OPERATOR'S MANUAL

Automated Blood Coagulation Analyzer

CA-1500

(American Edition)

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SYSMEX CORPORATION
KOBE, JAPAN

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- As a result of product improvements, details described in this manual may differ slightly from the actual product.
- Patient names and doctor names are entered for information and illustration purposes only, and do not imply real specific persons.

RECEIVING INSTRUCTIONS

The CA-1500 has been thoroughly tested before shipment, and has been packaged carefully to prevent damage from shipping and handling. Reagents and options have also been sent and will arrive at approximately the same time as the analyzer. Follow these guidelines when the system arrives:

- Check to see that the arrows on the sides of the packages are pointing up. If the arrows do not point up, remark this information on the bill of lading.
- Visually inspect the outside of the package for rips, dents, or possible shipping damage. Document any sign of damage on the bill of lading, regardless of how insignificant it may appear. *This is for your protection!*
- Notify your service representative that the CA-1500 system and its components have arrived.
- Wait for your service representative to unpack the system and open the packages.
- Follow the unpacking and storage instructions provided on the outside of the package. Special requirements such as refrigeration are clearly marked on the outside of the carton and will be included in the unpacking instructions and package inserts.

WARRANTY INFORMATION

All instruments manufactured by Sysmex® are warranted against defective materials or workmanship for a period of one year commencing on the installation date at the customer's required location.

This Warranty does not cover any defect, malfunction, or damage due to:

1. Accident, neglect or willful mistreatment of the product
2. Failure to use, operate, service, or maintain the product in accordance with the applicable Sysmex Operator's Manual
3. Failure to use the appropriate reagents or chemicals specified for the product

Ensure Safe Operation of The Instrument

Before operating this instrument, carefully read the "Ensure Safe Operation of the Instrument" and OPERATOR'S MANUAL, and strictly follow the instructions given in them.
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.
Please ensure you understand what they mean before proceeding to the text of the MANUAL.

Meaning of Signs

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 an 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 an operator, adverse effect on output, or may cause property damage.

Caution on Diagnosis

CAUTION: • This product is a clinical examination instrument for screening. In making clinical judgment based on analysis results, a physician is requested to take clinical examination results and other test results into consideration.

CE-mark

CE

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 directive:

-98/79/EC in-Vitro Diagnostics Directive

WARNING:

- **In the event the instrument emits an abnormal odor or any smoke, turn OFF the power switch immediately and disconnect the power plug from the wall socket.**
  If the instrument is used continuously in that state, there is a potential that fire, electrical shock, or injury may result.
  Contact your 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 a short circuit or smoke emission. If such trouble should occur, turn OFF the power immediately and disconnect the power plug from the wall socket. Then contact your service representative for inspection.

- **Do not touch the electrical circuits inside the cover. Especially if your hands are wet, there is a potential that electrical shock may result.**

- **During an analysis, do not open the light shield lid and put in hands or fingers. That could cause injury. When the light shield lid is opened during an analysis, an alarm sounds and the operation stops.**

- **Always wear Latex or non Latex examination gloves when performing maintenance work or inspection.**
  Use specified tools and parts.
  After work is over, wash your hands with disinfectant.
  There is a possibility that those areas of your hands which came in contact with blood could suffer infection.

- **Be careful when handling samples.**
  Always wear Latex or non Latex examination gloves; otherwise infection by bacteria could result. If sample splash happened to enter your eye or a cut, wash it off with plenty of water, and immediately see a physician.

- **When handling waste liquid, or disassembling/assembling the related parts, do not touch the waste liquid.**
  If it is contaminated with blood, infection of bacteria may result. If you should touch the waste liquid inadvertently, wash it off with disinfectant first, then wash it off with soap.

When Handling Reagent

- **If a reagent happens to enter your eye, wash out your eyes immediately using plenty of water, and take medical treatment at once.**
- **If you should swallow it inadvertently, call for a physician immediately, drink plenty of water, and induce vomiting.**
- **If it happens to adhere to your hands or skin, wash the affected area using plenty of water.**

- **When discarding waste liquid, instrument consumables and instrument, take proper disposing steps as these are medical, infectious, and industrial wastes.**
  If they are contaminated with blood, infection of bacteria may result.

- **Do not modify the instrument. Its modification is prohibited by Pharmaceutical Affairs Law.**

WARNING:

Power Supply, Connection, and Grounding

- **Never put the power plug in any socket other than the AC 117, 220 or 240 V socket.**
  Otherwise, fire or electrical shock will result.

- **When installing the instrument, be sure to ground it.**
  Otherwise, fire or electrical shock will result.

Handling Power Supply Cord

- **Take care not to damage the power cord, place a heavy device on it, or pull it forcibly.**
  Otherwise, the wire may break causing fire or electrical shock.

- **When connecting the instrument to a peripheral (host computer, etc.), be sure to switch OFF the power beforehand.**
  Otherwise, electrical shock or instrument failure may result.

When Using the Sample Barcode

- **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

Use of Reagents

- **After unpacking, be sure not to allow dust, dirt, or bacteria to come in contact with the reagent.**
- **Do not use reagents which have expired.**
- **Handle a reagent gently to prevent formation of bubbles.**
- **A reagent is a chemical substance employed for external diagnosis and cannot be used for any medical treatment.**
- **Take care not to spill a reagent. If it spills, wipe it off immediately using a wet cloth or the like.**
- **Follow other instructions described on the Package Insert in each reagent.**

Use of Instrument

- **When performing maintenance work or inspection, use specified tools and parts. Do not use substitute parts, or modify the instrument. It is hazardous.**
- **Those who have no or only limited experience in using instrument are recommended to have guidance or assistance of those with sufficient experience.**
- **If the instrument has developed a trouble by any chance, a person in charge of it should take steps within the range specified in the OPERATOR'S MANUAL. As to troubles other than mentioned, contact your service representative for assistance or service.**
- **Unpacking, installation, and confirmation of initial setup must be done by your service representative.**

Environment for Use

- **Install the instrument in a place which is not subject to water splash.**
- **Install the instrument 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.**
- **Do not install the instrument near chemical storage or a place where a gas is generated.**

INTRODUCTION

Thank you for purchasing the Sysmex® Automated Blood Coagulation Analyzer CA-1500.
Carefully read the OPERATOR'S MANUAL for correct use of the unit.
Keep this MANUAL in good condition after reading. It will continue to be of your help in finding specific information about this instrument.

Ordering of Supplies and Replacement Parts
If you need to order supplies or replacement parts, please contact your local representative.

Service and Maintenance
Please contact the Service Department of your local representative.

Training courses
For further information please contact the representative in your country.

Personnel
This instrument may only be operated by trained personnel having been instructed in its operation. Only persons who have appropriate training must perform maintenance and repair work.

CONTENTS OF THIS MANUAL

To make full use of the functions of this instrument, thoroughly read this manual and use the instrument as directed. The Operator's Manual is made up of the eleven chapters and appendices listed below.

Chapter 1: Introduction	Provides an overview of the instrument, explaining its equipment, operating procedures, and messages as well as points to be careful about during installation.
Chapter 2: Sample Preparation	Explains how to prepare the instrument, reagents, and samples before performing analyses.
Chapter 3: Work List	Explains how to register sample ID numbers and analysis parameters.
Chapter 4: Sample Analysis	Describes how to analyze samples and explains operating procedures, from order information entry to shutdown.
Chapter 5: Display & Processing of Analysis Results	Explains stored data screen displays and the processing of external output and other analysis results.
Chapter 6: Maintenance & Supplies Replacement	Explains the periodic maintenance procedures and how to replace reagent and other supplies.
Chapter 7: Quality Control	Explains how to perform quality control analyses and how to print and store quality control data.
Chapter 8: Setting Standard Curves	Explains how to prepare standard curves.
Chapter 9: Troubleshooting	Explains the error messages and how to troubleshoot.
Chapter 10: Functional Description	Explains the coagulation detection principles. Also lists the names and functions of the each parts and controls.
Chapter 11: Instrument Setup	Explains how to preset the instrument's various settings, such as the data analysis settings (including limits that indicate abnormal data) and detailed reagent information settings.
Appendix A: Installation	Explains how to install the CA-1500.
Appendix B: Technical Information	Includes host computer data format and communication specifications, ID barcode specifications, test protocol list, and other reference materials.
Appendix C: Wand Barcode Reader	The wand barcode reader is explained here. (The wand barcode reader is an option.)
Appendix D: Vacuum Adjustment	Explains how to adjust the vacuum pressure.
Appendix E: External Pneumatic Unit	Explains the external pneumatic unit.

PREMISES FOR SIGNS

Meaning of Signs

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 an 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 an operator, adverse effect on output, or may cause property damage.

CAUTION: • 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.

Document Conventions

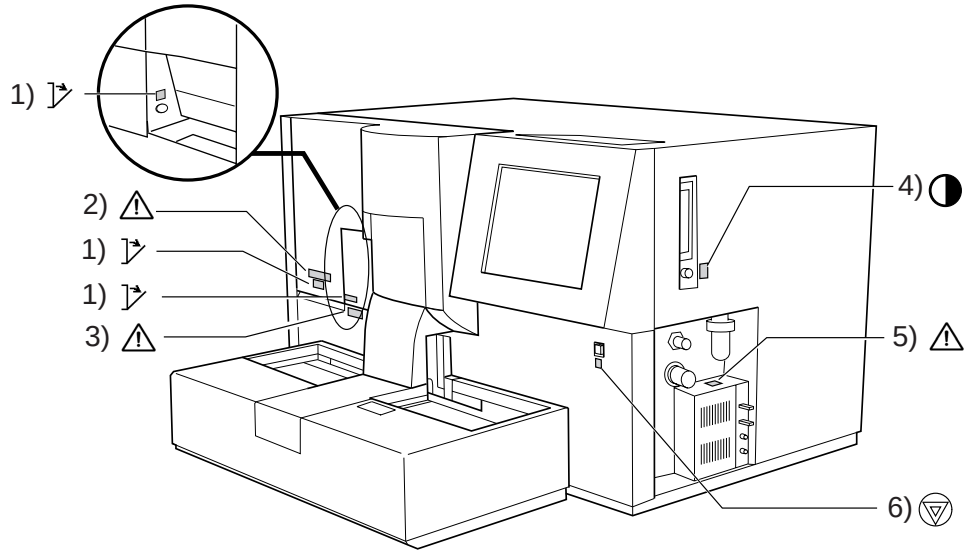
In explaining operation, this manual uses the conventions as shown below.

- The keys on the panel keyboard are expressed within square brackets.
  For example: [Start], [Print], [↑]
- The display on LCD appears within quotation marks.
  For example: "Ready", "Validated"

NOTE:
- LCD and printing described in this manual may differ from those in practice.
- As a result of product improvements, details described in this manual may differ slightly from the actual product.

Markings on the Instrument

CA-1500 Main Unit



1) Push here, and this door will open.

2)

CAUTION

Transportation arm will suspend operation when this lid is open.

3)

WARNING

To avoid hardware damage, do not push the STAT cover when LED lights in red.

4) Turn this knob to control brightness.

5)

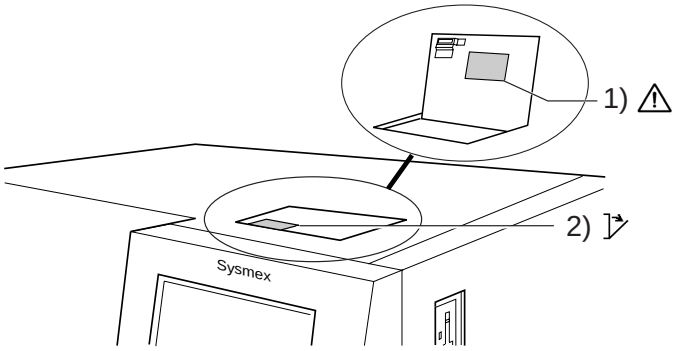
WARNING

Remove the power before attempting to replace the lamp.

Perform lamp calibration after replacing the lamp.

6) Fast Stop (Mechanical Stop)

Reaction Tube Hopper



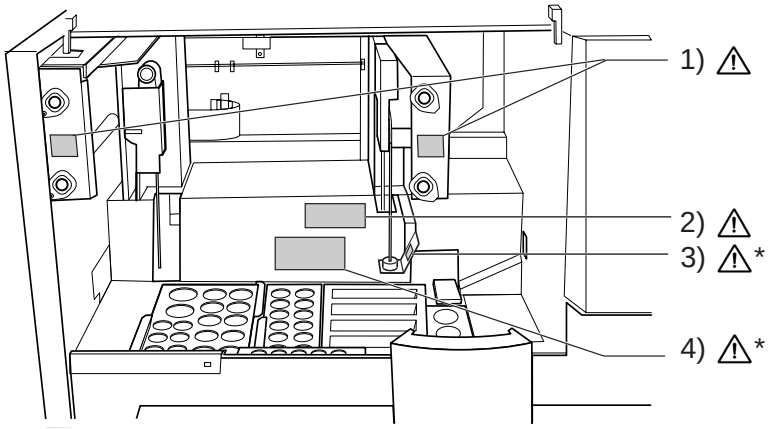
1)

CAUTION

Do not fill the hopper above the red line.
Hopper capacity is approximately 300 tubes.

2) Push here, and this door will open.

Front Interior



1)

CAUTION

When moving the arm,
pull up the pipette to the top.

2)

CAUTION

Use the buffer solution after equilibrating to the room temperature.

3) *

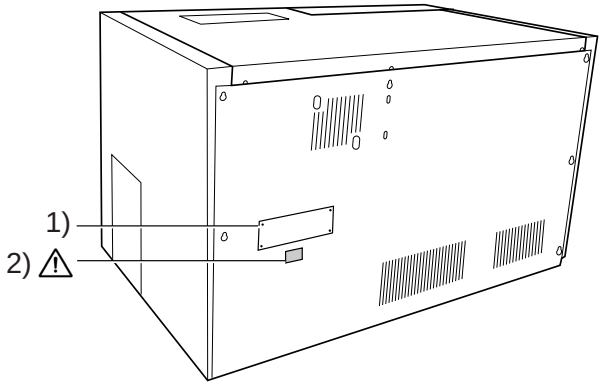
WARNING
Piercer Inside

4) *

WARNING
Handle the piercer with care.
The tip of the piercer is sharp.
If it touches your hands or fingers,
you may be injured or be infected.
Be careful especially when replacing.

* These Markings are affixed only when a Cap Piercer Unit is Installed.

Rear



1) Name Plate

SN Serial Number

Date of Manufacture

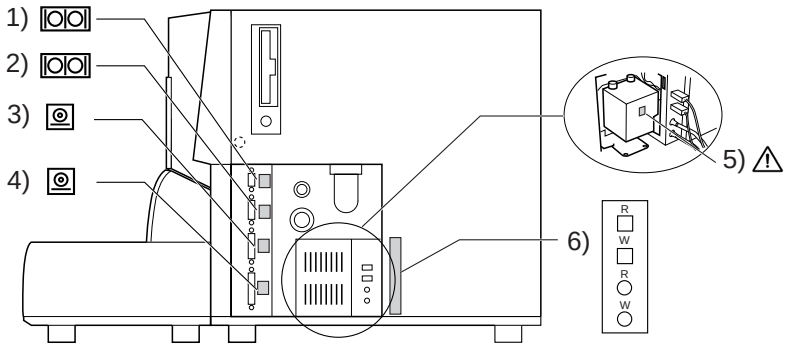
Name of Manufacturer

IVD For *In Vitro Diagnostic* Use

2)

WARNING
To avoid electrical shock,
disconnect supply before servicing.

Right Side



1) RS-232C Serial Port

2) RS-232C Serial Port (HC Connector)

3) Parallel Port (GP Connector)

4) Parallel Port (DP Connector)

5)

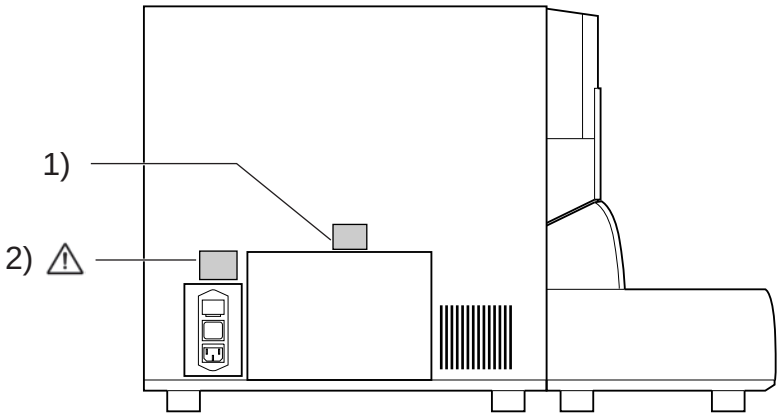
WARNING!

- IF THE LAMP IS HOT, USE HEAVY GAUZE OR APPROPRIATE PROTECTION WHEN HANDLING THE LAMP.
- REMOVE THE POWER BEFORE ATTEMPTING TO REPLACE THE LAMP.

6) The meanings of these abbreviations are:

R: Rinse
W: Waste

Left Side



1)

WARNING

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.

2)

WARNING

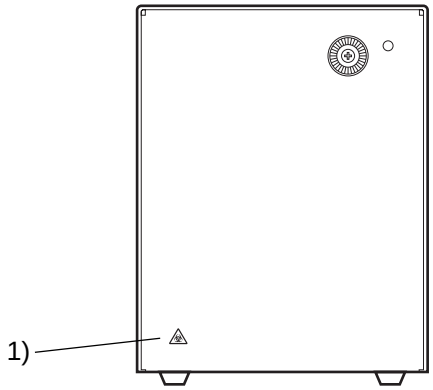
- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

WARNING

This equipment must be earthed.

External Pneumatic Unit (Option)

Front of the Pneumatic Unit

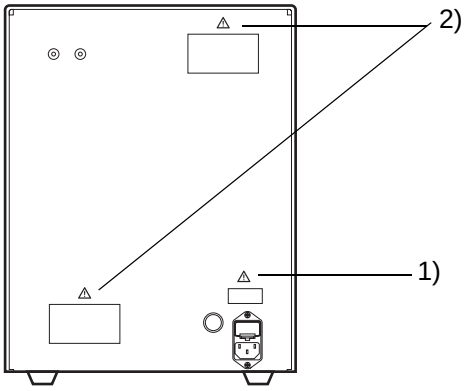


1)

RISK OF INFECTION

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

Rear of the Pneumatic Unit



1)

WARNING

- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

2)

WARNING

Do not block the exhaust openings on the rear of the pneumatic unit.

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1. INTRODUCTION

The Sysmex® CA-1500 is a fully automated blood coagulation analyzer *For In Vitro Diagnostic Use* to perform blood coagulation tests in clinical laboratories.

Chapter 1 provides an overview of the instrument and analysis procedures that should be read before the CA-1500 is used in a daily routine.
The major elements of Chapter 1 are listed below.

Instrument Overview
Provides an overview of the CA-1500's functions and describes options that enable the instrument to be used efficiently.

Analysis Procedure Overview
Provides an overview of the analysis procedure, LCD screen display, and Touch Panel key operation.

Installation Precautions
Explains matters that require confirmation before installing the instrument, such as the installation space, required equipment, and environmental conditions.

Instrument Specifications
Provides the instrument specifications.

Menu Tree
Shows a menu tree of the CA-1500.

2. INSTRUMENT OVERVIEW

The CA-1500 is a fully automated blood coagulation analyzer *For In Vitro Diagnostic Use* that can quickly analyze large volume of samples with a high degree of accuracy. The CA-1500 can analyze samples using Coagulation, Chromogenic and Immunoassay Methods. The analyzed data can be retained as stored data, displayed, and printed (if optional printer is provided). The instrument also has a number of built-in functions, including priority processing of STAT samples and quality control.
A cap piercer unit can be installed as a factory option.

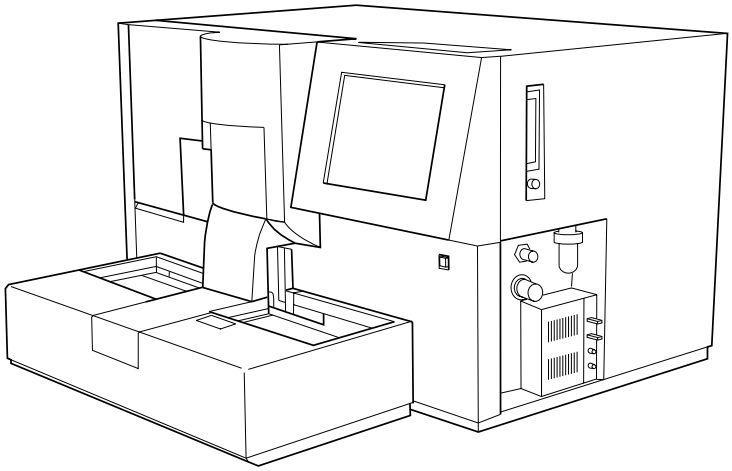


Figure 1-2-1: Overview of CA-1500

3. OPTIONAL UNITS

To enable the instrument to be used efficiently, several optional units have been provided.

- ID Barcode Reader: During analysis, reads the barcode that are affixed to the tubes, and automatically sets the sample ID numbers.
- Data Printer: Prints the analysis data onto a ticket format.
- Graphic Printer: Prints the analysis data with coagulation curves on letter or A4-size paper.
- Wand Barcode Reader: Reads the reagent barcode, and automatically sets the reagent information.

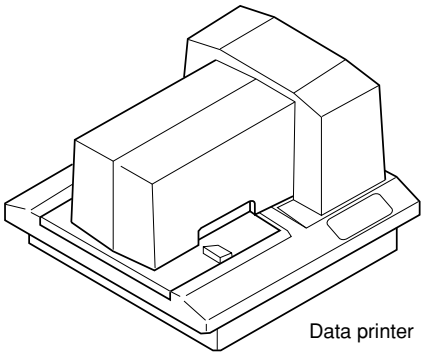


Figure 1-3-1: Data Printer

- External Pneumatic Unit: When CA-1500 is used at high altitudes, there is the possibility of a pressure error. The external pneumatic unit is effective in preventing the pressure error.

4. OUTLINE OF OPERATION

Analysis is performed after analysis order information is registered (entered) in the Work List program. The order information (consisting of sample ID numbers and analysis parameters) can be registered in one of the three ways described below.

- Manual registration:
  The order information is registered (entered) manually in the screen.
- On-line registration (Manual inquiry):
  Rack numbers and sample ID numbers are registered manually, and the analysis parameters are received from the host computer (option).
- On-line registration (Auto inquiry):

The analysis parameters are received from the host computer (option), based on the sample ID numbers that are read by the ID barcode reader (option).

Analysis procedures for each registration method are as follows:

<table>
<tr><th>Manual Registration</th><th>On-line Registration
(Manual Inquiry)</th><th>On-line Registration
(Auto Inquiry)</th></tr>
<tr><td colspan="3">Check before turning ON power</td></tr>
<tr><td colspan="3">Power ON</td></tr>
<tr><td colspan="3">Self-check</td></tr>
<tr><td colspan="3">Ready</td></tr>
<tr><td colspan="3">Preparation of reagents</td></tr>
<tr><td rowspan="2">Work List
(Manual registration)</td><td>Preparation of samples</td><td rowspan="2">Preparation of samples</td></tr>
<tr><td rowspan="2">Work List
(Press [HC] key.)</td></tr>
<tr><td>Preparation of samples</td></tr>
<tr><td colspan="3">Press [Start] key.</td></tr>
<tr><td colspan="3">Execution of analysis</td></tr>
<tr><td colspan="3">Ready</td></tr>
<tr><td colspan="3">Power OFF</td></tr>
<tr><td colspan="3">Post-analysis operations</td></tr>
</table>

Table 1-4-1: Operation Flow

- : Indicates actions performed by the operator.
- **READY** : The message "Ready" will appear on the LCD screen, indicating that analysis, setting, data processing, and other operations can be executed.

5. ANALYSIS PARAMETERS AND CALCULATED PARAMETERS

The CA-1500 uses citrated human plasma and serum to analyze and calculate the parameters shown below. Additional analysis and calculation parameters can be registered as well.

The following list shows the analysis and calculation parameters that could be analyzed by the CA-1500.

Method	Analysis parameters	Calculation parameters
Coagulation	Prothrombin Time (PT)	Prothrombin Activity Percent* Prothrombin Ratio INR Derived Fbg
	Activated Partial Thromboplastin Time (APTT)	
	Fibrinogen clotting time (Fbg)	Fibrinogen concentration
	Thrombin Time (TT)	
	Thrombotest (TTO)*	Thrombotest Activity Percent*
	Normotest (NT)*	Normotest Activity Percent*
	Extrinsic Factor Deficiency Assay (II, V, VII, X)	Factor II Activity Percent Factor V Activity Percent Factor VII Activity Percent Factor X Activity Percent
	Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII)	Factor VIII Activity Percent Factor IX Activity Percent Factor XI Activity Percent Factor XII Activity Percent
	Protein C Coagulometric (PCc)	Protein C Activity Percent
	Batroxobin Time	
	Lupus Anticoagulant Screening(LA1) Lupus Anticoagulant Confirmation(LA2)	LA1/LA2 Ratio
	Protein S	Protein S Activity Percent
Chromogenic	Antithrombin III (AT III)	Antithrombin III Activity Percent
	α2-Antiplasmin (α2PI)	α2-Antiplasmin Activity Percent
	Plasminogen (Plg)	Plasminogen Activity Percent
	Protein C (PC)	Protein C Activity Percent
	Heparin	Heparin IU/mL
	Factor VIII Chromogenic (F VIII CH)	Factor VIII Activity Percent
Immunoassay	Fibrin Degradation Product (FDP)**	FDP Concentration**
	D-Dimer	D-Dimer concentration
	von Willebrand Factor Antigen (vWF Ag)*	von Willebrand Factor Percent*

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

Table 1-5-1: Analysis Parameters and Calculation Parameters

CAUTION: • Serum samples which are extracted with special sample tubes are used for analyzing FDP*, and plasma samples are used for other analysis parameters.
If you analyze a wrong sample, correct analysis results will not be obtained

* Available for use only in Asia.

NOTE: • You can set up to 3 types of calculation parameters each for an analysis parameter.

6. LCD SCREEN AND TOUCH PANEL

The instrument's status, analysis results, and all other information are displayed on the CA-1500's LCD screen. The LCD screen consists of the System Status Area, Data Processing Area, and Menu Area. Pressing the areas in which keys are shown will activate the functions indicated by the keys.

6.1 LCD Screen

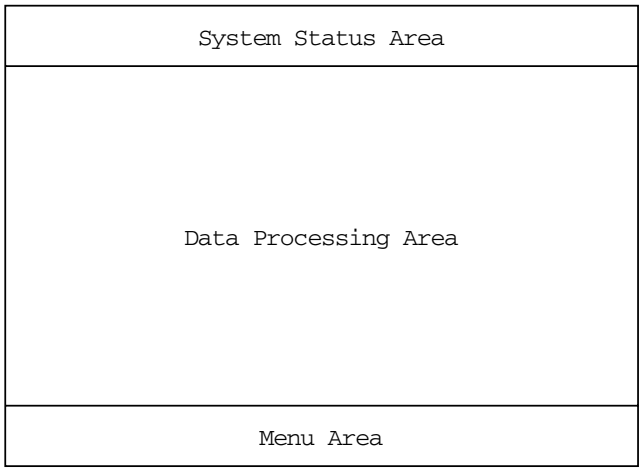


Figure 1-6-1: Display Screen

System Status Area
The System Status Area shows the [Sysmex] key, error messages, status of analyses, status of peripheral equipment, and other information.

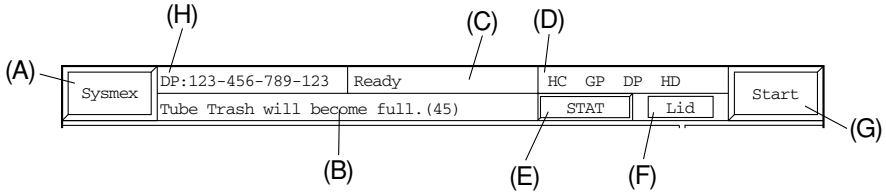


Figure 1-6-2: System Status Area

(A) Sysmex key
If you press this key, the Sysmex menu will appear, as well as the Screen Print, Error Log, and Auto QC menu windows. If an alarm sounds after an instrument error occurs, the [Alarm Reset] key will appear. If you press the [Screen Print] key, the screen that was displayed before the [Sysmex] key was pressed will be printed out by the graphic printer (GP) if provided. Pressing the [Error Log] key will display the error history.
Pressing the [Auto QC] key will display the window for selecting analysis parameters to automatically execute quality control analysis.
For details on the [Alarm Reset] key, see *Chapter 9, Section 4.3: Troubleshooting Guide*. For details on the [Error Log] key, see *Chapter 9, Section 3: HOW TO DISPLAY ERROR LOG*. For details on the [Auto QC] key, see *Chapter 2, Section 7: QUALITY CONTROL*.

(B) Error Messages
This area displays an error message that currently occurs. If two or more errors have occurred simultaneously, check the Error Log.
For details, see *Chapter 9: TROUBLESHOOTING*.

(C) Analysis Status
This area displays the current analysis status of the instrument. Messages such as "Ready", "Dispensing" and "Waiting" will be displayed.

(D) Status of Peripheral Equipment
This area displays the status of connections with peripheral equipment.

- **HC (Host Computer)**
  No indication : Host Computer is set to "Not Connected".
  HC : Ready for communication with Host Computer.
  HC (green back-light) : Currently communicating with Host Computer.
  HC (red back-light) : Error/abnormality in Host Computer is preventing communication.
- **GP (Graphic Printer)**
  No indication : Graphic Printer is set to "Not Connected".
  GP : Graphic Printer is ready for printing.
  GP (green back-light) : Graphic Printer is currently printing.
  GP (red back-light) : Error/abnormality is preventing Graphic Printer from printing.
- **DP (Data Printer)**
  No indication : Data Printer is set to "Not Connected".
  DP : Data Printer is ready for printing.
  DP (green back-light) : Data Printer is currently printing.
  DP (red back-light) : Error/abnormality is preventing Data Printer from printing.
- **HD (Hard Disk)**
  No indication : Hard Disk is not being accessed.
  HD (green back-light) : Hard Disk is currently being accessed to read or write.
  HD (red back-light) : Error/abnormality is preventing Hard Disk from being accessed.

CAUTION: • Do not turn OFF the power while the hard disk is being accessed. Stored data can be lost.

(E) [STAT] key
If you press this key, the Work List screen (which is used for STAT sample analyses) will appear. For details, see *Chapter 4, Section 3: ANALYZING STAT SAMPLES*.

(F) Lid Signal
This signal indicates whether the light shield lid can be opened.
Lid (green back-light): The light shield lid can be opened.
Lid (red back-light): The light shield lid should not be opened.

WARNING: • If the indicator shows that the light shield lid should not be opened, do not open it or place your hands or fingers inside. You could get injured. If the light shield lid is opened during an analysis, an alarm will sound and operation will stop.

(G) [Start] key
This key is used to start and interrupt analysis. Depending on the status of the instrument, the key will change between [Start], [Interrupt], and [Resume].

(H) Data Printer Next Sample ID Number
If an optional data printer is connected, the sample ID number for the analysis results to be printed next will appear.

Data Processing Area
The Data Processing Area will display the progress of analysis, work list, stored data list, coagulation curve, quality control data, standard curve data, current instrument settings, and other information. When the power is turned ON, the analysis progress screen (Main Menu screen) will appear.
If needed to check, the confirmation window will appear. After checking a message on the confirmation window, press the [OK] key. The confirmation window will disappear.

Menu Area
The Menu Area displays menus that are used to select functions. To select a menu, lightly press the key that indicates the desired menu item. When the power is turned ON, a system check will be automatically executed and then the Main Menu screen will appear. The Main Menu is the basic menu that is used to select the functions that the instrument is equipped with.

NOTE:
- If a key has not been pressed for over 5 minutes, the LCD backlight will become slightly dimmer. To return the LCD to its original brightness, touch anywhere on the LCD screen.
- If the LCD screen is always very bright or very dim, adjust it by turning the brightness control knob located on the right side of the main unit.

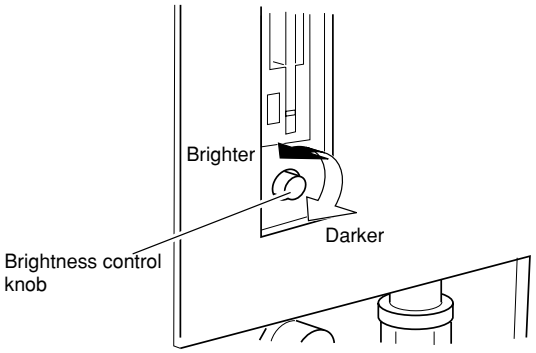


Figure 1-6-3: Brightness Control Knob

6.2 Touch Panel Keys

The LCD screen is also a Touch Panel. Areas that are indicated by ▭ are keys. By pressing a key, you can display, print-out, or set information that you need.

Basic Key Operation

Parameter keys: Are used to display the screens used for parameter-related settings and to switch the information that is displayed for parameters. Press the key for the parameter you wish to select. Its color will change to sky blue.

[↑], [↓], [←], and [→] keys: Are used to move the cursor. If parameters are listed, press these keys to move the cursor to the parameter you wish to select.

Numeric keys: Are displayed when it is necessary to enter a sample ID number, date, numerical figures, and other information. Press the numeric keys to enter the information.

Example of numeric keys used to enter a sample ID number

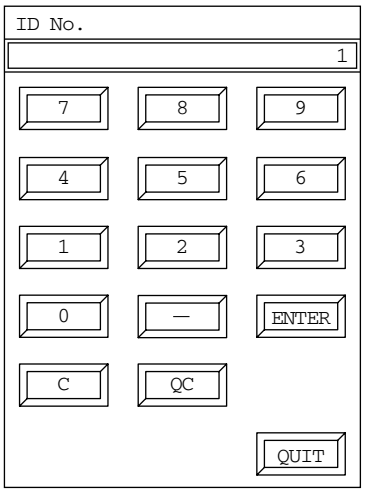


Figure 1-6-4: Numeric Keys

If you press a numeric or special character key, the number that was entered will appear in the numeric key input display.
If you press [C] key, the last number or special character entered will be deleted.
After entering the numbers, press the [ENTER] key to set the entered value. Press the [QUIT] key to cancel the entered value and quit numeric key operation.

Alphanumeric keys:

Are displayed when it is necessary to use alphanumeric characters, such as when entering the name of reagents. Press the alphanumeric keys to enter the information.

Example of keys used to enter a reagent name

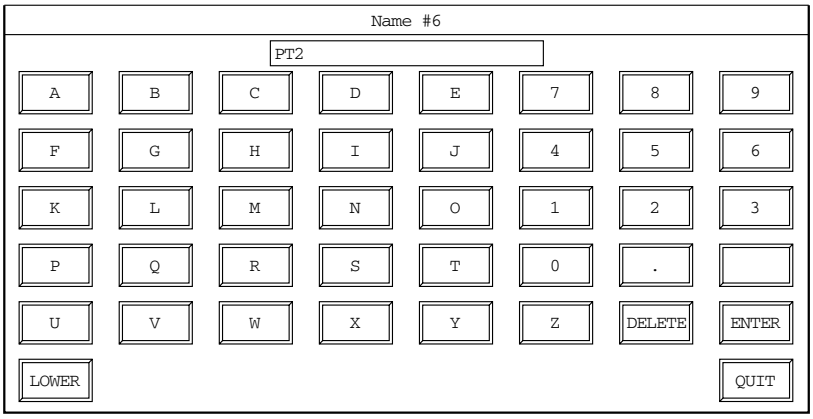


Figure 1-6-5: Alphanumeric Keys (Uppercase)

To enter lowercase (small) letters, press the [LOWER] key. The keys now represent lowercase letters.

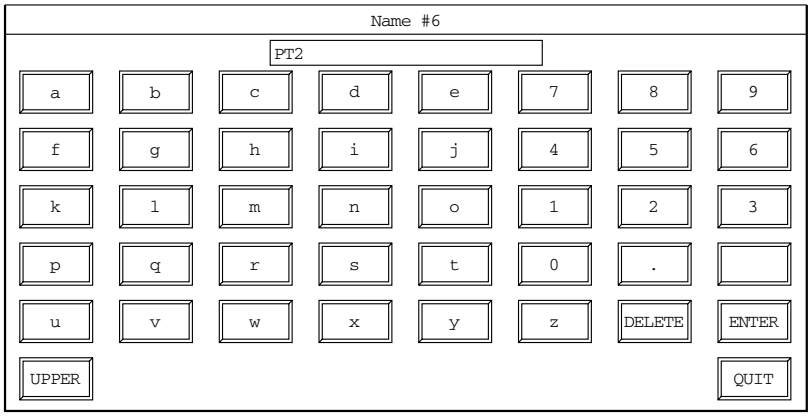


Figure 1-6-6: Alphanumeric Keys (Lowercase)

If you press an alphanumeric key, the character that was entered will appear in the alphanumeric key input display.
If you press the [DELETE] key, the last alphanumeric character entered will be deleted.
After entering the characters, press the [ENTER] key to set the entered information. Press the [QUIT] key to cancel the entered information and quit alphanumeric key operation.

7. PASSWORDS

Important programs are protected by a password so that the programs can be executed under the control of a supervisor.
When a program that is protected by a password is to be executed, a Password Entry window will appear. To execute the program, enter the preset password and press the [Enter] key.
For details on how to set and change the password, see *Chapter 11, Section 8.3: Password Settings*.

8. EMERGENCY STOP PROCEDURE

Should the instrument need to be shut down in an emergency, such as a power failure in the laboratory, immediately turn OFF the power.
Note that the mechanical stop switch located at the bottom of the LCD screen will immediately stop the operation of the mechanical unit, but will not turn OFF the power.

9. ALARMS

The CA-1500 makes four types of alarm sounds.

1. Key Entry
   A short beep (lasting approximately 0.1 second) sounds each time a key is pressed on the LCD Touch Panel.

2. Sample Pipetting Completed
   Two short beeps followed by a long beep will sound after all the samples have been pipetted to the sample plates or after an interruption.

3. Analysis Completed
   Three short beeps followed by a long beep will sound after all registered samples have been analyzed.

4. Instrument Error
   A long beep will sound following the occurrence of an instrument error.
   The sound will continue until the [Alarm Reset] key is pressed.
   When an alarm sounds, the [Alarm Reset] key will be displayed in place of the [Sysmex] key.

10. PACKAGING

The CA-1500 is thoroughly checked before it is shipped from the factory, and is carefully packaged to withstand shocks during shipment.
After the CA-1500 has been delivered, check the packaging. Make sure that the instrument is free of exterior damage.
Your service representative will unpack and install the instrument after delivery and will also set the initial settings.
See *Appendix A: INSTALLATION* to verify the contents of the delivered product.

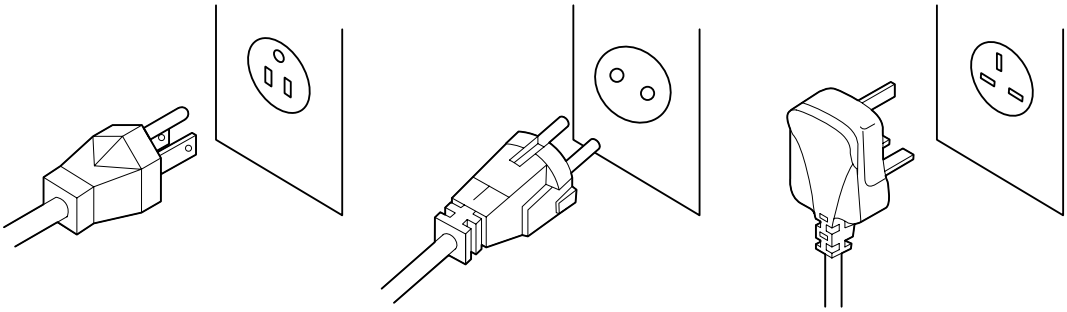
11. INSTALLATION ENVIRONMENT

11.1 Installation and Relocation

The CA-1500 is installed by your Service representative. In case relocation becomes necessary after installation, contact your service representative.
Problems resulting from the relocation of the instrument by anyone other than a service representative are not covered by the Warranty even if it is in the warranty period.

11.2 Grounding

The instrument power supply cord uses a 3-prong plug. When the power supply socket is 3-prong (with grounded), simply plug it to the socket.



117 VAC Spec. 220 VAC Spec. 240 VAC Spec.

Figure 1-11-1: Plugs

WARNING: • Make sure to ground the instrument. Inadequate grounding could cause electrical shocks.

NOTE: • The number of power supply sockets required is 3 including optional Data Printer and Graphic Printer.

11.3 Installation Space

To ensure that the instrument fulfills its function, it is important to install it in an appropriate place:

- Select a place that is close to the power supply and suitable drain.
- Select a level and steady surface to avoid functional errors.
- Secure a place spacious enough for maintenance and service. Giving consideration to heat radiation by the instrument, provide at least 50 cm distance from the wall to side, rear, and top panels.

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

You may need some more desktop space if optional Data Printer and Graphic Printer are provided.

	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main Unit	780	500	500	75
Sampler	580	280	270	9.5

When a cap piercer unit is installed, the instrument weight is 78 kg.

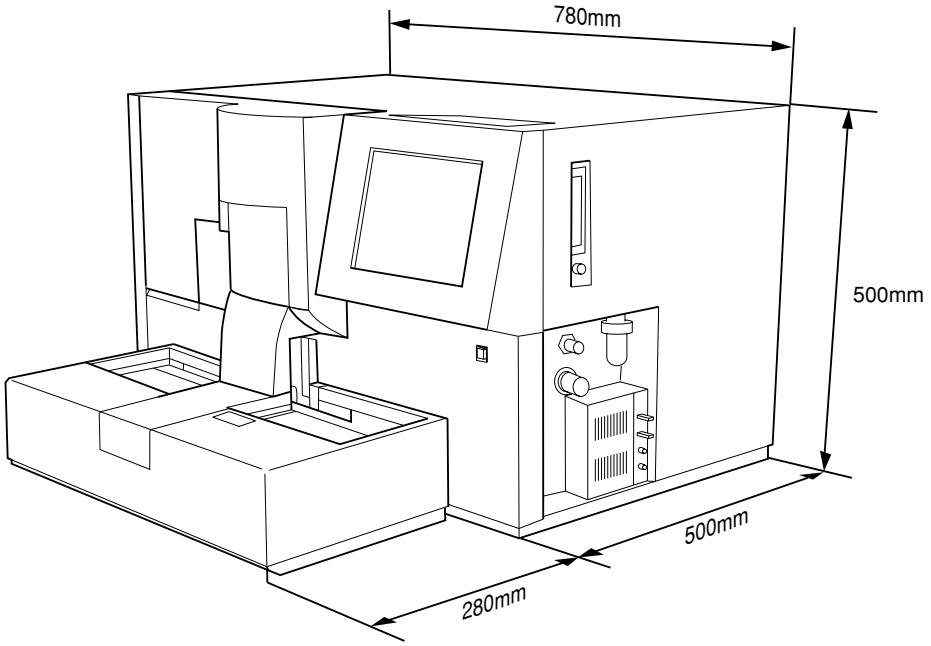


Figure 1-11-2: Instrument Dimensions

11.4 Installation Environment

- Use the instrument at an ambient temperature of 15° C - 30° C (optimum: 23° C).
- Use it at a relative humidity range of 30% - 85%.
- When air conditioning is used, a maximum cooling capacity of about 600 kcal/hour is required to offset the heat from the instrument.
- Avoid a place that can become extremely hot or cold.
- Avoid a place that can be exposed to direct sunlight.
- Choose a well-ventilated place.
- Avoid a place close to a wireless telegraph or communication facility where high frequency waves can be generated or radio interference can occur.

12. INSTRUMENT SPECIFICATIONS

Analysis parameters/Calculation parameters
See *Section 5: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS* in this chapter.

Simultaneous Random Analysis of 15 Parameters
Random analysis is possible.

Throughput
Maximum: Approx. 120 tests/hour
Average (during simultaneous analysis of 2 parameters: PT and APTT): Approx. 80 tests/hour

Required Sample
The value in ( ) is applicable when the cap piercer unit is installed.

Prothrombin Time (PT):	50 µL
Activated Partial Thromboplastin Time (APTT):	50 µL
Fibrinogen concentration (Fbg):	10 µL
Thrombotest (TTO)*:	20 µL
Normotest (NT)*:	10 µL
Thrombin Time (TT):	50 µL
Extrinsic Factor Deficiency Assay (II, V, VII, X):	5 µL
Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII):	5 µL
Antithrombin III (AT III):	16 µL (Berichrom° Antithrombin III (A))
α2-Antiplasmin (α2PI):	16 µL (Berichrom° α2Antiplasmin)
Plasminogen (Plg):	16 µL (Berichrom° Plasminogen)
Protein C (PC):	15 µL (Berichrom° Protein C)
Protein C Coagulometric (PCcl):	5 µL
Protein S (PSAc):	16 µL (Protein S Ac Reagent)
Heparin:	20 µL
Chromogenic (F VIII CH):	10 µL
Fibrin Degradation Product (FDP)**:	
Latex Test BL-2 P-FDP	16 (18) µL
D-Dimer:	
D-Dimer PLUS*	50 µL
Advanced D-Dimer#	50 µL
INNOVANCE° D-Dimer	13 µL
Batroxobin Time:	50 µL
Lupus Anticoagulant Screening (LA1):	100 µL
Lupus Anticoagulant Confirmation (LA2):	100 µL
von Willebrand Factor Antigen (vWF Ag)*:	
vWF.m	15 µL (vWF Ag Reagent)
vWF.l	75 µL (vWF Ag Reagent)
vWF.h	5 µL (vWF Ag Reagent)

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

Analysis Principles

1. Coagulation Method
   - Coagulation Reaction Detection Method (Scattered Light Detection Method)
     Irradiates red light (660 nm) onto a mixture of blood plasma and reagent and detects the change in turbidity (when the fibrin clots are formed) as the change in scattered light. The coagulation time is measured.

   - Coagulation Point Detection Method (Percentage Detection Method)
     Calculates the coagulation time as the time required to achieve the amount of scattered light that is set for the coagulation detection point, using the amount of scattered light that is present just after the start of detection as 0%, and the amount of scattered light that is present at the completion of coagulation as 100%.

2. Chromogenic Method
   Starts a reaction by mixing plasma, reagent, and substrate; then detects the change in absorbance and calculates the result.

3. Immunoassay Method
   Starts a reaction by mixing plasma and latex reagent; then detects the change that occurs in the absorbance of the latex aggregate and calculates the result.

Range of Analysis

1) Fibrinogen Concentration
   Can analyze from 25 mg/dL to 1000 mg/dL. For 450 mg/dL and higher, however, performs automatic redilution analysis (1:20 dilution) in high-concentration mode; and for 50 mg/dL and below, performs automatic redilution analyses (1:5 dilution) in low-concentration mode. The operator can set redilution concentration as required.

Detection Time

Detects within the maximum detection time, and measures the result.
Typical maximum detection time: 100 seconds for PT and Fbg; 190 seconds for others.
Maximum detection time in automatic extended mode: 600 seconds for each parameter

Manufacturer's Reproducibility Data

Prothrombin Time (PT):	C.V. 2% or less
Activated Partial Thromboplastin Time (APTT):	C.V. 2% or less
Fibrinogen (Fbg):	C.V. 4% or less
Thrombotest (TTO)#:	C.V. 4% or less
Normotest (NT)#:	C.V. 4% or less
Thrombin Time (TT):	C.V. 10% or less
Extrinsic Factor Deficiency Assay (II, V, VII, X):	C.V. 5% or less
Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII):	C.V. 5% or less
Antithrombin III (AT III):	C.V. 5% or less
α2-Antiplasmin (α2PI):	C.V. 5% or less
Plasminogen (Plg):	C.V. 5% or less
Protein C (PC):	C.V. 5% or less
Batroxobin Time:	C.V. 4% or less
Lupus Anticoagulant Screening (LA1):	C.V. 4% or less
Lupus Anticoagulant Confirmation (LA2):	C.V. 4% or less

Not available in the USA.

The data above are variation coefficients for coagulation times (in seconds) or for the amount of change in activity% (AT III, α2PI, Plg, PC) taken from 8 or 10 analyses of Siemens Normal Control Plasma with the reagents used below:

Dade® Thromboplastin C Plus
Dade® Actin® Activated Cephaloplastin Reagent
Calcium Chloride Solution (0.025 mol/L)
Dade® Fibrinogen Determination Reagents
Dade® Owren's Veronal Buffer
CA Series Complex Factor TTO #
CA Series Complex Factor HPT #
Factor Deficient Plasma
Berichrom° Antithrombin III (A) Reagent
Berichrom° α2-Antiplasmin Reagent
Berichrom° Plasminogen Reagent
Berichrom° Protein C Kit
Test Thrombin Reagent
Batroxobin Reagent
LA1 Screening Reagent
LA2 Confirmation Reagent

Fibrin Degradation Products (FDP):	
Latex Test BL-2 P-FDP*	C.V. 10% or less
D-Dimer:	
D-Dimer PLUS #	C.V. 10% or less
Advanced D-Dimer ##	C.V. 10% or less

The above are concentration variation coefficients taken from 10 analyses of D-Dimer Control Plasma I with D-Dimer PLUS# reagent or Advanced D-Dimer## reagent.

* Available for use only in Asia.
\# Not available in the USA.
\## Available for use only in the United States of America.

Protein C Coagulometric (PCcl):	C.V. 5% or less
Protein S (PSAc):	C.V. 20% or less
Heparin:	C.V. 5% or less
Factor VIII Chromogenic (F VIII CH):	C.V. 5% or less
von Willebrand Factor (vWF Ag)#:	C.V. 5% or less

Not available in the USA.

The data above are variation coefficients for the amount of change in activity%(PCc, PS, F VIII CH) or the concentration of Heparin (IU/mL) and vWF (%) taken from 8 analyses of Siemens Normal Control Plasma or Ci-trol® Heparin Control High, with the reagents used below:

Protein C Reagent (coagulometric)
Protein S Ac
Berichrom° Heparin Reagent
Factor VIII Chromogenic Assay
vWF Ag
Calcium Chloride Solution (0.025 mol/L)
Dade® Owren's Veronal Buffer

This data has been internally generated using Sysmex validated test protocols. Sysmex does not guarantee results for any instruments which has been modified without Sysmex approval or for any test protocols which are not approved by Sysmex.

CAUTION:
- Results should always be evaluated in conjunction with clinical and other laboratory findings.
- Independently of the concentration of analyte, unspecific reactions may be obtained in some cases and therefore the dilution of samples may lead to discordant results in certain cases.

Reproducibility Data according to FDA Guidelines (Total CV values)

Prothrombin Time (PT):	C.V. 2% or less (Unit: Second)
Activated Partial Thromboplastin time (APTT):	C.V. 2.5% or less (Unit: Second)
Fibrinogen (Fbg):	C.V. 10% or less (Unit: g/dL)
Thrombin Time (TT):	C.V. 5.1% or less (Unit Second)
Batroxobin Time:	C.V. 4.1 % or less (Unit Second)
Lupus Anticoagulant Screening (LA1):	C.V. 1.5 % or less (Unit Second)
Lupus Anticoagulant Confirmation (LA2):	C.V. 0.7 % or less (Unit Second)
Extrinsic Factor Deficiency Assay (II, V, VII, X):**	C.V. 5% or less (Unit: Activity %)
Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII):***	C.V. 5% or less (Unit: Activity %)
Antithrombin III (AT III):	C.V. 10% or less (Unit: Activity %)
Protein C (PC):	C.V. 7.5% or less (Unit: Activity %)
Plasminogen (Plg):	C.V. 6.5% or less (Unit: Activity %)
α2-Antiplasmin (α2Pl):	C.V. 13.5% or less (Unit: Activity %)
Protein C coagulometric (PCc):	C.V. 8% or less (Unit: Activity %)
Protein S Activity (PSAc):	C.V. 9% or less (Unit: Activity %)
Heparin:	C.V. 11% or less (Unit: IU/mL)
Factor VIII chromogenic (F VIII CH):	C.V. 11% or less (Unit: Activity %)
Advanced D-Dimer#:	C.V. 15% or less (Unit: mg/L FEU)
INNOVANCE° D-Dimer:	C.V. 15% or less (Unit: mg/L FEU)****

** Data evaluated for Factor VII only.

*** Data evaluated for Factor VIII only.

**** The coefficient of variation for **INNOVANCE**° D-Dimer is taken from 80 Samples of **INNOVANCE**° D-Dimer Control 1 and **INNOVANCE**° D-Dimer Control 2.

The data above are variation coefficients for coagulation times [or concentration variation coefficients (D-Dimer)] (in seconds) or for the amount of change in activity% (AT III, PC, Plg, α2PI, PCc, F VIII CH) taken from 40 analyses of Siemens Control Plasma N, Siemens Control Plasma P, a pathological pool, [Advanced D-Dimer Control Plasma 1 and 2, **INNOVANCE**° D-Dimer Control Plasma 1 and 2, and normal plasma pool] with the reagent used below:

Dade® Innovin® Reagent
Dade® Actin® FSL Activated PTT Reagent
Calcium Chloride Solution (0.025 mol/L)
Dade® Owren's Veronal Buffer
Test Thrombin Reagent
Batroxobin Reagent
LA1 Screening Reagent
LA2 Confirmation Reagent
Factor Deficient Plasma
Dade® Thrombin Reagent
Berichrom° Antithrombin III (A) Kit
Berichrom° Protein C
Berichrom° Plasminogen
Berichrom° α2-Antiplasmin
Protein C Reagent, (coagulometric)
Protein S Activity (PSAc)
Berichrom° Heparin
Factor VIII Chromogenic Assay
Advanced D-Dimer#

INNOVANCE° D-Dimer

Available for use only in the USA.

Display
Graphic display employs a liquid crystal display (LCD).

Printing
Permits graphic printing through an optional graphic printer.

External Input/Output
Equipped with an RS-232C serial port (bit serial voltage signal).

Reagent Cooling
Cooling unit keeps the reagent holder temperature cool using Peltier elements.
Reagent holders: 36 wells (15°C ± 2°C when the room temperature is within 15°C - 30°C)

Reagent Dispensing
Reagent probe detects the liquid surface of reagent, and aspirates and dispenses reagent through a syringe.

Sample Dispensing
Sample probe detects the liquid surface of sample, pipettes sample from the tubes in the sample rack, and dispenses it to the sample plates. In addition, the probe aspirates samples from the sample plates, and dispenses to reaction tube (when in normal mode).
When the amount of sample is minimal, the sample probe can pipette sample from the tubes, and dispenses it directly to the reaction tube (when in micro-sample mode).
Automatic re-analyses cannot be executed when in micro-sample mode. Also, the analysis cannot be executed in micro-sample mode by using the sample tubes with the cap when a cap piercer unit is installed.

Sample Plates
50 wells per plate, with a maximum of 5 plates placed at a time.
Used in normal mode and for standard curves and other multistage dilution analyses.

Reaction Tubes

Reaction tubes:	Approx. 300 tubes loaded in the hopper and supplied automatically

Detector

Optical detector:	8 wells (scattered light detection unit); 4 wells (transmitted light detection unit)
Incubator:	14 wells

Temperature Control

Detector:	37°C±1.0°C
Sample incubator:	37°C±1.0°C
Reagent incubation probe:	37°C±1.0°C

Applies when room temperature is within 15°C - 30°C.

Time to Reach Temperature Setting
Reaches preset temperature within 30 minutes after power is turned ON (when the room temperature is within the specified range).

Processing of STAT Samples
Sample processing can be interrupted to allow priority analysis for STAT samples. STAT samples can be set in dedicated holders or sample racks.

Automatic Re-analysis Function
When upper and lower limit values are set for re-analysis, the system will automatically execute re-analysis and dilution analysis as needed (when in normal mode).

Analysis Interrupt Function
Through settings, this function interrupts the analysis of only those parameters that cannot be analyzed (for example, when reagent runs out) and continues to analyze all other parameters.

Profile Settings
Set of multiple preset test parameters (profile) can be prepared through one-time key input.

Stored Data Capacity
Analysis data: 1000 samples (maximum of 15,000 tests)

Quality Control
$\bar{x}$ control (L-J control), Westgard Rule: 540 points × 20 files, 25 parameters

Standard Curve
6 points, 25 parameters

Auto QC
The unit can be set up to automatically execute quality control analysis at regular intervals. After the specified time period (time that was preset from the QC Setting screen) has passed since the last quality control analysis, the unit will automatically execute an analysis for quality control.

MDA (Multi-Dilution Analysis)
During an MDA, the same sample is analyzed using multiple dilution ratios. Analyzing the results of measurements taken using various dilution ratios makes it possible to check the effects of inhibitors and activators in the sample.

Power

Rated voltage:	117, 220, or 240 VAC ±10%
Frequency:	50 Hz or 60 Hz
Power consumption:	720 VA or less (including the main unit, sampler unit and optional ID Barcode Reader, and excluding optional printers)
Heat Compensation Required:	Approx. 2457 BTU/h (Approx. 619 kcal/h)

Dimensions/Weight

Main Unit: 780 (W) × 500 (D) × 500 (H) mm; approx. 75 kg
Sampler: 580 (W) × 280 (D) × 273 (H) mm; approx. 9.5 kg
When a cap piercer unit is installed, the instrument weight is approx. 78 kg.

Environmental Requirements

Temperature: 15°C to 30°C
Relative Humidity: 30% to 85%
Grounding: Hospital Grade Grounding

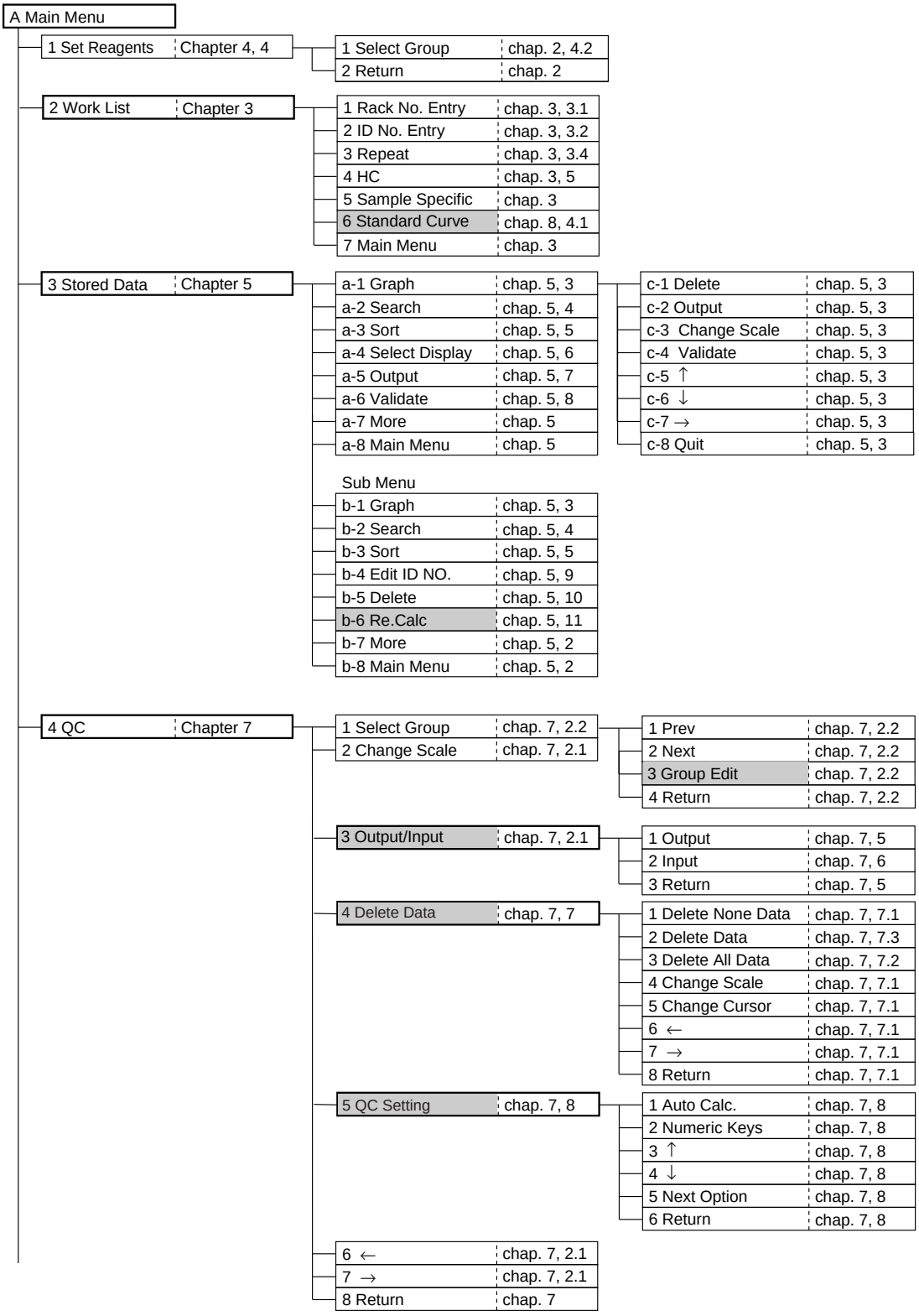
Protection Type

Class I Equipment

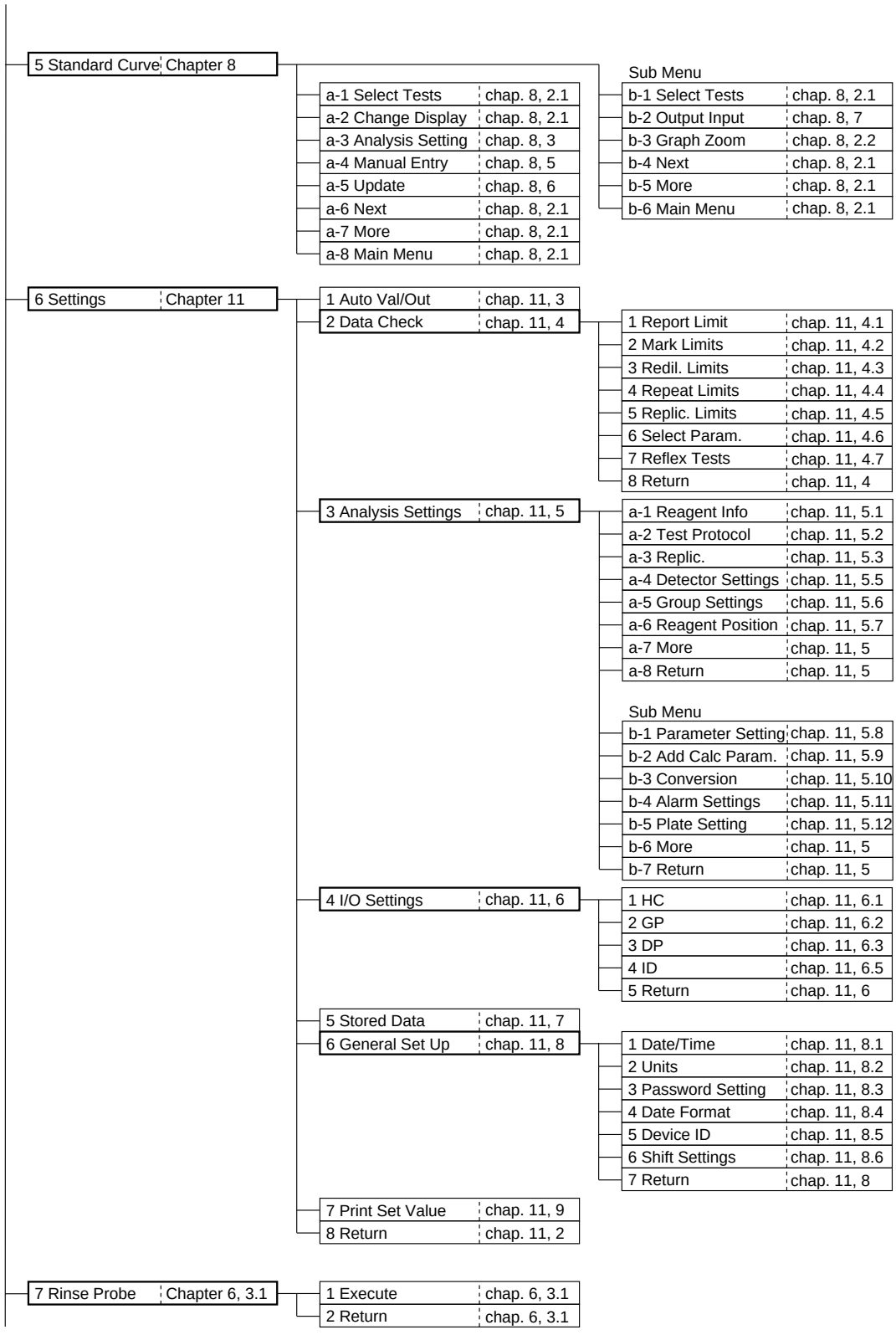
Storage Condition (Transportation)

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

13. MENU TREE



: If set, password has to be entered.


5 Standard Curve Chapter 8
a-1 Select Tests chap. 8, 2.1
a-2 Change Display chap. 8, 2.1
a-3 Analysis Setting chap. 8, 3
a-4 Manual Entry chap. 8, 5
a-5 Update chap. 8, 6
a-6 Next chap. 8, 2.1
a-7 More chap. 8, 2.1
a-8 Main Menu chap. 8, 2.1
Sub Menu
b-1 Select Tests chap. 8, 2.1
b-2 Output Input chap. 8, 7
b-3 Graph Zoom chap. 8, 2.2
b-4 Next chap. 8, 2.1
b-5 More chap. 8, 2.1
b-6 Main Menu chap. 8, 2.1
6 Settings Chapter 11
1 Auto Val/Out chap. 11, 3
2 Data Check chap. 11, 4
1 Report Limit chap. 11, 4.1
2 Mark Limits chap. 11, 4.2
3 Redil. Limits chap. 11, 4.3
4 Repeat Limits chap. 11, 4.4
5 Replic. Limits chap. 11, 4.5
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7 Reflex Tests chap. 11, 4.7
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3 Analysis Settings chap. 11, 5
a-1 Reagent Info chap. 11, 5.1
a-2 Test Protocol chap. 11, 5.2
a-3 Replic. chap. 11, 5.3
a-4 Detector Settings chap. 11, 5.5
a-5 Group Settings chap. 11, 5.6
a-6 Reagent Position chap. 11, 5.7
a-7 More chap. 11, 5
a-8 Return chap. 11, 5
Sub Menu
b-1 Parameter Setting chap. 11, 5.8
b-2 Add Calc Param. chap. 11, 5.9
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4 ID chap. 11, 6.5
5 Return chap. 11, 6
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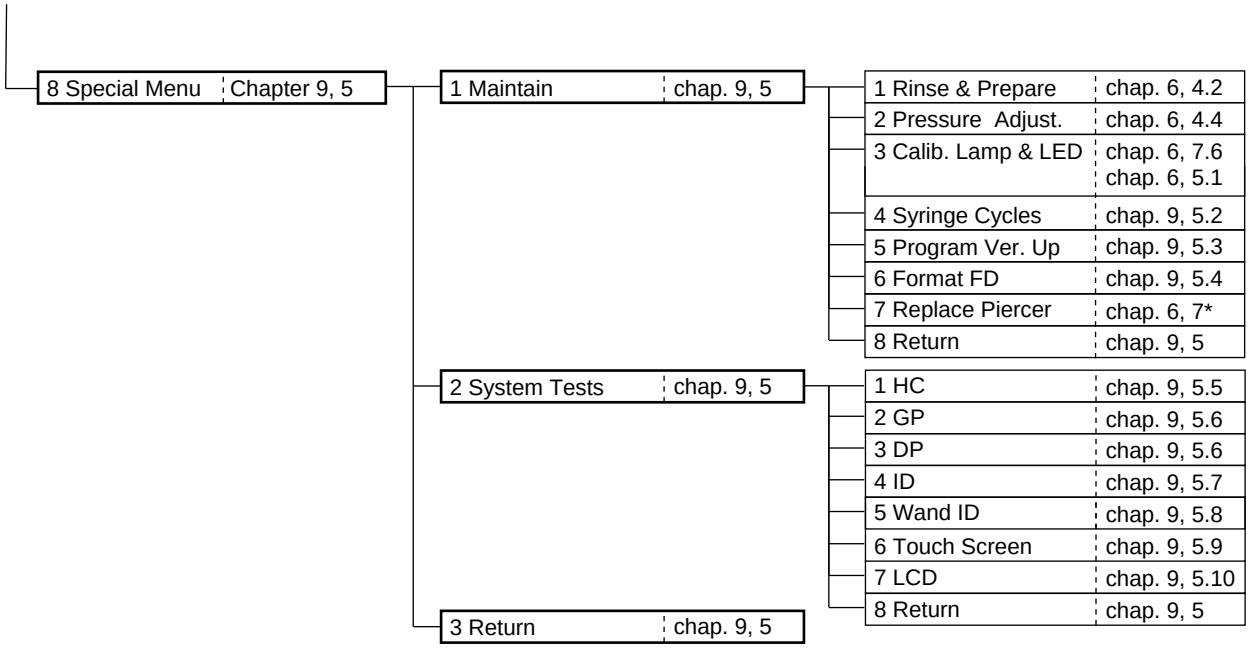
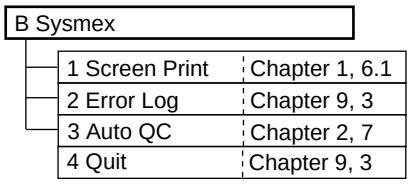
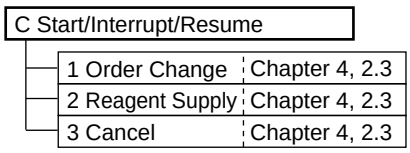
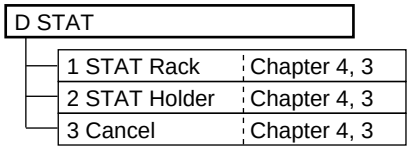
6 General Set Up chap. 11, 8
1 Date/Time chap. 11, 8.1
2 Units chap. 11, 8.2
3 Password Setting chap. 11, 8.3
4 Date Format chap. 11, 8.4
5 Device ID chap. 11, 8.5
6 Shift Settings chap. 11, 8.6
7 Return chap. 11, 8
7 Print Set Value chap. 11, 9
8 Return chap. 11, 2
7 Rinse Probe Chapter 6, 3.1
1 Execute chap. 6, 3.1
2 Return chap. 6, 3.1
: If set, password has to be entered.









* Will appear only when a cap piercer unit is installed.

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1. INTRODUCTION

Before beginning analysis, it is necessary to prepare the instrument, reagents, and samples. Prepare for analysis by following the steps described below.

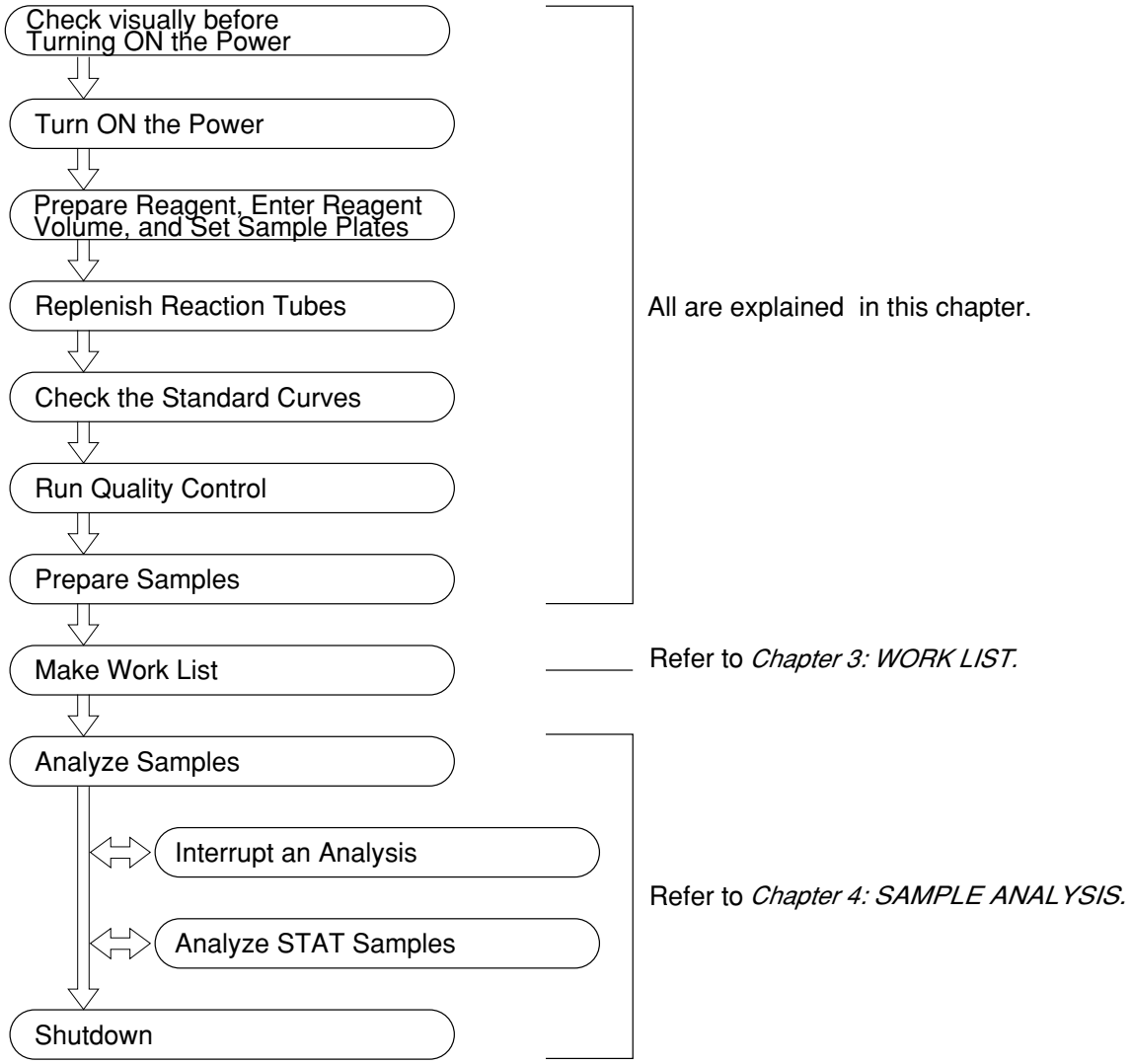


Figure 2-1-1: Analysis Flow Chart

2. BEFORE TURNING ON THE POWER

Before turning ON the power to the instrument, check the following items:

1. Rinse Solution Tank
If the level of the rinse solution is low, fill the rinse tank with distilled water or deionized water.

2. CA-1500 Instrument Visual Check
Check the tubing and cord connections. Make sure that no tubes are disconnected or kinked and that the power cord is securely plugged into the AC outlet.

3. Printer Paper
If a printer is provided, make sure that it contains the amount of paper necessary for the number of samples to be processed that day.

3. TURNING ON THE POWER

Turn ON the power switch that is located on the left side of the main unit. The instrument will automatically perform a self-check and enter "Ready" status (in other words, it will be ready to perform analysis).

(1) Turn the power switch to ON.
A self-check will automatically be performed. During the self-check, the following screen will appear. It will take approx. 60 seconds to complete.

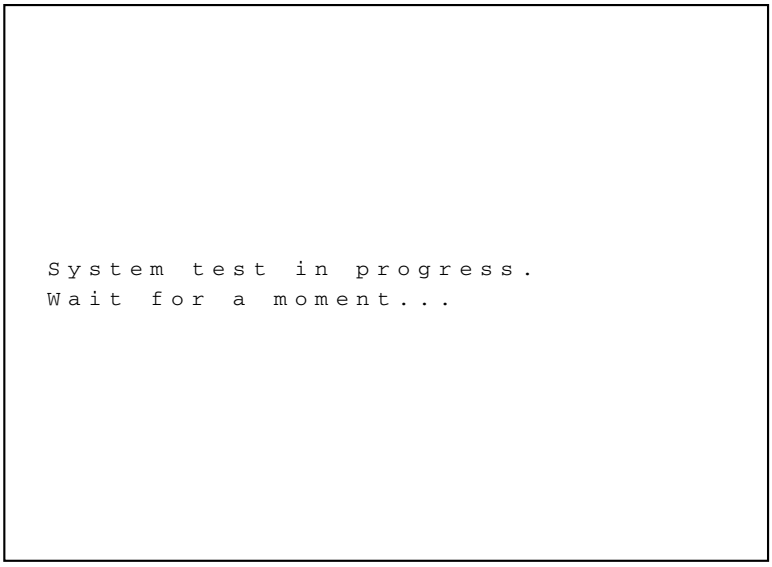


Figure 2-3-1: Initial Display

(2) When the self-check is completed without finding any error, the program will be loaded. After the program is loaded, the Main Menu screen will appear.

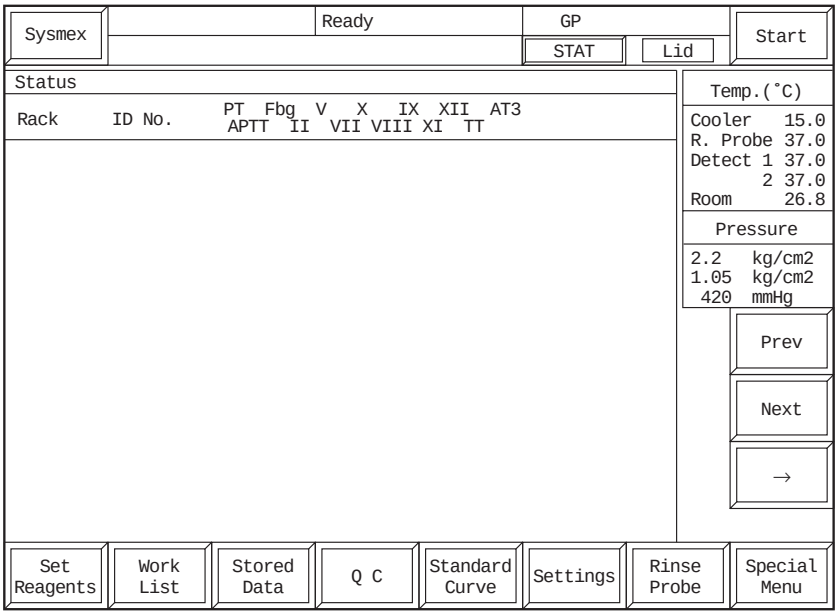


Figure 2-3-2: Main Menu Screen

CAUTION • After the power is turned ON, it will take a maximum of 30 minutes for the intensity of the Lamp unit to stabilize. Before starting to analyze Chromogenic and Immunological assays wait 30 minutes. If you start to analyze earlier, while the light intensity is unstable, the analysis results may be incorrect.

NOTE: • After the power is turned ON, it will take a maximum of 30 minutes for the detector block to reach the prescribed temperature to perform analysis. When the temperature reaches within the specified range, the message "Not Ready" will change to "Ready".

4. REAGENT PREPARATION

4.1 Preparing Reagents

Prepare the required volume of coagulation reagents, Owren's Veronal buffer, and reagent rinse solution for the anticipated work load.
For further information please refer to additional Reagent Information.

Parameter	Reagent	Consumption/Test*
PT	PT Reagent	100 µL
APTT	APTT Reagent	50 µL
	Calcium Chloride Solution	50 µL
Fbg	Thrombin Reagent	50 µL
	Owren's Veronal Buffer	90 µL
	Probe Rinse Solution CA CLEAN I	50 µL
TTO#	Thrombotest Reagent	125 µL
	Owren's Veronal Buffer	30 µL
NT#	Normotest Reagent	125 µL
	Owren's Veronal Buffer	40 µL
TT	Test Thrombin Reagent	100 µL
	Probe Rinse Solution CA CLEAN I	100 µL
Batroxobin Time	Batroxobin Reagent	100 µL
	Probe Rinse Solution CA CLEAN I	100 µL
LA1	LA1 Screening Reagent	100 µL
	Probe Rinse Solution CA CLEAN I	100 µL
LA2	LA2 Confirmation Reagent	100 µL
	Probe Rinse Solution CA CLEAN I	100 µL
Extrinsic Factor Deficient Assay	PT Reagent	100 µL
	Factor-deficient Plasma	50 µL
	Owren's Veronal Buffer	45 µL
Intrinsic Factor Deficient Assay	APTT Reagent	50 µL
	Calcium Chloride Solution	50 µL
	Factor-deficient Plasma	50 µL
	Owren's Veronal Buffer	45 µL
AT III	Activator	175 µL
	Substrate	33 µL
	Owren's Veronal Buffer	112 µL
	Probe Rinse Solution CA CLEAN I	350 µL
α2PI	Activator	175 µL
	Substrate	35 µL
	Owren's Veronal Buffer	112 µL
	Probe Rinse Solution CA CLEAN I	210 µL
	Probe Rinse Solution CA CLEAN II	175 µL
Plg	Activator	175 µL
	Substrate	35 µL
	Owren's Veronal Buffer	112 µL
	Probe Rinse Solution CA CLEAN I	350 µL
PC	Activator	150 µL
	Substrate	34 µL
	Probe Rinse Solution CA CLEAN I	300 µL

\# Not available in the USA.
* Specified for reagents as detailed in Chapter 1.

Parameter	Reagent	Consumption/Test*
Protein C Coagulometric	Protein C Deficient Plasma	45 µL
	Protein C Activator	50 µL
	APTT Reagent for Protein C	50 µL
	Calcium Chloride Solution	50 µL
	Probe Rinse Solution CA CLEAN I	95 µL
Protein S Ac	Protein S Ac Deficient Plasma	122 µL
	Protein S Ac APC Reagent	58 µL
	Protein S Ac Starting Reagent	145 µL
FDP (Latex Test BL-2 P-FDP##)	Stabilizing Reagent	66 µL
	Latex Reagent	94 µL
	Diluent	112 µL
D-Dimer	Accelerator	25 µL
	Latex Reagent	150 µL
	Probe Rinse Solution CA CLEAN I	50 µL
D-Dimer (**INNOVANCE°** D-Dimer)	Diluent	13 µL
	Supplement	17 µL
	Buffer	61 µL
	Reagent	56 µL
vWF Ag**	vWF Buffer	60 µL
	vWF Latex Reagent	90 µL
	Owren's Veronal Buffer	15 µL (vWF.m)
		0 µL (vWF.l)
		25 µL (vWF.h)
Heparin	ATIII Reagent	20 µL
	Factor Xa Reagent	170 µL
	Substrate	40 µL
	Probe Rinse Solution CA CLEAN I	200 µL
Factor VIII chromogenic	Owren's Veronal Buffer	120 µL
	Factor X Reagent	40 µL
	Factor IXa Reagent	40 µL
	Substrate Reagent	120 µL
	Probe Rinse Solution CA CLEAN I	300 µL
Rinse solution	Distilled Water (in the rinse tank)	Approx. 28 mL per test

* Specified for reagents as detailed in Chapter 1.
Available for use only in Asia.
** Not available in the USA.

Whenever analysis starts, 300 µL of CA CLEAN I is used to rinse the probe.
The volume of Owren's Veronal buffer that is used per test includes the amount of diluent that is used for each analysis parameter.

Prepare each reagent, taking into consideration the number of samples for each parameter to be analyzed. Since not all of the reagent in a container can be used, prepare an extra amount for each container as shown below.
The extra volume stated for Sample Cup Conical is the value when a Sample Cup Conical 4 mL (code No.424-1160-8) is used.
Since the extra volume for D1 to D14 is large it is necessary to either pool two or more vials, or transfer to a Sample Cup or an SLD vial.

Container	Extra Volume Required*
Siemens 5 mL reagent vial (GW5)	0.8 mL (0.8 mL, 1.8 mL)**
Siemens 15 mL reagent vial (GW15)	1.4 mL
Siemens 25 mL reagent vial (GW25)	1.4 mL
Plasma FDP reagent vial 5 mL (PFDP5 mL)***	0.6 mL
CA series TTO, HpT reagent vial 10 mL (TTO 10mL)	1.0 mL
Sample Cup 4 mL (Cup 4 mL)	0.2 mL (0.2 mL, 0.6 mL)**
CA CLEAN I (CA CLEAN I)	2.1 mL (2.1 mL, 5.6 mL)**
Supply part container (PV-10)	1.2 mL (1.2 mL, 2.3 mL)**
Supply part container (SLD)	0.3 mL (0.3 mL, 0.8 mL)**

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

** The extra volumes required for the reagent set in reagent setting positions D1 to D14 and E1 to E3 when no CP and CP are installed are shown in ( ) respectively.

*** Available for use only in Asia.

CA CLEAN I and II are necessary to clean the external and internal surfaces of the probe. 5 mL (8 mL, when the cap piercer unit is installed of additional CA CLEAN I or II is necessary to clean the external surface of the probe completely. Prepare an extra amount for each vial as shown below.

Container	Extra Volume Required
Supply part container (PV-10)	Approx. 2.0 mL (3.0 mL)*
CA CLEAN I (CA CLEAN 1)	Approx. 5.5 mL (8.0 mL)*

* When a cap piercer unit is installed, the required extra reagent volume is shown in ( ).

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

4.2 Setting the Reagents and Sample Plates (when the Wand Barcode Reader is Not Used)

Set the prepared reagents and factor-deficient plasma into the reagent holders. Set them while displaying the Consumable screen.
Then set the sample plates.

1. Setting the Reagents

(1) From the Main Menu screen, press the [Set Reagents] key. The Consumable screen will appear. For details on the Consumable screen, see *Chapter 4, Section 4: CHECKING THE AMOUNT OF REMAINING CONSUMABLE*.

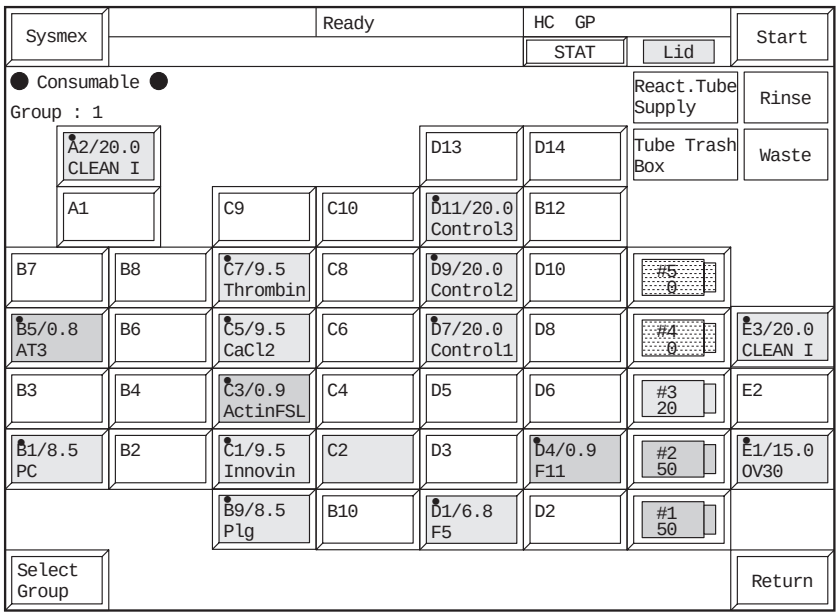


Figure 2-4-1: Consumable Screen

(2) Select the parameter group to analyze. From the Consumable screen, press the [Select Group] key. The Change Group screen will appear. Press the key for the parameter group you wish to analyze.

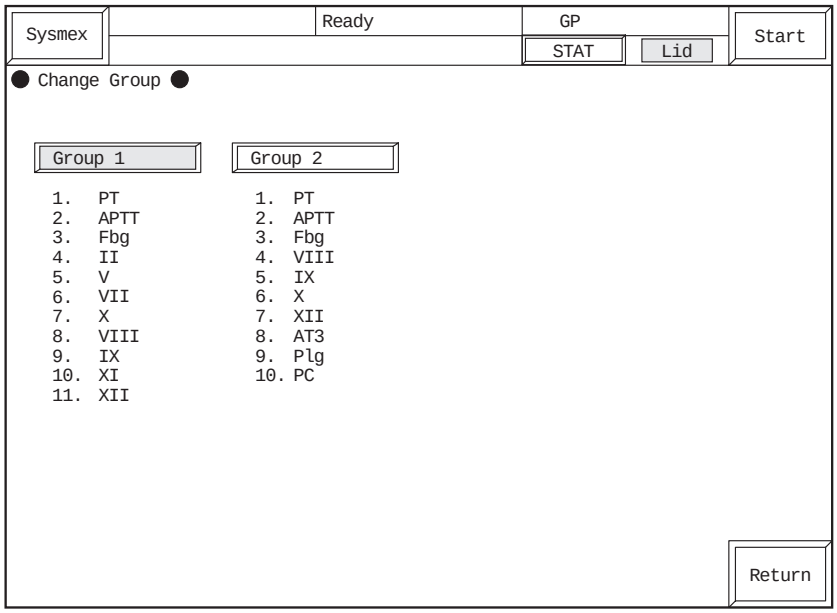


Figure 2-4-2: Change Group Screen

(3) Press the [Return] key. The Consumable screen will reappear, and the positions of the reagents of the selected parameter groups will be displayed.

CAUTION:
- If the reagent is different when the parameter group is switched, reagent vials have to be replaced. The corresponding reagent holder position key on the Consumable screen will turn to pink to indicate those vials needing to be replaced.

NOTE:
- Set the reagent position for each parameter group. For details on how to set the parameter group, see *Chapter 11, Section 5.6: Parameter Group Settings.*

(4) Confirm that the area labeled "Lid" has turned green; then open the light shield lid.

(5) Set the reagent etc. into the reagent holder according to the display of the reagent position.
If there is a gap between the reagent bottle and reagent holder when you set the bottle into the holder, insert the adapter provided.
Siemens 5 mL reagent vial (GW5) and provided push vial PV-10 can be set in the reagent holder B1 through B10, D1 through D14 without using any adapter.

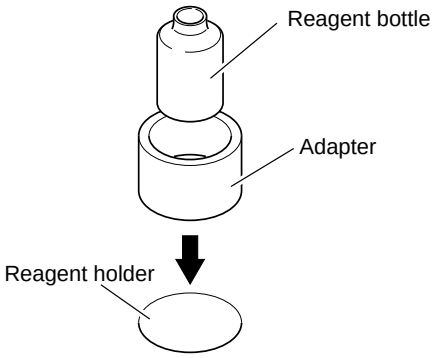


Figure 2-4-3: Setting the Reagent Bottle

Set the Owren's Veronal buffer and reagent rinse solution in place in the containers provided. When the provided push vial PV-10 is used, insert the provided adapter.
As for the position where each reagent can be set and the adapter to be used, *see Chapter 6, Section 7: REAGENT SET POSITION AND ADAPTER LIST.*

WARNING
- When handling materials derived from human plasma, handle all materials as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after handling such materials.
- Mixing CA CLEAN I and CA CLEAN II will result in the release of poisonous chlorine gas. Extra care should be taken to assure these reagents are not mixed.
- If the same reagent is set in multiple holders, use the same container.

CAUTION
- Set each reagent in its designated position. Failure to do so can cause incorrect analysis results.
  If a reagent is accidentally set in a wrong position and analysis is performed, clean the probe with rinse solution. For details on how to clean the probe, see *Chapter 6, Section 3.1: Cleaning the Probes*.
- Take steps to prevent contaminants and dust from getting inside reagent bottles and rinse solution containers. If contaminated, correct analysis results will not be obtained.
- Cap the Owren's Veronal Buffer and the rinse solution containers as well as other reagents if no analysis is to be performed for an extended time period.

CAUTION:
- Set CA CLEAN I to both Holder A2 and Holder E3.
- Set CA CLEAN II to the Holder A1.
- After analysis has been completed, cap the CA CLEAN I and CA CLEAN II vials.
- Use a correct adapter.
- Six types of adapter are available. (For details, see *Chapter 6, Section 6.8: Supply Parts List*.)
- Use the adapter which fits with the least looseness.

2. Changing the reagent positions

This section will explain how to set the holder arrangement for reagent, diluent, rinse solution, factor-deficient plasma, control plasma, and calibrator.

(1) Press the key to the reagent holder position where arrangement is changed on the Consumable screen. The window for reagent information input will appear.

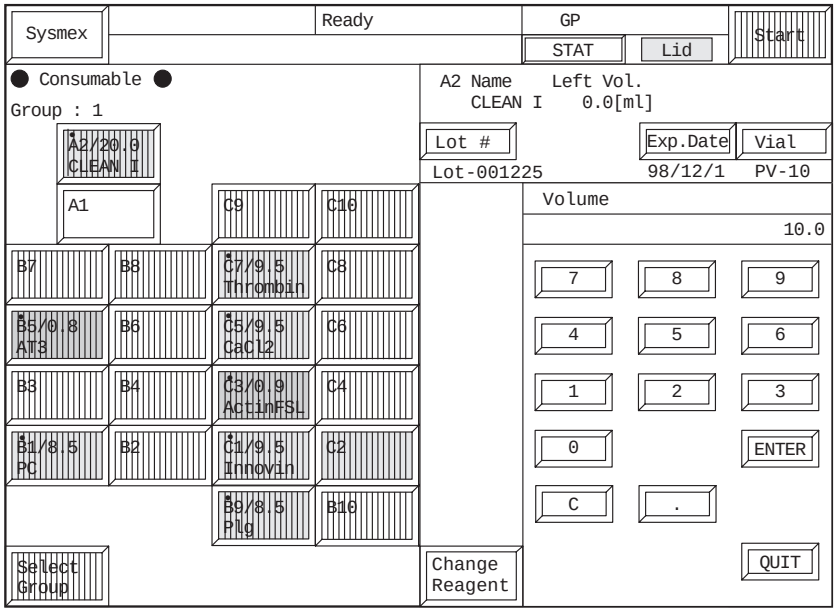


Figure 2-4-4: Entering the Reagent Volume

(2) Press the [Change Reagent] key, the Select Reagent window will appear. The reagents that can be set into the selected holder will appear in the Select Reagent window. The reagent that has already been selected is displayed with the blue back-lit No. to the left.

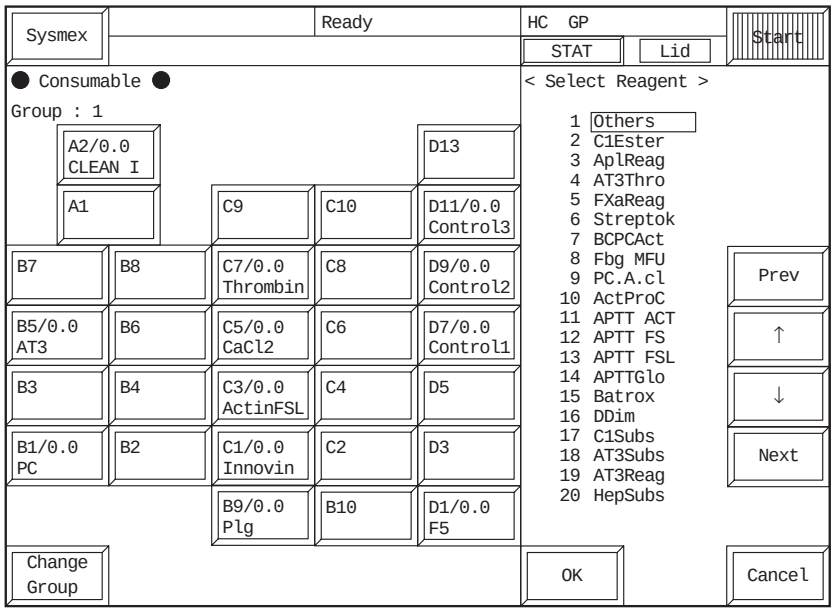


Figure 2-4-5: Select Reagent Window

(3) From the Select Reagent window, press the [↑] and [↓] keys to move the cursor to the reagent that you wish to set; then press the [OK] key.
If you select "None" in the Select Reagent window, the reagent information for the reagent holder will be deleted.

NOTE:

- The reagent which can be set at the reagent position can be selected from among the reagent that reagent information is set in the instrument. For how to set the reagent information, see *Chapter 11, Section 5.1: Reagent Information Settings.*
- The same reagent can be set to the reagent holder position in up to three places. When the same reagent is set to two or three places. ■ ■, or ■ ■ ■ is indicated in the top left in the reagent holder position key.
- The marking at the top left in the reagent holder position key indicates the order in which the reagent is used. When the reagent in the first vial ("■") runs out, instrument will use the same reagent of the second vial ("■ ■"), then the third ("■ ■ ■").

3. Entering the Reagent Volume

Enter the reagent volume when setting the monitoring of the remaining volume.

(1) Press the key to the reagent holder position where entering the reagent volume on the Consumable screen. The window for reagent information input will appear.

(2) Enter the reagent volume with the numerical keys, and press the [ENTER] key.

NOTE: • For details on reagent volume monitoring, see *Chapter 11, Section 5.11: Alarm Settings*.

4. Changing the Reagent Information

The reagent lot number, expiration date, and the vial type that has already been set can be changed.

(1) Press the key to the reagent holder position where reagent information is changed on the Consumable screen. The window for reagent information input will appear.

(2) To change the lot number, press the [LOT #] key, and alphanumeric keys will be displayed. Enter the lot number and press the [ENTER] key.

(3) To change the expiration date, press the [Exp. Date] key, and the numeric keys will be displayed. Enter the expiration date and press [ENTER] key.

(4) To change the set vial type, press the [Vial] key, and vial type selection window will be displayed.
On the vial type selection window, press [↑] or [↓] key to move the cursor to the appropriate vial and press [ENTER] key.

CAUTION • Set the correct container, or CA-1500 cannot aspirate the reagent correctly.
• PT reagents:
If you set a new lot number for PT reagent, please update the ISI value in the standard curve menu, if the ISI value is not updated the CA-Instruments might report incorrect INR values. For details on how to update the ISI value, see *Chapter 8, Section 5: PREPARING STANDARD CURVE THROUGH MANUAL INPUT*.

(5) When all the reagent information is changed, press [QUIT] key. The change confirmation window will be displayed.
Press the [Continue], [Set], or [Cancel] key.
[Continue] key: Used to continue the setting of reagent information.
[Set] key: Updates the reagent information and returns to the Consumable screen.
[Cancel] key: Cancels the reagent information and returns to the Consumable screen.

NOTE:
- When the lot number, expiration date and the vial type of a new reagent are changed on the Consumable screen, the reagent information set on the reagent information screen will be changed automatically. For how to set the reagent information, see *Chapter 11, Section 5.1: Reagent Information Settings.*

5. Setting the sample plates

(1) Set the sample plates in the direction shown in the figure. To replace a used plate, see *Chapter 6, Section 6.2: Replacing the Sample Plates*.

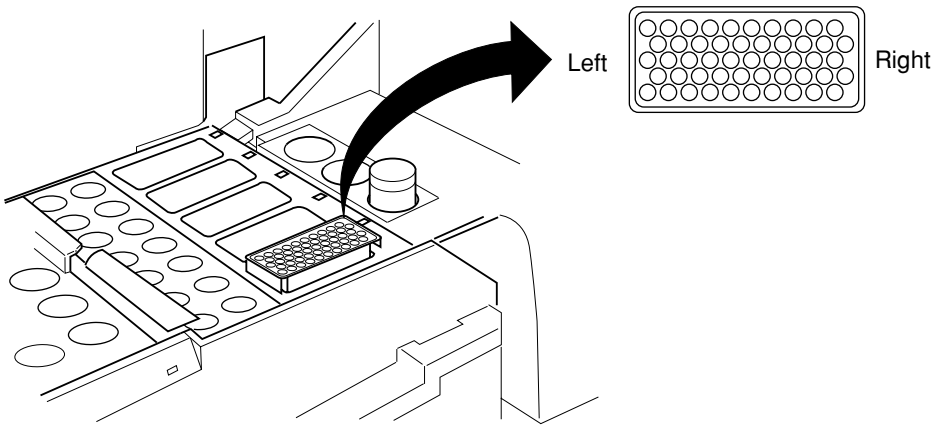


Figure 2-4-6: Setting the Sample Plate

(2) Close the light shield lid.

4.3 Setting the Reagents (when the Wand Barcode Reader is Used)

When the reagent name, lot number and the vial type for the reagent set at the reagent position are the same, set the reagent according to the procedure of *Section 4.2, 1.: Setting the Reagents*. When the reagent name, lot number and vial type for the reagent set at the reagent position are different, this information can be set by reading the reagent barcode with an optional wand barcode reader using the following procedure.

(1) Press the key to the reagent holder position on the Consumable screen. The window for reagent information input will appear.

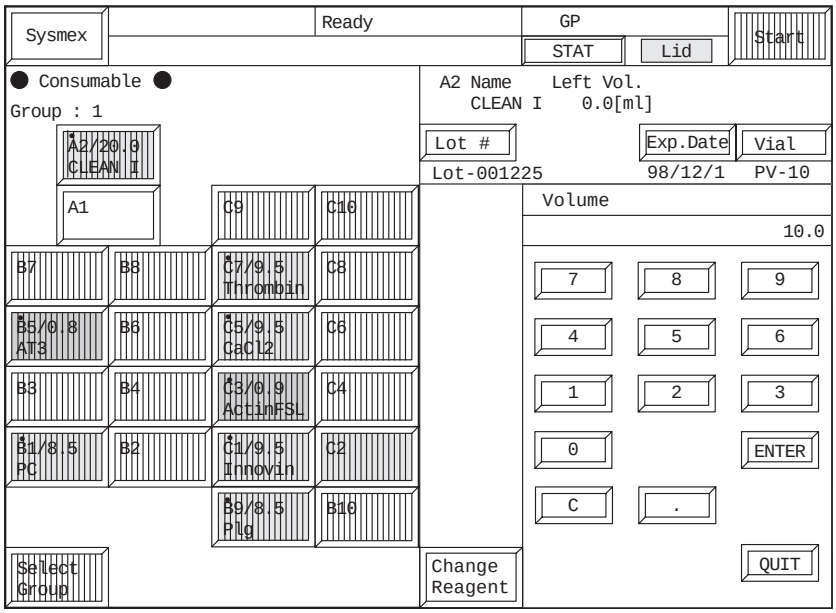


Figure 2-4-7: Entering the Reagent Volume

(2) Read the reagent barcode with the wand barcode reader. The reagent name, lot number, expiration date and vial type will be automatically displayed.

CAUTION:
- The barcode might not be able to be read if a drop of water is on the barcode label.
  Wipe the drop of water off before setting the reagent.
- The barcode does not encode for the expiration date.

NOTE:

- In the following cases, it is necessary to set by manual input even when an optional wand barcode reader is used.
- When changing the read reagent name, lot number, expiration date or vial type
- When using a reagent without a reagent barcode label
- When using the diluent

  For how to set the reagent information, see *Chapter 11, Section 5.1: Reagent Information Settings.*
- When the reagent barcode is read by an optional wand barcode reader, the confirmation window of the following (1) to (6) might be displayed.

(1) When a reagent barcode which does not match the setting of reagent information is read

The reagent information unregistered confirmation window will appear.

Press the [OK] key if the reagent name, the lot number, and information on the container are correct. This reagent information is set on the reagent information screen automatically.

Set the expiration date on the reagent information screen.

When reagent information is wrong, press the [Cancel] key. Set correct reagent information by the manual input on the Reagent Information screen. As for the reagent information screen, *see Chapter 11, Section 5.1: Reagent Information Settings*.

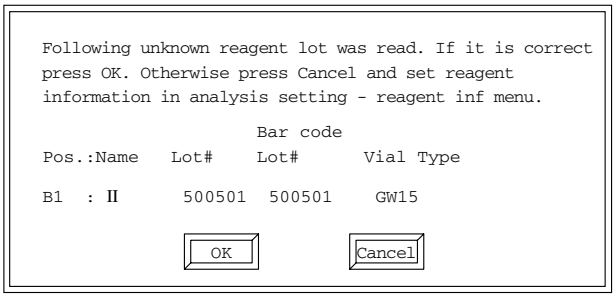


Figure 2-4-8: Reagent Information Unregistered Confirmation Window

CAUTION:

- The same number as the barcode lot number will be displayed in the lot number position. When the lot number is different from the actual one, press the [OK] key, and correct the lot number on the Reagent Information screen. For details on the reagent information screen, see *Chapter 11, Section 5.1: Reagent Information Settings.*

NOTE:

NOTE:

- The barcode lot number is the lot number described on the barcode label affixed to the reagent bottle.
  For details on the barcode lot number, see *Chapter 11, Section 5.1: Reagent Information Settings*.

(2) When the reagent barcode does not match reagent information list

The reagent ID unregistered confirmation window will appear. Set reagent information by manual input on the reagent information screen. As for the reagent information screen, *see Chapter 11, Section 5.1: Reagent Information Settings*.

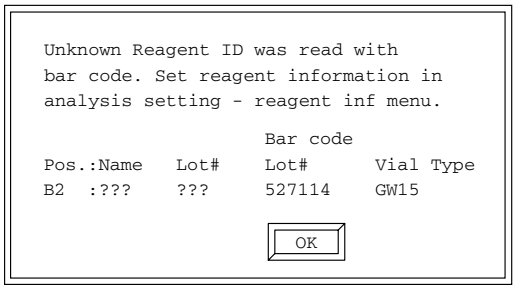


Figure 2-4-9: Reagent ID Unregistered Confirmation Window

(3) When the reagent lot number differs from that used for the standard curve analysis

The Standard Curve Confirmation window will appear. Press the [OK] key, and create a new standard curve using the reagent of new lot number. For details on creating standard curves, see *Chapter 8: SETTING STANDARD CURVES.*

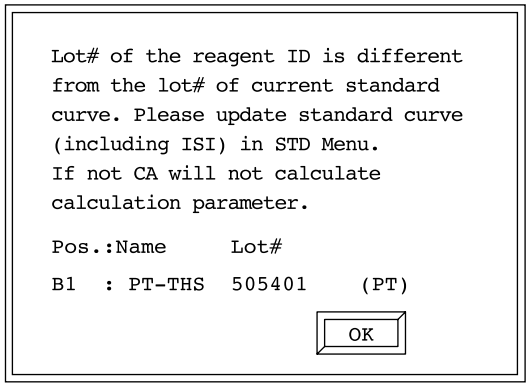


Figure 2-4-10: Standard Curve Confirmation Window

NOTE:

(**4) When file number is not set in the quality control file**
The QC File Confirmation window will appear. Press the [OK] key, and set level and file number on the reagent information screen. For details, see *Chapter 11, Section 5.1: Reagent Information Settings.*

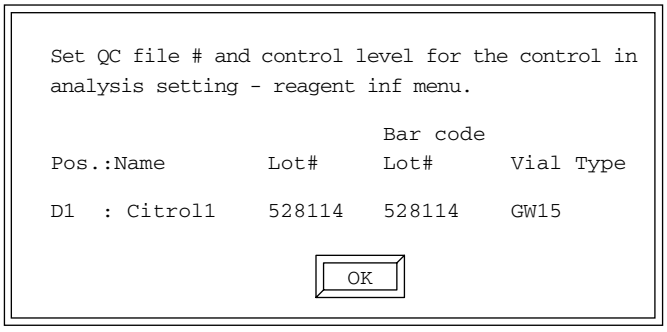


Figure 2-4-11: QC File Confirmation Window

(5) When the reagent to be set exceeds 40 types
The reagent registered number confirmation window will appear. Press the [OK] key, and delete an unnecessary reagent on the reagent information screen. Again, set the reagent. As for the reagent information screen, *see Chapter 11, Section 5.1: Reagent Information Settings*.

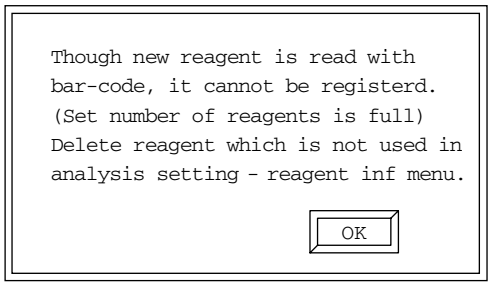


Figure 2-4-12: Reagent Registered Number Confirmation Window

NOTE: **(6) When installing same reagent in four places or more**
The same reagent confirmation window will appear. Press the [OK] key, and delete one of the same reagent in the holder displayed in the window, then set the reagent. For details, see *Chapter 11, Section 5.1: Reagent Information Settings.*

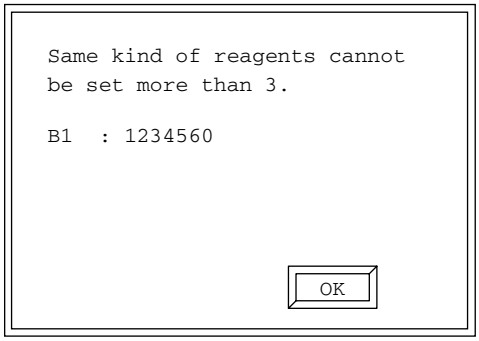


Figure 2-4-13: Same Reagent Confirmation Window

(3) Press [QUIT] key. The change confirmation window will be displayed.
Press the [Continue], [Set], or [Cancel] key.
[Continue] key: Used to continue the setting of reagent information.
[Set] key: Updates the reagent information and returns to the Consumable screen.
[Cancel] key: Cancels the reagent information and returns to the Consumable screen.

NOTE:
- When the reagent barcode is read by the wand barcode reader on the Consumable screen, and when the lot number, expiration date and the vial type of a new reagent are set, information on the reagent will be added to the reagent information settings. For how to set the reagent information, see *Chapter 11, Section 5.1: Reagent Information Settings.*

5. REPLENISHING REACTION TUBES

Prepare and replenish the number of reaction tubes that are needed for your analysis.

(No. of reaction tubes required) = (No. of parameters) × (No. of samples)

(1) To open the reaction tube hopper, press on the front part of the cover to pop up; then open.

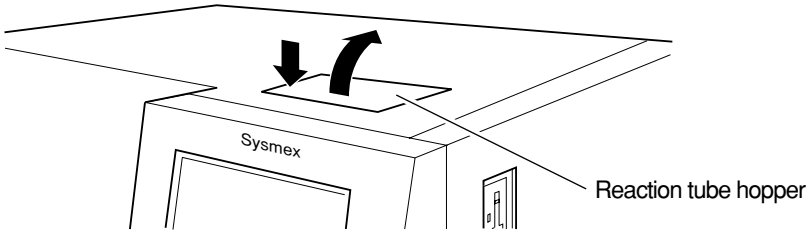


Figure 2-5-1: Opening the Reaction Tube Hopper

(2) Add the reaction tubes. The reaction tube hopper can hold up to 300 reaction tubes.

CAUTION:	• Do not forcibly overfill the hopper. This will cause jamming.

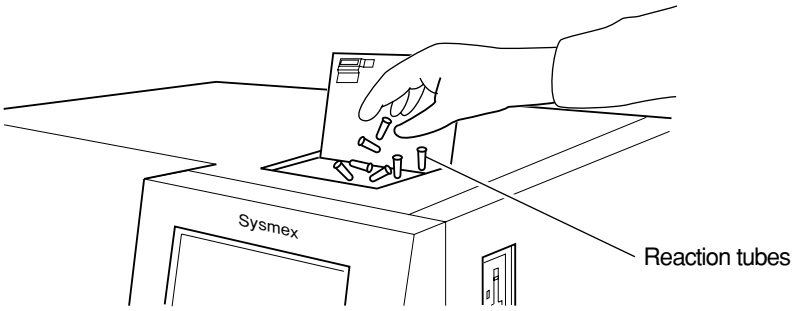


Figure 2-5-2: Replenishing the Reaction Tubes

(3) Close the reaction tube hopper lid.

CAUTION:	• Reaction tubes are for single use only or incorrect result may occur. • Use the specified reaction tubes only (SU-40).

6. CHECKING THE STANDARD CURVE

Before performing an analysis, make sure that the standard curve is correctly set.

CAUTION:
- If the standard curve is not set correctly, it may not be possible to calculate the PT ratio, PT-INR, and other calculated parameters.
- PT reagents:
  If a new lot number for PT reagent has been set previously, please update the ISI value.

(1) Press the [Standard Curve] key from the Main Menu.
The Standard Curve screen will appear.

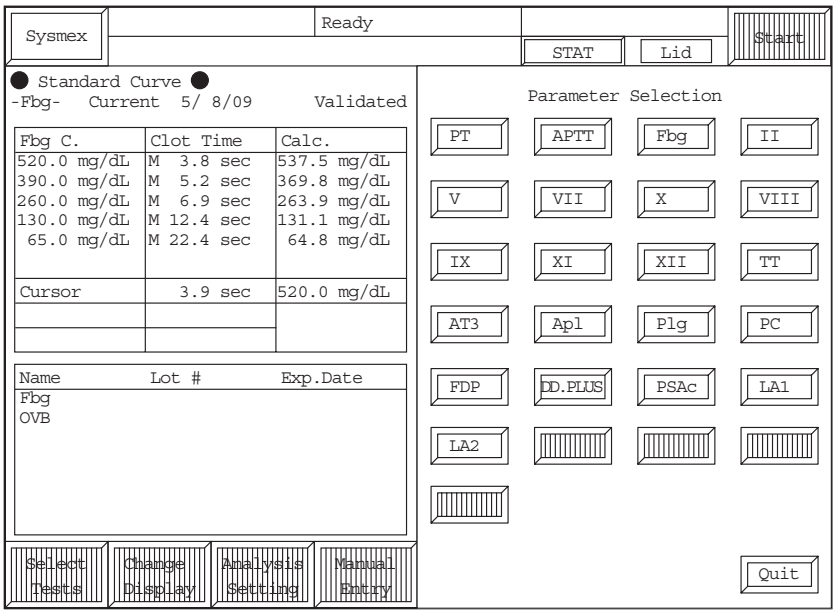


Figure 2-6-1: Standard Curve Screen

(2) Press the key for the analysis parameter you wish to check.
The standard curve for the selected parameter will appear.

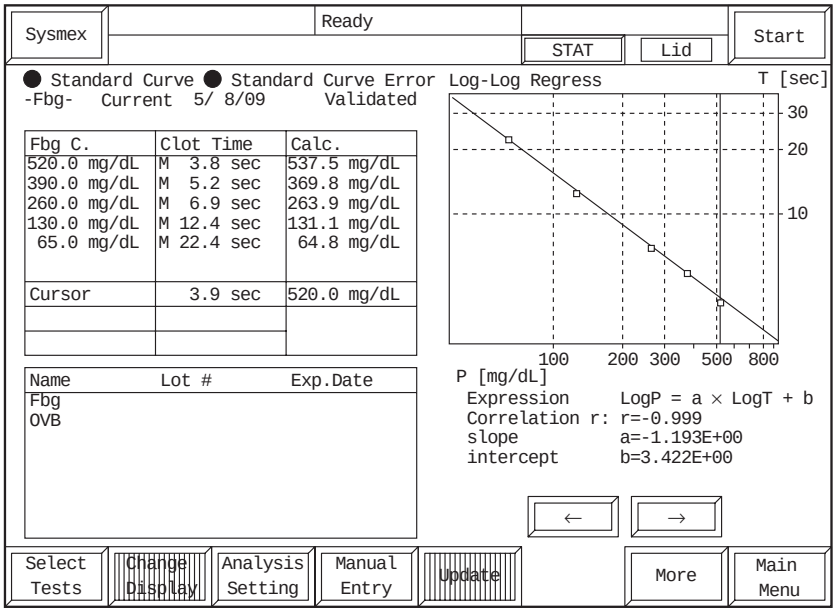


Figure 2-6-2: Standard Curve for Selected Parameter

(3) Check the standard curve for other analysis parameters.
If you press the [Select Tests] key, the Parameter Selection window will appear. Press the key for an analysis parameter you wish to check, and display its standard curve. In the same way, check the standard curve for each analysis parameter.

(4) Press the [Main Menu] key.
The standard curve setting program will end.

If the settings are incorrect, set correctly in accordance with *Chapter 8: SETTING STANDARD CURVES*.

7. QUALITY CONTROL

To maintain reliable analysis data, it is necessary to implement quality control. With the CA-1500, a quality control file number (QC01 - QC20) can be registered as a sample ID number, the control material (control plasma) is analyzed, and the analysis data is stored in a quality control file. This data and a quality control program are used to monitor changes in the instrument and reagent system that take place over time (day-to-day or hour-to-hour).

For details on quality control, see *Chapter 7: QUALITY CONTROL*.

Implementing Quality Control
Set the control material into a sample rack or reagent holder for analysis.
Quality control analysis are executed according to two methods: a manual method of registering and analyzing, and an automatic method of analyzing at regular intervals.
The following explanation will apply to those cases in which the control material is set into a sample rack.

(1) Register the quality control sample ID number.
From the Work Load List screen, press the [ID No. Entry] key; then, using the numeric keys, enter the quality control sample ID number (QC01 - QC20).
When the QC sample is set in the reagent holder, QC sample ID No. (QC File No.) is fixed and displayed.

(2) Register the analysis parameter.

(3) Set the control material into the sample rack, and place the rack in the right rack pool.

(4) Press the [Start] key.
The analysis will be performed, and the analysis data will be automatically stored in the quality control file.

(5) Display the Quality Control screen, and check the QC chart.
For details, see *Chapter 7, Section 2: QC CHART DISPLAY.*

CAUTION: • If a QC sample is placed in a reagent holder, QC analysis cannot be executed using the QC sample currently under analysis. Analyze after the current QC analysis is completed.

NOTE:
- Quality control analysis is performed according to the same procedures as routine sample analysis. For details on how to register sample ID numbers and analysis parameters, see *Chapter 3: WORK LIST*. For details on analysis procedures, see *Chapter 4: SAMPLE ANALYSIS*.
- If a quality control sample is placed in a reagent holder for analysis, the quality control sample will be analyzed prior to any ordinary samples. If a quality control analysis is to be executed after a specified sample has been analyzed, place the sample in the sample rack and analyze.

Implementing Automatic Quality Control (Auto QC)

With this CA-1500, you can place quality control samples in the reagent holders and automatically execute quality control analysis.

After the specified time period (time that was preset from the QC Setting screen) has passed since the last quality control analysis, the CA-1500 will automatically execute an analysis for quality control.

In order to use this function, you must set up the automatic quality control function from the QC Setting screen.

For details on how to set up the quality control function, see *Chapter 7, Section 8: QUALITY CONTROL SETTINGS.*

(1) Press the [Sysmex] key located at the upper left part of the screen.
The Sysmex menu will appear.

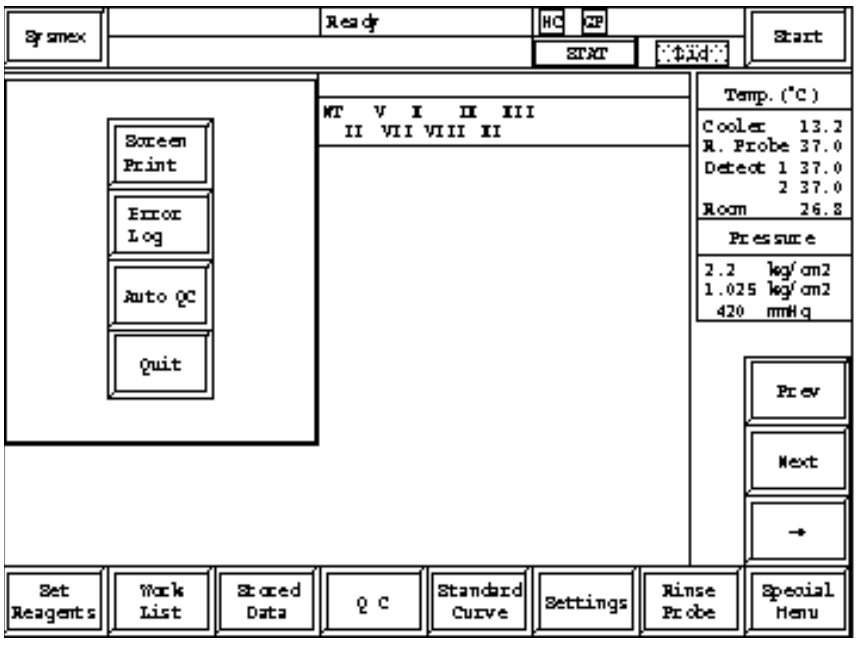


Figure 2-7-1: Sysmex menu

(2) Press the [Auto QC] key.
The parameter selection window will appear.
Pressing the parameter keys, select parameters for automatic quality control analysis; then press the [Select] key.
After the specified time period (time that was preset from the QC Setting screen) has passed since the selected parameters' last quality control analysis, a quality control analysis will automatically be executed. To discontinue parameter selection, press the [Cancel] key.

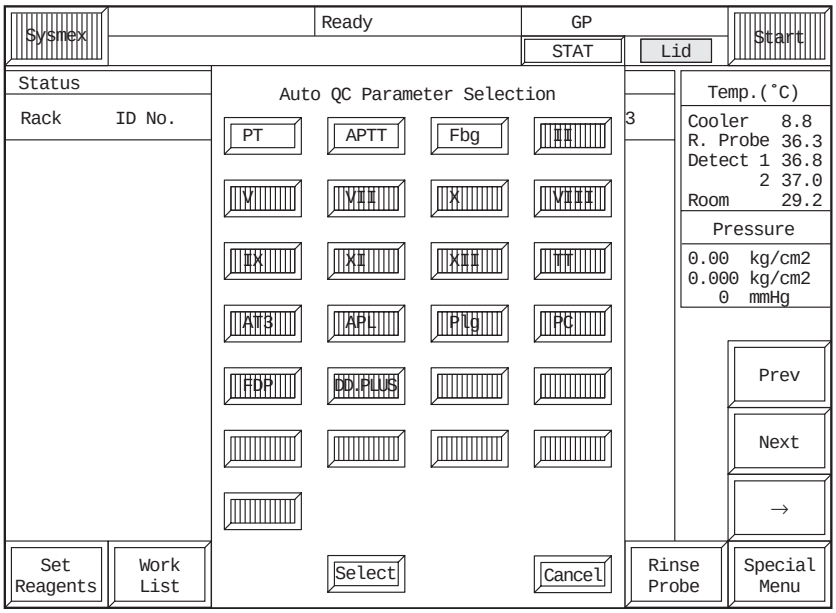


Figure 2-7-2: Parameter Selection Window

CAUTION:

- If the CA-1500 is set up to use the automatic quality control function, it will automatically start quality control analysis even when in Ready mode, when the unit normally does not execute analysis.
- The aforementioned selection is possible only for parameters for which [Yes] is selected in "Execute Auto QC" as described in *Chapter 7, Section 8: QUALITY CONTROL SETTINGS.*
- Use the quality control samples and reagents in accordance with the manufacturer's recommendations as described on the package insert.
- When a QC sample is placed in a reagent holder and the QC sample to be analyzed by an Auto QC is currently analyzed, this QC sample will not be analyzed by the Auto QC at that timing. Execute the Auto QC analysis after the current QC analysis is completed.

NOTE:
- The following setup is required when reagent holders are used during quality control analyses:
- Set up the quality control samples and applicable file numbers for the reagent information. See *Chapter 11, Section 5.1: Reagent Information Settings.*
- Place the quality control samples in reagent positions D1 to D14. See *Chapter 11, Section 5.7: Reagent Position Settings.*

8. SAMPLE PREPARATION

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

NOTE:
- STAT samples in a sample tube or sample cup can also be set in the STAT sample holders, as well as in the sample racks.
- If a cap piercer unit is installed, an analysis can be made with or without the cap.

8.1 Preparing 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-cell components.

(3) Set, in the sample rack provided, the centrifuged sample 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.

Anticoagulant	3.8% sodium citrate solution, 3.2% sodium citrate solution, or 3.13%* sodium citrate solution
Useable Tube (If a cap piercer unit is installed, see Table 2-8-1: Applicable Evacuated Blood Collection Tubes and Test Tube Adapters	OD: 10 mm Length: 65 mm - 78 mm OD: 13 mm Length: 65 mm - 78 mm OD: 15 mm Length: 65 mm - 78 mm Tubes of which inner diameter is 9.4 mm or less cannot be used except for the following. • VACUTAINER Plus Plastic Citrate Tube (HEMOGARD Closure) 1.8 mL, 2.7 mL • VACUETTE Sandwich Coagulation Tube 3.0 mL, 3.5 mL When using these special tubes the correct tube type must be selected in the tube type selection setting. See *Chapter 11, Section 5.11: Alarm Settings*.
Minimum Sample Volume	• Centrifuged sample See Figure 2-8-2, 2-8-4, 2-8-6, 2-8-8, 2-8-10 and 2-8-12: "Minimum Required Sample Volume When Centrifuged." • Blood plasma only See Figure 2-8-1, 2-8-3, 2-8-5, 2-8-7, 2-8-9 and 2-8-11: " Minimum Required Sample Volume for Plasma Only."

*Not available in the USA.

CAUTION: Precautions when handling plasma:
- Containers should be plastic or silicone-coated glass tube.
- As anticoagulant, use 3.8%, 3.2% or 3.13%* sodium citrate solution. When any other anticoagulant is used, sedimentation may occur and correct analysis result may not be obtained.
- Mix blood and sodium citrate solution in an accurate ratio of 9 parts to 1 part, respectively.
  When the mixing ratio varies, coagulation time varies, occasionally leading to incorrect analysis result.
- Store samples in the refrigerator and analyze within 4 hours of collecting.
  After 4 hours, or if they are stored improperly, correct analysis results may not be obtained.

*Not available in the USA.

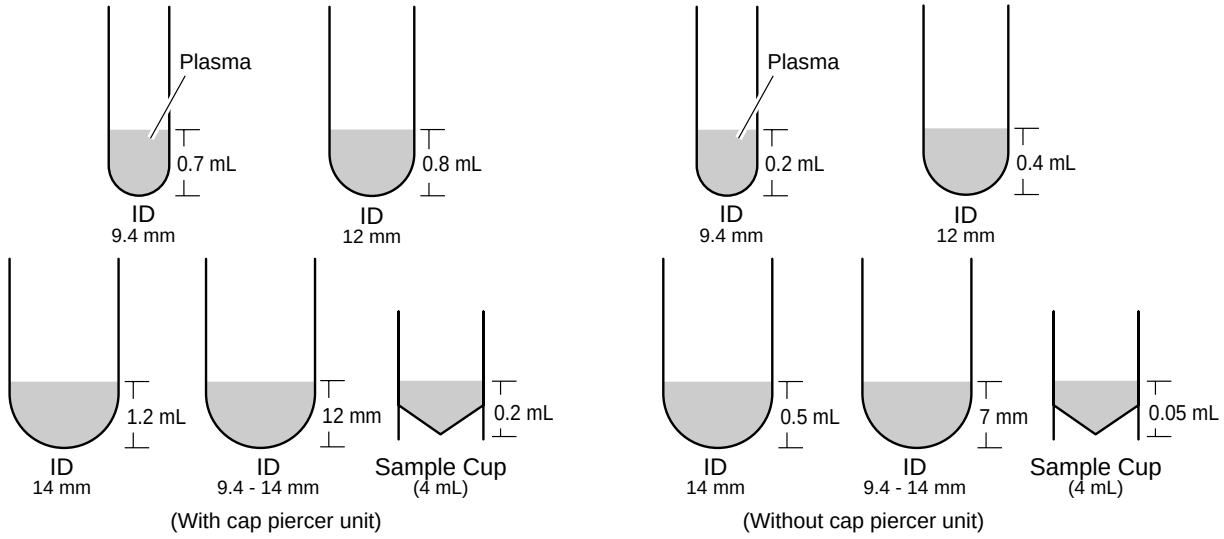


Figure 2-8-1: Minimum Required Sample Volume for Plasma Only (Tube Type Selection Setting: Default)

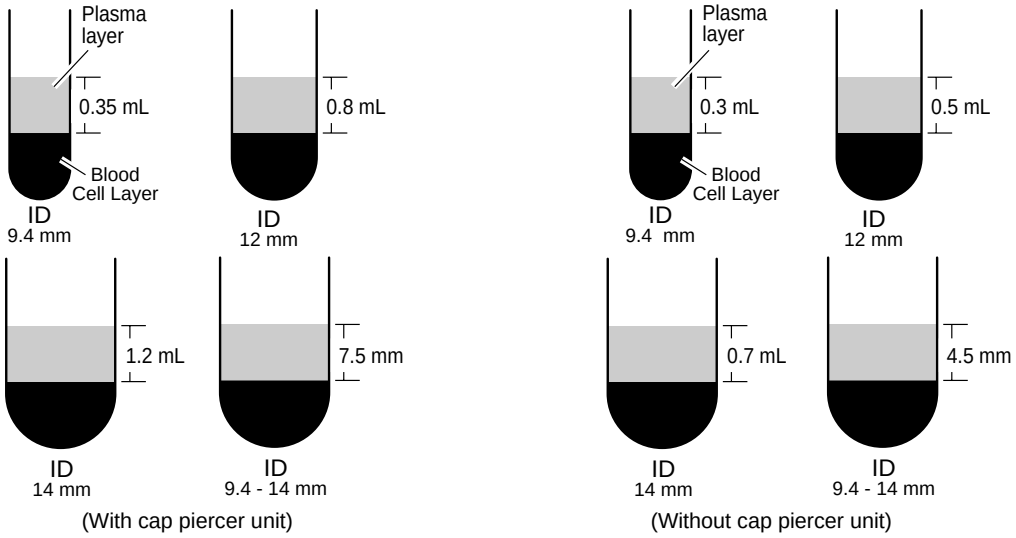


Figure 2-8-2: Minimum Required Sample Volume for Centrifuged Sample (Tube Type Selection Setting: Default)

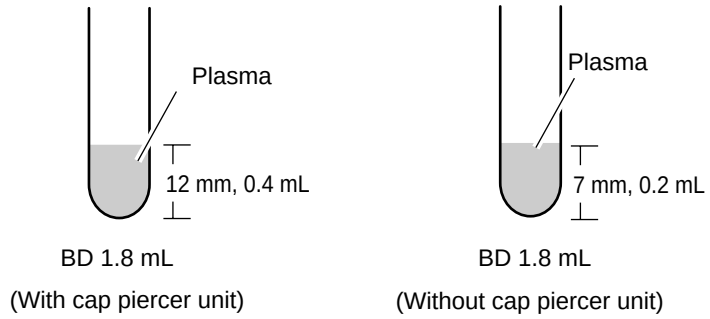


Figure 2-8-3: Minimum Required Sample Volume for Plasma Only (Tube Type Selection Setting: BD 1.8 mL)

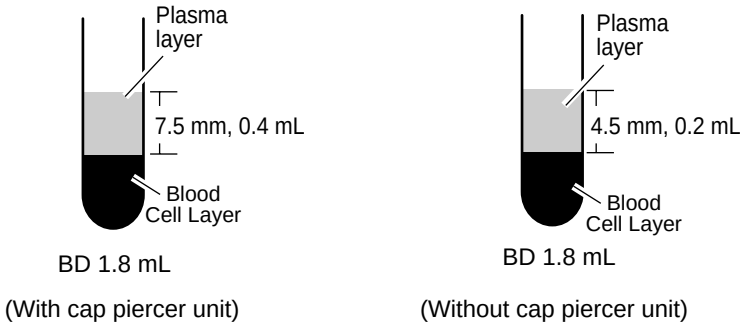


Figure 2-8-4: Minimum Required Sample Volume for Centrifuged Sample (Tube Type Selection Setting: BD 1.8 mL)

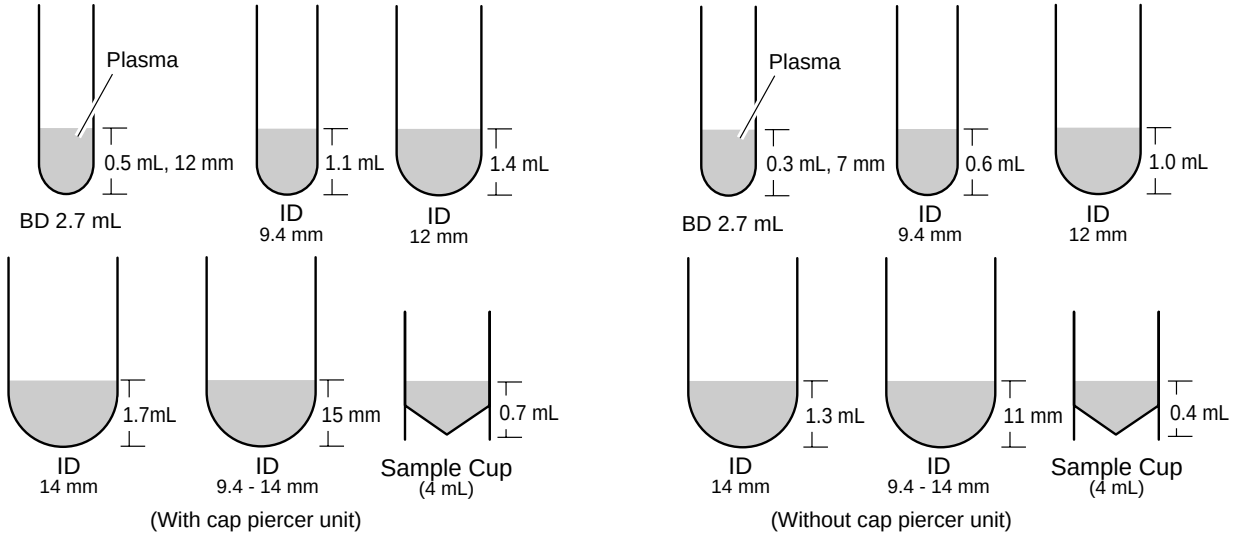


Figure 2-8-5: Minimum Required Sample Volume for Plasma Only (Tube Type Selection Setting: BD 2.7 mL)

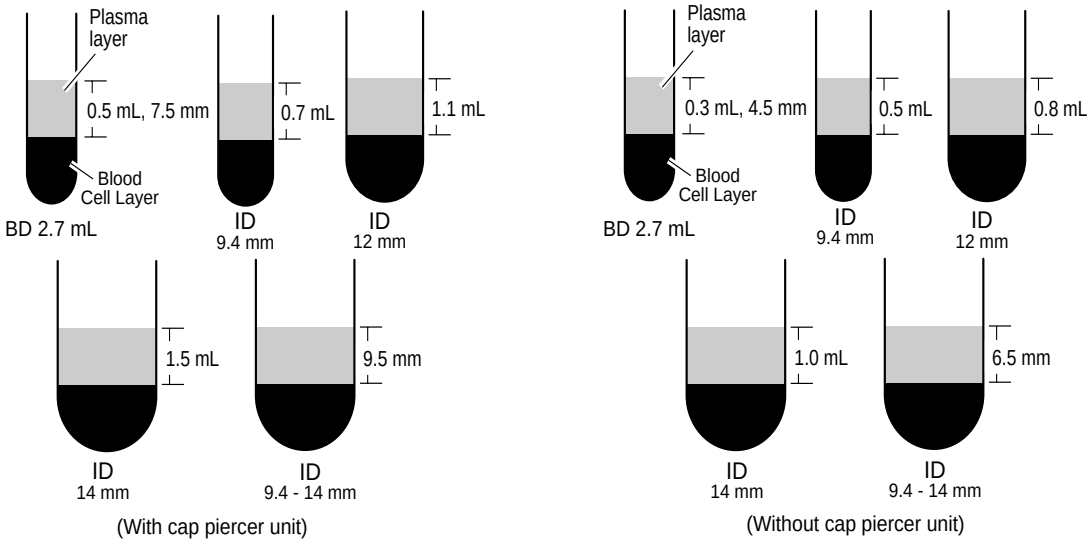


Figure 2-8-6: Minimum Required Sample Volume for Centrifuged Sample (Tube Type Selection Setting: BD 2.7 mL)

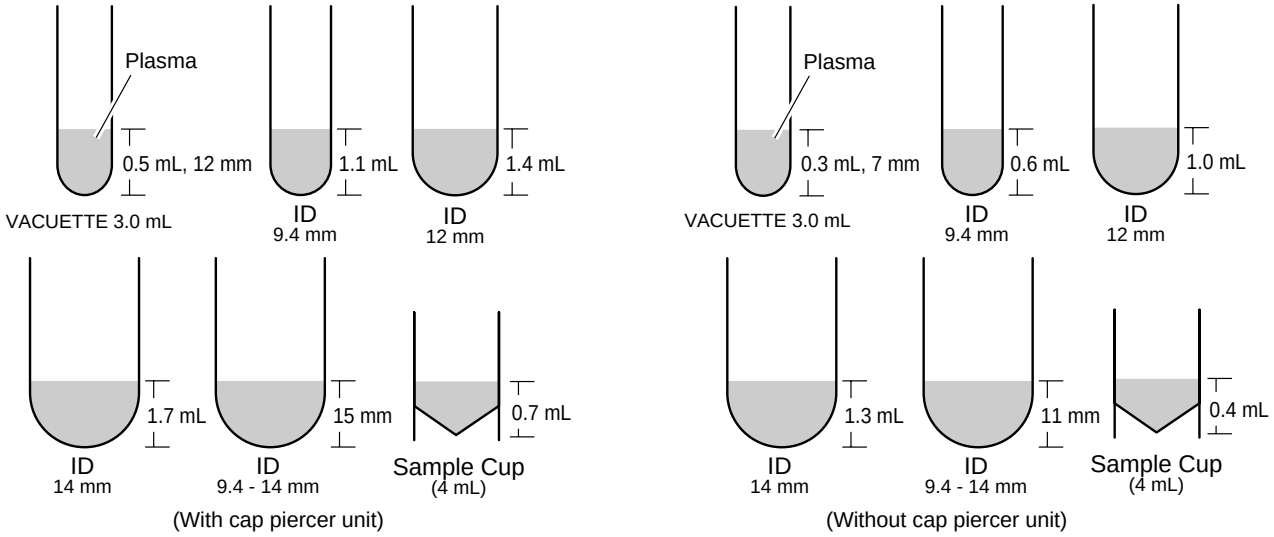


Figure 2-8-7: Minimum Required Sample Volume for Plasma Only (Tube Type Selection Setting: VACUETTE 3.0 mL)

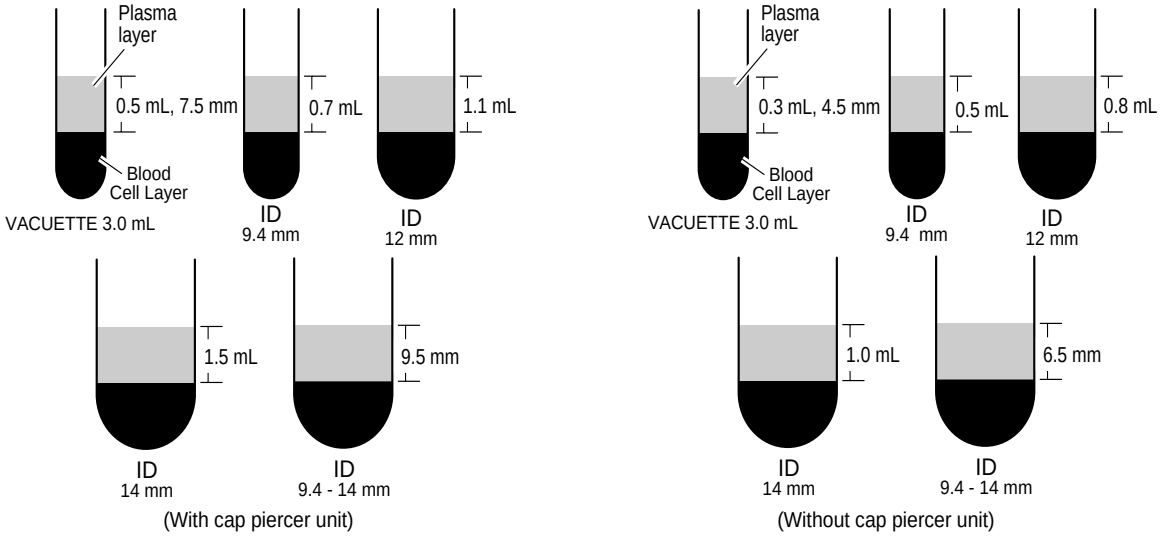


Figure 2-8-8: Minimum Required Sample Volume for Centrifuged Sample (Tube Type Selection Setting: VACUETTE 3.0 mL)

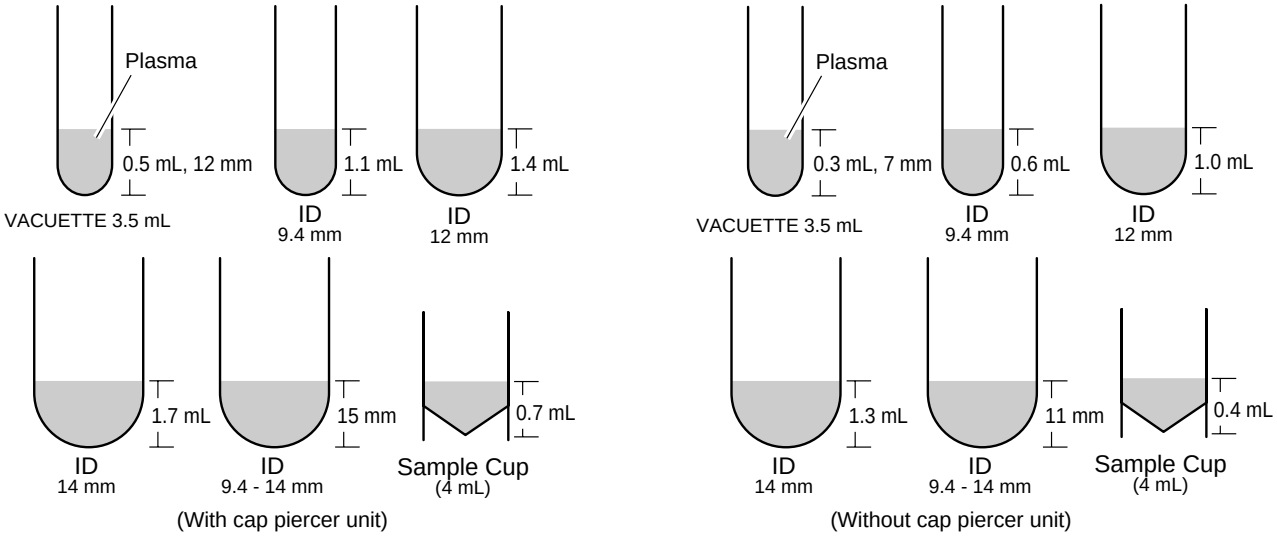


Figure 2-8-9: Minimum Required Sample Volume for Plasma Only (Tube Type Selection Setting: VACUETTE 3.5 mL)

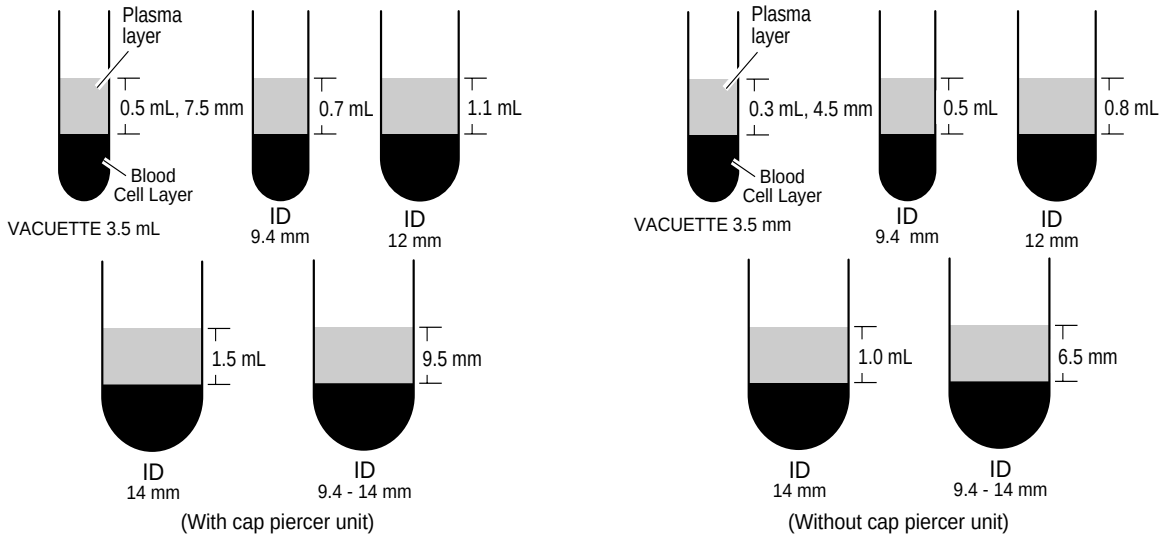


Figure 2-8-10: Minimum Required Sample Volume for Centrifuged Sample (Tube Type Selection Setting: VACUETTE 3.5 mL)

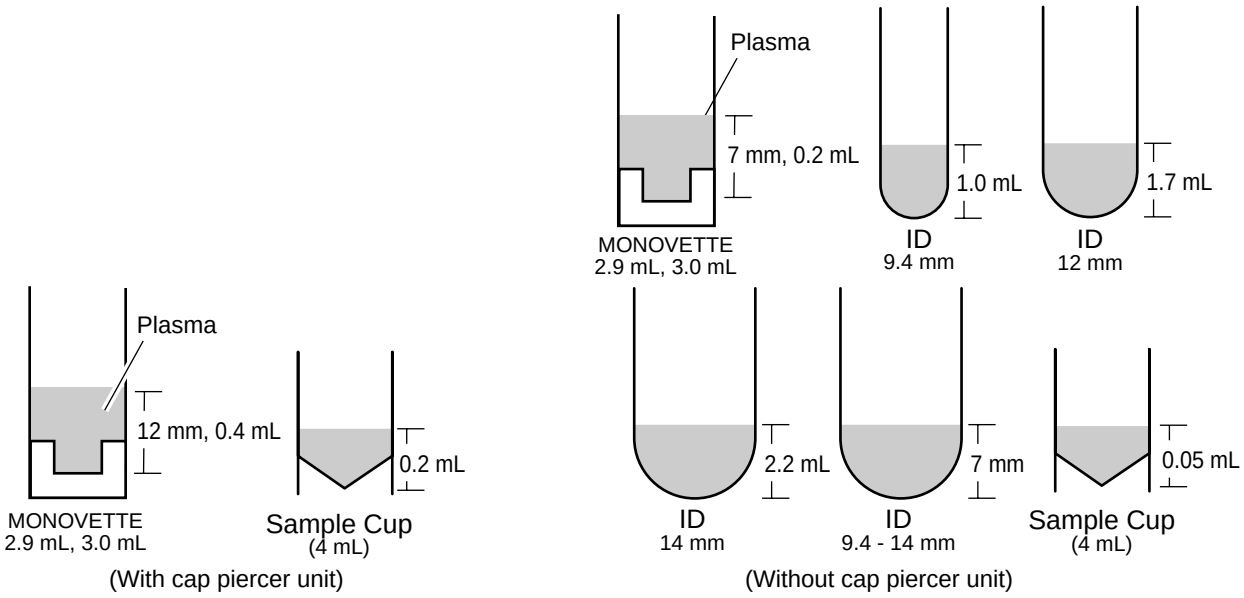


Figure 2-8-11: Minimum Required Sample Volume for Plasma Only (Tube Type Selection Setting: MONOVETTE)

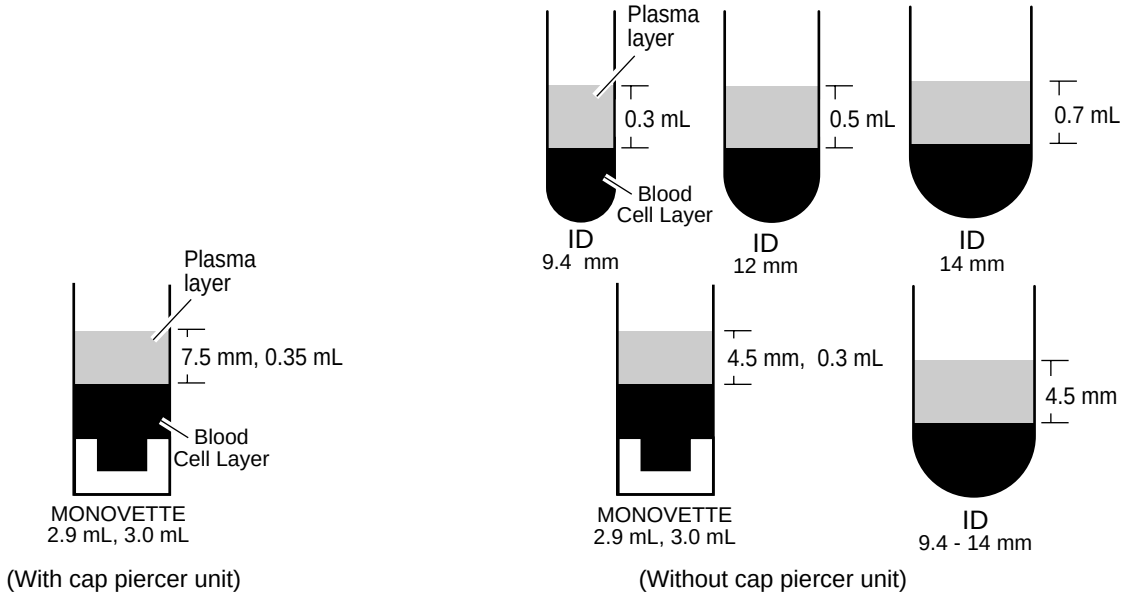


Figure 2-8-12: Minimum Required Sample Volume for Centrifuged Sample (Tube Type Selection Setting: MONOVETTE)

CAUTION: •The aforementioned sample volume is the minimum volume, so prepare an extra amount for the parameters you will analyze. In normal mode, the extra sample volume is necessary as dead volume. See the following table. And if the instrument is set up to perform replication analyses and/or automatic re-analyses, twice the normal volume will be required for the applicable parameters. If the specified test tube is not used or if the sample volume is insufficient, air and/or blood cells may get aspirated, preventing correct analysis results from being obtained.

Instrument Type	Cap of Test Tube	Tube Type selection setting											
		Default		BD 1.8 mL		BD 2.7 mL		VACUETTE 3.0 mL		VACUETTE 3.5 mL		MONOVETTE	
		Maximum Test Volume (µL)	Dead Volume (µL)	Maximum Test Volume (µL)	Dead Volume (µL)	Maximum Test Volume (µL)	Dead Volume (µL)	Maximum Test Volume (µL)	Dead Volume (µL)	Maximum Test Volume (µL)	Dead Volume (µL)	Maximum Test Volume (µL)	Dead Volume (µL)
without cap pierecer	open	450	50	450	50	450	50	450	50	450	50	450	50
with cap piercer	open	380	120	380	120	380	120	380	120	380	120	380	120
	close	350	150	330	170	350	150	350	150	310	190	350	150

CAUTION: •Simultaneous multiparameter analyses will not be performed when total required sample volumes exceed these values. (For replication analyses and/or automatic re-analyses, twice the normal volume will be required; therefore, carefully calculate the volume of blood plasma when setting up the sample.)

For example, when automatically reanalyzing PT and APTT (two parameters) of a centrifuged sample (in normal mode with cap) with a cap piercer unit installed, using sample tubes with inside diameter of 12 mm and the Tube Type is set to “Default”, the required sample volume would be:
(50 µL for PT + 50 µL for APTT) × 2 for re-analyses
+ 150 µL for minimum required sample volume of cap piercer unit
+ 800 µL for minimum required sample volume of centrifuged sample
= 1150 µL

When analyzing PT and APTT (two parameters) of a blood plasma sample in micro-sample mode without a cap piercer unit installed, using sample tubes with inside diameter of 12 mm and the Tube Type is set to “Default”, the required sample volume would be:
50 µL for PT + 50 µL for APTT
+ 400 µL for minimum required sample volume of blood plasma sample
= 500 µL

CAUTION:
- The test tube adapter (Holding Material No.58) of 13-14 mm outer diameter is installed in the sample rack at the time of shipment from the factory. When you use test tubes with outer diameter other than 13-14 mm, remove this adapter, and install an optional test tube adapter referring to the following.

Part number	Outer diameter	Test tube adapter
366-1291-1	10-11 mm OD	Holding Material No.113
366-1232-1	11-13 mm OD	Holding Material No.59
-	14-15 mm OD	Not necessary

- If sample volume is not sufficient, even when using a sample cup, a "Probe Crash" or other error may occur.

Sample Tube	OD × Length	Tube Adapter	Tube Fill Volume	Tube Type selection Setting											
				Default		BD 1.8 mL*7		BD 2.7 mL		VACUETTE 3.0 mL		VACUETTE 3.5 mL		MONOVETTE	
				CP	OP*8	CP	OP*9	CP	OP*10	CP	OP*11	CP	OP*12	CP	OP
VACUTAINER	13 mm × 75 mm (HEMOGARD Closure)	Holder No. 59*1	4.5 mL	○*2	○	×	×	○ *2, *6	○*6	○ *2, *6	○*6	○ *2, *6	○*6	×	○
	10.25 mm × 64 mm (Conventional Stopper)	Holder No. 113*1	2.7 mL	×	○*3	×	×	×	○ *3, *6	×	○ *3, *6	×	○ *3, *6	×	○*3
	10.25 mm × 47 mm (Conventional Stopper)	Holder No. 59*1 + BD Rack Adapter*4	1.8 mL	×	○*3	×	×	×	○ *3, *6	×	○ *3, *6	×	○ *3, *6	×	○*3
VACUTAINER Plus Plastic Citrate Tube	13 mm × 75 mm (HEMOGARD Closure)	Holder No. 59*1	1.8 mL	×	×	○*2	○*2	×	×	×	×	×	×	×	×
			2.7 mL	×	×	×	×	○*2	○*2	×	×	×	×	×	×
VACUETTE	13 mm × 75 mm	Holder No. 59*1	4.0 mL	○	○	×	×	○*6	○*6	○*6	○*6	○*6	○*6	×	○
VACUETTE Sandwich Coagulation Tube	13 mm × 75 mm	Holder No. 59*1	3.0 mL	×	×	×	×	×	×	○*2	○*2	×	×	×	×
			3.5 mL	×	×	×	×	×	×	×	×	○*2	○*2	×	×
LIP-VAC	13 mm × 75 mm	Holder No. 58	4.0 mL	○	○	×	×	○*6	○*6	○*6	○*6	○*6	○*6	×	○
MONOVETTE *13	13 mm × 65 mm	Holder No. 58	2.9 mL	×	○	×	×	×	○*6	×	○*6	×	○*6	○*5	○
	11.5 mm × 66 mm	Holder No. 59*1	3.0 mL	×	○	×	×	×	○*6	×	○*6	×	○*6	○*5	○
VENOJECT II	13.2 mm × 78 mm	Holder No. 58	1.8 mL	○	○	×	×	○*6	○*6	○*6	○*6	○*6	○*6	×	○
			2.7 mL	○	○	×	×	○*6	○*6	○*6	○*6	○*6	○*6	×	○
			4.5 mL	×	○	×	×	×	○*6	×	○*6	×	○*6	×	○

Table 2-8-1: Applicable Evacuated Blood Collection Tubes, Test Tube Adapters and Tube Type selection setting

CAUTION:

O/CP Can be used as capped tube when cap piercer is installed. Sample tubes which are not described in the table are not validated by Sysmex.

O/OP Can be used as open tube regardless of specification. Whether cap piercer is installed or not, open tubes which are described in the table of Chapter 2, Section 8.1 Preparing Plasma can be used.

× Not suitable for use.

*1 Holders No.59 and No. 113 are optional accessories. Please contact your local representative for further information.

*2 Do not perform 3 or more piercing operations without equilibrating the pressure in the tube by releasing the cap.

*3 Micro-mode sampling mode only.

*4 BD Part No. #366438. Please contact your local Becton Dickinson Preanalytical Solutions representative to order. When using BD rack adapter ensure correct attachment of barcode labels to avoid barcode read error.

*5 The sample rack for MONOVETTE tube must be used.

*6 The minimum required sample volume is greater than that when the tube type selection setting is “Default”. See *Chapter2, Section 8.1: Preparing Plasma.*

*7 Sample Cup (4 mL) is not suitable for use.

*8 An inner diameter of greater than 9.4 mm is required for all test tubes.

*9 Only VACUTAINER Plus Plastic Citrate Tube 1.8 mL (HEMOGARD Closure) is suitable for use.

*10 VACUTAINER Plus Plastic Citrate Tube 2.7 mL (HEMOGARD Closure) and a tube whose inner diameter is greater than 9.4 mm is suitable for use.

*11 VACUETTE Sandwich Coagulation Tube 3.0 mL and a tube whose inner diameter is greater than 9.4 mm is suitable for use.

*12 VACUETTE Sandwich Coagulation Tube 3.5 mL and a tube whose inner diameter is greater than 9.4 mm is suitable for use.

*13 Only MONOVETTE 2.9 mL and 3.0 mL are suitable for use.

CAUTION:

• "MONOVETTE" is to be used when a cap piercer unit is installed, use the "Sample Rack (For MONOVETTE tubes)." When analyzing in normal mode, set up " MONOVETTE " via the instrument settings. See *Chapter 11, Section 5.11: Alarm Settings*.
If MONOVETTE is used without being set up, and the sample volume is 1.0 mL or less, the sample tube may be broken. Air may also get aspirated, preventing correct analysis results from being obtained.

CAUTION: If a cap piercer unit is installed:

- Micro-sample mode, standard curve, quality control, and STAT sample holder analysis cannot be performed while the cap is on.
- Do not perform four or more piercing operations using the same cap for each sample tube, and do not perform piercing operations if the total volume aspirated exceeds 1.3 mL for three operations.
- Use the specified holder for the sample tubes. Failure to do so can cause the piercer or other equipment to fail or get damaged.
- Sometimes when caps are placed back on tubes, the tube interior gets pressurized and/or sample adheres on top of the cap. These things will not cause data-related problems, but you may get infected with pathogens.
- Be sure that sample does not adhere to the cap of a centrifuged collection tube. If it adheres, proper sample aspiration may not be performed due to mulfunction of the liquid surface sensor, and correct analysis results may not be obtained.

CAUTION: Precautions regarding sample volume when a cap piercer unit is installed

- Use only the specified sample tube according to the tube type selection setting when performing an analysis with the cap on. If the sample volume is low, the sample tube may be broken. Air or blood cells may also get aspirated, sample to sample carryover may occur and/or “Probe Crash” may occur, preventing correct analysis results from being obtained.
- If the specified amount of sample is not collected into the sample tube, rinse solution from the piercer may enter the tube, due to vacuum, preventing correct analysis results from being obtained. Use only tubes that contain the specified volume of sample.
- If performing an analysis without the cap on, make sure that the surface of the sample is less than 10 mm above the upper surface of the rack. If it is higher, the level cannot be monitored.
- If performing an analysis with the cap on, make sure that the surface of the sample is less than 3 mm above the upper surface of the rack. If it is higher, the level cannot be monitored.
- If using a sample cup, do not set up samples that are low in volume. A "Sample Probe Crash" error may occur.

CAUTION: Precautions regarding use of Terumo VENOJECT II when a cap piercer unit is installed

- When VENOJECT II is used, the contents of a sample can spill if, after use, the cap is broken and the sample tube falls down. This can lead to the transmission of disease; therefore, handle with care.
- The 4.5 mL VENOJECT II tubes cannot be used, because the surface of the sample will be more than 3 mm above the upper surface of the rack, preventing the surface detection.
- When using 1.8- or 2.7-mL VENOJECT II tubes, do not perform two or more piercing operations. It may not be possible to detect the liquid surface. If a reusable cap is used, an additional three piercing operations can be performed. However, the total volume aspirated cannot exceed 1.3 mL for three operations.

CAUTION: Precautions regarding use of 4.5 mL VACUTAINER (HEMOGARD Closure) when a cap piercer unit is installed.

- When using 4.5 mL VACUTAINER (HEMOGARD Closure) tubes, do not perform three or more piercing operations, or the correct amount of sample may not get aspirated, due to vacuum, preventing correct analysis results from being obtained.

CAUTION: Precautions regarding use of 1.8 - or 2.7 - mL VACUTAINER (Conventional Stopper) tubes without the cap on.

- 1.8 - or 2.7 - mL VACUTAINER (Conventional Stopper) tubes can be used in micro mode, but cannot be used in normal mode.
  Air may also get aspirated, preventing correct analysis results from being obtained. A “Sample Probe Sampling Error” or “Insufficient Sample” error may occur.

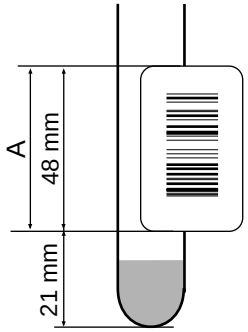
8.2 Preparing Serum

Refer to the Package Insert of each reagent. Minimum required sample volume is the same as described for plasma.

CAUTION:
- Correct analysis results will not be obtained if serum samples and plasma samples are interchanged in error.
- It is recommended that you have different racks to analyze serum samples and plasma samples.

8.3 Affixing Barcode Labels (Option)

If the instrument is equipped with an optional ID barcode reader and barcodes are to be read, affix barcode label to the tube.
To ensure correct reading of barcode, a barcode label has to be affixed at the proper position. Refer to the figure below in affixing a barcode label.



Affix the label so that the effective barcode will be positioned within area A.

Figure 2-8-2: Affixing the Barcode Label

WARNING
- If the sample barcode is used, use a check digit whenever possible.
  If no check digit is used, there is an increased risk of incorrect barcode reading.
- Observe the following precautions about affixing barcode labels.
  If the barcode label is not affixed correctly, the barcode could be misread, causing sample handling errors.
  - Affix labels so that the bars on the label are arranged horizontally when the tubes are placed in the rack.
  - Affix the label correctly, in the required position.
  - Do not affix multiple labels.
  - Affix labels so that they are free of surface wrinkles.
  - The barcode label must not peel off the tube (do not use labels that peel easily).
  - The sample tubes with affixed barcode labels must slide smoothly in and out of the rack.

CAUTION: • If a sample rack is used, place the tube in the sample rack so that the barcode labels correctly face to the barcode reader.

The following chart shows sample processing under various conditions.

In this processing mode, the registered information in the Work List is applied for the sample. If no Sample ID is registered in the Work List, the sample ID read by the ID reader is assigned to the sample.
If no analysis order information is registered, the system inquires the order information from the host computer, and processes the sample according to the order.

NOTE: • There is another processing mode to ignore the information registered in the Work List. Contact your representative for assistance.

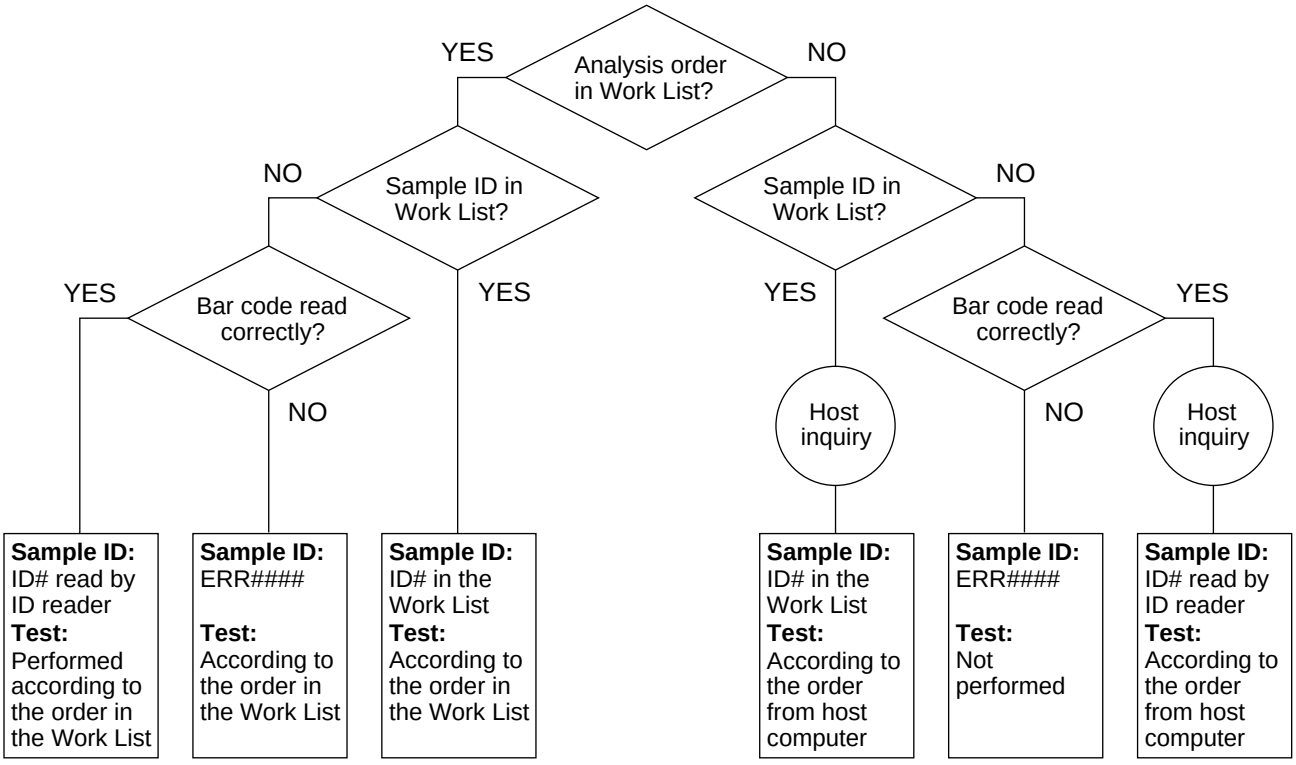


Figure 2-8-3: Sample Processing

8.4 Setting the Sample Rack into the Sampler

(1) Set the sample rack onto the sampler.
To set, align the sampler guide and sample rack groove. Up to 5 racks can be set at a time.

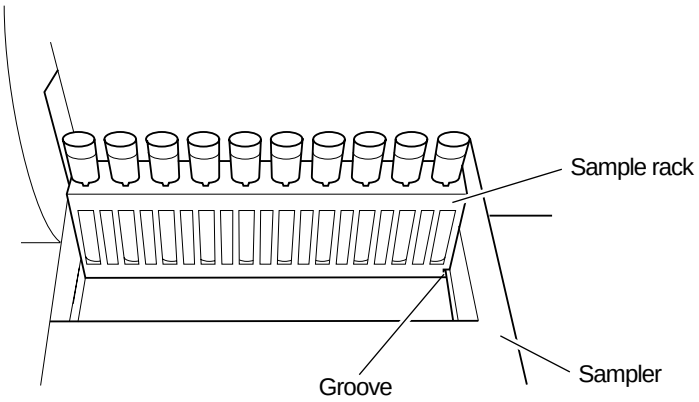


Figure 2-8-4: Setting the Sample Rack

CAUTION: • If the sample is left at room temperature for an extended period of time, sample will be aged and correct analysis result may not be obtained. Place samples on the sampler immediately before the analysis starts.

CAUTION: • If the sample rack is not correctly set, instrument failure may result.

CHAPTER 3 WORK LIST

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6. AUTOMATIC INQUIRY (OPTION) 3-15

7. ADDITIONAL REGISTRATION 3-15

1. INTRODUCTION

The CA-1500 analyzes all samples according to analysis order information. The following four methods of registering order information (consisting of tube position, sample ID number and analysis parameter) are available:

1) Manual registration method by means of the numeric keys and analysis parameter keys
2) Method of receiving sample ID numbers and analysis parameters from the host computer by tube position number
3) Method of receiving analysis parameters from the host computer by sample ID number (when analyzing with STAT sample holders)
4) Method of receiving order information from the host computer by sample ID number read by optional barcode reader

This chapter will explain the procedure for registering order information.

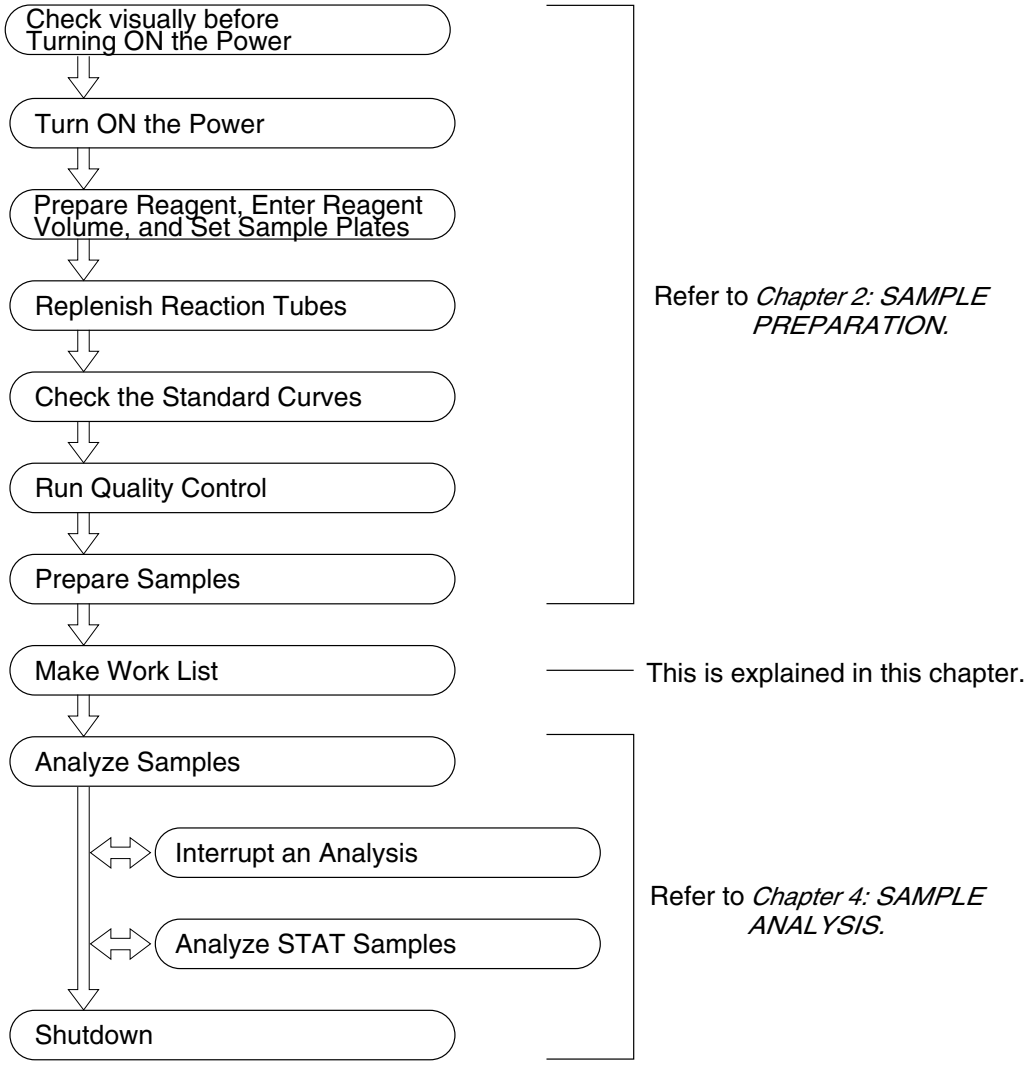

Figure 3-1-1: Analysis Flow Chart

2. WORK LOAD LIST SCREEN

The Work Load List screen is used to register order information.

2.1 Displaying the Work Load List Screen

(1) From the Main Menu screen, press the [Work List] key.
The Work Load List screen will appear.

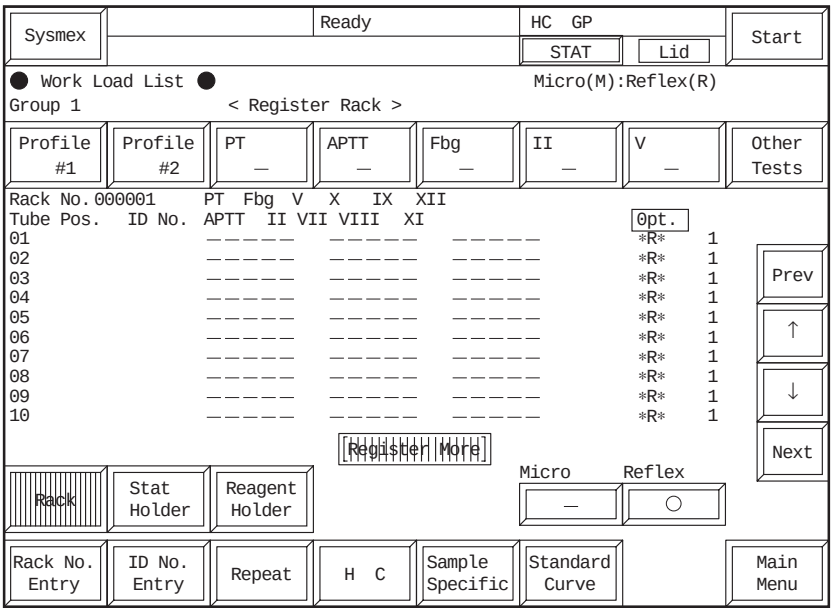

Figure 3-2-1: Work Load List Screen

(2) Press the key for the location in which the sample is set ([Rack], [Stat Holder], or [Reagent Holder]).
The sample can be set in the sample rack, STAT sample holder, or reagent holder and then analyzed. A work list should be prepared for each location in which samples are set.

Set Location	Samples that Can Be Set
Sample rack	Routine samples, STAT samples, calibrators, and quality control samples
STAT sample holder	STAT samples
Reagent holder	Calibrators and quality control samples

CAUTION:

- In the Work Load List screen, press the [STAT] key located at the top of the screen to register order information. Routine order information cannot be registered if the [Stat Holder] key is pressed.
  For details on analyzing STAT samples, see *Chapter 4, Section 3: ANALYZING STAT SAMPLES.*
- The following setup is required when reagent holders are used during quality control analyses:
  - Set up the quality control samples and applicable file numbers for the reagent information.
    See Chapter 11, Section 5.1: Reagent Information Settings.
  - Place the quality control samples in reagent positions D1 to D14.
    See *Chapter 11, Section 5.7: Reagent Position Settings.*

NOTE:

- Analysis precedence differs according to the location of the samples.
  Analyses are executed in the following order of precedence: STAT holder, sample rack (STAT samples), reagent holder, and then sample rack (other than STAT samples).
  Analyses of samples in STAT holders and reagent holders are executed in order, starting from the holder with the smallest number.

2.2 Contents Displayed on Work Load List Screen

Rack Registration

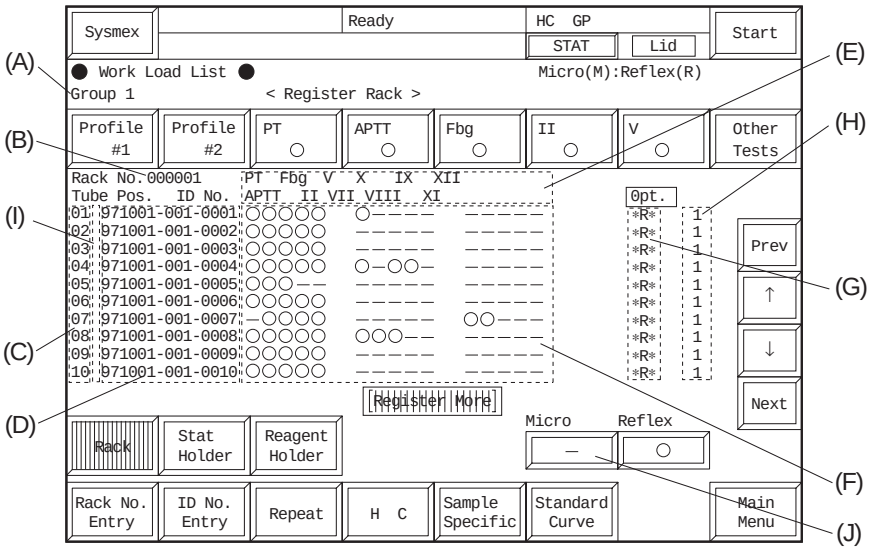

Figure 3-2-2: Work Load List (Rack)

STAT Sample Holder Registration

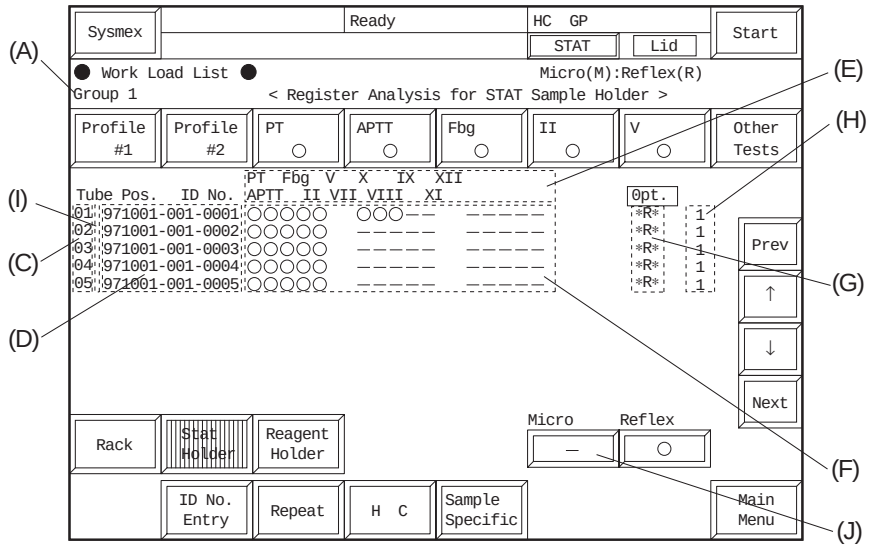

Figure 3-2-3: Work Load List (STAT Sample Holder)

Reagent Holder Registration

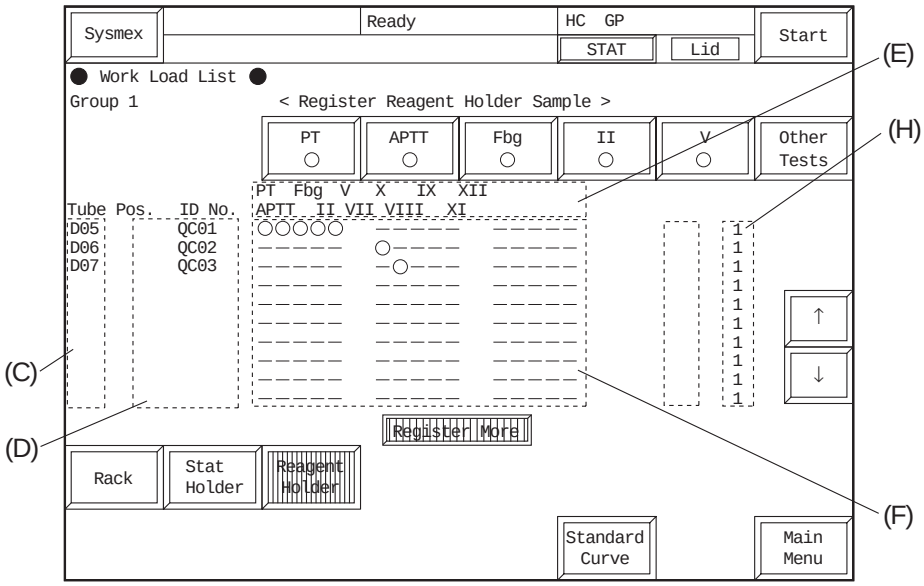

Figure 3-2-4: Work Load List (Reagent Holder)

(A) Group: Displays the name of the parameter group that is currently selected.

(B) Rack No.: Displays the 6-digit number that is assigned when the rack is registered.

(C) Tube Pos.: When the rack is registered, the tube positions are displayed as 01 to 10. When STAT sample holder analysis is registered, the STAT sample holder positions are displayed as 01 to 05.
When reagent holder samples are registered, the reagent holder positions are displayed.

(D) ID No.: The Sample ID numbers are registered using numerals and hyphens (-) and can be entered up to 15 digits. When quality control samples are registered, ID number from QC01 to QC20 are used.

(E) Analysis parameter: The analysis parameter name that is set in the currently selected parameter group is displayed.
Parameter that cannot be analyzed at all because of insufficient reagent is displayed with a red back-light.
Parameter that cannot be analyzed for all registered samples because of insufficient reagent will be displayed with a yellow back-light. In this case, you have to either reduce the number of analyses, or add the reagent.

(F) Analysis progress: The status of each sample will be displayed in the following back-light colors.

Back-light Color	Meaning
White	Not registered
Blue	Registered but has not been analyzed
Green	Analysis in progress
Light Blue	Analysis has been completed

The status of each analysis parameter will be displayed via the following symbols.

Symbol	Meaning
○	Will be analyzed
—	Will not be analyzed
◎	Analysis in progress
●	Analysis completed without any error
×	Analysis not completed due to an error

(G) Flag: Flags will be displayed for each sample when detailed settings are changed.

Flag	Meaning
M	Micro-sample mode (measured in micro-sample mode)
R	Will conduct a reflex test.
C	Redilution, re-analysis, or dilution ratio setting has been changed. You can see details using Sample Specific screen.

(H) Group number: Parameter group number is displayed.

(I) STAT sample flag: Displays "S" for the STAT samples.

(J) Micro-sample mode: Even if the sample volume is minimal, you can analyze in the Micro-sample Mode.
In this case, the sample will be analyzed without dispensing in the sample plate, but will be dispensed directly into the reaction tube, and analyzed. (The second dilution and after will be performed by dispensing into the sample plate.)
However, the automatic re-analysis will not be performed.

CAUTION: • When a cap piercer unit is installed, the analysis cannot be performed in the Micro-sample Mode in the sample tubes with the cap. Analyze after manually removing the cap.

2.3 Contents Displayed on Sample Specific Screen

For samples except for calibrators and quality control samples, detailed settings are made with regard to re-dilution, re-analysis, dilution ratio, and dilution series of MDA (Multi-Dilution Analysis). The Sample Specific screen is used to make those settings.
If you press the [Sample Specific] key on the Work Load List screen, the Sample Specific screen will appear.

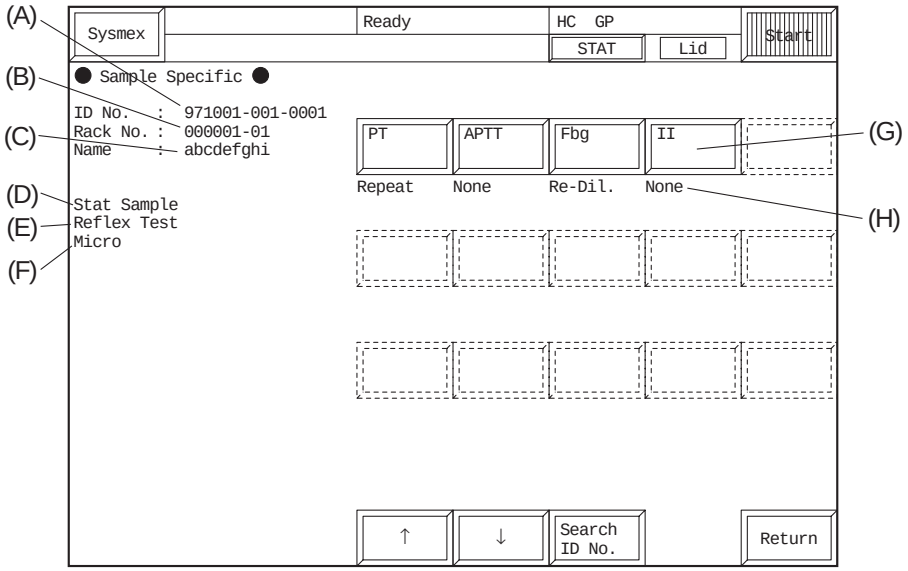

Figure 3-2-5: Sample Specific Screen

(A) ID No.: The sample ID number is displayed.

(B) Rack (Holder) No.: During rack registration, the rack number and tube position number are displayed. During STAT sample holder analysis registration, the STAT sample holder number is displayed.

(C) Name: The patient's name is displayed, if downloaded from an optional host computer.

(D) Stat Sample: Will be displayed if it is a STAT sample.

(E) Reflex Test: Will be displayed if reflex test is selected.

(F) Micro: Will be displayed if micro-sample mode is selected.

(G) Analysis parameter keys: Parameters that will be analyzed via the Work Load List screen are displayed. Press this key to set the re-analysis method.

(H) Re-Dil., Repeat, Dilution Ratio: Analysis parameter settings are displayed.

Contents Displayed	Content of Analysis		
	Redilution	Re-analysis	Dilution Ratio
Re-Dil. Repeat	○	○	—
Re-Dil.	○	—	—
Repeat	—	○	—
1/2 Dil. or 1/4 Dil.	—	—	1/2 dilution or 1/4 dilution
2/1 Dil.	—	—	2/1 dilution
None	—	—	—

○ : Will be analyzed
—: Will not be analyzed

MDA Dilution Series (MDA, MDA high, MDA low)

Contents Displayed	Contents of Analysis
MDA	Analyze at concentration of 1/1, 1/2, and 1/4.
MDA high	Analyze at concentration of 1/8, 1/16, and 1/32.
MDA low	Analyze at concentration of 2/1, 5/1, and 10/1.

When the number of points set for the MDA dilution series is 2, the system will analyze up to the second dilution.

CAUTION:

- When the MDA dilution series (MDA, MDA high, MDA low) is set up, redilutions, repeat analyses, and reflex tests will not be executed.
- When redilutions and repeat analyses have been set up from the setup menu to be executed, the [Re-Dil] and [Repeat] keys will appear. For details on redilution settings, see *Chapter 11, Section 4.3: Redilution Analysis Settings* and for details on repeat analysis settings, see *Chapter 11, Section 4.4: Repeat Analysis Settings.* The keys for 1/2 dilution analysis, 2/1 dilution analysis, MDA, MDA high, and MDA low will appear only when analysis can be executed. (For parameters which are not diluted by the test protocol (PT, APTT, etc.), redilution analysis cannot be executed.)
- Redilution and re-analysis cannot be set for a sample which is ordered in micro-sample mode in the sample rack, but dilution ratio and MDA dilution series can be set.
- MDA low may not produce linear analysis data due to effect of natural inhibitors (AT III, PC etc.).

3. MANUAL REGISTRATION

Using the Work Load List screen, manually register the analysis order.
This section will provide an explanation by using the rack registration method as an example. For STAT sample holder analysis registration and reagent holder sample set registration, skip the operations pertaining to keys that are not shown on the Work Load List screen. To register standard curve analysis, see *Chapter 8, Section 4.1: Standard Curve Analysis Registration.*

3.1 Registering the Rack Number

(1) Press the [Rack No. Entry] key.
The numeric keys that are used to enter the rack number will appear.

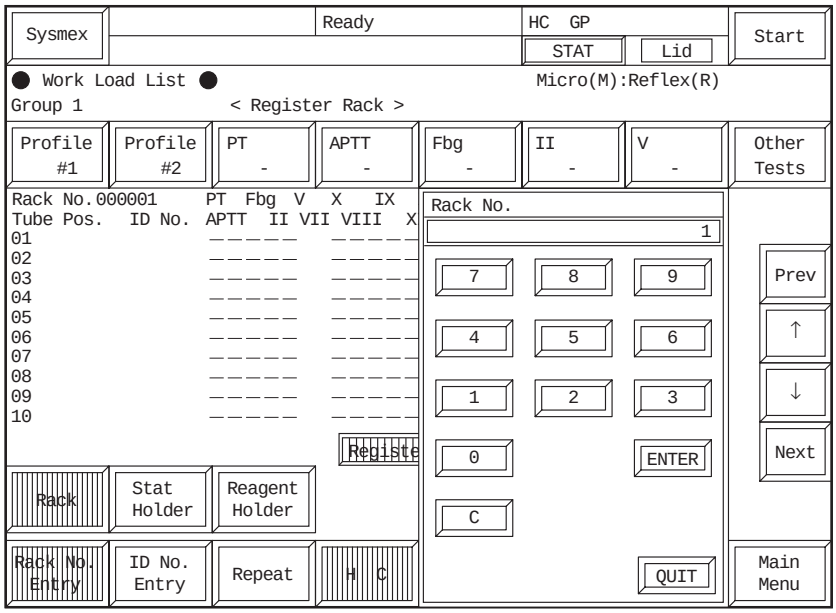

Figure 3-3-1: Rack No. Entry Screen

(2) Enter the rack number using 6-digit numerals; then press the [ENTER] key.
The rack number entered and tube position numbers, 01 through 10, will be displayed.

3.2 Registering the Sample ID Number

(1) Select the sample that you wish to register.
By use of the [↑] and [↓] keys, the cursor can be moved to the sample.

(2) Press the [ID No. Entry] key.
The numeric keys that are used to enter the sample ID number will appear.

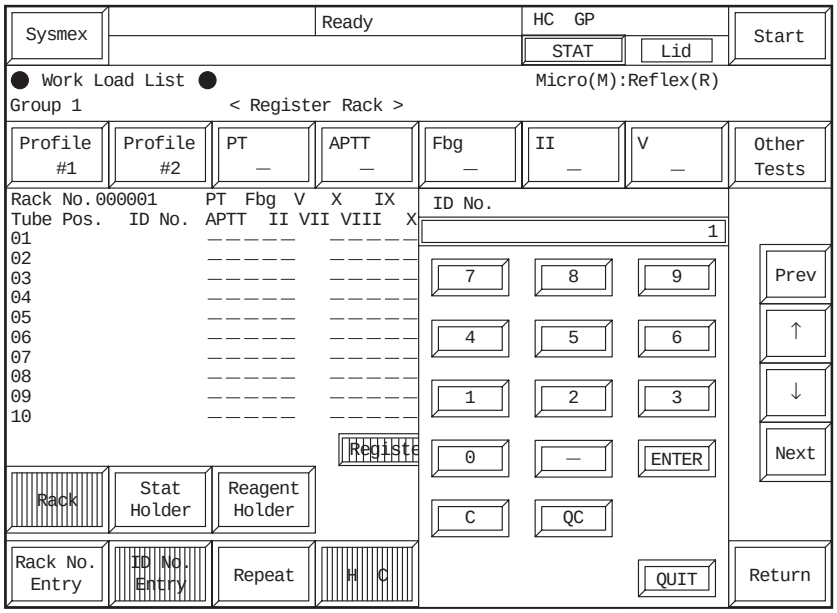

Figure 3-3-2: ID No. Entry Screen

(3) Enter the sample ID number, then press the [ENTER] key.
The sample ID number can be registered with up to 15 digits consisting of numerals and hyphens (-). The hyphens, however, cannot be entered consecutively or as the first or the last digits of the sample ID number. The quality control samples can be registered as "QC01" through "QC20".

NOTE:
- If an analysis is started without a sample ID number being registered, a sample ID number will automatically be assigned. After the power is turned ON, the number will start from "000000000000001" and increment by 1 thereafter.

3.3 Registering the Analysis Parameter

(1) Select the sample that you wish to register.
By use of the [↑] and [↓] keys, the cursor can be moved to the sample.

(2) Press the key for the analysis parameter (such as [PT], [APTT], or [Fbg]) to register the parameter. Each time you press the analysis parameter key, the symbols "○" (will be analyzed) and "–" (will not be analyzed) will alternate.
To view the keys for analysis parameters that are not displayed, press the [Other Tests] key.

NOTE:
- If "Profile #1" and "Profile #2" are being set by the parameter group setting, pressing the [Profile #1] or [Profile #2] key will allow you to register a series of preselected tests.
  For details on how to set Profile #1 and Profile #2 parameters, see *Chapter 11, Section 5.5: Parameter Group Settings.*

(3) For micro-samples, press the [Micro] key. The "○" symbol will be displayed.
Each time you press the [Micro] key, the symbols "○" (Micro-sample Mode) and "–" (Normal Mode) will alternate. When the Micro-sample Mode is selected, reflex test will become "–" (not available). (For the Micro-sample Mode, see *Chapter 3, Section 2.2: Contents Displayed on Work Load List Screen, (J)*.)

(4) To perform a reflex test, press the [Reflex] key. The "○" symbol will be displayed.
Each time you press the [Reflex] key, the symbols "○" (execute) and "–" (do not execute) will alternate. However, you cannot set "○" (execute) in the Micro-sample Mode.

(5) To set a redilution, repeat analysis, and/or dilution ratio, press the [Sample Specific] key.
The Sample Specific screen will appear.

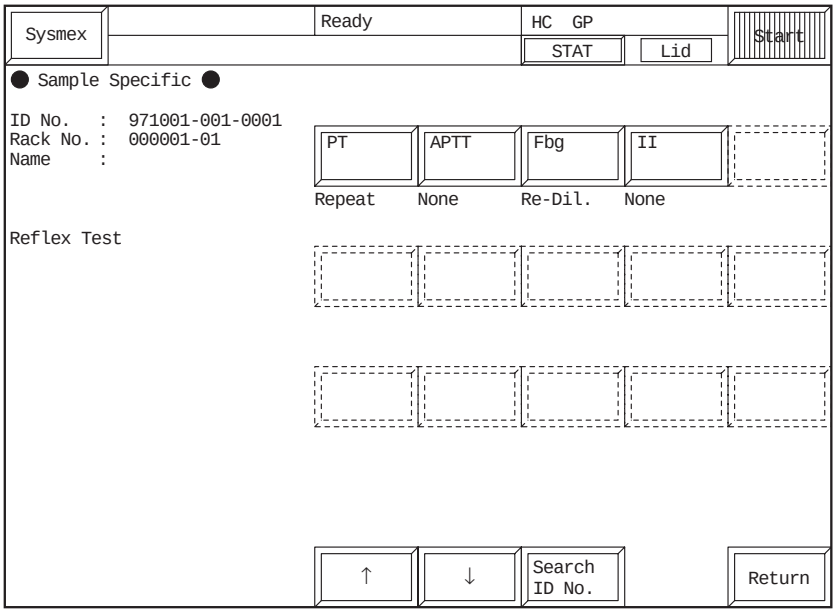

Figure 3-3-3: Sample Specific Screen

(6) Press the key for the analysis parameter to be re-analyzed.
The Selection of re-run method window will appear.

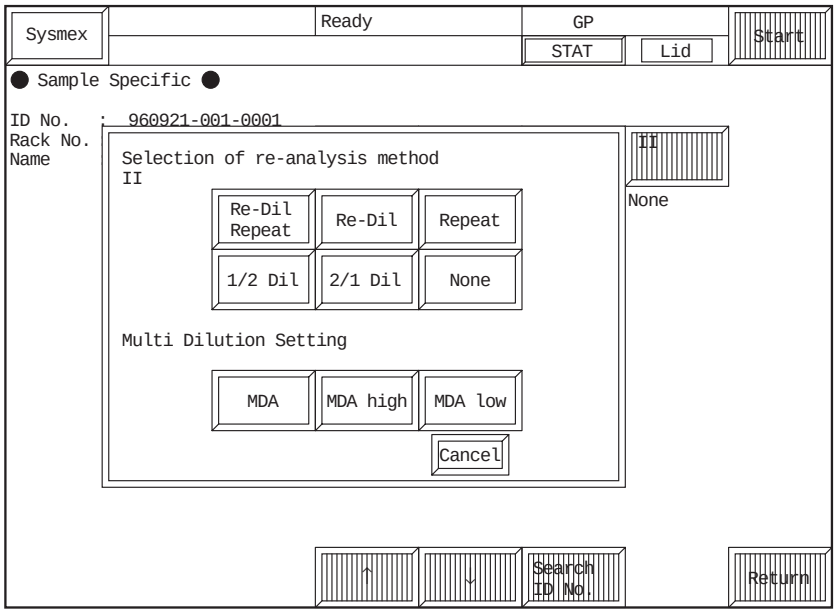

Figure 3-3-4: Selection of Re-analysis Method Window

(7) Press the key for the re-analysis method.
The selected re-analysis method will be displayed below the key for the analysis parameter.

(8) After setting is completed, press the [Return] key.
The Work Load List screen will reappear.

CAUTION:

- When redilutions and repeat analyses have been set up from the setup menu to be executed, the [Re-Dil] and [Repeat] keys will appear. For details on redilution settings, see *Chapter 11, Section 4.3: Redilution Analysis Settings* and for details on repeat analysis settings, see *Chapter 11, Section 4.4: Repeat Analysis Settings.*
- The keys for 1/2 dilution analysis, 2/1 dilution analysis, MDA, MDA high, and MDA low will appear only when analysis can be executed. (For parameters which are not diluted by the test protocol (PT, APTT, etc.), re-dilution analysis cannot be executed for MDA LOW and 2/1 dilution analysis.)

3.4 Registering with the Repeat Key

It is possible to repeat the registration. In this case, sample ID numbers are registered as consecutive numbers. Same analysis parameters are also registered. Further, if analysis parameters are registered for samples that will be re-analyzed, the same analysis parameters and sample specific parameters (re-dilution, reanalysis, reflex test and micro-sample mode) will be set.

CAUTION:
- Registration with repeat key cannot be performed for sample ID numbers (QC01 - QC20) for quality control analysis, sample ID number (calibrator name) for standard curve analysis, and sample ID number "0."

(1) Using the [↑] and [↓] keys, move the cursor to the sample that you wish to duplicate analysis parameters.

(2) Press the [Repeat] key.
The numeric keys that are used to specify the number of repetitions will appear.

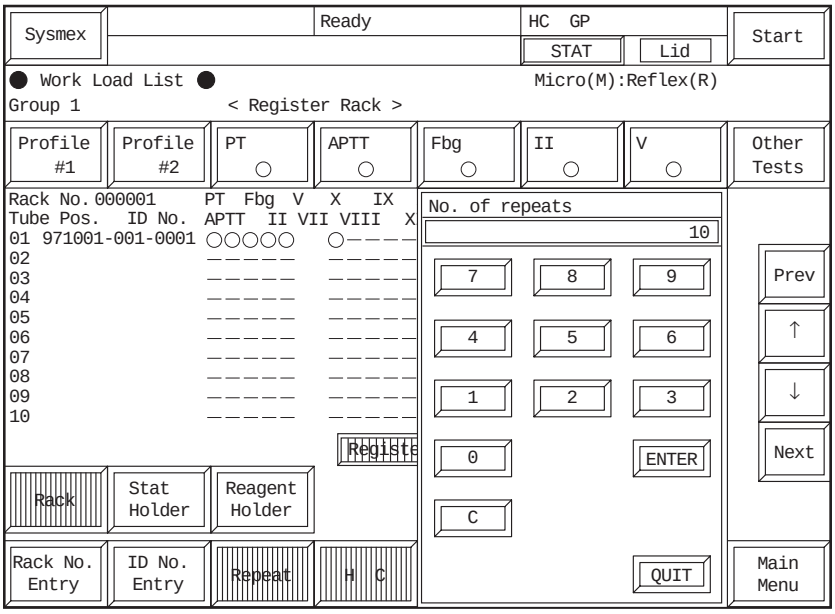

Figure 3-3-5: No. of Repeats Entry Screen

(3) Using the numeric keys, enter the number of repetitions; then press the [ENTER] key.
The number of repeats includes the sample at the cursor position.

4. INQUIRY BY RACK NUMBER (OPTION)

If host computer and CA-1500 are connected with bi-directional communication, you can inquire and register 1 rack of order information based on the rack number. To do so, the host computer settings must be as follows:

Status:	Connected
Inquiry:	Manual
Class:	Class B

For details, see *Chapter 11, Section 6.1: Host Computer Settings.*

(1) From the Work Load List screen, enter the rack number.
For details on how to enter the rack number, see *Section 3.1: Registering the Rack Number* in this chapter.

(2) Press the [HC] key.
The order information that has been inquired by rack number will appear on the screen.

(3) Verify the order information.

5. STAT SAMPLE INQUIRY (OPTION)

If host computer and CA-1500 are connected with bi-directional communication, you can inquire and register analysis parameters based on the sample ID number of the sample that is set in the STAT sample holder. To do so, the host computer settings must be as follows:

Status:	Connected
Inquiries:	Manual or Auto
Class:	Class B

For details, see *Chapter 11, Section 6.1: Host Computer Settings.*

(1) From the Work Load List screen for STAT sample holder analysis, enter the sample ID number.
For details on how to enter the sample ID number, see *Section 3.2: Registering the Sample ID Number* in this chapter.

(2) Press the [HC] key.
The analysis parameters that have been inquired by sample ID number will appear on the screen.

(3) Verify the analysis parameters.

6. AUTOMATIC INQUIRY (OPTION)

If host computer and CA-1500 are connected with bi-directional communication and an optional ID barcode reader is installed, you can inquire and register analysis parameters based on sample ID numbers that are read by the barcode reader. In such cases, it is not necessary to prepare the work list manually.
The host computer settings and barcode settings must be as follows:

Host computer
- Status: Connected
- Inquiry: Auto
- Class: Class B

Barcode reader
- Status: Connected
- Tube ID Label: Used

For details, see *Chapter 11, Section 6.1: Host Computer Settings* and *Chapter 11, Section 6.5: Barcode Settings.*

CAUTION:
- If the sample ID number has already been registered manually, an inquiry will be done by using that ID number, without the barcode label being read.
- If the analysis parameter has already been registered manually, an analysis will be done by using that registered parameter.
- If a sample rack is used, place the tube in the sample rack so that the barcode labels correctly face to the barcode reader.
- For details on barcode label position, *see Chapter 2, Section 8.2: Affixing Barcode Labels (Optional).*

NOTE:
- If a barcode reading error occurs, the sample ID number will be a consecutive number that starts with "ERR000000000001" after the power has been turned ON.

7. ADDITIONAL REGISTRATION

While the status is "Dispensing", if you wish to add and analyze new samples in the current batch, register the analysis order in the Work Load List and press the [REGISTER MORE] key. Analysis of those additionally registered samples will follow continuously.

CHAPTER 4 SAMPLE ANALYSIS

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   2.2 Displaying the Analysis Status 4-4
   2.3 Interrupting Analysis 4-5

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5. EMERGENCY STOP 4-15

6. SHUTDOWN 4-16

1. INTRODUCTION

This chapter will explain the operating procedure from the start of analysis to shutdown.

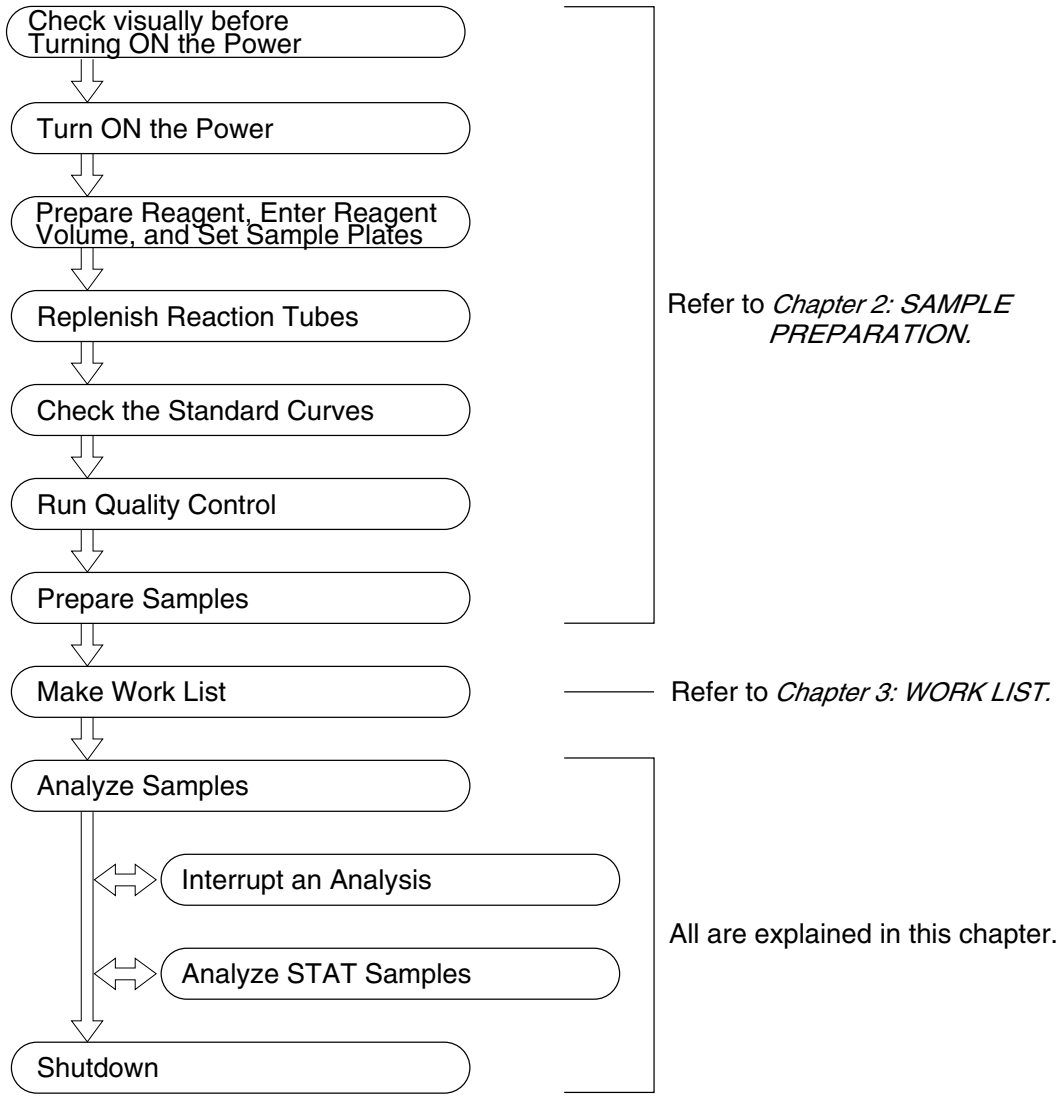

Figure 4-1-1: Analysis Flow Chart

2. ANALYSIS

2.1 Start of Analysis

This section will explain the analysis process.

(1) Check the instrument status display.
Analysis can start if "Ready" is indicated in the status display area at the top of the screen.

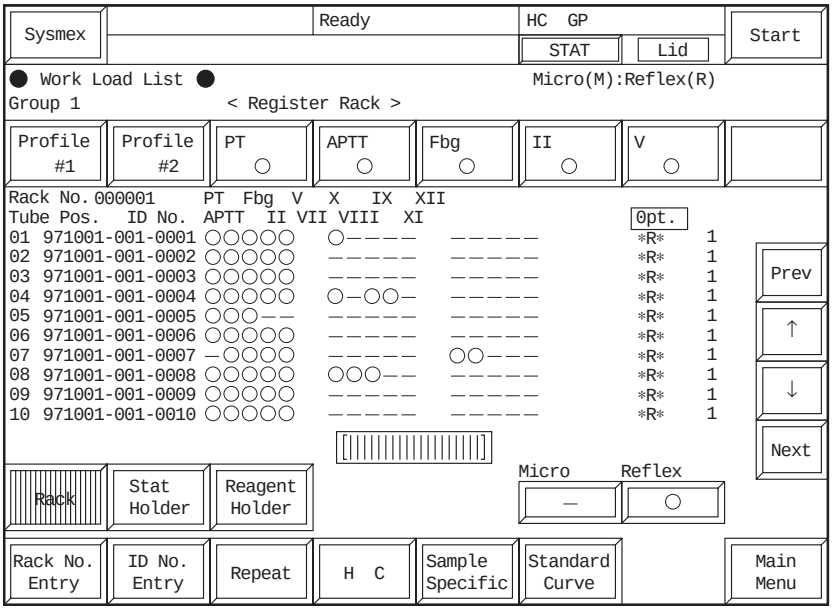

Figure 4-2-1: Checking the Status Display

(2) Press the [Start] key.
The analysis will start and the message "Dispensing" will appear in the status display area.

WARNING: • During an analysis, do not open the light shield lid or place your hands or fingers inside. You can get injured. If the light shield lid is opened during analysis, an alarm will sound and the operation will stop.

CAUTION: • After the power is turned ON, it will take a maximum of 30 minutes for the intensity of the Lamp unit to stabilize. Before starting to analyze Chromogenic and Immunological assays wait 30 minutes. If you start to analyze earlier, while the light intensity is unstable, the analysis results may be incorrect.

CAUTION:

- Switching the power OFF during analysis could result in permanent damage to the instrument. To turn OFF the power, wait until the analysis is completed and the message "Ready" appears in the status display area.
- Check that the right and left rack pools of the sampler and the analysis line are free of dirt and foreign bodies.
- Check that no dirt or foreign bodies are stuck to the bottom of the rack, and that the rack is not damaged or deformed.
- During sampler analysis operation, do not push racks in as far as the analysis line by hand.
- Take care to avoid touching racks on the analysis line during sampler analysis operation.

NOTE:

- During an analysis, the [Start] key will change into the [Interrupt] key. And when an analysis is interrupted, the key will change to [Resume].
- When an analysis has started, the Work Load List cannot be changed. If an analysis is interrupted, however, those samples that have not been analyzed yet can be changed or canceled.
- Analysis precedence differs according to the location of the samples.
  Analyses are executed in the following order of precedence: STAT holder, sample rack (STAT samples), reagent holder, and then sample rack (other than STAT samples).
  Analyses of samples in STAT holders and reagent holders are executed in order, starting from the holder with the smallest number.

2.2 Displaying the Analysis Status

The Work Load List screen or Main Menu screen can be used to check the status of each sample's analysis.
The status of each analysis parameter will be displayed via the following symbols:

– : Will not be analyzed.
○: Will be analyzed.
◎: Analysis in progress.
●: Analysis completed without any error.
× : Analysis not completed due to an error.
● (red): Analysis was completed without any error; however, calculation parameters are not calculated due to no standard curve being set or due other causes. On the Work Load List screen, back-light color for samples that are currently being analyzed will change to green. If analysis is completed, back-light color will change to light blue.

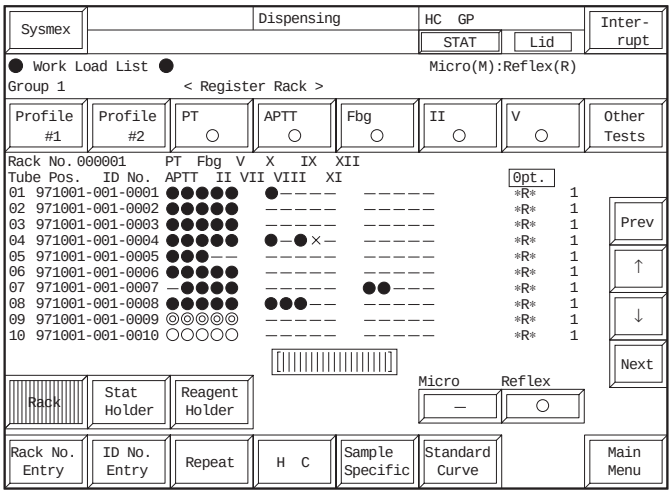

Figure 4-2-2: Work Load List Screen

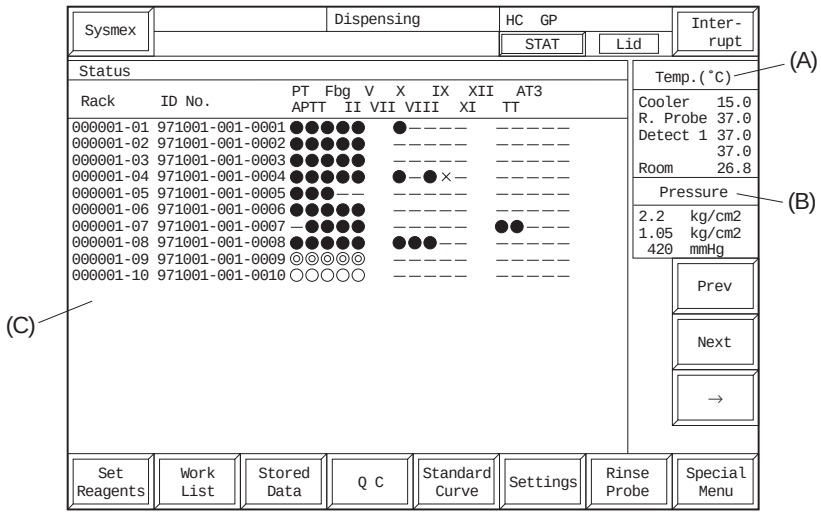

Figure 4-2-3: Main Menu Screen

Contents Displayed on Main Menu Screen

(A) Temp.

- Cooler: Temperature of reagent holder is displayed.
- R. Probe: Temperature of reagent probe is displayed.
- Detect: Temperature of detector block is displayed.
- Room: Temperature inside the instrument is displayed.

(B) Pressure

Pressure (2.2 kg/cm^2), pressure (1.0 kg/cm^2), and vacuum (400 mmHg) are displayed in order from the top.

(C) Status

Status of analysis is displayed. The analysis status display has the same content as that of the Work Load List screen. Pressing the [Prev] and [Next] keys will display the status of the analyses that are not shown on the current screen. Pressing the [→] key will display the status of analysis of parameters that are not currently displayed.

2.3 Interrupting Analysis

Interrupt the analysis when you need to change the Work Load List or to replenish reagent.

NOTE: • Interruption for STAT sample analysis is executed by a different procedure. See *Section 3: ANALYZING STAT SAMPLES* in this chapter.

(1) Press the [Interrupt] key.
The Interrupt Analysis window will appear.

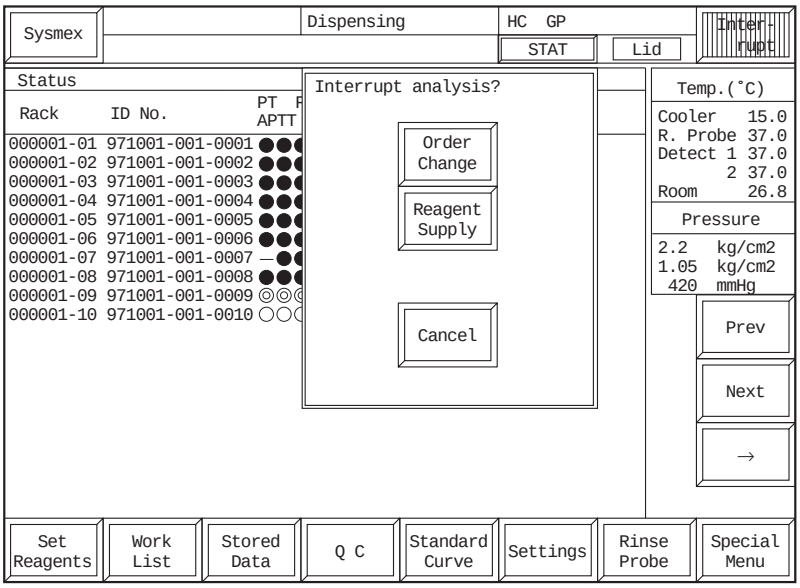

Figure 4-2-4: Interrupt Analysis Window

(2) Press the key that represents the reason for interrupting the analysis.
[Order Change] key: Press to change the registered order information.
[Reagent Supply] key: Press to replenish reagent, sample plates or reaction tubes.
[Cancel] key: Press to cancel interruption of analysis.

If the [Order Change] or [Reagent Supply] key is pressed, dispensing of new samples is suspended, and the message "Being Interrupted" will appear until the instrument becomes ready for changing order or replenishing reagents and consumable. After the interrupting preparation is completed, the message will disappear and the status display area at the top of the screen will change to "Waiting".

(3) Now, the order information can be changed or the reagent and consumable can be supplied.
For details on replacing consumable supplies, see *Chapter 6, Section 6: REPLACING SUPPLIES*.

(4) Press the [Resume] key.
The analysis will restart.

NOTE:
- If you do not wish to resume the analysis, press the Mechanical Stop switch during interruption to put the instrument in Ready status. However, if an unanalyzed sample remains in a sample plate, an analysis error ("X") will result.

3. ANALYZING STAT SAMPLES

Analysis of STAT samples can be given priority over analysis of other samples. Two methods of analysis are available: a method of setting STAT samples into a sample rack, and a method of setting them into STAT sample holders.

3.1 Interrupting Analysis

To analyze a STAT sample, the ongoing analysis must be temporarily interrupted.

(1) Press the [STAT] key.
The STAT Sample Setting Position Selection window will appear.

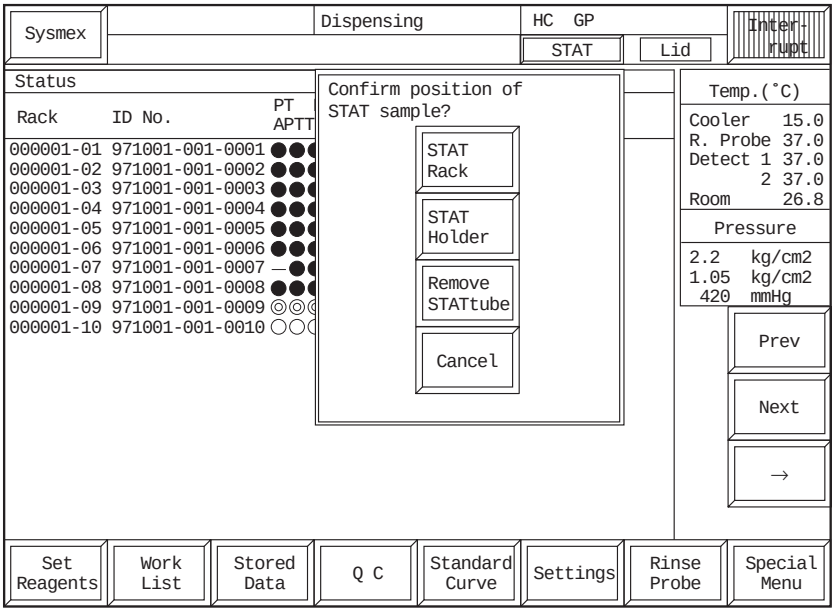

Figure 4-3-1: STAT Sample Setting Position Selection Window

(2) Press the key for the position in which you wish to set the STAT sample.
If the [STAT Rack] or [STAT Holder] key is pressed, the ongoing analysis will be interrupted and the message "Being Interrupted" will appear. If you do not wish to interrupt the analysis, press the [Cancel] key. After a short time, the message will disappear and a message prompting you to set the STAT sample will appear.

3.2 Analyzing STAT Samples in Sample Rack

(1) Remove the sample racks from the analysis line where sampling is in progress. Manually remove all sample racks whose samples have been analyzed. Manually move the sample racks containing unanalyzed samples to the right rack pool.

CAUTION:
- When moving sample racks to the right rack pool, do not change the order in which the racks are lined up in the pool. If you change the order in which the racks are lined up, the analysis cannot be performed in accordance with the Work Load List.

(2) When the message prompting you to set the STAT samples appears, press the [OK] key. The Work Load List screen for rack registration will appear.
If automatic inquiry is set, the Rack No. Entry window will be displayed.

(3) Register the analysis order.
See *Chapter 3: WORK LIST*.

(4) Set the sample rack in which the STAT samples are placed on the measurement line of the right rack pool.

CAUTION:
- Correct analysis results will not be obtained if the serum samples and plasma samples have replaced each other.
- It is recommended that you use different racks to analyze the serum samples and plasma samples.

(5) Press the [Resume] key.
The analysis will start. When STAT sample dispensation is completed, the interrupted analysis will automatically resume starting with the sample whose analysis was interrupted.

CAUTION:
- If you need to analyze more STAT samples placed in a rack, just set the next STAT sample rack right after the previous rack.

3.3 Analyzing STAT Samples in STAT Sample Holders

(1) When the message prompting you to set the STAT samples appears, press the [OK] key. The Work Load List screen for STAT sample holder registration will appear.

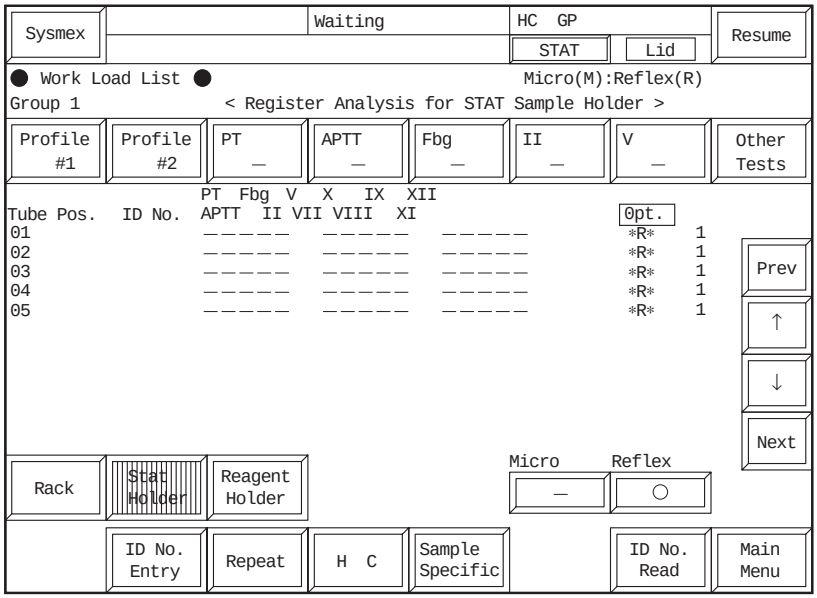

Figure 4-3-2: Work Load List Screen (STAT Sample Holder Registration)

(2) Enter the sample ID number.
Press the [ID No. Entry] key, then enter the sample ID number
It is also possible to input the sample ID number automatically according to the following procedures with an optional wand barcode reader.
Press the [ID No. Read] key. (The [ID No. Read] key is displayed only when an optional wand barcode reader is used.)
Be sure to read the barcode label with an optional wand barcode reader.
The read sample ID numbers will be displayed in the reading window once the sample is placed in a STAT holder position.

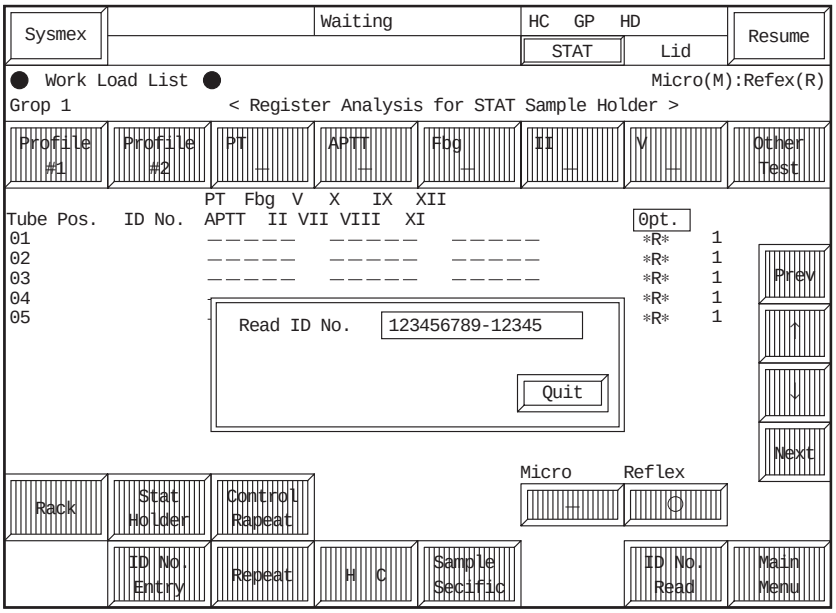

Figure 4-3-3: Read ID No. Window

Confirm the displayed ID number and set the test tube in the STAT sample holder. The sample ID number will be entered in the set position on the Analysis Registration screen. Multiple STAT samples can be read consecutively.
Press [Quit] key after completion of STAT samples identification.
The Read ID No. window will disappear and will reappear to the Work Load List screen of the STAT sample holder analysis registration.

(3) Register the analysis order.
See *Chapter 3: WORK LIST.*

(4) Verify that the STAT sample cover LED is green; then push the STAT sample cover in to open.

CAUTION: • If the STAT sample cover LED is red, the STAT sample cover cannot be opened. If you try to open by force, permanent damage to the instrument can result.

(5) Set the container that holds the STAT sample into the STAT sample holder.

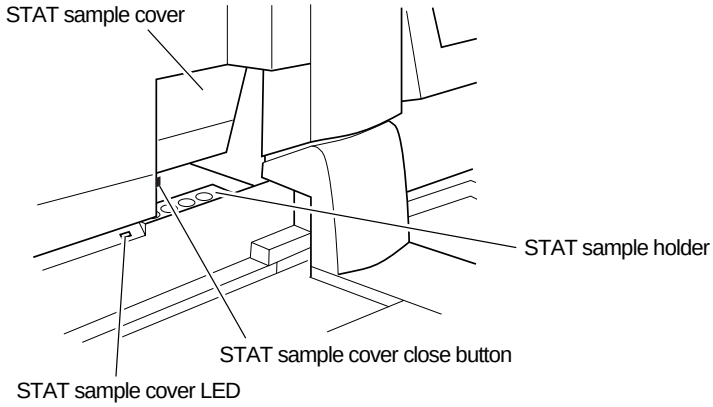

Figure 4-3-4: Setting Container

CAUTION:
- Correct analysis results will not be obtained if serum samples and plasma samples are interchanged in error.
- Capped sample tubes are not acceptable on the STAT holder even if the CP Unit is installed.

CAUTION:
- Use the correct holder for tubes or sample cups and set securely.
  OD 10 - 12 mm tube : Tube holder No. 1
  OD 13 - 14 mm tube and sample cup : Tube holder No. 3
  OD 15 mm tube : No holder is required.
  For details on holders, see *Chapter 6, Section 6.8: Supply Parts List.*

(6) Press the STAT sample cover close button, and the STAT sample cover will close gently.

(7) Press the [Start] or [Resume] key.
The analysis will start. When the STAT sample analysis is completed, the interrupted analysis will automatically resume starting with the sample whose analysis was interrupted.

NOTE:
- Cancellation of STAT sample analysis can only be achieved at a time before [Start] or [Resume] key is pressed. In order to cancel STAT sample analysis set all order information of STAT sample to " _ " (will not be analyzed) then press the [Start] or [Resume] key.
- If the [Return] key is pressed during registration of the STAT sample order, re-operate from the [STAT] key located on the upper right of the screen.
- If the [Start] or [Resume] key is pressed, the order information in the STAT sample holder cannot be changed.

(8) After the STAT sample analysis is completed, verify that the STAT sample cover LED is green; then open the STAT sample cover, and remove the container that was set in the STAT sample holder.
If the STAT sample cover LED is red, press the [STAT] key. The selection window for STAT sample setting position will appear.
Press the [Remove STAT tube] key. The analysis will be interrupted, and the message "Being Interrupted" will appear. When the interruption process is completed, the message will disappear, and the STAT sample cover LED will turn to green. Then, the message prompting you to remove the STAT sample will appear.
To continue the STAT sample analysis, press the [STAT Holder] key or [STAT Rack]. The analysis will be interrupted, and the container in the STAT sample holder can be removed.

CAUTION:
- If a container whose sampling has not been completed remains in the STAT sample holder, a message will appear. Check the STAT sample Work Load List screen, and then remove only the containers whose sampling has been completed.

4. CHECKING THE AMOUNT OF REMAINING CONSUMABLE

Display the Consumable screen and check the amount of consumable supplies that remain. If you press the [Set Reagents] key on the Main Menu, the Consumable screen will appear.

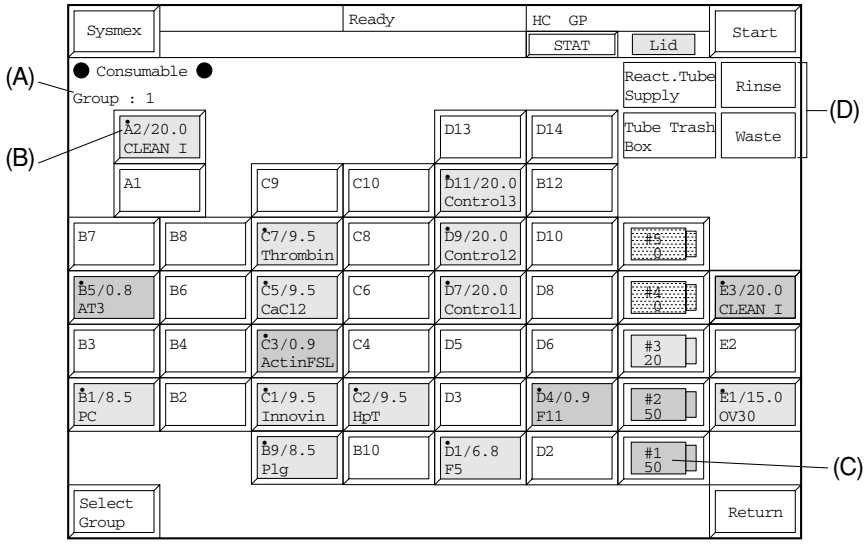

Figure 4-4-1: Consumable Screen

The reagent keys and sample plate keys of the Consumable screen are physically aligned in the same positions as the reagent holders, sample plates, and reagent rinse solution and diluent setting positions.

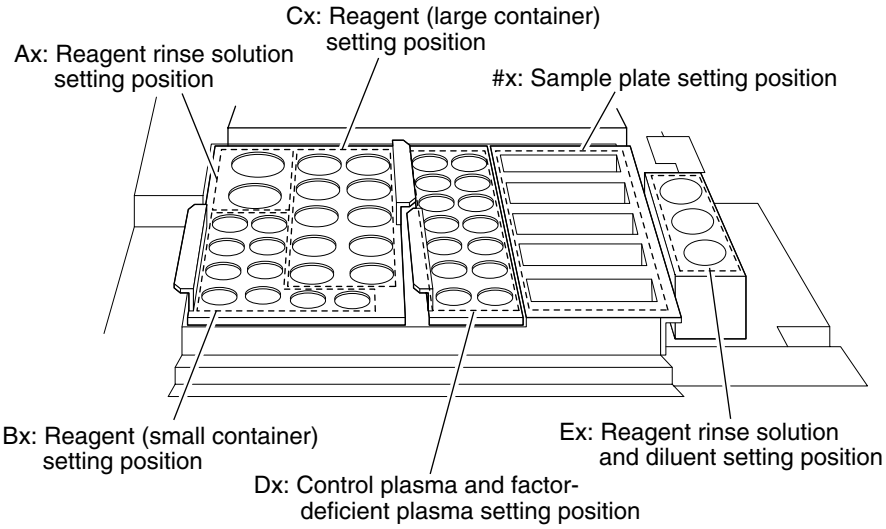

Figure 4-4-2: Setting Position

Contents Displayed on Consumable Screen

(A) Group: Name of selected parameter group is displayed.

(B) Reagent key: Reagent holder position (Ax - Ex), remaining reagent volume, and reagent name are displayed.
Color of the key will change depending on the available reagent volume.
- Colorless: Reagent is not set.
- Green: Reagent volume is sufficient.
- Yellow: Reagent volume is low (analysis is possible).
- Red: Reagent volume is insufficient (analysis is not possible).
- Pink: Reagent position is incorrect and must be replaced.

(C) Sample plate: Sample plate setting positions (#x) and number of unused wells are displayed.
Color will change depending on the usage condition.
- Colorless: Sample plate is not set.
- Green: Not used at all.
- Yellow: Being used, but unused wells exist.
- Red: Entire plate has already been used.

(D) Other consumable
- React. Tube Supply: Color is used to indicate remaining quantity of reaction tubes.
  - Green: 10 tubes or more
  - Red: Less than 10 tubes
- Tube Trash Box: Color is used to indicate condition of tube trash box.
  - Green: Sufficient space is available
  - Yellow: Will be full soon
  - Red: Full
- Rinse: Color is used to indicate remaining volume of rinse solution in the rinse tank.
  - Green: Sufficient
  - Red: Insufficient
- Waste: Color is used to indicate the volume of waste fluid in the optional waste tank.
  - Green: Sufficient room is available
  - Red: Full

NOTE: • [Rinse] key and [Waste] key are displayed only if the alarm is set in the Settings program. See *Chapter 11, Section 5.11: Alarm Settings* for the procedures.

5. EMERGENCY STOP

If a problem occurs during an analysis, you can press the Mechanical Stop switch to stop the probe movement.

CAUTION:	• If an emergency stop is executed, all samples being analyzed will end with an error.

(1) Press the Mechanical Stop switch located below the LCD screen.

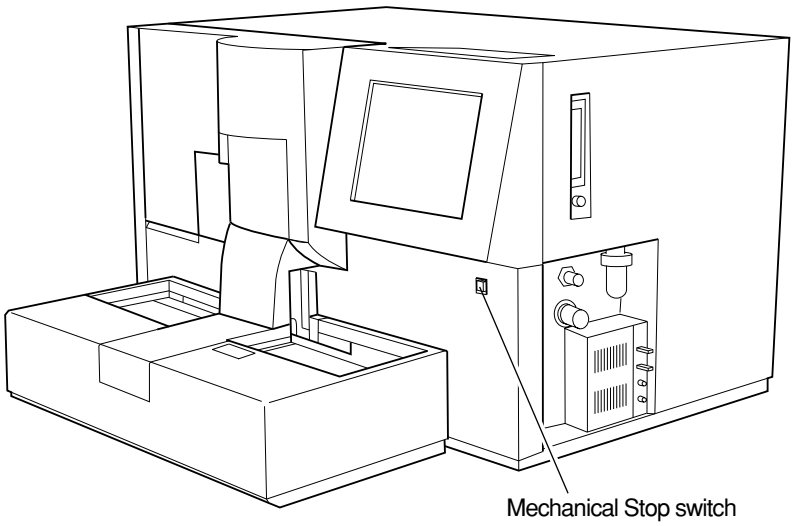

Figure 4-5-1: Mechanical Stop Switch

All analysis operations will stop.
If samples are currently being analyzed, a message window will appear, asking you if you wish to cancel the analysis. If you press the [Cancel] key, the analysis will immediately end.
If samples are not currently being analyzed, or if an analysis is completed or interrupted, a message window will appear, asking you if you wish to resume the operation. If you press the [OK] key, the operation will resume. If you press the [Cancel] key, the instrument will return to "Ready" status, without resuming.

6. SHUTDOWN

Clean the probes, and then turn the power OFF.

CAUTION:
- At the end of each day's operations or after operating the instrument, at least once every 24 hours, perform daily maintenance. For details, see *Chapter 6: MAINTENANCE & SUPPLIES REPLACEMENT*.

(1) Clean the probes. For details, see *Chapter 6, Section 3.1: Cleaning the Probes.*

(2) Verify that the status display area at the top of the screen shows "Ready".

(3) Turn the power switch to OFF.

CHAPTER 5 DISPLAY & PROCESSING OF ANALYSIS RESULTS

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1. INTRODUCTION

The CA-1500 displays and outputs analysis results and information that is helpful for the interpretation of the analysis results. This chapter will explain the processing of analysis results, such as the screen display and output of stored data.

List Display
The Stored Data List screen is used to display and output stored data. It displays a list of stored data analysis results and sample information. This section explains the contents of the list display and how to call of the Stored Data List screen.

Graphic Display
Explains the contents and how to display the coagulation curves for all stored data.

Searching
Explains how to search for samples that match specified conditions.

Sorting
Explains how to change the sequence of the list display.

Selecting the Display
Explains how to select and display only those samples that meet specified conditions.

Output
Explains how to print out (option) specified stored data, output the data to the host computer (option), and save on a floppy disk.

Data Validation
Explains how to confirm that all stored data is reportable data and how to indicate that the data has been validated. Applicable to models with data validation function.

Editing the Sample ID Number
Explains how to edit the sample ID number for the stored data.

Deleting
Explains how to delete stored data which is no longer needed.

Recalculating
Explains how to recalculate stored data calculation parameters.

2. STORED DATA LIST DISPLAY

If you press the [Stored Data] key on the Main Menu screen, the Stored Data List screen will appear. The stored data for up to 20 samples will be displayed per screen. To display old stored data, press the [Prev] or [↑] key to scroll the screen up. You can also scroll left and right to switch the parameters to be displayed.

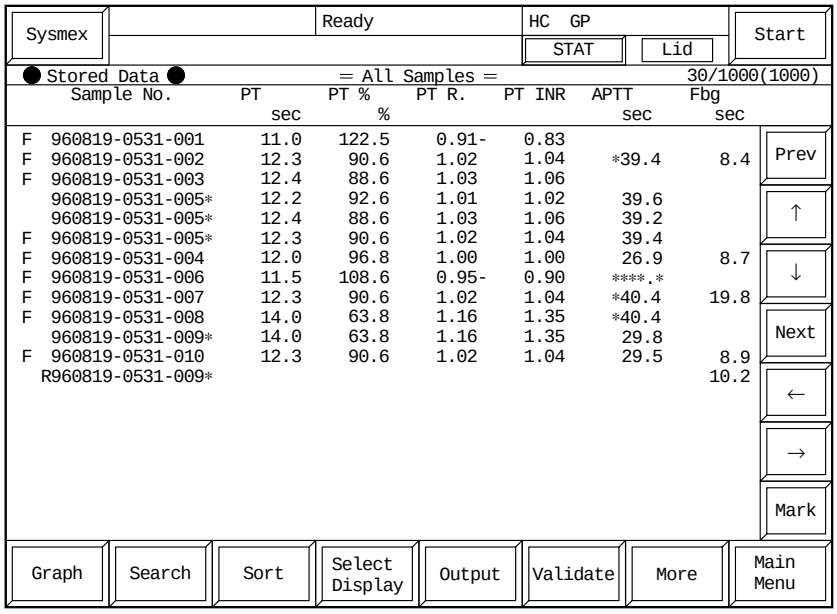


Figure 5-2-1: Stored Data List Screen

Contents Displayed on Stored Data List Screen

Analysis Results

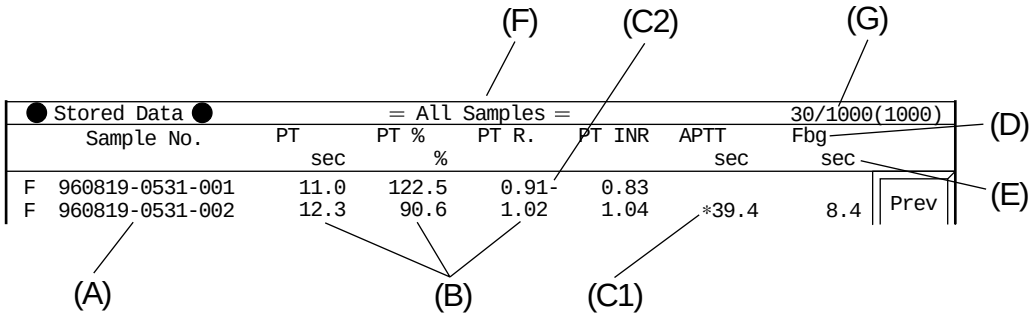


Figure 5-2-2: Stored Data List Screen (Analysis Results)

Sample Information

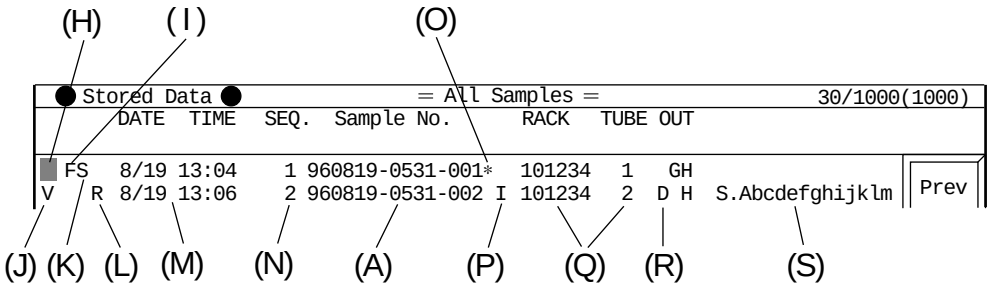


Figure 5-2-3: Stored Data List Screen (Sample Information)

(A) Sample No.:
Sample ID number will be displayed.
Green back-light color indicates those samples that have not been calculated.
Yellow back-light color indicates those samples that have not completed the analysis due to a momentary power failure or turning off the power.

(B) Calculation parameters, coagulation time, and dOD:
Calculation results, coagulation time, or dOD will be displayed for each parameter. If the calculation of a parameter was not performed correctly, the following will appear:

***.*	Could not obtain analysis data due to an error.
---.-	Could not calculate parameter.
+++.+	Value exceeded the displayable range.
///./	Could not calculate the mean.

(C1) Abnormal flag (left):
If an abnormal value is obtained, the following symbols will appear to the left of the data:

*	Data disparity exists between replication analysis results, or error occurred.
!	Data obtained from dilution analysis.
<	Data exceeded the lower Report Limit.
>	Data exceeded the upper Report Limit.

(C2) Abnormal flag (right):
If an abnormal value is obtained, the following symbols will appear to the right of the data:

-	Data exceeded the lower Mark Limit.
+	Data exceeded the upper Mark Limit.
X	Calculation parameter has not been calculated for reasons such as no standard curve being set.

(D) Parameter:
Up to 6 parameter names will be displayed per screen.

(E) Unit:
Unit for each parameter is displayed.

(F) Display mode:
Currently selected display mode is displayed. See *Section 6: SELECTING THE STORED DATA DISPLAY* in this chapter.

(G) No. of stored data in memory: Displays (in order) number of marked samples, number of samples that are selected for the current display mode, and total number of data stored in memory.

(H) Mark: Will be displayed when mark is attached using [Mark] key.

(I) Mean/Final report data flag: "m" Mean data when replication analyses are executed.
"F" Data for final report
If the "m" and "F" flags are both applied, the "F" flag has the higher priority. For details on replication settings, see *Chapter 11, Section 5.3: Replication Settings*.

(J) Validation flag: "V" is displayed if the data has been validated. Applicable only to models with data validation function.

(K) STAT sample flag: "S" is displayed, if data is for a STAT analysis sample.

(L) Re-analysis flag: "R" is displayed, if data is from a re-analysis test.

(M) Date/Time: Displays the date and time when analysis was started.

(N) SEQ.: Sequential number is displayed. Numbering starts after the power is turned ON.

(O) Same sample ID number flag: "*" is displayed, if the same sample ID number exist within the same date.

(P) Barcode flag: "I" is displayed, if the sample ID number is read by the bar-code reader (option).
"I" in red back-light is displayed, if ID read error occurred.

(Q) Rack No./tube position No.: Displays rack number and tube position number.

(R) Data output status flag: For data that has been sent to the data printer, graphic printer or host computer, "D" (data printer), "G" (graphic printer), or "H" (host computer) disappears respectively.

(S) Name: Patient's name if downloaded from the host computer (option) is displayed.

Operating the Stored Data List Screen Keys
If you press the [More] key, the menu at the bottom of the screen will toggle.

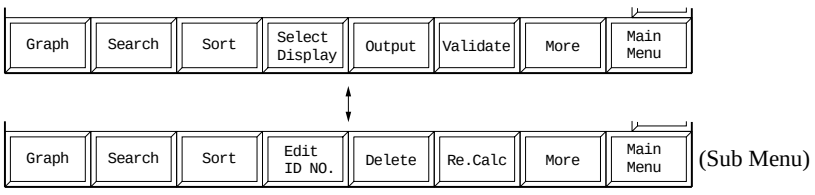


Figure 5-2-4: Switching the Menu

[Prev] key: List scrolls up one screen (20 samples).

[↑] key: Cursor moves vertically upward by one sample. When the cursor is at the top position on the screen, the list scrolls up one line.

[↓] key: Cursor moves vertically downward by one sample. When the cursor is at the bottom position on the screen, the list scrolls down one line.

[Next] key: List scrolls down one screen (20 samples).

[←], [→] keys: Scrolls horizontally; parameters to be displayed change in order.

[Mark] key: Attaches or deletes mark. See *Section 12: MARKING STORED DATA* in this chapter.

NOTE:
- When outputting or deleting stored samples, affix marks to identify the targeted stored data. When a mark is attached, a yellow ■ symbol will be displayed at the left side of the listed data.

[Graph] key: Displays coagulation curve for the specified data. See *Section 3: STORED DATA GRAPHIC DISPLAY* in this chapter.

[Search] key: Search the specified stored data. See *Section 4: SEARCHING STORED DATA* in this chapter.

[Sort] key: Change the sequence of the list display. See *Section 5: SORTING STORED DATA* in this chapter.

[Select Display] key: Specifies conditions and displays only specified stored data. See *Section 6: SELECTING THE STORED DATA DISPLAY* in this chapter.

[Output] key: Sends data to the printer or to the host computer. See *Section 7: OUTPUTTING STORED DATA* in this chapter.

[Validate] key: Validate the data. (Applicable to models with data validation function) See *Section 8: VALIDATING STORED DATA* in this chapter.

[Main Menu] key: Displays the Main Menu screen.

[Edit ID No.]: Edit the sample ID number. See *Section 9: EDITING THE SAMPLE ID NUMBER OF STORED DATA* in this chapter.

[Delete] key: Deletes stored data which is no longer needed. See *Section 10: DELETING STORED DATA* in this chapter.

[Re.Calc] key: Recalculate the calculation parameters. See *Section 11: RECALCULATING STORED DATA* in this chapter.

3. STORED DATA GRAPHIC DISPLAY

From the Stored Data List screen, move the cursor to the stored data whose coagulation curve you wish to display; then press the [Graph] key. The Stored Data Graphic Display screen will appear. The coagulation curves of up to six parameters can be displayed on one screen. For MDA (Multi-Dilution Analysis), data of one parameter will be displayed on one screen.

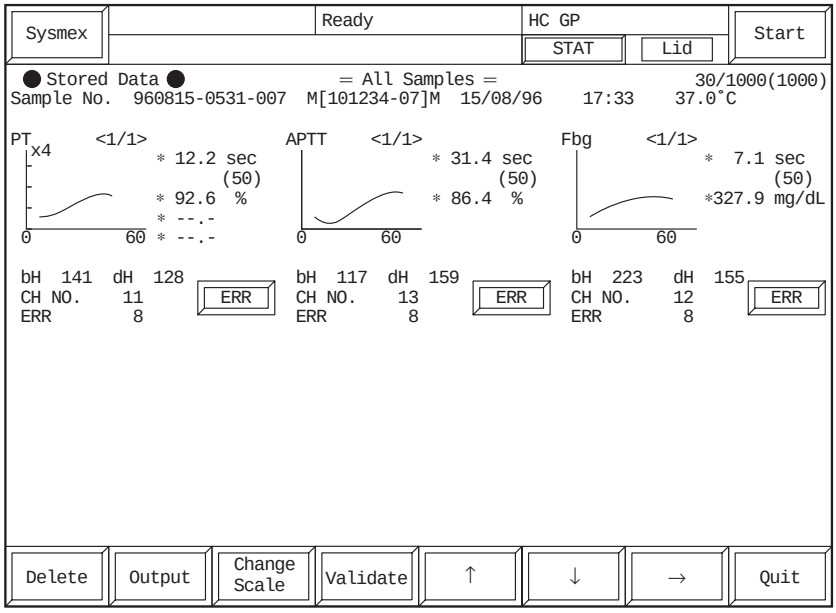


Figure 5-3-1: Stored Data Graphic Display Screen

Contents Displayed on Stored Data Graphic Display Screen (Excluding MDA)

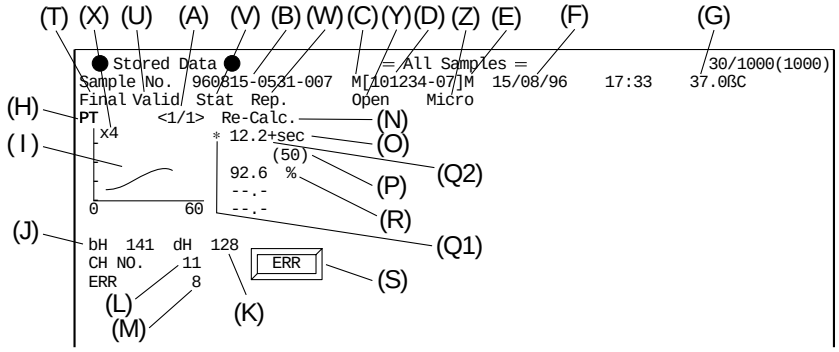


Figure 5-3-2: Stored Data Graphic Display Screen

(A) Dilution ratio: Dilution ratio is displayed.

(B) Sample No.: Sample ID number is displayed.
Green back-light indicates that calculation parameter has not been calculated due to, for example, no available standard curve.

(C) Sample ID number attributes: Method of setting sample ID number is expressed by the following symbols:
"M": Manual registration
"A": Automatic assignment
"B": Barcode reading
"C": Inquiry to host computer
(space): Not set

(D) Rack No./tube position No.: Rack number and tube position number are displayed.

(E) Order attributes: Method of order registration is expressed by the following symbols:
"M": Manual registration
"A": Default order setting when barcode reading failed
"C": Inquiry to host computer
(space): Not set

(F) Date/time analyzed: Displays date and time when analysis was started.

(G) Temperature: Temperature of detector block when analysis started is displayed. "- -.-" is displayed, when duplicate analysis is performed.

(H) Parameter: Name of parameter is displayed.

(I) Coagulation curve: Horizontal axis of this graph represents time or dOD, and vertical axis represents the scattered light intensity. The time scale is shown at the right end of the horizontal axis. For mean data, the curve will not be displayed.

(J) bH (baseline): Displays the scattered light intensity of the sample at the start time.

(K) dH (difference): Displays the difference in the scattered light intensity during the reaction process.

(L) CH No.: Displays the detection channel No. used for analysis.

(M) ERR: Error code is displayed if an error occurred during analysis.

(N) Re-Calc.: "Re-Calc." is displayed if the data was recalculated.

(O) Coagulation time/dOD: Displays the coagulation time or dOD.

(P) Coagulation detection point: Displays the preset coagulation detection point only for Coagulation Methods.

(Q1) Abnormal flag (left): If an abnormal value is obtained, the following symbols will appear to the left of the data:

*	Data disparity exists between replication analysis results, or error occurred.
!	Data obtained from dilution analysis.
<	Data exceeded the lower Report Limit.
>	Data exceeded the upper Report Limit.

(Q2) Abnormal flag (right): If an abnormal value is obtained, the following symbols will appear to the right of the data:

-	Data exceeded the lower Mark Limit.
+	Data exceeded the upper Mark Limit.
X	Calculation parameter has not been calculated for reasons such as no standard curve being set.

(R) Calculation parameters: Calculation results are displayed. If the calculation of a parameter was not performed correctly, the following will appear:

***.*	Could not obtain analysis data due to an error.
---.-	Could not calculate parameter.
+++.+	Value exceeded the displayable range.
///./	Could not calculate the mean.

(S) [ERR] key: Will appear when there is an error. If you press this key, the error details window will appear. If you press the [OK] key, the error details window will close.

(T) Final report data flag:

m	Mean data when replication analyses are executed.
F	Data for final report

If the "m" and "F" flags are both applied, the "F" flag has the higher priority. For details on replication settings, see *Chapter 11, Section 5.3: Replication Settings*.

(U) Validation flag: "Valid" will be displayed, if the data has been validated. (Applicable to models with data validation function)

(V) STAT sample flag: "Stat" is displayed for a STAT sample.

(W) Re-analysis data flag: "Rep." is displayed for a re-analysis sample.

(X) Scale Magnification: Scale magnification is displayed when the sample has small dH value and the graph is displayed. There are three magnifications; x4, x8 and x16, the instrument will automatically select the most suitable scale.

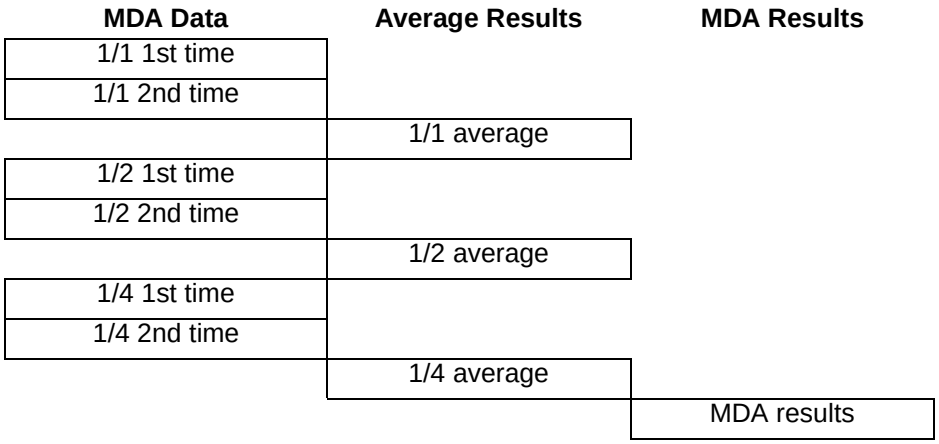
(Y) Closed analysis flag: (only when Cap Piercer Unit is installed) "Closed" is displayed if analysis is executed with the cap. "Open" is displayed if analysis is executed without the cap.

(Z) Micro-sample flag: "Micro" is displayed if the analysis is executed in micro-sample mode.

Contents Displayed on Stored Data Graphic Display Screen (MDA Parameters)

During an MDA (Multi-Dilution Analysis), the same sample is analyzed using multiple dilution ratios. Analyzing the results of measurements by using various dilution ratios makes it possible to check the effects of inhibitor and activator in the sample.

Example: MDA results (case in which MDA dilution series is two-cycle MDA)



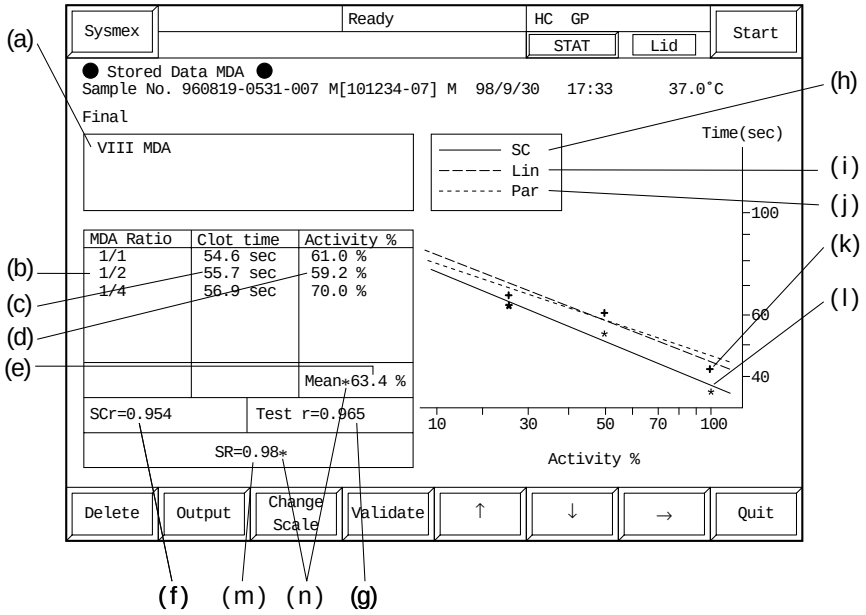


Figure 5-3-3: MDA Stored Data Graphic Display Screen

(a) Parameter name:
The parameter for which the MDA analysis was executed is displayed.

(b) Dilution ratio:
The ratio of dilution (compared to a standard analysis) is displayed.

(c) Coagulation time (dOD):
The coagulation time or dOD (average of two measurements, if applicable) is displayed for each dilution ratio.

(d) Activity % (concentration):
The activity % or concentration is calculated from the standard curve based on the coagulation time or dOD (average of two measurements, if applicable) for each dilution ratio, and the values that are converted from the dilution ratios are displayed.

(e) Average:
The average activity % or concentration (average values for each dilution ratio when two measurements are taken) is displayed as MDA analysis results.

(f) SCr:
The correlation coefficient for the standard curve is displayed.

(g) Test r:
The correlation coefficient for the MDA data is displayed.

(h) SC:
The standard curve is displayed. The horizontal axis will represent the activity % or concentration, and the vertical axis will represent the coagulation time or dOD.

(i) Lin:
A line is displayed that approximates the MDA data based on the method of least squares. The horizontal axis will represent the dilution ratio % (with 1/1 equivalent to 100%), and the vertical axis will represent the coagulation time or dOD.

(j) Par:
A standard curve that passes through the analysis results for the smallest dilution ratio is displayed along with lines parallel to it.

(k) MDA data:
This is MDA data obtained from each dilution ratio.

(l) Standard curve data:
This is data pertaining to the standard curve, including each of its points.

(m) SR:
The Slope Ratio (of the MDA analysis data to the standard curve data) is displayed. This value becomes an index to examine the influence of inhibitor and accelerator.

(n) Abnormal value flag:
When exceeding the limit value of MDA SR, this is displayed in both SR and Average. For the setting of mark limit, *see Chapter 11, Section 4.2: Mark Limit Settings*.

CAUTION:	• The Stored Data Graphic Display screen for an MDA parameter will appear only when the stored data list is displayed and the cursor is in the area of the MDA results.

NOTE:	• The horizontal and vertical axes of the graph can be changed from the calculation parameters setup menu. For details on how to set up the calculation parameters, see *Chapter 11, Section 5.8: Calculation Parameter Settings.*

Operating the Stored Data Graphic Display Screen Keys

[Delete] key:	Deletes unneeded stored data. See *Section 10: DELETING STORED DATA* in this chapter.
[Output] key:	Sends data to the printer or host computer. See *Section 7: OUTPUTTING STORED DATA* in this chapter.
[Validate] key:	Validate the data. (Applicable to models with data validation function) See *Section 8: VALIDATING STORED DATA* in this chapter.
[↑] key:	Displays the upward (one older) sample in the stored data list.
[↓] key:	Displays the downward (one newer) sample in the stored data list.
[→] key:	Switches to the other analysis parameter in order.
[Quit] key:	Returns the system to the Stored Data List screen.
[Change Scale] key:	For a sample which has a small dH value, the scale of the graph is changed and displayed.

4. SEARCHING STORED DATA

Using the Stored Data List screen, you can select the top of the list, the bottom of the list, or specify the sample ID number. You can also display stored data at the top and the bottom of the list whose date is the same as that of the stored data currently at the cursor.

If you press the [Search] key on the Stored Data List screen, the Search menu window will appear.

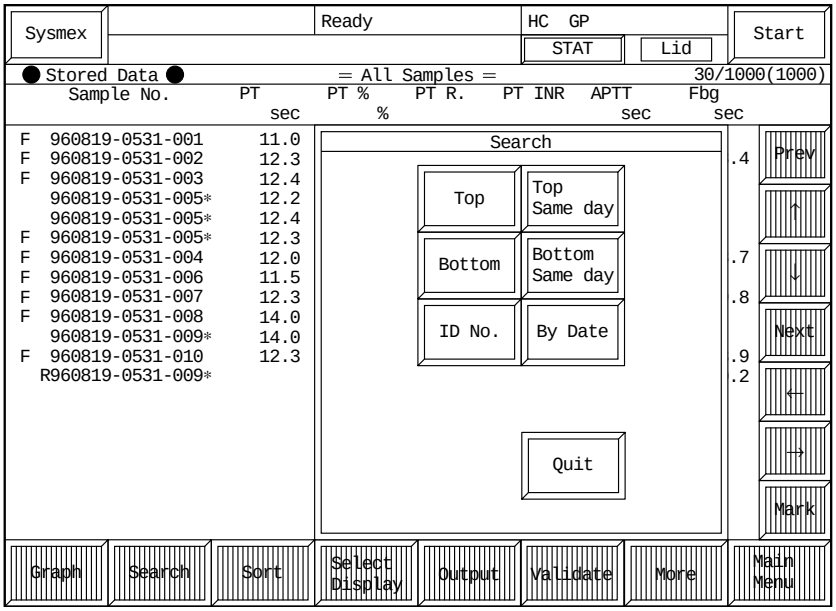


Figure 5-4-1: Search Menu Window

Operating the Search Menu Window Keys

[Top] key: Moves the oldest stored data to the top of the screen, and displays a list of 20 samples.

[Top Same day] key: Moves the oldest stored data, whose date is the same as that of the current cursor position, to the top of the screen and displays a list of 20 samples.

[Bottom] key: Moves the latest stored data to the center of the screen, and displays a list of 10 samples.

[Bottom Same day] key: Moves the latest stored data, whose date is the same as that of the current cursor position, to the bottom of the screen and displays a list of 20 samples.

[ID No.] key: Initiates searches for the sample whose sample ID number is specified.

(1) If you press the [ID No.] key, the numeric keys that are used to specify the sample ID number will appear.

(2) Enter the sample ID number; then press the [ENTER] key.
If the stored data for the entered sample ID number exists, the stored data list will be moved to the top of the screen and a list of 20 samples will be displayed.
If there are multiple stored data for the appointed sample ID number within the same date, the latest data will be displayed.
If an appointed sample ID number does not exist, a message will appear. If you press the [OK] key, the system will return to the Stored Data List screen.

[By Date] key: Displays the sample(s) for a specified date.

(1) Press the [By Date] key. The Sample By Date screen will appear.

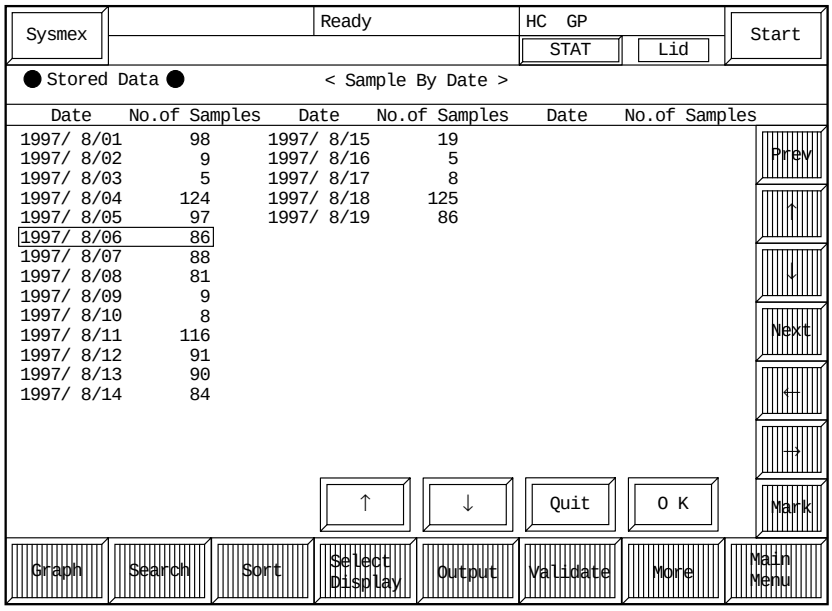


Figure 5-4-2: Sample By Date Screen

(2) Pressing the [↑] and [↓] keys, move the cursor to the date that you wish to search; then press the [OK] key.
The stored data at the top of the list for the specified date will move to the top of the screen, and a list of 20 samples will be displayed.

[Quit] key: Closes the Search menu window without searching.

5. SORTING STORED DATA

Using the Stored Data List screen, you can rearrange and display stored data by order information, sample ID number, or chronological sequence of analysis.

Using the Stored Data List screen, press the [Sort] key. The Sort menu window will appear.

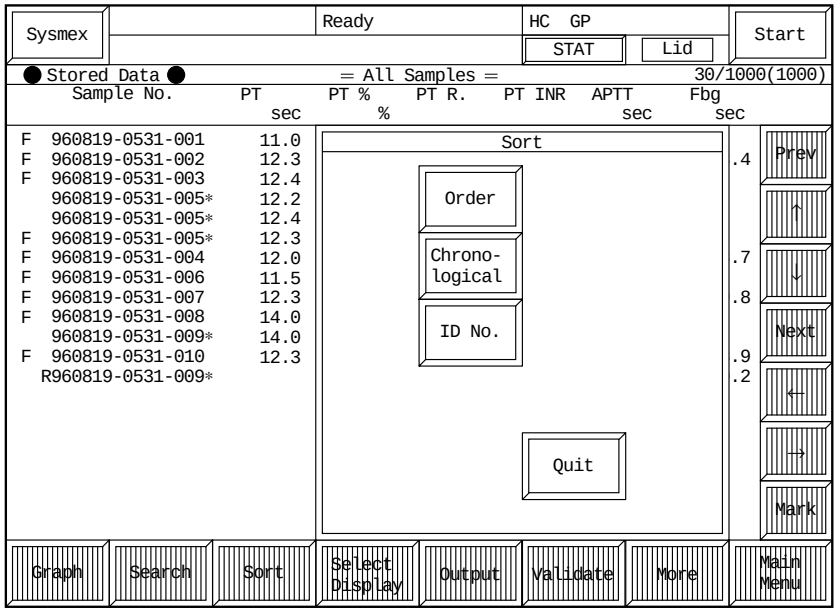


Figure 5-5-1: Sort Menu Window

Operating the Sort Menu Window Keys

[Order] key: Used to arrange the stored data according to order information and display stored data with replicate analysis and re-analysis results.

[Chronological] key: Used to rearrange the stored data according to chronological sequence of analysis. Moves stored data that is at the cursor position to the top of the screen, and displays a list of 20 samples.

[ID No.] key: Used to rearrange the stored data according to the sample ID number within the same date. Moves stored data that is at the cursor position to the top of the screen, and displays a list of 20 samples.

[Quit] key: Closes the Sort menu window without sorting.

6. SELECTING THE STORED DATA DISPLAY

Using the Stored Data List screen, you can select and limit the data to be displayed according to selected conditions.

Using the Stored Data List screen, press the [Select Display] key. The Select Display menu window will appear.

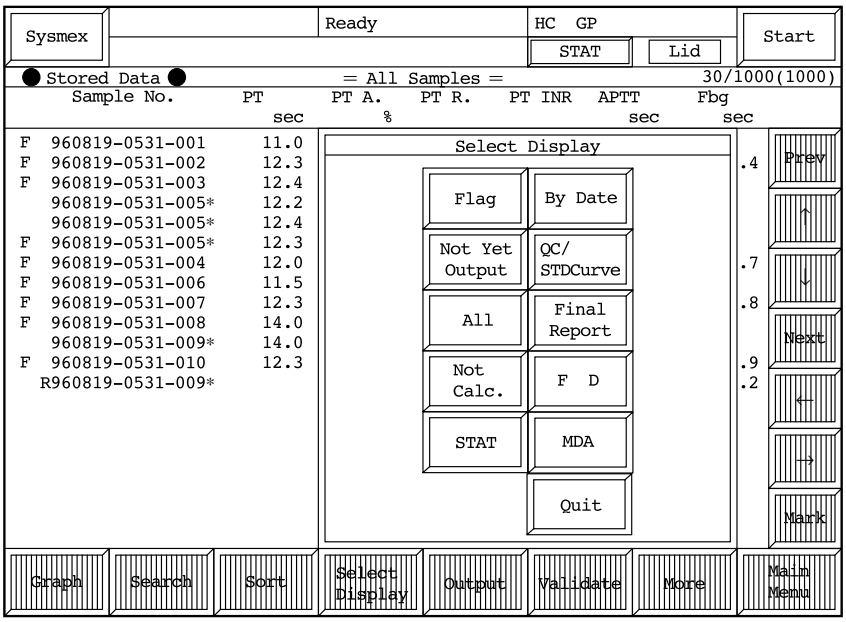


Figure 5-6-1: Select Display Menu Window

Operating the Select Display Menu Window Keys

[Flag] key:

Displays only specified stored data that is flagged.

(1) Press the [Flag] key. The Select Flag window will appear.

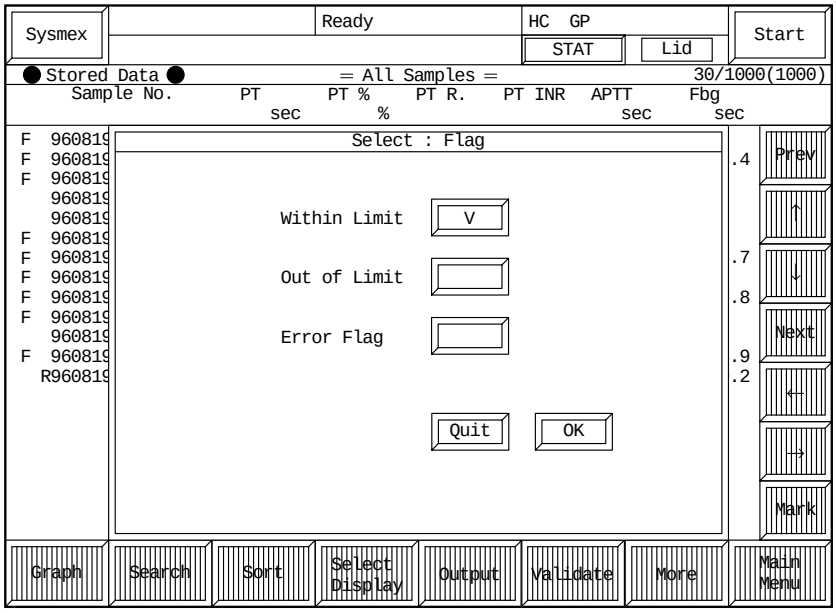


Figure 5-6-2: Select Flag Window

(2) Press the desired key that represents the flag conditions for the stored data you wish to display. The "V" mark will be displayed.
To delete the "V", press the flag key again.

(3) Press the [OK] key.
Only the stored data to which the specified flag is attached will be displayed.

[By Date] key: Displays only the stored data of the specified date.

(1) Press the [By Date] key. The Select Date screen will appear.

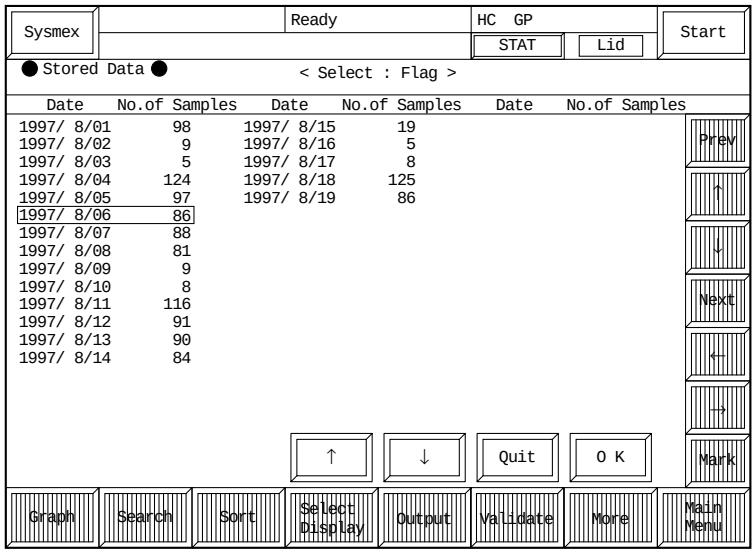


Figure 5-6-3: Select Date Screen

(2) Press the [↑] and [↓] keys, and move the cursor to the date of the stored data you wish to display; then press the [OK] key.
Only the stored data of the specified date will be displayed.

[Not Yet Output] key: Displays only stored data having the specified output status.

(1) Press the [Not Yet Output] key. The Select Not Output window will appear.

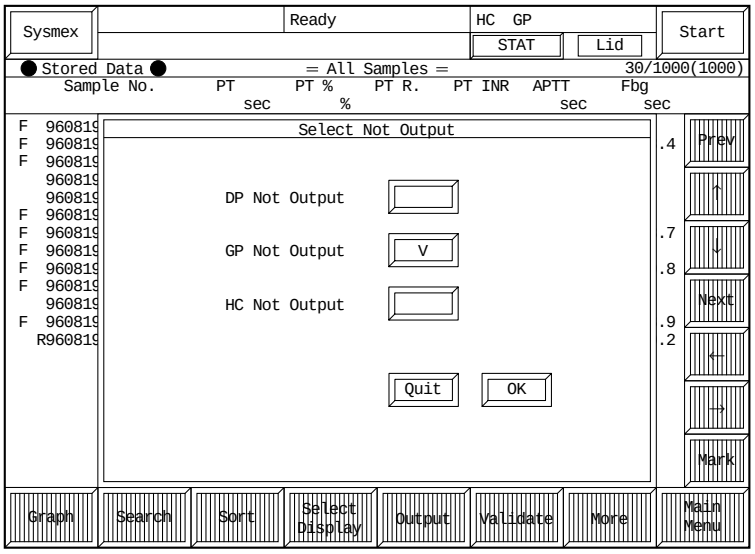


Figure 5-6-4: Select Not Output Window

(2) Press the key that represents the output status for the stored data you wish to display. "V" mark will be displayed. Only one type of output status can be specified. If a "V" mark is newly displayed for one of the output status, a "V" mark that is currently displayed for another status will be deleted.

(3) Press the [OK] key.
Only the stored data that meets the specified output status will be displayed.

[QC/STD Curve] key: Displays only quality control data and standard curve analysis data.

[All] key: Displays all stored data.

[Final Report] key: Displays final report data.

[Not Calc.] key: Displays only stored data for parameters that could not be calculated because their standard curves were not set or not confirmed.

[FD] key: Displays stored data that is stored on a floppy disk.

(1) Press the [FD] key. The Floppy Disk Insert Confirmation window will appear.

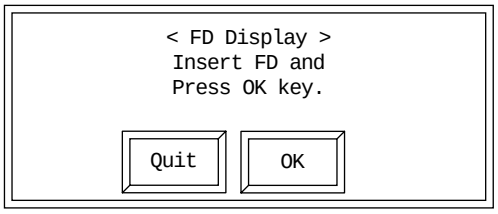


Figure 5-6-5: Floppy Disk Insert Confirmation Window

(2) Insert the floppy disk into the floppy disk drive. To exit the FD Display program, press the [Quit] key.

(3) Press the [OK] key.
The data that is stored on the floppy disk will be read and then displayed.

[STAT] key: Displays only STAT sample data.

[MDA] key: Displays only analysis results of MDA (Multi-Dilution Analysis).

[Quit] key: Closes the Select Display menu window without executing a display selection.

7. OUTPUTTING STORED DATA

Analysis results that are in memory as stored data can be printed out to an optional data printer or graphic printer, output to an optional host computer, and/or saved on a floppy disk. Current data, marked data, or all data can be selected as the data to be output.

7.1 Outputting

(1) From the Stored Data List screen, press the [Output] key.
Before pressing the [Output] key, use the cursor to select the stored data to be output.
The Select Sample menu window will appear.

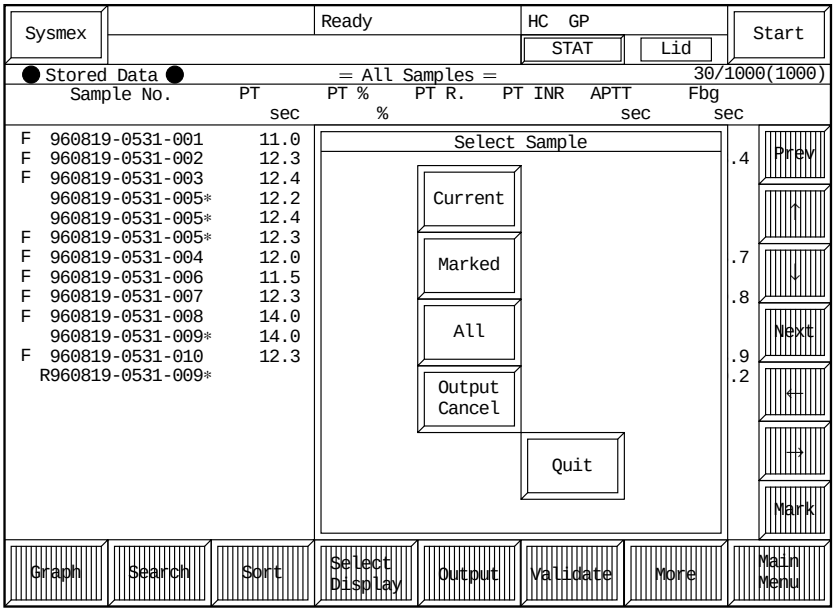


Figure 5-7-1: Select Sample Menu Window

(2) Press the key for the stored data you wish to output.

[Current] key:	Outputs only the stored data at the cursor position.
[Marked] key:	Outputs only the stored data that is marked.
[All] key:	Outputs all stored data.
[Output Cancel] key:	Cancels output, but is effective only when output has already started.
[Quit] key:	Cancels the output program and closes the Select Sample menu window.

When samples are being selected, the Select Device menu window will appear.

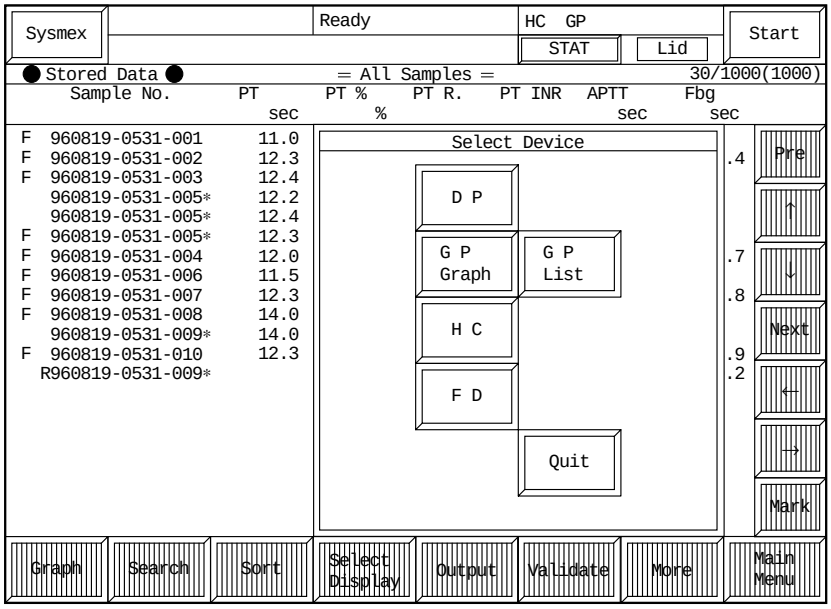


Figure 5-7-2: Select Device Menu Window

(3) Press the key for the desired output device.

[DP] key: Sends the specified stored data to the data printer (option).

[GP Graph] key: Sends the coagulation curve of the specified stored data to the graphic printer (option).

[GP List] key: Sends a list of the specified stored data to the graphic printer (option).

[HC] key: Outputs the specified stored data to the host computer (option).

[FD] key: Saves the specified stored data on a floppy disk. For details, see the following sub-section "Saving Data on a Floppy Disk".

[Quit] key: Cancels the output program and closes the Select Device menu window.

When the output device is selected, outputting starts.

Saving Data on a Floppy Disk

(1) Press the [FD] key. The Floppy Disk Insert Confirmation window will appear.

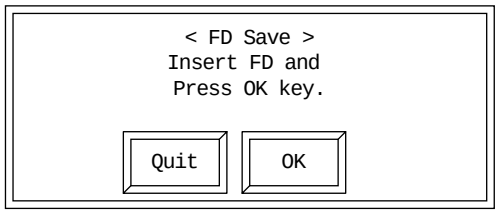


Figure 5-7-3: Floppy Disk Insert Confirmation Window

(2) Insert a pre-formatted floppy disk into the floppy disk drive. If you decide not to save the data, press the [Quit] key.

(3) Press the [OK] key.
After the data is saved on the floppy disk, the system will return to the Stored Data List screen.
If the capacity of the inserted floppy disk is insufficient, a message will appear. If that happens, insert a pre-formatted empty floppy disk and press the [OK] key.

7.2 Examples of Printout (Option)

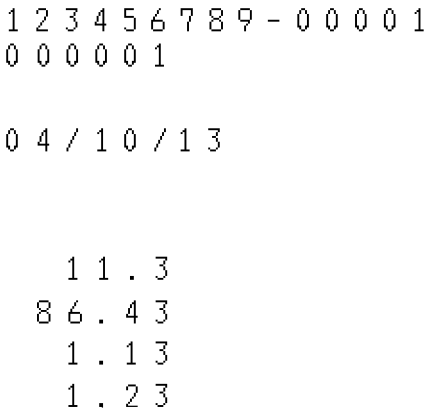


Figure 5-7-4: Printout Example (DP)

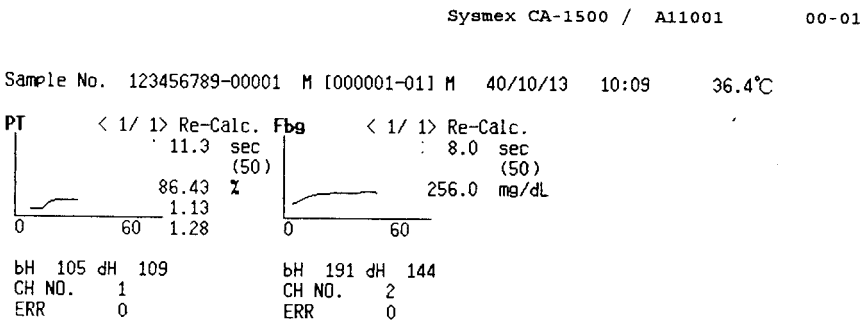


Figure 5-7-5: Printout Example (GP - Graph)

```
                                                Sysmex CA-1500 /  A11001       00-01

ID      123456789-00001  PT        11.3 sec  86.43 %      1.13        1.28
                         Fbg        8.0 sec  256.0 mg/dL
 10/13 10:09 000001-01

--------------------------------- ------------------------------------------------------------

ID      123456789-00002  PT        11.2 sec  87.04 %      1.12        1.25
                         Fbg        8.1 sec  235.7 mg/dL
 10/13 10:09 000001-01
```

Figure 5-7-6: Printout Example (GP - List)

8. VALIDATING STORED DATA

If the instrument is equipped with a validation function, confirm that all stored data is reportable data, validate the data, and attach a validation mark to the data that has been validated.

NOTE:
- A validation mark can also be attached automatically, depending on the analysis results. For details, see *Chapter 11, Section 3: AUTO MODE SETTINGS*.

(1) From the Stored Data List screen, press the [Validate] key.
The Validation Marking Menu will appear.

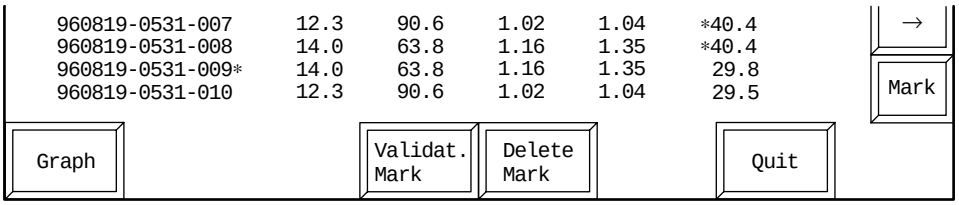


Figure 5-8-1: Validation Marking Menu

(2) Move the cursor to the stored data that you wish to validate.

NOTE:
- To validate, first press the [Graph] key to display the coagulation curve. The Stored Data Graphic Display screen will appear. To return to the List screen, press the [List] key.

(3) Attach or delete the mark by pressing the validation mark keys.

[Validat. Mark] key: Attaches a validation mark to the stored data that is at the cursor position (or stored data that is displayed on the Stored Data Graphic Display screen).
For the stored data which has been validated, "V" (red) is displayed at the left edge of the list. "Valid" is displayed on the Stored Data Graphic Display screen.

[Delete Mark] key: Deletes the validation mark from the stored data that is at the cursor position (or stored data that is displayed on the Stored Data Graphic Display screen).

CAUTION:
- Even if you quit the Validation Marking menu, you cannot cancel those data that was once validated.

(4) When validation is completed, press the [Quit] key.
A confirmation window will appear.

[OK] key:	Validates the data and quits the Validation Marking menu. If automatic output has been set, validated data will be automatically output.
[Quit] key:	Cancels further validation and quits the Validation Marking menu.

9. EDITING THE SAMPLE ID NUMBER OF STORED DATA

You can edit the sample ID number of the stored data, if the data has not been validated yet.

NOTE:
- If the data has been validated, however, the sample ID number cannot be edited.

(1) If the [Edit ID No.] key is not currently displayed, press the [More] key to display the sub menu.

(2) Move the cursor to the stored data whose sample ID number you wish to edit.

(3) Press the [Edit ID No.] key. The numeric keys will be displayed. The sample ID number indicated by the cursor will appear in the numeric keys' number display area.

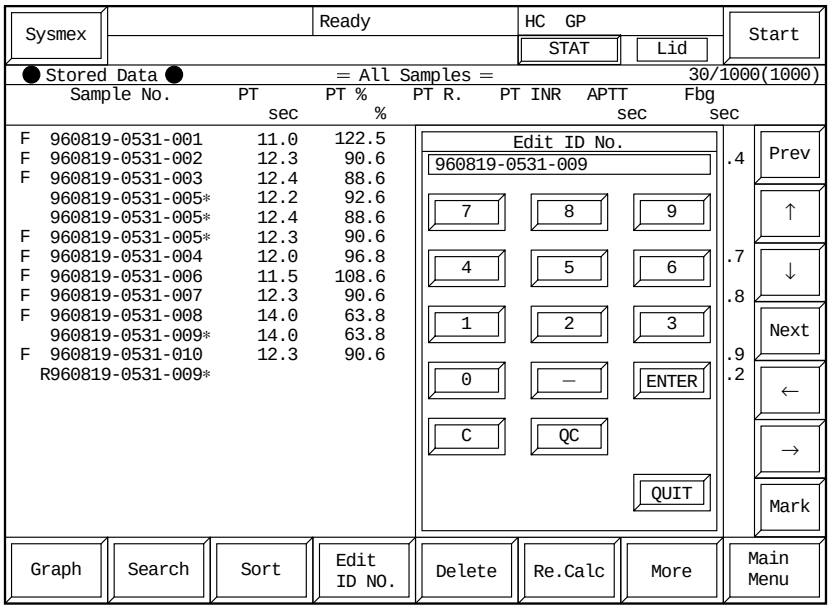


Figure 5-9-1: Edit ID No. Window

(4) Enter the new sample ID number, and press the [ENTER] key.
The sample ID number indicated by the cursor will change to the entered sample ID number. The cursor will move to the next sample, and the numeric keys' number display area will display the sample ID number for the next stored data. To stop editing, press the [QUIT] key.

NOTE:
- If you edit a sample ID number, the order of the list will change. If the list is arranged according to sample ID number, there is no need to sort again after the sample number has been edited.

10. DELETING STORED DATA

Unneeded stored data can be deleted. Current data, marked data, or all data can be selected as the data to be deleted.

CAUTION: • Data that has been deleted cannot be recovered. Carefully verify before deleting data.

(1) If the [Delete] key is not currently displayed, press the [More] key to display the sub menu.

(2) Use the cursor to select the stored data to be deleted.

(3) From the Stored Data List screen, press the [Delete] key. The Select Sample menu window will appear.

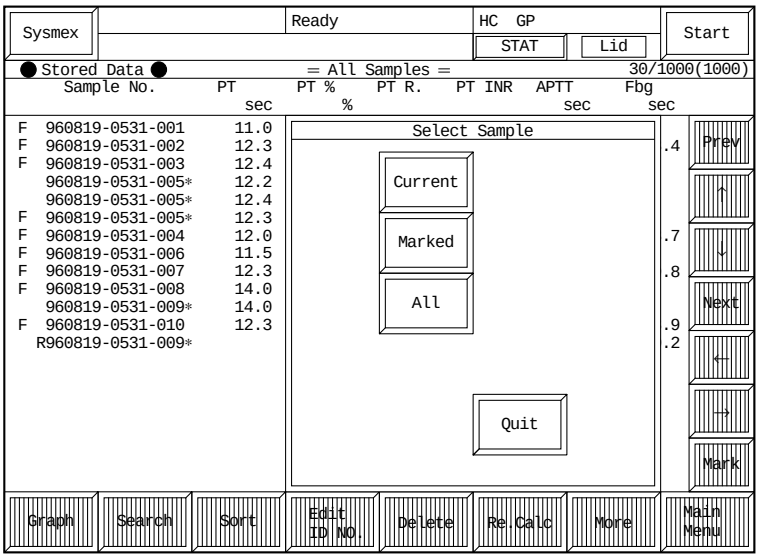


Figure 5-10-1: Select Sample Menu

(4) Press the key for the stored data you wish to delete.
[Current] key: Deletes only the stored data at the cursor position.
[Marked] key: Deletes only the stored data that has been marked.
[All] key: Deletes all stored data that has been selected to display.
[Quit] key: Cancels the delete program and closes the Select Sample menu window.

When samples are being selected for deletion, a confirmation message window will appear.

(5) Press the [OK] key.
The selected stored data will be deleted.
To stop deleting, press the [Quit] key.

11. RECALCULATING STORED DATA

Selected stored data can be recalculated for the calculation parameters. Current data, marked data, or data that has not been calculated can be selected as data to be recalculated.

CAUTION:
- Once recalculated, the original values cannot be recovered. Carefully verify before recalculating.
- If the data has been validated, however, the recalculation cannot be performed.
- The recalculation is not reflected in the MDA result.

(1) If the [Re.Calc] key is not currently displayed, press the [More] key to display the sub menu.

(2) Use the cursor to select the stored data to be recalculated.

(3) From the Stored Data List screen, press the [Re.Calc] key. The Select Sample Menu window will appear.

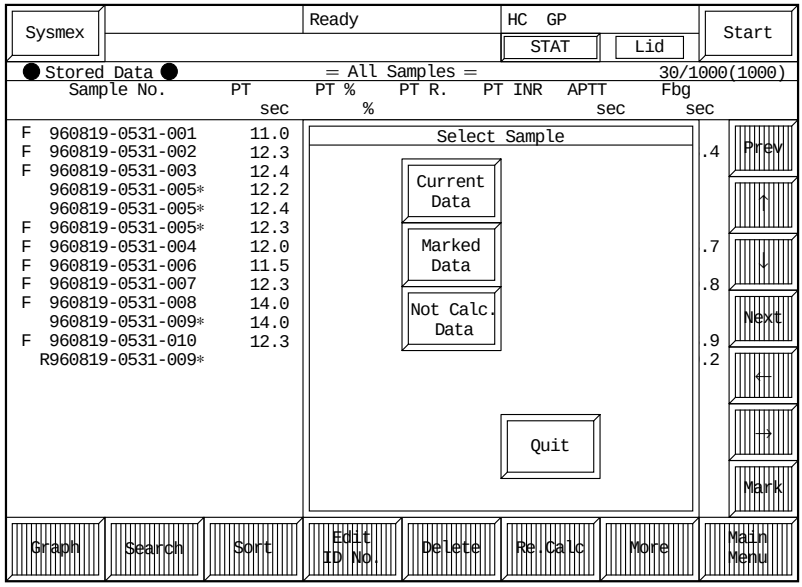


Figure 5-11-1: Select Sample Menu Window

(4) Press the key for the stored data you wish to recalculate.

[Current Data] key:	Recalculates only the stored data at the cursor position.
[Marked Data] key:	Recalculates the stored data that has been marked.
[Not Calc. Data] key:	Recalculates all the stored data that has not been recalculated.
[Quit] key:	Stops the selection procedure and closes the Select Sample Menu window.

(5) When samples are being selected for recalculation, the Select Test window will appear.

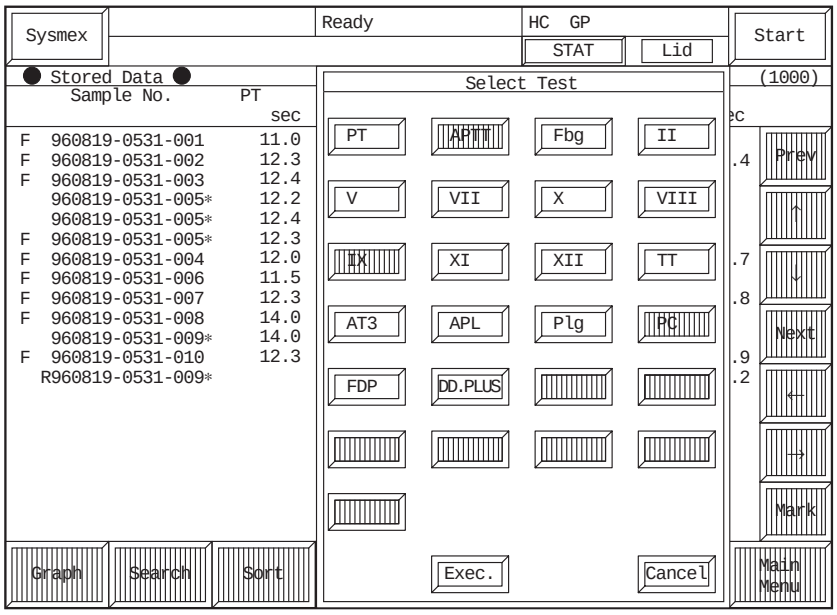


Figure 5-11-2: Select Test Window

(6) Press the key for the parameter that you wish to recalculate; then press the [Exec.] key. The selected parameter for the selected stored data will be recalculated. To stop recalculating, press the [Cancel] key.
If there is a parameter in the selected stored data whose calculation is completed, a confirmation message will appear. To recalculate, press the [OK] key. To stop, press the [Quit] key.

CAUTION:
- Once recalculated, the original values cannot be recovered. Carefully verify before recalculating.

CAUTION:
- The parameter key for recalculation will be masked when the standard curve is not set, or when the standard curve is not accepted, or when the Standard Curve Error occurs.
  Check the standard curve if it is masked.
  For details on the standard curve, see *Chapter 8: SETTING STANDARD CURVES.*

12. MARKING STORED DATA

To specify stored data that you wish to output or delete, mark the data.

(1) From the Stored Data List screen, press the [Mark] key.
The Marking Menu will appear.

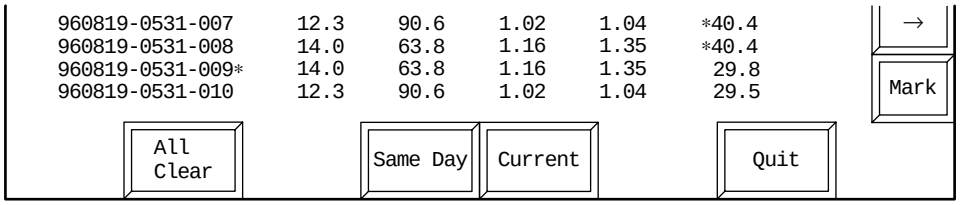


Figure 5-12-1: Marking Menu

(2) Move the cursor to the stored data that you wish to mark.

(3) Press the key to attach or to delete the mark.

[All Clear] key:	Deletes all marks that have already been attached.
[Same Day] key:	Marks the data that have the same date as the stored data at the cursor position.
[Current] key:	Marks the stored data that is at the cursor position. Deletes the mark that was attached.
[Quit] key:	Stops the marking procedure.

A yellow "■" symbol will be displayed at the left side of the list for stored data that is marked.

CHAPTER 6 MAINTENANCE & SUPPLIES REPLACEMENT

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1. INTRODUCTION

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 the probes
  Discard the used reaction tubes
  Discard waste (if provided)
  Remove condensation from the reagent trays
  Check and discard trap chamber fluid

- **Weekly Maintenance**
  Prime the hydraulic line with rinse solution
  Clean the instrument

- **Monthly Maintenance**
  LED Calibration

- **As-Needed Maintenance**
  Adjust the pressure (Whenever Pressure Related Error Occurred)
  Cleaning the Piercer Shaft

This chapter describes supplies replacement in addition to those inspection items mentioned above:

- **Supplies Replacement**
  Replenish reagents
  Replace sample plates
  Supply reaction tubes
  Replace fuses
  Replenish rinse solution
  Replace the lamp
  Replacing the Piercer (when a Cap Piercer Unit is Installed)

2. CA-1500 MAINTENANCE CHECKLIST

Month Year

DAILY MAINTENANCE

Maintenance item \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean the probes																															
Discard the used reaction tubes																															
Discard waste																															
Remove condensation from the reagent trays																															
Check and discard trap chamber fluid																															
Signature																															

WEEKLY MAINTENANCE/SUPPLIES REPLACEMENT

Maintenance item	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature
Prime the hydraulic line with rinse solution							
Clean the instrument							

MONTHLY MAINTENANCE/SUPPLIES REPLACEMENT

Maintenance item	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature
LED Calibration							

AS-NEEDED MAINTENANCE/SUPPLIES REPLACEMENT

Maintenance item	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature	Date/Signature
Adjust the pressure							
Cleaning the Piercer Shaft (when a Cap Piercer Unit is Installed)							
Replace the fuses							
Replace the lamps							
Replacing the Piercer (when a Cap Piercer Unit is Installed)							

3. DAILY MAINTENANCE AND INSPECTION

3.1 Cleaning the Probes

Clean the sample probe and reagent probe at the completion of the day's work or at least every 24 hours.

WARNING
- When cleaning probes, handle all instrument parts as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after cleaning.
- When cleaning the probes, always start from the top to the bottom. If you worked from the bottom toward the top, the probe could pierce your finger or hand.
  The probe could also be bent.
- When a cap piercer is installed, do not touch the piercer tip.
  The tip of the piercer is sharply pointed and extremely dangerous. Handle with care.

(1) From the Main Menu screen, press the [Rinse Probe] key.
The Rinse Probe screen will appear.

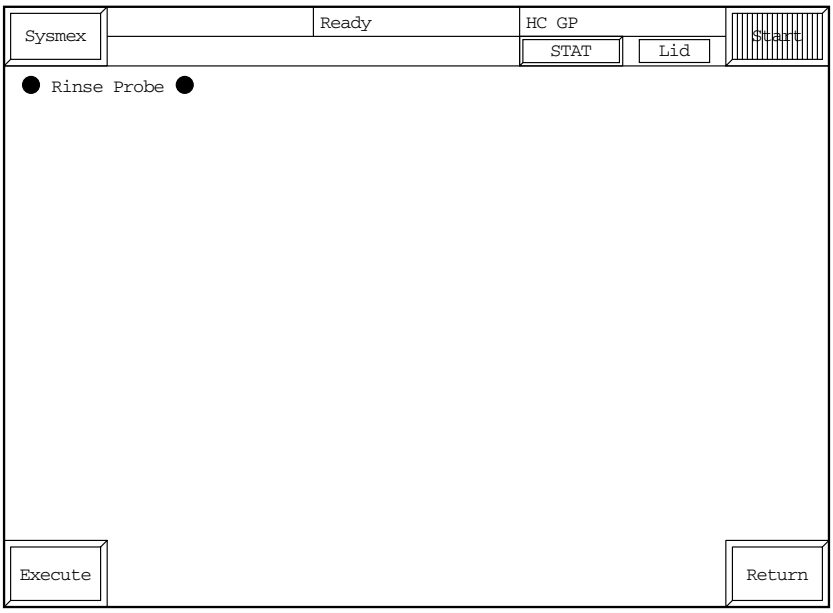


Figure 6-3-1: Rinse Probe Screen

(2) Set CA CLEAN I to both the reagent holders A2 and E3.

(3) Press the [Execute] key.
Probe cleaning will start. It will take approx. 3 minutes to complete the cleaning.

(4) Press the [Return] key.

If the outside of the probe is still noticeably dirty after cleaning, dip gauze or lint-free tissue paper in alcohol (isopropyl alcohol) and wipe the probe from top to bottom.
Refer to *Chapter 6, Section 6.2 Cleaning the Piercer Shaft* for details.

3.2 Discarding the Used Reaction Tubes

The used reaction tubes are automatically thrown in the trash box. At completion of every 200 tests, or at least once every 24 hours, discard the used reaction tubes from the trash box and clean it with tap water.

WARNING • When discarding used reaction tubes, handle all used tubes as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after discarding. Also, medical waste materials should be properly disposed of.

(1) While the power remains ON and instrument status is "Ready", pull up the trash box slightly and then draw it out from the left side panel.
Although a message "Tube Trash has not been set" will appear, disregard this.

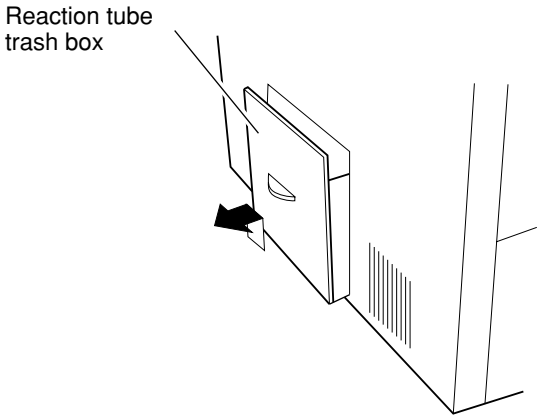


Figure 6-3-2: Reaction Tube Trash Box

(2) Discard the used reaction tubes.

(3) Clean the reaction tube trash box with tap water, and thoroughly wipe off moisture from the reaction tube trash box.

(4) Restore the reaction tube trash box.
After wiping off the moisture thoroughly, replace it.
If the volume monitoring is set to monitoring by number of reaction tubes in the trash box (that is, "Tube Trash Sample Number Alarm" is selected on the Alarm Setting screen; see *Chapter 11, Section 5.10: "ALARM SETTINGS"*), a message will appear asking if you wish to reset the number of used reaction tubes. If the tubes have been discarded, press the [OK] key. If you do not wish to discard or reset, press the [Cancel] key.

CAUTION: • If tubes are discarded after the power is turned OFF, press area (A) of the Consumable screen after the power is turned ON next time; then reset the number of used reaction tubes.

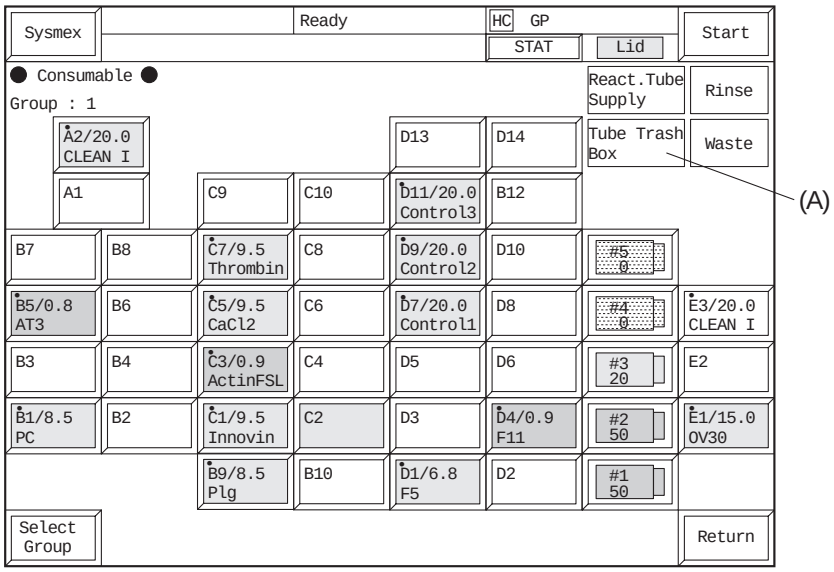


Figure 6-3-3: Consumable Screen

3.3 Discarding Waste (If Provided)

At completion of the day's analysis, discard the waste fluid that has collected in the waste tank, if provided. (Following procedures assume the power remains ON.)

WARNING • When discarding waste, handle waste as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after discarding. Also, medical waste and infected waste should be properly disposed of.

(1) If the tank becomes full with waste during analysis, an alarm will sound and a confirmation screen will appear.
Press the [OK] key and then wait shortly until the analysis is interrupted (analysis interrupting procedures will be activated).
When the system becomes ready for waste disposal, a message will appear.

(2) Open the cap from the waste tank.
Turn the cap counterclockwise and take out the float switch carefully avoiding splashes or drips.

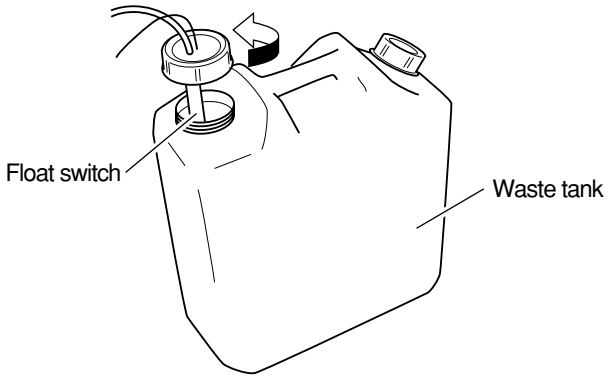


Figure 6-3-4: Waste Tank

(3) Discard waste fluid and empty the waste tank.

(4) Insert the float switch into the tank, and turn the cap clockwise.

(5) Make sure that the tubing is securely connected and is not kinked.

(6) Press the [Resume] key.

CAUTION: • When the tank has become full after dispensing all samples, the Analysis Start Confirmation screen will not appear and step (6) above is not required.

3.4 Removing Condensation from the Reagent Trays

After completion of the day's analysis or at least once every 24 hours, check to see if condensation has formed on the reagent trays. Remove any if found.

WARNING
- Before cleaning the reagent trays, turn the power OFF and unplug the power cord. Failure to do so can result in electrical shock.
- When cleaning the reagent trays, handle all instrument parts as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after cleaning.

(1) Turn OFF the power.

(2) Open the light shield lid.

(3) Pull out the reagent trays.

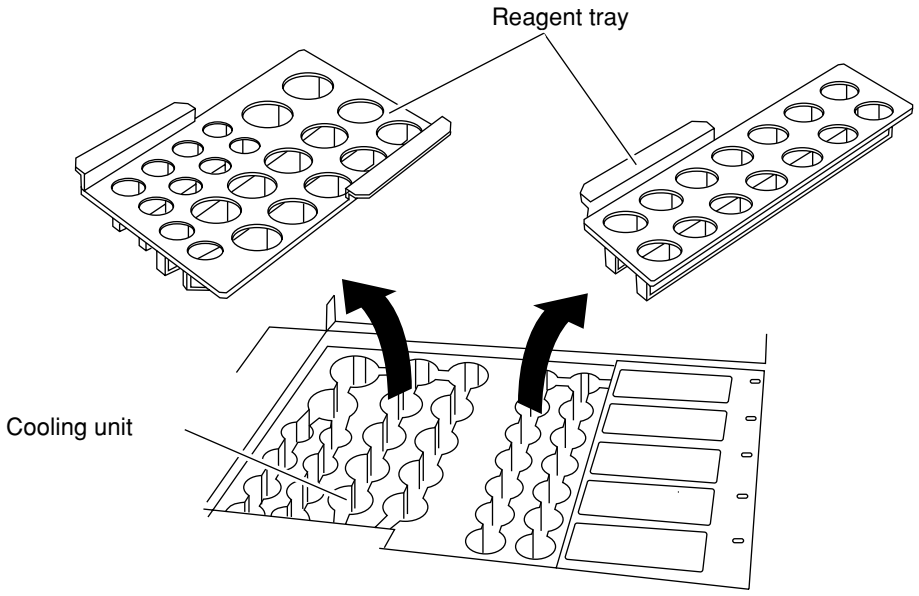


Figure 6-3-5: Removing the Reagent Tray

(4) Using a paper towel, remove the condensation from the cooling unit.

(5) Reinsert the reagent trays.

(6) Close the light shield lid.

3.5 Checking and Discarding Trap Chamber Fluid

After completion of day's analysis, check the trap chamber fluid level and discard any fluid that has collected.

WARNING • When discarding fluid in the trap chamber, handle the fluid as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after discarding.

CAUTION:
- If fluid collects everyday, the hydraulic system may have failed. Contact your service representative.
- Pay attention to the direction of the float in the chamber. Place it with its pointed end facing upward.

(1) Turn OFF the power and wait approximately 30 seconds.

(2) The trap chamber is located on the right side of the instrument. Turn the trap chamber clockwise and remove it.

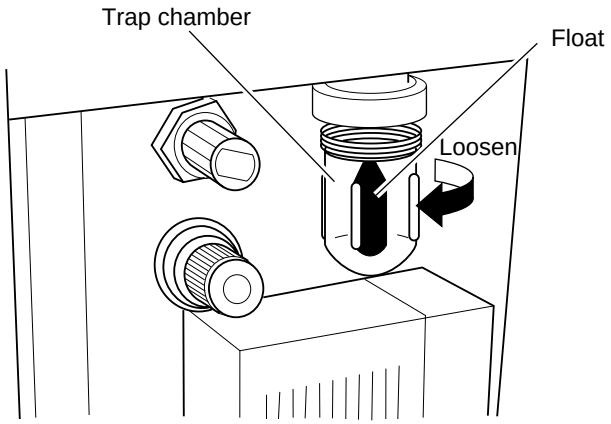


Figure 6-3-6: Checking the Trap Chamber

(3) Discard the collected fluid, and re-attach the trap chamber. Make sure that the float is inside and float direction is correct.

4. WEEKLY MAINTENANCE AND INSPECTION

4.1 Priming the Hydraulic Line with Rinse Solution

Every Monday morning, or whenever the instrument has been left without operation for a day or more regardless of its power ON or OFF, refill the hydraulic line with rinse solution.

(1) Check that there is sufficient rinse solution in the rinse tank and waste tank is empty, if it is provided.

(2) From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.

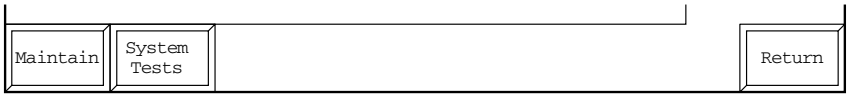


Figure 6-4-1: Special Menu

(3) Press the [Maintain] key.
The Maintenance sub menu will appear.

Figure 6-4-2: Maintenance Sub menu

(4) Press the [Rinse & Prepare] key.
The Prime & Deprime Rinse Execution screen will appear.

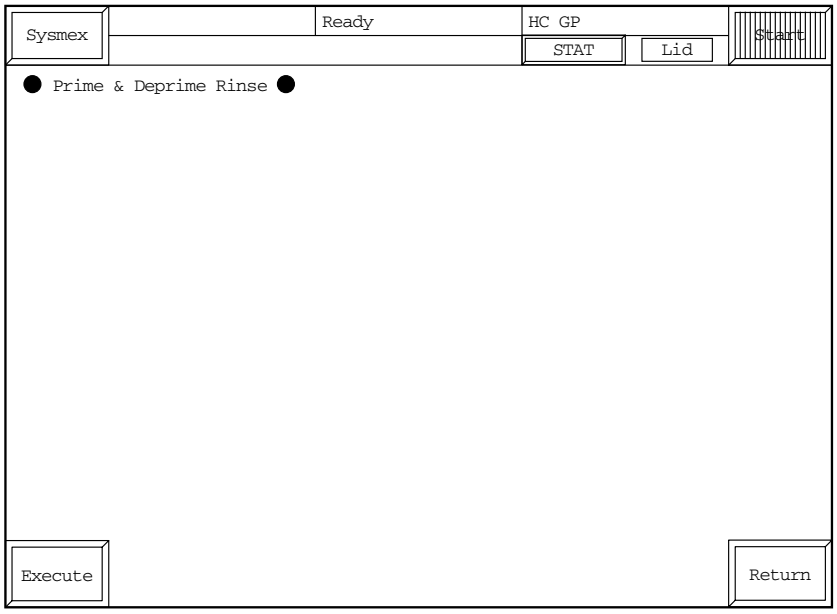


Figure 6-4-3: Prime & Deprime Rinse Execution Screen

(5) Press the [Execute] key.
Priming with rinse solution will start. While the priming is taking place, the time remaining will be displayed on the screen.

(6) Press the [Return] key.
The Maintenance sub menu will reappear.

4.2 Cleaning the Instrument

To ensure the instrument will be maintained in good condition, clean it once a week.

WARNING
- Before cleaning the instrument, be sure to turn the power OFF and unplug the power cord. This is necessary to avoid the risk of electrical shock.
- When cleaning the instrument, handle all instrument parts as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after cleaning.

1. Clean the instrument exterior.

(1) Turn OFF the power.

(2) Using a paper towel that has been moistened with water and a neutral detergent, wipe off the exterior; then wipe again with a soft, dry paper towel.

2. Clean the instrument interior.

(1) Open the light shield lid.

(2) Pull out the reagent trays.

(3) Using a paper towel that has been moistened with water and a neutral detergent, wipe over the interior; then wipe again with a soft, dry paper towel. Clean the removed reagent trays in the same way.

(4) Insert the reagent trays.

(5) Close the light shield lid.

CAUTION:
- Never use any other cleaning solution than water and neutral detergent. Otherwise, the surface coating may be damaged.

5. MONTHLY MAINTENANCE AND INSPECTION

5.1 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 service representative if you need this setting to be adjusted.

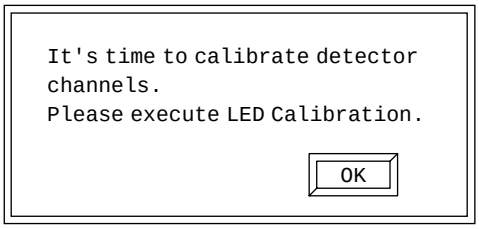


Figure 6-5-1: LED Calibration Confirmation Window

Press the [OK] key, and perform the LED Calibration according to the following procedures.

(1) From the Main Menu screen, press the [Special Menu] key to switch the menu.

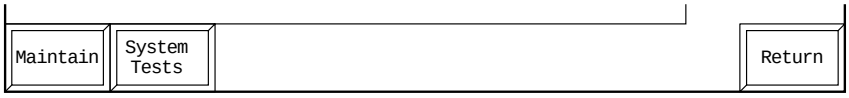


Figure 6-5-2: Special Menu

(2) Press the [Maintain] key.
The Maintenance sub menu will appear.

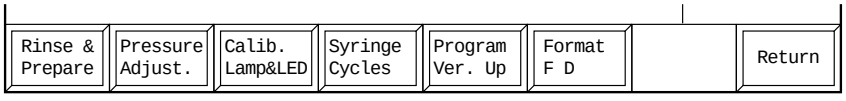


Figure 6-5-3: Maintenance Sub Menu

(3) Press the [Calib. Lamp & LED] key.
The Lamp & LED Calibration screen will appear.

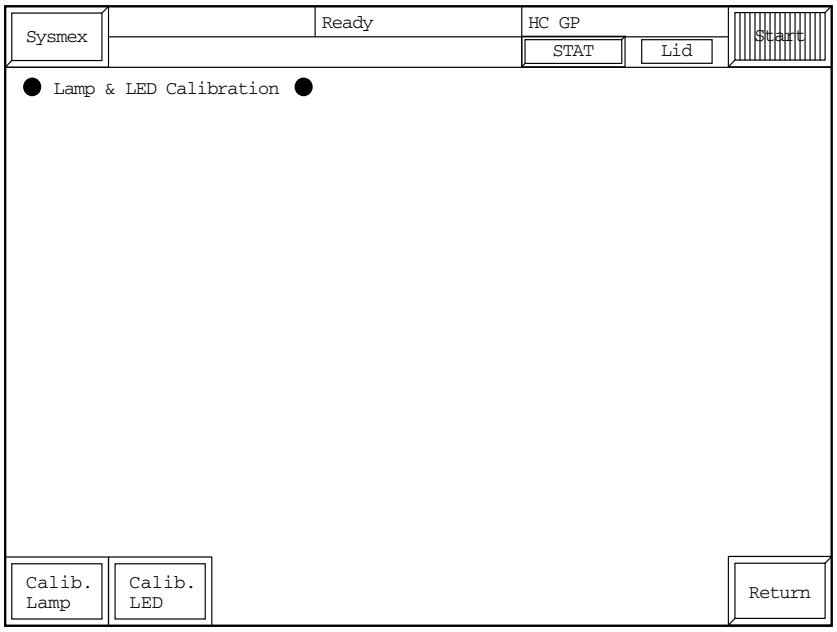


Figure 6-5-4: Lamp & LED Calibration screen

(4) Press the [Calib. LED] key.
The LED Calibration screen will appear.

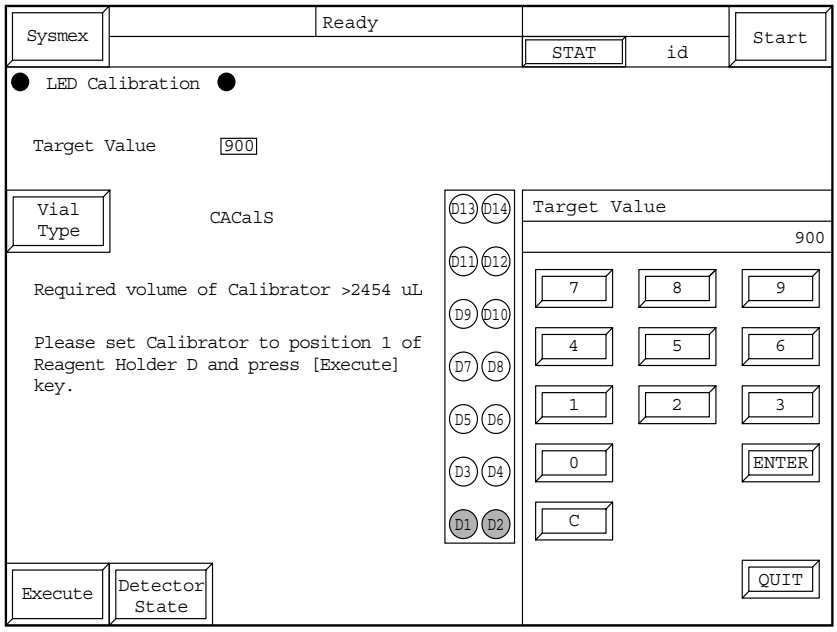


Figure 6-5-5: Lamp & LED Calibration screen

NOTE: • The last calibration day and a present status can be checked by pressing the [Detector State] key.

(5) Enter the Target Value.
Enter an indicated value (100-999) displayed in the calibrator for the calibration with the alphanumeric keys, and press the [ENTER] key.

(6) When setting the CA Cal S container, press the [Vial Type] key.
The container selection window will appear.
Move the cursor by pressing the [↑] and [↓] key to the container to be selected, and press the [OK] key.

(7) Check that CA CLEAN I is set, and place CA Cal S vial in the reagent rack position D1.

CAUTION • Use the adapter suitable for the container to be set or the calibrator may not be correctly aspirated by the pipette and correct calibration may not be obtained.

NOTE: • Supplied Holder No.110 is suitable for the CA Cal S container to be set directly on the reagent holder.

(8) Press the [Execute] key.
The confirmation window will appear.

(9) Press the [OK] key.
The LED calibration is started, and the window shown while calibrating will appear.
When the calibration is completed, the LED Calibration Update Confirmation screen will appear.
The message will be displayed on the screen when there is a channel with a calibration error.

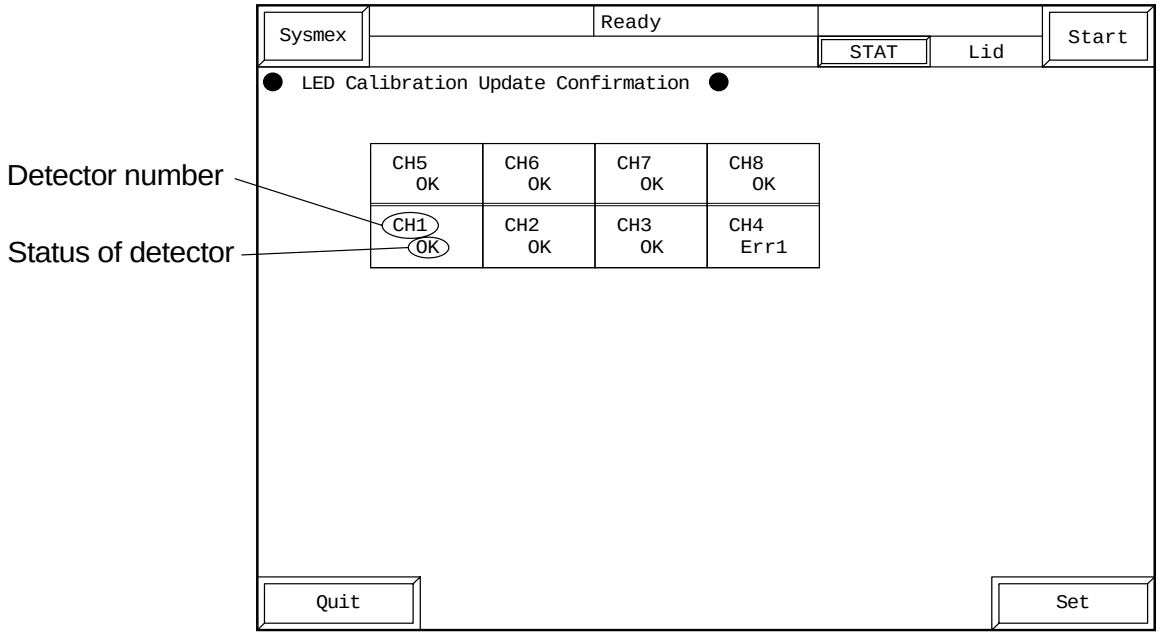


Figure 6-5-6: LED Calibration screen

CAUTION:

- The alarm beeps when the adjustment processing is discontinued due to an abnormality of the instrument, and an error message and the message window for re-performing the LED Calibration appear.

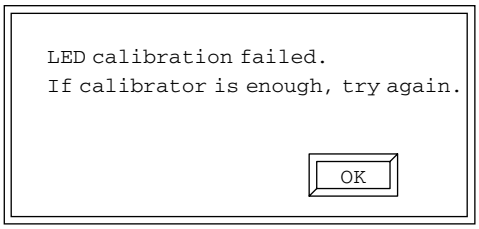


Figure 6-5-7: Confirmation Window

(10) When updating a new adjustment value, press the [Set] 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 window will appear.

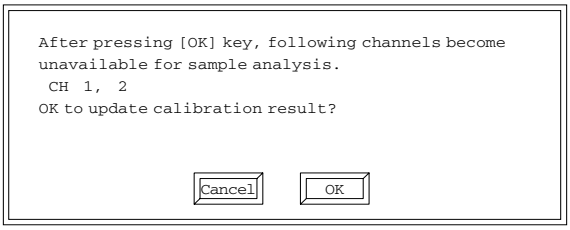


Figure 6-5-8: Confirmation Window

Pressing the [Cancel] key to return to the LED Calibration Update Confirmation screen.
Pressing the [OK] key to save the new adjustment value, and returns to the LED Calibration screen.

When all channels have calibration errors
The confirmation window will appear.

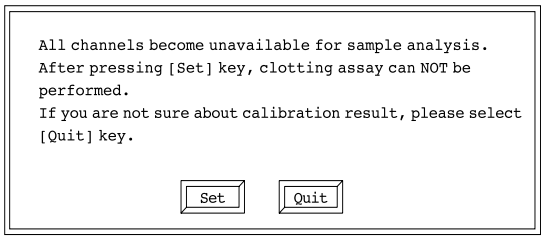


Figure 6-5-9: Confirmation Window

Pressing the [Set] key to save the new adjustment value, returns to the LED Calibration screen.
Pressing the [Quit] key to abandon the new adjustment value, returns to the LED Calibration screen.

(11) Press the [Quit] key to abandon the new adjustment value.
The confirmation window will appear.

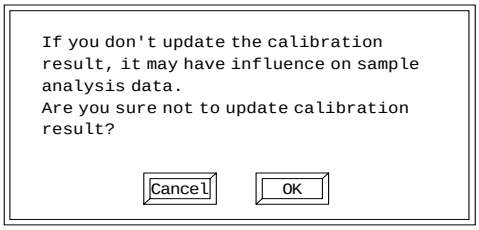


Figure 6-5-10: Confirmation Window

Press the [Cancel] key to return to the LED Calibration Update Confirmation screen.
Press the [OK] key to abandon the new adjustment value and return to the LED Calibration screen.

(12) After the calibration is completed, press the [Quit] key on the LED Calibration screen.
The message window will appear asking to remove the calibrator for the calibration from the reagent rack D1 and set the former reagent.

(13) Press the [OK] key.
Returns to the Lamp & LED Calibration screen.

(14) Take out the calibrator for the Calibration, and set the former reagent.

(15) Press the [Return] key.
Returns to the Maintenance sub menu.

6. AS-NEEDED MAINTENANCE AND INSPECTION

6.1 Adjusting the Pressure

The pressures from the built-in pneumatic unit are adjusted to 0.22 MPa (2.2 kg/cm^2) and 0.10 MPa (1.0 kg/cm^2). These pressures are constantly monitored by pressure sensors. If an abnormality is detected, an error message will appear.
If any pressure related error message is displayed, check the tubing connections for leaks. If nothing abnormal is found, adjust the pressure.
When a vacuum adjustment kit is installed, refer to *APPENDIX D* and adjust the vacuum.
To adjust the pressure, turn the adjustment knob (located on the right side of the instrument) as you check the current pressure readings on the Pressure Adjustment screen.

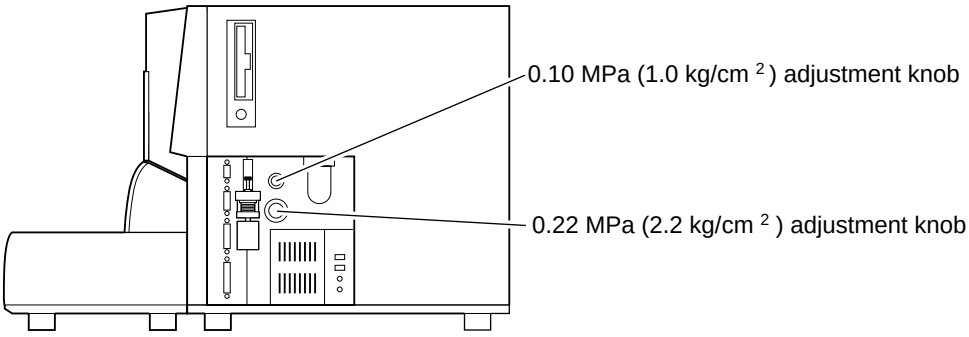


Figure 6-6-1: Location of the Pressure Adjustment Knobs

Displaying the Pressure Adjustment Screen

(1) From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.

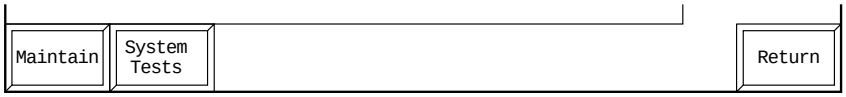


Figure 6-6-2: Special Menu

(2) Press the [Maintain] key.
The Maintenance sub menu will appear.

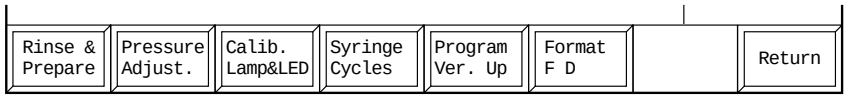


Figure 6-6-3: Maintenance Sub menu

(3) Press the [Pressure Adjust.] key.
The Pressure Adjustment screen will appear.

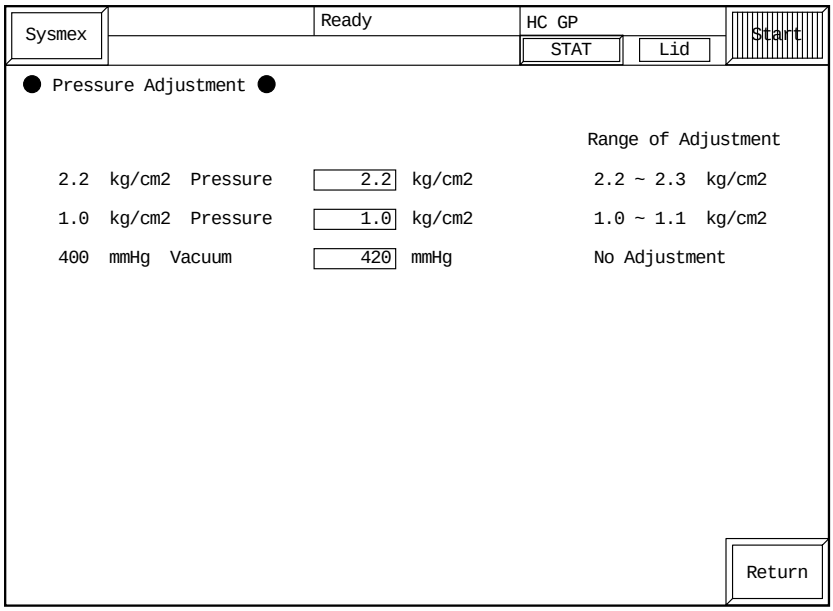


Figure 6-6-4: Pressure Adjustment Screen

Press the [Return] key to return to the Maintenance sub menu.

Adjusting the 2.2 kg/cm^2 (0.22 MPa) Pressure

(1) Loosen the fixing screw on the 0.22 MPa (2.2 kg/cm^2) adjustment knob by turning a screwdriver counterclockwise while the adjustment knob is held to prevent from rotating.

(2) Adjust the pressure by turning the adjustment knob as you check the current value for the 2.2 kg/cm^2 (0.22 MPa) pressure on the Pressure Adjustment screen.
The pressure will rise as you turn the adjustment knob clockwise.

Target: 2.2 kg/cm^2 (0.22 MPa) - 2.3 kg/cm^2 (0.23 MPa)

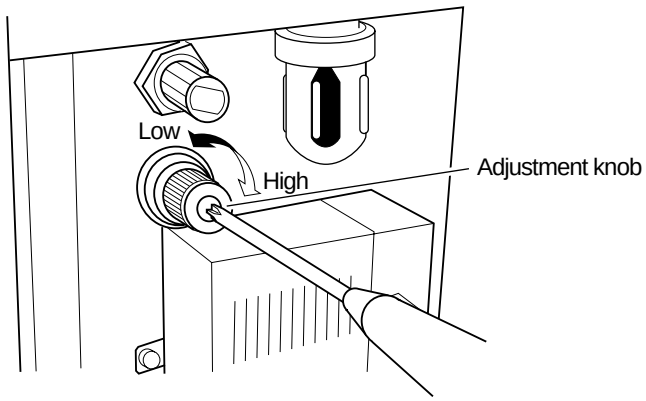


Figure 6-6-5: Adjusting the 2.2 kg/cm^2 (0.22 MPa) Pressure

CAUTION:
- Always adjust the pressure so as to raise it to the specified level. If the pressure is too high, lower it to a value that is below the specified pressure; then slowly raise the pressure. Failure to do so can prevent correct pressure adjustment.

(3) After adjustment, tighten the fixing screw while taking care not to allow the adjustment knob to rotate.

(4) When 2.2 kg/cm^2 (0.22 MPa) pressure was adjusted, verify the 1.0 kg/cm^2 (0.10 MPa) pressure and adjust if required.

Adjusting the 1.0 kg/cm^2 (0.10 MPa) Pressure

(1) Pull the 0.10 MPa (1.0 kg/cm^2) adjustment knob toward you to unlock.

(2) Adjust the pressure by turning the adjustment knob as you check the current value for the 1.0 kg/cm^2 (0.10 MPa) pressure on the Pressure Adjustment screen.
The pressure will rise as you turn the adjustment knob clockwise.

Target: 1.0 kg/cm^2 (0.10 MPa) - 1.1 kg/cm^2 (0.11 MPa)

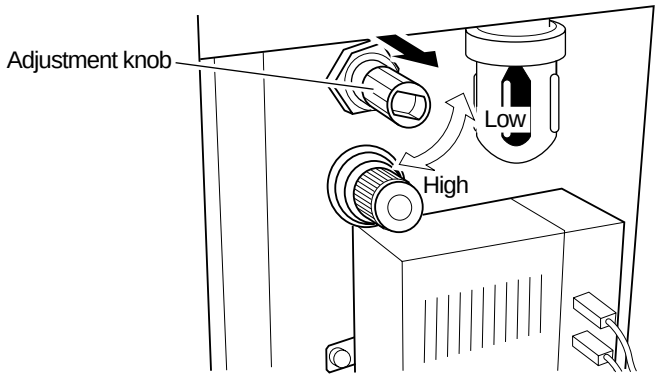


Figure 6-6-6: Adjusting the 1.0 kg/cm^2 (0.10 MPa) Pressure

CAUTION:
- Always adjust the pressure so as to raise it to the specified level. If the pressure is too high, lower it to a value that is below the specified pressure; then slowly raise the pressure. Failure to do so can prevent correct pressure adjustment.

(3) After adjustment, prevent the adjustment knob from turning by pressing it in until it locks.

6.2 Cleaning the Piercer Shaft (when a Cap Piercer Unit is Installed)

If the out side of the piercer is noticeably dirty, dip gauze or lint-tissue paper in alcohol (isopropyl alcohol) and wipe off the piercer from top to bottom.

WARNING • When wiping off the piercer, handle all instrument parts as biologically hazardous.
Wear latex or non-latex examination gloves and wash your hands with disinfectant solution after wiping.
When wiping off the piercer, always start from the top to the bottom. If you worked from the bottom toward the top, the piercer could piercer your finger or hand. The piercer could also be bent.
The tip of piercer is sharply pointed and extremely dangerous. Handle with care.

CAUTION • Do not to touch the piercer with the hand which may be changed with static electricity, while instrument power is ON.
It could cause the instrument failure.
Turn OFF the power when you intend to touch the piercer.
Execute a probe rince using CA CLEAN I before wiping off the piercer with alcohol (isopropyl alcohol).
If the piercer is cleaned with alcohol first, dirt will remain on the piercer which may cause carryover and a correct result may not be obtained.

(1) From the Main Menu screen, press the [Special Menu] key. The special Menu will appear.

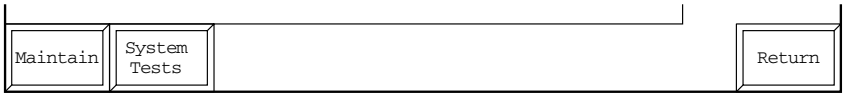


Figure 6-6-7: Special Menu

(2) Press the [Maintain] key.
The Maintenance sub menu will appear.

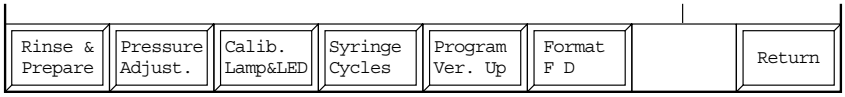


Figure 6-6-8: Maintenance Sub menu

(3) Press the [Replace Piercer] key.
The Replace Piercer screen will appear.

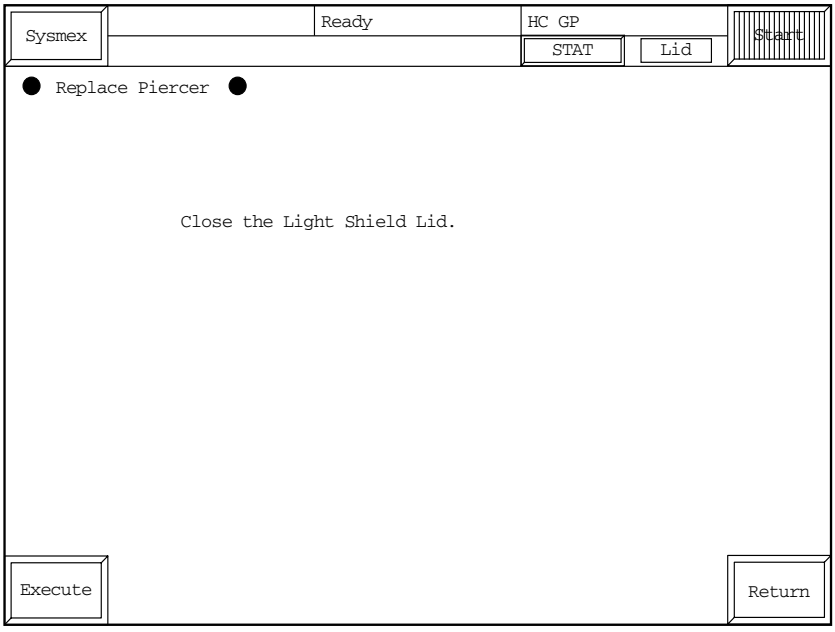


Figure 6-6-9: Replace Piercer screen

(4) Close the light shield lid. Then, press the [Execute] key. Soon after the instrument starts the operation, a message will appear on the screen, and the operation will be completed. In this status, turn OFF the power of the instrument, and open the light shield lid.

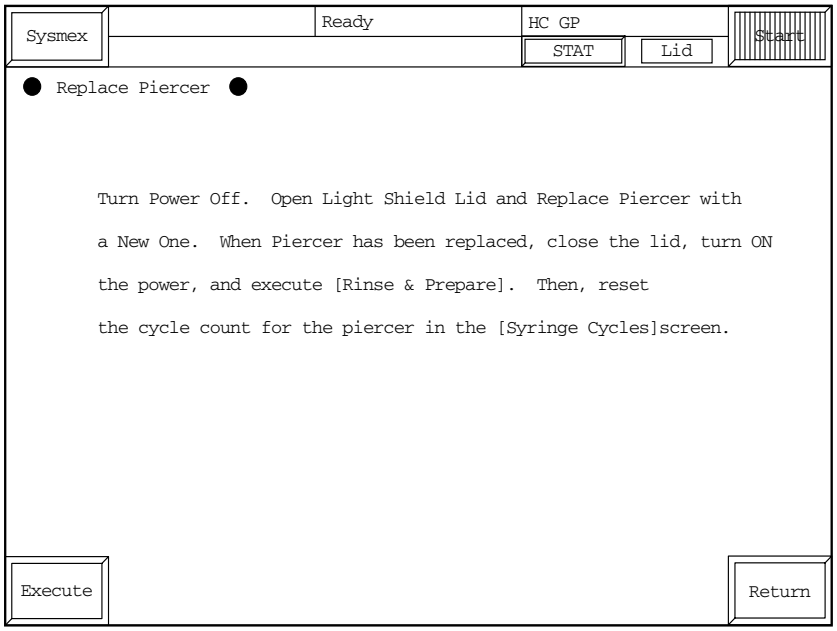


Figure 6-6-10: Replace Piercer screen

(5) Wipe off the piercer.

WARNING • Before wiping off the piercer, turn OFF the power and disconnect the power cord from the outlet.
Failure to do so can result in electrical shock.
• The tip of the piercer is sharply pointed and extremely dangerous. When wiping off the piercer, wear Latex or non Latex examination gloves and handle with care. After the operation is completed, wash your hands with disinfectant.

1) Move the sample arm as far forward as possible (above the sampler unit).

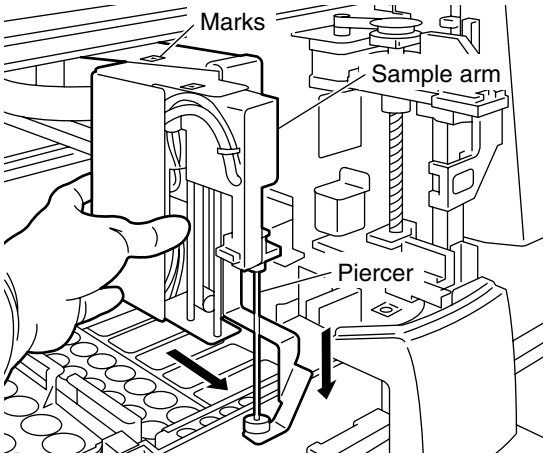


Figure 6-6-11: Move the Sample Arm

2) Hold the piercer base and lower the piercer.

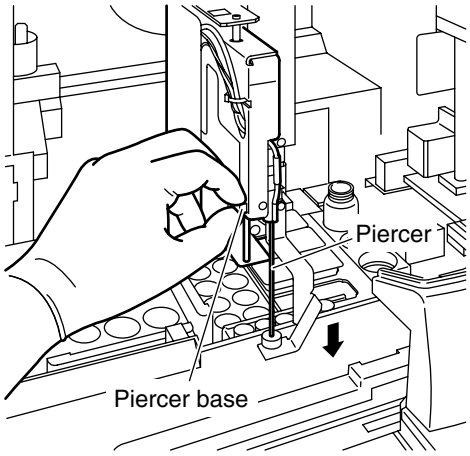


Figure 6-6-12: Lower the Piercer

3) While holding the piercer with one hand, take the alcohol (isopropyl alcohol) by the other hand and with DOWNWARD motions wipe off the shaft of piercer to remove any binding of whole blood or plasma.

4) Hold the piercer base and upper the piercer to the uppermost position.

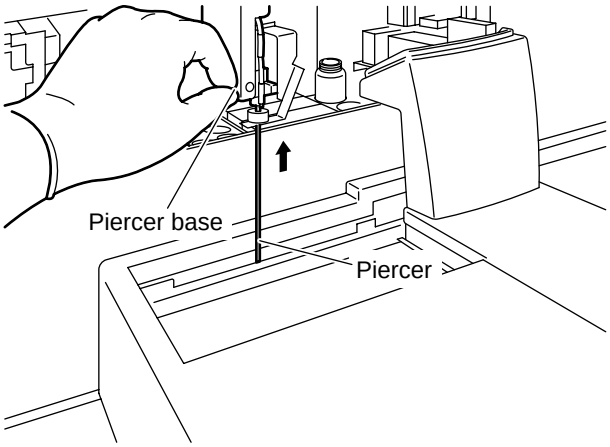


Figure 6-6-13: Upper the Piercer

5) Verify that the piercer is in the uppermost position. Then move the sample probe toward the rear until the top marks are aligned.

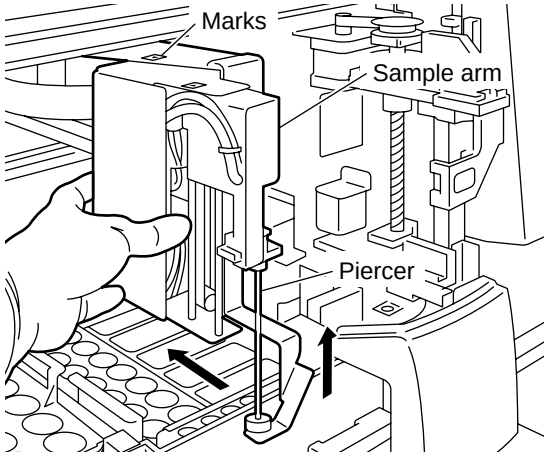


Figure 6-6-14: Lifting Piercer and Moving the Sample Probe

(6) Close the light shield lid, and turn ON the power of the instrument.

7. REPLACING SUPPLIES

7.1 Replenishing Reagents

If the reagent runs out during an analysis, an error message "Insufficient Reagent (Reagent Name)" will appear and the analysis will be interrupted. (This applies only when the Reagent Volume Alarm is set to "Stop All". For details, see *Chapter 11, Section 5.11: Alarm Settings*.)

(1) A "Being Interrupted" message will appear.
Wait shortly until the interruption process is completed. When the system is ready for replenishing reagent, a message will appear.

CAUTION:
- For dispensed and incubated samples, parameters that have not had reagent added will have an "X" marked on the Main Menu screen. Re-register and re-analyze those parameter that are marked by an "X".

(2) From the Main Menu screen, press the [Set Reagents] key.
The Consumable screen will appear. For details on the contents of the Consumable screen, see *Chapter 4, Section 4: CHECKING THE AMOUNT OF REMAINING CONSUMABLE*.

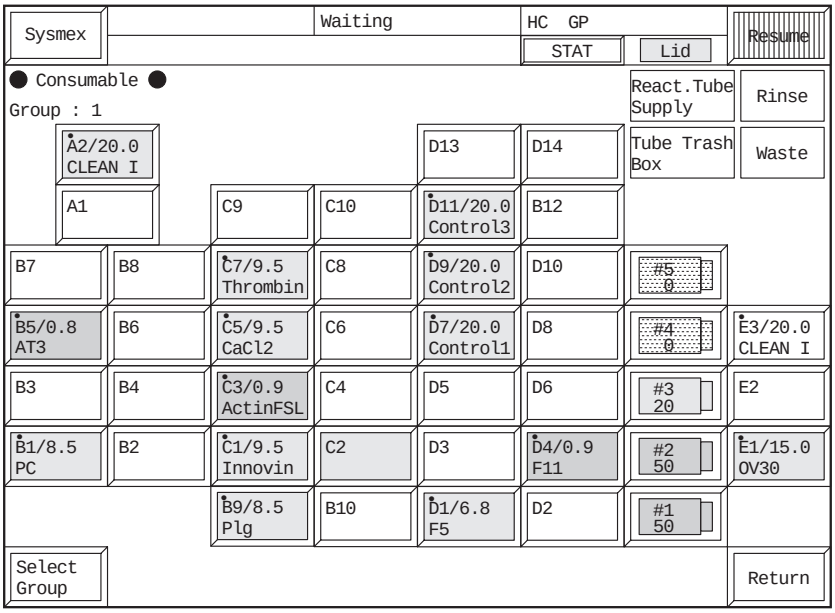


Figure 6-7-1: Consumable Screen

(3) Confirm that the "Lid" signal (status of cover opening) is green; then open the light shield lid.
(4) Set the reagent into the reagent holder.

WARNING • When handling materials derived from human plasma, handle all materials as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands with disinfectant solution after handling such materials.

CAUTION • Set each reagent in its designated position. Failure to do so will cause incorrect analysis results
If a reagent is accidentally set in a wrong position and the analysis is performed, thoroughly clean the probe with rinse solution. For details on how to clean the probe, see *Section 3.1: Cleaning the Probes* in this chapter.
• Take steps to prevent contaminants and dust from getting inside reagent bottles and rinse solution containers. If contaminated, correct analysis results may not be obtained.

(5) If the Reagent Volume Alarm is set to "Reagent Volume", enter the preset reagent volume. If you press the key for the reagent holder position, the numeric keys for reagent volume input will appear. Enter the reagent volume and press the [ENTER] key. The reagent volume will be set. For details on reagent volume monitoring, see *Chapter 11, Section 5.11: Alarm Settings*.

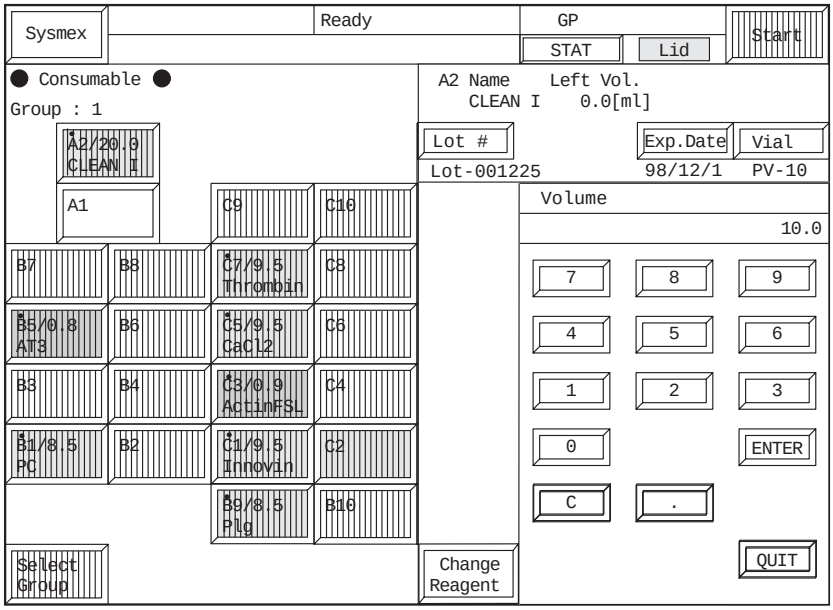


Figure 6-7-2: Setting the Reagent Volume

(6) Close the light shield lid.

(7) Press the [Resume] key. Analysis will continue.

7.2 Replacing Sample Plates

If unused wells in the sample plate run out during an analysis, an error message "Sample Plate completely used. Replace Plate." will appear and analysis will be interrupted.

(1) A "Being Interrupted" message will appear.
Wait for a few minutes until the interruption process is completed. When the system is ready for replacing plates, a message will appear.

(2) Confirm that the "Lid" signal (status of cover opening) is green; then open the light shield lid.

CAUTION • If you remove a sample plate that is fresh (lit with green LED) or that is partly used (lit with red LED), a message window will appear instructing you to return the sample plate to its original position. Replace the original sample plate back into its original position.

NOTE: • For the part number of sample plate, see *Section 6.8: Supply Parts List* in this chapter.

(3) Replace the sample plate(s).
Remove the sample plate that you are replacing, and set an unused, fresh sample plate in its place.
Set the sample plate in the direction shown in the figure.

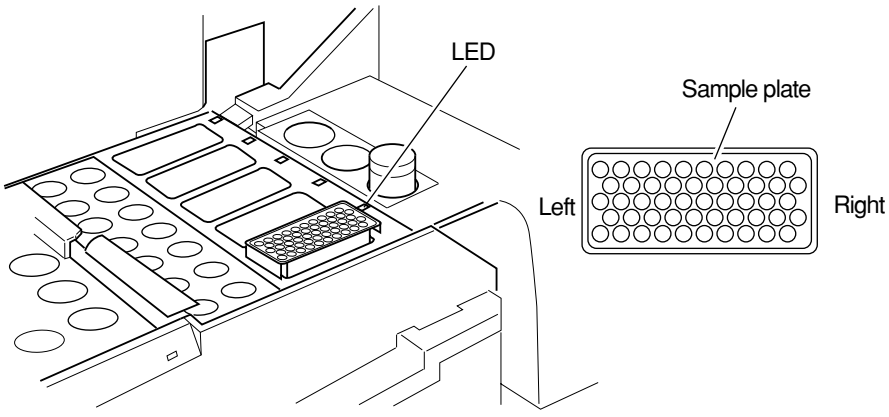


Figure 6-7-3: Replacing the Sample Plate

CAUTION: • Use only unused sample plates. You cannot use a partially used plate because CA-1500 will not recognize the used wells.

NOTE:

- LED to the right side of each sample plate indicates one of the following (however, note that this signal will not be updated even if sample plates are manually replaced):
  OFF: Sample plate is not set.
  ON (green): Sample plate has not been used at all.
  ON (red): Sample plate is partially used.
  Flashing (red): Sample plate has been completely used.

(4) Close the light shield lid.

(5) Press the [Resume] key.
The analysis will continue.

7.3 Replenishing Reaction Tubes

If the reaction tubes run short during analysis, the error message "Replenish Reaction Tubes" will be displayed. If you supply the instrument with reaction tubes while this message is displayed, the analysis will continue without interruption.
If there are no more reaction tubes, the analysis will be interrupted and the message "No Reaction Tubes" will appear. Replenish reaction tubes; then press the [Resume] key. The analysis will continue.

(1) To open the reaction tube hopper, press on the front part of the cover to pop it up; then open.

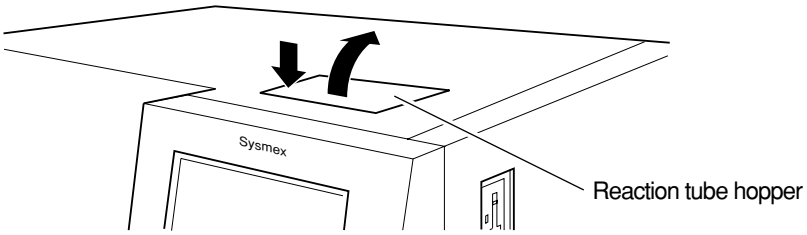


Figure 6-7-4: Opening the Reaction Tube Hopper

(2) Replenish reaction tubes. The reaction tube hopper will hold up to 300 tubes.

CAUTION:	•Do not forcibly overfill the hopper. This will cause jamming.

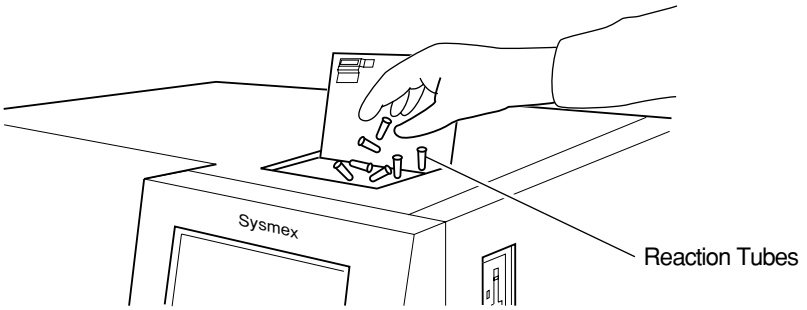


Figure 6-7-5: Replenishing the Reaction Tubes

(3) Close the reaction tube hopper lid.

CAUTION:	• Reaction tubes are for single use only or incorrect results may occur. • Use the specified reaction tubes only (SU-40).

NOTE:	• For the part number of reaction tube, see *Section 6.8: Supply Parts List* in this chapter.

7.4 Replenishing Rinse Solution

If the rinse solution runs out during an analysis, an error message "Replenish Rinse fluid" will appear and the analysis will be interrupted. Replenish with rinse solution as described in the procedure below.

(1) A "Being Interrupted" message will appear.
Wait shortly until the interruption process is completed. When the system is ready for replenishing rinse fluid, a message will appear.

CAUTION • Do not touch the float switch with your hand.
If dust or foreign matter adheres to the float switch, the tank interior will get contaminated. If the interior gets contaminated, correct analysis results may not be obtained. If your hand or other object touches the float switch, wash off the float switch with rinse solution (or distilled water) and then attach it to the tank.

(2) Turning the cap counterclockwise, open the rinse tank cap that does not have tubing and float switch connected.

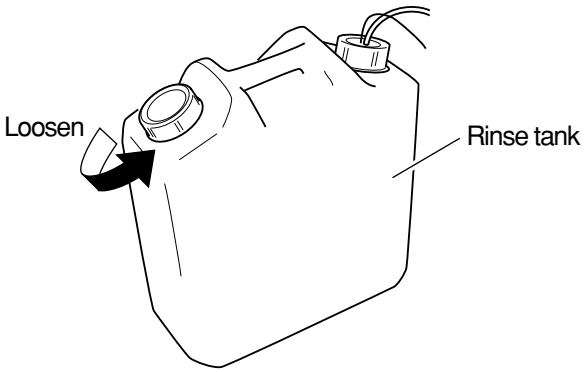


Figure 6-7-6: Opening the Rinse Tank Cap

(3) Fill up the rinse tank with rinse solution (distilled water).

(4) Tighten the cap clockwise to close.

(5) Make sure that the tubing is securely connected and is not kinked.

(6) Press the [Resume] key.
The analysis will continue.

7.5 Replacing Fuses

If a fuse is blown, replace it as described in the procedure below.

WARNING • To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.

(1) Turn OFF the power and unplug the power cord.

(2) Using a regular screwdriver, press the notch upward and pull out the fuse holder cap.

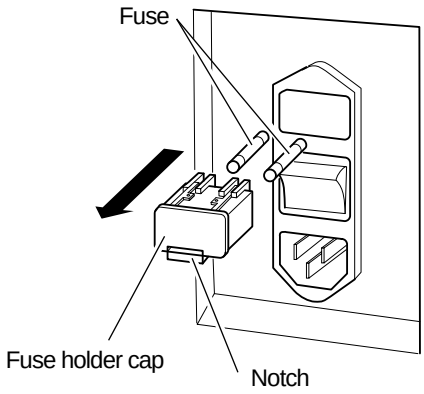


Figure 6-7-7: Removing the Fuse Holder Cap

(3) Replace the fuse and attach the fuse holder cap to the instrument.

CAUTION • For continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

Specification	Part No.	Description	Fuse Type
117 VAC	266-5014-4	Fuse 250V 10A CES14-10A-N1 (N.AMERICA)	Time Lag
220/240 VAC	266-5296-1	Fuse 250V 5A No. 19195 (EUROPE)	Time Lag

Table 6-7-1: Fuse Specifications

NOTE: • When an External Pneumatic Unit is installed, refer to APPENDIX E and replace the fuse in the External Pneumatic Unit.

7.6 Replacing the lamp

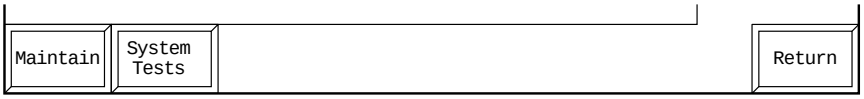
The average lifetime* of the lamp is 2000 hours. The lamp may fail before the average lifetime, due to conditions of use or inconsistencies in manufacturing.
In actual operation, it is recommended replacing the lamp between 1000 hours and 2000 hours of use. Always keep a spare lamp available, to be ready for a sudden lamp failure.
An instruction message, "Change Lamp Unit" appears on the screen when the lamp intensity declines. Make sure to replace the lamp before it fails.

* The average lifetime is the mathematical average of the lifetime of many lamps. As such it is the time it takes for half of the lamps to fail.

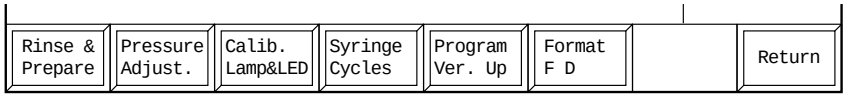
WARNING
- Before starting lamp calibration, wait 30 minutes after the main unit is powered on until the intensity of the lamp has stabilized. If you start lamp calibration before 30 minutes has passed and while the light intensity is unstable, the lamp may not be calibrated correctly and the analysis results may be incorrect.
- If the message "Replace Lamp Unit" appears during analysis, further aliquotting is interrupted and the analysis parameters for chromogenic/immunoassay methods which are marked with a "◎" (i.e. "Being analyzed") are marked with an "X" (i.e. "Analysis error"). As for the samples marked with an "X" (i.e. judged as an analysis error), reanalyze after replacing the lamp and calibrating the new lamp unit following the procedure described in this section.

NOTE:
- When only coagulation analysis parameters are to be analyzed: Use the following procedures to make settings so that the analysis parameters for the chromogenic/immunoassay method are not analyzed.
- When set to "Not Analyzed":
  Since the message "Replace Lamp Unit" does not appear even when the lamp has burned out, the analysis parameters for the coagulation method can be analyzed.

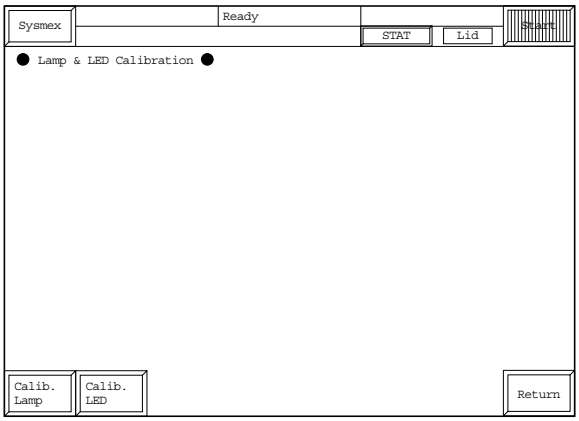
(1) From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.



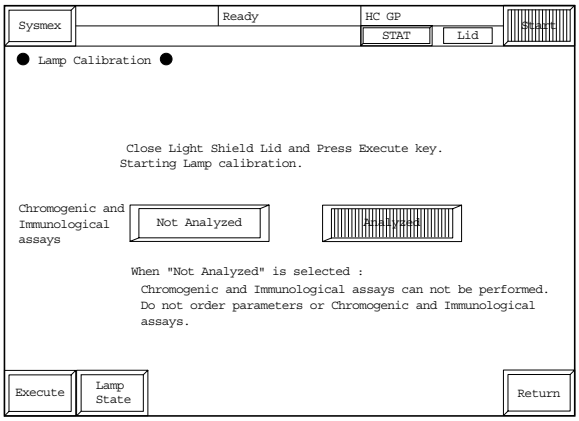
(2) Press the [Maintain] key.
The maintenance sub menu will appear.



(3) Press the [Calib. Lamp & LED] key.
The Lamp & LED Calibration screen will appear.



(4) Press the [Calib. Lamp] key.
The lamp calibration screen will appear.



(5) Make the setting to select whether or not analysis parameters using chromogenic/immunoassay methods are to be analyzed by selecting either of the following keys.

[Not Analyzed] key: Analysis parameters for chromogenic/immunoassay method are not analyzed. If you have selected this key, do not register the analysis order for the chromogenic/immunoassay methods.

[Analyzed] key: Analysis parameters for chromogenic/immunoassay methods are analyzed.

(6) Press the [Return] key.
The maintenance sub menu will reappear.

WARNING

- When the [Not Analyzed] key has been selected, analysis parameters for chromogenic/immunoassay methods cannot be analyzed. Do not register the analysis orders for chromogenic/immunoassay methods. If you have falsely registered the analysis order for the chromogenic/immunoassay methods, the analysis results of the parameters for the chromogenic/immunoassay methods will be marked with an "X" (i.e. "Analysis error"). Also in this case, if the analysis is performed in Micro-sample mode, the sample amount required for the analysis order for the chromogenic/immunoassay method is not aspirated; if the analysis is performed in the Standard mode, the sample amount required for the analysis order for the chromogenic/immunoassay methods is aspirated.
- When the [Not Analyzed] key has been selected, the lamp calibration is not available.
- If a lamp is installed, it goes on even when the [Not Analyzed] key has been selected.
- Make sure to calibrate the lamp when the [Analyzed] key is selected after a long period of use without replacing the lamp with the [Not Analyzed] key selected. If you analyze samples without calibrating the lamp, the analysis results may be incorrect.

WARNING• Before replacing the lamp, turn the power OFF and unplug the power cord. Failure to do so can result in electrical shock.

(1) Turn OFF the power and unplug the power cord.

(2) Loosen the thumb screw of the exterior lamp cover located on the right side of the instrument. Gently slide the cover toward the front side, pull it out, and remove it.

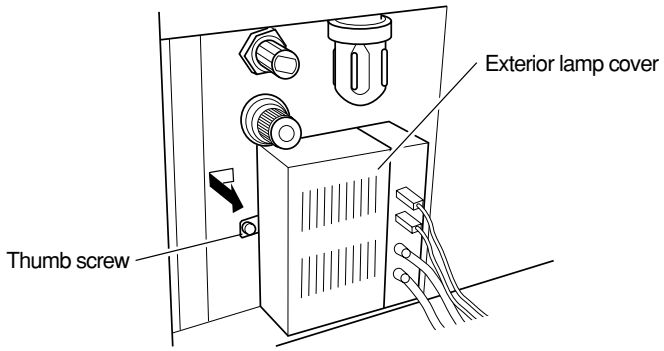


Figure 6-7-8: Removing the Exterior Lamp Cover

NOTE: • For the lamp part number, see *Section 6.8: Supply Parts List* in this chapter.

(3) Loosen two thumb screws (2 turns will be enough), and remove the lamp cover.

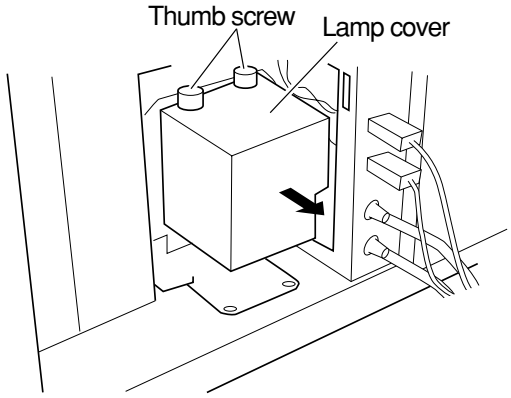


Figure 6-7-9: Removing the Lamp Cover

WARNING • After turning the power OFF, wait 30 minutes to allow the lamp to become cool.

(4) Press the clamp of the connector and remove the connector.

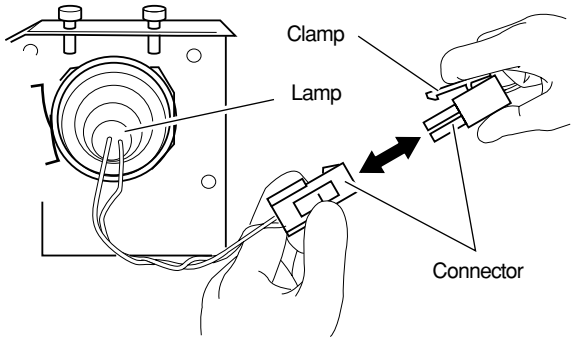


Figure 6-7-10: Removing the Connector

(5) Lamp could be still hot! Touch carefully.
Holding down the lamp brace, remove the lamp from the lamp holder.

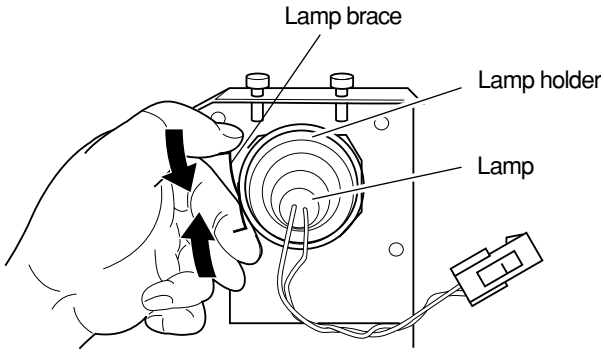


Figure 6-7-11: Removing the Lamp from the Lamp Holder

(6) Install a new lamp in the reverse order of removal.

CAUTION: • Do not touch inside and outside of the lamp reflector with your bare fingers. Lamp performance could be effected.
If you transfer oil or protein from your fingers, the lamp may be damaged when the temperature rises.

(7) After installing the lamp and replacing the covers, reconnect the power cord and turn ON the power switch. Wait for 30 minutes until the intensity of the lamp stabilizes.

(8) From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.

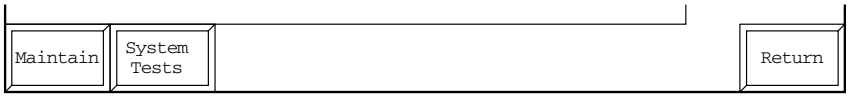


Figure 6-7-12: Special Menu

(9) Press the [Maintain] key.
The Maintenance sub menu will appear.

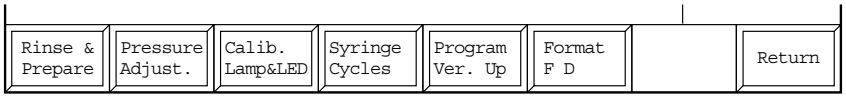


Figure 6-7-13: Maintenance Sub menu

(10) Press the [Calib. Lamp & LED] key.
The Lamp & LED Calibration screen will appear.

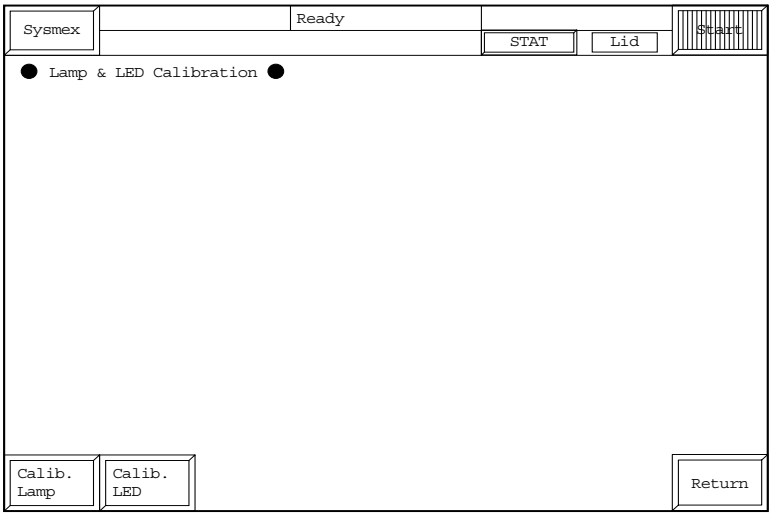


Figure 6-7-14: Lamp & LED Calibration screen

(11) Press the [Calib. Lamp] key.
The Lamp Calibration screen will appear.

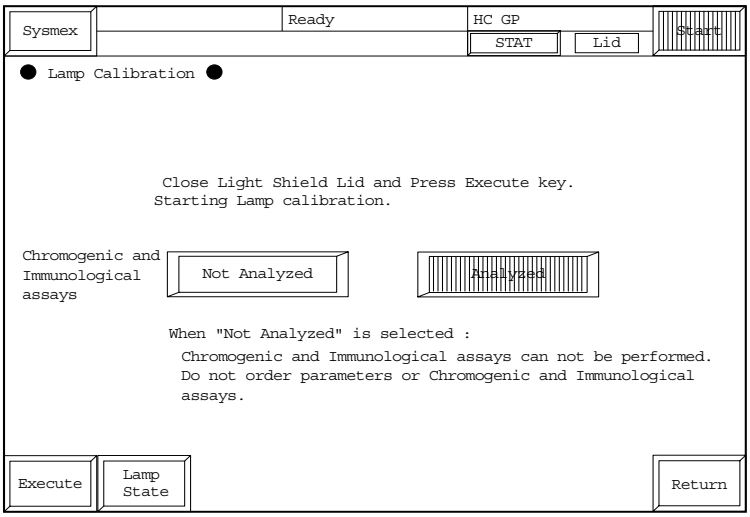
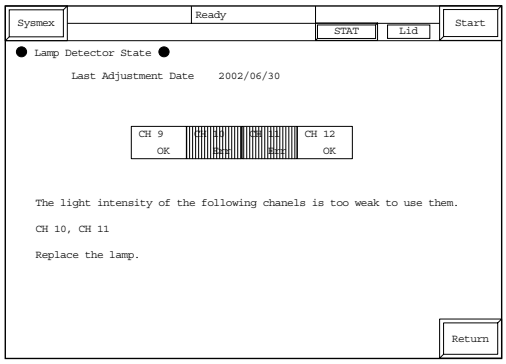


Figure 6-7-15: Lamp Calibration screen

(12) Close the light shield lid, and press the [Execute] key.
Lamp calibration will start and the Adjustment window will appear.

(13) Press the [Return] key.
The Maintenance sub menu will reappear.

NOTE: CA-1500 can show the lamp status
(1) Press the [Lamp State] key.
The Lamp Detector State screen appear.



Weak channels will not be used for sample analysis, so the throughput may decrease.
When all channels are weak, Chromogenic and Immunological assays cannot be performed.
If there are any weak channels, replace the lamp. After replacing the lamp, perform a lamp calibraton.

7.7 Replacing the Piercer (when a Cap Piercer Unit is Installed)

When the count of cap piercing analysis (piercing operation) exceeds 30,000 times, replace the piercer. The message "Replace Piercer" will be displayed when the count exceeds 30,000 times.

WARNING • A piercer is a consumable part. When the count of piercing operation exceeds 30,000 times, a piercer may be worn or bent. Therefore, replace the piercer when the count of cap piercing analysis (piercing operation) exceeds approximately 30,000 times. Note that a piercer may sometimes wear out before operations of 30,000 times depending on the conditions.

NOTE: • For the piercer part number, see *Section 6.8: Supply Parts List* in this chapter.

(1) From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.

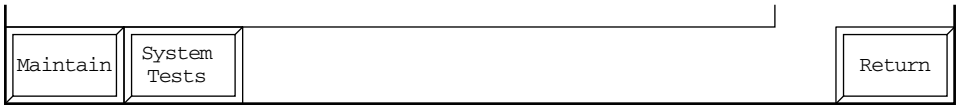


Figure 6-7-16: Special Menu

(2) Press the [Maintain] key.
The Maintenance sub menu will appear.

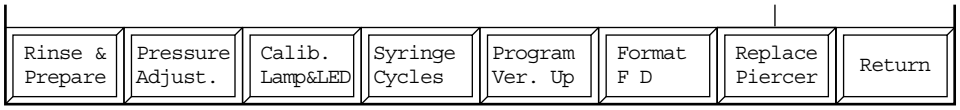


Figure 6-7-17: Maintenance Sub menu

(3) Press the [Replace Piercer] key.
The Replace Piercer screen will appear.

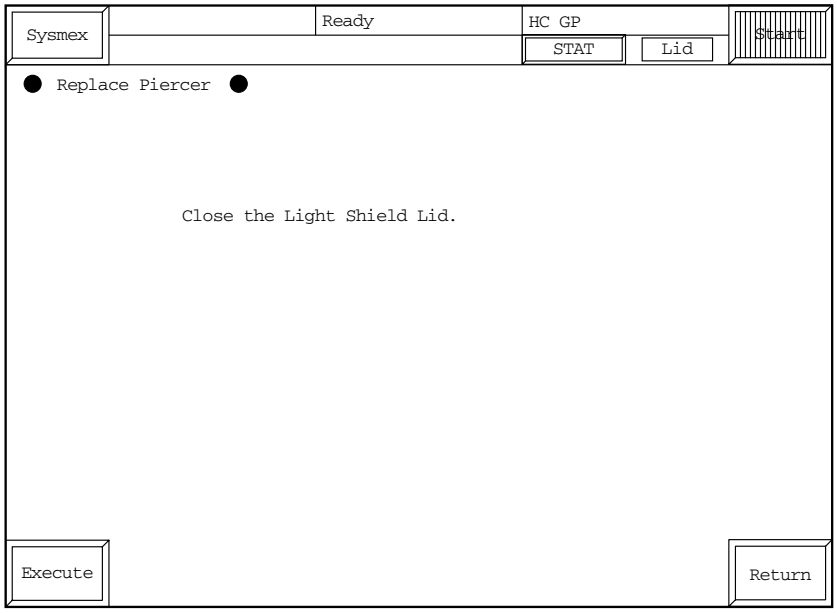


Figure 6-7-18: Replace Piercer screen

(4) Close the light shield lid. Then, press the [Execute] key. Soon after the instrument starts the operation, a message will appear on the screen, and the operation will be completed. In this status, turn OFF the power of the instrument, and open the light shield lid.

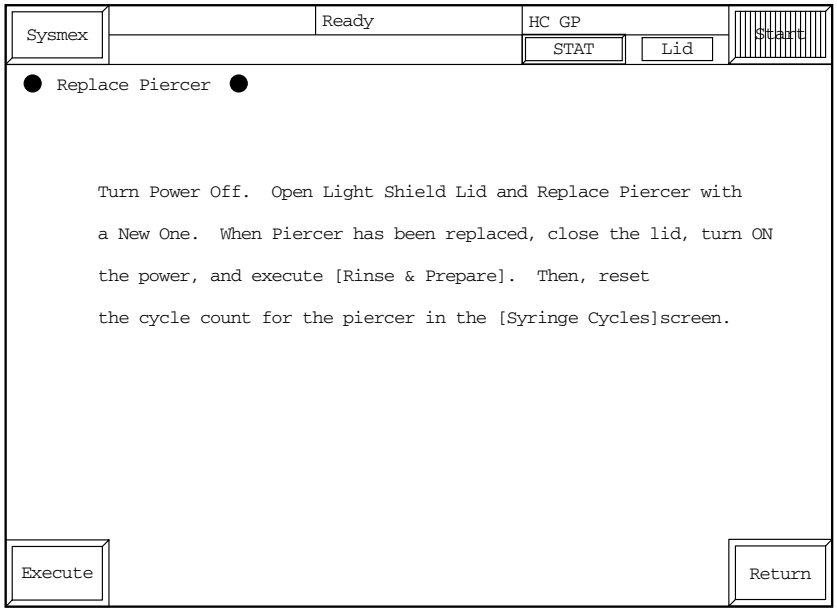


Figure 6-7-19: Replace Piercer screen

(5) Remove the piercer.

WARNING
- Before replacing the piercer, turn OFF the power and disconnect the power cord from the outlet.
  Failure to do so can result in electrical shock.
- The tip of the piercer is sharply pointed and extremely dangerous. When replacing the piercer, wear Latex or non Latex examination gloves and do not touch the piercer tip. After the operation is completed, wash your hands with disinfectant.

1) Move the sample arm as far forward as possible (above the sampler unit).

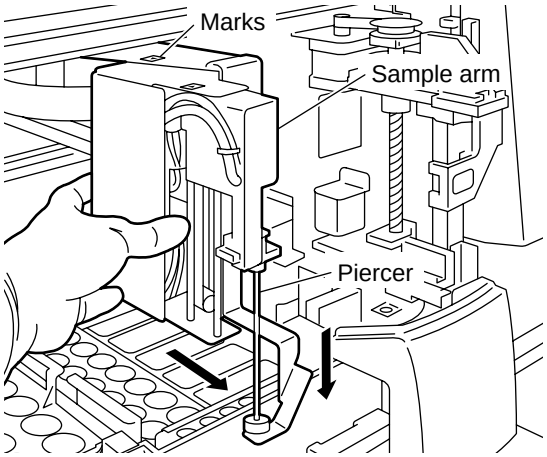


Figure 6-7-20: Move the Sample Arm

2) Disconnect the cord that is connected to the piercer.

3) Loosen the tube-connection screw that connects the tube to the upper part of the piercer.

4) As shown in the figure, holding the piercer base that fixes the piercer, remove the screw that fastens the piercer.
Do not touch the screw other than the marked piercer fixing screw.

WARNING • Do not touch the bottom of the piercer guide.
The piercer may be dropped.

5) Remove the fixture that fixes the piercer.

6) Remove the piercer by tilting slightly toward you and pulling upward.

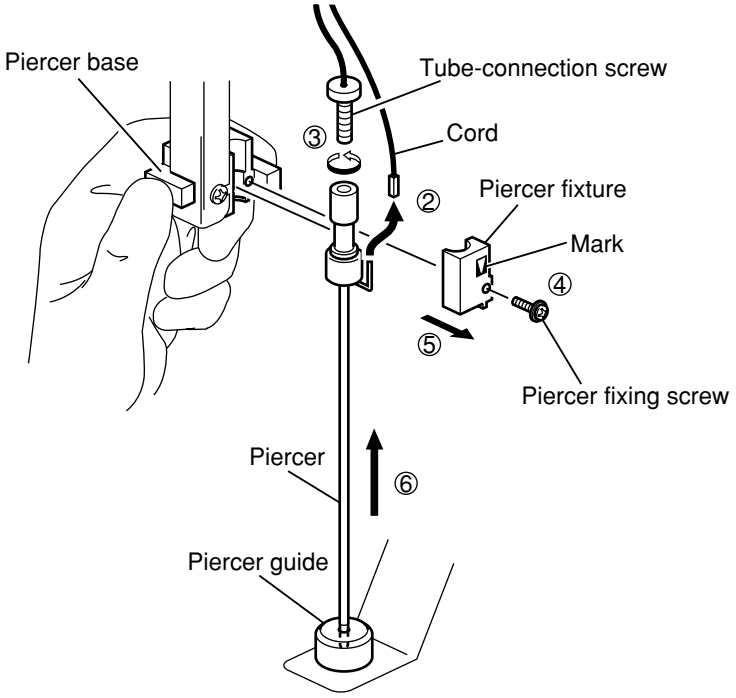


Figure 6-7-21: Removing the Piercer

7) Discard the used piercer in a safe place to prevent stick injury.

(6) Install the new piercer.

1) Remove the tube that protects the piercer tip.

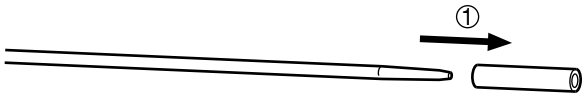


Figure 6-7-22: Removing the Protection Tube

2) Insert the piercer tip into the piercer guide. Make sure that the piercer is not overly tilted.

3) Insert the tube connection screw into the dent at the upper part of the piercer. Then insert the upper part of the piercer into the piercer base that fixes the piercer. When doing so, align the flat edge (that is on the side of the upper part of the piercer) with the part that projects from the fixture.

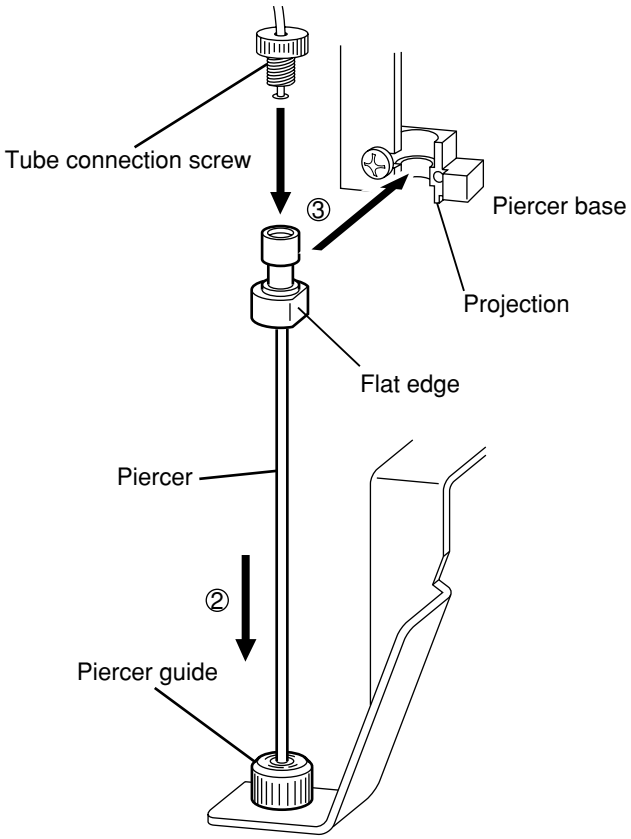


Figure 6-7-23: Installing the Piercer

WARNING • Do not touch the bottom of the piercer guide. The piercer may be dropped.

4) Insert the piercer fixture in place and attach the piercer fixing screw; then, holding the piercer fixture, tighten the piercer fixing screw.

5) Tighten the tube-connection screw that connects the tube.

6) Connect the cord.

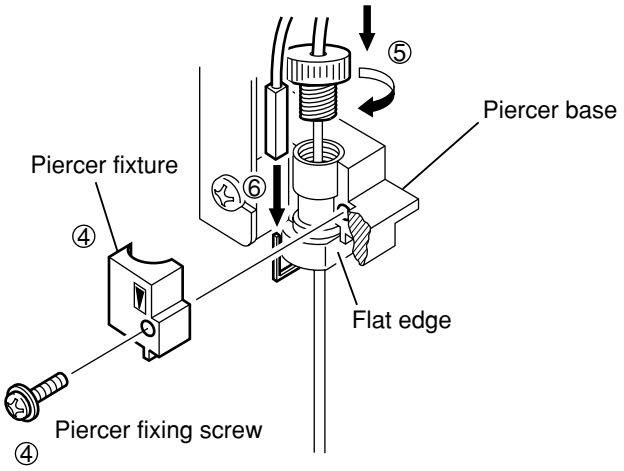


Figure 6-7-24: Connecting the Cord

7) Verify that the piercer is in the uppermost position. Then move the sample probe toward the rear until the top marks are aligned.

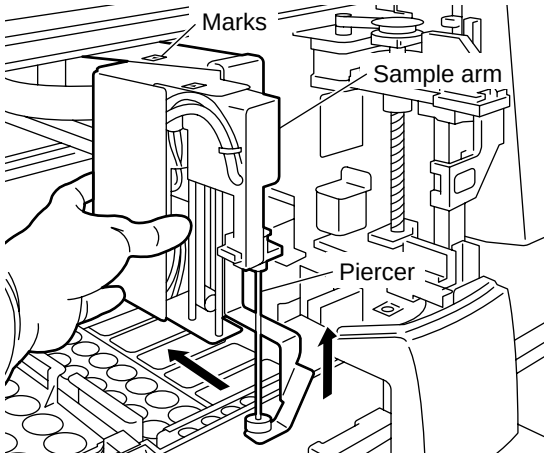


Figure 6-7-25: Lifting Piercer and Moving the Sample Probe

(7) Close the light shield lid, and turn ON the power of the instrument.

(8) From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.

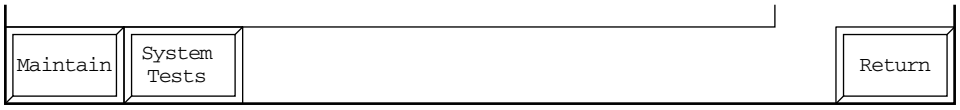


Figure 6-7-26: Special Menu

(9) Press the [Maintain] key.
The Maintenance sub menu will appear.

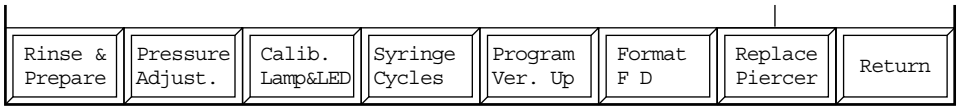


Figure 6-7-27: Maintenance Sub menu

(10) Press the [Rinse & Prepare] key.
If you press the [Execute] key, the mechanical unit's reset function will be activated and the priming with rinse solution will start.
Wait shortly until the operation is completed.
After the operation is completed, press the [Return] key.

(11) Press the [Syringe Cycles] key. The Syringe Cycle Count screen will appear.

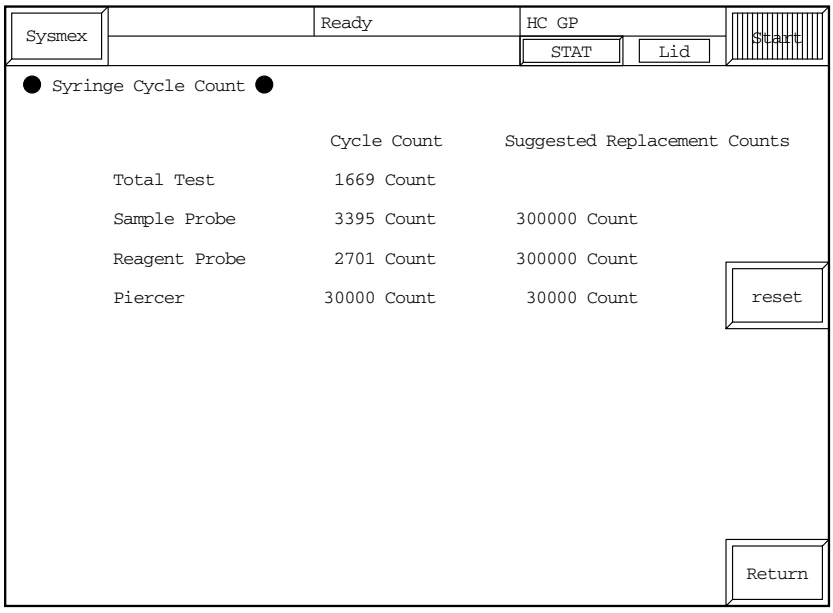


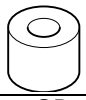
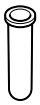
Figure 6-7-28: Syringe Cycle Count screen

Press the [reset] key, which is to the right of the part labeled "Piercer." When the message "CP Counter is cleared." appears on the screen, press the [OK] key. The number of piercer operation cycles will change to 0. To cancel clearing the CP cycle count, press the [Cancel] key.

(12) After the piercer cycle count has been reset, press the [Return] key.
If the piercer cycle count has been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue resetting the piercer cycle count.
[Set] key:	Updates the piercer cycle count and returns the system to the Maintenance sub menu.
[Quit] key:	Cancels the piercer cycle count and returns the system to the Maintenance sub menu.

7.8 Supply Parts List

Part number	Description	Remarks
981-0481-8	PIERCER CA-15H (PM)	
964-0631-3	CA CLEAN I (GSA-500A)	Probe rinse reagent (Alkaline)
964-0611-9	CA CLEAN II (GSZ-500A)	Probe rinse reagent (Acidic)
266-5014-4	Fuse 250V 10A CES14-10A-N1 (N.AMERICA)	Main Unit, for 117V spec.
266-5296-1	Fuse 250V 5A No. 19195 (EUROPE)	Main Unit, for 220 V /240V specs.
424-2400-4	Container M20 (20 L)	For rinse and waste containers
366-1231-8	TUBE HOLDER NO. 58	14 mm diameter collection tube adapter, for Sample Rack
366-1232-1	TUBE HOLDER NO. 59	13 mm diameter collection tube adapter, for Sample Rack
366-1291-1	TUBE HOLDER NO. 113	11 mm diameter collection tube adapter, for Sample Rack
363-2562-1	Holder No. 93	Siemens GW5 reagent adapter, 30 mm OD
363-2566-6	Holder No. 97	Sample cup adapter, 30 mm OD 
363-2567-0	Holder No. 98	Sample cup adapter, 23 mm OD
363-2568-3	Holder No. 99	For rinse and diluent vial adapter
363-2579-4	Holder No.110	CA Cal S container adapter
226-3227-4	Lamp Hlgn JCR/M (6V 10W) H20-3L	
541-1352-1	Push Vial PV-10	22 mm OD x 40 mm high
013-1771-4	SLD Vial Assy	10/pack
904-0721-9	REACTION TUBE (SU-40)	3,000/box 

Part number	Description	Remarks
367-1850-9	Reagent Tray No. 1	
367-1851-2	Reagent Tray No. 2	
541-1285-9	Rubber Cap for Vial 651907	CaCl2 or H2O vial cap
424-1160-8	Sample Cup Conical 4 mL	
974-0771-3	Sample Plate (SAP-400A)	
833-3316-4	Sample Rack Assy (CA-6K/PM)	For Monovette
424-3303-3	Sample Rack No. 3	
833-3895-6	Sample Rack No. 3 w/Holder #55	
541-0623-6	Screw Bottle No. 7 (WHT)	
367-8741-5	Stirrer Teflon 4040-03	
367-1105-2	TUBE TRASH NO. 5	
363-1931-4	Tube Holder No. 1	10 mm dia. collection tube adapter, for STAT sample holder
363-1933-1	Tube Holder No. 3	13 mm dia. collection tube adapter, for STAT sample holder
541-1284-5	Vial 651907 22x60 10 mL	Vial for CaCl2 or H2O
963-1991-0	Waste Bottle Comp. CA-6K	20 L Container with float switch
367-2190-3	CA-1500 TRASH BOX (L)	400 reaction tube capacity

NOTE:

- Ordering of Supplies and Replacement Parts
  If you need to order supplies or replacement parts, please contact your local representative.
- Service and Maintenance
  Please contact the Service Department of your local representative.
- Training courses
  For further information please contact the representative in your country.

8. REAGENT SET POSITION AND ADAPTER LIST

8.1 Adapter List According to Container

Container type	Standard volume	Rack Holder					Remarks
		A 36 X 2 OD	B 24 X 10 OD	C 31 X 10 OD	D 24 X 14 OD	E 36 X 3 OD	
Sample Cup 4 mL	4 mL	Holder No.98 + Holder No.99	Holder No.98	Holder No.97	Holder No.98	Holder No.98 + Holder No.99	For Transfer
PV-10	10 mL	Holder No.99	Direct	Holder No.93	Direct	Holder No.99	For Transfer
GW5	5 mL	-	Direct	Holder No.93	Direct	-	
GW15	15 mL	-	X	Direct	X	-	
GW25	25 mL	-	X	Direct	X	-	
CA CLEAN 1	50 mL	Direct	X	X	X	Direct	
PFDP 5 mL	5 mL	Holder No.99	Direct	Holder No.93	-	-	
SLD	5 mL	Holder No.99	Direct	Holder No.93	Direct	Holder No.99	For Transfer

-: Not applicable, ×: Insertion impossible

8.2 Reagent Set Position List (Coagulation Method)

Parameter	Product name	Description	Volume	Rack Holder A 36 X 2 OD	Rack Holder B 24 X 10 OD	Rack Holder C 31 X 10 OD	Rack Holder D 24 X 14 OD	Rack Holder E 36 X 3 OD	Container type	Remark
PT	Dade® Thromboplastin• C Reagent	-	4 mL	-	Direct	Holder No.93	-	-	GW5	
			10 mL	-	X	Direct	-	-	GW15	
	Dade® Innovin® Reagent	-	10 mL	-	X	Direct	-	-	GW15	
			20 mL	-	X	Direct	-	-	GW25	
	Thromborel® S Reagent	-	2 mL	-	Direct	Holder No.93	-	-	GW5	
			4 mL	-	Direct	Holder No.93	-	-	GW5	
			10 mL	-	X	Direct	-	-	GW15	
APTT	Dade® Actin® Activated Cephaloplastin Reagent	-	2 mL	-	Direct	Holder No.93	-	-	GW5	
		-	10 mL	-	X	Direct	-	-	GW15	
	Dade® Actin® FS Activated PTT Reagent	-	2 mL	-	Direct	Holder No.93	-	-	GW5	
		-	10 mL	-	X	Direct	-	-	GW15	
	Dade® Actin® FSL Activated PTT Reagent	-	2 mL	-	Direct	Holder No.93	-	-	GW5	
		-	10 mL	-	X	Direct	-	-	GW15	
	Pathromtin° SL	-	5 mL	-	Direct	Holder No.93	-	-	GW5	
	Calcium Chloride Solution	-	15 mL	-	X	Direct	-	-	GW15	
Fbg	Dade® Thrombin Reagent	-	1 mL	-	Direct	Holder No.93	-	-	GW5	
		-	5 mL	-	X	Direct	-	-	GW15	
Protein S	Protein S Activity (PSAc)	Protein S Ac Deficient Plasma	1 mL	-	Direct	Holder No.93	-	-	GW5	
		Protein S Ac APC Reagent	2 mL	-	Direct	Holder No.93	-	-	GW5	
		Protein S Ac Starting Reagent	5 mL	-	Direct	Holder No.93	-	-	GW5	
PCc	Protein C Reagent	Protein C Activator	3 mL	-	Direct	Holder No.93	-	-	GW5	
		APTT Reagent for Protein C	10 mL	-	X	Direct	-	-	GW15	
		Protein C Deficient Plasma	1 mL	-	Direct	Holder No.93	-	-	GW5	
BTX	Batroxobin Reagent	-	5 mL	-	Direct	Holder No.93	-	-	GW5	
LA1	LA1 Screening Reagent	-	2 mL	-	Direct	Holder No.93	-	-	GW5	
LA2	LA2 Confirmation Reagent	-	1 mL	-	Direct	Holder No.93	-	-	GW5	
TT	Test Thrombin	-	5 mL	-	Direct	Holder No.93	-	-	GW5	
Detergent	CA CLEAN I	-	50 mL	Direct	-	-	-	Direct	Attached	
	CA CLEAN II	-	500 mL /5 L	Transfer to PV-10. Holder No.99	-	-	-	Transfer to PV-10. Holder No.99	PV-10 (Transfer)	
Owren's Veronal Buffer		-	500 mL	-	-	-	-	Transfer to PV-10. Holder No.99	PV-10 (Transfer)	

-: Not applicable, ×: Insertion impossible

8.3 Reagent Set Position List (Chromogenic Method / Immunoassay Method)

Parameter	Product name	Description	Volume	Rack Holder			Container type	Remarks
				A 36 X 2 OD D 24 X 14 OD E -	B 24 X 10 OD	C 31 X 10 OD		
ATIII	Berichrom° Antithrombin III (A) Reagent	Thrombin Reagent	15 mL	-	×	Direct	GW15	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
		Substrate Reagent	3 mL	-	Direct	Holder No.93	GW5	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
α2PI	Berichrom° α2-Antiplasmin Reagent	Plasmin (human)	5 mL	-	Direct	Holder No.93	GW5	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
		Substrate Reagent	2 mL	-	Direct	Holder No.93	GW5	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
Plg	Berichrom° Plasminogen Reagent	Storeptkinase Reagent	5 mL	-	Direct	Holder No.93	GW5	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
		Substrate Reagent	2 mL	-	Direct	Holder No.93	GW5	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
PC	Berichrom° Protein C Reagent	Protein C Activator	10 mL	-	×	Direct	GW15	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
		Substrate Reagent	3 mL	-	Direct	Holder No.93	GW5	
				-	Transfer to Sample Cup 4 mL. Holder No.98	Transfer to Sample Cup 4 mL. Holder No.97	Sample Cup 4 mL (Transfer)	
DD	D-Dimer PLUS Reagent* Advanced D-Dimer**	D-Dimer Reagent	4 mL	-	Direct	Holder No.93	GW5	
DDi	**INNOVANCE°** D-Dimer	DDi.DIL	5 mL	-	Direct - Positions D2, D4, D6, D8, D10, D12	-	GW5	
		DDi.SUP	2.6 mL	-	Direct	Holder No.93	GW5	
		DDi.BUF	5 mL	-	Direct	Holder No.93	GW5	
		DDi.REA	4 mL	-	Direct	Holder No.93	GW5	
vWF	von Willebrand Factor Antigen (vWF Ag)*	vWF Buffer	5 mL	-	Direct	Holder No.93	GW5	
		vWF Latex Reagent	6 mL	-	Direct	Holder No.93	GW5	1)
Heparin	Berichrom° Heparin	AT III Reagent	1 mL	-	Direct	Holder No.93	GW5	
		Factor Xa Reagent	10 mL	-	×	Direct	GW15	
		Substrate Reagent	2 mL	-	Direct	Holder No.93	GW5	
Factor VIII	Factor VIII Chromogenic Assay	Factor X Reagent	3 mL	-	Direct	Holder No.93	GW5	2)
		Factor IXa Reagent	3 mL	-	Direct	Holder No.93	GW5	3)
		Substrate Reagent	8 mL	-	×	Direct	GW15	4)

-: Not applicable, ×: Insertion impossible

* Not available in the USA
** Available for use only in the USA.
1) Consists of 2 mL Latex Reagent + 4 mL Diluent for Latex Reagent
2) Consists of Factor X Reagent + 3 mL water.
3) Consists of Factor IXa Reagent + 3 mL water.
4) Consists of Substrate Reagent + 1 mL water + 7 mL Stopping Buffer.

8.4 Reagent Set Position List (Plasma / Standard Plasma)

Parameter	Product name		Rack Holder		Container type	Remarks
		Volume	A 36 X 2 OD B 24 X 10 OD C 31 X 10 OD E 36 X 3 OD	D 24 X 14 OD		
FII	Factor-II Deficient Plasma	1 mL	-	Direct	GW5 (*)	
FV	Factor-V Deficient Plasma	1 mL	-	Direct	GW5 (*)	
FVII	Factor-VII Deficient Plasma	1 mL	-	Direct	GW5 (*)	
FX	Factor-X Deficient Plasma	1 mL	-	Direct	GW5 (*)	
FVIII	Factor-VIII Deficient Plasma	1 mL	-	Direct	GW5 (*)	
FIX	Factor-IX Deficient Plasma	1 mL	-	Direct	GW5 (*)	
FXI	Factor-XI Deficient Plasma	1 mL	-	Direct	GW5 (*)	
FXII	Factor-XII Deficient Plasma	1 mL	-	Direct	GW5 (*)	
DD	D-Dimer Accelerator	5 mL	-	Direct	GW5 (*)	
Standard Calibrator	Standard Human Plasma	1 mL	-	Direct	GW5 (*)	
	PT Calibration Plasma Kit	1 mL	-	Direct	GW5 (*)	
	Fibrinogen Standard	0.5 mL	-	Transfer to Sample Cup 4 mL. Holder No.98	Sample Cup 4 mL (Transfer)	
	D-Dimer Standard Plasma	1 mL	-	Transfer to Sample Cup 4 mL. Holder No.98	Sample Cup 4 mL (Transfer)	
	INNOVANCE° D-Dimer Calibrator	1 mL	-	Transfer to Sample Cup 4 mL. Holder No.98	Sample Cup 4 mL (Transfer)	
Control	Ci-Trol® Control Level 1	1 mL	-	Direct	GW5 (*)	
	Ci-Trol® Control Level 2	1 mL	-	Direct	GW5 (*)	
	Ci-Trol® Control Level 3	1 mL	-	Direct	GW5 (*)	
	Control Plasma N	1 mL	-	Direct	GW5 (*)	
	Control Plasma P	1 mL	-	Direct	GW5 (*)	
	Control Plasma U	1 mL	-	Direct	GW5 (*)	
	D-Dimer Control Plasma I	1 mL	-	Direct	GW5 (*)	
	D-Dimer Control Plasma II	1 mL	-	Direct	GW5 (*)	
	INNOVANCE° D-Dimer Control Plasma 1	1 mL	-	Direct	GW5 (*)	
	INNOVANCE° D-Dimer Control Plasma 2	1 mL	-	Direct	GW5 (*)	

-: Not applicable
* In the instrument equipped with CP Unit (Cap Piercer Unit), it is necessary to pool two or more vials of reagent in order to meet the extra reagent volume requirement as described in *Chapter 2, Section 4.1: Preparing Reagents.*

CHAPTER 7 QUALITY CONTROL

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8. QUALITY CONTROL SETTINGS 7-24

1. INTRODUCTION

Quality control is implemented to ensure that highly reliable data is obtained over the long term and to constantly monitor instrument and reagent system conditions to prevent inaccurate results from being reported.
The CA-1500 analyzes control plasma and other samples (quality control samples) and statistically manages the results.

1.1 Quality Control File

The CA-1500 can maintain 20 quality control files (QC01 - QC20), with each file capable of saving up to 540 items of data. Up to 25 analysis parameters can be saved per file.

NOTE:

- To enable simultaneous quality control of both the current and new lots when quality control sample lots are switched, quality control files QC01 to QC10 are used for the current control, and the remaining QC11 to QC20 files are used to evaluate the new lots. When quality control files QC11 to QC20 are used, make sure to set the reagent name, lot number, expiration date, and file number on the Reagent Information Setting screen. See *Chapter 11, Section 5.1: Reagent Information Settings.*
  Quality control files QC01 to QC10 and QC11 to QC20 are related in order and can be simultaneously displayed on the screen. See *Section 4.2: Switching between Current and New Lots* in this chapter.

1.2 Quality Control Analysis

When a quality control analysis is performed, the quality control sample is placed into a sample rack or reagent holder and the subsequent procedure is the same as that for an ordinary analysis. The quality control file number (QC01 to QC20) is registered as the sample ID number. Also, the system will be automatically set in the Micro-sample Mode (see *Chapter 3, Section 2.2: Contents Displayed on Work Load List Screen, (J).*) in the quality control analysis.

CAUTION

- When a cap piercer unit is installed, the quality control analysis cannot be performed in the sample tubes with the cap. Analyze after manually removing the cap.

Quality control analyses can also be executed automatically at regular intervals. For details, see *Chapter 2, Section 7: QUALITY CONTROL* and *Section 8: QUALITY CONTROL SETTINGS* in this chapter.
In addition, the two quality control methods listed below are available. They can be selected by setting the number of analysis replications.

$\bar{X}$ control: Uses the average of two consecutive analyses made on a QC sample.

L-J control: Uses the data from a single analysis made on a QC sample. With L-J control, the range of control is easily affected by the reproducibility of analysis; thus, the range is wider than that of $\bar{X}$ control.

CAUTION:
- Use the quality control samples and reagents in accordance with the usage methods described in the package insert accompanied in each control material.

NOTE:
- The following setup is required when reagent holders are used during quality control analyses:
- Set up the quality control samples and applicable file numbers for the reagent information.
  See *Chapter 11, Section 5.1: Reagent Information Settings.*
- Place the quality control samples in reagent positions D1 to D14.
  See *Chapter 11, Section 5.7: Reagent Position Settings.*

1.3 QC Error Check

To check quality control errors, you can choose from either a Control Limit method or Multi Rule method.

Control Limit Method
Error checks are made based on control limits that are set (shown in the table below).

Control Limit	Error Check Method/Action
Upper Stop	If a quality control analysis result exceeds this value, an error is generated and the CA-1500 will stop analyzing.
Upper Flag	If a quality control analysis result exceeds this value, a QC error is generated.
Target	This is the target value for the quality control analysis.
Lower Flag	If a quality control analysis result is below this value, a QC error is generated.
Lower Stop	If a quality control analysis result is below this value, an error is generated and the CA-1500 will stop analyzing.

Multiple Rule Method
With the Multi Rule method of Westgard (rule), QC checks are made based on the mean (average) value and the standard deviation (SD) that are set.

Mean: Target of quality control analysis
SD: Information for checking error (regarded as standard deviation)

Rule	Error Check Method
1-2s	The result of 1 quality control analysis exceeded ±2SD limit.
1-3s	The result of 1 quality control analysis exceeded ±3SD limit.
2-2s	The result of 2 consecutive quality control analyses exceeded ±2SD limit.
4-1s	The result of 4 consecutive quality control analyses exceeded ±1SD limit.
R-4s	The difference between this result and the previous quality control analysis result exceeds 4SD.
10x	The results of 10 consecutive quality control analyses all deviated to the same side of the average.

Action taken for each rule can be set individually.

2. QC CHART DISPLAY

2.1 Displaying a QC Chart

If you press the [QC] key from the Main Menu screen, the Quality Control screen will appear. The Quality Control screen can simultaneously display the QC charts of 3 files. Each QC chart displays the data from the latest 60 data points. If you press the [Change Scale] key, you can view the latest 180 data points. Monthly means (averages) can also be displayed.

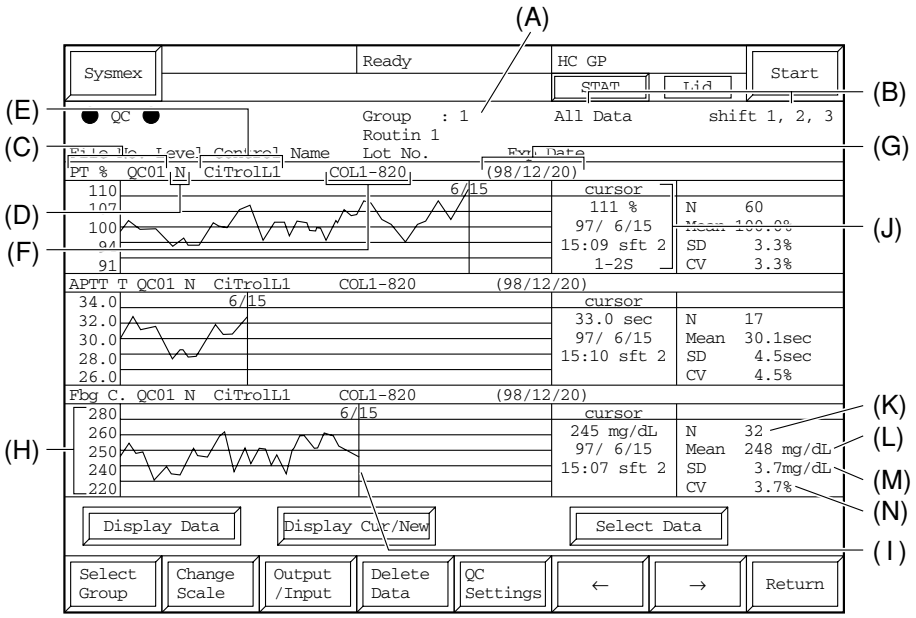

Figure 7-2-1: Quality Control Screen

Contents Displayed on Quality Control Screen

(A) Display Group: The number and name of the group is displayed.

(B) Display Data: The type of data being displayed appears. To change the type of data, press the [Select Data] key.

(C) File No.: The QC control parameter and file number are displayed.

(D) Level: The level of the quality control sample is displayed. The level can be selected for each sample at the user's discretion.

(E) Control Name: The name of the quality control sample is displayed.

(F) Lot No.: The lot number of the quality control sample is displayed.

(G) Exp. Date: The expiration date of the quality control sample is displayed.

(H) Scale: If the Control Limit method is used to check quality control errors, the upper stop, upper flag, target, lower flag, and lower stop limits will be listed in order.
If the Multiple Rule method is used, the mean +3SD, mean +2SD, mean, mean -2SD, and mean -3SD will be listed in order.

(I) Cursor Position: The displayed control data are indicated.
Use the [←] and [→] keys to move the cursor left or right.

(J) Cursor: The control data that corresponds to the cursor position is displayed. The analysis data (calculation data), date/time analyzed, shift classification, and error information codes are displayed.
If monthly means are displayed, the date/time analyzed will be the month in which the analysis was performed.
An error information code will be displayed when an error has been detected by the QC error check. The codes shown below will be displayed when applicable.

Control Limit Method

Code	Meaning of Error
S.U.L.	The quality control analysis result exceeded the "upper stop" limit.
U.L.	The quality control analysis result exceeded the "upper flag" limit.
L.L.	The quality control analysis result fell below the "lower flag" limit.
S.L.L.	The quality control analysis result fell below the "lower stop" limit.

Multiple Rule Method

Code	Meaning of Error
1-2s	One quality control analysis result exceeded ±2SD limit.
1-3s	One quality control analysis result exceeded ±3SD limit.
2-2s	Two consecutive quality control analysis results exceeded ±2SD limit.
4-1s	Four consecutive quality control analysis results exceeded ±1SD limit.
R-4s	The difference between this result and the previous quality control analysis result exceeded 4SD.
10x	The results of 10 consecutive quality control analyses all deviated to the same side of the average.

(K) N: Displays the number of control data specified.

(L) Mean: Displays the mean (average) of the control data specified.

(M) SD: Displays the standard deviation of the control data specified.

(N) CV: Displays the coefficient of variation of the control data specified.

NOTE:
- Data that is determined to be in error by the QC error check will be indicated by a red * point in the QC chart. If monthly means are shown, months that include erroneous data will be indicated by a red ∗ point.

Operating the Quality Control Screen Keys

To process an individual file out of the 3 files that are displayed, you have to first select a file. To select a file, press the screen where the QC chart is displayed.

[Select Group] key: Used to select the group of files to display on the QC screen.

(1) If you press the [Select Group] key, the Group Selection for Display screen will appear.

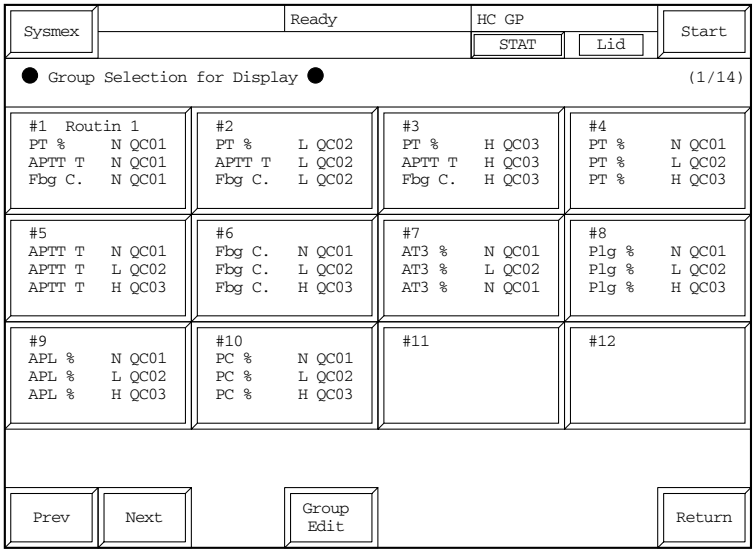

Figure 7-2-2: Group Selection for Display Screen

(2) Press the key for the file group you wish to display. If the key for the desired file group is not on the screen, press the [Prev] and [Next] keys to switch screens.

For details on how to set the display group, see *Section 2.2: Editing the Display Group* in this chapter.

[Change Scale] key: Alternately switches the QC chart scale between data for 60 points and 180 points.

[Output/Input] key: Used to print control data and QC charts, save data on floppy disks, and read saved data.

For details on printing, see *Section 5: OUTPUTTING QUALITY CONTROL DATA* in this chapter. For data saving, see *Section 6: READING QUALITY CONTROL DATA* in this chapter.

[Delete Data] key:	Used to delete unneeded quality control data. See *Section 7: DELETING QUALITY CONTROL DATA* in this chapter.
[QC Settings] key:	Used to set various kinds of information pertaining to quality control. See *Section 8: QUALITY CONTROL SETTINGS* in this chapter.
[←], [→] keys:	Used to move the cursor of the selected file in the direction of the arrow. If monthly means are displayed, the cursors for all files will move together.
[Display Data] key:	Used to display a list of the selected file's data. See *Section 3: QUALITY CONTROL DATA LIST DISPLAY* in this chapter.
[Display Current/New] key:	Used to simultaneously display the selected file and the QC chart of the same quality control sample of the current and new lots. See *Section 4: SWITCHING BETWEEN QUALITY CONTROL DATA OF CURRENT AND NEW LOTS* in this chapter.
[Select Data] key:	Used to switch between types of data displayed on the QC screen. See *Section 2.3: Selecting the Display Data* in this chapter.

2.2 Editing the Display Group

Register the files you wish to display on the QC screen as a display group.
Up to 160 types of display groups can be registered. To register, use the Display Group Editing screen.

1. Display Group Editing Screen

(1) Press the [Select Group] key on the QC screen. The Group Selection for Display screen will appear.

(2) Press the [Group Edit] key.
The Display Group Editing screen will appear.

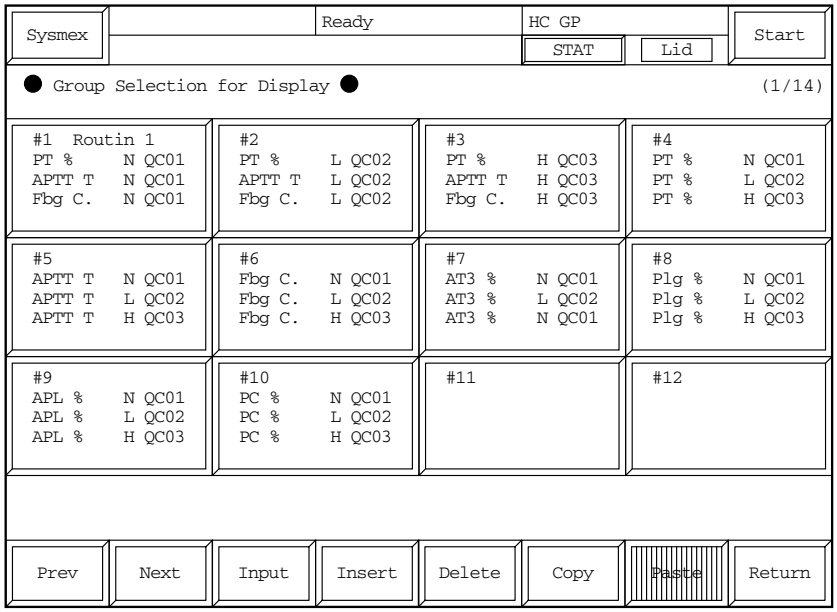

Figure 7-2-3: Display Group Editing Screen

Twelve display groups per screen will appear in order of display group number. If you press the [Prev] or [Next] key, the previous or next 12 display groups will appear. Registered file information will be displayed for groups that have already been registered.

2. New Registration and Modification of a Display Group

(1) From the Display Group Editing screen, press the key for the display group number you wish to set.

> **NOTE:** • If you wish to newly register a display group between display groups that are already registered, you can insert the display group. After pressing the key for the display group in the desired position, press the [Insert] key. The display groups that follow the inserted display group will move back one position each.

(2) Press the [Input] key.
The Display Group Input screen will appear.

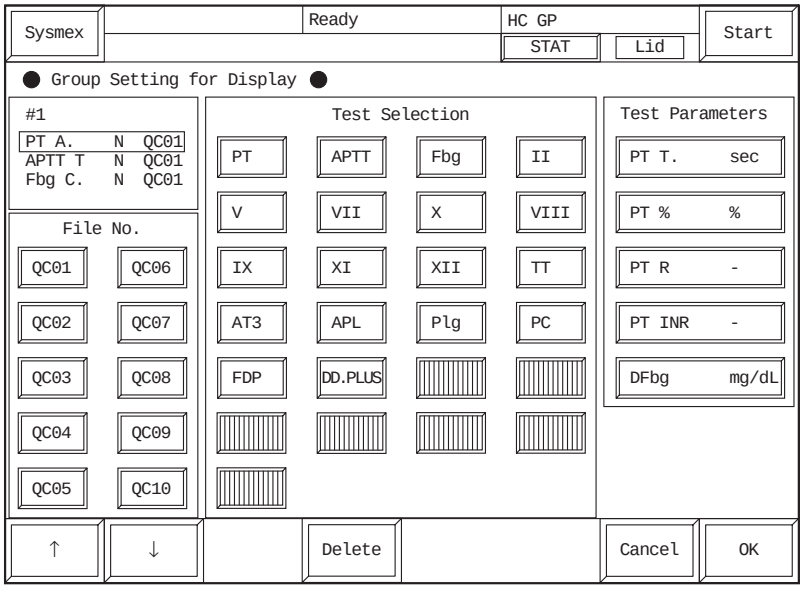

Figure 7-2-4: Display Group Input Screen

(3) Press the File Number and Test Parameter keys to select the files to display on the QC screen. QC01 to QC10 are available for the File Number.
The Test Parameter keys will change when the Test Selection keys are pressed.
Using the [↑] and [↓] keys, move the cursor and set the files of the upper, middle, and lower rows. Pressing the [Delete] key will delete a file that has been set.

(4) Enter the name of the display group.
If you use the [↑] key and move the cursor to the right of the display group number, the alphanumeric keys (which are used to enter display group name) will appear. Enter the name of the display group; then press the [ENTER] key.

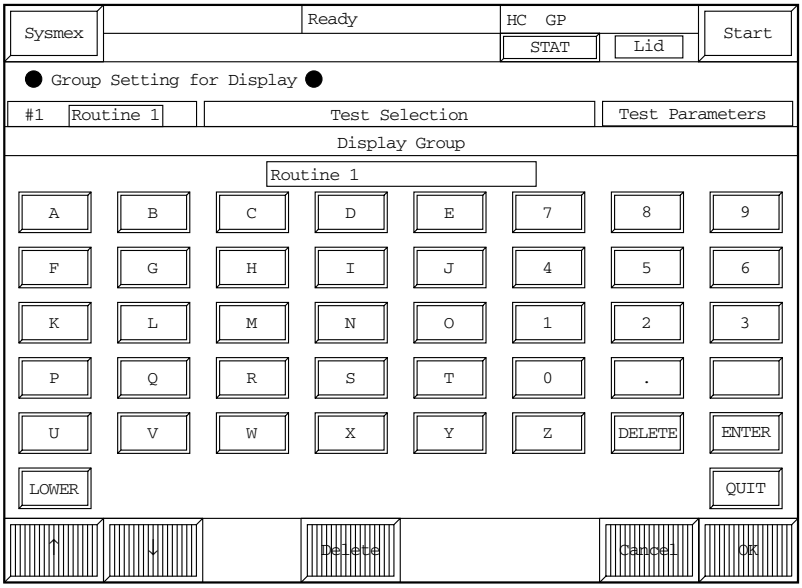

Figure 7-2-5: Entering the Display Group

(5) After setting is completed, press the [OK] key.
The modification or registration of the display group that was set will be performed, and the Display Group Editing screen will reappear.
If you press the [Cancel] key, the modification or registration will be canceled and the Display Group Editing screen will reappear.

CAUTION:
- QC11 to QC20 can not be used for the display group registration. For details on displaying QC11 to QC20, see *Section 4: SWITCHING BETWEEN QUALITY CONTROL DATA OF CURRENT AND NEW LOTS* in this chapter.

NOTE:
- When registering a display group whose setting is similar to that of a display group that is already registered, it is convenient to use the copy and paste function.
  Select the display group that is already registered, and press the [Copy] key. Then select the display group that is to be newly registered, and press the [Paste] key. The contents of the pasted display group will now be the same as the registered contents of the copied display group.

3. Deleting a Display Group

(1) From the Display Group Editing screen, select the display group you wish to delete by pressing its numbered key.

(2) Press the [Delete] key.
The selected display group will be deleted, and the display groups that follow the deleted display group will move forward one position each.

2.3 Selecting the Display Data

Specify the type of data to display on the QC screen.
You can choose between two types of data: "All Data" and "Monthly Means." And when shift operation is implemented, the time period of each shift can be specified.

(1) From the QC screen, press the [Select Data] key.
The Change Data to Display window will appear.

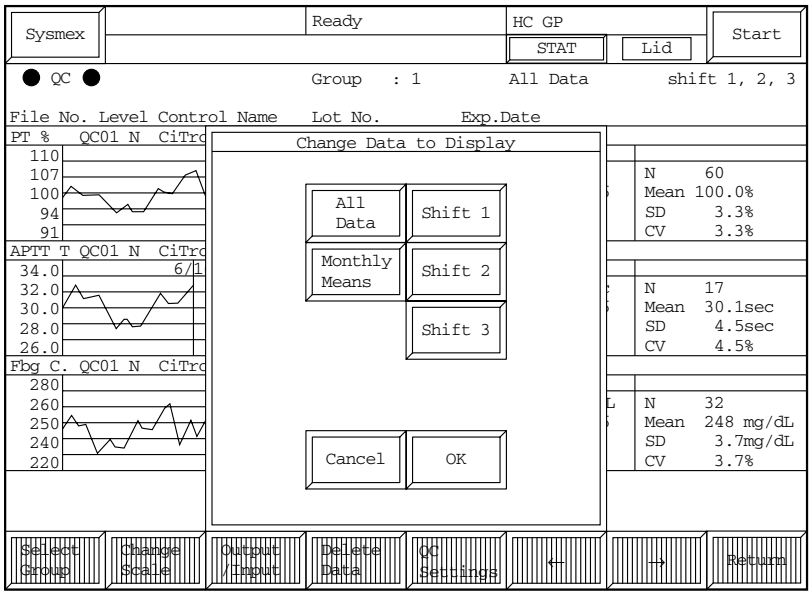

Figure 7-2-6: Change Data to Display Window

(2) Press either the [All Data] or [Monthly Means] key.

(3) Press the key for the time period of the shift.
You can specify multiple shift time periods.

(4) Press the [OK] key.
The QC charts for the specified type of data will appear.
Pressing the [Cancel] key will cancel the selection of display data.

3. QUALITY CONTROL DATA LIST DISPLAY

Display a list of the QC data.

(1) Select the file you wish to list on the QC screen.

(2) Press the [Display Data] key.
The List Display screen for the quality control data will appear. Data will be displayed in order from the oldest data, and the page containing the latest data will appear. To switch the display, press the [Prev] and [Next] keys.
The displayed content will differ depending on the type of data that is shown on the QC screen.

All Data Display

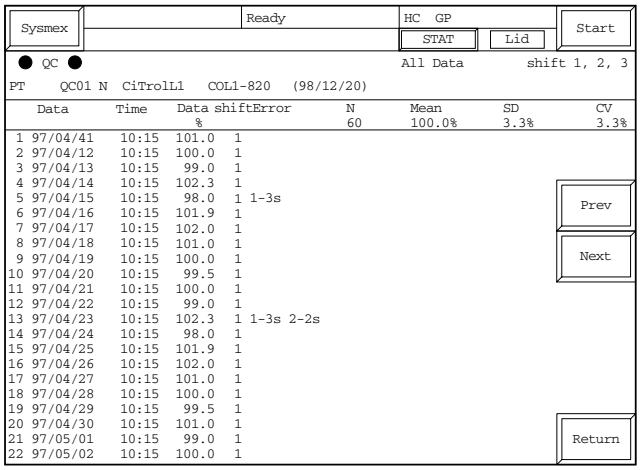

Figure 7-3-1: All Data Display Screen

Monthly Means Display

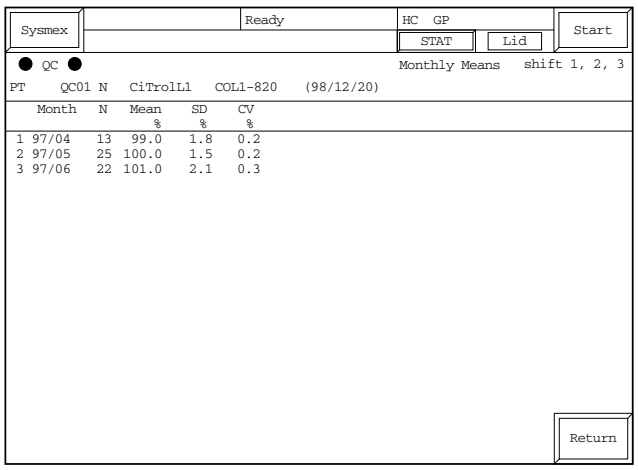

Figure 7-3-2: Monthly Means Display Screen

If you press the [Return] key, the QC screen will reappear.

4. SWITCHING BETWEEN QUALITY CONTROL DATA OF CURRENT AND NEW LOTS

When quality control sample lots are switched, the CA-1500 implements simultaneous quality control of both the current and new lots and also evaluates the new sample lot.
Of the 20 quality control files (QC01 - QC20), QC01 to QC10 are used for actual control, and QC11 to QC20 are used to evaluate the new lots. Quality control files QC01 - QC10 and QC11 - QC20 are accommodated in order and can be simultaneously displayed on the screen. Moreover, when switching to a new sample, you can easily replace all of the current sample's parameters.

4.1 Displaying the Current and New Lots

Using the QC screen, specify the file whose current and new lot data you wish to display; then press the [Display Cur/New] key. The current/new Lot Display screen will appear.
Data from the current sample will be displayed above the data from the new sample.

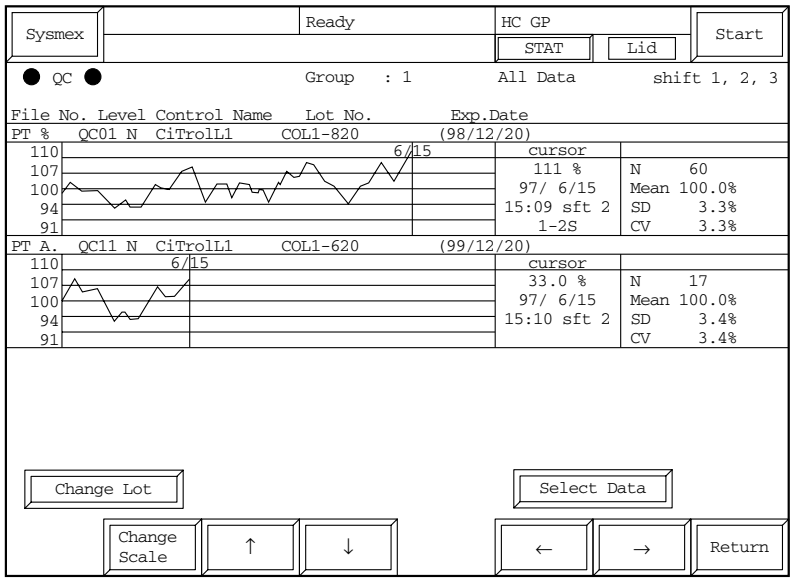

Figure 7-4-1: Current/New Lot Display Screen

Operating the Current/New Lot Display Screen Keys

[Change Scale] key: Alternately switches the QC chart scale between data for 60 points and 180 points.

[↑], [↓] keys: Used to display the control charts of preceding or following parameters that are within the same file.

[←], [→] keys: Used to move the cursor of the selected file in the direction of the arrow. If monthly means are displayed, the cursors for all files will move together.

[Return] key:	Stops the display of current and new lots and then displays the QC screen.
[Change Lot] key:	Shifts quality control sample to the new lot. See *Section 4.2: Switching between Current and New Lots* in this chapter.
[Select Data] key:	Used to switch between types of data displayed on the Current/New Lot Display screen. Operation is same with the [Select Data] key on the QC screen. See *Section 2.3: Selecting the Display Data* in this chapter.

4.2 Switching between Current and New Lots

(1) From the Current/New Lot Display screen, press the [Change Lot] key.
The Lot Change Confirmation window will appear.

(2) Press the [OK] key.
The lot change will be executed, the file for the current lot will be deleted, and the file number for the new lot will replace the file number for the current lot.
If you press the [OK] key, the file number settings for reagent information will be also changed. For details, see *Chapter 11, Section 5.1: Reagent Information Settings.*
Pressing the [Quit] key will stop the lot change operation.

5. OUTPUTTING QUALITY CONTROL DATA

The QC file control data and control charts can be printed out on an optional graphic printer, and the control data can be saved on a floppy disk.

(1) Select the data to be output.
The data to be output will be the type of data that is being displayed on the QC screen. See *Section 2.3: Selecting the Display Data* in this chapter, and select the data to output.

(2) From the QC screen, press the [Output/Input] key.
The QC External Input/Output screen will appear.

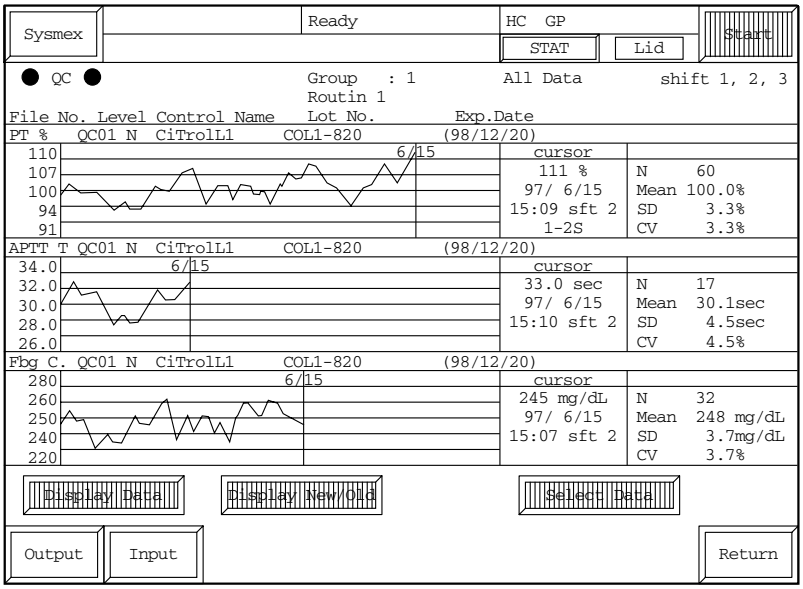

Figure 7-5-1: QC External Input/Output Screen

(3) Press the [Output] key.
The QC Output Selection screen will appear.

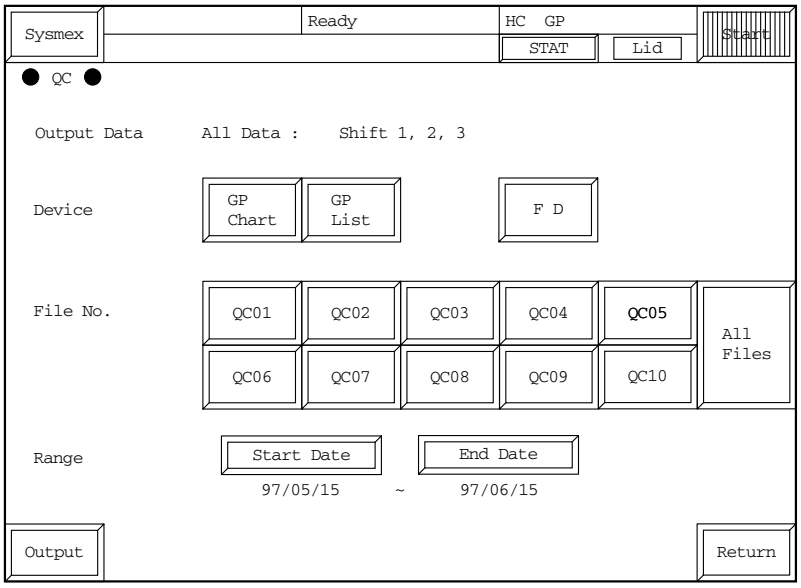

Figure 7-5-2: QC Output Selection Screen

(4) Press the "Device" key.

[GP Chart] key: Activates the graphic printer to print the control chart from the specified file.

[GP List] key: Activates the graphic printer to print the control data from the specified file.

[FD] key: Sends the control data from the specified file onto a floppy disk for storage.

(5) Press the file number key for the file you wish to output.

[QC01] to [QC10] keys: Used to select the file and corresponding evaluation file to be output.

[All Files] key: Outputs files that are used for actual control (QC01 - QC10) and corresponding files that are used for evaluation.

(6) If the output data is "All Data", set the output range by date.
[Start Date] key: Used to set the start date of the data to be output.

[End Date] key: Used to set the end date of the data to be output.

If you press the [Start Date] and [End Date] keys, the numeric keys for entering the respective date will appear.

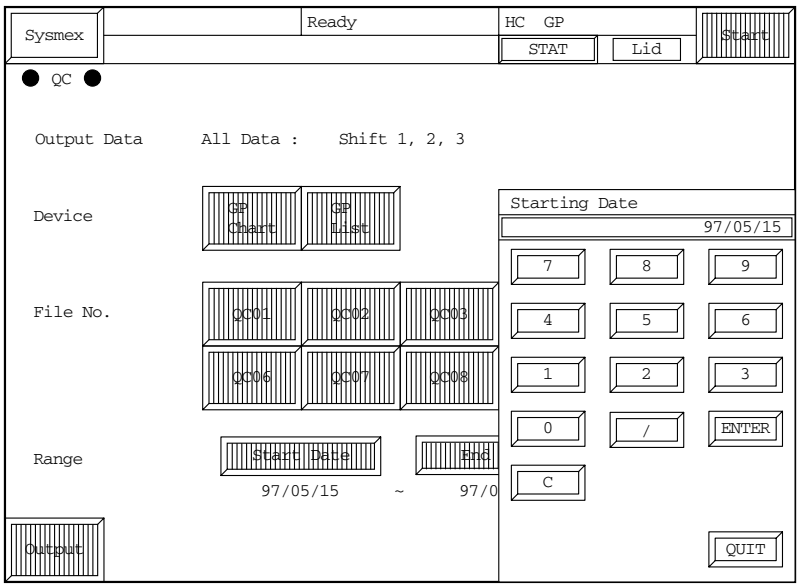

Figure 7-5-3: Setting the Output Range

Enter the date (xx/xx/xx); then press the [ENTER] key.

(7) Press the [Output] key.
External output will start and a message window will appear that indicates outputting is in progress.
To save data on a floppy disk, see "Saving Data on a Floppy Disk" below.
If you press the [Quit] key, outputting will stop.

Saving Data on a Floppy Disk

(1) If you press the [Output] key, the FD Save Confirmation window will appear.

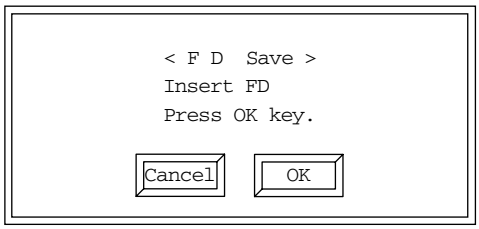

Figure 7-5-4: FD Save Confirmation Window

(2) Insert a floppy disk into the floppy disk drive.
To cancel the saving of data, press the [Cancel] key.

CAUTION:
- If the quality control file you wish to save already exists on the floppy disk, it will be overwritten when saving is executed. A message will appear asking if it is OK to overwrite the current data. If it is OK to overwrite the data, press the [OK] key; and if you wish to cancel saving, press [Cancel].

(3) Press the [OK] key.
The floppy disk will be overwritten, and will then return to the QC External Input/Output screen.
If the capacity of the inserted floppy disk is insufficient, a message window will appear. If that happens, insert a new floppy disk and press the [OK] key.

6. READING QUALITY CONTROL DATA

Read the quality control data that is stored on the floppy disk.

(1) From the QC screen, press the [Output/Input] key.
The QC External Output/Input screen will appear.

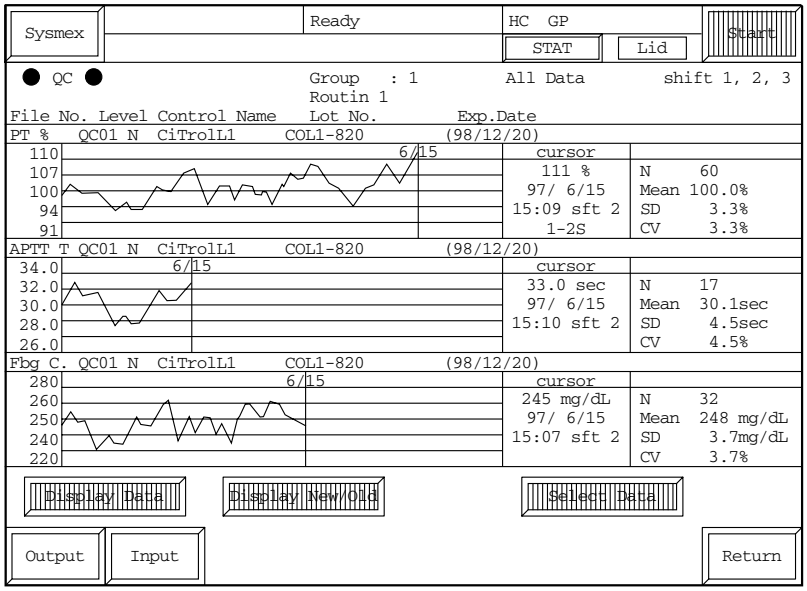

Figure 7-6-1: QC External Output/Input Screen

(2) Press the [Input] key.
The Confirmation window will appear.

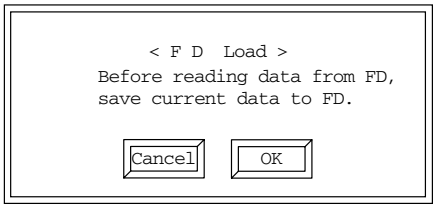

Figure 7-6-2: Confirmation Window

(3) To read data from the floppy disk, press the [OK] key.
Then, the FD Load Confirmation window will appear.

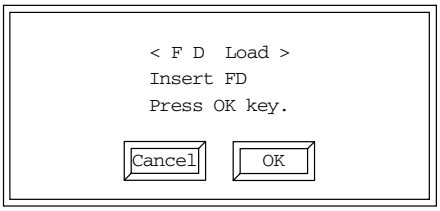

Figure 7-6-3: FD Load Confirmation Window

(4) Insert the floppy disk into the floppy disk drive, and press the [OK] key.
The contents of the floppy disk will be checked, and a "Loading..." message will appear.
If an error occurs, such as the inserted floppy disk containing no quality control data, a message will appear. Insert the correct floppy disk and press the [OK] key.
After the contents have been checked, the QC Input Selection screen will appear.

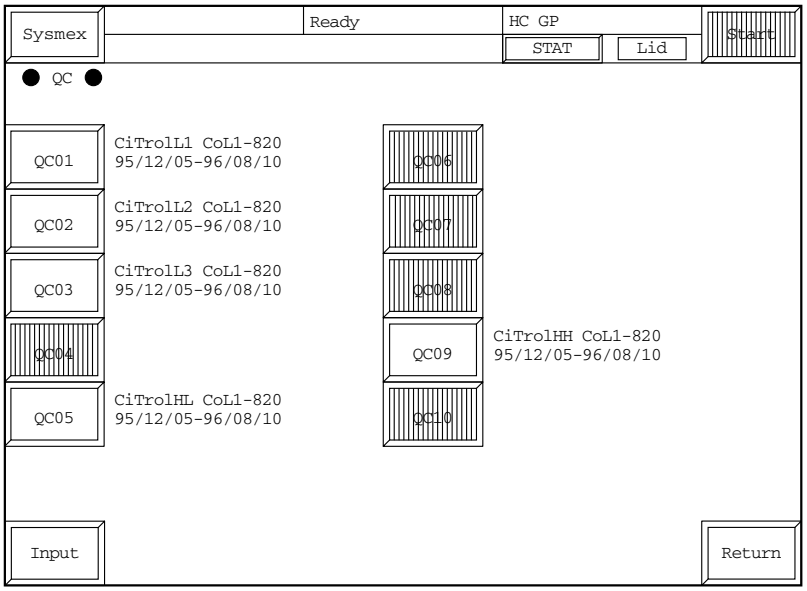

Figure 7-6-4: QC Input Selection Screen

To the right of the file number keys will appear quality control data that is saved on the floppy disk, including the control name, lot number, and range of the control data.

(5) To make a selection, press the file number key for the file you wish to read (input).

(6) Press the [Input] key.
Reading will begin and a "Reading" message will appear.
If you press the [Quit] key, reading will be canceled.

CAUTION:
- If the quality control data you wish to read already exists, it will be overwritten when reading is executed.
  A message will appear asking if it is OK to overwrite the current data. If it is OK to overwrite the data, press the [OK] key; and if you wish to discontinue, press [Quit] key.

After reading is completed, a QC chart will appear, showing the data that has been read.

7. DELETING QUALITY CONTROL DATA

Quality control data which is no longer needed can be deleted.
You can select the data you wish to delete through one of the following methods:

- [Delete None Data] key:
  Deletes all control data, with analysis error, contained in all the files.

- [Delete All Data] key:
  Deletes all control data from one file that is shown on the QC screen.

- [Delete Data] key:
  Deletes the control data, by specifying a range, in one file that is shown on the QC screen.

To delete data, press the [Delete Data] key on the QC screen and use the Delete Data sub menu.

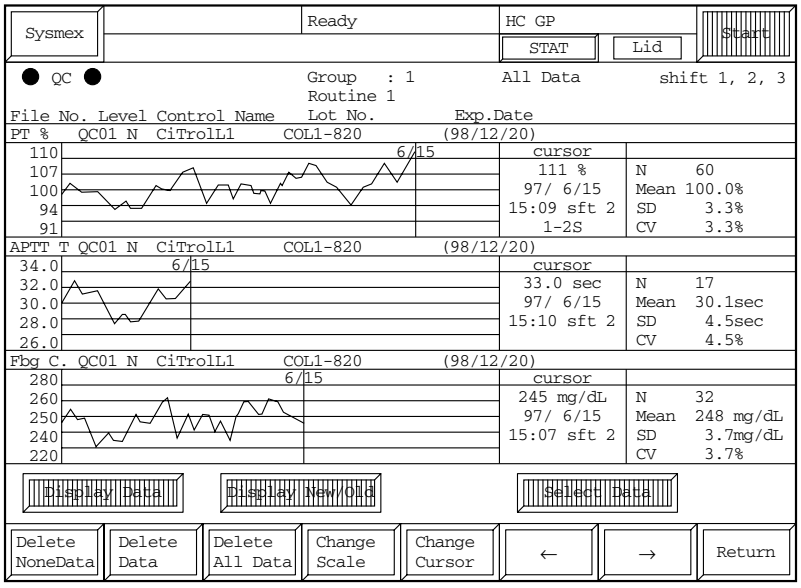

Figure 7-7-1: Deleting QC Data

7.1 Deleting Control Data with Analysis Errors

CAUTION: • Data that has been deleted cannot be recovered. Carefully verify before deleting data.

(1) From the Delete Data sub menu on the QC screen, press the [Delete None Data] key.
A confirmation message window will appear.

(2) Press the [OK] key.
All control data, with analysis error, contained in all the files will be deleted.
To stop deleting, press the [Quit] key.

7.2 Deleting All Control Data from One File

CAUTION: • Data that has been deleted cannot be recovered. Carefully verify before deleting data.

(1) Display the QC chart of the control data you wish to delete.
See *Section 2: QC CHART DISPLAY* in this chapter.

(2) Press the displayed part of the QC chart you wish to delete, to select the file.

(3) Display the Delete Data sub menu.

(4) Press the [Delete All Data] key.
A confirmation message window will appear.

(5) Press the [OK] key.
All control data in the selected file displayed will be deleted.
To stop deleting, press the [Quit] key.

7.3 Deleting Control Data within a Specified Range

CAUTION:	• Data that has been deleted cannot be recovered. Carefully verify before deleting data.

(1) Display the QC chart of the control data you wish to delete.
See *Section 2: QC CHART DISPLAY* in this chapter.

(2) Press the displayed part of the QC chart you wish to delete to select the file.

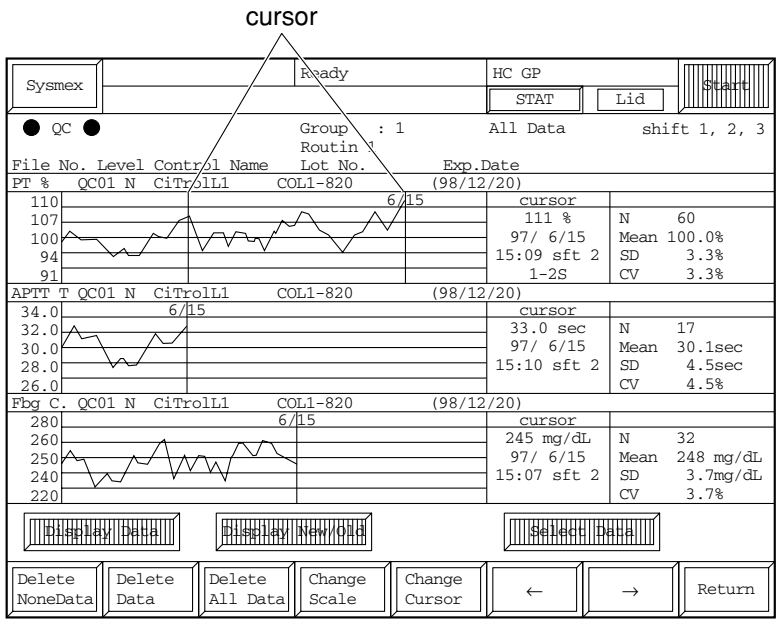

Figure 7-7-2: Specifying the Range

(3) Display the Delete Data sub menu.

(4) Using the cursors, specify the range you wish to delete.
To specify the range, two cursors will be displayed. Pressing the [Change Cursor] key will change the active cursor, and pressing the [←] and [→] keys will move them left and right. The data that is within the range indicated by the two cursors will be targeted for deletion.

(5) Press the [Delete Data] key.
A confirmation message window will appear.

(6) Press the [OK] key.
The control data that is within the specified range will be deleted.
To stop deleting, press the [Quit] key.

8. QUALITY CONTROL SETTINGS

Enter the various settings that pertain to quality control.

To select the file whose quality control data you wish to set, press the displayed part of the control chart on the QC screen; then press the [QC Settings] key.
The QC Settings screen for the selected file will appear.

QC Error Check by Control Limit Method

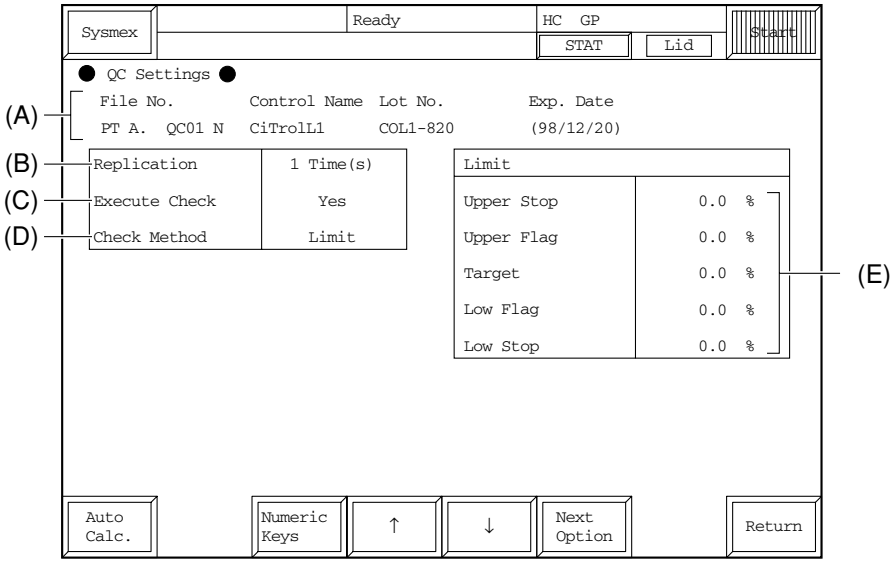

Figure 7-8-1: QC Settings Screen (for Limit)

QC Error Check by Multiple Rule Method

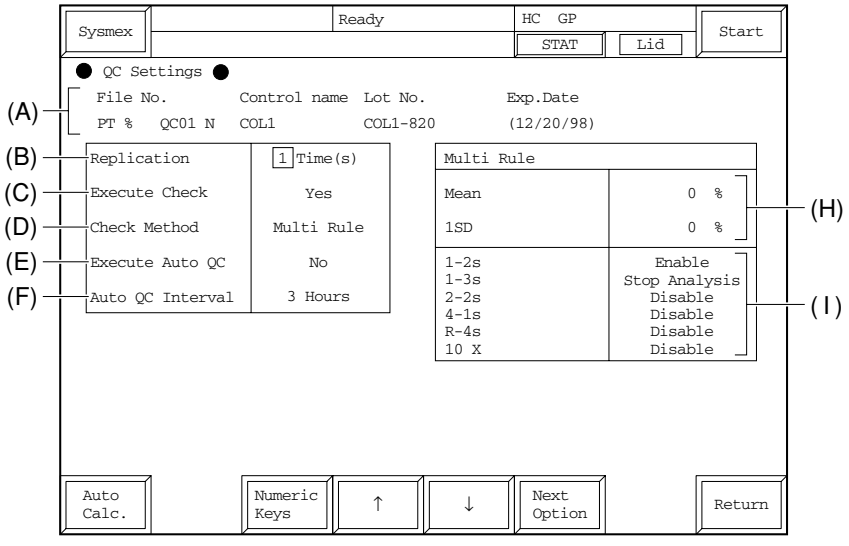

Figure 7-8-2: QC Settings Screen (for Multi Rule)

Contents Displayed/Set on QC Settings Screen

Parameter (A) shows information that is set through the control plasma reagent information setting.
Parameters (B) through (G) show information that is currently set with this screen.

	Displayed/Set Parameters	Meaning	Setting Range
(A)	QC file information	Control parameters, file number, level, reagent name, lot number, and expiration date of quality control sample are displayed.	-
(B)	Replications	Sets the quality control replications.	1 or 2 times
(C)	Execute Check	Sets whether QC error check will be executed.	Yes/No
(D)	Check Method	Sets the QC error check method when such check are to be executed.	Limit/Multiple Rule
(E)	Execute Auto QC	Sets whether QC analysis will be executed automatically.	Yes/No
(F)	Auto QC Interval	Sets the time to execute QC analysis automatically.	1 to 24 hours (by 1 hour)
(G)	Limit	Sets the control limits for making QC check.	Range of control parameter data
(H)	Mean/SD	Sets the mean and standard deviation for making QC check.	Range of control parameter data
(I)	Multi Rule	Sets the action to take when an error is detected during error check.	*

* Select from the following, actions to take for each Multiple Rule check.

- Disable: Error check will not be made.
- Enable: Error message will be displayed, but analysis will continue.
- Stop Analysis: Error message will be displayed and analysis will be interrupted.

Operating the QC Settings Screen Keys

[Auto Calc.] key: Executes calculations based on control data that is stored in the file, and automatically sets the following parameters:

- Control limits from Control Limit method
  Upper stop: Target + 3SD*
  Upper flag: Target + 2SD*
  Target: Mean of all control data
  Lower flag: Target - 2SD*
  Lower stop: Target - 3SD*
  *SD indicates one standard deviation of all control data.
- Mean and SD from Multiple Rule method
  Mean: Mean (average) of all control data
  SD: Standard deviation of all control data

[↑], [↓] keys: Used to move the cursor to select a setting item.

[Next Option] key: Press this key to switch to the order setting option for "Replications", "Execute Check", "Check Method" and "Multi Rule."

Setting with the Numeric Keys

If you do not use the [Auto Calc.] key to set the control limits (Control Limit method) or mean and standard deviation (Multiple Rule method), use the numeric keys to enter and set the information. When the cursor is moved to a setting parameter, "Numeric" key will be displayed. Press the [Numeric] key, and the numeric keys will appear.

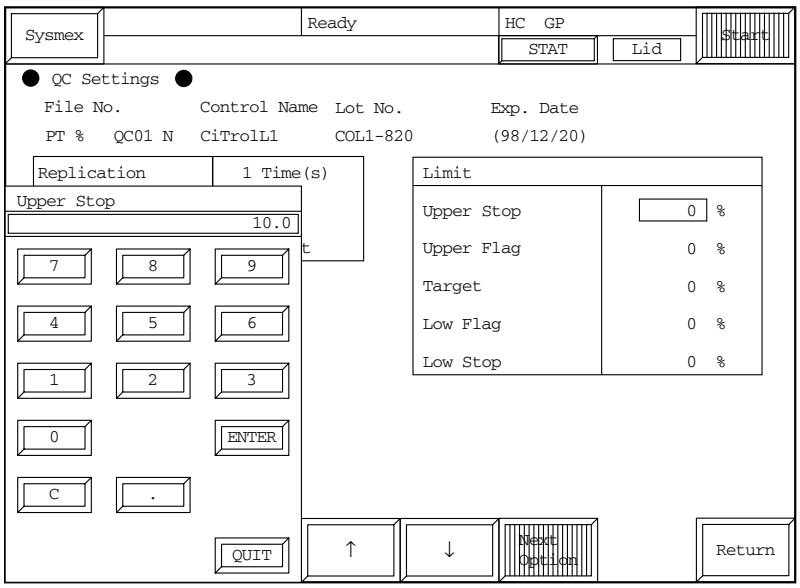

Figure 7-8-3: Setting with the Numeric Keys

Enter the setting; then press the [ENTER] key. If you press the [QUIT] key, the setting will not change.

To Quit Setting

After completing the settings, press the [Return] key.
If the setting was changed, the Update Confirmation window will appear. Press the [Continue], [OK], or [Cancel] key.

[Continue] key:	Used to continue quality control settings.
[OK] key:	Updates the currently set contents and returns the system to the QC screen.
[Cancel] key:	Cancels the currently set contents and returns the system to the QC screen.

CHAPTER 8 SETTING STANDARD CURVES

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1. INTRODUCTION

A standard curve is a parameter that is used to calculate the calculation parameters based on analysis results such as coagulation time and difference in the optical density (dOD).

A standard curve can be prepared by means of the following methods:

- Manual input: Parameters are entered via numeric keys.
- Automatic dilution and analysis: One type of calibrator is analyzed through automatic dilution and analysis, and each parameter is automatically calculated.
- Manual dilution and analysis: Several types of calibrators from the same series which were previously assayed to their activity or concentration, and each parameter is automatically calculated.

2. DISPLAYING STANDARD CURVES

2.1 Displaying the Standard Curve Screen

If you press the [Standard Curve] key on the Main Menu screen, the Standard Curve screen will appear. The Parameter Selection window will also appear, allowing you to select a parameter to display.

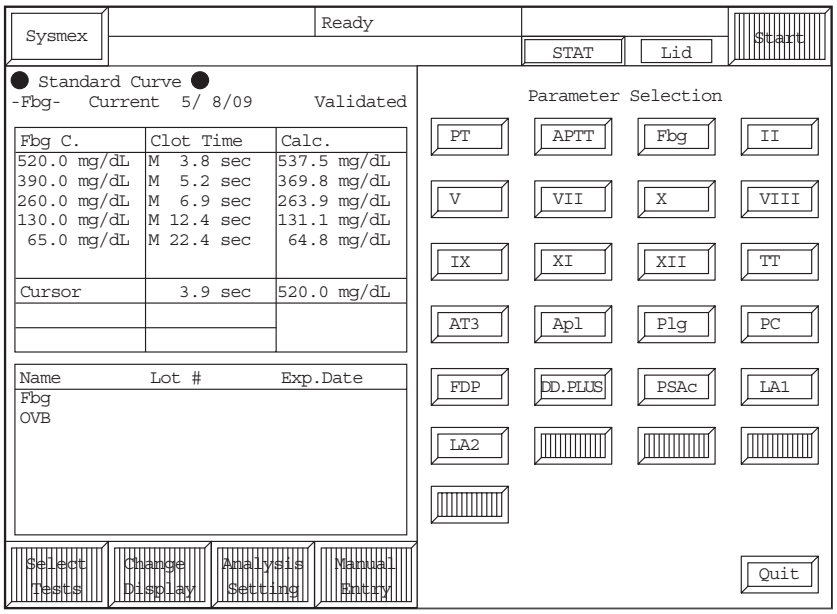

Figure 8-2-1: Standard Curve Screen

If you press the key for a parameter you wish to display, the standard curve will appear. When you reset a parameter whose standard curve has already been prepared, you can separately or simultaneously display the existing (current) standard curve and the (new) standard curve that you are newly setting. To switch the display, press the [Change Display] key.

Separate Display

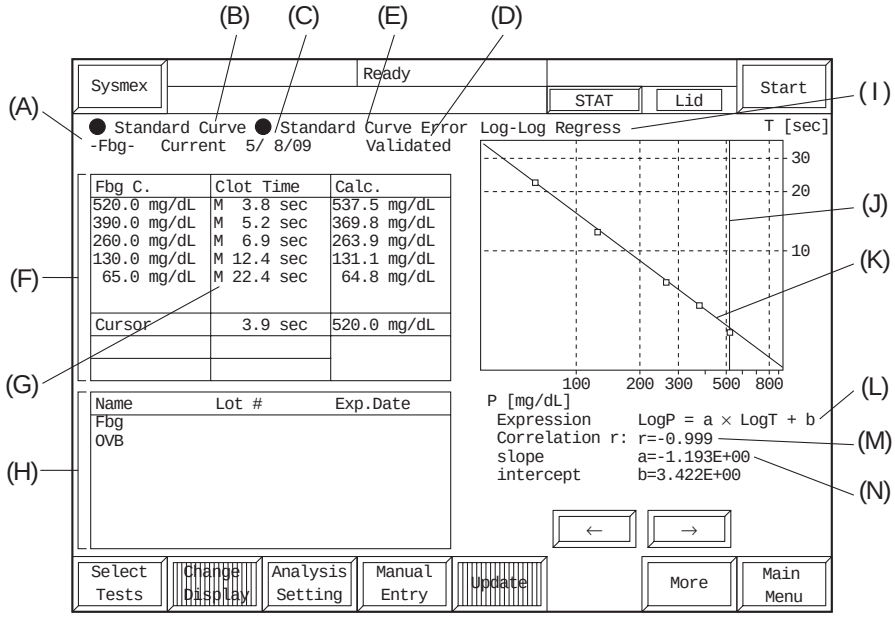

Figure 8-2-2: Standard Curve (Current)

Simultaneous Display

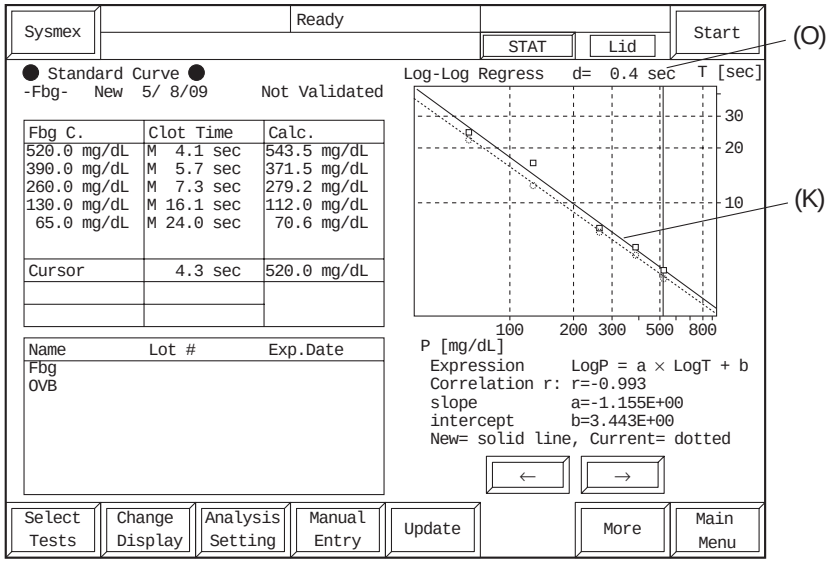

Figure 8-2-3: Standard Curve (Current & New)

Contents Displayed on Standard Curve screen

(A) Parameter: Name of analysis parameter is displayed.

(B) Standard curve type: If the standard curve being displayed is the existing (current) standard curve, "Current" will appear. If it is the new standard curve, "New" will appear. And if the current and new standard curves are being displayed together, "New" will appear.

(C) Date updated: Date that the standard curve was set is displayed.

(D) Validation information: If the standard curve is one that has been accepted, "Validated" will appear. If the standard curve is one that has not been accepted, "Not Validated" will appear.

(E) Standard curve error information: If it cannot be used as a standard curve, "Standard Curve Error" will appear. A standard curve cannot be used in the following cases:

- Analysis data does not increase constantly in relation to activity percent or concentration.
- Analysis data does not decrease constantly in relation to activity percent or concentration.
- Only one point of standard curve data is set.

(F) Standard curve data:

- Analysis data: Displays coagulation time or dOD for the points that are set as standard curve data. For calculated value, displays activity percent or concentration that is calculated from the standard curve.
- Current: Displays coagulation time or dOD at the cursor position on the standard curve graph.
- Normal: Displays normal value used to calculate ratio.
- ISI: Displays ISI (International Sensitivity Index) used to calculate INR (International Normalized Ratio).

* For a simultaneous display, new standard curve data is displayed.

(G) Manual input flag: "M" is displayed when standard curve data is manually input.

(H) Reagent information: Displays information (name, lot number, and expiration date) pertaining to reagents, calibrator, and other elements that are used to analyze standard curve data.

(I) Graph type: Type of standard curve graph is displayed.

(J) Cursor:	Coagulation time or dOD at this cursor position is displayed as standard curve data (cursor). Pressing the [←] and [→] keys moves the cursor to the left and right.
(K) Standard curve graph:	Displays standard curve whose vertical axis represents analysis data and whose horizontal axis represents activity percent or concentration. For a simultaneous display, the current standard curve is represented by a dotted line, and the new standard curve by a solid line.
(L) Expression:	Displays correlation formula whose vertical axis represents analysis data and whose horizontal axis represents activity percent or concentration.
(M)r:	If the expression formula approximates with a straight line, a coefficient of correlation will appear. * For a simultaneous display, a coefficient of correlation for the new standard curve data is displayed.
(N) a, b:	Constants that are derived from approximate expression formula are displayed.
(O) d:	For a simultaneous display, the disparity between the two standard curves at the cursor position on the standard curve graph (difference between analysis data) will be displayed.

Operating the Standard Curve Screen Keys

If you press the [More] key, the menu at the bottom of the screen will change.

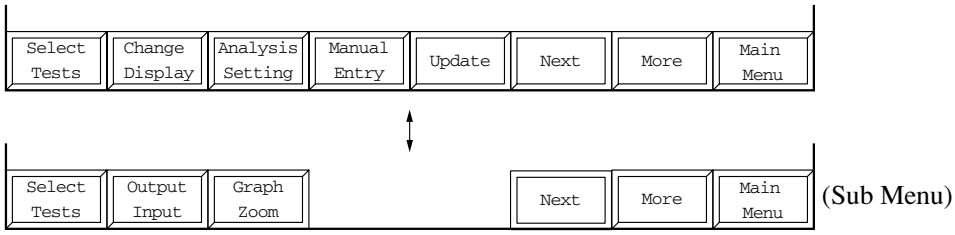

Figure 8-2-4: Standard Curve Screen Keys

[Select Tests] key: Displays other parameter.

(1)Press the [Select Tests] key. The Parameter Selection window will appear.

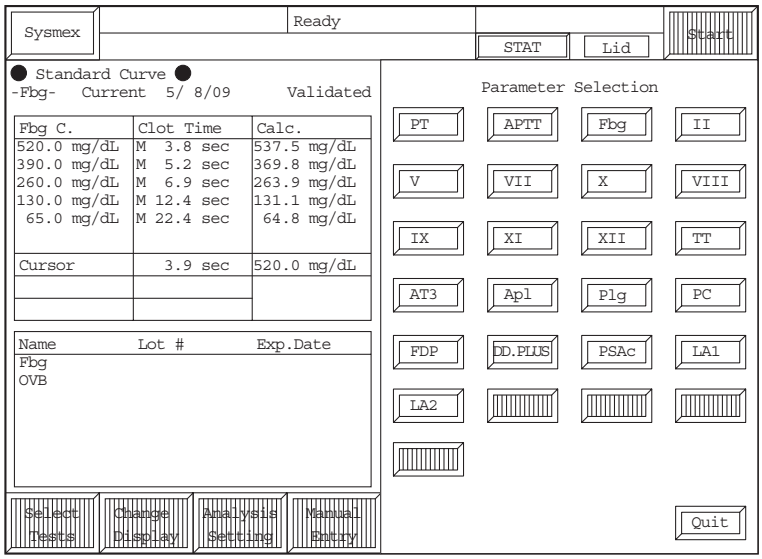

Figure 8-2-5: Parameter Selection Window

(2) Press the key for the parameter you wish to display.
The selected standard curve will be displayed. To stop selecting a parameter, press the [Quit] key.

[Change Display] key: Switches between the current standard curve and the new standard curve.

(1) Press the [Change Display] key. The Select Display window will appear.

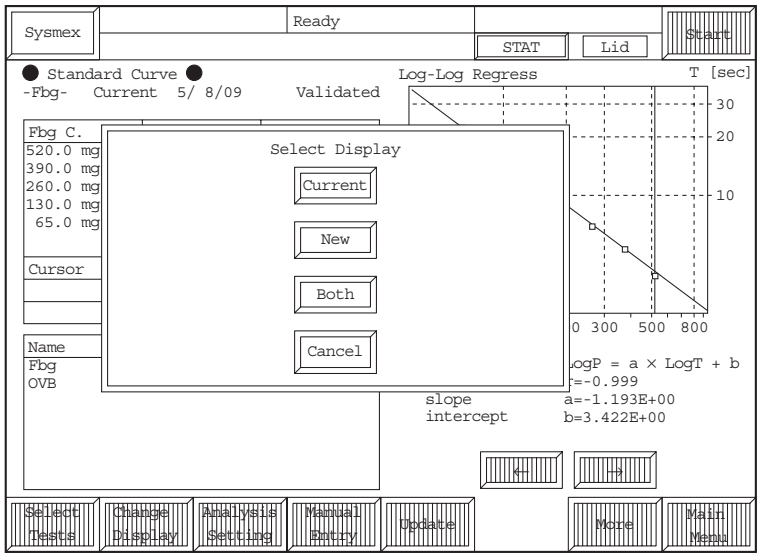

Figure 8-2-6: Select Display Window

(2) Press the key for the standard curve you wish to display.
If you press the [Current] key, the current standard curve will be displayed.
If you press the [New] key, the new standard curve will be displayed.
If you press the [Both] key, both standard curves will be displayed.
To stop changing the display, press the [Cancel] key.

[Analysis Setting] key: Used to set standard curve analysis.
See *Section 3: SETTING STANDARD CURVE ANALYSIS* in this chapter.

[Manual Entry] key: Used to initiate numeric key input of standard curve data.
See *Section 5: PREPARING STANDARD CURVE THROUGH MANUAL INPUT* in this chapter.

[Update] key: Used to decide whether to accept new standard curve.
See *Section 6: ACCEPTING PREPARED STANDARD CURVE* in this chapter.

[Next] keys: Used to display standard curve of DFbg (Derived fibrinogen).

[←], [→] keys: Used to move the cursor to the left and right on the standard curve graph.

[Main Menu] key: Cancels the settings and returns the system to the Main Menu screen.

[Output Input] key: Used to print, to write, or to read standard curve data.
For details on printing and saving, see *Section 7: OUTPUTTING STANDARD CURVE* in this chapter.
For details on reading from floppy disk, see *Section 8: READING STANDARD CURVE* in this chapter.

[Graph Zoom] key: Used to enlarge and display standard curve graphs.
See *Section 2.2: Displaying the Standard Curve Graph Zoom Screen* in this chapter.

2.2 Displaying the Standard Curve Graph Zoom Screen

To enlarge and display the standard curve graph, either press the [Graph Zoom] key from the sub menu of the Standard Curve screen, or press the standard curve graph that appears on the Standard Curve screen.

Separate Display

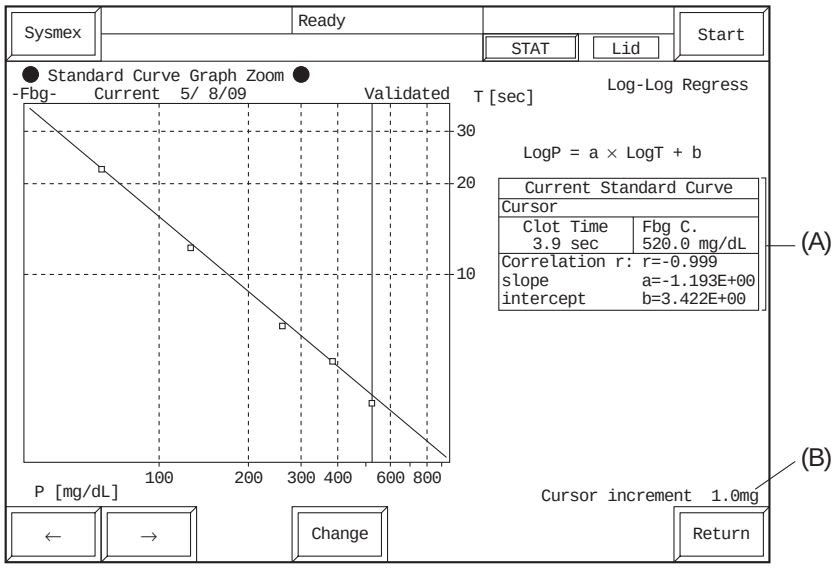

Figure 8-2-7: Standard Curve Graph Zoom Screen (Current)

Simultaneous Display

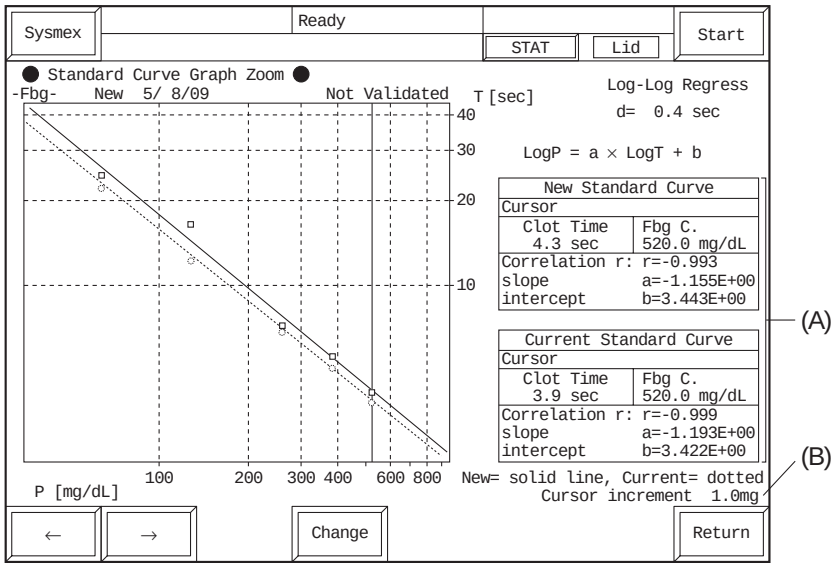

Figure 8-2-8: Standard Curve Graph Zoom Screen (Current & New)

Contents Displayed on Standard Curve Graph Zoom Screen

(A) Standard curve data (cursor): Values that correspond to the standard curve graph's cursor position are displayed for each standard curve.

(B) Cursor Increment: The amount that the cursor moves is displayed when the [←] or [→] key is pressed once. This can be changed by pressing the [Change] key. Display parameters other than those mentioned above are the same as those displayed on the Standard Curve screen. See *Section 2.1: Displaying the Standard Curve Screen* in this chapter.

Operating the Standard Curve Graph Zoom Screen Keys

[←], [→] keys: Used to move the cursor to the left and right on the standard curve graph.

[Change] key: Used to change the amount of cursor movement.

(1) Press the [Change] key. Numeric keys will appear, allowing you to enter the amount of cursor movement.

(2) Enter the amount of cursor movement; then press the [ENTER] key. The amount of cursor movement will change.
To discontinue, press the [QUIT] key.

[Return] key: Cancels the operation and returns the system to the Standard Curve screen.

3. SETTING STANDARD CURVE ANALYSIS

To prepare a standard curve analysis, use the Standard Curve Analysis Setting screen to make settings for the analysis.

3.1 Displaying the Standard Curve Analysis Setting Screen

From the Standard Curve screen, press the [Analysis Setting] key. The Standard Curve Analysis Setting screen will appear. The Standard Curve Analysis Setting screen will differ between automatic dilution and analysis, and manual dilution and analysis. You can change the screen by pressing the "Change Mode" key.

Setting Screen for Automatic Dilution and Analysis

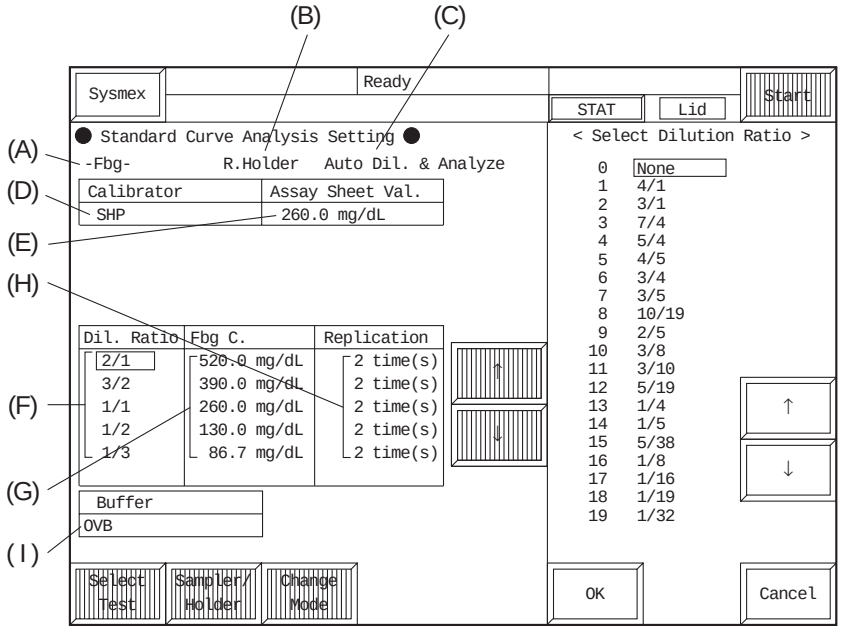

Figure 8-3-1: Standard Curve Analysis Setting Screen (Auto Dilution)

Setting Screen for Manual Dilution and Analysis

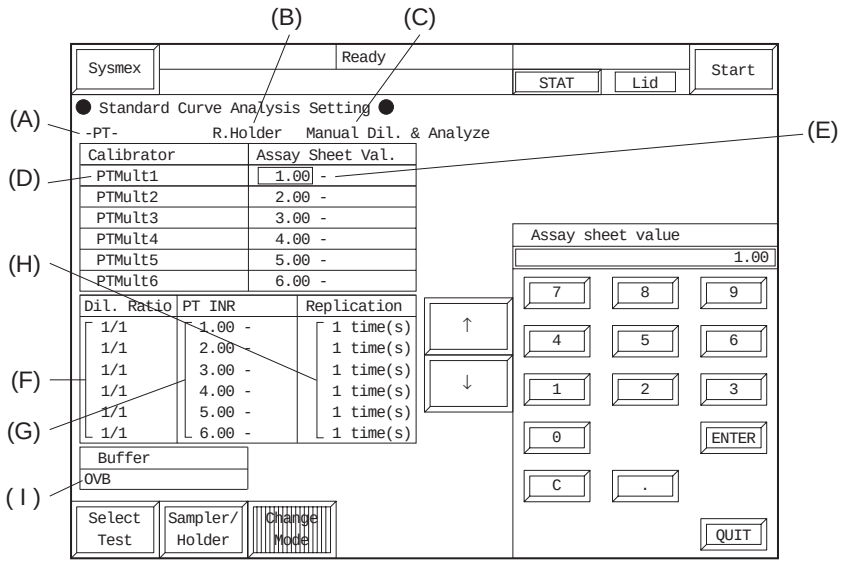

Figure 8-3-2: Standard Curve Analysis Setting Screen (Manual Dilution)

Contents Displayed and to be Set on Standard Curve Analysis Setting Screen
Setting parameters are displayed on the left side of the screen, and parameter selections or numeric keys for setting the parameter are displayed on the right.

(A) Parameter: Displays name of parameter to be set.

(B) Sampler/R. Holder: Enters the setting position of the calibrator.

(C) Analysis mode: Used to select whether to perform analysis by automatic dilution or manual dilution.

(D) Calibrator: Used to select the calibrator. You can set one level for automatic dilution analysis, and up to 6 levels for manual dilution analysis.

(E) Assay sheet Val.: Used to enter the assay value of the calibrator.

(F) Dil. Ratio: Can set up to six levels (points) of dilution ratio for calibrator analysis.
During manual dilution analysis, the ratio is fixed at 1/1.
For the parameter whose calculation method is Real number - Real number linear approximation or polygonal line, the dilution ratio can be set at 0/1. At such time, the instrument analyzes without aspirating the calibrator.
For the parameter whose calculation method is AKIMA 0, "0/1" is displayed automatically in the last line (the sixth point) of the dilution ratio at the automatic dilution analysis. "0/1" is displayed automatically in the top line (the first point) of the dilution ratio at the manual dilution analysis.
However, the point of "0/1" will not be analyzed. It will be a standard curve which contains origin (0,0).

(G) Activity percent / concentration: Each point's activity percent or concentration is displayed. During automatic dilution, these are calculated through assay sheet value and dilution ratio. During manual dilution, these become the assay sheet value.

(H) Replication: Used to set the number of replications of each point, using a range of 0 to 10 times. Points that are set at 0 times are not analyzed.

(I) Buffer: Used to set the buffer (diluent) to use during standard curve analysis. Set for the parameter for which the protocol setting of analysis procedures determined that buffer dilution will not be used.

3.2 Setting Automatic Dilution Analysis

This section will explain how to make the settings needed to analyze one type of calibrator through automatic dilution.
Pressing the [↑] and [↓] keys located in the center of the screen, move the cursor to each setting parameter. On the right side of the screen are displayed the parameter selections or numeric keys for setting the parameter that is indicated by the cursor.

(1) Press the [Select Test] key.
The Parameter Selection window that is used to select the parameter will appear.

(2) Press the key of the parameter for the analysis settings.
The Standard Curve Analysis Setting screen for the selected parameter will appear.

(3) If the current screen is the Analysis Setting screen for manual dilution and analysis, press the [Change Mode] key. The Analysis Setting screen for automatic dilution and analysis will appear.

(4) Press the [Sampler/Holder] key; then set the calibrator setting position.
Each time the [Sampler/Holder] key is pressed, "Sampler" and "R. Holder" will alternately appear.

(5) Set the calibrator (reagent).
Move the cursor to the "Calibrator", and press the [Select Reagent] key. The Select Reagent window will appear.

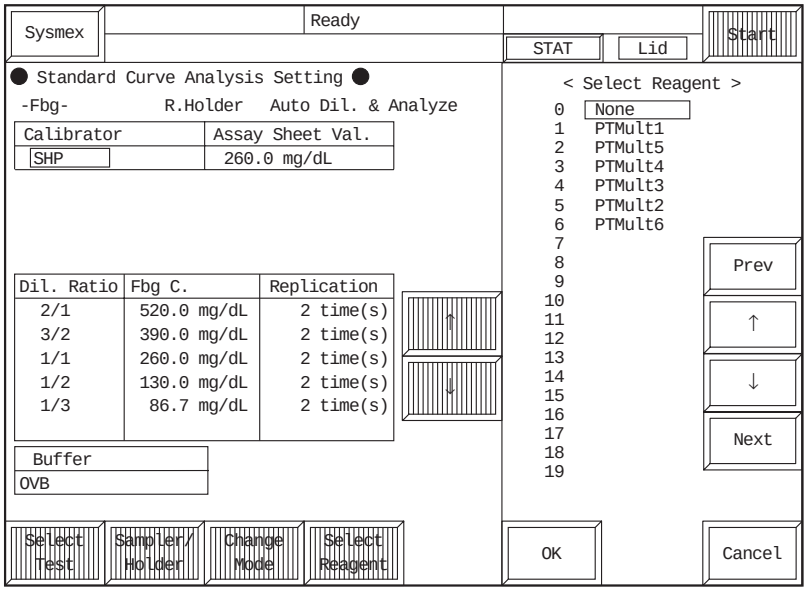

Figure 8-3-3: Select Reagent Window

Using the [↑] and [↓] keys on the Select Reagent window, select the calibrator; then press the [OK] key. When you press the [OK] key, the selected calibrator will become set.

NOTE:
- The calibrator can be selected from the reagents which are set in *Chapter 11, Section 5.1: Reagent Information Settings*.

(6) Set the assay sheet value (calibrator assay value).
Move the cursor to the "Assay Sheet Value"; the numeric keys will appear. Using the numeric keys, enter the assay sheet value; then press the [ENTER] key. When you press the [ENTER] key, the entered value will become set.

(7) Set up to six levels (points) of dilution ratio.
Move the cursor to the "Dil. Ratio"; then press the [Select Dil. Ratio] key. The Select Dilution Ratio window will appear.

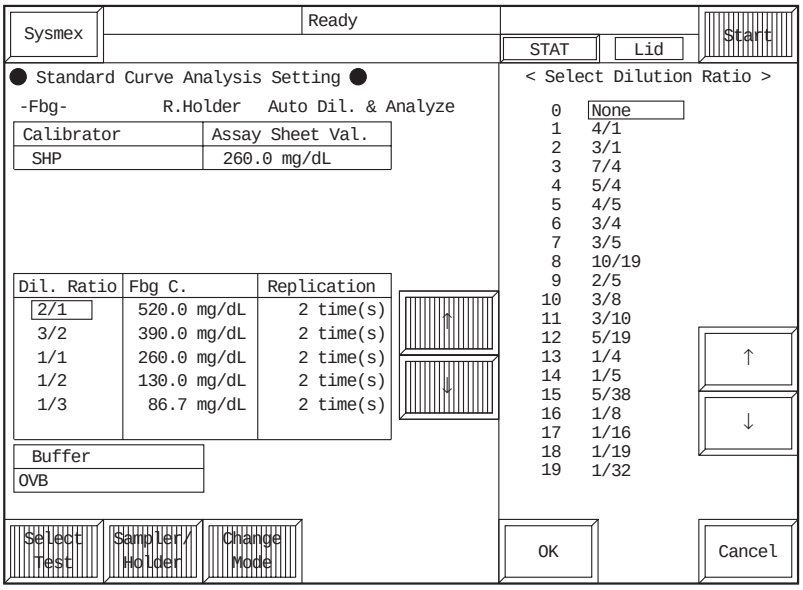

Figure 8-3-4: Select Dilution Ratio Window

Using the [↑] and [↓] keys on the Select Dilution Ratio window, select the dilution ratio; then press the [OK] key. When you press the [OK] key, the selected dilution ratio will become set.

CAUTION:
- For the parameter whose calculation method is AKIMA 0, even if the [↑] or [↓] key is pressed, the cursor will not move to the last line ("0/1") of the dilution ratio and the dilution ratio cannot be changed.

(8) Set the number of replications to a value between 0 and 10.
Move the cursor to the "Replications" area; the numeric keys will appear. Enter the number of analysis replications for the level (point) selected with the numeric keys; then press the [ENTER] key. When you press the [ENTER] key, the entered number of replications will become set.

NOTE:
- When the Akima Method is selected, set up the dilution ratio that covers a measurement range equally. Please note that the measuring range must be defined in raw values (dOD or seconds) and not in concentration units. Otherwise the reading of the concentration results from the standard curve might be incorrect.

(9) Set the buffer (diluent).
Set for the parameter for which the protocol setting of analysis procedures determined that buffer will not be used. Move the cursor to the "Buffer" area; then press the [Select Reagent] key. The Select Reagent window will appear.

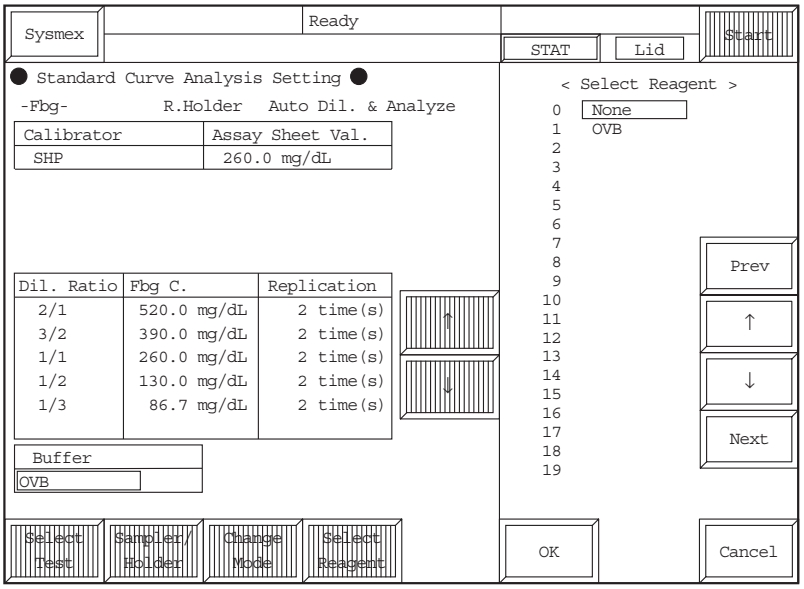

Figure 8-3-5: Select Reagent Window

Using the [↑] and [↓] keys on the Select Reagent window, select the buffer; then press the [OK] key. When you press the [OK] key, the selected buffer will become set.

NOTE:
- If a DFbg standard curve will be used with PT parameter, after the PT standard curve analysis setting has been performed, press the [Next] key to display the DFbg Standard Curve Analysis Setting screen; then set up the parameters.

(10) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [OK], or [Cancel] key.

[Continue] key:	Used to continue the setting of standard curve analysis.
[OK] key:	Updates the settings and returns the system to the Standard Curve screen.
[Cancel] key:	Cancels the settings and returns the system to the Standard Curve screen.

3.3 Setting Manual Dilution Analysis

Settings are made with several levels of calibrators from the same series which were previously assayed according to activity percent or concentration.
Pressing the [↑] and [↓] keys located in the center of the screen, move the cursor to each setting parameter. On the right side of the screen are displayed the parameter selections or numeric keys for setting the parameter that is indicated by the cursor.

(1) Press the [Select Test] key.
The Parameter Selection window that is used to select the parameter will appear.

(2) Press the key of the parameter for the analysis settings.
The Standard Curve Analysis Setting screen for the selected parameter will appear.

(3) If the current screen is the Analysis Setting screen for automatic dilution and analysis, press the [Change Mode] key. The Analysis Setting screen for manual dilution and analysis will appear.

(4) Press the [Sampler/Holder] key; then set the calibrator setting position.
Each time the [Sampler/Holder] key is pressed, "Sampler" and "R. Holder" will alternately appear.

(5) Set up to six levels of calibrator.
Move the cursor to the "Calibrator", and press the [Select Reagent] key. The Select Reagent window will appear.

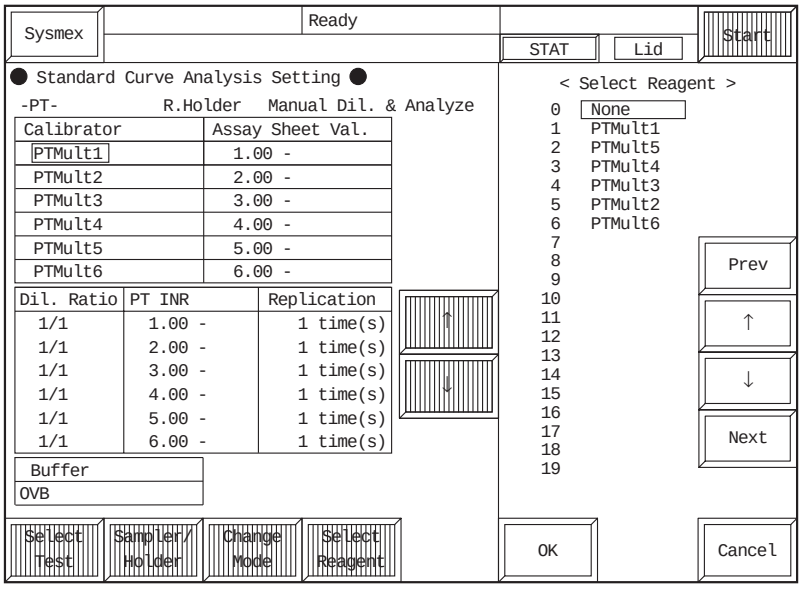

Figure 8-3-6: Select Reagent Window

Using the [↑] and [↓] keys on the Select Reagent window, select the calibrator; then press the [OK] key. When you press the [OK] key, the selected calibrator will become set.

NOTE: • The calibrator can be selected from the reagents which are set in *Chapter 11, Section 5.1: Reagent Information Settings*.

(6) Set the assay sheet value (calibrator assay value).
Move the cursor to the "Assay Sheet Value"; the numeric keys will appear. Using the numeric keys, enter the assay sheet value; then press the [ENTER] key. When you press the [ENTER] key, the entered value will become set.

(7) Set the number of replications to a value between 0 and 10.
Move the cursor to the "Replications" area. The numeric keys will appear. Enter the number of analysis replications for the level (point) selected with the numeric keys; then press the [ENTER] key. When you press the [ENTER] key, the entered number of replications will become set.

NOTE: • If a DFbg standard curve will be used with PT parameter, after the PT standard curve analysis setting has been performed, press the [Next] key to display the DFbg Standard Curve Analysis Setting screen; then set up the parameters.

(8) After the settings are completed, press the [Return] key.
If the settings have been changed, the update confirmation window will appear. Press the [Continue], [OK], or [Cancel] key.

[Continue] key:	Used to continue the setting of standard curve analysis.
[OK] key:	Updates the settings and returns the system to the Standard Curve screen.
[Cancel] key:	Cancels the settings and returns the system to the Standard Curve screen.

4. PREPARING STANDARD CURVE THROUGH ANALYSIS

As with routine samples, standard curve order information is first registered on the Work Load List screen; analysis then occurs to prepare the standard curve.

4.1 Standard Curve Analysis Registration

The Work Load List screen is used to register order information for standard curve analysis.

(1) From the Main Menu screen, press the [Work List] key. The Work Load List screen will appear.

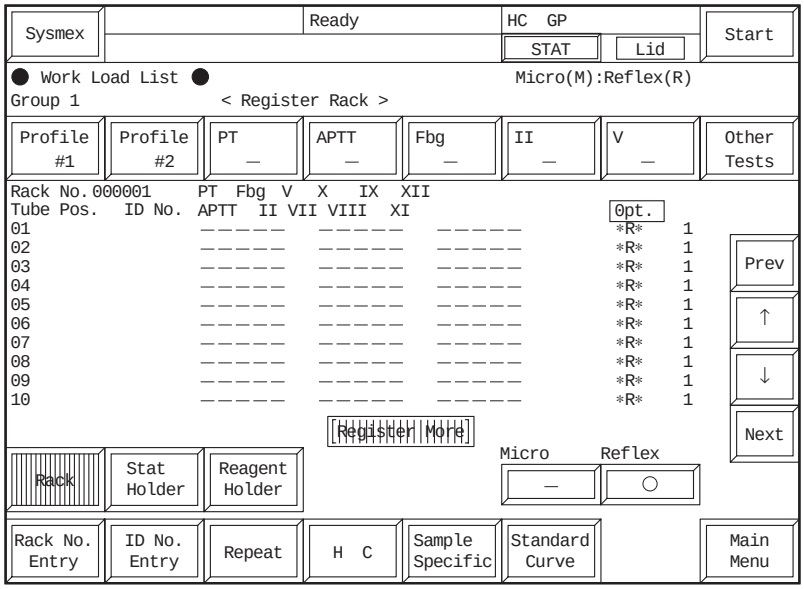

Figure 8-4-1: Work Load List Screen

(2) Press the key for the location in which the calibrator is set (either the [Rack] or [Reagent Holder] key).

CAUTION: • When a STAT sample holder is used, a standard curve analysis can not be executed.

(3) If the calibrator is to be set in the rack, set the tube position number.

(4) Press the [Standard Curve] key. (When a rack is used, the key will be displayed only when no order is set.)
The Standard Curve Parameter Settings screen will appear.

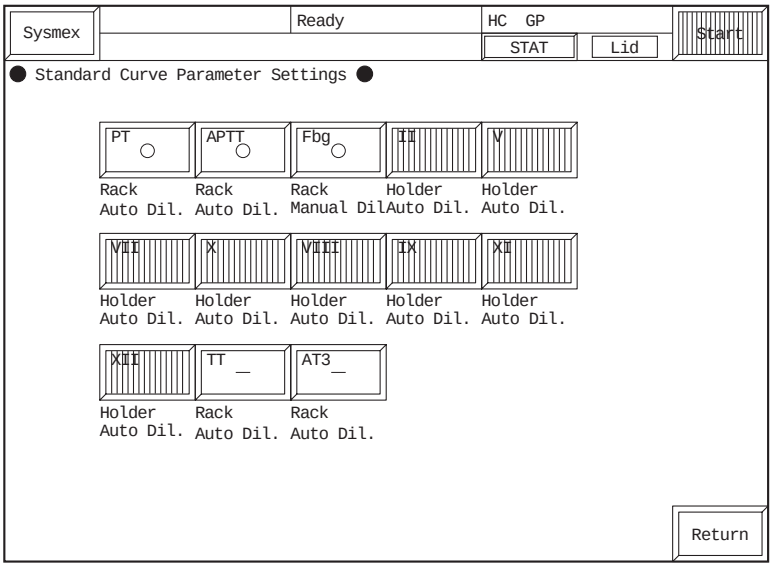

Figure 8-4-2: Standard Curve Parameter Settings Screen

NOTE:

- When a reagent holder is used, set the calibrator in reagent positions D1 to D14. See *Chapter 11, Section 5.7: Reagent Position Settings.*
- The parameter keys for standard curve analysis will be masked when the standard curve analysis setting is not correct, or when the standard curve is not accepted, or when the standard curve analysis is not completed.
- While analyzing the standard curve, the standard curve analysis which using the calibrator currently under analysis, cannot be added. In this case, the keys of standard curves under analysis will be masked.
  After the current standard curve analysis is completed, execute the additional analysis.

Under the parameter keys are displayed the set calibrator position, which was defined in the Standard Curve Analysis Setting screen, and the analysis method.
For details on how to set the position and analysis method, see *Section 3: SETTING STANDARD CURVE ANALYSIS* in this chapter.

(5) Press the key for the parameter that you wish to analyze. The symbol "○" (will analyze) will be displayed.

Each time you press the parameter key, the symbols "○" (will analyze) and "-" (will not analyze) will alternate.

(6) Press the [Return] key.
The Standard Curve work load list will appear.

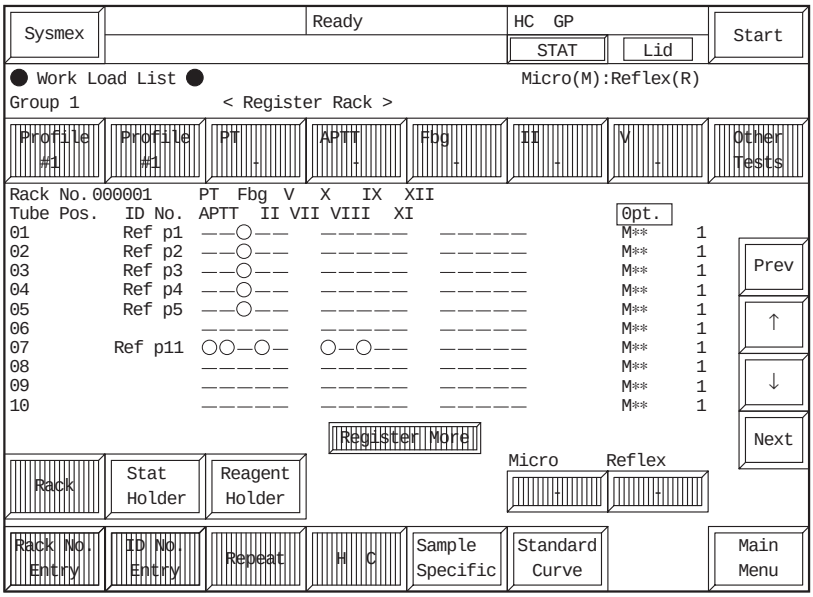

Figure 8-4-3: Work Load List (Rack Sample Registration)

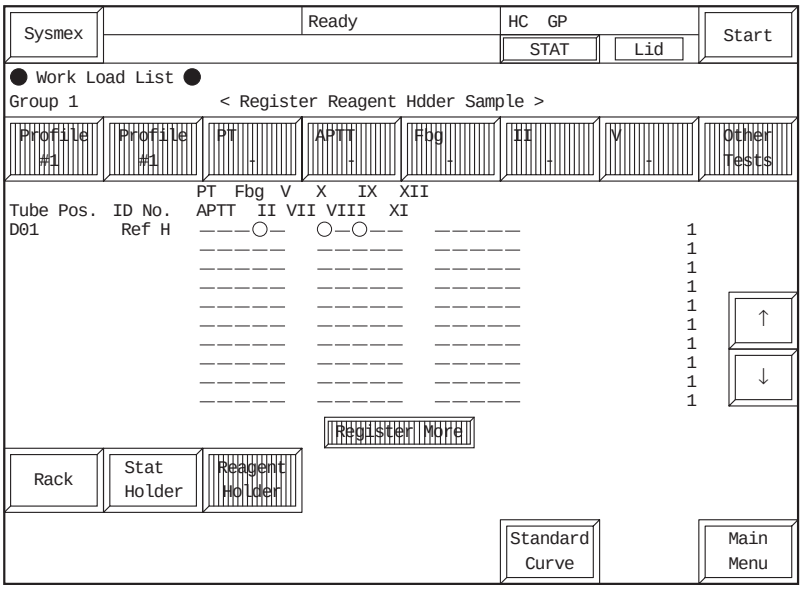

Figure 8-4-4: Work Load List
(Reagent Holder Sample Registration)

(7) Check the contents of the work list.

4.2 Standard Curve Analysis

This section will explain how to perform analysis in order to prepare a standard curve.
Use Micro-sample Mode to set standard curve analysis.
(See *Chapter 3, Section 2.2: Contents Displayed on Work Load List Screen, (J).*)

CAUTION: • When a cap piercer unit is installed, the standard curve analysis cannot be performed in the sample tubes with the cap. Analyze after manually removing the cap.

(1) Register the standard curve order information.
See *Section 4.1: Standard Curve Analysis Registration* in this chapter.

(2) Set the calibrator, using a suitable method described below.
If setting in rack :
Set the calibrator into the sample rack according to the arrangement shown on the Work Load List screen. Set the sample rack (into which the calibrator was set) into the right rack pool of sampler.
If setting in reagent holder:
Set the calibrator into the reagent holder according to the reagent holder position shown on the Work Load List screen.

(3) Press the [Start] key.
The analysis will start.

(4) After the analysis is completed, use the Standard Curve screen to check the newly prepared standard curve; then decide whether or not to accept it.
See *Section 6: ACCEPTING PREPARED STANDARD CURVE* in this chapter.

CAUTION:
- For samples that are analyzed before a standard curve analysis is executed, the concentration is calculated from the existing standard curve.
- When calculating the concentration using a new standard curve, recalculate using stored data. For details on how to recalculate, see *Chapter 5, Section 11: RECALCULATING STORED DATA.*
- For samples that are analyzed after a standard curve analysis is executed, the concentration is not calculated until a standard curve has been accepted for use. After a standard curve has been accepted, the concentration is automatically calculated from the new standard curve. If the new standard curve is not accepted, the concentration is automatically calculated from the existing standard curve. For details, see *Section 6: ACCEPTING PREPARED STANDARD CURVE* in this chapter.
- If the power to the unit is shut off before the standard curve has been accepted for use, the new standard curve will disappear. After completion of a standard curve analysis, be sure to update the standard curve.

CAUTION:
- While analyzing the standard curve, the standard curve analysis using the calibrator currently under analysis cannot be added. After the current standard curve analysis is completed, execute the additional analysis.

NOTE:
- Standard curve analysis and routine sample analysis can be executed simultaneously.
- When a calibrator is placed in a reagent holder in order to execute a standard curve analysis, the standard curve is analyzed before the routine sample.

5. PREPARING STANDARD CURVE THROUGH MANUAL INPUT

Using the numeric keys, enter the parameters for the standard curve.

(1) Using the Standard Curve screen, display the parameters for which you wish to prepare the standard curve.
Press the [Select Test] key to display the Parameter Selection window; then press the key for the parameter for which you wish to prepare the standard curve.

(2) Press the [Manual Entry] key.
The Manual Entry of Standard data window will appear.

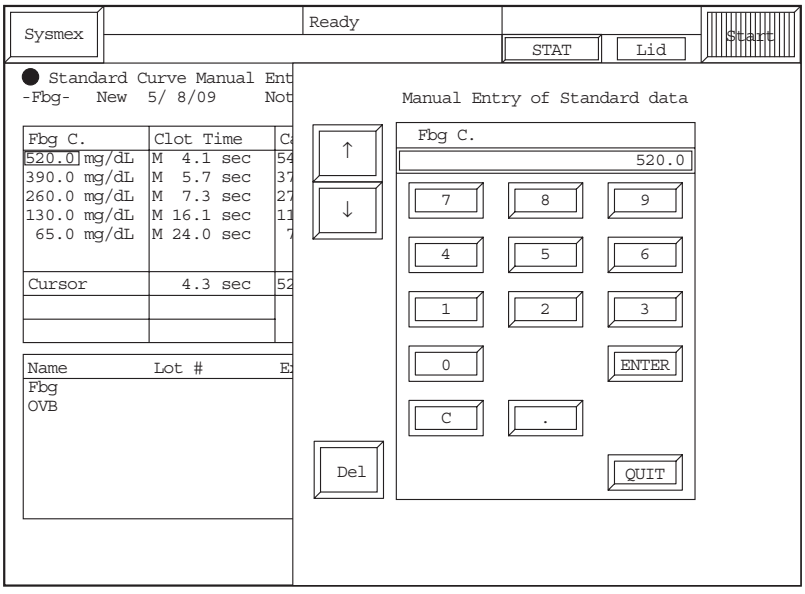

Figure 8-5-1: Manual Entry of Standard Curve data Window

(3) Set each parameter .
Pressing the [⇑] and [↓] keys on the Manual Entry of Standard data window, move the cursor to each setting parameter.

CAUTION:
- For the parameter whose calculation method is AKIMA 0, "0 and 0" is displayed in the top line.
  Even if the [⇑] or [↓] key is pressed, the cursor will not move to the top line and the top line cannot be changed.
- ISI values for prothrombin time assays must be entered directly as they appear on the current reagent labeling.
  Any changes of reagent lot, software upgrades, major servicing, etc., require verification of the ISI value.
  Failure to enter the correct ISI value will cause incorrect International Normalized Ratio (INR) results.

Using the numeric keys, enter the value for the selected field with the cursor. Then press the [ENTER] key to set the entered value.
If you move the cursor to the next field with the [⇑] and [↓] keys without pressing the [ENTER] key, the entered values will be canceled.

(4) After setting is completed, press the [QUIT] key on the Manual Entry of Standard data window.
If the standard curve settings were changed, the Standard Curve screen will simultaneously display the current standard curve and newly prepared standard curve.

(5) Decide whether or not to accept the new standard curve.
See *Section 6: ACCEPTING PREPARED STANDARD CURVE* in this chapter.

6. ACCEPTING PREPARED STANDARD CURVE

Using the Standard Curve screen, check the newly prepared standard curve; then decide whether or not to accept the curve.

(1) Display the Standard Curve screen.
From the Main Menu screen, press the [Standard Curve] key. The Standard Curve screen will appear. If the standard curve has been newly prepared, the Standard Curve screen will simultaneously display the current standard curve and newly prepared standard curve.

(2) Select the analysis parameter whose standard curve needs to be checked.
Press the [Select Test] key to display the Parameter Selection window; then press the key for the analysis parameter for which the standard curve should be checked.

(3) Check the standard curve; then press the [Update] key.
The menu at the bottom of the screen will switch to the Standard Curve Update menu.

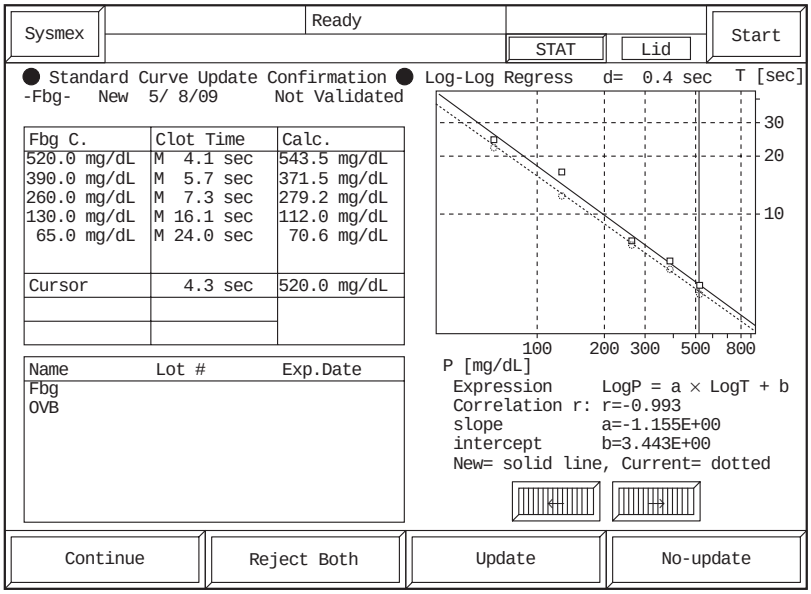

Figure 8-6-1: Standard Curve Update Menu

(4) Decide whether to accept the new standard curve; then press the appropriate key.

[Continue] key: Returns system to original menu when decision to accept is not made.

[Reject Both] key: Appears only when a standard curve analysis is executed. Rejects new standard curve. And when stored data includes calculation parameters that have not been calculated, calculations are not carried out even from the existing standard curve.

[Update] key: Accepts the new standard curve.

[No-update] key: Rejects the new standard curve.

CAUTION:
- If the power to the unit is shut off before a standard curve has been accepted for use, the new standard curve will disappear. After preparing a standard curve, be sure to decide whether to accept it for use.
- If some analyzed data have errors (e.g. CCE Error) in standard curve measurement, “Standard Curve Warning” is indicated with red in the standard curve update menu screen.
  Confirm the data in the stored data screen. If there is a problem, analyze again. Otherwise, update the standard curve.

NOTE:

- For samples analyzed after a standard curve analysis is executed, if there is stored data for which the activity % (or concentration) has not been calculated, the activity % will automatically be calculated based on the new standard curve if the curve is accepted, and will automatically be calculated based on the existing standard curve if the new curve is not accepted.
- New standard curve cannot be accepted in the cases listed below. Moreover, the [Update] key will be masked and a message "Standard Curve Error" will appear.
  - Analysis data does not increase constantly in relation to activity percent or concentration.
  - Analysis data does not decrease constantly in relation to activity percent or concentration.
  - Only one point of standard curve data is set.

7. OUTPUTTING STANDARD CURVE

The standard curve can be printed out by the graphic printer and the standard curve data can be saved on a floppy disk.
When printing out on the graphic printer, the standard curve displayed on the Standard Curve screen will be printed.
When saving on a floppy disk, the standard curve data displayed on the Standard Curve screen will be saved; however, only the current standard curve will be saved even if current and new are simultaneously displayed.

(1) Using the Standard Curve screen, display the standard curve that you wish to output.
Press the [Select Test] key to display the Parameter Selection window; then press the key for the parameter that you wish to output.
Press the [Change Display] key to display the Select Display window; then press the key for the standard curve that you wish to output.

(2) Press the [More] key to display the sub menu.

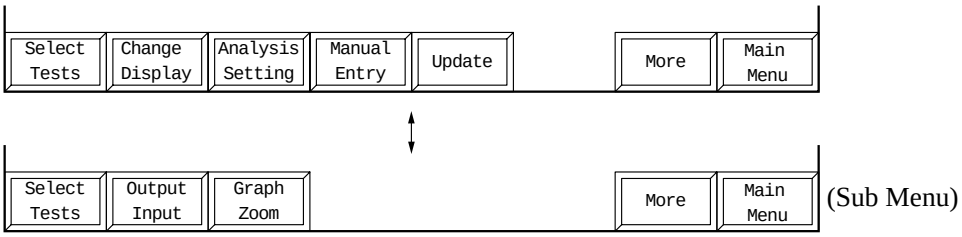

Figure 8-7-1: Sub menu

(3) Press the [Output Input] key.
The menu at the bottom of the screen will switch to the Standard Curve Output Input menu.

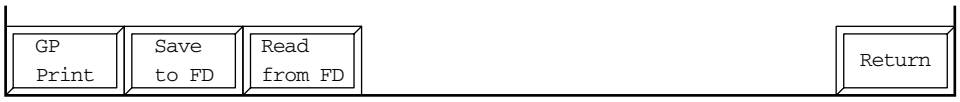

Figure 8-7-2: Standard Curve Output Input Menu

(4) Press the key for the appropriate output or input device.

[GP Print] key:	Sends the standard curve to the graphic printer. Press the [GP Print] key. The Print Confirmation message window will appear. Press the [OK] key to start printing, or press the [Cancel] key to stop printing.
[Save to FD] key:	Saves the standard curve data on a floppy disk. See "Saving on a Floppy Disk" below.

Saving on a Floppy Disk

(1) Press the [Save to FD] key. The Floppy Disk Confirmation window will appear.

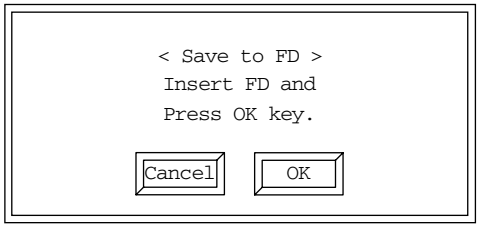

Figure 8-7-3: Floppy Disk Confirmation Window

(2) Insert a floppy disk into the floppy disk drive. To cancel saving, press the [Cancel] key.

CAUTION:
- If the standard curve data of the parameter that you wish to save already exists on the floppy disk, it will be overwritten when saving is executed.
  A message will appear asking if it is OK to overwrite the current data. If it is OK to overwrite the data, press the [OK] key; and if you wish to cancel, press [Cancel].

(3) Press the [OK] key.
The data will be saved on the floppy disk.
If the room on the inserted floppy disk is insufficient or if any other error occurs, a message window will appear. If that happens, insert a preformatted empty floppy disk and press the [OK] key.

8. READING STANDARD CURVE

Read the standard curve data that is stored on a floppy disk.
The same standard curve data as that of the parameter displayed on the Standard Curve screen will be read.

(1) Using the Standard Curve screen, display the standard curve that you wish to read.
Press the [Select Tests] key to display the Parameter Selection window; then press the key for the parameter that you wish to read.

(2) Press the [More] key to display the sub menu.

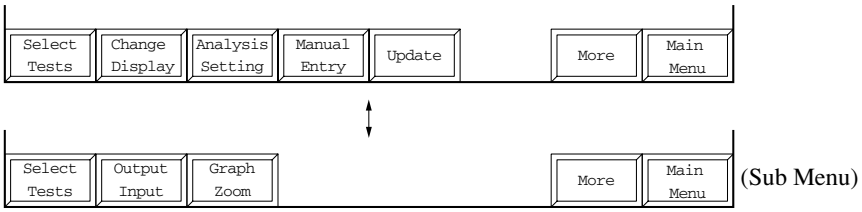

Figure 8-8-1: Sub menu

(3) Press the [Output Input] key.
The menu at the bottom of the screen will switch to the Standard Curve Output Input menu.

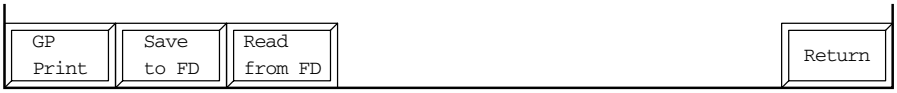

Figure 8-8-2: Standard Curve Output Input Menu

(4) Press the [Read from FD] key.
The Floppy Disk Confirmation window will appear.

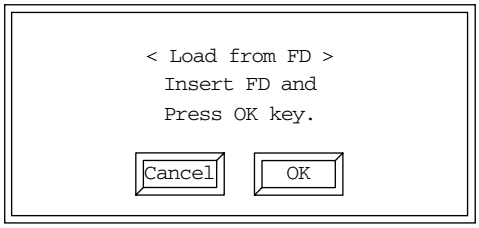

Figure 8-8-3: Floppy Disk Confirmation Window

(5) Insert the floppy disk into the floppy disk drive.
To cancel reading, press the [Cancel] key.

(6) Press the [OK] key.
Reading will be executed and a "Loading..." message will appear.
If the standard curve is not on the inserted floppy disk or if any other error occurs, a message window will appear. If that happens, insert a current floppy disk and press the [OK] key. After reading is completed, the standard curve read will be displayed as the new standard curve and the menu at the bottom of the screen will change.

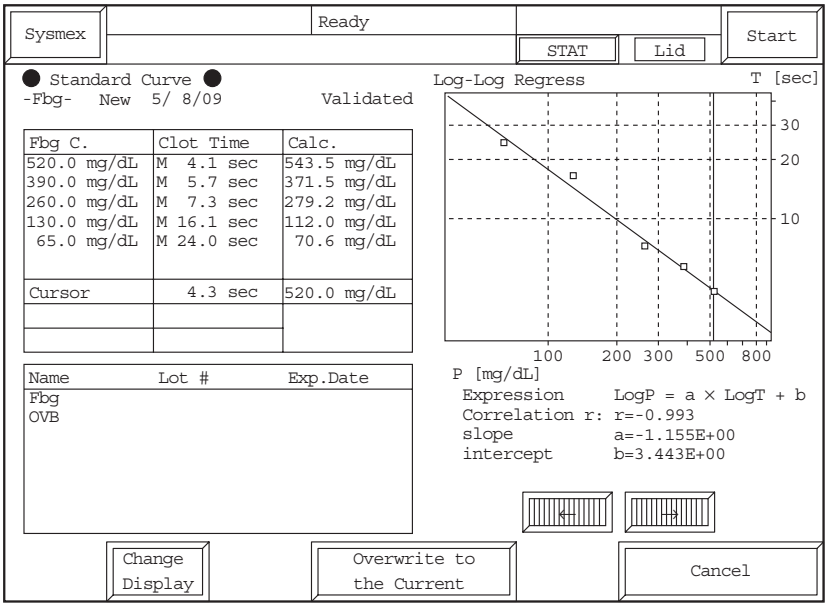

Figure 8-8-4: Standard Curve Screen (After FD Reading)

(7) Decide what to do with the read standard curve.

[Change Display] key:	Enables you to display the current standard curve data before deciding.
[Overwrite to the Current] key:	Replaces the current standard curve with the standard curve read from the floppy disk.
[Cancel] key:	Cancels the process and discards the standard curve data read from the floppy disk.

CHAPTER 9 TROUBLESHOOTING

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3. HOW TO DISPLAY ERROR LOG 9-3

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   - 5.10 LCD Screen Test 9-43

1. INTRODUCTION

This chapter explains the error messages that are displayed by the CA-1500, as well as failures that can occur and the corrective action for the operator to take if a failure occurs. If the instrument does not return to the normal operating condition even after you have taken the action described in this chapter, contact your service representative for assistance.
This chapter will principally cover the content listed below.

How to Display the Error Log
Each time an error occurs, the instrument records it. The instrument can record up to 189 errors. The error data that is recorded can be displayed as an error log.

Troubleshooting by Error Message
This section provides a list of the error messages that can appear on the screen when a problem occurs. It also explains the corrective action to take.

Instrument Check
This section explains how to test whether the instrument is operating properly, and how to display instrument maintenance items.

2. WHEN YOU SUSPECT AN ERROR

1. Turning the power ON does not start the instrument.	•Is the power cord connected securely? •Is the fuse blown? Refer to *Chapter 6, Section 6.5: Replacing the Fuse*. •Is the power supplied to AC outlet?
2. When the power is ON, nothing is displayed and "beep" keeps sounding.	• There is a possibility that memory error has occurred. Turn OFF the power, and turn it ON again 1 - 2 minutes later.
3. The screen displays nothing.	• Is LCD brightness properly adjusted? Refer to *Chapter 1, Section 6.1: LCD Screen*.
4.Fluid leaks from the instrument.	•Turn OFF the power and wipe off leaked fluid. If fluid leakage persists after turning ON the power, contact your service representative.
5. An error occurs.	Search the following message lists for the error in question and refer to the corresponding pages in Troubleshooting: **Message List** To search the pages, the error messages are listed in "Alphabetical" and "Functional" orders. **Troubleshooting** Probable causes and corrective action for each error message are described.

WARNING:• When servicing, handle leaked fluid as biologically hazardous. Wear Latex or non Latex examination gloves and wash your hands in disinfectant solution after servicing.

3. HOW TO DISPLAY ERROR LOG

Each time an error occurs, the instrument will record it. The instrument will record up to 189 errors as a log, or history, along with the date and time that the errors occurred. For each of the error messages in the log, the corrective action and other detailed information can also be displayed.

(1) Press the [Sysmex] key located in the upper left part of the screen. The Sysmex menu will appear.

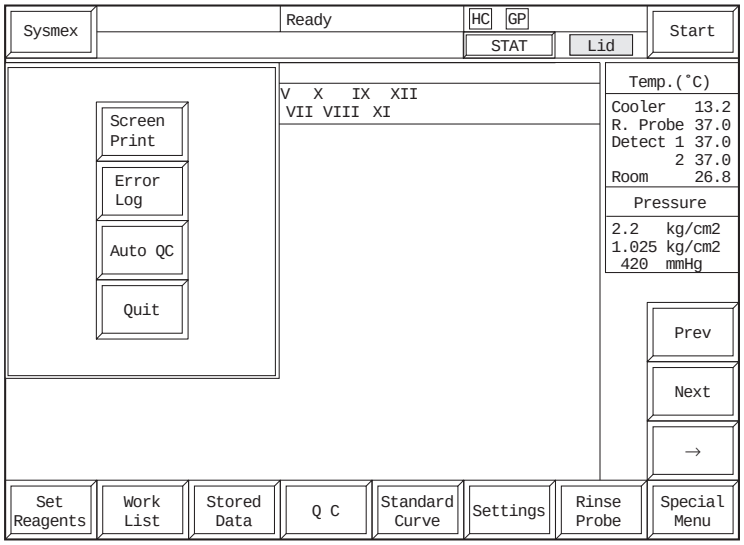

Figure 9-3-1: Sysmex Menu

(2) Press the [Error Log] key. The Error Log screen will appear. The date, time, and error message for 21 errors will be displayed on each page. Information on up to 189 errors can be displayed. To switch pages, press the [Page Up] and [Page Down] keys.

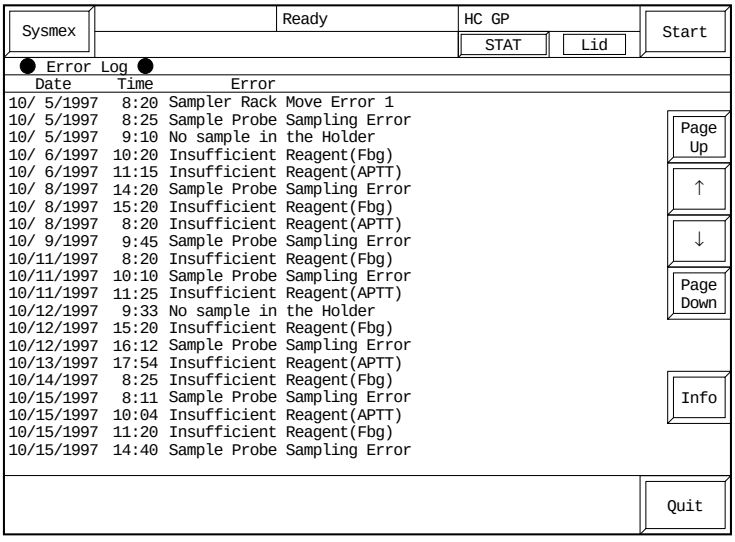

Figure 9-3-2: Error Log Screen

(3) To display detailed information on individual error message, press the [↑] and [↓] keys to move the cursor to the error message.

(4) Press the [Info] key. The Detailed Information screen will appear.

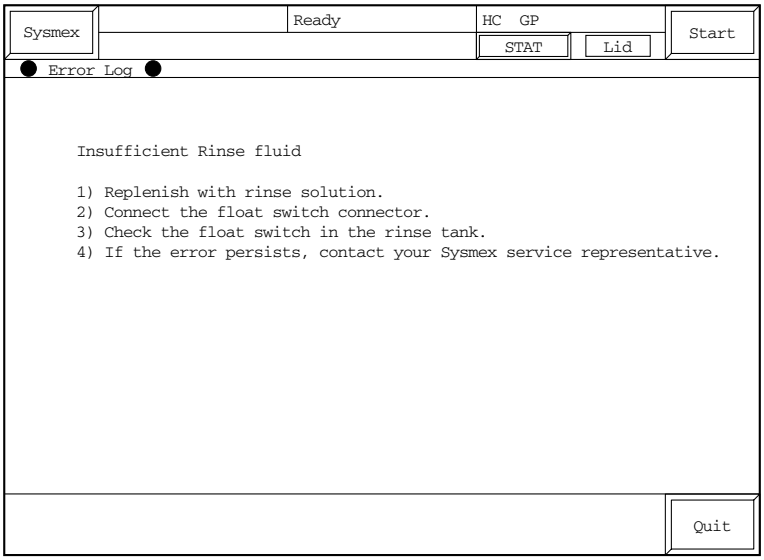

Figure 9-3-3: Detailed Information Screen

(5)Press the [Quit] key to return to the Error Log screen.

(6)To exit the Error Log screen, press the [Quit] key again. The original screen will appear.

4. TROUBLESHOOTING BY ERROR MESSAGE

4.1 Alphabetical Error Message Index

1.0 kg/cm^2 Pressure Error 9-12
2.2 kg/cm^2 Pressure Error 9-12

[B]
Barcode Scanner Error 9-27
Buffer Sampling Error 9-19

[C]
Catcher Error (Down). 9-15
Catcher Error (Trash) 9-15
Catcher Error (X) 9-15
Catcher Error (Y) 9-15
Catcher Error (Z) 9-15
Catching Reaction Tube Failed 9-20
Check Reagent Syringe 9-19
Check Reagent Volume 1 (Warning). 9-20
Check Reagent Volume 2 (Interrupt). 9-20
Check Sample Syringe 9-18
Close STAT sample cover.. 9-30
CP Unit Error 9-31

[D]
Detector Adjustment Error 9-24
Discard Waste. 9-13

[E]
Empty the Tube Trash. 9-30
Empty the Tube Trash. 9-31
Expired Reagent ("Reagent Name"). 9-24

[G]
GP Error 9-25
GP Paper Empty 9-25

[H]
HC ACK Code Error 9-26
HC ACK Time Out. 9-26
HC Communication Error 9-26
HC CTS Time Out 9-26
HC ETX Time Out 9-26
HC Off Line 9-26
HC Order is wrong 9-25
HC Reception Count Error 9-26
HC STX Time Out 9-26
HC Transmission Count Error 9-26

[I]
Instructions Not Found In Host Computer 9-26
Insufficient Buffer ("Name") 9-19
Insufficient Reagent ("Reagent Name") 9-17
Insufficient Reagent ("Reagent or Control Name") 9-17
Insufficient Rinse fluid 9-13
Insufficient Sample ("Rack No. - Tube Position") 9-16

[L]
Lamp Filter Error 9-31
Light Shield Lid is open. 9-30

[M]
Mechanical Stop Switch was pressed 9-30

[N]
No Reaction Tubes 9-19
No Sample in the Holder ("Rack No. - Tube Position") 9-16
No Test tubes in the rack ("Rack No. - Tube Position") 9-23

[P]
Power Turned Off During Operation 9-30
Plate full - Replace Plate 9-19

[Q]
QC Data Error 9-25
QC Exceeds Stop Limit ("File No. ", "Parameter Name") 9-27
QC Exceeds Stop Limit (1-2S) ("File No. ", "Parameter Name") 9-27
QC Exceeds Stop Limit (1-3S) ("File No. ", "Parameter Name") 9-28
QC Exceeds Stop Limit (10X) ("File No.", "Parameter Name") 9-29
QC Exceeds Stop Limit (2-2S) ("File No.", "Parameter Name") 9-28
QC Exceeds Stop Limit (4-1S) ("File No.", "Parameter Name") 9-28
QC Exceeds Stop Limit (R-4S) ("File No.", "Parameter Name") 9-28
QC Flag Limit ("File No.", "Parameter Name") 9-27
QC Flag Limit (1-2S) ("File No.", "Parameter Name") 9-27
QC Flag Limit (1-3S) ("File No.", "Parameter Name") 9-28
QC Flag Limit (10X) ("File No.", "Parameter Name") 9-29
QC Flag Limit (2-2S) ("File No.", "Parameter Name") 9-28
QC Flag Limit (4-1S) ("File No.", "Parameter Name") 9-28
QC Flag Limit (R-4S) ("File No.", "Parameter Name") 9-28

[R]
Rack Position Error at Start 9-23
RAM Error 9-25
Reaction Tube jammed 9-20
Reagent Probe Crash Sensor Error 9-18
Reagent Probe Crash ("Position") 9-18
Reagent Probe Error (X) 9-14
Reagent Probe Error (Y) 9-14

Reagent Probe Error (Z) 9-14
Reagent Probe Sampling Error ("Reagent Name") 9-17
Reagent Syringe Error 9-18
Replace Lamp Unit. 9-31
Replace Piercer. 9-31
Replenish Reaction Tubes 9-20
Replenish Rinse fluid 9-13
ROM Error 9-25

[S]

Sample Plate Error 9-20
Sample Probe Crash Sensor Error 9-18
Sample Probe Crash ("Position") 9-17
Sample Probe Error (X) 9-14
Sample Probe Error (Y) 9-14
Sample Probe Error (Z) 9-14
Sample Probe Sampling Error 9-16
Sample Rack Full 9-23
Sample Syringe Error 9-18
Sampler Rack Feed In Function Error 9-21
Sampler Rack Feed In Home Position Error 9-21
Sampler Rack Feed Out Function Error 9-22
Sampler Rack Feed Out Home Position Error 9-22
Sampler Rack Move Error 1. 9-22
Sampler Rack Move Error 2. 9-22
Sampler Rack Shift Function Error 9-21
Sampler Rack Shift Home Position Error 9-21
Set Diluent or Reagent 9-29
Set more than two points 9-29
Set Sample Rack. 9-23
Settings Lost 9-24
Standard Curve Error 9-29
Standard Curve Warning 9-29
Stored Data Error 9-24

[T]

Temperature Error ("Location", "High/Low") 9-12
Tube Trash has not been set. 9-30
Tube Trash is full. 9-31

[V]

Vacuum Error 9-12

[W]

Waste is full 9-13

4.2 Error Message Index by Function

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4.3 Troubleshooting Guide

The errors that appear on the screen are classified as shown below.

Instrument Errors (in analysis mechanism, pressure, and temperature adjustment, etc.)

- An analysis will stop if an instrument error occurs. Take corrective action within the limits shown in this chapter. If the error is not corrected even after you have taken the prescribed corrective action, contact your service representative.

Precautionary Messages

- Precautionary messages are displayed to urge caution at the start of an analysis and at other times.

Analysis Data Errors

- On the stored data graphic display, a 3-character error code "ERR xxx" is displayed; on the stored data list display, an asterisk "*" is displayed.
- For analysis that generates an error, "***.*" will be displayed for the data that relates to the error.
- For parameters whose analysis was interrupted, an "×" will be displayed on the Work Load List screen and Main Menu screen.
- Re-analysis is required for the parameter whose analysis is interrupted due to an instrument error, and for the parameter that generates an analysis error.

If the instrument generates an error, an error message will appear at the top of the screen, an alarm will sound, and the [Sysmex] key will change to the [Alarm Reset] key.

(1) Press the [Alarm Reset] key to stop the alarm.

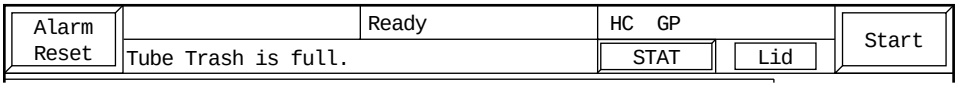

Figure 9-4-1: Screen when an Error Occurs

4.4 Corrective Action

1. Pressure Errors

Error Message	
•2.2 kg/cm^2 Pressure Error **•1.0 kg/cm^2 Pressure Error**	
Probable Cause	1) Air leakage from the pressure line in the main unit. 2) Pressure adjustment is incorrect. 3) Pneumatic system has failed.
Corrective Action	1) Check the pressure line for loosened nipple or tubing. 2) Adjust the pressure. (See *Chapter 6, Section 6.1: Adjusting the Pressure* for the procedures.) 3) If the error persists, contact your service representative.

Error Message	
•Vacuum Error*	
Probable Cause	1) Fluid back-flows into the trap chamber, or air leakage from the vacuum line in the main unit. 2) Air leakage from the vacuum line in the main unit. 3) Pneumatic system has failed.
Corrective Action	1) Discard fluid in the trap chamber, (See *Chapter 6, Section 3.5: Checking and Discarding Trap Chamber Fluid* for the procedures.), or check the trap chamber. 2) Check the vacuum line for loosened nipple or tubing. 3) Adjust the vacuum. 4) Contact your service representative.

*When a vacuum adjustment kit is installed, refer to *APPENDIX D* and adjust the vacuum.

NOTE: • When an External Pneumatic Unit is installed, refer to APPENDIX E.

2. Temperature Errors

Error Message	
•Temperature Error ("Location*", "High/Low") *** The "Location" can be one of the following: R. Probe, Detect 1, Detect 2, Cooler, and Room.**	
Probable Cause	1) Room temperature is unsuitable. (Temperature range: 15°C - 30°C) 2) Thermistor (temperature sensor) has failed.
Corrective Action	1) Use an air conditioner to control the temperature. 2) Contact your service representative.

3. Chamber Errors

Error Message	
•Waste is full	
Probable Cause	1) Waste line tubing is blocked or kinked. 2) Float switch in the internal waste chamber has failed.
Corrective Action	1) Check if the waste line tubing is blocked or kinked. 2) Check the float switch in the internal waste chamber. 3) If error persists, contact your service representative.

Error Message	
•Discard Waste	
Probable Cause	1) Waste tank is full of waste fluid. 2) Float switch in the waste tank has failed.
Corrective Action	1) Discard the waste fluid. 2) Check the float switch in the waste tank.

Error Message	
•Replenish Rinse fluid	
Probable Cause	1) Rinse chamber (inside instrument) has no more rinse solution. 2) Float switch in rinse chamber has failed.
Corrective Action	1) Replenish rinse solution, and then prime rinse solution to hydraulic line. For the procedures to replenish rinse solution, see *Chapter 6, Section 6.4: Replenishing Rinse Solution*; and for the procedures to prime rinse solution, see *Chapter 6, Section 4.1: Priming the Hydraulic Line with Rinse Solution*. 2) If error persists, contact your service representative.

Error Message	
•Insufficient Rinse fluid	
Probable Cause	1) Level of the rinse solution in the rinse tank is low. 2) Float switch connector for the rinse tank is disconnected. 3) Float switch in the rinse tank has failed.
Corrective Action	1) Replenish with rinse solution. For the procedures to replenish rinse solution, see *Chapter 6, Section 6.4: Replenishing Rinse Solution*. 2) Connect the float switch connector. 3) Check the float switch in the rinse tank. 4) If error persists, contact your service representative.

4. Motor Errors

Error Message	
•**Sample Probe Error (X)** •**Sample Probe Error (Y)**	
Probable Cause	1) Something is obstructing movement of sample probe. 2) Movement of sample probe unit is abnormal.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 3) If error persists, the instrument is probably malfunctioning. Contact your service representative.

Error Message	
•**Sample Probe Error (Z)**	
Probable Cause	1) Something is obstructing movement of sample probe. 2) Movement of the sample probe unit is abnormal.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 3) If error persists, the instrument is probably malfunctioning. Contact your service representative.

Error Message	
•**Reagent Probe Error (X)** •**Reagent Probe Error (Y)** •**Reagent Probe Error (Z)**	
Probable Cause	1) Something is obstructing movement of reagent probe. 2) Movement of reagent probe unit is abnormal.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 3) If error persists, the instrument is probably malfunctioning. Contact your service representative.

Error Message	
•**Catcher Error (X)** •**Catcher Error (Y)**	
Probable Cause	1) Something is obstructing movement of catcher unit. 2) Movement of catcher unit is abnormal.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 3) If error persists, the instrument is probably malfunctioning. Contact your service representative.

Error Message	
•**Catcher Error (Z)** •**Catcher Error (Down)**	
Probable Cause	1) Reaction tube that should be trashed remains in the incubation well or detector well. 2) Something is obstructing operation of catcher unit. 3) Movement of catcher unit is abnormal.
Corrective Action	1) Remove reaction tube. 2) Remove obstructing object or matter, if present. 3) If error persists, contact your service representative.

Error Message	
•**Catcher Error (Trash)**	
Probable Cause	1) Tube trash box is full. 2) Something is obstructing operation of catcher unit. 3) Movement of catcher unit is abnormal.
Corrective Action	1) Discard reaction tubes in the tube trash box. 2) Remove obstructing object or matter, if present. 3) If error persists, contact your service representative.

5. Syringe Errors

Error Message	
•No Sample in the Holder ("Rack No. - Tube Position")	
Probable Cause	1) Sample is not set. 2) Amount of plasma is insufficient.
Corrective Action	1) Check the sample at the tube position in the rack No. indicated. 2) Set the required amount of plasma at the tube position in the rack No. indicated.

Error Message	
•Insufficient Sample ("Rack No. - Tube Position")	
Probable Cause	1) Amount of sample used for re-analyzing is insufficient in the sample plate. 2) Inside diameter of tube or sample cup is too small. 3) Sample pipetting syringe is faulty.
Corrective Action	1) Set the required amount of plasma at the tube position in the rack No. indicated. 2) Use a tube or a sample cup whose inside diameter is 9.4 mm or more. 3) If error persists, contact your service representative.

Error Message	
•Sample Probe Sampling Error	
Probable Cause	1) Amount of plasma is insufficient. 2) Inside diameter of tube or sample cup is too small. 3) Sample pipetting syringe is faulty.
Corrective Action	1) Set the required amount of plasma. 2) Use a tube or a sample cup whose inside diameter is 9.4 mm or more. 3) If error persists, contact your service representative.

Error Message	
•Reagent Probe Sampling Error ("Reagent Name")	
Probable Cause	1) Amount of reagent is insufficient. 2) Inside diameter of reagent container or sample cup is too small. 3) Reagent dispensing unit is faulty. 4) Type of container (vial) which is set to the sample holder is different from the reagent information settings.
Corrective Action	1) Set the required amount of reagent. 2) Use a reagent container or a sample cup whose inside diameter is 9.4 mm or more. 3) If error persists, contact your service representative. 4) Change vial type in the reagent information settings.

Error Message	
•Insufficient Reagent ("Reagent Name") **•Insufficient Reagent ("Reagent or Control Name")**	
Probable Cause	1) There is no reagent, or required amount of reagent is not set. 2) Inside diameter of reagent container or sample cup is too small. 3) Type of container (vial) which is set to the sample holder is different from the reagent information settings.
Corrective Action	1) Set the required amount of the indicated reagent. See *Chapter 6, Section 6.1: Replenishing Reagents*. 2) Use a reagent container or a sample cup whose inside diameter is 9.4 mm or more. 3) Change vial type in the reagent information settings.

Error Message	
•Sample Probe Crash ("Position*") *** The "Position" can be one of the following: Sampler, Feeder, Rinse, Plate, STAT Holder, Reagent Holder D, Reagent Holder E and CP crash at rinse (when the CP unit is installed).**	
Probable Cause	1) Tube in the sample aspiration position contains no sample or a limited amount. 2) Something is obstructing lowering of sample probe. 3) Sample probe alignment is incorrect.
Corrective Action	1) Set the required amount of plasma. 2) Remove obstructing object or matter (if present) from indicated position. 3) If error persists, contact your service representative.

Error Message	
•Reagent Probe Crash ("Position*") *** The "Position" can be one of the following: Rinse or Reagent Name.**	
Probable Cause	1) There is no reagent, or only limited amount, in reagent position. 2) Inside diameter of reagent container or sample cup is too small. 3) Something is obstructing lowering of reagent probe. 4) Reagent probe alignment is incorrect. 5) Type of container (vial) which is set to the sample holder is different from the reagent information settings.
Corrective Action	1) Set the required amount of reagent. 2) Use a reagent container or a sample cup whose inside diameter is 9.4 mm or more. 3) Remove obstructing object or matter (if present) from indicated position. 4) If error persists, contact your service representative. 5) Change vial type in the reagent information settings.

Error Message	
•Sample Probe Crash Sensor Error **•Reagent Probe Crash Sensor Error**	
Probable Cause	Probe crash sensor is faulty.
Corrective Action	If error persists, contact your service representative.

Error Message	
•Sample Syringe Error	
Probable Cause	Problem occurred during operation of the sample syringe.
Corrective Action	If error persists, contact your service representative.

Error Message	
•Reagent Syringe Error	
Probable Cause	Problem occurred during operation of the reagent syringe.
Corrective Action	If error persists, contact your service representative.

Error Message	
•Check Sample Syringe	
Probable Cause	Sample syringe operation exceeded 300,000 cycles.
Corrective Action	Syringe may need a service. Contact your service representative.

Error Message	
•Check Reagent Syringe	
Probable Cause	Reagent syringe operation exceeded 300,000 cycles.
Corrective Action	Syringe may need a service. Contact your service representative.

Error Message	
•Insufficient Buffer ("Name")	
Probable Cause	There is no buffer, or required amount of buffer is not set.
Corrective Action	1) Set the required amount of the indicated buffer. See *Chapter 6, Section 6.1: Replenishing Reagents*.

Error Message	
•Buffer Sampling Error	
Probable Cause	1) Amount of buffer is insufficient. 2) Sample dispensing syringe is faulty.
Corrective Action	1) Replenish with diluent. See *Chapter 6, Section 6.1: Replenishing Reagents*. 2) If error persists, the instrument is probably malfunctioning. Contact your service representative.

Error Message	
•Plate full - Replace Plate.	
Probable Cause	Sample plate is completely used.
Corrective Action	Remove used sample plates, and set new sample plates. For the procedures to replace a sample plate, see *Chapter 6, Section 6.2: Replacing the Sample Plates*.

Error Message	
•No Reaction Tubes	
Probable Cause	1) There are no reaction tubes. 2) Reaction tube is caught in the rail between the feeder and the hopper.
Corrective Action	1) Supply reaction tubes; then press [Resume] key. See *Chapter 6, Section 6.3: Supplying Reaction Tubes*. 2) Remove the jammed reaction tube.

Error Message	
•Replenish Reaction Tubes	
Probable Cause	There are no reaction tubes.
Corrective Action	Supply reaction tubes. See *Chapter 6, Section 6.3: Supplying Reaction Tubes*.

Error Message	
•Catching Reaction Tube Failed	
Probable Cause	1) Catcher failed to catch a reaction tube. 2) Reaction tube jammed in the feeder unit.
Corrective Action	1) Remove the reaction tube between the feeder and the hopper. 2) Remove the jammed reaction tube from the feeder unit.

Error Message	
•Reaction Tube jammed	
Probable Cause	1) Reaction tube is caught in the rail between the feeder and the hopper. 2) Reaction tube jam sensor is faulty.
Corrective Action	1) Remove the jammed reaction tube. 2) If error persists, contact your service representative.

Error Message	
•Sample Plate Error	
Probable Cause	New sample plate is not set.
Corrective Action	Set a new sample plate. See *Chapter 6, Section 6.2: Replacing the Sample Plates*.

Error Message	
•Check Reagent Volume 1 (Warning)	
Probable Cause	Amount of reagent is less than the short reagent alarm limit.
Corrective Action	Replenish the reagent. See *Chapter 6, Section 6.1: Replenishing Reagents*.

Error Message	
•Check Reagent Volume 2 (Interrupt)	
Probable Cause	Amount of reagent is less than the short reagent interrupt limit.
Corrective Action	Replenish the reagent. See *Chapter 6, Section 6.1: Replenishing Reagents*.

6. Sampler Errors

Error Message	
•Sampler Rack Feed In Function Error	
Probable Cause	1) Rack is not correctly set. 2) Rack remains on the measurement line. 3) Something is obstructing the rack feed-in operation. 4) Rack feed-in mechanism is faulty.
Corrective Action	1) Reset the rack correctly. 2) Remove the rack from the measurement line, and reset it on the right rack pool. 3) Remove obstructing object or matter, if present. 4) Reset the rack. 5) If error persists, contact your service representative.

Error Message	
•Sampler Rack Feed In Home Position Error	
Probable Cause	1) Something is obstructing movement of the rack feed-in lever. 2) Rack feed-in mechanism is faulty.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Reset the rack. 3) If error persists, contact your service representative.

Error Message	
•Sampler Rack Shift Function Error	
Probable Cause	1) Rack remains on the measurement line in the left rack pool. 2) Something is obstructing the rack shift operation. 3) Rack shift mechanism is faulty.
Corrective Action	1) Remove the rack from the measurement line in the left rack pool, and reset the rack in the right rack pool. 2) Remove obstructing object or matter, if present. 3) Reset the rack. 4) If error persists, contact your service representative.

Error Message	
•Sampler Rack Shift Home Position Error	
Probable Cause	1) Something is obstructing the rack shift mechanism operation. 2) Rack shift mechanism is faulty.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Reset the rack. 3) If error persists, contact your service representative.

Error Message	
•Sampler Rack Move Error 1	
Probable Cause	1) Rack is not correctly set. 2) Something is obstructing the rack shift operation. 3) Rack shift mechanism is faulty.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Reset the rack. 3) If error persists, contact your service representative.

Error Message	
•Sampler Rack Move Error 2	
Probable Cause	1) Rack was moved or touched during analysis interruption. 2) Rack shift monitoring sensor is faulty.
Corrective Action	1) Reset the rack. 2) If error persists, contact your service representative.

Error Message	
•Sampler Rack Feed Out Function Error	
Probable Cause	1) Something is obstructing the rack feed-out mechanism operation. 2) Rack feed-out mechanism is faulty. 3) Rack feed-out mechanism operation sensor is faulty.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Reset the rack. 3) If error persists, contact your service representative.

Error Message	
•Sampler Rack Feed Out Home Position Error	
Probable Cause	1) Something is obstructing the rack feed-out mechanism operation. 2) Rack feed-out mechanism is faulty. 3) Rack feed-out mechanism operation sensor is faulty.
Corrective Action	1) Remove obstructing object or matter, if present. 2) Reset the rack. 3) If error persists, contact your service representative.

Error Message	
•Sample Rack Full	
Probable Cause	1) Left rack pool is filled up with racks that have been analyzed. 2) Rack full sensor is faulty.
Corrective Action	1) Remove analyzed racks from the left rack pool; then reset racks on the measurement line or in the right rack pool. 2) If error persists, contact your service representative.

Error Message	
•Set Sample Rack	
Probable Cause	1) Rack is not set in the right rack pool. 2) Racks not set correctly in right rack pool 3) Rack detection sensor is faulty.
Corrective Action	1) Set a rack. 2) Reset the rack. 3) If error persists, contact your service representative.

Error Message	
•Rack Position Error at Start	
Probable Cause	1) Rack is left on the measurement line. 2) Rack shift operation sensor is faulty.
Corrective Action	1) Remove the rack from the measurement line, and reset the rack you wish to analyze in the right rack pool. 2) If error persists, contact your service representative.

Error Message	
•No Test tubes in the rack ("Rack No. - Tube Position")	
Probable Cause	1) Sample is not set in the rack. 2) Tube detection sensor is faulty.
Corrective Action	1) Check the rack. 2) If error persists, contact your service representative.

7. Analysis Errors

Error Message	
•Expired Reagent ("Reagent Name")	
Probable Cause	1) A set reagent is passed the expiration date. 2) No expiration date is set in the reagent information setting screen; or setting is incorrect.
Corrective Action	1) Replace with a new reagent, and set expiration date of the new reagent by setting reagent information. For the procedures to replace reagent, see *Chapter 6, Section 6.1: Replenishing Reagents*; and to set expiration date, see *Chapter 11, Section 5.1: Reagent Information Settings*. 2) Set expiration date by setting reagent information. For the procedures to set expiration date, see *Chapter 11, Section 5.1: Reagent Information Settings*.

Error Message	
•Detector Adjustment Error	
Probable Cause	Detector block sensitivity is abnormal.
Corrective Action	Check installation of lamp; then readjust. If error persists, contact your service representative.

Error Message	
•Settings Lost	
Probable Cause	Settings are invalid.
Corrective Action	Check settings.

8. Memory Errors

Error Message	
•Stored Data Error	
Probable Cause	Error occurred in the stored data on the hard disk or backup memory.
Corrective Action	1) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 2) If error persists, the instrument is probably malfunctioning. Contact your service representative.

Error Message	
•QC Data Error	
Probable Cause	Error occurred in the stored data on the hard disk.
Corrective Action	1) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 2) If error persists, contact your service representative.

Error Message	
•ROM Error **•RAM Error**	
Probable Cause	1) Electric noise interference 2) Microcomputer device failure
Corrective Action	1) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 2) If error persists, contact your service representative.

9. External Device Errors

Error Message	
•GP Paper Empty	
Probable Cause	Graphic printer is out of paper.
Corrective Action	Replenish paper for the graphic printer.

Error Message	
•GP Error	
Probable Cause	1) Graphic printer is off-line. 2) Graphic printer's power is OFF. 3) Connection cable for the graphic printer is disconnected.
Corrective Action	1) Switch the graphic printer to on-line. 2) Turn ON the graphic printer power switch. 3) Check that the connection cable for the graphic printer is securely connected.

Error Message	
•HC Order is wrong	
Probable Cause	Order (rack No. or sample ID No.) is incorrect at the order inquiry to the host computer.
Corrective Action	Check the order of the host computer.

Error Message	
•HC Off Line	
Probable Cause	1) Connection cable is disconnected. 2) Host computer's power is OFF. 3) Host computer is not ready to receive signals.
Corrective Action	1) Check that the cable is securely connected. 2) Turn ON the host computer. 3) Check the operation of the host computer.

Error Message	
•HC Communication Error **•HC CTS Time Out** **•HC ACK Code Error** **•HC Transmission Count Error** **•HC Reception Count Error**	
Probable Cause	Communication with host computer is abnormal.
Corrective Action	Check host computer.

Error Message	
•HC ACK Time Out **•HC STX Time Out** **•HC ETX Time Out**	
Probable Cause	Host computer did not respond within the prescribed time-out time (15 sec).
Corrective Action	Check the host computer.

Error Message	
•Instructions Not Found In Host Computer	
Probable Cause	Order inquiry was sent to the host computer, but "No order" (999) was returned.
Corrective Action	Check that an order is registered in the host computer.

Error Message	
•Barcode Scanner Error	
Probable Cause	Operation of the barcode scanner is faulty.
Corrective Action	1) Turn OFF the power switch, wait a few seconds, and then turn it back ON. 2) If error persists, contact your service representative.

10. Quality Control and Standard Curve Analysis Errors

Error Message	
•QC Flag Limit ("File No.", "Parameter Name")	
Probable Cause	Results of quality control analysis exceeded the upper or the lower flag limit.
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•QC Exceeds Stop Limit ("File No.", "Parameter Name")	
Probable Cause	Results of quality control analysis exceeded the upper or the lower stop limit.
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•QC Flag Limit (1-2S) ("File No.", "Parameter Name") **•QC Exceeds Stop Limit (1-2S) ("File No.", "Parameter Name")**	
Probable Cause	Results of QC analysis exceeded limit (mean ±2SD).
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•QC Flag Limit (1-3S) ("File No.", "Parameter Name") **•QC Exceeds Stop Limit (1-3S) ("File No.", "Parameter Name")**	
Probable Cause	Results of QC analysis exceeded limit (mean ±3SD).
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•QC Flag Limit (2-2S) ("File No.", "Parameter Name") **•QC Exceeds Stop Limit (2-2S) ("File No.", "Parameter Name")**	
Probable Cause	Results of QC analysis exceeded limit (mean ±2SD) 2 consecutive times.
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•QC Flag Limit (4-1S) ("File No.", "Parameter Name") **•QC Exceeds Stop Limit (4-1S) ("File No.", "Parameter Name")**	
Probable Cause	Results of QC analysis exceeded limit (mean ±1SD) 4 consecutive times.
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•QC Flag Limit (R-4S) ("File No.", "Parameter Name") **•QC Exceeds Stop Limit (R-4S) ("File No.", "Parameter Name")**	
Probable Cause	Difference from the previous QC analysis results exceeds 4SD.
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•QC Flag Limit (10X) ("File No.", "Parameter Name") **•QC Exceeds Stop Limit (10X) ("File No.", "Parameter Name")**	
Probable Cause	Results of ten consecutive QC analysis strayed to the same side of the target.
Corrective Action	1) Check to see if the control plasma and reagents are within the expiration date. 2) Check that the control plasma is stored correctly. 3) Repeat QC analysis.

Error Message	
•Set more than two points	
Probable Cause	There are less than two standard curve analysis points.
Corrective Action	Set at least two points.

Error Message	
•Set Diluent or Reagent	
Probable Cause	Diluent or reagent used to dilute the standard curve analysis sample is not set in the setting program screen.
Corrective Action	Set the diluent or reagent correctly in the standard curve analysis setting menu.

Error Message	
•Standard Curve Error	
Probable Cause	Preset standard curve data is abnormal.
Corrective Action	Set a correct standard curve.

Error Message	
•Standard Curve Warning	
Probable Cause	Some analyzed data have errors.
Corrective Action	Confirm the data in the stored data screen. If there is a probrem, analyze again. Otherwise, update the standard curve.

11. Operation Errors

Error Message	
•Power Turned Off During Operation	
Probable Cause	Power shut off during analysis.
Corrective Action	Usually analysis has not been completed when this error occurs. Check stored data. If analysis has not been completed, register order information again and perform analysis.

Error Message	
•Mechanical Stop Switch was pressed	
Probable Cause	Mechanical stop switch was pressed.
Corrective Action	Perform resume operation. See *Chapter 4, Section 5: EMERGENCY STOP*.

Error Message	
•Close STAT sample cover.	
Probable Cause	STAT sample cover is open when starting analysis or during analysis.
Corrective Action	Close the STAT sample cover.

Error Message	
•Light Shield Lid is open.	
Probable Cause	Light shield lid is open when starting analysis or during analysis.
Corrective Action	Close the light shield lid.

12. Other Errors

Error Message	
•Empty the Tube Trash.	
Probable Cause	Reaction tube trash box is about full of reaction tubes (approx. 250 tubes).
Corrective Action	Discard reaction tubes that are in the tube trash box. See *Chapter 6, Section 3.2: Discarding the Used Reaction Tubes*.

Error Message	
•Tube Trash has not been set.	
Probable Cause	Tube trash box is not set.
Corrective Action	Set the tube trash box.

Error Message	
•Tube Trash is full. **•Empty the Tube Trash.**	
Probable Cause	Tube trash box is full of reaction tubes.
Corrective Action	Discard reaction tubes that are in the tube trash box. See *Chapter 6, Section 3.2: Discarding the Used Reaction Tubes*.

Error Message	
•Lamp Filter Error	
Probable Cause	Lamp unit operation is faulty.
Corrective Action	If error persists, contact your service representative.

Error Message	
•Replace Lamp Unit.	
Probable Cause	The light quantity of the lamp decreased because of the lamp life. (The life of the lamp is generally about 2000 hours in 100% duty cycle.)
Corrective Action	Replace the lamp. See *Chapter 6, Section 6.6: Replacing the Lamp*.

Error Message	
•Replace Piercer.	
Probable Cause	Piercing operation has reached 30,000 times. It is time to replace the piercer needle.
Corrective Action	Replace the piercer needle.

Error Message	
•CP Unit Error	
Probable Cause	Cap piercer operation is faulty.
Corrective Action	If error persists, contact your service representative.

4.5 Analysis Data Errors

Error Code	Message	Probable Cause	Corrective Action
ERR001	Temp. Error	Temperature error occurred during analysis of the sample.	See “Temperature Errors.”
ERR002	Slight Coagulation	Detected reaction is extremely small.	Check sample for contaminants; Verify delivery of the sample and reagent; Re-analyze the sample. If repeat result is equivalent to the original result, report the value obtained at the 50% coagulation detection point.
ERR004	Analysis Time Over	Analysis not completed within the normal detection time.	Check sample for contaminants; Verify delivery of sample and reagent; Re-analyze the sample. If re-analysis gives results without an asterisk (*) the result may be reported. If there is an (*) with the re-analysis result, the sample may not be capable of forming a clot. Follow your laboratory’s alternate protocol.
ERR008	Coagulation Curve Error	Coagulation curve abnormalities: 1) Slope drops in areas. 2) Slope is too steep in areas. 3) Coagulation time was extended for Fbg due to air bubbles caused by cold buffer.	Equilibrate buffer to room temperature, then re-analyze.
ERR016	Overflow (Turbidity Level Over)	Turbidity too high to allow analysis.	Check sample for contaminants; Verify delivery of sample and reagent; Re-analyze the sample. If re-analysis results in an error message, follow your laboratory’s alternate protocol.
ERR032	No Coagulation	Coagulation was not detected.	Make overall evaluation of whether error was made in sample (such as storage conditions or collection) or reagent (such as storage conditions).
ERR064	Aged Sample	Prescribed time has passed after the sample was pipetted to the Sample Plate.	Re-analyze the sample.
ERR100	Range Over	Exceeded analysis range.	Make overall evaluation of whether error was made in sample (such as storage conditions or collection) or reagent (such as storage conditions).
ERR128	Early Reaction Error	An abnormal reaction was detected at an initial stage of the coagulation.	Re-analyze the sample.

Table 9-4-1: Analysis Data Errors

ERR401	Trans Light Low	Transmitted light is extremely low.	Check reagent and lamp; then re-analyze.
ERR402	Trans Light High	Transmitted light is extremely high.	Check reagent and lamp; then re-analyze.
ERR404	No Linearity	Reaction curve lacks linearity.	Re-analyze.
ERR408	Reaction Curve Error	Reaction curve switched to the opposite direction.	Check setting and reagent; then re-analyze.
ERR416	Range Over	Excess antigens are present (Immunoassay Method only).	Dilute sample and re-analyze.
ERR464	Aged Sample	Prescribed time has passed after the sample was pipetted to the Sample Plate.	Re-analyze the sample.
ERR528	No polynomial adjustment	Reaction curve could not be polynomially approximated.	Re-analyze the sample.
ERR656	Range in non-linear	Reaction curve is not linear or could not be linearly approximated.	Re-analyze the sample.
ERR999	Analysis Failed	Could not analyze because of plasma shortage or instrument error.	Prepare required amount of plasma; then re-analyze.

Table 9-4-2: Analysis Data Errors

NOTE:
- ERR4xx indicates an error caused by chromogenic or immunoassay method.

5. INSTRUMENT CHECK

This section will explain how to test whether the instrument is operating properly, and how to display instrument maintenance items.

5.1 Displaying the Instrument Check Menus

This section will explain how to display menus to check the instrument.

1. Operation of Special Menu Keys

If you press the [Special Menu] key on the Main Menu screen, the special menu will appear.

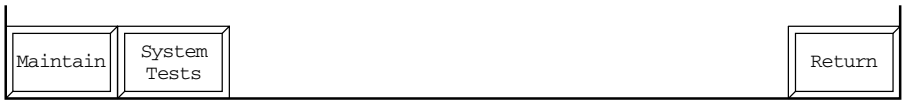

Figure 9-5-1: Special Menu

[Maintain] key: Displays Maintenance sub menu.
[System Tests] key: Displays System Tests sub menu.
[Return] key: Displays Main menu.

2. Operation of Maintenance Sub menu Keys

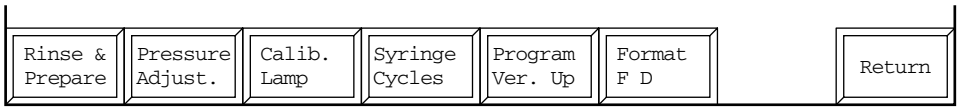

Figure 9-5-2: Maintenance Sub menu

[Rinse & Prepare] key: Primes rinse solution to the hydraulic lines. See *Chapter 6, Section 4.1: Priming the Hydraulic Line with Rinse Solution*.

[Pressure Adjust.] key: Adjusts the pressure. See *Chapter 6, Section 5.1: Adjusting the Pressure*.

[Calib. Lamp] key: Calibrates the lamp when the lamp is replaced. See *Chapter 6, Section 6.6: Replacing the Lamp*.

[Syringe Cycles] key: Displays the number of syringe cycles. See *Section 5.2: Displaying the Syringe Cycle Count* in this chapter.

[Program Ver. Up] key: Displays the program version. See *Section 5.3: Displaying the Program Version* in this chapter.

[Format FD] key: Formats floppy disks. See *Section 5.4: Formatting a Floppy Disk* in this chapter.

[Return] key: Displays the Special Menu.

3. Operation of System Tests Sub menu Keys

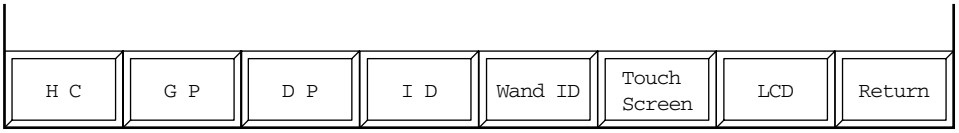

Figure 9-5-3: System Tests Sub menu Keys

[HC] key: Tests the communication with host computer. See *Section 5.5: Communication Test* in this chapter.

[GP] and [DP] keys: Tests the printing ability of the graphic printer (GP) and data printer (DP). See *Section 5.6: Print Test* in this chapter.

[ID] key: Executes barcode reader tests. See *Section 5.7: Sample Barcode Reader Test* in this chapter.

[Wand ID] key: Executes an optional wand barcode reader test. See *Section 5.8: Wand Barcode Reader Test* in this chapter.

[Touch Screen] key: Tests the touch panel keys. See *Section 5.9: Touch Panel Key Test* in this chapter.

[LCD] key: Tests the colors of the LCD screen. See *Section 5.10: LCD Screen Test* in this chapter.

[Return] key: Displays the Special Menu.

5.2 Displaying the Syringe Cycle Count

This section will explain how to display the number of syringe cycles.

From the Maintenance sub menu, press the [Syringe Cycles] key. The Syringe Cycle Count screen will appear.

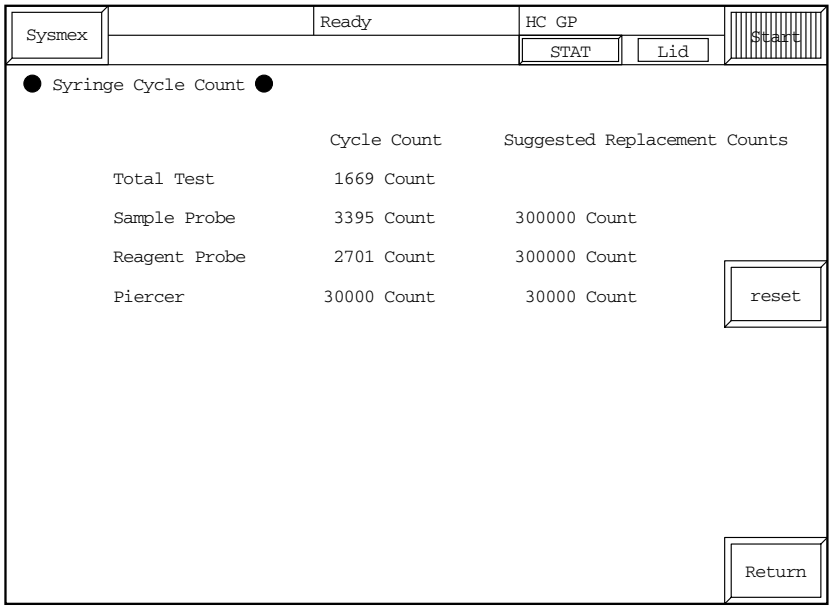

Figure 9-5-4: Syringe Cycle Count Screen

To return to the Maintenance sub menu, press the [Return] key.
If a cap piercer unit is not installed, the piercer cycle count and [reset] key are not displayed.

5.3 Displaying the Program Version

This section will explain how to display the program version.

From the Maintenance sub menu, press the [Program Ver. Up] key. The Program Version screen will appear.

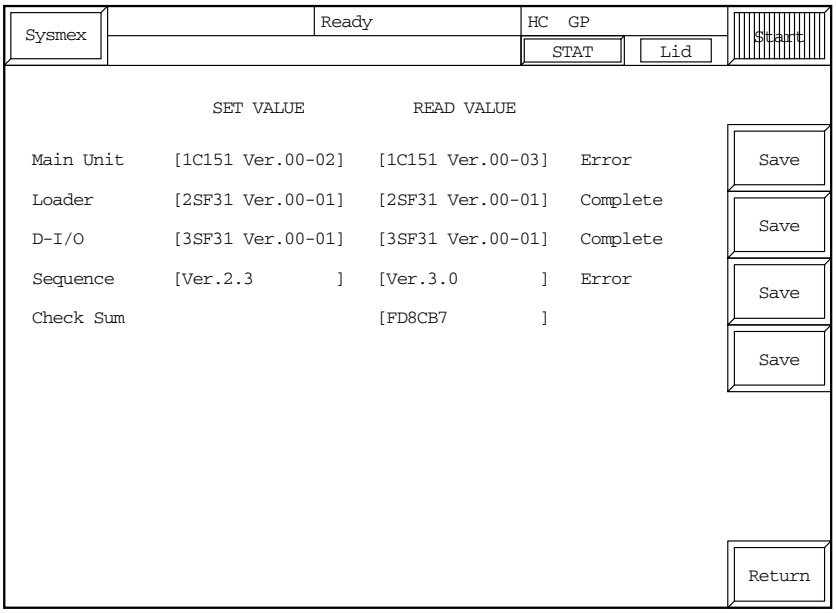

Figure 9-5-5: Program Version Screen

The preset version and currently running version will be displayed. If these versions agree, the message "Complete" is displayed. If they are different, the message "Error" will appear. Check the version; then press the [Save] key to set the new version.

To return to the Maintenance sub menu, press the [Return] key.

5.4 Formatting a Floppy Disk

This section will explain how to format a floppy disk.

(1) From the Maintenance sub menu, press the [Format FD] key. An FD Confirmation window will appear.

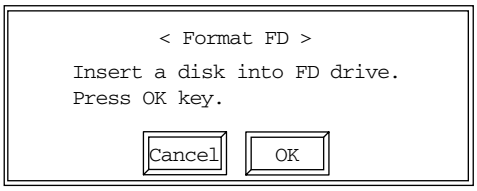

Figure 9-5-6: Format FD Confirmation Window

(2) Insert a floppy disk into the floppy disk drive. To cancel the operation, press the [Cancel] key.

(3) Press the [OK] key. The FD Format execution confirmation window will appear. To cancel the operation, press the [Cancel] key.

(4) Press the [OK] key. The floppy disk will be formatted, and the message "Formatting Disk" will be displayed. After the disk is formatted, a confirmation window will appear asking whether you wish to format another disk.

(5) Press the [OK] or [Cancel] key.

[OK] key:	Formats another floppy disk. When the FD Confirmation window appears, replace the first floppy disk with a second disk and complete the process as before.
[Cancel] key:	Discontinues formatting and returns to the Maintenance sub menu.

5.5 Communication Test (Option)

This section will explain how to test the communication with a host computer.

(1) From the System Tests sub menu, press the [HC] key. The Serial Interface Communication Test screen will appear.

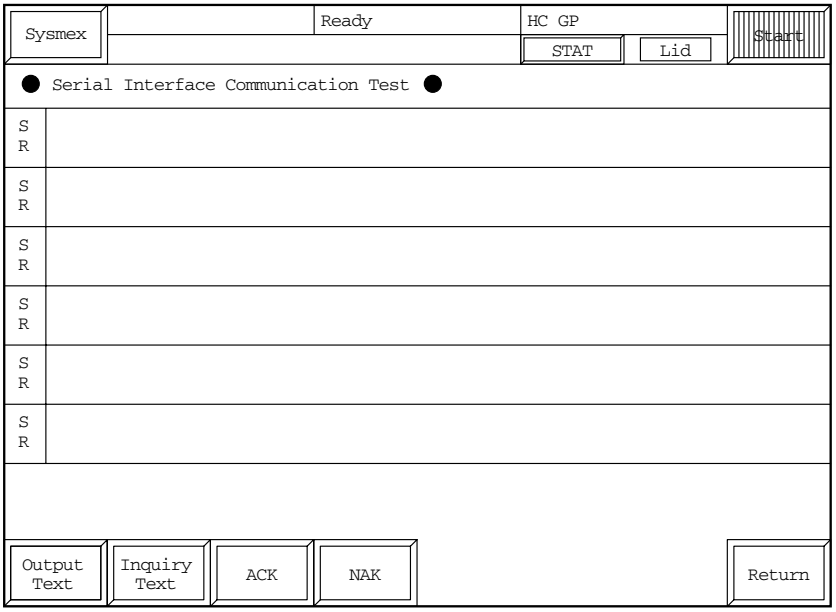

Figure 9-5-7: Serial Interface Communication Test Screen

(2) Press the key for the text to communicate.

[Output Text] key:	Sends simulated data of analysis results.
[Inquiry Text] key:	Sends simulated inquiry data of text and receives order text.
[ACK] key:	Sends ACK response.
[NAK] key:	Sends NAK response.

Sent data will appear on the "S" line of the screen in green characters.
Received data will appear on the "R" line of the screen in blue characters.

(3) When the test is completed, press the [Return] key.
The System Tests sub menu will reappear.

5.6 Print Test (Option)

This section will explain how to test the printing ability of the optional graphic printer and the optional data printer.

(1) From the System Tests sub menu, press the key for the desired printer to be tested.

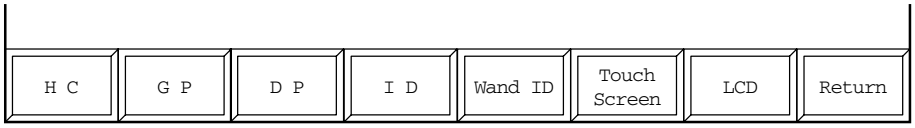

Figure 9-5-8: System Tests Sub menu

[GP] key: The graphic printer will print the screen that is currently displayed.
[DP] key: The data printer will print dummy data in the preset print format.

5.7 Sample Barcode Reader Test (Option)

This section will explain how to execute an optional barcode reader test.

(1) From the System Tests sub menu, press the [ID] key. The Barcode Reader Test screen will appear.

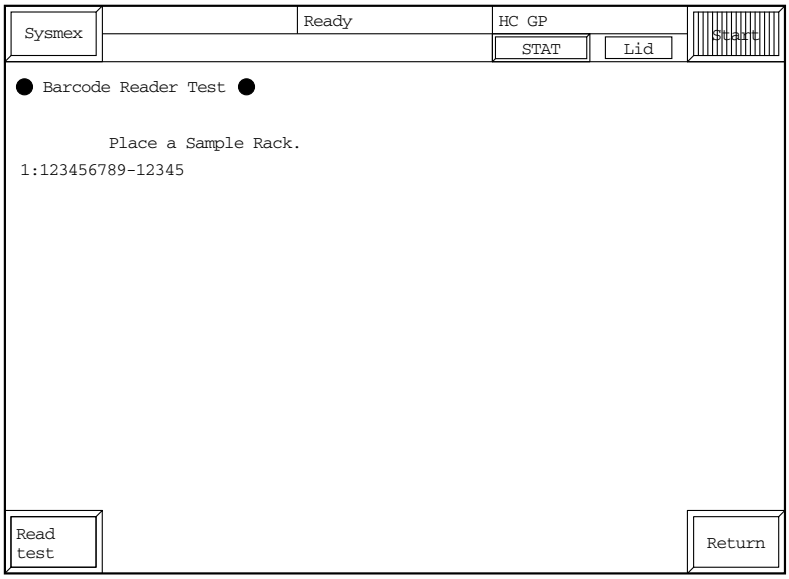

Figure 9-5-9: Barcode Reader Test Screen

(2) Take the rack that holds the tubes to which the barcode label is affixed, and set it in the right rack pool of sampler.

(3) Press the [Read test] key. The rack will be automatically fed in, and the barcode reader will read the barcode. If a read error occurs, an error message will be displayed.

(4) When the test is completed, press the [Return] key. The System Tests sub menu will reappear.

5.8 Wand Barcode Reader Test (Option)

This section will explain how to execute an optional wand barcode reader test.

(1) From the Main Menu screen, press the [Special Menu], [System Tests], and then [Wand ID] key. The Wand Barcode reader Test screen will appear. (The [Wand ID] key is displayed only when an optional wand barcode reader is used.)

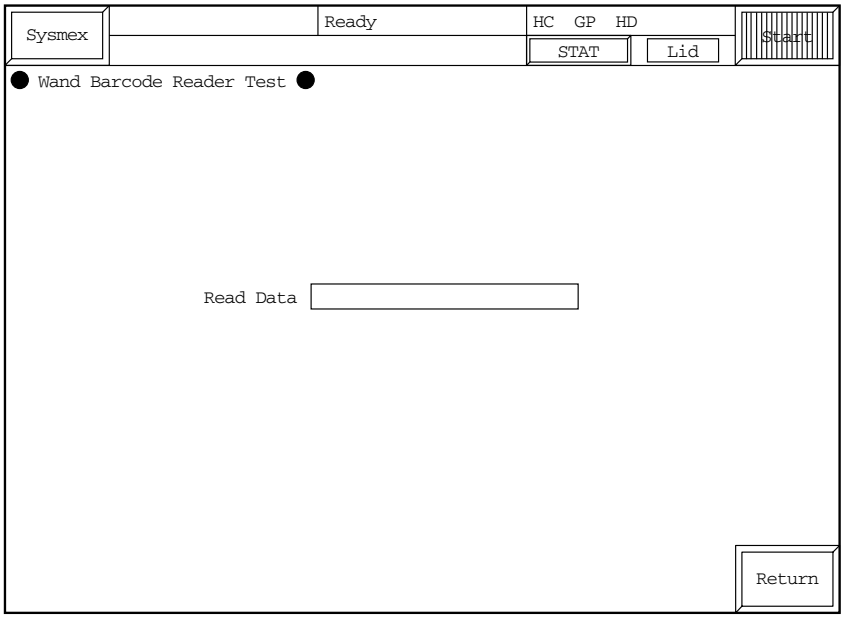

Figure 9-5-10: Wand Barcode Reader Test Screen

(2) Read a barcode label using wand barcode reader. The read sample ID number will be displayed.

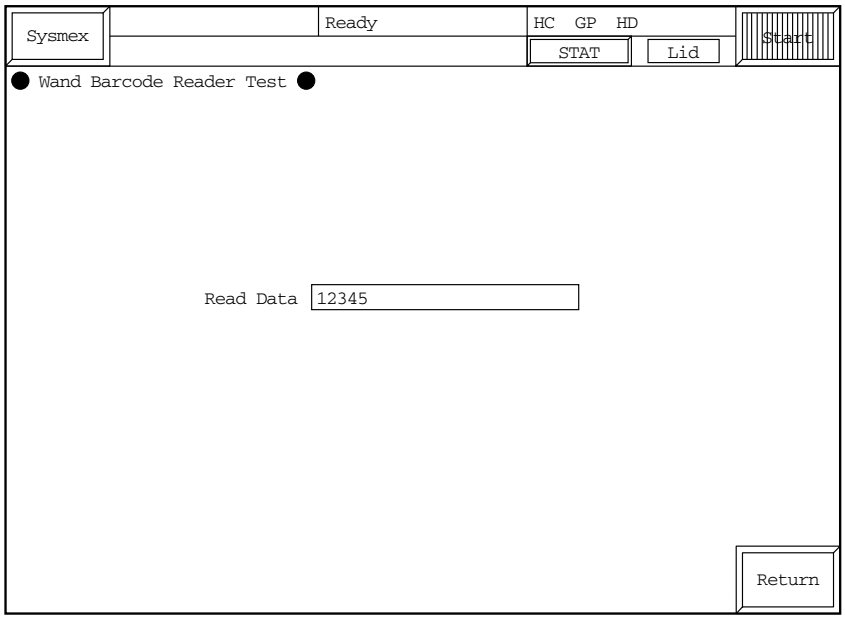

Figure 9-5-11: Wan Barcode Reader Test Screen

(3) When the test is completed, press the [Return] key. The System test sub menu will appear.

5.9 Touch Panel Key Test

This section will explain how to test the Touch Panel keys.

(1) From the System Tests sub menu, press the [Touch Screen] key. The Touch Panel Key Test screen will appear.

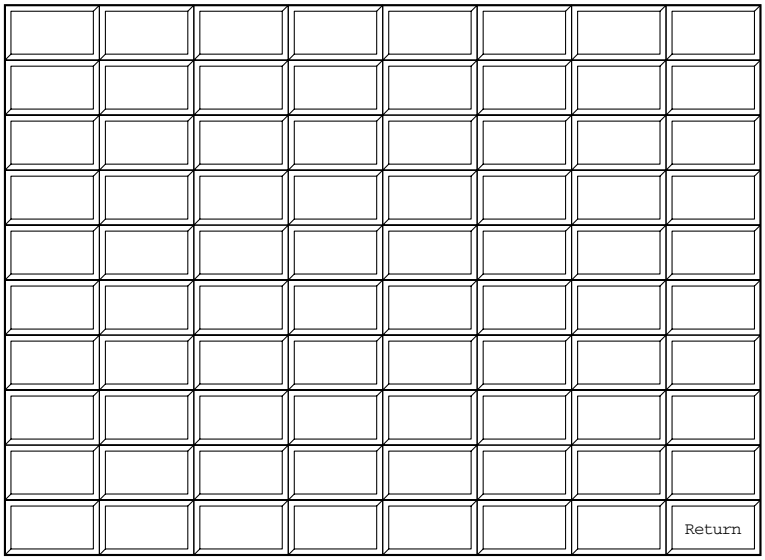

Figure 9-5-12: Touch Panel Key Test Screen

(2) Press a key other than the [Return] key. The color will change to sky blue while the key is being pressed. The key will be blue when not pressed.

(3) When the test is completed, press the [Return] key. The System Tests sub menu will reappear.

5.10 LCD Screen Test

This section will explain how to test the colors of the LCD screen.

(1) From the System Tests sub menu, press the [LCD] key. The LCD Test screen will appear.

(2) Lightly press the screen. The color of the screen will change in order. If you do not press the screen, it will automatically change every 10 seconds. After the final color is displayed, the System Tests sub menu will reappear.

Screen Color Change
Black → Red → Green → Yellow → Blue → Pink → Light blue → White → Black → Dark green → Dark yellow → Dark blue → Dark pink → Blue → Off-white

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1. INTRODUCTION

This chapter explains the coagulation detection principles and analysis flow in the CA-1500.

Detection Principles
Explains the detection principles for Coagulation Method, Chromogenic Method and Immunoassay Method.

Analysis Flow
Describes the required sample volume and reagent volume for each analysis parameter.

Name and Function of Each Component
Describes the name and functions of the major components in the instrument.

2. DETECTION PRINCIPLES FOR COAGULATION METHOD

After a fixed quantity of blood plasma has been warmed for a certain time period, reagent is added. The sample to which the reagent has been added is then exposed to light having a wavelength of 660 nm, and the turbidity of the blood during the coagulation process (transformation of fibrinogen into fibrin) is detected as the change in scattered light intensity.
From this change in scattered light intensity, a coagulation curve is prepared and the coagulation time is found by means of the Percentage Detection Method.

2.1 Optical Detection Method (Scattered Light Detection Method)

The CA-1500 utilizes the Optical Detection Method and thus detects the change in turbidity of blood during the coagulation process as the change in scattered light intensity.
Light that is emitted from a light source reaches the sample. The scattered light intensity is received by a photodiode, which converts the light intensity into electrical signals. These signals are stored and calculated by a microcomputer in order to find the coagulation time.

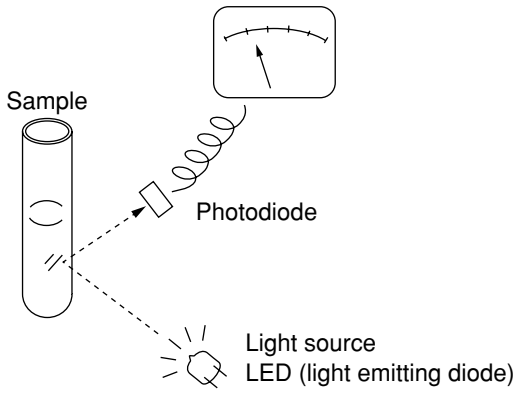

Figure 10-2-1: Optical Detection System

2.2 Blood Coagulation and Scattered Light Intensity

The relationship between blood coagulation and scattered light is described below.

Step 1: Add warmed reagent to plasma that has also been warmed for a certain time period.

Step 2: Scattered light is weak and there is almost no change in the sample immediately after the reagent is added.

Steps 3 - 4: As the reaction gradually progresses, fibrin clots begin to form. At the same time, the sample becomes cloudy and a sharp increase in scattered light intensity is detected.

Step 5: After coagulation is completed, the increase in scattered light intensity ceases and stabilizes at a certain scattering level.

As described above, the CA-1500 can record the blood coagulation process as the change in scattered light intensity and then can output the coagulation curve.

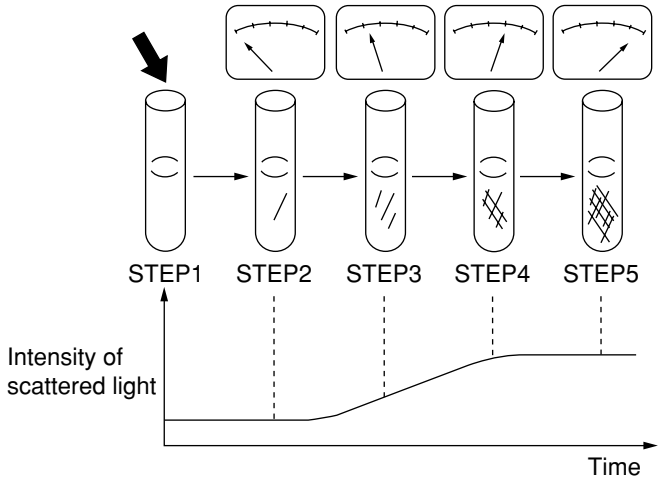

Figure 10-2-2: Blood Coagulation Time and Intensity of Scattered Light

2.3 Coagulation Point Detection Method (Percentage Detection Method)

To detect the coagulation time, the Percentage Detection Method is employed.
The level of scattered light intensity that is present right after the coagulation reagent is added but before coagulation has started is defined as 0%, and the level of scattered light intensity that is present after coagulation is completed is defined as 100%. The time that it takes for the level of scattered light intensity to reach the preset detection percentage is found from the coagulation curve. This is defined as the coagulation time. (The coagulation detection point is set at 50% in the figure below.) With this method, the coagulation time can be detected even if small changes in scattered light intensity take place.
The coagulation time can thus be detected using samples that show small changes in scattered light intensity (low-fibrinogen samples) or even samples whose speed of change is only slight (samples with extended coagulation time).

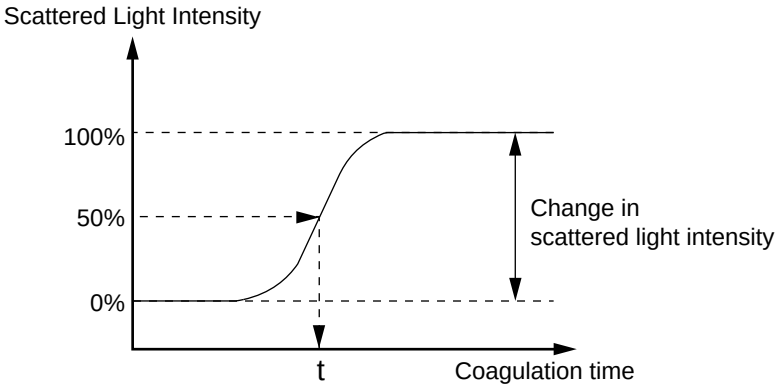

Figure 10-2-3: Determination of Coagulation Time

2.4 Standard Curve for Coagulation Method

For parameters whose detection principle is the Coagulation Method, a linear relationship exists between the coagulation time and activity percent (or concentration) when they are plotted on a log-log graph. The CA-1500 can make use of the aforementioned relationship to prepare standard curves. The standard curves are made by joining consecutive pairs of concentrations (or activity percent) with straight lines. The two ends of the standard curves are made by extending the line made between the pair of concentration points (or activity percent) that are nearest the end.

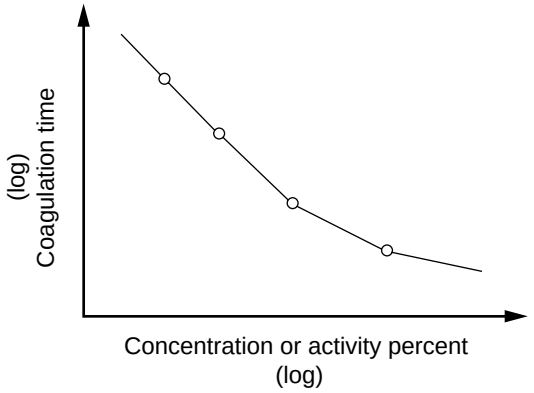

Figure 10-2-4: Standard Curve for Coagulation Method

By changing the settings, you can also select the following standard curve format:
(1) Log-log linear approximation (or polygonal line)
(2) Real number-reciprocal number linear approximation (or polygonal line)
(3) Real number-real number linear approximation (or polygonal line)
(4) Log-real number linear approximation (or polygonal line)
(5) Log-reciprocal number linear approximation (or polygonal line)
(6) Real number-log linear approximation (or polygonal line)
(7) Reciprocal number-real number linear approximation (or polygonal line)
(8) Reciprocal number-reciprocal number linear approximation (or polygonal line)
(9) Reciprocal number-log linear approximation (or polygonal line)
(10) AKIMA method interpolation (Real number)

2.5 Calculation of PT Ratio and INR Value

The CA-1500 can calculate a PT ratio and display it, if the normal PT value has been entered in the Standard Curve program. The International Normalized Ratio (INR) will be displayed and printed with analysis results if the International Sensitivity Index (ISI) of the PT reagent has also been entered in the Standard Curve program.
Please note that the ISI value depends on the lot number of PT reagent.

$$\text{PT ratio} = \frac{\text{PT coagulation time of sample plasma}}{\text{normal PT value}}$$

$$\text{INR} = (\text{PT ratio})^{\text{ISI}}$$

CAUTION:
- ISI values for prothrombin time assays must be entered directly as they appear on the current reagent labeling.
  Any changes of reagent lot, software upgrades, major servicing, etc., require verification of the ISI value.
  Failure to enter the correct ISI value will cause incorrect International Normalized Ratio (INR) results.

2.6 Analysis Flow

- **PT Flow**

Sample Volume	Plasma	50 µL
Reagent Volume	PT reagent	100 µL

Table 10-2-1: Sample/Reagent Volume - PT

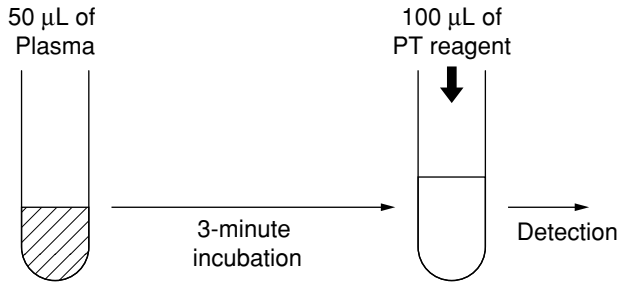

Figure 10-2-5: PT Flow

- **APTT Flow**

Sample Volume	Plasma	50 µL
Reagent Volume	APTT reagent	50 µL
	Calcium Chloride Solution	50 µL

Table 10-2-2: Sample/Reagent Volume - APTT

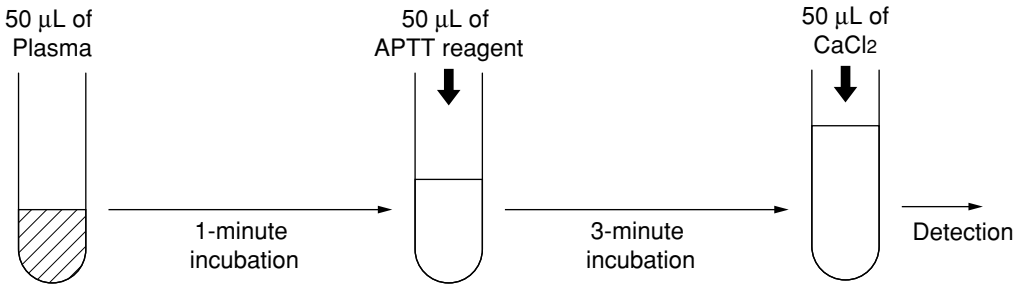

Figure 10-2-6: APTT Flow

- **Fbg Flow**

Sample Volume	Plasma	10 µL
Reagent Volume	Thrombin reagent	50 µL
	Owren's Veronal buffer	90 µL

Table 10-2-3: Sample/Reagent Volume - Fbg

* Samples with high Fbg concentration are prepared with 5 µL of plasma and 95 µL of buffer for redilution analysis.
Samples with low Fbg concentration are prepared with dilution ratio of 1/5 (20 µL of plasma with 80 µL of buffer) for redilution analysis.

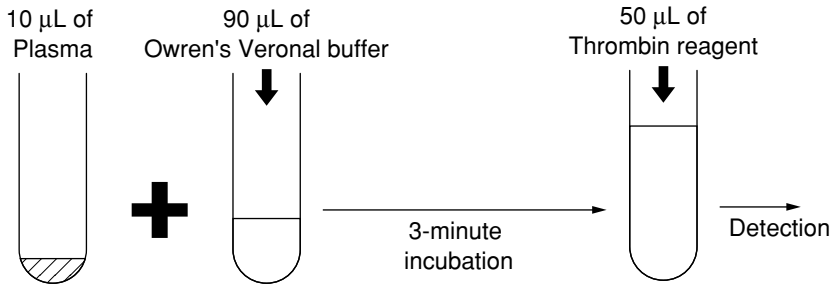

Figure 10-2-7: Fbg Flow

- **TTO Flow***

Sample Volume	Plasma	20 µL
Reagent Volume	Thrombotest reagent	125 µL
	Owren's Veronal buffer	30 µL

Table 10-2-4: Sample/Reagent Volume - TTO

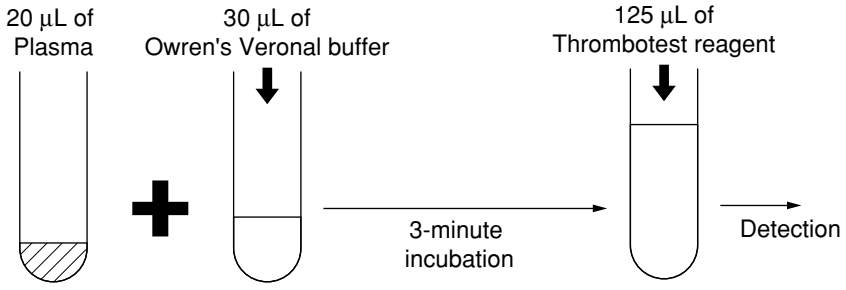

Figure 10-2-8: TTO Flow

* Not available in the USA.

- **NT Flow***

Sample Volume	Plasma	10 µL
Reagent Volume	Normotest reagent	125 µL
	Owren's Veronal buffer	40 µL

Table 10-2-5: Sample/Reagent Volume - NT

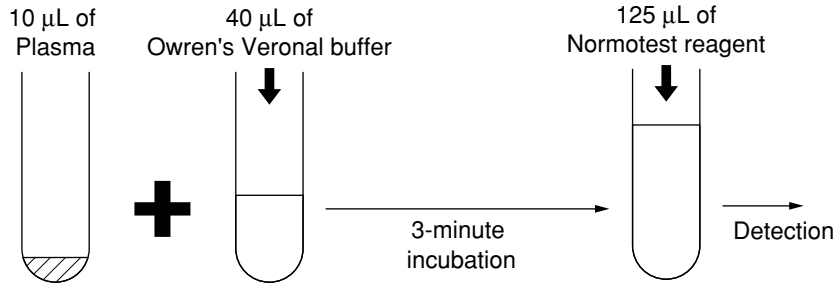

Figure 10-2-9: NT Flow

- **TT Flow**

Sample Volume	Plasma	50 µL
Reagent Volume	Thrombin Time reagent	100 µL

Table 10-2-6: Sample/Reagent Volume - TT

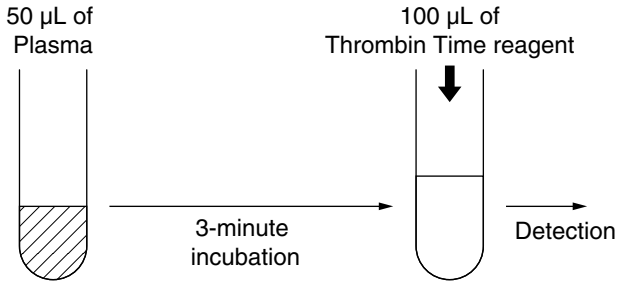

Figure 10-2-10: TT Flow

* Not available in the USA.

- **Extrinsic Factor Measurement Flow**

Sample Volume	Plasma	5 µL
Reagent Volume	PT reagent	100 µL
	Owren's Veronal buffer	45 µL
	Factor-deficient plasma	50 µL

Table 10-2-7: Sample/Reagent Volume - Extrinsic Factor

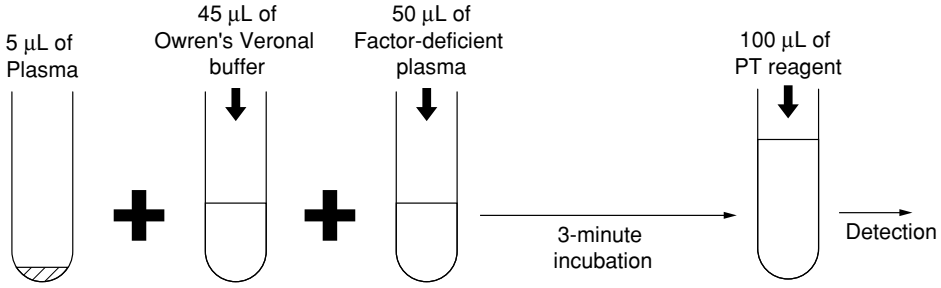

Figure 10-2-11: Extrinsic Factor Measurement Flow

- **Intrinsic Factor Measurement Flow**

Sample Volume	Plasma	5 µL
Reagent Volume	APTT reagent	50 µL
	Calcium Chloride Solution	50 µL
	Owren's Veronal buffer	45 µL
	Factor-deficient plasma	50 µL

Table 10-2-8: Sample/Reagent Volume - Intrinsic Factor

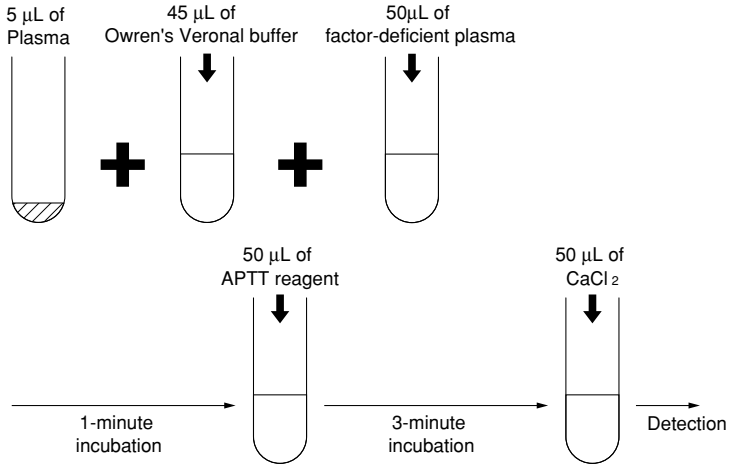

Figure 10-2-12: Intrinsic Factor Measurement Flow

3. DETECTION PRINCIPLES FOR CHROMOGENIC METHOD

After a fixed quantity of blood plasma has been warmed for a certain time period, reagent and substrate are added. The sample is then exposed to light of a defined wavelength. As soon as blood plasma and substrate are brought together, light absorbent molecules are formed, whose concentration is detected as the change in transmitted light.

3.1 Transmitted Light Detection Method

The optical system for the Transmitted Light Detection Method is shown below.
Light from the light source is separated into 405 nm, 575 nm and 800 nm components by one of three filters. The filtered light passes through the sample and reaches a photodiode, where the transmitted light is converted into electrical signals. The change in the intensity of this transmitted light is stored and calculated by microcomputer, and the change in absorbance per minute (ΔOD/min) is determined.

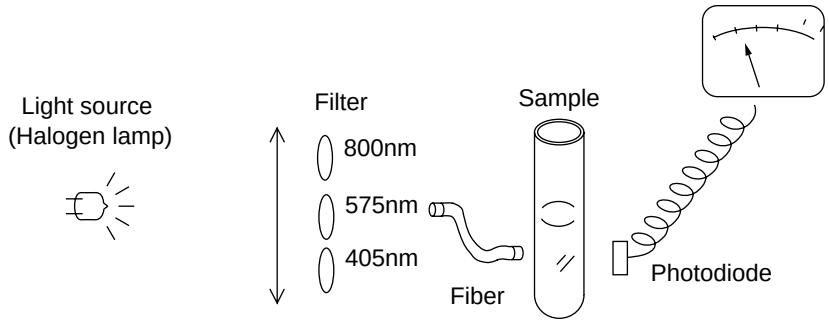

Figure 10-3-1: Transmitted Light Detection System

NOTE: • Applications are currently supported using 405 nm and 800 nm wavelength. A 575 nm filter is available for applications as designed by the operator.

3.2 Calculating the Change in Light Absorbance

The change in light absorbance per minute can be determined from the linear regression of the absorbance data between the start and the end points that were preset as described in *Chapter 11, Section 5.5: Detector Settings.*

3.3 Standard Curve for Chromogenic Method

In general with regard to parameters whose detection principle is the Chromogenic Method, a linear relationship exists between the change in light absorbance (ΔOD/min) and the concentration (or activity percent) when they are plotted on a real number graph. The CA-1500 can make use of the aforementioned relationship to prepare standard curves. And as with the Coagulation Method, by changing the settings, you can also accommodate other standard curves.

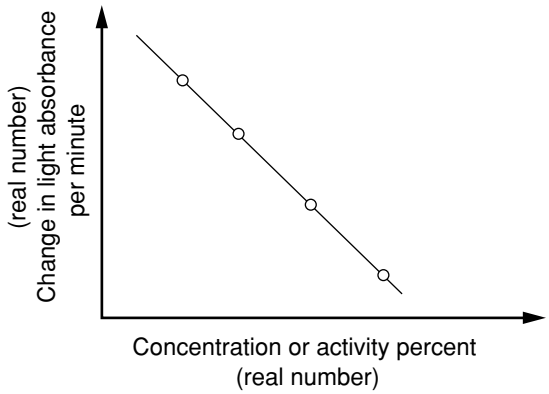

Figure 10-3-2: Standard Curve for Chromogenic Method

3.4 Analysis Flow

- **AT III Flow**

Sample Volume	Plasma	16 µL
Reagent Volume	Activator	175 µL
	Substrate	33 µL
	Owren's Veronal buffer	112 µL

Table 10-3-1: Sample/Reagent Volume - AT III

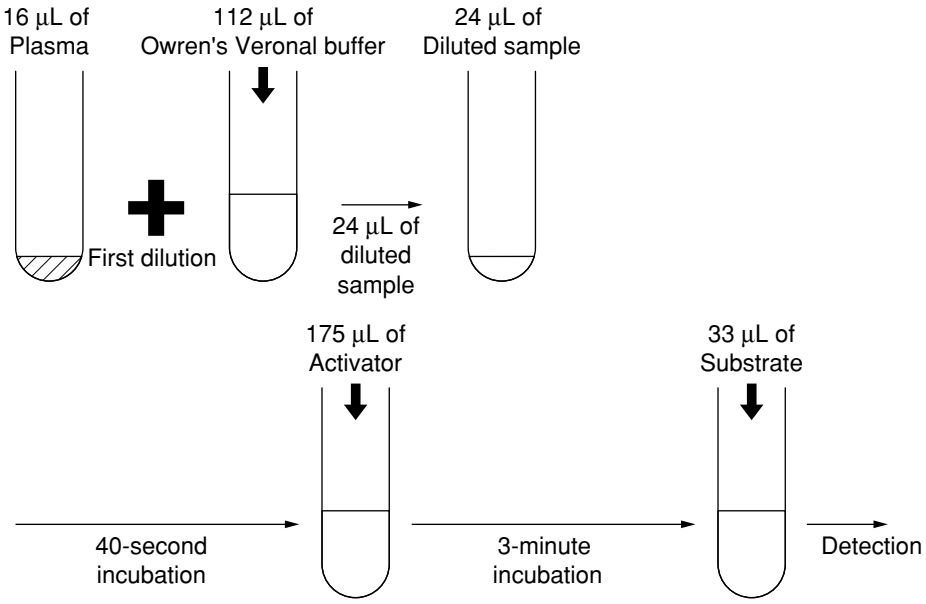

Figure 10-3-3: AT III Flow

- **α2PI Flow**

Sample Volume	Plasma	16 μL
Reagent Volume	Activator	175 μL
	Substrate	35 μL
	Owren's Veronal buffer	112μL

Table 10-3-2: Sample/Reagent Volume - α2PI

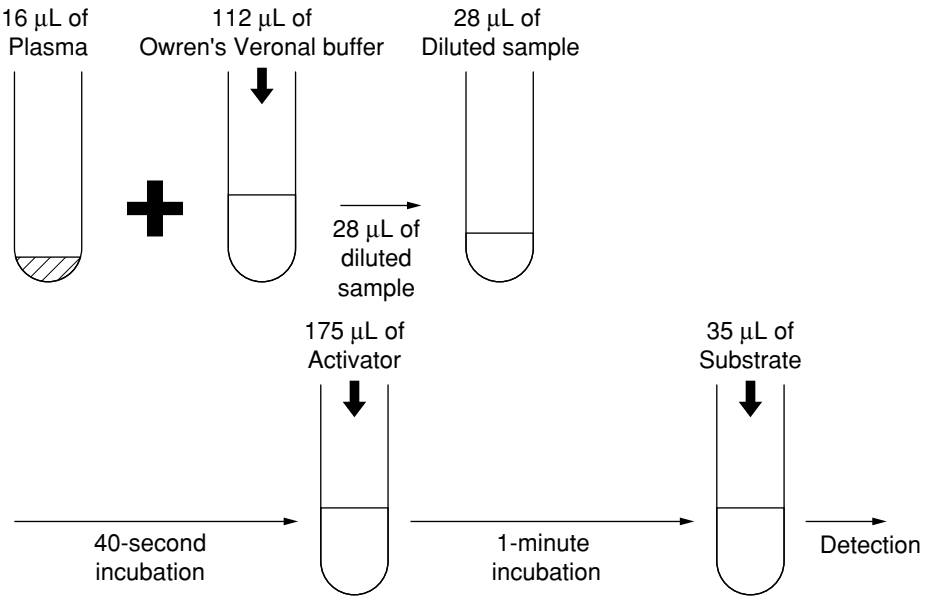

Figure 10-3-4: α2PI Flow

- **Plg Flow**

Sample Volume	Plasma	16 µL
Reagent Volume	Activator	175 µL
	Substrate	35 µL
	Owren's Veronal buffer	112 µL

Table 10-3-3: Sample/Reagent Volume - Plg

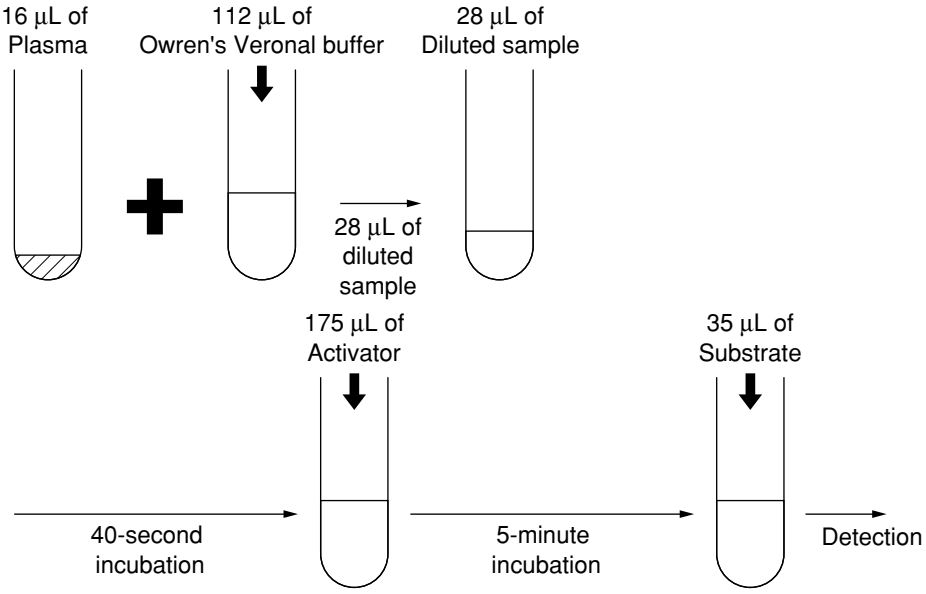

Figure 10-3-5: Plg Flow

- **PC Flow**

Sample Volume	Plasma	15 µL
Reagent Volume	Activator	150 µL
	Substrate	34 µL
	Owren's Veronal buffer	15 µL

Table 10-3-4: Sample/Reagent Volume - PC

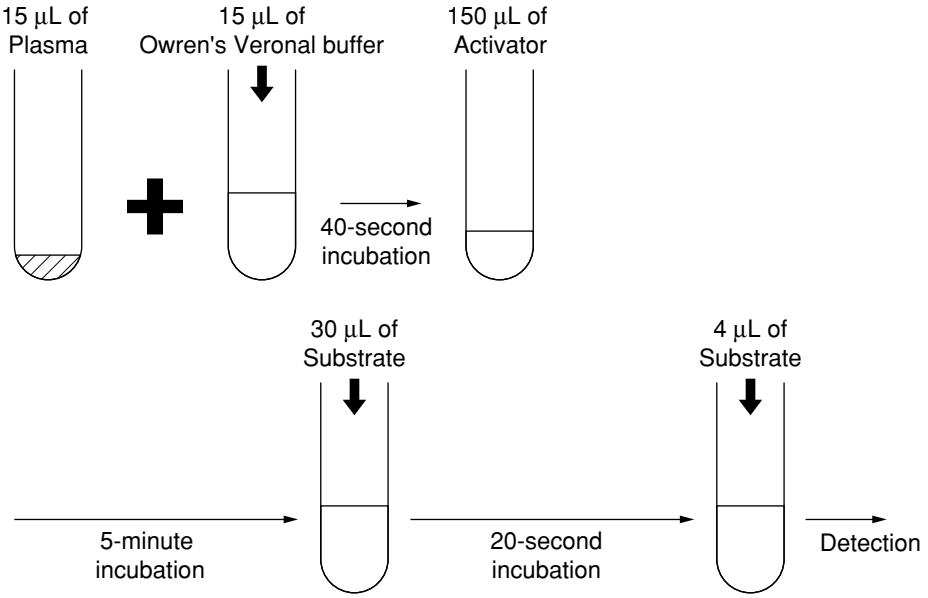

Figure 10-3-6: PC Flow

4. DETECTION PRINCIPLES FOR IMMUNOASSAY METHOD

After a fixed amount of sample has been warmed for a certain time period, stabilizing reagent and antibody sensitive reagent may be added. The sample is then exposed to light of a defined wavelength, and the change in light absorbance caused by the antigen antibody reaction is detected as the change in transmitted light.

4.1 Transmitted Light Detection Method

The optical system for the Transmitted Light Detection Method is shown below.
Light from the light source is separated into 405 nm, 575 nm and 800 nm components by one of three filters. The filtered light passes through the sample and reaches a photodiode, where the transmitted light intensity is converted into electrical signals. The change in the amount of this transmitted light is stored and calculated by a microcomputer, and the change in absorbance per minute (ΔOD/min) is determined.

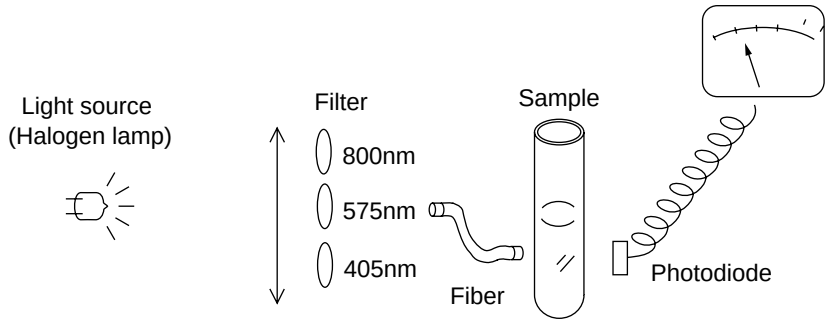

Figure 10-4-1: Transmitted Light Detection System

NOTE:	• Applications are currently supported using 405 nm, 575 nm and 800 nm wavelength.

4.2 Calculating the Change in Light Absorbance

The change in light absorbance per minute can be determined from the linear regression of the absorbance data between the start and end points that were preset as described in *Chapter 11, Section 5.5: Detector Settings.*

4.3 Standard Curve for Immunoassay Method

A linear relationship exists between the change in light absorbance (ΔOD/min) and the concentration (or activity percent) when both parameters are plotted on a real number graph. The CA-1500 can make use of the aforementioned relationship to prepare standard curves. Standard curves are made by joining consecutive pairs of concentration (or activity percent) with straight lines. The two ends of the standard curves are made by extending the line made by the pair of concentration points (or pair of activity percent points) that is nearest the end.

NOTE:

- In cases where the antigen concentration is excessively high, the prozone phenomenon may be observed. Hence an increase in antigen concentration is accompanied by a decrease in light absorbance. When the prozone phenomenon occurs, the reported antibody concentration will be lower than the actual value; thus, the instrument will display an error message. When that happens, dilute the sample and re-analyze.

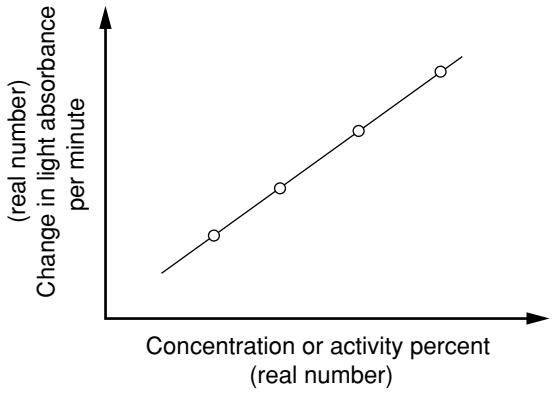

Figure 10-4-2: Standard Curve for Immunoassay Method

4.4 Analysis Flow

- **FDP Flow** (Latex Test BL-2 P-FDP)**

Sample Volume	Plasma	16 µL
Reagent Volume	Stabilizing reagent	66 µL
	Latex reagent	94 µL
	Diluent	112 µL

Table 10-4-1: Sample/Reagent Volume - FDP

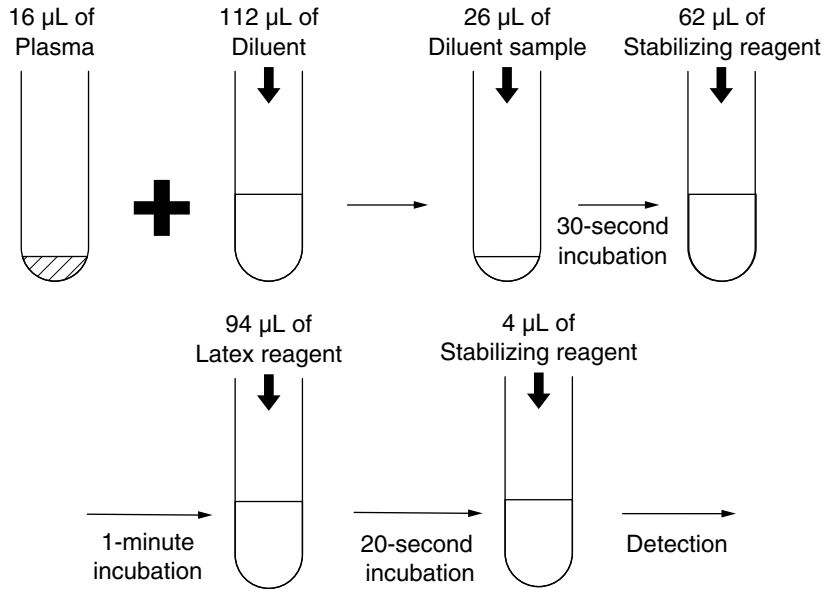

Figure 10-4-3: FDP Flow

** Available for use only in Asia.

- **D-Dimer Flow**

Sample Volume	Plasma	50 µL
Reagent Volume	Accelerator	25 µL
	Latex Reagent	150 µL

Table 10-4-2: Sample/Reagent Volume - D-Dimer PLUS*/Advanced D-Dimer#

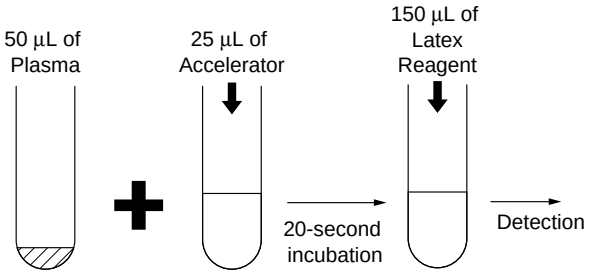

Figure 10-4-4: D-Dimer PLUS*/Advanced D-Dimer#

* Not available in the USA.
\# Available for use only in the USA.

- **INNOVANCE° D-Dimer Flow**

Sample Volume	Plasma	13 µL
Reagent Volume	Diluent	13 µL
	Supplement	17 µL
	Buffer	61 µL
	Reagent	56 µL

Table 10-4-3: Sample/Reagent Volume - INNOVANCE° D-Dimer

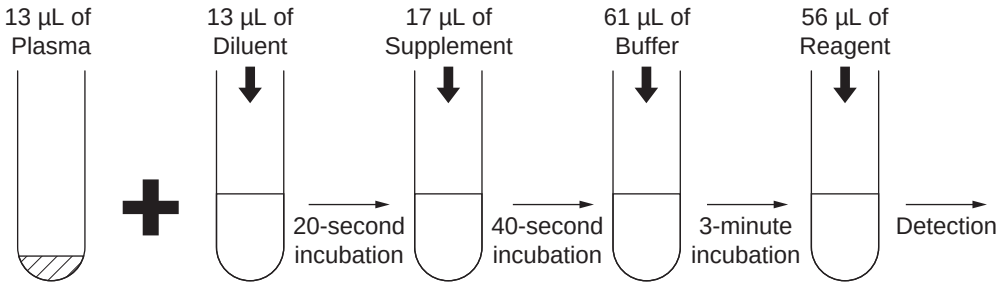

Figure 10-4-5: INNOVANCE° D-Dimer

5. ANALYSIS MECHANISM

The CA-1500 employs units of the mechanical, hydraulic, and electrical systems, and performs analysis according to the procedure described below.

1. Samples in the right rack pool are carried to the aspiration position by sampler operation.

2. The sample probe aspirates the required amount of sample plasma from the sample rack. The required amount is automatically calculated for each sample and depends on the pre-set analysis parameters and number of replications (repetitions).

3. The aspirated sample plasma is dispensed into the sample plates (in Normal mode). The aspirated sample plasma is dispensed into the reaction tubes (in Micro-sample mode).

4. The sample probe aspirates the sample plasma from the sample plates, and then dispenses it into the reaction tubes (in Normal mode).

5. The sample-containing reaction tubes are warmed (incubated) for a certain time period.

6. The reagent probe aspirates a certain amount of the prescribed reagent from the reagent vial in the reagent trays. The reagent is warmed within the reagent probe for a certain time period.

7. The sample that was warmed in the incubator is carried by the catcher to the reagent dispensing position, and the reagent inside the reagent probe is added.

8. The sample tube to which the reagent has been added is agitated by the catcher and then carried to the detector block, where detection of analysis simultaneously starts.

9. In the detector block, coagulation reaction is detected through the change in scattered light or transmitted light.

10. The reaction tubes of samples that have been analyzed are transported by the catcher to the tube trash box for disposal.

6. INSTRUMENT COMPONENTS AND FUNCTIONS

6.1 Front

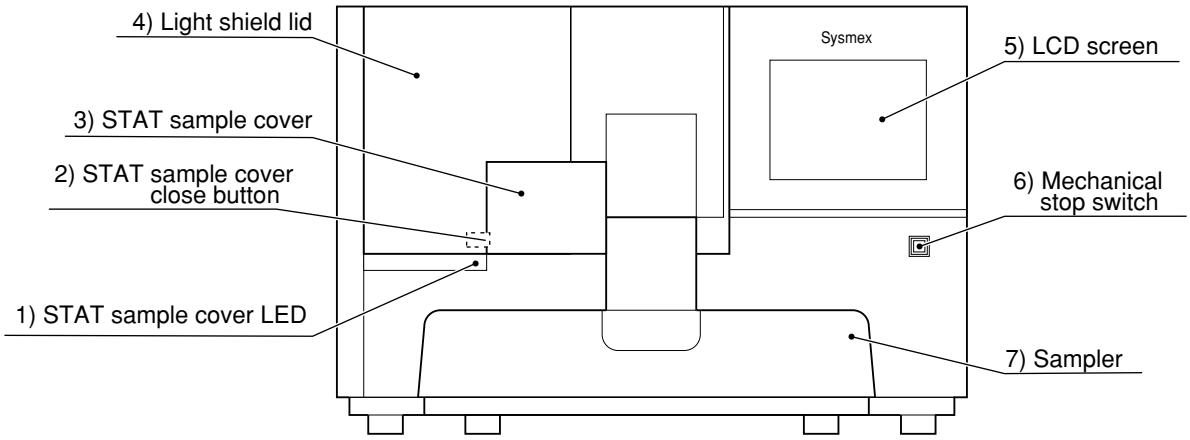

Figure 10-6-1: Front View

1) STAT sample cover LED
This LED indicates whether it is permissible to open the STAT sample cover. When it is permissible to open the cover, the LED will be green; when not permissible, red.

2) STAT sample cover close button
To close the STAT sample cover, press this switch so that the cover will gently close.

3) STAT sample cover
To set a sample in a STAT sample holder, verify the "STAT sample cover LED" turns green; then press this cover in to open.

4) Light shield lid
To inspect and clean the instrument, the light shield lid can be opened upward with your hand when the system is "Ready" or the instrument power is OFF.
To replace reagents and sample plates, you may open this lid only when the "Lid" signal at the top of the LCD screen turns green while the system is analyzing.

5) LCD screen/Touch panel
The LCD screen displays coagulation curves, analysis results, error messages, and order registration. And since it is a touch-panel screen, you can perform operations and make settings simply by pressing the keys shown on the screen.

6) Mechanical stop switch
Press this switch to immediately stop the instrument mechanical movement. However, if the system program is still running, it will ask if you wish to terminate analysis completely.

7) Sampler
The sampler automatically transports samples that are set in the sample rack to the aspiration position.

6.2 Front Interior

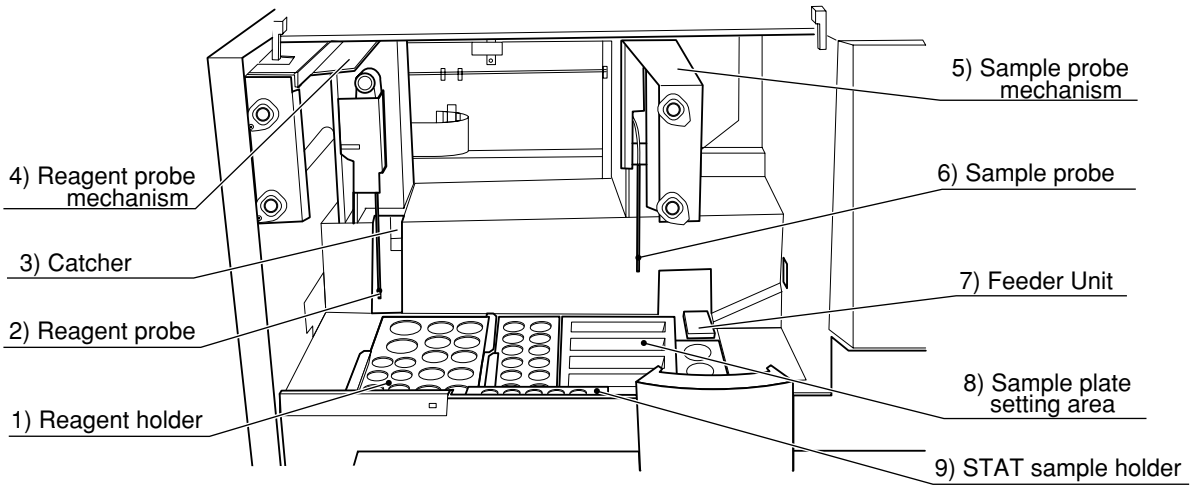

Figure 10-6-2: Front Interior

1) Reagent holder
Has a cooling function, and holds reagents according to the arrangement set in the Consumable screen.

2) Reagent probe
Has a heater function, and aspirates reagent, incubates the reagent within a specified temperature, and dispenses it into the sample.

3) Catcher
Gets a reaction tube from the feeder unit, and transfers it to the incubator well, to the detector well, and to the trash box.

4) Reagent probe mechanism
Moves the reagent probe in X-Y-Z directions.

5) Sample probe mechanism
Moves the sample probe in X-Y-Z directions.

6) Sample probe
Aspirates and dispenses samples, control plasma, calibrators, and buffers (diluents).

7) Feeder unit
Aligns reaction tubes from the hopper, and supplies to the catcher.

8) Sample plate setting area
Holds up to 5 sample plates.

9) STAT sample holder
Holds up to 5 STAT samples at a time.

6.3 Left Side

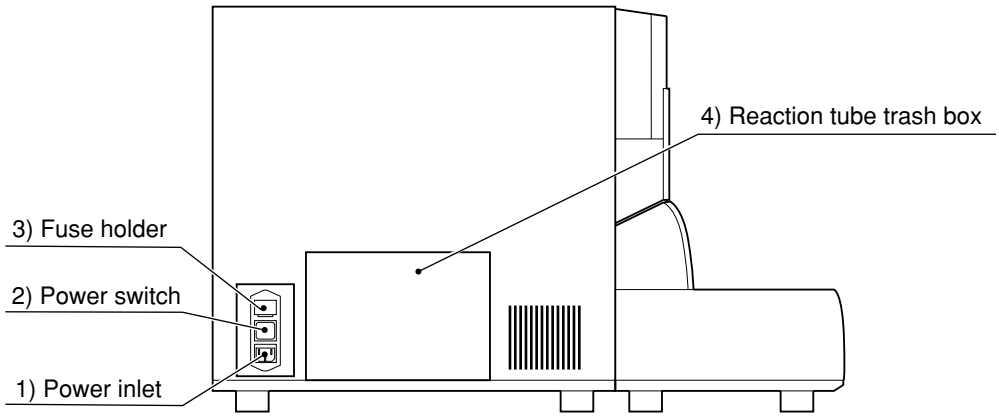

Figure 10-6-3: Left Side View

1) Power inlet
Connects the provided power cord to supply power to the unit.

2) Power switch
Turns the power ON and OFF.

CAUTION:	• Do not turn the power ON and OFF repeatedly in a short interval.

3) Fuse holder

Two time-lag type fuses are installed in this fuse holder. The rating will be different depending on the instrument specification as below.

Specification	Part No.	Description	Type
117 VAC	266-5014-4	Fuse 250V 10A CES14-10A-N1 (N.AMERICA)	Time Lag
220/240 VAC	266-5296-1	Fuse 250V 5A No. 19195 (EUROPE)	Time Lag

Table 10-6-1: Fuse Specifications

WARNING: • To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.

CAUTION: • For continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

4) Reaction tube trash box

Receives and holds approx. 200 used reaction tubes. A larger trash container for approx. 400 reaction tubes is an optional extra. Clean with tap water every time tubes are discarded or at least once a day.

6.4 Right Side

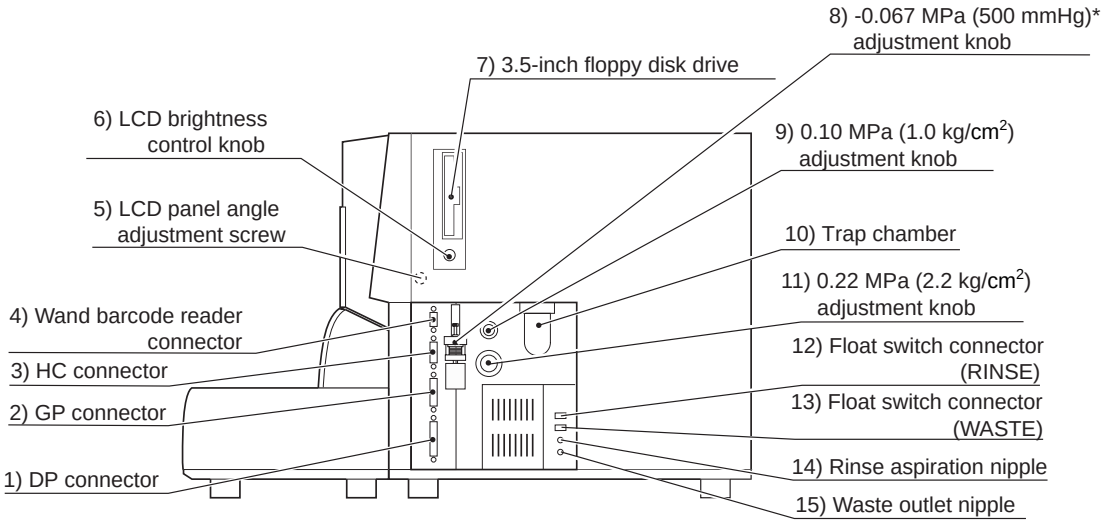

Figure 10-6-4: Right Side View

1) DP connector
Connects an optional data printer (ticket printer).

2) GP connector
Connects an optional graphic printer.

3) HC connector
Connects an optional host computer.

4) Wand barcode reader connector
Connects an optional wand barcode reader.

5) LCD screen angle adjustment screw
Allows adjusting the angle of the LCD screen. This screw is located inside the right side panel. See *Appendix A, Section 11, step (8)* for the procedures.

6) LCD brightness control knob
Adjusts the brightness of the LCD screen. Since this LCD screen has an automatic power saving function, touch anywhere on the LCD screen prior to any adjustment.

7) 3.5-inch floppy disk drive

Either of the following floppy disks can be used:

- Preformatted 2HD floppy disks (MS-DOS) that are available in the market
- Quality control floppy disks that are provided by Sysmex

CAUTION: •When inserting the floppy disk, floppy disk label should face to the right (back of the instrument).

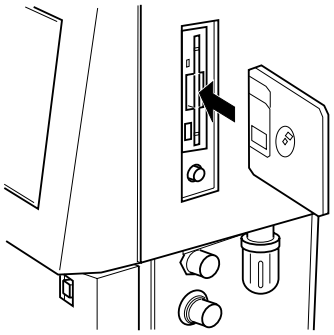

Figure 10-6-5: Inserting Direction of FD

8) -0.067 MPa (500 mmHg) adjustment knob*

Adjusts the vacuum to -0.067 MPa (500 mmHg)

*When a vacuum adjustment kit is installed, refer to *APPENDIX D* and adjust the vacuum. Otherwise the knob does not exist.

9) 0.10 MPa (1.0 kg/cm^2) adjustment knob

Adjusts the pressure to 0.10 MPa (1.0 kg/cm^2).

10) Trap chamber

Prevents reagent from flowing back into the compressor.

11) 2.2 MPa (2.2 kg/cm^2) adjustment knob

Adjusts the pressure to 2.2 MPa (2.2 kg/cm^2).

12) Float switch connector (RINSE)

This connector is for the rinse solution float switch.

13) Float switch connector (WASTE)

This connector is not used when the waste is drained to the sewer.
This connector is used for the waste fluid float switch, when an optional waste tank is provided.

14) Rinse aspiration nipple

Rinse solution is aspirated via this nipple from the rinse tank.

15) Waste outlet nipple

Waste fluid is discharged via this nipple to the sewer or an optional waste tank.

6.5 Top

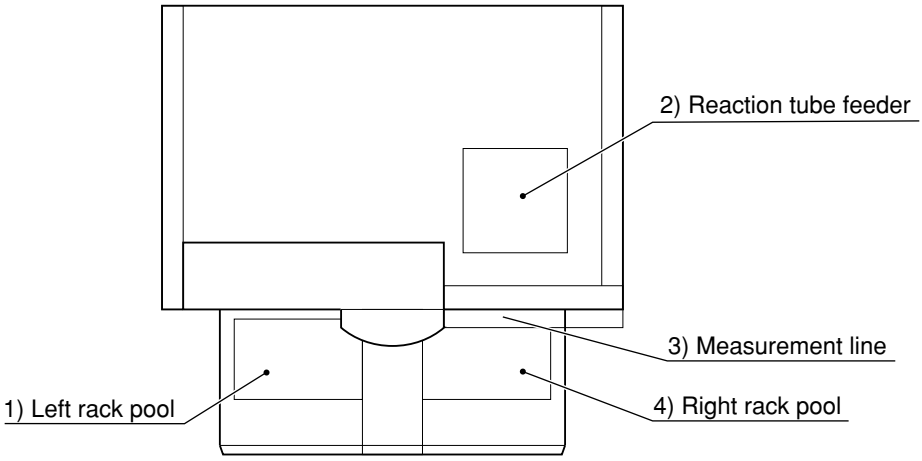

Figure 10-6-6: Top View

1) Left rack pool
Receives sample racks whose aspiration has been completed.

2) Reaction tube hopper
Holds up to 300 reaction tubes, and automatically supplies to the feeder unit for analysis.

CAUTION:	• Do not overfill the hopper. This will cause jamming.

3) Measurement line
Routine samples in the sample rack are automatically fed in to this measurement line from the right rack pool.
For STAT samples, place the sample rack containing STAT samples on this measurement line in the right rack pool. See *Chapter 4, Section 3.2: Analyzing STAT Samples in Sample Rack* for details.

4) Right rack pool
Holds up to 5 sample racks on which samples to be analyzed are set.

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9.3 Saving the Settings 11-87

1. INTRODUCTION

System setup of the CA-1500 will be performed by your Service Representative when the instrument is installed. However, the settings can be changed by using this program. This chapter explains how to use this setting program.

Auto Mode Settings
Can preset automatic data validation.

Data Check Settings
Can preset upper and lower limits for use in checking the analysis results.

Analysis Settings
Can preset the analysis parameters, reagents, calculation parameters, parameter groups, and other settings related to analysis.

I/O Settings
Can preset the interface parameters for the host computer that is connected to the CA-1500, as well as printer parameters for the optional graphic and data (ticket) printers and other conditions.

Stored Data Display Format Settings
Can preset the parameters for the analysis results that will be displayed on the Stored Data List screen, as well as the order in which they will appear.

System Settings
Can preset parameters that pertain to the overall CA-1500 system.

Output of Settings
Can print out setting values on the graphic printer and save them on a floppy disk. Can also load settings that were saved on a floppy disk.

2. INSTRUMENT SETTINGS

To set up the instrument's setting.
From the Main Menu, press the [Settings] key. The Settings sub menu will appear.

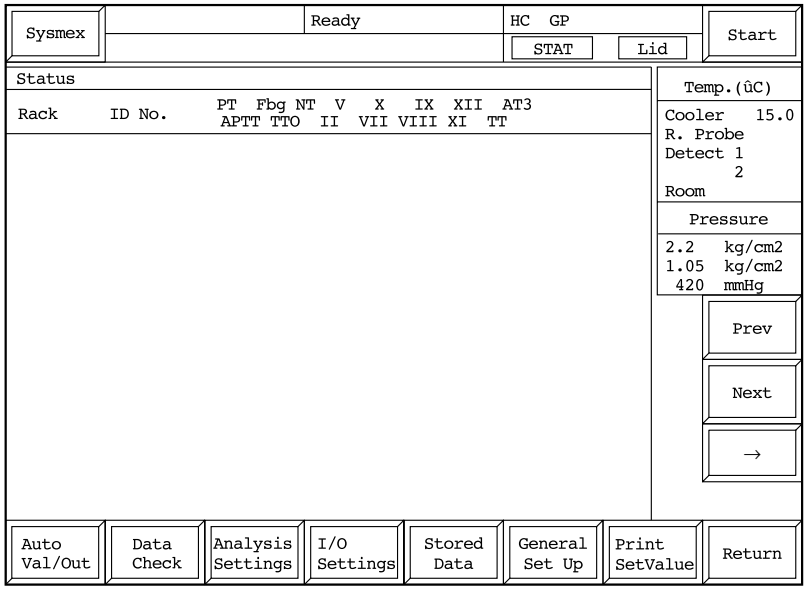


Figure 11-2-1: Settings Sub menu

Operating the Settings Sub menu Keys

[Auto Val/Out] key: Used to set the targeted samples and output conditions for automatically transmitting and printing data. Also used to preset automatic data validation. See *Section 3: AUTO MODE SETTINGS* in this chapter.

[Data Check] key: Used to set upper and lower limits for use in checking the analysis results.
See *Section 4: DATA CHECK SETTINGS* in this chapter.

[Analysis Settings] key: Used to set the analysis parameters, reagents, calculation parameters, parameter groups, and other settings related to analyses. See *Section 5: ANALYSIS SETTINGS* in this chapter.

[I/O Settings] key: Used to set the interface parameters for the optional host computer, as well as printer parameters for the optional graphic and data (ticket) printers and other conditions. See *Section 6: I/O SETTINGS* in this chapter.

[Stored Data] key: Used to set the parameters for analysis results that will be displayed on the Stored Data List screen, as well as the order in which they will appear. See *Section 7: STORED DATA DISPLAY FORMAT SETTINGS* in this chapter.

[General Set Up] key:	Used to preset parameters that pertain to the overall CA-1500 system. See *Section 8: SYSTEM SETTINGS* in this chapter.
[Print Set Value] key:	Used to print out setting values on the graphic printer and save them on a floppy disk. Also used to load settings that were saved on a floppy disk. See *Section 9: OUTPUT OF SETTINGS* in this chapter.
[Return] key:	Returns the system from the Settings sub menu to the Main Menu screen.

3. AUTO MODE SETTINGS

This section will explain how to set up the system to automatically output data pertaining to analyzed samples to an optional data (ticket) printer, an optional graphic printer, and an optional host computer. This section will also explain how to set up automatic data validation.

NOTE:
- Automatic data validation can be set up in models that use the data validation function. With data validation models, data that has been specified by the operator is automatically output after being validated. If the instrument is set up to automatically validate data, the data will be automatically validated and output when analysis is performed.

(1) From the Settings sub menu, press the [Auto Val/Out] key.
The Auto Mode Settings screen will appear.

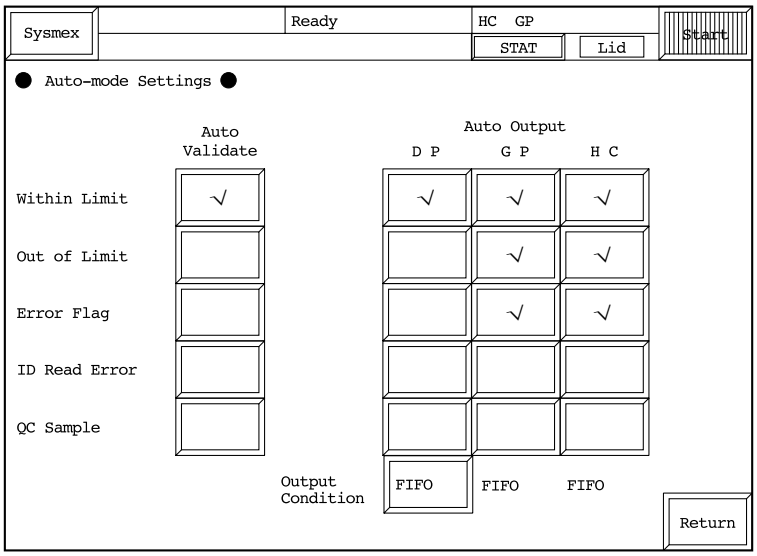


Figure 11-3-1: Auto Mode Settings Screen

(2) Decide whether to set up automatic data validation for each sample that will be automatically processed. Set by pressing the Auto Validate key for each sample. A "√" symbol (validated) and a blank space (not validated) will alternately appear each time the key is pressed.

NOTE:
- The Auto Output (output device) display area will differ depending on which device is connected. The content of the data that is automatically output will also differ depending on the content of each device's data output. See *Section 6: I/O SETTINGS* in this chapter.

(3) For each sample that will be automatically processed, set the parameter for the output devices that will automatically process the data.
A "√" symbol (automatically output) and a blank space (will not automatically output) will alternately appear each time the key is pressed.
For the DP, output condition has to be set. When the key is pressed, "FIFO" (First-In-First-Out) and "LAST" (Last Data only) switches alternately.

"FIFO" Prints those results that have not yet printed on the data printer with the oldest data first.

"LAST" Prints the latest result.

(4) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

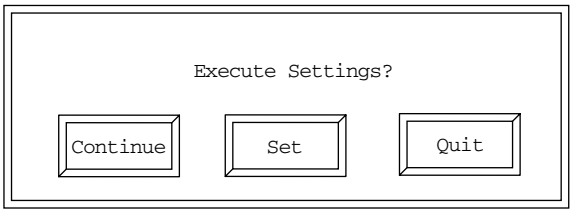


Figure 11-3-2: Update Confirmation Window Screen

[Continue] key: Used to continue the setting of automatic output or automatic data validation.

[Set] key: Updates the settings and returns the system to the Settings sub menu.

[Quit] key: Cancels the settings and returns the system to the Settings sub menu.

CAUTION:
- In the case below, the data will not be updated even if the setting is changed. The [Set] key in the Update Confirmation window will be disabled.
- Analyzing samples.
- As for the Analysis Settings, the changed data will not be updated in the following cases as well.
- Order is being set on the Work Load List.
- Sample whose analysis has not been completed remains on the sample plate.

4. DATA CHECK SETTINGS

This section will explain how to preset upper and lower limits for use in checking analysis results.

The Data Check Setting screen will be used to make the settings.
From the Settings sub menu, press the [Data Check] key. The Data Check sub menu will appear.

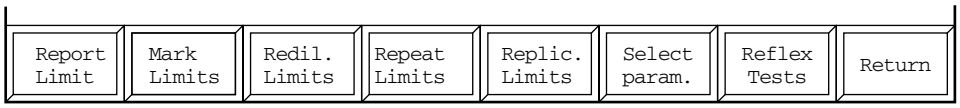


Figure 11-4-1: Data Check Sub menu

Operating the Data Check Setting Screen Keys

[Report Limit] key: Used to set upper and lower limits in order to monitor the analysis system's report limits. See *Section 4.1: Report Limit Settings* in this chapter.

[Mark Limits] key: Used to set upper and lower limits in order to monitor abnormal samples. See *Section 4.2: Mark Limit Settings* in this chapter.

[Redil. Limits] key: Used to set upper and lower limits in order to automatically perform redilution analysis based on analysis results. See *Section 4.3: Redilution Analysis Settings* in this chapter.

[Repeat Limits] key: Used to set upper and lower limits in order to automatically perform repeat analysis based on analysis results. See *Section 4.4: Repeat Analysis Settings* in this chapter.

[Replic. Limits] key: For analysis parameters that are analyzed twice, used to set replication difference limits in order to check whether the analysis results (coagulation time or dOD) are disparate. See *Section 4.5: Replication Difference Limit Settings* in this chapter.

[Select Param.] key: Used to select parameters to use for checking the results of analyzed parameter. See *Section 4.6: Data Check Parameter Settings* in this chapter.

[Reflex Tests] key: Used to set criteria to automatically analyze additional parameters dependent upon the results of analyzed parameters. See *Section 4.7: Reflex Test Settings* in this chapter.

[Return] key: Returns the system to the Settings sub menu.

4.1 Report Limit Settings

This section will explain how to set upper and lower report limits in order to monitor the analysis results against report limits. If the analysis results exceed the preset report limit range, one of the following report limit flags will appear with the analysis results:

- >: Parameter exceeded the upper report limit.
- <: Parameter exceeded the lower report limit.

NOTE: • A report limit flag takes priority over a mark limit flag. For details on the mark limit flag, see *Section 4.2: Mark Limit Settings* in this chapter.

(1) From the Data Check sub menu, press the [Report Limit] key.
The Report Limit Setting screen will appear.

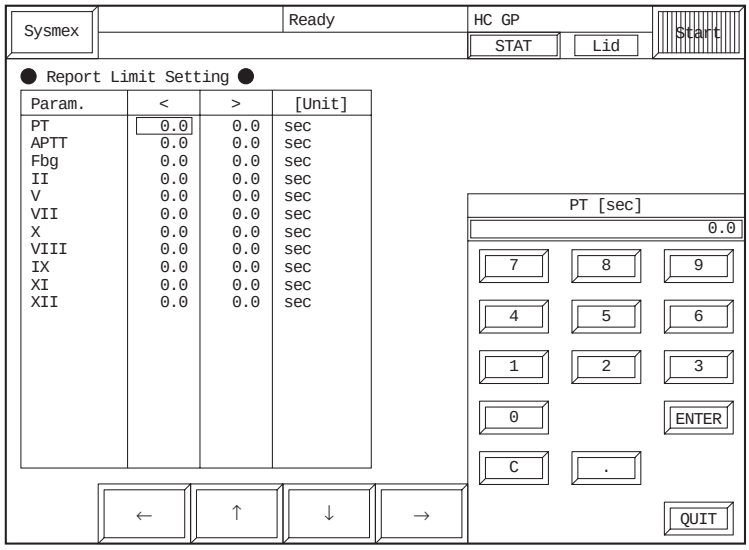


Figure 11-4-2: Report Limit Setting Screen

(2) Pressing the [↑], [↓], [←], and [→] keys, move the cursor to the parameter you wish to set.
If you press the [↑] key when the cursor is at the top position on the screen, the setting parameter will scroll up one line until the first parameter is reached. If you press the [↓] key when the cursor is at the bottom position on the screen, the setting parameter will scroll down one line.

(3) Using the numeric keys, enter a limit value; then press the [ENTER] key.
If "0" is set as both the upper and lower limits, report limits will not be monitored.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key: Used to continue the setting of report limits.

[Set] key: Updates the settings and returns the system to the Data Check sub menu.

[Quit] key: Cancels the settings and returns the system to the Data Check sub menu.

4.2 Mark Limit Settings

This section will explain how to set upper and lower mark limits in order to monitor abnormal results. If the analysis results exceed the preset normal range, one of the following mark limit flags will appear with the analysis results:

- +: Parameter exceeded the upper mark limit.
- -: Parameter exceeded the lower mark limit.

NOTE: • A report limit flag takes priority over a mark limit flag. For details on the report limit flag, see *Section 4.1: Report Limit Settings* in this chapter.

(1) From the Data Check sub menu, press the [Mark Limits] key.
The Patient Mark Limits Setting screen will appear.

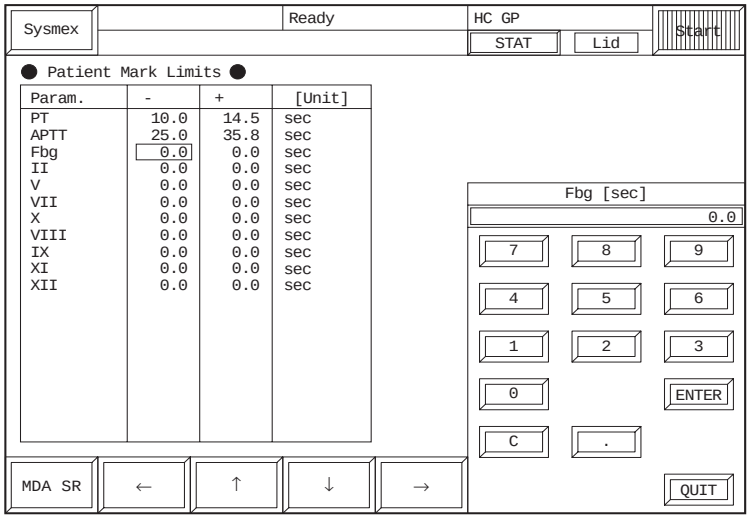


Figure 11-4-3: Patient Mark Limits Setting Screen

(2) Pressing the [↑], [↓], [←], and [→] keys, move the cursor to the parameter you wish to set.
If you press the [↑] key when the cursor is at the top position on the screen, the setting parameter will scroll up one line. If you press the [↓] key when the cursor is at the bottom position on the screen, the setting parameter will scroll down one line.

(3) Using the numeric keys, enter a limit value; then press the [ENTER] key.
If "0" is set as both the upper and lower limits, mark limits will not be monitored.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of mark limits.
[Set] key: Updates the settings and returns the system to the Data Check sub menu.
[Quit] key: Cancels the settings and returns the system to the Data Check sub menu.

(5) To set the limit values of the MDA Slope Ratio, press the [MDA SR] key.

(6) To set the upper and lower limit values, follow the steps (2) to (4) mentioned above.
When the SR of the MDA analysis result exceeds the upper or lower SR limit value, a flag (*) is displayed with the analysis result.
For details, see *Chapter 5, Section 3: STORED DATA GRAPHIC DISPLAY, MDA Graphic Display.*

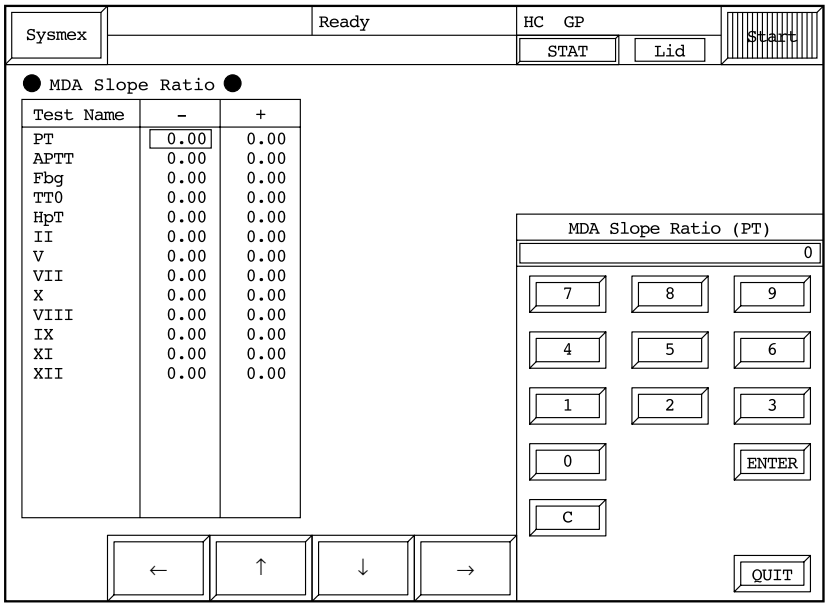


Figure 11-4-4: MDA Slope Ratio Limits Setting Screen

4.3 Redilution Analysis Settings

This section will explain how to set upper and lower limits in order to automatically perform redilution analysis based on analysis results. If the upper limit is exceeded, double the normal dilution ratio (8 times for immunoassay method) and perform redilution analysis. If the lower limit is exceeded, halve the normal dilution ratio and perform redilution analysis.

CAUTION:
- Re-dilution analysis cannot be executed even if re-dilution is selected for parameters which do not have an auto standard curve or dilution buffer in the test protocol.

NOTE:
- A redilution analysis takes priority over repeat analysis. For details on repeat analysis, see *Section 4.4: Repeat Analysis Settings* in this chapter.
- A "!" flag will be attached to the results achieved by redilution analysis.
- Automatic redilution analysis will not be executed, if the sample is analyzed in the Micro-sample Mode.

(1) From the Data Check sub menu, press the [Redil. Limits] key.
The Redilution Analysis Limits Setting screen will appear.

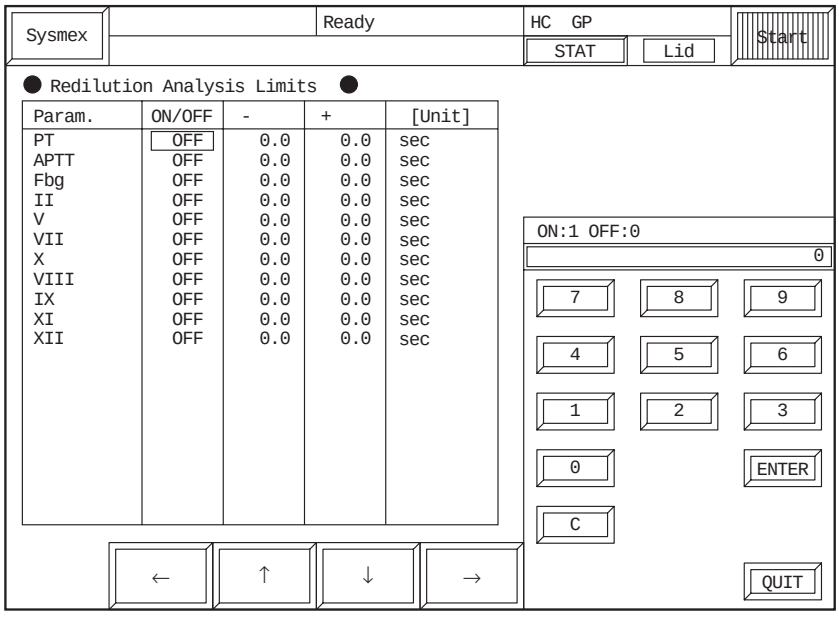


Figure 11-4-5: Redilution Analysis Limits Setting Screen

(2) Pressing the [↑], [↓], [←], and [→] keys, move the cursor to the parameter you wish to set.
If you press the [↑] key when the cursor is at the top position on the screen, the setting parameter will scroll up one line. If you press the [↓] key when the cursor is at the bottom position on the screen, the setting parameter will scroll down one line.

(3) Set each parameter.

ON/OFF:	Used to select whether to perform a redilution analysis. Using the numeric keys, enter 0 (OFF: Do not redilute) or 1 (ON: Redilute); then press the [ENTER] key.
-:	Used to set the lower limit required to perform a redilution analysis. Using the numeric keys, enter the lower limit; then press the [ENTER] key.
+:	Used to set the upper limit required to perform a redilution analysis. Using the numeric keys, enter the upper limit; then press the [ENTER] key.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue the setting of redilution analysis.
[Set] key:	Updates the settings and returns the system to the Data Check sub menu.
[Quit] key:	Cancels the settings and returns the system to the Data Check sub menu.

4.4 Repeat Analysis Settings

This section will explain how to set upper and lower limits in order to automatically perform repeat analysis based on analysis results.

NOTE:
- A redilution analysis takes priority over a repeat analysis.
  For details on redilution analysis, see *Section 4.3: Redilution Analysis Settings* in this chapter.
- If the number of analysis replications is set to 2, repeat analysis will not be performed.
  For details on analysis replications, see *Section 5.3: Replication Settings* in this chapter.

(1) From the Data Check sub menu, press the [Repeat Limits] key.
The Repeat Analysis Limits Setting screen will appear.

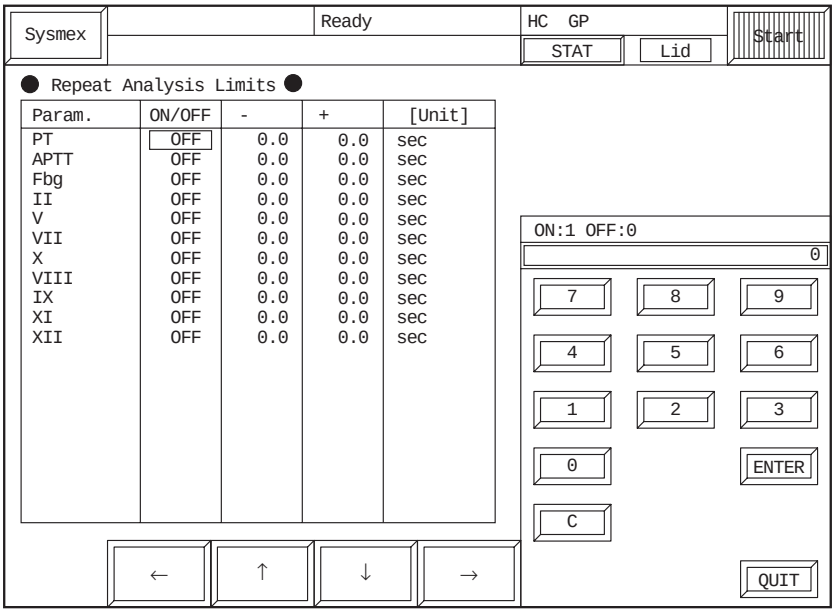


Figure 11-4-6: Repeat Analysis Limits Setting Screen

(2) Pressing the [↑], [↓], [←], and [→] keys, move the cursor to the parameter you wish to set.
If you press the [↑] key when the cursor is at the top position on the screen, the setting parameter will scroll up one line. If you press the [↓] key when the cursor is at the bottom position on the screen, the setting parameter will scroll down one line.

(3) Set each parameter.

ON/OFF: Used to select whether to perform repeat analysis. Using the numeric keys, enter 0 (OFF: Do not perform repeat analysis) or 1 (ON: Perform repeat analysis); then press the [ENTER] key.

-: Used to set the lower limit required to perform repeat analysis. Using the numeric keys, enter the lower limit; then press the [ENTER] key.

+: Used to set the upper limit required to perform repeat analysis. Using the numeric keys, enter the upper limit; then press the [ENTER] key.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key: Used to continue the setting of repeat analysis.

[Set] key: Updates the settings and returns the system to the Data Check sub menu.

[Quit] key: Cancels the settings and returns the system to the Data Check sub menu.

4.5 Replication Difference Limit Settings

This section will explain how to set replication difference limits in order to check whether the analysis results (coagulation time or dOD) are disparate when analysis parameters are analyzed twice.
The replication difference limit is set as a ratio of difference between two analyses, to the average value.

NOTE:
- If two analysis results are determined to be disparate, a "∗" flag will be attached to the average of the analysis results.

(1) From the Data Check sub menu, press the [Replic. Limits] key.
The Replication Difference Limits Setting screen will appear.

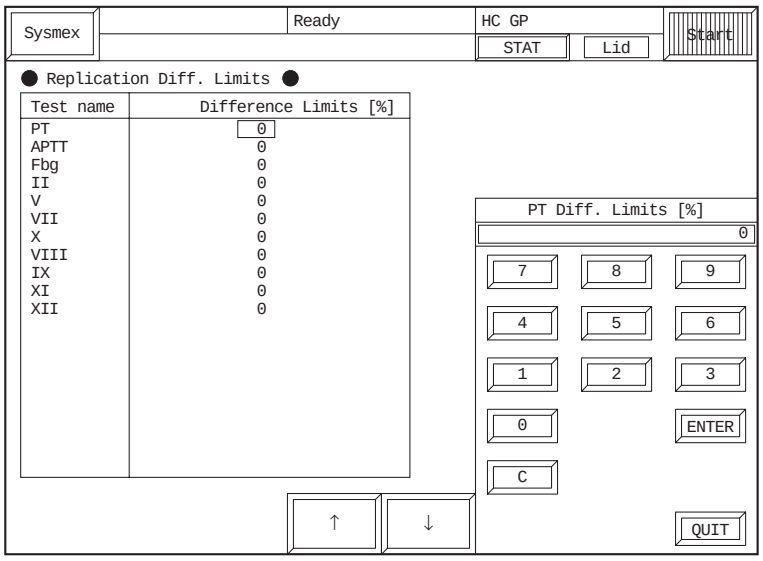


Figure 11-4-7: Replication Difference Limits Setting Screen

(2) Pressing the [↑] and [↓] keys, move the cursor to the parameter you wish to set.
If you press the [↑] key when the cursor is at the top position on the screen, the setting parameter will scroll up one line. If you press the [↓] key when the cursor is at the bottom position on the screen, the setting parameter will scroll down one line.

(3) Using the numeric keys, enter the replication difference limits; then press the [ENTER] key.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of replication difference limits.
[Set] key: Updates the settings and returns the system to the Data Check sub menu.
[Quit] key: Cancels the settings and returns the system to the Data Check sub menu.

4.6 Data Check Parameter Settings

This section will explain how to set which data check parameters should be used to check the results of an analysis parameter. The data check parameters will differ depending on each analysis parameter. As example, for the PT, selections could be made from the coagulation time, activity percent, PT ratio, and others.

(1) From the Data Check sub menu, press the [Select Param.] key.
The Data Check Parameter Selection screen will appear.

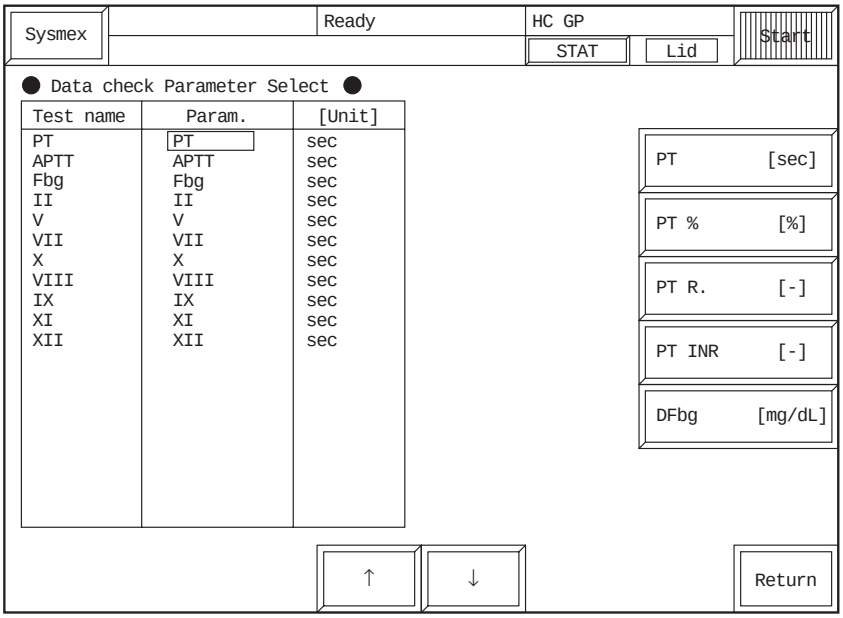


Figure 11-4-8: Data Check Parameter Selection Screen

(2) Pressing the [↑] and [↓] keys, move the cursor to the parameter you wish to set.
If you press the [↑] key when the cursor is at the top position on the screen, the setting parameter will scroll up one line. If you press the [↓] key when the cursor is at the bottom position on the screen, the setting parameter will scroll down one line.
Parameters that can be selected for the data check parameter will appear on the right side of the screen.

(3) Press a key for the data check parameter that you wish to set.

(4) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key: Used to continue the setting of data check parameters.

[Set] key: Updates the settings and displays the Data Check Parameter Update Confirmation window. If you press the [OK] key, the system will return to the Data Check sub menu.
If data check parameters have been updated, reset the report limits, mark limits, redilution analysis, and repeat analysis. For details on how to set report limits, see *Section 4.1: Report Limit Settings* in this chapter, for mark limits, see *Section 4.2: Mark Limit Settings* in this chapter; for redilution analysis, see *Section 4.3: Redilution Analysis Settings* in this chapter; and for repeat analysis, see *Section 4.4: Repeat Analysis Settings* in this chapter.

[Quit] key: Cancels the settings and returns the system to the Data Check sub menu.

4.7 Reflex Test Settings

This section will explain how to set conditions to automatically analyze an additional analysis parameter based on the results of an analysis.

A reflex test is an analysis of a prescribed parameter that is triggered when the results of a given analysis meet certain conditions required to execute the analysis. You can set up to 60 types of reflex tests. A data check is not performed on the results of a reflex test.

Conditional Analysis Parameters

1) Conditions are set either by one conditional expression or by two conditional expressions. If they are set by two conditional expressions, the word "AND" is inserted between the two expressions.

2) Parameters appear on the left side of conditional expressions, and numerals on the right. For value comparisons, the symbols "<" and ">" are set.

3) The word "THEN" is inserted after the condition(s) to set the order of the analysis parameters.

Examples:

- PT % < 80.0 [%] AND APTT > 40.0 [sec] THEN Fbg
  Meaning: If PT % is less than 80.0%, and if APTT is more than 40.0 seconds, then analyze Fbg.

- PT % < 80.0 [%] THEN APTT
  Meaning: If PT % is less than 80.0%, analyze APTT.

Selecting the Conditional Expression

(1) From the Data Check sub menu, press the [Reflex Tests] key.
The Reflex Tests Setting screen will appear.

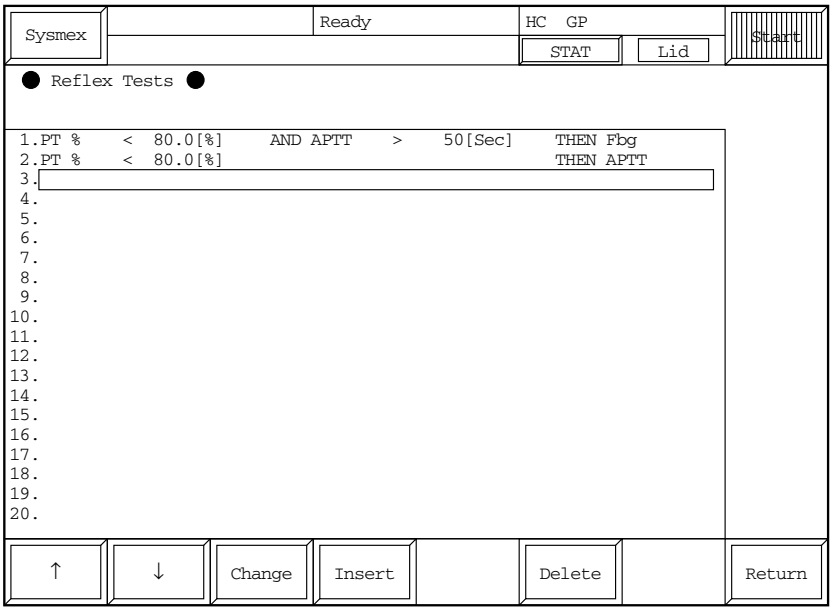


Figure 11-4-9: Reflex Tests Settings Screen

(2) Pressing the [↑] and [↓] keys, move the cursor to the line you wish to set.
If you press the [↑] key when the cursor is at the top position on the screen, the setting parameter will scroll up one line. If you press the [↓] key when the cursor is at the bottom position on the screen, the setting parameter will scroll down one line.

Adding a Reflex Test

To newly set a reflex test, make your entry into a blank line. If you wish to set a reflex test between two tests that have already been set, move the cursor to the desired line; then press the [Insert] key. A blank line will be inserted at the cursor position.

Deleting a Reflex Test

To delete a reflex test, move the cursor to the line that contains the reflex test you wish to delete; then press the [Delete] key.

(3) Set the conditions and analysis parameters.
Press the [Change] key. The Reflex Tests Change menu will appear. The change menu will change each time the cursor is moved to a parameter to set.

Left Side of Conditional Expression

Figure 11-4-10: Reflex Tests Change Menu

Value Comparison

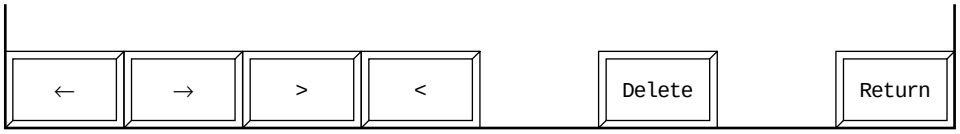


Figure 11-4-11: Reflex Tests Change Menu

Right Side of Conditional Expression

Figure 11-4-12: Reflex Tests Change Menu

Analysis Parameters

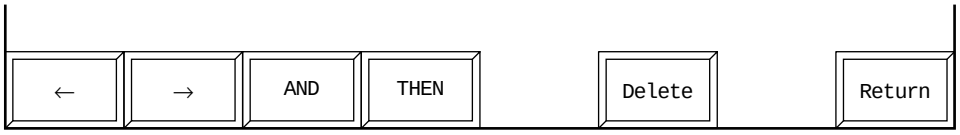


Figure 11-4-13: Reflex Tests Change Menu

Operating the Reflex Tests Change Menu Keys

[←] and [→] keys: Used to move the cursor.

[Param.] key: Used to select the parameter.
(1) If you press the [Param.] key, the Parameter Selection window will appear. Press a key for a desired parameter. The Condition Selection window will appear.
(2) Press a key for a parameter.

[>] and [<] keys: Used to compare two values.

[Numeric Keys] key: Used to select numerals for the right side of a conditional expression.
(1) Press the [Numeric Keys] key. The numeric keys will appear.
(2) Enter the numerals for the conditional expression; then press the [ENTER] key.

[AND] key: Used to set the second conditional expression. If you press the [AND] key, the word "AND" will appear after the first conditional expression.

[THEN] key: Used to set the analysis parameter. If you press the [THEN] key, the Parameter Selection window will appear. Press the key for the parameter that you wish to analyze.

(4) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of reflex tests.
[Set] key: Updates the settings and returns the system to the Data Check sub menu.
[Quit] key: Cancels the settings and returns the system to the Data Check sub menu.

CAUTION: If "DFbg - > Fbg" reflex test is set, Fbg is performing diluted analysis as follows;

Reflex Setting (example)	Analysis Method for Fbg (in the test protocol setting)	DFbg results (example)	Fbg dilution
DFbg > 450 [mg] THEN Fbg	"for Fbg"	500	1/2 dilution*
		300	not performed
DFbg < 100 [mg] THEN Fbg		50	2/1 dilution*
	"for Fbg. MFU" (not "for Fbg")	500	1/1 dilution
		300	not performed
		50	1/1 dilution

*To perform dilution analysis, buffer must be set in the test protocol setting. For an assay which has no sample dilution, do not select "for Fbg" as "Analysis Method" in the test protocol setting, or incorrect analysis results might be obtained.

NOTE:
- If a setting contains a mistake, the Invalid Setting window will appear when you press the [Set] key on the Update Confirmation window. If that happens, press the [OK] key to return to the Reflex Tests Change menu.
- Reflex tests are performed with the same sample within a well on the sample plate. An extra sample volume for the number of parameters will be drawn from the test tube when the reflex test is set.
- Automatic redilution analysis will not be executed, if the sample is analyzed in the Micro-sample Mode.

5. ANALYSIS SETTINGS

This section will explain how to preset the analysis parameters, reagents, calculation parameters, parameter groups, and other settings related to analysis.

Analysis settings are selected from the Analysis Settings sub menu.
From the Settings sub menu, press the [Analysis Settings] key. The Analysis Settings sub menu will appear. The Analysis Settings sub menu has two pages, and can be switched back and forth by using the [More] key.

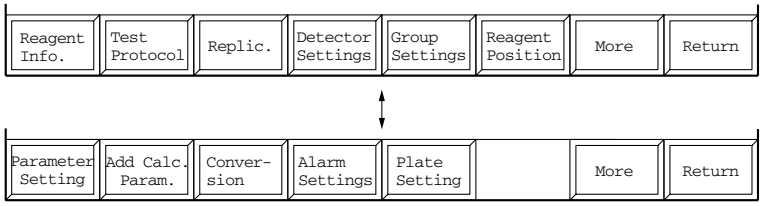


Figure 11-5-1: Analysis Settings Sub menus

Operating the Analysis Settings Sub menu Keys

[Reagent Info.] key: Used to set information for reagents, diluent, and rinse solution that are placed in reagent holders. See *Section 5.1: Reagent Information Settings* in this chapter.

[Test Protocol] key: Used to set the maximum detection time for analyzing an extended sample. Also used to set the test protocol (analysis procedure) for new analysis parameters. See *Section 5.2: Test Protocol (Programmable Test) Settings* in this chapter.

[Replic.] key: Used to set the number of replications for each parameter and the number of dilution series points for MDA. See *Section 5.3: Replication Settings* and *Section 5.4: MDA Settings* in this chapter.

[Detector Settings] key: Used to set coagulation time calibration for the Coagulation Method, and analysis limits within the linear range for the Chromogenic Method or Immunoassay Method. See *Section 5.5: Detector Settings* in this chapter.

[Group Setting] key: Used to set parameter combination groups and Profile #1 and Profile #2. See *Section 5.6: Parameter Group Settings* in this chapter.

[Reagent Position] key: Used to set the arrangement of reagent, diluent, rinse solution, factor-deficient plasma, control plasma, and calibrator in the holders. See *Section 5.7: Reagent Position Settings* in this chapter.

[More] key: Switches between the Analysis Settings sub menus.

[Return] key: Returns the system to the Settings sub menu.

[Parameter Setting] key:	Used to set calculation parameters. See *Section 5.8: Calculation Parameter Settings* in this chapter.
[Add Calc. Param.] key:	Used to create formulas to calculate parameters. See *Section 5.9: New Calculated Parameter Settings* in this chapter.
[Conversion] key:	Used to set conversion formula for analysis parameters. See *Section 5.10: Conversion Settings* in this chapter.
[Alarm Settings] key:	Used to set up a method of monitoring the volume of aspirated sample, remaining reagent, and other liquids. See *Section 5.11: Alarm Settings* in this chapter.
[Plate Setting] key:	Used to determine whether to dispense samples to sample plates, and other settings. See *Section 5.12: Sample Plate Settings* in this chapter.

5.1 Reagent Information Settings

This section will explain how to set information for reagents that are placed in reagent holders, diluent holders, and rinse solution holders.

NOTE:

- When Sysmex specified wand barcode reader is used, it is possible to set the reagent information automatically by reading the barcode label with an optional wand barcode reader on the Consumable screen and the Reagent Position Setting screen.
  For details, see *Chapter 2, Section 4.3: Setting the Reagents (when the Wand Barcode Reader is Used)* and *Section 5.7: Reagent Position Settings* in this chapter.
  For details on the wand barcode reader, contact your service representative.

Setting Parameter	Description
Reagent Type	Set the type of reagent to be registered. Setting parameters listed below can be set via the screen which pertains specifically to each reagent type.
Reagent ID (*1)	Set the ID number allocated to the reagent product, using up to 4 characters.
Reagent Name (*1, *2)	Set the name of the reagent, using up to 8 characters. Select the name on the Select Reagent window.
Lot Number (*2)	Set the lot number of the reagent, using up to 12 characters.
Barcode Lot Number (*2)	When using an optional wand barcode reader, set the number which shows the lot described on the barcode label affixed to the reagent bottle.
Expiration Date	Set the expiration date of the reagent.
Init. Volume	Set the volume of the reagent vial being used. Set within the range of 0.0 to 60.0 mL. The value that is set will become the remaining reagent volume default value that appears on the Consumable screen.
Alarm Limit	Set the volume that will trigger an alarm during reagent volume monitoring, alerting the operator that the remaining reagent is low. Set within the range of 0.0 to 60.0 mL.
Interrupt Limit	Set the volume that will trigger an analysis interruption due to insufficient reagent during reagent volume monitoring. Set within the range of 0.0 to 60.0 mL.
Vial Type	Set the type of vial that will be used when the reagent is set. This information will be used when the volume of remaining reagent is calculated.
Level	Set the activity level of the control plasma. Set only for control plasma.
File Number	Set the quality control file number (01 to 20). File numbers 01 to 10 are used for current control. 11 to 20 are used to evaluate the new samples when the lots of QC sample are switched. Set only for control plasma.

CAUTION:
- When switching between the current and new lots, quality control file numbers are changed.

*1: When a reagent ID is set, a reagent name is set automatically.
Also, a reagent ID can be automatically set by selecting a reagent name on the Select Reagent window.

*2: A reagent ID, a lot number, and a barcode lot number are affixed to the following labels of the reagent bottles.

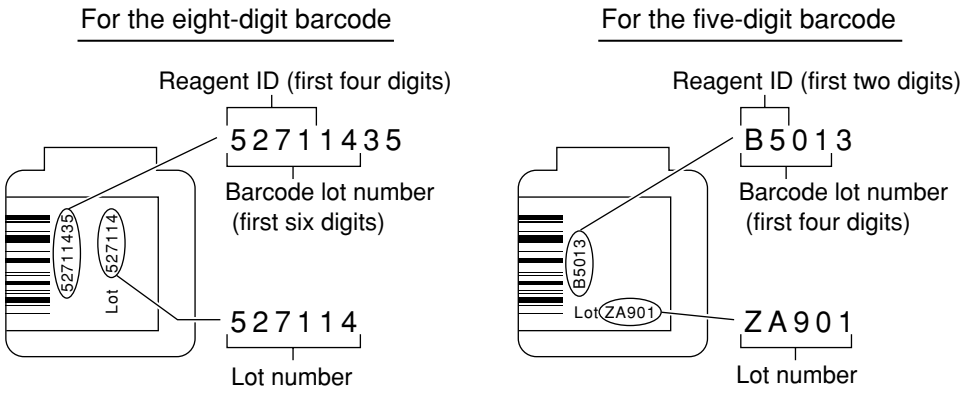


Figure 11-5-2: Label Content of Reagent Bottles

CAUTION:
- When the optional wand barcode reader is used, for the barcode lot number, enter the first six digits for the eight-digit barcode and enter the first four digits for the five-digit barcode. The barcode is not recognized if not correctly entered.
- Set the reagent information such as the reagent ID and the barcode lot number, etc. correctly.
  If set incorrectly, the reagent cannot be recognized correctly when read with the barcode reader, a wrong reagent may be aspirated resulting in an affected analysis result.
- When the reagent ID has been changed, the reagent cannot be analyzed, or a wrong reagent may be aspirated resulting in an affected analysis result. When the reagent ID has been changed, set the test protocol and the reagent position. For details, see *Section 5.2: Test Protocol (Programmable Test) Settings* and *Section 5.7: Reagent Position Settings* in this chapter.

1. Manual settings of reagent information

(1) From the Analysis Settings sub menu, press the [Reagent Info] key.
The Reagent Information/Type Selection screen will appear.

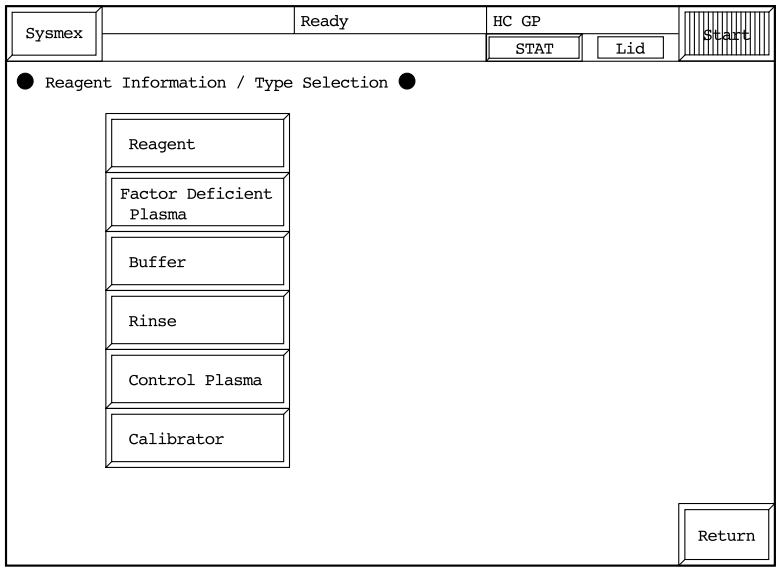


Figure 11-5-3: Reagent Information/Type Selection Screen

(2) Press the key for the type of reagent that you wish to set.
The Reagent Information screen for the specified reagent type will appear.
And, from the Reagent Information screen, press the [Select Type] key.
The Type Selection screen for reagent will appear.

Example: Reagent Information Setting Screen for Reagent

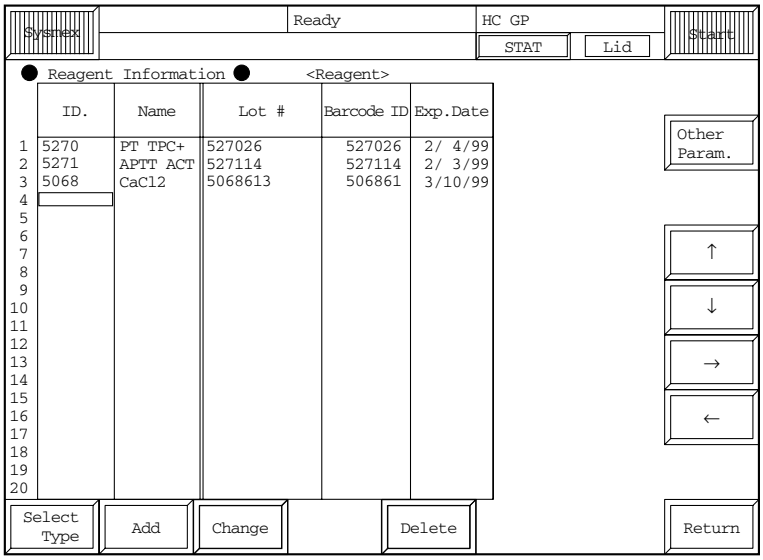


Figure 11-5-4: Reagent Information Setting Screen for Reagent

Example: Reagent Information Setting Screen for Control Plasma

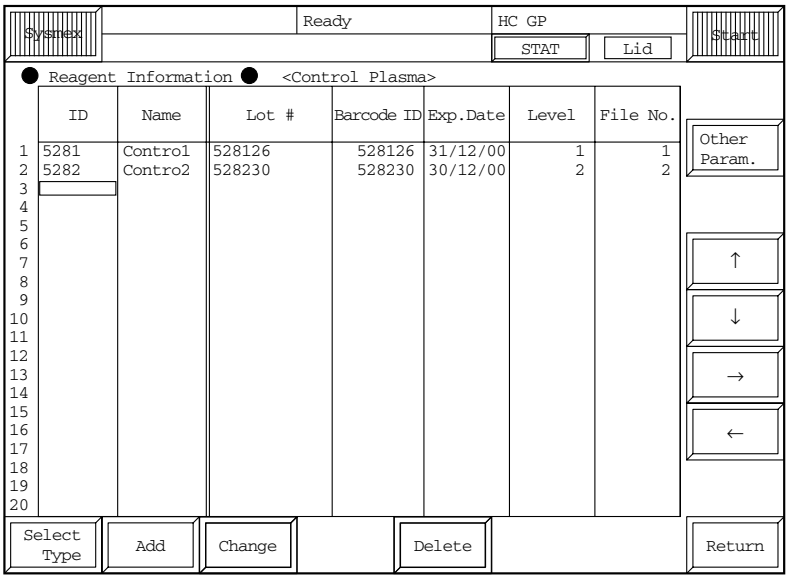


Figure 11-5-5: Reagent Information Setting Screen for Control Plasma

To view setting parameters that are not currently being displayed, press the [Other Param.] key.

Adding Reagent Information

(1) To newly set a reagent, make your entry into an empty line. If you wish to set a reagent between two reagents that have already been set, move the cursor to the desired line by pressing the [↑] and [↓] keys; then press the [Add] key. A blank line will be inserted at the cursor position. The Select Reagent screen for reagent will appear.

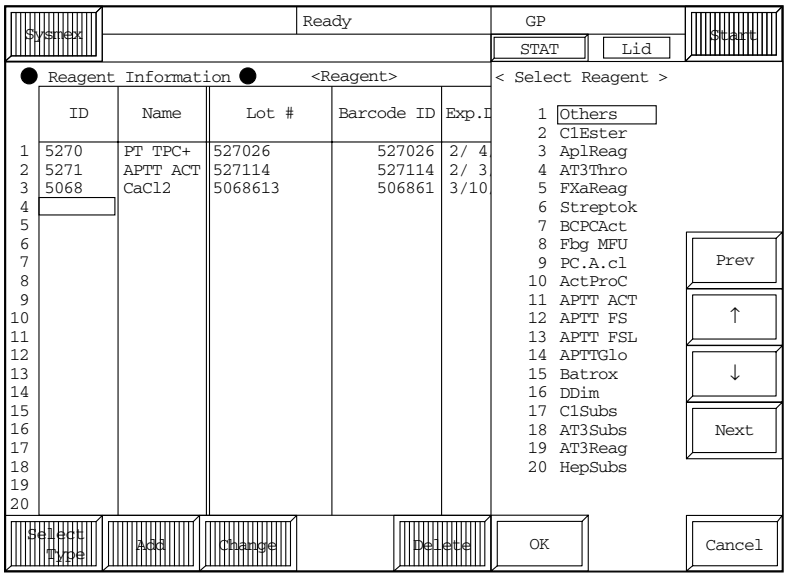


Figure 11-5-6: Select Reagent Window

From the Select Reagent window, press the [↑] and [↓] keys to move the cursor to the reagent that you wish to select; then press the [OK] key. The reagent ID and reagent name will be displayed.

If the applicable name does not appear in the Select Reagent window, move the cursor to "Others" and press the [OK] key. The alphanumeric keys will appear. Using the alphanumeric keys, enter the reagent ID; then press the [ENTER] key. Enter U000 to U999 manually when you use the reagent bottle without the barcode label.

NOTE:
- When inputting information other than the reagent ID described on the barcode label, enter U000 to U999.
  If other ID is set, there is a possibility of causing trouble such as the analysis can not be performed.

Pressing the [→] key, move the cursor to the reagent name. Press the [Change] key. The Input Reagent Name window will appear

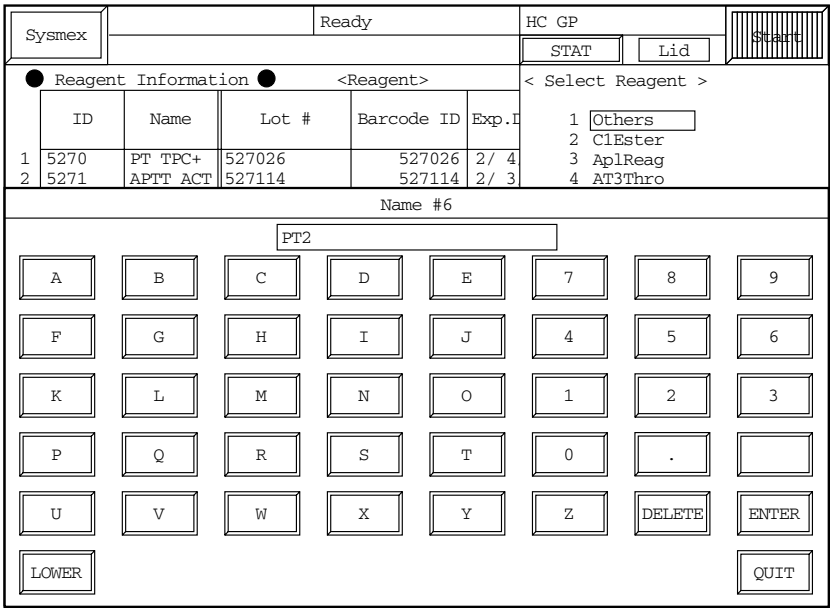


Figure 11-5-7: Input Reagent Name Window

Enter the reagent name on the Input Reagent Name window, then press the [ENTER] key.

CAUTION:

- When the optional wand barcode reader is used, for the barcode lot number, enter the first six digits for the eight-digit barcode and enter the first four digits for the five-digit barcode. The barcode is not recognized if not correctly entered.
- Set the reagent information such as the reagent ID and the barcode lot number, etc. correctly.
  If set incorrectly, the reagent cannot be recognized correctly when read with the barcode reader, a wrong reagent may be aspirated resulting in an affected analysis result.
- When the reagent ID has been changed, the reagent cannot be analyzed, or a wrong reagent may be aspirated resulting in an affected analysis result. When the reagent ID has been changed, set the test protocol and the reagent position. For details, see *Section 5.2: Test Protocol (Programmable Test) Settings* and *Section 5.7: Reagent Position Settings* in this chapter.

(2) Set the lot number, expiration date, init. volume (standard volume), short reagent alarm limit, short reagent interrupt limit, level, and file number.
Move the cursor to each setting parameter; then press the [Change] key. The numeric keys or alphanumeric keys will appear. Using the numeric keys or alphanumeric keys, enter each parameter; then press the [ENTER] key.

(3) Set the vial type.
Move the cursor to the "Vial Type", then press the [Change] key. The Select Vial Type window will appear.

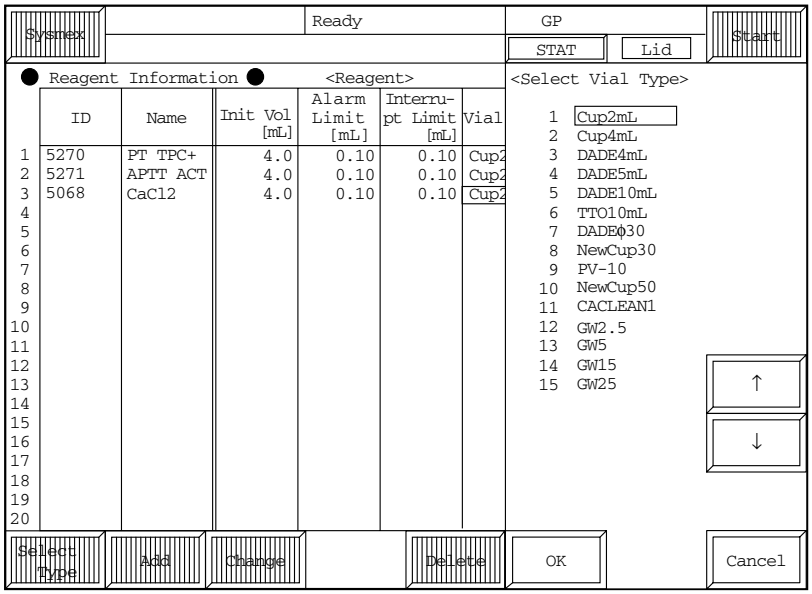


Figure 11-5-8: Select Vial Type Window

From the Select Vial Type window, press the [↑] and [↓] keys to move the cursor to the vial that you wish to select; then press the [OK] key.

CAUTION • Set the correct container, or CA-1500 cannot aspirate the reagent correctly.
As for the position where each reagent can be set and the adapter to be used, *see Chapter 6, Section 7: REAGENT SET POSITION AND ADAPTER LIST*.

CAUTION: • When setting the same two reagents or more, a different container cannot be set.

Changing Reagent Information
To change reagent information which has already been set, press the [↑], [↓], [←], and [→] keys to move the cursor to the line that contains the reagent information you wish to change; then press the [Change] key.
The numeric keys or alphanumeric keys will be displayed.
Enter each parameter with the numeric keys or the alphanumeric keys, and press the [ENTER] key.
When the [Change] key is pressed at the cursor is in the "Vial Type", the Select Vial Type window will appear.
Pressing the [↑] and [↓] keys, move the cursor to the vial type that you wish to select on the Select Vial Type window, and press the [OK] key.

Deleting Reagent Information
To delete reagent information, press the [↑] and [↓] keys to move the cursor to the line that contains the reagent information you wish to delete; then press the [Delete] key. The line at the cursor position is deleted, and the lines will be shifted up to their upper line.

CAUTION: • Reagent information can be set for up to 40 reagents.
Delete information on the reagents which become unnecessary.

(4) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of reagent information.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.2 Test Protocol (Programmable Test) Settings

This section will explain how to set the maximum detection time for analyzing extended samples. This section will also explain how to set the test protocol (analysis procedures) for new analysis parameters.

1. Setting the Maximum Detection Time for Analysis Parameters in Coagulation Method

This section will explain how to set the maximum detection time for regular analysis parameters. The regular analysis parameters are the Coagulation Method's PT, APTT, Fbg, TTO*, NT* and TT ; the Extrinsic Factor Deficient Assay II, V, VII, and X; and the Intrinsic Factor Deficient Assay VIII, IX, XI, and XII.

* Not available in the USA.

CAUTION:
- With regard to analysis parameters of the Chromogenic Method and Immunoassay Method, the maximum detection time (stop time of linear range in "Detector Settings") is displayed but cannot be set.
  For details on how to set linear-range start and stop times for analysis parameters of the Chromogenic Method and Immunoassay Method, see *Section 5.5: Detector Settings* in this chapter.
- The user is responsible for any change of the analysis procedure, as the correct result might not be obtained.

(1) From the Analysis Settings sub menu, press the [Test Protocol] key.
The Test Protocol Setting screen for PT will appear.

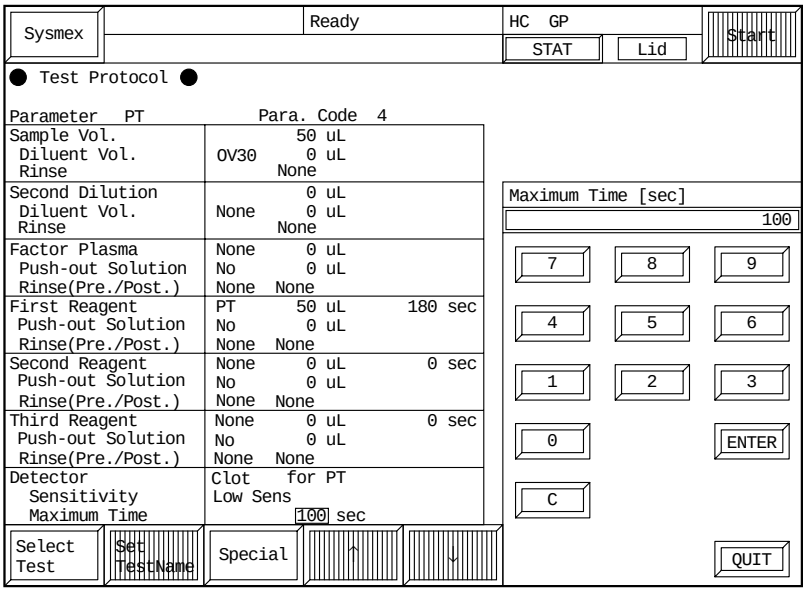


Figure 11-5-9: Test Protocol Setting Screen (for PT)

(2) Press the [Select Test] key.
The Parameter Selection window will appear.

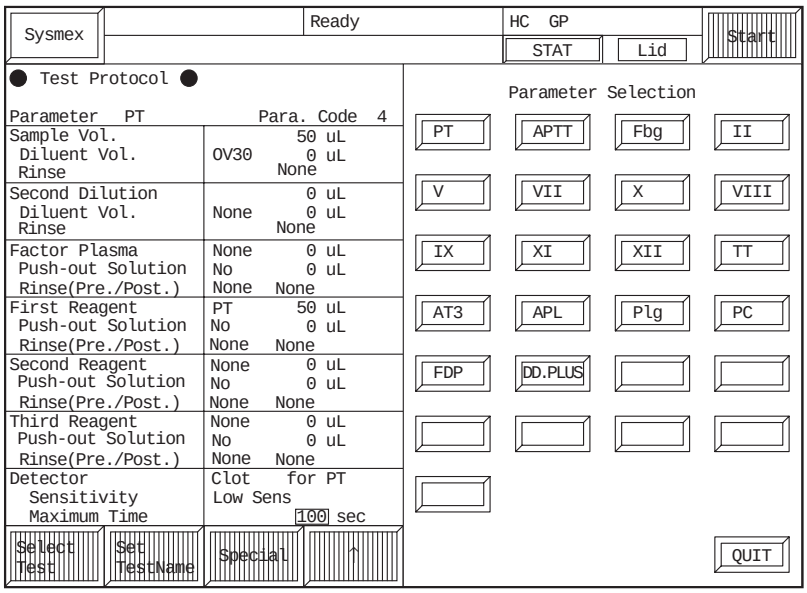


Figure 11-5-10: Parameter Selection Window

(3) From the Parameter Selection window, press the key for the parameter that you wish to set.
The Test Protocol Setting screen for the selected parameter will appear.

(4) Press the [↑] and [↓] keys to move the cursor to the Maximum Time. The numeric keys will appear. Using the numeric keys, enter the maximum detection time; then press the [ENTER] key.

(5) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of test protocols (analysis procedures).
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

2. Setting Test Protocol for New Analysis Parameters (Programmable Test)

This section will explain how to set the name and test protocol for new analysis parameters. Refer to the table below when setting.

Setting Parameter		Description
1. Parameter Name		Set the analysis parameter name, maximum of 7 characters.
2. Parameter Code		This code is used for communication with the host computer. Set the code, maximum of 2-digit integer. (*1)
3. Sample	Sample Volume (μL)	Set the sample volume to be aspirated first. Set as 0 or a value within the range of 4 to 100.
	Diluent Volume Aspirated (μL)	Set the diluent and its volume used to dilute the sample. Set the volume of the diluent as 0 or a value within the range of 4 to 120. (*2)
	Rinse Solution	Set a rinse solution to rinse the probe after aspirating the sample.
4. Second Dilution	Diluted Sample Volume Aspirated (μL)	Set the volume of the sample to be aspirated during the second step dilution. Set the aspiration volume as 0 or a value within the range of 4 to 100. The sample prepared in step 3 will be used for the second dilution.
	Diluent Volume (μL)	Set the diluent and its volume used to dilute the sample during the second dilution. Set the volume of the diluent as 0 or a value within the range of 4 to 120. (*3)
	Rinse Solution	Set a rinse solution to rinse the probe after aspirating the sample.
5. Factor Deficient Plasma (the First Reagent to the Third Reagent)	Reagent Volume (μL), Timing (sec)	Set the reagent type, reagent volume, and timing of addition. Set the volume of the factor-deficient plasma as 0 or a value within the range of 4 to 100. Set the volume for the first reagent to the third reagent as 0 or a value within the range of 4 to 200. (*4) Set the timing of addition within the range of 0 to 990.
	Push-out Solution Volume (μL)	Select whether distilled water is used to push out the reagent volume required, when adding the first reagent to the third reagent to the sample. Set the volume of the distilled water within the range of 0 to 50. (*4)
	Rinse (Pre./Post.)	Set the rinse solution and the rinse frequency (×1, ×2 or ×3) to use for cleaning before and after reagents are added.
6. Detector	Detector	Set the detection and analysis methods. For detection methods, you can select from Coagulation, Chromogenic, and Immunoassay Methods.
	Sensitivity, Wavelength, Inc/Dec	Set the sensitivity, wavelength and dOD increase or decrease for the Chromogenic and Immunoassay Methods. If a condition differs from a setting, a reaction curve error will result.
	Maximum Time (sec)	Set the time extension for automatically extended analysis. Set to a value within the range of 100 to 600. For Chromogenic and Immunoassay Methods, the stop time of linear range in the "Detector Settings" will be displayed.

*1: Refer to Appendix B: Host Format for the parameter codes.

*2: Set the diluent volume to a value that when combined with the sample aspiration volume will be at least 20 μL and not more than 135 μL.

*3: Set the diluent volume to a value that when combined with the diluted sample aspiration volume will be at least 20 μL and not more than 135 μL.

*4: Set the reagent volume and push-out solution volume to a value such that the total volume in the reaction tube will be at least 150 μL and not more than 250 μL.

(1) From the Analysis Settings sub menu, press the [Test Protocol] key.
The Test Protocol Setting screen for PT will appear.

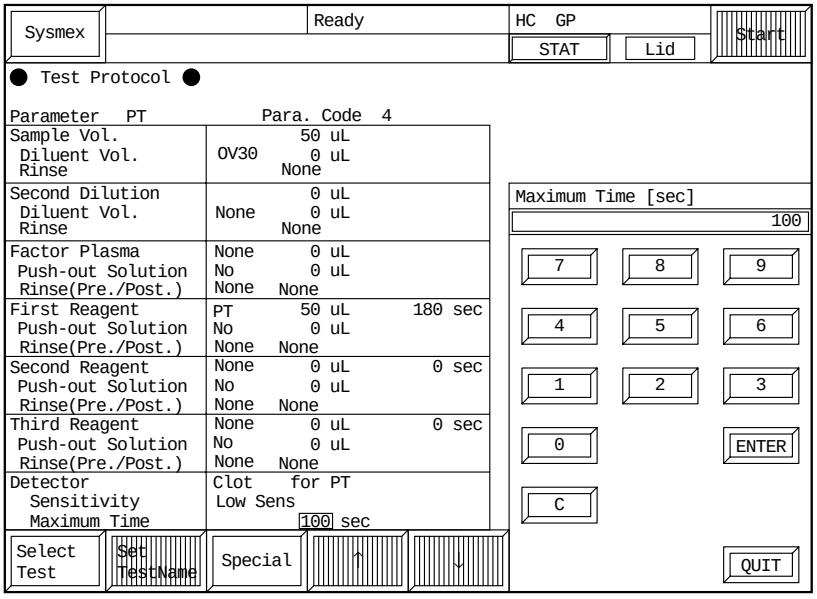


Figure 11-5-11: Test Protocol Setting Screen (for PT)

(2) Press the [Select Test] key.
The Parameter Selection window will appear.

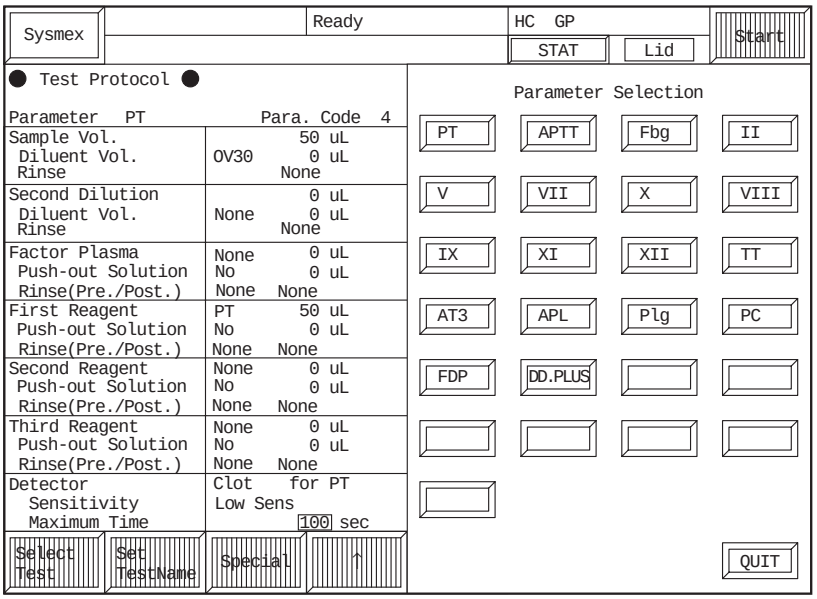


Figure 11-5-12: Parameter Selection Window

(3) From the Parameter Selection window, press the blank key on which no parameter name is displayed.
The Test Protocol Setting screen for the new analysis parameter will appear.

(4) Set each type of reagent.
Pressing the [↑] and [↓] keys, move the cursor to the type of reagent; then press the [Change] key. The Select Reagent window for the reagent type will appear.

NOTE:
- The Select Reagent window displays the reagents that were set by type in *Section 5.1: Reagent Information Settings* in this chapter.
- If you select "None" in the reagent list, the setting will become "None", indicating that reagent will not be aspirated.

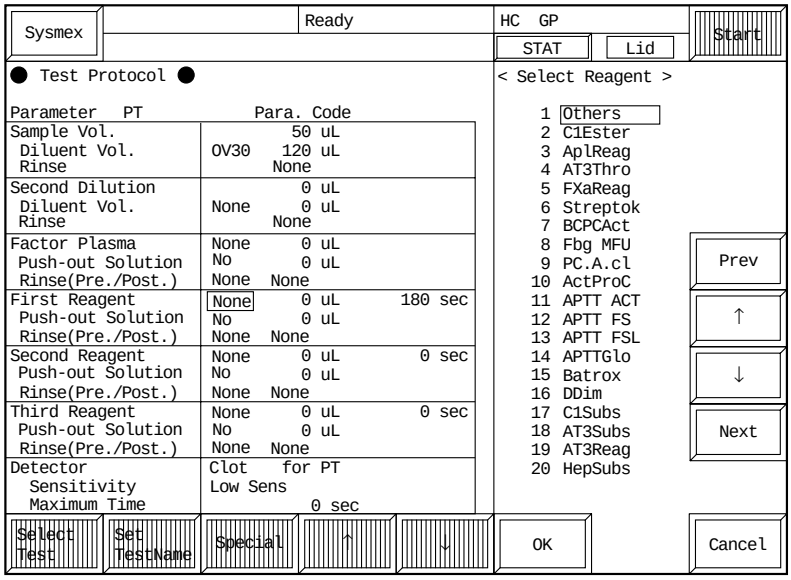


Figure 11-5-13: Select Reagent Window

From the Select Reagent window, press the [↑] and [↓] keys to move the cursor to the reagent that you wish to select; then press the [OK] key.

(5) Select the use of the buffer for a push-out solution for factor-deficient plasma or other sample/reagent.
Move the cursor to the buffer. The numeric keys will appear. Enter 1 (YES) or 0 (No); then press the [ENTER] key.

(6) Set the volume.
Move the cursor to the volume that you wish to set. The numeric keys will appear. Using the numeric keys, enter the volume and press the [ENTER] key.

(7) Set the rinse frequency.
Move the cursor to the rinse. The numeric keys will appear. Enter 0, 1 (×1), 2 (×2) or 3 (×3); then press the [ENTER] key.

(8) Set the detection method.
Move the cursor to the detector. The numeric keys will appear. Enter 0 (Coagulation Method), 1 (Chromogenic Method), or 2 (Immunoassay Method); then press the [ENTER] key.

(9) Set the analysis method.
Move the cursor to the desired analysis method; then press the [Change] key. The Select Analysis Method window will appear.

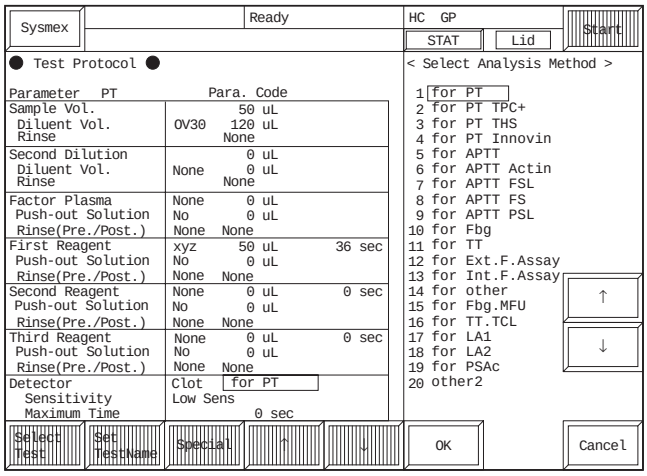


Figure 11-5-14: Select Analysis Method Window

From the Select Analysis Method window, press the [↑] and [↓] keys to move the cursor to the analysis method that you wish to select; then press the [OK] key.

Analysis Method can be selected from the following.

Coagulation Method	Chromogenic Method	Immunoassay Method
for PT	for AT3	for FDP**
for PT TPC+	for Plg	for D-Dimer
for PT THS	for APL	for IMMUNO3
for PT Innovin	for PC	for LPIA D-Dimer**
for APTT	for CHROM1	for vWF.Ag*
for APTT Actin	for CHROM2	for IMMUNO1
for APTT FSL		for IMMUNO2
for APTT FS		for P.FDP***
for APTT PSL		
for Fbg		
for TTO*		
for NT (HpT)*		
for TT		
for Ext. F. Assay		
for Int. F. Assay		
for other		
for Fbg. MFU		
for TT. TCL		
for LA1		
for LA2		
for PSAc		
for other2		

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

When using any PT-reagent or APTT-reagent which is not listed above, select "for PT" or "for APTT", respectively.

(10) Set the sensitivity, wavelength, and dOD increase/decrease.
Move the cursor to the sensitivity, wavelength, and increase/decrease; the numeric keys will appear.
For the sensitivity, enter 0 (low sensitivity) or 1 (high sensitivity); then press the [ENTER] key.
For the wavelength, enter 0 (405 nm) , 1 (575 nm) or 2 (800 nm); then press the [ENTER] key.
For the increase/decrease, enter 0 (increase) or 1 (decrease); then press the [ENTER] key.

(11) Set the maximum detection time.
Move the cursor to the maximum detection time; the numeric keys will appear. Using the numeric keys, enter the maximum time and press the [ENTER] key.

(12) Set the test name.
Press the [Set Test Name] key. The alphanumeric keys will appear. Using the alphanumeric keys, enter the test name; then press the [ENTER] key.

(13) Set the parameter code.
Pressing the [↑] and [↓] keys, move the cursor to the desired parameter code. The numeric keys will appear. Using the numeric keys, enter the parameter code; then press the [ENTER] key.

(14) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Cancel] key.

[Continue] key:	Used to continue the setting of test protocols (analysis procedures) for new parameters.
[Set] key:	Updates the settings and returns the system to the Analysis Settings sub menu.
[Cancel] key:	Cancels the settings and returns the system to the Analysis Settings sub menu.

3. Displaying the change history of the test protocol

The change history of the test protocol can be checked.

(1) From the Analysis Settings sub menu, press the [Test Protocol] key.
The Test Protocol Setting screen will appear.

(2) Press the [Special] key.
The Special sub menu will appear.

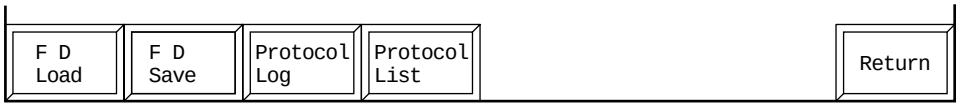


Figure 11-5-15: Special Sub Menu

(3) From the Special sub menu, press the [Protocol Log] key.
The Test Protocol Log screen that displaying the analysis parameter name, change date and change description will appear.

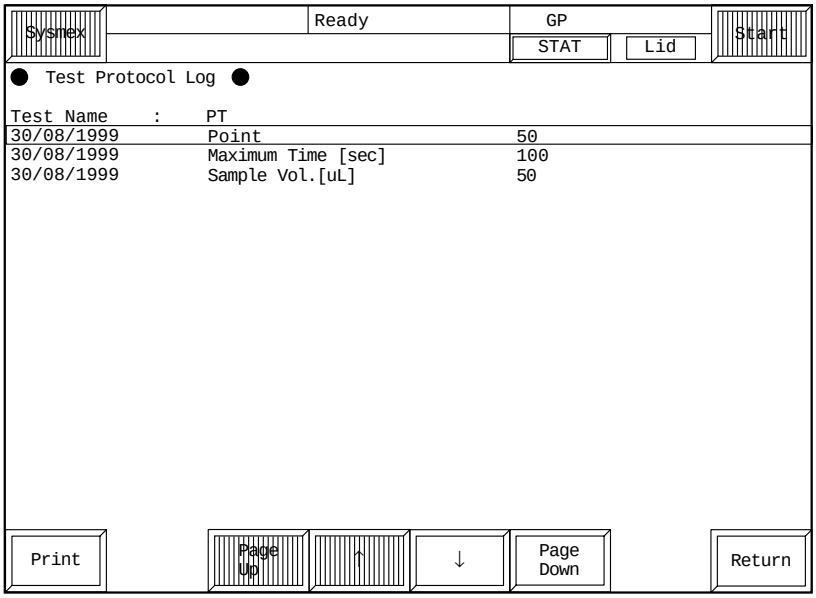


Figure 11-5-19: Test Protocol Log Screen

4. Displaying the list of all parameters of the test protocol

The list of all parameters of the test protocol can be checked.

(1) From the Analysis Settings sub menu, press the [Test Protocol] key.
The Test Protocol Setting screen will appear.

(2) Press the [Special] key.
The Special sub menu will appear.

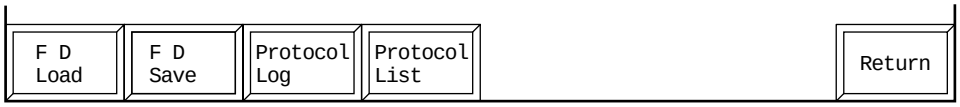
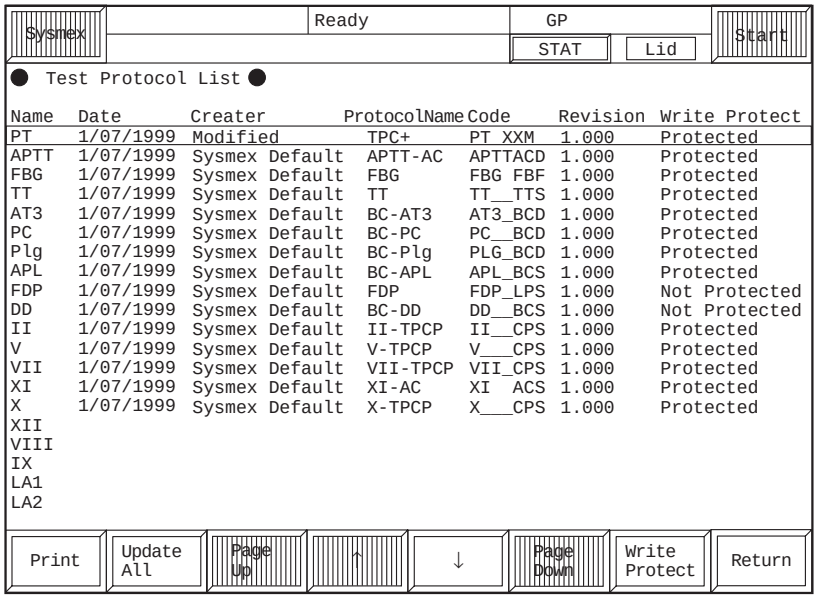


Figure 11-5-17: Special Sub Menu

(3) Press the [Protocol List] key.
The Test Protocol List screen for all parameters that displaying the parameter name, date, originator, test protocol name, code, revision and write-protect will appear.



Name	Date	Creater	ProtocolName	Code	Revision	Write Protect
PT	1/07/1999	Modified	TPC+	PT_XXM	1.000	Protected
APTT	1/07/1999	Sysmex Default	APTT-AC	APTTACD	1.000	Protected
FBG	1/07/1999	Sysmex Default	FBG	FBG FBF	1.000	Protected
TT	1/07/1999	Sysmex Default	TT	TT__TTS	1.000	Protected
AT3	1/07/1999	Sysmex Default	BC-AT3	AT3_BCD	1.000	Protected
PC	1/07/1999	Sysmex Default	BC-PC	PC__BCD	1.000	Protected
Plg	1/07/1999	Sysmex Default	BC-Plg	PLG_BCD	1.000	Protected
APL	1/07/1999	Sysmex Default	BC-APL	APL_BCS	1.000	Protected
FDP	1/07/1999	Sysmex Default	FDP	FDP_LPS	1.000	Not Protected
DD	1/07/1999	Sysmex Default	BC-DD	DD__BCS	1.000	Not Protected
II	1/07/1999	Sysmex Default	II-TPCP	II__CPS	1.000	Protected
V	1/07/1999	Sysmex Default	V-TPCP	V___CPS	1.000	Protected
VII	1/07/1999	Sysmex Default	VII-TPCP	VII_CPS	1.000	Protected
XI	1/07/1999	Sysmex Default	XI-AC	XI ACS	1.000	Protected
X	1/07/1999	Sysmex Default	X-TPCP	X___CPS	1.000	Protected
XII						
VIII						
IX						
LA1						
LA2						

Figure 11-5-18: Test Protocol List Screen

5. Batch updating of the test protocol from FD

The test protocol can be updated from the floppy disk in a batch.

(1) Display the Test Protocol List screen.
(For details on how to display, see *4. Displaying the list of all parameters of the test protocol* in this section.)

(2) Move the cursor to a target parameter by pressing the [↑] key or [↓] key.
Be sure to display "Not Protected" on the test protocol by pressing the [Write Protect] key, and display "Protected" on the test protocol not to be updated.

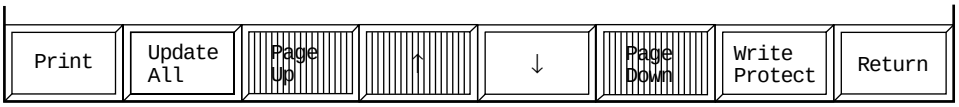


Figure 11-5-19: Test Protocol List Screen

[Write Protect] key: The display of "Not Protected" and "Protected" is alternately switching. The parameter of the "Not Protected" display can be overwritten by loading from FD. The parameter of the "Protected" display cannot be overwritten even if loading from FD.
[Update All] key: Within the test protocols displayed as "Not Protected", if the parameter name or the creator changes and the test protocol name and code are the same as the test protocol stored on FD that test protocol will be updated.

(3) Press the [Update All] key. The FD Insertion Confirmation window will appear.

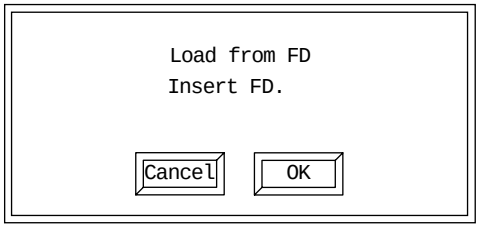


Figure 11-5-20: FD Insertion Confirmation Window

(4) Insert the Test Protocol FD into the floppy disk drive.
Pressing the [Cancel] key to cancel loading from the disk, and the FD Insertion Confirmation window will disappear.

(5) Press the [OK] key.
Loading the data will start and the Now Loading window will appear.
When loading is completed, the list of the test protocol will appear.

6. Setting Test Protocols by Loading from a Floppy Disk

This section will explain how to set test protocols (analysis procedures) by loading from the floppy disk.

(1) From the Analysis Settings sub menu, press the [Test Protocol] key.
The Test Protocol Setting screen for PT will appear.

(2) Press the [Select Test] key.
The Parameter Selection window will appear.

(3) Press the key for the parameter to load.
When you wish to load a new parameter, from the Parameter Selection window, press the blank key on which no parameter name is displayed. The Test Protocol Setting screen for the selected parameter will be displayed.

(4) From the Test Protocol Setting screen, press the [Special] key.
The Special sub menu will appear.

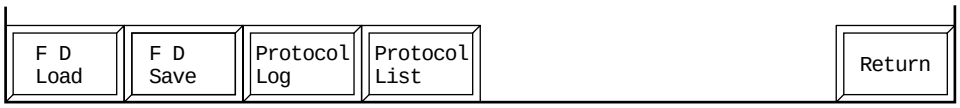


Figure 11-5-21: Special Sub menu

(5) Press the [FD Load] key.
The FD Insertion Confirmation window will appear.

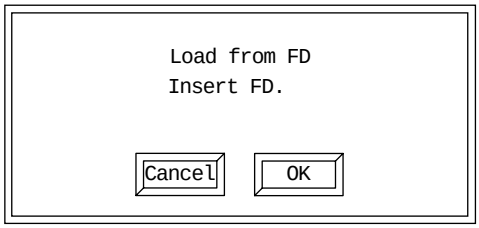


Figure 11-5-22: FD Insertion Confirmation Window

(6) Insert the floppy disk that contains the test protocols into the floppy disk drive.
To cancel loading from the disk, press the [Cancel] key.

(7) Press the [OK] key.
A list of the test protocols that are saved on the floppy disk will be displayed.

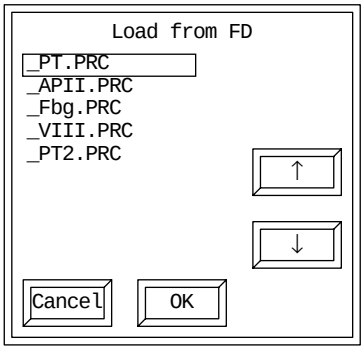


Figure 11-5-23: List of Test Protocols

(8) Pressing the [↑] and [↓] keys, move the cursor to the test protocol that you wish to load; then press the [OK] key.
Loading will begin and a message will appear, informing the operator that loading is in progress.
To discontinue loading, press the [Cancel] key.
If reagent information has not been set for the reagent that was set by the test protocol that was loaded, a message will appear asking to check the reagent. Check the reagent and press the [OK] key. After the confirmation window disappears, set the information for the new reagent. For details on how to set reagent information, see *Section 5.1: Reagent Information Settings* in this chapter.

7. Saving Test Protocols on a Floppy Disk

This section will explain how to save test protocols (analysis procedures) on a floppy disk. Test protocols can be saved for each test parameter shown on the Test Protocol Setting screen.

(1) From the Analysis Settings sub menu, press the [Test Protocol] key.
The Test Protocol Setting screen for PT will appear.

(2) Press the [Select Test] key.
The Parameter Selection window will appear.

(3) Press the parameter key for the test protocol that you wish to save.
The Test Protocol Setting screen for the selected parameter will appear.

(4) From the Test Protocol Setting screen, press the [Special] key.
The Special sub menu will appear.

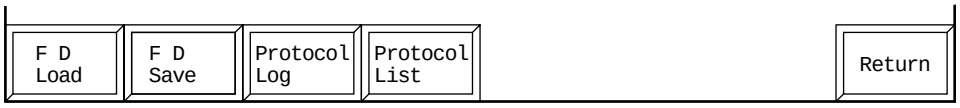


Figure 11-5-24: Special Sub menu

(5) Press the [FD Save] key.
The FD Insertion Confirmation window will appear.

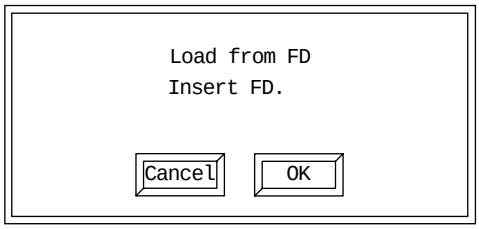


Figure 11-5-25: FD Insertion Confirmation Window

(6) Insert a floppy disk into the floppy disk drive.
To cancel saving, press the [Cancel] key.

(7) Press the [OK] key.
The data will be saved on the floppy disk; then the system will return to the Test Protocol Setting screen.
If the memory of the inserted floppy disk is insufficient, a message window will appear. If that happens, insert a preformatted empty floppy disk and press the [OK] key.

5.3 Replication Settings

This section will explain how to set up the instrument to automatically execute replicate analysis on each parameter. The average of the analysis results will be calculated for each sample, and calculation parameters will be calculated using the average.
Mean analysis data will be flagged "m".

NOTE:
- Redilution analysis and reflex test are also performed following replication settings.
- For QC samples and standard curve samples, set the number of replications for those samples in those respective programs.

(1) From the Analysis Settings sub menu, press the [Replic.] key.
The Replication Setting screen will appear.

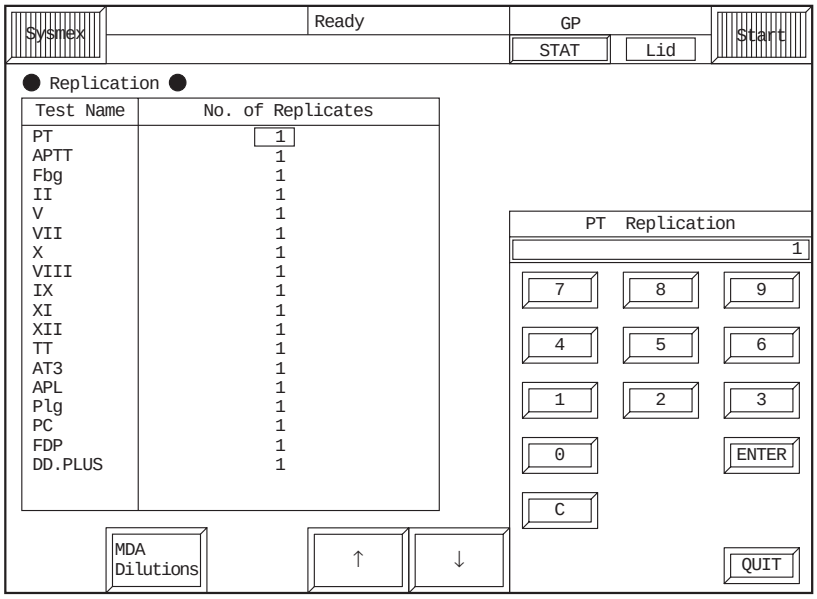


Figure 11-5-26: Replication Setting Screen

(2) Pressing the [↑] and [↓] keys, move the cursor to the parameter that you wish to set.

(3) Using the numeric keys, enter the number of replications (1 or 2); then press the [ENTER] key.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of replications.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.4 MDA Settings

During an MDA (Multi-Dilution Analysis), the same sample is analyzed using multiple dilution ratios. By analyzing the results of measurements taken using various dilution ratios, the effects of inhibitor and activator in the sample can be examined. For each analysis parameter, you can select the point number of dilution series from three types: (1) MDA, (2) MDA high, and (3) MDA low.

(1) From the Replication Setting screen, press the [MDA Dilutions] key.
The MDA Settings screen will appear.

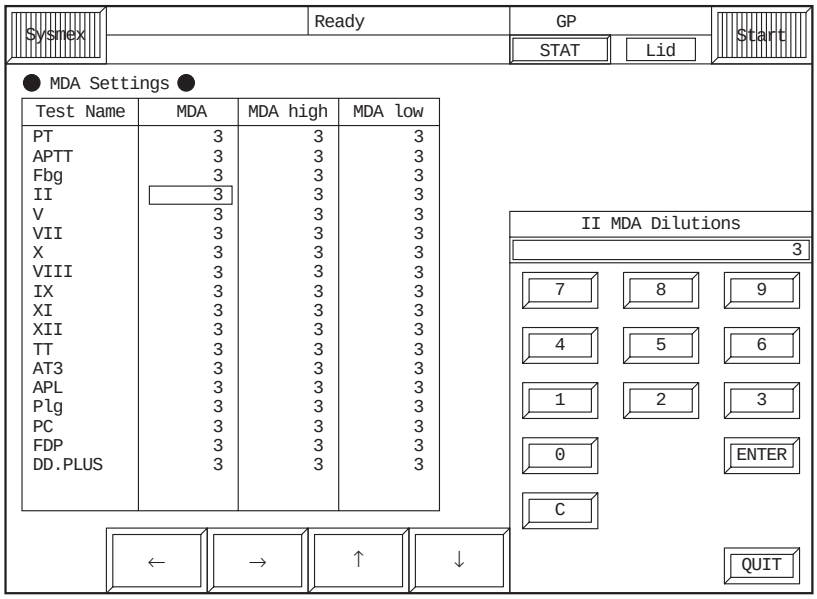


Figure 11-5-27: MDA Settings Screen

(2) Pressing the [↑], [↓], [←], and [→] keys, move the cursor to the parameter that you wish to set.

(3) Using the numeric keys, enter the number of points (2 or 3) that you wish to set; then press the [ENTER] key.

	3	2
MDA	1/1, 1/2, 1/4	1/1, 1/2
MDA high	1/8, 1/16, 1/32	1/8, 1/16
MDA low	2/1, 5/1, 10/1	2/1, 5/1

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of MDA.
[Set] key: Updates the settings and returns the system to the Replication Setting screen.
[Quit] key: Cancels the settings and returns the system to the Replication Setting screen.

5.5 Detector Settings

Using the Coagulation Method, you can calibrate the coagulation time by changing the coagulation detection point, based on the Percentage Detection Method.
And using the Chromogenic Method and Immunoassay Method, you can change the reading start and end points for data to use in linear regressions.

(1) From the Analysis Settings sub menu, press the [Detector Settings] key.
The Detection Settings screen will appear.

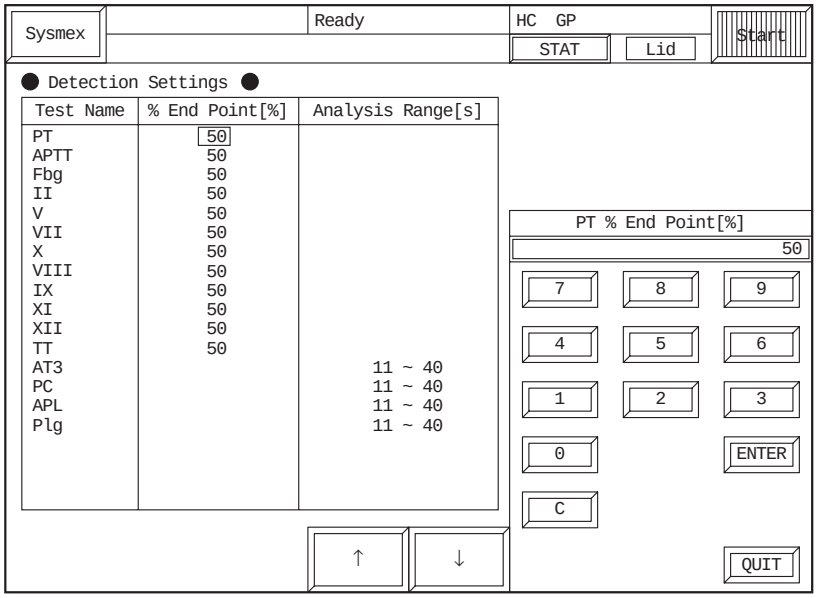


Figure 11-5-28: Detector Settings Screen

(2) Pressing the [↑] and [↓] keys, move the cursor to the parameter that you wish to set.

(3) Using the numeric keys, enter the value that you wish to set; then press the [ENTER] key. Set the coagulation detection points from 2% to 80% at increments of 1%. Set the analysis range from 3 to 600 seconds at increments of 1 second.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key .
[Continue] key: Used to continue the detector Settings.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.6 Parameter Group Settings

This section will explain how to set parameter groups, Profile #1 and Profile #2. Analysis parameter groups are groups of often-used parameters that are set up in a manner that permits the parameters to be quickly registered at the time of analysis.
And for parameters that belong to the aforementioned groups and are used frequently, this section will explain how to assign them to [Profile #1] or [Profile #2] keys that are found on the Work Load List screen.

CAUTION: • Analysis parameters that are not set in a group cannot be analyzed.

(1) From the Analysis Settings sub menu, press the [Group Settings] key.
The Parameter Group 1 Setting screen will appear.

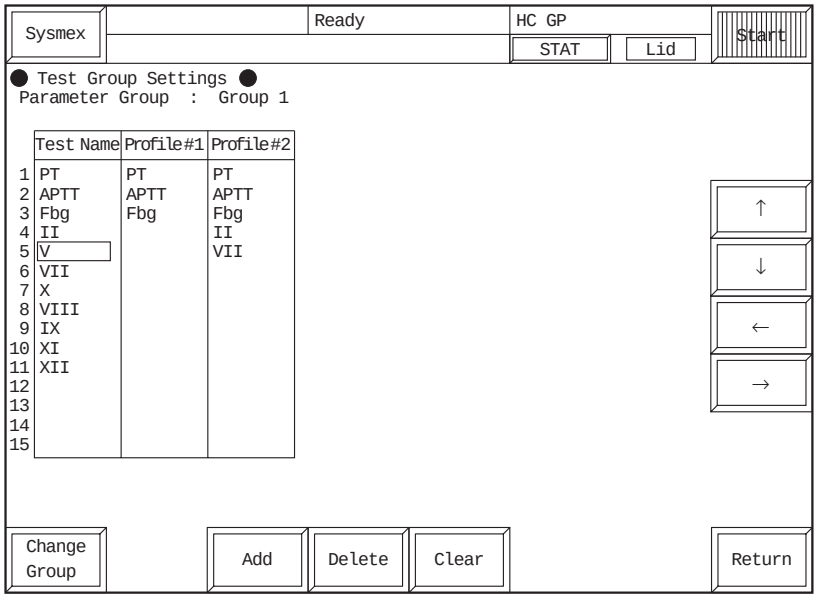


Figure 11-5-29: Parameter Group 1 Setting Screen

To set Parameter Group 2, press the [Change Group] key. Parameter Group 2 Setting screen will appear.

(2) To add a parameter to a Parameter Group or to Profile #1 or Profile #2, press the [↑], [↓], [←], and/or [→] keys to move the cursor to the position where you wish to add. Press the [Add] key.
The Analysis Parameter Selection window will appear. Press the key for the analysis parameter that you wish to add. The selected analysis parameter will be added. If an analysis parameter was already at the cursor position, it and the parameters that follow it will move down one each position.

(3) To delete a parameter from Profile #1 or Profile #2, press the [↑], [↓], [←], and/or [→] keys to move the cursor to the parameter that you wish to delete. Press the [Delete] key. The analysis parameter that is at the cursor position will be deleted, and the parameters that follow it will move up one position each.

NOTE:
- If you wish to delete all of the items in all groups that are displayed on the screen, press the [Clear] key. If you press the [Clear] key, a Deletion Confirmation window will appear. To delete, press the [OK] key. To cancel, press the [Cancel] key.

(4) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key: Used to continue the setting of groups.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.7 Reagent Position Settings

This section will explain how to set the holder arrangement for reagent, diluent, rinse solution, factor-deficient plasma, control plasma, and calibrator.

1. When the Wand Barcode Reader is Not Used

NOTE:
- Reagent positions can be set on the Consumable screen according to the same procedure.
  Maximum of only three reagent holder positions can be set for the same reagents.
  For how to set the reagent positions on the Consumable screen, see *Chapter 2, Section 4.2: Setting the Reagents and Sample Plates (when the Wand Barcode Reader is Not Used).*

(1) From the Analysis Settings sub menu, press the [Reagent Position] key.
The Reagent Position Setting screen for Group 1 will appear.

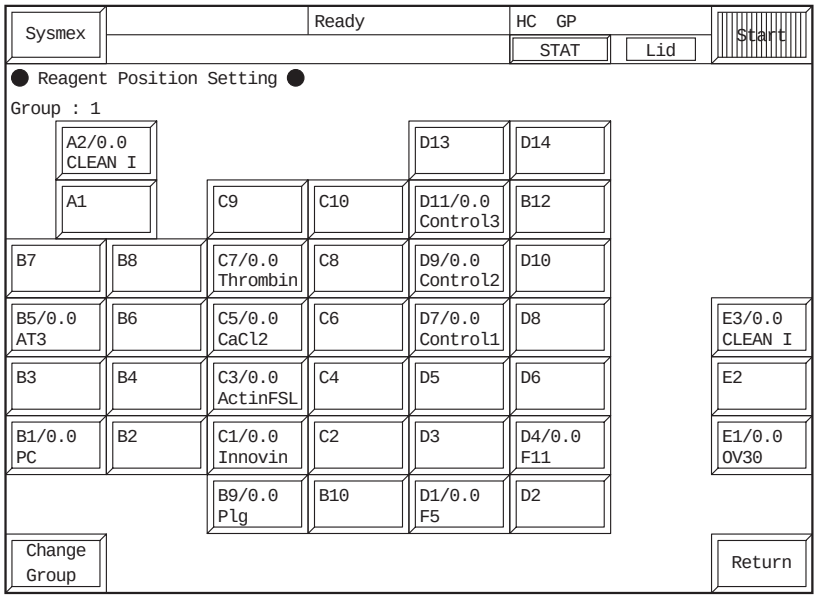


Figure 11-5-30: Reagent Position Setting Screen (for Group 1)

To set the reagent positions for Group 2, press the [Change Group] key. The Reagent Position Setting screen for Group 2 will appear.

NOTE:
- Set the reagent position for each parameter group. For details on how to set the parameter group, see *Chapter 11, Section 5.6: Parameter Group Settings.*

(2) Press the keys for the holder that you wish to set.
The lot number of a current reagent, and the container for the set reagent will be displayed.

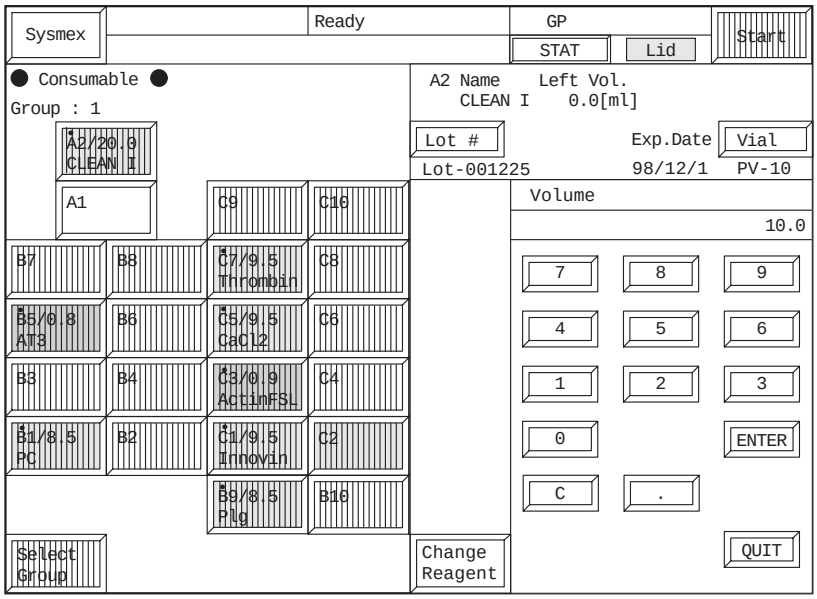


Figure 11-5-31: Entering the Reagent Volume

(3) Press the [Change Reagent] key, the Select Reagent window will appear. The reagents that can be set into the selected holder will appear in the Select Reagent window.
The reagent that has already been selected is displayed with the blue back-lit No. to the left.

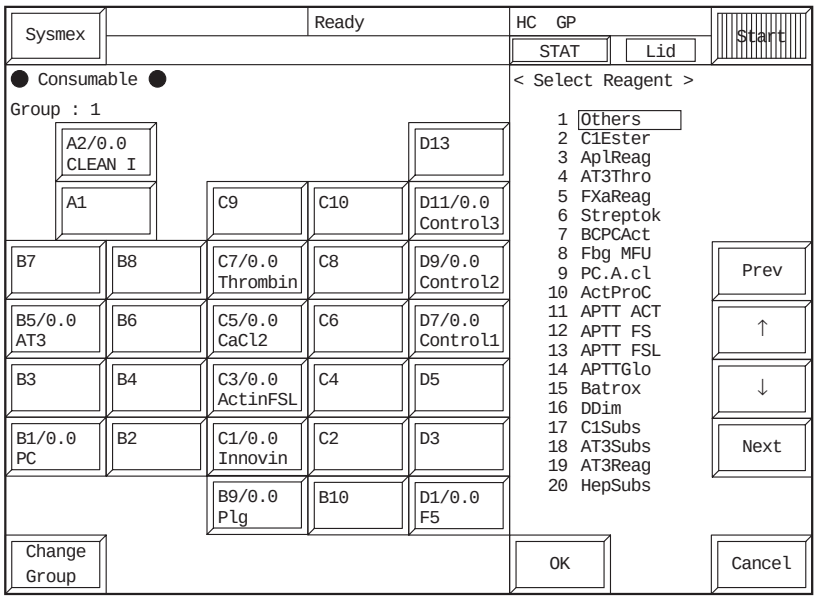


Figure 11-5-32: Select Reagent Window

(4) From the Select Reagent window, press the [↑] and [↓] keys to move the cursor to the reagent that you wish to set; then press the [OK] key.
If you select "None" in the Select Reagent window, the reagent information for the reagent holder will be deleted.

(5) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of reagent positions.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

NOTE:

- If a reagent position that corresponds to a parameter in a group has not been set, press the [Set] key from the Update Confirmation window. A confirmation window for the reagent that does not have a position set will appear. Press the [OK] key; the confirmation window will disappear. Then either reset the reagent holder again, or delete the parameter through group settings. For details on how to delete analysis parameters through group settings, see *Section 5.6: Parameter Group Settings* in this chapter.
- The reagent lot number and vial type can be changed on the Reagent Position Setting screen.
  (1) Press the key to the reagent holder position where reagent information is changed. The window for reagent information input will appear.
  (2) To change the lot number, press the [LOT #] key, and alphanumeric keys will be displayed. Enter the lot number and press the [ENTER] key.
  (3) To change the set vial type, press the [Vial] key, and vial type selection window will be displayed.
  On the vial type selection window, press [↑] or [↓] key to move the cursor to the appropriate vial and press [ENTER] key.

CAUTION • Set the correct container, or CA-1500 cannot aspirate the reagent correctly.

- When the reagent lot number or vial type is changed on the Reagent Position Setting screen, information on the reagent stored by setting reagent information will be changed as well. For how to set the reagent information, see *Chapter 11, Section 5.1: Reagent Information Settings.*

2. When the Wand Barcode Reader is Used

This section will explain how to set the holder arrangement for reagent, diluent, rinse solution, factor-deficient plasma, control plasma and calibrator by reading the reagent barcode with an optional wand barcode reader.

(1) From the Analysis Settings sub menu, press the [Reagent Position] key.
The Reagent Position Setting screen for Group 1 will appear.
To set the reagent positions for Group 2, press the [Change Group] key. The Reagent Position Setting screen for Group 2 will appear

(2) Press the keys for the holder that you wish to set.
The lot number of a current reagent, and the container for the set reagent will be displayed.

(3) Read the reagent barcode with the optional wand barcode reader. The reagent name, lot number, expiration date and the vial type will be automatically displayed.

CAUTION:
- The barcode might not be able to be read if a drop of water is on the barcode label.
  Wipe the drop of water off before setting the reagent.

NOTE:
- When the reagent barcode is read by the wand barcode reader on the reagent position setting screen and when the lot number, expiration date and vial type of a new reagent are set, information on the reagent will be added to the reagent information settings. For how to set the reagent information, see *Section 5.1: Reagent Information Settings* in this chapter.
- In the following cases, it is necessary to set by manual input even when an optional wand barcode reader is used.
- When changing the read reagent name, lot number or vial type
- When using reagent without the reagent barcode label
- When using diluent
  For how to set the reagent information, see *Section 5.1: Reagent Information Settings in this chapter.*
- When the reagent barcode is read by an optional wand barcode reader, the confirmation windows might be displayed. For details on the confirmation windows, see *Chapter 2, Section 4.3: Setting the Reagents (when the Wand Barcode Reader is Used).*

5.8 Calculation Parameter Settings

This section will explain how to set calculation parameters.
You can set three types of calculation parameters for each analysis parameter:

- Calculation parameter 1: Activity percent and concentration
- Calculation parameter 2: Ratio
- Calculation parameter 3: INR
- Calculation parameter 4: Derived Fbg concentration

(1) From the Analysis Settings sub menu, press the [Parameter Setting] key.
The Calculation Parameter Settings screen will appear.

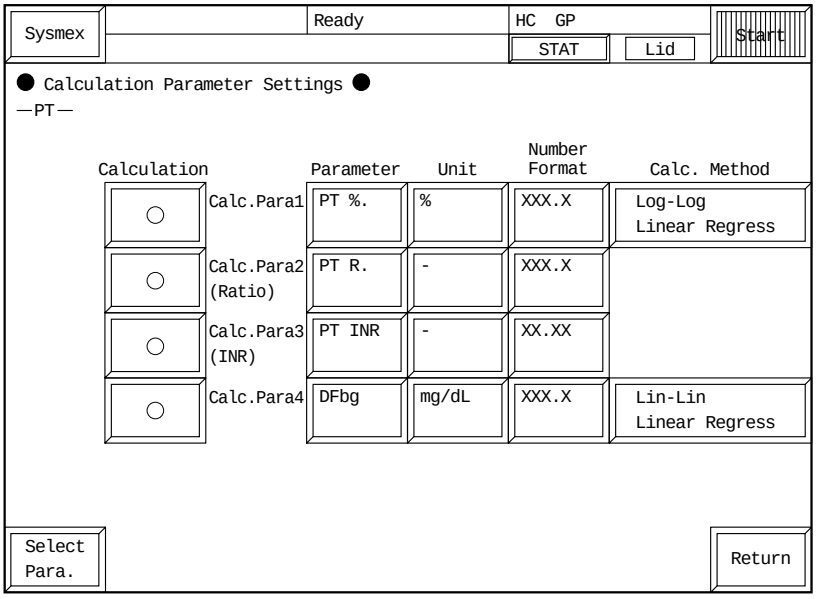


Figure 11-5-33: Calculation Parameter Settings Screen

(2) Press the [Select Para] key.
The Parameter Selection window will appear.

(3) Press the parameter key for the calculation parameter that you wish to set.
The calculation parameters of the selected parameter will appear.

(4) Determine which calculation parameters will be calculated.
Each time you press the Calculation key, it will switch between "○" (calculate) and "– " (do not calculate).

(5) Set the name of each calculation parameter.
Press the key for the parameter. Alphanumeric keys will appear. Using alphanumeric characters, spaces, and %, enter the name of the calculation parameter, using up to seven characters. Then press the [ENTER] key.

(6) Set the unit for each calculation parameter.
Each time you press the unit key, the unit will change in order.

NOTE: • The unit will change in the order that they are registered on the Unit Setting screen. See *Section 8.2: Unit Settings* in this chapter.

(7) Set the number of digits that calculation parameter will have to the right of the decimal point. Each time you press the Number Format key, the formats "X.XXX", "XX.XX", "XXX.X", "XXXX" and ".XXXX" will change in order.

CAUTION: • Sometimes the display of stored data will be abnormal after the number format is changed. First delete all the stored data, and then make the change.

(8) Set the measured data of the standard curve for Calculation Parameter 1, as well as the type of calculation parameter axis (PT %) and type of expression.
Press the Calc. Method key. The Calculation Method Setting window will appear.

NOTE: • When registering a new parameter, it is suggested to set as follows.
Coagulation Method: Log-Log, Point-Point
Chromogenic Method: Lin-Lin, Linear Regression
Immunoassay Method: Lin-Lin, Point-Point

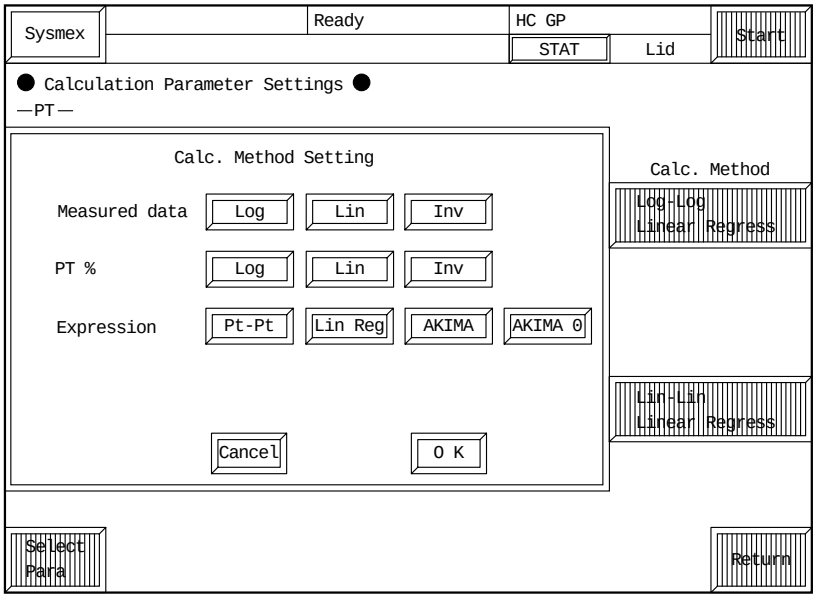


Figure 11-5-34: Calculation Method Setting Window

For each parameter, press the key that represents the format you wish to set. After setting the calculation method, press the [OK] key. The calculation method will be set.
When the [AKIMA 0] is selected by the approximate expression, though the analysis is not performed at creating a standard curve, a standard curve which passes the point that shows the concentration "0" and the difference in the optical density (dOD) "0" is automatically drawn.

* AKIMA: Interpolation by multinomial approximation
AKIMA 0: AKIMA expression which passes through the origin

CAUTION:
- If you change the calculation method, the content of the standard curve will also change. After setting, check the standard curve.

NOTE:
- When the Akima method is selected, select dilution ratios which are appropriate for the measurement range of the assay i.e. the upper and lower limits of the curve should not extend beyond the measurement range. Please note that the measuring range must be defined in raw values (dOD or seconds) and not in concentration units. Otherwise the reading of the concentration results from the standard curve might be incorrect.

(9) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [OK], or [Cancel] key.

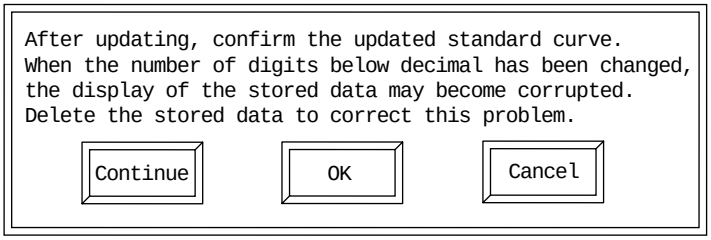


Figure 11-5-35: Update Confirmation Window

[Continue] key: Used to continue the setting of calculation parameters.
[OK] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Cancel] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.9 New Calculated Parameter Settings

This section will explain how to create a formula for calculating a calculation parameter.

NOTE:
- Formulas cannot be set for analysis parameters and calculation parameters that are assured on the CA-1500.
  For details on the analysis parameters and calculation parameters that the CA-1500 assures, see *Chapter 1, Section 5: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS*.

(1) From the Analysis Settings sub menu, press the [Add Calc. Param.] key.
The New Calculated Parameters screen will appear.

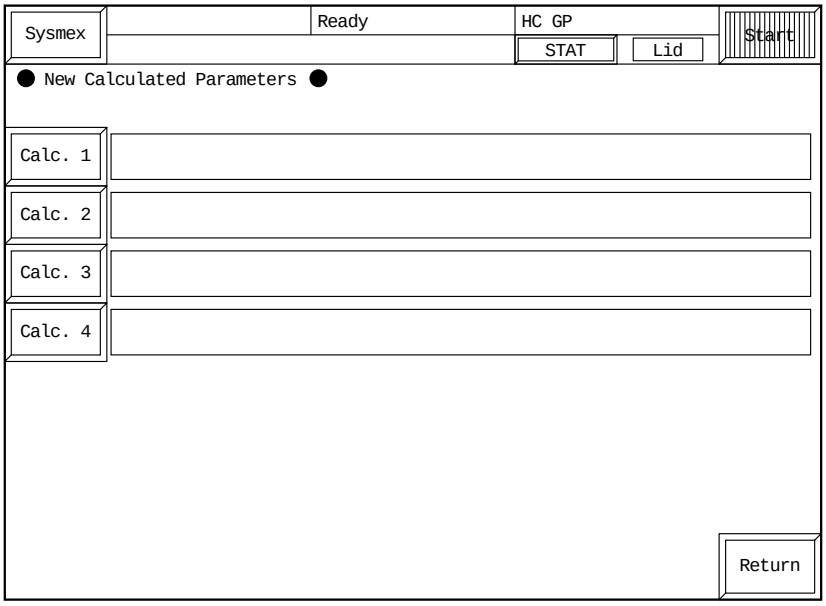


Figure 11-5-36: New Calculated Parameters Screen

(2) Press the key for the formula that you wish to set.
The setting screen for the selected formula will appear.

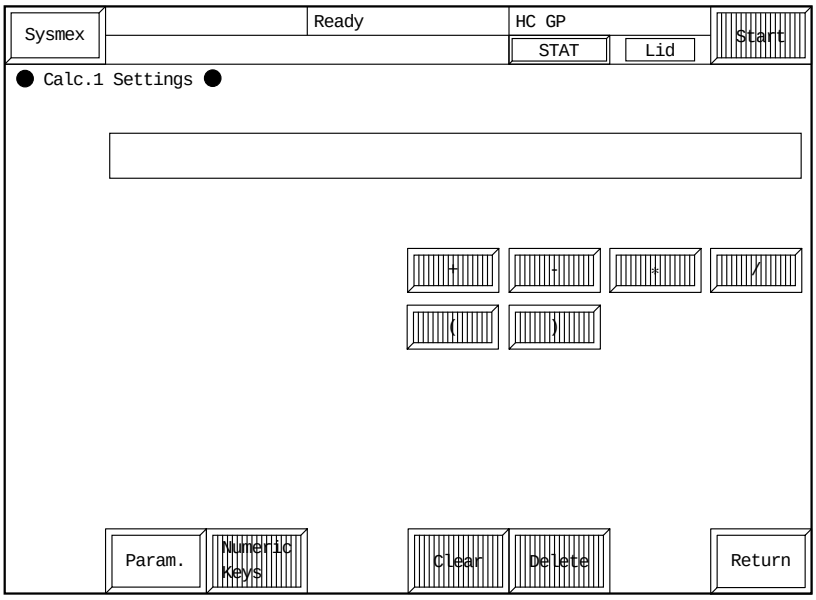


Figure 11-5-37: Calc. 1 Settings Screen

(3) Press the [Param.] key.
The Parameter Selection window will appear.

(4) Press the analysis parameter key to create a formula.
The calculation parameter keys will appear.

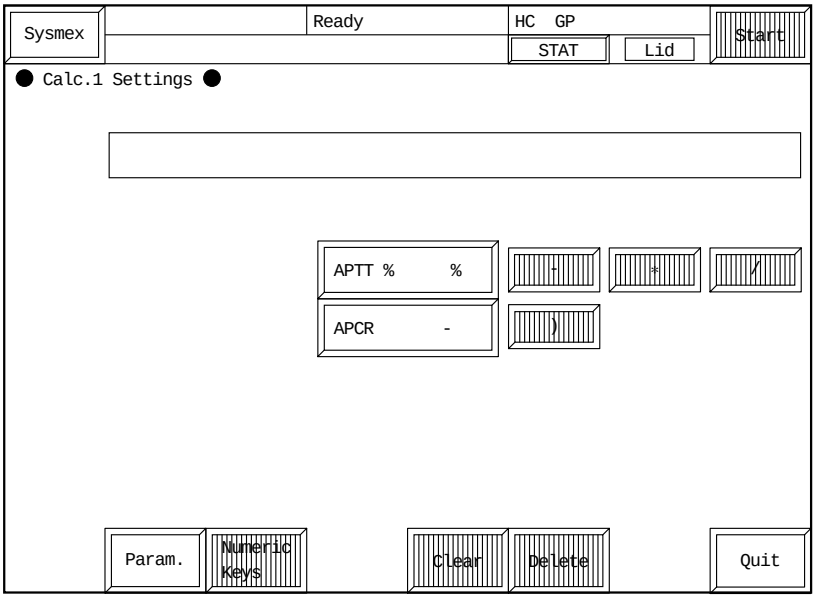


Figure 11-5-38: Calculation Parameter Keys

(5) Press the calculation parameter key to create a formula.
The formula's left side and equal sign (=) will be set.

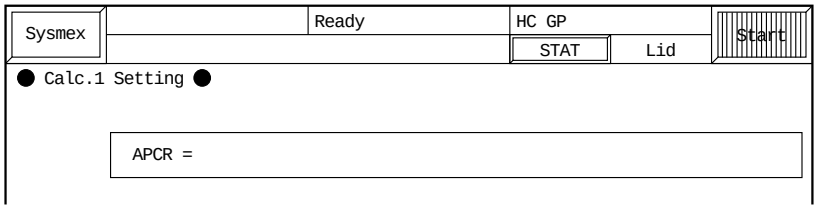


Figure 11-5-39: Creating Formula

(6) Enter the formula's right side.
Using the calculation parameters, numerals, and [+], [-], [*], [/], [(], and [)] keys, enter the formula. Using the same procedure as that for entering the formula's left side, display the calculation parameters; then press the applicable key to enter the information. You cannot, however, set the calculation parameter that has been set on the left side.
To enter numerals, first press the [Numeric Keys] key to display the numeric keys; then enter the numerals. If you press the [Clear] key, the entire formula display area will be cleared. If you press the [Delete] key, the formula's last numeral, operation symbol, or parameter will be deleted.

CAUTION:
- The priority of operator in this system doesn't comply with the general mathematical one.
  Use parentheses to clarify the priority of the operators, when two or more types of operators are included in a formula.
  Only one type of operators is allowed in the parentheses.
  e.g. When you use the formula, "y = a / b / c * d", enter "y = (a / b / c) * d".

(7) After the formula has been created, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue creating a formula.
[Set] key:	Updates the formula and returns the system to the New Calculated Parameters screen.
[Quit] key:	Returns the system to the New Calculated Parameters screen without updating the formula.

NOTE:
- If the formula has not been correctly created and you then press the [Set] key from the Update Confirmation window, a Formula Confirmation window will appear. If that happens, press the [OK] key to return to the Formula Setting (Calc. 1 Settings) screen.

(8) After each formula has been created, press the [Return] key from the New Calculated Parameters screen.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Cancel] key.
[Continue] key: Used to continue the setting of new calculation parameters.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Cancel] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.10 Conversion Settings

This section will explain how to set constant values in the conversion formula for analysis parameters.
It will also explain how to set "a" (a constant) and "b" (Y-intercept) in the conversion formula y = ax + b.
Example: Conversion formula for TT
Correlation for TT method 1 and CA-1500 y = 1.05x + 2.1
To convert CA-1500 TT to method 1 insert a = 1.05 and b = 2.1

(1) From the Analysis Settings sub menu, press the [Conversion] key.
The Conversion Formula Setting screen will appear. Only analysis parameters that were registered in accordance with the test protocol will be displayed.

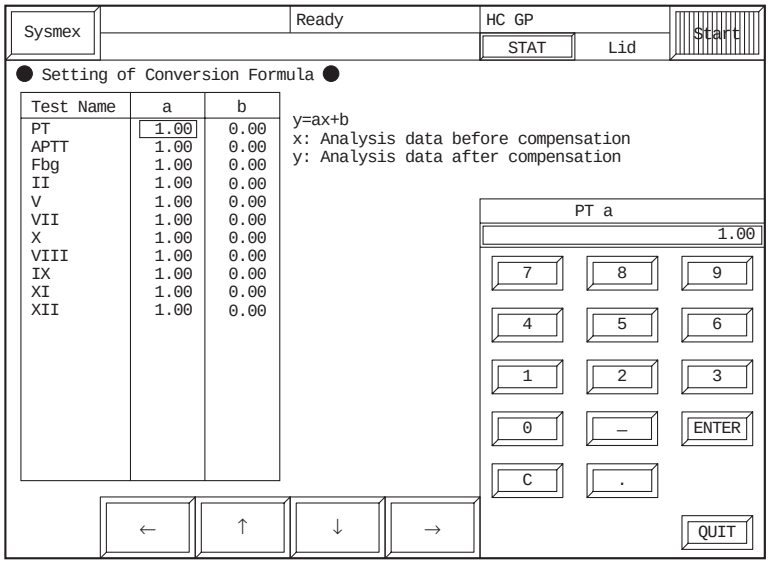


Figure 11-5-40: Conversion Formula Setting Screen

(2) Set "a" (constant) and "b" (Y-intercept) for each analysis parameter.
Pressing the [↑], [↓], [←], and [→] keys, move the cursor to the parameter you wish to set. Set "a" and "b" within the range of -99.99 to 99.99.
If there are 21 or more parameters, and you press the [↓] key when the cursor is at the bottom position on the screen, the analysis parameters will scroll down one line. And if you press the [↑] key when the cursor is at the top position, the analysis parameters will scroll up one line.

(3) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of the conversion formula.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.11 Alarm Settings

This section will explain how to set up a method of monitoring the volume of aspirated sample, remaining reagent, and others. When monitoring is activated, an error message will appear if the remaining volume becomes short.

(1) From the Analysis Settings sub menu, press the [Alarm Setting] key.
The Alarm Settings screen will appear.

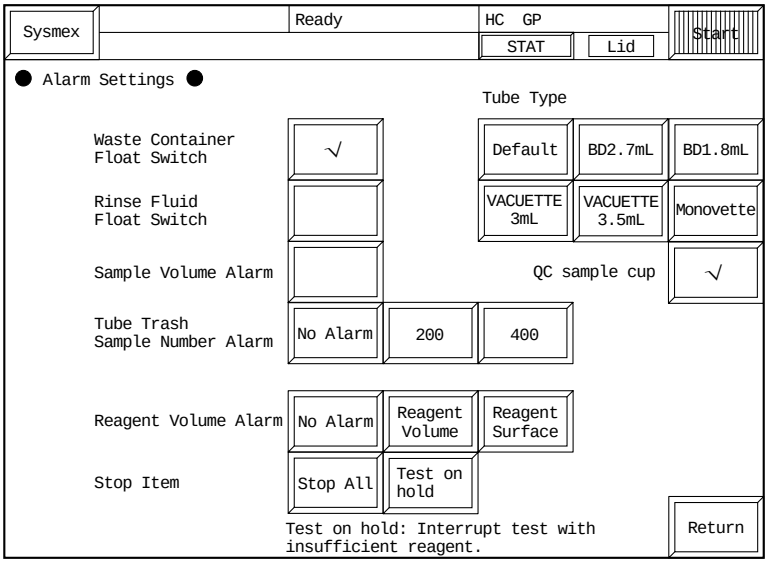


Figure 11-5-41: Alarm Settings Screen

(2) Decide whether to monitor the waste fluid in the waste container, rinse fluid in the rinse tank, volume of aspirated sample, and number of reaction tubes in the tube trash box (200 or 400). Set by pressing the [Waste Container Float Switch], [Rinse Fluid Float Switch], [Sample Volume Alarm], and/or [Tube Trash Sample Number Alarm] key. A "√ " symbol (activated) and a blank space (not activated) will alternately appear each time the key is pressed.

When the Sample Volume Alarm is activated, a message will appear at the start of the analysis if the samples of several parameters registered in Work List cannot be dispensed to the sample plates.
When the Tube Trash Sample Number Alarm is activated (200 or 400), the reaction tubes whose samples have been analyzed are counted and an alarm is output when the trash box becomes full.

CAUTION:
- When using the accessory reaction tube trash box (200 reaction tube capacity), an alarm will not be output when the trash box becomes full if the Tube Trash Sample Number alarm is set to [400]. This will cause an instrument fault. Only set the Tube Trash Sample Number alarm to [400] when using the optional accessory "CA-1500 Trash Box (L)".
- Discard used reaction tubes in the trash box after completing the day's analysis even if the Tube Trash Sample Number alarm has not been output.

(3) Press the appropriate key to set the reagent volume monitoring alarm.

[No Alarm] key: Remaining reagent will not be monitored. If this is set, the reagent will be regarded as empty only after the probe cannot detect the liquid surface in any of the reagent vials set for that reagent. Samples being incubated will generate analysis errors; therefore, you have to interrupt the analysis before the reagent runs out.

[Reagent Volume] key: Activates monitoring of the remaining volume, which is calculated by subtracting the volume of reagent used from the volume that was entered during reagent preparation.

[Reagent Surface] key: The amount of the reagent will be calculated from the depth at which the probe reaches the liquid surface, and will monitor amount the remaining.

(4) Press the desired key to set the method by which the analysis will be interrupted when a volume monitoring alarm is activated (Stop Item).

[Stop All] key: Interrupts all analysis when the volume of reagent becomes short.

[Test on hold] key: Interrupts only analysis parameters whose volume of reagent becomes short.

CAUTION:
- Even if the "Test on hold" method in "Stop Item" is selected to interrupt analysis when reagent becomes short, all analysis will be interrupted if the reagent for Micro-sample mode becomes short.

(5) Set whether to use the following special test tube.

- VACUTAINER Plus Plastic Citrate Tube (HEMOGARD Closure) 1.8 mL, 2.7 mL
- VACUETTE Sandwich Coagulation Tube 3.0 mL, 3.5 mL
- MONOVETTE 2.9 mL, 3.0 mL

Applicable test tubes for each tube type selection setting, *See Chapter 2, Section 8.1: Preparing Plasma*.

CAUTION • When “MONOVETTE” is not selected, a MONOVETTE tube is used and the sample inside is not enough for an analysis, the pipette or piercer may hit the bottom of the sample tube. This may result a sample tube broken and/or the pipette or piercer bent.

NOTE:

- When “BD 1.8 mL”, “BD 2.7 mL”, “VACUTAINER 3.0 mL” or “VACUETTE 3.5 mL” is selected, the pipette or piercer dips deeply into the sample tube. If an applicable tube other than the above special tubes is used, a larger volume of blood will be required.
  When “MONOVETTE” is selected, the pipette or piercer does not go down deeply into the sample tube. If an applicable tube other than the MONOVETTE is used, a larger volume of blood will be required.
  For information on the minimum required sample volume for each tube type selection setting, see *Chapter 2, Section 8.1: Preparing Plasma.*

(6) When sample cups are used for QC analysis, set this item to ON (place a "√ " mark). Regardless of the tube type selection setting, the minimum required sample volume for all the applicable sample tubes including sample cups for QC analysis becomes the same as “Default” tube type setting.

(7) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Cancel] key.

[Continue] key: Used to continue the setting of alarms.
[Set] key: Updates the settings and returns the system to the Analysis Settings sub menu.
[Cancel] key: Cancels the settings and returns the system to the Analysis Settings sub menu.

5.12 Sample Plate Settings

This section will explain how to set whether or not samples are dispensed into sample plates, the number of samples to load in a plate at a time and the time to flag samples that have been left in the sample plate for an extended time. The content that is set will become the work list default information. Note that automatic re-analysis and automatic redilution functions will be disabled when the "Micro Sample" Mode is selected.

(1) From the Analysis Settings sub menu, press the [Plate Setting] key.
The Sample Plate Setting screen will appear.

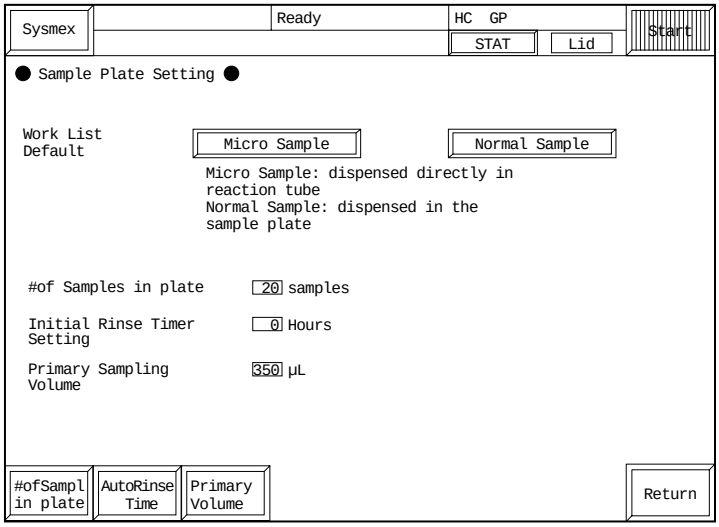


Figure 11-5-42: Sample Plate Setting Screen

(2) Press the appropriate key to set the work list default.

[Micro Sample] key: Micro-sample mode in which samples will not be dispensed into the sample plate, but dispensed directly into the reaction tube.
(See *Chapter 3, Section 2.2: Contents Displayed on Work Load List Screen, (J)*.)

[Normal Sample] key: Normal sample mode in which samples will be dispensed into the sample plate.

(3) Set the number of samples dispensed concurrently.
Press the [# of Samples in plate] key to display the numeric keys. Using the numeric keys, enter the number in the range of 1 - 50 samples. This No. of samples will be drawn and dispensed in the sample plate concurrently.

(4) Set the execution interval for the initial rinse using CA CLEAN I at start of analysis.
When analysis is normally completed, the initial rinse using CA CLEAN I will not be performed during the setting period even if the next analysis is started.
However, rinsing will be performed at start of analysis immediately after the power is turned on or after the emergency stop.
Press the [Auto Rinse Timer] key to display the numeric keys.
The number in the range of 0 to 24 can be entered.
It is recommended to use the equipment at the default value (0).
If changing this value, use the equipment after confirming that there is no adverse effect to analysis due to carry over.

(5) Only when SIS and DPS are connected, set the primary sampling volume for an automatic inquiry to the host computer.
Press the [Primary Volume] key to display the numeric keys.
The number in the range of 4 to 450 can be entered. (4 to 350 when a cap piercer unit is installed)
In this case, the instrument takes this input primary volume every time regardless of the analysis order.
However, when SIS and DPS are not connected, the instrument takes the necessary primary volume for the analysis order and for the re-analysis automatically regardless of this setting.
For all aspirating volume of the sample, see *Chapter 2: Sample Preparation*.

(6) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the sample plate settings.
[Set] key: Updates the settings and returns to the Analysis Settings sub menu.
[Quit] key: Cancels the settings and returns to the Analysis Settings sub menu.

6. I/O SETTINGS

This section will explain how to preset the interface parameters for the optional host computer, as well as printer parameters for the optional graphic and data (ticket) printers and other conditions.

Use the setting screens to set up the peripheral device .
From the Settings sub menu, press the [I/O Settings] key. The I/O Settings sub menu will appear.

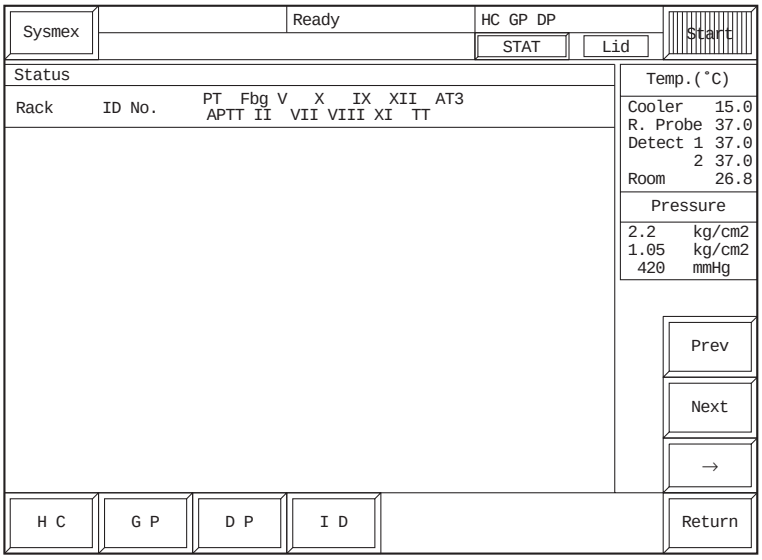


Figure 11-6-1: I/O Settings Sub menu

[HC] key: Used to set the interface parameters for the optional host computer. See *Section 6.1: Host Computer Settings* in this chapter.

[GP] key: Used to set the printer parameters for the optional graphic printer. See *Section 6.2: Graphic Printer Settings* in this chapter.

[DP] key: Used to set the printer parameters and print format for the optional data (ticket) printer. See *Section 6.3: Data Printer Settings* or *Section 6.4: Data Printer Print Type Settings* in this chapter.

[ID] key: Used to set the usage conditions for the optional barcode reader. See *Section 6.5: Barcode Settings* in this chapter.

[Return] key: Returns the system to the Settings sub menu.

6.1 Host Computer Settings (Option)

This section explains how to set the interface parameters for the optional host computer.

From the I/O Settings sub menu, press the [HC] key. The Host Computer Settings screen will appear.
Host Computer Settings has two screens. If you press the [More] key, the second screen will appear. If you press the [Prev.] key while the second screen is being displayed, the first screen will appear.

First Screen

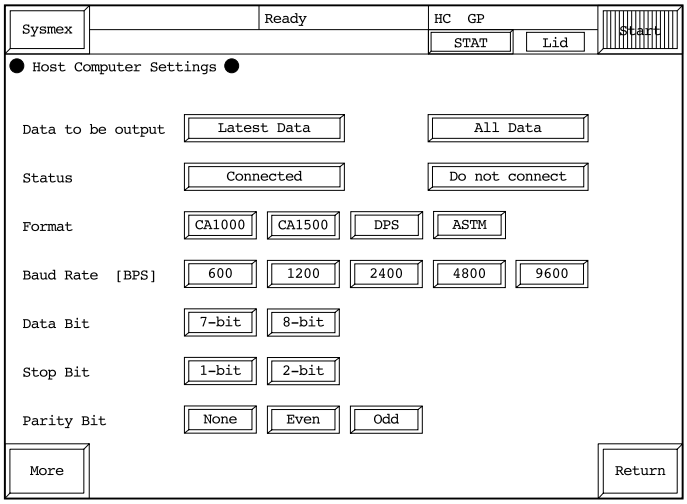


Figure 11-6-2: Host Computer Settings Screen (First Screen)

Second Screen

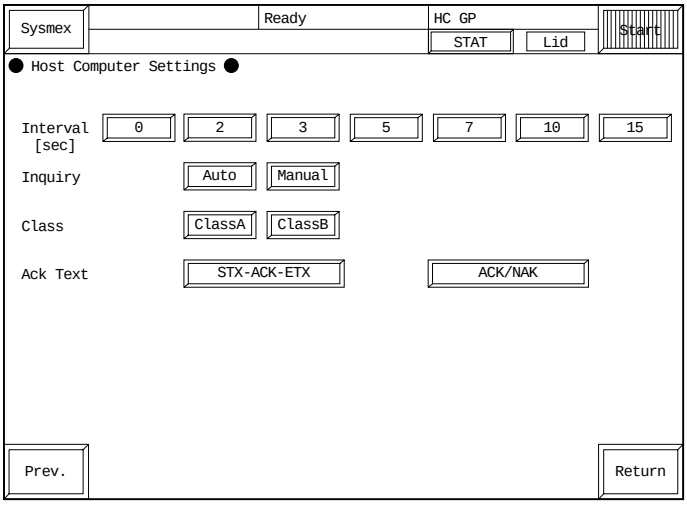


Figure 11-6-3: Host Computer Settings Screen (Second Screen)

Contents Displayed/Set on Host Computer Settings Screen

Setting Parameters	Description	Selections
Data to be Output	Set the analysis data to output automatically when analyzing.	Latest Data/All Data
Status	Decide whether or not to connect to the host computer.	Connected/ Do not Connect
Format	Set the data format to output to the host computer. The CA-1000's output format includes a 13-digit sample ID number and 11-digit patient name. If the CA-1000 format is selected, the first two digits of the ID number and the first four digits of the patient name are omitted.	CA1000/CA1500/ DPS/ ASTM
Baud Rate (BPS)	Set the RS-232C baud rate.	600/1200/2400/4800/ 9600
Data Bit	Set the RS-232C data bit length.	7-bit/8-bit
Stop Bit	Set the RS-232C stop bit length.	1-bit/2-bit
Parity Bit	Set the type of RS-232C parity check.	None/Even/Odd
Interval (sec)	Set the interval time to transmit.	0/2/3/5/7/10/15
Inquiry	Set the method of making inquiry to the host computer regarding analysis orders. Select [Auto] when making inquiry using sample ID numbers read with the barcode reader. Select [Manual] when making inquiry using rack numbers or sample ID numbers that are entered manually.	Auto/Manual
Class	Set the communication protocol.	Class A/Class B
ACK Text	Set the acknowledgment text format. Select STX-ACK-ETX when adding STX or ETX to the acknowledgment text.	STX-ACK-ETX/ ACK/NAK

To set each parameter, press the key that represents the desired selection.

After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue setting up the host computer.
[Set] key: Updates the settings and returns the system to the I/O Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the I/O Settings sub menu.

NOTE:
- To select the ASTM format, use communication procedures in accordance with the standard ASTM E1381-91. For details, contact your service representative.

6.2 Graphic Printer Settings (Option)

This section will explain how to set the printer parameters for the optional graphic printer.

From the I/O Settings sub menu, press the [GP] key. The Printer Settings screen will appear.

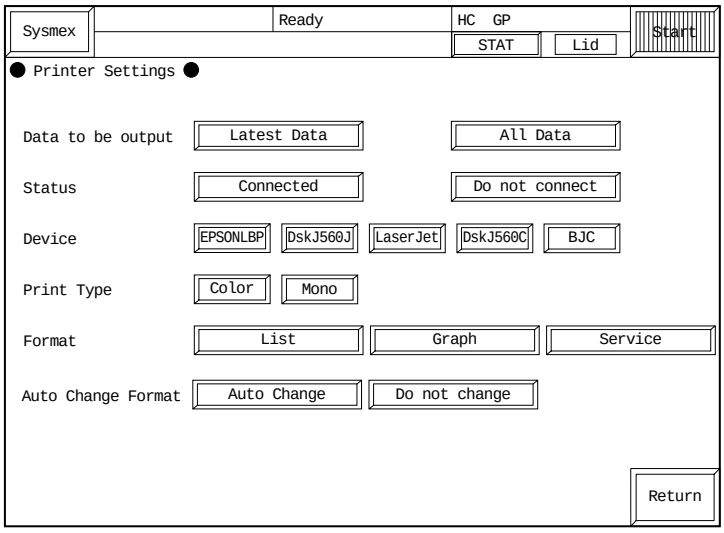


Figure 11-6-4: Graphic Printer Settings Screen

Contents Displayed/Set on Graphic Printer Setting Screen

Parameters	Description	Selections
Data to be Output	Set the data to be printed automatically when analyzing.	Latest Data/All Data
Status	Whether or not to connect graphic printer.	Connected/Do not Connect
Device	Set the printer model.	Epson LBP, DeskJet560J, Laser Jet, DeskJet560C, BJC
Print Type	Set color or black-and-white (mono) printing.	Color/Mono
Format	Set the print format for the stored data. •List: Printing of lists •Graph: Printout of coagulation curves •Service: Graphic printout with analysis data	List/Graph/Service
Auto Change Format	When the format setting is set to "Graph", whether or not to print those results with "No Coagulation" or "Abnormal coagulation" in service format.	Auto Change/ Do not change

To set each parameter, press the key that represents the desired selection.

After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue graphic printer settings.
[Set] key: Updates the settings and returns the system to the I/O Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the I/O Settings sub menu.

6.3 Data Printer Settings (Option)

This section will explain how to set the printer parameters and print format for the optional data (ticket) printer.

From the I/O Settings sub menu, press the [DP] key. The Ticket Printer Settings screen will appear.

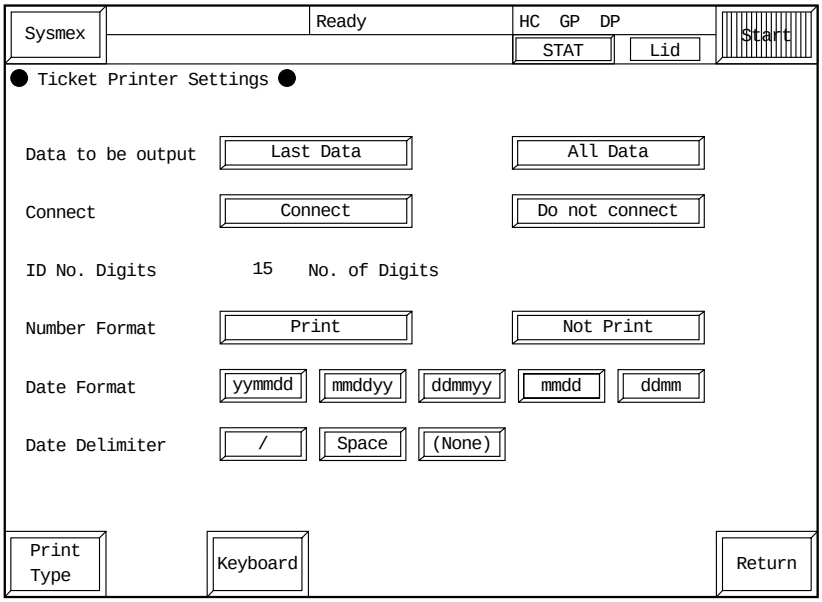


Figure 11-6-5: Ticket Printer Setting Screen

Contents Displayed/Set on Ticket Printer Settings Screen

Parameters	Description	Selections
Data to be Output	Set the analysis data to be printed automatically when analyzing.	Last Data/All Data
Connect	Whether or not to connect to the data printer.	Connect/Do not connect
ID No. Digits	Set the number of digits for the sample ID No.	1 to 15
Number Format	Whether or not to print the decimal point.	Print/Not Print
Date Format	Set the print format for the date.	yymmdd/mmddyy/ddmmyy/ mmdd/ddmm
Date Delimiter	Set the delimiter for the year, month and day.	"/", Space, (None)
Print Type	Set the print format for the data printer. See *Section 6.4: Data Printer Print Type Settings* in this chapter.	-

To set each parameter, press the key that represents the desired selection.

For "ID No. Digits", press the [Keyboard] key to display the numeric keys. Using the numeric keys, enter the No. of digits for the sample ID number.

After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue data printer settings.
[Set] key: Updates the settings and returns the system to the I/O Settings sub menu.
[Quit] key: Cancels the settings and returns the system to the I/O Settings sub menu.

6.4 Data Printer Print Type Settings (Option)

This section will explain how to set the print format on the optional data (ticket) printer.

From the Ticket Printer Settings screen, press the [Print Type] key. The Print Format Settings screen will appear.

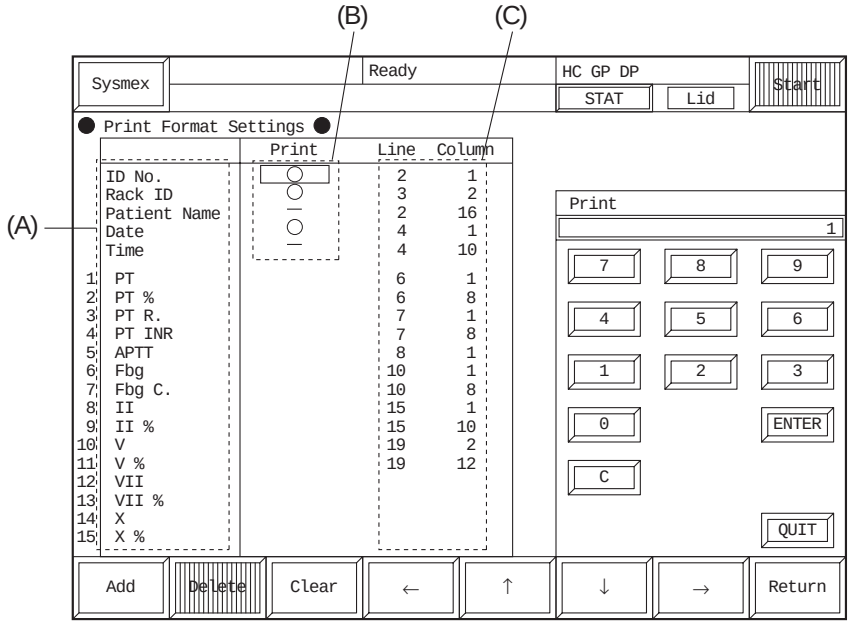


Figure 11-6-6: Print Format Settings Screen

Contents Displayed/Set on Print Format Settings Screen

(A) Printing Parameters: Used to set the parameters to print (analysis parameters and calculation parameters). Up to 40 parameters can be set. To set, press the [Add], [Delete], and [Clear] keys.
The sample ID number, rack number, patient name, date, and time are not set with the predetermined values. To set whether to print or not, see "(B) Print".

(B) Print: Determine whether or not to print the sample ID number, rack number, patient name, date, and time. To print, display "○"; and to not print, display "– ".

(C) Line/Column: Sets the print position for parameters that will be printed.

Operating the Print Format Settings Screen Keys

[Add] key: Used to add additional parameters to print.

(1) Press the [Add] key. The Parameter Selection window will appear.

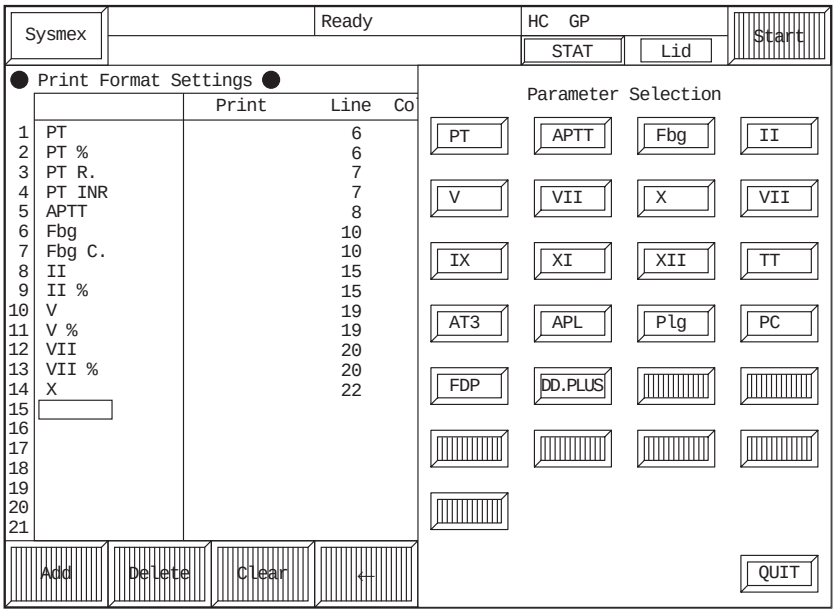


Figure 11-6-7: Parameter Selection Window

(2) Press the key for the parameter that you wish to add.
The parameter selection key that corresponds to the analysis parameter will appear.

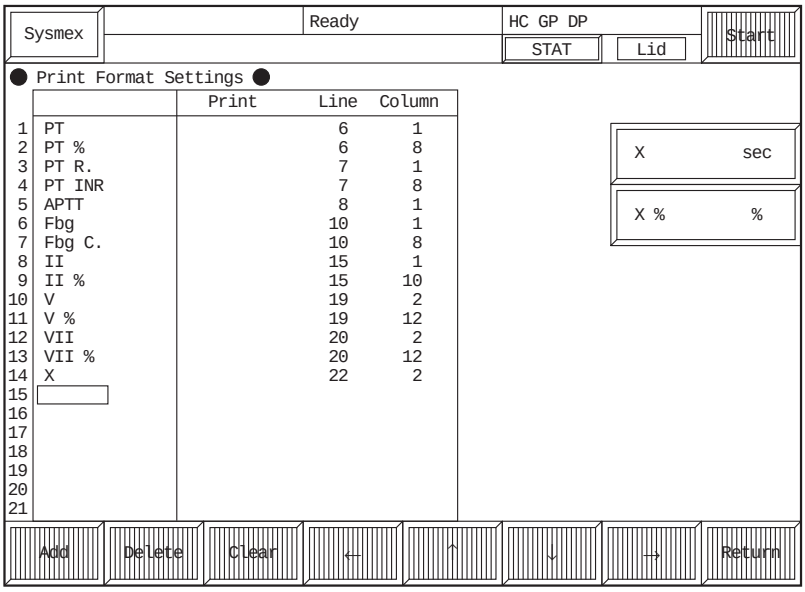


Figure 11-6-8: Parameter Selection Key

(3) Press the key for the parameter that you wish to add.
The selected parameter will be added at the bottom of the print parameter.

[Delete] key: Deletes parameter that you do not need to be printed.

(1) Move the cursor to the parameter that you do not need to print.

(2) Press the [Delete] key. The parameter line at the cursor position will be deleted, and the parameters that follow the cursor position will move up one line each.

[Clear] key: Deletes all parameters that are set. When the [Clear] key is used to delete parameters, the only existing parameters that will remain are the "ID No.", "Rack ID", "Patient Name", "Date" and "Time".

[←], [↑], [↓], and [→] keys: Used to move the cursor in the direction of the arrow.

The numeric keys are used to set the "Print" parameters. If the cursor is moved to a "Print" parameter, the numeric keys will appear. To set "○" (print), enter 1; and to set "– " (do not print), enter 0.

The numeric keys are also used to set the lines and columns. If the cursor is moved to a line or column, the numeric keys will appear. To set, enter the print position.

After the settings are completed, press the [Return] key. The system will return to the Ticket Printer Settings screen.

CAUTION:

- When you can not print correctly even if the print format settings are changed, you need to change the settings of the print start position, line spacing, character spacing, and margin, etc. in the Data Printer. For details, contact your service representative.

6.5 Barcode Settings (Option)

This section will explain how to set the usage conditions for the optional barcode reader.

WARNING • 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.

From the I/O Settings sub menu, press the [ID] key. The Barcode Settings screen will appear.

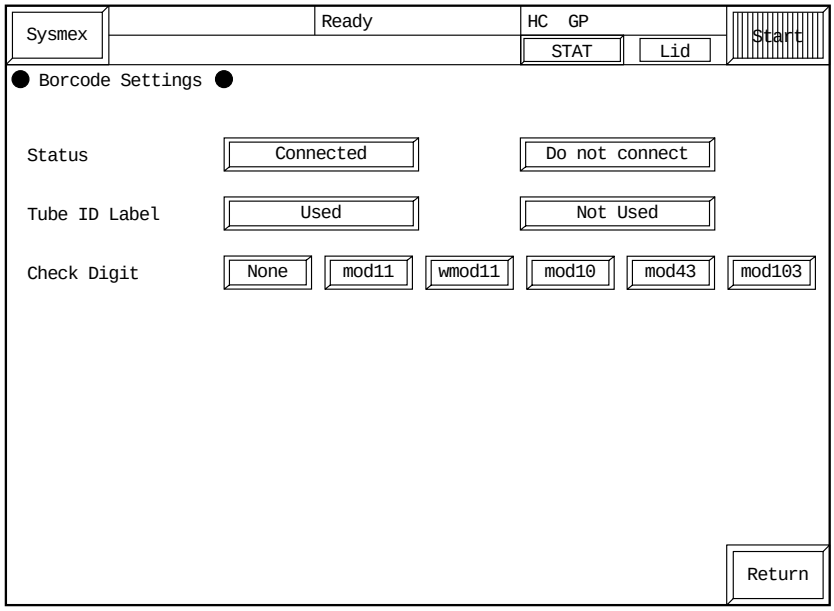


Figure 11-6-9: Barcode Settings Screen

Contents Displayed/Set on Barcode Settings Screen

Setting Parameters	Description	Selections
Status	Whether or not to connect the barcode reader.	Connected/Do not connect
Tube ID Label	Whether or not to use the tube barcode.	Used/Not Used
Check Digit	Set the check digit for the barcode affixed to the tube. •None: No check digit •mod11: Modulus 11 •wmod11: Weighted modulus 11 •mod10: Modulus 10 •mod43: Modulus 43 •mod103: Modulus 103	None/mod11/wmod11/ mod10/mod43/mod103

CAUTION:
- When an optional wand barcode reader is used, barcodes can be read by using the wand barcode reader.
  Only Modulus 10, Modulus 43 and Modulus 103 can be used as the check digit for the barcode on the test tube.

To set each parameter, press the key that represents the desired selection.

After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue the setting of barcode.
[Set] key:	Updates the settings and returns the system to the I/O Settings sub menu.
[Quit] key:	Cancels the settings and returns the system to the I/O Settings sub menu.

7. STORED DATA DISPLAY FORMAT SETTINGS

This section will explain how to preset the parameters for the analysis results that will be displayed on the Stored Data List screen, as well as the order in which they will appear. Up to 40 parameters can be set.

CAUTION:
- If the settings have been changed, the data for the stored data list display will be rearranged for the display settings. It will take a maximum of 30 minutes to process this. Wait for a while, without turning OFF the power.

To set up, use the Set Stored Data Format screen.
From the Settings sub menu, press the [Stored Data] key. The Set Stored Data Format screen will appear.

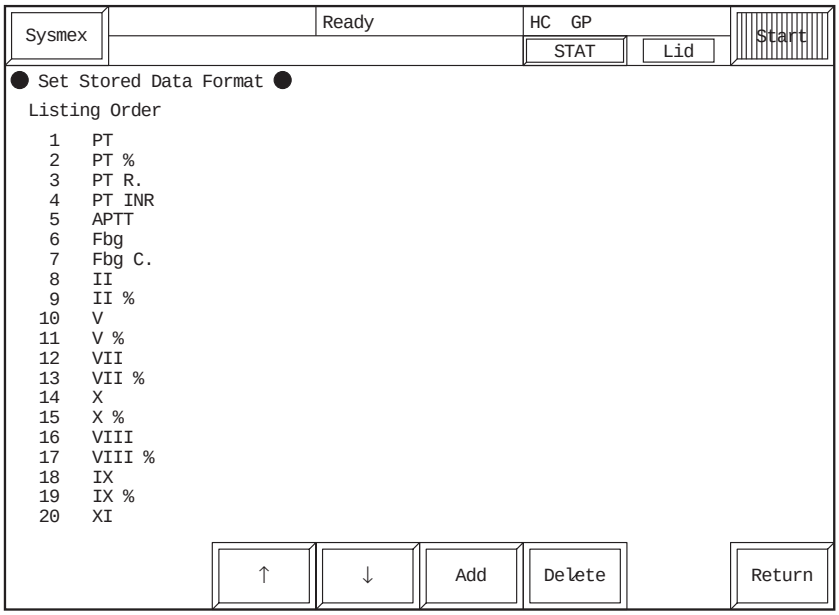


Figure 11-7-1: Set Stored Data Format Screen

Up to 20 parameters will be displayed in a single screen. If 21 or more parameters are set, the screen will scroll down one line if you press the [↓] key when the cursor is at the bottom position of the screen. If you press the [↑] key when the cursor is at the top position of the screen, the screen will scroll up one line.

Operating the Set Stored Data Format Screen Keys

[↑] and [↓] keys: Used to move the cursor.

[Add] key: Used to add additional parameters to display. Can add parameters by inserting them at the cursor position.

(1) Move the cursor to the position where you wish to insert the parameter to be displayed.

(2) Press the [Add] key. The Parameter Selection window will appear.

(3) Press the key for the parameter that you wish to add. The parameter selection key that corresponds to the analysis parameter will appear.

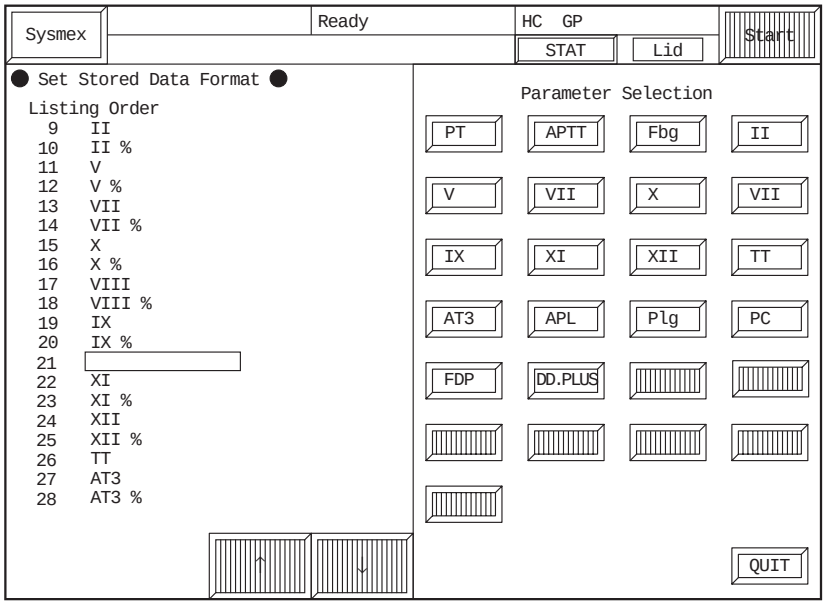


Figure 11-7-2: Parameter Selection Window

(4) Press the key for the parameter that you wish to add. The selected parameter that is at the cursor position will be set, and the parameters that follow the cursor position will move down one line each.

[Delete] key: Deletes parameters that will not be displayed.
(1) Move the cursor to the parameter that you do not wish to display.
(2) Press the [Delete] key. The parameter line at the cursor position will be deleted, and the parameters that follow the cursor position will move up one line each.

After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.
[Continue] key: Used to continue the setting of stored data display format.
[Set] key: Updates the settings and returns the system to the Settings sub menu. The data for the stored data list display will be reconstructed. Reconstruction will require a maximum of 30 minutes of processing time. Wait for a while, without turning OFF the power.
[Quit] key: Cancels the settings and returns the system to the Settings sub menu.

8. SYSTEM SETTINGS

This section will explain how to set parameters that pertain to the overall CA-1500 system.

From the Settings sub menu, press the [General Set Up] key. The General Setup sub menu will appear.

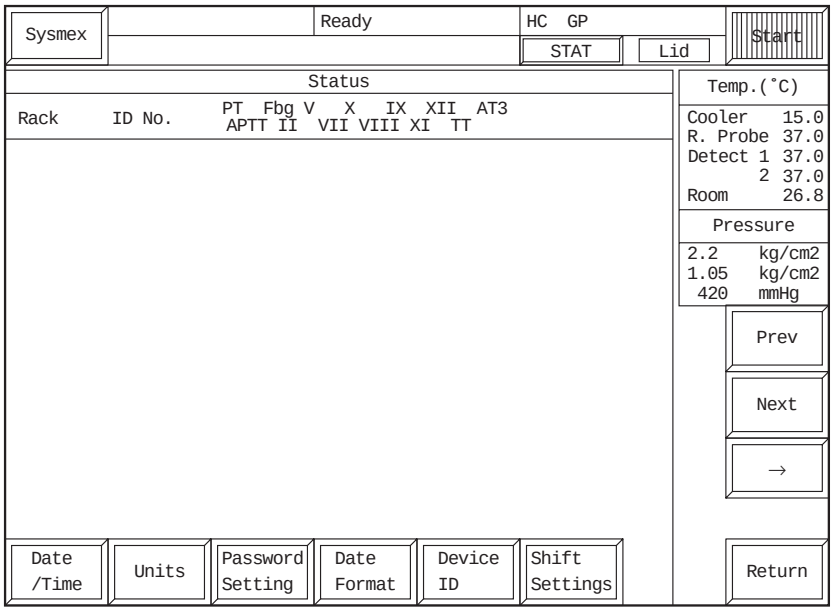


Figure 11-8-1: General Set Up Screen

[Date/Time] key: Used to set the date and time. See *Section 8.1: Date/Time Settings* in this chapter.

[Units] key: Used to set the coagulation time unit format and new units. See *Section 8.2: Unit Settings* in this chapter.

[Password Setting] key: Used to set the password. See *Section 8.3: Password Settings* in this chapter.

[Date Format] key: Used to set the date format. See *Section 8.4: Date Format Settings* in this chapter.

[Device ID] key: Used to set identification number for identifying an analyzer when several analyzers are to be installed. See *Section 8.5: Device ID Settings* in this chapter.

[Shift Settings] key: Used to set the starting times for shifts when shift operation is conducted. See *Section 8.6: Shift Operation Settings* in this chapter.

[Return] key: Used to return to the Settings sub menu.

8.1 Date/Time Settings

This section will explain how to set the date and time.
The CA-1500 has a built-in clock; thus, there is no need to set the date and time each day.

(1) From the General Setup sub menu, press the [Date/Time] key.
The Date/Time Setting screen will appear.

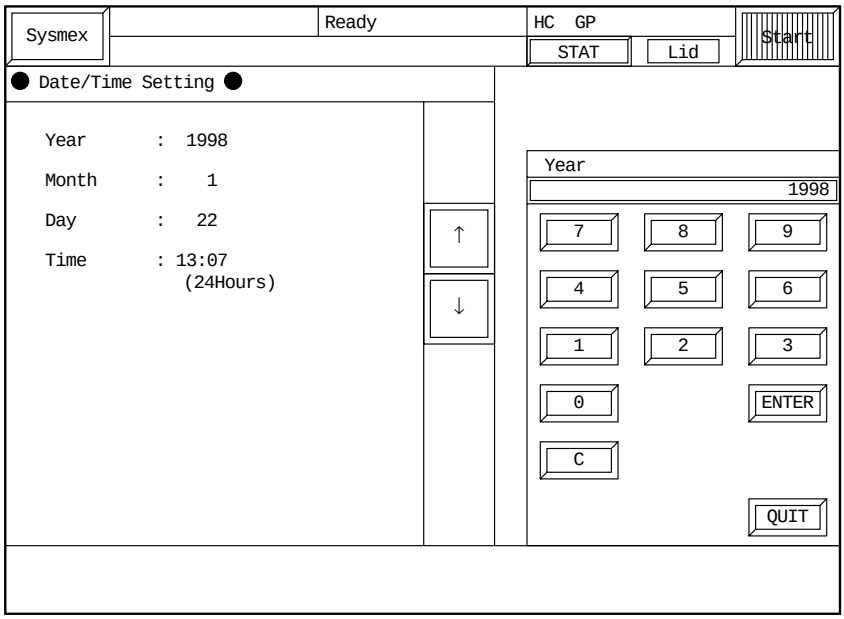


Figure 11-8-2: Date/Time Setting Screen

(2) Set the parameters.
Pressing the [↑] and [↓] keys, move the cursor to the parameter you wish to set. Using the numeric keys, enter the values. Enter the time using a 24-hour clock in the "hr: min" format.

(3) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue setting the date and time.
[Set] key:	Updates the settings and returns the system to the General Setup sub menu.
[Quit] key:	Cancels the settings and returns the system to the General Setup sub menu.

8.2 Unit Settings

This section will explain how to set the coagulation time unit format and also how to register additional new units for new analysis parameters and calculation parameters.

From the General Setup sub menu, press the [Units] key. The Unit Settings screen will appear.

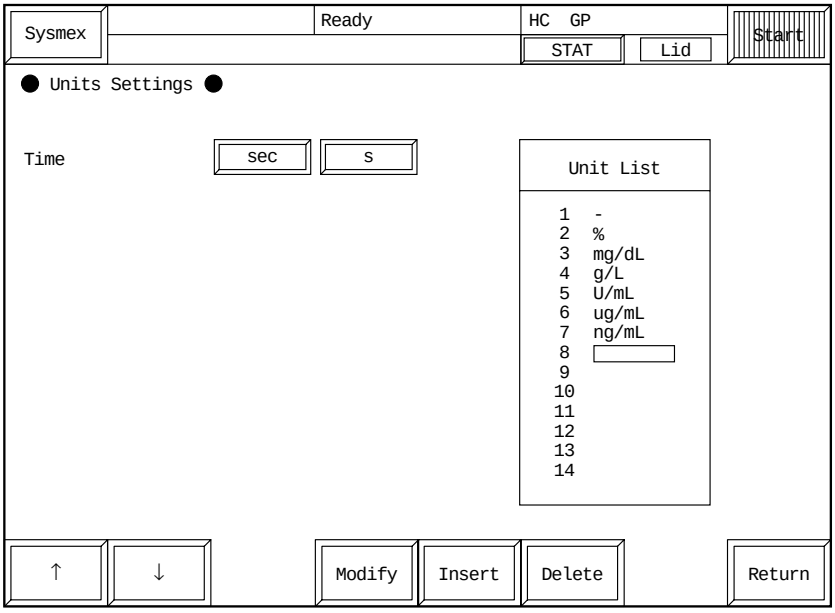


Figure 11-8-3: Unit Settings Screen

Contents Displayed/Set on Unit Settings Screen

Coagulation Time: Set the format to use for the coagulation time units. Set by pressing either [sec] (seconds in CGS system of units) or [s] (seconds in SI system of units) key.

Unit Lists: Set the units to use for the analysis parameters and/or calculation parameters. There are 14 types of units that can be set; however, the units listed in 1 through 7 are predetermined values and thus cannot be modified or deleted.
To modify, register, or delete units, use the [Modify], [Insert], and [Delete] keys.

Operating the Unit Settings Screen Keys

[↑] and [↓] keys:Used to move the cursor to the units listed in 8 through 14 of the Unit Lists.

[Modify] key: Used to register and modify units.

(1) Move the cursor to the unit that you wish to modify. To register an addition, move the cursor to a line where a unit is not set.
(2) Press the [Modify] key. Alphanumeric keys will appear for entering the unit.
(3) Enter the unit that you wish to set; then press the [ENTER] key. It will be set according to the unit entered.

[Insert] key: Shifts each unit downward that appears after the cursor position. Used to newly register a unit at the cursor position.

[Delete] key: Deletes the unit at the cursor position. After deletion, the units that appear after the cursor position shift upward.

After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key: Used to continue the setting of units.
[Set] key: Updates the settings and returns the system to the General Setup sub menu.
[Quit] key: Cancels the settings and returns the system to the General Setup sub menu.

8.3 Password Settings

This section explains how to set passwords.

NOTE:
- Important programs are protected by passwords to ensure that the programs are executed under the management of the person responsible for the instrument. For details on the program protected by a password, see *Chapter 1, Section 13: MENU TREE*. When a program that is protected by a password is to be executed, a Password Input window will appear. If you enter the preset password and press the [Enter] key, the program will be executed.

(1) From the General Setup sub menu, press the [Password Setting] key.
The Password Setting screen will appear. If the password is not registered, the New Password Check screen will appear.

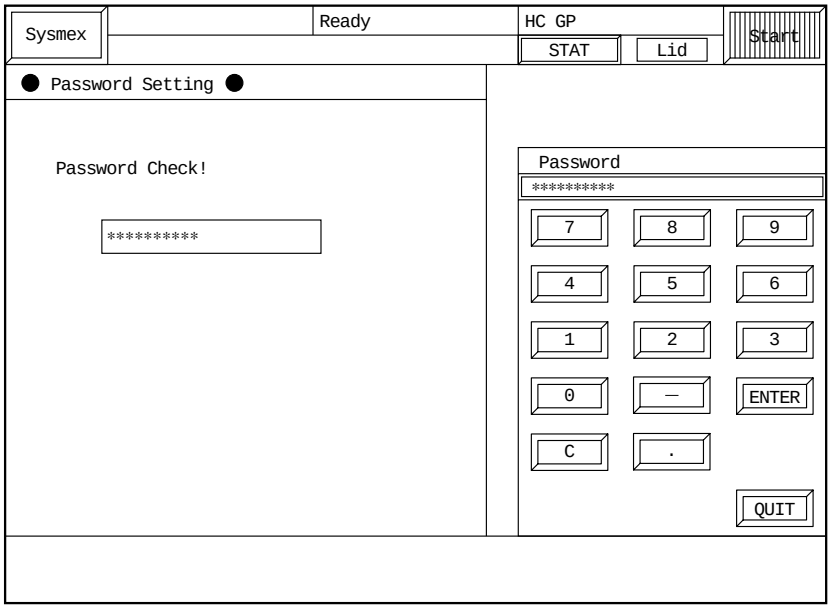


Figure 11-8-4: Password Setting Screen

NOTE:
- The values that appear in the screen's display area for the password and numeric keys will all be masked with "*" symbols. This prevents other people from seeing the password when it is being set.

(2) Using the numeric keys, enter the preset password; then press the [ENTER] key. If the entered password is correct, the New Password Check screen will appear.

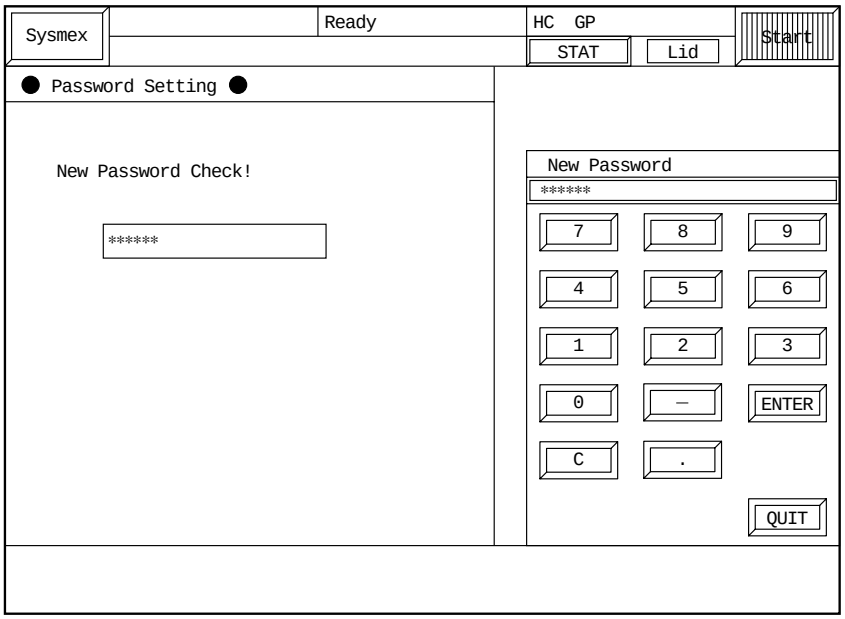


Figure 11-8-5: New Password Check Screen

(3) Using the numeric keys, enter the new password; then press the [ENTER] key. The password must consist of numerals (0 - 9) and can extend up to 12 digits. If you set a new password, a message will appear asking you to reenter the number as a means to confirm that the entry is correct.

NOTE:
- If you do not wish to set a password, you can delete the password by one of the following methods:
  - •Enter 0 only; then press the [ENTER] key.
  - •Press the [c] key to clear; then press the [ENTER] key.

(4) Using the numeric keys, enter the new password again; then press the [ENTER] key. If the entered password is the same as the password you entered previously, an Update Confirmation window will appear. If the entered password is different from the password you entered previously, set the new password again.

(5) From the Update Confirmation window, press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue the setting of passwords.
[Set] key:	Updates the settings and returns the system to the General Setup sub menu.
[Quit] key:	Cancels the settings and returns the system to the General Setup sub menu.

8.4 Date Format Settings

This section will explain how to set the date format. These settings will be effective with regard to the screen display, printer printout, and host computer output.

(1) From the General Setup sub menu, press the [Date Format] key.
The Date Format Setting screen will appear.

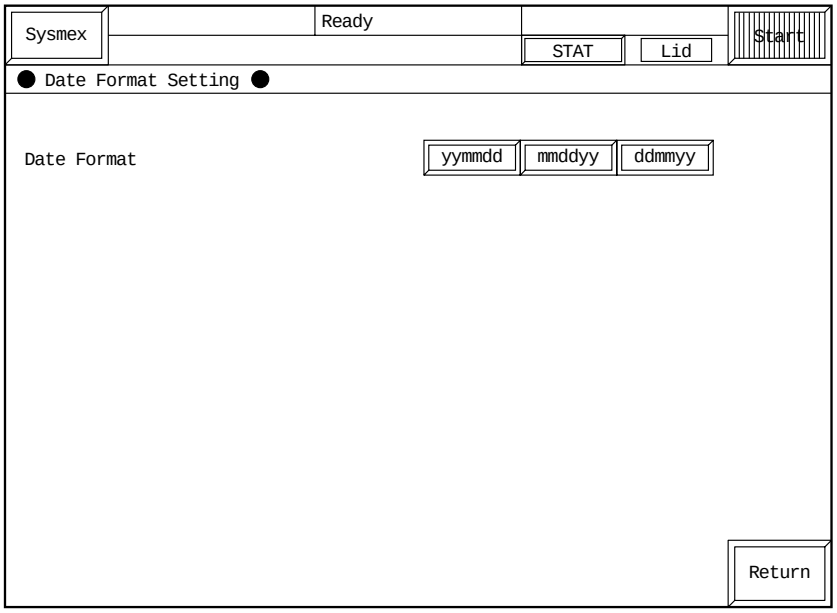


Figure 11-8-6: Date Format Setting Screen

(2) Press the key for the date format that you wish to set.

(3) After the settings are completed, press the [Return] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue the setting of the date format.
[Set] key:	Updates the settings and returns the system to the General Setup sub menu.
[Quit] key:	Cancels the settings and returns the system to the General Setup sub menu.

8.5 Device ID No. Settings

This section will explain how to set the identification number for identifying an analyzer when several analyzers are to be installed.

(1) From the General Setup sub menu, press the [Device ID] key.
The Device ID No. Setting screen will appear.

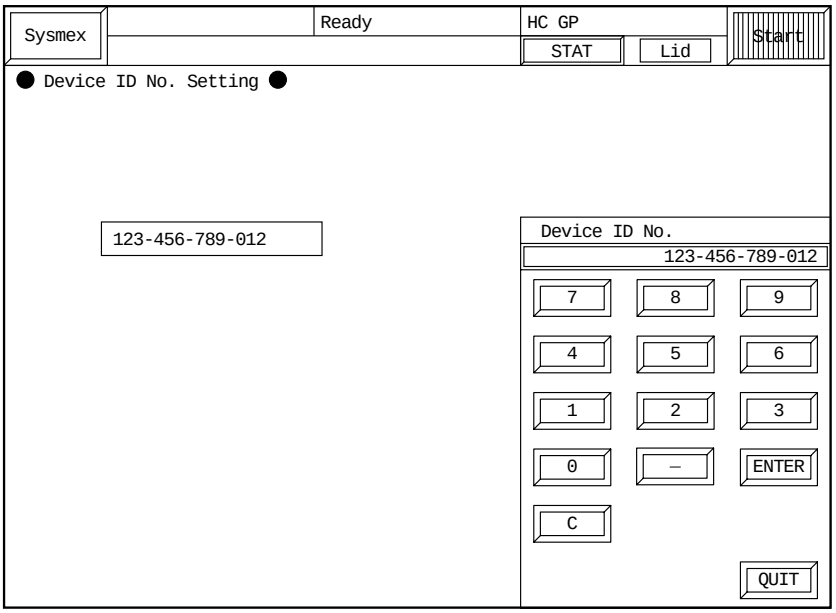


Figure 11-8-7: Device ID No. Setting Screen

(2) Using the numeric keys, enter the identification number that you wish to set; then press the [Enter] key.
The device ID number must consist of numerals (0 - 9) and hyphens (-), and can extend up to 15 digits.

(3) After the settings are completed, press the [Quit] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue setting of the device identification number.
[Set] key:	Updates the settings and returns the system to the General Setup sub menu.
[Quit] key:	Cancels the settings and returns the system to the General Setup sub menu.

8.6 Shift Operation Settings

This section will explain how to set the starting time for each shift when shift operation is conducted. When shift operation is set, the quality control files can be managed for each shift.

(1) From the General Setup sub menu, press the [Shift Settings] key.
The Shift Operation Settings screen will appear.

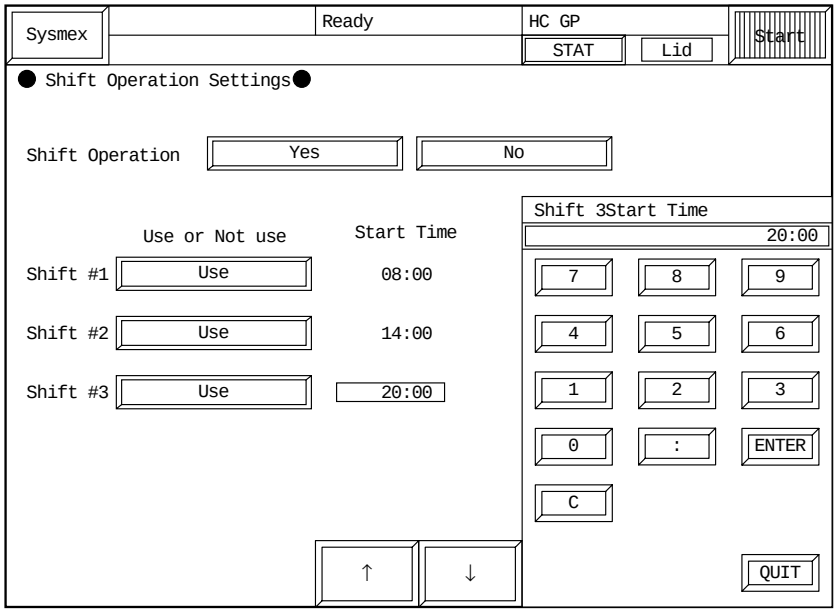


Figure 11-8-8: Shift Operation Settings Screen

(2) Set the "Shift Operation" parameter.
Set by pressing the [Yes] or [No] key. If you select [Yes], then set the "Use or Not Use" and "Start Time" parameters for each shift.

(3) Pressing the "Use or Not Use" keys for each shift, select whether or not to use each shift. If you select "Use", numeric keys for entering the start time will appear. Enter the start time using a 24-hour clock and the "hr: min" format; then press the [ENTER] key. The start time will be set.

(4) After the settings are completed, press the [QUIT] key.
If the settings have been changed, the Update Confirmation window will appear. Press the [Continue], [Set], or [Quit] key.

[Continue] key:	Used to continue setting shift operations.
[Set] key:	Updates the settings and returns the system to the General Setup sub menu.
[Quit] key:	Cancels the settings and returns the system to the General Setup sub menu.

9. OUTPUT OF SETTINGS

Settings can be printed out on the optional graphic printer and saved on a floppy disk. Settings that are saved on a floppy disk can also be loaded into memory. If you press the [Print Set Value] key on the Settings sub menu, the Print Settings screen will appear.

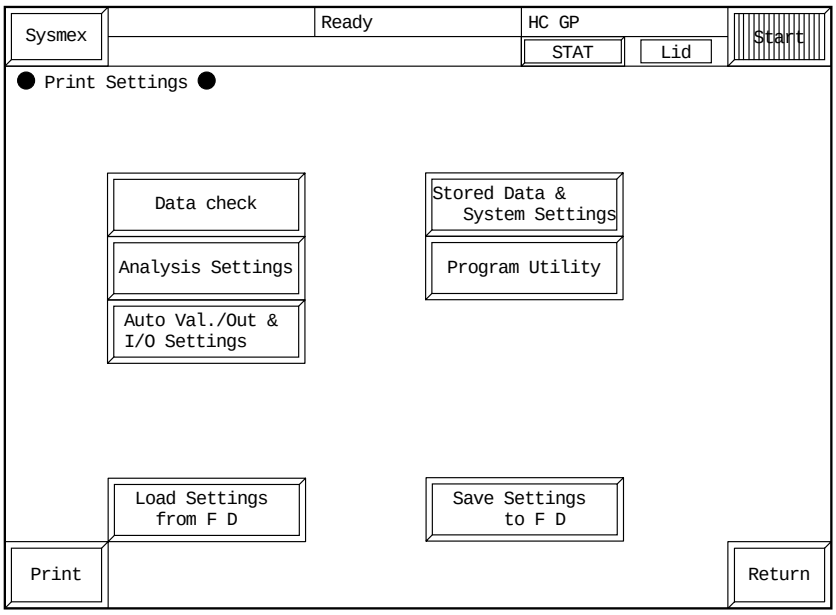


Figure 11-9-1: Print Settings Screen

Operating the Print Settings Screen Keys

[Data Check], [Analysis Settings],
[Auto Val./Out & I/O Settings],
[Stored Data & System Settings],
and [Program Utility] keys: Used to select list printout settings.
[Load Settings from FD] key: Loads the settings from the floppy disk into memory.
[Save Settings to FD] key: Saves the settings on a floppy disk.
[Print] key: Starts the printing of selected settings.
[Return] key: Returns the system to the Settings sub menu.

For details on using the graphic printer, see *Section 9.1: Printing the Settings* in this chapter.
For details on loading from the floppy disk, see *Section 9.2: Loading the Settings* in this chapter.
For details on saving on a floppy disk, see *Section 9.3: Saving the Settings* in this chapter.

9.1 Printing the Settings (Option)

This section will explain how to use the graphic printer to print out the settings.

(1) Press the key for the setting that you wish to print out.

[Data Check] key:	Prints out a list of data check settings.
[Analysis Settings] key:	Prints out a list of analysis settings.
[Auto Val./Out & I/O Settings] key:	Prints out a list of settings that pertain to auto mode and peripheral device .
[Stored Data & System Settings] key:	Prints out a list of stored data and system settings; however, does not print out passwords.
[Program Utility] key:	Prints out the program version.
[Return] key:	Cancels printing and returns the system to the Settings sub menu.

(2) Press the [Print] key.
Printing will start and a message will appear, informing the user that printing is in progress. To stop printing, press the [Print Stop] key.

9.2 Loading the Settings

This section will explain how to load settings that were saved on the floppy disk.

CAUTION: • If you download, all settings will be overwritten.

(1) Press the [Load Settings from FD] key.
The FD Insertion Confirmation window will appear.

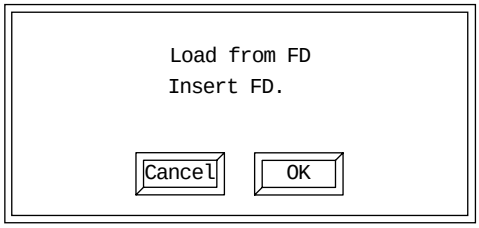


Figure 11-9-2: FD Insertion Confirmation Window

(2) Insert the floppy disk that contains the settings into the floppy disk drive.
To cancel loading, press the [Cancel] key.

(3) Press the [OK] key.
The settings will be loaded from the floppy disk and a message will appear, informing the user that loading is in progress. To stop, press the [Cancel] key. After loading is completed, all of the settings will be replaced by the settings that were loaded.

9.3 Saving the Settings

This section will explain how to save settings on a floppy disk.

(1) Press the [Save Settings to FD] key.
The FD Saving Confirmation window will appear.

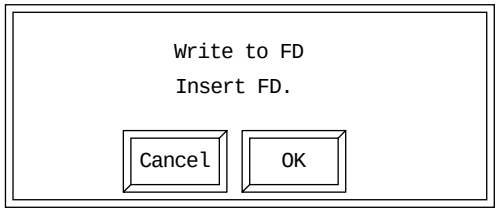


Figure 11-9-3: FD Saving Confirmation Window

(2) Insert a preformatted floppy disk into the floppy disk drive.
To cancel saving, press the [Cancel] key.

(3) Press the [OK] key.
The settings will be saved on the floppy disk, and the system will return to the Print Settings screen. If the room on the inserted floppy disk is insufficient, a message window will appear. If that happens, insert a preformatted empty floppy disk and press the [OK] key.

APPENDIX A INSTALLATION

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1. INTRODUCTION

This product is a clinical analysis instrument. Your service representative is responsible for unpacking, installing, and initial setup to ensure its proper and safe operation. This section will give some essential information on this instrument.

2. CHECK BEFORE INSTALLATION

Make sure that the CA-1500 is free from external flaws and check the quantity of the supply parts.

Unpacking checklist

Part number	Description	Quantity			Remarks
		117V	220V	240V	
923-8092-8	Power Cord No. 15 (C-2/N. America)	1	0	0	
265-4731-5	Power Cord 4622-007-0092(Europe)	0	1	0	
265-4733-2	Power Cord No. 7687	0	0	1	
266-5014-4	Fuse 250V 10A CES14-10A-N1 (N.AMERICA)	2	0	0	Main Unit
266-5296-1	Fuse 250V 5A No. 19195 (Europe)	0	2	2	Main Unit
913-2953-4	Float Switch No. 14 Assy (C3/CA-6K)	1	0	0	For 20 L rinse cubitainer
963-2001-9	Float Switch No. 19 Assembly	1	0	0	For M20 waste container
953-1082-1	Float Switch Assy No. 17 (C2/CA-6K)	0	1	1	For M20 rinse container
369-7993-1	Indication Mark No. 678	0	1	1	Paste on M20 container
424-2400-4	M20 Container (20 L)	1	0	0	Waste Tank
424-2400-4	M20 Container (20 L)	0	1	1	Rinse Tank
973-5291-1	FLP 1C152 Assy	1	1	1	
983-8851-1	FLP 2C152 Assy	1	1	1	Protocol FD
363-2562-1	Holder No. 93	4	4	4	Siemens GW5 reagent adapter
363-2566-6	Holder No. 97	4	4	4	Sample cup adapter, 30 mm OD
363-2567-0	Holder No. 98	5	5	5	Sample cup adapter, 23 mm OD
363-2568-3	Holder No. 99	3	3	3	Rinse/Buffer vial adapter
363-2579-4	Holder No. 110	1	1	1	CA Cal S container adapter
369-5999-5	Indication Mark No. 969	1	1	1	Reagent Name Label, for Reagent Trays
BB696646	JCR6V10W20H-SY	1	1	1	
461-2045-0	Operator's Manual CA-1500	0	1	1	
461-2662-6	Operator's Manual CA-1500 (American Edition)	1	0	0	
541-1352-1	Push Vial PV-10	2	2	2	22 mm OD x 40 mm high
854-0031-1	Reaction Tube Assy (500/box)	1	1	1	
367-1850-9	Reagent Tray No. 1	1	1	1	(Larger one)
367-1851-2	Reagent Tray No. 2	1	1	1	(Smaller one)
424-1160-8	Sample Cup Conical 4 mL	20	20	20	
984-0011-7	Sample Plate No. 402 Assy (5 pcs/pack)	1	1	1	
541-1456-1	Polyethylene bottle 50 mL	1	1	1	
367-2191-7	Trash Box CA-15H (SMALL)	1	1	1	

Table A-2-1: CA-1500 Unpacking Check List (1)

Part number	Description	Quantity			Remarks
		117V	220V	240V	
363-1933-1	Tube Holder No. 3	5	5	5	13 mm OD test tube, for Stat holder
442-5338-7	Tube Polyurethane 4 mmID x 6 mmOD	20 M	20 M	20 M	
963-0801-5	Wiring Cord No. 2188	0	1	1	(Ref. Section 9.2)
462-2387-0	Screwdriver philips A6002	1	1	1	For CA-1500+CP or CA-1500+BR/CP

Table A-2-1: CA-1500 Unpacking Check List (2)

Part number	Description	Quantity	Usage
833-3313-3	Sample Rack (6/Pack)	1	
321-3067-0	Sampler Mounting Metal No. 12	2	
348-3812-1	Screw Binding M3x6 (SUS)	4	
348-1927-4	Screw Binding M4x6 (FE)	2	

Table A-2-2: OPSU-6 Unpacking Check List

NOTE:

- Ordering of Supplies and Replacement Parts
  If you need to order supplies or replacement parts, please contact your local representative.
- Service and Maintenance
  Please contact the Service Department of your local representative.
- Training courses
  For further information please contact the representative in your country.

3. INSTALLATION SPACE

To ensure that the instrument performs to its full extent, it should be installed in an appropriate place.

- Select a place that is close to the power supply and suitable drain.
- Select a level and steady surface to avoid functional errors.
- Allow space for maintenance and service. Giving consideration to heat radiation by the instrument, keep at least 50 cm clearance between the wall and the instrument's side, rear, and top panels.

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

If optional data printer and/or graphic printer is provided, additional desktop space is required. (Required desktop space varies depending on the printer models selected.)

	Width (mm)	Depth (mm)	Height (mm)	Weight (kg)
Main Unit	780	500	500	75
Sampler	580	280	270	9.5

When a cap piercer unit is installed, the instrument weight is 78 kg.

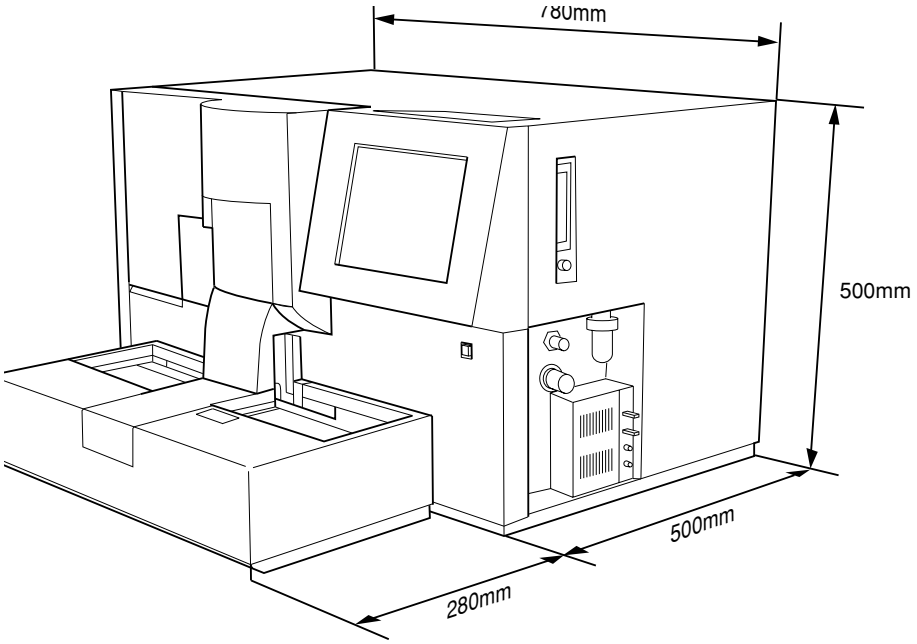

Figure A-3-1: Instrument Dimensions

4. REMOVING SHIPPING CLAMPS

(1) Gently peel off the fixing tapes on the outer cover.

(2) Loosen three fixing screws, and pull forward to you to remove the top plate.

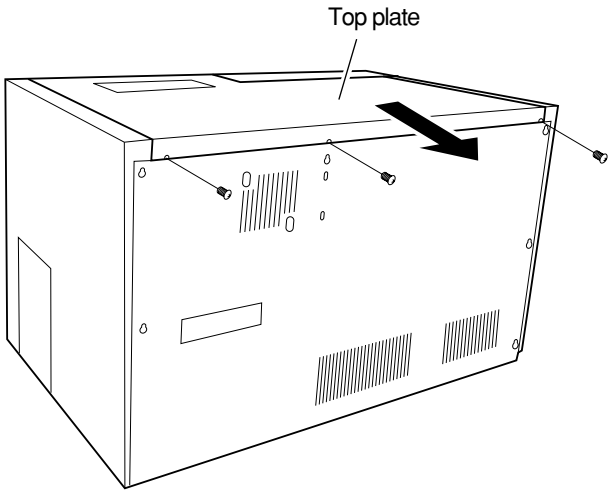

Figure A-4-1: Removing the Top Plate

(3) Remove two fixing plates which fix the reagent probe to the left side in the instrument. Remove the three screws and remove fixing plate (A). Move the reagent syringe forward, remove the four screws (① - ④), loosen the two screws (⑤ and ⑥), and remove fixing plate (B). Screws to be removed (② - ④) are blue. Do not remove screws which aren't blue.

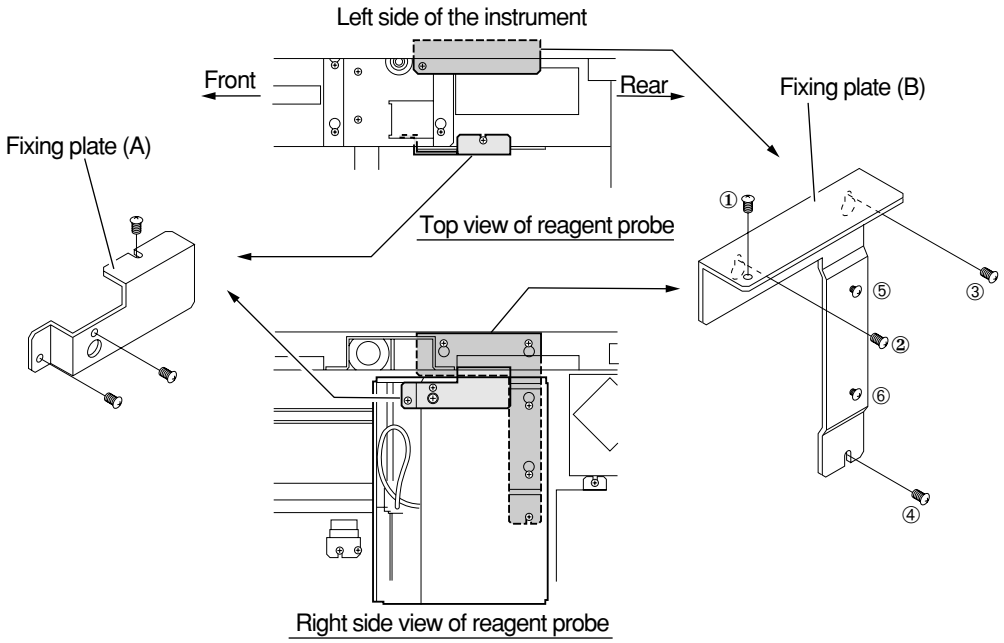

Figure A-4-2: Removing Fixing Plates (A) & (B)

(4) Remove two fixing plates which fix the sample probe at the center in the instrument. Remove fixing plate (C), move the sample probe forward, and remove fixing plate (D).

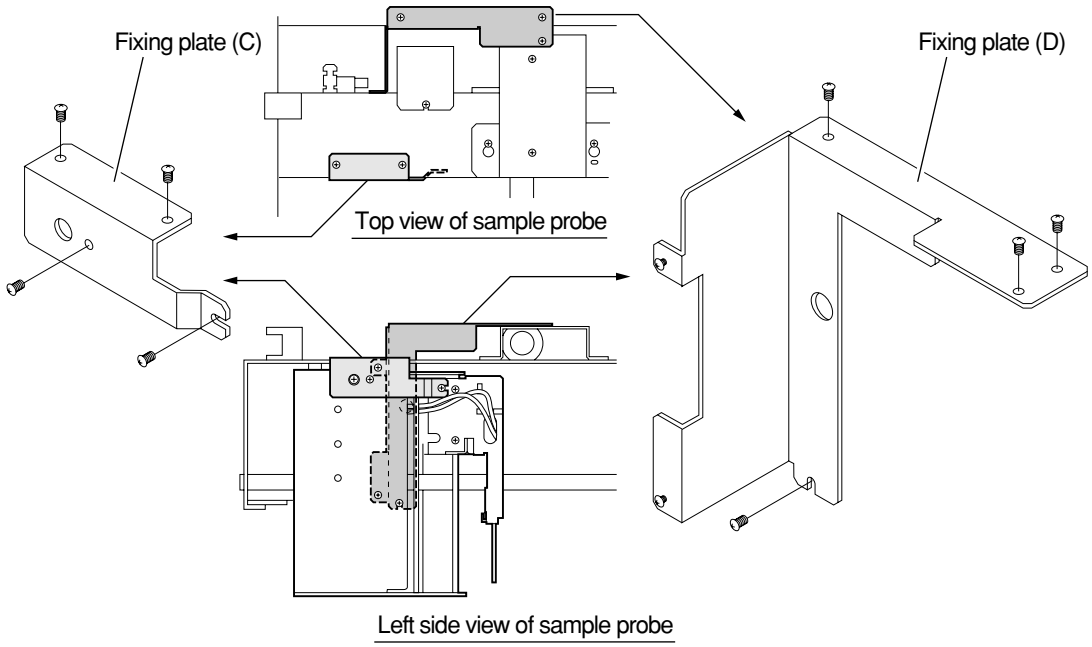

Figure A-4-3: Removing Fixing Plates (C) & (D)

(5) Remove the fixing plate which fixes the catcher at the left back in the instrument. Fixing plate (E) is located at the left-bottom.

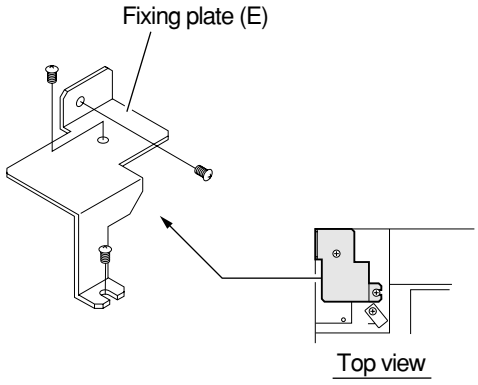

Figure A-4-4: Removing Fixing Plate (E)

(6) Loosen two screws and remove the right side panel.

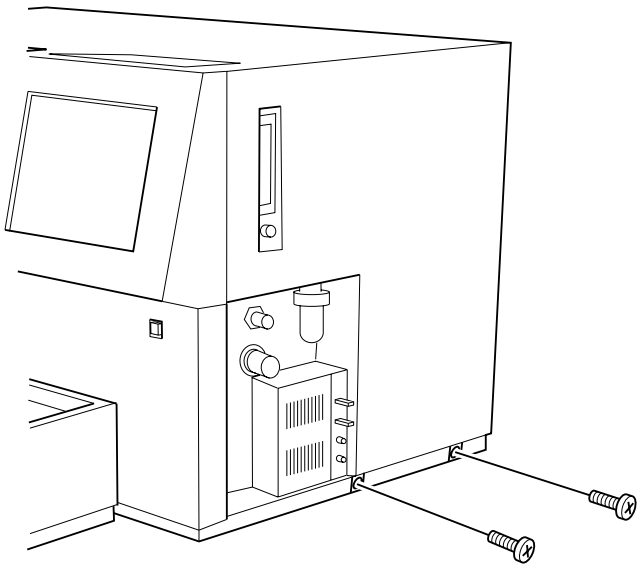

Figure A-4-5: Removing the Right Side Panel

(7) Loosen six screws and two spacers that fix the compressor unit in place.

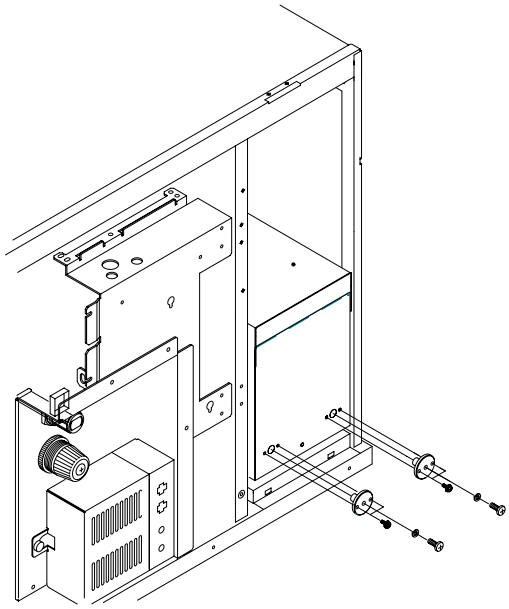

Figure A-4-6: Removing the Compressor Fixing Screws and Spacers

5. CONNECTING THE SAMPLER

Attach the sampler unit to the main unit.

(1) Insert two sampler mounting metals to the main unit front, and tighten each mounting with two M3x6 screws.

(2) Insert the sampler slightly so that the sampler mounting metals come into the guide holes on the rear of the sampler unit. Maintain a clearance between the main unit and the sampler.

(3) Connect the sampler connector to the cable connector of the main unit.

(4) Place the connector into the main unit, and push the sampler into the main unit.

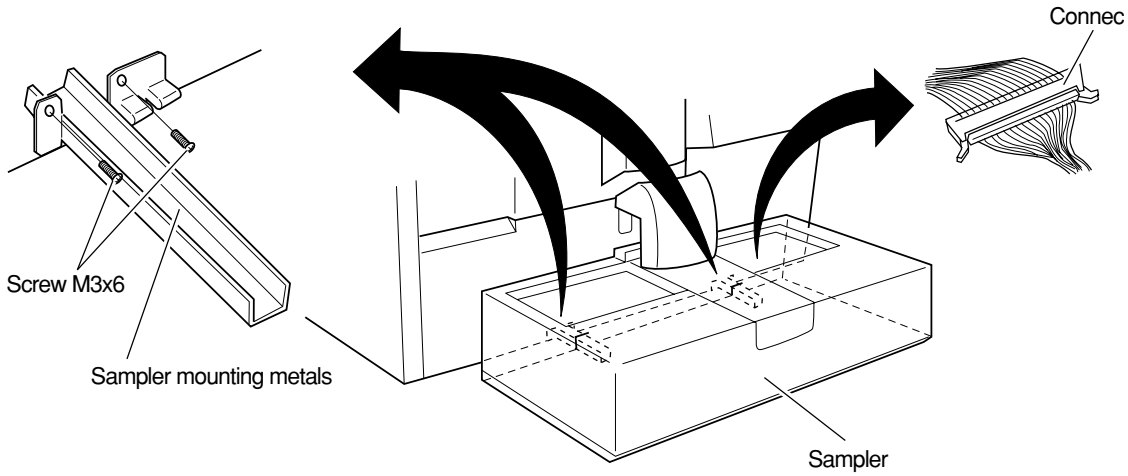

Figure A-5-1: Connecting the Sampler

(5) Secure the attachment of the sampler unit to the main unit chassis with the two screws M4x6 as provided.

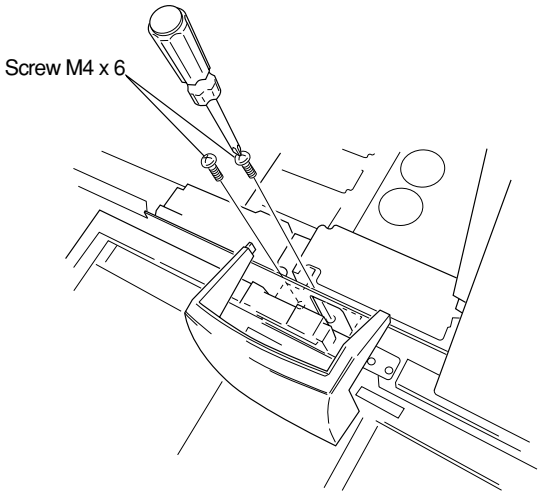

Figure A-5-2: Securing the Sampler

6. INSTALLING BARCODE READER (OPTION)

Your service representative will install, setup and adjust the ID Barcode Reader, if it is provided.

7. SETTING THE REACTION TUBE TRASH BOX

Insert the reaction tube trash box provided.

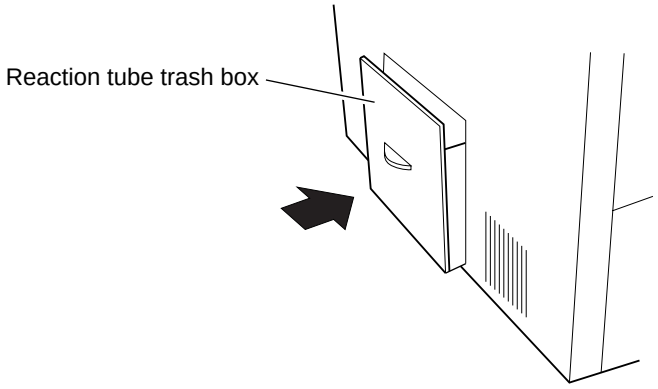

Figure A-7-1: Setting the Trash Box

8. SETTING THE REAGENT TRAYS

Insert the reagent trays provided.

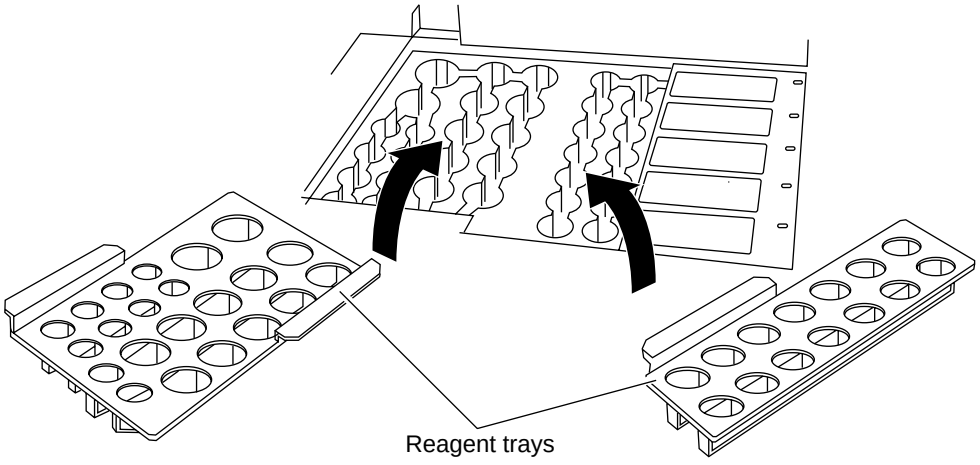

Figure A-8-1: Setting the Reagent Trays

Affix the indication mark No. 969 on the reagent tray to indicate the reagent name. The position of reagents should be determined by the customer. The reagent name labels may be affixed at a later time by referring to Chapter 2, Section 4.2 and etceteras.

9. CONNECTING THE RINSE TANK AND WASTE TANK

Connect the rinse tank, the waste tubing, and an optional waste tank. The rinse tank is used to hold rinse solution for cleaning the hydraulic system. The waste tubing is used to lead the waste fluid to the sewer system. If a sewer system is not available, an optional waste tank is required to temporarily accumulate the waste fluid which is discarded after analysis.

9.1 Connecting the Rinse Tank

(1) Connect the rinse aspiration nipple to the rinse tank nipple with the polyurethane tube provided.

(2) Connect the float switch cable to the float switch connector (RINSE).

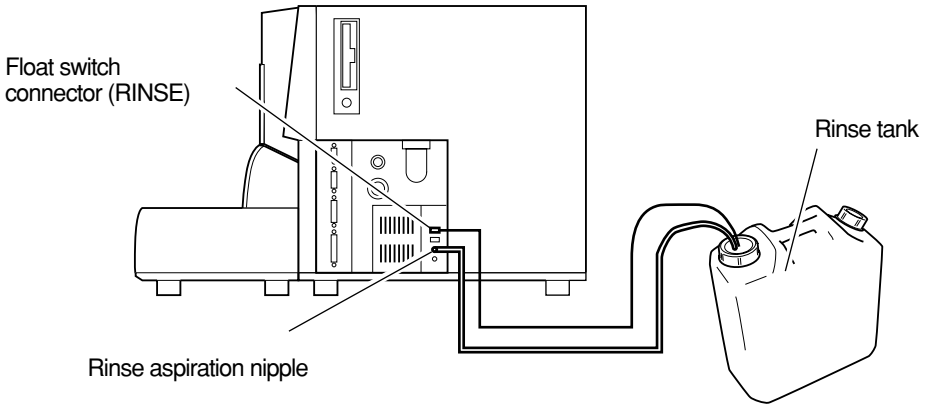

Figure A-9-1: Connecting the Rinse Tank

9.2 Connecting the Waste Tubing

(1) Connect the waste outlet nipple to the waste sewer system with a polyurethane tube provided.

(2) If an optional waste tank is not used, connect the provided Wiring Cord No. 2188 to properly configure the Alarm Settings. Refer to *Chapter 11, Section 5.11 Alarm Settings* for details.

9.3 Connecting the Waste Tank (Option)

If a waste sewer system is not available, prepare an optional waste tank.

(1) Connect the waste outlet nipple to the waste tank with the polyurethane tube provided.

(2) Connect the float switch cable to the float switch connector (WASTE).
In this case, Wiring Cord No. 2188 is not used.

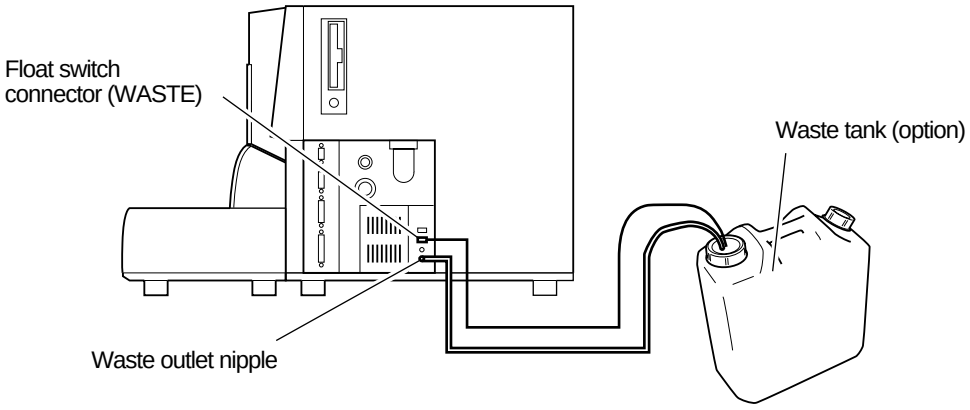

Figure A-9-2: Connecting the Waste Tank (Option)

10. CONNECTING THE POWER CORD AND CONNECTION CORD

Connect the power cord provided. When the output to the optional printers and host computer is desired, connect the instrument to each device with the connection cord and carry out the setup.

10.1 Connecting the Power Cord

(1) Make sure the power switch is OFF. The power is OFF when the power switch "O" is pressed.

CAUTION• Confirm the power switch is OFF ("O" is pressed), before connecting the power cord. Otherwise, there is a risk of electrical shock.

(2) Connect the power cord to the power connector under the power switch on the left side.

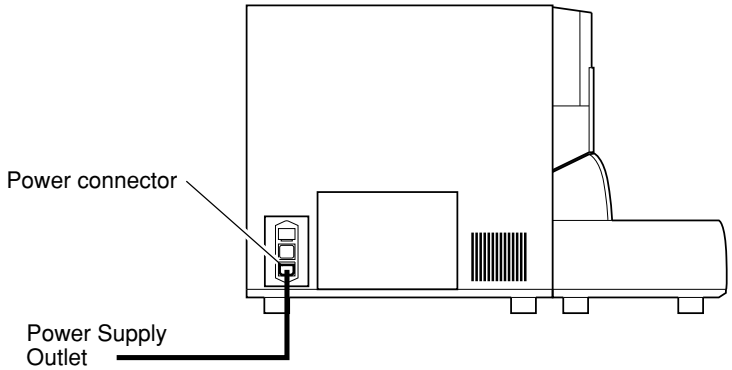

Figure A-10-1: Connecting the Power Cord

(3) Insert the provided power cord into a power supply outlet.

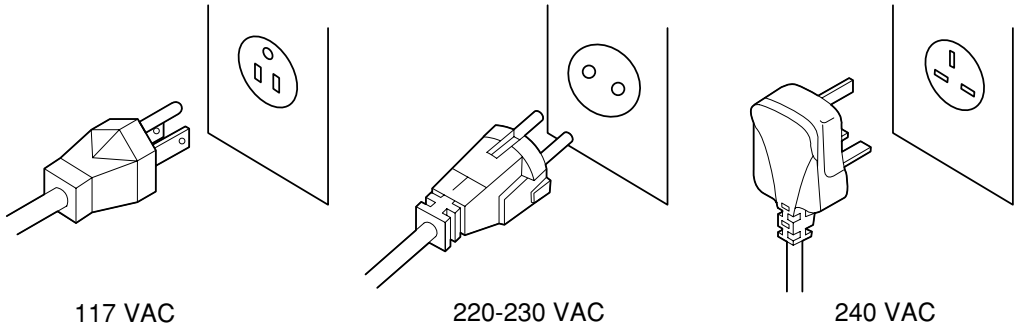

Figure A-10-2: Connecting with Power Supply Outlet

CAUTION• Do not, for any reason, bypass the ground connection. Otherwise, there is a risk of electrical shock.

10.2 Connecting the Connection Cord

CAUTION· Confirm the power switch is OFF ("O" is pressed), before routing the connection cord. Otherwise, the unit may be damaged.

(1) Make sure the power switch is OFF. The power is OFF when the power switch "O" is pressed.

(2) Connect with each device using connection cords.

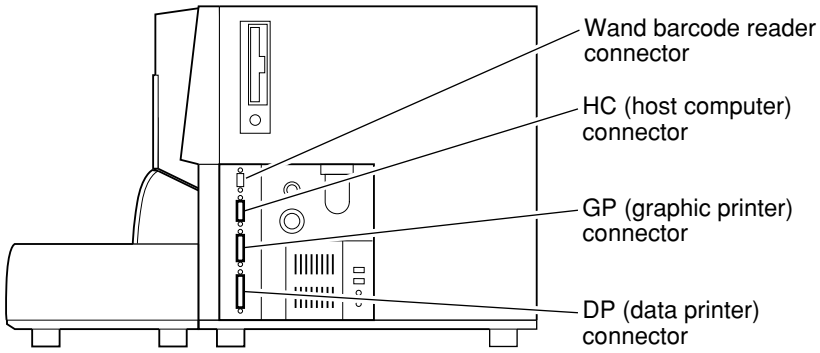

Figure A-10-3: Connectors

(3) Perform the necessary settings for the connected devices.
Refer to *Chapter 11, Section 6: I/O Settings*.

11. PRIMING WITH RINSE SOLUTION AND ADJUSTMENTS

If there is not sufficient rinse solution inside the hydraulic line of the CA-1500, correct results will not be obtained. Prime the rinse solution inside the hydraulic line, as follows.

(1) Replenish the rinse tank with rinse solution (distilled water).
Refer to *Chapter 6, 6.4: Replenishing Rinse Solution*.

(2) Turn the power switch ON.
The power is ON when the power switch "|" is pressed. After the power switch is turned ON, the instrument carries out the self-check, and loads the program. Then, the Main Menu screen appears.

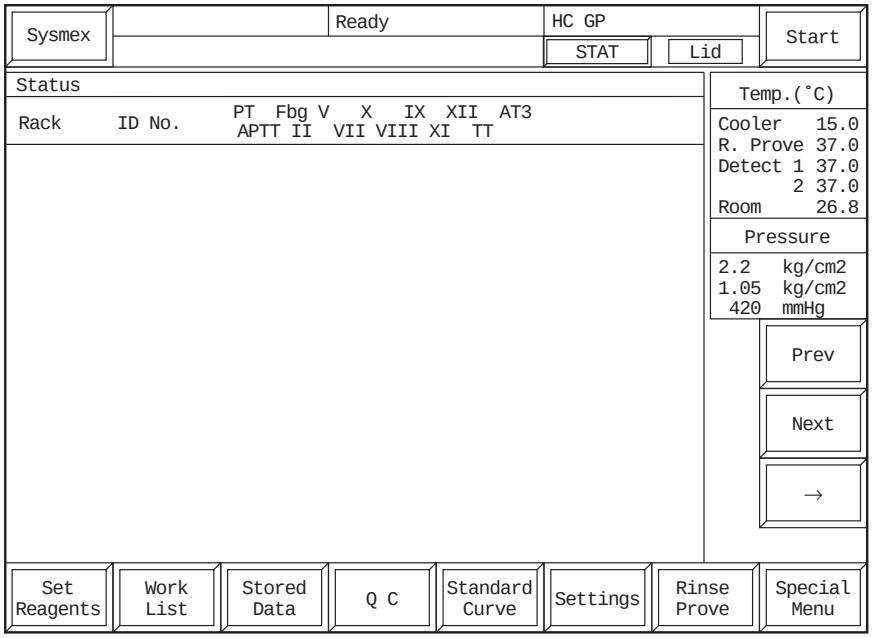

Figure A-11-1: Main Menu Screen

(3) Adjust the LCD brightness.
Turn the brightness control knob on the right side of the main unit to adjust the LCD brightness.

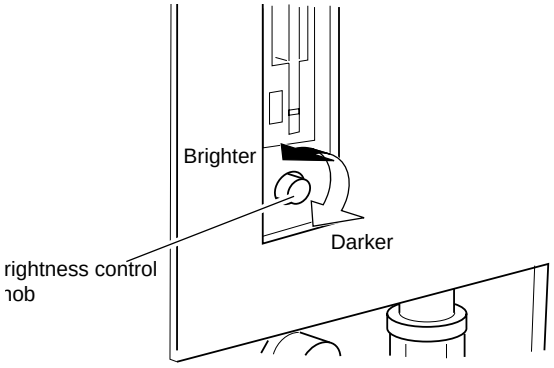

Figure A-11-2: Adjusting the LCD Brightness

(4) Press [Special Menu] key on the Main Menu screen. The special menu will appear.

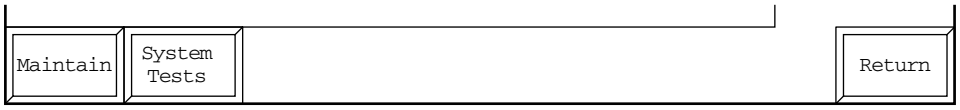

Figure A-11-3: Special Menu

(5) Press [Maintain] key. The maintenance sub menu will appear.

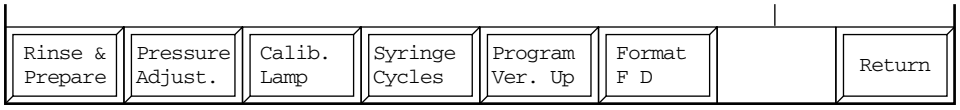

Figure A-11-4: Maintenance Sub menu

(6) Press [Rinse & Prepare] key.
The Prime & Deprime Rinse screen will appear.

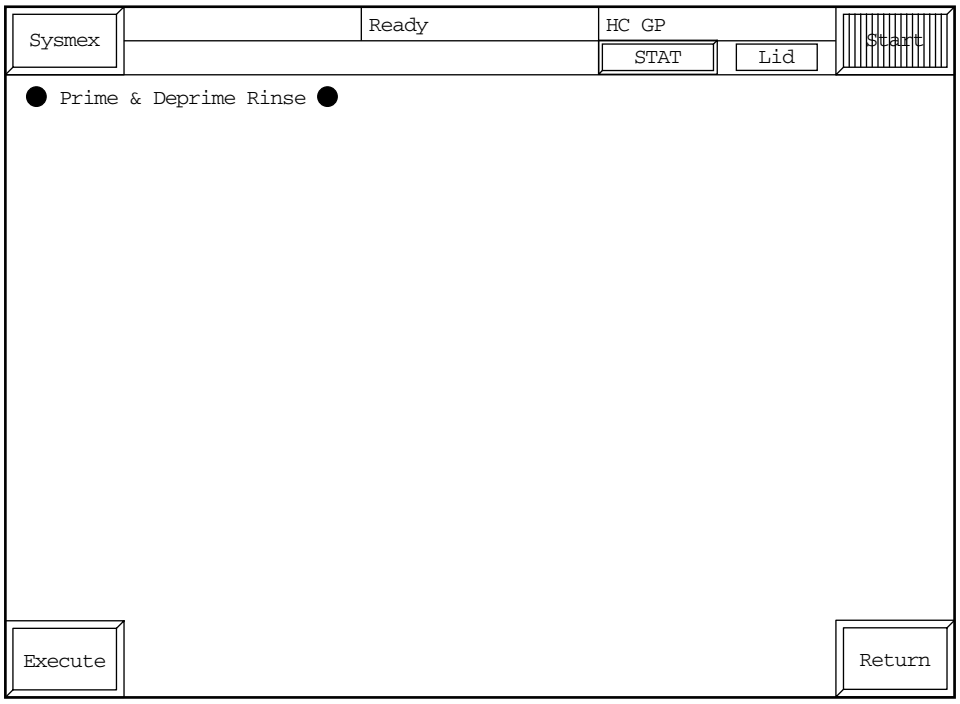

Figure A-11-5: Prime & Deprime Rinse Screen

(7) Press [Execute] key.
The priming with rinse solution will start. The remaining time is displayed on the screen during the priming.

(8) Adjust the LCD panel angle.
Loosen 2 screws on the right side panel.
Then, slightly lift up the right side panel and remove it.

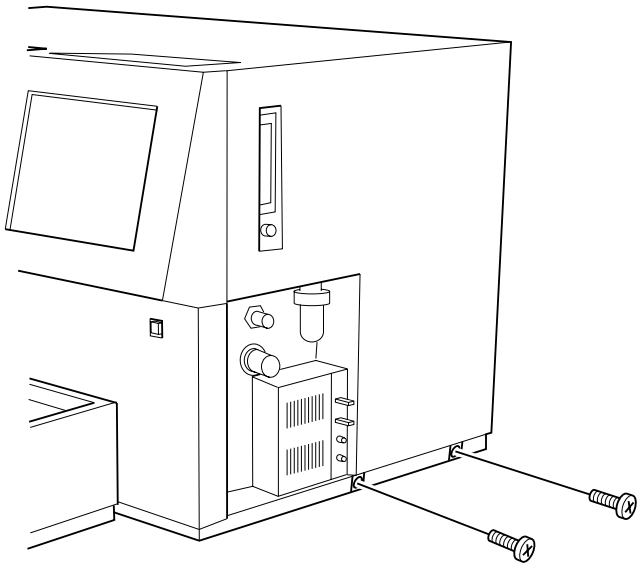

Figure A-11-6: Removing the Right Side Panel

Insert a screwdriver into the hole located next to the front side of the LCD brightness control knob, and loosen the screw by turning counterclockwise.
Pull up the lower edge of the LCD panel to find a best position for the operator to view the screen.

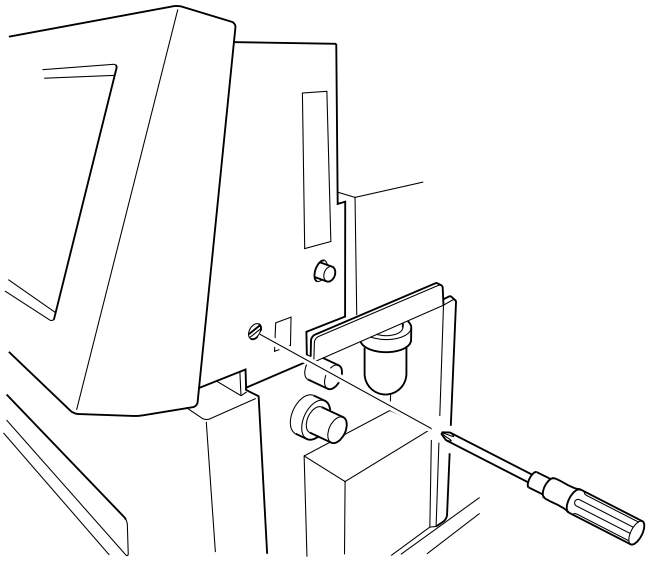

Figure A-11-7: Adjusting the LCD Panel Angle

(9) Set the date and time. Refer to Chapter 11, Section 8.1 for the procedure.

APPENDIX B TECHNICAL INFORMATION

1. OUTPUT FORMAT FOR HOST COMPUTER (OPTION) B-1
   - 1.1 Hardware B-1
   - 1.2 Software B-3
   - 1.3 Text Format B-5
   - 1.3.1 Analysis Data Text Format B-6
   - 1.3.2 Order Inquiry Text Format B-9
   - 1.3.3 Order Information Text Format B-12

2. ID BARCODE SPECIFICATIONS B-15
   - 2.1 Acceptable Barcode B-15
   - 2.2 Dimension of Barcode Elements B-16
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   - 2.4 PCS (Print Contrast Signal) B-16
   - 2.5 Reflection Characteristics of Label Surface B-16
   - 2.6 Irregularity and Roughness of Printing B-17
   - 2.7 Dimensions of Barcode Label B-17
   - 2.8 Check Digit B-18

1. OUTPUT FORMAT FOR HOST COMPUTER (OPTION)

The bit serial voltage type, which conforms to the RS-232C interface, is used for host computer communication. The serial interface port for the connection with the host computer is on the right panel of the main unit.

1.1 Hardware

1. Connector

- The connector to the host computer is located on the right panel of the main unit.
- Use a 9-pin D-SUB, female connector.
- Fixing screws for this connector are in inch-specification.

2. Connector Signals

Pin No.	Signal name	Signal direction
1		
2	Receive Data (RxD)	from Host to CA-1500
3	Transmit Data (TxD)	to Host from CA-1500
4	Data Terminal Ready (DTR)	to Host from CA-1500
5	Signal Ground (SG)	
6	Data Set Ready (DSR)	from Host to CA-1500
7	Request to Send (RTS)	to Host from CA-1500
8	Clear to Send (CTS)	from Host to CA-1500
9		

Table B-1-1: Pin Assignment

3. Communication Format

The data is communicated in the asynchronous, half duplex mode. (Asterisk mark * indicates the setting at the time of shipment from the factory.)

Baud rate: 600, 1200, 2400, 4800, *9600 (BPS)
Code: 7 bit, *8 bit
Stop bit: 1 bit, *2 bit
Parity: *None, Even, Odd
Interval: 0, *2, 3, 5, 7, 10, 15 (seconds)

4. Signal Level

Signal level conforms to JIS C6361.

Level	Data signal	Control signal
+3V or higher	Logic "0", Start bit	ON
-3V or lower	Logic "1" ,Stop bit	OFF

Table B-1-2: Signal Level

5. Interface Circuit

- Output circuit

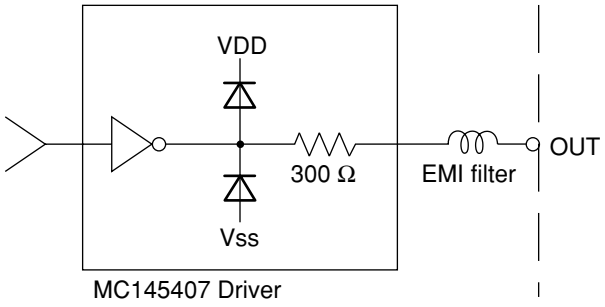


Figure B-1-1: Interface Output Circuit

- Input circuit

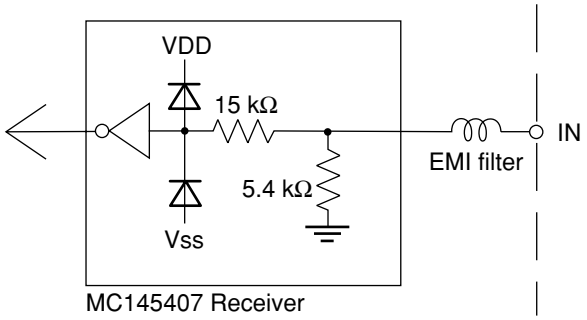


Figure B-1-2: Interface Input Circuit

1.2 Software

1. Communication Format

1) Code

ASCII codes are used for output.

2) Structure of Text

"STX"(02 H) is sent prior to data and "ETX"(03 H) is sent at the end of data.

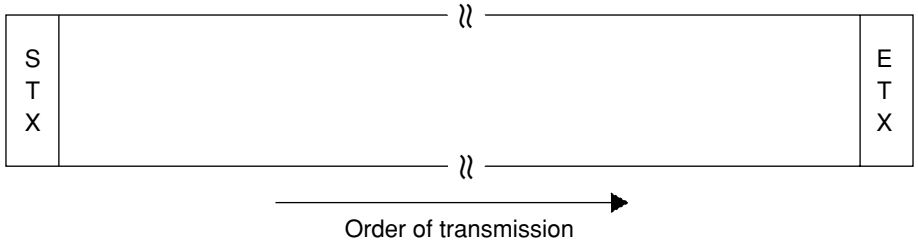


Figure B-1-3: Order of Transmission

3) Communication Protocol

The following two protocols are provided in the system, and can be selected according to the system status.

- Class A
  One-way transmission to the host computer without requiring ACK nor NAK from host computer.
- Class B
  The CA-1500 transmits data and then waits for ACK or NAK to complete the data transmission.
  ACK and NAK can be sent between STX and ETX.

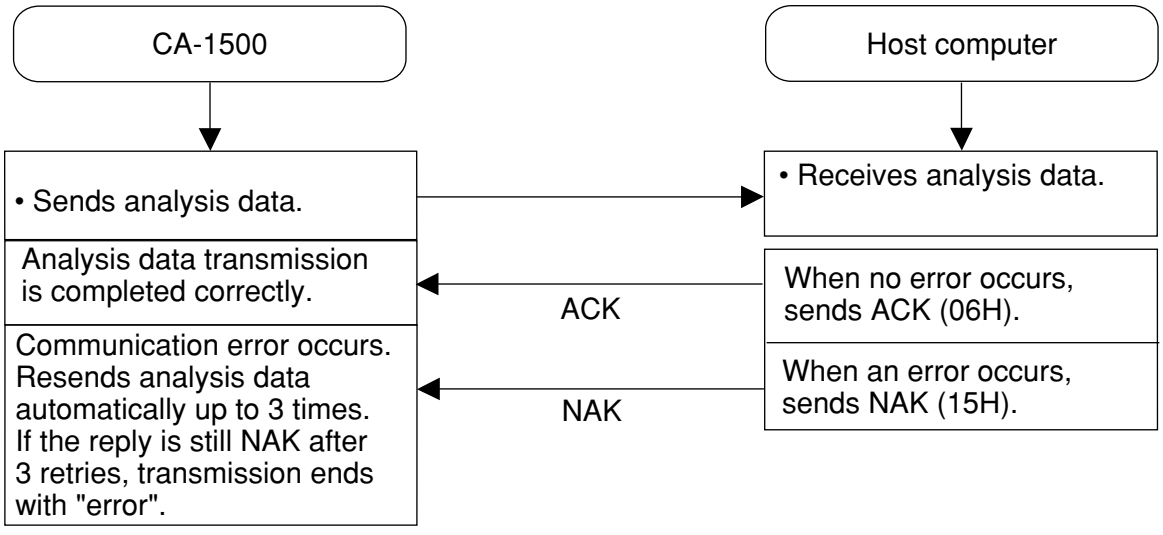


Figure B-1-4: Analysis Data Transmission

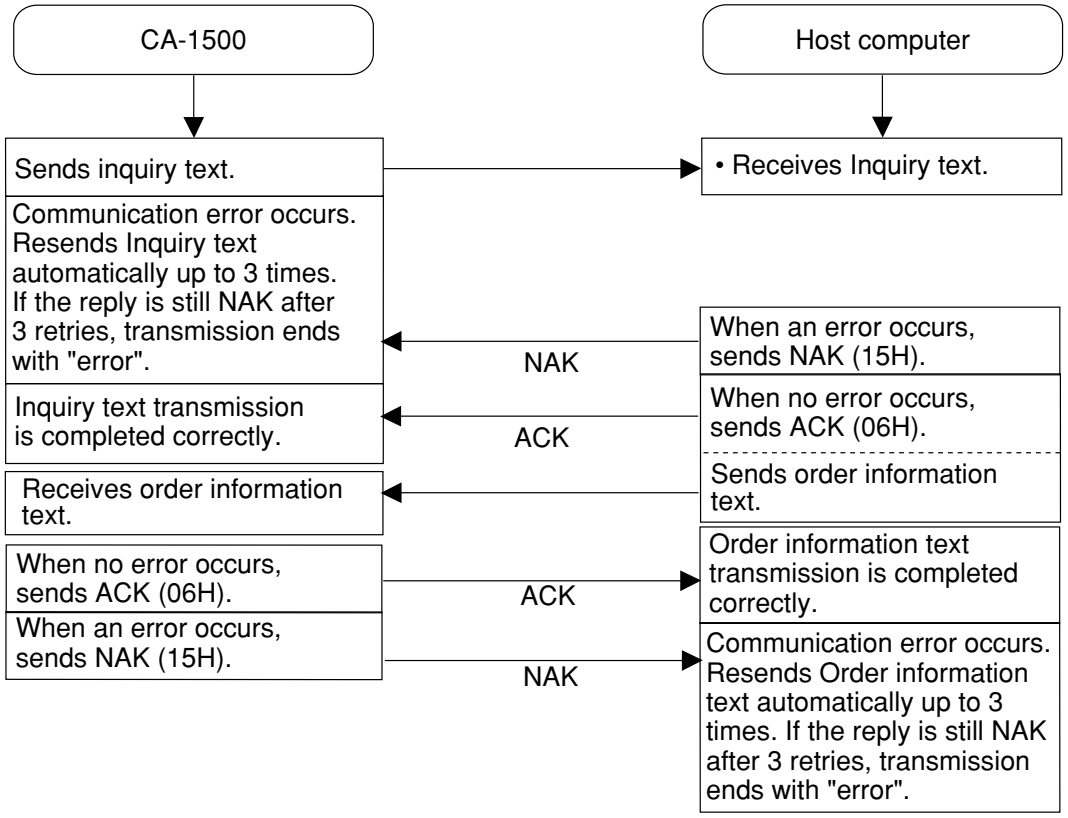


Figure B-1-5: Order Inquiry and Order Information Texts Transmission

4) Transmission Errors

If the CA-1500 detects a transmission error, data transmission is interrupted and an error message is displayed on the LCD screen. Re-transmission is carried out by the operator. Transmission errors occur in the following situations.

- The control signal DSR is OFF.
- After the data is output, the control signal CTS is not turned ON within 5 seconds.
- In case of parity error, overrun error, or frame error
- When the data is transmitted, no response is sent from the host computer within 15 seconds. (Class B only)
- When the data is transmitted, other than ACK and NAK is sent from the host computer. (Class B only)
- When the data is transmitted, NAK is received 4 times. (Class B only. The CA-1500 automatically re-sends the same data up to 3 times when NAK is received.)
- When the transmission initial word (STX) or ending word (ETX) is not received**.**

5) Transmission Interval

The transmission interval time between the data can be selected. The interval time in the case of class B means the period after receiving the response of ACK/NAK until starting the next data transmission.

6) Process Time Required
If no control signal lines are used, the response to the CA-1500 must be sent with a delay time of 0.2 seconds or more.

1.3 Text Format

There are two types of communication text formats for the CA-1500. Make an appropriate setting on the Host Computer Setting screen. For details, see *Chapter 11, Section 6.1: Host Computer Settings*.

NOTE:
- There are two format types for the host computer output.
  Format type: CA-1000, CA-1500
  * (When CA-1000 is selected, the sample ID number of the transmission data is 13 digits excluding the most significant 2 digits, the patient name is 11 characters excluding the first (left most) 4 characters, and the rack No. is 4 digits excluding the most significant 2 digits.)
  The CA-1500 format is selected at the time of shipment from the factory.

- **Analysis Data Text (Output)**
  The analysis data is output.
  There are two methods for output: Automatic transmission (real-time basis) after each analysis is completed, and batch transmission from the stored data list.

- **Order Inquiry Text (Output)**
  The analysis parameters, or the sample ID number and analysis parameters are inquired for prior to an analysis. There are two methods for inquiry: Inquiry by a sample ID number read from the barcode label, and by pressing the [HC] key from the Work Load List screen.

- **Order Information Text (Input)**
  After transmitting the order inquiry text, order information text is received from the host computer for an order instruction.
  * Class B communication is required to use the function of order inquiry and analysis order information.

1.3.1 Analysis Data Format

Value in ( ) indicate the value when CA-1000 is selected.

Parameter	No. of Characters	Example
STX	1	(02 H)
Text Distinction Code I	1	Fixed to "D".
Text Distinction Code II	1	"1" (normal data) or "2" (mean data)
Text Distinction Code III	2	Fixed to "21"
Block Number	2	"01"
Total Number of Blocks	2	"01"
Sample Distinction Code	1	"U", "E", "S", "C"
Date	6	"980313"
Time	4	"1325"
Rack Number	6 (4)	"000001"
Tube Position Number	2	"01"
Sample ID Number	15 (13)	"123-456-789-012"
ID Information	1	"M", "A", "B", "C"
Patient Name	15 (11)	"XX...XX"
Analysis Parameter, Data 1	9	
Analysis Parameter, Data 2	9	
Analysis Parameter N, Data N	9	
ETX	1	(03 H)
Total	60 +9N (52 +9N)	

Table B-1-3: Analysis Data Format

- **Order of Transmission**
  The order of transmission is from the top parameter to the bottom; the most significant digit first and the least significant digit last. Zero suppression is not performed.

- **Block Number and Total Number of Blocks**
  The analysis data is divided for transmission so that one block contains 255 or less characters.
  The block number is the sequence number of the divided text.
  The total number of blocks is the total number of divided text.
  Normally, block number and number of blocks are "01".

- **Sample Distinction Code**
  The types of analysis data are shown.
  U: Routine analysis data
  E: STAT analysis data
  S: Standard curve analysis data
  C: Quality control analysis data

- **Date and Time**
  Set the date and time when the analysis was performed. The date format conforms to the format set in the date/time setting program. Time follows the 24-hour system. Zero suppression is not performed.

- **Rack Number**
  The rack number indicates the 6-(4-)digit number ("000001" - "999999") assigned to each sample rack. Zero suppression is not performed.
  For the STAT sample holder, it becomes "STAT H" (if CA-1000 format is selected, "0000"). For the reagent holder, it becomes "D1" - "D14" (if CA-1000 is selected, spaces (20 H)).

- **Tube Position Number**
  The tube position number indicates the sample tube position (01 - 10) in the sample rack, the holder position (01 - 05) of STAT sample, and the reagent holder (spaces (20 H)). If the tube position number is expressed by numerals, zero suppression is not performed.

- **Sample ID Number**
  The sample ID number consists of 15 (13) digit numerals. A hyphen "-" (2D H) may be inserted between numerals. The hyphen "-" is included in the 15 (13) digits. Zero suppression is not performed. The most significant digits are filled with spaces (20 H) if it is less than 15 (13) digits.

- **ID Information**
  The ID information indicates the method in which the sample ID number is registered.
  M: Manual entry
  A: Automatically assigned by the instrument
  B: Read by ID barcode reader
  C: Set by the host computer order information

- **Patient Name**
  The patient name consists of 15 (11) characters with character codes including spaces but excluding control codes.

- **Analysis Parameter, Data**

Parameter	No. of Characters	
Parameter Code	3	(OOO)
Data	5	(OOOO.O) [sec], [s]
		(□OOO.O) [%], [mg/dL], [µg/L]
		(□O.OOO) [ ], [g/L], [U/mL], [µg/mL]
		(□OO.OO) Ratio, INR, [mg/L]
Flag	1	"□", "+", "-", "*", "!", "<", ">", "×"

Table B-1-4: Analysis Parameter, Data

1) Parameter Code

04x: PT	05x: APTT	06x: Fbg
08x: TTO#	09x: NT#	12x: Factor II
15x: Factor V	17x: Factor VII	18x: Factor VIII
19x: Factor IX	20x: Factor X	21x: Factor XI
22x: Factor XII	30x: AT III	31x: α2PI
32x: Plg	33x: PC	51x: TT
60x: FDP##	61x: D. Dimer	

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.

* Additional parameter codes may be added in the future. When the host computer receives a parameter code not mentioned above, prepare a host computer program that will ignore the data of such a parameter code or can allocate a parameter to new codes.
\# Not available in the USA.
Available for use only in Asia.

2) Data

Because the decimal point is not transmitted, the host computer must add the appropriate decimal point specified for each parameter.
The position of decimal point varies depending on the unit.

Time: OOOO.O → OOOOO (*1)
Activity percent: OOO.O → □OOOO (*2)
PT ratio: OO.OO → □OOOO (*2)
INR: OO.OO → □OOOO (*2)
Fbg concentration: □O.OOOg/L or □OOO.Omg/dL → □OOOO (*2)
D-Dimer concentration: OO.OOmg/L or OOOOµg/L → □OOOO (*2)
Difference in Optical Density (dOD):
Chromogenic Method: OO.OOO → OOOOO (*2)
Immunoassay Method: O.OOOO → OOOOO (*2)

□indicates a space (20 H).

1. If coagulation time cannot be obtained such as in the case of an analysis error, "" is entered instead of "O" for the number of characters. However, "/" enters in the case of mean data.
*2. If data cannot be calculated in cases when the standard curve is not set or the coagulation time is not obtained, "-" is entered instead of "O" for the number of characters. And if the data cannot be calculated due to no coagulation time being obtained in cases of instrument error, space (20 H) is entered instead of "O" for the number of characters.

3) Flags

space:	No error
+	Over the upper control limit
-	Under the lower control limit
*	Analysis error occurred, disparate data of mean data occurred, or Fbg was over analysis range.
!	Coagulation time was obtained by re-dilution analysis.
<	Under the lower report limit
>	Over the upper report limit
×	Calculation parameter is not calculated because standard curve is not set.

1.3.2 Order Inquiry Text Format

Value in ( ) indicate the value when CA-1000 is selected.

Parameter	No. of Characters	Example
STX	1	(02 H)
Text Distinction Code I	1	Fixed to "R".
Text Distinction Code II (Inquiry key)	1	"1" (Rack No., Tube Position No.) or "2" (Sample ID No.)
Text Distinction Code III	2	Fixed to "21"
Block Number	2	"01"
Total Number of Blocks	2	"01"
Sample Distinction Code	1	Fixed to space (20 H)
Date	6	"980131"
Time	4	"1325"
Rack Number	6 (4)	"000001"
Tube Position Number	2	"01"
Sample ID Number	15 (13)	"123-456-789-012"
ID Information	1	"M", "A", "B", space(20 H)
Patient Name	15 (11)	"XX...XX"
Analysis Parameter, Data 1	9	
Analysis Parameter, Data 2	9	
Analysis Parameter N, Data N	9	
ETX	1	(03 H)
Total	60 +9N (52 +9N)	

Table B-1-5: Order Inquiry Text Format

- **Order of Transmission**
  The order of transmission is from the top parameter to the bottom; the most significant digit first and the least significant digit last. Zero suppression is not performed.

- **Block Number and Total Number of Blocks**
  The analysis data is divided for transmission so that one block contains 255 or less characters.
  The block number is the sequence number of the divided text.
  The total number of blocks is the total number of divided text.
  Normally, block number and number of blocks are "01".

- **Date and Time**
  Set the date and time when the inquiry was performed. The date format conforms to the format set in the date/time setting program. Time follows the 24-hour system. Zero suppression is not performed.

- **Rack Number**
  This is the inquiry number in the case of inquiry by rack number, consisting of the 6-(4-)digit number ("000001" - "999999").
  For the STAT sample holder, it becomes "STAT H" (if CA-1000 format is selected, "0000").

- **Tube Position Number**
  The tube position number indicates the sample tube position (01 - 10) in the rack, and the holder position (01 - 05) for STAT sample.

- **Sample ID Number**
  A number is indicated here in the case of inquiry by sample ID number. A hyphen "-" (2D H) may be inserted between numerals. The hyphen "-" is included in the 15 (13) digits. In the case of inquiry by rack number and tube position number, if there is a sample ID number which has been manually input by the user, this manually entered sample ID number is used.

- **ID Information**
  The ID information indicates the method in which the sample ID number is registered.
  M: Manual entry
  A: Automatically assigned ID No. when ID read error occurs (*)
  B: Read by ID barcode reader
  Space (20 H): When sample ID number is not set
  In the case of inquiry by rack number and tube position number, space (20 H) is set.

* In the case of an ID read error, sequential numbers starting from "□□ERR0000000001" will be assigned. □ indicates a space (20 H).

- **Patient Name**
  The patient name consists of 15 (11) characters with character codes including spaces but excluding control codes.

- **Analysis Parameter, Data**

Parameter	No. of Characters	
Parameter Code	3	(OOO)
Reserved	6	six spaces (20 H)

Table B-1-6: Analysis Parameter, Data

1) Parameter Code

040: PT	050: APTT	060: Fbg
080: TTO#	090: NT#	120: Factor II
150: Factor V	170: Factor VII	180: Factor VIII
190: Factor IX	200: Factor X	210: Factor XI
220: Factor XII	300: AT III	310: α 2PI
320: Plg	330: PC	510: TT
600: FDP##	610: D. Dimer	

NOTE: • Additional parameter codes may be added in the future.

* Additional parameter codes may be added in the future. When the host computer receives a parameter code not mentioned above, prepare a host computer program that will ignore the data of such a parameter code or can allocate a parameter to new codes.
\# Not available in the USA.
\## Available for use only in Asia.

2) Reserved
All spaces (20 H)

1.3.3 Order Information Text Format

The same format as the Inquiry Text Format is used for the Order Information Text Format.

Value in ( ) indicate the value when CA-1000 is selected.

Parameter	No. of Characters	Example
STX	1	(02 H)
Text Distinction Code I	1	Fixed to "S".
Text Distinction Code II (Inquiry key)	1	"1" (Rack No., Tube Position No.) or "2" (Sample ID No.)
Text Distinction Code III	2	Fixed to "21"
Block Number	2	"01"
Total Number of Blocks	2	"01"
Sample Distinction Code	1	"U", "E", "C"
Date	6	"980131"
Time	4	"1325"
Rack Number	6 (4)	"000001"
Tube Position Number	2	"01"
Sample ID Number	15 (13)	"123-456-789-012"
ID Information	1	"A", "B", "C"
Patient Name	15 (11)	"XX...XX"
Analysis Parameter, Data 1	9	
Analysis Parameter, Data 2	9	
Analysis Parameter N, Data N	9	
ETX	1	(03 H)
Total	60 +9N (52 +9N)	

Table B-1-7: Order Information Text Format

- **Order of Transmission**
  The order of transmission is from the top parameter to the bottom; the most significant digit first and the least significant digit last. Zero suppression is not performed.

- **Block Number and Total Number of Blocks**
  The analysis data is divided for transmission so that one block contains 255 or less characters.
  The block number is the sequence number of divided text.
  The total number of blocks is the total number of divided text.
  Normally, block number and number of blocks are "01".

- **Sample Distinction Code**
  The types of analysis data are shown.
  U: Routine analysis data
  E: STAT analysis data
  C: Quality control analysis data

- **Date and Time**
  Set the date and the time when the order was performed. The date format conforms to the format set in the date/time setting program. Time follows the 24-hour system. Zero suppression is not performed.

- **Rack Number**
  This is the Rack Number in which the sample to be analyzed is installed, consisting of 6-(4-)digit number ("000001" - "999999").
  For the STAT sample holder, it becomes "STAT H" (if CA-1000 format is selected, "0000").

- **Tube Position Number**
  The tube position number indicates the sample tube position (01 - 10) in the rack, and the holder position (01 - 05) for STAT sample.

- **Sample ID Number**
  The sample ID number is shown here. A hyphen "-" (2D H) may be inserted between numerals. The hyphen "-" is included in the 15 (13) digits. In the case of ordering QC file number, "QC01" - "QC20" should be used.

- **ID Information**
  The ID information indicates the method in which the sample ID number is registered.
  C: Input from the host computer
  A: Automatically assigned ID No. when ID read error occurs
  B: Read by ID barcode reader
  M: Manual entry

- **Patient Name**
  The patient name consists of 15 (11) characters with character codes including spaces but excluding control codes.

- **Analysis Parameter, Data**

Parameter	No. of Characters	
Parameter Code	3	(OOO)
Reserved	6	Six spaces (20 H)

Table B-1-8: Analysis Parameter, Data

1) Parameter Code

040: PT	050: APTT	060: Fbg
080: TTO#	090: NT#	120: Factor II
150: Factor V	170: Factor VII	180: Factor VIII
190: Factor IX	200: Factor X	210: Factor XI
220: Factor XII	300: AT III	310: α 2PI
320: Plg	330: PC	510: TT
600: FDP##	610: D. Dimer	
000: There is no analysis parameter for the inquired sample. (*1)		
999: There is no analysis parameter for the inquired sample and the later samples. (*2)		

*1: When there is no analysis parameter for the inquired sample ID number, set "000" for the parameter code.

*2: When there is no analysis parameter for the inquired sample and the later samples, set "999" for the parameter code. When the CA-1500 receives "999", CA-1500 will not inquire the following tube positions. This code is provided for the cases when there is no setting of analysis order in the host computer, or when there is no analysis order because the sample ID number, or the rack number and tube position number is not found.

Not available in the USA.

Available for use only in Asia.

NOTE: • Additional parameter codes may be added in the future.

2) Reserved

All spaces (20 H)

2. ID BARCODE SPECIFICATIONS

By affixing a barcode label on a sample tube, the sample ID number or QC File No. can be automatically read. When using barcode labels, make sure they meet the barcode label specifications applicable to the CA-1500 ID barcode reader.
The specifications of the barcode label are described in this section.

WARNING • 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.

2.1 Acceptable Barcode

The types of barcode acceptable to the instrument and the check digit(s) are listed below.

(1) Sample ID No.

Type of Barcode	Check Digit	No. of Digits
ITF	Not used	1 - 15 digits (Sample ID No.)
	Modulus 10	1 - 15 digits (Sample ID No.) + 1 digit (Check digit) = 16 digits Max.
NW-7 (CODABAR) (*)	Not used	1 - 15 digits (Sample ID No.)
	Modulus 11	+ 1 digit (Check digit) = 16 digits Max.
	W. Modulus 11	
CODE-39	Not used	1 - 15 digits (Sample ID No.)
	Modulus 43	1 - 15 digits (Sample ID No.) + 1 digit (Check digit) = 16 digits Max.
JAN-13	Modulus 10	12 digits (Sample ID No.) + 1 digit (Check digit) = 13 digits Max.
JAN-8	Modulus 10	7 digits (Sample ID No.) + 1 digit (Check digit) = 8 digits Max.
CODE-128	Modulus 103	1 - 15 digits (Sample ID No.) + 1 digit (Check digit) = 16 digits Max.

*As the Start and Stop codes, use one of the characters "A", "B", "C", "a", "b" and "c".

Table B-2-1: Barcode and Check Digit

NOTE: • When "C" or "c" is used, make sure that the number is not the same as the QC File number.

(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", ... "QC20"	Not Used or 1 digit

*1: Start and Stop codes can be any of the characters "C" or "c".
*2: Possible applicable QC File No. is 1 through 9, and must be filled with the same number in all digits.

2.2 Dimension of Barcode Elements

Narrow Element ≧ 200 µm
Wide Element ≦ 1.2 mm
Narrow element ≦ Gap between characters ≦ Wide Element

2.3 Narrow/Wide Ratio

For each character, the wide element to narrow element ratio must comply with the following:
Narrow (Max.) : Wide (Min.) = 1 : 2.2 or more
Narrow (Min.) : Narrow (Max.) = 1 : 1.3 or less
Wide (Min.) : Wide (Max.) = 1 : 1.4 or less

2.4 PCS (Print Contrast Signal)

$$PCS = \frac{\text{Reflectivity of the space - Reflectivity of the black inked bar}}{\text{Reflectivity of the space}}$$

Standard: PCS value ≧ 0.45

The analysis method conforms to *JIS (Japanese Industrial Standards) X0501, "5.3 Optical Characteristics of Barcode Symbols".*

2.5 Reflection Characteristics of Label Surface

A laminated label cannot be read.

2.6 Irregularity and Roughness of Printing

When a bar element is magnified by a microscope, the following may be observed.

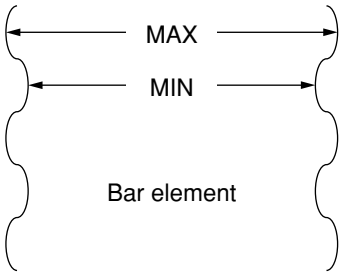


Figure B-2-1: Magnified Bar

When the variation coefficient (S) in the width of a bar is defined:

$$S = \frac{MAX - MIN}{MAX} \times 100\%$$

Then the variation coefficient (S) must be 20 % or less.

2.7 Dimensions of Barcode Label

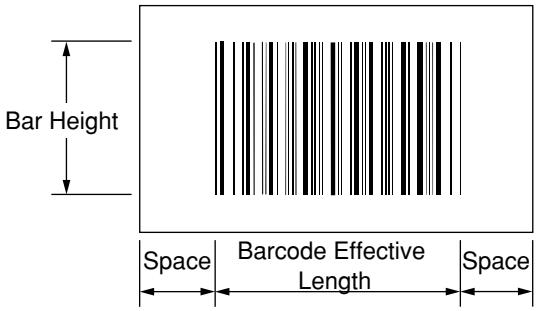


Figure B-2-2: Barcode Label

Space: 5 mm or more
Barcode Effective Length: 48 mm or less (Optimum: 40 mm or less)
Bar Height: 20 mm or more (Rack label height: 6 mm or more)

2.8 Check Digit

To improve the reliability of an ID No. read, check digit(s) can be added.
Taking the sample ID No. of "258416" as an example, this section explains how to calculate the check digit for modulus 11 and weighted modulus 11.

1) Modulus 11

(1) Each digit is weighted:

	2	5	8	4	1	6
	×	×	×	×	×	×
Weight	7	6	5	4	3	2
	14	30	40	16	3	12

(2) Add up the multiplied results as given below:
S = 14 + 30 + 40 + 16 + 3 + 12 = 115

(3) When S is divided by 11, calculate the remainder and obtain the complement of the remainder. This complement will be the check digit.
115 ÷ 11 = 10 with remainder 5
11 - 5 = 6, thus the check digit is 6.
However, all English symbols except the numerals of 0 - 9 are regarded as 0 in making the calculation. Also, when S is divisible by 11 with remainder 0 and when calculation of the check digit results in 10, zero is entered as the check digit.

2) Weighted Modulus 11

Weighted modulus 11 has two sets of weight. When the check digit is computed to 10 as a result of applying the first weight set, the second weight set is applied. The result should always be between 0 and 9. The calculation method is exactly the same as modulus 11 except for the difference in weighting.

(1) Weighing Each Digit.

Weight:	W12	W11	W10	W9	W8	W7	W6	W5	W4	W3	W2	W1
First Set:	6	3	5	9	10	7	8	4	5	3	6	2
Second Set:	5	8	6	2	10	4	3	7	6	8	5	9

	2	5	8	4	1	6
	×	×	×	×	×	×
Weight	8	4	5	3	6	2
	16	20	40	12	6	12

(2) Add up the multiplied results as given below:
S = 16 + 20 + 40 + 12 + 6 + 12 = 106

(3) When S is divided by 11, calculate the remainder and obtain the complement of the remainder. This complement will be the check digit.
106 ÷ 11 = 9 with remainder 7
11 - 7 = 4, thus the check digit is 4.
However, all English symbols except the numerals of 0 - 9 are regarded as 0 in making the calculation. Also, when S is divisible by 11 with remainder 0 and when calculation of the check digit results in 10, zero is entered as the check digit.

NOTE: • Weight for the 13th to 15th digits is assumed to be 0.

3) Modulus 10/Weight 3

This Modulus 10/Weight 3 method is used in the bar code symbology such as JAN, NW-7 and ITF (Interleaved 2 of 5). The check digit computation method is shown as follows;

(1) The least significant digit (most right 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 (most left 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.
Multiply the sum by 3, as: 13 x 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 most right 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.
Multiply the sum by 3, as: 7 x 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 an odd number 7 in this case. Therefore, "0" is added to the most significant digit (most left digit) and check-digit is appended to the data, as 05243624.

4) Modulus 43

Modulus 43 is the check digit computation method used in CODE-39 symbology. A value is assigned to each of the 43 characters. 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
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".

5) Modulus 103

Modulus 103 is the check-digit computation method used in the 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. Then, divide the sum by 103. To obtain a check-digit, convert the remainder to the corresponding character in the table .

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 x 1 = 17
2 18 x 2 = 36
3 19 x 3 = 57
– 13 x 4 = 52
4 20 x 5 = 100
5 21 x 6 = 126
6 22 x 7 = 154
7 23 x 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
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				

APPENDIX C WAND BARCODE READER

1. CONNECTING WAND TYPE BARCODE READER (OPTION) C-1
   - 1.1 Connecting the Connector C-1
   - 1.2 Connector Signals C-1
   - 1.3 Communication Format C-2
   - 1.4 Signal Level C-2
   - 1.5 Barcode Reader Type C-2
   - 1.6 Limitations C-2

2. BARCODE READER SPECIFICATION C-3

1. CONNECTING WAND TYPE BARCODE READER (OPTION)

1.1 Connecting the Connector

NOTE: • Use of barcode reader is optional. For installation please contact your Service representative.

Connect an optional Wand type Barcode Reader to the connector (spare) on the right panel of the main unit. Use a 9-pin D-SUB, female connector.

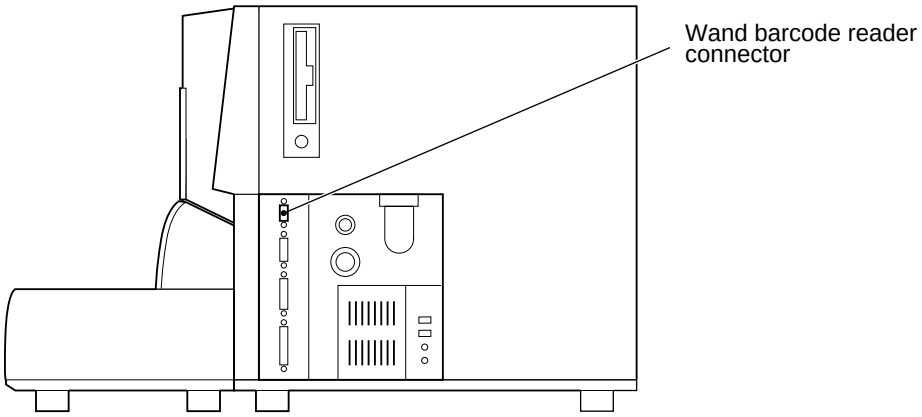


Figure C-1-1: Wand Barcode Reader Connector

1.2 Connector Signals

Pin No.	Signal name	Signal direction
1	N.C.	
2	Receive Data (RxD)	from BCR to CA-1500
3	Transmit Data (TxD)	to BCR from CA-1500
4	Data Terminal Ready (DTR)	to BCR from CA-1500
5	Signal Ground (SG)	
6	Data Set Ready (DSR)	from BCR to CA-1500
7	Request to Send (RTS)	to BCR from CA-1500
8	Clear to Send (CTS)	from BCR to CA-1500
9	N.C.	

Table C-1-1: Pin Assignment

1.3 Communication Format

The data is communicated in an asynchronous, half duplex mode.

Baud rate: 2400 (BPS)
Code: 7 bit
Stop bit: 1 bit
Parity: Even

1.4 Signal Level

Signal level conforms to EIA RS-232C.

Level	Data signal	Control signal
+3V or higher	Logic "0", Start bit	ON
-3V or lower	Logic "1", Stop bit	OFF

Table C-1-2: Signal Level

1.5 Barcode Reader Type

The same type as the BCH-5402-STA (DENSEI) is used.

NOTE:
- The types of barcode acceptable to the instrument are as follows:
  ITF (Interleaved 2 of 5) and Modulus 10 / Weight 3 check digit.
  CODE-128
  CODE-39 and Modulus 43 check digit
- CA-1500 does not supply power to the barcode reader.

1.6 Limitations

If the ITF (Interleaved 2 of 5) for the barcode is used, use Modulus 10 / Weight 3 method check digit.

2. BARCODE READER SPECIFICATION

This instrument requires to the barcode reader following specifications.

1. Supported Barcode
ITF (Interleaved 2 of 5) and Modulus 10 / Weight 3 check digit
CODE-128
CODE-39 and Modulus 43 check digit

2. Power Supply
The barcode reader must have the power supply by itself. (The CA-1500 does not supply power to the barcode reader.)

3. Narrow Bar Width
Readable narrow bar width is 0.19 mm. (The allowed narrow bar width of reagent label is 0.19 mm to 0.25 mm.)

4. Communication Format
The data is communicated in the asynchronous, half duplex mode.

Baud rate: 2400 (BPS)
Code: 7 bit
Stop bit: 1 bit
Parity: Even
Supported Code: ANSI ASCII
Format:

Read Data	Terminator (CR)

Terminator: CR (13), (No header)
Check Digit: Suppress (Does not transmit check digit.)

5. Connector
The 9-pin D-SUB, male connector is required. (The CA-1500 provides a 9-pin D-SUB, female connector.)

6. Connector Signals

Pin No.	Signal name	Signal direction
1	N.C.	
2	Receive Data (RxD)	from BCR to CA-1500
3	Transmit Data (TxD)	to BCR from CA-1500
4	Data Terminal Ready (DTR)	to BCR from CA-1500
5	Signal Ground (SG)	
6	Data Set Ready (DSR)	from BCR to CA-1500
7	Request to Send (RTS)	to BCR from CA-1500
8	Clear to Send (CTS)	from BCR to CA-1500
9	N.C.	

Table C-2-1: Pin Assignment

7. Signal Level

Signal level conforms to EIA RS-232C.

Level	Data signal	Control signal
+3V or higher	Logic "0", Start bit	ON
-3V or lower	Logic "1", Stop bit	OFF

Table C-2-2: Signal Level

APPENDIX D VACUUM ADJUSTMENT

1. INTRODUCTION D-1

2. MAINTENANCE D-1

3. TROUBLESHOOTING D-4

1. INTRODUCTION

To prevent the early degradation of the pressures from the built-in pneumatic unit, vacuum adjustment is performed.

2. MAINTENANCE

The vacuum from the built-in pneumatic unit is adjusted to -0.067 MPa (500 mmHg). This vacuum is constantly monitored by pressure sensor. If an abnormality is detected, an error message will appear.
If vacuum is out of the adjustment range, check the tubing connections for leaks. If nothing abnormal is found, adjust the vacuum.

To adjust the vacuum, turn the adjustment knob (located on the right side of the instrument) as you check the current vacuum readings on the Pressure Adjustment screen.

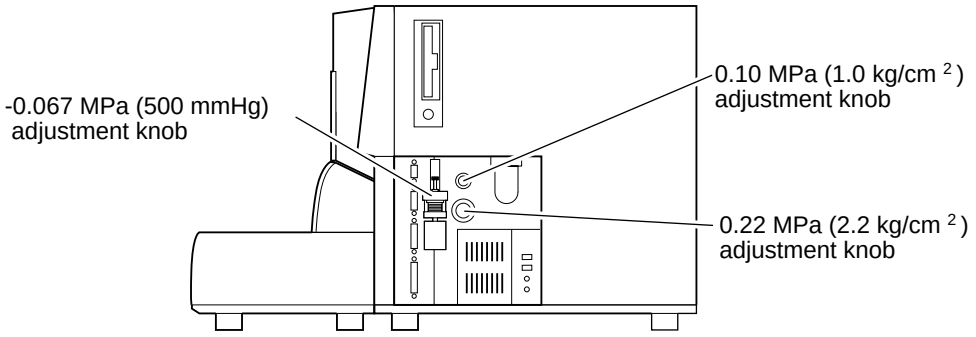


Figure D-2-1: Location of the Pressure Adjustment Knobs

Displaying the Pressure Adjustment Screen
(1) From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.

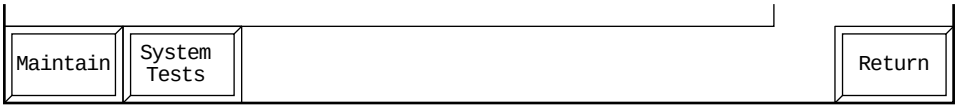


Figure D-2-2 : Special Menu

(2) Press the [Maintain] key. The maintenance sub menu will appear.

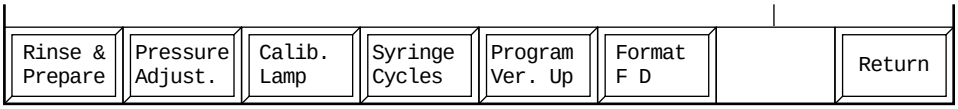


Figure D-2-3 : Maintenance Sub menu

(3) Press the [Pressure Adjust.] key. The Pressure Adjustment screen will appear.

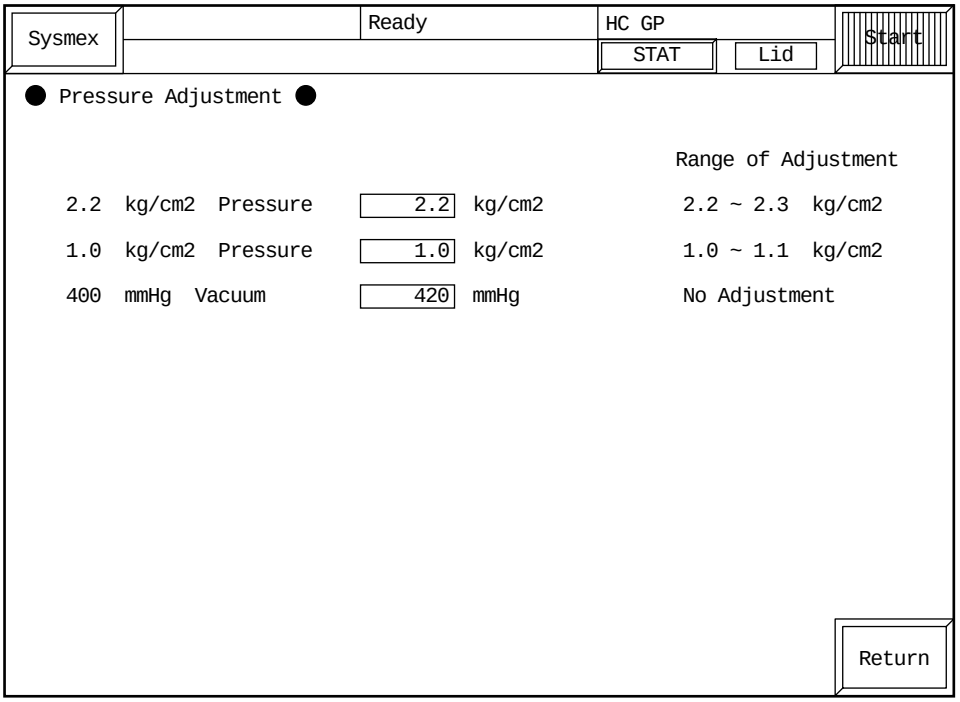


Figure D-2-4 : Pressure Adjustment Screen

Press the [Return] key to return to the Maintenance sub menu.

Adjusting the -0.067 MPa (500 mmHg) vacuum

(1) Loosen the fixing nut on the -0.067 MPa (500 mmHg) adjustment knob located on the right side of the instruments

(2) Adjust the vacuum by turning the adjustment knob as you check the current value for the 400 mmHg vacuum on the Pressure Adjustment screen.
The vacuum will rise as you turn the adjustment knob clockwise.

Target: -0.067 MPa (500 mmHg) -
-0.071 MPa (530mmHg)

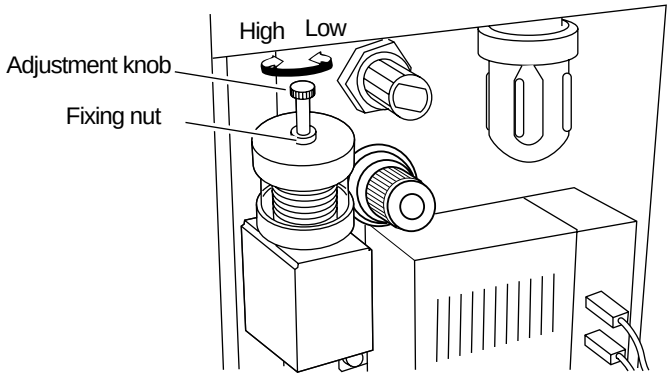


Figure D-2-5 : Adjusting the -0.067 MPa (500 mmHg) Vacuum

CAUTION:	• Always adjust the vacuum so as to raise it to the specified level. If the vacuum is too high, lower it to a value that is below the specified vacuum, and then slowly raise the vacuum. • Adjust the vacuum to -0.067 MPa (500 mmHg) - -0.071 MPa (530 mmHg) although displayed as "400 mmHg Vacuum" on the Pressure Adjustment Screen.

(3) After adjustment, tighten the fixing nut while taking care not to allow the adjustment knob to rotate.

3. TROUBLESHOOTING

Error Message	
Vacuum Error	
Probable Cause	1) Fluid back-flows into the trap chamber. 2) Air leakage from the vacuum line in the main unit. 3) Vacuum adjustment is incorrect. 4) Pneumatic system has failed.
Corrective Action	1) Discard fluid in the trap chamber, (See the CA-1500 Operator's Manual *Chapter 6, Section 3.5: Checking and Discarding Trap Chamber Fluid* for the procedures.). 2) Check the vacuum line for loosened nipple or tubing. 3) Adjust the vacuum 4) Contact your service representative.

APPENDIX E EXTERNAL PNEUMATIC UNIT

1. INTRODUCTION E-1

2. OVERVIEW OF THE EXTERNAL PNEUMATIC UNIT E-2

3. MAINTENANCE E-4

4. TROUBLESHOOTING E-5
   4.1 Corrective Action E-5
   4.2 Confirm Adjustment knob (for 2.2 kg/cm^2 Pressure) E-5

1. INTRODUCTION

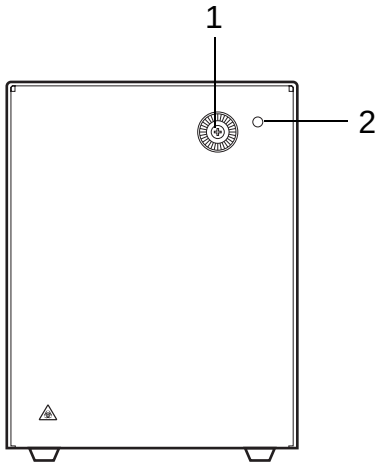
When CA-1500 is used at high altitudes, there is the possibility of a pressure error. The external pneumatic unit is effective in preventing the pressure error.

2. OVERVIEW OF THE EXTERNAL PNEUMATIC UNIT

Pneumatic Unit
Supplies compressed air to the Main Unit.

WARNING:
- To avoid electrical shock, disconnect supply before servicing.
- For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.

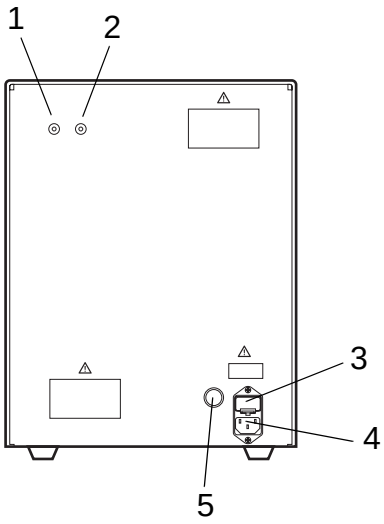
Front of the Pneumatic Unit



1 2.2 kg/cm^2 (0.22 MPa) regulator
Adjusts the 2.2 kg/cm^2 (0.22 MPa) pressure supplied to the Main Unit.

2 Pilot lamp
It lights when the Pneumatic Unit power supply is ON.

Rear of the Pneumatic Unit



1 Pressure outlet nipple
Used to supply pressure to the Main Unit. Connected to the pressure inlet nipple of the Main Unit.

2 Vacuum outlet nipple
Vacuum is supplied to the Main Unit through this nipple. Connected to the vacuum inlet nipple of the Main Unit.

3 Fuse
This is a time-lag fuse for 250V 4A (117V), 250V 3.15A (220-240V). Do not insert any fuse that does not match this rating.

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

4 Power connector
Supplies power via power cable provided.

5 Pneumatic Unit control connector
Used as the input connector for turning ON/OFF of Pneumatic Unit power. Connected to the Pneumatic Unit control output connector of the Main Unit.

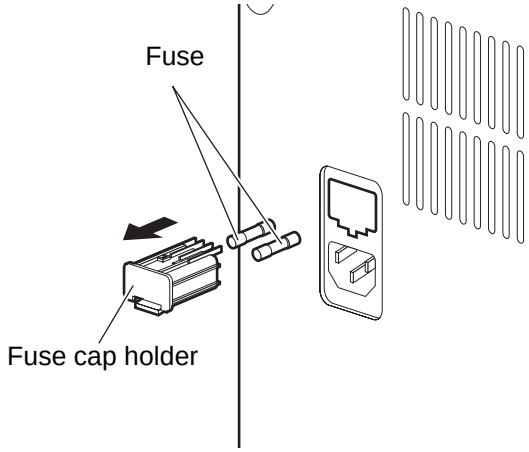
3. MAINTENANCE

Replacing fuses
Over-current protection fuses are used in the Main Unit and Pneumatic Unit. When a fuse is blown, replace it by the following procedure.

WARNING:
- To avoid electrical shock, disconnect supply before servicing.
- For continued protection against the risk of fire, replace only with a fuse of the specified type and current ratings.

(1) Turn OFF the power of the Main Unit and disconnect the power cords for the Main Unit and the Pneumatic Unit.
(2) With a screwdriver, remove the fuse cap holder.

Pneumatic Unit (rear)



(3) Replace the fuse and attach the fuse holder cap to the instrument.

WARNING:
- To avoid electrical shock, disconnect supply before servicing.
- For continued protection against the risk of fire, replace only with a fuse of the specified type and current ratings.

Pneumatic Unit

Specification	Part No.	Description	Fuse Type	Quantity
100 - 117 VAC	266-5011-3	Fuse 250V 4A ST4-4A-N1	Time Lag	2
220 - 240 VAC	266-5293-0	Fuse 250V 3.15A No. 19195	Time Lag	2

4 TROUBLESHOOTING

4.1 Corrective Action

Error Message	
•2.2 kg/cm^2 Pressure Error **•1.0 kg/cm^2 Pressure Error**	
Probable Cause	1) Air leakage from the pressure line in the main unit. 2) Pressure adjustment is incorrect. 3) Pneumatic unit power supply is suspended. 4) Pneumatic system has failed.
Corrective Action	1) Check the pressure line for loosened nipple or tubing. 2) Adjust the pressure. (See *Chapter 6, Section 6.1: Adjusting the Pressure.*) 3) Check the Pneumatic Unit power cord connection. 4) If the error persists, contact your service representative.

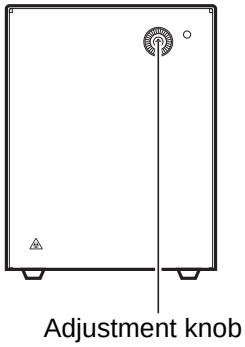
Error Message	
•Vacuum Error*	
Probable Cause	1) Fluid -flows back into the trap chamber, or there is air leakage from the vacuum line in the main unit. 2) There is air leakage from the vacuum line in the main unit. 3) Pneumatic unit power supply is suspended. 4) Pneumatic system has failed.
Corrective Action	1) Discard fluid in the trap chamber, (See *Chapter 6, Section 3.5: Checking and Discarding Trap Chamber Fluid.*), or check the trap chamber. 2) Check the Pneumatic Unit power cord connection. 3) If the error persists, contact your service representative.

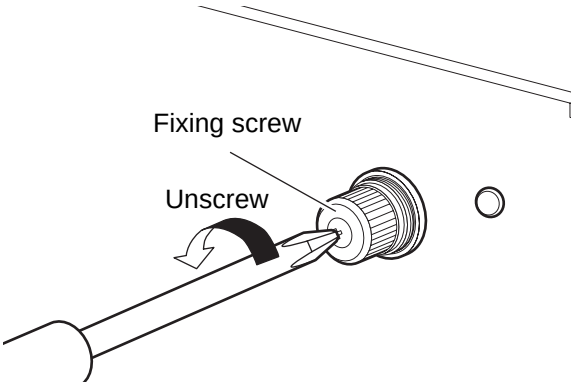
4.2 Confirm Adjustment knob (for 2.2 kg/cm^2 Pressure)

The 2.2 kg/cm^2 (0.22 MPa) pressure should be adjusted with the adjustment knob in the main unit. (Refer to 6.1 Adjusting the pressure)

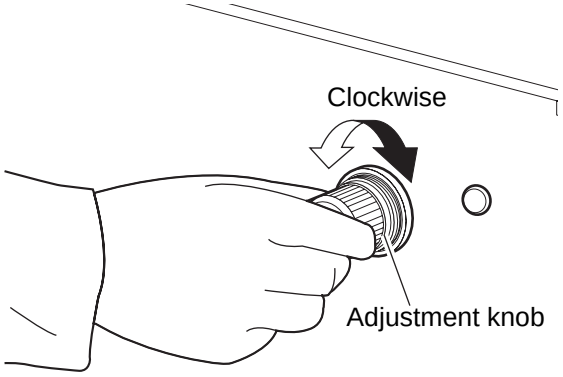
When the 2.2 kg/cm^2 (0.22 MPa) pressure cannot be raised to 2.2 kg/cm^2, you should check the adjustment knob on the external pneumatic unit.

(1) Loosen the fixing screw on the 2.2 kg/cm^2 (0.22 MPa) adjustment knob by turning a screwdriver counter-clockwise while the adjustment knob is held to prevent it from rotating.





(2) Check that the adjustment knob has been turned clockwise as far as it can go.



(3) After checking, tighten the fixing screw while taking care not to allow the adjustment knob to rotate.

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