Automated Blood Coagulation Analyzer

CS-2000*i*/CS-2100*i*

Software Guide

Sysmex Corporation

KOBE, JAPAN

Code No. AQ061411
SMN: 10720153
Date of Last Revision: April 2013
Software Version: 01-63 onwards

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1. Introduction

Thank you for purchasing this Sysmex CS-2000*i*/CS-2100*i* fully automated blood coagulation analyzer.
The CS-2000*i*/CS-2100*i* is a fully automated blood coagulation analyzer for In Vitro Diagnostic use that can quickly analyze a large volume of samples with a high degree of accuracy.
This instrument can analyze samples using coagulation, chromogenic and immunoassay methods. The analyzed data can be retained in the stored joblist, displayed and printed. (Printing is only possible if the optional printer is connected.)
The instrument also has a number of built-in functions, including automatic setting of reagent by a barcode, priority processing of STAT samples and quality control.
A cap piercer unit can be installed as a factory option.

* CS-2000*i*: without cap piercer unit
CS-2100*i*: with cap piercer unit

The contents of screens illustrated in this manual are as displayed under Windows XP.

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Ordering of Supplies and Replacement Parts

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

Service and Maintenance

Please contact the Service Department of your local representative.

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1.1 Manual composition

The CS-2000*i*/CS-2100*i* manual comprises the following two sections.
Read it carefully so that you can use the equipment correctly. After reading the manual, store it carefully where it will be available any time you need it.

(1) CS-2000*i*/CS-2100*i* Instructions for Use (Volume 1)
This manual gives a summary of the CS-2000*i*/CS-2100*i* and explains its basic operations and analysis procedures.

(2) CS-2000*i*/CS-2100*i* Software Guide (Volume 2)
This manual explains the operation procedure for each screen.

Table 1-01: Composition of the instructions for use

CHAPTER 1 Introduction	Manual composition, meanings of symbols used in this document, trademarks, system overview
CHAPTER 2 Safety Information	Safety information for usage
CHAPTER 3 Design and Function	Nomenclature and function summary
CHAPTER 4 Operation	Screen composition and basic operations
CHAPTER 5 Sample Preparation	Procedure from switching the power ON until the start of analysis * The screen explanations give reference destinations in the Software Guide. For details on the operation procedures for each screen, see the Software Guide.
CHAPTER 6 Analysis	Procedure from the start of analysis until shutdown * The screen explanations give reference destinations in the Software Guide. For details on the operation procedures for each screen, see the Software Guide.
CHAPTER 7 Maintenance and Supplies Replacement	Maintenance items, replacement of supplies, supplies list
CHAPTER 8 Troubleshooting	Error log, error handling methods, error messages
CHAPTER 9 Technical Information	Device specifications, functional descriptions, packing, checkpoints for before and after installation

The provided instructions, reagents, instrument, software and customizable features have been validated for this system to optimize product performance and meet product specifications. User defined modifications are not supported as they may affect performance of the system and test results. It is responsibility of the user to validate any modifications made to these instructions, reagents, instrument or software.

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Table 1-02: Composition of the Software Guide

CHAPTER 1 Introduction	Manual composition, meanings of symbols used in this document, trademarks
CHAPTER 2 Order Registration	Order related screens, functions and operation procedures
CHAPTER 3 Joblist	Joblist related screens, functions and operation procedures
CHAPTER 4 Browser	Browser related screens, functions and operation procedures
CHAPTER 5 Reagent Screen	Reagent related screens, functions and operation procedures
CHAPTER 6 Quality Control	Quality control related screens, functions and operation procedures
CHAPTER 7 Calibration Curve	Calibration curve related screens, functions and operation procedures
CHAPTER 8 System Setup	Setup related screens, functions and operation procedures
CHAPTER 9 Utility Tools	Utility tool related screens, functions and operation procedures
CHAPTER 10 GNU General Public License	GNU General Public License explanation

1.2 Hazard information in this manual

Note, Information, Caution and Warning statements are presented throughout this manual to call attention to important safety and operational information. Non-compliance with this information compromises the safety features incorporated in the analyzer.

Caution!
Average risk. Ignoring this warning could result in property damage or incorrect measurement results.

Information
Minor risk. Observe these considerations when operating this instrument.

Note:
Background information and practical tips.

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1.3 Protected names

- Sysmex is a registered trademark of SYSMEX CORPORATION.
- CA CLEAN I and CA CLEAN II are trademarks of SYSMEX CORPORATION.
- VENOJECT, Venosafe and VENOJECT II are registered trademarks of TERUMO Corporation.
- VACUTAINER is a registered trademark of Becton, Dickinson and Company.
- HEMOGARD is a trademark of Becton, Dickinson and Company.
- VACUETTE is a registered trademark of C.A. GREINER und Söhne GmbH.
- MONOVETTE is a registered trademark of SARSTEDT.
- Windows is a registered trademark of Microsoft Corporation in the United States and other countries.
- Linux is a registered trademark or trademark of Linus Torvalds in the United States of America and other nations.
- Other registered trademarks or trademarks referenced are property of their respective owners.

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

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2. Order Registration

This chapter describes the registration method for analysis orders (sample numbers and analysis parameters).

2.1 Overview

The CS-2000*i*/CS-2100*i* performs analyses in accordance with analysis orders.
The analysis order (sample number and analysis parameter) registration methods are "order" and "STAT order", depending on the analysis reagents and the sample setting position.

1. Order

Orders are either "rack order", "holder calibration curve order" or "holder QC order".

- Rack order
  Rack orders are used when samples or control materials are set in racks and the sampler is used to perform the analysis.
  The rack order screen is used for rack orders. (See "Chapter 2: 2.3 Registering rack routine sample and QC analysis orders")
- Holder calibration curve order
  Calibration curve analysis calibrators placed on the reagent table are used to perform calibration curve analysis.
  The holder calibration curve order screen is used for holder calibration curve orders. (See "Chapter 2: 2.4 Holder calibration curve analysis order registration")
- Holder QC order
  Control materials placed on the reagent table are used to perform QC analysis.
  The holder QC order screen is used for holder QC orders.
  (See "Chapter 2: 2.5 Holder QC order registration")

2. STAT

STAT orders are orders for which the samples are placed in STAT holders for analysis.
The STAT order registration screen is used for STAT orders. (See "Chapter 2: 2.6 Registration of STAT orders")

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2.2 Registration of orders

1. Order screen display

For orders, orders can be registered to analyze samples placed in a rack or a reagent table.
The order screen is used for registering orders.

- Press **Order** on the IPU menu screen toolbar.

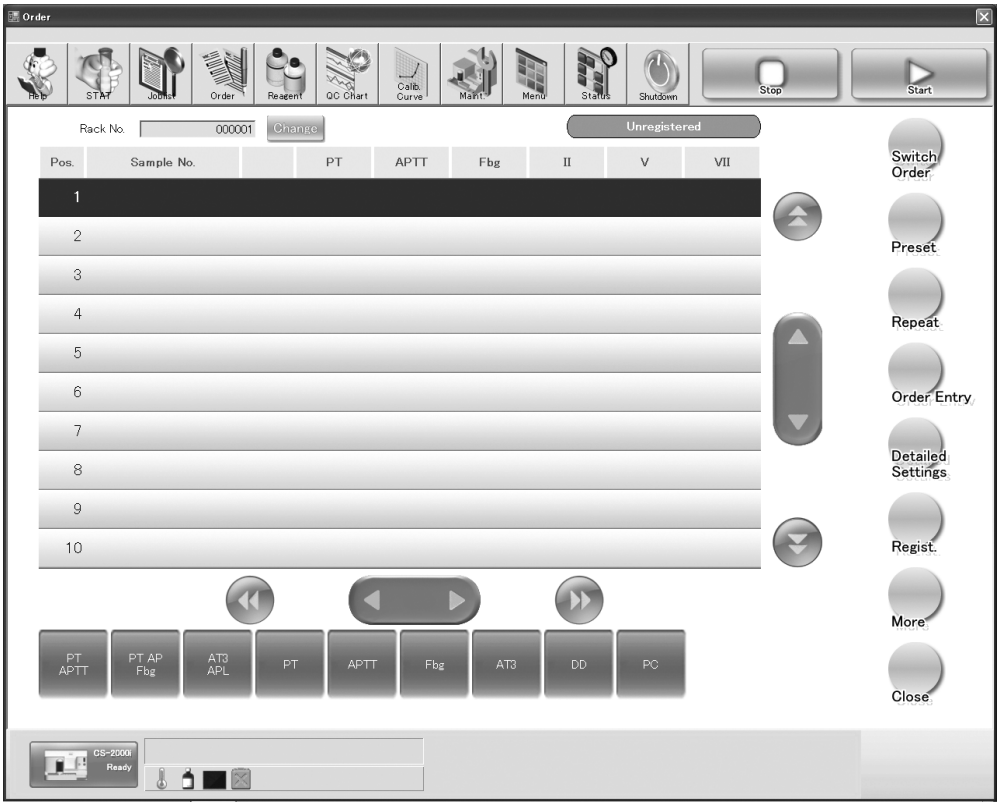

Figure 2-01: Order screen (rack order screen)

The order screen contains the three types and is switched to the corresponding order screens to register analysis orders. (See “Chapter 2: 2.2: 3. Changing the order screen” for information on switching order screens).

- Registration of analysis orders for rack routine samples and quality control
  ⇨ Rack order screen
- Registration of holder calibration curve analysis orders
  ⇨Holder calibration curve order screen
- Registration of holder QC analysis orders
  ⇨Holder QC order screen

STAT orders are registered from the STAT sample registration screen.
⇨STAT sample registration screen (See “Chapter 2: 2.6 Registration of STAT orders”.)

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The sample can be set in the sample rack or STAT sample holder and then analyzed. A work list should be prepared for each location in which samples are set.

Table 2-01: Location to set samples

Set Location	Samples that can be set
Sample rack	Routine samples and quality control samples
STAT sample holder	STAT samples
Reagent table	Calibrators and quality control samples

Caution!
Register analysis orders for STAT samples from the STAT sample order registration screen for the holder.

Note:
Analysis of STAT samples has priority over routine, QC or calibration curve samples.

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2. Content displayed on the order registration screen

Rack order screen

The rack order screen can be used to register analysis orders for routine samples or quality control samples that use racks (up to 100 racks).
If the rack order screen is displayed while a rack is selected that contains samples on the joblist that have not yet been analyzed (their analysis status is “Pending”), it can be used to check the order content that has already been registered.

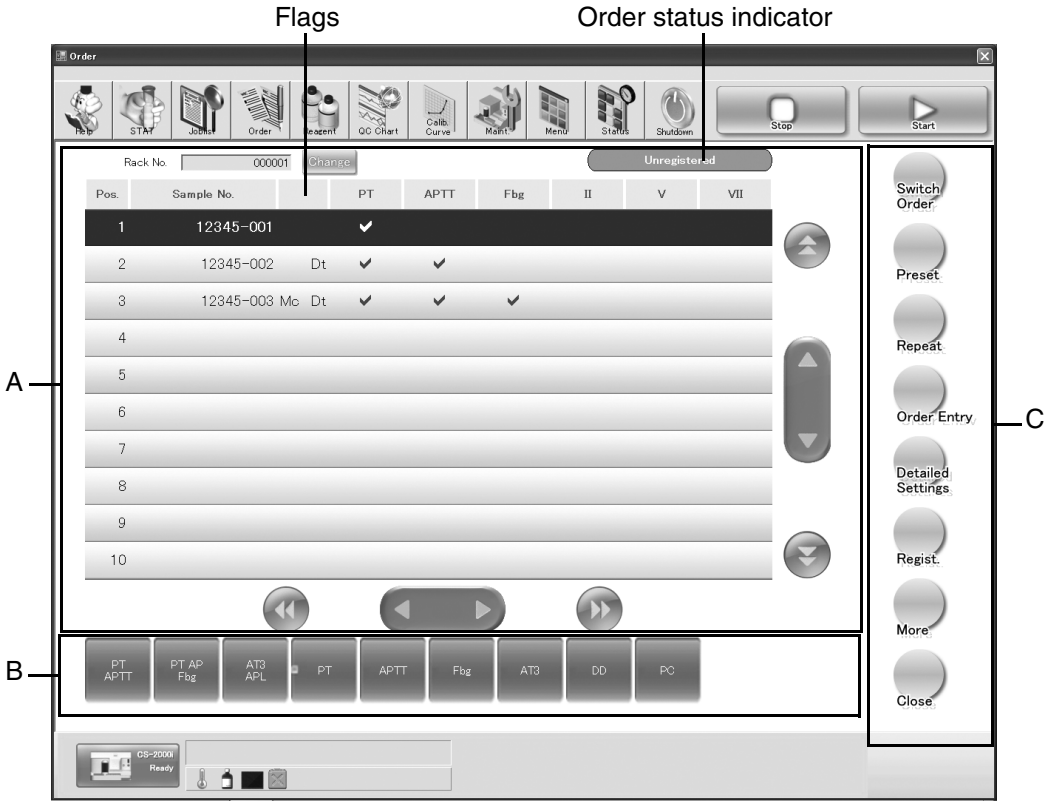

Figure 2-02: Order screen (rack order screen)

A Rack order display area
Registered orders for each rack are displayed.

Rack No.	The rack number is displayed. **Change** can be pressed to display the rack number input dialog box and input the rack number. The mouse and keyboard can be used for direct input into this field.
Change	The rack number input dialog box will appear. (See “Chapter 2: 2.2: 4. Inputting the rack number”.) This button cannot be used when the order status indicator shows “Editing” or “Registered”.
Order status indicator	The order status for the displayed rack is indicated as “Registered”, “Unregistered” or “Editing”.
Pos.	Displays the location of the tube in the rack.

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Sample No. Sample number is displayed.
Press **Order Entry** on the operation panel to display the order input dialog box, then input the sample number.

Flags Flags indicate the status of detailed settings for the order. They indicate whether any changes have been made in the detailed order settings (any change from the default analysis settings) and the analysis mode.

Table 2-02: Flag display

		Changing detailed settings	
		Yes	**No**
Analysis mode	**Normal**	"Dt"	" " (space)
	Micro	"Mc Dt"	"Mc"

Note:
If the sample volume is minimal, you can analyze in micro-sample mode.
In micro-sample mode, functions such as automatic re-analysis will not be operated.

Parameters The assay group name will appear. All valid assay groups registered under assay group settings are displayed from the left, in the display order.

Check Parameters for which there are orders have a check mark "✓" displayed.
Orders can be input using the order input dialog box or the profile button. A cell can be directly pressed to order (reverse the "✓"). The cursor also moves at that time.

Note:
Orders which had "✓" input directly on the rack order screen are analyzed as normal orders. To register a quality control order, input the analysis order from display the order input dialog box.

▶▶ Switches the display items (columns) one page to the right.

◀◀ Switches the display items (columns) one page to the left.

◀ ▶ Moves the displayed items (columns) one place to the left or right.

▲ Switches the displayed order one rack up. At that stage, the cursor always moves to the Pos.1 line.

▼ Switches the displayed order one rack down. At that stage, the cursor always moves to the Pos.1 line.

▲ ▼ Moves the cursor up and down. The cursor will not move between racks.

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B Profile button display area
Buttons for the profiles registered in the order list are displayed in the profile button display area.

Profile button	One or more parameters that have been registered under Customize are made into a set and ordered. When a button is pressed, a mark appears on the Profile button. Use the Customize dialog box to register and change Profile button.

C Operation panel area
Operation buttons used on the rack order screen are displayed.

1st page

Switch Order	The Change Order dialog box will appear. (See “Chapter 2: 2.2: 3. Changing the order screen”.)
Preset	The Read Out Preset dialog box will appear. (See “Chapter 2: 2.2: 6. Loading presets”)
Repeat	The repeat input dialog box will appear. (See “Chapter 2: 2.3: 2. Repeat input”.)
Order Entry	The order input dialog box will appear. (See “Chapter 2: 2.3: 1. Order input”.) If the selected order is not able to be edited at that time, the edit parameters are also disabled and only **Cancel** is enabled in the order input dialog box.
Detailed Settings	The detailed settings dialog box will appear. (See “Chapter 2: 2.3: 3. Detailed settings”.) If the selected order is not able to be edited at that time, the edit parameters are also disabled and only **Cancel** is enabled in the detailed settings dialog box.
Regist.	Registers the order input from the rack order screen. Once registered, the content of the order is reflected in the joblist screen. The indicator on the rack order screen changes to “Registered” and the order for the rack cannot be edited from the order screen. This button is displayed while orders that have not yet been registered or that are being edited are displayed.
Edit	The indicator on the Rack order screen goes to “Editing”, enabling editing of orders in this rack. This button is displayed while orders that have been registered are displayed.

2nd page

Line Clear	Deletes data in the line indicated as registered.
Customize	The Customize dialog box will appear. (See “Chapter 2: 2.2: 5. Customize”.)
Save preset	The Save preset dialog box will appear. (See “Chapter 2: 2.2: 7. Saving presets”)

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Common to the 1st and 2nd page

More	If the Operation panel comprises multiple pages, use this button to switch between pages.
Close	Closes the Order Registration screen.

3. Changing the order screen

The order screen can be changed from the change order dialog box.

1. Press **Switch Order** on the operation panel.
   The Change Order dialog box will appear.

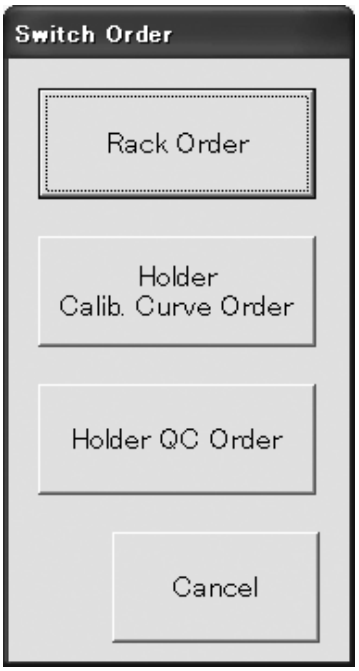

Figure 2-03: Change Order dialog box

2. Press the button for the order screen you wish to display.

Rack Order	The rack order screen is displayed.
Holder Calib. Curve Order	The holder calibration curve order screen appears.
Holder QC Order	The holder QC order screen is displayed.
Cancel	Closes the change order dialog box and returns to the previous screen.

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4. Inputting the rack number

Rack numbers can be input from the rack number input dialog box.

1. Press **Change** for the rack number on the rack order screen.
   The rack number input dialog box will appear.

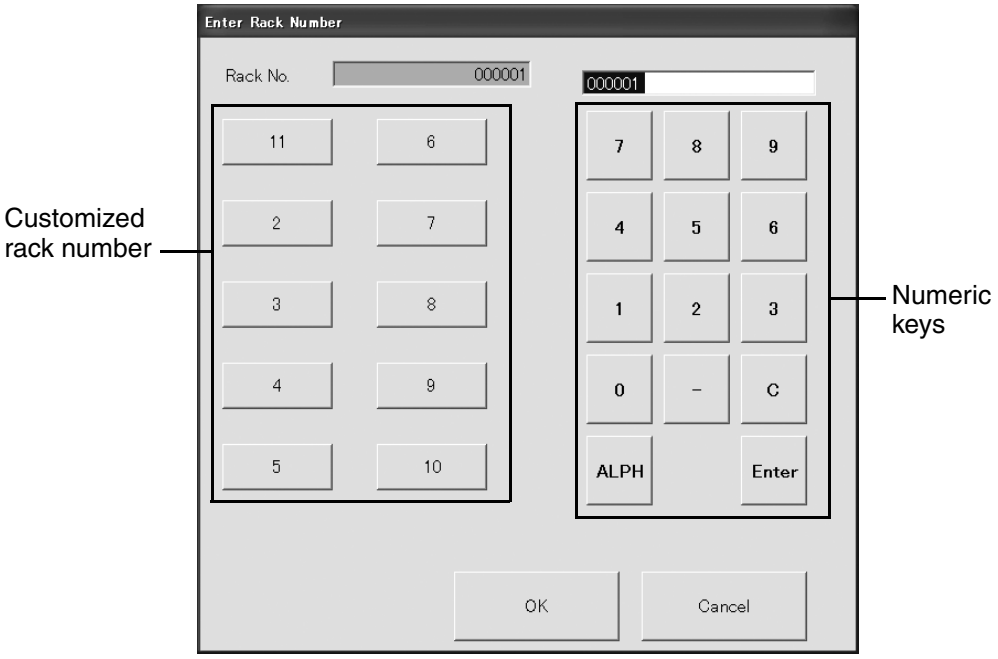

Figure 2-04: Rack number input dialog box

Rack No.	The rack number is displayed.
Customized rack number	The customized rack numbers will appear. The buttons set from the customize dialog box are displayed (see “Chapter 2: 2.2: 5. Customize”).
Numeric keys	The numeric keys will be displayed.

2. Input the rack number and press **OK**.
   Confirm the input rack number and close the rack number input dialog box.
   Press **Cancel** to discard the input rack number and close the rack number input dialog box.

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5. Customize

The profile buttons and the customized rack number buttons can be customized.
The Customize button only appears on the operation panel of the rack order screen.

1. Press **Customize** on the operation panel.
   The Customize dialog box will appear.

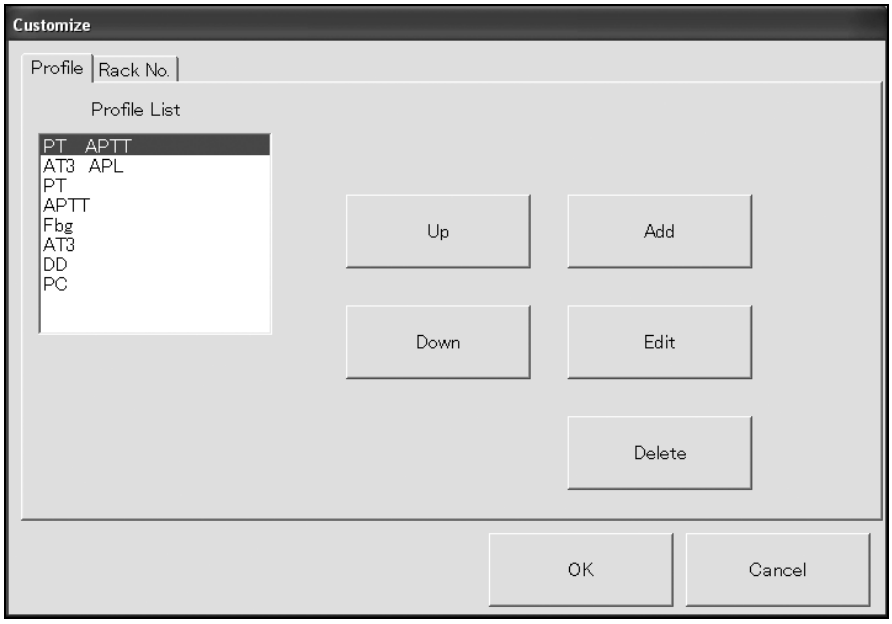

Figure 2-05: Customize dialog box

Profile tab	Profiles can be set. (See “Chapter 2: 2.2: 5.: Profile Settings”.)
Rack No. tab	Rack numbers can be set. (See “Chapter 2: 2.2: 5.: Rack number setting”.)
OK	Confirms the setting content, then closes the Customize dialog box.
Cancel	Discards the setting content, then closes the Customize dialog box.

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Profile Settings

One or Multiple analysis parameters can be registered as a profile.
Profiles can be customized from the Profiles tab of the customize dialog box. Up to 10 profiles can be set.

1. Click on the **Profile** tab of the customize dialog box.
   The setting screen for profiles is displayed.

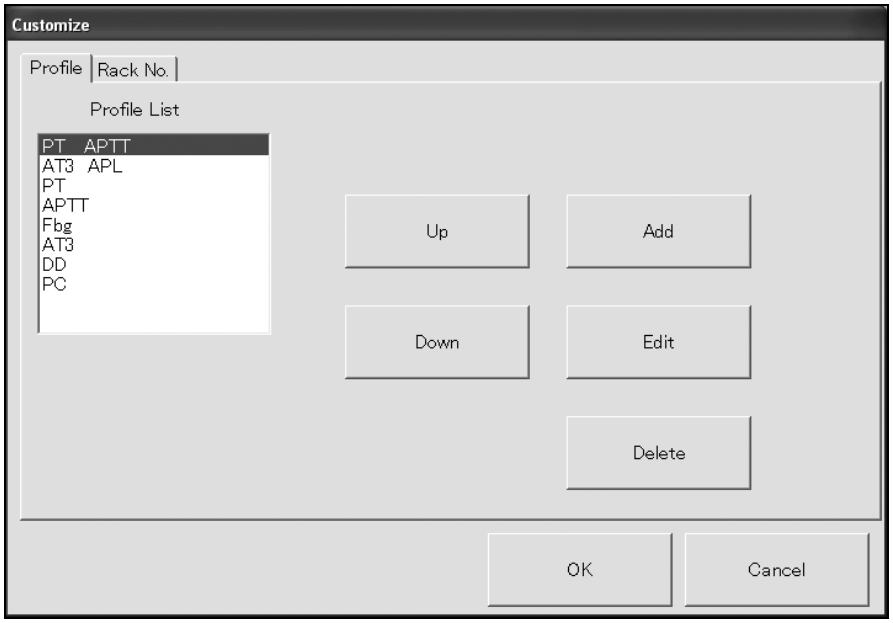

Figure 2-06: Customize dialog box (Profiles tab)

Profile	Displays and edits the name of the profile that is selected from the profile list.
Profile List	A list of profiles that have already been registered is displayed.
Up	Moves the cursor position in the profile list up one line.
Down	Moves the cursor position in the profile list down one line.
Add	Adds a new profile to the bottom line of the profile list. The default name of the profile when added is “New”. If the name given to the profile is the same as one already registered, a warning dialog box appears and the profile cannot be registered. The parameters in a profile can be edited under **Parameter Group Settings**.
Delete	Deletes the name of the profile that is selected from the profile list. Profiles below the deleted one will be moved up in the displayed list.
Edit	The parameter group definition dialog box is displayed and can be used to set the profile parameters.

2. Edit the profile list.

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3. If it is necessary to edit profile parameters, press **Edit**.
   The Parameter Group Definition dialog box will appear. Use the profile parameter setting dialog box to set the parameters on the Profiles tab.

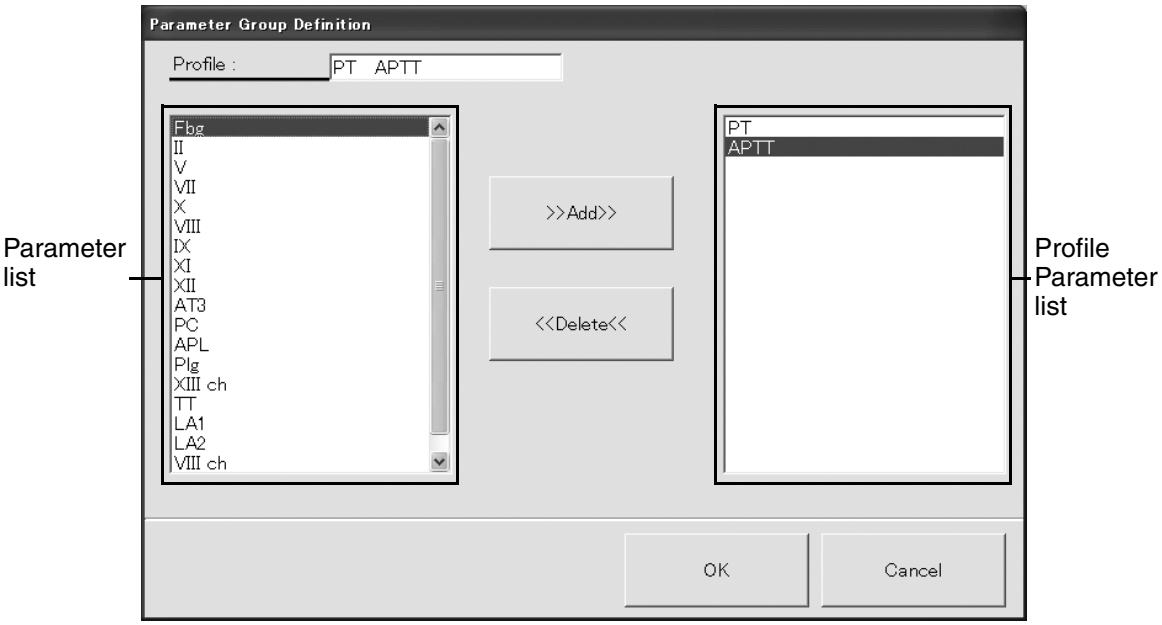

Figure 2-07: Parameter Group Definition dialog box

Profile	The name of the profile selected on the Profiles tab of the customize dialog is displayed. It is possible to directly input a name of a profile. Numerals, alphabetic characters and underbar spaces can be input.
Parameter list	A list of parameters that can be set for a profile is displayed.
Profile parameter list	A list of parameters that have already been set for the profile is displayed.
Add	The parameters that have been selected in the parameter list are added to the bottom of the profile parameters list. Parameters added to the profile parameters list are deleted from the parameters list and remaining parameters on the list are moved up.
Delete	The parameters that have been selected among the profile parameters are deleted from that list. The deleted parameters are inserted into the parameters list according to its display order.

4. Press **OK** once setting is complete.
   The customize dialog box will appear.
5. Press **OK** on the customize dialog box.
   A dialog box appears asking for a restart.
   Press **Cancel** on the customize dialog box to discard the changed settings and close the customize dialog box.

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6. Press **OK**.

> **Note:**
> These settings become effective after the system has been restarted.

Rack number setting
Rack numbers can be customized from the rack number tab of the customize dialog box. Numbers for up to ten racks can be set.

1. Click on the **Rack No.** tab of the customize dialog box.
   The rack number setting screen is displayed.

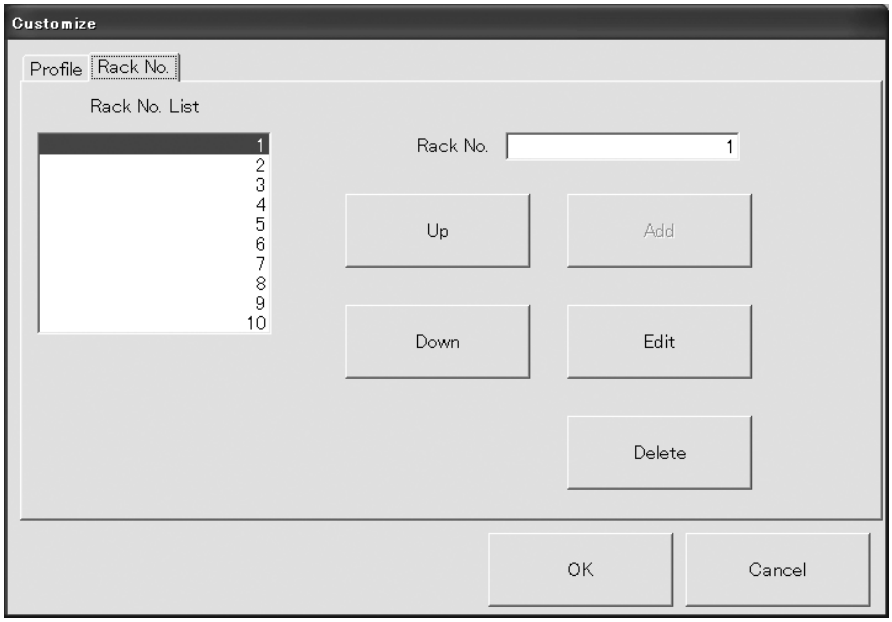

Figure 2-08: Customize dialog box (rack numbers tab)

Rack No. List	A list of rack numbers that have already been registered is displayed.
Rack No.	Displays/inputs the rack number selected in the rack number list.
Up	Moves the cursor position in the rack number list up one line.
Down	Moves the cursor position in the rack number list down one line.
Add	Adds a new rack number. The added rack number is displayed on the bottom line of the rack number list.
Edit	Edits the rack numbers that have already been registered.
Delete	Deletes the rack number selected in the rack number list.

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2. Edit the rack number.

   When adding a new rack number
   Input the rack number you want to add in **Rack No.**, then press **Add**.
   The added rack number is displayed in the rack number list.

   When editing the rack number
   Move the cursor position to the rack number you want to edit in the rack number list. Input the rack number to be edited in **Rack No.**, then press **Edit**.
   The edited rack number is displayed in the rack number list.

3. Press **OK** once editing is complete.
   A dialog box appears asking for a restart.
   Press **Cancel** to discard the changed settings and close the customize dialog box.

4. Press **OK.**

> **Note:**
> These settings become effective after the system has been restarted.

6. Loading presets

Preset orders can be loaded to the order registration screen.

1. Press **Preset** on the operation panel.
   The Read Out Preset dialog box is displayed.

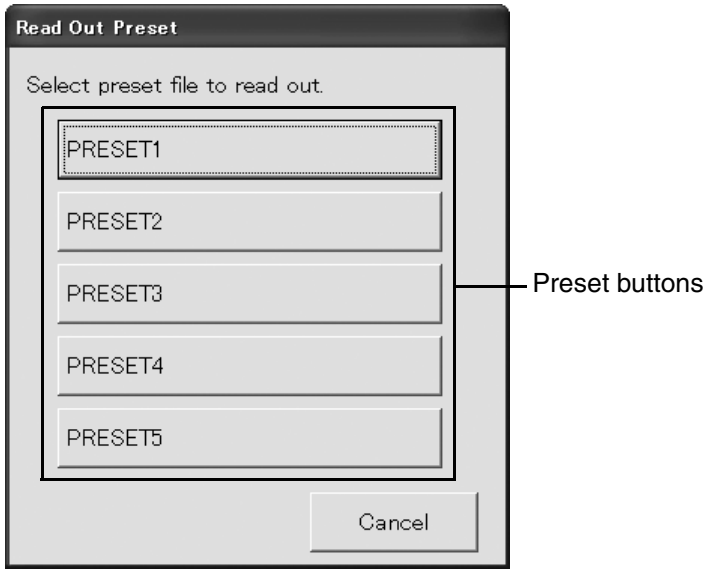

Figure 2-09: Read Out Preset dialog box

Preset buttons	The preset files set under the Save preset dialog box are displayed. (See “Chapter 2: 2.2: 7. Saving presets”).
Cancel	Close the Read Out Preset dialog box without loading a preset order.

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2. Press the Preset button.
   The order set to the preset file on the Order Registration screen is displayed.

> **Note:**
> Use preset loading if you frequently register orders with the same content (QC analysis, etc.). For details on how to save preset files, see “Chapter 2: 2.2: 7. Saving presets”.

7. Saving presets

Up to five preset files can be saved on the Order Registration screen.

1. Input the order on the Order Registration screen.
2. Press **Save preset** on the operation panel.
   The Save preset dialog box will appear.

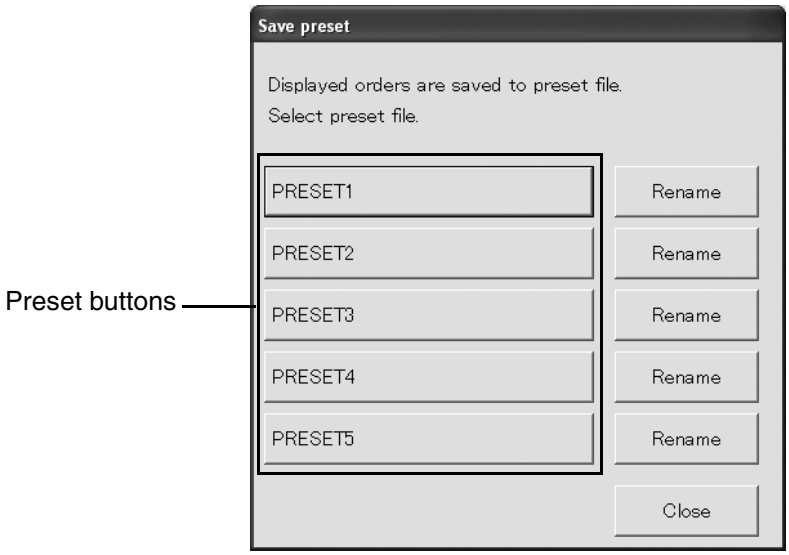

Figure 2-10: Save preset dialog box

Preset buttons	The preset files for the save destination will appear.
Rename	The Change Preset Name dialog box will appear. Change the preset name and press **OK**.

Figure 2-11: Change Preset Name dialog box

Close	Close the Save preset dialog box.

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3. Press the Preset button.
   The Check Preset dialog box appears.
4. Press **OK**.
   The order input on the Order Registration screen is saved to the preset file.

2.3 Registering rack routine sample and QC analysis orders

The method for registering analysis orders for racks of routine or QC samples is described below.

1. Order input

Input the order using the rack and tube position selected on the rack order screen.

1. Select the rack and tube position on the rack order screen for which to input the order.

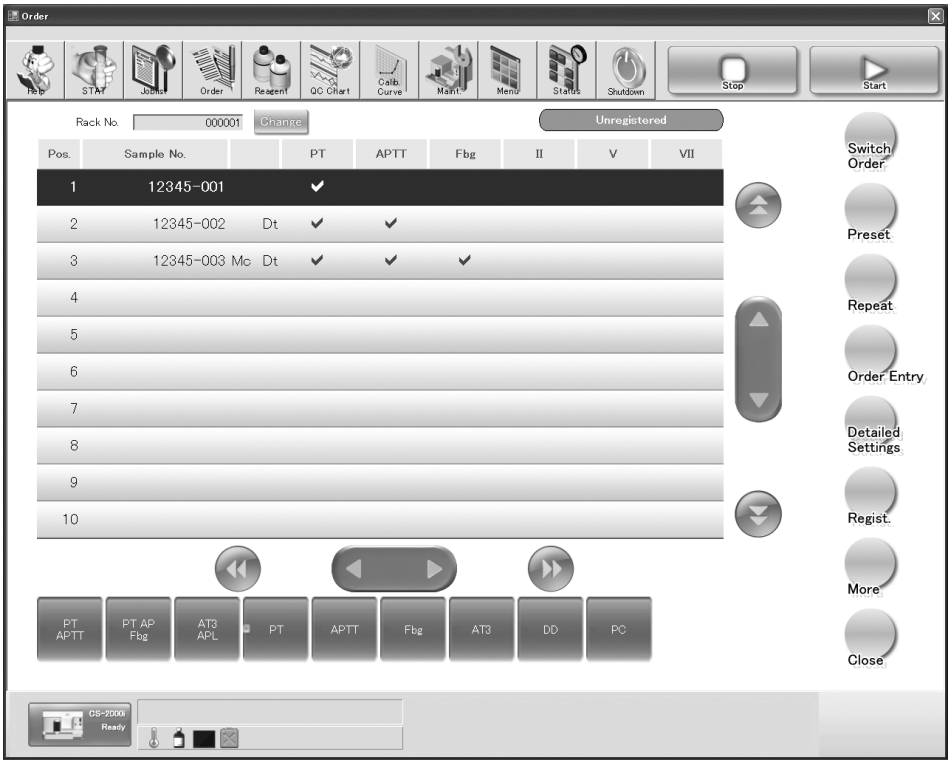

Figure 2-12: Order screen (rack order screen)

2. Press **Order Entry** on the operation panel.
   The order input dialog box will appear.

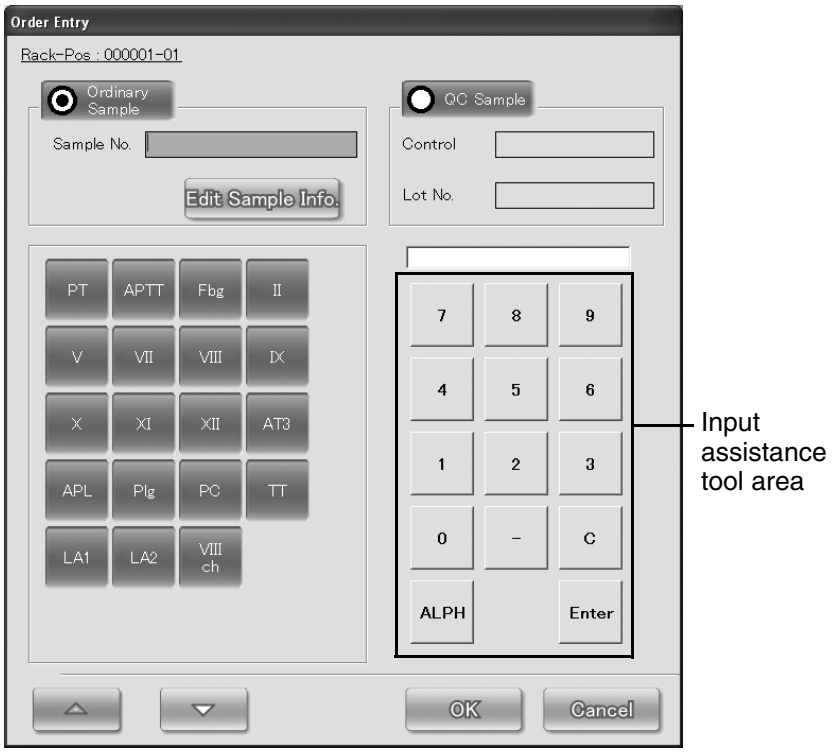

Figure 2-13: Order input dialog box
(If "Ordinaly sample" is selected as the sample type)

Rack-Pos.	The rack number and tube position will appear.
Ordinary Sample	Press to register routine samples. Sample ID number must be entered.
Sample No.	Input the sample number. If the cursor is in this field, the numeric keys are displayed as an input assistance tool.
Edit Sample Info.	The Edit Sample Information dialog box will appear.
QC Sample	Press to register QC samples. The control and lot number must be input.
Control	Input the control to use. If the cursor is in this field, the control list is displayed as an input assistance tool. The control list displays the list of controls registered for quality control. This field cannot be used if **Ordinary Sample** is selected as the sample type.

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Lot No.	If **QC Sample** is selected as the sample type, input the lot number of the control to use. If the cursor is in this field, the list of control lot numbers is displayed as an input assistance tool. The list of control lot numbers displays the lot numbers that have been added for quality control using that control and which are within their expiry dates. This field cannot be used if **Ordinary Sample** is selected as the sample type.
Assay Group	Select the parameters (assay group) to analyze. The analysis parameters are displayed with check boxes, so check the boxes for the parameters to analyze. The analysis parameter check boxes are displayed for the number of registered parameters and if there are more than 20 parameters, use **More** to switch between pages.
More	Switches the displayed page if there are 21 or more parameters. “Current page/Total” is displayed under the button.
Input assistance tool area	This area displays input assistance tools that can be used to input rack-tube positions, sample numbers, controls and lot numbers.
▲	Switches to order input for the next rack-tube position up.
▼	Switches to order input for the next rack-tube position down.

Note:

- Alphanumeric characters and hyphens can be used for sample numbers. Up to 15 characters can be input.
  Alphanumeric characters are only A-Z, a-z, and 0-9. Localized characters cannot be input.
- This instrument has a function for protecting personal information for service use. Patient names are subject to this function, but sample numbers are not. Take care when using content which could be used to identify the patient for a sample number.

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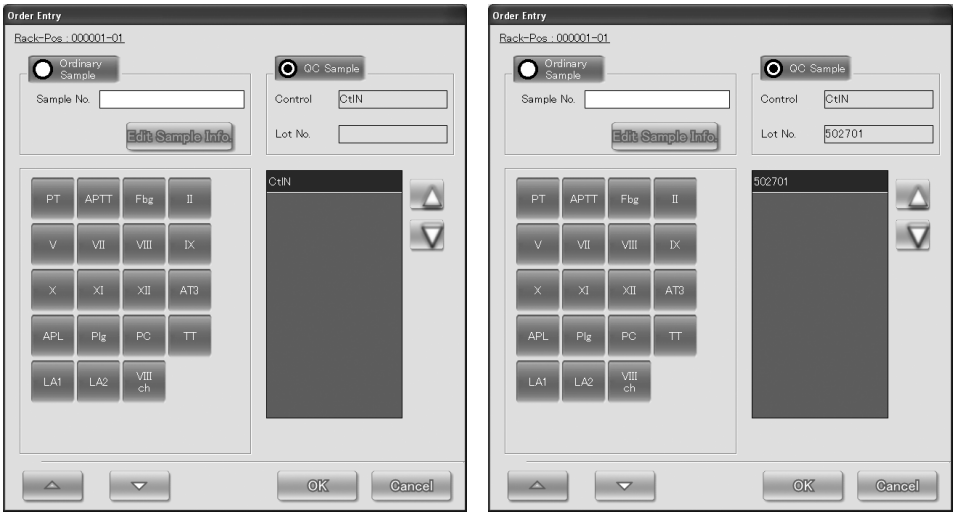
The dialog box used for inputting controls and lot numbers are shown below.



(For control input) **(For lot number input)**

Figure 2-14: Order input dialog box
(If "QC Sample" is selected as the sample type)

3. Select the assay group for which to implement quality control, then select the control type and lot number to use.
   If sample numbers (QC01–QC20) for quality control are used, refer to "Chapter 2: 2.3: 4. Order input (registering quality control analysis orders manually)".
4. Press **OK** once input is complete.
   The input content is reflected in the order screen and the order input dialog box closes. At that stage, the cursor position moves to the rack-tube position that was input last.
   Press **Cancel** to discard the input content and close the order input dialog box.
5. Select an order that has been registered on the rack order screen, then press **Regist.** on the operation panel. The order is registered and reflected in the joblist screen.

Note:
When analysis is started without pressing **Regist.** on the operation panel, orders entered on the screen are automatically registered.

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2. Repeat input

Analysis order (analysis parameters and detailed settings) at the selected rack-tube position on the rack order screen can be set to repeat automatically.
However, sample information will not be copied. Sample numbers on the rack order screen are assigned by counting up in increments of one from the selected order.
If the number of repeats extends to the next rack, the number for the next racks is assigned as one higher than the selected rack number.
Quality control orders cannot be repeated.
This operation button only appears on the operation panel of the rack order screen.

1. Select the analysis order at the rack-tube position to be used for repeat input, then press **Repeat** on the operation panel.
   The repeat entry dialog box will appear.

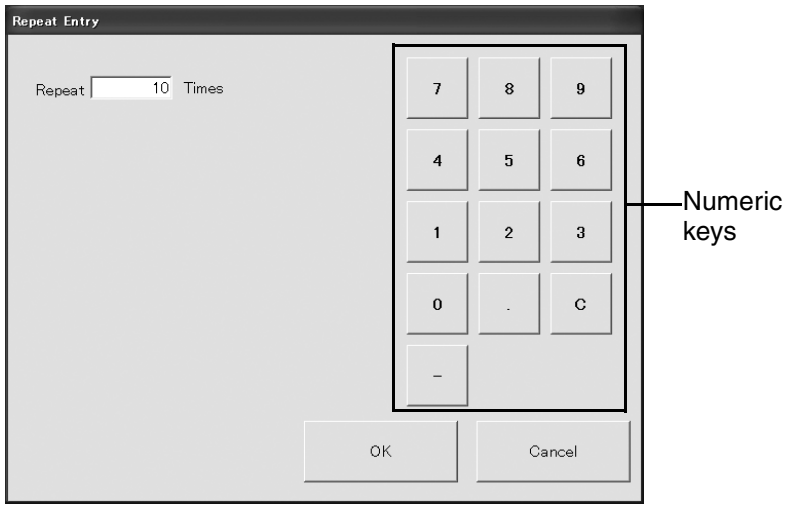

Figure 2-15: Repeat input dialog box

Repeat	Input the number of repetitions. When the repeat input dialog box is displayed, the number of samples from the current cursor position to the lowest position in the same rack on the rack order screen is displayed.
Numeric keys	Input the number of repetitions.

2. Input the number of repetitions and press **OK**.
   The order is repeated as many times as the input number of repetitions and the repeat entry dialog box closes. The cursor position on the rack order screen after the repetitions is the same as the original order position.
   Unless the number of repetitions has been blank or is outside the input range, a warning dialog box is displayed and the repeat entry dialog box does not close.
   Press **Cancel** to close the repeat entry dialog box.

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3. Detailed settings

The detailed analysis method can be set for the rack-tube position that is selected on the rack order screen. This operation button is not displayed on the operation panel of the holder calibration curve order screen.

1. Press **Detailed Settings** on the operation panel.
   The detailed settings dialog box will appear.

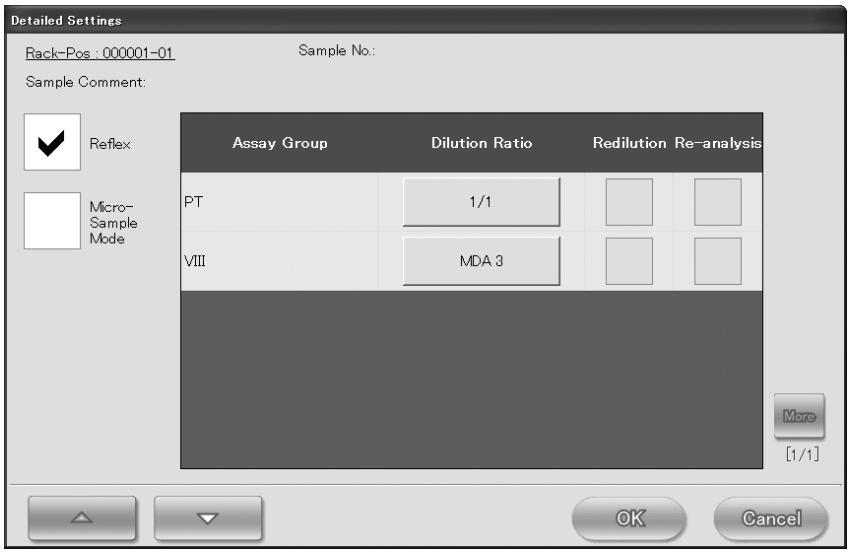

Figure 2-16: Detailed settings dialog box

Rack-Pos.	The rack-tube position to make detailed settings for will appear. If the rack-tube position has not been input by order input, the display is blank.
Sample No.	The ordered sample number to make detailed settings for will appear. If the sample number has not been input by order input, the display is blank.
Sample Comment	Sample comment is displayed to allow input for sample information that have been input by the order input. This display is blank if no sample comments have been input.
Reflex	Sets whether or not to perform reflex analysis. Check the box to perform reflex analysis. If that is checked, micro-sample mode cannot be used. Remove the check mark from the box to avoid performing reflex analysis.
Micro-Sample Mode	Sets whether or not to perform analysis in micro-sample mode. Check the box to perform analysis in micro-sample mode. If that is checked, reflex analysis, redilution and repeat analysis cannot be used. Remove the check mark from the box to perform analysis in normal (aspiration) mode.

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Assay Group	The parameters ordered for analysis by order input (the assay group) are displayed. If six or more parameters are ordered, use **More** to switch the page.
Dilution Ratio	Sets the dilution ratio. Press the buttons to display the dilution ratio selection box. The button is marked with the set dilution ratio.
Redilution	Sets whether or not to perform redilution analysis. Check the box to perform redilution analysis automatically. However, this box cannot be checked if the analysis is performed in micro-sample mode, or if MDA is specified as the dilution ratio.
Re-Analysis	Sets whether or not to perform repeat analysis. Check the box to perform repeat analysis automatically. However, this box cannot be checked if the analysis is performed in micro-sample mode, or if MDA is specified as the dilution ratio.
More	Switches the displayed list page if there are 6 or more parameters. “Current page/Total” is displayed under the button.
▲	The dialog box switches to display content for the next rack-tube position up on the rack order screen.
▼	The dialog box switches to display content for the next rack-tube position down on the rack order screen.

2. Perform detailed setting for the analysis.

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3. Press **Dilution Ratio** to change the dilution ratio.
   The dilution ratio dialog box will appear.

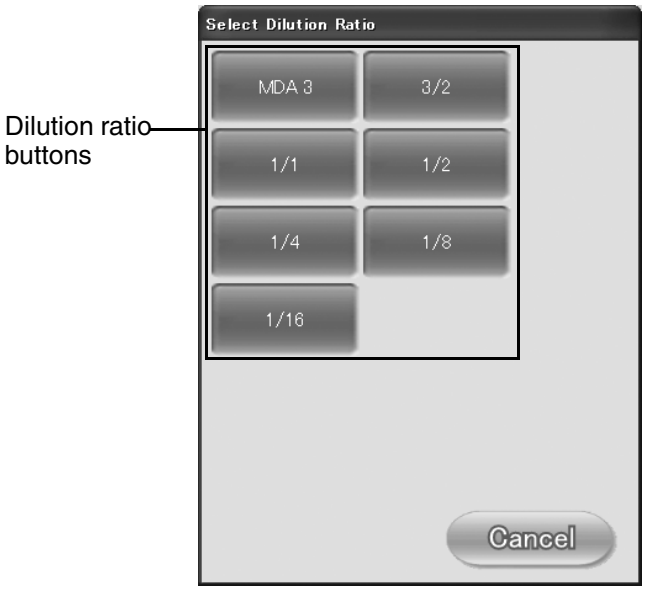

Figure 2-17: Dilution ratio selection dialog box

Dilution ratio buttons	Dilution ratios available for selection are displayed.
Cancel	Closes the dilution ratio selection dialog box.

4. Press appropriate button to set the desired dilution ratio.
   The dialog box closes and the ratio is set.
5. Press **OK** to end detailed setting.
   The input content is reflected in the order screen and the detailed settings dialog box closes. At that stage, the cursor position moves to the rack-tube position that was input last.
   Press **Cancel** to discard the input content and close the detailed settings dialog box.

Note:
- If the dilution ratio has been altered, remove the check mark from Reflex. Also remove check marks from Redilution and Re-Analysis for altered parameters. When performing Reflex, Redilution or Re-analysis, manually check the corresponding box.
- Reflex, Redilution and Re-analysis will not be executed, if the sample is analyzed in the micro-sample mode.

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4. Order input (registering quality control analysis orders manually)

Sample numbers (QC01–QC20) can be used to register manual quality control orders from the Rack Order screen and perform QC analysis.

1. Set the QC barcode. (For details see “Chapter 6: 6.8 QC barcode setting”)
2. Press **Order** on the toolbar of the IPU menu screen.
   The Rack Order screen is displayed.
3. Select the rack-tube position to be used for order input, then press **Order Entry** on the operation panel.
   The order input dialog box is displayed.
4. Place a check against **QC Sample**.
5. Input a quality control sample number (QC01–QC20) as the **Sample No.** under **Ordinary Sample**.
6. Click on the assay group to analyze, to add a mark.

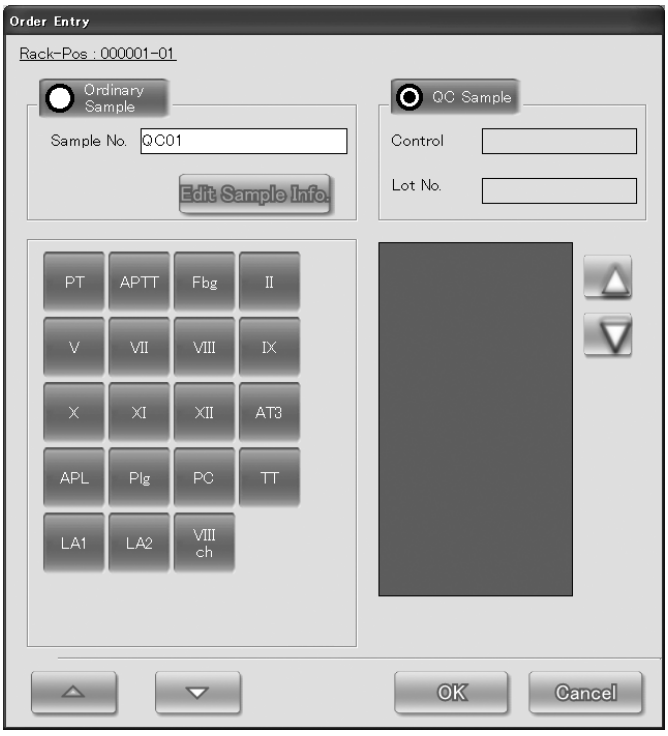

Figure 2-18: Order input dialog box

7. Press **OK**.
   The input content is reflected in the rack order screen and the order input dialog box closes.
8. On the rack order screen, select the order to register, then click on **Regist.** on the operation panel.
   The order is registered, and reflected in the joblist screen.

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2.4 Holder calibration curve analysis order registration

The Holder Calibration Curve Order screen can be used to register a calibration curve order using a calibrator placed on the reagent table.
Press **Switch Order** on the operation panel to display a holder calibration curve order screen.

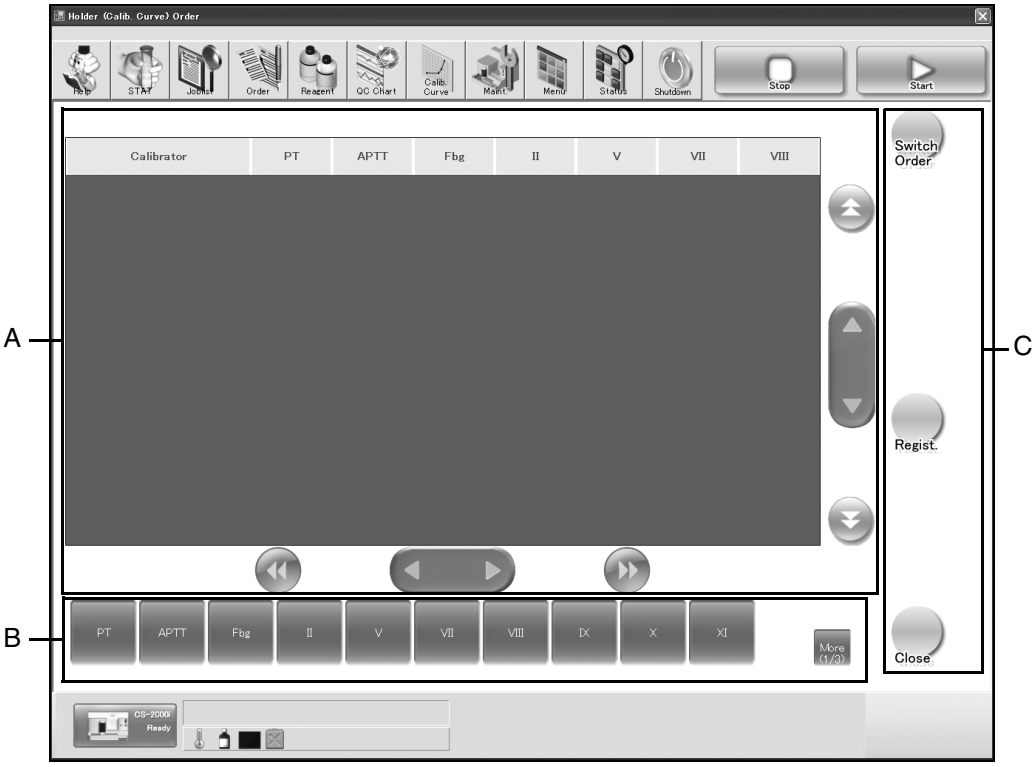

Figure 2-19: Holder Calibration Curve Order screen

A Holder calibration curve order display area
Registered calibration curve orders for each holder are displayed.

Calibrator	Calibrators used for analysis are displayed.
Order parameters	The assay group name will appear. All valid assay groups registered under assay group settings are displayed from the left, in the display order. Parameters for which there are orders have a check mark "✓" displayed.
▶▶	Shifts the parameters one page to the right.
◀◀	Shifts the parameters one page to the left.
◀ ▶	Press ▶ to move the selection cursor one column to the right. Press ◀ to move the selection cursor one column to the left.
▲▲	Shifts the samples one page up.
▼▼	Shifts the samples one page down.

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▲ ▼	Press ▲ to move the selection cursor one line up. Press ▼ to move the selection cursor one line down.

B Order parameter buttons area

Buttons are displayed for the parameters registered in the order list.

Parameter buttons	Buttons are displayed for all assay groups, including calibration curve assay parameters inside assay groups. Press a button to display the calibration curve order input dialog box. (See “Chapter 2: 2.4: 1. Order input”.)

C Operation panel area

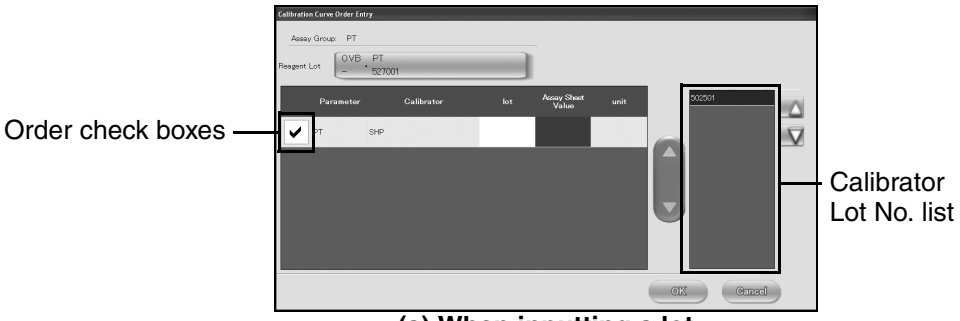
Operation buttons used on the holder calibration curve order screen are displayed.

Switch Order	The Change Order dialog box will appear. (See “Chapter 2: 2.2: 3. Changing the order screen”.)
Regist.	Registers the order input from the holder calibration curve order screen. Once registered, the content of the order is reflected in the joblist screen and is not displayed in the holder calibration curve order screen.
Close	Closes the holder calibration curve order screen.

Revised April 2013

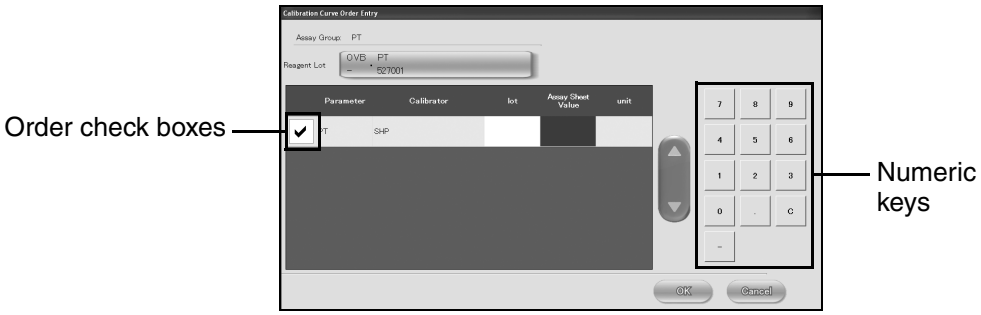
1. Order input

1. Select the assay group for which to analyze a calibration curve.
   The calibration curve order input dialog box will appear.
2. Input an order for a calibration curve analysis using a calibrator placed on the reagent table.



(a) When inputting a lot

Figure 2-20: Calibration Curve Order Input dialog box -01



(b) When inputting display values

Figure 2-21: Calibration Curve Order Input dialog box -02

Assay Group	The parameters for inputting the calibration curve order (the assay group) are displayed. The parameters selected on the holder calibration curve order screen are displayed.
Reagent Lot	Sets the reagent lots to use in calibration curve analysis. This area comprises buttons and the reagent lots used are displayed on the buttons. Press a button to display the reagent lot selection dialog box.
Order check boxes	Set calibration curve analysis orders. Make check marks for the parameters to receive calibration curve analysis. If the check mark is omitted, calibration curve analysis will not be performed for that parameter.

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Parameter	The parameter registered for calibration curve (assay parameter) is displayed. Assay parameter is only displayed if it is registered as assay parameter for which to input calibration curve orders and for which a calibrator has been registered.
Calibrator	Calibrators used in calibration curve analysis are displayed. Calibrators registered under the calibration curve settings for assay parameter settings are displayed.
lot	Sets the calibrator lot to use in calibration curve analysis. Cells can be selected from the list by pressing them directly. The lot number with the most distant expiry date is displayed from among the lots set on the reagent table. The display is blank if none are set on the reagent table.
Assay Sheet Value	Inputs the calibrator display value. The value can be input by pressing the cell directly. When the cursor is here, the numeric keys are displayed as the input assistance tool, for use in input.
unit	The unit for the assay parameter is displayed. If there is no unit, the display is left blank.
Calibrator Lot No. list (When inputting a lot)	If the input cursor is on the lot, the calibrator lot is displayed on the list. The list displays the lot numbers for calibrators that are listed under calibrators and are set on the reagent table. The display is blank if none is set on the reagent table. The lot number selected on the calibrator lot No. list will be set for the lot. At that stage, the display value is also updated to correspond to the lot.
▲ (When inputting a lot)	Moves the selection cursor one line up in the calibrator lot list.
▼ (When inputting a lot)	Moves the selection cursor one line down in the calibrator lot list.
Numeric keys (When inputting display values)	The numeric keys are displayed while the input cursor is on the display value. Use to input the display value.

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3. Press **Reagent Lot** to select the reagent lot.
   The Reagent Lot Selection dialog box will appear.

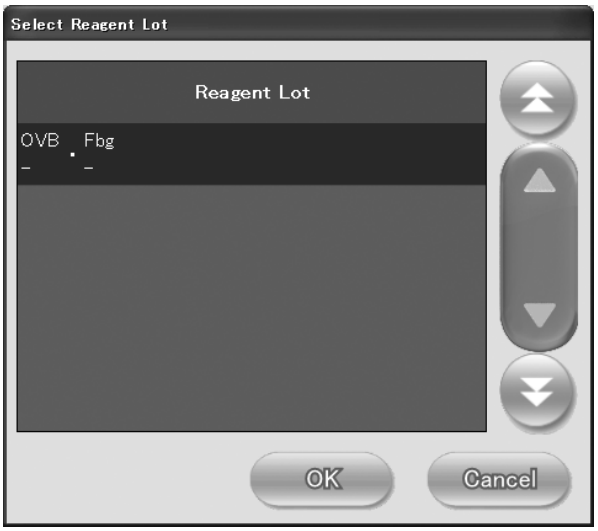

Figure 2-22: Reagent Lot Selection

Reagent Lot — The list of reagent lots (sets) that are in place on the reagent table and can be used for calibration curve setting is displayed.
The list displays one reagent lot (set) on two lines. The upper line shows the reagent name and the lower shows the lot number.
Use ▲ and ▼ to move the cursor up and down.

4. Select the reagent lot from the reagent lot list, then press **OK**.
   The reagent lot selected from the reagent lot list is reflected in the calibration curve order input dialog box and the Reagent Lot Selection dialog box closes.
   Press **Cancel** to close the Reagent Lot Selection box dialog box.
5. Make check marks next to parameters for which to analyze calibration curve analysis.
6. Select the lot number of the calibrator.
7. Enter the assay value of the calibrator.
8. Repeat steps 5-7 for each parameter.
9. Press **OK** once calibration curve order input is complete.
   The content input from the calibration curve order input dialog box is reflected in the rack calibration curve order screen and the calibration curve order input dialog box closes.
   Press **Cancel** to discard the content input to the calibration curve order input dialog and close the dialog box.
10. Press **Regist.** to confirm the calibration curve order.
    The input order is reflected on the Joblist screen.

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Note:
When analysis is started without pressing **Regist.** on the operation panel, orders entered on the screen are automatically registered.

2.5 Holder QC order registration

Holder QC order screen allows you to place QC samples on the reagent table and register orders for their analysis.
Press **Switch Order** on the operation panel to display the Holder QC Order screen.

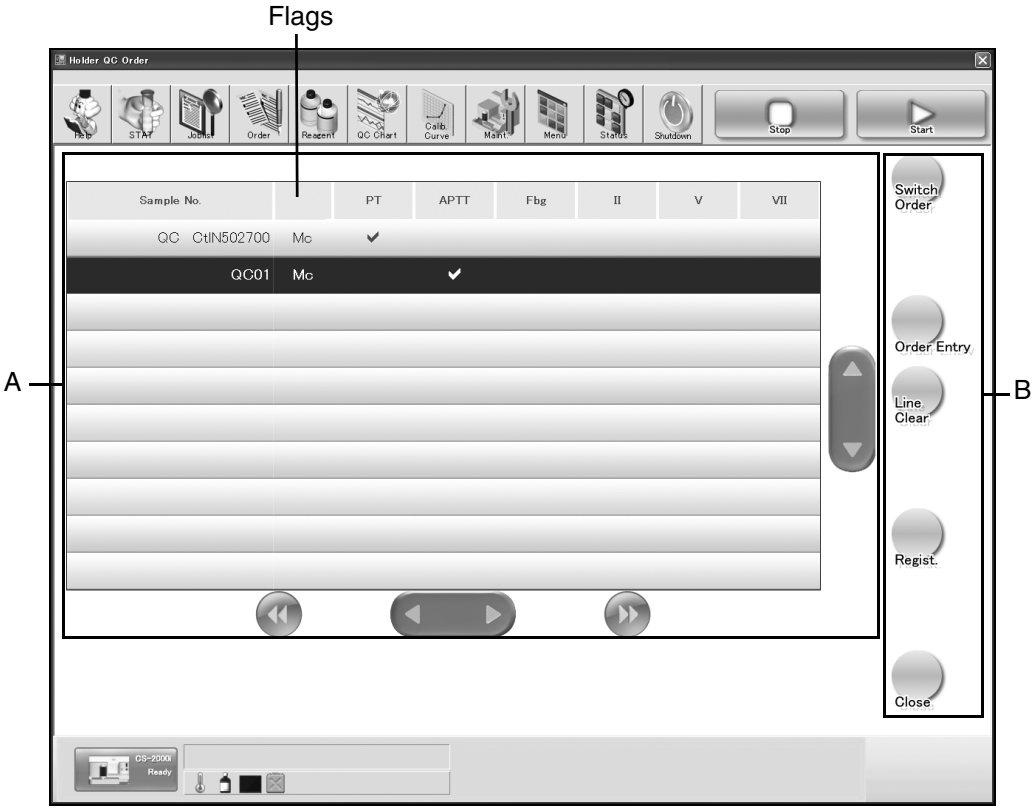

Figure 2-23: Holder QC order screen

A Holder QC Order display area
This area displays registered holder QC orders.

Sample No.	Sample number is displayed.
Flags	Analysis mode is displayed. “Mc” is displayed, indicating micro-sample mode.

Note:
Holder QC is always analyzed in micro-sample mode.

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Order parameters	The assay group name is displayed. Assay group names that have been registered under assay group settings, have **Perform QC** checked, and are valid are displayed from the left in display order. Parameters for which there are orders have check mark "✓" displayed.
▶▶	Switches the display items (columns) one page to the right.
◀◀	Switches the display items (columns) one page to the left.
◀ ▶	Press ▶ to move the selection cursor one column to the right. Press ◀ to move the selection cursor one column to the left.
▲ ▼	Press ▲ to move the selection cursor one line up. Press ▼ to move the selection cursor one line down.

B Operation panel area

Switch Order	The Change Order dialog box will appear. (See "Chapter 2: 2.2: 3. Changing the order screen".)
Order Entry	The order input dialog box will appear. (See "Chapter 2: 2.3: 1. Order input".)
Line Clear	Deletes data in the line indicated as registered.
Regist.	Register the order that was input from the holder QC order screen. Once registered, the content of the order is reflected in the joblist screen. Orders registered in the joblist cannot be edited from the Order screen.
Close	Closes the holder QC order screen.

1. Order input

1. On the Holder QC Order screen, select the line into which to input the order.
2. Press **Order Entry** on the operation panel.
   The order input dialog box will appear.

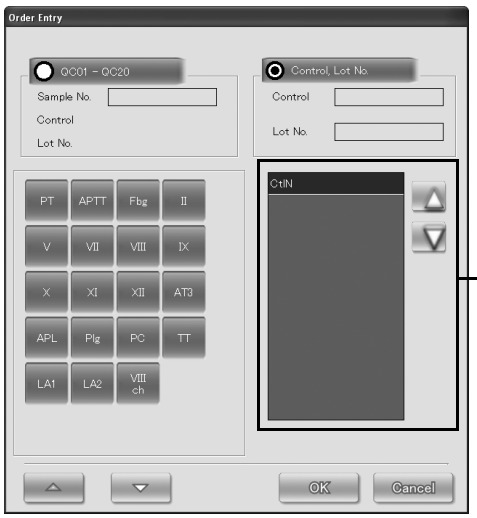

Figure 2-24: Order input dialog box

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QC01-QC20	When selecting from the QC sample numbers to order, press this button.
Sample No.	Input the QC sample number. When the cursor is in this field, the list of QC sample numbers (QC01-QC20) is displayed in the input assistance tool area. The list of sample numbers displays those for which a control has been set under the QC barcode settings. For details, see “Chapter 6: 6.8 QC barcode setting”.
Control	The control name set for the selected number from QC01-QC20 is displayed.
Lot No.	The lot number set for the selected number from QC01-QC20 is displayed.
Control, Lot No.	When selecting the control and lot number to order, press this button.
Control	Input the control to use. When the cursor is in this field, the control list is displayed in the Input assistance tool area. The control list displays the controls that have been registered for quality control and are placed on the reagent table.
Lot No.	Input the lot number of the control to use. When the cursor is in this field, the control lot number list is displayed in the Input assistance tool area. The control lot number list displays lot numbers that have been added to QC lots for this control, have been placed on the reagent table, and are within the expiration date.
Assay Group	Select the parameters (assay group) to analyze. The analysis parameters are displayed with check boxes, so check the boxes for the parameters to analyze. The analysis parameter check boxes are displayed for the number of registered parameters and if there are more than 20 parameters, use **More** to switch between pages.
More	Switches the displayed page if there are 21 or more parameters. “Current page/Total” is displayed under the button.
Input assistance tool area	This area displays the input assistance tool used when inputting sample numbers, controls and lot numbers for QC purposes.
▲	Switches to order input for the next line up.
▼	Switches to order input for the next line down.

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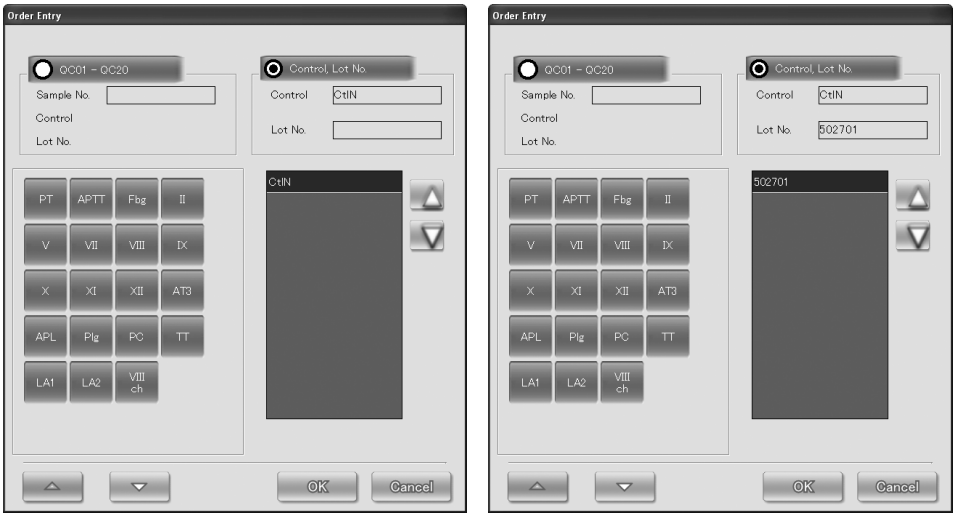
The dialog boxes for each order specification method are shown below.



(For control input) **(For lot number input)**

Figure 2-25: Order Input dialog box
(when “Control, Lot No.” is selected as the order specification method)

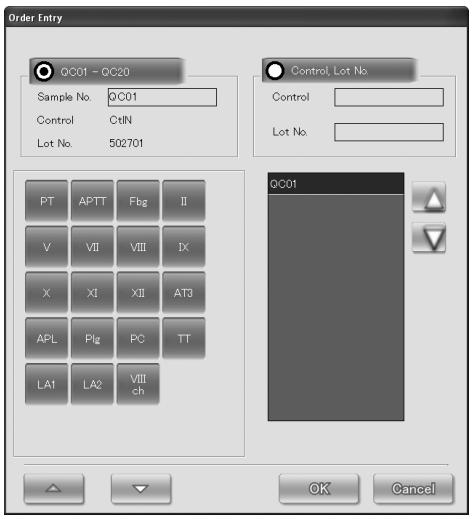


Figure 2-26: Order Input dialog box
(when “QC01-QC20” is selected as the order specification method)

3. Select the assay group for which to implement quality control, then select the control type and lot number to use.
   When “QC01-QC20” is selected, select the QC sample number (QC01-QC20).
4. Press **OK** once input is complete.
   The input content is reflected in the order screen and the order input dialog box closes. Press **Cancel** to discard the input content and close the order input dialog box.
5. Press **Regist**. on the operation panel. The order is registered and reflected in the joblist screen.

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Note:
When analysis is started without pressing **Regist.** on the operation panel, orders entered on the screen are automatically registered.

2.6 Registration of STAT orders

With STAT orders, analysis orders can be registered for the samples which are placed in STAT holders.

1. **Display of the STAT order registration screen**
   Press **STAT** on the toolbar to place a STAT order.

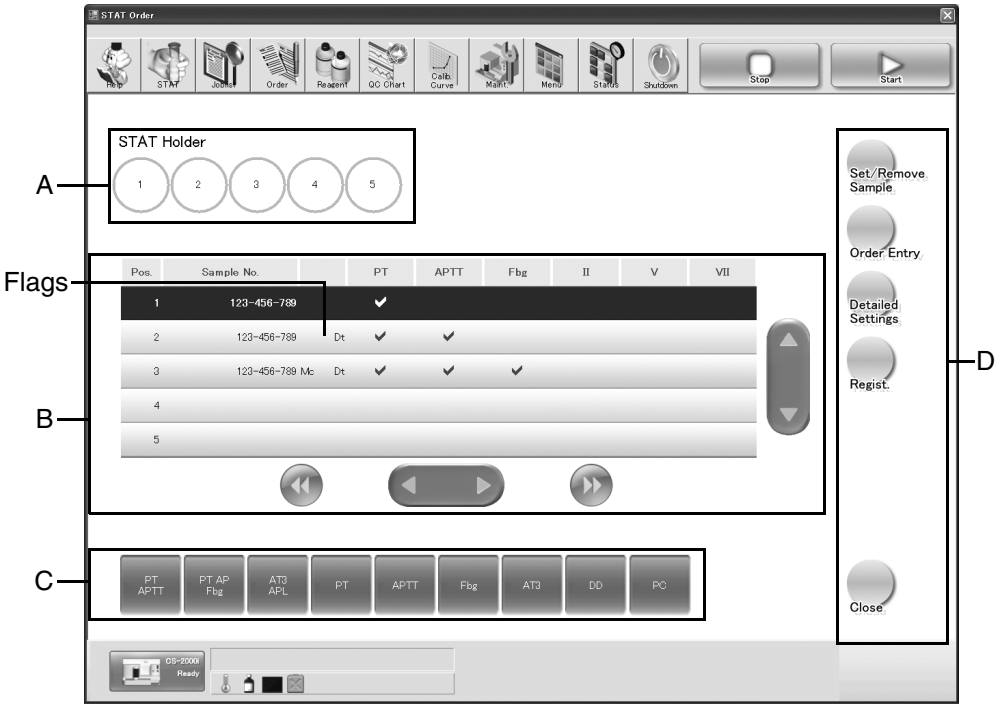

Figure 2-27: STAT order screen

The STAT order screen is composed as described below.

A Indicator display area
The status of samples set in the STAT holder, and the analysis status, are displayed.

B Order list display area
Orders are displayed for the samples placed in the STAT holder.

C Profile button display area
Profile buttons registered by customization are displayed here.

D Operation panel area
Operation buttons used on the STAT order screen are displayed.

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The various areas are described below.

Indicator display area
The status of samples set in the STAT holder and the analysis status are displayed by indicators.

The displayed indicators distinguish STAT samples by status.

Table 2-03: STAT sample status

		Analysis orders		
		Unconfirmed/ None	**Confirmed**	**Analyzed**
Sample	**No**	(1)		
	Yes	(2)	(3)	(4)

Table 2-04: Indicator types and status

Indicator	Status
White	Samples can be set. (1)(2)
Red	The sample cannot be removed because it has not yet been analyzed nor dispensed. (3)
Blue	The sample can be removed because dispensing and analysis have been completed. (4)

Order list display area
Registered orders are displayed in the order list display area.

Pos. Displays the location of the STAT holder.

Sample No. Sample number is displayed.
Press **Order** on the operation panel to display the order input dialog box, then input the sample number. A mouse and keyboard can be used for direct input.

Flags Flags indicate the status of detailed settings for the order. They indicate whether any changes have been made in detailed order settings (any change from the default analysis settings), and the analysis mode.

Table 2-05: Flag display

		Changing detailed settings	
		Yes	**No**
Analysis mode	**Normal**	“Dt”	“ ” (space)
	Micro	“Mc Dt”	“Mc”

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Note:
If the sample volume is minimal, you can analyze in micro-sample mode.
In micro-sample mode, expanded functions such as automatic re-analysis will not be performed. When there are many analysis parameters, it takes time to complete analysis because dispensing is performed directly from the tube or the sample cup.

Parameters	The assay group name will appear.
Check	The parameter for which there is an order has a check mark "✓" displayed. Orders can be input using the order input dialog box or by pushing the profile button. A cell can also be clicked directly to order (reverse the "✓").
▶▶	Switches the display items (columns) one page to the right.
◀◀	Switches the display items (columns) one page to the left.
◀ ▶	Moves the displayed item (column) one place to the left or right.
▲ ▼	Moves the cursor up and down.

Profile button display area
Buttons for the profile orders registered in the order list are displayed in the profile button display area.

Profile button	One or more parameters that have been registered under Customize are made into a set and ordered. When a button is pressed, a mark appears on the Profile button. Use the Customize dialog box to register and change Profile button.

Operation panel area
Operation buttons used on the STAT order screen are displayed.

Set/Remove Sample	Moves the STAT sample holder to a position where it is accessible. When the STAT holder moves to an accessible position, the STAT/buffer table cover LED of the Main Unit turns green, indicating that the cover can be opened.
Order Entry	The order input dialog box will appear. (See "Chapter 2: 2.3: 1. Order input".) If the selected order is not able to be edited at that time, the edit parameters are also disabled and only the **Cancel** is enabled in the order input dialog box.

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Detailed Settings	The detailed settings dialog box will appear. (See “Chapter 2: 2.3: 3. Detailed settings”.) If the selected order is not able to be edited at that time, the edit parameters are also disabled and only the **Cancel** is enabled in the detailed settings dialog box.
Regist.	Registers the order input from the STAT order screen. Once registered, the content of the order is reflected in the joblist screen.
Close	Closes the STAT order registration screen.

2. Sample preparation and the start of analysis

The preparation of STAT samples and the method for starting analysis are described below.

1. Press **Set/Remove Sample** on the operation panel.
   The Confirmation dialog box will appear.
2. Press **OK** on the Confirmation dialog box to interrupt analysis and move the STAT holder to an accessible position.
   The Executing dialog box appears until the movement is complete.
3. When STAT holder movement is complete, the Executing dialog box closes automatically.
   At that stage, the STAT/buffer table cover LED of the Main Unit turns green, indicating that the cover can be opened.
   Open the STAT/buffer table cover and set the sample in the STAT holder.
4. Input the order for the sample set in the STAT sample holder, then press **Regist.**
5. Close the STAT/buffer table cover and press **OK** on the barcode read dialog box
   The barcode reading will start.
6. Press the Start button on the Main Unit, or **Start** on the IPU menu screen toolbar.
   STAT sample analysis starts.
7. After STAT sample analysis, press **Set/Remove Sample**.
   Take the analyzed sample out of the STAT holder.

Revised April 2013

3. Joblist

This chapter explains the functions of the joblist.
Orders and progress/analysis results can be displayed using the joblist.

3.1 Overview

Major joblist functions:

Order
Orders are registered via the operation panel on the main screen of the joblist. For details, see “Chapter 2 Order Registration”.

Browser
Analysis results are graphically displayed via the operation panel on the main screen of the joblist. For details, see “Chapter 4 Browser”.

Validate
Analysis results are validated in two ways, automatic or manual validation.

Display condition
The display conditions for the analysis results list can be set.

Find
Analysis results displayed in the analysis results list can be searched.

Marking
Selected results in an analysis results list are marked.

Print
Analysis results are printed out.

Host output
Analysis results are output to the host.

Delete
Selected results in an analysis results list are deleted.

Edit
Analysis orders are edited for the samples not yet analyzed, or sample information is edited for already analyzed samples.

Recalculate
Calculated parameters can be recalculated.

Export
Selected results in an analysis results list are exported.

Customization
Display parameters in a joblist are customized.

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3.2 Joblist display

The display function can display all registered orders (samples/QC/calibration curves), their state of progress and analysis results.

> **Note:**
> When a new analysis result is obtained, the list is updated within 30 seconds. However, when in mark mode, the list is not updated until mark mode is ended.

The joblist can be displayed by the method below.

- Press **Joblist** on the toolbar.

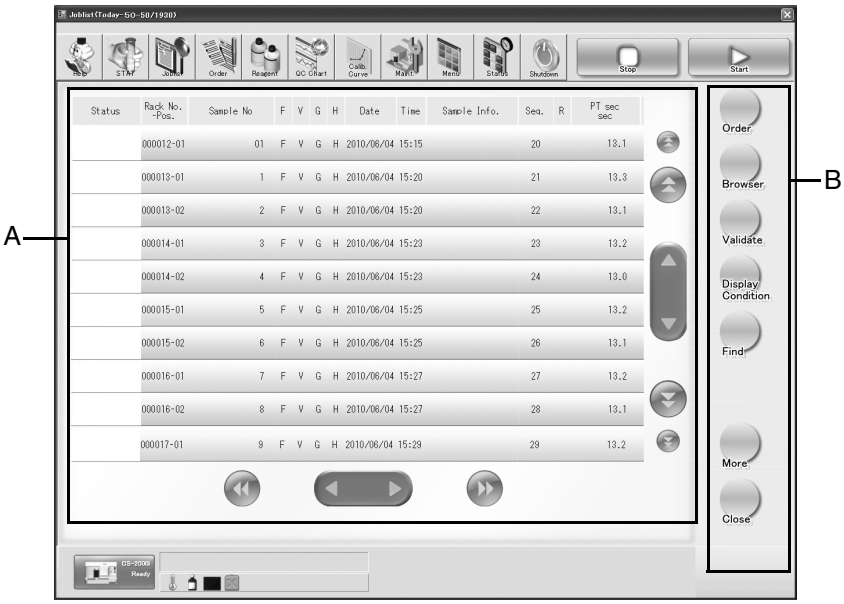

Figure 3-01: Result Display screen (joblist main screen)

A List display area
Information on all registered orders for samples, QC and calibration curves are displayed together with the analysis results. The display can be changed using tabs. The tabs and the listed content within each tab can be set using the Customize function.

List	Displays job information as a list. Up to 20 lines can be displayed on one screen. The displayed parameters (columns) can be customized. See “Table 3-01 Table of list display items” for information on list display items.
⏫	Moves the line selection cursor to the line at the start of the list.
⏬	Moves the line selection cursor to the line at the end of the list.

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▲▲	Displays the page above. The cursor does not move in the process.
▼▼	Displays the next page down. The cursor does not move in the process.
▲	Moves the line selection cursor up one line. When the cursor reaches the top displayed line, the display scrolls up one line.
▼	Moves the line selection cursor down one line. When the cursor reaches the bottom displayed line, the display scrolls down one line.
◀◀	Scrolls one page to the left. Page scrolling scrolls parameters other than fixed parameters.
▶▶	Scrolls one page to the right. Page scrolling scrolls parameters other than fixed parameters.
◀	Scrolls one parameter to the left. Parameter scrolling scrolls parameters other than fixed parameters.
▶	Scrolls one parameter to the right. Parameter scrolling scrolls parameters other than fixed parameters.

B Operation panel area

Buttons for operating the main screen of the joblist are displayed.

1st page

Order	Displays the Order Registration main screen.
Browser	Displays the analysis result in the cursor line in the browser window.
Validate	Performs validation of analysis results.
Display Condition	A Display Conditions dialog box appears. Use it to select conditions for inclusion in the list display. The buttons are marked with the names of display conditions.
Find	The Find dialog box is displayed to allow searching for a specific sample etc. within the displayed list.

2nd page

Mark	Appends marks to analysis results. The operation panel is changed to mark mode.
Print	Prints out analysis results. The Printing dialog box will appear.
HC Output	The analysis data is output to the host. The Host Output dialog box will appear.
Delete	Analysis results for completed analyses and orders that have not yet been analyzed can be deleted. The Deleting dialog box appears.

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Edit — If analysis of the sample in the line selected in the list display area has not yet started, the Modify Order screen is displayed. If analysis has been completed, the Edit Sample Information dialog box is displayed. A warning dialog box appears if the sample is being analyzed.

Recalculate — This function recalculates calculated parameters. The Select Test to Recalculate dialog box will appear.

3rd page

Export — Exports analysis results displayed in the analysis results list. The Export dialog box will appear.

Customize — Customizes the Joblist screen. The Customize dialog box will appear.

Common to the 1st to 3rd pages

More — If the Operation panel comprises multiple pages, use this button to switch between pages.

Close — The Joblist screen closes.

Table 3-01: Table of list display items

Parameters	Summary and display explanation		
Status	Displays whether analysis of the sample has started and whether it has been completed.		
	Pending	Indicates a job that has been ordered but which has not started analysis.	
	Processing	Indicates that one of the analysis parameters is being analyzed.	
	On Hold	Indicates that all analysis parameters have been completed but the calibration curve has not been confirmed, so calculation parameters cannot be calculated.	
	“ ” (space)	This indicates that analysis of all analysis parameters has been completed normally.	
	Review	This indicates that analysis of all analysis parameters has been completed but a issue that requires confirmation by the user has occurred in one or more parameters.	
	Error	This indicates that analysis of all analysis parameters has been completed but an error has occurred in one or more parameters.	
Rack No. - Pos.	Indicates the rack number and tube position where the sample was placed. For the STAT Sample Table, STAT-Holder No. (1-5) is displayed. If calibrators have been placed on the reagent table, “REAG” is displayed.		
Sample No.	Indicates sample ID numbers and whether any numbers have been duplicated. If any sample ID numbers are duplicated and have the same analysis date, an asterisk “*” is displayed on the right side of the sample ID number.		
F (Final flag)	This flag marks the final data in a set of analysis data containing multiple lines.	F	Indicates that this is the final line.
		“ ” (space)	Indicates that this is not the final line.

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Table 3-01: Table of list display items

Parameters	Summary and display explanation		
V (Validation flag)	This flag indicates the validation status of the analysis result.	V	Indicates that the result has been validated.
		" " (space)	Indicates that the result has not been validated.
G (Not output indicator)	Indicates that the result has not been printed out.	G	Indicates that the result has not been printed out.
H (Not output indicator)	Indicates that the result has not been output to the host.	H	Indicates that the result has not been output to the host.
Date (Analysis date and time)	Indicates the date and time when analysis of the sample began.		
Seq (serial No.)	Displays the sequential number, counting from when the power was turned ON.		
Sample No. Attribute (ID Information)	Indicates the origin of the sample ID No.	A	Indicates that the number was assigned automatically by the instrument.
		B	Indicates that the number was read from a barcode.
		C	Indicates that the number was specified by the host.
		M	Indicates that the number was input manually.
Sample Info.	Indicates the results of the check for inhibitors in the sample (only in normal mode) and the sample volume check.	"Hem"	Indicates that the hemolytic check exceeded the acceptance limit.
		"H*"	Indicates that the influence of turbidity or other inhibitor in the sample prevented an accurate hemolytic check.
		"Ict"	Indicates that the icteric check exceeded the acceptance limit.
		"I*"	Indicates that the influence of turbidity or other inhibitor in the sample prevented an accurate icteric check.
		"Lip"	Indicates that the lipemic check exceeded the acceptance limit.
		"L*"	Indicates that strong turbidity in the sample prevented an accurate lipemic check.
		"Vol"	Indicates that the sample volume check exceeded the preset range.
		"-"	Indicates that no volume check was carried out for that sample.
		" " (space)	Indicates that hemolytic, icteric and lipemic checks were all below the acceptance limits and the sample volume check fell within the preset range.

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Table 3-01: Table of list display items

Parameters	Summary and display explanation		
Sample Type	Indicates the sample category: Routine sample/ STAT sample/QC sample/ calibrator.	" " (space)	Indicates that the sample is a routine sample.
		S	Indicates that the sample is a STAT sample.
		Q	Indicates that the sample is a QC sample.
		C	Indicates that the sample is a calibrator.
Analysis Seq.	If the line includes parameters subject to multiple analysis, the numbers are displayed sequentially in mean data calculation units. "m" is displayed for mean data.	"1"-"10"	Indicates how many times replicate analysis results have been obtained, before averaging. "1" is displayed if this is the first duplicated analysis result, before averaging.
		m	Indicates that this is the mean data from replicate analysis results.
		" " (space)	Indicates that replicate analysis was not performed.
R (R flag)	This flag indicates a re-analysis (reflex test, repeat analysis or rediluted analysis).	R	Indicates that the sample has been re-analyzed.
		" " (space)	Indicates that the sample has not been re-analyzed.
Analysis mode	Indicates the setting status of the order.	N	Indicates a standard mode analysis.
		M	Indicates a Micro-sample mode analysis.
CP (Closed analysis)	Indicates that the sampling was closed (with cap closed).	CP	Indicates that the sample received closed sampling.
		" " (space)	Indicates that the sample did not receive closed sampling.
Detailed settings	Indicates whether detailed settings (performance of reflex tests, dilution ratios, etc.) were changed.	Dt	Indicates that a detailed setting was changed from the regulation value for any analysis parameter.
		" " (space)	Indicates that no detailed setting was changed from the regulation value for any analysis parameter.
Sample comment	Displays a comment about the sample. Input is only possible for analysis results.		
Patient Name	The patient name, as received from the host computer, is displayed.		
Validation	Indicates the date and time of validation.		
Validating User	The login ID of the user who validated the sample is displayed. If the sample has been validated and auto validation was used, " " (space) is displayed.		

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Table 3-01: Table of list display items

Parameters	Summary and display explanation		
Date/Time Ordered	Displays the date and time of order registration. The format of display is determined by the system setting.		
Ed (Edit flag)	This flag indicates whether the sample information has been edited after the completion of analysis	Ed	Indicates that the sample information has been edited.
		" " (space)	Indicates that the sample information has not been edited.
Assay Parameter	Displays the results of all analyzed assay parameters or marks indicating the state of progress. If dilution analysis was performed, the analysis results are corrected to the results for a dilution ratio of 1/1 for the purpose of display.	"✔"	Indicates that the parameter has not been measured.
		"◎" (Black)	Indicates that dispensing is in progress.
		"◎" (Green)	Indicates that heating is in progress.
		"◎" (Red)	Indicates that measurement is in progress.
		Numerical analysis results	Indicates that analysis is complete.

Note:
Alphanumeric characters can be used for sample comment and patient name. Alphanumeric characters are only A-Z, a-z, and 0-9. Localized characters cannot be input.

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3.3 Display analysis results

Assessment flags are displayed for analysis values and results for parameters which have been fully analyzed. The background color changes according to the analysis result. If an error etc. occurs, the display of analysis results, assessment flags on analysis results and background colors are as shown below.

Table 3-02: Analysis result display in the event of an error

Display	Display explanation
"***.**"	Displayed if analysis data was not obtained due to an error or other cause.
"---.--"	Displayed if calculated parameters could not be calculated, or if a mean could not be calculated.
"XXX.XX"	Displayed if the lack of a confirmed calibration curve prevented the calculation of a calculated parameter.
"+++.++"	Displayed if the number of displayed digits is exceeded.
"///.//"	In case of multiple analysis, this is displayed if there was an input value error in the mean calculation process.

Table 3-03: Assessment flags

Flags	Flag explanation	Priority order	Flag position
"*"	Displayed if there were disparate data among the results of multiple analyses, if the data confidence was judged to be low because the MDA slope ratio was judged to be abnormal, or if the data confidence was low for any other reason.	1	Left
"!"	Displayed when the result is from dilution analysis (dilution rate different from the analysis protocol setting).	2	Left
"<"	Indicates when the check parameter value has exceeded the lower report limit.	3	Left
">"	Indicates when the check parameter value has exceeded the upper report limit.	3	Left
"+"	Indicates when the check parameter value has exceeded the mark limit value on the "+" side.	4	Right
"-"	Indicates when the check parameter value has exceeded the mark limit value on the "-" side.	4	Right

Displayed when only one assessment flag, left or right, is present. When multiple flags have been issued, the one according to priority is displayed. In normal circumstances, no flags are present.

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The background color of the status indicator and result flag columns in the list can change, depending on the analysis status and result for the sample. The relationship between the background color and the analysis status is as shown below.

Table 3-04: Relationship between the background color and analysis status

Background color	Analysis status
Blue	“Pending” (not yet analyzed)
Green	“Processing” (being analyzed)
No color	“ ” (space) (analysis completed)
Yellow	“Review”, “On Hold” (analysis complete, review required)
Red	“Error” (analysis completed with error)

3.4 Validation

The validation function consists of both automatic and manual validation.

Auto validation

Once the analysis finishes, it is validated according to the preset conditions. (See “Chapter 8: 8.3 System settings”.)

Manual validation

Samples that have not been validated can be validated manually. Once the validation is complete, the analysis results are output automatically (printed/transferred to host computer) according to the preset conditions.

Validation is performed for the completed sample. If the data for a single sample covers multiple lines due to multiple analyses or re-analysis, the analysis results that are related to the selected line are combined and validated.

1. Select the line to validate from the joblist.
2. Press **Validate** on the operation panel.
   The sample on the selected line is validated and the validated results are output according to the automatic output settings.

Note:

- In the following cases a warning dialog will be displayed. Press **OK** to close the warning dialog.
  - When **Validate** is pressed for a sample that has not finished for analysis.
  - When **Validate** is pressed from a log-in account without permissions (“night operator” authority).
- About displaying the list of validated samples
  - The validate flag turns into a V.
  - The current date/time is entered for the validation date/time.
  - The user account name at the time becomes the validating user. (When it is validated automatically, the validating user is “ ” (space).)

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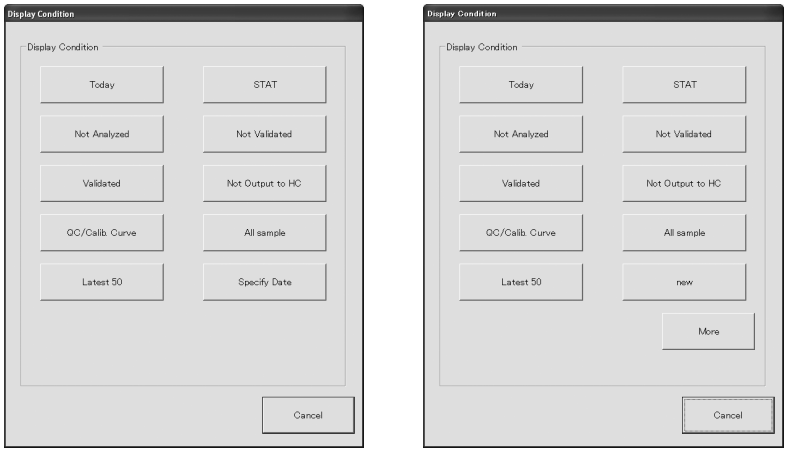
3.5 Select display conditions

The Display Condition dialog box can be used to set the content displayed in the list.

Information
The number of samples displayed in the list increases depending on the selected display condition. This may take minutes to display the joblist. If the display condition is changed during analysis, next sample aspiration is paused until the joblist is completely displayed.

1. Press **Display Condition** on the operation panel.
   The Display Conditions dialog box will appear.



(Up to 10 display condition buttons) **(11 or more display condition buttons)**

Figure 3-02: Display Conditions dialog box

Display Condition	The buttons set by customizing display conditions are displayed. The buttons which have not been set by customizing display conditions are not displayed on the Display Conditions dialog box.
More	If there are 11 or more display condition buttons, this button switches between pages. It is not displayed if there are 10 or less display condition buttons.
Cancel	Closes the Display Condition dialog box.

2. Press the button for **Display Condition**.
   The list display for the joblist is filtered and sorted according to the selected display condition and the Display Condition dialog box is closed.
   When the display conditions are switched, all marks selected up to that point are canceled.

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Date specification

If **Specify Date** is selected under Display Conditions, the Specify Date dialog box is displayed.

Figure 3-03: Specify Date dialog box

Calendar	A calendar is displayed for specifying the date. Any one date can be selected.
◀	Display the calendar for the previous month.
▶	Display the calendar for the next month.
Display	The list display of the joblist is filtered and sorted according to the display conditions selected from the Display Conditions dialog box, and the date selected from the calendar, and the Specify Date dialog box and the Display Conditions dialog box close.
Close	Close the Specify Date dialog box, and go back to the Display Conditions dialog box.

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3.6 Find

In the Find dialog box, Sample No., Rack No. or Patient Name can be used as the search key to search in the listed sample information.

1. Press **Find** on the operation panel.
   The Find dialog box is displayed.

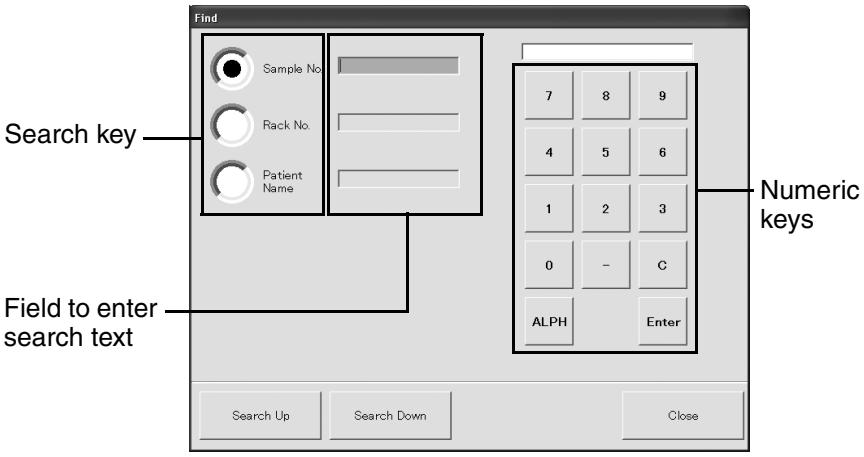

Figure 3-04: Find dialog box

Search key	Selects the search target. Select one of the following: **Sample No.** **Rack No.** **Patient Name** The selection is retained even if the Find dialog box is closed. The initial search key after the power is turned ON is sample ID number.
Field to enter search text	This is the field for entering search text. The search text is retained even if the Find dialog box is closed. The display becomes blank when the search key is changed or after the power is switched ON.
Numeric keys	Use this keypad to input sample ID numbers, rack numbers and patient names.
Search Up	The search runs upwards through the list, starting at the current cursor position.
Search Down	The search runs downwards through the list, starting at the current cursor position. When a line matching the search terms is found, the cursor moves to that line. If there are no matching lines, a Warning dialog box is displayed.
Close	Closes the Find dialog box.

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2. Select the search key, then input the search text string in the field to enter search text.

Note:
"*" can be used as wildcards so that the entire word need not be spelled out.
*: * is used as a substitute for zero or more characters. Searching for 9* would return data beginning with 9, including 91, 985, etc. Searching for *9 would return data ending with 9, including 589, 1009, etc.

3. Press **Search Up** or **Search Down** to start the search.
When a line matching the search terms is found, the cursor moves to that line. If there are no matching lines, a Warning dialog box is displayed. Change the search terms and search again.

Figure 3-05: Warning dialog box

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3.7 Adding/deleting marks

Marks can be attached to analysis results (lines) displayed in the analysis results list. Lines with marks attached are displayed with green background.

1. Press **Mark** on the operation panel.
   The operation panel changes to mark mode and the button for attaching marks appears on the panel.

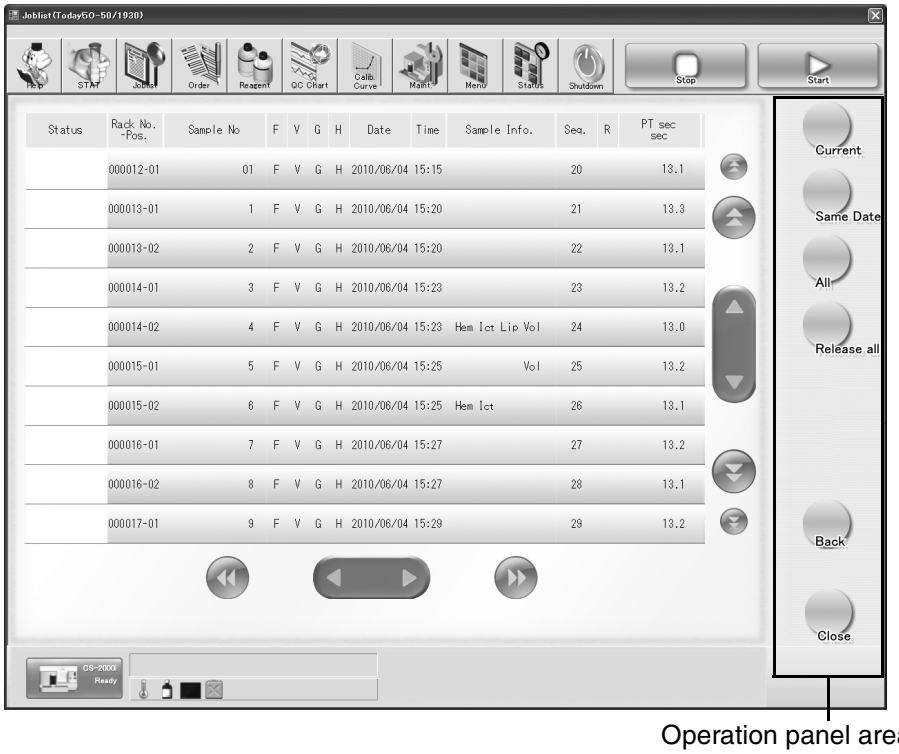

Figure 3-06: Joblist screen (Marking mode)

Operation panel area

Current	The mark status of the line selected in the list is reversed. If the button is pressed while a marked line is selected, the mark is removed and the cursor moves to the next line.
Same Date	All lines with the same analysis date as the cursor line are marked.
All	All lines displayed in the list are marked.
Release all	Clears all marks.
Back	Ends mark mode.

2. Press the control button to attach and clear marks.
3. Press **Back**.

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Note:
When a new analysis result is obtained in mark mode, the list is not updated until mark mode is ended.

3.8 Printing analysis results

The analysis results displayed in the analysis results list can be printed out.

Note:
When unvalidated results are printed, the output is for laboratory use only (“Laboratory use only” is printed in the background). Even if an unvalidated analysis result has been printed out, the flag “G” that shows no print with printer on the joblist screen is not changed.

1. Select or mark the line to Print from the analysis results list.
2. Press **Print** on the operation panel.
   The Printing dialog box will appear.

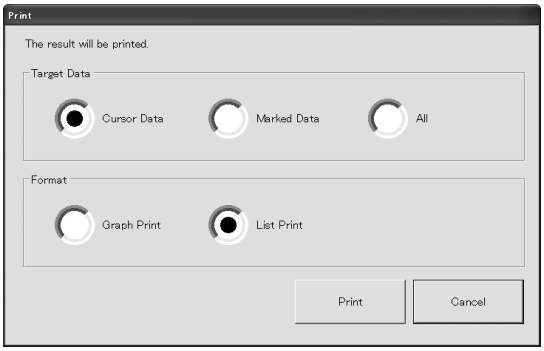

Figure 3-07: Printing dialog box

Target Data	Indicates the data for printing.
Cursor Data	Select to make the current cursor line a printing selection.
Marked Data	Select to make marked lines printing selections.
All	Select to make all lines for displayed analysis results printing selections.
Format	Specifies the format for printing.
Graphic Print	Select for report (GP) output.
List Print	Select for list print output.

3. Specifies the content and the format for printing.

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4. Press **Print**.
   The Printing dialog box is closed and the specified print selection is printed in the specified print format. The Spooling dialog box is displayed while the print selection information is being output to the printer spooler.
   Press **Cancel** to discard the specified print settings and close the Printing dialog.

Figure 3-08: Spooling dialog box

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3.9 Deleting displayed analysis results

Analysis results displayed in the analysis results list can be deleted.

Information
The only samples that can be deleted are those with orders that have not been analyzed yet and those for which analysis has been completed. Samples that are being analyzed cannot be deleted. Deletion affects samples completely, so when a line is deleted, all related lines (concerning the same sample) are also deleted.

1. Select or mark the samples for deletion from the analysis results list.
2. Press **Delete** on the operation panel.
   The Deleting dialog box appears.

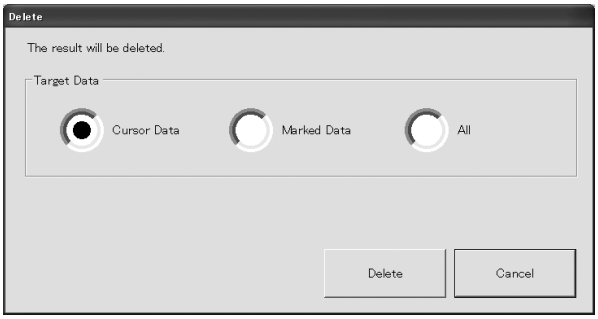

Figure 3-09: Deleting dialog box

Target Data	Specifies the data for deletion.
Cursor Data	Select to make the current cursor line a deletion selection.
Marked Data	Select to make marked lines deletion selections.
All	Select to make all lines for displayed analysis results deletion selections.

3. Specify the data for deletion.
4. Press **Delete**.
   Closes the Deleting dialog box and deletes all data specified to be deleted. However, if the deletion selections include samples that have not completed analysis, a warning dialog box will appear. Press **OK**. The lines will not be deleted at that time.
   Press **Cancel** to cancel the deletion and close the Deleting dialog box.

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3.10 Editing sample information

Sample information editing is performed on samples which have already been analyzed. Validated samples cannot be edited. If a single sample covers multiple lines, due to multiple analysis or re-analysis, the editing results are reflected in all the lines concerned. An Edit flag is attached when sample information has been edited.

1. Select a sample (line) in the analysis results list for which analysis is complete, then press **Edit** on the operation panel.
   The Edit Sample Information dialog box will appear.

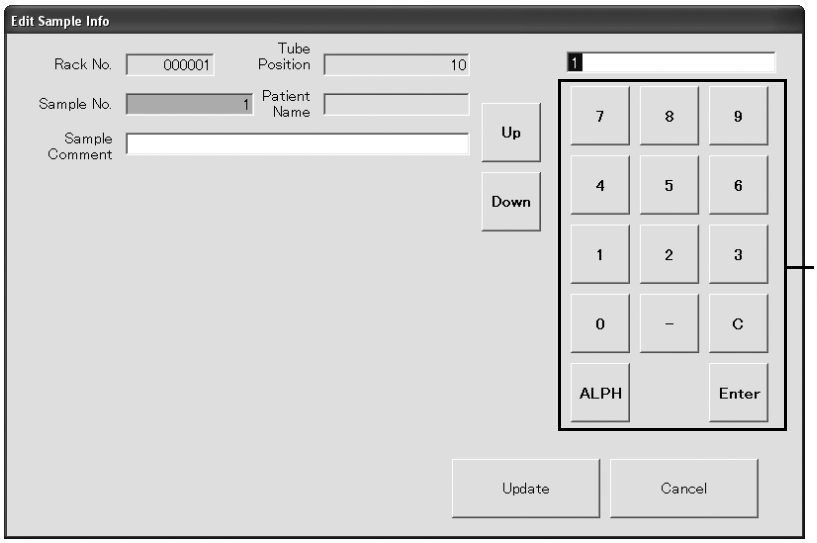

Figure 3-10: Sample Info Editing dialog box

Rack No.	The rack number is displayed.
Tube Position	The tube position is displayed.
Sample No.	This is the field for entering the sample ID number.
Patient Name	The patient name, as received from the host computer, is displayed.
Sample Comment	This is the field for entering sample comment.
Up	The cursor moves to the next input field above.
Down	The cursor moves to the next input field below.
Numeric keys	Use this to input sample ID number.

Note:
Alphanumeric characters can be used for sample comment and patient name. Alphanumeric characters are only A-Z, a-z, and 0-9. Localized characters cannot be input.

2. Edit the sample information.
3. Press **OK** on the operation panel.
   Saves the settings of the Sample Info Editing dialog box and closes the dialog. Press **Cancel** to discard the settings from the Sample Info Editing dialog and close the Sample Info Editing dialog box.

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3.11 Recalculation of calculated parameters

A new calibration curve can be set, and that curve is used to recalculate calculated parameters.

1. Select or mark the analysis result lines to recalculate.
2. Press **Recalculate** on the operation panel.
   The Select Test to Recalculate dialog box will appear.

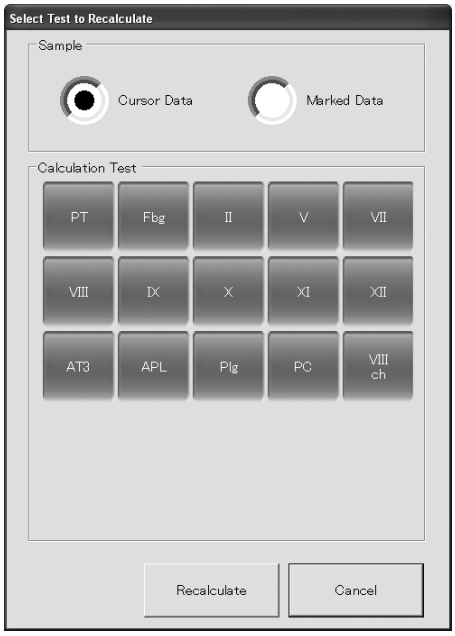

Figure 3-11: The Select Test to Recalculate dialog box

Sample	Specify the subject samples.
Cursor Data	Select to make the current cursor line the subject.
Marked Data	Select to make marked lines subjects.
Calculation Test	Specify the subject parameters.
Recalculate	Perform recalculation.
Cancel	Close the Select Test to Recalculate dialog box without performing recalculation.

3. Specify subject samples and parameters.
4. Press **Recalculate**.
   After recalculation, the dialog box will appear.
5. Press **OK**.

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Caution!

If samples or parameters are included that cannot be calculated, the following dialog box is displayed.
Press **OK** to close the dialog box.

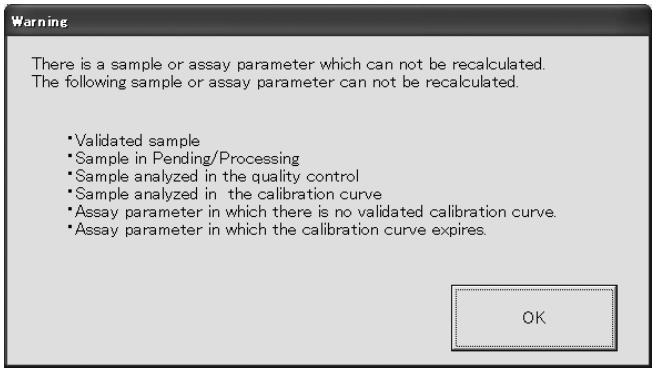

Figure 3-12: Recalculation warning dialog box

Note:

- Recalculation is not possible while the instrument is analyzing.
- Assay parameters which have been recalculated are flagged.
  Press the **Detail** in the browser main screen to check the Details dialog box.
  For more information, see “Chapter 4: 4.2: 2. Detail display”.
- After recalculation, the calculation results are not output to the host computer and the printer automatically.

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3.12 Exporting analysis results

Analysis results displayed in the analysis results list can be exported to a file in CSV format. The exported content is the same as the output for list printing.

1. Select or mark the analysis result lines to export.
2. Press **Export** on the operation panel.
   The Export dialog box will appear.

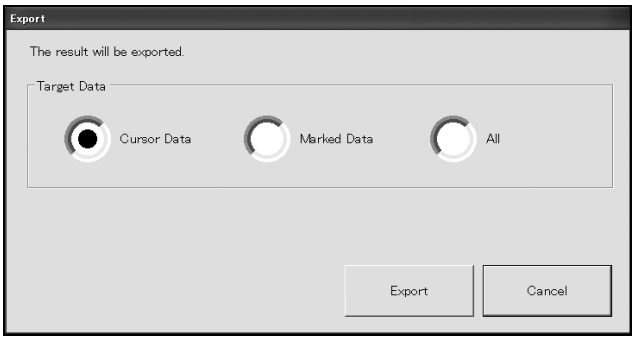

Figure 3-13: Export dialog box

3. Select the data to export, and press **Export**.
   The analysis results are output to the file in CSV format.

3.13 Customizing the joblist screen

The customization function can change the parameters displayed in the analysis results display screen (the joblist screen) and the display conditions (filtering, sorting and viewing conditions).

1. Customizing displayed parameters

1. Press **Customize** on the operation panel.
   The Customize dialog box will appear.
2. Select the **Displayed Prameter** tab.
   The screen for setting the display parameters is displayed.

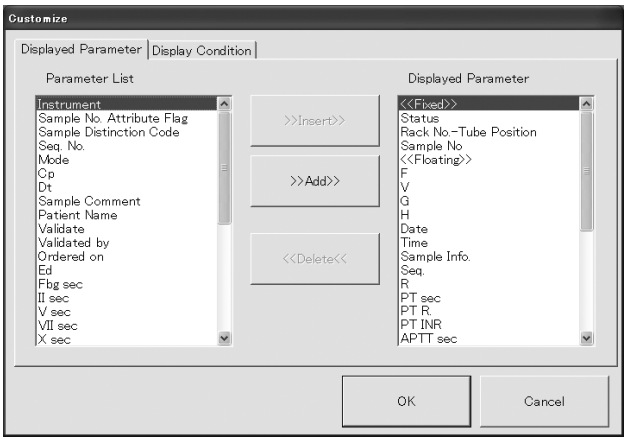

Figure 3-14: Customize dialog box-Display Item

Parameter List	Displays the list of parameters that can be displayed in the joblist. Only one line can be selected in the list display.
Displayed Parameter	This is the field for setting the displayed parameters.
>>Insert>>	Inserts the parameter selected in the **Parameter List** into the **Displayed Parameter** List at the cursor position. The inserted parameter is deleted from the **Parameter List** at that time.
>>Add>>	Adds the parameter selected in the **Parameter List** at the bottom of the **Displayed Parameter** List and moves the cursor to the bottom of the list of **Displayed Parameter** List. At this stage, the parameter is deleted from the **Parameter List**.
<<Delete<<	Deletes the parameter selected under **Displayed Parameter** List. At this stage, the deleted parameter is added to the **Parameter List** at the original position and the cursor moves to the original position of the list.

3. Press **OK** to end settings.
   The displayed parameter settings are reflected in the Customize dialog box and the Customize dialog box closes.
   Press **Cancel** to discard the Displayed Parameter settings and close the Customize dialog box.

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2. Customizing display conditions

1. Press **Customize** on the operation panel.
   The Customize dialog box will appear.
2. Select the **Display Condition** tab.
   The screen for setting display conditions is displayed.

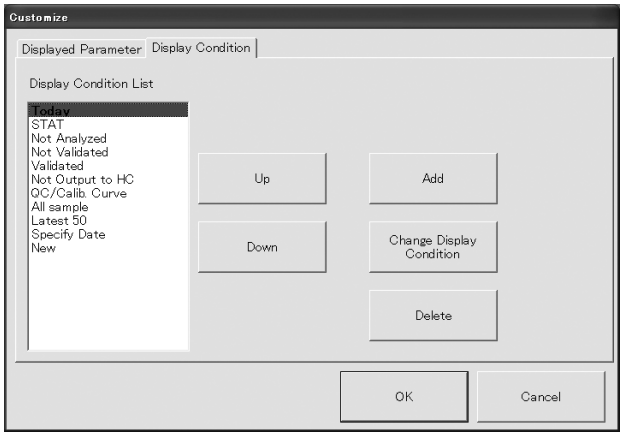

Figure 3-15: Customize dialog box-Display Condition

Display Condition List	Displays the list of registered display conditions. Only one line can be selected in the list display. When the dialog box is first displayed, the top line is selected.
Up	Moves the condition selected in the List of Display Conditions up one line.
Down	Moves the condition selected in the List of Display Conditions down one line.
Add	Adds a display condition to the bottom line of the List of Display Conditions. When added, the default name for the condition is “New”. If the number of display conditions registered is already at the maximum, a warning dialog box is displayed and it is not possible to add more.
Change Display Condition	Displays the Filter/Sort/View Settings dialog box for making filter/sort/view settings to the display conditions selected in the List of Display Conditions.
Delete	Unneeded display conditions can be deleted by deleting the Display Condition selected in the List of Display Conditions.

3. Press **OK** to end settings.
   Display Condition settings are reflected in the Customize dialog box and the Customize dialog box closes.
   Press **Cancel** to discard the Display Condition setting and close the Customize dialog box.

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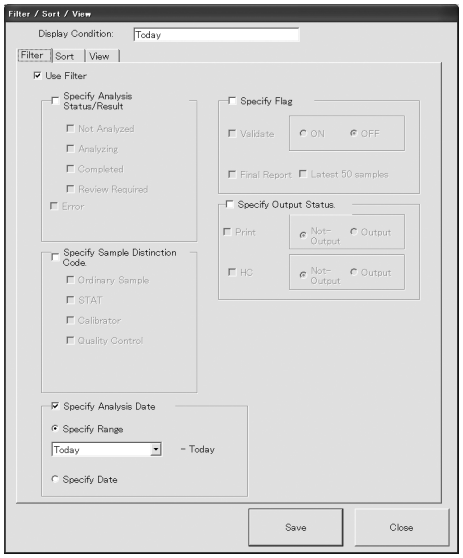
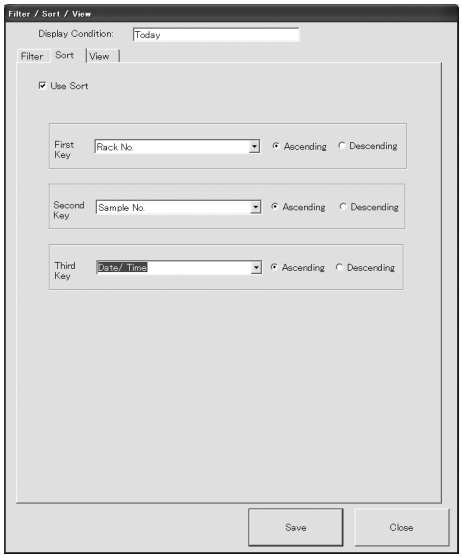
3. Filter/Sort/View Settings dialog box

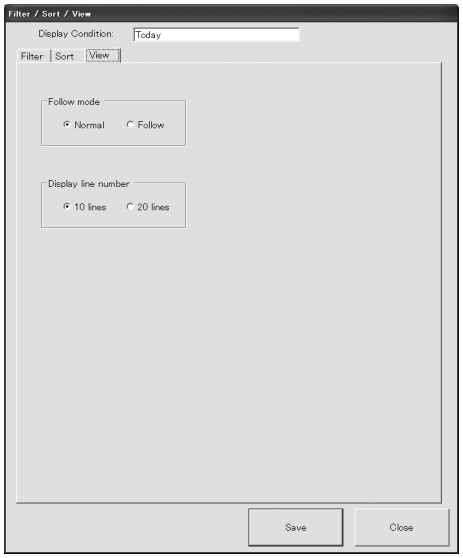
1. Press **Customize** on the operation panel.
   The Customize dialog box will appear.
2. Select the **Display Condition** tab.
   The screen for setting display conditions is displayed.
3. Press **Change Display Condition**.
   The Filter/Sort/View Settings dialog box is displayed.



(Filter tab)



(Sort tab)



(View tab)

Figure 3-16: Filter/Sort/View Settings dialog box

Display Condition	This is the field for editing the name of the display condition. Up to 10 characters can be input.

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Filter tab

Use Filter	Sets whether or not to use the filter function. Add a check mark: Use the filter function. Remove the check mark: Do not use the filter function.
Specify Analysis Status/Result	Sets whether or not to specify the analysis status and results. Add a check mark: Specify the analysis status and results. Remove the check mark: Do not specify the analysis status and results.
Not Analyzed	Specifies results that have not yet been analyzed.
Analyzing	Specifies results that are being analyzed.
Completed	Specifies results that were completed without error.
Review Required	Specifies results that need review.
Error	Specifies results that have errors.
Specify Sample Distinction Code	Sets whether or not to specify the sample category. Add a check mark: Specify the sample category. Remove the check mark: Do not specify the sample category.
Ordinary Sample	This specifies routine samples (non-MDA analysis).
STAT	This specifies STAT samples.
Calibrator	This specifies calibrators.
Quality Control	This specifies quality control (QC).
Specify Flag	Sets whether or not to specify flags. Add a check mark: Specify flags. Remove the check mark: Do not specify flags.
Validate	Specifies validation flags.
Final Report	Specifies final report flags.
Latest 50 samples	Specify the latest 50 sample flags.
Specify Output Status	Sets whether or not to specify the external output status. Add a check mark: Specify the external output status. Remove the check mark: Do not specify the external output status.
Print	Specifies print output status.
HC	Specifies HC output status.
Specify Analysis Date	Sets whether or not to specify the analysis date. Add a check mark: Specify the analysis date. Remove the check mark: Do not specify the analysis date.

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Specify Range — Set the date range for filter display.
The filter start date can be selected from **Today**, **2 days before**, **3 days before** and **One week before**.
Filter end date is the present date.

Specify Date — When selecting display conditions, the measurement date can be specified.

Sort tab

Use Sort — Sets whether or not to use the sort function.
Add a check mark: Use the sort function.
Remove the check mark: The display is sorted in ascending order of analysis date and time.

First key - Third key — Selects a sort key. The selection options below will be displayed.
None
Rack Number
Sample Number
Date (Analysis date and time)
Seq.
(Selection options other than “None” will not be displayed if they have already been selected for a different key.)

Ascending — Sort the list in ascending order.

Descending — Sort the list in descending order.

View tab

Follow mode — If a new line is added to the joblist, this setting specifies whether or not to move to the screen containing that line.

Normal — Do not move screens.

Follow — Move to the screen with that line.
* If the screen has been changed by this mode, the data cannot be edited or output.

Display line number — Set the number of lines to display on the joblist.
Choose between **10 lines** and **20 lines**.

4. Press **Save** to end settings.
   The settings of the Display Conditions Filter/Sort/View Settings dialog box are saved and the dialog box closes.
   Press **Close** to close the dialog without saving the settings made in the Display Conditions Filter/Sort/View Settings dialog box.

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4. Browser

This chapter describes the functions of the browser.
The browser can be used for graphical displays of analysis results.

4.1 Overview

Major browser functions:

Validate	Analysis results are validated.
Print	Analysis results are printed out.
Host Output	Analysis results are output to the host.
Editing sample information	Sample information for analysis results is edited.
Export	Raw data (binary) from analysis results are exported.
Customize	Display sequence of browser window is customized.

4.2 Browser main window display

Analysis results for the line selected in the joblist can be displayed graphically in the browser main window.

1. Press **Joblist** in the toolbar on the IPU menu screen.
   The joblist main screen will appear.
2. Select the line for the analysis result to display, then press **Browser** on the operation panel.
   The browser main screen will appear.

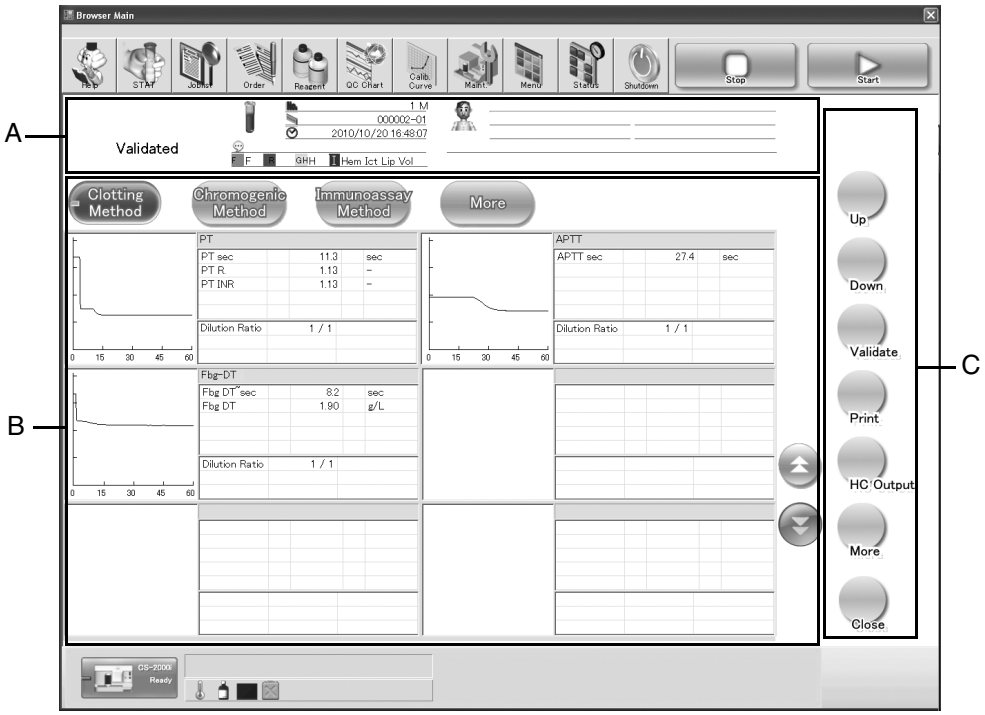

Figure 4-01: Browser main screen

A Sample information display area

Sample information is displayed for the analysis results that are on graphical display.

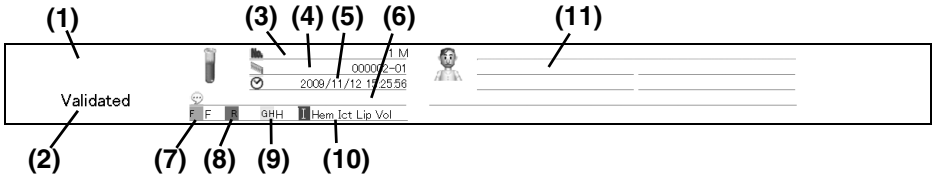

Figure 4-02: Sample information display area

(1) Analysis status	Analysis status is displayed. The display format is the same as for the joblist status display.
(2) Validation status	Validation status of analysis results is displayed.
(3) Sample No.	Sample number and sample number attribute are displayed.
(4) Rack-pos.	Rack number + "- (hyphen)" + tube position are displayed.
(5) Analysis date and time	Date and time of analysis are displayed.
(6) Sample comment	Sample comment input from the IPU is displayed.
(7) F flag	F flags are displayed. The content and format of the display are the same as for the joblist.
(8) R flag	R flags are displayed. The content and format of the display are the same as for the joblist.
(9) Not output indicator	Indicates samples that have not been externally output. The content and format of the display are the same as for the joblist.
(10) Sample info.	The results of the HIL check and sample volume check are displayed.
(11) Patient Name	The patient name, as received from the host computer, is displayed.

B Graphical display area

Analysis results for each parameter (referred to below as the assay group) are displayed graphically. This area is composed of tabs and the tabs set from the tab list for display customization are displayed as well as the **More** tab. If all assay groups have been assigned to tabs other than the **More** tab, the **More** tab is not displayed. Up to 30 assay groups can be graphically displayed on one tab and up to six tabs can be displayed. The tab names and the assay groups shown on them can be customized. Up to six graphs can be shown on each page within a tab. If there are seven or more, use ⏬ and ⏫ in the lower right to change the displayed page. Up to 30 assay groups on each tab and five pages of content can be displayed.

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C Operation panel area

The operation buttons which apply to the graphically displayed analysis results are displayed. Operation buttons apply to all graphically displayed analysis results.

1st page

Up	Makes the next line above the cursor position on the job screen the graphically displayed analysis result.
Down	Makes the next line below the cursor position on the job screen the graphically displayed analysis result.
Validate	Validates the graphically displayed analysis result (on the line selected by the cursor in the joblist). However, validation can only be performed on analysis results for which analysis is complete.
Print	Prints the graphically displayed analysis result (on the line selected by the cursor in the joblist).
HC Output	Outputs the graphically displayed analysis result (on the line selected by the cursor in the joblist) to the host. However, host output can only be performed on analysis results which have been validated.

2nd page

Edit Sample Info.	Sample information for the graphically displayed analysis results can be edited. However, sample information editing can only be performed on samples for which analysis is complete. The function is the same as editing from the operation panel on the joblist screen. For details, see “Chapter 3: 3.10 Editing sample information”.
Export	Exports the graphically displayed analysis result (on the line selected by the cursor in the joblist) as raw data (binary).
Customize	The Customize dialog box is displayed to allow customization of the display content (tab names and assay groups within tabs) in the graphical display area of the browser main screen.

Common to the 1st and 2nd page

More	If the Operation Panel comprises multiple pages, use this button to switch between pages.
Close	Closes the browser screen.

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1. Graphical display of assay groups

Graphical display of the assay groups differs for each group, depending on the types of analysis results. Analysis results are of the following types:

Table 4-01: Types of analysis results

No.	Types of analysis results	
1	Analysis results with reaction curves	
2	Analysis results without reaction curves	Mean and final analysis results
3		MDA analysis results
4		Analysis results for Formula calculation parameters

Graphical display of analysis results with reaction curves

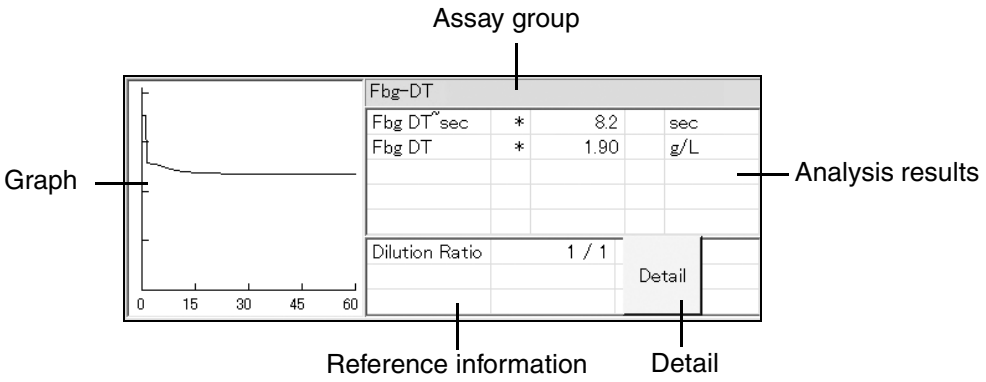

Figure 4-03: Results with reaction curves

Assay group The assay group that is displayed graphically is indicated here. The assay group has the display name registered for it under Settings–Assay group settings (similarly below).

Graph The reaction curve used for calculation of analysis results is displayed. Click in this area to switch to the details screen. (See “Chapter 4: 4.8: 1.: Analysis results with reaction curves”.) The reaction curve is drawn with a black line. The display ranges for the X- and Y-axes of the graph differ according to the analysis algorithms employed for the analysis methods under the assay group settings. The relationship between the analysis algorithm and the axis display range is as described below.

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Table 4-02: Analysis algorithm and axis display range

		Analysis algorithm			
		Percentage detection method	Rate method	VLin method	Drifting Baseline method
X-axis	Range	Photometric time 0-Max *1)	0-Photometric time *2)	0-Photometric time *2)	0-Photometric time *2)
	Units	sec	sec	sec	sec
Y-axis	Range	0-4095	0-3544	0-3544	0-7089
	Units	A/D value	OD	OD	OD

*1) The optimum time is automatically calculated from the analysis results and displayed.

*2) Photometric time is set in the test protocol for each assay group.

Analysis results

Analysis results with reaction curves are listed. The display composition for analysis results is as follows:

Table 4-03: Display composition for analysis results with reaction curves

Assay parameter*1)	Value*2)	Unit*3)

*1) The assay parameter has the display name registered under Settings–Assay group settings–Assay parameter settings (similarly below). If the wavelength was changed to perform the measurement, an “&” is displayed after the assay parameters.

*2) Value includes assessment flags.

*3) The unit set under the assay parameter settings is displayed.

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Reference information The dilution ratio is displayed as reference information.

Detail The details dialog box appears when **Detail** is pressed. See “Chapter 4: 4.2: 2. Detail display” for the details dialog box.

The color of the Detail button and the summaries of results are as stated below.

Table 4-04: Display color for the Detail button

Button color	Result summary
Red	Red display indicates an error in the measurement result.
Yellow	Yellow display indicates low reliability in the analysis results, or a calculated parameter that could not be calculated.
Gray	Gray display indicates that a comment has been appended to the analysis results.

The button is not displayed before or during analysis, or if the analysis results are normal.

Graphical display of mean and final analysis results

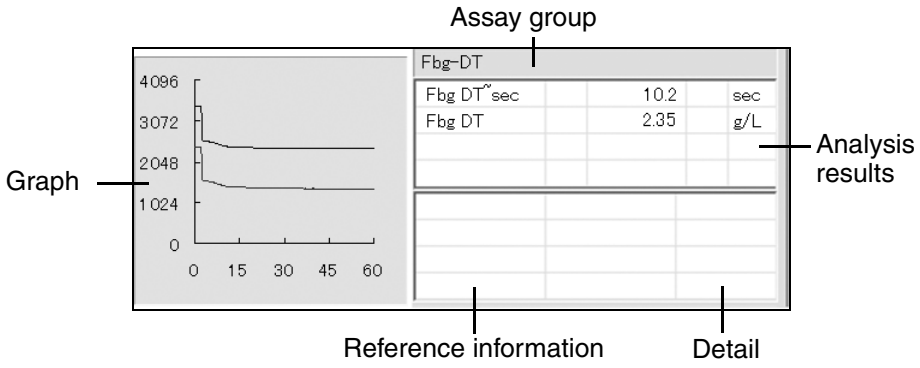

Figure 4-04: Mean and final results

Assay group The assay group that is displayed graphically is indicated here. The assay group has the display name registered under Settings–Assay group settings (similarly below).

Graph The reaction curve used for calculation of analysis results is displayed. Click in this area to switch to the details screen. (See “Chapter 4: 4.8: 1.: Mean and final analysis results”.)
Reaction curves are drawn with a black line for the first analysis (serial no.) and with a blue line for the second.
The display ranges for the X- and Y-axes of the graph differ according to the analysis algorithms employed for the analysis methods under the assay group settings.
The relationship between the analysis algorithm and the axis display range is as described below.

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Table 4-05: Analysis algorithm and axis display range

		Analysis algorithm			
		Percentage detection method	Rate method	VLin method	Drifting Baseline method
X-axis	Range	Photometric time 0-Max[*1)]	0-Photometric time [*2)]	0-Photometric time [*2)]	0-Photometric time [*2)]
	Units	sec	sec	sec	sec
Y-axis	Range	0-4095	0-3544	0-3544	0-7089
	Units	A/D value	OD	OD	OD

[*1)] The optimum time is automatically calculated from the analysis results and displayed.

[*2)] Photometric time is set in the test protocol for each assay group.

Analysis results

Mean and final analysis results are listed. The display composition for analysis results is as follows:

Table 4-06: Display composition for mean and final analysis results

Assay parameter[*1)]	Value[*2)]	Unit[*3)]

[*1)] The assay parameter has the display name registered under Settings–Assay group settings–Assay parameter settings (similarly below).

[*2)] Value includes assessment flags.

[*3)] The unit set under the assay parameter settings is displayed.

Reference information

The dilution ratio is displayed as reference information.

Detail

The details dialog box appears when **Detail** is pressed. See “Chapter 4: 4.2: 2. Detail display” for the details dialog box.

The color of the Detail button and the summaries of results are as stated below.

Table 4-07: Display color for the Detail button

Button color	Result summary
Red	Red display indicates an error in the measurement result.
Yellow	Yellow display indicates low reliability in the analysis results, or a calculated parameter that could not be calculated.
Gray	Gray display indicates that a comment has been appended to the analysis results.

The button is not displayed before or during analysis, or if the analysis results are normal.

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Graphical display of MDA analysis results (final)

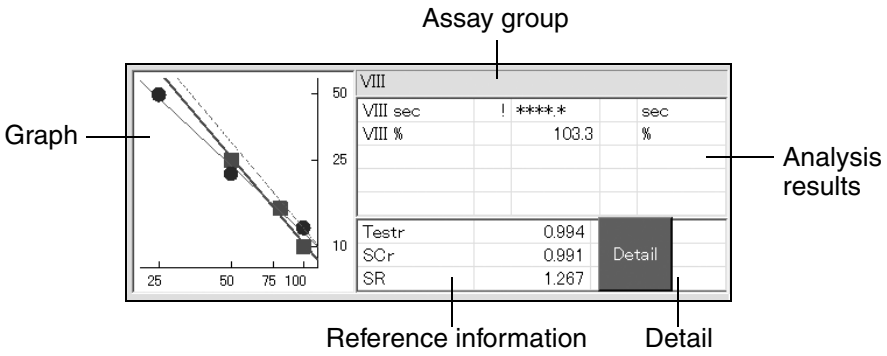

Figure 4-05: MDA results

Assay group The assay group that is displayed graphically is indicated here. The assay group has the display name registered under Settings-Assay group settings (similarly below).

Graph The MDA graph is displayed. Click in this area to switch to the details screen. (See “Chapter 4: 4.8: 1.: MDA analysis results (final)”.) The calibration curve, MDA analysis results and guide curve are displayed.

Analysis results The MDA analysis results are listed. The display comprises the following elements:

Table 4-08: Composition of the MDA analysis results display

Assay parameter*1)	Value*2)	Unit*3)

*1) The assay parameter has the display name registered under Settings-Assay group settings-Assay parameter settings (similarly below).

*2) Value includes assessment flags.

*3) The unit set under the assay parameter settings is displayed.

Reference information Testr, SCr and SR values are displayed as reference information.

Revised April 2013

Detail

The details dialog box appears when **Detail** is pressed. See “Chapter 4: 4.2: 2. Detail display” for the details dialog box.

The color of the Detail button and the summaries of results are as stated below.

Table 4-09: Display color for the Detail button

Button color	Result summary
Red	Red display indicates an error in the measurement result.
Yellow	Yellow display indicates low reliability in the analysis results, or a calculated parameter that could not be calculated.
Gray	Gray display indicates that a comment has been appended to the analysis results.

The button is not displayed before or during analysis, or if the analysis results are normal.

Graphical display of analysis results for Formula calculation parameters

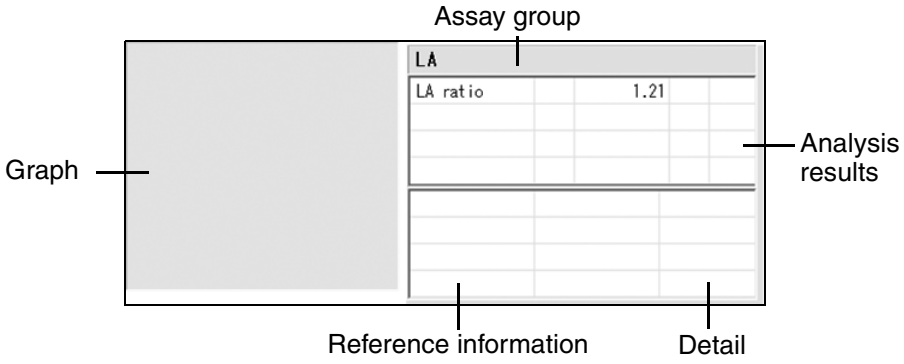

Figure 4-06: Results for Formula calculation parameters

Assay group

The assay group that is displayed graphically is indicated here. The assay group has the display name registered under Settings–Assay group settings (similarly below).

Graph

The graph will not appear. This area is blank. The graph will still not be displayed even if this area is clicked to switch to the details screen.

Analysis results

Analysis results for Formula calculation parameters are listed. The display composition for analysis results is as follows:

Table 4-10: Display composition for analysis results for Formula calculation parameters

Assay parameter*1)	Value*2)	Unit*3)

*1) The assay parameter has the display name registered under Settings–Assay group settings–Assay parameter settings (similarly below). If the wavelength was changed to perform the measurement, an “&” is displayed after the assay parameters.

*2) Value includes assessment flags.

*3) The unit set under the assay parameter settings is displayed.

Reference information

The reference information is left blank for Formula calculation parameters.

Detail

The details dialog box appears when **Detail** is pressed. See “Chapter 4: 4.2: 2. Detail display” for the details dialog box.

The color of the Detail button and the summaries of results are as stated below.

Table 4-11: Display color for the Detail button

Button color	Result summary
Red	Red display indicates an error in the measurement result.
Yellow	Yellow display indicates low reliability in the analysis results, or a calculated parameter that could not be calculated.
Gray	Gray display indicates that a comment has been appended to the analysis results.

The button is not displayed before or during analysis, or if the analysis results are normal.

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2. Detail display

Press **Detail** displayed in the graphical display for one assay group to display the details dialog box.

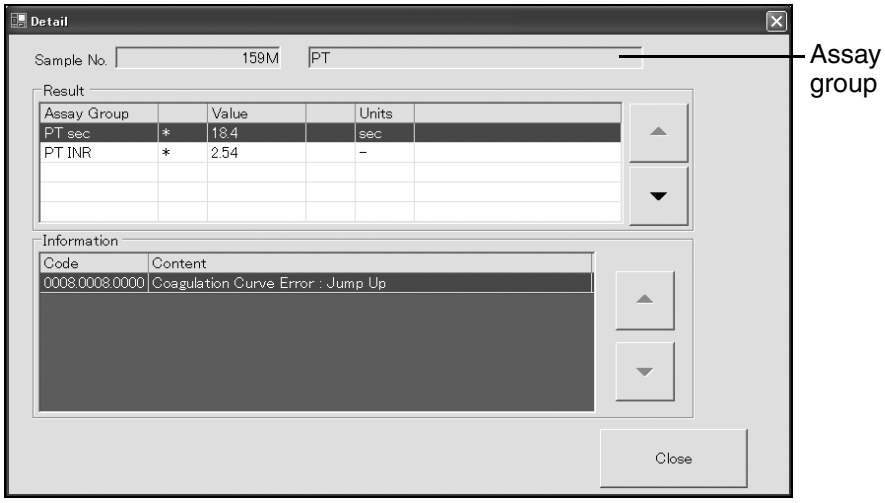

Figure 4-07: Details dialog box

Sample No.	Sample number is displayed. The format and content of the display are the same as that for the sample information display area of the browser main screen.
Assay group	The assay group is displayed. The format and content of the display are the same as that for the assay group for one parameter graphical display in the browser main screen.
Result	All analysis results in the assay group are displayed. The format and content of the display are the same as that for the analysis results for one parameter graphical display in the browser main screen.
Information	Displays the code that occurred under the assay parameters selected in the results list, together with their content.
Close	Closes the details dialog box.

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4.3 Validation

Validation validates previously unvalidated analysis results. Analysis results displayed graphically (for one line in the joblist) on the browser main screen are subject to validation. This function is only enabled when the logged-in user is a facility manager, lab technician, or other user with equal or higher permissions. If the logged-in user has a lower level of clearance, a warning dialog is displayed and validation is not available.

1. On the joblist main screen, select the line for the analysis result to validate, then press **Browser** on the operation panel.
   The browser main screen is displayed and the analysis results are graphically displayed.
2. Press **Validate** on the operation panel.
   The graphically displayed analysis results are validated.

Note:
Validation cannot be performed on analysis results for which analysis has not been completed (their status is “Pending” or “Processing”).

4.4 Print

The printing function can produce printouts of the analysis results that are graphically displayed on the browser main screen. Print selections are assay groups analyzed in one line of the joblist. The sequence follows the set sequence of assay groups.

1. On the joblist main screen, select the line for the analysis result to print, then press **Browser** on the operation panel.
   The browser main screen is displayed, and the analysis results are graphically displayed.
2. Press **Print** on the operation panel.
   The Confirmation dialog box will appear.
3. Press **Print** on the Confirmation dialog box.
   The graphically displayed analysis results are printed. At that stage, ‘not output’ indicators in the sample information display area of the browser main screen change to ‘printer output’.
   However, if unvalidated analysis results are printed while they are on graphical display, the printed documents are marked “Laboratory Use Only” and the ‘not output’ indicators in the sample information display area of the browser main screen do not change to ‘printer output’.

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4.5 HC Output

The host output function can output to the host those analysis results that are graphically displayed on the browser main screen. Host output data are assay groups analyzed in one line of the joblist.

1. On the joblist main screen, select the line for the analysis result to be output to the host, then press **Browser** on the operation panel.
   The browser main screen is displayed and the analysis results are graphically displayed.
2. Press **HC Output** on the operation panel.
   The Confirmation dialog box will appear.
3. Press **OK**.

Note:
- When host output is performed, 'not output' indicators in the sample information display area of the browser main screen change to 'host output'.
- Unvalidated analysis results cannot be output to the host.

4.6 Export

The export function can export raw data and evaluation results for the analysis results that are graphically displayed on the browser main screen.
Analysis results displayed graphically on the browser main screen are subject to export. All exported files are in binary form.

1. On the joblist main screen, select the line for the analysis result to export, then press **Browser** on the operation panel.
   The browser main screen is displayed, and the analysis results are graphically displayed.
2. Press **Export** on the operation panel.
   The Confirmation dialog box is displayed.
3. Press **OK**.

Note:
The raw data and evaluation results are saved under the specified file name in the folder stated below. The folder will be created automatically if it does not already exist.
- Folder
  Desktop/BrowserExport/ymd/sample number/
  (YMD is the date of the export operation).
- File name
  Raw data: ymdhms[*1)]_AG[*2)]_sample number_sequence number.dat
  Evaluation results: ymdhms[*1)]_AG[*2)]_sample number_sequence number.FK3

[*1)] Date (YYYYMMDD) and time (hhmmss) of when detection was completed are assigned folder and file name. The format of display is determined by the system setting.

[*2)] The assay group name is displayed.

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4.7 Customize

The display content (tab names and assay groups within tabs) in the graphical display area of the browser main screen can be customized.
The graphical display area of the browser main screen consists of up to six tabs (five user-customizable tabs and one non-customizable tab).
Up to 30 assay groups can be displayed for each user-customizable tab.
Customize can add and delete tabs and tab names for user-customizable tabs and the assay groups displayed in each tab can be set.
This function is only enabled when the logged-in user is a facility manager, lab technician, or other user with equal or higher permissions. If the logged-in user has a lower level of clearance, a warning dialog is displayed and customization is not available.

1. Tab addition and editing of assay groups displayed within a tab

1. Press **Customize** on the operation panel.
   The Customize dialog box will appear.

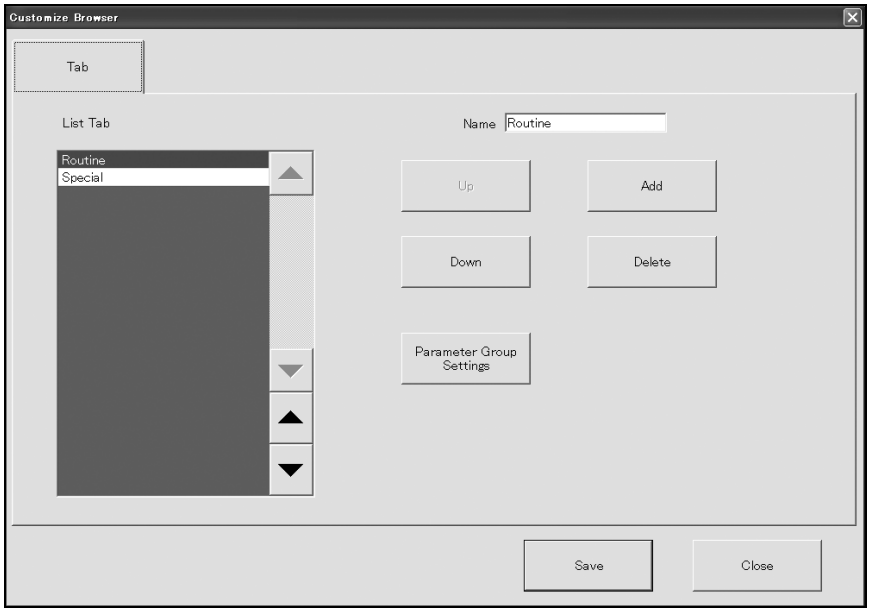

Figure 4-08: Customize dialog box

List Tab	A list of registered tabs (user-customizable tabs) is displayed. The display sequence of tabs in the browser main window follows the sequence of this list. The Other tab, which cannot be customized, is not displayed.
Name	Inputs the name of the tab selected in **List Tab**, using up to 10 characters.
Up	Moves the tab selected in **List Tab** to one line higher.
Down	Moves the tab selected in **List Tab** to one line lower.

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Add	Adds a user-customizable tab to the bottom line of **List Tab**. When added, the default name for the tab is “New tab”. No parameters are set for display at that time. Five tabs are user customizable. If five tabs have already been set, no more can be added.
Delete	Deletes the tab selected in **List Tab**.
Parameter Group Settings	The display parameter settings dialog box is displayed for setting the parameters to be displayed in the tab selected from **List Tab**.
Save	Saves the setting content for the Customize dialog box. At that stage, a warning dialog box is displayed if any tabs exist for which the display parameters have not been set and the Customize dialog box does not close.
Close	Closes the Customize dialog box. At that stage, a confirmation dialog box appears if there is any unsaved setting content.

2. Press **Add** to add a tab. To edit the content of a tab that has already been registered, select the tab to edit from **List Tab**.
3. Press **Parameter Group Settings**.
   The Parameter Group Settings dialog box will appear.

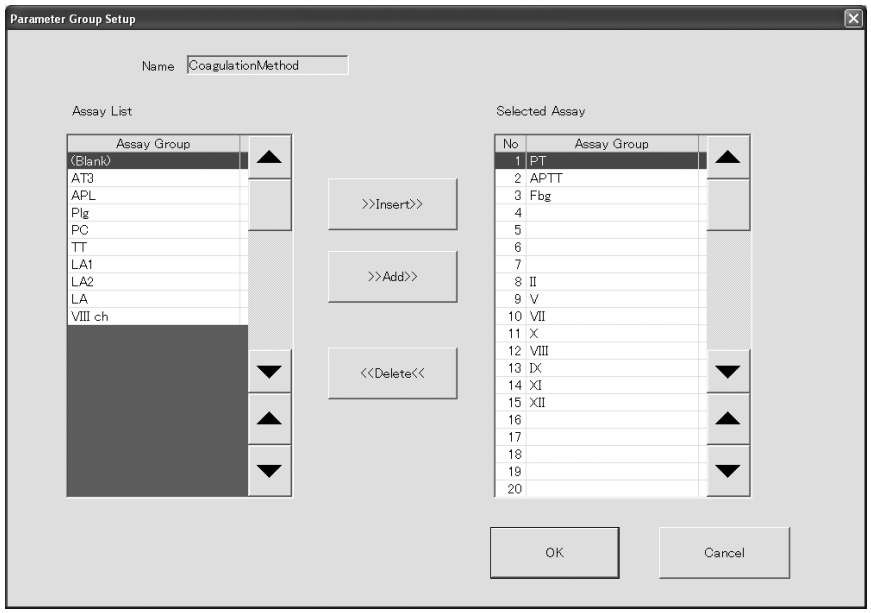

Figure 4-09: Parameter Group Settings dialog box

Name

Displays the name of the tab for setting displayed parameters. Displayed parameter settings apply to the tab selected in the tab list on the Customize dialog box.

Assay List

The assay groups registered under Settings–Assay group settings are listed. Assay groups set as display parameters are not displayed.

Selected Assay

Set displayed parameters are displayed. No. indicates the display location on the browser main screen. The relationship between the No. on the browser main screen and the display position is as described below.

Table 4-12: No. on the browser main screen and display location

Page	Browser main window display (within the tab)	
1	No. 1	No. 2
	No. 3	No. 4
	No. 5	No. 6
2	No. 7	No. 8
	No. 9	No. 10
	No. 11	No. 12
3	No. 13	No. 14
	No. 15	No. 16
	No. 17	No. 18
4	No. 19	No. 20
	No. 21	No. 22
	No. 23	No. 24
5	No. 25	No. 26
	No. 27	No. 28
	No. 29	No. 30

>>Insert>>

Inserts the assay group selected in the Assay List into the Selected Assay at the cursor position. The assay group inserted into the Selected Assay is deleted from the Assay List. Up to 30 parameters can be set.

>>Add>>

Adds the parameter selected in the Assay List into the bottom line of the Selected Assay. The assay group added to the Selected Assay is deleted from the Assay List. Up to 30 parameters can be set.

<<Delete<<

The assay group selected from the Selected Assay can be deleted from those parameters. The deleted assay group is displayed according to the assay display sequence in the Assay List.

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4. Set the assay groups to display inside the tab, then press **OK**.
   The setting content from the Displayed Parameter Settings dialog box is reflected in the Customize dialog box and the Displayed Parameter Settings dialog box closes.
   Press **Cancel** to discard settings entered in the Displayed Parameters Settings dialog box closes.
5. After adding a tab, change its name if necessary.
6. Press **Save** in the Customize dialog box.

2. Renaming tabs

1. Select the tab to rename from **List Tab** in the Customize dialog box.
2. Input the new tab name as the tab **Name**.
3. Press **Save**.

3. Deleting tabs

1. Select the tab to delete from **List Tab** in the Customize dialog box.
2. Press **Delete**.
3. Press **Save**.

Note:
Assay groups that are only displayed in a deleted tab will be displayed in the non user-customizable Other tab.

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4.8 Detailed graphical display

Detailed graphical display can be used for analysis results.

1. Click on the graph for each parameter displayed in the browser main window. The detailed information screen will appear.

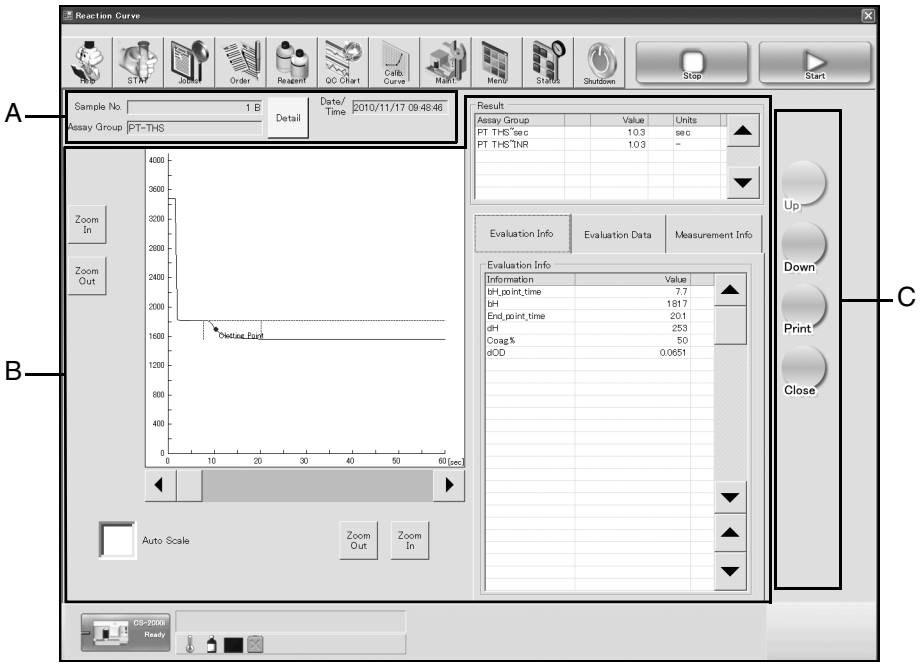

Figure 4-10: Detailed information screen

The composition of the detailed information screen of the browser is as follows:

A Parameter information display area
Parameter information is displayed here for the parameters on detailed graphical display.

Sample No.	Sample number is displayed. The format and content of the display are the same as for the browser main screen.
Date/Time	Date and time of analysis are displayed. The format of display is determined by the system setting. The analysis date and time are the date and time at which the assay group was analyzed.
Assay Group	The assay group is displayed. The format and content of the display are the same as for the browser main screen.
Detail	This is displayed if one or more errors occurred in the analysis results. The details dialog box appears when **Detail** is pressed. See “Chapter 4: 4.2: 2. Detail display” for the details dialog box.

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The color of the Detail button and the summaries of results are as stated below.

Table 4-13: Display color for the Detail button

Button color	Result summary
Red	Red display indicates an error in the measurement result.
Yellow	Yellow display indicates low reliability in the analysis results, or a calculated parameter that could not be calculated.
Gray	Gray display indicates that a comment has been appended to the analysis results.

The button is not displayed before or during analysis, or if the analysis results are normal.

B Detailed display area

Detailed analysis results and detailed graphics for the assay group are displayed.

C Operation panel area

The operation buttons which apply to the detailed graphically displayed analysis results are displayed. Operation buttons apply to all detailed graphically displayed analysis results.

Up — Changes the graphical display to the next line above the cursor position on the joblist screen. The display is blank if the subject assay parameter has not been analyzed.

Down — Changes the graphical display to the next line below the cursor position on the joblist screen. The display is blank if the subject assay parameter has not been analyzed.

Print — This function performs printing of the analysis results on detailed graphical display.

Close — The browser details window closes, returning to the browser main window.

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1. Detailed display of graphics and analysis results

Analysis results and graphics are displayed in detail in the detailed display area. Detailed display varies according to the type of analysis result.

Analysis results with reaction curves

The detailed screen for analysis results with reaction curves is as follows:

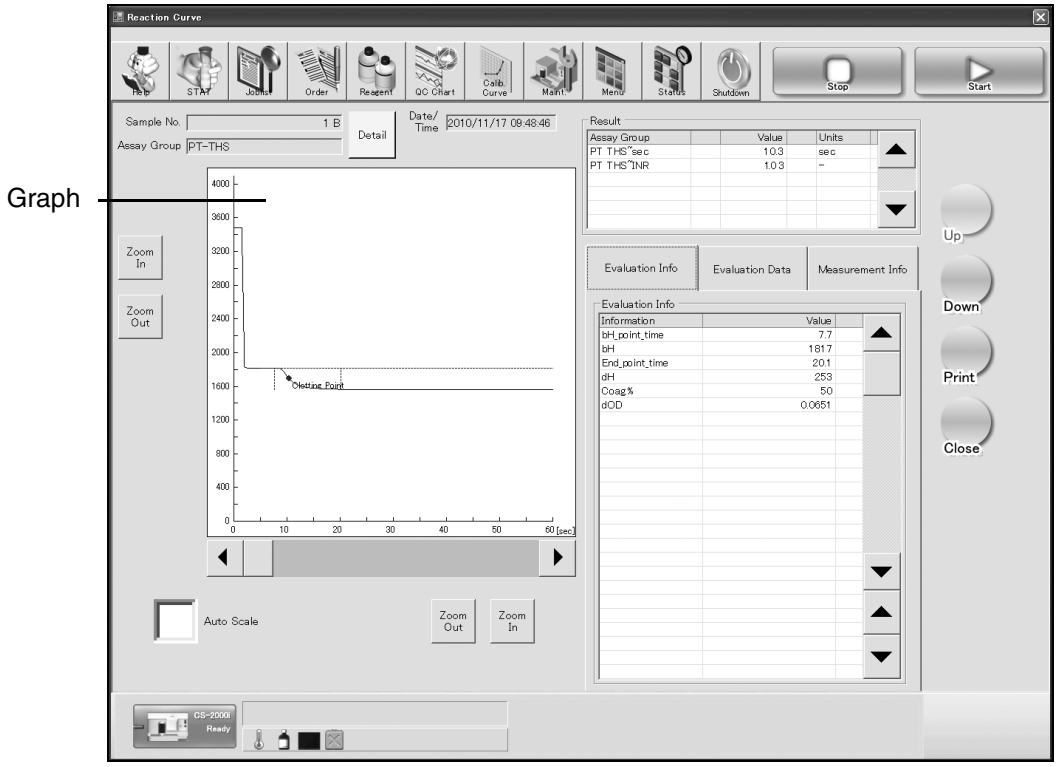

Figure 4-11: Detailed screen for analysis results with reaction curves

Graph

The reaction curve is displayed. The format and content of the display are the same as for the browser main screen. However, units, auxiliary lines and point markings are displayed according to the analysis algorithm for the analysis method.

Table 4-14: Graph display content and display format

<table>
<tr><th rowspan="2"></th><th colspan="4">Analysis algorithm</th></tr>
<tr><th>Percentage detection method</th><th colspan="2">Rate method</th><th>Drifting Baseline method</th></tr>
<tr><td>Units</td><td>X-axis: sec
Y-axis: A/D value</td><td colspan="2">X-axis: sec
Y-axis: OD</td><td>X-axis: sec
Y-axis: OD</td></tr>
<tr><td rowspan="3">Auxiliary lines</td><td>bH: Horizontal line at the baseline</td><td colspan="2">Start Time: Vertical line at the approximated start time</td><td rowspan="3">–</td></tr>
<tr><td>End Time: Vertical line at the end of coagulation</td><td colspan="2">End Time: Vertical line at the approximated end time</td></tr>
<tr><td>bH Time: Vertical line at the baseline detection time</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Point marks</td><td>Clotting Point</td><td colspan="2">–</td><td rowspan="2">–</td></tr>
<tr><td>A ● mark is added at the coagulation detection point.</td><td colspan="2"></td></tr>
</table>

Arrow button (◀▶) and bar where the display position is shown are displayed when both the X- and Y-axes are zoomed. The display position can be moved by pushing the arrow button (◀▶).

Note:
When assay parameters of different wavelengths are included within an assay group, the wavelength graph is only displayed for the first assay parameter.

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Zoom In (vertical)	The vertical axis is zoomed. The current scale doubles with each click: 2X → 4X → 8X → 16X → 32X → 64X → 128X.
Zoom Out (vertical)	The vertical axis is zoomed out. The current scale halves with each click: 1/2X → 1/4X → 1/8X → 1/16X → 1/32X → 1/64X → 1/128X.
Auto Scale	Inserts a check mark to display the graph at an automatic scale. In that case, the vertical axis is displayed with the largest possible scale. For the horizontal axis, the optimum time range for the analysis results is calculated automatically and used for the display. The check mark is removed when the **Zoom In** or **Zoom out** button is pressed for the vertical or horizontal axis.
Zoom In (horizontal)	The horizontal axis is zoomed. The current scale doubles with each click: 2X → 4X → 8X → 16X → 32X → 64X → 128X.
Zoom Out (horizontal)	The horizontal axis is zoomed out. The current scale halves with each click: 1/2X → 1/4X → 1/8X → 1/16X → 1/32X → 1/64X → 1/128X.
Result	Analysis results for all assay parameters in the assay group are displayed. The format and content of the display are the same as for the analysis results on the browser main screen.

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Evaluation Info

Reference information on the analysis is displayed. The displayed parameters vary with the analysis algorithm employed for the analysis method. The relationship between the analysis algorithm and the analysis information is as described below.

Table 4-15: Analysis algorithm and analysis information

	Analysis algorithm			
	Percentage detection method	**Rate method**	**VLin method**	**Drifting Baseline method**
Parameters	bH ⇨ Baseline	Slope ⇨Slope of the reaction speed detection section		DB_DeltaAdjusted ⇨delta
	bH_point_time ⇨Baseline detection time	Start_time ⇨Reaction speed detection start time		DB_ymini ⇨|y(mini)|
	dH ⇨Reaction intensity	End_time ⇨Reaction speed detection end time		DB_regl ⇨regl
	End_point_time ⇨Coagulation end point detection time	Coefficient of correlation ⇨Coefficient of correlation over the reaction speed detection section		DB_regr ⇨regr
	Coag.% ⇨Coagulation time detection %	proA_slope ⇨dOD/min for prozone A, if a prozone check was performed.		DB_mN ⇨m_N*direct
	Wave[nm] ⇨Wavelength after switching, if an automatic wavelength switch was performed	proB_slope ⇨dOD/min for prozone B, if a prozone check was performed.		DB_bN ⇨b_N*direct

Evaluation Data

Analysis data (for the time of coagulation between 1-100% light transmission) is displayed. Screen display for coagulation time detection % has a pale green background, with an added "⇨" when it is printed. This information is only displayed when the analysis algorithm employed by the analysis method is the percentage detection method. This tab is not displayed in other circumstances.

Measurement Info

Analysis information is displayed.

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Mean and final analysis results

The detailed screen for mean and final analysis results is as follows:

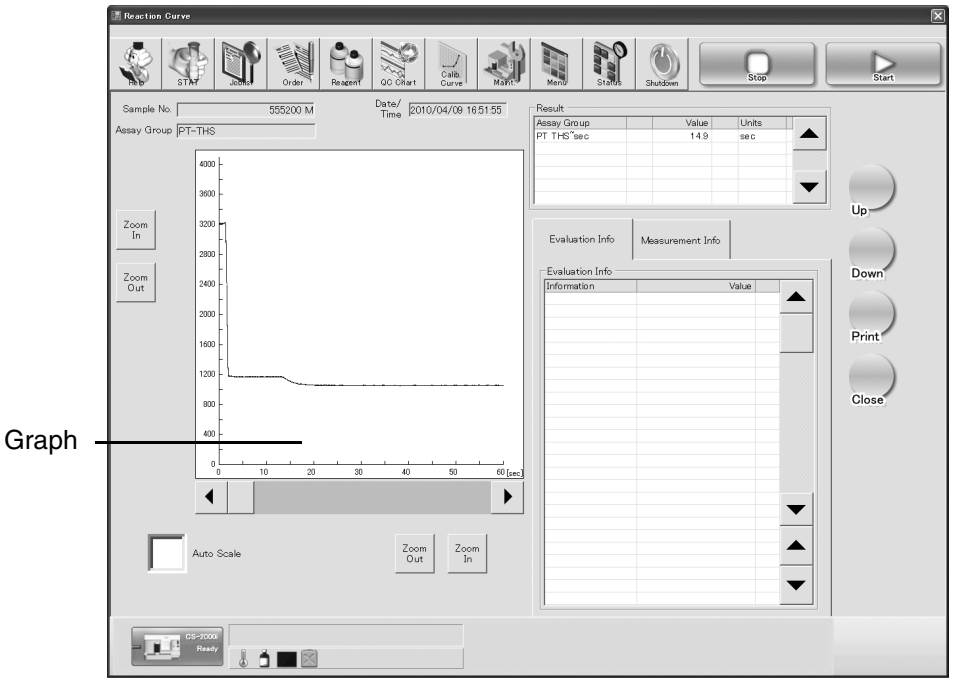

Figure 4-12: Detailed screen for mean and final analysis results

Graph	The reaction curve is displayed. The format and content of the display are the same as for the browser main screen. Arrow button (◀▶) and bar where the display position is shown are displayed when both the X- and Y-axes are zoomed. The display position can be moved by pushing the arrow button (◀▶).
Zoom In (vertical)	The vertical axis is zoomed. The current scale doubles with each click: 2X → 4X → 8X → 16X → 32X → 64X → 128X.
Zoom Out (vertical)	The vertical axis is zoomed out. The current scale halves with each click: 1/2X → 1/4X → 1/8X → 1/16X → 1/32X → 1/64X → 1/128X.
Auto Scale	Insert a check mark to display the graph at an automatic scale. In that case, the vertical axis is displayed with the largest possible scale. For the horizontal axis, the optimum time range for the analysis results is calculated automatically and used for the display. The check mark is removed when the **Zoom In** or **Zoom out** button is pressed for the vertical or horizontal axis.
Zoom In (horizontal)	The horizontal axis is zoomed. The current scale doubles with each click: 2X → 4X → 8X → 16X → 32X → 64X → 128X.

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Zoom Out (horizontal)	The horizontal axis is zoomed out. The current scale halves with each click: 1/2X → 1/4X → 1/8X → 1/16X → 1/32X → 1/64X → 1/128X.
Result	Analysis results for all assay parameters in the assay group are displayed. The format and content of the display are the same as for the analysis results on the browser main screen.
Evaluation Info	Analysis information is displayed. All codes of errors that occurred during analysis result calculations are displayed.
Measurement Info	The dilution ratio is displayed as analysis information.

MDA analysis results (final)

The detailed screen for MDA analysis results is as follows:

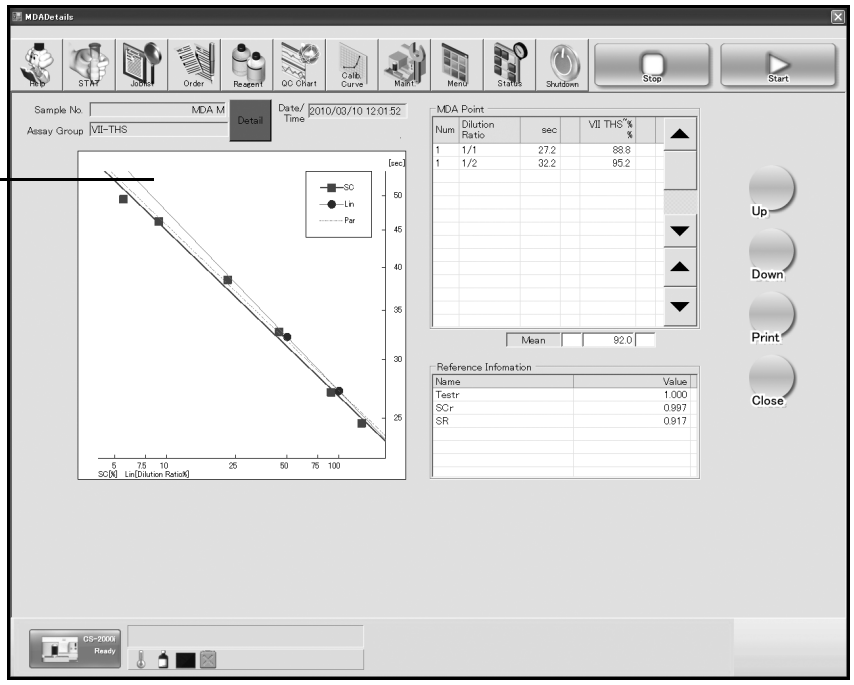

Figure 4-13: The MDA analysis results details screen

Graph

The MDA graph is displayed. The format and content of the display is the same as for the browser main screen.

Table 4-16: Graph display content and display format

X axis	Units: % for the calibration curve, dilution ratio (%) for the MDA analysis results.
Y axis	Units: Time (s)
Key	SC: Calibration curve Lin: MDA analysis Par: Line parallel to the calibration curve
Calibration Curve	Plots: Displayed in green ■ Line: Displayed in green
MDA analysis results	Plots: Displayed in blue ● Line: Displayed in magenta
Guide line (line parallel to the calibration curve)	The line which passes through the plot closest to an MDA dilution ratio of 1/1 and runs parallel to the calibration curve. Line: Displayed as a red broken line

MDA Point

Information on the MDA points is displayed. The form and content of the display is as described below.

Table 4-17: MDA point display content and display format

Num	The number of times analysis was performed is displayed.
Dilution Ratio	The dilution ratio is displayed.
sec	Time of analysis (s) is displayed.
%	The activity% value, converted to 1/1, is displayed.
Mean	The averaged activity% value, converted to 1/1, is displayed.

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Reference Info.

The MDA results are displayed. The format and content of the display is the same as the reference information on the browser main screen.

Table 4-18: Reference information display content and display format

Testr	The correlation coefficient for the MDA analysis is displayed.
SCr	The correlation coefficient for calibration curve is displayed.
SR	The MDA slope ratio (ratio between the gradients of the MDA analysis data and the calibration curve) is displayed. This value is an indicator for investigating the impact of inhibitors and activators.

2. Detailed printing

This function can perform printing of the analysis results on the detailed graphical display.

1. Press **Print** on the operation panel of the browser details window.

Note:
- If unvalidated analysis results (joblist lines) are printed, they have “Laboratory Use Only” printed in the background.
- The scale of the graph is automatic, regardless of the screen display state.

Blank page

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5. Reagent Screen

This chapter explains the functions of the Reagent screen.
The Reagent screen can display the status of the reagent tables in the instrument.

5.1 Overview

Major reagent screen functions:

Replacement and addition of reagents

Replacement and addition of reagents is performed as you check the Reagent screen. (For details, see “Chapter 5: 5.4: 5. : Replacement or addition of reagents and washing solution” in the Instructions for Use.)

Edit reagent information

Information on the reagent placed in the reagent holder is edited on the Reagent screen.

Set the reagent lot usage

Specifies which reagent lot to use for each test parameter.

5.2 Check the reagent set positions

1. Content displayed on the Reagent screen

The positions where the reagents are set and status of use can be checked.

1. Press **Reagent** on the toolbar.
   The Reagent screen will appear.

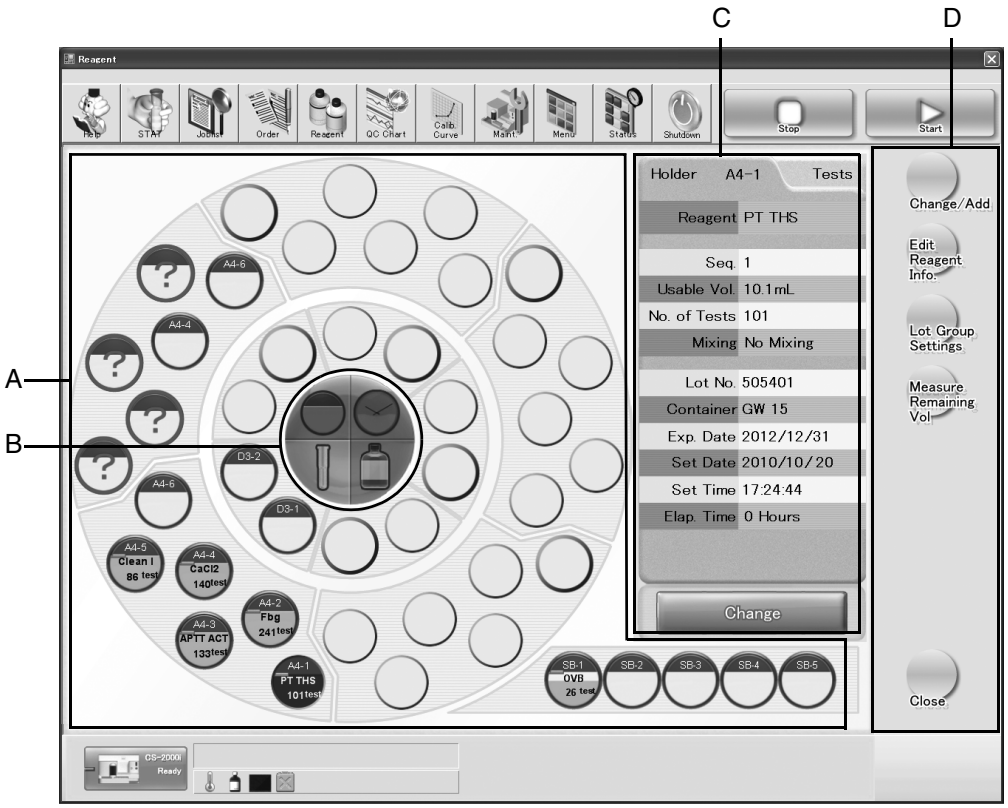

Figure 5-01: Reagent screen

A Reagent table status indicator area

The instrument reagent table structure and reagent holders are shown diagrammatically and the status of the reagent vial in the reagent holder is indicated. The selected reagent holder is indicated by a blue circle around it. Change the selected holder by clicking on another reagent holder. The functions for the operation buttons displayed in the operation panel area can be performed on the selected reagent holder (on the vial placed in that holder).

B Reagent holder display switch buttons

Pressing a button switches the display below the reagent holder. The buttons and display content are as shown below.

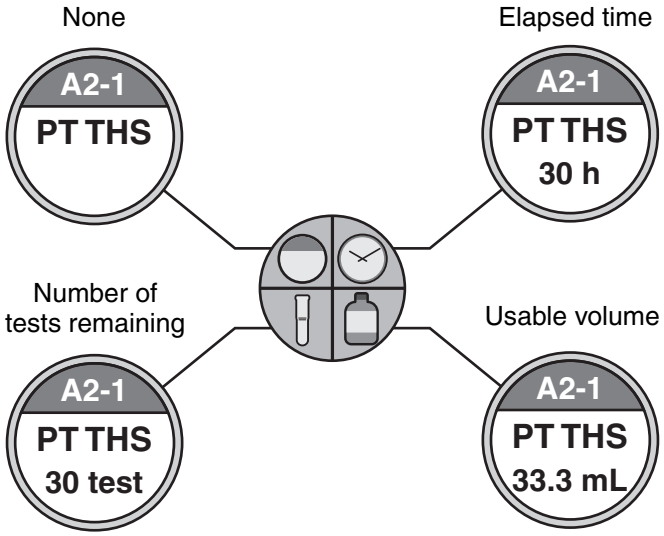

Figure 5-02: Display switch buttons and reagent holder displays

C Reagent holder information display area

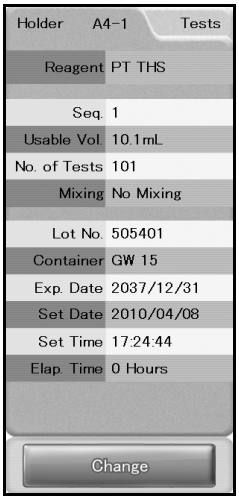

Figure 5-03: Reagent holder information display area (holder details tab)

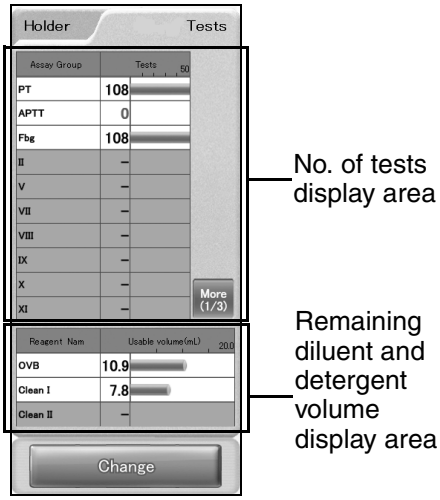

Figure 5-04: Reagent holder information display area (No. of tests tab)

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• Displaying detailed holder information

Information on the reagent vial placed in the reagent holder selected in the reagent table status indicator area (marked with the blue circle) is displayed. If there is no reagent vial in the selected reagent holder position, only the holder number is displayed and other display items are blank. If there is no rack, the holder number is also blank.

Holder No.	The holder number is displayed.
Reagent	Reagent name is displayed. This is blank if reading of the reagent barcode failed.
Seq.	The sequence in which reagents will be used is displayed if multiple reagents were set at the same time.

Note:

The sequence for usage of reagents is determined on the basis of the following conditions.

Prioritized condition:	Date and time of reagent setting (the reagent that was set earlier is prioritized)
Second prioritized condition:	Reagent period of validity (Reagents closer to the expiry of their period of validity are prioritized)
Third prioritized condition:	Position of reagent setting (the reagent that was set in a holder with a smaller holder number is prioritized)

Usable Vol.	The usable remaining volume is displayed. However, this is blank if the remaining reagent volume is not known.

Note:

The number of digits displayed for the reagent usage volume follows the conditions below.

Display to the second decimal place:	If an SLD mini cup is used and the usage volume is 1.0 mL or less
Display to the first decimal place:	Cases other than above

No. of Tests	The number of tests remaining is displayed. If the type of reagent is control, calibrator, detergent, or diluent, "-" (hyphen) is displayed. However, this is blank if the remaining reagent volume is not known.
Mixing	Indicates whether or not mixing is used.
Lot No.	Displays the lot number. This is blank if reading of the reagent barcode failed.
Container	The vial type is displayed. This is blank if reading of the reagent barcode failed.

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Exp. Date	The expiration date is displayed. The format of display is determined by the system setting.
Set Date	The date the system recognizes as the date of placement of the reagent vial is displayed. The format of display is determined by the system setting. It is updated when the system recognizes that a vial has been changed, or when a different date is input by the user.
Set Time	The time the system recognizes as the time of placement of the reagent vial is displayed. The format of display is determined by the system setting. It is updated when the system recognizes that a vial has been changed, or when a different date is input by the user.
Elap. Time	The time which has elapsed since the reagent was set is displayed.
Change	If the insufficient reagent state is not canceled after reagent replacement, the **Change** button is displayed when that reagent holder is selected. Press the **Change** button to change remaining reagent status to “Remaining volume unknown”.

• Displaying No. of tests

The number of tests which can be analyzed in each assay group, and the remaining volumes of diluent and detergent are displayed.

No. of tests display area

Assay Group	The assay group display name will appear.
Tests	The number of tests which can be analyzed in each assay group is calculated on the basis of the test protocol settings, and displayed. The cylinder graph is displayed as described below. If multiple reagents are used for an analysis, the one with the largest warning number of tests is used for the threshold value. Warning number of tests < Number of tests: Pale blue Warning number of tests ≥ Number of tests: Yellow Remaining volume unknown: Gray (if the remaining volume is unknown for any reagent, the lower part of the cylinder graph turns gray, and the upper part turns pale blue or yellow.)

Caution!
Usage of rinse fluid may be increased for some assay groups, so set an ample volume of rinse fluid.

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More	This is displayed if there are 11 or more parameters. Press the button to change pages.

The background is gray for assay groups for which any of the reagents necessary for analysis is not on the reagent table.

Remaining diluent and detergent volume display area
The diluents names, detergent names and usable volumes are displayed, together with cylinder graphs corresponding to their usable volumes. The cylinder graph is displayed as described below. The volume used per test can be set using the reagent master registration dialog box.

Warning number of tests < (usable volume/ volume used per test): Pale blue
Warning number of tests ≥ (usable volume/ volume used per test): Yellow
Remaining volume unknown: Gray (if the remaining volume is unknown for any vial, the lower part of the cylinder graph turns gray, and the upper part turns pale blue or yellow.)

The background is gray for diluents and detergents that are not on the reagent table.

D Operation panel area
Operation buttons used on the Reagent main screen are displayed here. The buttons affect the reagent holder selected in the reagent table status indicator area (the reagent vial placed in that holder).

Change/Add	Replace and add reagents. The reagent replacement and addition dialog box is displayed. This dialog box is only displayed during analysis. Other than during analysis, the selected reagent holder is immediately moved to a position where it can be replaced.
Edit Reagent Info.	The reagent information edit dialog box is displayed so that reagent information can be edited.
Measure Remaining Vol.	Measures the remaining volumes of the reagents placed on reagent tables A and B and the buffer table.
Lot Group Settings	The reagent lot usage settings dialog box is displayed.
Close	Closes the Reagent screen.

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2. Reagent table structure

The structure of the reagent tables is as described below. The circles in each table represent reagent holders and ● indicates reagent holder positions ready for mixing.

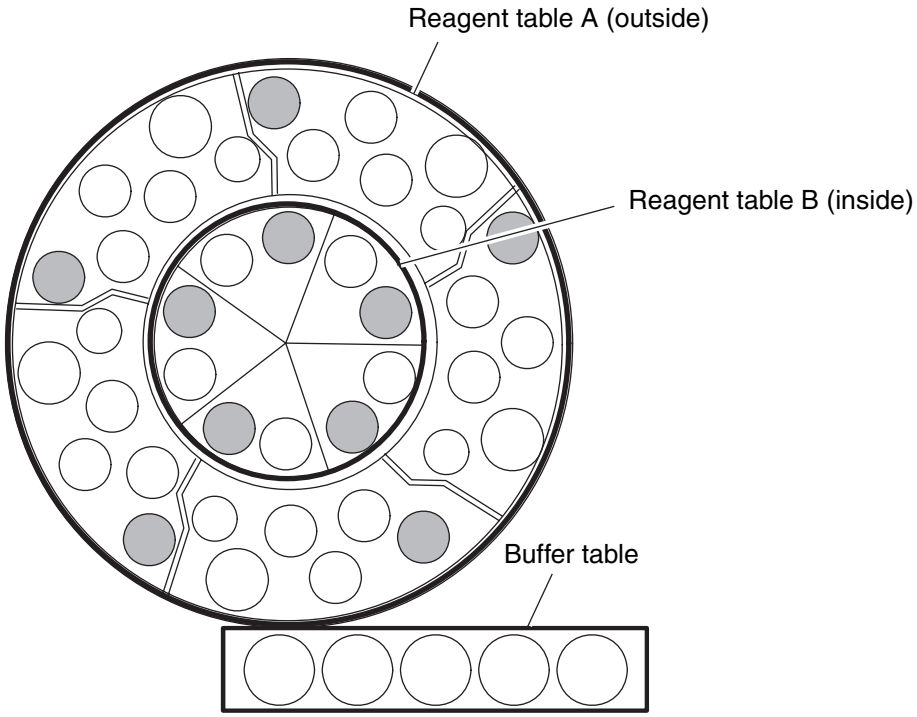

Figure 5-05: Reagent table structure

Reagent tables A and B are cooled holders, while the buffer table is a non-cooled holder.

The mixer only operates during Analysis mode, according to the set mixing conditions (interval, mixing time, mixing strength). When the interval is exceeded, the mixing time and strength for initial mixing are used. (When the status of the instrument is “Ready” and reagents are not mixed for long periods, there is the possibility or precipitation, so mixing conditions can be set to mix more strongly than usual.)

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3. Identification of reagent racks and reagent holders

Reagent tables A and B can each hold 5 racks and the racks are identified by their barcode labels.
There is no reagent rack for the buffer table. Insert the reagent vial in a suitable reagent holder and set it directly.
The rack form symbols and the rack identification numbers are as stated below.

Table 5-01: Rack form symbols and rack identifier numbers

Reagent table	Rack form symbols	Rack identifier numbers
Reagent table A	A-C	0-9
Reagent table B	D-F	0-9
Buffer table	-	-

Caution!
Always use SLD mini cups with the specialized reagent racks for SLD mini cups. If you place the wrong reagent rack, it can cause probe crash or sampling errors, so the control and calibrator may not be aspirated correctly, which would influence the analysis results.

Note:
A reagent rack with the rack form symbol C is a specialized reagent rack for SLD mini cups. Reagent vials other than SLD mini cups cannot be placed in such racks. See “Chapter 5: 5.4 Analysis reagent preparation” in the Instructions for Use for information on reagent vials and reagent racks that can be used as SLD mini cups.
If a GW5 container is recognized in a specialized reagent rack for SLD mini cups, the container type is displayed as SLDmini (GW5) and it is handled as an SLD mini cup.

Up to five racks at a time can be set on each reagent table, A and B. Rack identifier numbers 0-9 are used to allow for spare racks. If two racks have the same combination of rack form symbol and rack identifier number, those racks cannot be used at the same time. When two racks are set, only the one that was identified first is recognized.
Reagent table A has six reagent holders per rack, while reagent table B has two reagent holders per rack. Reagent holders are identified by their barcode labels in the same way as racks. The numbers for each holder are as stated below.

Table 5-02: Holder identifier numbers

Reagent table	Holder identifier numbers
Racks on reagent table A	1-6
Racks on reagent table B	1-2
Buffer table	1-5

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The relationship between the holder position and the holder identification number within each rack is as stated below.

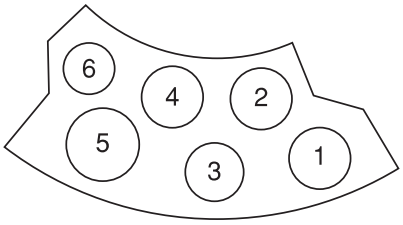

Figure 5-06: Racks within reagent table A

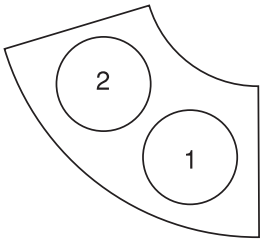

Figure 5-07: Racks within reagent table B

A reagent rack is loaded or unloaded for the purposes of loading or unloading reagents. For the buffer table, vials are placed directly into reagent holders.
Reagent replacement and addition are performed after the specific rack is moved to the reagent replacement position (the place where the cover opens and closes) and the table carrying it stops.
At that time, the accessibility status for the rack is indicated by its color, regardless of the presence or absence of racks and reagent vials. The relationship between rack accessibility and color is as stated below.

Table 5-03: Colors displayed and the accessibility status

Rack color	Access status	Overview
Green	Accessible (Ready)	This status means that the reagent rack can be replaced. At that time, the cover accessibility indicator LED on the Main Unit turns green.
Yellow	Waiting	This is the state between when the reagent addition/replacement request is issued and when analysis is complete and replacement is possible. At that time, the cover accessibility indicator LED on the Main Unit is red.
No color (same as background color)	Running (access not possible)	In this state the reagent table on which the reagent rack is placed is in operation. During analysis, all racks are in this state. At that time, the cover accessibility indicator LED on the Main Unit is red.

The cover accessibility indicator LED on the Main Unit indicates whether reagent cover A, reagent cover B and the diluent/STAT cover can be opened and closed.

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4. Reagent holder display

A circle of a reagent holder displays the information on the reagent vials as shown below.

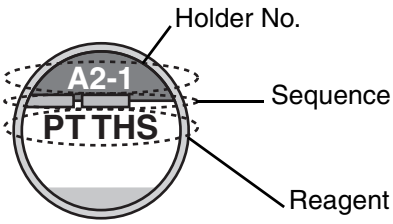

Figure 5-08: Reagent holder display

Holder No.	The holder number is displayed. The holder number consists of “Rack form symbol + rack identifier + “-” (a hyphen) + holder identifier number”. Nothing is shown if no rack is in place.
Sequence	The sequence in which reagents will be used is displayed if multiple reagents were set at the same time. The reagent to be used first has one mark, the second two marks, and the third three marks. The reagents to be used fourth or later, and those in access lock 1 or access lock 2 status, do not have any marks displayed.
Reagent	Reagent name is displayed. Nothing is shown if no reagent vial is in place.

The maximum number of display characters is eight. If the reagent name exceeds eight characters, only the first eight will be displayed.

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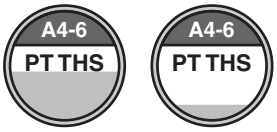
5. Remaining reagent volume

The remaining reagent volume can be known from the background color of the reagent holder. The relationship between the color and the remaining reagent volume is as shown below. No color is displayed (background color only) for holders that contain no reagent vials.

Table 5-04: Reagent holder background color and remaining reagent volume

Reagent holder display examples	Reagent holder background color	Remaining volume color	Remaining reagent
	Gray	–	Remaining volume unknown
	White	Pale blue	Reagent remaining (remaining volume is displayed visually in four levels)
	Cream	Pale blue	Remaining volume warning
	Pink	–	Reagent empty

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6. Reagent holder marking

When the following mark is superimposed on the display of any reagent holder, it indicates the status of that reagent holder.

Table 5-05: Marks and access status

Mark	Mark color	Status	Overview
	Red	Access lock 1	This state occurs if the following conditions are applicable. - If a mixed and refrigerated reagent is mistakenly placed in a different holder. - If a barcode is read that is not registered in the reagent master. - If diluent is placed on reagent table A or B. - If a reagent other than control or calibrator is placed in a specialized reagent rack for SLD mini cups.
	Red	Access lock 2	This state occurs if the reagent has expired.
	Red	Barcode read error	This state occurs if a barcode read error occurs.
	Yellow	Unregistered reagent lot	This status occurs if the read reagent ID was not registered in the lot master.

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5.3 Edit reagent information

Press **Edit Reagent Info.** to edit the information on the reagent placed in the reagent holder.

1. Select the reagent holder for editing reagent information from the reagent table status indicator area.
2. Press **Edit Reagent Info.** on the operation panel.
   The Reagent Information Editing dialog box will appear.

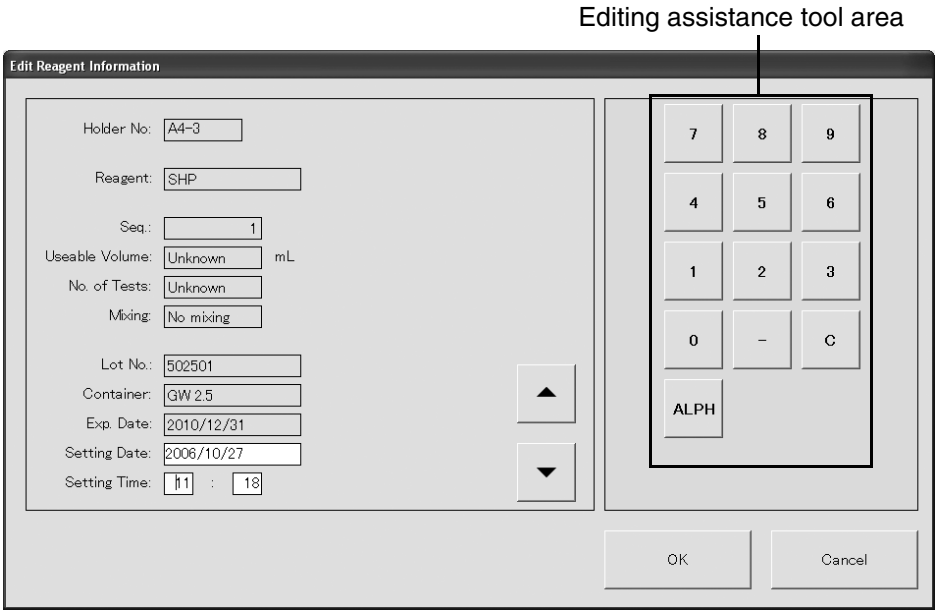

Figure 5-09: Reagent Information Editing dialog box (when editing lot No.)

Holder No.	The holder number is displayed.
Reagent	This is the field for editing reagent name. The name can be selected from the reagent name list displayed by the editing assistance tool. All reagents registered in the reagent master are displayed in the list. This field can only be edited when reagent barcode reading has failed.
Seq.	This is the field for editing usage sequences. The usage sequence is displayed for one reagent.
Useable Volume [mL]	The usable volume is displayed.

Note:
The number of digits displayed for the reagent usage volume follows the conditions below.

Display to the second decimal place: If an SLD mini cup is used and the usage volume is 1.0 mL or less
Display to the first decimal place: Cases other than above

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No. of Tests	The number of tests remaining is displayed. If the type of reagent is control, calibrator, detergent, or diluent, "-" (hyphen) is displayed. However, this is blank if the remaining reagent volume is not known.
Mixing	Indicates whether or not Regular Mixing of reagent master is used.
Lot No.	This is the field for editing lot number. The lot number can be selected from the lot number list displayed by the editing assistance tool. Lot number for reagent selected by the name from the list, and which are within the expiry limit registered in the reagent lot master are listed in order of reagent lot number, with the smallest at the top. This field can only be edited when reagent barcode reading has failed.
Container	This is the field for editing container type. The container can be selected from the container type list displayed by the editing assistance tool. The list contains those of the container types registered in the container master that can be set at the current holder position. They are listed alphabetically from the top. This field can only be edited when reagent barcode reading has failed.
Exp. Date	The expiration date is displayed. Use the calendar displayed in the editing assistance tool to input date. The format of display is determined by the system setting.
Setting Date	This is the field for editing set date. Use the calendar displayed in the editing assistance tool to input date. The format of display is determined by the system setting.
Setting Time	This is the field for editing set time. Use the numeric keys displayed in the editing assistance tool to input time.
▲	The cursor moves to the next for editing field above.
▼	The cursor moves to the next for editing field below.

Editing assistance tool area
Input assistance tools that can be used for editing reagent information are displayed.

OK	Saves the setting content of the Reagent Information Edit dialog box and closes the dialog. When editing reagent information for holders which failed reagent barcode reading, if the reagent name, lot number and container type are all updated, the update of reagent information cancels analysis interruption of any parameters that were interrupted for that reagent.
Cancel	Discards the setting content of the Reagent Information Edit dialog box and closes the dialog.

3. Perform editing as required.
4. Press **OK**.

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Note:
Reagent information can be input for reagents for which barcode reading failed, and for reagents not registered to the reagent lot master.

5.4 Set the reagent lot usage

One type of reagent can be used for multiple test parameters.
Furthermore, different lots can be specified for one test parameter.
The reagent lot usage setting function makes it possible to specify which reagent lot to use for each test parameter.

1. Select the reagent for which to set reagent lot usage.
2. Press **Reagent Lot** on the operation panel.
   The Lot Group Settings dialog box appears for the selected reagent.
   Up to 60 parameter tabs can be displayed (6 parameters per page) and if there are 7 or more parameters, the ◀, ▶ button to switch the tab page is displayed to the right of the tab.

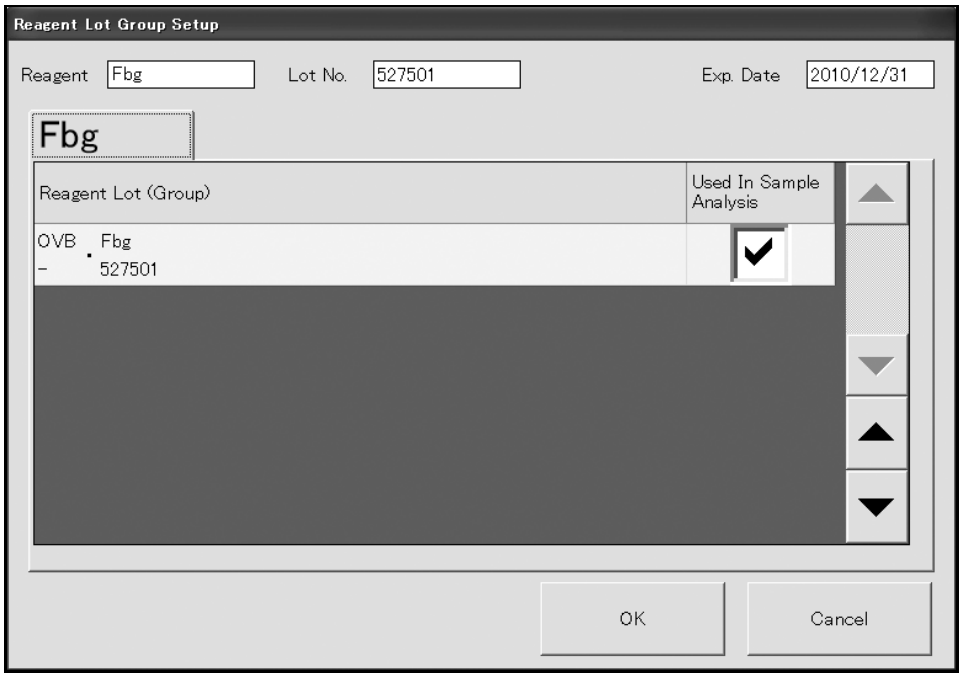

Figure 5-10: Lot Group Settings dialog box

Reagent	Reagent name is displayed.
Lot No.	The lot number is displayed.
Exp. Date	The expiration date is displayed. The format of display is determined by the system setting.

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Reagent Lot (Group)	The reagent combination to be used for the reagents placed on the reagent table is displayed. If lot management is not performed, the lot number is displayed as "-" (hyphen).
Used In Sample Analysis	Validates reagents that have their reagent lots (combinations) checked. Validated reagent lots (combinations) are used in sample analysis (routines). Checked: Validated. Not checked: Not yet validated.

3. Make check marks to select reagent lots to use and to validate, as required.
4. Press **OK**.
   Save the setting content of the Reagent Lot Usage Setting dialog box and the dialog closes.
   Press **Cancel** to discard the setting content of the Reagent Lot Usage Setting dialog box and the dialog closes.

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Blank page

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6. Quality Control

This chapter explains quality control, which is implemented to ensure that highly reliable data is obtained over the long term and to constantly monitor instrument status to prevent any problems from arising.

Caution!
Use the quality control samples and reagents in accordance with the usage methods described in the package insert accompanying each material.

6.1 Overview

The CS-2000*i*/CS-2100*i* analyzes control plasma and other reference samples and statistically manages the results. The parameters (assay parameters) managed by quality control are registered in the QC master of the master registry.
Quality control can manage up to 750 parameters. The parameters are displayed graphically, one per chart and up to 1,200 data points can be saved per parameter. When the 1,201st point is added, the oldest data point is automatically deleted.
When QC analysis is performed, an analysis may be interrupted or an alarm generated, depending on the analysis results, in line with the judgment rules set.
In addition, the two quality control methods listed below are available. They can be selected by setting the number of analysis replications.

$\overline{X}$ control: Uses the average of two consecutive analyses made on a QC sample.

L-J control: Uses the data from a single analysis made on a QC sample. With L-J control, the range of control is easily affected by the reproducibility of analysis; thus, the range is wider than that of $\overline{X}$ control.
Major quality control functions:

QC chart display
The results of QC analysis are displayed in a progressive line graph for each assay parameter.

Error search
QC error data is searched.

Data validation
Details of QC data is validated. When there is an error in QC data, it is possible to set it so that error data is excluded from the calculation of the Mean, SD and CV, as well as whether to make it an error search item.

Change cursor
The cursor in the QC chart is changed.

Set target/limit
Target/limits are set.

Auto QC setting
Sets whether or not to perform Auto QC.

QC barcode setting
Controls can be set for sample numbers used for quality control.

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Delete

Selected QC analysis results are deleted.

Add a new lot

A new control lot can be added.

Changing lots

The lot used for determining whether a QC error has occurred can be changed.

Change scale

The number of points to be displayed in a screen can be changed.

Changing display data

The data displayed in a chart can be changed.
For information on operations, see the Instructions for Use.

Print report

Specified QC analysis data are printed out as a report.

Print

QC analysis results are printed out.

Export

QC analysis results can be exported.

Customize

The order for displaying QC charts can be customized.

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6.2 QC charts display screen

The QC analysis results for assay parameters recorded in the QC master are displayed for each parameter in a progressive line graph.
The QC Chart display screen (QC main screen) can be displayed in either of the following ways.

- Press **QC Chart** on the toolbar.
- Press **QC Chart** on the menu screen.

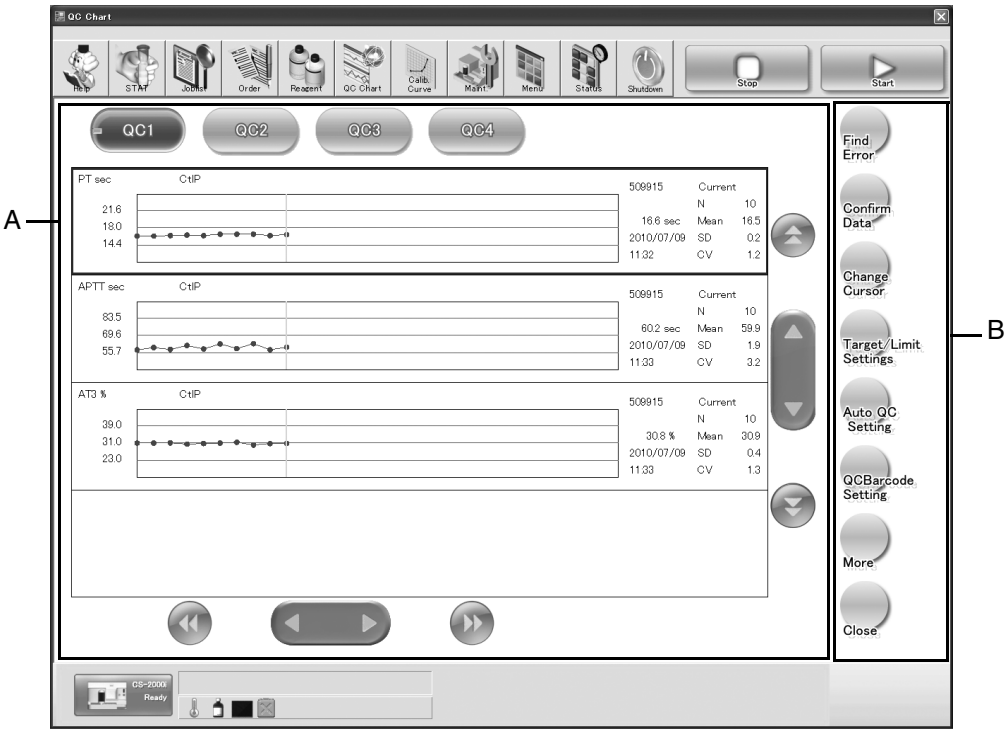

Figure 6-01: QC chart display screen (QC main screen)

A QC chart display function

QC chart is displayed. The displayed group can be changed using tabs. Up to 4 charts can be displayed on 1 page. The display group and parameters within a group can be set with the display customization function.

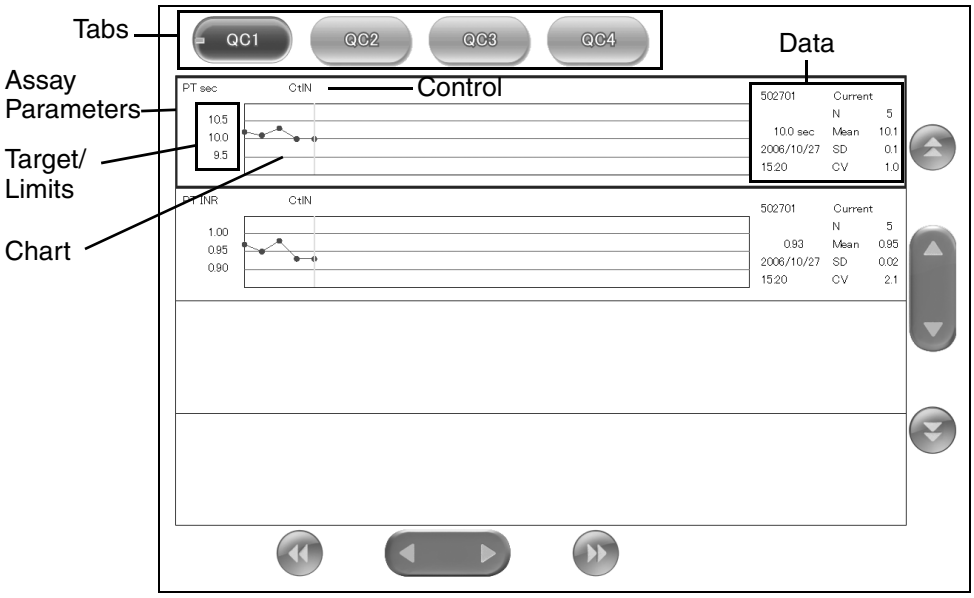

Figure 6-02: QC chart display area

Tabs	Both tabs set up in the tab list and the Other tab can be displayed by customizing the display. When all assay parameters have been assigned to tabs besides Other, the Other tab will not be displayed.
Assay Parameters	Displays the names of assay parameters.
Control	Displays the name of the control.
Target/Limits	
Upper	Displays the upper limit set under the target/limit settings.
Target	Displays the target.
Lower	Displays the lower limit set under the target/limit settings.
Chart	QC analysis results are shown for each lot in a progressive line graph. When there is no data for a QC chart, only the target line is shown. If there is just one point, that value is plotted as the target. From the 2nd point on, the upper and lower lines are shown at 2SD. When a value has been set for the target/limit, even if there is not any data in the QC chart, the target, upper and lower lines are shown.
Line and plot colors	The current lot is shown in green, while a new lot is cyan.
Plotting	If the number of data is lower than the display area, chart is aligned and plotted to the left and if the number of data exceeds the display area, the latest data is plotted on the right edge.

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Plotting shapes

In order to differentiate the lots of a reagent, the shapes ●, ■, ◆ and ▲ are assigned in order to reagent lots. If the number of lots of a reagent exceeds 4, the order starts over again with ●.

Display of errors

QC error data is plotted with a red X mark on top of the normal plot. When the analysis results in a QC analysis are masked, it is deemed to be a QC analysis error and is plotted with X on the upper line of the display area. If a low reliability flag (*) is attached to a result in the QC analysis and a value is obtained, the value is used for evaluating the QC analysis error and the value is used for plotting (if it is within the judgment rule, no QC analysis error will occur).

Data

Information about the data shown in the chart is displayed. Two columns of control data are displayed, lot information, and numerical data on the cursor position on the left and on the right, accumulated control chart data including the cursor position data.

Table 6-01: Structure of the information

Left column	Right column
Control lot No.	Lot use status
	N
Analysis results	Mean
Analysis date	SD
Analysis time	CV

The format of analysis date and time display are determined by the system settings.
In the status of lot use, “Current”, “New” and “ ” (space) are displayed. N displays the Number of data. However, this does not include data that is excluded from automatic calculation.
The Mean is shown only when there are one or more data points. When there is not any data, the display is left blank. SD and CV are shown only when there are 2 or more data points. When there are less than 2, the display is left blank.

▲▲ Moves the chart display 1 page up, if the QC chart within a tab consists of more than one page.

▲ Moves the chart selecting cursor one chart up, if the QC chart display within a tab consists of 2 or more charts.

▼ Moves the chart selecting cursor one chart down, if the QC chart display within a tab consists of 2 or more charts.

▼▼ Moves the chart display 1 page down, if the QC chart display within a tab consists of more than one page.

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◀◀	Moves the chart display 1 page to the left, if the selected chart display consists of more than one page.
◀	Moves the data selecting cursor inside the chart one point to the left, if the selected chart display contains 2 or more points (QC analysis results). The mouse can also be used to move the cursor.
▶	Moves the data selecting cursor inside the chart one point to the right, if the selected chart display contains 2 or more points (QC analysis results). The mouse can also be used to move the cursor.
▶▶	Moves the chart display 1 page to the right, if the selected chart display consists of more than one page.

B Operation panel area

1st page

Find Error	Moves the cursor to a QC chart where an error point exists.
Confirm Data	The Data Details dialog box will appear. Use this function to check details of the data at the cursor position.
Change Cursor	The operation panel switches into the Change Cursor mode. Use this function to select data inside QC charts with the cursor.
Target/Limit Settings	The Target/Limit Definition dialog box will appear. Use it to change the target/limits. However, if displayed data is “Current+New”, this button does not work.
Auto QC Setting	The Auto QC Setting dialog box is displayed. Use it to cancel or resume Auto QC.
QCBarcode Setting	Controls can be set for sample numbers used for quality control. The QC Barcode setting dialog box is displayed.

2nd page

Delete	Use this function to delete QC data.
Add Lot	The New Lot Addition dialog box will appear. Use this function to add new lots.
Change Lot	The Lot Change dialog box will appear. Use this function to switch control lots.
Change Scale	The Change Scale dialog box will appear. Use this function to change the number of points displayed on a chart.
Switch Display	The Change Display Data dialog box will appear. Use this function to change the display content of a chart.
Print Report	The QC Print dialog will appear. Use this function to print QC data as a report.

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3rd page	
Print	The Print dialog box will appear. Use this function to print out selected QC data.
Export	Export QC analysis results.
Customize	The Customize dialog box will appear. Use this function to customize the tabs and display parameters within the display area of QC charts.
Common to the 1st to 3rd page	
More	If the Operation Panel comprises multiple pages, use this button to switch between pages.
Close	The QC Control screen closes, returning to the previous screen.

6.3 Searching for QC error charts

Press **Find Error** on the control panel to search for charts in which other QC errors occurred.
If **Find Error** is pressed more than once, each time you do so, charts with QC errors become selected. If such a chart does not exist, the following dialog is displayed.

Figure 6-03: Confirmation dialog box

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6.4 Checking QC error data

When a QC error occurs on the current lot, the background of the QC chart turns red or yellow.
When the analysis is interrupted it turns red and when an error message is displayed it turns yellow.
Follow the procedure below to check the analysis data.

1. Press **Confirm Data** on the operation panel.
   A Data Details dialog box will appear.

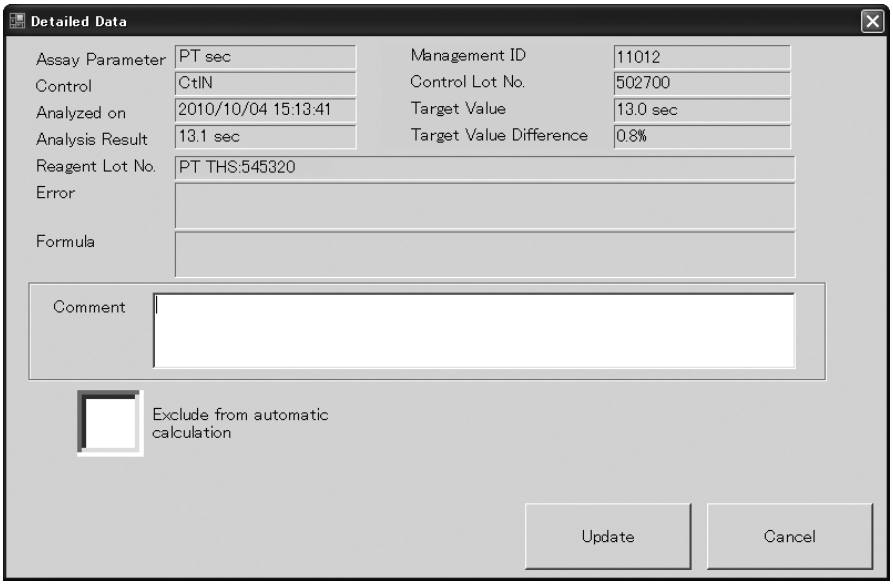

Figure 6-04: Data Details dialog box

Assay Parameter	The assay parameter name is displayed.
Management ID	The Management ID of the assay group is displayed. It is blank in the case of quality control data for calculated parameter results.
Control	The control name is displayed.
Control Lot No.	The control lot number is displayed.
Analyzed on	The date and time when the quality control was judged an error is displayed.
Target Value	The target is displayed.
Analysis Result	The analysis results are displayed.
Target Value Difference	The ratio of the analysis result to the target is displayed. The ratio can be calculated by the formula below. $\frac{\lvert\text{Analysis result} - \text{Target}\rvert}{\text{Target}} \times 100\ (\%)$
Reagent Lot No.	The name and lot number of the reagent used in analysis are displayed. It is blank in the case of quality control data for calculated parameter results.

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Error In case of a QC error, judgment reasons are displayed. Otherwise, the display is left blank.

Table 6-02: QC error list

Error	Judgment method	
The quality control analysis result exceeded the “upper stop” limit.	Upper Stop	Control Limit method
The quality control analysis result exceeded the “upper flag” limit.	Upper Limit	
The quality control analysis result fell below the “lower flag” limit.	Lower Limit	
The quality control analysis result fell below the “lower stop” limit.	Lower Stop	
One quality control analysis result exceeded ±2SD limit.	1-2s	Multi Rule method
One quality control analysis result exceeded ±3SD limit.	1-3s	
Two consecutive quality control analysis results exceeded ±2SD limit.	2-2s	
Four consecutive quality control analysis results exceeded ±1SD limit.	4-1s	
Five consecutive quality control analysis results exceeded ±0.5SD limit.	5-0.5s	
The difference between this result and the previous quality control analysis result exceeded 4SD.	R-4s	
The results of 7 consecutive quality control analyses monotonic increased or decreased.	7T	
The results of 10 consecutive quality control analyses all deviated to the same side of the target.	10x	

Formula The calculation formula for the calculated parameter is displayed.
It is only displayed in the case of quality control data for calculated parameter results.
It is normally blank for quality control data.
Assay parameters specified in the formula are substituted with the analysis results.

Comment Comments can be registered.

Exclude from automatic calculation The data can be excluded from automatic calculation when the analysis result is suspicious.
Add a check mark: N (number of data), Mean, SD and CV are excluded from automatic calculation. Data excluded from calculation is omitted in plotting the line graph in the QC chart.
Remove the check mark: N (number of data), Mean, SD and CV are calculated automatically. Line graphs are plotted in the QC chart.

2. Check the analyzed data on the Data Details dialog box.
   - Check the **Exclude from automatic calculation** check box in order to exclude the selected data from calculation. Data excluded from calculation is omitted in plotting the line graph.
   - Enter a comment in the comment field, if required.

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3. After the settings are completed, select **Update** to close the Data Details dialog box. The chart screen is updated.
   Press **Cancel** to cancel the update and close the dialog box.

6.5 Change cursor

You can change the data-selecting cursor within the chart that is displayed in the QC chart screen.

1. Press **Change Cursor** on the operation panel.
   The operation panel switches into the Change Cursor mode. The change cursor button is displayed on the operation panel.

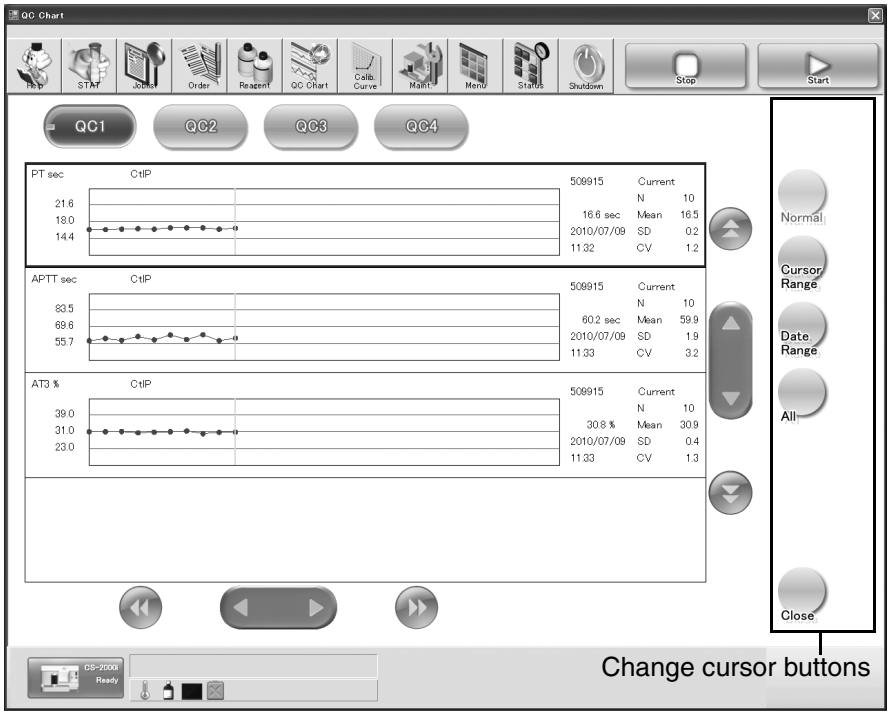

Figure 6-05: Buttons on the operation panel when in Change Cursor mode

Change cursor buttons

Normal	One cursor is shown on the chart. **Cursor Range**, **Date Range** and **All** return the cursor to the range selection mode.
Cursor Range	Two cursors are shown on the chart. One cursor is fixed to the original position and the other moves using the scroll bar, selecting the space between the two.
Date Range	Date range selection dialog box will appear for specifying the date and selecting the range.
All	All the subject charts are selected.
Close	With the current cursor status, the operation panel goes to the normal mode.

2. Switches the data selection cursor using the Change Cursor button.

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If the date range is selected

The Date Range Selection dialog box will appear.

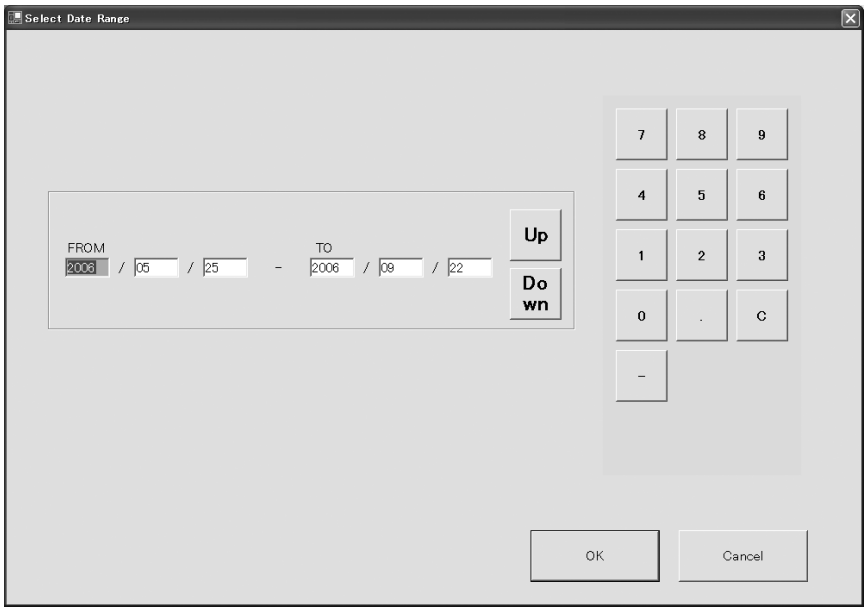

Figure 6-06: Date Range Selection dialog box

1. Enter the start date (yyyy/mm/dd, mm/dd/yyyy, dd/mm/yyyy) for the range selected in **FROM** and the end date (yyyy/mm/dd, mm/dd/yyyy, dd/mm/yyyy) for the range selected in **TO**, then press **OK**. The allowed range setting is 1800/01/01 – 2037/12/31.

Note:

- If any of the Cursor Range, Date Range or All is pressed, the background of the range selected in the chart becomes light blue.
- If the cursor is switched to Standard or All, Mean, SD and CV are re-calculated for all data and if it is switched to Range or Date Range, the Mean, SD and CV data are re-calculated in the range selected.

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6.6 Set target/limit

The target/limit setting function can be used to set targets/limits for the assay parameter selected in the QC chart. More detailed judgment rules can be checked by pressing the **Detailed Condition** button to view the Detailed Error Check Condition dialog box. Judgment is based on the upper and lower stop limits and upper and lower flag limits set on the Target/Limit Definition dialog box and the rules set on the Detailed Error Check Condition dialog box. A result is judged to be a quality control error if any one of the limits is exceeded or any one of the rules is applicable.

Detailed judgment rules are set using the quality control setting function for assay group setting. For details, see “Chapter 8: 8.11 Quality control settings”.

Target/Limit setting procedure

1. Move the chart selection cursor to the chart to set targets/limits for.
2. Press **Target/Limit** on the operation panel.
   The Target/Limit Definition dialog box will appear.

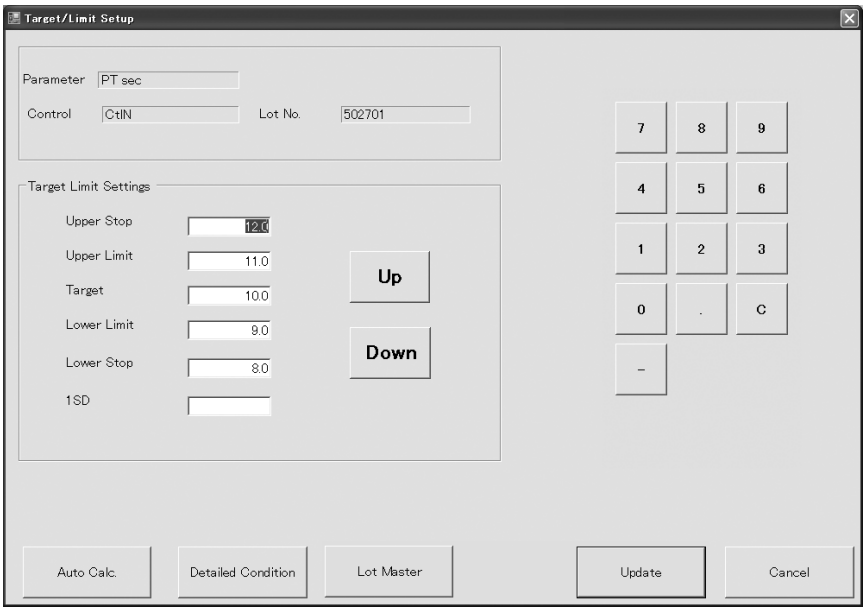

Figure 6-07: Target/Limit Definition dialog box

Target Limit Settings

Upper Stop	Inputs the upper stop limit value.
Upper Limit	Inputs the upper limit value.
Target	Inputs the target value.
Lower Limit	Inputs the lower limit value.
Lower Stop	Inputs the lower stop limit value.
1SD	Inputs the 1SD value.

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Note:
Be sure to input a value for **1SD**.
Click on **Auto Calc.** to calculate the value from the current quality control data and set the result as the 1SD value.
If there is not enough data for automatic calculation, manually input a value equal to half the difference between **Target** and **Upper Limit** (or **Lower Limit**).
Errors can occur in quality control analysis results if **1SD** is not set.

Auto Calc.

Calculate the mean and 1SD values from the current control data and set the values below to the edit parameters.

Upper Stop: Mean value + 3SD

Upper Limit: Mean value + 2SD

Target: Mean

Lower Limit: Mean value – 2SD

Lower Stop: Mean value – 3SD

If there is only one control data point, only the target is updated, using the calculation above, and other edit parameters are not updated. If there are no points of control data, no edit parameters are updated.

Detailed Condition

The Detailed Error Check Condition dialog box will appear. Detailed rules can be checked. Settings can be changed using the quality control setting function for each assay group setting.

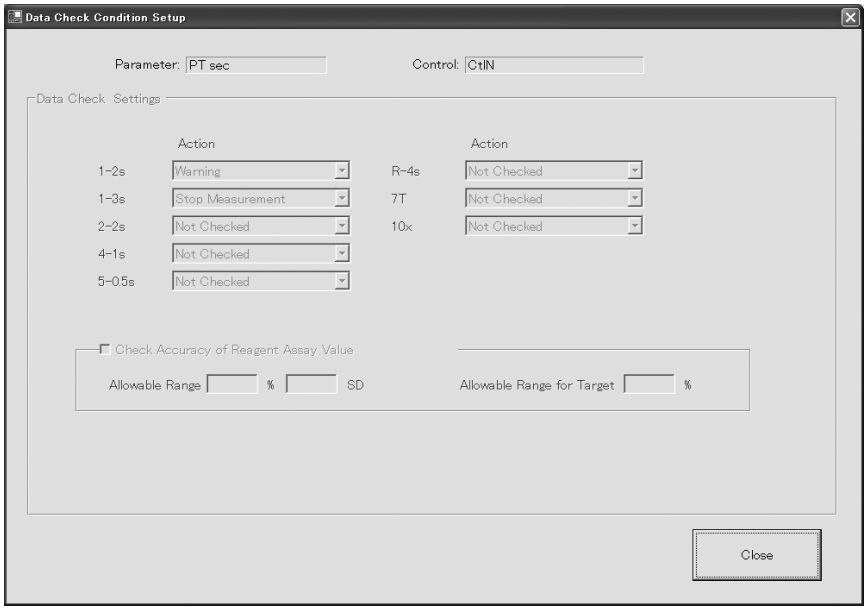

Figure 6-08: Detailed Error Check Condition dialog box

Lot Master	Load targets/limits from the detailed reagent information of the reagent lot master.

3. Press **Update** after setting each parameter.
   The settings are updated and the Target/Limit Definition dialog box closes.
   Press **Cancel** to cancel the update and close the Target/Limit Definition dialog box.

6.7 Auto QC setting

Auto QC can be temporarily cancelled and then resumed.

1. Press **Auto QC Setting** on the operation panel.
   The Auto QC Setting dialog box is displayed.

Figure 6-09: Auto QC Setting dialog box

Auto QC analysis parameters	Assay group names which have been set for Auto QC under the assay group settings are displayed. Check marks are added to parameters subject to Auto QC. When the instrument is switched on, all parameters are checked. Remove check marks to avoid performing Auto QC for those parameters.
More	Switches the displayed page if there are 21 or more parameters. “Current page/Total” is displayed under the button.
OK	Confirm the edited content, then close the dialog box. Parameters which were changed from being set for no Auto QC to performing Auto QC have their Auto QC analysis orders registered to the joblist, and automatic analysis starts at fixed intervals. When a parameter is changed from performing to not performing Auto QC, its automatic analysis is stopped.

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Cancel	Discard the edited content, then close the dialog box.

2. Edit the Auto QC analysis parameters, then press **OK.**

6.8 QC barcode setting

Controls can be registered for the sample number (QC01–QC20) for quality control.

1. Press **QCBarcode Setting** on the operation panel.
   The QC Barcode setting dialog box will appear.

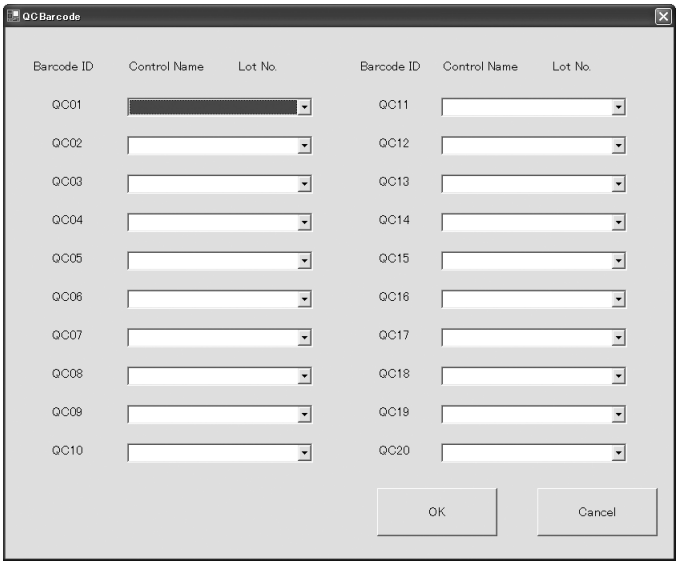

Figure 6-10: QC Barcode Setting dialog box

Barcode ID	The barcode IDs that can be set are displayed.
Control Name /Lot No.	Specify the control and lot number.
OK	Register the settings and close the QC Barcode Setting dialog box.
Cancel	Cancel the settings and close the QC Barcode Setting dialog box.

2. Specify the control name and lot number.
3. Press **OK**.

6.9 Delete

Unnecessary QC data in the chart displayed on the QC chart display screen can be deleted.

1. Select the point you wish to delete in the change cursor mode. (For details see “Chapter 6: 6.5 Change cursor”.)
   If it is 1 point, select **Normal** on the operation panel and set the cursor to the point you wish to delete.
   If they are consecutive multiple points, select **Cursor Range** or **Date Range** and select the range of points you wish to delete.
   To delete all the points, press **All**.
2. Press **Delete** on the operation panel of the QC main screen.
   The delete confirmation dialog will appear.
3. Press **OK**.

> **Note:**
> If the points are deleted, Mean, SD and CV will be re-calculated from the data remaining after the deletion.

6.10 Adding a new lot

When changing the control lot, add new lots according to the procedure below.

1. Move the chart selection cursor to the chart to set for the new lot.
   The new lot is added to the assay group that belongs to the selected chart.
2. Press **Add Lot** on the operation panel.
   The New Lot Addition dialog box will appear.

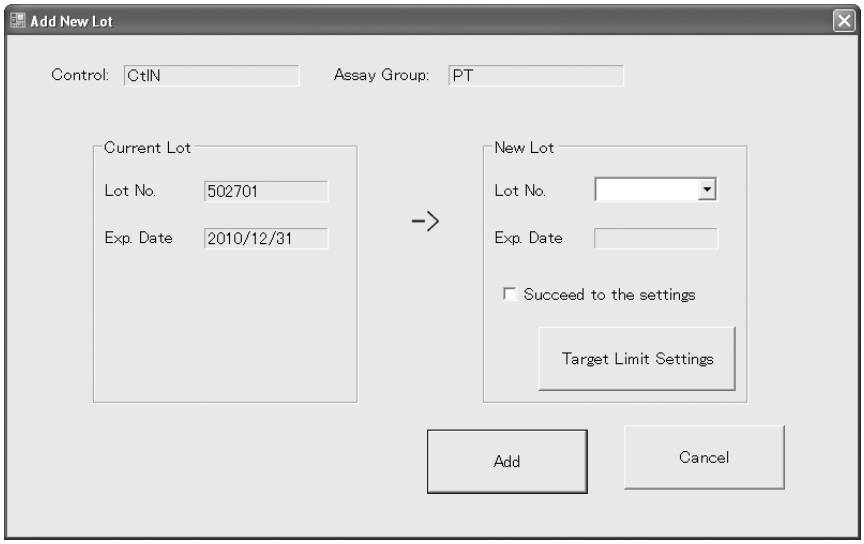

Figure 6-11: New Lot Addition dialog box

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3. Select a new lot from **Lot No.** of **New Lot** and press **Add**.
   New lots are added to the chart and the New Lot Addition dialog box will close.
   Press **Cancel** to cancel adding new lots and close the dialog box.
   If the check mark next to **Succeed to the settings** is removed, the target/limit can be set for the new lots. Press **Target Limit Settings**. For details, see “Chapter 6: 6.6 Set target/limit”.

Note:
If sample numbers (QC01–QC20) for quality control are used, add or update the sample numbers when adding new control lots.
For details see “Chapter 6: 6.8 QC barcode setting”.

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6.11 Changing lots

Run quality control with the added lot, check the results from the chart and use the lot change function to change to the new lot if there is no problem. When changing a new lot to the current lot, the target and limits for the new lot become the target and limits for the current lot. The chart displayed as “New” in the New Lot Addition dialog box will be displayed as “Current”. After the change, the “New” chart and the new lot target and limits are blank.

Caution!
- Only “Current” for the current lot is subject to error judgment. Note that “New” for the new lot is not subject to error judgment.
- Only “Current” in the current lot is analyzed for vial QC. Note that “New” for the new lot is not analyzed for vial QC.

Note:
- “Current” lot data will be deleted when the lots are changed.
- QC analysis results can be exported to CSV format files. We recommend that the necessary data is exported before changing the lot.
  For details, see “Chapter 6: 6.16 Export”.

1. Move the chart selection cursor to the chart to change the lot for.
   The lot change applies to the assay group that belongs to the selected chart.
2. Press **Change Lot** on the operation panel.
   The Lot Change dialog box will appear. Press **Change Lot** to change the new lot to the current lot.

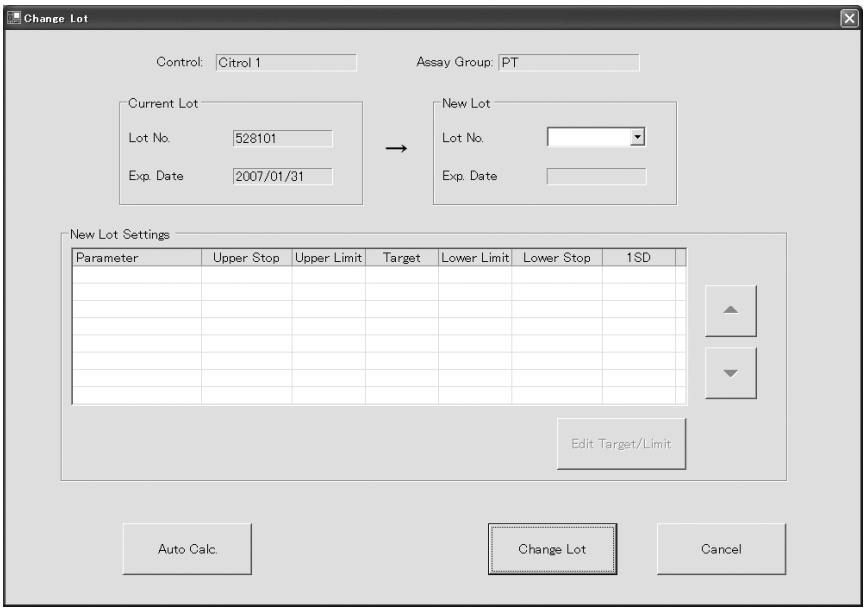

Figure 6-12: Lot Change dialog box

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6.12 Change scale

This can change the number of QC points displayed in the QC chart display area.

1. Press **Change Scale** on the operation panel.
   The Change Scale dialog box will appear.

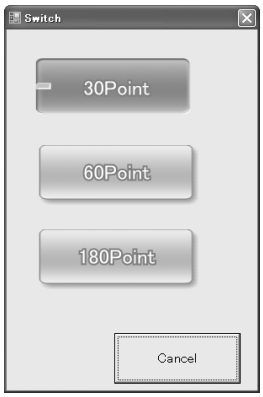

Figure 6-13: Change Scale dialog box

2. Press the button for the number of QC points displayed in the QC chart display area.
   The scale selected in the Change Scale dialog box is applied for all the charts.

6.13 Changing display data

If a new lot is added, the display data can be changed using the Change Display Data dialog box.

1. Move the chart selecting cursor to the chart with the new lot added.
2. Press **Switch Display** on the operation panel.
   The Change Display Data dialog box will appear.

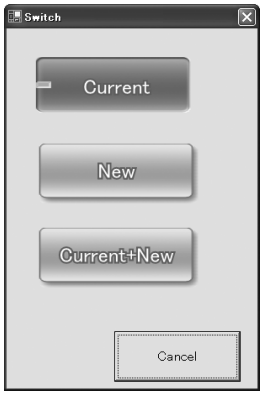

Figure 6-14: Change Display Data dialog box

Current	Only the current lot data is shown in the chart.
New	Only the new lot data is shown in the chart.
Current+New	Both current and new data are displayed in the charts.

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6.14 Print report

Specified QC analysis results can be printed out as a report.

1. Press **Print Report** on the operation panel.
   The QC Print dialog box will appear.

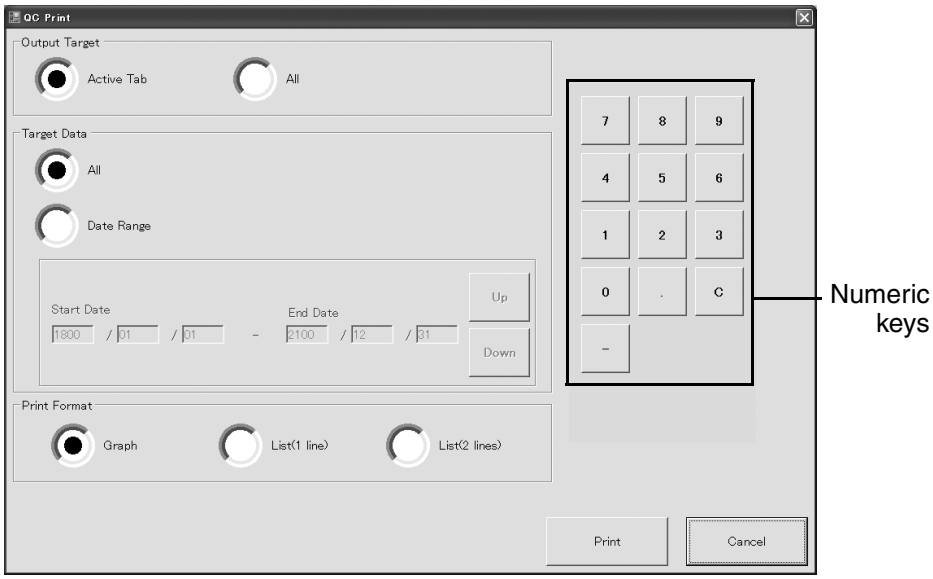

Figure 6-15: QC Print dialog box

Output Target	Select output parameters. There are two selection options, as below.
Active Tab	Prints all the assay parameters in the tab selected in the QC chart.
All	Prints all the assay parameters in all the tabs displayed in the QC chart.
Target Data	Selects the target data. There are two selection options, as below.
All	Prints all the control data of each assay parameter.
Date Range	Prints the control data within the range of the specified date range for each assay parameter. If the date range is specified, the Mean, SD, CV and the number of data within that range are printed as the data information.
Start Date	Enter the print output start date. The allowed range setting is 1800/01/01-2037/12/31 (yyyy/mm/dd). The date input format is determined by the system setting.
End Date	Enter the print output end date. The allowed range setting is 1800/01/01-2037/12/31 (yyyy/mm/dd). The date input format is determined by the system setting.
Up	Moves the selection one text box to the left.
Down	Moves the selection one text box to the right.

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Print Format	Select the print format. There are three selection options, as below.
Graph	Prints the graph of QC chart data.
List(1 line)	Prints a list of one plot data in one line.
List(2 lines)	Prints a list of one plot data in two lines.

Note:
When **List(1 line)** is selected, part of the reagent lot list or comments may not be printed for assay groups using a number of reagents.
Select **List(2 lines)** to print all the data.

Numeric keys	Use them to enter the print output start date and print output end date.

2. Set each parameter and press **Print**.
   Prints out the content currently set in the print dialog box and the print dialog box closes.
   Press **Cancel** to cancel printing and close the print dialog box.

6.15 Print

QC analysis results can be printed out.

1. Move the chart selecting cursor to the chart to be printed.
2. Select the points to print in the Change Cursor mode.
   If there is 1 point, select **Normal** and move the cursor to the plot to print.
   For a sequence of points, select **Cursor Range** or **Date Range** and select the range of points you wish to print.
   To plot all, select **All**.
3. Press **Print** on the operation panel.
   The Printing dialog box will appear.

Figure 6-16: Printing dialog box

4. Select the format to print in from **Print Format**.

Graph	Prints the graph of QC chart data.
List(1 line)	Prints a list of one plot data in one line.
List(2 lines)	Prints a list of one plot data in two lines.

Note:
When **List(1 line)** is selected, part of the reagent lot list or comments may not be printed for assay groups using a number of reagents.
Select **List(2 lines)** to print all the data.

5. Press **Print**.

Note:
When Results Output is selected under Print Format:
- Prints up to 3 reagent lots from among those used for analysis. However, reagents not subject to lot control cannot be printed.
- The content of comments entered in the Data Details dialog are printed. However, when the “Exclude from automatic calculation” is checked, “Omit” is printed and then the comments are printed.

6.16 Export

Export QC analysis results to a file in CSV format.

1. Select the charts to export.
2. Press **Export** on the operation panel.
   The Save As dialog box will be displayed.
3. Specify the location and file name to save, then press **Save**.
   The chart contents are output to the file in CSV format.

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6.17 Customize display

The QC charts screen includes a maximum of 5 custom tabs and one non-customizable Other tab. Charts for a maximum of 150 parameters can be displayed in each custom tab. The Other tab can display charts for 750 parameters. When all assay parameters have been assigned to tabs besides Other, the Other tab will not be displayed. Using the Customize Display function, it is possible to set the tabs to display on the QC charts screen as well as the items to display within the tabs.

1. Adding/editing tabs

1. Press **Customize** on the operation panel.
   The Customize dialog box will appear.

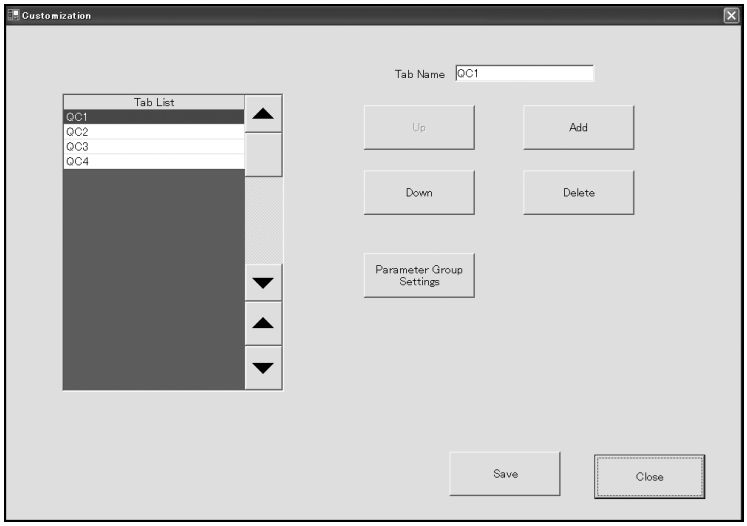

Figure 6-17: Customize dialog box

Tab List	Displays a list of registered tabs. When the dialog box is first displayed, the top line is selected. The Other tab is not displayed in the tab list.
Tab Name	The name of the tab that is selected in the tab list can be edited with up to 10 characters.
Up	Moves the selected tab one line up in the list of tabs.
Down	Moves the selected tab one line lower in the list of tabs.
Add	Adds a new tab at the bottom of the tab list. When added, the name of the tab is “New Tab.” If the maximum number of custom tabs has already been registered, a warning dialog will appear and a new tab cannot be added.
Delete	Deletes the tab selected in the tab list. Assay parameters that were displayed only in the tab that was deleted at such time will be displayed in the Other tab.
Parameter Group Settings	Displays the Display Parameters Settings dialog box, which is for setting the display parameters of the tab that is selected in the tab display.

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Save	The settings made in the Customize dialog box are saved and the dialog closes.
Close	Discards the settings made in the Customize dialog box and closes it.

2. To add a tab, press **Add**. To edit the content of an existing tab, select the tab to edit from the tab list.
3. Press **Parameter Group Settings** to make settings for the display parameters in a tab.
   The Display Parameters Settings dialog box will appear.

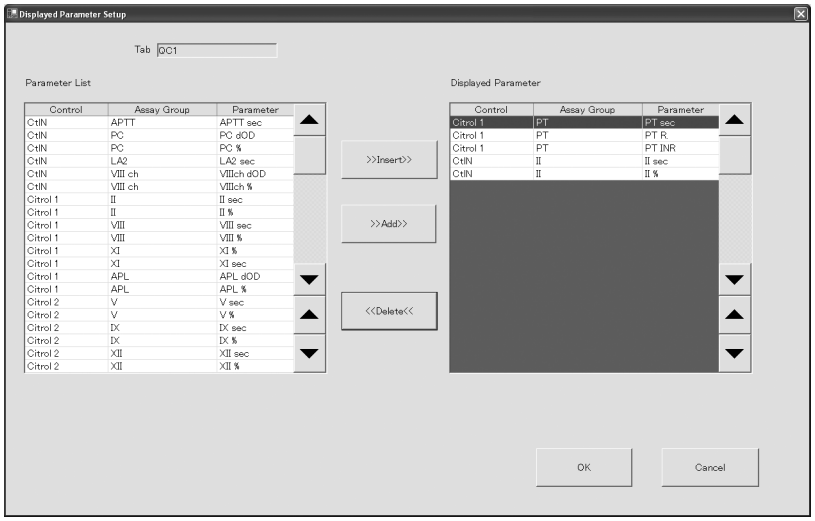

Figure 6-18: Display Parameters Settings dialog

Tab	Displays the name of the tab to set for displayed parameters.
Parameter List	Displays a list with all the parameters registered for QC. Just one line can be selected in the list display. When the dialog box is first displayed, the top line is selected. Blank lines cannot be selected. The following content is displayed in each column.
Control	Displays the name of the control.
Assay Group	Displays the assay group names.
Parameter	Displays the names of assay parameters.
Displayed Parameter	Sets the display parameters.
>> Insert >>	Insert the parameter selected in the **Parameter List** into the **Displayed Parameter** at the cursor position. However, if the number of display parameters is already at the maximum, a warning dialog is displayed and the parameter cannot be inserted.

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>> Add >>	Adds the parameter selected in the **Parameter List** at the bottom of the **Displayed Parameter** and moves the cursor to the bottom of the list of **Displayed Parameter**. However, if the number of display parameters is already at the maximum, a warning dialog is displayed and the parameter cannot be added.
<< Delete <<	Deletes the parameter selected under **Displayed Parameter**.

4. To insert the parameter to be displayed at the cursor position of the **Displayed Parameter**, select the parameter to be inserted from the **Parameter List** and press **>> Insert >>**.
   To add the parameter to be displayed at the bottom line of the **Displayed Parameter**, select the parameter to be inserted from the **Parameter List** and press **>> Add >>**.
   To delete, select the parameter you wish to delete from the **Displayed Parameter** and press **<< Delete <<**.
5. Press **OK**.
   The setting content from the Displayed Parameter Settings dialog box is reflected in the Customize dialog box and the Displayed Parameter Settings dialog box closes.
   Press **Cancel** to discard settings made in the Displayed Parameters Settings dialog box and close the dialog.
6. Press **Save** in the Customize dialog box.

2. Deleting tabs

1. Press **Customize** on the operation panel.
   The Customize dialog box will appear.
2. Select the tab to delete from the **Tab List** and press **Delete**.
3. Press **Save**.

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7. Calibration Curve

This chapter explains the calibration curve function, which is a method for calculating each assay parameter, based on analysis results such as coagulation time and difference in the optical density (dOD).

7.1 Overview

There is a calibration curve for each assay group and each set of reagent lots. There can be up to 10 sets of reagent lots. For each set of reagent lots there may be a Not Validated curve (one or none), a Validated curve (one or none) and Old curves (up to 10). Each curve has calibration curve tabs for each of the assay parameters selected under Assay group settings-Assay parameter settings.
During analysis, the validated curve from among the calibration curves matching the reagent lot used in the analysis is used to calculate the calculation parameters.

A calibration curve can be prepared by the following methods:
- Auto-Dilution
  Analyzes one type of calibrator through automatic dilution to prepare the calibration curve.
- Multiple calibrator analysis
  The calibration curve can be made by analyzing multiple calibrators.
- Manual input
  Parameters are set using the numeric keys.

The calibration curve condition settings below can be set from the assay parameter calculation method setting screen.
- Calibration curve type
- Graph axis setting
- Interpolation method
- Dilution ratio
- Replication
- Calibrator type

Major calibration curves functions:

Calibration Curve Display
The display of tabs inside the calibration curve area differs depending on the type of calibration curve.

Validation
Validates the calibration curve. Once a calibration curve has been validated, the validated calibration curve is applied to routine and STAT samples.

Detailed display
Detailed displays are used to display detailed points in a calibration curve and to compare curves.

Edit
Edit is used to edit data points for preparing a calibration curve, expiration date of a calibration curve or other information.

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Print

Prints the displayed calibration curve.

Calib. Info.

Displays the calibrator lot number and expiration date.

Delete

Deletes the displayed calibration curve.

7.2 Calibration curve order registration

1. Press **Order** on the toolbar.
   The Order screen will appear.
2. Press **Switch Order** on the operation panel.
   The Switch Order screen will appear.

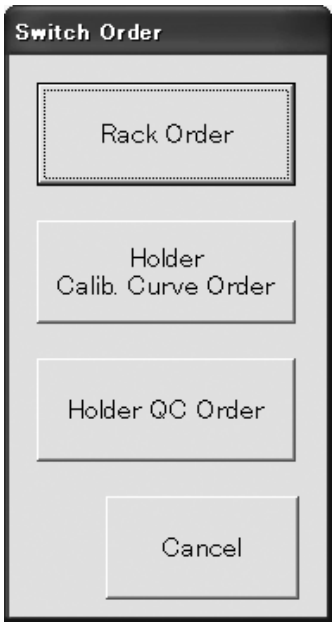

Figure 7-01: Switch Order dialog box

3. Press **Holder Calib. Curve Order.**
   The Holder Calibration Order screen will appear.

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The Holder Calibration Curve Order screen can be used to register an analysis order for a calibration curve analysis using a calibrator placed on the reagent table.

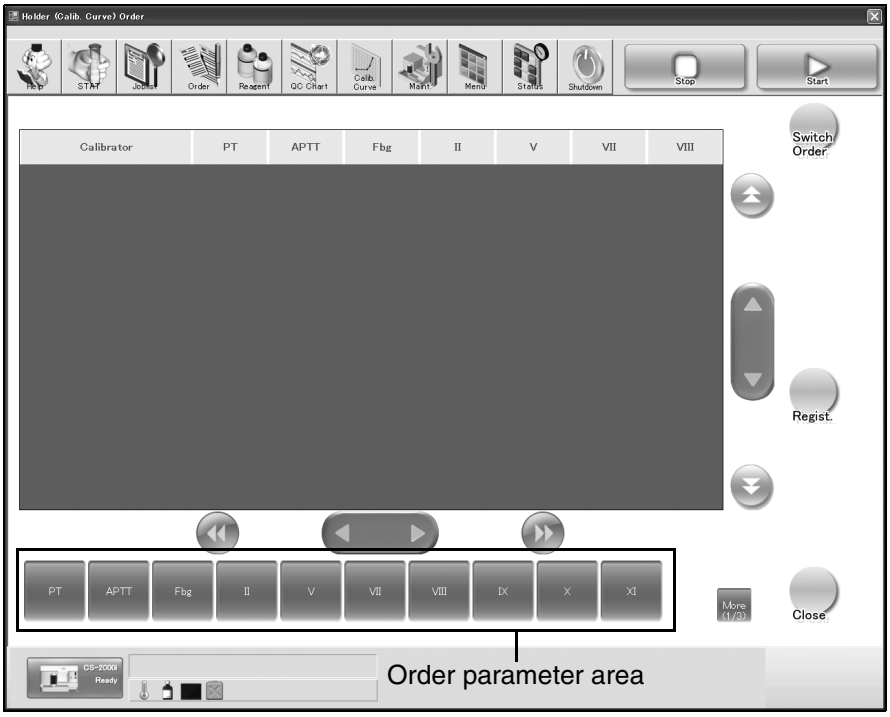

Figure 7-02: Holder Calibration Curve Order screen

4. Press the button of parameters you wish to register in the Order Parameter area of the Holder Calibration Curve Order screen.
   The Calibration Curve Order Input dialog box will appear.

Figure 7-03: Example when entering a lot in the Calibration Curve Order Input dialog

Figure 7-04: Example when entering a display value in the Calibration Curver Order Input dialog

5. Press **Reagent Lot**.
   The reagent lot combination selection dialog box is displayed.
6. Select the reagent lot combination, and press **OK**.
   The reagent lot combination selection dialog box is closed.
7. Make check marks next to assay parameters for which to analyze a calibration curve analysis.
8. Click the lot number on the calibrator lot No. list.
9. Enter the display value of the calibrator.
10. Press **OK**.
    The settings are saved and the Calibration Curve Order Input dialog closes.

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7.3 Displaying calibration curves

It is possible to check, edit and validate analyzed calibration curves on this screen.

1. Press **Calib. Curve** on the toolbar.
   The Calibration Curve Display screen will appear.

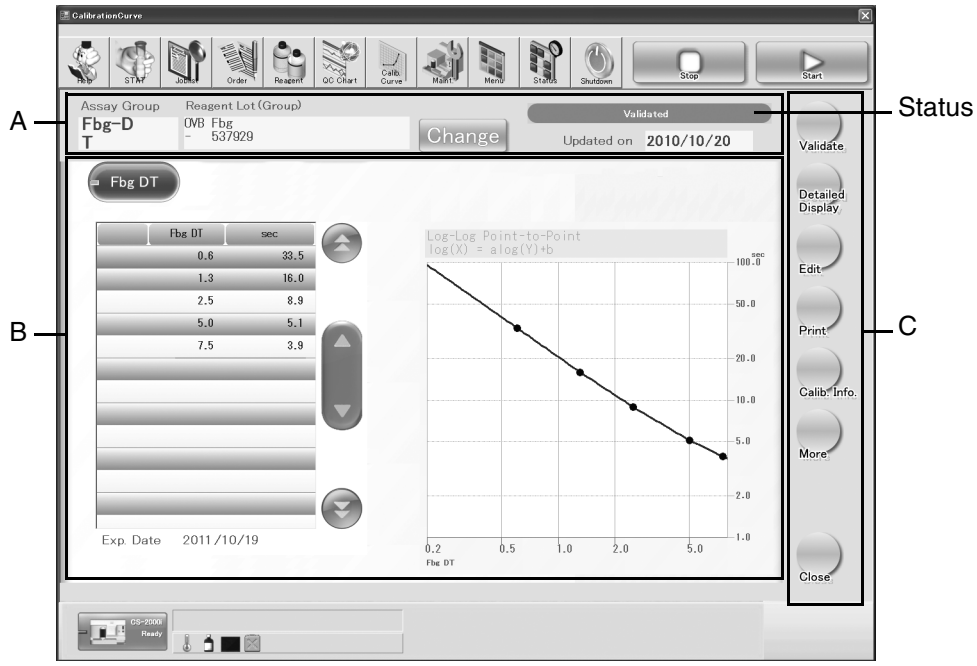

Figure 7-05: Calibration Curve screen

A Calibration curve display parameter area

Assay Group Displays the name of the assay group of the calibration curve displayed.

Reagent Lot (Group) Displays the reagent lot of the calibration curve displayed.

Status Displays the current status of the displayed calibration curve.

“Validated”:	When the calibration curve has been validated.
“Not Validated”:	When the calibration curve has not been validated.
“Not Validated Error”:	When an unvalidated curve has an error.
“No Calibration Curve”:	When the calibration curve has not been made.

Calibration curve errors happen in the following cases:

- If the analysis data does not show monotonic increase or monotonic decrease for activity% or concentration.
- If only one point of calibration curve data is set.

- To change between parameters and reagent lots (groups)

1. Press **Change**. Select parameters from the Assay Group Selection dialog box which appears.

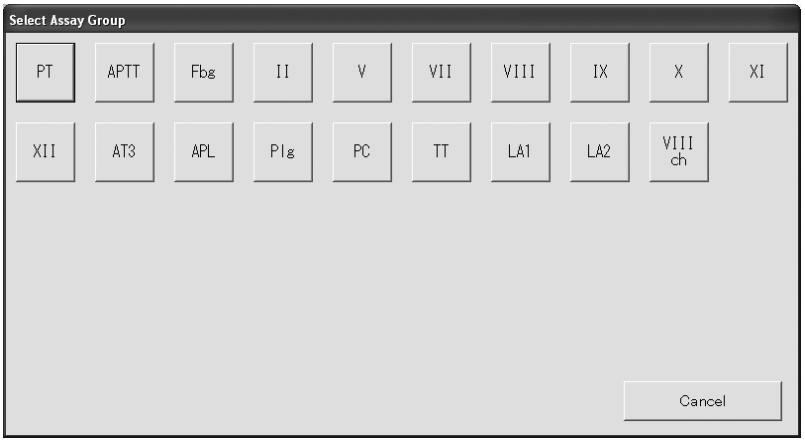

Figure 7-06: Assay Group Selection dialog box

2. The Select Reagent Lot (Group) dialog box appears. Press the button for the reagent lot (group) to display the calibration curve for.

Figure 7-07: Select Reagent Lot (Group) dialog box

3. The Calibration Curve Display screen will appear.

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B Calibration curve display area

The calibration curve display area shows the calibration curve for the parameter set in the calibration curve parameter setting area. If the parameters include multiple assay parameters which have calibration curves, multiple tabs are displayed that can be used to switch the display between assay parameters.
The mean value is displayed if repeated analyses were performed.
The flags and point figures for the calibration curve data are as follows:

Table 7-01: Relations between calibration curve data, flags and point figures

Calibration curve data	Flags	Point figures	Explanation
Manual input points	“M”	■	Points input manually
Analysis points	“ ”(space)	●	Measured points

There are three types of calibration curve. The content displayed in the calibration curve display area varies as below, depending on the type of calibration curve.

- If a “Normal” type calibration curve is displayed

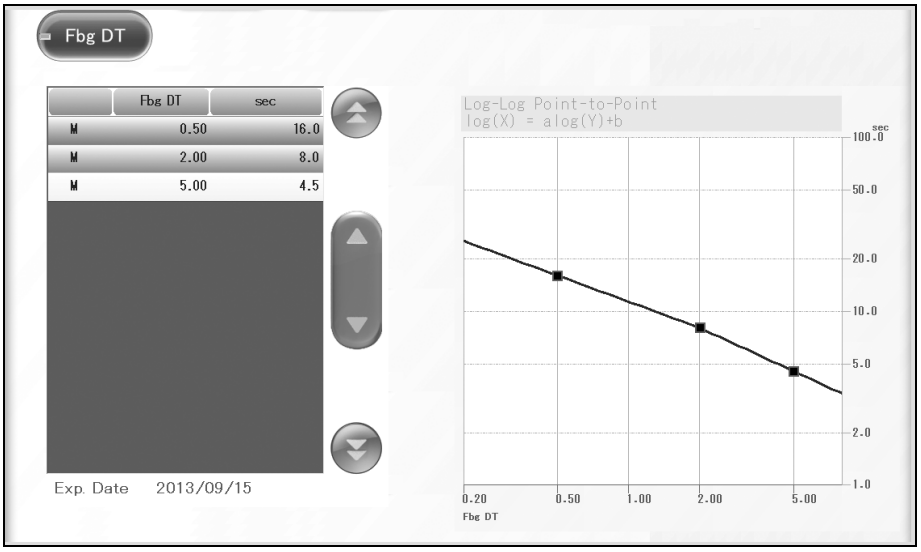

Figure 7-08: Normal calibration curve display

- If a “Ratio” type calibration curve is displayed

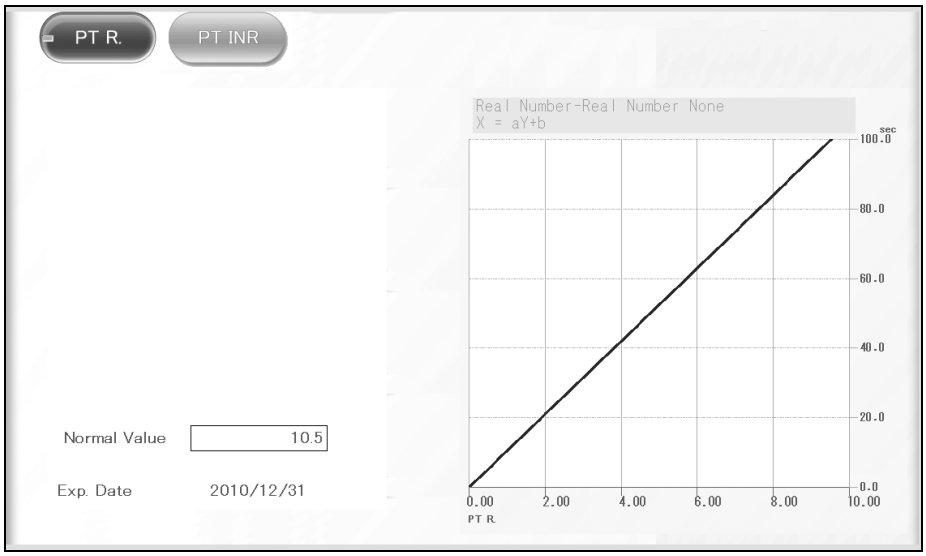

Figure 7-09: Ratio calibration curve display

Use this curve to calculate ratios. Ratios are calculated by the formula below.

$$\text{Ratio} = \frac{\text{Analysis value}}{\text{Normal value}}$$

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- If the “INR (ISI Input)” type calibration curve is displayed

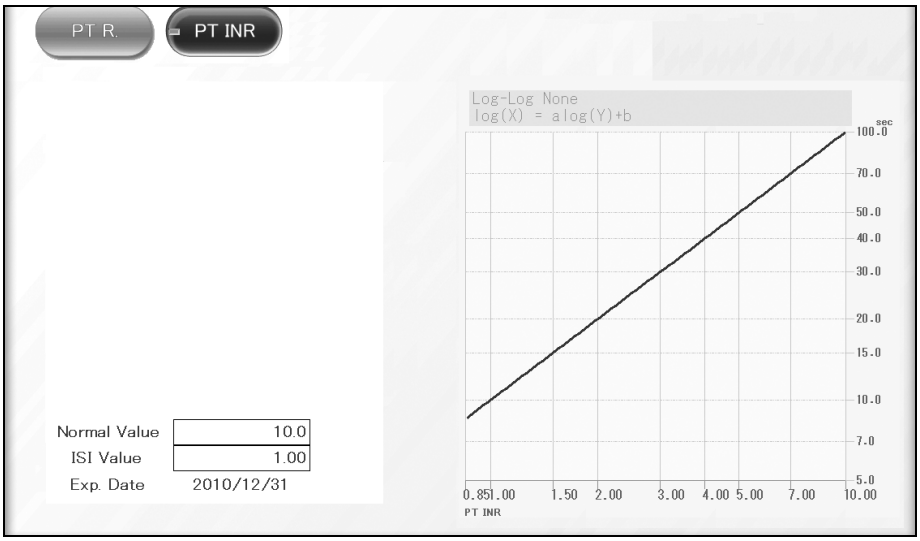

Figure 7-10: INR calibration curve display

Use this to input the ISI value and the normal value and calculate INR. INR is calculated by the formula below.

$$INR = \left(\frac{\text{Analysis value}}{\text{Normal value}}\right)^{ISI}$$

To enter the ISI and normal values, press the **Edit** key on the operation panel to display the edit dialog box, then input the values.

Caution!
ISI values for prothrombin time assays must be entered directly as they appear on the current reagent labeling.
Any changes of reagent lot, software upgrades, major servicing, etc., require verification of the ISI value.
Failure to enter the correct ISI value will cause incorrect International Normalized Ratio (INR) results.

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C Operation panel area

Operation buttons are displayed in the operation panel area for the calibration curve screen. The operation buttons work for all the calibration curve tabs shown in the calibration curve display area.

1st page

Validate	Validates and sets a flag for not validated calibration curves. By doing so, it is possible to use such calibration curves for routine and STAT samples. There can only be one active calibration curve for a given reagent lot (Group). When a not validated calibration curve is made active, the calibration curve that had been active to that point becomes inactive.
Detailed Display	Switches the calibration curve screen to the detailed mode, which enables comparison of calibration curves. This button works with one tab in the current display in the calibration curve display area.
Edit	Switches the calibration curve screen to the edit mode, which enables editing of calibration curves, etc. If the **Edit** function is implemented while the active calibration curve is being displayed, a copy of the active calibration curve is made and an not validated calibration curve is created. At this time, if the calibration curve is not validated, it is overwritten.
Print	Prints the displayed calibration curve.
Calib. Info.	Displays the calibrator lot number and expiration date.

2nd Page

Delete	Deletes the displayed calibration curve.

Common to the 1st and 2nd page

More	If the Operation Panel consists of multiple pages, use this button to switch between pages.
Close	Closes the Calibration Curve screen.

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7.4 Validate

Validation makes the validation status of the calibration curve “Validated”. Once the calibration curve has been validated, it can be applied to routine and STAT samples. There can only be one validated calibration curve for a given reagent lot (Group). When an unvalidated calibration curve is validated, the previous validated calibration curve becomes an “Old” curve. “Old” calibration curves can be referred to as comparison subjects in detailed display.

Validation procedure

1. Press **Calib. Curve** on the toolbar to display the calibration curve to be validated (parameter, reagent lot (Group)).
2. Press **Validate** on the operation panel.
   The Validation of Calibration Curve dialog box is displayed.

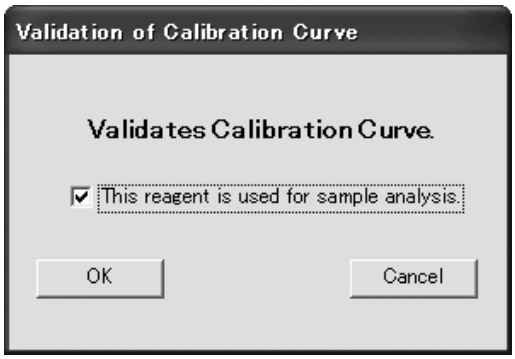

Figure 7-11: Validation of Calibration Curve dialog box

This reagent is used for sample analysis.	Add a check mark to use for sample analysis. Remove the check to avoid using the reagent lot for sample analysis.
OK	Validate the calibration curve. The calibration curves for all displayed assay parameters become Validated. In the following circumstances, validation cannot be performed, and a warning dialog box appears. • When there are calibration curve analysis orders that have not yet been analyzed, or are being analyzed. • When an error has occurred affecting the calibration curve that is to be validated. • When there are multiple assay parameters and calibration curves are not ready for all of them.
Cancel	Close the Validation of Calibration Curve dialog box without validating calibration curves.

Caution!
For parameters for which calibration curves are not used, add a check for **Used In Sample Analysis** in the Lot Group Settings dialog box. (For details, see “Chapter 5: 5.4 Set the reagent lot usage”).

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7.5 Detailed display

For the curves that are displayed, it is possible to display points on a curve in detail or make a comparison of curves for one tab (assay parameter). The compared calibration curves are not displayed until they are selected.

1. Press **Calib. Curve** on the toolbar to display the calibration curve (parameter, reagent lot (Group)) to be displayed in detail.
2. Select the tab (assay parameter) for the detailed display, then display the calibration curves.
3. Press **Detailed Display** on the operation panel.
   The calibration curve screen goes into the detailed mode for the selected tab.

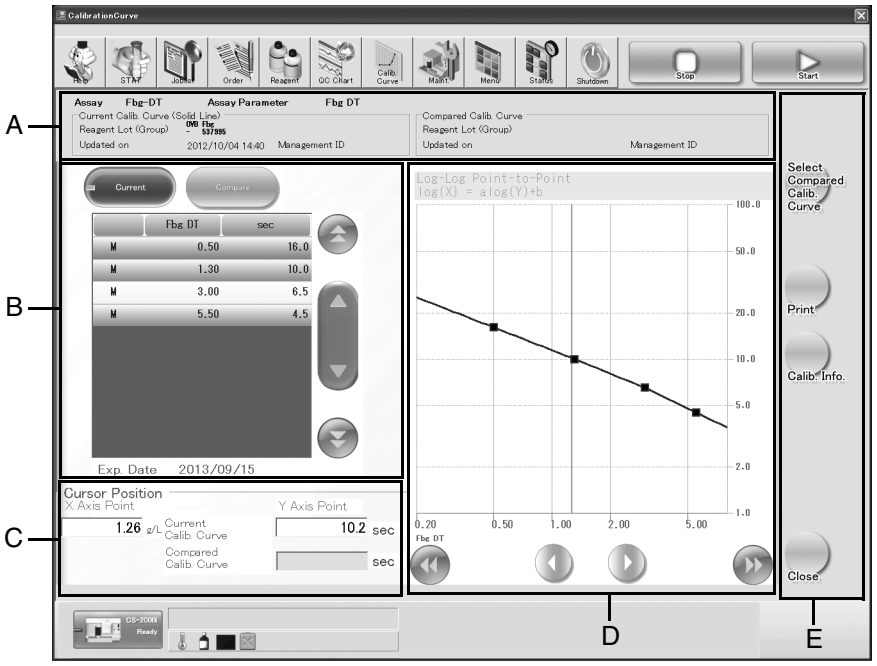

Figure 7-12: Calibration Curve display screen (Detail mode)

A Parameter information display area

Assay	Displays the names of parameters to be displayed in detail for a calibration curve.
Assay Parameter	Displays the names of assay parameters to be displayed in detail for a calibration curve.
Current Calib. Curve (Solid Line)	Displays the reagent lot (Group) of the current calibration curve.
Compared Calib. Curve (Broken Line)	Displays the reagent lot (Group) of the calibration curves being compared.

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B Point info display area

Current tab Displays info on the points of the current calibration curve.

Compared tab Displays info on the points of the calibration curve being compared. If no curves to compare are selected, the chart showing point info is left blank.

C Cursor position data display area

X Axis Point Displays the cursor's X-axis point. It is possible to enter a value in the range of 0-99999 directly. When doing so, once the Enter key is pressed to confirm the entry, the cursor moves to the X-axis point entered and the Y-axis point is calculated and displayed.

Y Axis Point:

Current Calib. Curve Displays the Y-axis point on the current calibration curve relative to the cursor's X-axis point. It is possible to enter a value in the range of 0-99999 directly. In this case, once the Enter key is pressed to confirm the entry, the cursor will move to the position of the X-axis that corresponds to the Y-axis input, then the X-axis and the Y-axis point of the calibration curve to be compared will be calculated and displayed.

Compared Calib. Curve Displays the Y-axis point on the compare calibration curve relative to the cursor's X-axis point. It is possible to enter a value in the range of 0-99999 directly. In this case, once the Enter key is pressed to confirm the entry, the cursor will move to the position of the X-axis that corresponds to the Y-axis input, then the X-axis and the Y-axis point of the current calibration curve will be calculated and displayed.

D Graph display area

Graph The calibration curve graph is displayed. If calibration curves to compare are selected, the current calibration curve and calibration curves to be compared are displayed. When in the detailed display mode, calibration curves to be compared are not selected. "X-axis-Y-axis, Approximate Class, Correlation Coefficient, Approximate Formula" are displayed on the graph. They are only displayed when the interpolation type for the correlation coefficient is linear. The graph has one vertical axis cursor. The cursor can be moved to the left/right with the buttons at the bottom of the graph. Also, the cursor position is displayed in the cursor position data display area. When in the detailed screen display mode, the cursor is displayed on the right edge.

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◀◀	Moves the cursor one point to the left.
▶▶	Moves the cursor one point to the right.
◀	Moves the cursor to the left.
▶	Moves the cursor to the right.

E Operation panel area

Select Compared Calib. Curve	Displays the Select Calibration Curve to Compare dialog box so the calibration curve to compare with the current calibration curve can be selected.
Print	Prints the current calibration curve and the curve being compared.
Calib. Info.	Displays the calibrator lot number and expiration date. For details, see “Chapter 7: 7.8 Calib. Info.”
Close	Closes the Calibration Curve Detailed mode screen and returns to the calibration curve main screen.

To compare calibration curves:

1. Press **Select Compared Calib. Curve** on the operation panel.
   The Select Calibration Curves to Compare dialog box opens.

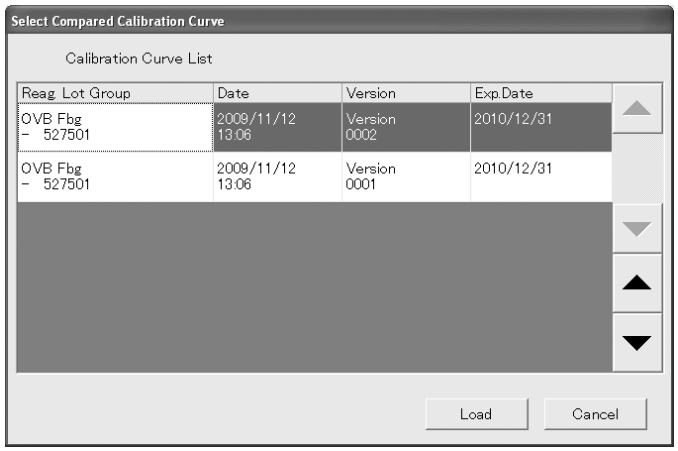

Figure 7-13: Select Calibration Curves to Compare dialog

2. Select the calibration curves you wish to compare from the **Calibration Curve List** and press **Load**.

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7.6 Edit

The edit function can be used to edit data points for preparing calibration curves, the expiration dates of calibration curves and other information. If the calibration curve is “Not Validated”, the edit dialog box for that curve appears when **Edit** is pressed. If the curve is “Validated” a copy is made of it when **Edit** is pressed and the edit dialog box appears for the copied calibration curve. If there is already a “Not Validated” calibration curve, it is overwritten by the copy.

1. Editing calibration curves

1. Press **Calib. Curve** on the toolbar to display the calibration curve (parameter, reagent lot (Group)) for editing.
2. Press **Edit** on the operation panel.
   The Calibration Curve Editing dialog box will appear.

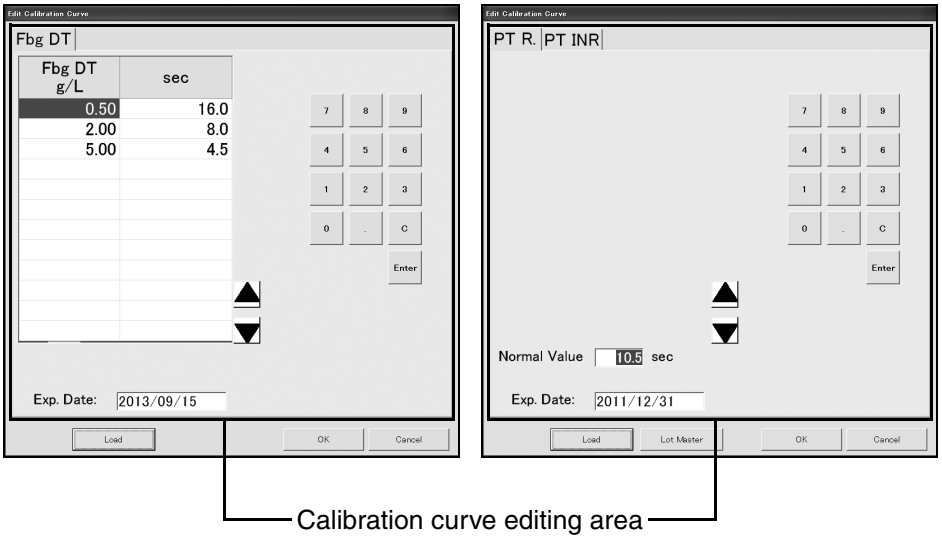

Figure 7-14: Calibration Curve Editing dialog box

Calibration curve editing area
The area is for editing calibration curve data. A tab is displayed for each assay parameter, just like in the Calibration Curve main screen.

Load	Displays the Calibration Curve Load Selection dialog.
Lot Master	Loads the normal and ISI values from the detailed reagent information of the reagent lot master. This button appears only when the calibration curve type is “Ratio” or “ISI Input”.

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OK	After evaluating for calibration curve errors, it saves the edits to the calibration curve and closes the Calibration Curve dialog. At this time, the date/time of the calibration curve is updated. If Create Origin Automatically is ON, in accordance with the calculation rules set for the assay group, it checks whether the origin (0,0) is included in the Edit point; if it is not included, (0,0) is automatically added. If a Max point value has been set up, the minimum point is changed to (0,0).
Cancel	Discards the edits to the calibration curve and closes the Edit Calibration Curve dialog box.

3. Edit the calibration curve.
   The calibration curve editing area tab will differ depending on the type of calibration curve.

   Normal calibration curves
   The display for a calibration curve editing area for a normal calibration curve is as follows.

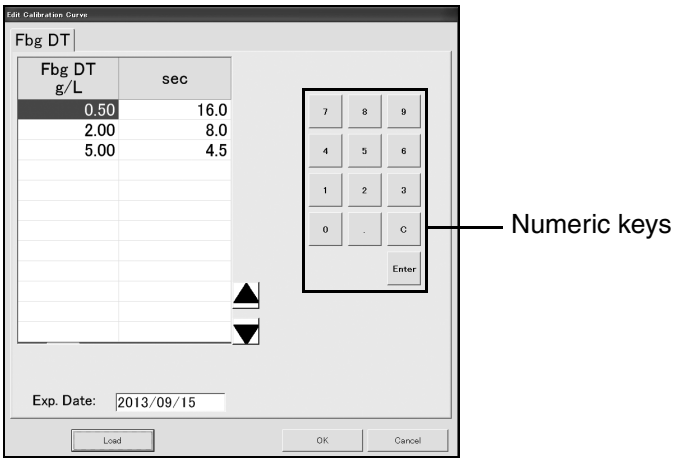

Figure 7-15: Editing area for a normal calibration curve

X-axis Point	The X-axis data points that constitute the calibration curve can be edited within the range of 0-99999. When in the Editing mode display, the current data points are displayed. If there are not any current data points, it will be blank.
Y-axis Point	The Y-axis data points that constitute the calibration curve can be edited. When in the Editing mode display, the current data points are displayed. If there are not any current data points, it will be blank.

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Exp. Date	The expiration date of this calibration curve can be edited within the range of 1800/ 1/ 1 to 2037/12/31 (yyyy/mm/dd). When in the Editing mode display, the current expiration date is displayed. If there is no current expiration date, it will be blank. The format of the expiration date display is determined by the system setting.
▲	Moves the selection one editing field forward.
▼	Moves the selection one editing field back.
Numeric keys	Use them to enter X-axis Point, Y-axis Point and expiration date.

Ratio calibration curves

The display for a calibration curve editing area for ratio calibration curves is as follows.

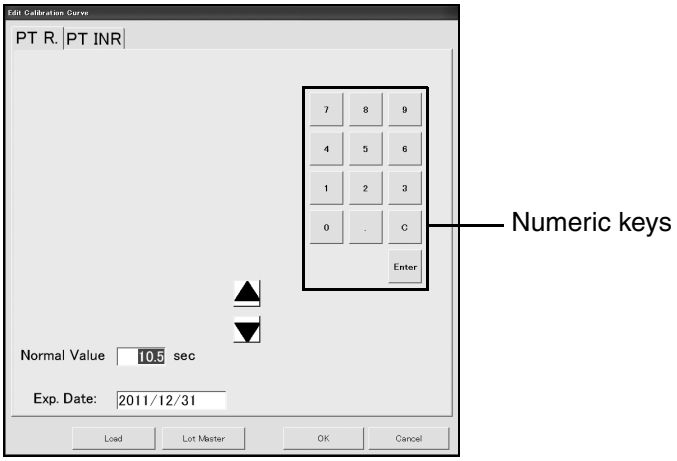

Figure 7-16: Ratio calibration curve editing area

Normal Value	The normal value used for calculating a ratio can be edited within the range of 0-99999. When in the Editing mode display, the current normal value is displayed. If there is not a current normal value, it will be blank.
Exp. Date	The expiration date of this calibration curve can be edited within the range of 1800/ 1/ 1 to 2037/12/31 (yyyy/mm/dd). When in the Editing mode display, the current expiration date is displayed. If there is no current expiration date, it will be blank. The format of the expiration date display is determined by the system setting.
▲	Moves the selection one editing field forward.
▼	Moves the selection one editing field back.
Numeric keys	Use them to enter the normal value and expiration date.

INR calibration curve ("INR (ISI Input)" type)
The display of the calibration curve editing area for INR calibration curve is as follows.

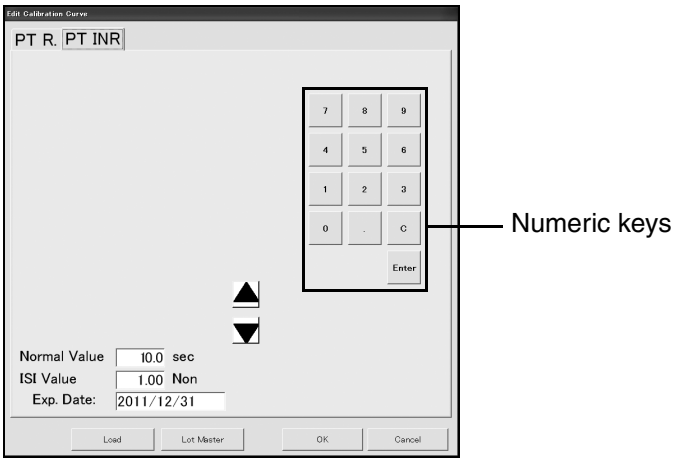

Figure 7-17: Editing area for INR calibration curve

Normal Value	The normal value used for calculating INR can be edited within the range of 0-99999. When in the Editing mode display, the current normal value is displayed. If there is not a current normal value, it will be blank.
ISI Value	The ISI value used for calculating INR can be edited within the range of 0.00-99.99. When in the Editing mode display, the current ISI value is displayed. If there is not a current ISI value, it will be blank.
Exp. Date	The expiration date of this calibration curve can be edited within the range of 1800/ 1/ 1 to 2037/12/31 (yyyy/mm/dd). When in the Editing mode display, the current expiration date is displayed. If there is no current expiration date, it will be blank. The format of the expiration date display is determined by the system setting.
▲	Moves the selection one editing field forward.
▼	Moves the selection one editing field back.
Numeric keys	Use them to enter the ISI and normal values and expiration date.

4. Press **OK**.

Caution!
ISI values for prothrombin time assays must be entered directly as they appear on the current reagent labeling.
Any changes of reagent lot, software upgrades, major servicing, etc., require verification of the ISI value.
Failure to enter the correct ISI value will cause incorrect International Normalized Ratio (INR) results.

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2. Loading calibration curves

It is possible with the Calibration Curve Editing dialog to load a different calibration curve for the same parameter.

1. Press **Load** in the Edit Calibration Curve dialog.
   This displays the Calibration Curve Load Selection dialog.

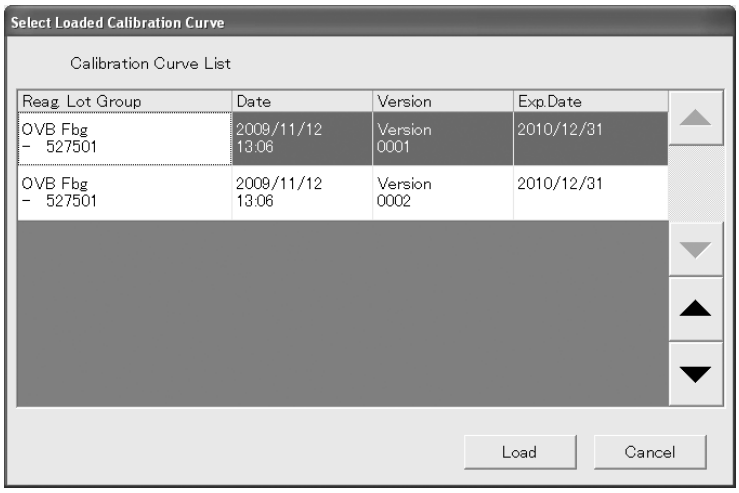


Figure 7-18: Calibration Curve Load Selection dialog

2. Select the file to be load and press **Load**.

3. Loading from reagent lot masters

The normal and ISI values can be loaded from the detailed calibrator information of reagent lot masters. The values can be loaded only when the calibration curve type is “Ratio” or “ISI Input”.

1. Press **Lot Master** in the Calibration Curve Editing dialog box.
   The information loaded from reagent lot masters is displayed on the Calibration Curve Editing dialog box.

7.7 Print

The printing function prints the displayed calibration curve.

Print procedure

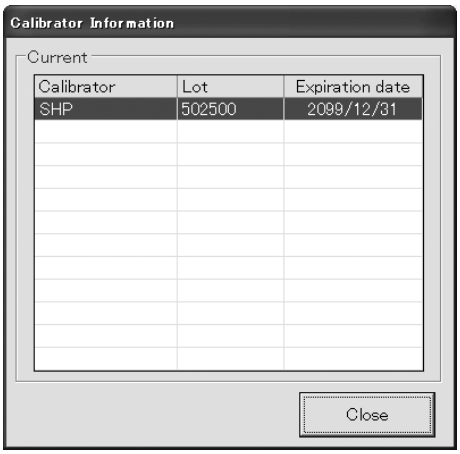
1. Press **Calib. Curve** on the toolbar to display the calibration curve to be printed (parameter, reagent lot (Group)).
2. Press **Print** on the operation panel.
   The displayed calibration curve is printed.
   One page is printed for each assay parameter.

7.8 Calib. Info.

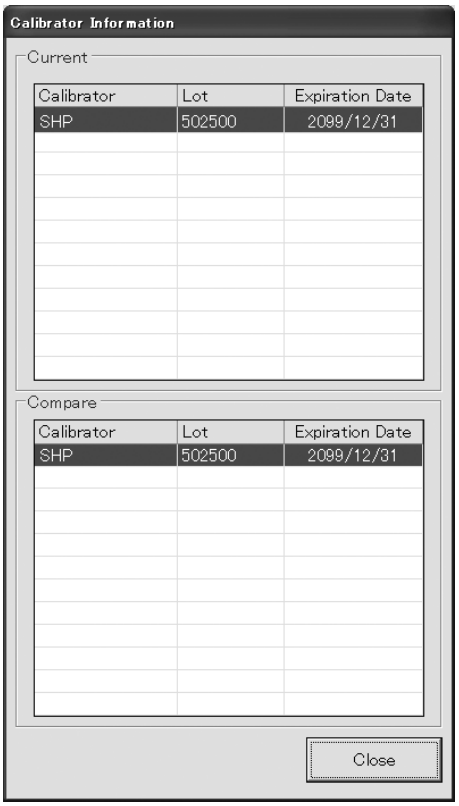
The Calib. Info display function displays the calibrator lot number and expiration date.

Display procedure

1. Press **Calib. Curve** on the tool bar to display the calibration curve (Assay Group, Reagent Lot (Group)) for which to display Calib. Info.
2. Press **Calib. Info.** on the operation panel.
   The Calibrator Information dialog box is displayed.



(Calibration Curve screen)



(Calibration Curve screen
(Detail mode))

Figure 7-19: Calibrator Information dialog box

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Calibrator	The calibrator name is displayed.
Lot	The calibrator lot number is displayed.
Expiration Date	The calibrator lot expiration date is displayed.
Close	Closes the Calibrator Information dialog box.

7.9 Delete

The delete function deletes the displayed calibration curve.

Delete procedure

1. Press **Calib. Curve** on the toolbar to display the calibration curve to be deleted (parameter, reagent lot (Group)).
2. Press **Delete** on the operation panel.

7.10 Calibration curve calculation specifications

If there is a low-reliability flag on the data input (clotting time, dOD) for calculations, a low-reliability flag (*) will also be put on the results calculated from the calibration curve. If the input data is masked with an “*” like “****”, the calculated results will also be masked with a “-” like “----”. If there is no calibration curve validated for a set of related data, it will be masked with with “XXX” and “X”.
After the conversion is made on the input data axis, a linear or a polynomial expression is used to calculate the result. In the cases of line graphs, calculation will be performed with the formula for the input range of data. If an extrapolated range is specified and the result goes outside the range, a larger value will be > extrapolated range threshold, a smaller value will be < extrapolated range threshold.

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8. System Setup

This chapter describes system setup, such as parameters that affect the instrument's systems as a whole and registration of user information.

8.1 Overview

Major system setup functions:

System settings
Parameter settings that affect the instrument's system as a whole are set.

User management
User information is registered.

Reagent master registration
Reagent masters are registered.

Reagent lot master registration
Reagent lot masters are registered.

Assay group settings
The following parameters are set for assay groups:
- Basic settings
- QC settings
- Reflex test settings
- Repeat analysis settings
- Test protocol settings

Formula calculation settings
Parameters can be set for Formula calculations.

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8.2 Displaying the settings screen

System setups are made from the settings screen.
Use any of the methods below to display the settings screen.

- Press **Settings** on the IPU menu screen.

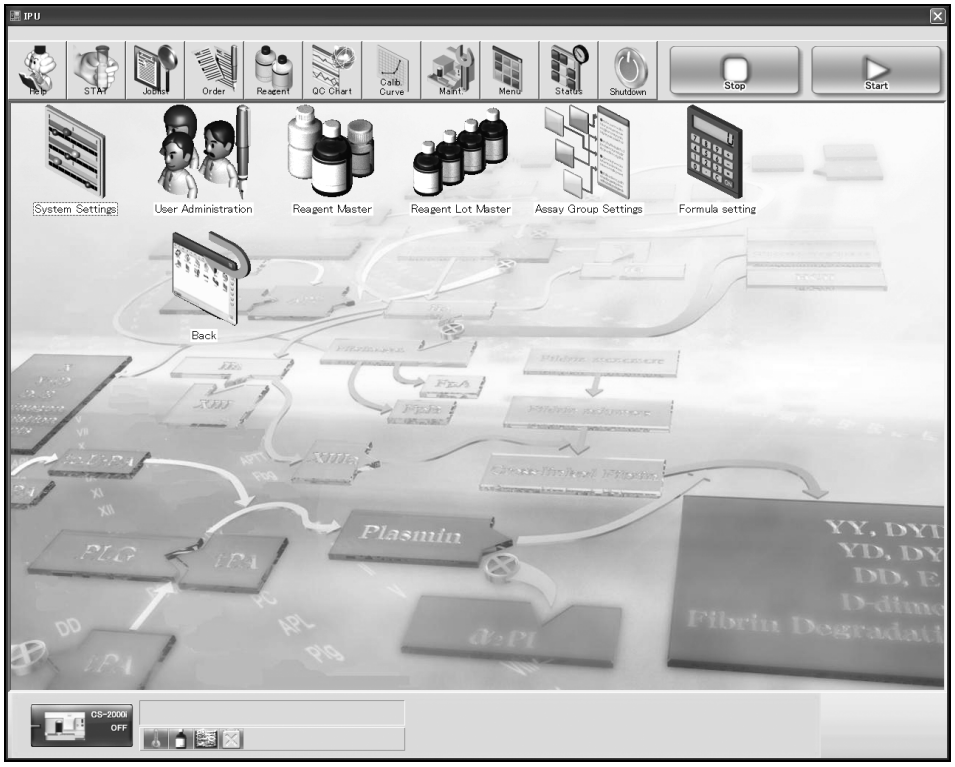

Figure 8-01: Settings screen

System Settings	The system settings dialog box is displayed for performing system settings.
User Administration	The user registration dialog box is displayed for registering user information for use.
Reagent Master	The reagent master dialog box is displayed for registering reagent masters.
Reagent Lot Master	The reagent lot master dialog box is displayed for registering reagent lot masters.
Assay Group Settings	The assay group setting dialog box is displayed for setting assay groups.
Formula setting	The Formula Setup dialog box is displayed to make Formula calculation settings.
Back	Return to the IPU menu screen.

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8.3 System settings

System settings are performed using the system settings dialog box.
It can be used to make settings for the system as a whole. The IPU must be restarted after system settings are changed.

1. Press **System Settings** on the settings screen.
   The system settings dialog box will appear.

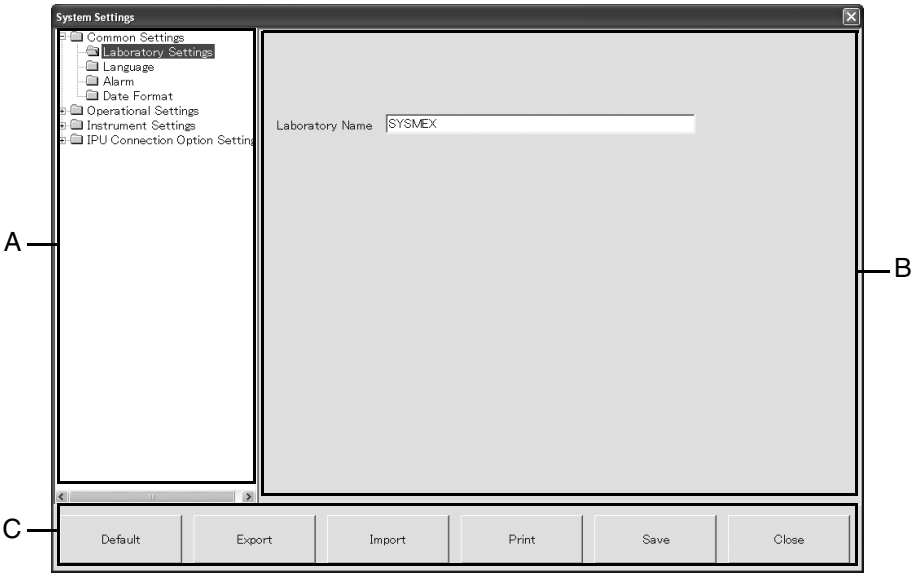

Figure 8-02: System settings dialog box

A Setting parameter tree
The settings categories for the system settings are displayed.

B Setting area
This area is used for making settings for the parameter selected in the parameter tree. The display changes according to the category selected in the setting parameter tree.

C Setting operation button area

Default	The Reset System Settings to the Default dialog box will appear. The general set up settings will be restored to the default.
Export	The Save As dialog box will be displayed. This function outputs the system settings to an external storage device.
Import	The open dialog box will appear. System setting files previously output to external storage device using the export function can be loaded and written over the settings.
Print	System settings content can be printed out.
Save	Register the setting made using the system settings dialog box. The registration confirmation dialog box appears if setting values have been changed. A warning dialog box appears if no setting values have been changed.

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Close	Close the system settings dialog box. A warning dialog box is displayed at that time if any settings in the dialog box have not been registered.

1. Categories in the setting parameter tree

Common Settings

Common settings are the settings for common categories to all functions. The common setting categories are as follows:

Laboratory Settings	Set the institution information.
Language	Set the display language to be used for messages and the like which are displayed on the IPU screen.
Alarm	Set the alarm sounds to use when errors occur.
Date Format	This section explains how to set the date format.

Operational Settings

Operational settings are operation related parameter settings. The operational setting categories are as follows:

HIL Check	Set the judgment levels for HIL checks (hemolytic check, icteric check and lipemic check), and the method for displaying measurement results for samples exceeding those levels.
Sample Volume Check	Set whether or not to perform the sample volume check and the sample volume range.
Automatic Validation	Set whether or not to automatically validate samples that have completed analysis. Only validated samples can be output to the host computer.
Automatic Output	Set whether or not to output automatically to the printer or host computer with samples that have completed analysis.
Order Inquiry	Set the method to use for order inquiry on the host computer.
Sample Aspiration	Display the detergent used for primary sample aspiration.

Instrument Settings

Instrument settings are instrument related parameter settings. The instrument setting parameters are as follows:

Instrument Information	Set the device nickname.
Normal Mode	Set the sample aspiration mode.
Sample Tube Type	Set each type of sample tube.
Monitoring	Set whether or not to monitor the drain float switches, the rinse float switch and the number of cuvettes in the trash box and how to interrupt operation when a reagent runs out.
Barcode	Set whether or not to use sample and rack barcodes and the barcode type and check digit to use.

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IPU Connection Option Settings

IPU Connection Option Settings are IPU connection option related parameter settings. The setting parameters are as follows:

Host Computer (HC)	Set connection with the host computer and the connection method.
Printer (GP)	Set the printer connection.

2. Institution settings

Set the name of the institution.

1. Select **Common Settings** → **Laboratory Settings** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

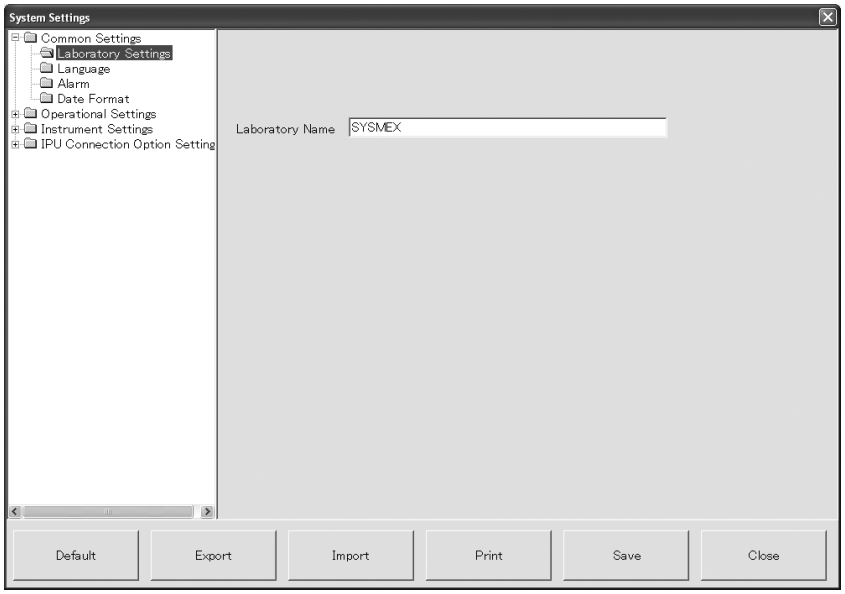

Figure 8-03: System settings dialog box (institution settings)

2. Set the institution name under **Laboratory Name**. Input up to 32 characters.
   The content set here is printed out when printing is performed by various functions (QC, browser etc.).
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

3. Display language

The display language for the IPU can be set.

1. Select **Common Settings** → **Language** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

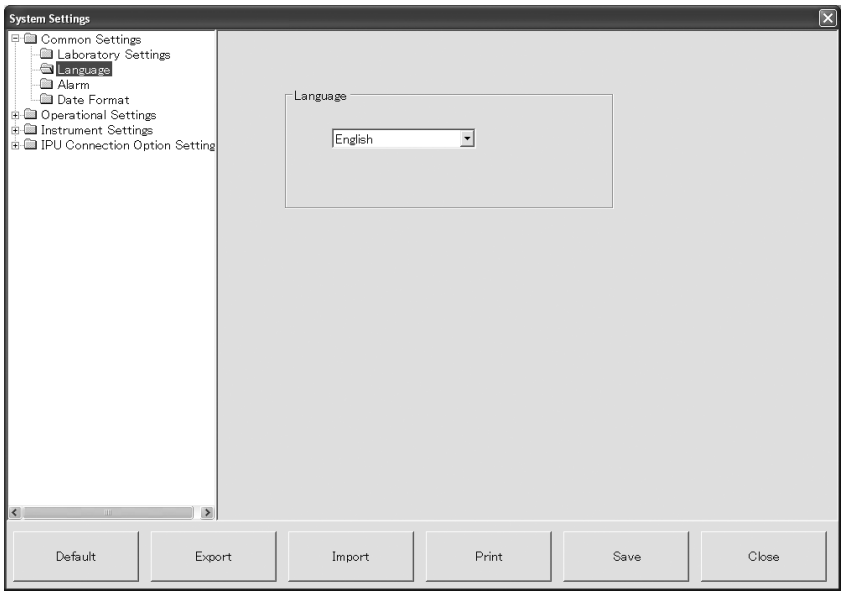

Figure 8-04: System settings dialog box (display language)

2. Select the IPU display language from **Language**.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Note:
These settings become effective after the system has been restarted.

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4. Alarm

Alarm sounds to use when errors occur can be set.

1. Select **Common Settings** → **Alarm** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

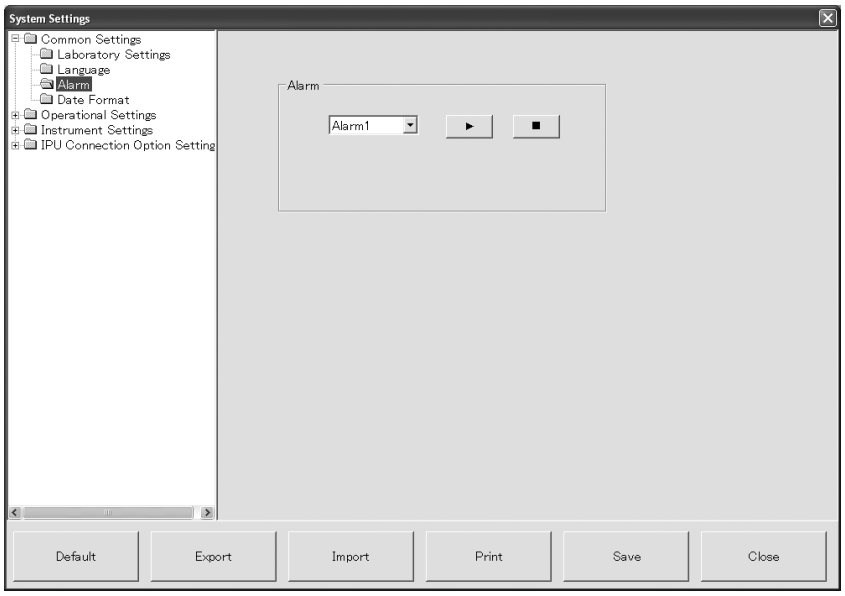

Figure 8-05: System settings dialog box (alarm)

2. Select the alarm.
   Select from **Alarm1** to **Alarm10**.

Alarm1 – Alarm5	Does not sound continuously (alarm stops automatically).
Alarm6 – Alarm10	Sounds continuously (alarm keeps on sounding until action is taken to stop it).

3. Press ▶.
   The alarm sounds.
4. Press ■.
   The alarm stops.
5. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Note:
These settings become effective after the system has been restarted.

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5. Date setting

The format can be set for how the date is displayed and printed.

1. Select **Common Settings** → **Date Format** from the setting parameter tree of the system settings dialog box.
   The selected parameter is displayed in the setting area.

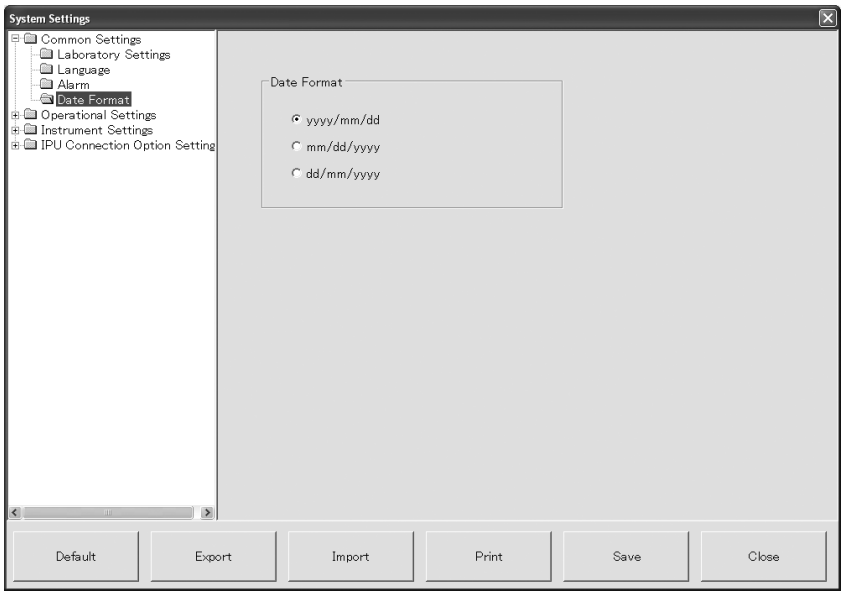

Figure 8-06: System settings dialog box (date setting)

2. Select the date display format from **Date Format**.
   Choose between **yyyy/mm/dd, mm/dd/yyyy** and **dd/mm/yyyy**.

Note:
The parts of the display format are as follows:
yyyy: Four-digit year, mm: Two-digit month, dd: Two-digit date

3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Note:
These settings become effective after the system has been restarted.

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6. HIL check settings

The judgment levels for HIL checks (hemolytic check, icteric check and lipemic check), and the method for displaying measurement results for samples exceeding those levels can be set.

1. Select **Operational Settings** → **HIL Check** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

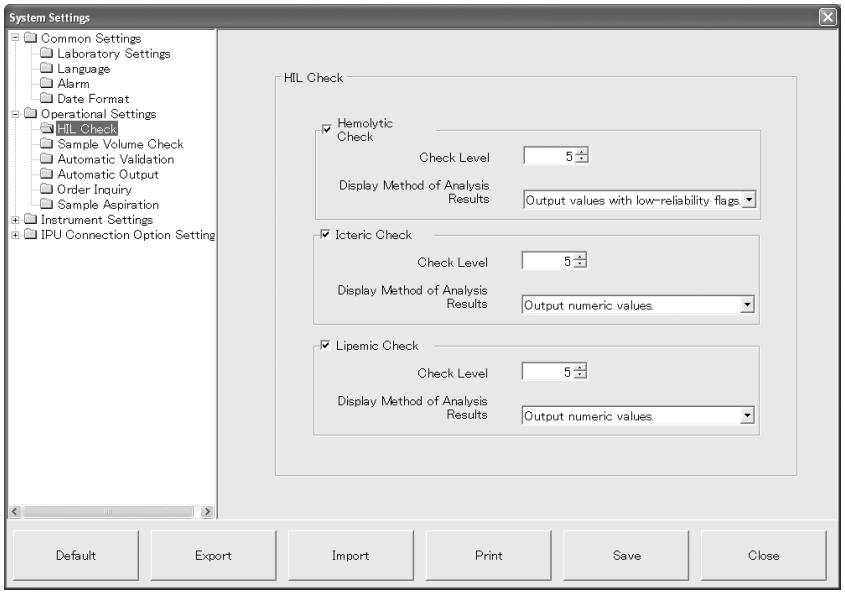

Figure 8-07: System setting dialog box (HIL check)

Hemolytic Check — Set whether or not to perform hemolytic checks. Add a check mark to perform hemolytic check. Remove the check mark to avoid performing the hemolytic check.

Check Level — Set the judgment value for hemolytic checks.

Display Method of Analysis Results — Select the method for displaying analysis results for samples which exceeded the judgment value in the hemolytic check. The options are **Output numeric values**., **Output values with low-reliability flags.** and **Output masked values.**. If **Output numeric values.** is selected, the analysis results are output without any change. If **Output values with low-reliability flags.** is selected, the analysis results are displayed with an assessment flag "*" on the left. If **Output masked values.** is selected, the assessment flag "*" is displayed with the analysis result as "****.*".

Icteric Check — Set whether or not to perform icteric checks. Add a check mark to perform icteric check. Remove the check mark to avoid performing the icteric check.

Check Level — Set the judgment value for icteric checks.

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Display Method of Analysis Results	Select the method for displaying analysis results for samples which exceeded the judgment value in the jaundice check. The options are **Output numeric values.**, **Output values with low-reliability flags.** and **Output masked values.**. If **Output numeric values.** is selected, the analysis results are output without any change. If **Output values with low-reliability flags.** is selected, the analysis results are displayed with an assessment flag "*" on the left. If **Output masked values.** is selected, the assessment flag "*" is displayed with the analysis result as "****.*".
Lipemic Check	Set whether or not to perform lipemic checks. Add a check mark to perform lipemic check. Remove the check mark to avoid performing the lipemic check.
Check Level	Set the judgment value for lipemic check.
Display Method of Analysis Results	Select the method for displaying analysis results for samples which exceeded the judgment value in the lipemic check. The options are **Output numeric values.**, **Output values with low-reliability flags.** and **Output masked values.**. If **Output numeric values.** is selected, the analysis results are output without any change. If **Output values with low-reliability flags.** is selected, the analysis results are displayed with an assessment flag "*" on the left. If **Output masked values.** is selected, the assessment flag "*" is displayed with the analysis result as "****.*".

2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Caution!
- Samples of abnormal color may have an impact on analysis values, so they should be handled with care.
- If lamp calibration is not performed after lamp replacement, it may be impossible to make correct judgments.

Note:
These settings become effective after the system has been restarted.

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7. Sample volume check

Set whether or not to perform the sample volume check and the sample volume range. If analysis results for the samples which fell outside the preset range, sample volume flags are displayed.

1. Select **Operational Settings** → **Sample Volume Check** from the setting parameter tree of the System Settings dialog box.
   The setting parameters are displayed in the setting area.

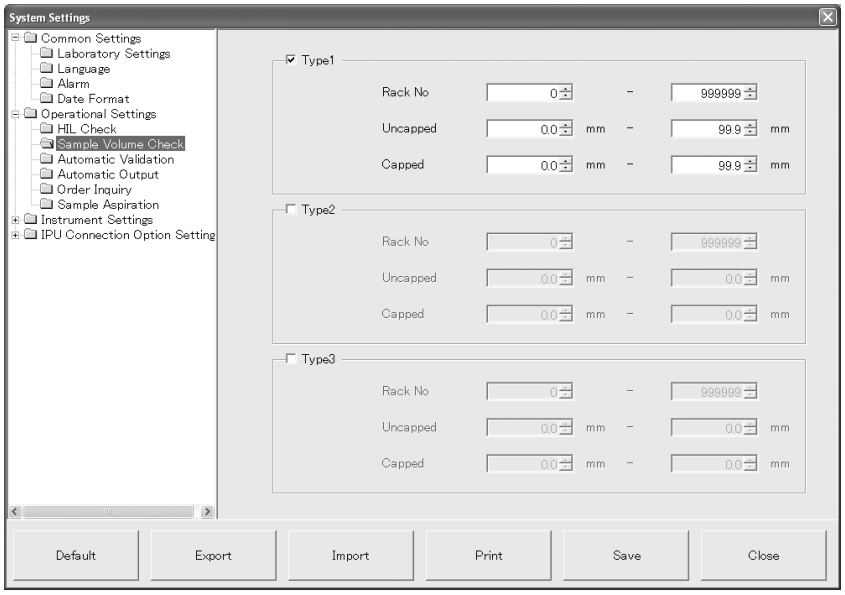

Figure 8-08: System Settings dialog box (Sample Volume Check)

Type1 - Type3	Check the type for which a check is performed. When doing so, the following items must be specified. Remove the check mark from the type for which a check is not performed. A total of three sample volume ranges can be set.
Rack No	Sets the rack number for which a sample volume check is performed.
Uncapped	Sets the range when a check is performed with a sample tube uncapped.
Capped	Sets the range when a check is performed with a sample tube capped.

2. Set each of the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

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8. Auto validation

Set whether or not to validate analyzed samples automatically.

1. Select **Operational Settings** → **Automatic Validation** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

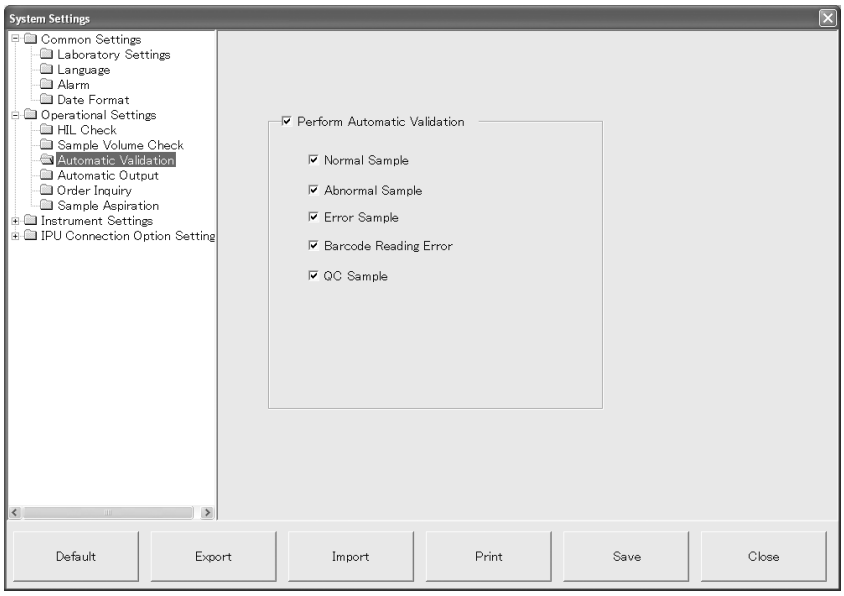

Figure 8-09: System settings dialog box (auto validation)

Perform Automatic Validation	Set whether or not to validate analyzed samples automatically. Add a check mark to use auto validation. Remove the check mark to avoid using automatic validation.
Normal Sample - QC Sample	If auto validation is used, set the items to be validated. Samples with check marks are validated.

2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

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9. Auto output

Analysis results which have been calculated and validated can be output automatically. Settings can be made for which results are subject to auto reporting and whether reports are output.
Refer to instrument settings and IPU connection option settings for settings related to the graphic printer (GP) and the host computer (HC) to which reports are output.

1. Select **Operational Settings** → **Automatic Output** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

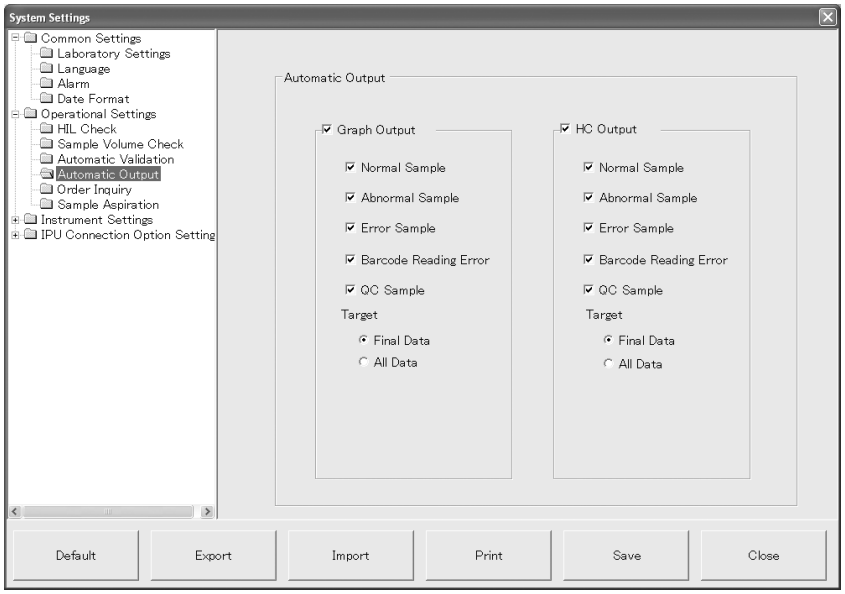

Figure 8-10: System settings dialog box (auto report)

Graph Output	Set whether or not to automatically report (GP) output samples that have completed analysis. Add a check mark to use auto (GP) report. Remove the check mark to avoid using auto (GP) report.
Normal Sample - QC Sample	If auto (GP) report is used, set the items to be output. Samples with check marks are automatically output.
Target	If auto (GP) report is used, select the type of data to output to the printer, from **Final Data** and **All Data**.

HC Output	Set whether or not to automatically export validated results to the host computer. Add a check mark to use HC output. Remove the check mark to avoid using HC output.
Normal Sample - QC Sample	Set the items to be automatically output to the host computer. Add a check mark for each item that should be automatically output. Remove the check mark for items that should not be automatically output.
Target	If auto output is used, select the type of data to send to the host computer, from **Final Data** and **All Data**.

2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Note:
If the instrument is connected to the host computer by CR-800 format, only the last data is output automatically, even if the setting for data to be output is all data.

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10.Order inquiry

Set the search method to use for order inquiry on the host computer.

1. Select **Operational Settings** → **Order Inquiry** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

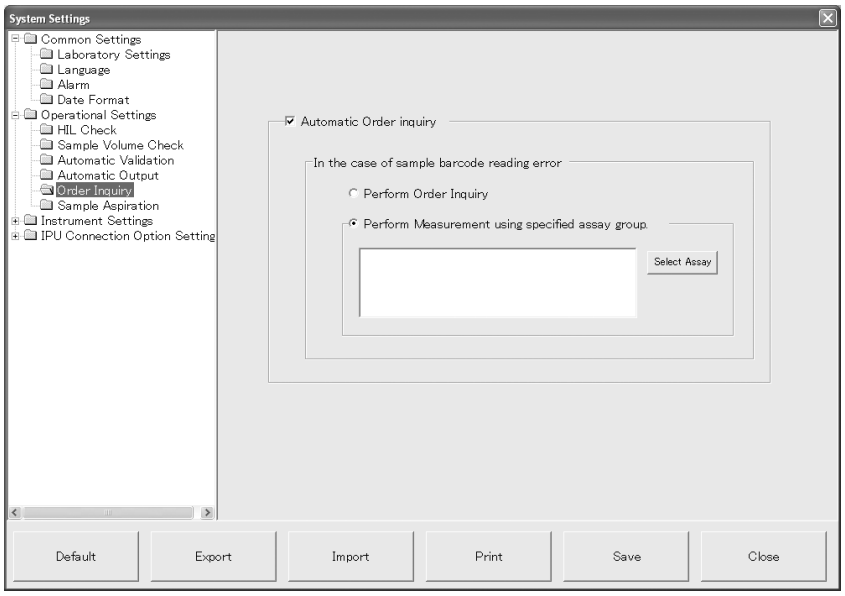

Figure 8-11: System settings dialog box (order inquiry)

Automatic Order inquiry — Set whether or not to perform automatic order inquiry on the host computer. Add a check mark to perform automatic order inquiry. Remove the check mark to avoid using the function.

In the case of sample barcode reading error — If automatic order inquiry from the host computer is used, set how the system should process in the event of a sample barcode read error. Only make this setting if there is a check mark for automatic order inquiry.

Perform Order Inquiry — (With the error number as the sample number) Run automatic order inquiry on the host computer.

Perform Measurement using specified assay group — Analyze the specified fixed parameter in the next field, without running an automatic order inquiry on the host computer.

List of fixed parameters — Up to sixty parameters (assay groups) can be displayed as fixed parameters to be used for analysis.
If ten parameters or more are set, a scrollbar appears.

Select Assay — The Select Test dialog box appears and can be used to edit fixed parameters. Parameters can only be edited if there is a check mark for analysis with fixed parameters.

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2. Set the parameters.
3. Press **Select Assay** to edit the fixed parameters.
   The Select Test dialog box will appear.

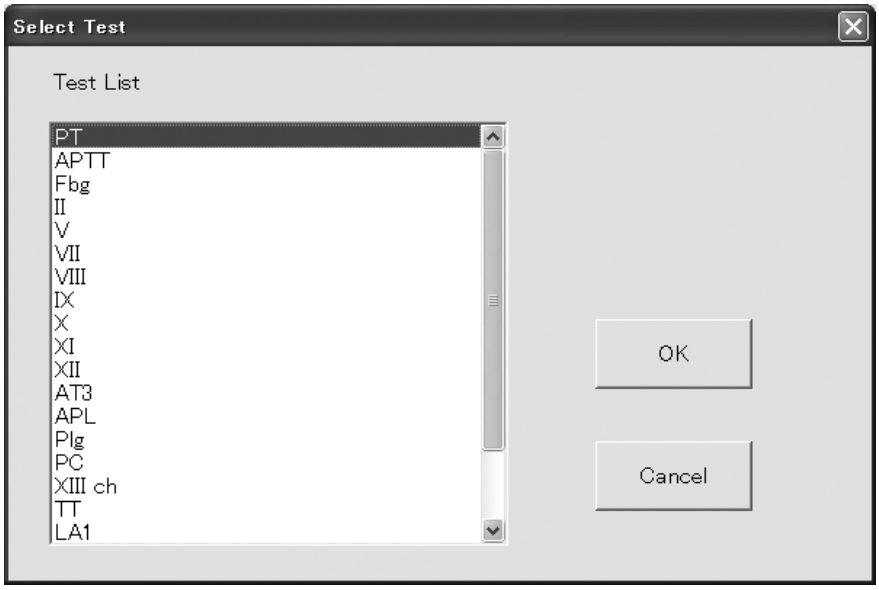

Figure 8-12: Select Test dialog box

Test List	Select the tests when a sample barcode could not be read.

4. Select the analysis parameters and press **OK**.
   The set analysis parameters are reflected in the fixed parameter list and the Select Test dialog box closes.
   Press **Cancel** to close the Select Test dialog box.
5. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

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11.Sample aspiration

The detergent used for primary sample aspiration can be displayed.

1. Select **Operational Settings** → **Sample Aspiration** from the setting parameter tree of the system settings dialog box.
   The detergent used for primary sample aspiration is displayed.

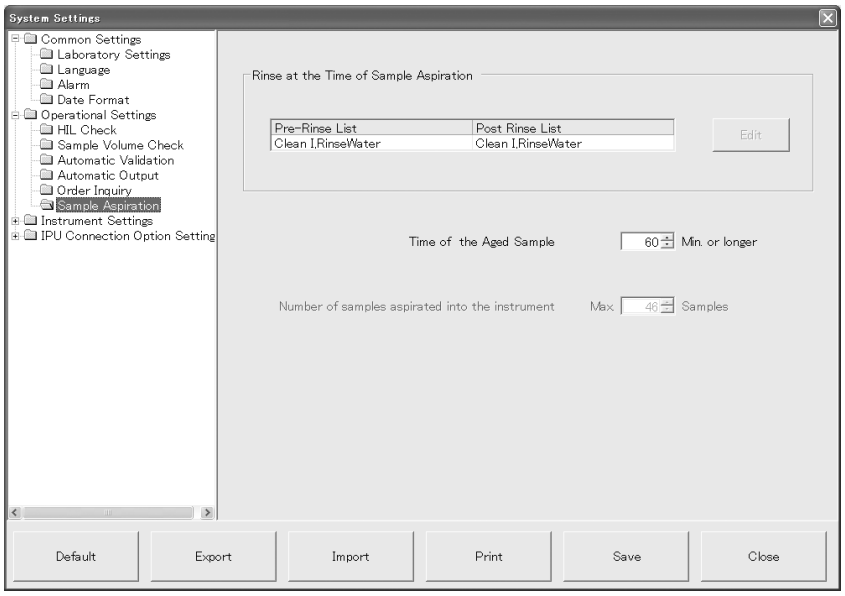

Figure 8-13: System settings dialog box (sample aspiration)

Rinse at the Time of Sample Aspiration

Pre-Aspiration Rinse List	Detergents used for pre-rinsing are listed in order of use.
Post-Aspiration Rinse List	Detergents used for post-rinsing are listed in order of use.
Time of the Aged Sample	When **Suspend the test** is checked on **Analysis in case of insufficient reagent** after selecting **System Settings** → **Instrument Settings** → **Monitoring**, analysis is suspended for parameters which use the reagent if a reagent runs out. However, primary sample aspiration continues. When the reagent is replenished, secondary dispensing is performed for the aspirated sample and analysis restarts. Sets the time of the aged sample from between primary sample aspiration and secondary dispensing.

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Number of samples aspirated into the instrument	When **Suspend the test** is checked on **Analysis in case of insufficient reagent** after selecting **System Settings** → **Instrument Settings** → **Monitoring**, analysis is suspended for parameters which use the reagent if a reagent runs out. However, primary sample aspiration continues. When the reagent is replenished, analysis restarts from the aspirated sample. The maximum number of primarily aspirated samples is displayed.

12.Instrument information

Instrument name and serial number are presented as instrument information. The device nickname can also be set.

1. Select **Instrument Settings** → **Instrument Information** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

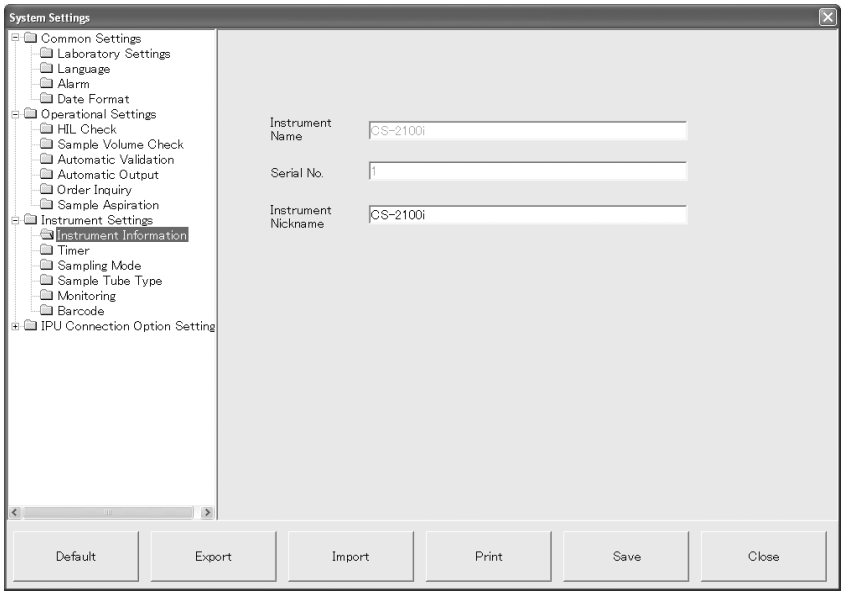

Figure 8-14: System settings dialog box (instrument information)

Instrument Name	The instrument name is displayed.
Serial No.	The Serial number of the instrument is displayed.
Instrument Nickname	Set the device nickname. Input up to 15 alphanumeric characters.

Note:
Alphanumeric characters are only A-Z, a-z, and 0-9. Localized characters cannot be input.

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2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

> **Note:**
> These settings become effective after the system has been restarted.

13.Aspiration mode

The sample aspiration mode can be set.

1. Select **Instrument Settings** → **Sampling Mode** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

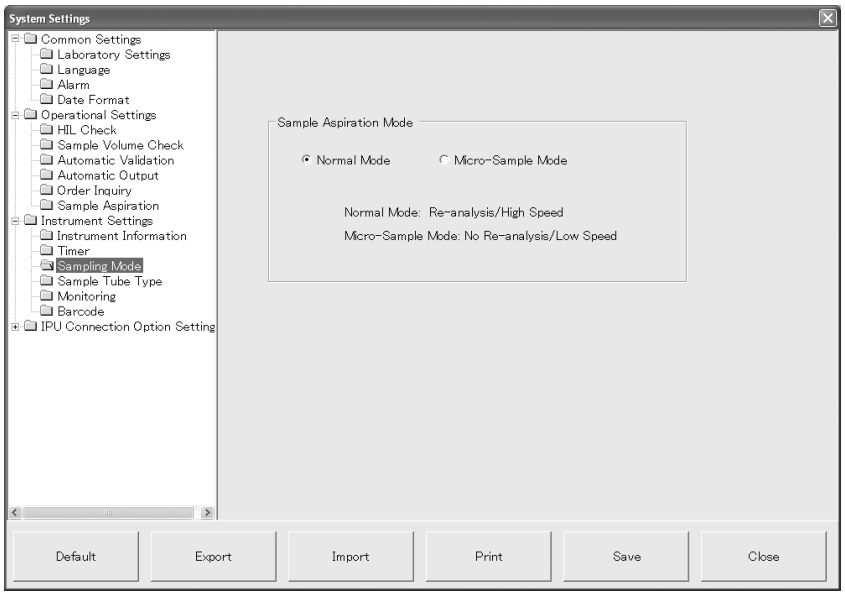

Figure 8-15: System settings dialog box (aspiration mode)

Sample Aspiration Mode

Normal Mode	This is the standard mode. Repeat analyses can be performed.
Micro–Sample Mode	This is the micro-sample mode. Analysis using a capped sample tube cannot be performed.

2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

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Note:
These settings become effective after the system has been restarted.

14.Sample tube types

Set the types of sample tubes which can be used for analyses.

1. Select **Instrument Settings** → **Sample Tube Type** from the setting parameter tree of the system settings dialog box.
   The setting area displays the name of the currently-set sample tube type.

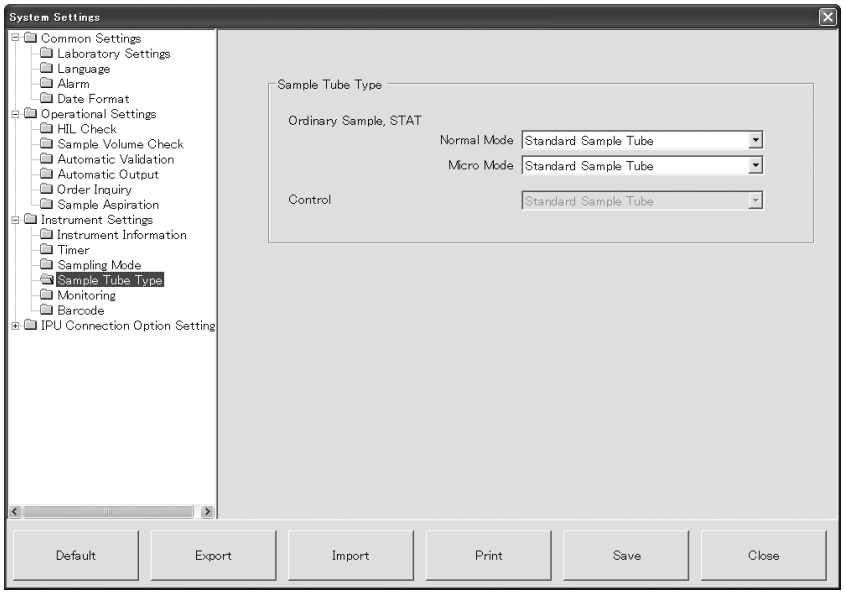

Figure 8-16: System settings dialog box (sample tube type)

2. Set the sample tube used in **Normal Mode** and **Micro Mode**.
   Only **Standard Sample Tube** can be selected for **Control** and no changes in setting are available. A sample cup can also be used with **Standard Sample Tube** selected.
   See “Chapter 5: 5.10: 1. : Table 5-20 Usable types of evacuated blood collection tubes and test tube adapters” in the Instructions for Use to confirm the type of sample tube used and select the appropriate setting.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Note:
- These settings become effective after the system has been restarted.
- As the specification of the sample tube (diameter of sample tube, thickness of air layer, bottom shape, thickness, internal pressure etc.) varies between types, different aspiration methods must be set for analysis with each tube type.
- Identifying the type of sample tube makes it possible to aspirate sample from the tube.
- The following volume and sampling method change with the sample tube type.
  Sample volume which can be aspirated
  Extra volume
  Sample aspiration method
  Sample volume monitoring method

15.Monitoring

This is used to set whether or not to monitor the drain float switches, the rinse float switch and the number of cuvettes in the trash box and how to interrupt operation when a reagent runs out.

1. Select **Instrument Settings** → **Monitoring** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

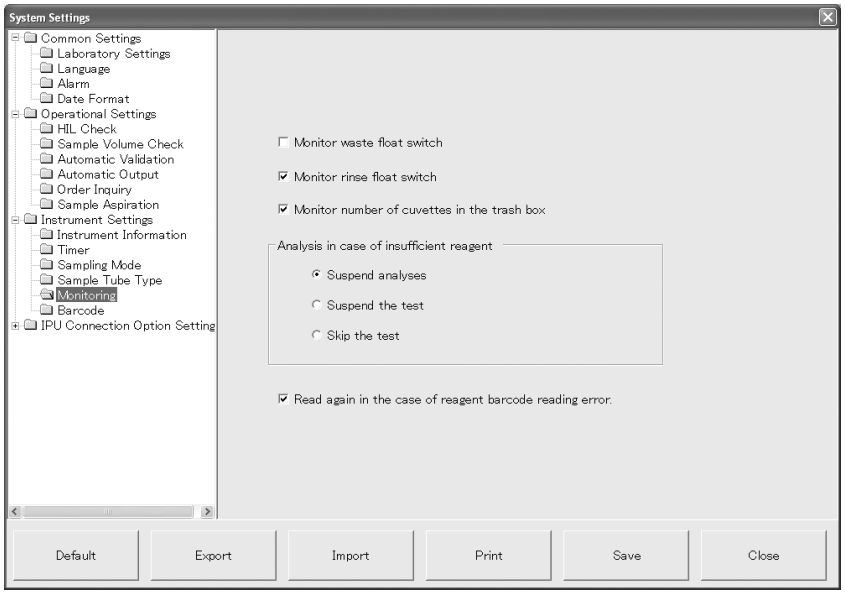

Figure 8-17: System settings dialog box (monitoring)

Monitor waste float switch	Set whether or not to monitor the drain float switch of the waste tank. Add a check mark to perform monitoring. Remove the check mark to avoid monitoring.
Monitor rinse float switch	Set whether or not to monitor the rinse float switch of the rinse tank. Add a check mark to perform monitoring. Remove the check mark to avoid monitoring.

Monitor number of cuvette in the trash box	Set whether or not to monitor the number of cuvettes in the cuvette trash tray. Add a check mark to perform monitoring. Remove the check mark to avoid monitoring.

Analysis in case of insufficient reagent

Suspend analyses	When a reagent runs out, sample aspiration and dispensing are suspended for all parameters. When the reagent is replenished, analysis restarts from the aspirated sample.
Suspend the test	When a reagent runs out, analysis is suspended for parameters which use that reagent, but continues for all other parameters. When the reagent is replenished, analysis restarts from the aspirated sample.
Skip the test	When a reagent runs out, analysis stops for parameters which use that reagent, but continues for all other parameters. If there are samples for which orders have already been received, the analysis result becomes an error from the point at which the reagent ran out. Order inquiry will not be performed for parameters for which any reagent has run out.

Read again in the case of reagent barcode reading error	Set whether or not to try again if reading of the reagent barcode failed. Add a check mark to try to read the barcode again. Remove the check mark to avoid reading again.

2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Note:
These settings become effective after the system has been restarted.

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16.Barcodes

It is possible to set whether or not to use sample and rack barcodes and the barcode type and check digit to use.

1. Select **Instrument Settings** → **Barcode** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

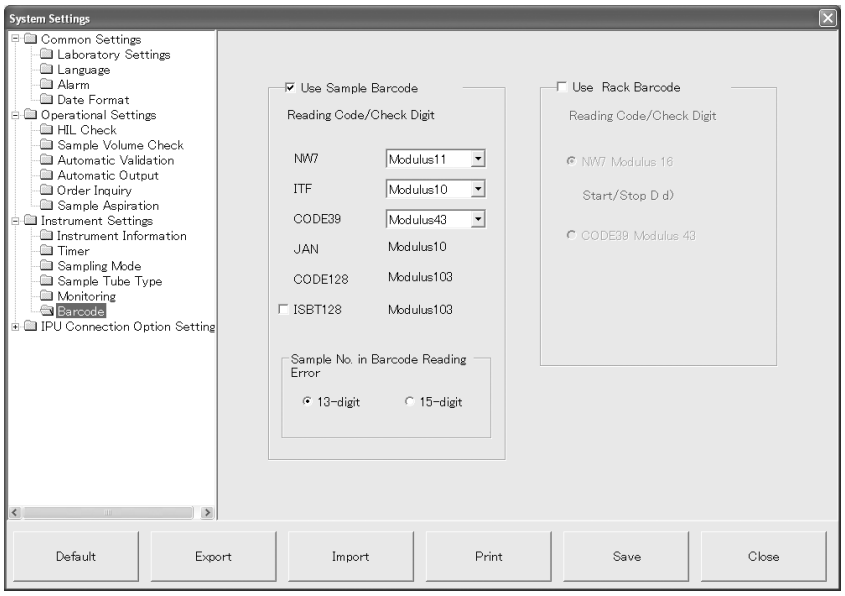

Figure 8-18: System settings dialog box (barcode)

Use Sample Barcode	Set whether or not to use sample barcodes. Add a check mark to use barcodes. Remove the check mark to avoid using barcodes.
Reading Code/ Check Digit	These can be set if the check mark is attached to allow the use of sample barcodes.
NW7	The four check digit options if CODABAR/NW7 barcodes are used are **None, Modulus 11, Weighted modulus 11, Modulus 16.**
ITF	The two check digit options if ITF barcodes are used are **None** and **Modulus 10.**
CODE39	The two check digit options if CODE39 barcodes are used are **None** and **Modulus 43**.
JAN	The check digit to use with JAN/EAN/UPC barcodes is **Modulus 10**.
CODE128	The check digit to use with CODE128 barcodes is **Modulus 103**.
ISBT128	Set whether or not to use ISBT128 barcodes. Add a check mark to use barcodes. Remove the check mark to avoid using barcodes. The check digit to use with ISBT128 barcodes is **Modulus 103**.

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Sample No. in Barcode Reading Error	If an error occurred in reading the sample barcode, select whether the automatically assigned sample number should have **13 digits** or **15 digits**.
Use Rack Barcode	Set whether or not to use Rack barcodes. Add a check mark to use barcodes. Remove the check mark to avoid using barcodes.
Reading Code/ Check Digit	Select either **NW7** or **CODE39** as the reading code for rack barcodes. If NW7 is selected, use “D” or “d” as the start and stop codes and make the check digit Modulus 16. If CODE39 is used, the corresponding check digit is Modulus 43.

2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

Note:

- These settings become effective after the system has been restarted.
- Read tests of sample barcodes can be carried out from the Sample Barcode Reading Test dialog box for Test Operation.

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17.Host computer

Settings can be made for whether or not to connect to the host computer and the method for doing so.

1. Select **IPU Connection Option Settings** → **Host Computer** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

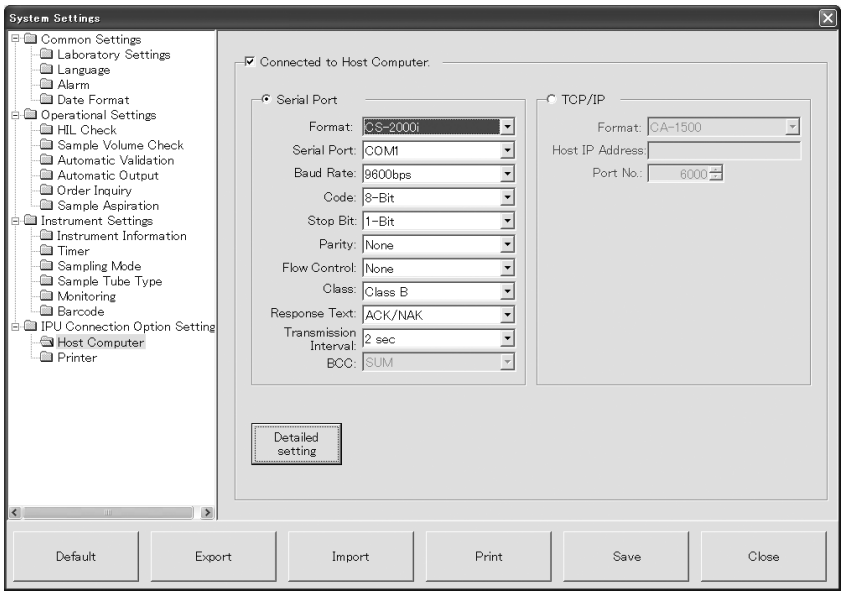

Figure 8-19: System settings dialog box (host computer)

Connected to Host Computer — Set whether or not to connect to the host computer. Add a check mark to connect. Remove the check mark to avoid connecting.

Serial Port — Select if the serial port is the method for communicating with the host computer. If it is selected, settings can be made for the following items. These can only be selected if **Connected to Host Computer** is set.

- **Format** — If the communications method is serial, select the format from **CA-1000**, **CA-1500**, **PC-DPS(C)**, **ASTM1381-95/1394-95**, **ASTM1381-02/1394-97**, **CR-800** or **CS-2000i**.
- **Serial Port** — If the communications method is through the serial port, select the serial port to use for serial communications, from **COM1** and **COM2**.
- **Baud Rate** — If the communications method is through the serial port, select the baud rate (communication speed) for serial communications, from **300**, **2400**, **4800**, **9600** and **19200**.
- **Code** — If the communications method is through the serial port, select the data bit length (character bits) for serial communications, from **7-Bit** and **8-Bit**.

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Stop Bit	If the communications method is through the serial port, select the stop bit length for serial communications, from **1-Bit**, **1.5-Bit** and **2-Bit**.
Parity	If the communications method is through the serial port, select the parity bit for serial communications, from **None**, **Odd** and **Even**.
Flow Control	If the communications method is through the serial port, remove the check marks for serial communications flow control, from **None** and **CTS/RTS**.
Class	If the communications method is through the serial port, select the communications protocol to use for serial communications from the options below.
Class A	Select to communicate with the host computer without handshaking.
Class B	Select to handshake with the host computer in the course of communication.
Response Text	If the format is CA-1000, CA-1500 or PC-DPS(C), select **ACK/NAK** or **STX-ACK-ETX** for whether or not to add STX, ETX to the Response Text used in communication with the host computer.
Transmission Interval	If the communications method is serial, select the transmission interval from **0 sec**, **1 sec**, **2 sec**, **5 sec** or **10 sec**.
BCC	If the format is CR-800, the BCC (Block Check Code) calculation method can be selected from **SUM** or **XOR**.
TCP/IP	Select if TCP/IP is the method for communicating with the host computer. If it is selected, settings can be made for the following items. This can only be selected if the setting is to **Connected to Host Computer.**
Format	If the communications method is TCP/IP, select the format from **CA-1000**, **CA-1500**, **PC-DPS(C)**, **ASTM1381-02/1394-97** or **CS-2000i**.
Host IP Address	If the communication method is TCP/IP, set the IP address of the host computer. Input the number in the format below. ***.***.***.*** Each *** is a number. (0-255)
Port No.	If the communication method is TCP/IP, set the port number of the host computer. The setting range is 1024-65535.

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Detailed setting Pressing this button displays either of the following two dialog boxes depending on the format selected.

(When **CS-2000i** is selected in **Format**)

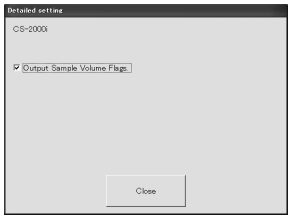

Figure 8-20: Detailed setting dialog box 1

Output Sample Volume Flags. Set whether or not to output sample volume flags to the host computer.
Add a check mark to output sample volume flags to the host computer.
Remove a check mark when to not output sample volume flags to the host computer.

(When **ASTM1381-95/1394-95** or **ASTM1381-02/1394-97** is selected in **Format**)

Figure 8-21: Detailed setting dialog box 2

Output HIL Flags. Set whether or not to output HIL flags to the host computer.
Add a check mark to output HIL flags to the host computer.
Remove a check mark to not output HIL flags to the host computer.

Output Sample Volume Flags. Set whether or not to output sample volume flags to the host computer.
Add a check mark to output sample volume flags to the host computer.
Remove a check mark when to not output sample volume flags to the host computer.

Output Sample Volume flags only in case of defective sample volume. Set the output conditions for sample volume flags when using HC output.
Add a check mark to issue a sample volume flag in the event of an error and output sample information to the host computer only in case of defective sample volume.
Remove a check mark to always issue a sample volume flag in normal circumstances or in the event of an error and output sample information to the host computer.

Output the software version. Set whether or not to output version numbers to the host computer.
Add a check mark to output the software version to the host computer.
Remove a check mark to not output the software version to the host computer.

Add a [CR] at the end of a record.	Set whether or not to output a [CR] at the end of a record to the host computer. Add a check mark to output a [CR] at the end of a record to the host computer. Remove a check mark to not output a [CR] at the end of a record to the host computer.

Caution!

- When using **CA-1000**, **CA-1500** or **PC-DPS(C)** as **Format**, contact your local representative. If the host computer processes the following actions, the receivable number of digits may become less than those of analysis results, causing incorrect analysis results to appear on the host computer display.
  - Ignores one high-order digit of the transmission data to receive only four low-order digits for **Clot Time**, **dOD**, **activity%** and **concentration**.
  - Ignores two high-order digits of the transmission data to receive only three low-order digits for **ratio** and **INR value**.
- Changing the settings for whether assay parameters are valid or invalid may prevent the transfer of correct analysis results to the host computer. If the valid/invalid settings for assay parameters have been changed, change the settings on the host computer as well, and confirm that the analysis results are transferred to the host computer correctly.

2. Set the parameters.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

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18.Printer

It is possible to set the printer connection.

1. Select **IPU Connection Option Settings** → **Printer** from the setting parameter tree of the system settings dialog box.
   The setting parameters are displayed in the setting area.

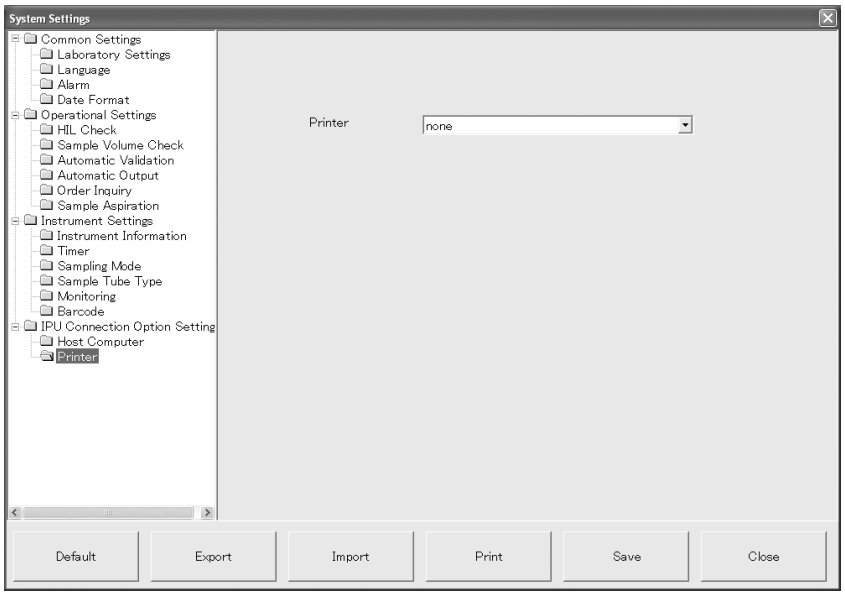

Figure 8-22: System settings dialog box (printer)

2. Select the printer connection from the available connections.
   Select **none**, as is displayed, or a printer driver from the list of drivers installed in the IPU.
3. Press **Save** to register after finishing setting. Press **OK** on the registration confirmation dialog box which appears.
   To continue with making settings in another category, select that category from the setting parameter tree.

19.Initialization of system setting values

The system setting values can be restored to the factory defaults.

1. Press **Default** in the system settings dialog box.
   The Reset System Settings to the Default dialog box will appear.

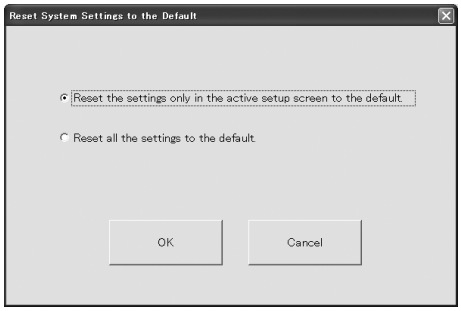

Figure 8-23: Reset System Settings to the Default dialog box

2. Select which setting values to restore to defaults. Select whether to restore only the currently-selected settings, or all system settings.
3. Press **OK**.
   Close the Reset System Settings to the Default dialog box and load the default values. The loaded settings are automatically reflected in the IPU, even if the Save button is not pressed.
   To cancel loading, press the **Cancel** key.

20.Backing up system setting values

Current system setting can be saved to a file.

1. Press **Export** in the system settings dialog box.
   The Save As dialog box will be displayed.
2. Specify the location and file name to save, then press **Save**.

21.Loading system setting values

System setting values can be loaded from a file to replace the current setting values.

1. Press **Import** in the system settings dialog box.
   The open dialog box will appear.
2. Specify the file to load, the press **Open**.

22.Printing system setting values

Current system setting values can be printed out.

1. Press **Print** in the system settings dialog box.

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8.4 User management

Information on users who use the instrument is stored in the IPU. The aim of user management is to prevent improper access to the IPU. A logon name and password must be entered to log on. The various functions of the IPU are restricted according to user permissions, so the operations that a user can perform after logging on are limited by that user's permissions.
The IPU has a preregistered user by factory default, and it cannot be deleted or altered. Up to 100 users can be registered in total, including the preregistered user.

1. User registration/editing

1. Select **User management** on the settings screen.
   The user registration dialog box appears.

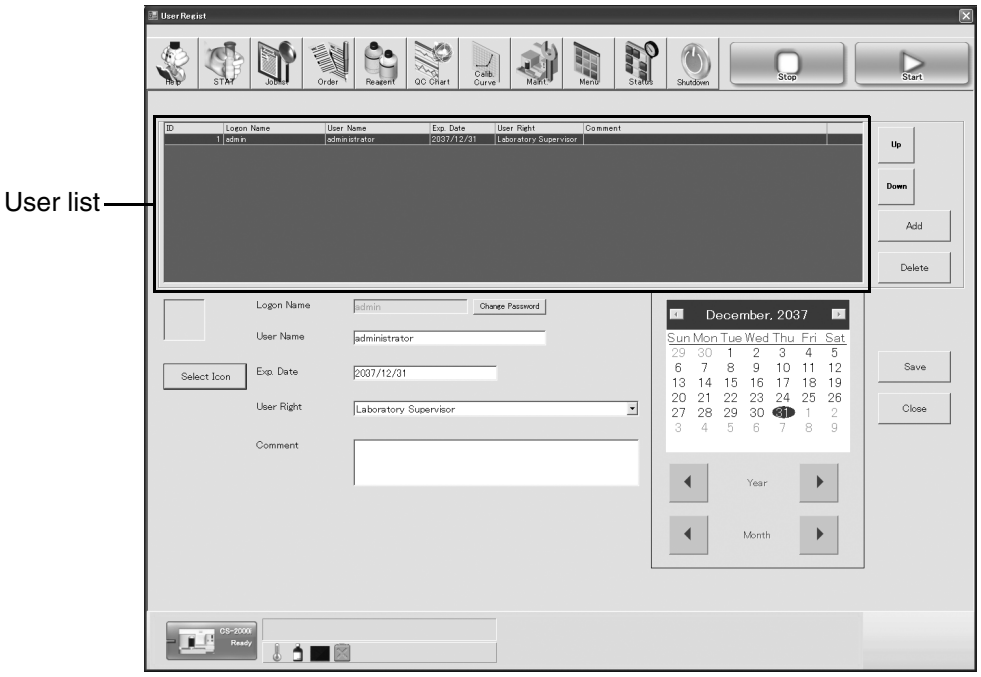

Figure 8-24: User registration dialog box

User list	ID - comment for registered users are displayed.
ID	User ID is displayed.
Logon Name	The logon name for the user selected on the user list can be set using up to 8 characters. When a user is selected on the user list, the logon name for that user is displayed. This is a compulsory item. It cannot be registered as a blank.
User Name	The user name for the user selected on the user list can be set using up to 10 characters. When a user is selected on the user list, the user name for that user is displayed.
Exp. Date	Set the expiration date of the password. The setting range is 1900/ 1/ 1 – 2037/12/31 (yyyy/mm/dd).

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User Right	Set user permissions from the options of **Laboratory Supervisor**, **Lab Technician** or **Night Operator**. They are displayed in order of permission level, with the highest at the top. Only levels below the logged-in user can be selected.
Comment	Enter a comment about the user in up to 20 characters.

2. To edit the information about a user who has already been registered, select the user to edit from the user list. Press **Add** to register a new user.
3. Set the parameters.
4. Press **Save**.

Preregistered user by factory default
The following user is registered by default when the instrument is shipped. Editing of the preregistered user such as deletion and permission changes is not possible.

Table 8-01: Preregistered user by factory default

ID	Logon Name	Password	User Name	Exp. Date	User Right	Comment	Overview
1	admin	admin	Lab. Supervisor	31/12/2037 (dd/mm/yyyy)	Lab. Supervisor	(Blank)	This is the user used by the facility manager. There are permissions for the implementation of all functions.

Caution!
As shown in the table above, the password has been set by factory default.
Change the password when logging in for the first time.
For details, see “Chapter 8: 8.4: 3. Changing passwords”.

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User permissions

The following limitations are based on user permissions.

Table 8-02: Limitation of functions according to user permissions

Function		Lab Supervisor/ Lab technician	Night operator
Order Registration	Registering rack routine sample and QC analysis orders	○	○
	Holder calibration curve analysis order registration	○	○
	Holder QC order registration	○	○
	Registration of STAT orders	○	○
Joblist	Joblist display	○	○
	Validation	○	—
	Select display conditions	○	○
	Find	○	○
	Adding/deleting marks	○	○
	Printing analysis results	○	○
	HC Output	○	○
	Deleting displayed analysis results	○	—
	Editing sample information	○	○
	Recalculation of calculated parameters	○	—
	Exporting analysis results	○	○
	Customizing the joblist screen	○	—
Browser	Browser main window display	○	○
	Validation	○	—
	Print	○	○
	HC Output	○	○
	Export	○	○
	Customize	○	—
	Detailed graphical display	○	○
Reagent Screen	Check the reagent set positions	○	○
	Edit reagent information	○	○
	Set the reagent lot usage	○	—

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Table 8-02: Limitation of functions according to user permissions

Function		Lab Supervisor/ Lab technician	Night operator
Quality Control	QC charts display screen	○	○
	Checking QC error data	○	—
	Change cursor	○	○
	Set target/limit	○	—
	Auto QC setting	○	○
	QC barcode setting	○	○
	Print	○	○
	Delete	○	—
	Adding a new lot	○	—
	Changing lots	○	—
	Change scale	○	○
	Changing display data	○	○
	Print report	○	○
	Export	○	○
	Customize display	○	—
Calibration Curve	Validate	○	—
	Detailed display	○	○
	Edit	○	—
	Print	○	○
	Delete	○	—
	Calib. Info	○	○
System Setup	System settings	○	—
	User management*	○	○
	Reagent master registration	○	—
	Reagent lot master registration	○	○
	Assay group settings	○	—

○: Can be implemented —: Cannot be implemented

* The following restrictions are placed on user management.

User display: The logon user (self) and users of lower rank are displayed in the dialog box. Other users besides the logon user with the same permissions are not displayed.

User information/Password change: The user can change user information and passwords for the logon user (self) and users of lower rank.

User addition/User deletion: The user can also add and delete users of lower rank.

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2. Delete user

1. Select the user to delete from the user list in the user registration dialog box.
2. Select **Delete** on the user registration dialog box.
   The delete confirmation dialog box appears.
3. Select **OK** on the delete confirmation dialog box.

3. Changing passwords

1. Select the user from the user list on the user registration dialog box for whom to change the password is to be changed.
2. Press **Change Password**.
   The Change Password dialog box will appear.

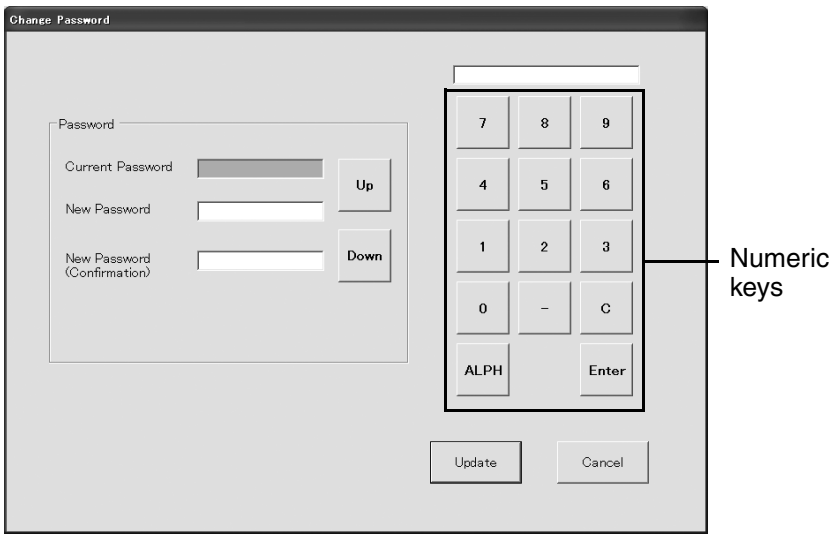

Figure 8-25: Change password dialog box

Current Password	Enter the current password to change the password. Password characters are displayed as "*".
New Password	Input the new password to register using up to 12 characters. Password characters are displayed as "*".
New Password (Confirmation)	For confirmation, re-enter the new password. Password characters are displayed as "*". At the registration stage, this entry is compared to the new password. Registration is not possible if there is a mismatch.
Up	Move the cursor up to the next field.
Down	Move the cursor down to the next field.
Numeric keys	This is used to enter the password.

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3. Enter the password, using the numerical keys.
   For new registration, enter the new password under **New Password** and **New Password (Confirmation)**.
   To change the registration, enter the current password under **Current Password**, then enter the new password under **New Password** and **New Password (Confirmation)**.
4. Press **Update**.
   The settings in the change password dialog box are registered and the dialog box closes.
   Press **Cancel** to discard settings made in the change password dialog box and close it.

4. Icon selection

1. Select the user from the user list in the user registration dialog box for whom to register or change an icon.
2. Press **Select Icon**.
   The icon setting dialog box will appear.
3. Specify the location and file name under which the icon is saved, then press **Open**.

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8.5 Reagent master registration

Reagent masters can be registered.

> **Caution!**
> The operator is personally responsible for changing the registered reagent information. Furthermore, the warranty for this product only covers the use in the factory default settings.

1. Registration of reagents to the reagent master/editing of registered reagent information

1. Press **Reagent Master** on the settings screen.
   The reagent master registration dialog box appears.

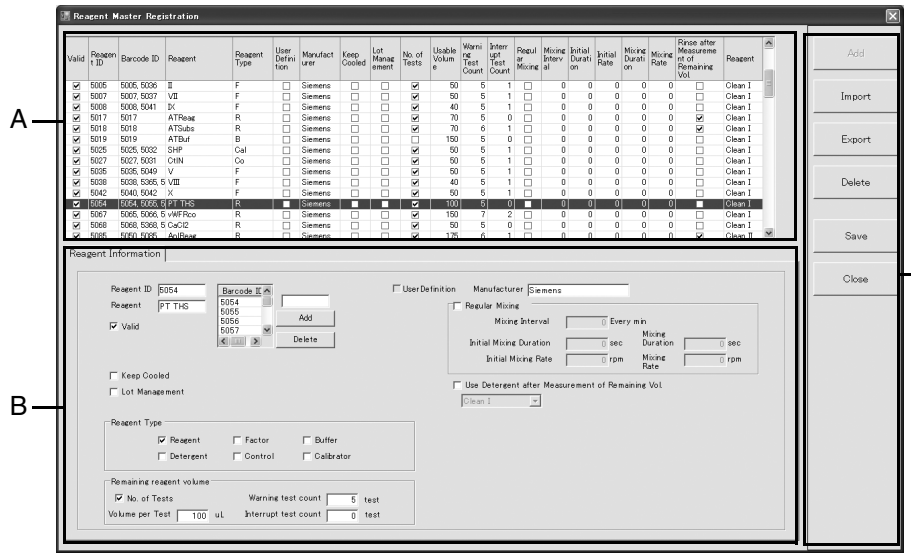

Figure 8-26: Reagent master registration dialog box

A List of reagents
The reagent list is displayed.

B Reagent information
Information for the reagent selected in the reagent list is displayed.

Reagent ID	Set the reagent ID.
Reagent	Set a reagent name.
Valid	Set whether or not to display this reagent on other screens (the reagent screen and the reagent selection dialog box). Add a check mark to display the reagent. Remove the check mark to avoid displaying it.
Barcode ID	Set the ID that is used on the reagent barcode label to identify the reagent.

Keep Cooled Set whether or not cooling is required. Add a check mark if cooling is required. Remove the check mark if cooling is not required. A warning will be displayed if a reagent that requires cooling is placed in a reagent holder that is not cooled.

Reagent Type Set the type of the reagent.

Remaining reagent volume

No. of Tests Set whether or not to display the number of remaining tests on the Reagent screen. When a check mark is added, the number of tests is displayed by calculating the remaining volume for one test. When the check mark is removed, "-" (hyphen) is displayed for the number of remaining tests.

Caution!
The number of tests that can be analyzed and those obtained by calculating the remaining volume for one test may differ for the diluent used in multiple assay groups and the calibrators analyzed by changing dilution ratios.

Volume per Test (µL) Set the volume of the reagent used for one test. (If remaining reagent volume is displayed in terms of a number of tests, this volume is used to calculate that number. In some cases, the volume used may vary depending on the test parameter, but this value is used to determine the number of remaining tests).

Warning test count Set the warning number of tests for remaining reagent volume. When the remaining number of tests for the reagent set in the instrument falls below the amount sufficient for the number of tests for warning, "Reagent volume will be short" is displayed.

Interrupt test count Set the number of tests for remaining reagent volume to trigger a pause. When the same reagent is set in multiple reagent vials, the reagent is automatically switched if the remaining number of tests for the reagent used falls below the amount sufficient for the number of tests for a pause. When there is no switchable reagent available or only one reagent vial set in the instrument, "The analyses are suspended because the reagent is used up" is displayed.

Caution!
Changing the value for the Interrupt test count may affect the automatic reagent switchover when the same reagent is set in multiple reagent vials, or extra volume of the reagent.

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User Definition The display indicates whether or not the set information has been edited by a user. If it has been edited, the system automatically judges so and adds a check mark. No check mark is added if the information was not edited.

Manufacturer The manufacturer name is displayed if the reagent information was provided by the manufacturer. “Sysmex” is displayed for Sysmex products and “Siemens” for Siemens Healthcare Diagnostics products.

Regular Mixing Set whether or not to perform regular mixing. Add a check mark to perform regular mixing. Remove the check mark to avoid using regular mixing. When the instrument (the reagent holder) is in a state that permits mixing, such as during Analysis, mixing is performed at the set mixing interval and speed for the set mixing duration. When the status of the instrument is “Ready” for long periods and the mixing interval has been exceeded, such as after starting the instrument or installing the reagent, mixing is performed at the set initial mixing speed and for the set initial mixing duration.

Caution!
If periodic mixing of reagents is performed, set the number of interrupted tests so that the probe does not come into contact with the stir bar. If no suitable setting is made for the number of interrupted tests, it can cause probe crash or sampling errors, so the reagent may not be aspirated correctly, which would influence the analysis results.
Follow the procedure below to calculate the number of interrupted tests.

Table 8-03: Vials and capacity and number of interrupted tests

Vial and capacity	Interrupt test count
Siemens reagent vial 5 mL (GW5)	1200 µL/[Volume per Test (µL)]
Siemens reagent vial 15 mL (GW15)	1600 µL/[Volume per Test (µL)]
Siemens reagent vial 25 mL (GW25)	1600 µL/[Volume per Test (µL)]

Mixing Interval Set the interval between reagent mixing operations in minutes.

Initial Mixing Duration Set the duration of mixing to be used if the reagent mixing interval is exceeded or if the reagent is mixed for the first time after placement in seconds.

Initial Mixing Rate Set the mixing speed to be used if the reagent mixing interval is exceeded or if the reagent is mixed for the first time after placement.

Mixing Duration Set the duration of reagent mixing operation in seconds.

Mixing Rate Set the mixing speed for reagent mixing.

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Use Detergent after Measurement of Remaining Vol.	Set whether or not to rinse with detergent after detecting the level with the probe when measuring remaining reagent volume. Add a check mark to perform it. Remove the check mark to avoid performing it. If the check mark has been added, the detergent to use can be selected.

Caution!
For reagents that are set as requiring post-rinsing in the reagent protocol of the test protocol settings, add a check mark for **Use Detergent after Measurement of Remaining Vol.** to set detergent.
It may not be possible to obtain accurate analysis results if detergent is not set, because reagents could be contaminated when their remaining volume is measured.

C Operation Panel area

Add	Add a line below the line selected in the reagent list.
Import	The Open dialog box will appear. The reagent list previously output to external storage device using the export function can be loaded.
Export	The Save As dialog box will be displayed. This function outputs the selected reagent list to external storage device.
Delete	The deletion confirmation dialog box for the line selected in the reagent list is displayed. Press **OK** to delete the selected line. Press **Cancel** to avoid deleting the selection.
Save	Register the content edited in the reagent information display/editing area.
Close	Close the reagent master registration screen and return to the next higher screen.

2. To edit the information about a reagent which has already been registered, select the reagent to edit from the reagent list.
3. Set the parameters. Press **Add** to register a new reagent.
4. Press **Save**.
5. Press **Close**.
   A dialog box appears asking for a restart.
6. Press **OK**.
   Register the settings made using the reagent master registration dialog box.

Note:
These settings become effective after the system has been restarted.

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2. Deleting a reagent

1. Select the reagent to delete from the reagent list.
2. Press **Delete**.
   The delete confirmation dialog box appears.
3. Press **OK**.
   The selected line will be deleted.
   Press **Cancel** to avoid deleting the selection.

3. Backing up reagent masters

The reagent selected in the reagent list can be saved to a file.

1. Select the reagent to export from the reagent list.
2. Press **Export.**
   The Save As dialog box will be displayed.
3. Specify the location and file name to save, then press **Save**.

4. Loading reagent masters

Reagent masters can be loaded from a file to replace the current settings.

1. Press **Import** in the reagent master registration dialog box.
   The Open dialog box will appear.
2. Specify the file to load, the press **Open**.

Note:
Reagent information is stored in the instrument when the reagent is placed in the reagent holder. To carry on using a reagent for which the reagent master setting has changed, remove it from the instrument and then put it back, so that the barcode is read. It can then be used.

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8.6 Reagent lot master registration

Reagent lot masters can be registered.

1. Press **Reagent Lot Master** on the settings screen.
   The reagent lot master registration dialog box appears.

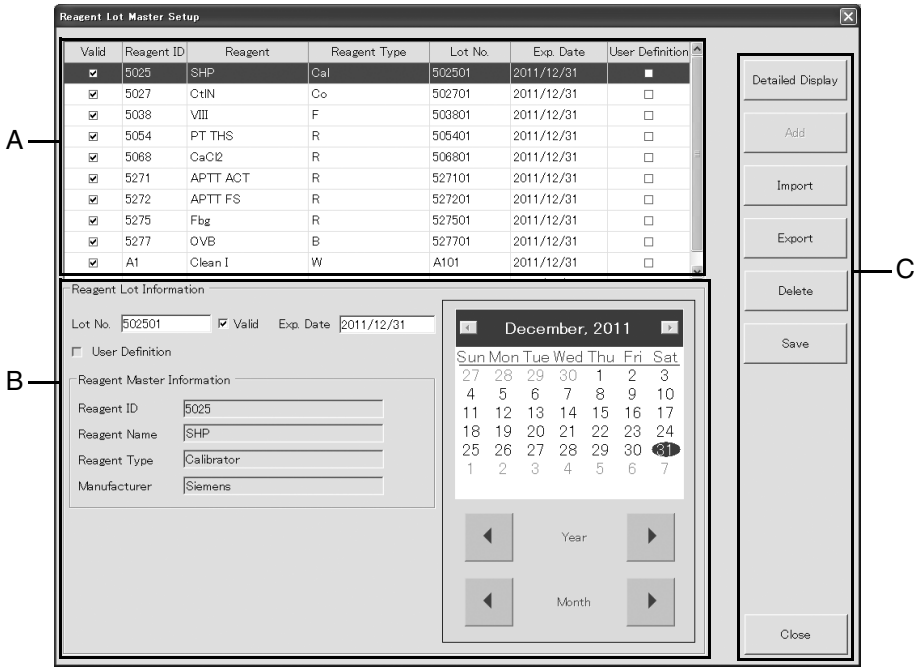

Figure 8-27: Reagent lot master registration dialog box

A Reagent lot list
The list of reagent lots is displayed.

B Reagent lot information
Information for the reagent selected in the reagent lot list is displayed.

Lot No. — Set the reagent lot number using up to six alphanumeric characters.

> **Note:**
> Alphanumeric characters are only A-Z, a-z, and 0-9. Localized characters cannot be input.

Valid — Set whether or not to display this reagent lot on other screens (the reagent screen and the reagent lot selection dialog box). Add a check mark to display the reagent lot. Remove the check mark to avoid displaying it.

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Exp. Date	Set the expiration date of the reagent. The setting range is up to 2037/12/31 (yyyy/mm/dd). Set in date order.
User Definition	The display indicates whether or not the set information has been edited by a user. If it has been edited, the system automatically judges so and adds a check mark. No check mark is added if the information was not edited.
Reagent ID	The reagent ID of the reagent master information under the set lot number is displayed.
Reagent Name	The reagent name of the reagent master information under the set lot number is displayed.
Reagent Type	The reagent type of the reagent master information under the set lot number is displayed.
Manufacturer	The reagent manufacturer of the reagent master information under the set lot number is displayed.

C Operation Panel area

Detailed Display	Display the detailed reagent information read from the reagent barcode.
Add	Add a line below the line selected in the reagent lot list.
Copy	Copy the content of the line selected in the reagent lot list, then add a line.
Print	Print a table of the reagent lot list.
Import	The Open dialog box will appear. The reagent lot list previously output to external storage device using the export function can be loaded.
Export	The Save As dialog box will be displayed. This function outputs the selected reagent lot list to external storage device.
Delete	The deletion confirmation dialog box for the line selected in the reagent lot list is displayed. Press **OK** to delete the selected line. Press **Cancel** to avoid deleting the selection.
Save	Register the content edited in the reagent lot information display/editing area.
Close	Close the reagent lot master registration screen and return to the next higher screen.

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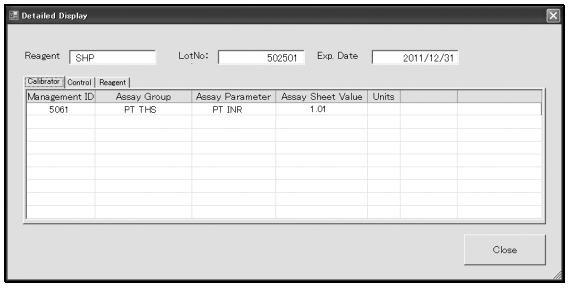
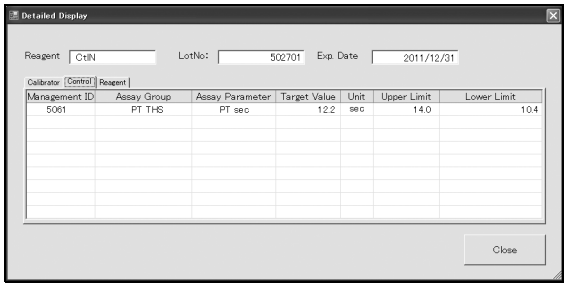
1. Displaying detailed reagent information

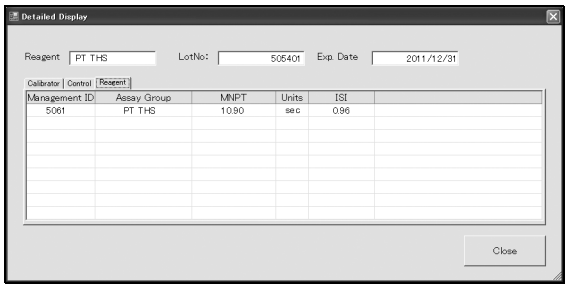
1. Select the reagent lot you wish to display the detailed information from the reagent lot list.
2. Press **Detailed Display**.
   One of the following detailed reagent information dialog boxes is displayed depending on the reagent type.



(when the reagent type is “Calibrator”)



(when the reagent type is “Control”)



(when the reagent type is “Reagent”)

Figure 8-28: Detailed Display dialog box

Reagent	The reagent name read from the barcode is displayed.
LotNo	The reagent lot number read from the barcode is displayed.
Exp. Date	The expiration date of the reagent read from the barcode is displayed.
Management ID	The Management ID of the assay group read from the barcode is displayed.
Assay Group	The assay group name corresponding to the Management ID is displayed. “-” is displayed when there is no assay group registered under assay group settings that corresponds to the Management ID.
Assay Parameter	The assay parameter name registered in the assay group is displayed. “-” is also displayed for the assay parameter while “-” is displayed for the assay group.
Unit(s)	Units set under the assay parameter settings are displayed.

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Assay Sheet Value	The display value read from the barcode is displayed. The display value is displayed only when the reagent type is “Calibrator”.
Target Value	The target value read from the barcode is displayed. The target value is displayed only when the reagent type is “Control”.
Upper Limit	The upper limit value read from the barcode is displayed. The upper limit value is displayed only when the reagent type is “Control”.
Lower Limit	The lower limit value read from the barcode is displayed. The lower limit value is displayed only when the reagent type is “Control”.
MNPT	The MNPT value read from the barcode is displayed. The MNPT value is displayed only when the reagent type is “Reagent”.
ISI	The ISI value read from the barcode is displayed. The ISI value is displayed only when the reagent type is “Reagent”.

2. Add reagent lot information

1. Set the necessary parameters for the added reagent lot.
2. Press **Add**. A line is added to the reagent lot list.

3. Edit reagent lot information

1. Select the reagent lot to edit from the reagent lot list.
2. Set the parameters.
3. Press **Save**.

4. Copy reagent lot information

1. Select the reagent to copy from the reagent lot list.
2. Press **Copy**.
   A line is added to the reagent lot list and the information from the selected line is copied into it.

5. Backing up reagent lot information

The reagent lot information selected in the reagent lot list can be saved to a file.

1. Select the reagent lot to export from the reagent lot list.
2. Press **Export**.
   The Save As dialog box will be displayed.
3. Specify the location and file name to save, then press **Save**.

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6. Loading reagent lot information

1. Press **Import** in the Reagent lot master registration dialog box.
   The Select Import Method dialog box is displayed.

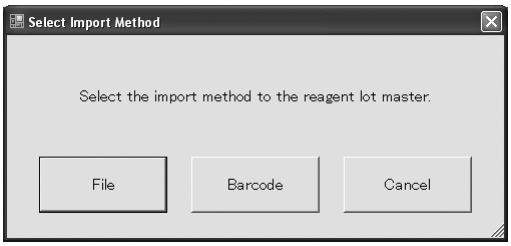
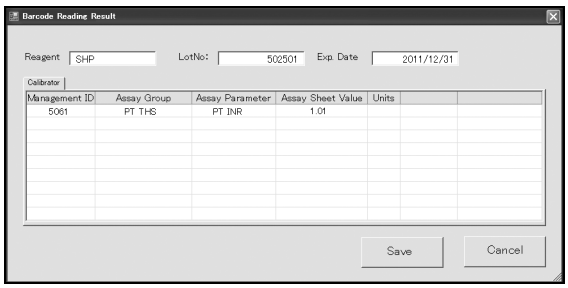
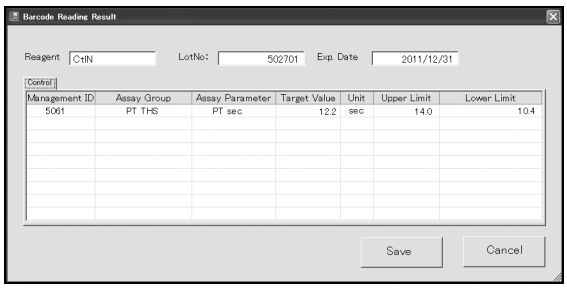


Figure 8-29: Select Import Method dialog box

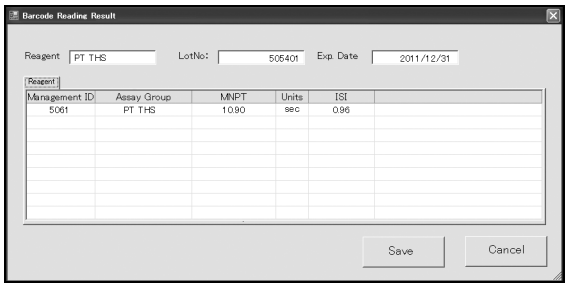
2. Press **File** or **Barcode**.
   The File Selection dialog box appears when **File** is pressed.
   The barcode read dialog box appears when **Barcode** is pressed.
3. When **File** is pressed, specify the file to load, then press **Open**. When **Barcode** is pressed, the barcode is read.
   One of the following Barcode Reading Result dialog boxes appears depending on the read reagent type after reading the barcode.



(for “Calibrator”)



(for “Control”)



(for “Reagent”)

Figure 8-30: Barcode Reading Result dialog box

4. Check the reading result, then press **Save**.
   The reading result is saved. Press **Cancel** not to save the reading result.

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Note:
If the same reagent lot as the one read by the barcode has already been registered, a confirmation message appears asking if the reagent lot master is overwritten.
Press **OK** to save the barcode reading result in the reagent lot master.
Press **Cancel** not to save the barcode reading result.

7. Deleting a reagent lot

1. Select the reagent to delete from the reagent lot list.
2. Press **Delete**.
   The delete confirmation dialog box appears.
3. Press **OK**.
   The selected line will be deleted.
   Press **Cancel** to avoid deleting the selection.

Note:
Reagent information is stored in the instrument when the reagent is placed in the reagent holder. To carry on using a reagent for which the reagent lot master setting has changed, remove it from the instrument and then put it back, so that the barcode is read. It can then be used.

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8.7 Overview of assay group settings

Settings can be made for assay groups.

Caution!

- It may not be possible to obtain correct analysis results if the assay group settings are changed.
  The operator is personally responsible for any such changes.
  Furthermore, the warranty for this product only covers use of the factory default settings of assay groups with the management ID of 0 to 19999. The manufacturer's recommended settings are protected by the management ID and cannot be changed. Settings that cannot be changed are displayed in blue.
- Do not change assay group settings during the analysis. Doing so may affect the analysis results or cause the analysis to be disabled.
- The IPU and the Main Unit must be restarted after assay group settings are changed. The new settings become effective after the system has been restarted.

Note:

- Parameters which can be changed are limited according to permissions of logon users.
- During changes to assay group settings, a warning dialog box is displayed if another assay group is selected without registering the changes.
  Press **OK** to register the changes and switch the selection.
  If the user presses **Cancel**, the selection will switch without registering the changes (discards them).
  Press **Continue** to return to the assay group that is being set.

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1. Press **Assay Setting** on the setting screen.
   The assay group setting dialog box will appear.

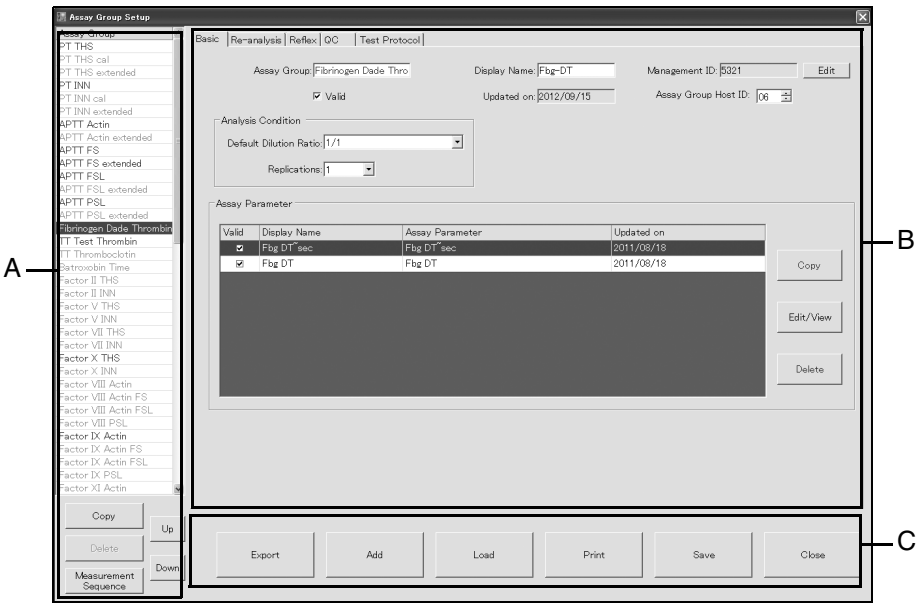

Figure 8-31: Assay group setup dialog box

A List of assay groups

All registered assay groups are displayed. When the dialog box is displayed, the top assay group is selected. Up to 35 lines can be displayed on one page. This is the same display order even when the assay group list is displayed for another function. If the selection is changed to another assay group while the settings are being changed for another, the selection change warning dialog box is displayed to allow the user to choose whether or not to register the changes.

Copy	Copies the selected assay group in the list of assay groups and creates an assay group having the same contents.
Delete	Deletes the assay group selected in the assay group list. The deletion confirmation dialog box is displayed before the deletion is carried out.
Up	Moves the selected assay group in the list of assay groups to one line higher.
Down	Moves the selected assay group in the list of assay groups to one line lower.
Measurement Sequence	Change the order sequence of assay group.

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B Setting area
This area is used for making settings for the assay group selected in the assay group list. The area is composed of multiple tabs. When the dialog box is displayed, the contents of its leftmost tab is on display.

Basic tab	This is the tab for making basic settings for the assay group.
Reflex tab	This is the tab for making reflex settings for the assay group.
Re-Analysis tab	This is the tab for making repeat analysis settings for the assay group.
QC tab	This is the tab for making QC settings for the assay group.
Test Protocol tab	This is the tab for making test protocol settings for the assay group.

C Setting button area
Buttons are arranged in this area for making overall operations on the system settings.

Export	The Save As dialog box will appear. Outputs the selected assay group to an external storage device.
Add	The File Selection dialog box will appear. Adds the assay group information loaded from a file. (Adding new assay groups)
Load	The File Selection dialog box will appear. Overwrites the assay group information loaded from a file to any existing assay group. (Updating existing assay groups)
Print	Prints the content of settings for the assay groups selected in the list of assay groups.
Save	The changes in content are registered.
Close	Closes the Assay Group Setup dialog box and returns to the next higher screen.

2. Select the assay group set in the assay group list.
3. Make the necessary settings in each tab. For the settings in each tab, see “Chapter 8: 8.8 Basic settings”-“Chapter 8: 8.12 Test protocol settings”.
4. Press **Save**.
5. Press **Close**.
   A dialog box appears asking for a restart.
6. Press **OK**.
   Register the settings made using the assay group setup dialog box.

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1. Copying assay groups

1. Select the assay group to copy from the assay group list in the Assay Group Setup dialog box, then press **Copy**.
   The Confirmation dialog box is displayed. A Management ID of the assay group in user definitions that has already been assigned is automatically increased by one.
2. Press **OK**.

2. Deleting assay groups

1. Select the assay group to delete from the assay group list in the assay group settings dialog, then press **Delete**.
   The Confirmation dialog box will appear.
2. Press **OK**.

3. Change the order sequence of assay group

1. Press **Measurement Sequence**
   The Measurement Sequence dialog box will appear.

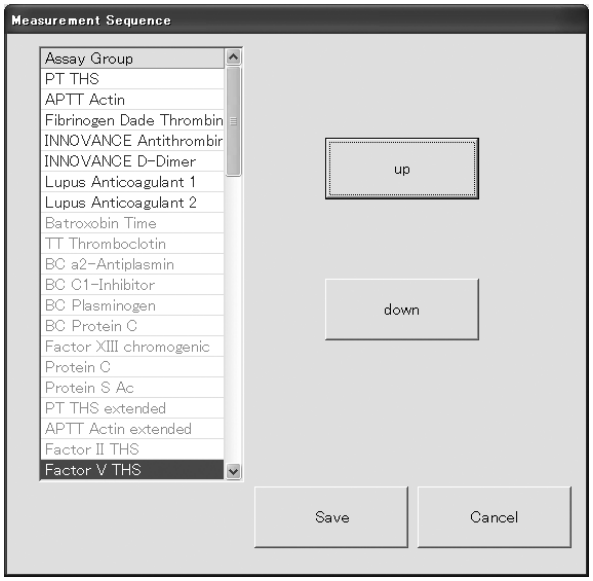

Figure 8-32: Measurement Sequence dialog box

2. Change the order sequence of assay group with **up** or **down**.
3. Press **Save**.

Note:
A throughput will be influenced if the measurement sequence is changed.
The operator is personally responsible for any such changes.

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4. Exporting assay groups

1. Select the assay group to export from the assay group list in the Assay Group Setup dialog box, then press **Export**.
   The Save As dialog box will appear.
2. Specify the location and file name to save, then press **OK**.

5. Adding assay groups

1. Press **Add**.
   The File Selection dialog box will appear.
2. Select the file to add and press **OK**.
3. Select the method for adding the file in the Confirmation dialog box.

6. Loading assay groups (Updating assay groups)

1. Select the assay group from the assay group list in the Assay Group Setup dialog box which to a file is loaded, then press **Load**.
   The File Selection dialog box will appear.
2. Select the file to load and press **OK**.
3. Select the method for loading the file in the Confirmation dialog box.

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8.8 Basic settings

The basic settings tab of the assay group setting dialog can be used to make basic settings for the assay group selected in the assay group list.

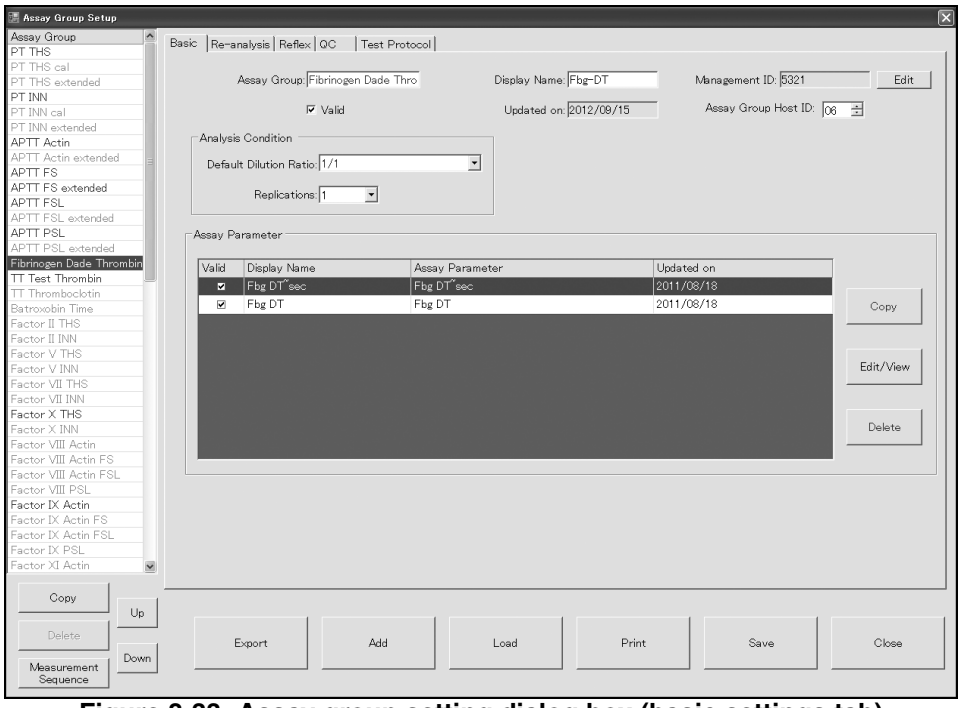

Figure 8-33: Assay group setting dialog box (basic settings tab)

Assay Group The assay group name is displayed.

Note:
Only alphanumeric characters, "-" (hyphen) and "( )" (brackets) can be used in the assay group name.

Display Name The display name of the assay group is displayed. The display name is the one used as the assay group name in other functions.

Management ID The Management ID of the assay group is displayed. Assay groups are divided into the following groups and management ID is assigned to each group.

Table 8-04: Management ID Groups

Group	Management ID
Assay groups set by the manufacturer	0 - 19999
Assay groups set by the customer	20000 - 99999

Edit Displays the dialog box for confirming changes in management ID.

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Valid	Set whether or not to make the assay group valid. It can be used for analysis if it is valid. Add a check mark to make it valid. Remove the check mark to invalidate the assay group.
Updated on	The updated date of the assay group is displayed. The format of display is determined by the system setting. When the updated date of assay parameters within the assay group is updated, the updated date of the assay group is also updated.
Assay Group Host ID	The host ID of the assay group is displayed. The setting range is 01 – 98. The search of the host is carried out using the assay group host ID and the assay parameter host ID.

Note:

00 and 99 cannot be set because they are used as special ID numbers specified by the host computer when it performs an order inquiry.

00: This ID indicates that the analysis assay group for the sample that is the subject of the inquiry is not on the host computer, so the sample should not be analyzed and analysis should move on to the next sample.

99: This ID indicates that information on the sample that is the subject of the inquiry cannot be found on the host computer, so the sample should not be analyzed and subsequent analyses should be stopped.

Analysis Condition

Default Dilution Ratio	The default dilution ratio or dilution series at the time of performing analysis can be selected. The dilution ratios can be set under the test protocol settings.
Replications	The number of replications for analysis can be selected. The selection range is 1 – 2 times.

Assay Parameter

Valid	Assay parameters in the assay group are indicated as either valid or invalid.
Display Name	The display name for the assay parameter is displayed
Assay Parameter	The assay parameter name is displayed.
Updated on	The update date for the assay parameter is displayed. The format of display is determined by the system setting.
Copy	The assay parameter selected in the assay parameters list is copied to create the same parameter in the list.
Edit/View	The assay parameter settings dialog is displayed to edit the assay parameter settings selected in the assay parameter list.
Delete	Delete the assay parameter selected in the assay parameter list.

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Note:
Only alphanumeric characters, "-" (hyphen) and "( )" (brackets) can be used in the assay parameter name.

1. Assay parameter settings

Settings can be made for assay parameters.

Add/edit assay parameters

1. To add an assay parameter, press **Add** in the assay parameters for the basic settings tab. To edit a registered assay parameter, select the assay parameter to edit, then press **Edit**.
   The assay parameter settings dialog box will appear.

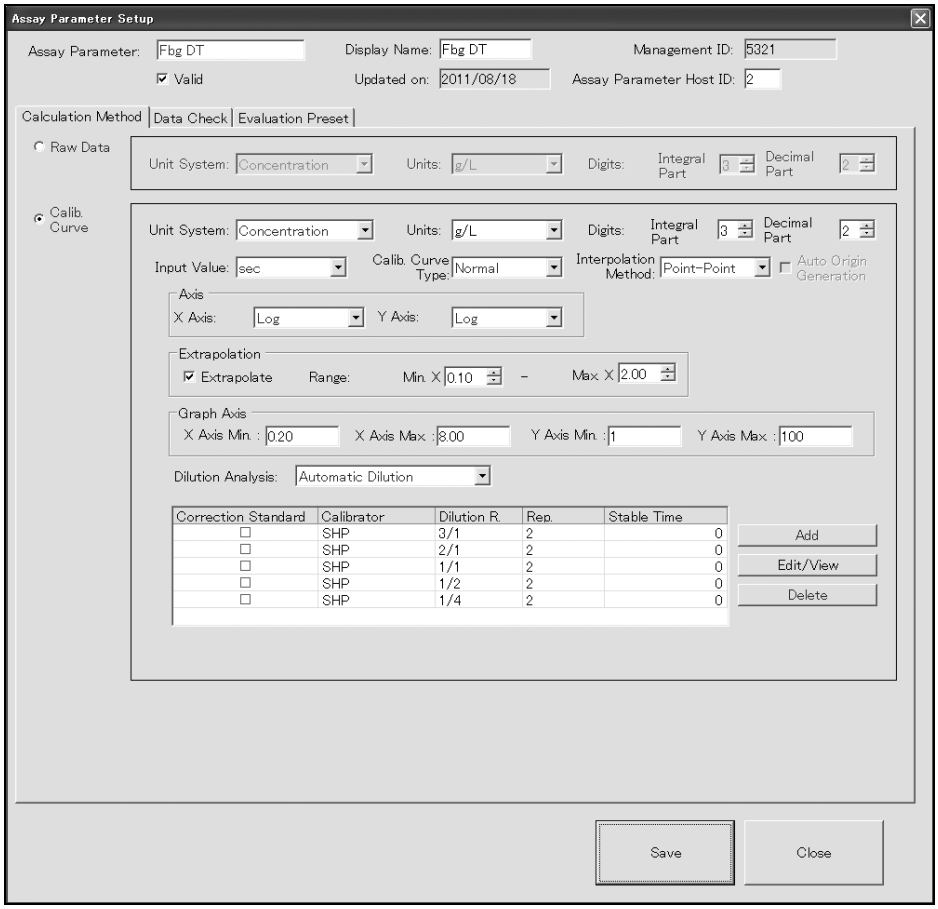

Figure 8-34: Assay parameter settings dialog box

Assay Parameter	The assay parameter name is displayed.
Display Name	The display name for the assay parameter is displayed. The display name is the one used as the assay parameter name in other functions.
Management ID	The Management ID of the assay group is displayed.

Valid	Set whether or not to make the assay parameter valid. It can be used for analysis if it is valid. Add a check mark to make it valid. Remove the check mark to invalidate it.

Caution!
Changing the settings for whether assay parameters are valid or invalid may prevent the transfer of correct analysis results to the host computer. If the valid/invalid settings for assay parameters have been changed, change the settings on the host computer as well, and confirm that the analysis results are transferred to the host computer correctly.

Updated on	The update date for the assay parameter is displayed. The format of display is determined by the system setting.
Assay Parameter Host ID	Set the host ID for the assay parameters. The setting range is 1 – 5. The search of the host is carried out using the assay group host ID and the assay parameter host ID.
Calculation Method tab	Set the calculation methods for the assay parameters.
Data Check tab	Set the data check methods for the assay parameters.
Evaluation Preset Tab	Makes detailed parameter settings for data analysis.

2. Set the parameters.
   For the calculation method tab, see “Chapter 8: 8.8: 1.: Calculation method settings”.
   For the data check tab, see “Chapter 8: 8.8: 1.: Data check settings”.
3. Press **Save**.
   Register the settings and close the assay group setting dialog box. If the assay parameter setting has been changed, the registration confirmation dialog is displayed. So press **OK**.
   Press **Cancel** to cancel the changes made in the assay parameter settings and close the assay parameter settings dialog box. The confirmation dialog box appears if assay parameter settings have been changed.

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Calculation method settings

Settings can be made for the assay parameter calculation method from the calculation method tab.

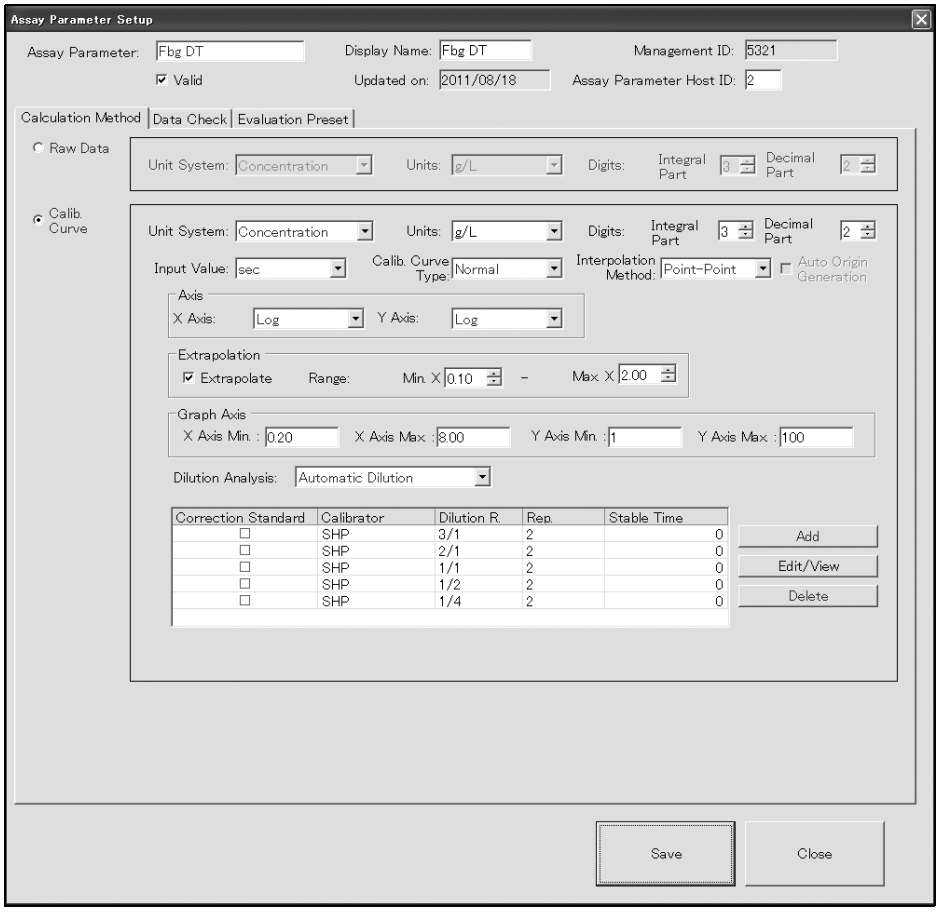

Figure 8-35: Assay parameter settings dialog box (calculation method tab)

Raw Data

Unit System — Select the units for using raw data as parameters, from **Clot Time, change in light absorbance quantity, activity%**, **concentration**, **ratio** and **INR value**.

Units — Select the units for using raw data as parameters, from **-**, **sec**, **dOD**, **%**, **mg/dL**, **g/L**, **U/mL**, **µg/mL**, **ng/mL**, **µg/L**, **mg/L**, **IU/mL** and **FEU**.

Digits

Integral Part — When raw data is displayed, the number of integer digits can be set in the range 1 – 5.

Decimal Part — When raw data is displayed, the number of decimal place digits can be set in the range 0 – 4.

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Caution!
- When using **CA-1000**, **CA-1500** or **PC-DPS(C)** as **Format**, contact your local representative. If the host computer processes the following actions, the receivable number of digits may become less than those of analysis results, causing incorrect analysis results to appear on the host computer display.
  - Ignores one high-order digit of the transmission data to receive only four low-order digits for **Clot Time**, **dOD**, **activity%** and **concentration**.
  - Ignores two high-order digits of the transmission data to receive only three low-order digits for **ratio** and **INR value**.

Calib. Curve

Unit System Select the units for parameters calculated from calibration curves, from **Clot Time**, **change in light absorbance quantity**, **activity%**, **concentration**, **ratio** and **INR value**.

Units Select the units for parameters calculated from calibration curves, from **-**, **sec**, **dOD**, **OD**, **abs**, **mAbs**, **%**, **mg/dL**, **g/L**, **U/mL**, **µg/mL**, **ng/mL**, **µg/L**, **mg/L**, **IU/mL** and **FEU**.

Digits

Integral Part When parameters calculated from calibration curves are displayed, the number of integer digits can be set in the range 1 – 5.

Decimal Part When parameters calculated from calibration curves are displayed, the number of decimal place digits can be set in the range 0 – 4.

Caution!
- When using **CA-1000**, **CA-1500** or **PC-DPS(C)** as **Format**, contact your local representative. If the host computer processes the following actions, the receivable number of digits may become less than those of analysis results, causing incorrect analysis results to appear on the host computer display.
  - Ignores one high-order digit of the transmission data to receive only four low-order digits for **Clot Time**, **dOD**, **activity%** and **concentration**.
  - Ignores two high-order digits of the transmission data to receive only three low-order digits for **ratio** and **INR value**.

Input Value Select the input values for calibration curves from **sec**, **dOD** and **dH**.

Calib. Curve Type Select the calibration curve type, from **Normal**, **Ratio**, **INR(Normal)** and **INR(ISI Input)**.

Interpolation Method If the calibration curve is replaced by an approximation formula, the interpolation method can be selected, between **none**, **linear** and **broken line**. If the calibration curve type is ratio/INR, interpolation is not used, so **None** should be selected.

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Auto Origin Generation	Set whether or not to plot the calibration curve by automatically adding the (0,0) point. Add a check mark to automatically generate the origin point. Remove the check mark to avoid generating the point.
Axis	
X Axis	Select the type of calibration curve X-axis, between **real**, **relative** and **reverse numbers**.
Y Axis	Select the type of calibration curve Y-axis, between **real**, **relative** and **reverse numbers**.
Extrapolation	
Extrapolate	Set whether or not to use extrapolation of the calibration curve. Add a check mark to allow extrapolation of the calibration curve. At this stage, the extrapolation range must be specified. Remove the check mark to avoid extrapolation.
Range	
Min.	Set the lower limit for extrapolation (the ratio between the minimum value of the setting point for the calibration curve calculation result and the lower limit value for extrapolation).
Max.	Set the upper limit for extrapolation (the ratio between the maximum value of the setting point for the calibration curve calculation result and the upper limit value for extrapolation).
Graph Axis	
X Axis Min.	Set the minimum value for the X-axis display range of the calibration curve graph.
X Axis Max.	Set the maximum value for the X-axis display range of the calibration curve graph.
Y Axis Min.	Set the minimum value for the Y-axis display range of the calibration curve graph.
Y Axis Max.	Set the maximum value for the Y-axis display range of the calibration curve graph.
Dilution Analysis	Choose the dilution method, from **Automatic Dilution** or **Manual Dilution**.
Dilution analysis method list	Up to 12 dilution analyses can be performed.
Correction Standard	Display the point to be used as the standard for 1 Point Correction.
Calibrator	The calibrator name is displayed for the calibrator used in dilution analysis for calibration curves.
Dilution R.	The ratio of dilution for dilution analysis for calibration curves is displayed.
Rep.	The number of replications (1 – 5) for dilution analysis for calibration curves is displayed.

Stable Time	Stable time is displayed. If the calibrator elapsed time exceeds the set stable time, a confirmation dialog box is displayed at the start of analysis.
Add	A new dilution analysis is added to the bottom line of the dilution analysis method list. The dilution settings dialog box will appear. For the addition method, see “Chapter 8: 8.8: 1.: Dilution analysis method settings”.
Edit/View	The dilution settings dialog box is displayed to edit the dilution analyses for the calibrator selected in the dilution analysis method list. For the editing method, see “Chapter 8: 8.8: 1.: Dilution analysis method settings”.
Delete	The dilution analysis for the calibrator selected in the dilution analysis method list is deleted.

1. Select the calculation method, from **Raw Data** and **Calib. Curve**.
2. Set the parameters for the selected calculation method.

Note:
The Correction standard cannot be set when you are logged-on with user right. If you want to it, contact your service representative.

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Dilution analysis method settings

The dilution analysis method for calibration curves can be set.

1. Select **Calib. Curve** from the **Calculation Method** tab and press **Add** in the **Dilution Analysis Method** setting. Press **Edit/View** to edit the registered dilution analysis method.
   The dilution settings dialog box will appear.

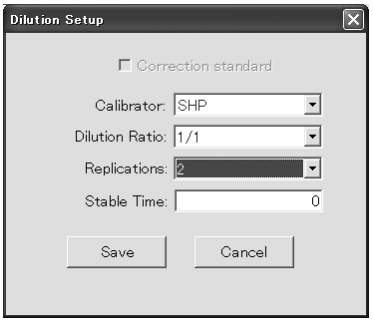

Figure 8-36: Dilution settings dialog box

Correction standard	Display whether or not to use the point as the standard for 1 Point Correction.
Calibrator	The list of calibrators registered in the reagent master is displayed. Select the calibrator to use in the calibration curve dilution analysis.
Dilution Ratio	Either **None** or the list of dilution ratios set under the test protocol is displayed. Select the ratio of dilution at the time of dilution analysis for calibration curves.
Replications	Select the number of replications at the time of dilution analysis for calibration curves. Select in the range 1 – 5 times.
Stable Time [h]	Input the stable time. If the calibrator elapsed time exceeds the set stable time, a confirmation dialog box is displayed at the start of analysis.

2. Press **Save** after setting each parameter.
   Save the settings of the calibration curve dilution settings dialog box and close the dialog box.
   Press **Cancel** to cancel settings and close the calibration curve dilution settings dialog box.

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Data check settings

Assay parameter data checking settings can be made from the data check tab.

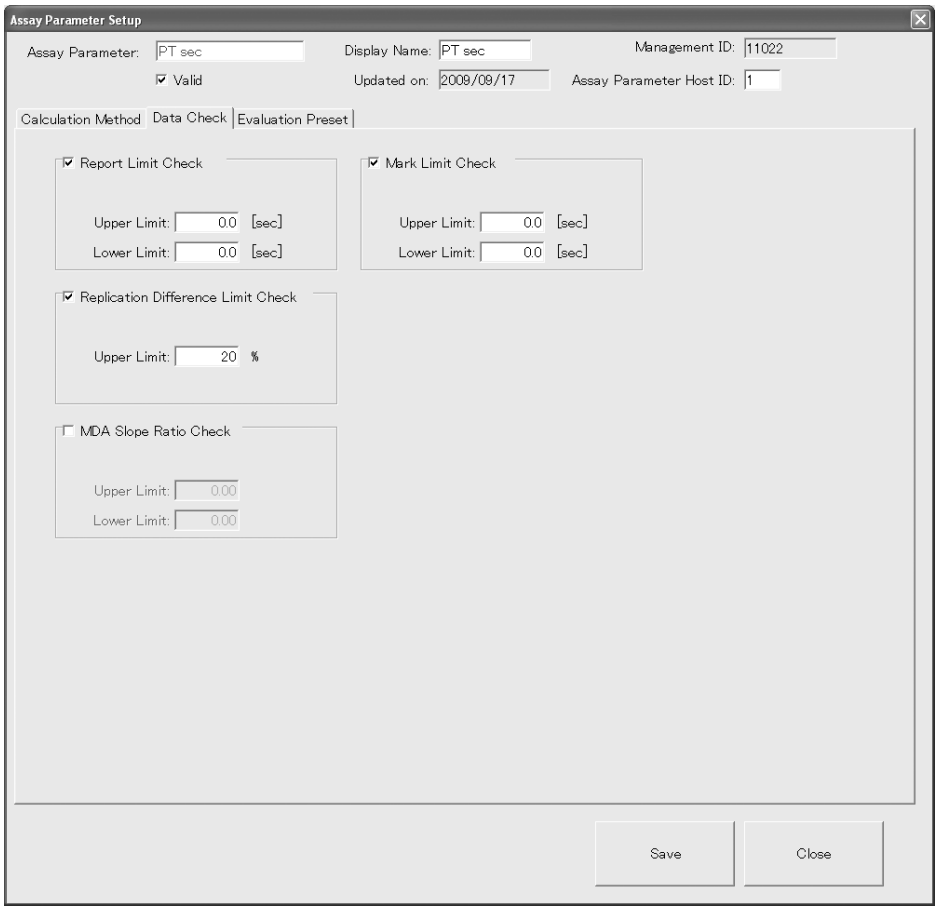

Figure 8-37: Assay parameter settings dialog box (data check tab)

Report Limit Check — Set whether or not to perform report limit judgment (monitoring of the analysis limits of the instrument). Add a check mark to perform the judgment. At this stage, the upper and lower limits must be specified. Remove the check mark to avoid performing the judgment.

Upper Limit — The report limit judgment upper limit value is displayed. The value can be input directly. If this value is exceeded, it triggers a report limit error and a “>” flag is added to the analysis results.

Lower Limit — The report limit judgment lower limit value is displayed. The value can be input directly. If this value falls short of this limit, it triggers a report limit error and a “<” flag is added to the analysis results.

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Mark Limit Check	Set whether or not to perform error limit value judgment. Add a check mark to perform the judgment. At this stage, the upper and lower limit of error judgment must be specified. Remove the check mark to avoid performing the judgment.
Upper Limit	The upper limit value for error limit value judgment is displayed. The value can be input directly. If this value is exceeded, it triggers an error judgment limit value error and a “+” flag is added to the analysis results.
Lower Limit	The lower limit value for error limit value judgment is displayed. The value can be input directly. If the result is below this value, it triggers an error judgment limit value error and a “-” flag is added to the analysis results.
Replication Difference Limit Check	Set whether or not to perform replicate analysis divergence judgment. Add a check mark to perform the judgment. At this stage, the allowable divergence must be specified for the replicate analysis divergence. Remove the check mark to avoid performing the judgment.
Upper Limit	The allowable divergence for replicate analysis divergence judgment is displayed. The value can be input directly. If the allowable value is exceeded, it triggers a replicate analysis divergence judgment error and a “*” flag is added to the analysis result mean value.
MDA Slope Ratio Check	For parameters for which the calculation method is calibration curve, set whether or not to use MDA slope ratio judgment. Add a check mark to perform the analysis. At this stage, the upper and lower limit of MDA slope ratio must be specified. Remove the check mark to avoid doing so.
Upper Limit	The upper limit value for the MDA slope ratio judgment is displayed. The value can be input directly. If this value is exceeded, it triggers an MDA slope ratio error, and a “*” flag is added to the final result of the analysis results.
Lower Limit	The lower limit value for the MDA slope ratio judgment is displayed. The value can be input directly. If this value is not reached, it triggers an MDA slope ratio error, and a “*” flag is added to the final result of the analysis results.

1. Set the parameters.

Note:
A report limit flag takes priority over an error limit judgment value flag.

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Evaluation preset settings

Detailed parameter settings can be made on the Evaluation Preset tab.
The items that are displayed in part C of the screen will vary according to the evaluation algorithm that is selected.

Caution!
It may not be possible to obtain correct analysis results if the evaluation preset settings are changed.
The operator is personally responsible for any such changes.
Furthermore, the warranty for this product only covers use of the factory default settings of assay groups with the management ID of 0 to 19999.

Note:
For details on evaluation presets, contact your local technical representative.

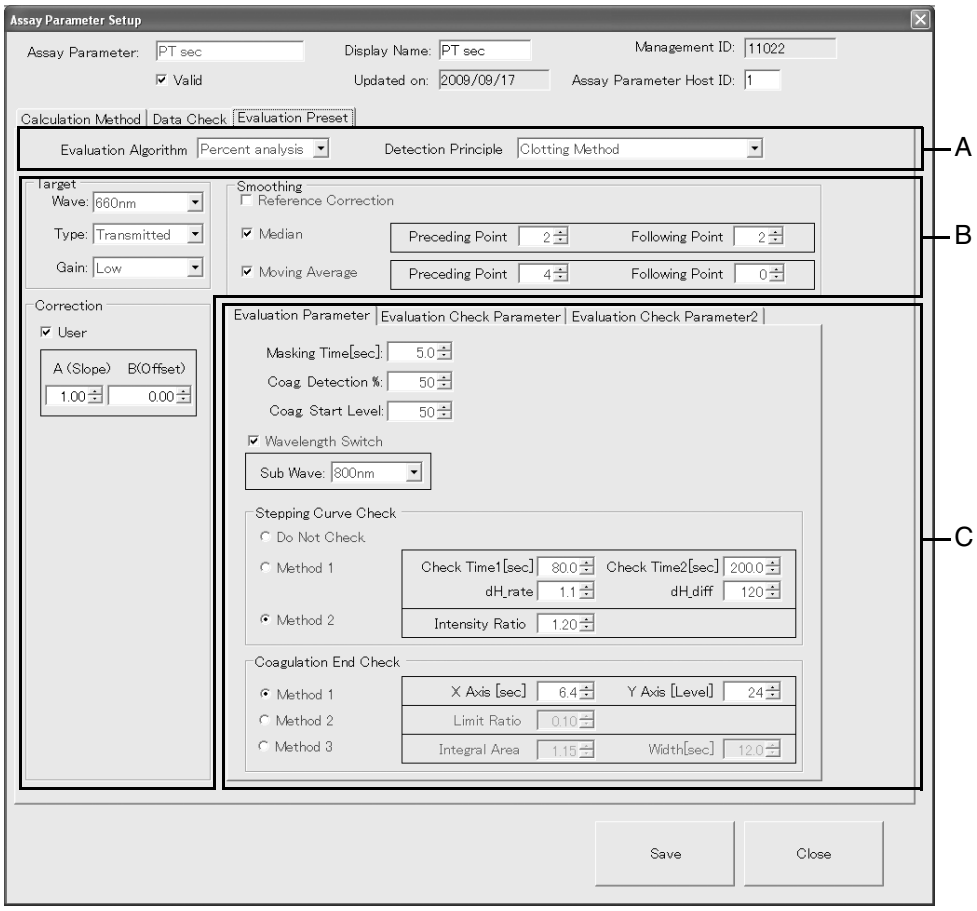

Figure 8-38: Assay Parameter Setup dialog box (Evaluation Preset tab)

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A Header setting area for evaluation presets
Makes settings in the header area for evaluation presets.

Evaluation Algorithm Select an evaluation algorithm from among **Percent analysis**, **Rate analysis** and **VLin analysis**.

Detection Principle Select a detection principle from among **Clotting Method**, **Chromogenic Method** and **Immunoassay Method**.

B Shared parameter settings area
Makes settings of parameters that are shared for all evaluation algorithms.

Target

Wave Select a wavelength from among **405nm**, **575nm** and **660nm**.

Type **Transmitted** is displayed.

Gain Select a gain from between **High** and **Low**.

Smoothing

Reference Correction Sets whether or not to remove oscillation from the light source using Reference filtering. Add a check mark to remove it. Remove the check when not removing it.

Median Sets whether or not to remove sudden noise elements using Median filtering. Add a check mark to remove it. In that case, the following items must be specified. Remove the check when not removing it.
In Median filtering, all the data in the range specified between the **Preceding Point** and the **Following Point** is sorted and the median value is used as data after filtering.

Preceding Point Specify the number of data points (prior to a given point) to include when calculating median values. The setting range is 1 – 10.

Following Point Specify the number of data points (following a given point) to include when calculating median values. The setting range is 1 – 10.

Moving Average Sets whether or not to remove regularly occurring noise elements using Moving averaging filtering. Add a check mark to remove them. In that case, the following items must be specified. Remove the check when not removing them.
In Moving average filtering, the average of data in the range specified between the **Preceding Point** and the **Following Point** is used as data after filtering of a given point.

Preceding Point Specify the number of data points (prior to a given point) to include when calculating moving average values. The setting range is 1 – 10.

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Following Point	Specify the number of data points (following a given point) to include when calculating moving average values. The setting range is 1 – 10.
Correction	The measurement results (coagulation time (sec.) and change in light absorbance (dOD)) can be corrected. Corrected values are calculated with the following formula. Corrected value = (A × measured results) + B
User	Sets whether or not to perform User correction. Add a check mark to perform the correction. In that case, the following items must be specified. Remove the check mark when not performing the correction.
A (Slope)	Sets the slope. The setting range is 0.00 –10.00.
B (Offset)	Sets the offset. The setting range is -10.00 – 10.00 (Percent analysis) or -10.0000 – 10.0000 (Rate analysis/VLin analysis.)

C Individual parameter setting area

Sets individual parameters, which vary with the selected evaluation algorithm.

- When using Percent analysis

① Evaluation parameter settings

Various parameters and the method for calculating coagulation time can be set on the Evaluation Parameter tab.

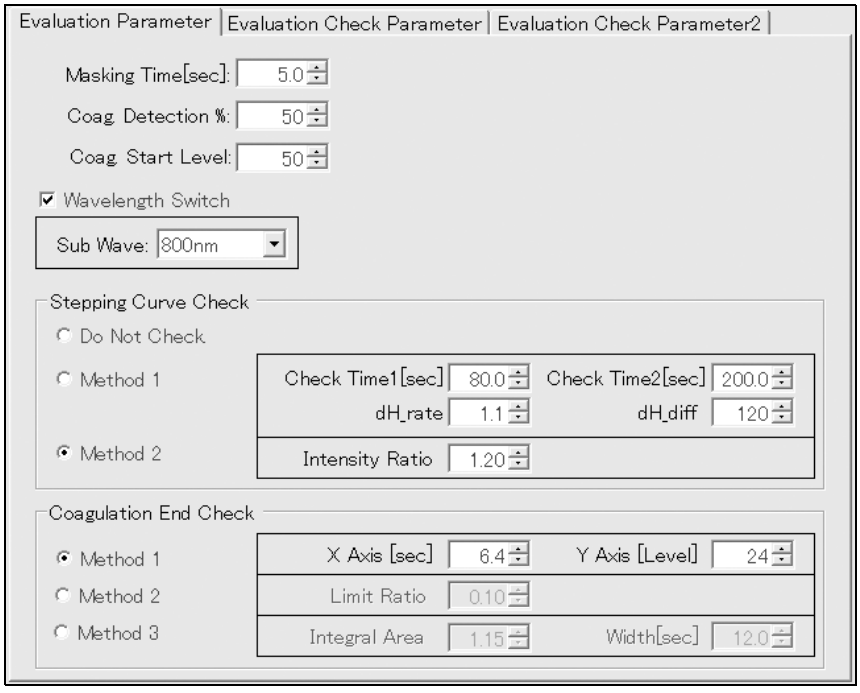

Figure 8-39: Evaluation Parameter tab (Percent analysis)

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MaskingTime [sec] Sets the masking time. The setting range is 0 – 100.0.

Coag. Detection % Sets the percentage value used for detecting the coagulation time. The setting range is 0 – 100.

Coag. Start Level Sets the threshold for the reaction intensity at the start of coagulation reaction. The setting range is 0 – 4095.

Wavelength Switch Sets whether or not to perform changing of wavelengths. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it.

Sub Wave Select a sub-wavelength from among **340nm**, **405nm**, **575nm**, **660nm** and **800nm**.

Stepping Curve Check Select one of the following: **Do Not check**, **Method 1** or **Method 2**.

Do Not check Does not check for two-stage reaction.

Method 1 Judged as an error when the following conditions are fulfilled at the same time.

- If the difference (delta-dH) between the reaction intensity (delta), obtained from **Check Time1** and **Check Time2** respectively, and the reaction intensity (dH) at the coagulation endpoint is greater than **dH_diff**.
- If the reaction intensity rates (delta/dH) of these are greater than **dH_rate**.

The check is conducted only if the coagulation endpoint has already been detected at either the **Check Time1** or **Check Time2**.

Check Time1 [sec] Sets the first check time. The setting range is 0.1 – 3600.0.

Check Time2 [sec] Sets the second check time. The setting range is 0.1 – 3600.0.

dH_rate Sets the threshold value of the rate. The setting range is 0.1 – 10.0.

dH_diff Sets the threshold value of the difference. The setting range is 1 – 1000.

Method 2 Judged as an error when the following conditions are fulfilled.

- The ratio (Ave_delta/dH) of the reaction intensity (dH) at the coagulation endpoint to the difference (Ave_delta) between averaged transmitted light after a coagulation end time (Ave) and a baseline exceeds **Intensity Ratio**.

Intensity Ratio Sets the threshold value of the ratio. The setting range is 0.01 – 10.00.

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Coagulation End Check Select one of the following: **Method 1**, **Method 2** and **Method 3**.

Method 1 If the changes in the amount of transmitted light from the judgment point until it crosses the **X-axis [sec]** is within the **Y-axis [Level]** level, then the judgment point is made the coagulation reaction stop point.

X Axis [sec] Sets the time range of time for reaction stop judgment. The setting range is 0.0 – 3600.0.

Y Axis [Level] Sets the upper limit for the level in changes of the amount of transmitted light. The setting range is 1 – 100.

Method 2 If the ratio (Slope2/Slope1) of the slope (Slope1) in the segment from the coagulation start point to the judgment point and the slope (Slope2) after the judgment point (same width in terms of time as from the coagulation reaction start point to the judgment point) is smaller than the **Limit Ratio**, then the judgment point is made the coagulation reaction end point.

Limit Ratio Sets the threshold value of the change rate. The setting range is 0.01 – 1.00.

Method 3 In the area bounded by the baseline and the reaction curve, areas (S1 and S2), set by **Width [sec]** before and after the judgment point, are calculated.
If the ratio (S2/S1) of the areas before and after is smaller than the **Integral Area**, then the judgment point is made the coagulation reaction stop point.

Integral Area Sets the threshold value of the area ratio. The setting range is 1.00 – 2.00.

Width [sec] Sets the width of the segment for calculating the area. The setting range is 1.0 – 3600.0.

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② Evaluation check parameter settings
Settings for error check judgment values can be made on the Evaluation Check Parameter tab.

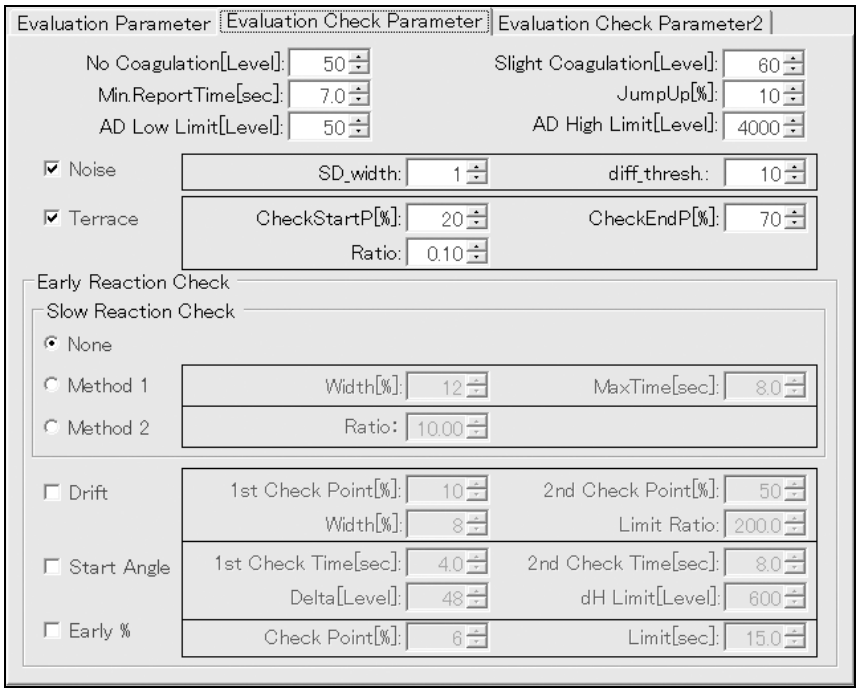

Figure 8-40: Evaluation Check Parameter tab (Percent analysis)

No Coagulation [Level] Sets the threshold value for the No Coagulation check. If the reaction intensity (dH) fails to reach the threshold value, it is judged an error. The setting range is 0 – 4095.

Slight Coagulation [Level] Sets the threshold value for the Slight Coagulation check. If the reaction intensity (dH) fails to reach the threshold value, it is judged an error. The setting range is 0 – 4095.

Min. Report Time [sec] Sets the threshold value for the RangeOver check. If the measurement result (coagulation time) fails to reach the threshold value, it is judged an error. The setting range is 0.0 – 3600.0.

JumpUp [%] Sets the threshold value for the Jump Up check. If the change in coagulation percentage in one given time is equal to or greater than the threshold value, it is judged an error. The setting range is 1 – 100.

AD Low Limit [Level] Sets the threshold value for the Turbidity Level Over check. If the amount of transmitted light detected is equal to or less than the threshold value after the masking time, it is judged an error. The setting range is 0 – 4095.

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AD High Limit [Level] Sets the threshold value for the Trans Light High check. If the amount of transmitted light detected is equal to or greater than the threshold value after the masking time, it is judged an error. The setting range is 0 – 4095.

Noise Sets whether or not to perform a Noise check. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it.
It is judged an error if the difference (diff) between the value (Ave1-nSD1) which is the average (Ave1) of the amount of transmitted light from the masking time to 0% detected time minus the **SD_width** times the standard deviation (SD1), and the value (Ave2 + nSD2) which is the average (Ave2) of the amount of transmitted light after the coagulation end time plus the **SD_width** times the standard deviation (SD2) is less than **diff_thresh**.

- **SD_width** Sets the SD width to check. The setting range is 1 – 100.
- **diff_thresh** Sets the threshold value for judging the difference. The setting range is -4095 – 4095.

Terrace Sets whether or not to perform a Terrace check. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it.
It is judged an error if, in a segment from the **CheckStartP** to **CheckEndP**, the ratio (Time/All Time) between the time (Time) required for the coagulation percent to rise 1% and the time (All Time) between coagulation 1% to 100% is equal to or greater than the **Ratio**.

- **CheckStartP [%]** Sets the percent of coagulation to start the check. The setting range is 1 – 100.
- **CheckEndP [%]** Sets the percent of coagulation to end the check. The setting range is 1 – 100.
- **Ratio** Sets the threshold value for judging the time ratio. The setting range is 0.00 – 1.00.

Early Reaction Check

- **Slow Reaction Check** Selects **None**, **Method 1** or **Method 2**.
  - **None** Does not perform Slow Reaction Check.
  - **Method 1** It is judged an error if the reaction time (Time2 - Time1) in the **Width** segment centered on the coagulation detection % is equal to or greater than the **MaxTime**.
    - **Width [%]** Sets the check width. The setting range is 1 – 100.

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MaxTime [sec]	Sets the threshold value to be judged. The setting range is 0.0 – 3600.0.
Method 2	It is judged an error if error judgment conditions in **Method 1** are fulfilled and if the reaction time ratio is lower than the **Ratio** value before the time required for coagulation.
Ratio	Sets the threshold value for judging the reaction time ratio. The setting range is 1.00 - 100.00.
Drift	Sets whether or not to perform a Drift check. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it. It is judged an error if the ratio (dT1/dT2) of the reaction times (dT1 and dT2) in the **Width** segments centered on each of the initial 2 points (**1st Check Point** and **2nd Check Point**) in the coagulation reaction is less than the **Limit Ratio**/100.
1st Check Point [%]	Sets the coagulation % of the 1st checkpoint. The setting range is 1 – 100.
2nd Check Point [%]	Sets the coagulation % of the 2nd checkpoint. The setting range is 1 – 100.
Width [%]	Sets the check width. The setting range is 1 – 100.
Limit Ratio	Sets the threshold value to be judged. The setting range is 0.0 – 1000.0.
Start Angle	Sets whether or not to perform a Start Angle check. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it. It is judged an error if the difference in the reaction intensities (dH1 and dH2) in the initial coagulation reaction (**1st Check Time** and **2nd Check Time**) is equal to or greater than **Delta**. If a reaction intensity (dH) of measured results is equal to or less than the **dH Limit**, then it is judged a StartAngle1 error, if greater than the **dH Limit**, then it is a StartAngle2 error.
1st Check Time [sec]	Sets the first check time. The setting range is 0.0 – 3600.0.
2nd Check Time [sec]	Sets the second check time. The setting range is 0.0 – 3600.0.
Delta [Level]	Sets the threshold value for judging the difference. The setting range is 0 – 4095.
dH Limit [Level]	Sets the threshold value for judging the reaction intensity. The setting range is 0 – 4095.

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Early % Sets whether or not to perform an Early % check. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it.
It is judged an error if the time (Time) in the **Check Point** is less than the **Limit**.

Check Point [%] Sets the coagulation % of the checkpoint. The setting range is 1 – 100.

Limit [sec] Sets the threshold value to be judged. The setting range is 0.0 – 3600.0.

③ Evaluation check parameter2 settings
Settings for error check judgment values can be made on the Evaluation Check Parameter2 tab.

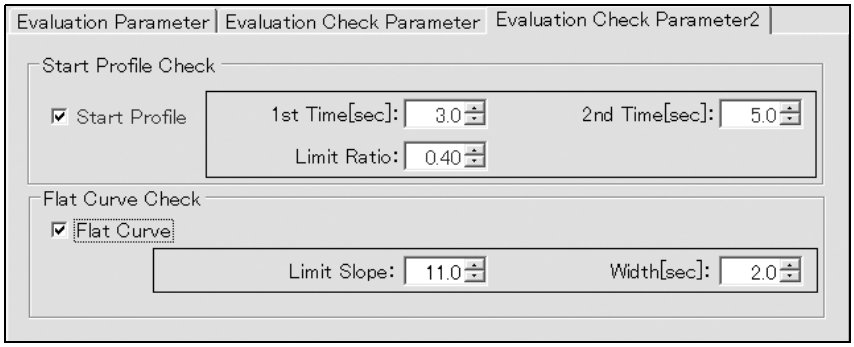

Figure 8-41: Evaluation Check Parameter2 tab (Percent analysis)

Start Profile Check

Start Profile Sets whether or not to perform a Start Profile check. Add a check mark when performing it. When doing so, the following items must be specified. Remove the check mark when not performing it.
Assumes that the decreased amount of transmitted light in the initial coagulation reaction (**1st Time** and **2nd Time**) is Delta and reaction intensity is dH. It is judged an error if Delta/dH is equal to or greater than **Limit Ratio**.

1st Time[sec] Sets the first check time. The setting range is 1.8 - 3600.0.

2nd Time[sec] Sets the second check time. The setting range is 1.8 - 3600.0.

Limit Ratio Sets the threshold value to be judged. The setting range is 0.00 - 1.00.

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Flat Curve Check

Flat Curve	Sets whether or not to perform a Flat Curve check. Add a check mark to perform it. When doing so, the following items must be specified. Remove the check mark when not performing it.
Limit Slope	Sets the threshold value to be judged for Flat Curve check. The setting range is 0.0 - 999.9.
Width[sec]	Sets the width of a segment to calculate the slope of transmitted light intensity centered upon the coagulation point. The setting range is 2.0 - 6.0.

- When using Rate analysis

① Evaluation parameter settings
Parameters for finding the dOD can be set on the Evaluation Parameter tab.

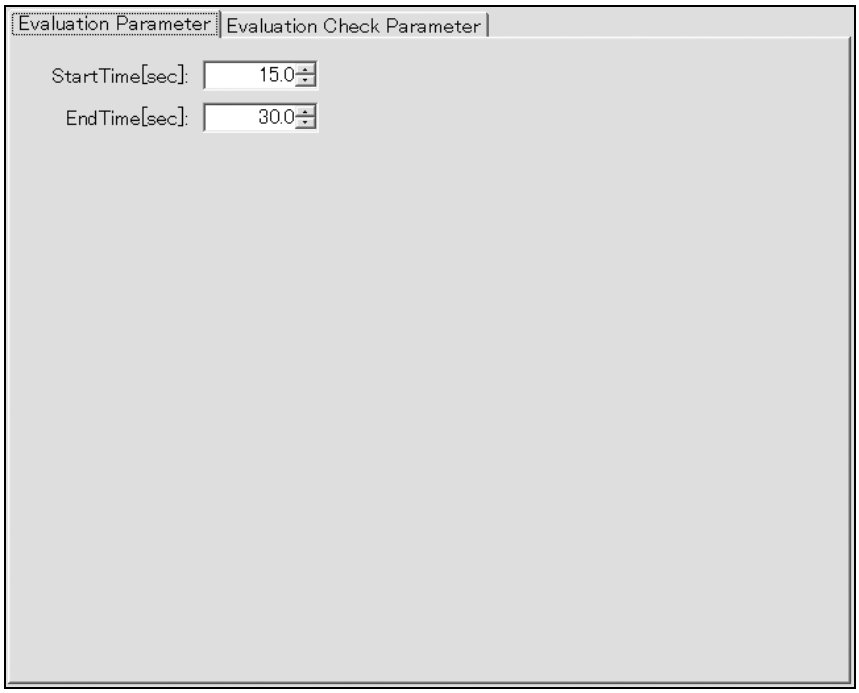

Figure 8-42: Evaluation Parameter Tab (Rate analysis)

StartTime [sec]	Sets the start time. The setting range is 0.0 – 3600.0.
EndTime [sec]	Sets the end time. The setting range is 0.0 – 3600.0.

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② Evaluation check parameter settings
Settings for error check judgment values can be made on the Evaluation Check Parameter tab.

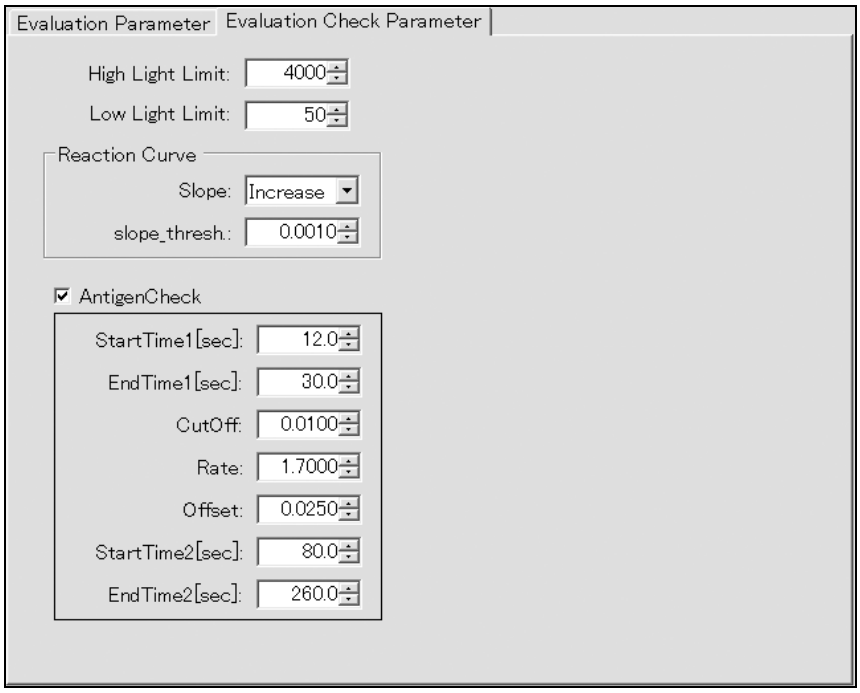

Figure 8-43: Evaluation Check Parameter tab (Rate analysis)

High Light Limit — Sets the threshold value for the Trans Light High check. It is judged an error if in the interval between the **StartTime** and the **EndTime** the amount of transmitted light detected exceeds the threshold. The setting range is 0 – 4095.

Low Light Limit — Sets the threshold value for the Trans Light low check. It is judged an error if in the interval between the **StartTime** and the **EndTime** the amount of transmitted light detected goes below the threshold. The setting range is 0 – 4095.

Reaction Curve — It is judged an error if the change in light absorbance during the period from the **StartTime** to the **EndTime** is equal to or greater than the **slope_thresh** as well as if the change in direction (whether increasing or decreasing) is different from the **slope**.

Slope — Select a change (slope) in light absorbance from between **Increase** and **Decrease**.

slope_thresh — Sets the threshold for the change in light absorbance. The setting range is 0.0000 – 10.0000.

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AntigenCheck

Sets whether or not to perform an Antigen Excess check. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it.
If the antigen (or antibody) concentration is extremely high in an antigen antibody reaction, the reaction may be suppressed. In such a case, in conjunction with the increase in antigen concentration, there is a decrease in the change in light absorbance, and the measured results may be lower than the actual antigen concentration. This check detects this kind of antigen excess. It is judged an error if the following conditions line up.

- When SlopeB is equal/greater than the CutOff
  SlopeA ≥ (**Rate** × **SlopeB** + **Offset**)
- When SlopeB does not reach the CutOff
  SlopeA ≥ (**Rate** × **CutOff** + **Offset**)

  SlopeA: Amount of change in light absorbance in unstable area

  SlopeB: Amount of change in light absorbance in linear range

StartTime1 [sec]

Sets the start time for the unstable range. The setting range is 0.0 – 3600.0.

EndTime1 [sec]

Sets the end time for the unstable range. The setting range is 0.0 – 3600.0.

CutOff

Sets the CutOff threshold for antigen excess. The setting range is 0.0000 – 9.9999.

Rate

Sets the Rate for antigen excess. The setting range is -9.9999 – 9.9999.

Offset

Sets the Offset threshold for antigen excess. The setting range is -9.9999 – 9.9999.

StartTime2 [sec]

Sets the start time for the linear range. The setting range is 0.0 – 3600.0.

EndTime2 [sec]

Sets the end time for the linear range. The setting range is 0.0 – 3600.0.

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● When using VLin analysis

① Evaluation parameter settings
Parameters for finding the dOD can be set on the Evaluation Parameter tab.

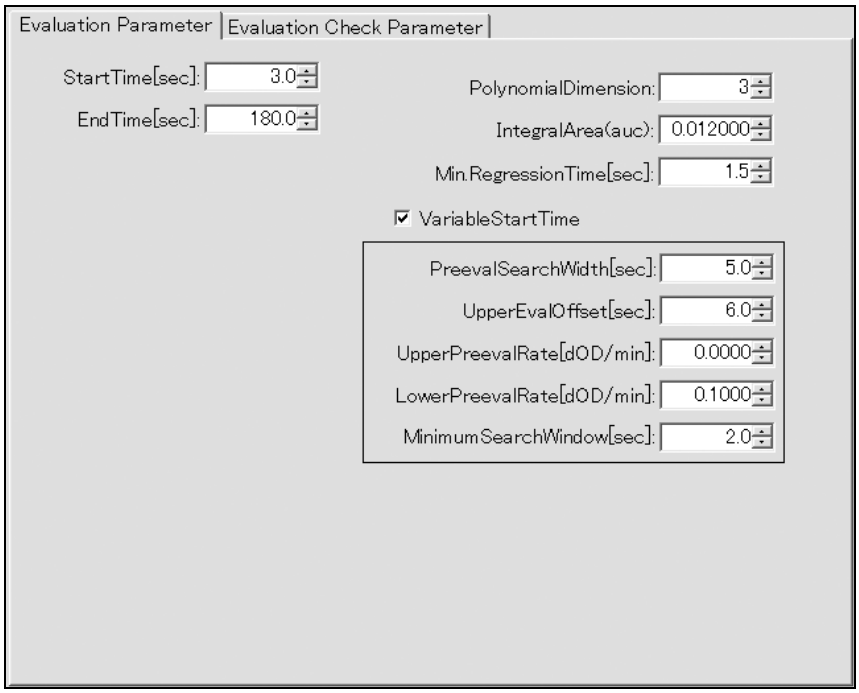

Figure 8-44: Evaluation Parameter tab (VLin analysis)

StartTime [sec]	Sets the start time. The setting range is 0.0 – 3600.0.
EndTime [sec]	Sets the end time. The setting range is 0.0 – 3600.0.
PolynomialDimension	Sets the next number in the polynomial dimension. The setting range is 2 – 9.
IntegralArea(auc)	Sets the error threshold when finding the linear range. The setting range is -9.999999 – 9.999999.
Min. RegressionTime [sec]	Sets the minimum interval of time for finding the maximum reaction speed. The setting range is 0.0 – 3600.0.
VariableStartTime	Sets whether or not to perform the calculation of variable start time. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it. Variable start times are calculated under the following parameters, and the start times of polynomial dimension are retarded.
PreevalSearchWidth [sec]	Sets the Pre-evaluation search width. The setting range is 0.0 – 3600.0.
UpperEvalOffset [sec]	Sets the upper limit for variable start times. The setting range is 0.0 – 3600.0.

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UpperPreevalRate [dOD/min]	Sets the upper limit for the slope. The setting range is -9.999999 – 9.999999.
LowerPreevalRate [dOD/min]	Sets the lower limit of the slope. The setting range is -9.999999 – 9.999999.
Minimum SearchWindow [sec]	Sets the time range for finding the minimum reaction speed. The setting range is 0.0 – 3600.0.

② Evaluation check parameter settings
The judgment values for error checks can be set on the Evaluation Check Parameter tab.

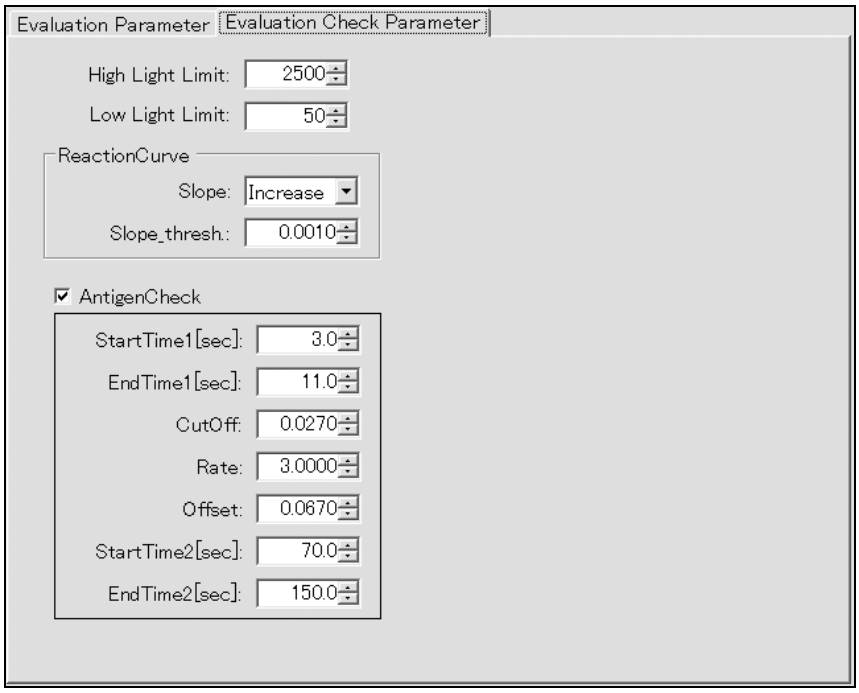

Figure 8-45: Evaluation Check Parameter tab (VLin analysis)

High Light Limit	Sets the threshold value for the Trans Light High check. It is judged an error if in the interval between the **StartTime** and the **EndTime** the amount of transmitted light detected exceeds the threshold. The setting range is 0 – 4095.
Low Light Limit	Sets the threshold value for the Trans Light low check. It is judged an error if in the interval between the **StartTime** and the **EndTime** the amount of transmitted light detected goes below the threshold. The setting range is 0 – 4095.

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Reaction Curve

It is judged an error if the change in light absorbance during the period from the **StartTime** to the **EndTime** is equal to or greater than the **slope_thresh** as well as if the change in direction (whether increasing or decreasing) is different from the **slope**.

Slope

Select a change (slope) in light absorbance from between **Increase** and **Decrease**.

slope_thresh

Sets the threshold for the change in light absorbance. The setting range is 0.0000 – 10.0000.

AntigenCheck

Sets whether or not to perform an Antigen Excess check. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it.
If the antigen (or antibody) concentration is extremely high in an antigen antibody reaction, the reaction may be suppressed. In such a case, in conjunction with the increase in antigen concentration, there is a decrease in the change in light absorbance, and the measured results may be lower than the actual antigen concentration. This check detects this kind of antigen excess. It is judged an error if the following conditions line up.

- When SlopeB is equal/greater than the CutOff
  SlopeA ≥ (**Rate** × **SlopeB** + **Offset**)
- When SlopeB does not reach the CutOff
  SlopeA ≥ (**Rate** × **CutOff** + **Offset**)

  SlopeA: Amount of change in light absorbance in unstable area

  SlopeB: Amount of change in light absorbance in linear range

StartTime1 [sec]

Sets the start time for the unstable range. The setting range is 0.0 – 3600.0.

EndTime1 [sec]

Sets the end time for the unstable range. The setting range is 0.0 – 3600.0.

CutOff

Sets the CutOff threshold for antigen excess. The setting range is 0.0000 – 9.9999.

Rate

Sets the Rate for antigen excess. The setting range is -9.9999 – 9.9999.

Offset

Sets the Offset threshold for antigen excess. The setting range is -9.9999 – 9.9999.

StartTime2 [sec]

Sets the start time for the linear range. The setting range is 0.0 – 3600.0.

EndTime2 [sec]

Sets the end time for the linear range. The setting range is 0.0 – 3600.0.

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2. Assay parameter deletion

1. Select the assay parameter to delete, from the list of assay parameters in the basic settings tab.
2. Press **Delete**.
   The delete confirmation dialog box appears.
3. Press **OK**.
   The selected assay parameter is deleted.
   Press **Cancel** to avoid deleting the selection.

8.9 Reflex settings

The reflex settings tab of the assay group setting dialog can be used to make reflex test settings for the assay group selected in the assay group list.
The reflex test is a function that automatically performs analysis of another parameter, according to the result or error found by the first analysis. The reflex test is not performed if the parameter that it would automatically analyze was analyzed in the first analysis. This setting sets the conditions under which a reflex test analysis would be performed on one of the parameters of the assay group being set. Up to 10 conditions can be set.
There is an order of priority for reflex judgments, and the reflex judgment formula list displays them in order of priority, with the highest at the top.

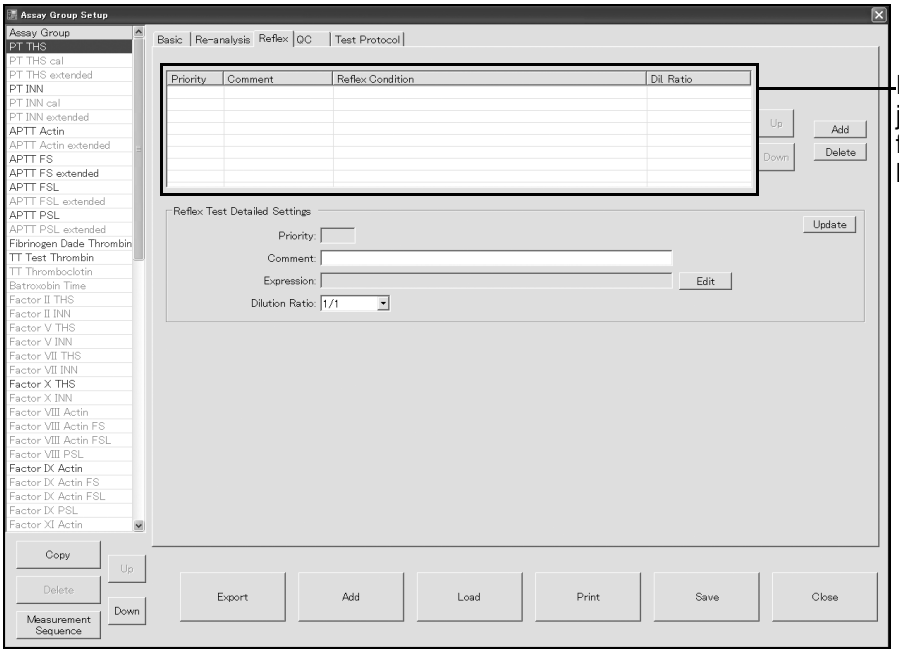

Figure 8-46: Assay group settings dialog box (reflex test settings tab)

Note:
Reflex tests will not be executed, if the sample is analyzed in the micro-sample mode.

Reflex judgment formula list
The list of judgment formulae for performing a reflex test displays the formulae in order of priority. Up to eight lines can be displayed and a scroll bar is displayed if there are more than eight lines.

Priority	The priority order is displayed.
Comment	Comments on the reflex test are displayed.
Reflex Condition	The judgment formula list for reflex tests will appear.
Dilu. Ratio	The dilution ratio for reflex tests is displayed.
Up	Move the selected assay group in the reflex judgment formula list to one line higher, raising its priority.
Down	Move the selected assay group in the reflex judgment formula list to one line lower, lowering its priority.
Add	The reflex judgment formula input dialog box will appear.
Delete	The setting for the line selected in the reflex judgment formula list is deleted.

Reflex Test Detailed Settings

Priority	The priority order selected in the reflex judgment formula list is displayed.
Comment	Comments on the reflex judgment formulae are displayed. If no comments have been registered, the display is left blank.
Expression	The judgment formula selected in the reflex judgment formula list is displayed.
Edit	The reflex judgment formula input dialog box is displayed to edit the judgment formula selected in the reflex judgment formula list.
Dilution Ratio	The dilution ratio list set in the test protocol is displayed. The dilution ratio for reflex analysis can be selected.

1. Adding/editing a reflex test condition

1. To edit a reflex test condition which has already been registered, select the condition to edit from the reflex judgment formula list. Press **Add** to register a new formula.
2. Set the parameters.

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3. Press **Edit** to edit the judgment formula for the reflex test.
   The reflex judgment formula input dialog box will appear.

Figure 8-47: Reflex Judgment Formula Input dialog box

Expression	The input judgment formula is displayed.
All Clear	Delete the judgment formula.
Delete	Delete one parameter to the left of the cursor in the judgment formulae.
Assay Parameter	
List of assay parameters	A list is displayed of the assay parameters available for use in the judgment formula.
Entry	Inserts the assay parameter selected in the assay parameters list into the judgment formula at the cursor position.
Error	
List of errors	A list is displayed of the errors available for use in the judgment formula.
Entry	Inserts the error selected in the error list into the judgment formula at the cursor position.
/, *, -, +, (,), AND, OR keys	Select the operators to use in the judgment formula.
>=, <=, >, <, = keys	Select the equal signs etc. to use in the judgment formula.
Numeric keys	Select the numbers to use in the judgment formula.

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4. Enter the judgment formula, using the lists and buttons and press **OK**.
   The input judgment formula is reflected and the reflex judgment formula input dialog box closes.
   Press **Cancel** to cancel the input judgment formula and close the reflex judgment formula input dialog box.
5. To continue making settings on another tab, press the relevant tab. Press **Save** to register changes.

8.10 Repeat analysis settings

The repeat analysis settings tab of the assay group settings dialog can be used to make repeat analysis settings for the assay group selected in the assay group list. For the assay group being set under the repeat analysis settings, set the conditions for performing redilution analysis and repeat analysis automatically and the dilution ratios for use with redilution analysis. A redilution analysis takes priority over a repeat analysis.
Up to ten conditions for both redilution analysis and repeat analysis can be set. Multiple set conditions are judged as OR, but as the dilution ratio is specified for redilution analysis, multiple redilutions will never be performed at the same time. Therefore, redilution analyses are prioritized and the conditions in the redilution analysis conditions list are displayed in order of priority, with the highest at the top.

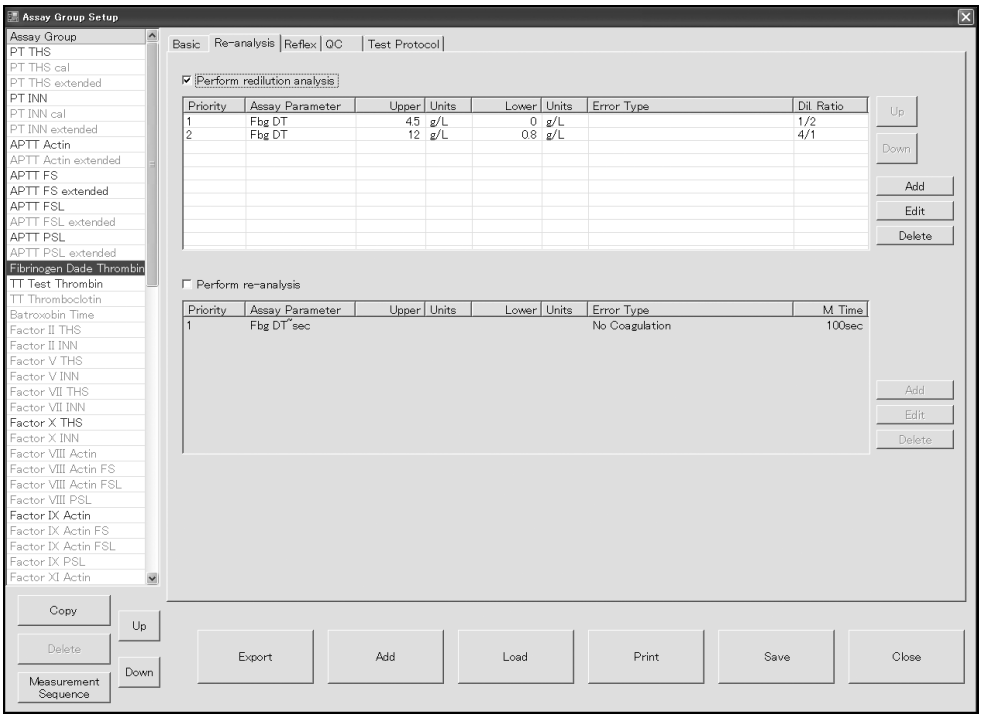

Figure 8-48: Assay group settings dialog box (repeat analysis settings tab)

Note:
Redilution analysis and Re-analysis will not be executed, if the sample is analyzed in the micro-sample mode.
Therefore, results of samples measured in the micro-sample mode may only be released if the results are within the concentration range of the calibration curve. Sample results outside the concentration range of the calibration curve are extrapolated, and therefore, have a greater potential to be inaccurate.

Perform redilution analysis
Set whether or not to perform redilution analysis. Add a check mark to perform the analysis. Remove the check mark to avoid doing so.
Analysis is performed according to the analysis conditions in the list. The analysis conditions are composed of the parameters below. Up to ten are listed, with the highest priority at the top of the list.

Priority	The priority order is displayed.
Assay Parameter	The assay parameter name is displayed.
Upper Limit	The upper limit value is displayed. Redilution analysis is performed if the value is exceeded.
Units	Units are displayed.
Lower Limit	The lower limit value is displayed. Redilution analysis is performed if the value is not reached.
Units	Units are displayed.
Error Type	The error type is displayed. Redilution analysis is performed if this error occurs.
Dil. Ratio	The dilution ratio is displayed.
Add	The repeat analysis detailed settings dialog box is displayed to add redilution analysis conditions. For the method for adding redilution analysis conditions, see “Chapter 8: 8.10: 2. Repeat analysis detailed settings”. This is only valid if **Perform redilution analysis** is checked.
Edit	The repeat analysis detailed settings dialog box is displayed to edit the redilution analysis conditions selected in the redilution analysis list. For the method for editing redilution analysis conditions, see “Chapter 8: 8.10: 2. Repeat analysis detailed settings”. This is only valid if **Perform redilution analysis** is checked.
Delete	Delete the redilution analysis condition selected in the list of redilution analysis conditions. This is only valid if **Perform redilution analysis** is checked.

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Perform re-analysis
Set whether or not to perform repeat analysis. Add a check mark to perform the analysis. Remove the check mark to avoid doing so.
The analysis is performed according to the analysis conditions in the list. The analysis conditions are composed of the parameters below. Up to ten are listed.

Priority	The priority order is displayed.
Assay Parameter	The assay parameter name is displayed.
Upper Limit	The upper limit value is displayed. Repeat analysis is performed if the value is exceeded.
Units	Units are displayed.
Lower Limit	The lower limit value is displayed. Repeat analysis is performed if the value is not reached.
Units	Units are displayed.
Error Type	The error type is displayed. Repeat analysis is performed if this error occurs.
M Time (Measurement Time [sec])	Measurement time is displayed.
Add	The repeat analysis detailed settings dialog box is displayed to add repeat analysis conditions. For the method for adding repeat analysis conditions, see “Chapter 8: 8.10: 2. Repeat analysis detailed settings”. This is only valid if **Perform re-analysis** is checked.
Edit	The repeat analysis detailed settings dialog box is displayed to edit the repeat analysis conditions selected in the repeat analysis list. For the method for editing repeat analysis conditions, see “Chapter 8: 8.10: 2. Repeat analysis detailed settings”. This is only valid if **Perform re-analysis** is checked.
Delete	Delete the repeat analysis condition selected in the list of repeat analysis conditions. This is only valid if **Perform re-analysis** is checked.

1. Add/edit conditions for redilution and repeat analyses

1. To add/edit conditions for redilution analysis, add a check mark to **Perform redilution analysis**.
2. Press **Add** to add redilution analysis conditions. To edit a registered condition, select the condition to edit from the redilution analysis conditions list, then press **Edit**.
   The repeat analysis detailed settings dialog box will appear.
   See “Chapter 8: 8.10: 2. Repeat analysis detailed settings” for the operation of the repeat analysis detailed settings dialog box.
3. To add/edit conditions for repeat analysis, add a check mark to **Perform re-analysis**.

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4. Press **Add** to add repeat analysis conditions. To edit a registered condition, select the condition to edit from the repeat analysis conditions list, then press **Edit**.
   The repeat analysis detailed settings dialog box will appear.
   See “Chapter 8: 8.10: 2. Repeat analysis detailed settings” for the operation of the repeat analysis detailed settings dialog box.
5. To continue making settings on another tab, press the relevant tab. Press **Save** to register changes.

2. Repeat analysis detailed settings

1. Press **Add** or **Edit** on the repeat analysis settings tab.
   The repeat analysis detailed settings dialog box will appear.

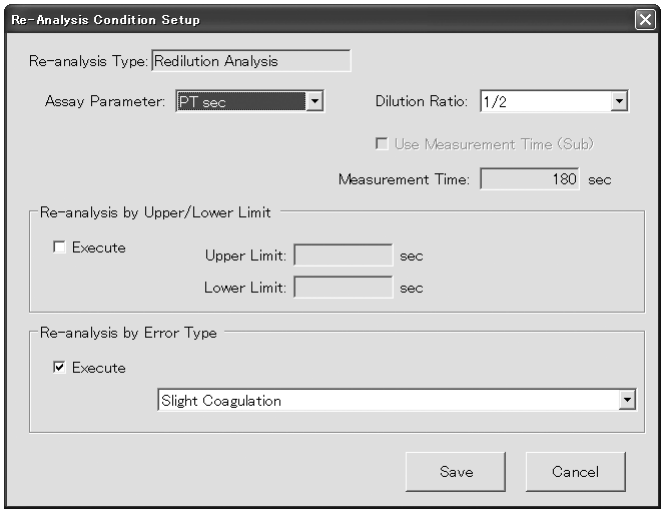

Figure 8-49: Repeat analysis detailed settings dialog box

Re-analysis Type — The repeat analysis implementation content will appear. It is displayed as “Repeat analysis” if detailed settings are to be made for repeat analysis, or “Redilution analysis” if detailed settings are to be made for redilution analysis.

Assay Parameter — Assay parameters can be selected.

Dilution Ratio — The dilution ratio set in the test protocol is set. The dilution ratio can be selected. This can only be selected if the repeat analysis implementation content is **Redilution analysis**.

Setting of Measurement Time in Re-analysis

Use Measurement Time (Sub) — Set whether or not to use the measurement time (sub) set under test protocol settings when performing re-analysis. Add a check mark to use the measurement time (sub). Remove the check when the measurement time (sub) should not be used.

Measurement Time — If the check mark was added to **Use Measurement Time (Sub)**, the measurement time (sub) will be displayed. If the check mark was removed, measurement time (main) is displayed.

Re-analysis by Upper/ Lower Limit

Execute — Set whether or not to perform repeat analysis according to the upper and lower limits. Add a check mark to perform it. At this stage, the upper and lower limits for repeat analysis must be set. Remove the check mark to avoid performing it.

Upper Limit — The upper limit for repeat analysis will appear. Repeat analysis is performed if the value is exceeded. If the value is not set, the display is left blank.

Lower Limit — The lower limit for repeat analysis will appear. Repeat analysis is performed if the value is below the lower limit. If the value is not set, the display is left blank.

Re-analysis by Error Type

Execute — Set whether or not to perform repeat analysis due to errors. Add a check mark to perform it. At this stage, the error types for repeat analysis must be set. Remove the check mark to avoid performing it.

Error Type — The error type defined by analysis is displayed. Repeat analysis is performed if this error occurs.

2. Set each parameter, and press **Save**.
   Confirm the setting content, then close the dialog box.
   Press **Cancel** to discard the settings and close the dialog box.

3. Delete redilution analysis conditions

1. Add a check mark to **Perform redilution analysis**.
2. Select the analysis condition to delete from the redilution analysis conditions list, then press **Delete**.

4. Delete repeat analysis conditions

1. Add a check mark to **Perform re-analysis**.
2. Select the analysis condition to delete from the repeat analysis conditions list, then press **Delete**.

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8.11 Quality control settings

The QC settings tab of the assay group setting dialog can be used to make QC settings for the assay group selected in the assay group list.

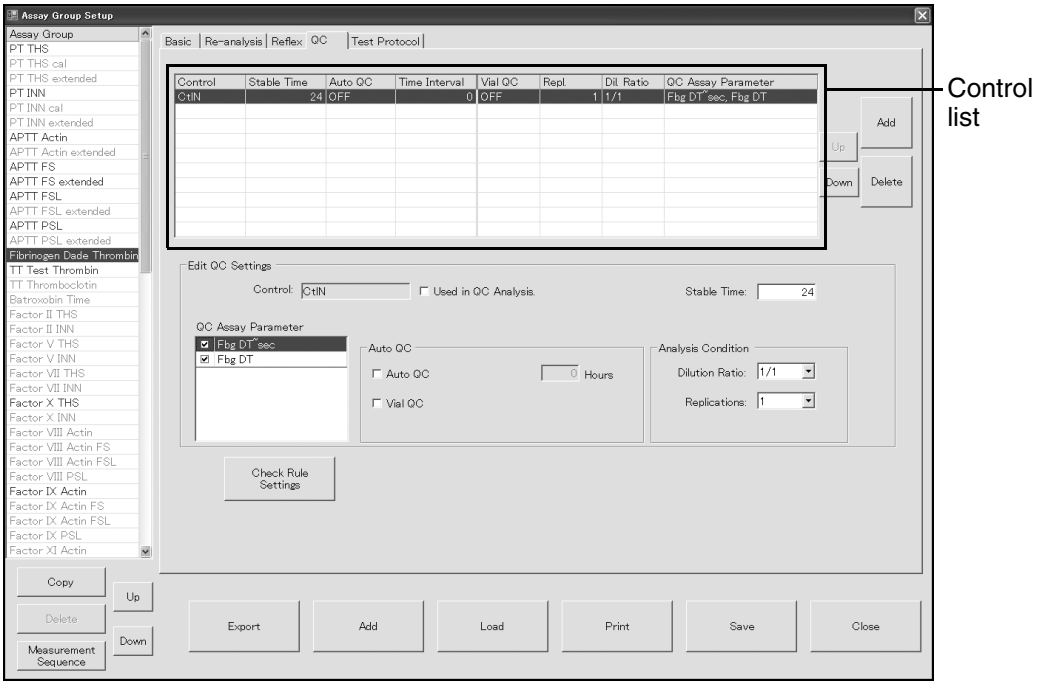

Figure 8-50: Assay group settings dialog box (QC settings tab)

Control list	QC setting information is displayed as a list. The information selected by the cursor is displayed on the **Edit QC Settings**.
Up	Moves the selection in the list of controls one line higher.
Down	Moves the selection in the list of controls one line lower.
Add	The control selection dialog box will appear. If a control is added, it is inserted as a new line above the cursor position.
Delete	The setting for the line selected in the control list is deleted. The delete confirmation dialog box will appear. When the control is deleted, the chart no longer appears on the QC screen.

Edit QC Settings

Control The control name for the line selected in the control list is displayed.

Used in QC Analysis Set whether or not to use the control for the line selected in the control list for quality control. Add a check mark to use it. When a check mark is added, that parameter is then displayed on the Other tab in the QC chart. Remove the check mark to avoid using it for QC.

Stable Time [h] Input the stable time. If the control elapsed time exceeds the set stable time, a confirmation dialog box is displayed at the start of analysis.

QC Assay Parameter Set whether or not to use assay parameters in the assay group for QC. Add a check mark to use them. Remove the check mark to avoid using them it.

Auto QC

Auto QC Set whether or not to perform QC analysis at fixed intervals. To perform such analyses, add a check mark, then enter the Auto QC interval, in the range 1–24. Remove the check to avoid performing the analyses.

Vial QC Set whether or not to perform vial QC. Add a check mark to perform it. Remove the check mark when not performing it. If the check is added, QC analysis is performed automatically before reagent is aspirated from a new reagent vial. For STAT sample analysis and calibration curve analysis, vial QC is omitted even if the check mark is added.

Caution!
Only “Current” in the current lot is analyzed for vial QC. Note that “New” for the new lot is not analyzed for vial QC.

Analysis Condition

Dilution Ratio The dilution ratio for QC analysis can be selected. The dilution ratio from the list of Test Protocol Settings-Dilution Ratio Settings is displayed.

Replications The number of replications for QC analysis can be selected. You can select one or two. If two is selected, QC errors are judged from the mean results, and the values are plotted in the chart. Divergence judgment is not performed, even if there are two analyses.

Check Rule Settings The Judgment Rule Setting dialog is displayed for the assay parameter selected with the cursor. See “Chapter 8: 8.11: 2. Judgment rule setting” for the judgment rule setting method.

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1. Set the parameters.
   See “Chapter 8: 8.11: 1. Adding controls” for the method for adding controls.
   See “Chapter 8: 8.11: 2. Judgment rule setting” for the judgment rule setting method.
2. To continue making settings on another tab, press the relevant tab. Press **Save** to register changes.

1. Adding controls

1. Press **Add** on the quality control setting tab.
   The control selection dialog box will appear.

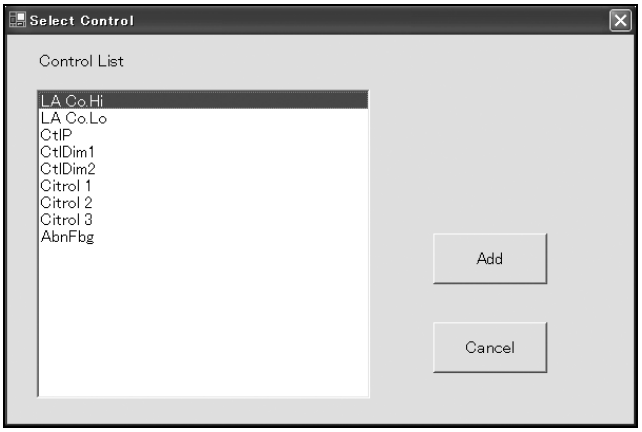

Figure 8-51: Control selection dialog box

Control List	The controls which have their reagent type set as control under the reagent master settings are displayed.

2. Select the control to add from the control list.
3. Press **Add**.
   The control selected in the control list is added to the control list on the QC settings tab of the assay group settings dialog box, and the control selection dialog box closes.
   Press **Cancel** to cancel the addition and close the control selection dialog box.

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2. Judgment rule setting

With the Multi Rule method of Westgard (rule) condition, QC check is made.

1. Press **Check Rule Settings** button on the quality control setting tab.
   The Set Judgment Rule dialog box will appear.

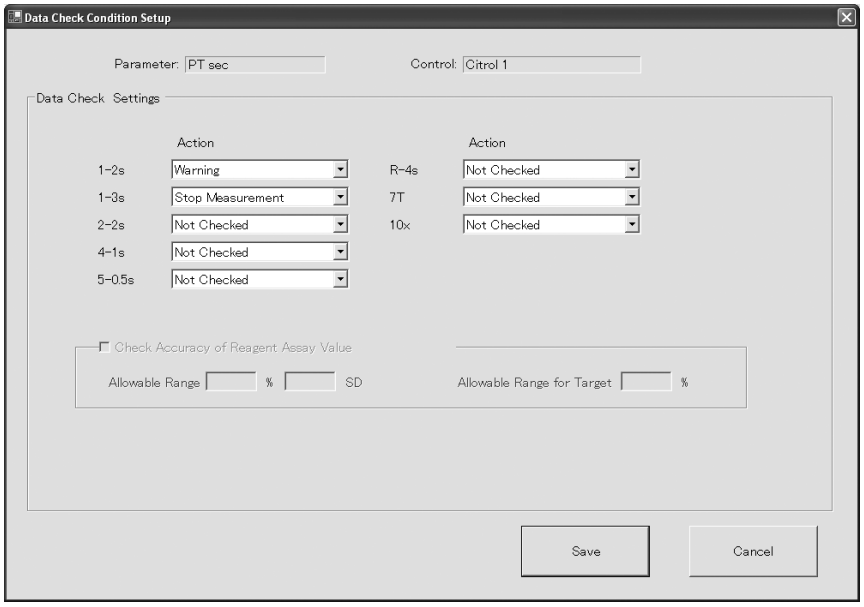

Figure 8-52: Set Judgment Rule dialog box

Parameter	The name of the assay parameter for which to set the judgment rule is displayed.
Control	The name is displayed for the control used in QC analysis of the assay parameter for which to set the judgment rule.
Data Check Settings	Select from the following options for each parameter. **Stop Measurement:** Analysis will be interrupted. **Warning:** The warning is displayed in the status bar. **No Checked:** Monitoring will not be performed.
1-2s	Set the process to apply if the QC analysis result is below the range. (Target-2SD) ≤ data ≤ (Target+2SD)
1-3s	Set the process to apply if the QC analysis result is below the range. (Target-3SD) ≤ data ≤ (Target+3SD)
2-2s	Set the process to apply if the QC analysis result is below the range for two consecutive results. (Target-2SD) ≤ data ≤ (Target+2SD)
4-1s	Set the process to apply if the QC analysis result is below the range for four consecutive results. (Target-1SD) ≤ data ≤ (Target+1SD)

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5-0.5s	Set the process to apply if the QC analysis result is below the range for five consecutive results. (Target-0.5SD) ≤ data ≤ (Target+0.5SD)
R-4s	Set the process to apply if the QC analysis result diverges from the previous result by more than 4SD.
7T	Set the process to apply if the change in seven consecutive QC analysis results is consistently in one direction (seven consecutive increases or decreases).
10x	Set the process to apply if ten consecutive QC analysis results are all in the same direction from the target (ten consecutive results are all lower/higher than the target).

2. Set each parameter and press **OK**.
   The settings made in the Set Judgment Rule dialog box are registered and the dialog box closes.
   Press **Cancel** to discard the settings and close the dialog box.

Note:
"Data" is the analysis result and "Target" and "SD" are the target and 1SD set as the target/limit on the QC screen.

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8.12 Test protocol settings

The test protocol settings tab of the assay group setting dialog can be used to make the test protocol settings for the assay group selected in the assay group list.

> **Caution!**
> It may not be possible to obtain correct analysis results if the test protocol settings are changed. The operator is personally responsible for any such changes. Furthermore, the warranty for this product only covers use of the factory default settings.

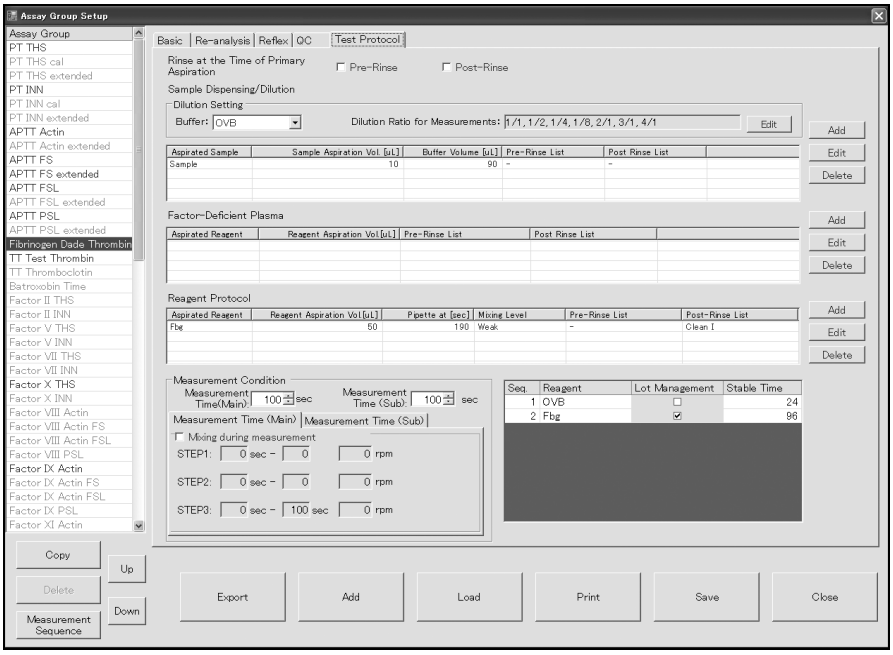

Figure 8-53: Assay group settings dialog box (test protocol settings tab)

Rinse at the Time of Primary Aspiration

Pre-Aspiration Rinse — If the check mark is added, a pre-rinse is performed before primary aspiration of the sample. If the check mark is removed, the pre-rinse is omitted.

Post-Aspiration Rinse — If the check mark is added, a post-rinse is performed after primary aspiration of the sample. If the check mark is removed, the post-rinse is omitted.

Sample Dispensing/ Dilution — The sample aspiration and dilution procedure list is displayed.

Dilution Setting

Buffer — Select the diluent solution name.

Dilution Ratio for Measurements — The dilution ratio used for analysis is displayed.

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Edit	The Dilution ratio selection dialog box is displayed for setting the dilution ratio to be used for measurements.
Aspirated Sample	The name of the aspirated sample is displayed.
Sample Aspiration Vol. [µL]	The aspirated sample volume is displayed.
Buffer Volume [µL]	The diluent solution volume is displayed.
Mixing Level	The mixing intensity is displayed.
Pre-Rinse List	The names of the reagents that are used for pre-rinsing are listed in the order that the rinses are performed.
Post-Rinse List	The names of the reagents that are used for post-rinsing are listed in the order that the rinses are performed.
Add	The Test protocol detailed settings dialog box is displayed so a new procedure may be added at the bottom of the procedure list.
Edit	The Test protocol detailed settings dialog box is displayed so the procedure in the selected line of the procedure list may be edited.
Delete	Deletes the procedure in the line selected in the procedure list.
Factor-Deficient Plasma	The procedure list for factor-deficient plasma is displayed.
Reagent	The name of the aspirated reagent is displayed.
Reagent Aspiration Vol. [µL]	The volume of the aspirated reagent is displayed.
Pre-Rinse List	The names of the reagents that are used for pre-rinsing are listed in the order that the rinses are performed.
Post-Rinse List	The names of the reagents that are used for post-rinsing are listed in the order that the rinses are performed.
Add	The Test protocol detailed settings dialog box is displayed so a new procedure may be added at the bottom of the procedure list.
Edit	The Test protocol detailed settings dialog box is displayed so the procedure in the selected line of the procedure list may be edited.
Delete	Deletes the procedure in the line selected in the procedure list.
Reagent Protocol	The procedure list for the reagent is displayed.
Aspirated Reag.	The name of the aspirated reagent is displayed.
Reagent Aspiration Vol. [µL]	The volume of the aspirated reagent is displayed.
Pipette at [sec]	Warming time is displayed.
Mixing Level	The mixing intensity is displayed.
Pre-Rinse List	The names of the reagents that are used for pre-rinsing are listed in the order that the rinses are performed.

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Post-Rinse List The names of the reagents that are used for post-rinsing are listed in the order that the rinses are performed.

Add The Test protocol detailed settings dialog box is displayed so a new procedure may be added at the bottom of the procedure list.

Edit The Test protocol detailed settings dialog box is displayed so the procedure in the selected line of the procedure list may be edited.

Delete Deletes the procedure in the line selected in the procedure list.

Measurement Condition

Measurement Time (Main) [sec] Sets the measurement time (Main). The setting range is 20 – 1800 (20 second steps).

Measurement Time (Sub) [sec] Sets the measurement time (sub). The setting range is 20 – 1800 (20 second steps).

Perform mixing during measurement Sets whether or not to perform mixing during measurement. Add a check mark to perform this. In that case, the following items must be specified. Remove the check mark when not performing it.
Mixing is broken down into three segments and the number of rotations can be changed.

STEP1

Start time [sec] A mixing start time of 0 is displayed for the first segment.

End time [sec] Enter a mixing end time for the first segment.

Number of rotations [rpm] Enter a number of mixing rotations for the first segment. The setting range is 100 – 1800.

STEP2

Start time [sec] Displays the mixing end time of the first segment as the mixing start time of the second segment.

End time [sec] Enter a mixing end time for the second segment.

Number of rotations [rpm] Enter a number of mixing rotations for the second segment. The setting range is 100 – 1800.

STEP3

Start time [sec] Displays the mixing end time of the second segment as the mixing start time of the third segment.

End time [sec] Displays the **Measurement Time** as the mixing end time for the third segment.

Number of rotations [rpm] Enter a number of mixing rotations for the third segment. The setting range is 100 – 1800.

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Caution!
If mixing is set to occur during light measurement, set mixing intensity to **Middle**, **Weak**, **Very Weak**, or **None** for the last reagent to be added.
If mixing intensity is set to **Strong**, it can cause errors in the reaction curve, and it may not be possible to obtain accurate analysis results.

Reagent List

Reagent	The reagent list used in the procedures for Sample Dispensing/Dilution, Factor-Deficient Plasma and Reagents is displayed in the sequence in the set procedure.
Lot Management	Set whether or not to perform lot management. Add a check mark to perform lot management. Remove the check mark to omit lot management.
Stable Time [h]	Input the stable time. If the reagent elapsed time exceeds the set stable time, a confirmation dialog box is displayed at the start of analysis.

Setting the dilution ratio to be used in measurements

1. Press **Edit** for the **Dilution Setting** on the **Test Protocol** tab.
   The Select Dilution Ratios dialog box opens.

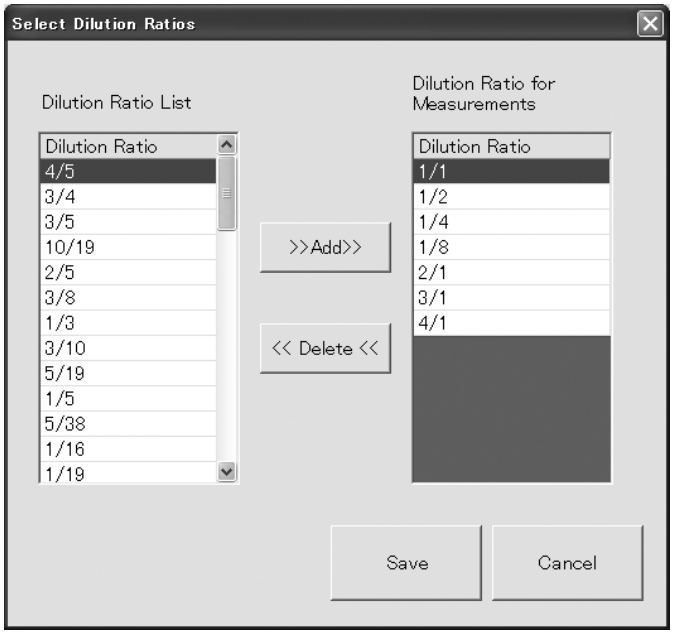

Figure 8-54: Select Dilution Ratios dialog box

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Dilution Ratio List	The dilution ratios recorded in the dilution ratio master are displayed in the order in which they were recorded.
Dilution Ratio for Measurements	A list of dilution ratio for measurements is displayed, in the order that they were recorded to the dilution ratio master.
Add	Adds the dilution ratio selected in the Dilution Ratio List to the Dilution Ratio for Measurements list and deletes the ratio from the Dilution Ratio List.
Delete	Deletes the dilution ratio in the Dilution Ratio for Measurements list and adds it to the Dilution Ratio List. "1/1" cannot be deleted from the Dilution Ratio for Measurements list.

2. Set the **Dilution Ratio for Measurements**.
3. Press **Save**.
   The content of your settings are saved and the Select Dilution Ratios dialog box closes.
   If you press **Cancel**, the content of your setting is aborted and the Select Dilution Ratios dialog box closes.

Note:
When (sample dispensed volume in the last line of the Sample Dispensing/ Dilution list) × (dilution ratio) is less than 4µL, measurements can only be made at dilution ratios of 1/8 or less.
When more than one dilution ratio is measured at one time, as with MDA, measurements can be made only when all the dilution ratios meet the conditions.

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Adding & editing test protocols

1. To add a new test protocol, press **Add** on the Sample Dispensing/Dilution, Factor-Deficient Plasma, Reagent Protocol table. To edit a registered test protocol, select the test protocol to edit, then press **Edit**.
   The Test Protocol dialog box will open.

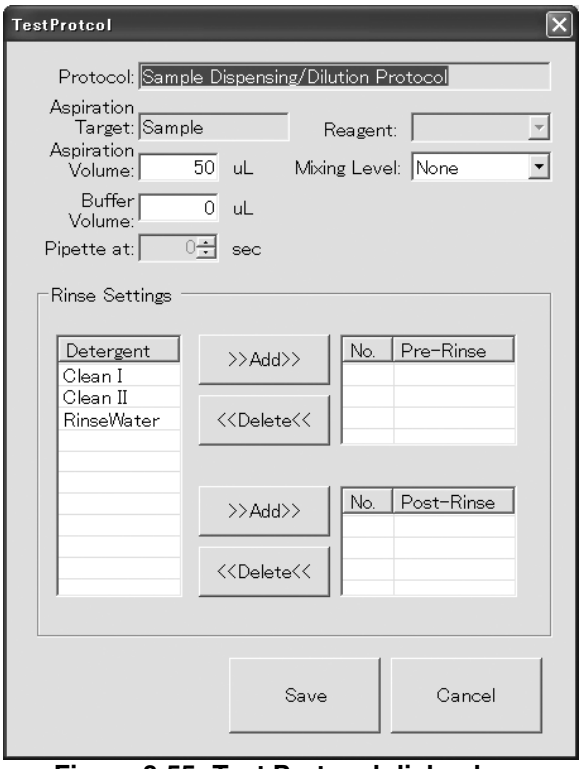

Figure 8-55: Test Protocol dialog box

Table 8-05: Settings and display parameters in the Test Protocol dialog box

Parameters	Explanation	Setting Range / Content Displayed		
		Sample Dispensing/ Dilution	**Factor-Deficient Plasma**	**Reagent Protocol**
Aspiration Target	The aspiration target is displayed.	When the 1st line is selected, **Sample** is displayed; from the 2nd line on, **Dilution** is displayed.	**Factor-Deficient Plasma** is displayed.	**Reagent** is displayed.
Reagent	Sets the reagent to be added.	No setting available.	Reagents set to "Factor" can be selected according to type of reagent.	Reagents set to "Reagent" can be selected according to type of reagent.
Aspiration Volume	Sets the aspiration volume (µL).	The setting range is 4 – 150.	The setting range is 20 – 150.	The setting range is 0, 20 – 200.
Buffer Volume	Sets the buffer volume (µL). If the dilutant in the test protocol setting is on **None**, then no setting is available.	The setting range is 0, 4 – 150.	No setting available.	No setting available.
Pipette at	Sets the time (sec) from the warming start.	No setting available.	No setting available.	The setting range is 0 – 600 (10 second steps). Set intermediary reagents to even numbers in the 10s digit and make the last reagent that is added an odd number in the 10s.
Mixing Level	Select the intensity of mixing at reagent addition.	No setting available.	No setting available.	**None**, **Very Weak**, **Weak**, **Middle** and **Strong** can be selected. **Strong** can only be performed when it is the last reagent to be added.
Add	Adds the detergent that is selected in the Detergent List to the Pre-Rinse (Post-Rinse) List.	-		
Delete	Deletes the detergent selected in the Pre-Rinse (Post-Rinse) list from the list.	-		

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* Measurements can be made only when the total volume of aspirated sample, buffer and aspirated reagent are as follows.

  150µL ≤ aspirated sample + buffer + aspirated reagent (total amount of parts in bold) ≤ 300µL
* Measurement can be made only if the settings for the procedures for Sample Dispensing/Dilution are as follows.

  CS-2000*i* : Volume of aspirated sample + buffer ≥ aspirated sample in the next line + 50µL

  CS-2100*i* : Volume of aspirated sample + buffer ≥ aspirated sample in the next line + 130µL

2. Set each of the parameters.
3. Press **Save**.
   The content of your settings are saved and the Test Protocol dialog box closes.
   If you press **Cancel**, the content of your setting is aborted and the Test Protocol dialog box closes.

Caution!

- If the mixing level is set to **Very Weak**, a mixing motor error cannot be detected. We recommend setting the mixing level to **Weak**, **Middle** or **Strong** for at least one procedure in the same test protocols so that an error can be detected.
- If mixing is set to occur during light measurement, set mixing intensity to **Middle**, **Weak**, **Very Weak**, or **None** for the last reagent to be added.
  If mixing intensity is set to **Strong**, it can cause errors in the reaction curve, and it may not be possible to obtain accurate analysis results.

Deleting Test Protocols

1. Select the test protocol to delete from the Sample Dispensing/Dilution, Factor-Deficient Plasma, Reagent Protocol table.
2. Press **Delete**.
   The delete confirmation dialog box appears.
3. Press **OK**.
   The selected test protocol is deleted.
   If you press **Cancel**, the selection is not deleted.

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8.13 Formula calculation settings

New measurement parameters can be created from the results for multiple analysis parameters.

1. Press **Formula setting** on the Settings screen.
   The Formula Setup dialog box will appear.

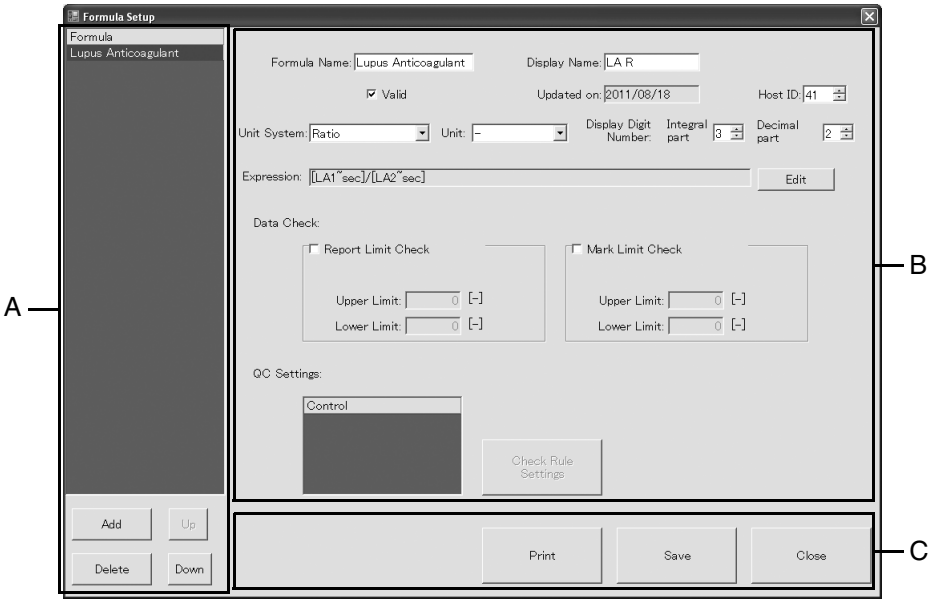

Figure 8-56: Formula Setup dialog box

A List of Formula
The Formula calculation parameters are displayed.

Add	Adds the Formula calculation parameter.
Delete	Deletes the Formula calculation parameter selected in the list.
Up	Moves the selected Formula calculation parameter in the list to one line higher.
Down	Moves the selected Formula calculation parameter in the list to one line lower.

B Setting area
This area is used for making settings for the Formula calculation parameter selected in the List of Formula.

Formula Name	The name of the Formula calculation parameter is displayed.
Abbreviation	The abbreviated name of the Formula calculation parameter is displayed.

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Valid	Set whether or not to make the Formula calculation parameter valid. It can be used for analysis if it is valid. Add a check mark to make it valid. Remove the check mark to invalidate the Formula calculation parameter.
Updated on	The updated date of the Formula calculation parameter is displayed. The format of display is determined by the system setting.
Host ID	The host ID of the Formula calculation parameter is displayed.
Unit System	Select the unit system for Formula calculation parameter from **Clot Time**, **change in light absorbance quantity**, **activity%**, **concentration**, **ratio** and **INR value**.
Unit	Select the units for Formula calculation parameter from **-**, **sec**, **dOD**, **OD**, **abs**, **mAbs**, **%**, **mg/dL**, **g/L**, **U/mL**, ***µg/mL***, **ng/mL**, ***µg/L***, **mg/L**, **IU/mL** and **FEU**.
Display Digit Number	
Integral Part	The number of integer area digits can be set, in the range 1-5, for use when analysis results calculated from Formula calculations are displayed.
Decimal Part	The number of decimal area digits can be set, in the range 0-4, for use when analysis results calculated from Formula calculations are displayed.
Expression	The calculation expression is displayed.
Edit	The Expression Entry dialog box is displayed to input calculation expressions.
Data Check	
Report Limit Check	Set whether or not to perform report limit judgment (monitoring of the analysis limits of the instrument). Add a check mark to perform the judgment. At this stage, the upper and lower limits must be specified. Remove the check mark to avoid performing the judgment.
Upper Limit	The report limit judgment upper limit value is displayed. The value can be input directly. If this value is exceeded, it triggers a report limit error and a “>” flag is added to the analysis results.
Lower Limit	The report limit judgment lower limit value is displayed. The value can be input directly. If this value falls short of this limit, it triggers a report limit error and a “<” flag is added to the analysis results.
Mark Limit Check	Set whether or not to perform error limit value judgment. Add a check mark to perform the judgment. At this stage, the upper and lower limit of error judgment must be specified. Remove the check mark to avoid performing the judgment.

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Upper Limit	The upper limit value for error limit value judgment is displayed. The value can be input directly. If this value is exceeded, it triggers an error judgment limit value error and a “+” flag is added to the analysis results.
Lower Limit	The lower limit value for error limit value judgment is displayed. The value can be input directly. If the result is below this value, it triggers an error judgment limit value error and a “-” flag is added to the analysis results.
QC Settings	The content of quality control on calculated parameter results can be set.
Control	The controls that can be used in quality control settings (controls that are set in common for assay parameters in calculated parameter formula) controls are displayed in a list. Displayed parameters are displayed on the Other tab of the QC chart display screen.
Check Rule Settings	The screen for setting quality control error judgment rules for the selected controls is displayed. Judgment is performed according to the Westgard MultiRule conditions. See “Chapter 8: 8.11: 2. Judgment rule setting” for judgment rule settings.

C Setting button area

Buttons are arranged in this area for making operations on the settings.

Print	Print out Formula calculation settings.
Save	Register the settings made using the Formula Setup dialog box.
Close	Close the Formula Setup dialog box.

2. Set the parameters.
3. Press **Save**.

Note:
- These settings become effective after the system has been restarted.
- The Profile button is automatically displayed on the Order screen after the **Save** button is pressed.

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Edit the calculation expression

1. Press **Edit** on the Formula Setup dialog box.
   The Expression Entry dialog box is displayed.

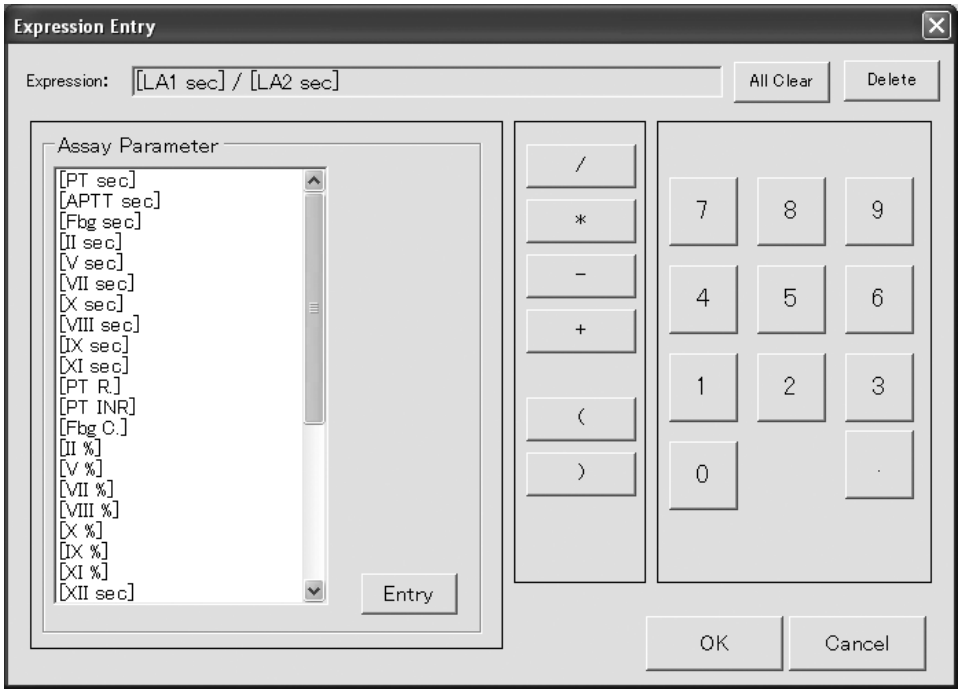

Figure 8-57: Expression Entry dialog box

Expression	The input calculation expression is displayed.
All Clear	Delete the calculation expression.
Delete	Delete one parameter to the left of the cursor in the calculation expression.
Assay Parameter	
List of assay parameters	The assay parameters list available for use in the calculation expression is displayed.
Entry	Insert the assay parameter selected in the assay parameters list into the calculation expression at the cursor position.
/, *, -, +, (,) keys	Select the operators to use in the calculation expression.
Numeric keys	Select the numbers to use in the calculation expression.

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2. Enter the calculation expression, using the lists and buttons and press **OK**.
   The input calculation expression is reflected in the expression on the Formula Setup dialog box and the Expression Entry dialog box closes.
   Press **Cancel** to cancel the input calculation expression and close the Expression Entry dialog box.

Note:

- Assay parameters which are Formula calculation parameter cannot be used in Formula calculation expression.
- Buttons that are grayed out cannot be used.

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9. Utility Tools

This chapter explains the functions of the utility tools installed in this instrument.

9.1 Backing up setting values/analysis results

You can back up setting values and analysis results.

1. Backing up only updated data since the last backup

You can back up updated data since the last backup.
The backup files are saved and added to the same folder as the last backup.

> **Note:**
> When backing up only updated data, analysis result data (waveform data) for the last 30 days can be saved.
> Saved analysis result data (waveform data) exceeding 30 days will be automatically deleted.

1. Exit the IPU.
   Press ☒ on the upper right corner of the screen to close the IPU display screen.
2. From the Windows start menu, select **All Programs** → **CS-Tools** → **Backup**.
   The Backup dialog box appears.

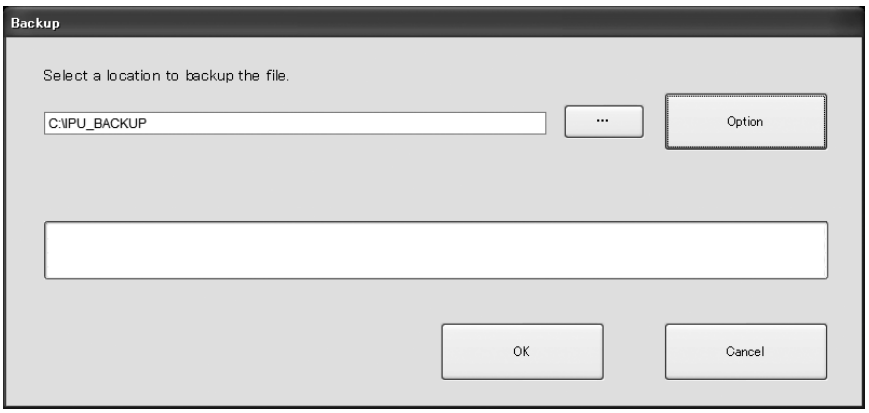

Figure 9-01: Backup dialog box

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3. Press **Option**.
   The Option dialog box appears.

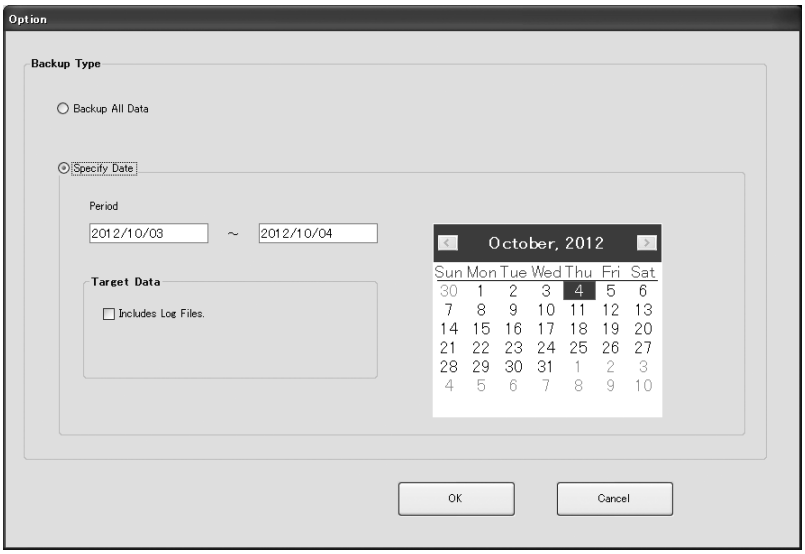

Figure 9-02: Option dialog box

4. Confirm the settings in **Backup Type**.
   - Select **Specify Date** if it is not selected.
   - Confirm that the last backup date and the present date are specified in **Period**. If not, enter the date(s) from the calendar shown in the dialog box.
   - Confirm the setting in **Target Data**.

   Includes Log Files. Add a check mark if you want to back up the log files. Log files for the period specified in **Period** are backed up.

5. Press **OK**.
   The dialog box closes.
6. Press **OK** in the Backup dialog box.
   The backup process starts and the progress bar appears.
   The Confirmation dialog box appears when the backup process is complete.
7. Press **OK**.
   The dialog box closes.
   A **XXXXXXXX_XXXXXX_BACKUP** folder is created at the specified destination and the backup file is saved in the folder (XXXXXXXX_XXXXXX shows the backup date and time (yyyy/mm/dd_hh/mm/ss)).
8. Press **Cancel** in the Backup dialog box.
   The dialog box closes.
9. Start up the IPU and the Main Unit.

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2. Backing up all data

You can back up all setting values/analysis result data.
Backup may take time depending on the amount of data stored in the IPU.

1. Exit the IPU.
   Press ✕ on the upper right corner of the screen to close the IPU display screen.
2. From the Windows start menu, select **All Programs** → **CS-Tools** → **Backup**.
   The Backup dialog box appears.

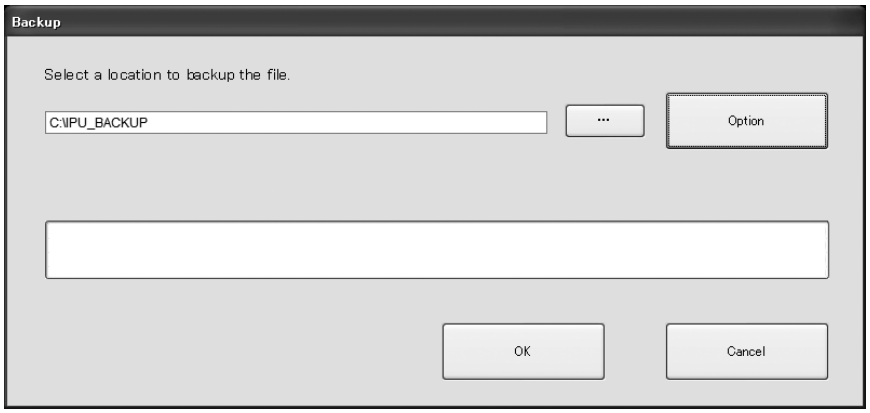

Figure 9-03: Backup dialog box

3. Press ··· of **Select a location to backup the file.**
   A folder selection dialog box appears.
4. Specify the save destination of the file, enter the file name, and press **OK**.
   The dialog box closes, and the path of the saved destination is displayed in **Select a location to backup the file.** of the Backup dialog box.
5. Press **Option**.
   The Option dialog box appears.

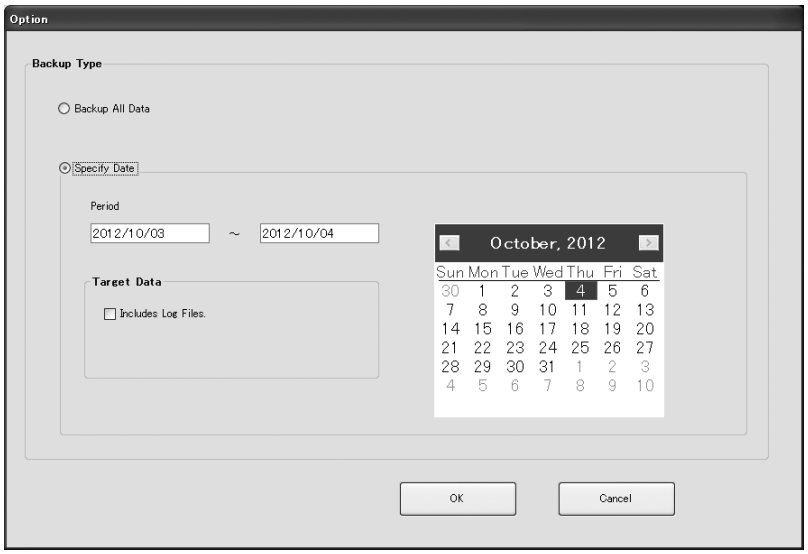

Figure 9-04: Option dialog box

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6. Select **Backup All Data** in **Backup Type**.
7. Press **OK**.
   The dialog box closes.
8. Press **OK** in the Backup dialog box.
   The backup process starts and the progress bar appears.
   The Confirmation dialog box appears when the backup process is complete.
9. Press **OK**.
   The dialog box closes.
   A **XXXXXXXX_XXXXXX_BACKUP** folder is created at the specified destination and the backup file is saved in the folder (XXXXXXXX_XXXXXX shows the backup date and time (yyyy/mm/dd_hh/mm/ss)).
10. Press **Cancel** in the Backup dialog box.
    The dialog box closes.
11. Start up the IPU and the Main Unit.

9.2 Loading setting values/analysis values (restoring)

You can load the information on setting values/analysis values.

1. Restoring data for last 30 days

You can restore setting values and analysis result data (waveform data) for the last 30 days in a specified folder.
Loading only analysis result data (waveform data) for the last 30 days can reduce the time required for restoring.

1. Exit the IPU.
   Press ☒ on the upper right corner of the screen to close the IPU display screen.
2. From the Windows start menu, select **All Programs** → **CS-Tools** → **Restore**.
   The Restore dialog box appears.

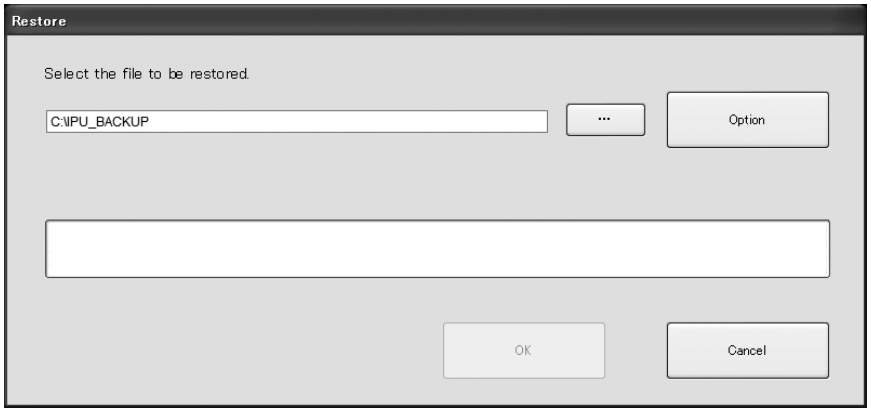

Figure 9-05: Restore dialog box

3. Press ··· of **Select the file to be restored.**
   A folder selection dialog box appears.

4. Select the folder in which the file you wish to load is saved, and press **OK**.
   The dialog box closes, and the specified path is displayed in **Select the file to be restored.** of the Restore dialog box.
5. Press **Option**.
   The Option dialog box appears.

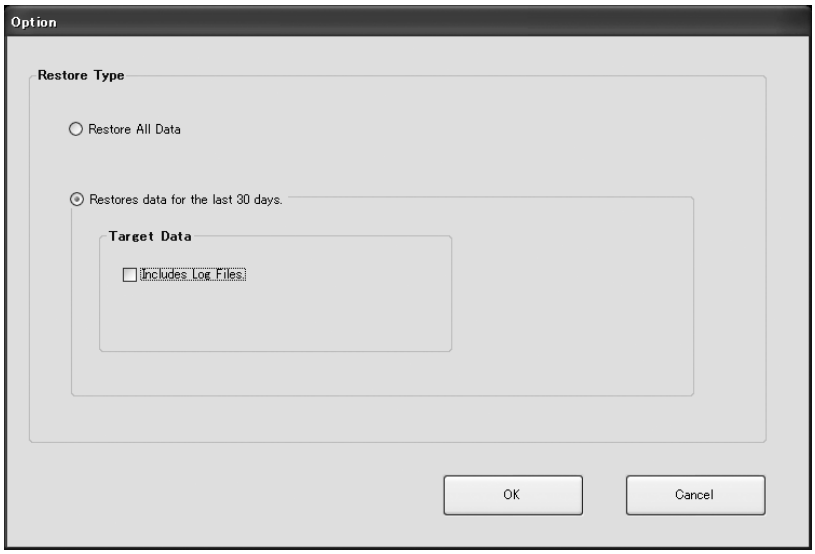

Figure 9-06: Option dialog box

6. Confirm the settings in **Restore Type**.
   - Select **Restores data for the last 30 days.** if it is not selected.
   - Confirm the setting in **Target Data**.

Includes Log Files.	Add a check mark if you want to restore the log files. Log files for the last 30 days are restored.

7. Press **OK**.
   The dialog box closes.
8. Press **OK** of the Restore dialog box.
   The restoring process starts and the progress bar appears.
   The Confirmation dialog box appears when the restore process is complete.
9. Press **OK**.
   The dialog box closes.
10. Press **Cancel** in the Restore dialog box.
    The dialog box closes.
11. Start up the IPU and the Main Unit.
    The setting values and analysis results are restored.

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2. Restoring all data

You can restore all setting values/analysis result data in the specified folder.
Restoring may take time depending on the amount of backup file data.

1. Exit the IPU.
   Press ☒ on the upper right corner of the screen to close the IPU display screen.
2. From the Windows start menu, select **All Programs** → **CS-Tools** → **Restore**.
   The Restore dialog box appears.

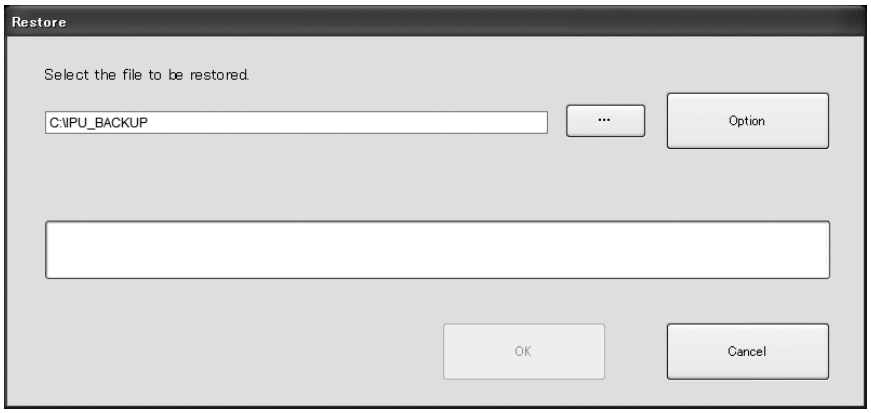

Figure 9-07: Restore dialog box

3. Press ··· of **Select the file to be restored.**
   A folder selection dialog box appears.
4. Select the folder in which the file you wish to load is saved, and press **OK**.
   The dialog box closes, and the specified path is displayed in **Select the file to be restored.** of the Restore dialog box.
5. Press **Option**.
   The Option dialog box appears.

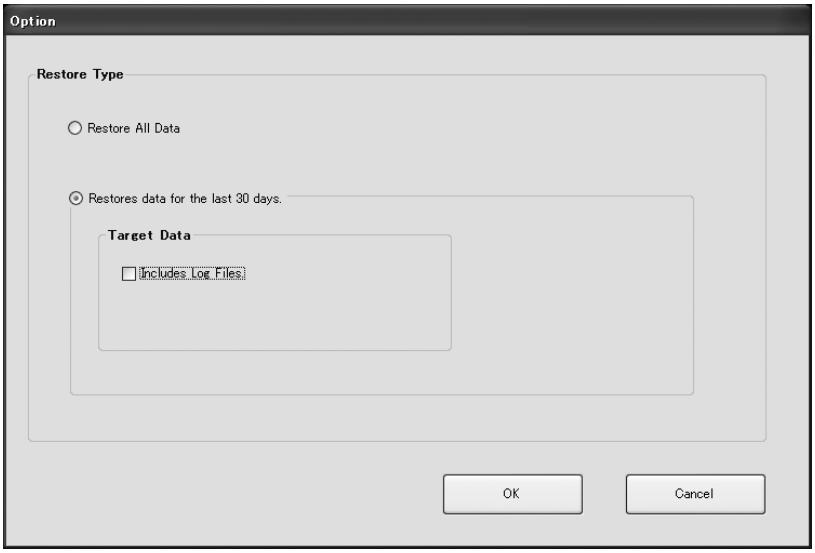

Figure 9-08: Option dialog box

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6. Select **Restore All Data** in **Restore Type**.
7. Press **OK**.
   The dialog box closes.
8. Press **OK** of the Restore dialog box.
   The restoring process starts and the progress bar appears.
   The Confirmation dialog box appears when the restore process is complete.
9. Press **OK**.
   The dialog box closes.
10. Press **Cancel** in the Restore dialog box.
    The dialog box closes.
11. Start up the IPU and the Main Unit.
    The setting values and analysis results are restored.

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9.3 Screen image print tool

Screen images can be printed or saved to a file.

1. Printing screen images

1. Display the screen you wish to print.
2. Press the “Print Screen” key on the keyboard.
   The image is imported to the screen image print tool.
   The Print Screen dialog box appears.

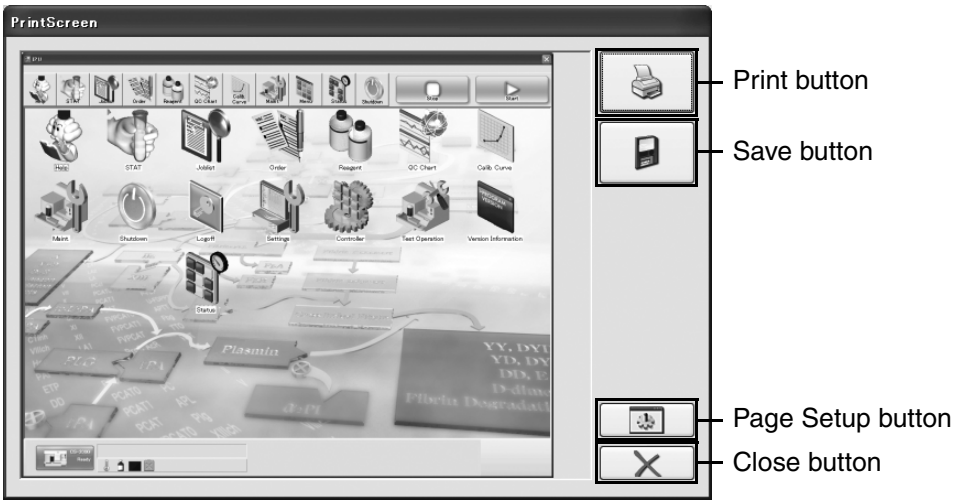

Figure 9-09: Print Screen dialog box

3. Press the Print button.
   The screen image is printed.

2. Saving screen images

1. Display the screen you wish to save.
2. Press the “Print Screen” key on the keyboard.
   The image is imported to the screen image print tool.
   The Print Screen dialog box appears.
3. Press the Save button.
4. Enter the folder name and file name to save.
5. Press **OK**.
   The screen image is saved.

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