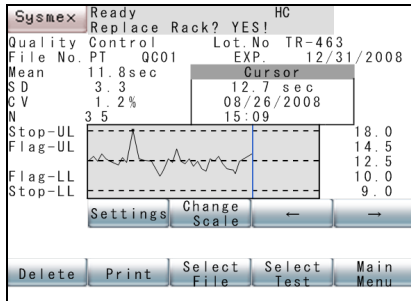
To execute the QC Program, it is necessary to set replication, control parameters, control limits, Lot No., and expiry date.

The parameters to be set for QC File are:

| | | |
|------------|--|---|
| Replicates | Sets the times of quality control analysis. | |
| Parameter | Sets the parameters for analysis results that are the object of quality control. | |
| Limit | Upper Stop | If a QC data exceeds this upper limit, the instrument stops analysis. |
| | Upper Flag | If a QC data exceeds this upper limit, the instrument flags the data as an error. |
| | Target | Target value of QC data |
| | Lower Flag | If a QC data exceeds this lower limit, the instrument flags the data as an error. |
| | Lower Stop | If a QC data exceeds this lower limit, the instrument stops analysis. |
| Lot No. | Sets a lot No. for samples to be used in quality control. | |
| EXP. | Sets an expiry date on samples to be used in quality control. | |

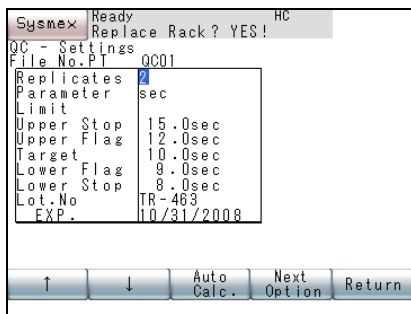
1. On the Quality Control screen, display the QC Chart of the file to set parameters for.

For how to display QC Chart, refer to “Select QC Chart” of “8.4 Display QC Charts”.



2. Press **[Settings]** key on the Quality Control screen.

The current settings of the selected file are displayed on the QC Settings screen.



Using **[↑]** and **[↓]** keys, move the cursor to select the parameters to be set.

3. Set replicates using **[Next Option]** key.

Each time **[Next Option]** key is pressed, “1” and “2” are changed alternately.

4. Set a control parameter using **[Next Option]** key.

Each time **[Next Option]** key is pressed, a parameter set as a standard curve parameter is changed over.



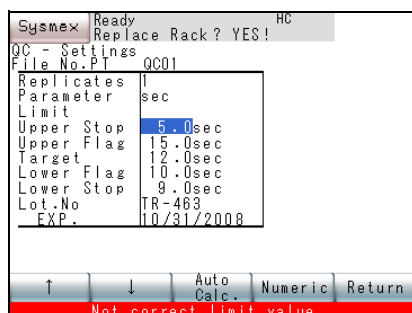
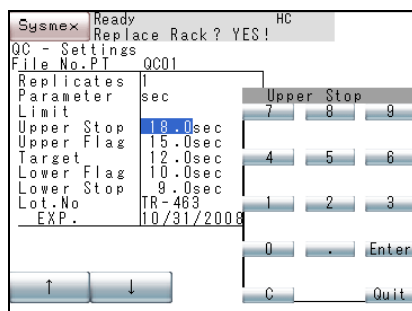
Information

Analysis results will not be stored in a QC File if a Standard Curve is not set and QC control parameters are set as calculation parameters.



Note

- As control parameters, you can select the analysis parameters set in Test Name and Standard Curve Parameter setting. The parameters linked to the standard curve are selected from the parameters which were set at link source.
- Do not change the QC control parameter after setting the target values or the limits of the control. Check the target value and the control limits always before confirming the QC Settings screen.
- When changing control parameters, delete all control data of a QC File to be changed.



5. Enter control limits using the numeric keys.

When the “Limit” parameter is selected, [Next Option] key will be changed to [Numeric] key. Press [Numeric] key to display the numeric keys.



Information

In setting control limits, the following conditions have to be met.

$\text{Lower Stop} \leq \text{Lower Flag} \leq \text{Upper Flag} \leq \text{Upper Stop}$

$\text{Lower Stop} < \text{Upper Stop}$

If the QC Settings screen is quit without satisfying the above conditions, the cursor will be positioned at the upper control limit and the error message “Not correct limit value” will appear. Since the cursor will not move, enter proper settings.



Note

Press [Auto Calc.] key, and the limit values will be automatically calculated from QC data stored in the file, as in the following.

Target: Mean of control data

Upper Flag: Mean of control data + 2SD of control data

Lower Flag: Mean of control data - 2SD of control data

Upper Stop: Mean of control data + 3SD of control data

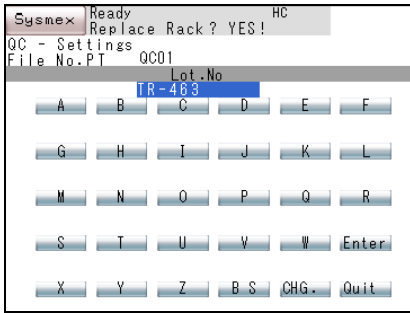
Lower Stop: Mean of control data - 3SD of control data

6. Press [Enter] key on the numeric keys.

The setting is changed to the entered numeral and the cursor moves to the next parameter. For a parameter whose setting is not to be changed, change the cursor position with [↑] and [↓] keys.

7. Press [Quit] key.

Setting by the numeric keys is completed.



8. Set Lot No.

By moving the cursor to Lot No., **[Next Option]** key will be changed to **[Lot No]** key.

Press **[Lot No.]** key to display the Lot No. Entry Screen.

Each time the **[CHG.]** key is pressed, the enter mode changes from capital alphabet → small alphabet → the numeric keys in this order.

Lot No. up to 12 digits can be set.

9. Press **[Enter]** key on the Lot No. Entry screen.

The setting is changed to the Lot No. entered and the cursor moves to the next parameter. To cancel setting, press **[Quit]** key, and the screen will return to the Quality Control screen without changing the setting.

10. Enter Expiry date using the numeric keys.

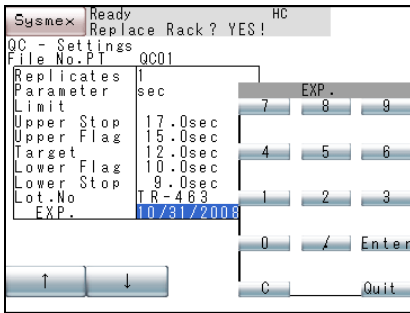
When the cursor is moved to “EXP.”, **[Next Option]** key will be changed to **[Date]** key. Press **[Date]** key to display the numeric keys.

Using the numeric keys, enter the date in accordance with System Setting - Date Format.

11. Press **[Enter]** key on the numeric keys.

The setting will be changed to the expiry date entered and the cursor will move to the next parameter.

To cancel setting, press **[Quit]** key, and the screen will return to Quality Control screen without changing the setting.

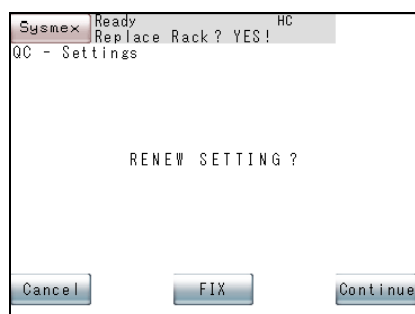


Information

- When the entered date is in a wrong format, the expiry date will not be corrected by pressing **[Enter]** key. The cursor also does not move. Enter again in a correct format.
- If you attempt to use the QC File that has passed its expiry date, then the confirmation screen with the error message will appear immediately after **[Start]** key is pressed.
- The correct calculation parameters cannot be obtained if they have expired.

12. Press **[Return]** key on the QC Settings screen.

The Renew Confirmation screen will appear.



13. Press **[FIX]** key, **[Continue]** key, or **[Cancel]** key.

[FIX]: Renews the setting and returns to the Quality Control screen.

[Continue]: Returns to the QC Settings screen and allows continuous operation.

[Cancel]: Cancels the renewed setting and returns to the Quality Control screen.



Information

Check that the values of QC Settings are right. If a wrong value is input, the condition of the instrument cannot be controlled correctly.

Entering setting items by hand-held barcode reader (optional)

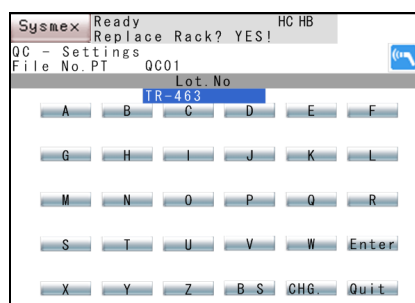
For the items below, data read by hand-held barcode reader can be entered.

- Lot No.
- Expiration date
- Target
- Upper Flag
- Lower Flag

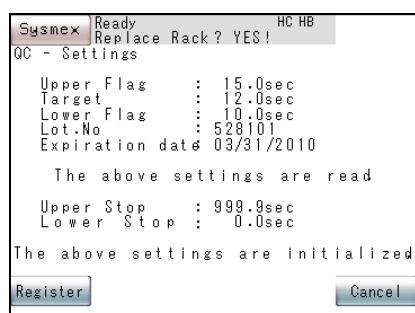


Note

To use the hand-held barcode reader, it is necessary to make the connection setting to “Connected”.



1. If the hand-held barcode reader is connected, an icon indicating that hand-held barcode reader is ready to read appears on the upper right of the QC settings screen.

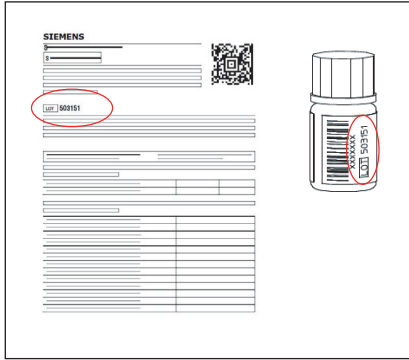


2. Read the barcode of the reference value table attached to the QC sample.

If the barcode is read normally, a confirmation screen appears.

Press the **[Register]** key on the confirmation screen to enter the values and return to the QC settings screen.

Press the **[Cancel]** key to cancel the entry, discard the values and return to the QC settings screen.



Information

- Check that the label lot No. of QC sample is the same as that in reference value table attached, and then read the barcode of the reference value table.
- Verify that the type of the control (e.g. normal, pathologic) corresponds to the selected QC File.
- If the barcode of a different lot is read and input, the condition of the instrument cannot be controlled correctly.
- Barcodes can be used only for the QC sample produced by Sysmex or Siemens. Reference value table is not attached to some QC sample.
- The upper stop and lower stop for analysis pause will not be applied until auto calculating or manual setting is performed.
- Do not change the QC control parameter after reading the target values or the limits of the control. Check the target value and the control limits always before confirming the QC Settings screen.



Note

The lower stop for analysis pause is set to “0”, and the upper stop for analysis pause is set to the maximum available value automatically.



If an unexpected barcode type is read (e.g. calibrator instead of control), an error screen appears.

Press the **[Conf.]** key to return to the QC settings screen.

8.3 Execute Quality Control

To maintain the reliability of analyzed data, quality control has to be performed. When QC sample (control plasma, pooled plasma, etc.) is registered with ID No. (QC01 - QC06) and then analyzed, the analysis data is kept in the QC File. It is by processing this analysis data with the QC Program that instrument and reagent stability that varies from time to time is monitored.

1. Set quality control samples on the sample rack.
2. Register the QC Sample Nos.

Press **[ID No. Entry]** key in the Main Menu screen, and using the numeric keys, enter ID Nos. for quality control (**[QC] [0] [1] - [QC] [0] [6]**).

3. Register the analysis parameters.

Specify samples in the Main Menu screen using **[↑]** and **[↓]** keys and analysis parameter keys. Mark "O" for the parameters to be analyzed.

4. Press **[Start]** key at the right upper corner in the screen.

Analysis data is automatically kept in the QC File.



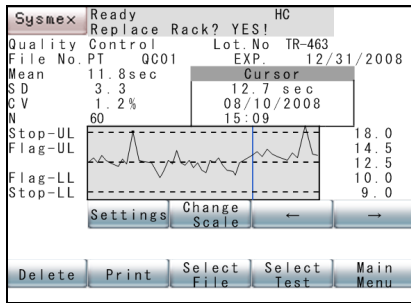
Note

Analysis data with "Slight Coagulation" and "Analysis Time Over" error will be also stored. Other error data cannot be stored.

5. Confirm the QC Chart.

The instrument executes QC Program and confirms the QC Chart.

8.4 Display QC Charts



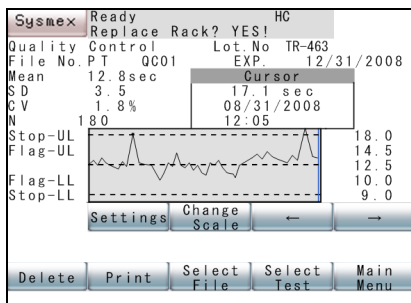
QC data is displayed in the Quality Control screen which is the initial screen of QC Program. When you press [QC] key on the Main Menu screen, the Quality Control screen will appear.

The QC Chart shows the latest 60-point data. By pressing [Change Scale] key, you can select the latest 60-point data or the stored 180-point data.



Note

[Change Scale] key will appear only when there is data in a file.



The Quality Control screen displays the following QC data:

- File No.: Parameter and File No. in the QC Chart being displayed
- Lot No.: Lot No. of the QC sample in use for Quality Control
- Exp.: Expiry date of the QC sample in use for Quality Control
- Mean: Mean of QC data
- SD: Standard deviation of QC data
- CV: Reproducibility coefficient of variation of QC data
- N: No. of QC data. When analysis is made twice, its mean value is taken as the data, so the number of data is 1.
- Stop_UL: When result of QC analysis exceeds this limit, subsequent analyses are canceled.
- Flag_UL: When result of QC analysis exceeds this limit, it is QC error.
- TARGET: A target QC value
- Flag_LL: When result of QC analysis goes below this limit, it is QC error.
- Stop-LL: When result of QC analysis goes below this limit, subsequent analyses are canceled.



Note

The point mark "■" indicates data where the results of QC analysis exceed STOP-UL or are below STOP-LL.

Cursor: The position of control data being displayed. You can move it to right or left by using [←] and [→] keys. When there is no data in the file, neither [←] key nor [→] key will be displayed.

Cursor position data:

Analysis data (calculated parameter) and analysis date of the QC data in the cursor position

Select QC Chart

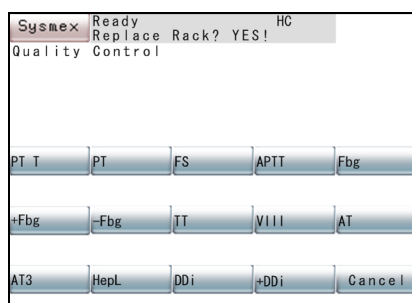
The instrument stores 6 different QC Files for each parameter (max 14 parameters).

To delete, set, or print a QC File, the QC Chart of the desired QC File has to be displayed.

1. Press **[QC]** key on the Main Menu screen.
The Quality Control screen will appear.
2. Press **[Select Test]** key on the Quality Control screen.
The Local Menu for Select Test will appear.
3. Press the parameter key on the Local Menu.

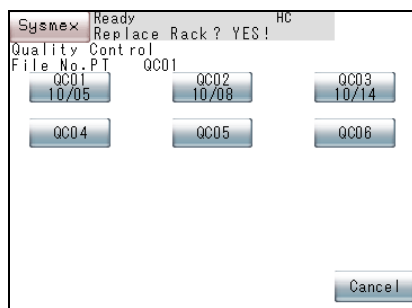
The Select File screen for the selected parameter will appear.

To cancel the change of the parameter, press **[Cancel]** key. With the parameter remaining unchanged, the Quality Control screen will return.



Note

When the current parameter is one which has the QC Chart displayed, press **[Select File]** key on the Quality Control screen.



4. Press the key of a file on Select File Screen.
The QC Chart of the selected file will be displayed on the Quality Control screen.

To cancel the change of the file, press **[Cancel]** key. With the parameter remaining unchanged, the Quality Control screen will return.



Note

The key for each file will display the date of the latest analysis. Those files with no analysis date do not have any data.

8.5 Delete QC File

To start Quality Control anew, the existing data in the QC Files has to be deleted. Specifically, to change the type or lot of control plasma, it is necessary to delete the existing data in the files.

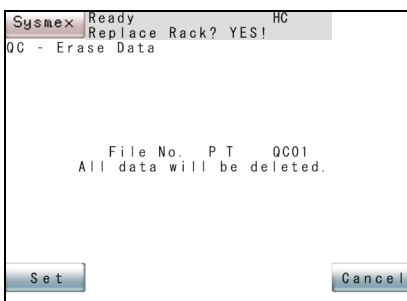
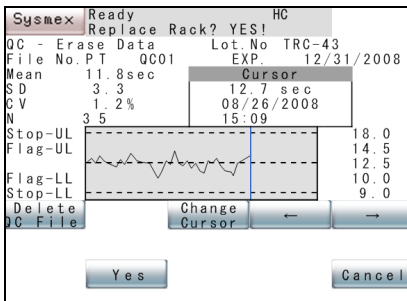
With this program, data can be deleted for each analysis parameter of an \bar{X} and L-J control file (QC01 - QC06).



Note

[Delete] key is not displayed when the file has no data.

1. Display the QC Chart of the desired file to be deleted.
For how to display the QC Chart, refer to “Select QC Chart” of “8.4 Display QC Charts”.
2. Press **[Delete]** key on the Quality Control screen.
The Local Menu for deletion will appear.
3. Press **[Delete QC File]** key on the Local Menu.
4. Press **[Yes]** key on the Local Menu.
The screen for confirming deletion of all data in a specified file will appear.
5. Press **[Set]** key or **[Cancel]** key.
[Set]: Deletes all data in a specified file and returns to Quality Control Screen.
[Cancel]: Cancels the deletion and returns to Quality Control Screen.



Caution!

Once data has been deleted, it cannot be recovered.

8.6 Delete QC Data

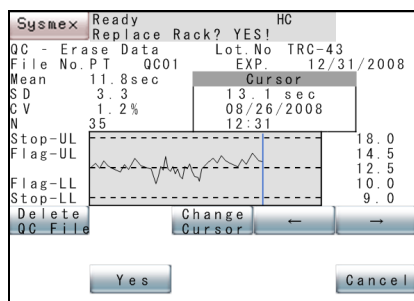
When this process is selected, two cursors will be displayed, and the data between those cursors can be deleted from the QC Chart.

1. Display the QC Chart from which you want to delete QC data.

For how to display the QC Chart, refer to “Select QC Chart” of “8.4 Display QC Charts”.

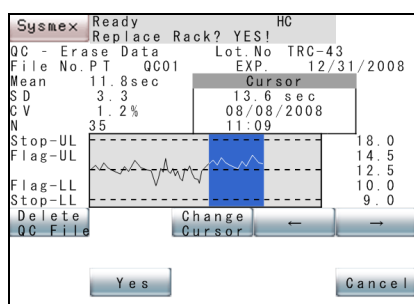
2. Press **[Delete]** key on the Quality Control screen.

The Local Menu for deletion will appear and the cursor for setting the range to be deleted will appear on the latest data.



3. Press **[←]** key on the Local Menu.

The cursor will move, forming two cursor lines, which are used to highlight the data range to be deleted.



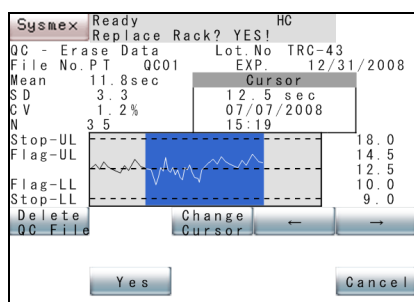
4. Using **[←]** and **[→]** keys on the Local Menu, move the cursors and set the data range to be deleted.

Press the **[Change Cursor]** key to select the range-setting cursor.

The cursor position data area displays the data for the range-setting cursor.

5. Press **[Yes]** key on the Local Menu.

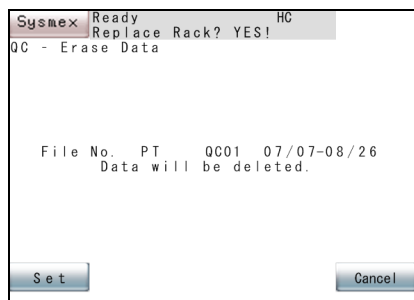
The screen confirming the range to be deleted will be displayed.



6. Press **[Set]** key or **[Cancel]** key on the Deletion Confirmation screen.

[Set]: Executes the deletion and quits the program.

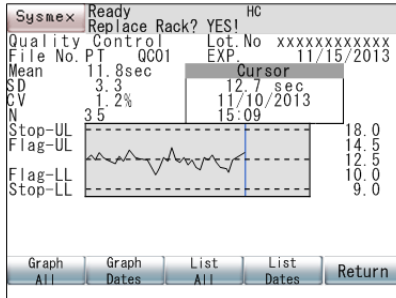
[Cancel]: Cancels the deletion and returns to the Quality Control screen.



8.7 Print QC data

The QC data can be printed by the built-in printer by the following procedure:

1. Display the QC Chart you want to print.
For how to display the QC Chart, refer to “Select QC Chart” of “8.4 Display QC Charts”.
2. Press **[Print]** key on the Quality Control screen.
The Local Menu for print setting will be displayed.
3. Press the **[Graph All]** key, the **[Graph Dates]** key, the **[List All]** key, or the **[List Dates]** key.



[Graph All] key:

Starts printing QC data and QC charts. (Refer to “Print All”)

[Graph Dates] key:

Displays the date specification print screen. Executes graphical printing of the specified period. (Refer to “Date Specification Print”).

[List All] key:

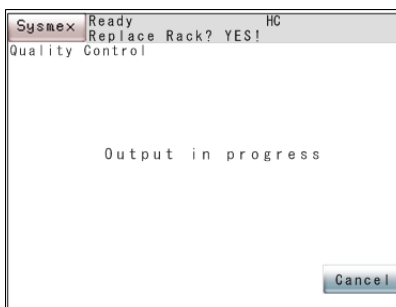
Starts printing QC data and data lists. (Refer to “Print All”)

[List Dates] key:

Displays the date specification print screen. Executes printing of the specified list period. (Refer to “Date Specification Print”)

Print All

Press the **[Graph All]** key or the **[List All]** key to start printing.



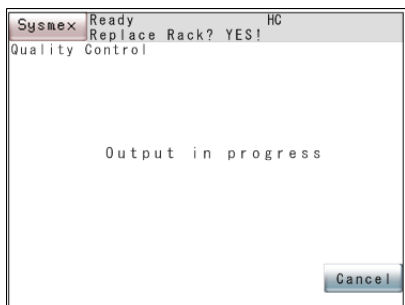
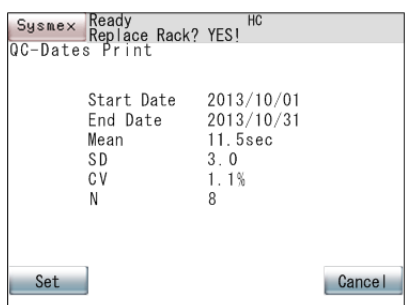
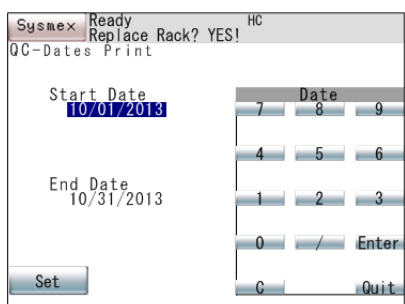
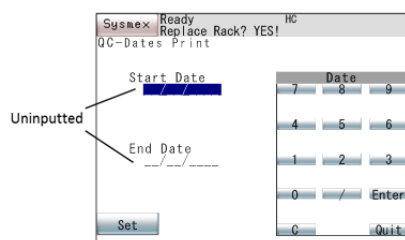
When **[Cancel]** key is pressed on the “Output in progress” message screen, printing will be canceled and the Quality Control screen will return.



Note

- The number of data that can be printed is all data for either 180 or 60 points, selected by **[Change Scale]** key.
- A “*” mark at the right edge of the printed list indicates that quality control analysis results for that data exceeded STOP-UL or fell below STOP-LL.

Date Specification Print



1. Enter the period you want to print with the numeric keys.
Enter the dates with the numeric keys in the format specified in System Settings - Date Format

2. Press the **[Enter]** key in the numeric keys.

The start date or end date changes to the entered date and the cursor moves to the next item.

To cancel date specification print, press the **[Quit]** key. You will return to the QC screen.

Note

- If the start date and end date are not entered, print all is executed.
- If only the start date is not entered, printing of the range from the oldest data to the end date is executed.
- If only the end date is not entered, printing of the range from the start date to the most recent data is executed.

3. Press the **[Set]** key in the date specification print screen.

The confirmation screen appears.

4. Press the **[Set]** key or the **[Cancel]** key.

[Set] key: Starts date specification print.

[Cancel] key: Returns you to the QC screen.

Note

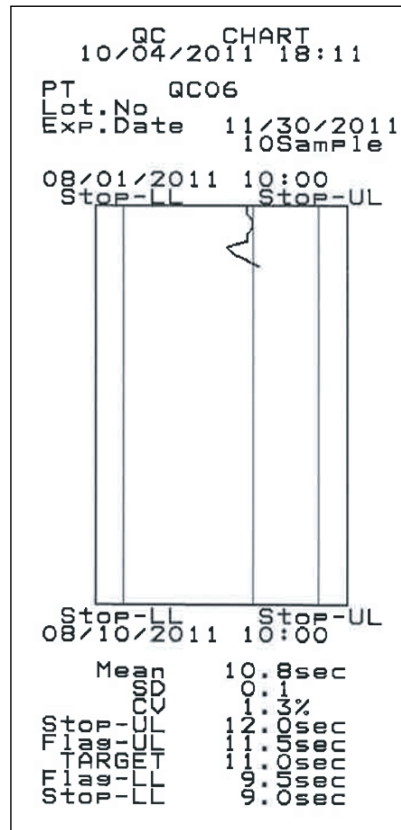
When dates are specified, mean values, S.D., and C.V. are recalculated over the specified period.

To cancel printing and return to the QC screen, press the **[Cancel]** key in the printing screen.

Note

- The number of data items printed is the data in the specified period within 180 points or 60 points, as selected with the **[Change Scale]** key.
- An asterisk "*" at the right end of a printed list indicates QC analysis result data that was over STOP-UL or under STOP-LL.

Graphic printout



List printout

| QC CHART | 10/04/2011 18:11 |
|---------------------|------------------|
| PT QC06 | |
| Lot.No QC06 | |
| Exp.Date 11/30/2011 | |
| 10Sample | |
| 08/01/2011 10:00 | |
| 08/10/2011 10:00 | |
| Mean | 10.8 sec |
| Stdev | 0.1 sec |
| Target | 12.0% |
| Flag | 1.00 sec |
| Stop | 9.0 sec |

| | | |
|-----------|-------------------------------------|------------|
| 9. | Setting Standard Curve | 9-1 |
| 9.1 | Display Standard Curve | 9-1 |
| 9.2 | Standard Curve Analysis | 9-3 |
| 9.3 | INR Manual Dilution Analysis | 9-9 |
| 9.4 | Manual Entry | 9-14 |
| 9.5 | Standard Curve Files | 9-16 |
| 9.6 | Set Reagent Information | 9-21 |
| 9.7 | Set Calculation Parameters | 9-24 |
| 9.8 | Standard Curve Conversion | 9-27 |
| 9.9 | Print Standard Curve | 9-28 |



9. Setting Standard Curve

The Standard Curve is a set of parameters used to determine each calculation parameter, based on the coagulation time and $\Delta OD/\text{min}$ in the analysis results.

9.1 Display Standard Curve

Description is given here on standard curve data and how to make its graphic display.

Data Display

| % | sec | Lot.No | EXP. |
|-------|-------|---------|------------|
| 129.0 | 66.7 | VIII | 12/20/2012 |
| 86.0 | 72.1 | PTT FSL | 12/20/2012 |
| 43.0 | 82.2 | CaCl2 | 12/20/2012 |
| 21.5 | 92.9 | VB | 12/20/2012 |
| 10.7 | 104.0 | Calibr. | 01/31/2013 |
| 0.0 | 0.0 | | |

Buttons: Select Test, Graph, Print, Lot No. Entry, Main Menu

| % | sec | Lot.No | EXP. |
|--------|-------|---------|------------|
| 129.0 | 66.7 | VIII | 12/20/2012 |
| 86.0 | 72.1 | PTT FSL | 12/20/2012 |
| 43.0 | 82.2 | CaCl2 | 12/20/2012 |
| 21.5 | 92.9 | VB | 12/20/2012 |
| 10.7 | 104.0 | Calibr. | 01/31/2013 |
| 0.0 | 0.0 | | |
| Normal | 0.0 | | |
| ISI | 0.0 | | |

Buttons: Select Param., More, STD Calc., Main Menu

1. Press [**Standard Curve**] key on the Main Menu screen.

The PT Standard Curve Data screen will appear.

The contents displayed on the Standard Curve Data screen are:

(M): Displayed when some of standard curve data is manually input.

Cal Date: The date on which the Standard Curve is set

Reagent Name: Name of reagent

Lot No.: Lot No. of reagent (up to 12 digits)

EXP.: Expiry date of a reagent

<Standard Curve Data>

Activity/Concentration:

Percent activity or concentration.

Up to 6 points can be set for each parameter.

(A lower-position point indicates a lower activity or concentration.) Displayed when activity or concentration is set in [**Select Param.**] key.

Coagulation Time - Reaction Speed:

Coagulation time or reaction speed for 6-point activity or concentration

Normal: Normal value used for finding the ratio. Displayed when the ratio or INR is set by [**Select Param.**] key.

ISI: International Sensitivity Index to calculate INR. Displayed when INR is set by [**Select Param.**] key.



Caution!

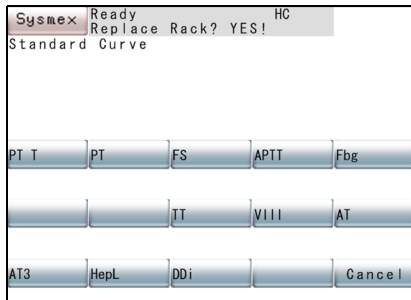
When analysis is made after expiry date has passed, coagulation activity (PT ratio, PT-INR, etc.) cannot be accurately calculated.

In processing **[Lot No. Entry]**, set a new reagent Lot No. and expiry date. When **[Start]** key is pressed after expiry date passed, the message “Check Reagent Expiry” appears, with the alarm sounding.



Note

[Next] key is displayed when dFbg or PT-INR Calibration is set by **[Select Param.]** key of standard curve for PT parameter.



2. Press **[Select Test]** key on the Standard Curve Data screen.



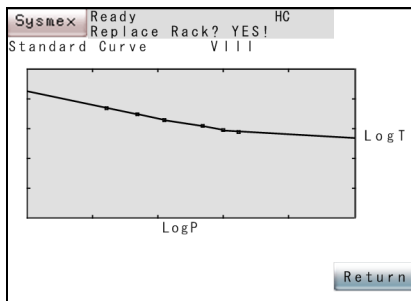
Note

The key for analysis parameters which have been linked to the standard curve is masked.

3. Press the analysis parameter key to display the standard curve data of the selected analysis parameter.

When **[Cancel]** key is pressed, the screen will return to the original data's standard curve data screen.

Graphic Display



1. Press **[Graph]** key on the Standard Curve Data screen.

The contents displayed on the Graphic Display screen are:

Standard Curve Graph:

Plots activity or concentration on X axis and coagulation time or reaction rate on Y axis.

Expression: Displays a expression such as $\text{Log P} = a * \text{Log T} + b$ from the plotted data.

P: Coagulation activity (Concentration)

T: Coagulation time (Reaction speed)

Correlation: Correlation coefficient of approximate expression

a, b: Constant derived from analysis results

**Note**

When “Log Lin” or “Lin-Lin” is set on Select Parameters screen, Correlation, rate, and offset are displayed.

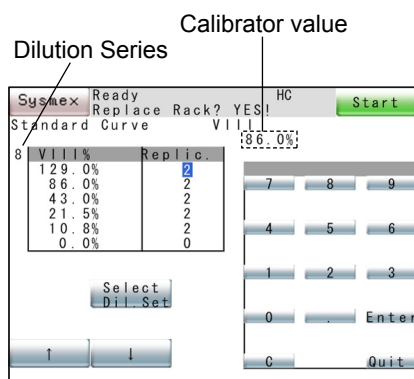
9.2 Standard Curve Analysis

Auto Dilution

The instrument automatically analyzes a set dilution ratio and plots a standard curve.

To create a Standard Curve using a sample diluted manually, refer to “Manual Dilution” on the following page. To analyze an INR standard curve in which “Calibration” has been selected as the calculation method, refer to “9.3 INR Manual Dilution Analysis”.

1. Set a reference sample at the tube position No. 1 of the sample rack and set it on the sampler.
2. Display the standard curve data of a parameter you want to set.
For detailed information, refer to “9.1 Display Standard Curve”.
3. Press [**Standard Analysis**] key on the Standard Curve Data screen.
4. Use the numeric keys to enter the calibrator value.

**Caution!**

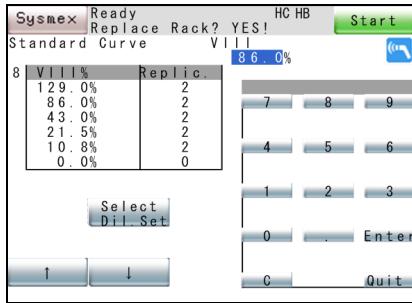
- Input the calibrator value as described in the calibrator value table. If a wrong value is input, the correct analysis result may not be obtained.
- If the calibrator value of a different lot is input, the correct analysis result may not be obtained.
- When the reagent lot is changed, perform standard curve analysis.

Calibrator value can also be entered by hand-held barcode reader (optional).

**Note**

To use the hand-held barcode reader, it is necessary to make the connection setting to “Connected”.

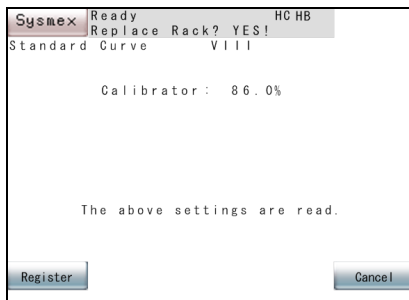
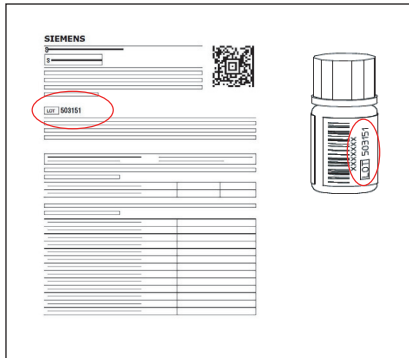
Setting Standard Curve



If the hand-held barcode reader is connected, an icon indicating that hand-held barcode reader is ready to read appears on the upper right of the screen.

Information

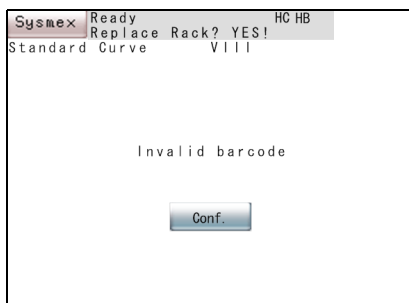
- Check that the label lot No. of calibrator is the same as that in calibrator value table attached, and then read the barcode of the calibrator value table.
- Barcodes can be used only for the samples produced by Sysmex or Siemens. Calibrator value table is not attached to some samples.



If calibrator values of the calibrator is read normally, a confirmation screen appears.

Press the **[Register]** key on the confirmation screen to enter the values and return to the calibrator value entry screen.

Press the **[Cancel]** key to cancel the entry, discard the values and return to the calibrator value entry screen.



If the barcode read is of a different sample or if the calibrator type is a different one such as for multi-calibrator, an error screen appears.

Press the **[Conf.]** key to return to the calibrator value entry screen.

5. Press **[Select Dil. Set]** key and select a series of dilution desired.

Note

The dilution series number indicates 1 - 12 for automatic dilution series numbers, or “M” for manual dilution.

The dilution ratios are listed below.

| | Dilution Ratios provided for Auto Dilution | Dilution Series No. |
|--------------------------------------|--|---------------------|
| Analysis parameters without dilution | 1/1, 1/2, 1/4, 1/8, 1/16, 1/32 | 1 |
| | 1/1, 4/5, 3/5, 2/5, 1/5, 0/1 | 2 |
| | 1/1, 1/2, 1/4, 1/8, 1/16, 0/1 | 3 |
| | 1/1, 1/2, 1/3, 1/4, 1/5, 3/20 | 4 |
| | 1/2, 1/4, 1/8, 1/16, 1/32, 0/1 | 5 |
| | 10/19, 5/19, 5/38, 1/19, 1/38, 1/95 | 6 |
| | 1/1, 2/3, 1/4, 1/8, 1/32, 0/1 | 13 |
| | Set manually | M |
| Analysis parameters with dilution | 1/1, 1/2, 1/4, 1/8, 1/16, 1/32 | 1 |
| | 1/1, 4/5, 3/5, 2/5, 1/5, 0/1 | 2 |
| | 1/1, 1/2, 1/4, 1/8, 1/16, 0/1 | 3 |
| | 1/1, 1/2, 1/3, 1/4, 1/5, 3/20 | 4 |
| | 1/2, 1/4, 1/8, 1/16, 1/32, 0/1 | 5 |
| | 10/19, 5/19, 5/38, 1/19, 1/38, 1/95 | 6 |
| | 2/1, 1/1, 1/2, 1/4, 1/8, 0/1 | 7 |
| | 3/2, 1/1, 1/2, 1/4, 1/8, 0/1 | 8 |
| | 2/1, 3/2, 1/1, 1/2, 1/3, 0/1 | 9 |
| | 3/2, 1/1, 1/2, 1/4, 1/8, 1/16 | 10 |
| | 4/1, 3/1, 2/1, 1/1, 1/2, 1/3 | 11 |
| | 5/4, 1/1, 3/4, 1/2, 1/4, 1/8 | 12 |
| | 1/1, 2/3, 1/4, 1/8, 1/32, 0/1 | 13 |
| | 2/1, 1/1, 1/2, 1/4, 1/8, 1/16 | 14 |
| | 4/1, 2/1, 1/1, 1/2, 1/4, 1/8 | 15 |
| | 5/4, 1/1, 3/4, 1/2, 1/4, 0/1 | 16 |
| | 3/2, 5/4, 1/1, 1/2, 1/4, 1/8 | 17 |
| | 6/5, 1/1, 7/10, 2/5, 1/5, 1/10 | 18 |
| | 1/2, 2/5, 3/10, 1/5, 1/10, 0/1 | 19 |
| Set manually | M | |

Notes: Factory setting is the setting at the time of shipment.

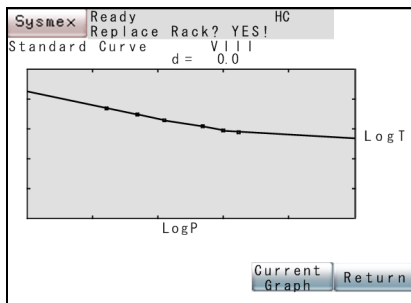
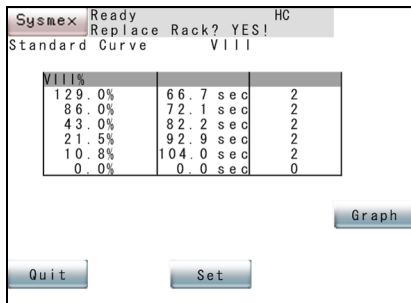
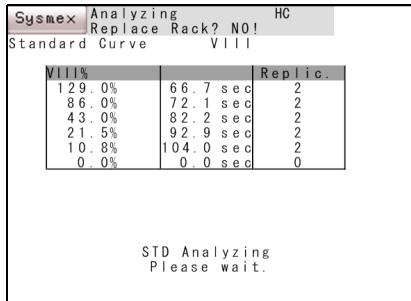
Zero percent (0%) applies only when calculation method of “Lin-Lin” is selected in parameter selection.

6. Enter replicates at each dilution point using the numeric keys.

Replicates can be set 0 - 3.

The cursor can be moved by pressing [↑] and [↓] keys.

Setting Standard Curve



- Press **[Start]** key at the right upper corner of the screen.

While analysis is taking place, the message “STD Analyzing Please wait.” is displayed.



Information

Two or more points are required to start Standard Curve analysis.

- When analysis is over, the screen for checking whether to use the analysis data as Standard Curve Data is displayed.

[Set] key: Sets the analysis data as Standard Curve data and returns to the Standard Curve Data screen.

[Quit] key: Discards the analysis data and returns to the Standard Curve Data screen.

[Next] key: Displays the Setting screen for a different calculation parameter.



Information

When **[Set]** key is pressed, the standard curve that was used up to that time is automatically saved to a backup file. (Refer to “9.5 Standard Curve Files”.)

Press **[Graph]** key to display the new Standard Curve data as graph (solid line with square plots).

When **[Current Graph]** key is pressed, the current Standard Curve graph (dotted-line graph with triangular plots) will appear in addition. Press it again to hide the current graph.

Press **[Return]** key to return to Standard Curve Data screen without updating the new standard curve.



Note

The “d” in a graph indicates the difference in coagulation time between the new and old Standard Curves at 1:1 as a deviation amount.

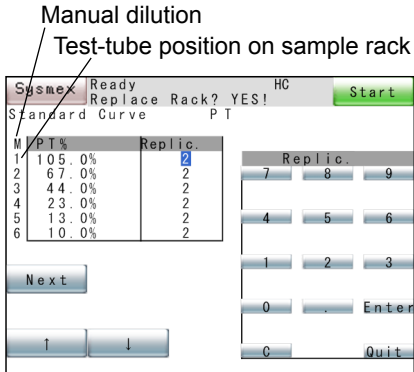
Manual Dilution

The instrument analyzes multiple calibrators of the same series, for which activity and other values are already known, and then creates a standard curve.

- Set standard samples in position.

Beginning with test-tube position 1 on the sample rack, a maximum of 6 samples can be set.

- Display the standard curve data for the parameter you wish to set.
- Press **[Standard Analysis]** key.
- Press **[Select Dil. Set]** key and select “M”.



5. Use the numeric keys to enter the activity percentage or concentration for each point. For details about settings for this calculation procedure, refer to “9.7 Set Calculation Parameters”. To the left of the table is displayed the sample rack test-tube positions. “1” indicates sample rack test-tube position 1.

Caution!

- Input the calibrator value as described in the calibrator value table. If a wrong value is input, the correct analysis result may not be obtained.
- If the calibrator value of a different lot is input, the correct analysis result may not be obtained.
- When the reagent lot is changed, perform standard curve analysis.
- When preparing a diluted sample, if it is prepared at wrong dilution ratios, the correct analysis result may not be obtained.

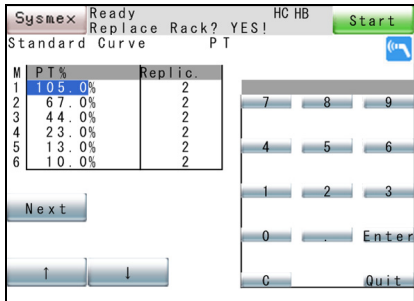
Information

Put the calibrator for the set value in the same sample rack test-tube position as the number shown on the settings screen.

Activity percentage and concentration can also be entered by hand-held barcode reader (optional).

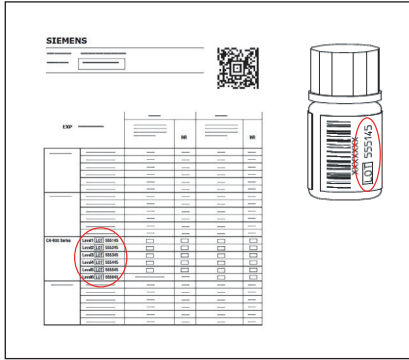
Note

To use the hand-held barcode reader, it is necessary to make the connection setting to “Connected”.



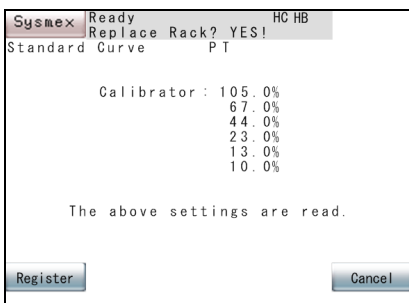
If the hand-held barcode reader is connected, an icon indicating that hand-held barcode reader is ready to read appears on the upper right of the screen.

Setting Standard Curve



i Information

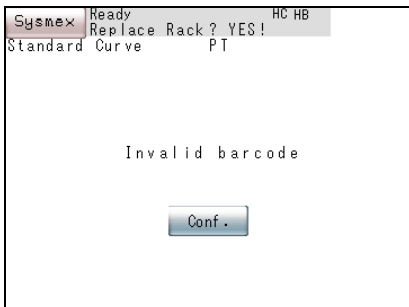
- Check that the label lot No. of calibrator is the same as that in calibrator value table attached, and then read the barcode of the calibrator value table.
- Barcodes can be used only for the samples produced by Sysmex or Siemens. Calibrator value table is not attached to some samples.
- Master curve information (e.g. master curve for derived Fibrinogen) which is providing both, activity percentage or concentration and the respective analysis data cannot be read via hand-held barcode reader.



If calibrator values of the calibrator are read normally, a confirmation screen appears.

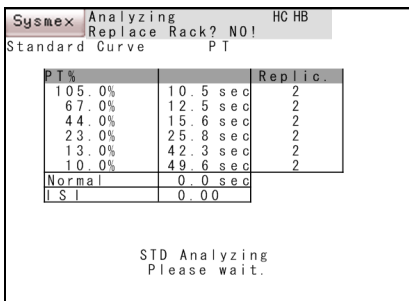
Press the **[Register]** key on the confirmation screen to enter the values and return to the activity percentage or concentration entry screen.

Press the **[Cancel]** key to cancel the entry, discard the values and return to the activity percentage or concentration entry screen.



If the barcode read is of a different sample or if the calibrator type is a different one such as for single-calibrator, an error screen appears.

Press the **[Conf.]** key to return to the activity percentage or concentration entry screen.



6. Use the numeric keys to input the analysis count for each point. The analysis count can be set from 0 - 3. The cursor can be moved with **[↑]** and **[↓]** keys.
7. Press **[Start]** key on the top right of the screen to begin analysis. During analysis, the message “STD Analyzing. Please wait.” is displayed.

i Information

2 or more points are required in order to begin Standard Curve analysis.

| Sysmex Ready HC | | |
|--------------------|----------|---------|
| Replace Rack? YES! | | |
| Standard Curve P T | | |
| PT% | P T | Replic. |
| 105.0% | 10.5 sec | 2 |
| 67.0% | 12.5 sec | 2 |
| 44.0% | 15.6 sec | 2 |
| 23.0% | 25.8 sec | 2 |
| 13.0% | 42.3 sec | 2 |
| 10.0% | 49.6 sec | 2 |
| Normal | 0.0 sec | |
| ISI | 0.00 | |

Next Graph

Quit Set

8. When analysis is completed, a screen appears asking the operator whether or not to apply the analysis data as Standard Curve Data.

[Set] key: Sets the analysis data as Standard Curve Data and returns to the Standard Curve Data screen.

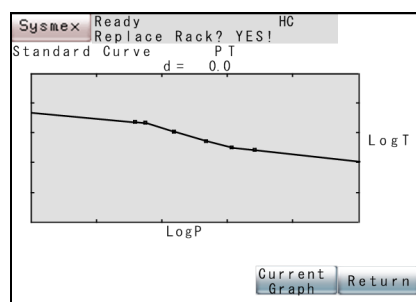
[Quit] key: Discards the analysis data and returns to the Standard Curve Data screen.

[Next] key: Displays the Setting screen for a different calculation parameter.



Information

When **[Set]** key is pressed, the standard curve that was used up to that time is automatically saved to a backup file. (Refer to “9.5 Standard Curve Files”.)



Press **[Graph]** key to display the new standard curve data as graph (solid line with square plots).

Press **[Current Graph]** key to display the current (old) standard curve graph (dotted line with triangular plots in addition). Press it again to hide the current standard curve graph from the screen and switch to the new standard curve.

Press **[Return]** key to return to Standard Curve Data screen without updating the new standard curve.



Note

The “d” in a graph indicates the difference in coagulation time between the new and old Standard Curves at 1:1 as a deviation amount.

9.3 INR Manual Dilution Analysis

The instrument can analyze multiple calibrators for INR and creates a Standard Curve for INR.

To switch to input the ISI value and to use the calibrators, refer to “9.7 Set Calculation Parameters”.

1. Set standard samples in position.
Beginning with test-tube position 1 on the sample rack, a maximum of 6 samples can be set.
2. Display the standard curve data for the parameter you wish to set.
3. Press **[Standard Analysis]** key.

Setting Standard Curve

Manual dilution
Test-tube position on sample rack

| INR | Replic. |
|------|---------|
| 0.99 | 2 |
| 1.19 | 2 |
| 1.43 | 2 |
| 2.14 | 2 |
| 3.64 | 2 |
| 4.77 | 2 |

4. Use the numeric keys to input an INR value for each point.
To the left of the table is displayed the sample rack test-tube positions. "1" indicates sample rack test-tube position 1.



Caution!

- Input INR, % as described in the INR value table. If a wrong value is input, the correct analysis result may not be obtained.
- If the INR value of a different lot is input, the correct analysis result may not be obtained.
- When the reagent lot is changed, perform standard curve analysis.



Information

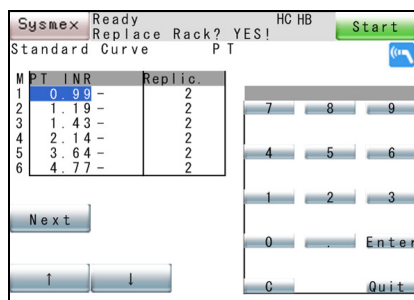
Put the calibrator for the set value in the same sample rack test-tube position as the number shown on the Settings screen.

INR value can also be entered by hand-held barcode reader (optional).



Note

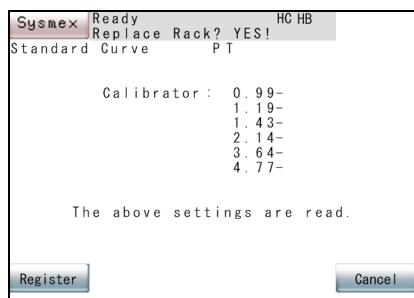
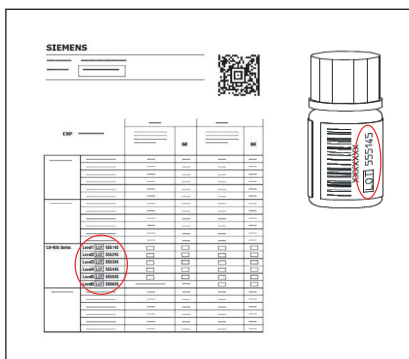
To use the hand-held barcode reader, it is necessary to make the connection setting to "Connected".



If the hand-held barcode reader is connected, an icon indicating that hand-held barcode reader is ready to read appears on the upper right of the screen.

Information

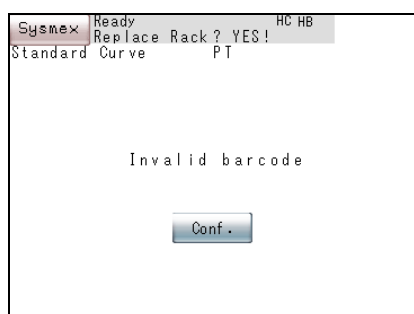
- Check that the label lot No. of calibrator is the same as that in INR value table attached, and then read the barcode of the INR value table.
- Barcodes can be used only for the samples produced by Sysmex or Siemens.
INR value table is not attached to some samples.



If INR values of the calibrator are read normally, a confirmation screen appears.

Press the **[Register]** key on the confirmation screen to enter the values and return to the INR value entry screen.

Press the **[Cancel]** key to cancel the entry, discard the values and return to the INR value entry screen.



If the barcode read is of a different sample or if the calibrator type is a different one such as for single-calibrator, an error screen appears.

Press the **[Conf.]** key to return to the INR value entry screen.

Setting Standard Curve

| M | PT% | Replic. |
|---|--------|---------|
| 1 | 105.0% | 2 |
| 2 | 67.0% | 2 |
| 3 | 44.0% | 2 |
| 4 | 23.0% | 2 |
| 5 | 13.0% | 2 |
| 6 | 10.0% | 2 |

Next

7 8 9

4 5 6

1 2 3

0 . Enter

c Quit

↑ ↓

- Use the numeric keys to input the analysis count for each point.

The analysis count can be set from 0 - 3.

The cursor can be moved with [↑] and [↓] keys.

- Use the numeric keys to enter the activity percentage and concentration.

If this is also valid for calculation parameter 1, then each time [Next] key is pressed, the Setting screen for a different calculation parameter is displayed. Set activity percentage and concentration in the same way as (4) and (5) above.



Note

Entering the activity percentage (concentration) here, in addition to the INR value, allows two types of Standard Curve to be set: INR and activity percent.

| PT | INR | Replic. |
|--------|----------|---------|
| 0.99- | 10.4 sec | 2 |
| 1.19- | 12.6 sec | 2 |
| 1.43- | 15.2 sec | 2 |
| 2.14- | 22.8 sec | 2 |
| 3.64- | 38.5 sec | 2 |
| 4.77- | 50.3 sec | 2 |
| Normal | 10.6 sec | |
| ISI | 1.00 | |

Next

STD Analyzing
Please wait.

- Press [Start] key on the top right of the screen to begin analysis.

During analysis, the message “STD Analyzing. Please wait.” is displayed. Each time [Next] key is pressed, the Setting screen for a different calculation parameter is displayed.



Information

2 or more points are required in order to begin Standard Curve analysis.

| PT | INR | Replic. |
|--------|----------|---------|
| 0.99- | 10.4 sec | 2 |
| 1.19- | 12.6 sec | 2 |
| 1.43- | 15.2 sec | 2 |
| 2.14- | 22.8 sec | 2 |
| 3.64- | 38.5 sec | 2 |
| 4.77- | 50.3 sec | 2 |
| Normal | 10.6 sec | |
| ISI | 1.00 | |

8. When analysis is completed, a screen appears asking the operator whether or not to apply the analysis data as Standard Curve Data.

[Set] key: Sets the analysis data as Standard Curve Data and returns to the Standard Curve Data screen.

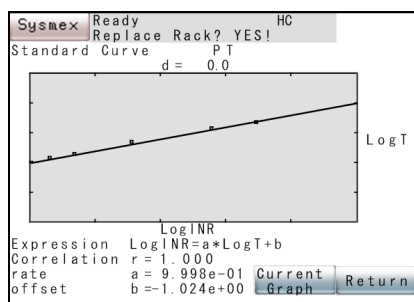
[Quit] key: Discards the analysis data and returns to the Standard Curve Data screen.

[Next] key: Displays the Setting screen for a different calculation parameter.



Information

When **[Set]** key is pressed, the standard curve that was used up to that time is automatically saved to a backup file. (Refer to “9.5 Standard Curve Files”.)



Press **[Graph]** key to display the new standard curve data as graph (solid line with square plots).

Press **[Current Graph]** key to display the current (old) standard curve graph (dotted line with triangular plots in addition). Press it again to hide the current standard curve graph from the screen and switch to the new standard curve.

Press **[Return]** key to return to Standard Curve Data screen without updating the new standard curve.



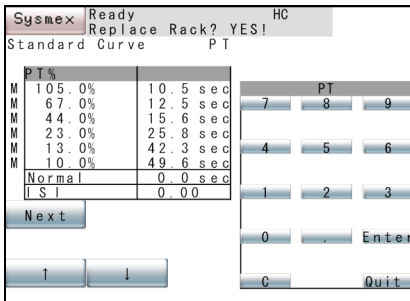
Note

- The “d” in a graph indicates the difference in coagulation time between the new and old Standard Curves at 1:1 as a deviation amount.
- If the INR calibrator is not used for calculation parameter 1, follow the steps below.
 1. Perform Standard Curve analysis for calculation parameter 3 (INR) with the INR calibrator.
 2. Make a note of the normal value and calculated ISI.
 3. Set the calculation method for calculation parameter 3 to “ISI input”.
 4. Perform Standard Curve analysis for calculation parameter 1 with the activity percentage or concentration calibrator.
 5. Manually input ISI and normal value of 2 above.

9.4 Manual Entry

Set Standard Curve data manually using the numeric keys. Normal PT value and ISI value is entered manually at this stage.

1. Display the Standard Curve data of the desired parameter.
For detail, Refer to “9.1 Display Standard Curve”.
2. Press **[Manual Entry]** key on the Standard Curve Data screen to display the Manual Entry screen.



3. Press the Standard Curve data on the numeric keys.
As to the parameters requiring calculation (PT ratio, PT-INR, etc.), enter the normal value and the ISI value. The cursor can be moved by pressing **[↑]** and **[↓]** keys.



Caution!

- ISI values for prothrombin time assays must be entered directly as they appear on the current reagent labeling. Any changes of reagent lot, software upgrades, major servicing, etc., require verification of the ISI value. Failure to enter the correct ISI value will cause incorrect International Normalized Ratio (INR) results.
- If the ISI value of a different lot is input, the correct INR may not be obtained.



Note

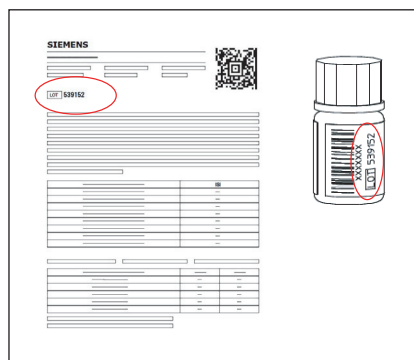
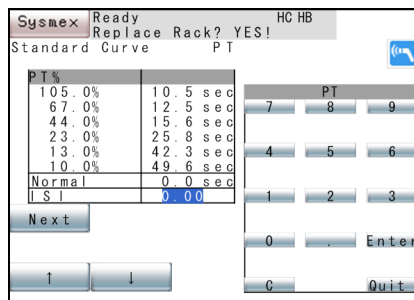
- When the Standard Curve data is zero (0), it is judged as no setting.
- In entering data, press numeric keys, then confirm by pressing **[Enter]** key.

Normal value and ISI value can also be entered by hand-held barcode reader (optional).



Note

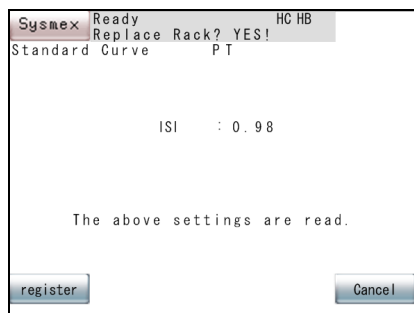
To use the hand-held barcode reader, it is necessary to make the connection setting to “Connected”.



If the hand-held barcode reader is connected, an icon indicating that hand-held barcode reader is ready to read appears on the upper right of the screen.

i Information

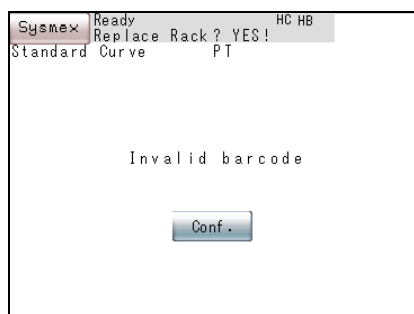
- Check that the label lot No. of the reagent is the same as that in ISI value table attached, and then read the barcode of the ISI value table.
- Barcodes can be used only for the samples produced by Sysmex or Siemens. Normal value and ISI value table is not attached to some reagents.
- When the reagent lot changes and becomes different from the one used to create the standard curve, change the lot number of the reagent information and set the standard curve again. When setting the standard curve, check the ISI value, normal value of PT and calibrator value of the calibrator, and change those values if necessary.



If the ISI value of the HC reagent is read normally, a confirmation screen appears.

Press the **[Register]** key on the confirmation screen to enter the values and return to the Manual Entry screen.

Press the **[Cancel]** key to cancel the entry, discard the values and return to the Manual Entry screen.



If the barcode read is of a different reagent, an error screen appears. Press the **[Conf.]** key to return to the Manual Entry screen.

- Enter the PT reagent lot specific normal value using the numeric keys.



Note

Typically, the value table of the PT reagent does not contain the normal value.

| PT % | | 10.5 sec | Replic. |
|--------|--------|----------|---------|
| M | 105.0% | 10.5 sec | 2 |
| M | 67.0% | 12.5 sec | 2 |
| M | 44.0% | 15.6 sec | 2 |
| M | 23.0% | 25.8 sec | 2 |
| M | 13.0% | 42.3 sec | 2 |
| M | 10.0% | 49.6 sec | 2 |
| Normal | | 0.0 sec | |
| ISI | | 0.98 | |

Buttons: Next, Graph, Quit, Set, Continue

- Press **[Quit]** key on the numeric keys.

The screen for checking whether to use entered data as the standard curve is displayed.

[Continue] key: Returns to the Manual Entry screen.

[Set] key: Sets the entered data as Standard Curve data and returns to the Standard Curve screen.

[Quit] key: Discards the entered data and returns to the Standard Curve screen.

[Next] key: Displays the Setting screen for a different calculation parameter.



Information

When **[Set]** key is pressed, the standard curve that was used up to that time is automatically saved to a backup file. (Refer to “9.5 Standard Curve Files”.)

Press **[Graph]** key to confirm the new Standard Curve (solid line with square plots).

For detail, refer to “9.2 Standard Curve Analysis”.

9.5 Standard Curve Files

This section explains how to work with standard curve files.

| % | sec | Lot.No | EXP |
|-------|-------|---------|------------|
| 129.0 | 66.5 | VIII | 12/20/2012 |
| 86.0 | 72.0 | PTT FSL | 12/20/2012 |
| 43.0 | 82.4 | CaCl2 | 12/20/2012 |
| 21.5 | 92.0 | OVB | 12/20/2012 |
| 10.8 | 104.5 | Calibr. | 12/20/2012 |
| 0.0 | 0.0 | | |

Buttons: Load File, Save File, Graph, Print, Return

For each measurement parameter, standard curve information (standard curve data, ISI, normal values, reagent information, calculation parameter settings) is stored in a standard curve file and can be loaded.

The standard curve file contains all information on the standard curve.

Displaying Standard Curve Files

| % | | sec | Reagent | Lot. No | EXP. |
|-------|-------|---------|---------|---------|------------|
| 129.0 | 66.5 | VIII | | | 12/20/2012 |
| 86.0 | 72.0 | PIT FSL | | | 12/20/2012 |
| 43.0 | 82.4 | CaCl2 | | | 12/20/2012 |
| 21.5 | 92.0 | OVB | | | 12/20/2012 |
| 10.8 | 104.5 | Calibr. | | | 12/20/2012 |
| 0.0 | 0.0 | | | | |

Standard Curve VIII File No.1(1/4)
 Cal Date 06/03/2012

Load File Save File
 Graph Print Return

- Press **[STD File]** key on the Standard Curve screen.
The Factor VIII standard curve file No.1 is displayed.

- (M): Displayed when some of standard curve data is manually input.
- Cal Date: This is the date on which the standard curve was set, not the date on which the standard curve file was saved.
- Reagent Name: Name of reagent
- Lot No.: Lot No. of reagent (up to 12 digits)
- EXP.: Expiry date of a reagent



Information

In the standard curve file, the file name and page number are stated in the upper right of the screen.

- Manually-saved file
 - File No.1 (1/4)
 - File No.2 (2/4)
 - File No.3 (3/4)
- Automatically-saved file
 - Backup (4/4)

<Standard Curve Data>

Activity/Concentration:

Percent activity or concentration.

Coagulation Time - Reaction Speed:

Coagulation time or reaction speed for 6-point activity or concentration.

Normal: Normal value used for finding the ratio.

ISI: International Sensitivity Index to calculate INR

Setting Standard Curve

- Press [->] key on the Standard Curve File screen.
On the Standard Curve File screen, use [->] and [-<] keys to move between pages of the standard curve file.
The display content of the Standard Curve File screen is as shown below.

| Sysmex | | Ready | Replace Rack? YES! | HC |
|----------------|-------|---------------------|--------------------|----|
| Standard Curve | | VIII | File No. 2(2/4) | |
| VIII% | | Cal Date 07/23/2012 | | |
| % | sec | Lot.No | EXP. | |
| 129.0 | 66.7 | VIII | 12/31/2012 | |
| 86.0 | 72.1 | PTT FSL | 12/31/2012 | |
| 43.0 | 82.2 | CaCl2 | 12/31/2012 | |
| 21.5 | 92.9 | OVB | 12/31/2012 | |
| 10.8 | 104.0 | Calibr. | 12/31/2012 | |
| 0.0 | 0.0 | | | |

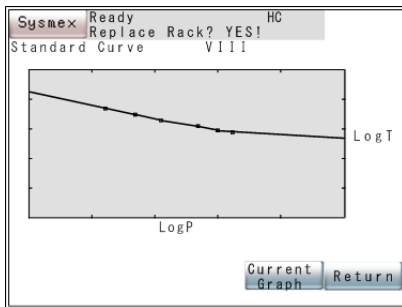
Load File Save File ← →

Graph Print Return

[-<] and [->] keys: Switch pages.

[Next] key: The Settings screen for the next calculation parameter will appear.

Press [Graph] key to check the graph of the standard curve file (the plot is a square solid line).



Press [Current Graph] key to display the standard curve graph currently in use.

Press it again to remove the standard curve graph currently in use (the graph in which the plot is a triangle of dotted lines) from the screen and switch to just the graph of the standard curve file.

Saving Standard Curve Files

| Sysmex | | Ready | Replace Rack? YES! | HC |
|----------------|-------|---------------------|--------------------|----|
| Standard Curve | | VIII | File No. 2(2/4) | |
| VIII% | | Cal Date 06/03/2012 | | |
| % | sec | Lot.No | EXP. | |
| 129.0 | 66.7 | VIII | 12/20/2012 | |
| 86.0 | 72.1 | PTT FSL | 12/20/2012 | |
| 43.0 | 82.2 | CaCl2 | 12/20/2012 | |
| 21.5 | 92.9 | OVB | 12/20/2012 | |
| 10.7 | 104.0 | Calibr. | 01/31/2013 | |
| 0.0 | 0.0 | | | |

STD Standard Manual More
File Analysis Entry

Select Test Graph Print Lot No. Main Menu
Entry

The standard curve information currently in use is overwritten by the selected standard curve file.

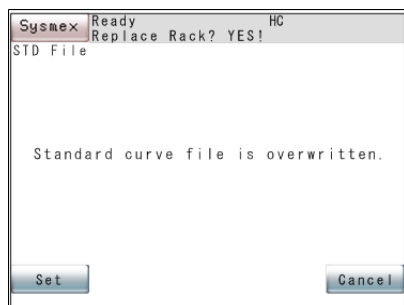


Caution!

The standard curve information for all calculation parameters (PT, activity %, INR and dFbg) is saved and loaded as a set.

It is not possible to save and load standard curve information for individual calculation parameters.

- From the Standard Curve Data screen, display the measurement parameters to save on that screen.
For the display methods for the Standard Curve Data screen, refer to “9.1 Display Standard Curve”.
- Press [STD File] key on the Standard Curve Data screen.
Select the standard curve file to save.
Use [->] and [-<] keys to make the selection.



- Press **[Save File]** key on the Standard Curve File screen. The Standard Curve Save screen will appear.

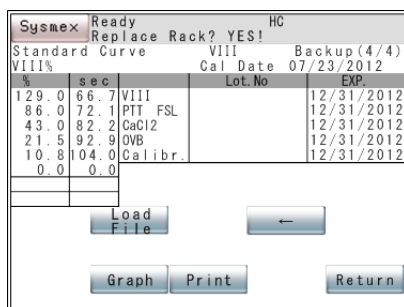
[Set] key: Saves the data of the standard curve currently in use to the displayed standard curve file and returns to the Standard Curve Data screen.

[Cancel] key: Does not save the data to the standard curve file and returns to the Standard Curve Data screen.

i Information

The standard curve that was used up to that time is automatically saved to a backup file. It is not possible to save manually to a backup file.

Automatic Backup



When standard curve information is updated, the standard curve information that was used up to that time is saved to a backup file.

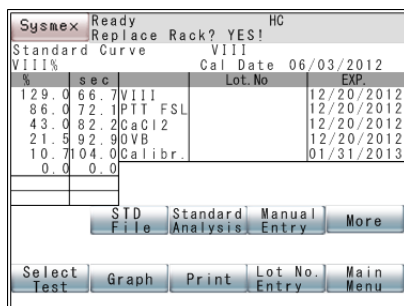
The following operations update the standard curve information:

- When a standard curve analysis was performed and the standard curve was updated
- When a standard curve was entered manually and the standard curve was updated
- When a standard curve file was loaded

i Information

An automatic backup file will not be saved only by updating reagent information or parameter settings.

Loading Standard Curve Files

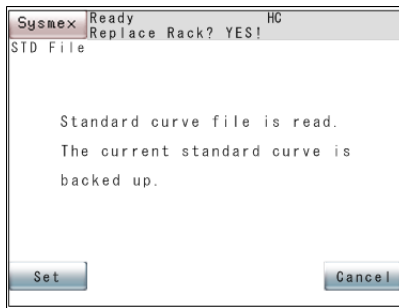


The displayed standard curve file is loaded as the standard curve data in use.

! Caution!

The standard curve information for all calculation parameters (PT, activity %, INR and dFbg) is saved and loaded as a set. It is not possible to save and load standard curve information for individual calculation parameters.

Setting Standard Curve



1. From the Standard Curve Data screen, display the measurement parameters to load on the Standard Curve Data screen. For the display methods for the Standard Curve Data screen, refer to “9.1 Display Standard Curve”.
2. Press **[STD File]** key on the Standard Curve Data screen. Select the standard curve file to be loaded. Use **[->]** and **[<-]** keys to make the selection.
3. Press **[Load File]** key on the Standard Curve File screen. The Standard Curve Load screen will appear.

[Set] key: Loads the displayed standard curve data as the standard curve data in use and returns to the Standard Curve Data screen.

[Cancel] key: Does not load the data to the standard curve data in use and returns to the Standard Curve Data screen.



Caution!

It may not be possible to obtain accurate analysis results if information for a different lot is loaded.



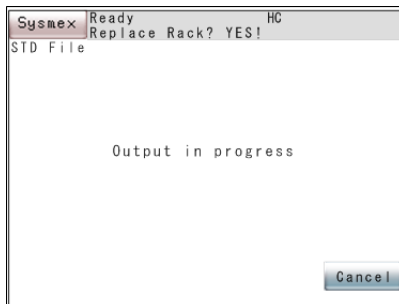
Information

The standard curve that was used up to that time is automatically saved to a backup file.

Printing Standard Curve Files

The displayed standard curve file can be printed by the built-in printer by the following procedure:

1. From the Standard Curve Data screen, display the measurement parameters to print on that screen. For the display methods for the Standard Curve Data screen, refer to “9.1 Display Standard Curve”.
2. Press **[STD File]** key on the Standard Curve Data screen. From the Standard Curve File screen, select the standard curve file to load. Use **[->]** and **[<-]** key to make the selection.
3. Press **[Print]** key on the Standard Curve File screen. The message "Output in progress" is displayed during printing. Press **[Cancel]** key during printing to cancel printing and return to the Standard Curve Data screen.



Note

Expression, correlation, rate and offset are not printed in standard curve file data.

9.6 Set Reagent Information

Set Lot Nos. and Expiry dates of analysis reagent, reference plasma and diluents.

When the expiry date has passed, the message “Check Reagent Expiry” will appear at start of analysis.



Caution!

When the reagent lot changes and becomes different from the one used to create the standard curve, change the lot number of the reagent information and set the standard curve again.

When setting the standard curve, check the ISI value, normal value of PT and calibrator value of the calibrator, and change those values if necessary.

1. Press **[Lot No. Entry]** key on the Standard Curve Data screen.
The Lot No. Entry Menu screen will appear.
2. Press **[Reagent1]** key, **[Reagent2]** key, etc. depending on which reagent you want to set.

Lot No. Entry screen (character key screen) will appear.

| Sysmex Ready HC | | Replace Rack? YES! | |
|-----------------|------|--------------------|------------|
| Standard Curve | | PT | |
| PT% | (M) | Cal Date | 11/10/2008 |
| 105.0 | 10.5 | PT INN | 12/31/2008 |
| 67.0 | 12.5 | | |
| 44.0 | 15.6 | | |
| 23.0 | 25.8 | OVB | 01/31/2009 |
| 13.0 | 42.3 | Calibr. | 01/31/2009 |
| 10.0 | 49.6 | | |
| Normal | 10.6 | | |
| ISI | 1.00 | | |

Dil

Reagent1 Calibrat or Return



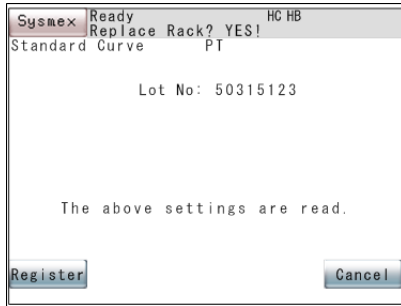
Note

Regarding reagent selection key (**[Reagent1]** key etc.) in the lower part of the screen, the number of the reagents set by **[Settings]** → **[Analysis Settings]** → **[Test Protocol]** is displayed.

3. Enter Lot No.
[CHG.] key: Each time this key is pressed, character changes in the order of capital alphabet → small alphabet → numeric keys.
[BS] key: Deletes one character to the left of the cursor.

| Sysmex Ready HC | | Replace Rack? YES! | |
|-----------------|------|--------------------|-------|
| Standard Curve | | PT | |
| Lot.No | | | |
| A | B | C | D |
| E | F | G | H |
| I | J | K | L |
| M | N | O | P |
| Q | R | S | T |
| U | V | W | Enter |
| X | Y | Z | BS |
| CHG. | Quit | | |

Setting Standard Curve



When the reagent lot No. is read correctly from a ID barcode, a confirmation screen is displayed.

Press **[Register]** key on the confirmation screen to input the value and return to the Lot No. Entry screen (character key screen).

Press **[Cancel]** key to cancel input, discard the value, and return to the Lot No. Entry screen (character key screen).



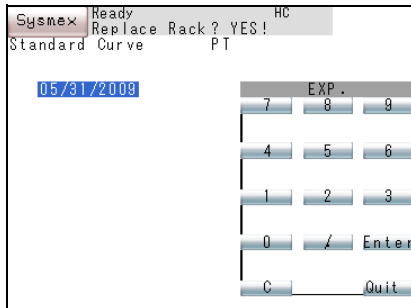
Caution!

- The barcode ID stuck to the reagent vial and the reagent lot No. are not the same.
- After reading the barcode, check the reagent lot No. Change it if necessary.

4. Press **[Enter]** key.

Then EXP. Entry screen will appear.

5. Enter the expiry date.



Note

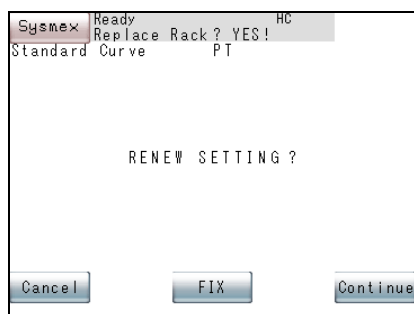
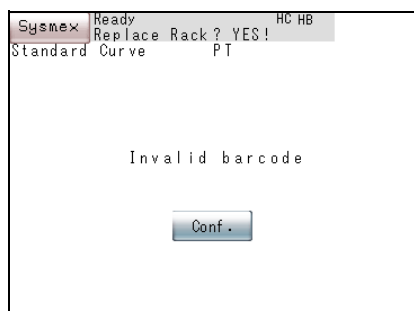
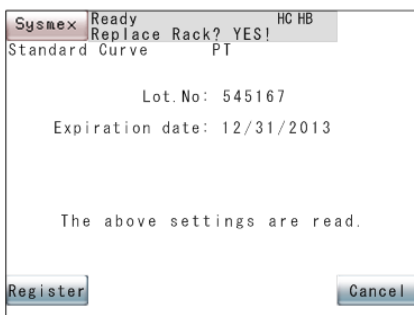
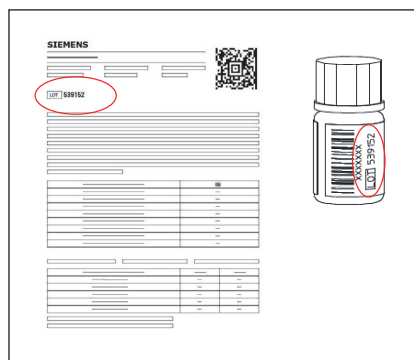
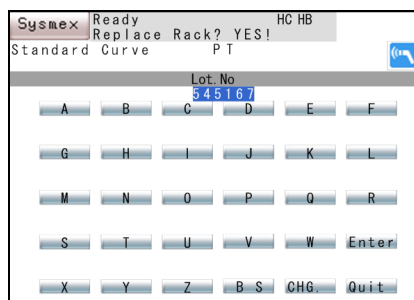
- Enter the expiry date in the format set in System Setting - Date format; include “/” between numerals.
- When **[Enter]** key is pressed, the Lot No. Entry screen will return.

Lot No. and expiry date can also be entered by hand-held barcode reader (optional).



Note

To use the hand-held barcode reader, it is necessary to make the connection setting to “Connected”.



An icon indicating that hand-held barcode reader is ready to read appears on the upper right of the screen.

i Information

- Barcodes can be used only for the samples produced by Sysmex or Siemens.
- When the reagent lot changes and becomes different from the one used to create the standard curve, change the lot number of the reagent information and set the standard curve again.
- The barcode with lot information and expiry date is not attached to some reagent.

When the reagent lot No and expiry date are read correctly from a 2D barcode, a confirmation screen appears.

Press the **[Register]** key on the confirmation screen to enter the values and return to the Lot No. Entry screen.

Press the **[Cancel]** key to cancel the entry, discard the values and return to the Lot No. Entry screen.

If the barcode read is of a different reagent, an error screen appears. Press the **[Conf.]** key to return to the Lot No. Entry screen.

6. To stop expiry date entry, press **[Quit]** key. The Lot No. Entry Menu screen will appear.

7. Press **[Cancel]** key on the Lot No. Entry Menu screen. The Renew Confirmation screen will appear.

[Continue] key: Returns to the Lot No. Entry Menu screen.

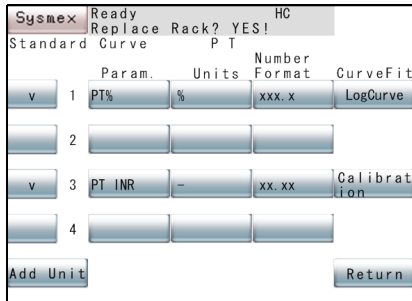
[FIX] key: Renews the setting and returns to the Standard Curve Data screen.

[Cancel] key: Discards the setting and returns to the Standard Curve Data screen.

9.7 Set Calculation Parameters

The parameters requiring calculation are set. Examples are PT% and PT-INR.

Depending on a unit selected, a corresponding decimal point mode is automatically used.



1. Press **[Select Param.]** key on the Standard Curve Data screen.

The contents of the settings will appear.

The contents in the display screen are:

- “v” Mark: Yes --- Indicates that the setting is valid.
No ---- Indicates that the setting is invalid.
- CalcItem 1: Calculation item equivalent to percent activity (concentration)
- CalcItem 2: Item for calculating ratio
- CalcItem 3: Item for calculating INR
- CalcItem 4: Item for calculating dFbg (Displayed only when dFbg is set for PT.)
- Units: - (No units), %, mg/dL, g/L, U/mL, INR, µg/mL, µg/L, IU/mL, mg/L
- Number Format: Depending on a unit selected, a corresponding decimal point mode is automatically used. Manual setting is also possible.

| | |
|-------|--------|
| - | XX. XX |
| % | XXX. X |
| mg/dL | XXXX |
| g/L | X. XXX |
| U/mL | XX. XX |
| INR | XX. XX |
| µg/mL | XXX. X |
| µg/L | XXXX |
| IU/mL | XX. XX |
| mg/L | XX. XX |



Note

The decimal point mode selected here is also applied to the data stored in the memory.

Curve Fit: Indicates calculation method.

- CalcItem 1: Log Curve: Log-log polygonal line
- Log Lin: Log-log linear approximation
- Lin-Lin: Real number - real number linear approximation

Lin PT-PT: Real - real linear approximation (or polygonal line)

AKIMA: Akima method interpolation

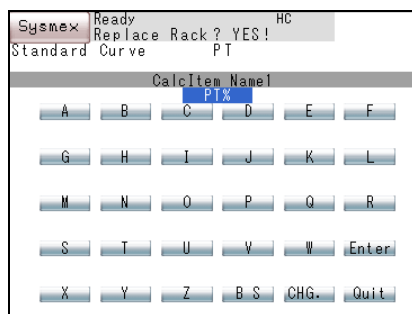
AKIMA(0): Akima method interpolation

CalcItem 3: ISI Input: Input ISI value
Calibration: Use calibrator for INR



Note

To create a Standard Curve by following the procedures of “9.3 INR Manual Dilution Analysis”, set CalcItem3 to “Calibration”. If “ISI Input” is selected, INR is calculated based on the ISI value and normal value which were set in “9.4 Manual Entry”. When the AKIMA method is selected, set up the dilution ratio that covers a measurement range equally. Please note that the measuring range must be defined in raw values (dOD or seconds) and not in concentration units. Otherwise the reading of the concentration results from the standard curve might be incorrect.



2. Validate Calc Item.

Press the key on the left of CalcItem 1 - 3 to display “v”.

3. Register the calculation parameter name.

Press **[Param.]** key to display character key screen.

Press a character key and fix using **[Enter]** key.

A name with a maximum of 7 characters can be set.

[CHG.] key: Each time this key is pressed, characters change in the order of capital alphabet → small alphabet → numeric keys.

[BS] key: Deletes one character to the left of the cursor.

4. Select units.

Each time **[Units]** key is pressed, units change over. Each time the unit is selected, “Number Format” is displayed.



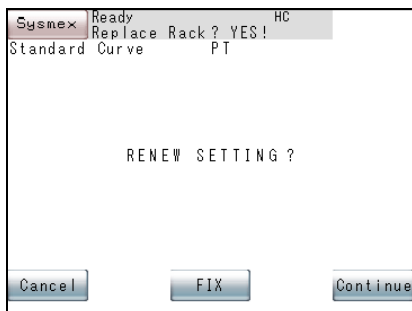
Note

Units can be added. Refer to “How to Add Unit” described later for details.

5. Select calculation method.

Press a calculation method desired.

Setting Standard Curve



- To quit selection of parameters, press **[Return]** key.

When changes are made in settings, the Renew Confirmation screen appears.

When no changes are made in settings, the Standard Curve screen returns.

[Continue] key: Returns to the Select Param. screen.

[FIX] key: Renews the settings and returns to the Standard Curve Data screen.

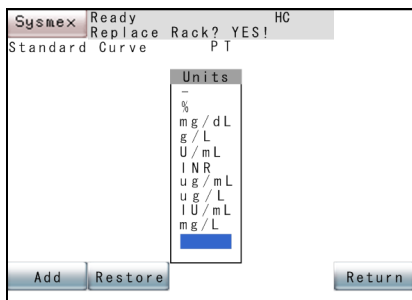
[Cancel] key: Discards the settings and returns to the Standard Curve Data screen.



Caution!

If calculation parameters are changed after the plotting of a Standard Curve, data coordination will become impossible. When calculation parameters are changed, always perform standard curve analysis again.

How to Add Unit



- Press **[Add Unit]** key to display the units currently registered.

[Add] key: Displays character key screen for entering units.

[Restore] key: Deletes an added unit.

[Return] key: Quits unit adding.

- Press **[Add]** key to enter a unit from the character key screen.

[CHG.] key: Each time this key is pressed, characters change in the order of capital alphabet → small alphabet → numeric keys.

[BS] key: Deletes all data.

- Press **[Enter]** key.

- To end addition of units, press **[Quit]** key.

When settings are changed, the Renew Confirmation screen appears.

When no changes are made in settings, the Units Display screen returns.

[Continue] key: Returns to the Units Display screen.

[FIX] key: Renews the settings and returns to the Select Param. screen.

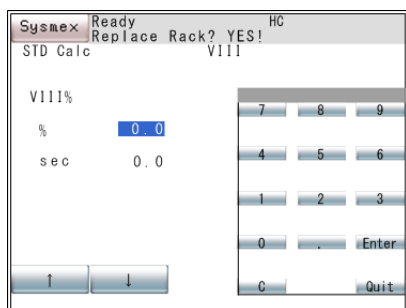
[Cancel] key: Discards the settings and returns to the Select Param screen.



Note

9 different units are registered at time of shipment.
- (No Unit), %, mg/dL, g/L, U/mL, INR, µg/mL, µg/L, IU/mL
A maximum of 12 different units can be set.

9.8 Standard Curve Conversion



This section explains how to convert standard curves. Standard curve information can be used for conversion.

1. Press **[STD Calc]** key on the Standard curve screen.
The Standard Curve Conversion screen will display the numeric keys to enter calculation parameter values.



Information

If there is no valid calculation parameter, **[STD Calc]** key will not appear.

2. Enter the calculation parameter value, then press **[Enter]** key.
The value entered at the cursor position will be displayed. The converted value is displayed at the upper or lower level.

[↑] key: Moves the cursor up by one row.
When the cursor is on the top line, it moves to the bottom line.

[↓] key: Moves the cursor down by one row.
When the cursor is on the bottom line, it moves to the top line.

[Next] key: The screen for the next calculation parameter will appear.

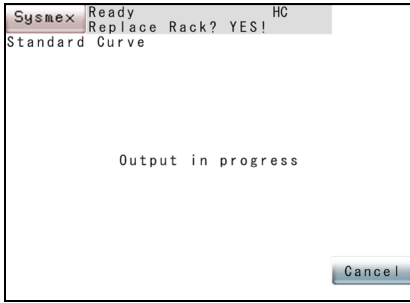
3. Press **[Quit]** key on the numeric keys.
The Standard Curve Data screen returns.



Information

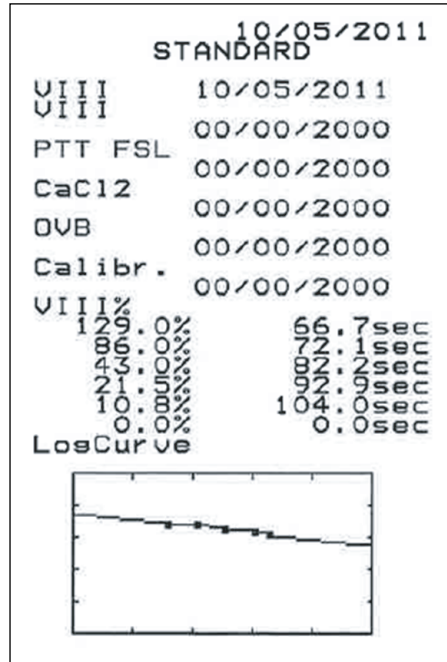
- Standard curves for which the calculation method was AKIMA or AKIMA(0) cannot be converted.
- The converted value is displayed as "" in the following cases:
 - When the calculated second count or dOD value is negative
 - When the converted value overflows
 - When divide by zero occurs in the conversion
- The converted value is displayed as "0" in the following cases:
 - When the calculated concentration or activity % value is negative

9.9 Print Standard Curve



1. Press **[Print]** key on the Standard Curve Data display screen.
During printout, the message “Output in progress” is displayed.

Example of printout



Note

When the calculation method is set to “Log Lin” or “Lin-Lin”, expression, correlation, rate, and offset are printed out.

| | | |
|------------|--|-------------|
| 10. | Instrument Setup | 10-1 |
| 10.1 | General Information | 10-1 |
| 10.2 | Setup of Automatic Transfer/Printout | 10-2 |
| 10.3 | Judgment on Analysis Result | 10-4 |
| 10.4 | Replication Range | 10-6 |
| 10.5 | Report Limit | 10-7 |
| 10.6 | Setup of Test Name | 10-8 |
| 10.7 | Reagent Name | 10-9 |
| 10.8 | Test Protocol | 10-10 |
| 10.9 | Replication | 10-19 |
| 10.10 | Setup of Test Group | 10-20 |
| 10.11 | Reagent Holder | 10-21 |
| 10.12 | Setup of Reagent Volume Monitoring | 10-23 |
| 10.13 | Setting of Conversion Formula | 10-24 |
| 10.14 | Devices to be connected | 10-24 |
| 10.15 | Setup of System | 10-27 |
| 10.16 | Password Settings | 10-28 |
| 10.17 | Printout of Settings | 10-30 |
| 10.18 | Addition of New Analysis Parameters | 10-31 |
| 10.19 | Reagent Name/Holder List | 10-32 |



10. Instrument Setup

10.1 General Information

The instrument will be installed and set up by your local service representative. However, the setup program can be utilized to change settings of the instrument.

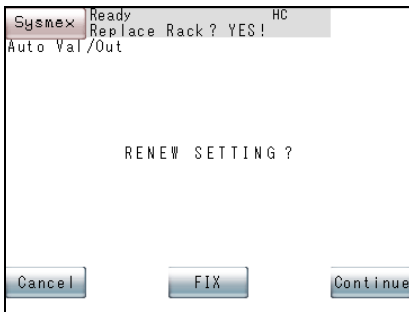
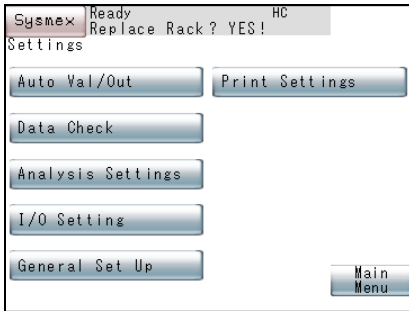
This chapter describes how to apply this setup program.

- Setup of Automatic Transfer/Printout
This program allows setting of those samples whose data will be automatically transferred and printed out.
- Judgment on Analysis Result
This program allows setting the upper and lower limits in attaching flags to analysis results.
 - Mark Limits
 - Replication range
 - Report Limits
- Analysis Setup
Analysis settings on parameters, reagents, etc. can be made.
 - Set Test Name
 - Set Reagents Name
 - Test Protocol
 - Set Replication
 - Test Group
 - Reagents Holder
 - Alarm Settings
 - Conversion
- Devices to be Connected
External device conditions, including host computer interface conditions and barcode scanner usage conditions, can be set up.
- Setup of System
System status can be set up:
 - Date/Time
 - Date format
 - Password
- Printout of Settings
The settings can be printed out by the built-in printer.

Basic Operation of Setup Program

Follow the procedure shown below to display each setting screen, and change the set values.

1. Press **[Special Menu]** key on the Main Menu screen.
The contents of the Main Menu will change over.
2. Press **[Settings]** key on the Main Menu screen.
The Setting Menu screen will appear.
3. Press a key for parameter to be set.
The screen for setting a desired parameter will appear.
4. Perform setting as required.
5. When the setting is completed, press **[Quit]** key or **[Return]** key.
The Renew Confirmation screen will appear.



6. Press **[FIX]** key, **[Continue]** key, or **[Cancel]** key.
[FIX] key: Changes to the renewed setting and returns to the Setting Menu screen.
[Continue] key: Returns to the original setting screen and allows continued operation.
[Cancel] key: Cancels the renewed setting and returns to the Setting Menu screen.

10.2 Setup of Automatic Transfer/Printout

With this program, it is possible to set samples whose data can be automatically transferred or printed out after completion of analysis. Instructions of automatic transfer/printout can be sent to the IP (built-in printer) and HC (host computer).

1. Press **[Auto Val/Out]** key on the Setting Menu screen.
The Auto Val/Out Setting screen will display the output samples currently specified.
“v” mark is displayed in the output sample keys that are set.



Note

When Host Computer Status is set “Not Connected”, the keys for HC will not appear.

| | | |
|--------------------|----------|--------|
| Sysmex | Ready | HC |
| Auto Val/Out | | |
| Replace Rack? YES! | IP | HC |
| Within Limit | v | v |
| Out of Limit | | |
| Error Flag | | |
| QC Sample | | |
| Format | No Graph | Return |

- Press the sample key you want to set. That key will be marked with “v” which sets the sample.

Unless all samples are marked with “v”, automatic transfer/printout is not performed.



Note

“v” mark appear and disappear alternately each time the key is pressed.

The samples that can be specified are shown below. Output samples can be set for both of IP (built-in printer) and HC (host computer).

Within Limit: Analysis data of a sample which has no abnormality and error (QC and Standard Curve samples excluded)

Out of Limit: Analysis data of a sample which exceeded Mark Limits (QC and error samples excluded)

Error Flag: Analysis data of a sample that developed some error during analysis (QC and Standard Curve samples excluded)

QC Sample: Analysis data measured for QC and standard curve setting

- Set a printout format for automatic printout by IP (built-in printer).

The Format will change over each time the key is pressed as follows:

- Print + Graph:** The parameter data is automatically printed out in list format and graph.
- No Graph:** The parameter data is automatically printed out in list format (data, time, sample ID, rack position, result).
- Analysis:** The parameter data is automatically printed out in analysis format (detailed coag. curve information and graph).
- Auto + Graph:** When an error such as “Coag Curve Error” etc. occurs on a parameter, the parameter data with graph is automatically printed out in analysis format.
- Auto No Graph:** When an error such as “Coag Curve Error” etc. occurs on a parameter, the parameter data without graph is automatically printed out in analysis format.

- When setting is completed, press **[Return]** key.

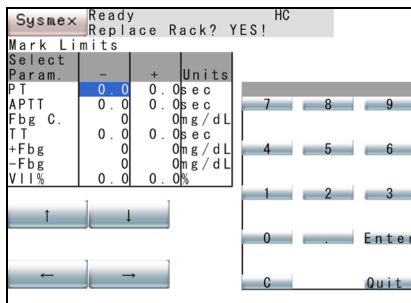
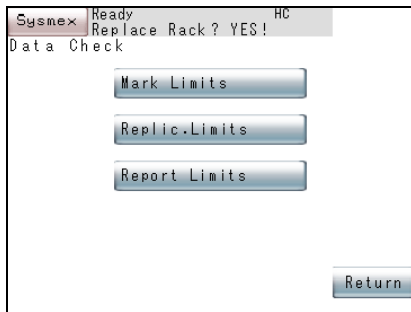
The Renew Confirmation screen will appear. Press the appropriate key.

10.3 Judgment on Analysis Result

This program allows setting the normal range upper and lower limits as Mark Limits, and setting also parameters for those limits.

Any analysis data exceeding the upper or lower Mark Limits is flagged with “+” or “-” signs, respectively.

How to Set Mark Limits



1. Press **[Data Check]** key on the Setting Menu screen.
The Data Check Menu screen will appear.
2. Press **[Mark Limits]** key on the Data Check Menu.
The Mark Limit Setting screen will display the currently-set Mark Limits.
3. Using **[↑]** key, **[↓]** key, **[←]** key, or **[→]** key, move the cursor to select limit values to be set.
Move the cursor to a limit value to display the numeric keys.
Move the cursor to the lowermost position, and press **[↓]** key to display the next page.
4. Using the numeric keys, enter the limit values and press **[Enter]** key.
The limit value in the current cursor position is set and the cursor moves to the next limit value to be set.



Note

- When the lower limit value (-) is greater than the upper limit value (+), judgement is handled in the following manner.
 - “-” mark if value > entered lower limit value
 - No mark if value ≤ entered lower limit value and value ≥ entered upper limit value
 - “+” mark if value < entered upper limit value

Example:

When 200 is set for the lower limit (-) and 100 for the upper limit (+), a value exceeding 200 is marked “-” and a value less than 100 is marked “+”.

No mark is put on any value between 100 and 200.

**Note**

- When “0” is assigned to both upper and lower limits or an identical value is assigned to both the upper limit (+) and lower limit (-), judgment is not made.
- Abnormal flags are displayed according to the following priority.
 1. *
 2. <, >
 3. +, -

5. When setting is completed, press [**Quit**] key.

The Renew Confirmation screen will appear. Press the appropriate key.

How to Select Parameters

1. Display the Mark Limit Setting screen.

For key operation, refer to “How to Set Mark Limits”.

2. Move the Cursor to “Select Param”.

The [**Next Option**] key will appear on the Mark Limit Setting screen.

3. Press [**Next Option**] key.

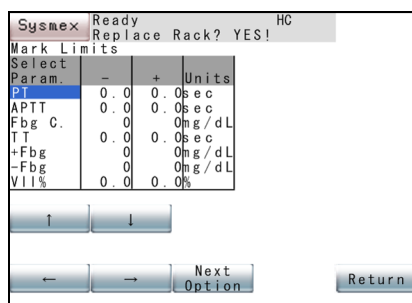
Options that can be set as parameters will be displayed. Those options are the parameters and coagulation time that are selected in Standard Curve Parameter setting.

4. Specify an optional parameter.

When a parameter is changed, the units will automatically change.

5. When setting is completed, press [**Quit**] key.

The Renew Confirmation screen will appear. Press the appropriate key.

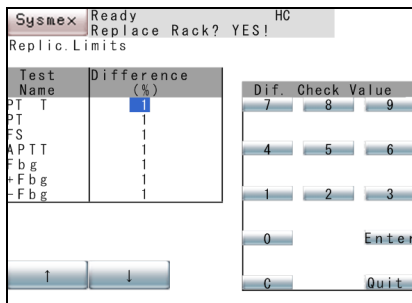
**Note**

- Judgement is not performed if the “v” mark is removed (parameters not used) from a set parameter when standard curve parameters are set. Parameters set here are common with parameters set for Report Limit.
- The parameters linked to the standard curve are selected from the linked parameters which are valid.

10.4 Replication Range

This program allows setting the upper limit ratio for replication range. For analysis parameters for which the analysis count is 2 or more, the mean values for seconds and $\Delta OD/min$ in analysis results are calculated. When the difference between each analysis result and the mean falls beyond the upper limit of replication range, that analysis result is interpreted to have become disparate and the “*” mark is attached to the mean value.

1. Press **[Data Check]** key on the Setting Menu screen.
The Data Check Menu screen will appear.
2. Press **[Replic. Limits]** key on Data Check Menu screen.
The Replic. Limit Setting screen will display the currently-set replication range.



3. Using **[↑]** and **[↓]** keys, move the cursor to select analysis parameters.

Move the cursor to the lowermost position, and press **[↓]** key to display the next page.



Note

Replication range can be set for seconds and $\Delta OD/min$ of analysis results. It cannot be set for calculation parameters.

4. Using the numeric keys, enter the replication range and press **[Enter]** key.

Settings in the cursor position will be set and the cursor will move to the next parameter to be set.



Note

When “0” is set, the replication range will not be judged.

5. When setting is completed, press **[Quit]** key.

The Renew Confirmation screen will appear. Press the appropriate key.

10.5 Report Limit

This program allows setting the upper and lower limits of Report Limit. When analysis result exceeds the upper limit of Report Limit, “>” will appear and when the result exceeds the lower limit, “<” will appear.



Note

Judgment parameters can be selected in the **[Settings]** → **[Data Check]** → **[Mark Limits]** program. Refer to “10.3 Judgment on Analysis Result”.

| Param | < | > | Units |
|--------|-----|------|-------|
| PT | 0.0 | 0.0 | sec |
| APTT | 0.0 | 0.0 | sec |
| Fbg C. | 5.0 | 45.0 | mg/dL |
| TT | 0.0 | 0.0 | sec |
| +Fbg | 100 | 90.0 | mg/dL |
| -Fbg | 2.5 | 2.25 | mg/dL |
| Vil% | 0.0 | 0.0 | % |

1. Press **[Data Check]** key on the Setting Menu screen.
The Data Check Menu screen will appear.
2. Press **[Report Limits]** key on Data Check Menu screen.
The Report Limit Setting screen will display the currently-set Report Limits.
3. Using **[↑]**, **[↓]**, **[←]** and **[→]** keys, move the cursor to specify a parameter to be set.
Move the cursor to the lowermost position, and press **[↓]** key to display the next page.
4. Using the numeric keys, enter the report limits and press **[Enter]** key.
Settings in the cursor position will be set and the cursor will move to the next parameter to be set.



Note

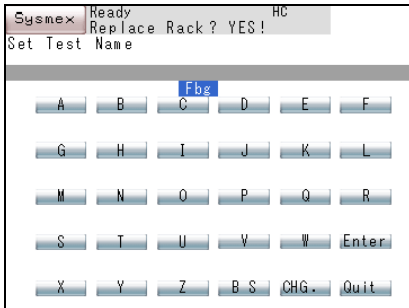
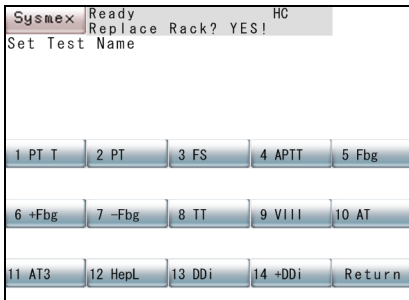
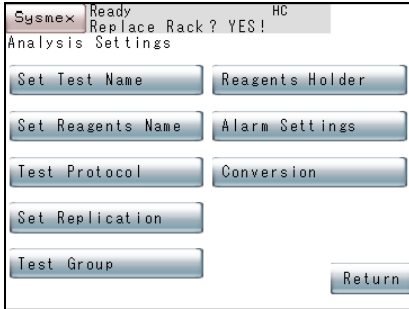
- If the value is set to “0”, Report Limit judgement will not be made.
- When both upper and lower limits are identical, judgment will not be made.
- Abnormal flags are displayed according to the following priority.
 1. *
 2. <, >
 3. +, -

5. When setting is completed, press **[Quit]** key.
The Renew Confirmation screen will appear. Press the appropriate key.

10.6 Setup of Test Name

This program allows setting test name.

1. Press [**Analysis Settings**] key on the Setting Menu screen.
The Analysis Setting Menu screen will appear.
2. Press [**Set Test Name**] key on the Analysis Setting Menu screen.
The Test Name Selection screen will appear.



3. Press the key for setting test name.
The Test Name Setting screen will appear.
4. Enter the test name and press [**Enter**] key.
The test name entered will be set.
Each time you press [**CHG.**] key on the Test Name Setting screen, display mode will change in the order of English capital letters → English small letters → numeric keys.
5. When the test name is entered, press [**Quit**] key.
Screen returns to the Test Name Selection screen and you can continue the same procedure if additional setting is necessary.
6. When setting is completed, press [**Return**] key.
The Renew Confirmation screen will appear. Press the appropriate key.



Note

When [**FIX**] key is pressed to update the setting, and the same test name has been already set, a screen indicating that it is impossible to update will be displayed. When [**OK**] key is pressed, the Test Name Selection screen will appear. Reset a test name.

10.7 Reagent Name

This program allows setting reagent name.

1. Press [**Analysis Settings**] key on the Setting Menu screen.
The Analysis Setting Menu screen will appear.
2. Press [**Set Reagents Name**] key on the Analysis Setting Menu screen.

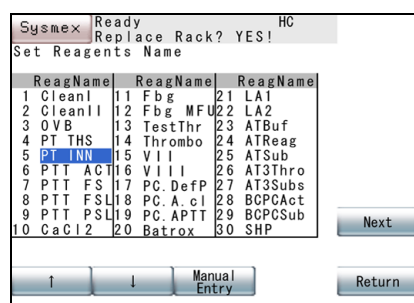
The Reagent Name Setting screen will display the names of the currently-set reagents.



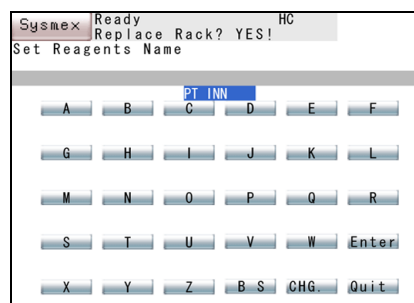
Information

If the reagent name is changed, the analysis result may change.

Fully confirm the name before changing. Only the use in the factory settings is covered by our warranty.



3. Using [**↑**] and [**↓**] keys, move the cursor to specify a reagent to be set.
If no reagent name is displayed, press [**Next**] key to display the next page.
4. Press [**Manual Entry**] key on the Reagent Name Setting screen.
The Reagent Name Entry screen will appear.



5. Enter the reagent name and press [**Enter**] key.
The reagent name entered will be set on the specified reagent holder.
Each time you press [**CHG.**] key on the Reagent Name Entry screen, display mode will change in the order of English capital letters → English small letters → numeric keys.
6. When the reagent name is entered, press [**Quit**] key.
Screen returns to the Reagent Name Setting Screen and you can continue the same procedure if additional setting is necessary.
7. When setting is completed, press [**Return**] key.
The Renew Confirmation screen will appear. Press the appropriate key.



Caution!

Do not set the reagent name to blank.



Note

When a reagent name that has been already set is entered, the renewed setting will be canceled, and the Reagent Name Setting screen will reappear. The cursor will be placed on the canceled reagent name.

10.8 Test Protocol

This program allows the test protocol and parameter codes to be set for each analysis parameter. It also allows parameters to be linked or unlinked to/from the standard curve..



Caution!

The user is responsible for any change of the test protocol, as the correct result might not be obtained.

How to Set Test Protocol

1. Press **[Analysis Settings]** key on the Setting Menu screen.

The Analysis Setting Menu screen will appear.

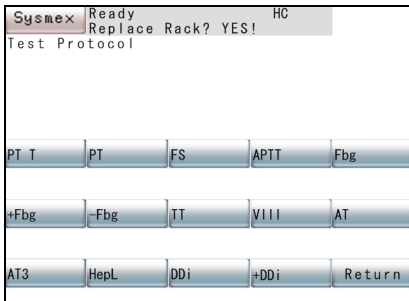
2. Press **[Test Protocol]** key on the Analysis Setting Menu screen.

The Analysis Parameter Selection screen will appear.

3. Press the key to select an analysis parameter

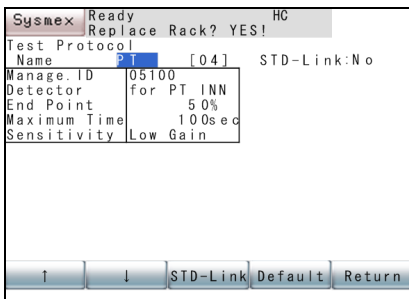
The Test Protocol Entry screen will appear.

When **[Return]** key is pressed, the Analysis Setting Menu screen will reappear.



4. Using **[↑]** and **[↓]** keys, move the cursor to specify a parameter to be set.

- To reset the test protocol to default setting
Press **[Default]** key, and select a test protocol to be reset to default setting. Refer to “Initialization of Test Protocol”.



Note

Please check any default setting loaded from the instrument's memory with regards to latest application information from the reagent manufacturer.

- Link of standard curve for analysis parameters
When a specified analysis parameter and other parameters are linked with standard curve, the following messages are displayed.
No: Other analysis parameters are not linked to the standard curve.
Master: Other analysis parameters are linked to the standard curve. (This parameter is the master.)
Analysis Parameter Name:
The indicated analysis parameter (master) is linked to the standard curve. For the link setting of standard curve, refer to “Link of Standard Curve”.

**Note**

How to set test protocol differs depending on the detection method.

- Clotting Method:
Coagulation detection point, maximum detection time, sensitivity
- Chromogenic Method and Immunoassay Method:
Start point, end point, sensitivity, wave length

5. Using [**D**etector], [**N**ext Option], [**S**elect Reagent], and numeric keys, enter the test protocol.

The details on the entry of the test protocol is as follows.

- 1) Parameter code:

Enter two digits of parameter code.

This code is used for communication with the host computer. Set the same code as for the host computer.

The factory default setting is shown below.

- Clotting Method

| | | | |
|----------|----------|---------|----------|
| 04: PT | 05: APTT | 06: Fbg | 17: VII |
| 18: VIII | 25: PCcI | 26: BXT | 27: LA1 |
| 28: LA2 | 50: +Fbg | 51: TT | 52: -Fbg |

- Chromogenic Method

| | | |
|-------------|----------|---------|
| 30: AT, AT3 | 33: BCPC | 34: Hep |
|-------------|----------|---------|

- Immunoassay Method

| | | | |
|----------------|---------|----------|----------|
| 61: DDPI, DDi | 65: vWF | 66: -vWF | 67: +vWF |
| 70: +DDP, +DDi | 80: WFa | 81: +WFa | 82: -WFa |



Information

The same parameter code cannot be set for more than one parameter.

2) Manage. ID

Sets the Management ID.



Information

The management ID is associated with the information of the barcode which is attached to the reagent, control, and calibrator.

If the management ID is changed to a different one, the correct value cannot be read from the barcode, and the correct analysis result may not be obtained.

3) Detector

Determines the detection method.

Press [**Analysis Method**] key to select the detection method.

For selection of the detection method, refer to "Selection of Detection Method".

4) End Point / Start Time

a) Sets a coagulation detection point for clotting methods. The coagulation detection point can be set in 1% increments within the range of 2% to 80%.

b) Sets the start time for evaluation on chromogenic or immunoassay methods. The start time can be set in 1-second increments within the range of 3 seconds to 600 seconds. In some cases for chromogenic or immunoassay methods, the entry of the start time may not be applicable. This is a feature of a V-Lin-Integral analysis method. Refer to "13.3 Detection Principle of Immunoassay Method" or ask your local service representative for additional information.

5) Maximum Time / End Time

a) Sets a maximum detection time for clotting methods. The maximum time can be set within the range of 100 seconds to 600 seconds.

b) Sets the end time for evaluation on chromogenic or immunoassay methods. The end time can be set in 1-second increments within the range of the analysis start point plus 15 seconds to 600 seconds. In some cases for chromogenic or immunoassay methods, the entry of the end time may not be applicable. This is a feature of a V-Lin-Integral analysis method. Refer to "13.3 Detection Principle of Immunoassay Method" or ask your local service representative for additional information

6) Sensitivity

Sets the sensitivity of the detector.

Press **[Next Option]** key to select the sensitivity.

- Low Gain
- High Gain

7) Wave length

Sets wave length of the light source. (Only for the Chromogenic Method or Immunoassay Method)

Press **[Next Option]** key to select wave length.

- 405 nm Inc. (Chromogenic)
- 405 nm Dec. (Chromogenic)
- 575 nm Inc. (Immunoassay)
- 575 nm Dec. (Immunoassay)



Information

- With the Chromogenic Method, set to 405 nm Inc.
- With the Immunoassay Method, set to 575 nm Inc.

| Sysmex Ready | | HC | |
|--------------------|-------|--------|-------------|
| Replace Rack? YES! | | | |
| Test Protocol | PT | [0.4] | STD-Link:No |
| Sample Vol. | ***** | 5.0 μL | |
| Dil. Vol. | ***** | 0 μL | |
| Pre. Rinse | ***** | x 0 | 7 8 9 |
| Post. Rinse | ***** | x 0 | |
| 2nd. Dil. | | | |
| D. Samp Vol. | | 0 μL | 4 5 6 |
| Dil. Vol. | ***** | 0 μL | |
| Pre. Rinse | ***** | x 0 | 1 2 3 |
| Post. Rinse | ***** | x 0 | |
| | | 0 | Enter |
| | | C | Quit |

As for the setting position of sensitivity or wave length, move the cursor using **[↓]** key to display the screen for setting samples and second-step dilution.

8) Sample Vol

Sets how much sample to aspirate.

The volume can be set within the range of 4 μL, in 1 μL increments. If no diluent is used, set to 20 μL or more.

9) Dil. Vol

Sets the reagent type and volume.

Press [**Select Reagent**] key to select the type of reagent. Refer to “Selection of Reagent” described later.

The volume can be set within the range of 4 μL to 120 μL , in 1 μL increments.

If no diluent is used, enter 0 μL .

If diluent is used only when standard curve is created, set the diluent name and enter 0 μL .



Information

Make sure that the sum of diluent volume and sample aspiration volume will be within a range of 20 μL to 130 μL .

10) Pre.Rinse, PostRinse (Sample)

Sets the cycle of the rinse before/after aspirating the samples.

Press [**Select Reagent**] key to select the type of reagent. Refer to “Selection of Reagent” described later.

The cycle can be set to maximum of 9 cycles (x0 - x9).

If no rinse is performed, enter 0.

11) D.Samp Vol (2nd.Dil)

Sets the sample aspiration volume in second step dilution.

The volume can be set within the range of 4 μL to 100 μL , in 1- μL increments. If it is not used, enter 0 μL .

12) Dil. Vol (2nd.Dil)

Sets the reagent type and volume.

Press [**Select Reagent**] key to select the type of reagent. Refer to “Selection of Reagent” described later.

The volume can be set within the range of 4 μL to 120 μL , in 1 μL increments. If it is not used, enter 0 μL .



Information

Make sure that the sum of diluent volume and sample aspiration volume for second step dilution will be within a range of 20 μL to 130 μL .

13) Pre.Rinse, PostRinse (2nd.Dil)

Set the cycle of the rinse before/after aspirating the sample.

Press [**Select Reagent**] key to select the type of reagent. Refer to “Selection of Reagent” described later.

The cycle of the rinse can be set to maximum of 9 cycles (x0 - x9).

If no rinse is performed, enter 0.

| Sysmex | | Ready | HC |
|---------------|---------|--------------------|-------------|
| Test Protocol | | Replace Rack? YES! | |
| Name | PT | [0.4] | STD-Link:No |
| Reagent 1 | PT INN | 100uL | |
| Reag.Vol. | ***** | x 0 | 7 8 9 |
| Pre.Rinse | ***** | x 0 | |
| Post.Rinse | Clean I | x 1 | |
| Reagent 2 | ***** | 0sec | |
| Reag.Vol. | ***** | 0uL | 4 5 6 |
| Pre.Rinse | ***** | x 0 | |
| Post.Rinse | ***** | x 0 | |
| Reagent 3 | ***** | 0sec | 1 2 3 |
| Reag.Vol. | ***** | 0uL | |
| Pre.Rinse | ***** | x 0 | |
| Post.Rinse | ***** | x 0 | 0 Enter |
| | | | Quit |

As for the setting position of diluent volume for second step dilution, move the cursor using [↓] key to display the screen for setting reagent.

14) Reagent 1

Sets the interval between the heating start time of sample and the adding of reagent 1.

The interval can be set in 30-second increments, beginning from a minimum setting of 30 seconds. However, if the rinse is set for immediately after sample aspiration, then an additional 30 seconds is needed for each rinse cycle. In the same way, an additional 30 seconds is needed for each rinse cycle if the rinse is set for before reagent 1.

15) Reag. Vol (Reagent 1)

Sets the volume of reagent 1.

Press [**Select Reagent**] key to select the type of reagent. Refer to “Selection of Reagent” described later.

The reagent volume used can be set to 0 μ L, or within the range of 4 μ L to 200 μ L, in 1- μ L increments.

**Information**

Make sure that the entire volume in the reaction tube will be 220 μ L or less.

16) Pre.Rinse, PostRinse (Reagent 1)

Sets the cycle of the rinse for reagent 1.

Press [**Select Reagent**] key to select the type of the rinse. Refer to “Selection of Reagent” described later.

The cycle of the rinse can be set to maximum of 9 cycles (x0 - x9).



Information

When using a reagent, be sure to set the number of following rinse cycles to 1 or above.

17) Reagent 2, Reagent 3

The interval between heating start and the addition of reagent 2 and 3 should be set to no less than the previous interval plus 30 seconds. If the rinse is set for before the reagents, an additional 30 seconds is needed for each rinse cycle.

For example, if no rinse is set for before the reagents, and the addition time for reagent 1 is set to 180 seconds, then the addition time for reagent 2 must be set to 210 seconds or longer.

If reagent 2 and 3 are not used, enter 0 sec for reagent addition time, make no setting for reagent fluid, and 0 μ L for reagent volume.

As to the other items, set the same conditions as for the reagent 1.



Information

When using a reagent, be sure to set the number of following rinse cycles to 1 or above.

- When setting is completed, press **[Quit]** key.

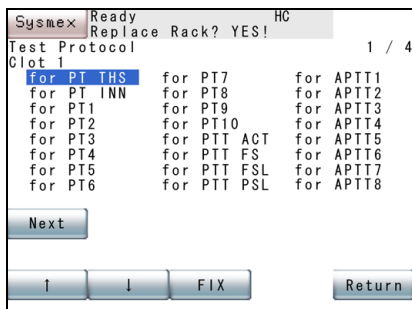
The Renew Confirmation screen will appear. Press the appropriate key.



Note

When a setting condition is not met, the cursor will move to the incorrect setting, and an error message will appear.

Selection of Detection Method



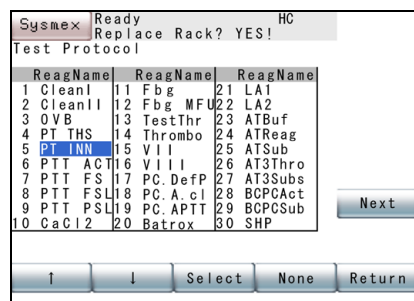
On the setting position of Detector, press **[Analysis Method]** key to display the Detection Method Selection screen.

Using **[↑]** and **[↓]** keys, move the cursor to specify the detection method. After the selection, press **[FIX]** key to set the specified method.

When a desired method is not displayed, press **[Next]** key to change over the detection method display.

When **[Return]** key is pressed, the selection is canceled, and the Test Protocol Entry screen will reappear.

Selection of Reagent



On the setting position of Dil. Vol, Reag. Vol, Pre-Rinse and Post-Rinse press **[Select Reagent]** key to display the Reagent Selection screen.

Using **[↑]** and **[↓]** keys, move the cursor to select a reagent. After the selection, press **[SELECT]** key to set the specified reagent.

When a desired reagent is not displayed, press **[Next]** key to change over the reagent display.

When **[None]** key is pressed, non-specified reagent (*****) is set, then the Test Protocol Entry screen will reappear.

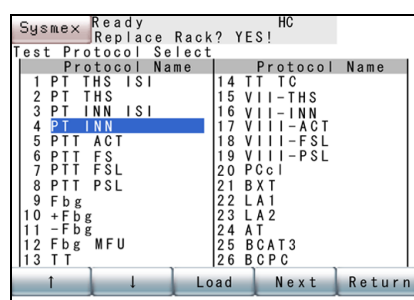
When **[Return]** key is pressed, the selection is canceled, and the Test Protocol Entry screen will reappear.



Note

Only the reagent names set in “10.7 Reagent Name” will be displayed.

Initialization of Test Protocol



When **[Default]** key is pressed with the cursor placed on the parameter name, the Test Protocol Select screen will appear.

Using **[↑]** and **[↓]** keys, move the cursor to select a protocol to be initialized (load default setting). After the selection, press **[Load]** key to initialize the specified protocol.

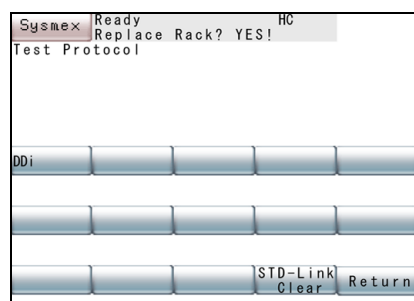
This function can be also used to make change from PT-THS to PT-TPC+.



Caution!

When a test protocol is read, be sure to check the content of the test protocol.

Link of Standard Curve



When **[STD-Link]** key is pressed with the cursor placed on a parameter name which is not defined Master, the screen for selecting analysis parameters for linking to the standard curve will appear.

The screen will display only parameters which are analyzed by the same detection (analysis) method.

When the key for the analysis parameter (master) to link is pressed, that analysis parameter will be linked to the standard curve. The Test Protocol Setting screen will then reappear.

To cancel the link, press **[STD-Link Clear]** key.

When **[Return]** key is pressed, the setting remains unchanged, and the Test Protocol Entry screen will reappear.



Information

- When a parameter is linked to the standard curve, test protocol can be set for the Management ID, parameter code, sample volume and diluent volume only.
- For the final total volume of the aspirated sample plus diluent, set the same volume as that used for the common parameter (Master). For the other parameters, the test protocol for the analysis parameter (master) linked to the standard curve is set.
- If a test protocol of the link source (master) is changed in the setting of linking a parameter to the standard curve, check the test protocols for the parameters linked to the standard curve.
- When the link to the standard curve is canceled, the test protocol for the analysis parameter (master) linked to the standard curve is set except for the setting of sample dilution.

Example of standard curve link setting

The procedure is explained below for linking +Fbg to the standard curve, with Fbg as the link source (master).

1. Set an analysis parameter for Fbg and +Fbg.
Refer to “10.6 Setup of Test Name”.
2. Set detection method for Fbg and +Fbg to “for Fbg”.
“OFF” will be displayed on the Test Protocol Entry screen.
Refer to “How to Set Test Protocol” described above for details.
3. Press **[STD-Link]** key on the Test Protocol Entry screen for +Fbg.
The screen for selecting analysis parameters linked to the standard curve will appear.
4. Press **[Fbg]** key to make the link setting of standard curve valid.
“STD-Link: Fbg” will be displayed on the Test Protocol Setting screen to set to test protocol for Fbg.



Note

The following is the standard curve link setting at the time of shipment.

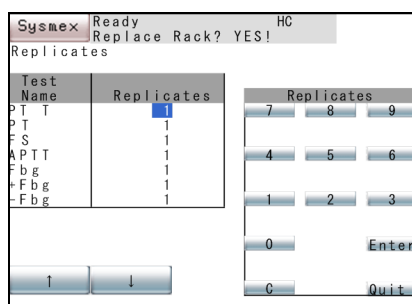
| Parameter for standard curve link setting | Link source (master) |
|---|----------------------|
| +Fbg | Fbg |
| -Fbg | Fbg |
| +DDP* | DDPI |
| +Ddi* | Ddi |
| +vWF* | vWF |
| -vWF* | vWF |
| +WFa* | WFa |
| -WFa* | WFa |

(*) CA-660 only

10.9 Replication

This program allows setting replication for each analysis parameter. When two or more analyses are set, the mean is calculated and displayed.

1. Press [**Analysis Settings**] on the Setting Menu screen.
The Analysis Setting Menu screen will appear.
2. Press [**Set Replication**] key on the Analysis Setting Menu screen.
The Replicate Setting screen will display replication for each analysis parameter.
3. Using [**↑**] and [**↓**] keys, move the cursor to specify an analysis parameter to be set.
4. Using the numeric keys, enter the replicates and press [**Enter**] key.
The replicates in the cursor position will be set and the cursor will move to the next parameter to be set.



Note

The value that can be set as the replicates is 1 - 10.

5. When setting is completed, press [**Quit**] key.
6. The Renew Confirmation screen will appear. Press the appropriate key.

10.10 Setup of Test Group

This program allows setting a test group for Work List.

1. Press **[Analysis Settings]** on the Setting Menu screen.

The Analysis Setting Menu screen will appear.

2. Press **[Test Group]** key on the Analysis Setting Menu screen.

The Test Group Setting screen will display the currently-set test group.

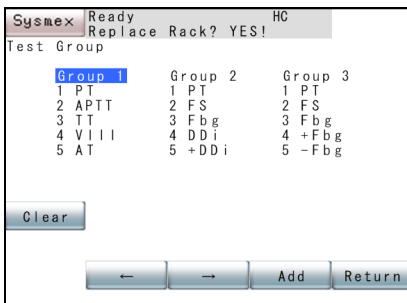
3. Using **[↑]** and **[↓]** keys, move the cursor to select a group to be set.

Three types of group can be selected.

By pressing **[Clear]** key, you can erase all parameters of the selected test group.

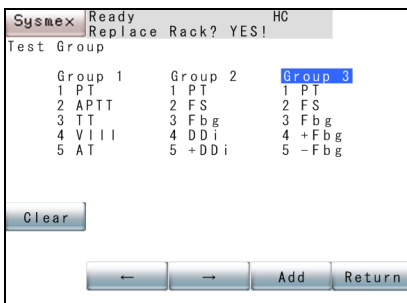
4. Press **[Add]** key.

The Test Group Addition screen will appear.



Information

If **[Add]** key is pressed in the group with 5 parameters registered, the Test Group Addition screen will not appear.



5. Press the key for an analysis parameter to be added on the Test Group Addition screen.

An analysis parameter whose key was pressed is added to the test group, and the cursor moves to the next number.

When no key for analysis parameter to be added is displayed, press **[More]** key to change over the analysis parameter display.



Information

The same parameter cannot be added more than once in the same group.

**Note**

+Fbg is an analysis parameter with an alternative dilution ratio of 1:20 (2 times the usual Fbg concentration).

-Fbg is an analysis parameter with an alternative dilution ratio of 1:5 (half the usual Fbg concentration).

+DDP is an analysis parameter with an alternative dilution ratio of 1:8 the usual DDPI concentration.

+Ddi is an analysis parameter with an alternative dilution ratio of 1:20 (8 times the usual Ddi concentration).

+vWF is an analysis parameter with an alternative dilution ratio of 1:6 (3 times the usual vWF concentration).

-vWF is an analysis parameter with an alternative dilution ratio of 1:1 (half the usual vWF concentration).

+Wfa is an analysis parameter with an alternative dilution ratio of 1:20 (4 times the usual Wfa concentration).

-Wfa is an analysis parameter with an alternative dilution ratio of 4:5 (quarter the usual Wfa concentration).

6. When setting is completed, press **[Return]** key.

The Renew Confirmation screen will appear. Press the appropriate key.

**Note**

When 13 or more of reagents or 5 or more in total of diluent and rinse solution are set in a group, the changed setting will be canceled, and the Test Group Setting screen will reappear.

10.11 Reagent Holder

This program can be used to set the positions and container types of the reagents held by the reagent holder. When aspirating reagent, the probe height is automatically changed to match the container that has been set.

1. Press **[Analysis Settings]** key on the Setting Menu screen.
The Analysis Setting Menu will appear.
2. Press **[Reagents Holder]** key on the Analysis Setting Menu screen.
The Reagent Holder Setting screen will display the reagent and container that is set to reagent holder for each analysis sample group.

| Pos. | ReagName | Vial Name |
|------|----------|-----------|
| 1 | PT INN | Cup |
| 2 | TestThr | Cup |
| 3 | | Cup |
| 4 | | |
| 5 | PTT FSL | Cup |
| 6 | ATReag | Cup |
| 7 | CaCl2 | Cup |
| 8 | ATSub | Cup |
| 9 | VIII | Cup |
| 10 | AT Buf | Cup |
| 11 | CleanI | PV-10 |
| 12 | OVB | PV-10 |
| 13 | CleanII | Cup |

3. Press **[Change Group]** key, and select a group to be analyzed.
Each time you press the key, the display will change over in the following order.

- Group 1
- Group 2
- Group 3

4. Using **[↑]** and **[↓]** keys, move the cursor to specify a reagent name for reagent holder to be set.



Note

The numbers shown in the left column of the table indicate those for reagent holders.

5. Press **[Select Reagent]** key.

The screen for selecting a reagent will appear.



Note

The screen will display the reagents used for the parameters that have been set in analysis groups.

| ReagName | ReagName | ReagName |
|------------|----------|----------|
| 1 CleanI | | |
| 3 OVB | | |
| 4 PT INN | | |
| 8 PTT FSL | | |
| 10 CaCl2 | | |
| 13 TestThr | | |
| 18 VIII | | |
| 28 AT Buf | | |
| 29 ATReag | | |
| 30 ATSub | | |

6. Using **[↑]** and **[↓]** keys, move the cursor to select a reagent.

7. Press **[SELECT]** key.

The Reagent Holder Setting screen will reappear, and the selected reagent will be set.

If no reagent is set, press **[None]** key instead of **[SELECT]** key.

8. Using **[↑]** and **[↓]** keys, move the cursor to specify a container for the reagent to be set.

9. Press **[Next Option]** key to select a reagent container.

Each time you press the **[Next Option]** key, “GW5”, “PV-10”, “Cup” and “SLD Vial” appear in sequence.

| Symbol | Meaning |
|----------|--|
| GW5 | Siemens GW5 |
| PV-10 | Push Vial PV-10 (22 mm OD x 40 mm high) provided in supply parts |
| Cup | Sample Cup Conical 4 mL (*) |
| SLD Vial | Provided in supply parts |

(*) When the container is used, an adapter must be provided. Refer to “10.19 Reagent Name/Holder List”.

10. When setting is completed, press **[Return]** key.

The Renew Confirmation screen will appear. Press the appropriate key.



Caution!

Set the container which is to be set in the reagent holder. If the wrong container is set, correct analysis results cannot be obtained.



Note

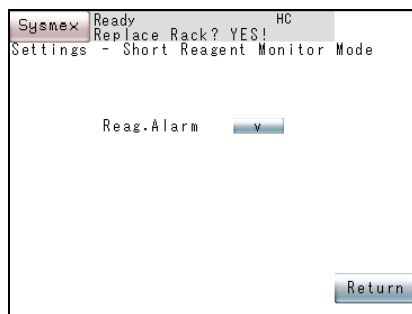
In the following cases, an error occurs when the **[FIX]** key is pressed, and the Reagent Holder Setting screen will reappear. The analysis parameter for which an error occurred will be highlighted.

- A reagent has not been set for all parameters in the group.
- The reagents set for rinse solution and diluent have been set to any of reagent holder Nos. 1 to 8.

10.12 Setup of Reagent Volume Monitoring

This program allows setting validity/invalidity of reagent volume monitoring. If reagent volume monitoring is set to “v”, then the reagent volume is checked at the start of analysis. If the volume is insufficient, an error message will appear.

1. Press **[Analysis Settings]** key on the Main Menu screen.
The Analysis Setting Menu screen will appear.
2. Press **[Alarm Settings]** key on the Analysis Setting Menu screen.
The Reagent Volume Monitoring Setting screen will display the current settings.
When Valid is set, “v” mark will appear.
3. Press the “Reag. Alarm” key. “v” mark will appear in the key to validate the setting of reagent volume monitoring.



Note

“v” mark appears and disappears alternately each time the key is pressed.

4. When setting is completed, press **[Return]** key.

The Renew Confirmation screen will appear. Press the appropriate key.

10.13 Setting of Conversion Formula

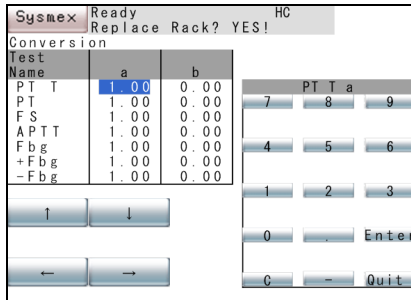
This program is used to set the values used in the conversion formula for analysis parameters. Set “a” (rate) and “b” (offset) for the conversion formula “ $Y = ax + b$ ”.

1. Press **[Analysis Settings]** key on the Setting Menu screen.
The Analysis Setting Menu screen will appear.
2. Press **[Conversion]** key on the Analysis Setting Menu screen.
The Conversion Formula Setting screen will appear.
3. Using **[↑]**, **[↓]**, **[←]**, and **[→]** keys, move the cursor to select a parameter to be set.
4. Enter a value for data conversion using numeric keys, and press **[Enter]** key.

The value selected by the cursor will be set, and the cursor will move to the next value to be set.

5. When the setting is completed, press **[Quit]** key.

The Renew Confirmation screen will appear. Press the appropriate key.



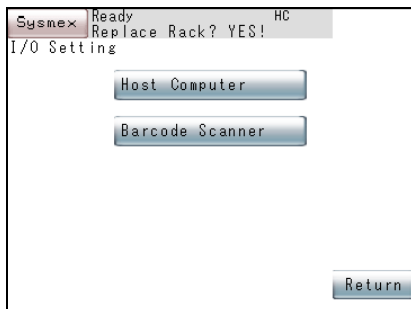
10.14 Devices to be connected

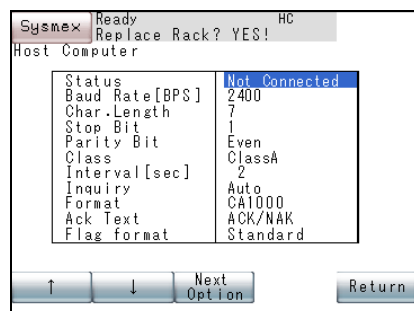
This program allows setting the interface conditions for transmitting data to the host computer and the conditions for using the barcode scanner or other external devices.

Host Computer

This program allows setting the interface conditions for the host computer.

1. Press **[I/O Setting]** key on the Setting Menu screen.
The I/O Setting Menu screen will appear.
2. Press **[Host Computer]** key on the Device Setting Menu screen.
The Host Computer Setting screen will display the currently-set interface conditions.





3. Using [↑] and [↓] keys, move the cursor to specify a parameter to be set.
4. Press [Next Option] key and specify the conditions.
A condition will change over each time you press [Next Option] key.

The table below shows the interface conditions that can be set. (The underlined values indicate the factory default setting.)

| | |
|------------------|---|
| Status | Sets connection with the host computer. Select “Connected” or “ <u>Not connected</u> ”. If “Not connected” is set, display of HC - which shows the status of external device - will disappear. |
| Baud Rate [BPS] | Sets baud rate of RS232C. Select from “600”, “1200”, “ <u>2400</u> ”, “4800”, “9600”. |
| Character Length | Sets data bit length of RS232C. Select “ <u>7-bit</u> ” or “8-bit”. |
| Stop Bit | Sets stop bit length of RS232C. Select “ <u>1-bit</u> ” or “2-bit”. |
| Parity | Sets the protocol of RS232C parity check. Select “None”, “Odd”, or “ <u>Even</u> ”. |
| Class | Sets the protocol of transfer. Select “ <u>Class A</u> ” (No response) or “Class B” (With response) |
| Interval [sec] | Sets interval of transfer to the host computer. Select “0”, “ <u>2</u> ”, “3”, “5”, “7”, “10”, “15”. |
| Inquiry | Sets how to make inquiry. Select “ <u>Auto</u> ” or “Manual”. |
| Format | Sets output format. Select “ <u>CA1000</u> ”, “CA500” or “ASTM”. |
| ACK Text | Sets ACK Text mode. Select “STX-ACK-ETX”, or “ <u>ACK/NAK</u> ”. |
| Flag format | Set the combination of data mask indication and flag indication. Select “ <u>Standard</u> ”, or “CA-500”. |

5. When setting is completed, press [Return] key.
The Renew Confirmation screen will appear. Press the appropriate key.

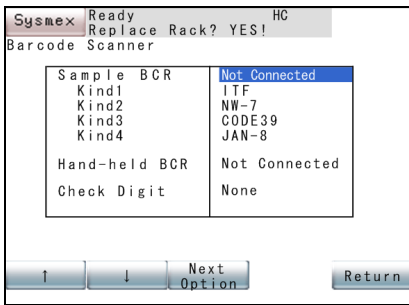
Barcode Scanner

This program allows setting the conditions for using barcode scanner.

1. Press **[I/O Setting]** key on the Setting Menu screen.
The Device Setting Menu will appear.
2. Press the **[Barcode Scanner]** key on the Device Setting Menu.
The Barcode Scanner Setting screen will display the currently-set usage conditions.
3. Using **[↑]** and **[↓]** keys, move the cursor to a parameter to be set.
4. Press **[Next Option]** key to set the conditions.

A condition will change over each time **[Next Option]** key is pressed.

The table below shows the interface conditions that can be set. (The underlined values indicate the factory default setting.)



| | |
|-----------------|---|
| Barcode Scanner | Sets connection with the barcode scanner. Select “Connected” or “ <u>Not connected</u> ”. |
| Kind 1-4 | Sets the types of barcode. None/ <u>ITF</u> / <u>NW-7</u> / <u>CODE39</u> / <u>JAN-13</u> / <u>JAN-8</u> / <u>CODE128</u> Selecting identical barcodes (excluding “None”) is an error. |
| Hand-held BCR | Sets connection with the hand-held barcode reader. Select “Connected” or “ <u>Not connected</u> ”. |
| Check Digit | Sets Check Digit. <u>None:</u> <u>No Check Digit.</u> Mod. 11: Modulus 11 W Mod. 11: Weighted Modulus 11 Mod. 43: Modulus 43 Mod. 10: <u>Modulus 10</u> |



Warning!

- Use the check-digit as much as possible.
- If the check-digit cannot be used, affix the barcode label so that the bars on the label are horizontal to reduce the risk of the incorrect reading of the barcode label.



Note

Check digit setting is common to the sample barcode scanner and hand-held barcode reader.

- When setting is completed, press **[Return]** key.
The Renew Confirmation screen will appear. Press the appropriate key.

10.15 Setup of System

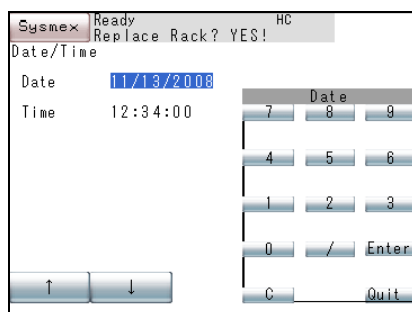
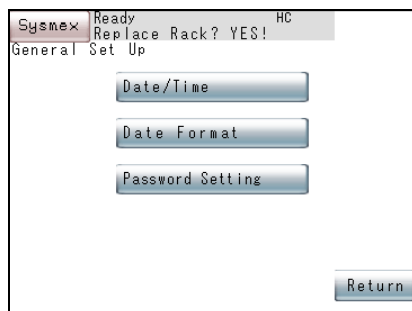
This program allows setting the instrument system status.

Date/Time

With this program, date and time can be set.

The instrument has a built-in clock, so there is no need to set date and time every day. Should the power be turned off, the built-in clock is powered by an internal battery.

- Press **[General Set Up]** key on the Setting Menu screen.
The General Set Up Menu screen will appear.
- Press **[Date/Time]** key on the General Set Up Menu screen.
The Date/Time Setting screen will display current date and time.



- Using **[↑]** and **[↓]** keys, move the cursor to select Date or Time.
- Using the numeric keys, set Date and Time, and press **[Enter]** key.
The parameter in the cursor position is set and the cursor will move to the next parameter.



Information

- When entry is made in the wrong format, setting is not executed.
- If the number of day or month is a single digit, enter it with a 0 preceding it.
- Enter the time in a 24-hour clock system.

- When setting is completed, press **[Quit]** key.
The Renew Confirmation screen will appear. Press the appropriate key.

Date Format

This program allows setting a date format.

Date format is available in three types:

- Year/Month/Day
- Month/Day/Year
- Day/Month/Year

1. Press **[General Set Up]** key on the Setting Menu screen.

The General Set Up Menu screen will appear.

2. Press **[Date Format]** key on the General Set Up Menu screen.

The Date Format Setting screen will display the currently-set date format.

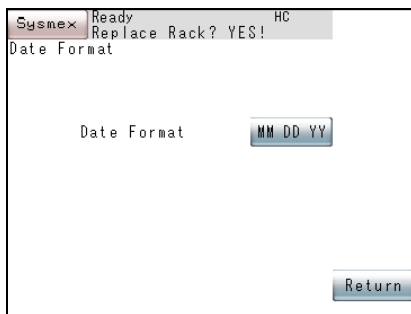
3. Press the key that indicates a date format and select a format.

Each time you press the Date Format key, the indication changes over as follows:

YY/MM/DD → MM/DD/YY → DD/MM/YY

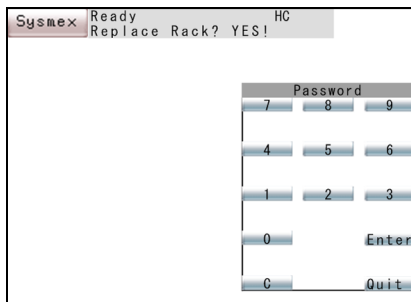
4. When setting is completed, press **[Return]** key.

The Renew Confirmation screen will appear. Press the appropriate key.



10.16 Password Settings

Enter Password



Some programs on QC, standard curve, and analysis setting require a password to limit the use of the instrument to authorized personnel. When these programs are selected, the message “Enter Password” will be displayed. Enter the pre-set password and press **[Enter]** key. If the entered password agrees with the pre-set one, the program will be executed.

Use a password properly as it is important in managing the instrument.

A password is a maximum of 12 digits consisting of numerics (0 - 9).

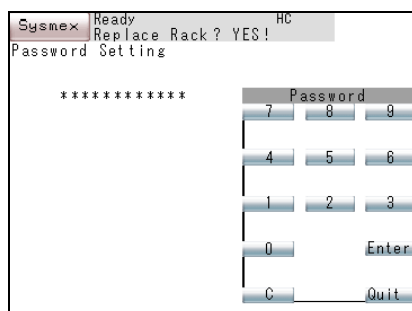
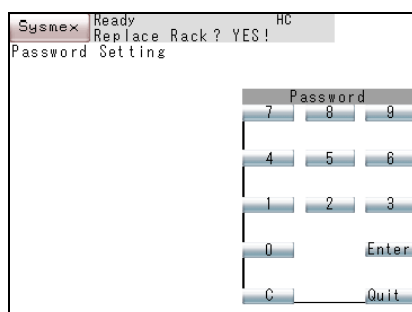
Set or Change Password

Following are the procedures for setting and changing a password.



Note

When **[C]**, **[0]**, **[Enter]**, **[Quit]**, or **[Fix]** key is used to set as a password, password check is not done, and the Password Entry screen will be skipped.



1. Press **[General Set Up]** screen on the Setting Menu screen.
The General Set Up Menu screen will appear.
2. Press **[Password Setting]** key on the General Set Up Menu screen.
The Password Setting screen will appear.

When a password is already set, enter it on the Password Setting screen displayed.

3. Using the numeric keys, set a password and press **[Enter]** key.
When changing a password which was already set, "*****" is displayed. Enter the new password.



Note

Using numerals (0 - 9), set a maximum of 12 digits for a password.

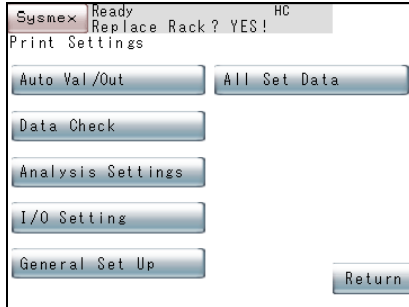
4. When setting is completed, press **[Quit]** key.
The Renew Confirmation screen will appear. Press the appropriate key.

10.17 Printout of Settings

This program allows printing out the settings by the built-in printer.

1. Press **[Print Settings]** key on the Setting Menu screen.

The Print Setting Menu screen will appear.



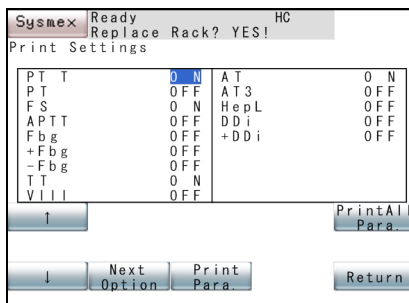
2. Press a key for parameter to be printed.

When **[Auto Val/Out]**, **[I/O Settings]**, **[General Set Up]**, or **[All Set Data]** is selected:

Printout of set value will start.

When **[Data Check]** or **[Analysis Settings]** is selected:

The Printout Parameter Selection screen will appear. Specify an analysis parameter to be printed.



Using **[↑]** and **[↓]** keys, move the cursor to the parameter to be set, and press **[Next Option]** key to change over ON/OFF.

After the setting, press any of the following keys to perform printout process.

[Print All Para.] key: Prints out all parameters regardless of ON/OFF setting.

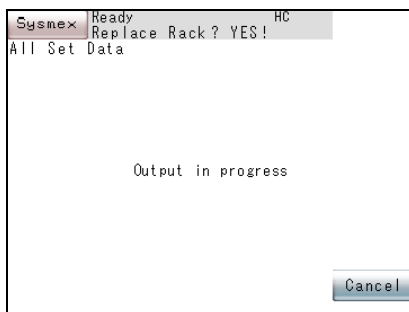
[Print Para.] key: Prints out only the parameter that has been set to ON.

[Return] key: Returns to the Print Setting Menu screen without printout.

3. Printout of set parameter will start.

The “Output in progress” screen will appear.

To cancel printout, press **[Cancel]** key.



Note

When **[General Set Up]** key or **[All Set Data]** key is pressed, a password will not be printed out.

4. When printout is over, the Print Setting Menu screen will return.

10.18 Addition of New Analysis Parameters

This section briefly explains the settings required for addition of new analysis parameters.

1. Set a name of analysis parameter. (Refer to “10.6 Setup of Test Name”.)
Set a parameter to be newly registered using up to four characters.
2. Set a reagent name. (Refer to “10.7 Reagent Name”.)
Set a reagent required for analyzing the new parameter using up to seven characters.
3. Set the test protocol. (Refer to “10.8 Test Protocol”.)
Set the detection method, aspiration volume of sample, and reagent volume.)
4. Set the number of replicates. (Refer to “10.9 Replication”.)
Select one analysis or two analyses.
5. Set a test group. (Refer to “10.10 Setup of Test Group”.)
Select Group 1, 2, or 3.
6. Set a reagent holder. (Refer to “10.11 Reagent Holder”.)
Select “Cup”, “PV-10”, “GW5” and “SLD Vial”.
7. Set the reagent volume monitoring. (Refer to “10.12 Setup of Reagent Volume Monitoring”.)
Perform the setting only when reagent volume monitoring is made valid.
8. Set the conversion formula. (Refer to “10.13 Setting of Conversion Formula”.)
Perform the setting only when conversion formula is needed.

10.19 Reagent Name/Holder List

The reagents which can be used, their names as set for this instrument, and their corresponding containers are as follows.

| Test Name | Reagent | Reagent Name | Volume | Vial Type | Remark | |
|--|--|--|---------|-----------|---|---|
| PT | Thromborel [®] S Reagent | PT THS | 4 mL | GW5 | | |
| | | | 10 mL | – | Reagent must be transferred before use. * | |
| | Dade [®] Innovin [®] Reagent | PT INN | 4 mL | GW5 | | |
| | | | 10 mL | – | Reagent must be transferred before use. * | |
| | | | 20 mL | – | Reagent must be transferred before use. * | |
| | APTT | Dade [®] Actin [®] Reagent | PTT ACT | 2 mL | GW5 | |
| 10 mL | | | | – | Reagent must be transferred before use. * | |
| Dade [®] Actin [®] FS Reagent | | PTT FS | 2 mL | GW5 | | |
| | | | 10 mL | – | Reagent must be transferred before use. * | |
| Dade [®] Actin [®] FSL Reagent | | PTT FSL | 2 mL | GW5 | | |
| | | | 10 mL | – | Reagent must be transferred before use. * | |
| Pathromtin [®] SL | | PTT PSL | 5 mL | GW5 | | |
| Calcium Chloride Solution (0.025 mol/L) | | CaCl ₂ | 15 mL | – | Reagent must be transferred before use. * | |
| Fbg | | Dade [®] Thrombin Reagent | Fbg | 1 mL | GW5 | |
| | | | | 5 mL | – | Reagent must be transferred before use. * |
| | Multifibren [®] U | Fbg MFU | 2 mL | GW5 | | |
| | | | 5 mL | GW5 | | |
| TT | Test Thrombin Reagent | Test Thr | 5 mL | GW5 | | |
| | Thromboclotin | Thrombo | 10 mL | – | Reagent must be transferred before use. * | |
| BXT | Batroxobin | Batrox | 5 mL | GW5 | | |
| VII | Clotting Factor-VII Deficient Plasma | VII | 1 mL | GW5 | | |
| VIII | Clotting Factor-VIII Deficient Plasma | VIII | 1 mL | GW5 | | |
| PCcl | Protein C Deficient Plasma | PC.DefP | 1 mL | GW5 | | |
| | Activator | PC.A.cl | 3 mL | GW5 | | |
| | PC APTT | PC.APTT | 10 mL | – | Reagent must be transferred before use. * | |

| Test Name | Reagent | Reagent Name | Volume | Vial Type | Remark |
|---------------------|---|--------------|--------|-----------|---|
| LA1/LA2 | LA1 Screening Reagent | LA1 | 2 mL | GW5 | |
| | LA2 Confirmation Reagent | LA2 | 1 mL | GW5 | |
| AT | INNOVANCE [®] Antithrombin | ATReag | 2.7 mL | GW5 | |
| | | ATSub | 2.7 mL | GW5 | |
| | | AT Buf | 5 mL | GW5 | |
| AT3 | Berichrom [®] Antithrombin III (A) | AT3Thro | 5 mL | GW5 | |
| | | | 15 mL | – | Reagent must be transferred before use. * |
| | | AT3Subs | 3 mL | GW5 | |
| Hep HepU HepL | Berichrom [®] Heparin | AT3Reag | 1 mL | GW5 | |
| | | FXaReag | 10 mL | – | Reagent must be transferred before use. * |
| | | HepSubs | 2 mL | GW5 | |
| BCPC | Berichrom [®] Protein C | BCPCAct | 5 mL | GW5 | |
| | | | 10 mL | – | Reagent must be transferred before use. * |
| | | BCPCSub | 3 mL | GW5 | |
| DD | D-Dimer PLUS | DD.PI.A | 3 mL | GW5 | |
| | | | 5 mL | GW5 | |
| | | DD.PI.R | 3 mL | GW5 | |
| | | | 4 mL | GW5 | |
| | INNOVANCE [®] D-Dimer | DDi.DIL | 5 mL | GW5 | |
| | | DDi.SUP | 2.6 mL | GW5 | |
| | | DDi.BUF | 5 mL | GW5 | |
| | | DDi.REA | 4 mL | GW5 | |
| vWF | vWF Ag | vWFBuf | 5 mL | GW5 | |
| | | vWFReag | 2 mL | GW5 | |
| WFa | INNOVANCE [®] VWF Ac | WFAcI | 2 mL | GW5 | |
| | | WFAcII | 3.5 mL | GW5 | |
| | | WFAcIII | 2.5 mL | GW5 | |
| | CA CLEAN [™] I | CleanI | 50 mL | – | Reagent must be transferred before use. * |
| | CA CLEAN [™] II | CleanII | 45 mL | – | Reagent must be transferred before use. * |
| | Owren's Veronal Buffer | OVB | 500 mL | – | Reagent must be transferred before use. * |

(*) When reagent needs to be shifted to the other container, please set and use the container or the adapter which is mentioned in the following table.

| Container | Adapter |
|-----------|----------------------------|
| Cup | Holder No. 89 (363-2558-6) |
| Reag Vial | None |
| SLD Vial | None |

11. Maintenance and Supplies Replacement11-1

| | | |
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11. Maintenance and Supplies Replacement

11.1 Maintenance Schedule

To ensure the instrument will serve you in the optimal operating condition, it requires periodic maintenance. Follow the maintenance schedule as described below and keep the result in the Maintenance Checklist.

Daily Maintenance

- Clean Sample Probe (Refer to Section 11.2.)
- Discard Used Reaction Tubes (Refer to Section 11.3.)
- Dispose of Waste (Refer to Section 11.4.)
- Remove Dew from Reagent Rack (Refer to Section 11.5.)

Monthly Maintenance

- LED Calibration (Refer to Section 11.6.)

Yearly Maintenance

- Replace Rinse Filter (Refer to Section 11.7.)

As Needed Maintenance

- Replace Fuse (Refer to Section 11.8.)
- Check Printer Paper Supply (Refer to Section 11.9.)
- Check and Drain Trap Chamber (Refer to Section 11.10.)
- Prime Rinse Solution to Hydraulic Line (Refer to Section 11.11.)
- Filter inspection and cleaning (Refer to Section 11.12.)
- Clean Instrument (Refer to Section 11.13.)

Supplies Replacement

- Replenish Reagent (Refer to Section 11.14.)
- Replenish Reaction Tubes (Refer to Section 11.15.)
- Replenish Rinse Solution (Refer to Section 11.16.)

Carefully read the following **Warning** and **Caution** before conducting maintenance of the instrument and replacing supplies, to ensure safe operation.



Warning!

- When closing the light shield cover, be sure to hold the handle.
If it is closed by holding other parts, the hand or finger may get pinched or injured.
- Be sure to fully open the light shield cover and check that it will not fall down by its own weight.
If the light shield cover falls down, there is a risk of causing injury on the head.
- Turn the power off before performing maintenance operations (excluding operations that require screen handling) to prevent shock.

11.2 Clean Sample Probe

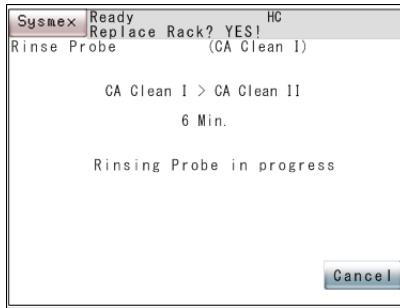
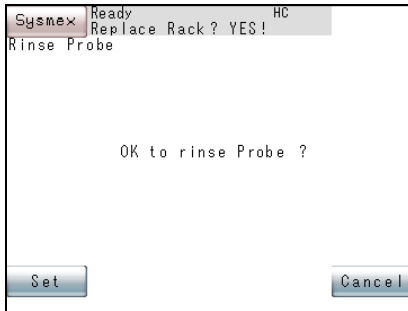
Follow the procedure below to clean the sample probe at the end of a day's analysis or, if the instrument is used continuously, once every 24 hours. If after cleaning there is still noticeable dirt on the outside of the sample probe, then turn the instrument power OFF and clean the probe with gauze or other material moistened with alcohol.



Caution!

If the probe is used for more than 60 tests, the data may be affected by the accumulation of dirt. Perform rinse probe.

1. Press [**Special Menu**] key on the Main Menu screen.
The contents of the Main Menu will change over.



2. Press **[Rinse Probe]** key on the Main Menu screen.
The Rinse Probe screen will display “OK to rinse Probe?”
3. Press **[Set]** key or **[Cancel]** key on the Rinse Probe screen.
[Set] key: Executes Probe Rinse Operation.
[Cancel] key: Cancels Probe Rinse Operation and returns the screen to the Main Menu.
4. Press **[Set]** key to start rinse operation. The message “Rinsing Probe in progress” will appear. To stop rinse operation when “Rinsing Probe in progress”, press **[Cancel]** key. However, after **[Cancel]** key is pressed, some time may be required before the system returns to “Ready” status.



Warning!

- CA CLEAN™ II is an acidic cleaning agent. It should not come in contact with skin or clothing. If it happens rinse skin or clothing with plenty of water to avoid injury or damage.
- CA CLEAN™ I contains sodium hypochlorite. Be sure to use CA CLEAN™ I and CA CLEAN™ II in different containers. If CA CLEAN™ I is directly mixed with acid solution such as CA CLEAN™ II, chlorine gas is produced, which is very dangerous.
- Do not open the light shield cover until the screen appears. If you put the hand or finger in, it may be injured. If the cover is opened during operation, the alarm rings and the operation stops.



Caution!

If the operation is canceled, restart it immediately. Otherwise, CA CLEAN™ I, CA CLEAN™ II may remain in the probe, causing incorrect analysis results.



Note

CA CLEAN™ I, CA CLEAN™ II aspiration and probe rinsing take about 6 minutes.

5. Probe rinse operation ends.
When rinse operation is over, the Main Menu screen will return.

11.3 Discard Used Reaction Tubes

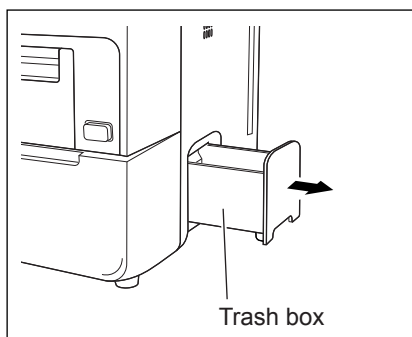
The used reaction tubes automatically fall into the trash box. At completion of the analyses, discard the used reaction tubes from the trash box and clean it. Capacity of trash box is approximately 60 tubes.



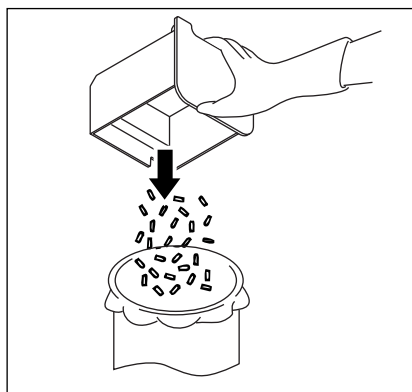
Risk of Infection

When discarding waste liquid, instrument consumables and instrument, take proper steps to dispose of them as medical, infectious and industrial wastes. If they are contaminated with blood, there is a possibility of bacterial infection occurring.

Take care not to spill waste liquid that may have collected in the trash box.



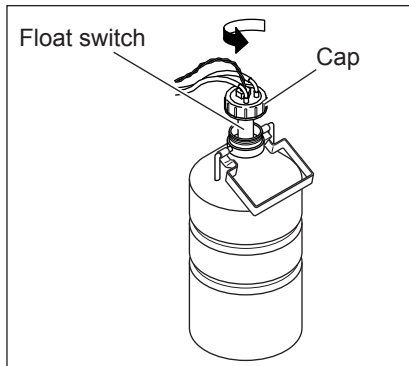
1. Pull out the trash box from the instrument's right side panel.



2. Discard the used reaction tubes.
3. Clean the trash box with tap water.
4. Dry the trash box and restore it in place.

11.4 Dispose of Waste

When a day's analyses are completed, or when the waste bottle is full, discard the waste that has collected in the waste bottle.



1. Turn the cap of the waste bottle counterclockwise and take out the float switch.



Warning!

Pay attention no waste is splashed around.
Be careful that no waste is splashed. If splashed, wear latex gloves and wipe with gauze or a towel moistened with 1:2 diluted CA CLEAN™ I, then wipe with a towel moistened with water, and finally wipe with a dry soft towel.

2. Discard waste liquid.
3. Put the float switch into the waste bottle, and turn the cap clockwise to tighten it securely. Check for any kink, etc. in the tube.



Caution!

- When the bottle becomes full of waste, the alarm will sound and the confirmation screen will appear. Press **[Conf.]** key and wait until Analysis Start Confirmation screen or "Ready" appears (Interrupt process is executed).
Then, discard waste by the procedure described above. After discarding, close the waste bottle cap and press **[Start]** key.
- When the bottle has become full after the dispensing of all samples, the Analysis Start Confirmation screen will not appear.



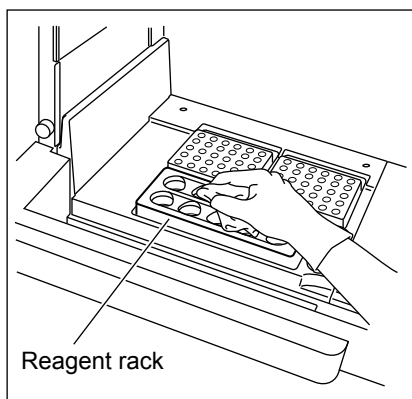
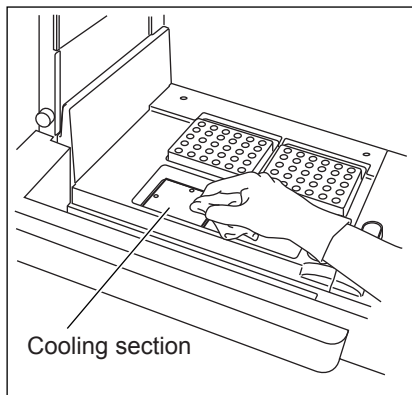
Information

When analysis is made with the rinse bottle lying flat, there is a possibility that correct analysis result may not be obtained.
Make sure the rinse bottle is not lying flat.

11.5 Remove Dew from Reagent Rack

After completion of the day's analyses or once in 24-hour continuous operation, check to see that dew has not formed on the reagent rack. Remove any if found.

1. Open the light shield cover and check that it will not fall down with its own weight.
2. Use paper towel or lint-free tissue to wipe off any condensation from the cooling section.



3. Insert paper towel or lint-free tissue into the four holes on the left side of the reagent rack and wipe off any condensation.
4. Close the light shield cover.

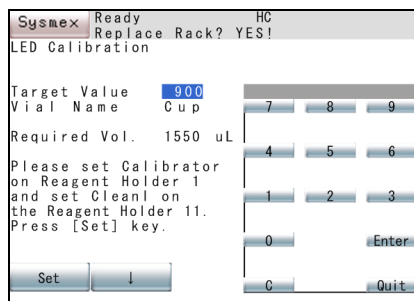
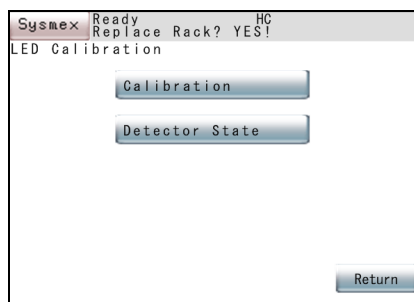
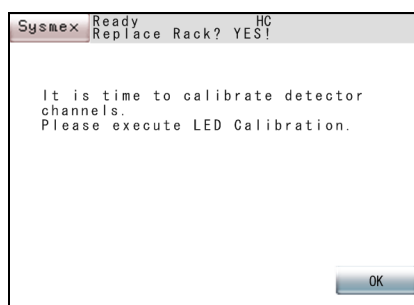
11.6 LED Calibration

The LED Calibration confirmation window will appear at the instrument power ON, if passing one month from the last day of LED Calibration if DFbg is required since DFbg is sensitive to changes in scattered light intensity.



Note

If DFbg is not a required parameter, quarterly calibration is required. The default setting for LED calibration is 30 days. Please contact your local service representative if you need this setting to be adjusted.



Press **[OK]** key, and perform the LED Calibration according to the following procedures.

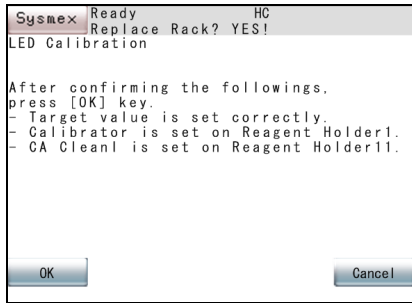
1. Press **[Special Menu]** key on the Root Menu screen to display **[Special Operate]** key.
2. Press **[Special Operate]** key.
The Special Operation Menu screen will appear.
3. Press **[LED Calibration]** key.
The LED Calibration Menu screen will appear.



Note

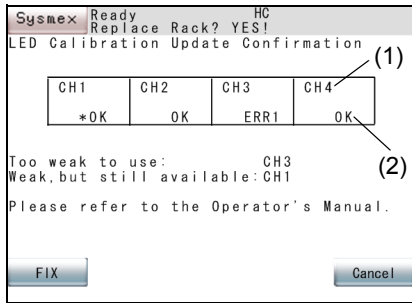
The last calibration day and a present status can be checked by pressing **[Detector State]** key.

4. Press **[Calibration]** key.
The LED Calibration screen will appear.
5. Enter a target value.
Enter an indicated value (100 - 999) which is given in the calibrators table of assigned values for calibration using the numeric keys, and press **[Enter]** key.
6. Select a container of the calibrator for calibration.
Move the cursor to “Vial Type” using **[↑]** and **[↓]** keys, and press **[Next]** key to select the container.
Each time **[Next]** key is pressed, the types of registered containers will be displayed in order.
7. Set the calibrator for calibration to the reagent holder 1.
(Refer to “5.6 Prepare Reagents” : “3. Set the reagents on the rack.”.)
8. Set CA CLEAN I to the reagent holder 11.
9. Press **[Set]** key.
The confirmation screen will appear.



10. Press **[OK]** key.

LED calibration will start, and the screen indicating calibration in progress will be displayed.



When the operation is completed, the LED Calibration Update Confirmation screen will appear.

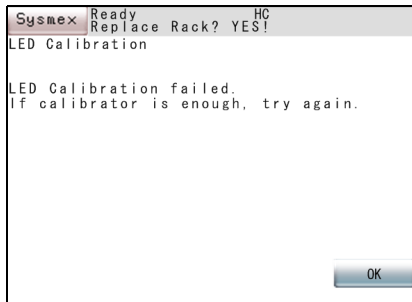
Displayed contents

- (1) Channel No.
- (2) OK: Available
- *OK: Available. However, replacement is required within a few months.
- ERRxx: Not available



Caution!

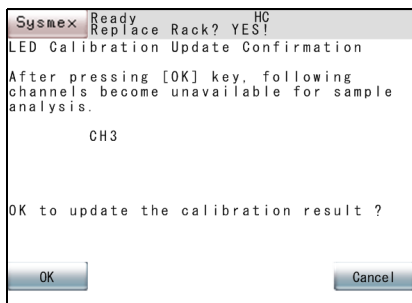
If the calibration process has failed, the message prompting to restart LED calibration will be displayed.



11. When updating a new adjustment value, press **[FIX]** key.

When the status of all channels is OK

The new adjustment value is saved, and returns to the LED Calibration screen.

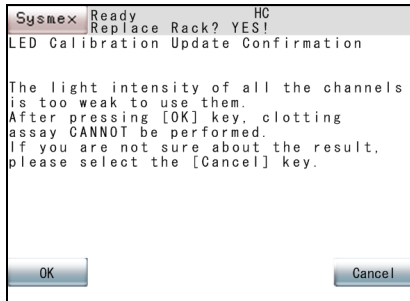


When there is a channel with a calibration error

The confirmation screen will appear.

Press **[Cancel]** key to return to the LED Calibration Update Confirmation screen.

Press **[OK]** key to save the new adjustment value, and return to the LED Calibration screen.



When all channels have calibration errors

The confirmation screen will appear.

Pressing **[OK]** key to save the new adjustment value, returns to the LED Calibration screen.

Pressing **[Cancel]** key to abandon the new adjustment value, returns to the LED Calibration screen.

12. Press **[Cancel]** key on the LED Calibration Update Confirmation screen to abandon the new adjustment value.

The confirmation screen will appear.

Press **[Cancel]** key to return to the LED Calibration Update Confirmation screen.

Press **[OK]** key to abandon the new adjustment value and return to the LED Calibration screen.

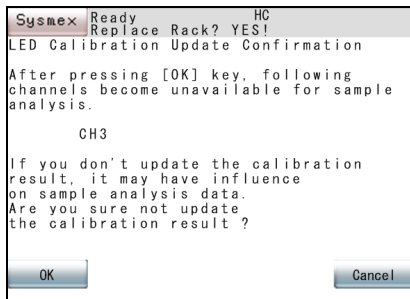
13. After the calibration is completed, press **[Quit]** key on the LED Calibration screen.

The message screen will appear asking to remove the calibrator for the calibration from the reagent holder No. 1 and set the former reagent.

14. Press **[OK]** key.

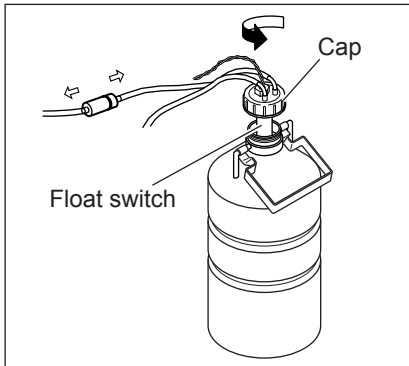
Returns to the LED Calibration screen.

15. Take out the calibrator for the calibration, and set the former reagent.



11.7 Replace Rinse Filter

The Rinse Filter is placed in the tubing between the Rinse Bottle and the instrument rear panel nipple. Replace the Rinse Filter once every year, as follows.



1. Turn OFF the instrument power.
If you fail to turn OFF the instrument power, the rinse fluid may splash when you open the Rinse Bottle lid.
2. Turn the cap of the Rinse Bottle counterclockwise to release the pressure from the bottle.
3. Disconnect the tubings from the Rinse Filter.



Information

Prepare a damp towel or a tissue paper to absorb the rinse fluid dropping from the tubings.

4. Install a new Rinse Filter so that the side with the black marking enters to the Rinse Bottle. Tightly cap the cap of the Rinse Bottle. Then, turn ON the power to resume normal operation.

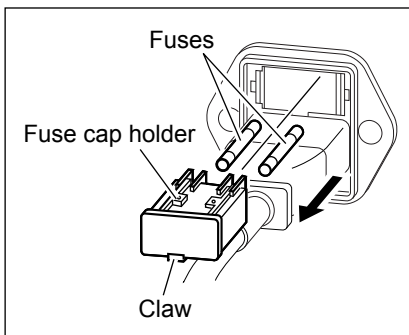
11.8 Replace Fuse

Overcurrent protection fuses are used on the rear panel. When fuses are blown, replace them according to the following procedure:



Warning!

To avoid risk of electric shock, disconnect the power cord before replacing the fuse.



1. Turn off the power supply and disconnect the power cord.
2. Remove the fuse cap holder.
Remove the fuse cap holder at the rear panel while pushing its claw up using a flat-tip screwdriver.

3. Replace the fuses and attach the fuse cap holders.



Warning!

For continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

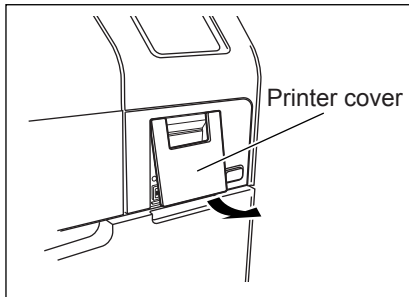
| Part No. | Description | Fuse Type |
|----------|----------------|-----------|
| BC963426 | Fuse 250V 4.0A | Time Lag |

11.9 Supply Printer Paper

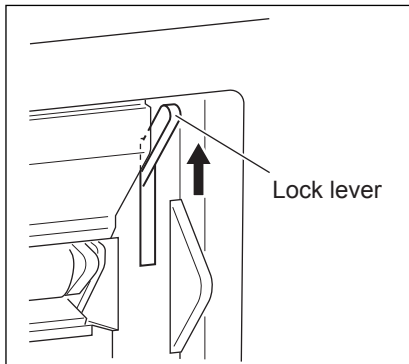
When the built-in printer has run out of paper, replenish printer paper by the following procedure:

1. Remove the printer cover.

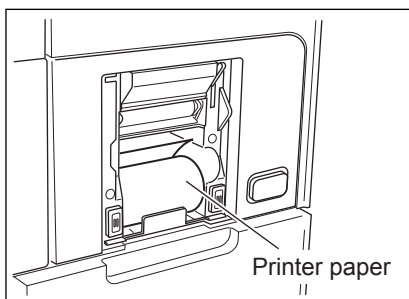
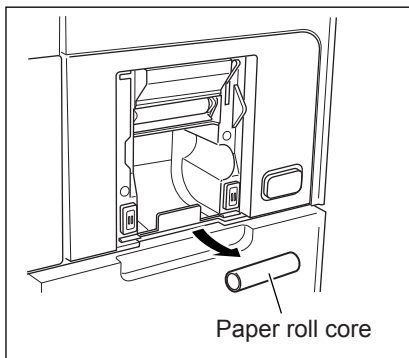
The printer cover can be removed by raising its lower edge.

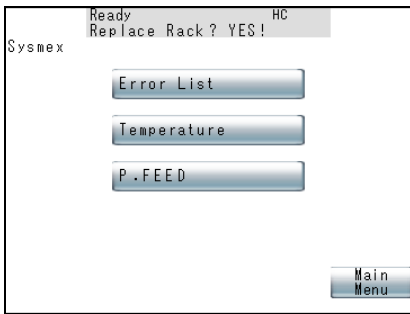
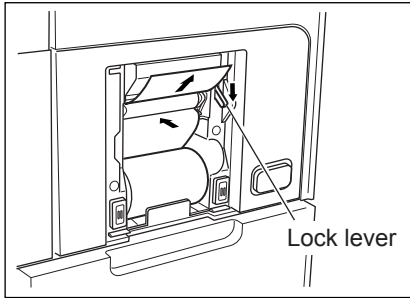


2. Raise the lock lever to unlock.



3. Remove the paper roll core and attach a new printer paper roll.

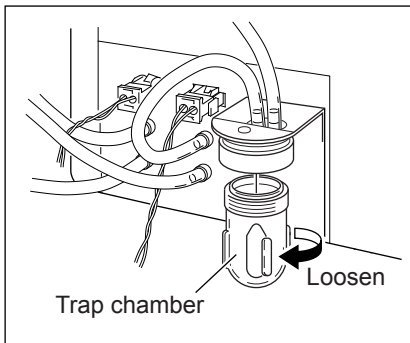




4. Pass the printer paper as shown below and push down the lock lever to lock.
5. Press **[Sysmex]** key, then press **[P. FEED]** key on the Sysmex Menu screen to feed printer papers.
6. Attach the printer cover.

11.10 Check and Drain Trap Chamber

Check the water level in the trap chamber and drain water that has collected.



1. Remove the chamber.
Turn the chamber clockwise and remove.
2. Discard water.
Discard water that has collected in the chamber.
3. Attach the chamber, and turn the chamber counterclockwise.
Make sure the float is inside.



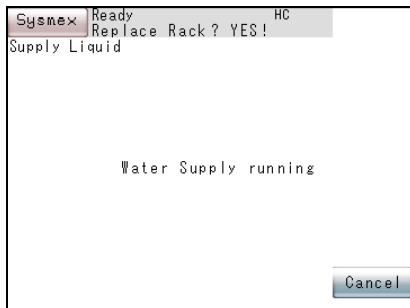
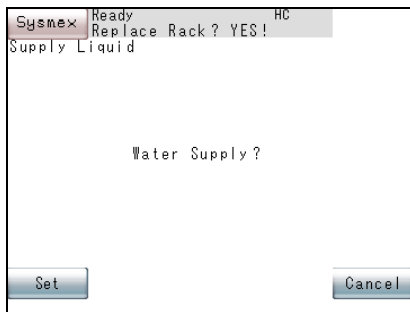
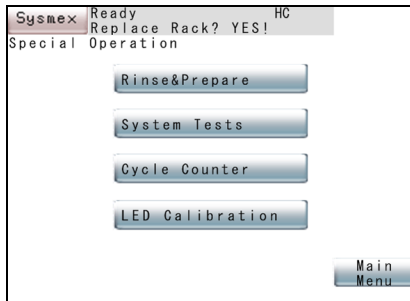
Caution!

If water is found to collect daily, a failure of the instrument may be suspected. Contact your local service representative.

11.11 Prime Rinse Solution to Hydraulic Line

In case the instrument has been left idle for a long period, refill the hydraulic line with rinse solution.

1. Press [**Special Menu**] key on the Main Menu screen.
The contents of the Main Menu will change over.
2. Press [**Special Operate**] key on the Main Menu screen.
The Special Operation Menu screen will appear.
3. Press [**Rinse & Prepare**] key on the Special Operation Menu screen.
The Supply Liquid Confirmation screen will display the message “Water Supply?”



4. Press [**Set**] key or [**Cancel**] key on the Supply Liquid Confirmation screen.

[**Set**] key: Executes water supply.

[**Cancel**] key: Cancels water supply and returns the screen to the Special Operate Menu.

5. Press [**Set**] key. Water supply will begin and the message “Water supply running” will appear. To stop water supply while it is in progress, press [**Cancel**] key.



Note

Refilling the hydraulic line with rinse solution takes roughly 35 sec.

6. When water supply is finished, the screen will return to the Special Operation Menu.

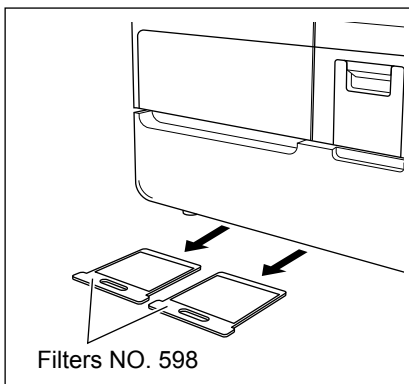
11.12 Filter inspection and cleaning

The main unit includes a filter to block the entry of dust. The filter should be cleaned regularly.



Caution!

- The filter should be cleaned regularly. If the filter gets clogged, it prevents the intake of air from outside to the interior of the instrument through the rear panel, potentially causing abnormal temperature errors etc. It also encourages infiltration of air through the reagent table cover, so that if the reagents are left for long periods with their lids not closed, condensation, or evaporation of the reagents, could have an influence on data.
- Do not use water to wash the filter.

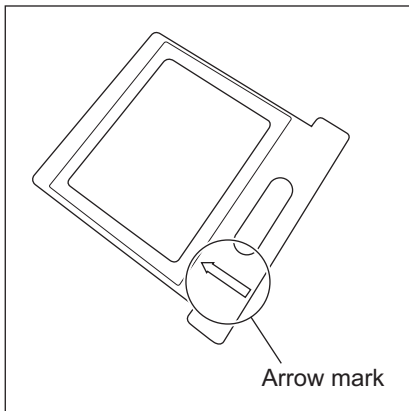


1. Remove filter NO.598 as shown in the figure on the left (top).
2. Use a vacuum cleaner or similar tool to remove dust from the filter.
3. After cleaning, push filter NO.598 fully back into place, in the reverse order of removal.



Note

Replace the filters with new ones if they are very dirty.



Insert the filter with the arrow mark face up.

11.13 Clean Instrument

To ensure instrument reliability, clean it in periodic intervals.



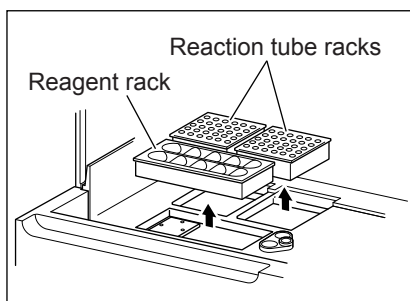
Warning!

- Before cleaning the instrument, be sure to turn off the power supply and unplug the power cord. This is necessary to avoid the risk of electrical shock. When cleaning the instrument, always wear latex or non latex examination gloves. After completion of work, wash hands with disinfectant. Handle all instrument parts as biologically hazardous. There is a risk of infection with pathogens etc.
- When cleaning the dried debris of the sample or reagent, wear latex gloves and wipe off the debris with a gauze or a towel moistened with 1:2 diluted CA CLEAN™ I, then wipe with a towel moistened with water, and finally wipe with a dry soft towel.

Clean the Instrument Exterior

1. Wipe off stains using a cloth soaked with water and neutral detergent.
2. Wipe the exterior using a dry cloth.

Clean the Instrument Interior



1. Open the light shield cover and check that it will not fall down with its own weight.
2. Take out the reaction tube racks and reagent rack.
3. Using a cloth soaked with water and neutral detergent, wipe off stains.

Clean likewise the reaction tube racks and reagent rack that were taken out before.

4. Wipe off stains using a dry soft cloth.
5. Close the light shield cover.



Information

Never use any other cleaning solution than water and neutral detergent. Otherwise, the surface coating may be damaged.

11.14 Replenish Reagent

When reagent has become insufficient, the error message “Insufficient Reagent (1 - 13)” will appear, and the alarm will sound. Replenish the insufficient reagent (No. 1 - 13).

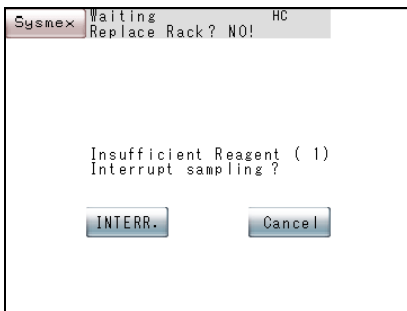
How to Replenish Reagent

1. The Insufficient Reagent Check Message screen will appear.
Dispense for an analysis for which reagent is insufficient will be interrupted.



Note

If another reagent should become insufficient while “Insufficient Reagent Check” message is displayed, the message for this reagent will be displayed after **[INTERR.]** key or **[Cancel]** key is pressed.



2. Press **[INTERR.]** key or **[Cancel]** key.

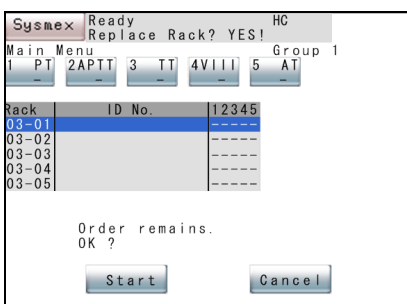
[INTERR.] key: Interrupts analysis and displays the “Waiting” screen. When analysis of dispensed sample is over, the next analysis will not be executed.

[Cancel] key: Interrupts analysis but continues analysis of parameters other than the parameter for which reagent is insufficient; this continuation is confined to the rack which is in progress. The next rack will not be processed.



Note

- The parameters for those dispensed samples that have not been dispensed with reagent will be marked with “X” in Work List.
- If neither **[INTERR.]** key nor **[Cancel]** key is pressed for some time, **[Cancel]** will be executed automatically.



3. When analysis of dispensed samples is over, the Analysis Start Confirmation screen will appear.



Note

When **[Cancel]** key is pressed on the Insufficient Reagent Check Message screen, the analyses for which reagents are insufficient are marked “X” in Work List, and the Analysis Start Confirmation screen will not appear.

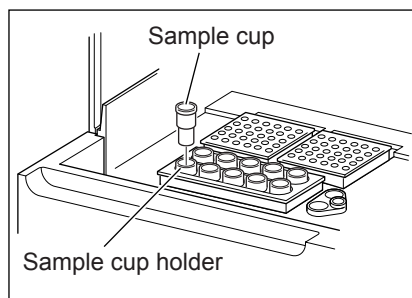
4. Prepare a new reagent.

Make sure its expiry date has not passed, and prepare the new reagent in accordance with the procedure described in the package insert supplied with it.



Caution!

Strictly follow the procedures described in the supplied package insert or other application information provided by the manufacturer of the reagent. Otherwise, correct result will not be obtained.



5. Open the light shield cover and check that it will not fall down with its own weight.
6. Set the reagent bottles in the reagent holder. If the sample cup holder is set, feed reagent into the sample cups.
7. Close the light shield cover.
8. Press **[Start]** key or **[Cancel]** key on the Analysis Start Confirmation screen.

[Start] key: Starts analysis after interruption.

[Cancel] key: Stops analysis and returns the screen to the Main Menu.



Information

The parameters marked with "X" in Work List must be reanalyzed.



Note

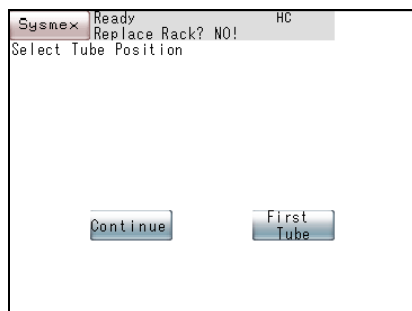
The parameters whose analyses were interrupted or those whose analyses failed are marked with "X" in Work List.

9. Press **[Start]** key to start analysis after interruption.
The screen confirming the first tube position will appear.

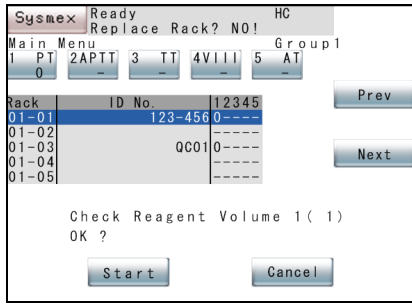
10. Press **[Continue]** key or **[First Tube]** key.

[Continue] key: Starts with the reaction tube that follows the last used tube in the previous analysis.

[First Tube] key: Starts with the upper extreme-right tube in the right-hand reaction tube rack.



When Reagent Volume Monitoring Function is Used



When the reagent volume monitoring is set Valid, the remaining volume is calculated in the Work List. When the reagent volume estimate value is “0” or less, the message “Check Reagent Volume” will appear.

- [Start]** key: Starts analysis, and the reagent volume monitoring function does not work.
- [Cancel]** key: Cancels analysis and returns the screen to the Main Menu.



Information

The parameters marked with “X” in the Work List must be reanalyzed.



Note

For setting the reagent volume monitoring, refer to “10.12 Setup of Reagent Volume Monitoring”.

11.15 Replenish Reaction Tubes

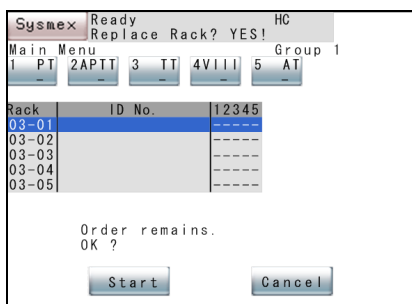
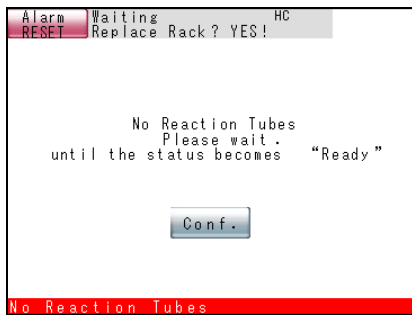
When reaction tubes are used up during analysis, the alarm will sound and the error message will appear. Stop analysis and replace reaction tubes.

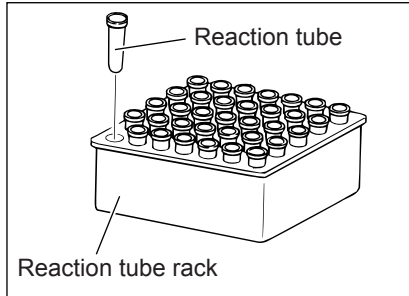
1. The message “No Reaction Tubes Please wait” will appear. The instrument starts the interruption process.

2. Press **[Conf.]** key.

The alarm stops and “Waiting” screen will appear. When analysis of samples being incubated is completed, analysis is interrupted.

3. When analysis of the samples being incubated is complete, the Analysis Start Confirmation screen appears.
4. Open the light shield cover and check that it will not fall down with its own weight.





5. Take out the reaction tube rack and set the reaction tubes.
6. Set the reaction tube rack on the specified place on the table stage.



Warning!

Reaction tubes are intended for single use only. If used more than once, rewashed, or recycled, inaccurate measuring results may be obtained due to the effect of possible contamination. Inaccurate results could lead to inappropriate patient diagnosis or treatment.

7. Close the light shield cover.
8. Press **[Start]** key or **[Cancel]** key on the Analysis Start Confirmation screen.

[Start] key: Starts analysis after interruption.

[Cancel] key: Interrupts analysis and returns to the Main Menu screen.



Information

The parameters marked with "X" on the Work List must be reanalyzed.

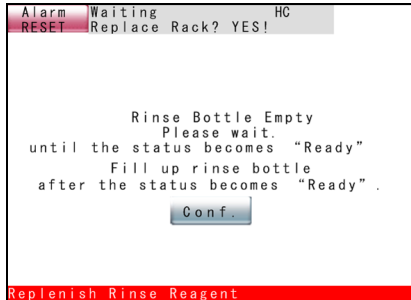


Note

The parameters whose analyses were interrupted or those whose analyses failed are marked with "X" in the Work List.

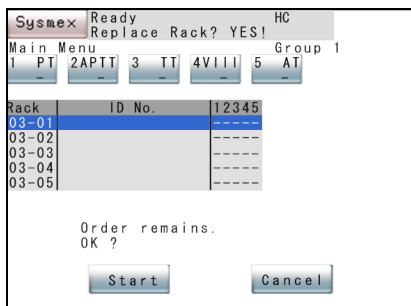
11.16 Replenish Rinse Solution

When rinse solution becomes insufficient during analysis, the confirmation screen will appear with the error message. Replenish rinse solution in accordance with the following procedure:



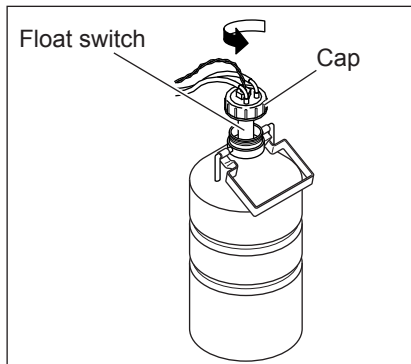
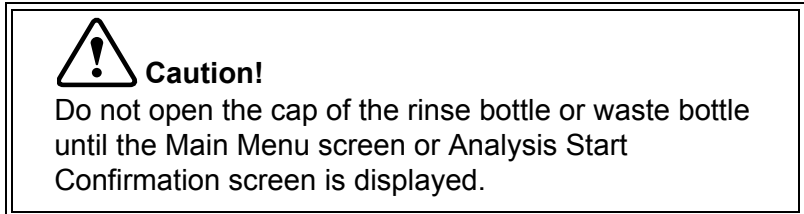
1. Press **[Conf.]** key.

The alarm stops and “Waiting” screen will appear. When analysis of samples being incubated is complete, analysis is interrupted.



2. The Analysis Start Confirmation screen appears.

When analysis of the samples being incubated is complete, the Analysis Start Confirmation screen appears.



3. Slightly turn the cap counterclockwise to release the pressure from the bottle.
4. Open the cap and remove the float switch.
5. Refill the rinse bottle with distilled water.
6. Put the float switch in the bottle and securely tighten the cap clockwise.

Check for any kink, etc. in the tube.

7. Press **[Start]** key or **[Cancel]** key on the Analysis Start Confirmation screen.

[Start] key: Starts analysis after interruption.

[Cancel] key: Interrupts analysis and returns the screen to the Main Menu.



Caution!









- When analysis is made with the rinse bottle lying flat, there is a possibility that correct analysis result may not be obtained. Make sure the rinse bottle is not lying flat.
- If the power is turned off with the rinse bottles lying flat, the solution may flow back into the instrument. Before turning off the power switch, confirm that the bottles are not lying flat.
- Do not touch the float switch and the inside of the cap. If dust or dirt sticks to the cap inside, the bottle inside may be contaminated, possibly leading to incorrect results. If fingers happen to touch the cap inside, wash them with rinse solution before attaching.
- In removing the tube from the instrument, first turn the cap leftward to release the accumulated internal pressure beforehand. Otherwise, rinse solution will spill over.
- When replacing the rinse bottle, do not leave the instrument with the bottle removed for a long period. Leaving the instrument with the bottle removed for long periods may result in malfunction.



Note

The parameters whose analyses were interrupted or those whose analyses failed are marked with “X” in Work List.

11.17 Supply Parts List

| Part No. | Description | Min. lot | Remarks |
|------------|------------------------------------|------------|---|
| 964-0631-3 | CA CLEAN™ I (GSA-500A) | 1 pc. | Detergent, 50 mL per bottle |
| BT565104 | CA CLEAN™ II (GSZ-520A) | 1 pc. | Detergent, 45 mL per bottle |
| BC963426 | Fuse 250V 4.0A | 1 pc. | |
| 663-0212-2 | Sample Tube Spacer 10 mm Diamet | 1 pc. | for STAT Sample Holder  |
| 663-5117-3 | Sample Tube Spacer 13 Phi | 1 pc. | for STAT Sample Holder  |
| 366-1789-1 | Tube Holder No. 58 (White) | 1 pc. | for Sample Rack  |
| 366-1793-6 | Tube Holder No. 113 (White) | 1 pc. | for Sample Rack  |
| 363-2536-4 | Holder No. 70 (Sample cup adapter) | 1 pc. | for Sample Rack  |
| 363-2558-6 | Holder No. 89 | 1 pc. | for Reagent Rack  |
| 921-0354-9 | Paper Thermal F1-2 | 5 pcs. | Thermal paper for the built-in Printer |
| 541-1352-1 | Push Vial PV-10 | 10 pcs. | Reagent vial |
| 013-1771-4 | SLD Vial Assy | 10 pcs. | Reagent vial |
| 904-0721-9 | Reaction Tube (SU-40) | 3,000 pcs. |  |
| 664-0167-9 | Filter Assy for Rinse Bottle | 1 pc. | |
| 424-1160-8 | Sample Cup Conical 4 mL | 100 pcs. |  |
| 424-3334-9 | Sample Rack No. 3 (White) | 1 pc. | |
| 833-3895-6 | Sample Rack No. 3 w/Holder #55 | 1 pc. | |
| AJ046225 | Reaction Tube Trash Box | 1 pc. | |



Warning!

- CA CLEAN™ I is an alkaline solution. Avoid contact with it. If you get it on your skin or clothing immediately wash it off with large volumes of water.
- CA CLEAN™ II is an acidic cleaning agent. It should not come in contact with skin or clothing. If it happens rinse skin or clothing with plenty of water to avoid injury or damage.
- Extra care should be taken to make sure CA CLEAN™ I is not mixed and used with acidic solutions such as CA CLEAN™ II. Direct mixing of CA CLEAN™ I and an acidic solution will result in the highly hazardous release of poisonous chlorine gas.



Note

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

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| | | |
|------------|----------------------------------|-------------|
| 12. | Troubleshooting | 12-1 |
| 12.1 | Introduction | 12-1 |
| 12.2 | Error Corrective Procedure | 12-2 |
| 12.3 | Analysis Data Error | 12-14 |
| 12.4 | Sysmex Menu | 12-15 |
| 12.5 | Special Operation | 12-17 |
| 12.6 | Cycle Counter | 12-21 |



12. Troubleshooting

12.1 Introduction

This chapter describes the error messages displayed with this instrument, potential failures, and proper action that the operator should take in the event of failures.

If the action described in this chapter should fail to restore the instrument to normal status, contact your local service representative for assistance.

The major contents of this chapter are:

- Troubleshooting by Error Message
This section contains a list of the error messages displayed on the LCD screen in the event of trouble, with corrective procedures.
- Sysmex Menu
This section describes Sysmex Menu at the upper left corner of the Main Menu screen. This menu makes it possible to display instrument's temperature, error list, and feed of printer paper.
- Special Operation
This section describes the programs necessary for maintenance of this instrument and operation testing.

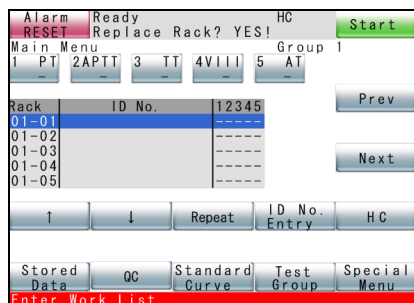
Troubleshooting Guide

The errors displayed on the LCD screen can be divided as in the following:

- Instrument Errors (analysis operation, pressure, temperature monitoring, etc.)

Analysis operation stops when an error occurs in the instrument. Take action within the range allowed in this chapter.

If the error is not eliminated by taking applicable measures, contact your local service representative for assistance.



Note

When the instrument develops an error, an error message appears in the left lower corner of the LCD screen, and [Sysmex] key changes to [ALARM RESET] key.

Press [ALARM RESET] key to stop the alarm.

When the [ALARM RESET] key is pressed, the error is recorded in the Error List.

- Messages for calling attention

Attention-calling messages are displayed when you are preparing to start operation, etc.

- Error in Analysis Data

When a coagulation curve or coagulation time is judged to be abnormal, a error code “ERR xxx” and error message are printed by the built-in printer.

When there is no error, “ERR 0” is printed.



Note

- When an error occurs in a sample, the analysis data relative to the error is displayed “***.*.”
- A parameter whose analysis has been interrupted has “X” displayed in Work List.
- Repeat analysis is required in the case of either an instrument error (shown as “X” in the Work List) or an analysis error (shown as “***.*” in the stored Data and on print out).

12.2 Error Corrective Procedure

The error messages are listed in alphabetical order.

[Barcode Scanner Error]

| | |
|-------------------|---|
| Probable Cause | 1) Barcode scanner malfunctions. |
| Corrective Action | 1) Turn the power switch OFF. After waiting for several seconds, turn it ON again. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Barcode Scanner Driver Error]

| | |
|-------------------|--|
| Probable Cause | 1) There is an obstruction in the Barcode Scanner Drive. |
| Corrective Action | 1) Remove any foreign materials. |

[Change Sample Rack] <Attention-calling message>

| | |
|-------------------|---|
| Probable Cause | <ol style="list-style-type: none"> 1) Sample rack remains set, even after analysis is completed. 2) Failure of sample rack sensor. 3) The sampler drawer was not pulled out for the rack replacement. 4) Failure of sampler drawer sensor. |
| Corrective Action | <ol style="list-style-type: none"> 1) Replace sample rack. 2) Check for any dirt or foreign matters on the placement part of the sample rack. 3) Pull out the sampler drawer and replace the sample rack. 4) Check for any dirt or foreign matters around rails of the sampler drawer and remove if any. 5) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Check Control Expiry] <Attention-calling message>

| | |
|-------------------|--|
| Probable Cause | 1) One had failed to set expiry date for control plasma or made setting error. |
| Corrective Action | 1) Set the expiry date by pressing [QC] → [Settings]. Refer to “8.2 QC File Setting”. |

[Check Reagent Expiry (Reagent Holder No.)] <Attention-calling message>

| | |
|-------------------|---|
| Probable Cause | 1) One had failed to set expiry date or made setting error. |
| Corrective Action | 1) Set the expiry date by pressing [Standard Curve] → [Lot No. Entry]. Refer to “9.6 Set Reagent Information”. |

[Check Reagent Volume 1 (Reagent Holder No.)] <Attention-calling message>

| | |
|-------------------|---|
| Probable Cause | When reagent volume monitoring is set to “v”; <ol style="list-style-type: none"> 1) Reagent volume necessary for analyses exceeds remaining volume. |
| Corrective Action | 1) Replenish reagent and reset reagent volume. |

[Check Syringe Unit]

| | |
|-------------------|---|
| Probable Cause | An error occurs each time analysis begins. <ol style="list-style-type: none"> 1) Syringe cycles exceeded 300,000. |
| Corrective Action | 1) Syringe needs to be replaced. Contact your local service representative. |

[Enter Work List] <Attention-calling message>

| | |
|-------------------|---|
| Probable Cause | 1) No entry in Work List. |
| Corrective Action | 1) Enter the analysis order in the Work List. |

[Exist same sample No.] <Only if ID Barcode reader is connected>

| | |
|-------------------|--|
| Probable Cause | <ol style="list-style-type: none"> 1) Same ID number exists in a rack. 2) Something is preventing free movement of the barcode reader. 3) Operation error of barcode reader drive mechanism. |
| Corrective Action | <ol style="list-style-type: none"> 1) Check samples with same ID number. 2) Remove any dirt or foreign matters on the barcode reader drive mechanism. 3) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[HBCR Time Out]

| | |
|-------------------|--|
| Probable Cause | 1) Communication with the hand-held barcode reader has exceeded the timeout duration (1 second). |
| Corrective Action | 1) Check that the external device conditions setting of the instrument correct. |

[HC ACK Code Error]

| | |
|-------------------|---|
| Probable Cause | 1) Communication with the host computer failed. |
| Corrective Action | <ol style="list-style-type: none"> 1) Check the error log in the host computer. 2) Check the Host Computer Setting in the instrument. |

[HC ACK Time Out]

| | |
|-------------------|--|
| Probable Cause | 1) Communication with the host computer exceeded Time Out (15 sec.). |
| Corrective Action | <ol style="list-style-type: none"> 1) Check the host computer. 2) Check the Host Computer Setting in the instrument. |

[HC Communication Error]

[HC CTS Time Out]

| | |
|-------------------|---|
| Probable Cause | 1) Communication with the host computer failed. |
| Corrective Action | <ol style="list-style-type: none"> 1) Check the error log in the host computer. 2) Check the Host Computer Setting in the instrument. |

[HC ETX Time Out]

| | |
|-------------------|--|
| Probable Cause | 1) Communication with the host computer exceeded Time Out (15 sec.). |
| Corrective Action | <ol style="list-style-type: none"> 1) Check the host computer. 2) Check the Host Computer Setting in the instrument. |

[HC Off line]

| | |
|-------------------|--|
| Probable Cause | 1) The connector cable is disconnected. 2) The host computer is not turned on. 3) The host computer is not ready to receive (off-line). |
| Corrective Action | 1) Check the connection state. 2) Turn on the host computer. 3) Check the host computer on-line status. 4) Check the Host Computer Setting in the instrument. |

[HC Reception Count Error]

| | |
|-------------------|---|
| Probable Cause | 1) Communication with the host computer failed. |
| Corrective Action | 1) Check the error log in the host computer. 2) Check the Host Computer Setting in the instrument. |

[HC STX Time Out]

| | |
|-------------------|--|
| Probable Cause | 1) Communication with the host computer exceeded Time Out (15 sec.). |
| Corrective Action | 1) Check the host computer. 2) Check the Host Computer Setting in the instrument. |

[HC Transmission Count Error]

| | |
|-------------------|---|
| Probable Cause | 1) Communication with the host computer failed. |
| Corrective Action | 1) Check the error log in the host computer. 2) Check the Host Computer Setting in the instrument. |

[Instructions Not Found in HC]

| | |
|-------------------|--|
| Probable Cause | 1) When inquiry was made to the host computer, No Order (999) was sent back. |
| Corrective Action | 1) Check to see that Work List is registered in HC. |

[Insufficient Reagent (Holder No.)]

| | |
|-------------------|---|
| Probable Cause | 1) No reagent or insufficient reagent is set. |
| Corrective Action | 1) Set required volume of reagent. |

[Insufficient Reaction Tube] <Attention-calling message>

| | |
|-------------------|--|
| Probable Cause | 1) The tests entered for analysis exceed the remaining reaction tubes (A maximum of 60 tests). |
| Corrective Action | 1) Reduce the number of the tests entered for analysis. |

[Interrupt by Mechanical Stop] <Attention-calling message>

| | |
|-------------------|--|
| Probable Cause | 1) Mechanical Stop switch has been pressed. |
| Corrective Action | 1) Discard any reaction tubes remaining in the detector wells and re-test. |

[Invalid Settings]

| | |
|-------------------|--------------------------------|
| Probable Cause | 1) Problem in settings. |
| Corrective Action | 1) Enter appropriate settings. |

[Light Shield Open]

| | |
|-------------------|--|
| Probable Cause | 1) The light shield cover is open when beginning operation/during operation. |
| Corrective Action | 1) Close the light shield cover. |

[Mixing motor error detected]

| | |
|-------------------|---|
| Probable Cause | 1) An error occurred on the mixing motor. |
| Corrective Action | 1) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[No Paper]

| | |
|-------------------|---|
| Probable Cause | 1) No printer paper is set. |
| Corrective Action | 1) Set printer paper. Refer to “11.9 Supply Printer Paper”. |

[No Reaction Tubes]

| | |
|-------------------|---|
| Probable Cause | 1) No reaction tubes. 2) Reaction tube position error. |
| Corrective Action | 1) Replenish reaction tubes. |

[No Sample (Rack Position)]

| | |
|-------------------|--|
| Probable Cause | Plasma aspiration error 1) No sample collection tube in sampler rack. 2) Plasma in sample is insufficient. |
| Corrective Action | 1) Set the sample in the sample rack. 2) Set required volume of plasma. |

[No set reagent in the holder]

| | |
|-------------------|---|
| Probable Cause | 1) Reagents are missing in the reagent holder. |
| Corrective Action | 1) Check the reagent names for all groups in the Reagent Holder menu. |

[Order Remains] <Attention-calling message>

| | |
|-------------------|--|
| Probable Cause | 1) Some orders still remain probably because analysis interruption or mechanical stop was performed. |
| Corrective Action | 1) If the analysis for the order not analyzed is necessary, restart the analysis after the interruption operation is completed and the instrument is ready to analyze. |

[Pressure Pump Error]

| | |
|-------------------|--|
| Probable Cause | 1) The silicone tube is disconnected from the rinse bottle. 2) The cap on the rinse bottle is not securely tightened. 3) Pump failure or tube disconnection in the instrument. |
| Corrective Action | 1) Properly connect the tube. 2) Securely tighten the bottle cap. 3) Contact your local service representative. |

[Printer Error]

| | |
|-------------------|---|
| Probable Cause | 1) The lever to set printer paper is not pushed down. |
| Corrective Action | 1) Push down the lever. Refer to “11.9 Supply Printer Paper”. |

[Probe Crash]

| | |
|-------------------|--|
| Probable Cause | 1) No or insufficient sample plasma or reagent in tubes or sample cups at sample aspiration position or reagent aspiration position. 2) Something is preventing probe descending. 3) Probe is out of position. |
| Corrective Action | 1) Prepare plasma and reagent in required volume. 2) Remove any foreign matters. 3) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[QC Data Error]

| | |
|-------------------|---|
| Probable Cause | 1) Backup Memory Error. |
| Corrective Action | 1) Turn the power switch OFF. After waiting for several seconds, turn it ON again. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[QC Limit Error]

| | |
|-------------------|---|
| Probable Cause | 1) QC analysis result exceeded the set ranges of Upper or Lower Limit. |
| Corrective Action | 1) Check whether control plasma expiry date has passed or not. Check also whether it has been stored properly. |

[QC Limit Error (Stop)]

| | |
|-------------------|---|
| Probable Cause | 1) QC analysis result exceeded the set range of Upper Stop or Lower Stop Limit. |
| Corrective Action | 1) Check whether control plasma expiry date has passed or not. Check also whether it has been stored properly. |

[Replace Sample Rack] <Attention-calling message>

| | |
|-------------------|---|
| Probable Cause | 1) The rack was lifted or removed during analysis interruption. 2) Sample rack sensor failure. |
| Corrective Action | 1) Check that the sample is correct, then set the rack in place. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Replace Sample Rack Drawer] <Attention-calling message>

| | |
|-------------------|--|
| Probable Cause | 1) The sampler was pulled out before analysis began. 2) Failure of the sampler pullout sensor. |
| Corrective Action | 1) Close the sampler. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Replace STAT Sample] <Attention-calling message>

| | |
|-------------------|--|
| Probable Cause | 1) STAT sample has not been placed. 2) Light Shield Cover was opened and STAT sample was placed. 3) Failure of sampler drawer sensor. |
| Corrective Action | 1) Pull out the sampler drawer and place the STAT sample. 2) Check the STAT sample was placed correctly. 3) Check any dirt or foreign matters around rails of the sampler drawer and remove if any. 4) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Replenish Rinse Reagent]

| | |
|-------------------|--|
| Probable Cause | 1) Rinse solution in the rinse bottle is insufficient. 2) The float switch connector in the rinse bottle is disconnected. |
| Corrective Action | 1) Replenish rinse solution (distilled water). 2) Connect the float switch connector. |

[Sampling Error (Position)]

| | |
|-------------------|---|
| Probable Cause | Dispensing error 1) Plasma in sample is insufficient. 2) Check reagent volume 1 (position). 3) Vial Type setting is wrong. 4) Sample tube or sample cup inner diameter is too small. 5) Dispense mechanism error. |
| Corrective Action | 1) Set required volume of plasma. 2) Set required volume of reagent. 3) Correct the Vial Type setting. 4) Use tube of at least 9.4 mm ID. 5) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Set more than two points]

| | |
|-------------------|---|
| Probable Cause | 1) There are fewer than two Standard Curve analysis points. |
| Corrective Action | 1) Set two or more points. |

[Set Sample Rack] <Attention-calling message>

| | |
|-------------------|---|
| Probable Cause | 1) The sample rack is not set. 2) The sample rack is set in the opposite direction. 3) Sample rack sensor failure. |
| Corrective Action | 1) Set the rack. 2) Set the rack in proper direction. 3) Check for any dirt or foreign matters on the placement part of the sample rack. 4) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Settings are broken]

| | |
|-------------------|--|
| Probable Cause | 1) The power has been turned OFF during the writing of the setting data. 2) Backup battery has run out. |
| Corrective Action | 1) Contact your local service representative. |

[Settings are repaired]

| | |
|-------------------|---|
| Probable Cause | 1) The power has been turned OFF during the storing or restoring of settings. 2) BBURAM battery has run out. |
| Corrective Action | 1) Replace the BBURAM battery. |

[Settings differs from backup]

| | |
|-------------------|---|
| Probable Cause | 1) The circuit board has been replaced. 2) Has been started with a program card of other instruments. 3) After the storing of the setting, the power has been turned OFF right before the automatic backup. |
| Corrective Action | 1) Contact your local service representative. |

[Standard Curve Warning] <Attention-calling error>

| | |
|-------------------|--|
| Probable Cause | 1) Some analyzed data have errors. |
| Corrective Action | 1) Check the data in Stored data screen. If there is a problem, analyze again. Otherwise, update the standard curve. |

[Standard Curve Error] <Attention-calling error>

| | |
|-------------------|---|
| Probable Cause | 1) Data of set Standard Curve does not increase or decrease constantly. 2) Some analyzed data have errors. |
| Corrective Action | 1) Set proper Standard Curve data. |

[Stored Data Error]

| | |
|-------------------|---|
| Probable Cause | 1) Backup Memory Error. |
| Corrective Action | 1) Turn the power switch OFF. After waiting for several seconds, turn it ON again. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Syringe Error]

| | |
|-------------------|---|
| Probable Cause | 1) Syringe error during operation. |
| Corrective Action | 1) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Temp. Error (High)/Cooler]

[Temp. Error (Low)/Cooler]

[Temp. Error (High)/Detector]

[Temp. Error (Low)/Detector]

[Temp. Error (High)/Incubator]

[Temp. Error (Low)/Incubator]

[Temp. Error (High)/Room]

[Temp. Error (Low)/Room]

| | |
|-------------------|---|
| Probable Cause | 1) Room temperature is out of specification (15 - 35°C). 2) Failure of temperature monitoring sensor |
| Corrective Action | 1) Control temperature by air conditioning, etc. 2) Contact your local service representative. |

[Temp. Sensor Error /Cooler]

[Temp. Sensor Error /Detector]

[Temp. Sensor Error /Incubator]

[Temp. Sensor Error /Room]

| | |
|-------------------|---|
| Probable Cause | 1) Thermistor or its monitoring circuit has a failure. |
| Corrective Action | 1) Turn the power switch OFF. After waiting for several seconds, turn it ON again. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[The error list was cleared]

| | |
|-------------------|--|
| Probable Cause | 1) The power was turned off during error registration. |
| Corrective Action | 1) The error list is automatically cleared. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Time to replace Catcher unit]

| | |
|-------------------|--|
| Probable Cause | Error occurs every time starting the analysis 1) Operation times of catcher unit exceed 25,000. |
| Corrective Action | 1) As it is necessary to replace the catcher unit. Contact your local service representative. |

[Trash box is not set]

| | |
|-------------------|---|
| Probable Cause | <ol style="list-style-type: none"> 1) Trash box is not set. 2) Trash box is not fully inserted. 3) Trash box is removed during the analysis. 4) Analysis has been started with the trash box being removed. |
| Corrective Action | <ol style="list-style-type: none"> 1) Set the trash box. 2) Fully insert the trash box. |

[Tube Catch Error (Position)]

| | |
|-------------------|--|
| Probable Cause | <ol style="list-style-type: none"> 1) Failure to catch a reaction tube. 2) The reaction tube catch mechanism is faulty. |
| Corrective Action | <ol style="list-style-type: none"> 1) Remove any reaction tubes lying in the instrument. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Tube Release Error (Position)]


| | |
|-------------------|--|
| Probable Cause | <ol style="list-style-type: none"> 1) Failure to release reaction tube. |
| Corrective Action | <ol style="list-style-type: none"> 1) Remove any reaction tubes that are lying on the analysis stage or being gripped. 2) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Turned Off During Operation] <Attention-calling message>

| | |
|-------------------|--|
| Probable Cause | <ol style="list-style-type: none"> 1) Power switch was turned off during operation. |
| Corrective Action | <ol style="list-style-type: none"> 1) Discard any reaction tubes remaining in the detector wells and re-test. |

[Vacuum Pump Error]

| | |
|-------------------|--|
| Probable Cause | <ol style="list-style-type: none"> 1) The silicone tube is disconnected from the waste bottle. 2) The cap on the waste bottle is not securely tightened. 3) The trap chamber is full. 4) Pump failure or tube disconnection in the instrument. |
| Corrective Action | <ol style="list-style-type: none"> 1) Properly connect the tube. 2) Securely tighten the bottle cap. 3) Empty the trap chamber. (Refer to “11.10 Check and Drain Trap Chamber”.) 4) Contact your local service representative. |



Caution!
When a Vacuum Pump Error occurs, waste liquid may collect in the trash box.

[Voltage Low Limit]

| | |
|-------------------|--|
| Probable Cause | <ol style="list-style-type: none"> 1) Momentary power failure occurred. 2) The voltage to the power supply is fluctuating. |
| Corrective Action | <ol style="list-style-type: none"> 1) Confirm whether power failure occurred or not. 2) Supply the voltage from the other branch circuit. 3) When the error recurs, the instrument may have a problem. Contact your local service representative. |

[Waste Bottle is full]

| | |
|-------------------|--|
| Probable Cause | <ol style="list-style-type: none"> 1) The waste bottle is full. 2) The float switch connector in the waste bottle is disconnected. |
| Corrective Action | <ol style="list-style-type: none"> 1) Dispose of waste liquid. 2) Connect the float switch connector. |

[X Axis Home Position Error]

[Y Axis Home Position Error]

| | |
|-------------------|---|
| Probable Cause | <ol style="list-style-type: none"> 1) Something is impairing XY mechanism operation. 2) XY mechanism operation error. |
| Corrective Action | <ol style="list-style-type: none"> 1) Remove any foreign matters. 2) Turn the power switch OFF. After waiting for several seconds, turn it ON again. 3) If the error recurs, the instrument may have a problem. Contact your local service representative. |

[Z Axis Down Error]

[Z Axis Home Position Error]

| | |
|-------------------|---|
| Probable Cause | <ol style="list-style-type: none"> 1) Reaction tubes have not been discarded and remain in the incubation block or detector. 2) Something is impairing Z-mechanism operation. 3) Z-mechanism move error. 4) The tube trash drawer is full. |
| Corrective Action | <ol style="list-style-type: none"> 1) Remove any reaction tubes. 2) Remove any foreign matters. 3) Turn the power switch OFF. After waiting for several seconds, turn it ON again. 4) Empty the tube trash drawer. 5) When the error recurs, the instrument may have a problem. Contact your local service representative. |

12.3 Analysis Data Error

Clotting Method

| Error Code & Message | Probable Cause | Action/Step |
|----------------------------------|---|---|
| ERR[1] Temp Error | Temperature error occurs during sample analysis. | Refer to “Temperature Error”. |
| ERR[2] Slight Coagulation | Coagulation reaction detected is very small. | Reanalyze and make comprehensive judgment, taking sample, reagent, etc. into consideration. On Fbg, analyze -Fbg. |
| ERR[4] Analysis Time Over | Coagulation is not completed within detection time. | Reanalyze and make comprehensive judgment, taking sample and reagent, etc. into consideration. |
| ERR[8] Coag. Curve Error | Coagulation Curve Error 1) Sections of down-slanting curve are found. 2) Steeply-slanting sections are found. 3) Because of cool buffer (Owren’s Veronal buffer) and other factors, bubbles are generated causing extended coagulation time (Fbg). | Bring buffer to room temperature before performing reanalysis. |
| ERR[16] Turbidity Level Over | Turbidity is too high to make analysis. | If applicable, centrifuge the plasma in case of turbidity again and re-analyze the sample. |
| ERR[32] No Coagulation | Coagulation reaction can not be detected. | Make comprehensive judgment, taking various aspects into consideration, including whether or not any error is involved in samples (storage status, blood collecting procedure, etc.) and reagents (storage status). On Fbg, analyze -Fbg. |
| ERR[64] Measurement Error | Analysis failed due to insufficient volume of plasma or an error of the instrument. | Prepare a required volume of plasma and perform reanalysis. |
| ERR[100] Range Over | Analysis range is exceeded. | Make comprehensive judgment, taking various aspects into consideration, including whether or not any error is involved in samples (storage status, blood collecting procedure, etc.) and reagents (storage status). |
| ERR[128] Early Reaction Error | An abnormal reaction was detected at an initial stage of the coagulation. | Re-analyze the sample. |



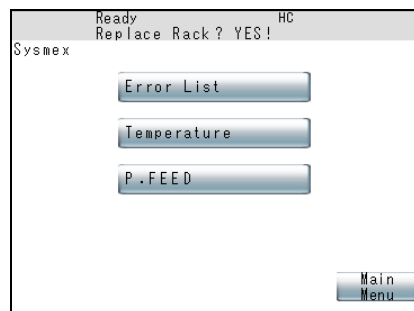
Caution!

“Caution: Review Curve” will accompany some of the error messages. When this message is printed, review the curve to determine if the result is acceptable. Reanalyze the sample as needed.

Chromogenic Method/Immunoassay Method

| Error Code & Message | Probable Cause | Action/Step |
|--------------------------------------|---|---|
| ERR[401] Trans Light Low | Transmitted light is extremely low. | Check the reagent, and reanalyze. |
| ERR[402] Trans Light High | Transmitted light is extremely high. | Check the reagent, and reanalyze. |
| ERR[404] No Linearity | Linearity of reaction curve is insufficient. | Reanalyze. |
| ERR[408] Reaction Curve Error | Reaction curve has changed in reverse direction. | Check the setting and the reagent, and reanalyze. |
| ERR[416] Range Over | Excessive antigen (only for Immunoassay Method). | Carry out dilution or take other steps, then reanalyze. On DDPI, analyze +DDP, DDi, +DDi, vWF, +vWF, -vWF, WFa, +WFa, -WFa. |
| ERR[528] No polynomial adjustment | The reaction curve could not be approximated to a polynomial. | Reanalyze. |
| ERR[656] Range in non-linear | During analysis of the reaction curve, changes were non-linear, or else the curve could not be approximated to a straight line. | Reanalyze. |

12.4 Sysmex Menu



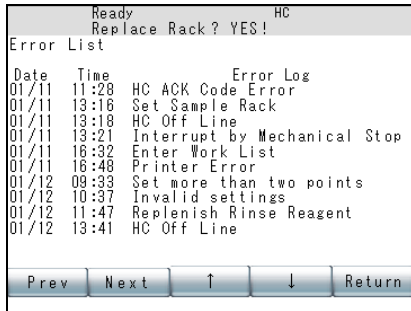
Press **[Sysmex]** key in the upper left corner of the LCD screen to display the Sysmex Menu screen.

Error List

Regarding messages for instrument errors and attention-calling errors, a maximum of 100 messages are recorded and displayed.

1. Press **[Sysmex]** key.

The Sysmex Menu screen will appear.



2. Press **[Error List]** key.
Date, Time, and Content of the error are displayed.
3. Press **[Return]** key to return to the Sysmex Menu screen.
4. Press **[Main Menu]** key on the Sysmex Menu screen to return to the original screen.

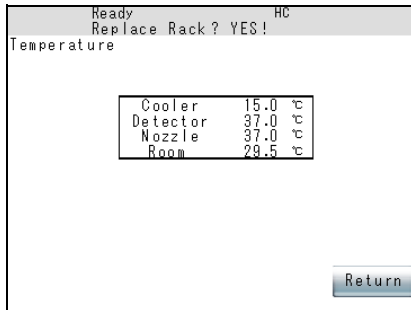
Temperature

Monitored temperature of each place is displayed.



Note

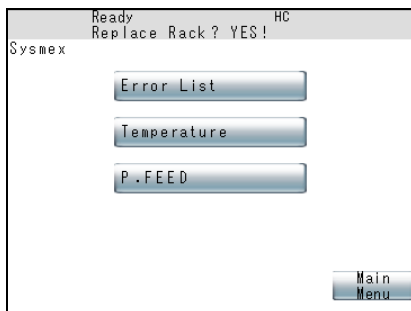
When a set temperature is reached with power supply on, “Ready” appears.



1. Press **[Sysmex]** key.
The Sysmex Menu screen will appear.
2. Press **[Temperature]** key.
Monitored temperatures are displayed.
Cooler: Displays temperature of the reagent cooling section.
Detector: Displays temperature of the detector.
Nozzle: Displays temperature of the probe.
Room: Displays temperature of the room.
3. Press **[Return]** key to return to the Sysmex Menu screen.
4. Press **[Main Menu]** key on the Sysmex Menu screen to return to the original screen.

P. FEED (Paper feed)

Paper is fed to the built-in printer.



1. Press **[Sysmex]** key.
The Sysmex Menu screen will appear.
2. Press **[P. FEED]** key.
Roughly 10 mm of built-in printer paper is fed out.
3. Press **[Main Menu]** key on the Sysmex Menu screen to return to the original screen.

12.5 Special Operation

This instrument incorporates a system test program for checking that the electrical system and software system are operating properly and a program for instrument maintenance.



Note

The maintenance program can be executed only when the instrument is displaying “Ready” or “Not Ready”. Analysis operation and testing cannot be executed at the same time.

Priming

When this instrument is installed for the first time or it has been idle for long time, there may be bubbles in the hydraulic line.

To get correct analysis results, it is necessary to execute this program and supply rinse solution into the hydraulic line.



Note

At initial installation, the above operation is performed by your local service representative.

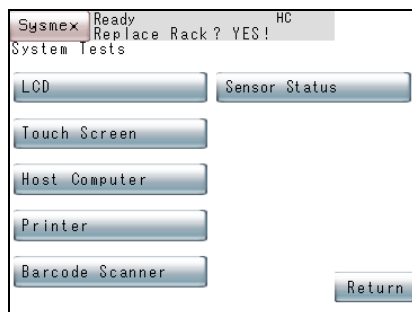
For Priming, refer to “11.11 Prime Rinse Solution to Hydraulic Line”.

System Tests Menu screen

Whether the electrical system and software system of this instrument are operating properly or not can be checked by executing System Tests.

Perform the tests on the System Tests Menu screen. Follow the steps shown below to display the screen.

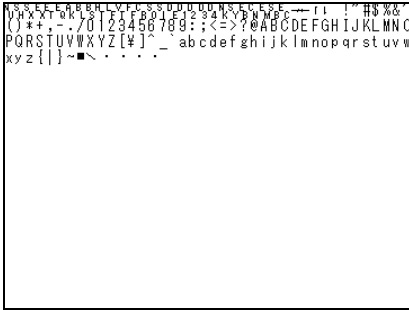
1. Press [**Special Menu**] key on the Main Menu screen to display [**Special Operate**] key.
The Special Operation Menu screen will appear.
2. Press [**Special Operate**] key.
The Special Operation Menu screen will appear.
3. Press [**System Tests**] key.
The System Tests Menu screen will appear.



LCD

This program checks whether LCD display can be performed properly or not.

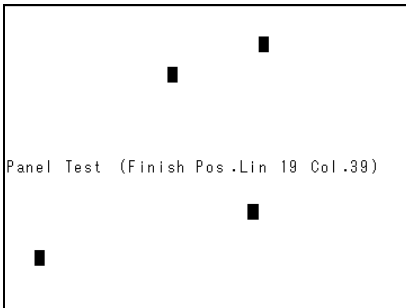
1. Press **[LCD]** key on the System Test Menu screen.
The fonts screen will appear as the LCD System Test screen.
2. When any place on the panel is pressed, the display screen changes over.
Three display screens in all are available.
3. When **[Return]** key on the panel is pressed on the third LCD System Test screen, the program is completed.



Touch Screen

This program allows checking whether entry from the LCD touch panel can be received properly or not. If it is normal, the panel at the touched place is highlighted.

1. Press **[Touch Screen]** key on the System Test Menu screen.
The Touch Panel System Test screen will appear.
2. Press any place on the panel to test entry on the touch screen.

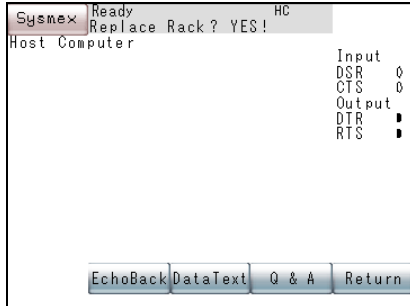


Note

- The touched place on the panel is highlighted.
When the same place is touched again, the display returns to the original one.
- The touch panel can recognize a key of 20 lines x 40 rows.

3. To quit the touch panel system test, press the touch panel in the lower right corner.

Host Computer



This program allows testing connection of the host computer.

1. Press **[Host Computer]** key on the System Test Menu screen.
The Host Computer Test screen will appear.
2. Press the appropriate key.

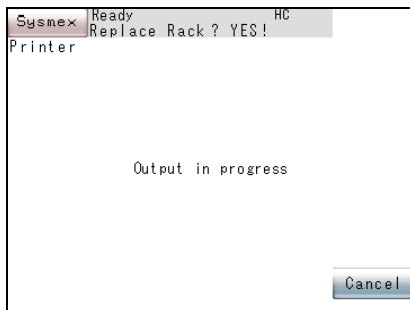
- [EchoBack]** key: Displays the data received and transmits it as it is.
- [Data Text]** key: Transmits fixed data.
- [Q & A]** key: Makes an inquiry and transmits ACK or NAK.
- [Return]** key: Ends the program. (Returns to the System Test Menu screen.)



Note

- When Host Computer Status is set “Not Connected”, **[EchoBack]**, **[DataText]** and **[Q & A]** keys are not displayed. “Not Connected” message is displayed on left top side of the screen.
- If the host computer is set to “Class A”, then **[EchoBack]** and **[Q & A]** keys are not displayed.

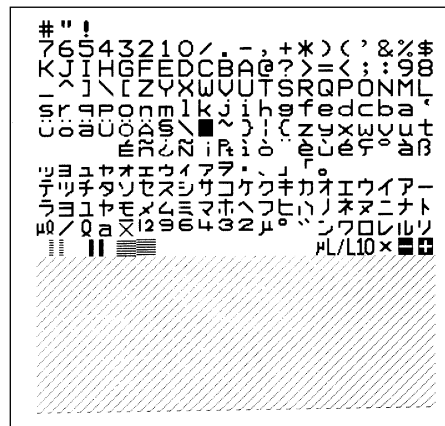
Printer



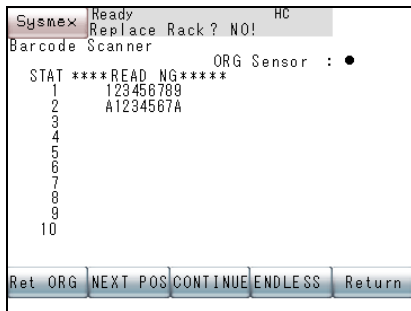
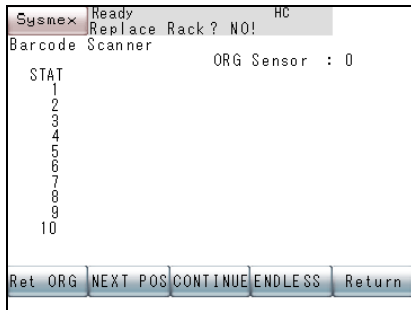
This program allows test printing to the built-in printer.

1. Press **[Printer]** key on the System Test Menu screen.
Test printing to the built-in printer will be executed.
2. When test printing is over, this program is completed.

Example of printout

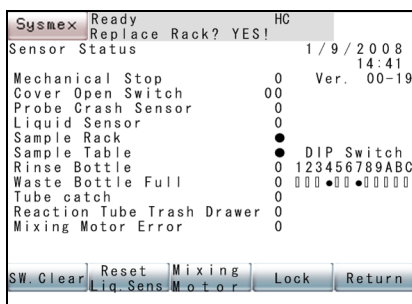


Barcode Scanner



- Press **[Barcode Scanner]** key on the System Tests Menu screen.
 - Setting when the barcode scanner is “Not connected”.
When the barcode scanner is set to “Not connected”, the scanner cannot be operated and only the **[Return]** key is displayed.
[Return] key: Quits the program. (Returns to the System Tests Menu.)
 - Setting when the barcode scanner is connected
Data read by the barcode scanner is displayed.
If it failed to read (including Check Digits NG), “****READING****” is displayed.
[Ret ORG] key: Moves the barcode scanner to the home position at the right end.
[NEXT POS] key: Moves the barcode scanner to the left by one position, reads the barcode, and displays the result.
[CONTINUE] key: Moves the barcode scanner to the home position at the right, moves the rack position leftward from STAT sample to 10th sample for reading, then displays the results.
[ENDLESS] key: Keeps movement and reading by **[CONTINUE]** key until the Mechanical Stop switch is pressed.
[Return] key: Quits the program. (Returns to System Tests Menu.)

Sensor Status



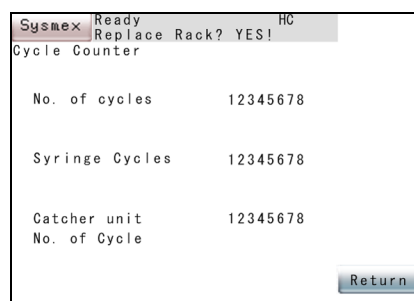
This program allows checking the status of the sensors attached to each unit of the instrument.

- Press **[Sensor Status]** key on the System Tests Menu screen.
The Sensor Status screen will appear.
Press **[SW. clear]** key to renew the sensor status.
Press **[Reset Liq. Sens]** key to reset the liquid level sensor.
Press **[Vibrate]** key to mix with the vibrating motor for 3 sec.
Press **[Lock]** key to lock the sampler.
Press **[Unlock]** key to release sampler lock.
- To quit the program, press **[Return]** key.

12.6 Cycle Counter

This program allows checking the cycles of each unit to confirm the instrument performance.

1. Press [**Special Menu**] key on the Main Menu screen to display [**Special Operate**] key.
2. Press [**Special Operate**] key.
The Special Operation Menu screen will appear.
3. Press [**Cycle Counter**] key.



The Cycle Counter screen will appear.

Syringe Cycles: The No. of cycles that the syringe motor has turned to measure a predetermined volume of reagent or plasma. One is counted by analyzing one parameter.

No. of Cycles: The accumulated total No. of counts that the instrument has made analysis. One parameter is counted once.

Catcher unit No. of Cycles:
Number of times of catches to move the reaction tube. One is counted by analyzing one parameter.



Information

- When syringe cycles exceed 300,000, the error message "Check Syringe Unit" is displayed each time analysis begins.
- When operation times of the catch unit reach 25,000, an error message appears every time starting the analysis.

4. Press [**Return**] key to quit the program.

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| | | |
|------------|--|-------------|
| 13. | Functional Description | 13-1 |
| 13.1 | Detection Principle of Clotting Method (PT, APTT, Fbg, TT, PCcl, BXT, LA1, LA2, Factor Deficiency) | 13-1 |
| 13.2 | Detection Principle of Chromogenic Method (AT3, AT, PC, Hep: CA-660 only) | 13-4 |
| 13.3 | Detection Principle of Immunoassay Method (D-Dimer, vWF, WFa: CA-660 only) | 13-5 |
| 13.4 | Analysis Mechanism | 13-7 |
| 13.5 | Analysis Flow | 13-8 |
| 13.6 | Reference Procedures | 13-17 |



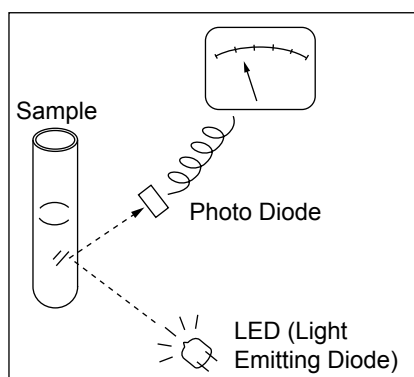
13. Functional Description

This chapter explains the detection principles, analysis methodology, and individual analysis procedures in the instrument.

13.1 Detection Principle of Clotting Method (PT, APTT, Fbg, TT, PCcl, BXT, LA1, LA2, Factor Deficiency)

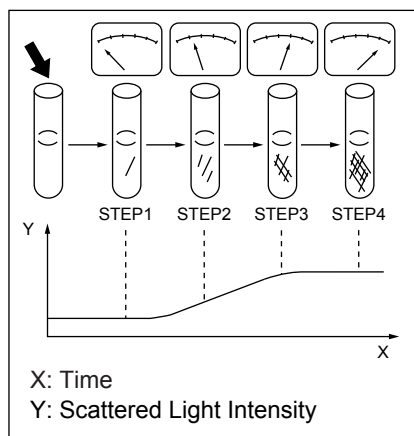
The instrument employs the photo-optical clot detection method. By using a red light (660 nm) to illuminate the sample plasma/reagent mixture, the instrument detects the changes in scattered light intensity due to increased turbidity as Fibrinogen changes to Fibrin. The coagulation curve is drawn by taking the time and the scattered light intensity as the X and Y axis respectively. The coagulation time is determined by a percentage detection method.

Optical Detection Method



The instrument determines the clotting time by measuring changes in the intensity of light scattered by a sample due to increased turbidity. The layout of the optical system is shown in the figure on the left. Light rays from the light-emitting diode (LED) are reflected and scattered by the sample. A photo diode absorbs the scattered light and converts the detected intensity into electrical signals. A microprocessor monitors these signals and uses them to compute the clotting time of the sample.

Coagulation and Scattered Light

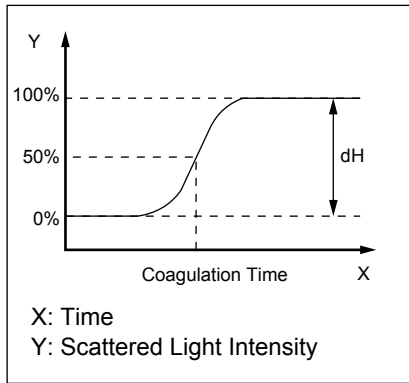


The correlation between scattered light intensity and elapsed time is shown in the figure on the left.

Warmed plasma is rapidly mixed with warmed reagent. Immediately after mixing, scattered light intensity is low (step 1). As coagulation proceeds, the sample becomes turbid due to fibrin clot formation and the scattered light intensity increases drastically (steps 2-3). When coagulation is complete, the scattered light intensity stabilizes (step 4).

The instrument can store this change in scattered light intensity in memory, and output a coagulation curve.

Percentage Detection Method

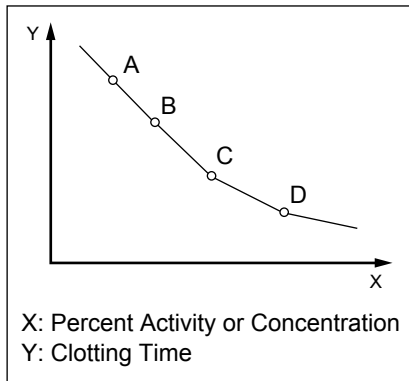


Determination of the clot time:

Scattered light intensity immediately after the reagent is added to the sample is defined as 0%. After the sample becomes fully turbid and coagulation is complete, scattered light intensity is defined as 100% (see the figure on the left). The coagulation time is obtained from the coagulation curve by taking the clotting time at a preset point on the coagulation curve (for example, 50%, as showing in the figure on the left).

This method allows determination of the coagulation time even on those specimens demonstrating only a slight change in scattered light intensity. As a result, the instrument may be effectively utilized for a low-fibrinogen plasma sample that has an almost imperceptible change in scattered light intensity or a slowly clotting plasma sample with a long clotting time.

Clotting Method Using Standard Curve



In order to calculate the concentration or percent activity of Prothrombin, Fibrinogen and other coagulation factors, this instrument utilizes a standard curve drawn using analysis data or values which have been manually entered. The standard curve uses the clotting time for the vertical (Y) axis, and uses the logarithm of percent activity or concentration of the reference plasma for the horizontal (X) axis as shown in the figure on the left.



Caution!

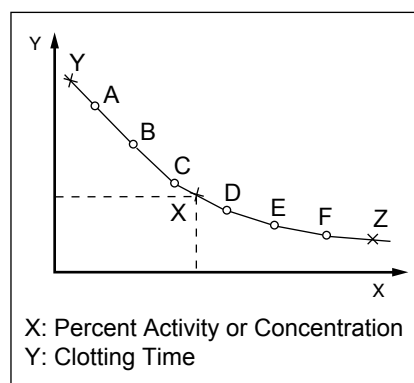
If the default setting is changed, analysis results may be altered. Examine the contents thoroughly before making changes to the default setting. Note that our warranty covers only the results in the default setting.



Note

There are 6 different types of standard curve available on this instrument as below. They can be selected in Standard Curve setting program. Refer to “9.7 Set Calculation Parameters” for the selection.

- Log Curve: Log - Log, point plotted graph
- Log Lin: Log - Log, linear graph
- Lin - Lin: Real - Real, linear graph
- Lin Curve: Real - Real, point plotted graph
- AKIMA
- AKIMA (0)



Calculation Principle

- Linear regression formulas are utilized to express the relationship between the clotting time and percent activity or concentration. The points are expressed as a straight line when plotted on a logarithmic scale.
- In the example shown in the figure on the left below, the analysis data result for a certain sample (point X) plots between points C and D. In this case, the percent activity or concentration is calculated by a logarithmic formula, utilizing points C and D.
- If analysis data results plot outside A through F, the percent activity or concentration is calculated by logarithmic formula utilizing the nearest two points. For instance, the percent activity or concentration of point Y is calculated by a logarithmic formula, utilizing points A and B; and point Z is calculated by a logarithmic formula utilizing points E and F.

Calculation of PT Ratio and INR Value

The instrument has the ability to calculate a PT ratio value if the normal PT value for the laboratory's patient population has been entered in the PT Standard Curve setting menu. The International Normalized Ratio (INR) will be printed as part of the sample result if the International Sensitivity Index (ISI) of the thromboplastin reagent has been entered in the PT Standard Curve setting menu.

The PT normal value and the ISI value may be manually entered in the PT Standard Curve setting menu. Refer to "9. Setting Standard Curve" for the procedure, if needed.

The PT ratio is calculated by the instrument as follows:

$$\text{PT ratio} = \frac{t}{\text{PT normal value}}$$

t = actual clotting time of PT sample

PT normal value = normal PT value for the laboratory's patient population

The INR value is calculated as follows:

$$\text{INR} = (\text{PT ratio})^{\text{ISI}}$$

ISI = International Sensitivity Index determined by individual manufacturer of Thromboplastin reagent, or Local SI value calculated by INR calibrator



Information

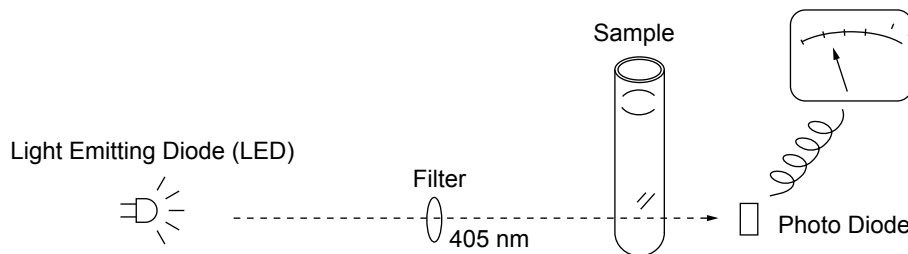
ISI values for prothrombin time assays must be entered directly as they appear on the current reagent labeling. Any changes of reagent lot, software upgrades, major servicing, etc., require verification of the ISI value. Failure to enter the correct ISI value will cause incorrect International Normalized Ratio (INR) results.

13.2 Detection Principle of Chromogenic Method (AT3, AT, PC, Hep: CA-660 only)

After a predetermined volume of blood plasma has been warmed for a certain time period, reagent and substrate are added. The sample is then exposed to light (405 nm), and the change in light absorbance for floating para-nitroaniline pigment (transmitted light) is detected. Then the activity is found.

Transmitted Light Detection Method

The layout of the optical system is shown in the figure below. Light from the Light Emitting Diode (LED) is filtered to 405 nm. This is fed to a sample. The instrument detects the changes in the light absorbance of dye such as para-nitroaniline and etc., which passed through the samples without being interrupted by the clots. A photo diode receives the transmitted light and converts the detected intensity into electrical signals. A microprocessor monitors these signals and uses them to compute the change in optical density of the sample.



Calculating the Change in Light Absorbance

The change in light absorbance is found from the absorbance data between the start and end points that were preset in “10.8 Test Protocol” in accordance with either of the following methods.

1. The change in light absorbance per minute is found from the linear regression of the absorbance data.
2. The change in light absorbance is found in accordance with V-Lin-Integral analysis method. This method uses the maximum reaction speed of the reaction curve calculated from the primary regression to obtain the change in light absorbance.

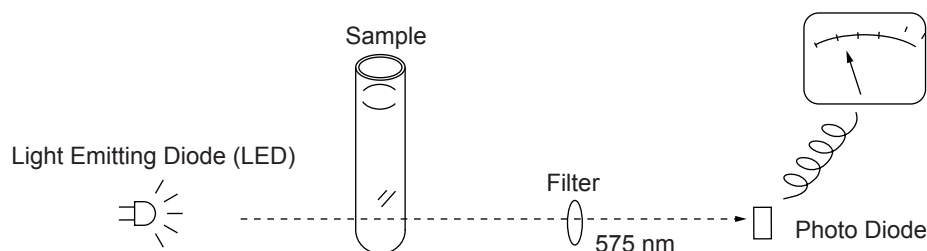
13.3 Detection Principle of Immunoassay Method (D-Dimer, vWF, WFa: CA-660 only)

After a predetermined volume of sample has been warmed for a certain time period, stabilizing reagent and antibody sensitive reagent are added. The sample is then exposed to light (575 nm), and the change in light absorbance caused by antibody sensitive reagent during the antigen antibody reaction is detected as the change in transmitted light.

Transmitted Light Detection Method

The optical system for the Transmitted Light Detection Method is shown below.

Light transmitting a sample from the light source is separated into 575-nm components by a filter. The separated light reaches a photodiode, where the transmitted light is converted into electrical signals. The change in the amount of this transmitted light is stored and calculated by microcomputer, and the change in absorbance per minute ($\Delta OD/min$) is determined.

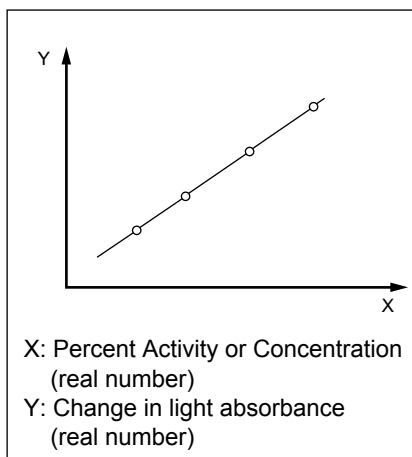


Calculating the Change in Light Absorbance

The change in light absorbance is found from the absorbance data between the start and end points that were preset in “10.8 Test Protocol” in accordance with either of the following methods.

1. The change in light absorbance per minute is found from the linear regression of the absorbance data.
2. The change in light absorbance is found in accordance with V-Lin-Integral analysis method. This method uses the maximum reaction speed of the reaction curve to determine the optimum analysis interval, and then measures the change in light absorbance over 1 minute.

Standard Curve from Chromogenic Method or Immunoassay Method



A functional relationship exists between the change in light absorbance ($\Delta OD/min$) and the percent activity (or concentration) when both parameters are plotted on a real number graph.

This instrument can make use of the aforementioned relationship to prepare standard curves.

1. Standard curves are made by joining consecutive pairs of percent activity (or concentration) with straight lines. The two ends of the standard curves are made by extending the line made by the pair of percent activity points (or pair of concentration points) that is the nearest end.
2. AKIMA method can be also used to make standard curves. This is a method of interpolation for making smooth standard curves which intersect measurement points. AKIMA (0) is a standard curve which has been corrected by AKIMA method so as to pass through (0 sec, 0 dOD/min.).
3. The change in light absorbance and concentration (or percent activity) are plotted as real axes, and straight lines are made by approximating the intervals between measurement points.

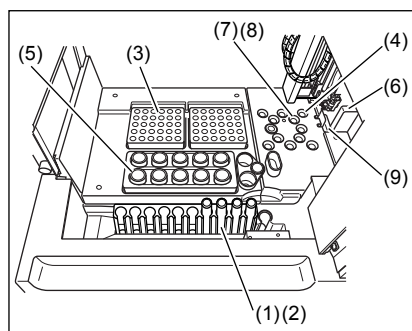


Note

Within a zone in which the antigen concentration is excessively high, the prozone phenomenon can be seen in which an increase in antigen concentration is met with a decrease in the change in light absorbance.

When the prozone phenomenon occurs, the antibody concentration will be lower than the actual value, and the instrument will display an error message. When that happens, dilute the sample to the dilution ratio that you wish and reanalyze.

13.4 Analysis Mechanism



The instrument performs an analysis according to the procedure described below:

1. When the samples are set in a sample rack loaded in the Sampler, place the rack at the appropriate analysis position. Analysis begins at the sample in Tube Position No. 1 according to the preset analysis setting for each sample.

The test tubes in the sample rack are then placed at the sample aspiration position one after another.

2. The Heated Probe aspirates the required volume of plasma from the sample rack.

The required sample volume is calculated automatically from the number of test parameters specified for each of the samples.

3. The Heated Probe then dispenses the aspirated sample into a reaction tube in a sample tube rack.

4. The reaction tube containing a sample plasma is then transferred to the incubation well by the catcher hand, and incubated (warmed) for a specific amount of time.

5. The Heated Probe aspirates a certain amount of a specified reagent from the reagent vial in the reagent rack. The aspirated reagent is warmed for a certain period of time in the Heater Probe.

6. The sample catcher transports the reaction tube to the reagent dispensing position, and the incubated reagent is dispensed into the reaction tube while being held by the catcher hand.

7. The sample catcher mixes the sample with reagent by vibrating the reaction tube while holding it.

8. Then the reaction tube is transported to a detection well and illuminated with a red light.

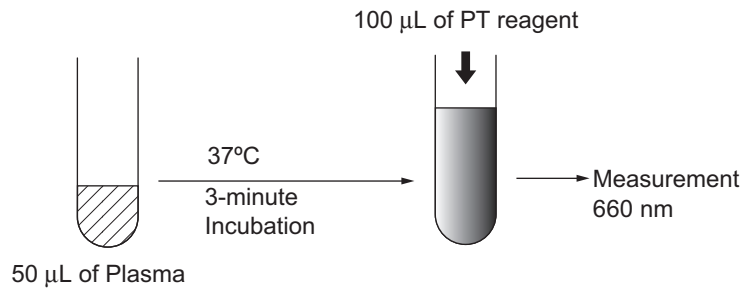
9. In the detector, the reaction is detected through the change in scattered light or transmitted light.

10. After the procedure, the sample catcher transports the reaction tube and discards it in the tube trash drawer.

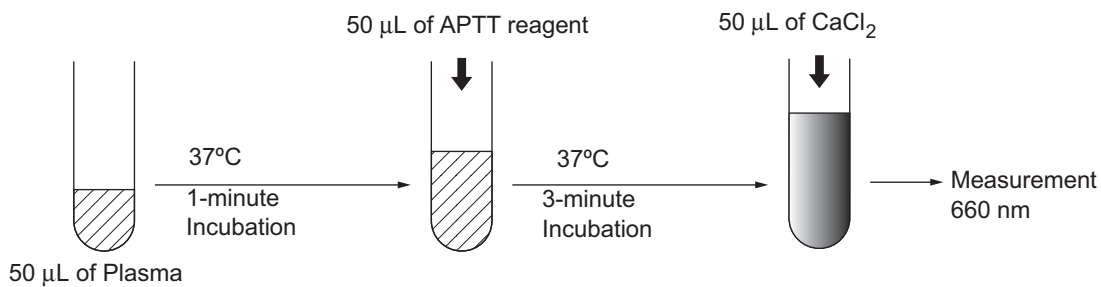
13.5 Analysis Flow

The required volumes of reagent and sample, and the analysis flow for each parameter, are described in this section. Refer to the package insert of each reagent for more information.

PT Flow



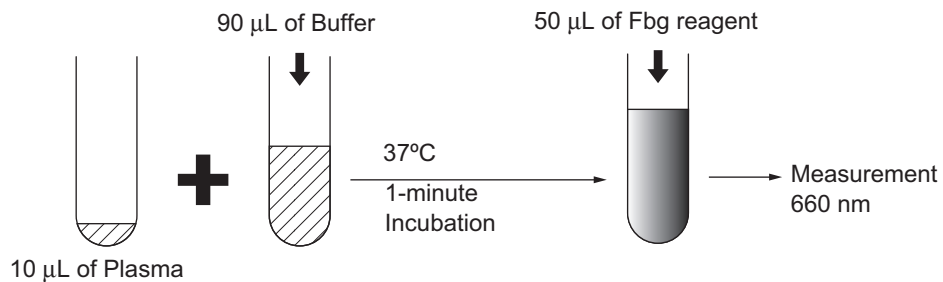
APTT Flow



Note

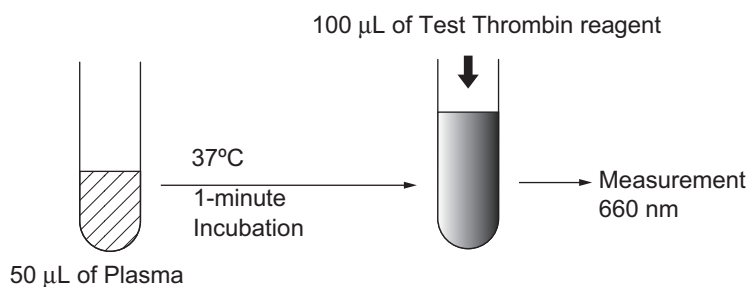
- Any change in the APTT Incubation Time could affect the analysis results significantly. Follow the reagent manufacturer's instruction. Examine the optimum setting at your laboratory before changing the APTT Incubation Time.
- Each laboratory should follow the optimum APTT reagent incubation time recommended by the reagent manufacturer in the product package insert.
- This setting cannot be changed during an analysis procedure.

Fibrinogen Flow

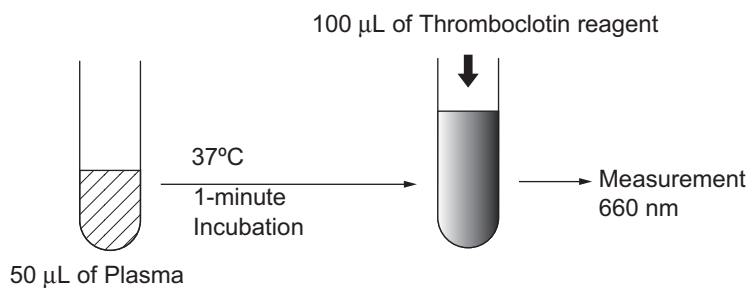


When analyzing high-concentration Fbg (+Fbg), analyze with a dilution ratio of 1:20. With low-concentration Fbg (-Fbg), analyze with a dilution ratio of 1:5.

TT (Thrombin Time with Test Thrombin Reagent) Flow

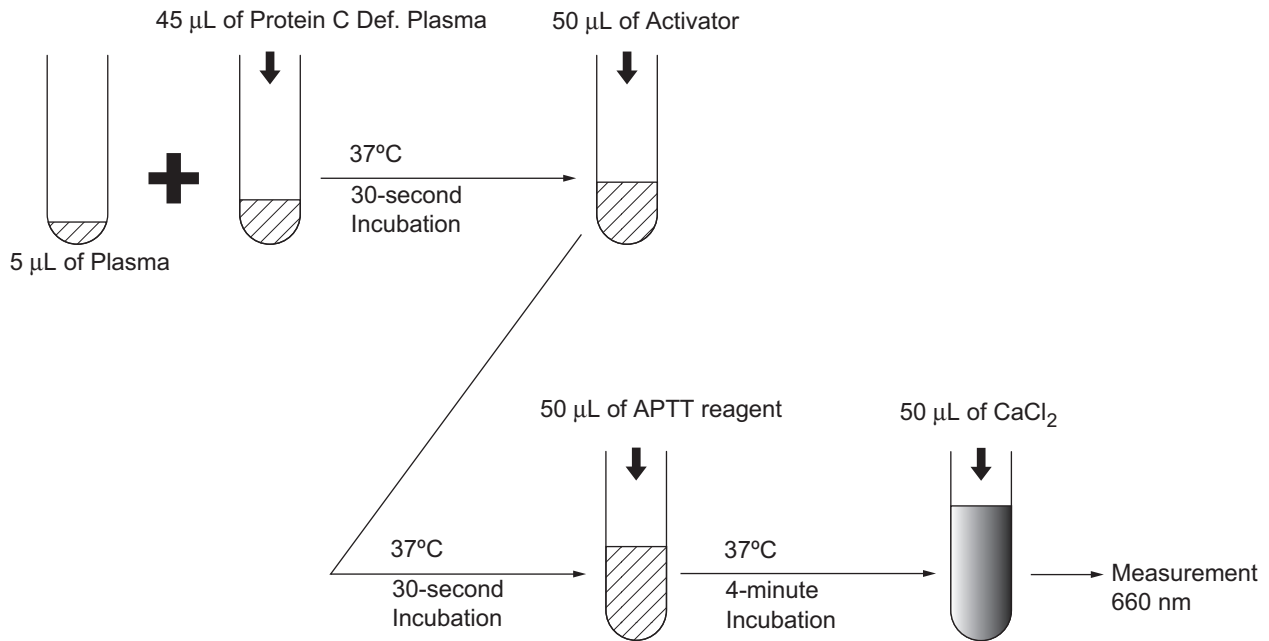


TT TC (Thrombin Time with Thromboclotin Reagent) Flow

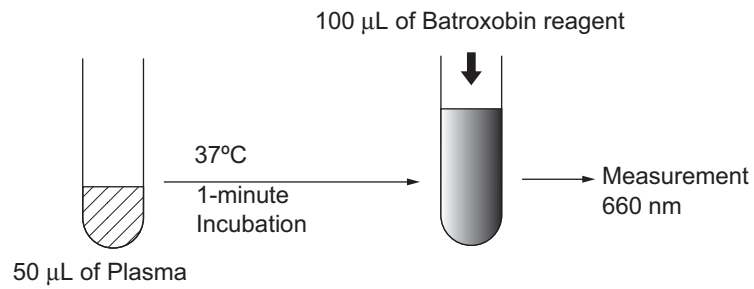


Functional Description

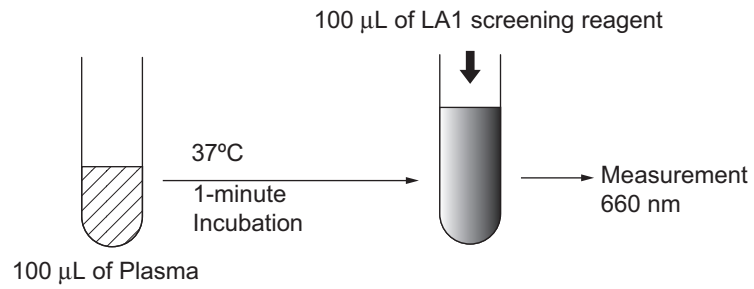
PCcl Flow



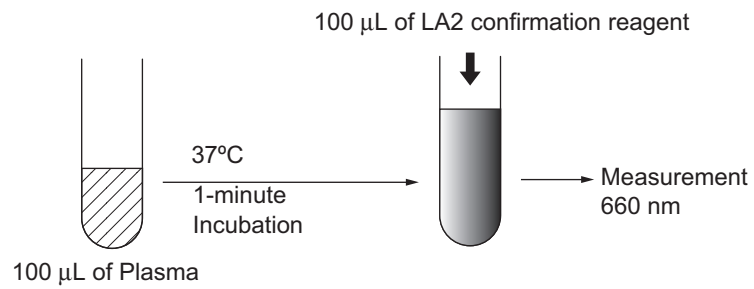
BXT Flow



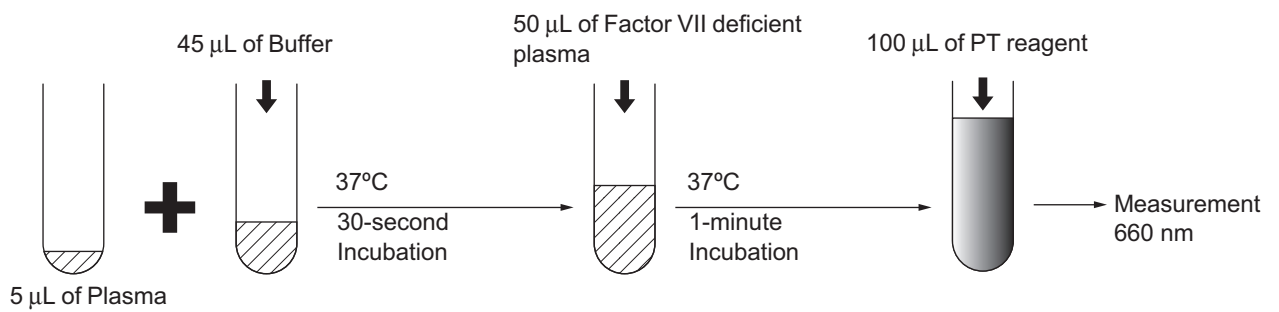
LA1 Flow



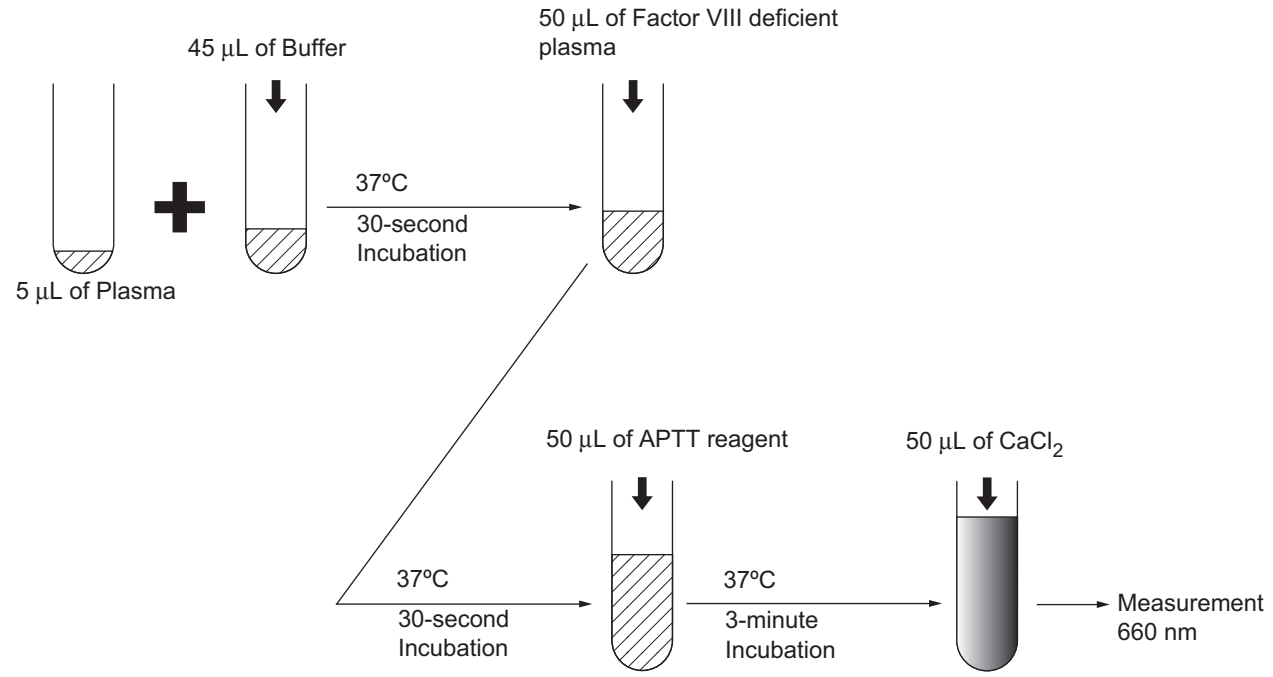
LA2 Flow



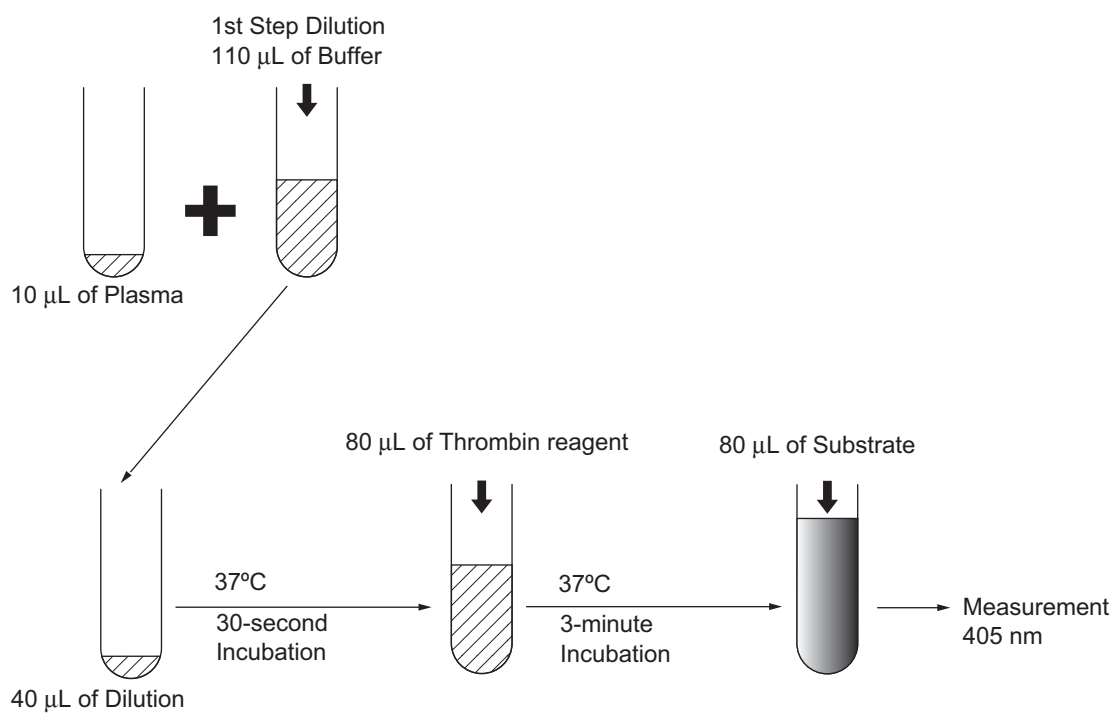
Extrinsic Factor Assay Flow



Intrinsic Factor Assay Flow

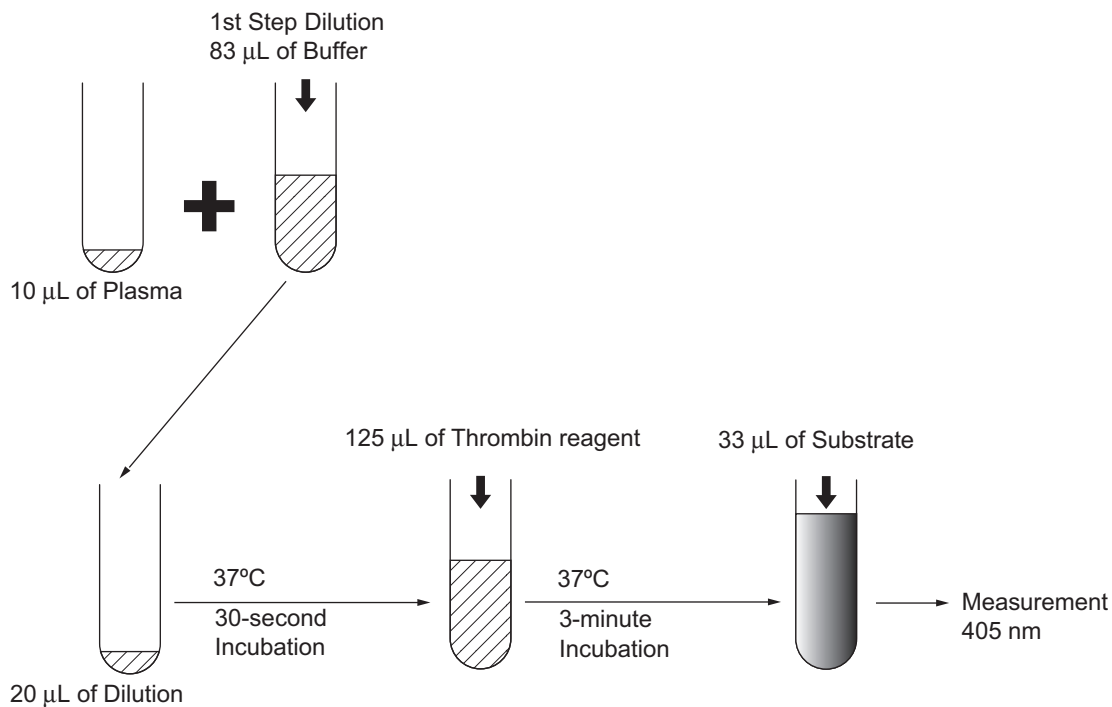


AT Flow (When INNOVANCE[®] Antithrombin is used)

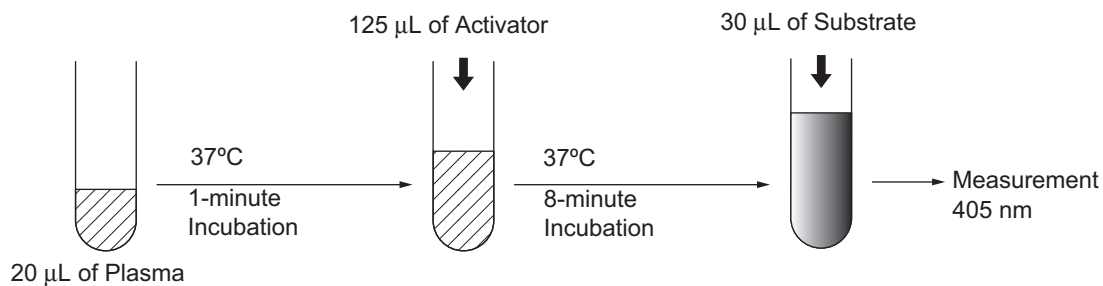


September 2011

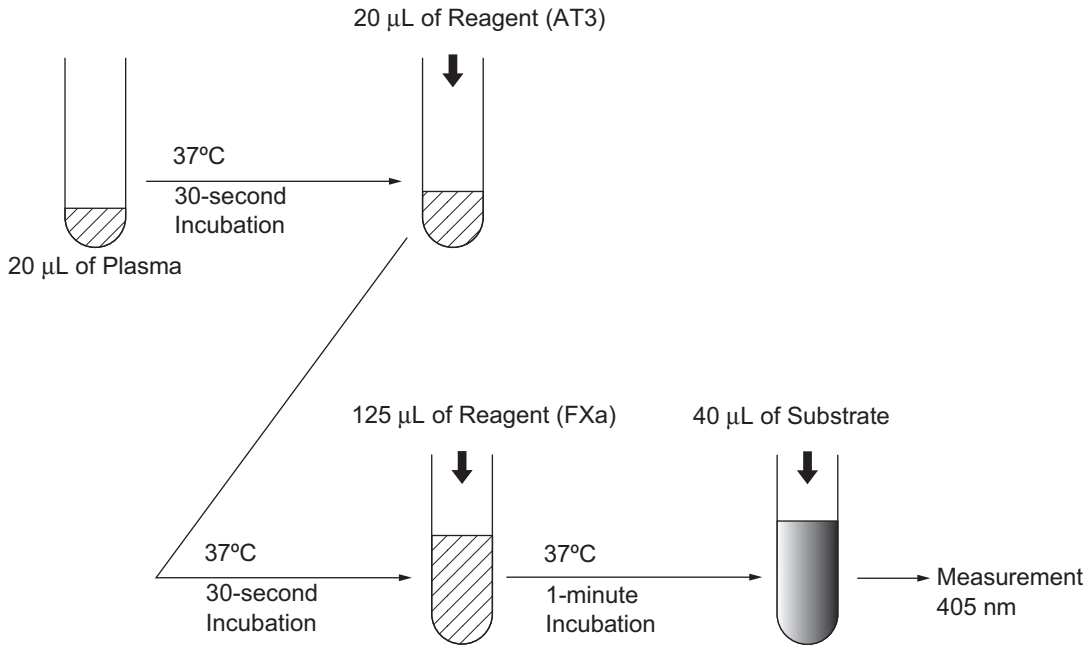
AT3 Flow (When Berichrom[®] Antithrombin III (A) is used)



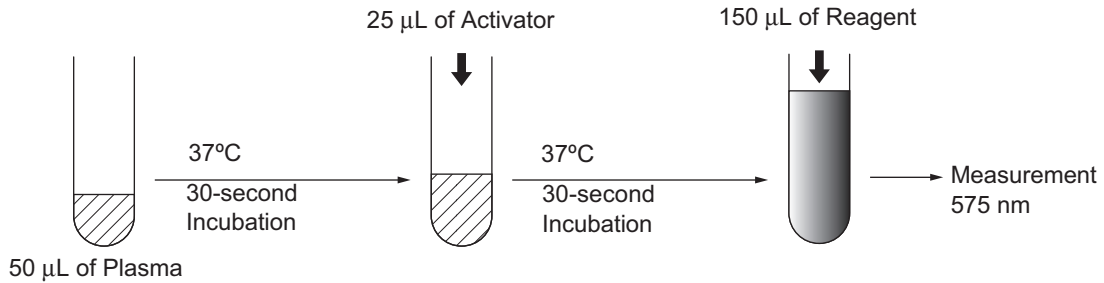
PC Flow (When Berichrom[®] Protein C is used)



Hep Flow (When Berichrom[®] Heparin is used)

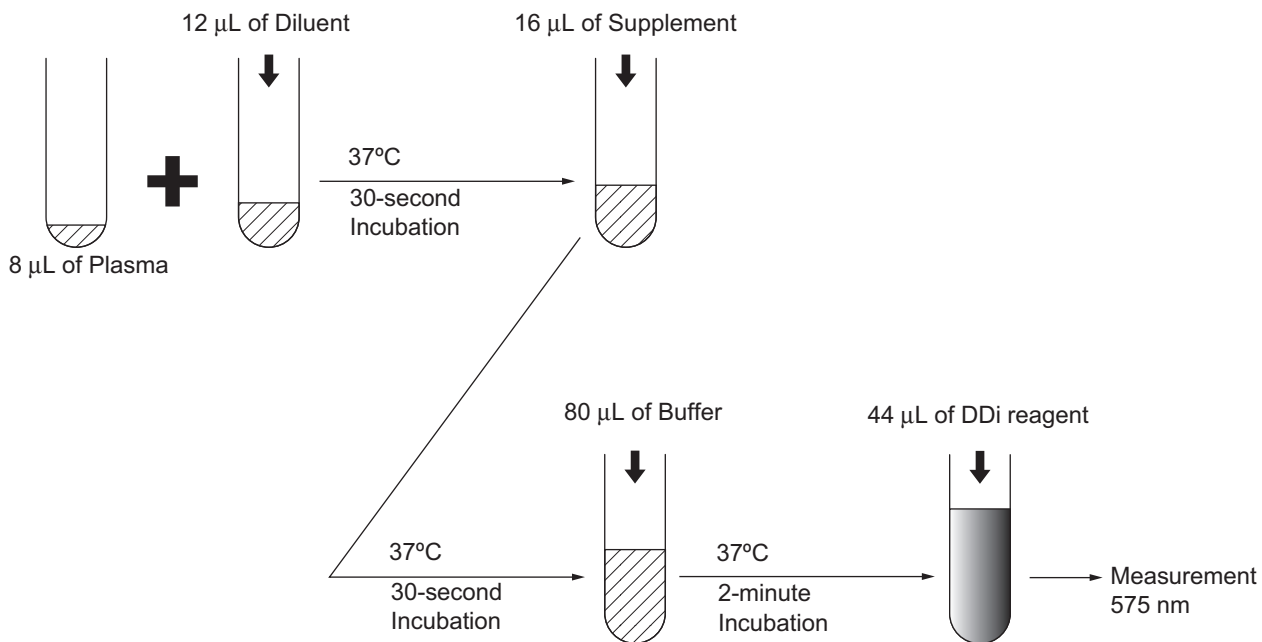


DDPI Flow



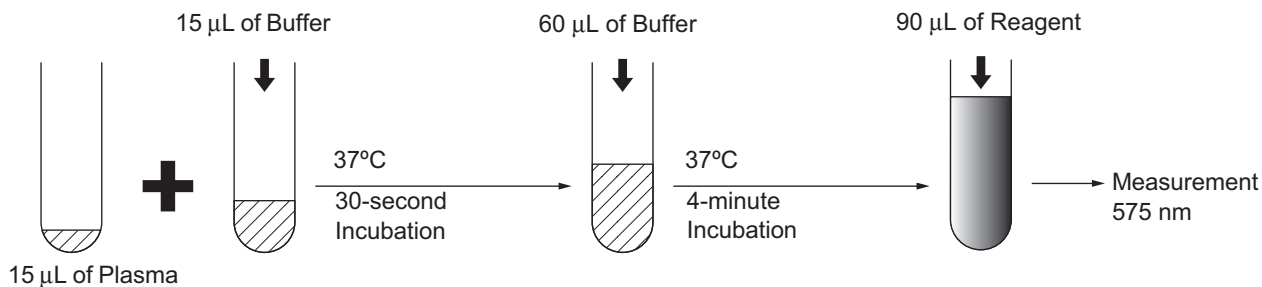
When analyzing high-concentration D-Dimer Plus (+DDP), analyze with a dilution ratio of 1:8 compared to the standard dilution.

DDi Flow (When INNOVANCE® D-Dimer is used)



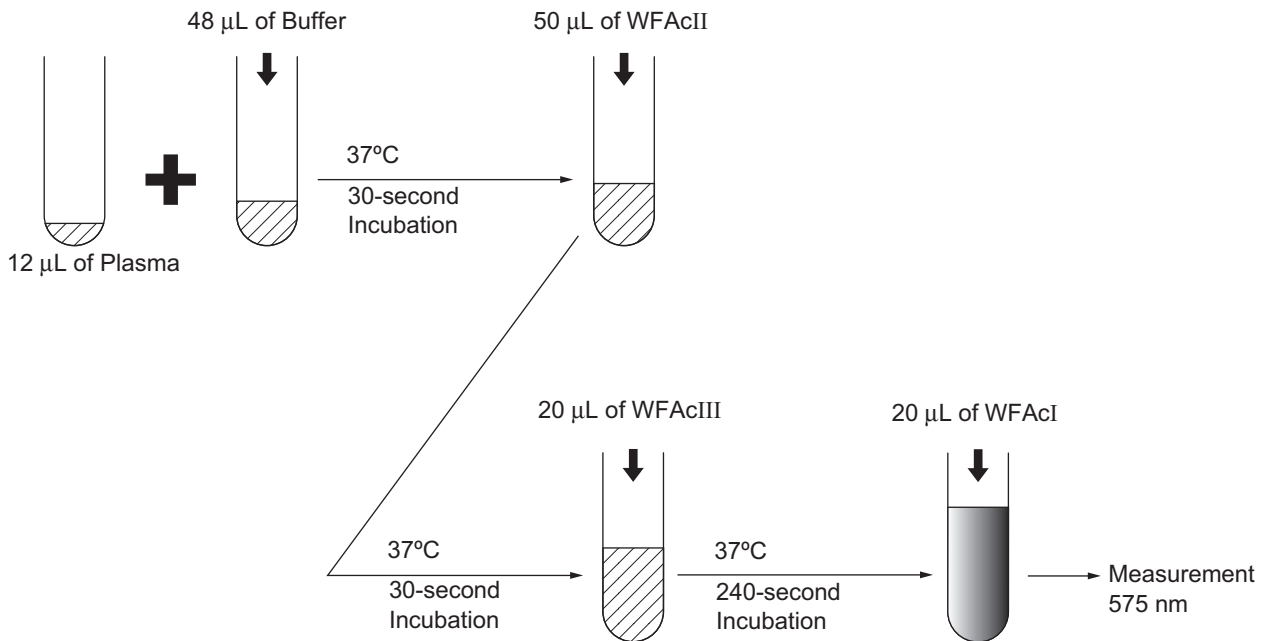
When analyzing high-concentration INNOVANCE® D-Dimer (+Ddi), analyze with a dilution ratio of 1:8 compared to the standard dilution.

vWF Flow (When vWF Ag is used)



When analyzing high-concentration vWF (+vWF), analyze with a dilution ratio of 1:3 compared to the standard dilution. With low-concentration vWF (-vWF), analyze with a dilution ratio of 2:1 compared to the standard dilution.

WFa Flow (When INNOVANCE® VWF Ac is used)



When analyzing high-concentration WFa (+WFa), analyze with a dilution ratio of 1:4 compared to the standard dilution. With low-concentration WFa (-WFa), analyze with a dilution ratio of 4:1 compared to the standard dilution.

13.6 Reference Procedures

The National Committee for Clinical Laboratory Standards (NCCLS) provides the following reference method information:

H21-A5, “Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays” (01/2008)

H47-A2, “One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test”; Approved Guideline - Second Edition (05/2008)

H30-A2, “Procedure for the Determination of Fibrinogen in Plasma” (11/2001)

You can obtain these procedures for a small fee by writing to the following address.

National Committee for Clinical Laboratory Standards
771 East Lancaster Avenue
Villanova, PA 19085
USA

After instrument installation, stability should be monitored through the use of established quality control procedures.

You should promptly perform maintenance or troubleshooting whenever you note significant shifts or trends in quality control data. Also the operator should confirm reagent integrity, complete all maintenance procedures and operate the instrument as described in this operator’s manual.

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| | | |
|------------|--|-------------|
| 14. | Technical Information | 14-1 |
| 14.1 | Instrument Specifications | 14-1 |
| 14.2 | Factory Settings | 14-7 |
| 14.3 | Installation | 14-12 |
| 14.4 | Serial Interface for Host Computer | 14-18 |
| 14.5 | Text Format | 14-25 |
| 14.6 | ID Barcode | 14-35 |



14. Technical Information

14.1 Instrument Specifications

| | | |
|---|--|--|
| Name | Automated Blood Coagulation Analyzer CA-600 series | |
| Model | CA-620/CA-660 | |
| Analysis parameters/ Calculated parameters | Prothrombin Time (PT) | Analysis: sec. Calculated parameters: %, PT ratio, INR, Derived Fbg (dFbg) |
| | Activated Partial Thromboplastin Time (APTT) | Analysis: sec. |
| | Fibrinogen (Fbg) | Analysis: sec. Calculated parameter: mg/dL or g/L |
| | Thrombin Time (TT) | Analysis: sec. |
| | Factor Assay (VII, VIII) | Analysis: sec. Calculated parameters: % |
| | Protein C coagulometric (PCcl) | Analysis: sec. Calculated parameters: % |
| | Batroxobin Time (BXT) | Analysis: sec. |
| | Lupus Anticoagulant (LA1, LA2) | Analysis: sec. |
| | Antithrombin (AT, AT3)* | Analysis: Δ OD/min. Calculated parameter: % |
| | Protein C chromogenic (BCPC)* | Analysis: Δ OD/min. Calculated parameters: % |
| | Heparin (Hep, HepL, HepU)* | Analysis: Δ OD/min. Calculated parameters: IU/mL |
| | D-Dimer (DDPI, DDi)* | Analysis: Δ OD Calculated parameters: μ g/L, mg/L |
| | von Willebrand Factor (vWF, WFa)* | Analysis: Δ OD Calculated parameters: % |

(*) CA-660 only

| | | |
|--|---|---|
| Analysis Principles | Coagulation Reaction Detecting Method (Scattered Light Detection Method) | A mixture of plasma and reagent is exposed to red light (660 nm). Turbidity change occurring when Fibrinogen is transformed to Fibrin is detected as a change in its scattered light, then coagulation time is measured. |
| | Coagulation Point Detection Method (Percent Detection Method) | Assume that scattered light intensity just after detection commencement is 0%, and the intensity when coagulating reaction has ended is 100%, then the time interval taken until the scattered light set at the coagulation detecting point has been reached is the coagulation time. |
| | Chromogenic Method* (Colorimetric Method /Rate Method) | Plasma, reagent, and substrate are mixed to start reaction, and change in extinction of pigment in free P-nitroaniline is detected and activity value is calculated. |
| | Immunoassay Method* | Sample and Latex reagent are mixed to start reaction, and variation in absorbance of produced Latex clump is detected and calculated. |
| Simultaneous 5-parameter random Analysis | Random analysis is possible. (5 parameters from PT, APTT, Fbg, TT, Factor Deficiency, PCcl, BXT, LA1, LA2, AT, AT3, BCPC, Hep, DDPI, DDi, vWF and WFa) | |
| Detection Time | <p>Coagulation reaction is detected within maximum detection time and coagulation time is measured.</p> <p>Typical maximum detection time</p> <p style="text-align: right;">100 sec. for PT 100 sec. for Fbg 190 sec. for others (Clotting Method) 30 sec. for AT3 180 sec. for D-Dimer</p> <p>Maximum detection time that can be set</p> <p style="text-align: right;">600 sec. for each parameter</p> | |
| Processing Capability | <p>PT single parameter analysis: 60 tests/h (Maximum)</p> <ul style="list-style-type: none"> • However, this is the value starting from the time the first result is output. • The processing speed varies depending on the reagent used. | |

(*) CA-660 only

| | | | |
|--------------------------|---------------------------------------|--------------------------|--------|
| Plasma Volume Required | Prothrombin Time | (PT) | 50 µL |
| | Activated Partial Thromboplastin Time | (APTT) | 50 µL |
| | Fibrinogen | (Fbg) Thrombin | 10 µL |
| | | (Fbg MFU) Multifibren® U | 100 µL |
| | Thrombin Time | (TT) Test Thrombin | 50 µL |
| | | (TT TC) Thromboclotin | 100 µL |
| | Extrinsic Factor Assay | (VII) | 5 µL |
| | Intrinsic Factor Assay | (VIII) | 5 µL |
| | Protein C coagulometric | (PCcl) | 5 µL |
| | Batroxobin Time | (BXT) | 50 µL |
| | Lupus Anticoagulant | (LA1, LA2) | 100 µL |
| | Antithrombin | (AT) | 10 µL |
| | Antithrombin III | (AT3) | 10 µL |
| | Protein C | (BCPC) | 20 µL |
| | Heparin | (Hep, HepU, HepL) | 20 µL |
| | D-Dimer | (DDPI) D-Dimer Plus | 50 µL |
| (DDi) INNOVANCE® D-Dimer | | 8 µL | |
| von Willebrand Factor | (vWF) vWF Ag | 15 µL | |
| | (WFa) INNOVANCE® VWF Ac | 12 µL | |
| Reagents Required | Refer to “5.6 Prepare Reagents”. | | |

| | | | |
|----------------|--------------------------|--------------------|---|
| Analysis Range | Fibrinogen Concentration | Thrombin | <p>With an applicable reagent, the range between 50 mg/dL and 1000 mg/dL can be analyzed.</p> <p>However, over 500 mg/dL is analyzed via dilution in high concentration mode (+Fbg: 1:20 dilution).</p> <p>Under 90 mg/dL is analyzed via dilution in low concentration mode (-Fbg: 1:5 dilution).</p> |
| | D-Dimer Concentration | D-Dimer PLUS | <p>With an applicable reagent, the range between 50 µg/L and 9999 µg/L can be analyzed.</p> <p>However, over 2000 µg/L is analyzed via dilution in high concentration mode (+DDP: 1:8 dilution compared to the standard dilution).</p> |
| | | INNOVANCE® D-Dimer | <p>With an applicable reagent, the range between 0.19 mg/L and 35.20 mg/L can be analyzed.</p> <p>However, over 4.40 mg/L is analyzed via dilution in high concentration mode (+DDi: 1:8 dilution compared to the standard dilution).</p> |
| | von Willebrand Factor % | vWF Ag | <p>With an applicable reagent, the range between 6.0% and 600.0% can be analyzed.</p> <p>However, over 200.0% is analyzed via dilution in high concentration mode (+vWF: 1:3 dilution compared to the standard dilution).</p> <p>Under 12.5% is analyzed via dilution in low concentration mode (-vWF: 2:1 dilution compared to the standard dilution).</p> |
| | | | INNOVANCE® VWF Ac |



Caution!

Results should always be evaluated in conjunction with clinical and other laboratory findings.
Independently of the concentration of samples, non-specific reactions may be obtained in some cases and therefore the dilution of samples may lead to discordant results in certain cases.

| | |
|-------------------------------------|--|
| Display and Entry | 4.5 in x 3.4 in liquid crystal display (with color LCD backlight) Touch panel type |
| Printout | Internal printer prints out analysis data and graphic prints |
| External Input/Output | Bit serial voltage signal (RS-232C) |
| Cooling of Reagents | The cooling unit performs cooling with the Peltier element*. Reagent holder: 4-positions (15°C±2°C, when room temperature is 15 - 35°C) |
| Reagent Dispensing | The incubation pipette detects the reagent surface and aspirates/dispenses reagent with the syringe. |
| Sample Dispensing | The incubation pipette detects the sample surface, aspirates a sample with the syringe from a tube on the rack, and dispenses it into a reaction tube in the reaction tube rack. |
| Reaction Tube | Reaction tube: 60 MAX (30-tube rack x 2) |
| Detector | Photo Detection Unit: 6 wells (4 wells for coagulation analysis, 1 well for chromogenic analysis, and 1 well for Immunoassay analysis*) The light-emitting diode for photodetection is ON only during analysis. Heater Section: 6-well |
| Temperature Control | Detector: 37°C±1.0°C Sample Incubator Section: 37°C±1.0°C Reagent Pipette: 37°C±1.0°C (When room temperature is 15 - 35°C) Cooling Unit*: 15°C±2°C |
| Time Taken to Reach Set Temperature | Within 30 minutes after power supply turn-on (when room temperature is within the temperature range of 15-35°C) |
| STAT Sample Processing | The routine analysis can be interrupted for preferential processing of a specified sample contained in a sample collection tube. |
| Number of Stored Samples | Analysis data: 600 samples (a maximum of 3000 tests) |
| Quality Control | \bar{X} Control (L-J Control): 180 points x 6 files, 14 parameters |
| Standard Curve | 6 points, 14 parameters |

Technical Information

| | |
|---|---|
| Electrical Rating | <p>Rated Voltage: 100 - 240 V AC</p> <p>Frequency: 50 Hz or 60 Hz</p> <p>Power consumption (Main unit): 300 VA or less</p> <p>Heat Compensation Required: Approx. 1024 BTU/h (258 kcal/h)</p> |
| Dimensions and Weight | <p>Width (±3%): Approx. 566 mm</p> <p>Depth (±3%): Approx. 490 mm</p> <p>Height (±3%): Approx. 490 mm</p> <p>Weight (±3%): Approx. 43 kg</p> <p>The dimensions exclude the projections.</p> |
| Protection Type | Class I Equipment |
| EMC (Electro-magnetic compatibility) | <p>This equipment is in conformity to the following IEC (EN) standard.</p> <p>IEC61326-2-6:2005 (EN61326-2-6:2006) Electrical equipment for measurement, control and laboratory use -EMI requirements</p> <p>-EMI (Class B)</p> <p>-EMS (Immunity test requirements for equipment intended for use in industrial locations)</p> |

(*) CA-660 only.

14.2 Factory Settings

Automatic Transfer/Printout

| | IP | HC |
|---------------|-------|---------|
| Within Limit: | Valid | Invalid |
| Out of Limit: | Valid | Invalid |
| Error Flag: | Valid | Invalid |
| QC Sample | Valid | Invalid |

| | |
|--------|----------|
| Format | No Graph |
|--------|----------|

Test Name

| CA-620 | CA-660 |
|--------|--------|
| PT T | PT T |
| PT I | PT I |
| FS | FS |
| FSL | FSL |
| Fbg | Fbg |
| +Fbg | +Fbg |
| -Fbg | -Fbg |
| TT | TT |
| VIII | VIII |
| | AT |
| | AT3 |
| | HepL |
| | DDi |
| | +DDi |

Reagents Name

| CA-620 | CA-660 |
|---------|---------|
| CleanI | CleanI |
| CleanII | CleanII |
| OVb | OVb |
| PT THS | PT THS |
| PT INN | PT INN |
| PTT ACT | PTT ACT |
| PTT FS | PTT FS |
| PTT FSL | PTT FSL |
| PTT PSL | PTT PSL |
| CaCl2 | CaCl2 |
| Fbg | Fbg |
| Fbg MFU | Fbg MFU |
| TestThr | TestThr |
| Thrombo | Thrombo |
| VII | VII |
| VIII | VIII |
| PC.DefP | PC.DefP |
| PC.A.cl | PC.A.cl |
| PC.APTT | PC.APTT |
| Batrox | Batrox |
| LA1 | LA1 |
| LA2 | LA2 |
| | ATBuf |
| | ATReag |
| | ATSub |
| | AT3Thro |
| | AT3Subs |
| | BCPCAct |
| | BCPCSub |
| | SHP |
| | AT3Reag |
| | FXaReag |
| | HepSubs |
| | DD.Pl.A |
| | DD.Pl.R |
| | DDi.DIL |
| | DDi.SUP |

| CA-620 | CA-660 |
|--------|---------|
| | DDi.BUF |
| | DDi.REA |
| | vWFBuF |
| | vWFReag |
| | WFAcI |
| | WFAcII |
| | WFAcIII |

Test Group

| CA-620 | | | CA-660 | | |
|---------|---------|---------|---------|---------|---------|
| Group 1 | Group 2 | Group 3 | Group 1 | Group 2 | Group 3 |
| PT T | | PT I | PT T | PT I | PT I |
| FSL | | FS | FSL | FS | FS |
| TT | | Fbg | TT | Fbg | Fbg |
| VIII | | +Fbg | VIII | DDi | +Fbg |
| | | -Fbg | AT | +DDi | -Fbg |

Reagents Holder

| Position | CA-620 | | | | | |
|----------|----------|-----------|----------|-----------|----------|-----------|
| | Group 1 | | Group 2 | | Group 3 | |
| | ReagName | Vial Name | ReagName | Vial Name | ReagName | Vial Name |
| 1 | PT THS | Cup | | | PT INN | Cup |
| 2 | Test Thr | Cup | | | | |
| 3 | | | | | Fbg | Cup |
| 4 | | | | | | |
| 5 | PTT FSL | Cup | | | PTT FS | Cup |
| 6 | | | | | | |
| 7 | CaCl2 | Cup | | | CaCl2 | Cup |
| 8 | | | | | | |
| 9 | VIII | Cup | | | | |
| 10 | | | | | | |
| 11 | CleanI | PV-10 | CleanI | PV-10 | CleanI | PV-10 |
| 12 | OVb | PV-10 | OVb | PV-10 | OVb | PV-10 |
| 13 | CleanII | Cup | CleanII | Cup | CleanII | Cup |

| Position | CA-660 | | | | | |
|----------|----------|--------|----------|--------|----------|--------|
| | Group 1 | | Group 2 | | Group 3 | |
| | ReagName | Holder | ReagName | Holder | ReagName | Holder |
| 1 | PT THS | Cup | PT INN | Cup | PT INN | Cup |
| 2 | Test Thr | Cup | | | | |
| 3 | | | Fbg | Cup | Fbg | Cup |
| 4 | | | DDi.BUF | Cup | | |
| 5 | PTT FSL | Cup | PTT FS | Cup | PTT FS | Cup |
| 6 | ATReag | Cup | DDi.REA | Cup | | |
| 7 | CaCl2 | Cup | CaCl2 | Cup | CaCl2 | Cup |
| 8 | ATSub | Cup | DDi.SUP | Cup | | |
| 9 | VIII | Cup | | | | |
| 10 | ATBuf | Cup | DDi.DIL | Cup | | |
| 11 | CleanI | PV-10 | CleanI | PV-10 | CleanI | PV-10 |
| 12 | OVB | PV-10 | OVB | PV-10 | OVB | PV-10 |
| 13 | CleanII | Cup | CleanII | Cup | CleanII | Cup |

Host computer

| | |
|------------------|---------------|
| Status | Not connected |
| Baud Rate [BPS] | 2400 |
| Character Length | 7-bit |
| Stop Bit | 1-bit |
| Parity | Even |
| Class | Class A |
| Interval [sec] | 2 |
| Inquiry | Auto |
| Format | CA1000 |
| ACK Tex | ACK/NAK |
| Flag format | Standard |

Barcode Scanner

| | |
|-----------------|---------------|
| Barcode Scanner | Not connected |
| Kind 1 | ITF |
| Kind 2 | NW-7 |
| Kind 3 | CODE39 |
| Kind 4 | JAN-8 |
| Hand-held BCR | Not connected |
| Check Digit | None |

Date Format

MM/DD/YY

14.3 Installation

Introduction

This product is a clinical test instrument. A representative is responsible for unpacking, installing, and initial setup to ensure its proper and safe operation. The next several pages will give some essential information for installation of this instrument.

Check before Installation

Make sure that the instrument is free from external flaws and check the quantity of the provided parts.

Provided parts check list

| Part No. | Description | Quantity |
|------------|---|----------|
| AG818297 | Program Card | 1 |
| 073-2752-0 | Sample Rack (White) | 1 |
| 241-9223-6 | Ferrite Core | 1 |
| AU071498 | Instruction For Using Ferrite Core | 1 |
| BX177453 | Label No.966 (Reagent Indication Mark) | 1 |
| CT904571 | 2D barcode reader (1900GSR-1) | 1 |
| BV088995 | KIT NO.191 (Connection cable of 2D barcode reader) | 1 |

Instrument provided parts check list

| Part No. | Description | Quantity | |
|------------|--|----------|--------|
| | | CA-620 | CA-660 |
| AS244534 | Filter No.598 | 2 | 2 |
| 043-3581-4 | Trap Chamber Complete | 1 | 1 |
| 663-7175-7 | Screw w/Knob TL-233-3 | 1 | 1 |
| BP577416 | Rinse Bottle Assy (5L) | 1 | 1 |
| AS977096 | Waste Bottle Assy (5L) | 1 | 1 |
| AJ387179 | Reagent Rack Assy | 1 | 1 |
| AJ046225 | Reaction Tube Trash Box | 1 | 1 |
| CQ773511 | Holder Assy No.181 (Reaction Tube Rack) | 2 | 4 |
| 363-2558-6 | Holder No.89 (Sample Cup Adapter of Reagent Rack) | 2 | 2 |
| 663-5117-3 | Sample Tube Spacer 13 Phi | 1 | 1 |
| 541-1352-1 | Push Vial PV-10 | 2 | 2 |
| 013-1771-4 | SLD Vial Assy (10/Pack) | 1 | 1 |

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| Part No. | Description | Quantity | |
|------------|--------------------------|----------|--------|
| | | CA-620 | CA-660 |
| 424-1160-8 | Sample Cup Conical (4mL) | 1 | 1 |
| 541-0541-8 | Reaction Tube | 60 | 60 |
| 462-4842-7 | Paper Thermal F1-2 | 2 | 2 |
| BC963426 | Fuse 250V 4.0A | 2 | 2 |



Note

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

Installation Space

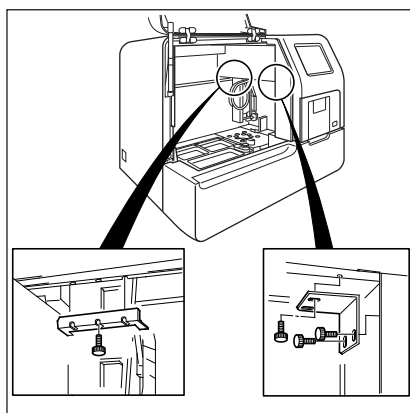
Refer to “Installation Space” of “4.2 Installation Location”.

Remove Shipping Clamps

Remove the shipping clamps used on movable components of the instrument.

1. Open the front cover of the main unit.
2. Remove the X-Y mechanism fixing metals.

Two fixing metals are retained with screws as shown. Loosen the screws and remove the metals.

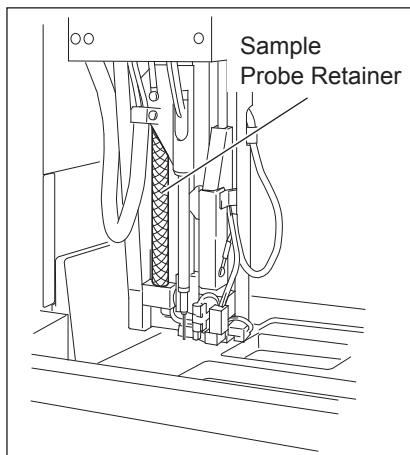


Information

Unless the fixing metals are removed, the instrument cannot operate.

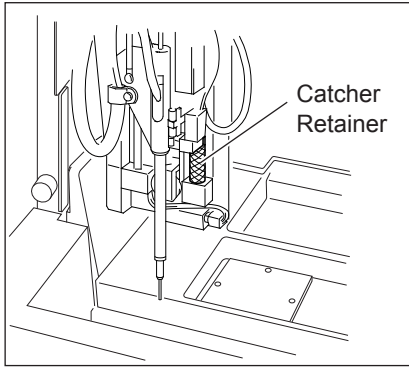
3. Move the sample probe unit by hand to a place where it is easy to operate.

Remove the sample probe retainer.



Information

Unless the retainer is removed, the instrument cannot operate.



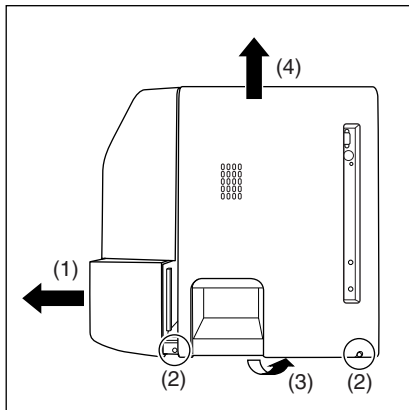
4. Raise the sample probe by hand to a place where it is easy to operate.
Remove the catcher retainer.



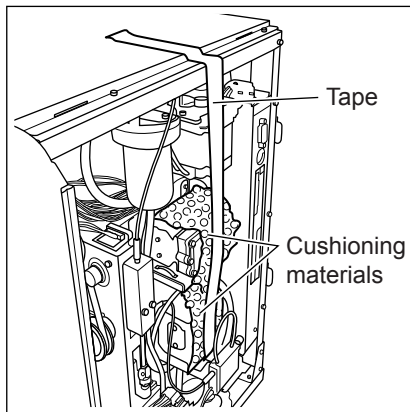
Information

Unless the retainer is removed, the instrument cannot operate.

Remove Shipping Fixtures

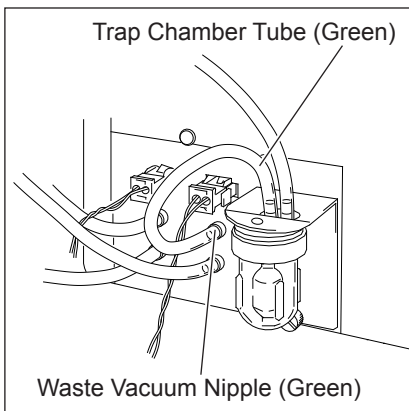


1. Pull out the sampler until the screw becomes visible.
2. Unscrew the fixing screws (two areas).
3. Pull out the bottom of the side cover.
4. Lift up and remove the side cover.



5. Remove the tape fixing the cushioning material.
6. Remove the cushioning material (two areas).
7. Attach the side cover in the reverse order of removal.

Attach Trap Chamber



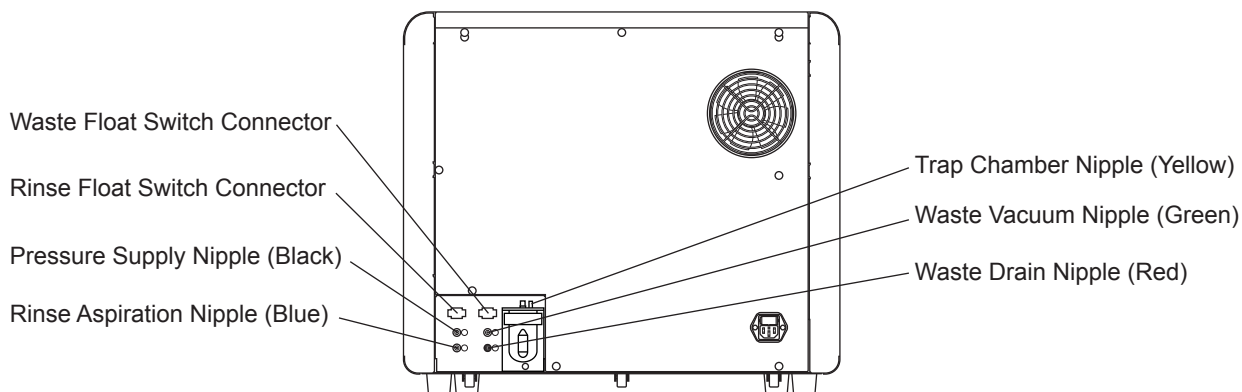
1. Attach the supplied trap chamber to the rear panel.
Connect the trap chamber tube (green) to the waste vacuum nipple (green) on the rear panel.



refer to "2.5 Avoidance of Infections"

Connect Rinse Bottle and Waste Bottle

Connect the rinse bottle and the waste bottle to the nipples on the instrument rear panel.

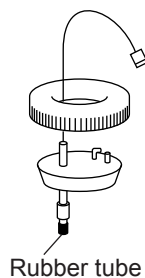


1. Connect Rinse Bottle.

- 1) Connect the rinse bottle to the pressure supply nipple (black), and rinse aspiration nipple (blue) on the rear panel, at places where the color matches with the bottle.
- 2) Connect the level-detecting float switch to the float switch connector on the rear panel.

2. Connect Waste Bottle.

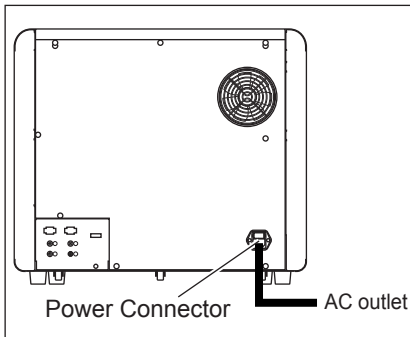
- 1) Connect the waste bottle tube (red) to the waste drain nipple (red) on the rear panel. Connect the waste bottle tube (yellow) to the trap chamber nipple (yellow).
- 2) Connect the level-detecting float switch to the float switch connector on the rear panel.



i Information

- Even at a facility equipped with the waste channel (drain system), the waste bottle should be connected. Also, put the rinse bottle and the waste bottle at the same level as the instrument. Be sure not to use any other tube than the supplied one; otherwise, the instrument's hydraulic system may fail to operate properly.
- Remove the rubber tube that locks the float switch in the rinse bottle and waste bottle. This rubber tube serve to prevent vibration in transit.

Connect Power Cord and Connection Cord

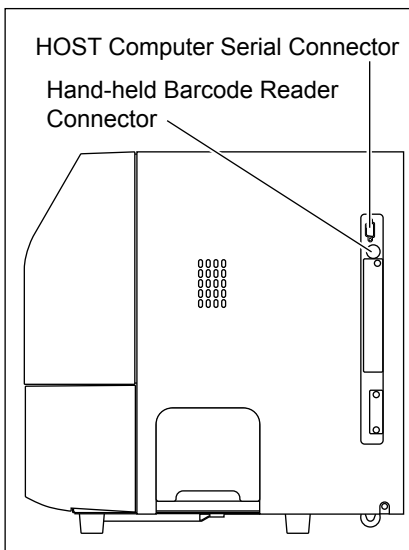


1. Connect the supplied power cord.
 - 1) Make sure the power switch is OFF, at “O”.



Caution!

Confirm the power switch is OFF, at “O” before routing the power cord. Make sure to ground the AC outlet; otherwise, there is a hazard of electrical shock.



2. Connect the cable to link with the host computer.
 - 1) Make sure the power switch is OFF, at “O”.
 - 2) Connect the connection cord to Host Computer Serial Connector on the right side panel and tighten the screw to fix it.
3. Connect the hand-held barcode reader.
 - 1) Make sure the power switch is OFF, at “O”.
 - 2) Connect the hand-held barcode reader cord to Hand-held Barcode Reader Connector on the right side panel.



Information

Confirm the power switch is OFF, at “O”, before routing the connection cord; otherwise, there is a hazard of electrical shock.



Note

- For setting host computer interface parameters and hand-held barcode reader connection, refer to “10.14 Devices to be connected”.
- The connection cord for the host computer and hand-held barcode reader are not included in the supply parts.

Set Print Paper

Refer to “11.9 Supply Printer Paper”.

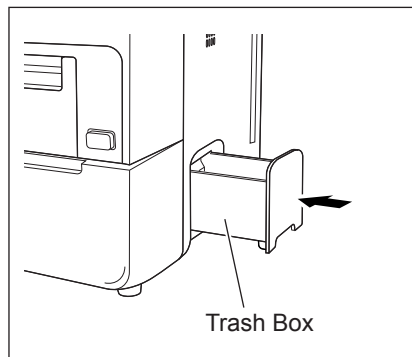
Adjust LCD Contrast

Refer to “Contrast Adjustment for LCD Screen” of “4.3 Basic Instrument Settings”.

Replenish Rinse Solution

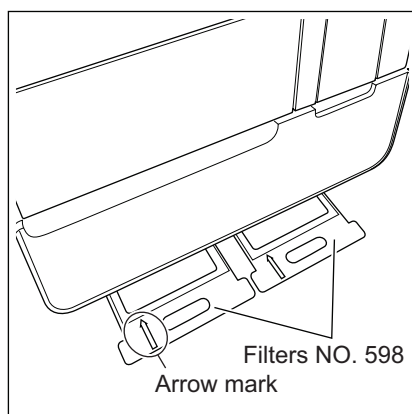
Refer to “11.11 Prime Rinse Solution to Hydraulic Line”.

Set Trash Box



Set the supplied trash box.

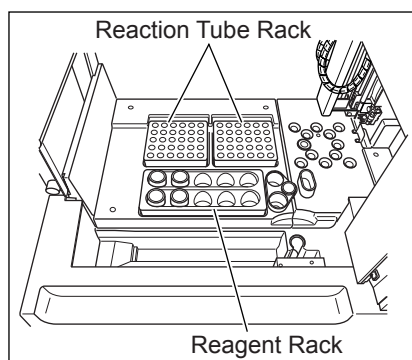
Set Filters



Insert the filters NO. 598 (two pieces) all the way in until they hit the back wall, with the arrow mark face up.

Make sure to insert the filters in line with the bottom plate guides of the instrument.

Set Reagent Rack and Reaction Tube Rack



Set the supplied reagent rack and reaction tube rack.

Affix Indication Mark Label No. 966 on the reagent rack.

14.4 Serial Interface for Host Computer

A serial interface is available on the Main Unit rear panel for connecting to a host computer. The bit serial voltage type, which conforms to the RS-232C interface, is used for input and output to and from this instrument.

Connection

Connect an EIA RS-232C V.24 standard 9-pin D-SUB, female (body = female and pins = male) connector (DB-9S) to the serial interface on the Main Unit rear panel. Fixing screws for this connector have a thread which is measured in needs.

Input/Output Signals

| Pin | Signal Name | Flow Direction |
|-----|---------------------------|-----------------------|
| 1 | | |
| 2 | Receive Data (RxD) | IN (From Host to CA) |
| 3 | Transmit Data (TxD) | OUT (To Host from CA) |
| 4 | Data Terminal Ready (DTR) | OUT (To Host from CA) |
| 5 | Signal Ground (SG) | |
| 6 | Data Set Ready (DSR) | IN (From Host to CA) |
| 7 | Request to Send (RTS) | OUT (To Host from CA) |
| 8 | Clear to Send (CTS) | IN (From Host to CA) |
| 9 | | |

Communication Format

Asynchronous Half Duplex Mode

Communication Settings

Setting program “Settings” - “I/O Setting” - “Host Computer” has to be executed to set the interface parameters. Underlined items are selected as the initial configuration. Refer to “10.14 Devices to be connected”.

| Items | Selections | | | | | | |
|-------------------|----------------|----------------------|---------------|------|------|----|----|
| Status | Connected | <u>Not Connected</u> | | | | | |
| Baud Rate (BPS) | 600 | 1200 | <u>2400</u> | 4800 | 9600 | | |
| Character Length | <u>7-Bit</u> | | 8-Bit | | | | |
| Stop Bit | <u>1-Bit</u> | | 2-Bit | | | | |
| Parity | None | <u>Even</u> | | | Odd | | |
| Class | <u>Class A</u> | | Class B | | | | |
| Interval (second) | 0 | <u>2</u> | 3 | 5 | 7 | 10 | 15 |
| Inquiry | Auto | | <u>Manual</u> | | | | |

| Items | Selections |
|----------|----------------------------|
| Format | <u>CA1000</u> CA500 ASTM |
| ACK Text | STX-ACK-ETX <u>ACK/NAK</u> |

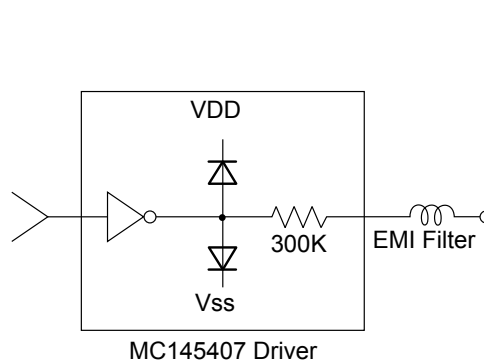
Signal Level

Signal level of the RS-232C conforms to the EIA RS-232C V.24 standard.

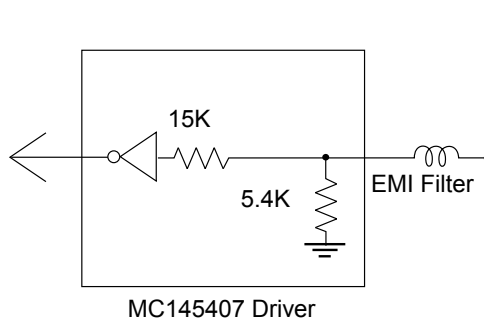
| Level | Binary State | Function |
|----------------|----------------------|----------|
| +3 V or Higher | Logic "0", Start Bit | ON |
| -3 V or Lower | Logic "1", Stop Bit | OFF |

Interface Circuit

Output Circuit



Input Circuit



Software

1. Code

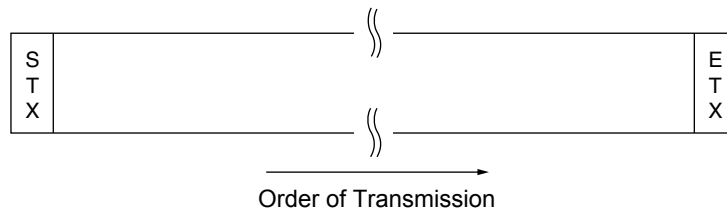
ASCII codes are used in this interface.

2. General Function

| Function | Description |
|--|---|
| Analysis data output | Auto Out -- This instrument automatically sends out analysis data after each analysis has been completed. |
| | Stored Data (batch output) -- This instrument sends out data from the stored data in a batch. |
| Inquiry (output) and settings from host computer (input) | When this instrument makes an inquiry about order information for the Rack No. and Tube Position No., the host computer gives order information and the sample ID number for each sample in the rack to the instrument. |
| | According to ID No. read by the optional barcode reader, the host computer gives order information for each sample. |

3. Framing of Text

STX (02 in hexadecimal code) is sent prior to data and ETX (03 in hexadecimal code) is sent following data. The text length is within 255 bytes.



4. Communication Protocol

The following 2 protocols are provided in the system. The factory configuration is Class A. Refer to “10.14 Devices to be connected” for setting information.

| Class | Description |
|---------|---|
| Class A | One-way transmission to the host computer without requiring ACK (06 in hexadecimal) nor NAK (15 in hexadecimal) from host computer. |
| Class B | This instrument transmits data and then waits for ACK or NAK to complete the data transmission, which is more secure transmission protocol. |

5. Text Format

The following 3 kinds of formats are provided in the system.

| Text Format | Contents of Text |
|---|---|
| Analysis data format (output) | Output analysis data. When Auto Out is selected or when serial output of stored data is performed, analysis data will be output. |
| Inquiry text for ID No. and parameter(s) settings | This instrument asks host computer about parameter(s) or about both ID No. and parameter(s). |
| Settings text for ID No. and parameter(s) | Host computer responds to this instrument the analysis parameter(s) or both ID No. and analysis parameter(s). |

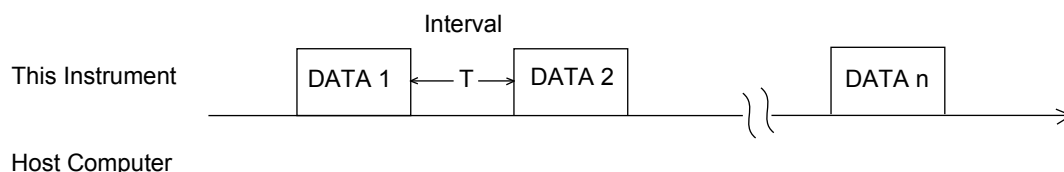
Class A

Data is transmitted in the form of a text or blocks. The host computer checks the start and end characters as well as the parity bit received after each character, but does not transmit any response. Therefore, the instrument will not wait for the response ACK (06 in hexadecimal) or NAK (15 in hexadecimal) from the host computer and transmits data to the host computer in one direction with two control signals (CTS and DSR) only.

This instrument transmits the following data without requiring data from the host computer in Class A mode.

- Auto output of analysis data - Real-time output
- Output of stored data - Batch output

Data will be transmitted by the interval time set in the serial interface settings.



Class B

This class is identical to Class A except for the receiving side. When the host computer receives transmitted data, the host computer transmits a response followed by a sequence. If necessary the host computer also checks the contents of the text (or block). This instrument waits for the response ACK or NAK from the host computer in addition to two control signals (CTS and DSR) and transmits the next sample data upon receiving ACK from the host computer.

The instrument transmits the following data in Class B mode.

| Function | Description |
|--|---|
| Analysis data output | Auto Out -- This instrument automatically sends out analysis data after each analysis has been completed. |
| | Stored Data (batch output) -- This instrument sends out data from the stored data in a batch. |
| Inquiry (output) and settings from host computer (input) | When this instrument makes an inquiry about order information for the Rack No. and Tube Position No., the host computer gives order information and the sample ID number for each sample in the rack to the instrument. Inquiry is made when the [HC] key is pressed in the Work List program. |
| | According to ID No. read by the optional barcode reader, the host computer gives order information for each sample. |

Analysis Data Output from This Instrument to Host Computer

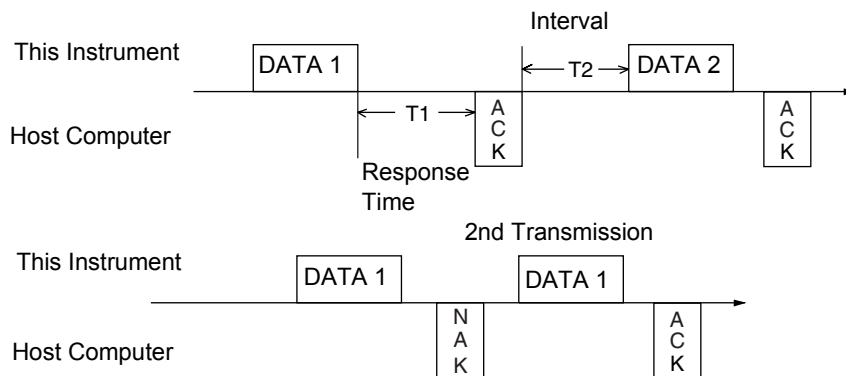
This instrument transmits analysis data text to the host computer in the following sequence.

1. This instrument transmits analysis data text to the host computer.
2. The host computer sends ACK (06 H) when the data is received correctly, and sends NAK (15 H) if a communication error occurs.
3. If the reply is ACK, the instrument will complete communication. If the reply is NAK, the instrument will send the same text again (retrying up to 3 times).
4. If the reply is still NAK after sending the same text the third time, the instrument terminates the communication.



Note

“STX-ACK-ETX” and “STX-NAK-ETX” can be selected instead of ACK and NAK. Refer to “10.14 Devices to be connected” for procedures.



Analysis Order Inquiry to Host Computer

Transmission Protocol should be fixed in Class B to make inquiries regarding order information to the host computer. Selecting Class A will lead to an incorrect communication without showing an error message.

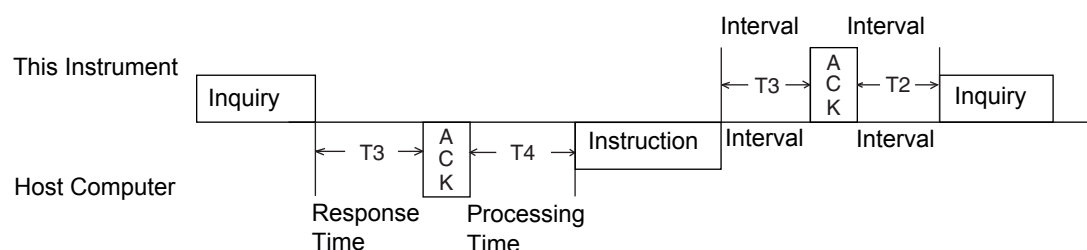
The instrument inquires the order information and receives order information text from the host computer in the following sequence.

1. The instrument sends order inquiry text to the host computer.
2. The host computer verifies the received data and responds by sending NAK (15H) when an error exists. When no error exists, host computer sends ACK (06H) and the order information text that was requested.
3. If the instrument receives NAK from the host computer, the instrument re-sends the inquiry text (retrying up to 3 times). If the instrument receives NAK after 3 retries, the instrument terminates the communication.

If the instrument receives ACK, the instrument verifies the order information text and sends NAK when an error exists. When no error exists, the instrument sends ACK to the host computer.

4. If the host computer receives ACK from the instrument, the host computer completes the communication of order information for one sample.

If NAK is received from the instrument, the host computer re-sends the order information text to the instrument (retrying up to 3 times).



Time Interval

The time interval between two data transmissions to the host computer can be selected with the setting program. The interval time means the period after this instrument received the response of ACK/NAK from the host computer until the instrument starts transmission of the next data in Class B mode.

The instrument sends text after the “T2” interval. The interval time can be set in the serial interface settings at 0, 2, 3, 5, 7, 10 or 15 seconds.

Time-Out Setting

When response time “T1” (shown in Figure C-5) or “T3” or processing time “T4” exceeds the time-out setting, the instrument will terminate the communication. Time-out settings is fixed to 15 seconds.



Note

Processing time “T4” is the time that is required for the host computer to process setting text.

Processing Time

For communication without the use of a control wire, response time “T1” or “T3”, and processing time “T4” must be set to an interval of 0.2 seconds or longer. Contact your local service representative for assistance.

If there is no order setting for parameter(s)

When a parameter is not analyzed, enter “000” for the parameter as the setting code.

When there is no analysis parameter order set in the host computer, enter “999” as the setting code. When the instrument receives “999”, the instrument terminates inquiry about analysis parameters of the samples in that rack, and no sample will be analyzed.

Transmission Errors

If this instrument detects an error after transmitting data, an error message will be displayed and transmission of data will be terminated. The customer has to resolve the following error status to transmit data again.

| Error Message | Description |
|--|--|
| Off Line | DSR is OFF. |
| HC CTS Time Out | CTS does not become ON within 5 seconds after entering a command to transmit data to host computer (RTS turns ON). |
| HC Communication Error | Parity Error, Overrun Error or Frame Error occurs. |
| HC ACK Code Error | Host computer does not send a correct response code to this instrument. |
| HC ACK Time Out | Host computer does not send the response ACK nor NAK to this instrument within 15 seconds after transmitting data. |
| HC Reception Count Error | This instrument receives NAK after three retries, or failed to receive data four times (transmits NAK 4 times). |
| HC STX Time Out | After receiving ACK, this instrument does not receive setting text within 15 seconds. |
| HC ETX Time Out | After receiving STX, this instrument can not receive ETX of setting text within 15 seconds. |
| Instruction Not Found in Host Computer | In response to analysis parameter of rack position #1, host computer sends “999” as the analysis parameter setting text. |

14.5 Text Format

The instrument transmits (1) Analysis Data, (2) Inquiry Data, and (3) Order Information Data. This data is distinguished by the Text Distinction Code I. Text Distinction Code I is “D” for the Patient Sample Data, “R” for the Inquiry Data, or “S” for the Order Information Data.

Analysis Data Format

| Parameter | No. of Characters | Example |
|---------------------------|-------------------|---|
| STX | 1 | (02 H) |
| Text Distinction Code I | 1 | “D” |
| Text Distinction Code II | 1 | “1” or “2” |
| Text Distinction Code III | 2 | “21” |
| Block Number | 2 | “01” |
| Total Number of Blocks | 2 | “01” |
| Sample Distinction Code | 1 | “U”, “E”, “S” or “C” |
| Date | 6 | “010131” (yy/mm/dd, mm/dd/yy or dd/mm/yy) |
| Time | 4 | 1325 (hh:mm in 24-hour clock) |
| Rack Number | 4 | “0001” (0001-9999) |
| Tube Position Number | 2 | “01” (01-10) |
| Sample ID Number | 15 (or 13) | “123-4567-8901” |
| ID Information | 1 | “M”, “A”, “B” or “C” |
| Patient Name | 11 | “xxxxxxxxxx” Spaces (20H), or characters except for the control codes. |
| Data 1 | 9 | |
| Data 2 | 9 | |
| • | • | |
| • | • | |
| • | • | |
| Data n | 9 | |
| ETX | 1 | (03 H) |

- (a) Text Length = $54 + (9 \times n)$ bytes
 The text length varies depending on the number of parameters.
 Analysis data should not exceed 255 characters. If it exceeds 255 characters, the analysis data will be divided into blocks.
- (b) The order of transmission is from the top parameter to the bottom. The data sent is the most significant digit first, i.e., left to right. Zero suppression is not performed.

- (c) The decimal point is not sent. If necessary, add the decimal point on the host computer side as shown in the example.
- (d) Text Distinction Code I is “D” for the analysis data.
Text Distinction Code II is type of analysis data:
 “1”: Normal single analysis data
 “2”: Mean data of replication analyses.
Text Distinction Code III is always “21”.
- (e) Block number and total number of blocks are both usually “01”.
The block number is the serial number of divided blocks.
The total number of blocks is the number of total blocks divided.

(f) Sample Distinction Code

| Symbol | Type of Data: |
|--------------|-------------------------------|
| U | Routine analysis data |
| E | STAT analysis data |
| S | Standard curve analysis data |
| C | Quality control analysis data |
| (space, 20H) | Type of sample is unknown. |

- (g) Date and time is the time when the analysis data was obtained. Date format conforms the format set in the setting program. Zero suppression is not performed.
- (h) Time is expressed in 24-hour clock system. Zero suppression is not performed.
- (i) Rack No. indicates the 4-digit Rack No. assigned to each rack which is “0001” through “0099”. STAT samples are assigned a sequential number by the system. Zero suppression is not performed.



Note

A sequential number is the number counted up by one each time after turning ON the power.

- (j) Tube Position No. is the position number in which the sample was placed within a rack. “01” through “10” can be set when the sample was set in a sample rack. “00” is output for the STAT sample. Zero suppression is not performed.
- (k) Sample ID number consists of 15 digits including hyphens “-” (2D in hexadecimal code). Zero suppression is not performed. When No. of digits for the ID number is set in the Settings, Output/Input, HC program, the most significant digit(s) are not output computer if it is set lower than 15 digits.
- (l) ID information indicates how the sample ID number was entered or read.

| Symbol | Description |
|--------|--|
| M | The sample ID number was entered manually. |
| A | The sequential number was applied to the sample ID number automatically. |
| B | The sample ID number was read by the barcode reader. |
| C | The sample ID number was downloaded from the host computer. |



Information

If sample ID was edited from the Stored Data Screen, its sample ID attribute will “M”.

- (m) Reserved (Eleven spaces (20H) are set.)
- (n) Data n

| Parameter | No. of Characters | Example |
|----------------|-------------------|--|
| Parameter Code | 3 | Refer to Table “Parameter Code”. |
| Data | 5 | Refer to Table “Data”. |
| Flag | 1 | “_”, “+”, “-”, “!”, “*”, “<” or “>”. Refer to Table “Flag”. |

- Parameter Code

| Parameter Code | Parameter | Parameter Code | Parameter |
|----------------|-----------|----------------|-----------|
| 04X | PT | 30X | AT3 |
| 05X | APTT | 33X | BCPC |
| 06X | Fbg | 34X | Hep |
| 50X | +Fbg | 61X | DDPI |
| 52X | -Fbg | 70X | +DDP |
| 51X | TT | 61X | DDi |
| 17X | VII | 70X | +DDi |
| 18X | VIII | 65X | vWF |
| 25X | PCcl | 66X | -vWF |
| 26X | BXT | 67X | +vWF |
| 27X | LA1 | 80X | WFa |
| 28X | LA2 | 81X | +WFa |
| 30X | AT | 82X | -WFa |

Where, X is:

- 1: Time
- 2: Activity percent/concentration
- 3: Ratio
- 4: INR
- 5: dFbg



Note

Additional parameter codes may be added in the future.
The host computer may receive a parameter code not mentioned above; therefore, prepare a host computer program that will ignore such data of a parameter code.

- Data

Data is sent without a decimal point.

| Data | Units | Output Format | |
|-----------------------|------------|---------------------------|---------|
| | | Actual data → Data format | |
| Coagulation time | sec, s | XXXX.X | → OXXXX |
| Activity % | % | XXX.X | → OXXXX |
| | No unit | X.XXX | → OXXXX |
| PT ratio, INR | | XX.XX | → OXXXX |
| Fbg concentration | mg/dL | XXX.X | → OXXXX |
| | g/L | X.XXX | → OXXXX |
| D-Dimer concentration | μg/L | XXXX | → OXXXX |
| | mg/L (FEU) | XX.XX | → OXXXX |



Caution!

If your host computer receives PT ratio and INR with form of X.XX, contact your local service representative.



Note

- X stands for a figure, O stands for a blank space (20 H).
- When the coagulation time could not be obtained because of an analysis error, an asterisk (*) appears instead of “X” as the coagulation time. If there is an analysis error of mean data, a slash (/) appears in stead of “X”.
- In case of no standard curve, illegal data, or if no coagulation occurs, an appropriate number of hyphens “-” appear instead of “X”. Also if an analysis error occurs due to a hardware problem, spaces (20 H) appear instead of “X”.

- Flag

A flag indicates whether or not an error occurred during analysis.

| Flag | Meaning |
|-------|--|
| space | No error |
| + | Over the Upper Patient Limit |
| - | Under the Lower Patient Limit |
| * | Error occurred during analysis, Fbg data exceeds the analysis range, or replicate difference is too big. |
| d | Coagulation time was obtained by re-dilution. |
| > | Over the Upper Report Limit |
| < | Under the Lower Report Limit |



Note

- The “d” changes depending on the flag format in the host computer setting.
Standard: “d”
CA-500: “!”
Refer to “10.14 Devices to be connected”.
- The priority order of each flags is (*), (<) or (>), (+) or (-), (d) a space “ ” in that order.

Inquiry Data Format


| Parameter | No. of Characters | Example |
|---------------------------|-------------------|--|
| STX | 1 | (02 H) |
| Text Distinction Code I | 1 | “R” |
| Text Distinction Code II | 1 | “1” or “2” |
| Text Distinction Code III | 2 | “21” |
| Block Number | 2 | “01” |
| Total Number of Blocks | 2 | “01” |
| Sample Distinction Code | 1 | |
| Date | 6 | “010131” (yy/mm/dd, mm/dd/yy or dd/mm/yy) |
| Time | 4 | 1325 (hh:mm in 24-hour clock) |
| Rack Number | 4 | “0001” (0001-9999) |
| Tube Position Number | 2 | “01” (01-10) |
| Sample ID Number | 15 (or 13) | “123-4567-8901” |
| ID Information | 1 | “M”, “A”, “B”, “C” or a space “ ” |
| (Reserved) | 11 | “xxxxxxxxxx”; Eleven Spaces (20H), or characters except for the control codes. |
| Analysis parameter 1 | 9 | |
| Analysis parameter 2 | 9 | |
| • | • | |
| • | • | |
| • | • | |
| Analysis parameter n | 9 | |
| ETX | 1 | (03 H) |

(a) Text Length = 54 + (9 × n) bytes

The text length varies depending on the number of parameters.

Inquiry data should not exceed 255 characters. If it exceeds 255 characters, the inquiry data will be divided into blocks.

- (b) The order of transmission is from the top parameter to the bottom. The data sent is the most significant digit first, i.e., left to right. Zero suppression is not performed.
- (c) The decimal point is not sent. If necessary, add the decimal point on the host computer side as shown in the example.
- (d) Text Distinction Code I is “R” for the inquiry data.
Text Distinction Code II is type of inquiry:
 - “1”: The key word is “Rack No. and Tube Post.”
 - “2”: The key word is “Sample ID No.”
Text Distinction Code III is always “21”.
- (e) Block number and total number of blocks are both usually “01”.
The block number is the serial number of divided blocks.
The total number of blocks is the number of total blocks divided.
- (f) A space (20H) is sent for the Sample Distinction Code.
- (g) Date and Time when the inquiry is made. Date is transmitted in the form set by the Setting program. Time is expressed in 24-hour clock system. Zero suppression is not performed.
- (h) Rack No. indicates the Rack No. for which the inquiry is made.
“0001” through “0099” can be set. Zero suppression is not performed.
- (i) Tube Position No. is the position number in which the sample was placed within a rack. “01” through “10” can be set. “00” is output for the STAT sample. Zero suppression is not performed.
- (j) Sample ID number indicates the sample ID number for which the inquiry is made. Sample ID number consists of 15 digits including hyphens “-” (2D in hexadecimal code). When the ID number of 13 digits or less is set, the set ID number is placed in the least significant digits and space(s) (20 H) are padded to the most significant digits to fill up 15 digits.
When inquiry is made by the Rack No., sample ID number will be filled with spaces.

 **Note**
When the barcode label could not be read due to an error or no label is attached on the sample tube, the sample ID No. will become “ERR000000001”.

- (k) ID information indicates how the sample ID number was entered or read.

| Symbol | Description |
|---------|--|
| M | The sample ID number was entered manually. |
| A | The sequential number was applied to the sample ID number automatically. |
| B | The sample ID number was read by the barcode reader. |
| C | The sample ID number was set by the host computer. |
| (space) | The sample ID number was inquired from the host computer with the Rack No. |

- (l) Reserved and 11 spaces (20H) are filled.

(m) Data n

| Parameter | No. of Characters | Example |
|----------------|-------------------|----------------------------------|
| Parameter Code | 3 | Refer to Table “Parameter Code”. |
| (Reserved) | 6 | All spaces (20H). |

- Parameter Code

| Parameter Code | Parameter | Parameter Code | Parameter |
|----------------|-----------|----------------|-----------|
| 040 | PT | 300 | AT3 |
| 050 | APTT | 330 | BCPC |
| 060 | Fbg | 340 | Hep |
| 500 | +Fbg | 610 | DDPI |
| 520 | -Fbg | 700 | +DDP |
| 510 | TT | 610 | DDi |
| 170 | VII | 700 | +DDi |
| 180 | VIII | 650 | vWF |
| 250 | PCcl | 660 | -vWF |
| 260 | BXT | 670 | +vWF |
| 270 | LA1 | 800 | WFa |
| 280 | LA2 | 810 | +WFa |
| 300 | AT | 820 | -WFa |



Note

Additional parameter codes may be added in the future.
 The host computer may receive a parameter code not mentioned above; therefore, prepare a host computer program that will ignore such data of a parameter code.

- Reserved

All characters are spaces (20H).

Order Information Data Format

| Parameter | No. of Characters | Example |
|---------------------------|-------------------|--|
| STX | 1 | (02 H) |
| Text Distinction Code I | 1 | “S” |
| Text Distinction Code II | 1 | “1” or “2” |
| Text Distinction Code III | 2 | “21” |
| Block Number | 2 | “01” |
| Total Number of Blocks | 2 | “01” |
| Sample Distinction Code | 1 | “U”, “E”, “S” or “C” |
| Date | 6 | “010131” (yy/mm/dd, mm/dd/yy or dd/mm/yy) |
| Time | 4 | 1325 (hh:mm in 24-hour clock) |
| Rack Number | 4 | “0001” (0001-9999) |
| Tube Position Number | 2 | “01” (01-10) |
| Sample ID Number | 15 (or 13) | “123-4567-8901” |
| ID Information | 1 | “A”, “B” or “C” |
| Patient Name | 11 | “xxxxxxxxxxx” Spaces (20H), or characters except for the control codes. |
| Analysis parameter 1 | 9 | |
| Analysis parameter 2 | 9 | |
| • | • | |
| • | • | |
| • | • | |
| Analysis parameter n | 9 | |
| ETX | 1 | (03 H) |

- (a) Text Length = $(54+9 \times n)$ bytes
The text length varies depending on the number of parameter.
Order information data should not exceed 255 characters. If it exceeds 255 characters, the order information data will be divided into blocks.
- (b) The order of transmission is from the top parameter to the bottom. The data sent is the most significant digit first, i.e., left to right. Zero suppression is not performed.
- (c) The decimal point is not sent. If necessary, add the decimal point on the host computer side as shown in the example.

- (d) Text Distinction Code I is “S” for the order information data.

Text Distinction Code II is type of inquiry:

“1”: The key word is “Rack No. and Tube Pos.”

“2”: The key word is “Sample ID No.”

Text Distinction Code III is “21”.

- (e) Block number and total number of blocks are both usually “01”.

The block number is the serial number of divided blocks.

The total number of blocks is the number of total blocks divided.

- (f) Sample Distinction Code

| Symbol | Type of Data: |
|--------|-------------------------------|
| U | Routine analysis data |
| E | STAT analysis data |
| S | Standard curve analysis data |
| C | Quality control analysis data |

- (g) Date and Time when the host computer ordered to the instrument. Date should be transmitted in the form set by the Setting program in the instrument. Time should be expressed in 24-hour clock system. Zero suppression is not performed.

- (h) Rack No. indicates the Rack No. into which the sample test tube is placed.

“0001” through “0099” can be set. It is suggested that the STAT sample is assigned a sequential number to distinguish from other STAT samples.

- (i) Tube Position No. is the position number in which the sample is placed within a rack. “01” through “10” can be set. “00” should be assigned for the STAT sample.

- (j) Sample ID number consists of 15 digits including hyphens “-” (2D in hexadecimal code). When the ID number of 13 digits or less is set, the set ID number is placed in the least significant digits and space(s) (20 H) are padded to the most significant digits to fill up 15 digits.

When the sample is the Quality Control material, assign the QC file number as

“QC01_____” through “QC06_____” in which the obtained QC data are to be stored. (“_” represents a space.)

- (k) ID information indicates how the sample ID number was entered or read.

| Symbol | Description |
|--------|--|
| C | The sample ID number was downloaded from the host computer. |
| A | The sequential number was applied to the sample ID number automatically. |
| B | The sample ID number was read by the barcode reader. |
| M | The sample ID number was entered manually. |

- (l) Reserved; 11 spaces (20H).

(m) Data n

| Parameter | No. of Characters | Example |
|----------------|-------------------|----------------------------------|
| Parameter Code | 3 | Refer to Table “Parameter Code”. |
| (Reserved) | 6 | All spaces (20H). |

• Parameter Code

| Parameter Code | Parameter | Parameter Code | Parameter |
|----------------|-----------|----------------|--|
| 040 | PT | 340 | Hep |
| 050 | APTT | 610 | DDPI |
| 060 | Fbg | 700 | +DDP |
| 500 | +Fbg | 610 | DDi |
| 520 | -Fbg | 700 | +DDi |
| 510 | TT | 650 | vWF |
| 170 | VII | 660 | -vWF |
| 180 | VIII | 670 | +vWF |
| 250 | PCcl | 800 | WFa |
| 260 | BXT | 810 | +WFa |
| 270 | LA1 | 820 | -WFa |
| 280 | LA2 | 000 | Not Analyzed |
| 300 | AT | 999 | Stop order inquiry for the following samples in the racks. |
| 300 | AT3 | | |
| 330 | BCPC | | |



Note

Additional parameter codes may be added in the future.
 The host computer may receive a parameter code not mentioned above; therefore, prepare a host computer program that will ignore such data of a parameter code.


(n) When no instruction found in host computer:

- If there is no setting parameter in response to the inquiry from the instrument for the ID number, host computer is requested to send “000” as the parameter code.
- If there is no setting parameter in response to the inquiry from the instrument for the Rack number, host computer is requested to send “999” as the parameter code. If the instrument receives “999”, it stops inquiring about following samples that are in the same sample rack.

14.6 ID Barcode

Applicable Barcodes

The types of barcodes acceptable to the instrument and the relation of the check-digit to each barcode type are as follows:




Warning!
Use the check-digit as much as possible. If the check-digit cannot be used, the potential of incorrect reading of the barcode label may be increased.

1. Sample ID No.

| Type of Barcode | Check-Digit | No. of Digits for Sample ID No. | No. of Digits for Check-Digit |
|--------------------------|---------------|---------------------------------|-------------------------------|
| NW-7 (CODABAR)* | Not Used | 1 - 15 digits | Not Applied |
| | Modulus 11 | 1 - 15 digits | 1 digit |
| | W. Modulus 11 | 1 - 15 digits | 1 digit |
| | Modulus 10 | 1 - 15 digits | 1 digit |
| CODE-39 | Not Used | 1 - 15 digits | Not Applied |
| | Modulus 43 | 1 - 15 digits | 1 digit |
| CODE-128 | Modulus 103 | 1 - 15 digits | 1 digit |
| ITF (Interleaved 2 of 5) | Not Used | 1 - 15 digits | Not Applied |
| | Modulus 10 | 1 - 15 digits | 1 digit |
| JAN-8 | Modulus 10 | 7 digits | 1 digit |
| JAN-13 | Modulus 10 | 12 digits | 1 digit |

*: Start and Stop code can be any one of the characters “A”, “B”, “C”, “a”, “b” and “c”.



Note
When “C” or “c” is used, make sure that the number should not be the same as the number of QC File No.

2. QC File No.

QC File No. can be read if printed with NW-7, CODE-39 or CODE-128.

| Type of Barcode | Check-Digit | No. of Digits (File No.) | No. of Digits for Check-Digit |
|---------------------|------------------------------|--------------------------------------|-------------------------------|
| NW-7 (CODABAR) *1 | Not Used | 4 to 13 digits *2 | Not Applied |
| CODE-39 CODE-128 | Either of “Use” or “Not Use” | 4 digits “QC01”, “QC02”, “QC12” | Not Used or 1 digit |

*1: Start and Stop code can be any one of the characters “C” and “c”.

*2: Possible applicable number is one of 1 through 9, and must be filled with the same number in all digits.

Dimensions of Elements

Barcodes consists of five elements: a narrow bar, a narrow space, a wide bar, a wide space, and a gap between characters. Each element has to comply with all of these equations:

- (a) Narrow element $\geq 150 \mu\text{m}$
- (b) Wide element $\leq 1.2 \text{ mm}$
- (c) Narrow element \leq Gap between characters \leq Wide element



Note

ITF does not require above mentioned item (c), since ITF does not use a gap between characters.

Requirements on Wide/Narrow Ratio

For each character, the ratio of the wide element and the narrow element has to comply with all the equations listed below:

$$\begin{array}{ccc} (1) & (2) & (3) \\ \frac{\text{Narrow(Max)}}{\text{Narrow(Min)}} \leq 1.3 & \frac{\text{Wide(Min)}}{\text{Narrow(Max)}} \geq 2.2 & \frac{\text{Wide(Max)}}{\text{Wide(Min)}} \leq 1.4 \end{array}$$

Here, the Narrow (Max) means the widest element of narrow elements in a character. The Narrow (Min) means the narrowest element of narrow elements in a character. The Wide (Min) means the narrowest element of the wide elements in a character and the Wide (Max) means the widest element of wide elements in a character.

Optical Requirements

1. Requirement on the Print Contrast Signal (PCS) is:

$$\text{PCS} = \frac{R_s - R_b}{R_s} \geq 0.45$$

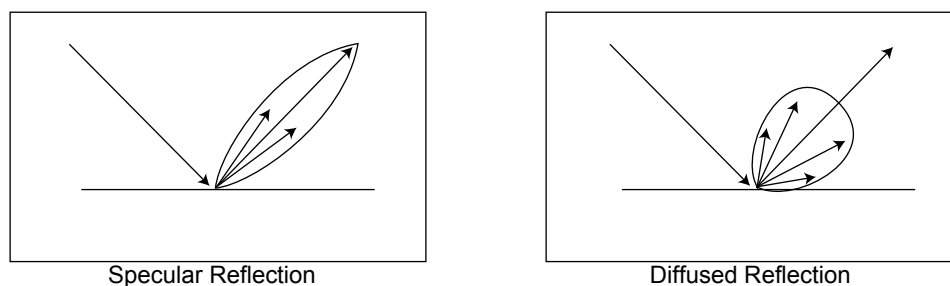
R_s : the reflectivity of the space (background)

R_b : the reflectivity of the black inked bar

The measuring method conforms to *the JIS (Japanese Industrial Standards) B9550, "5.3 Optical Characteristics of Barcode Symbols"*.

2. Reflective characteristics of the label surface

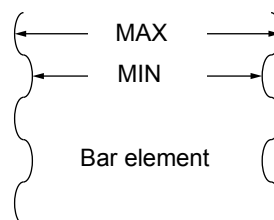
The barcode reader defines the white and black by the reflected light intensity when the light is applied to the label at an angle of approximately 25° . Therefore, most of the reflection of the label surface should be diffused reflection. For example, a laminated label may cause specular reflection, which will increase the reflection directivity too much and cause the ID reader to miss scan lines. See the following figures.



3. Irregularity and roughness of the printing

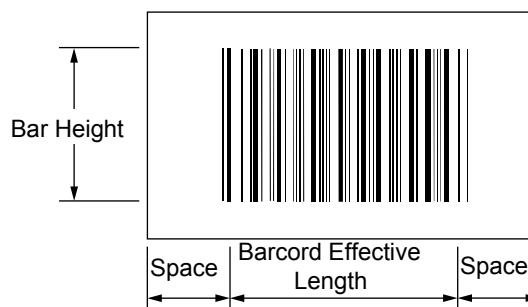
When a bar element is magnified, the following may be observed. The variation coefficient (S) in the width of a bar should be less than or equal to 20%.

$$S(\%) = \frac{\text{Max}-\text{Min}}{\text{Max}} \times 100$$



Dimensions of Barcode Label

- (a) The leading and trailing spaces should be greater than or equal to 5 mm.
- (b) The effective length of bars should be less than or equal to 40 mm. This length is related to the ease of placing the label. The physical absolute maximum length is 48 mm.
- (c) The bar height should be greater than or equal to 20 mm. This height is theoretically required to be at least 10 mm to scan lines. However, a label of which bar height is only 10-20 mm may cause problems as the tube may rotate to sufficiently prevent the instrument from reading the barcode.



- (d) For rack label, the bar height should be 6 mm or greater.

Check-Digit

The barcode ID system requires the check-digit(s) to be added on the barcode label to improve the reliability of the ID number.

(A) Modulus 10/Weight 3

This Modulus 10/Weight 3 method is used in the barcode symbology such as JAN/EAN/UPC, NW-7 and ITF (Interleaved 2 of 5). Check digit computation method is shown as follows;

1. The least significant digit (right most digit) and all digits that occur on the odd position from right to left within the data digits are defined as odd digits. All the digits are divided into two groups, odd digits and even digits.
2. Add all odd digits. Multiply the sum by 3.
3. Add all even digits.
4. Add the result of (2) and result of (3) above.
5. Subtract the foremost (least significant) digit from 10 to obtain the check-digit. In case of the ITF, the total number of the digits must be an even number. In such case, add "0" to the most significant digit (left most digit).

Example No. 1:

Calculation of the check-digit for the JAN code 4912345 (7 digits) is shown below:

1. Add odd digits (counted from the least significant digit): $5 + 3 + 1 + 4 = 13$.
Multiplied the sum by 3, as: $13 \times 3 = 39$
2. Add even digits: $4 + 2 + 9 = 15$
3. Add the results of (1) and (2) above, as: $39 + 15 = 54$
4. Check-digit is obtained by subtracting the right most digit of the sum of (3) above from 10 as:
 $10 - 4 = 6$
Hence the check-digit is 6.

Example No. 2:

Calculation of the check-digit for the ITF code 524362 (6 digits) is shown below:

1. Add odd digits : $2 + 3 + 2 = 7$.
Multiplied the sum by 3, as: $7 \times 3 = 21$
2. Add even digits: $6 + 4 + 5 = 15$
3. Add the results of (1) and (2) above, as: $21 + 15 = 36$
4. Obtain the check-digit as: $10 - 6 = 4$
Hence the check-digit is 4.

However, in Example No. 2, the sum of the total number of the data digits and the check-digit gives odd number 7 in this case. Therefore, "0" is added to the most significant digit (left most digit) and check-digit is appended to the data, as 05243624.

(B) Modulus 11

This Modulus 11 method is used in the barcode symbology such as CODE-11, NW-7 and CODABAR. Check digit computation method is shown as follows:

The following example uses the ID number 15-2345-6789.

1. Weight is multiplied to each digit as:

| | | | | | | | | | | | | |
|-----------|---|----|---|----|----|----|----|---|----|----|----|----|
| ID Number | 1 | 5 | - | 2 | 3 | 4 | 5 | - | 6 | 7 | 8 | 9 |
| | × | × | × | × | × | × | × | × | × | × | × | × |
| Weight | 3 | 2 | 1 | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 |
| | 3 | 10 | 0 | 20 | 27 | 32 | 35 | 0 | 30 | 28 | 24 | 18 |

The weight of the ID number is 3, 2, 1, 6, 5, 4, 3, 2 is applied to each one from the least significant to the most significant digit. The position of the check-digit is in the least significant digit of the ID number and its weight is 1.

2. Add each product as given below:

$$\text{Sum} = 3 + 10 + 0 + 20 + 27 + 32 + 35 + 0 + 30 + 28 + 24 + 18 = 227$$

3. Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

$$227/11 = 20; \text{ remainder} = 7,$$

$$11 - 7 = 4,$$

Hence the check-digit is 4.

Note that all symbols other than numbers are calculated as zero(0). The check-digit will be zero (0) when the resulted check-digit is 10 or 11.

4. This check digit is appended to the ID number;
the barcode label is now 15-2345-67894.
5. When the ID Reader reads this barcode label, the instrument computes the check-digit(s) and recognizes the read as a valid read if the remainder is 0 or 1.

(C) Weighted Modulus 11

This Weighted Modulus 11 method is used in the barcode symbology such as NW-7 and CODABAR. Check-digit computation method is shown as follows:

The following example uses the ID number 15-2345-6789.

1. Weighted Modulus-11 has two sets of the weight:

The first weight set is 2, 6, 3, 5, 4, 8, 7, 10, 9, 5, 3, 6

The second weight set is 9, 5, 8, 6, 7, 3, 4, 10, 2, 6, 8, 5

Each digit is applied to one digit of the ID number, from the least significant to the most significant digit. The second weight set is used when the check digit is computed to “10” as the result of using the first weight set. All symbols are assumed 0 (zero) in the calculation.

Therefore, the first weight set is multiplied to each digit as given below:

NOTE: The weight for the 13th, 14th and 15th digit is 0 (zero).

| | | | | | | | | | | | | |
|-----------|---|----|---|----|----|----|----|---|----|----|----|----|
| ID Number | 1 | 5 | - | 2 | 3 | 4 | 5 | - | 6 | 7 | 8 | 9 |
| | × | × | × | × | × | × | × | × | × | × | × | × |
| Weight | 6 | 3 | 5 | 9 | 10 | 7 | 8 | 4 | 5 | 3 | 6 | 2 |
| | 6 | 15 | 0 | 18 | 30 | 28 | 40 | 0 | 30 | 21 | 48 | 18 |

- Add each product as given below:

$$\text{Sum} = 6 + 15 + 0 + 18 + 30 + 28 + 40 + 0 + 30 + 21 + 48 + 18 = 254$$

- Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

$$254/11 = 23; \text{ remainder} = 1,$$

$$11 - 1 = 10,$$

The check-digit is now computed by using the second weight set as:

| | | | | | | | | | | | | |
|-----------|---|----|---|---|----|----|----|---|----|----|----|----|
| ID Number | 1 | 5 | - | 2 | 3 | 4 | 5 | - | 6 | 7 | 8 | 9 |
| | × | × | × | × | × | × | × | × | × | × | × | × |
| Weight | 5 | 8 | 6 | 2 | 10 | 4 | 3 | 7 | 6 | 8 | 5 | 9 |
| | 5 | 40 | 0 | 4 | 30 | 16 | 15 | 0 | 36 | 56 | 40 | 81 |

- Add each product as given below:

$$\text{Sum} = 5 + 40 + 0 + 4 + 30 + 16 + 15 + 0 + 36 + 56 + 40 + 81 = 323$$

- Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

$$323/11 = 29; \text{ remainder} = 4,$$

$$11 - 4 = 7,$$

Hence the check-digit is 7.

- This check digit is appended to the ID number;

the barcode label is now 15-2345-67897.

- When the ID Reader reads this barcode label, the instrument computes the check-digit by using the first weight set and recognizes the read as a valid read if the remainder is 0. If the remainder is not 0, the instrument computes the check-digit by using the second weight set and recognizes the read as a valid read if the remainder is 0.

(D) Modulus 16

The Modulus 16 is the check-digit computation method used in NW-7 and CODABAR symbologies. Since the NW-7 and CODABAR symbologies use 4 kinds of start/stop codes, these start/stop codes are computed from the data digits.

The following example uses the ID number D998147D.

1. Add the values of all the data characters including the start and stop codes. The numerical value of each of the data character is given below:

| Character | Value | Character | Value | Character | Value |
|-----------|-------|-----------|-------|-----------|-------|
| 0 | 0 | 7 | 7 | . | 14 |
| 1 | 1 | 8 | 8 | + | 15 |
| 2 | 2 | 9 | 9 | A | 16 |
| 3 | 3 | - | 10 | B | 17 |
| 4 | 4 | \$ | 11 | C | 18 |
| 5 | 5 | : | 12 | D | 19 |
| 6 | 6 | / | 13 | | |

$$\text{Sum} = 19 + 9 + 9 + 8 + 1 + 4 + 7 + 19 = 76$$

2. Divide the sum by 16 and get the remainder. Then subtract the remainder from 16. The result is the check-digit. When the remainder is 0, check-digit becomes 16. In such a case set the check-digit to "0".

$$76/16 = 4; \text{ remainder} = 12,$$

$$16 - 12 = 4,$$

Hence the check-digit is 4.

3. This check-digit is appended to the left of the stop code in the ID number; the barcode label is now D9981474D.
4. When the ID Reader reads this barcode label, the instrument computes the check-digit and recognizes the read as a valid read if the remainder is 0.

(E) Modulus 43

Modulus 43 is the check digit computation method used in CODE-39 symbology. Each of 43 characters is assigned each value. All characters are converted into the value and computed.

The following example uses the ID number 258-416.

1. Add the values of all the data characters. The numerical value of each of the data characters is given below:

| Character | Value | Character | Value | Character | Value |
|-----------|-------|-----------|-------|-----------|-------|
| 0 | 0 | F | 15 | U | 30 |
| 1 | 1 | G | 16 | V | 31 |
| 2 | 2 | H | 17 | W | 32 |
| 3 | 3 | I | 18 | X | 33 |
| 4 | 4 | J | 19 | Y | 34 |

| Character | Value | Character | Value | Character | Value |
|-----------|-------|-----------|-------|-----------|-------|
| 5 | 5 | K | 20 | Z | 35 |
| 6 | 6 | L | 21 | - | 36 |
| 7 | 7 | M | 22 | . | 37 |
| 8 | 8 | N | 23 | Space | 38 |
| 9 | 9 | O | 24 | \$ | 39 |
| A | 10 | P | 25 | / | 40 |
| B | 11 | Q | 26 | + | 41 |
| C | 12 | R | 27 | % | 42 |
| D | 13 | S | 28 | | |
| E | 14 | T | 29 | | |

$Sum = 2 + 5 + 8 + 36 + 4 + 1 + 6 = 62$

2. Divide the sum by 43 and get the remainder.
 $62/43 = 1$; remainder = 19
3. Find the check-character. The check-character is that character whose value is equal to the remainder. In this example, the letter “J” has the value of 19 which is equal to the remainder. Therefore “J” is the check-character.
4. This check-character is appended to the ID number, after the least significant digit. The barcode label is now “258-416J”.

(F) Modulus 103

Modulus 103 is the check-digit computation method used in CODE-128 symbology.

CODE-128 takes three different character table depending on the start code. Each of 128 characters is assigned a value as shown in the following table. All characters are then converted to their corresponding values and computed.

1. All characters except the stop code are converted to their corresponding values according to the table.
2. The first character, such as “Start (Code A)”, indicates that the Code A set is used until other code set is specified. Multiply the most significant digit by 1, multiply the second digit by 2, multiply the third digit by 3, and so on.
3. Add all the products.
4. Divide the sum by 103.
5. Convert the remainder to the corresponding character in the table. This is the check-digit.

The following example uses the ID number Start (Code A) 123-4567.

1. Convert each character into values using Code A set, and multiply by the weight.

Start (Code A)103 = 103

- 1 $17 \times 1 = 17$
- 2 $18 \times 2 = 36$
- 3 $19 \times 3 = 57$
- $13 \times 4 = 52$
- 4 $20 \times 5 = 100$
- 5 $21 \times 6 = 126$
- 6 $22 \times 7 = 154$
- 7 $23 \times 8 = 184$

2. The sum of the products is 829.
3. This sum is divided by 103 as; $829/103 = 8$ and remainder is 5.
4. The corresponding character for the value 5 is %. Hence the check-digit is %.

| Value | Code A | Code B | Code C | Value | Code A | Code B | Code C |
|-------|---------|---------|--------|-------|--------|--------|--------|
| 0 | (space) | (space) | 00 | 54 | V | V | 54 |
| 1 | ! | ! | 01 | 55 | W | W | 55 |
| 2 | “ | “ | 02 | 56 | X | X | 56 |
| 3 | # | # | 03 | 57 | Y | Y | 57 |
| 4 | \$ | \$ | 04 | 58 | Z | Z | 58 |
| 5 | % | % | 05 | 59 | [| [| 59 |
| 6 | & | & | 06 | 60 | \ | \ | 60 |
| 7 | ' | ' | 07 | 61 |] |] | 61 |
| 8 | (| (| 08 | 62 | ^ | ^ | 62 |
| 9 |) |) | 09 | 63 | _ | _ | 63 |
| 10 | * | * | 10 | 64 | NUL | ` | 64 |
| 11 | + | + | 11 | 65 | SOH | a | 65 |
| 12 | , | , | 12 | 66 | STX | b | 66 |
| 13 | - | - | 13 | 67 | ETX | c | 67 |
| 14 | . | . | 14 | 68 | EOT | d | 68 |
| 15 | / | / | 15 | 69 | ENQ | e | 69 |
| 16 | 0 | 0 | 16 | 70 | ACK | f | 70 |
| 17 | 1 | 1 | 17 | 71 | BEL | g | 71 |
| 18 | 2 | 2 | 18 | 72 | BS | h | 72 |
| 19 | 3 | 3 | 19 | 73 | HT | i | 73 |
| 20 | 4 | 4 | 20 | 74 | LF | j | 74 |

| Value | Code A | Code B | Code C | Value | Code A | Code B | Code C |
|-------|--------|--------|--------|-------|----------------|--------|--------|
| 21 | 5 | 5 | 21 | 75 | VT | k | 75 |
| 22 | 6 | 6 | 22 | 76 | FF | l | 76 |
| 23 | 7 | 7 | 23 | 77 | CR | m | 77 |
| 24 | 8 | 8 | 24 | 78 | SO | n | 78 |
| 25 | 9 | 9 | 25 | 79 | SI | o | 79 |
| 26 | : | : | 26 | 80 | DLE | p | 80 |
| 27 | ; | ; | 27 | 81 | DC1 | q | 81 |
| 28 | < | < | 28 | 82 | DC2 | r | 82 |
| 29 | = | = | 29 | 83 | DC3 | s | 83 |
| 30 | > | > | 30 | 84 | DC4 | t | 84 |
| 31 | ? | ? | 31 | 85 | NAK | u | 85 |
| 32 | @ | @ | 32 | 86 | SYN | v | 86 |
| 33 | A | A | 33 | 87 | ETB | w | 87 |
| 34 | B | B | 34 | 88 | CAN | x | 88 |
| 35 | C | C | 35 | 89 | EM | y | 89 |
| 36 | D | D | 36 | 90 | SUB | z | 90 |
| 37 | E | E | 37 | 91 | ESC | { | 91 |
| 38 | F | F | 38 | 92 | FS | | 92 |
| 39 | G | G | 39 | 93 | GS | } | 93 |
| 40 | H | H | 40 | 94 | RS | ~ | 94 |
| 41 | I | I | 41 | 95 | US | DEL | 95 |
| 42 | J | J | 42 | 96 | FNC3 | FNC3 | 96 |
| 43 | K | K | 43 | 97 | FNC2 | FNC2 | 97 |
| 44 | L | L | 44 | 98 | SHIFT | SHIFT | 98 |
| 45 | M | M | 45 | 99 | CODE C | CODE C | 99 |
| 46 | N | N | 46 | 100 | CODE B | FNC4 | CODE B |
| 47 | O | O | 47 | 101 | FNC4 | CODE A | CODE A |
| 48 | P | P | 48 | 102 | FNC1 | FNC1 | FNC1 |
| 49 | Q | Q | 49 | 103 | START (Code A) | | |
| 50 | R | R | 50 | 104 | START (Code B) | | |
| 51 | S | S | 51 | 105 | START (Code C) | | |
| 52 | T | T | 52 | | STOP | | |
| 53 | U | U | 53 | | | | |

Applicable Characters

The valid characters for the ID barcode system are numerals (0-9) and a hyphen (-).

CODABAR (NW-7) and CODE-39 may use the other characters such as alphabets, however the instrument ID system does not recognize them. The ID number allows up to thirteen digits. The application of hyphens in an ID number should adhere to the following rules:

1. Hyphens must be placed between other characters.
2. The ID number cannot begin or end with a hyphen.
3. Hyphens are included as part of the allowable maximum number of 13 characters.
4. When calculating check character of an ID number that includes hyphens, the hyphen in CODABAR (NW-7) is calculated as 0 (zero), and hyphen in CODE-11 is calculated as 10 in decimal. In the CODE-39 symbology, the hyphen is calculated as 0 (zero) for Modulus 11, and as 36 for Modulus 43.
5. ITF cannot recognize the hyphen since this symbology does not allow such a character.

Effective Barcode Length

For the NW-7 (CODABAR) and CODE-39 symbologies, the ID number can consist a minimum of 1 digit, and a maximum of 13 digits. For the other symbologies, the minimum number of digits depends on the symbology used and the application of the check-digit.

Quality Control Barcode Label

The instrument performs quality control by using the auto sampler. When using this program, the barcode label is prescribed by the following:

CODABAR (NW-7)

The CODABAR (NW-7) employs the start/stop codes “a”, “b”, “c”, or “d”. The instrument defines the ID number as the quality control data when the ID number is sandwiched by two start/stop codes of “c” and has the same number in each digit.

For example, the ID number “c1111111c” is read as “File No. 1” of the quality control program.

CODE-128

CODE-128 employs alphabetical characters. Therefore, the instrument defines the ID number as quality control data when the ID number is read as “QC-” and is followed by 8-digit Lot number.

Affixing Barcode Label

Refer to “5.10 Prepare Samples” for the correct barcode label position.

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16. Appendix (A)

16.1 Maintenance CheckList

DAILY MAINTENANCE Month Year

| Maintenance item | Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|--------------------------------|-----|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|
| Clean Sample Probe | | | | | | | | | | | | | | | | |
| Discard used reaction tubes | | | | | | | | | | | | | | | | |
| Dispose of waste | | | | | | | | | | | | | | | | |
| Remove dew from reagent holder | | | | | | | | | | | | | | | | |
| Initial | | | | | | | | | | | | | | | | |

| Maintenance item | Day | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|--------------------------------|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Clean Sample Probe | | | | | | | | | | | | | | | | | |
| Discard used reaction tubes | | | | | | | | | | | | | | | | | |
| Dispose of waste | | | | | | | | | | | | | | | | | |
| Remove dew from reagent holder | | | | | | | | | | | | | | | | | |
| Initial | | | | | | | | | | | | | | | | | |

SUPPLIES REPLACEMENT

| Maintenance item | Date/Initial | Date/Initial | Date/Initial | Date/Initial |
|--------------------------|--------------|--------------|--------------|--------------|
| Replenish reagent | | | | |
| Replenish reaction tubes | | | | |
| Replenish rinse solution | | | | |

Appendix (A)

MONTHLY MAINTENANCE

| Maintenance item | Date/Initial | Date/Initial | Date/Initial | Date/Initial |
|------------------|--------------|--------------|--------------|--------------|
| LED Calibration | | | | |

YEARLY MAINTENANCE

| Maintenance item | Date/Initial | Date/Initial | Date/Initial | Date/Initial |
|------------------------|--------------|--------------|--------------|--------------|
| Replenish Rinse Filter | | | | |

AS NEEDED MAINTENANCE

| Maintenance item | Date/Initial | Date/Initial | Date/Initial | Date/Initial |
|--|--------------|--------------|--------------|--------------|
| Supply printer paper | | | | |
| Replace fuse | | | | |
| Check and drain trap chamber | | | | |
| Prime rinse solution to hydraulic line | | | | |
| Filter inspection and cleaning | | | | |
| Clean instrument | | | | |

16.2 Reagents

| Reagent Name: | | | |
|---------------|-------------|--------------|---------------------------|
| Lot No. | Expiry date | replaced on: | replaced by: (initial) |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| Reagent Name: | | | |
|---------------|-------------|--------------|---------------------------|
| Lot No. | Expiry date | replaced on: | replaced by: (initial) |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| Reagent Name: | | | |
|---------------|-------------|--------------|---------------------------|
| Lot No. | Expiry date | replaced on: | replaced by: (initial) |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| Reagent Name: | | | |
|---------------|-------------|--------------|---------------------------|
| Lot No. | Expiry date | replaced on: | replaced by: (initial) |
| | | | |
| | | | |
| | | | |
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