Sysmex

INSTRUCTIONS FOR USE

Automated Blood Coagulation Analyzer

CA-500 series

SYSMEX CORPORATION
KOBE, JAPAN

Code No. 461-2655-0
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Software version 00-17 and onwards

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1. Introduction

1.1 Introduction

The Sysmex® Automated Blood Coagulation Analyzer CA-500 series is a compact fully-automated instrument capable of 5-parameter random analysis for In Vitro Diagnostic use.

This instrument incorporates latest technologies as represented by micro-computers, thus enabling analysis of multiple parameters with increased flexibility. Of PT, APTT, Fbg, Thrombin Time (Coagulation Method), and Antithrombin III (Chromogenic Method: Can be analyzed only with CA-530, CA-540, CA-550 and CA-560), D-Dimer (Immunology Method: Can be analyzed only with CA-550 and CA-560), etc., this instrument is able to analyze 5 parameters simultaneously. In addition, it has a number of functions including preferential processing of STAT samples and a built-in quality control function. Moreover, it allows analyzed data to be displayed and printed out together with reaction curves, thus making it possible to obtain highly reliable analysis results.

Analysis Parameters and Detection Principles

Parameter	Test name	Applied
Prothrombin Time	PT	Coagulation Method
Activated Partial Thromboplastin Time	APTT	Coagulation Method
Fibrinogen	Fbg	Coagulation Method
Thrombin Time	TT	Coagulation Method
Protein C coagulometric	PCcl	Coagulation Method
Batroxobin	BXT	Coagulation Method
LA1 Screening*	LA1	Coagulation Method
LA2 Confirmation*	LA2	Coagulation Method
Factor Assay**	II, V, VII, VIII, IX, X, XI, XII	Coagulation Method
Antithrombin III	AT3	Chromogenic Method
α2-Antiplasmin*	APL	Chromogenic Method
Plasminogen*	Plg	Chromogenic Method
Protein C chromogenic	BCPC	Chromogenic Method
Heparin	Hep	Chromogenic Method
D-Dimer Plus*, Advanced D-Dimer***	DDPl, AdDD	Immunoassay Method
P-FDP****	PFDP	Immunoassay Method

(*) Not available in the USA.

(**) Data evaluated for factors VII and VIII only.

(***) Only available for use in the USA.

(****) Only available for use in Asia.

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Manufacturer

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European Representative

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Ordering of Supplies and Replacement Parts

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

Service and Maintenance

Please contact the Service Department of your local Sysmex representative.

Training Courses

For further information please contact the Sysmex 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.

CA-500 series instruments with serial numbers shown below or smaller numbers only conform to the 89/336/EEC electromagnetic compatibility.

CA-510	A1342
CA-520	A1017
CA-530	A1902
CA-540	A3883
CA-550	A1051
CA-560	A1110

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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.

Important

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.

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1.3 Names

- Sysmex is a registered trademark of SYSMEX CORPORATION in the USA, in Germany and other countries.
- CA CLEAN I and CA CLEAN II are trademarks of SYSMEX CORPORATION in the USA, in Germany and other countries.

- Actin, Ci-Trol, Data-Fi and Innovin are registered trademarks of Dade Behring Inc in the USA, in Germany and other countries.
- Dade is a registered trademark of Dade Behring Inc.
- Pathromtin and Thromborel are registered trademarks of Dade Behring Marburg GmbH in Germany and other countries and are trademarks of Dade Behring Marburg GmbH in the USA.
- VACUTAINER is a registered trademark of Becton, Dickinson and Company.
- VACUETTE is a registered trademark of Greiner Bio-One GmbH.

- Other trademarks referenced are property of their respective owners.

1.4 Serial Number

CA-500 series instruments with serial numbers below or smaller

CA-510	A1300
CA-520	A1018
CA-530	A1805
CA-540	A3405

will not have the capability to manage more than 7 Assays/Standard curves and they are limited to use 7×6 QC files.

1.5 Revision History

Version		Date	Changes
Manual	Software		
1.0	00-13	October 2001	Launch Version
2.0	00-15	January 2003	Second Edition
2.0	00-15	May 2003	Minor Correction
2.0	00-15	September 2003	Minor Correction
2.0	00-15	November 2003	To conform with IVD Directive
2.0	00-17	April 2004	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 instrument shall only be used for in vitro analysis of human blood or artificial control blood. It may not be used for any other purpose.

Only reagents and cleaning solutions mentioned in this manual are permitted for use.

By observing the specified conditions of use, the frequency of cleaning and maintenance work can be reduced.

2.2 General Information

Warning

- Keep long hair, fingers and clothing away from rotating 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.

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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.

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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.
- Do not install near devices that cause signal noise, such as radios and centrifugal machines.
- Do not install near chemicals storage or in a place where gas is generated.

2.4 Avoidance of Infections

Risk of Infection

- In principle, all parts and surfaces of the instrument must be regarded as infective.
- Never touch waste, or parts having been in contact with waste, with bare hands.
- Should you inadvertently come in contact with potentially infective materials or surfaces, immediately rinse skin thoroughly with plenty of water, then follow the antiseptic regulations of your laboratory.
- Be careful when handling samples. Always wear latex or non latex examination gloves; otherwise contamination could result. If a sample happens to enter your eye or a cut, wash it off with plenty of water, and immediately visit a physician.
- Control plasma may also be infective. Wear latex or non latex examination gloves during QC process. If plasma happens to enter your eye or a cut, wash it off with plenty of water, and immediately visit a physician.
- Use care when handling waste liquid. If it adheres to the skin or clothing, wash it off using an antiseptic solution.

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2.5 Handling of Reagents

Warning

- Avoid direct contact with reagents. Reagents can cause irritation of the eyes, skin and mucous membranes.
- If a reagent happens to adhere to the hand or the skin of another area, wash it off immediately using plenty of water.
- If a reagent happens to enter your eye, wash it off immediately using plenty of water, and take medical treatment at once.
- If you should swallow it inadvertently, call for a physician immediately, drink a large volume of water, and then induce vomiting.
- CA CLEAN I is a strong alkaline cleaning material. It should not come in contact with skin or clothing. If it happens nevertheless, rinse skin or clothing with plenty of water to avoid injury or damage.

Caution

- Read the instructions described on the reagent containers.
- After unpacking, be sure not to allow dust, dirt, or bacteria into the reagents.
- Do not use reagents that have passed the expiration period.
- Handle a reagent gently to prevent formation of bubbles. Shake carefully if necessary.
  Do not use directly after transportation.
- Take care not to spill a reagent. If it has spilled, wipe it off immediately using a wet cloth or something.
- 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.
- The CA CLEAN I rinse solution contains sodium hypochlorite. If the material makes contact with the instrument's surfaces, it will affect the surface finish. There is a danger of corrosion. Immediately wipe up CA CLEAN I with a damp cloth.
- A reagent is a chemical substance employed for external diagnosis and cannot be used for any medical treatment.

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2.6 Maintenance of the Instrument

Risk of Infection

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.

Warning

When carrying out inspection and maintenance of the instrument, use only the specified tools and parts. Never use substitute parts or modify parts. Such actions are dangerous and prohibited by the Pharmaceutical Affairs Law.

2.7 Disposal of Materials

Risk of Infection

When discarding waste liquid, instrument consumables and instrument, take proper steps to dispose of them as medical, infective and industrial wastes.
If they are contaminated with blood, there is a possibility of bacterial infection occurring.

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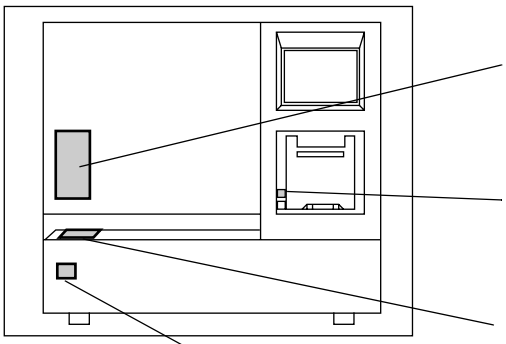
2.8 Markings on the Instrument

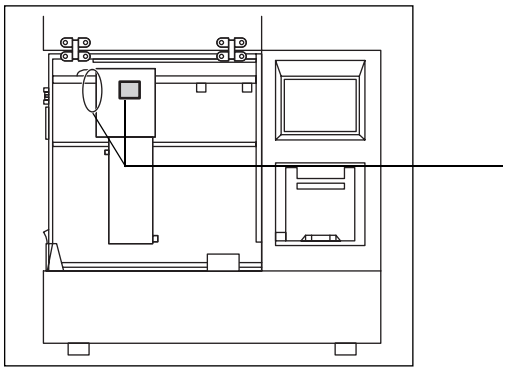


Warning
DO NOT place your fingers and hands inside while analyzing. Pipette can move in any direction.

Fast Stop (Mechanical Stop)

Warning
DO NOT press on the sampler unit to prevent damage.

Risk of Infection
In principle, all parts and surfaces of the instrument must be regarded as infective.



Warning
When the arm is to be moved while the pipette is in the down position, pull up the pipette to the same height as catcher, and move the arm.

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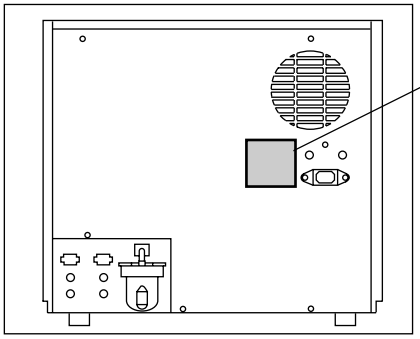
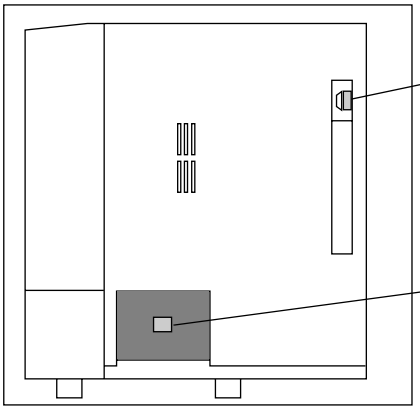


Warning

To avoid risk of electrical shock, disconnect the power cord before replacing the fuse.

Warning

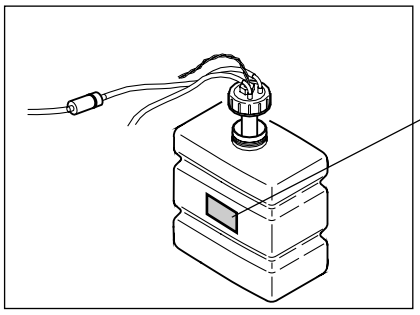
Proper use of the appropriate power cord assures adequate grounding for the system. Failure to properly ground the instrument bypasses important safety features and may result in an electrical hazard.



RS-232C Serial Port (HC Connector)

Risk of Infection

To avoid contact with biohazardous materials, gloves must be worn when handling the tube trash and used reaction tubes.
Wash your hands with an antimicrobial solution after completing the procedure.



Warning

To avoid dusts or contaminants entering the rinse bottle, ensure the float switch does not touch any surfaces when replenishing distilled water. Dusts or contaminants will cause malfunction of the solenoid value.

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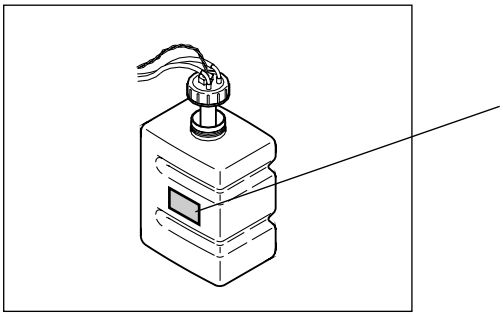

Risk of Infection

The waste container and contents should be considered potentially biohazardous. Do not handle the waste container without proper protective equipment. Wear gloves when handling. Wash your hands with an antiseptic solution after completing the procedure.

2.9 Personnel

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.

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.

2.10 Storage Condition (Transportation)

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

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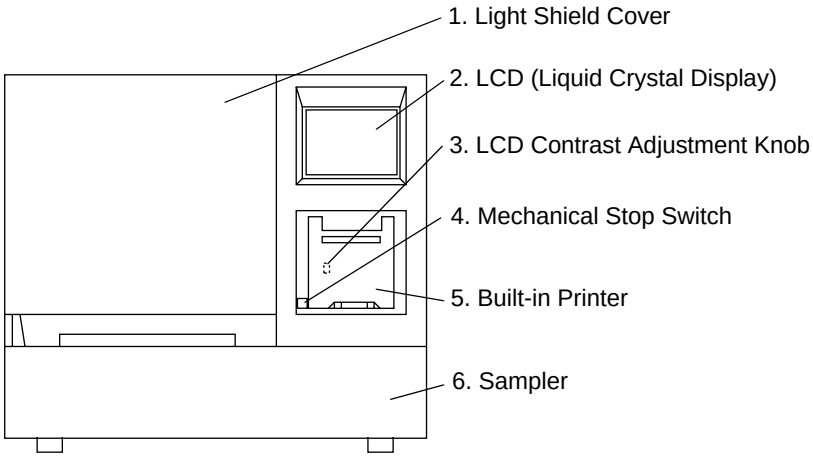
3. Design and Function

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.

> **Important**
> 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. 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.

3. LCD Contrast Adjustment Knob

   Controls LCD contrast. This knob is located inside the printer cover.

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4. Mechanical Stop Switch

   Used to immediately stop the mechanical unit in the instrument in the event of an emergency. Note that the power of the instrument is not turned off even when this switch is turned on. If emergency stop of the instrument is required due to power failure of the laboratory, immediately turn off the power of the instrument.

Important

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

5. 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.

6. 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.

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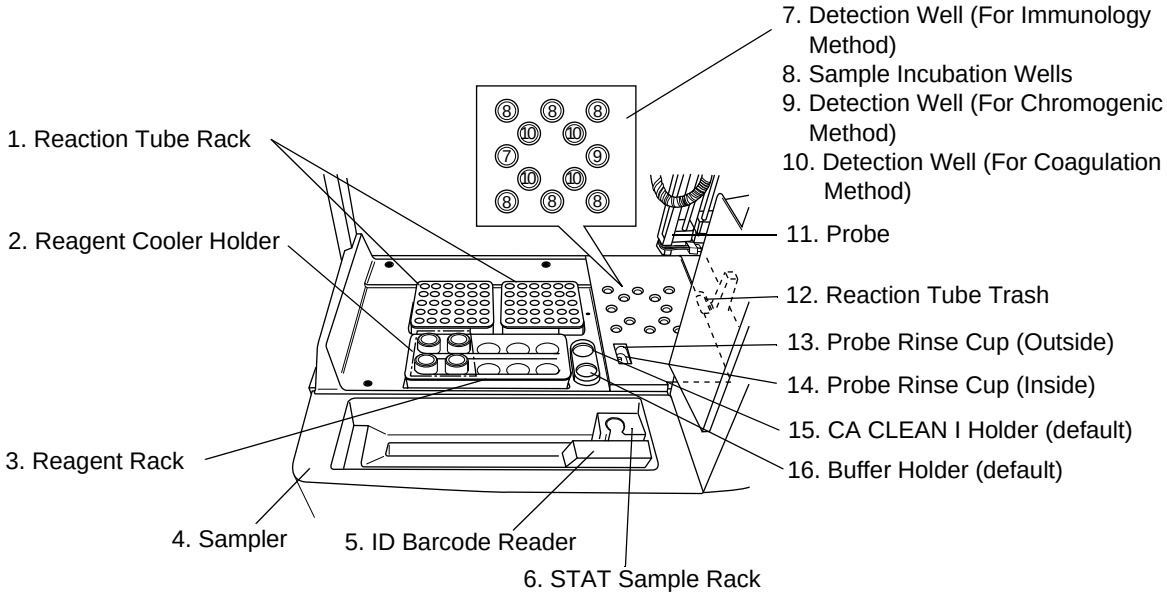
Front Interior (When Opening Light Shield Cover)



1. Reaction Tube Rack

   Two reaction tube racks can be set. One rack holds up to 30 reaction tubes (SU-40). Tube position numbers are assigned from the right rear position of the right rack (No. 1) and count upwards moving toward the front.

2. Reagent Cooler Holders (For CA-530, CA-540, CA-550 and CA-560 only)

   Can hold up to 4 vials with cooler function.

3. 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.

4. Sampler

   Can hold one sample rack.

5. ID Barcode Reader (Optional on CA-510, CA-530 and CA-550)

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

6. 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.

7. Detection well (For Immunology Method: CA-550 and CA-560 only)

   Detection well for the immunologic sample. The number of wells is one. The detector is always kept at 37.0ºC ± 1.0ºC.

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8. Sample Incubation Wells

   Six incubation wells are provided, and these wells are kept at 37.0ºC ± 1.0ºC.

9. Detection Well (For Chromogenic Method: CA-530, CA-540, CA-550 and CA-560 only)

   Detection well for the chromogenic sample. The number of wells is one. The detector is always kept at 37.0ºC ± 1.0ºC.

10. Detection Wells (For Coagulation Method)

    Four scattered light detection wells are provided, and these wells are kept at 37.0ºC ± 1.0ºC.

11. Probe

    This pipette is used to aspirate samples and reagents. It is kept at 37.0ºC ± 1.0ºC.

12. Reaction Tube Trash

    Used reaction tubes are disposed into this trash.

13. Probe Rinse Cup (Outside)

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

14. Probe Rinse Cup (Inside)

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

15. 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.

16. 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.

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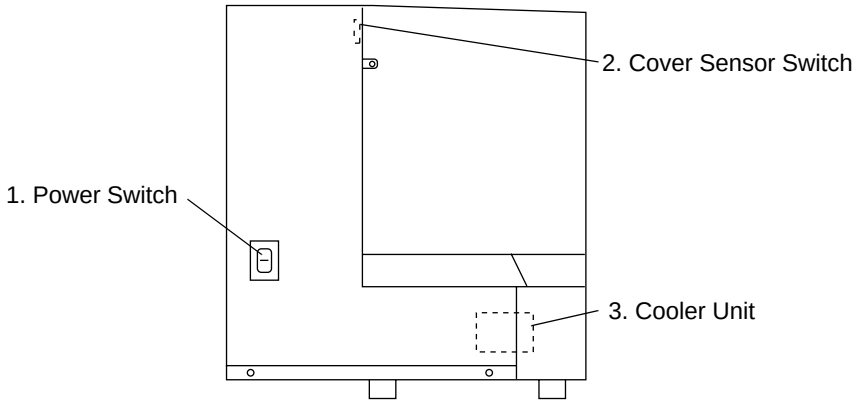
Left Side



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.

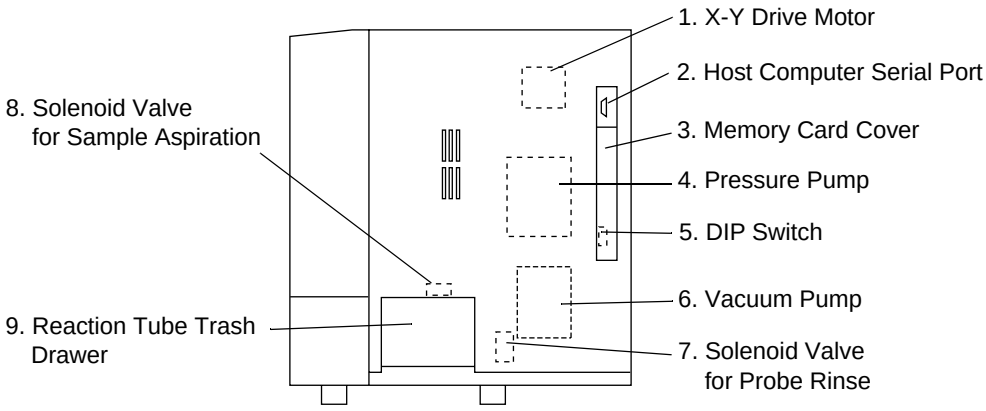
2. Cover Sensor Switch

   This monitors if the Light Shield Cover is closed.

3. Cooler Unit

   This keeps the reagent cool.

Right Side



1. X-Y Drive Motor

   This motor drives the Probe unit in the X-axis and Y-axis directions.

2. Host Computer Serial Port

   For connecting to an external host computer.

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3. Memory Card Cover

   This card has PROM chips to load the CA-500 program into RAM memory. (Intended for your local service representative use only)

4. Pressure Pump

   Supplies the pressure. The instrument cannot function properly at lower pressures.

5. DIP Switch

   Changes the system settings.

   (Intended for your local service representative use only)

6. Vacuum Pump

   Supplies vacuum. The instrument cannot function properly if the vacuum level is lower.

7. Solenoid Valve for Probe Rinse

   This valve controls the supply of the rinse solution to the rinse cup unit.

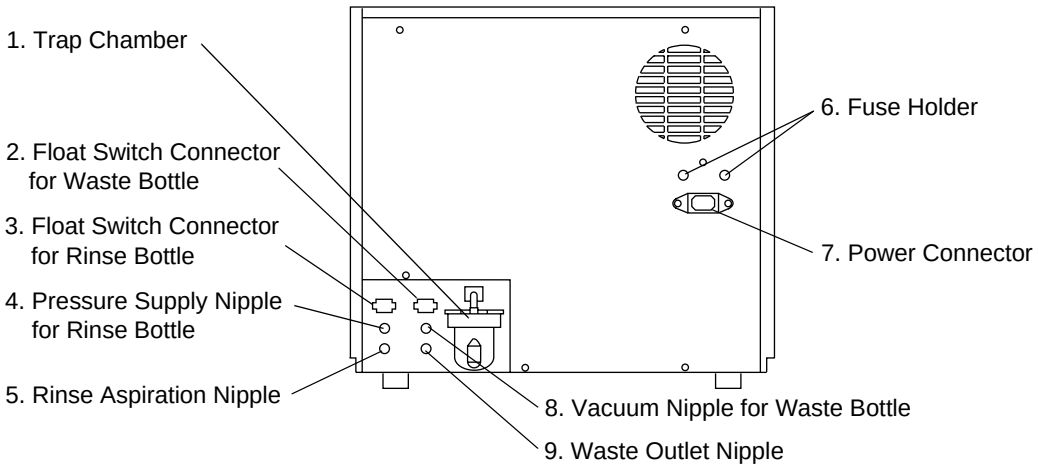
8. Solenoid Valve for Sample Aspiration

   This valve controls the aspiration of sample plasma with high accuracy.

9. Reaction Tube Trash Drawer

   Used for storing used reaction tubes.

Rear



1. Trap Chamber

   Prevents the waste fluid from flowing back to affect the vacuum pump, in the event of an abnormality with the instrument.

2. Float Sensor Connector for Waste Bottle (“WASTE”)

   For connecting the float sensor switch, located on the waste container, for detecting the waste fluid level.

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3. Float Sensor Connector for Rinse Bottle (“RINSE”)

   For connecting the float sensor switch, located on the rinse container, for detecting rinse water level.

4. Pressure Supply Nipple for Rinse Bottle (Colored Black)

   To be connected via a tube with the Rinse Bottle.

> **Important**
> 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.

5. Rinse Aspiration Nipple (Colored Blue)

   For aspirating the rinse water from the Rinse Bottle. To be connected via a tube to the Rinse Bottle.

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

6. Fuse Holder

   Two time-lag type fuses are installed in this Fuse Holder. Replace with the correct type of fuse (supplied). The rating will be different depending on the instrument specification as below.

Specification	Part No.	Description	Fuse Type	Location
117 VAC	266-5106-0	Fuse 250V 6.3A ST4-6.3A-N1 (N.Amer)	Time Lag	Rear Panel
220-240 VAC	266-5293-0	Fuse 250V 3.15A No. 19195 (Europe)	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.

7. Power Connector

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

8. Vacuum Nipple for Waste Bottle (Colored Green)

   To be connected via a tube with the Trap Chamber.

9. Waste Outlet Nipple (Colored Red)

   For draining waste fluids. Must be connected via a tube to the Waste Bottle.

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3.2 Operation Flow

<table>
<tr><th>Manual Order Registration</th><th>On-Line Order Registration
(Manual Inquiry)</th><th>On-Line Order Registration
(Auto Inquiry)</th></tr>
<tr><td colspan="3">Inspection Before Turning On Power</td></tr>
<tr><td colspan="3">Turn On Power
• Self Check</td></tr>
<tr><td colspan="3">Ready</td></tr>
<tr><td colspan="3">Prepare Reagents</td></tr>
<tr><td>Register Analysis
(Manual Registration)</td><td>Prepare Samples</td><td rowspan="3">Prepare Samples</td></tr>
<tr><td>Prepare Samples</td><td>Register Analysis
Press [HC] key</td></tr>
<tr><td colspan="3">Press [Start] key
• Execution of Analysis
• Completion of Analysis</td></tr>
<tr><td colspan="3">Ready</td></tr>
<tr><td colspan="3">Turn Off Power</td></tr>
<tr><td colspan="3">Operation After Completion of Analysis</td></tr>
</table>

: 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.

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4. Installation Environment

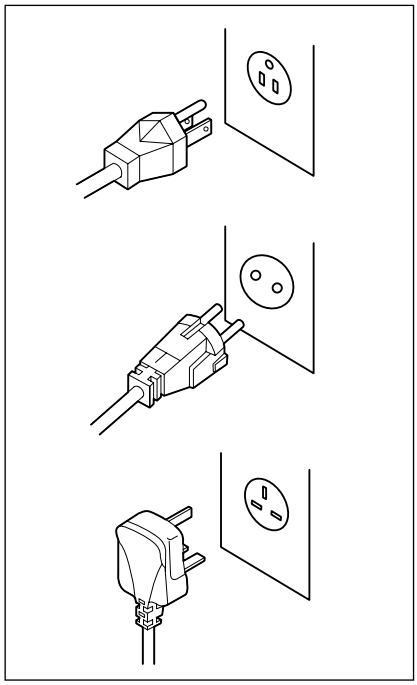
4.1 Installation and Relocation

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.

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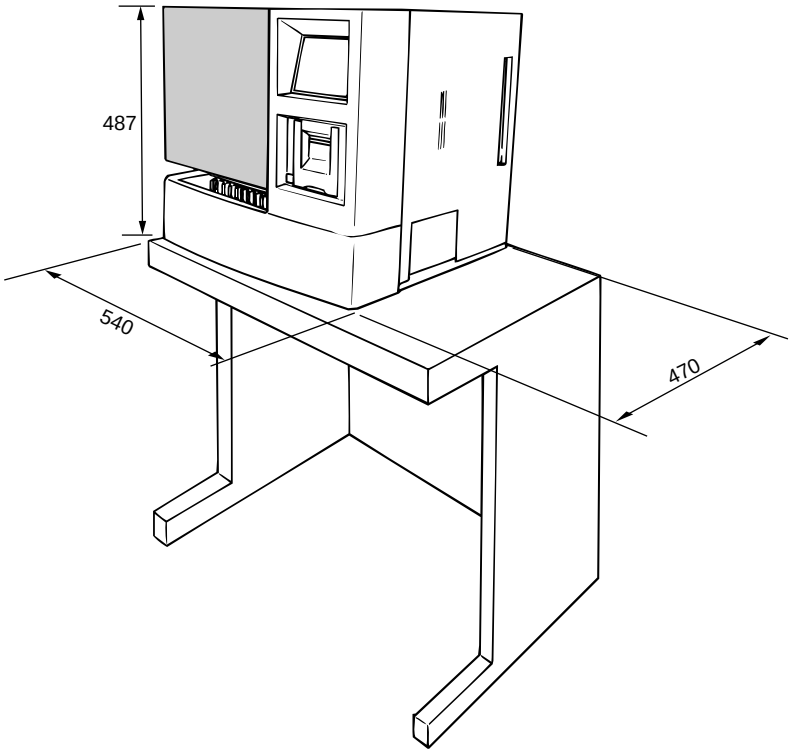
The dimensions of the instrument are shown below. The power cord is 1.8 m long.

	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main unit	540	470	487	Approx. 45



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.

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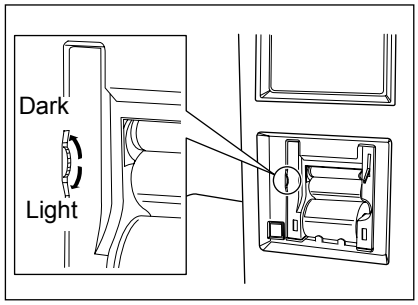
Installation Environment

- Use the instrument at an ambient temperature of 15 - 35ºC.
- 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 wireless telegraph, 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 Root Menu screen.

   The contents of the Root Menu will change over.

2. Press **[Settings]** key on the Root Menu screen.

   The Setting Menu screen will appear.

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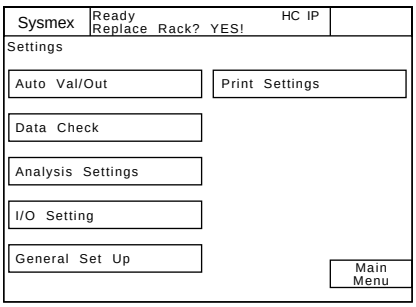
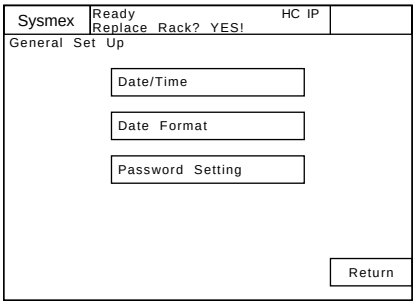
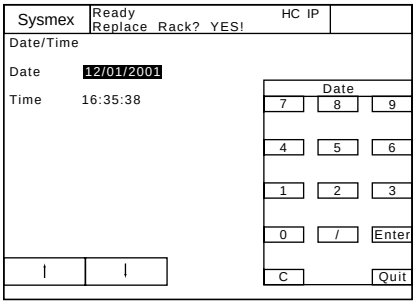


3. Press **[General Set Up]** key on the Setting Menu screen.
   The General Set Up Menu screen will appear.



4. Press **[Date/Time]** key on the General Set Up Menu screen.
   The Date/Time Setting screen will display current date and time.

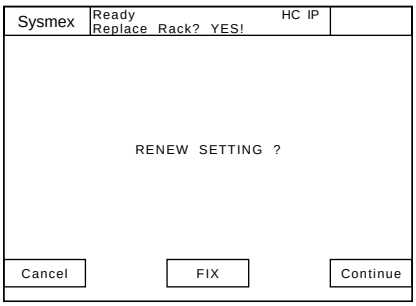


5. Using **[↑]** and **[↓]** keys, move the cursor to select Date or Time.
6. Using the numeric keys, set Date and Time, and press **[Enter]** key.
   The parameter in the cursor position is set and the cursor will move to the next parameter.

Important

- 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.

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5. Operation 5-1

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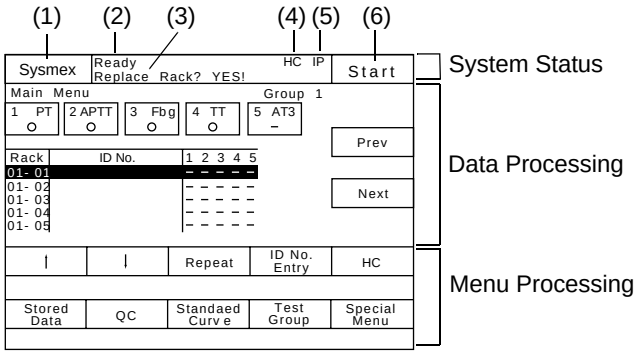
5. Operation

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)

   The host computer is set to “Connected”. “HC” appears when sample data for automatic output becomes available.

5. IP (Internal Printer)

   “IP” appears when sample data for automatic output to the internal printer becomes available.

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6. **[Start]/[INTERR]** key

   Press this key to start/stop the sampler 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 (Root 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 Root Menu appears. The Root Menu is the basic menu for selecting functions of this instrument.

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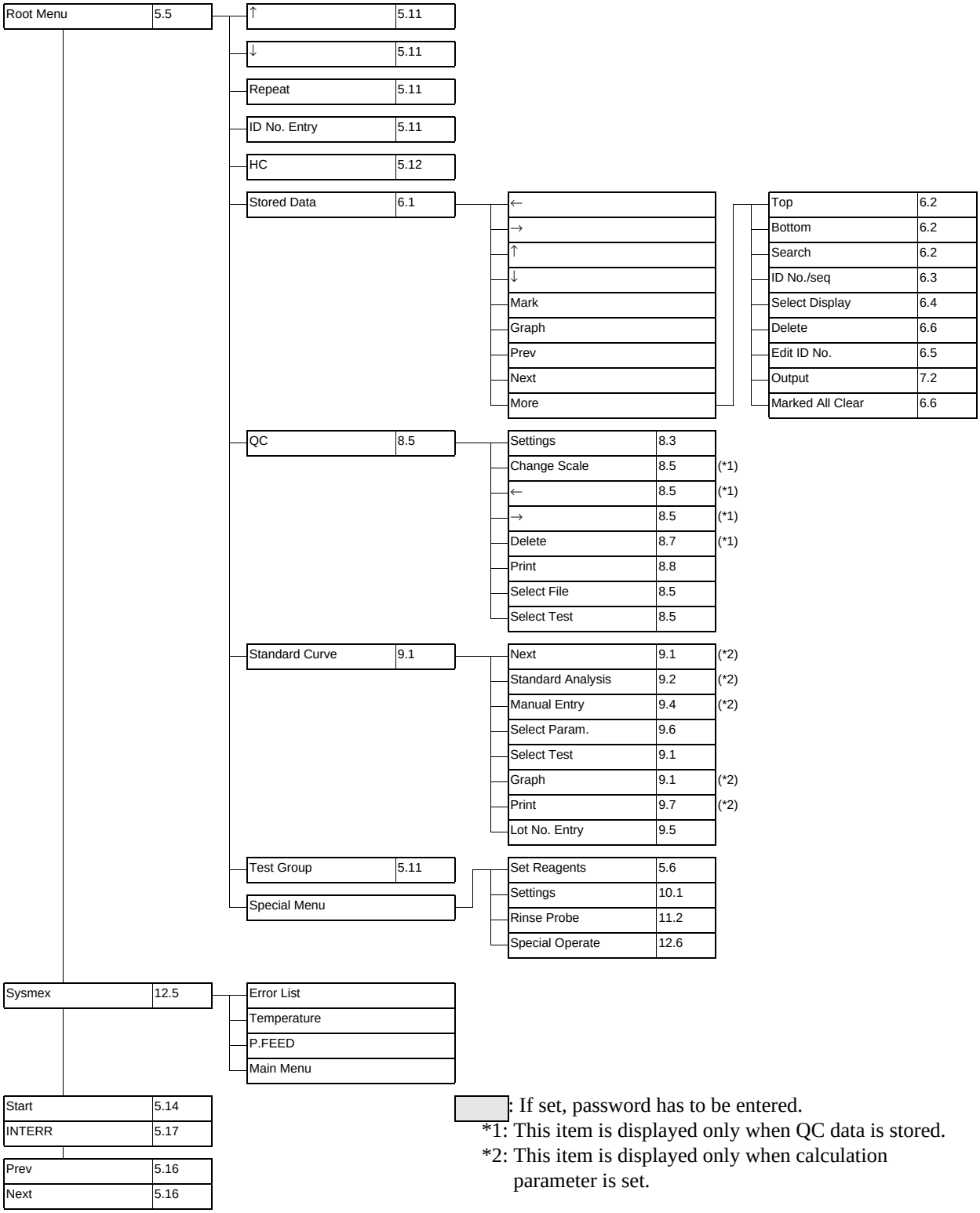
5.2 Menu Tree



: 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.

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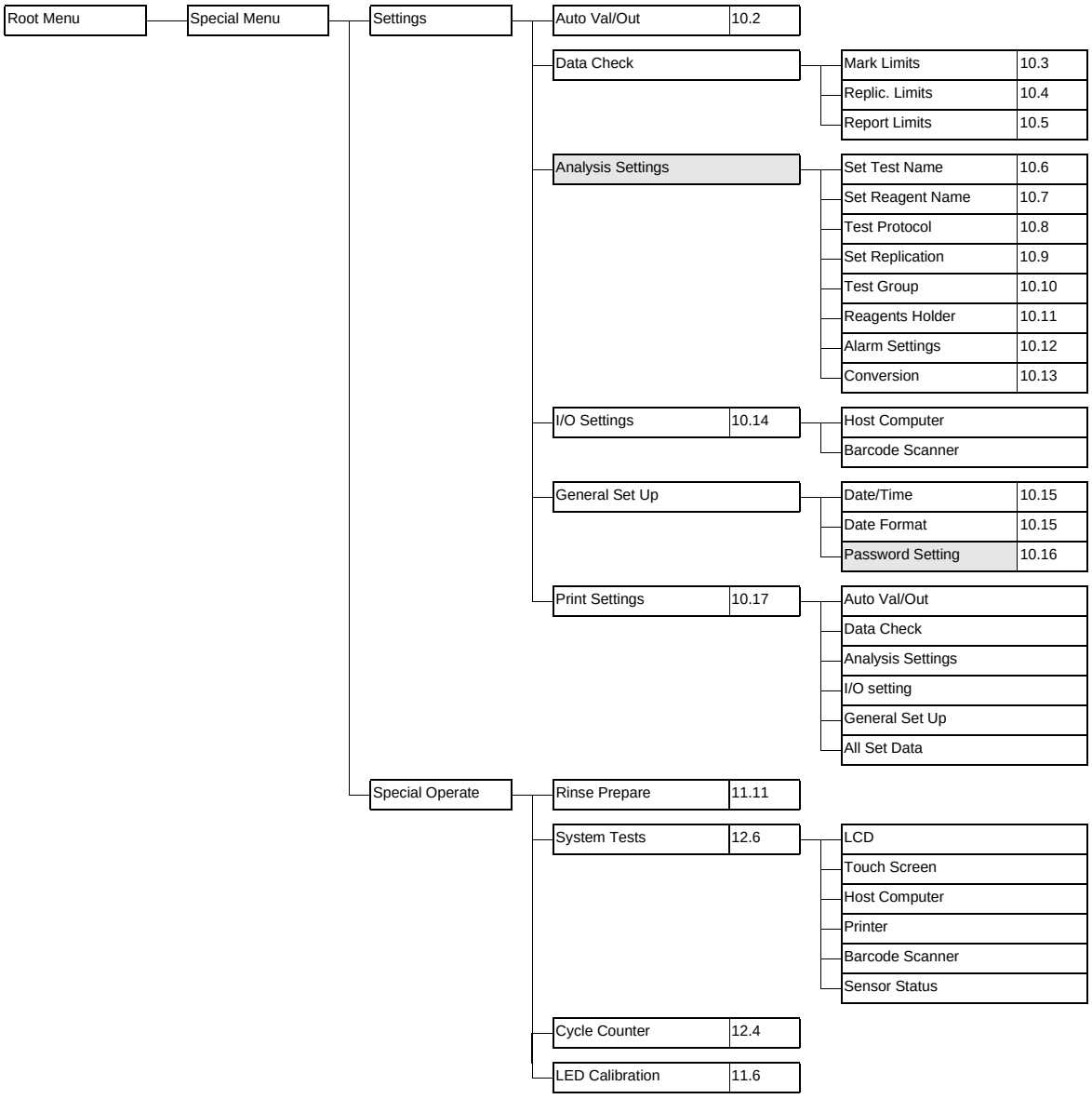

: If set, password has to be entered.

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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 “11.15 Replenish Rinse Solution”.

Caution

When analysis is made with the rinse bottle laid down, there is a possibility that correct analysis result may not be obtained. Make sure the rinse bottle is standing upright.

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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”.

Risk of Infection

When disposing of waste liquid, always wear latex or non latex examination gloves. After work is over, wash the hands in anti-septic solution.
If hands are contaminated with blood, which could result in infection by pathogenic organisms, give careful consideration to the hazards of medical or infective waste materials.

Important

When analysis is made with the waste bottle laid down, waste may flow back into the vacuum pump, causing the pump to fail.
Make sure the waste bottle is standing upright.

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, check to see the connection cord is securely connected.

Check Tube Trash Drawer

When used reaction tubes remain in the tube trash drawer, discard them.

As to discarding, refer to “11.3 Discard Used Reaction Tubes”.

Check Printer Paper

Check to see the internal 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.

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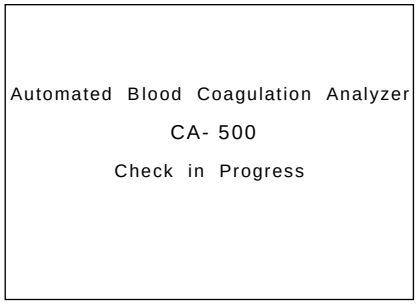
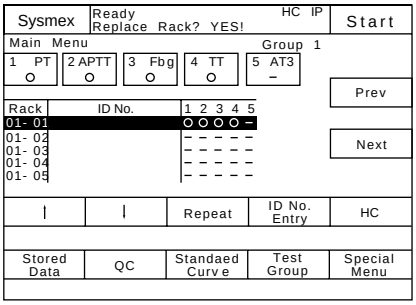
5.5 Turn ON the Power

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 Root Menu screen will appear.

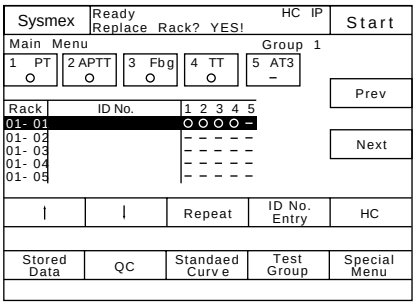


2. When the detector and cooler reach an analysis-permitting temperature, the Root Menu screen displays “Ready”.

> **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

When automatic output to the internal printer or host computer becomes necessary, make this confirmation.



1. Confirm that the System Status area displays “HC” and “IP”.
2. Confirm the settings for 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.

Parame-ter	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
TT	Thrombin Clotting Time Reagent	100 µL
PCcl	Protein C Deficient Plasma	45 µL
	Protein C Activator	50 µL
	PC APTT Reagent	50 µL
	Calcium Chloride Solution	50 µL
BXT	Batroxobin Reagent	100 µL
LA1*	LA1 Screening Reagent	100 µL
LA2*	LA2 Confirmation Reagent	100 µL
AT3	Berichrom° Antithrombin III (A)	
	Thrombin Reagent	125 µL
	Substrate	33 µL
	Owren's Veronal Buffer	83 µL
BCPC	Berichrom° Protein C	
	Protein C Activator	125 µL
	Substrate	30 µL
APL*	Berichrom° α2-Antiplasmin	
	Antiplasmin Reagent	125 µL
	Substrate	25 µL
	Owren's Veronal Buffer	112 µL
Plg*	Berichrom° Plasminogen	
	Streptokinase Reagent	125 µL
	Substrate	25 µL
	Owren's Veronal Buffer	112 µL

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Parame-ter	Reagent	Consumption per Test
Hep	Berichrom° Heparin	
	AT3 Reagent	20 µL
	FXa Reagent	125 µL
	Heparin Substrate	40 µL
DDPl*	D-Dimer PLUS	
	Accelerator	25 µL
	Latex Reagent	150 µL
AdDD**	Advanced D-Dimer	
	Accelerator	25 µL
	Latex Reagent	150 µL
PFDP***	Latex Test BL-2 P-FDP	
	Reagent	66 µL
	Latex	94 µL
	P-FDP Diluents	112 µL
Rinse Solution	Distilled Water (Rinse Bottle)	Max. 24 mL per test
	CA CLEAN I	10 µL more than the required reagent volume.

(*) Not available for use in the USA.

(**) Only available for use in the USA.

(***) Only available for use in Asia.

The amount of Owren's Veronal Buffer 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 24 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.

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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. 20 mL
  CA CLEAN I: Approx. 125 µL
  Owren's Veronal Buffer: Approx. 200 µL (*)
  (*)only when parameters are analyzed for the Chromogenic Method or Immunology Method

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

Sample cup conical (4 mL):	Approx. 0.2 mL
Dade® Behring 4 mL vial:	Approx. 1.0 mL
Dade® Behring 5 mL vial (GW5):	Approx. 0.8 mL
TTO, NT 3 mL vial:	Approx. 0.4 mL
Push Vial PV-10 (22 mm OD × 40 mm high):	Approx. 0.9 mL
SLD Vial:	Approx. 0.4 mL

The extra volumes shown are the maximum which may be required. 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.

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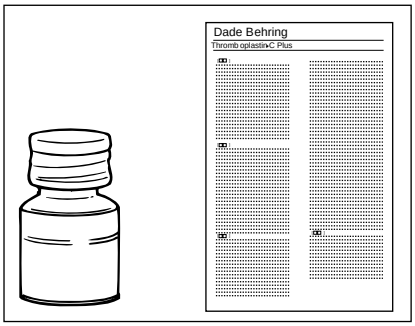
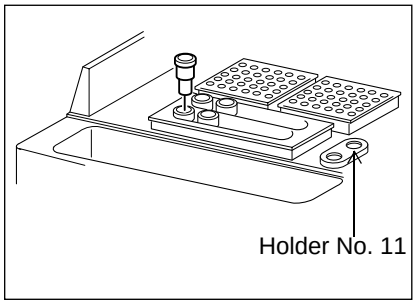


1. Prepare Reagents.

   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. 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).

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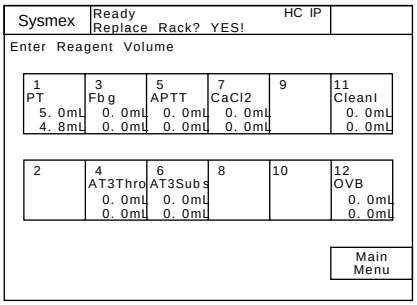
Register Reagent Volume



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

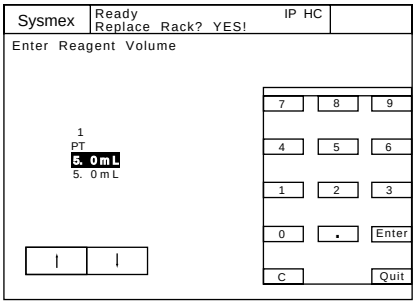
   The contents of the Root Menu will change over.

2. Press **[Set Reagents]** key in the Root 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.

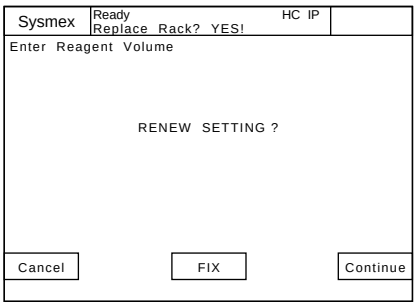
   By pressing **[↑]** and **[↓]** keys, movement can be effected to the preceding or following reagent holder No.

> 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 Root Menu screen.

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

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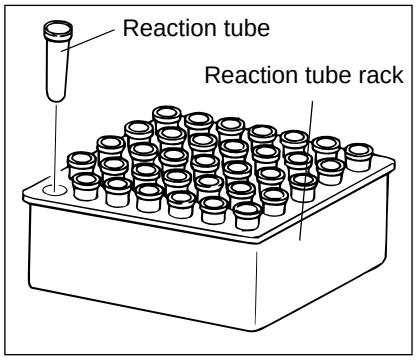
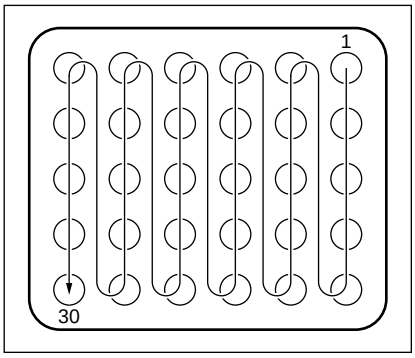
5.7 Set Reaction Tubes





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 for single use only or incorrect results may occur.

Important

- 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). The reaction tubes (SUA-400A) for CA-6000, etc. or those 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.

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5.8 Confirm Standard Curve

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

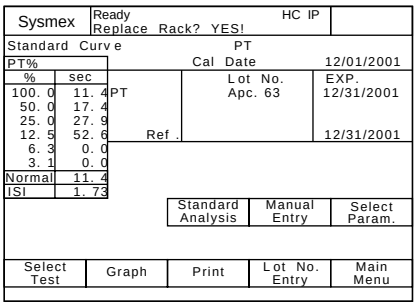
> **Caution**
> Unless the standard curve is properly set, percent activity, concentration, and other calculation parameters cannot be reported.

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

   The Standard Curve screen will be displayed.

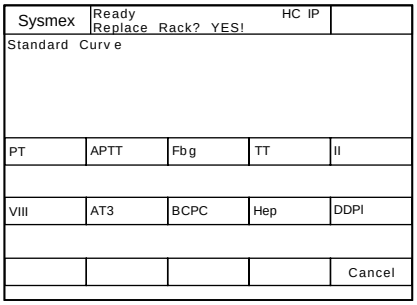
2. Press **[Select Test]** key on the Standard Curve screen.

   The Select Test screen will appear.



3. Press the analysis parameter key to be confirmed.

   The standard curve data of the parameter selected will appear on the standard curve screen.



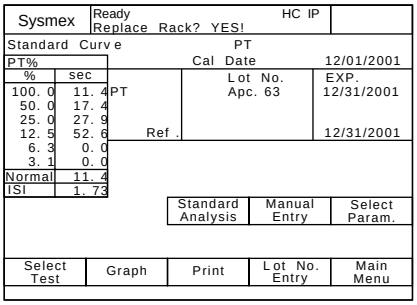
4. Press **[Graph]** key.

   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”.



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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”.

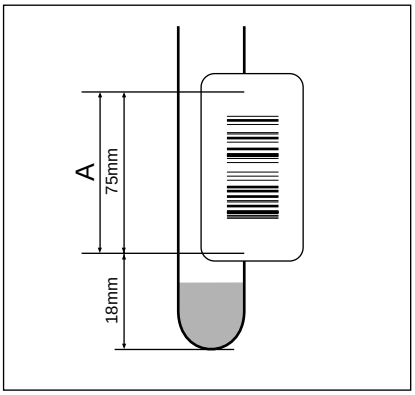
5.10 Prepare Samples

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.

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 mixture at 3000 rpm for 15 minutes to separate plasma components from blood components.

   *Not for use in the USA.



   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.

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Anticoagulant	3.8% sodium citrate solution 3.2% sodium citrate solution 3.13% sodium citrate solution*
Useable	OD: 10 - 15 mm HT: 65 -100 mm (Tubes less than 8 mm in ID cannot be used)

*Not for use in the USA.

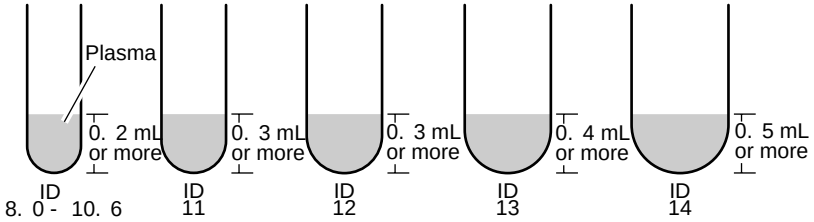
Caution

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.

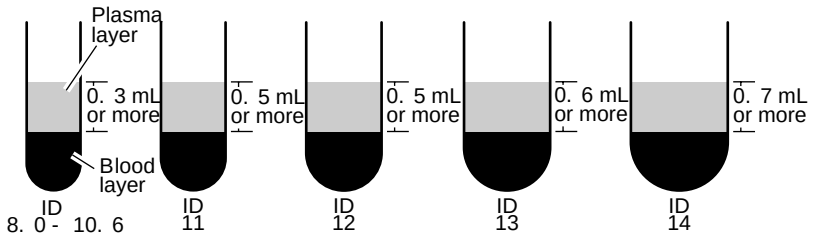
*Not for use in the USA.

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

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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	2, 3 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 which 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 × 75 mm, 2.7 mL
  - VACUETTE Sandwich Coagulation Tube, 13 mm × 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.

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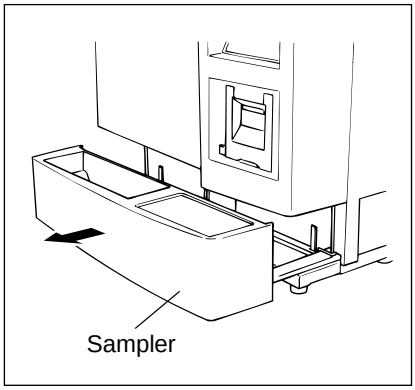
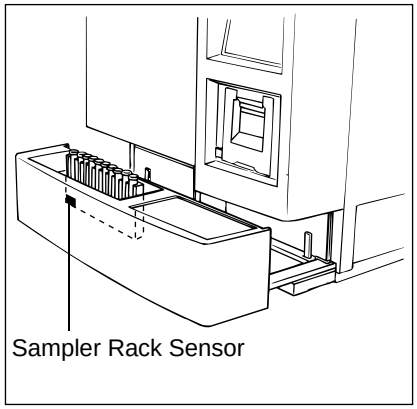
Caution

- 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 (ϕ10 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 “Sample Probe Crash”.
  For samples, prepare the required volume plus 100 µL.



2. Pull out the sampler.



3. Set the sample rack in the sampler.

   Only one rack (10 samples) can be set.

Important

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.

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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.

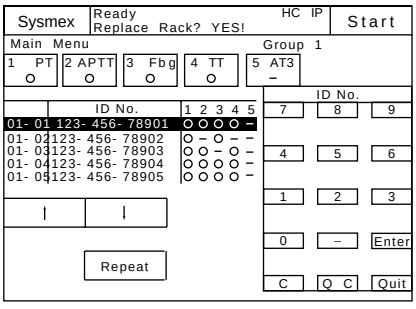
There are four procedures for setting sample ID Nos. and analysis parameters:

- 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 bar-code scanner so that analysis information will be automatically received from the host computer. (Refer to “5.13 Automatic Inquiry”.)

Important

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 Root 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.

Important

- 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.

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 Root 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 Root 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”.

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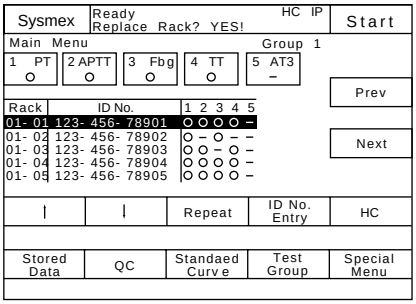
3. Press **[Return]** key.

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

> **Note**
> Using this **[Test Group]** function, Fbg with alternative dilution ratios can be displayed.
> - + 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 Root Menu screen

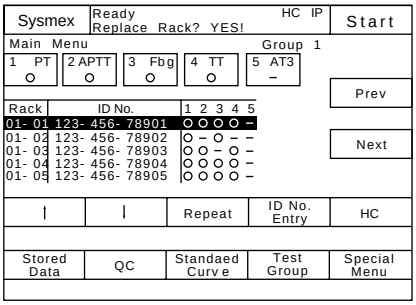
   Press **[↑]** and **[↓]** keys to move the cursor to a sample to be set.

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 Root Menu screen or ID No. Entry screen, press **[Repeat]** key.

> **Important**
> 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 Root 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		• No inquiry to host computer • Analysis with automatically-assigned sample ID No. and manually entered order	• No inquiry to host computer • No analysis
With barcode scanner	Reading normal	• No inquiry to host computer • Analysis with sample ID No. from barcode and manually entered order of barcode	• Inquiry made to host computer using sample ID No. from barcode • Analysis with sample ID No. and order from host computer
	Reading error	• No inquiry to host computer • Analysis with error No. and manually entered order	• 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.".

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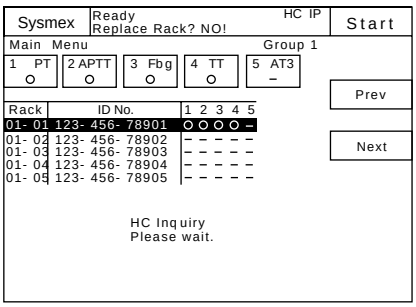


2. Press **[Start]** key.

   Instrument makes inquiries to the host computer using the manually entered ID No. for one sample at a time. It then displays the analysis information on the screen, and starts analysis when the inquiries for 10 samples are completed.

Important

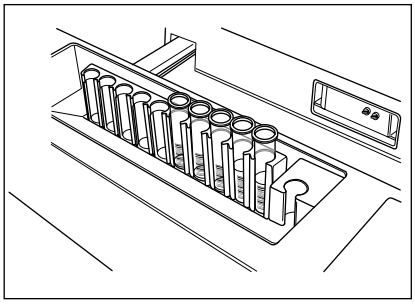
- Inquiry is not performed for those samples on which both ID Nos. and analysis parameters have been set.
- Inquiry is not performed either for those samples on which ID Nos. have not yet been set.

Automatic Inquiry (with barcode scanner)

When the instrument is bidirectionally connected with the host computer, and the optional barcode scanner is fitted, the instrument can receive analysis information for one rack (10 samples), based on the ID Nos. read with the barcode scanner.

The host computer must be set in the conditions shown below. For detail, refer to "10.14 Devices to be connected".

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



1. Set the samples in the sample rack.

   Set the samples with the barcode labels facing toward you for reading.

2. Pull out the sampler, set the sample rack, and push it in.
3. Press **[Start]** key.

   The sample ID Nos. for one rack are read from the barcode labels, and inquiries are made to the host computer for those ID Nos. When the analysis information is received, it is displayed on the screen and analysis is started.

Caution

Remove any foreign matters, if exists, on barcode drive mechanism.

Note

- Should any error occur in reading barcode labels, the sample ID Nos. become "ERR0000000001" and increase in sequence. Inquiry is not performed.

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> **Note**
> - 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

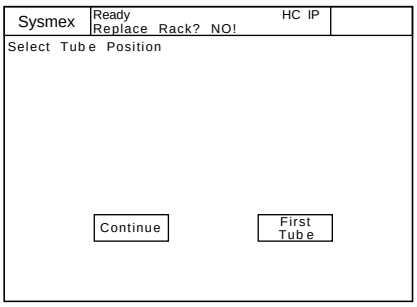
With completion of analysis preparation and registration of analysis information, the instrument is now ready to start analysis.

1. Check the system status display of the instrument.

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

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

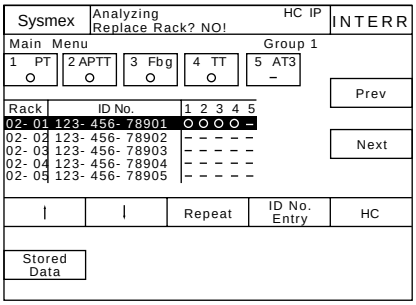
   The screen confirming the first tube's initial position will appear.



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.



> **Important**
> 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.

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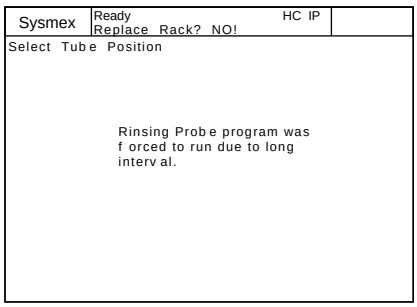

Note

- When analysis begins, if 24 hours have been passed from the previous run, following will be displayed and rinsing program will run automatically to replace rinse and buffer solutions in the hydraulic lines. It will take approximately 3 minutes.
- 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-530, CA-540, CA-550 and CA-560 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 "5.18 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.

Important

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

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

5.15 Automatic Sensitivity Adjustment of the Detector (for CA-530, CA-540, CA-550 and CA-560 only)

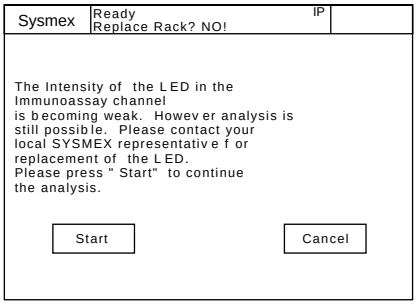
At the start of analysis at either of the times below, sensitivity adjustment of the detector is performed automatically.

- 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 Immunology Method parameters are included, adjustment is performed for the Immunology Method detectors.

First, 200 µL Owren'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 Immunology Method (for CA-550 and CA-560 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:
  "The Intensity of the LED in the Chromogenic channel is becoming weak."
- For the Immunology Method detector :
  "The Intensity of the LED in the Immunoassay channel is becoming weak."
- For both the Immunology Method detector and the Chromogenic Method detector:
  "The Intensity of the LED in the Chromogenic and Immunoassay channels are becoming weak."

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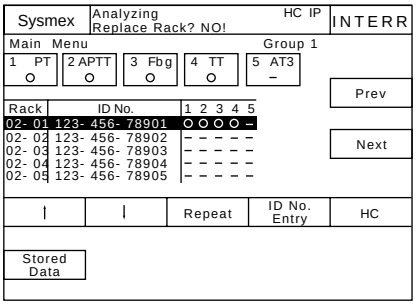
> **Note**
> Analysis can still be performed after the replace-detector message has appeared.

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

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

5.16 Display Analysis Result

Analysis Status Display (Root Menu screen)



Analysis status of each sample is displayed on the Root 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.

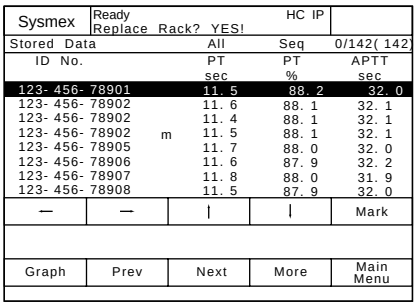
   ○: Analysis is requested.

   ◎: Analysis is in progress.

   ●: Analysis is completed.

   × : Analysis is not completed due to interruption or error.

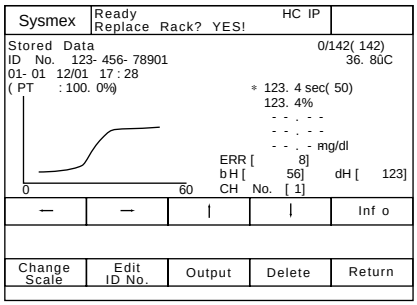
Display and Printout of Sample Data



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

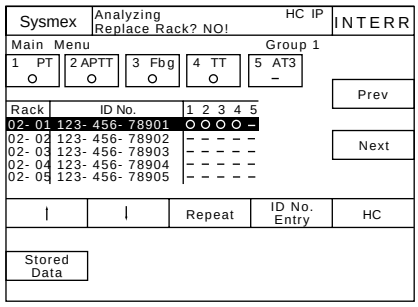
   Analysis data will be displayed in the list format.
2. To display coagulation curves, press **[Graph]** key.

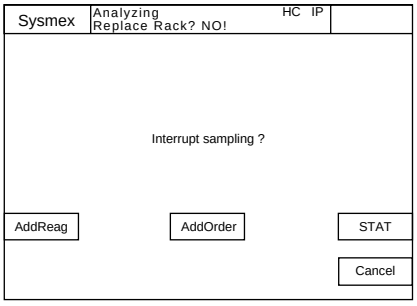
   Move the cursor to the sample whose coagulation curve you wish to display, and press **[Graph]** key.



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

5.17 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 “5.19 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 Root Menu screen returns and “Ready” is displayed.

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

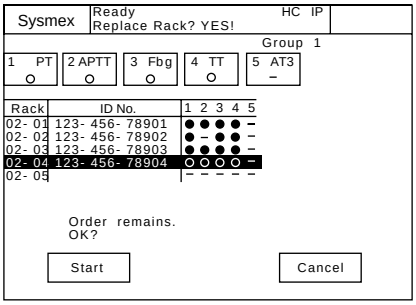
   When you want to interrupt analysis, do not press **[Resume]** key.

   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 Root Menu.

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

5.18 Add Samples

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

   The Interruption Confirmation screen will be displayed.

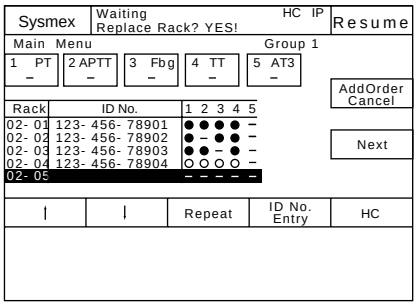
2. Press **[AddOrder]** key on the Interruption Confirmation screen.

   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.



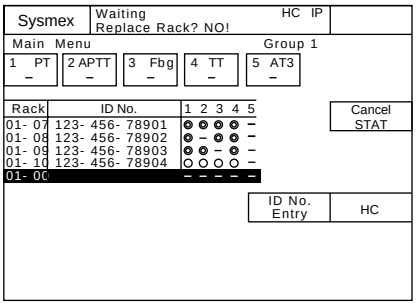
> **Important**
> - Registered sample ID Nos. and orders cannot be modified.
> - Additional orders can only be registered to a position after the final rack position of the registered orders.

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.

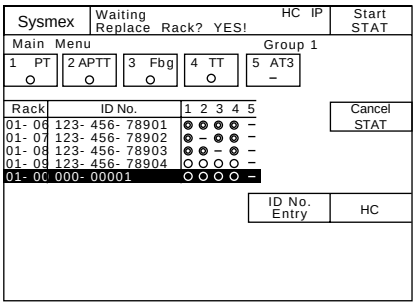
> Note
> To cancel addition of orders, press **[AddOrderCancel]** key.

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

5.19 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.

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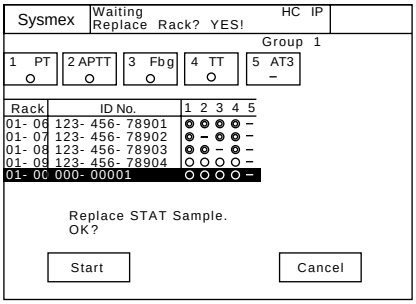

6. Press **[Start STAT]** key.
   Analysis of a STAT sample starts.

> **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.

7. 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.

5.20 Emergency Stop

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

> **Important**
> - Should the analyzer 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 main unit.
> - Note that the above-mentioned switch differs from the emergency mechanical stop switch (red switch) on the front of the instrument. When the red mechanical stop switch is pressed, the mechanical system comes to a stop but the power supply is not turned off.

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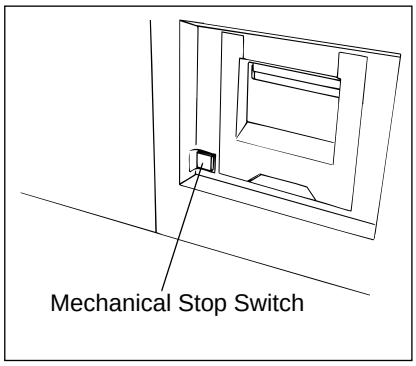
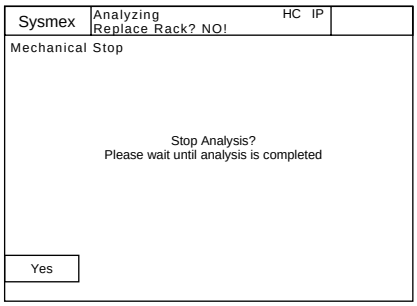


1. Press the Mechanical Stop switch (red switch).

   Analysis operation will stop immediately.

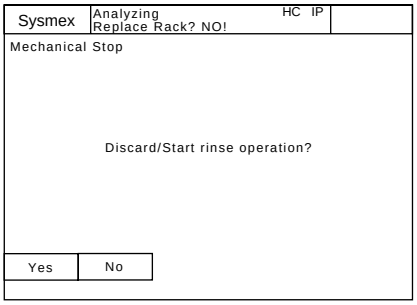
2. When the Mechanical Stop switch is pressed during photo detection, the screen for confirming whether to stop photo detection comes on.



3. 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 "×" 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.

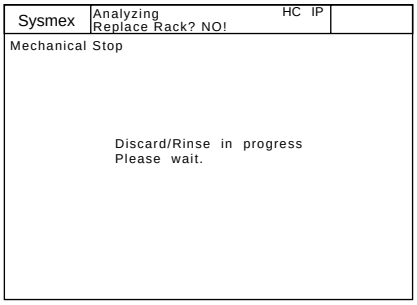


4. To start discard/rinse operation, press **[Yes]** key.

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

   The discard/rinse operation will be executed.

> Note
>
> In what case is rinse operation not possible
> The system is stopped and starting operation could damage the sample probe.



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

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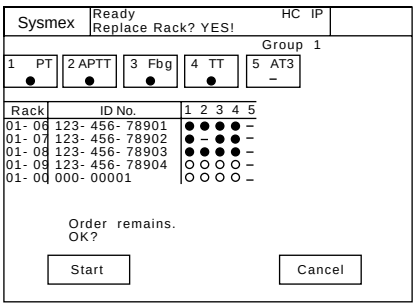

7. Press **[Start]** key or **[Cancel]** key.

   [Start] key: Starts analysis.

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

5.21 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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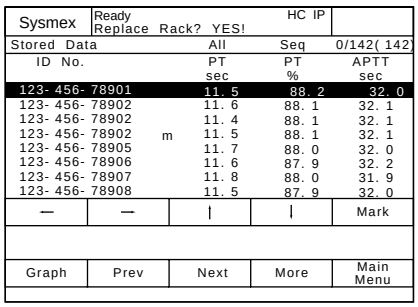
6. Display and Processing of Analysis Results

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 300 samples (1500 tests) and reaction curves of the latest 600 tests. 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 Root 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.

List Display

When **[Stored Data]** key on the Root 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.

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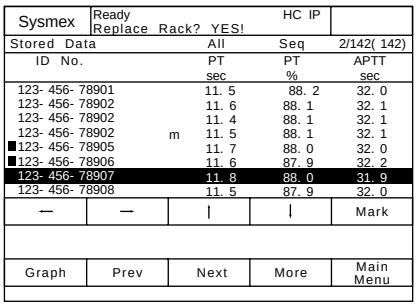


Key operation on the List Display screen is as follows:

[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).

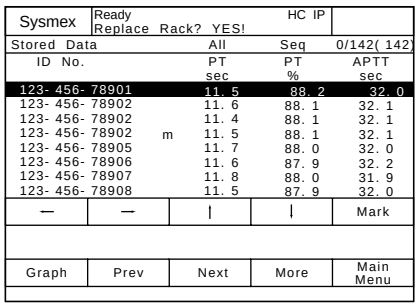
[←] [→] key: Turns over a page (scrolls sideways).

[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 Root 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, ΔOD/min:

The calculation results and coagulation time or ΔOD/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.

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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 ΔOD/min.

! (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

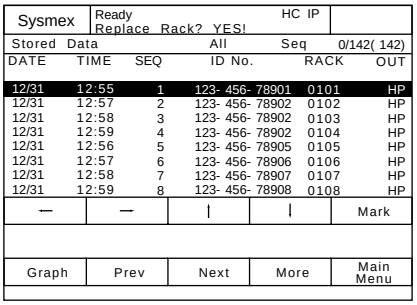
+ (on right of data): A data that exceeds the Upper Mark Limits

- (on right of data): A data that exceeds the Lower Mark Limits

> **Note**
> "*" has a higher display priority than ">" and "<" flags.

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.

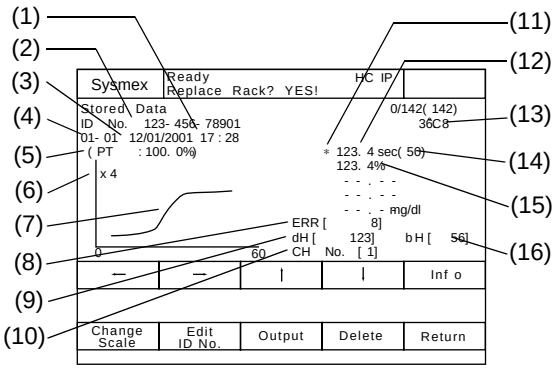
P: When output to the built-in printer, the flag disappears.

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.

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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 Immunology 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.

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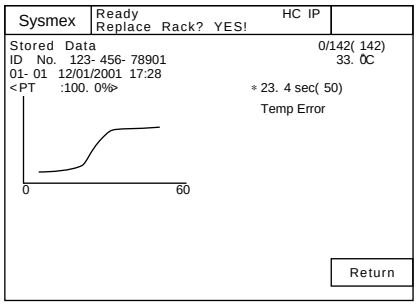


2. Press **[Return]** key of Error Detail Window.

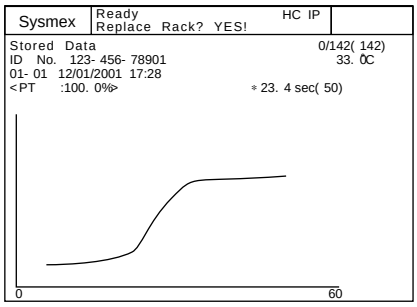
   The Error Detail window will be closed.

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.



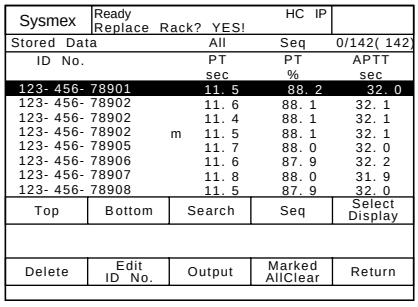
2. Press an area of reaction curve graph on the Graphic Enlargement window.

   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.

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Search by ID No.

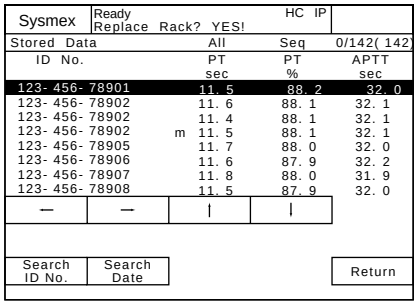
Analysis data of a specified sample ID No. can be searched from stored data.

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

   The Local Menu for search will appear.

2. Press **[Search ID No.]** key.

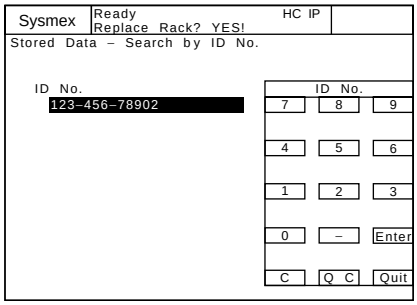
   The Search by ID No. screen will appear.



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.



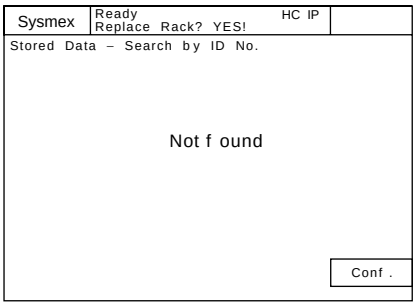
4. Press **[Enter]** key on the ID No. numeric keys.

   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.

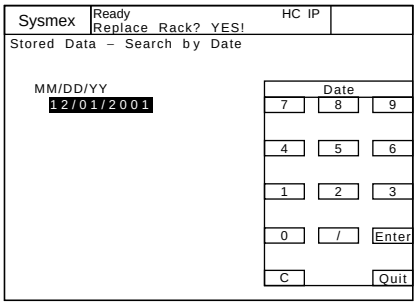
   When analysis data of the specified ID No. is found, a list of analysis data the List will indicate the analysis data at the head of the screen. The cursor is on the analysis data corresponding to the ID No.

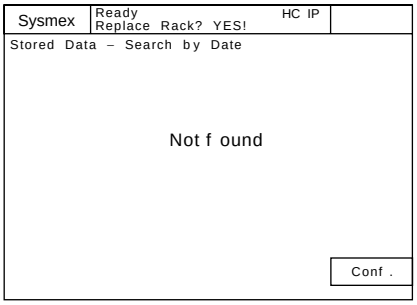
   When analysis data corresponding to an entered ID No. is not found, the Confirmation Message screen will appear.



   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.

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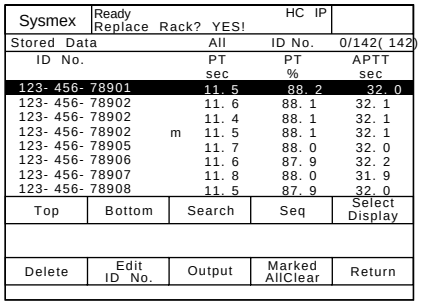
6.3 Sort in Sequence of Sample ID Nos. and Analyses

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

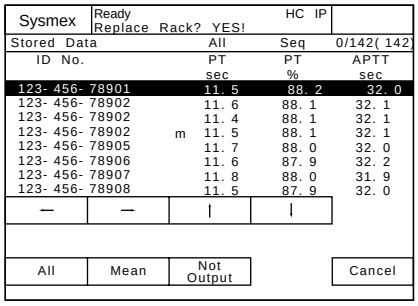
As the condition for displaying a list, All Data can be specified.

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

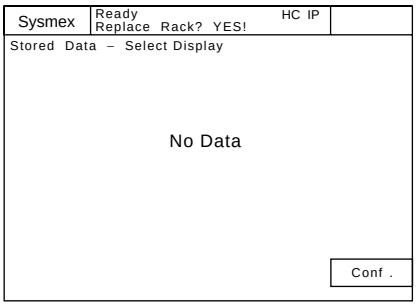
   The Local Menu for selecting a display will appear.
2. Press **[All]** key on the Local Menu.

   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

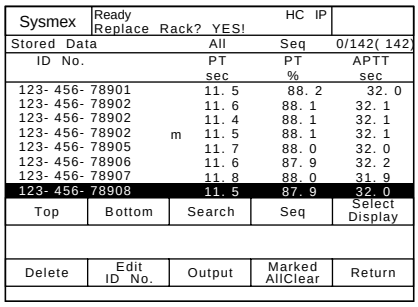


As the condition for displaying a list, Mean Data can be specified.

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.



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.

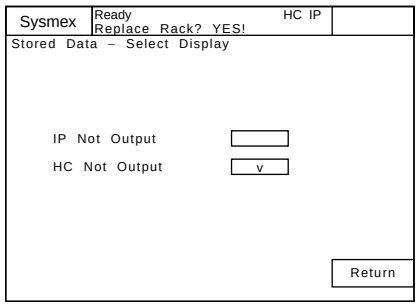
   To cancel selection, press **[Cancel]** key. The Stored Data List Display screen will return.

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.

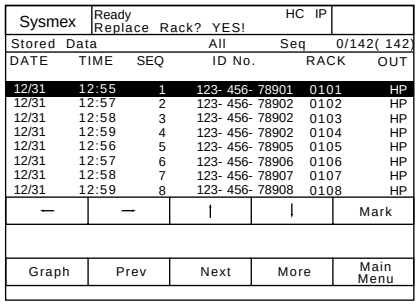
3. On the Not Output Data Selection screen, press the key to select the Not Output data to display. The selected data is indicated with a "v".

   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.



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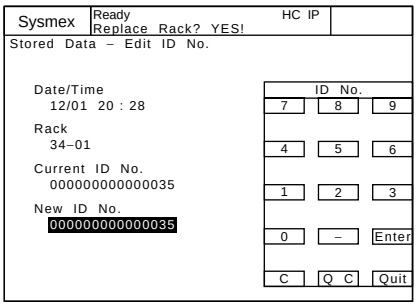
> **Note**
>
> - When an output was performed with the display condition "Not output data" selected, the output flag will be changed but the data will remain in the "Not output data" display even though the data has been output.
> - In this case, exit from the "Not output data" display by pressing **[Main 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 Root 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.
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

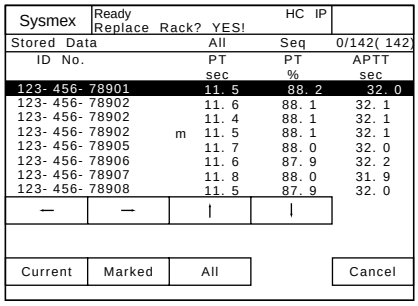
From the analysis data, the data in the current cursor position can be deleted.

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.

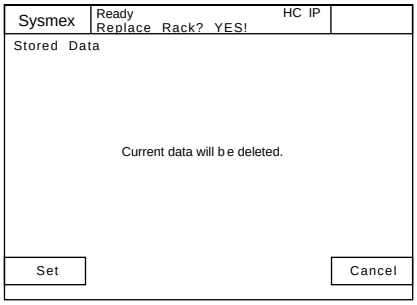
   The Deletion Confirmation screen will appear.



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.



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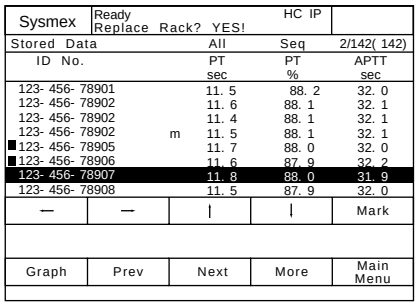
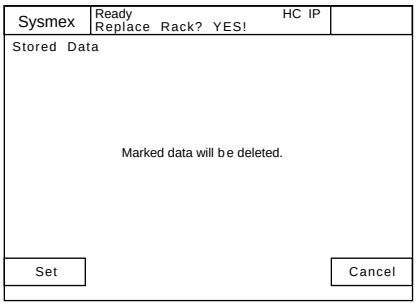
Marked Data





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.

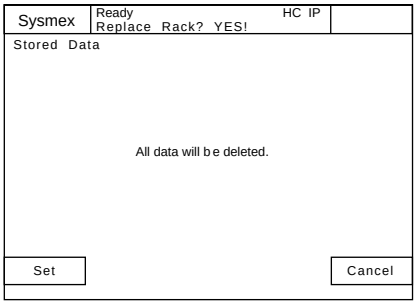
   The Local Menu for deletion will appear.
4. Press **[Marked]** key on the Local Menu.

   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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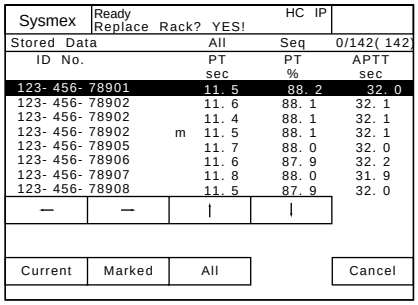
7. Output

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”.

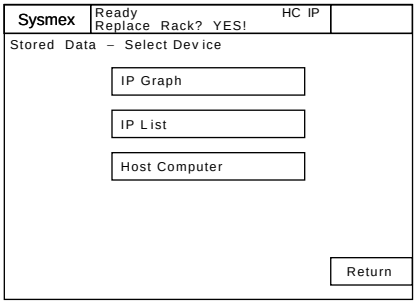
7.2 Output of Analysis Data

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.

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.

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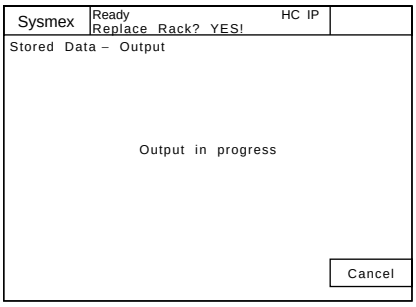
Important

- Referring to “IP Graph”, when Automatic Transfer/Printout Setting is formatted for printout with graph, a graph will be attached; when it is formatted for data analysis printout, analysis result is printed out.
  Refer to “10.2 Setup of Automatic Transfer/Printout” for the procedures.
- However, analysis result will be lost if power has been turned OFF then ON, and the data with graph will be printed instead.
- When the graph is not stored, the data without graph will be printed even if the data with graph is selected. (The graph is stored for the latest 600 tests.)
- The scale of the coagulation curve automatically changes depending on the error.
- Referring to “IP Graph” and “IP List”, when Automatic Transfer/Printout Setting is formatted for auto change depending on the error, an analysis data will be attached.



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.

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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.

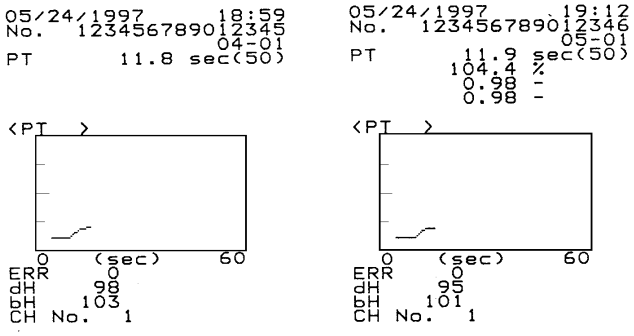
2. Select a device on the Select Device screen.

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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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.

8.1 Quality Control Methods

With the CA-500, two QC Programs are available:

$\overline{X}$ 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 $\overline{X}$ 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.

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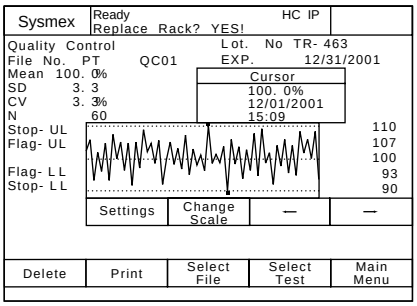

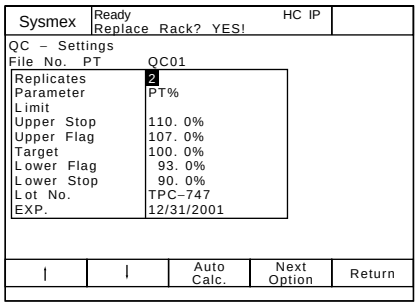

1. On the Quality Control screen, display the QC Chart of the file to set parameters for.

   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 Quality Control Setting 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.

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.
- When changing control parameters, delete all control data of a QC File to be changed.

Important

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.

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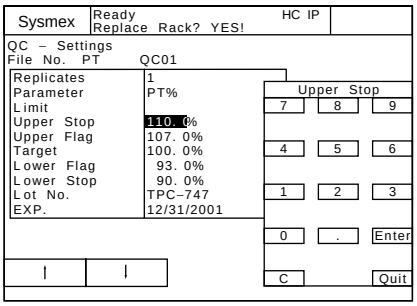

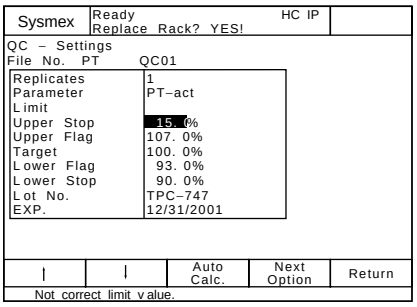

5. Enter control limits using the numeric keys.

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

Important

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

Lower Stop ≤ Lower Flag ≤ Upper Flag ≤ Upper Stop

Lower Stop < Upper Stop

If the Quality Control Setting 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.

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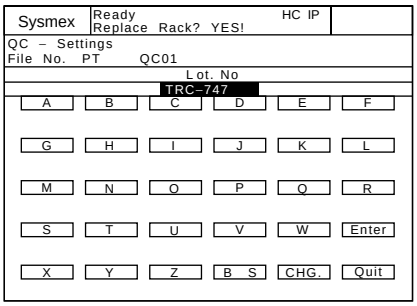


8. Set Lot No.

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

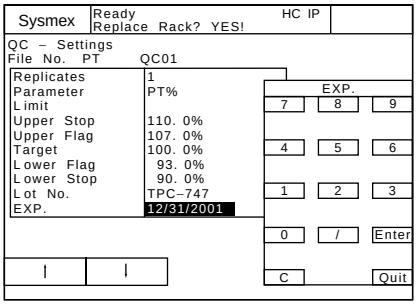
   Press **[Lot No.]** key to display the Lot No. Entry Screen.

   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.

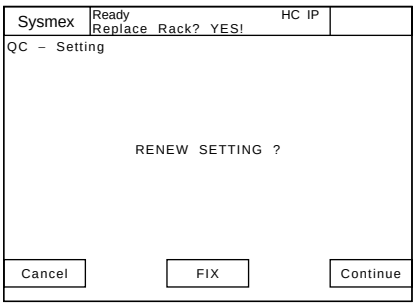
    The setting will be changed to the expiry date entered and the cursor will move to the next parameter.

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

> **Note**
>
> - 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.

12. Press **[Return]** key on the Quality Control Setting 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 Quality Control Setting screen and allows continuous operation.

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

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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 Root 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 Root 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.

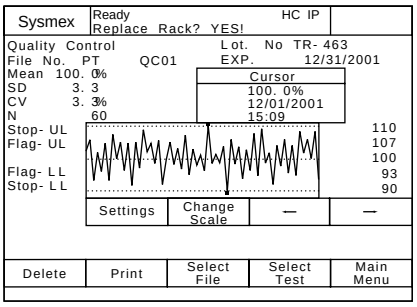
   Analysis data is automatically kept in the QC File.

> **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.

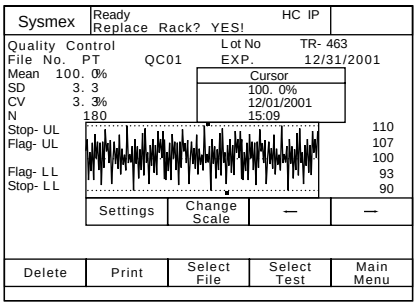
8.4 Display QC Charts



QC data is displayed in the Quality Control screen which is the initial screen of QC Program. When you press **[QC]** key on the Root 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 Root 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.

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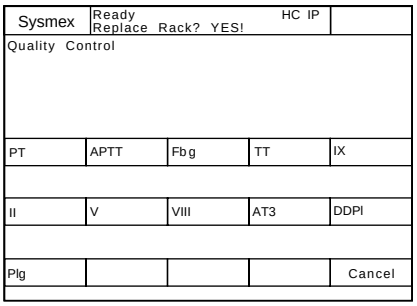
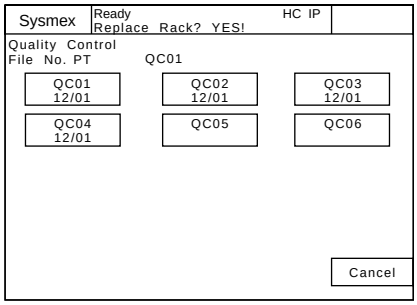


3. Press the parameter key on the Local Menu.

   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 $\overline{X}$ 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.

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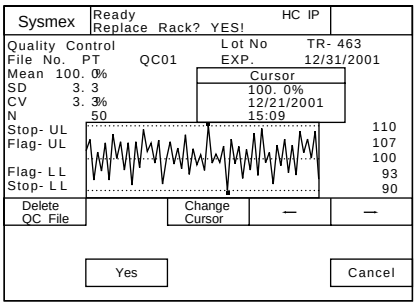
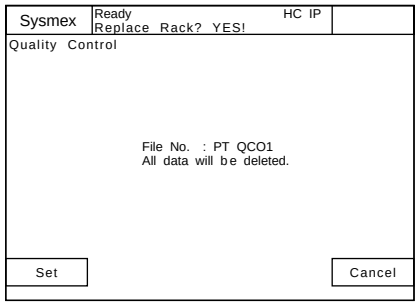


3. Press **[Delete QC File]** key on the Local Menu.
4. Press **[Yes]** key on the Local Menu.

   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.

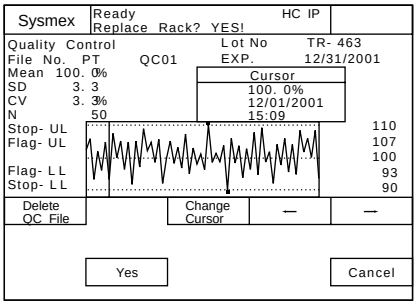
8.6 Delete QC Data

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.

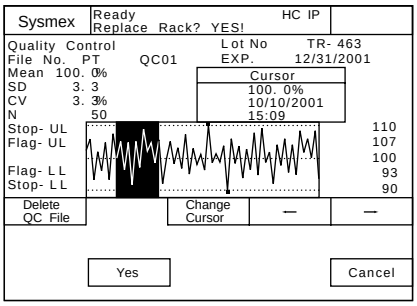
   For how to display the QC Chart, refer to “Select QC Chart” of “8.4 Display QC Charts”.
2. Press **[Delete]** key on the Quality Control screen.

   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.



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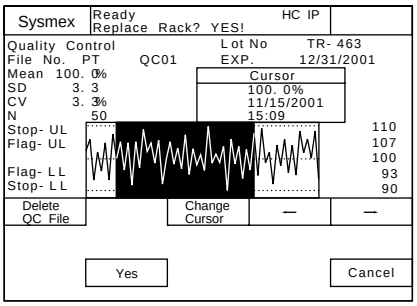
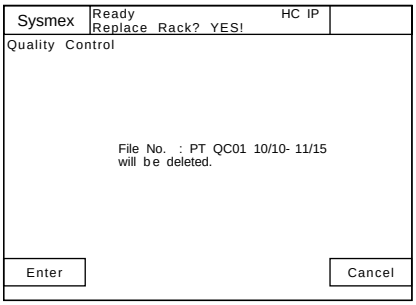




4. Using **[←]** and **[→]** keys on the Local Menu, move the cursors and set the data range to be deleted.

   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.

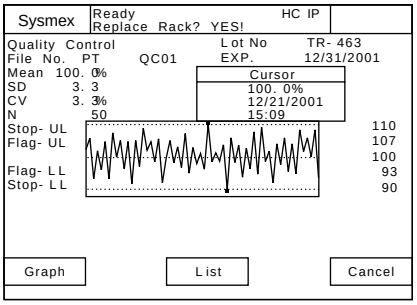
   The Local Menu for print setting will be displayed.

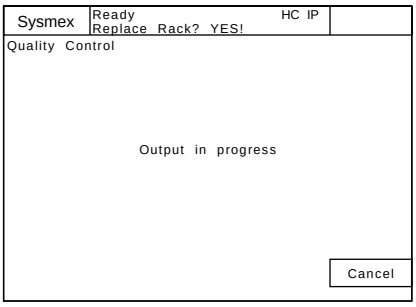
3. Press **[Graph]** key or **[List]** key.

   [Graph] key: Prints out QC data and QC chart.

   [List] key: Prints out QC data and data lists.

   [Cancel] key: Returns to the Quality Control screen without printout.



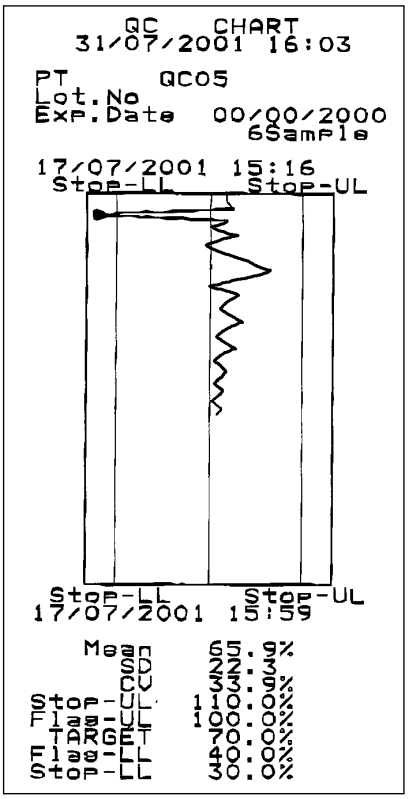


When **[Cancel]** key is pressed on the “Output in progress” message screen, printing will be canceled and the Quality Control screen will return.

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.

Graphic printout



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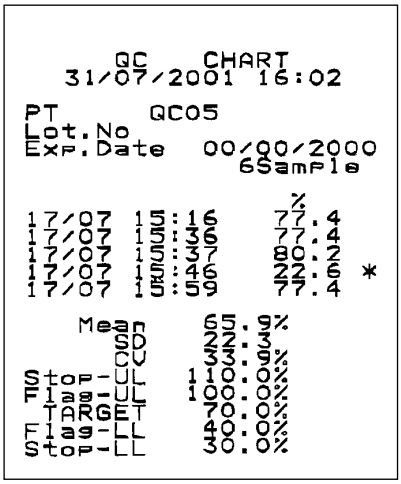
List printout



```
        QC    CHART
  31/07/2001 16:02

PT        QC05
Lot.No
Exp.Date   00/00/2000
             6Sample

                     %
17/07 15:16      77.4
17/07 15:36      77.4
17/07 15:37      80.2
17/07 15:46      22.6  *
17/07 15:59      77.4

    Mean         65.9%
      SD         22.3
     CV%         33.9%
Stop-UCL        110.0%
Flag-UCL        100.0%
  TARGET         70.0%
Flag-LCL         40.0%
Stop-LCL         30.0%
```

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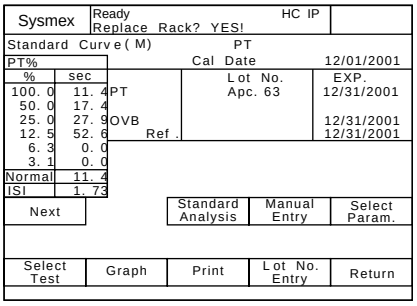
9. Setting Standard Curve

The Standard Curve is a set of parameters used to determine each calculation parameter, based on the coagulation time and ΔOD/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



1. Press **[Standard Curve]** key on the Root 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.

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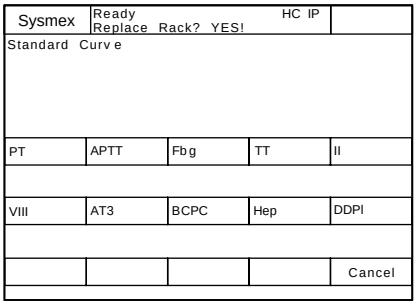
Caution

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.

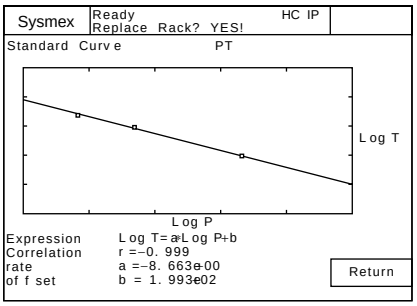
Note

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 Log P = a * 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

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

9.2 Standard Curve Analysis

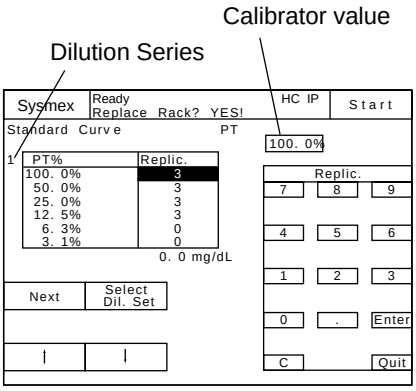
Auto Dilution

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.
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	2
	1/1, 1/2, 1/4, 1/8, 1/16, 0/1	3
	1/1, 1/2, 1/3, 1/4, 1/5	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
	Set manually	M

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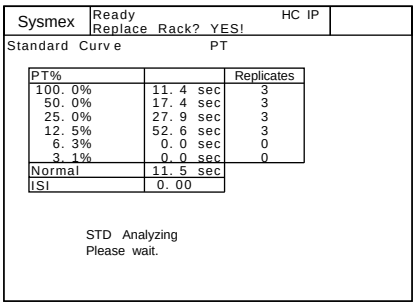
	Dilution Ratios provided for Auto Dilution	Dilution Series No.
Analysis parameters with dilution	1/1, 1/2, 1/4, 1/8, 1/16, 1/32	1
	1/1, 4/5, 3/5, 2/5, 1/5	2
	1/1, 1/2, 1/4, 1/8, 1/16, 0/1	3
	1/1, 1/2, 1/3, 1/4, 1/5	4
	1/2, 1/4, 1/8, 1/16, 1/32, 0/1	5
	10/19, 5/19, 5/38, 1/19, 1/38, 1/95	6
	2/1, 1/1, 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	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	12
	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.

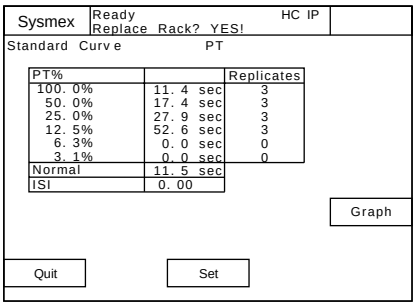
   The cursor can be moved by pressing **[↑]** and **[↓]** keys.



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

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

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



8. 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.

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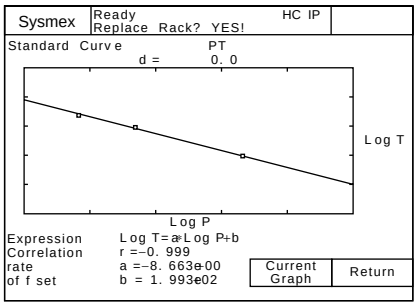


Press **[Graph]** key to display the new Standard Curve data as graph (solid line with square plots).

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 difference in coagulation time between the new and old Standard Curves at 1:1 is displayed as deviation amount d.

Manual Dilution

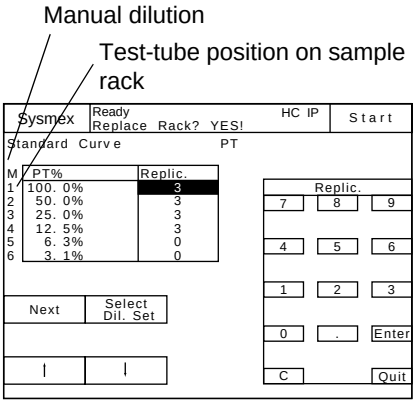
The instrument analyzes multiple calibrators of the same series, for which activity and other values are already known, and then creates a standard curve.

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.
4. 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 “9.6 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.

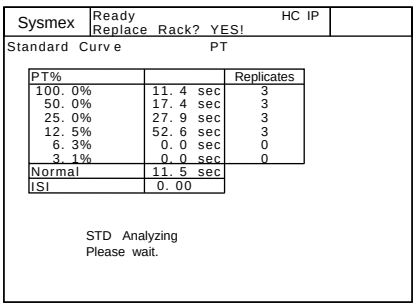


> **Important**
> Put the calibrator for the set value in the same sample rack test-tube position as the number shown on the settings screen.

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

   The analysis count can be set from 0 - 3.

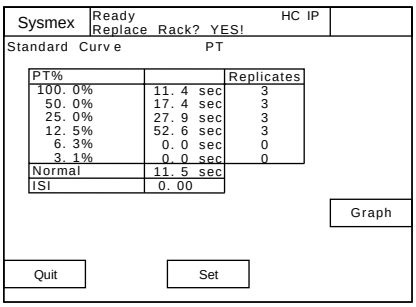
   The cursor can be moved with **[↑]** and **[↓]** keys.



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

   During analysis, the message “STD Analyzing. Please wait.” is displayed.

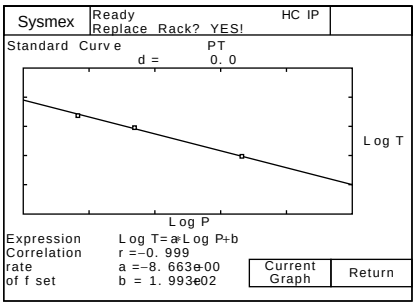
> **Important**
> 2 or more points are required in order to begin Standard Curve analysis.



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.



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 difference in coagulation time between the new and current standard curves at 1:1 is displayed as deviation amount d.

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 “9.6 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.

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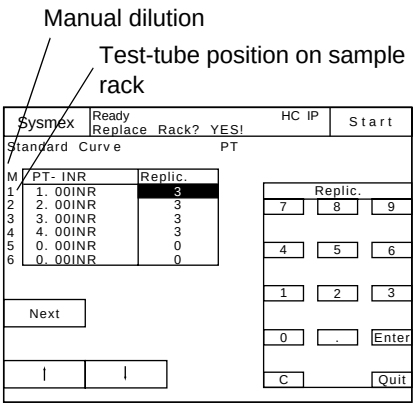
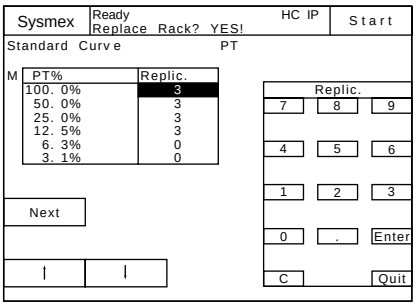


4. Use the numeric keys to input an INR value for each point.

   To the left of the table is displayed the sample rack test-tube positions. “1” indicates sample rack test-tube position 1.

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



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

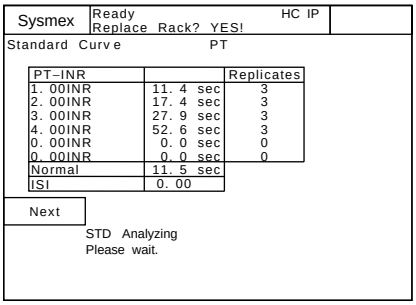
   The analysis count can be set from 0 - 3.

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

6. 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.

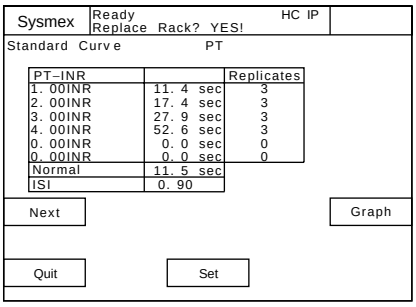
> Note
> Entering the activity percentage (concentration) here, in addition to the INR value, allows two types of Standard Curve to be set: INR and activity percent.



7. 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.

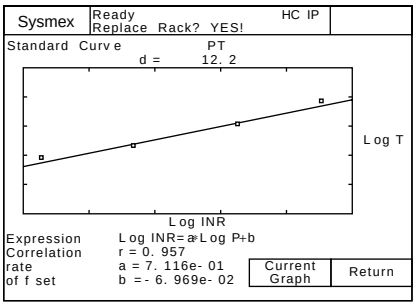
> **Important**
> 2 or more points are required in order to begin Standard Curve analysis.



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.



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

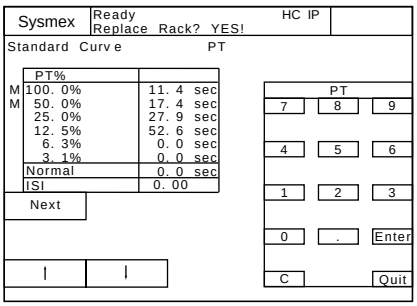
Press **[Current Graph]** key to display the current (old) standard curve graph (dotted line with triangular plots in addition). Press it again to hide the current standard curve graph from the screen and switch to the new standard curve.

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

> **Note**
>
> - The difference in coagulation time between the new and current standard curves at 1:1 is displayed as deviation amount d.
> - 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

> **Note**
>
> “M” is displayed on the left of the line inputted by Manual Entry, if CA-500 series instrument of which serial number is larger than or equal to the following number.
>
> | | |
> |---|---|
> | CA-510 | A1300 |
> | CA-520 | A1018 |
> | CA-530 | A1805 |
> | CA-540 | A3405 |
> | CA-550 | A1001 |
> | CA-560 | A1001 |



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.

> **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.

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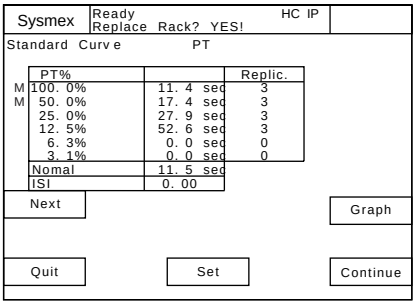


4. Press **[Quit]** key on the numeric keys.

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

   [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.

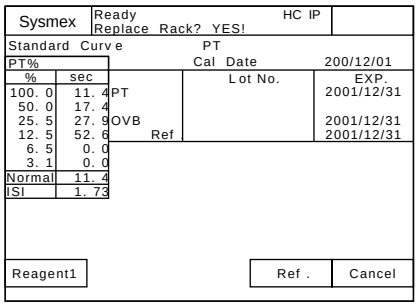
> **Note**
>
> Standard Curve data require 2 or more points. When renewal is made with less than 2 points, the message “Set more than two points” will appear. In this case, set the Standard Curve again properly.

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 Set Reagent Information

> **Note**
>
> Set Lot No. and Expiry date of diluent too, if CA-500 series instruments of which serial number is larger than or equal to the following number.
>
> | | |
> |---|---|
> | CA-510 | A1300 |
> | CA-520 | A1018 |
> | CA-530 | A1805 |
> | CA-540 | A3405 |
> | CA-550 | A1001 |
> | CA-560 | A1001 |



Set Lot Nos. and Expiry dates of analysis reagent, reference plasma.

When the expiry date has passed, the message “Check Reagent Expiry” will appear at start of analysis.

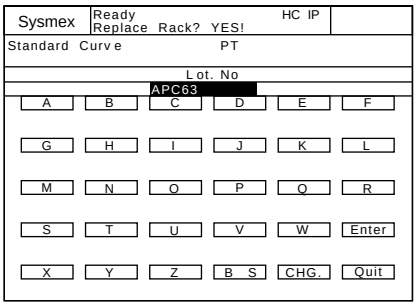
1. Press **[Lot No. Entry]** key on the Standard Curve Data screen.

   The Lot No. Entry Menu screen will appear.

2. Press **[Reagent1]** key or **[Reagent2]** key, depending on which reagent you want to set.

   Lot No. Entry screen (character key screen) will appear.

> **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.



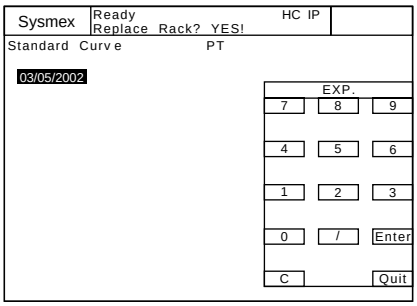
3. Enter Lot No.

   [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.

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.

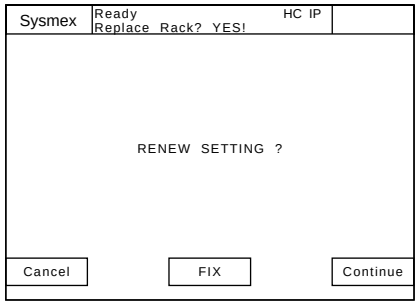
6. To stop expiry date entry, press **[Quit]** key.
7. When settings are changed, the Renew Confirmation screen appears.

   When no changes made in settings, the Standard Curve Data screen returns.

   [Continue] key: Returns to the Entry screen.

   [FIX] key: Renews the setting and returns to the Standard Curve Data screen.

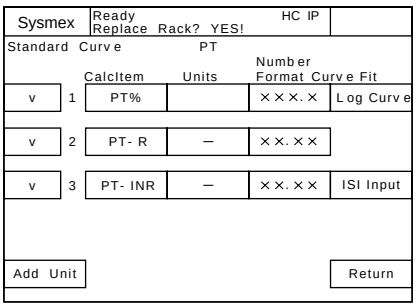
   [Cancel] key: Discards the setting and returns to the Standard Curve Data screen.



9.6 Set Calculation Parameters

The parameters requiring calculation are set. Examples are PT%, PT ratio, 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

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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

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	XXX. X
g/L	X. XXX
U/mL	XX. XX
INR	XX. XX
µg/mL	XXX. X
µg/L	XXXX
IU/mL	XXX.X

Note

The decimal point mode selected here is also applied to the data stored in the memory.

Curve Fit: Indicates calculation method.

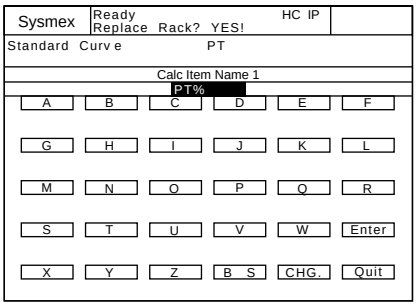
CalcItem 1:	Log Curve:	Log-log polygonal line
	Log Lin:	Log-log linear approximation
	Lin-Lin:	Real number - real number linear approximation
	Lin PT-PT:	Real number - real number polygonal line
	AKIMA:	Akima method interpolation
	AKIMA(0):	Akima method interpolation
CalcItem 3:	ISI Input:	Input ISI 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".

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.

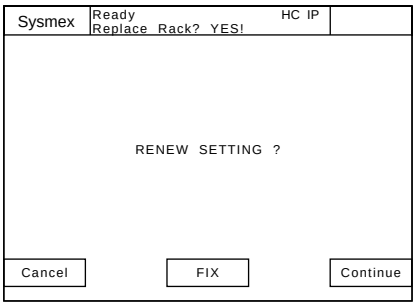
4. Select units.

   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.



6. 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 unit (decimal point position) or calculation method is changed after the plotting of a Standard Curve, data coordination will become impossible. When a unit is changed, always set a new Standard Curve, Mark Limits Settings and Report Limits Settings.

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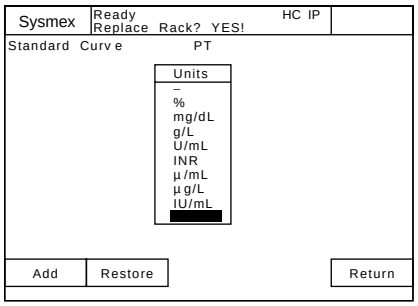
How to Add Unit



1. 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.

2. 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.

3. Press **[Enter]** key.

4. To end addition of units, press **[Quit]** key.

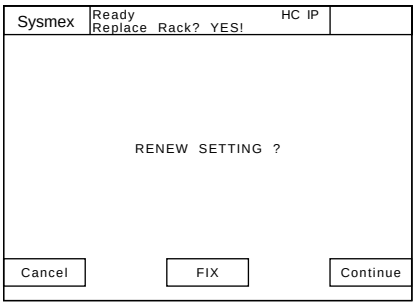
   When settings are changed, the Renew Confirmation screen appears.

   When no changes are made in settings, the Units Display screen returns.

   [Continue] key: Returns to the Units Display screen.

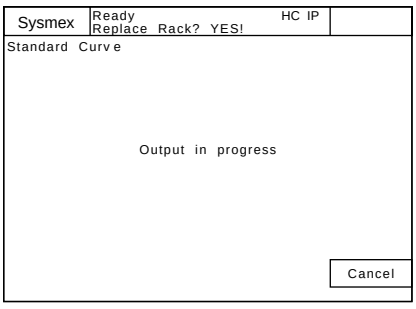
   [FIX] key: Renews the settings and returns to the Select Param. screen.

   [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.

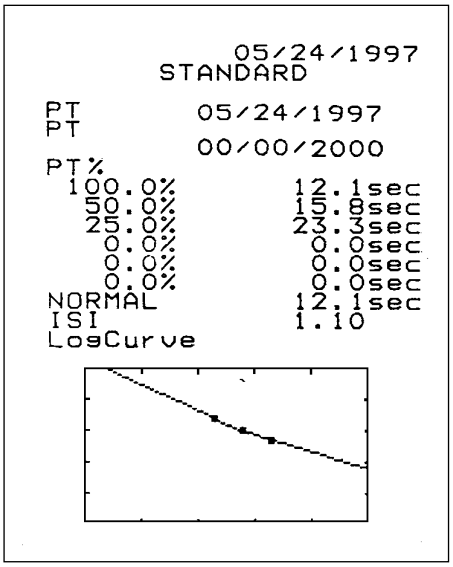
9.7 Print Standard Curve



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.

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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.

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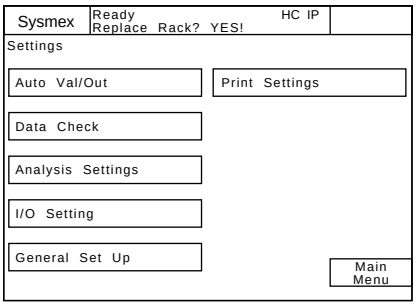
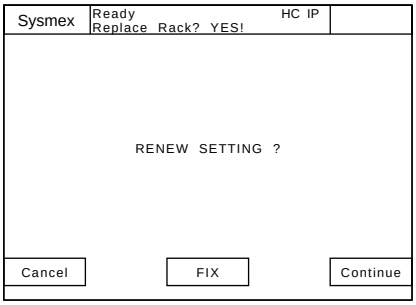
Basic Operation of Setup Program





Follow the procedure shown below to display each setting screen, and change the set values.

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

   The contents of the Root Menu will change over.

2. Press **[Settings]** key on the Root 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.

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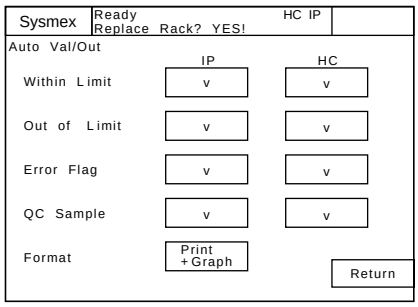

2. Press the sample key you want to set. That key will be marked with "v" which sets the sample.

   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

3. 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:

   - No Graph
   - Analysis
   - Auto + Graph
   - Auto No Graph
   - Print + 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.

   Print + Graph: The parameter data is automatically printed out in list format and graph.

4. When setting is completed, press **[Return]** key.

   The Renew Confirmation screen will appear. Press the appropriate key.

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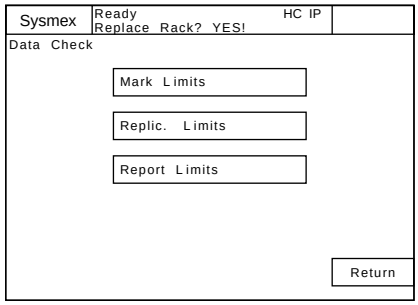
10.3 Judgment on Analysis Result

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

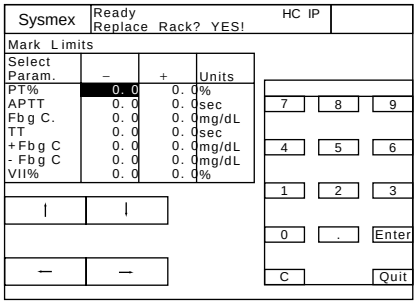


1. Press **[Data Check]** key on the Setting Menu screen.

   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.

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> **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.

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

   The Renew Confirmation screen will appear. Press the appropriate key.

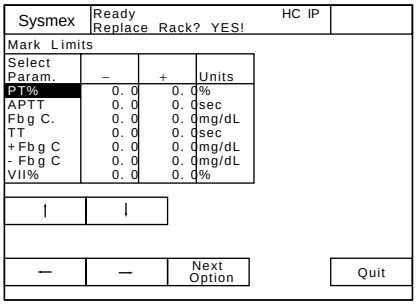
How to Select Parameters

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.

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10.4 Replication Range

This program allows setting the upper limit ratio for replication range.

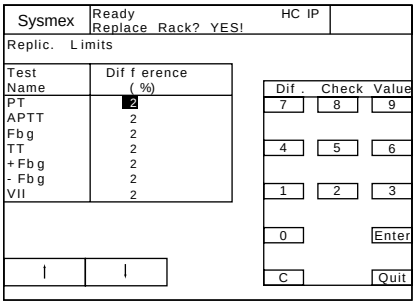
For analysis parameters for which the analysis count is 2 or more, the mean values for seconds and ΔOD/min in analysis results are calculated. When the difference between each analysis result and the mean falls beyond the upper limit of replication range, that analysis result is interpreted to have become 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 ΔOD/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.

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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.

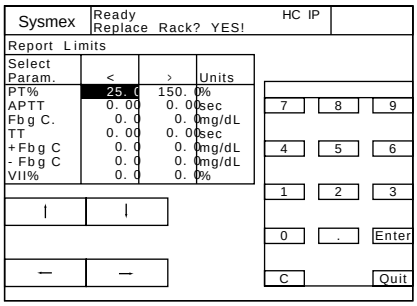
> Note
> Judgment parameters can be selected in the **[Settings]** → **[Data Check]** → **[Mark Limits]** program. Refer to “10.3 Judgment on Analysis Result”.

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.

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

   The Renew Confirmation screen will appear. Press the appropriate key.

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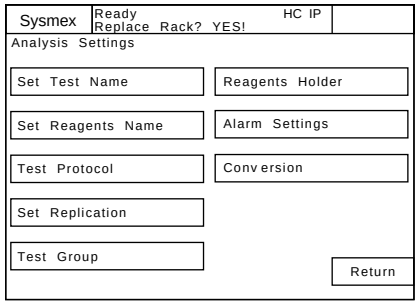
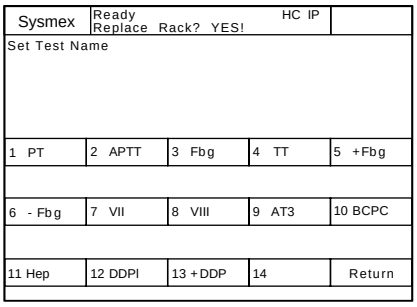
10.6 Setup of Test Name

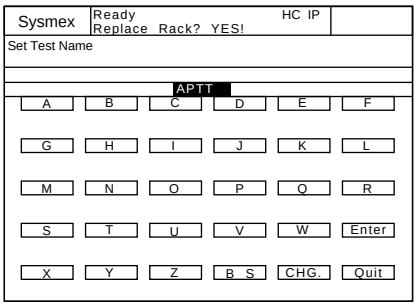
This program allows setting test name.

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.

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10.7 Reagent Name

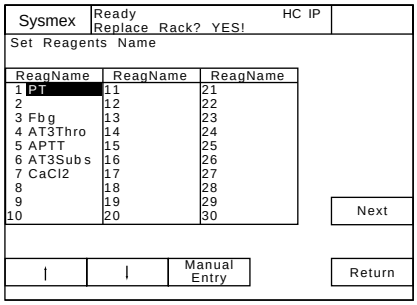
This program allows setting reagent name.

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.

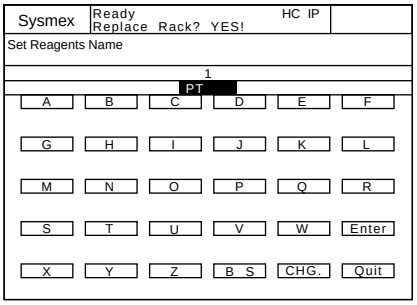


3. Using **[↑]** and **[↓]** keys, move the cursor to specify a reagent to be set.

   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.

> **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.

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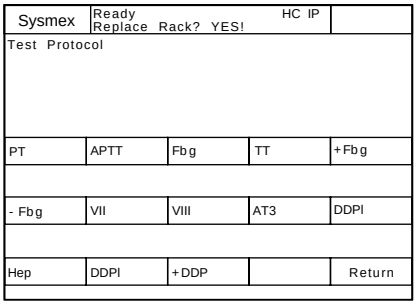
10.8 Test Protocol

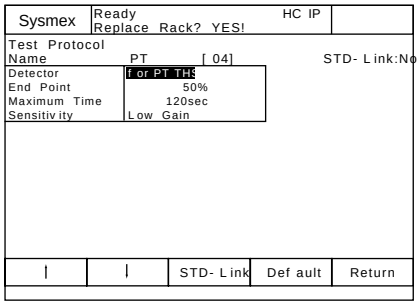
This program allows the test protocol and parameter codes to be set for each analysis parameter. It also allows parameters to be linked or unlinked to/from the standard curve..

> **Caution**
> Change of analysis procedure may not obtain the right result. When you change, carry out in user's own responsibility.

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".
   - 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.)

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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.
>
> - Coagulation Method:
>   Coagulation detection point, maximum detection time, sensitivity
> - Chromogenic Method and Immunology Method:
>   Start point, end point, sensitivity, wave length

5. Using **[Detector]**, **[Next Option]**, **[Select 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.

   - Coagulation Method

04: PT	05: APTT	06:Fbg	12: II
15:V	17: VII	18: VIII	19: IX
20: X	21: XI	22: XII	25: PCcl
26: BXT	27: LA1*	28: LA2*	50: +Fbg
51: TT	52: -Fbg		

   - Chromogenic Method

30: AT3	31: APL*	32: Plg*	33: PC Chrom
34: Hep			

   - Immunology Method

61: DDPl*, AdDD**	62: PFDP***	70: +DDP*, +AdD**
72: +PFD***		

   (*) Not available for use in the USA.

   (**) Only available for use in the USA.

   (***) Only available for use in Asia.

Important

The same parameter code cannot be set for more than one parameter.

2) 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”.

3) 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 immunology 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 immunology 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 Immunology Method" or ask your local service representative for additional information.

4) 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 immunology 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 immunology 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 Immunology Method" or ask your local service representative for additional information

5) Sensitivity

Sets the sensitivity of the detector.

Press **[Next Option]** key to select the sensitivity.

- Low Gain
- High Gain

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6) Wave length

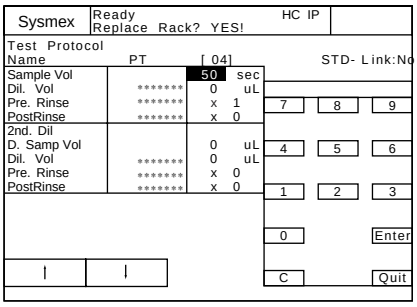
Sets wave length of the light source. (Only for the Chromogenic Method or Immunology Method)

Press **[Next Option]** key to select wave length.

- 405 nm Inc. (Chromogenic)
- 405 nm Dec. (Chromogenic)
- 575 nm Inc. (Immunology)
- 575 nm Dec.(Immunology)

Important

- With the Chromogenic Method, set to 405 nm Inc.
- With the Immunology Method, set to 575 nm Inc.



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.

7) 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.

8) 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

Important

Make sure that the sum of diluent volume and sample aspiration volume will be within a range of 20 µL to 130 µL.

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9) 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.

10) 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 to100 µL, in 1- µL increments. If it is not used, enter 0 µL.

11) 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 to120 µL, in 1 µL increments. If it is not used, enter 0 µL.

Important

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.

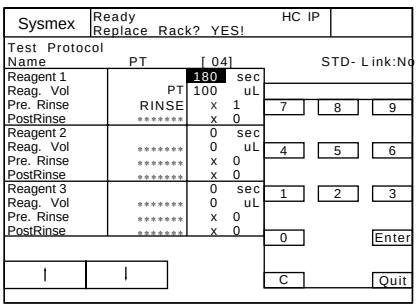
12) Pre.Rinse, PostRinse (2nd.Dil)

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.



As for the setting position of diluent volume for second step dilution, move the cursor using **[↓]** key to display the screen for setting reagent.

13) 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.

14) 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 volume can be set within the range of 4 µL to 200 µL, in 1-µL increments.

Important

Make sure that the entire volume in the reaction tube will be 220 µL or less.

15) 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).

Important

When using a reagent, be sure to set the number of following rinse cycles to 1 or above.

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16) 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 neither is used, enter 0 µL in reagent volume.

As to the other items, set the same conditions as for the reagent 1.

Important

When using a reagent, be sure to set the number of following rinse cycles to 1 or above.

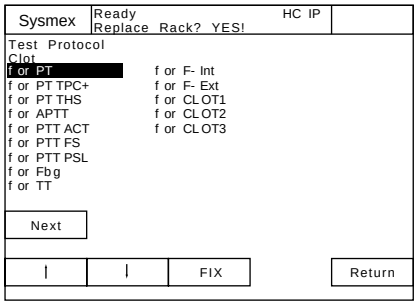
6. When setting is completed, press **[Quit]** key.

   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.

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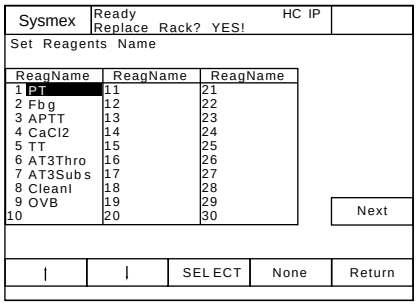
Selection of Reagent



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.

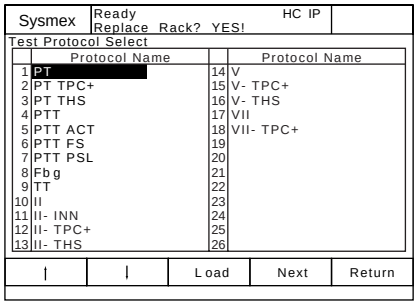
When a desired reagent is not displayed, press **[Next]** key to change over the reagent display.

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

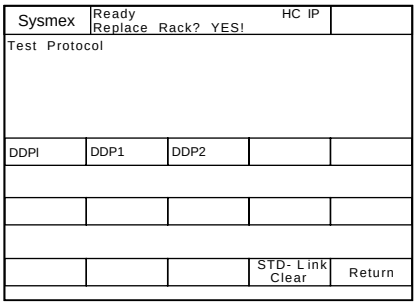


When **[Default]** key is pressed with the cursor placed on the parameter name, the Test Protocol Select screen will appear.

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+.

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.

Important

When a parameter is linked to the standard curve, test protocol can be set for the parameter code, sample volume and diluent volume only. However, 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.

The sample dilution ratio of the linked test protocol has to be checked, if the sample dilution ratio of the master test protocol has been changed.

Note

If CA-500 series instrument of which serial number is smaller than or equal to the following number, Std Link setting of Fbg cannot be deleted.

If the total sample volume of Fbg test protocol has been changed, the sample volume for the linked test protocol +Fbg and -Fbg will be overwritten for consistency reasons. Check the sample dilution ratio of +Fbg and -Fbg.

CA-510	A1299
CA-520	A1017
CA-530	A1804
CA-540	A3404

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.

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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*	DDPl*
+AdD**	AdDD**

(*) Not available for use in the USA.

(**) Only available for use in the USA.

10.9 Replication

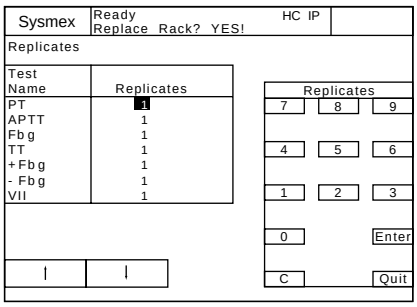
This program allows setting replication for each analysis parameter. When two or more analyses are set, the mean is calculated and displayed.

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.

   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.

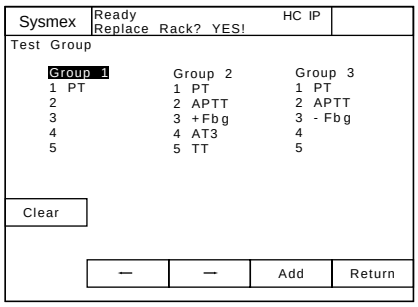
2. Press **[Test Group]** key on the Analysis Setting Menu screen.

   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.

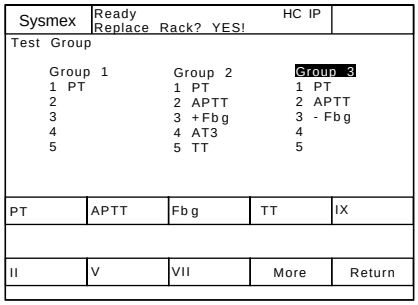
   By pressing **[Clear]** key, you can erase all parameters of the selected test group.



4. Press **[Add]** key.

   The Test Group Addition screen will appear.

> **Note**
> 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.

> **Important**
> 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 (half the usual Fbg concentration).
> -Fbg is an analysis parameter with an alternative dilution ratio of 1:5 (2 times the usual Fbg concentration).
> +DDP* is an analysis parameter with an alternative dilution ratio of 1:8 the usual DDPl* concentration.
> +AdD** is an analysis parameter with an alternative dilution ratio of 1:8 the usual AdDD** concentration.
> (*) Not available for use in the USA.
> (**) Only available for use in the USA.

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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

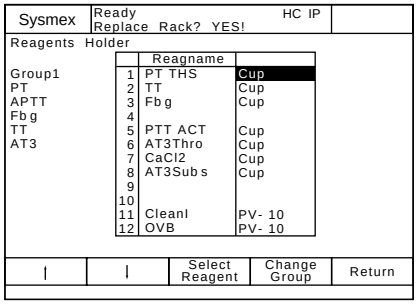
This program can be used to set the positions and container types of the reagents held by the reagent holder. When aspirating reagent, the probe height is automatically changed to match the container that has been set.

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.



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

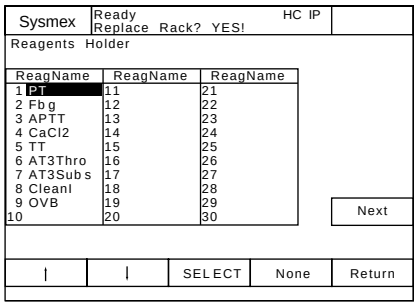
4. Using **[↑]** and **[↓]** keys, move the cursor to specify a reagent name for reagent holder to be set.

> 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.



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, “D-4”, “D-3”, “GW5”, “PV-10” , “Cup” and “SLD Vial” appear in sequence.

Symbol	Meaning
D-4	Dade® Behring 4 mL reagent vial
D-3	Dade® Behring 3 mL reagent vial (*)
GW5	Dade® Behring GW5
PV-10	Push Vial PV-10 (22 mm OD x 40 mm high) provided in supply parts
Cup	Sample Cup Conical 2 mL or 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.

> **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.

> **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.

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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.

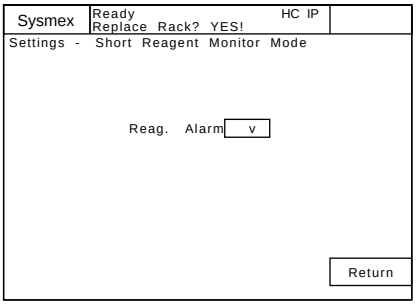
1. Press **[Analysis Settings]** key on the Root Menu screen.

   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

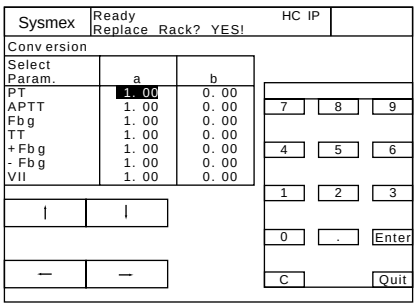
This program is used to set the values used in the conversion formula for analysis parameters. Set “a” (rate) and “b” (offset) for the conversion formula “Y = ax + b”.

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.

[Barcode] key is displayed only on the device with the barcode scanner.

Host Computer

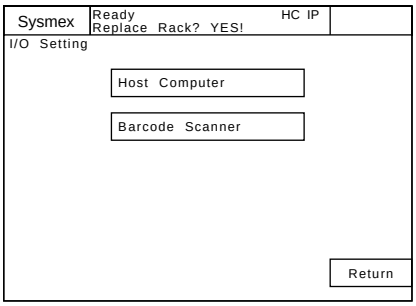
This program allows setting the interface conditions for the host computer.

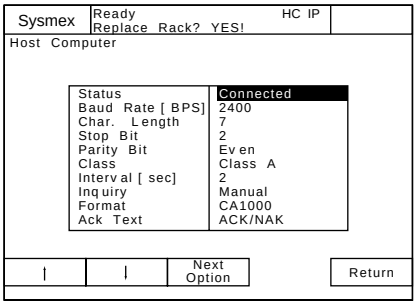
1. Press **[I/O Setting]** key on the Setting Menu screen.

   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 "Not connected". 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", "2400", "4800", "9600".
Character Length	Sets data bit length of RS232C. Select "7-bit" or "8-bit".
Stop Bit	Sets stop bit length of RS232C. Select "1-bit" or "2-bit".
Parity	Sets the protocol of RS232C parity check. Select "None", "Odd", or "Even".
Class	Sets the protocol of transfer. Select "Class A" (No response) or "Class B" (With response)

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Interval [sec]	Sets interval of transfer to the host computer. Select “0”, “2”, “3”, “5”, “7”, “10”, “15”.
Inquiry	Sets how to make inquiry. Select “Auto” or “Manual”.
Format	Sets output format. Select “CA1000”, “CA500” or “ASTM”.
ACK Text	Sets ACK Text mode. Select “STX-ACK-ETX”, or “ACK/NAK”.

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 bar-code label.

5. When setting is completed, press **[Return]** key.

   The Renew Confirmation screen will appear. Press the appropriate key.

Barcode (Only for Instrument with Barcode-Scanner)

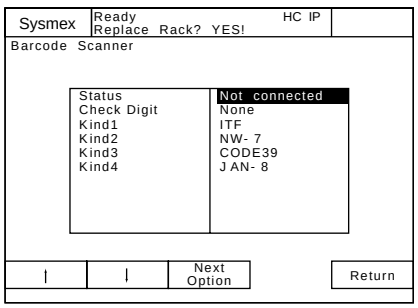
This program allows setting the conditions for using barcode.

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.)

Status	Sets connection with the barcode scanner. Select “Connected” or “Not connected”.
Check	Sets Check Digit. None: No Check Digit. Mod. 11: Modulus 11 W Mod. 11: Weighted Modulus 11 Mod. 43: Modulus 43 Mod. 10: Modulus 10
Kind 1-4	Sets the types of barcode. None/ITF/NW-7/CODE39/JAN-13/JAN-8/CODE128 Selecting identical barcodes (excluding “None”) is an error.

5. 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.

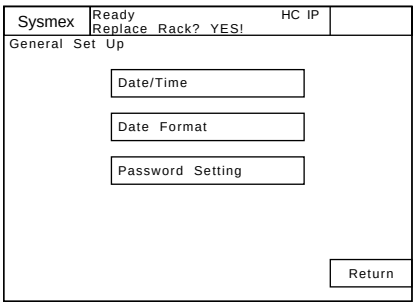
The instrument has a built-in clock, so there is no need to set date and time every day. Should the power be turned off, the built-in clock is powered by an internal battery.

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

   The General Set Up Menu screen will appear.

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

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



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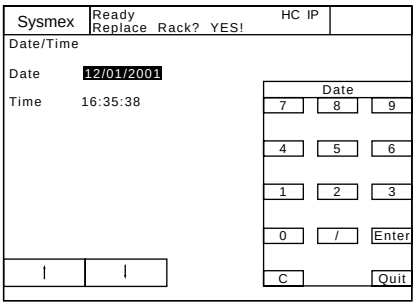


3. Using **[↑]** and **[↓]** keys, move the cursor to select Date or Time.
4. Using the numeric keys, set Date and Time, and press **[Enter]** key.

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

> **Important**
> - 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.

5. 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.

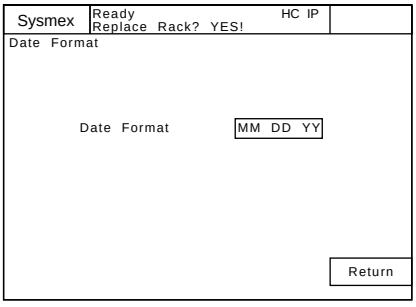
Date format is available in three types:

- 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.

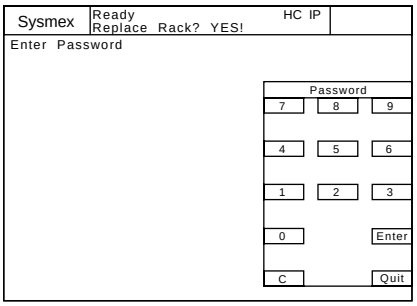
> Note
> When **[C]**, **[0]**, **[Enter]**, **[Quit]**, or **[Fix]** key is used to set as a password, password check is not done, and the Password Entry screen will be skipped.

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

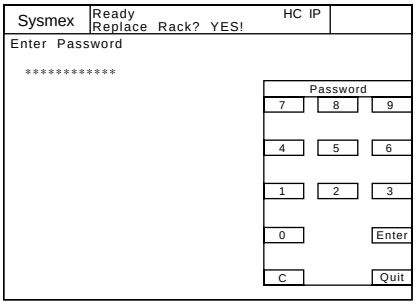
   The General Set Up Menu screen will appear.

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.

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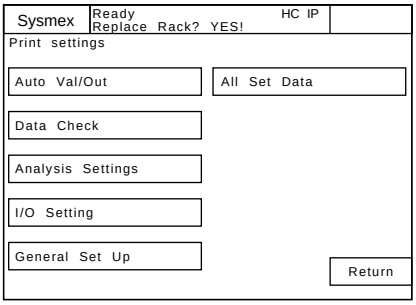
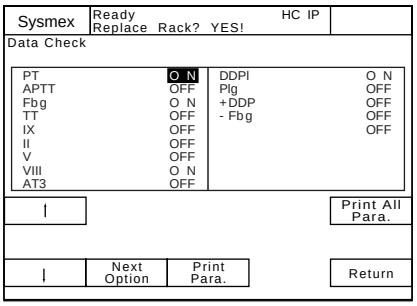
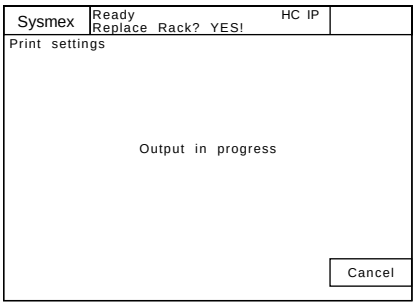
10.17 Printout of Settings







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”, “D-4”, “D-3”, “Reag Vial” , “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.

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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	2 mL	GW5	
			4 mL	GW5	
			10 mL	–	Reagent must be transferred before use. *
	Dade® Innovin® Reagent	PT INN	10 mL	–	Reagent must be transferred before use. *
			20 mL	–	Reagent must be transferred before use. *
	Dade® Thromboplastin C•Plus	PT TPC+	4 mL	GW5	
			10 mL	–	Reagent must be transferred before use. *
APTT	Pathromtin° SL	PTT PSL	5 mL	GW5	
	Dade® Actin® Activated Cephaloplastin Reagent	PTT ACT	2 mL	GW5	
			10 mL	–	Reagent must be transferred before use. *
	Dade® Actin® FS Activated PTT Reagent	PTT FS	2 mL	GW5	
			10 mL	–	Reagent must be transferred before use. *
	Dade® Actin® FSL Activated PTT Reagent	PTT FSL	2 mL	GW5	
			10 mL	–	Reagent must be transferred before use. *
	Calcium Chloride Solution (0.025 mol/L)	CaCl2	15 mL	–	Reagent must be transferred before use. *
Fbg	Dade® Thrombin Reagent	Fbg	1 mL	GW5	
			5 mL	–	Reagent must be transferred before use. *
TT	Test Thrombin Reagent	Test Thr	5 mL	GW5	
II	Clotting Factor-II Deficient Plasma**	II	1 mL	GW5	
V	Clotting Factor-V Deficient Plasma**	V	1 mL	GW5	
VII	Clotting Factor-VII Deficient Plasma**	VII	1 mL	GW5	
X	Clotting Factor-X Deficient Plasma**	X	1 mL	GW5	
VIII	Clotting Factor-VIII Deficient Plasma**	VIII	1 mL	GW5	
IX	Clotting Factor-IX Deficient Plasma**	IX	1 mL	GW5	
XI	Clotting Factor-XI Deficient Plasma**	XI	1 mL	GW5	
XII	Clotting Factor-XII Deficient Plasma**	XII	1 mL	GW5	
LA1	LA1 Screening Reagent***	LA1	2 mL	GW5	

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Test Name	Reagent	Reagent Name	Volume	Vial Type	Remark
LA2	LA2 Confirmation Reagent***	LA2	1 mL	GW5	
BXT	Batroxobin Reagent	Batrox	5 mL	GW5	
AT3	Berichrom° Antithrombin III (A)	AT3Thro	15 mL	–	Reagent must be transferred before use. *
		AT3Subs	3 mL	GW5	
APL	Berichrom° α2-Antiplasmin	AplReag	5 mL	GW5	
		PlSubs	2 mL	GW5	
Plg	Berichrom° Plasminogen	Strepto	5 mL	GW5	
		PlSubs	2 mL	GW5	
BCPC	Berichrom° Protein C	BCPCAct	10 mL	–	Reagent must be transferred before use.*
		BCPCSub	3 mL	GW5	
Hep	Berichrom° Heparin	AT3Reag	1 mL	GW5	
		FXaReag	10 mL	–	Reagent must be transferred before use.*
		HepSubs	2 mL	GW5	
DDPl	D-Dimer PLUS***	DD.Pl.A	5 mL	GW5	
		DD.Pl.R	4 mL	GW5	
AdDD	Advanced D-Dimer****	Ad.DD.A	5 mL	GW5	
		Ad.DD.R	4 mL	GW5	
PFDP	Latex Test BL-2 P-FDP*****	PFDP.B	5 mL	–	Reagent must be transferred before use. *
		PFDP.L	5 mL	–	Reagent must be transferred before use. *
	P-FDP Diluent	PFDP.SB	40 mL	–	Reagent must be transferred before use. *
	CA CLEAN I	CleanI	50 mL	–	Reagent must be transferred before use. *
	CA CLEAN II	CleanII	500 mL	–	Reagent must be transferred before use. *
			5 L	–	Reagent must be transferred before use. *
	Owren's Veronal Buffer	OVB	500 mL	–	Reagent must be transferred before use. *

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(*) This reagent cannot be used, but require use of the below containers and adapters.

Container	Adapter
Cup	Holder No. 89 (363-2558-6)
Reag Vial	None
SLD Vial	None

(**) Data evaluated for Factors VII and VIII only.

(***) Not available for use in the USA.

(****) Only available for use in the USA.

(*****) Only available for use in Asia.

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11. Maintenance and Supplies Replacement 11-1

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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

- Check Printer Paper Supply (Refer to Section 11.8.)
- Replace Fuse (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.)
- Clean Instrument (Refer to Section 11.12.)

Supplies Replacement

- Replenish Reagent (Refer to Section 11.13.)
- Replenish Reaction Tubes (Refer to Section 11.14.)
- Replenish Rinse Solution (Refer to Section 11.15.)

Carefully read the following **Warning** and **Caution** before conducting maintenance of the instrument and replacing supplies, to ensure safe operation.

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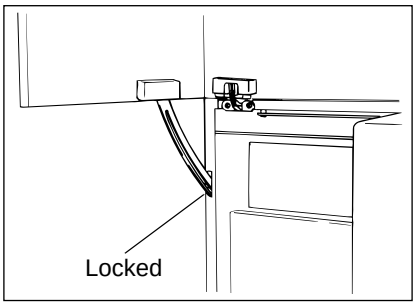

Warning

The light shield cover is designed to be locked when fully opened. When you open the light shield cover to start servicing, make sure that the cover locks. If it does not, the cover could fall and cause injuries to your head, etc.

Risk of Infection

Be sure to wear latex or non latex examination gloves before starting maintenance. After the maintenance is completed, wash hands with antiseptic solution. If hands should be contaminated by blood, there is a hazard of infection by pathogenic bacteria.

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.

Risk of Infection

- The end of the sample probe is sharp. Handle with sufficient caution.
- When cleaning the probe, always wear latex or non latex examination gloves. Wipe off the sample probe from top to bottom. After completion of operation, be sure to wash hands with antiseptic solution. Should hands be contaminated with blood, there is a hazard of infection by pathogenic bacteria, etc. Also, medical waste and infective waste should be properly disposed of.

1. Press **[Special Menu]** key on the Root Menu screen.
   The contents of the Root Menu will change over.
2. Press **[Rinse Probe]** key on the Root Menu screen.
   The Rinse Probe screen will display “OK to rinse Probe?”

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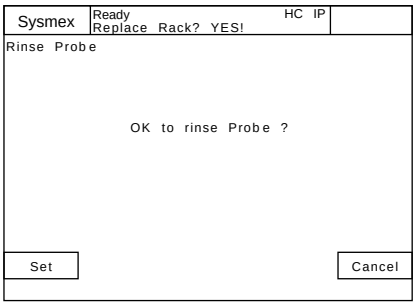
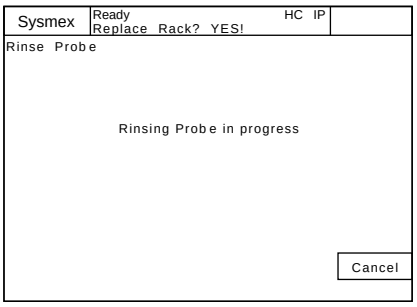


3. Press **[Set]** key or **[Cancel]** key on the Rinse Probe screen.

   [Set] key: Executes Probe Rinse Operation.

   [Cancel] key: Cancels Probe Rinse Operation and returns the screen to the Root 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.

Caution

If the operation is canceled, restart it immediately. Otherwise, CA CLEAN I may remain in the probe, causing incorrect analysis results.

Note

CA CLEAN I aspiration and pipette rinsing take about 3 minutes.

5. Probe rinse operation ends.

   When rinse operation is over, the Root Menu screen will return.

11.3 Discard Used Reaction Tubes

The used reaction tubes automatically fall into the trash drawer. At completion of the analyses, discard the used reaction tubes from the trash drawer and clean it. Capacity of trash drawer is approximately 60 tubes.

Risk of Infection

When discarding used reaction tubes, always wear latex or non latex examination gloves. After completion of operation, be sure to wash hands with antiseptic solution. Should hands be contaminated with blood, there is a hazard of infection by pathogenic bacteria, etc. Also, medical waste and infective waste should be properly disposed of.

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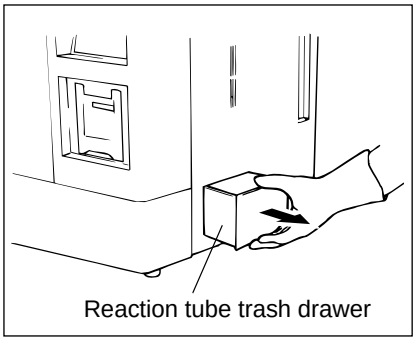
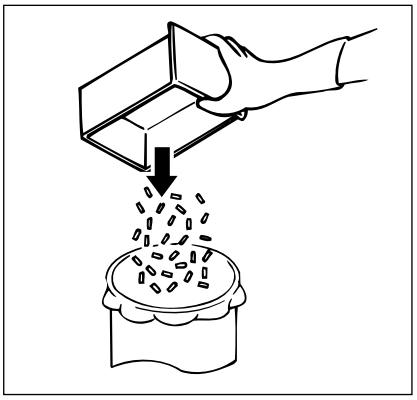


1. Pull out the reaction tube trash drawer from the instrument's right side panel.



2. Discard the used reaction tubes.
3. Clean the reaction tube trash drawer with tap water.
4. Dry the reaction tube trash drawer and restore it in place.

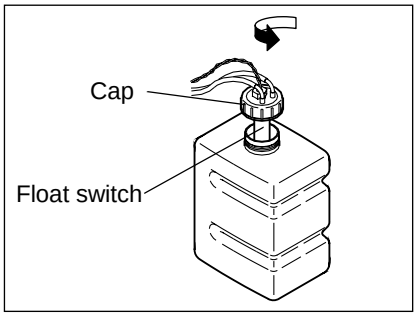
11.4 Dispose of Waste

When a day's analyses are completed, or when the waste bottle is full, discard the waste that has collected in the waste bottle.

Risk of Infection

When disposing of waste, always wear latex or non latex examination gloves. After completion of operation, wash hands with antiseptic solution.

Should hands be contaminated with blood, there is a hazard of infection by pathogenic bacteria, etc. Also, medical waste and infective waste should be properly disposed of.



1. Turn the cap of the waste bottle counterclockwise and take out the float switch.
2. Discard waste liquid.

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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.

Caution

When the bottle has become full after the dispensing of all samples, the Analysis Start Confirmation screen will not appear.

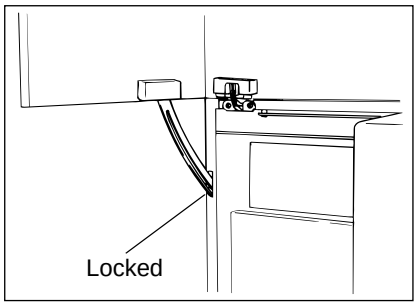
Important

When analysis is made or the power is turned off 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 standing upright.

11.5 Remove Dew from Reagent Rack (for CA-530, CA-540, CA-550 and CA-560 only)

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 confirm that it is locked.



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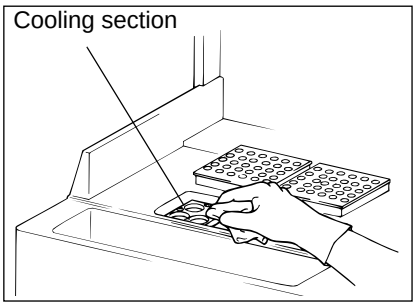
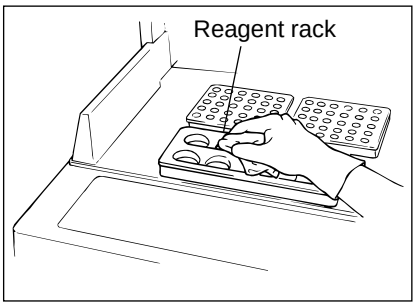


2. Use paper towel or lint-free tissue to wipe off any condensation from the cooling section.

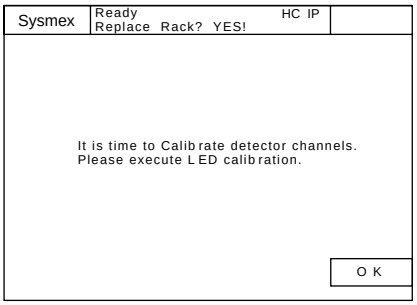


3. Insert paper towel or lint-free tissue into the four holes on the left side of the reagent rack and wipe off any condensation.
4. Close the light shield cover.

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 **[Calibration]** key.

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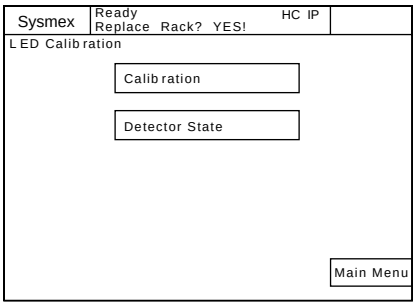
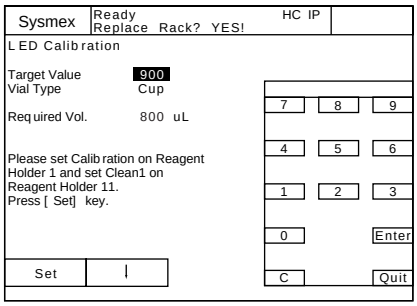


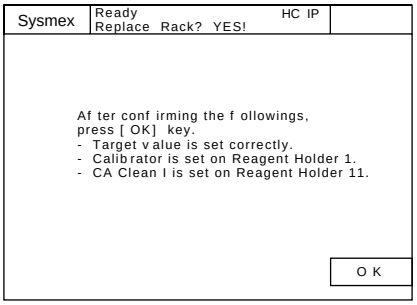
The LED Calibration Menu screen will appear.

> **Note**
> The last calibration day and a present status can be checked by pressing **[Detector State]** key.

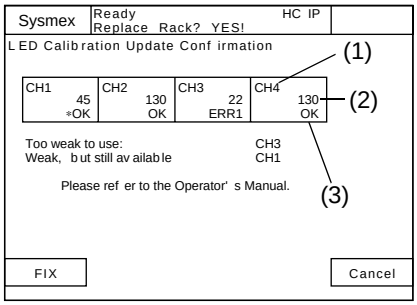
4. Press **[Calibration]** key.
   The LED Calibration screen will appear.



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.
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.

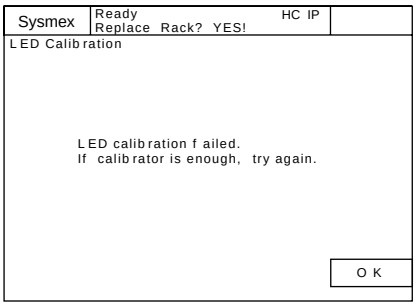
(2) LED status

(3) OK: Available

*OK: Available. However, replacement is required within a few months.

ERRxx: Not available

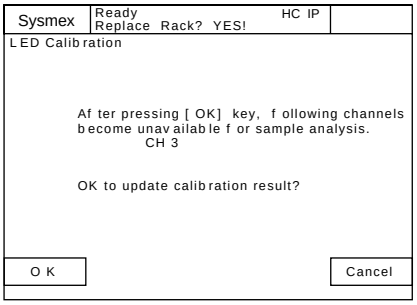
> **Caution**
> If the calibration process has failed, the message prompting to restart LED calibration will be displayed.



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.

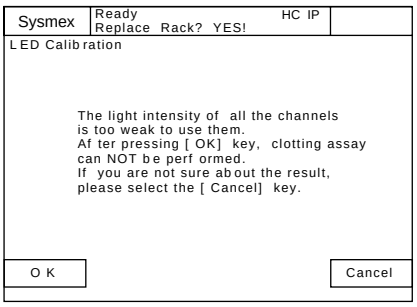


When there is a channel with a calibration error

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.

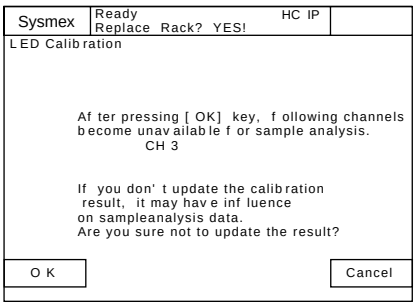
Pressing **[Cancel]** key to abandon the new adjustment value, returns to the LED Calibration screen.

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.

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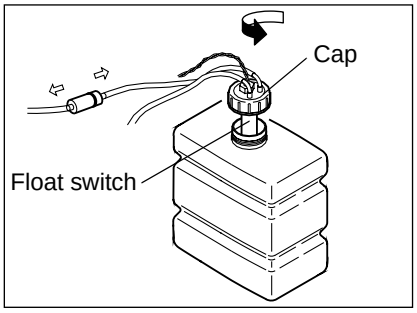
11.7 Replace Rinse Filter

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.

> **Important**
> Prepare a damp towel or a tissue paper to absorb the rinse fluid dropping from the tubings.

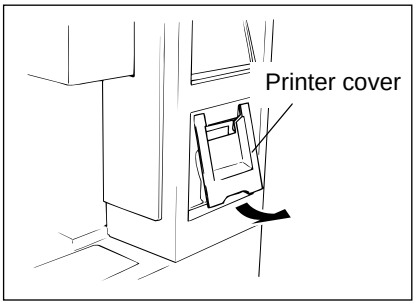
4. Install a new Rinse Filter so that the side with the black marking enters to the Rinse Bottle. Tightly cap the cap of the Rinse Bottle. Then, turn ON the power to resume normal operation.

11.8 Supply Printer Paper

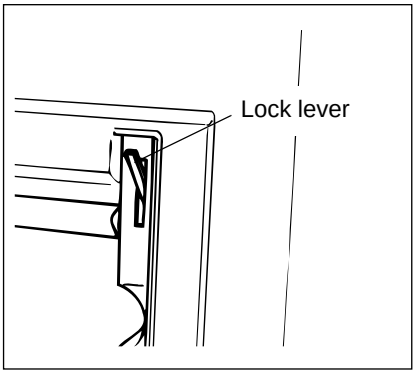
When the built-in printer has run out of paper, replenish printer paper by the following procedure:

1. Remove the printer cover.

   The printer cover can be removed by raising its lower edge.



2. Raise the lock lever to unlock.



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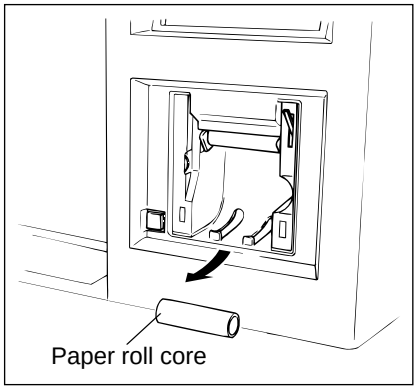
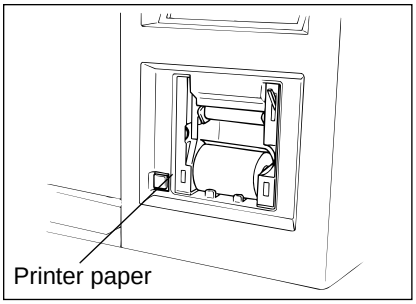
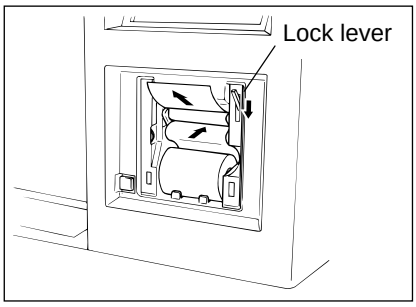
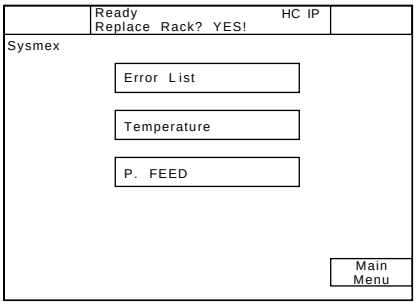


3. Remove the paper roll core and attach a new printer paper roll.





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.

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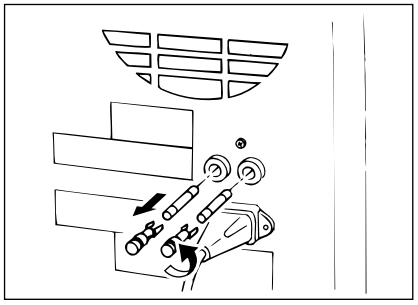
11.9 Replace Fuse

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. Using a screwdriver, turn the fuse cap holders counterclockwise and remove them from the rear panel.
3. Replace the fuses and attach the fuse cap holders by turning them clockwise.

> **Warning**
> For continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

Specification	Part No.	Description	Fuse Type
117 VAC	266-5106-0	Fuse 250 V 6.3 A ST4-6.3A-N1 (N.Amer)	Time Lag
220-240 VAC	266-5293-0	Fuse 250 V 3.15 A No. 19195 (Europe)	Time Lag

11.10 Check and Drain Trap Chamber

Check the water level in the trap chamber and drain water that has collected.

> **Risk of Infection**
> In draining the trap chamber, always wear latex or non latex examination gloves. Upon completion of operation, wash hands with antiseptic solution.
> If hands are contaminated with blood, there is a hazard of infection by pathogenic bacteria.

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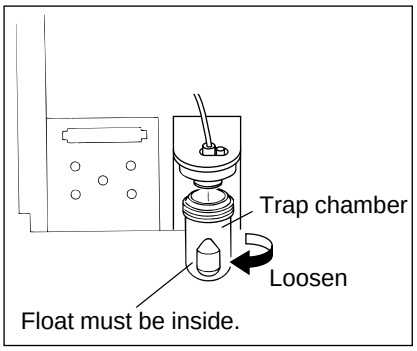


1. Remove the chamber.

   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

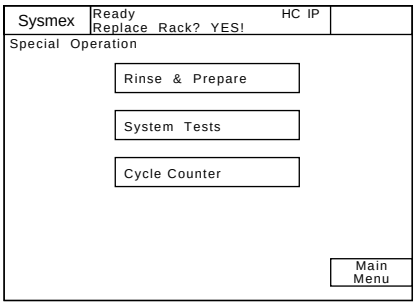
In case the instrument has been left idle for a long period, refill the hydraulic line with rinse solution.

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

   The contents of the Root Menu will change over.

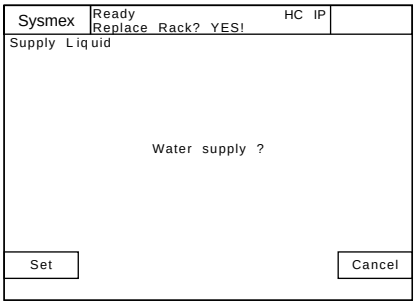
2. Press **[Special Operate]** key on the Root Menu screen.

   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]: Cancels water supply and returns the screen to the Special Operate Menu.

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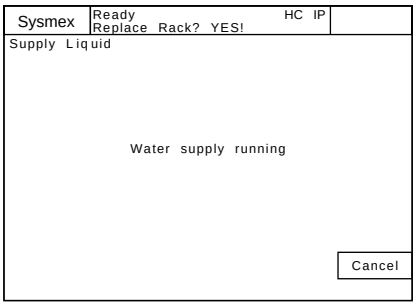


5. Press **[Set]** key. Water supply will begin and the message “Water supply running” will appear. To stop water supply while it is in progress, press **[Cancel]** key.

> **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 Clean Instrument

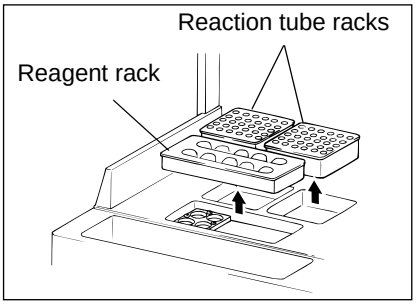
To ensure instrument reliability, clean it in periodic intervals.

> **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. Upon completion of cleaning, wash hands with antiseptic solution. If hands should be contaminated with blood, there is a hazard of infection by pathogenic bacteria.

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 make sure the lock is engaged.
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.

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5. Close the light shield cover.

> **Important**
> Never use any other cleaning solution than water and neutral detergent. Otherwise, the surface coating may be damaged.

11.13 Replenish Reagent

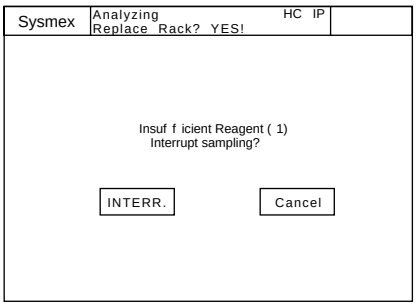
When reagent has become insufficient, the error message “Insufficient Reagent (1 - 12)” will appear, and the alarm will sound. Replenish the insufficient reagent (No. 1 - 12).

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 be come 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.

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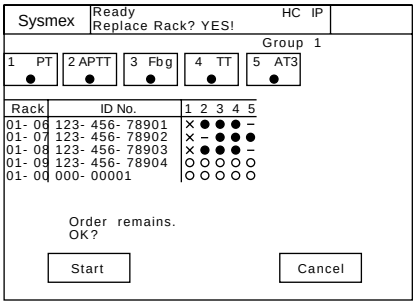


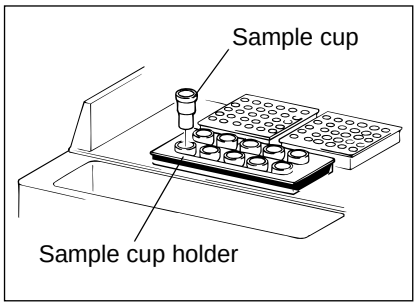
3. When analysis of dispensed samples is over, the Analysis Start Confirmation screen will appear.

> **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. Otherwise, correct result will not be obtained.



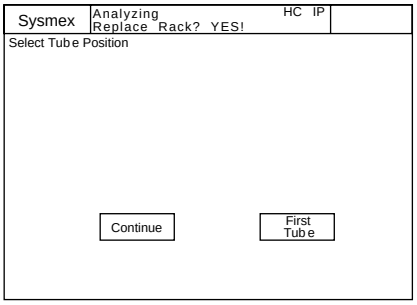
5. Open the light shield cover and make sure the lock is engaged.
6. Set the reagent bottles in the reagent holder. If the sample cup holder is set, feed reagent into the sample cups.
7. Close the light shield cover.
8. Press **[Start]** key or **[Cancel]** key on the Analysis Start Confirmation screen.

   [Start] key: Starts analysis after interruption.

   [Cancel] key: Stops analysis and returns the screen to the Root Menu.

> **Important**
> 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.

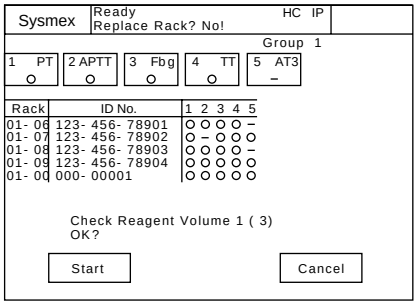
   The screen confirming the first tube position will appear.

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 Root Menu.

Important

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".

11.14 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.

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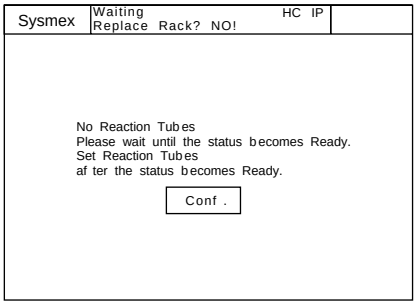
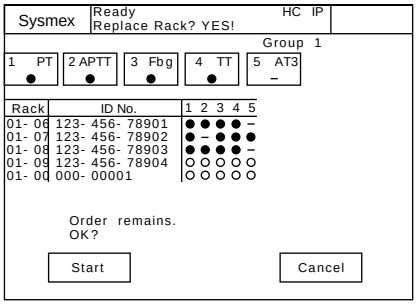
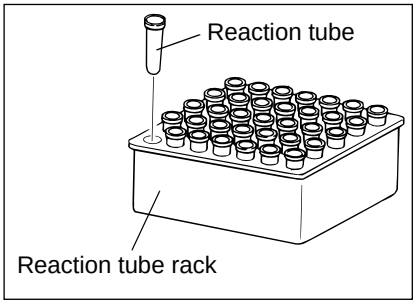


2. Press **[Conf.]** key.

   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 make sure the lock is engaged.



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.

> **Caution**
> Reaction tubes are for single use only or incorrect result may occur.

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.

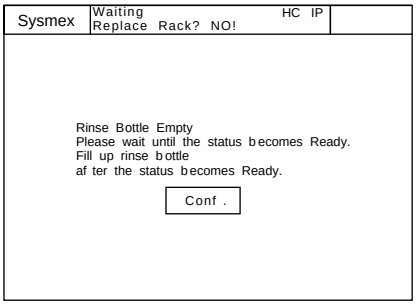
   [Cancel] key: Interrupts analysis and returns to the Root Menu screen.

> **Important**
> 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.

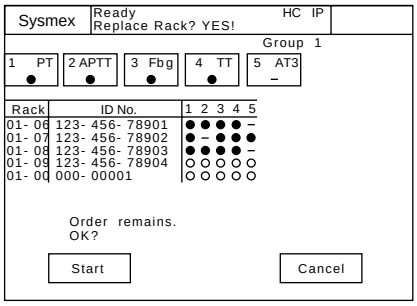
11.15 Replenish Rinse Solution

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.

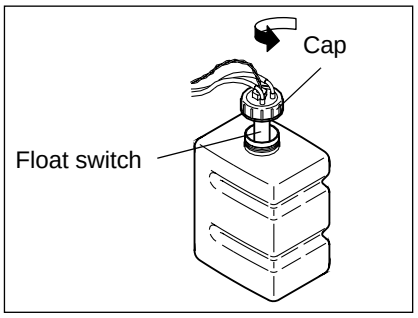
   The alarm stops and “Waiting” screen will appear. When analysis of samples being incubated is complete, analysis is interrupted.



2. The Analysis Start Confirmation screen appears.

   When analysis of the samples being incubated is complete, the Analysis Start Confirmation screen appears.

> **Caution**
> Do not open the cap of the rinse bottle or waste bottle until the Root Menu screen or Analysis Start Confirmation screen is displayed.



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 Root Menu.

> **Caution**
> - When analysis is made with the rinse bottle laid down, there is a possibility that correct analysis result may not be obtained. Make sure the rinse bottle is standing upright.

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Caution

- 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.

Note

The parameters whose analyses were interrupted or those whose analyses failed are marked with “X” in Work List.

11.16 Supply Parts List

Part No.	Description	Remarks
964-0631-3	CA CLEAN I (GSA-500A)	Detergent, 50 mL per bottle
266-5293-0	Fuse 250V 3.15A No. 19195 (Europe)	
266-5106-0	Fuse 250V 6.3A ST4-6.3A-N1 (N.Amer)	
663-0212-2	Sample Tube Spacer 10 mm Diamet	for STAT Sample Holder 
663-0213-6	Sample Tube Spacer 13 Phi	for STAT Sample Holder 
366-1231-8	Tube Holder No. 58	for Sample Rack 
366-1291-1	Tube Holder No. 113	for Sample Rack 

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Part No.	Description	Remarks
363-2536-4	Holder No. 70 (Sample cup adapter)	for Sample Rack 
363-2558-6	Holder No. 89	for Reagent Rack 
363-2559-0	Holder No. 90 (TTO)	for Reagent Rack 
921-0351-8	Paper Thermal F1-2 (5/pack)	Thermal paper for the built-in Printer, 5 rolls per pack
541-1352-1	Push Vial PV-10	Reagent vial
013-1771-4	SLD Vial Assy (10/pack)	Reagent vial
904-0721-9	Reaction Tube (SU-40) (3,000/box)	Common supply with CA-1000 
664-0167-9	Filter Assy for Rinse Bottle	
424-1250-6	Sample Cup Conical 2 mL	
424-1251-0	Sample Cup Conical 4 mL	
424-3303-3	Sample Rack No. 3	
833-3895-6	Sample Rack No. 3 w/Holder #55	
663-0207-3	Reaction Tube Trash Box	

Warning

CA CLEAN I is a alkaline solution. Avoid contact with it. If you get it on your skin or clothing immediately wash it off with large volumes of water.

Note

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

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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 Root 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.

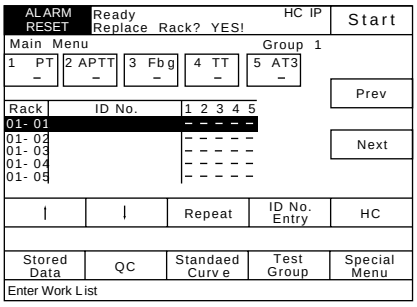
Troubleshooting Guide

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.

[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 “8.3 QC File Setting”.

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[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 "9.5 Set Reagent Information".

[Check Reagent Volume 1 (Reagent Holder No.)] <Attention-calling message>

Probable Cause	When reagent volume monitoring is set to "v"; 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. 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	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	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.

[HC ACK Code 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 ACK 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.

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[HC Communication Error]
[HC CTS Time Out]

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 ETX 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 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.

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[Instructions Not Found in HC]

Probable Cause	1) When inquiry was made to the host computer, No Order (000) 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 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.

[No Paper]

Probable Cause	1) No printer paper is set.
Corrective Action	1) Set printer paper. Refer to “11.8 Supply Printer Paper”.

[No Reaction Tubes]

Probable Cause	1) No reaction tubes. 2) Reaction tube position error.
Corrective Action	1) Replenish reaction tubes.

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[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 “11.8 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.

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[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.

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[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.

[Reset Sample Rack] <Attention-calling message>

Probable Cause	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	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.

[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.

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[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.

[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.

[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.

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[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.

[Tube Catch Error (Position)]

Probable Cause	1) Failure to catch a reaction tube. 2) The reaction tube catch mechanism is faulty.
Corrective Action	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	1) Failure to release reaction tube.
Corrective Action	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.

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[Turned Off During Operation] <Attention-calling message>

Probable Cause	1) Power switch was turned off during operation.
Corrective Action	1) Discard any reaction tubes remaining in the detector wells and re-test.

[Vacuum Pump Error]

Probable Cause	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	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.

[Voltage Low Limit]

Probable Cause	1) Momentary power failure occurred. 2) The voltage to the power supply is fluctuating.
Corrective Action	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	1) The waste bottle is full. 2) The float switch connector in the waste bottle is disconnected.
Corrective Action	1) Dispose of waste liquid. 2) Connect the float switch connector.

[X Axis Home Position Error]
[Y Axis Home Position Error]

Probable Cause	1) Something is impairing XY mechanism operation. 2) XY mechanism operation error.
Corrective Action	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.

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[Z Axis Down Error]

[Z Axis Home Position Error]

Probable Cause	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	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.

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12.3 Analysis Data Error

Coagulation 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.	Carry out dilution, etc., then reanalyze.
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.

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Chromogenic Method/Immunology 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 Immunology Method).	Carry out dilution or take other steps, then reanalyze. On DDPl*, analyze +DDP*, AdDD**, +AdD**.
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.

(*) Not available for use in the USA.

(**) Only available for use in the USA.

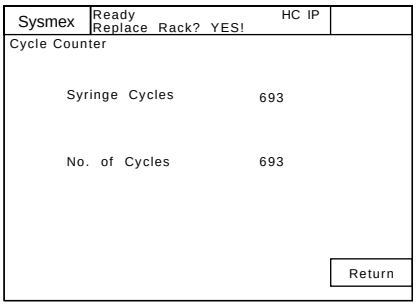
12.4 Cycle Counter

This program allows checking the cycles of each unit to confirm the instrument performance.

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 **[Cycle Counter]** key.

   The Cycle Counter screen will appear.

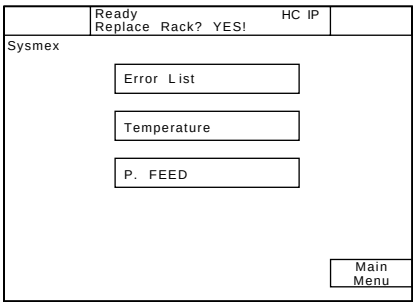


   Syringe Cycles: The No. of cycles that the syringe motor has turned to measure a predetermined volume of reagent or plasma. One count is made per cycle.

   No. of Cycles: The accumulated total No. of counts that the instrument has made analysis. One parameter is counted once.

   - When syringe cycles exceed 300,000, the error message “Check Syringe Unit” is displayed each time analysis begins.
4. Press **[Return]** key to quit the program.

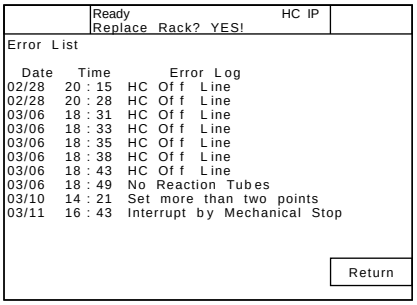
12.5 Sysmex Menu



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 10 messages are recorded and displayed.



1. Press **[Sysmex]** key.

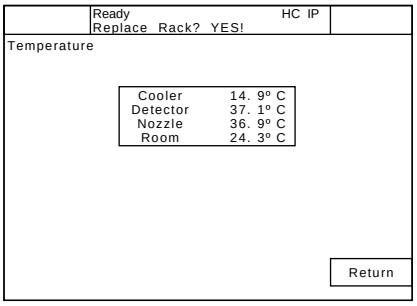
   The Sysmex Menu screen will appear.
2. Press **[Error List]** key.

   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.

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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.

12.6 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”.

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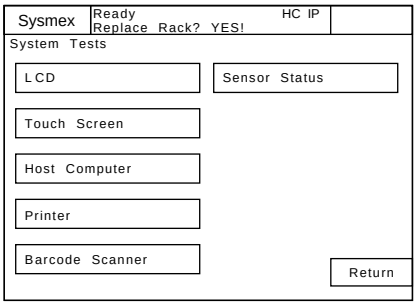
System Tests Menu screen



Whether the electrical system and software system of this instrument are operating properly or not can be checked by executing System Tests.

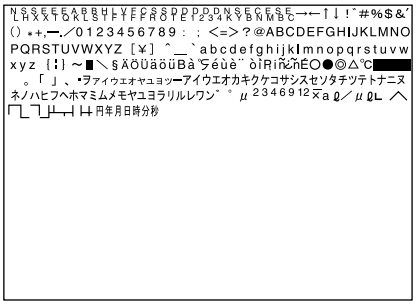
Perform the tests on the System Tests Menu screen. Follow the steps shown below to display the screen.

1. Press **[Special Menu]** key on the Root Menu screen to display **[Special Operate]** key.
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



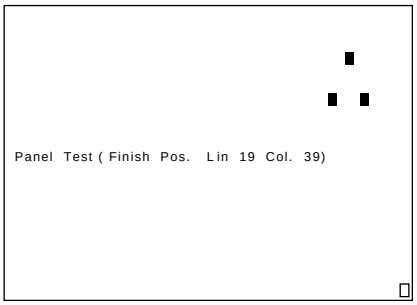
This program checks whether LCD display can be performed properly or not.

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.

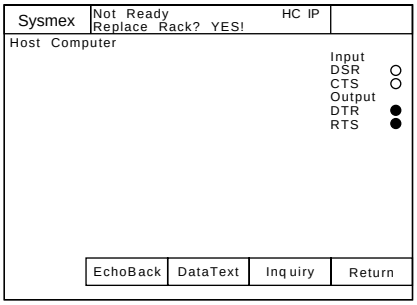
> **Note**
>
> - The touched place on the panel is highlighted.
>   When the same place is touched again, the display returns to the original one.
> - The touch panel can recognize a key of 20 lines x 40 rows.

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.

[Inquiry] key: Makes an inquiry and transmits ACK or NAK.

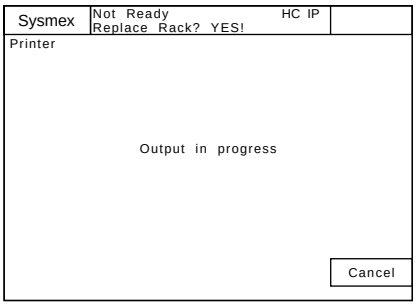
[Return] key: Ends the program. (Returns to the System Test Menu screen.)

> Note
>
> - When Host Computer Status is set “Not Connected”, **[EchoBack]**, **[DataText]** and **[Inquiry]** 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 **[Inquiry]** 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

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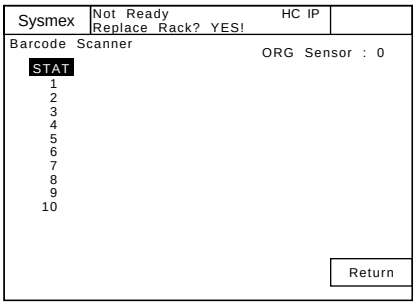
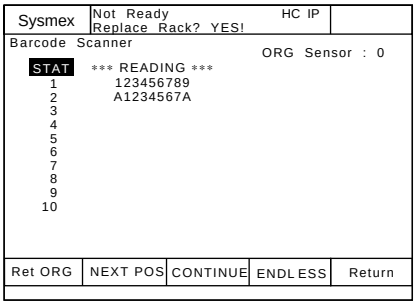
Barcode Scanner





1. 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.

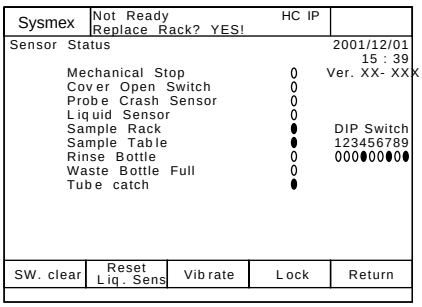
   [CONTINUE] key: Moves the barcode scanner to the home position at the right, moves the rack position leftward from STAT sample to 10th sample for reading, then displays the results.

   [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.



1. 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.

2. To quit the program, press **[Return]** key.

13. Functional Description 13-1

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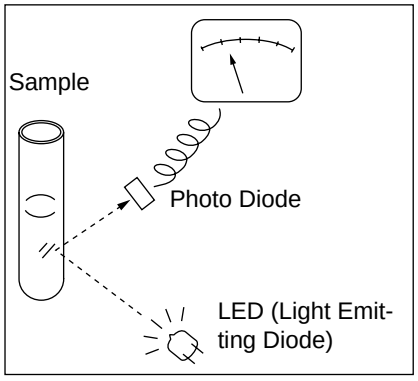
13. Functional Description

This chapter explains the detection principles, analysis methodology, and individual analysis procedures in the instrument.

13.1 Detection Principle of Coagulation Method (PT, APTT, Fbg, TT, PCcl, BXT, LA1*, LA2*, Factor Deficiency)

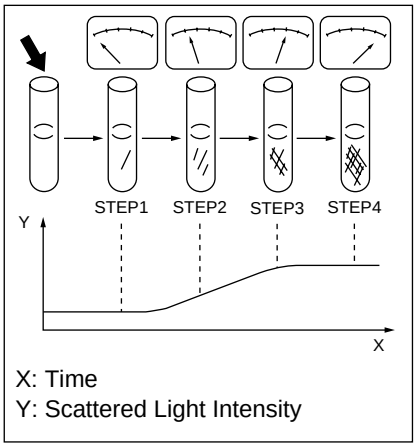
The instrument employs the photo-optical clot detection method. By using a red light (660 nm) to illuminate the sample plasma/reagent mixture, the instrument detects the changes in scattered light intensity due to increased turbidity as Fibrinogen changes to Fibrin. The coagulation curve is drawn by 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.

(*) Not available for use in the USA.

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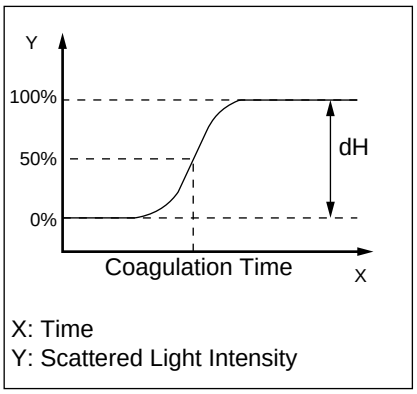
Percentage Detection Method



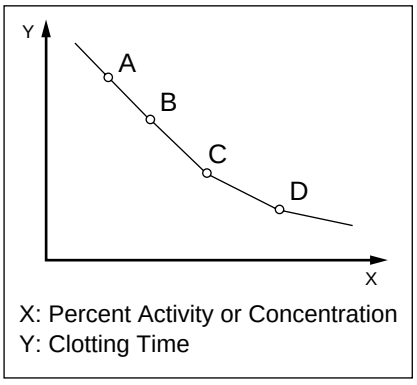
X: Time
Y: Scattered Light Intensity

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.

Coagulation Method Using Standard Curve



X: Percent Activity or Concentration
Y: Clotting Time

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.

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 “9.6 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)

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.

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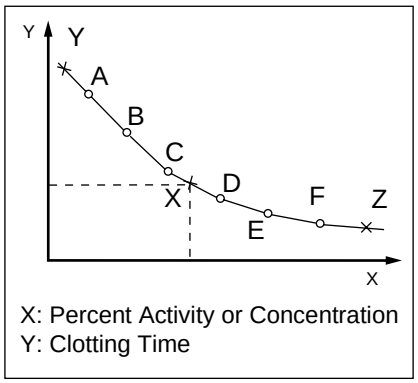

X: Percent Activity or Concentration
Y: Clotting Time

Calculation Principle

(a) 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.

(b) 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.

(c) 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

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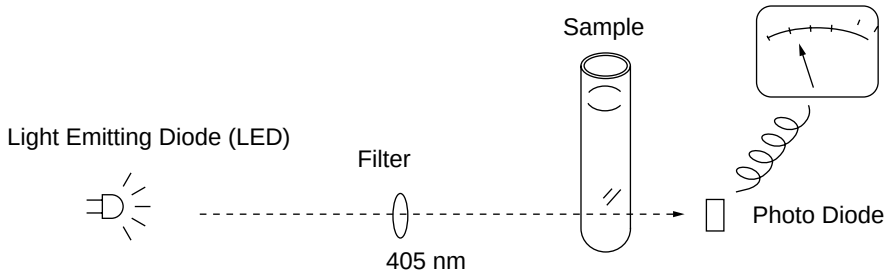
13.2 Detection Principle of Chromogenic Method (AT3, APL*, Plg*, PC, Hep : CA-530, CA-540, CA-550 and CA-560 only)

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.



(*) Not available for use in the USA.

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.

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13.3 Detection Principle of Immunology Method (D-Dimer, P-FDP* : CA-550 and CA-560 only)

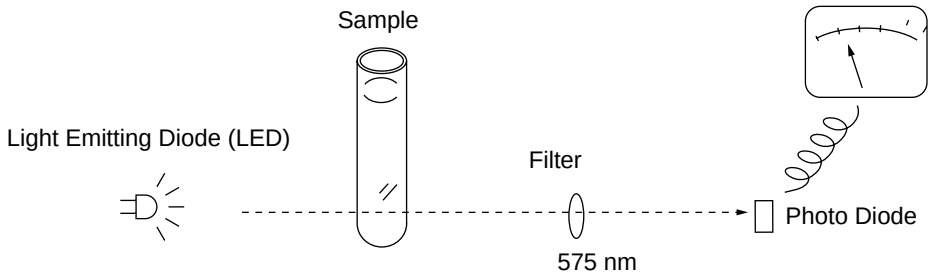
After a predetermined volume of sample has been warmed for a certain time period, stabilizing reagent and antibody sensitive reagent are added.

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 (ΔOD/min) is determined.



(*) Not available for use in the USA.

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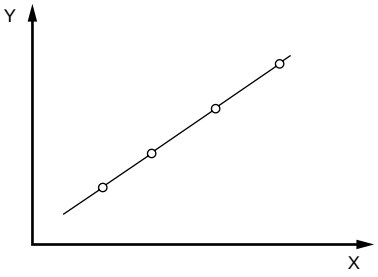
Calculating the Change in Light Absorbance

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 Immunological Method



X: Percent Activity or Concentration (real number)
Y: Change in light absorbance (real number)

A functional relationship exists between the change in light absorbance (ΔOD/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.

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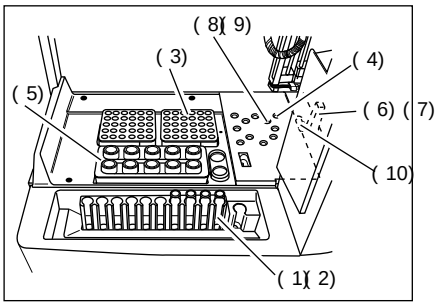
13.4 Analysis Mechanism



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.

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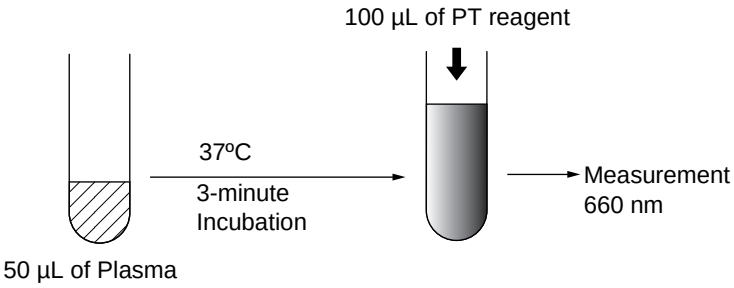
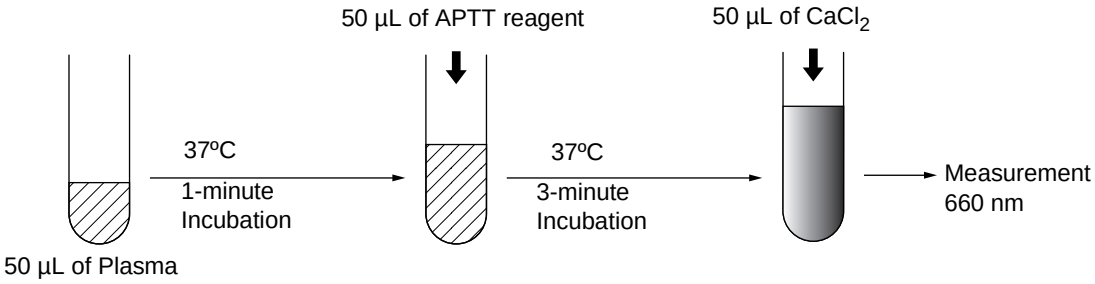
PT Flow



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. Draw a new standard curve after the new APTT Incubation Time is set.
- 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.
- The factory configuration is set at 120 sec at time of shipment.

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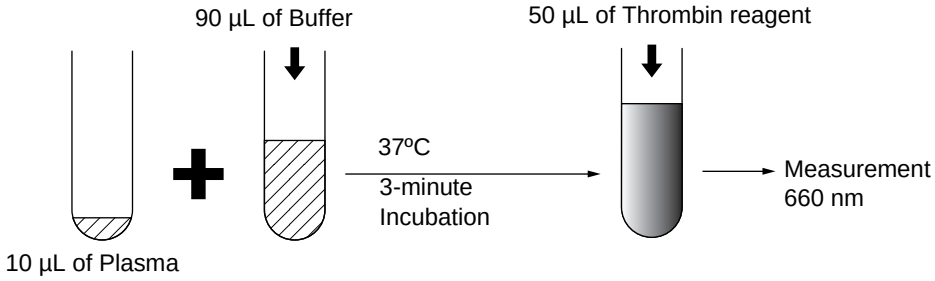
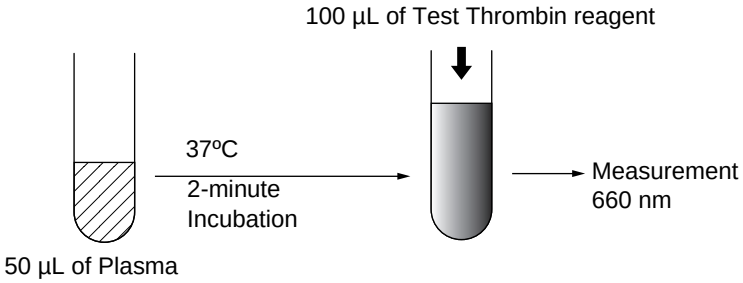
Fibrinogen Flow



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



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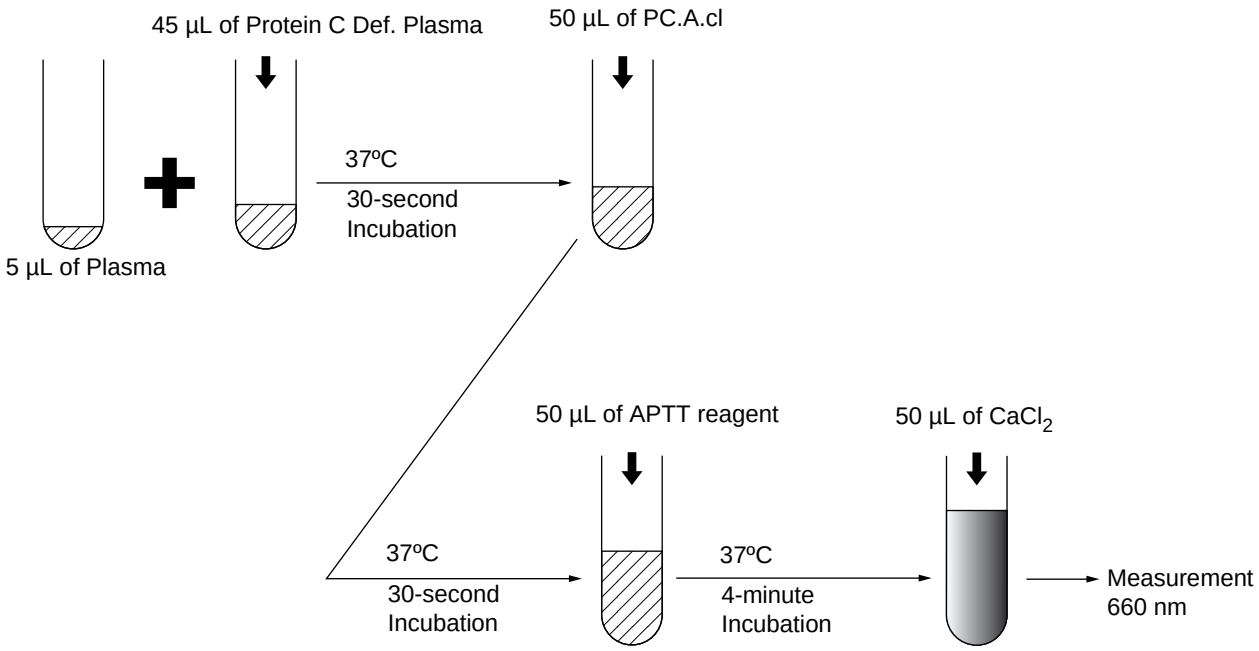
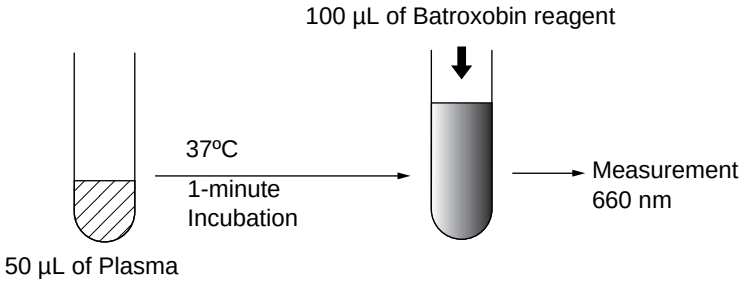
PCcl Flow



BXT Flow



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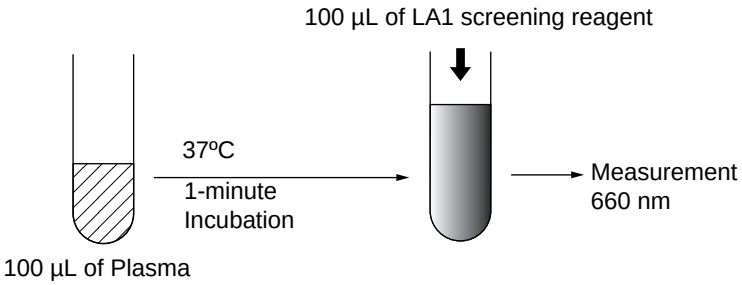
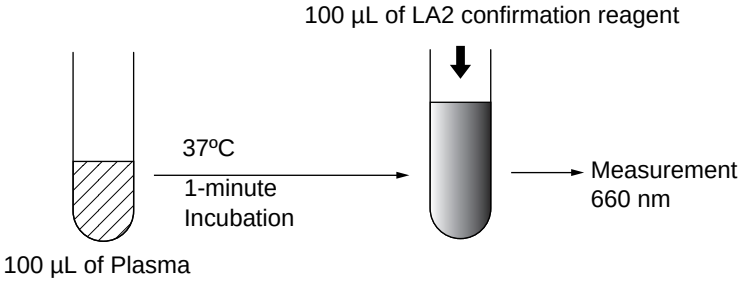
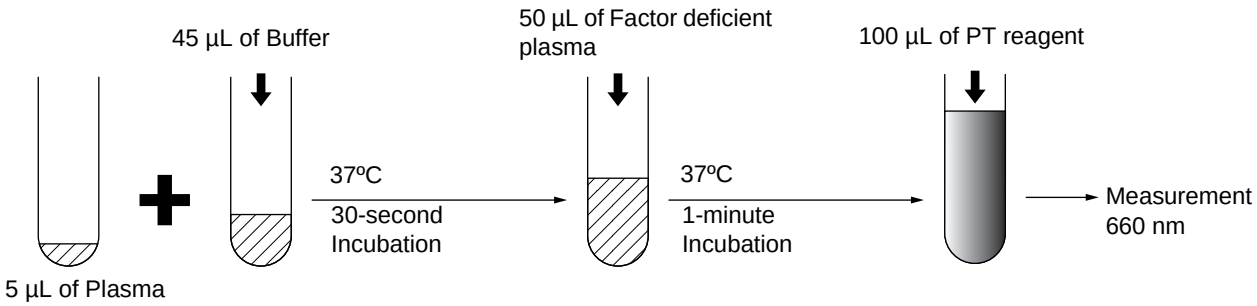
LA1 Flow*



LA2 Flow*



Extrinsic Factor Assay Flow



(*) Not available for use in the USA.

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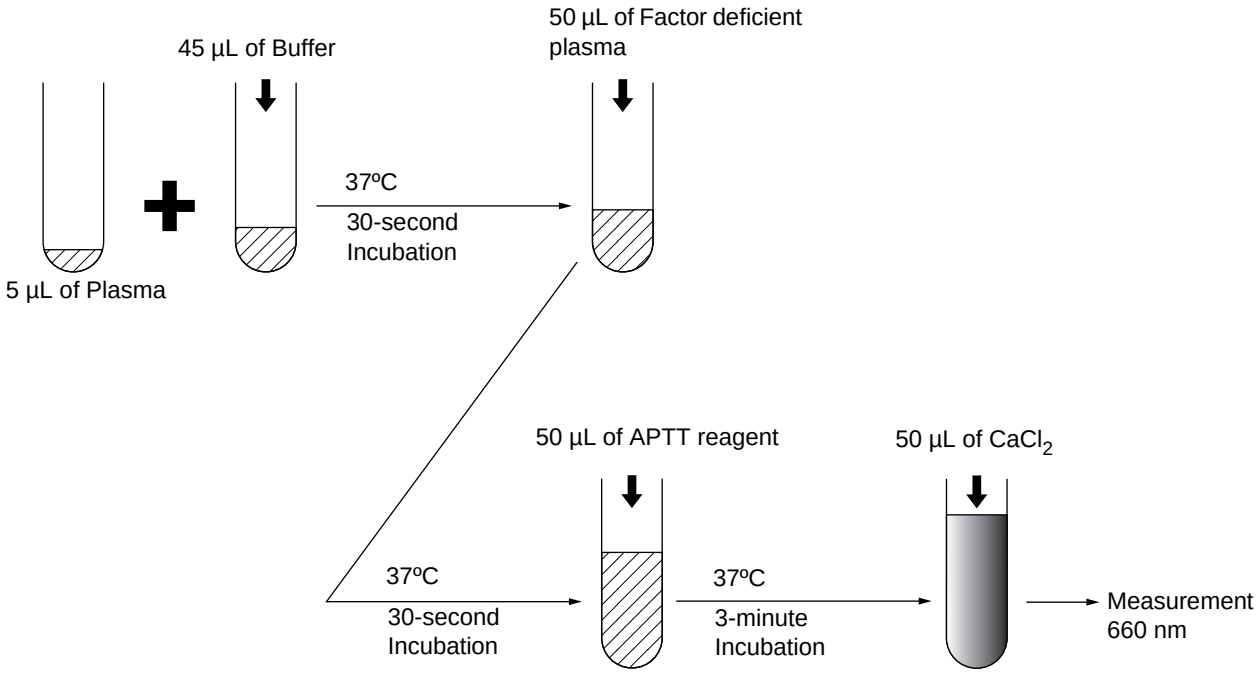
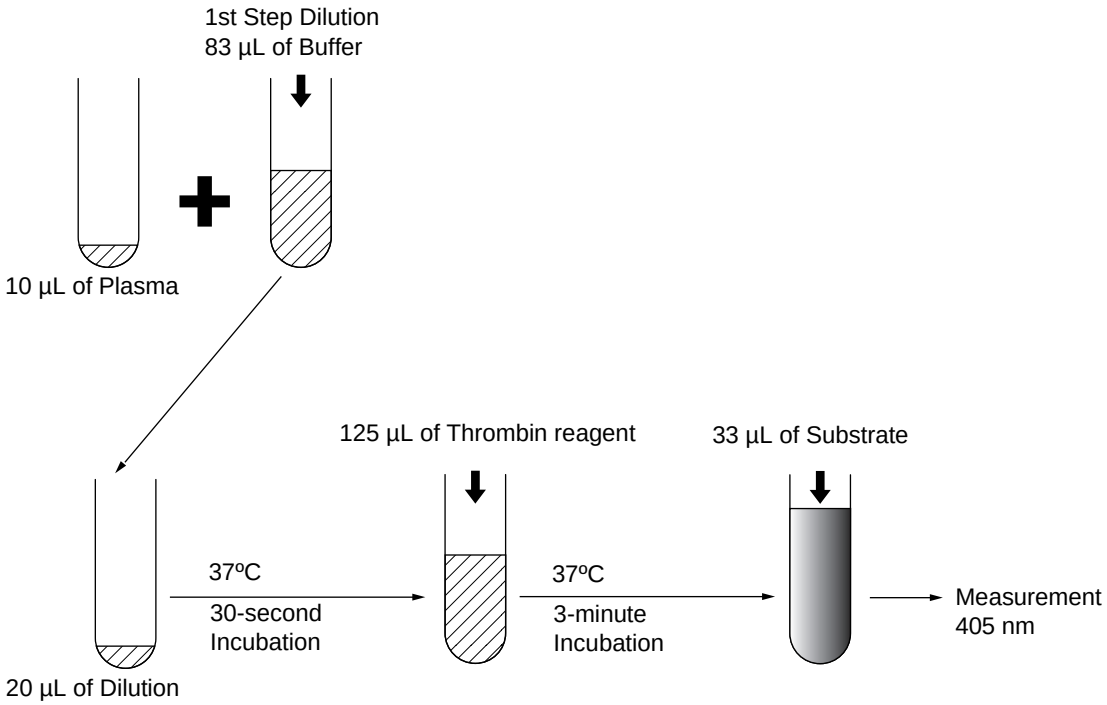
Intrinsic Factor Assay Flow



AT3 Flow (When Berichrom° Antithrombin III (A) is used)



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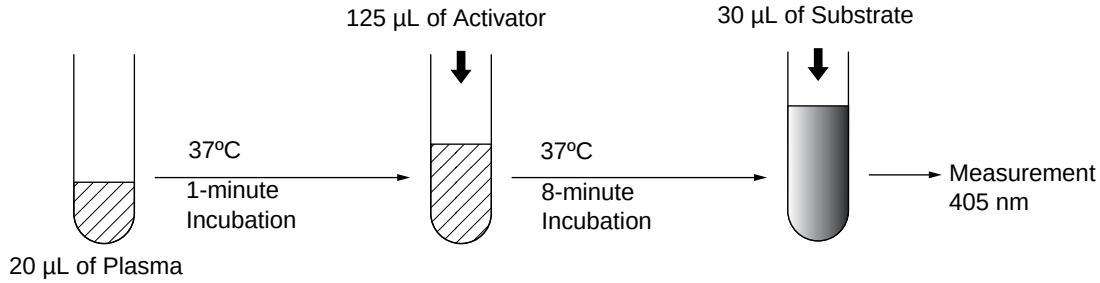
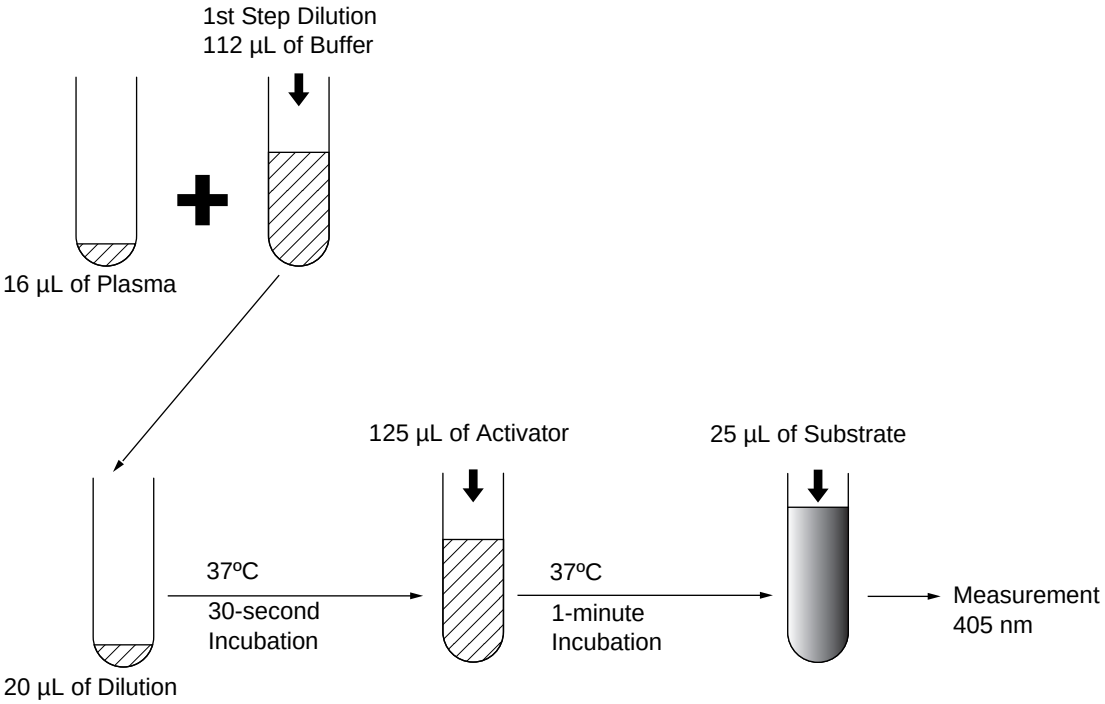
PC Flow (When Berichrom° Protein C is used)



APL Flow (When Berichrom° α2-Antiplasmin is used)*



(*) Not available for use in the USA.

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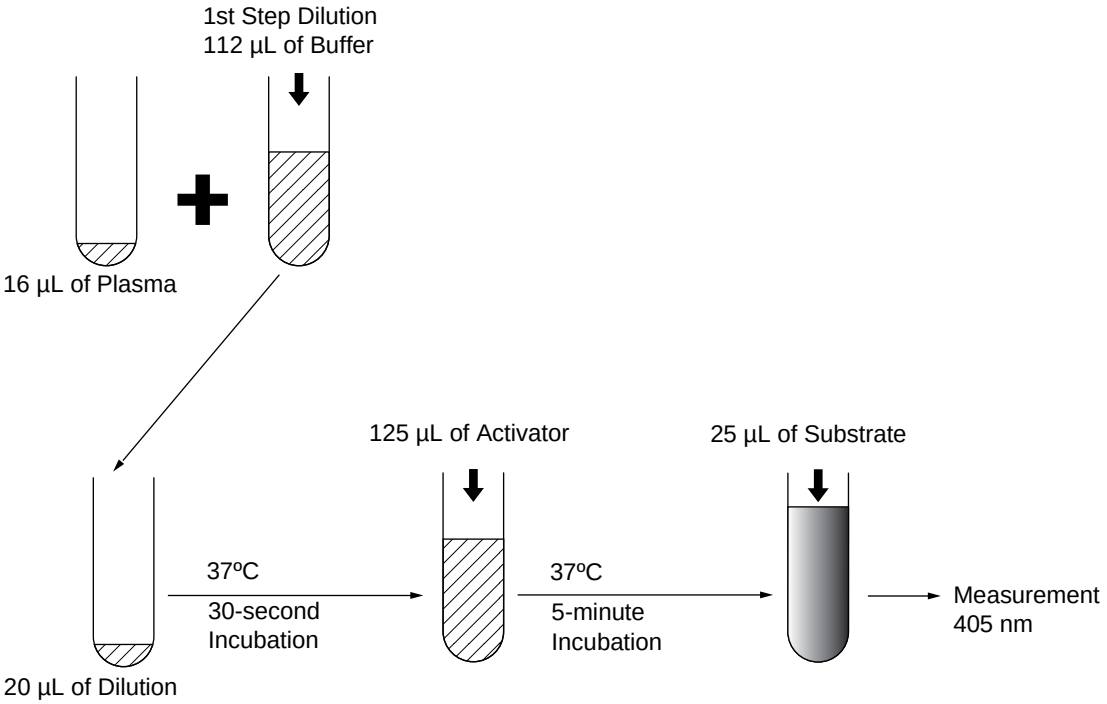
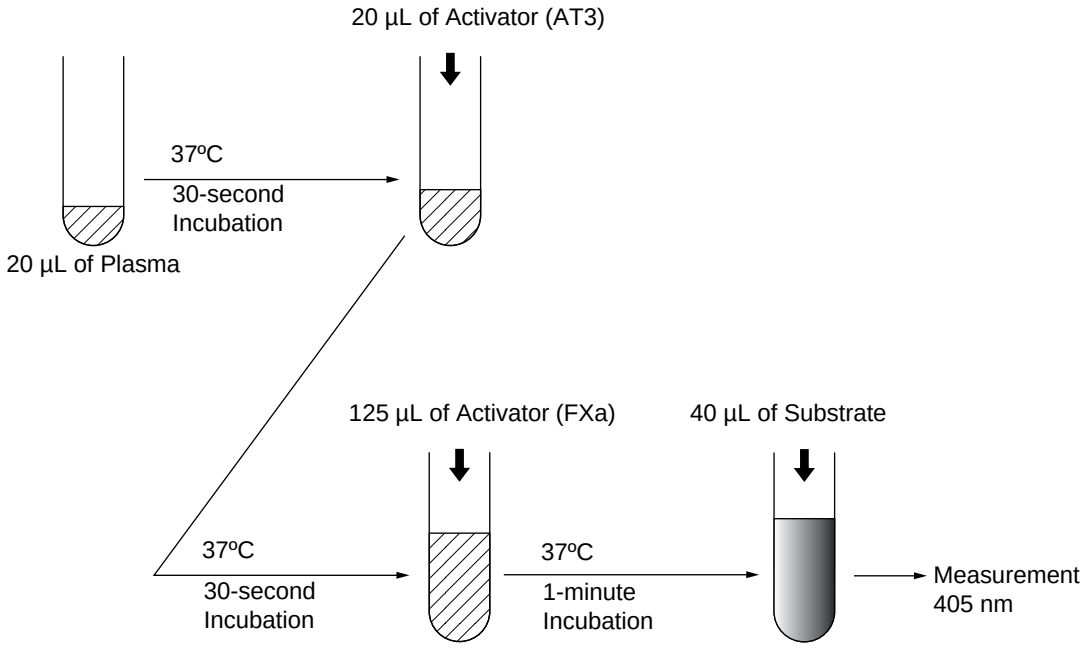
Plg Flow (When Berichrom° Plasminogen is used)*



Hep Flow (When Berichrom° Heparin is used)



(*) Not available for use in the USA.

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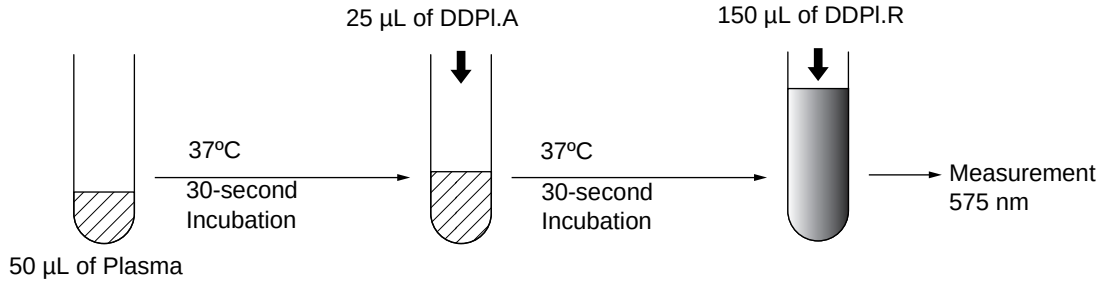
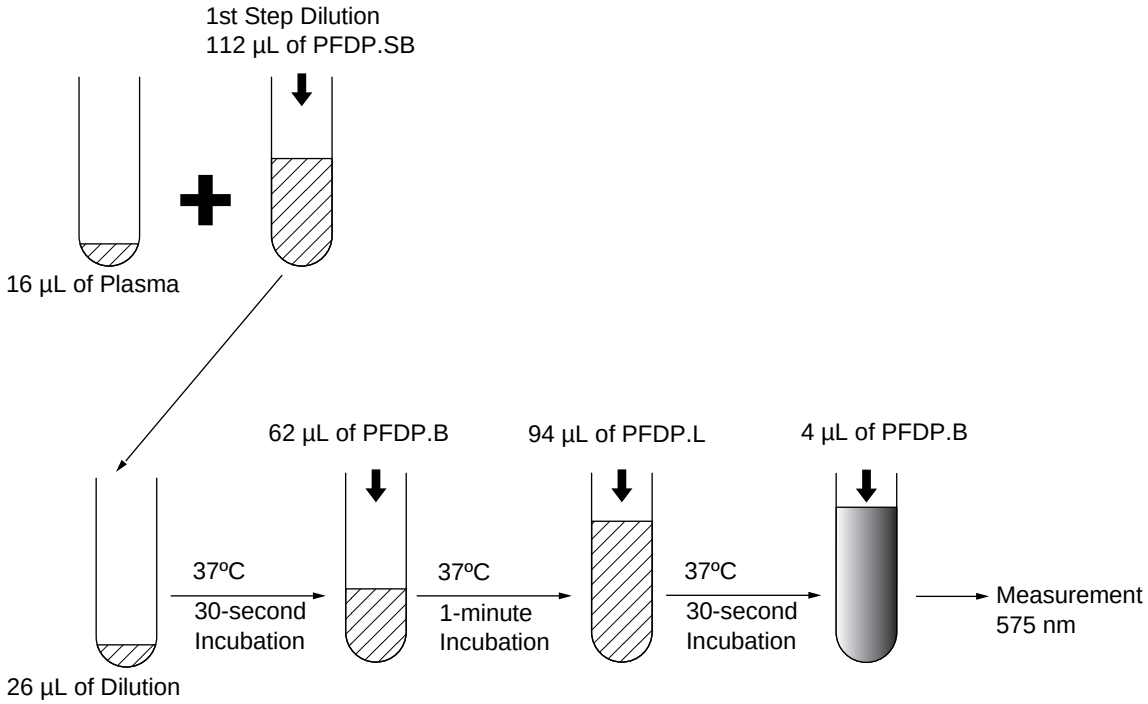
DDPl Flow*



PFDP Flow**



(*) Not available for use in the USA.

(**) Only available for use in Asia.

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13.6 Reference Procedures

The National Committee for Clinical Laboratory Standards (NCCLS) provides the following reference method information:

H21-A2, “Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays”

H28-T, “One-Stage Prothrombin Time”

H29-T, “Activated Partial Thrombin Time”

H30-T, “Procedure for the Determination of Fibrinogen in Plasma”

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 Instrument Specifications

Name	Automated Blood Coagulation Analyzer CA-500 Series	
Model	CA-510/CA-520/CA-530/CA-540/CA-550/CA-560	
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
	Thrombin Time (TT)	Analysis: sec.
	Protein C coagulometric (PCcl)	Analysis: sec. Calculated parameters: %
	Batroxobin (BXT)	Analysis: sec.
	LA1 Screening (LA1)*	Analysis: sec.
	LA2 Confirmation (LA2)*	Analysis: sec.
	Factor Assay (II, V, VII, VIII, IX, X, XI, XII)**	Analysis: sec. Calculated parameters: %
Model	CA-530/CA-540/CA-550/CA-560	
Analysis parameters/ Calculated parameters	Antithrombin III (AT3)*	Analysis: ΔOD/min. Calculated parameter: %
	Protein C chromogenic (BCPC)	Analysis: ΔOD/min. Calculated parameters: %
	α2-Antiplasmin (APL)*	Analysis: ΔOD/min. Calculated parameters: %
	Plasminogen (Plg)*	Analysis: ΔOD/min. Calculated parameters: %
	Heparin (Hep)	Analysis: ΔOD/min. Calculated parameters: IU/mL
Model	CA-550/CA-560	
Analysis parameters/ Calculated parameters	D-Dimer (DDPl)	Analysis: ΔOD Calculated parameters: µg/L
	D-Dimer (AdDD***)	Analysis: ΔOD Calculated parameters: mg/L (FEU)
	P-FDP (PFDP)****	Analysis: ΔOD Calculated parameters: µg/mL

(*) Not available for use in the USA.
(**) Data evaluated for factors VII and VIII only.
(***) Only available for use in the USA.
(****) Only available for use in Asia.

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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.
	Immunology 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, PCcl, BXT, LA1***, LA2***, Factor Deficiency, AT3, BCPC, APL***, Plg***, Hep, DDPl***, AdDD**** and PFDP*****)	
Detection Time	Coagulation reaction is detected within maximum detection time and coagulation time is measured. Typical maximum detection time Maximum detection time that can be set	120 sec. for PT 100 sec. for Fbg 190 sec. for others (Coagulation Method) 30 sec. for AT3 180 sec. for D-Dimer 150 sec. for P-FDP 600 sec. for each parameter
Processing Capability	Maximum: Approx. 54 tests/hr Average (Simultaneous analysis of 3 parameters - PT, APTT, Fbg): Approx. 43 tests/hr Analysis of AT3 parameter: Approx. 18 tests/hr Analysis of DDPl*** parameter: Approx. 10 tests/hr Average (Simultaneous analysis of 4 parameters - PT, APTT, Fbg, AT3): Approx. 32 tests/hr Average (Simultaneous analysis of 4 parameters - PT, APTT, Fbg, DDPl***): Approx. 24 tests/hr	

(*) CA-530, CA-540, CA-550 and CA-560 only.
(**) CA-550 and CA-560 only.
(***) Not available for use in the USA.
(****) Only available for use in the USA.
(*****) Only available for use in Asia.

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Analysis Range	Fibrinogen Concentration	The range between 25 mg/dL and 1000 mg/dL can be analyzed. However, over 450 mg/dL is analyzed via dilution in low concentration mode (1:20 dilution). Under 50 mg/dL is analyzed via dilution in high concentration mode (1:5 dilution).
	D-Dimer Concentration	With an applicable reagent with D-Dimer PLUS*, the range between 50 µg/L and 9999 µg/L can be analyzed. However, 2000 µg/L or more is analyzed via dilution in high concentration mode (+DDP*, 1:8 dilution).
	P-FDP*** Concentration	With an applicable reagent, the range between 2.5 µg/mL and 480 µg/mL can be analyzed. However, 60 µg/L or more is analyzed via dilution in high concentration mode (+PFD***, 1:8 dilution).
Plasma Volume Required	Prothrombin Time (PT):	50 µL
	Activated Partial Thromboplastin Time (APTT):	50 µL
	Fibrinogen (Fbg):	10 µL
	Thrombin Time (TT with Test Thrombin*):	50 µL
	PCcl:	5 µL
	Batroxobin (BXT):	50 µL
	LA1 Screening (LA1)*:	100 µL
	LA2 Confirmation (LA2)*:	100 µL
	Extrinsic Factor Deficiency (II, V, VII, X):	5 µL
	Intrinsic Factor Deficiency (VIII, IX, XI, XII):	5 µL
	Antithrombin III (AT3) (Berichrom Antithrombin III (A)):	10 µL
	Protein C (BCPC):	20 µL
	α2-Antiplasmin (APL)*:	16 µL
	Plasminogen (Plg)*:	16 µL
	Heparin (Hep):	20 µL
	D-Dimer (DDPl*, AdDD**):	50 µL
	P-FDP (PFDP)***:	16 µL
Reagents Required	Refer to “5.6 Prepare Reagents”.	

(*) Not available for use in the USA.

(**) Only available for use in the USA.

(***) Only available for use in Asia.

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Manufacturers Reproducibility Data

Reproducibility	Prothrombin Time (PT)	C. V. 2% or less
	Activated Partial Thromboplastin Time (APTT)	C. V. 2% or less
	Fibrinogen (Fbg)	C. V. 5% or less
	Thrombin Time (TT)	C. V. 10% or less
	PCcl	C. V. 5% or less
	Batroxobin (BXT)	C. V. 4% or less
	LA1 Screening (LA1)*	C. V. 4% or less
	LA2 Confirmation (LA2)*	C. V. 4% or less
	Extrinsic Factor Deficiency (II, V, VII, X)	C. V. 5% or less
	Intrinsic Factor Deficiency (VIII, IX, XI, XII)	C. V. 5% or less
	Antithrombin III (AT3)	C. V. 5% or less
	Protein C (BCPC)	C. V. 5% or less
	α2-Antiplasmin (APL)*	C. V. 5% or less
	Plasminogen (Plg)*	C. V. 5% or less
	Heparin (Hep)	C. V. 5% or less
	The above data are variation coefficients for coagulation time (seconds) and activity percentage (AT3, APL, Plg, PC, Hep) when Dade® Ci-Trol® Level I (control plasma) is analyzed 10 times using the reagents below. • Dade® Thromboplastin·C plus • Dade® Actin® • 20 mM, 25mM Calcium Chloride Solution • Owren's Veronal Buffer • Data-Fi®·Fibrinogen* • Batroxobin Reagent • Berichrom° Antithrombin III (A) • Berichrom° α2-Antiplasmin • Berichrom° Plasminogen • Berichrom° Protein C • Berichrom° Heparin	
	D-Dimer (DDPl*) The above data is the variation coefficient when a standard solution of D-Dimer (concentration 400 - 600 µg/mL) is analyzed 10 times using the reagents below. • D-Dimer PLUS* • Advanced D-Dimer**	 C. V. 10% or less C. V. 10% or less

(*) Not available for use in the USA.

(**) Available for use only in the USA.

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.

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Reproducibility Data according to FDA Guidelines

Reproducibility	Prothrombin Time (PT)	C. V. 5 % or less (Unit: Seconds)
	Activated Partial Thromboplastin Time (APTT)	C. V. 3 % or less (Unit: Seconds)
	Fibrinogen (Fbg)	C. V. 6 % or less (Unit: Seconds)
	Thrombin Time (TT)	C. V. 7 % or less (Unit: Seconds)
	Protein C clotting (PCcl)	C. V. 6 % or less (Unit: activity-%)
	Batroxobin (BXT)	C. V. 2 % or less (Unit: Seconds)
	Extrinsic Factor Deficiency (VII)*	C. V. 9 % or less (Unit: activity-%)
	Intrinsic Factor Deficiency (VIII)**	C. V. 8 % or less (Unit: activity-%)
	Antithrombin III (AT3)	C. V. 10 % or less (Unit: activity-%)
	Protein C chromogenic (BCPC)	C. V. 4% or less (Unit: activity-%)
	Heparin (Hep)	C. V. 8% or less (Unit: IU/mL)
	Advanced D-Dimer***	C. V. 3% or less (Unit: mg/L FEU)
	The above data are variation coefficients for coagulation times in seconds, activities in activity percentage or concentrations in IU/ml or mg/dl (Fbg) taken from 40 analyses of Dade® Behring Control Plasma N, Control Plasma P, Ci-Trol®, pathological plasma pool or normal plasma pool using the reagents below. • Thromborel® S Reagent • Dade® Actin® FSL Activated PTT Reagent • Calcium Chloride Solution (0,025 mol/L) • Owren's Veronal Buffer • Test Thrombin Reagent • Factor Deficient Plasma • Berichrom° Antithrombin III • Protein C Reagent • Berichrom° Protein C Reagent • Berichrom° Heparin Reagent • Dade® Thrombin Reagent • Batroxobin Reagent • Advanced D-Dimer***	

(*) Data evaluated for Factor VII only.

(**) Data evaluated for Factor VIII only.

(***) Available for use only in the USA.

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.

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Display and Entry	3.2 in x 4 in liquid crystal display (with black and white 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 (15ºC±2ºC, when room temperature is 15 - 35ºC)
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.	
SAMPLE TUBE	Sample 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 immunology analysis**) The light-emitting diode for photodetection is ON only during analysis.
	Heater Section:	6-well
Temperature Control	Detector:	37ºC±1.0ºC
	Sample Incubator Section:	37ºC±1.0ºC
	Reagent Pipette:	37ºC±1.0ºC (When room temperature is 15 - 35ºC)
	Cooling Unit*:	15ºC±2ºC
Time Taken to Reach Set Temperature	Within 30 minutes after power supply turn-on (when room temperature is within the temperature range of 15-35ºC)	
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:	300 samples (a maximum of 1500 tests) (Latest 600 tests only for coagulation curve)
Quality Control	$\overline{X}$ Control (L-J Control):	180 points x 6 files, 14 parameters
Standard Curve	6 points, 14 parameters	
Electrical Rating	Rated Voltage:	117 V AC ± 10%, or 230 V AC ± 15%
	Frequency:	50 Hz or 60 Hz
	Power consumption (Main unit):	380 VA or less (with CA-550) 400 VA or less (with CA-560)
	Heat Compensation Required:	Approx. 1365 BTU/h (344 kcal/h)
Dimensions and Weight	Width (±3%):	Approx. 540 mm
	Depth (±3%):	Approx. 470 mm
	Height (±3%):	Approx. 487 mm
	Weight (±3%):	Approx. 45 kg
	The dimensions exclude the projections.	
Protection Type	Class I Equipment	

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EMC (Electro-magnetic compatibility)	This equipment is in conformity to the following IEC (EN) standard. IEC 61326-1: 97+A1: 98 (EN 61326: 97+A1) Electrical equipment for measurement, control and laboratory use -EMI requirements -EMI (Class B) -EMS (Immunity test requirements for equipment intended for use in industrial locations)

(*) CA-530, CA-540, CA-550 and CA-560 only.

(**) CA-550 and CA-560 only.

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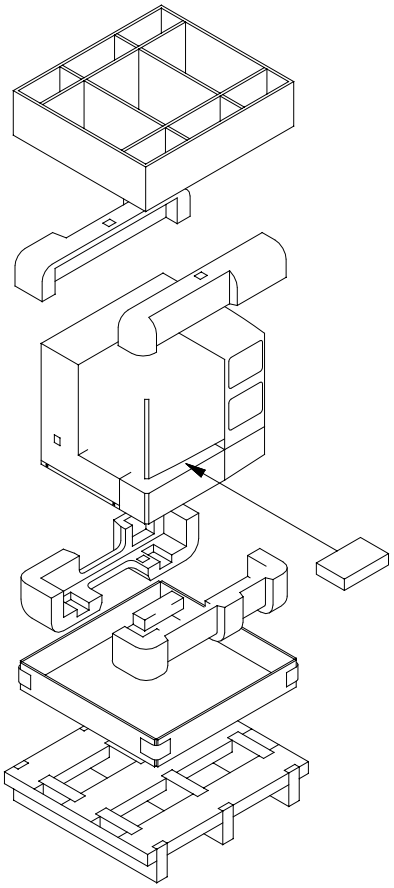
14.2 Installation

Introduction

This product is a clinical test instrument. A Sysmex 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 the instrument is free from external flaws and check the quantities of the supplied parts.



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Unpacking Check List

Part No.	Description	Quantity		
		117 V	220-240 V	220-240 V for U.K.
461-2655-0	INSTRUCTION FOR USE CA-500 series	1	1	1
266-5293-0	Fuse 250V 3.15A No. 19195 (Europe)	-	2	2
266-5106-0	Fuse 250V 6.3A ST4-6.3A-N1 (N.Amer)	2	-	-
663-0213-6	Sample Tube Spacer 13 Phi	1	1	1
369-5982-2	Indication Mark No.954 (CA-510, CA-520, CA-530 and CA-540 only)	1	1	1
369-5088-5	Indication Mark No. 1068 (CA-550 and CA-560 only)	1	1	1
921-0351-8	Paper Thermal F1-2 (2/Pack)	1	1	1
265-4731-5	Power Cord 4622-007-0092 (Europe)	-	1	-
265-4723-5	Power Cord F1686 (U.K.)	-	-	1
793-0012-1	Power Cord No. 4 (N.Amer)	1	-	-
541-1352-1	Push Vial PV-10	2	2	2
541-0541-8	Reaction Tube	60	60	60
663-0206-0	Reagent Rack Assy	1	1	1
663-0209-1	Rinse Bottle Assy (2 L)	1	-	-
663-0407-4	Rinse Bottle Assy (2 L/EU/UK)	-	1	1
663-0402-6	Rinse Bottle Assy (5 L) *	1	-	-
663-0405-7	Rinse Bottle Assy (5 L/EU/UK) *	-	1	1
833-3895-6	Sample Rack No. 3 w/Holder #55	1	1	1
663-0208-7	Reaction Tube Rack **	4 (2)	4 (2)	4 (2)
663-0211-9	Trap Chamber Complete	1	1	1
663-0207-3	Reaction Tube Trash Box	1	1	1
663-0210-5	Waste Bottle Assy (2 L)	1	1	1
663-0408-8	Waste Bottle Assy (2 L/EU/UK)	-	1	1
663-0403-0	Waste Bottle Assy (5 L) *	1	-	-
663-0406-1	Waste Bottle Assy (5 L/EU/UK) *	-	1	1
013-1771-4	SLD Vial Assy (10/pack)	1	1	1
363-2558-6	Holder No.89	2	2	2

(*) CA-550 and CA-560 only.

(**) The number in ( ) is for CA-510, CA-520, CA-530 and CA-540.

Note

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

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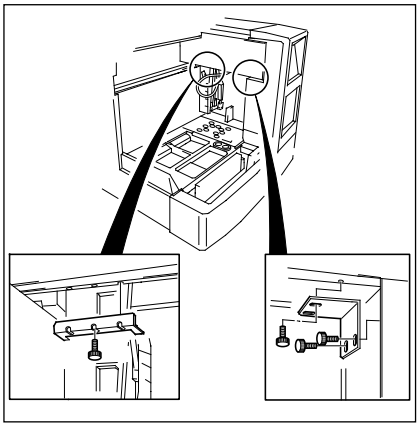
Installation Space

Refer to “Installation Space” of “4.2 Installation Location”.

Remove Shipping Clamps

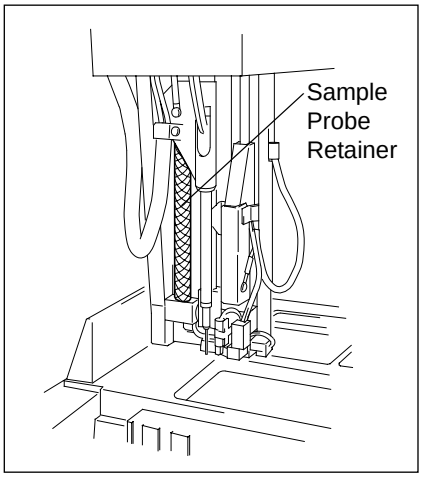
Remove the shipping clamps used on movable components of the instrument.



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.

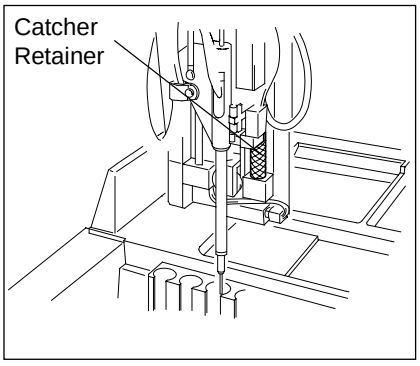
> **Important**
> Unless the fixing metals are removed, the instrument cannot operate.



3. Move the sample probe unit by hand to a place where it is easy to operate.

   Remove the sample probe retainer.

> **Important**
> 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.

> **Important**
> Unless the retainer is removed, the instrument cannot operate.

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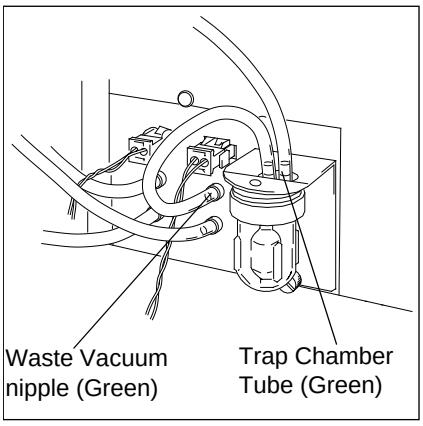
Attach Trap Chamber



1. Attach the supplied trap chamber to the rear panel.

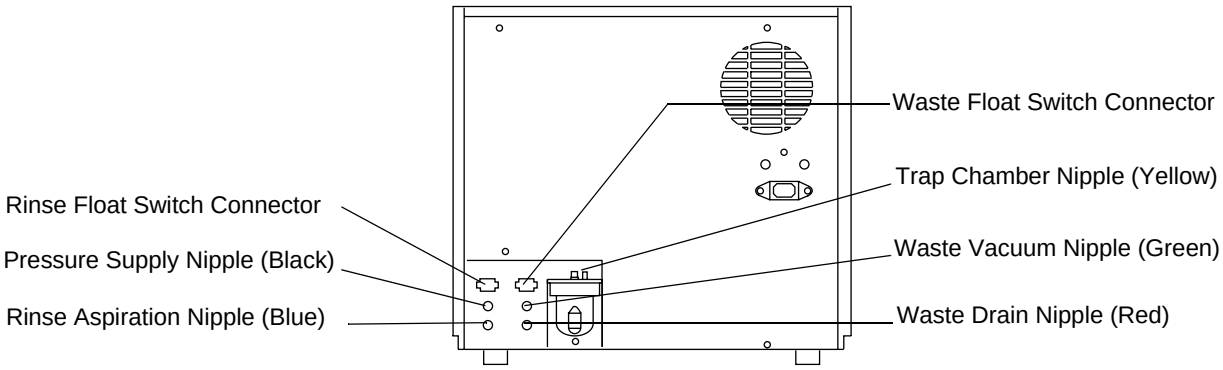
   Connect the trap chamber tube (green) to the waste vacuum nipple (green) on the rear panel.

Risk of Infection

When draining the trap chamber, always wear latex or non latex examination gloves. After completing the operation, be sure to wash hands in anti-septic solution. If hands should be contaminated with blood, there is a hazard of being infected by pathogenic bacteria.

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.

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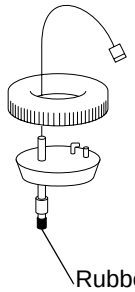
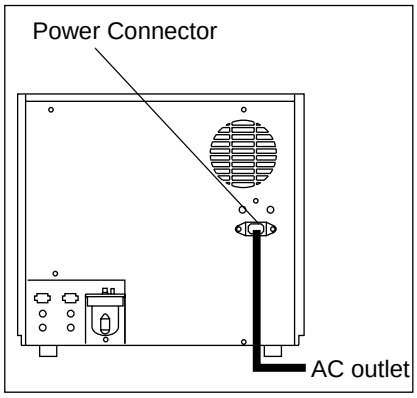


Important

- 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.

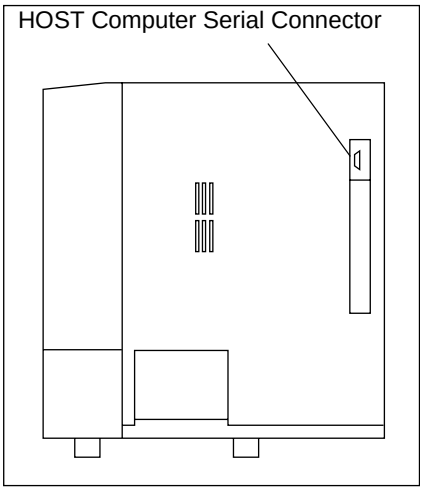
Connect Power Cord and Connection Cord



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.

Important

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, refer to “10.14 Devices to be connected”.
- The connection cord for the host computer is not included in the supply parts.

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Set Print Paper

Refer to “11.8 Supply Printer Paper”.

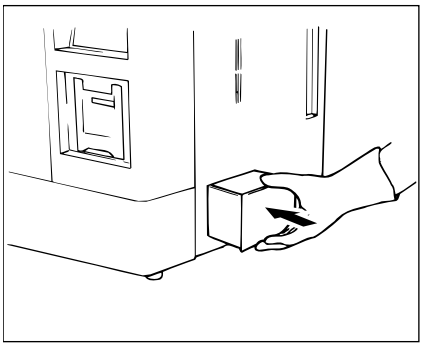
Adjust LCD Contrast

Refer to “ Contrast Adjustment for LCD Screen” of “4.3 Basic Instrument Settings”.

Replenish Rinse Solution

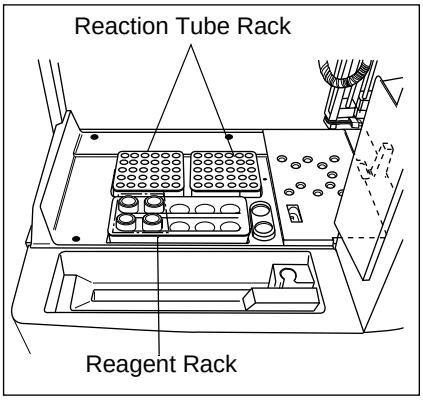
Refer to “11.11 Prime Rinse Solution to Hydraulic Line”.

Set Tube Trash Drawer



Set the supplied tube trash drawer.

Set Reagent Rack and Reaction Tube Rack



Set the supplied reagent rack and reaction tube rack.

Affix Indication Mark No. 954, No. 1068 on the reagent rack.

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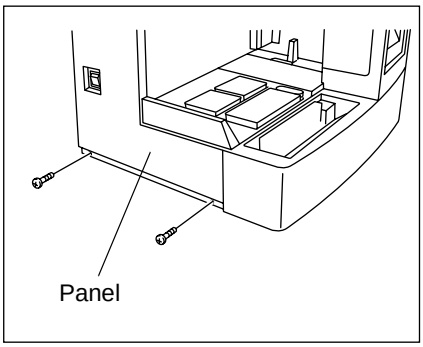
Install Sampler with ID Barcode Scanner (Option)

An optional Barcode Scanner is installed on the CA-550, as follows.

1. Remove the left side panel of the main unit.

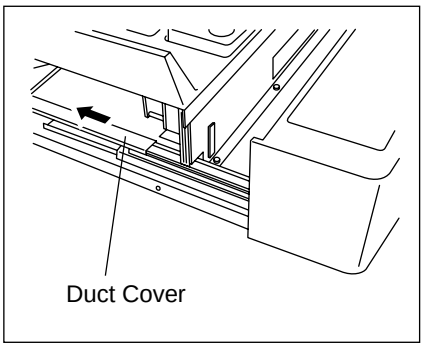
   Loosen the screws as shown to remove the panel.



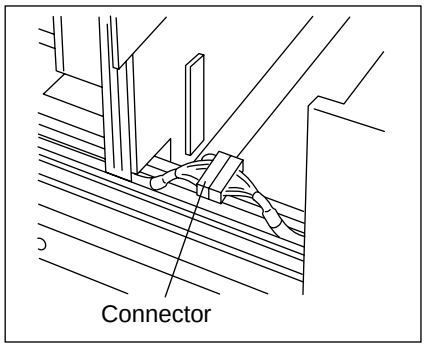
2. Remove the sampler.

   1) Pull the sampler forward.

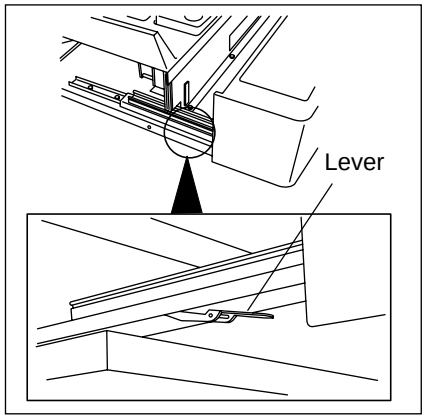
      Pull it out until it stops against the stopper.



   2) Remove the duct cover for the sampler slide rail by sliding it backward.



   3) Pull out the connector from the duct, and disconnect the connector.



   4) Remove the sampler.

      Release the stoppers by pushing the stopper levers with your fingers, and remove the sampler.

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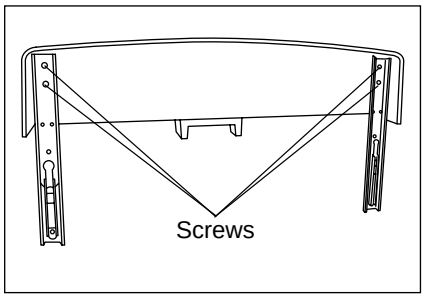


3. Attach the slide rail to the sampler with the ID barcode scanner.

   1) Remove the slide rail from the removed sampler.

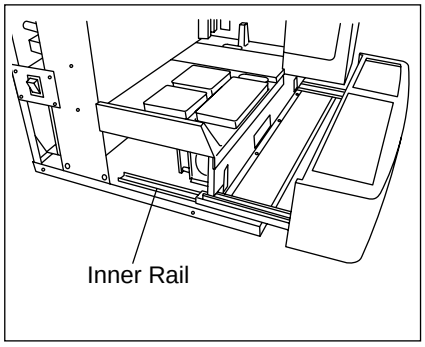
      Loosen the screws as shown and remove the slide rail from the sampler.

      Take care not to lose the slide rail, screws, or washers that were removed, as they must be attached to the sampler with the ID barcode scanner.

   2) Attach the slide rail to the sampler with the ID barcode scanner.

      Mount the duct-attached slide rail to the sampler onto the side where the cable protrudes. All four screws should be temporarily tightened.

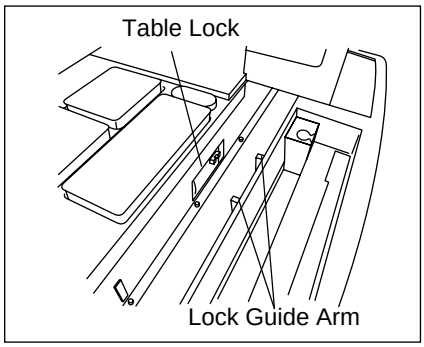
   3) Insert the cable from the sampler into the slide rail duct.



4. Install the sampler with the ID barcode scanner to the main unit.

   1) While finger-pushing the stopper lever to release the stopper, push in the sampler a few centimeters on the inner rails of the main unit.

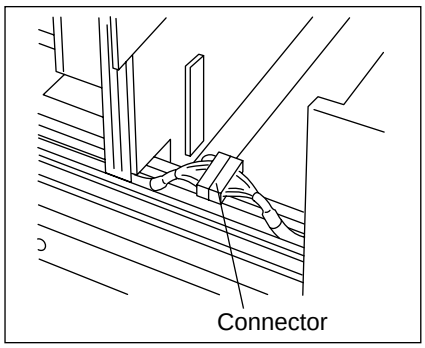
> **Important**
> Do not let go with your hands until you are sure the sampler with ID barcode scanner will not disconnect.



   2)Push the sampler with ID barcode scanner in parallel.

   Push it in until the lock guide arms fit in the table lock of the main unit. As you push it, the sampler will feel heavier, but keep pushing little by little.

> **Important**
> The table lock is only 1 mm apart from the lock guide arms. In pushing, take care not to allow the lock guide arm to contact the under panel.



   3) Connect the connector and put it in the duct.

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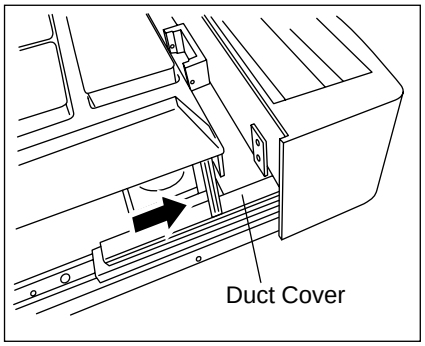

4) Attach the duct cover.

The duct cover should be attached so that it will cover the outlet for the cable of the sampler with ID barcode scanner.

5) Repeat pushing in and pulling out the sampler with ID barcode scanner several times.

6) With the sampler pulled out in parallel, fully tighten the screws that were temporarily tightened before.

7) Make sure that the sampler with ID barcode scanner will slide in and out smoothly.

5. Attach the left side panel of the main unit.
6. The instrument is ready to be set up by your local service representative.

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14.3 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 Not Connected
Baud Rate (BPS)	600 1200 2400 4800 9600
Character Length	7-Bit 8-Bit
Stop Bit	1-Bit 2-Bit
Parity	None Even Odd
Class	Class A Class B
Interval (second)	0 2 3 5 7 10 15
Inquiry	Auto Manual

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Items	Selections
Format	CA1000 CA500 ASTM
ACK Text	STX-ACK-ETX ACK/NAK

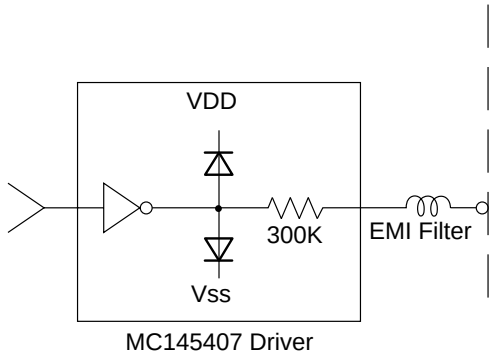
Signal Level

Signal level of the RS-232C conforms to the EIA RS-232C V.24 standard.

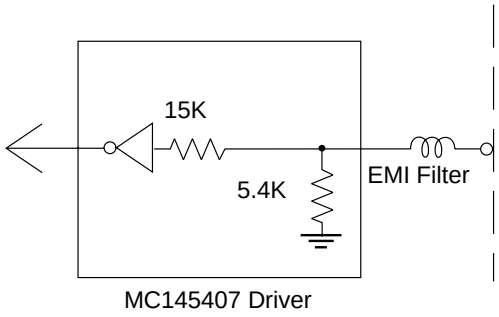
Level	Binary State	Function
+3 V or Higher	Logic “0”, Start Bit	ON
-3 V or Lower	Logic “1”, Stop Bit	OFF

Interface Circuit

Output Circuit



Input Circuit



Software

1. Code

ASCII codes are used in this interface.

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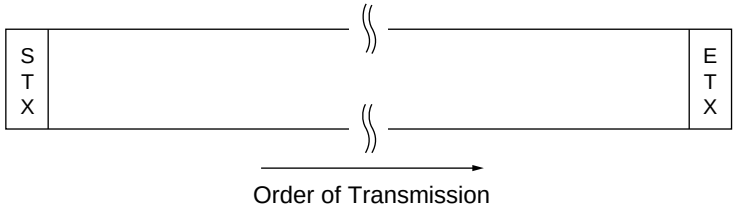
2. General Function

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.

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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).

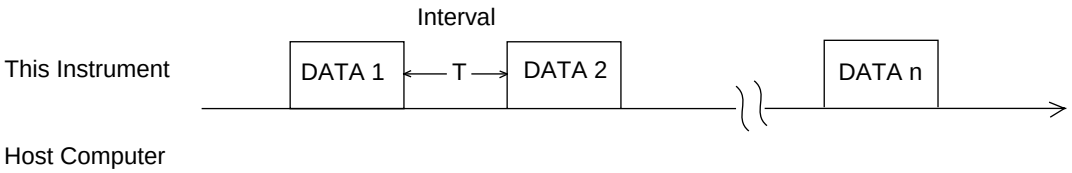
Class A

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.

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The instrument transmits the following data in Class B mode.

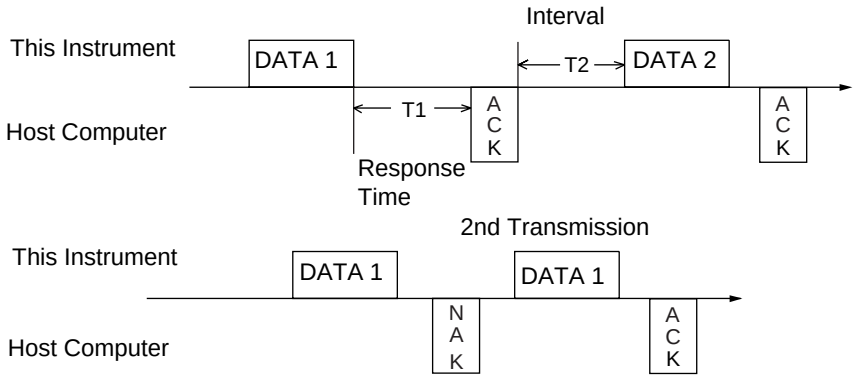
Function	Description
Analysis data output	Auto Out -- This instrument automatically sends out analysis data after each analysis has been completed.
	Stored Data (batch output) -- This instrument sends out data from the stored data in a batch.
Inquiry (output) and settings from host computer (input)	When 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

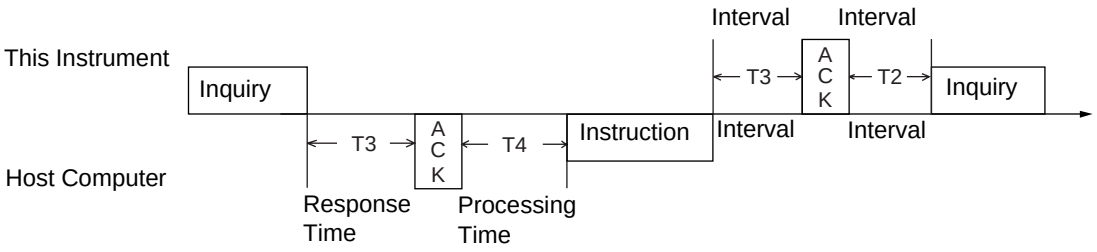
Transmission Protocol should be fixed in Class B to make inquiries regarding order information to the host computer. Selecting Class A will lead to an incorrect communication without showing an error message.

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.

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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.

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14.4 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	“xxxxxxxxxxx” 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 × 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.

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(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
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.

(m) Reserved (Eleven spaces (20H) are set.)

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(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	27X	LA1
05X	APTT	28X	LA2
06X	Fbg	30X	AT3
08X	TTO	31X	APL
12X	II	32X	Plg
15X	V	33X	PC Chrom
17X	VII	34X	Hep
18X	VIII	50X	+Fbg
19X	IX	51X	TT
20X	X	52X	-Fbg
21X	XI	61X	DDPl*, AdDD**
22X	XII	62X	PFDP***
25X	PCcl	70X	+DDP*, +AdD**
26X	BXT	72X	+PFD

(*) Not available for use in the USA.
(**) Available for use only in the USA.
(***) Available for use only in Asia.

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.

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- Data

  Data is sent without a decimal point.

Data	Units	Output Format Actual data → Data format
Coagulation time	sec, s	XXXX.X → XXXXX
Activity %	%	XXX.X → OXXXX
	No unit	X.XXX → OXXXX
PT ratio, INR		XX.XX → OXXXX
Fbg concentration	mg/dL	OXXX.X → OXXXX
	g/L	OX.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.
!	Coagulation time was obtained by re-dilution.
>	Over the Upper Report Limit
<	Under the Lower Report Limit

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> **Note**
> The priority order of each flags is (*), (<) or (>), (+) or (-), (!) 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	A space (20H)
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	"xxxxxxxxxxx"; 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.

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(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 “ERR0000000001”.

(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.

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(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	270	LA1
050	APTT	280	LA2
060	Fbg	300	AT3
080	TTO	310	APL
120	II	320	Plg
150	V	330	PC Chrom
170	VII	340	Hep
180	VIII	500	+Fbg
190	IX	510	TT
200	X	520	-Fbg
210	XI	610	DDPl*, AdDD**
220	XII	620	PFDP***
250	PCcl	700	+DDP*, +AdD**
260	BXT	720	+PFD

(*) Not available for use in the USA.
(**) Available for use only in the USA.
(***) Available for use only in Asia.

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).

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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” 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
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).

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- Parameter Code

Parameter Code	Parameter	Parameter Code	Parameter
040	PT	300	AT3
050	APTT	310	APL
060	Fbg	320	Plg
080	TTO	330	PC Chrom
120	II	340	Hep
150	V	500	+Fbg
170	VII	510	TT
180	VIII	520	-Fbg
190	IX	610	DDPl*, AdDD**
200	X	620	PFDP***
210	XI	700	+DDP*, +AdD**
220	XII	720	+PFD
250	PCcl	000	Not Analyzed
260	BXT	999	Stop order inquiry for the following samples in the racks.
270	LA1		
280	LA2		

(*) Not available for use in the USA.
(**) Available for use only in the USA.
(***) Available for use only in Asia.

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.

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14.5 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.

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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 ≥ 150 µm

(b) Wide element ≤ 1.2 mm

(c) Narrow element ≤ Gap between characters ≤ 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:

(1) $$\frac{\text{Narrow(Max)}}{\text{Narrow(Min)}} \leq 1.3$$

(2) $$\frac{\text{Wide(Min)}}{\text{Narrow(Max)}} \geq 2.2$$

(3) $$\frac{\text{Wide(Max)}}{\text{Wide(Min)}} \leq 1.4$$

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:

$$PCS = \frac{Rs - Rb}{Rs} \geq 0.45$$

Rs: the reflectivity of the space (background)

Rb: 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.

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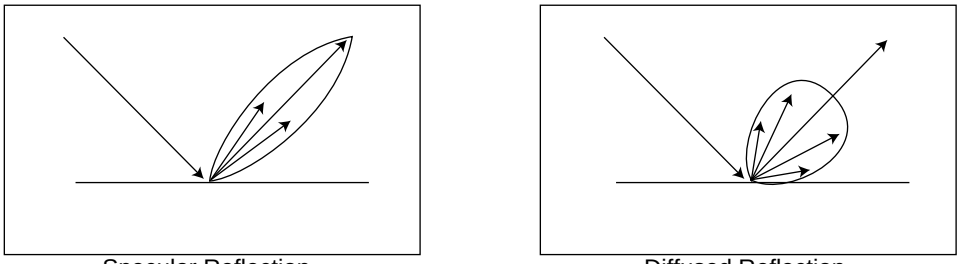
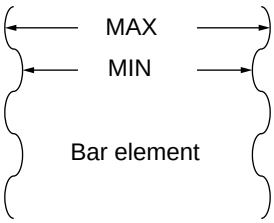


3. Irregularity and roughness of the printing

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%.

$$S(\%) = \frac{\text{Max-Min}}{\text{Max}} \times 100$$

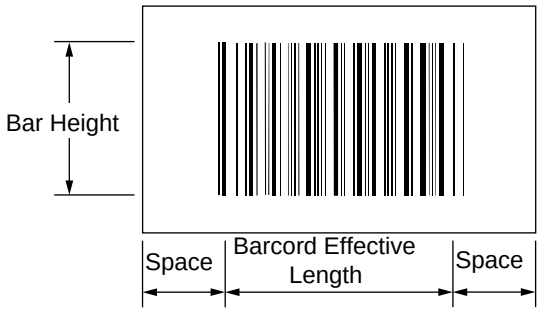


Dimensions of Barcode Label

(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.

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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.

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(B) Modulus 11

This Modulus 11 method is used in the barcode symbology such as CODE-11, NW-7 and CODA-BAR. 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:

   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; 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 CODA-BAR. 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:

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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

2. Add each product as given below:

   Sum = 6 + 15 + 0 + 18 + 30 + 28 + 40 + 0 + 30 + 21 + 48 + 18 = 254

3. 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; 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

4. Add each product as given below:

   Sum = 5 + 40 + 0 + 4 + 30 + 16 + 15 + 0 + 36 + 56 + 40 + 81 = 323

5. 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; remainder = 4,

   11 - 4 = 7,

   Hence the check-digit is 7.

6. This check digit is appended to the ID number;

   the barcode label is now 15-2345-67897.

7. 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.

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(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		

   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; 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

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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 bar-code 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.

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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
21	5	5	21	75	VT	k	75

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Value	Code A	Code B	Code C	Value	Code A	Code B	Code C
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 “c11111111c” 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

Day / Maintenence item	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															

Day / Maintenence item	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				

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MONTHLY MAINTENENCE

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				
Clean instrument				

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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)