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• Actin and Ci-Trol are registered trademarks of Dade International Inc.
• Eppendorf is a registered trademark of Eppendorf-Netherler-Hinz GmbH.
• Other trademarks referenced are property of their respective owners.

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• The display screens shown in this manual may differ slightly from the actual displays.
• 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-50 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 accompanying 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, record 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-50 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 you and others from suffering injuries and damage to property. The illustrations and meaning are described in the following. Do understand what they mean before proceeding to the text of the MANUAL.

Meaning of Signs

![WARNING](warning.png)

**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](caution.png)

**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](caution.png)

**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.
WARNING

• In the event the instrument emits abnormal odor or any smoke, turn OFF the power immediately and disconnect the power plug from the wall socket.
  If the instrument is used continuously in that state, there is a hazard that fire, electrical shock, or injury may result.
  Contact your Sysmex service representative for inspection.

• Take care not to spill blood or reagent, or drop wire staples or paper clips into the instrument.
  Those might cause 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 Sysmex service representative for inspection.

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

• During an analysis, do not open the pipette guide and put in hands or fingers.
  That could cause injury. When the pipette guide is opened during an analysis, an alarm sounds and the operation stops.

• Always wear rubber 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 rubber 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 Reagent
  • If a reagent happens to enter your eye, wash it off immediately using plenty of water, and take medical treatment at once.
  • If you should swallow it inadvertently, call for a physician immediately, drink plenty of water, and throw up.
  • If it happens to adhere to your hands or skins, wash it off using plenty of water.

• When discarding used reaction tubes and instrument consumables, take proper disposing steps as 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.
<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
</table>
| **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), be sure to switch OFF the power beforehand.  
    Otherwise, electrical shock or instrument failure may result. |
Use of Reagents
• After unpacking, be sure not to allow dust, dirt, or bacteria to come in touch with the reagent.
• Do not use reagents which have expired.
• Handle a reagent gently to prevent formation of bubbles.
• 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 Sysmex service representative for assistance or service.
• Unpacking, installation, and confirmation of initial setup must be done by your Sysmex 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, strong lighting, etc.
• Do not give the instrument a strong vibration or impact.
• Do not install the instrument near a chemical storage or a place where a gas is generated.

Recommended Pipette and Pipette Chip
• We recommended that you use the following pipettes and pipette chips to add plasma and dispense/add reagents.
  • Pipette: Eppendorf reference 4910 (50 - 200 µL)
  • Pipette Eppendorf 300 µL chip
For details on the usage of the pipette and pipette chip, refer to the instruction manuals attached to them.
INTRODUCTION

Thank you for purchasing the Sysmex® Automated Blood Coagulation Analyzer CA-50. 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.
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 ten chapters and appendices listed below.

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<th>Chapter 1: Introduction</th>
<th>Provides an overview of the instrument, explaining its equipment, operating procedures, and messages as well as points to be careful about during installation.</th>
</tr>
</thead>
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<td>Chapter 2: Analysis Preparation</td>
<td>Explains how to prepare the instrument, reagents, and samples before performing analyses.</td>
</tr>
<tr>
<td>Chapter 3: Sample Analysis</td>
<td>Describes how to analyze samples and explains registration procedures for sample ID numbers and analysis parameters.</td>
</tr>
<tr>
<td>Chapter 4: Display of Analysis Results</td>
<td>Explains the screen displays and the processing of external output.</td>
</tr>
<tr>
<td>Chapter 5: Maintenance &amp; Supplies Replacement</td>
<td>Explains the periodic maintenance procedures and how to replace reagent and other supplies.</td>
</tr>
<tr>
<td>Chapter 6: Quality Control</td>
<td>Explains how to perform quality control analyses and how to print and store quality control data.</td>
</tr>
<tr>
<td>Chapter 7: Setting Standard Curves</td>
<td>Explains how to prepare standard curves.</td>
</tr>
<tr>
<td>Chapter 8: Troubleshooting</td>
<td>Explains the error messages and how to troubleshoot.</td>
</tr>
<tr>
<td>Chapter 9: Functional Description</td>
<td>Explains the coagulation detection principles. Also lists the names and functions of the each parts.</td>
</tr>
<tr>
<td>Chapter 10: Instrument Setup</td>
<td>Explains how to preset the instrument’s various settings, such as the data measure settings (including limits that indicate abnormal data) and the test protocol settings.</td>
</tr>
<tr>
<td>Appendix A: Installation</td>
<td>Explains how to install the CA-50.</td>
</tr>
<tr>
<td>Appendix B: Technical Information</td>
<td>Includes data output format for host computer and other reference materials.</td>
</tr>
</tbody>
</table>
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: "PT", "QC"

**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.
CA-50 OPERATOR’S MANUAL
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1. INTRODUCTION

The Sysmex® CA-50 is an 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-50 is used in a daily routine. The major elements of Chapter 1 are listed below.

**Instrument Overview**
Provides an overview of the CA-50’s functions.

**Analysis Procedure Overview**
Provides an overview of the analysis procedure, LCD screen display, and 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-50.
2. INSTRUMENT OVERVIEW

The CA-50 is an automated blood coagulation analyzer that can quickly analyze samples with a high degree of accuracy. The CA-50 can analyze samples using a Coagulation Method; and the analyzed data can be displayed on its LCD screen and printed by the built-in printer. The CA-50 also has some supplemental functions including quality control.

Figure 1-1: Overview of CA-50
3. OUTLINE OF OPERATION

The CA-50 performs an analysis by the following procedure.

Table 1-1: CA-50 Analysis Procedure

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check before turning ON power</td>
<td>Power ON</td>
</tr>
<tr>
<td></td>
<td>Self-check</td>
</tr>
<tr>
<td>Ready</td>
<td>Preparation for analysis</td>
</tr>
<tr>
<td></td>
<td>Work List</td>
</tr>
<tr>
<td></td>
<td>Press [START] key</td>
</tr>
<tr>
<td></td>
<td>Execution of sample incubation</td>
</tr>
<tr>
<td></td>
<td>Addition of reagents</td>
</tr>
<tr>
<td></td>
<td>Execution of analysis</td>
</tr>
<tr>
<td></td>
<td>Discard used reaction tubes</td>
</tr>
<tr>
<td>Ready</td>
<td>Power OFF</td>
</tr>
<tr>
<td>Operation after analysis completion</td>
<td></td>
</tr>
</tbody>
</table>

- Indicates actions performed by the operator.
- Indicates that the instrument is in the ready status. At this time, the detector LED of each channel will light up in green indicating that you can perform operations such as analysis and settings.
4. ANALYSIS PARAMETERS AND CALCULATION PARAMETERS

The CA-50 can 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 can be analyzed by the CA-50.

**Table 1-2: CA-50 Analysis Parameters and Calculation Parameters**

<table>
<thead>
<tr>
<th>Method</th>
<th>Analysis parameter</th>
<th>Calculation parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagulation Method</td>
<td>Prothrombin Time (PT)</td>
<td>Prothrombin Activity Percent</td>
</tr>
<tr>
<td></td>
<td>Activated Partial Thromboplastin Time (APTT)</td>
<td>Prothrombin Ratio</td>
</tr>
<tr>
<td></td>
<td>Fibrinogen (Fbg)</td>
<td>INR</td>
</tr>
<tr>
<td></td>
<td>Thrombotest (TTO)</td>
<td>Derived Fbg</td>
</tr>
<tr>
<td></td>
<td>Normotest (NT)</td>
<td>Fibrinogen Concentration</td>
</tr>
<tr>
<td></td>
<td>Thrombin Time (TT)</td>
<td>Thrombotest Activity Percent</td>
</tr>
<tr>
<td></td>
<td>Extrinsic Factor Deficiency Assay (II, V, VII, X)</td>
<td>Normotest Activity Percent</td>
</tr>
<tr>
<td></td>
<td>Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII)</td>
<td>Factor II Activity Percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor V Activity Percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor VII Activity Percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor VIII Activity Percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor IX Activity Percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor X Activity Percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor XI Activity Percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor XII Activity Percent</td>
</tr>
</tbody>
</table>

⚠️ **CAUTION** • If you analyze with a wrong reagent, correct analysis results will not be obtained.

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

Interpretation of APTT Abnormal Early Reaction.

- APTT results less than or equal to 20.0 seconds, APTT results with NC (No Coagulation), SC (Slight Coagulation) or CCE (Coag. Curve Error) error messages, or abnormally short APTT results may be caused by an abnormal early reaction.
- APTT results with an abnormal early reaction can be identified in the analysis data.

- If an APTT result less than or equal to 20.0 seconds is obtained, the following steps should be taken:
  1. Verify sample and reagent integrity along with maintenance procedures.
  2. Print out the Analysis data.
     See Chapter 4, Section 4: OUTPUTTING ANALYSIS RESULT and
     Chapter 10, Section 4.2: Built-In Printer Settings.
     Note that the stored analysis results will be deleted, when you start a
     next analysis on the same channel or you turn OFF the power or so
     on.
  3. Observe time in the “2%” position.
  4. If that time is equal to or less than 15 seconds, then an abnormal early
     reaction may have occurred.
  5. Re-analyze the sample.
  6. If result is the same, it should not be reported.
  7. Review the previous patient history to determine acceptability of
     patient results. Results of the other parameters considered, then make
     overall evaluation.
  8. Follow your laboratory’s alternate protocol.

- An error code may or may not be associated with this result.
- An abnormal early reaction rarely occurs.
- The CA-50 should be set up so that any APTT results of less than or
  equal to 20.0 seconds will have a message of <20.1 seconds on the print-
  out.
- To set up this function see Chapter 10, Section 3.4: Report Limit Settings
  and enter 20.1 for the APTT lower limit.
- Remember to change the Built-in Printer Settings back to “List” after review
  of the analysis data.
5. LCD SCREEN AND INPUT KEYS

5.1 LCD Screen

The instrument’s status, analysis results, and all other information are displayed on the CA-50’s LCD screen. The screen is capable of displaying 16 characters by 2 lines maximum.

Display position of the each analysis channel on the screen

<table>
<thead>
<tr>
<th>CH3</th>
<th>CH4</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH1</td>
<td>CH2</td>
</tr>
</tbody>
</table>

**Figure 1-2: Display position of the each analysis channel on the screen**

On the Analysis screen, the LCD screen is split into four parts to show the data of respective channels from 1 to 4. Analysis parameters are abbreviated into two characters as shown below:

- PT: PT
- AP: APTT
- Fg: Fbg
- TO: TTO
- NT: NT
- TT: TT
- F2: Factor II
- F5: Factor V
- F7: Factor VII
- F8: Factor VIII
- F9: Factor IX
- I0: Factor X
- I1: Factor XI
- I2: Factor XII

**Settings Screen**

<table>
<thead>
<tr>
<th>ID No. Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select CH(1-4)?</td>
</tr>
</tbody>
</table>

**Figure 1-3: Example of Settings Screen**

On the Settings screen, parameters to be set or selected are displayed on the upper and lower lines.
5.2 Input Keys

By using the input keys, you can perform each setting such as entering numerals and selecting various parameters.

![Input Keys](image)

**Figure 1-4: Input Keys**

**Table 1-3: Operation of Input Keys**

<table>
<thead>
<tr>
<th>Key</th>
<th>Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/PT</td>
<td>Press to input the number &quot;1&quot; or select &quot;PT&quot;.</td>
</tr>
<tr>
<td>2/APTT</td>
<td>Press to input the number &quot;2&quot; or select &quot;APTT&quot;.</td>
</tr>
<tr>
<td>3/Fbg</td>
<td>Press to input the number &quot;3&quot; or select &quot;Fbg&quot;.</td>
</tr>
<tr>
<td>4/TTO</td>
<td>Press to input the number &quot;4&quot; or select &quot;TTO&quot;.</td>
</tr>
<tr>
<td>5/NT</td>
<td>Press to input the number &quot;5&quot; or select &quot;NT&quot;.</td>
</tr>
<tr>
<td>6/TT</td>
<td>Press to input the number &quot;6&quot; or select &quot;TT&quot;.</td>
</tr>
<tr>
<td>7/IN</td>
<td>Press to input the number &quot;7&quot; or select &quot;intrinsic factor&quot;.</td>
</tr>
<tr>
<td>8/EX</td>
<td>Press to input the number &quot;8&quot; or select &quot;extrinsic factor&quot;.</td>
</tr>
<tr>
<td>9/PRINT</td>
<td>Press to input the number &quot;9&quot; or print a menu.</td>
</tr>
<tr>
<td>0/Λ</td>
<td>Press to input the number &quot;0&quot;, scroll a menu up, or switch to the previous data.</td>
</tr>
<tr>
<td>-/./V</td>
<td>Press to input a hyphen or a decimal point, scroll a menu down, or switch to the next data.</td>
</tr>
<tr>
<td>C</td>
<td>Press to clear inputted data or stop an error beep.</td>
</tr>
<tr>
<td>SELECT</td>
<td>Press to switch between Menu and Ready, cancel updated data (when confirmed), or return to the previous screen.</td>
</tr>
<tr>
<td>QC</td>
<td>Press to input &quot;QC&quot; (when inputting an ID number).</td>
</tr>
<tr>
<td>FEED</td>
<td>Press to feed paper.</td>
</tr>
<tr>
<td>ENTER</td>
<td>Press to set inputted data or execute updated data (when confirmed).</td>
</tr>
</tbody>
</table>

**CAUTION:** • When a key has two or more functions, the function will be changed over depending on the situation when the key is pressed.
6. PASSWORDS

Important programs are protected by a password so that the programs can be executed under the control of a supervisor.

When a menu that is protected by a password is to be executed, a Password Entry window will appear. To execute the menu, enter the preset password and press the [Enter] key.

For details on how to set the password, see Chapter 10, Section 5.4: Password Settings.

7. ALARMS

The CA-50 makes three types of alarm sounds.

1. Key Entry
   A short beep will sound each time an input key is pressed.

2. Reagent addition timing
   Two short beeps followed by a long beep will sound to let you know the timing of adding reagents.

   The time allowed for reagent addition is preset at 10 seconds as default; 5 seconds before and after the time of addition. If you wish to change the allowed time, see Chapter 10, Section 3.2: Test Protocol Settings.

   Table 1-4: Reagent Addition Timing Alarm

<table>
<thead>
<tr>
<th>Reagent addition allowed time (start)</th>
<th>5 seconds before</th>
<th>• • •</th>
<th>Reagent addition</th>
<th>• • •</th>
<th>Reagent addition allowed time (end)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two short beeps</td>
<td>No sound</td>
<td>A short beep</td>
<td>A long beep</td>
<td>A short beep</td>
<td>A long beep</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One beep per second</td>
<td>For 0.5 seconds</td>
<td>One beep per second</td>
<td>An error beep</td>
</tr>
</tbody>
</table>

   Allowed time for reagent addition

3. Error
   A long beep will sound when an error occurs on the instrument.
   The beep will continue to sound until the [C] key is pressed.
8. DETECTOR LED

The detector LED of each channel indicates the status as shown in the table below.

<table>
<thead>
<tr>
<th></th>
<th>During warming-up</th>
<th>Ready</th>
<th>During incubation</th>
<th>Reagent addition timing</th>
<th>During photo detection</th>
<th>Ready</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turns off</td>
<td>Lights up in green</td>
<td>Blinks in red</td>
<td>Blinks in green</td>
<td>Lights up in red</td>
<td>Lights up in green</td>
<td></td>
</tr>
</tbody>
</table>

9. PACKAGING

The CA-50 is thoroughly checked before it is shipped from the factory, and is carefully packaged to withstand shocks during shipment. After the CA-50 has been delivered, check the packaging. Make sure that the instrument is free of exterior damage. Your Sysmex service representative will unpack and install the instrument after delivery and will also set the initial settings.
10. INSTALLATION ENVIRONMENT

10.1 Installation and Relocation

The CA-50 is installed by your Sysmex Service representative. In case relocation becomes necessary after installation, see Appendix A: INSTALLATION to install the instrument correctly.

⚠️ WARNING ⚠️ When relocating the CA-50, be sure to wear rubber gloves. After the relocation, wash your hands with disinfectant solution. If your hands are contaminated with blood, infection by bacteria or the like can occur.

⚠️ CAUTION ⚠️ When relocating the CA-50, hold the instrument securely. If the instrument falls, you can get injured or the instrument can be damaged.

10.2 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.

![Figure 1-5: Plugs](image)


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

NOTE: • The number of power supply sockets required is 1.
10.3 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.
- Secure a place spacious enough for maintenance and service. Giving consideration to heat radiation by the instrument, provide at least 10 cm distance from the wall to the rear panel.

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

**Table 1-6: Instrument Dimensions**

<table>
<thead>
<tr>
<th>Width (mm)</th>
<th>Depth (mm)</th>
<th>Height (mm)</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>327</td>
<td>302</td>
<td>113</td>
<td>4.5</td>
</tr>
</tbody>
</table>

**Figure 1-6: Instrument Dimensions**

10.4 Installation Environment

- Use the instrument at an ambient temperature of 15°C - 35°C (optimum: 23°C).
- Use it at a relative humidity range of 30% - 85%.
- 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.
- Do not use in dusty areas.
11. INSTRUMENT SPECIFICATIONS

Analysis parameters/Calculation parameters
See Section 4: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS in this chapter.

Simultaneous Random Analysis of 4 Parameters
Random analysis is possible.

Required Sample
Prothrombin Time (PT): 50 µL
Activated Partial Thromboplastin Time (APTT): 50 µL
Fibrinogen (Fbg): 10 µL
Thrombotest (TTO): 20 µL
Normotest (NT): 10 µL
Thrombin Time (TT): 100 µL
Extrinsic Factor Deficiency Assay (II, V, VII, X): 5 µL
Intrinsic Factor Deficiency Assay (VIII, IX, XI, XII): 5 µL

Analysis Principles
Coagulation Method
1. 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. And measures the coagulation time.

2. 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%.

Range of Analysis
Fibrinogen Concentration
Can analyze from 50 mg/dL to 450 mg/dL.

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: 600 seconds for each parameter
Reproducibility

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

* The data above are variation coefficients for coagulation times (in seconds) or for the amount of change in activity% taken from 10 analyses of Dade Behring Ci-Trol Level 1 (control plasma), with the reagents below used.

- Thromboplastin•C plus
- Dade Behring Actin Activated Cephaloplastin Reagent
- 20 mM Calcium Chloride Solution
- Dade Behring Fibrinogen Determination Reagents
- Owren's Veronal Buffer
- CA Series Complex Factor TTO
- CA Series Complex Factor HPT
- Dade Behring Factor-deficient Plasma

Display
Displays characters on a liquid crystal display (LCD).

Printing
Permits graphic printing through a built-in printer. (Printer paper specification: F1-1, width: 58 mm)

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

Detector
Detector: 4 wells (Scattered light detector)

Incubator
Incubator: 5 wells

Reaction Tube Holder
Reaction tube holder: 8 wells

Temperature Control
Detector: 37°C±0.5°C
Incubator: 37°C±1°C
Applies when room temperature is within 15°C - 35°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).
INTRODUCTION

Quality Control
\( \bar{X} \) control (L-J control): 50 points \( \times \) 3 files, 14 parameters

Standard Curve
6 points, 14 parameters

Power
Rated voltage: 117 VAC\( \pm \)10\%, 230 VAC\( \pm \)15\%
Frequency: 50 Hz or 60 Hz
Power consumption: 90 VA or less
Temperature Compensation Required: Approx. 307 BTU/h (77 kcal/h)

Environmental Requirements
15°C - 35°C

Dimensions/Weight
Main Unit: 327 (W) \( \times \) 302 (D) \( \times \) 113 (H) mm; approx. 4.5 kg
Interpretation of APTT Abnormal Early Reaction.

- APTT results less than or equal to 20.0 seconds, APTT results with NC (No Coagulation), SC (Slight Coagulation) or CCE (Coag. Curve Error) error messages, or abnormally short APTT results may be caused by an abnormal early reaction.
- APTT results with an abnormal early reaction can be identified in the analysis data.
- If an APTT result less than or equal to 20.0 seconds is obtained, the following steps should be taken:

1. Verify sample and reagent integrity along with maintenance procedures.
2. Print out the Analysis data.
   - See Chapter 4, Section 4: OUTPUTTING ANALYSIS RESULT and Chapter 10, Section 4.2: Built-In Printer Settings.
   - Note that the stored analysis results will be deleted, when you start a next analysis on the same channel or you turn OFF the power or so on.
3. Observe time in the “2%” position.
4. If that time is equal to or less than 15 seconds, then an abnormal early reaction may have occurred.
5. Re-analyze the sample.
6. If result is the same, it should not be reported.
7. Review the previous patient history to determine acceptability of patient results. Results of the other parameters considered, then make overall evaluation.
8. Follow your laboratory’s alternate protocol.

- An error code may or may not be associated with this result.
- An abnormal early reaction rarely occurs.
- The CA-50 should be set up so that any APTT results of less than or equal to 20.0 seconds will have a message of <20.1 seconds on the print-out.
- To set up this function see Chapter 10, Section 3.4: Report Limit Settings and enter 20.1 for the APTT lower limit.
- Remember to change the Built-in Printer Settings back to “List” after review of the analysis data.
12. MENU TREE

Press the [SELECT] key.

1. Select Test
2. ID No. Entry
3. Display Data

Press the [Start] switch.

1. Select Test
2. Select File
3. Print
4. Delete a Point
5. Settings
6. Clear a File

1. Activity/Conc.
2. Ratio
3. INR
4. Dfbg

5. Standard Curve

1. Select Test
2. Input
3. Print
4. Settings
5. Clear

1. Activity/Conc.
2. Ratio
3. INR
4. Dfbg

5. Standard Curve

6. Settings

1. Meas. Settings
2. I/O Settings
3. System Setting
4. Print Settings

1. Temperature
2. Sensor
3. Key
4. Printer
5. Host Computer
6. LCD

7. Test Programs

The password has to be entered if it is set.
13. MAIN MENU

The Main Menu screen shows the menu for selecting and utilizing the functions provided with the CA-50.

When you press the [SELECT] key on the Ready screen, the Main Menu screen will appear. For details on the Ready screen, see Chapter 2, Section 3: TURNING ON THE POWER. You can scroll the menu up and down by using the [▲] and [▼] keys.

<table>
<thead>
<tr>
<th>MAIN MENU</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select Test</td>
<td>▲ ▼</td>
</tr>
<tr>
<td>2. ID No. Entry</td>
<td></td>
</tr>
<tr>
<td>3. Display Data</td>
<td>▲ ▼</td>
</tr>
<tr>
<td>4. QC</td>
<td></td>
</tr>
<tr>
<td>5. Standard Curve</td>
<td>▲ ▼</td>
</tr>
<tr>
<td>6. Settings</td>
<td></td>
</tr>
<tr>
<td>7. Test Programs</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1-7: Main Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the entry of ID numbers (ID No. Entry).
[3] key: Moves the screen to the display of detailed analysis results (Display Data).
[6] key: Displays the setting menu (Settings).
[7] key: Displays the test program menu (Test Programs).
[PRINT] key: Prints out the main menu.
[SELECT] key: Returns the screen to the Ready screen.
CHAPTER 2  ANALYSIS PREPARATION

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6. QUALITY CONTROL ...........................................................................2-7
7. SAMPLE PREPARATION .................................................................2-8
1. INTRODUCTION

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

Table 2-1: Analysis Flow Chart

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check visually before Turning ON the Power</td>
<td></td>
</tr>
<tr>
<td>Turn ON the Power</td>
<td></td>
</tr>
<tr>
<td>Prepare Reagents</td>
<td></td>
</tr>
<tr>
<td>Set Reaction Tubes and Reagents</td>
<td></td>
</tr>
<tr>
<td>Check Standard Curves</td>
<td></td>
</tr>
<tr>
<td>Run Quality Control</td>
<td></td>
</tr>
<tr>
<td>Prepare Samples</td>
<td></td>
</tr>
<tr>
<td>Make Work List</td>
<td></td>
</tr>
<tr>
<td>Analyze Samples</td>
<td></td>
</tr>
<tr>
<td>Start an Analysis</td>
<td>Refer to Chapter 3: SAMPLE ANALYSIS.</td>
</tr>
<tr>
<td>Add Reagents</td>
<td></td>
</tr>
<tr>
<td>Shutdown</td>
<td>All are explained in this chapter.</td>
</tr>
</tbody>
</table>
2. BEFORE TURNING ON THE POWER

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

1. **CA-50 Instrument Visual Check**
   Make sure that the power cord is securely plugged into the AC outlet. Also, check whether the used reaction tube is not left in the detector.

2. **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. Prepare extra paper when the remains of paper run short.

3. TURNING ON THE POWER

When you turn ON the power switch that is located on the right side, the instrument will automatically perform a self-check.

   (1) Turn ON the power switch.

   A self-check will automatically be performed. When the self-check is completed without finding any error, "OK" will be displayed on the screen and the built-in printer will output a test print.

   If an error occurs during the self-check, see Chapter 8: TROUBLESHOOTING.

   ![Figure 2-1: Self-Check Screen](image)

   ![Figure 2-2: Example of Test Print](image)

   When the self-check is completed, the detector and the incubator will be warmed up. During the warming-up, "warm" will be displayed on each channel of the screen.

   **NOTE:**
   - The analysis parameter that was used in the previous analysis is displayed on each channel.
Figure 2-3: Warming-Up Screen

The "warm" will disappear and the detector LED will light up in green one by one as soon as each channel completes the warming-up. It takes about 5 minutes to 30 minutes until the "warm" disappears.
This status is called "Ready." You can perform various operations such as analysis and settings on the channel that has entered the "Ready" status.

Figure 2-4: Ready Screen

If you press the [SELECT] key on this screen, the Main Menu screen will appear. For details on the Main Menu screen, see Chapter 1, Section 13: MAIN MENU.
4. REAGENT PREPARATION

4.1 Preparing the Reagents

Prepare the required volume of coagulation reagents and Owren’s Veronal buffer for the anticipated work load.

Table 2-2: Reagent Preparation

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reagent</th>
<th>Consumption/Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>PT Reagent</td>
<td>100 μL</td>
</tr>
<tr>
<td>APTT</td>
<td>APTT Reagent</td>
<td>50 μL</td>
</tr>
<tr>
<td></td>
<td>Calcium Chloride Solution</td>
<td>50 μL</td>
</tr>
<tr>
<td>Fbg</td>
<td>Thrombin Reagent</td>
<td>50 μL</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal Buffer</td>
<td>90 μL</td>
</tr>
<tr>
<td>TTO</td>
<td>Thrombotest Reagent</td>
<td>125 μL</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal Buffer</td>
<td>30 μL</td>
</tr>
<tr>
<td>NT</td>
<td>Normotest Reagent</td>
<td>125 μL</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal Buffer</td>
<td>40 μL</td>
</tr>
<tr>
<td>TT</td>
<td>Thrombin Time Reagent</td>
<td>50 μL</td>
</tr>
<tr>
<td>Extrinsic Factor</td>
<td>PT Reagent</td>
<td>100 μL</td>
</tr>
<tr>
<td>Deficient Assay</td>
<td>Factor-deficient Plasma</td>
<td>50 μL</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal Buffer</td>
<td>45 μL</td>
</tr>
<tr>
<td>Intrinsic Factor</td>
<td>APTT Reagent</td>
<td>50 μL</td>
</tr>
<tr>
<td>Deficient Assay</td>
<td>Calcium Chloride Solution</td>
<td>50 μL</td>
</tr>
<tr>
<td></td>
<td>Factor-deficient Plasma</td>
<td>50 μL</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal Buffer</td>
<td>45 μL</td>
</tr>
</tbody>
</table>

When you prepare reagents, take into account the analysis parameters and the number of samples to be analyzed.

### CAUTION:

- We recommend that you use the following pipettes and pipette chips to add plasma and dispense/add reagents.
- Pipette: Eppendorf reference 4910 (50 - 200 μL)
- Pipette chip: Eppendorf 300 μL chip

For details on the usage of the pipette and pipette chip, refer to the instruction manuals attached to them.
4.2 Setting the Reaction Tubes and Reagents

Set reaction tubes and reagents into the instrument.

(1) Set reaction tubes into the reaction tube holder. Prepare a sufficient number of reaction tubes beforehand.

![Figure 2-5: Setting the Reaction Tubes]

**CAUTION:**
- Be sure to use the specified reaction tube (SU-40).

(2) Dispense the reagents to be used into the sample cups, and set them into the incubator.

![Figure 2-6: Setting the Reagents]
ANALYSIS PREPARATION

**WARNING**

- Cap the sample cups that are set in the incubator if they are not used. If contaminants or dusts get in the reagent, or if the reagent evaporates, correct analysis results will not be obtained.
- Let the incubator incubate the reagents more than 10 minutes. If the incubation is insufficient, correct analysis results may not be obtained. As the reagent may deteriorate, do not use the APTT reagent incubated for 20 minutes or more and the other reagents incubated for 40 minutes or more.
- Do not replenish reagents. Correct analysis results may not be obtained.

**CAUTION:**

- Do not set the reagent of 2 mL or more in the incubator. The reagent will not reach the desired temperature.
- Be sure to use the specified sample cup (Uniflex Conical 4 mL or the equivalent).

5. **CHECKING THE STANDARD CURVES**

Before performing an analysis, print out standard curves and make sure that they are correctly set.

For the procedure to print out standard curves, see *Chapter 7, Section 5: PRINTING OUT THE STANDARD CURVE.*

**CAUTION:**

- If the standard curve is not set correctly, it is not possible to calculate the calculation parameters such as the PT %.

If the settings are incorrect, set them correctly referring to *Chapter 7: SETTING STANDARD CURVES.*
6. **QUALITY CONTROL**

To maintain reliable analysis data, it is necessary to implement quality control. With the CA-50, a quality control file number (QC1 - QC3) 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 6: QUALITY CONTROL*.

**Implementing Quality Control**

When performing a quality control analysis, dispense control material into a reaction tube. The procedure for a quality control analysis is the same as that for a sample analysis. For details, see *Chapter 3: SAMPLE ANALYSIS*.

1. Register the analysis parameter in the channel used for the analysis.

2. Press the [QC] key on the ID No. Entry screen, and input the ID number for quality control (any number from 1 to 3).

3. Dispense control material into a reaction tube and set it into the detector.


5. Add a reagent at the indicated timing, and close the pipette guide. The analysis will be performed, and the analysis data will be stored in a quality control file.

6. Print out a QC chart and check the status of analysis data.
7. SAMPLE PREPARATION

Prepare sample tubes containing plasma.

**NOTE:**
- When handling the sample, be sure to wear rubber gloves. After the operation is completed, wash your hands with disinfectant solution. Failure to do so can cause infection by bacteria.

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. Put only the centrifuged plasma into another test tube.

**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.
CHAPTER 3  SAMPLE ANALYSIS

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   3.2 Adding the Reagents ....................................................................... 3-8
   3.3 Registering and Analyzing the Next Sample ........................................... 3-11

4. SHUTDOWN .................................................................................... 3-12
1. INTRODUCTION

This chapter will explain the operating procedures for the order information registration and from the start of analysis to shutdown.

Table 3-1: Analysis Flow Chart

Refer to Chapter 2: ANALYSIS PREPARATION.

All are explained in this chapter.
2. WORK LIST

Register the analysis parameter and the sample ID number of each channel.

2.1 Selecting the Analysis Parameter

| NOTE: | • When the power is turned ON, the analysis parameter used in the previous analysis is displayed on each channel. |

(1) Press the [SELECT] key to enter the Main Menu screen.

```
MAIN MENU
1. Select Test
   \[ \[\[ \[\[ A \ V \]
2. ID No. Entry
3. Display Data
   \[ \[ \[ \[ A \ V \]
4. QC
5. Standard Curve
   \[ \[ \[ \[ A \ V \]
6. Settings
7. Test Programs
```

Figure 3-1: Main Menu Screen

(2) Press the [1] key on the Main Menu screen.
The Channel Selection screen will appear.

```
Select Test
Select CH(1-4)? 1
```

Figure 3-2: Channel Selection Screen

If you press the [SELECT] key, the display will return to the Main Menu screen (Figure 3-1).
(3) Input the channel number (any number from 1 to 4) on which you wish to select the analysis parameter, and press the [ENTER] key. However, when the replication measure mode is set (See Chapter 10, Section 3.6: Measure Mode & Sample Incubation Ready Check Settings.), select the channel number either 1 or 3. The Analysis Parameter Selection screen will appear. (The parameter set in the previous analysis is displayed.)

```
Select Test CH2
Test (PT-EX)? PT
```

**Figure 3-3: Analysis Parameter Selection Screen**

If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 3-2).

(4) Press the key for the desired parameter, and press the [ENTER] key. In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key. In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key. When you press the [IN] or [EX] key, the Factor Number Entry screen will appear. When you press any of the other keys, the display will return to the Channel Selection screen (Figure 3-2). Set the analysis parameter of the other channels in the same manner.

```
Select Test CH2
IN(8, 9, 11, 12)? 8
```

**Figure 3-4: Factor Number Entry Screen**

If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 3-2).

(5) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12. In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10. Then press the [ENTER] key. The display will return to the Channel Selection screen (Figure 3-2). Set the analysis parameter of the other channels in the same manner.
2.2 Registering the Sample ID Number

(1) Press the [SELECT] key to enter the Main Menu screen.

<table>
<thead>
<tr>
<th>MAIN MENU</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select Test</td>
</tr>
<tr>
<td>2. ID No. Entry</td>
</tr>
<tr>
<td>3. Display Data</td>
</tr>
<tr>
<td>4. QC</td>
</tr>
<tr>
<td>5. Standard Curve</td>
</tr>
<tr>
<td>6. Settings</td>
</tr>
<tr>
<td>7. Test Programs</td>
</tr>
</tbody>
</table>

Figure 3-5: Main Menu Screen


<table>
<thead>
<tr>
<th>ID No. Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select CH(1-4)?</td>
</tr>
</tbody>
</table>

Figure 3-6: Channel Selection Screen

If you press the [SELECT] key, the display will return to the Main Menu screen (Figure 3-5).

(3) Input the channel number (any number from 1 to 4) on which you wish to register the sample ID number, and press the [ENTER] key. The ID No. Entry screen will appear.

<table>
<thead>
<tr>
<th>ID No. Entry CH2</th>
</tr>
</thead>
<tbody>
<tr>
<td>123-456</td>
</tr>
</tbody>
</table>

Figure 3-7: ID No. Entry Screen

If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 3-6).
(4) Input the ID number, and press the [ENTER] key. The display will return to the Channel Selection screen (Figure 3-6). The sample ID number can be registered with up to 15 digits consisting of numerals and hyphens (-). The hyphens, however, cannot be used consecutively or as the first or last digits of the sample ID number.
When a quality control analysis is performed, press the [QC] key and input any number from 1 to 3.

**NOTE:**
- If you do not input a sample ID number after the power is turned ON, the number will be sequentially incremented from "1" in each analysis regardless of the channel or the analysis parameter.
- If a sample ID number is input, the number will be sequentially incremented from the ID number input last regardless of the channel or the analysis parameter.
- When a hyphen is used in the sample ID number, the subject of the automatic increment will be the digits after the hyphen. For example, when the sample ID number is "990601-99", the next number will be "990601-00."
- If "0" is input to the ID number, an external output will not be carried out. And, if "0", "QC1", "QC2", or "QC3" is input, the ID number will become only one time at the input without automatic incrementing.
3. SAMPLE ANALYSIS

When the detector LED is lit in green, you can perform an analysis on this channel. It is possible to perform analyses on multiple channels simultaneously.

The CA-50 has a function to turn off the detector LED indicating the Ready status and prevent an analysis from being started when the timings of reagent addition are expected to overlap one another.

---

**WARNING**

- Be sure to wear rubber gloves during the analysis. After the operation is completed, wash your hands with disinfectant solution. Failure to do so can cause infection by bacteria.
- Handle reaction tubes containing sample with extreme care in order to avoid any infection by bacteria.
  - When discarding used reaction tubes, take proper disposing steps as medical and infectious wastes.
- The total volume of blood and reagents must be in the range of 150 to 200 μL. If the volume exceeds this range, sample may spill out of the reaction tube when being mixed, resulting in infection by bacteria.

---

**CAUTION**

- Be careful not to spill blood or reagents into the detector. This may damage the instrument.
- Use the correct volume of blood and reagents. If the volume is improper, correct analysis results may not be obtained, or addition of reagents may not be detected. For the specific volume required for each analysis, see Chapter 9, Section 2.6: Analysis Flow.
- Use a new pipette chip each time. Replace the pipette chip with a new one even when you add the same reagent consecutively. If sample is contaminated with the other sample or reagent, correct analysis results will not be obtained.
- Be careful so that reagents or contaminants will not get in the reaction tube. Correct analysis results will not be obtained.
3.1 Start of Analysis

(1) Pipette plasma into a reaction tube and set it into the detector. At this time, push it into the bottom of the detector firmly.

![Setting Plasma](image)

Figure 3-8: Setting Plasma

(2) Press the [Start] switch. Incubation of plasma will start. The reagent to be added and the countdown of the remaining time before the reagent addition timing will be displayed on the screen. The detector LED will blink in red.

<table>
<thead>
<tr>
<th>PT</th>
<th>Fg</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP</td>
<td>PT 179</td>
</tr>
</tbody>
</table>

Figure 3-9: Display of Countdown

**CAUTION:**
- When you press the [Start] switch by mistake, you can cancel the analysis by pressing the [Start] switch again. However, the alarm sounds in this case, and stops the alarm by pressing the [C] key.
### 3.2 Adding the Reagents

When a reagent addition timing comes, an alarm will begin to sound and the detector LED will blink in green. The detailed operations of the alarm and the detector LED are as shown below:

**Table 3-2: Reagent Addition Timing Alarm**

<table>
<thead>
<tr>
<th>Reagent addition allowed time (start)</th>
<th>5 seconds before</th>
<th>• • •</th>
<th>Reagent addition</th>
<th>• • •</th>
<th>Reagent addition allowed time (end)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two short beeps</td>
<td>No sound</td>
<td>A short beep</td>
<td>A short beep</td>
<td>A long beep</td>
<td>A short beep</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One beep per second</td>
<td>For 0.5 seconds</td>
<td>One beep per second</td>
<td>An error beep</td>
</tr>
</tbody>
</table>

**Allowed time for reagent addition**

The time allowed for reagent addition is preset at 10 seconds as default; 5 seconds before and after the time of addition. If you wish to change the allowed time, see *Chapter 10, Section 3.2: Test Protocol Settings.*

**Table 3-3: Operation of Detector LED**

<table>
<thead>
<tr>
<th>During warming-up</th>
<th>Ready</th>
<th>During incubation</th>
<th>Reagent addition timing</th>
<th>During photo detection</th>
<th>Ready</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turns off</td>
<td>Lights up in green</td>
<td>Blinks in red</td>
<td>Blinks in green</td>
<td>Lights up in red</td>
<td>Lights up in green</td>
</tr>
</tbody>
</table>

(1) When the alarm begins to sound, take the reagent to be added with a pipette.

**CAUTION**

- When two or more reagents are set in the incubator, be careful not to mix up them. If an incorrect reagent is used, correct analysis results will not be obtained.
- Use the reagent incubated more than 10 minutes. If the incubation is insufficient, correct analysis results may not be obtained. Also, as the reagent may deteriorate, do not use the APTT reagent incubated for 20 minutes or more and the other reagents incubated for 40 minutes or more.
- Do not replenish reagents. Correct analysis results may not be obtained.
CAUTION: • We recommend that you use the following pipettes and pipette chips to pipette plasma and dispense/add reagents.
  • Pipette: Eppendorf reference 4910 (50 - 200 μL)
  • Pipette chip: Eppendorf 300 μL chip
For details on the usage of the pipette and pipette chip, refer to the instruction manuals attached to them.
• Use the pipette correctly calibrated.

(2) Add the reagent when a long beep sounds.
Add the reagent in a manner as to avoid bubbling the sample, while fixing the pipette chip to the pipette guide and applying the tip of the pipette chip to the inside wall of the reaction tube.

Figure 3-10: Adding the Reagent

⚠️ CAUTION • When you use multiple channels simultaneously, be careful not to mix up the detectors. If you add a reagent into an incorrect detector, correct analysis results will not be obtained.
CAUTION:

- Add the reagent to the reaction tube quickly after pipetting. However, handle the pipette gently when dispensing and slowly when pipetting.
- Add the reagent within the time allowed for the addition. If the reagent addition is not performed within the allowed time, an analysis error will occur.
- The pipette guide is designed for the use of the recommended pipette chip. If you use the other type of pipette chip, you may not be able to fix it properly and reagent addition may not be detected.
- When you add reagents, the tip of the pipette chip must be fixed in the area shown in Figure 3-10. If the tip is out of this area, reagent addition may not be detected.
- When you add reagents, the tip of the pipette chip must be in the area shown in the figure below. If the tip is out of this area, reagent addition may not be detected properly, and the sensor may detect the tip of the pipette chip as the reagent by mistake.

![Diagram](image)

- Do not add less than 50 µL of reagent. Reagent addition may not be detected properly.
- Do not add reagent when the volume of sample and reagent is 200 µL or more. Reagent addition may not be detected properly.

NOTE:

- You can prevent sample from bubbling by applying the tip of the pipette chip to the inside wall of the reaction tube.

When a reagent is added, mixing will start automatically, and the detector LED will light up in red. If the second reagent is required, the detector LED will blink in red and the countdown of the remaining time will appear again. Then go back to step (1) and add the reagent in the same manner. If the second reagent is not required, go to the next step.

(3) Close the pipette guide as soon as you add the reagent. Photo detection will start. ">>" will be displayed on the screen as the detection progresses.

![Display](image)

Figure 3-11: Display during Photo Detection
CAUTION:

- The pipette guide also serves as a lid to prevent disturbance light around the detector. If the stand is not closed within two seconds after the addition of reagent, an analysis error will occur. However, when you analyze the parameter for which the continuous addition of the reagent is necessary, it does not become an analysis error except at the last reagent addition.
- Do not open the pipette guide during photo detection. An analysis error will occur.

When the analysis is completed, the analysis parameter and analysis results will be displayed on the screen, and the detector LED will light up in green. For details on the data display, see Chapter 4: DISPLAY OF ANALYSIS RESULTS.

The analysis results can be outputted to the built-in printer or the host computer. For details on the settings of output, see Chapter 10, Section 4: I/O SETTINGS.

(4) Discard the used reaction tube.

WARNING

- Be sure to wear rubber gloves during the analysis. After the operation is completed, wash your hands with disinfectant solution. Failure to do so can cause infection by bacteria.
- Handle reaction tubes containing sample with extreme care in order to avoid any infection by bacteria.
- When discarding used reaction tubes, take proper disposing steps as medical and infectious wastes.

CAUTION:

- Close the pipette guide immediately after removing the used reaction tube. This will prevent the foreign object etc. being entered into the detector. Also, if the pipette guide is opened over 15 minutes, an error “Lid Open CH #” will occur.

3.3 Registering and Analyzing the Next Sample

When the analysis is completed at a certain channel, you can register the next sample and start an analysis even if the other channels are still in process. However, when the replication measure mode is selected, the registration and analysis of the next sample cannot be performed until both channels used in a pair complete the analysis.
4. **SHUTDOWN**

Check the status of the instrument, and then turn the power OFF.

**CAUTION:** • At the end of each day’s operations or after operating the instrument for 24 hours, perform daily maintenance. For details, see *Chapter 5: MAINTENANCE & SUPPLIES REPLACEMENT*. 
CHAPTER 4    DISPLAY OF ANALYSIS RESULT

1. INTRODUCTION ................................................................. 4-1
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   2.1 Displaying the Analysis Results ........................................ 4-1
   2.2 Printing Out the Analysis Results ...................................... 4-3
3. DISPLAYING DETAILED ANALYSIS RESULTS ........................... 4-5
4. OUTPUTTING ANALYSIS RESULTS ....................................... 4-7
1. INTRODUCTION

This chapter explains the method of displaying and outputting analysis results.

CAUTION: • The CA-50 stores only the last analysis results of each channel. Note that
the stored analysis results will be deleted in the following cases:
• When you change the analysis parameter.
• When you change the sample ID number.
• When you change the measure mode.
• When you start the next analysis on the same channel.
• When you turn OFF the power.

2. DISPLAYING AND PRINTING OUT ANALYSIS RESULTS

When an analysis is completed, the analysis parameter and the analysis results will be displayed
on the screen. They can be printed out by the built-in printer at the same time.

2.1 Displaying the Analysis Results

![Analysis Results Screen](image)

Analysis Parameter
The analysis parameter carried out on each channel is displayed.

Analysis Results
The analysis result of the preset data check parameter is displayed. For details on the data check
parameter settings, see Chapter 10, Section 3.3: Data Check Parameter & Mark Limit Settings.

NOTE: • When the replication measure mode is selected, the mean data of two
channels’ analysis results will be displayed. You can check the results of
each channel on the Display Data screen (see Chapter 4, Section 3:
DISPLAYING DETAILED ANALYSIS RESULTS).

![Analysis Results Screen in the Replication Measure Mode](image)
**Flag**
When the analysis results are judged to be abnormal, one of the flags shown below will appear on the left of the analysis results.

* : An error occurred, or data disparity exists between replication analysis results. (Priority: high)
> : Data exceeded the upper report limit. (Priority: middle)
< : Data exceeded the lower report limit. (Priority: middle)
+ : Data exceeded the upper mark limit. (Priority: low)
- : Data exceeded the lower mark limit. (Priority: low)

When two or more conditions are applicable, the flag of higher priority will be displayed.

The following figure shows the relation between the report limits and the mark limits. Note that this relation holds when the lower mark limit is smaller than the upper mark limit. For mark limits, it is possible that you set a smaller value (e.g. shorter time) as the upper limit and a larger value (e.g. longer time) as the lower limit. In this case, "+" will appear when the analysis results are smaller than the upper limit, and "-" will appear when the analysis results exceed the lower limit.

**Figure 4-3: Relation between Report Limits and Mark Limits**
2.2 Printing Out the Analysis Results

For printing out analysis results, there are three types of formats - list, graph, and analysis. For details on the setting of printout formats, see Chapter 10, Section 4.2: Built-In Printer Settings.

<table>
<thead>
<tr>
<th>Date &amp; time of analysis</th>
<th>09:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample ID number</td>
<td>123-456</td>
</tr>
<tr>
<td>Analysis parameter, coagulation time, and coagulation detection point</td>
<td>10.5 sec (50)</td>
</tr>
<tr>
<td>Activity percent</td>
<td>102.1 %</td>
</tr>
<tr>
<td>Ratio</td>
<td>0.98 -</td>
</tr>
<tr>
<td>INR</td>
<td>0.98 INR</td>
</tr>
<tr>
<td>DFbg</td>
<td>210.0 mg/dL</td>
</tr>
</tbody>
</table>

Figure 4-4: Printout Example (List)

<table>
<thead>
<tr>
<th>Date &amp; time of analysis</th>
<th>09:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature at the detector</td>
<td>37.0 °C</td>
</tr>
<tr>
<td>Sample ID number</td>
<td>123-456</td>
</tr>
<tr>
<td>Analysis parameter, coagulation time, and coagulation detection point</td>
<td>10.5 sec (50)</td>
</tr>
<tr>
<td>Activity percent</td>
<td>102.1 %</td>
</tr>
<tr>
<td>Ratio</td>
<td>0.98 -</td>
</tr>
<tr>
<td>INR</td>
<td>0.98 INR</td>
</tr>
<tr>
<td>DFbg</td>
<td>210.0 mg/dL</td>
</tr>
</tbody>
</table>

Figure 4-5: Printout Example (Graph)
Figure 4-6: Printout Example (Analysis)

*1: When there are errors in the analysis results, all the errors will be printed with messages.
   • For details on the errors, see Chapter 8, Section 3.3: Analysis Data Errors and Corrective Actions.

*2: This message will be printed when there is an abnormality in the coagulation curve.
   • In the case of mean data, "MEAN CH1&2" or "MEAN CH3&4" will be printed under the date. There is no coagulation curve and analysis data for mean data.
   • When the replication measure mode is selected, mean data and the data obtained on respective channels will be printed after the analysis is completed on two channels used in a pair.
3. DISPLAYING DETAILED ANALYSIS RESULTS

The Display Data screen displays detailed analysis results such as the results of all the calculation parameters selected.

(1) Press the [SELECT] key to enter the Main Menu screen.

```
MAIN MENU
1. Select Test
   ▴ V
2. ID No. Entry
3. Display Data
   ▴ V
4. QC
5. Standard Curve
   ▴ V
6. Settings
7. Test Programs
```

Figure 4-7: Main Menu Screen


```
Display Data
Select CH(1-4)?
```

Figure 4-8: Channel Selection Screen

If you press the [SELECT] key, the display will return to the Main Menu screen (Figure 4-7).
(3) Input the channel number (any number from 1 to 4) on which you wish to display detailed analysis results, and press the [ENTER] key.
The Display Data screen will appear.
You can scroll the screen up and down by using the [A] and [V] keys.

<table>
<thead>
<tr>
<th>ID No.</th>
<th>123-456</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>10.5 sec</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   The ID number of the channel selected and coagulation time will be displayed.

<table>
<thead>
<tr>
<th>ID No.</th>
<th>123-456</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>102.1 %</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   This display is available when the activity percent is selected as a calculation parameter.

<table>
<thead>
<tr>
<th>ID No.</th>
<th>123-456</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>0.98</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   This display is available when the ratio is selected as a calculation parameter.

<table>
<thead>
<tr>
<th>ID No.</th>
<th>123-456</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>0.98 INR</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   This display is available when the INR is selected as a calculation parameter.

<table>
<thead>
<tr>
<th>ID No.</th>
<th>123-456</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>210.0 mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   This display is available when the DFbg is selected as a calculation parameter.

<table>
<thead>
<tr>
<th>ID No.</th>
<th>123-456</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>CH2 E: 8 PH</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   Channel number, error code, and output flag will be displayed.
P: Data is not yet printed.
This will not be displayed when the data has been printed.
H: Data is not yet transmitted.
This will not be displayed when the data has been transmitted.
E: Error code

<table>
<thead>
<tr>
<th>ID No.</th>
<th>123-456</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT</td>
<td>CH2 37.0 C</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   Channel number and the temperature at the detector will be displayed.
In the case of mean data, this screen is not available.

Figure 4-9: Display Data Screen

- When the replication measure mode is selected, the screen will be scrolled in the order of mean data, channel 1 (or 3), and channel 2 (or 4) each time the [V] key is pressed. In this case, the same data will be displayed for both channel 1 (or 3) and channel 2 (or 4).
- When mean data is displayed, "m" will appear on the right of the analysis parameter. Also, the channel number in this case will be "1&2" or "3&4".
- If you press the [PRINT] key, the analysis results will be outputted to the designated device. For details on the settings of output, see Chapter 10, Section 4: I/O SETTINGS.
- If you press the [SELECT] key, the display will return to the Channel Selection screen (Figure 4-8).
- When the ID number consists of 11 digits or more, "ID No." will not be displayed. (Only the ID number will be displayed.)
4. OUTPUTTING ANALYSIS RESULTS

Output of analysis results will be performed automatically after the analysis is completed. If you wish to output the results again or when it was impossible to output them for some reason, you can output the data by the following procedure.

**CAUTION:**
- The CA-50 stores only the last analysis results of each channel. Note that the stored analysis results will be deleted in the following cases:
  - When you change the analysis parameter.
  - When you change the sample ID number.
  - When you change the measure mode.
  - When you start the next analysis on the same channel.
  - When you turn OFF the power.

(1) Press the [PRINT] key on the Display Data screen.
   When it is set to output the analysis results to the host computer, the Output Device Selection screen will appear.
   When this is not set, output to the built-in printer will start.

![Figure 4-10: Output Device Selection Screen](image)

If you press the [SELECT] key, the display will return to the Display Data screen (Figure 4-9).

(2) Select the desired output device.
   If you wish to select the built-in printer, press the [1] key; if the host computer, press the [2] key.

If you press the [1] key, the following screen will appear and the built-in printer will start printing out the analysis results.

![Figure 4-11: Printout Screen](image)

- If you press the [SELECT] key, the printout will be canceled and the display will return to the Output Device Selection screen (Figure 4-10).
- For details on the printout format, see Section 2.2: Printing Out the Analysis Results.
If you press the [2] key, the following screen will appear and the analysis results will be transmitted to the host computer.

![Sending]

![Quit:SELECT]

**Figure 4-12: Transmission Screen**

- If you press the [SELECT] key, the transmission will be canceled and the display will return to the Output Device Selection screen (Figure 4-10).
- For details on the settings of the host computer, see *Chapter 10, Section 4.3: Host Computer Settings and Appendix B.*
CHAPTER 5

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 reaction tube holder
  - Clean the incubator
  - Clean the pipette guide

• **Weekly Maintenance**
  - Clean the instrument
  - Cleaning by blower

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

• **Supplies Replacement**
  - Replace fuses
  - Replace printer paper
### CA-50 MAINTENANCE CHECKLIST

#### 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 reaction tube holder |     |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Clean the incubator       |     |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Clean the pipette guide   |     |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Signature                 |      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

#### WEEKLY MAINTENANCE/SUPPLIES REPLACEMENT

<table>
<thead>
<tr>
<th>Maintenance item</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean the instrument</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning by blower</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### AS-NEEDED MAINTENANCE/SUPPLIES REPLACEMENT

<table>
<thead>
<tr>
<th>Maintenance item</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
<th>Date/Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replace the fuses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Replace the printer paper</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. DAILY MAINTENANCE AND INSPECTION

3.1 Cleaning the Reaction Tube Holder, Incubator, and Pipette guide

If samples and/or reagents are contaminated with foreign matters, correct analysis results will not be obtained. Wipe off the reaction tube holder, incubator, and pipette guide after the operation is completed.

**WARNING**
- Before cleaning the reaction tube holder, incubator, and pipette guide, be sure to turn the power OFF and unplug the power cord. This is necessary to avoid the risk of electrical shock.
- Be sure to wear rubber gloves during the cleaning. After the cleaning is completed, wash your hands with disinfectant solution. If the instrument is contaminated with blood, infection by bacteria can occur.

1. Turn OFF the power and unplug the power cord.

2. Wipe off each part with a cloth that was moistened with water and wrung dry. When dirt is hard to remove, wipe off the instrument with a cloth that was moistened with water and a neutral detergent, and then wipe again with a soft, dry piece of cloth.

**CAUTION:**
- Never use any other cleaning solution than water and a neutral detergent. Otherwise, the surface coating may be damaged.
4. WEEKLY MAINTENANCE AND INSPECTION

4.1 Cleaning the Instrument

To maintain the instrument in good condition, it should be cleaned 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.
• Be sure to wear rubber gloves during the cleaning. After the cleaning is completed, wash your hands with disinfectant solution. If the instrument is contaminated with blood, infection by bacteria can occur.

(1) Turn OFF the power and unplug the power cord.

(2) Wipe off the dirt of the instrument surface with a cloth that was moistened with water and a neutral detergent, and then wipe again with a soft, dry piece of cloth.

(3) Remove the filter on the bottom surface. Wash it with water and dry it. Reinstall the filter on the instrument.

![Figure 5-1: Cleaning the Filter](image)

**CAUTION:** • Never use any other cleaning solution than water and a neutral detergent. Otherwise, the surface coating may be damaged.
4.2 Cleaning by Blower

Clean the detector and the built-in printer every week by using a blower brush provided in the supply part.

(1) Turn OFF the power and unplug the power cord.

(2) Remove the reagents placed in the incubator.

(3) Detach the brush from the end of a blower brush.

(4) Blow off dust on the surface of the instrument by using the blower with the pipette guide closed.

(5) Blow off dust of the outlet of the built-in printer.

(6) Open the pipette guide and remove the reaction tube in the detector. Blow off dust of the inside the detector hole with the blower. Blow the air approximately 20 times each channel. If a heavier dirt is expected, repeat blowing more.

Figure 5-2: Detaching the brush

Figure 5-3: Cleaning by blower
5. REPLACING SUPPLIES

5.1 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, pull out the two fuse holder caps on the rear face.

(3) Replace the fuses and attach the fuse holder caps to the instrument.

CAUTION • For continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

<table>
<thead>
<tr>
<th>Destination</th>
<th>Specification</th>
<th>Type</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>117V</td>
<td>F1 250V 0.8A</td>
<td>Time Lag</td>
<td>2</td>
</tr>
<tr>
<td>220 - 240V</td>
<td>F1 250V 0.4A</td>
<td>Time Lag</td>
<td>2</td>
</tr>
</tbody>
</table>
5.2 Replacing Printer Paper

When the built-in printer has run out of paper, replace it in the procedure below.

(1) Open the built-in printer cover.

(2) Remove the remained print paper and the paper roll core.

**CAUTION:**
- When you intend to remove a remained portion of the printer paper, remove the roll core from the paper roll, press the [FEED] key, and then pull the paper. At this time, pull the paper out in the direction to which the printer paper is ejected at an ordinary print operation.
- Do not pull out the paper while printing.

(3) Set a new printer paper roll, and insert the end of paper to the built-in printer.

![Figure 5-5: Setting a Printer Paper](image)

*Figure 5-5: Setting a Printer Paper*
MAINTENANCE & SUPPLIES REPLACEMENT

CAUTION:

• Insert the printer paper straight to the built-in printer. Otherwise, the paper may be caught or the life of the printer head may be shortened.
• Use a specified printer paper. Otherwise, print cannot be performed, or the paper may be caught.
  Specification: F1-1
• As for the printing side of the paper, insert the printer paper as shown in Figure 5-3.
• Do not make the printer paper detection sensor dirty.
  The presence of printing paper might not be able to be detected correctly when becoming dirty. Wipe off dirt with a soft and dry cloth.
• Do not replace the printer paper by the wet hand.
  It causes paper jam.

(4) Press the [FEED] key until the top of the printer paper comes out of the outlet.

CAUTION:

• When paper jam occurs while printing, turn OFF the power of the Main Unit, and remove the paper cutter by sliding it to the instrument rear side, and then remove the printer paper.
  When you install the paper cutter, push it until the click sound is heard according to the reversed procedure of removal.

5.3 Supply Parts List

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>904-0721-9</td>
<td>Reaction Tube SU-40</td>
<td></td>
</tr>
<tr>
<td>424-1251-0</td>
<td>Sample Cup Conical 4 mL  *1</td>
<td></td>
</tr>
<tr>
<td>921-0352-1</td>
<td>Printer Paper F1-1</td>
<td></td>
</tr>
<tr>
<td>266-5110-5</td>
<td>Fuse 250V 1A ST4-0.8A-N1 (N.Amer)</td>
<td>Main Unit, for 117V spec.</td>
</tr>
<tr>
<td>266-7132-4</td>
<td>Fuse S504 T0.4A-T</td>
<td>Main Unit, for 220V/240V specs.</td>
</tr>
<tr>
<td>369-5029-5</td>
<td>Indication Mark No. 1014  *2</td>
<td></td>
</tr>
<tr>
<td>665-8038-1</td>
<td>Filter CA-5D</td>
<td></td>
</tr>
<tr>
<td>421-9350-9</td>
<td>Blower Brush</td>
<td></td>
</tr>
</tbody>
</table>

*1 For the Sample Cup, Uniflex Conical 4 mL or the equivalent can be used.
*2 Indication Mark No. 1014 is a label on which the analysis parameter is printed, and be affixed on the incubator and/or around the detector etc.
CHAPTER 6 QUALITY CONTROL

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   1.3 QC Error Check ....................................................... 6-2

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1. INTRODUCTION

Quality control is implemented to ensure that highly reliable data is obtained over the long term and to constantly monitor the instrument condition to prevent inaccurate results from being reported.

The CA-50 analyzes control plasma and other samples (hereafter, quality control samples) and statistically manages the results.

1.1 Quality Control File

The CA-50 can maintain three quality control files (QC1 - QC3), with each file capable of saving up to 50 items of data. Up to 14 analysis parameters can be saved per file.

NOTE: • To enable simultaneous quality control of both the current and new samples when quality control sample lots are switched, quality control files QC1 and QC2 are used for current control, and the remaining QC3 file is used to evaluate the new samples.

1.2 Quality Control Analysis

A quality control analysis is performed using quality control samples in the same procedures as that for an ordinary analysis. The quality control file number (QC1 to QC3) is registered as the sample ID number. When the analysis is completed, it is automatically saved in the quality control file instructed by the ID number. (See Chapter 2, Section 6: QUALITY CONTROL.)

The two quality control methods listed below are available.

$\bar{x}$ control: Analyzes QC samples with setting of the replication measure mode, and uses the average value as control data.

L-J control: Analyzes QC samples with setting of the single measure mode, and uses the data as control data. 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.
• Change to the measure mode used usually after executing the quality control.
Here, the example for the quality control analysis is explained.

(1) Prepare two kinds of the quality control samples (normality and abnormality).

(2) Assign the ID number for a normal sample to QC1, and analyze PT, APTT, and Fbg respectively.

(3) Assign the ID number for an abnormal sample to QC2, and analyze PT, APTT, and Fbg respectively.

(4) Select QC1 and PT respectively in the Quality Control Menu screen by referring to Section 3: SELECTING THE QUALITY CONTROL FILE.

(5) Perform Section 4: PRINTING OUT THE QC CHART, and check the data by the Quality Control Menu screen.

(6) Perform (4) and (5) for APTT, Fbg, and also analyze PT, APTT, and Fbg for QC2 as well.

1.3 QC Error Check

To check quality control errors, you can use a Control Limit method.

Control Limit Method

Error checks are made based on control limits that are set (shown in the table below).

<table>
<thead>
<tr>
<th>Control Limit</th>
<th>Error Check Method/Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Flag</td>
<td>If a quality control analysis result exceeds this value, a QC error is generated.</td>
</tr>
<tr>
<td>Target</td>
<td>This is the target value for the quality control analysis.</td>
</tr>
<tr>
<td>Lower Flag</td>
<td>If a quality control analysis result is below this value, a QC error is generated.</td>
</tr>
</tbody>
</table>
2. QUALITY CONTROL MENU
2.1 Displaying the QC Chart

(1) Press the [SELECT] key to enter the Main Menu screen.

```
MAIN MENU
1. Select Test
   [ ] [ ]
2. ID No. Entry
3. Display Data
   [ ] [ ]
4. QC
5. Standard Curve
   [ ] [ ]
6. Settings
7. Test Programs
```

Figure 6-1: Main Menu Screen

The Quality Control Menu screen will appear.
You can scroll the screen up and down by using the [ ] and [ ] keys.

```
QC     QC1 PT
1. Select Test
   [ ] [ ]
2. Select File
3. Print
   [ ] [ ]
4. Delete a Point
5. Settings
   [ ] [ ]
6. Clear a File
```

Figure 6-2: Quality Control Menu Screen
Pressing the following key will select each menu function.

- **[1] key**: Moves the screen to the selection of quality control parameters (Select Test).
- **[2] key**: Moves the screen to the selection of quality control files (Select File).
- **[3] key**: Prints out a QC chart (Print).
- **[4] key**: Moves the screen to the deletion of quality control data (Delete a Point).
- **[5] key**: Moves the screen to the quality control settings (Settings).
- **[6] key**: Moves the screen to the deletion of quality control files (Clear a File).
- **[PRINT] key**: Prints out the quality control menu.
- **[SELECT] key**: Returns the screen to the main menu.

### 3. SELECTING THE QUALITY CONTROL FILE

#### 3.1 Selecting the Quality Control Parameter

Select the quality control parameter for which you wish to perform quality control. “PT” is selected as a default setting.

1. Press the `[1]` key on the Quality Control Menu screen.
   The Quality Control Parameter Selection screen will appear.

   ![Figure 6-3: Quality Control Parameter Selection Screen](image)

   If you press the `[SELECT]` key, the display will return to the Quality Control Parameter Selection screen (Figure 6-3).

2. Press the key for the desired parameter, and press the `[ENTER]` key.
   - In the case of an intrinsic factor assay (8, 9, 11, or 12), press the `[IN]` key.
   - In the case of an extrinsic factor assay (2, 5, 7, or 10), press the `[EX]` key.
   When you press the `[IN]` or `[EX]` key, the Factor Number Entry screen will appear.
   When you press any of the other keys, the display will return to the Quality Control Menu screen (Figure 6-2).

   ![Figure 6-4: Factor Number Entry Screen](image)

   If you press the `[SELECT]` key, the display will return to the Quality Control Parameter Selection screen (Figure 6-3).
(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12. In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10. Then press the [ENTER] key. The display will return to the Quality Control Menu screen (Figure 6-2).

### 3.2 Selecting the Quality Control File

Select the file for which you wish to perform quality control. “1” is selected as a default setting.


<table>
<thead>
<tr>
<th>Select File PT</th>
<th>File (1-3)? 1</th>
</tr>
</thead>
</table>

**Figure 6-5: Quality Control File Selection Screen**

If you press the [SELECT] key, the display will return to the Quality Control Menu screen (Figure 6-2).

(2) Input the file number (any number from 1 to 3) and press the [ENTER] key. The display will return to the Quality Control Menu screen (Figure 6-2).
4. PRINTING OUT THE QC CHART

You can print out the quality control data and the QC chart concerning the analysis parameters selected in Section 3.1: Selecting the Quality Control Parameter and the file selected in Section 3.2: Selecting the Quality Control File.

(1) Press the [3] key on the Quality Control Menu screen. The Printing screen will appear, and the quality control data will be printed out. If the printout is completed, the display will return to the Quality Control Menu screen (Figure 6-2).

![Figure 6-6: Printing Screen](image)

If you press the [SELECT] key, the printout will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

![Figure 6-7: Printout Example of Quality Control Data and QC Chart](image)

**NOTE:**
- "UL", "T", and "LL" shown in Figure 6-7 represent the followings:
  - UL: If the result of the quality control analysis exceeds this value, a quality control error will occur.
  - T: This is the target value for the quality control analysis.
  - LL: If the result of the quality control analysis is below this value, a quality control error will occur.
5. **DELETING THE QUALITY CONTROL DATA**

5.1 Deleting the Data

You can select and delete particular data from those concerning the analysis parameters selected in *Section 3.1: Selecting the Quality Control Parameter* and the file selected in *Section 3.2: Selecting the Quality Control File*.

**CAUTION:**

- Data that has been deleted cannot be recovered. Carefully verify before deleting data.


```
Delete QC1 Fbg
15/06 110.4mg/dL
```

**Figure 6-8: Deleting Data Selection Screen**

If you press the [SELECT] key, the deletion will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

2. Select the data that you wish to delete by using the [A] and [V] keys, and then press the [ENTER] key. The Deletion Confirmation screen will appear.

```
15/06 110.4mg/dL
Delete OK?
```

**Figure 6-9: Deletion Confirmation Screen**

If you press the [SELECT] key, the deletion will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

3. Press the [ENTER] key. The selected data will be deleted, and the display will return to the Quality Control Menu screen (Figure 6-2).
5.2 Deleting the File

You can delete all the data concerning the analysis parameters selected in *Section 3.1: Selecting the Quality Control Parameter* and the file selected in *Section 3.2: Selecting the Quality Control File*.

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

**NOTE:**
- All the data concerning the analysis parameter selected will be deleted. The data concerning the other parameters will remain.


   ![Image of File Confirmation Screen](Figure 6-10: File Confirmation Screen)

   If you press the [SELECT] key, the deletion will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

2. Press the [ENTER] key. The Deletion Confirmation screen will appear.

   ![Image of Deletion Confirmation Screen](Figure 6-11: Deletion Confirmation Screen)

3. Press the [ENTER] key. The file will be deleted, and the display will return to the Quality Control Menu screen (Figure 6-2).
6. QUALITY CONTROL SETTINGS

You can perform settings concerning the quality control over the analysis parameters selected in Section 3.1: Selecting the Quality Control Parameter and the file selected in Section 3.2: Selecting the Quality Control File.


![Control Parameter Selection Screen](image)

**Figure 6-12: Control Parameter Selection Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 6-16) will appear.

(2) Select the desired control parameter by using the [>] and [<] keys, and then press the [ENTER] key.

The control parameter will be switched in the order of “analysis parameter” (coagulation time), “Act.” (“Conc.” in the case of Fbg), “Ratio”, “INR”, and “DFbg” each time the [V] key is pressed. Note that only the parameters that have been selected as calculation parameters for the standard curve will be displayed. (See Chapter 7, Section 6: SETTING THE CALCULATION PARAMETERS.)

CAUTION: • When you change the control parameter, the saved quality control data will be deleted.

The Upper Limit Entry screen will appear.

![Upper Limit Entry Screen](image)

**Figure 6-13: Upper Limit Entry Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 6-16) will appear.

(3) Input an upper limit and press the [ENTER] key.

If you do not change the value, press the [ENTER] key only.

The Target Entry screen will appear.

![Target Entry Screen](image)

**Figure 6-14: Target Entry Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 6-16) will appear.
(4) Input a target and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Lower Limit Entry screen will appear.

![QC1 PT LL 10.1 sec](image)

**Figure 6-15: Lower Limit Entry Screen**

If you press the [ENTER] key, the display will return to the Control Parameter Selection screen (Figure 6-12).

(5) Input a lower limit and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Update Confirmation screen will appear.

![Save? Yes:ENTER No:SELECT](image)

**Figure 6-16: Update Confirmation Screen**

If you press the [SELECT] key, the update will be canceled and the display will return to the Quality Control Menu screen (Figure 6-2).

(6) Press the [ENTER] key.
The settings will be updated, and the display will return to the Quality Control Menu screen.

When the inputted upper limit is smaller than the lower limit, a setting error will occur.
Then an error message will appear on the screen and an alarm will sound.

![QC Setting Err](image)

**Figure 6-17: Error Notice Screen**

If you press the [C] key, the alarm will stop and the Upper Limit Entry screen (Figure 6-13) will appear. Then go back to step (3) and input the upper and lower limits again.

**NOTE:**
- “UL”, “Target”, and “LL” shown in Figures 6-13, 6-14 and 6-15 represent the followings:
  - **UL:** If the result of the quality control analysis exceeds this value, a quality control error will occur.
  - **Target:** This is the target value for the quality control analysis.
  - **LL:** If the result of the quality control analysis is below this value, a quality control error will occur.
CHAPTER 7 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 the coagulation time and dOD obtained by analysis.

**CAUTION** • The standard curve determines the accuracy of calculation parameters. Prepare proper standard curves for the reagents be used.

2. OBTAINING DATA FOR STANDARD CURVE

In order to obtain standard curve data, let the instrument analyze the sample whose activity percent or concentration has been determined beforehand.

The following are explained as an example of analyzing PT, Fbg, TTO, and NT respectively by four points.

**In the case of PT**

<table>
<thead>
<tr>
<th>Dilution Ratio</th>
<th>100 % (1/1)</th>
<th>50 % (1/2)</th>
<th>25% (1/4)</th>
<th>12.5 % (1/8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilution Method</td>
<td>Undiluted sample 1mL</td>
<td>500uL</td>
<td>500uL</td>
<td>500uL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>500uL Diluent</td>
<td>500uL Diluent</td>
<td>500uL Diluent</td>
</tr>
</tbody>
</table>

(1) Prepare 1 mL of sample whose activity percent has been determined.
(2) Mix the diluent (500 μL) and the sample (500 μL) to make 50% sample.
(3) Mix the diluent (500 μL) and the sample made in step (2) (500 μL), to make 25% sample.
(4) Mix the diluent (500 μL) and the sample made in step (3) (500 μL), to make 12.5% sample.
(5) Dispense 50 μL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(6) Input standard curve data based on the printed analysis results.
   For the method of inputting the data, see *Section 4: PREPARING THE STANDARD CURVE*.
(7) Print out the prepared standard curve for verification.
   For the method of printing out the standard curve, see *Section 5: PRINTING OUT THE STANDARD CURVE*. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.

**CAUTION:** • When you use commercially available calibrator plasma or a calibrator packed in a reagent kit, follow the instruction in the manual attached to it.
In the case of Fbg

<table>
<thead>
<tr>
<th>Dilution Ratio</th>
<th>200 % (2/1)</th>
<th>100 % (1/1)</th>
<th>50 % (1/2)</th>
<th>25 % (1/4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>200uL</td>
<td>500uL</td>
<td>500uL</td>
<td>500uL</td>
</tr>
<tr>
<td>Undiluted sample</td>
<td>Diluent</td>
<td>Diluent</td>
<td>Diluent</td>
<td>Diluent</td>
</tr>
</tbody>
</table>

(1) Prepare 200 µL of sample whose concentration has been determined.
(2) Mix the diluent (800 µL) and the sample (200 µL) to make 200% sample.
(3) Mix the diluent (500 µL) and the sample made in step (2) (500 µL), to make 100% sample.
(4) Mix the diluent (500 µL) and the sample made in step (3) (500 µL), to make 50% sample.
(5) Mix the diluent (500 µL) and the sample made in step (4) (500 µL), to make 25% sample.
(6) Dispense 100 µL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(7) Input standard curve data based on the printed analysis results. For the method of inputting the data, see Section 4: PREPARING THE STANDARD CURVE.
(8) Print out the prepared standard curve for verification. For the method of printing out the standard curve, see Section 5: PRINTING OUT THE STANDARD CURVE. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.
In the case of TTO

<table>
<thead>
<tr>
<th>Dilution Ratio</th>
<th>100 % (1/1)</th>
<th>50 % (1/2)</th>
<th>25 % (1/4)</th>
<th>12.5 % (1/8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilution Method</td>
<td>400uL</td>
<td>500uL</td>
<td>500uL</td>
<td>500uL</td>
</tr>
<tr>
<td></td>
<td>Undiluted sample</td>
<td>Diluent</td>
<td>Diluent</td>
<td>Diluent</td>
</tr>
</tbody>
</table>

(1) Prepare 400 μL of sample whose activity percent has been determined.
(2) Mix the diluent (600 μL) and the sample (400 μL) to make 100% sample.
(3) Mix the diluent (500 μL) and the sample made in step (2) (500 μL), to make 50% sample.
(4) Mix the diluent (500 μL) and the sample made in step (3) (500 μL), to make 25% sample.
(5) Mix the diluent (500 μL) and the sample made in step (4) (500 μL), to make 12.5% sample.
(6) Dispense 50 μL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(7) Input standard curve data based on the printed analysis results. For the method of inputting the data, see Section 4: PREPARING THE STANDARD CURVE.
(8) Print out the prepared standard curve for verification. For the method of printing out the standard curve, see Section 5: PRINTING OUT THE STANDARD CURVE. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.
In the case of NT

<table>
<thead>
<tr>
<th>Dilution Ratio</th>
<th>200 % (2/1)</th>
<th>100 % (1/1)</th>
<th>50 % (1/2)</th>
<th>25 % (1/4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undiluted</td>
<td>400μL</td>
<td>500μL</td>
<td>500μL</td>
<td>500μL</td>
</tr>
<tr>
<td>Diluent</td>
<td>600μL</td>
<td>500μL</td>
<td>500μL</td>
<td>500μL</td>
</tr>
</tbody>
</table>

(1) Prepare 400 μL of sample whose activity percent has been determined.
(2) Mix the diluent (600 μL) and the sample (400 μL) to make 200% sample.
(3) Mix the diluent (500 μL) and the sample made in step (2) (500 μL), to make 100% sample.
(4) Mix the diluent (500 μL) and the sample made in step (3) (500 μL), to make 50% sample.
(5) Mix the diluent (500 μL) and the sample made in step (4) (500 μL), to make 25% sample.
(6) Dispense 50 μL of sample for each dilution ratio into reaction tubes, and perform an analysis.
(7) Input standard curve data based on the printed analysis results.
   For the method of inputting the data, see Section 4: PREPARING THE STANDARD CURVE.
(8) Print out the prepared standard curve for verification.
   For the method of printing out the standard curve, see Section 5: PRINTING OUT THE STANDARD CURVE. If an abnormality is found in the standard curve, go back to step (1) and try the same procedure.

### 3. STANDARD CURVE MENU

(1) Press the [SELECT] key to enter the Main Menu screen.

```
MAIN MENU
1.Select Test  [✓]
2.ID No. Entry
3.Display Data  [✓]
4.QC
5.Standard Curve  [✓]
6.Settings
7.Test Programs
```

Figure 7-1: Main Menu Screen
(2) Press the [5] key on the Main Menu screen. The Standard Curve Menu screen will appear. You can scroll the menu up and down by using the [\( \wedge \)] and [\( \vee \)] keys.

```
STD         PT
1.Select Test
\[ \wedge \] [\( \vee \)]
2.Input
3.Print
\[ \wedge \] [\( \vee \)]
4.Settings
5.Clear
```

Figure 7-2: Standard Curve Menu Screen

Pressing the following key will select each menu function.

- [1] key: Moves the screen to the selection of analysis parameters (Select Test).
- [2] key: Moves the screen to the entry of standard curve data (Input).
- [3] key: Prints out the standard curve (Print).
- [4] key: Displays the calculation parameter setting menu (Settings).
- [5] key: Moves the screen to the deletion of the standard curve data (Clear).
- [PRINT] key: Prints out the standard curve menu.
- [SELECT] key: Returns the screen to the main menu.

**CAUTION:** You cannot use the [2], [3], and [5] keys when you have not selected calculation parameters in Section 6: SETTING THE CALCULATION PARAMETERS.
4. PREPARING THE STANDARD CURVE

Prepare a standard curve, based on the data obtained in Section 2: OBTAINING DATA FOR STANDARD CURVE.

4.1 Selecting the Analysis Parameter

Select the analysis parameter for which you wish to prepare the standard curve. "PT" is selected as a default setting.


![Select Test STD]

Test (PT-EX)? PT

Figure 7-3: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Standard Curve Menu screen (Figure 7-2).

(2) Press the key for the desired parameter, and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
When you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Standard Curve Menu screen (Figure 7-2).

![Select Test STD]

IN (8, 9, 11, 12)? 8

Figure 7-4: Factor Number Entry Screen

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 7-3).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Standard Curve Menu screen (Figure 7-2).
4.2 Inputting the Standard Curve Data

Input the following standard curve data concerning the parameter selected in Section 4.1: Selecting the Analysis Parameter. Items to be inputted will vary depending on the settings set in Section 6: SETTING THE CALCULATION PARAMETERS.

- Activity percent (concentration) and coagulation time:
  You can input data up to 6 points. Input 2 points at least.
- Normal:
  This is the value to calculate the ratio. This parameter is available when the ratio or the INR is selected as a calculation parameter.
- ISI:
  This is the value to calculate the INR. This parameter is available when the INR is selected as a calculation parameter.
- Standard concentration and dH:
  This is the value to calculate the DFbg. This parameter is available when the DFbg is selected as a calculation parameter.

**CAUTION:**
- If the ratio is not selected as a calculation parameter but the INR has been selected, the Normal Value Entry screen will appear. However, neither the display of the ratio nor the print of data are performed in this case.


<table>
<thead>
<tr>
<th>PT</th>
<th>100.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>STD1</td>
<td>12.5sec</td>
</tr>
</tbody>
</table>

**Figure 7-5: Activity Percent (Concentration) & Coagulation Time Entry Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.

(2) Input activity percent (concentration) and press the [ENTER] key. If you do not change the value, press the [ENTER] key only. Then input coagulation time and press the [ENTER] key. If you do not change the value, press the [ENTER] key only. Each time the [ENTER] key is pressed twice, the item will be switched in the order of "STD1", "STD2", "STD3", "STD4", "STD5", and "STD6". The values should be inputted in decreasing order of concentration, from STD1 to STD 6. When you input the value for STD6 and press the [ENTER] key, the Normal Value Entry screen (Figure 7-6) will appear depending on the calculation parameter settings. When none of these calculation parameters has been selected, the display will return to the screen to input the value for STD1. For default values, see Appendix B.
SETTING STANDARD CURVES

Figure 7-6: Normal Value Entry Screen

- This parameter will be displayed only when you have selected the ratio or the INR as a calculation parameter.
- If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.

CAUTION:
- Input is permitted to the decimal places shown below:
  - Activity %, mg/dL, IU, and time: One decimal place
  - g/L: Three decimal places
  - ISI: Two decimal places

(3) Input a normal value and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
Depending on the calculation parameter settings, either the ISI Entry (Figure 7-7) or the Standard Concentration & dH Entry screen (Figure 7-8) screen will appear. If neither of these calculation parameters has been selected, the display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).

Figure 7-7: ISI Entry Screen

- This parameter will be displayed only when you have selected the INR as a calculation parameter.
- If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.

(4) Input an ISI and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
Depending on the calculation parameter settings, the Standard Concentration & dH Entry screen will appear. If this parameter has not been selected, the display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).

Figure 7-8: Standard Concentration & dH Entry Screen

- This parameter will be displayed only when you have selected the DFbg as a calculation parameter.
- If you press the [SELECT] key, the Update Confirmation screen (Figure 7-9) will appear.
(5) Input the standard concentration and dH, and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).

CAUTION: • When you have inputted a wrong value, go back to the first step and input the value again.

(6) Press the [SELECT] key.
The Update Confirmation screen will appear.

Save? Yes:ENTER
No:SELECT

Figure 7-9: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Standard Curve Menu screen (Figure 7-2).

(7) Press the [ENTER] key.
The settings will be updated, and the display will return to the Standard Curve Menu screen (Figure 7-2).
If there is an error in the settings, an error message will appear on the screen and an alarm will sound.

STD Err PT

Figure 7-10: Error Notice Screen

If you press the [C] key, the alarm will stop and the display will return to the Activity Percent (Concentration) & Coagulation Time Entry screen (Figure 7-5).
5. PRINTING OUT THE STANDARD CURVE

Print out the content of standard curve settings for the parameter selected in Section 4.1: Selecting the Analysis Parameter.

(1) Press the [3] key on the Standard Curve Menu screen. The Printing screen will appear and the printout of the content of standard curve settings will start. The subject of the printout is limited to the calculation parameters selected in Section 6: SETTING THE CALCULATION PARAMETER. When the printout is completed, the display will return to the Standard Curve Menu screen (Figure 7-2).

Figure 7-11: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Standard Curve Menu screen (Figure 7-2).

Figure 7-12: Printout Example of Standard Curve
6. SETTING THE CALCULATION PARAMETERS

Set the calculation parameter for the analysis parameter selected in Section 4.1: Selecting the Analysis Parameter.

6.1 Calculation Parameter Setting Menu

If you press the [4] key on the Standard Curve Menu screen, the Calculation Parameter Setting Menu screen will appear. You can scroll the menu up and down by using the [>] and [<] keys.

Pressing the following key will select each menu function.
[1] key: Moves the screen to the setting of activity percent and concentration.
[2] key: Moves the screen to the setting of ratio.
[3] key: Moves the screen to the setting of INR.
[4] key: Moves the screen to the setting of DFbg. (Can be used in the case of PT.)
[PRINT] key: Prints out the calculation parameter setting menu.
[SELECT] key: Returns the screen to the standard curve menu.
6.2 Setting the Activity Percent and Concentration

Set whether to use the activity percent (concentration in the case of Fbg) as a calculation parameter.


![Figure 7-14: ON/OFF Selection Screen](image)

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-17) will appear.

2) Select whether to use the activity percent (concentration in the case of Fbg) by using the [▲] and [▼] keys, and then press the [ENTER] key. The display will be switched between "ON (use)" and "OFF (do not use)" each time the [▼] key is pressed. When "ON" is selected, the Unit Selection screen will appear.

![Figure 7-15: Unit Selection Screen](image)

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-17) will appear.

3) Select the desired unit by using the [▲] and [▼] keys, and press the [ENTER] key. The display will be switched in the order of "xxx.x %", "xxx.x mg/dL", "x.xxx g/L", "xx.xx –", and "x.xxx IU" each time the [▼] key is pressed. The Calculation Method Selection screen will appear.

![Figure 7-16: Calculation Method Selection Screen](image)

If you press the [ENTER] key, the display will return to the ON/OFF Selection screen (Figure 7-14).
(4) Select the desired calculation method by using the [A] and [V] keys, and press the [SELECT] key.
The display will be switched in the order of "Log. Pt. Pt", "Log. Regress", "Lin. Regress" each time the [V] key is pressed.
The Update Confirmation screen will appear.

Figure 7-17: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

(5) Press the [ENTER] key.
The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).
6.3 Setting the Ratio

Set whether to use the ratio as a calculation parameter.


```
PT   Ratio
     ON
```

**Figure 7-18: ON/OFF Selection Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-19) will appear.

(2) Select whether to use the ratio by using the [\] and [V] keys, and press the [ENTER] key.
The display will be switched between "ON (use)" and "OFF (do not use)" each time the [V] key is pressed.
The Update Confirmation screen will appear.

```
Save? Yes:ENTER
       No:SELECT
```

**Figure 7-19: Update Confirmation Screen**

If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

(3) Press the [ENTER] key.
The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).
6.4 Setting the INR

Set whether to use the INR as a calculation parameter.


```
PT   INR
ON
```

Figure 7-20: ON/OFF Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 7-22) will appear.

(2) Select whether to use the INR by using the [ ] and [ ] keys, and press the [ENTER] key. The display will be switched between "ON (use)" and "OFF (do not use)" each time the [ ] key is pressed. The Unit Selection screen will appear.

```
PT   INR
xx.xx  –
```

Figure 7-21: Unit Selection Screen

If you press the [ENTER] key, the display will return to the ON/OFF Selection screen (Figure 7-20).

(3) Select the desired unit by using the [ ] and [ ] keys, and press the [SELECT] key. The display will be switched between "xx.xx –" and "xx.xx INR" each time the [ ] key is pressed. The Update Confirmation screen will appear.

```
Save?  Yes:ENTER
No:SELECT
```

Figure 7-22: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

(4) Press the [ENTER] key. The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).
6.5 Setting the DFbg

Set whether to use the DFbg as a calculation parameter.


   PT DFbg
   ON

   **Figure 7-23: ON/OFF Selection Screen**

   If you press the [SELECT] key, the Update Confirmation screen (Figure 7-25) will appear.

2) Select whether to use the DFbg by using the [A] and [V] keys, and press the [ENTER] key. The display will be switched between "ON (use)" and "OFF (do not use)" each time the [V] key is pressed. The Unit Selection screen will appear.

   PT DFbg
   xxx.x mg/dL

   **Figure 7-24: Unit Selection Screen**

   If you press the [ENTER] key, the display will return to the ON/OFF Selection screen (Figure 7-23).

3) Select the desired unit by using the [A] and [V] keys, and press the [SELECT] key. The display will be switched between "xxx.x mg/dL" and "x.xxx g/L" each time the [V] key is pressed. The Update Confirmation screen will appear.

   **Figure 7-25: Update Confirmation Screen**

   If you press the [SELECT] key, the update will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

4) Press the [ENTER] key. The settings will be updated and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).
6.6 Printing Out the Calculation Parameter Settings

Print out the contents of the calculation parameter settings.

(1) Press the [5] key on the Calculation Parameter Setting Menu screen. The Printing screen will appear and printout of the calculation parameter settings will start. When the printout is completed, the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

![Figure 7-26: Printing Screen]

If you press the [SELECT] key, the printout will be canceled and the display will return to the Calculation Parameter Setting Menu screen (Figure 7-13).

![Figure 7-27: Printout Example of Calculation Parameter Settings]
7. DELETING THE STANDARD CURVE DATA

Delete the standard curve data concerning the analysis parameter selected in Section 4.1: Selecting the Analysis Parameter.

   The Deleting Data Confirmation screen will appear.

   STD PT
   Clear?

   Figure 7-28: Deleting Data Confirmation Screen

   If you press the [SELECT] key, the deletion will be canceled and the display will return to the Standard Curve Menu screen (Figure 7-2).

(2) Press the [ENTER] key.
   The Deletion Confirmation screen will appear.

   Clear? Yes:ENTER
   No:SELECT

   Figure 7-29: Deletion Confirmation Screen

(3) Press the [Enter] key.
   The data will be deleted and the display will return to the Standard Curve Menu screen (Figure 7-2).
CHAPTER 8  TROUBLESHOOTING

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1. INTRODUCTION

This chapter explains the error messages that are displayed by the CA-50, 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 Sysmex service representative for assistance.

This chapter will principally cover the content listed below.

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.

2. WHEN YOU SUSPECT AN ERROR

Table 8-1: Check Items When You Suspect an Error

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 1. Turning the power ON does not start the instrument. | • Is the power cord connected securely?  
• Is the fuse blown?  
Refer to Chapter 5, Section 5.1: Replacing Fuses.  
• 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 Appendix A, Section 7: Adjusting the LCD Brightness. |
| 4. An error occurs. | • Refer to Section 3: TROUBLESHOOTING BY ERROR MESSAGE in this chapter. |
3. TROUBLESHOOTING BY ERROR MESSAGE

3.1 Troubleshooting Guide

The errors that appear on the screen are classified as shown below.

Instrument Errors (in analysis mechanism, temperature adjustment, etc.)

- If an instrument error occurs, an error message will appear on the screen and an alarm will sound. To stop the alarm, press the [C] key.

**CAUTION:**

- When an error occurs, the alarm will keep sounding and the error message will be displayed on the screen until the [C] key is pressed.

- Analysis operation will stop when an instrument error occurs. Take corrective actions shown in this chapter.
  
  If the error is not corrected even after you have taken the prescribed corrective actions, contact your Sysmex service representative.

Analysis Data Errors

- If an analysis data error occurs, an error message will be printed on the printout of analysis results. When the printout by the graph or analysis format is selected, an error code (ERR xxx) will also be printed.
- "*" will be added to the data of sample on which an error occurs.
- Reanalysis is required for the parameter whose analysis was interrupted due to an instrument error, and for the parameter on which an analysis data error occurs.
### 3.2 Instrument Errors and Corrective Actions

#### Table 8-2: Instrument Errors and Corrective Actions

<table>
<thead>
<tr>
<th>Error Message</th>
<th>Probable Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBURAM Error (QC File)/ (Measurement)</td>
<td>An error occurred in the quality control data etc.</td>
<td>Check the quality control data. Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.</td>
</tr>
<tr>
<td>EEPROM Error (Service)/ (Settings)/ (STD)</td>
<td>There is an error in the settings.</td>
<td>Check the settings. Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.</td>
</tr>
<tr>
<td>HC ACK Code Error</td>
<td>ACK cannot be received from the host computer.</td>
<td>Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.</td>
</tr>
<tr>
<td>HC Communication Error</td>
<td>The communication with host computer is abnormal.</td>
<td>Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.</td>
</tr>
<tr>
<td>HC CTS Time Out</td>
<td>The host computer is not ready for receiving signals.</td>
<td>Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.</td>
</tr>
<tr>
<td>HC Off Line</td>
<td>The connection cable is disconnected. Host computer’s power is OFF.</td>
<td>Check that the cable is securely connected. Turn ON the host computer. Check the operation of the host computer. Re-output the data from the Display Data screen that displays detailed analysis results.</td>
</tr>
<tr>
<td>HC Reception Count Error</td>
<td>The reception of the NAK from the host computer exceeded the limit.</td>
<td>Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.</td>
</tr>
<tr>
<td>HC Transmission Count Error</td>
<td>The number of re-transmission to the host computer exceeded the limit.</td>
<td>Check the operation of the host computer and the condition of the connection cable. Re-output the data from the Display Data screen that displays detailed analysis results.</td>
</tr>
</tbody>
</table>
## Troubleshooting

<table>
<thead>
<tr>
<th>Error Message</th>
<th>Probable Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lid Open CH #</strong> *₁</td>
<td>The pipette guide was opened during analysis. Or, the pipette guide was not closed within two seconds after a reagent is added. Or, the pipette guide is opened in the Ready status over 15 minutes. (Excluding the operation in QC menu, Standard Curve menu, Settings menu and System Tests menu)</td>
<td>Discard the reaction tube in the detector and re-analyze the sample. Or, close the pipette guide.</td>
</tr>
<tr>
<td>Measurement Stop CH# *₁</td>
<td>The [Start] switch is pressed again until the analysis completion.</td>
<td>Analyze from the beginning again.</td>
</tr>
<tr>
<td>Paper Empty ---</td>
<td>Paper is not set in the printer or runs out.</td>
<td>Replenish paper.</td>
</tr>
<tr>
<td>Printer Error ---</td>
<td>The build-in printer clogged up.</td>
<td>Reset the paper in the printer.</td>
</tr>
<tr>
<td>QC Err++</td>
<td>Results of quality control analysis exceeded the upper limit.</td>
<td>Check control plasma and reagents.</td>
</tr>
<tr>
<td>QC Err-</td>
<td>Results of quality control analysis exceeded the lower limit.</td>
<td>Check control plasma and reagents.</td>
</tr>
<tr>
<td>QC Setting Err</td>
<td>Abnormal quality control setting is inputted.</td>
<td>Re-input a setting value.</td>
</tr>
<tr>
<td>RAM Error</td>
<td>The computer is faulty.</td>
<td>Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.</td>
</tr>
<tr>
<td>Reagent Err CH # *₁</td>
<td>Reagent was not added within the allowed time.</td>
<td>Discard the reaction tube in the detector and re-analyze the sample.</td>
</tr>
<tr>
<td>ROM Error</td>
<td>The program was not loaded successfully.</td>
<td>Turn OFF the power, wait a few seconds, and then turn it ON again. If the error recurs, contact your Sysmex service representative.</td>
</tr>
<tr>
<td>STD Err ## *₂</td>
<td>Abnormal standard curve data is inputted.</td>
<td>Re-input standard curve data, or obtain correct data by re-analysis.</td>
</tr>
<tr>
<td>Temperature Err (Reagent)</td>
<td>The temperature at the incubator was out of the control limit after “Ready”, or the incubator is faulty.</td>
<td>If the error recurs, contact your Sysmex service representative.</td>
</tr>
</tbody>
</table>

*₁: # shows the channel number (1 - 4) on which an error occurs.  
*₂: ## shows the name of the parameter in question.
3.3 Analysis Data Errors and Corrective Actions

Table 8-3: Analysis Data Errors and Corrective Actions

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Message</th>
<th>Probable Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERR 1</td>
<td>Temp Error Occur</td>
<td>The temperature at the incubator or detector was out of the control limit, or the incubator or detector is faulty.</td>
<td>See “Temperature Err” in Section 3.2: Instrument Errors and Corrective Actions.</td>
</tr>
</tbody>
</table>
| ERR 2      | Slight Coagulation       | Detected coagulation reaction is very weak. This error typically occurs if the sample is abnormal, e.g. low fibrinogen, or if a reagent problem exists. | The following steps should be taken:  
1) Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.  
2) Verify delivery of sample and reagent.  
3) Review the analysis data for clot formation. A weak clot formation may be due to an abnormally low fibrinogen level, factor deficiencies, or the presence of inhibitors.  
4) Re-analyze the sample.  
5) Upon repeating, if "Slight Coagulation" occurs again, review the previous patient history to determine acceptability of patient results.  
6) Results of the other parameters considered, then make overall evaluation. Follow your laboratory's alternate protocol.  
(When analysis parameter is APTT. *1) |
| ERR 4      | Analysis Time Over       | Coagulation was not completed within the prescribed detection time. The situation occurs when testing samples with prolonged clotting times. | Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc. And verify delivery of sample and reagent. When re-analyze the sample, if that given a same message again, the sample may not be capable of forming a firm clot. Review the previous patient history to determine acceptability of patient results. Results of the other parameters considered, then make overall evaluation. Follow your laboratory's alternate protocol. |

CAUTION • *1: When analysis parameter is APTT  
If the time in the “2%” position is equal to or less than 15 seconds, then an abnormal early reaction may be occurred. In addition, if re-analyzed result is the same, it should not be reported. Results of the other parameters considered, then make overall evaluation.  
See Chapter 1, Section 4: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS and refer to “Interpretation of APTT Abnormal Early Reaction”.

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Message</th>
<th>Probable Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| ERR 8      | Coag. Curve Error| Coagulation curve is unexpected fluctuation.  
1) Slope drops in areas.  
2) Slope is too steep in areas.  
3) Abnormality has occurred on the coagulation time for Fbg etc. due to air bubbles caused by cold buffer (Owren’s Veronal Buffer).  
4) The air bubbles mixed when the reagent was added to the reaction tube. | The following steps should be taken:  
1) Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.  
2) Verify delivery of sample and reagent.  
3) Review the analysis data for clot formation.  
4) Re-analyze the sample.  
5) Upon repeating, if “Coag. Curve Error” occurs again, review the previous patient history to determine acceptability of patient results.  
6) Results of the other parameters considered, then make overall evaluation. Follow your laboratory’s alternate protocol.  
(When analysis parameter is APTT. *1) |
| ERR 16     | Turbidity Level Over | Turbidity was too high to allow analysis. | Dilute and re-analyze. |
| ERR 32     | No Coagulation     | Coagulation was not detected. | The following steps should be taken:  
1) Check the sample for possible anticoagulant contamination, hemolysis, lipemia, etc.  
2) Verify delivery of sample and reagent.  
3) $dH \geq 10$: *2  
• Review the analysis data for clot formation. A weak clot formation may be due to an abnormally low fibrinogen level, factor deficiencies, or the presence of inhibitors.  
• Re-analyze the sample.  
• Review the previous patient history to determine acceptability of patient results.  
• Results of the other parameters considered, then make overall evaluation.  
• Follow your laboratory’s alternate protocol.  
(When analysis parameter is APTT. *1)  
$dH < 10$: *2  
• Review the original graph to determine if clotting occurred. (The analysis data will not print, if $dH < 10$)  
• Re-analyze the sample.  
• Upon repeating, if “No Coagulation” occurs again, review the previous patient history to determine acceptability of patient results.  
• Results of the other parameters considered, then make overall evaluation.  
• Follow your laboratory’s alternate protocol. |

**CAUTION**  
*1: When analysis parameter is APTT  
If the time in the “2%” position is equal to or less than 15 seconds, then an abnormal early reaction may be occurred. In addition, if re-analyzed result is the same, it should not be reported. Results of the other parameters considered, then make overall evaluation.  
See Chapter 1, Section 4: ANALYSIS PARAMETERS AND CALCULATION PARAMETERS and refer to “Interpretation of APTT Abnormal Early Reaction”.

**NOTE:**  
*2 For the procedure to observe $dH$: Amount of scattered light change in reactive process, see Chapter 4, Section 2.2: Printing Out Analysis Results.
<table>
<thead>
<tr>
<th>Error Code</th>
<th>Message</th>
<th>Probable Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERR 64</td>
<td>Analysis Failed</td>
<td>The pipette guide was opened during photo detection, or reagent was not added within the allowed time. Or, the analysis start switch was pressed again before analysis completion but after starting the analysis.</td>
<td>See &quot;Lid Open&quot;, &quot;Reagent Err&quot; and &quot;Measurement Stop&quot; in Section 3.2: Instrument Errors and Corrective Actions.</td>
</tr>
<tr>
<td>ERR100</td>
<td>Range Over</td>
<td>Variation of reaction curve is extremely high. This error message may indicate that the PT result was &lt;7 seconds, or the APTT result was &lt;15 seconds, or the Fbg result was &lt;3 seconds.</td>
<td>Check the sample, reagents and instrument condition. Review the analysis data for clot formation. If these conditions are acceptable, re-analyze the sample and review the previous patient history to determine acceptability of patient results. Results of the other parameters considered, then make overall evaluation. Follow your laboratory's alternate protocol.</td>
</tr>
</tbody>
</table>

**CAUTION:**
- When two or more errors occur simultaneously, the error code will be shown by the sum of error codes. (ERR 16, 32, and 64 can occur simultaneously only with the ERR 1, Temperature Error.) For example, when the Temperature Error and the Turbidity Level Over occur simultaneously, the error code to be displayed will be ERR 17.
4. INSTRUMENT CHECK

This section explains how to check the instrument to see that it is operating properly.

4.1 Test Program Menu

(1) Press the [SELECT] key to enter the Main Menu screen.

```
MAIN MENU
1. Select Test
2. ID No. Entry
3. Display Data
4. QC
5. Standard Curve
6. Settings
7. Test Programs
```

Figure 8-1: Main Menu Screen

The Test Program Menu screen will appear.
You can scroll the menu up and down by using the [A] and [V] keys.

```
Test Programs
1. Temperature
2. Sensor
3. Key
4. Printer
5. Host Computer
6. LCD
```

Figure 8-2: Test Program Menu Screen
Pressing the following key will select each menu function.

[1] key: Moves the screen to the display of temperatures (Temperature).
[2] key: Moves the screen to the sensor test (Sensor).
[3] key: Moves the screen to the key entry test (Key).
[4] key: Moves the screen to the built-in printer test (Printer).
[5] key: Moves the screen to the communication test (Host Computer).
[6] key: Moves the screen to the LCD screen test (LSD).
[PRINT] key: Prints out the test program menu.
[SELECT] key: Returns the screen to the main menu.

4.2 Display of Temperatures

Check the temperatures at the detector and the incubator. (Temperatures are shown in °C.)
When Ready status, the temperature of each channel’s detector is usually 37°C ± 0.5°C, and the
temperature of the incubator is 37°C ± 1°C.

(1) Press the [1] key on the Test Program Menu screen.
The Temperature Display screen will display the temperature at each channel’s detector.

```
3:37.0   4:37.0
1:37.0   2:37.0
```

**Figure 8-3: Temperature Display Screen 1**

(2) Press the [✓] key.
The screen will display the temperatures at the incubator and in the room.

```
Reagent:  37.0
Room     : 23.0
```

**Figure 8-4: Temperature Display Screen 2**

If you press the [SELECT] key, the display will return to the Test Program Menu screen
(Figure 8-2).
4.3 Sensor Test

Test the sensor that detects the closing and opening of the pipette guide, and the addition of reagents.


```
3:OP O 4:CL O
1:OP O 2:CL ●
```

*OP: Pipette guide is opened.*
*CL: Pipette guide is closed.*
*○: Addition of reagent is not detected.*
*●: Addition of reagent is detected.*

(2) Open and close each pipette guide, and check that the sensor correctly detects the closing and opening.

(3) Set a reaction tube in each channel and add 100 µL of Owren's Veronal Buffer with a pipette. Check that the sensor correctly detects the addition of Owren's Veronal Buffer. The display will change from "○" to "●", and the detector LED will change from green to red.

(4) Press the [Start] switch of each channel to activate the mixing motor.

(5) Press the [C] key to reset all channels. The display will change from "●" to "○", and the detector LED will change from red to green.

(6) Press the [SELECT] key. The detector LED will return to the original condition, and the display will return to the Test Program Menu screen (Figure 8-2).

**NOTE:**
*If you press the [▼] key on the Sensor Test screen, you can see the version of the program. To return to the previous screen, press the [▲] or the [▼] key.*

```
Ver. 00-01
```

Figure 8-6: Program Version Display Screen
4.4 Key Entry Test

Check the input keys to see that they are operating properly.


(2) Press any of the input keys. The name of the key pressed will be displayed on the lower line of the screen. However, when the [FEED] key is pressed, the name of the pressed key is not displayed on the screen but the paper feed of printer paper is carried out.

Figure 8-7: Key Entry Test Screen

If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

4.5 Built-in Printer Test

Print out dummy data and check the performance of the printer.

(1) Press the [4] key on the Test Program Menu screen. The Built-In Printer Test screen will appear, and a test printout will start. When the printout is completed, the display will return to the Test Program Menu screen (Figure 8-2).

Figure 8-8: Built-In Printer Test Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Test Program Menu screen (Figure 8-2).

Figure 8-9: Test Printout

(2) Check the printout.
4.6 Communication Test

Test the communication with the host computer.


| Data Text HC: ● | Send ? |

Figure 8-10: Communication Test Screen

CAUTION: • "●" in Figure 8-10 shows the status of the connection with the host computer (HC).
○: The host computer is ready for receiving signals.
●: The host computer is not ready for receiving signals.
   In this case, check the power of the host computer and the condition of the connection cable, and make them ready for communication.

If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

(2) Press the [ENTER] key.
The display will change from "Send?" to "Sending", and test text will be transmitted to the host computer. When the class B is selected, the CA-50 will wait for the response from the host computer.
When the transmission is completed, the display will change from "Sending" to "Send?". If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).

4.7 LCD Screen Test

Check the LCD screen to see that all the dots are intact.

The whole screen will be black for a test.

Figure 8-11: LCD Test Screen

(2) Check that all the dots are intact.
If you press the [SELECT] key, the display will return to the Test Program Menu screen (Figure 8-2).
CHAPTER 9  FUNCTIONAL DESCRIPTION

1. INTRODUCTION ................................................................. 9-1

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   2.1 Optical Detection Method (Scattered Light Detection Method) .............. 9-2
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   2.4 Standard Curve for Coagulation Method ............................................ 9-5
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   2.6 Analysis Flow ........................................................................ 9-6

3. ANALYSIS MECHANISM .......................................................... 9-10

4. INSTRUMENT COMPONENTS AND FUNCTIONS ................................... 9-11
   4.1 Front, Top, and Right Side ............................................................... 9-11
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1. INTRODUCTION

This chapter explains the coagulation detection principles and analysis flow in the CA-50.

Detection Principles
Explains the detection principles for Coagulation Method.

Analysis Flow
Describes the required sample volume and reagent volume for each analysis parameter.
2. DETECTION PRINCIPLES FOR COAGULATION METHOD

After a fixed quantity of blood plasma has been incubated 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 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-50 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 that is generated is received by a photodiode, which converts the light into electrical signals. These signals are stored and calculated by a microcomputer in order to find the coagulation time.

![Figure 9-1: Optical Detection System](image_url)
2.2 Blood Coagulation and Scattered Light Intensity

The relationship between blood coagulation and scattered light is described below.

Step 1: Add incubated reagent to plasma that has also been incubated 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-50 can record the blood coagulation process as the change in scattered light intensity and then output the coagulation curve.

---

**Figure 9-2: 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 if even 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 9-3: Determination of Coagulation Time](image-url)
2.4 Standard Curve for Coagulation Method

In general with regard to parameters whose coagulation detection principle is the Coagulation Method, a linear relationship exists between the time and activity percent (or concentration) when they are plotted on a log-log graph. The CA-50 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 9-4: Standard Curve for Coagulation Method](image)

By changing the settings, you can also select the following standard curve format:
1. Log-log linear approximation
2. Log-log polygonal line
3. Real number-real number linear approximation

2.5 Calculation of PT Ratio and INR Value

The CA-50 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.

\[
\text{PT ratio} = \frac{\text{PT coagulation time of sample plasma}}{\text{Normal PT value}}
\]

\[
\text{INR} = (\text{PT ratio})^{\text{ISI}}
\]
2.6 Analysis Flow

**CAUTION** • Follow the analysis flows shown below when performing the analyses. If the flow is not appropriate, the correct result cannot be obtained.
• When sample’s dilution magnification is changed, it is necessary to convert the analysis result. (High Fbg concentration, etc.)

- **PT Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>50 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>PT reagent</td>
<td>100 µL</td>
</tr>
</tbody>
</table>

Table 9-1: Sample/Reagent Volume - PT

![Figure 9-5: PT Flow](image)

- **APTT Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>50 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>APTT reagent</td>
<td>50 µL</td>
</tr>
<tr>
<td></td>
<td>Calcium Chloride Solution</td>
<td>50 µL</td>
</tr>
</tbody>
</table>

Table 9-2: Sample/Reagent Volume - APTT

![Figure 9-6: APTT Flow](image)
• **Fbg Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>10 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>Thrombin reagent</td>
<td>50 µL</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal buffer</td>
<td>90 µL</td>
</tr>
</tbody>
</table>

**Table 9-3: Sample/Reagent Volume - Fbg**

* Samples with high Fbg concentration are prepared with 5 µL of plasma and 95 µL of buffer for analysis. Samples with low Fbg concentration are prepared with dilution ratio of 1/5 (20 µL of plasma with 80 µL of buffer) for analysis. In this case, it is necessary to convert the analysis result.

**Figure 9-7: Fbg Flow**

• **TTO Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>20 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>TTO reagent</td>
<td>125 µL</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal buffer</td>
<td>30 µL</td>
</tr>
</tbody>
</table>

**Table 9-4: Sample/Reagent Volume - TTO**

**Figure 9-8: TTO Flow**
• **NT Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>10 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>NT reagent</td>
<td>125 µL</td>
</tr>
<tr>
<td></td>
<td>Owren's Veronal buffer</td>
<td>40 µL</td>
</tr>
</tbody>
</table>

| Table 9-5: Sample/Reagent Volume - NT |

![Flow diagram for NT Flow](image)

**Figure 9-9: NT Flow**

• **TT Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>100 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>Thrombin Time reagent</td>
<td>50 µL</td>
</tr>
</tbody>
</table>

| Table 9-6: Sample/Reagent Volume - TT |

![Flow diagram for TT Flow](image)

**Figure 9-10: TT Flow**
• **Extrinsic Factor Analysis Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>5 ( \mu )L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>PT reagent</td>
<td>100 ( \mu )L</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal buffer</td>
<td>45 ( \mu )L</td>
</tr>
<tr>
<td></td>
<td>Factor-deficient plasma</td>
<td>50 ( \mu )L</td>
</tr>
</tbody>
</table>

Table 9-7: Sample/Reagent Volume - Extrinsic Factor

![Extrinsic Factor Analysis Flow Diagram](image1)

Figure 9-11: Extrinsic Factor Analysis Flow

• **Intrinsic Factor Analysis Flow**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>Plasma</th>
<th>5 ( \mu )L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Volume</td>
<td>APTT reagent</td>
<td>50 ( \mu )L</td>
</tr>
<tr>
<td></td>
<td>Calcium Chloride Solution</td>
<td>50 ( \mu )L</td>
</tr>
<tr>
<td></td>
<td>Owren’s Veronal buffer</td>
<td>45 ( \mu )L</td>
</tr>
<tr>
<td></td>
<td>Factor-deficient plasma</td>
<td>50 ( \mu )L</td>
</tr>
</tbody>
</table>

Table 9-8: Sample/Reagent Volume - Intrinsic Factor

![Intrinsic Factor Analysis Flow Diagram](image2)

Figure 9-12: Intrinsic Factor Analysis Flow
3. ANALYSIS MECHANISM

The CA-50 employs units of the mechanical and electrical systems, and performs analysis according to the procedure described below.

1. The incubator warms (incubates) the reagent.

2. The sample-containing reaction tubes are warmed (incubated).

3. When the reagent is added, the addition is detected automatically, and the sample is agitated. Then detection of analysis starts.

4. In the detector block, coagulation reaction is detected through the change in scattered light.
4. INSTRUMENT COMPONENTS AND FUNCTIONS

4.1 Front, Top, and Right Side

![Figure 9-13: Front, Top, and Right Side View](image)

1. **Detector**
   - Analyzes samples.

2. **Pipette guide**
   - Used to hold the pipette chip when reagent is added and to cover the detector.
   - **WARNING**
     - Do not open the pipette guide during analysis and put your fingers or the like into it. Otherwise, you may get injured. When the pipette guide is opened during analysis, the alarm sounds, then the analysis stops.

3. **Built-in printer**
   - Prints analysis results and setting contents.
(4) **Power switch**  
Turns the power ON/OFF.

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Do not turn the power switch ON/OFF repeatedly in a short interval. If you do, it can cause the damage to the unit.</th>
</tr>
</thead>
</table>

(5) **measure mode LED**  
Indicates the measure modes (single measure mode [SINGLE], replication measure mode [DOUBLE]).

(6) **LCD screen**  
Displays analysis conditions, analysis results, and error messages.

(7) **Input key**  
Used to perform the operation and settings in the CA-50.

(8) **LCD brightness control knob**  
Turn this knob to adjust the brightness on the LCD screen.

(9) **Incubator**  
Warms (Incubates) the reagent in the sample cup.

(10) **Reaction tube holder**  
Used to set reaction tubes. Temperature control is not performed.

(11) **Detector LED**  
Indicates the timing to add reagents and the instrument's status.

(12) **Analysis start switch**  
Press this button to analyze samples.
4.2 Rear

Figure 9-14: Rear View

(1) Connector
Used to connect the host computer.

(2) Fuse
Two time-lag-type fuses are installed in this fuse holder. The rating will be different depending on the instrument specification as below.

<table>
<thead>
<tr>
<th>Specification</th>
<th>Part No.</th>
<th>Description</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>117VAC</td>
<td>266-5110-5</td>
<td>Fuse 250V1A ST-4-0.8A-N1 (N.Amer)</td>
<td>Time Lag</td>
</tr>
<tr>
<td>220/240VAC</td>
<td>266-7132-4</td>
<td>Fuse S504 T0.4A-T</td>
<td>Time Lag</td>
</tr>
</tbody>
</table>

**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 ratings.

(3) Power connector
Connects the provided power cord to supply power.
4.3 Bottom

Figure 9-15: Bottom View

(1) **Filter (Filter Media)**
Prevents dust from entering the instrument.
1. INTRODUCTION

System setup of the CA-50 will be performed by your Sysmex 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.

Measure Settings
Can preset the upper and lower limits for checking analysis results. Can also preset test protocols, measure modes, and other settings relating to analysis.

I/O Settings
Can preset the interface conditions for the host computer connected to the CA-50, and printout conditions for the built-in printer.

System Settings
Can preset parameters relating to the overall CA-50 system.
# 2. SETTING MENU

(1) Press the [SELECT] key to enter the Main Menu screen.

<table>
<thead>
<tr>
<th>MAIN MENU</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select Test</td>
</tr>
<tr>
<td>2. ID No. Entry</td>
</tr>
<tr>
<td>3. Display Data</td>
</tr>
<tr>
<td>4. QC</td>
</tr>
<tr>
<td>5. Standard Curve</td>
</tr>
<tr>
<td>6. Settings</td>
</tr>
<tr>
<td>7. Test Programs</td>
</tr>
</tbody>
</table>

![Figure 10-1: Main Menu Screen](image)

(2) Press the [6] key on the Main Menu screen. The Setting Menu screen will appear. You can scroll the menu up and down by using the [ísticas] and [Verdaderos] keys.

<table>
<thead>
<tr>
<th>Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Meas. Settings</td>
</tr>
<tr>
<td>2. I/O Settings</td>
</tr>
<tr>
<td>3. System Setting</td>
</tr>
<tr>
<td>4. Print Settings</td>
</tr>
</tbody>
</table>

![Figure 10-2: Setting Menu Screen](image)

Pressing the following key will select each menu function.

- [1] key: Displays the measure setting menu (Meas. Settings).
- [2] key: Displays the I/O setting menu (I/O Settings).
- [3] key: Displays the system setting menu (System Setting).
- [4] key: Prints out the contents of all the settings (Print Settings).
- [PRINT]key: Prints out the setting menu.
- [SELECT] key: Returns the screen to the main menu.
3. MEASURE SETTINGS

3.1 Measure Setting Menu

When you press the [1] key on the Setting Menu screen, the Measure Setting Menu screen will appear.
You can scroll the menu up and down by using the [A] and [V] keys.

![Figure 10-3: Measure Setting Menu Screen]

Pressing the following key will select each menu function.
[1] key: Displays the test protocol setting menu (Test Protocol).
[2] key: Displays the mark limit setting menu (Mark Limits).
[4] key: Displays the replication difference limit setting menu (Diff. Check).
[5] key: Moves the screen to the measure mode & sample incubation ready check settings (Measure Mode).
[6] key: Displays the conversion setting menu (Conversion).
[PRINT] key: Prints out the measure setting menu.
[SELECT] key: Returns the screen to the setting menu.
3.2 Test Protocol Settings

Set the test protocol (analysis procedure) for each analysis parameter.

⚠️ CAUTION ⚠️ If you change the test protocol (excluding the maximum detection time), correct analysis results may not be obtained. The change must be made on your own responsibility.

1. Test Protocol Setting Menu

When you press the [1] key on the Measure Setting Menu screen, the Test Protocol Setting Menu screen will appear. You can scroll the menu up and down by using the [A] and [V] keys.

Figure 10-4: Test Protocol Setting Menu Screen

Pressing the following key will select each menu function.

- [1] key: Moves the screen to the selection of analysis parameters (Select Test).
- [2] key: Moves the screen to the test protocol setting (Input).
- [3] key: Prints out the contents of the test protocol settings (Print).
- [PRINT] key: Prints out the test protocol setting menu.
- [SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter

Select the analysis parameter for which you wish to set the test protocol.


Figure 10-5: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

(2) Press the key for the desired parameter and press the [ENTER] key. The display will return to the Test Protocol Setting Menu screen (Figure 10-4).
3. Setting Test Protocol
Set a coagulation detection point (see Chapter 9, Section 2.3: Coagulation Point Detection Method (Percentage Detection Method), maximum detection time, and reagent addition allowed time (start and end).
See APPENDIX B, Section 2.4: Instrument Setting Parameters and Factory Default Settings for the settings of factory default.

NOTE: • For the intrinsic factor (IN) and the extrinsic factor (EX), only one test protocol can be set for each.

The Coagulation Detection Point Entry screen will appear.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>% End Point?</td>
<td>50%</td>
</tr>
</tbody>
</table>

Figure 10-6: Coagulation Detection Point Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(2) Input a coagulation detection point and press the [ENTER] key.
You can input the value in the range of 2 to 80%.
If you do not change the value, press the [ENTER] key only.
The Maximum Detection Time Entry screen will appear.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max time?</td>
<td>100sec</td>
</tr>
</tbody>
</table>

Figure 10-7: Maximum Detection Time Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(3) Input maximum detection time and press the [ENTER] key.
You can input the value in the range of 100 to 600 seconds for PT and Fbg, and 190 to 600 seconds for the other parameters.
If you do not change the value, press the [ENTER] key only.
The Sensitivity Selection screen will appear.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sense?</td>
<td>Low</td>
</tr>
</tbody>
</table>

Figure 10-8: Sensitivity Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.
(4) Select the desired sensitivity by using the [>] and [<] keys, and press the [ENTER] key. The display will be switched in the order of "High" and "Low" each time the [>] or [<] key is pressed. The First Reagent Addition Timing Entry screen will appear.

```
Protocol    PT
Reag1?      180sec
```

**Figure 10-9: First Reagent Addition Timing Entry Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(5) Input the timing of adding the first reagent within the range of 0 to 999, and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Allowed Time Starting Point Entry screen will appear.

```
Protocol    PT
Before?     5sec
```

**Figure 10-10: Allowed Time Starting Point Entry Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(6) Input how many seconds before the addition timing the allowed time should start within the range of 0 to 99, and press the [ENTER] key. See Chapter 3, Section 3.2: Adding the Reagents for the reagent addition allowed time.
If you do not change the value, press the [ENTER] key only.
The Allowed Time End Point Entry screen will appear.

```
Protocol    PT
After?      5sec
```

**Figure 10-11: Allowed Time End Point Entry Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-13) will appear.

(7) Input how many seconds after the addition timing the allowed time should end within the range of 0 to 99, and press the [ENTER] key.
If you do not change the value, press the [ENTER] key only.
The Second Reagent Addition Timing Entry screen will appear.

```
Protocol    PT
Reag2?      0sec
```

**Figure 10-12: Second Reagent Addition Timing Entry Screen**
INSTRUMENT SETUP

(8) Input the timing of adding the second reagent within the range of 0 to 999, and press the [ENTER] key.
   If you do not change the value, press the [ENTER] key only.
   When the second reagent is not required, check that the addition timing is displayed as "0". If any number except "0" is displayed, input "0" and press the [ENTER] key.
   The Allowed Time Starting Point Entry screen will appear.

(9) Input the reagent addition allowance time (Start) and (End) of the second reagent as well as above-mentioned (6) and (7).

(10) Press the [SELECT] key.
    The Update Confirmation screen will appear.

    ![Save? Yes:ENTER No:SELECT](image)

    **Figure 10-13: Update Confirmation Screen**

    If you press the [SELECT] key, the update will be canceled and the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

(11) Press the [ENTER] key.
    The settings will be updated and the display will return to the Test Protocol Setting Menu screen (Figure 10-4).
INSTRUMENT SETUP

4. Printing Out Test Protocol Settings

Print out the contents of the test protocol settings.

(1) Press the [3] key on the Test Protocol Setting Menu screen. The Printing screen will appear and the printout of the test protocol settings will start. When the printout is completed, the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

```
| Printing | Quit: SELECT |
```

**Figure 10-14: Printing Screen**

If you press the [SELECT] key, the printout will be canceled and the display will return to the Test Protocol Setting Menu screen (Figure 10-4).

```
15/06/1999 09:00
TEST PROTOCOL
APTT
  % End Point 50 %
  Maximum Time 190 sec
  Sensitivity Low
  Reagent1 60 sec
  Before 5 sec
  After 5 sec
  Reagent2 180 sec
  Before 5 sec
  After 5 sec

EX
  % End Point 50 %
  Maximum Time 190 sec
  Sensitivity Low
  Reagent1 180 sec
  Before 5 sec
  After 5 sec

The data of all parameters will be printed.
```

**Figure 10-15: Printout Example of Test Protocol Settings**
3.3 Data Check Parameter & Mark Limit Settings

Set the upper and lower limits to check for abnormal analysis results.
If analysis results exceed the preset normal range, either of the following mark limit flags will appear with the analysis results:
• +: Analysis results exceeded the upper mark limit.
• -: Analysis results exceeded the lower mark limit.

**NOTE:**

<table>
<thead>
<tr>
<th>Lower report limit</th>
<th>(Analysis range)</th>
<th>Upper report limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark Limit</td>
<td>(Normal range)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lower mark limit</td>
<td>Upper mark limit</td>
</tr>
</tbody>
</table>

- The above figure shows the relation between the mark limits and the report limits to be set in Section 3.4 Report Limit Settings. Note that the above relation holds when the lower mark limit is smaller than the upper mark limit. For mark limits, it is possible that you set a smaller value (e.g., shorter time) as the upper limit and a larger value (e.g., longer time) as the lower limit. In this case, "+" will appear when the analysis results are smaller than the upper limit, and "-" will appear when the analysis results are greater than the lower limit.

1. Mark Limit Setting Menu
When you press the [2] key on the Measure Setting Menu screen, the Mark Limit Setting Menu screen will appear.
You can scroll the menu up and down by using the [A] and [V] keys.

```
Mark Limits
1. Select Test
      A V
2. Input
3. Print
```

**Figure 10-16: Mark Limit Setting Menu Screen**

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the data check parameter and mark limit settings (Input).
[3] key: Prints out the contents of the mark limit settings (Print).
[PRINT] key: Prints out the mark limit setting menu.
[SELECT] key: Returns the screen to the measure setting menu.
2. **Selecting Analysis Parameter**
Select the analysis parameter for which you wish to set the mark limits.

The Analysis Parameter Selection screen will appear.

![Figure 10-17: Analysis Parameter Selection Screen](image)

If you press the [SELECT] key, the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

(2) Press the key for the desired parameter and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
If you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

![Figure 10-18: Factor Number Entry Screen](image)

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 10-17).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Mark Limit Setting Menu screen (Figure 10-16).

3. **Setting Data Check Parameter and Mark Limits**
Set the upper and lower limits to check for abnormal analysis results. Also, for each analysis parameter, select time or any of calculation parameters as a data check parameter to be used in checking analysis results.
When you set 0 or the same value for both of the upper and lower limits, data check against mark limits will not be performed.
The data check parameter set here will work as a data check parameter for report limits.

The Data Check Parameter Selection screen will appear.

![Figure 10-19: Data Check Parameter Selection Screen](image)

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-22) will appear.
(2) Select the desired data check parameter by using the [A] and [V] keys, and press the [ENTER] key. The display will be switched in the order of "analysis parameter" (coagulation time), "Act." ("Conc." in the case of Fbg), "Ratio", "INR", and "DFbg" each time the [V] key is pressed. Note that only the parameters that have been selected as the calculation parameters for standard curves will be displayed. The Lower Limit Entry screen will appear.

Mark Limits Fbg
- ? 100.0 mg/dL

Figure 10-20: Lower Limit Entry Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-22) will appear.

(3) Input a lower limit and press the [ENTER] key. If you do not change the value, press the [ENTER] key only. The Upper Limit Entry screen will appear.

Mark Limits Fbg
+ ? 400.0 mg/dL

Figure 10-21: Upper Limit Entry Screen

If you press the [ENTER] key, the display will return to the Data Check Parameter Selection screen (Figure 10-19).

(4) Input an upper limit and press the [ENTER] key. If you do not change the value, press the [ENTER] key only.


Save? Yes: ENTER
No: SELECT

Figure 10-22: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Mark Limit Setting Menu screen (Figure 10-16).

(6) Press the [ENTER] key. The settings will be updated and the display will return to the Mark Limit Setting Menu screen (Figure 10-16). Update is possible even when the inputted upper limit is smaller than the lower limit. However, in this case, "+" will appear with analysis results when the analysis results are smaller than the upper limit, and "-" will appear when the analysis results are greater than the lower limit.
4. Printing Out Mark Limit Settings
Print out the contents of the mark limit settings.

The Printing screen will appear and the printout of the mark limit settings will start. When
the printout is completed, the display will return to the Mark Limit Setting Menu screen
(Figure 10-16).

```
Printing
Quit: SELECT
```

Figure 10-23: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to
the Mark Limit Setting Menu screen (Figure 10-16).

```
15/06/1999 09:00
CHECK PARAMETER
PT    Act.  %
APTT  APTT  sec
Fbg   Conc. mg/dL
TTO   Act.  %
NT    Act.  %
TT    TT    sec
F8    Act.  %
F9    Act.  %
F11   Act.  %
F12   Act.  %
F2    Act.  %
F5    Act.  %
F7    Act.  %
F10   Act.  %

MARK LIMITS
-     +
PT    0.0 0.0 %
APTT  0.0 0.0 sec
Fbg   0.0 0.0 mg/dL
TTO   0.0 0.0 %
NT    0.0 0.0 %
TT    0.0 0.0 sec
F8    0.0 0.0 %
F9    0.0 0.0 %
F11   0.0 0.0 %
F12   0.0 0.0 %
F2    0.0 0.0 %
F5    0.0 0.0 %
F7    0.0 0.0 %
F10   0.0 0.0 %
```

Figure 10-24: Printout Example of Mark Limit Settings
3.4 Report Limit Settings

Set the upper and lower report limits to check for abnormal analysis results out of the preset analysis range.

If analysis results exceed the preset report limit range, the analysis results will be shown as follows:
• >: Upper limit: Analysis results exceeded the upper report limit.
• <: Lower limit: Analysis results exceeded the lower report limit.

For example, when the upper limit is set at 450 and analysis results exceed 450, the analysis results will be displayed as ">450". When the lower limit is set at 50 and analysis results are below 50, the analysis results will be displayed as "<50".

The data check parameter for report limits will be the same as that for mark limits. For details, see Section 3.3: Data Check Parameter & Mark Limit Settings

NOTE: • Report limits have precedence over mark limits.

1. Report Limit Setting Menu
You can scroll the menu up and down by using the [A] and [V] keys.

<table>
<thead>
<tr>
<th>Report Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select Test</td>
</tr>
<tr>
<td>2. Input</td>
</tr>
<tr>
<td>3. Print</td>
</tr>
</tbody>
</table>

Figure 10-25: Report Limit Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[PRINT] key: Prints out the report limit setting menu.
[SELECT] key: Returns the screen to the measure setting menu.
2. Selecting Analysis Parameter
Select the analysis parameter for which you wish to set the report limits.


![Figure 10-26: Analysis Parameter Selection Screen](image)

If you press the [SELECT] key, the display will return to the Report Limit Setting Menu screen (Figure 10-25).

(2) Press the key for the desired parameter and press the [ENTER] key. In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key. In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key. If you press the [IN] or [EX] key, the Factor Number Entry screen will appear. When you press any of the other keys, the display will return to the Report Limit Setting Menu screen (Figure 10-25).

![Figure 10-27: Factor Number Entry Screen](image)

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 10-26).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12. In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10. Then press the [ENTER] key. The display will return to the Report Limit Setting Menu screen (Figure 10-25).
3. **Setting Report Limits**

Set the upper and lower limits to check for abnormal analysis results out of the analysis range. When you set 0 or the same value for both of the upper and lower limits, data check against report limits will not be performed.


```
Report Lmts Fbg
< ? 50.0mg/dL
```

*Figure 10-28: Lower Limit Entry Screen*

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-30) will appear.

2. Input a lower limit and press the [ENTER] key. If you do not change the value, press the [ENTER] key only. The Upper Limit Entry screen will appear.

```
Report Lmts Fbg
> ? 450.0mg/dL
```

*Figure 10-29: Upper Limit Entry Screen*

If you press the [ENTER] key, the display will return to the Lower Limit Entry screen (Figure 10-28).

3. Input an upper limit and press the [ENTER] key. If you do not change the value, press the [ENTER] key only.


```
Save? Yes:ENTER
No:SELECT
```

*Figure 10-30: Update Confirmation Screen*

If you press the [SELECT] key, the update will be canceled and the display will return to the Report Limit Setting Menu screen (Figure 10-25).

5. Press the [ENTER] key. The settings will be updated and the display will return to the Report Limit Setting Menu screen (Figure 10-25). When the inputted upper limit is smaller than the lower limit, a setting error will occur and the Lower Limit Entry screen (Figure 10-28) will appear. Go back to step (2) and reenter report limits.
Print out the contents of the report limit settings.

The Printing screen will appear and the printout of the report limit settings will start. When
the printout is completed, the display will return to the Report Limit Setting Menu screen
(Figure 10-25).

![Figure 10-31: Printing Screen](image1)

If you press the [SELECT] key, the printout will be canceled and the display will return to
the Report Limit Setting Menu screen (Figure 10-25).

![Figure 10-32: Printout Example of Report Limit Settings](image2)
3.5 Replication Difference Limit Settings

Set the replication difference limit to check for disparate analysis results when the replication measure mode is selected. When the single measure mode is selected, the limit set here will be disabled. If the difference between the respective replication analysis results and their mean data exceeds the preset replication difference limit, “*” will appear on the left of the mean data.

1. Replication Difference Limit Setting Menu

When you press the [4] key on the Measure Setting Menu screen, the Replication Difference Limit Setting Menu screen will appear. You can scroll the menu up and down by using the [A] and [V] keys.

<table>
<thead>
<tr>
<th>Diff. Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select Test</td>
</tr>
<tr>
<td>[A] [V]</td>
</tr>
<tr>
<td>2. Input</td>
</tr>
<tr>
<td>3. Print</td>
</tr>
</tbody>
</table>

Figure 10-33: Replication Difference Limit Setting Menu Screen

Pressing the following key will select each menu function.

[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the setting of a replication difference limit (Input).
[3] key: Prints out the contents of the replication difference limit settings (Print).
[PRINT] key: Prints out the replication difference limit setting menu.
[SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter

Select the analysis parameter for which you wish to set the replication difference limit.


<table>
<thead>
<tr>
<th>Diff. Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test (PT-EX)? PT</td>
</tr>
</tbody>
</table>

Figure 10-34: Analysis Parameter Selection Screen

If you press the [SELECT] key, the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).
(2) Press the key for the desired parameter and press the [ENTER] key.
In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key.
In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key.
If you press the [IN] or [EX] key, the Factor Number Entry screen will appear.
When you press any of the other keys, the display will return to the Replication Difference
Limit Setting Menu screen (Figure 10-33).

![Figure 10-35: Factor Number Entry Screen](image)

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection
screen (Figure 10-34).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12.
In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10.
Then press the [ENTER] key.
The display will return to the Replication Difference Limit Setting Menu screen (Figure
10-33).

3. Setting Replication Difference Limit
Set the replication difference limit. When the limit is set at 0, data check against a replication
difference limit will not be performed. And, the replication difference limit is judged by the
analysis results of second count.

The Difference Limit Entry screen will appear.

![Figure 10-36: Difference Limit Entry Screen](image)

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-37) will appear.
(2) Input a replication difference limit and press the [ENTER] key. The difference limit to determine a replication analysis error must be based on the following formula:

\[
\text{Difference Limit} = \left( \frac{\text{Result of first or second analysis (second count)} - \text{Mean data (second count)}}{\text{Mean data (second count)}} \right) \times 100 
\]

If you do not change the value, press the [ENTER] key only. The Update Confirmation screen will appear.

Figure 10-37: Update Confirmation Screen

If you press the [SELECT] key, the update will be canceled and the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

(3) Press the [ENTER] key. The settings will be updated and the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

4. Printing Out Replication Difference Limit Settings

Print out the contents of the replication difference limit settings.

(1) Press the [3] key on the Replication Difference Limit Setting Menu screen. The Printing screen will appear and the printout of the replication difference limit settings will start. When the printout is completed, the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

Figure 10-38: Printing Screen

If you press the [SELECT] key, the printout will be canceled and the display will return to the Replication Difference Limit Setting Menu screen (Figure 10-33).

Figure 10-39: Printout Example of Replication Difference Limit Settings
3.6 Measure Mode & Sample Incubation Ready Check Settings

Select either the single measure mode or the replication measure mode. Also, it is possible to set the sample incubation ready check, which prevents an analysis from being started when the timings of reagent addition are expected to overlap one another.

**Single Measure Mode**

An analysis parameter and an ID number can be registered independently on each channel. When one channel completes an analysis, it is possible to register the next sample and start an analysis even if the other channels are still in process.

**Replication Measure Mode**

Perform analyses using two channels and calculate mean data from the data obtained by two channels. Channel 1 and 2, or channel 3 and 4 will be a pair. If you register an analysis parameter and an ID number on channel 1 or 3, the same settings will be applied to channel 2 or 4. The registration and analysis of the next sample cannot be started until both channels used in a pair complete the analysis.

**Sample Incubation Ready Check**

It is possible to set so as to prevent an analysis from being started when the timings of reagent addition are expected to overlap one another. In that case, the detector LED will turn off and an analysis will not start even if the [Start] switch is pressed. For example, as shown in Figure 10-40, when you try to analyze PT on multiple channels, the analysis on the second channel cannot be started for 20 seconds from the start of analysis on the first channel so as to avoid the overlap of reagent addition timings. The time in which the start of analysis is disabled is called waiting time. The waiting time when the same analysis parameter is analyzed on multiple channels will be the sum of the time allowed for reagent addition and reagent preparation time. The waiting time when different analysis parameters are analyzed simultaneously will vary depending on the condition of the overlap of reagent addition timings. If you change the allowed time and/or the reagent preparation time, the waiting time will change accordingly.

![Figure 10-40: Ready Check Mode](image-url)

| Measure Mode | Single |

**Figure 10-41: Measure Mode Setting Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-44) will appear.

(2) Select the desired measure mode by using the [△] and [▼] keys, and press the [ENTER] key. The display will be switched between "Single (single measure mode)" and "Double (replication measure mode)" each time the [△] or [▼] key is pressed. The Sample Incubation Ready Check Setting screen will appear.

| "Ready" Check | ON |

**Figure 10-42: Sample Incubation Ready Check Setting Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-44) will appear.

(3) Select whether to enable the check by using the [△] and [▼] keys, and press the [ENTER] key. The display will be switched between "ON (check)" and "OFF (do not check)" each time the [△] or [▼] key is pressed. The Reagent Preparation Time Entry screen will appear.

| Prepare Time | 0 sec |

**Figure: 10-43: Reagent Preparation Time Entry Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-44) will appear.
(4) Input the time required for preparing a reagent and press the [ENTER] key. You can input the value in the range of 0 to 99. If you do not change the value, press the [ENTER] key only. The display will return to the Measure Mode Setting screen (Figure 10-41).


![Save? Yes: ENTER
No: SELECT](Figure 10-44: Update Confirmation Screen)

If you press the [SELECT] key, the update will be canceled and the display will return to the Measure Setting Menu screen (Figure 10-3).

(6) Press the [ENTER] key. The settings will be updated changing the status of the measure mode LED as set, and the display will return to the Measure Setting Menu screen (Figure 10-3).
3.7 Conversion Settings

Set the constant values in the conversion formula for the coagulation time of each analysis parameter.
Set "a" (a constant) and "b" (Y-intercept) in the conversion formula "y = ax + b."

⚠️ CAUTION ⚠️ If you change the contents of the conversion formula, correct analysis results may not be obtained. The change must be made on your own responsibility.

1. Conversion Setting Menu
When you press the [6] key on the Measure Setting Menu screen, the Conversion Setting Menu screen will appear.
You can scroll the menu up and down by using the [▲] and [▼] keys.

![Figure 10-45: Conversion Setting Menu Screen](image)

Pressing the following key will select each menu function.
[1] key: Moves the screen to the selection of analysis parameters (Select Test).
[2] key: Moves the screen to the conversion setting (Input).
[3] key: Prints out the contents of the conversion settings (Print).
[PRINT] key: Prints out the conversion setting menu.
[SELECT] key: Returns the screen to the measure setting menu.

2. Selecting Analysis Parameter
Select the analysis parameter for which you wish to set the conversion formula.

The Analysis Parameter Selection screen will appear.

![Figure 10-46: Analysis Parameter Selection Screen](image)

If you press the [SELECT] key, the display will return to the Conversion Setting Menu screen (Figure 10-45).
(2) Press the key for the desired parameter and press the [ENTER] key. In the case of an intrinsic factor assay (8, 9, 11, or 12), press the [IN] key. In the case of an extrinsic factor assay (2, 5, 7, or 10), press the [EX] key. If you press the [IN] or [EX] key, the Factor Number Entry screen will appear. When you press any of the other keys, the display will return to the Conversion Setting Menu screen (Figure 10-45).

![Figure 10-47: Factor Number Entry Screen](image)

If you press the [SELECT] key, the display will return to the Analysis Parameter Selection screen (Figure 10-46).

(3) In the case of an intrinsic factor assay, input any of 8, 9, 11, and 12. In the case of an extrinsic factor assay, input any of 2, 5, 7, and 10. Then press the [ENTER] key. The display will return to the Conversion Setting Menu screen (Figure 10-45).

3. **Setting Conversion Formula**
Set the constant values in the conversion formula. You can input values in the range of -9.99 to 9.99 for both "a" and "b."


![Figure 10-48: Conversion Formula Entry Screen](image)

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-49) will appear.

(2) Input the value for "a" and press the [ENTER] key. If you do not change the value, press the [ENTER] key only.
(3) Input the value for "b" and press the [ENTER] key.
   If you do not change the value, press the [ENTER] key only.
   If you press the [SELECT] key, the Update Confirmation screen (Figure 10-49) will appear.

   ![Save? Yes:ENTER
   No:SELECT](Figure 10-49: Update Confirmation Screen)

   If you press the [SELECT] key, the update will be canceled and the display will return to
   the Conversion Setting Menu screen (Figure 10-45).

(4) Press the [ENTER] key.
   The settings will be updated and the display will return to the Conversion Setting Menu
   screen (Figure 10-45).

4. Printing Out Conversion Settings
   Print out the contents of the conversion settings.

   The Printing screen will appear and the printout of the conversion settings will start. When
   the printout is completed, the display will return to the Conversion Setting Menu screen
   (Figure 10-45).

   ![Printing
   Quit:SELECT](Figure 10-50: Printing Screen)

   If you press the [SELECT] key, the printout will be canceled and the display will return to
   the Conversion Setting Menu screen (Figure 10-45).

<table>
<thead>
<tr>
<th>15/06/1999</th>
<th>09:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATA CONVERSION</td>
<td></td>
</tr>
<tr>
<td>PT</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>APTT</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>Fbg</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>TTO</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>NT</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>TT</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F8</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F9</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F11</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F12</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F2</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F5</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F7</td>
<td>Y = 1.00X + 0.00</td>
</tr>
<tr>
<td>F10</td>
<td>Y = 1.00X + 0.00</td>
</tr>
</tbody>
</table>

   ![Figure 10-51: Printout Example of Conversion Settings](Sysmex CA-50 Operator's Manual -- Revised August 1999)
4. I/O SETTINGS

Set the interface conditions for the host computer connected to the CA-50, and printout
conditions for the built-in printer.

4.1 I/O Setting Menu

When you press the [2] key on the Setting Menu screen, the I/O Setting Menu screen will
appear.
You can scroll the menu up and down by using the [▲] and [▼] keys.

<table>
<thead>
<tr>
<th>I/O Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.Printer</td>
</tr>
<tr>
<td>[▲]</td>
</tr>
<tr>
<td>2.Host Computer</td>
</tr>
<tr>
<td>3.Print Settings</td>
</tr>
</tbody>
</table>

Figure 10-52: I/O Setting Menu Screen

Pressing the following key will select each menu function.
[1] key: Moves the screen to the built-in printer setting (Printer).
[2] key: Moves the screen to the host computer setting (Host Computer).
[PRINT] key: Prints out the I/O setting menu.
[SELECT] key: Returns the screen to the setting menu.

4.2 Built-In Printer Settings

Set the printout condition and printout format for the built-in printer.

The Auto Printout Selection screen will appear.

<table>
<thead>
<tr>
<th>Auto Print?</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
</tr>
</tbody>
</table>

Figure 10-53: Auto Printout Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-55) will
appear.
(2) Select the desired printout condition by using the [△] and [▼] keys, and press the [ENTER] key. The display will be switched between "All (Print out all analysis results when analysis is completed)" and "Err only (Print out analysis results only when an error occurs)" each time the [△] or [▼] key is pressed. The Printout Format Selection screen will appear.

<table>
<thead>
<tr>
<th>Print Format?</th>
<th>Graph</th>
</tr>
</thead>
</table>

**Figure 10-54: Printout Format Selection Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-55) will appear.

(3) Select the desired printout format by using the [△] and [▼] keys, and press the [ENTER] key. The display will be switched in the order of "List", "Graph", "Analysis", "AutoList", and "Auto" each time the [▼] key is pressed.

- **List**: Prints out the date of analysis, ID number, coagulation time, calculation data, channel number, and error message.
- **Graph**: Prints out a coagulation curve in addition to the contents of "List."
- **Analysis**: Prints out analysis data in addition to the contents of "Graph."
- **AutoList**: Prints out a "List" in the ordinary case. If there is an abnormality in the coagulation curve, print out an "Analysis" automatically.
- **Auto**: Prints out a "Graph" in the ordinary case. If there is an abnormality in the coagulation curve, print out an "Analysis" automatically.

(4) Press the [SELECT] key. The Update Confirmation screen will appear.

<table>
<thead>
<tr>
<th>Save?</th>
<th>Yes:ENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>No:SELECT</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 10-55: Update Confirmation Screen**

If you press the [SELECT] key, the update will be canceled and the display will return to the I/O Setting Menu screen (Figure 10-52).

(5) Press the [ENTER] key. The settings will be updated and the display will return to the I/O Setting Menu screen (Figure 10-52).
4.3 Host Computer Settings

Set the interface conditions for the host computer. Parameters that can be set are as shown below. For detailed data on the transmission from the host computer, see Appendix B.

Table 10-1: Host Computer Setting Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Selections</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connection</td>
<td>Yes/No</td>
<td>No</td>
</tr>
<tr>
<td>Baud rate</td>
<td>1200/2400/4800/9600 (bps)</td>
<td>2400</td>
</tr>
<tr>
<td>Character length</td>
<td>7/8 (bit)</td>
<td>7-bit</td>
</tr>
<tr>
<td>Stop bit</td>
<td>1/2 (bit)</td>
<td>1-bit</td>
</tr>
<tr>
<td>Parity bit</td>
<td>Even/Odd/None</td>
<td>Even</td>
</tr>
<tr>
<td>Interval</td>
<td>0/2/3/5/7/10/15 (sec.)</td>
<td>2</td>
</tr>
<tr>
<td>Class</td>
<td>Class A/Class B</td>
<td>Class B</td>
</tr>
</tbody>
</table>


![Host Connected?](Yes)

Figure 10-56: Connection Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(2) Select whether to output analysis results to the host computer by using the [A] and [V] keys, and press the [ENTER] key. The display will be switched between "Yes (Transmit analysis results to the host computer)" and "No (Do not transmit)" each time the [A] or [V] key is pressed. The Baud Rate Selection screen will appear.

![Baud Rate?](2400 bps)

Figure 10-57: Baud Rate Selection Screen

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.
(3) Select the desired baud rate by using the [▲] and [▼] keys, and press the [ENTER] key. The display will be switched in the order of "1200", "2400", "4800", and "9600" each time the [▼] key is pressed. The Character Length Selection screen will appear.

![Char. Length?](7bit)

**Figure 10-58: Character Length Selection Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(4) Select the desired character length by using the [▲] and [▼] keys, and press the [ENTER] key. The display will be switched between "7" and "8" each time the [▲] or [▼] key is pressed. The Stop Bit Selection screen will appear.

![Stop Bit?](1bit)

**Figure 10-59: Stop Bit Selection Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(5) Select the desired stop bit by using the [▲] and [▼] keys, and press the [ENTER] key. The display will be switched between "1bit" and "2bit" each time the [▲] or [▼] key is pressed. The Parity Bit Selection screen will appear.

![Parity Bit?](Even)

**Figure 10-60: Parity Bit Selection Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.
(6) Select the desired parity bit by using the [\textasciicircum] and [\textasciitilde] keys, and press the [ENTER] key. The display will be switched in the order of "Even", "Odd", and "None" each time the [\textasciitilde] key is pressed. The Interval Selection screen will appear.

![Interval Selection Screen](Figure 10-61)

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-63) will appear.

(7) Select the desired interval by using the [\textasciicircum] and [\textasciitilde] keys, and press the [ENTER] key. The display will be switched in the order of "0", "2", "3", "5", "7", "10", and "15" each time the [\textasciitilde] key is pressed. The Class Selection screen will appear.

![Class Selection Screen](Figure 10-62)

If you press the [ENTER] key, the display will return to the Connection Selection screen (Figure 10-56).

(8) Select the desired class by using the [\textasciicircum] and [\textasciitilde] keys, and press the [SELECT] key. The display will be switched between "ClassA (One-way transmission to the host computer)" and "ClassB (Receive the response from the host computer for each text)" each time the [\textasciicircum] or [\textasciitilde] key is pressed. The Update Confirmation screen will appear.

![Update Confirmation Screen](Figure 10-63)

If you press the [SELECT] key, the update will be canceled and the display will return to the I/O Setting Menu screen (Figure 10-52).

(9) Press the [ENTER] key. The settings will be updated and the display will return to the I/O Setting Menu screen (Figure 10-52).
4.4 Printing Out I/O Settings

Print out the contents of the I/O settings.

(1) Press the [3] key on the I/O Setting Menu screen. The Printing screen will appear and the printout of the I/O settings will start. When the printout is completed, the display will return to the I/O Setting Menu screen (Figure 10-52).

![Printer Quit:SELECT](Figure 10-64: Printing Screen)

If you press the [SELECT] key, the printout will be canceled and the display will return to the I/O Setting Menu screen (Figure 10-52).

<table>
<thead>
<tr>
<th>15/06/1999</th>
<th>09:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOST COMPUTER</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>Connected</td>
</tr>
<tr>
<td>Baud Rate</td>
<td>2400bps</td>
</tr>
<tr>
<td>Char. length</td>
<td>7bit</td>
</tr>
<tr>
<td>Stop bit</td>
<td>1bit</td>
</tr>
<tr>
<td>Parity bit</td>
<td>Even</td>
</tr>
<tr>
<td>Interval</td>
<td>2sec</td>
</tr>
<tr>
<td>Class</td>
<td>Class B</td>
</tr>
</tbody>
</table>

| PRINTER |       |
| Auto Print | ALL |
| Format | Graph |

![Figure 10-65: Printout Example of I/O Settings](Figure 10-65: Printout Example of I/O Settings)
INSTRUMENT SETUP

5. SYSTEM SETTINGS

Set the parameters relating to the overall CA-50 system.

5.1 System Setting Menu

When you press the [3] key on the Setting Menu screen, the System Setting Menu screen will appear. You can scroll the menu up and down by using the [▲] and [▼] keys.

![System Settings Menu Screen]

Pressing the following key will select each menu function.
- [1] key: Moves the screen to the date setting (Date).
- [2] key: Moves the screen to the time setting (Time).
- [3] key: Moves the screen to the password setting (Password).
- [PRINT] key: Prints out the system setting menu.
- [SELECT] key: Returns the screen to the setting menu.

5.2 Date Settings

Set the present date.

(1) Press the [1] key on the System Setting Menu screen. The Date Setting screen will appear.

![Date Setting Screen]

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-68) will appear.
(2) Input the present date and press the [ENTER] key.
The year must be inputted in 4 digits. If you input values out of the allowed range, the display will return to the original date even if the [ENTER] key is pressed.
The Update Confirmation screen will appear.

```
Save?  Yes:ENTER
No:SELECT
```

**Figure 10-68: Update Confirmation Screen**

If you press the [SELECT] key, the update will be canceled and the display will return to the System Setting Menu screen (Figure 10-66).

(3) Press the [ENTER] key.
The setting will be updated and the display will return to the System Setting Menu screen (Figure 10-66).

### 5.3 Time Settings

Set the present time.

The Time Setting screen will appear.

```
Time?
13:00:00
```

**Figure 10-69: Time Setting Screen**

If you press the [SELECT] key, the Update Confirmation screen (Figure 10-70) will appear.

(2) Input the present time and press the [ENTER] key.
The time must be inputted in the form of "hour:minute:second" and in the 24-hour form. If you input values out of the allowed range, the display will return to the original time even if the [ENTER] key is pressed.
The Update Confirmation screen will appear.

```
Save?  Yes:ENTER
No:SELECT
```

**Figure 10-70: Update Confirmation Screen**

If you press the [SELECT] key, the update will be canceled and the display will return to the System Setting Menu screen (Figure 10-66).

(3) Press the [ENTER] key.
The setting will be updated and the display will return to the System Setting Menu screen (Figure 10-66).
5.4 Password Settings

Set the password.

**NOTE:**
- Important menus can be protected by a password to ensure that they are executed under the management of the person responsible for the instrument. When you try to use the menu that is protected by a password, the Password Entry screen will appear. If you enter the preset password and press the [ENTER] key, the menu will appear on the screen. For the menus that can be protected by a password, see Chapter 1, Section 12: MENU TREE.

(1) Press the [3] key on the System Setting Menu screen. When a password has already been set, the Password Entry screen will appear. If you have not set a password, the Password Setting screen will appear. In this case, go to step (3).

Enter Password: ********

![Figure 10-71: Password Entry Screen](image)

If you press the [SELECT] key, the display will return to the System Setting Menu screen (Figure 10-66).

**NOTE:**
- The password displayed on the screen is masked with "*" symbols. This is for preventing other people from seeing the password when it is being entered.

(2) Input the present password and press the [ENTER] key. If the inputted password is correct, the Password Setting screen will appear.

Set Password? ********

![Figure 10-72: Password Setting Screen](image)

If you press the [SELECT] key, the display will return to the System Setting Menu screen (Figure 10-66).
(3) Input a new password and press the [ENTER] key. The password must consist of numerals from 0 to 9 and can extend up to 12 digits.

**NOTE:**
- When you do not wish to use a password, you can delete a password by pressing the [C] key, [0] key and then [ENTER] key.

Input the new password once again for verification and press the [ENTER] key. If the inputted password is correct, the Update Confirmation screen will appear. If it is incorrect, the Update Confirmation screen will not appear. You will be required to input the new password again.

```
Save? Yes:ENTER
    No:SELECT
```

**Figure 10-73: Update Confirmation Screen**

If you press the [SELECT] key, the update will be canceled and the display will return to the System Setting Menu screen (Figure 10-66).

(4) Press the [ENTER] key. The password will be updated and the display will return to the System Setting Menu screen (Figure 10-66).
6. PRINTING OUT ALL SETTINGS

Print out the contents of all the settings excluding the password. This also includes standard curve settings and quality control settings.


![Printout Confirmation Screen](Figure 10-74)

If you press the [SELECT] key, the display will return to the Setting Menu screen (Figure 10-2).

(2) Press the [ENTER] key. The Printing screen will appear and the printout of the settings will start. When the printout is completed, the display will return to the Setting Menu screen (Figure 10-2).

![Printing Screen](Figure 10-75)

If you press the [SELECT] key, the printout will be canceled and the display will return to the Setting Menu screen (Figure 10-2).

**NOTE:** Before starting the printout, confirm that a sufficient amount of paper is set in the printer. It takes about 13 minutes to print.
APPENDIX A: INSTALLATION

1. INTRODUCTION .......................................................... A-1
2. CHECK BEFORE INSTALLATION ...................................... A-1
3. INSTALLATION SPACE ................................................ A-2
4. CHANGING THE INSTALLATION DIRECTION OF PIPETTE GUIDE .... A-3
5. INSTALLING THE FILTER ............................................. A-5
   6.1 Connecting the Power Cord ........................................ A-5
   6.2 Connecting the Connection Cord .................................. A-7
7. ADJUSTING THE LCD BRIGHTNESS ................................. A-8
8. SETTING A PRINTER PAPER .......................................... A-9
1. INTRODUCTION

This product is a clinical analysis instrument. Your Sysmex 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-50 is free from external flaws and check the quantity of the supply parts.

Table A-1: CA-50 Unpacking Check List

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
<th>Quantity</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>923-8092-8</td>
<td>Power Cord No. 15 (C-2/N. Amer)</td>
<td>1 0 0</td>
<td></td>
</tr>
<tr>
<td>265-4731-5</td>
<td>Power Cord No.CS-30091</td>
<td>0 1 0</td>
<td></td>
</tr>
<tr>
<td>265-4728-3</td>
<td>Power Cord No.7650</td>
<td>0 0 1</td>
<td></td>
</tr>
<tr>
<td>266-5110-5</td>
<td>Fuse 250V1A ST4-0.8A-N1 (N.Amer)</td>
<td>2 0 0</td>
<td>Main Unit</td>
</tr>
<tr>
<td>266-7132-4</td>
<td>Fuse S504 T0.4A-T</td>
<td>0 2 2</td>
<td>Main Unit</td>
</tr>
<tr>
<td>461-2035-2</td>
<td>Operator’s Manual CA-50 (Eng)</td>
<td>1 1 1</td>
<td></td>
</tr>
<tr>
<td>424-1251-0</td>
<td>Sample Cup Conical 4 mL</td>
<td>20 20 20</td>
<td></td>
</tr>
<tr>
<td>541-0541-8</td>
<td>Reaction Tube Assy (30/box)</td>
<td>1 1 1</td>
<td></td>
</tr>
<tr>
<td>462-4841-3</td>
<td>Printer Paper F1-1</td>
<td>1 1 1</td>
<td></td>
</tr>
<tr>
<td>665-8038-1</td>
<td>Filter CA-5D</td>
<td>2 2 2</td>
<td></td>
</tr>
<tr>
<td>369-5029-5</td>
<td>Indication Mark No.1014</td>
<td>1 1 1</td>
<td></td>
</tr>
<tr>
<td>421-9350-9</td>
<td>Blower Brush</td>
<td>1 1 1</td>
<td></td>
</tr>
</tbody>
</table>
3. INSTALLATION SPACE

To ensure that the instrument performs to its full extent, it should be installed in an appropriate place.
Install the instrument on the flat plane.
- Select a place that is close to the power supply.
- Do not use in dusty areas.
- Select a place spacious enough for maintenance and service. Giving consideration to heat radiation by the instrument, keep at least 10 cm distance from the wall to the instrument's rear panel.

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

**Table A-2: Instrument Dimensions**

<table>
<thead>
<tr>
<th>Width (mm)</th>
<th>Depth (mm)</th>
<th>Height (mm)</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>327</td>
<td>302</td>
<td>113</td>
<td>4.5</td>
</tr>
</tbody>
</table>

**Figure A-1: Instrument Dimensions**
4. CHANGING THE INSTALLATION DIRECTION OF PIPETTE GUIDE

When shipped from the factory, the pipette guide is installed so that you can hold it with your right hand. In the following cases, change the installation direction.

- When you hold the pipette by the left hand and add the reagent
- When the pipette guide is not used to add the reagent

1. Remove the fixing screw from the pipette guide.

2. Remove the pipette guide in the direction shown by the arrow in Figure A-2.

**WARNING** - The fixing claw is provided with the pipette guide. Be careful not to break the claw when removing the stand.

![Figure A-2: Removing the Pipette guide](image-url)
(3) Change the direction, and install the pipette guide.
When you hold the pipette with your left hand, install the pipette guide so that it can be opened toward the left side.
When the pipette guide is not used, install the stand so that it can be opened in the direction against you.

Install the pipette guide in the reverse order of the step (2). Hook the claw, then install the pipette guide.

![Figure A-3: Installing the Pipette guide](image)

**CAUTION** • The pipette guide also works as the detector cover. Be sure to install the pipette guide even if you add the reagent without the stand. If you do not cover it, an analysis error occurs.
• The pipette guide cannot be installed so that it can be opened toward you.

(4) Install the fixing screw.
5. INSTALLING THE FILTER

Install the filter (filter media) to prevent dust etc. from entering in the instrument at the instrument bottom air intake.

![Filter Diagram]

Figure A-4: Installing the Filter

6. CONNECTING THE POWER CORD AND CONNECTION CORD

Connect the power cord provided. When the output to the host computer is necessary, connect the instrument to the device with the connection cord, and carry out the setup.

6.1 Connecting the Power Cord

(1) Make sure the power switch is OFF.

⚠️ WARNING • Before connecting the power cord, make sure that the power switch is OFF. Otherwise, there is a possibility of electrical shock.
(2) Connect the power cord to the power connector on the rear panel of the instrument.

![Figure A-5: Connecting the Power Cord](image)

(3) Insert the provided power cord into a power supply outlet. 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.

![Figure A-6: Connecting with Power Supply Outlet](image)

**WARNING** • Do not, for any reason, bypass the ground connection. Otherwise, there is a risk of electrical shock.
6.2 Connecting the Connection Cord

Use a connection cord matching with the host computer. Refer to Attachment B, Chapter 1, Section 1.1: Hardware.

(1) Make sure the power switch is OFF.

\begin{center}
\textbf{CAUTION} • Before routing the connection cord, make sure the power switch is OFF. Otherwise, the unit may be damaged.
\end{center}

(2) Connect the instrument to the host computer using the connection cord.

![Connection cord](image)

\textbf{Figure A-7: Connecting the Connection Cord}

(3) Perform the necessary settings for the host computer. Refer to \textit{Chapter 10, Section 4.3: Host Computer Settings}. 
7. ADJUSTING THE LCD BRIGHTNESS

Adjust the brightness of the LCD.

(1) Turn the power switch ON.

(2) Turn the brightness control knob to adjust the brightness of characters on the LCD to a desired level.

![Brightness control knob](image)

Figure A-8: Adjusting the LCD Brightness
8. SETTING A PRINTER PAPER

(1) Open the built-in printer cover.

(2) Set a printer paper, and insert the end of the paper to the built-in printer.

---

**CAUTION:**

- Insert the printer paper straight to the built-in printer. Otherwise, the paper may be caught or the life of the printer head may be shorten.
- Use a specified printer paper. Otherwise, print cannot be performed, or the paper may be caught.
  - Specification: F1-1
- As for the printing side of the paper, insert the printer paper as shown in Figure A-8.
- Do not make the printer paper detection sensor dirty.
  - The presence of printing paper might not be able to be detected correctly when becoming dirty. Wipe off dirt with a soft and dry cloth.
- Do not handle the printer paper by the wet hand.
  - It causes paper jam.
(3) Press and hold [FEED] key until the top of the printer paper comes out of the outlet.

**CAUTION:**

- When there is any remained portion of the printer paper, remove the roll core from the paper roll, press the [FEED] key, and then pull the paper. At this time, pull the paper out in the direction to which the printer paper is ejected at an ordinary print operation.
- Do not pull out the paper while printing.
- When paper jam occurs while printing, turn OFF the power of the Main Unit, and remove the paper cutter by sliding it to the instrument rear side, and then remove the printer paper.
- When you install the paper cutter, push it until the click sound is heard according to the reversed procedure of removal.
# APPENDIX B: TECHNICAL INFORMATION

1. OUTPUT FORMAT FOR HOST COMPUTER ............................................. B-1
   1.1 Hardware........................................................................... B-1
   1.2 Software............................................................................ B-2
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   2.1 QC Parameters and Factory Default Settings ............................. B-7
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1. OUTPUT FORMAT FOR HOST COMPUTER

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 rear panel of the instrument.

1.1 Hardware

1. Connector
   - The connector to the host computer is located on the rear panel of the instrument.
   - Use a 9-pin D-SUB, female connector.
   - Fixing screws for this connector are in inch-specification.

2. Connector Signals

Table B-1: Pin Assignment

<table>
<thead>
<tr>
<th>Pin No.</th>
<th>Signal name</th>
<th>Signal direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Receive Data (RxD)</td>
<td>from Host to CA-50</td>
</tr>
<tr>
<td>3</td>
<td>Transmit Data (TxD)</td>
<td>to Host from CA-50</td>
</tr>
<tr>
<td>4</td>
<td>Data Terminal Ready (DTR)</td>
<td>to Host from CA-50</td>
</tr>
<tr>
<td>5</td>
<td>Signal Ground (SG)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Data Set Ready (DSR)</td>
<td>from Host to CA-50</td>
</tr>
<tr>
<td>7</td>
<td>Request to Send (RTS)</td>
<td>to Host from CA-50</td>
</tr>
<tr>
<td>8</td>
<td>Clear to Send (CTS)</td>
<td>from Host to CA-50</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Communication Format

The data is communicated in the asynchronous, half duplex mode.

- Baud rate: 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.

Table B-2: Signal Level

<table>
<thead>
<tr>
<th>Level</th>
<th>Data signal</th>
<th>Control signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>+3V or higher</td>
<td>Logic &quot;0&quot;, Start bit</td>
<td>ON</td>
</tr>
<tr>
<td>-3V or lower</td>
<td>Logic &quot;1&quot;, Stop bit</td>
<td>OFF</td>
</tr>
</tbody>
</table>

5. Interface Circuit

MAX232 (or the equivalent) is used for the interface circuit of the bit serial voltage type.
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: 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 the
     host computer.
   • Class B
     The CA-50 transmits data and then waits for ACK or NAK to complete the data
     transmission.

Transmission Protocol of Analysis Data

* ACK and NAK can be arranged between STX and ETX.

Figure B-2: Analysis Data Transmission
4) **Transmission Errors**

If the CA-50 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-50 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.

1.3 **Text Format**

The type of communication format for the CA-50 is the analysis data text.

- **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 manual transmission from the displaying detailed analysis results.
1. Analysis Data Format

### Table B-3: Analysis Data Format

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No. of Characters</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>STX</td>
<td>1</td>
<td>(02 H)</td>
</tr>
<tr>
<td>Text Distinction Code I</td>
<td>1</td>
<td>Fixed to &quot;D&quot;</td>
</tr>
<tr>
<td>Text Distinction Code II</td>
<td>1</td>
<td>&quot;1&quot; (normal data) or &quot;2&quot; (mean data)</td>
</tr>
<tr>
<td>Text Distinction Code III</td>
<td>2</td>
<td>Fixed to &quot;21&quot;</td>
</tr>
<tr>
<td>Block Number</td>
<td>2</td>
<td>Fixed to &quot;01&quot;</td>
</tr>
<tr>
<td>Total Number of Blocks</td>
<td>2</td>
<td>Fixed to &quot;01&quot;</td>
</tr>
<tr>
<td>Sample Distinction Code</td>
<td>1</td>
<td>&quot;U&quot; (Routine analysis data), &quot;C&quot; (Quality control analysis data)</td>
</tr>
<tr>
<td>Date</td>
<td>6</td>
<td>&quot;OOOOOO&quot;</td>
</tr>
<tr>
<td>Time</td>
<td>4</td>
<td>&quot;OOOO&quot;</td>
</tr>
<tr>
<td>Rack Number</td>
<td>4</td>
<td>Fixed to &quot;0000&quot; (Not in use)</td>
</tr>
<tr>
<td>Tube Position Number</td>
<td>2</td>
<td>Fixed to &quot;00&quot; (Not in use)</td>
</tr>
<tr>
<td>Sample ID Number</td>
<td>15</td>
<td>(OO.... OO)</td>
</tr>
<tr>
<td>ID Information</td>
<td>1</td>
<td>&quot;M&quot; (Manual entry), &quot;A&quot; (Automatic assignment)</td>
</tr>
<tr>
<td>Reserved</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Analysis Parameter, Data 1</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Analysis Parameter, Data 2</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>...</td>
<td>* * *</td>
<td></td>
</tr>
<tr>
<td>Analysis Parameter N, Data N</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>ETX</td>
<td>1</td>
<td>(03 H)</td>
</tr>
</tbody>
</table>

Total: 54+N× 9 bytes

- **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
  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 switch. Zero suppression is not performed.

• **Sample ID Number**
  The sample ID number consists of 15 digit numerals. A hyphen "-" (2DH) may be
  inserted between numerals. The hyphen "-" is included in the 15 digits. Zero
  suppression is not performed. The most significant digits are filled with spaces (20H)
  if it is less than 15 digits.

• **ID Information**
  The ID information indicates the method in which the sample ID number is registered.
  M: Manual entry
  A: Automatic assignment by the instrument

• **Analysis Parameter, Data**

  Table B-4: Analysis Parameter, Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No. of Characters</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter Code</td>
<td>3</td>
<td>(OOO)</td>
</tr>
<tr>
<td>Data</td>
<td>5</td>
<td>(OOOO.O) [sec]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(OOOO.O) [%], [mg/dL], [IU]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(O.OOO) [g/L]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(OO.OO) INR, [-]</td>
</tr>
<tr>
<td>Flag</td>
<td>1</td>
<td>&quot;&quot;, &quot;+&quot;, &quot;,&quot;, &quot;,=&quot;, &quot;,&lt;&quot;, &quot;,&gt;&quot;</td>
</tr>
</tbody>
</table>

□ indicates a space (20 H).
1) Parameter Code

<table>
<thead>
<tr>
<th>Parameter Code</th>
<th>Table B-5: Parameter Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>04x: PT</td>
<td>05x: APTT</td>
</tr>
<tr>
<td>08x: TTO</td>
<td>09x: NT</td>
</tr>
<tr>
<td>12x: Factor II</td>
<td>15x: Factor V</td>
</tr>
<tr>
<td>18x: Factor VIII</td>
<td>19x: Factor IX</td>
</tr>
<tr>
<td>21x: Factor XI</td>
<td>22x: Factor XII</td>
</tr>
<tr>
<td>06x: Fbg</td>
<td></td>
</tr>
<tr>
<td>51x: TT</td>
<td></td>
</tr>
</tbody>
</table>

Where, x is:
1: Time
2: Activity percent/concentration
3: Ratio
4: INR
5: DFbg

* 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.

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: OOO.O → □OOOO (*2)
- Fbg concentration: □OOO.O → □OOOO (*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, "/" is entered 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. If the number of digits for the calculation data exceeds the specification, "+" is entered.

3) Flags

* Analysis error occurred, disparate data of mean data occurred.
< Over the upper report limit
> Under the lower report limit
+ Over the upper mark limit
- Under the lower mark limit
space: No error
2. FACTORY DEFAULT SETTINGS

2.1 QC Parameters and Factory Default Settings

Table B-6: QC Parameters and Factory Default Settings

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PT</th>
<th>APTT</th>
<th>Fbg</th>
<th>TTO</th>
<th>NT</th>
<th>TT</th>
<th>Intrinsic Factor</th>
<th>Extrinsic Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Target Value</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Lower Limit</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*1 Can be selected from the coagulation time or the calculation parameters. (However, parameters which are set to OFF in the standard curve calculation parameter settings cannot be selected.)

*2 The numerals of 4 digits are displayed, and the position of the decimal point varies depending on the selected parameter.
### 2.2 Standard Curve Data and Factory Default Settings

**Table B-7: Standard Curve Data and Factory Default Settings**

<table>
<thead>
<tr>
<th></th>
<th>Activity % or Concentration</th>
<th>Coagulation Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD1</td>
<td>100.0</td>
<td>0.0</td>
<td>Cannot be set when activity percent is OFF.</td>
</tr>
<tr>
<td>STD2</td>
<td>50.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD3</td>
<td>25.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD4</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD5</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>0.0</td>
<td>-</td>
<td>Can be set only when ratio or INR is ON.</td>
</tr>
<tr>
<td>ISI</td>
<td>0.0</td>
<td>-</td>
<td>Can be set only when INR is ON.</td>
</tr>
<tr>
<td>DFBg</td>
<td>0.0</td>
<td>-</td>
<td>Can be set only when DFBg is ON.</td>
</tr>
<tr>
<td>dH</td>
<td>0</td>
<td>-</td>
<td>Can be set only when DFBg is ON.</td>
</tr>
<tr>
<td><strong>APTT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD1</td>
<td>100.0</td>
<td>0.0</td>
<td>Can be set only when activity percent is ON.</td>
</tr>
<tr>
<td>STD2</td>
<td>50.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD3</td>
<td>25.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD4</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD5</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td><strong>Fbg</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD1</td>
<td>400.0</td>
<td>0.0</td>
<td>Cannot be set when concentration is OFF.</td>
</tr>
<tr>
<td>STD2</td>
<td>200.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD3</td>
<td>100.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD4</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD5</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td><strong>TTO</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD1</td>
<td>100.0</td>
<td>0.0</td>
<td>Cannot be set when activity percent is OFF.</td>
</tr>
<tr>
<td>STD2</td>
<td>50.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD3</td>
<td>25.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD4</td>
<td>12.5</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD5</td>
<td>6.3</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>0.0</td>
<td>-</td>
<td>Can be set only when ratio or INR is ON.</td>
</tr>
<tr>
<td>ISI</td>
<td>0.0</td>
<td>-</td>
<td>Can be set only when INR is ON.</td>
</tr>
<tr>
<td><strong>NT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD1</td>
<td>100.0</td>
<td>0.0</td>
<td>Cannot be set when activity percent is OFF.</td>
</tr>
<tr>
<td>STD2</td>
<td>50.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD3</td>
<td>25.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD4</td>
<td>12.5</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD5</td>
<td>6.3</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>0.0</td>
<td>-</td>
<td>Can be set only when ratio or INR is ON.</td>
</tr>
<tr>
<td>ISI</td>
<td>0.0</td>
<td>-</td>
<td>Can be set only when INR is ON.</td>
</tr>
<tr>
<td></td>
<td>Activity % or Concentration</td>
<td>Coagulation Time</td>
<td>Remarks</td>
</tr>
<tr>
<td>----</td>
<td>-----------------------------</td>
<td>------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>TT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD1</td>
<td>100.0</td>
<td>0.0</td>
<td>Can be set only when activity percent is ON.</td>
</tr>
<tr>
<td>STD2</td>
<td>50.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD3</td>
<td>25.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD4</td>
<td>12.5</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD5</td>
<td>6.3</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>STD6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>F8</td>
<td>STD1 100.0</td>
<td>0.0</td>
<td>Cannot be set when activity percent is OFF.</td>
</tr>
<tr>
<td></td>
<td>STD2 50.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STD3 25.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STD4 12.5</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STD5 6.3</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STD6 0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>F9</td>
<td>STD1 100.0</td>
<td>0.0</td>
<td>Cannot be set when activity percent is OFF.</td>
</tr>
<tr>
<td></td>
<td>STD2 50.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STD3 25.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STD4 12.5</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
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<tr>
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<td>STD4 12.5</td>
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### 2.3 Standard Curve Calculation Parameters and Factory Default Settings

Table B-8: Standard Curve Calculation Parameters and Factory Default Settings

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<tr>
<td></td>
<td>DFbg</td>
<td>OFF</td>
<td>mg/dL</td>
<td>Lin. Regress</td>
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<td>%</td>
<td>Log. Pt Pt</td>
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<td>Ratio</td>
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<td>INR</td>
<td>OFF</td>
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<td>Conc.</td>
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<td>mg/dL</td>
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<td>-</td>
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<tr>
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<td>INR</td>
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<td>-</td>
</tr>
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<td>TTO</td>
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<td>ON</td>
<td>%</td>
<td>Log. Pt Pt</td>
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<td>-</td>
</tr>
<tr>
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<td>INR</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
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<td>INR</td>
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<td>-</td>
</tr>
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<td>OFF</td>
<td>-</td>
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### 2.4 Instrument Setting Parameters and Factory Default Settings

#### Table B-9: Instrument Setting Parameters and Factory Default Settings

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<th>Fbg</th>
<th>TTO</th>
<th>NT</th>
<th>TT</th>
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<td>High</td>
<td>High</td>
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<tr>
<td>1st Reagent Addition Time</td>
<td>0 - 999 (sec)</td>
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<td>60</td>
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<td>5</td>
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<td>Sec/Conc./Ratio/INR ($^1$)</td>
<td>%</td>
<td>sec</td>
<td>mg/dL</td>
<td>%</td>
<td>%</td>
<td>sec</td>
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<td>Upper Limit</td>
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*1 Can be selected from the coagulation time or the calculation parameters.

*2 The numerals of 4 digits are displayed, and the position of the decimal point varies depending on the selected parameter. (However, parameters which are set to OFF in the standard curve calculation parameter settings cannot be selected.)
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<td>Connection Status</td>
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<td>Do not connect</td>
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<td>1-bit/2-bit</td>
<td>1-bit</td>
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<tr>
<td>Parity Bit</td>
<td>Even/Odd/None</td>
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<td>All/Err only</td>
<td>All</td>
</tr>
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