

[ Multiple mode (Hemoglobin / Calprotectin) ]

Be sure to read "Safety Precautions" before use. Safely use this product after reading this Operation Manual carefully. Store this Operation Manual in a safe place so that it can be referred to when necessary.

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- The content in this Operation Manual and system specifications may be changed without notice in order to make improvements.
- We are not responsible for any damages or the like if the system is not used in accordance with this Operation Manual.
- In vitro Diagnostic Medical Device Regulation (EU)2017/746

medical equipment.

•	EN 61010-1	:	Safety requirements for electrical equipment for measurement,
			control, and laboratory use Part 1: General requirements.
•	IEC 61010-2-101	:	Safety requirements for electrical equipment for measurement,
			control, and laboratory use - Part 2-101: Particular requirements for
			in vitro diagnostic (IVD) medical equipment.
•	EN 61326-1	:	Electrical equipment for measurement, control, and laboratory use.
			EMC requirements. General requirements.
•	EN 61326-2-6	:	Electrical equipment for measurement, control, and laboratory use.
			EMC requirements. Particular requirements. In vitro diagnostic (IVD)

# Introduction

#### Prior to reading this Operation Manual

OC-SENSOR PLEDIA is a fully automated fecal occult blood analyzer—that is, it is a movable and discrete clinical chemistry automatic analysis system (below, "system").

The system and its Operation Manual is meant for doctors, clinical laboratory technicians, and those who have received specialized education or training in test procedures that use diagnosis systems outside the body.

Read this Operation Manual carefully prior to use, in order to use the system properly.

Note that using the system in a manner not described in this Operation Manual or in conditions outside the system specifications could negatively impact the system's safety and performance. Be sure to use the system according to the instructions in this Operation Manual.

Operation Manual organization

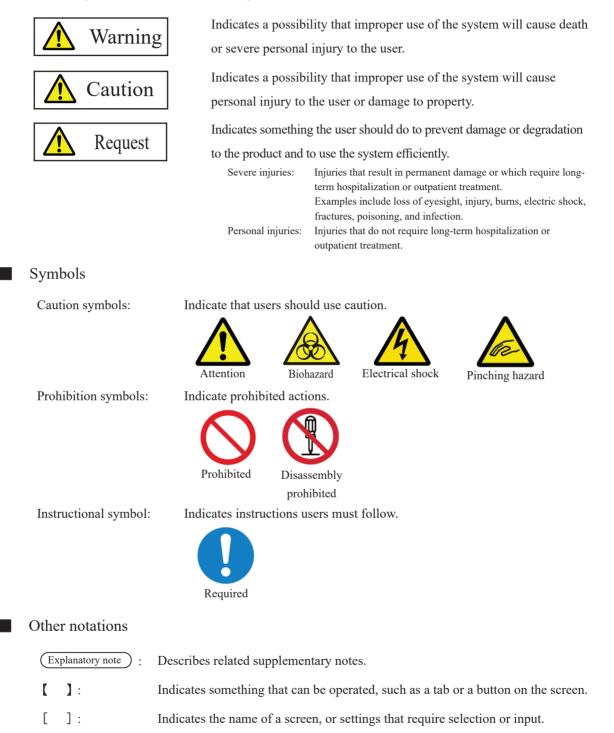
This Operation Manual	consists of the	e following chapters:
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Introduction	:	Describes the organization and notation of this Operation Manual, as well as "Safety Precautions" when using the system
Chapter 1 Overview	:	Gives an overview of the system, including measurement principles, analysis flow, as well as the names and functions of each part.
Chapter 2 Operation (Basic)	:	Gives an overview of initial settings prior to use, and describes basic operation of the system, such as daily operation.
Chapter 3 Operation (Applied)	:	Describes applied operation of the system, such as searching measured data, recalculation, output, and deletion of test data, as well as quality control.
Chapter 4 Support Functions	:	Describes support functions run prior to analysis, such as priming and cell blanking.
Chapter 5 Maintenance	:	Describes inspection and maintenance methods users should follow in order to safely use the system, maintain performance, and discover malfunctions and the like as early as possible.
Chapter 6 Settings	:	Describes details on initial settings for operating the system.
Chapter 7 Help	:	Describes analysis flow, as well as inspection and maintenance methods after use.
Chapter 8 Error Handling	:	Describes how to read the error screen.
Chapter 9 Operator/Latex Management Function (Option)	:	Describes how to Login/Logout, and managing Latex/QC Lots
Appendix	:	Describes data processing, analysis operations, printing examples, and errors.
Index/Glossary		

#### Operation Manual notation

This Operation Manual describes matters that must be followed in order to safely use the system, prevent danger to the user and others, and prevent damage to property.

#### "Warnings," "Cautions," and "Requests"



Indicates reference locations.

# Safety Precautions

Be sure to read this section before using the system.

#### Installation precautions

Power supplies and cords

#### \Lambda Warning

Prohibited

- Do not connect the power cord to an extension cord or an adaptor plug.
- Do not insert or remove the power plug with wet hands.
- Do not damage or alter the power cord.
- Do not apply excessive force to the power cord.
- Do not fasten the power cord using metal fixtures or the like.
- Do not use power cords other than that provided.

Failure to observe this precaution may lead to electric shock or fire.

🔥 Warn	ing	
Required	• Make sure that the sys Failure to observe this pre	stem is grounded. ecaution may lead to electric shock.
	• Connect to the approp	priate power supply.
	Power supply voltage	: ~100-240 V
Required	Frequency	: 50/60 Hz
	Power consumption	: 500 VA
	Socket	: The power plug uses a protective earth terminal.
		Use a fixed power socket (electrical outlet for medical use) that is correctly grounded.
	Failure to observe this pred	caution may lead to electric shock or fire.

#### Installation conditions

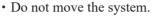
#### ▲ Caution

Kequired

- Use indoors.
  - Avoid exposure to water.
  - Avoid harmful effects that can result from barometric pressure, atmospheric temperature, humidity, poor ventilation, sunlight, dust, saline matter, or air including sulfur.
  - Install in a location that is flat and free of vibration or impact.
  - Install in a chemical storage area or in a location free from gas emission.

#### \Lambda Caution

Required

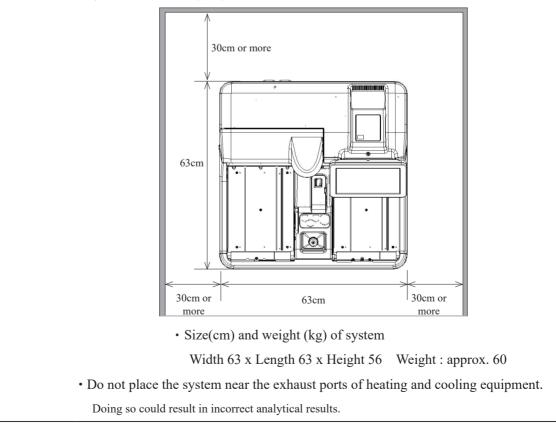


- This system should only be installed or moved by a maintenance person who has been certified by Eiken Chemical.
- Use a platform that can support the weight of the system. Make sure that the platform is stable.

If the system falls, it could cause unexpected injury.

• Install the system in a location with plenty of space, so as to not hinder operation or maintenance.

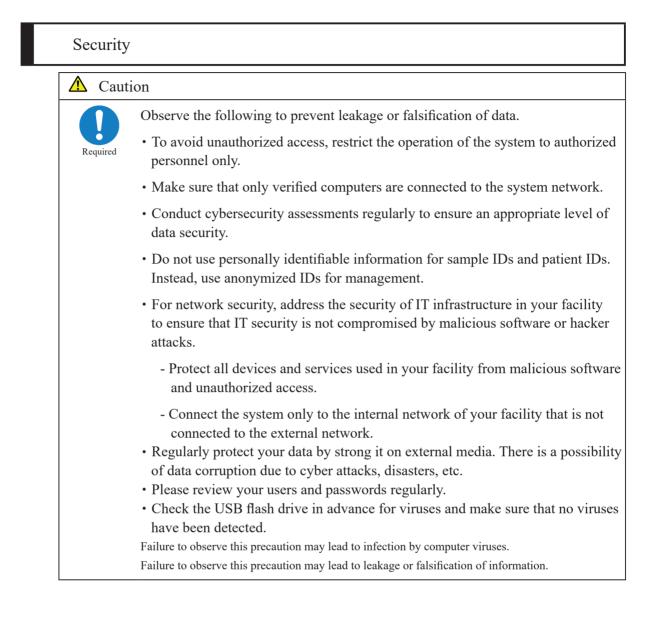
(Refer to the following diagram.)



🚹 Cautio	on	
	• Adhere to the following	environmental conditions:
Required	Usage conditions	Temperature: 15°C to 30°C Humidity: 20% to 80% (no condensation) Height of 2,000 m or less* Pollution degree 2* Overvoltage category II*
	Storage conditions	Temperature: 0°C to 55°C Humidity: 20% to 90% (no condensation)
	Transport conditions	Temperature: -20°C to 60°C Humidity: No more than 95% when the temperature is 25°C to 55°C (no condensation)

equipment for measurement, control, and laboratory use-Part 1: General requirements."

EMC (E	lectromagnetic Compatibility)
🛕 Caut	ion
	• This equipment is not intended for use in residential environments and may no
	provide adequate protection to radio reception in such environments.
Required	• TThis equipment is designed for use in a PROFESSIONAL HEALTHCARE
	FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a
	HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance
	is affected by electromagnetic interface, correct operation may be restored by
	increasing the distance between the equipment and the source of the interface
	• The electromagnetic environment must be evaluated before operating the
	device.
	• Do not use this device in proximity to sources if strong electromagnetic
	radiation (e.g. unshielded intentional RF sources), as these can interfere with
	proper operation.

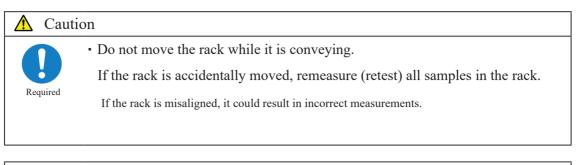


## Usage precautions

Work and operation precautions

🔥 Warn	ing
	• Wear protective equipment when handling samples.
Biohazard	• Wash your hands well after using the system.
	Failure to observe this precaution may lead to infection from samples.
	Dispose of drainage after using the system.
Biohazard	• Make sure that drainage does not leak into the area surrounding the device when
Dionazaru	detaching the drain tank hose.
	• Make sure the drain tank is empty prior to using the system.
	Failure to observe this precaution may lead to infection from samples.
	• Be careful not to let the sample container fall over when attaching / detaching
Dishagan	the sample rack or tray.
Bioliazard	Failure to observe this precaution may lead to infection/contamination from samples.
	Failure to observe this precaution may lead to loss samples.
	• Be careful of sample splattering when removing the sampling bottle from the
Biohazard	rack.
Dionazard	Failure to observe this precaution may lead to infection from samples.
	• Do not disassemble the system.
	• Do not remove any of the system's exterior parts.
Disassembly prohibited	Failure to observe this precaution may lead to electric shock.
Electrical shock	
	• Do not spill any samples or reagents inside the system.
Prohibited	Failure to observe this precaution may lead to electric shock.
	• Do not mix the washing solution with acid washing solution.
Prohibited	Failure to observe this precaution may damage the operator's health.

# Caution Do not open the cover of the analysis chamber during operation. Keep out of the operational range of the system during operation. Failure to observe this precaution may lead to injury or damage.



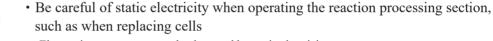
#### \Lambda Caution

- Connect each tank (purified water, wash solution, and drainage) correctly with each hose.
- Monitor the quality control function and positive rate change periodically. Failure to observe this precaution may lead to a false diagnosis.

#### 🛕 Caution

Required

Required



Electronic components may be damaged by static electricity.

For example, you can discharge static electricity by touching a grounded metal part around the device.

#### ▲ Caution

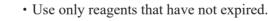
Required

- Use only recommended external media (such as USB memory). Contact us for details on recommended products.
- Manage external media appropriately. Check for viruses periodically. Failure to observe this precaution may lead to infection by a computer virus.

#### ▲ Caution

Required

Required



Failure to observe this precaution may lead to a false diagnosis.

#### Caution

• If the reagent compartment or buffer compartment becomes abnormally hot, dispose of the reagent or buffer that was set. Failure to observe this precaution may lead to a false diagnosis.

#### ▲ Caution



• Do not turn off the primary power switch until the system shut downs completely.

completely.

The hard disk(SSD) inside the system could be damaged and data could be lost.

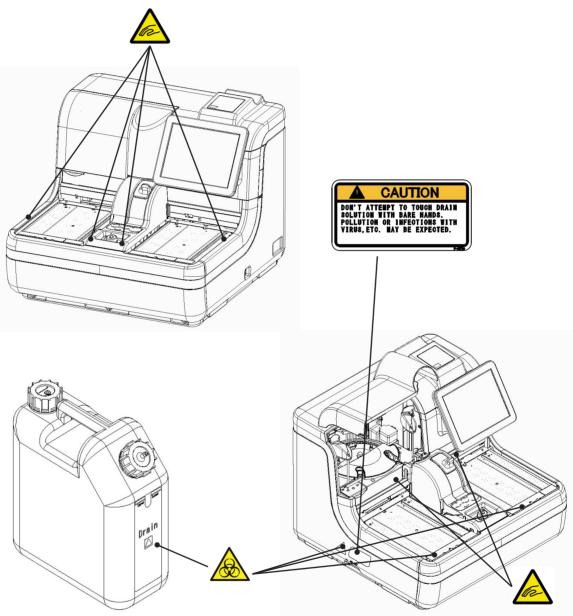
х

М	aintenance and inspections
	Warning
	• Wear protective equipment when maintaining and inspecting the system.
	• The tip of the nozzle is sharp. Use caution when handling it.
Bio	• The tip of the puncture needle is sharp. Use caution when handling it.
	Failure to observe this precaution may lead to infection from samples.
	Request
	<ul> <li>Inspect the system before starting operations each time.</li> <li>Check that there is no water leakage.</li> <li>No devices other than the designated ones should be connected.</li> </ul>
	<ul> <li>The environmental conditions are satisfied.</li> <li>Be sure to maintain and inspect the system daily, and keep it clean.</li> </ul>
	Request
	• If the system has not been used for some time, check that the system is operatin
	properly prior to use.
	Request
	• If system failure is suspected, do not touch the system, and do not attach a
	failure notice or other notification. Immediately contact the manufacturer or a
	legal representative.
Di	isposing of drainage and waste
	Warning
	• Dispose of drainage and waste (reagent containers, reaction containers,
	sampling bottles, and sample cups) appropriately in accordance with facility
D	safety management procedures and the instructions of the person in charge of
	infectious medical waste management.
	(Some examples of infectious medical waste include reagent containers, reaction containers,
	sampling bottles, and sample cups.)
	• Refer to the usage instructions attached to the reagent for information on how
	dispose of reagent containers and drainage.
	<ul><li>dispose of reagent containers and drainage.</li><li>Contact your dealer for information on disposing of the system.</li></ul>

## Caution labels and where they are affixed

The following caution labels are affixed to the system.

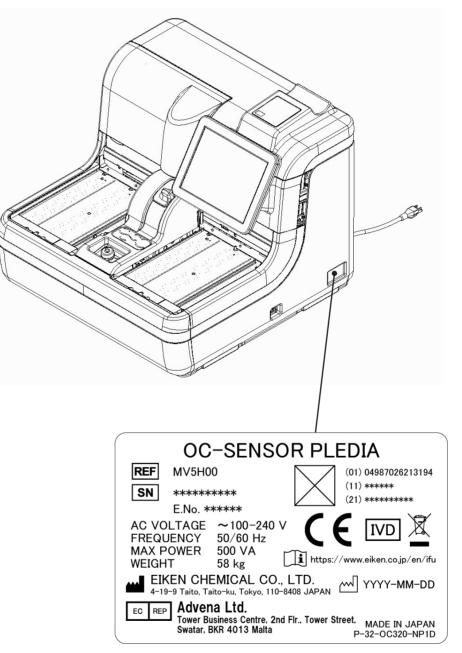
Understand where the caution labels are and what they mean before using the system.



Tank (for drain)

Caution Label	Meaning
	Keep out of operational range during system operation. Failure to observe this precaution may lead to injury.
	Do not handle drainage with bare hands. Failure to observe this precaution may lead to infection or contamination.

## Identification plate and where affixed



A two-dimensional code (GS1-DataMatrix) is printed in the  $"\boxtimes"$  area.

MEMO

# Table of Contents

## Introduction

Prior to readi	ng this Operation Manual ······ii
Operatio	n Manual organization ······ii
Operatio	n Manual notation ······ iii

## **Safety Precautions**

Installation precautions ······ iv
Usage precautions viii
Caution labels and where they are affixed xi
Identification plate and where affixedxii

## Chapter 1 Overview

1.1	OC-SENSOR PLEDIA Features ······ 2				
1.2	Use······2				
1.3	Measurement Principles2				
1.4	System Configuration 3				
1.5	Analysis Flow 5				
1.6	System Specifications6				
1.7	Reagents Used by System				
1.8	System Dimensions				
1.9	Names and Functions of Parts				
	1.9.1 Exterior parts ······10				
	1.9.2 Internal parts · · · · · · 12				
	1.9.3 Accessories/other ······14				

## Chapter 2 Operation (Basic) ———

2.1	Basic	Screen Operation
	2.1.1	[MENU] screen and functions
	2.1.2	Screen composition and button operation
	2.1.3	[Monitor] screen and functions
2.2	Start	ing the System
	2.2.1	Shut down normally (with all settings configured to "NO") · · · · · 27
	2.2.2	"Exchange buffer and wash sol to p. water" set to "YES" in Close
		mode, or Long suspense mode selected ······ 28
	2.2.3	"Cell blank" checked under "Settings of auto start up" in Close
		mode 30
	2.2.4	"Test" checked under "Settings of auto start up" in Close mode
2.2	Initio	1 Sattings
2.3		ll Settings
		System settings ······ 32
	2.3.2	Protocol settings ······ 34
2.4	Daily	Operation
	2.4.1	Daily operation flow
	2.4.2	Setting printer paper · · · · · · · · · · · · · · · · · · ·
	2.4.3	Check the drain tank (connected to system by maintenance person)
	2.4.4	Setting purified water ······40
	2.4.5	Setting wash solution ······ 41
	2.4.6	Setting buffer ······ 42
	2.4.7	Priming (normal prime, pipe line activation) ······ 44
	2.4.8	Measure cell blanks ······ 48
	2.4.9	Setting reagents (Pos1/Pos2/Pos3) 50
	2.4.10	Installing samples · · · · · · · · · · · · · · · · · · ·
	2.4.11	Starting tests •••••••59

	2.4.12	Adding samples (continue testing)
	2.4.13	Additional tests (changing test conditions while testing) ······ 74
	2.4.14	Cut-in analysis · · · · · · · · · · · · · · · · · ·
	2.4.15	Completing testing (normal close) •••••••82
	_	
2.5	Inspe	ction/Maintenance after Use
	2.5.1	Cleaning parts
	2.5.2	Opening the parts check list ••••••• 87
	2.5.3	Opening the error log · · · · · · · · · · · · 89
2.6	Syste	m shutdown (Close mode/Long suspense mode)
	2.6.1	Close mode ······90
	2.6.2	Long suspense ······94
2.7	Drain	Tank Processing   96

## Chapter 3 Operation (Applied)

3.1	Meas	sured Data Processing
	3.1.1	Opening the [Process data] screen ······98
	3.1.2	Displaying the [Test data] screen ······100
	3.1.3	Specifying measured data by measurement date
	3.1.4	Specifying measured data by range
	3.1.5	Reading "measured data" not in the list (reading again)108
	3.1.6	Reading "measured data" from external media
		(switching external media) · · · · · · 109
	3.1.7	Sorting measured data · · · · · 110
	3.1.8	Searching for measured data ······112
	3.1.9	Recalculating measured data ······116
	3.1.10	Outputting measured data ······120
	3.1.11	Deleting measured data · · · · · · · · · · · · · · · · · ·
	3.1.12	Copying measured data126

3.2	Editir	ng Sample IDs ······128
3.3	List	of Positive Samples
	3.3.1	Displaying the positive sample list · · · · · · · · · · · · · · · · · · ·
	3.3.2	Sorting positive sample data
	3.3.3	Specifying positive sample data by range
	3.3.4	Searching positive sample data
	3.3.5	Recalculating positive sample data ······ 140
	3.3.6	Calculating cut-off values from positive rates
	3.3.7	Outputting positive sample data
	3.3.8	Deleting positive sample data
3.4	List	of Error Samples
	3.4.1	Displaying the list of error samples150
	3.4.2	Sorting error sample data ·····152
	3.4.3	Specifying error sample data by range •••••••154
	3.4.4	Searching error sample data156
	3.4.5	Outputting error sample data · · · · · · · · · · · · · · · · · ·
	3.4.6	Deleting error sample data ·····160
3.5	Histo	gram
	3.5.1	Displaying histograms ······162
	3.5.2	Changing the histogram range166
	3.5.3	Outputting histograms168
3.6	Posit	tive Rate Change
	3.6.1	Displaying positive rate changes
	3.6.2	Configuring calculation conditions for positive rates
	3.6.3	Changing the range of positive rate change
	3.6.4	Outputting positive rate changes · · · · · · · · · · · · · · · · · · ·
	5.0.7	

Repli	cate
3.7.1	Displaying the replicate list (samples/STAT samples)178
3.7.2	Displaying the [Replicate (STD)] screen · · · · · 182
3.7.3	Saving replicate data (STD) to external media
3.7.4	Displaying the [Replicate (QC)] screen ······186
3.7.5	Sorting replicate data (samples/STAT samples)188
3.7.6	Specifying replicate data by range
3.7.7	Searching replicate data
3.7.8	Recalculating replicate data
3.7.9	Editing/recalculating calibration curves (samples/STAT samples)
3.7.10	Editing/recalculating calibration curves (STD) 200
3.7.11	Reading/registering calibration curves (samples/STAT samples)
3.7.12	Displaying/printing time courses (samples/STAT samples) ···· 204
3.7.13	Displaying/printing time courses (STD) ······205
3.7.14	Changing the range of the time course (samples/STAT samples)
3.7.15	Changing the range of the time course (STD) ······ 208
	3.7.1 3.7.2 3.7.3 3.7.4 3.7.5 3.7.6 3.7.7 3.7.8 3.7.9 3.7.10 3.7.10 3.7.11 3.7.12 3.7.13 3.7.14

## 3.8 Quality Control

3.8.1	Displaying the QC lot list ([QC lot select] screen) ······210
3.8.2	Selecting QC lots ······214
3.8.3	Deleting QC lots ······215
3.8.4	Changing STD/QC measurement process settings from the
	[QC lot select] screen ······216
3.8.5	Opening the [Intra-day/Inter-day] screen ······218
3.8.6	Editing (recalculating) inter/intra-day data
3.8.7	Deleting inter/intra-day data ······224
3.8.8	Specifying inter/intra-day data by range
3.8.9	Displaying the X-R control graph
3.8.10	Changing the range of the $\bar{X}$ -R control graph $\cdots 232$

3.9	Rack info		
	3.9.1	Displaying the [Rack info] screen ······234	
	3.9.2	Replacing trays (optional) ······238	
3.10	Mea	suring Using Sample Cups · · · · · · · · · · · · 239	

## Chapter 4 Support Function ———

4.1	Initialization ······242
4.2	Priming ······244
4.3	Cell Blanking ······245
4.4	Washing ······246

## Chapter 5 Maintenance

5.1	Inspec	ction/maintenance
	5.1.1	Opening the [Maintenance] screen ······250
	5.1.2	Clean touch panel (daily)251
	5.1.3	Clean conveyance line (daily) ······ 252
	5.1.4	Clean washing nozzle (weekly) ······253
	5.1.5	Clean sample & reagent nozzles (weekly) ······254
	5.1.6	Clean tray (weekly) ······255
	5.1.7	Clean racks (weekly) ······256
	5.1.8	Clean tank (monthly) ······257
	5.1.9	Replacing measurement cells (when cell blank value is abnormal)

## 5.2 List of Parts to Check and Exchange

5.2.1	Opening the [Parts check list] screen ······262
5.2.2	Changing parts ······263

## Chapter 6 Settings -

6.1	Syste	m settings
	6.1.1	Sample barcode settings (common)
	6.1.2	Sample barcode settings (detailed settings by barcode type) $\cdots 268$
	6.1.3	Rack No./QC No. ·····272
	6.1.4	Environment settings ······276
	6.1.5	Data output settings - [Destination]
	6.1.6	Data output settings - [Online settings] ······284
	6.1.7	Data output settings - [Test setting] · · · · · · 288
	6.1.8	Output format ·····290
	6.1.9	Alarm
	6.1.10	Screen saver ····· 296
	6.1.11	STD/QC analysis process settings
	6.1.12	Sample cup ····· 302
	6.1.13	Printing information on system settings
	6.1.14	Backing up information on system settings/protocol settings $\cdot \cdot 306$
	6.1.15	Restoring information on system settings/protocol settings ···· 307
6.2	Proto	col settings
	6.2.1	Samp/QC protocol settings

\_\_\_\_\_

#### 

## Chapter 7 Help \_\_\_\_\_

- 7.2 Opening the [Help] Screen from the [Monitor] Screen ······ 320

## Chapter 8 Error Handling —

8.1	How to Read [Error] Screens
8.2	Error Cancellation Buttons
8.3	Clearing Errors

## Chapter 9 Operator/Latex Management Function (Option)

9.1	LOGIN/LOGOUT······ 330	
9.2	Registering, Mondifying, and Deleting Operators	
	(ID Information) ······ 334	
9.3	Managing Latex/QC Lots······340	

## Appendix

## **1** Calculation Processing

1.1	STD/QC Sample Measured Data Check
1.2	Calibration curve calculation
1.3	DA value calculation
1.4	Measured Data (Concentration) Calculation and
	Qualitative Assessment
1.5	Prozone check ····································
1.6	Reagent Blank Check (A1 Check)
1.7	Calculate Cell Blank······354

## 2 Test Operations

2.1	Operation when first measuring a sample using	
	a "sample rack" (first test)	
2.2	Operation when retesting a sample using a "retest rack"	
	(retest)	
2.3	Operation when remeasuring a sample using a	
	"sample rack" (remeasure)	
2.4	Operation when measuring a sample again it using	
	a "dilute test rack" (dilute remeasure)	
2.5	Operation when measuring STD/QC samples	
2.6	Operation when performing cut-in analysis	

## **3** Printing examples

3.1	Positive sample printing	
3.2	Final result printing when using a dilute test rack or	
	when analyzing 15-times dilution simultaneously 374	
3.3	1 day, 2 day, 3 day printing	
3.4	Printing when measuring STD/QC samples	
3.5	Error message printing	

## 4 Handling the Printer

4.1	Setting printer paper	0
4.2	LED lamp display	1

#### 5 Error List

5.1	ERR# 0-1001	$\sim$	0-2005	(Main)
5.2	ERR# 1-000	$\sim$	1-200 (S	SS1) ······ 389
5.3	MES# 1-001	$\sim$	1-007 (\$	SS1) ······407
5.4	ERR# 2-001	$\sim$	2-200 (S	SS2) ······ 409
5.5	MES# 2-001	$\sim$	2-007 (\$	SS2)416

## 6 Save to External Media

6.1	Sample Measured Data Information ······418
6.2	Sample Replicate Information420
6.3	QC Measured Data Information 423
6.4	QC Replicate Information ······425
6.5	STD Measured Data Information ······427
6.6	STD Replicate Information 429
6.7	Time Course Data Information431
6.8	Histogram Information ······433
6.9	Positive Rate Change Information435
6.10	List of Error for Output to External Media ······437

## 7 Management USB Stick Setting

7.1	How to Set a Management USB Stick	••••••440
-----	-----------------------------------	-----------

## Index/Glossary

# Chapter 1 Overview

- 1.1 OC-SENSOR PLEDIA Features
- 1.2 Use
- 1.3 Measurement Principles
- 1.4 System Configuration
- 1.5 Analysis Flow
- 1.6 System Specifications
- 1.7 Reagents Used by System
- 1.8 System Dimensions
- 1.9 Names and Functions of Parts



# Chapter 1 Overview

This section gives a general outline of the system and describes the configuration of OC-SENSOR PLEDIA, a fully automated fecal occult blood analyzer (movable and discrete clinical chemistry automatic analysis system).

#### 1.1 OC-SENSOR PLEDIA Features

- OC-SENSOR PLEDIA (below, "system") is equipped with functions required for immunoanalytical equipment, such as automatic sample dilution, a wide range of measurements, carryover countermeasures, and prozone checking.
- The system is always in standby. Reagents and buffers are managed by the thermal insulation system allowing for 24-hour sample measurement.

#### 1.2 Use

The system determines the quantity of hemoglobin etc. in feces by detecting changes in transmitted light caused by latex agglutination reactions.

#### 1.3 Measurement Principles

#### Latex turbidimetry

An antigen-antibody reaction is a specific reaction that occurs between an antigenic determinant and the active group of an antibody. The amount of bonding depends on the concentrations of the antigen and antibody.

A latex agglutination reaction is the clumping of antigen- or antibody-sensitized polystyrene latex particles caused by an antigen-antibody reaction. A light beam is passed through the reaction liquid to measure changes in the intensity of the transmitted light beam. This method is called "latex turbidimetry." This system makes use of this "latex turbidimetry."

## 1.4 System Configuration

Body         Fully automated fecal occult blood analyzer (movable and discrete clinical chemistry automatic analysis system) OC-SENSOR PLEDIA         OC-320         1           Accessories         (1)         Software program         1         Preinstalled in disk(SSD)           (2)         Racks         -         -           ·Software program         1         Preinstalled in disk(SSD)           (2)         Racks         -           ·Sample racks         OC-RK-41A         2boxes         10 units/box           ·STD/QC racks         OC-RK-42A         1         2 units/box           ·Stample racks         OC-RK-33C         1         1 units/box           ·Dilute test rack         OC-RK-34C         1         1 units/box           ·Tank (for purified water)         NBU-4033-W2         1         10 L tank w/ zero-level sensor           ·Tank (for wash solution)         NBU-4033-W3         1         10 L tank w/ maximum-level sensor           ·Tank (for wash solution preparation)         NBU-4033-W4         1         5 L tank           ·for wash solution preparation)         NBU-4033-W4         1         5 L tank           ·for wash solution preparation)         NBU-4033-W4         1         5 L tank           ·for drain)         ·NBU-4033-W4         1	Name	ck the configuration prior to using	Model	Number	Remark
blood analyzer (movable and discrete clinical chemistry automatic analysis system)       Preinstalled         Accessories       (1) Software package       Preinstalled in disk(SSD)         (2) Racks       1       Preinstalled in disk(SSD)         (2) Racks       0C-SENSOR PLEDIA       Preinstalled in disk(SSD)         (2) Racks       0C-RK-41A       2boxes       10 units/box         -Sample racks       0C-RK-42A       1       2 units/box         ·StDi/OC racks       0C-RK-33C       1       1 units/box         ·Dilute test rack       0C-RK-34C       1       1 units/box         ·Dilute test rack       0C-RK-33C       1       10 L tank w/zero-level sensor         ·Tank (for purified water)       NBU-4033-W1       1       10 L tank w/zero-level sensor         ·Tank (for drain)       NBU-4033-W2       1       10 L tank w/zero-level sensor         ·Tank (for drain)       NBU-4033-W3       1       10 L tank w/zero-level sensor         ·Tank (for drain)       NBU-4033-W3       1       10 L tank w/zero-level sensor         ·Tank (for drain)       NBU-4033-W3       1       10 L tank w/axinum-level sensor         ·Tank (for drain)       SBL       1       5 L tank         ·Emoty bottle		Fully automated fecal occult			Keillärk
chemistry automatic analysis system)       Pre in stalled in disk(SSD)         Accessories       (1) Software program       1         ·Software program       1       Pre in stalled in disk(SSD)         ·Sample racks       OC-RK-41A       2boxes       10 units/box         ·Sample racks       OC-RK-42A       1       2 units/box         ·StTD/QC racks       OC-RK-33C       1       1 units/box         ·Dilute test rack       OC-RK-34C       1       1 units/box         ·Oilute test rack       OC-RK-34C       1       1 units/box         ·Tank       MBU-4033-W1       1       10 L tank         ·for purified water)       NBU-4033-W2       1       SL tank         ·for drain)       NBU-4033-W3       1       10 L tank         ·for drain)       NBU-4033-W3       1       10 L tank         ·for drain)       NBU-4033-W3       1       5 L tank         ·fank       SBL       1       5 L tank         ·for drain)       NBU-4033-W3       1       5 L tank         ·fank       SBL       1       5 L tank         ·for drain       NBU-4033-W4       1       5 L tank         ·for drain       PP200ML       1       1      <	Body		0C-320	1	
system) OC-SENSOR PLEDIA         Image: system of the					
ÓC-SENSOR PLEDIA         Image: Construct of the second secon					
(r) bornware program       1       Preinstalled in disk(SSD)         (2) Racks					
·Software program1disk(SSD)(2) Racks·································	Accessories	(1) Software package			
(2) Racksdisk(SSD)·Sample racksOC-RK-41A2boxes10 units/box·STD/QC racksOC-RK-42A12 units/box·Retest rackOC-RK-33C11 units/box·Dilute test rackOC-RK-34C11 units/box·Dilute test rackOC-RK-34C11 units/box·TankOC-RK-34C11 units/box·TankNBU-4033-W1110 L tank·(for purified water)NBU-4033-W215 L tank·TankNBU-4033-W215 L tank·(for drain)NBU-4033-W3110 L tank·TankNBU-4033-W3110 L tank·(for drain)NBU-4033-W415 L tank·TankNBU-4033-W415 L tank·(for wash solution preparation)NBU-4033-W415 L tank·Auxiliary tank5BL15 L tank·Empty bottle (for buffer)PB-111·BeakerPP200ML1·Tank nozzles2solution preparation)·Auxiliary tank22·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020"·Measurement cellsLX-CELL-1B51 boxConsumable supplies		. Software program		1	Preinstalled in hard
Sample racksOC-RK-41A2boxes10 units/box·STD/QC racksOC-RK-42A12 units/box·Retest rackOC-RK-33C11 units/box·Dilute test rackOC-RK-34C11 units/box(3) Tanks/bottles		· Software program		1	disk(SSD)
·STD/QC racksOC-RK-42A12 units/box·Retest rackOC-RK-33C11 units/box·Dilute test rackOC-RK-34C11 units/box(3) Tanks/bottles		(2) Racks			
·Retest rackOC-RK-33C11 units/box·Dilute test rackOC-RK-34C11 units/box(3) Tanks/bottles		•Sample racks	OC-RK-41A	2boxes	10 units/box
·Dilute test rackOC-RK-34C11 units/box(3) Tanks/bottles110 L tank w/ zero-level sensor·Tank (for purified water)NBU-4033-W1110 L tank w/ zero-level sensor·Tank 		·STD/QC racks	OC-RK-42A	1	2 units/box
(3) Tanks/bottles       10 L tank (for purified water)       NBU-4033-W1       1       10 L tank w/zero-level sensor         ·Tank (for wash solution)       NBU-4033-W2       1       5 L tank w/zero-level sensor         ·Tank (for drain)       NBU-4033-W2       1       10 L tank w/ zero-level sensor         ·Tank (for wash solution preparation)       NBU-4033-W3       1       10 L tank w/ maximum-level sense         ·Tank (for wash solution preparation)       NBU-4033-W4       1       5 L tank         ·Auxiliary tank       5BL       1       5 L tank         ·Empty bottle (for buffer)       PB-11       1         ·Beaker       PP200ML       1         ·Tank nozzles       2       Solution preparation) auxiliary tank         (4) Others       2       Solution preparation) auxiliary tank         ·Cap spacer       1       For 10 L tank         ·Cap spacer       1       For 5 L tank         ·Cap spacer       1       For buffer bottle         ·Sample cups       DSP-SC-20B       1 bag       Consumable supplies         ·Power cable       CP-114 or K-CP-700       1       -         ·Barcode labels for rack       3 sheets       "001-010", "011-020" "091-099"       -         ·Measurement cells       LX-CELL-1		·Retest rack	OC-RK-33C	1	1 units/box
Tank (for purified water)NBU-4033-W1110 L tank w/zero-level sensor'Tank (for wash solution)NBU-4033-W215 L tank w/zero-level sensor'Tank (for drain)NBU-4033-W3110 L tank w/zero-level sensor'Tank (for drain)NBU-4033-W3110 L tank w/maximum-level sensor'Tank (for wash solution preparation)NBU-4033-W415 L tank'Auxiliary tank5BL15 L tank'Empty bottle (for buffer)PB-111'BeakerPP200ML1'Tank nozzles2Attached to tank (for value) solution preparation)(4) Others-'End ringOC-RING-21'Cap spacer1For 10 L tank'Cap spacer1For 5 L tank'Cap spacer1For 5 L tank'Sample cupsDSP-SC-20B1 bag (Onsumable supplies)'Power cableCP-114 or K-CP-7001'Barcode labels for rack3 sheets"001-010", "011-020" "091-099"'Measurement cellsLX-CELL-1B51 boxConsumable supplies'Thermal roll paperP-58-401 rollConsumable supplies		•Dilute test rack	OC-RK-34C	1	1 units/box
(for purified water)NBU-4033-W11w/ zero-level sensor`Tank (for wash solution)NBU-4033-W215 L tank w/ zero-level sensor`Tank (for drain)NBU-4033-W3110 L tank w/ maximum-level sensor`Tank (for wash solution preparation)NBU-4033-W415 L tank`Auxiliary tank5BL15 L tank`Auxiliary tank5BL15 L tank`Empty bottle (for buffer)PB-111·BeakerPP200ML1`Tank nozzles2Attached to tank (for v solution preparation) auxiliary tank(4) Others2Attached to tank (for v solution preparation) auxiliary tank·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag Consumable supplies·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 box L onsumable supplies		(3) Tanks/bottles			
(tor purified water)w/ zero-level sensor'Tank (for wash solution)NBU-4033-W215 L tank w/ zero-level sensor'Tank (for drain)NBU-4033-W3110 L tank w/ maximum-level sensor'Tank (for wash solution preparation)NBU-4033-W415 L tank'Auxiliary tank5BL15 L tank'Auxiliary tank5BL15 L tank'Empty bottle (for buffer)PB-111'BeakerPP200ML1'Tank nozzles2Attached to tank (for solution preparation) auxiliary tank(4) Others2Solution preparation) auxiliary tank'End ringOC-RING-21'Cap spacer1For 10 L tank'Cap spacer1For 5 L tank'Cap spacer1For 5 L tank'Sample cupsDSP-SC-20B1 bag Solution preparation'Power cableCP-114 or K-CP-7001'Barcode labels for rack3 sheets"001-010", "011-020" "091-099"'Measurement cellsLX-CELL-1B51 box Consumable supplies			NBU-4033-W1	1	
(for wash solution)NBU-4033-W21w/ zero-level sensor·Tank (for drain)NBU-4033-W3110 L tank w/ maximum-level sensor·Tank (for wash solution preparation)NBU-4033-W415 L tank·Auxiliary tank5BL15 L tank·Auxiliary tank5BL15 L tank·Empty bottle (for buffer)PB-111·BeakerPP200ML1·Tank nozzles2Attached to tank (for v solution preparation) auxiliary tank(4) Others2Solution preparation) auxiliary tank·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable supplies				1	
·Tank (for drain)NBU-4033-W3110 L tank w/ maximum-level sens·Tank (for wash solution preparation)NBU-4033-W415 L tank·Auxiliary tank5BL15 L tank·Auxiliary tank5BL15 L tank·Empty bottle (for buffer)PB-111·BeakerPP200ML1·Tank nozzles2Attached to tank (for value solution preparation) auxiliary tank(4) Others2Attached to tank·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable supplies·Thermal roll paperP-58-401 rollConsumable supplies			NBU-4033-W2	1	
(for drain)NBU-4033-W31w/ maximum-level sense·Tank (for wash solution preparation)NBU-4033-W415 L tank·Auxiliary tank5BL15 L tank·Empty bottle (for buffer)PB-111·BeakerPP200ML1·Tank nozzles2Attached to tank (for v solution preparation) auxiliary tank(4) Others2Solution preparation) auxiliary tank·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable supplies·Thermal roll paperP-58-401 rollConsumable supplies		· · · · · · · · · · · · · · · · · · ·			
(for wash solution preparation)NBU-4033-W415 L tank·Auxiliary tank5BL15 L tank·Empty bottle (for buffer)PB-111·BeakerPP200ML1·Tank nozzles2Attached to tank (for solution preparation) auxiliary tank(4) Others2Solution preparation) auxiliary tank·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable suppliesThermal roll paperP-58-401 roll			NBU-4033-W3	1	w/ maximum-level sensor
(for wash solution preparation)5BL15 L tank·Auxiliary tank5BL15 L tank·Empty bottle (for buffer)PB-111·BeakerPP200ML1·Tank nozzles2Attached to tank (for volume solution preparation) auxiliary tank(4) Others2Solution preparation) auxiliary tank·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable supplies·Thermal roll paperP-58-401 rollConsumable supplies			NBU-4033-W4	1	5 L tank
·Empty bottle (for buffer)PB-111·BeakerPP200ML1·Tank nozzles2·Tank nozzles2(4) Others2·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1·Cap spacer1·Power cableCP-114 or K-CP-700·Power cable·CP-114 or K-CP-700·Barcode labels for rack3 sheets·Measurement cellsLX-CELL-1B5·Thermal roll paperP-58-40·Thermal roll paperP-58-40·Taper1·Cap spacer1·Cap spacer1·Cap spacer1·Cap spac		(for wash solution preparation)		-	
·BeakerPP200ML1·Tank nozzles2Attached to tank (for volution preparation) auxiliary tank(4) Others2Solution preparation) auxiliary tank(4) Others1For 10 L tank·End ringOC-RING-21·Cap spacer1For 5 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable supplies·Thermal roll paperP-58-401 rollConsumable supplies		•Auxiliary tank	5BL	1	5 L tank
·Tank nozzles2Attached to tank (for v solution preparation) auxiliary tank(4) Others21·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable supplies·Thermal roll paperP-58-401 rollConsumable supplies		•Empty bottle (for buffer)	PB-11	1	
·Tank nozzles2solution preparation) auxiliary tank(4) Others-·End ringOC-RING-2·Cap spacer1·Cap spacer1·Cap spacer1For 5 L tank·Cap spacer1·Cap spacer1Sample cupsDSP-SC-20B·Power cableCP-114 or K-CP-700·Barcode labels for rack3 sheets·Measurement cellsLX-CELL-1B5·Thermal roll paperP-58-40·I rollConsumable supplies		·Beaker	PP200ML	1	
·End ringOC-RING-21·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bag·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020"·Measurement cellsLX-CELL-1B51 boxConsumable supplies·Thermal roll paperP-58-401 rollConsumable supplies		•Tank nozzles		2	Attached to tank (for wash solution preparation) and auxiliary tank
·Cap spacer1For 10 L tank·Cap spacer1For 5 L tank·Cap spacer1For buffer bottle·Sample cupsDSP-SC-20B1 bagConsumable supplies·Power cableCP-114 or K-CP-7001·Barcode labels for rack3 sheets"001-010", "011-020" "091-099"·Measurement cellsLX-CELL-1B51 boxConsumable supplies·Thermal roll paperP-58-401 rollConsumable supplies		(4) Others			
·Cap spacer       1       For 5 L tank         ·Cap spacer       1       For buffer bottle         ·Sample cups       DSP-SC-20B       1 bag       Consumable supplies         ·Power cable       CP-114 or K-CP-700       1          ·Barcode labels for rack       3 sheets       "001-010", "011-020"       "091-099"         ·Measurement cells       LX-CELL-1B5       1 box       Consumable supplies         ·Thermal roll paper       P-58-40       1 roll       Consumable supplies		·End ring	OC-RING-2	1	
·Cap spacer       1       For buffer bottle         ·Sample cups       DSP-SC-20B       1 bag       Consumable supplies         ·Power cable       CP-114 or K-CP-700       1         ·Barcode labels for rack       3 sheets       "001-010", "011-020"         ·Measurement cells       LX-CELL-1B5       1 box       Consumable supplies         ·Thermal roll paper       P-58-40       1 roll       Consumable supplies		·Cap spacer		1	For 10 L tank
· Sample cups       DSP-SC-20B       1 bag       Consumable supplies         · Power cable       CP-114 or K-CP-700       1         · Barcode labels for rack       3 sheets       "001-010", "011-020"         · Measurement cells       LX-CELL-1B5       1 box       Consumable supplies         · Thermal roll paper       P-58-40       1 roll       Consumable supplies		·Cap spacer		1	For 5 L tank
·Power cable       CP-114 or K-CP-700       1         ·Barcode labels for rack       3 sheets       "001-010", "011-020"         ·Measurement cells       LX-CELL-1B5       1 box       Consumable supplies         ·Thermal roll paper       P-58-40       1 roll       Consumable supplies		·Cap spacer		1	For buffer bottle
·Barcode labels for rack       3 sheets       "001-010", "011-020"         ·Measurement cells       LX-CELL-1B5       1 box       Consumable supplies         ·Thermal roll paper       P-58-40       1 roll       Consumable supplies		•Sample cups	DSP-SC-20B	1 bag	Consumable supplies
·Barcode labels for rack     5 sneets     "091-099"       ·Measurement cells     LX-CELL-1B5     1 box     Consumable supplies       ·Thermal roll paper     P-58-40     1 roll     Consumable supplies		·Power cable	CP-114 or K-CP-700	1	
·Thermal roll paper     P-58-40     1 roll     Consumable supplies		·Barcode labels for rack		3 sheets	"001-010", "011-020", "091-099"
		·Measurement cells	LX-CELL-1B5	1 box	Consumable supplies
Papers Operation Manual NN1-1703 1		·Thermal roll paper	P-58-40	1 roll	Consumable supplies
	Papers	•Operation Manual	NN1-1703	1	
Tank label     1 Affixed to tank		·Tank label		1	Affixed to tank

Check the configuration prior to using the system.

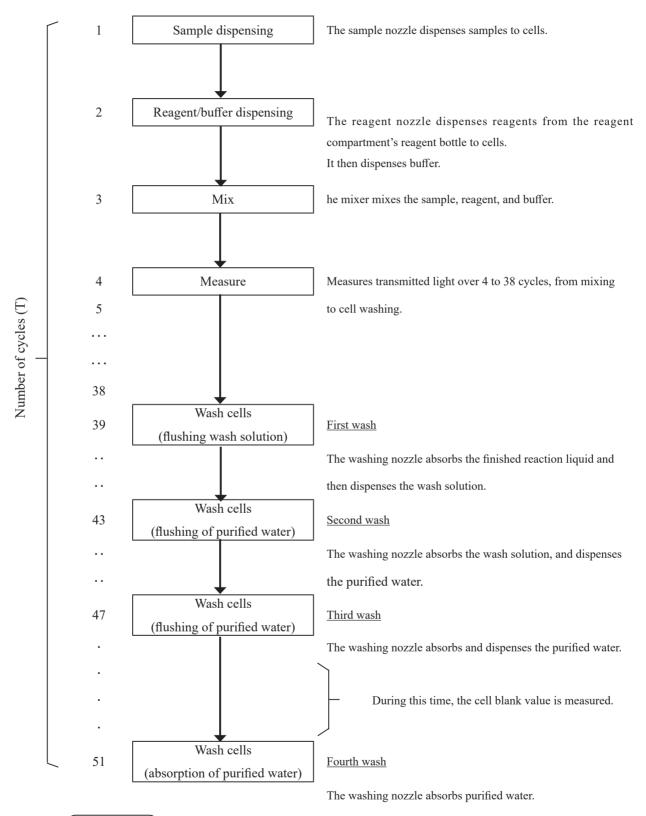
#### 1.4 System Configuration

#### Options

Name	Model	Number	Remark
Rack trays	OC-TR-20	1	2/box
Two-dimension code reader	OC-320-OP1	1	1/box
Temperature change driver board	OCP-NBP-	1	1/Box
	4033-502DU		(Buffer Temperature control system
			25°C-30°C)

#### 1.5 Analysis Flow

The analysis flow for this system is as follows:



Explanatory note : 11.3 seconds are required for a single cycle.

## 1.6 System Specifications

#### Basic specifications

Name	Specification
Measurement Principles	Latex turbidimetry
Method	Discrete method, random access method (Maximum of 2 items)
Test mode	1-Step rate
Samples	Feces
Processing capacity	160 tests/hour (including 1 measurement using sample cup)
Measurement method	1-day, 2-day, or 3-day
Sample setting	200 samples: 20 special 10-sample racks
Sample container	S sampling bottle (Eiken Chemical special bottle) Sample cup (DSP-SC-20B)
Calibration curve generation	Automatic generation of calibration curves
Stat sample setting	Up to 10 samples
Dilute test	15- or 250-times dilution
Measurement cells	Semi-disposable, 11-cell plastic holder (up to five loadable), automatic washing with wash solution and purified water
Sample dispensing	Non-disposable sampling (with a nozzle washing function)
Sample dispensing range	0 μL, 5-80 μL (1 μL unit)
Reagent dispensing	Non-disposable reagent sampling (with a nozzle washing function)
Reagent dispensing range	Latex reagent: 0 µL, 5-300 µL (1 µL unit) Buffer: 0 µL, 5-350 µL (1 µL unit)
Mix	Mixer (with washing function)
Barcode reading	Rack barcodes, sample barcodes, reagent barcodes
Prozone check	PRC method, RBC method
Check reagent blank	Detection using A1 value check
Number of analysis items	Hemoglobin, Calprotectin
	Latex reagent (24-hour control) 25°C-30°C heat block method
	Buffer (24-hour control) 35°C-41°C heat block method
Temperature control system	*25-30°C (The upper limit is room temperature) when using option
	(OCP-NBP-4033-502DU)
Light source	Reaction table40±0.5°C air bath methodLED (Wavelength: 660 nm)
Detector	Photo diode
Operation control/data processing	Multi-CPU system on internal LAN

Name	Specification
External online	RS-232C, Ethernet
Sample dispensing accuracy	20 $\mu$ L ±2 $\mu$ L, C.V. 1.0% or less
Reagent dispensing accuracy	220 μL ±2 μL, C.V. 1.0% or less
Buffer dispensing accuracy	300 μL ±10 μL, C.V. 1.0% or less
Security	Whitelist
Input method	Color LCD screen (10.5-inch), touch panel, barcode reader
Output method	Thermal printer (thermal paper width: 58 mm) Internal hard disk(SSD) External media over USB connection
Dimensions	Approx. 630 mm × approx. 630 mm × approx. 560 mm (W × D × H)
Weight	Approx. 58 kg
Power	~100-240 V 50/60 Hz 500 VA or less
Sound leve	65 dBA or less

within  $\pm 10\%$ .

#### Sample barcode specifications

Туре	No. of Digits	Check Digit	Remark
NW-7	5-17 digits (including start/stop character)	Modulus 10/3 weight Modulus 16 Modulus 11 Modulus 10/2 weight 7 check DR Weighing modulus 11 Loons	
ITF	6-15 digits	Modulus 10/3 weight	
IND 2 of 5	6-15 digits	None	
COOP 2 of 5	6-15 digits	None	
CODE39	5-15 digits (including start/stop character)	Modulus 43	
JAN	5-15 digits	Modulus 10/3 weight	
CODE128	5-15 digits	None	

#### Usable life

5 years (self-certified [based on manufacturer data]) from start of use (installation)

\* Assuming periodic inspection/maintenance, part replacement, and repairs/overhaul (when required after inspection) are conducting as described in this Operation Manual.

## 1.7 Reagents Used by System

Refer to the reagent's attached document for reagents used with this system.

#### Reagents for hemoglobin measurement

Product name	Product code	Package
OC-SENSOR DIANA Latex Reagent	V-PZ01	15 mL x 5
OC-SENSOR DIANA Buffer	V-PZ03	500 mL x 1
OC-Calibrator 2 kit	V-PH52	3 mL x 1
OC-Control LV1	V-PH53	5 mL x 2
OC-Control LV2	V-PH54	5 mL x 2
OC-Control LV3	V-PH59	5 mL x 2

#### Reagents for Calprotectin measurement

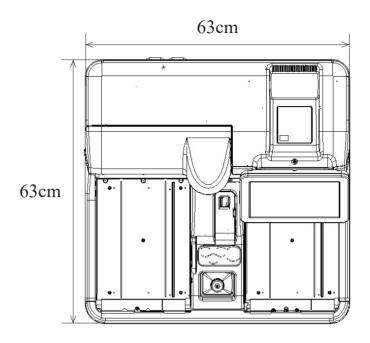
Product name	Product code	Package
OC-FCa Reagent (For OC-SENSOR PLEDIA)	V-PH11	Latex 8mL x 2 Buffer 15mL x 2
OC-FCa Calibrator	V-PH12	1 mL x 6
OC-FCa Control LV1	V-PH13	5 mL x 2
OC-FCa Control LV2	V-PH14	5 mL x 2



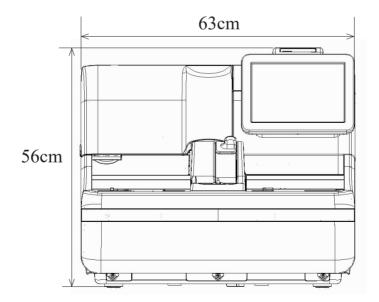
#### Common

Product name	Product code	Package
OC-SENSOR Sample Diluent	V-PH19	45 mL x 3

## 1.8 System Dimensions



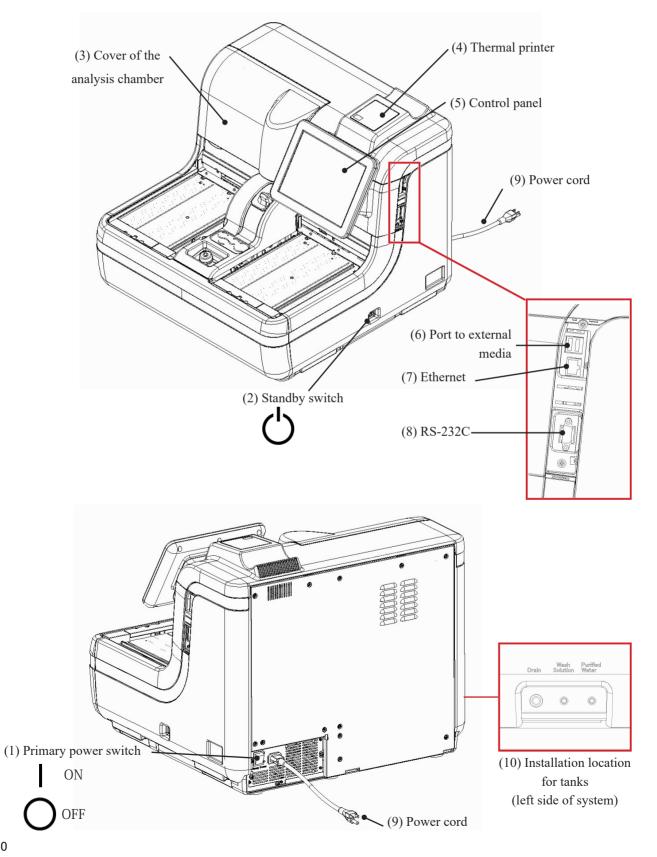
Top view

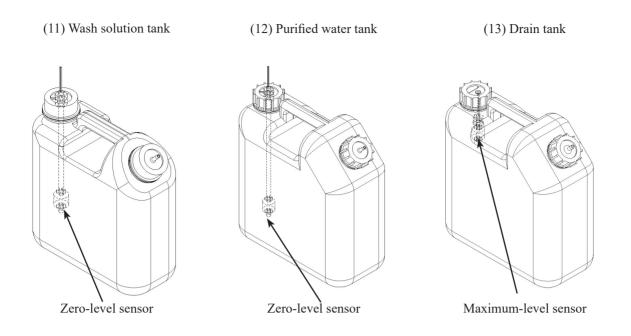


Front view

#### Names and Functions of Parts 1.9

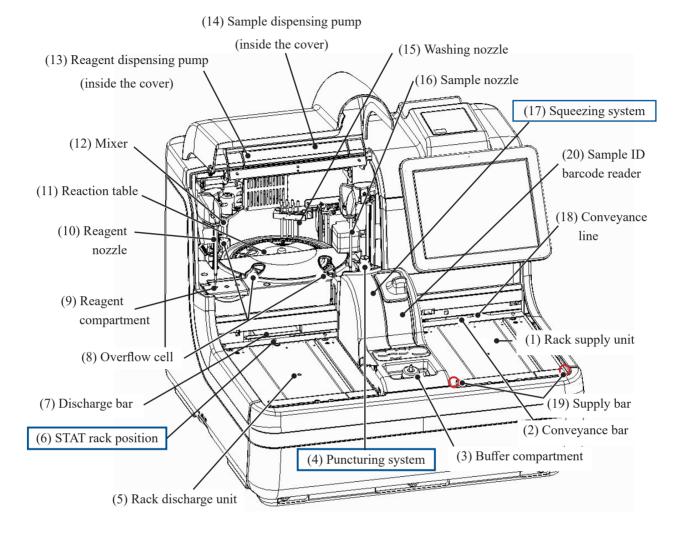
#### 1.9.1 Exterior parts

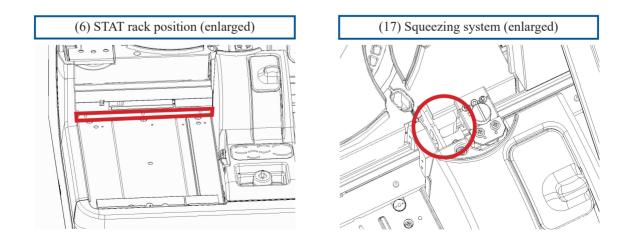




Name	Function
(1) Primary power switch	If the primary power switch is turned on, the system controls the temperature of the reagent compartment and buffer compartment. The primary power switch should normally be left on.
(2) Standby switch	If the standby switch is turned on, the system starts and controls the temperature of the reaction table.
(3) Cover of the analysis chamber	Safety feature to prevent accidents during system operation.
(4) Thermal printer	Prints setup conditions, measurement results, error messages, or other data.
(5) Control panel	Shows operation screens and analytical results. The screen can be touched directly to operate.
(6) Port to external media	Allows connection to external media for storage of measured data.
(7) Ethernet	Connects to the host computer.
(8) RS-232C	Connects to the host computer.
(9) Power cord	The power cord for this system.
(10) Installation location for tanks	Connects piping and wiring to the tanks (for wash solution, purified water, and drainage).
(11) Wash solution tank (Wash Solution)	Filled with wash solution.
(12) Purified water tank (Purified Water)	Filled with purified water.
(13) Drain tank (Drain)	Stores liquid disposed by washing the sample nozzle, reagent nozzle, mixer, and cells.

# 1.9.2 Internal parts



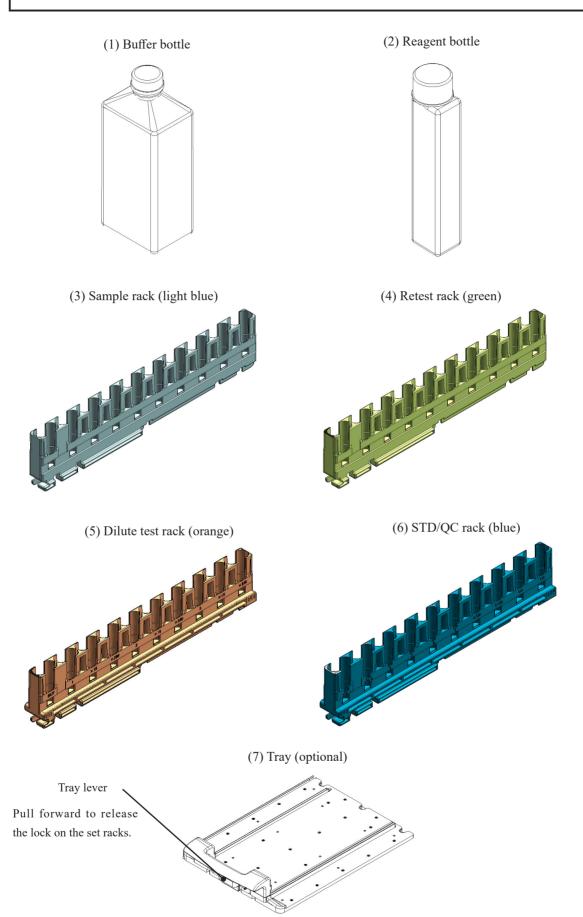


NN1-1703 Rev.3

(4) Puncturing system (enlarged)

1 Marcu       1 Marcu         (1) Rack supply unit       Location where racks are placed.         (2) Conveyance bar       Conveys a rack along the conveyance line.         (3) Buffer compartment       Location for setting the special 500 mL bottle for buffer. Constantly maintained at 35°C-41°C.         (4) Puncturing system       Punctures the double-layered aluminum seal attached to sampling bottles.         (5) Rack discharge unit       Location where racks are discharged from.         (6) STAT rack position       Location where rack is placed for cut-in analysis.         (7) Discharge bar       Feeds a rack to the rack discharge unit at the end of analysis.         (8) Overflow cell (OF)       Eor sample nozzles         Washes the inner and outer wall of sample nozzles using purified water and wash solution.       Drainage is sent to the drain tank.         For reagent nozzles       Washes mixer blades using purified water and wash solution.         Drainage is sent to the drain tank.       For reagent nozzles         (9) Reagent compartment       Location to set hemoglobin reagents, calprotectin reagents and calprotectin dilutions. Simultaneous installation is not possible.         (10) Reagent nozzle       Dispenses reagents.         (11) Reaction table       Performs antigen-antibody reaction and photometry.         (12) Mixer       Mixes samples and reagents.         (13) Reagent dispensing pump       Absorbs and f	Name	Function
Up to 20 racks can be placed.           (2) Conveyance bar         Conveys a rack along the conveyance line.           (3) Buffer compartment         Location for setting the special 500 mL bottle for buffer. Constantly maintained at 35°C-41°C.           (4) Puncturing system         Punctures the double-layered aluminum seal attached to sampling bottles.           (5) Rack discharge unit         Location where racks are discharged from.           (6) STAT rack position         Location where rack discharge unit at the end of analysis.           (7) Discharge bar         Feeds a rack to the rack discharge unit at the end of analysis.           (8) Overflow cell (OF)         For sample nozzles           Washes the inner and outer wall of sample nozzles using purified water and wash solution.         Drainage is sent to the drain tank.           For mixer         Washes the inner and outer wall of reagent nozzles using purified water.           Drainage is sent to the drain tank.         For mixer           Washes mixer blades using purified water and wash solution.         Drainage is sent to the drain tank.           For mixer         Washes mixer blades using purified water and wash solution.           Drainage is sent to the drain tank.         For mixer           (9) Reagent compartment         Location to set hemoglobin reagents, calprotectin reagents and calprotectin dilutions. Simultaneous installation is not possible.           (11) Reaction table         Performs an		
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(3) Buffer compartment       Location for setting the special 500 mL bottle for buffer. Constantly maintained at 35°C-41°C.         (4) Puncturing system       Punctures the double-layered aluminum seal attached to sampling bottles.         (5) Rack discharge unit       Location where racks are discharged from.         (6) STAT rack position       Location where rack is placed for cut-in analysis.         (7) Discharge bar       Feeds a rack to the rack discharge unit at the end of analysis.         (8) Overflow cell (OF)       For sample nozzles         Washes the inner and outer wall of sample nozzles using purified water and wash solution.       Drainage is sent to the drain tank.         For reagent nozzles       Washes the inner and outer wall of reagent nozzles using purified water.         Drainage is sent to the drain tank.       For reagent nozzles         Washes mixer blades using purified water and wash solution.       Drainage is sent to the drain tank.         For mixer       Washes mixer blades using purified water and wash solution.         Drainage is sent to the drain tank.       Eor mixer         Washes mixer blades using purified water and wash solution.       Drainage is sent to the drain tank.         For mixer       Washes measurement       Location to set hemoglobin reagents, calprotectin reagents and calprotectin dilutions. Simultaneous installation is not possible.         (9) Reagent nozzle       Dispenses reagents.       Intervent maintained at 25		
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(7) Discharge bar       Feeds a rack to the rack discharge unit at the end of analysis.         (8) Overflow cell (OF)       For sample nozzles Washes the inner and outer wall of sample nozzles using purified water and wash solution. Drainage is sent to the drain tank. For reagent nozzles Washes the inner and outer wall of reagent nozzles using purified water. Drainage is sent to the drain tank. For mixer Washes mixer blades using purified water and wash solution. Drainage is sent to the drain tank.         (9) Reagent compartment       Location to set hemoglobin reagents, calprotectin reagents and calprotectin dilutions. Simultaneous installation is not possible. Constantly maintained at 25°C-30°C.         (10) Reagent nozzle       Dispenses reagents.         (11) Reaction table       Performs antigen-antibody reaction and photometry.         (12) Mixer       Mixes samples and reagents.         (13) Reagent dispensing pump       Absorbs and flushes reagents and buffers.         (14) Sample dispensing pump       Absorbs and flushes samples.         (15) Washing nozzle       Dispenses samples. Also creates calibrator dilution series and dilutes during dilute tests.         (17) Squeezing system       Raises the sample's level of liquid in the sampling bottle.         (18) Conveyance line       Conveys racks from the rack supply unit to the conveyance line.	(5) Rack discharge unit	Location where racks are discharged from.
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(12) MixerMixes samples and reagents.(13) Reagent dispensing pumpAbsorbs and flushes reagents and buffers.(14) Sample dispensing pumpAbsorbs and flushes samples.(15) Washing nozzleWashes measurement cells.(16) Sample nozzleDispenses samples. Also creates calibrator dilution series and dilutes during dilute tests.(17) Squeezing systemRaises the sample's level of liquid in the sampling bottle.(18) Conveyance lineConveys racks from the rack supply unit to the conveyance line.(19) Supply barFeeds racks placed in the rack supply unit to the conveyance line.	(11) Reaction table	Performs antigen-antibody reaction and photometry.
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(18) Conveyance lineConveys racks from the rack supply unit to the rack discharge unit.(19) Supply barFeeds racks placed in the rack supply unit to the conveyance line.		Dispenses samples. Also creates calibrator dilution series and dilutes during
(19) Supply bar Feeds racks placed in the rack supply unit to the conveyance line.	(17) Squeezing system	Raises the sample's level of liquid in the sampling bottle.
	(18) Conveyance line	Conveys racks from the rack supply unit to the rack discharge unit.
	(19) Supply bar	Feeds racks placed in the rack supply unit to the conveyance line.

## 1.9.3 Accessories/other



Name	Function			
(1) Buffer bottle	Hemoglobin Buffer (OC-SENSOR DIANA Buffer).			
(2) Reagent bottle	Latex reagents and diluents for calprotectin			
(3) Sample racks				
(4) Retest rack				
(5) Dilute test rack	Holds sampling bottles and sample cups.			
(6) STD/QC racks				
(7) Tray (optional)	Used to place each rack.			

MEMO

# Chapter 2 Operation (Basic)

- 2.1 Basic Screen Operation
- 2.2 Starting the System
- 2.3 Initial Settings
- 2.4 Daily Operation
- 2.5 Inspection/Maintenance after Use
- 2.6 System shutdown (Close mode/Long suspense mode)
- 2.7 Drain Tank Processing



# Chapter 2 Operation (Basic)

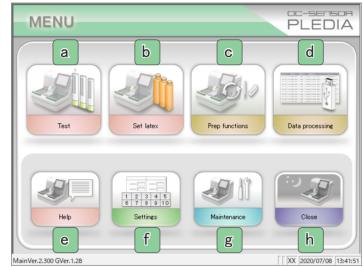
# 2.1 Basic Screen Operation

This section describes functions that can be run from the [MENU] screen, as well as buttons displayed on the screen and their basic operation.

2.1.1 [MENU] screen and functions

When the system is started, the [MENU] screen is displayed.

The following functions (from **a** - **h**) can be run from the [MENU] screen.

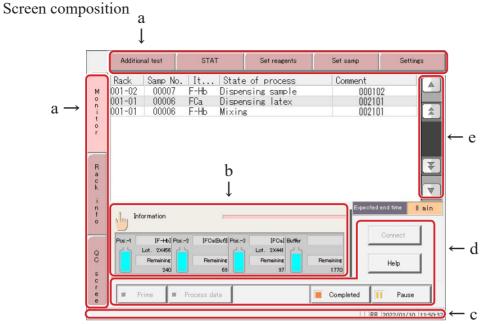


[MENU] screen

a	Test	Sets conditions for running tests (such as Test mode, Latex/CC settings, Set reagents, and Test setting).
b	Set latex	Set latex after reading the latex barcode. Touching the {Close} button completes reagent setting.
C	Prep functions	Display the [Prep functions] screen. Initialize, Prime, Cell blank, and Wash can be run from "Prep functions."
d	Data processing	Run "Process data" or "Process QC." A password must be entered to open the "Select measured data" screen (if a password is set).
е	Help	Display the [Help] screen. Used to confirm how to operate the system.
f	Settings	Perform "System settings" and "Protocol settings" for the system.
g	Maintenance	Confirm parts to check and exchange, or perform maintenance.
h	Close	Shut off the system. Running "Close mode" or "Long suspense" will automatically turn the standby switch off.

# 2.1.2 Screen composition and button operation

This section describes the {Buttons} and {tabs} displayed on the screen, and how to input settings.



#### [Monitor] screen

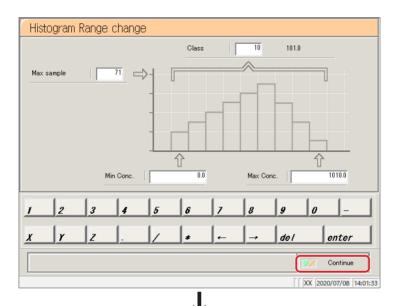
а	Tabs	Buttons to select functions in the same hierarchical directory at the top of the screen.
		They are located on the top and left side of the screen.
b	{Information} button	Touching the button displays the [Information] screen.
		Page 24 "2.1.3 [Monitor] screen and functions"
с	Status bar	Displays messages and the date.
d	Buttons	Buttons for running processes.
		Buttons are displayed according to the screen. ({Start/Cancel}, {Register/
		Cancel}, {abort}, etc.)
		Page 20 (Start/Cancel} button and {Register/Cancel} button"
e	Next page button	Switches the page up and down on the screen.

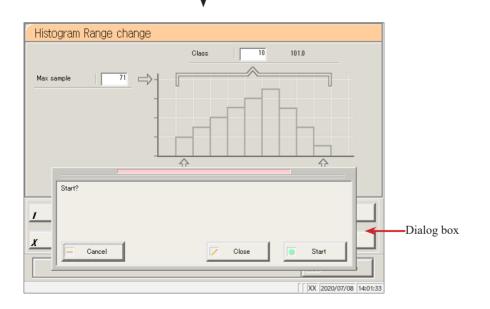
### {Start/Cancel} button and {Register/Cancel} button

There is a {Start/Cancel} button on the processing screen, and a {Register/Cancel} button on the setting screen. The description will now continue with the [Histogram Range change] and [Latex/ CC settings] screens as examples.

[Histogram Range change] screen

Touching the {Continue} button opens the dialog box.





{Start}: Start processing (in this case, change the histogram range).

{Close}: Cancel processing and return to the previous screen (in this case, the [Histogram] screen).

{Cancel}: The dialog box closes.

(Explanatory note): The {Del} button appears on screens such as Process data and Process QC.

Touching the {Del} button deletes the data in memory, but does not delete data from the hard disk(SSD). To update data, touch the {Register} button.

#### [Latex settings] screen

Touching the {Continue} button opens the dialog box.

Latex	setting	IS								
(F-Hb)			Po	s	1			←	CC No.	1
FCa(Buffer	r)]		Po	s	2					
FCa]			Po	s	3			←	CC No.	4
atex for C	CC[F-Hb]					Latex for C	C[FCa]			-
'os [	1		→save a:	s CC No	p. 1	Pos	3	→sav	ve as CC No.	4
CC No.	Da	ate		Latex lo	it	CC No.	Date		Latex lot	
1	20/03/	31 17:41		97003	3	4	20/04/09 18:2	4	97003	
2						5				
3						6				
1	1		1	1	1	1	1 1	1	1	1
	2	3	4	5	6	7	8	9	0 –	_
1	γ	z	_		*	←	→	de i	enter	.
			r	1						
CC	0	CC s	etting						<ul> <li>Continue</li> </ul>	
								X	( 2020/07/08	14:04:44
atex s	setting	S								
[F-НЬ]			D-							-
			"	s	1			←	CC No.	1
FCa(Buffer	r)]			s s	1			←	CC No.	1
	r)]		Po		1 2 3					1
(FCa)			Po	s	J	Latex for C	:c[FCa]			_
(FCa) .atex for C			Po	s s	3	Latex for C Pos	:C[FCa] 3	←		_
(FCa) .atex for C	СС[F-HЬ]		Po   Po →save a:	s s	) 3 ). 1			←	CC No.	4
FCa] atex for C os [	DC[F-Hb]		Po   Po →save a:	s s ⊧ CC No	3 0. 1 it	Pos CC No. 4	3	← →sav	CC No.	4
FCa] atex for C Pos CC No. 1 2	DC[F-Hb]	ate	Po   Po →save a:	s.− s.− s CC No Latex Io	3 0. 1 it	Pos CC No.	3 Date	← →sav	CC No.	4
(FCa) atex for C Pos	DC[F-Hb]	ate	Po   Po →save a:	s.− s.− s CC No Latex Io	3 0. 1 it	Pos CC No. 4	3 Date	← →sav	CC No.	4
1 2 3	DC[F-Hb] 1 Da 20/03/	ate	Po   Po →save a:	s.− s.− s CC No Latex Io	3 0. 1 it	Pos CC No. 4	3 Date	← →sav	CC No.	4
(FCa) Latex for C Pos	DC[F-Hb] 1 Da 20/03/	ate	Po   Po →save a:	s.− s.− s CC No Latex Io	3 0. 1 it	Pos CC No. 4	3 Date	← →sav	CC No.	4
FCa) atex for C os CC No. 1 2 3 F	DC[F-Hb] 1 Da 20/03/	ate	Po   Po →save a:	s.− s.− s CC No Latex Io	3 0. 1 it	Pos CC No. 4	3 Date	← →sav	CC No.	4

{Register}: Register settings (in this case, register Latex settings).

{Close}: Cancel setting registration and return to the previous screen (in this case, the [Test] screen).

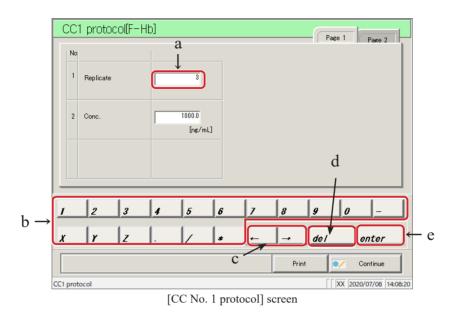
XX 2020/07/08 14:04:44

{Cancel}: The dialog box closes.

#### 2.1 Basic Screen Operation

#### Setting input

This section describes how to input, insert, and delete numerical values. ([MENU] - [Settings] - [Protocol settings] - [CC1 protocol])



#### Numerical input

- ① Touch the input field (a).
- (2) Touch the numeric keypad (b) and input the numerical value.
- 3 Touch {enter} (e) (confirm the numerical value).

#### Single character insertion

- ① Touch the input field (a).
- (2) Move the cursor to the left of the character to insert using the  $\{\leftarrow\}$  and  $\{\rightarrow\}$  buttons (c).

#### Single character deletion

- ① Touch the input field (a).
- (2) Move the cursor to the left of the character to delete using the  $\{\leftarrow\}$  and  $\{\rightarrow\}$  buttons (c).
- ③ Touch the {del} key (d).

(Explanatory note): Item settings can be skipped by inputting an asterisk (\*).

"\*" cannot be input for some settings. See the message displayed in the status bar at the bottom of the screen to confirm what can be input.

 Explanatory note
 : Input using the keypad is the same as input using the numeric keypad. (right page)

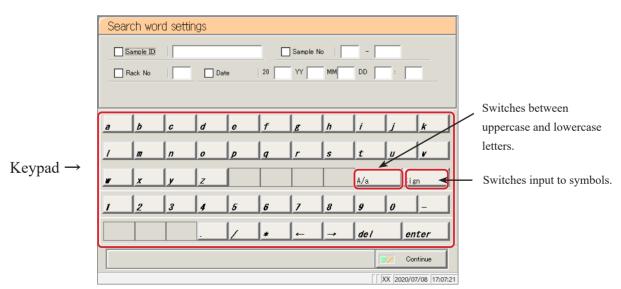
 Touch the {A/a} button to switch between uppercase and lowercase letters; touch the {Sign} button to input symbols.

## Radio buttons and check buttons

Radio buttons and check buttons are for selecting one or several items when configuring conditions.

	Items	Printer	Ext. media	Online		Items	Printer	Ext. media	Online
1	Small space				7	Flag(+-)			
2	New line				8	Date			
3	Rack No.				9	Value Format	• ****	***	
4	Sample No.				IL		○ ****	##	
5	Sample ID						ſ		
6	DA value						f		
					J				
_								•/	Continue

# fRadio buttonImage: Allow selection of a single item.gCheck buttonsImage: Allow selection of several items.



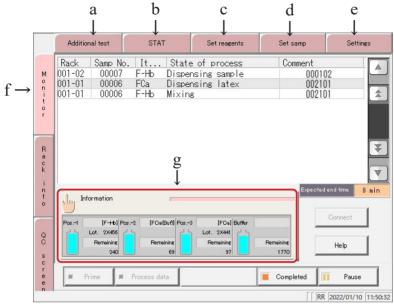
[Search word settings] screen

# 2.1.3 [Monitor] screen and functions

Touching the {Start} button on the [Test] screen starts the self check function.

After the self check is complete, the [Test] screen is displayed.

The following functions can be run from the [Test] screen.



[Test] screen

a	Additional test	Test conditions such as "Test mode" and "Latex/CC settings" can be changed while testing. Page 74 "2.4.13 Additional tests (changing test conditions while testing)"
b	STAT	Cut-in analysis for test racks and STD/QC racks can be run during testing.
c	Set reagents	Reagents 1 through 3 and the buffer can be set to the system during testing. Page 42 "2.4.6 Setting buffer" Page 50 "2.4.9 Setting reagents (Pos2/Pos3)"
d	Set samp	Racks can placed on the rack supply unit during testing. Page 52 "2.4.10 Placing samples"
e	Settings	Open the "System settings" screen. The system settings and protocol settings can be confirmed. Page 266 "Chapter 6 Settings"

f	Monitor	Monitor							
	Rack	The rack number and position in the rack of the sample (stat samples, STD samples, and QC samples) being tested is displayed.							
	Samp No.	The number of the sample (stat samples, STD samples, and QC samples) being tested is displayed.							
		Symbols shown after the sample number have the following meanings: A: Retest							
		A*: 15-times dilution retest A**: 250-times dilution retest							
-	Item name	The analysis items are displayed. F-Hb、FCa、							
	State of process	The current state of processing is displayed. The following is displayed: Dispensing sample Dispensing latex Mixing Reacting [# min] The time until analytical results are output is shown in the brackets ([]). Data (when the measurement has completed normally) Err* (when the measurement has not completed normally) (Explanatory note): *Main errors No Tube, Puncture Err, Sample Short, L. Dispense Err, S. Dispense Err, No Cal. Curve, Mixing error, Latex Blank Err, B/C Duplication, B/C Read NG B/C Read NG are displayed in the comment field.							
	Comment	The sample ID that was read is displayed. "Barcode read err" is displayed if the sample barcode could not be read.							
	Expected end time (min)	Display the expected time that washing will complete for all reaction cells and the system will stop. (Explanatory note) This time will not change while sample dispensing continues.							
g	{Information}	Touching the {Information} button opens the [Information] screen and displays Latex information, Test condition, and Latex settings information. Touching the {Close} button returns to the [Monitor] screen.							

# 2.1 Basic Screen Operation

		Additional test	STAT	Set reagents	Set samp	Settings
	M on it or	Rack         Samp N           001-02         00007           001-01         00006           001-01         00006	F-Hb Disper FCa Disper	e of process nsing sample nsing latex g	Comment 0001 00211 00211	1
$h \rightarrow$	R a c k i n f o	Information			Expected	lend time 8 min
$1 \rightarrow$	QC scree	Pos1 (F+b) F Lot. 2X466 Remainine 240	Remaining 69	3 [FCe] Buffer Lot. 2X441 Remaining 37	Remaining 1770	Connect Help Pause
	n				RR	2022/01/10 11:50:32

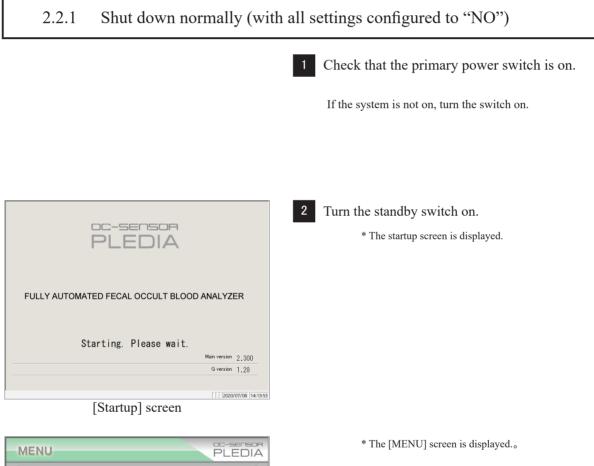
# [Monitor] screen

Rack info	The [Rack info] screen is displayed. The condition of the rack in the rack discharge unit can be confirmed here. Page 234 "3.9 Rack Information"
	•
	Page 734 "3 9 Rack Information"
QC screen	Opens the [QC lot select] screen, and displays the QC lot list.
	Switch the tab to display the inter-day/intra-day data and $\overline{X}$ -R control
	diagram.
	Page 210 "3.8 Quality Control"
Buttons	
{Connect}	If an abnormality communicating with an outside computer is detected and
	the communication is disconnected, the {Connect} button is displayed.
	Resume communication using the following method.
	(1) Resolve the communication error.
	(2) [Touch the {Connect} button.
	* Communication resumes and remaining data is output.
	Explanatory note If you stop the testing with the {Close} button,
	communication finishes even if there is data that has not
	been output. In this case, specify the range of measured
	data on the [Test data] screen and then output it.
{Help}	The [Help] screen opens.
	Page 318 "Chapter 7□Help"
{Completed}	Finish testing.
{Pause}	Pause testing.
{Prime}	Functions when testing of the sample placed on the rack supply unit is
- *	finished, and the system is waiting.
	Prime purified water and wash solution.
{Process data}	Functions when testing of the sample placed on the rack supply unit is
(	finished, and the system is waiting.
	Output measured data to a printer, external media, or online.
	{Connect} {Help} {Help} {Completed} {Pause}

# 2.2 Starting the System

When the system is started, the [MENU] screen is displayed. Operation once the system starts varies according to how the system was shut down. There are three patterns:

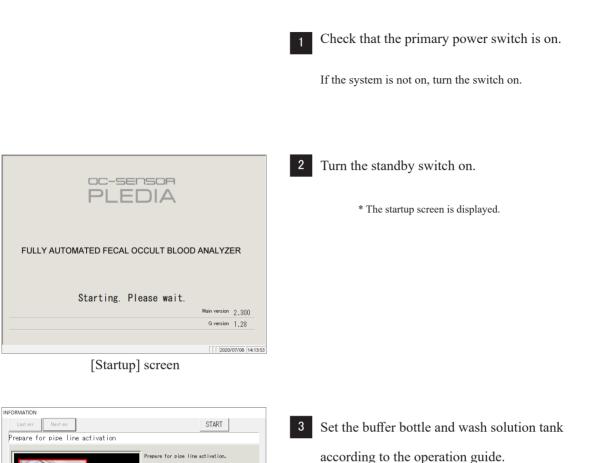
- Shut down normally (with all settings configured to "NO")
- "Exchange buffer and wash solution to purified water" set to "YES" in Close mode, or Long close mode selected
- "Cell blank settings" or "Test" checked under "Settings of auto start up" in Close mode

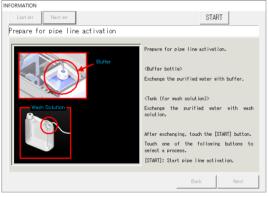




### 2.2 Starting the System

"Exchange buffer and wash solution to purified water" set to "YES" in 2.2.2 Close mode, or Long suspense mode selected

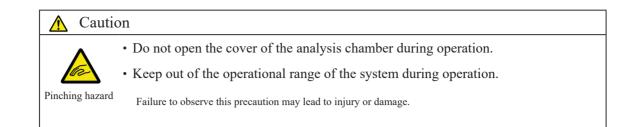




according to the operation guide.

- (1) Remove the bottle filled with purified water and the wash solution.
- (2) Set a buffer bottle filled with buffer.
- (3) Fill the wash solution tank with wash solution.
- (4) Touch the {Start} button.

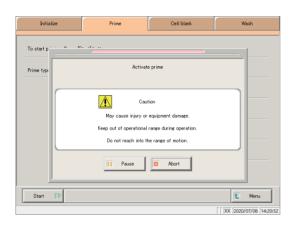
\* Pipe line activation begins.



4

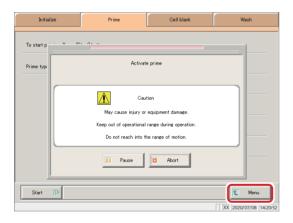
5

Activate prime



{Pause}:	Processing pauses.
{Start}:	Resume processing.
	If the Pause button is touched, it will change to
	the Start button.
{Abort}:	Abort processing.

\* When pipe line activation is complete the dialog box closes.





### Touch the $\{MENU\}$ button.

\* The system returns to the [MENU] screen.

#### 2.2 Starting the System

2.2.3 "Cell blank" checked under "Settings of auto start up" in Close mode

Check that the primary power switch is on. If the system is not on, turn the switch on OC-SENSOR PLEDIA 2 Turn the standby switch on. FULLY AUTOMATED FECAL OCCULT BLOOD ANALYZER \* The startup screen is displayed. Starting. Please wait. Main version 2.300 Giversion 1.28 2020/07/09 9:37:44 Cell blank 3 Cell blank measurement is run. Cell blank measure Caution May cause injury or equipment damage Do not open the covers or reach into the ra 
 ADC
 ABS
 No.
 ADC
 ABS
 No.

 23
 23
 34
 34
 34

 25
 25
 36
 36

 26
 37
 37
 39

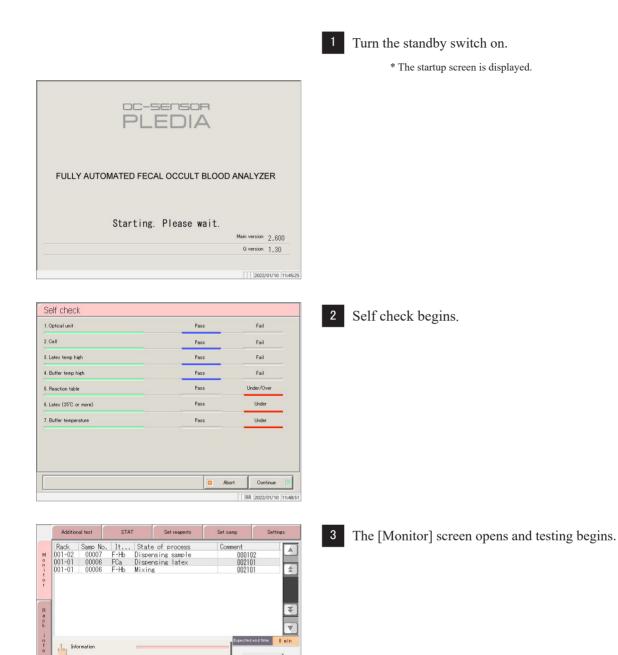
 29
 40
 41
 31
 44

 31
 42
 43
 44
 ADC 19011 18973 18980 19060 19116 ABS -8 0 -1 -19 -32 ADC ABS No. ADC ABS 45 No. 01 02 03 04 05 06 07 08 09 10 10 No. 12 13 14 15 16 17 18 19 20 21 22 46 47 48 49 50 51 52 53 54 55 II Pause Abort XX 2020/07/09 10:24:1 Initialize Cell blank Prime Wash When cell blank measurement is complete, touch the {Close} button. Cell blank measurement finished ADC ABS 18925 11 18925 11 19027 -12 18985 -2 18978 0 18732 55 18948 5 19072 -22 18966 1 19096 1 ABS -8 0 -1 -19 -32 -9 -14 8 -34 0 -12 ADC 19011 18973 18980 19060 19116 19036 18937 19036 18937 19125 18977 19027 ADC 18972 18944 19050 19081 18981 19040 19009 19011 18951 19079 19074 ABS ADC 19030 18936 18899 18996 18874 19070 18998 18920 19049 19086 18998 ABS -12 8 17 -5 22 -21 -5 12 -17 -26 -5 No. 34 35 36 37 38 39 40 41 42 43 44 ADC 18962 19032 19032 19106 19038 19009 19072 18981 18966 19000 ABS No. 01 02 03 04 05 06 07 08 09 10 11 No. 12 13 14 15 16 17 18 19 20 21 22 No. 23 24 25 26 27 28 29 30 31 32 33 No. 45 46 47 48 49 50 51 52 53 54 55 0 -17 -24 -1 -15 -8 -8 -8 5 -23 -22 2 -13 -1 -14 -8 -22 -1 1 -5 -13 Prin Close XX 2020/07/09 10:24:13 Cell blank Initialize Prime Wash 4 Touch the {MENU} button. To start cell blank measurement, Press [Start] butto 🔘 YES O NO Wash cell:

📜 Menu

Start

#### "Test" checked under "Settings of auto start up" in Close mode 2.2.4



Information Pos.-1

QC S C

Lot.

📕 Com

Pause RR 2022/01/10 11:50:32

# 2.3 Initial Settings

Initial settings must be configured to use the system for the first time.

Initial settings are broadly classified into two categories: "system settings" and "protocol settings."

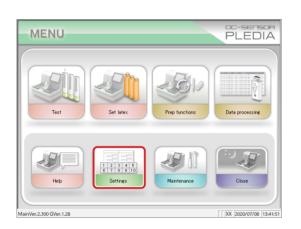
Touching the {Settings} button on the [MENU] screen displays a screen from which settings can be selected for both.

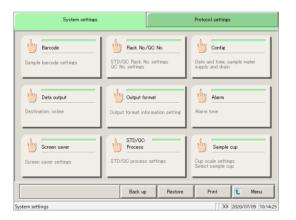
2

This section will give an overview of system settings and protocol settings.

See page 266 "Chapter 6 Settings" for details on operation.

# 2.3.1 System settings

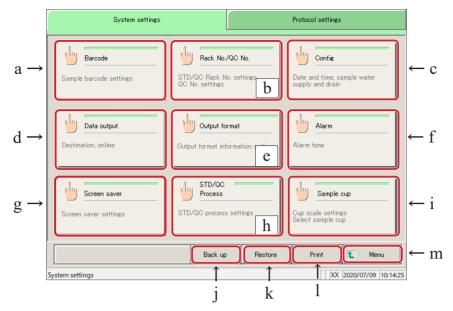




Touch the {Settings} button.

following page.)

Touch the {Button} for the item to configure. \* The settings screen for each is displayed. (See the

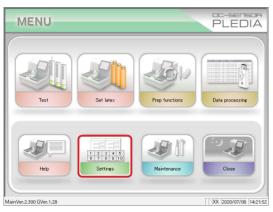


[System settings] screen

	D 1		
а	Barcode	Set conditions for reading sample barcodes.	
b	Rack No./QC No.	Register STD/QC racks, retest racks, and dilute test racks. Configure the	
		QC sequence number.	
c	Config	Configure the date.	
		Register a password for data processing.	
		Select the supply method for purified water and the drainage method for	
		drainage.	
		Select automatic rack supply.	
		Set the automatic logout time when using the operator/latex management	
		function.	
d	d Data Output Select the output destination for the data.		
	Ĩ	Select the format of data output to a printer, external media, or online.	
		Configure settings for online communication control.	
		Configure test items.	
e	Output format	Select the output format.	
		Select items for output to a printer, external media, or online.	
f	Alarm	Configure the type of alarm and how long it sounds.	
g	Screen saver	Configure the screen saver activated on the [MENU] screen.	
h	STD/QC Process	Configure conditions for checking measured data for STD samples/Q0	
		samples.	
i	Sample cup	Register the shape of the sample cup.	
j	Back up	Save system setting/protocol setting information to external media.	
k	Restore	Read system setting and protocol setting information saved to external	
		media, and restore it to the system.	
1	Print	Print system setting information.	
m	Menu	The system returns to the [MENU] screen.	

#### 2.3 Initial Settings

#### Protocol settings 2.3.2



Protocol settings Syst Barcode Rack No./QC No Confie STD/QC Rack No. settings QC No. settings Date and time, sample wa supply and drain Sample barcode setting: Alarm Data output Uutput format Output format informatic Alarm tone

Sample cup

Cup scale settings Select sample cup

Print 🚺

Menu XX 2020/07/09 10:14:25

STD/QC Process

STD/QC process setting

Back up Restore

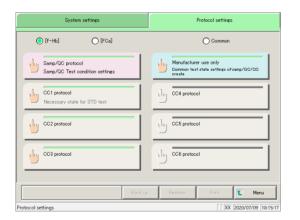
Screen saver

System settings

er settine:

Touch the {Settings} button.

2 Touch the {Protocol settings} tab.



**3** Touch the {Button} for the item to configure.

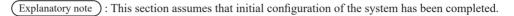
\* The settings screen for each is displayed. (See the following page.)

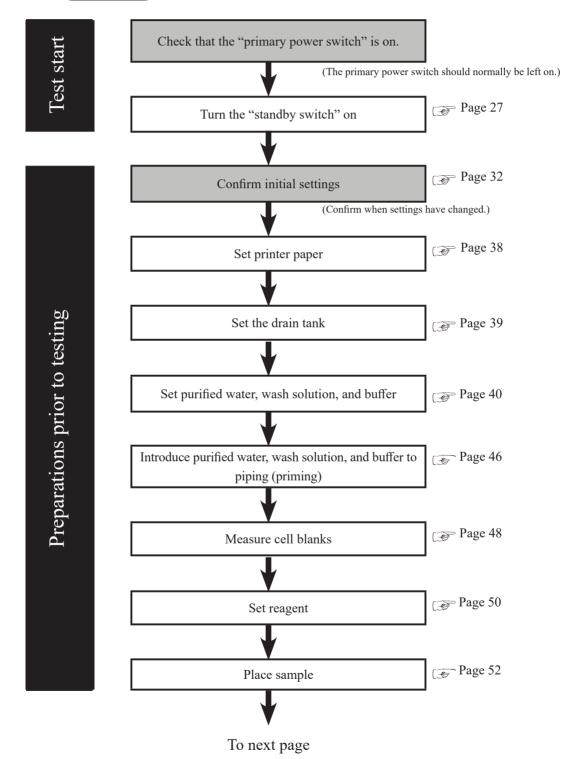
		System settings		Protocol settings		
	$a \rightarrow$	● [F-Hb] ○ [FCa]		Common		
	$b \rightarrow$	Samp/QC protocol Samp/QC Test condition settings		Manufacturer use only Common test state settings of samp/QD/DD create	← d	
		CC1 protocol Necessary state f	or STD test	Dij CC4 protocol		
$c \rightarrow \bigcirc $			CC5 protocol			
		CC3 protocol		Din CC6 protocol		
			Back up	Restore Print <b>Menu</b>	← e	
		Protocol settings	Protocol set		12.17	
а						
			protocol settings", and "Manufacturer settings" (for service personnel). [F-Hb],[FCa], [Common] Check any of the radio boutons. If [Common] is			
				an set [SAMP replicate count] a		
b	Samp/O(	C protocol		ons when measuring samples a		
	1 ~	1				
с	c CC1 to CC6 protocol Allows for registration of calibration No. 6.			istration of calibration curves	for protocols No. 1 through	
	NO. 6. CC No.1 to CC No.3 are [F-Hb], and CC No.4 to CC No.6 are [FCa].					
d	Manufacturer use Configure common conditions required for measuring samples, st					
	only					
e	Menu	Menu The system returns to the [MENU] screen.				
	(Close)			utton is displayed during testin	ng. The system returns to the	
			[Monitor] scree	en. )		

# 2.4 Daily Operation

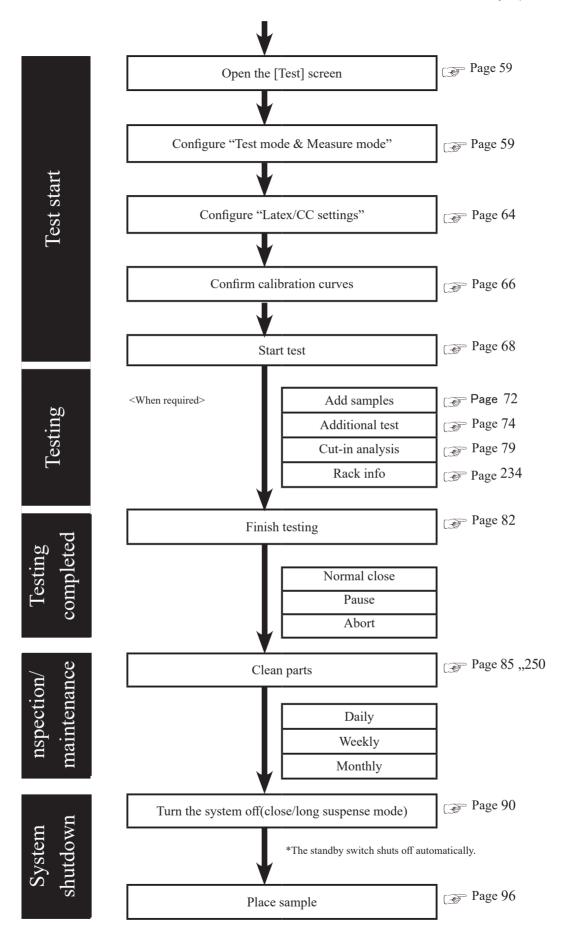
This section describes daily operation processes and procedures.

## 2.4.1 Daily operation flow





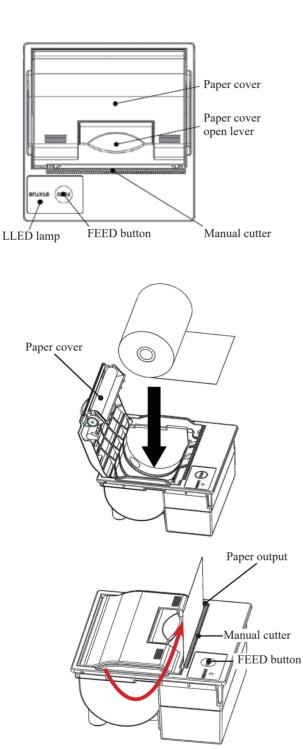
(Explanatory note) : If "Cell blank" is checked in "Auto start" in close mode, cell blank measurement will be

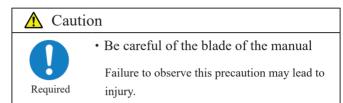


### 2.4 Daily Operation

# 2.4.2 Setting printer paper

This section describes printer paper setting.

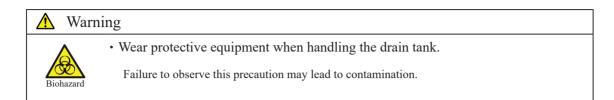




- Raise the paper cover open lever and open the cover.
- ② Set the paper as shown in the diagram to the left.(If this is set with the opposite facing, the system will be unable to print.)
- ③ Set the paper so that its edge sticks out of the paper output.
- Press both edges of the paper cover to close it.Confirm that the paper cover is locked.
- (5) Touch the FEED button.
- (6) Cut the paper using the manual cutter.

#### Check the drain tank (connected to system by maintenance person) 2.4.3

Confirm that the maximum level sensor and hose attached to the drain tank are connected to the system.



#### Caution ⚠

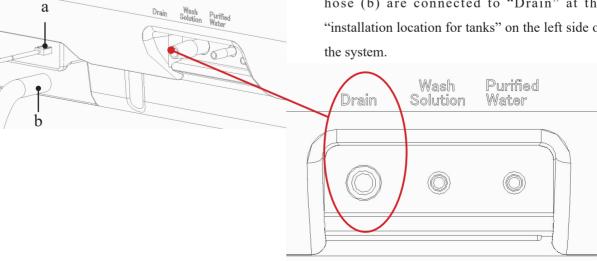


- Empty the drain tank prior to using the system.
  - If the system detects that the drain tank is full, dispensing will stop.
- Install the waste liquid tank below the equipment. If the waste tank is above the equipment, it may not be able to drain properly.

Attach a maximum-level sensor (a) and hose (b)

to each drain tank port (two).

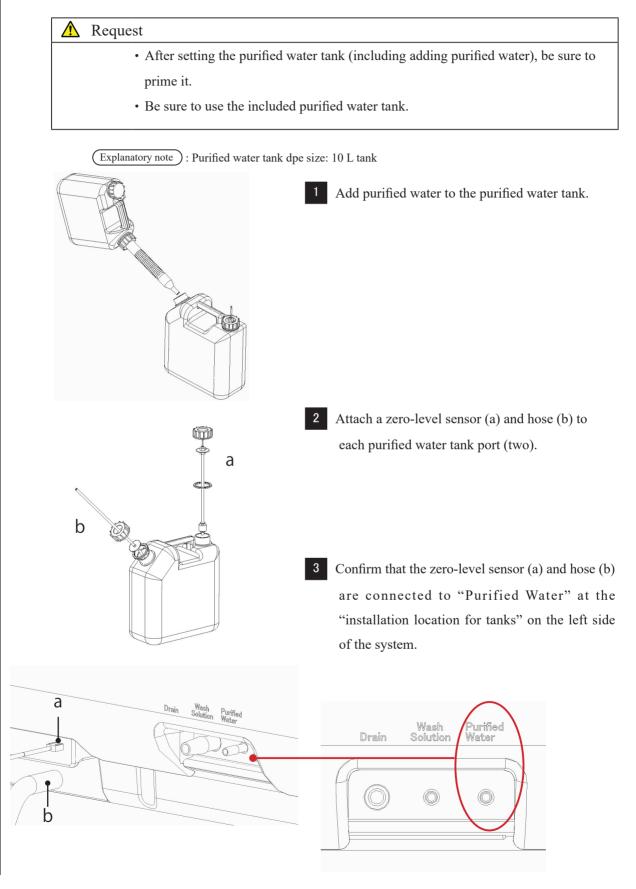
2 Confirm that the maximum-level sensor (a) and hose (b) are connected to "Drain" at the "installation location for tanks" on the left side of the system.



### 2.4 Daily Operation

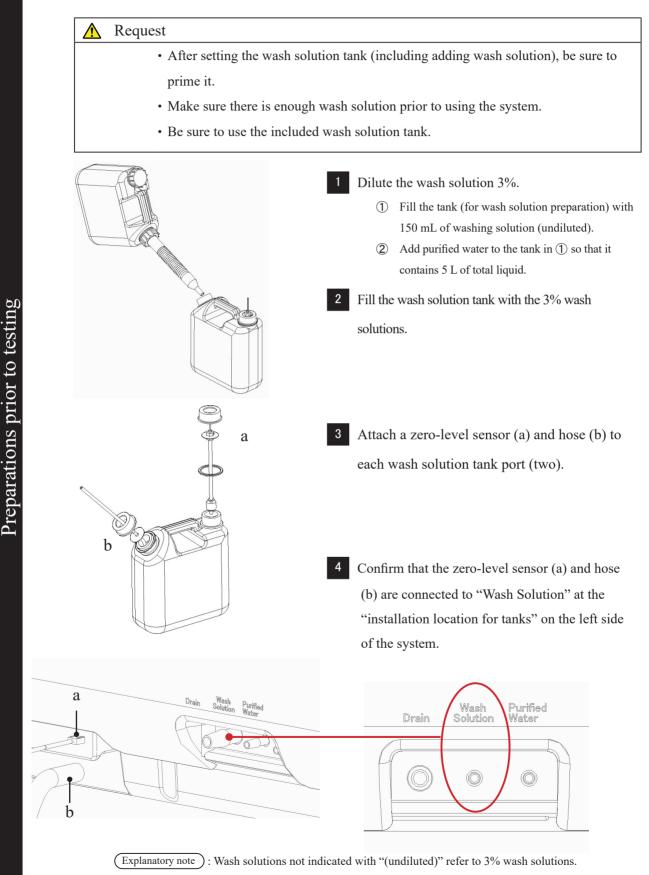
## 22.4.4 Setting purified water

Add purified water to the purified water tank.



### 2.4.5 Setting wash solution

Fill the wash solution tank with 3% distilled wash solution.



### 2.4 Daily Operation

# 2.4.6 Setting buffer

Set the buffer bottle for hemglobin analysis to the "buffer compartment."

Set the buffer for calprotectin in the reagent compartment.

Page 50 "2.4.9 Setting Reagents (Pos.-1/Pos.-2/Pos.-3)"

Request  $\wedge$ • After setting the buffer bottle (including adding purified water), be sure to prime it. (Explanatory note): After touching the {Reset} button on the [Set reagents] screen, priming automatically begins once the buffer bottle has been set. Explanatory note : If the buffer is reset, the number of remaining tests stored by the system will be deleted, and a new number of remaining tests will be stored (that is, the number of remaining tests will be overwritten). 1 Set the buffer bottle (a) to the buffer compartment (b). 2 b 2 Remove the cap of the buffer bottle, and insert the hose (c). Make a flat surface of the connector to the front. Flat surface 3 Touch the {Set latex} button on the [MENU] MENU PLEDIA screen.

Preparations prior to testing

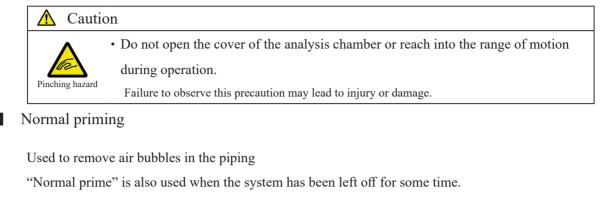
Set reagents	4 Touch the {Reset} button.
Barcode Lot No. Remaining	
Pos1[F-Hb] 9097003 97003 241	* The buffer is reset, and the number of remaining tes
Pos2[FCa(Bulfer)] 55	
	is displayed.
Pos3(FCa) 5397003 97003 199	
Buffer 1682 Reset	
	(Explanatory note): Touch the "Remaining tests" field fo
1 2 3 4 5 6 7 8 9 0 -	the buffer and use the numeric keypa
	to modify the value.
$X  Y  Z  .  /  *  \leftarrow  \rightarrow  del \qquad enter$	
Close	
Installation is available.	
Barcode         Lot No.         Remaining           Pos-1(F+b)         9097003         97003         241           Pos-2(FCalbullerit)         55         55           Pos-3(FCal)         5597003         97003         199	<ul> <li>Touch the {Close} button.</li> <li>* Pipe line activation begins.</li> <li>* The system returns to the [MENU] screen.</li> </ul>
Bufer	
1 2 3 4 5 6 7 8 9 0 -	
X Y Z . / ★ ← → del enter	
Close [])	
nstallation is available.	

(Explanatory note): If the remaining volume in [Information] - [Buffer bottle] is 50 mL or less, the number of remaining tests will be "0," and the user will be asked to change the buffer bottle via alarm and message.

#### 2.4 Daily Operation

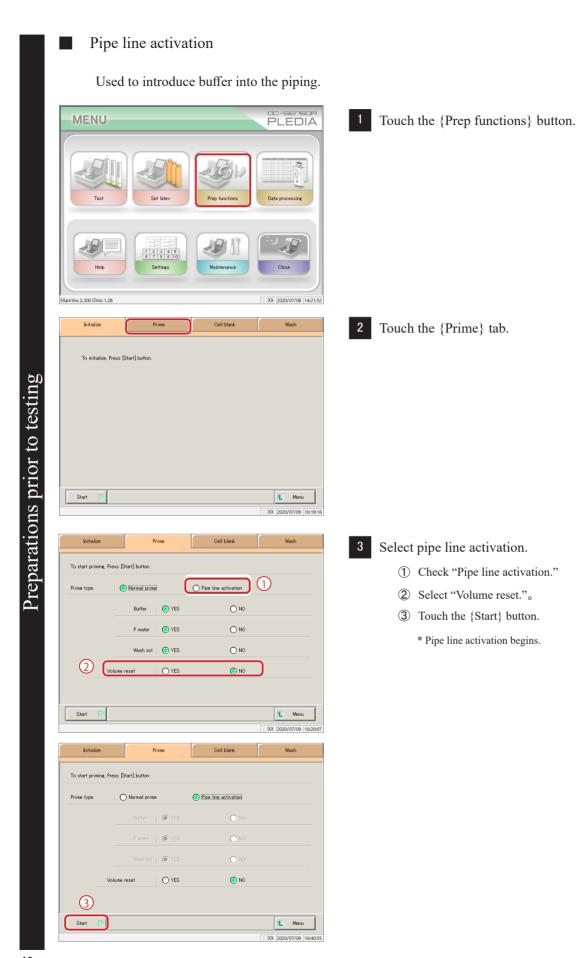
# 2.4.7 Priming (normal prime, pipe line activation)

There are two kinds of priming. "Normal prime" removes air bubbles in the piping, while "pipe line activation" introduces buffer to the piping.





Initialize	Prime	Cell blank	Wash	3 Select	t normal priming.	
To start priming, Press	s [Start] b			1	Check Normal prime.	
Prime type Pipe line activation				<ol> <li>Select items to prime.</li> </ol>		
	Buffer OYES	O NO			O YES: Prime.	
2 -	P water 🛛 🔘 YES	O NO			O NO: Do not prime.	
-	Wash sol 🛛 🔘 YES	O NO			Select whether or not to reset the buffer volume	
Volur	ne reset OYES	🔘 NO	J		([YES] or [NO]).	
3				3	Touch the {Start} button.	
Start			Menu		* Normal priming begins.	
	(Buffer/P. wat	ion equipment damage.			* When priming is complete, the dialog box closes.	
	Do not reach into th	e range of motion.		{Pause}:	Processing pauses.	
	Pause	Abort		{Start}:	Resume processing.	
	,				If the {Pause} button is touched, it will change	
					to the {Start} button.	
				{Abort}:	Abort processing.	
Explanate		e cover of the ottom right of		per is opened dur	ring normal priming, "Cover open" is displayed at	



Caution         May cause injury or equipment damage.         Keep out of operational range during operation.         Do not reach into the range of motion.         Image: Image: Abort         Pause: Image: Abort         Start}:         Resume processing.         If the {Pause} button is touched, it will change to the {Start} button.	Activate prime	4 Activ	* When priming is complete, the dialog closes.
	May cause injury or equipment damage. Keep out of operational range during operation. Do not reach into the range of motion.		Resume processing. If the {Pause} button is touched, it will change

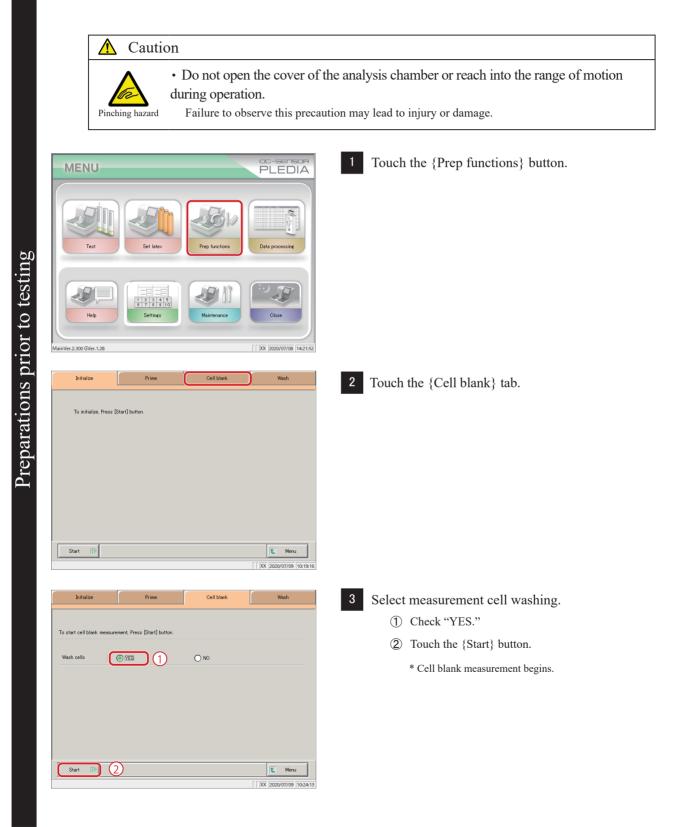
Explanatory note: If the cover of the analysis chamber is opened during pipe line activation, "Cover open"

is displayed at the bottom right of the screen.

# 2.4.8 Measure cell blanks

Run cell blanking to wash cells and evaluate them on a pass/fail basis.

If "Cell blank" is checked in "Auto start" in close mode, cell blank measurement will be automatically run when the system starts.



Initialia													
					Cell b	lank mea	sure						
<u> </u>	aution		cause inj ot open t					ge of n	iotion.				
No. ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS
01 19011	-8	12			23			34			45		
02 18973		13			24			35			46		
03 18980		14			25			36			47		
04 19060		15			26			37			48		
05 19116	-32	16			27			38			49 50		
06		17			28			40			50		
08		19			30			40			52		
09		20			31			42			53		
10		21			32			43			54		
11		22			33			44			55		
	_			Par	use		Abo	et			XX	2020/07/0	09 1
	-					lank mea		et			XX [2	2020/07/0	09 10
Ce	ution		ause inju	ity or ec	Cell bl	nt damae	sure ge.		notion.		XX	2020/07/0	09 11
No. ADC	ABS	Do no	ause inju t open th	ity or ec le cover: ABS	Cell bl quipme s or re No.	nt damae each into ADC	sure ge. the rang	ge of r No.	ADC	ABS	No.	ADC	AB
No. ADC 01 18948	ABS 31	Do no No.	ause inju t open th ADC 18984	ary or ec le cover ABS 22	Cell bl quipme s or re	nt damae ach into ADC 19040	sure ge. the rang ABS 10	ge of r No. 34	ADC 18992	20	No. 45	ADC 19029	AB
No. ADC 11 18948 02 18969	ABS 31 26	No.	ause inju t open th ADC 18964 19008	ary or eco le covers ABS 22 17	Cell bl quipme s or re No. 23 24	nt damae ach into ADC 19040 10162	sure se. the rans ABS 10 2736	ge of r No. 34 35	ADC 18992 19041	20 9	No. 45 46	ADC 19029 18955	AE
No. ADC 01 18948 02 18969 03 19004	ABS 31	Do no No.	ause inju t open th 18984 19008 19039	ary or ec le cover ABS 22	Cell bl quipme s or re No.	nt damag ach into ADC 19040 10162 18988	sure se. the rang ABS 100 2736 21	ge of r No. 34	ADC 18992 19041 18910	20	No. 45	ADC 19029 18955 19079	AE
No. ADC 01 18948 02 18969 03 19004 04 19017	ABS 31 26 18 15	No. 12 13 14 15	ADC 18984 1908 19089 19092	ABS 22 17 10 -1	Cell bl quipme s or re No. 23 24 25 26	nt damag ach into ADC 19040 10162 18988 19082	sure se. the ran 10 2/30 2/30	ge of r No. 34 36 37	ADC 18992 19041 18910 18999	20 9 39 19	No. 45 46 47 48	ADC 19029 18955 19079 19120	AE
No. ADC 01 18948 02 18969 03 19004 04 19017 05 18998	ABS 31 26 18	No. 12 13 14 15 16	ause inju t open th ADC 18984 19008 19039 190921	ABS 22 17 10 -1 7	Cell bl puipme s or re 23 24 25 26 27	nt damag ach into 19040 10162 18988 19082 18885	sure se. the rans 10 2736 21 45	ge of r No. 34 35 36 37 37	ADC 18992 19041 18910 18999 19006	20 9 39	No. 45 46 47 48 49	ADC 19029 18955 19079 19120 19135	AE
No. ADC 01 18948 02 18969 03 19004 04 19017	ABS 31 26 18 15 19	No. 12 13 14 15	ADC 18984 1908 19089 19092	ABS 22 17 10 -1	Cell bl quipme s or re No. 23 24 25 26	nt damag ach into ADC 19040 10162 18988 19082	sure se. the ran 10 2/30 2/30	ge of r No. 34 36 37	ADC 18992 19041 18910 18999	20 9 39 19 17	No. 45 46 47 48	ADC 19029 18955 19079 19120	AE
No. ADC 01 18948 02 18969 03 19004 04 19017 05 18998 06 19065	ABS 31 26 18 15 19 4	No. 12 13 14 15 16 17	ause inju t open th ADC 18984 19039 19039 19092 19051 19035	ABS 222 17 10 -1 7 7 11	Cell bl quipme s or re 23 24 26 26 27 27 28	nt damag ach into 19040 10162 19080 19082 18885 18730	sure ge. the rang 2736 2736 2736 2736 2736 31 0 45 81	ge of r No. 36 37 39	ADC 18992 19041 18910 18999 19006 19021	20 9 39 19 17 14	No. 45 46 47 47 48 49 50	ADC 19029 18955 19079 19120 19135 19089	AB 1 2 
No. ADC 1 18948 12 18969 13 19004 14 19017 15 18998 16 19065 17 19059 18 18939	ABS 31 26 18 15 19 4 5	No. 12 13 14 15 16 17 18	ause inju t open th ADC 18984 19008 19032 19051 19032 18973	ABS 22 17 10 -1 -1 11 25 14 24	Cell bl quipme s or re No. 23 24 25 26 27 27 29	nt damag ach into 19040 10162 18988 19082 18885 18885 18875 18875	sure se. the ran 2736 21 0 21 0 21 0 21 0 21 0 5 5	ge of r No. 36 37 38 39 40	ADC 18992 19041 18910 18999 19006 19021 19011	20 9 39 19 17 14 16	No. 45 46 47 49 50 51	ADC 19029 18955 19079 19120 19135 19089 19038	AE
No. ADC 01 18948 02 18969 03 19004 04 19017 05 18998 06 19065 07 19059 08 18939	ABS 31 26 18 15 19 4 5 33	No. 12 13 14 15 16 17 18 19	ause inju t open th 18984 19039 19052 19051 19055 18973	ABS 22 17 10 -1 7 11 25 14	Cell bl quipme s or re No. 23 245 26 27 28 29 30	ADC 19040 19040 19082 18988 19082 18885 18730 19087 18968	se. the ran 2736 21 0 45 81 0 226	ge of r No. 34 36 37 38 39 40 41	ADC 18992 19041 18910 18999 19006 19021 19011 19086	20 9 39 19 17 14 16 0	No. 45 46 47 48 49 50 51 52	ADC 19029 18955 19079 19120 19135 19089 19038 18998	AB 109 110 AB 1 1 1 1 1 1

## 4 Cell blank measure

# olarik medsure

\* When measurement is complete, the {Abort} button will change to {Close}.

(Explanatory note) : Cells that cannot be used are displayed in red.

(Explanatory note): When 10 or more cells can no longer be used "There are more than 10 unclean measurement cells. [COMMENT\_RANGE]Please exchange cells."[/COMMENT\_RANGE VALUE::This could reduce processing performance. Replace the measurement cells

Page 258 "5.1.9 Replacing measurement cells (when cell blank value is abnormal)"

					Cell	blank	measurer	nent fini	shed.					
No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	ABS	No.	ADC	AB
01	19011	-8	12	18972	0	23	19030	-12	34	18962	2	45	18925	1
02	18973	Ő	13	18944	6	24	18936	8	35	19032	-13	46	18923	1
03	18980	-1	14	19050	-17	25	18899	17	36	18982	-1	47	19027	-1
04	19060	-19	15	19081	-24	26	18996	-5	37	19106	-30	48	18985	-
05	19116	-32	16	18981	-1	27	18874	22	38	19038	-14	49	18978	
06	19015	-9	17	19040	-15	28	19070	-21	39	19009	-8	50	18732	5
07	19036	-14	18	19009	-8	29	18998	-5	40	19072	-22	51	18948	
08	18937	8	19	19011	-8	30	18920	12	41	18981	-1	52	19072	-2
09	19125	-34	20	18951	5	31	19049	-17	42	18966	1	53	18961	
10	18977	0	21	19079	-23	32	19086	-25	43	19000	-5	54	18966	
11	19027	-12	22	19074	-22	33	18998	-5	44	19031	-13	55	18980	-

5 Touch the {Print} button to print the measurement results.

\* The results of the measured cells are printed.

Touch the {Close} button.

- \* The system returns to the [Cell blank] screen.
- {Pause}: Processing pauses.
  {Start}: Resume processing. If the {Pause} button is touched, it will change to the {Start} button.
  {Print}: Print the measurement results.
  {Close}: Displayed when processing completes. The system returns to the measurement cell
  - washing selection screen.
- {Abort}: Abort processing.
- $\{MENU\}\colon$  The system returns to the [MENU] screen.

Λ

Request

#### 2.4.9Setting reagents (Pos.-1/Pos.-2/Pos.-3)

Read the reagent barcode for Pos-1 (the latex reagent for hemoglobin) and Pos-3 (the latex reaget for calprotectin), and then set the reagent bottle in the reagent compartment. Set the buffer for calprotectin into Pos-2.The positioning of the reagent bottles is Pos.-1, Pos.-2, and Pos.-3 in order, from the left of the reagent compartment.

There are two ways to enter barcodes: "input using barcode reader" and "keypad input."

Reagent barcode information

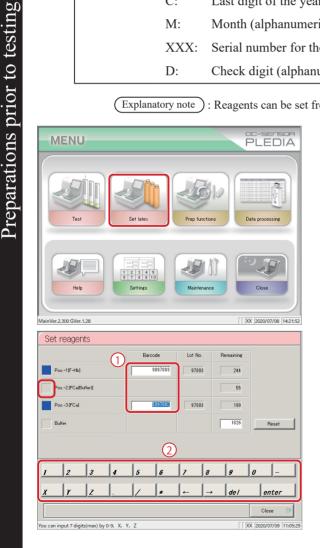
- Barcodes on reagent bottle labels are of the CODE 39 type, consisting mainly of eight characters (excluding the initial and terminal characters).
- When entering barcodes, follow the format below.

#### AACMXXXD (barcode)

- AA: Item code, two digits (numeric, 0 to 99; 90: feces Hb)
- C: Last digit of the year (numeric, 0 to 9)
- M: Month (alphanumeric, 1 to 9, or X, Y, or Z)
- XXX: Serial number for the year (numeric, 0 to 999)
- D: Check digit (alphanumeric)

(Explanatory note): Reagents can be set from the [Test] screen or the [Monitor] screen.

2



Touch the {Set latex} button.

Enter the reagent barcode.

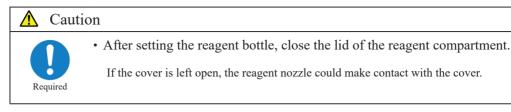
There is no barcode entry when setting the buffer fof calprotectin. Touch Pos-2  $\Box$ .

\* The check box turns blue.

<Keypad input>

- ① Touch the barcode field for the appropriate reagent. \* The check box turns blue.
- 2 Use the numeric keypad to enter the seven digits of the eight-digit barcode affixed to the reagent bottle, excluding the last digit (check digit).

(Explanatory note): If there is no calibration curve in the reagent lot, the "No CC" message is displayed.Create a calibration curve.



## \Lambda Request

• Close the lid of the reagent bottle when reading the reagent barcode.

Failure to observe this precaution could result in the reagent being spilled.

Barcode reading port Barcode reader lever Reagent hottle Reagent compartment Set reagents Pos -1(E-Hh Pos.-2 [FCalBuffer]

<Barcode reader input> (1) Touch the barcode field for the appropriate reagent. \* The check box turns blue (2) Lower the barcode reader lever. (3) Place the reagent bottle into the barcode reading port with the barcode surface facing to the front. \* The seven-digit barcode (excluding the check digit) is displayed. 3 When the barcode reader has finished reading, move the barcode reader lever to its original position. 4 4 Set the Pos.-1, Pos.-2, and Pos.-3 (in order from left to right) bottles to the reagent compartment. ① Open the lid of the reagent compartment. 2 Remove the cap of the reagent bottle. ③ Insert the reagent bottles into the reagent insertion port, with the barcode surface facing to the front. (4) After setting all reagents, close the lid of the reagent compartment. Touch the {Reset} button to reset the number of remaining tests for buffer. Touch the {Set complete} button. \* When the reagent bottle has been set, confirm the volume of the reagent bottle with the reagent nozzle.

\* The system returns to the [MENU] screen.

#### 

reagent is set.

(Explanatory note): If the number of remaining tests is "0" on the [Information] reagent bottle display, the

enter

Close

Preparations prior to testing

ou can input 7 digits(max) by 0-9, X, Y, Z

user will be asked to change the reagent bottle via alarm and message.

51

## 2.4.10 Installing samples

Place the rack to which samples have been set in the rack supply unit. If you are using a tray (optional), place the tray to which the sample rack has been set in the rack supply unit.

## 1 Set the sample (sampling bottle) to the rack.

Explanatory note ): Use a measurement mode and rack that suit the sample to be measured.

- When measuring a sample, specify the test mode and use a "sample rack."
- When remeasuring a sample, specify the remeasure/retest mode and use a "sample rack."
- When retesting a sample, use a "retest rack" (there is no need to specify a mode).

Page 52 "Setting samples using measurement method (1 day/2 day/3 day)"

When measuring an STD or QC sample, use an "STD/QC rack."

(There is no need to specify the mode.)

Page 55 "Setting STD/QC samples (Hemoglobin)"

- Page 57 "Setting STD/QC samples (Calprotectin)"
- When running a dilute test on a sample, use a "dilute test rack" (there is no need to specify a mode).
   Page 54 "Setting samples when running a dilute test"

Explanatory note ) : Install a sampling bottle vertically.

• When the installation of a sampling bottle at an angle, there is a possibility that the puncture is not performed normally.

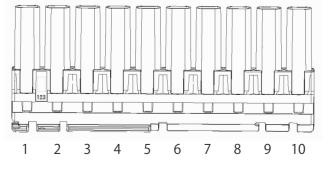
#### Setting samples using measurement method (1 day/2 day/3 day)

Sample arrangement on racks varies according to the measurement method (1 day/2 day/3 day). Samples are arranged on the rack as follows.

Page 59 "Setting test modes, measurement methods, and measurement modes"

# <1 day>

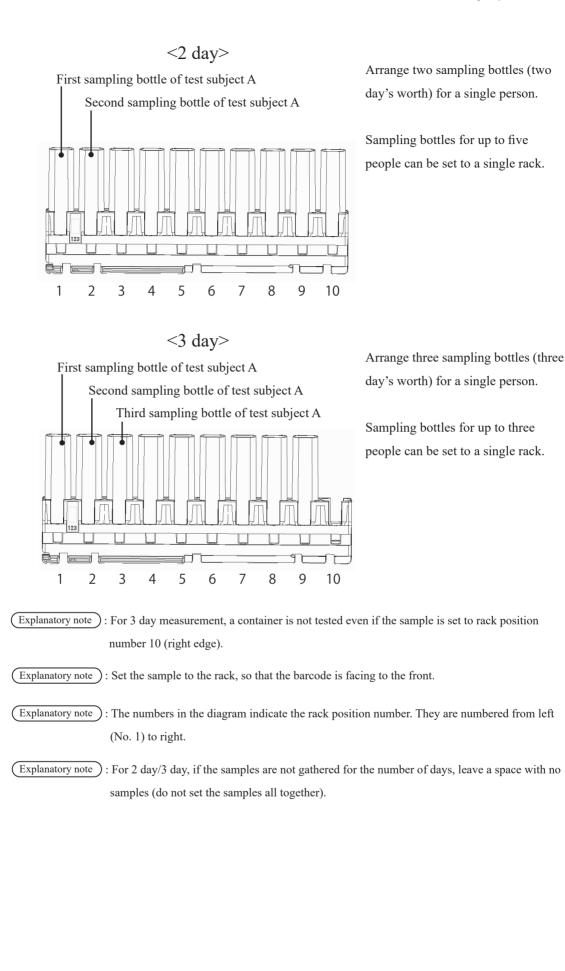
Sampling bottles can also be installed alone



Sampling bottles for up to ten people can be set to a single rack.

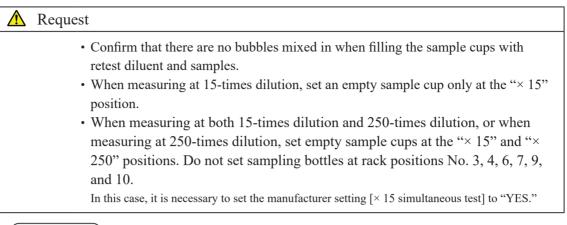
Explanatory note : Set the sampling bottle to the rack, so that the barcode is facing to the front.

Explanatory note): The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.



#### **Daily Operation** 2.4

Setting samples when running a dilute test



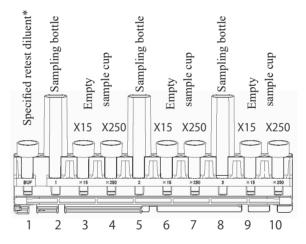
(Explanatory note): When running a dilute test, use the "dilute test rack."

Explanatory note ) : Customers cannot modify manufacturer settings.

Explanatory note): Set containers filled with diluted sample at rack positions No. 2, 5, and 8.

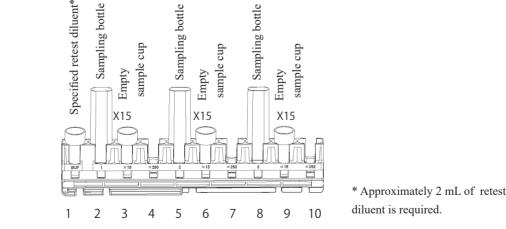
Either sampling bottles or sample cups may be used.

<Measuring at both 15-times dilution and 250-times dilution, or at 250-times dilution>



\* Approximately 2 mL of retest diluent is required.

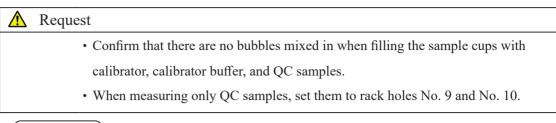
<Measuring at 15-times dilution>



Explanatory note : Set the sample to the rack, so that the barcode is facing to the front.

(Explanatory note): The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

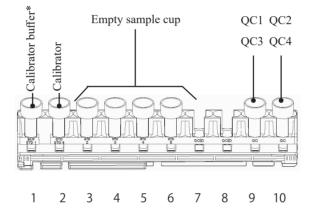
## Setting STD/QC samples (Hemoglobin)



 Explanatory note
 : When measuring STD samples and QC samples, use the "STD/QC rack."

 Explanatory note
 : It is possible to set only STD samples or only QC samples to the rack.

<When creating dilution series>



 (Explanatory note)
 : In the case of the hemoglobin, QC samples can be ID-managed by erection of containers with QCID (bar code for QC) attached to positions No. 7 and No. 8 in the rack.

\* Approximately 2 mL of calibrator buffer is required.

#### Calibration curve creation method (Hemoglobin: if a dilution series has not been created))

(1) Set calibrator, calibrator buffer, and empty sample cups to the STD/QC rack according to the tests to run.

(2) Enter the concentration listed in the INSTRUCTIONS FOR USE for the calibrator into

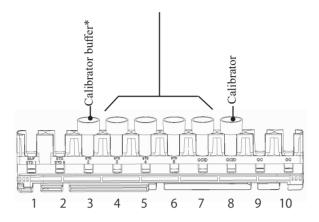
"Conc." in [Protocol settings] - [CC No. # protocol settings].

Page 314 "6.2.2 CC No. 1 to CC No. 6 protocol settings"

- (3) Place the STD/QC rack in the rack supply unit.
- (4) Touch the  $\{Start\}$  button on the [Test] screen.
  - \* Start testing.
    - \* When placing a QC sample, measure along with the QC sample.
    - \* A calibration curve is created.
- (5) Confirm that the calibration curve has been properly created.
- (6) Touch the {Register} or {Cancel} button.

#### <When dilution series have been prepared>

Sample cups for which a dilution series has been created (In order of concentration weakness, from left to right.)



Explanatory note: The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

Explanatory note): Do not set sample cups to rack positions No. 1 and No. 2.

#### Calibration curve creation method (Hemoglobin: if a dilution series has been created)

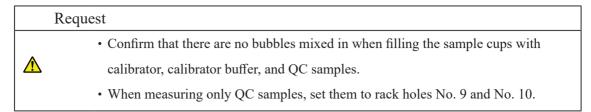
- (1) Set the calibrator to rack position No. 8.
- (2) Set the sample cups in order of concentration weakness in rack positions No. 4 through No. 7.
- (3) Set the calibrator buffer to rack position No. 3.
- (4) Place the STD/QC rack in the rack supply unit.
- (5) Touch the {Start} button on the [Test] screen.
  - \* Start testing.

\* When placing QC samples in rack positions No. 9 and No. 10, measure along with the QC samples.

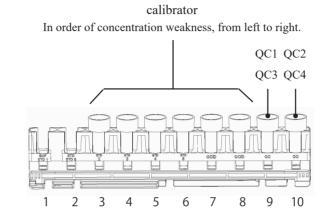
\* A calibration curve is created without creating a dilution series.

- (6) Confirm that the calibration curve has been properly created.
- (7) Touch the {Register} or {Cancel} button.

## Setting STD/QC samples (Calprotectin)



(Explanatory note): When measuring STD samples and QC samples, use the "STD/QC rack."



Explanatory note: The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.

(Explanatory note) : It is possible to set only STD samples or only QC samples to the rack.

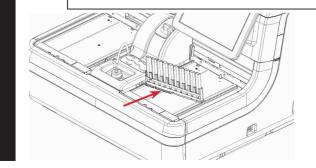
Placing a rack as is in the supply unit (standard specification)

2 Placing racks in the system

#### \Lambda Caution

Required

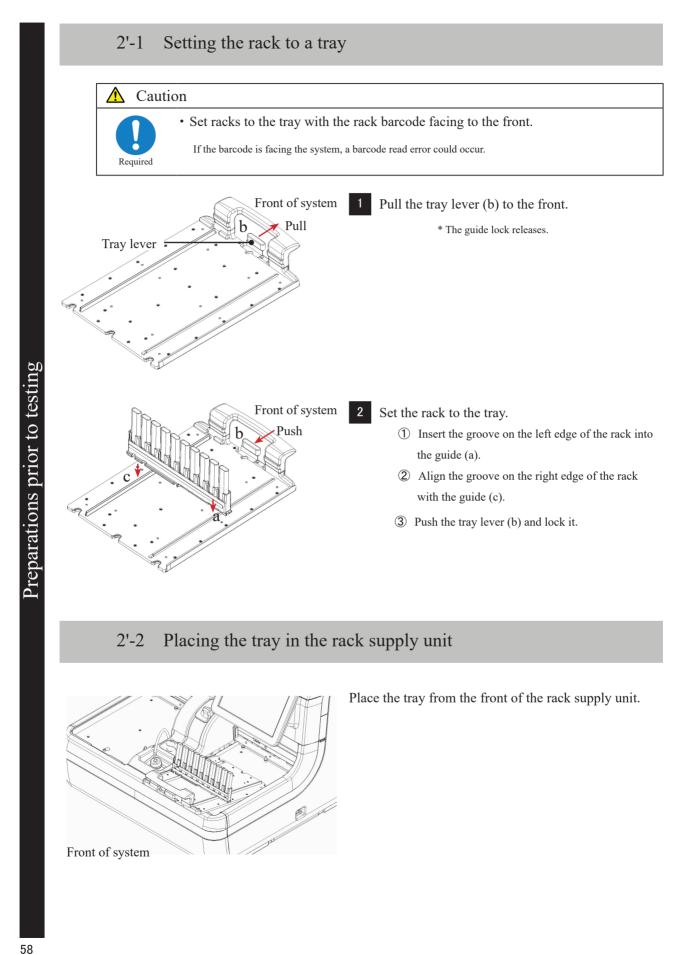
• Set racks to the system with the rack barcode facing to the front. If the barcode is facing the system, a barcode read error could occur.



Set the rack to the rack supply unit with rack position No. 1 on the left side.

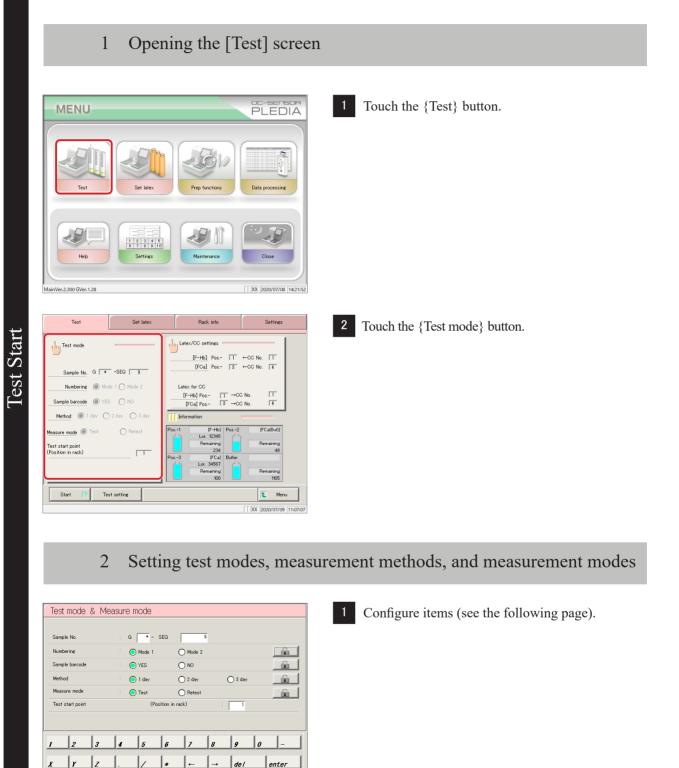
Set it so that the metal claws fit into the depressions on the lower left of the rack.

# Placing a rack in the rack supply unit using a tray (optional)



#### 2.4.11 Starting tests

Open the [Test] screen, and configure the test conditions displayed on the screen after selecting the {Test} tab. Test conditions are broadly categorized into "Test mode" and "Latex/CC settings." Touching the {Start} button starts testing after the self check is run.



enter Continue XX 2020/07/09 11:08:

b

Item	Range/Selection	Details
Sample No.	Kalige/Selection	Configure the number of the head sample.
$G \square - SEQ \square \square$		A sample number consists of a group number
		A sample number consists of a group number
Group No. (G)	*, 1-9	(G) and a sequence number (SEQ).
Sequence No. (SEQ)	1 - 99999	Enter "*" to skip configuring a group number.
(Maintained in memory until the		
system power is turned off.)		
Numbering		If there is a rack position in which a sample has
(Maintained in memory even if		not been set, configure how to allocate sequence
the system power is turned off.)		numbers.
	YES:	Allocate sequence numbers only to set samples.
		Even if there are empty positions, a "No tube"
		error will not occur.
	NO:	Allocate sequence numbers even to positions
		in which samples are not set.
		1 2 3 4 5 6 7 8 9 10 A "No tube" error will occur if there are any empty positions.

Continued on next page

(Explanatory note): Configuring group numbers allows for the positive rate change to be calculated per group.

(Explanatory note) : Serial numbers starting from the configured sequence number will be allocated to samples.

Item	Range/Selection	Details
Sample barcode		Configure whether or not to use sample barcodes.
		<ul> <li>Settings are also applied to [Settings] - [System</li> </ul>
		settings] - [Samp barcode settings].
(Configuration maintained in	YES:	Use sample barcodes.
memory even if the system power		
is turned off.)	NO:	Do not use sample barcodes.
	110.	Do not use sample barcodes.
Measurement method		Select the measurement method.
	1 day:	Measure using 1 day method.
(Configuration maintained in	2 day:	Measure using 2 day method.
memory even if the system power is turned off.)	3 day:	Measure using 3 day method.
Measure mode		Select the measurement mode.
(Configuration maintained in		$\cdot$ Measured data when remeasuring a sample in
memory until the system power is		remeasure/retest mode is applied to the positive
turned off.)		rate.
		$\cdot$ Measured data when using a retest rack or dilute
		test rack is not applied to the positive rate.
	Test:	Select when first making a measurement.
	Retest:	Select when remeasuring or retesting a sample.
Test/remeasure test	1 - 10	Configure the head rack test start position.
start position		$\cdot$ Sequence numbers are allocated from the test start
(position in rack)		position configured here.
(Not applied when starting new		$\cdot$ This setting does not apply to retest or dilute test
test.)		racks.

(Explanatory note) : Sequence numbers are managed for each measure mode (test mode, remeasure/retest mode, dilute test).

Test mode & Measure mode	2 Touch the {Continue} button.
Sample No. G • - SEQ 11	
Numbering Mode 1 Mode 2	
Sample barcode OYES ONO	
Measure mode  Test C Retest Test start point (Position in rack)	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	
Continue	
put range is 1 to 99999.	
Test mode & Measure mode	3 Touch the {Register} button.
	* The settings were registered.
Numberine         Image: Mode 1         Mode 2         Image: Im	
Method O 1 day O 2 day O 3 day	
Test start point (Position in rack)	
Register?	
Close     Presister	
X Close Register	> D (4
X Close Register	$\rightarrow$ Page 64
X Close Presister	→ Page 64 3 Configuring [Latex/CC settings]

Test Start

(Explanatory note) : Touch the {MENU} button to return to the [MENU] screen after registration.

# How to use the (padlock) button to avoid operation errors

There is a button that looks like a padlock on the right side of the [Test mode & Measure mode] screen. Touching this button locks the applicable settings so that they cannot be operated. Touching the button once more releases the lock and allows operation again. When locked it is orange; when unlocked it is gray.

Test mode	& Measu	ire mode								
Sample No.		G * -	SEQ	9						
Numbering		Mode 1	C	) Mode 2						– Lock (orange)
Sample barcode		YES	C	) NO						- LOCK (Oralige)
Method		🔵 1 day	C	) 2 day		🔿 8 day		<b>Í</b>		
Measure mode		🔘 Test	C	Retest				<u> </u>	+	– Lock release (gray)
Test start point		(Po	osition in rac	*k)		1				
	4 4		4	4	4	4	4			
1 2	3 4	5	6	7	8	9	0	_		
x r	z .		<u>*</u>	1.	1.	del	1	enter		
<u> </u>	iz i.			-	-	uer		enter		
							•/	Continue		
						11	XX 202	0/07/09 11:12:	12	

#### 3 Configuring [Latex/CC settings] Touching the {Test} button on the [MENU] screen opens the [Test] screen. This section will explain operation from the [Test] screen. A Request · Check that the lot number of the reagent to use is the same as that of the reagent for the calibration curve (CC No.). • If a calibration curve has not been prepared, do so prior to starting the test. If testing is started with mismatched reagent lots, a "No CC" error message will be displayed. Rack info Test Set late Touch the {Latex/CC settings} button. Test mod [E-Hb] Pos-←CC No 1 3 ←CC No. 4 [FCa] Pos.--SEQ [ or CC 1 [F-Hb] Pos: 1 →CC No 3 →CC No Gal Pos (FCalBuff) Test setting Start Latex settings 2 Configure the reagent and calibration curve. (F-Hb) (FCa/Buffer Pos [FCa] Latex for CC[F-Hb] (See the following page.) Pos.as CC N as CC No CC N Dat Latex lo Latex Int 20/03/31 174 97003 20/04/09 18:24 97003 ente CC setting Conti XX 2020/07/09 11:13: Explanatory note : [Latex/CC settings] can also be configured during testing on the [Additional test] screen. Explanatory note ) : Touch the {CC setting} button to open the [Protocol settings] screen. CC No. # protocol setting can be performed here. Page 314 "6.2.2 CC No. 1 to CC No. 6 protocol settings" Explanatory note : Touch the $\{CC\}$ button to open the [Check CC] screen. The measurement date and time, reagent lot information, and graph can be checked for each calibration curve. Page 66 " Calibration curve confirmation"

64

est Star

Item	Range/Selection	Details
[F-Hb] ←CC No.□	1~3	Setting the calibration curve number used for
		sample measurement when using the stool
		hemoglobin reagent.
[FCa] ←CC No.□	4 <b>~</b> 6	Establish the calibration curve number used in the
		measurement of samples when using the reagent
		for fecal calprotectin.
Latex for CC [F-Hb]	1~3	The reagent used (stool hemoglobin) is fixed.
Pos $\Box \rightarrow$ Save as CC		Registered CC No of the generated calibration
No. 🗆		curve. Setting.
Latex for CC [FCa]	4 <b>~</b> 6	The reagent used (fecal calprotectin) is fixed.
Pos $\Box \rightarrow$ Save as CC		Registered CC No of the generated calibration
No. 🗆		curve. Setting.

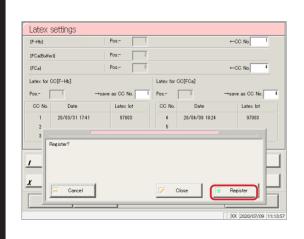
Test Start

(F-Hb)		P	'os	1				←CC No.	1
(FCa(Buffe	a)]	P	'os	2					
(FCa)		P	os	3				←CC No.	4
Latex for	CC[F-Hb]				Latex for (	CC[FCa]			
Pos	1	→save a	as CC No.	1	Pos	3	→	save as C	G No. 4
CC No.	Date		Latex lot		CC No.	Date		Late	ex lot
1	20/03/31 17:41		97003		4	20/04/09	18:24	9	7003
2					5				
3					6				
, [	2 3	4	5	6	7	8	9	0	-
r Í	r z	1		1.	1.	1.	del	1	enter
	1 2	ŀ					aer	4	enter

A list showing "Date" and "Latex lot" for the – registered CC number is displayed. If no calibration curve is registered, nothing is displayed.

Touch the {Continue} button.

CC No.	Date	Latex lot	CC No.	Date	Latex lot
1	20/03/31 17:41	97003	4	20/03/31 17:20	97003
2			5		
3			6		



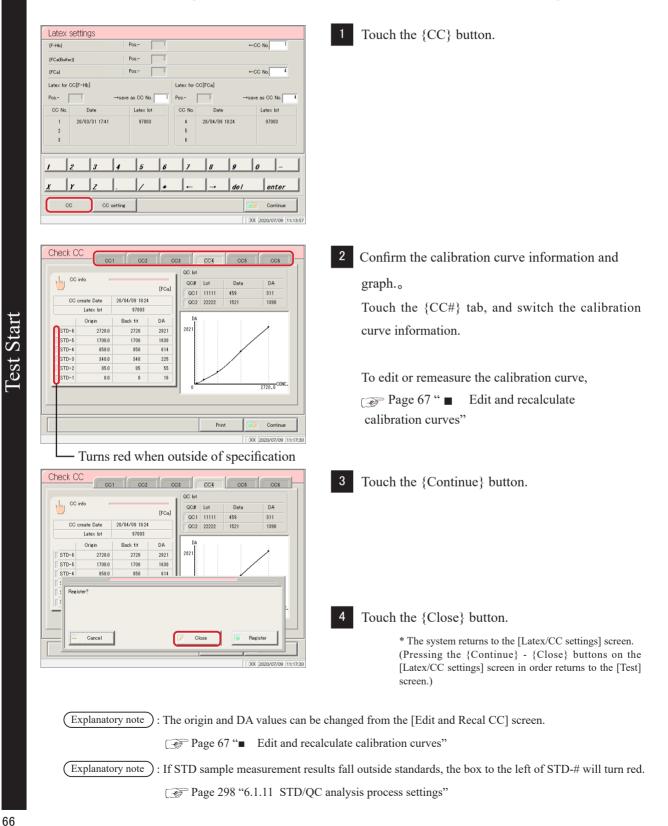
- 4 Touch the {Register} button.
  - \* The settings were registered.

→ Page 68
 4 Starting tests

## Calibration curve confirmation

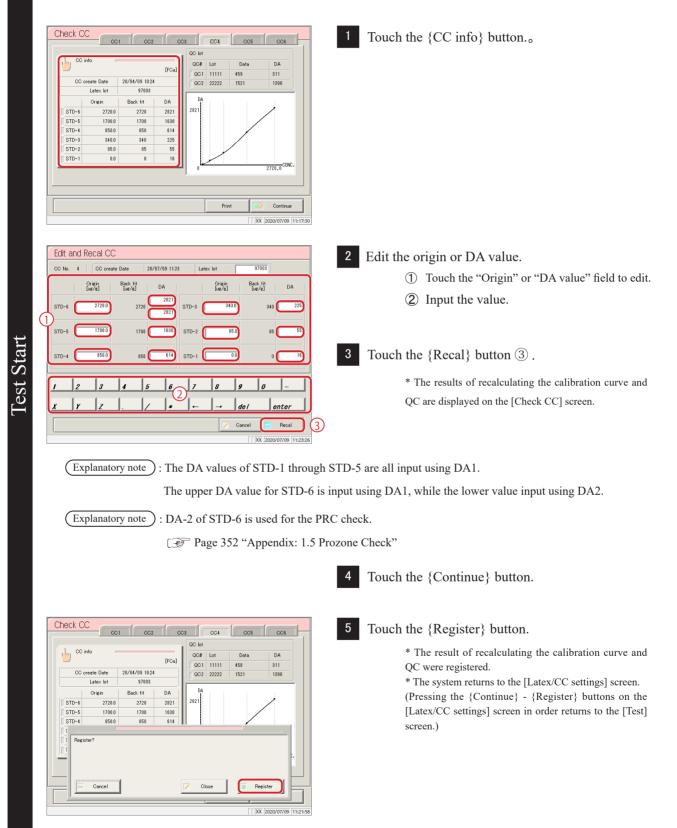
Touch the {CC} button on the [Latex/CC settings] screen to display calibration curve information (such as date and time, and reagent lot) and the calibration curve graph.

Use the tabs on the top of the screen to switch between calibration curves CC No. 1 through CC No. 6.



#### Edit and recalculate calibration curves

Touch the {CC info} button on the [Check CC] screen to open the [Edit and Recal CC] screen. Origins and DA values are edited using the keypad, and calibration curves can be recalculated.



4 Starting tests	
This section will explain the procedure	e from the [Test] screen.
Test Set latex Rack info Settings	1 Touch the {Start} button.
Jest mode         Sample No. G • -5E0         Numbering       Mode 1 ∩ Mode 2         Sample bacceb       YES         Sample bacceb       YES         Method       1 dv         Method       1 dv         Method       1 dv         Part       Period         Post       Text No. T         FF-b] Post       T-00 No. T         FF-b] Post       Text No. T         Post       Text Start point         Post       Text Start point         Post       Text Start point         Post       Text Start point         Text start point       Text start point         Post       Text Start point         Text start point       Text start point         Text start point	* Self check begins.
Self check         1. Optical unit       Pass       Fail         2. Cell       Pass       Fail         3. Latex temp high       Pass       Fail         4. Butfer temp high       Pass       Fail         5. Reaction table       Pass       Under/Over         6. Latex (25°C or more)       Pass       Under         7. Butfer temperature       Pass       Under         1. Optifer temperature       Pass       Under         1. Butfer temperature       Pass       Under	<ul> <li>2 Confirm the following diagnostic results <ol> <li>Optical unit (Detector)</li> <li>Cell</li> <li>Latex temp high (Reagent abnormal temperature)</li> </ol> </li> <li>4. Buffer temp high (Buffer abnormal temperature)</li> <li>5. Reaction table (Reaction table abnormal temperature)</li> <li>6. Latex (25°C or higher)</li> <li>7. Buffer temperature</li>  If self check results in "Fail",</ul>
Additional text     STAT     Set respents     Set samp     Settings       Rack     Samp No. 11t     State of process     Comment       001-02     00007     FHb     Dispensing latex     002101       001-01     00006     FCa     Dispensing latex     002101       001-01     00006     F-Hb     Mixing     002101	<ul> <li>Page 71 " Self check failed"</li> <li>Begin testing (sample dispensing automatically starts once priming and cell blank measurement preparation is complete prior to the test starting).</li> <li>* The cell blank value is calculated.</li> </ul>
Remaining Remain	Explanatory note       : If a calibration curve has not been created,         "There is no calibration curve for~. Measure STD." is displayed.         {Cancel}:       Cancel testing.         {Continue}:       Continue testing without a calibration curve. Or, begin measuring the calibration curve.
	ted during operation using {Abort}, pipe line activation is performed
when testing begins.	

# Viewing information

There is an {Information} button on the [Monitor] screen. The lot number, remaining tests for the reagent, and the remaining tests for the buffer are displayed in the button.

1

	Additional test	STAT	Set reagents	Set samp	Settings
Monitor	Rack         Same           001-02         0001           001-01         0001           001-01         0001	07 F-Hb Disa 06 FCa Disa	ate of process pensing sample pensing latex ing	Comment 00010 00210 00210	1
Rack inf	Information			Expected	end time 8 min
ò	3.00				
		e Remainine	SE-3 [FOa] Buffer Lot. 2X441 Remaining 37	Pernaining 1770	Connect Help

The images of the reagent bottle and buffer bottle show how much reagent is left in the bottles.

Light blue:	11% or more
Yellow:	10% or less
Red:	5% or less

Reagent Lot No.: Reagent lot number (five digits) Remaining tests: Displays how many tests (approximate) can be processed based on the amount of reagent and buffer in the bottles.

Testing

Lot No

Remaining

(F-Hb) (FCa(B (FCa)

ining buffe

Latex for CC [F-Hb]

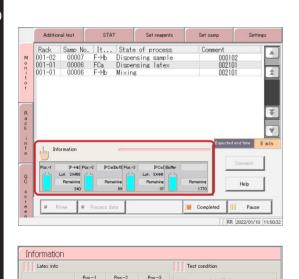
97003

241

8 Latex for CC [FCa

→CC No. 1

Pos.- 3



97003

200

1714

CC No. 4

MainVer.2.300 GVer.1.28

1 Close

Touch the {Information} button.

2 Confirm the information.

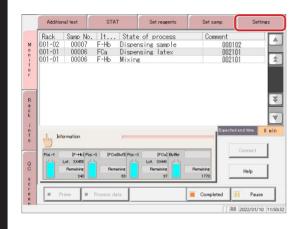
Touching the {Close} button returns to the [Monitor] screen.

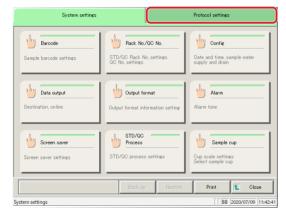
• Confirming settings on the {Settings} tab.

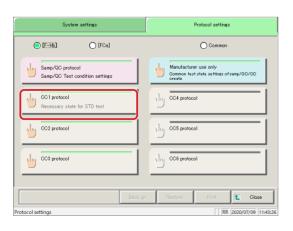
Touch the {Settings} tab when the [Monitor] screen or [Additional test] screen is displayed to confirm system settings and protocol settings.

Switching to the settings screen from the [Additional test] screen allows for the modification of "cut-off value," "QC LOT," and "Max/min QC control value" settings.

Switching to the settings screen from the [Monitor] screen allows for checking settings only.







1 Touch the {Settings} button.

2 Touch the button of the setting to confirm.

\* The setting screen is displayed.

To confirm protocol settings, touch the {Protocol settings} tab to switch to the appropriate screen.

- 3 Touch the button of the protocol setting to confirm.
  - \* The protocol settings screen is displayed.

Cesting

System settings	Protocol settings		
[F-Hb] O [FCa]	O Common		
Samp/QC protocol Samp/QC Test condition settings	Manufacturer use only Common test state settings of samp/QD/CC create		
CC1 protocol Necessary state for STD test	Din CC4 protocol		
CC2 protocol	In COS protocol		
CC3 protocol	Drug CC6 protocol		
	k ap Restare Print <b>T</b> Ci		

4 Touch the {Close} button. \* The system returns to the [Monitor] screen.

#### Self check failed

The method for handling a "Fail" result varies according to the diagnostic item. Refer to the following chart.

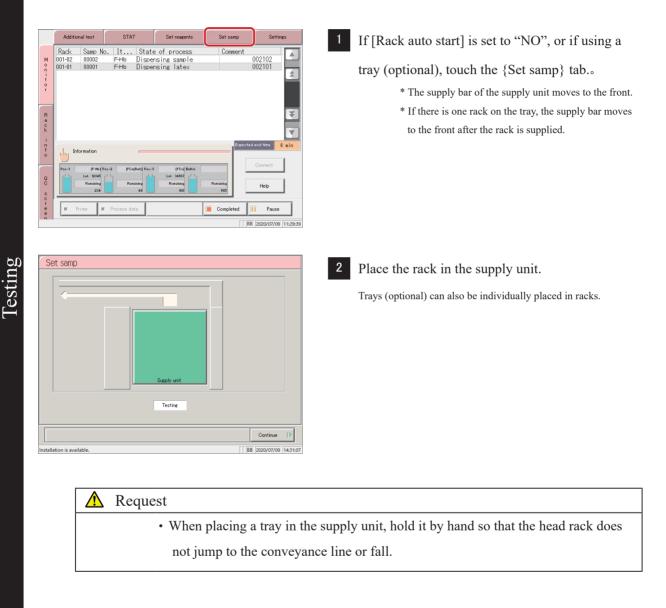
Diagnostic Item	Handling Method	
Optical unit	(1) Touch the {Abort} button.	
	$\rightarrow$ The previous and current values are shown, and "Register the	
	current detector maximum output value?" is displayed.	
	(2) Touch the {Register} button. (The current value is registered)	
Cell	Touch the {Abort} button.	
	Set the cell.	
Latex temp high	An error in the reagent compartment was detected when the standby	
	switch was turned on. Touch the {Abort} button.	
	Contact the "Customer Support Technical Center." Dispose of the	
	reagent.	
Buffer temp high	An error in the reagent compartment was detected when the standby	
	switch was turned on. Touch the {Abort} button.	
	Contact the "Customer Support Technical Center." Dispose of the buffer.	
Reaction table	Wait until the system reaches the set temperature.	
	When the system has reached the set temperature, the diagnostic re- changes to "OK" and operation continues.	
Latex (25°C or more)		
-()		
Buffer temperature	The {Continue} button can also be pressed to start testing without	
1	waiting until the temperature is reached.	

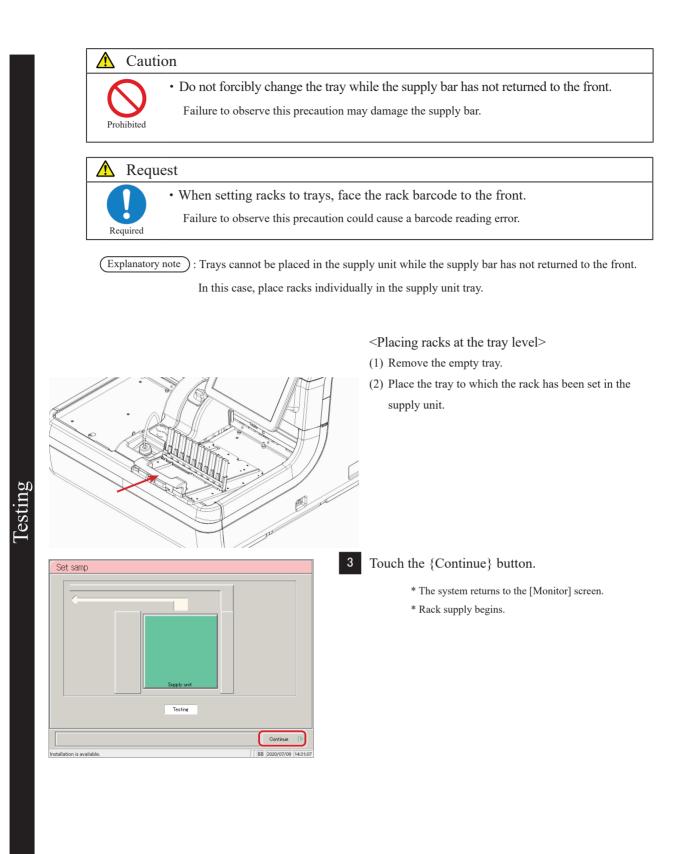
(Explanatory note): "Under/Over" is displayed if the self check shows that the reaction table temperature has not reached the set temperature; "Under" is displayed if the reagent or buffer has not reached the set temperature.

# 2.4.12 Adding samples (continue testing)

This section describes the procedure for adding samples to the rack supply unit during testing. Auto supply of the rack begins once the rack or tray is placed in the rack supply unit. (If [Config] - [Rack auto start] is set to "YES" Page 276 "6.1.4 Environment settings"

(Explanatory note): When the last rack in the supply unit (tray) is sent to the conveyance line, the supply bar automatically moves to the front.

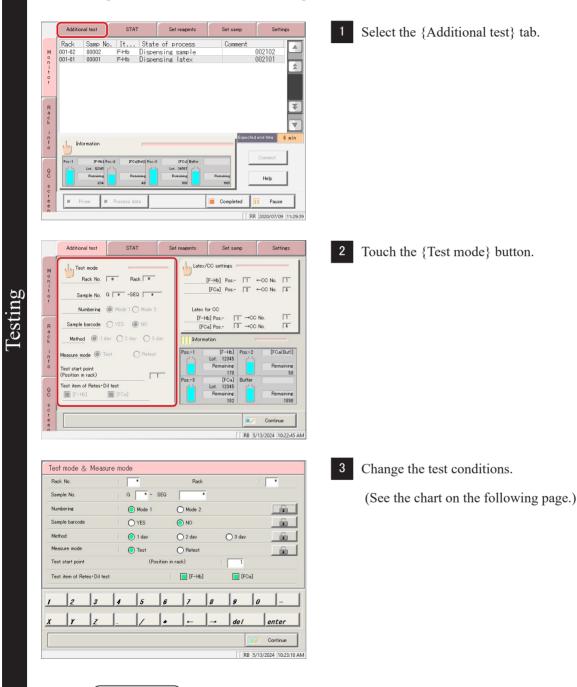




## 2.4.13 Additional tests (changing test conditions while testing)

Perform an "additional test" when changing test conditions and testing a sample, during testing. During additional testing, configure the "Rack No." and "Rack" to start testing with the modified conditions.

When testing of the number of specified racks is finished, the system returns the test conditions to their previous values. However, the sample number does not revert.



(Explanatory note): When the last rack in the rack supply unit (tray) is sent to the conveyance line, the supply bar automatically moves to the front.

Item	Range/Selection	Details
Rack No. 🗆	*(default)	Configure the [Rack No.] to start testing with the
	1-99	modified conditions.
		If the value is not changed from "*", an error will
		occur when the {Continue} button is touched.
	*(1.0.1)	
Rack 🗆	*(default)	Configure the [Rack] to test with the modified
	1-99	conditions.
		If "*" is input, all racks from the configured
		rack number will be tested with the modified
		conditions.
Sample No.		Configure the number of the head sample.
$G \square - SEQ \square$		A sample number consists of a group number
		(G) and a sequence number (SEQ).
Group No. (G)	*, 1-9	Enter "*" to skip configuring a group number.
Sequence No. (SEQ)	1 - 99999	If "*" is input for the sequence number,
		sequence numbers will be assigned in sequence
		from the previous sample number.
Numbering		If there is a position in which a sample has not
		been set, configure how to allocate sequence
		numbers.
	YES:	Allocate sequence numbers only to set samples.
		n nnnnnnn
		. 23, 50, 05
		Even if there are empty positions, a "No
		tube" error will not occur.
		Continued on next page

Explanatory note : Sequence numbers are allocated in serial order for each measure mode (test mode, remeasure/ retest mode, dilute test).

Range/Selection	Details
NO:	Allocate sequence numbers even to positions
	in which samples are not set.
	A "No tube" error will occur if there are
	any empty positions.
	Configure whether or not to use sample barcodes.
	· Settings are also applied to [Settings] - [System
	settings] - [Samp barcode settings].
YES:	Use sample barcodes.
NO:	Do not use sample barcodes.
	Select the measurement method.
1 day:	Measure using 1 day method.
2 day:	Measure using 2 day method.
3 day:	Measure using 3 day method.
	Select the measurement mode.
	• Measured data when remeasuring a sample
	in remeasure/retest mode is applied to the
	positive rate.
	• Measured data when using a retest rack or
	dilute test rack is not applied to the positive
	rate.
	Select when first making a measurement.
	Select when remeasuring a sample.
1-10	Configure the head rack dispensing start position.
	• This setting does not apply to retest or dilute test racks.
	• Sequence numbers are allocated from the
	YES: NO: 1 day: 2 day:

Continued on next page

NN1-1703 Rev.5

Testing

Item	Range/Selection	Details
Test item of Retes • Dil	[F-Hb]	Select the assay item.
test	[FCa]	Selection is possible if two analysis items are
		selected in the data output settings.
		Page 288 6.1.7 Data output settings -
		[Test settings]]
		Item settings cannot be made if order request
		settings have been made.

4

10

í.

F

enter



Test mode & Measure mode

005

G 2 - SEQ

O Mode

O YES

🔿 1 day

Test

5 6

(Pooi

| \* | +

Rack

O Mode 2

O NO

😑 2 day

O Retest

17

rack)

101

O 3 day

📘 [FCa]

9

del

Rack No.

Sample No

Sample ba

Method

Measure

Test start point

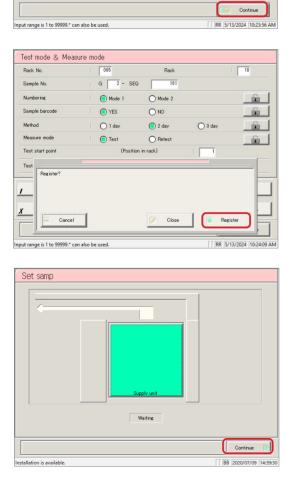
2

X

Test item of Retes Dil test

3

r z



Touch the {Continue} button.

5 Touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel test mode and measure mode selection,
	and return to the [Additional test] screen.
{Cancel}:	The dialog box closes.

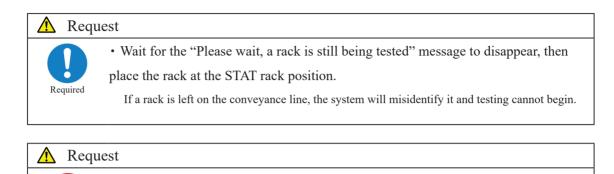
- 6 Touch the {Continue} button.
  - \* The system returns to the [Monitor] screen.
  - \* Rack supply begins.

<ul> <li>"Additional Twating" message changes to "Running additional test." Once testing is complete for all configured racks, the "Running additional test" message disappears.</li> <li>Explanatory note : If the number of racks has not been configured ("*" input), the "Running additional test" message is not displayed.</li> <li>Explanatory note : Additional tests cannot be made while the "Additional Testing" or "Running additional test" message are displayed.</li> <li>Canceling additional tests Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed.</li> <li>Imput: The following procedure to cancel additional tests when the "Additional Testing" message is displayed.</li> <li>Select the {Additional tests} tab.</li> </ul>		screen.	received, "Additional Testing" is displayed on the [Monitor]
<ul> <li>Explanatory note: If the number of racks has not been configured ("*" input), the "Running additional test" message is not displayed.</li> <li>Explanatory note: Additional tests cannot be made while the "Additional Testing" or "Running additional test" messages are displayed.</li> <li>Canceling additional tests</li> <li>Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed.</li> <li>Image: Additional tests</li> <li>Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed.</li> <li>Select the {Additional test} tab.</li> </ul>		"Additional Twating" message cl	hanges to "Running additional test."
not displayed. (Explanatory note) : Additional tests cannot be made while the "Additional Testing" or "Running additional test" messages are displayed. Canceling additional tests Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed. Select the {Additional test} tab. Select the {Additional test} tab.		Once testing is complete for all c	configured racks, the "Running additional test" message disappears
<ul> <li>Explanatory note : Additional tests cannot be made while the "Additional Testing" or "Running additional test" messages are displayed.</li> <li>Canceling additional tests         Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed.     </li> <li>Image: Compare to compare the test of process to compare the test of test of</li></ul>	Explanatory note : I	f the number of racks has not been	en configured ("*" input), the "Running additional test" message is
<ul> <li>Canceling additional tests</li> <li>Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed.</li> <li>Select the {Additional test} tab.</li> </ul>			
Canceling additional tests Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed. <b>Method Work Concess Method Wo</b>			while the "Additional lesting" or "Running additional test"
Use the following procedure to cancel additional tests when the "Additional Testing" message is displayed.			
displayed.	-		
Additional test       STAT       Set reagents       Set transport         Back       Samp No. 11t State of processs       Comment       000202         001-03       000003       Frits       Dispensing latex       0000201         001-03       000001       Frits       Dispensing latex       0000201         001-03       00002       Frits       Dispensing latex       0000201         001-03       000001       Frits       Main (Internation)       Image: Comment (Internation)         Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)         Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)         Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)         Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)         Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)         Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)       Image: Comment (Internation)         Image:		ing procedure to cancel add	ditional tests when the "Additional Testing" message is
Reck Same No. It State of process 001-04 00004 FHb Dispensing latex 000201 001-02 00002 FHb Mixing 000101 001-01 00001 FHb Reacting[Imin] 000101 with reading a recepting has a recepting for a recepti	displayed.		
	Rack         Same No.         It         State c           001-04         00004         F+Hb         Dispens           001-03         00003         F+Hb         Dispens           001-03         00002         F+Hb         Mixing           001-01         00001         F-Hb         Mixing           001-01         00001         F-Hb         Mixing           00001         F-Hb         Mixing         Reacting           00001         F-Hb         Reacting         Reacting           00001         F-Hb         Reacting         Reacting	of process Comment	1 Select the {Additional test} tab.

## 2.4.14 Cut-in analysis

Prohibited

Cut-in analysis for sample racks and STD/QC racks can be run during testing. (Cut-in analysis) The measurement mode and method for cut-in analysis are "Test mode" and "1 day," respectively. Cut-in analysis cannot be performed on retest racks and dilute test racks.



• Do not stop cut-in analysis when measuring an STD sample. The data being measured will be deleted.

Explanatory note): If a retest rack or dilute test rack is cut-in during cut-in analysis, the system will display "Rack barcode Unavailable" and the rack will be discharged to the STAT rack position.

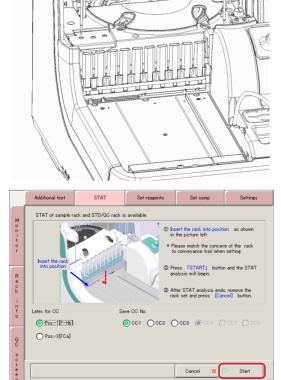


	Additional test	STAT	Set reagents	Set samp	Settings	1	Select the {STAT} ta
Rac 001- 001- 001-	04 00004 03 00003	F-Hb Dispe	e of process ensing sample ensing latex	Comment	000202 000201 000102		( )
	01-01 00001		ing[1min]		000101		* Rack supply sto
					¥		* The conveyance
				Prove de	Jend time 8 min		
	Information	-					
	Pos1 (F-Hb) P Lot. 12045 Remaining 204	os2 (PCa(But)) Pos. Remaining	0 (FCs) Buffer Lot. 34567 Rensining	Remaining 1105	Connect Help		
		Process data			Pause		
	<u> </u>			B	2020/07/09 15:21:15		
				[ [ B	2020/07/09 15:21:15		
	Additional test	STAT	Set reagents	Set samp	2020/07/09 15:21:15	2	Wait until the "There
		STAT ck and STD/QC rack		r			Wait until the "There
	STAT of sample ra	ck and STD/QC rack	is available.	Set samp	Settines		Wait until the "There Please wait." messag
	STAT of sample ra	ck and STD/QC rack	is available.	Set samp	Settines		
	STAT of sample ra	ck and STD/QC rack	is available.	Set samp	Settines		
	STAT of sample ro The ana	ck and STD/00 rack	is available. <b>B PRC</b> <b>PIG</b> ave CC No.	Set samp (S. St) RSC V	Settings		
	STAT of sample ra	ck and STD/00 rack	e rack 9 rack 9 Piet	Set samp (S. St) RSC V	Settings		
	STAT of sample re The ana Latex for CC Pog=I[F=Hb]	ck and STD/00 rack	is available. <b>B PRC</b> <b>PIG</b> ave CC No.	Set samp (S. St) RSC V	Settings		

\* Rack supply stops. \* The conveyance line rack is discharged.

ntil the "There are racks still in analysis. wait." message disappears.

AT of sample rack and STD/OC rack is available.  There are racks a analysis. Please (for CC Save CC No. ) PoscIEC+61  O CC1 O CC2 O CC3 (@) ) PoscAEFCa]  Cance Ks. Please wait.		CC and registration destination CC number.
Item	Range/Selection	Details
Latex for CC	Pos1 [F-Hb]	Select the reagent to use.
	Pos3 [FCa]	Pos-1: Fecal hemoglobin
		Pos-3: Fecal calprotectin
		Explanatory note Except for setting analysis items If reagent is selected, "not applicable to rach barcoding"The product is unloaded to the position where the interrupt rack is installed. Page286
Save CC No.	CC 1 ~ CC 3	Set the registration target CC No for the created calibration curve of fecal hemoglobin.
	CC 4 ~ CC 6	Registration destinations of the calibration curves fo the fecal calprotectin created Setting CC No.



Touch the {Start} button.

place the rack.

5

RR 2020/07/09 15:24:

\* The rack is conveyed to the right.

into the groove in the middle of the rack, and

STAT is available. Please install rack for cut in analys

<u>**Testing</u></u></u>** 



## 2.4.15 Completing testing (normal close)

To complete testing, touch the {Completed} button on the [Monitor] screen, and select {Normal close}. When testing is complete for all samples on the reaction table, the system returns to the [MENU] screen.

To pause or abort testing, see the sections explaining each operation. To "pause" testing, see page 83 " Pausing testing." To "abort" testing, see page 84 " Aborting testing.". NEORMATIO Touch the {CLOSE} button. CLOSE MUTE Next err Waiting To continue testing, place the sample rack in the rack supply unit. The analysis is completed. Page 72"2.4.12 Adding samples (You can continue testing) (continue testing)" Touch the {Completed} button. 2 State of proce 505 ng/mL 220 ng/mL 90 ng/mL 5 ng/mL No 4 001-10 \$ 001 001 001 001 -08 -07 -06 -05 -04 Rack 001-01 Help Pause 20/12/09 9:04: 3 Touch the {Close} button. It. -Hc -Hc State of proc 505 ng/mL 220 ng/mL 90 ng/mL \* The system returns to the [MENU] screen. 001-09 001-08 001-07 001-06 001-05 \* The results of the measured samples are printed. -Ht -Ht -Ht 00021 0001 001-04 001-03 00016 Rack 001-02 00014 QC Abort Cance Clos RR 2020/12/09 9:04:11 {Close}: Finish testing.

 $\{Cancel\}$ : The dialog box closes.

{Abort}: Finish testing during processing.

Testing completed

#### Pausing testing

Touching the {Pause} button on the [Monitor] screen pauses sample dispensing. (Reagent dispensing, mixing, detection, and washing operations are not stopped.)

	Addition	ial test	STAT		Set reagents	Set samp	Settings
	Rack	Samp No.	It	State of	of process	Comment	
М	001-10	00023	F-Hb	505	ns/mL		
0	001-09	00022	F-Hb	220	ns/mL		
n i	001-08	00021	F-Hb	90	ng/mL		\$
t o	001-07	00020	F-Hb	5	ng/mL		
ř	001-06	00019	F-Hb		OR		
	001-05	00018	F-Hb		OR		
_	001-04	00017	F-Hb		ng/mL		
R	001-03	00016	F-Hb		ng/mL		¥
a	001-02	00015	F-Hb		ng/mL		
c k	001-01	00014	F-Hb	0	ng/mL		
i							▼
n						E>pecte	d end time
f	Info	ormation					
Ť.,							
	Pos1	[F+tb] Pos	-2 [FCa(E	N(1) Pos3	[FCs] Buffer		Connect
Q	65	Lot. 12345 🚽			Lot. 97003		
õ		Remaining	Remai	ning	Remaining	Remaining	Help
s		224		72	100	4864	
с							
r e	F Pr	ine 🗖	Process dat			Completed	Pause
e n						U	
						E C R	R 2020/12/09 9:04:

STAT Set reagents State of proce 505 ng/mL 220 ng/mL 90 ng/mL 5 ng/mL Rack 001-10 001-09 001-08 001-07 001-06 001-05 001-04 001-03 001-02 001-01 Samp 000 No It. A Monitor 00023 00022 00021 00020 00019 00018 00017 00016 \$ ####### 793 ng/mL 355 ng/mL 89 ng/mL 0 ng/mL ¥ Rack 00015 i n f o Informatio Q He screes Pro cess data Completed RR 2020/12/09 9:04:1 Touch the {Pause} button.

\* The {Pause} button changes to the {Restart} button. \* Sample dispensing pauses.



Touch the {Restart} button. \* Operation is resumed.

Testing completed

#### 2.4 Daily Operation

#### Aborting testing

Touching the {Abort} button on the [Monitor] screen stops all operations and returns to the [MENU] screen.

	Addition	ial test	STAT		Set reagents	Set samp	Settings
1	Rack	Samp No	). It	State	e of process	Comment	
м	001-10	00023	F-Hb		05 ng/mL		
0	001-09	00022	F-Hb		20 ng/mL		
n	001-08	00021	F-Hb		90 ng/mL		(2)
t o	001-07	00020	F-Hb		5 ng/mL		
r I	001-06	00019	F-Hb		OR		
	001-05	00018	F-Hb		OR		
	001-04	00017	F-Hb	7	93 ng/mL		
	001-03	00016	F-Hb	3	55 ng/mL		¥
a	001-02	00015	F-Hb		89 ng/mL		
c I	001-01	00014	F-Hb		0 ng/mL		
							▼
i l'						Expec	ted end time
n f	Ju Info	ormation					
2	<u> </u>						1
		Lot. 12345 Remaining 224	Remai	ning 72	Lot. 97003 Remaining 100	Remaining 4854	Help
		Remaining	Process dat	72	Remaining		Help Pause [RR  2020/12/09  9:04:17
QC screen		Remaining 224		72	Remaining	4854	Pause
	Addition Rack	Remaining 224 ime	Process dat STAT	72	Remaining 100	4864	Pause           RR         2020/12/09         9:04:17           Settings         Settings
s cree	Addition Rack 001-10	Remaining 224	Process dat STAT	72	Remaining 100 Set reagents	4864 Completed	Pause RR  2020/12/09  9:04:17
	Addition Rack 001-10 001-09	Remaining 224 iime	Process dat STAT	72	Set resperts 2 of process 05 ns/mL 20 ns/mL	4864 Completed	Pause           RR         2020/12/09         9:04:17           Settings
	Addition Rack 001-10 001-09 001-08	Remaining 224 ime al test Samp No 00023 00022 00021	Process dat STAT b. It F-Hb F-Hb F-Hb	72	Set respents 2 of process 05 ng/mL 20 ng/mL	4864 Completed	Pause           RR         2020/12/09         9:04:17           Settings         Settings
M Don	Addition Rack 001-10 001-09 001-08 001-07	Remaining 224	Process dat STAT 5. It F-Hb F-Hb F-Hb F-Hb	72	Set respents a of process 50 ng/mL 20 ng/mL 30 ng/mL	4864 Completed	Pause           RR         2020/12/09         9:04:17           Settings
M Don iii	Addition Rack 001-10 001-08 001-08 001-07 001-06	Permaining 224	Process da STAT b. It F-Hb F-Hb F-Hb F-Hb F-Hb	72	Set respents a of process 05 ng/mL 20 ng/mL 30 ng/mL 5 ng/mL 0 0R	4864 Completed	Pause           RR         2020/12/09         9:04:17           Settings
MI phi r	Addition Rack 001-10 001-09 001-08 001-07 001-06 001-05	Persining 224 ime al test Samp Nk 00023 00022 00021 00020 00019 00018	Process dat STAT	State 5 2	Set respects a of process of process of pro/mL 00 ng/mL 00 ng/mL 00 ng/mL 00 ng/mL 00 ng/mL	4864 Completed	Pause           RR         2020/12/09         9:04:17           Settings
M D D T T	Addition Rack 001-00 001-08 001-07 001-06 001-05 001-05	Pernaining 224 ime Samp Nk 00023 00021 00021 00020 00021 00020 00019 00018	Process dat STAT D. It F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb	State 5 2	Set reagents a of process 05 ns/nL 20 ns/nL 20 ns/nL 5 ns/nL 0 ns/nL 30 ns/nL 0R 0R 0R 0R	4864 Completed	Pause           RR         2020/12/09         9:04:17           Settings
S cr e e n M O n i i t t o r	Addition Rack 001-10 001-09 001-08 001-07 001-06 001-05 001-03	Pernaining 224 ime all test Samp No 00023 00021 00021 00020 00019 00018 00017 00016	Process dat 5. It F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb	72 12	Set reserves a of process to ng/mL 20 ng/mL 5 ng/mL 0R 08 08 ng/mL	4864 Completed	RR (2023/12/09 (9:04:12 Settings
Mi Doniitor	Addition Rack 001-00 001-08 001-07 001-06 001-05 001-05	Pernaining 224 ime Samp Nk 00023 00021 00021 00020 00021 00020 00019 00018	Process dat STAT D. It F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb F-Hb	72 12	Set reagents a of process 05 ns/nL 20 ns/nL 20 ns/nL 5 ns/nL 0 ns/nL 30 ns/nL 0R 0R 0R 0R	4864 Completed	Pause           RR         2020/12/09         9:04:17           Settings

Cancel

Clo

RR 2020/12/09 9:04:17

Touch the {Completed} button.

2 Touch the {Abort} button.

- \* The system returns to the [MENU] screen.
- \* The result of the sample being measured is discarded.

{Close}:	Finish testing.
{Cancel}:	The dialog box closes.
{Abort}:	Finish testing during processing.

Testing completed

Rack info QC screen

## 2.5 Inspection/Maintenance after Use

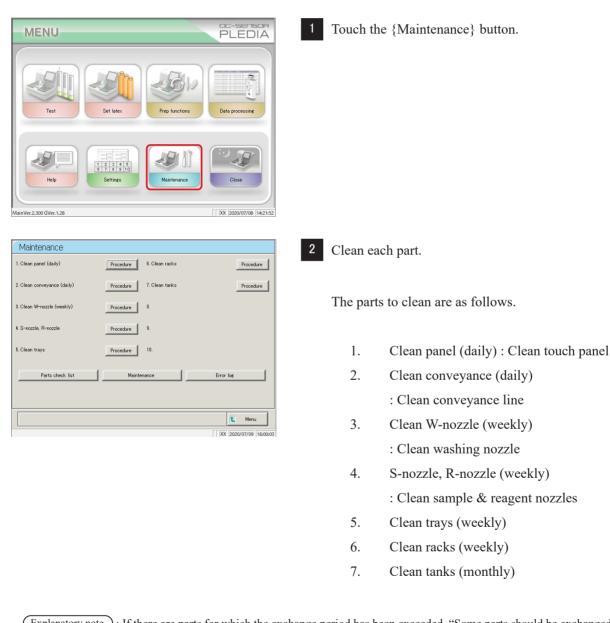
Run daily inspection and maintenance before turning the system off.

Touch the {Maintenance} button from the [MENU] screen to open the [Maintenance] screen.

"Inspection/maintenance" items are displayed on the screen. Follow the instructions on screen to clean each part periodically.

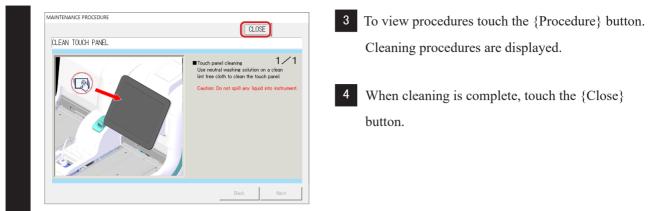
The "Parts check list" and "Error list" can also be displayed from the [Maintenance] screen. Check these as needed.

#### 2.5.1 Cleaning parts



 Explanatory note
 : If there are parts for which the exchange period has been exceeded, "Some parts should be exchanged.

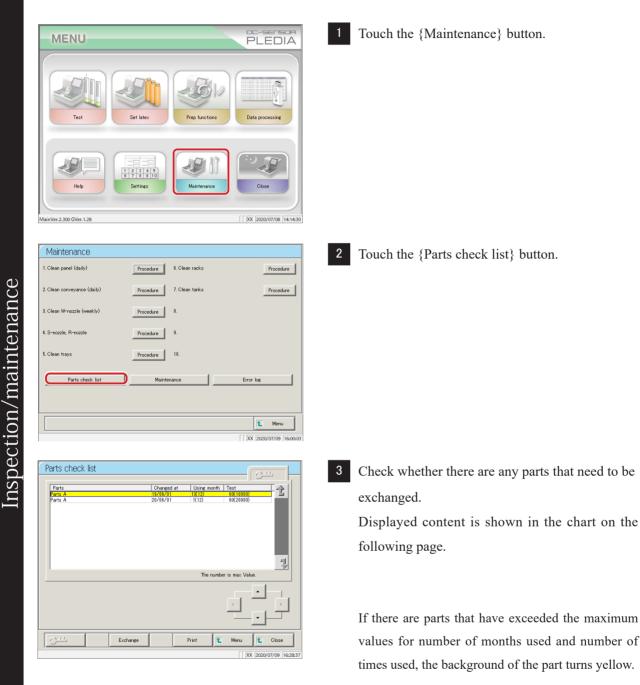
 Please check list of parts to check and exchange." is displayed.



Inspection/maintenance

#### 2.5.2 Opening the parts check list

The [Parts check list] screen displays parts, when they were last changed, the number of months they were used (maximum months used), and how many times they have been used (maximum times used).



No.	Item	Details	Remark
(1)	Parts	Name of the part to exchange	Up to 15 (full-width alphanumeric characters) or 7 (full-width characters) digits can be displayed.
(2)	Changed at	Date the part was exchanged (YY/MM/DD)	
(3)	The number of months used	The number of months used since last exchange	
	( )	Maximum months used	
4	Test	The number of times used since last exchange	
	( )	Maximum times used	



Parts check list

press [Start] to

	heck list				<del>ب</del> ا سر
Parts		Changed at	Using month		
1) Carts #		19/00/01	13(12)	60(10000) co/occol	
			Termula	ris max Value.	7
		 	Ine numbe	r is max value.	

Exchange parts

Print

Exchange

#### 4 Exchange the part.

- 1 Select the part to exchange (in yellow).
- (2) Exchange the part.
- 3 Touch the {Exchange} button.
- \* A confirmation dialog box asking "Exchange parts?" is displayed.
- {Exchange}: Touch after the part has been exchanged.
- {Print}: Print the parts check list.
- {MENU}: Return to the [MENU] screen.
- {Close}: Return to the [Maintenance] screen.
  - ④ Touch the {Start} button.
    - \* "Changed at" is updated to the current day.
    - \* "Using month" and "Test" are reset to "0."
    - \* The dialog box closes.

{Start}:	Part exchange information is updated.
{Cancel}:	The dialog box closes.

Explanatory note : Part can be exchanged even if a part that is not yellow is selected.

#### 2.5.3 Opening the error log

The [Error log] screen displays the date the error occurred, the error code, and the name of the error (details).

Up to 20 errors can be displayed on a single screen, and up to 1,000 errors can be displayed on a single list. If there are 21 or more errors, use the scroll bar to scroll the list.

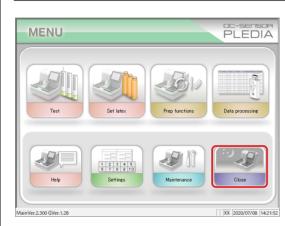


Inspection/maintenance

## 2.6 System shutdown (Close mode/Long suspense mode)

There are two methods to shut the system down: "Close mode" and "Long suspense." Select "Close mode" to shut the system down normally. Select "Long suspense" when the system will not be used for a long time. Both modes will automatically turn the standby switch off. (The primary power switch is not turned off.)

#### 2.6.1 Close mode



**O** YES

() YES

○ YES

C-blank

C-blank

**O** YES

() YES

() YES

C-blank

C-blank

C-blank

G-blank

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) C-blank

Test

Test

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07/09 17:17:5

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Test

Test

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Close

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() NO

NO

Touch the {Close} button.

2 If there are parts for which the exchange period has been exceeded, "Some parts should be exchanged. Please check list of parts to check and exchange." is displayed.

Touch the {Close} button and then the {MENU} button in order to return to the [MENU] screen. Page 87 "2.5.2 Opening the parts check list"

{Long suspense}: Transition to the [Long suspense] screen.

 Explanatory note
 : It is also possible to close without exchanging parts. To do so, touch the {Close mode} button, then select the process to run when complete. However, the same message will be displayed the next time the [Close mode] screen is opened.

3 If there are no parts for which the exchange period has been exceeded, select the process to run when complete.

(See the chart on the following page.)

# System shutdown

Close mode

zzle (cell cosk was

me parts should be exchanged

0 N0

Please check list of parts to check and exchange

NO

Cell was

FR

0: 0

SA 0:

Close mode

Exchange buffer and wash sol to a

uto start up

Cell wash

Nozzle/cell

SU

МО

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тн

FR

SA

#### 2.6 System shutdown (Close mode/Long suspense mode)

Item	Range/Selection	Details
Cell wash	YES:	Wash measurement cells when complete.
	NO:	Do not wash measurement cells when complete.
Exchange buffer and wash	YES:	Exchange with purified water.
sol to p. water	NO:	Do not exchange with purified water.
Nozzle/cell soak wash	YES:	Run soaking preservation.
	NO:	Do not run soaking preservation.

Close mode	OYES	<b>0</b> NO	
Exchange buffer and wash sol to p. water	O YES	© N0	
Nozzle/cell soak wash	O YES	© N0	
Settings of avido start up           Auto start up         SU         6:         6         MO           VU         6:         6         MO         NO           TU         0:         6         MO         NO           WE         0:         6         MO         NO           TH         0:         6         MO         NO           FR         0:         6         MO         NO	C-blank Test C-blank Test C-blank Test C-blank Test C-blank Test C-blank Test		
	Long suspense	Menu 🔽 Ci	ontinue

4 Touch the {Settings of auto start up} button.

- 5 Configure the day of the week and time to automatically start the system next (see the
  - following chart).
    - (1) Check the day of the week.
    - 2 Input the time.

Configure the operation to run automatically after start up, for each day of the week (see the following chart).

③ Check either "Nothing," "Cell blank," or "Test."

6 Register configured settings.

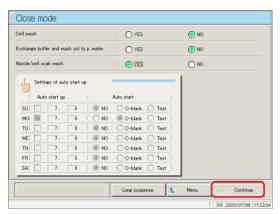
- (1) Touch the {Continue} button.
  - \* The dialog box opens.
- 2 Touch the {Register} button.

System shutdown

	Auto s	tart up 2			_(	Auto st	art			1
su 🛛	٦ <b>(</b>	7 :	0 min	O No	thing	O Cell b	lank		O Test	
мо	1	7 :	0 min		thing	🔵 Cell b	lanki		O Test	
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WE C	]	7 :	0 min	🔘 No	thing	⊖ Cell b	lank		O Test	
тн   🗆	ן נ	7 :	0 min	🔘 No	thing	O Cell b	lank		O Test	
FR	] [	7 :	0 min	🔘 No	thing	🔿 Cell b	lank		O Test	
SA 🛛	J	7 :	0 min	🔵 No	ithing	O Cell b	lank		O Test	
1 2	,	3	4	5	6	17	8	9	0	1
		3	19	0	0		0	9		
<u>x</u> )	/	z		/	*	-		de l		enter
	_								•/ (	Continue

Settings	of auto	start up			
Aut	o start up			Auto start	
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MO	7:	0 min	O Nothing	🕒 Cell blank	O Test
TU 🗌	7:	0 min	Nothing	🔘 Cell blank	O Test
WE 🗌	7:	0 min	Nothing	🔘 Cell blank	O Test
тн 🗌	1:	0 min	Nothing	🔘 Cell blank	O Test
FR	7:	0 min	() Nothing	🔿 Cell blank	() Test
	iter? Cancel			Close	Register
<u> </u>					XX 2020/07/09 17:2

Item	Range/Selection	Details
None	Check:	Display the [MENU] screen after starting.
	O Do not check:	Run the selected operation after starting.
Cell blank	Check:	Run [Prep functions] - [Cell blank] after starting, then display the results.
	O Do not check:	Do not run cell blank measurement after starting.
Test	Check:	Automatically start testing after starting. If a rack is not placed in the rack supply unit, the system operates for a short while, then enters standby mode.
	O Do not check:	Testing does not start automatically after starting.



Touch the {Continue} button. 7

Close mode Cell wash () YES 🔵 NO Exchange buffer and wash () YES 🔘 NO O YES O NO Nozzle/cell soak was Settings of auto start up Auto Auto star SU NO C-blank Test MC TU WE TH FR SA me and the drai Ple Cance XX

8

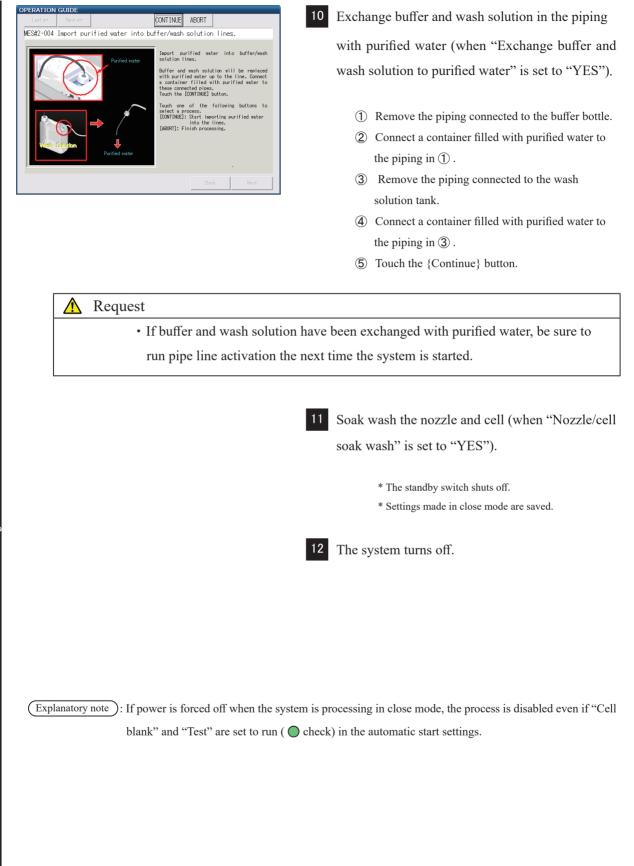
#### Run close mode.

① Confirm that the "purified water tank" and "wash solution tank" are not empty.

- Confirm that the "drain tank" is not full. 2
- 3 Touch the {Start} button.

{Start}: Run close mode.

- {Close}: Cancel close mode and return to the [MENU] screen.
- The dialog box closes. {Cancel}:
- 9 Start washing cells (when "Cell wash" is set to "YES").





Item	Range/Selection	Details
Cell wash	YES:	Wash cells when complete.
	NO:	Do not wash cells when complete.
Exchange buffer and wash	YES:	Exchange with purified water.
sol to p. water	NO:	Do not exchange with purified water.
Nozzle/cell soak wash	YES: NO:	Cannot be selected.

		4 Touch	the {Continue} button.
Cell wash			
Exchange buffer and wash sol to p. water			
Long suspense	Close mode	Continue	
Cell wash			lose mode.
Exchange buffer and wash sol to p. water	YES     O NO		Confirm that the "purified water tank" and "wa
Nozzle/cell soak wash	I O YES O NG		solution tank" are not empty.
		2	Confirm that the "drain tank" is not full.
		3	Touch the {Start} button.
Please confirm that DI water and w tank is empty before starting the ru	ash solution tanks contain sufficient volum n.	and the drain {Start}:	Run close mode.
		{Close}:	Cancel close mode and return to the [MENU]
- Cancel	Close	Start	screen.
		{Cancel}:	The dialog box closes.
		(When	n "Cell wash" is set to YES.) $\rightarrow$ to 8
OPERATION GUIDE Lasterr Nexterr MES#2-004 Import purified wa	CONTINUE ABORT		nge buffer and wash solution in the pipin
Lasterr MES#2-004 Import purified wa	ter into buffer/wash solutio	n lines.	
Lasterr MES#2-004 Import purified wa	ter into buffer/wash solution ifiedwater Jacot purified with purified with purified with solution lines. Buffer and wash so with purified water to be a container to be the total	tter into buffer/wash ution will be replaced up to the line. Cornect with purified water to button.	purified water (when "Exchange buffer a
Laster Nexter MES#2-004 Import purified wa	ter into buffer/wash solution ified water Beffer and mah solution bit on times. Beffer and mah so solution times. Beffer and mah so solution times. Beffer and mah so solution times. Touch the [ONTINUE]: Start in solution times. Solution times. Touch one of the solution times. Solution times. Solu	ter into buffer/wash ution will be realeased with purified water to button. following buttons to porting purified water	ourified water (when "Exchange buffer a solution to purified water" is set to "YES"
Lasterr MES#2-004 Import purified wa	ter into buffer/wash solution iidetwater Buffer and wash so with purified wash so with purified wash so with	tter into buffer/wash tter into buffer/wash ttion will be replaced with purified water to button. following buttons to sorting purified water lines. with purified water lines. Series (1) (1)	purified water (when "Exchange buffer a solution to purified water" is set to "YES Remove the piping connected to the buffer bott
Laster Nexter MES#2-004 Import purified wa	ter into buffer/wash solution ited meter Solution Union Buffer and wash so with purified wash so with purified wash container filled these convected pipe Touch the (CONTINUE): Starti Solicit a recoses. (CONTINUE): Starti into the	ter into buffer/wash ution will be replaced up to the line. Connect with purified water to button. following buttons to porting purified water lines. with purified water (1) (2)	purified water (when "Exchange buffer a solution to purified water" is set to "YES Remove the piping connected to the buffer bott
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Laster Nexter MES#2-004 Import purified wa	ter into buffer/wash solution ited meter Solution Union Buffer and wash so with purified wash so with purified wash container filled these convected pipe Touch the (CONTINUE): Starti Solicit a recoses. (CONTINUE): Starti into the	ter into buffer/wash ter into buffer/wash ution will be realesed with purified water to button. following buttons to porting purified water lines. ck Next Mext Mext Mext Mithe purified water (3)	purified water (when "Exchange buffer a solution to purified water" is set to "YES" Remove the piping connected to the buffer both Connect a container filled with purified water to the piping in ①. Remove the piping connected to the wash solution
Lasterr MES#2-004 Import purified wa	ter into buffer/wash solution ited meter Solution Union Buffer and wash so with purified wash so with purified wash container filled these convected pipe Touch the (CONTINUE): Starti Solicit a recoses. (CONTINUE): Starti into the	ther into buffer/wash ution will be replaced with purified water to button. following buttons to corting purified water ingenerating ck Rect (1) (2) (3) (4) (4) (4) (1) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4	purified water (when "Exchange buffer a solution to purified water" is set to "YES Remove the piping connected to the buffer bott Connect a container filled with purified water to the piping in ①. Remove the piping connected to the wash soluti tank.
Lasterr MES#2-004 Import purified wa	ter into buffer/wash solution ited meter Solution Union Buffer and wash so with purified wash so with purified wash container filled these convected pipe Touch the (CONTINUE): Starti Solicit a recoses. (CONTINUE): Starti into the	kter into buffer/wash tation will be realesed with purified water to button. following buttons to porting purified water lines. ck Next (1) (2) (3) (4)	purified water (when "Exchange buffer a solution to purified water" is set to "YES Remove the piping connected to the buffer bott Connect a container filled with purified water to the piping in ①. Remove the piping connected to the wash soluti tank. Connect a container filled with purified water to



8 Remove the purified water/wash solution/buffer piping.

#### 2.7 Drain Tank Processing

Remove the maximum-level sensor and hose attached to the drain tank, then dispose of the drainage in the tank.

Run through the procedure listed on page 39 "2.4.3 Setting the drain tank" in reverse to remove the maximum-level sensor and hose.





• Wear protective equipment when handling the drain tank.

Failure to observe this precaution may lead to contamination.

# Chapter 3 Operation (Applied)

- 3.1 Measured Data Processing
- 3.2 Editing Sample IDs
- 3.3 List of Positive Samples
- 3.4 List of Error Samples
- 3.5 Histogram
- 3.6 Positive Rate Change
- 3.7 Replicate
- 3.8 Quality Control
- 3.9 Rack info
- 3.10 Measuring Using Sample Cups



# Chapter 3 Operation (Applied)

# 3.1 Measured Data Processing

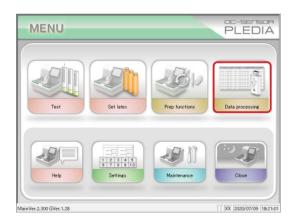
Select the measured data from the [Process data] screen, and then edit, delete, change the positive rate, or display the histogram.

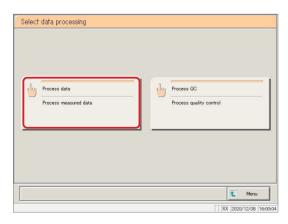
(Explanatory note): • Measured data is saved for each item.

- $\cdot$  Up to 100,000 sample and STAT sample tests can be saved to the hard disk(SSD).
- Once 100,000 tests have been reached the system will begin overwriting the oldest data.
- Up to 5,000 QC sample tests can be saved to the hard disk(SSD). Once 5,000 tests have been reached the system will begin overwriting the oldest data.

### 3.1.1 Opening the [Process data] screen

Open the [Process data] screen by touching the {Data processing} - {Process data} buttons on the [MENU] screen, or by touching the {Process data} button on the [Monitor] screen. A password will need to be entered if one was set in the environment settings.





- 1 <Opening from the menu screen>
  - (1) Touch the {Data processing} button.

(2) Touch the  $\{Process data\}$  button.

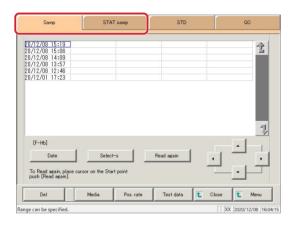
Additional test STAT Set reagents Set samp Settings Rack Samp No. 1t State of process Comment	<opening from="" monitor="" screen="" the=""></opening>
M     001-03	Touch the {Process data} button.
Check password	2 Enter a password (displayed when a password
After inputine password, please press [Enter].	was registered in [System settings] -[Config]).
Password	<ol> <li>Enter a password.</li> <li>Touch the {enter} key.</li> </ol>
I     2     3     4     5     6     7     8     9     0        X     Y     Z     .     /     #      de     2     enter       Vou can input 5-30 digits by 0-9XYZ,./     Cancel     Cancel     X     X     X     X	
Please select test to run. Selected test	3 Select the analysis items.
	○ [F-Hb]
G [F-Hb] C [FCa]	O [FCa]
	(1) Check the item ( $\bigcirc$ ).
	② [OK] Touch the button.
	[Cancel] : The dialog box closes.
Samp         STAT samp         STD         QC           20/12/08 15:19         20/12/08 15:06         20/12/08 15:07         20/12/08 15:07	4 The [Process data] screen was displayed.
20/12/08 12:46 20/12/01 17:23	<ul><li>* The {Samp} tab is selected.</li><li>* The measurement date and time list is displayed.</li></ul>
(F-He) Date Select-s Pead again To Read again, place cursor on the Start point	Explanatory note: The measurement date and time is the time the system started up.
push (Read agoin).	If there is no data to process, the time is
Range can be specified.	not displayed.

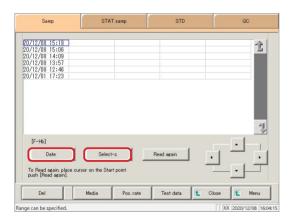
#### 3.1.2 Displaying the [Test data] screen

Select measured data by switching between the {Samp}, {STAT samp}, {STD}, and {QC} tabs on the [Process data] screen. Press the {Test data} button after selecting measured data and specifying a measurement date to display the specified data (the [Test data] screen varies according to whether the {Samp} or {STAT samp} tabs were selected, or the {QC} tab was selected).

Explanatory note : The displayed date and time is the date and time the standby switch was turned on. (That is, the system startup time.) Data measured until the standby switch is turned off is saved to the hard disk(SSD) as data from that day.

(Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.





{QC} tab

Page 186 "3.7.4 Displaying the [Replicate (QC)] screen"

2 Specify the measured data by date and time or

range.

<Specifying by measurement date and time> Touch the {Date} button, and specify the measurement date.

Page 104 "3.1.3 Specifying measured data by

2

measurement date"

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

Page 106 "3.1.4 Specifying measured data by

range" 2

(Explanatory note) : If {Date} or {Select-s} are not used, all displayed measured data (a max of 5,000 samples of data) will be processed.

28/12/01/1748 001-02 00006 [ -] PRC 1 27/12/01/1748 001-03 00006 [ +] PRC 1 27/12/01/1748 001-03 00007 [ +] PRC 1 27/12/01/1748 001-03 00007 [ +] PRC 1 27/12/01/1748 001-05 00007 [ +] PRC 1 27/12/01/1748 001-05 00010 [ -] PRC 1 27/12/01/1748 001-08 00011 [ -] PRC 1 27/12/01/1748 001-08 00012 [ +] PRC 1 27/12/01/1745 001-08 00012 [ +] PRC 1 27/12/01/1745 001-08 00002 [ +]	Samp			STAT sa	mp			STD		G	20
20/12/08 15:08         20/12/08 14:09         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/01 17:23         To Ped again         Date         Select=         Pead again         pask [read a	20/12/08 15.	9									
20/17/08       14:00         20/17/08       15:57         20/17/08       15:57         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:46         20/17/08       12:47         20/17/08       12:47         20/17/08       12:47         20/17/08       12:47         20/17/08       12:47         20/17/08       13:48         20/17/08       14:47         20/17/07       14:48         20/17/07       14:48         20/17/07       14:49         20/17/07       14:49         20/17/07       14:49         20/17/07       14:49         20/17/07       14:49         20/17/07       14:49 </td <td></td> <td>- 12  </td>											- 12
20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/08 13:57         20/12/01 17:23         Date         Select=s         Pead again         To Pead again, place cursor on the Start point         Date         Deate         Deate         Pead again, place cursor on the Start point         Deate         Deate         Pead again, place cursor on the Start point         Deate         Pead again         Igge can be specified.         Test data         Point Pead again         20/12/01 1748         Date         Sort         Select=s         Pead         Sort         Select=s         Sort         Select=s         Sort         Select=s         Serect											
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Del Output Copy ID edit Recal Search 🔽 Continue	20/12/01 1748 20/12/01 1748 20/12/01 1748 20/12/01 1748 20/12/01 1748 20/12/01 1748 20/12/01 1749 20/12/01 1749 20/12/01 1749 20/12/01 1749 20/12/01 1749 20/12/01 1749 20/12/01 1749 20/12/08 1855 20/12/08 1855 20/12/08 1855	001-01 001-02 001-03 001-04 001-05 001-05 001-06 001-07 001-08 001-09 001-10 001-01 001-01 001-02 001-03	SEQ. 00004 00005 00006 00007 00008 00009 00010 00011 00012 00013 00001 000013 00001 00002 00003	Data[ng/ 0	(mL)	Flag - - + + + - - + + + - - + + + + - - + + + + + - - - - - - - - - - - - -	Comment PRC PRC OR PRC OR PRC PRC PRC PRC PRC PRC PRC PRC			CC D 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
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	2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1149 2012/01 1149 2012/	001-01 001-02 001-03 001-04 001-05 001-06 001-07 001-08 001-09 001-01 001-01 001-02 001-04	SEQ. 00004 00005 00007 00008 00009 00010 00011 00012 000013 00001 000013 00004 Selec	Data[ng/ 0	(mL)	Flag 	Comment PRC PRC OR PRC OR PRC PRC PRC PRC PRC	Sample	ID		
	2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1148 2012/01 1149 2012/01 1149 2012/	001-01 001-02 001-03 001-04 001-05 001-06 001-07 001-08 001-09 001-01 001-01 001-02 001-04	SEQ. 00004 00005 00007 00008 00009 00010 00011 00012 000013 00001 000013 00004 Selec	Data[ng/ 0	(mL)	Flag 	Comment PRC PRC OR PRC OR PRC PRC PRC PRC PRC	Sample	ID		

{Samp} or {STAT samp} tabs were selected

3 Touch the {Test data} button.

{Close}: Return to the [Data process selection] screen. Or, return to the [Monitor] screen. (If {Test data} button on [Monitor] screen as touched.)

{MENU}: Return to the [MENU] screen.



4 The measured data was displayed.

(Explanatory note): During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is displayed in blue text.

	Test data			Replicate		
Date 20/12/01 17:29 20/12/01 17:29	Rack QC no 098-09 1 098-10 2	QC lot 11111 22222	SEQ. 00001 00002	Data[ng/mL]	Comment No CC No CC	
						7.
(F-Hb)	QCID Select	·	Search			
Del	Output				Search	Continue

{QC} tab was selected

Display	Details		Remark
Date	Date and tin	ne sample was measured	
RACK	Rack No I	Position number in rack	
SEQ.	Group No	Sequence No.	
Data [ng/mL] or [ug/g]	Measuremer (concentrati		
Flag	-, +, 1 +, 2 +	-, 3 +	
	Error inforn	nation (excluding reading errors)	
	UR	: Under range	Blank output for measured data and judgment result
Comment	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode inf	ormation on sampling bottles	
СС	Calibration data (CC No.)	curve used to calculate measured	
	Dilution for	mation	
	Space	: No dilution (test mode, remeasure mode)	
Dil	А	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

# Content displayed on [Test data] screen (Samp/STAT samp)

Display	Details		Remark
Date	Date and tin	ne QC sample was measured	
RACK	Rack No I	Position number in rack	The rack position number of QC samples is 9 or 10.
QC No.	QC No.1 - 4		
QC LOT	QC lot (five	digits)	
SEQ.	QC sequenc	e number	
Data [ng/mL] or [ug/g]	Measuremer (concentration		
	Error inform	nation (excluding reading errors)	
Comment	UR	: Under range	
Comment	OR	: Over range	
	PRC	: Prozone	
СС	Calibration data (CC number	curve used to calculate measured	
QC ID	QC ID of Q	C sample at cursor position	

Content displayed on [Test data] screen (QC)

Media

Range can be spe

Pos. rate

Test data

### 3.1.3 Specifying measured data by measurement date

Specify the measurement date of the measured data to display from the [Process data] screen.

Explanatory note : When entering the measurement date, if part of the year, month, or day is omitted, the system will begin a search from the latest measurement date to find the measured data with the latest date that matches the entered conditions. 3 on the following page (example) I (Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen. Explanatory note : A measurement date is not specified for STD measured data. STAT samp STO Sam Touch the tab of the measured data to display. 1 14/08/08 19:16 t {Samp} tab {STAT samp} tab {QC} tab (E-Hb) the Start poin Test data Pos. rate Media t Close Menu De nge can be s STAT sam Samp Touch the {Date} button. 2 t

Search wor	d setting	s								
Date	20	YY	мм	DD	) (	)				
1 2	3	4	5	6	7	8	9	0	-	1
x r	Z		1	*		<b> </b> →	de l		enter	1
							<b>2</b>	•/	Continue	ו
Search word settin	ngs							XX 202	0/12/08 16:1	12:16

Search word settings	
Date 20 YY MM DD	
Star?	
Image: Carcel     Image: Close	3 Start
Search word settings	XX 2020/12/08 16:12:16

14/07/18 10:03
त् रा
(F-Hb) Date Select-s Read again To Read again, place cursor on the Start point push (Read again).
Del         Media         Pos. rate         Test data         Close         Meriu           Range can be specified.         [] XX 2020/12/06         161100         161100         161100

#### 3 Specify the measurement date.

 Touch the input field and enter the year, month, and day.

If part of the year, month, or day is omitted, the system will begin a search from the latest measurement date to find the data with the latest date that matches the entered conditions.

(Example) If October 5 is entered and the year is omitted, the search will display only data for the current year. For example, if the current year is 2013:

> 2013/10/05 10:10 (displayed) 2013/10/05 10:15 (displayed) 2013/10/05 10:20 (displayed)

2012/10/05 14:25 (not displayed 2012/10/05 14:30 (not displayed 2012/10/05 14:35 (not displayed

- (2) Touch the {Continue} button.
- ③ Touch the {Start} button.
- {Start}: Search for data using the specified measurement date.
- {Close}: Cancel measurement date specification, and return to the [Data process selection] screen.

{Cancel}: The dialog box closes.

4 The data for the specified measurement date is displayed.

(Explanatory note): To specify a new measurement date, touch the {Clear} button.

All measured data is displayed, and the system returns to the state it was in before the range was specified.

#### 3.1.4 Specifying measured data by range

Specify the measured data to display using a measurement date and time range (start point/end point).

Specify the range by touching the measurement date and time on the [Process data] screen, or by using the cursor buttons.

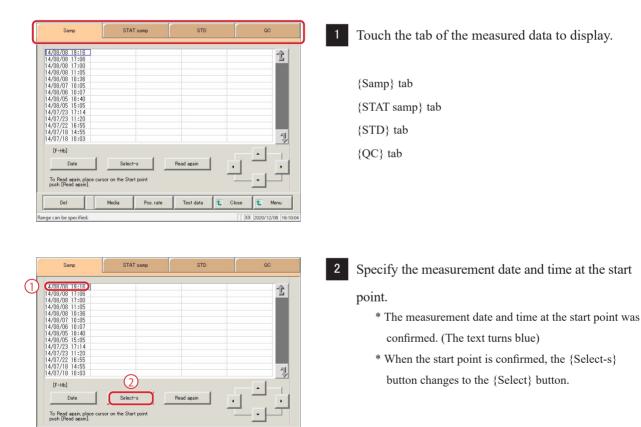
Specify the start point and touch the {Select-s} button to confirm the measured data at the start point.

Then, specify the end point and touch the {Select} button to confirm the measured data at the end point.

After confirming the start and end points, the measured data between the start and end points is specified as the range.

(Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

(Explanatory note) : If a range is not specified, <u>all data (up to 5,000 samples' worth)</u> displayed on screen will be processed.



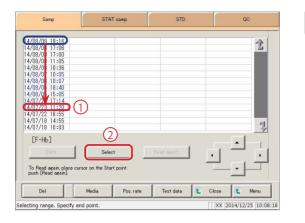
(Explanatory note): The date and time of the start and end points can also be specified using the cursor buttons.

Del

Pos. rate

Test data

1 Close



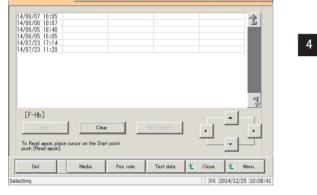
Sam

STAT sam

3 Specify the measurement date and time at the end

#### point.

- Touch the measurement date and time that will be the end point.
- (2) Touch the {Select} button.
  - \* The measurement date at the end point is confirmed.
  - \* When the end point is confirmed, the {Select} button changes to the {Clear} button.
- {Clear}: Clear the range specification.



The measured data for the specified range is displayed.

 Explanatory note
 : • If the dates and times specified for the start and end points are the same, the system will handle it as though only a single sample of measured data was specified.

 • To specify a new range, touch the {Clear} button. All measured data

#### 3.1.5 Reading "measured data" not in the list (reading again)

Up to 5,000 samples' worth of measured data can be displayed in the list and edited. (Up to 100,000 samples' worth of measured data can be saved to each test item.) Data must be read in order to edit measured data not displayed in the list. Specify the date and time that will be the start point from the list, select whether to display data before or after that point, then read the data to edit.

Explanatory note: See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the

[Process data] screen. Samp STAT san STD Q Touch the tab of the measured data to read. 1 14/08/07 19:38 00 40 Î {Samp} tab 1:20 3:05 1:08 1:50 1:00 3:27 {STAT samp} tab {STD}  $\{QC\}$ [F-Hb] Dat To Read again, pla Test data Pos rate XX 2020/12 2 Specify the start point and read the measured data. Samp (1) Touch the measurement date and time that will be È the start point. 14/03/18 14/03/17 14/03/13 14/03/07 14/03/07 14/03/06 14/03/06 14/03/05 14/03/04 1:08 4:30 3:09 0:41 (The cursor buttons at the bottom right of the screen can also be used to select this.) 11:13 2 Touch the {Read again} button. 4/04/09 4/04/08 14/03/27 18:48 14/03/27 09:12 -11 [F-Hb] ③ Select the reading method. (See the chart below.) (4) Touch the {Start} button. To Read again, pl sush [Read again \* Begin reading measured data. Pos. rate Test data ange can be specifie {Cancel}: Close the dialog box. /05/09 /05/08 /05/08 ì {Close}: Return to the [Data process selection] screen. Or, return to the [Monitor] screen. (When the {Test data} button has been touched on the monitor screen.) nod and gather 5000 s ore the date on the curs {MENU}: Return to the [MENU] screen. data after the date on the cu nge can be spec

Selection	Details
• Get data before the date on the cursor.	Read data from before the date and time at the cursor position. (This does not include the date and time at the cursor position.)
• Get new data after the date on the cursor.	Read data from after the date and time at the cursor position. (This does not include the date and time at the cursor position.)

#### Reading "measured data" from external media 3.1.6 (switching external media)

Read measured data saved to external media and display it on the screen.

This function is not available for STD and QC sample measured data.

(Explanatory note): See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

1

Samp	STAT samp	STD	QC	
14/08/06 14:05 1	4/07/02 14:51 14/06/02 13 4/07/02 13:12 14/05/30 13 4/07/02 10:56 14/05/29 09	:40 14/05/21 10:07	14/05/09 09:45 14/05/08 14:23 14/05/08 11:56	î
14/08/06 10:11 1 14/07/24 16:05 1 14/07/24 14:34 1	4/06/27 14:02 14/05/28 16 4/06/27 13:02 14/05/28 15 4/06/23 15:36 14/05/28 14	:19 14/05/20 09:24 :35 14/05/19 18:55 :14 14/05/19 14:26	14/05/08 10:34 14/04/23 16:21 14/04/23 10:16	
14/07/23 10:09 1 14/07/16 12:37 1	4/06/10 17:44 14/05/27 18 4/06/06 13:14 14/05/27 17	:40 14/05/16 13:05 :14 14/05/16 11:08 :46 14/05/15 14:56	14/04/22 18:23 14/04/22 14:54 14/04/22 13:38	
14/07/04 16:19 1 14/07/04 10:30 1	4/06/03 16:14 14/05/27 15	:28 14/05/15 14:06 :57 14/05/15 09:27 :13 14/05/14 11:40 :24 14/05/13 10:05	14/04/22 11:10 14/04/21 11:42 14/04/21 10:55 14/04/21 10:09	
	4/06/03 15:42 14/05/27 10 4/06/03 08:58 14/05/26 16		14/04/21 10:09	1
Date	Select-s	Read again		
To Read again, place push [Read again].	cursor on the Start point			_
Del	Media Pos. rate	Test data 🚺	Close 🚺 N	lenu

Samp	STA	T samp	STD		QC		
14/08/07         19:38           14/08/06         14:05           14/08/06         11:38           14/08/06         10:11           14/07/24         16:05           14/07/24         14:03           14/07/24         10:30           14/07/24         10:30           14/07/23         10:09           14/07/24         13:32           14/07/04         16:39           14/07/04         98:58	14/07/02 14:51 14/07/02 13:12 14/07/02 13:12 14/07/02 10:56 14/06/27 13:02 14/06/27 13:02 14/06/23 15:36 14/06/23 13:23 14/06/10 17:44 14/06/06 09:40 14/06/04 09:36 14/06/03 15:42	14/06/02 13:00 14/05/20 13:40 14/05/20 08:56 14/05/20 16:09 14/05/20 16:19 14/05/20 14:14 14/05/20 14:14 14/05/27 10:14 14/05/27 16:20 14/05/27 16:20 14/05/27 16:21 14/05/27 10:24	14/05/21 10:07 14/05/20 19:15 14/05/20 09:24 14/05/18 18:55 14/05/19 14:26 14/05/16 13:05 14/05/16 11:08 14/05/15 14:56 14/05/15 14:56 14/05/15 19:27 14/05/14 11:40	14/05/08 1 14/05/08 1 14/05/08 1 14/04/23 1 14/04/23 1 14/04/23 1 14/04/22 1 14/04/22 1 14/04/22 1 14/04/22 1 14/04/21 1	9:45 1:56 0:34 6:21 0:16 6:23 4:54 3:38 1:10 1:42 0:55 0:09 1:42 0:55 0:09 1:42 1:55		
14/07/03 18:23	14/06/03 08:58	14/05/26 16:29	14/05/12 11:04	14/04/18 0	9:16		
(F-Hb) Date Select-s Read again To Read again, place cursor on the Start point push (Read again).							
Del	Media	Pos. rate	Test data 🚺 🐛	Close	t Menu		
ange can be specified	l.			[ XX 2	020/12/08 16:10:0		

STAT san Sam 14/08/07 21:44 14/08/07 21:42 14/08/07 21:40 14/08/07 21:38 4/08/0 t 08/06 08/06 08/06 08/06 08/06 8/08 8/08 8/08 [F-Hb] Date To Read again, pla nush [Read again] Test data HD change Clos XX 2015/01/17 14:11:43 Range can be speci

Touch the tab of the measured data to read.

{Samp} tab {STAT samp} tab

2

- Touch the {Media} button.
- \* Read the data from the hard disk(SSD).
- \* Measured data (up to 5,000 samples' worth) saved to the external media is displayed.
- \* Data is displayed in order of date, with data having the latest measurement date and time displayed first.



Touch the {HD change} or {SSD change}button.

#### 3.1 Measured Data Processing

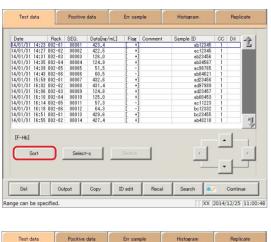
#### Sorting measured data 3.1.7

Sort the measured data by measurement date and time or group, and narrow down measured data to process.

When sorting by measurement date and time, measured data is displayed in ascending order by "date." When sorting by group, measured data is displayed in ascending order by "sample number group.

(Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

	Samp	STAT samp	STD		QC
5	14/08/06 11:38 01:11 14/07/24 18:05 14/07/24 18:05 14/07/24 18:05 14/07/24 10:99 14/07/24 10:99 14/07/16 12:37 14/07/06 13:32 14/07/06 13:32 14/07/04 10:30 14/07/04 09:58 14/07/03 18:23 14/07/03 18:23 14/07/03 18:23	4/07/02 13:12 14/05 4/07/02 0:56 14/05 4/06/27 14:02 14/05 4/06/27 14:02 14/05 4/06/23 15:36 14/05 4/06/03 15:36 14/05 4/06/04 017:44 14/05 4/06/06 09:40 14/05 4/06/04 09:40 14/05 4/06/03 18:14 14/05 4/06/03 18:14 14/05 4/06/03 08:58 14/05 4/06/03 08:58 14/05 5 select= a cursor on the Start point	//12 13:00 14/05/26 //20 13:40 14/05/20 //20 93:56 14/05/20 //28 16:19 14/05/20 //28 16:35 14/05/10 //28 15:35 14/05/19 //28 14:14 14/05/16 //27 18:14 14/05/15 //27 17:46 14/05/15 //27 16:28 14/05/15 //27 16:29 14/05/12 //27 10:24 14/05/13 //26 16:29 14/05/12 Read again 	10:07 14/05/08 19:15 14/05/08 19:25 14/05/08 19:25 14/04/23 14:26 14/04/23 13:05 14/04/22 11:08 14/04/22 11:08 14/04/22 14:56 14/04/22 11:04 14/04/21 10:05 14/04/21 11:04 14/04/21	14:23 11:56 10:34 16:21 10:16 16:23 14:54 13:38 11:10 11:42 10:55 10:09
	14/08/06 11:38 14/08/06 01:11 14/07/24 16:05 14/07/24 16:05 14/07/24 10:19 14/07/24 10:19 14/07/24 10:19 14/07/16 12:37 14/07/16 12:37 14/07/14 16:19 14/07/14 16:30 14/07/14 10:30 14/07/04 10:53 14/07/04 10:55 14/07/04 10:55 14/07/	4/07/02 13:12 14/05 4/07/02 10:56 14/05 4/06/27 14:02 14/05 4/06/27 13:02 14/05 4/06/23 15:36 14/05 4/06/23 15:36 14/05 4/06/10 17:24 14/05 4/06/10 17:24 14/05 4/06/10 17:24 14/05 4/06/10 318:14 14/05 4/06/03 18:14 14/05 4/06/03 08:58 14/05 4/06/03 08:58 14/05 5elect-s a cursor on the Start point	/02         3:00         14/05/26           /30         13:40         14/05/21           /29         95:50         14/05/21           /29         95:50         14/05/21           /29         95:50         14/05/21           /29         95:50         14/05/21           /28         16:25         4/05/16           /28         16:40         4/05/16           /28         16:40         4/05/16           /27         16:27         14/05/12           /27         15:27         14/05/12           /27         16:28         14/05/12           /27         16:21         14/05/12           /27         16:22         14/05/12           /26         16:29         14/05/12           /26         16:29         14/05/12           /26         16:29         14/05/12           /26         16:29         14/05/12           /26         16:29         14/05/12           /26         16:29         14/05/12	15:33 14/05/08 10:07 14/05/08 19:15 14/05/08 19:54 14/05/08 19:54 14/05/08 19:54 14/04/23 13:05 14/04/22 14:26 14/04/22 11:08 14/04/22 14:06 14/04/22 09:27 14/04/21 11:04 14/04/21 11:04 14/04/21	14:23 4 11:56 0 10:34 1 16:21 1 10:16 1 16:23 1 14:54 1 13:30 1 11:10 1 11:10 1 11:42 1 10:55 1 10:09 1
	Samp 14/08/07 19:38 14/08/06 14:05 14/08/06 14:05 14/08/06 14:05 14/08/06 10:31 10:31 10:32	Clear Clear cursor on the Start point Media Pos	Read again Read again		00



#### Histogram Replicate Fla 14/01/31 14:23 002-01 14/01/31 14:27 002-02 / ab12345 422. 126. 124. 51.1 60.5 432.6 431.4 124.8 125.0 57.3 64.3 429.6 ac12346 ab23456 ab34567 ac98765 ab84621 ad23456 ad97985 ad23457 ab00455 ac11223 bc12335 bc23455 002-02 002-03 002-05 002-05 002-06 002-01 002-02 002-02 002-03 002-04 3 Date sort Group sort Cancel Range can be specified XX 2014/12/25 11:00:4

Touch the {Sort} button.

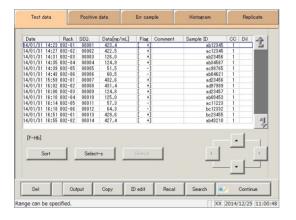
4

5 Touch the {Date sort} button or the {Group sort} button.

\* The sorted measured data is displayed.

- {Date sort}: Sort measured data in ascending order by measurement date and time.
- {Group Sort}: Sort measured data in ascending order by sample number group.
- {Cancel}: Cancel sorting measured data.

range"



6 Specify a range to further narrow down the measured data being displayed.

The procedure is the same as in the [Process data] screen. Page 106 "3.1.4 Specifying measured data by

NN1-1703 Rev.3

#### 3.1 Measured Data Processing

#### 3.1.8 Searching for measured data

Search measured data based on sample ID, sample number, rack number, and measurement date and time.

(Explanatory note) : Measured data cannot be searched for using the rack position number.

(Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

14/08/07 19:38	14/07/02 14:51	14/06/02 13:0	0 14/05/26 15:33	14/05/09 09:45	
14/08/06 14:05	14/07/02 13:12	14/05/30 13:4		14/05/08 14:23	T
14/08/06 11:38	14/07/02 10:56	14/05/29 09:5		14/05/08 11:56	
14/08/06 10:11	14/06/27 14:02	14/05/28 16:1			
14/07/24 16:05	14/06/27 13:02	14/05/28 15:3		14/04/23 16:21	
14/07/24 14:34	14/06/23 15:36	14/05/28 14:1		14/04/23 10:16	- 100
14/07/24 10:09	14/06/23 13:23	14/05/28 10:4		14/04/22 16:23	
14/07/23 10:09	14/06/10 17:44	14/05/27 18:1			- 60
14/07/16 12:37	14/06/06 13:14	14/05/27 17:4			- 60
14/07/08 13:32	14/06/06 09:40	14/05/27 16:2			- 60
14/07/04 16:19	14/06/04 09:36	14/05/27 15:5		14/04/21 11:42	- 60
14/07/04 10:30	14/06/03 16:14	14/05/27 15:1		14/04/21 10:55	
14/07/04 09:58	14/06/03 15:42	14/05/27 10:2			-1
14/07/03 18:23	14/06/03 08:58	14/05/26 16:2	3 14/05/12 11:04	14/04/18 09:16	
[F-Hb]					
Date	Select	H-s	Read again		
					· ·
	ace cursor on the Star	rt point			
push [Read again]	l.				
Del	Media	Pos. rate	Test data 🚺	Close 🚺	Menu

Samp	STA	T samp	STD	Q	0
14/08/06 14:05 14/08/06 11:38 14/08/06 10:11 14/08/06 10:11 14/07/24 16:05 14/07/24 14:34 14/07/24 10:09 14/07/16 12:37 14/07/08 13:32 14/07/04 10:30	14/07/02 14:51 14/07/02 13:12 14/07/02 01:56 14/06/27 14:02 14/06/23 15:36 14/06/23 15:36 14/06/10 17:44 14/06/06 13:14 14/06/06 13:14 14/06/03 16:14 14/06/03 16:14 14/06/03 16:14	14/06/02 13:00 14/05/30 13:40 14/05/28 09:56 14/05/28 15:19 14/05/28 14:14 14/05/28 14:14 14/05/28 14:14 14/05/27 18:10 14/05/27 15:15 14/05/27 15:13 14/05/27 15:13	14/05/26 15:33 14/05/21 10:07 14/05/21 19:15 14/05/20 09:24 14/05/19 18:55 14/05/19 14:26 14/05/16 13:05 14/05/16 11:00 14/05/15 14:56 14/05/15 14:56 14/05/15 14:50 14/05/15 14:50 14/05/13 10:05	14/05/09 09:45 14/05/08 14:23 14/05/08 11:56 14/05/08 10:34 14/04/23 18:21 14/04/23 10:16 14/04/22 16:23 14/04/22 14:54 14/04/22 13:38 14/04/22 11:10 14/04/21 10:55 14/04/21 10:55 14/04/21 10:59	
[F-Hb] Date	Select ce cursor on the Star Media	-sF	Read again	Close t	Menu

Touch the tab of the measured data to display.

{Samp} tab {STAT samp} tab {STD} {QC}

2 Specify the measured data by date and time or

#### range.

3

<Specifying by measurement date and time> Touch the {Date} button, and specify the measurement date.

Page 104 "3.1.3 Specifying measured data

by measurement date and time" 2

<Specifying by range>

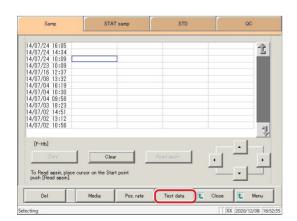
Touch the {Select-s} button, and specify the

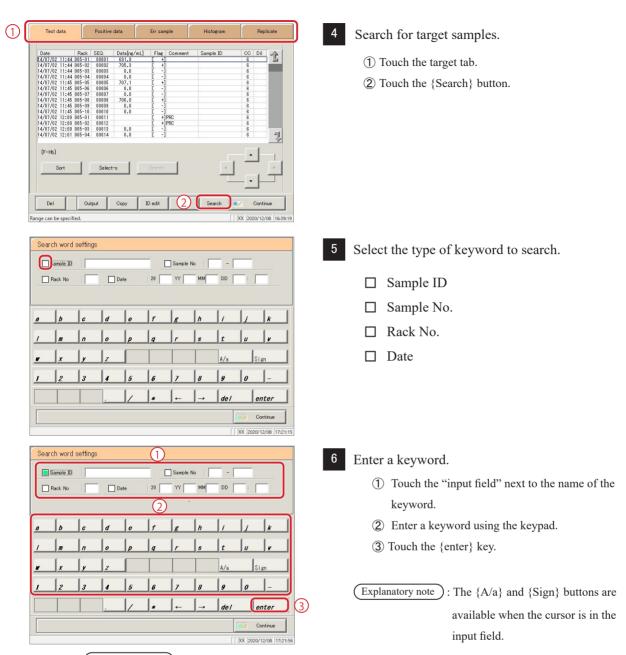
measurement date range.

Page 106 "3.1.4 Specifying measured data

by range" 2

Touch the {Test data} button.





(Explanatory note) : Entry of the group number and measurement date and time can be omitted. However, if a measurement date and time box is checked, it is necessary to input at least one of the

following: year, month, date, hour, and minute.

Sear	ch word	settings									
	Gample ID			#AB12	348	Sample	No	- [			
	Rack No			late	20	YY	мм	DD			
A	B	C	D	E	F	6	H	I	J	ĸ	
L	M	N	0	P	Q	R	s	I	U	V	1
#	x	r	Z					A/a	s	ign	1
1	2	3	4	5	6	7	8	9	0	-	1
			].	1	*	←	_	del	1	enter	1
										Continue	1
								[ [ XX		8/18 10:0	<b>9:31</b>

{A/a}: Switch input between uppercase and lowercase.{Sign}: Allows for input of symbols.

Search word settings

📘 Sample ID

Rack No

M

Start

You can input 15 digit

A B C

L #

1

Sea	Barch word settings           Samole ID           #AB12346           Samole No           Rack No           Date           20           YY           MM           DD           F           B           C           D           F           B									
	Sample ID			#AB1:	2846	Sample	No	-		
Rack No				Date	20	_ YY [	мм	DD	:	
	1	1	1	1	1	1	1	1	1	1
A	B	C	D	E	F	6	H	I	J	ĸ
L	M	N	0	P	Q	R	5	I	U	v
#	x	r	Z					A/a		Sign
,	2	3	4	5	6	7	8	9	0	-
			].	1	*	-	→	del	1	enter
								(	97	Continue
								[[]	( 2014/(	08/18 10:09

#AB12346

20 YY

Date

n

0 P Q

N

Cancel

Sample No -

Close

- -

J K

U V

Start

XX 2014/12/25 11:33:46

DD

Touch the {Continue} button.

9

Touch the {Start} button.

\* Start searching.

Positive data Test data Err sample Replicate Histogram Sample ID CC Dil 12 'mL] SEQ. 00015 00016 00017 00018 00004 00005 00008 00007 00008 00009 00009 00010 00011 00012 
 Date
 Rack

 14/02/04
 15:28
 002-03

 14/02/04
 15:32
 002-04

 14/02/04
 15:36
 002-05

 14/02/04
 15:38
 002-05

 14/02/04
 15:32
 010-01

 14/02/05
 15:20
 010-01
 Data[r 132.1 132.1 62. 65. 430.1 428.1 428.1 429.1 429.1 429.1 429.1 429.1 429.1 429.1 429.1 429.1 420.1 420.1 430.1 430.1 14/02/05 14/02/05 14/02/05 14/02/05 14/02/05 14/02/05 14/02/05 14/02/05 14/02/05 ų, [F-Hb] Selec Del Output Copy ID edit Recal Search Continue Range can be specified XX 2014/12/25 11:35:05

Search results are displayed.

{Search}: Allows search to continue.

3.1 Measured Data Processing

# MEMO

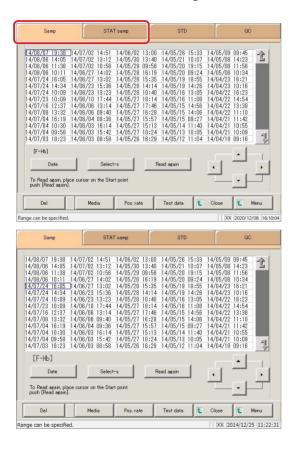
\_\_\_\_\_

\_\_\_\_\_

#### 3.1.9 Recalculating measured data

Recalculate measured data using modified cut-off values, as well as factors A and B.

- Explanatory note: The values used for judging measured data for which a range has been specified are shown in<br/>Cut off 1, Cut off 2, and Cut off 3.If the cut-off value differs according to the measured data, "0" will be displayed for Cut off 1,<br/>Cut off 2, and Cut off 3.
- Explanatory note: If the factor value differs according to the measured data, factor A and factor B are displayed as 1.00 and 0.00, respectively.
- (Explanatory note): Values configured in the [Recalculation condition settings] screen are not applied to protocol settings. Recalculation is a form of calculation for the purpose of correction using values configured in condition settings. It is not fitting calculation to a calibration curve.



STAT sam

Clea

Pos. rate

Test data

Close

STD

QC

t

Samp

/24 16:05 /24 14:34

[F-Hb]

To Read again, place push [Read again].

Del

1 Touch the tab of the measured data to recalculate.

{Samp} tab {STAT samp} tab

Specify the measured data by date and time or

#### range

2

3

<Specifying by measurement date and time>

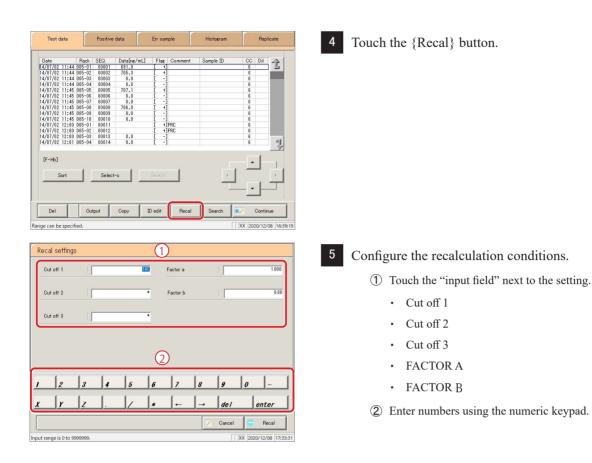
Touch the {Date} button, and specify the measurement date.

Page 104 "3.1.3 Specifying measured data by measurement date and time" 2

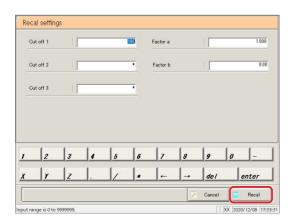
<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

- Page 106 "3.1.4 Specifying measured data by range" 2
- Touch the {Test data} button.

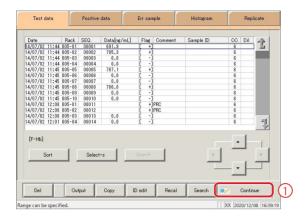


Setting	Input Range
Cut off 1	0-9,999,999
Cut off 2	0 to 9,999,999; * (input omitted)
Cut off 3	0 to 9,999,999; * (input omitted)
FACTOR A	0.001-99,999.999
FACTOR B	-999.99-999.99



6 Touch the {Recal} button.

{Cancel}: Cancel recalculation and return to the [Test data] screen



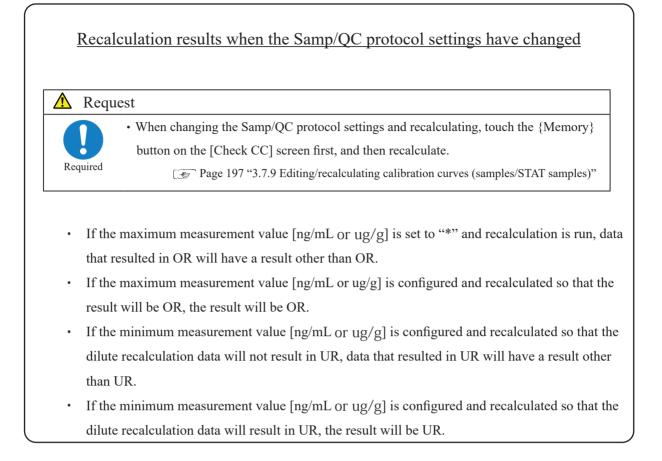
Test data Positive da		data	a Err sample			Replicate		
		050	D + 1 + 1 + 1			0.1.00		
Date 4/02/04 15:2	Rack	SEQ. 00015	Data[ng/mL] 132.6	Flag	Comment	Sample ID #AB12346	CC Dil	1
4/02/04 15:2 4/02/04 15:3		00015	132.0	[ 2+]		#AB12346	2	
4/02/04 15:3		00016	62.7	[ 1+]			2	-
4/02/04 15:3		00017	65.1	[ 1+]			2	
4/02/05 15:2		00004	430.5	[ 3+]			4	-
4/02/05 15:2		000004	428.9	[ 3+]			4	-
4/02/05 15:2		000006	428.2	[ 3+]			4	-
4/02/05 15:3		00007	421.0	[ 3+]			4	
4/02/05 15:4		00008	421.4	[ 3+]			4	
4/02/05 15:4		00009	429.8	[ 3+]			4	
4/02/05 16:0		00010	428.5	[ 3+]			4	
4/02/05 16:0	9 010-02	00011	430.8	[ 3+]			4	
4/02/05 16:1	1 010-03	00012	430.6	[ 3+]			4	Concernant of
4/02								1
[F·	er? Cancel			1	Close	5   <b>(</b> R	2) legister	

The recalculated measured data was displayed.

To update the recalculated data:

7

- (1) Touch the {Continue} button.
- 2 Touch the {Register} button in the dialog box.



### 3.1.10 Outputting measured data

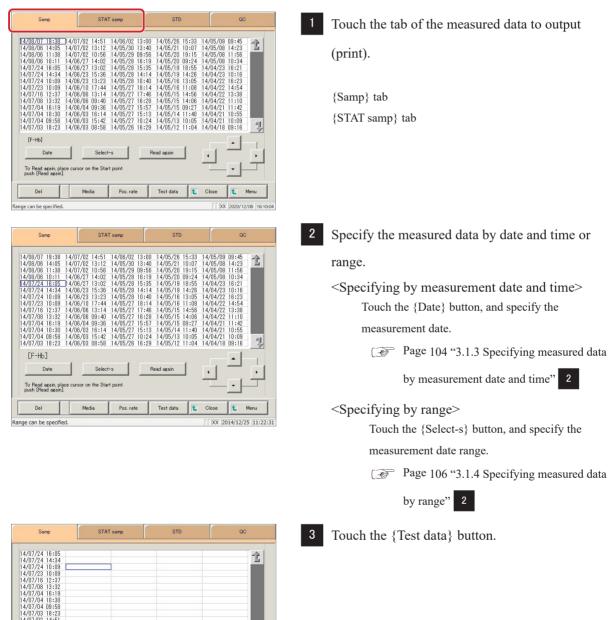
Specified measured data is output to the selected output destination.

- Printing measured data
- · Saving measured data to external media
- · Outputting measured data to a host computer online

(Explanatory note): When there is both 15-times dilution and 250-times dilution measured data, the final results

are judged.

If testing was stopped for either 15-times dilution or 250-times dilution, or if the measured data for either was deleted by the operator, the final results are not judged.

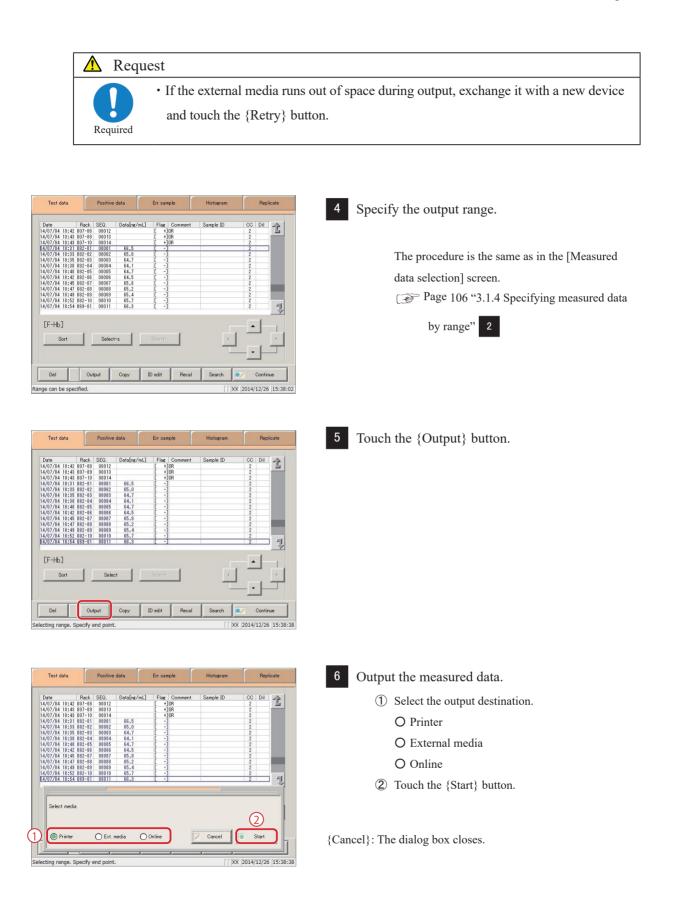


[F-Hb]

To Read again, place

Clea

Pos. rat



Explanatory note : If an error has occurred in communicating the measurement results, "Online" cannot be selected in the [Output destination selection] dialog box.

Test data		Positive	data	Err sam	ple	Histogram		Repl	licate
Date	Rack	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC	Dil	
14/07/04 10:42		00012			OR		2		15
14/07/04 10:43	007-09	00013		[ +]	OR		2		_
14/07/04 10:43	007-10	00014		[ +]	OR		2		1
14/07/04 18:31		00001	66.5	[ -]			2		
14/07/04 18:33	082-02	00002	65.0	[ -]			2		
14/07/04 18:35		00003	64.7	[ -]			2		
14/07/04 18:38		00004	64.1	[ -]			2		
14/07/04 18:40		00005	64.7	[ -]			2		
14/07/04 18:42		00006	64.5	[ -]			2		
14/07/04 18:45		00007	65.8	[ -1			2		_
14/07/04 18:47		00008	65.2				2		
14/07/04 18:49		00009	65.4	[ -]			2		
14/07/04 18:52		00010	65.7	[ -]			2		
14/07/04 18:54	069-01	00011	66.3	-			2	_	- 1 I
[F Outputine Left data		wait. [ 9]					Cancel		. 1

0

- \* The following information is output to the selected output destination.
- \* When output is complete the [Outputting] dialog closes.

# MEMO

\_\_\_\_

\_\_\_\_\_

#### 3.1.11 Deleting measured data

Delete measured data for the specified measurement date and time.

If a range is not specified, all displayed data (up to 5,000 samples' worth) will be deleted.

(Explanatory note): See page 98 "3.1.1 Opening the [Process data] screen" for in	nformation on displaying the
[Process data] screen.	
Samp STAT samp STD QC 1 Touch the tab of the r	measured data to display.
4008/07_18:38       4/07/02       14:55       4/06/02       13:00       14/05/26       15:33       14/05/08       14:26       14/07/02       13:12       14/05/26       15:33       14/05/26       15:33       14/05/26       15:33       14/05/26       15:33       14/05/26       15:33       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/26       15:36       14/05/27       16:36       14/05/27       16:36       14/05/27       16:36       14/05/27       16:36       14/04/22       16:32       14/05/27       16:38       14/05/27       16:38       14/04/22       16:32       14/05/27       16:38       14/04/22       16:32       14/05/27       16:38       14/04/22       16:38       14/04/22       16:38       14/06/27       16:38       14/06/21       16:36       14/06/21       16:36       14/06/21       16:36       14/06/27	

(Explanatory note): STD measured data cannot be deleted.

Samp	S	rAT samp	STD	STD		QC	
4/08/07 19:38	14/07/02 14:5	1 14/06/02 13	:00 14/05/26 15	.99 14	/05/09 09:	45 0	
	14/07/02 13:1				/05/08 14:		
	14/07/02 10:5				/05/08 11:		
	14/06/27 14:0				/05/08 10:		
	14/06/27 13:0				/04/23 16:		
	14/06/23 15:3				/04/23 10:		
	14/06/23 13:2				/04/22 16:		
	14/06/10 17:4				/04/22 14:		
	14/06/06 13:1				/04/22 13:	38	
	14/06/06 09:4				/04/22 11:		
	14/06/04 09:3		:57 14/05/15 09		/04/21 11:	42	
4/07/04 10:30	14/06/03 16:1	4 14/05/27 15	:13 14/05/14 11	:40 14,	/04/21 10:	55	
4/07/04 09:58	14/06/03 15:4	2 14/05/27 10	:24 14/05/13 10	:05 14,	/04/21 10:	09	
4/07/03 18:23	14/06/03 08:5	8 14/05/26 16	:29 14/05/12 11	:04 14,	/04/18 09:	16	
Date To Read again, pla push [Read again].		ect-s	Read again	[			
To Read again, play			Read again			Menu	
To Read again, pla push [Read again]. Del	ce cursor on the S	itart point		• •		Menu 12/26 [15:49:	
To Read again, pla push [Read again]. Del	Media	itart point		• • •			
To Read again, pla push (Read again). Del	Media	Pos. rate	Test data			12/26  15:49:	
To Read again, pla- push (Read again). Del e can be specifie Samp 4/04/23 16:21 4/04/23 10:15 4/04/22 16:23	Media	Pos. rate	Test data			2/26  15:49: QC	
To Read again, plap push (Pead again) pel [Pead again] e can be specifie Samp 4/04/23 16:21 4/04/23 16:23 4/04/22 16:23 4/04/22 13:38	Media	Pos. rate	Test data			2/26  15:49: QC	
To Read again, plap push [Read again] Del e can be specifie Samp 4/04/23 16:21 4/04/23 10:16 4/04/23 10:16 4/04/22 16:23 4/04/22 13:38	Media	Pos. rate	Test data			2/26  15:49: QC	
To Read again, plap push (Pead again) pel (Pead again) re can be specifie Samp 4/04/23 16:21 4/04/23 16:23 4/04/22 16:23 4/04/22 13:38 4/04/22 13:38	Media	Pos. rate	Test data			2/26  15:49: QC	
To Read again, play perfective again, play pe	Media	Pos. rate	Test data			2/26  15:49: QC	
To Read again, plap push (Read again) e can be specifie Samp 4/04/23 16:21 4/04/23 10:16 4/04/23 16:23 4/04/22 14:54 4/04/22 13:38 4/04/22 11:10	Media	Pos. rate	Test data			2/26  15:49: QC	

2 Specify the data to delete using a measurement date and time range (start point/end point).
(It is not necessary to specify the range when deleting all data.)



3 Touch the {Del} button.

[F-Hb]

cting

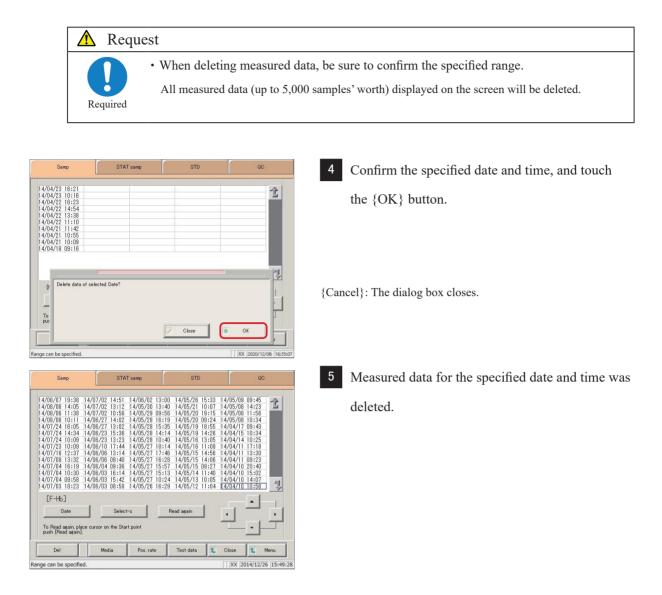
To Read again, place push [Read again]. on the Start point

Pos. rate

Test data

Close

Close **E** Menu



### 3.1.12 Copying measured data

Copy specified measured data to other measured data.

Copied information includes sample IDs, measured data, judgment results, and comments.

Explanatory note : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.

STAT sam Same 09:45 14:23 11:56 10:34 09:43 10:34 10:34 14/08/07 19:38 t 4:02 3:02 5:36 3:23 7:44 3:14 18:55 14:20 13:05 11:08 14:50 14:00 09:27 11:40 :40 :36 :14 10:05 4/07/04 09:58 4/07/03 18:23 : 42 : 58 비 [F-Hb] To Read again, pla push [Read again] Test data Media Pos. rate t Close Del nge can be specifie XX 20 20/12/08

Touch the tab of the measured data to display.

{Samp} tab {STAT samp} tab {QC} tab

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time> Touch the {Date} button, and specify the measurement date.

Page 104 "3.1.3 Specifying measured data

by measurement date and time" 2

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

Page 106 "3.1.4 Specifying measured

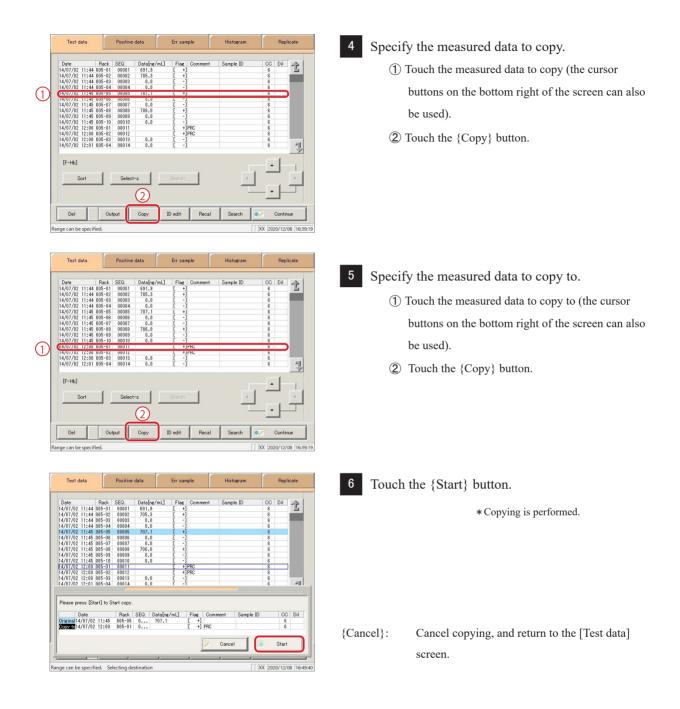
data by range" 2

Touch the {Test data} button.

3

Samp STAT sam STD QC 4/07/24 16:05 4/07/24 14:34 4/07/24 10:09 4/07/23 10:09 4/07/16 12:37 È [F-Hb] Clear r on the Start point To Read again, place cu sush [Read again]. Pos. rate Test data Del Media Close XX 2020/12/08

Explanatory note: When copying measured data to other data, individual data obtained through replicate testing will not be copied.



## 3.2 Editing Sample IDs

Edit sample IDs for data selected on the [Test data] screen.

 (Explanatory note) : If [Duplicated check] is set to "YES" in [Samp barcode settings] on the [System settings] · [Samp barcode settings] screen, a duplication check is run for sample IDs. However, a duplication check is not run when editing sample IDs for "retest data" or "dilute test data."

Samp	STA	T samp STD		QC	QC	
4/08/07 19:38 4/08/06 14:05 4/08/06 11:38	14/07/02 14:51 14/07/02 13:12 14/07/02 10:56	14/06/02 13:00 14/05/30 13:40 14/05/29 09:56	14/05/21 10:07	14/05/09 09:45 14/05/08 14:23 14/05/08 11:56	t	
4/08/06 10:11 4/07/24 16:05 4/07/24 14:34	14/06/27 14:02 14/06/27 13:02 14/06/23 15:36	14/05/28 16:19 14/05/28 15:35 14/05/28 14:14	14/05/20 09:24 14/05/19 18:55 14/05/19 14:26	14/05/08 10:34 14/04/17 09:43 14/04/15 10:34		
4/07/24 10:09 4/07/23 10:09 4/07/16 12:37 4/07/08 13:32	14/06/23 13:23 14/06/10 17:44 14/06/06 13:14 14/06/06 09:40	14/05/28 10:40 14/05/27 18:14 14/05/27 17:46 14/05/27 16:28	14/05/16 11:08 14/05/15 14:56	14/04/14 10:25 14/04/11 17:18 14/04/11 13:30 14/04/11 09:23		
4/07/04 16:19 4/07/04 10:30 4/07/04 09:58	14/06/04 09:36 14/06/03 16:14 14/06/03 15:42	14/05/27 15:57 14/05/27 15:13 14/05/27 10:24	14/05/15 09:27 14/05/14 11:40	14/04/10 20:40 14/04/10 15:02 14/04/10 14:07		
4/07/03 18:23 [F-Hb]	14/06/03 08:58	14/05/26 16:29	14/05/12 11:04	14/04/10 10:56	7	
Date	Select		Read again		Ŀ	
To Read again, pla push [Read again]	ace cursor on the Star	t point				
Del	Media	Pos. rate	Test data 🚺 🐛	Close 🚺	Menu	

Samp	STA	Tsamp	STD		QC		
4/08/07 19:38	14/07/02 14:51	14/06/02 13:0					
4/08/06 14:05	14/07/02 13:12	14/05/30 13:4					
4/08/06 11:38	14/07/02 10:56	14/05/29 09:5					
4/08/06 10:11	14/06/27 14:02	14/05/28 16:1					
4/07/24 16:05	14/06/27 13:02	14/05/28 15:3					
4/07/24 14:34	14/06/23 15:36	14/05/28 14:1					
4/07/24 10:09	14/06/23 13:23	14/05/28 10:4					
4/07/23 10:09	14/06/10 17:44	14/05/27 18:1					
4/07/16 12:37	14/06/06 13:14	14/05/27 17:4					
4/07/08 13:32	14/06/06 09:40	14/05/27 16:2					
4/07/04 16:19	14/06/04 09:36	14/05/27 15:5					
4/07/04 10:30	14/06/03 16:14	14/05/27 15:1:					
4/07/04 09:58	14/06/03 15:42	14/05/27 10:2			07		
4/07/03 18:23	14/06/03 08:58	14/05/26 16:2	3 14/05/12 11:04	4 14/04/10 10:	56 🤳		
[F-Hb]					1		
Date	Selec	t-s	Read again		" L		
To Read again, place cursor on the Start point push (Read again).							
Del	Media	Pos. rate	Test data	Close 1	Menu		

Touch the tab of the measured data to display.

{Samp} tab {STAT samp} tab

2 Specify the measured data by date and time or range.

<Specifying by measurement date and time>

Touch the {Date} button, and specify the measurement date.

Page 104 "3.1.3 Specifying measured data

by measurement date and time" 2

<Specifying by range>

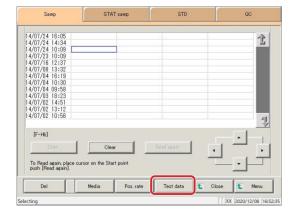
Touch the {Select-s} button, and specify the measurement date range.

leasurement date range.

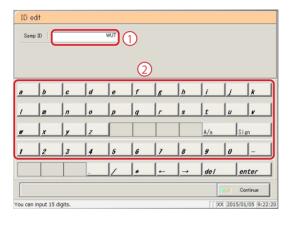
Page 106 "3.1.4 Specifying measured data

by range" 2

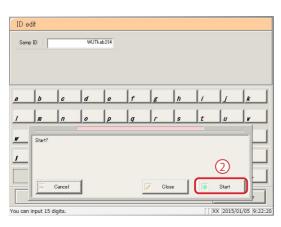
3 Touch the {Test data} button.



Test data		Positive	data	Err san	nple	Histogram	R	eplicate
Date	Back	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC Di	
4/07/02 11:44	005-01	00001	691.9	[ +]			6	- 15
4/07/02 11:44		00002	705.3	( +)		-	6	_
4/07/02 11:44		00003	0.0	1 1		(1	6	
4/07/02 11:44		00004	0.0	í -1		U U	6	
4/11//112 11:45	005-05	00005	707.0	1 +1		1	К	
4/07/02 11:45	005-06	00006	0.0	[ -]			6	
4/07/02 11:45	005-07	00007	0.0	[ -]			6	
4/07/02 11:45	005-08	00008	706.0	[ +]			6	
4/07/02 11:45	005-09	00009	0.0	[ -]			6	
4/07/02 11:45		00010	0.0	[ -]			6	
4/07/02 12:00	005-01	00011		[ +]	PRC		6	
4/07/02 12:00	005-02	00012		[ +]	PRC		6	
4/07/02 12:00		00013	0.0	[ -]			6	
4/07/02 12:01	005-04	00014	0.0	[ -]			6	-1
(F-Hb) Sort		Select	-s	Search				- -
Del	Our	tput	Сору	ID edit	Recal	Search	●∕ Cor	tinue



ID e	dit									
Sam	p ID		WUT	kab234						
a	b	c	d	0	f	ß	h	i	i	k
1		n	0	p	q	r	5	t	u	
*	x	y	z					A/a	5	ign
1	2	3	4	5	6	7	8	g	0	
				1/	*	-	→	del		enter
You can	input 15 (	digits.						[[ <b>X</b>	X 2015/	01/05 9:22:2



4

#### Select the sample ID.

- ① Touch the sample ID to edit (sample IDs can also be selected by using the {Cursor} buttons to move the cursor).
- (2) Touch the {ID edit} button.



#### 5 Input the sample ID.

- ① Touch the "input field" of the sample ID.
- (2) Enter the sample ID using the keypad.
- A/a: Switch input between uppercase and lowercase.
- {Sign}: Allows for input of symbols.

#### 6 Update the sample ID.

- ① Touch the {Continue} button.
- (2) Touch the {OK} button in the dialog box. \* The edited sample ID is stored.

- {Cancel}: Cancel editing the sample ID, and return to the [Test data] screen.
- The dialog box closes. {Cancel}:

NN1-1703 Rev.3

### 3.3 List of Positive Samples

Display the samples that were measured in test mode or remeasure mode and received "positive judgment" in a list.

Positive samples displayed in the list can be sorted, searched, recalculated, output, cut-off back calculated, and deleted.

Explanatory note : • Error samples do not have judgment results, and thus are not displayed on the list.

 $\cdot$  OR, RBC, and PRC samples are positive samples.

• Samples that were measured in test mode or remeasure mode are displayed on the list.

#### 3.3.1 Displaying the positive sample list

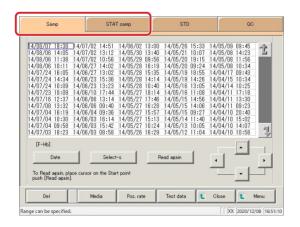
Two display modes are available for the positive sample list: sample mode and testee mode. The positive rate is shown in either mode. Calculation is performed as follows.

Sample mode:	Positive rate (%) = Number of positive samples $\div$ Number of all samples $\times$ 100
	("Number of all samples" is the number of samples within the range specified on
	the [Test data] screen.)
Testee Mode:	Positive rate (%) = Number of positive testees $\div$ Number of all testees $\times$ 100
	("Number of all testees" is the number of testees within the range specified on the
	[Test data] screen.

(Explanatory note): • Only positive measured data is displayed in sample mode.

- For testee mode, if even a single sample is positive in the 2 day or 3 day measured data, all measured data for that patient is displayed.
- For testee mode, positive samples are displayed reversed.

Explanatory note : All data will be displayed if no range is specified.



Touch the tab of the measured data to display.

{Samp} tab {STAT samp} tab

2 Specify the measured data by date and time or

#### range.

<Specifying by measurement date and time> Touch the {Date} button, and specify the measurement date.

Page 104 "3.1.3 Specifying measured data

by measurement date" 2

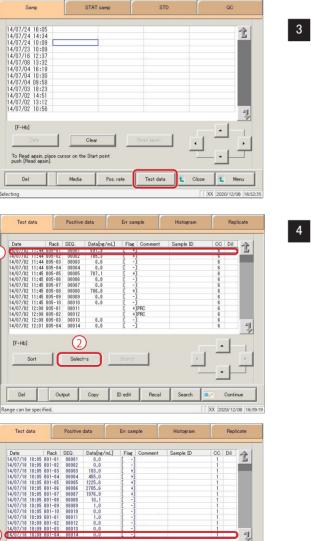
<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

Page 106 "3.1.4 Specifying measured data



Touch the {Test data} button.



Specify the measured data by range of

measurement date and time.

① Touch the measurement date and time at the start point (the cursor buttons at the bottom right of the screen can also be used to select this).

2 Touch the {Select-s} button.

\* The text in the row of the specified date and time turns blue. (Start point)

\* The {Select-s} button changes to the {Select} button.

- ③ Touch the measurement date and time at the end point (the cursor buttons at the bottom right of the screen can also be used to select this).
- ④ Touch the {Select} button.
   \* The text in the row of the specified range turns blue. (End point)

{Sort}:Sort the displayed measured data.{Select-s}:Confirm start point data for the specified range.{Select}:Confirm end point data for the specified range.{Clear}:Clear the specified range.

Page 110 "3.1.7 Sorting measured data" 4

(3

(F-Hb)

De

(4)

Output

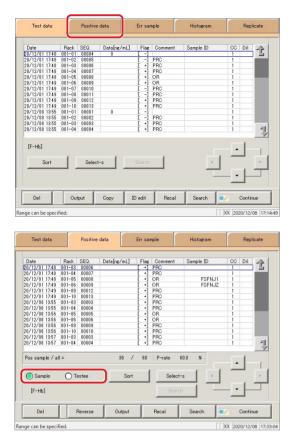
Сору

ID edit

Recal Search

XX

#### 3.3 List of Positive Samples



Touch the {Positive data} tab.

5

\* The specified list of positive samples is displayed.

6 Positive samples are displayed by sample or by testee.

<When selecting sample mode> Touch the {Sample} button.

<When selecting testee mode> Touch the {Testee} button.

When the positive sample has been updated through recalculation, deletion, etc.:

① Touch the {Continue} button.

(2) Touch the {Register} button in the dialog box.

\* Updated positive sample data is registered.

{Del}:	Delete specified positive sample data.
	Page 148 "3.3.8 Deleting positive sample data"
{Reverse}:	Calculate the cut-off value using the input positive rate.
	Page 142 "3.3.6 Calculating cut-off values from positive rates"
{Output}:	Output specified positive sample data.
	Page 146 "3.3.7 Outputting positive sample data"
{Recal}:	Recalculate measured data using modified cut-off values, as well as factors A and B.
	Page 140 "3.3.5 Recalculating positive sample data"
{Search}:	Search positive samples based on sample ID, sample number, rack number, and
	measurement date and time.
	Page 138"3.3.4 Searching positive sample data"

Display	Details		Remark
Date	Date and tin	me sample was measured	
RACK	Rack No	Position number in rack.	
SEQ.	Group No.	- Sequence No.	
Data [ng/mL] or [ug/g]	Measureme (concentrat		
Flag	+, 1 +, 2	+, 3 +	
	Error inform errors)	nation (excluding reading	
Comment	UR	: Under range	Blank output for measured data and judgment result
	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode int	formation on sampling bottles	
СС		curve used to calculate ata (CC No.)	
	Dilution in	formation	
	Space	: No dilution (test mode, remeasure mode)	
Dil	А	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

Content displayed on the [Positive data] screen

Explanatory note : During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is displayed in blue text.

### 3.3.2 Sorting positive sample data

Positive samples specified on the [Test data] screen can be sorted by measurement date and time, and by group. When sorting by measurement date and time, positive samples are displayed in ascending order by "date."

When sorting by group, positive samples are displayed in ascending order by "sample number group."

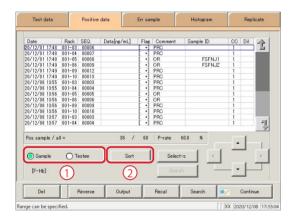
This section describes the procedure from the [Positive data] screen.

- Page 130 "3.3.1 Displaying the positive sample list" 1 through 5
- Explanatory note: If a range is not specified, all positive samples displayed on the [Positive data] screen will be sorted.

Explanatory note: The range of positive samples can also be specified using the {Select-s} button on the [Positive data] screen.

1

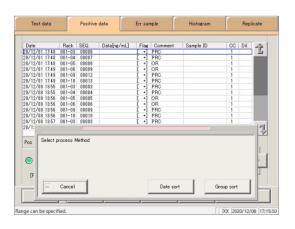
The method is the same as on page 136 "3.3.3 Specifying positive sample data by range."



Select the display mode for positive samples to

sort (by sample/testee).

- 1 Touch the {Sample} or {Testee} buttons.
- (2) Touch the  $\{Sort\}$  button.



2 Touch the {Date sort} button or the {Group sort} button.

\* The sorted measured data is displayed.

- {Date sort}: Sort measured data in ascending order by measurement date and time.
- {Group Sort}: Sort measured data in ascending order by sample number group.

{Cancel}: Cancel sorting. The dialog box closes.

Test data		Positive data		Err sa	mple	Histogram	Rep	licate
Date	Rack	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC Dil	
20/12/01 17:48	001-03	00006		[+]	PRC		1	T
20/12/01 17:48	001-04	00007		[+]	PRC		1	-
20/12/01 17:48	001-05	00008		[ +]	OR	FSFNJ1	1	
20/12/01 17:49	001-06	00009		[+]	OR	FSFNJZ	1	
20/12/01 17:49	001-09	00012		[ +]	PRC		1	
20/12/01 17:49	001-10	00013		[+]	PRC		1	
20/12/08 13:55	001-03	00003		[+]	PRC		1	
20/12/08 13:55	001-04	00004		[ +]	PRC		1	
20/12/08 13:56	001-05	00005		[+]	OR		1	
20/12/08 13:56	001-06	00006		[ +]	OR		1	
20/12/08 13:56	001-09	00009		[ +]	PRC		1	
20/12/08 13:56	001-10	00010		[ +]	PRC		1	
20/12/08 13:57	001-03	00003		[ +]	PRC		1	
20/12/08 18:57	001-04	00004		[+]	PRC		1	- 1
Pos sample / ai Sample [F-Hb]		estee	36 / Sort	60	P-rate 6 Select- Scarch			- -
Del		Reverse	Output		Recal	Search	🖊 Conti	nue
	fied.						XX 2020/12	

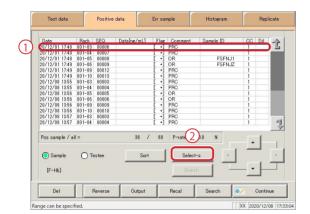
**3** Positive sample data was sorted.

### 3.3.3 Specifying positive sample data by range

Touch the measurement date and time on the [Positive data] screen or operate the cursor buttons to specify positive sample data by range of measurement date and time (start point/end point). Specify the date and time at the start point and touch the {Select-s} button to confirm the positive sample data at the start point. Next, specify the date and time at the end point and touch the {Select} button to confirm the positive sample data at the end point. After the start and end points are confirmed, the positive sample data between the start and end points is specified.

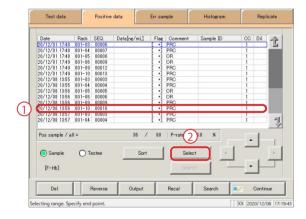
This section describes the procedure from the [Positive data] screen.

Page 130 "3.3.1 Displaying the positive sample list" 1 through 5



Specify the measured data at the start point.

- 1 Touch the date and time that will be the start point.
- (2) Touch the {Select-s} button.
  - \* The measured data at the start point was confirmed.
  - \* When the start point is confirmed, the {Select-s} button changes to the {Select} button.



2

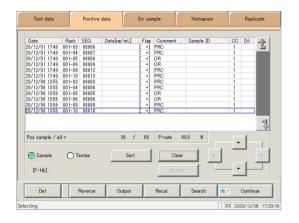
#### Specify the measured data at the end point.

- 1 Touch the date and time that will be the end point.
- Touch the {Select} button.
  - \* The measured data at the end point was confirmed.
  - \* When the end point is confirmed, the {Select} button changes to the {Clear} button.
- {Select-s}: Confirm the measured data at the start point.{Select}: Confirm the measured data at the end point.{Clear}: Clear the specified range.

Explanatory note: If the measured data specified for the start and end points is the same, the system will handle it as though only a single sample of measured data was specified.

(Explanatory note): To specify a new range of measured data, touch the {Clear} button. All measured data is displayed, and the system returns to the state it was in before the range was specified.

3



Positive sample data was specified.

\* The specified measured data is displayed.

(Explanatory note): The display mode for positive samples can be switched with the {Sample} or {Testee} buttons.

#### 3.3.4 Searching positive sample data

Search positive samples based on sample ID, sample number, rack number, and measurement date and time.

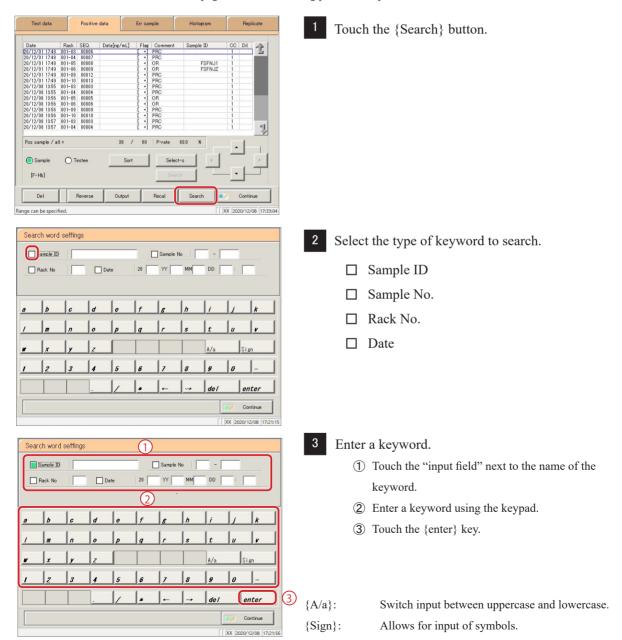
This section describes the procedure from the [Positive data] screen.

Page 130 "3.3.1 Displaying the positive sample list" 1 through 5

(Explanatory note) : If a range is not specified, all positive samples displayed on the [Positive data] screen will be searched. Measured data cannot be searched for using the rack position number.

Explanatory note: The range of positive sample data can also be specified using the {Select-s} button on the [Positive data] screen. The method is the same as on page 136 "3.3.3 Specifying positive sample data by range."

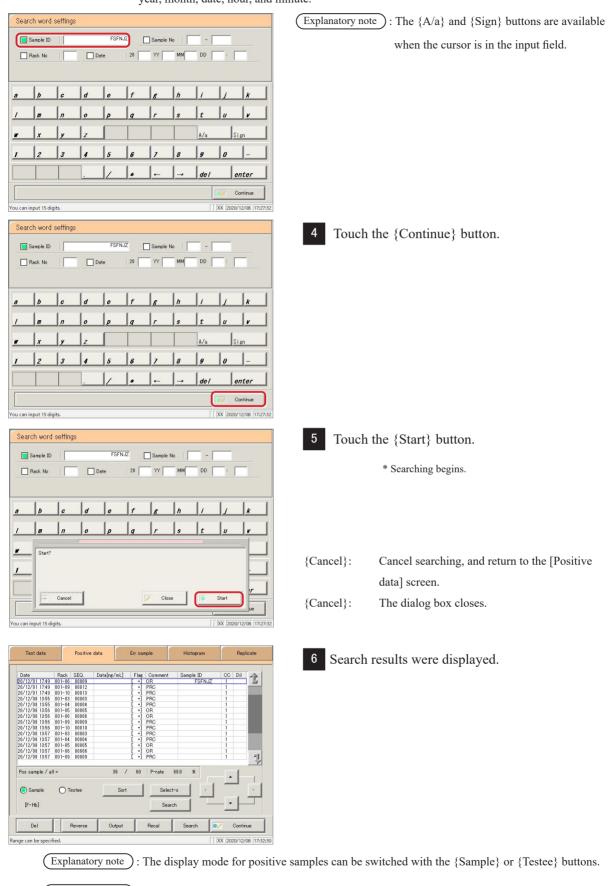
(Explanatory note): Sort positive sample data using the {Sort} button on the [Positive data] screen. The method is the same as on page 134 "3.3.2 Sorting positive sample data."



#### 3.3 List of Positive Samples

(Explanatory note): Entry of the group number and measurement date and time can be omitted. However, if a

measurement date and time box is checked, it is necessary to input at least one of the following: year, month, date, hour, and minute.



Explanatory note: The search range is the range specified on the [Test data] screen.

#### Recalculating positive sample data 3.3.5

Recalculate measured data using modified cut-off values, as well as factors A and B.

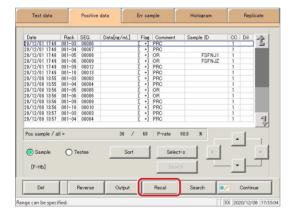
This section describes the procedure from the [Positive data] screen.

Page 130 "3.3.1 Displaying the positive sample list" 1 through 5

- (Explanatory note): The values used for judging measured data for which a range has been specified are shown in Cut off 1, Cut off 2, and Cut off 3.
  - · If the cut-off value differs according to the measured data, "0" will be displayed for Cut off 1, Cut off 2. and Cut off 3.
  - · If the factor value differs according to the measured data, factor A and factor B are displayed as 1.00 and 0.00, respectively.
- (Explanatory note) : Values configured in the [Recalculation condition settings] screen are not applied to protocol settings. Recalculation is a form of calculation for the purpose of correction using values configured in condition settings. It is not fitting calculation to a calibration curve
- Explanatory note : Recalculation applies not only to data displayed on the [Positive data] screen, but to all data specified on the [Test data] screen.
- Explanatory note : The range of positive samples can also be specified using the {Select-s} button on the [Positive data] screen.

2

The method is the same as on page 136 "3.3.3 Specifying positive sample data by range."

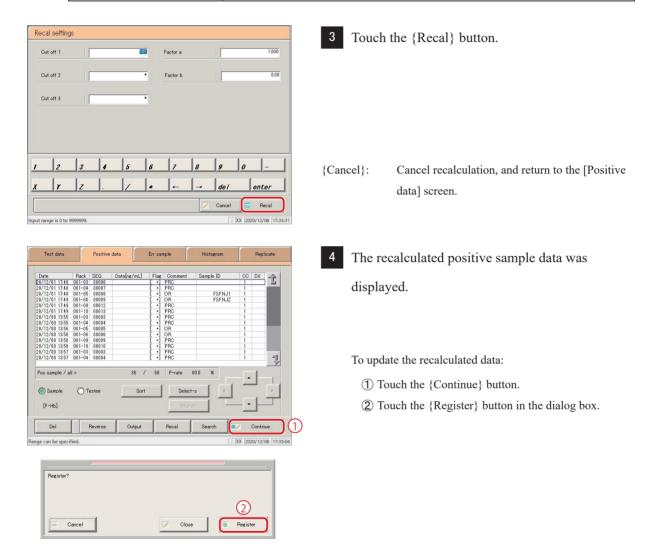


Recal settings Cut off Cut off Factor I (2)enter de l Cancel ut range is 0 to

Touch the {Recal} button.

- Configure the recalculation conditions.
  - 1) Touch the "input field" next to the setting.
  - Enter numbers using the numeric keypad. 2
  - Touch the {enter} key. 3
    - Cut off 1
    - Cut off 2
    - Cut off 3
    - FACTORA
    - FACTOR B

Setting	Input Range
Cut off 1	0 to 9,999,999
Cut off 2	0 to 9,999,999; * (input omitted)
Cut off 3	0 to 9,999,999; * (input omitted)
FACTOR A	0.001 to 99,999.999
FACTOR B	-999.99 to 999.99



(Explanatory note): The display mode for positive samples can be switched with the {Sample} or {Testee} buttons.

\Lambda Requ	lest
	• When changing the Samp/QC protocol settings and recalculating, touch the
Required	{Memory} button on the [Check CC] screen first, and then recalculate.
	Page 197 "3.7.9 Editing/recalculating calibration curves (samples/STAT samples)"

### 3.3.6 Calculating cut-off values from positive rates

The cut-off value is back calculated using the measured data of the displayed positive sample and the input positive rate. Cut-off values are calculated differently in sample mode and testee mode.

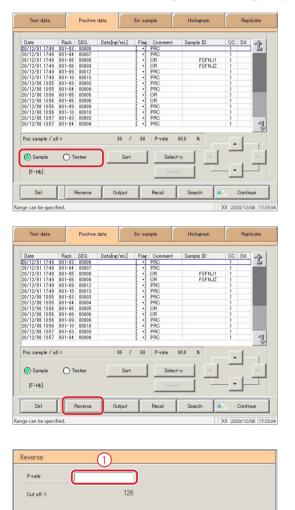
This section describes the procedure from the [Positive data] screen.

Page 130 "3.3.1 Displaying the positive sample list" 1 through 5

Explanatory note : • If no range is specified, cut-off values are calculated with "all measured data" and with "input positive rate."

2

• The range of positive samples is specified using the {Select-s} button on the [Positive data] screen. Page 136 "3.3.3 Specifying positive sample data by range"



6

After input positive rate, touch [Enter] to Start Reverse calucial

Continue

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1 Select the display mode for positive samples (by sample/testee).

Touch the {Sample} or {Testee} buttons.

Touch the {Reverse} button.

- 3 Enter the positive rate.
  - ① Touch the input field for the positive rate.
  - ② Enter the positive rate using the numeric keypad. Input range: 0.0 to 100.0
  - ③ Touch the {enter} key.

\* Calculate the cut-off value.

P-rate         NO.0           Cut off 1:         126	4 The calculated cut-off value is displayed in the Cut off 1 field. Cut-off value range: 0 to 9,999,999
I       Z       3       4       5       6       7       8       9       0       -         X       Y       Z       .       /       .	5 Touch the {Continue} button.
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	6 Touch the {Memory} button. * Applied to Cut off 1 on the [Recal settings] screen.
Register?         Cancel         Cancel         Close         Memory         After input positive rate, touch [Enter] to Start Reverse calucitation.	{Memory}:Save calculation results to memory.{Close}:Cancel calculation, and return to the [Process data] screen.{Cancel}:The dialog box closes.
Test data         Positive data         Err sample         Histogram         Replicate           Date         Resk         SEO         Date         Replicate         Replicate           Date         Resk         SEO         Date         Replicate         Replicate           Date         Resk         SEO         Date         Replicate         Replicate           Date         Resk         SEO         Date         Resk         SEO         Date           Date         Resk         SEO         Date         Resk         SEO         Date           Date         Resk         SEO         Date         Resk         Seo         Date           Date         Resk         SEO         Date         Resk         Sample         D         D           Date         Resk         Seo         Date         Resk         Sample         D         D           Date         Resk         Date         Sec         D         D         D         D           Date         Resk         Sec         D         D         D         D         D         D         D         D         D         D         D         D         D         <	7 Touch {Continue}.

#### 3.3 List of Positive Samples

	Rack	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC Dil	
20/12/09 08:59	001-03	00006	355	[+]			1	11
20/12/09 08:59	001-09	00012	220	[ +]			1	
20/12/09 09:00	001-03	00016	355	[+]			1	
20/12/09 09:00	001-04	00017	793	[ +]			1	
20/12/09 09:00	001-05	00018		[+]	OR		1	
20/12/09 09:00	001-06	00019		[ +]	OR		1	
20/12/09 09:00	001-09	00022	220	[ +]			1	
20/12/09 09:00	001-10	00023	505	[+]			1	
20/12/09 09:05	001-03	00026	355	[+]			1	
20/12/09 09:05	001-04	00027	793	[+]			1	
20/12/09 09:05	001-05	00028		[+]	OR		1	
20/12/09 09:05	001-06	00029		[+]	OR		1	-
20/12/09 09:05 20/1:	001-09	00032	220	[+]			1	1.001
2071.								1
Pos Registe	?							
-								
•								
-								
(F)							_	

8 Touch {Register}.

{Register}:	Register the cut-off value.
{Close}:	Cancel registration, and return to the [Reverse]
	screen.
{Cancel}:	The dialog box closes.

 Explanatory note
 : Pressing the {Continue} button will apply the calculated cut-off value to cut-off value 1 on the [Recal settings] screen. Image: Page 140 "3.3.5 Recalculating positive sample data"

 When changes have been applied to cut-off value 1 on the [Recal settings] screen, cut-off values 2 and 3 change to "\*." Use cut-off values 1, 2, and 3 to calculate when recalculating.

(Explanatory note) : If the measured data for the Nth positive sample is PRC or OR, the cut-off value is not calculated.

#### Calculation methods for cut-off values according to display mode

Two display modes are available: sample mode and testee mode. Cut-off value calculation for each mode is as follows.

Sample mode: N = Input positive rate  $\div$  Number of all samples  $\times$  100 (fractional portions rounded down to nearest integer) (N = the number of samples that should be positive)

#### (Explanatory note):

- 1. Decimal points are rounded down for the number of samples.
- 2. For cut-off values, the measured data of the Nth sample becomes an integer shown when less than the number. (Integer between 0 and 9,999,999)

Example 1: Nth sample measured data:  $100.1 \rightarrow 100$ .

Example 2: Nth sample measured data:  $100 \rightarrow 99$ .

3. When N = 0 in the examples in 2 above, the cut-off value is an integer that exceeds the first measured data.

Example: First sample measured data:  $100.1 \rightarrow 101$ .

4. When there are multiple measured data identical to the Nth sample, they may not follow the specifications listed in 2 and 3 above.

Example: There are 29 samples with measured data of 200 and 71 samples with measured data of 100, for a total of 100 samples. Calculating the cut-off value at a positive rate of 30% results in a cut-off value of 99.

However, if recalculated with a cut-off value of 99, the positive rate will be 100%.

Testee mode: N = Positive rate  $\div$  Number of all testees  $\times$  100 (N = number of testees that should be positive)

(Explanatory note):

1. Decimal points are rounded down for the number of testees.

2. For cut-off values, the measured data of the Nth testee becomes an integer shown when less than the number (an integer between 0 and 9,999,999).

Example 1: Nth testee measured data:  $100.1 \rightarrow 100$ .

Example 2: Nth testee measured data:  $100 \rightarrow 99$ .

#### 3.3.7 Outputting positive sample data

Output positive sample data specified on the "list of positive samples" to the selected output destination.

- · Printing positive sample data
- · Saving positive sample data to external media
- · Outputting positive sample data to a host computer online

This section describes the procedure from the [Positive data] screen.

Page 130 "3.3.1 Displaying the positive sample list" 1 through 5

- Explanatory note : If an error has occurred in communicating the measurement results, "Online" cannot be selected in the [Output destination selection] dialog box.
- (Explanatory note): When there is both 15-times dilution and 250-times dilution measured data, a qualitative assessment is performed.

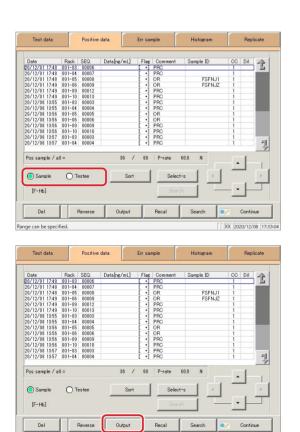
If testing was stopped for either 15-times dilution or 250-times dilution, or if the measured data for either was deleted by the operator, a qualitative assessment is not performed.

(Explanatory note): When outputting time code course data, set "Time course to Ext. media" to YES in [Settings] - [System settings] - [Output settings].

1

2

XX 2020/12/08 17:3



Select the display mode for positive samples (by sample/testee).

Touch the {Sample} or {Testee} buttons.

Touch the {Output} button.

nge can be specified

Test data	Positive data	Err sample	Histogram	Replicate	3 Outpu	t the positive sample data.
Date F 20/12/01 17:48 00 20/12/01 17:48 00	lack SEQ. Data[ng 1-03 00006 1-04 00007	+ PBC	Sample ID		1	Select the output destination.
20/12/01 17:48 00 20/12/01 17:49 00 20/12/01 17:49 00	1-05 00008 1-06 00009 1-09 00012	[ +] OR [ +] OR [ +] PRC	FSFNJ1 FSFNJZ	1 1 1		O Printer
20/12/08 13:55 00	1-10 00013 1-03 00003 1-04 00004 1-05 00005	[ +] PRC [ +] PRC [ +] PRC [ +] PRC [ +] OR				O Ext. media (External media)
20/12/08 13:56 00 20/12/08 13:56 00 20/12/08 13:56 00 20/12/08 13:56 00	1-06 00006 1-09 00009 1-10 00010	[ +] OR [ +] PRC [ +] PRC				O Online
20/12/08 13:57 00 20/12/08 13:57 00		[ *] PRC [ *] PRC		1	2	Touch the {Start} button.
20/12/01 17:48 00	Positive data	[ +] PRC [ +] PRC	Cancel Histogram	2 51art XX [2020/12/06 [17:33:04] Replicate		<ul> <li>* Specified positive sample data is output to the selected output destination.</li> <li>* When output has completed, the system returns to the [Positive data] screen.</li> </ul>
20/12/01 17:48 00 20/12/01 17:49 00 20/12/01 17:49 00 20/12/01 17:49 00 20/12/01 17:49 00 20/12/08 18:55 00 20/12/08 18:56 00 20/12/08 18:56 00 20/12/08 18:56 00	1-05         00008           1-06         00009           1-09         00012           1-10         00013           1-03         00003           1-04         00004           1-05         00006           1-06         00006           1-08         00006           1-09         00006           1-08         00000           1-10         00010           1-03         00003	(+) OR (+) OR (+) PRC (+) PRC	FSFNJ1 FSFNJZ			
Outputing. Plea	ise wait. [6]			Cancel	{Cancel}:	Cancel output, and return to the [Positive data] screen.

 Explanatory note
 : When "Ext. media" has been selected for the output destination and no external media is connected, "Not connected with external media." is displayed. Connect the external media and touch the {Retry} button.

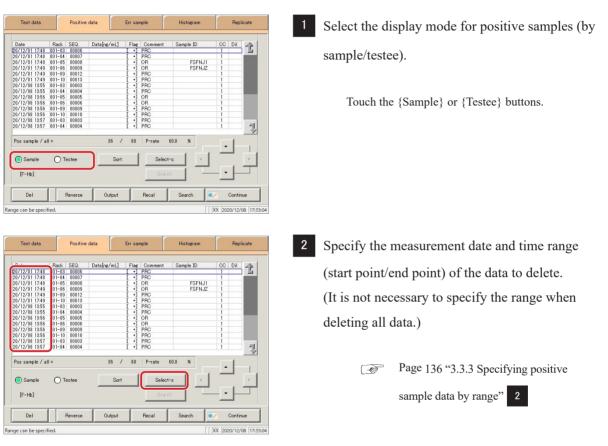
 Explanatory note
 : If the external media runs out of space during output, "There is not enough space on the external media. Replace it with new media." is displayed. Replace with new media and touch the {Retry} button. Resume data output.

### 3.3.8 Deleting positive sample data

Delete positive sample data for the selected measurement date and time.

This section describes the procedure from the [Positive data] screen.

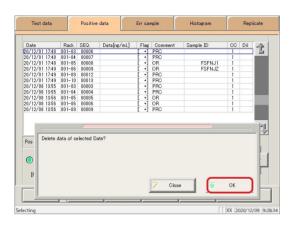
Page 130 "3.3.1 Displaying the positive sample list" 1 through 5

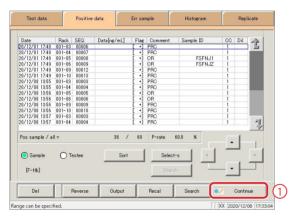


(Explanatory note): If a range is not specified, all positive samples displayed on the [Positive data] screen will be deleted.

Test data		Positive	data	Err sa	mple	Histogram		Repl	icate
Date	Rack	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC	Dil	
20/12/01 17:48	001-03	00006		+	PRC		1		T
20/12/01 17:48	001-04	00007		[+]	PRC		1		-
20/12/01 17:48	001-05	00008		[ +]	OR	FSFNJ1	1		
20/12/01 17:49	001-06	00009		[ +1	OR	FSFNJZ	1		
20/12/01 17:49	001-09	00012		[+]	PRC		1		
20/12/01 17:49	001-10	00013		[ +]	PRC		1		
20/12/08 13:55	001-03	00003		[ +]	PRC		1		
20/12/08 18:55	001-04	00004		( +)	PRC		1		
20/12/08 13:56	001-05	00005		[+]	OR		1		
20/12/08 13:56	001-06	00006		[+]	OR		1		
20/12/08 18:56	001-09	00009		[+]	PRC		1		
20/12/08 18:56 Pos sample / a () Sample (F-Hb)	=	coocos	38 / Sort						
Pos sample / a	"= O™				P-rate			Contin	

Touch the {Del} button.





aok SEQ. Data[n	g/mL] Flag Commen	t Sample ID	CC Dil
1			
ncel	Ck	ise	Register 2
	ncel	ncel 📝 Ck	ncel 📝 Close 🦉 💽

4 Confirm the specified date and time, and touch the {OK} button.

- {OK}: Delete data for the specified date and time.
- {Close}: The dialog box closes.
- 5 Positive sample data for the specified date and time was deleted.

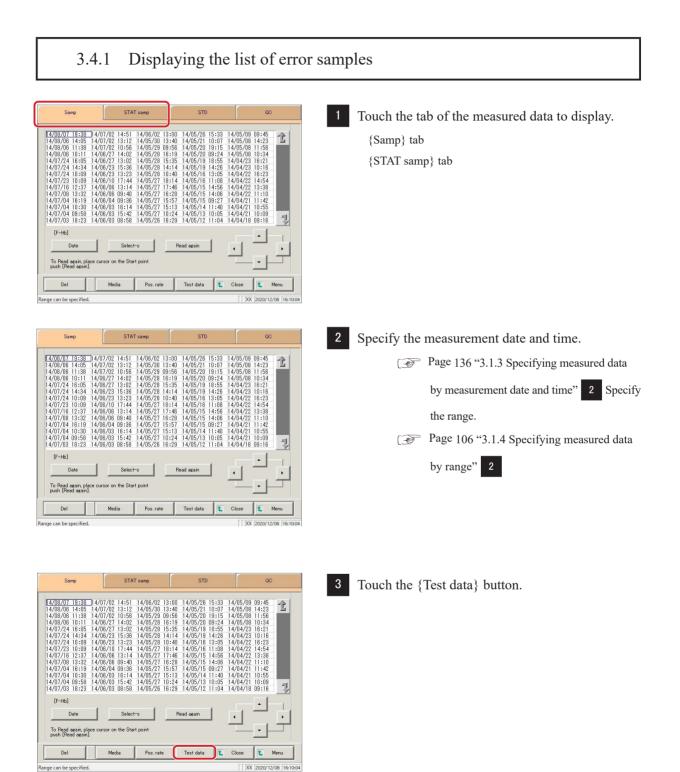
To update positive sample data:

- (1) Touch the  $\{Continue\}$  button.
- (2) Touch the {Register} button in the dialog box.

## 3.4 List of Error Samples

Display a list of error samples.

Error samples displayed in the list can be sorted, searched, output, and deleted.



Date	Back	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	00	Dil	$\sim$
20/12/09 08:59	001-01	00004	0	[ -1			1		T I
20/12/09 08:59	001-02	00005	89	Î -1			1		_
20/12/09 08:59	001-04	00007		î î	Latex blank err		1		
20/12/09 08:59	001-05	00008		ÎÎ	Latex blank err		1		
20/12/09 08:59	001-06	00009		11	Latex blank err		1		
20/12/09 08:59	001-07	00010		î î	Latex blank err		1		
20/12/09 08:59	001-08	00011	90	Î-Î			1		
20/12/09 08:59	001-10	00013		[]	Latex blank err		1		
20/12/09 09:00	001-01	00014	0	[-]			1		
20/12/09 09:00	001-02	00015	89	[-]			1		
20/12/09 09:00	001-07	00020	5	[-]			1		
20/12/09 09:00	001-08	00021	90	[ -]			1		
20/12/09 09:05	001-01	00024	0	[-]			1		
20/12/09 09:05	001-02	00025	89	[-]			1		킛
[F-Hb]		Selec		Search		-			 ,   ]
Del	Out	haut 1	Copy I	Dedit	Recal	Search	~	Continue	

4 7

Touch the {Err sample} button.

\* The list of error samples is displayed.

Content displayed on the [Err sample] screen

Display	Details		Remark
Date	Date and tin	ne sample was measured	
RACK	Rack No I	Position number in rack	
SEQ.	Group No	Sequence No.	
Data [ng/mL] or [ug/g]	Measureme	nt results	
Flag	-, +, 1 +, 2 +	-, 3 +	
	Error inform	nation (excluding reading errors)	
	UR	: Under range	Blank output for measured data and judgment result
Comment	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode inf	ormation on sampling bottles	
CC	Calibration data (CC No	curve used to calculate measured (b.)	
	Dilution inf	ormation	
	Space	: No dilution (test mode, remeasure mode)	
Dil	А	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

Explanatory note : During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is

displayed in blue text.

#### 3.4 List of Error Samples

#### 3.4.2 Sorting error sample data

Error samples specified from measured data can be sorted by measurement date and time, and by group.

When sorting by measurement date and time, error samples are displayed in ascending order by "date."

When sorting by group, error samples are displayed in ascending order by "sample number group."

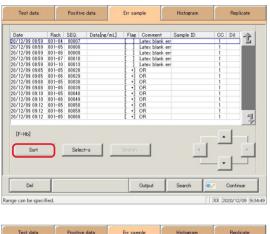
This section describes the procedure from the [Err sample] screen.

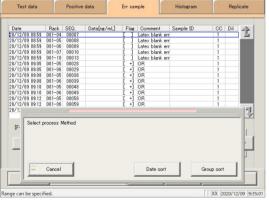
Page 150 "3.4.1 Displaying the list of error samples" 1 through 4

Explanatory note): If a range is not specified, all error samples displayed on the [Err sample] screen will be sorted.

(Explanatory note): The range of error samples can also be specified using the {Select-s} button on the [Err sample] screen.

The method is the same as on page 154 "3.4.3 Specifying error sample data by range."





Touch the {Sort} button.

2 Touch the {Date sort} button or the {Group sort}

button.

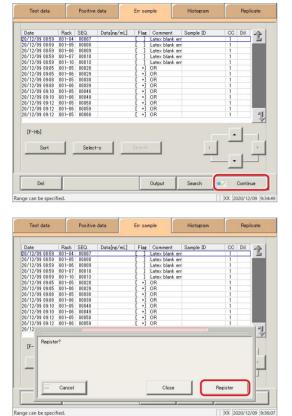
\* Sorted results are displayed.

{Date sort}:	Sort measured data in ascending order by
	measurement date and time.

{Group Sort}: Sort measured data in ascending order by sample number group.

{Cancel}: The dialog box closes.

#### 3.4 List of Error Samples



3

Register the sorted results.

① Touch the {Continue} button.

#### 2 Touch the {Register} button.

- \* Sorted results were registered.
- \* The system returns to the [Process data] screen.

{Register}:	* Sorted data is registered.
{Close}:	Cancel registration, and return to the [Process
	data] screen.
{Cancel}:	The dialog box closes.

Positive data

Select-s

Test data

[E-Hb]

001-06 0000 001-07 0001 001-07 0001 001-05 0002 001-05 0002 001-05 0003 001-06 0003 001-06 0003 001-06 0004 001-05 0004 001-06 0005

(1

Err sample

Laf OF OF OF OF OF OF Histogram

AB1234

### 3.4.3 Specifying error sample data by range

Touch the measurement date and time on the [Err sample] screen or operate the cursor buttons to specify positive sample data by range of measurement date and time (start point/end point). Specify the start point and touch the {Select-s} button to confirm the error sample data at the start point.

Specify the end point and touch the {Select} button to confirm the error sample data at the end point.

After the start and end points are confirmed, the error sample data between the start and end points is specified.

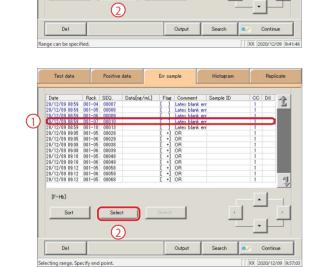
This section describes the procedure from the [Err sample] screen.

t

Page 150 "3.4.1 Displaying the list of error samples" 1 through 5

Specify the error sample data at the start point.

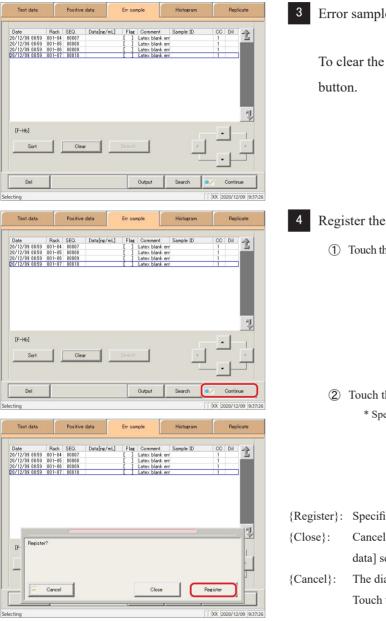
- ① Touch the date and time that will be the start point.
- (2) Touch the {Select-s} button.
  - \* The data at the start point was confirmed. (The text in the row of the specified date and time turns blue.)
  - \* When the start point is confirmed, the {Select-s} button changes to the {Select} button.
- 2 Specify the <u>error sample data</u> at the end point.
  - ① Touch the data row that will be the end point. (The text in the row of the specified range turns blue.)
  - (2) Touch the {Select} button.
    - \* The data for the specified range is displayed.
    - \* When the end point is confirmed, the {Select} button changes to the {Clear} button.
- {Select-s}: Confirm start point data for the specified range.{Select}: Confirm end point data for the specified range.{Clear}: Clear the specified range.



Explanatory note : If the data specified for the start and end points is the same, the system will handle it as though only a single sample of data was specified.

(Explanatory note) : To specify a new range of data, touch the {Clear} button.

All data is displayed, and the system returns to the state it was in before the range was specified.



Error sample data was specified.

To clear the specified range, touch the {Clear} button.

Register the error sample data.

(1) Touch the  $\{Continue\}$  button.

(2) Touch the {Register} button.\* Specified data was registered.

{Register}:	Specified data is registered.
{Close}:	Cancel registration, and return to the [Process
	data] screen.
{Cancel}:	The dialog box closes.
	Touch the {Clear} button to specify a new range.

#### Searching error sample data 3.4.4

Search error samples based on sample ID, sample number, rack number, and measurement date and time.

This section describes the procedure from when the [Err sample] screen is displayed.

Page 150 "3.4.1 Displaying the list of error samples" 1 through 5

- (Explanatory note): If a range is not specified, all error samples displayed on the [Err sample] screen will be searched.
- (Explanatory note): Measured data cannot be searched for using the rack position number.
- (Explanatory note): The range of error sample data can also be specified using the {Select-s} button on the [Err sample] screen.

The method is the same as on page 154 "3.4.3 Specifying error sample data by range."

(Explanatory note): Sort error sample data using the {Sort} button on the [Err sample] screen.

The method is the same as on page 152 "3.4.2 Sorting error sample data."

2

3

 ${A/a}:$ 

Test data		Positive	data	Err sa	nple	Histogram	Replic	ate
Date	Rack	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC Dil	
20/12/09 08:59	001-04	00007	batapigs may	1100	Latex blank en		1	11
20/12/09 08:59	001-05	00008		11	Latex blank en		1	-
20/12/09 08:59	001-06	00009		i i	Latex blank en		1	
20/12/09 08:59	001-07	00010		î î	Latex blank en		1	
20/12/09 08:59	001-10	00013		i i	Latex blank en		1	
20/12/09 09:05	001-05	00028		Ē +1	OR		1	
20/12/09 09:05	001-06	00029		[+]	OR		1	
20/12/09 09:08	001-05	00038		[ +]	OR		1	
20/12/09 09:08	001-06	00039		[+]	OR		1	
20/12/09 09:10	001-05	00048		[ +]	OR	AB1234	1	
20/12/09 09:10	001-06	00049		[ +]	OR		1	
20/12/09 09:12	001-05	00058		[+]	OR		1	
20/12/09 09:12	001-06	00059		[ +]	OR		1	
20/12/09 09:12	001-05	00068		[+]	OR		1	1
[F-Hb] Sort		Select	-s	Search		-		   
Del	Τ				Output	Search	/ Continu	e

Search word settings ample ID Sample No Rack No Date enter Continue XX 2020/12/09 9:38

Search word settings (1)Sample ID Sample No 20 YY DD Rack No Date  $\mathcal{G}$ 0 9 del enter (3) Continue XX 2020/12/09 9:38

Touch the {Search} button.

Select the type of keyword to search.

- □ Sample ID
- □ Sample No.
- □ Rack No.
- □ Date

Enter a keyword.

- 1) Touch the "input field" next to the name of the keyword.
- 2 Enter a keyword using the keypad.
- 3 Touch the {enter} key.

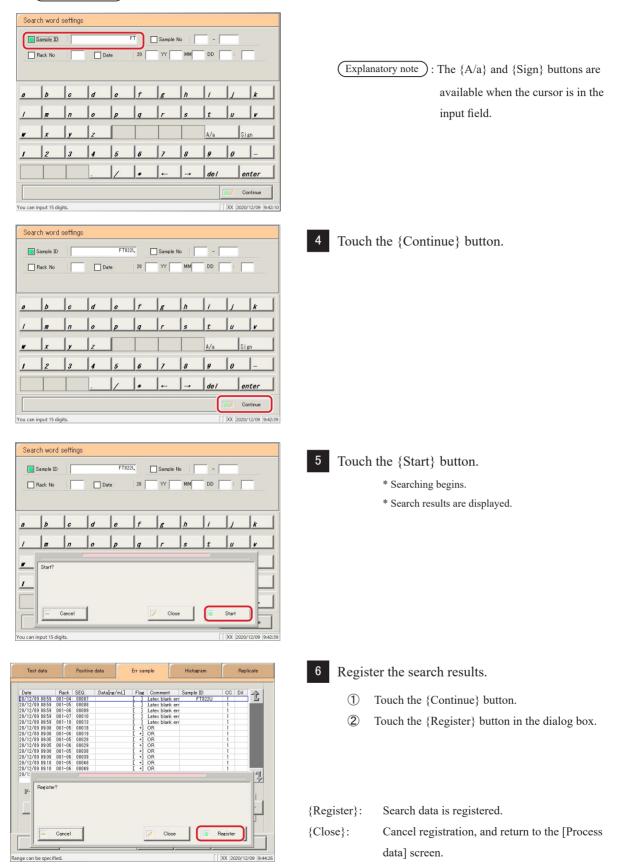
Switch input between uppercase and lowercase. {Sign}: Allows for input of symbols.

#### 3.4 List of Error Samples

(Explanatory note): Entry of the group number and measurement date and time can be omitted. However, if a

measurement date and time box is checked, it is necessary to input at least one of the following: year, month, date, hour, and minute.

(Explanatory note): The measured data specified on the [Test data] screen will be searched.



#### 3.4.5 Outputting error sample data

Output error sample data specified on the "list of error samples" to the selected output destination.

- Printing error sample data
- · Saving error sample data to external media
- · Outputting error sample data to a host computer online

This section describes the procedure from when the [Err sample] screen is displayed.

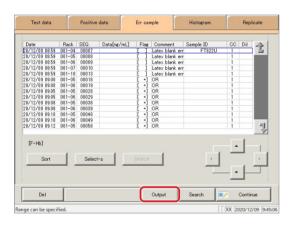
Page 150 "3.4.1 Displaying the list of error samples" 1 through 5

(Explanatory note): If an error has occurred in communicating the measurement results, "Online" cannot be

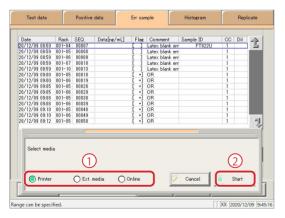
selected in the [Output destination selection] dialog.

Explanatory note : When there is both 15-times dilution and 250-times dilution measured data, a qualitative assessment is performed.

If testing was stopped for either 15-times dilution or 250-times dilution, or if the measured data for either was deleted by the operator, a qualitative assessment is not performed.



1 Touch the {Output} button.



Output the error sample data.

2

- 1 Select the output destination.
  - O Printer
  - O Ext. media (External media)
  - O Online
- (2) Touch the {Start} button.

{Start}:	Data is output.
(0 1)	TT1 1'1 1

Test data		Positive	data	Err sa	mple	Histogram	Rep	licate
Date	Back	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC Dil	ΙA
20/12/09 08:59	001-04	00007	Dottopigs may	1	Latex blank err		1	16
20/12/09 08:59	001-05	00008		11	Latex blank err		1	
20/12/09 08:59	001-06	00009		ΪÍ	Latex blank err		1	
20/12/09 08:59	001-07	00010		î î	Latex blank err		1	
20/12/09 08:59	001-10	00013		i i	Latex blank err		1	
20/12/09 09:00	001-05	00018		[+]	OR		1	
20/12/09 09:00	001-06	00019		[+]	OR		1	
20/12/09 09:05	001-05	00028		[ +]	OR		1	
20/12/09 09:05	001-06	00029		[+]	OR		1	
20/12/09 09:08	001-05	00038		[+]	OR		1	
20/12/09 09:08	001-06	00039		[+]	OR		1	
20/12/09 09:10	001-05	00048		[+]	OR		1	
20/12/09 09:10	001-06	00049		[+]	OR		1	
20/12/09 09:12	001-05	00058		[+]	OR		1	-1
Outputing, I	Please w	ait. [ 17]				7	Cancel	
							Odricer	

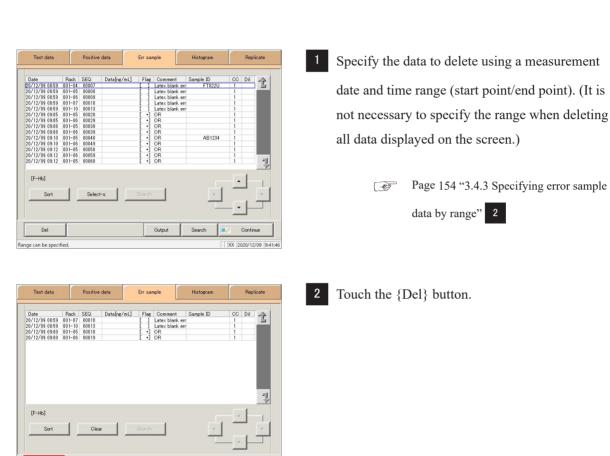
Error sample data is output to the selected output destination.

# 3.4.6 Deleting error sample data

Delete error sample data for the specified measurement date and time.

This section describes the procedure from the [Err sample] screen.

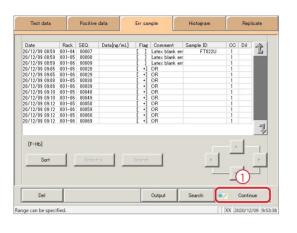
Page 150 "3.4.1 Displaying the list of error samples" 1 through 5



Test data	Positive da	ata	Err san	nple	Histogram	Rep	licate	3
20/12/09 08:59 001 20/12/09 08:59 001 20/12/09 08:59 001 20/12/09 09:00 001	-07 00010	Data[ng/mL]		Comment Latex blank e Latex blank e OR OR		CC Dil 1 1 1 1	2	
(F- Delete data	of selected Date	?				;		{Ok {Cle
electing				Z Close		ок	2/09 9:53:08	(Ch

- Confirm the specified date and time, and touch the {OK} button.
- OK}:Data for the specified date and time is deleted.[Close]:The dialog box closes.

(Explanatory note): If a range is not specified, all samples displayed on the [Err sample] screen will be deleted.



Date	Rack	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC	Dil	$\Delta$
0/12/09 08:59	001-04	00007		[ ]	Latex blank err	FT822U	1		1
0/12/09 08:59	001-05	00008		[ ]	Latex blank err		1		
0/12/09 08:59	001-06	00009		[]	Latex blank err		1		
0/12/09 09:05	001-05	00028		[ +]	OR		1		
0/12/09 09:05	001-06	00029		[+]	OR		1		
0/12/09 09:08	001-05	00038		[ +]	OR		1		
0/12/09 09:08	001-06	00039		[ +]	OR		1		
0/12/09 09:10	001-05	00048		[+]	OR		1		
0/12/09 09:10	001-06	00049		[ +]	OR		1		
0/12/09 09:12	001-05	00058		[+]	OR		1		
0/12/09 09:12	001-06	00059		[ +]	OR		1		
0/12/09 09:12	001-05	00068		[ +]	OR		1		
0/12/09 09:12	001-06	00069		[+]	OR		1		
[F- Registe	r? Cancel				Close	(	2) Register		

4 The error sample data for the specified date and time was deleted.

To update error sample data:

- 1 Touch the {Continue} button.
- (2) Touch the {Register} button in the dialog box.

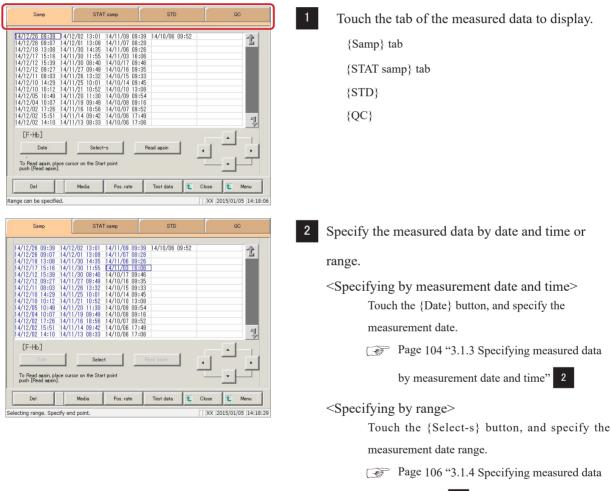
# 3.5 Histogram

Display a histogram for the specified measured data.

Histograms can be output to the selected output destination and their ranges can be changed.

# 3.5.1 Displaying histograms

Display a histogram for the specified measured data.

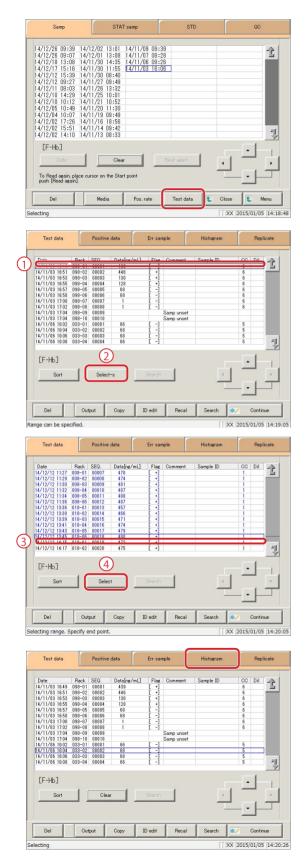




(Explanatory note): Measured data calculated in the test or remeasure modes will be displayed on the histogram.

3

(Explanatory note): A histogram for all data will be displayed if no range is specified.



Touch the {Test data} button.

4 Specify the measured data by range of

measurement date and time.

- Touch the measurement date and time at the start point (the cursor buttons at the bottom right of the screen can be used to select this).
- (2) Touch the {Select-s} button.
  - \* The text in the row of the specified date and time turns blue (start point).
  - \* The {Select-s} button changes to the {Select} button.
- ③ Touch the measurement date and time at the end point (the cursor buttons at the bottom right of the screen can be used to select this).
- ④ Touch the {Select} button.

\* The text in the row of the specified range turns blue (end point).

- {Select-s}: Confirm start point data for the specified range.
- {Select}: Confirm end point data for the specified range.
- {Clear}: Cl
  - Clear the specified range.
  - 5 Touch the {Histogram} tab.

Histogram	1010 444 Samp Output	The cursor's numer	6       The histogram was displayed.         {Close}:       Return to the [Test data] screen.         displayed on the histogram can be moved with the cursor buttons.       ic information is displayed in ★ .         display is as shown in a, b, and c below.
<u>#.#</u> - <u>#</u> ↑ a	± <u># # sample</u> ↑ ↑ b c	a : b : c :	Measured data minimum Measured data maximum Number of samples within the range between the measured data maximum and minimum

3.5 Histogram

MEMO

-

#### 3.5 Histogram

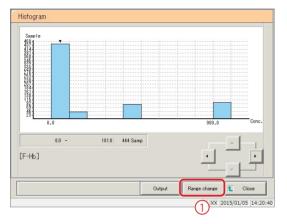
# 3.5.2 Changing the histogram range

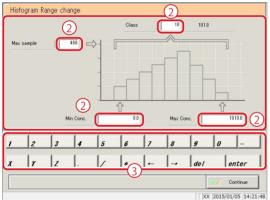
Input "Max sample," "Min Conc.," "Max Conc.," or "Class" to modify the histogram range. This section describes the procedure from the [Histogram] screen.

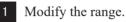
Page 162 "3.5.1 Displaying histograms" 1 through 5

Explanatory note : Measured data calculated in the test or remeasure modes will be displayed on the histogram.

(Explanatory note): All data will be subject to range modification if no range is specified.







① Touch the {Range change} button.

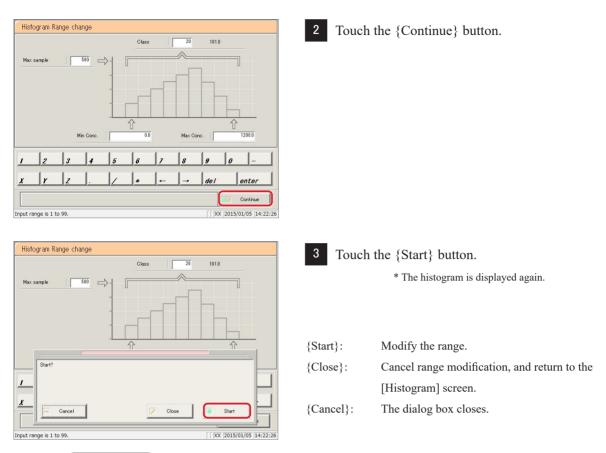
(2) Touch the input field for the condition to change.

- Max sample
- Min Conc.
- Max Conc.
- Class

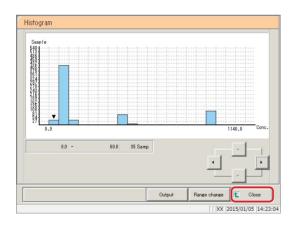
③ Modify the setting with the numeric keypad.

Setting	Input Range
Max sample	0 - 9,999
Min Conc.	0 - 999,999,999.9
Max Conc.	0 - 999,999,999.9
Class	1 - 99

(Explanatory note): "Class" is the number of segments the histogram is divided into



(Explanatory note): Range modification is not saved to the hard disk(SSD).



4 Touch the {Close} button.

\* The system returns to the [Test data] screen.

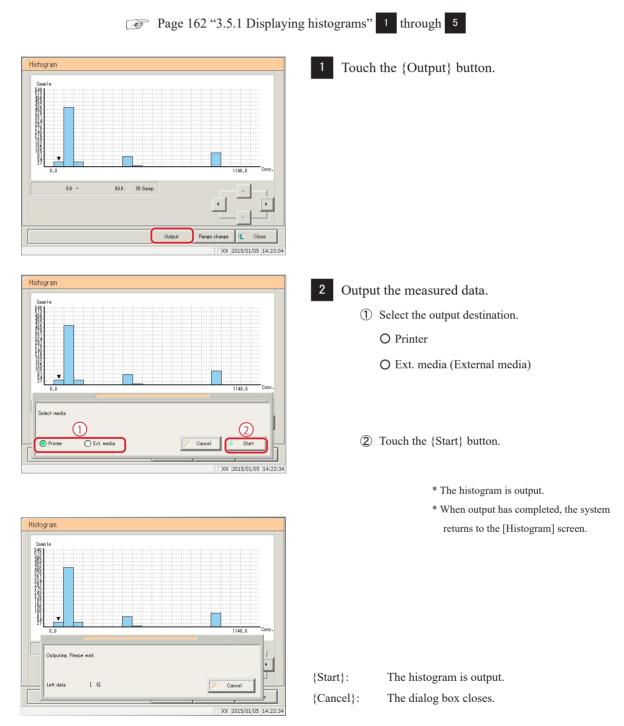
#### 3.5 Histogram

# 3.5.3 Outputting histograms

Output histograms (data) to external media or a printer.

- Printing histograms
- Saving histograms to external media

This section describes the procedure from the [Histogram] screen.



3.5 Histogram

MEMO

-

# 3.6 Positive Rate Change

Display the positive rate change of measured data.

Modify maximum/minimum positive rates, or output positive rate changes to external media or a printer.

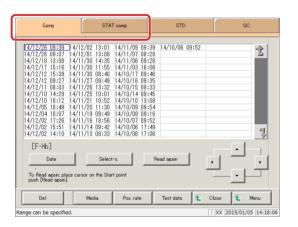
Explanatory note: The system can store up to ten years of positive rate changes. A single year's worth of data can be displayed at once.

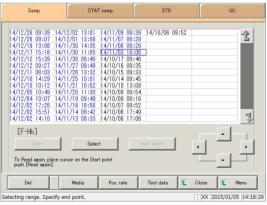
#### 3.6.1 Displaying positive rate changes

Two display modes are available: sample mode and testee mode.

Page 130 "3.3.1 Displaying the positive sample list"

Explanatory note : This applies to samples that were measured in test or remeasure mode and found to be "positive."





Touch the tab of the measured data to display. {Samp} tab {STAT samp} tab

- 2 Specify the measured data by date and time or range.
  - <Specifying by measurement date and time> Touch the {Date} button, and specify the

measurement date.

Page 104 "3.1.3 Specifying measured data by

measurement date and time" 2

<Specifying by range>

Touch the {Select-s} button, and specify the measurement date range.

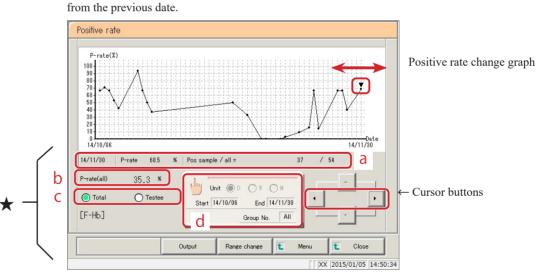
Page 106 "3.1.4 Specifying measured data by

range" 2

#### 3.6 Positive Rate Change

<ul> <li>Explanatory note: Selecting "Testee" displays the values for the number of positive testees/number of all testees.</li> <li>The positive rate change graph was displayed.</li> <li>Output }: Output positive rate changes to the selected location.</li> <li>Range change }: Change the maximum/minimum positive rates.</li> <li>[MENU]: Return to the [MENU] screen.</li> <li>(Close}: Return to the [MENU] screen.</li> </ul>	<ul> <li>In the part of the second secon</li></ul>	Samp STAT samp STD QC	3 Touch the {Pos. rate} button.
<ul> <li>Explanatory note): Selecting "Testee" displays the values for the number of positive testees/number of all testees.</li> <li>Positive rate</li> <li>Positive rate&lt;</li></ul>	<ul> <li>Clear reduction</li> <li>Cle</li></ul>	14/12/26 09:07 14/12/01 13:08 14/11/07 08:28 14/12/01 21:08 14/11/30 14:35 14/11/06 09:28 14/12/01 15:16 14/11/30 11:55 14/11/03 16:06 14/12/12 09:27 14/11/27 08:49 14/12/12 09:27 14/11/27 08:49 14/12/10 16:28 14/11/25 10:61 14/12/10 16:28 14/11/15 00:49 14/12/10 16:71 14/11/19 09:49 14/12/04 10:07 14/11/19 09:49 14/12/04 10:75 14/11/19 18:56	
Del       The positive rate change graph was displayed.         Image: Control of the selected for the selecte	Del       Wedu       Postrate       Itestees.         Selecting       The positive rate change graph was displayed.         Image: Comparison of the positive rate change stop in the selected location.         Image: Change in the positive rate change in the selected location.         Image: Change in the maximum/minimum positive rates.		Explanatory note: Selecting "Testee" displays the values for
Selecting          Postfive rate       Image: Construction of the positive rate change graph was displayed.         Image: Construction of the positive rate change graph was displayed.         Image: Construction of the positive rate change graph was displayed.         Image: Construction of the positive rate change graph was displayed.         Image: Construction of the positive rate changes to the selected location.         Image: Change the maximum/minimum positive rates.         Image: Change the maximum/minimum positive rates.         Image: Change the Image: Change: Change the Image: Change: Chang	Selecting       The positive rate change graph was displayed.         Image: Control of the positive rate change graph was displayed.       Image: Control of the positive rate change graph was displayed.         Image: Control of the positive rate change graph was displayed.       Image: Control of the positive rate change graph was displayed.         Image: Control of the positive rate change graph was displayed.       Image: Control of the positive rate changes to the selected location.         Image: Control of the positive rate change is the positiv	To Read again, place cursor on the Start point push (Read again, )	the number of positive testees/number of
<ul> <li>Positive rate</li> <li>Protection</li> <li>Protection<td>Positive rate Positive rate Image: A state of the positive rate of the posit</td><td>Del Media Pos.rate Test data 💽 Close 💽 Menu</td><td>all testees.</td></li></ul>	Positive rate Positive rate Image: A state of the positive rate of the posit	Del Media Pos.rate Test data 💽 Close 💽 Menu	all testees.
<ul> <li>The positive rate change graph was displayed.</li> <li>The positive rate change graph was displayed.</li> <li>Output positive rate changes to the selected location.</li> <li>Range change}: Change the maximum/minimum positive rates.</li> <li>[MENU]: Return to the [MENU] screen.</li> <li>Close}: Return to the [Process data] screen.</li> </ul>	<ul> <li>4 The positive rate change graph was displayed.</li> <li>4 The positive rate change graph was displayed.</li> <li>4 The positive rate change graph was displayed.</li> <li>4 Output positive rate changes to the selected location.</li> <li>4 (Output): Output positive rate changes to the selected location.</li> <li>4 (Range change): Change the maximum/minimum positive rates.</li> </ul>	Selecting [[XX  2015/01/05  14:18:48]	
<ul> <li>{Output}: Output positive rate changes to the selected location.</li> <li>{Range change}: Change the maximum/minimum positive rates.</li> <li>[MENU]: Return to the [MENU] screen.</li> <li>{Close}: Return to the [Process data] screen.</li> </ul>	{Output}: Output positive rate changes to the selected location. {Range change}: Change the maximum/minimum positive rates.		4 The positive rate change graph was displayed.
Company realing craning C month	[F-Hb] Group No. All [MENU]: Return to the [MENU] screen.	100         0	{Range change}:       Change the maximum/minimum positive rates.         [MENU]:       Return to the [MENU] screen.

Explanatory note : The "▼" symbol displayed on the positive rate change graph can be moved with the cursor buttons. The cursor's numeric information is displayed in ★ (a through d). (Refer to the following diagram.)
 Explanatory note : The cursor's numeric information is managed in units of measurement date. If the date is changed during testing, the data that was output after the date changed is managed separately from the data



Measurement dates, positive rates, numbers of positive samples, and all samples (sample mode)
 Measurement dates, positive rates, number of positive testees, number of all testees (testee mode)

- b: Positive rates for all samples (positive rates for all data displayed)
- c: Button to switch between sample mode and testee mode
- d: Calculation condition settings for {Date settings} button positive rates

Page 172 "3.6.2 Configuring calculation conditions for positive rates"

# 3.6.2 Configuring calculation conditions for positive rates

Configure the measurement start date, measurement close date, and positive rate calculation unit (day, week, month), then calculate the positive rate. Positive rate changes can also be displayed by group number of the sample number (if "All" is selected for group selection, positive rate changes are displayed for all data).

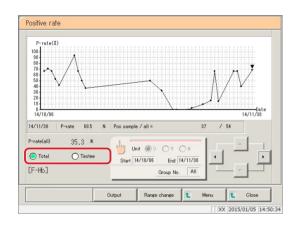
This section describes the procedure from the [Positive rate change] screen.

Page 170 "3.6.1 Displaying positive rate changes"

Explanatory note: The range from the start date until the close date may be a maximum of one year long. Touch the input field to enter a date.

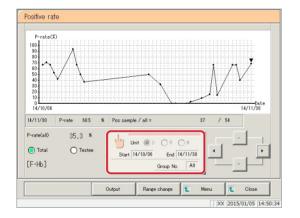
2

3



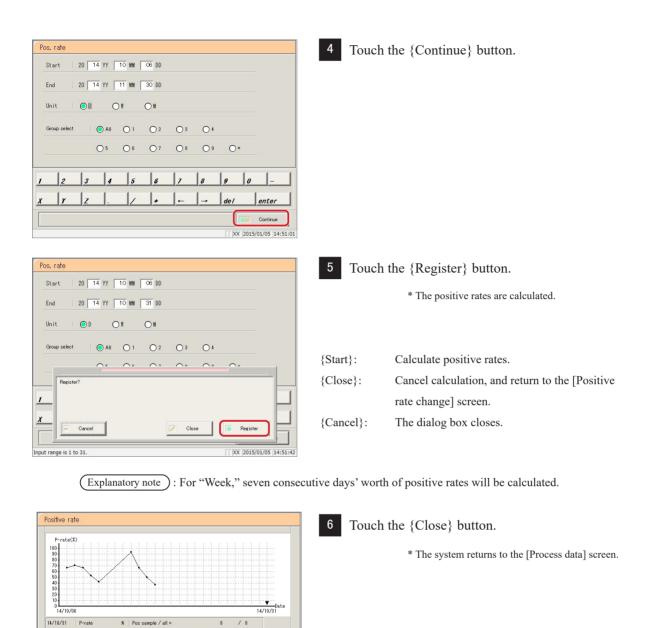
1 Select the display mode for positive samples (by sample/testee).

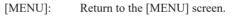
Touch the {Sample} or {Testee} buttons.



Pos. rate 20 14 YY 10 MM 06 DI End 20 [ 14 YY Unit 01 O M 01 Group select 01 O 2 03 O 4 06 07 08 0.9 0.5  $\cap$ enter del Continue XX 2015/01/05 14:51:01 Touch the {Date settings} button.

- Configure the calculation conditions.
  - ① Enter a start date (year/month/day).
  - ② Enter a close date (year/month/day).
  - ③ Select a calculation unit (day/week/month).
  - ④ To display by group number, select a number ("\*" displays the positive rate changes for samples for which a group has not been specified).





<Month calculation example>

P-rate(all)

🔵 Total

[F-Hb]

60.8 %

O Teste

Unit 🔘

Range change

Start 14/10/0

Start date is December 29, 2012, close date is February 15, 2013

End 14/10/8

Group No. All

- → Calculate "December positive rate" using data measured from December 29 until December 31,
   2012
- $\rightarrow$  Calculate "January positive rate" using data measured in January 2013

XX 2015/01/05 14:52:

 $\rightarrow$  Calculate "February positive rate" using data measured from February 1 until February 15, 2013

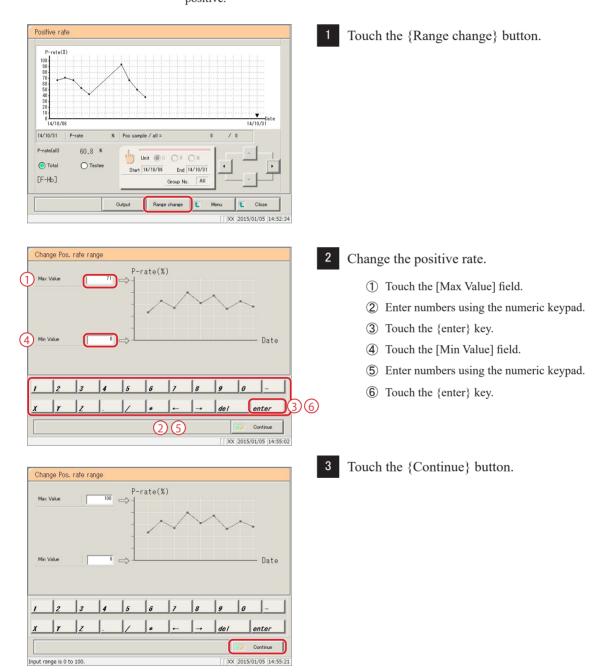
# 3.6.3 Changing the range of positive rate change

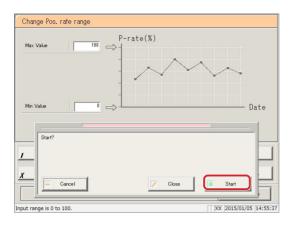
Enter the "Max Value" and "Min Value," then change the range of positive rate change.

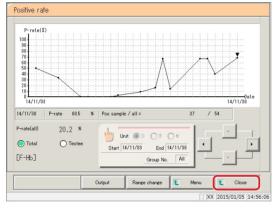
This section describes the procedure from the [Positive rate change] screen.

Page 170 "3.6.1 Displaying positive rate changes"

Explanatory note : This applies to samples that were measured in test or remeasure mode and found to be "positive."







Touch the {Start} button.

\* The positive rate change is displayed again.

{Start}:	Calculate positive rates.
{Close}:	Cancel calculation, and return to the [Positive
	rate change] screen.
{Cancel}:	The dialog box closes.

5

4

Touch the {Close} button.

\* The system returns to the [Measured data select] screen.

### 3.6.4 Outputting positive rate changes

Output positive rate changes to external media or a printer.

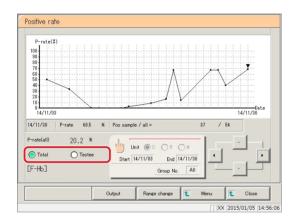
- Printing positive rate changes
- · Saving positive rate changes to external media

This section describes the procedure from the [Positive rate change] screen.

Page 170 "3.6.1 Displaying positive rate changes"

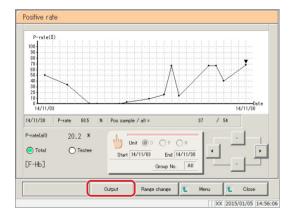
Explanatory note : This applies to samples that were measured in test or remeasure mode and found to be "positive."

2



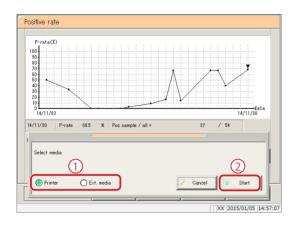
Select the display mode for positive samples (by Total/Testee).

Touch the {Total} or {Testee} buttons.



Touch the {Output} button.

#### 3.6 Positive Rate Change

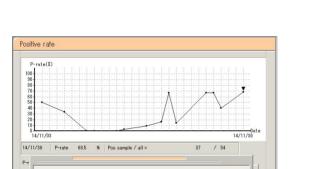


3

Output positive rate changes.

- 1 Select the output destination.
  - O Printer
  - O Ext. media (External media)
- 2 Touch the {Start} button.
  - \* Positive rate changes are output.
  - \* When output has completed, the system returns to the [Positive rate change] screen.

{Start}:	Output positive rate changes.
{Cancel}:	The dialog box closes.



•

Can

XX 2015/01/05 14:57:52

Outputing. Please wait

Left data

[ 13]

Display the replicate data of the measured data specified on the [Test data] screen.

# 3.7.1 Displaying the replicate list (samples/STAT samples)

Display the replicate data for samples and STAT samples.

(Explanatory note) : All data will be displayed if no range is specified.

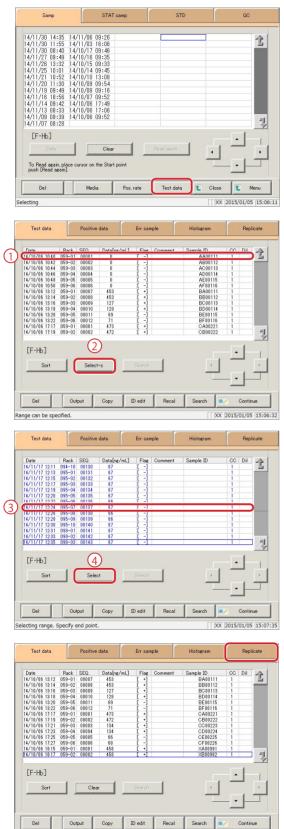
Samp	STAT samp	STD	ac	1 Touch the tab of the measured data to display.
1 4/12/26 09:07 14 1/12/17 31:08 14 1/12/17 15:16 14 1/12/17 15:16 14 1/12/12 09:27 14 1/12/12 09:27 14 1/12/10 00:38 14 1/12/10 01:21 14 1/12/10 01:11 14 1/12/10 01	/11/30 14:35 14/11/06 09:2 /11/30 11:55 14/11/03 16:0 /1/30 08:40 14/10/17 09:4 /11/27 09:49 14/10/16 09:3 /11/26 13:32 14/10/15 09:3 /11/25 10:01 14/10/14 09:4 /11/25 10:52 14/10/10 13:0	Read again	2015/01/05 14:18:06	{Samp} tab {STAT samp} tab
14/12/26 09:07 14, 14/12/18 13:08 14, 14/12/17 15:16 14,	STAT samp           /12/02         13:01         14/11/09         09:3           /12/01         13:08         14/11/07         09:3           /12/01         13:55         14/11/06         09:2           /11/30         11:55         14/11/08         08:0           /11/30         11:55         14/11/08         18:0	8 6	oc 1	2 Specify the measured data by date and time or range.
14/12/12 09:27 14, 14/12/11 08:03 14, 14/12/10 14:29 14, 14/12/10 10:12 14, 14/12/05 10:49 14, 14/12/04 10:07 14, 14/12/02 17:26 14, 14/12/02 15:55 14,	/11/30 08:40 14/10/17 09:4 /11/27 09:48 14/10/16 09:3 /11/28 13:32 14/10/15 09:3 /11/28 10:01 14/10/14 09:4 /11/21 10:52 14/10/10 13:0 /11/20 11:50 14/10/08 09:1 /11/18 09:48 14/10/08 09:1 /11/16 18:56 14/10/07 09:5 /11/14 09:42 14/10/06 17:0	5 3 5 8 4 6 2 9	Ţ	<specifying and="" by="" date="" measurement="" time=""> Touch the {Date} button, and specify the measurement date.</specifying>
[F-Hb] Date To Read again, place of push (Read again).	Select	Read again		<ul><li>Page 104 "3.1.3 Specifying measured data by measurement date and time"</li></ul>
Del Selecting range. Specify	Media Pos. rate end point.	Test data 💽 Clo	se Menu XX 2015/01/05 15:05:54	<specifying by="" range=""></specifying>

Touch the {Select-s} button, and specify the

measurement date range.

Page 106 "3.1.4 Specifying measured data by

range" 2



**3** Touch the {Test data} button.

4 Specify the measured data by range of

measurement date and time.

- Touch the measurement date and time at the start point (the cursor buttons at the bottom right of the screen can also be used to select this).
- (2) Touch the {Select-s} button.
   \* The text in the row of the specified date and time turns blue (start point).

\* The {Select-s} button changes to the {Select} button.

- (3) Touch the measurement date and time at the end point (the cursor buttons at the bottom right of the screen can also be used to select this).
- (4) (Touch the  $\{\text{Select}\}\$  button.

\* The text in the row of the specified range turns blue (end point).

- {Select-s}: Confirm start point data for the specified range.
- {Select}: Confirm end point data for the specified range.

Clear the specified range.

{Clear}:

5

XX 2015/01/05 15:07:52

Touch the {Replicate} tab.

\* The replicate list is displayed.

Date	Rack	SEQ.	Data[ng/mL]	Flag	Comment	Sample ID	CC	Dil	->
4/10/00 13:12	008-01	00007	455	L *J		BAUUIII	1.1		
1/10/06 13:12	059-01	00007	456	[+]		BA00111	1		
4/10/06 18:12	059-01	00007	456	[+]		BA00111	1		
1/10/06 13:12	059-01	00007	453	[+]		BA00111	1		
1/10/06 13:12	059-01	00007	448	[+]		BA00111	1		
1/10/06 13:12	059-01	00007	453	[ +]		BA00111	1		
1/10/06 13:12	059-01	00007	454	[ +]		BA00111	1		
1/10/06 13:12	059-01	00007	451	[+]		BA00111	1		
1/10/06 13:12	059-01	00007	450	[ +]		BA00111	1		
1/10/06 13:12	059-01	00007	454	[+]		BA00111	1		
1/10/06 13:14	059-02	00008	457	[ +]		BB00112	1		
1/10/06 13:14	059-02	00008	449	[+]		BB00112	1		
4/10/06 13:14	059-02	00008	449	[ +]		BB00112	1		
4/10/06 13:14	059-02	00008	453	[ +]		BB00112	1		-1,
[F-Hb] Sort		Sele	ict-s	Searc	'n		-[•		•
		ourse	Recal	Sea	. [			Continu	

6 The replicate list (samples/STAT samples) was displayed.

{CC }:	Edit and re	calculate the calibration curve of the specified replicate data.
	Ĩ	Page 197 "3.7.9 Editing/recalculating calibration curves"
{Time course}	: Display tin	ne course data.
	Ĩ	Page 204 "3.7.12 Displaying/printing time courses
		(samples/STAT samples)"
{Recal} :	Recalculate	e replicate data using modified cut-off values, as well as factors
	A and B.	
	(F	Page 194 "3.7.8 Recalculating replicate data"
{Search} :	Search sam	ples based on sample ID, sample number, rack number,
	and measu	rement date and time.
	(F	Page 192 "3.7.7 Searching replicate data"
(		

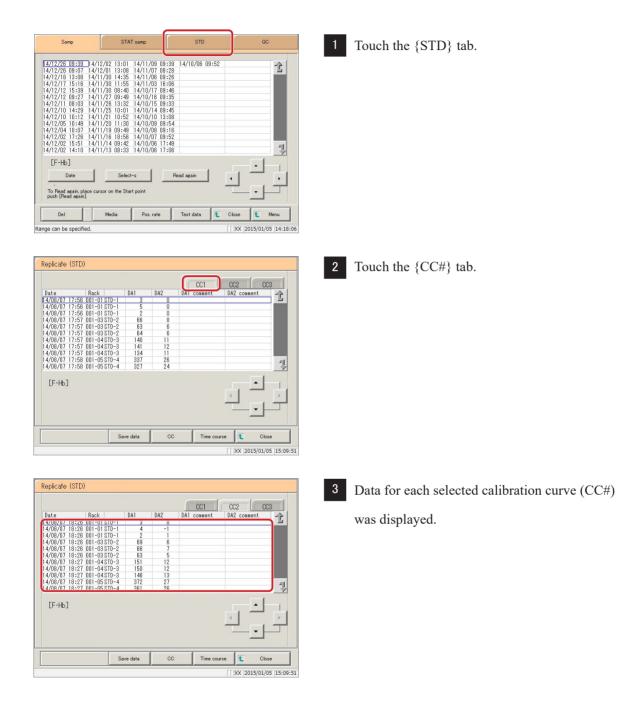
Display	Details		Remark
Date	Date and tin	ne sample was measured	
RACK	Rack No I	Position number in rack.	
SEQ.	Group No	Sequence No.	
Data [ng/mL] or [ug/g]	Measuremen (concentrati		
Flag	-, +, 1 +, 2 +	-, 3 +	
	Error inform	nation (excluding reading errors)	
Comment	UR	: Under range	Blank output for measured data and judgment result (displayed during dilute test)
	OR	: Over range	Output only judgment result
	PRC	: Prozone	Output only judgment result
Sample ID	Barcode info	ormation on sampling bottles	
СС	Calibration curve used to calculate measured data (CC No.)		
	Dilution information		
	Space	: No dilution (test mode, remeasure mode)	
Dil	А	: No dilution (Retest mode)	
	A15	: 15-times dilution (Dilution test mode)	
	A250	: 250-times dilution (Dilution test mode)	

Content displayed on the [Replicate] screen

Explanatory note : During a dilute test, if no dilution and 15-times dilution are both tested, the final result row is displayed in blue text.

# 3.7.2 Displaying the [Replicate (STD)] screen

Display STD replicate data.



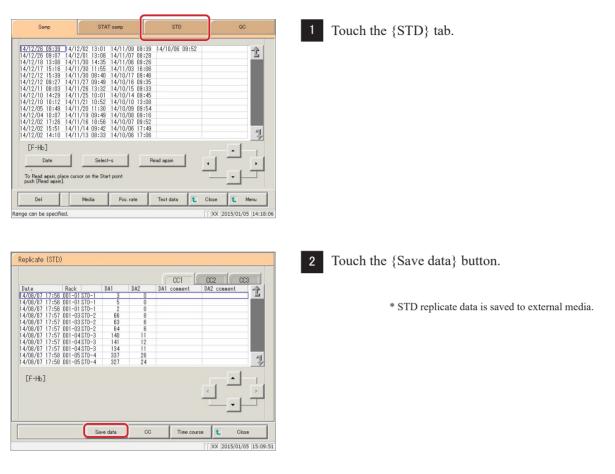
Content displayed on the [Replicate (STD)] screen

Display	Details	Remark
Date	Date and time STD was measured	
RACK	Rack No Position number in rack	
DA1	Amount of change for ABS (A#) A3-A1	Page 350
DA2	Amount of change for ABS (A#) A2-A1	"Appendix: 1.3 DA value calculation"
DA1comment	Comment for DA1	
DA2comment	Comment for DA2	

(	
{Save data}:	Save replicate data to external media.
	Page 184 "3.7.3 Saving replicate data (STD) to external media"
{CC}:	Edit and recalculate the calibration curve of the specified replicate data.
	Page 197 "3.7.9 Editing/recalculating calibration curves"
{Time course}:	Display the [Time course data] screen.
	Page 205 "3.7.13 Displaying/printing time courses (STD)"
	Page 208 "3.7.15 Changing the range of the time course (STD)"
{Close}:	Return to the [Measured data select] screen.
l	

## 3.7.3 Saving replicate data (STD) to external media

Open the [Replicate (STD)] screen, then save the replicate data displayed on the screen to external media.



 Explanatory note
 : If no external media is connected, "Not connected with external media." is displayed.

 Connect the external media and touch the {Retry} button.

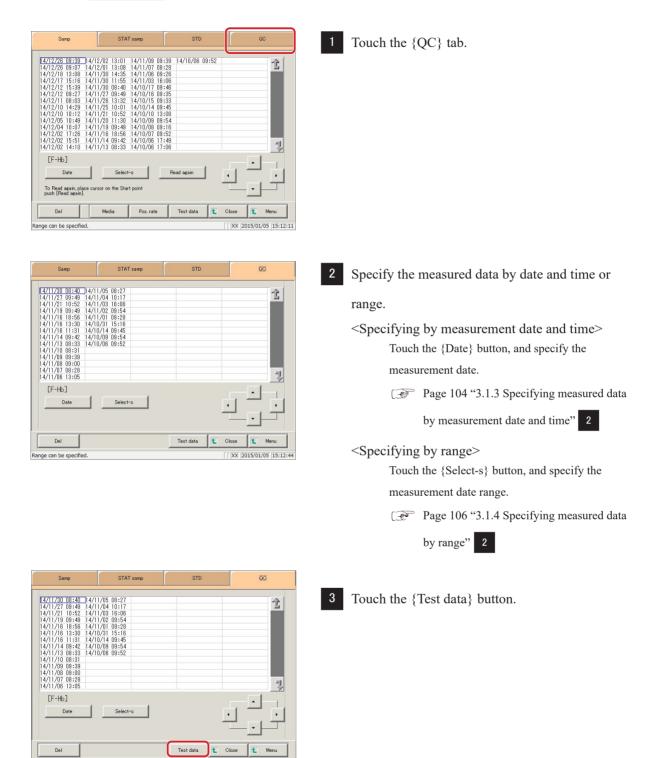
MEMO

-

# 3.7.4 Displaying the [Replicate (QC)] screen

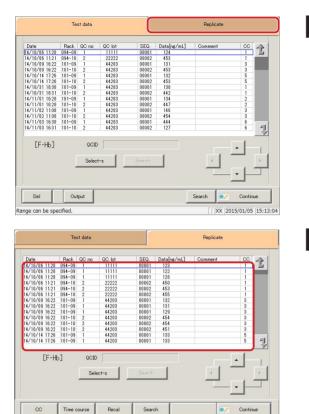
Display QC replicate data.

(Explanatory note): All data will be displayed on the screen if no range is specified.



XX 2015/01/05 15:12:44

Range can be specified



ange can be specifi

4 Touch the {Replicate} tab.

5 The [Replicate (QC)] screen was displayed.

\* Test items and QC IDs are displayed.

XX 2015/01/05 15:13:30

Display	Details	Remark
Date	Date and time STD was measured	
RACK	Rack No Position number in rack	
QC No.	QC sample number	
QC LOT	QC sample lot number	
Seq.	QC sample sequential number	
Data [ng/mL] or [ug/g]	QC sample measured data	
Comment	QC IDs and barcode reading errors	
СС	Calibration curve numbers (numbers 1 through 6)	

{CC}:	Edit and recalculate the calibration curve of the specified replicate data.
	Page 197 "3.7.9 Editing/recalculating calibration curves (samples/STAT samples)"
{Time course}:	Display time course data.
	Page 204 "3.7.12 Displaying/printing time courses (samples/STAT samples)"
{Recal}:	Recalculate replicate data using modified cut-off values, as well as factors A and B.
	Page 194 "3.7.8 Recalculating replicate data"
{Search}:	Search samples based on sample ID, sample number, rack number, and measurement date and
	time.
	Page 192 "3.7.7 Searching replicate data"

#### Sorting replicate data (samples/STAT samples) 3.7.5

Sort sample and STAT sample replicate data by measurement date and time or by group, and narrow down measured data to process.

When sorting by measurement date and time, replicate data is displayed in ascending order by "date." When sorting by group, replicate data is displayed in ascending order by "sample number group."

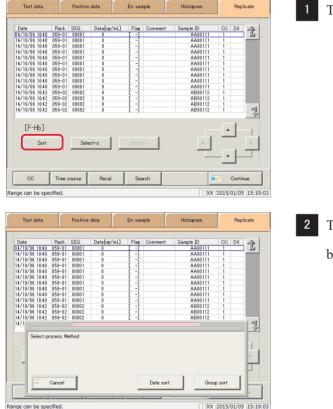
This section describes the procedure from the [Replicate] screen.

Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" 1 through 5

Explanatory note : If a range is not specified, all samples displayed on the [Replicate] screen will be sorted.

(Explanatory note) : The range of samples can also be specified using the {Select-s} button on the [Replicate] screen.

The method is the same as on page 190 "3.7.6 Specifying replicate data by range.



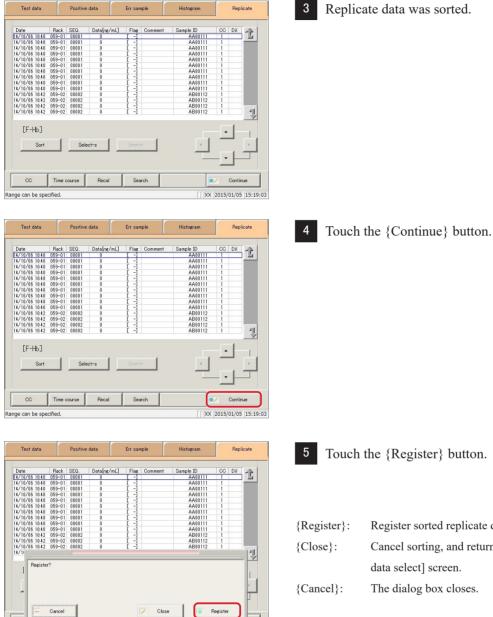
Touch the {Sort} button.

Touch the {Date sort} button or the {Group sort} button.

{Date sort}:	Sort measured data in ascending order by
	measurement date and time.

- {Group Sort}: Sort measured data in ascending order by sample number group.
- {Cancel}: The dialog box closes.

ange can be sp



XX 2015/01/05 15:19:03



Touch the {Register} button.

{Register}:	Register sorted replicate data.
{Close}:	Cancel sorting, and return to the [Measured
	data select] screen.
{Cancel}:	The dialog box closes.

\_

Range can be specified

\_

### 3.7.6 Specifying replicate data by range

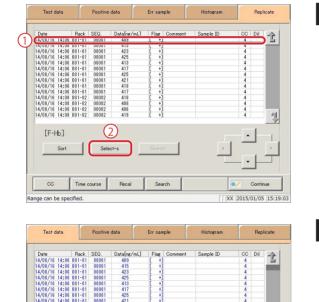
Touch the measurement date and time on the [Replicate] screen or operate the cursor buttons to specify replicate data by range of measurement date and time (start and end points).

Specify the start point and touch the {Select-s} button to confirm the replicate data at the start point. Specify the end point and touch the {Select} button to confirm the replicate data at the end point. After the start and end points are confirmed, the replicate data between the start and end points is specified.

This section describes the procedure from the [Replicate] screen.

Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" 1 through 5

2



408

ID edit

XX 2015/01/05 15:16:4

6

Selec

Specify replicate data at the start point.

- 1 Touch the date and time that will be the start point.
- 2 Touch the {Select-s} button.

\* Data at the start point is confirmed (the text in the row of the specified date and time turns blue).

\* When the start point is confirmed, the {Select-s} button changes to the {Select} button.



① Touch the date and time that will be the end point.

\* The text in the row of the specified range turns blue.

(2) Touch the {Select} button.

\* The data for the specified range is displayed.

\* When the end point is confirmed, the {Select} button changes to the {Clear} button.

{Select-s}:	Confirm start point data for the specified range.
{Select}:	Confirm end point data for the specified range.
{Clear}:	Clear the specified range.

(1

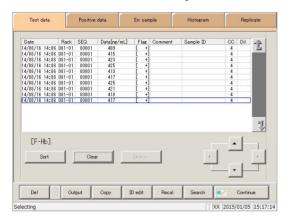
[F-Hb]

Explanatory note : If the replicate data selected for the start and end points is the same, the system will handle it as though only a single sample of replicate data was specified.

3

(Explanatory note): To specify a new range of replicate data, touch the {Clear} button.

All replicate data is displayed, and the system returns to the state it was in before the range was specified.



Replicate data was specified.

\* The specified replicate data is displayed.

#### 3.7 Replicate

# 3.7.7 Searching replicate data

Search replicate data based on sample ID, sample number, rack number, and measurement date and time.

This section describes the procedure from the [Replicate] screen.

Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" 1 through 5

Explanatory note : If a range is not specified, all error samples will be searched.

Replicate data cannot be searched for using the rack position number.

(Explanatory note): The range of replicate data can also be specified using the {Select-s} button on the [Replicate] screen.

The method is the same as on page 190 "3.7.6 Specifying replicate data by range."

Explanatory note: The replicate data can also be sorted using the {Sort} button on the [Replicate] screen.

The method is the same as on page 188 "3.7.5 Sorting replicate data (samples/STAT samples)."

Test data	Positive data	Err sample	Histogram	Replicate	1 To	uch the {Search} button.
Date Ra 14/10/06 10:40 059	ck SEQ. Data[ng/m -01 00001 0	[-]	Sample ID AA00111			
14/10/06 10:40 059 14/10/06 10:40 059 14/10/06 10:40 059 14/10/06 10:40 059 14/10/06 10:40 059	-01 00001 0		AA00111 AA00111 AA00111 AA00111			
14/10/06 10:40 059 14/10/06 10:40 059 14/10/06 10:40 059	-01 00001 0 -01 00001 0 -01 00001 0	[ -] [ -]	AA00111 AA00111 AA00111	1		
14/10/06 10:40 059 14/10/06 10:40 059 14/10/06 10:42 059 14/10/06 10:42 059 14/10/06 10:42 059	-01 00001 0 -02 00002 0 -02 00002 0		AA00111 AA00111 AB00112 AB00112	1 1 1 1		
14/10/06 10:42 059 14/10/06 10:42 059	-02 00002 0 -02 00002 0	[-]	AB00112 AB00112	1 1		
[F-Hb]	Select-s	Search	E.			
Sort	- Select=s	Search				
CC Ti	me course Recal	Search		Continue		
ange can be specifie	d.		∏  XX	2015/01/05 15:19:03	_	
Search word set	tings				2 Se	lect the type of keyword to search.
Rack No	Date	20 YY	No   -   MM DD		[	☐ Sample ID
					[	☐ Sample No.
a b c	. d o	f g	h i	j k	Г	☐ Rack No.
<u>/ m /</u>	n o p	g r	s t	u v		☐ Date
<b>#</b> x )	Z		A/a	Sign	L	
1 2 3	3 4 5	6 7	8 9	0 -		
		* ~	→ de l	enter		
				Continue		
Search word set	Hings	(1)			3 En	ter a keyword.
Sample ID	ļ	Sample	No			<ol> <li>Touch the "input field" next to the name of the</li> </ol>
Rack No	Date	20 YY	MM DD			keyword.
	1 1	2				<ul><li>2 Enter a keyword using the keypad.</li></ul>
a b	c d e	f g	<u>h i</u>	j k		<ul><li>3 Touch the {enter} key.</li></ul>
1	n o p	q r	s t	<u>u</u> v		Touch the jenter, key.
<u> </u>			A/a	Sign		
1 2	3 4 5	6 7	8 9			
		→ <b>*</b>	_→de/			Switch input between uppercase and lowercas
				Continue XX 2020/12/09 9:38:37	{Sign}:	Allows for input of symbols.

(Explanatory note) : Entry of the group number and measurement date and time can be omitted. However, if a measurement date and time box is checked, it is necessary to input at least one of the

following: year, month, date, hour, and minute.

(Explanatory note): The search range is the range specified on the [Test data] screen.

_	ch word	settings			_					
<u> </u>	Sample ID			XAO	<u> </u>	Sample			_	
	Rack No			Date	20	YY	ММ	DD	:	
A	B	c	D	E	F	6	#	1	J	ĸ
L	1	//	0	P	9	R	s	r	1	l v
	x	r	Z							
#	1	1	12	_				A/a	4	Sign
1	2	3	4	5	6	7	8	9	0	
				1	*	-	_	del		enter
									•/	Continue
ou can	input 15 d	ligits.						[ XX	2015/0	1/05 15:21

Search word settings XA00991 Sample ID Sample No Rack No Date 20 YY DD N 1 n 0 de enter Continue You can input 15 digit XX 2015/01/05 15:21:1

XA00991

20 YY

Date

0 P Sample No

DD

U V

XX 2015/01/05 15:22:2

Search word settings

1

📘 Sample ID

Rack No

nge can be spe cified

# Start (Explanatory note) : The  $\{A/a\}$  and  $\{Sign\}$  buttons are available when the cursor is in the input field.

Touch the {Continue} button.

4

5 Touch the {Start} button

\* Searching begins.

\* Search results are displayed.

6 Register the search results.

- ① Touch the {Continue} button.
- (2) Touch the {Register} button in the dialog box.

Register?	
	0

1 Cance ou can input 15 digits XX 2015/01/05 15:21:4 Positive data Err sample 
 Date
 Pack.

 [I4/16/08 18:15 058-01
 058-01

 [I4/16/08 18:15 058-01
 058-01

 [I4/16/08 18:15 058-01
 058-01

 [I4/16/08 18:15 058-01
 14/16/08 18:15 058-01

 [I4/16/08 18:15 058-01
 14/16/08 18:15 058-01

 [I4/16/08 18:15 058-01
 I4/16/08 18:15 058-01

 [I4/16/08 18:15 058-01
 I4/16/08 18:15 058-01

 [I4/16/08 18:15 058-01
 I4/16/08 18:17 058-02

 [I4/16/08 18:17 058-02
 I4/16/08 18:17 058-02

 [I4/16/08 18:17 058-02
 I4/16/08 18:17 058-02

 [I4/16/08 18:17 058-02
 14/16/08 18:17 058-02
 Data[ 451 455 460 459 459 458 464 458 464 455 461 459 453 454 456 [F-Hb] CO Search Time cours

# 3.7.8 Recalculating replicate data

Recalculate replicate data using modified cut-off values, as well as factors A and B. Edited calibration curves can also be used for recalculation.

This section describes the procedure from the [Replicate] screen.

Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" 1 through 5

(Explanatory note): • The values used for judging replicates for which a range has been specified are shown in Cut off 1, Cut off 2, and Cut off 3.

• If the cut-off value differs according to the measured data, "0" will be displayed for Cut off 1, Cut off 2, and Cut off 3.

- Explanatory note : If the factor value differs according to the replicate data, factor A and factor B are displayed as 1.00 and 0.00, respectively.
- Explanatory note : Values configured in the [Recalculation condition settings] screen are not applied to protocol settings.
- (Explanatory note): If the {Memory} button on the [Check CC] screen is touched before touching the {Recal} button, recalculation will be performed using the calibration curve in memory.

Example 1:

{Recal} run on CC1 and CC2 after saving with {Memory}

- → Data that references CC1 and CC2 is fit to the calibration curve in memory, then recalculation is performed.
- → Data that does not reference CC1 and CC2 is not fit to the calibration curve, then corrective calculation (factor A/factor B/dilution ratio calculation) is performed.
- Example 2:

{Recal} run after saving CC2 to CC1 with {Memory}

- → Data that references CC1 is fit to the calibration curve in memory, then recalculation is performed.
- → Data that does not reference CC1 is not fit to the calibration curve in memory, then corrective calibration (factor A/factor B/dilution ratio calculation) is performed.
- Example 3:

{Recal} is run without saving using {Memory} on the [Check CC] screen

→ Cut-off, factor A, and factor B recalculation is performed, then calibration curve fitting calculation is not performed.

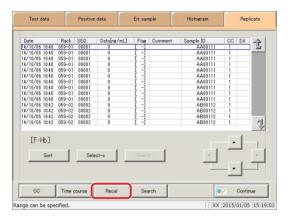
Explanatory note : Recalculation results are applied to measured data, positive sample data, error sample data, and histograms.

After registering recalculation results, they are also applied to values on the [Positive change] screen.

(Explanatory note) : If a range is not specified, all replicate data displayed on the [Replicate] screen will be recalculated.

Explanatory note : The range of replicate data can also be specified using the {Select-s} button on the [Replicate] screen.

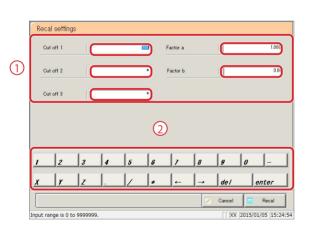
The method is the same as on page 190 "3.7.6 Specifying replicate data by range."



1 Touch the {Recal} button.

Explanatory note : If recalculating using an edited calibration curve, first save the edited calibration curve to memory prior to recalculation.

Page 197 "3.7.9 Editing/recalculating calibration curves" 7 through



2 Configure the recalculation conditions.

1 Touch the "input field" next to the setting.

(2) Enter numbers using the numeric keypad.

- Cut off 1
- Cut off 2
- Cut off 3
- FACTOR A
- FACTOR B

{Cancel}: Cancel recalculation, and return to the [Replicate] screen.

Setting	Input Range
Cut off 1	0 - 9,999,999
Cut off 1	0 to 9,999,999; * (input omitted)
Cut off 3	0 to 9,999,999; * (input omitted)
FACTOR A	0.001 - 99,999.999
FACTOR B	-999.99 - 999.99

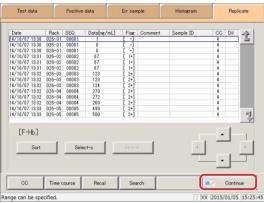
Out off 1				50	Factor a				1.000
Out off 2				100	Factor b				0.00
				*					
Out off 8				_					
Out off 3									
Out off 8									
Cut off 8	3	4	5	6	7	8	9	0	-

**3** Touch the {Recal} button.

\* Recalculation performed with the conditions that were input.

(Explanatory note): If the calibration curve was not saved to memory (if the {Memory} button was not touched),

recalculation is performed with cut-off, factor A, and factor B, then calibration curve fitting



calculation is not performed.

Replicate

4 Touch the {Continue} button.

5 Touch the {Register} button.

{Register	}: R	egister the recalculation results.
{Close}:	C	ancel registration, and return to the [Replicate]
	s	creen.
{Cancel}:	Т	he dialog box closes.

Data[ng/mL] Flag ( ient 026-01 026-02 026-02 026-03 026-03 026-03 026-03 026-04 026-04 026-04 00001 00002 00002 00003 00003 00003 00003 00004 00004 00004 67 67 123 123 124 270 272 269 499 14 14 14 1 XX 2015/01/05 15:25:45 Range can be specified

Err sample

Positive data

Test data

196

# 3.7.9 Editing/recalculating calibration curves (samples/STAT samples)

Edit the origin and DA values of the calibration curve, then recalculate or save the recalculated calibration curve to memory.

Calibration curves displayed on the screen can also be (memory) saved to other calibration curves (CC numbers), and calibration curve fitting calculation can be redone.

This section describes the procedure from the [Replicate] screen.

Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" 1 through 3

(Explanatory note): The following DA values can be input through calibration curve editing.

STD-1 through STD-5: DA1

STD-6: DA1, DA2

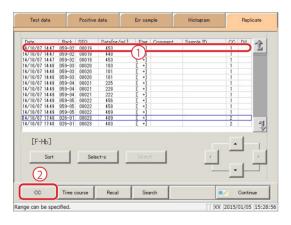
(Explanatory note): DA-2 of STD-6 is used for the PRC check.

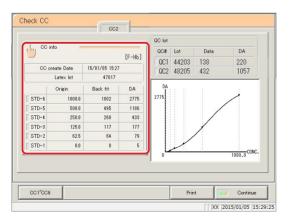
Page 352 "Appendix: 1.5 Prozone Check"

Explanatory note : If a range is not specified, all replicate data displayed on the [Replicate] screen will be recalculated.

Explanatory note: The range of replicate data can also be specified using the {Select-s} button on the [Replicate] screen.

The method is the same as on page 190 "3.7.6 Specifying replicate data by range"





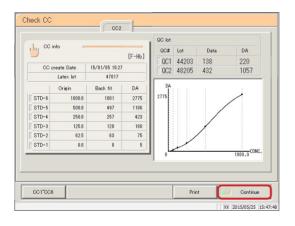
- Display the calibration curve.
  - 1 Touch the row of the applicable data.
  - (2) Touch the  $\{CC\}$  button.
    - \* The calibration curve of the specified replicate data is displayed.

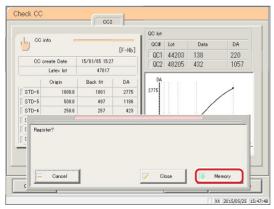
Touch the {CC info} button.

2

Edit and Recal CC CC No. 2 CC create Date 15/01/05 15:27 Latex lot Back fit [ng/mL] (1)Back fit [næ/mL] Origin [ng/ml] Origin [ng/mL] DA DA 1000.0 STD-8 125.0 500.0 62.5 STD-5 495 1186 STD-2 250.0 433 0.0 260 STD-3 0 4 5 6 17 9 12 1. del 1 . enter Cancel Recal [ XX 2015/01/05 15:29:38 

Edit ar	id ke	cal CC							
CC No.	2	CC creat	e Date	15/01/05 15:2	7	Latex lot		47017	
	6	Origin ng/mL]	Back fit [ng/mL]	DA		Or [ne/	igin (mL]	Back fit [ng/mL]	DA
STD-6		1000.0	1002	2775	STD-3		125.0	117	180
STD-5		500.0	495	1186	STD-2	2	62.5	64	75
STD-4		250.0	260	423	STD-1		0.0	0	5
1	2	3	4	5 6	7	8	9	0	-
x	r	Z		/ *	•	-  -	. de	1	enter
							🖊 Can	cel 🔚	Recal
put rang	je is -9	99999 to 99	999.				[]	XX 2015/0	1/05 15:30





3 Edit the data.

1 Touch the input field for the item to edit.

(2) Enter a value.

Explanatory note : The following items can be input through calibration curve editing. STD-1 - STD-5 : DA1 STD-6 : DA1, DA2

4 Touch the {Recal} button.

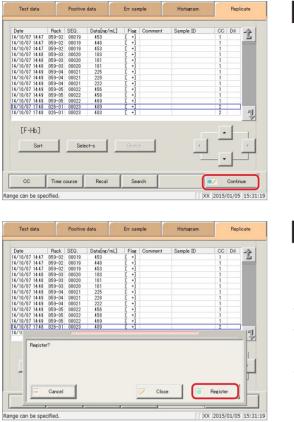
\* The result of recalculating the calibration curve and QC is displayed.

5 Touch the {Continue} button.

6 Touch the {Memory} button.

\* The calibration curve data is saved to memory (it is not registered to the system).

{Memory}:	Save calibration curve data to memory.
{Close}:	Cancel saving to memory, and return to the
	[Replicate] screen.
{Cancel}:	The dialog box closes.



7 Touch the {Continue} button.

8 Touch the {Register} button.

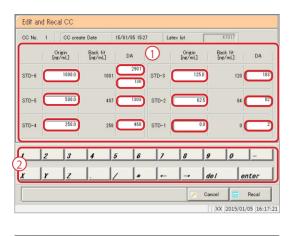
{Register}:	Register the recalculation results.
{Close}:	Cancel registration, and return to the [Replicate]
	screen.
{Cancel}:	The dialog box closes.

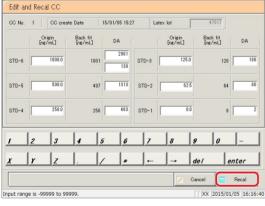
# 3.7 Replicate

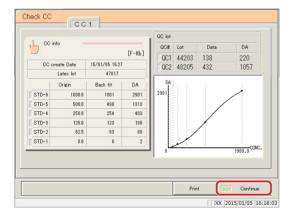
# 3.7.10 Editing/recalculating calibration curves (STD)

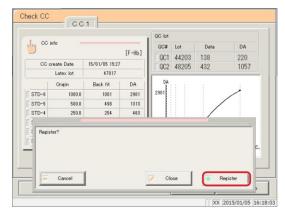
Edit the origin and DA values of the calibration curve, then recalculate or save the recalculated calibration curve to the hard disk(SSD).

	Samp	STAT samp	STD	ac	1 Touch the {STD} tab.
	14/12/17 15:16 14/12/12 15:39 14/12/12 09:27 14/12/10 14:29 14/12/10 14:29 14/12/10 10:12 14/12/10 10:12	14/12/01         13:00         14/11/07         08:1           14/12/01         13:50         14/11/03         16:5           14/11/00         11:55         14/11/03         16:1           14/11/00         11:55         14/11/03         16:1           14/11/00         11:55         14/11/03         16:1           14/11/20         13:2         14/10/11/03         16:1           14/11/27         19:3:2         14/10/16         19:1           14/11/20         13:3:2         14/10/16         19:1           14/11/20         13:3:2         14/10/16         19:1           14/11/20         13:3:2         14/10/16         19:1           14/11/20         13:3:2         14/10/16         19:1           14/11/20         13:3:3         14/10/09         14/11/16           14/11/16         19:5:6         14/10/09         14/11/16           14/11/16         19:5:6         14/10/07         14/11/16           14/11/16         19:5:6         14/10/07         14/11/16           14/11/16         19:5:6         14/10/07         14/11/16           14/11/11/10         19:3:3         14/10/06         17:1           14/11/14	28 26 06 46 35 33 45 08 54 18 52 49 06 Fead again	Close Menu (X) (2015/01/05 [16:13:07	
2	Replicate (STD)           1412         12.40           1412/10         15.40           1412/10         15.40           1412/10         15.40           1412/10         15.50           1412/10         15.50           1412/10         15.50           1412/10         15.50           1412/10         15.51           1412/10         15.51           1412/10         15.51           1412/10         15.51           15.7         1412/10	Back         Inal         Ina?           01-01 ST0-1         2         -1           01-01 ST0-1         2         -1           01-01 ST0-1         1            01-01 ST0-2         84         -1           01-01 ST0-1         2         -1           01-03 ST0-2         84         -1           01-03 ST0-2         84         -1           01-03 ST0-2         82         1           01-03 ST0-2         82         1           01-04 ST0-3         183         11           01-04 ST0-3         183         11           01-04 ST0-3         187         11           01-04 ST0-3         187         11           01-05 ST0-4         463         2	7 2 3 3 3 3 3 3	002 003	<ul> <li>2 Select the calibration curve.</li> <li>① Touch the {CC#} tab.</li> <li>② Select the measurement date and time.</li> <li>③ Touch the {CC} button.</li> <li>* The calibration curve is displayed.</li> </ul>
	Check CC CC create C CC create C STD-6 STD-6 STD-7 STD-7 STD-7 CTD-7 CC Create C STD-7 ST	lot 47017	001 44203 13 002 48205 43 2301 0 0 Print		3 Touch the {CC info} button.









4 Edit the calibration curve.

- 1 Touch the input field for the item to edit.
- (2) Enter a value.

(Explanatory note) : The following items can be input through calibration curve editing. STD-1 - STD-5 : DA1 STD-6 : DA1, DA2

Touch the {Recal} button.

5

6

\* The result of recalculating the calibration curve is displayed.

Touch the {Continue} button.

Touch the {Register} button.

\* The calibration curve was registered.

{Re	gister}:	Register the calibration curve data.
{Cl	ose}:	Cancel registration, and return to the [Replicate
		(STD)] screen.
{Ca	ncel}:	The dialog box closes.

#### 3.7 Replicate

# 3.7.11 Reading/registering calibration curves (samples/STAT samples)

Read calibration curves and display them on the screen, or register displayed calibration curves to other calibration curves (calibration curves are registered to the hard disk(SSD)).

This section describes the procedure from the [Check CC] screen.

Page 197 "3.7.9 Editing/recalculating calibration curves (samples/STAT samples)"

CC info	. –			QC lot	Lot	Data	DA		
			[F-Hb]	QC1		138	220		
CC crea	ate Date	15/01/05 16:19		QC2		432	1057		
I	atex lot	47017				=			
1	Origin	Back fit	DA	DA					
STD-6	1000.0	1001	2901	2901			/		
STD-5	500.0	497	1303			1			
STD-4	250.0	256	468			1			
STD-3	125.0	120	183			1			
STD-2	62.5	64	82		1				
STD-1	0.0	0	2		1 Aller		CONC		
CC1°CC6					Prin		Continue	5:20:01	
		1		_ QC lot	Prir			5:20:01	
eck CC		1		QC lot	Prir			5:20:01	
eck CC		1	[F-Hb]	QC#	Lot	Data	DA	5:20:01	
ock CC	ate Date	15/01/05 16:19			Lot	[ [  XX   2	015/01/05 16	5:20:01	
CC info CC info CC crea	ate Date	15/01/05 16:19 47017		0C# 0C1 0C2	Lot 44203	Data 138	DA 220	5:20:01	
In CC info CC crea	ate Date	15/01/05 16:19		QC2 QC1 QC2 DA	Lot 44203	Data 138	DA 220	5:20:01	
CC info CC crea	ate Date atex lot Origin 1000.0	15/01/05 16:19 47017 Back fit 1001	DA 2901	0C# 0C1 0C2	Lot 44203	Data 138	DA 220	5:20:01	
CC info CC cree CC cree STD-6 STD-5	ate Date atex lot Origin 1000.0 500.0	15/01/05 16:19 47017 Back fit 1001 497	DA 2901 1303	QC2 QC1 QC2 DA	Lot 44203	Data 138	DA 220	5:20:01	
CC crei	ate Date atex lot Origin 1000.0	15/01/05 16:19 47017 Back fit 1001	DA 2901	QC2 QC1 QC2 DA	Lot 44203	Data 138	DA 220	5:20:01	
CC info CC cree STD-6 STD-5	ate Date atex lot Origin 1000.0 500.0	15/01/05 16:19 47017 Back fit 1001 497	DA 2901 1303	QC2 QC1 QC2 DA	Lot 44203	Data 138	DA 220	5:20:01	
CC info CC cree STD-6 STD-5	ate Date atex lot Origin 1000.0 500.0	15/01/05 16:19 47017 Back fit 1001 497 256	DA 2901 1303 468	QC2 QC1 QC2 DA	Lot 44203 48205	Data 138	DA 220	5:20:01	
CC cree CC cree STD-6 STD-4	ate Date	15/01/05 16:19 47017 Back fit 1001 497 256	DA 2901 1303 468	0C#	Lot 44203 48205	Data 138 432	DA 220 1057	2	

Read the calibration curve.

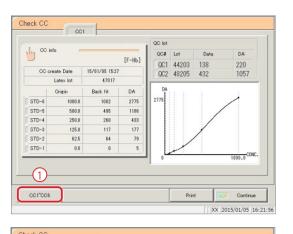
(Calibration curve CC1 is displayed.) ① Touch the {CC1} ~ {CC6} buttons. F-Hb : CC1 ~ CC3

- FCa : CC4 ~ CC6
- (2) Select the calibration curve (CC2 through CC3).
- 3 Check "Reading."
- (4) Touch the  $\{Start\}$  button.
  - \* The calibration curve is read.

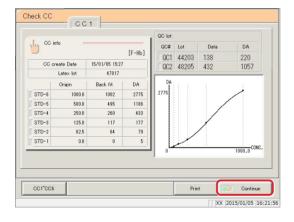
Cancel}: The dialog box closes.

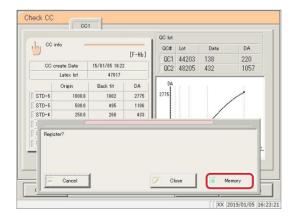
Explanatory note : "Reading" causes the specified calibration curve to be read and displayed on the screen.

Explanatory note : If the reagent lot of the displayed calibration curve differs from that of the calibration curve selected for reading, the calibration curve is not read.



CC inf	,		[F-Hb]	QC#	Lot	Data	DA
CC cre	ate Date	15/01/05 15:27		QC1	44203 48205	138 432	220 1057
	atex lot	47017		602	40200	402	1007
	Origin	Back fit	DA	DA			
STD-6	1000.0	1002	2775	2775			/
STD-5	500.0	495	1186			/	
STD-4	250.0	260	433			1	
		· · · · ·				-	
0 001	O∞	2 🔘 0	C3	0 004		0 005	0 000
Registe	R	O Reading		3)			
-							





2

Register the calibration curve shown on the screen.

(1) Touch the  $\{CC1\} \sim \{CC6\}$  buttons.

- ② Select the calibration curve of the registration destination.
- 3 Check "Register."
- (4) Touch the  $\{Start\}$  button.
  - \* The calibration curve is registered to the hard disk(SSD).
- {Cancel}: The dialog box closes.
- 3 Touch the {Continue} button.

- {Print}: Print the calibration curve.
- 4 Touch the {Memory} button.
  - \* The system returns to the [Replicate] screen.
- {Memory}: Save the calibration curve to memory. {Close}: Cancel saving to memory, and return to the [Replicate] screen. {Cancel}: The dialog box closes.

### 3.7 Replicate

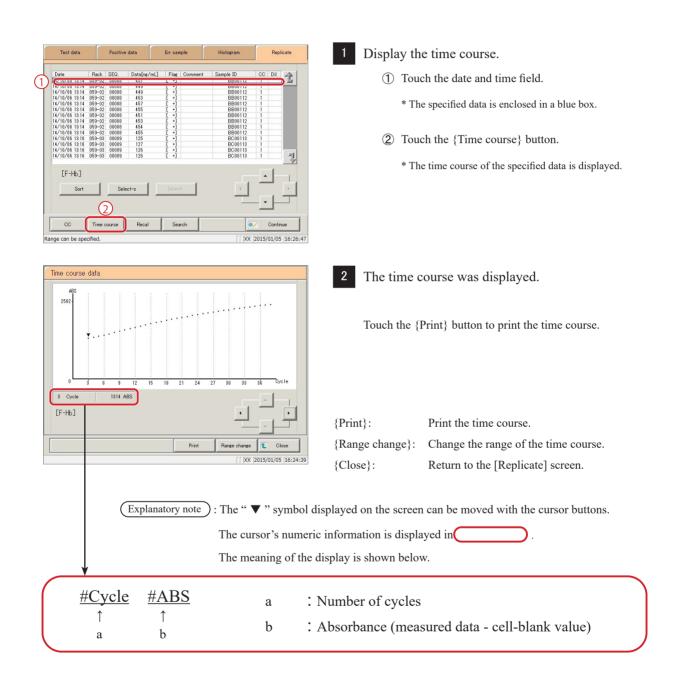
3.7.12 Displaying/printing time courses (samples/STAT samples)

Display the time course of the replicate data (samples/STAT samples).

The time course (graph), number of cycles (cycles), and absorbance (ABS) are displayed on the screen.

This section describes the procedure from the [Replicate] screen.

Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)" 1 through 3



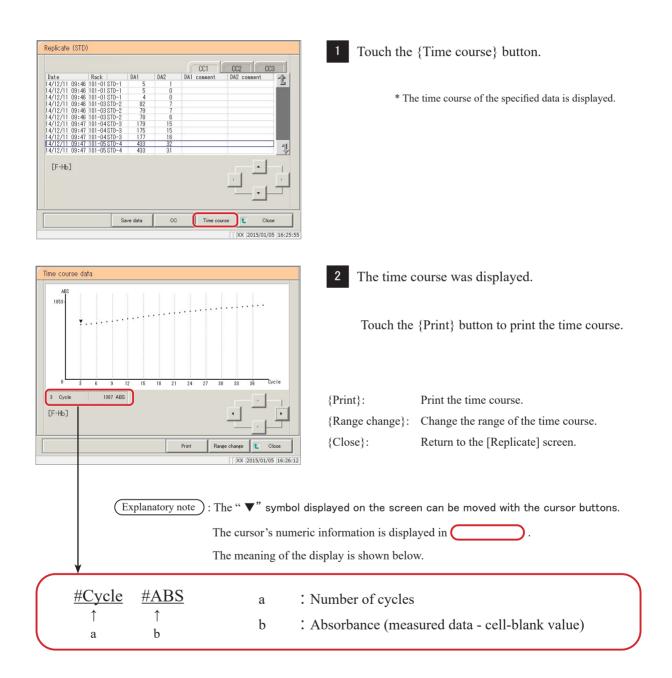
# 3.7.13 Displaying/printing time courses (STD)

Display the time course of the replicate data.

The time course (graph), number of cycles (cycles), and absorbance (ABS) are displayed on the screen.

This section describes the procedure from the [Replicate (STD)] screen.

Page 182 "3.7.2 Displaying the [Replicate (STD)] screen"



#### Replicate 3.7

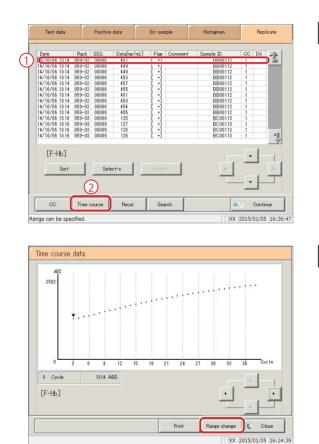
Changing the range of the time course (samples/STAT samples) 3.7.14

Enter the "Max Value" and "Min Value" and change the range on the [Time course data Range change] screen.

This section describes the procedure from the [Replicate] screen.

1 through 3 Page 178 "3.7.1 Displaying the replicate list (samples/STAT samples)"

(Explanatory note): Time course data for which the range has been changed is not saved to the hard disk(SSD).



Display the time course.

1 Touch the date and time field.

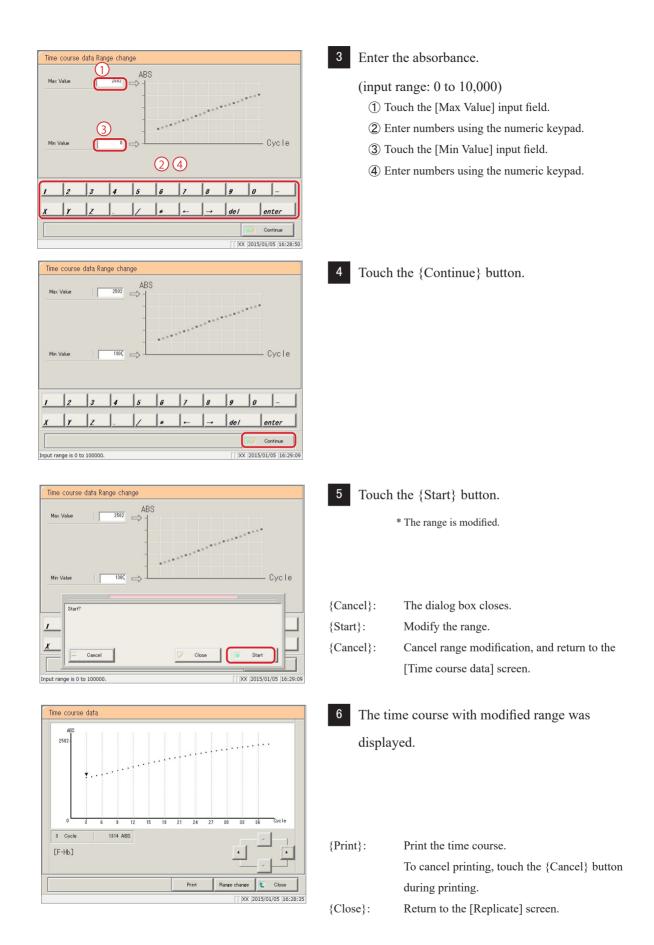
\* The specified data is enclosed in a blue box.

- (2) Touch the {Time course} button.
  - \* The time course of the specified data is displayed.

2

Touch the {Range change} button.

{Print}:	Print the time course.
{Range change}:	Change the range of the time course.
{Close}:	Return to the [Replicate] screen.



NN1-1703 Rev.3

#### 3.7 Replicate

# 3.7.15 Changing the range of the time course (STD)

Enter the "Max Value" and "Min Value" and change the range on the [Time course data Range change] screen.

This section describes the procedure from the [Replicate (STD)] screen.

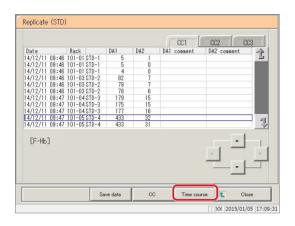
Page 182 "3.7.2 Displaying the [Replicate (STD)] screen"

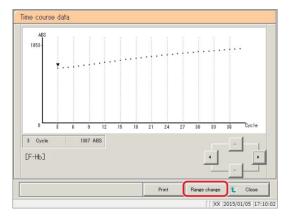
(Explanatory note): Time course data for which the range has been changed is not saved to the hard disk(SSD).

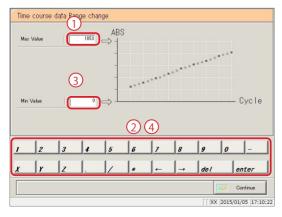
1

2

3







- Display the time course.
  - 1 Touch the date and time field.

\* The specified data is enclosed in a blue box.

(2) Touch the {Time course} button.

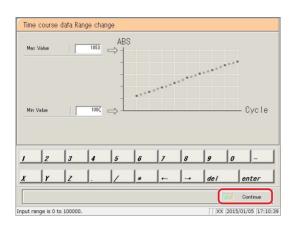
\* The time course of the specified data is displayed.

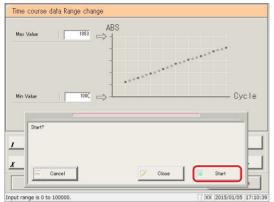
Touch the {Range change} button.

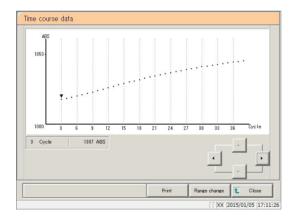
Enter the absorbance.

(input range: 0 to 10,000)

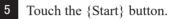
- 1 Touch the [Max Value] input field.
- (2) Enter numbers using the numeric keypad.
- ③ Touch the [Min Value] input field.
- (4) Enter numbers using the numeric keypad.







4 Touch the {Continue} button.



{Start}:	Modify the range.
{Close}:	Cancel range modification, and return to the
	[Time course data] screen.
{Cancel}:	The dialog box closes.

- 6 The time course with modified range was displayed.
- {Print}: Print the time course. To cancel printing, touch the {Cancel} button during printing. {Close}: Return to the [Replicate (STD)] screen.

# 3.8 Quality Control

The QC lot list, inter/intra-day data, and  $\bar{X}-R$  control graph are displayed in quality control. Quality control also allows for editing inter/intra-day data, and changing the range of the  $\bar{X}-R$  control graph.

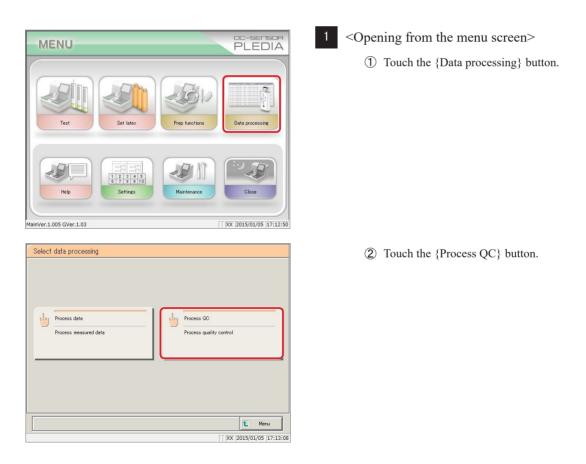
# 3.8.1 Displaying the QC lot list ([QC lot select] screen)

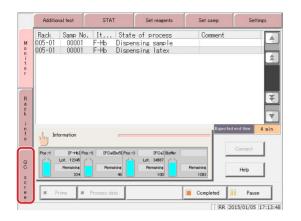
Touch the {Data processing} - {Process QC} buttons from the [MENU] screen, or touch the {Quality control} tab on the [Monitor] screen to display the QC lot list ([QC lot select] screen). (Test items must be selected and the {Start} button must be operated.)

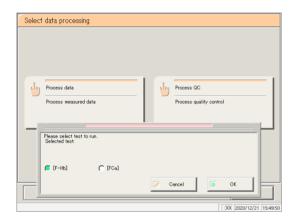
In addition to the {QC lot select} tab, this screen also has {Intra-day/Inter-day} and {X-R control graph} tabs.

Page 210 "3.8.1 Displaying the QC lot list ([QC lot select] screen)"

(Explanatory note) : If there is no measured data, other tabs cannot be switched to from the {QC lot select} tab screen.







$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	QC lot select		Intra-day/	Inter-day	X-R control		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	QC	🔘 QC1	O QC2	0 003			
[F-Hb] How many months' data? I = 2 $J = 2$ $J =$	QC lot						
$\begin{bmatrix} F-Hb \end{bmatrix}$ How many months' data? $\begin{bmatrix} 12 & Mon \\ I & Z & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 0 & - \\ X & Y & Z & . & / & * & \leftarrow & \rightarrow & de1 & enter \\ \end{bmatrix}$	44203 1111	1				1	
$\begin{bmatrix} F-Hb \end{bmatrix}$ How many months' data? $\begin{bmatrix} 12 & Mon \\ I & Z & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 0 & - \\ X & Y & Z & . & / & * & - & de1 & enter \\ \end{bmatrix}$							
How many months' data? $1  2  3  4  5  6  7  8  9  0  -$ $X  Y  Z  .  /  *  \leftarrow  \rightarrow  de1  enter$							
I = 2 = 3 = 4 = 5 = 6 = 7 = 8 = 9 = 0 = - $X = Y = Z = -7 = 4 = 1 = 0$	[F-Hb]				<u></u> _		
$X   Y   Z   .    /    *    \leftarrow    \rightarrow    del    enter$	How many month	hs' data?	12	Mon	· _	Ŀ	
$X   Y   Z   .    /    *    \leftarrow    \rightarrow    del    enter$							
$X   Y   Z   .    /    *    \leftarrow    \rightarrow    del    enter$	1 2	24	5 6	17 10	a   a	1_ 1	
	/ <u>/</u>	3 7	0	1 0	30		
Del Lot setting Continue	x r	Ζ.	/ *		• de l	enter	
	Del	1			t setting	Continue	
[ XX [2015/01/05 ]17:							

<Opening from the monitor screen>

Touch the {QC screen} tab.

Select the analysis items.

○ [F-Hb]

2

- ⊖ [FCa]
  - (1) Check the item ( $\bigcirc$ ).
  - 2 [OK] Touch the button.

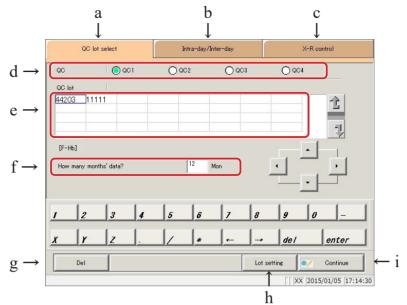
[Cancel] : The dialog box closes.

3 The [QC lot select] screen opened.

- {QC lot select} tab
- {Intra-day/Inter-day} tab
- $\{\bar{X}-R \text{ control graph}\}$  tab

\* The recently used QC lots are displayed in order.

(Displayed from left to right, up to down.)



[Screen]: QC lot select screen

а	QC lot select	The "QC lot list" saved to QC1 through QC4 is displayed.
b	Intra-day/Inter-day	Intra-day and inter-day data for the specified QC# and QC lots are displayed.
с	– X–R control graph	Displays X-R control graphs of intra-day/inter-day data.
d	QC	Select the QC# of the QC lot to display.
e	QC lot	The QC lot of the selected QC# is displayed. Select the QC lot to use.
f	□ Mon	Specify the QC lot to use by in month units. Enter the number of months for data processing.
g	Del	Delete the selected QC lot.
h	Lot setting	The [STD/QC process settings] screen is displayed.
i	Continue	Register the modified data.

3.8 Quality Control

MEMO

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#### 3.8 Quality Control

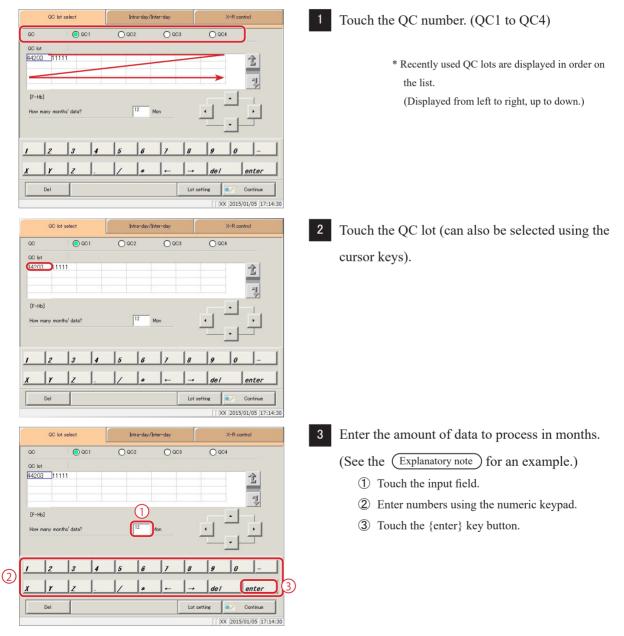
### 3.8.2 Selecting QC lots

Open the [QC lot select] screen to display the QC lot list. The QC number and QC lot selected from this list will be processed on the {Intra-day/Inter-day} and  $\overline{X}$ -R control graph} tabs.

- Page 218 "3.8.5 Opening the [Intra-day/Inter-day] screen"
- Page 228 "3.8.9 Displaying the X-R control graph"

This section describes the procedure from the [QC lot select] screen.

Page 210 "3.8.1 Displaying the QC lot list ([QC lot select] screen)"



 Explanatory note
 : The QC lot list shows data from the month of the latest data to the specified number of months back (from 1 to 36 months, entered in single month units).

 Example 1: "1 mon" entered with June 15 as current date: June 1 to June 15

 Example 2: "3 mon" entered with June 15 as current date: April 1 to June 15

# 3.8.3 Deleting QC lots

Delete QC number-QC lot selected in "3.8.2 Selecting QC lots."

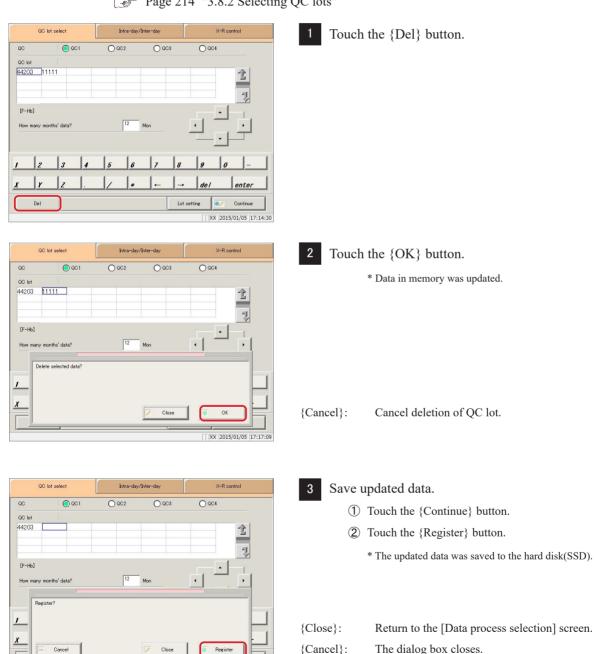
After selecting the QC lot to delete, touch the {Continue} button, then touch the {OK} button in the dialog box.

Data for which QC number-QC lot has been deleted is updated in the hard disk(SSD).

\* If the {OK} button is not touched, the updated data is only in memory, and is not updated in the hard disk(SSD).

This section will explain from the point where the procedure in "3.8.2 Selecting QC lots" 2 has been

completed.



XX 2015/01/05 17:18:0

Page 214 "3.8.2 Selecting QC lots"

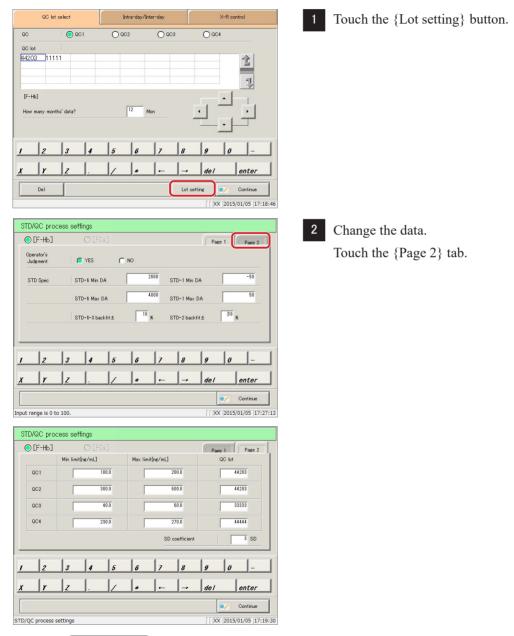
# 3.8.4 Changing STD/QC measurement process settings from the [QC lot select] screen

Pressing the {Lot setting} button on the [QC lot select] screen opens the [STD/QC process settings] screen. From here settings can be changed.

This is the same screen that opens when the {STD/QC process settings} button is touched on the [MENU] - [Settings] - [System settings] screen. However, settings cannot be modified during testing.

This section describes the procedure from the [QC lot select] screen.

Page 210 "3.8.1 Displaying the QC lot list ([QC lot select] screen)"



(Explanatory note): For details on settings, see page 298 "6.1.11 STD/QC analysis process settings"

3.8 Quality Control

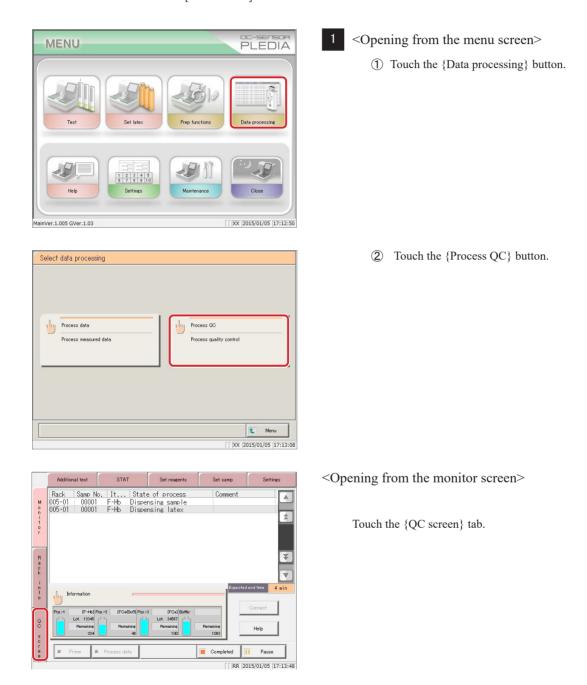
MEMO

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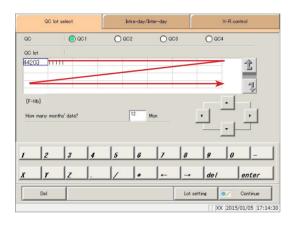
# 3.8.5 Opening the [Intra-day/Inter-day] screen

Touching the {Intra-day/Inter-day} tab on the [QC lot select] screen opens the {Intra-day/Inter-day} screen. The inter/intra-day data of the QC number-QC lot specified on the [QC lot select] screen is displayed.

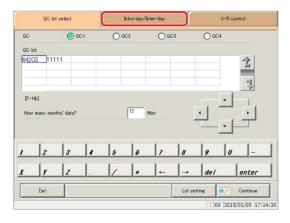
(Explanatory note) : See page 98 "3.1.1 Opening the [Process data] screen" for information on displaying the [Process data] screen.



Additi	onal test	STAT		Set reagents	Set samp	Settings
Rack	Samp No	. It	State	e of process	Comment	
001-10		F-Hb		0 ng/mL		Ľ
001-09		F-Hb		0 ng/mL		-
001-08		F-Hb		6 ng/mL		1
001-07		F-Hb	66	36 ng/mL		
001-06		F-Hb	95	54 ng/mL		
001-05		F-Hb	47	71 ng/mL		
001-04		F-Hb	24	17 ng/mL		
001-03		F-Hb		12 ng/mL		
001-02		F-Hb		31 ns/mL		
001-01	00011	F-Hb		0 ng/mL		
						- I nit
Sele	e select test : cted test F-Hb]	o run.	ia]	Z Cano	iel 💽	ок ]
-			_		J.	
-						



Q	IC lot select		Intra-day/I	nter-day		X-R con	trol
QC	🔘 QC1	0	QC2	0 003	0	QC4	
QC lot	1						
(4203	11111						1
							-1
(F-Hb)						- <u>-</u> -	
How many	months' data?		12	Mon	•	_	·
						- <u>-</u> -	
1 2	3	4 5	6	7	8 9	0	
x y	Z	. /	*	-	→   de		enter
Del					Lot setting	•/	Continue
					[]	XX 2015/0	01/05 17:14:30



- 2 Select the analysis items.○ [F-Hb]
  - ⊖ [FCa]
    - (1) Check the item ( $\bigcirc$ ).
    - ② [OK] Touch the button.

[Cancel] : Moves to the previous screen.

3 The

The [QC lot select] screen opened. \* The recently used QC lots are displayed in order.

(Displayed from left to right, up to down.)

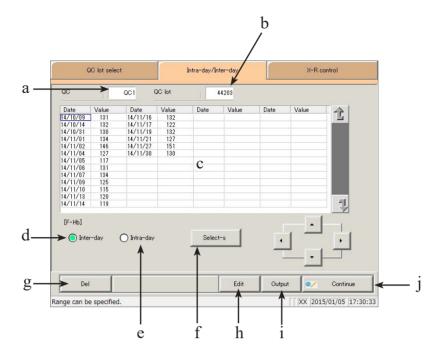
4 Select the QC and QC lot.

Page 214 "3.8.2 Selecting QC lots"

5

Touch the {Intra-day/Inter-day} tab.

\* The [Intra-day/Inter-day] screen is displayed. (See the following page.)



[Screen]: Intra-day/inter-day data

a	QC	The QC (QC1 to QC4) that was specified on the [QC lot select] screen is displayed.
b.	QC lot	The QC lot specified on the [QC lot select] screen is displayed.
с	Quality control data (The measurement date and mean value.)	Inter-day data selectedThe measurement date and mean value of the specified QC/QC lot isdisplayed.Intra-day data selectedThe measurement time and mean value of the specified QC/QC lot isdisplayed.
d	Inter-day	Display the inter-day data (measurement date/mean value).
e	Intra-day	Display the intra-day data (measurement date and time/mean value).
f	{Select-s}	Specify the range of inter-day or intra-day data. The range of data can also be specified using the cursor buttons.
g	{Del}	Delete the specified inter-day or intra-day data.
h	{Edit}	Edit inter-day or intra-day data.
i	{Output}	Output inter-day or intra-day data (printer, external media).
j	{Continue}	Register edited inter-day or intra-day data to the hard disk(SSD). The data [Registration confirmation] screen is displayed; touch the {Register} button.

3.8 Quality Control

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# 3.8.6 Editing (recalculating) inter/intra-day data

Touching the {Intra-day/Inter-day} tab on the [QC lot select] screen opens the {Intra-day/Inter-day} screen. The inter-day or intra-day data of the specified QC number-QC lot is displayed. Select a radio button to switch between inter-day and intra-day data.

Inter-day: Edit each item of intra-day data. Intra-day: Edit each item of replicate data.

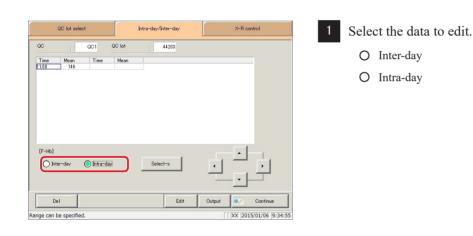
This section will explain from the procedure, having switched from the [QC lot select] screen to the [Intra-day/Inter-day] screen.

\* This assumes that the QC lot has already been selected on the [QC lot select] screen.

Page 218 "3.8.5 Opening the [Intra-day/Inter-day] screen"

(Explanatory note) : If there is no measured data, other tabs cannot be switched to from the {QC lot select} tab screen.

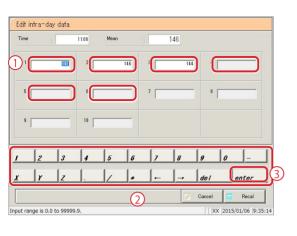
(Explanatory note) : Up to ten measurements may be made per day for a single QC lot and QC number. Results of the 11th or later measurement for the day will not be stored.

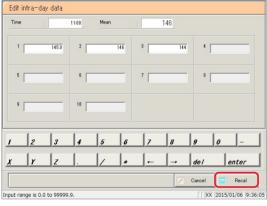


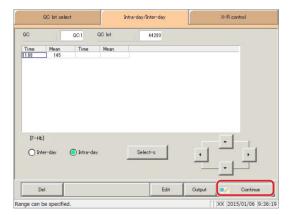
QC lot select	Intra-day/Inter-day	X-R control
QC QC1	QC lot 44203	
Time         Mean         Time           1182         146         146	Mean	
(F-Hb) O Inter-day 💿 Intra-da	Select~s	
Del	Edit	Output 💽 Continue
Range can be specified.		XX 2015/01/06 9:34:55

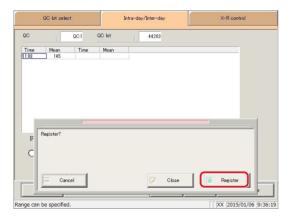
Touch the {Edit} button.

#### 3.8 Quality Control









- 3 Edit inter-day data (or intra-day data). ① Touch the input field for the data.
  - (2) Enter numbers using the numeric keypad.
  - ③ Touch the {enter} key button.

Touch the {Recal} button. 4

- {Cancel}: Cancel editing inter-day or intra-day data. The system returns to the [Intra-day/Inter-day] screen.
- 5
  - Touch the {Continue} button. \* The new mean value is displayed.

6

Touch the {Register} button. \* Recalculated results were registered.

{Close}: Return to the [Data process selection] screen. The dialog box closes. {Cancel}:

# 3.8.7 Deleting inter/intra-day data

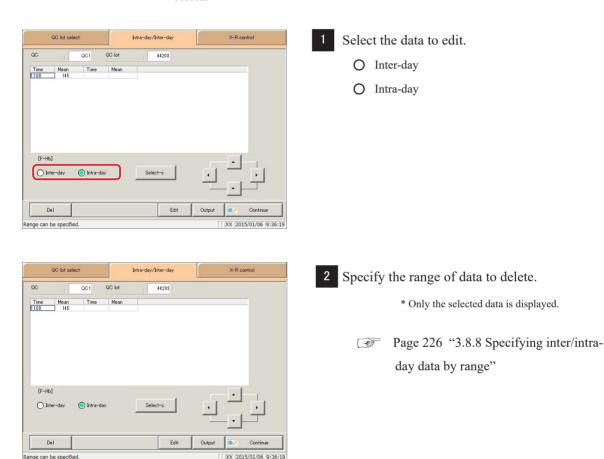
Specify a range of data on the [Intra-day/Inter-day] screen, then delete inter-day or intra-day data. When deleted, specified data will no longer appear on the screen. However, data is not updated until the {Register} button is touched (hard disk(SSD) data is not updated).

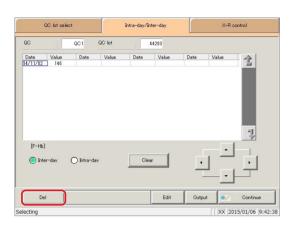
This section will explain from the procedure, having switched from the [QC lot select] screen to the [Intra-day/Inter-day] screen.

\* This assumes that the QC lot has already been selected on the [QC lot select] screen.

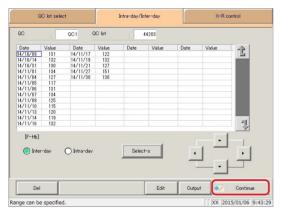
Page 218 "3.8.5 Opening the [Intra-day/Inter-day] screen"

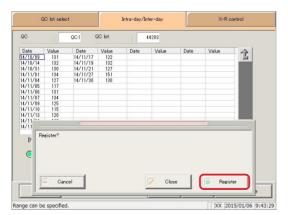
Explanatory note: If there is no measured data, other tabs cannot be switched to from the {QC lot select} tab screen.











3 Touch the {Del} button.



Touch the {OK} button.

\* Data in memory is updated.

\* Data specified on the screen is deleted.

{Cancel}: Cancel the deletion of inter/intra-day data.



Touch the {Continue} button.

6 Touch the {Register} button.

{Close}: Return to the [Data process selection] screen. {Cancel}: The dialog box closes.

# 3.8.8 Specifying inter/intra-day data by range

Specify the data using a measurement date and time range on the [Intra-day/Inter-day] screen (start point/end point).

Use this to delete inter/intra-day data in bulk, or when displaying the X-R control graph.

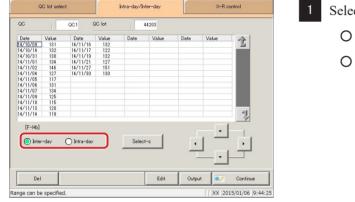
This section will explain from the procedure, having switched from the [QC lot select] screen to the [Intra-day/Inter-day] screen.

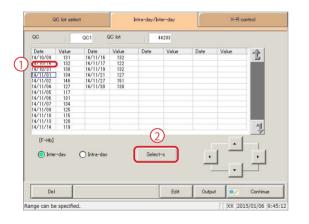
2

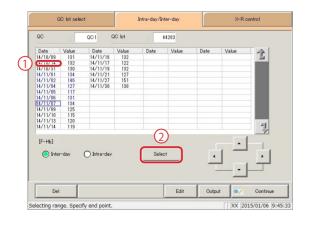
3

 $\ast$  This assumes that the QC lot has already been selected on the [QC lot select] screen.

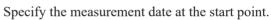
Page 218 "3.8.5 Opening the [Intra-day/Inter-day] screen"







- 1 Select the data to specify.
  - O Inter-day
  - O Intra-day



 Touch the measurement date that will be the start point.

(2) Touch the {Select-s} button.

\* The data at the start point was confirmed.

- \* When the start point is confirmed, the {Select-s} button changes to the {Select} button.
- Specify the measurement date at the end point.
  - Touch the measurement date that will be the end point.
  - (2) Touch the {Select} button.
    - \* The data at the end point was confirmed.
    - \* When the end point is confirmed, the {Select} button changes to the {Clear} button.

{Select-s}:	Confirm start point data for the specified range.
{Select}:	Confirm end point data for the specified range.
{Clear}:	Cancel the range specification.

- Explanatory note: If the data selected for the start and end points is the same, the system will handle it as though only a single sample of data was specified.
- Explanatory note: To specify a new range of data, touch the {Clear} button. All data is displayed, and the system returns to the state it was in before the range was specified.
- (Explanatory note) : If the [X-R control graph] screen is opened without opening the [Intra-day/Inter-day] screen from the [QC lot select] screen first, all data will be specified.

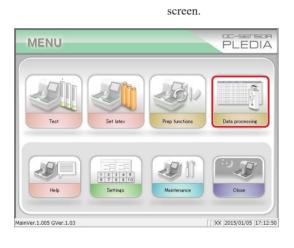
# 3.8.9 Displaying the X-R control graph

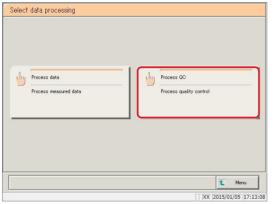
Displays  $\overline{X}$ -R control graphs of intra-day/inter-day data.

If inter-day data is selected on the [QC lot select] screen, the X-R control graph for inter-day data is displayed.

If intra-day data is selected on the [QC lot select] screen, the X-R control graph for intra-day data is displayed.

(Explanatory note) : If there is no measured data, other tabs cannot be switched to from the {QC lot select} tab





	Additional test	STAT	Set reagents	Set samp	Settings
Monitor	Rack Samp N 005-01 00001 005-01 00001	F-Hb Disper	e of process nsing sample nsing latex	Comment	
Rack info	Information			Expected	1
00 %0 <b>~</b> 00	Pos1 (F+b) F Lot. 12345 Remaining 224	Remaining 48	3 [FOa] Buffer Lot. 34567 Remaining 100	Remaining 1083	Connect Help Pause )15/01/05 [17:13:48

<Opening from the menu screen>

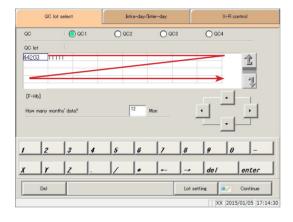
1 Touch the {Data processing} button.

(2) Touch the {Process QC} button.

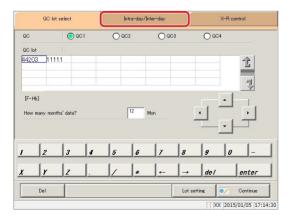
<Opening from the monitor screen>

Touch the {QC screen} tab.

1	Addition	al test	STAT		Set reage	ents	Set samp	Settings	
	Rack	Samp No.	. It	State	of proce	ss	Comment		7
	001-10	00020	F-Hb		0 ng/mL				-
	001-09	00019	F-Hb		0 ng/mL				-
	001-08	00018	F-Hb		6 ng/mL				4
	001-07	00017	F-Hb		6 ng/mL				
	001-06	00016	F-Hb		4 ng/mL				
	001-05	00015	F-Hb		1 ng/mL				
-	001-04	00014	F-Hb		7 ng/mL				
	001-03	00013	F-Hb		2 ng/mL			r	Å
	001-02	00012	F-Hb		1 ng/mL			Þ	-
	001-01	00011	F-Hb		0 ng/mL				
									V
		_						n	in
		select test to red test: -Hb]	run.	a]	Z	Cancel		ок	1
	1	-		_		1			-
							DD	2015/01/05 17:	13



Q	C lot select		Intra-day/Inter-day			X-R control		
QC	🛛 🔘 QC 1	С	QC2	0 003	)	O QC4		
QC lot								
44909	1111						1	
							7	
[F-Hb]								
How many	months' data?		12	Mon	F		F	
						<u> </u>		
1 2	3	4 5	6	7	8	9 0		
x Y	Z	. /	*	-	<b> </b> →	de l	enter	
Del					Lot setti	ne 💌	Continue	
						[ XX 201	5/01/05 17:14:30	



- 2 Select the analysis items.○ [F-Hb]
  - ⊖ [FCa]
    - (1) Check the item ( $\bigcirc$ ).
    - (2) [OK] Touch the button.

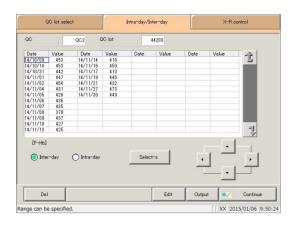
[Cancel] : Moves to the previous screen.

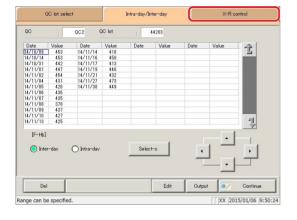
 3 The [QC lot select] screen opened.
 \* The recently used QC lots are displayed in order. (Displayed from left to right, up to down.)

4 Select the QC and QC lot.

Page 214 "3.8.2 Selecting QC lots"

5 Touch the {Intra-day/Inter-day} tab.





40 101	select	Intr	a-day/Inter-day	X-R	K-R control	
QC   QC	02 QC lot	44203	14/10/09	453 ne/mL R	0	
Max Value Min Value		600.0 +3SD 300.0 -3SD	495.3 Mea 376.8	n 436.1	••	
+					UCL	
+3SD	7017	*				
Mean		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	$\bigvee$	$\sim \sim$		
					LCL	
R					LCL	
R R			Λ		LCL	
R			$\overline{\bigwedge}$		LCL	
19	09		$\bigwedge$			
	09		$\bigwedge$	ange change 🚺 💽		

6 Select the data to display an  $\overline{X}$ -R control graph

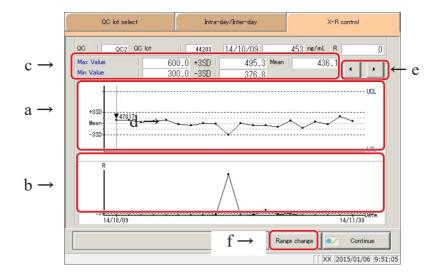
#### for.

Page 226 "3.8.8 Specifying inter/intra-day data by range"

Touch the  $\{X - R \text{ control graph}\}$  tab. 7

The X-R control graph was displayed. 8

(Explanatory note) : An R graph's maximum control limit value is calculated based on the total measurement determined across multiple repeated measurements. If the number of repeated measurements varies, it is calculated based on the total measurement of the smallest number of measurements.



[Screen] : X–R control graph

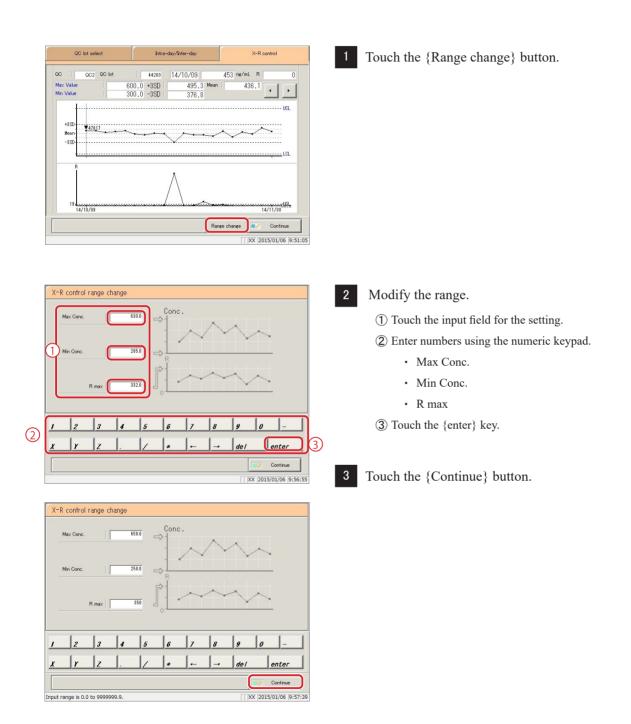
a	– X graph (upper graph)	<ul> <li>Data is displayed for the measurement date and measurement time.</li> <li>The overall mean and ± #SD are displayed.</li> <li>The maximum control limit value (UCL) and minimum control limit value (LCL) set on the [System settings] - [STD/QC process settings] screen are displayed in blue.</li> <li>Data that meets the criteria of less than LCL value + 1 or not less than ULC value + 1 is plotted in red.</li> </ul>
b.	R graph (lower graph)	<ul> <li>A range of data is displayed for the measurement date and measurement time.</li> <li>The R upper limit value is displayed.</li> </ul>
c	Max limit	The maximum control limit value (UCL) set on the [System settings] -     [STD/QC process settings] screen is displayed.
	Min limit	The minimum control limit value (LCL) set on the [System settings] -     [STD/QC process settings] screen is displayed.
	+ #SD	<ul> <li>Calculated + # SD value</li> <li>The standard deviation coefficient (# = 1 to 9) set on the [System settings] - [STD/QC process settings] screen is displayed.</li> </ul>
	- #SD	<ul> <li>Calculated - # SD value</li> <li>The standard deviation coefficient (# = 1 to 9) set on the [System settings] - [STD/QC process settings] screen is displayed.</li> </ul>
	Mean	Calculated mean value
d	▼ (in graph)	<ul> <li>Shows that a calibration curve that was used has changed.</li> <li>The reagent lot is displayed next to the ▼ symbol.</li> </ul>
e	{◀},{►}	• Move the cursor (vertical line) displayed in the graph.
f	{Range change}	• Change the range (maximum concentration, minimum concentration, R maximum) of the $\bar{X}$ -R control graph.

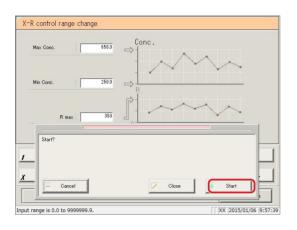
# 3.8.10 Changing the range of the X-R control graph

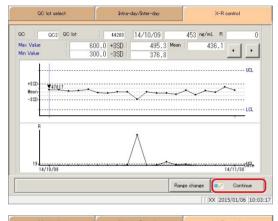
Change the range of the X–R control graph.

This section will begin explaining from the [X-R control graph] screen.

Page 228 "3.8.9 Displaying the X-R control graph"







		elect		Fille	-day/Inter-day				A-R (	control	
QC	_ QC:	QC lot		44203	14/10/09		453	ne/mL	R		0
Max Va Min Val			600.0		495.3			436	8.1	4	
Min Val	liue		300.0	-320	376.8					_	
	· · · · · ·										UCL
+33 Mea		017	~				~		/	~	
-35					$\checkmark$	~	~				
											1.0
											LCL
	Pagintar?										LCL
	Register?										LCL
	Register?										LCL
	Register?										LCL
	Register?										LCL
									0		
	_ 0	Cancel			Ci	DSe			Regis	ster	LCL
	_ 0				Ci	DSe	] (		Regis	ster	

4 Touch the {Start} button. \* The  $\bar{X}$ -R control graph with modified range is displayed.

{Close}:	Cancel range modification, and return to the
	[X–R control graph] screen.
{Cancel}:	The dialog box closes.

#### 5 Touch the {Continue} button.

	-
6	Tou

#### uch the {Register} button.

\* The  $\bar{X}$ -R control graph is registered.

\* The system returns to the [Data process selection] screen.

{Close}:	Cancel $\bar{X}$ -R control graph registration, and
	return to the [Data process selection] screen.
{Cancel}:	The dialog box closes.

# 3.9 Rack info

Touch the {Rack info} button on the [Test] screen or [Monitor] screen to confirm rack information, change trays, and more.

<Available functions on the rack information screen>

- Analytical information about the rack on the rack discharge unit
- Type of measured rack (STD/QC rack, retest rack, dilute test rack, sample rack)
- Rack position number
- Sample status display (error, OR/PRC, positive, normal, unfinished, unset)
- Rack information printing
- Tray (optional) replacement

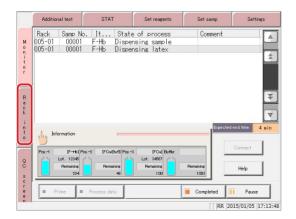
 Explanatory note
 : Rack information for up to 500 racks can be stored after the system is started (up to 25 racks can be displayed). This rack information is deleted if the power is turned off (rack information remains if power is lost due to a power outage or the like).

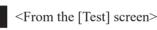
## 3.9.1 Displaying the [Rack info] screen

Touch the {Rack info} tab and display rack information.

This section will explain from the [Test] screen and [Monitor] screen.

Test Set latex	Rack info Settings
Test mode	[F-Hb] Pos-
Sample No. G 🔺 -SEQ 🗐	[FCa] Pos 3 ←CC No. 4
Numbering  Mode 1  Mode 2	Latex for CC
Sample barcode  VES  NO	[F-Hb] Pos 1 →CC No. 1 [FCa] Pos 3 →CC No. 4
Method 🔘 1 day 🔿 2 day 🔿 3 day	Information
Measure mode  Test	Pos1 (F-Hb) Pos2 (FCa(But)) Lot. 12345
Test start point	Remaining Remaining 234 48
(Position in rack)	Pos3 [FCa] Buffer Lot. 34567
	Remaining Remaining 100 1105
Start Test setting	T Menu
	XX 2020/07/09 11:07:07

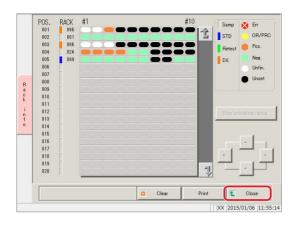




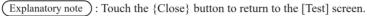
Touch the {Rack info} tab.

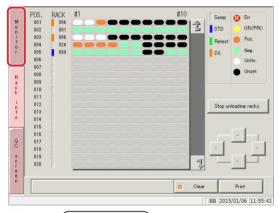
<From the [Monitor] screen>

Touch the {Rack info} tab.



2 The [Rack info] screen was displayed. \* Information about the rack that was last discharged is displayed at the top of the screen.





(Explanatory note): Touch the {Monitor} tab to return to the [Monitor] screen.

b a	b a I I
R 003 004 005 006 007 007 007 008 007 007 008 009 009 009 009 009 009 009 009 009	Samp       Fr         OF/PRC       003       003       004       003       004       005       005       001 <t< th=""></t<>
a Rack info White × in a red background	Analytical information about the rack on the rack discharge unit Error (including sample barcode reading errors and order errors)
Yellow	OR/PRC
Yellowish orange	Positive sample
Light green	Normal sample
White	Unfinished
Black	Unset
b RACK No.	Rack number and measurement rack (displayed to left of rack number)
Gray	Sample rack (normal)
Blue	STD/QC rack
Green	Retest rack
Orange	Dilute test rack
c {Stop unloading racks.} Or, {Restart unloading racks.}	<ul> <li>Change the tray.</li> <li><procedure> <ul> <li>(1) Touch the {Stop unloading racks.} button.</li> <li>When touched it changes to {Restart unloading racks.}.</li> <li>(2) Remove the rack discharge unit tray.</li> <li>(3) Place an empty tray in the rack discharge unit.</li> <li>(4) Touch the {Restart unloading racks.} button.</li> </ul> </procedure></li> </ul>
d {Clear}	Delete rack information.
	<procedure> (1) Touch the {Clear} button.</procedure>
	<ul><li>(1) Fouch the {OK} button in the confirmation dialog box.</li></ul>
( <b>D</b> ' 4)	(Touching the {Cancel} button cancels rack information deletion.)
e {Print}	Print rack information.
f {Close}	Return to the [Test] screen.

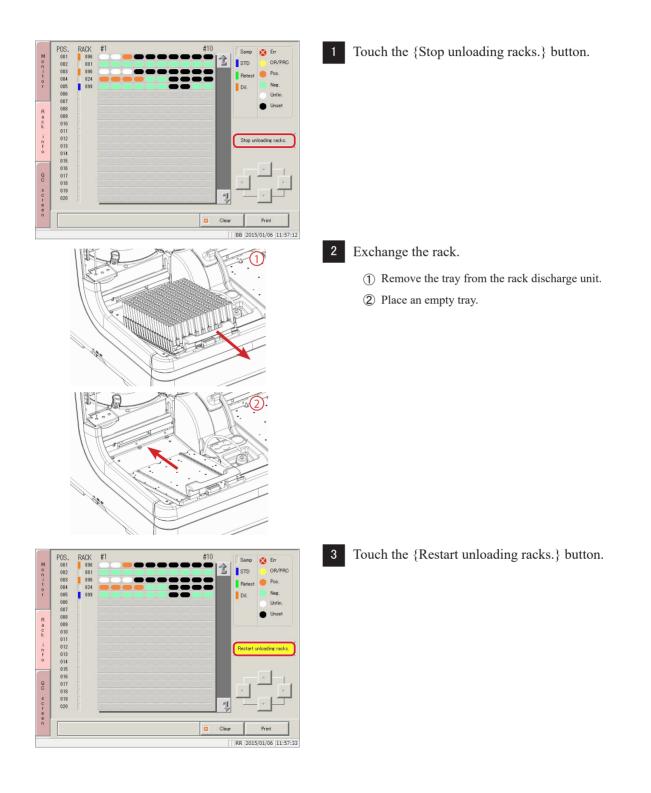
Explanatory note : If "Numbering" is set to "NO" in [Test] - [Request test/select operation], Unset (white) is displayed as an error (× in red).

### 3.9.2 Replacing trays (optional)

When a tested rack has been discharged to the rack discharge unit, replace it with an empty tray and clear the "rack information."

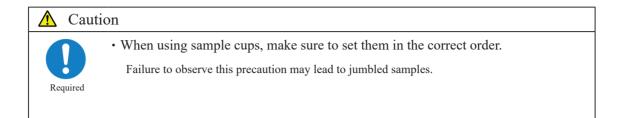
This section will begin explaining from the [Rack info] screen.

Page 234 "3.9.1 Displaying the [Rack info] screen"



# 3.10 Measuring Using Sample Cups

The following settings must be changed when measuring samples using sample cups.



#### Modification of rack number settings

Cups will stick out of a normal sample rack, so a wide rack (STD rack or dilute test rack) must be used.

Some rack number settings will need to be changed on the [Rack/QC sequence No. settings] screen to use STD racks or dilute test racks.

Page 272 "6.1.3 Rack No./QC No."

Modification of sample barcode settings

Sample barcode labels cannot be affixed to sample cups. Set "Sample barcode" to "NO" on [Samp barcode settings] - [Common]. MEMO

# Chapter 4 Support Functions

- 4.1 Initialization
- 4.2 Priming
- 4.3 Cell Blanking
- 4.4 Washing



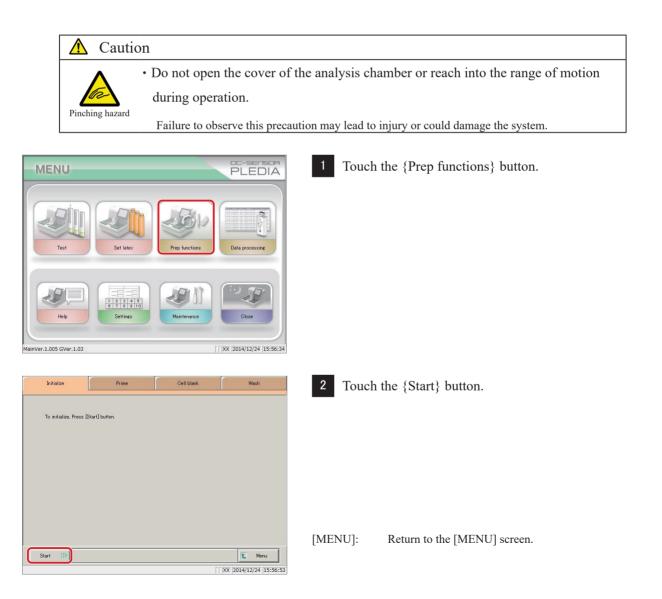
# Chapter 4 Support Functions

# 4.1 Initialization

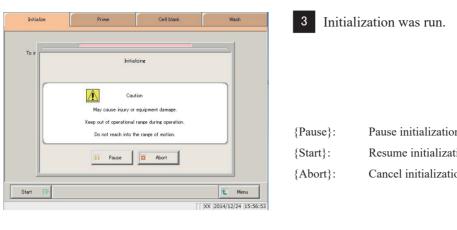
Initialize (move to standby position) each system component. The following components are initialized:

Sample nozzle	Reagent nozzle	Cell washing nozzle
• Mixer	Reaction table	
Puncturing system	Squeezing system	
• Supply bar	Conveyance bar	Discharge bar

Touch the {Prep functions} button on the [Menu] screen to display the [Initialize] screen.



#### 4.1 Initialization



Initialize	Prime	Cell blank	Wash
To initialize, Press [S	itart] button.		
Start 🏢			😢 Menu
			XX 2014/12/24 15:56:53

{Pause}:	Pause initialization.
{Start}:	Resume initialization.
{Abort}:	Cancel initialization.



4 Initialization completed.

# 4.2 Priming

There are two kinds of priming. "Normal prime" removes air bubbles in the piping, while "pipe line activation" introduces buffer, wash solution, and purified water into piping.

Normal prime:	Used to remove air bubbles in the piping.
	Also used when the system has been left unused for a while.
Pipe line activation:	Used to introduce buffer, wash solution, and purified water into piping.
	P.P

Page 44 "2.4.7 Priming (normal prime/pipe line activation)"

# 4.3 Cell Blanking

Run cell blanking to wash cells and evaluate them on a pass/fail basis.

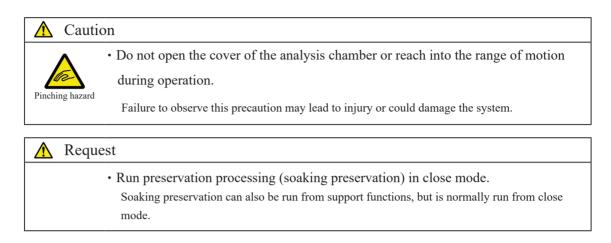
If "Cell blank" is checked in "Auto start" in close mode, cell blank measurement will be automatically run when the system starts.

Page 48 "2.4.8 Measuring cell blanks"

Page 90 "2.6.1 Close mode"

# 4.4 Washing

Touch the {Wash} tab on the [MENU]-[Prep functions] screen to display the [Wash] screen. Select the wash part and preservation processing (soaking preservation), then touch the {Start} button. Washing of each part begins.





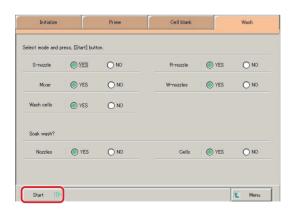


Initialize	Prime	Cell blank	Wash
ect mode and press. [Start] b	utton.		
S-nozzle	O NO	R-nozzle OYES	5 O NO
Mixer OYES	O NO	W-nozzles OYES	
Wash cells OYES	O N0		
Soak wash?			
Nozzles OYES	O N0	Cells OYES	S O NO
Start 顺			Menu 2014/12/24 16:00

3 Select whether or not to wash each part ("YES"

or "NO").

Wash Part	Range/Selection	Details
Washing		
S-nozzle (Sample nozzle)	YES:	Wash sample nozzle.
	NO:	Do not wash sample nozzle.
R-nozzle (Reagent nozzle)	YES:	Wash reagent nozzle.
	NO:	Do not wash reagent nozzle.
Mixer	YES:	Wash mixer.
	NO:	Do not wash mixer.
W-nozzles	YES:	Wash cell washing nozzle.
(Cell washing nozzle)	NO:	Do not wash cell washing nozzle.
Wash cells	YES:	Washes measurement cells.
	NO:	Do not wash measurement cells.
Preservation processing		
Nozzles	YES:	Run soaking preservation for nozzles and mixer.
	NO:	Do not run soaking preservation for nozzles and
		mixer.
Cells	YES:	Run soaking preservation for measurement cells.
	NO:	Do not run soaking preservation for measurement
		cells.



4 Touch the {Start} button.

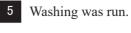
[MENU]: Return to the [MENU] screen.

(Explanatory note): Soaking preservation of measurement cells is a process where residual liquid in cells is

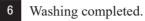
absorbed using the washing nozzle, then the cell is filled with purified water using the sample nozzle.



	Prime		Cell blank		Wash
ress, [Start] butt	on.				
O YES	O NO		R-nozzle	YES	O NO
O YES	O NO		W-nozzles	YES	O NO
TES (	O NO				
YES	O NO		Cells	O YES	O NO
					1 Menu
	VES	ress. [Ster1] button.	Image: Start Jourton.           Image: Start Jourton.	Image: Start button.           Image: Start button.	Image: Start] button.           Image: Start] button.           Image: Start] Start]           Image: Start]



{Pause}:	Pause washing.
{Start}:	Resume washing.
{Abort}:	Cancel washing.



# Chapter 5 Maintenance

- 5.1 Inspection/maintenance
- 5.2 List of Parts to Check and Exchange



# Chapter 5 Maintenance

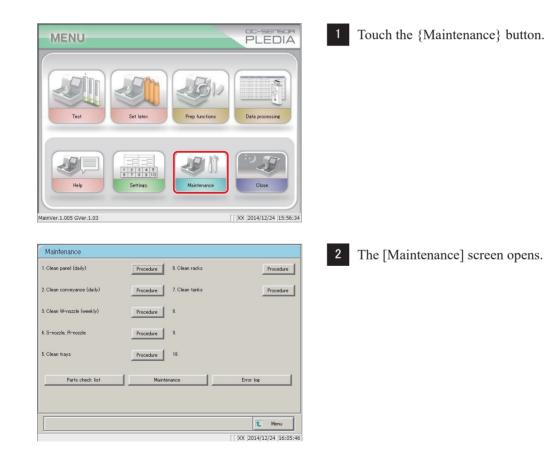
# 5.1 Inspection/maintenance

The [Maintenance] screen displays inspection and maintenance items to run at each frequency (daily, weekly, monthly).

Touch the {Procedure} button to reference inspection and maintenance procedures.

# 5.1.1 Opening the [Maintenance] screen

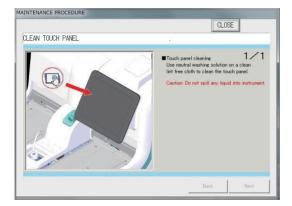
Touch the {Maintenance} button on the [MENU] screen to open the [Maintenance] screen.



# 5.1.2 Clean touch panel (daily)

Touch the {Procedure} button to the right of [1. Clean panel (daily)] on the [Maintenance] screen to display the cleaning procedure.

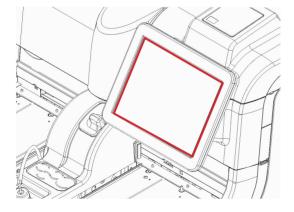
Maintenance		
1. Clean panel (daily)	Procedure 6. Clean racks	Procedure
2. Clean conveyance (daily)	Procedure 7. Clean tanks	Procedure
3. Clean W-nozzle (weekly)	Procedure 8.	
4. S-nozzle, R-nozzle	Procedure 9.	
5. Clean trays	Procedure 10.	
Parts check list	Maintenance	Error log
		1 Menu
		XX 2014/12/24 16:05:46



#### Procedure

Use "LCD panel cleaner" to wipe the touch panel clean. If "LCD panel cleaner" is not available, use a cloth that has been soaked in mild detergent to wipe the panel clean.

Caution: Wring the cloth out thoroughly.



{Close}: Return to the [Maintenance] screen.

#### 5.1 Inspection/maintenance

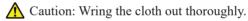
### 5.1.3 Clean conveyance line (daily)

Touch the {Procedure} button to the right of [2. Clean conveyance (daily)] on the [Maintenance] screen to display the cleaning procedure.

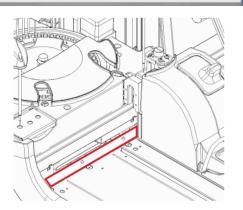
Maintenance			
1. Clean panel (daily)	Procedure	6. Clean racks	Procedure
2. Clean conveyance (daily)	Procedure	7. Clean tanks	Procedure
3. Clean W-nozzle (weekly)	Procedure	8.	
4. S-nozzle, R-nozzle	Procedure	9.	
5. Clean trays	Procedure	10.	
Parts check list	Mainter	nance	Error log
			t Menu
			[ XX 2014/12/24 16:05:46
MAINTENANCE PROCEDURE			
CLEAN CONVEYANCE LINE			CLOSE
CLEAN CUNVEYANCE LINE			
		Use neutr	ice line cleaning 1 1 1 al detergent on a clean cloth to conveyance line.
		Caution: E	Do not spill any liquid into instrument.

#### Procedure

- 1 Soak a soft cloth in mild detergent.
- ② Use the cloth from ① to wipe the conveyance line clean (the area enclosed in the red box in the diagram to the left).



{Close}: Return to the [Maintenance] screen.



# 5.1.4 Clean washing nozzle (weekly)

Touch the {Procedure} button to the right of [3. Clean W-nozzle (weekly)] on the [Maintenance] screen to display the cleaning procedure.

Maintenance	
1. Clean panel (daily) Procedure 6. Clean racks Procedure	
2. Clean conveyance (daily) Procedure 7. Clean tanks Procedure	
3. Clean W-nozzle (weekly) Procedure 8.	
4. S-nozzle, R-nozzle 9.	
5. Clean trays Procedure 10.	
Parts check list Maintenance Error log	
t Meru	
[ ] [XX  2014/12/24  16:05:46]	
MAINTENANCE PROCEDURE	
CLOSE	Procedure
CLEAN WASHING NOZZLES	(1) Soak a soft cloth in ethanol.
Washing Nozzle cleaning L 1 Use a clean cloth with a cloha to clean the first 20mm of the nozzle edge.	② Use the cloth from ① to wipe the area around
Caution Do not spill any liquid into instrument Caution The nozele edge is sharp, use caution when clearing.	mm from the tip of the washing nozzle clean.
	min nom me up of the washing hozzle clean.
the first 20mm of the nozzle edge	<b>A</b> Caution: Wring the cloth out thoroughly.
Back Next	🛕 Caution: Be especially careful when handling th
	washing nozzle.
M. M. Cila	The tip of the nozzle is sharp and could cause injury.
	1
	{Close}: Return to the [Maintenance] screen.

#### 5.1 Inspection/maintenance

# 5.1.5 Clean sample & reagent nozzles (weekly)

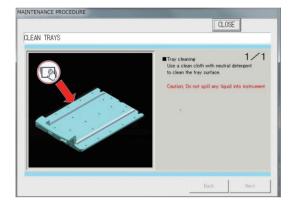
Touch the {Procedure} button to the right of [4. S-nozzle, R-nozzles] on the [Maintenance] screen to display the cleaning procedure.

Maintenance	
1. Clean panel (daily) Procedure 6. Clean racks Procedure	
2. Clean conveyance (daily) Procedure 7. Clean tanks Procedure	
3. Clean W-nozzle (weekly) Procedure 8.	
4. S-nozzle 9.	
5. Clean trays Procedure 10.	
Parts check list Maintenance Error log	
[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]	
MAINTENANCE PROCEDURE	Procedure
CLOSE	Contraction of the state in state of the second state of the se
Dispense nozzle cleaning 1/1 Use a clean cluth with alcohol to clean	① Soak a soft cloth in ethanol.
Use a clear costri wiri accino to clean the first 20min of the nozzle edge. Caution: Do not spill any liquid into instrument	(2) Use the cloth from (1) to wipe the area around 20
Caution: Do hot spin any notability and the section of the caution in the nozele edge is sharp, use caution when cleaning.	mm from the tip of the sample nozzle and reagen
	nozzle clean.
The first 20mm of the nozzle edge	
Back Next	A Caution: Wring the cloth out thoroughly.
	A Caution: Be especially careful when handling the
	sample nozzle and reagent nozzle.
	The tip of the nozzle is sharp and could cause injury.
	{Close}: Return to the [Maintenance] screen.
Sample nozzle	
	2
Reagent nozzle	
20m	
20m	

## 5.1.6 Clean tray (weekly)

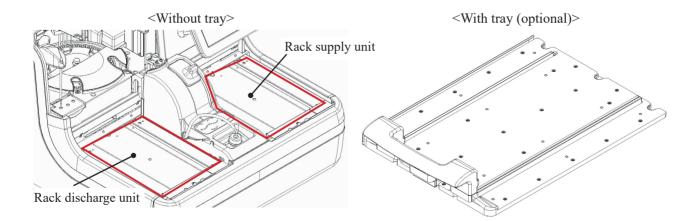
Touch the {Procedure} button to the right of [5. Clean trays] on the [Maintenance] screen to display the cleaning procedure.

	Maintenance		
	1. Clean panel (daily)		Procedure
4. S-mozzle, R-mozzle 9. 5. Clean trays 9. 10. Parts check list Maintenance Error log Menu	2. Clean conveyance (daily)	Procedure 7. Clean tanks	Procedure
5. Clean trays Procedure 10. Parts check list Maintenance Error log	3. Clean W-nozzle (weekly)	Procedure 8.	
Parts check list Maintenance Error log	4. S-nozzle, R-nozzle	Procedure 9.	
E Menu	5. Clean trays	Procedure 10.	
	Parts check list	Maintenance	Error log
			🛍 Menu
XX 2014/12/24 10:03			XX 2014/12/24 16:05:46



#### Procedure

- 1 Soak a soft cloth in mild detergent.
- ② Use the cloth from ① to wipe the rack supply/ discharge unit and tray surface clean.
- ▲ Caution: Wring the cloth out thoroughly.

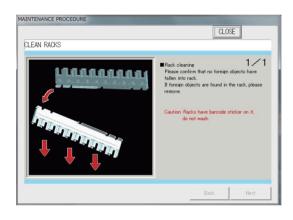


#### 5.1 Inspection/maintenance

### 5.1.7 Clean racks (weekly)

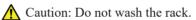
Touch the {Procedure} button to the right of [6. Clean racks] on the [Maintenance] screen to display the cleaning procedure.

Maintenance		
1. Clean panel (daily)	Procedure 6. Clean rack	rs Procedure
2. Clean conveyance (daily)	Procedure 7. Clean tank	(S Procedure
3. Clean W-nozzle (weekly)	Procedure 8.	
4. S-nozzle, R-nozzle	Procedure 9.	
5. Clean trays	Procedure 10.	
Parts check list	Maintenance	Error log
		1 Menu
		XX 2014/12/24 16:05:46

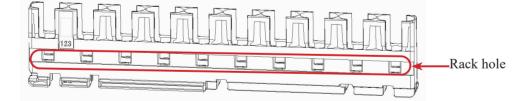




- (1) Check that there are no foreign objects in the rack holes.
- ② If there are any foreign objects, remove them (for example, by turning the rack over and shaking it).



Doing so could cause the barcode affixed to the rack to peel off.



#### 5.1.8 Clean tank (monthly)

Touch the {Procedure} button to the right of [7. Clean tanks] on the [Maintenance] screen to display the cleaning procedure. Clean the tank once per month.

Maintenance				
1. Clean panel (daily)	Procedure	6. Clean racks	P	rocedure
2. Clean conveyance (daily)	Procedure	7. Clean tanks		rocedure
3. Clean W-nozzle (weekly)	Procedure	8.		
4. S-nozzle, R-nozzle	Procedure	9.		
5. Clean trays	Procedure	10.		
Parts check list	Mainte	nance	Error log	
			L	Menu
			XX 2014/12/2	24 16:05:46



#### Procedure

<Normal cleaning>

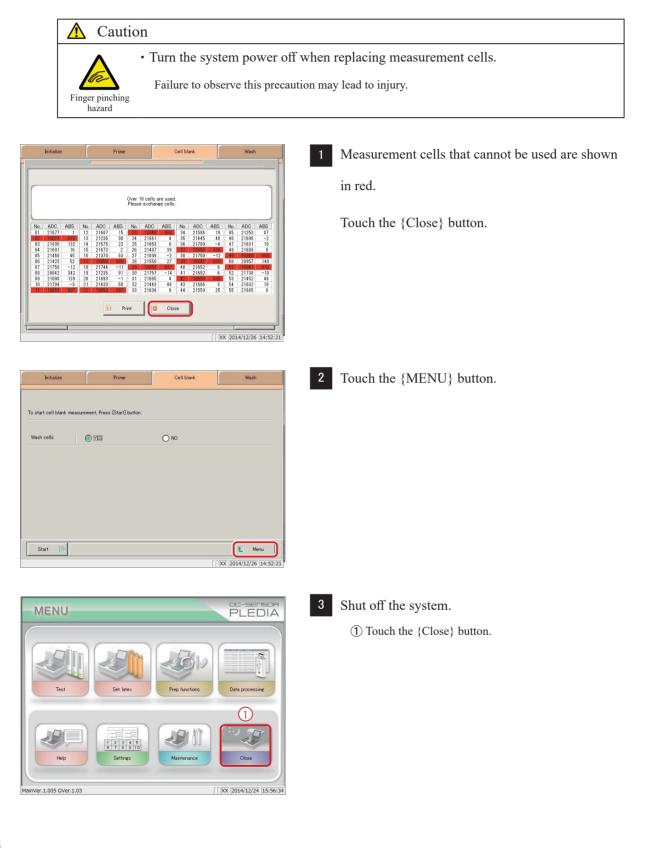
After thoroughly cleaning the tank with tap water, rinse it lightly with distilled water.

<If tank is extremely dirty>

- 1 Clean the tank thoroughly with tap water.
- Fill the tank with tap water and LX wash solution. Tap water: 2 L, LX wash solution: 20 mL
- ③ Close the tank lid tightly and shake the tank (if very dirty, set it aside for around one hour).
- ④ Rinse the tank thoroughly with tap water, so that no wash solution remains.
- (5) Rinse the tank lightly with distilled water.

# 5.1.9 Replacing measurement cells (when cell blank value is abnormal)

When 10 or more measurement cells can no longer be used during cell blank measurement, "There are more than 10 unclean measurement cells. This could reduce processing performance. Replace the measurement cells" is displayed. Follow the procedure below to replace the measurement cells.



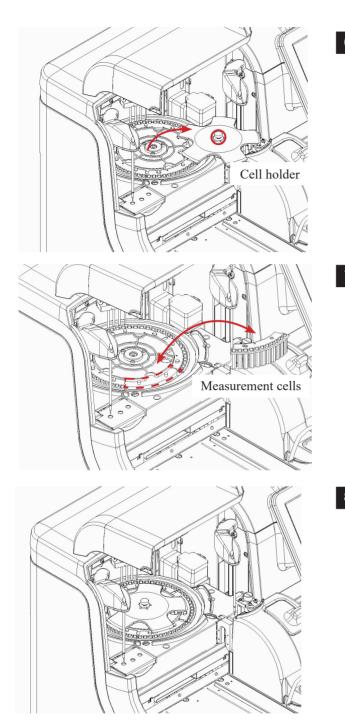
- (2)Close mode Cell was OIYES N0 Exchange () YES () NO () YES 🔘 NO of auto start SU C-blar Test MO NO ( C-blank Test TU Test C-blan WE NO C-blank Test TH Test ) NO C-blank FR SA Test Test NO NO C-blank ) C-blank () NO 3 Long su: Contin XX 2014/12/26 14:5 Close mode Cell wash OYES N0 Exchange () YES O NO () YES O NO of auto start ) C-blank se confirm that DI w ient volume and the drai WE TH FR SA (4)Start Cancel Close XX 2014/12/26 14:54:0 YMMMA 1 Spe Reaction table Sample nozzle Reagent nozzle X 1 Light blocking cover
- ② Select "NO" for "Cell wash," "Exchange buffer and wash sol to p. water" and "Nozzle/cell soak wash."
- 3 Touch the {Continue} button.

(4) Touch the  $\{Start\}$  button.

4 If the sample nozzle and reagent nozzle are on the reaction table, move them by hand so as to not hinder work.

5 Remove the light blocking cover.

#### 5.1 Inspection/maintenance



6 Remove the cell holder.

- ① Loosen the screw.
- 2 Remove the cell holder.

#### 7 Replace the measurement cells.

- ① Remove the dirty measurement cells.
- ② Set the new measurement cells.

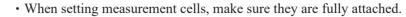
\* Replace all five.

8 I1

Install the cell holder and light blocking cover in order to their original locations.

Follow the removal procedure in reverse to install the parts.

#### \Lambda Caution



Failure to observe this precaution may impact measurement results.

#### 🚹 Caution



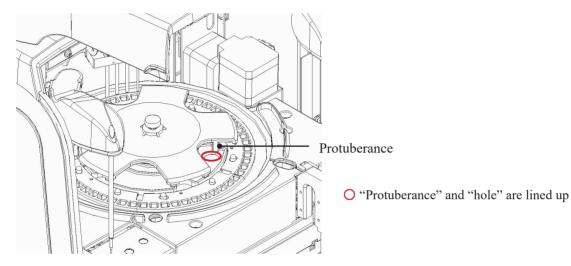
Required

• When setting the cell holder, install so that the cover is pinched by the reaction table fixing screw.

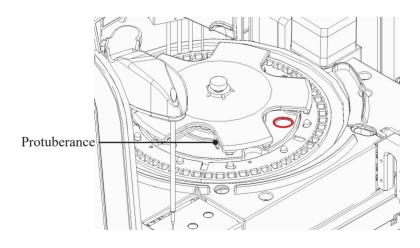
table fixing screw.

If the fixing screw is covered by the cover the system will be unable to measure properly.

<Example: acceptable installation>



<Example: poor installation>



\* "Protuberance" and "hole" are not lined up

# 5.2 List of Parts to Check and Exchange

The [Parts check list] screen displays registered parts, when they were last changed, the number of months they were used, and how many times they have been used.

# 5.2.1 Opening the [Parts check list] screen

Touch {Parts check list} on the [Maintenance] screen to open the [Parts check list] screen. The line for parts that need to be changed (that have exceeded the set number of usage months or number of uses) are displayed in yellow.

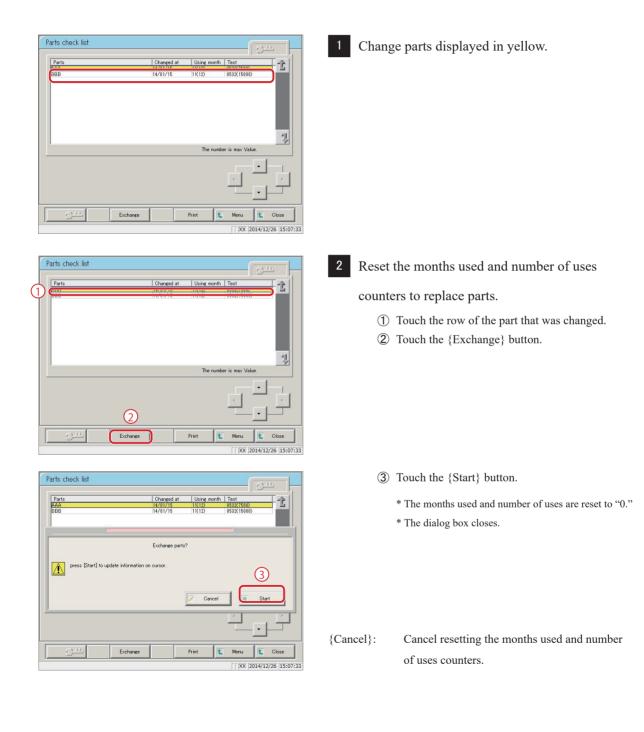


(Explanatory note): The rows of parts that need to be changed turn yellow.

#### 5.2.2 Changing parts

Change parts that need to be replaced.

This section describes the procedure from the [Parts check list] screen.



MEMO

# Chapter 6 Settings

- 6.1 System settings
- 6.2 Protocol settings



# Chapter 6 Settings

# 6.1 System settings

In order to use the system for the first time, the system settings must be configured. Once set, settings will not need to be touched during everyday analysis unless changes are made. See page 32 "2.3.1 System settings" for an overview of "system settings" items.

## 6.1.1 Sample barcode settings (common)

Set common setting items for reading sample barcodes.



Touch the {Settings} button.

(Explanatory note): The [System settings] screen can also be displayed by touching the {Settings} button on the [Test] screen.

System settings			Protocol setting	5
Barcode Sample barcode settings	Rack No/QC STD/QC Rack No. se QC No. settings		Date and time, a supply and drain	sample water
Destination, online	Output format		Alarm Alarm	
Screen saver Screen saver settings	STD/QC Process STD/QC	tings	Cup scale setti Select sample o	res
	Back up	Restore	Print	L Menu

2 Touch the {Barcode} button.

Common Code39	ΠF		JAN	NW-7	IND20	f5   Co	ode 128	Coop2of5
Sample barcode	6	YES	C NO					
Duplicated check		YES	🖉 NO					
Decode accord times		10						
2 3	4	5	6	7	8	9	0	-
2 3 Y Z	4	5	6	7  ←	<i>8</i>  →	g de l	1.	

3 Configure the settings in the {Common} tab.

Setting	Choice/Setting	Details
Sample barcode	YES:	Barcodes are affixed to samples.
	NO:	Barcodes are not affixed to samples.
Duplicated check		From when the system starts up to when the power is
		turned off:
	YES:	<u>Check</u> whether a sample with the same barcode has
		already been read.
	NO:	Do not check whether a sample with the same
		barcode has already been read.
		However, even if this is set to "YES" duplicated
		check is not performed when the measure mode is
		"retest" or "dilute test."
Decode accord times	Numerical input	The recommended value is around ten times.

(Explanatory note): Decode accord times

When reading a sample barcode, the sample ID barcode reader scans the barcode a maximum of 500 times. The number of times the barcode was read correctly is called the number of decode times.

"Decode accord times" is the number of times a barcode must be read for the system to determine that the barcode has been read correctly.

Increasing the number of decode accord times can prevent misreading barcodes, but increases the frequency of "barcode reading errors."

Samp barcode setting	]\$				
Common Code39	TTF	JAN NW-7	IND2of5	Code 128	Coop2of5
Sample barcode	🍊 YES	C NO			
Duplicated check	C YES	C NO			
Decode accord times	10				
1 2 3	4 5	6 7	8 9	0	-
x y z	. /	∗  ←	→   a	101 a	onter
				•/ 0	Continue
Samp barcode settings			[	XX 2014/1	2/24 14:35:31

 Configure detailed settings for each barcode type.
 Page 268 "6.1.2 Sample barcode settings (detailed settings by barcode type)"

## 6.1.2 Sample barcode settings (detailed settings by barcode type)

In addition to common settings, [Samp barcode settings] includes settings for each type of barcode. Usable barcodes include CODE39, ITF, JAN, NW-7, IND2of5m CODE128, and COOP2of5. Barcodes are selected by switching the {Barcode names } tab.

This section will begins explaining from the {Samp barcode settings} screen.

Page 266 "6.1.1 Sample barcode settings (common)"

Samp barcode settings Common Code39 ITF JAN NH-7 BADarls Code128 Coop2a15 Sample barcode YES NO Duplicated check YES NO Decode accord times 10	1Touch the tab of the type of barcode to configure.Example:Touch the {NW-7} tab.(This explanation assumes that NW-7 has been selected.)
1       2       3       4       5       6       7       8       9       0       -         X       Y       Z       .       /       *       →       del       onter         Samp barcode settings       [] [XX [2014/12/24 [14:35:31]	2 Configure each item.
Common     Code39     TF     JAN     NHE?     IND2x/5     Code128     Coop2x/5       Use this type (4 types available at once)     Image: Comparison of the state of t	(See Charts 6.1.1 through 6.1.4.)

(Explanatory note): The check digit calculation method cannot be changed for Code39, JAN, or ITF barcodes.

XX 2014/12/24 14:36:48

	np barco	de settin	gs							
C	ommon	Code39	ITF		JAN	NW-7	IND2	of5 Co	de 128	Coop2of5
	📘 Use this	type (4 typ	oes availabl	e at once)						
Die	rit		*							
Sta	rt/stop									
Cha	aracter del		🌀 YES	0	40	Check digi	it inspectio	m C YE	s 🬾	NO 2
	1	1	1	1	10	1	it inspectio	m C YE	s 6	NO 2
	aracter del	3	YES	5	6	Check digi	it inspectio	m C YE	s 6	NO 2
1 X	1	1	1	1	1	1	1	1	0	NO 2 enter
1	2	3	1	1	1	1	1	9	0	

Touch the {Continue} button.

Samp barcode settings

Samp barcode settings Common Code38 TTF JAN NW-7 [ND2ot5 Code128 Coop2rt6]	4 Touch	the {Register} button.
Use this type (1 types available at once)  Digit  Start/stop  Churacter del  YES NO CHeck digit inspection C YES NO 2		
Register?	{Register}	: Register configured settings.
	{Close}	: Cancel registration of sample barcode settings,
Close Perister	{Cancel}	and return to the [System settings] screen. : The dialog box closes.

 Explanatory note
 : If "YES" is selected for "Check digit inspection," the system will perform a check digit inspection using the last character of the barcode (the digit before the start/stop character) as the check digit.

Chart 6.1.1 Samp barcode settings

Setting	Choice/Setting	Details
Use this type (4 types		Check the barcode to use.
available at once)		Up to four types of barcodes can be selected at the
		same time.
Digit		Configure the number of digits for sample barcodes.
Sample 🗌 digits		Enter "*" to skip checking the barcode digit.
		(Used when sample barcodes have multiple digits.)
		The input range varies according to whether "Start/stop
		character delete" is set to "YES" or "NO."
		For details, see Chart 6.1.2.
Start/stop		Set whether or not to delete the start/stop character.
Character del		(Available when NW-7 is selected.)
	YES:	Delete start/stop character.
	NO:	Do not delete start/stop character.
Check digit inspection		Decide whether or not to perform check digit
		inspection.
	YES:	Perform check digit inspection.
	NO:	Do not perform check digit inspection.
Check digit calculation	See Chart 6.1.3	Configure the check digit calculation method.
method		

(Explanatory note): See Chart 6.1.3 for information on input numbers and calculation methods for check digits.

Chart 6.1.2 Barcode digit input range

Barcode Type	Start/Stop Character	Input	Range	
	Delete	Upper Limit	Lower Limit	
NW-7	YES	17	5	
NW-7 (2)	None	15	5	
ITF				
IND2of5	Disabled	15	6	
COOP2of5				
CODE39				
JAN	Disabled	15	5	
CODE128				

## Chart 6.1.3 Input No. and Calculation <u>method</u>

Input No.	Calculation Method
1	Modulus 10/3 weight
2	Modulus 16
3	Modulus 11
4	Modulus 10/2 weight
5	Modulus 10/3 weight
6	7 check DR
7	Weighing modulus
8	Loons

### Chart 6.1.4 Barcode Type and Calculation Method

Barcode Type	Calculation Method
CODE39	Modulus 43 (fixed)
JAN	Modulus 10/3 weight (fixed)
ITF	Modulus 10/3 weight (fixed)
NW-7	Modulus 10/3 weight
	Modulus 16
	Modulus 11
	Modulus 10/2 weight
	7 check DR
	Weighing modulus
	Loons
IND2of5	No check digit
CODE128	No check digit
COOP2of5	No check digit

### 6.1.3 Rack No./QC No.

Configure the STD/QC rack number, retest rack number, dilute test rack number, and QC sequence number. The system identifies the type of rack from the rack number. During testing, racks with numbers other than STD/QC rack numbers, retest rack numbers, dilute test rack numbers configured here are treated as "sample racks."

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"

Barcode Config Back No/QC No Rack No. se Date and time, s supply and drain Alarm Data output UI Output format STD/QC Process Sample cup Screen saver Cup scale settings Select sample cup Back up Re: Print t Men XX 2014/12/24 14:34:59 System settings

©[F-Hb] ○[	FCa]	O Common			
STD/QC Rack No(QC1•2)	Min	098	Max	099	
STD/QC Rack No(QC3+4)	Min	*	Max	*	
QC sequence No.	QC1	1 QC2	2 QC3	3 QC4 4	
Retest Rack No	Min	094	Max	095	
Dil. Rack No	Min	096	Мах	097	
2 3 4	5	6 7	8 5	0  0  -	
rz.	1	<b>*</b>   ~	_ → _ a	le i enter	_
				Continue	

Rack/QC sequence No. set	tings				
	Ca]	O Common			
STD/QC Rack No(QC1-2)	Min	098	Max	099	
STD/QC Rack No(QC3-4)	Min	*	Max	*	
QC sequence No.	QC1	1 QC2	2 QC3	3 QC4	4
Retest Rack No	Min	094	Max	095	
Dil. Rack No	Min	096	Max	097	
1 2 3 4	5	6 7	8	9 0	1- 1
x y z .	1/	* -		de i	onter
				· · · · ·	Continue
Rack/QC sequence No. settings				XX 2020	/12/21 16:51:44

2

Select the analysis items.

1 Touch the {Rack No./QC No.} button.

Check the item ( $\bigcirc$ ).

- [F-Hb]
- [FCa] .
- [Common]



Configure each item.

(See page 274)

Rack/QC sequence	O [FCa]		Common				
STD/QC Rack No(QC1:	) Mi	n		Max		1	
STD/QC Rack No(QC3+4	) Mi	n		Max		]	
QC sequence No.	Q	>1	QC2	QC3		204	
Retest Rack No	Mi	n	094	Max	095	5	
Dil. Rack. No	Mi	n	096	Max	093	Ī	
1 2 3	4	5 6	7	8	9	,  _	1
r r z	.	/ *	-	<b> </b> →	del	enter	
					•/	Continue	]
k/QC sequence No. settir	ıqs				[ ] XX	2020/12/21 16:	51:29
Rack/QC sequence	No. settings	;					
O[F-Hb]	O [FCa]		Common				

O[F-Hb]	)[FCa]	Common			
STD/QC Rack No(QC1+2)	Min		Max		
STD/QC Rack No(QC3·4)	Min		Max		
QC sequence No.	QC1	QC2	QC3	QC4	
Retest Rack No	Min	094	Max	095	
Dil. Rack No	Min	096	Max	097	
1 2 3	4 5 6	5 7	8 9	0 -	1
x y z	. / .		→ de	l enter	1
				Continue	
Rack/QC sequence No. settings				XX 2020/12/21 16:51:	29

Rack				1
0		Min	Max	
	[F-Hb]	098	099	h.
STD.	STD/QC Rack No(QC1+2)			
STD/	STD/QC Rack No(QC3+4)	*	*	
	[FCa]	998	999	F
QC s	STD/QC Rack No(QC1+2)			
Rete	STD/QC Rack No(QC3·4)	•	*	
Dil. F	Retest Rack No	094	095	H
	Dil. Rack No	096	097	Ľ.
1	Register?			
	Register?			
<u>x</u>				
	Close	Cancel	Register	

- Touch the {Continue} button.

\* A dialog box appears to confirm changes/registration

5 Confirm the changes and touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel rack/QC sequence number configuration, and
	return to the [System settings] screen.
{Cancel}:	The dialog box closes.

(Explanatory note): If no changes were made, the range for each test item/rack number is not displayed.

(Explanatory note) : If there are duplicate rack numbers, the values of the duplicate locations will be red.

(Explanatory note): If the maximum and minimum rack number values are reversed, the values will be red.

(Explanatory note) : If only one value of the rack number range setting is "\*" that location will be red (if the value input changes after entering "\*").

Setting	Choice/	Details
	Setting	
Selection of analysis items	[F-Hb]	Select the analysis items.
	[FCa]	
	[Common]	
STD/QC Rack No. (QC1·QC2)	1 - 999	Configure a range of STD/QC rack numbers (QC1/
Min:		QC2).
Max:		Enter "*" to disable range specification.
		Example 1: If entering rack number 094:
		Enter 94.
		Example 2: If registering only one rack:
		Enter the same rack number for the minimum
		and maximum (maximum = minimum).
STD/QC Rack No. (QC3·QC4)	1 - 999	Configure a range of STD/QC rack numbers
Min:		(QC3/QC4).
Max: QC sequence No.	1 - 99999	Enter "*" to disable range specification. Configure the QC sequence number.
QC1: QC2: QC3: QC4:		<ul> <li>Enter "*" to disable range specification.</li> <li>There are two ways to set QC sequence numbers.</li> <li>(1) Allocate numbers individually to each QC sequence number</li> <li>(2) Set QC1 as the initial value, and assign numbers in sequence for QC2 though QC4 from QC1</li> <li>For (2), if a value in entered for QC1 and</li> </ul>
		<ul> <li>"*" is set for other QC values, sequence numbers will be allocated in sequence from QC1 for QC2 on.</li> <li>(Explanatory note) : If set by serial number, values</li> </ul>
		are retained in the system until its power is turned off.
Retest Rack No	1 - 999	Configure a range of retest rack numbers.
Min:		Enter "*" to disable range specification.
Max:		
Dil. Rack No	1 - 999	Configure a range of dilute test rack numbers.
Min:		Enter "*" to disable range specification.
Max:		

Chart 6.1.5 Rack/QC Sequence Settings

(Explanatory note): Enter "\*" to disable rack number configuration.

If "\*" is entered for either the minimum or maximum, the other value (maximum or minimum) is automatically set as "\*," and rack number configuration is disabled.

Explanatory note : STD/QC rack numbers (QC1/QC2) and STD/QC rack numbers (QC3/QC4) cannot both be disabled.

Explanatory note : See chart 6.1.6 for details on enabling and disabling setting items by selecting analysis items.

Selection of analysis items Setting	[F-Hb]	[FCa]	[Common]
STD/QC Rack No. (QC1·QC2)	Enable	Enable	Disable
STD/QC Rack No. (QC3·QC4)	Enable	Enable	Disable
QC sequence No.	Enable	Enable	Disable
Retest Rack No	Disable	Disable	Enable
Dil. Rack No	Disable	Disable	Enable

Chart 6.1.6 Disabling and Enabling Setting Items Based on Assay Item Selection

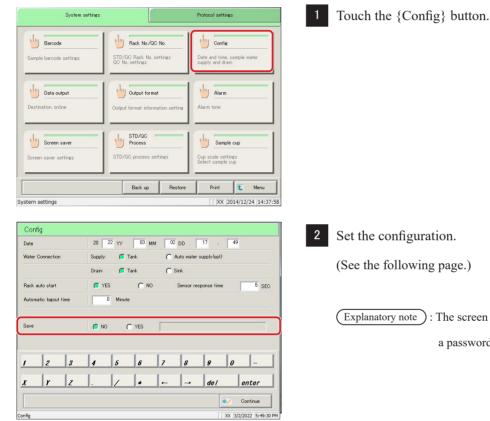
### 6.1.4 Environment settings

The following settings are configured in the environment settings.

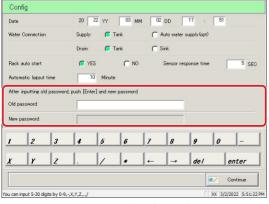
- Date and time settings
- Water supply and water drainage methods •
- Automatic rack supply (sample setting wait time) .
- Automatic logout .
- · Password registration

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"



Password not registered



(Explanatory note): The screen varies based on whether

a password is registered or not.

Date       YY: 0 to 99,       Configure the year, month, day, and time.         20YY, MM, DD, HH, MM       MM: 1 to 12,       Dist 1 to 31,         Dist 1 to 31,       HH: 1 to 24,       Select the water supply/drainage methods.         Water connection       Supply water from tank.       Auto water         Supply water from tank.       Auto water       Autowater         Drain       Tank       Drain water to tank.         Drain       Tank       Drain water to tank.         Rack auto start       Select automatic rack supply.       Supply rack automatically.         Sensor response time (SEC)       0 to 00       Not       Do not supply rack automatically.         Sensor response time (SEC)       0 to 90       When "Rack auto start" is set to "YES," configure the time from when the rack is placed in the supply unit, to when all racks are completely placed (sensor response time)         Automatic logout time       0 to 99       When the Operator mode is set, if the automatic logout time passes while the [MENU] screen is still displayed after logging in, automatic logout function is disabled setting 0 minutes.         Save       Select whether to register a password or not for data processing.         Save       Sto 30 characters (0 to 9, -X, Y, Z,)       On on tegister a password.         Nove password       S to 30 characters (0 to 9, -X, Y, Z,)       When a password.	Setting	Choice/Setting	Details
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Explanatory note : To use no password, do not input a password, then touch the {Continue} button to complete registration.

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Cont Date Water Rack & Autom Save	Connection auto start atic logout	time	Supply: Drain: C YES	r Ta Ta Minute	nk nk O NO YES	C Au C Si	ito water sk Sensor res	17 : supply (opt	)	9	

4 Touch the {Continue} button.

5 Touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel environment configuration and return to
	the [System settings] screen.
{Cancel}:	The dialog box closes.

# MEMO

#### 6.1.5 Data output settings - [Destination]

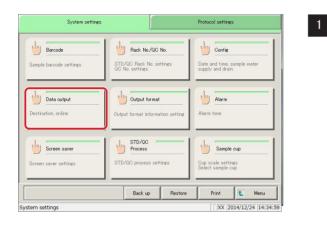
The following settings are configured in "Destination."

- Measured data printer output (print)
- · Measured data external media output
- · Time course external media output
- · Measured data online output
- · STAT online output

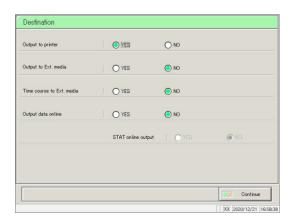
This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"

2







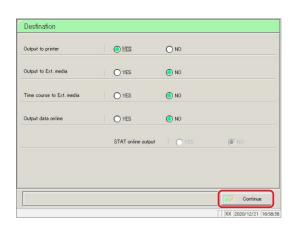
Touch the {Data output} button.

Touch the {Destination} button.

3 Select the output destination for the data (see the following page).

Setting	Choice/Setting	Details
Output to printer		Select whether to print measured data or not.
	MDG	
	YES	Print measured data in real time during testing.
		If you would like to "Print Saving mode" in
		which only the "STD/ QC" measurement result
		and the error is printed, please contact us.
	NO	Do not print measured data.
Output to Ext. media		Select whether to automatically send measured
		data to external media when testing is complete.
	YES	Output to external media.
	120	
	NO	Do not output to external media.
Time course to Ext. media		Select whether to output time course to external
		media or not.
	YES	Output to external media.
	NO	Do not output to external media.
Output data online		Select whether to output measured data online
		or not.
		Detailed online output settings are made on the
		[Online settings] screen.
	YES	Output online.
	NO	Do not output online.
STAT online output		Select whether to output sample data measured
		during cut-in analysis online or not.
		Online output of measured data is available if
		set to "YES."
	YES	Output cut-in analysis measured data online.
	NO	Do not output out in analysis managed date
	NO	Do not output cut-in analysis measured data online.
		omme.

(Explanatory note): If all [Destination] settings are set to "NO," nothing will be output to external media.



Destination			
Output to printer	O YES	O NO	
Output to Ext. media	O YES	O NO	
Time course to Ext. media	O YES	O NO	
Output data online	O YES	NO NO	
Register?			
- Cancel		Close	Register
			XX 2020/12/21 16:58:5

# 4 Touch the {Continue} button.

{Register}:	Register configured settings.
{Close}:	Cancel data output selection, and return to the
	[Data output destination settings] screen.
{Cancel}:	The dialog box closes.

# MEMO

## 6.1.6 Data output settings - [Online settings]

Configure the following conditions to control online communication.

- Order request
   Communication mode
- Data length
  - Transmission procedure
- Separator

.

Output settings

Destination

For details, see "OC-PLEDIA Computer Interface Specifications."

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"

•

Parity

Delimiter

1



Touch the {Data output} button.

.

Baud rate

Check character

Stop bit



Dutput to Ext. media		0.100	@	Test		
		O YES	🖲 NO			
Time course to Ext.	media	O YES	🔘 NO	Feces		
Dutput data online		O YES	NO NO			-
STAT online output		O YES	( NO	🔳 (F-1	-1b]	FCa]
		0.00				
Online setting	s 🗖			Ì		
<u> </u>						
Baudrate		rder request	NO			
Length	8 1	irans.	ACK/NAK			
Parity	None [	Delimiter	STX/ETX			
Stop bit	1 0	Xhk. Char	NO			
					_	1_
				1	Menu	1 Close
					[]]	XX 2020/12/21 16:5

Test setting

Online se	Hings					
Order reques	t   O YES	о о	0			
Com mode	O OC sens	or isi 🔿 DIA	iNA	🔿 LAN	) AS	тм
Baudrate	0 2400	O 4800	9600	O 19200	0 38400	
Length	07		Parity	None	O Even	O Odd
Stop bit	0 1	O 2	Trans.	O NONE	ACK/NAH	(
Delimiter	● STX/ET>					
	() B00	0.000			10	() NO

3 Select online communication conditions (see the

following page).

284

Setting	Choice/Setting	Details
Order requirement		In online communication, select whether to
		place an order request to a higher-level system
		or not.The order
	YES	Request an order.
	NO	Do not request the order.
Com mode		Select the communication mode.
	OC sensor io	OC sensor io compatibility mode.
	OC sensor DIANA	OC sensor DIANA compatibility mode.
	LAN	LAN communication mode.
	ASTM	ASTM communication mode.
Baud rate		Select the communication speed.
2000 1000	2400	2400 baud rate
	4800	4800 baud rate
	9600	9600 baud rate
	19200	19200 baud rate
	38400	38400 baud rate
Length		Select the data length.
Length	7 (bit)	Select the data length.
	8 (bit)	Select when sending two-byte characters.
Parity		Select parity checking.
	NONE	Do not check parity.
	EVEN	Run even number parity checking.
	ODD	Run odd number parity checking.
Stop bit		Select the stop bit.
	1	One bit.
	2	Two bits.
Trans.		Select the transmission control procedure.
	NONE	Do not use a transmission control procedure. (No
		procedure)
	ACK/NAK	Use ACK/NAK method.
Delimiter		Select the delimiter
	STX/ETX	
	CR/LF	
	CF	
Chk. char		Select the error detection method.
	BCC	
	SUM	
	None	Do not use check character.
Separator		Select whether or not to insert a separator
		comma (,) in between data items.
	YES	Separate using a comma.
	NO	Do not separate.

(Explanatory note) : Delimiter, check character, and separator are all set to "NO" for LAN communication.

Explanatory note : The delimiter is set to "STX/ETX" for ASTM communication. This cannot be controlled on the screen.

(Explanatory note) : The check character for ASTM communication is "SUM1, SUM2." This cannot be controlled on the screen.

Online set	tings					
Order reques	YES	0	10			
Com mode	O OC sense		ANA		🖲 AST	м
Baudrate	0 2400	O 4800	9600	0 19200	0 38400	
Length	01		Parity	None	O Even	O Odd
Stop bit	01	O 2	Trans.	O NONE	ACK/NAK	
Delimiter						
Chk. Char		O SUM	NO NO	Separator	O YES	🔘 NO
Chk. Char		O sum (	NO NO	Separator	I O YES	NO 🖲
Chk. Char	() BCO	O sum (	ONO	Separator		NO     Continue
Chk. Char		O anw (	• NO	Separator		Continue
Chk. Char		O sum (	0 NO	Separator		Continue
Chk. Char		O sum (	NO	Separator		Continue
	tings	() SUM ()		Separator		Continue
Online set	tings	() () ()	40	Separator		Continue 120/12/21 16:59:1
Online set	tlings t O YES	() () ()	40			Continue 120/12/21 16:59:1

A ACK MAN

Regi

XX 2020/12/21 16:59:24

Close

0

Stop F

Delim Chk. C Cancel

4 Touch the {Continue} button.



{Register}:	Register configured settings.
{Close}:	Cancel online configuration, and return to the
	[Output settings] screen.
{Cancel}:	The dialog box closes.

# MEMO

Output settings

۲

9600 Order rec

8 Trans

None Delimite

1 Chk. Cha

NO

NO

NO

NC

NO

ACK/NAK

STX/ETX

Destination

Output to Ext. media

Output data online

STAT online output

Online settings

Baudrate

Length Parity

Stop bit

Time course to Ext. mer

Output to printer

#### 6.1.7 Data output settings - [Test settings]

Setting the analysis items to be handled by the device.

Test Items

O Fecal

□ [F-Hb] Hemoglobin

□ [FCa] Calprotectin

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"



Test setting

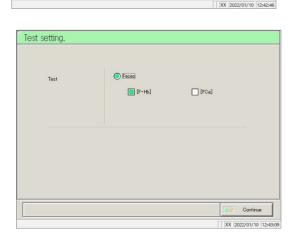
[F-Hb]

📜 Menu 🚺 Close

Tes

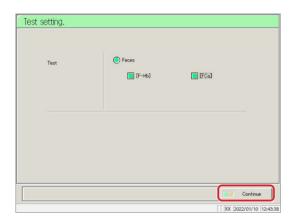
[Data output] Touch the button.

2 [Test setting] Touch the button.



Select the assay item (see next page).

Setting	Choice/Setting	Details
Test Items		Select the assay item.
	[F-Hb]	Fecal hemoglobin
	[FCa]	Fecal calprotectin



Test setting.		
Test	Feces	[FGa]
Register?		
Cancel	Close	e Register
		XX 2022/01/10 12:44:00

4 [Continue] Touch the button.

5 [Register] Touch the button.

[Register] : You can register the settings.

[Cancel] : Aborts Test settings and returns to the screen.

[Close] : The dialog box closes.

#### 6.1.8 Output format

Configure the output formats for data (such as rack, sample number, and sample ID), for each output destination (printer, external media, online).

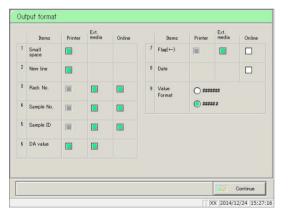
Rack, sample number, and sample ID settings cannot be changed for printer output.

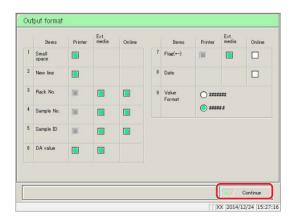
This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"

1



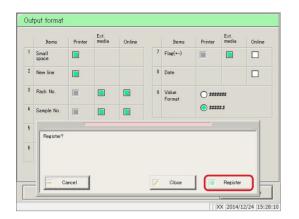




Touch the {Output format} button.

2 Select the output item (see the following page).

**3** Touch the {Continue} button.



Touch the {Register} button.

4

(Explanatory note): Checked items will be output.

Output Items	Details
1. Small space (narrow)	
Printer	Line spacing when printing to a printer is narrowed.
2. New line	
Printer	<ul><li>A new line is inserted in the following locations when printing to a printer.</li><li>Between measured data</li></ul>
	Between items when multiple items were tested
	(This applies to printing during real time printing and measured data processi
3. Rack No.	1
External media	The rack number and rack position number are output.
Online	The rack number and rack position number are output.
4. Sample No.	
External media	Output the sample number.
Online	Output the sample number.
5. Sample ID	
External media	Output the sample ID.
Online	Output the sample ID.
6. DA value	
Printer	Print the DA value to a printer.
External media	Output the DA value.
7. Flag(+-)	
External media	Output the judgment results.
Online 8. Date	Output the judgment results.
o. Date Online	Output the measurement date and time.
9. Value format	Select the output format of measured data.
#######	Output as an integer.
#####.#	Output up to the first decimal place (all measured data is rounded
	up).

(Explanatory note) :All information applies when outputting to a hard disk(SSD), regardless of the output format settings.

(Explanatory note): If ASTM communication is set as the communication mode on the [Online settings] screen,

only the [Value format] setting is applied. Other settings are ignored.

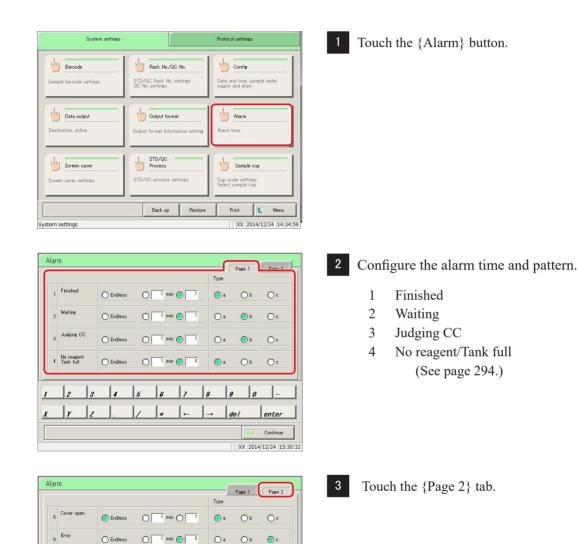
#### System settings 6.1

#### 6.1.9 Alarm

Configure the time and pattern for alarms to sound when testing is completed, the system is waiting for a new rack to be placed, when there is an operation error, or other situations. The [Alarm] screen is composed of two pages. Switch pages by touching the {Page 1} and {Page 2} tabs.

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"



7 Key inpu

Output erro

2

Y

0

0

6 17 ٥a Оb 00

0.

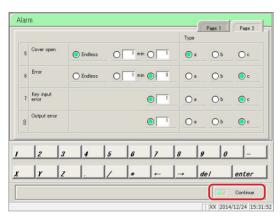
Ob 00

0 9

> enter Continue [ XX 2014/12/24 15:31:52

del

						Туре		
5	Cover open	Endless	0	1 mi		٥	Ob	00
6	Error	O Endless	0	1 mi	0 3	0.	O٥	<b>O</b> ¢
7	Key input error				0	0.	O۵	<b>•</b> •
8	Output error				0	0.	O۵	© c
	2 3	4	5	6	7	8 g	0	-
_	r z	<u> .</u>	1	*	-	→ d	e/	enter
							0/	Continue



4	(
---	---

Configure the alarm time and pattern.

- 5 Cover open
- 6 Error

8

- 7 Key input error
  - Output error (See page 295.)
- 5 Touch the {Continue} button.

{Register}:	Register configured settings.
{Close}:	Cancel alarm configuration and return to the
	[System settings] screen.
{Cancel}:	The dialog box closes.

5         Cover open         © Endless         1 min         1         © a         b           6         Error         Erroless         1 min         3         0 a         0 b           7         Key input         Image: 1         0 a         0 b           8         Output error         Image: 1         0 a         0 b	0 c 0 c				
6     0 Endless     1 min     3     0 a     0 b       7     Key input     0     1     0 a     0 b       0utout error					
Output error     Output error	<b>•</b> ••				
8 Output error	0.				
0	<u> </u>				
8 Register?					

{Page 1} tab Output Items	Details
1. Finished	Sounds when testing of the sample placed in the rack supply unit
	is finished, and the system is waiting.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99)
	The alarm will stop once it has sounded the specified number of
	times
Type a	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Туре с	Alarm sounds with type c.
2. Waiting	Sounds to notify the user when the rack supply is fed from the
	rack supply unit.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99)
	The alarm will stop once it has sounded the specified number of
_	times
Type a	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Туре с	Alarm sounds with type c.
3. Judging CC	Sounds when the system is waiting for the operator's
	determination following calibration curve judgment.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99) Configure the number of times for the alarm to sound. (1 to 99)
Times	The alarm will stop once it has sounded the specified number of
	times
Туре а	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Туре с	Alarm sounds with type c.
4. No reagent	Sounds when the system detects insufficient reagent, buffer, wash
Tank full	solution, or purified water, or when the drain tank is full.
Endless	Continues to sound until the error is cleared.
min	Configure the time (minutes) for the alarm to sound. (1 to 99)
Times	Configure the number of times for the alarm to sound. (1 to 99)
	The alarm will stop once it has sounded the specified number of
	times
Туре а	Alarm sounds with type a.
Type b	Alarm sounds with type b.
Туре с	Alarm sounds with type c.

{Page	13	tab
11 ugo	- 1	iuo

{	Page	2}	tab

Output Items		Details
5. Cover open		Sounds when the protective cover is opened during operation.
En	ndless	Continues to sound until the error is cleared.
	min	Configure the time (minutes) for the alarm to sound. (1 to 99)
]	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of
		times
	ype a	Alarm sounds with type a.
	ype b	Alarm sounds with type b.
	ype c	Alarm sounds with type c.
6. Error		Sounds when an operational error has occurred.
En	ndless	Continues to sound until the error is cleared.
	min	Configure the time (minutes) for the alarm to sound. (1 to 99)
1	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of
		times
Т	ype a	Alarm sounds with type a.
T	ype b	Alarm sounds with type b.
Т	ype c	Alarm sounds with type c.
7. Key input error		Sounds when an incorrect entry is made using the keypad.
]	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of
		times
	ype a	Alarm sounds with type a.
	ype b	Alarm sounds with type b.
	ype c	Alarm sounds with type c.
8. Output error		Sounds when there is an error with the output destination when
		outputting to a printer or online.
1	Times	Configure the number of times for the alarm to sound. (1 to 99)
		The alarm will stop once it has sounded the specified number of
		times
Т	ype a	Alarm sounds with type a.
T	ype b	Alarm sounds with type b.
Т	ype c	Alarm sounds with type c.

#### System settings 6.1

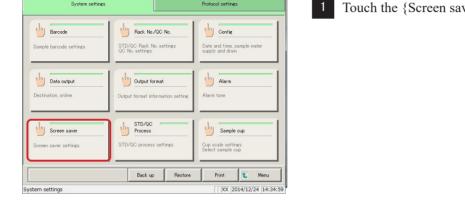
#### 6.1.10 Screen saver

The screen saver starts up when there is no keypad activity on the [MENU] screen.

The time required until the screen saver starts is configured in the screen saver settings

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"



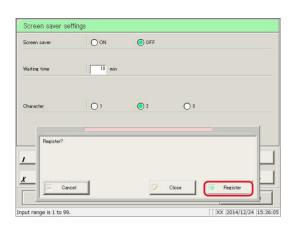
Screen saver settings									
Screen save	r	OON	É	OF	F				
Waiting time		10	min						
Character		01		<b>O</b> 2		O 3			
1 2	3	4	5	6	7	8	9	0	-
x r	Z		1	*	-	<b>→</b>	del		enter
								0/ (	Continue
Input range is	s 1 to 99.						[ XX	2014/1	2/24 15:34

Screen saver sett	ings			
Screen saver	O ON	OFF		
Waiting time	10 min			
Character	01	<b>O</b> 2	O 3	
. 1. 1.	1. 1.	1. 1.	1. 1. 1	1 1
1 2 3	4 5	6 7	8 9 0	2
x y z	. /	* ~	→ del	enter
				Continue
Input range is 1 to 99.			[ XX 20	14/12/24 15:34:49

Touch the {Screen saver} button.

2 Configure settings for the screen saver (see the following page).

Touch the {Continue} button. 3



4 Touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel screen saver configuration and return to
	the [System settings] screen.
{Cancel}:	The dialog box closes.

Setting	Choice/Setting	Details
Screen saver		Select whether or not to start the screen saver
		when the configured wait time has elapsed.
		Starts.
	ON	Does not start.
	OFF	
Waiting time	1 to 99 minutes	Input the waiting time.
Character		Select the character.
	Character 1	Character 1 starts.
	Character 2	Character 2 starts.
	Character 3	Character 3 starts.

#### 6.1.11 STD/QC analysis process settings

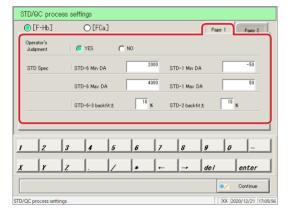
Configure the conditions for checking measured data for STD/QC samples. The [STD/QC process settings] screen is composed of two pages. STD specifications are set in {Page 1}, while limit values for each QC# are set in {Page 2}. Touch the tabs to switch pages.

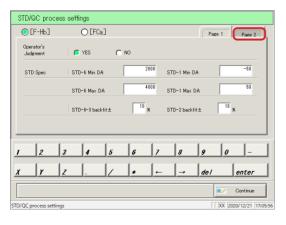
2

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"







Touch the {STD/QC Process} button.

Configure STD specifications (see page 300).

Touch the {Page 2} tab.

STD/QC process settings ⊙[F-Hb] O[FCa] te 1 Page 2 Max limit[ng/mL] it[ne/ml.] QC lot 128.0 173.0 11111 QC1 QC2 383.0 518.0 22222 60.0 90.0 33333 QC3 230.0 270.0 ..... QC4 SD coeffici 3 SD 5 0 19 12 7  $|_z$ enter 1 del X Continue XX 2020/12/21 17:06:1 STD/QC process setti

STD/QC pro	cess set	tings							
⊙[F-Hb]		O [FC:	a]				Part	• 1 I (	Page 2
	Min limit	[næ/ml.]		Max lim	it[ng/mL]			QC lot	
QC1		13	28.0	Γ	1	73.0		1111	1
QC2		3	83.0	Γ	ŧ	18.0		2222	2
QC3			60.0	Γ		90.0		3333	3
QC4		2	30.0	Γ	\$	70.0		4444	4
					SD	coefficient			3 SD
1 2	3	4	5	6	1	8	9	0	
x r	Z	<u> .</u>	1	*	-		de l	el	nter
							(	●∕ Co	ntinue
TD/QC process set	ttings						[]	XX 2020/	12/21 17:06:1

STD/QC proc	cess settings		
⊙[F-Hb]	○[FCa]		Page 2
	Min limit[ng/mL]	Max limit[ng/mL]	QC lot
QC1	128.0	173.0	11111
QC2	383.0	518.0	22222
QC3	60.0	90.0	33333
QC4	230.0	270.0	44444
I Register	? Cancel	Ciose	Register
TD/QC process set	tings		XX 2020/12/21 17:06:2

4 Configure QC control limit values (page 301).

Touch the {Continue} button.

- 6 Touch the {Register} button.
- {Register}: Register configured settings.
  {Close}: Cancel [STD/QC process] and return to the
   [System settings] screen.
  {Cancel}: The dialog box closes.

{Page 1} tab		
Setting	Choice/Setting	Details
(Analysis Items)		Select the assay item.
	[F-Hb]	Fecal hemoglobin
	[FCa]	Fecal calprotectin
Operator judgment		Select whether or not the operator makes a
1 5 8		judgment following STD/QC measurement.
	YES	Operator makes a judgment.
		The system will wait for the operator's
		judgment following STD/QC measurement,
		so it will enter standby.
	NO	Operator does not make judgment.
		If the measured data is normal, measurement
		continues. If there is an error, the system
		enters standby and waits for the operator's
		judgment.
STD Spec		Configure specifications for each STD point.
		The system will determine STD pass/fail
		using the configured specifications.
STD-6 Min DA	-9999 - 99999	Check using DA1 value.
STD-6 Max DA	-9999 - 99999	Configure so that minimum < maximum.
STD-6 to 3 back fit		
±(%)	0 - 100	Check using the deviation from origin.
	0000 00000	
STD-1 Min DA	-9999 - 99999	Check using DA1 value.
STD-1 Max DA	-9999 - 99999	Configure so that minimum < maximum.
STD-2 DA back fit	0 100	Check using the deviation from origin
±(%)	0 - 100	Check using the deviation from origin.

{Page 1} tab

Explanatory note : When measuring a QC sample only, the system will not wait for operator judgment even if the measured data is outside the limit value. Processing continues.

Explanatory note :See page 343 "Appendix: 1.1 STD/QC Sample Measured Data Check" for information on how to check STD/QC measured data.

{Page 2} tab

Setting	Choice/Setting	Details
		Configure the maximum/minimum control limit values for QC1 through 4. QC pass/fail is determined using the
		maximum/minimum values set for each QC#.
QC1 to QC4		
Min limit		
[ng/mL] or $[\mu g/g]$	0.0 - 99999999.9	Configure so that minimum < maximum.
Max limit		5
[ng/mL] or [ $\mu$ g/g]		
	A string of characters	
	composed from 0	
QC LOT	through 9, X, Y, and Z.	
	(Up to five half-width	
	characters.))	
		The standard deviation coefficient can be set
		from 1 to 9 SD (initial setting is 3 SD).
SD coefficient □ SD	1 - 9	The standard deviation coefficient is used
		when calculating the X-R control graph on
		Process QC.

#### 6.1 System settings

#### 6.1.12 Sample cup

Configure the shape of the sample cup. Two types of containers can be registered:  $\{Cup 1\}$  and  $\{Cup 2\}$ .

Touch the appropriate tab to switch between containers 1 and 2.

Explanatory note : Only one type of container can be used during testing. Two types of containers cannot be used at the same time.

This section describes the procedure from the [System settings] screen.

Page 266 "6.1.1 Sample barcode settings (common)"

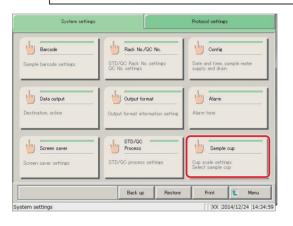
▲ Caution

č

Required

• Confirm the correct size of the sample cup.

If an incorrect size is configured, the nozzle may be inserted into the liquid too deeply when absorbing the sample, or it may absorb air, leading to incorrect analysis.



Sample cup info set	tings					Cup 1		n 2
Use this type of s	ample cup							
f ( c c c c c c c c c c c c c c c c c c	a	10.2 m	m d	12	.5 mm	e [	12.0 mm	
e ↓	c b	9.8 m	m e	25	.1 mm			
←b→	d c	22.5 m	m f	10	1.0 mm			
				,				
1 2 3	4	5	6	7	8	9	0	-
x y z			*	<u>ب</u>	<b>→</b>	de l	ent	9r
							/ Contir	Ne
Sample cup info settings						[ XX ]	2014/12/24	15:40:19

 Sample cup info settings
 Cup 1
 Cup 2

 Use this type of sample cup
 0
 102 mm
 1125 mm
 0
 120 mm

 I
 2
 3
 4
 5
 6
 7
 8
 0

 I
 2
 3
 4
 5
 6
 7
 8
 0

 I
 2
 3
 4
 5
 6
 7
 8
 0

 I
 2
 3
 4
 5
 6
 7
 8
 0

 I
 2
 3
 4
 5
 6
 7
 8
 0

 I
 2
 3
 4
 5
 6
 7
 8
 0

 I
 2
 3
 4
 5
 6
 7
 8
 0

 I
 2
 3
 4
 5
 6
 7
 8
 0

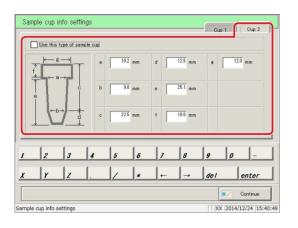
 I
 2
 3
 5

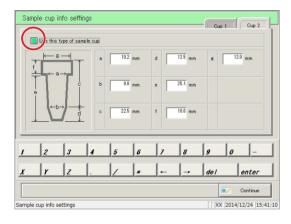
Touch the {Sample cup} button.

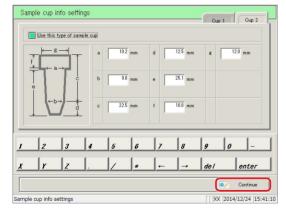
2 Configure the information for sample cup {Cup 1} (see page 304).

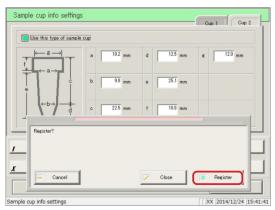
Touch the {Cup 2} tab, and switch to the settings screen.

3









4 Configure the information for sample cup {Cup 2} (see page 304) .

5 Check "Use this type of sample cup."

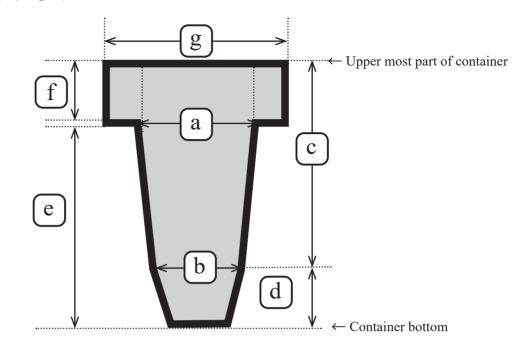
To select container 1, touch the {Cup 1} tab, and switch to the settings screen.

6 Touch the {Continue} button.

7 Touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel [Sample cup info settings] and return to
	the [System settings] screen.
{Cancel}:	The dialog box closes.

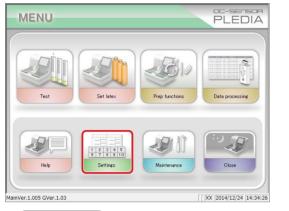
## {Cup 1}/{Cup 2} tabs



Setting	Setting Range	Details
a		Inside diameter of straight part
b	8.0 - 12.7 (mm)	Inside diameter of tapered part
c		Length of straight part
d	0.0.20.0 (mm)	Length of tapered part
e	0.0 - 29.0 (mm)	Length from container bottom to top face of rack
f	0.0 - 10.0 (mm)	Length of straight part at the uppermost part of the container
g	8.0 - 22.0 (mm)	Inside diameter of straight part at the uppermost part of the container

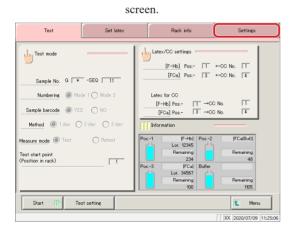
#### 6.1.13 Printing information on system settings

Print information registered to system settings.



Touch the {Settings} button.

(Explanatory note): The [System settings] screen can also be displayed by touching the {Settings} button on the [Test]





**2** T

Touch the {Print} button.

\* All setting information registered to [System settings] will be printed.

#### 6.1 System settings

#### 6.1.14 Backing up information on system settings/protocol settings

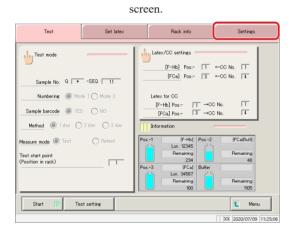
1

Back up information on system settings and protocol settings.



Touch the {Settings} button.

(Explanatory note): The [System settings] screen can also be displayed by touching the {Settings} button on the [Test]







2 ′

Touch the {Back up} button.

\* Information on [System settings] and [Protocol settings] will be backed up to the external media.

{Cancel}: Cancel the backup. {Start}: Start the backup.

#### Restoring information on system settings/protocol settings 6.1.15

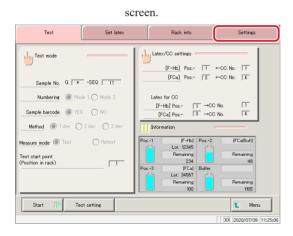
Read information on system settings and protocol settings from external media, and restore to the system.

1

Touch the {Settings} button.



(Explanatory note): The [System settings] screen can also be displayed by touching the {Settings} button on the [Test]



setting Protocol settings Barcode Config Rack No /QC No. STD/QC Rack No. sett Date and time, si supply and drain Alarm Data output Utput format STD/QC Process Sample cup Cup scale settings Select sample cup Back up Print t Mer System settings XX 2014/12/24 14:34:59



2

Touch the {Restore} button.

restore.

\* The settings in [System settings] and [Protocol settings] will be restored from the external media to the system.

{Cancel}:	Cancel restor
{Start}:	Start restore.

### 6.2 Protocol settings

Protocol settings are largely split into three condition settings.

- Conditions when measuring samples and QC samples (sample/QC protocol settings)
- · Calibration curve settings used by protocols (CC No. 1 to CC No. 6 protocol settings)
- Common conditions when measuring samples, STD samples, and QC samples (manufacturer settings)

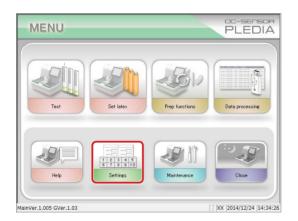
Protocol settings will not need to be touched during everyday analysis flow unless changes are made.

Manufacturer settings are configured at the factory and cannot be changed by the user.

#### 6.2.1 Samp/QC protocol settings

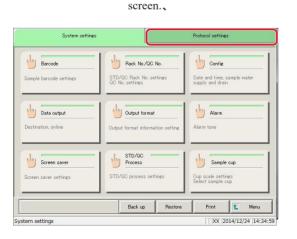
Configure conditions when measuring samples (including STAT samples) and QC samples. The setting screen is composed of two pages. Pages can be switched using the tabs.

1



Touch the {Settings} button.

(Explanatory note): The [System settings] screen can also be displayed by touching the {Settings} button on the [Test]



2 Touch the {Protocol settings} tab.

O Common
Manufacturer use only Dommon test state settings of semp/QD/CC create
و این CC4 protocol
a ling CC6 protocol
1 CC6 protocol
up Restore Print <b>E Menu</b>

System settings	Protocol settings
● [F-Hb] ○ [FCa]	O Common
Samp/QC protocol Samp/QC Test condition settings	Manufacturer use only Common test state settings of samp/QD/CD create
CC1 protocol Necessary state for STD test	Jin CG4 protocol
CC2 protocol	CO5 protocol
CC3 protocol	CC6 protocol
Back ptocol settings	up Restore Print <b>t</b> Menu

				N	lo.					
1	Samp Replicate		10		5	Cut off	3			* [ng/mL]
2	QC Replicate		3		6	Min Val	ue			30.0 [ng/mL]
3	Cut off 1		10 [ng/m		7	Max Va	lue			[ng/mL]
4	Cut off 2			*						
	2 3	4	5	6	1	7	8	9	10	. [_
_	2 3		0	0	-	<u> </u>	0	3		
	Y Z		1	*	1	~		de	1	enter
_										

ło.					No.					
1	Samp Replicate	Γ	10	D	5 Cuto	ff 3	[		* [ne/ml]	
2 QC Replicate			3		6 Min Value			30.0		
									[ng/mL]	
3	Cut off 1			100	7 Max	/alue	[		1000.0	
			(ne	/mL]					[ng/ml]	
4	Cut off 2		[ng/	* /mL]						
	2 3	4	5	6	17	8	9	0	[-	
									_	
_	Y Z		1	*	+		del		enter	
							1			

- Select the assay item.
- [F-Hb]
- [FCa]

3

• [Common] (Common setting of two analysis items)

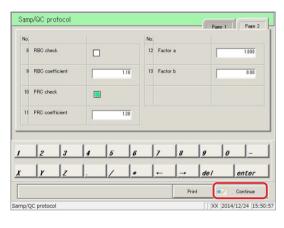
Explanatory note :The items that can be set vary depending on the selected assay item.

4 Touch the {Samp/QC protocol} button.

5 Configure items (see page 311).

6 Touch the {Page 2} tab.

No.		T.			No.				Page 1	Page 2
8 RBC c	heck				12	Factor	a			1.000
9 RBC c	oefficient			1.10	13	Factor	r b			0.00
10 PRC d	heck									
11 PRC o	pefficient			1.30						
2	3	4	5	6		7	8	g	0	
r	Z		1	*		←	<b> </b> →	de	/	enter
							Pr	int	•/	Continue



Sam	p/QC protocol			(	Page 1 Page 2
No.			No.		
8	RBC check		12	Factor a	1.000
9	RBC coefficient	1.10	13	Factor b	0.00
10	PRC check				
11	PRC coefficient	1.30			
<u> </u> x	Register?				
	Cancel		2	Close	Register
Samp/C	C protocol				XX 2014/12/24 15:51:36

7 Configure items (see page 312).

- {Print}: Print [Sample/QC protocol] settings.
- 8 Touch the {Continue} button.

9 Touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel [Sample/QC protocol] settings, and
	return to the [Protocol settings] screen.
{Cancel}:	The dialog box closes.

{Page	1}	tab

	Setting	Settings	Details	
1	Sample Replicate	1 to 10 times	Configure	the number of times to measure samples.
2	QC Replicate	1 to 10 times	Configure	the number of times to measure QC samples.
3	Cut off 1		Configure	e the judgment criteria for Cut off 1.
		0 - 99999999 (integer)	1+	Measured data is "above Cut off 1 value" or "Cut off 2 or lower"
			-	Measured data is "setting value or lower"
4	Cut off 2		Configure	the judgment criteria for Cut off 2.
		*, 0 - 99999999 (integer)	2+	Measured data is "above setting value," "larger than Cut off 1," or "Cut off 3 or less" If set to "*," Cut off 2 judgment will not be performed. Cut off 1 < Cut off 2
5	Cut off 3		Configure	the judgment criteria for Cut off 3.
		*, 0 - 99999999 (integer)	3+	Measured data is "above setting value" If set to "*," Cut off 3 judgment will not be performed. Cut off 2 < Cut off 3
6	Min Value	0.0 - 99999999.9	UR	Displayed when measured data is "Min Value" or lower during dilute testing.
7	Max Value	0.0 - 99999999.9	OR	Displayed when measured data is larger than "Max Value."

$\{Page 2\}$	tab
--------------	-----

È			
	Setting	Settings	Details
8	RBC check		Set whether or not to run RBC checking. Check to have it run. → Page 352 " ■ RBC method"
9	RBC coefficient	1.0 - 2.0	Samples with an absorbance larger than the absorbance × "RBC coefficient" of STD-6 at the RBC detection point are determined to be prozone samples. → Page 352 " ■ RBC method"
10	PRC check		Set whether or not to run PRC checking. Check to have it run. → Page 353 " ■ PRC metod"
11	PRC coefficient	0.01 - 2.00	<ul> <li>Samples with a DA2 value larger than the DA2 value × "PRC coefficient" of STD-6 at the second detection point (T2) are determined to be prozone samples.</li> <li>Page 353 " ■ PRC metod"</li> </ul>
12	Factor A	0.001 - 9999.999	Measured data = $A \times$ concentration value + B
13	Factor B	-999.999 - 999.999	Neasured data – A ^ concentration value + B

6.2 Protocol settings

MEMO

#### 6.2.2 CC No. 1 to CC No. 6 protocol settings

Configure conditions required for measurement of STD samples.

Up to six calibration curves can be registered (CC numbers 1 through 6).

The setting screen is composed of two pages. Pages can be switched using the tabs.

This section describes the procedure from the [Protocol settings] screen.

Page 308 "6.2.1 Sample/QC protocol settings"

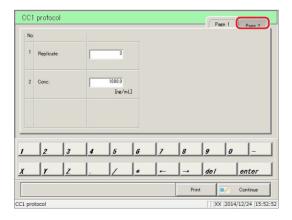
System settings	Protocol settings
[F-+b]     [FOa]     [Same/OC protocol     Same/OC Test condition settings	Common
CC1 protocol Necessary state for STD test	
CC2 protocol	
CC3 protocol	1 CC6 protocol
Back. Protocol settings	up Rostore Print <b>Menu</b>

2

(Explanatory note): When [Common] is selected, the [CC No. # Protocol Setting] button does not work.

No								- Fat	ge 1	Dage 9
1	Replicate			3						
2	Conc.			1000.0 [ng/n	nL]					
_	2	3	4	5	6	7	8	9	0	
2	Y	Z	1.	1	*	-		de l		enter
_							Pri	. ()	7	Continue

Configure items (see page 316).



**3** Touch the {Page 2} tab.

{Print}: Print [CC No. # protocol] settings.

No	1	001	CC2	STD Conc. [ng/mL]	No		001	CC2	ST	D Conc. ∉/mL]
3	STD-6			1000.0	6	STD-8				125.0
4	STD-5			500.0	7	STD-2			<b>_</b>	62.5
5	STD-4			250.0	8	STD-1			[	0.0
	2	3	4	5 6	,	7	8	9	0	[_
	r	z		/ *	,	←	<b> </b> →	de l		enter
							Prir	nt 🚺	1	Continue

001	l proto	ol					Page	1 Page 2
No		CC1	CC2	STD Conc. [ng/mL]	No	001	CC2	STD Conc. [ng/mL]
3	STD-6			1000.0	6 STD-3			125.0
4	STD-5			500.0	7 STD-2			62.5
5	STD-4			250.0	8 STD-1			0.0
	2	3	4	5 6	7	8	9	0 -
	r	Z		/ *	-	_ <b>_</b>	de l	enter
						Prin	it [	V Continue
	otocol							2014/12/24 15:5

CC1	protoc	col						Page		Page 2
No		CC1	CC2	STD Conc. [ng/mL]	No		CC1	CC2	STD C [ne/r	Conc. mL]
3 5	STD-6			1000.0	6	STD-8			<b>_</b>	125.0
4 8	STD-5			500.0	7	STD-2			<b></b>	62.5
5 5	STD-4			250.0	8	STD-1				0.0
<i>i</i> x	Regist					Clo	28		Register	
1 prot	ocol							[ XX	2014/12/	24 15:53:

4 Configure items (see page 316)

- {Print}: Print registered [CC No. # protocol] settings.
- 5 Touch the {Continue} button.

- 6 Touch the {Register} button.

{Register}:	Register configured settings.
{Close}:	Cancel [CC No. # protocol] settings, and return
	to the [Protocol settings] screen.
{Cancel}:	The dialog box closes.

#### 6.2 Protocol settings

	Setting	Settings	Details
1	Replicate	1 to 10 times	Configure the number of times to measure STD samples.
2	Conc.	0- 99999.9	Configure the concentration listed in the INSTRUCTIONS FOR USE for calibrator. Configuring the calibrator concentration will automatically calculate and configure the STD concentration for STD-1 through 6 on the second page. * This item cannot be entered in [FCa].

## {Page 2} tab

	Setting	Settings	Details
3	STD-6	0.1 - 99999999.9	Configure the STD concentration of STD-6.
4	STD-5	0.1 - 99999999.9	Configure the STD concentration of STD-5.
5	STD-4	0.1 - 99999999.9	Configure the STD concentration of STD-4.
6	STD-3	0.1 - 99999999.9	Configure the STD concentration of STD-3.
7	STD-2	0.1 - 99999999.9	Configure the STD concentration of STD-2.

(Explanatory note):STD-2 through STD-6 are automatically configured when "calibrator concentration" on the

first page is set.

Settings for STD-2 through STD-6 can be changed using the keypad.

# Chapter 7 Help

- 7.1 Opening the [Help] Screen from the [MENU]Screen
- 7.2 Opening the [Help] Screen from the [Monitor] Screen



## Chapter 7 Help

The [Help] screen is used to confirm the analysis flow, input methods on settings screens, and how to operate the system including sample placement.

Touch the {Help} button on the [MENU] screen or the {Help} button on the [Monitor] screen to open the [Help] screen table of contents. Then, select the button of the item to check.

## 7.1 Opening the [Help] Screen from the [MENU] Screen



Touch the {Help} button.

- Touch the button of the item to check.
  - 1. Test flow
  - 2. How to input
  - Setting reagents Purified water, Wash sol. Buffer, Latex
  - 4. Set samples
  - 5. Test

Change test mode Change measure mode Change Latex settings Create CC

6. Dispose

Example: Touch the {5. Test} button.



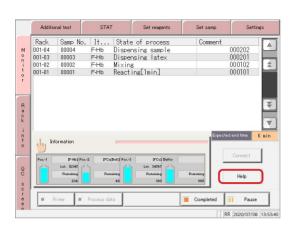


3 The page (1/#) is displayed at the top right of the screen.

Use the {Next} and {Back} buttons to check content.

{Next}:	Display the next page.
{Back}:	Display the previous page.
{CLOSE}:	Return to the [HELP] screen.

## 7.2 Opening the [Help] Screen from the [Monitor] Screen



lelp -contents-	
. Test flow	5. Test
. How to input	Change test mode
I. Set reagents	Change measure mode
Purified water, Wash sol.	Change Latex settings
Buffer, Latex	Create CC
l. Set samples	8. Dispose
	t Close
	[ XX 2015/01/17 15:19

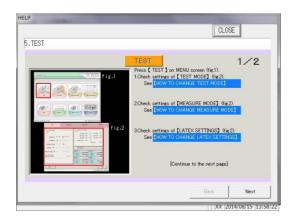
Touch the {Help} button.

- Touch the button of the item to check.
- 1. Test flow

2

- 2. How to input
- Setting reagents Purified water, Wash sol.
  - Buffer, Latex
- 4. Set samples
- 5. Test
  - Change test mode
    - Change measure mode
    - Change Latex settings
  - Create CC
- 6. Dispose

Example: Touch the  $\{5. \text{ Test}\}$  button.

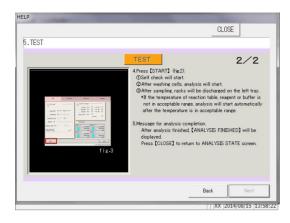


3 The page (1/#) is displayed at the top right of the

screen.

Use the {Next} and {Back} buttons to check content.

{Next}:	Display the next page.
{Back}:	Display the previous page.
{CLOSE}:	Return to the [Help] screen.



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# Chapter 8 Error Handling

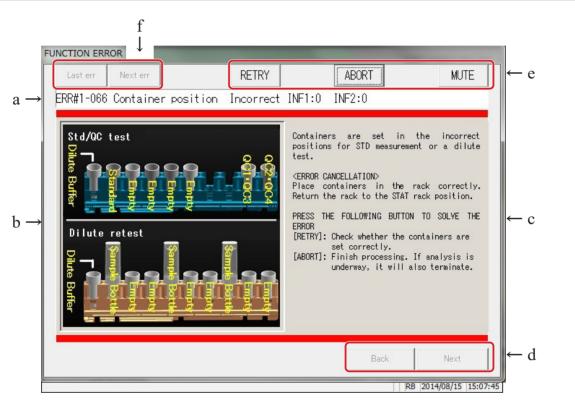
- 8.1 How to Read [Error] Screens
- 8.2 Error Cancellation Buttons
- 8.3 Clearing Errors



## Chapter 8 Error Handling

In the event of an error, the [Error] screen is displayed. If several errors have occurred, the following page is displayed. Touch {Next err}to display errors.

## 8.1 How to Read [Error] Screens



[Error] screen

а	Error status	Displays the error number and name.
b	Error location	Displays the location of the error using a graphic.
c	Error cause and cancellation method	Displays the cause of the error and how to clear it.
d	Page buttons	Switch pages when the handling method for a single error spans multiple pages.
	{Back}	Display the previous page.
	{Next}	Display the next page.
e	Error cancellation buttons	Buttons to recover from errors.
f	Error switching buttons	Switch the error display when multiple errors have occurred.
	{Last err}	Display the previous error.
	{Next}	Display the next error.

NN1-1703 Rev.3

## 8.2 Error Cancellation Buttons

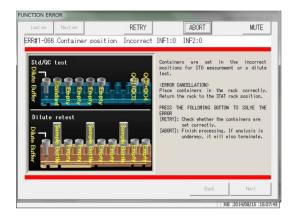
Buttons for clearing errors are displayed at the top of the [Error] screen. The following are operations after a cancellation button has been touched:

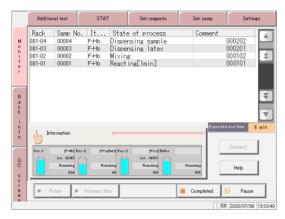
Button Name	Function
{RETRY}	Retry processing on the sample for which an error had occurred.
{PASS}	Cancel processing for the sample that is being tested, and process the next sample.
{ABORT}	Terminate processing. If selected during testing, terminates processing for the sample being tested.
{CONTINUE}	Restart the operation of the working part that was halted due to error detection
{CLOSE}	Close the screen
{MUTE}	Mute the alarm.

(Explanatory note) : The cancellation buttons that are displayed depend on what error has occurred.

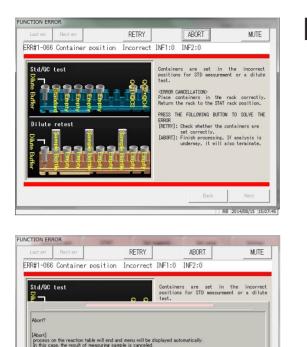
## 8.3 Clearing Errors

Clear errors using the following procedure:





- Confirm the error.
  - 1 Confirm the error and its location.
  - (2) Select the cancellation button from the error cancellation methods and touch it.
     (37) Page 325 "8.2 Error Cancellation Buttons"
- 2 For all cancellation buttons other than the {ABORT} button, the error is cleared and operation continues.



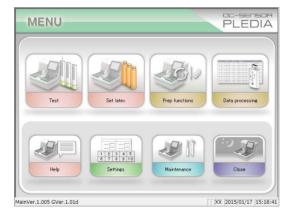
#### (continued)

<If the {ABORT} button was selected>

(1) Touch the  $\{ABORT\}$  button.

(2) Touch the {Abort} button.

- \* Reaction table processing is aborted, and the system returns to the [MENU] screen. The result of the sample being measured is canceled.
- {Cancel}: Abort is canceled and the system returns to the [Error] screen.
- {Close}: Reaction table processing is terminated and the system returns to the [MENU] screen.



Gancel

Close

2015/01/14 111:15:4

after p

(Explanatory note): If an error occurs in the following situations, the process is aborted without the Abort confirmation

dialog box being displayed even if the {ABORT} button is touched.

- Errors occurring during maintenance or support functions (errors outside of testing)
- Errors occurring on the reaction table (errors that cannot be normally closed)

MEMO

## Chapter 9 Operator/Latex Management Function (Option)

- 9.1 LOGIN/LOGOUT
- 9.2 Registering, Modifying, and Deleting Operators (ID Information)
- 9.3 Managing Latex/QC Lots



# Chapter 9 Operator/Latex Management Function (Option)

This function is used to manage the operators that are using the system and expiration dates for latex being used with the system, in conformance with ISO15189 [Medical laboratories — Requirements for quality and competence.]

In order to use this function, operator information (ID information) must be registered and lot numbers must be entered when setting latex.

Explanatory note : "Analysis" cannot be set in [Auto Startup/Auto Start Settings] for the completion mode when using the operator/latex management function.

Settings of	auto star	t up						
Auto	start up			Auto sta	rt			
su 🗌	0 :	0 min	Nothing	O Cell bla	ink	(	) Test	
MO 🗌	0 :	0 min	Nothing	O Cell bla	ink	(	🔵 Test	
TU 🗌	0 :	0 min	Nothing	O Cell bla	ink	(	🔵 Test	
WE	0 :	0 min	Nothing	O Cell bla	ink	(	) Test	
TH 🗌	0:	0 min	Nothing	O Cell bla	ink	(	🔵 Test	
FR	0 :	0 min	Nothing	O Cell bla	ink	(	) Test	
SA 🗌	0 :	0 min	Nothing	O Cell bla	ink	(	) Test	
1 2	3	4	5 6	7	8	9	0 -	
x r	Z		/ *		<b>_</b>	del	enter	
							Continue	
						XX :	2018/03/06 15	:17:20

### 9.1 LOGIN/LOGOUT

You must login to use all functions on the [MENU] screen. Enter the ID information on the [LOGIN] screen to login. The ID of the user who is logged in is shown on the [MENU] screen. After logging in, if there is no operation on the [MENU] screen for a certain period of time, you will be automatically logged out.

Page 276 "6.1.4 Environment settings"



### 9.1.1 LOGIN

Start the system and run either introduction priming or cell blank measurement to open the [LOGIN] screen.

LOG	IN : Remainin	g numbers	of registra	tion						
0	ID				РАЗ	SWORD				Update
NA		1	1	1	1	1	1	1	1	1
a	b	C	d	e	f	ß	h	i	j	k
1	m	n	0	p	q	r	5	t	u	V
*	x	y	Z					A/a	5	lign
1	2	3	4	5	6	7	8	9	0	_
				1/	*	-		del	_0	enter
0/	Registe	r 🛛	Change	Info	🔏 Dele	ete 📘	ZDeleta	e al l	/ LOGIN	N / LOGOUT
								[ [ X	< 2018/0	3/06 15:31:

1 Enter the ID and then touch[enter].Confirm the name of the operator that is displayed.

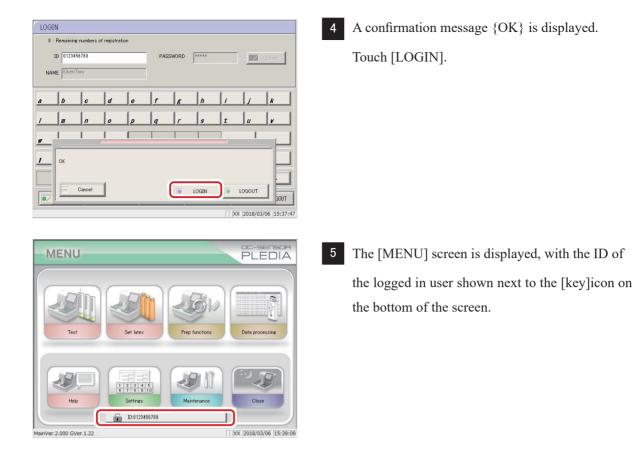
	ID 01234 ID 01234 AME Eiken	56789	of registra	tion	PAS	SWORD	1			Update
a	b	c	d	e	f	ß	h	i	j	k
1	m	n	0	p	q	r	5	t	u	v
#	x	y	Z					A/a	s	ign
1	2	3	4	5	6	1	8	9	0	_
				1	*	-	<b> </b> →	del	_[	enter
•/	Registe	r 🛛 🔼	Change	Info	Z Dela	ete	∠De l'et e	e al I 🔍	/ LOGIN	N / LOGOUT
put P	assword							[ XX	2018/0	3/06 15:33:

LOGIN 8 : R ID NAME	emaining n 0123456		registration	n	PASSV	NORD *	9000K			lpdate
a	b	c	d	e	f	g	h	i	j	k
/	m	n	0	p	q	r	5	t	u	v
,	x	y	z					A/a	Sig	n
1	2	3	4	5	6	7	8	9	0	
			]	/	*	←	<b>→</b>	de l	en	ter
●∕ Re	egister	<b>•</b> ⁄ a	nange In	fo 💽	Delete		Delete a		LOGIN /	LOGOUT

2 Enter the PASSWORD and then touch [enter].

3 Touch [LOGIN/LOGOUT].

#### 9.1 LOGIN/LOGOUT



(Explanatory note): Touching [enter] without entering ID information will display that [MENU] screen without logging in.

### 9.1.2 LOGOUT



8 : Remaining numbers of registration           ID         0123456789           NAME         EikenTaro					PASSWORD					
a	b	c	d	e	f	B	h	i	j	k
/	m	n	0	p	q	r	5	t	u	l v
#	x	y	z					A/a	s	ign
1	2	3	4	5	6	7	8	9	0	-
				1/	*	←	<b> </b> →	de l		enter
•/	Register	• •/	Change	Info	🖌 Dele	te 📕	⊿Delete			I / LOGOUT 3/06  15:40

LOGIN 8 : F bers of registrat ID 012345678 PASSWORD NAME EikenTa a ſ ſ # ОK LOGIN LOGOUT GOUT XX 2018/03/06 15:40:14

1 Touch the[key] icon (the ID of the logged in user is shown next to it) at the bottom of the [MENU] screen.

2 Touch [LOGIN/LOGOUT].

3 Touch [LOGIN].

The system returns to the [MENU] screen, andthe ID display area switches to a message {Please login.}. You are now logged out.

## 9.2 Registering, Modifying, and Deleting Operators (ID Information)

Up to 11 operators (including one administrator) can be registered. The remaining numbers of registration are shown on the top-left of the [LOGIN] screen. The first ID that is registered (the ID registered when the remaining numbers of registration are 11) will be the administrator.

2

3

9.2.1 Registering ID Information

This method is used to register new ID information.

Open the [LOGIN] screen.If another operator is logged in, touch the [Key] icon on the [MENU] screen to logout. Once you return to the [MENU] screen, touch the [Key] icon again.

Touch [Register].Confirm the name of the

operator that is displayed.

LOGI	IN .										
9 : Remaining numbers of registration											
	ID				PAS	PASSWORD Update					
NA	ме				1						
	1	1	1	1	1	1	1	-	1	1	
a	b	c	d	e	f	E	h	i	j	k	
1	m	n	0	p	q	r	5	t	u	l v	
"	x	y	z					A/a	s	ign	
1	2	3	4	5	6	7	8	9	0	-	
				/	*	←	→	de l		enter	
💽 Register 🖉 Gnamge Info 📝 Delete 📝 Delete all 💽 LOGIN / LOGOUT											
								[ [ XX	2018/0	3/06 15:26:	

LOG	IN										
•	: Remainin	ig numbers	of registra	ation	_						
	ID				PA:	PASSWORD Update					
	IME										
a	b	c	d	e	f	E	h	i	j	k	
1	m	<i>n</i>	0	p	q	r	5	t	u	v	
*	x	y	z					A/a	5	iign (	
1	2	3	4	5	6	7	8	9	0		
				1/	1.*			del	ſ	enter	
	Registe		Change	Info	Zi Del	oto	∕ <b>i</b> Delete	1			
	melore	<u> </u>	- winkinge		Ver Der		Ne reve	, in the second s		3/06 15:26:5	

Enter the password and then touch [enter].

#### 9.2 Registering, Modifying, and Deleting Operators (ID Information)

LOG	LOGIN												
9	9 : Remaining numbers of registration												
	ID 0123	456789			PAS	SWORD	*****		•/	Update			
NA	ME Eiker	Taro											
	1	1	-	-	1	-	-	1	1	1 1			
a	b	c	đ	e	f	ß	h	i	j	k			
1	m	n	0	p	q	r	5	t	u	v			
#	x	y	Z					A/a	S	ign			
1	2	3	4	5	6	1	8	g	0				
					*	<b>_</b>	→	de l		ontor			
	🥂 Register 📝 Change Info 📝 Delete 📝 Delete all 📝 LOGIN / LOGOUT												
	[] [XX  2018/03/06  15:29:54												

4 Touch [Update].A confirmation message

{ Register the entered information.} is displayed.

Explanatory note : If you touch [enter] without entering the ID information,

the "One or more required fields are empty" message is displayed.

ID 01	ning numbers 3456789 enTaro	of registri	ation	PA	SSWORD			•/	Update
a b	c	d	e	f	ß	h	i	i	k
1 m	n	0	p	q	r	5	t	u	v
<u></u>	1	1					<u>.</u> .	1.	
	ter the enter		ition					ОК	

5 Touch [Update]

ID information registration is complete. ID information will not be registered if you touch [Cancel].

#### 9.2.2 Change ID

This method is used to change ID information that has already been registered.

LOG		numbero	of registra	tion							
C : Remaining numbers of registration     PASSWORD     Opdere     NAME											
a	b	c	đ	e	f	ß	h	i	j	k	
1	m	n	0	p	q	r	5	t	u	v	
*	x	y	z					A/a	S	ign	
1	2	3	4	5	6	7	8	g	0		
					*	-	<b> </b> →	de l	_(	enter	
•/	Register		Change	Info 📘	🔏 Dele	ite 📘	⊿Delete	all 🌒	/ LOGIN	I / LOGOUT	
								[[ <b>X</b>	2018/0	3/06 15:43:5	

Enter the ID and then touch [enter]. Confirm the name of the operator that is displayed.

		numbers o	f registrat	ion								
ID 0123456789												
NAM	E EikenT	aro										
	1	1	1	1	1	1	1	1	1	1		
a	b	С	đ	e	f	8	h	i	j	k		
/	m	n	0	p	q	r	5	t	u	v		
#	x	y	Z					A/a	s	ign		
1	2	3	4	5	6	7	8	9	0	-		
			1	1/	*			del	ſ	enter		
•⁄ F	Register		Ohange I	info 📘	🖉 Dele	te 📘	∠Delete			I / LOGOUT		

LOG	IN											
8	:Remaining	numbers	of registra	tion								
	ID 0123456789 PASSWORD ***** Update											
NA	ME Eiken1	l'aro										
a	6	6	d	e	f	ß	h	<i>i</i>	li	k		
7	1	1	0	0	a		5	t	u lu			
		<u>n</u>	0	p	<i>q</i>	r	5					
#	x	у	z					A/a	S	ign		
1	2	3	4	5	6	7	8	9	0			
					*	←	<b> </b> →	de l		ontor		
V Register () Change Info												
[[ XX [2018/03/06  15:45:01												

2 Enter the PASSWORD and then touch [enter].

3 Touch [Change Info].The PASSWORD field is cleared.

(Explanatory note) : Entering an ID and password that have already been registered will activate the [Change Info] button.

- 9.2 Registering, Modifying, and Deleting Operators (ID Information)
- LOGIN 8 : Re aining numbers of registration ID 12345678 PASSWORD NAME EikenTaro в h a A/a H 3 enter de l ●/ LOGIN / LOGOUT XX 2018/03/06 15:48:25

LOGI	LOGIN												
8 :	8 : Remaining numbers of registration												
:	ID 01234	56789			PAS	SWORD	*****			Update			
NAN	1E Eiken	Taro											
	1	1	1	1	1	1	1	1	1	1 1			
<u>a</u>	b	c	đ	e	f	B	h	i	j	k			
1	m	n	0	p	q	r	5	t	u	v			
*	x	y	Z					A/a	8	ign			
	1	1	1	1	1	1	1	(	1	1 1			
1	2	3	4	5	6	7	8	9	0				
					*	-		de i		onter			
	Register Change Info Z Delete ZDelete all 🔽 LOGIN / LOGOUT												
	[ [XX  2018/03/06  15:48:54												

LOGI	IN												
8	Remaini	ne numbers	s of registra	ation									
ſ	ID 0123456789 PASSWORD ***** Vupdate												
NAI	NAME EkkenTaro												
a	b	c	d	e	f	ß	h	i	j	k			
1		n	0	p	q	r	5	t	u	v			
"	1	1	1					<u> </u>	1				
1	Regist	er the ente	red informa	tion									
		Cancel							ОК				
								[[]	X 2018/0	3/06 15:48:54			

4 Enter the new ID information and then touch [enter].

Touch [Update].

6 A confirmation message { Register the entered information?} is displayed.

ID information registration is complete. ID information will not be registered if you touch [Cancel].

The ID information is updated with the new information.

#### 9.2.3 Deleting ID Information

ID information for individual operators can be deleted by the administrator or the individual operator. The administrator can also delete all ID information that has been registered.

LOG	IN											
8 : Remaining numbers of registration												
ID PASSWORD Update												
NAME												
	,											
a	b	c	d	e	f	B	h	i	j k			
7	[	<i>n</i>	0	p	a	r	5	t	u v	1		
<u></u>					4			<u> </u>				
#	x	у	z					A/a	Sign			
1	2	3	4	5	6	7	8	9	0 -			
				1/	*	←	→	de i	enter			
Register A Ghange Info A Delete all R LOGIN / LOGOUT												
[ XX 2018/03/06 15:50:13												

LOGIN													
8 : F	Remaining r	umbers of	registration	n	_								
IC	0123456	789			PASSWORD Update								
NAME	EikenTa	°0			<u> </u>								
	1	1	1	1	1	1	1	1	1 1 1				
<u>a</u>	b	c	d	e	f	E	h	i	j k				
1	m	n	0	p	q	r	\$	t	u v				
#	x	y	z					A/a	Sign				
1	2	3	4	5	6	7	8	9	0 _				
	the test of t												
●∕ R	Register Change Info Celete Celete all 💌 LOGIN / LOGUT												
Input Pass	nput Password												

LOGIN												
8 :	Remaining	numbers of	registratio	n								
	ID 0123456	3789			PASS	WORD	****		Update			
NAM	IE EikenTa	iro										
	1	1	1	1	1	1	1	1 1 1				
8	b	c	đ	e	f	E	h	i	j k			
1	m	n	0	p	q	r	5	t	u v			
*	x	y	z					A/a	Sign			
1	2	3	4	5	6	7	8	g	0 _			
	de l onter											
•/	💌 Register 🔍 Change Info 😥 Delete 🖉 Delete all 💽 LOGIN / LOGOUT											
	[ XX 2018/03/06 15:51:10											

LOGIN													
10	10 : Remaining numbers of registration												
	ID 11111	l			PAS	SWORD			Update				
NA	ME 11111				]								
8	b	c	đ	e	f	ß	h	i	j k	4			
1		n	0	p	q	r	5	t	u v				
	x	y y	Z					A/a	Sign	1			
1	2	3	4	5	6	7	8	9	0 -	1			
	$\begin{array}{cccccccccccccccccccccccccccccccccccc$												
•/	Register 💽 Change Info 🔟 Delete 💽 Delete all 💽 LOGIN / LOGOUT												
	[]XX [2020/12/24 [9:24:32]												

Enter the ID and then touch [enter]. Confirm the name of the operator that is displayed.

2 Enter the PASSWORD and then touch [enter].

3 Touch [Delete].

A "Delete displayed operator information" confirmation message appears.

If you are an administrator,

a "Delete all imformation except administrator in the registration list" confirmation message is displayed.

- 9.2 Registering, Modifying, and Deleting Operators (ID Information)
  - 4 A confirmation message { Delete the operator information in the registration list which displayed.} is displayed.

Touch [OK].

•/	<u> </u>	Galicon						<u> </u>	UK	GOUT
								[ <b> </b> X	K 2018/03	/06 15:51:10
LOGI	N									
8 :	Remainin	e numbers	of registra	rtion						
1	ID 01234	56789			PAS	SWORD	88888			Update
NAM	1E Eiken	Taro			-		,			
	1									
a	b	c	d	e	f	E	h	i	j	k
1	m	n	0	p	q	r	5	t	u	v
	1	1	1					<b>.</b>	1.	1
	Delete a	all informat Cancel	ion except	administra	tor in the re	egistration	list	•	OK	
								[ [ X	K 2018/03	/06 15:51:10

PASSWORD \*\*\*\*

e f

1 1 1

Т

Delete

q r

 $\square$ 

LOGIN

8 : Remaining num ID 0123456789

NAME E

a

\*

LO	GIN									
9 : Remaining numbers of registration										
ID			PAS	SWORD				Update		
NAME			-		,					
a	b	c	d	e	f	ß	h	i	j	k
7	m	n	0	p	q	r	5	t	u	v
"	x	y	z					A/a	s	i gn
1	2	3	4	5	6	7	8	9	0	
				/	*	_	<b>_</b>	de i		enter
•	🖊 Registe	er 🖂	Change	Info	Z Dele	te 📘	ZDeleta	e al 🌘	/ LOGIN	I / LOGOUT
								[ [ XX	2018/0	3/06 15:52:20

5 The system returns to the [LOGIN] screen.

To delete ID information for all operators, the administrator must touch [Delete all] during Step.

## 9.3 Managing Latex/QC Lots

When a lot number is entered when setting latex, the expiration date is calculated from the lot number information.

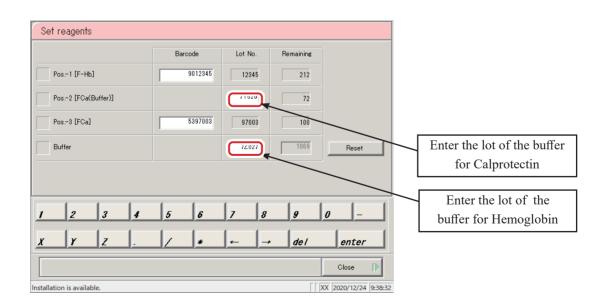
When sample or QC measurement is performed, the lot number and expiration date are recorded in the analysis results.

Explanatory note : Analysis can be performed even if the latex is past its expiration date, so always check the expiration date.

Lot management information	Details	
Operator ID	The ID of the operator that is logged in.	
Latex lot(*1)	The lot of the latex that was used.	
Latex expiration date(*1)	The expiration date of the latex, calculated from the lot number entered when setting latex.	
Buffer lot(*1)(*2)	The lot of the buffer that was used.	
Buffer expiration date(*1)	The expiration date of the buffer, calculated from the lot number entered when setting buffer.	
QC lot(*1)	The lot of the QC that was used.	
QCexpiration date(*1)	The expiration date of the QC, calculated from the lot number entered when setting QC.	

\*1 If the dispensing operation is not performed, "" is output for the lot and expiration date.

\*2 Enter the lot of the buffer on the reagent set screen.



# Appendix

- 1 Calculation Processing
- 2 Test Operations
- 3 Printing examples
- 4 Handling the Printer
- 5 Error List
- 6 Save to External Media
- 7 Management USB Stick Setting



## 1 Calculation Processing

The following calculations are processed during testing:

- 1.1 STD/QC Sample Measured Data Check
- 1.2 Calibration curve calculation
- 1.3 DA value calculation
- 1.4 Measured Data (Concentration) Calculation and Qualitative Assessment
- 1.5 Prozone check
- 1.6 Reagent Blank Check (A1 Check)
- 1.7 Calculate Cell Blank

## 1.1 STD/QC Sample Measured Data Check

Check whether the measurement results for STD or QC samples are correct.

1.	S	STD sample measured data check						
		① Check that the calibration curve is rising from bottom left to top right from						
		the magnitudes of the DA1 values at each point.						
		② Check whether the magnitudes of DA1 values at adjoining points are not						
		the same. If they are the same, the result is judged as "abnormal."						
		③ Check the deviation (%) between the origin and back fit.						
		The specifications for each STD are as follows:						
		• STD-1 "Abnormal" if outside DA upper/lower range						
		• STD-2						
		"Abnormal" if deviation is not within $\pm 10\%$ of the origin						
		• STD-5						
		STD-6 "Abnormal" if outside DA upper/lower range						
	1	₩						
2.	ς	QC sample measured data check						

Check based on the control limit values set in the [STD/QC process settings] screen.

The result is judged as "abnormal" in the following cases:

- The minimum control limit value is less than 1
- The maximum control limit value is +1 or more

## 1.2 Calibration curve calculation

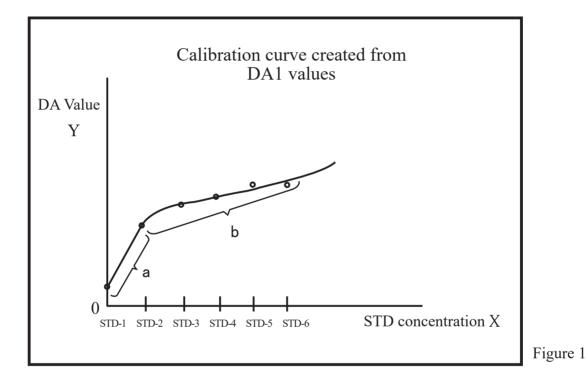
There are three curve types: Aloka curve, linear and cubic curve, and Cubic spline curve.

#### Aloka curve

Fits an Aloka curve to plotted DA1 value to obtain a calibration curve.

Aloka curves are composed of a linear fit portion and a cubic fit portion.

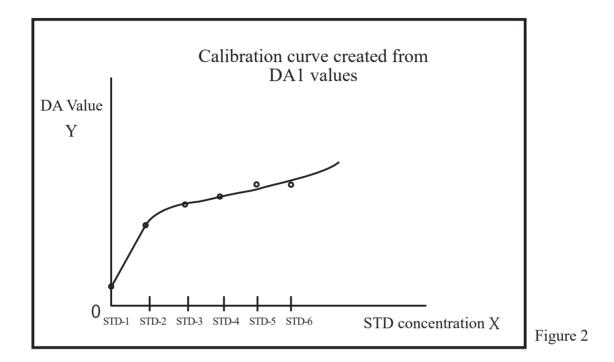
- Linear fit  $\rightarrow$  between STD-1 and STD-2 (Figure 1-a)
- Cubic fit  $\rightarrow$  between STD-2 and STD-6 (Figure 1-b)



STD concentration (X):	Converted logarithmically, and a cubic-polynomial fitting is performed.		
	$X = log_{10}$ (STD concentration)		
DA value (Y):	R converted logarithmically, and a cubic-polynomial fitting is performed.		
	$Y = \log_{e} \{R \div (1-R)\}$		
R:	Converted value for Aloka curve		
	$R = (DA value - NSB) \div (B0 - NSB)$		
	NSB = Cmin - KL (Cmax - Cmin)		
	B0 = Cmax + KH (Cmax - Cmin)		
	KL = 0.2, KH = 0.2		
Cmax:	DA value maximum		
Cmin:	DA value minimum		

<Zero concentration point measured>

A linear line is fitted to the DA values of STD-1 and STD-2.



DA values used by calibration curve

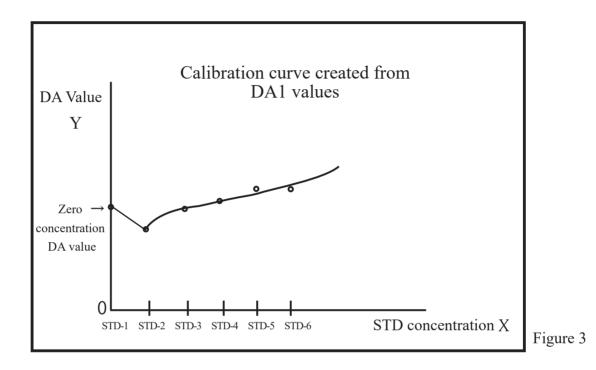
Replicate  $n \ge 3$ : The mean DA value excluding the maximum and minimum values Replicate n < 3: The mean DA value

#### 1 Calculation Processing

<DA value at zero concentration point larger than DA value at STD-2 concentration point>

Regression analysis is not performed between STD-1 and STD-2.

With this kind of calibration curve, measured data cannot be calculated from a DA value lower than the DA value of STD-2.



(Explanatory note): In cubic regression calculation, calculation is performed with X and Y reversed.

(X: DA value, Y: concentration value)

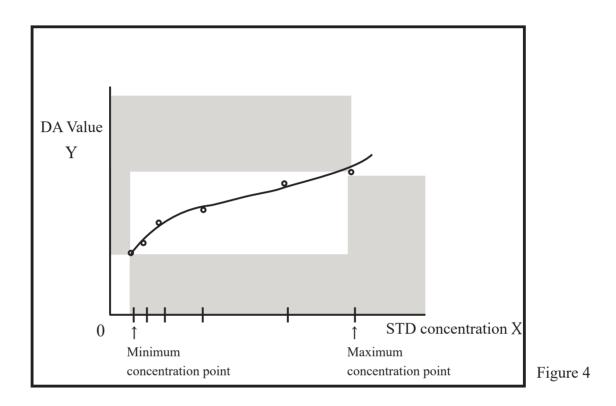
In Aloka curve calculation, X and Y are not reversed.

DA value normalization is not performed

(normalized DA value = DA value  $\div$  DA value of maximum concentration point).

#### Incalculable range of measured data

The range outside maximum DA value, minimum DA value, and B0 cannot be calculated. The range outside the maximum and minimum concentration values also cannot be calculated (the shaded regions in Figure 5).



#### 1 Calculation Processing

#### Linear and cubic curves

A linear line and cubic line are fitted to the DA1 values.

- Linear fit  $\rightarrow$  between STD-1 and STD-2 (Figure 1-a)
- Cubic fit  $\rightarrow$  between STD-2 and STD-6 (Figure 1-b)

The DA value of the linear STD-2 point is calculated using Newton's method from the cubic line.

Page 345 " ■ Aloka curve <Zero concentration point measured>"

#### Cubic spline curve

Regress DA1 with a cubic spline curve to create a calibration curve.

A cubic polynomial approximation of each interval from STD-1 to STD-6.

$$Y = F_{3i} \cdot X^{3} + F_{2i} \cdot X^{2} + F_{1i} \cdot X + F_{0i} \quad (i:0 \sim 4)$$
  
STD-1 ~ STD-2 interval :  $F_{30} \quad F_{20} \quad F_{10} \quad F_{00}$   
STD-2 ~ STD-3 interval :  $F_{31} \quad F_{21} \quad F_{11} \quad F_{01}$   
STD-3 ~ STD-4 interval :  $F_{32} \quad F_{22} \quad F_{12} \quad F_{02}$   
STD-4 ~ STD-5 interval :  $F_{33} \quad F_{23} \quad F_{13} \quad F_{03}$   
STD-5 ~ STD-6 interval :  $F_{34} \quad F_{24} \quad F_{14} \quad F_{04}$ 

<DA value at zero concentration point larger than DA value at STD-2 point>

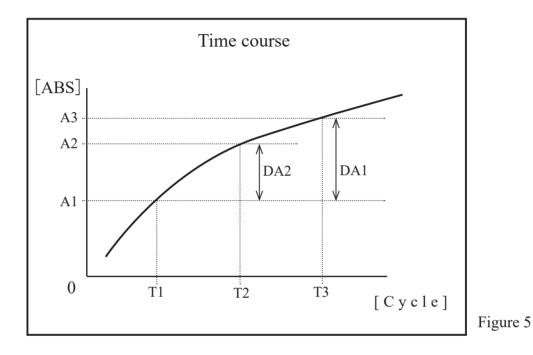
Page 346 " ■ Aloka curve <DA value at zero concentration point larger than DA value at STD-2 concentration point>

## 1.3 DA value calculation

DA values are final measurement results. Measured data (concentration value: X) is calculated from DA values and calibration curves. When a reagent is dispensed to a cell that has dispensed a sample, latex agglutination proceeds and absorbance (ABS) changes.

The time course shows changes in absorbance.

The time course is monitored once a sample is dispensed into a cell (see Figure 5).



T1: 1st detection point	A1: T1 absorbance
T2: 2nd detection point	A2: T2 absorbance
T3: 3rd detection point	A3: T3 absorbance

A1, A2 and A3 are the mean values of absorbance of two consecutive cycles. Example: T1 = 6, T2 = 8, T3 = 33 [Cycle]

A1 = (Absorbance of the 6th cycle + absorbance of the 5th cycle)  $\div$  2

A2 = (Absorbance of the 8th cycle + absorbance of the 7th cycle)  $\div$  2

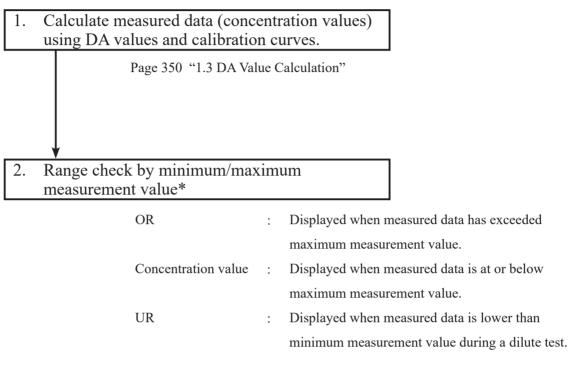
A3 = (Absorbance of the 33rd cycle + absorbance of the 32nd cycle)  $\div$  2

DA values are the amount of change for A1, A2, and A3.

DA1: A3 - A1 DA2: A2 - A1

## 1.4 Measured Data (Concentration) Calculation and Qualitative Assessment

Measured data (concentration values) is calculated from DA values and the calibration curve, normalized measured data and cut-off values are compared, and a qualitative assessment is performed.



Page 308 "6.2.1 Sample/QC protocol settings"

\* Measured data is the value prior to correction (such as correction by factor A/B or by applying a dilution ratio).

#### 1 Calculation Processing

### 1.5 Prozone check

Prozone checking is conducted using two methods: RBC method and PRC method.

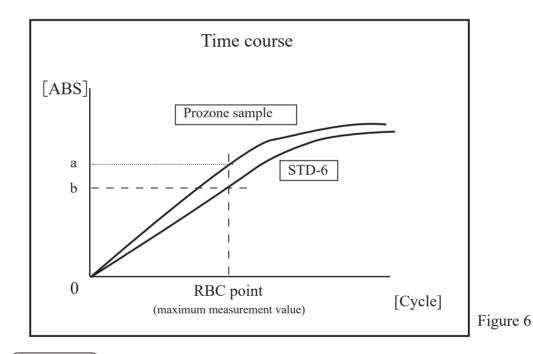
RBC method: Compare the absorbance of the RBC points in STD-6 (maximum concentration point) and the sample.

PRC method: Compare the DA2 values in STD-6 (maximum concentration point) and the sample.

#### RBC method

Compare the RBC point sample absorbance (a) and STD-6 absorbance (b), if the following relationship is formed, designate the sample as "prozone samples."

(b)  $\times$  RBC method coefficient < (a)



Explanatory note : The RBC method coefficient is set in "9RBC method coefficient" on {Page 2} of the [Protocol settings] · [Samp/QC protocol] screen.

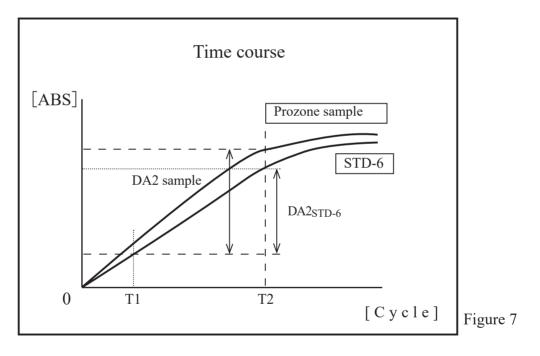
Explanatory note: The sample absorbance (a) and STD-6 absorbance (b) are the mean values of each RBC point and its previous point.

Example: When the RBC point is 5, (a) and (b) are each the value of (5th cycle absorbance + 4th cycle absorbance)  $\div$  2.

#### PRC method

Compare the DA2 values of the sample and STD-6, forming the following relationship. Standing samples are designated as "prozone samples."

 $DA2_{STD-6} \times PRC$  method coefficient  $< DA2_{sample}$ 



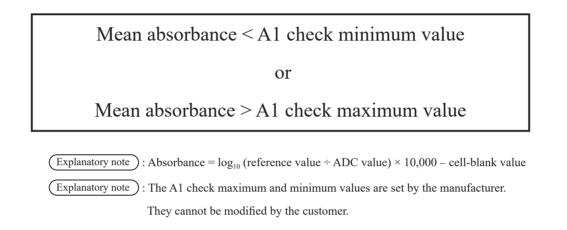
 $DA2_{sample}$ : DA2 value of prozone sample

DA2<sub>STD-6</sub>: DA2 value of STD-6

## 1.6 Reagent Blank Check (A1 Check)

Checks whether or not a reagent was dispensed normally using the absorbance of the T1 cycle. ADC values of the T1 cycle and the T1-1 cycle are averaged to obtain absorbance, which is compared with the maximum and minimum values of the A1 check.

If either of the following conditions is met, an error message appears displaying "Latex blank error."



## 1.7 Calculate Cell Blank

Perform detection for each cycle for each of the 55 cells after the start analysis.

• For the 55th cell, the ADC mean value is calculated using ADC values measured during the period of time between dispensing of purified water with the 3rd nozzle and absorbing of purified water with the 4th nozzle (four cycles), and this ADC mean value is used as the reference value.

Reference value = (ADC mean value)

= Four-cycle Accumulation of ADC values ÷ 4 (Cycles)

• For each of the 1st to 54th cells, calculate the mean value of ADC values in the same way as with the 55th cell, and calculate a cell-blank value according to the following equation.

Cell-blank value

=  $Log_{10}$  (Reference value  $\div$  ADC average)  $\times$  10,000

354

MEMO

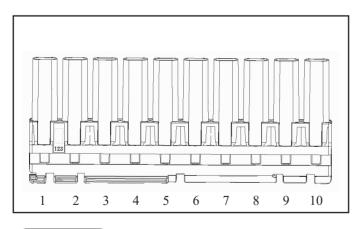
## 2 Test Operations

This section describes test operations according to the rack or measure mode being used.

- 2.1 Operation when first measuring a sample using a "sample rack" (first test)
- 2.2 Operation when retesting a sample using a "retest rack" (retest)
- 2.3 Operation when remeasuring a sample using a "sample rack" (remeasure)
- 2.4 Operation when diluting a sample again and measuring it using a "dilute test rack" (dilute test)
- 2.5 Operation when measuring STD/QC samples
- 2.6 Operation when performing cut-in analysis

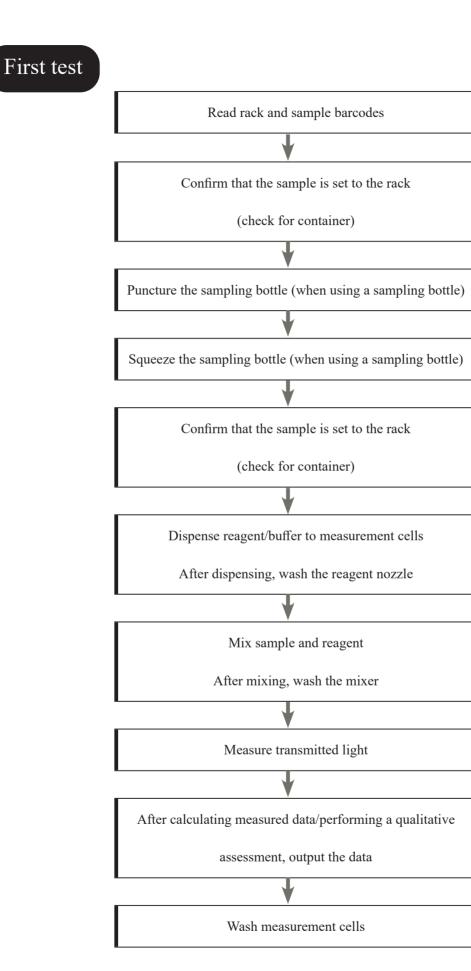
2.1 Operation when first measuring a sample using a "sample rack" (first test)

This section describes the "first test" operation. The sample is set as in the following figure.



(Explanatory note): The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.
 (Explanatory note): If the accessory end ring is attached to a rack, racks from the one with the ring will not be

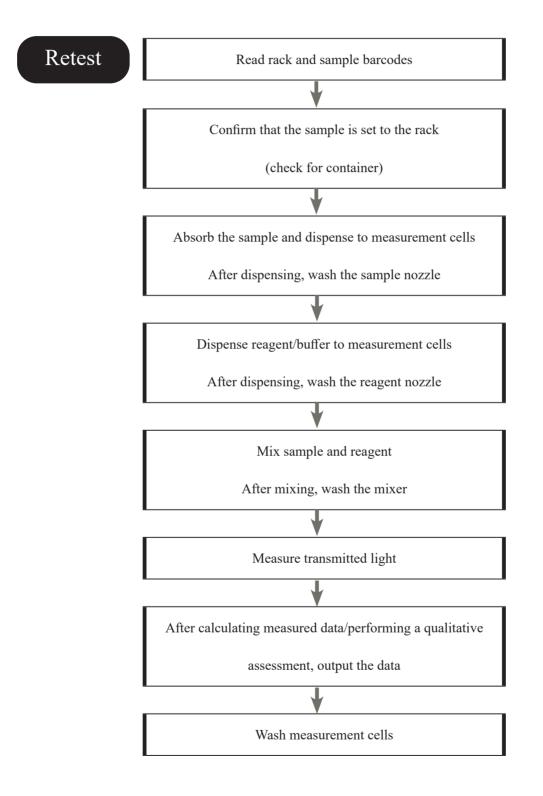
analyzed.



## 2.2 Operation when retesting a sample using a "retest rack" (retest)

This section describes the "retest" operation.

Analyzed samples will be reanalyzed, so do not puncture the sampling bottle. Otherwise, the procedure is the same as that for "first test."



(Explanatory note): Retest results have no impact on the positive rate.

"Duplicated sample barcode checking" is not performed during retests.

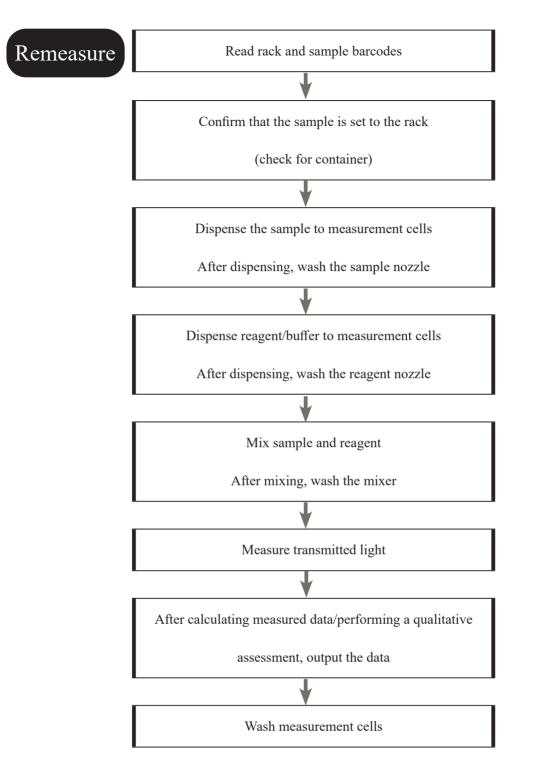
#### 2 Test Operations

# 2.3 Operation when remeasuring a sample using a "sample rack" (remeasure)

This section describes the "remeasure" operation.

Measured samples will be remeasured, so do not puncture the sampling bottle.

Otherwise, the procedure is the same as that for "first test."



#### 2 Test Operations

## 2.4 Operation when measuring a sample again it using a "dilute test rack" (dilute remeasure)

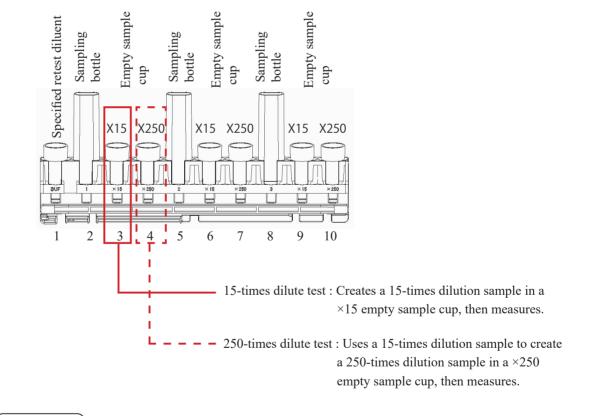
This section describes the "dilute test" operation.

Analyzed samples will be reanalyzed, so do not puncture the sampling bottle.

If the dilute test rack is used, automatic dilution will be performed. There are two dilution operations: 15-times dilution and 250-times dilution. The system determines which to use based on the arrangement of sample cups in the rack.

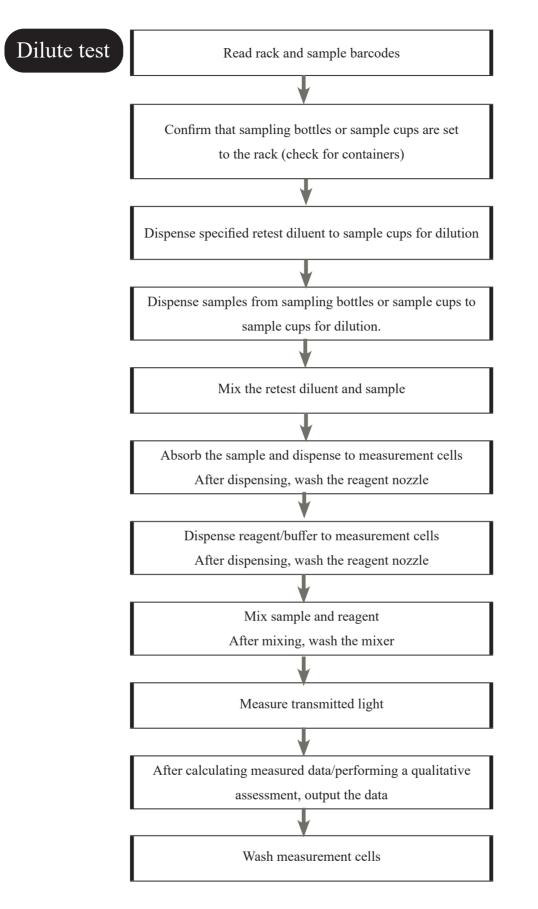
	Request
	• Use the dilute test rack when remeasuring a sample that had a dilute test performed on it. Do not use the retest rack.
Explan	natory note) : See page 272 "6.1.3 Rack No./QC No." for information on how to set the retest rack
	or dilute test rack numbers.
	atominate . There are true dilution and the times dilution and 250 times dilution. The another

(Explanatory note): There are two dilution operations: 15-times dilution and 250-times dilution. The system determines which to use based on the containers arranged on the rack.



(Explanatory note): ×15 simultaneous analysis involves creating 15-times dilution and 250-times dilution samples, and then measuring them (same as with 250-times dilute test).

Explanatory note : The numbers in the diagram indicate the rack position number. They are numbered from left (No. 1) to right.



(Explanatory note): "Duplicated sample barcode check" is not performed during dilute tests.

### 2.5 Operation when measuring STD/QC samples

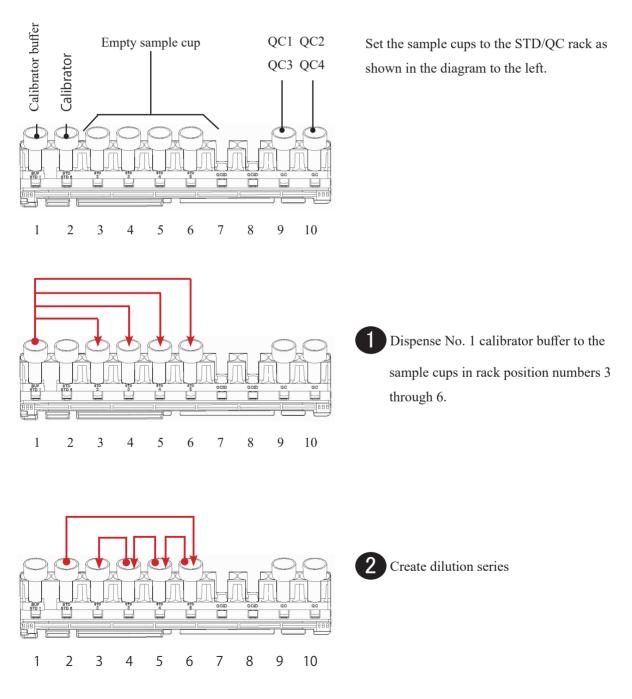
This section describes the operation when measuring STD/QC samples.

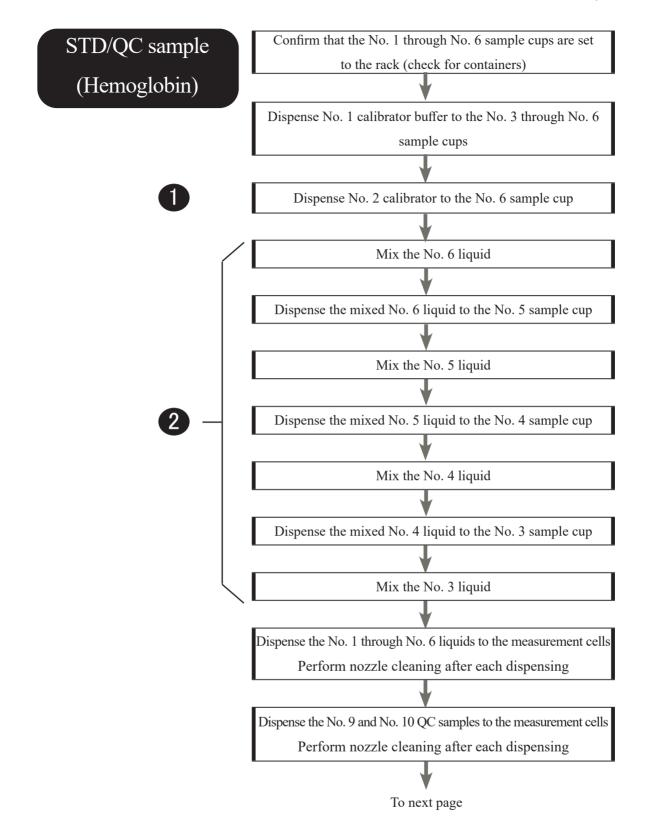
When STD/QC racks are placed in the rack supply unit, a calibration curve is created and the samples set to the rack are measured.

Calibration curves are created using "Latex/CC settings" specified on the [Test] screen. Created calibration curves are registered to "Registration CC No." on the [Test] screen.

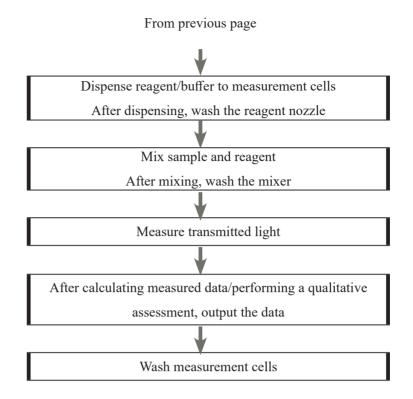
Page 64 "3 Configuring [Latex/CC settings]"

#### 2.5.1 Measurement of STD and QC in the case of hemoglobin

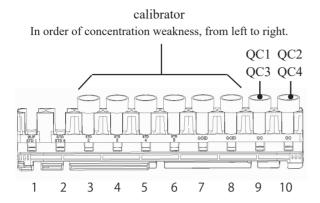




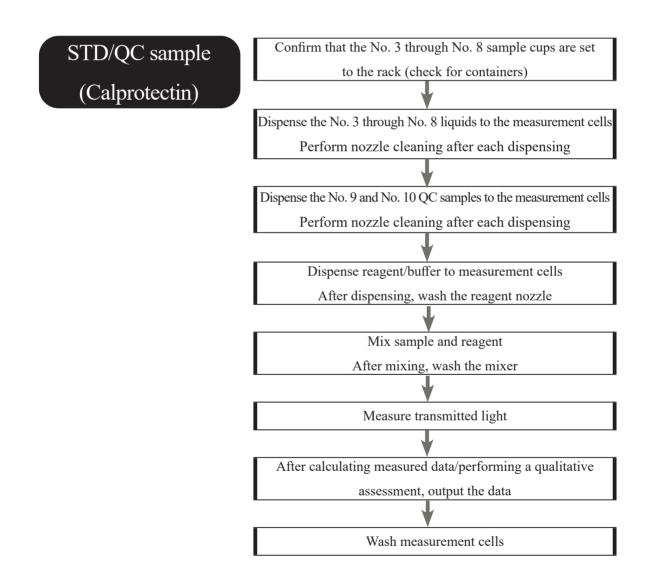
#### 2 Test Operations



#### 2.5.2 Measurement of STD and QC in the case of calprotectin

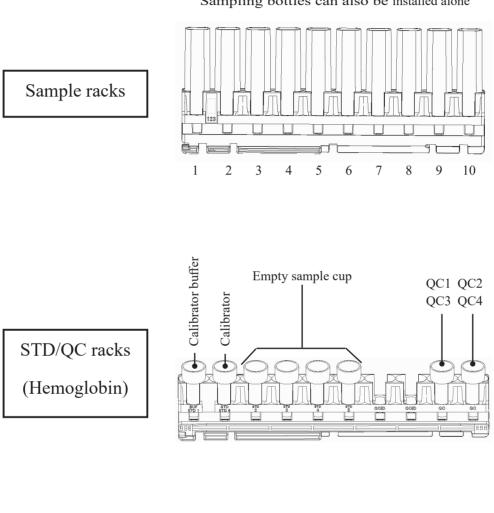


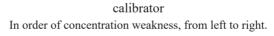
Set the sample cups to the STD/QC rack as shown in the diagram to the left.

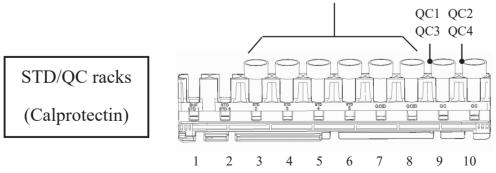


#### Operation when performing cut-in analysis 2.6

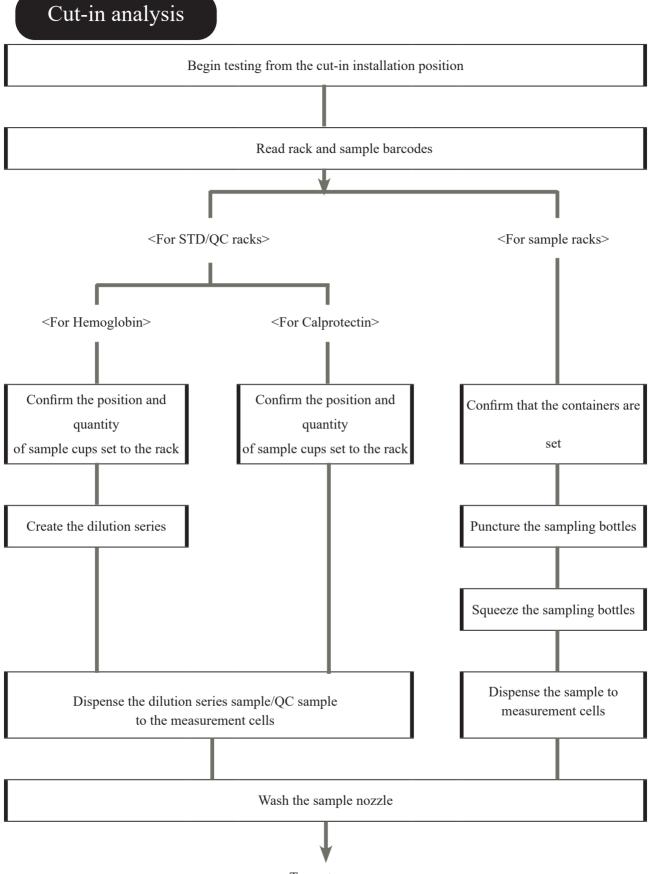
This section describes the "cut-in analysis" operation. Cut-in analysis uses sample racks and STD/QC racks. Retest racks and dilute test racks can not be used. Set samples to sample racks and STD/QC racks as follows:







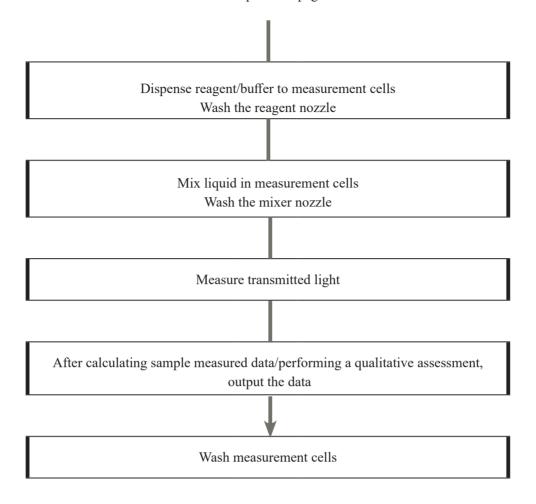
### Sampling bottles can also be installed alone





#### 2 Test Operations

From previous page



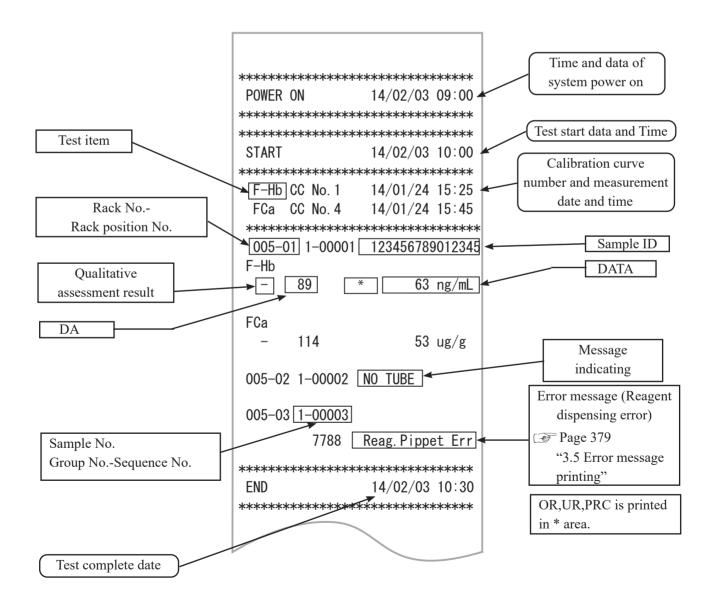
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# 3 Printing examples

This section describes various printing examples.

- 3.1 Negative sample printing
- 3.2 Final result printing when using a dilute test rack or when analyzing 15-times dilution simultaneously
- 3.3 1 day, 2 day, 3 day printing
- 3.4 Printing when measuring STD/QC samples
- 3.5 Error message printing



### 3.1 Positive sample printing

```
<When replicate number = 1>
```

"Sample information" and positive "analytical results" are printed in bold.

005–01 F–Hb –	1-00001	123456789012345
	50	50 ng/mL
005-02 F-Hb	1-00002	234567890123451
F-HD +	200	200 ng/mL

<When replicate number > 1 and mean value is a positive sample>

The mean value row only is printed in bold.

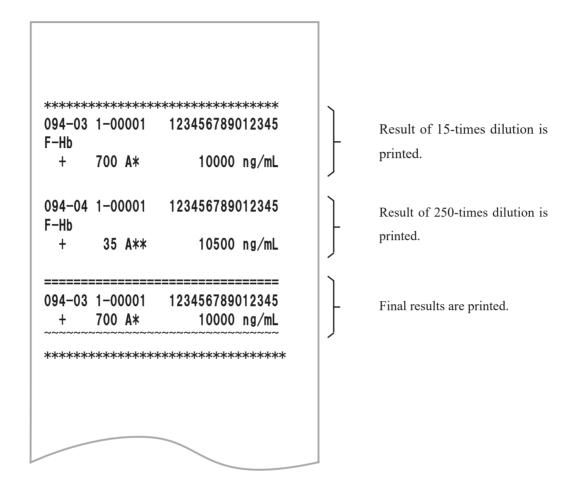
(Example : replicate = 2)

005–01 F–Hb	1-00001	123456789012345
_	95	95 ng/mL
+	110	110 ng/mL
+		103 ng/mL

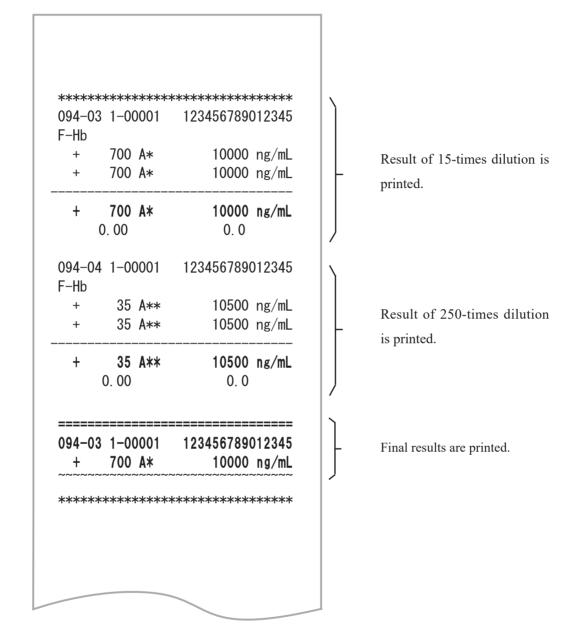
#### 3 Printing examples

# 3.2 Final result printing when using a dilute test rack or when analyzing 15-times dilution simultaneously

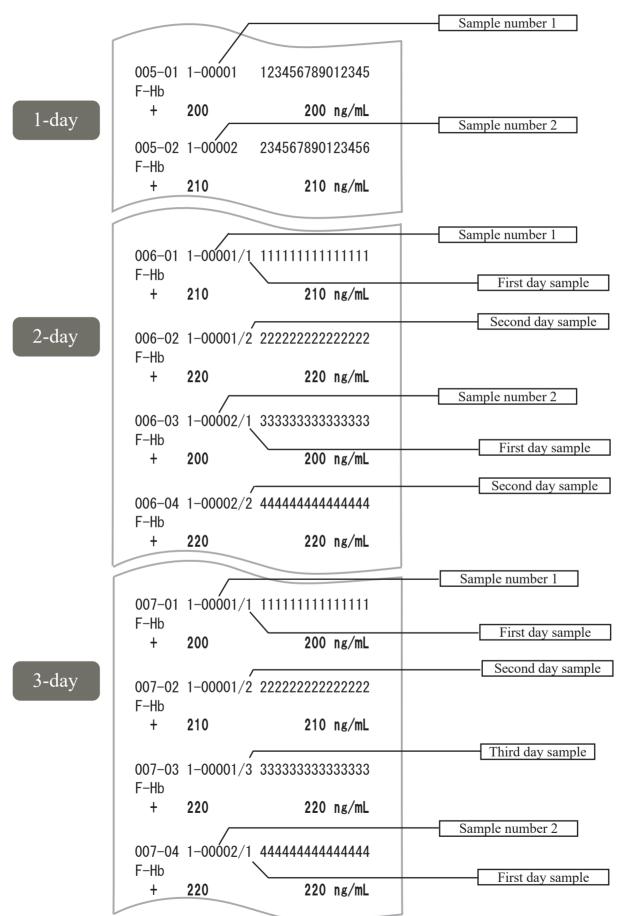
<When replicate number = 1>

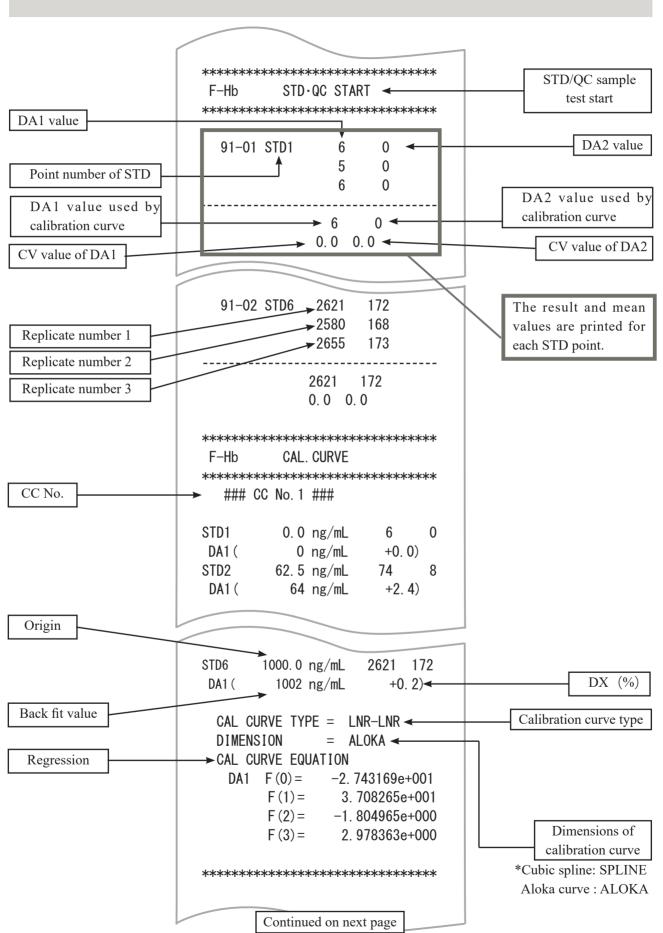


<When replicate number > 1>



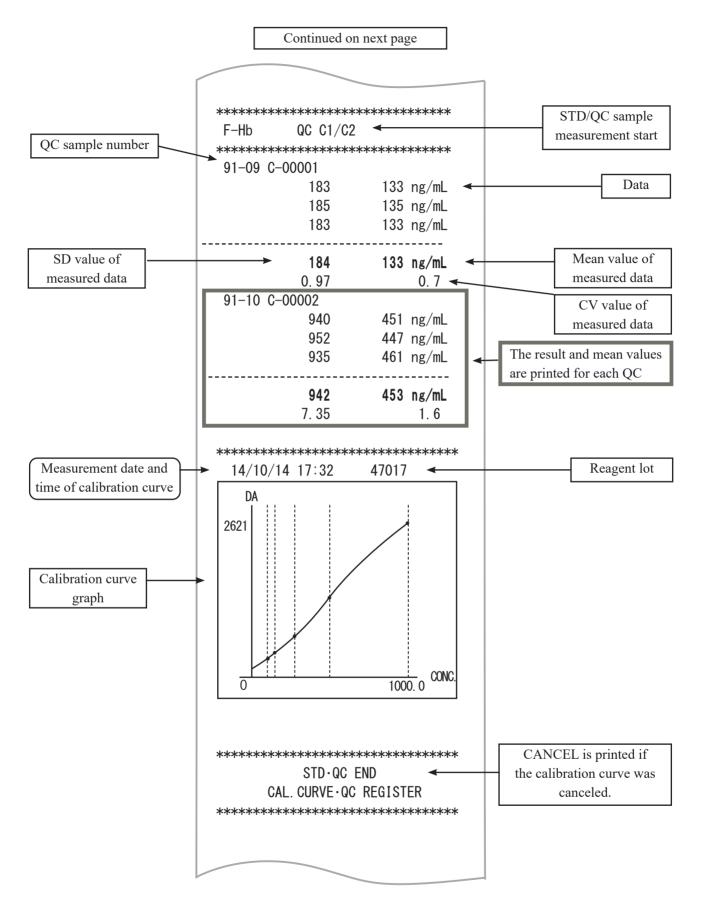
### 3.3 1 day, 2 day, 3 day printing





### 3.4 Printing when measuring STD/QC samples

#### 3 Printing examples



## 3.5 Error message printing

The meanings of error messages are shown in the chart below.

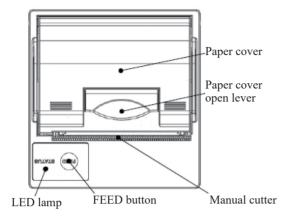
+ 200 200 ng/mL 205-02 1-0002 NO TUBE 205-03 1-0003					
k************************************	*****	*****	******	*****	1
************************************	POWER C	ON	14/02/03	09:00	
START       14/02/03 10:00         ************************************	******	******	*******	*****	
************************************	******	*****	******	*****	
F-Hb CC No. 1 14/01/24 15:25 ************************************	START		14/02/03	10:00	
k************************************	******	*****	******	*****	
005-01       1-0001       123456789012345         F-Hb       +       200       ng/mL         005-02       1-0002       NO       TUBE         005-03       1-0003	F-Hb CC N	No. 1	14/01/24	15:25	
F-Hb + 200 200 ng/mL 205-02 1-0002 NO TUBE 205-03 1-0003	******	*****	******	*****	
+ 200 200 ng/mL 205-02 1-0002 NO TUBE 205-03 1-0003	005-01 1-0	-0001	1234567890	012345	
005-02 1-0002 NO TUBE	F-Hb				
005-03 1-0003	+ 200	0	200	ng/mL	
	005-02 1-0	-0002	NO TUBE		
F-Hb	005-03 1-0	-0003			
	F–Hb				
7788 Reag. Pippet Err	778	788 🤇	Reag. Pippe	et Err	$\leftarrow$
******	******	*****	******	*****	

Error Message Text	Meaning
Sample Short	Sample insufficient
No Latex	No reagent
Latex Short	Reagent insufficient
Mixing Error	Mixing error
Latex Blank Error	Reagent blank error
No Cal. Curve	No calibration curve
Cal.Curve1 Error	STD error (DA1)
Cal.Curve2 Error	STD error (DA2)
S. Dispense Err	Sample dispensing error
L. Dispense Err	Reagent dispensing error
Puncture Error	Puncture error
None Result	No final results
Order Error	Order error
No Tube	Sample not placed
B/C Duplication	Double barcode
B/C Read NG	Barcode reading error
No Order	No Order
Printer Offline	Printer connection error and re-connection

Explanatory note : There are cases where before and after the printing of the "Printer Offline" is overlapping.

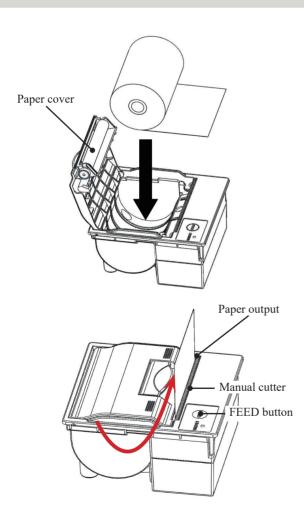
# 4 Handling the Printer

This section describes printer paper setting and LED lamp displays.



▲ Caution		
Required	• Be careful of the blade of the manual Failure to observe this precaution may lead to injury.	

### 4.1 Setting printer paper



- Raise the paper cover open lever and open the cover.
- (2) Set the paper as shown in the diagram to the left.(If this is set with the opposite facing, the system will be unable to print.)
- ③ Set the paper so that its edge sticks out of the paper output.
- Press both edges of the paper cover to close it.Confirm that the paper cover is locked.
- (5) Touch the FEED button.
- (6) Cut the paper using the manual cutter.

## 4.2 LED lamp display

If the LED lamp is lit or blinking, there is a printer error.

#### <Normal status>

LED lamp	Printer Status
Lit green	Waiting to print
Blinking green	Initializing

<When an auto carriage return error has occurred>

LED lamp	Printer Status
Blinking red	Abnormal temperature (when it has been detected that the temperature is around 70°C or higher)
Lit red	Out of paper

<When a carriage return error has occurred >

LED lamp	Printer Status
Blinking red, green	Voltage upper limit error (when it has been detected that the voltage is around 9.2 V or higher)
Blinking red, green	Voltage lower limit error (when it has been detected that the voltage is around 4.0 V or lower)

# 5 Error List

This section describes error messages that are displayed on the screen, as well as error messages printed to a printer.

### 5.1 ERR# 0-1001 - 0-2005 (Main)

Error No.	On-screen Message (Upper)			
ERR#0-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen		
1001	G communication error G Communication error	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN]: Turn off the system power. [CLOSE]: CLOSE ERROR DISPLAY		
1003	Unexpected command received Unexpected command received	(Not displayed on screen) Operation will continue automatically.		
1005	No reply from GLIFE command No Reply from GLIFE Command	(Not displayed on screen) Touch the [SHUT DOWN] button to turn off the system power. Finish the sample process currently being tested.		
1006	No reply from G command No Reply from G Command	(Not displayed on screen) Touch the [SHUT DOWN] button to turn off the system power. Finish the sample process currently being tested.		
1007	Abort failed Abort failed	(Not displayed on screen) PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN]: Turn off the system power. [CLOSE]: CLOSE ERROR DISPLAY		
1008	Multiple absorbance data were received in the same cycle. Multiple absorbance	Result Data is not affected. However, if this occurs repeatedly, please contact us. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: CLOSE ERROR DISPLAY</error>		
ERR	ERR# 0-1100 ~			
1101	Online ACK timeout error Online ACK timeout	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.		
1102	Online NAK count error Online NAK count	(Not displayed on screen) There was a fault in communication with an external computer.		
1103	Online data reception error Online data reception error	Operation will continue automatically. (Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.		
1111	Online connection error Online connection error	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.		

Error No.	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen	
ERR#0-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen	
1112	Online transmission error [Reception failed]	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.	
	Online transmission error [Reception failed]		
1113	Online transmission error [Faulty data received] Online transmission error [Faulty data received]	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.	
1114	Online transmission error [Timeout error] Online transmission error [Timeout error]	(Not displayed on screen) There was a fault in communication with an external computer. Operation will continue automatically.	
ERR	# 0-1400 <b>~</b>		
1404	Detector error	(Not displayed on screen) Touch the [ABORT] button to display the detector maximum output registration screen. Select either [REGISTER] or [CANCEL], and	
	Detector error	restart the system. Finish the sample process currently being tested.	
1409	Insufficient test reagents	Reagent low volume. Analysis stopped. Reagents need to be set on the reagent setting screen, so press the [CLOSE] button to clear the warning message. Caution: Do not restart analysis until you have set the reagents and cleared the low reagent condition. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</error>	
	Insufficient test reagents	[CLOSE]: Close the warning message.	
1410	Insufficient test buffer	Buffer low volume. Analysis stopped. Buffer needs to be set on the reagent setting screen, so press the [CLOSE] button to clear the warning message. Caution: Do not restart analysis until you have set the buffer and cleared the low buffer condition. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</error>	
	Insufficient test buffer	[CLOSE]: Close the warning message.	
	No buffer left	<ul><li>(Not displayed on screen)</li><li>(1) Open the [Set reagents] screen.</li></ul>	
1412	No buffer left	<ul> <li>(2) Add buffer.</li> <li>(3) (If you will update buffer information and run normal priming once reagents have been set). Touch the [RESET] button.</li> <li>(4) Touch the [Set complete] button.</li> </ul>	
1415	Reference cell acquisition failed Reference cell acquisition failed		
		[COERCE]: Update the reference value and continue cell blank measurement.	

Error No.	On-screen Message (Upper)	
ERR#0-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
	Double sample barcode	(Not displayed on screen)
1416	Double sample barcode	A sample barcode is duplicated. This sample will not be tested. Operation will continue automatically.
1417	Sample barcode reading error	(Not displayed on screen) A sample barcode couldn't be read. This sample will be tested. Operation will continue automatically.
	Sample barcode reading error	(Not displayed on sensen)
1418	Sample barcode digit error	<ul><li>(Not displayed on screen)</li><li>In sample barcode reading, a sample with a number of barcode digits exceeding the limit was found. This sample will be tested.</li><li>Operation will continue automatically.</li></ul>
	Sample barcode digit error	operation will continue automatically.
1419	Reagent barcode reading error	(Not displayed on screen) A reagent barcode couldn't be read. Try reading again. Operation will
	Reagent barcode reading error	continue automatically.
1420	Reagent barcode check digit error	(Not displayed on screen) An error is detected in a reagent barcode check digit inspection.
1420	Reagent barcode check digit error	Try reading again. Operation will continue automatically.
1423	Insufficient purified water Warning	Insufficient purified water Warning: Due to insufficient purified water in the tank (for purified water), sample dispensing is halted. During operation of the system, you cannot exchange tanks or add purified water. Press the [CLOSE] button to clear the warning message at this point. Notification will be provided later again when it is safe to change the tank or to add purified water. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</error>
	Insufficient purified water	[CLOSE]: Close the warning message.
1424	Insufficient wash solution Warning Insufficient wash solution	Due to insufficient wash solution in the tank (for wash solution), sample dispensing is halted. During operation of the system, you cannot exchange tanks or add the wash solution. Press the [CLOSE] button to clear the warning message at this point. Notification will be provided later again when it is safe to change the tank or to add purified water. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close the warning message.</error>
1425	Drain tank full Warning Drain tank full	Due to the drain tank being full, sample dispensing is halted. During operation of the system, you cannot exchange tanks. Press the [CLOSE] button to clear the warning message at this point. Notification will be provided later again when it is safe to change the tank or to add purified water. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Close the warning message.</error>

Error No.	On-screen Message (Upper)	
ERR#0-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
1.420	Cell check error	(Not displayed on screen)
1430	Cell check error	No cell has been set. Touch the [Abort] button and set the cells.
1431	All cell blank error	(Not displayed on screen) Cell blank status is abnormal for all cells. Touch the [Abort] button and change the cells.
	All cell blank error Reagent blank error	(Not displayed on screen)
1435	Reagent blank erfor	Latex blank is abnormal. Operation will continue automatically.
	Reagent blank error	
1436	Cell Blank Error	(Not displayed on screen) Cell blank status is abnormal. Operation will continue automatically.
	Cell Blank Error	To replace the cells, touch the [Abort] button.
1437	Transportation Result Data Error	(Not displayed on screen) An error is detected in a reagent barcode check digit inspection.
1437	Transportation Result Data Error	Try reading again. Operation will continue automatically.
1438	Container check results error	(Not displayed on screen) SAMPLE CHECK FAIL This sample will not be tested. Operation will continue automatically.
	Container check results error	
1439	Maximum number of samples reached Warning	Rack loading stopped due to reaching maximum number of sample analysis after a system start up. Close error display. If testing, close the instrument under main analysis screen of [Completed]. After system restart, new analysis can be started. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: CLOSE ERROR DISPLAY</error>
	Maximum number of samples reached	
	Program error	Close error display. Close the instrument under main analysis screen
1440	Program Error	of [Completed] <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: CLOSE ERROR DISPLAY</error>

Error No.	On-screen Message (Upper)	Emergend Classing Mathed Displayed On severe
ERR#0-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
ERR	# 0-1500 ~	
1501	Startup failed Startup failed	(Not displayed on screen) Unable to start system. Touch the [SHUT DOWN] button to turn off the system power.
1502	Analysis end processing failed Analysis end processing failed	(Not displayed on screen) Unable to complete testing. Touch the [SHUT DOWN] button to turn off the system power.
1503	Program end processing failed Program end processing failed	(Not displayed on screen) Unable to shut system down. Touch the [SHUT DOWN] button to turn off the system power.
1504	A required file cannot be found.	FILE MISSING INF1: Missing file No. 1 = Config.ini 2 = Support.ini <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN] Shut down the system.</error>
1505	No file func.ini is abnormal or cannot be found.	(Not displayed on screen) A file cannot be found. Touch the [SHUT DOWN] button to turn off the system power.
	func.ini is abnormal or cannot be found.	
1506	kinou.dat is abnormal or cannot be found. Kinou.dat Abnormal	(Not displayed on screen) A file cannot be found. Touch the [SHUT DOWN] button to turn off the system power.
1509	Necessary common memory cannot be found. No common memory	(Not displayed on screen) Memory cannot be found. Touch the [SHUT DOWN] button to turn off the system power.

Error No.	On-screen Message (Upper)	
ERR#0-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
1511	(Message not printed)	PROGRAM ERROR (MEMORY) due to file setting failure INF1: Common memory No. 1-46 No. 01: Sample barcode (SysTBer.tx1) No. 02: Ravie information (SysRack.tx1) No. 03: Environment setting (SysEnv.tx1) No. 04: Data output (SysOfOut.tx1) No. 05: Output format (SysForm.tx1) No. 05: Output format (SysForm.tx1) No. 06: RS232C setting (SysENt.tx1) No. 07: Analysis method (SysSofur.tx1) No. 07: Sercensaver (SysStafur.tx1) No. 08: Alarm setting (SysAlm.tx1) No. 09: Sercensaver (SysStafur.tx1) No. 09: Sercensaver (SysSofur.tx1) No. 09: Sercensaver (SysSofur.tx1) No. 10: STD-QC run (SysTubt.tx1) No. 11: Sample cup (SysTubt.tx1) No. 11: Sample cup (SysTubt.tx1) No. 12: Order Test (SysOdrAna.tx1) No. 13: SAMP-QC protocol (PrtCml.tx1) No. 15: Scommon protocol 1 (PrtComl.tx1) No. 15: Common protocol 1 (PrtComl.tx1) No. 16: Common protocol 1 (PrtComl.tx1) No. 18: Test mode (SokuMode.dat) No. 20: Remaining volume (SyslauZ.an.dat)    PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SHUT DOWN] Shut down the system.   PROGRAM ERROR (MEMORY) due to file setting failure INF1: MEMORY No.1 ~ 46 No.21: Buffer volume (KBufZan.dat) No.22: Signate (Acad.fad.t) No.23: Supply unit (KUnitInf.dat.) No.24: Unload unit (HUnitInf.dat.) No.23: Supply unit (SutSt.dat.dat.) No.23: Supply unit (SutSt.dat.dat.) No.24: Unload unit (HUnitInf.dat.) No.25: Starpe information () No.33: Subsystem () No.33: Subsystem () No.33: Subsystem () No.34: Additional analysis (C) No.35: Starpe ratus (C) No.35: Starpe ratus (C) No.35: Starpe ratus (C) No.35: Starpe ratus (S-2 Parts.dat.) No.24: Unload unit () No.35: Starpe ratus (C) No.35: Starper status (C) No.35: Regreent Sta
		[ SHUTDOWN ] :Shut down the system.

Error No.	On-screen Message (Upper)		
ERR#0-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen	
ERR	ERR# 0-1600 ~		
1601	COM port is not properly connected COM port error	PRINT ERROR COM PORT CONNECTION FAIL CHECK CONNECTION <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: CLOSE ERROR DISPLAY</error>	
ERR	# 0-2000 ~		
2001	Waiting (Message not printed)	The analysis is completed. (You can continue testing)	
2002	Supply unit Exchange trays (Message not printed)	The supply unit tray can be exchanged.	
2003	Prepare for pipe line activation.	Prepare for pipe line activation. <buffer bottle=""> Exchange the purified water with buffer. <tank (for="" solution)="" wash=""> Exchange the purified water with wash solution. After exchanging, touch the [START] button. Touch one of the following buttons to select a process. [START]: Start pipe line activation.</tank></buffer>	
2004	(Message not printed) Shutdown error Warning Shutdown error Warning	The system was shut down abnormally last time. The hard disk(SSD) may be damaged. If there is something wrong with the hard disk(SSD) after system startup, please contact our company. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CLOSE]: Start up the system.</error>	
2005	Hard disk damaged Warning or SSD damaged Warning Hard disk damaged Warning or SSD damaged Warning	A check found that the hard disk(SSD) is damaged. * Self-restoration was performed; however, the disk cannot be fully restored. Replace the hard disk(SSD).	

## 5.2 ERR# 1-000 - 1-200(SS1)

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
000	Unknown error Unknown error	A fault occurred in communication within the system. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also
		terminate.
001	Sample nozzle Jam (liquid level detection)	The sample nozzle jammed during detection of the liquid level of a sample. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <error cancellation=""> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish analysis.</error>
	SAMP Jam (LSU)	
004	Sample nozzle Jam (liquid level detection)	The sample nozzle jammed during detection of the liquid level of a sample. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <error cancellation=""> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the liquid level of the same sample again. [ABORT]: Finish processing.</error>
	SAMP Jam (LSU)	
005	Sample nozzle Jam (STD)	The sample nozzle jammed during detection of the liquid level of a sample. Creation of a dilution series failed <error cancellation=""> Check for sufficient storage of buffer and standard and place new sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
	SAMP Jam (STD)	

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
007	Sample nozzle Jam	The sample nozzle jammed during sample absorption. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <error cancellation=""> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause.</error>
	SAMP Jam (SSIP)	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish analysis.
008	Sample nozzle Jam	The sample nozzle jammed during sample absorption. If the rack is misaligned, dispensed samples on the conveyance line may become jumbled. In this case, a retest is recommended. <error cancellation=""> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause.</error>
	SAMP Jam (SSIP)	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing.
010	Sample nozzle Jam (Dispensing to cells)	The sample nozzle jammed when it was dispensing to a cell. The nozzle may be in improper alignment with the reaction table. <error cancellation=""> If misalignment of the reaction table is the cause of the jamming of the nozzle, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</error>
	SAMP Jam (Cell)	[Pass]: Skip dispensing of the sample. [ABORT]: Finish analysis. If analysis is underway, it will also terminate.
011	Sample nozzle Jam (STD)	The sample nozzle jammed while dispensing a sample to a sample cup in the creation of an STD dilution series. Unable to run dilution series. <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Page] Displayment the male in process.</error>
	SAMP Jam (STD)	[Pass]: Discharge the rack in process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No.	On-screen Message (Upper)	Emers and Classing Mathed Displayed On second
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
012	Sample nozzle Jam (OF) SAMP Jam (OF)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <error cancellation=""> If the sample nozzle is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Wash the nozzle and start normal operations. [ABORT]: Finish analysis.</error>
013	Sample nozzle Jam (OF) SAMP Jam (OF)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <error cancellation=""> If the sample nozzle is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish analysis.</error>
014	Sample nozzle Jam (OF) SAMP Jam (OF)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.</error>
015	Sample nozzle Jam (dilute test) SAMP Jam (DIL)	In the creation of a dilution series for a dilution test, the sample nozzle jammed while dispensing to a sample cup on the rack. The nozzle or rack may be misaligned. <error cancellation=""> If misalignment of the rack is not the cause of the jamming of the nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
016	No sample No sample	(Not displayed on screen) No sample was detected. Operation will continue automatically.
017	No sample (STAT STD) No sample (INT STD)	No sample was detected. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
018	Sample dispensing error	No sample was detected Operation will continue automatically.
019	Sample dispensing error Sample nozzle Liquid level error SAMP Liquid level error	(Not displayed on screen) Detected liquid level is abnormal. Operation will continue automatically.
020	Sample nozzle Liquid level error (STAT STD)	Detected liquid level is abnormal. The metallic portion at the tip of the sample nozzle may be conducting electrically through the remaining drops. <error cancellation=""> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</error>
	SAMP Liquid level error (INT STD)	[Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
021	Sample nozzle Absorption error SAMP Absorption error	(Not displayed on screen) Absorption by the sample nozzle was not performed normally. Operation will continue automatically.
022	Insufficient sample	(Not displayed on screen) Sample amount is insufficient. Operation will continue automatically.
023	Insufficient sample (STAT STD)	Sample amount is insufficient. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also</error>
024	Insufficient sample (INT STD) Absorption error by sample nozzle (STAT STD) SAMP Absorption error (INT	terminate. Absorption by the sample nozzle was not performed normally. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also</error>
	STD) Detection error Purified water level in OF	terminate. No purified water was detected in OF on the sample nozzle side. Purified water may have not been supplied due to a reason such as
032		broken piping. <error cancellation=""> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</error>
	Purified water Pump trouble (OF)	[RETRY]: Restart purified water supply. [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
033	Detection error Purified water level in OF Purified water Pump trouble (OF)	No purified water was detected in OF on the sample nozzle side. Purified water may have not been supplied due to a reason such as broken piping. <error cancellation=""> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the liquid level of purified water again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
034	Detection error Wash solution level in OF Wash solution Pump trouble	No wash solution was detected in OF on the sample nozzle side. The wash solution may have not been supplied due to pipe breakage or other reason. <error cancellation=""> Perform another attempt after checking that the piping is not broken. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart supply of the wash solution and clean the nozzle. [ABORT]: Finish processing. If analysis is underway, it will also</error>
035	(OF) Detection error Wash solution level in OF Wash solution Pump trouble (OF)	<ul> <li>Inderversion processing. If analysis is underway, it will also terminate.</li> <li>No wash solution was detected in OF on the sample nozzle side.</li> <li>The wash solution may have not been supplied due to pipe breakage or other reason.</li> <li><error cancellation=""></error></li> <li>Perform another attempt after checking that the piping is not broken.</li> <li>If the same error occurs, abort processing.</li> <li>PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</li> <li>[RETRY]: Detect the liquid level of wash solution again.</li> <li>[ABORT]: Finish processing. If analysis is underway, it will also terminate.</li> </ul>
040	Rack on conveyance line Rack online	A rack is placed on the conveyance line. <error cancellation=""> Perform another attempt after manually removing the rack from the conveyance line. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check for racks on the conveyance line again. [ABORT]: Finish processing.</error>
042	Supply unit 1 No tray Supply unit 1 No tray	The tray is flowing over the supply unit, or no tray is in place. <error cancellation=""> Place trays on the supply unit. Ensure that the trays are placed directly on the unit. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check for racks again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
043	Supply unit 1 Rack supply error Supply unit 1 Rack supply error	A rack was not supplied normally from the supply unit to the conveyance line. <error cancellation=""> Arrange the racks on the tray in an orderly manner. Correctly place racks if they are not perpendicular. Remove any obstacles. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart rack supply. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
044	Supply unit 1 Supply bar return error Supply unit 1 Return error	The supply bar of the supply unit was not returned to the front normally. <error cancellation=""> Remove any obstacles. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Retry returning the supply bar to the front. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
045	Discharge unit 1 No tray Discharge unit 1 No tray	The tray is flowing over the discharge unit, or no tray is in place. <error cancellation=""> Place trays on the discharge unit. Ensure that the trays are placed directly on the unit. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check for racks again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
046	Discharge unit 1 Abnormal discharge Discharge unit 1 Abnormal discharge	A rack could not be discharged to the discharge unit. <error cancellation=""> Remove the rack on the discharge tray, make sure the discharge tray is fixed properly. and execute "RETRY". Execute "ABORT" where rack is unable to discharge for Rack would not be at discharge position due to Rack Transfer is not working properly. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt discharge again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
047	Discharge unit 1 Rack full Discharge unit 1 Rack full	Rack discharge is halted because the discharge unit is full. <error cancellation=""> Close the error message. Exchange trays using the rack information screen. After exchanging, touching the button to complete the exchange will discharge the rack on the conveyance line to the discharge unit. Touch the following button. [CLOSE]: Close the alarm message.</error>

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
048	Conveyance bar in system Working error	The conveyance bar in the system did not work correctly. A fault may have occurred in the conveyance bar component. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt to move the conveyance bar again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
	Conveyance bar Error	
050	Puncturing component Working error	A fault occurred in the puncturing component. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt puncturing again.</error>
	Puncturing Error	[ABORT]: Finish processing. If analysis is underway, it will also terminate.
052	Puncturing component Jam	The puncturing component jammed. The component may be caught on a sampling bottle. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt puncturing again. [Pass]: Skip processing of sample. [ABORT]: Finish processing. If analysis is underway, it will also</error>
	Puncturing Jam	terminate.
053	Barcode Reader Error	There is a hardware-related error with the barcode reader. Unable to read barcode. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also</error>
	Barcode Reader Error	terminate.
054	Squeezing Error	The squeezing component did not work correctly. <error cancellation=""> Remove any obstacles. If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Retry squeezing. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
	Squeezing Error	terminate.

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
055	Squeezing Error Squeezing Error	The squeezing component did not work correctly. The status of the squeezing component is unknown, so the rack cannot be conveyed. <error cancellation=""> Abort processing after the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
	Container position Incorrect	Containers are set in the incorrect positions for STD measurement or a
057	(FCa)	<ul> <li>containers are set in the incorrect positions for STD measurement of a dilute test.</li> <li><error cancellation=""></error></li> <li>Place containers in the rack correctly. Return the rack to the STAT rack position.</li> <li>PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</li> <li>[RETRY]: Check whether the containers are set correctly.</li> </ul>
	Container position Incorrect (FCa)	[ABORT]: Finish processing. If analysis is underway, it will also terminate.
059	Purified water/buffer tank Sensor error	The sensor of the buffer tank did not switch to OFF. Possible causes are as follows: - Malfunctioning of sensor - Sample nozzle clogging - Malfunctioning of syringe pump or electromagnetic valve - Dirty buffer tank <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also</error>
	Purified water/buffer Sensor error Purified water/buffer tank	terminate. Purified water is not stored in the purified water/buffer tank (that is,
060	Insufficient purified water	<ul> <li>not the purified water tank) in the system.</li> <li>Purified water may have not been supplied due to a reason such as broken piping.</li> <li><error cancellation=""></error></li> <li>Continue processing after checking that the piping is not broken.</li> <li>If the same error occurs, abort processing.</li> </ul>
	Purified water Insufficient (buffer)	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Pump purified water and restart sampling. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
061	Purified water/buffer tank Insufficient purified water	<ul> <li>Purified water is not stored in the purified water/buffer tank (that is, not the purified water tank) in the system.</li> <li>Purified water may have not been supplied due to a reason such as broken piping.</li> <li><error cancellation=""></error></li> <li>Perform another attempt after checking that the piping is not broken.</li> <li>If the same error occurs, abort processing.</li> <li>PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</li> </ul>
	Purified water Insufficient (buffer)	[RETRY]: Pump purified water again. [ABORT]: Finish processing.

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
065	Discharge unit 1 Rack conveyance error Discharge 1 Discharge error	Rack discharge was not completed correctly.Because dispensed samples on the discharge line may becomejumbled, a retest is recommended in this case. <error cancellation="">Abort processing after the reaction table is at rest.PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR[ABORT]: Finish processing. If analysis is underway, it will alsoterminate.</error>
066	Container position Incorrect Container position Incorrect	Containers are set in the incorrect positions for STD measurement or a dilute test. <error cancellation=""> Place containers in the rack correctly. Return the rack to the STAT rack position. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check whether the containers are set correctly. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
067	No buffer	No buffer remains in the rack for STD measurement or a dilute test. <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. [RETRY]: Restart STD measurement or dilute test. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
	No buf.	
068	Insufficient buffer	The buffer at the top position of a rack is insufficient for STD measurement or a dilute test. <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. Touch one of the following buttons to cancel the error. [RETRY]: Restart STD measurement or dilute test. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
	Insufficient buf.	

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
095	Rack barcode Reading error	A rack barcode could not be read. <error cancellation=""> Check the following. - Is a barcode labeled on the rack? - Is the orientation of the rack correct? - Is the barcode reader lever not tilted forward? If the same error occurs after another attempt, exchange the rack with a new one or the label with a new one before another attempt. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Reread the label. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
096	Rack conveyance error Supply 1 Rack conveyance error	The supplied rack was not conveyed normally. The conveyance bar in the system may be detached. <error cancellation=""> Abort processing after the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
098	Rack barcode Unavailable Rack barcode Unavailable	The retest and dilution test racks are unavailable in a cut-in analysis. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Reread the label. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate. Explanatory note): By setting the analysis items at the time of interrupt analysis request If other reagents are selected, this error will also be issued. Page 79 "Cut-in analysis"
ERR	# 1-100 ~	
100	Discharge unit 1 Rack full Discharge unit 1 Rack full	Rack discharge is halted because the discharge unit is full. <error cancellation=""> Perform another attempt after exchanging trays. There is no need to use the rack info. screen to exchange trays. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Discharge the rack. [ABORT]: Finish processing.</error>

Error No. ERR#1-	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
LINN#1-	Printed Message (Lower)	
103	No buffer	(Not displayed on screen) Buffer was used up during a dilute test.
	No buf.	Operation will continue automatically.
104	Insufficient buffer	(Not displayed on screen) The volume of buffer became insufficient during a dilute test.
	Insufficient buf.	Operation will continue automatically.
105	STAT Rack Detected	A rack was detected at the STAT Rack position. <error cancellation=""> Perform another attempt after manually removing the rack from the STAT rack position. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Recheck for a rack at the STAT Rack position. [ABORT]: Finish processing. If analysis is underway, it will also</error>
	Stat Rack Detected	terminate.
110	Sample nozzle Jam (STD)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing.</error>
	SAMP Jam (STD)	[1.12 ortr], 1 mon provoonig.

Error No.	On-screen Message (Upper)	Emergend Classing Mathed Displayed On severe
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
112	Sample nozzle Liquid level error (STD) SAMP Liquid level error (STD)	Detected liquid level is abnormal. The metallic portion at the tip of the sample nozzle may be conducting electrically through the remaining drops. <error cancellation=""> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. Check for sufficient storage of buffer and standard and place new sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also</error>
	- · · ·	terminate.
113	No sample (STD)	No sample was detected. <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement.</error>
	No sample (STD)	[Pass]: Finish processing of the rack. [ABORT]: Finish processing.
114	Insufficient sample (STD) Insufficient sample (STD)	Sample amount is insufficient. <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack.</error>
115	Sample nozzle Jam (STD) SAMP Jam (STD)	[ABORT]: Finish processing. In the creation of an STD dilution series, the sample nozzle jammed during absorption from a sample cup on a rack. Creation of a dilution series failed <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing.</error>
116	Sample nozzle Absorption error (STD) SAMP Absorption error (STD)	

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
119	Rack conveyance bar origin error Rack Bar ORC error	Unable to detect the origin of the conveyance line rack conveyance bar. Because dispensed samples on the discharge line may become jumbled, a retest is recommended in this case. <error cancellation=""> Abort processing after the reaction table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
120	Sample nozzle Jam (STAT STD) SAMP Jam (INT STD)	The sample nozzle jammed in the OF position. The nozzle may be misaligned. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also</error>
123	Sample nozzle Jam (STAT STD) SAMP Jam (INT STD)	terminate. The sample nozzle jammed during detection of the liquid level of a sample. Creation of a dilution series failed <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
124	SAMP Jam (INT STD) SAMP Jam (INT STD)	The sample nozzle jammed while dispensing a sample to a sample cup in the creation of an STD dilution series. Creation of a dilution series failed <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
125	No buffer (STAT STD)	No buffer remains in the top position of a rack for STD measurement or a dilute test. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
126	No buf. (INT STD) Insufficient buffer (STAT STD) Insufficient buf. (INT STD)	The volume of buffer at the top position of a rack is insufficient for STD measurement or a dilute test. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
127	Sample nozzle Jam (STAT STD)	In the creation of an STD dilution series, the sample nozzle jammed during absorption from a sample cup on a rack. Creation of a dilution series failed <error cancellation=""> Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry.</error>
	SAMP Jam (INT STD)	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.
128	Sample nozzle Liquid level error SAMP Liquid level error	Liquid level was detected as abnormal. Operation will continue automatically.
129	Sample nozzle Liquid level error (STAT STD)	Liquid level was detected as abnormal. <error cancellation=""> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Finish processing of the rack.</error>
	SAMP Liquid level error (INT STD)	[ABORT]: Finish processing. If analysis is underway, it will also terminate.
130	Sample nozzle Liquid level error (STD)	Liquid level was detected as abnormal. <error cancellation=""> Use cloth, such as gauze, to remove water or other liquid droplets from the tip of the sample nozzle, if any. Check for sufficient storage of buffer and standard, and place sample cups in the rack before a retry.</error>
	SAMP Liquid level error (STD)	PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Restart measurement. [Pass]: Finish processing of the rack. [ABORT]: Finish processing.
135	Barcode reading Timeout	No reply was received from the barcode reader. Check system status, which is output to INF1, INF2, and INF3. Please let our company know of this status. In the event of this error, you need to turn off the system. When the Menu screen appears after aborting, turn off the system in Close mode. Then turn on the system. If analysis is being performed, abort processing when the reaction
	Barcode reading Timeout	table is at rest. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.

Error No.	On-screen Message (Upper)	
ERR#1- Printed Message (Lower) Errors and Clearing Met	Errors and Clearing Method Displayed On-screen	
140	Sample nozzle Z-axis origin error	The Z-axis origin of the sample nozzle was detected abnormal. <error cancellation=""> If the same error occurs after a pass, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [Pass]: Skip the sample. [ABORT]: Finish processing. If analysis is underway, it will also</error>
	SAMPZ ORG error	terminate.
141	Sample nozzle Z-axis origin error	The Z-axis origin of the sample nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also</error>
	SAMPZ ORG error	terminate.
142	Sample nozzle Z-axis origin error (STD)	The Z-axis origin of the sample nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the Z-axis origin again, and finish rack processing. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
	SAMPZ ORG error (STD)	
143	Sample nozzle Z-axis origin error (STAT STD) SAMPZ ORG error (INT STD)	The Z-axis origin of the sample nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the Z-axis origin again, and finish rack processing. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
144	Rack conveyance bar origin error Rack Bar ORG error	Unable to detect the origin of the conveyance line rack conveyance bar. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Re-initialize and check the origin. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
145	Supply unit 1 origin error Supply unit 1 ORG error	Original position sensor and limit sensor of supply unit1 are on at same time. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check sensors again, and supply or discharge rack. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
146	SAMPT ORG error	The theta-axis origin of the sample nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Theta-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
147	Sample nozzle P-axis origin error SAMPP ORG error	The P-axis origin of the sample nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect P-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
148	Sample nozzle Jamming sensor error SAMP Jamming Sensor error	Jamming sensor of sample nozzle is on. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis original position again, and check jamming sensor. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
149	Sample nozzle P-axis origin error SAMPP ORG error	The P-axis origin of the sample nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [SKIP]: Skip the sample. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
150	No STAT Rack (Message not printed)	No STAT Rack is detected. Set the rack. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Recheck for a rack at the STAT rack position. [RETURN]: Return to the STAT screen.</error>

Error No.	On-screen Message (Upper)	
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
180	Sample nozzle Jam SAMP Jam	The sample nozzle jammed. The nozzle may be misaligned. <error cancellation=""> If misalignment of the rack is not the cause of the jamming of the sample nozzle, remove the cause. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.</error>
181	Rack on conveyance line (RSTART) Rack on conveyance line (RSTART)	A rack is left on the conveyance line, due to a power failure. <error cancellation=""> Manually remove as many racks on the line as possible. Manually remove the rack left at the front of supply unit 1 after touching [START]. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [START]: Discharge the rack at the front of supply unit 1 to the position for placement of the STAT rack. [PASS]: Leave the racks on the conveyance line.</error>
188	Residue in cell (soaking)	A residual liquid was detected in a cell during cell soaking. The absorption by the washing nozzle may have not been completed normally. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Absorb residues in the cell again. [ABORT]: Finish processing.</error>
189	Sample nozzle Liquid level error SAMP Liquid level error (soaking)	The liquid level was detected as abnormal during cell soaking. The system may be conducting electrically through liquid droplets on the tip of the sample nozzle. <error cancellation=""> Use cloth, such as gauze, to remove liquid droplets from the tip of the sample nozzle, if any. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect the liquid level of the same sample again. [ABORT]: Finish processing.</error>
190	Sample nozzle Jam (Cell soaking)	The sample nozzle jammed in a cell during cell soaking. The sample nozzle may be misaligned. <error cancellation=""> If the sample nozzle is in improper alignment with the reaction table, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.</error>

Error No.	On-screen Message (Upper)	Emore and Classing Mathed Displayed On serior
ERR#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
195	There is no dispensing liquid (dispensing accuracy)	(Not displayed on screen) There is no sample in the container in the first hole of the rack in a dispensing accuracy check for samples. Touch the [Abort] button and finish processing.
	No liquid (dispensing check)	Toden the [Abort] button and minsh processing.
200	Illegal receiving command	(Not displayed on screen) A fault occurred in communication within the system. Operation will continue automatically.
	ILLEGAL COMMAND	Operation will continue automaticany.
202	No rack was found when the rack supply operation was started. (Message not printed)	No rack was found when rack supply was started. Rack auto start is halted. If the same error occurs even after repositioning, the auto start sensor may be malfunctioning.

# 5.3 MES# 1-001 - 1-007(SS1)

Error No.	On-screen Message (Upper)	
MES#1-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
001	Set racks (Message not printed)	<ul> <li>(Not displayed on screen)</li> <li>There are no remaining racks to process.</li> <li>To continue processing, position racks in the supply unit and touch</li> <li>[CONTINUE].</li> <li>Touch one of the following buttons to select a process.</li> <li>[CONTINUE]: Process the newly set rack continuously.</li> <li>[ABORT]: Finish processing.</li> </ul>
002	Detect liquid level (Message not printed)	<ul> <li>(Not displayed on screen)</li> <li>Processing is halted at the step of liquid level detection. Check whether the liquid level is detected correctly.</li> <li>Touch one of the following buttons to select a process.</li> <li>[CONTINUE]: Detect the liquid level for the next hole.</li> <li>[RETRY]: Detect the liquid level at the first hole again.</li> <li>[ABORT]: Finish processing.</li> </ul>
003	Check puncturing component (rack conveyance) (Message not printed)	<ul> <li>(Not displayed on screen)</li> <li>The puncturing component is brought to a halt.</li> <li>Check whether the alignment (X, Y, and Z) of the puncturing needle with the container is correct.</li> <li>Touch one of the following buttons to select a process.</li> <li>[CONTINUE]: Continue the process.</li> <li>[ABORT]: Finish processing.</li> </ul>
004	Check squeezing component (rack conveyance) (Message not printed)	<ul> <li>(Not displayed on screen)</li> <li>The squeezing component is halted at the container-squeezing step.</li> <li>Check whether the squeezing component squeezes containers correctly.</li> <li>Touch one of the following buttons to select a process.</li> <li>[CONTINUE]: Continue the process.</li> <li>[ABORT]: Finish processing.</li> </ul>
005	Check rack on supply unit tray. (Message not printed)	Return the rack supply unit or the rack on the tray to the front. (See the figure to the left.) Notice : When returning the rack to the front, lift the rack up temporarily. Failure to observe this precaution may result in the pin catching and the rack falling over. PRESS THE FOLLOWING BUTTON [CONTINUE]: Starts cut-in analysis.

Error No.	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
MES#1-	Printed Message (Lower)	Errors and Creating Method Displayed On-screen
006	Check that there is no liquid leaking from the nozzle tip. (Message not printed)	The setting time has passed. Check that there is no liquid dripping from the nozzle tip. <error cancellation=""> PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Finish the leak check.</error>
007	The rack supply operation will start (Message not printed)	(Not displayed on screen) The rack will be supplied.

# 5.4 ERR# 2-001 - 2-200(SS2)

Error No.	On-screen Message (Upper)	
ERR#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
000	Unknown error Unknown error	<ul> <li>(Not displayed on screen)</li> <li>A fault occurred in communication within the system.</li> <li>PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</li> <li>[ABORT]: Finish processing. If analysis is underway, it will also terminate.</li> </ul>
081	Reagent nozzle Jam (reagent bottle) Reagent Jam (bottle)	The reagent nozzle jammed during detection of the liquid level of a reagent. The reagent nozzle may be in improper alignment with the reagent bottle mouth. <error cancellation=""> Check for orientation of inserted reagent bottles. If the reagent nozzle tip does not cover the reagent bottle mouth, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Resume reagent dispensing in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
082	Reagent nozzle Jam (reagent absorption) Reagent Jam (REAG SIP)	(Not displayed on screen) The reagent nozzle jammed during absorption of a reagent. Operation will continue automatically.
084	Reagent nozzle Jam (dispensing to cell) Reagent Jam (REAG DISP)	The reagent nozzle jammed when it was dispensing to a cell. <error cancellation=""> If the reaction table is in improper alignment with the reagent nozzle, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Resume reagent dispensing in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also</error>
085	Reagent nozzle Jam (OF)	terminate. The reagent nozzle jammed in the OF position. The reagent nozzle may be misaligned. <error cancellation=""> If the reaction table is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Wash the nozzle. [ABORT]: Finish analysis.</error>
086	Reagent Jam (OF) No reagent	(Not displayed on screen) No reagent is left.
	No reagent Reagent nozzle Abnormal	Operation will continue automatically. (Not displayed on screen)
088	liquid level detected Reagent Incorrect level (REAG)	Detected liquid level is abnormal. Operation will continue automatically.

Error No.	On-screen Message (Upper)	Eman and Charing Mathed Displayed On seven
ERR#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
091	Reagent nozzle Jam (reagent bottle) Reagent Jam (bottle)	The reagent nozzle jammed during detection of the liquid level of a reagent. The reagent nozzle may be in improper alignment with the reagent bottle mouth. <error cancellation=""> Check for orientation of inserted reagent bottles. If the reagent nozzle tip does not cover the reagent bottle mouth, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.</error>
093	Reagent nozzle Jam (OF) Reagent Jam (OF)	The reagent nozzle jammed in the OF position. The reagent nozzle may be misaligned. <error cancellation=""> If the reaction table is in an incorrect OF position, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move the nozzle down again. [ABORT]: Finish processing.</error>
095	Mixer Operation error Mixer Operation error	The mixer did not work normally. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Start the mixer again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
096	Mixer Operation error Mixer Operation error	The mixer did not work normally. <error cancellation=""> Abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
097	Mixer Jam Mixer Jam	The mixer jammed. <error cancellation=""> If the same error occurs after continuation, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the mixer in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
099	Mixer Jam Mixer Jam	The mixer jammed. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Start the mixer again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>

Error No.	On-screen Message (Upper)			
ERR#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen		
ERR	ERR# 2-101 ~ 200			
101	Cell washing component Operation error	The cell washing component did not work normally. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR</error>		
101		[RETRY]: Start the cell washing component again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.		
103	Cell washing Operation error Cell washing component Absorption error Cell washing Absorption error	The cell washing component detected liquid leakage during cell washing. The contents of a cell could not be absorbed due to a problem such as breakage or clogging of the piping to the drain tank. <error cancellation=""> Check for pipe breakage to the drain tank, and continue processing. If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the cell washing operation in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>		
104	Cell washing component Liquid spill	The cell washing component detected a liquid leakage. The contents of a cell may have spilled over or splashed during cell washing. <error cancellation=""> If the same error occurs after continuation, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the cell washing operation in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>		
	Cell washing Liquid spill Cell washing component Jam	The cell washing component jammed. <error cancellation=""></error>		
105		The washing nozzle may be in improper alignment with a cell. If the same error occurs after continuation, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Start the cell washing operation in the next cycle. [ABORT]: Finish processing. If analysis is underway, it will also		
	Cell washing Jam	terminate.		
106	Cell washing component Absorption error	The cell washing component detected liquid leakage during cell washing. The contents of a cell could not be absorbed due to a problem such as breakage or clogging of the piping to the drain tank. <error cancellation=""> Check for pipe breakage to the drain tank, and perform another attempt.</error>		
	Cell washing Absorption error	If the same error occurs, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Start absorbing the contents of the cell. [ABORT]: Finish processing.		

Error No.	On-screen Message (Upper)	
ERR#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
107	Cell washing component Jam Cell washing Jam	The cell washing component jammed. The washing nozzle may be in improper alignment with a cell. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Move down the cell washing component again. [ABORT]: Finish processing.</error>
108	Cell washing component Liquid spill Cell washing Liquid spill	The cell washing component detected a liquid leakage. The contents of a cell may have spilled over or splashed during cell washing. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Check liquid spill sensor again. [ABORT]: Finish processing.</error>
110	Insufficient purified water Insufficient purified water	The volume of purified water in the corresponding storage tank is insufficient. <error cancellation=""> Continue processing after adding purified water. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
111	Insufficient wash solution Insufficient wash solution	The volume of wash solution in the corresponding storage tank is insufficient. <error cancellation=""> Perform another attempt after adding wash solution. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
112	Drain tank Full Drain tank full	The drain tank is full. <error cancellation=""> Discard the contents of the tank. Continue processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>

Error No.	On-screen Message (Upper)	
ERR#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
114	Reagent dispensing instruction error Reagent dispensing instruction error	Unable to continue operation due to a program problem. <error cancellation=""> Abort and check the settings. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
130	Detection Error (retry) Detection Error (retry)	(Not displayed on screen) An error occurred in detection, so another attempt was made automatically. Operation will continue automatically.
131	Detection Error Detection Error	<ul> <li>(Not displayed on screen)</li> <li>An error occurred in detection. Another attempt was made automatically, again resulting in abnormal results.</li> <li>PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Perform detection again.</li> <li>[ABORT]: Finish processing. If analysis is underway, it will also terminate.</li> </ul>
132	Reagent nozzle Liquid level detection error Reagent Liquid level error (REAG)	Liquid level was detected as abnormal. Continue processing automatically.
133	Timeout	The process timed out. Continue processing automatically.
134	Timeout	The process timed out. Check system status, which is output to INF1, INF2, and INF3. Please let our company know of this status. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Attempt the timed-out process again. [ABORT]: Finish processing. The menu screen will appear during system startup. If analysis is underway, it will also terminate.
135	Timeout Mixer Rotation error Mixer error	Unable to mix as the mixer rotation component is malfunctioning. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
136	Mixer Rotation error Mixer error	Unable to mix as the mixer rotation component is malfunctioning. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing. If analysis is underway, it will also terminate.
140	Reagent nozzle Z-axis origin error Reagent Z ORG error	A reagent nozzle Z-axis origin error was detected. <error cancellation=""> Is the reagent compartment cover open? If the cover is open, close it. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing.</error>

Error No.	On-screen Message (Upper)	
ERR#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
141	Reagent nozzle Z-axis origin error Reagent Z ORG error	A reagent nozzle Z-axis origin error was detected. <error cancellation=""> Is the reagent compartment cover open? If the cover is open, close it. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis origin again.</error>
	Reagent nozzle Theta-axis	[ABORT]: Finish processing. Reagent nozzle Theta-axis original position detection error.
142	origin error Reagent T ORG error	<error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Theta-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
143	Reagent nozzle P-axis origin error Reagent P ORG error	The P-axis origin of the reagent nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect P-axis origin again. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
144	Reagent nozzle Jamming Sensor error Reagent Jamming Sensor error	<error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Detect Z-axis original position again, and check jamming sensor. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
147	Reagent nozzle P-axis origin error Reagent P ORG error	The P-axis origin of the reagent nozzle was detected abnormal. <error cancellation=""> If the same error occurs after another attempt, abort processing. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [CONTINUE]: Continue the process. [ABORT]: Finish processing. If analysis is underway, it will also terminate.</error>
150	Liquid leak check Liquid leak check	The time designated for checking leaks has passed. Check for leaks on the nozzle tip. Press the button below to complete the check after nozzle washing. [CONTINUE]: Resume the operation.

Error No.	On-screen Message (Upper)	Emergen and Classing Mathed Displayed On second
ERR#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
151	OF purified water supply error OF purified water supply error	The reagent nozzle was dropped at the OF position, but the system was unable to check the purified water. Check the OF position purified water supply component. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Resume purified water supply. [ABORT]: Finish processing.
152	OF purified water supply error OF purified water supply error	The reagent nozzle was dropped at the OF position, but the system was unable to check the purified water. Check the OF position purified water supply component. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [RETRY]: Resume purified water supply. [ABORT]: Finish processing.
192	Reagent nozzle Jam Reagent Jam (maintenance)	[ABORT]: Finish processing.         The reagent nozzle jammed. <error cancellation="">         PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR         [RETRY]: Move the nozzle down again.         [ABORT]: Finish processing.</error>
193	No reagent (dispensing test)	(Not displayed on screen) No reagent was remaining in a dispensing accuracy check for reagents. PRESS THE FOLLOWING BUTTON TO SOLVE THE ERROR [ABORT]: Finish processing.
200	Illegal receiving command ILLEGALCOMMAND	(Not displayed on screen) A fault occurred in communication within the system. Continue processing automatically.

#### 5 Error List

## 5.5 MES# 2-001 - 2-007(SS2)

Error No.	On-screen Message (Upper)	
MES#2-	Printed Message (Lower)	Errors and Clearing Method Displayed On-screen
001	Check dispensing volume (Message not printed)	<ul> <li>(Not displayed on screen)</li> <li>Check the dispensing volume for cell washing.</li> <li>The line in the central area of the cell indicates the proper liquid level.</li> <li>To continue processing, return the cell to the reaction table, and touch</li> <li>[CONTINUE].</li> <li>Touch one of the following buttons to select a process.</li> <li>[CONTINUE]: Check the dispensing volume of the next nozzle.</li> <li>[ABORT]: Finish processing.</li> </ul>
002	Position sample cup	(Not displayed on screen) Position a sample cup in the 2nd reagent position. Position a sample cup and continue processing. Touch one of the following buttons to select a process. [CONTINUE]: Dispense latex or buffer into the newly positioned sample cup.
	(Message not printed)	[ABORT]: Finish processing.
003	Check liquid level detection position (Message not printed)	<ul> <li>(Not displayed on screen)</li> <li>Processing is halted at the step of liquid level detection.</li> <li>Check whether the liquid level is detected correctly.</li> <li>Touch one of the following buttons to select a process.</li> <li>[CONTINUE]: Put the nozzle back to the OF position.</li> <li>[RETRY]: Move the nozzle up and detect liquid level again.</li> <li>[ABORT]: Finish processing.</li> </ul>
004	Import purified water into buffer/wash solution lines. (Message not printed)	Import purified water into buffer/wash solution lines. Buffer and wash solution will be replaced with purified water up to the line. Connect a container filled with purified water to these connected pipes. Touch the [CONTINUE] button. Touch one of the following buttons to select a process. [CONTINUE]: Start importing purified water into the lines. [ABORT]: Finish processing.
	Drain water from the system	(Not displayed on screen)
005	(Message not printed)	Drain water from the system. Remove the pipes from the purified water tank, wash solution tank, and buffer bottles. Touch one of the following buttons to select a process. [CONTINUE]: Start draining off water. [ABORT]: Finish processing.
	Check absorption performance	(Not displayed on screen)
006	(Message not printed)	Check absorption performance. Position a bottle containing a reagent, such as tap water, in the first reagent position, and continue processing. Touch one of the following buttons to select a process. [CONTINUE]: Start liquid level detection. [ABORT]: Finish processing.

Error No.	On-screen Message (Upper)	Errors and Clearing Method Displayed On-screen
MES#2-	Printed Message (Lower)	Enors and Clearing Method Displayed on selech
007	Dispensed volume # [µL] # times	<ul> <li>(Not displayed on screen)</li> <li>"Dead volume" is defined as the difference between the volume of a liquid placed in the reagent bottle (before measurement of dead volume) and the total dispensed volume.</li> <li>Touch the following button to finish processing.</li> <li>[ABORT]: Finish processing.</li> </ul>
	Dispensed volume: # Times: #	

Saves the following data to external media: sample measured data information, sample replicate information, QC measured data information, QC replicate information, STD measured data information, STD replicate information, time course data information, histogram information, and positive rate change information.

Output data are variable-length data.

## 6.1 Sample Measured Data Information

Saves measured data information on samples and stat samples



6

[File name: ocsamp.csv]

No.	Item	Reference ( $\Delta$ : Blank [20H])	Output
1	Data type	Measured data: 'N $\triangle$ ' Stat data: 'S $\triangle$ ' Retest (including dilution test) data: 'A $\triangle$ ' When data is edited, $\triangle$ becomes E. (Example) Measured data is edited :'NE'	-
2	Date of analysis	Date of analysis e.g.) Sep. 23, 2016 → 2016/09/23	-
3	Time of analysis	Time of analysis (24-hour indication) e.g.) 2:5 pm $\rightarrow$ 14:05	-
4	Rack No.	Barcode information on racks	Do
5	Position in rack	Position in rack: 1–10	Do
6	Sample ID	Barcode information on sampling bottles (*2)	Do
7	Sample group No.	Group number of a sample: $0-9$ (Stat samples: $\Delta$ ) (If "*" is set to this number, "0" is given.)	Do
8	Sample sequence no.	Serial number of measurement: 1–999999 • Number ranges are predetermined. Samples: 1–99999 Stat samples: 1–99999	Do
9	Measurement method counter	Classification of measurement method by day: 1–3 (Number of samples for each subject) (Dilute remeasure: ' $\Delta$ ')	-
10	Number of replicates	Number of replicates for a replicate test: 1–10	-
11	DA value	Values at 1st to 3rd detection points. See Appendix 1.3 "Calculate DA Value."	Do

No.	Item	Reference ( $\Delta$ : Blank [20H])	Output
12	Measured data	Calculated data: Up to 7 digits in the integer part and 1 digit in the decimal part. (*1) (the number of digits in the decimal part can be changed from "Output Format Settings.")	-
13	Flag (+, -)	Qualitative Flag (+, -) of measured data by the cut-off values: (*1) $\Delta$ -, $\Delta$ +, 1+, 2+ and 3+	Do
14	SD values	SD values of measured data (statistic)	-
15	CV values	CV values of measured data (statistic)	-
16	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
17	Final results	"*" is recorded as final results of 15- or 250-times dilution tests. (*1)	-
18	Test item code	Test item code It does not output at the time of order error. For the CSV format is displayed as ",,".	Do (*3)
19	Test item name	Test item name It does not output at the time of order error. For the CSV format is displayed as ",,".	Do (*3)
20	Unit	Unit of test item	Do (*3)
21	Cut off 1	Value of cut off 1	Do (*3)
22	Cut off 2	Value of cut off 2 (Undefined is "*".)	
23	Cut off 3	Value of cut off 3 (Undefined is "*".)	
24	Operator ID	ID of the operator that LOGIN	Do (*3)
25	Latex lot	Lot of using Latex	Do (*3) (*4)
26	Latex expiration date	The expiration date of the Latex	Do (*3) (*4)
27	Buffer lot	Lot of using Buffer	Do (*3) (*4)
28	Buffer expiration date	The expiration date of the Buffer	Do (*3) (*4)

(Explanatory note)

- The name of an item is given in the header of a file, and is followed by data.
- Items are divided by commas (,).
- Delimiter CR/LF follows a comma that follows an error code. A file ends with "EOF."
- Zero suppression is performed on items other than the date and time of analysis.
- If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."
- (\*1) "\*" is not recorded if final results of 15- or 250-times dilution tests consist of UR data, OR data, PRC data, or datafree errors.

In these cases, spacing is provided to fields of measured data and to Flag (+, -) of 15- or 250-times dilution tests.

- (\*2) When Two-dimensional code is used (optional), sample ID is output up to 50 digits.
- (\*3) Contact us for changing No.18-No.28.
- (\*4) If dispense operation cannot be performed, " " is displayed for the lot and expiration date.

#### Example of Sample Measured Data Information Output

Data type, Date of analysis, Time of analysis, Rack number, Rack position, Sample ID, Sample group number, Sample sequence number, Measurement method counter, Number of replicates, DA Value, Measured data, Flag (+, -), SD value, CV value, Error code, Final result, Test item code, Test item name, Unit, Cut off 1, Cut off 2, and Cut off 3,Operator ID, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

Example1 : Only 15 times dilution measurement result (F-Hb) A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,110,1058,3+,0,0,,,90,F-Hb,ng/mL,100,200,300

Example2 : Only 250 times dilution measurement result (F-Hb) A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,110,17633,3+,0,0,,,90,F-Hb,ng/mL,100,200,300

Example3 : The final result is 250 times with 15 times and 250 times dilution measurement (FCa) (15 times dilution result) A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,4523,,,,,,05,53,FCa,ug/g,100,200,300 (250 times dilution result) A ,2016/07/18,11:39,032,1,123456789012345,0,1,1,1,110,17633,3+,0,0,,\*,53,FCa,ug/g,100,200,300

Example4 : When operator / reagent management function is enabled (F-Hb) N,2018/02/24,14:02,5,1,123456789012345,0,1,1,10,272,148,+,3.3,2.2,,,90,F-Hb,ng/mL,100,\*,\*,eiken,7Z02 7,2018/12/31,7Y019,2018/11/30

## 6.2 Sample Replicate Information

Saves information on each replicate of samples or stat samples

No.	Item	Remark	Output
1	Data type	See Appendix 6.1, "Sample Measured Data Information."	-
2	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
4	Relative cell No.	Cell No: 1–55	-
5	Rack No.	See Appendix 6.1, "Sample Measured Data Information."	Do
6	Rack position	See Appendix 6.1, "Sample Measured Data Information."	Do
7	Sample ID	See Appendix 6.1, "Sample Measured Data Information." (*1)	Do
8	Sample group No.	See Appendix 6.1, "Sample Measured Data Information."	Do
9	Sample sequence No.	See Appendix 6.1, "Sample Measured Data Information."	Do

[File name: ocrsamp.csv]

No.	Item	Remark	Output
10	CC No.	CC No. for sample measurement: 1–6	-
11	Replicate counter	Replicate No. for a replicate test: 1–10	-
12	A1 value	See Appendix 1.3, "Calculate DA Value."	-
13	A2 value	See Appendix 1.3, "Calculate DA Value."	-
14	A3 value	See Appendix 1.3, "Calculate DA Value."	-
15	DA1 value	See Appendix 1.3, "Calculate DA Value."	Do
16	DA2 value	See Appendix 1.3, " Calculate DA Value." The value is output even if no measured data are obtained.	Do
17	Measured data	See Appendix 6.1, "Sample Measured Data Information."	-
18	Flag (+, -)	See Appendix 6.1, "Sample Measured Data Information."	Do
19	Error code	See "List of Error Codes for Output to External Media."	-
20	Final result	See Appendix 6.1, "Sample Measured Data Information."	-
21	Test item code	Test item code	Do(*2)
22	Test item name	Test item name	Do(*2)
23	Unit	Unit of test item	Do(*2)
24	Cut off 1	Value of cut off 1	Do(*2)
25	Cut off 2	Value of cut off 2 (Undefined is "*".)	
26	Cut off 3	Value of cut off 3 (Undefined is "*".)	
27	Operator ID	ID of the operator that LOGIN	Do(*2)
28	Latex lot	Lot of using Latex	Do(*2) (*3)
29	Latex expiration date	The expiration date of the Latex	Do(*2) (*3)
30	Buffer lot	Lot of using Buffer (If not input ",,")	Do(*2) (*3)
31	Buffer expiration date	The expiration date of the Buffer (If the deadline cannot be determined ",,")	Do(*2) (*3)

(Explanatory note)

- The name of an item is given in the header of a file, and is followed by data.
- Items are divided by commas (,).
- Delimiter CR/LF follows a comma that follows an error code. A file ends with "EOF."
- Zero suppression is performed on items other than the date and time of analysis.
- If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."
- "SAMPLE UNSET" is not output as an item of Sample Replicate Information.
- Sample Replicate information is not output in case of "No order" or "Order error".
- (\*1) When Two-dimensional code is used (optional), sample ID is output up to 50 digits.
- (\*2) Contact us for changing No.21-No.31.
- (\*3) If dispense operation cannot be performed, " " is displayed for the lot and expiration date.

#### Example of Sample Replicate Information Output

Data type, Date of analysis, Time of analysis, Relative cell number, Rack number, Rack position, Sample ID, Sample group number, Sample sequence number, CC number, Replicate counter, A1 value, A2 value, A3 value, DA1 value, DA2 value, Measured data, Flag (+, -), Error code, Final result, Test item code, Test item name, Unit, Cut off 1, Cut off 2, and Cut off 3,Operator ID, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

Example1 : cut-off of 1 only (F-Hb) N ,2016/07/18,11:39,1,032,1,123456789012345,0,1,5,1,1353,1369,1569,216,16,147.0,+,,,90,F-Hb,ng/ mL,100,\*,\* N ,2016/07/18,14:39,2,032,1,123456789012345,0,1,5,2,1354,1369,1572,218,15,148.0,+,,,90,F-Hb,ng/ mL,100,\*,\*

Example2 : cut-off 1, 2, 3 (F-Hb) N,2016/07/18,11:40,3,032,2,33333,0,2,5,1,1392,1448,2490,1098,56,452.0,3+,,,90,F-Hb,ng/ mL,100,200,300 N,2016/07/18,14:40,4,032,2,33333,0,2,5,2,1384,1439,2447,1063,55,443.0,3+,,,90,F-Hb,ng/ mL,100,200,300

Example3: When the operator/reagent control function is activated (F-Hb)

N,2018/2/24,14:02,1,5,1,123456789012345,0,1,1,1,1409,1430,1692,283,21,152,+,,,90,F-Hb,ng/mL,100,\*,\* ,eiken,7Z027,2018/12/31,7Y019,2018/11/30

N,2018/2/24,14:02,2,5,1,123456789012345,0,1,1,2,1389,1408,1657,268,19,146,+,,,90,F-Hb,ng/mL,100,\*,\* ,eiken,7Z027,2018/12/31,7Y019,2018/11/30

N,2018/2/24,14:02,3,5,1,123456789012345,0,1,1,3,1389,1411,1669,280,22,151,+,,,90,F-Hb,ng/mL,100,\*,\* ,eiken,7Z027,2018/12/31,7Y019,2018/11/30

## 6.3 QC Measured Data Information

Saves QC measured data

## [File name: ocqc.csv]

No.	Item	Remark	Output
1	Data type	QC Data: 'Cx' x: QC no. of 1–4.	-
2	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
4	Rack no.	See Appendix 6.1, "Sample Measured Data Information."	Do
5	Rack position	See Appendix 6.1, "Sample Measured Data Information."	Do
6	Sample sequence no.	See Appendix 6.1, "Sample Measured Data Information."	Do
7	QC lot	QC lot number	-
8	Number of replicates	See Appendix 6.1, "Sample Measured Data Information."	-
9	DA value	See Appendix 6.1, "Sample Measured Data Information."	Do
10	Measured data	See Appendix 6.1, "Sample Measured Data Information."	-
11	Flag (+, -)	Not output.	-
12	SD value	See Appendix 6.1, "Sample Measured Data Information."	-
13	Error code	See "List of Error Codes for Output to External Media."	-
14	Test item code	Test item code	Do(*2)
15	Test item name	Test item name	Do(*2)
16	QC ID	ID of QC (*1)	Do(*2)
17	Unit	Unit of test item	Do(*2)
18	Operator ID	See Appendix 6.1, "Sample Measured Data Information."	Do(*2)
19	QC expiration date		Do(*2)
20	Latex lot	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)
21	Latex expiration date	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)
22	Buffer lot	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)
23	Buffer expiration date	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)

Explanatory note

- The name of an item is given in the header of a file, and is followed by data.
- Items are divided by commas (,).
- Delimiter CR/LF follows a comma that follows an error code. A file ends with "EOF."
- Z Zero suppression is performed on items other than the date and time of analysis.
- If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."
- (\*1) When Two-dimensional code is used (optional), sample ID is output up to 50 digits.
- (\*2) Contact us for changing No.14-No.23
- (\*3) If dispense operation cannot be performed, " " is displayed for the lot and expiration date.

Example of QC Measured Data Information Output

Data type, Date of analysis, Time of analysis, Rack number, Rack position, Sample sequence number, QC lot, Number of replicates, DA value, Measured data, Flag (+, -), SD value, Error code, Test item code, Test item name, QC ID, and Unit, Operator ID,QC expiration date, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

Example1 : Normal (F-Hb) C1,2016/04/23,16:02,099,9,1,14102,3,222,150.7,,2.5,,90,F-Hb, 12345678901234,ng/mL

Example2 : When the operator/reagent control function is activated (F-Hb) C1,2018/02/24,13:16,098,9,1,7Z007,3,271.148,,2.5,,90,F-Hb,, ng/mL,eiken,2018/12/31,7Z027,2018/ 12/31,7Y019,2018/11/30

## 6.4 QC Replicate Information

Saves information on each QC replicate

## [File name: ocrqc.csv]

No.	Item	Remark	Output
1	Data type	See Appendix 6.3, "QC Measured Data Information"	-
2	Date of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
3	Time of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
4	Relative cell no.	See Appendix 6.2, "Sample Replicate Information"	-
5	Rack no.	See Appendix 6.1, "Sample Measured Data Information"	Do
6	Rack position	See Appendix 6.1, "Sample Measured Data Information"	Do
7	Sample sequence no.	See Appendix 6.1, "Sample Measured Data Information"	Do
8	QC lot	See Appendix 6.3, "QC Measured Data Information"	-
9	CC no.	See Appendix 6.2, "Sample Replicate Information"	-
10	Replicate counter	See Appendix 6.2, "Sample Replicate Information"	-
11	A1 value	See Appendix 1.3, "Calculate DA Value."	-
12	A2 value	See Appendix 1.3, "Calculate DA Value."	-
13	A3 value	See Appendix 1.3, "Calculate DA Value."	-
14	DA1 value	See Appendix 1.3, "Calculate DA Value."	Do
15	DA2 value	See Appendix 1.3, "Calculate DA Value."	Do
16	Measured data	See Appendix 6.1, "Sample Measured Data Information"	-
17	Flag (+, -)	Not output.	-
18	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
19	Test item code	Test item code	Do(*2)
20	Test item name	Test item name	Do(*2)
21	QC ID	ID of QC (*1)	Do(*2)
22	Unit	Unit of test item	Do(*2)

No.	Item	Remark	Output
23	Operator ID	See Appendix 6.1, "Sample Measured Data Information."	Do(*2)
24	QC expiration date		Do(*2)
25	Latex lot	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)
26	Latex expiration date	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)
27	Buffer lot	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)
28	Buffer expiration date	See Appendix 6.1, "Sample Measured Data Information."	Do(*2) (*3)

(Explanatory note)

- The name of an item is given in the header of a file, and is followed by data.
- Items are divided by commas (,).
- Delimiter CR/LF follows a comma that follows an error code. The file ends with "EOF."
- Zero suppression is performed on items other than the date and time of analysis.
- If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."
- (\*1) When Two-dimensional code is used (optional), sample ID is output up to 50 digits
- (\*2) Contact us for changing No.19-No.28
- (\*3) If dispense operation cannot be performed, " " is displayed for the lot and expiration date.
  - Example of QC Replicate Information Output

Data type, Date of analysis, Time of analysis, Relative cell number, Rack number, Rack position, Sample sequence number, QC lot, CC number, Replicate counter, A1 value, A2 value, A3 value, DA1 value, DA2 value, Measured data, Flag (+, -), Error code, Test item code, Test item name, QC ID, and Unit, Operator ID, QC expiration date, Latex lot, Latex expiration date, Buffer lot, Buffer expiration date

Example1 : Normal (F-Hb)

C1,2016/04/23,16:02,13,099,9,1,14102,1,1,1353,1370,1573,220,17,149.0,,,90,F-Hb,123456789012345,ng/mL

C1,2016/04/23,16:02,14,099,9,1,14102,1,2,1364,1380,1592,228,16,154.0,,,90,F-Hb,123456789012345,ng/mL

C1,2016/04/23,16:02,15,099,9,1,14102,1,3,1352,1367,1572,220,15,149.0,,,90,F-Hb,123456789012345,ng/mL

Example2 : When the operator/reagent control function is activated (F-Hb) C1,2018/02/24,13:16,28,098,9,1,7Z007,1,1,1395,1416,1670,275,21,149.0,,,90,F-Hb,,ng/mL,eiken,2018/12/ 31,7Z027,2018/12/31,7Y019,2018/11/30 C1,2018/02/24,13:16,29,098,9,1,7Z007,1,2,1393,1412,1668,275,19,149.0,,,90,F-Hb,,ng/mL,eiken,2018/12/ 31,7Z027,2018/12/31,7Y019,2018/11/30 C1,2018/02/24,13:16,30,098,9,1,7Z007,1,3,1384,1403,1648,264,19,145.0,,,90,F-Hb,,ng/mL,eiken,2018/12/ 31,7Z027,2018/12/31,7Y019,2018/11/30

426

## 6.5 Standard Measured Data Information

Saves STD measured data information

#### [File name: ocstd.csv]

No.	Item	Remark	Output
1	Date of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
2	Time of analysis	See Appendix 6.1, "Sample Measured Data Information"	-
3	Latex lot	Latex lot No. (consisting of five alphanumeric characters)	-
4	Rack No.	See Appendix 6.1, "Sample Measured Data Information"	Do
5	Rack position	See Appendix 6.1, "Sample Measured Data Information"	Do
6	STD point No.	Detection point No. (STD1–STD6): 1–6	-
7	DA1 value	See Appendix 1.3, "Calculate DA Value."	Do
8	DA2 value	See Appendix 1.3, "Calculate DA Value."	Do
9	DA1 back fit	Concentration estimated by fitting DA1 to a calibration curve	-
10	DA1CV value	CV value of DA1 (statistic)	-
11	DA2CV value	CV value of DA2 (statistic)	-
12	DA1SD value	SD value of DA1 (statistic)	-
13	DA2SD value	SD value of DA2 (statistic)	-
14	Origin	STD concentration of CC protocol	-
15	Number of replicates	Number of replicates for a replicate test: 1–10	-
16	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
17	Test item code	Test item code	-
18	Test item name	Test item name	-

#### (Explanatory note)

- The name of an item is given in the header of a file, and is followed by data.
- Items are divided by commas (,).
- Delimiter CR/LF follows a comma that follows an error code. The file ends with "EOF."
- Zero suppression is performed on items other than the date and time of analysis.
- If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."

#### Example of STD Measured Data Information Output

Date of analysis, Time of analysis, Latex lot, Rack number, Rack position, STD point number, DA1 value, DA2 value DA1 back fit, DA1CV value, DA2CV value, DA1SD value, DA2SD value, Origin, Number of replicates, Error code, Test item code, and Test item name

2016/08/07,14:34,11111,098,1,1,6,1,0.0,0.0,0.0,0.0,0.0,0.0,3,,90,F-Hb 2016/08/07,14:34,11111,098,3,2,83,7,64.0,0.0,0.0,0.0,0.0,62.5,3,,90,F-Hb 2016/08/07,14:35,11111,098,4,3,191,15,120.0,0.0,0.0,0.0,0.0,125.0,3,,90,F-Hb 2016/08/07,14:36,11111,098,5,4,461,28,257.0,0.0,0.0,0.0,0.0,250.0,3,,90,F-Hb 2016/08/07,14:36,11111,098,6,5,1233,63,496.0,0.0,0.0,0.0,0.0,500.0,3,,90,F-Hb 2016/08/07,14:37,11111,098,2,6,2738,144,1001.0,0.0,0.0,0.0,0.0,1000.0,3,,90,F-Hb

## 6.6 Standard Replicate Information

Saves information on each STD replicate

#### [File name: ocrstd.csv]

No.	Item	Remark	Output
1	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
2	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Latex lot	Latex lot No. (consisting of five alphanumeric characters)	-
4	Relative cell no.	See Appendix 6.2, "Sample Replicate Information."	-
5	Rack no.	See Appendix 6.1, "Sample Measured Data Information."	Do
6	Rack position	See Appendix 6.1, "Sample Measured Data Information."	Do
7	STD point no.	See Appendix 6.5, "STD Measured Data Information."	-
8	Replicate counter	See Appendix 6.2, "Sample Replicate Information."	-
9	A1 value	See Appendix 1.3, "Calculate DA Value."	-
10	A2 value	See Appendix 1.3, "Calculate DA Value."	-
11	A3 value	See Appendix 1.3, "Calculate DA Value."	-
12	DA1 value	See Appendix 1.3, "Calculate DA Value."	Do
13	DA2 value	See Appendix 1.3, "Calculate DA Value."	Do
14	Error code	See Appendix 6.10, "List of Error Codes for Output to External Media."	-
15	Test item code	Test item code	-
16	Test item name	Test item name	-

(Explanatory note)

- The name of an item is given in the header of a file, and is followed by data.
- Items are divided by commas (,).
- Delimiter CR/LF follows a comma that follows an error code. The file ends with "EOF."
- Zero suppression is performed on items other than the date and time of analysis.
- If "Do" is set to "Output" for an item, you can change the setting so as not to output the item at "Output Format Settings."

#### Example of STD Replicate Information Output

Date of analysis, Time of analysis, Latex lot, Relative cell number, Rack number, Rack position, STD point number, Replicate counter, A1 value, A2 value, A3 value, DA1 value, DA2 value, Error code, Test item code, and Test item name

2016/08/07,14:34,11111,10,098,1,1,1,1345,1346,1351,6,1,,90,F-Hb 2016/08/07,14:34,11111,11,098,1,1,2,1321,1321,1327,6,0,,90,F-Hb 2016/08/07,14:34,11111,12,098,3,2,1,1330,1340,1417,87,10,,90,F-Hb 2016/08/07,14:34,11111,13,098,3,2,2,1336,1342,1419,83,6,,90,F-Hb 2016/08/07,14:34,11111,14,098,4,3,1,1347,1360,1533,186,13,,90,F-Hb 2016/08/07,14:35,11111,15,098,4,3,2,1344,1359,1535,191,15,,90,F-Hb 2016/08/07,14:35,11111,16,098,5,4,1,1372,1400,1848,476,28,,90,F-Hb 2016/08/07,14:35,11111,17,098,5,4,2,1360,1388,1821,461,28,,90,F-Hb 2016/08/07,14:35,11111,17,098,5,4,2,1360,1388,1821,461,28,,90,F-Hb 2016/08/07,14:35,11111,18,098,6,5,1,1397,1461,2677,1280,64,,90,F-Hb 2016/08/07,14:36,1111,20,098,2,6,1,1480,1626,4218,2738,146,,90,F-Hb 2016/08/07,14:36,1111,21,098,2,6,2,1470,1611,4147,2677,141,,90,F-Hb

## 6.7 Time Course Data Information

Saves time course data information

#### [File name: tcourse.csv]

No.	Item	Remark	Output
1	Cell information 1	Time course information on relative cell 1	-
	•	I	•
			-
		•	•
n	Cell information n	Time course information on relative cell n	-

#### Cell information #

No.	Item	Remark	Output
1	Date of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
2	Time of analysis	See Appendix 6.1, "Sample Measured Data Information."	-
3	Relative cell no.	See Appendix 6.2, "Sample Replicate Information."	-
4	Reference value	See Appendix 1.7, "Calculate Cell Blank."	-
5	Cell-blank value	See Appendix 1.7, "Calculate Cell Blank."	-
6	ABS value of cycle 1	See Appendix 1.3, "Calculate DA Value."	-
7	ABS value of cycle 2	See Appendix 1.3, "Calculate DA Value."	-
	•	•	•
	•	•	•
	•	•	•
60	ABS value of cycle 55	See Appendix 1.3, "Calculate DA Value."	-
61	Test item code	Test item code	-
62	Test item name	Test item name	-

(Explanatory note)

- There is no header for the file, and only data are shown.
- Items are divided by commas (,).
- Delimiter CR/LF follows a comma that follows reference value and cell information. The file ends with "EOF."
- Zero suppression is performed on items other than the date and time of analysis.

#### Example of Time Course Data Information Output

 $2016/07/23, 16:51, 1, 14127, 14, 176, 1393, 1350, 1341, 1343, 1347, 1351, 1356, 1361, 1367, 1374, 1380, 1385, 1391, 1398, 1404, 1410, 1417, 1424, 1430, 1436, 1441, 1448, 1453, 1459, 1463, 1471, 1476, 1480, 1482, 1490, 1494, 1496, 1499, 1507, 1513, 1512, 1517, 0, 0, 0, 0, 0, 0, 12, 0, 0, -1, 0, 154, 156, 159, 162, 163, 90, F-Hb \\ 2016/07/23, 16:51, 2, 14127, 0, 184, 1375, 1320, 1314, 1315, 1316, 1318, 1319, 1320, 1322, 1324, 1325, 1327, 1328, 1328, 1328, 1329, 1331, 1331, 1330, 1331, 1332, 1331, 1331, 1333, 1333, 1332, 1333, 1333, 1332, 1335, 1335, 1331, 1331, 1330, 1331, 1331, 1330, 1331, 1331, 1331, 1331, 1330, 1331, 1331, 1331, 1330, 1331, 13$ 

## 6.8 Histogram Information

Saves histogram information

#### [File name: ochstgrm.txt]

No.	Item	Remark	Output
1	Title 1	"Histogram"	-
2	Title 2	"Date range"	-
3	Period of time	First date of calculation data	-
4	Period of time	Final date of calculation data	-
5	Title 3	"Test item name"	-
6	Test item code	Test item code	-
7	Test item name.	Test item name	
8	Title 4	"Measurement range", "Number of samples"	
9	Measurement range	Minimum and maximum limits of each class: Minimum limit - Maximum limit	
10	Number of samples	Number of samples in a class	
11	Title 5	"Total number of samples"	
12	Total number of samples	Total number of samples	

(Explanatory note)

- As shown in the example below, a file begins with "HISTOGRAM."
- Items are divided by commas (,).
- Delimiter CR/LF follows the title, date range, number of samples, and total number of samples. A file ends with "EOF."

#### Example of Histogram Information Output

HISTOGRAM Date range, 2016/10/22,2016/10/23 Measurement range, Number of samples Test item name,90,F-Hb 0.0-26.0,25 26.0-52.0,5 52.0-78.0,12 78.0-104.0,2 104.0-130.0,0 130.0-156.0,1 156.0-182.0,2 182.0-208.0,1 208.0-234.0,0 234.0-260.0,1 Total number of samples, 49

### 6.9 Positive Rate Change Information

Saves positive rate change information

No. Item Remark Output "POSITIVE RATE CHANGE ACCORDING TO Title 1 1 \_ TESTEE" "Date" 2 Title 2 3 Date The first date of a week or month in calculation of \_ positive rates by week or month Title 3 "Test item name" 4 5 Test item code Test item code 6 Test item name. Test item name \_ 7 Title 4 "Positive rate (%)" \_ Rate of testees with positive rates to the total testees 8 Positive rate (%) -(Positive testees  $\div$  Total testees  $\times$  100)

Positive rate change according to testee [File name: socprmps#.txt]

(Explanatory note)

• "#" for a file name depends on the file type.

t: Positive rate change for all samples

- 0-9: Positive rate change for the group indicated by the number (0: Group not specified)
- As shown in the example below, a file begins with "POSITIVE RATE CHANGE ACCORDING TO TESTEE."
- Items are divided by commas (,).
- Delimiter CR/LF follows the title, date, positive rate change. A file ends with "EOF."

#### Example of Positive Rate Change According to Testee Output

POSITIVE RATE CHANGE ACCORDING TO TESTEE Date, 2016/10/22,2016/10/23 Test item name,90,F-Hb Positive rate (%), 66.7,46.9

#### Positive rate change according to sample [File name: socprmsa#.txt]

No.	Item	Remark	Output
1	Title 1	"POSITIVE RATE CHANGE ACCORDING TO SAMPLE"	-
2	Title 2	"Date"	-
3	Date	The first date of a week or month in calculation of positive rates by week or month	-
4	Title 3	"Test item name"	-
5	Test item code	Test item code	-
6	Test item name.	Test item name	-
7	Title 4	"Positive rate (%)"	-
8	Positive rate (%)	Rate of samples with positive rates to the total samples (Positive samples $\div$ Total samples $\times$ 100)	-

(Explanatory note)

- "#" for a file name depends on the file type.
- t: Positive rate change for all samples
- 0-9: Positive rate change of the group indicated by the number (0: Group not specified)
- As shown in the example below, a file begins with "POSITIVE RATE ACCORDING TO SAMPLE."
- Items are divided by commas (,).
- Delimiter CR/LF follows the title, date, positive rate change. A file ends with "EOF."



Example of Positive Rate Change According to Sample Output

POSITIVE RATE CHANGE ACCORDING TO SAMPLE Date, 2016/10/22,2016/10/23 Test item name,90,F-Hb Positive rate (%), 66.7,46.9

# 6.10 List of Error Codes for output to external Media

Code	Error	Measured data	Remark
10	BARCODE READING ERROR	Yes	
20	DOUBLE BARCODE ERROR (Check within a day)	-	Does not appear if "NO" is selected for "DUPLICATED SAMPLE BARCODE CHECK".
01	INSUFFICIENT SAMPLE/NO SAMPLE	-	Dispensing is not performed.
02	NO LATEX	-	
03	RBC (PROZONE)	Yes	
04	PRC (PROZONE)	*	
05	OR (OVER RANGE)	*	
06	UR (UNDER RANGE)	-	
07	SAMPLE DISPENSING ERROR (such as jamming in the sample nozzle)	-	Dispensing is not performed. Also appears in the case of a puncturing error.
08	LATEX DISPENSING ERROR (such as jamming in the reagent nozzle)	-	Dispensing is not performed.
09	Mixer error (such as jamming in the mixer)	-	It does not mixing.
0A	LATEX BLANK ERROR (A1 CHECK)	-	Abnormal latex blank
0B	NO CC	-	Includes mismatching of CC lot.
0C	UNSET	-	I received an instruction from the host system without an order.
30	Combined error of Errors 10 and 01	-	Order request communication did not complete successfully. An order different from the requested sample ID and item code was returned.
90	Combined error of Errors 10 and 02	-	Doesn't appear if MODE 1 is selected for NUMBERING MODE.
11	Combined error of Errors 10 and 03	-	
12	Combined error of Errors 10 and 04	-	
13	Combined error of Errors 10 and 05	Yes	
14	Combined error of Errors 10 and 06	*	
15	Combined error of Errors 10 and 07	*	
16	Combined error of Errors 10 and 08	-	
17	Combined error of Errors 10 and 09	-	
18	Combined error of Errors 10 and 08	-	
19	Combined error of Errors 10 and 09	-	

Code	Error	Measured data	Remark
1A	Combined error of Errors 10 and 0A	-	
1B	Combined error of Errors 10 and 0B	-	

- \* "11" to "1B" errors are combinations of two errors. No other combinations than those stated above are produced under present circumstances.
- \* "NO LATEX" error appears when the remaining volume of the first latex bottle is found to be  $0 \ \mu$ L before reagent is dispensed. Normally, latex is supplied from the second latex bottle before the contents of the first latex bottle become empty ( $0 \ \mu$ L). Moreover, analysis will be stopped before the contents of the second latex bottle become empty ( $0 \ \mu$ L). The NO LATEX error will not normally appear.
- \* Measured data and Flag (+, -) will be output in the case of an error in which "Yes" appears in the corresponding "Measured Data" box in the list described above.

Blanks (20H) are output as the Measured data and Flag (+, -) fields in the case of an error in which "-" appears in the corresponding "Measured Data" box in the list described above.

Blanks as measured data and Flag (+, -) will be output in the case of an error in which "\*" appears in the corresponding "Measured Data" box in the list described above.

\* NUMBERING MODE

In the "Mode 1" setting containers are detected and sample numbers are assigned only to container-mounted positions. In the "Mode 2" setting sample numbers are assigned to all positions, including blank positions (container-free positions). Error code "90" is output for blank positions.

\* If an end ring is positioned in a rack when Mode 2 is selected, no information is output from the ring's position through the last position of the rack.

If no end ring is positioned in Mode 2, error code "90" is output on all blank positions.

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<sup>(\*1)</sup> DA1 value in 15-times dilution  $\ge$  DA1 value in 250-times dilution

(\*2) DA1 value in 15-times dilution < DA1 value in 250-times dilution

(\*3) Error status

If an error occurs in a 250-times dilution test, the error of a final result indicates an error status in a 250-times dilution test. If no error occurs in a 250-times dilution test, the error of a final result indicates an error status in a 15-times dilution test.

(\*4) This varies depending on the communication mode setting.

# Management USB Stick Setting

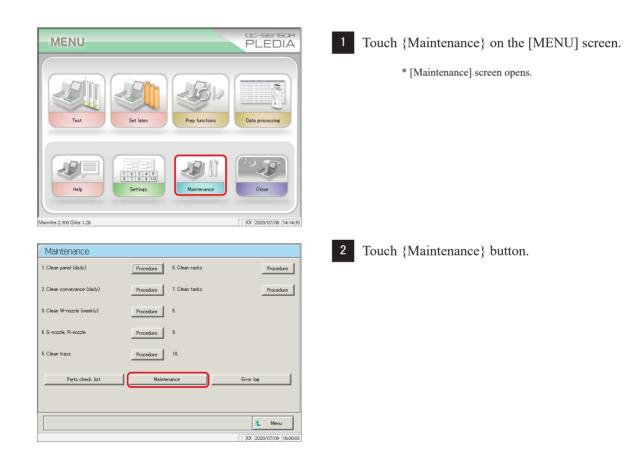
When saving measurement data or other data to a USB stick, the USB stick needs to be set as a management USB stick first.

This section describes the procedure to set a USB stick as a management USB stick.

 (Explanatory note)
 : If you are using the operator and reagent management function, you need to log in with the administrator ID in order to set up management USB stick.

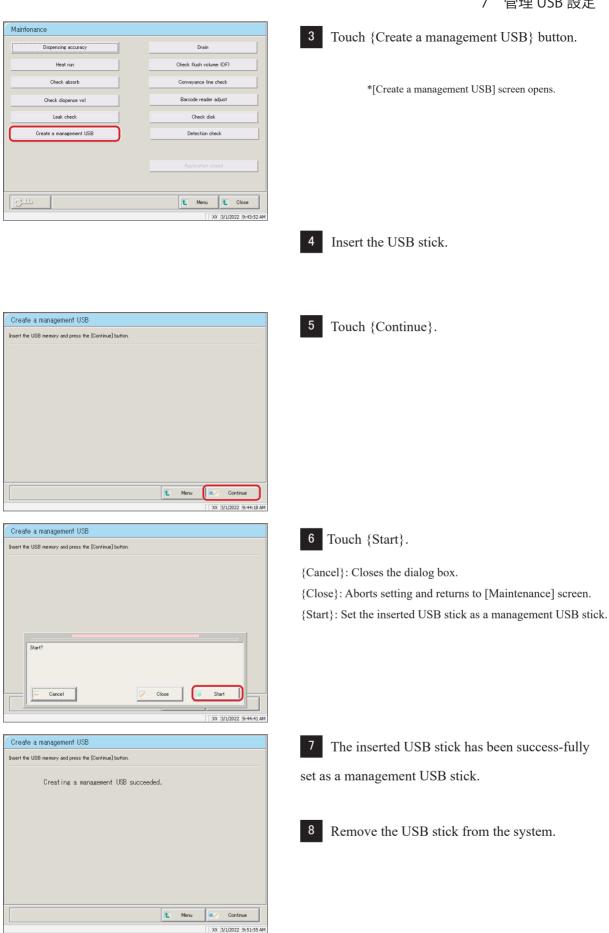
Page 330 "Chapter 9 Operator/Latex Management Function (Option)"

## 7.1 How to Set a Management USB Stick



7

#### 7 管理 USB 設定



# Index/Glossary

# Index

1	Δ
r	~

Abort	325
Additional test	74
Alarm	33,292
Aloka curve	344
Automatic start	30,31,90
Automatic start up	30,31,90

#### В

Back up	306
Buffer setting	42

#### С

Calibration curve		
	Calibration curve calculation	344
	Calibration curve confirmation	66
	Calibration curve editing/recalculation	67,197,200
	Calibration curve reading/registration	202
CC No.# protocol settings		35,314
Close mode		90
Conveyance line		12,13,252
Cut-in analysis		79,369
Cut-off value		140,142,145,
		194,308

D		
DA value calculation		350
Daily operation flow		36
Dilution test mode		54,362
Drain tank		
	Drain Tank Processing	96
	Drain tank setting	39

Е

E			
	Environment settings		33,27
	Error		
		Error cancellation	32
		Error Cancellation Buttons	32
		Error Handling	32
		Error log	8
	Error sample		
		Error sample data deletion	16
		Error sample data output	15
		Error sample data searching	15
		Error sample data sorting	15
		Error sample range specification	15
		Error sample list display	15
	External media		
		External media switching	10
		External media output	120,146,15
			168,17
Н			
	Help		31
	Histogram		
		Histgram display	16
		Histgram range change	16
		Histgram output	16
I			
	Information		25,6
	Initialization		24
	Inspection/maintenance		
		Inspection/maintenance, cleaning parts	8
		Inspection/maintenance, inspection change parts	8
	Intra-day/Inter-day	Inspection/maintenance, inspection change parts	8
	Intra-day/Inter-day	Inspection/maintenance, inspection change parts Intra-day/inter-day data deletion	
	Intra-day/Inter-day		22
	Intra-day/Inter-day	Intra-day/inter-day data deletion	8 22 22 22

L

	Linear and cubic curves		348
	Long suspense		94
М			
	Management USB stick		440
	Max limit		230, 231,298
	Measured data		
		Measured data copying	120
		Measured data deletion	124
		Measured data measurement date specification	104
		Measured data output	120
		Measured data range specification	10
		Measured data reading	10
		Measured data recalculation	11
		Measured data screen display	10
		Measured data searching	11:
		Measured data select screen display	98
		Measured data sorting	11
	Measurement cells		25
	Measurement method		52,7
	Measure mode		52,7
	Min limit		230, 231,29
	Monitor screen		19,2
N			
	Normal close		2
0			
	Outline contract		100 146 15

Online output		120,146,158
Operator information (ID	information)	
	Change ID	336
	Deleteing ID information	338
	Registering ID information	334
Operator/latex manageme	ent function	330
Output format		33,290
Output settings		33,280,284,288

Positive Rate Change		
	Positive rate change calculation conditions	17
	Positive rate change display	17
	Positive rate change output	17
	Positive rate change range change	17
Positive sample		
	Positive sample data deletion	14
	Positive sample data output	14
	Positive sample data range specification	13
	Positive sample data recalculation	14
	Positive sample data searching	13
	Positive sample data sorting	13
	Positive sample list display	13
Printer output		120,146,15
		168,17
Printing examples		37
Priming		
	Normal priming	4
	Pipe line activation	4
Protocol settings		34,30
	Protocol settings backup	30
	Protocol settings restore	30
Prozone check		35

	QC lot deletion	215
	QC lot list display	210
	QC lot selection	214
Quality Control		210

|--|

R graph		231
Rack info		234
Rack/QC sequence num	ber	33,272
Range specification		106,136,154,
		190,226
Reagent		
	Reagent setting	50
	Check reagent blank	354
Remeasurement/retest	mode	52
Replicate		
	Replicate data range specification	190
	Replicate data recalculation	194
	Replicate data saving	184
	Replicate data searching	192
	Replicate data sorting	188
	Replicate list display	178
	Replicate screen display	182,186
Restore		33,307

## S

>			
	Samp barcode settings		33,266,268
	Samp/QC protocol settings		35,308
	Sample ID settings		128
	Sample cups		239
	Sample cup settings		33,302
	Samples		
		Installing samples	52
		Samples adding	72
	Screen saver		33,206
	Settings		24,70,265
	STD/QC analysis process settings		33,216,298
	Spline curve		348
	System settings		32,266,306
		System settings backup	306
		System settings printing	305
		System settings restore	307

Test		
	Analysis abort	84
	Analysis Flow	Ę
	Analysis normal close	82
	Analysis pause	83
	Analysis start	59
	Test Operations	356
Test mode		52
Time course		
	Time course display/printing	204,205
	Time course range change	206,208
Tray replacement (optional)		238

#### W

Wash solution setting	41

## Х

X graph		231
_ X−R control graph		
A IN CONCION graph	_	
	X-R control graph display	228
	_ X−R control graph range change	232

# Glossary

А	
	Absorbance
	A1, A2, A3 Logarithm of ratio of strength of incident light striking sample (Io) and strength of transmitted light (I) (i.e. Io/I)
В	
	Back fit value
	The value obtained by fitting absorbance to a calibration curve
D	
	DA
	Absorbance difference. Calculated as the amount of change in absorbance. For example, DA1 = A3 - A1 [ABS] DA2=A2-A1[ABS]
	DIL(Dil)
	Retest diluent
	Data
	The concentration value of hemoglobin or transferrin. Calculates measured data (concentration values) using DA values and calibration curves.
	Dilution test mode
	Tests the sample once again after the sample is diluted (15 or 250 times). However, it is not punctured.
J	

#### Jamming

An error where something is touching the sample nozzle or mixer.

#### Ρ

#### PRC method

Method that compares the DA2 values of STD-6 (the highest concentration of an STD sample series) and a patient sample

#### Prozone

Phenomenon where there are excessive antibodies or antigens, and observable reactions in a mixture of specific antigens and antibodies no longer occur. This is seen in high value samples. Samples where the amount of change decreases in the late stage of a reaction are referred to as prozone samples.

#### Q

#### QC (sample)

Control sample Also referred to as reference material or reference sample

QC value check

Check based on the control limit values set in the [STD/QC measurement process settings] screen.

Specification: The minimum control limit value is less than 1: abnormal The maximum control limit value is +1 or greater: abnormal

#### R

#### **RBC** method

Method that compares the absorbance at the RBC point (in the initial stage of a reaction) of the highest concentration of an STD sample series (STD-6) and a patient sample

#### Remeasure mode

Measures the sample again. One measure mode

Remeasured samples are handled in the same manner as first test samples.

#### Retest mode

Retests sample depending on test results. However, it is not punctured. One measure mode

#### S

#### STD (sample)

The calibrator sample. Also referred to as standard material or standard sample.

#### Т

### Test mode

Measures a sample for the first time. One measure mode.

#### Time course

Results (graph) of measuring/recording changes in absorbance as time passes



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